

# *Draft Systematic Review*

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Number xx

## **Lower Limb Prosthesis**

**Prepared for:**

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## **Purposes of Review**

**Assess validity of measures used in adults with lower limb amputation, whether patient characteristics can predict relative effectiveness of different lower limb prosthesis (LLP) components, and long-term use of LLPs.**

## **Key Messages**

- 61 ambulatory and functional outcomes, and other measures, have been evaluated, of which 19 have been validated and found reliable in studies applicable to the Medicare population. However, many studies use nonvalidated measures.
- A small number of studies, only half of which used validated measures generally did not find patient or other characteristics that may predict who would most benefit from a given LLP component.
- The few studies that assessed long-term use of LLP found that between 11% and 22% of patients abandoned their LLP after 1 year; people with transfemoral (above the knee) amputations are more likely to abandon their prostheses than those with transtibial (below the knee) amputations. About 11% to 37% of people with LLP use them only indoors 1 to 7 years after they first received the prostheses.

This report is based on research conducted by an Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. xxx-xxxx-xxxxx). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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## Preface

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## **Key Informants and Technical Expert Panel**

[pending]

The list of Technical Experts who provided input to this report:

\* Provided input on Draft Report.

## **Peer Reviewers**

Prior to publication of the final evidence report, we [are seeking] input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

The list of Peer Reviewers [will] follows:

# Lower Limb Prosthesis

## Structured Abstract

**Background.** Lower limb prosthesis (LLP) candidates are a heterogeneous group. Many LLP options exist and how to best match an amputee with a LLP is unclear. Optimal selection of devices is hampered by limited studies, as well as use of a wide range of evaluation metrics, some of which have not been validated in this population.

**Methods.** We addressed questions pertaining to: assessing validity, reliability, and related metrics for assessment techniques, predictor tools, and outcome measures in lower limb amputees; determining which patient and other characteristics may predict which LLP component may be best for different lower limb amputees (i.e., assessing heterogeneity of treatment effect); determining whether patient expectations align with their outcomes with LLPs; evaluating whether patients are satisfied with the process of obtaining their LLPs; and describing the long-term continued use of LLPs by those prescribed a prosthesis. We searched six databases and other sources through November 30, 2016 [to date] for eligible studies.

**Results.** We found 92 eligible studies that assessed performance characteristics of 61 measures (assessment techniques, prediction tools, and outcome measures). Of these, 29 have been both validated and found reliable, but only 19 are generally applicable to the Medicare population. These measures mostly assess ambulation and function in people with lower limb prostheses. Of 11 studies that provide data to allow assessment of heterogeneity of treatment effect, five used both validated predictors and outcomes, three of which assessed microprocessor knees. These studies mostly included younger men with unilateral transfemoral amputations due to trauma. Overall, studies did not identify participant characteristics that predict which lower limb amputees would most benefit from a given component (low strength of evidence), whether restricted to validated predictor and outcome measures, assessing all predictors and measures, or based on a multivariable prediction model. Two studies provide low strength evidence that people are satisfied with their encounters with their prosthetists. No eligible study addressed how study participants' preprescription expectations of ambulation align with their functional outcomes. Based on eight eligible studies there is moderate strength of evidence that about 11 to 22 percent of lower limb amputees who receive a LLP prescription abandon the prosthesis at about 1 year and that people with unilateral transfemoral amputations are about twice as likely to abandon their LLP than those with unilateral transtibial amputations. There is low strength of evidence that 11 to 37 percent of LLP recipients use their prostheses only indoors.

**Conclusions.** Numerous measures of ambulation, function, quality of life, and other patient-centered outcomes exist for people with lower limb amputations: however, relatively few have evidence of reliability and validity in studies representative of the Medicare population. The validated measures should be used to form a core set of measures for use in future research studies of LLP. Currently, there is not evidence to support the selection of specific components for patient subgroups to maximize ambulation, function, and quality of life or to minimize abandonment or limited use. Further high quality research in representative samples of people with LLPs is needed to inform optimal matching of prosthetic components to patients and to assess patient expectations and satisfaction with care.

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# Evidence Summary

## Background

An estimated 1.9 million people in the U.S. are living with limb loss, a number expected to double by 2050 mostly due to the rising prevalence of diabetes.<sup>1,2</sup> The management of lower limb amputees with respect to lower limb prostheses (LLPs) is a complicated problem. LLP candidates are a heterogeneous group with distinct needs dependent upon age, etiology of limb loss, level of amputation, comorbidities and health status, postoperative stage, and rehabilitation status. Many LLP options exist, comprising numerous permutations of components, the anatomy they replace, their sophistication, and other attributes, including those pertaining to cosmesis and comfort.

The current standard approach for matching patients to prostheses relies heavily on performance-based assessments, self-assessments, and wearable monitoring technologies that record patient activity;<sup>3</sup> although prosthetists often rely on clinical judgment to match patients to prostheses. Numerous metrics exist to assess the patient functional status, but no consensus “gold standard” assessment schema exists.

The major contextual challenges in providing data to inform matching of LLPs to patients pertain to the large heterogeneity in patient characteristics and attributes of the LLPs; the fact that it is unclear which patient characteristics and LLP attributes are important to best match a patient to a specific LLP; disagreements about what constitutes an optimal matching of patients with LLPs; and poor clinical outcomes and wasted resources associated with suboptimal LLP allocations.

## Objectives of the Systematic Review

This review’s Key Questions and study eligibility criteria were designed to assist CMS to better understand the state of the evidence regarding how best to match patients with LLPs that would yield best outcomes for them, and related issues. It is important to note that this review does not fully cover the field of evaluation of LLPs. Specifically, it excludes from evaluation biomechanical and other nonpatient-centered intermediate outcomes. It also does not attempt to review all evidence about comparisons between specific components. Instead, it largely focuses on those comparisons, which provide within-study data to allow assessment about how components compare in different subpopulations of patients based on their characteristics. The review also focuses on people who may be eligible to be covered by CMS, whether due to age or disability. Therefore the review is restricted to adults with an emphasis on those with dysvascular, cancer, or trauma-related amputations, but excluding studies of exclusively military amputees with battle-related trauma (who are generally covered by Department of Defense and/or Veterans Health Administration insurance). Furthermore, the review excludes studies from low-income or resource settings not applicable to the U.S.

## Key Questions

Preliminary Key Questions (KQ) and protocol were discussed in depth with a panel of key informants (stakeholders representing patients [amputees], clinicians, prosthetists, rehabilitation, and physical therapy), with the sponsor, and were publicly posted in December, 2016. Based on

feedback from commenters and further discussion with the sponsor the Key Questions (and study eligibility criteria) were revised to improve clarity, focus the topics more closely with the sponsor's needs, and to evaluate measures and outcomes of interest to stakeholders.

The following are the Key Questions (KQ) addressed by the review:

**KQ 1.** What **assessment techniques** used to measure functional ability of adults with major lower limb amputation have been evaluated in the published literature?

1a. What are the measurement properties of these techniques, including: reliability, validity, responsiveness, minimal detectable change, and minimal important difference?

1b. What are the characteristics of the participants in these studies?

**KQ 2.** What **prediction tools** used to predict functional outcomes in adults with major lower limb amputation have been evaluated in the published literature?

2a. What are their characteristics, including technical quality (reliability, validity, responsiveness), minimal detectable change, and minimal important difference?

2b. What are the characteristics of the participants in these studies?

**KQ 3.** What **functional outcome measurement tools** used to assess adults who use a LLP have been evaluated in the published literature?

3a. What are their characteristics, including technical quality (reliability, validity, responsiveness), minimal detectable change, and minimal important difference?

3b. What are the characteristics of the participants in these studies?

**KQ 4.** In adults who use a lower limb prosthesis, how do the **relative effects** on ambulatory, functional, and patient-centered outcomes **of different prosthetic components** or levels of components/prostheses **vary based on study participant characteristics**?

4a. What **assessment techniques** that have been evaluated for measurement properties were used in these studies?

- 4a.i. How do the characteristics of the participants in eligible studies that used these specific assessment techniques compare to the characteristics of the participants in the studies that evaluated the assessment techniques (as per KQ 1b)?
- 4a.ii. What is the association between these preprescription assessment techniques and validated outcomes with the LLP in these studies?
- 4b. What **prediction tools** that have been evaluated for measurement properties were used in these studies?
  - 4b.i. How do the characteristics of the participants in eligible studies that used these specific prediction tools compare to the characteristics of the participants in the studies that evaluated the prediction tools (as per KQ 2b)?
  - 4b.ii. What is the association between preprescription assessment techniques and validated outcomes with the LLP in these studies?
- 4c. What **functional outcome measurement tools** that have been evaluated for measurement properties were used in these studies?
  - 4a.i. How do the characteristics of the participants in eligible studies that used these specific functional outcomes compare to the characteristics of the participants in the studies that evaluated the outcomes (as per KQ 3b)?

**KQ 5.** How do study participants' preprescription **expectations of ambulation** align with their functional outcomes?

- 5a. How does the level of agreement vary based on the characteristics listed in KQ 4, including level of componentry incorporated into their LLP?

**KQ 6.** What is the level of patient **satisfaction with the process** of accessing a LLP (including experiences with both providers and payers)?

- 6a. How does the level of patient satisfaction vary based on the characteristics listed in KQ 4, including level of componentry incorporated into their LLP?

**KQ 7. At 6 months, 1 year, and 5 years after receipt of a LLP,** (accounting for intervening mortality, subsequent surgeries or injuries) what percentage of individuals...?

- i. Maintain bipedal ambulation
- ii. Use their prostheses only for transfers
- iii. Use prostheses only indoors
- iv. Have abandoned their prostheses
- v. Have major problems with prosthesis

7a. How do these percentages vary based on the following characteristics?

7b. What were the reasons for suboptimal use of the prosthetic device?

## Methods

### Search Strategy

We conducted literature searches of studies in PubMed, both the Cochrane Central Trials Registry and Cochrane Database of Systematic Reviews, EMBASE, and CINAHL/PSYCInfo databases to identify primary research studies and systematic reviews meeting our criteria. The searches were conducted on November 30, 2016. [The searches will be updated in all databases upon submission of the draft report for peer and public review.] No publication date or language restrictions were applied.

### Study Eligibility Criteria

Specific eligibility criteria varied for each KQ, but criteria for populations, interventions, and study designs of interest were the same for most KQ. Fuller criteria details are in the full report.

### Population of Interest

Adults with lower limb amputation (KQ 1 and 2) or who are being evaluated for or already have a lower limb prosthesis (LLP) (all KQ)

**Exclude** if study includes *only* participants with battle-related trauma

**Exclude** if study includes *only* congenital amputations (and not otherwise Medicare eligible)

**Exclude** if study includes *only* children  $\leq 18$  years old

- If a study has a mixed population (related to battle trauma, congenital amputations, or pediatrics) and they report subgroup data based on these factors, include analyses of relevant populations (exclude substudy data on excluded populations). If study reports only combined data (e.g., adults and children), include overall study, but note issue related to population.

**Exclude** if study conducted in low income or low resource country

## Interventions or Predictors of Interest

### KQ 1-3 Measures:

- Assessment techniques (measures or tools used prior to prescription to assess patient's overall functional status) (KQ 1)
  - *Exclude* single factors (e.g., time since surgery, fasting blood glucose)
- Predictor tools (used prior to prescription to predict functional outcomes with prosthesis) (KQ 2)
  - *Exclude* single factors (e.g., time since surgery, fasting blood glucose)
- Outcome measures (assessed in people using LLP) (KQ 3)
  - Functional, patient centered, or ambulatory outcomes per KQ 4

### KQ 4-7:

Custom fabricated lower limb prosthesis

Specific prosthetic component, including foot/ankle, knee, socket, liner, pylon and suspension, or components with specific characteristics (e.g., shock absorbing, torque, multiaxial, computer assisted, powered, flexion, microprocessor)

New or existing definitive or replacement prosthetics

*Exclude* immediate postoperative prosthetics (used temporarily prior to definitive or replacement prostheses immediately after amputation surgery)

*Exclude* studies comparing only rehabilitation, physical therapy, or training techniques or regimens

*Exclude* evaluation of orthotics and of implanted devices

## Outcomes of Interest

### KQ 1-3:

- Assessments of reliability, validity, responsiveness, minimal detectable change, or minimal important difference, and floor/ceiling effect

### KQ 4, 5:

- Functional or patient-centered outcomes (measured or related to status in the community)
  - *Exclude* (simple) preference
- Ambulatory functional outcomes
  - *Exclude* biomechanical measures
- Adverse effects of LLP

### KQ 6:

- Patient satisfaction measures with process of accessing LLP

### KQ 7:

- Maintenance of bipedal ambulation
- Use of prostheses only for transfers
- Use of prostheses only indoors

- Abandonment of prostheses (not using prosthesis)
- Major problems with prosthesis
- Reasons for suboptimal use of LLP (as defined by above outcomes)

## Eligible Study Designs

### All KQ:

- Published, peer reviewed study
- Any language (that can be read by research team or machine translated)
- No publication or study date restriction
- *Exclude* case reports

### KQ 1-3:

- Any assessment of validity, reliability, and related characteristics
- *Exclude* studies of validation of translations of non-English scales, indexes, etc.
- Any study design
- $N \geq 20$  lower limb amputees
- No minimum followup time

### KQ 4:

- Direct comparison between any two components, any relevant study design
- *Must include an analysis or reporting of differences in relative effect between components by a patient characteristic of interest (see text of KQ 4) or report sufficient participant-level data to allow such an analysis*
- No minimum sample size (other than excluding case reports)
- No minimum followup time

### KQ 5, 6:

- Any study design, including qualitative studies
- No minimum sample size (other than excluding case reports)
- No minimum followup time

### KQ 7:

- Either longitudinal with followup since original lower limb prosthesis prescription or cross-sectional at timepoint after amputation or prescription
- Minimum followup time
  - $\geq 6$  month followup from time of LLP prescription, or
  - $\geq 1$  year followup from time of amputation, if no data reported about time since LLP prescription
- Minimum sample size:  $N \geq 100$

## Setting

- Any except *exclude exclusively* postacute (postsurgical) setting or inpatient rehabilitation (immediately postamputation)

# Results

## Summary of Studies

The literature searches yielded 10,285 citations and an additional 224 references were screened from review articles and existing systematic reviews. Of these, 331 articles were retrieved in full text. We excluded 236 articles. Of note, 79 studies compared lower limb prosthesis components but did not report subgroup analyses, regression analyses, or individual patient data which would allow subgroup analyses. Thus, we found 92 eligible studies, of which 72 provided validation or related analyses addressing KQ 1 to 3, 11 provided data relevant to KQ 4, no studies for KQ 5, two studies for KQ 6, and 8 studies relevant to KQ 7.

## Key Questions 1 to 3

Pertaining to KQs 1 to 3, we summarize 72 studies addressing the validity, reliability, and related metrics for 61 measures (assessment techniques, prediction tools, and outcome measures) and subscales of many of these.

Table A summarizes the findings regarding reliability, (overall) validity, the minimal detectable change (MDC), the minimal (clinical) important difference (MID), the responsiveness, and floor or ceiling effects. Most notable is that while some measure of validity has been assessed for most measures (n=53), other characteristics are less frequently evaluated. Reliability has been assessed for 40 measures and the MID was estimated for only one measure (the L test of Functional Mobility).

All 40 measures that have been assessed for reliability were found to be reliable (at least to an adequate extent). Of the 53 measures assessed for validity, 47 have been validated (either as a single measure, or for all or most of their subscales); although four of these were found to be only weakly validated. Among the 47 validated measures, seven have been validated for only some or most of their subscales (marked as “mixed” in A, or with footnotes). Furthermore, only 29 measures have evidence to support both reliability and validity; seven of these, though, have been found to have either floor or ceiling effects in whole or in part.

However, among the 61 measures, only 35 have been evaluated in samples of lower limb amputees deemed to be generally applicable to the Medicare population, based primarily on either the percentage of participants with dysvascular conditions or their ages. These are highlighted in Table 1-3.1 by having bold text in the Population column. Among these 35, 27 have evidence of validity, in whole or in part, and 25 have evidence of reliability. In total, 19 measures have been found to have evidence of both reliability and validity in study participants generally applicable to the Medicare population. These include:

- 2 minute walk test (2MWT)
- Activities-specific Balance Confidence (ABC)
- Amputee Body Image Scale, revised (ABIS-R)
- Berg Balance Scale (BBS)
- Climbing Stairs Questionnaire
- Frenchay Activities Index, 15 item (FAI-15)
- Houghton Score
- Locomotor Capabilities Index (LCI)



- Patient-Reported Outcomes Measurement Information System 29-item profile (PROMIS-29)
- Prosthesis Evaluation Questionnaire (PEQ)
- Quality of Life in Neurological Conditions – Applied Cognition/General Concerns (NQ-ACGC)
- Rising and Sitting Down Questionnaire
- Satisfaction with Prosthesis (SAT-PRO)
- Special Interest Group of Amputation Medicine/Dutch Working Group on Amputations and Prosthetics (SIGAM/WAP)
- Trinity Amputation and Prosthesis Experience Scale (TAPES)
- Timed Up and Go (TUG)
- Transfemoral Fitting Predictor (TFP)
- Walking speed, 10 meters
- Walking Questionnaire

Of these 19 measures, only the Houghton Score has been evaluated for and found to demonstrate responsiveness. Floor or ceiling effects have been found for four of these measures (or their subscores): LCI, PROMIS-29, PEQ, and NQ-ACGC.

**Table A. Summary of Performance of Measures in People With Lower Limb Amputations**

Measure	N <sup>A</sup>	Population <sup>B</sup>	Reliability	Validity <sup>C</sup>	MDC <sup>D</sup>	MID <sup>D</sup>	Responsiveness	Floor/Ceiling
180 Degree Turn Test	1	U, TT		Weak				
2MWT	5	B/U, TF, TT, Vasc	Yes	Yes	Yes <sup>D</sup>			
6MWT	3	U, TF, TT, Tr	Yes	Yes	Yes <sup>D</sup>			
AAS	2	U, TF, TT, Mix		Yes				
ABC	5	B/U, TF, TT, Mix	Yes	Yes	Yes <sup>D</sup>			No
ABIS	1	B/U, TF, TT, Vasc	Yes	No				
ABIS-R	2	B/U, TF, TT, Vasc	Yes	Yes				
AMP	2	U, TF, TT, Tr	Yes	Yes	Yes <sup>D</sup>			
AMPSIMM	1	U, TF, TT, TM, Vasc		Yes			Yes	No
ADAPT	1	U, TF, Tr	Yes					
AQoL	1	U, TF, TT, Mix		Weak				
Barthel Index	2	U, TF, Mix		Yes				
BBS	5	U, TF, TT, Vasc	Yes	Yes				No
BIQ	1	TF, TT, Vasc	Yes					
CAPE CAS	1	TF, TT		Yes				
Climbing Stairs Questionnaire	4	B/U, TF, TT, Vasc	Yes	Yes				
FAI-15	2	U, TF, TT, Vasc	Yes	Yes				
FAI-18	1	U, TF, TT, Mix	Yes	Yes				
FIM	5	U, TF, TT, Vasc	No	No			Yes	Yes <sup>F</sup>
FSST	1	U, TT		Yes				
Harold Wood/Stanmore Mobility Grade	3	TF, TT, Mix		No				
HADS	1	B/U, TF, TT		Yes				
Houghton Score	5	B/U, TF, TT, Vasc	Yes	Yes			Yes	No
IES subscales	1	U, TF, TT, Tr		Yes				
IPAQ	1	TF, TT, Mix	Adequate					
LCI (various)	15	B/U, TF, TT, Mix	Yes	Yes <sup>H</sup>				Yes
L test	2	TF, TT, Mix	Yes	Yes		Yes <sup>D</sup>	Yes	
OPCS	1	U, TF, TT		Yes				
OPUS	1	U, TF, TT	Yes				Yes	No
PGI	1	U, TF, Vasc	No	No				
PROMIS-29	2	U, TF, TT, Mix	Yes	Mix <sup>K</sup>	Yes <sup>D</sup>			Yes (most)
PSFS	1	U, TF, TT	Yes		Yes <sup>D</sup>			No
PFI	1	U, TF, TT	Yes	Yes			Yes	Yes (most)
PEQ (various)	8	B/U, TF, TT, Mix	Yes	Mix <sup>I</sup>	Yes <sup>D</sup>			Mix <sup>J</sup>
PLUS-M	4	B/U, TF, TT, Mix	Yes		Yes <sup>D</sup>			No
PROS	1	TF, TT, Vasc		Yes				
NQ-ACGC	2	U, TF, TT, Mix	Yes	Yes	Yes <sup>D</sup>			Yes
Q-TFA	1	U, TF, Tr	Yes	Yes				Mix <sup>L</sup>
Rising and Sitting Down Questionnaire	3	B/U, TF, TT, Vasc	Yes	Yes				

Measure	N <sup>A</sup>	Population <sup>B</sup>	Reliability	Validity <sup>C</sup>	MDC <sup>D</sup>	MID <sup>D</sup>	Responsiveness	Floor/Ceiling
RMDQ	1	TF, TT, Tr		Yes				
RMI	2	B/U, TF, TT, Mix	Yes	Yes			Yes	No
Russek's Code	1	TF, TT,		<b>No</b>				
SAT-PRO	1	<b>U, Vasc</b>	Yes	Yes				
SF-12	6	B/U, TF, TT, Mix		Yes				
SF-36	17	B/U, TF, TT, Mix		Mixed <sup>N</sup>			Yes (PF) <sup>O</sup>	
SF-36V	1	B/U, TF, TT	Yes		Yes <sup>D</sup>			No
SIP	4	U, TF, TT	Yes	Mix <sup>P</sup>			Yes	Yes <sup>Q</sup>
SSQN6	1	<b>Vasc</b>		<b>No</b>				
SCS	3	<b>U, TF, TT, Mix</b>	Yes		Yes <sup>D</sup>			No
SIGAM/WAP	2	<b>B/U, TF, TT, Vasc</b>	Yes	Yes				
Step Activity Monitors	2	U, TF, TT, Mix		Yes				
TAPES	6	<b>B/U, TF, TT, Mix</b>	Yes (various)	Yes <sup>R</sup>				
TMMS	1	U, TF, TT, Tr		Weak				
TUG	8	<b>U, TF, TT, Vasc</b>	Yes	Yes	Yes <sup>D</sup>			
TFP	1	<b>U, TF, Vasc</b>	Yes	Yes				
Walking speed, 10 meters	2	<b>U, TF, TT, Vasc</b>	Yes	Yes				
Walking speed, 15.2 meters (50 feet)	1	<b>U, TM, Vasc</b>		Yes				
Walking Questionnaire	3	<b>TF, TT, Vasc</b>	Yes	Yes				
WHODAS 2	1	nd		Weak				
WHOQOL-BREF subscales	5	U, TF, TT, Mix	Yes	Yes				No

Abbreviations: 180 Degree Turn Test, 2MWT = 2 minute walk test, 6MWT = 6 minute walk test, AAS = Amputees activity survey, ABC = Activities-specific Balance Confidence, ABIS(-R) = Amputee Body Image Scale (revised), ADAPT = Assessment of Daily Activity Performance in Transfemoral amputees, AIMS = Arthritis Impact Measurement Scale, AMP = Amputee Mobility Predictor, AMPSIMM = Amputee Single Item Mobility Measure, AQoL = Assessment of Quality of Life, BBS = Berg Balance Scale, CAPE = Clifton Assessment Procedures for the Elderly, Census and Surveys, FAI = Frenchay Activities Index, FIM = Functional Independence Measure, HADS = Hospital Anxiety and Depression Scale, IES = Impact of Event Scale, IPAQ = International Physical Activity Questionnaire, L Test = L Test of Functional Mobility, LCI = Locomotor Capabilities Index, MDC = minimal detectable change, MIC = minimal (clinical) important difference, Neuro-QoL ACGC = Neurological Disorders Applied Cognition General Concerns Short Form, NQ-ACGC = Quality of Life in Neurological Conditions – Applied Cognition/General Concerns, OPCS = Office of Population, OPUS = Orthotic Prosthetic User's Survey, PAM = Patient activity monitor, PEQ = Prosthesis Evaluation Questionnaire, PFI = Physical Function Index, PGI = Patient Generated Index, PLUS-M = Prosthetic Limb Users Survey of Mobility, PMQ = Prosthetic Mobility Questionnaire, PROMIS-29 = Patient-Reported Outcomes Measurement Information System 29-item profile, PROS = Prosthetist's Perception of Client's Ambulatory Abilities, PSFS = Patient Specific Functional Scale, Q-TFA = Questionnaire for Persons with a Transfemoral Amputation, QoL = Quality of Life, RMDQ = Roland Morris Disability Questionnaire, RMI = Rivermead Mobility Index, SAT-PRO = Satisfaction with Prosthesis, SCS = Socket Comfort Score, SF = Short Form Health Survey, SIGAM = Special Interest Group in Amputee Medicine, SIP = Sickness Impact Profile, SSQN6 = Saranson's 6-item Social Support Questionnaire, TAPES = Trinity Amputation and Prosthesis Experience Scales, TFP = Transfemoral Fitting Predictor, TMMS = Trait Meta Mood Scale, TUG = Timed Up and Go.15D HRQoL = 15D Health Related Quality of Life instrument, WHODAS 2 = World Health Organization Disability Assessment Schedule version 2, WHOQOL-BREF = World Health Organization Quality of Life abbreviated.

<sup>A</sup> Number of studies

<sup>B</sup> Bold text signifies that the study samples were deemed generally applicable to the Medicare population; text in italics if deemed not applicable. B = bilateral amputations, B/U = both bilateral and unilateral amputations, CA = cancer amputations, nd = no data reported describing participants, TF = transfemoral amputations, TM = transmetatarsal amputations, Tr = at least a plurality of trauma amputations, TT = transtibial amputations, Mix = a mix of amputation etiologies, nd = no data on amputation characteristics, U = unilateral amputations, Vasc = at least a plurality of dysvascular etiologies. If a category was omitted (i.e., unilateral vs. bilateral, amputation level, amputation etiology), there were insufficient data reported to summarize that category.

<sup>C</sup> Weak indicates that there is weak evidence of validity. Measures for which validity was assessed and no evidence was found to support validity are highlighted in bold.

<sup>D</sup> Yes indicates that and MDC or MID have been reported.

<sup>E</sup> Motor score validated at discharge from inpatient rehabilitation, but not at admission to rehabilitation. Subscales also not validated.

<sup>F</sup> Chair transfer subscale has a ceiling effect. Other subscales and total do not.

<sup>G</sup> Average prosthetic use per day validated; average falls per month and average prosthetic use per week were not validated.

<sup>H</sup> Most variations found to be valid; Basic LCI was not.

<sup>I</sup> Validated: Mobility, Mobility modified, Ambulation, Social burden, and Wellbeing subscales. Not validated: Appearance, Frustration, Perceived responses, Residual limb health, Sounds, Transfer, and Usefulness subscales.

<sup>J</sup> Ceiling effects found for Transfer and Wellbeing, but not for Ambulation, Mobility, or Usefulness subscales. These subscales did not have floor effects.

<sup>K</sup> Validated: Depression, Physical Function, and Social Role Satisfaction subscales. Not validated: Anxiety, Fatigue, Pain Interference, and Sleep Disturbance subscales.

<sup>L</sup> Ceiling effect for Prosthetic Use subscale, not for Global or Prosthetic Mobility subscales. No floor effects.

<sup>N</sup> Except Emotional Problems, Emotional Role Limitations, Energy/Fatigue subscales.

<sup>O</sup> Reported only for Physical Functioning (PF) subscale.

<sup>P</sup> Validated: Ambulation, Body Care and Movement, Emotional Stability subscales, and overall score. Inconsistent validation for Physical Scale subscale. Not validated: Physical Autonomy and Communication, Social Behavior, Somatic Autonomy, Mobility Control, Mobility Range, and Mobility subscales.

<sup>Q</sup> Floor effects for Bodily Care and Movement and Mobility subscales. No floor effects for Ambulation subscale and overall score. No ceiling effects for these measures.

<sup>R</sup> Except Gender subscale. Only weak evidence for total overall score validity.

## Key Question 4

In adults who use a lower limb prosthesis, how do the **relative effects** on ambulatory, functional, and patient-centered outcomes **of different prosthetic components** or levels of components/prostheses **vary based on study participant characteristics?**

### Overall Summary of Studies

In total, we found 11 studies (in 12 articles) that directly compared different LLP components and provided sufficient data to allow subgroup analyses based on participant characteristics. Ten studies included between 5 and 168 users of LLP; one included 899 amputees. Five studies evaluated microprocessor knees (compared to mechanical knees), two evaluated other knee components, two evaluated ankle/foot components, and one each evaluated pylons or sockets. The largest study developed a regression model to evaluate predictive ability of a wide range of participant characteristics. An older study reported a correlation analysis between participant characteristics and outcomes and also subgroup analyses without statistical comparisons between subgroups. One study provided subgroup comparisons with statistical analyses; three studies reported subgroup results but did not statistically compare subgroups and six studies reported individual patient data which allowed *post hoc* subgroup analyses. Overall, the studies do not provide evidence that any specific subgroup of patients consistently have differentially better outcomes with any specific component than other subgroups of patients.

Only one study was randomized; no study attempted to blind patients or providers (which may have been impossible for many components), but studies also did not blind outcome assessors (which may have been difficult for most studies); since all studies were one- or two-way crossover studies, by definition the groups of patients evaluating each component were equivalent; dropout rates were low across studies; only one study conducted multivariable analyses comparing subgroups; and only two studies statistically evaluated heterogeneity of treatment effect (differences among subgroups).

There is an important caveat about the determination of whether outcome measures have been validated (in Table 4.4 and for the text sections following the tables). We consider variations and modifications of measures to be separate measures that would each need to be validated. This applies both to modifications of existing measures (which, by definition, are no longer the same measure) and to variations such as walking and cadence tests conducted over different lengths of time or distance walked. Thus, the 2 minute walk test is distinct from the 6 minute walk test and from walking tests of other times or distances. In addition, when determining whether a measure used in a study has been validated we did not give the study the benefit of the doubt when measures were inadequately defined. For example, walk tests for which no time or distance was reported are, by definition, considered to be not validated.

A relatively small percentage of comparative studies report sufficient data to allow subgroup analysis and evaluation of heterogeneity of treatment effect (12%, 11 of 90 otherwise eligible studies). Of these 11 studies, only five used validated measures. Only one of the eligible studies was a randomized trial, but it did not evaluate validated subgroups. Only two studies evaluated heterogeneity of treatment effect; most reported individual participant level data without conducting their own subgroup analyses. Across studies, a scattering of statistically significant differences in relative effects of different components were found based on different subgroup

comparisons. However, these were not consistent across, and often within, studies. Only one study analyzed the most important aspect of the KQ, namely whether any study participant characteristics (or set of characteristics) can accurately and effectively predict which patients will most benefit from a given component. However, the study was methodologically and analytically flawed and compared a specific microprocessor knee (Genium) to any prior used knee (mostly another microprocessor knee, C-Leg). This study was conducted in largely younger men (average age 49 years, 83% men) two-thirds of whom had traumatic etiologies for their amputations. Despite finding numerous statistically significant associations between participant characteristics and functional outcomes, the study concluded that no model accurately predicted relative outcome (between the Genium microprocessor knee and, mostly, the C-Leg microprocessor knee).

Overall studies that investigated subgroup effects did not identify participant characteristics that predict which lower limb amputees would most benefit from a given component. Based on the methodology used to assess strength of evidence, the studies warrant a low strength of evidence that evaluated patient characteristics do not predict which patients would most benefit from a given LLP component (Table B). However, it may be more accurate to conclude that the evidence is currently sparse and fails to adequately address whether different subgroups of amputees are more or less likely to benefit from given specific components. Most studies were very underpowered to find statistically significant evidence of differences among subgroups, with on average only about 30 participants per study (excepting one larger regression analysis). Only five of the 11 studies used validated outcomes. Similar conclusions are reached for this subset of studies. In fact, these studies were even smaller, with on average only about 12 participants each. One large study attempted to develop a model to predict success with microprocessor knees; however the study failed to use a validated outcome and had several methodological and analytic flaws, and thus provides insufficient additional evidence regarding who would most benefit from a microprocessor knee. Furthermore, across all studies, study participants were in general not likely to be representative of the Medicare population, being both mostly young and with amputations due to trauma, with relatively few people with dysvascular disease.

**Table B. Key Question 4 Evidence Profile**

Outcome	No. Studies (N)	Study Limitations	Consistency	Precision	Reporting Bias	Directness*	Other Issues	Findings	SoE Grade
Validated outcomes (univariable)	5 (64)	Medium †	Consistent	Imprecise	Undetected	Indirect ‡	High degree of multiple testing; mostly evaluations of knee components; mostly K2 or K3 level, unilateral transfemoral amputations due to traumatic etiologies	Mostly no significant differences in relative effect based on participant characteristics	Low
All outcomes (univariable)	10 (296)	Medium †	Consistent	Imprecise	Undetected	Indirect ‡	Nonvalidated outcomes, high degree of multiple testing; mostly K2 to K4 level, unilateral transfemoral amputations due to traumatic etiologies	Mostly no significant differences in relative effect based on participant characteristics	Low
Ambulatory and functional outcomes, nonvalidated (multivariable model)	1 (899)	High §	NA	Precise	Undetected	Indirect #	K2 to K4 (mostly K3) level, mostly traumatic etiologies	Flawed study concluded no model accurately predicted relative outcomes. A large set of variables individually were associated with better outcomes with the microprocessor knee.	Insufficient

Abbreviations: KQ = Key Question, NA = not applicable, RoB = risk of bias, SoE = strength of evidence.

\* Representative of either (or both) older adults (≥65 years old) or those with dysvascular amputations.

† Nonrandomized studies, univariable analyses (mostly individual participant data reports), generally lack of evaluation of heterogeneity of treatment effect, mostly small studies.

‡ Both relatively young age amputees and primarily people with amputations due to trauma in most studies. Almost all (that reported) had unilateral transfemoral amputations.

§ Nonrandomized, likely biased sample of participants, nonvalidated outcomes, unclear which outcome(s) used in final models, unclear and possibly flawed analytic methods. See text.

# Highly selected participants who had been assessed as likely to benefit from a microprocessor knee, possibly biased dropouts, relatively young and two-thirds had trauma etiology.

## Key Question 5

How do study participants' preprescription **expectations of ambulation** align with their functional outcomes?

KQ 5 asked how study participants' preprescription expectations of ambulation align with their functional outcomes. We found no study that addressed this issue.

## Key Question 6

What is the level of patient **satisfaction with the process** of accessing a LLP (including experiences with both providers and payers)?

Two studies addressed this question. One surveyed individuals about satisfaction with upper or lower prosthetic limbs and related services. The second reported data about satisfaction with the prosthetist appointments in a study designed to assess the reliability and construct validity of the Orthotics and Prosthetics National Office Outcomes Tool in clients with LLPs.<sup>4</sup>

A moderate risk of bias study (of generally younger adults about one-third of whom had dysvascular disease) found that at least three-quarters of people receiving a LLP were satisfied with the process of accessing their LLP and a high risk of bias study (in which about half had Medicare or Medicaid insurance) found that on average clients were satisfied with their visits to their prosthetists' offices (average score about 83 of 100). Together, the studies provide low strength evidence that people are satisfied with their encounters with their prosthetists (Table C).



**Table C. Key Questions 5 and 6 Evidence Profile**

Outcome	No. Studies (N)	Study Limitations	Consistency	Precision	Reporting Bias	Directness*	Other Issues	Findings	SoE Grade
Alignment of outcomes with expectations (KQ 5)	0	NA	NA	NA	NA	NA	NA	None	Insufficient
Satisfaction with process (KQ 6)	2 (~1663)	Medium	Consistent	Precise	Undetected	Direct †	Nonvalidated outcomes	Clients generally satisfied with their encounters with their prosthetists	Low

Abbreviations: KQ = Key Question, NA = not applicable, SoE = strength of evidence.

\* Representative of either (or both) older adults (≥65 years old) or those with dysvascular amputations.

† One study included a wide range of prosthetics practices; about half the participants had Medicare or Medicaid as a primary payer. The other study was less representative.

## Key Question 7

**At 6 months, 1 year, and 5 years after receipt of a LLP, (accounting for intervening mortality, subsequent surgeries or injuries) what percentage of individuals...?**

- i. Maintain bipedal ambulation
- ii. Use their prostheses only for transfers
- iii. Use prostheses only indoors
- iv. Have abandoned their prostheses
- v. Have major problems with prosthesis

We found eight studies with at least 100 participants who were followed for at least 6 months after prescription of a LLP. Most studies of amputees with outcomes of interest were rejected because the analyses were not restricted to people with prescribed prostheses and were thus mostly analyses of predictors for not receiving a prescription for LLP. The studies analyzed between 109 and 555 participants for between 1 and 7 years (except for two studies that implied long-term followup, but did not report a timeframe. The studies only sparsely covered the subquestions pertaining to specific outcomes, particularly related to questions about different outcomes in different subgroups of amputees.

Table D summarizes the strength of evidence for each outcome and subgroup analysis with data. For most outcomes of interest, there is low strength of evidence because studies mostly had methodological limitations, the populations analyzed were often not directly applicable to the Medicare population, some studies were inconsistent with each other, and few studies reported the outcomes of interest. Subgroup analyses in single studies tended to be underpowered to detect differences, mostly leading to determinations that the evidence was insufficient. However, we found a moderate strength of evidence, based on six studies, that about 11 to 22 percent of lower limb amputees who receive a LLP prescription abandon the prosthesis (stop using it) at about 1 year; these studies are generally representative of people with LLP, in particular older adults and those with dysvascular etiologies. Three of these studies provide low strength of evidence that people with unilateral transfemoral amputations are about twice as likely to abandon their LLP than those with unilateral transtibial amputations. Potential differences among other subgroups had insufficient evidence due to conflicting results among three studies or only a single, imprecise study with data. Also based on four, generally representative studies, there is low strength of evidence that 11 to 37 percent of LLP recipients use their prostheses only indoors; however, these studies are somewhat inconsistent and imprecise. There is low strength of evidence about how likely different subgroups of people use their prostheses only indoors, suggesting that people with transfemoral amputations, or who are older, or with bilateral amputations are more likely to be limited to indoor use. There is insufficient evidence about why people abandon their prostheses.

**Table D. Key Question 7 Evidence Profile**

Outcome	Subgroup	No. Studies (N)	Study Limitations	Consistency	Precision	Reporting Bias	Directness*	Other Issues	Findings	SoE Grade
Failure to maintain bipedal ambulation	All participants	1 (148)	High	NA	Precise	Undetected	Indirect	Unclear outcome,	7% (95% CI 4, 12) at 7 years	Low
Use of prosthesis only for transfers	All participants	2 (316)	High	Inconsistent	Precise	Undetected	Indirect	Old studies	4% (95% CI 2, 8) at 1 year, 22% (95% CI 15, 30) at unknown time	Low
	TF vs. TT	1 (196)	High	NA	Imprecise	Undetected	Indirect	25 years old	No significant difference	Insufficient
	Bilateral vs. unilateral	1 (110)	High	NA	Imprecise	Undetected	Indirect	None	No significant difference	Insufficient
	Age	1 (196)	High	NA	Imprecise	Undetected	Indirect	25 years old	Nonsignificantly higher limited used with older age	Insufficient
Use of prosthesis only indoors	All participants	4 (1040)	Medium	Inconsistent	Imprecise	Undetected	Direct	None	11-37% at 1 to 7 years	Low
	TF vs. TT	2 (337)	High	Inconsistent	Precise	Undetected	Direct	None	Twice as many TF use only indoors (1 study, P=0.008), no difference (1 study)	Low
	Age	1 (196)	High	NA	Precise	Undetected	Direct	None	Older more likely to use only indoors (P=0.042)	Low
	Bilateral vs. unilateral	1 (141)	High	NA	Precise	Undetected	Direct	None	Bilateral more than twice as likely to use only indoors (P=0.0006)	Low
Abandonment of prosthesis	All participants	6 (1153)	Medium	Consistent †	Precise	Undetected	Direct	None	11-22% at 1 year (or undefined)†	Moderate
	TF vs. TT	3 (538)	High	Consistent	Precise	Undetected	Direct	None	TF more likely to abandon prosthesis than TT	Low
	Bilateral vs. unilateral	3 (452)	High	Inconsistent	Imprecise	Undetected	Direct	None	Nonsignificant, but conflicting directionality	Insufficient
	Age	2 (397)	High	Inconsistent	Imprecise	Undetected	Direct	None	Older nonsignificantly more likely to abandon (1 study), no difference in age (1 study)	Insufficient
	Multiple	1 (201)	High	NA	Imprecise	Undetected	Indirect	Multiple testing	No significant associations	Insufficient
Major problems with prosthesis	All participants	0	NA	NA	NA	NA	NA	NA	None	Insufficient
Reasons for poor outcomes	All participants	1 (201)	High	NA	Imprecise	Undetected	Indirect	None	Various general categories of reasons reported	Insufficient

Abbreviations: NA = not applicable, RoB = risk of bias, SoE = strength of evidence, TF = transfemoral amputation, TT = transtibial amputation.

\* Applicability to the Medicare population (based on mean age and percent with dysvascular amputations).

† Except that one outlier study from Taiwan found that only 0.9% of study participants abandoned their prostheses at a mean of 28 months.

## Discussion

A large number of studies have evaluated lower limb prostheses (LLP) for people with major lower limb amputations. We found nearly 100 studies that compare at least two prostheses or components that likely report ambulatory, functional, or other patient-centered outcomes. There are many additional studies that evaluated only biomechanical properties of the components and likely several hundred studies that evaluate just a single component. However, we found few studies that evaluated (or at least provided data to allow evaluation of) heterogeneity of treatment effect. From the amputee's and the clinician's perspective, among the most important questions is which prosthesis (comprised of which prosthetic components) would best enable maximal function for a given individual? Given the large number of component types (knee, foot/ankle, socket, etc.) and the range of features for each of these, the process of determining which LLP configuration is best for individuals is quite complex. The majority of the evidence addresses the question of which components maximize ambulation and function in the average patient, as opposed to which component would best suit the needs of a given individual. Suboptimal matching of patients to LLPs may unnecessarily increase health care utilization, prevent attainment of maximal patient function, and defer realization of improved quality of life attainable with an appropriate prosthetic.

Further limiting and complicating the evidence base, there are a very large number of measures that are used in the surgical, rehabilitation, and prosthesis literature to assess overall patient function, predict future outcomes, and measure various aspects of ambulation, function, quality of life issues, and other patient-centered outcomes. While some of the scales and scores used in these studies were developed specifically to assess lower limb amputees, many were designed for other populations. Many of the measures used in LLP research studies have either not been validated in the population of interest or were created *ad hoc* for each study. This review found that among the small number of comparative studies that provided heterogeneity of treatment effects data, fewer than half used both validated predictors (or subgroups based on basic participant characteristics) and validated outcomes.

We found that a large number of measures that have been validated (to a lesser or greater extent), 33 of which have, in whole or in part, been found to be both reliable and validated in lower limb amputees. These measures address many aspects of patients' function, ambulation, and quality of life. To improve the accuracy, interpretability, and, importantly, the reproducibility of the literature, we would strongly encourage future researchers to maximize the use of validated measures. Where validated measures of interest are lacking, proposed research measures should first be validated before use in future studies. We would also encourage journal editors to require use of validated measures.

However, the studies were highly variable in who was analyzed and how instruments and measures were validated, etc. We, therefore, recommend that researchers who are using this report to determine which measures to use for their own studies also review the primary studies to determine whether the measures have been sufficiently validated for their needs and have been tested in a sample of people representative to their study population.

## Evidence and Analysis Limitations

Despite the large literature base for research on LLP, relatively few studies address the questions of interest for this review, particularly related to heterogeneity of treatment effect, patient expectations and satisfaction, and long-term use of LLP after prescription.

Assessment of reliability, validity, and other measure properties is open to interpretation. By the strictest definition, a measure would be considered to be valid and appropriate for use in a given study, only if there is good evidence regarding the multiple aspects of validity for the specific population, conditions, and outcomes under evaluation. For example, that a measure demonstrates convergent validity with a given related measure does not imply that it also can distinguish differences related to subgroups of patients or an intervention effect. We took a liberal approach in our literature synthesis. We considered a measure to be validated if there was evidence of any type of validity (other than face/content). We, thus, categorized the evidence and dichotomized data so that measures were classified as valid or not valid. The overall logic for our approach was that the question of interest for this general review of all measures used in LLP research is whether a measure has been validated for any purpose. It is incumbent on each study's researchers to determine whether given measures are valid—and appropriate—for their study purposes.

This review attempts to particularly highlight the evidence applicable to the Medicare population. This is a challenge to do and requires judgment, which many may disagree with. Very few of the studies were limited to participants over the age of 65 years. None was limited to people with disabilities, at least in terms of what would allow them to qualify for Medicare. Extremely few studies reported the type of medical insurance study participants had (although, many of the studies were conducted in Europe and other countries other than U.S.). We categorized studies to be likely generalizable to the Medicare population based on having a relatively large percentage of participants with dysvascular etiologies for their lower limb amputations (also including diabetes) and/or likely including about half or more of participants over age 65 years. This system, though, is imperfect.

Although not a limitation, per se, it should be noted that this review makes no attempt to make conclusions about the overall effects of different LLP components. Key Question 4 addressed whether there is evidence regarding heterogeneity of treatment effects, particularly with validated measures, in the field of LLP research. As previously described, the evidence base addressing heterogeneity of treatment effect, particularly with validated measures, is quite small. Only a single study attempted to truly address the question at hand, but did not use a validated outcome measure, and was methodologically and analytically flawed. The applicability of these studies to the general population of people with LLPs may be somewhat limited, as the studies mostly evaluated knees and were mostly conducted in younger men with unilateral transfemoral amputations due to trauma. Furthermore, implicitly or explicitly, most of these studies included only people who were deemed (by their prosthetists) to be likely to benefit from their new (generally more complex) component. This may bias these studies toward finding no difference between subgroups of individuals in relative effect of the compared components since everyone was more likely than average to do better with the new component. In all of these studies, all patients used all evaluated LLPs. However, most of the studies that analyzed heterogeneity of treatment effect or provided data to allow subgroup analyses were observational and did not control for underlying differences during use of one component or the other. For example, studies did not describe or control for rehabilitation, training, or acclimation with each of the components. In particular, in the pre-post studies (where everyone switched from an old (simpler) to a new (more complex) LLP, one would expect that patient characteristics such as age, strength, and mobility will also have changed. These are important issues for the underlying analyses comparing the components; although, the effect of this limitation of the comparative studies on assessing heterogeneity of treatment effect is unclear. If the bias is similar in different

subgroups (e.g., the new component is favored in part due to bias equally among transtibial and transfemoral amputees), then the bias would cancel out when assessing differences in relative effect (of the two components) between the two subgroups (transtibial versus transfemoral). As discussed, the single large study with regression modeling is likely highly biased and may be analytically flawed, so it is insufficient to provide reliable evidence.

No or very few studies were found to address questions about patient expectations and satisfaction with care.

Few studies met eligibility criteria regarding long-term LLP use after prescription. The primary reason why potentially relevant studies were excluded was that they evaluated long-term ambulation and function after surgery including patients who never received an LLP. We also restricted the studies to those with at least 100 people to allow for some degree of precision in estimates. Smaller studies may have provided additional data, but their estimates would have been less precise (and subgroup analyses in these studies would be even less likely to be statistically significant due to lack of power). Among the eligible studies, the most common outcome of interest was LLP abandonment (or lack of use). Studies generally failed to report on indoor-only use of LLPs and other outcomes. Studies also mostly did not report information on why people limited or stopped their use of LLPs.

## **Future Research Recommendations**

### **General Recommendations**

Future research is needed to adequately address most of the questions in this review. While numerous measures have been validated, at least in part, additional studies are needed to confirm the measurement properties and to better generalize their validity (etc.) to more scenarios of people with lower limb amputations.

To as great an extent as possible, studies should assess validated, patient-centered outcomes related to ambulation, function, quality of life, and related outcomes. Continued use of ad hoc and nonvalidated measures greatly limits the interpretability, usability, representativeness, and overall value of the studies. Ideally, studies should use a core set of validated, patient-centered outcomes (in addition to other study-specific outcomes, as needed). This would allow comparability across studies and pooling of study findings (e.g., meta-analysis). A large body of individual, one-off analyses with unique outcomes will provide a much weaker evidence base than a smaller body of comparable studies. Noncomparable studies will continue to be more likely to be of little use to prosthetists, treating physicians, patients, policymakers, and other decisionmakers, and therefore will more likely be ignored.

### **Studies of Heterogeneity of Treatment Effect**

Particularly for a clinical field as varied as lower limb prosthetics, there is a great need to understand how best to choose among the myriad LLP and component choices for an individual patient. Lower limb amputees are clearly a highly heterogeneous group with distinct needs dependent upon age, etiology of limb loss, level of amputation, comorbidities and health status, postoperative stage, and rehabilitation status. Better understanding of which component would be best for which patient could both maximize individual's ambulation, function, and quality of life and minimize waste due to either abandonment or due to "over-prescription," where people are given LLPs with specific capabilities that they cannot benefit from. Therefore, many more

studies are needed to adequately assess heterogeneity of treatment effect. The goal of these studies should not be to simply find subgroup differences, but instead should be to predict which set of characteristics best predicts which component is best for which patient. This will require generally larger studies to allow for meaningful regression analyses. As with all studies, these should take care to include a representative and unbiased sample of lower limb amputees. Eligibility criteria and analytic methods should be employed to maximize participation and inclusion in final models. Robust analytic methods and complete and transparent reporting are essential. Appropriate, and clear, measures of model performance should be used and reported. We recommend the following specific metrics, although others may be more appropriate based on specific analyses conducted.<sup>5,6</sup> The most useful metrics of global performance are the (root) mean square error or Brier score. Less useful metrics are global statistics of fit, and the various pseudo- $R^2$  metrics. These global metrics are difficult to interpret correctly, particularly if there is class imbalance when a small percentage of participants experience a given outcome. Metrics of discrimination should also be reported, including the receiver operating characteristics (ROC) curve, area under the ROC curve (AUC), and accuracy measures (e.g., sensitivity and specificity). It is also important to report analyses of calibration. Assessments of calibration are numerous, but the most common is a simple calibration plot that orders observations in percentiles of increased predicted risk, and plots the observed percent of responders in each percentile. Conclusions about predictive performance require a thorough evaluation of the performance itself.

## **Studies on Expectations, Satisfaction With Services, and Long-Term Followup**

Studies on the relationship between patient expectations and outcomes are needed, as are additional studies of patient satisfaction with prosthetic services (and how to improve prosthetic services to improve satisfaction).

Additional large, long-term followup studies are needed to understand problems and limitations people are having with their prostheses, rates of abandonment or limited use, and reasons for these limitations and abandonment. Explanations of the prevalence of abandonment and limited use of LLPs and of why this occurs can yield further research in how to minimize underuse of LLP and resultant limited ambulation.

## **Conclusions and Clinical Implications**

Numerous measures of ambulation, function, quality of life, and other patient-centered outcomes exist for people with lower limb amputations and LLPs. Those that have been validated should be used to form a core set of measures for use in future research studies of LLP. This would enhance the value, interpretability, reproducibility, and comparability of the future studies, and would allow more coherent summarization of the evidence. Researchers should minimize the use of nonvalidated or *ad hoc* measures, but instead should validate the new measures before their use. In particular, researchers with an interest in assessing LLPs for the Medicare population would be best served to focus on those measures with evidence of reliability and validity for this population. The majority of the evidence addresses the question of which components maximize ambulation and function in the average patient, as opposed to which component would best suit the needs of a given individual. A small evidence base does not support which components should be selected for which patient to maximize their



ambulation, function, and quality of life or to minimize abandonment or limited use. However, this does not imply that there is evidence that no patient characteristics could effectively predict which patients would most benefit from one or another specific component. There is low strength of evidence that patients are generally satisfied with the prosthetic services they receive. However, further high quality research is needed to better assess the properties of measures (assessment techniques, prediction tools, and outcome measures), particularly for the Medicare population, and to answer all these questions and to assess patient expectations and satisfaction with care.

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# Introduction

## Background

An estimated 1.9 million people in the U.S. are living with limb loss, a number expected to double by 2050 mostly due to the rising prevalence of diabetes.<sup>1,2</sup> The management of lower limb amputees with respect to lower limb prostheses (LLPs) is a complicated problem. LLP candidates are a heterogeneous group with distinct needs dependent upon age, etiology of limb loss, level of amputation, comorbidities and health status, postoperative stage, and rehabilitation status. Many LLP options exist, comprising numerous permutations of components, the anatomy they replace, their sophistication, and other attributes, including those pertaining to cosmesis and comfort. In addition, patients may require multiple LLPs (initial, preparatory, definitive, or replacement prosthetics, or those for specific types of activities). Compared to the general population, LLP patients exhibit lower overall physical and emotional health (e.g., increased risk for cardiovascular disease,<sup>3</sup> anxiety, and depression<sup>4</sup>) and higher mortality (estimated 5-year mortality rates for amputees range between 50<sup>5</sup> and 74 percent<sup>6</sup>; estimated 1-year mortality is 36% for amputees >65 years old<sup>7</sup>).

The most common cause of major lower limb loss among adults is dysvascular disease, primarily due to diabetes and peripheral artery disease, accounting for about 81 percent of lower limb amputees.<sup>2</sup> Trauma accounts for about 17 percent of major lower limb amputation. Cancer is a relatively uncommon cause of lower limb amputation in adults (2%). About two-thirds or all amputees are men; although among older adults ( $\geq 65$  years), 46 percent are women. Dysvascular disease is a more common amputation etiology among older than younger adults. Amputation etiology has an important impact on patient survival and functional ability. Among Medicare recipients, about the same percentage of lower limb amputees have transfemoral as transtibial amputations.<sup>8</sup>

The current standard approach for matching patients to prostheses relies heavily on performance-based assessments, self-assessments, and wearable monitoring technologies that record patient activity;<sup>9</sup> although prosthetists and other clinicians often rely on clinical judgment to match patients to prostheses. Numerous outcome measurement tools (OMTs) exist to assess the patient functional status, but no consensus “gold standard” assessment schema exists. Similarly, numerous instruments (or techniques) are used to assess current amputee function or status and tools have been developed to predict future outcomes, including successful use of LLPs. Constructs of reliability (e.g., test-retest, interrater, internal consistency) or validity (e.g., face, content, construct, criterion) of existing OMTs, assessment techniques, and prediction tools have been evaluated in the amputee population for the most frequently used measures.<sup>10</sup> However, it is unclear to what degree studies with functional and patient-centered outcomes use validated instruments and outcomes. It is also unclear whether the population of amputees included in validation (etc.) studies is generalizable to the population of participants in studies of LLP components and, in turn, whether these study populations are applicable to the more general population of users of LLPs.

LLPs replace the functionality of a missing limb to as great a degree as possible. Medicare covers custom fabricated LLPs in accordance with Local Coverage Determination (LCD): Lower Limb Prostheses (L33787).<sup>11</sup> As for all items to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. A LLP is covered

when the beneficiary: 1) will reach or maintain a defined functional state within a reasonable period of time; and 2) is motivated to ambulate. Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician, considering factors including, but not limited to, the beneficiary's past medical history, the beneficiary's current overall health condition including the status of the residual limb and the nature of other medical problems. Some prosthetic components are limited to beneficiaries with a functional ability at or above a certain level.

As indicated by Medicare coverage guidance,<sup>12</sup> clinical assessments of beneficiary rehabilitation potential must be based on the classification levels listed in Table 1. The Medicare Functional Classification Level (MFCL or K level) system broadly defines five classification levels that can be attained with an LLP and range from 0 (no ability or potential to ambulate or transfer; LLP will not enhance quality of life or mobility) to 4 (ability or potential to exceed basic ambulation skills). The classification level assigned is used to determine the medical necessity of certain componentry, and thus to match the ultimate LLP to the beneficiary's clinical needs.

**Table 1. Lower limb extremity prosthesis function levels, per CMS (K levels)**

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Level 0:	Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility
Level 1:	Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
Level 2:	Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
Level 3:	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
Level 4:	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

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Definitions per CMS (Centers for Medicare and Medicaid Services).<sup>11</sup>

In practice it is difficult for clinicians to assess medical necessity for a patient to receive the most appropriate component (whether of higher or lower level or sophistication). Determination of a patient's potential functional abilities requires an assessment of current condition and ability and potential to ambulate. In practice, therefore, OMTs must both assess and predict function to help guide prosthetists, treating physicians, and beneficiaries. However, it is unclear to what extent measures of current function and status are able to predict future function.

A major methodological challenge in addressing selection of OMTs for routine use pertains to the assessment of predictive validity. Predictive tests should be valued with respect to their ability to predict future important outcomes. However, outcomes are determined by the whole patient management strategy which involves the baseline assessment, the LLP that a patient is given based on this assessment, patient health and changes in patient health, and any additional care (e.g., physical therapy, rehabilitation) that the patient receives. Thus, it is inherently

challenging to assess the value of a baseline OMT assessment by itself, particularly if the choice of LLP is influenced by the initial OMT assessment.

Variability and subjectivity in assigning or predicting the K level of prospective LLP recipients may inadvertently lead to inefficient or inappropriate LLP matching.<sup>13</sup> This can occur if a person receives a LLP allowed for lower K levels when a LLP allowed only for higher K levels would enable better function, or if a person receives a LLP approved for higher K levels, which might be unnecessarily complex for an individual who would have equivalent or better function with a simpler component.

Options for configuring LLPs are abundant, as LLP are highly customized devices, comprising combinations of components that replace missing anatomy and function. Components of a given type can differ in terms of functional sophistication (e.g., articulated componentry may be passive, with undamped movement, have mechanical or hydraulic dampening, or have electronic control), materials used, weight, aesthetics, comfort, and other factors. A major question is how to match patients with LLPs (both by K levels as well as by other characteristics) to optimize functional and other patient-centered outcomes. Because there are many different patients and many possible LLPs, there are numerous possible matchings. However, it is unclear which patient-level characteristics or LLP-level attributes predict a good matching, or how to weigh patient functional potential against their current functional level in the matching process.

The major contextual challenges in providing data to inform matching of LLPs to patients pertain to the large heterogeneity in patient characteristics and attributes of the LLPs; the fact that it is unclear which patient characteristics and LLP attributes are important to best match a patient to a specific LLP; disagreements about what constitutes an optimal matching of patients with LLPs; and poor clinical outcomes and wasted resources associated with suboptimal LLP allocations. Specifically, patients who are in need of LLPs are heterogeneous in terms of etiology of limb loss, amputation type (level of amputation, uni- or bilateral), age, comorbidities, frailty, general health status factors, expected life span, mental health status (e.g., depression, posttraumatic stress syndrome), family and social support, and many other factors, including whether they have fragile skin or allergies towards socket liners or other materials. These factors may affect their actual and perceived current and maximum attainable functional ability, and the likelihood that they will receive and use an LLP.<sup>8,16</sup>

## **Objectives of the Systematic Review**

The purposes of this systematic review are to 1) identify validated patient assessment techniques, prediction tools and OMTs that have been validated for use in persons with lower limb amputation; 2) identify and summarize studies that compare the differential relative effect of LLP components based on LLP users' characteristics; 3) determine whether these studies use instruments and OMTs that have been validated in the lower limb amputee population; 4) determine whether patient expectations align with their outcomes with LLPs; 5) evaluate whether patients are satisfied with the process of obtaining their LLPs; and 6) describe the long-term continued use of LLPs by those prescribed a prosthesis. This systematic review may also identify areas where evidence gaps exist related to the prescription of LLP so that recommendations may be made concerning the study designs and outcome measures that best inform patient oriented function, quality of life and service satisfaction in this realm.

This review's Key Questions and study eligibility criteria were designed to assist CMS to better understand the state of the evidence regarding how best to match patients with LLPs that

would yield best outcomes for them, and related issues. It is important to note that this review does not fully cover the field of evaluation of LLPs. Specifically, it excludes from evaluation biomechanical and other nonpatient-centered intermediate outcomes. It also does not attempt to review all evidence about comparisons between specific components. Instead, it largely focuses on those comparisons, which provide within-study data to allow assessment about how components compare in different subpopulations of patients based on their characteristics. The review also focuses on people who may be eligible to be covered by CMS, whether due to age or disability. Therefore the review is restricted to adults with an emphasis on those with dysvascular, cancer-, or trauma-related amputations, but excluding studies of exclusively military amputees with battle-related trauma (who are generally covered by Department of Defense and/or Veterans Health Administration insurance). Furthermore, the review excludes studies from low-income or resource settings not applicable to the U.S.

## Key Questions

Preliminary Key Questions (KQ) and protocol were discussed in depth with a panel of key informants (stakeholders representing patients [amputees], clinicians, prosthetists, rehabilitation, and physical therapy), with the sponsor, and were publicly posted in December, 2016. Based on feedback from commenters and further discussion with the sponsor the Key Questions (and study eligibility criteria) were revised to improve clarity, focus the topics more closely with the sponsor's needs, and to evaluate measures and outcomes of interest to stakeholders. The following are the Key Questions (KQ) addressed by the review:

**KQ 1.** What **assessment techniques** used to measure functional ability of adults with major lower limb amputation have been evaluated in the published literature?

1a. What are the measurement properties of these techniques, including: reliability, validity, responsiveness, minimal detectable change, and minimal important difference?

1b. What are the characteristics of the participants in these studies?

**KQ 2.** What **prediction tools** used to predict functional outcomes in adults with major lower limb amputation have been evaluated in the published literature?

2a. What are their characteristics, including technical quality (reliability, validity, responsiveness), minimal detectable change, and minimal important difference?

2b. What are the characteristics of the participants in these studies?

**KQ 3.** What **functional outcome measurement tools** used to assess adults who use a LLP have been evaluated in the published literature?

3a. What are their characteristics, including technical quality (reliability, validity, responsiveness), minimal detectable change, and minimal important difference?

3b. What are the characteristics of the participants in these studies?

**KQ 4.** In adults who use a lower limb prosthesis, how do the **relative effects** on ambulatory, functional, and patient-centered outcomes **of different prosthetic components** or levels of components/prostheses **vary based on study participant characteristics**?

Prosthetic components include:

- Foot/ankle
- Knee
- Socket
- Liner
- Suspension
- Pylon
- Other

Study participant characteristics of interest include:

- K level
- Level of amputation
- Etiology of amputation
- Prior function (prior to new or replacement LLP)
- Current function
- Expected potential function/level of activity and activities (e.g., athletics, uneven surface walking)
- Time since amputation
- Initial vs. subsequent limb LLP
- Unilateral vs bilateral LLP
- Time since last assessment
- Age
- Comorbidities that may affect use of LLP (e.g., congestive heart failure, vascular dysfunction, skin ulceration/damage, visual dysfunction, peripheral neuropathy, local cancer treatment, other lower limb disease)
- Type, setting, and description of rehabilitation, physical therapy, training

- Periampputation surgery information, including surgical details, inpatient rehabilitation details, wound status
- Residence setting
- Use of assistive devices
- Comfort of existing prosthesis (for patients receiving replacement LLP)
- Psychosocial characteristics
- Cognitive function
- Family (etc.) support system
- Training and acclimation with LLP

4a. What **assessment techniques** that have been evaluated for measurement properties were used in these studies?

4a.i. How do the characteristics of the participants in eligible studies that used these specific assessment techniques compare to the characteristics of the participants in the studies that evaluated the assessment techniques (as per KQ 1b)?

4a.ii. What is the association between these preprescription assessment techniques and validated outcomes with the LLP in these studies?

4b. What **prediction tools** that have been evaluated for measurement properties were used in these studies?

4b.i. How do the characteristics of the participants in eligible studies that used these specific prediction tools compare to the characteristics of the participants in the studies that evaluated the prediction tools (as per KQ 2b)?

4b.ii. What is the association between preprescription assessment techniques and validated outcomes with the LLP in these studies?

4c. What **functional outcome measurement tools** that have been evaluated for measurement properties were used in these studies?

4a.i. How do the characteristics of the participants in eligible studies that used these specific functional outcomes compare to the characteristics of the participants in the studies that evaluated the outcomes (as per KQ 3b)?

- KQ 5.** How do study participants' preprescription **expectations of ambulation** align with their functional outcomes?
- 5a. How does the level of agreement vary based on the characteristics listed in KQ 4, including level of componentry incorporated into their LLP?
- KQ 6.** What is the level of patient **satisfaction with the process** of accessing a LLP (including experiences with both providers and payers)?
- 6a. How does the level of patient satisfaction vary based on the characteristics listed in KQ 4, including level of componentry incorporated into their LLP?
- KQ 7. At 6 months, 1 year, and 5 years after receipt of a LLP,** (accounting for intervening mortality, subsequent surgeries or injuries) what percentage of individuals...?
- i. Maintain bipedal ambulation
  - ii. Use their prostheses only for transfers
  - iii. Use prostheses only indoors
  - iv. Have abandoned their prostheses
  - v. Have major problems with prosthesis
- 7a. How do these percentages vary based on the following characteristics?
- Patient residence and setting
    - Living situation (e.g., homebound, institutionalized, community ambulation)
    - Setting for rehabilitation, physical therapy, or training (e.g., in-home or at facility)
  - Patient characteristics
    - Age
    - Level of amputation
    - Number of lower limbs amputated (unilateral vs. bilateral)
    - Prior level of function (prior to onset of extremity disability)
    - Current level of function
    - Etiology of amputation
    - Time since amputation
    - Comorbidities (e.g., diabetes, CVD, PVD)
    - Operative treatment
    - Use of assistive device



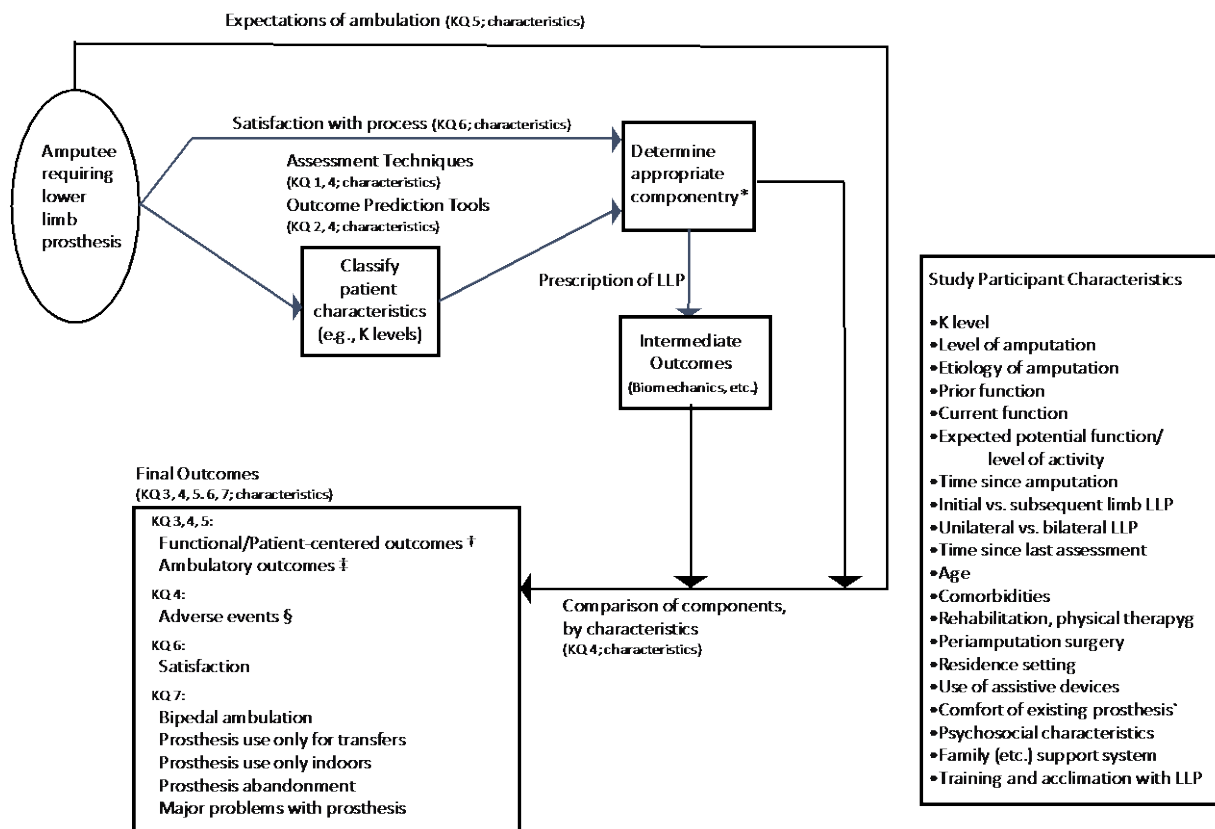
- Cosmesis of the prosthesis
- Comfort of the prosthesis
- Cognitive function
- Other
- Prosthetic componentry

7b. What were the reasons for suboptimal use of the prosthetic device?

## Analytic Framework

The following analytic framework (Figure 1) graphically illustrates the synthesis of the KQs and their elements

Figure 1. Analytic framework for assessment and assignment of lower limb prostheses, including Key Questions



Abbreviations: KQ = key question(s), LLP = lower limb prosthesis.

\* Components include: feet/ankles, knees, sockets, liners, suspension, pylons, and others.

- † Functional and patient-centered outcomes include: quality of life, disability measures, activities of daily living, mobility measures, including use of prostheses only for transfers, self-care, pain, fatigue after use (e.g., end of day), daily activity, time LLP worn per day, falls, satisfaction with LLP, and others (but not simple preference of one component over another).
- ‡ Ambulatory outcomes include: gait speed, step count, walk distance; uneven or wet surface, low lighting walking; ramps and incline traversing; step/stair climbing function; ambulatory function measured in the community setting (e.g., self-report or activity monitors); achievement of bipedal ambulation; and other patient-centered ambulatory function measures.
- § Adverse events include: skin ulcers and infections, injuries from falls due to mechanical failure, and other problems with prostheses.

## Methods

The Evidence-based Practice Center (EPC) conducted the review based on a systematic review of the published scientific literature, using established methodologies as outlined in the Agency for Healthcare Research and Quality (AHRQ) Methods Guide for Effectiveness and Comparative Effectiveness Reviews.<sup>14</sup> Prospero registration number pending.

### Search Strategy

We conducted literature searches of studies in PubMed, both the Cochrane Central Trials Registry and Cochrane Database of Systematic Reviews, EMBASE, and CINAHL/PSYCInfo databases to identify primary research studies and systematic reviews meeting our criteria. The searches were conducted on November 30, 2016. [The searches will be updated in all databases upon submission of the draft report for peer and public review.] No publication date or language restrictions were applied. Appendix A presents the literature search strategies (for each searched database). We perused the reference lists of published relevant systematic reviews. Any comparative studies (Key Question [KQ] 4) or long-term followup studies (KQ 7) found from existing systematic reviews were assessed and incorporated *de novo* from the original article. For KQ 1-3, we searched for existing systematic reviews (about validation of instruments and measures) and for additional primary studies. Peer and public review [will provide] an additional opportunity for experts in the field and others to ensure that no relevant publications have been missed.

### Study Eligibility Criteria

Specific eligibility criteria varied for each KQ, but criteria for populations, interventions, and study designs of interest were the same for most KQ. For each criterion category, we state which KQ each set of criteria apply to.

### Population of Interest

#### All KQ:

- Adults with lower limb amputation who are being evaluated for or already have a lower limb prosthesis (LLP)
  - **Exclude** if study includes *only* participants with battle-related trauma
  - **Exclude** if study includes *only* congenital amputations (and not otherwise Medicare eligible)
  - **Exclude** if study includes *only* children  $\leq 18$  years old
    - If a study has a mixed population (related to battle trauma, congenital amputations, or pediatrics) and they report subgroup data based on these factors, include analyses of relevant populations (exclude substudy data on excluded populations). If study reports only combined data (e.g., adults and children), include overall study, but note issue related to population.
  - **Exclude** if study conducted in low income or low resource country

### **KQ 1-2:**

- Also allow studies of amputees, whether or not they use LLPs (i.e., allow studies evaluating assessment techniques and predictor tools in amputees who do not [yet] have a LLP)

## **Interventions or Predictors of Interest (and Measures for KQ 1-3)**

### **All KQ:**

- Custom fabricated lower limb prosthesis
- Specific prosthetic component, including foot/ankle, knee, socket, liner, pylon and suspension, or components with specific characteristics (e.g., shock absorbing, torque, multiaxial, computer assisted, powered, flexion, microprocessor)
- New or existing definitive or replacement prosthetics
  - **Exclude** immediate postoperative prosthetics (used temporarily prior to definitive or replacement prostheses immediately after amputation surgery)
  - **Exclude** immediate postoperative prosthetics (used temporarily prior to definitive or replacement prostheses immediately after amputation surgery)
  - **Exclude** evaluation of orthotics and of implanted devices

### **KQ 1-3 Measures:**

- Assessment techniques (measures or tools used prior to prescription to assess patient's overall functional status) (KQ 1)
  - Tests, scales, questionnaires that assess current functional or health status
  - Include patient history and physical examination
  - Measures of physical function and functional capacity (e.g., parallel bar ambulation without LLP)
    - **Exclude** single factors (e.g., time since surgery, fasting blood glucose)
- Predictor tools (used prior to prescription to predict functional outcomes with prosthesis) (KQ 2)
  - Tests, scales, questionnaires
    - **Exclude** single factors (e.g., time since surgery, fasting blood glucose)
- Outcome measures (assessed in people using LLP) (KQ 3)
  - Functional, patient centered, or ambulatory outcomes per KQ 4

### **KQ 4:**

- As listed for all KQ

### **KQ 5, 7:**

- Receipt of a definitive or replacement LLP (regardless of componentry)

### **KQ 6:**

- Undergo process of accessing a definitive or replacement LLP (regardless of componentry)

## **Comparators of Interest**

### **KQ 1-3:**

- Reference standards, as applicable

### **KQ 4:**

- LLPs with different components (e.g., feet/ankles, knees, sockets, pylons, liners, suspension), or that differ in other ways (studies must be comparative)

### **KQ 5-7:**

- No comparators required

## **Outcomes of Interest**

### **KQ 1-3:**

- Assessments of reliability, validity, responsiveness, minimal detectable change, or minimal important difference, and floor/ceiling effect

### **KQ 4, 5:**

- Functional or patient-centered outcomes (measured or related to status in the community)
  - Quality of life
  - Disability measures
  - Activities of daily living
  - Mobility measures, including use of prostheses only for transfers
  - Self-care
  - Pain
  - Fatigue after use (e.g., end of day)
  - Daily activity
  - Time LLP worn per day
  - Falls
  - Satisfaction with LLP
    - **Exclude** (simple) preference
- Ambulatory functional outcomes
  - Gait speed, step count, walk distance
  - Uneven or wet surface, low lighting walking
  - Ramps and incline traversing
  - Step/stair climbing function
  - Ambulatory function measured in the community setting (e.g., self-report or activity monitors)
  - Achievement of bipedal ambulation

- Other patient-centered ambulatory function measures
  - **Exclude** biomechanical measures
- Adverse effects of LLP
  - Skin ulcers/infections, (injuries from) falls due to mechanical failure, etc.
  - Other problems with prosthesis

#### **KQ 6:**

- Patient satisfaction measures with process of accessing LLP

#### **KQ 7:**

- Maintenance of bipedal ambulation
- Use of prostheses only for transfers
- Use of prostheses only indoors
- Abandonment of prostheses (not using prosthesis)
- Major problems with prosthesis
- Reasons for suboptimal use of LLP (as defined by above outcomes)

### **Eligible Study Designs**

#### **All KQ:**

- Published, peer reviewed study or publicly available theses, dissertations, etc.
- Any language (that can be read by research team or machine translated)
- No publication or study date restriction
  - **Exclude** case reports

#### **KQ 1-3:**

- Any assessment of validity, reliability, and related characteristics
  - **Exclude** studies of validation of translations of non-English scales, indexes, etc.
- Any study design
- $N \geq 20$  lower limb amputees
- No minimum followup time

#### **KQ 4:**

- Direct comparison between any two components, any relevant study design
- *Must include an analysis or reporting of differences in relative effect between components by a patient characteristic of interest (see text of KQ 4) or report sufficient participant-level data to allow such an analysis*
- No minimum sample size (other than excluding case reports)
- No minimum followup time

#### **KQ 5, 6:**

- Any study design, including qualitative studies
- No minimum sample size (other than excluding case reports)

- No minimum followup time

### **KQ 7:**

- Either longitudinal with followup since original lower limb prosthesis prescription or cross-sectional at timepoint after amputation or prescription
- Minimum followup time
  - $\geq 6$  month followup from time of LLP prescription, or
  - $\geq 1$  year followup from time of amputation, if no data reported about time since LLP prescription
- Minimum sample size:  $N \geq 100$

### **Setting**

- Any residence including community ambulation, homebound, and institutionalized
- Clinical or laboratory setting (for evaluation of specific ambulatory function outcomes)
- Rehabilitation setting (e.g., physical therapy clinic, in-home)
  - *Exclude exclusively* postacute (postsurgical) setting or inpatient rehabilitation (immediately postamputation)

### **Study Selection**

All citations (abstracts) found by literature searches and other sources were independently screened by two researchers. At the start of abstract screening, we implemented a training session, in which all researchers screened the same articles and conflicts were discussed. During double-screening, the team met regularly to reconcile conflicts and continue training. All screening was done in the open-source, online software Abstrackr (<http://abstrackr.cebm.brown.edu/>). During abstract screening, liberal eligibility criteria were applied to minimize the risk of rejecting pertinent studies. All potentially relevant studies were entered into an evidence map, in which basic study data were extracted from the abstract (KQ addressed, study design, country, sample size, measure(s) being validated or assessed [for KQ 1-3), and rejection reason [as applicable]). Remaining studies relevant to KQ 1-3 were reviewed in full text and measures being validated by the studies were entered into the evidence map; we also noted whether these studies were already included in known existing systematic reviews. Studies pertaining to KQ 4 (subgroup comparisons) were reviewed in full-text and information regarding whether the articles reported subgroup or regression analyses or individual patient level characteristics and results were entered into the evidence map; full-text articles were also reviewed to determine whether outcomes of interest were reported. Studies pertaining to KQ 7 (long-term follow-up) were also reviewed in full text to confirm that outcomes of interest were reported and to enter duration of follow-up into the evidence map. Studies pertaining to KQ 5 and 6 were also reviewed in full text to confirm eligibility, but no additional data were entered into the evidence map.

## Data Extraction

For all KQ, we extracted publication information, study design, eligibility and population descriptions including details about lower limb status (e.g., amputation level), outcome descriptions, and results.

For KQ 1 to 3, data were extracted into a specially designed spreadsheet form. We captured sample descriptors (amputation level, amputation etiology, mean age, sample size), measure/instrument type (assessment techniques, prediction tools, and outcome measures), measure/instrument name, instrument subscale/subquestion as appropriate, measure/instrument description or definition, evaluated property (validity, reliability, responsiveness, minimal detectable change, minimal important difference, and floor/ceiling effect), aspect of the measure (e.g., internal consistency, test-retest reliability, interrater reliability, content/face validity, criterion validity, convergent/concurrent validity, divergent/discriminant validity, predictive validity, construct validity, structural validity), the comparator (what the measure is being compared to), the metric used to assess the measure (e.g., Spearman  $r$  or effect size), the value of the metric, and the strength of the property (if relevant). Based on criteria summarized in Table 2, we determined whether each aspect is supported within each study.

Reliability addresses whether the tool gives a consistent answer. For the reliability property, we determined that measures were “reliable” with each study if any reliability metric (internal consistency, test-retest, interrater, or intrarater) was deemed to be adequate.

Validity addresses whether a tool measures what it claims to measure. There are several aspects of validity. Content (or face) validity considers the common sense and intrinsic meaning of the measure (e.g., that steps per day measures walking activity). Criterion validity addresses the extent to which a measure is related (e.g., correlated) to the “gold standard” ; however, since “gold standards” do not exist for the functional outcomes of interest, this specific metric is largely theoretical for our purposes. Convergent (or concurrent) validity assesses the degree to which two measures hypothesized to be related are actually related. Predictive validity refers to the comparison with a future outcome (e.g., current health status and future mortality). Divergent (or discriminant) validity tests whether measures that are theoretically not related are, in fact, statistically unrelated (e.g., lack of correlation between age and comfort measures). Construct validity addresses, overall, whether a measure tests what it claims to be measuring. Structural validity, assessed through factor analysis, Rasch or item response theory methods, assesses the fit of a model (a set of questions or traits). Rasch analysis may be conducted to maximize the homogeneity of the trait and to allow greater reduction of redundancy (i.e., increase simplicity) without sacrificing information.

For the validity property, we noted content validity, but did not use it to determine overall validity. If a study had an *a priori* hypothesis about the criteria necessary to determine validity, we used these criteria. Otherwise, we required evidence of either criterion validity, convergent validity, or construct validity. Similar to content validity, presence of divergent or structural validity was noted, but were not, alone, considered sufficient for overall validity. For KQ 2 (predictive tools), if a study found predictive validity, this was also deemed sufficient for overall validity.

Responsiveness addresses whether an instrument is sufficiently sensitive to capture important changes in the measure. Measures were “responsive” if they met any of the predetermined cutoffs for metrics such as effect size and standardized response mean.

Minimal detectable change and minimum (clinical) important difference were both extracted as reported.



Floor/ceiling effects were deemed to be present if more than 15 percent of the sample had the minimum or maximum possible value for the given scale (i.e., they hit the floor or ceiling of the scale). When this occurred, we captured a description of the sample characteristics.

Each study was assessed to determine whether the measures being evaluated were assessment techniques, prediction tools, or outcome measures. Although conceptually these categories of measures are distinct (see *Study Eligibility Criteria/Interventions or Predictors of Interest (and Measures for KQ 1-3)/KQ 1-3 Measures*), in practice distinguishing which category a study and measure belongs in is open to interpretation. To categorize outcomes we used the following approach: For KQ 1 (assessment techniques), we included measures described by studies as assessment techniques and studies that included lower limb amputees either prior to prosthesis use or at the time of evaluation for a new or replacement LLP. For KQ 2 (prediction tools), we included measures for which predictive validity was assessed. For KQ 3 (outcome measures), we included all other measures, which were evaluated in people with existing LLPs or were described (explicitly or implicitly) as outcome measures.

**Table 2. Metrics for Evaluation of Reliability, Validity, and Related Measures**

<p>Reliability</p> <ul style="list-style-type: none"> <li>Internal consistency <ul style="list-style-type: none"> <li>Cronbach alpha <ul style="list-style-type: none"> <li>Excellent <math>\geq 0.80</math></li> <li>Adequate 0.60-0.79</li> <li>Poor (“not reliable”) <math>&lt; 0.60</math></li> </ul> </li> <li>Rasch analysis person-separation reliability index <ul style="list-style-type: none"> <li>Excellent <math>\geq 0.90</math></li> <li>Good 0.80-0.89</li> </ul> </li> </ul> </li> <li>Test-retest, interrater, intrarater <ul style="list-style-type: none"> <li>Intraclass correlation coefficient (ICC) for continuous data</li> <li>Kappa for categorical data <ul style="list-style-type: none"> <li>Excellent <math>\geq 0.80</math></li> <li>Good 0.60-0.79</li> <li>Poor (“not reliable”) <math>&lt; 0.60</math></li> </ul> </li> </ul> </li> </ul> <p>Require: Test-interval be defined, large enough, and well justified  Require: <math>N \geq 30</math>  Require: Defined training of testers and test administration</p>
<p>Validity</p> <p>(If an <i>a priori</i> hypothesis is reported, describe that and whether valid based on the hypothesis; otherwise use criteria below)</p> <ul style="list-style-type: none"> <li>Content validity <ul style="list-style-type: none"> <li>Content of measure either has face validity (e.g., steps per day) or is based on evidence-based or consensus-based process (e.g., patient survey, expert panel, Delphi process, focus groups, interviews) or well-documented decision process</li> <li>Not sufficient for “overall” validity</li> </ul> </li> <li>Criterion validity* <ul style="list-style-type: none"> <li>Criterion standard scores (for norm-based scores, cited age-matched normative values, etc.)</li> <li>Well defined and justified criterion standard (“gold standard”)</li> </ul> </li> <li>Convergent (concurrent) validity <ul style="list-style-type: none"> <li>Strength and direction of <i>a priori</i> correlation (<math>r</math> or <math>r_s</math> [standardized]) <ul style="list-style-type: none"> <li>Large <math>\geq 0.5</math></li> <li>Moderate 0.3-0.5</li> <li>Small 0.1 to 0.29</li> </ul> </li> <li>Intraclass correlation coefficient for continuous data <ul style="list-style-type: none"> <li>Excellent <math>\geq 0.80</math></li> <li>Good 0.60-0.79</li> <li>Poor (“not reliable”) <math>&lt; 0.60</math></li> </ul> </li> <li>Statistical significant association of <i>a priori</i> hypothesis in regression analysis <ul style="list-style-type: none"> <li>Would be weak evidence, if only this analysis is reported</li> </ul> </li> </ul> </li> <li>Divergent (discriminant) validity</li> </ul>

<ul style="list-style-type: none"> <li>Low correlation (&lt;0.1) in testing different constructs</li> <li>Predictive validity (only for Key Question 2) <ul style="list-style-type: none"> <li>Correlation or regression strength with future outcome (with prosthesis)</li> </ul> </li> <li>Construct validity <ul style="list-style-type: none"> <li>Differences between known groups hypothesized to be different in the key construct</li> <li>Diagnostic test measures (e.g., compared to concurrent controls, nonamputees)</li> <li>Factor analysis or principal component analysis <ul style="list-style-type: none"> <li>N ≥10 per item</li> <li>Root mean square error of approximation ≤0.05-0.08</li> <li>Standardized response means ≤0.08</li> <li>Model fit measures ≥0.95</li> </ul> </li> </ul> </li> <li>Structural validity (Rasch testing) <ul style="list-style-type: none"> <li>Evidence from factor analysis</li> <li>Fit statistics are between 0.05 and 1.5 (i.e., items fit the model)</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>Responsiveness <ul style="list-style-type: none"> <li>Whether responsiveness statistics have been reported</li> <li>Effect size with pooled standard deviation</li> <li>Effect size with baseline standard deviation</li> <li>Standardized response mean</li> <li>Guyatt responsiveness index</li> <li>Receiver operating characteristic curve</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>Minimal detectable change / Minimum (clinical) important difference <ul style="list-style-type: none"> <li>Record values reported derived from <ul style="list-style-type: none"> <li>Test-retest analyses</li> <li>90% or 95% confidence interval</li> </ul> </li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>Floor/ceiling effect <ul style="list-style-type: none"> <li>≥15% of sample within the margin of error of the minimum or maximum value</li> </ul> </li> </ul>

\* Criterion validity is largely theoretical for the measures of interest since there are not “gold standards” to compare to.

For KQs 4 and 7, data were extracted into the Systematic Review Data Repository (SRDR, <https://srdr.ahrq.gov>) into specially-designed data extraction forms. Studies that reported comparisons of interest were fully extracted into SRDR; however, for studies that reported only individual patient data, we extracted those data into spreadsheet forms. From these data, we calculated means and ran t-tests to compare subgroups of interest.

Studies pertaining to KQs 5 and 6 were extracted qualitatively directly into text describing the studies.

## Risk of Bias Assessment

For KQs 4-7, we assessed risk of bias with the Cochrane Risk of Bias tool (assessing randomization, allocation concealment, blinding, intention-to-treat analysis, reporting bias, attrition bias, and other biases), and selected questions from the Newcastle-Ottawa Scale for observational studies (assessing representativeness of the study sample, outcome assessment, comparability of the people in compared study groups, and analytic method<sup>15, 16</sup>—in particular whether multivariable analyses were conducted). For each risk of bias/study quality question, we assessed whether there was high risk of bias (e.g., lack of blinding), low risk of bias (e.g., adequate randomization), or unclear risk of bias (if there was inadequate reporting to assess). For KQ 4, we also assessed whether adequate heterogeneity of treatment effect analyses were conducted.

For each study, we determined an “overall quality” based on the risk of bias for each assessed factor. The overall quality assessment was based on the best judgment of the reviewers. Special emphasis was placed on whether outcome assessors were blinded and, for KQ 4, whether

outcomes were validated and multivariable analyses were conducted. Overall quality was assessed as high, moderate, or low risk of bias.

## Data Synthesis

### Narrative and Tabular Synthesis

Included studies are presented in summary tables with the important features of the study populations, design, intervention, and risk of bias. All outcome results [will be] available in SRDR and [will be] publically available (<http://srdr.ahrq.gov>).

For KQ 1 to 3, each measure assessed by the eligible studies are described in terms of their validity, reliability, and related metric.

For KQ 4, studies are organized by whether they used and reported validated measures, as per KQ 1 to 3). Findings of the studies are summarized within this construct. Studies for KQ 5 and 6 are briefly summarized. Studies for KQ 7 are summarized, with an emphasis on between-group comparisons, where available.

### Post Hoc Analyses

For KQ 4, most studies did not report statistical analyses comparing subgroups. Either they reported subgroup findings without statistically comparing the subgroups or they reported individual patient data for both participant characteristics and outcomes. In these cases, we compared subgroups of interest with t tests or chi-squared tests. For all analyses (reported or conducted by us), we report the P value of the comparison between subgroups. Where  $P < 0.05$ , we provide the quantitative difference between subgroup effects in the Appendix results data tables and, in the main text tables summarizing each study, a narrative description of which subgroup has a greater effect with which LLP component. Where  $P \geq 0.05$ , we omit the comparative data.

We further calculated a Bonferroni-corrected P value for each study. To calculate the corrected P value we divided 0.05 by the total number of statistical analyses reported in the articles and those conducted for this review. Most studies had a large number of individual analyses (up to 135 comparisons). Without correcting P values, a large number of analyses would be statistically significant at the  $P = 0.05$  level due to chance alone. We chose the Bonferroni correction since it is relatively conservative (although, arguably overconservative) and we could not attempt to correct for correlations between analyses within studies. In the overall summary table of the findings of the comparative studies and in the text we describe only the comparisons which are statistically significant after correction of the P value threshold.

### Summarizing Findings Across Studies

For KQ 4 to 7, for each comparison of interventions, we determined a conclusion (or summary of findings across studies) for each outcome with sufficient evidence (i.e., not insufficient evidence, see *Grading the Strength of Evidence*).

For KQ 4, we concluded the evidence “favors” one intervention (over the other) when

- when the preponderance of studies found a statistically significant difference in the same direction, and/or
- when the preponderance of studies found statistically nonsignificant effect sizes that were either greater than 1.25 or less than 0.80.

- However, if the 95 percent confidence intervals were highly imprecise (beyond *both* 0.50 and 2.00), the conclusion was “unclear” regardless of the magnitude of the point estimate.
- If a conclusion was based on a statistically nonsignificant effect size, the strength of evidence (see below) was low (it could not be moderate or high).

We concluded that interventions had similar effects (noted in tables as favoring “either”) when the preponderance of studies’ effect sizes were between 0.80 and 1.20, were not statistically significant, and were not highly imprecise, as defined in the bullets above, or inconsistent (across studies).

When studies were sparse, effect size estimates were highly imprecise, or studies were highly inconsistent (e.g., with point estimates ranging from 0.14 to 3.03), we deemed the findings to be “unclear” (with an insufficient strength of evidence).

## **Grading the Strength of Evidence**

For KQ 4 to 7, we graded the strength of the body of evidence (SoE) as per the AHRQ Methods Guide on assessing the SoE.<sup>17</sup> We assessed the SoE for each outcome of interest. Following the standard AHRQ approach, for each intervention and comparison of intervention, and for each outcome, we assessed the number of studies, their study designs, the study limitations (i.e., risk of bias and overall methodological quality), the directness of the evidence to the KQs, the consistency of study results, the precision of any estimates of effect, the likelihood of reporting bias, and the overall findings across studies. Throughout the report, all estimates with 95 percent confidence or credible interval beyond 0.5 and 2.0 were considered to be highly imprecise. Based on these assessments, we assigned a SoE rating as being either high, moderate, low, or having insufficient evidence to estimate an effect. Outcomes with highly imprecise estimates, highly inconsistent findings across studies, or with data from only one study were deemed to have insufficient evidence to allow for a conclusion (with the exception that particularly large, generalizable single studies could provide at least low SoE). The data sources, basic study characteristics, and each SoE dimensional rating are summarized in “Strength of Evidence” tables detailing our reasoning for arriving at the overall SoE ratings.

## **Peer Review**

A draft version of this report [is being] reviewed (from Xxx # to Xxx #, 2017) by invited and public reviewers, including [pending]. These experts were either directly invited by the Evidence-based Practice Center or offered comments through a public review process. Revisions of the draft [will be] made, where appropriate, based on their comments. The draft and final reports [will also be] reviewed by the Task Order Officers and an Associate Editor from another Evidence-based Practice Center. However, the findings and conclusions are those of the authors, who are responsible for the contents of the report.

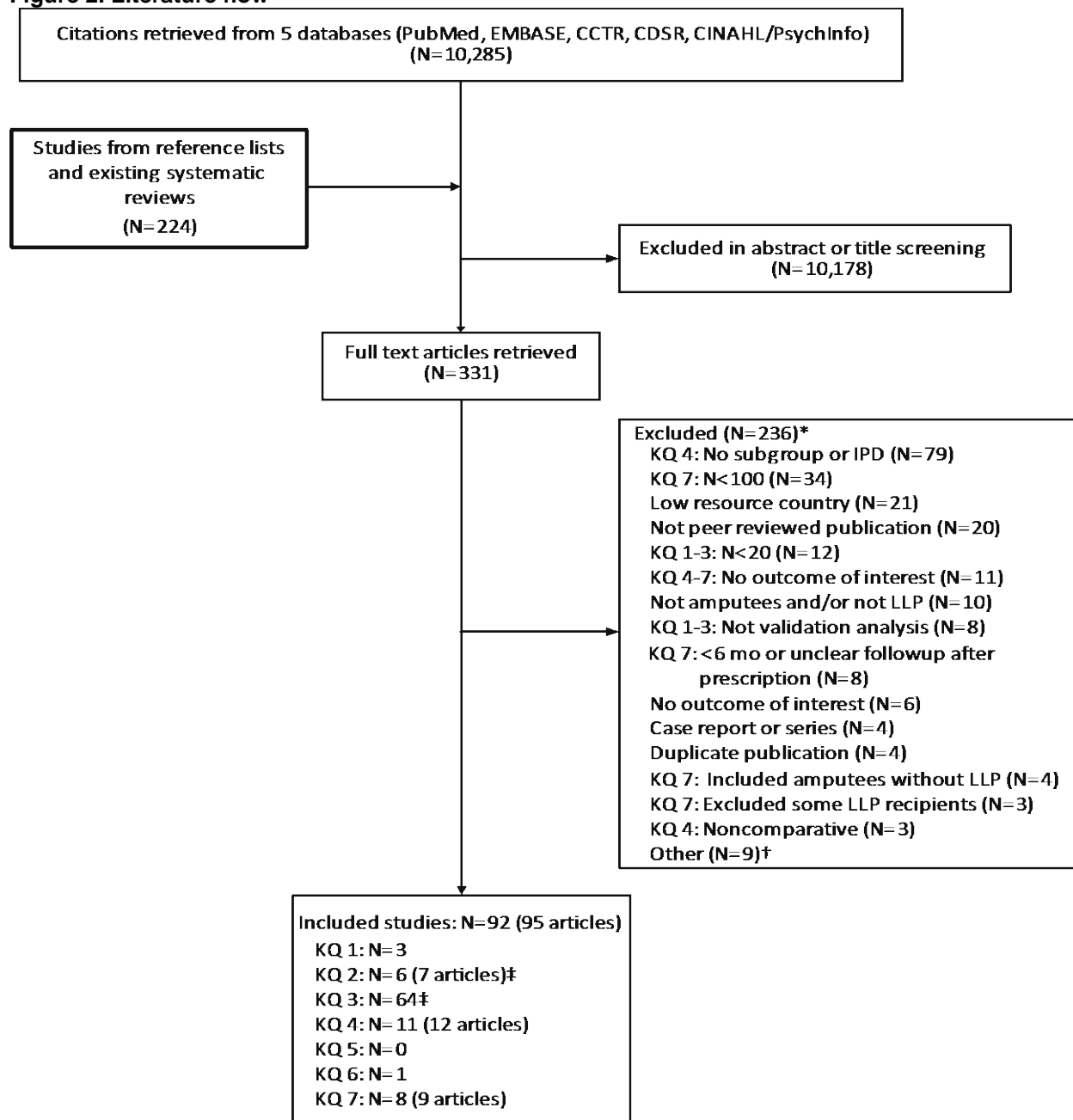
# Results

## Summary of Studies

The literature searches yielded 10,285 citations and an additional 224 references were screened from review articles and existing systematic reviews (Figure 2). Of these, 331 articles were retrieved in full text. We excluded 236 articles for the reasons listed in Figure 2 (see Appendix B). Of note, 79 studies compared lower limb prosthesis (LLP) components but did not report either subgroup analyses, regression analyses, or individual patient data which would allow subgroup analyses. Thus, we found 92 eligible studies (in 95 articles), of which 72 provided validation or related analyses addressing Key Questions (KQ) 1 to 3, 11 (in 12 articles) provided data relevant to KQ 4, no studies for KQ 5, two studies for KQ 6, and 8 studies (in 9 articles) relevant to KQ 7.

Pertaining to KQs 1 to 3, we summarize 92 studies addressing the validity, reliability, and related metrics for a large number of measures or instruments. Across the 92 studies, studies included between 20 to 1291 lower limb amputees (with or without prostheses). Among studies reporting age, the mean age of participants ranged from 35 to 73 years. Across studies, approximately 91 percent of participants had unilateral amputations (and 9 percent had bilateral amputations). Approximately 63 percent had transtibial amputations and 31 percent had transfemoral amputations; amputations at other levels were rare (about 6% of participants). About half (48%) of participants had vascular etiologies for their amputation and the same percentage had traumatic amputations; other causes were relatively rare.

**Figure 2. Literature flow**



\* 3 articles that were included for KQ 3 were potentially relevant for KQ 4 or 7, but were not eligible for them.

† No analyses of interest (N=2), pediatric population (N=2), unclear technology (N=2), battle injury (N=1), retracted publication (N=1), not primary publication (n=1).

‡ 1 study was included for both KQ 2 and KQ 3.

Abbreviations: CCTR = Cochrane Central Trials Registry, CDSR = Cochrane Database of Systematic Reviews, IPD = individual patient data, KQ = Key Question, LLP = lower limb prosthesis.

## Key Question 1

What **assessment techniques** used to measure functional ability of adults with major lower limb amputation have been evaluated in the published literature?

The distinction between assessment techniques (used to assess patient function prior to new or replacement prescription of a LLP), prediction tools (used to assess future outcomes) and outcome measures (used to assess patient function, etc. with their new or replacement LLP) is not as clear-cut as their definitions would imply. Most, if not all, outcome measures can be used as an assessment technique, and in studies this is routinely done at study baseline. It is also reasonable for most measures that have been designed as assessment techniques to be used to assess patient function, etc. with their LLP (i.e., as an outcome measure). Here we limit the list of assessment techniques to those measures either described by studies as assessment techniques or studies that explicitly included lower limb amputees prior to prosthesis use or at the time of evaluation for a new or replacement LLP.

### Summary of Studies and Participant Characteristics

Three tools have been evaluated as assessment techniques among people with lower limb amputations (Tables 1.1 and 1.2). More detailed study-level data are in Appendix C.

The evaluated assessment techniques were

- Prosthetist's Perception of Client's Ambulatory Abilities (PROS)
- Short Form Health Surveys (SF-12 and SF-36, and components, including a newly derived score PF-15)
- Transfemoral Fitting Predictor (TFP)

### Assessment Techniques

#### Prosthetist's Perception of Client's Ambulatory Abilities

The PROS is one of the subscales developed for the Orthotics and Prosthetics National Office Outcomes Tool (OPOT). The PROS consists of a series of questions asked of the prosthetist to assess the client's ability to climb stairs, walk, and use assistive devices.

In Hart 1999,<sup>18</sup> PROS was administered in a convenience sample of patients who were being evaluated for their first or replacement prosthesis and then readministered at follow-up 8 weeks later. About two-thirds of the study participants had dysvascular amputation etiologies. Mean age was about 56 years. About half had Medicare or Medicaid as their primary insurance. Although moderately correlated, the analyses did not support the *a priori* hypotheses about the strength of correlations between the PROS with the physical component summary scale (PCS) of the SF-36 or the PF-10. However, PROS demonstrated construct validity, differentiating patients by age group, amputation level, and K level. Moderate to small effect sizes were reported for transtibial and transfemoral amputees respectively.

#### Short Form Health Survey

The SF-12 and SF-36 are generic measures of health-related QoL designed originally for the general population. The SF-36 can be scored as two summary measures, called the physical

component score (PCS) and the mental component score (MCS) and eight subscales (physical functioning, bodily pain, role limitations due to physical health problems [role physical], role limitations due to personal or emotional problems [role emotional], emotional well-being, social functioning, energy/fatigue, and general health perceptions). Among people with LLPs, the SF instruments have been analyzed as a whole and parsed into numerous components subsets (from pairs of specific questions to the whole score). We summarize across all variations of the analyses.

### **Original SF-36**

Several components of SF-36 have been shown to be internally consistent and reliable (Table 1.2). It is not clear if other components were not reliable or if they were not analyzed for reliability. Overall in Hart 1999,<sup>18</sup> SF-36 and its components was found to be validated among a representative sample of patients who are being evaluated for their first or a replacement prosthesis (about half with Medicare or Medicaid insurance). There is evidence of convergent, construct, and structural validity for various subcomponents of the SF-36 scale. Similar to the reporting on reliability, it is unclear whether unreported subcomponents were not validated or were not analyzed. Responsiveness was demonstrated for both the PCS and MCS summary measures. Other aspects of validity, and MDC, MID, and floor/ceiling effects were not reported or analyzed.

### **PF-15: A Derivation of SF-36**

Hart 1999 also added 11 questions to the physical functioning (PF) scale with the goal of reducing their expectation of a floor and ceiling effect of the PF-10 (a subscale from SF-12) and to improve its construct validity; the 21 questions were streamlined to 15 through Rasch analysis.<sup>18</sup> The PF-15 demonstrated construct validity and internal consistency at initial to followup timepoints ( $\alpha = 0.89-90$ ). The PF-15 had a more normal distribution than the original PF-10, with slight ceiling effect, but it could not distinguish between K levels.

### **Transfemoral Fitting Predictor**

The TFP is a 9-item instrument with two subscales that describes graded tasks and aims to assess the prosthetic potential of transfemoral amputees.

One study (Condie 2011) evaluated this instrument in 92 adults (age not reported) with unilateral transfemoral amputations, most of whom were dysvascular amputees undergoing postoperative rehabilitation.<sup>19</sup> Principal component analysis demonstrated that there were two constructs within the nine items, and thus two subscales were identified; less demanding activities, and more demanding activities. In this population, both subscales had very good inter-rater reliability and internal consistency. TMP scores were different for patients who did and did not receive a prosthesis. Other aspects validity of the instrument were not assessed.

See section, below, *Key Questions 1 to 3 Summary* for overall summary.



**Table 1.1. Assessment Techniques: Studies, and Participant Characteristics**

Instrument: Subscale	Studies, n	Studies	Total N	Bi	Uni	TF	Kn	TT	TM	Trau	Vasc	CA	Other	NR	Age*
PROS	1	Hart 1999 <sup>18</sup>	840	nd	nd	171	nd	653	29†	260	516	nd	114	0	56.3
SF-12/36 ‡	1	Hart 1999 <sup>18</sup>	840	nd	nd	171	nd	653	29†	260	516	nd	114	0	56.3
TFP	1	Condie 2011 <sup>19</sup>	92	0	92	92	0	0	0	nd	76	nd	11	5	nd

\* Mean and range within studies in parentheses, in years.

† Ankle disarticulation. There were 37 classified as “other”.

‡ Also evaluated for Key Question 3.

Abbreviations: Bi = bilateral amputation, CA = cancer etiology, Kn = through the knee amputation, NA = not applicable (no subscale), nd = no data reported, NR = etiology not reported, Other = other etiology, PROS = Prosthetist’s Perception of Client’s Ambulatory Abilities, SF-12/36 = 12/36-Item Short Form Health Survey (and its components), TF = transfemoral amputation, TFP = Transfemoral Fitting Predictor, TM = transmetatarsal amputation, Trau = trauma etiology, TT = transtibial amputation, Uni = unilateral amputation, Vasc = dysvascular etiology.

**Table 1.2. Assessment Techniques: Reliability, Validity, and Other Characteristics**

Instrument	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
PROS	nr	Yes	nr	nr	No (Pearson r < hypothesized)	nr	Yes (P<0.05 by age, amputation level, K level)	nr	nr	nr	Yes	nr	nr
SF-12/36*, **	Yes‡ (Cronbach α 0.61-0.92)	Yes	nr	nr	Yes§ (Pearson r P<0.05)	nr	Yes# (P<0.05 by age, amputation level, K level)	Yes, PF-10 & PF-21 (Rasch)	nr	nr	Yes, PCS and MCS	nr	No (PF-15)
TFP	Yes (interrater ICC >0.8; Cronbach α 0.92)	Yes	nr	nr	nr	nr	Yes (PCA, by prosthetic receipt)	nr	nr	nr	nr	nr	nr

\* Including subscores.

† Pearson product moment correlations statistically significant with SF-36 physical component summary scale and most of its components, but not the mental components summary scale and most of its components.

‡ PF-10 (physical functioning questions), BP-2 (bodily pain questions), RP-2 (role physical questions), RE-2 (role emotional questions), MH-2 (mental health questions). Also PF-15.

§ Pearson product moment correlations mostly statistically significant between different subscales/components of SF-12/36

# Various subscales, including physical and mental components summary scales.

\*\* Also evaluated for Key Question 3.

Abbreviations: DAM = Discriminant Analysis Model, ICC = Intraclass correlation coefficient, MCS = Mental Component Score, MDC = minimal detectable change, MIC = minimal (clinical) important difference, nr = not reported PCA = principal component analysis, PCS = Physical Component Score, PF = physical functioning subscales, PROS = Prosthetist’s Perception of Client’s Ambulatory Abilities, SF-12/36 = 12/36-Item Short Form Health Survey (and its components), TFP = Transfemoral Fitting Predictor.

## Key Question 2

What **prediction tools** used to predict functional outcomes in adults with major lower limb amputation have been evaluated in the published literature?

### Summary of Studies and Participant Characteristics

Eleven prediction tools or subscales have been evaluated in people with lower limb amputations. The tools are summarized in Tables 2.1 and 2.2. More detailed study-level data are in Appendix C.

The evaluated prediction tools were the

- 180 Degree Turn Test
- 2 Minute Walk Test (2MWT)
- Activities-specific Balance Confidence scale (ABC)
- Barthel Index
- Berg Balance Scale (BBS)
- Clifton Assessment Procedure for the Elderly (CAPE) and the CAPE component score
- Cognitive Assessment Scale (CAS)
- Four Square Step Test
- Functional Independence Measure (FIM)
- Houghton Scale
- Locomotor Capabilities Index (LCI)
- Timed Up and Go (TUG)

## Predictive Tools

### 180 Degree Turn Test

The 180 Degree Turn Test is a video evaluation of the 180° turn of the Timed Up and Go (TUG) test, evaluating number of steps, time to complete, and turn steadiness.

In Dite 2007,<sup>20</sup> 40 people, two-thirds with dysvascular conditions (mean age 61.6 years), were evaluated first at discharge from inpatient rehabilitation. Number of steps to turn differed between persons with dysvascular amputation who had multiple falls at 6 months and those who did not, with 100 percent sensitivity and 74 percent specificity. Turn time also yielded relatively high sensitivity (85%) and specificity (78%); however, turn steadiness had low sensitivity (31%), but high specificity (85%).

### 2 Minute Walk Test

The 2MWT measures the distance walked along a straight, uncarpeted hallway for a 2-minute time period. Rest periods are permitted in order for participants to reach the farthest distance possible within the specified amount of time without further encouragement.

In Brooks 2001,<sup>21</sup> predictive validity of an initial 2MWT for future distance walked was demonstrated in a subgroup of 69 patients who had participated in a rehabilitation program, the majority of whom had dysvascular amputation etiology. The 2MWT, administered immediately

after initial prosthetic fitting was correlated with distance walked at 3 months ( $r = 0.568$ ). Convergent validity was demonstrated through correlations between the 2MWT and both the Houghton score ( $r = 0.493$ ) and the PF-10 ( $r = 0.479$ ). Age was negatively correlated with the 2MWT ( $r = -0.289$ ). Known-group validity was found in the 2MWT differentiating among men and women with transtibial amputations ( $P < 0.001$ ). The 2MWT changed significantly between baseline measures, hospital discharge and 3 month followup, providing evidence of responsiveness.

### **Activities-Specific Balance Confidence scale**

The ABC scale assesses self-reported balance confidence.

The scale was found to have predictive validity to predict failure to reach community walking with a LLP after 1 year. The area under the curve (AUC) was 0.927 among 40 participants of mean age 57 years old with transfemoral or transtibial amputations (5 bilateral) and unreported amputation etiology. (The AUC is a measure of diagnostic test accuracy evaluating test sensitivity and specificity; the closer the AUC approaches 1.0, the more accurate the test.)

### **Barthel Index**

The Barthel Index is a measure of basic activity of living (ADL) performance, where higher scores represent greater levels of functional independence.

In multivariate analysis of data from 48 patients (mean age 75.2 years old, the majority of whom had dysvascular unilateral transfemoral, through-knee, or transtibial amputation etiology)<sup>22</sup> pre-morbid and discharge Barthel Index scores were significantly different for patients who achieved successful rehabilitation (defined as discharge from a skilled nursing facility [SNF] to an independent living situation) 1 year after SNF admission for participants of mean age 75.2 years old with primarily dysvascular unilateral transfemoral, through knee, or transtibial amputation etiology ( $P < 0.001$ ).

### **Berg Balance Scale**

The BBS assesses static and dynamic balance ability with 14 tasks.

In Wong 2016,<sup>23</sup> a study of 40 participants of mean age 57 years old with transfemoral or transtibial amputations and unreported amputation etiology, two items of the BBS subscale were strongly associated with failure to reach community prosthetic walking level after 1 year: retrieve object from the floor (AUC=0.771) and look behind over shoulders (AUC=0.875), supporting the predictive validity of these two items.

### **Clifton Assessment Procedures for the Elderly and Cognitive Assessment Scale**

The CAPE scale assesses cognitive and psychomotor functions. The CAS score is obtained by adding the scores of all the mental functioning items.

One study of 32 patients with transfemoral or transtibial amputations (mean age 66.4 years but no data on amputation etiology) demonstrated predictive validity of the CAS reporting a correlation of 0.45 between the total CAPE score administered 2 to 4 weeks after amputation and the Harold Wood Stanmore mobility grade achieved 8 to 14 months after amputation.<sup>24</sup> The correlation between CAPE and mobility was 0.92 for a subset of patients with no medical comorbidities.

## **Four Square Step Test**

The FSST is a timed physical assessment of a sequence of steps.

In Dite 2007,<sup>20</sup> 40 people, two-thirds with dysvascular conditions (mean age 61.6 years), were evaluated first at discharge from inpatient rehabilitation. Scores on the FSST test differed between persons with dysvascular amputation who had multiple falls at 6 months and those who did not, with 92 percent sensitivity and 93 percent specificity. In addition, FSST scores were significantly different for persons who lower limb amputees with a history of multiple falls, as compared to those with no such history, supporting construct validity of the measure.

## **Functional Independence Measure**

The FIM score assesses functional independence and is used widely in inpatient rehabilitation facilities. The score is made up of 18 items, which are used to calculate a motor subscore and a cognitive subscore.

In Leung 1996,<sup>25</sup> total FIM and motor FIM scores at admission and discharge from inpatient rehabilitation facilities were used to predict a dichotomized version of the Houghton Scale of Prosthetic mobility Scale (successful and failed prosthetic ambulators) administered 3 to 12 months after discharge. In 41 patients with lower limb amputation (the majority unilateral transfemoral or transtibial, but no data on etiology or age), the only significant correlation observed was between the discharge motor FIM scale and prosthetic mobility score ( $r= 0.58$ ). There were no significant correlations between the admission motor FIM score and high versus low Houghton scores.

## **Houghton Scale**

The Houghton scale of prosthetic use for mobility is a self-reported scale that quantifies daily prosthesis wear, use of prosthesis, use of assistive devices, and perceived stability when using the prosthesis on various terrains.

Wong 2016,<sup>23</sup> a study of 40 participants of mean age 57 years old with transfemoral or transtibial amputations (5 bilateral) and unreported amputation etiology, evaluated whether the current score on the scale could predict failure to maintain or obtain community prosthetic walking level after 1 year. The scale was found to have predictive validity with an AUC of 0.885.

## **Locomotor Capabilities Index**

The LCI assesses an individual's perceived independence in performing 14 activities while wearing a prosthesis. The LCI is one of the scales of originally developed as part of the Prosthetic Profile of the Amputee (PPA). The entire LCI may be summed to provide a single score, or two 7-item subscales of the LCI can be calculated: basic items and advanced items. The original version used a 4-point ordinal scale; hence it is often called the LCI-4. The LCI-5 was designed to reduce potential ceiling effects of the LCI, by employing a 5-level response scale instead of a 4-level scale.

Two studies evaluated LCI as a prediction tool. Study participants were mostly under about age 62 and about half, overall, had dysvascular amputation etiologies. In Dite 2007,<sup>20</sup> at discharge from inpatient rehabilitation in 40 participants, two-thirds with dysvascular lower limb amputation, scores on the LCI advanced test differed between persons with dysvascular amputation who had multiple falls at 6 months and those who did not, with 43 percent sensitivity and 91 percent specificity. A study of 50 people aged 38 to 62 years with with unilateral

transfemoral or transtibial amputations, about half from trauma (Franchignoni 2004<sup>26</sup>), provided evidence of concurrent validity of the the LCI and LCI-5 with strong correlations with the Rivermead Mobility Index (RMI) ( $r = 0.735$ ) and FIM ( $r=0.612$ ). Convergent validity was found as the LCI had large correlations with RMI ( $r = 0.735$ ) and FIM (0.612). Convergent validity among the LCI and LCI-5 was also found to be large ( $r = 0.994$ ). The LCI was found to have known group validity by differentiating participants by age ( $r = -0.554$ ) and by amputation level (transfemoral vs. transtibial,  $P<0.001$ ). The LCI was found to have predictive validity for the RMI ( $r = 0.752$ ), the TWT ( $r = -0.667$ ), the FIM instrument (0.617), LCI (0.765), and LCI-5 (0.622).

## **LCI-5**

In Franchignoni 2004,<sup>26</sup> correlations between the LCI and LCI-5 were ( $r=0.994$ ) The LCI-5 was correlated with the RMI ( $r = 0.757$ ), the TWT ( $r = -0.708$ ), the FIM instrument (0.622). The LCI-5 was found to be responsive to change after training with an effect size of 1.40, which was larger than the ES for the LCI. Excellent reliability among a subgroup of 37 participants was found for the LCI-5 (ICC 0.984). Construct validity for the LCI-5 was supported with differences in scores by age and amputation level.

## **Timed Up and Go**

The TUG test measures the amount of time it takes an amputee to get up from an armless chair.

In Dite 2007,<sup>20</sup> 40 people, two-thirds with dysvascular conditions (mean age 61.6 years), were evaluated first at discharge from inpatient rehabilitation. At discharge from inpatient rehabilitation in 40 persons with dysvascular lower limb amputation the TUG test differed between persons with dysvascular amputation who had multiple falls at 6 months and those who did not, with 85 percent sensitivity and 74 percent specificity .

See section, below, *Key Questions 1 to 3 Summary* for overall summary.

**Table 2.1. Prediction Tools: Studies, and Participant Characteristics**

Instrument: Subscale	Studies, n	Studies	Total N	Bi	Uni	TF	Kn	TT	TM	Trau	Vasc	CA	Other	NR	Age†
180 Degree Turn Test	1	Dite 2007	40	0	40	0	0	40	0	0	0	0	26	14	61.6 (nd)
2MWT †	1	Brooks 2001 <sup>21</sup>	69 (290*)	51	239	60	0	179	0	0	194	0	0	96	66.3 (21-94)
ABC †	1	Wong 2016 <sup>23</sup>	40	5	35	13	0	24	0	0	0	0	0	40	57 (nd)
Barthel Index †	1	Eijk 2012 <sup>22</sup>	48	0	48	17	5	23	0	1	45	1	1	0	75.2 (nd)
BBS †: Item 9—Retrieve object from floor, Item 10—Look behind/over shoulder	1	Wong 2016 <sup>23</sup>	40	5	35	13	0	24	0	0	0	0	0	40	57 (nd)
CAPE	1	Hanspal 1997 <sup>24</sup>	32	nd	nd	17	0	15	0	0	0	0	0	32	66.4 (54-72)
FSST	1	Dite 2007	40	0	40	0	0	40	0	0	0	0	26	14	61.6 (nd)
FIM †	1	Leung 1996 <sup>25</sup>	33	1	32	8	0	24	0	0	0	0	0	33	nd
Houghton Scale †	1	Wong 2016 <sup>23</sup>	40	5	35	13	0	24	0	0	0	0	0	40	57 (nd)
LCI †	2	Dite 2007, <sup>20</sup> Franchignoni 2004 <sup>26</sup>	90	0	90	30	0	60	0	29	42	0	5	14	51 (38-62), 61.6 (nd)
TUG †	1	Dite 2007	40	0	40	0	0	40	0	0	0	0	26	14	61.6 (nd)

\* Total study included 290 participants, for whom amputation details are provided; however, 2MWT evaluated at followup in only 69.

† Also evaluated for Key Question 3.

Abbreviations: 2MWT = 2 minute walk test, ABC = Activities-specific Balance Confidence, BBS = Berg Balance Scale, Bi = bilateral amputation, CA = cancer etiology, CAPE = Clifton Assessment Procedures for the Elderly, CAS = Cognitive Assessment Scale, FIM = Functional Independence Measure, FSST = Four Square Step Test, Kn = through the knee amputation, LCI = Locomotor Capabilities Index, NA = not applicable (no subscale), nd = no data reported, NR = etiology not reported, Other = other etiology, TF = transfemoral amputation, TM = transmetatarsal amputation, Trau = trauma etiology, TT = transtibial amputation, TUG = Timed Up and Go, Uni = unilateral amputation, Vasc = dysvascular etiology.

**Table 2.2. Prediction Tools: Reliability, Validity, and Other Characteristics**

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Predictive Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
180 Degree Turn Test		nr	Yes (weak)	nr	nr	nr	nr	Yes: Sn 31-100%, Sp 78-85%	Yes: P<0.001	nr	nr	nr	nr	nr	nr
2MWT*		nr	Yes	nr	nr	Yes: Pearson r -0.289 to 0.493	nr	Yes: Pearson r 0.568	Yes: P<0.001	nr	nr	nr	nr	nr	nr
ABC*		nr	Yes	nr	nr	nr	nr	Yes: AUC 0.927	nr	nr	nr	nr	nr	nr	nr
Barthel Index*		nr	Yes	nr	nr	nr	nr	Yes: Beta = 0.53, R <sup>2</sup> = 56.6, P <0.001	nr	nr	nr	nr	nr	nr	nr
BBS*	Item 9: retrieve object from floor	nr	Yes	nr	nr	nr	nr	Yes: AUC 0.771	nr	nr	nr	nr	nr	nr	nr
	Item 10: look behind/over shoulder	nr	Yes	nr	nr	nr	nr	Yes: AUC 0.875	nr	nr	nr	nr	nr	nr	nr
CAPE		nr	Yes	nr	nr	nr	nr	Yes: Pearson r 0.93	nr	nr	nr	nr	nr	nr	nr
	CAS	nr	Yes	nr	nr	nr	nr	Yes: Pearson r 0.81	nr	nr	nr	nr	nr	nr	nr
FSST		nr	Yes	nr	nr	nr	nr	Yes: Sn 92%, Sp 93%	Yes	nr	nr	nr	nr	nr	nr
FIM*	Admission motor subscore	nr	No	nr	nr	nr	nr	No: Spearman r 0.18	nr	nr	nr	nr	nr	nr	nr
	Discharge motor subscore	nr	Yes	nr	nr	nr	nr	Yes: Spearman r 0.58	nr	nr	nr	nr	nr	nr	nr
Houghton scale*		nr	Yes	nr	nr	nr	nr	Yes: AUC 0.885	nr	nr	nr	nr	nr	nr	nr
LCI*		Yes: ICC 0.984	Yes	nr	nr	Yes: Spearman r 0.612 to 0.994	nr	Yes: Spearman r - 0.667 to 0.765	Yes: P<0.001	nr	nr	nr	Yes: ES 1.09	nr	Yes: 46%
LCI-5*		Yes: ICC 0.984	Yes	nr	nr	Yes: Spearman r 0.618 to 0.746	nr	Yes: Spearman r - 0.708 to 0.788	Yes: P<0.001	nr	nr	nr	Yes: ES 1.40	nr	nr
TUG*		nr	Yes	nr	nr	nr	nr	Yes: Sn 85%, Sp 74%	Yes	nr	nr	nr	nr	nr	nr

Abbreviations: 2MWT = 2 minute walk test, ABC = Activities-specific Balance Confidence scale, AUC = area under the curve, BBS = Berg Balance Scale, FIM = Functional Independence Measure, LCI = Locomotor Capabilities Index, nr = not reported (no data), MDC = minimal detectable change, MIC = minimal (clinical) important difference, Sn = sensitivity, Sp = specificity.

\* Also evaluated for Key Question 3.



## Key Question 3

What **functional outcome measurement tools** used to assess adults who use a LLP have been evaluated in the published literature?

### Summary of Studies and Participant Characteristics

Fifty-three tools have been evaluated as outcome measures in people with lower limb amputations and LLPs (Tables 3.1 and 3.2). Some of these have also been evaluated under Key Questions 1 and 2. More detailed study level data are in Appendix C.

The evaluated functional outcome measurement tools were:

- 2 minute walk test (2MWT)
- 6 minute walk test (6MWT)
- Amputees Activity Survey (AAS)
- Activities-Specific Balance Confidence (ABC) scale
- Amputee Body Image Scale (ABIS)
- Amputee Body Image Scale-Revised (ABIS-R)
- Amputee Mobility Predictor (AMP)
- Amputee Single Item Mobility Measure (AMPSIMM)
- Assessment of Daily Activity Performance in Transfemoral Amputees (ADAPT)
- Assessment of Quality of Life (AQoL)
- Barthel Index
- Berg Balance Scale (BBS)
- Body Image Questionnaire (BIQ)
- Climbing Stairs Questionnaire
- Frenchay Activities Index (FAI)
- Functional Independence Measure (FIM)
- Harold Wood/Stamore Mobility Grade
- Hospital Anxiety and Depression Scale (HADS)
- Houghton scale
- Impact of Events Scale (IES)
- International Physical Activity Questionnaire (IPAQ)
- Locomotor Capabilities Index (LCI)
- L Test of Functional Mobility
- Office of Population Censuses and Surveys Scale (OPCS)
- Orthotics and Prosthetics Users' Survey (OPUS)
- Patient Generated Index (PGI)
- Patient-Reported Outcomes Measurement Information System 29-item profile (PROMIS-29)
- Patient-Specific Functional Scale (PSFS)
- Physical Function Index (PFI)
- Prosthesis Evaluation Questionnaire (PEQ)
- Prosthetic Limb Users Survey of Mobility (PLUS-M)

- Quality of Life in Neurological Conditions – Applied Cognition/General Concerns (NQ-ACGC)
- Questionnaire for Persons with a Transfemoral Amputation (Q-TFA)
- Rising and Sitting Down Questionnaire
- Roland Morris Disability Questionnaire (RMDQ)
- Rivermead Mobility Index (RMI)
- Russek’s Code
- Satisfaction with Prosthesis (SAT-PRO)
- Short Form Health Surveys (SF-12, SF-36, SF-36V)
- Sickness Impact Profile (SIP)
- Six-Item Brief Social Support Questionnaire (SSQN6)
- Socket Comfort Score (SCS)
- Special Interest Group of Amputation Medicine/Dutch Working Group on Amputations and Prosthetics (SIGAM/WAP)
- Six-Item Brief Social Support Questionnaire (SSQN6)
- Step Activity Monitors
- Trinity Amputation and Prosthesis Experience Scale (TAPES)
- Trait Meta Mood Scale (TMMS)
- Timed Up and Go (TUG) test
- Walking Speed, 10 meters
- Walking Speed, 15.2 meters (50 feet)
- Walking Questionnaire
- World Health Organization Disability Assessment Schedule 2.0 (WHODAS2)
- World Health Organization Quality-of-Life Scale (WHOQOL-BREF)

## **Outcome Measures**

### **2 Minute Walk Test**

The 2MWT is a test used to measure the functional ability of amputees by measuring the distance they walk in 2 minutes.

Nine studies evaluated the 2MWT.<sup>21, 27-34</sup> Participants mostly had unilateral, transtibial amputations due vascular disease, with a wide age range. The 2MWT displayed reliability, convergent validity, and construct validity. Additionally, the 2MWT demonstrated an MDC 90 of 112.5.

### **6 Minute Walk Test**

The 6MWT is a test used to measure the functional ability of amputees by measuring the distance they can walk in 6 minutes.

Three studies evaluated the 6MWT.<sup>13, 34, 35</sup> Participants mostly had unilateral amputations, about one-third transfemoral and about one-half transtibial. Only about 10 percent had vascular etiologies for their amputations, with a wide age range. The 6MWT displayed both convergent and construct validity. Additionally, the 2MWT demonstrated an MDC 90 of 147.5.

## **Amputee Activities Survey**

The AAS is a 20-item questionnaire that allows amputee subjects to describe their average daily activity level.

In two studies of mostly people with unilateral transfemoral or transtibial amputations, 17 percent due to vascular conditions,<sup>13, 36</sup> the survey was assessed to determine if it showed differences among amputees with different K levels. The AAS was shown to have construct validity and concurrent validity.<sup>36</sup> Preliminary evidence of responsiveness was presented, with statistically significant differences observed, however no responsiveness statistics were provided.

## **Activities-Specific Balance Confidence**

The ABC scale assesses self-reported balance confidence.

In nine studies with over 2000 participants with mostly unilateral transfemoral or transtibial amputations were evaluated. About had dysvascular conditions, with a wide age range. The ABC displayed reliability, construct validity, and content validity. ABC scores were significantly worse for patients who did not achieve community ambulation as measured by the Houghton scale.<sup>37</sup> Additionally, the ABC demonstrated an MDC 90 of 0.49 and a MDC 95 of 0.58.<sup>38</sup> Floor and ceiling effects were not found.

## **Amputee Body Image Scale**

The ABIS is a 20-item scale that uses a 5 level rating scale to assess amputee perception and feeling of bodily experience.

In a sample of 145 participants with lower limb amputation, of whom about had dysvascular etiologies,<sup>39</sup> the ABIS displayed internal consistency reliability and moderate correlations with several TAPES subscales. However the ABIS did not fit a Rasch model well, and six items were deleted to produce the revised ABIS (ABIS-R).

## **Amputee Body Image Scale-Revised**

The ABIS-R measure is an adaptation of the ABIS that includes 14 items and 3-level rating scale.

Two studies evaluated ABIS-R, about half of whom had dysvascular disease and who had a wide age range.<sup>39, 40</sup> In the study that developed ABIS-R after evaluating ABIS,<sup>39</sup> Rasch analysis from data from 145 persons lower limb amputee prosthesis users demonstrated demonstrated good reliability and internal consistency. Additionally, in both studies the ABIS-R was moderately correlated with several related TAPES subscales and the Depression subscale of the ABIS-R displayed reliability and moderate convergent validity.

## **Amputee Mobility Predictor**

The AMP measures functional capabilities of an amputee both with a prosthesis (AMPPRO) and without (AMPnoPRO).

In a study of 160 lower limb amputees, with mostly amputation etiologies other than dysvascular conditions, the AMPnoPRO and the AMPPRO were found to have reliability, convergent validity, and construct validity.<sup>13</sup> In another study of mostly older adults (mean age 66 years) with unreported amputation etiologies, the AMP Total was found to have reliability and had an MDC 90 of 3.4.<sup>34</sup>

## **Amputee Single Item Mobility Measure**

The AMPSIMM is a single-item self-reported mobility measure wherein amputees select one statement about their level of mobility from 6 potential responses.

The AMPSIMM, tested in a sample of 113 lower limb amputees, most with dysvascular conditions, was demonstrated concurrent validity with measures such as the LCI-5 and TAPES functional restriction score, and hours of prosthesis use.<sup>41</sup> AMPSIMM scores were significantly different by amputation level. Responsiveness was demonstrated by large changes in scores from 6 weeks to 12 months post amputation. No significant floor or ceiling effects were observed.

## **Assessment of Daily Activity Performance in Transfemoral Amputees**

The ADAPT test measures the functional ability of transfemoral amputees in regard to daily activities.

In a small study of 20 mostly younger unilateral transfemoral amputees, six of whom had dysvascular disease, the ADAPT test was found to have reliability.<sup>42</sup>

## **Assessment of Quality of Life**

The AQoL consists of 15 questions covering five domains of health-related quality of life: illness, independent living, social relationships, physical senses, and psychologic wellbeing.

One study (Miller 2008) evaluated the instrument in 58 adults with unilateral transfemoral or transtibial amputations, half with dysvascular conditions.<sup>43</sup> The test was found to be associated with a measure of arm muscle area (a nutritional assessment) by regression analyses only (Table 1.2). Thus, there is weak evidence of validity of the AQoL as an assessment technique among unilateral lower limb amputees. Other measures of validity, along with reliability and other aspects have not been assessed.

## **Barthel Index**

The Barthel Index measures independence in activities of daily living.

In a sample of 45 patients with unilateral transfemoral amputation for vascular disease and also with hemiparesis. Barthel index change scores during inpatient rehabilitation were greater for persons with mild versus moderate hemiparesis, providing evidence of construct validity. The Barthel Index was found to have mixed construct validity.<sup>44</sup> Note, though, as described under Key Question 1, a study reported evidence of predictive validity for the Barthel index.<sup>22</sup>

## **Berg Balance Scale**

The BBS is a 14-item performance measure designed to assess balance.

Three studies of mostly unilateral amputees, about half of whom had dysvascular conditions, with a wide range of ages, evaluated BBS.<sup>29, 30, 37</sup> The BBS displayed strong interrater reliability and internal consistency, convergent validity with measures of related constructs, and construct validity (distinguishing between scores of mobility aid users, and those afraid of falling). BBS scores were significantly different for amputees who did and did not achieve community ambulation as measured by the Houghton scale. No floor or ceiling effects were demonstrated.

## **Body Image Questionnaire**

The BIQ was derived from a Body Shape Questionnaire for Eating Disorders to assess body image dissatisfaction.

In a study of 107 participants with a mix of amputations, 40 percent of which were due to dysvascular conditions, internal consistency was reported with  $\alpha=0.90$ .<sup>45</sup>

## **Climbing Stairs Questionnaire**

The Climbing Stairs Questionnaire consists of 15 items with dichotomous response options that assess perceived limitations in walking and climbing stairs among those with lower limb amputations who live at home.

Across four studies of mostly unilateral transtibial or transfemoral amputees from dysvascular conditions, with a wide age range,<sup>46-49</sup> the Climbing Stairs Questionnaire demonstrated reliability and convergent validity. Construct validity for the Climbing Stairs Questionnaire was largely supported.

## **Frenchay Activities Index**

### **FAI-15**

The FAI-15 is a 15-item self-report measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities.

Two studies evaluated FAI-15 in participants with transtibial or transfemoral amputations, about half of who had dysvascular conditions, with a wide age range.<sup>31, 50</sup> The FAI-15 displayed acceptable internal consistency and test-retest reliability and convergent validity with related measures. There was some evidence to indicate construct validity with group differences observed by etiology of amputation, mobility device use, age and years as an amputee, but no differences in scores between BK and AK amputees as hypothesized.

### **FAI-18**

The FAI-18 is a modified version on the FAI-15 which includes three additional items to improve the utility of the measure in younger age groups with traumatic etiologies.

One study of mostly younger amputees (<55 years), with mostly traumatic amputations (60%) found that the FAI-18 displayed reliability and convergent validity, and structural validity.<sup>31</sup> There was some evidence to support hypotheses related to construct validity, however there were no differences in scores between transfemoral and transtibial subgroups, as hypothesized.

## **Functional Independence Measure, Amputation Function Subscore**

The FIM is an 18-item observational measure that assesses function in terms of need for assistance and level of independence. It addresses six life areas: self-care, sphincter control, mobility, locomotion, communication and social cognition. It can be scored overall, or using the 13-item motor score or 5-item cognitive score.

Three studies of mostly younger amputees, only 25 percent of whom were reported to have dysvascular conditions evaluated FIM.<sup>25, 36, 51</sup> Concurrent validity of the FIM is supported through correlations with related measures. Preliminary evidence of responsiveness was demonstrated through changes observed between admission to and discharge from inpatient rehabilitation facilities, but no responsiveness statistics were reported.

## **Overall Score**

The subscore displayed responsiveness but did not display reliability, convergent, or construct validity. The overall score did not demonstrate either a floor or ceiling effect.

## **FIM Amputation Function Subscore**

An amputation subscore is composed of three mobility items: transferring, walking on level surfaces, climbing stairs.

In one study of 107 generally young adults (mean age 35 years) for whom amputation etiology was not reported, internal consistency of the FIM Amputation Function Subscore was not acceptable ( $\alpha=0.55$ ).<sup>51</sup> Concurrent validity was demonstrated with the SIP-PD, LCI, and PFI and reported standardized response means and effect sizes for changes in scores from 3 to 12 months, and 12 to 24 months after amputation, providing evidence of individual items and the combined items that supported responsiveness of the FIM Amputation Function Subscore.

## **Chair Transfer**

The subscore displayed reliability and responsiveness but did not display convergent or construct validity. The subscore did not demonstrate a floor effect but did demonstrate a ceiling.

## **Climb Stairs**

The subscore displayed reliability and responsiveness but did not display convergent or construct validity. The subscore did not demonstrate either a floor or ceiling effect.

## **Walk on a Level Surface**

The subscore displayed reliability and responsiveness but did not display convergent or construct validity. The subscore did not demonstrate either a floor or ceiling effect.

## **Harold Wood/Stanmore Mobility Grades**

The Harold Wood/Stanmore Mobility Grades measure achieved prosthetic mobility.

In three studies whose populations were incompletely described, but with a wide range of ages, evidence to support convergent validity was not found.<sup>45, 54, 55</sup> Although mobility scores for working and not-working amputees were significantly different., these data were not considered as evidence supporting construct validity.

## **Hospital Anxiety and Depression Scales**

The HADS measures symptoms of Anxiety and Depression on 7-item subscales each of their respective symptomologies.

A study of 38 people, mostly with unilateral transtibial amputations, all related to diabetes (mean age 66 years), found evidence of convergent validity for both the Anxiety and Depression subscores.<sup>40</sup>

## **Houghton Scale**

The 4-question self-reported Houghton Scale reflects a person's perceptions of daily prosthesis use and function in various walking conditions.

Across four studies,<sup>28, 37, 56-58</sup> of generally older adults, about half of whom had dysvascular conditions, the Houghton scale displayed reliability, criterion validity, convergent

validity, construct validity, and responsiveness with reported effect sizes of 0.29 to 1.62. There was no evidence of either a floor or a ceiling effect.

### **Impact of Event Scale**

The IES is a self-report measure that can be used to assess impact of any specific life event.

One study evaluated two of the scale's categories: Intrusion and Avoidance. The study included mostly younger adults with non-dysvascular amputation etiologies.<sup>53</sup> The Avoidance subscale and the Intrusion subscale were found to have convergent validity with moderate to large correlations with TAPES, as hypothesized by the study authors. No evidence supporting reliability, other aspects of validity or responsiveness was found.

### **International Physical Activity Questionnaire**

The IPAQ is a 25 item self-report measure that evaluates physical activity within four categories: Leisure time, Domestic and gardening (yard), Work-related, and Transport-related.

In a study of 22 lower limb amputees with mostly traumatic causes, the IPAQ was found to have poor to adequate internal consistency ( $\alpha=0.53-0.53$ ).<sup>59</sup> No evaluation of validity was reported.

### **Locomotor Capabilities Index**

The LCI assesses an individual's perceived independence in performing 14 activities while wearing a prosthesis. The LCI is one of the scales of originally developed as part of the Prosthetic Profile of the Amputee (PPA). The entire LCI may be summed to provide a single score, or two 7-item subscales of the LCI can be calculated: basic items and advanced items. The original version used a 4-point ordinal scale; hence it is often called the LCI-4. The LCI-5 was designed to reduce potential ceiling effects of the LCI, by employing a 5-level response scale instead of a 4-level scale.

In addition to the two studies that were deemed to have evaluated LCI (or LCI-5) as prediction tools, 13 studies more generally evaluated LCI (or LCI-5). Among 1447 total participants, about 40 percent had dysvascular etiologies and the median study had a mean age of 59 years.<sup>20, 36, 44, 47, 51, 52, 57, 60-65</sup>

### **Overall Score**

The subscore displayed evidence of reliability, convergent validity, and divergent validity. The LCI-4 demonstrated a strong floor effect., with more than half of the sample in one large study, scoring the highest possible score. There was no evidence of construct validity or a ceiling effect.

### **Advanced**

The subscore displayed reliability, convergent validity, and floor effects. There was no evidence of construct, validity or ceiling effects.

### **Basic**

The subscore displayed evidence of reliability and a floor effect. There was some evidence of convergent validity and no evidence of construct validity or a ceiling.

## **L Test of Functional Mobility**

The L Test is a modified version of the Timed Up & Go (TUG) test where the time it takes an individual to rise from an armless chair, walk 3 meters, perform a right-angle turn, and continue walking 7 meters before turning around 180° and walking back along the same path and sitting down is recorded in seconds.

In two studies with 126 lower limb amputees,<sup>66, 67</sup> one-third with dysvascular disease (mean age about 57 years), the L Test was moderately to strongly correlated to related measures including the TUG, the 2MWT, the 10 meter walk, BBS and other performance measures, as hypothesized. However, the correlation between the PEQ mobility subscale and the L Test was small. L test scores differed for clinically different groups as hypothesized. An MCID of 4.5 seconds was reported with AUC of 0.67 for discriminating between persons who had and had not undergone a minimally clinically important change. Inter- and intrarater reliability were reported to be excellent.

## **Office of Population Censuses and Surveys Scale**

The OPCS assesses disability and impairment in the community.

One study of 34 mostly unilateral transtibial and transfemoral amputees, with a mean age of 57 years, but for whom amputation etiology was not reported,<sup>36</sup> found convergent validity for the OPCS with statistically significant associations between the OPCS and related measures; although no correlation coefficients were provided. Preliminary evidence of responsiveness was presented, with statistically significant differences observed between admission and discharge to inpatient rehabilitation, however no responsiveness statistics were provided.

## **Orthotics and Prosthetics Users' Survey**

The OPUS is a self-report survey that contains separate subscales that assess measures Lower-limb function, Health-related quality of life, and Satisfaction with an orthotic or prosthetic device specifically for individuals who use orthotic or prosthetic devices.

In a study of mostly older adults (mean age 66 years) with unreported amputation etiologies,<sup>34</sup> the subscales had variable test-retest reliability: for Lower Limb Function the ICC was 0.67 (adequate reliability), for Quality of Life the ICC was 0.85 (excellent reliability), and for Satisfaction the ICC was 0.50 (poor reliability). MDC values were reported and no floor or ceiling effects were reported.

## **Patient Generated Index**

Patient-centered quality of life is assessed through the PGI, in which patients are asked to list important areas of their life that have been impacted by their condition, and then rate those areas, and the importance of those areas to them.

In a study of 42 people with unilateral transfemoral amputations, almost all due to dysvascular conditions,<sup>68</sup> the PGI was found to have poor reliability and weak convergent validity with the SF-12 PCS and moderate correlation with the SF-12 MCS.

## **Patient-Reported Outcomes Measurement Information System**

PROMIS-29 is a compilation of self-report instruments that measure eight symptom and quality of life constructs across patient populations: physical function, anxiety, depression, fatigue, sleep disturbance, social role satisfaction, pain interference, and pain intensity.



Two studies evaluated PROMIS-29, with over 1000 unilateral transtibial and transfemoral amputees, about half with dysvascular etiologies.<sup>69, 70</sup> Evidence for reliability of all subscales in the lower limb amputee population was demonstrated. MDCs for subscales were reported. The depression, physical function, and pain intensity subscales displayed construct validity. The remaining subscales showed some evidence of construct validity. The anxiety, depression, and pain interference subscales displayed a floor while only the social role satisfaction subscale displayed a ceiling.

### **Patient-Specific Functional Scale**

The PSFS is an individualized assessment of patient-specific activities, which they find difficult to perform due to their amputation and how they would rate their current abilities to complete those activities.

In a study of mostly older adults (mean age 66 years) with unreported amputation etiologies,<sup>34</sup> the PSFS was assessed for reliability and responsiveness per item as well as by a total score. Items 1-5 demonstrated good reliability, and the total score was found to have excellent reliability. The MDC 90 for the items and the total scores ranged from 3.1 (Items 3 and 5) to 11 (Total). No data on convergent validity, construct validity or responsiveness was identified.

### **Physical Function Index**

The PFI is a generic measure consisting of 14 self-report items related to ability to perform various physical tasks.

In a study of 107 generally young (mean age 35 years) unilateral amputees whose etiologies were not reported,<sup>51</sup> overall PFI internal consistency was greater than 0.70, no floor or ceiling effects were observed for the overall score. Evidence for PFI reliability, convergent validity, and responsiveness has been reported. Data have been reported for five individual PFI items as follows:

#### **Overall Score**

This item displaced reliability, convergent validity, and responsiveness. There was no evidence of construct validity, a floor, or a ceiling.

#### **Climb Stairs**

This item displaced reliability, convergent validity, responsiveness, a floor, and a ceiling. There was no evidence of construct validity.

#### **Run at Steady Pace**

This item displaced reliability, convergent validity, responsiveness, and a ceiling. There was no evidence of construct validity or a floor.

#### **Squat to Pick Up Object**

This item displaced reliability, convergent validity, responsiveness, and a ceiling. There was no evidence of construct validity or a floor.

## **Walk at Steady Pace**

This item displaced reliability, convergent validity, responsiveness, a floor, and a ceiling. There was no evidence of construct validity.

## **Prosthesis Evaluation Questionnaire**

The original PEQ is a questionnaire designed to evaluate prosthesis function and prosthesis-related quality of life in individuals with lower limb loss. It consists of 82 items and uses a linear analog scale response format. Nine scales are computed from 42 items (ambulation, appearance, frustration, perceived response, residual limb health, social burden, sounds, utility, well being). The 40 remaining items pertain to other evaluation areas and are not grouped into scales. However, several investigators have combined the ambulation scale with transfer items to create a mobility subscale. Several investigators have modified the response format of several PEQ scales and used Likert scales of various lengths.

Overall, eight studies have evaluated PEQ and its variations in people with lower limb amputations.<sup>34, 57, 58, 70-73</sup> These included about 2000 people with mostly unilateral transtibial amputations, over one-third related to dysvascular conditions. Most studies had mean ages in the 60s. The original validation paper reported that all scales except transfers, had acceptable internal consistency.<sup>72</sup> All scales (both visual analog and Likert 7-response formats), except perceived responses had adequate test-retest reliability.<sup>34, 72</sup>

## **Mobility Scale: Original Visual Analog Scale, 7-point Likert Scale, and 10-Point Likert Scale Versions**

Evidence of reliability and convergent validity of the mobility subscale (both the 12 item and 13 item versions) was provided in several papers. The mobility subscale displayed evidence of concurrent validity, and MDC has been reported. Neither the original nor the Likert-7 mobility subscale showed evidence of a floor or a ceiling.

## **Mobility Scale- 12/5 Version**

Rasch analysis of the PEQ mobility scale resulted in recommendations to delete one item and change the response scale. This new version of the scale, the PEQ-MS 12/5, demonstrated excellent internal consistency, construct and convergent validity.

## **Perceived Response Visual Analog Scale and Modified by 7-Point Likert Scale**

ICC for test retest reliability was poor for both the original (visual analog) and Likert 7 versions (ICC = 0.41-0.56).

## **Residual Limb Health Visual Analog Scale and Modified by 7-Point Likert Scale**

ICC for test retest reliability was acceptable for both the original (visual analog) and Likert 7 versions (ICC = 0.79-0.80).

## **Social Burden Visual Analog Scale and Modified by 7-Point Likert Scale**

ICC for test retest reliability was acceptable for both the original (visual analog) and Likert 7 versions (ICC = 0.64-0.81).

### **Sounds Visual Analog Scale and Modified by 7-Point Likert Scale**

ICC for test retest reliability was acceptable for both the original (visual analog) and Likert 7 versions (ICC = 0.79-0.84).

### **Transfer 7-Point Likert Scale**

This is a 5-item scale assessing difficulty in performing various transfer tasks. ICC for test retest reliability was acceptable for both the original (visual analog) and Likert 7 versions (0.73-0.75). One study used the transfer items to create a transfer scale, but found a strong ceiling effect.

### **Utility Visual Analog Scale and Modified by 7-Point Likert Scale**

ICC for test retest reliability was acceptable for both the original (visual analog) and Likert 7 versions (ICC = 0.79).

### **Well-Being Visual Analog Scale and Modified by 7-Point Likert Scale**

ICC for test retest reliability was acceptable for both the original (visual analog) and Likert 7 versions (ICC = 0.70-0.87). A strong ceiling effect was observed in the Likert version of this scale.

### **Prosthetic Limb Users Survey of Mobility**

The PLUS-M is a 44-item self-report measure that assesses perceived mobility in people with lower limb amputation.

Four studies with more than 1700 amputees have included both unilateral and bilateral amputees with mostly transtibial and transfemoral amputations,<sup>38, 70, 74, 75</sup> about 40 percent due to dysvascular conditions. Significant differences in PLUS-M scores were reported by Medicare Functional Classification level. Several fixed, short form versions and a computer adaptive test (CAT) version of the PLUS-M have been developed.

#### **12-Item Short Form**

The subscale displayed reliability, a MDC 90 of 4.50, and a MDC 95 of 5.36. No floor or ceiling effects were found.

#### **7-Item Short Form**

The subscale displayed reliability, a MDC 90 of 4.69, and a MDC 95 of 5.59. No floor or ceiling effects were found.

#### **Computerized Adaptive Test**

The CAT displayed reliability, a MDC 90 of 6.42, and a MDC 95 of 7.65. No floor or ceiling effects were found.

### **Quality of Life in Neurological Conditions – Applied Cognition/General Concerns**

The NQ-ACGC short form of a larger item bank consists of 8 items that measure general cognitive abilities, including memory, attention, and decision-making.

In two studies of over 1200 unilateral amputees, about 40 percent of whom had dysvascular conditions,<sup>70, 76</sup> the NQ-ACGC short form displayed reliability and construct

validity. The NC-ACGC demonstrated a MDC 90 of 6.67 and a MDC 95 of 7.94. A ceiling effect was observed.

### **Questionnaire for Persons With a Transfemoral Amputation**

The Q-TFA measures use, mobility, problems, and global health, both as separate scores and as a total score, for nonelderly transfemoral amputees.

In a study of 156 unilateral transfemoral amputees, mostly related to trauma,<sup>77</sup> the Q-TFA was found to have excellent reliability for all subscales and the Global score. Content validity was demonstrated in the Prosthetic Mobility subscale. Each of the subscales demonstrated concurrent validity. The prosthetic use subscale had a ceiling effect, with 31 percent of participants with the highest score. Other subscales did not have floor or ceiling effects.

### **Rising and Sitting Down Questionnaire**

The Rising and Sitting Down Questionnaire is a 39 item self-report measure assessing limitations in the activities of rising and sitting down, using a dichotomous response format.

In three studies with almost 400 mostly unilateral amputees with dysvascular etiologies,<sup>47-49</sup> the Rising and Sitting Down Questionnaire was found to have good reliability. Convergent validity of the Questionnaire was demonstrated. Construct validity was largely supported, however there were no differences between scores of bilateral versus unilateral amputees as hypothesized.

### **Roland Morris Disability Questionnaire**

The RMDQ is a measure of functional capacity.

In a single study of 46 amputees, none with dysvascular conditions and mostly younger (mean age 48 years), convergent validity was found for the RMDQ.<sup>78</sup>

### **Rivermead Mobility Index**

The RMI assesses mobility as a cumulative index.

In two studies of 340 lower limb amputees, about one-third with dysvascular conditions, with a wide range of ages, reliability of the RMI was found to be excellent.<sup>79, 80</sup> Evidence for convergent validity was also found. There was also evidence of responsiveness, but no ceiling effect.

### **Russek's Code**

Russek's Code is a classification index developed for lower limb amputations and used to assess functional abilities with a prosthesis.

A single study of 772 lower limb amputees with undescribed age and amputation etiology evaluated Russek's Code.<sup>65</sup> Weak evidence for construct validity was found.

### **Satisfaction with Prosthesis**

The SAT-PRO questionnaire is 15 item self-report tool measuring satisfaction with a prosthesis.

One study of 55 unilateral transfemoral and transtibial amputees, all due to dysvascular dysfunction and all at least 60 years old evaluated the SAT-PRO.<sup>81</sup> It displayed reliability and construct validity.

## Short Form Health Surveys

The SF-12 and SF-36 are generic measures of health-related QoL designed originally for the general population. The SF-36 can be scored as two summary measures, called the physical component score (PCS) and the mental component score (MCS) and eight subscales (physical functioning, bodily pain, role limitations due to physical health problems [role physical], role limitations due to personal or emotional problems [role emotional], emotional well-being, social functioning, energy/fatigue, and general health perceptions). Among people with LLPs, the SF instruments have been analyzed as a whole and parsed into numerous components subsets (from pairs of specific questions to the whole score). A summary across variations is presented here.

In addition to the evaluation of SF-12 and SF-36 as an assessment technique (Key Question 1) by one study, 16 studies with almost 2500 lower limb amputees evaluated these scales as outcome measures.<sup>34, 78, 82-95</sup> Only 17 percent of the study participants were reported to have dysvascular conditions and study participants were generally young adults (mean ages generally <50 years). Convergent validity was supported for the General Health subscale of the SF-36. Four subscales did not support construct validity (SF-36 Emotional Problems, SF-36 Emotional Role Limitations, SF-36 Energy/Fatigue, SF-36 Mental Health Composite Scale score [MCS]); all other SF-36 subscales presented mixed evidence for construct validity. Construct validity was found for the SF-12 MCS and SF-12 Physical Health Composite Scale score (PCS). Other metrics of validity were not reported.

The SF-36V is a version of the SF-36 that has been adapted for greater precision in assessing the health status among the veteran population. This adaptation includes minor alterations to the scoring of two sections such that the precision to identify differences at the lower end of the health status continuum may be achieved. The SF-36V was found to be a reliable instrument. For the three component scores presented, MDCs were displayed ranging from 17.1 to 34.2. Other metrics of validity were not reported.

## Sickness Impact Profile

The SIP is a generic, self-report measure used to assess the impact of illness on health-related functional status. There are 136- and 68-item versions; the longer version has been evaluated among amputees. The SIP is divided into several subscales, included physical dimension (SIP-PD), ambulation, mobility, body care and movement, among others, and overall score.

Overall, four studies have evaluated the various SIP measures in 290 unilateral amputees, who were generally younger adults (mean age about 44 years) and whose amputation etiologies were not described.<sup>49, 51, 96, 97</sup>

## Overall Score

In a single study with 20 amputees, the SIP-136 overall score demonstrated reliability, convergent validity, divergent validity, and responsiveness.<sup>96</sup> There was no evidence of construct validity, a floor, or a ceiling.

## SIP-PD

Three studies have evaluated the Physical Dimension subscore in amputees.<sup>51, 96, 97</sup> The three studies differed in whether they found evidence of construct validity regarding whether the SIP-PD score was associated with a wide range of patient and amputation characteristics. However, there is evidence of convergence with LCI and PFI scores and associations with

walking speeds and return to usual activity. Evidence of responsiveness was reported. No floor effect was found.

### **Ambulation**

This subscale demonstrated reliability, convergent validity, and responsiveness. There was no evidence of construct validity, a floor, or a ceiling.

### **Body Care and Movement**

This subscale demonstrated reliability, convergent validity, responsiveness, and a floor. There was no evidence of construct validity or a ceiling.

### **Mobility**

This subscale demonstrated reliability, but a large floor effect (63%). There was no evidence of construct validity or a ceiling. There was some evidence for convergent validity.

### **Six-Item Brief Social Support Questionnaire**

The SSQN6 is a tool to measure perceived social support.

One study of 59 lower limb amputees with dysvascular conditions reported that construct validity was not supported, though the SSQN6 was found to have convergent validity.<sup>89</sup>

### **Socket Comfort Score**

The SCS is a one-item measure of prosthetic socket comfort that is scored from 0-10.

Three studies, with 345 mostly unilateral transtibial and transfemoral amputees, about one-third of whom had dysfunctional conditions evaluated the Socket Comfort Score.<sup>54, 70, 98</sup> Test-retest reliability ICC ranged from 0.63 to 0.79, depending upon mode of administration. MDC values were published. Potential ceiling effects were observed (14% of sample).

### **Special Interest Group of Amputation Medicine/Dutch Working Group on Amputations and Prosthetics**

The SIGAM/WAP scale measures ambulation mobility (with walking aids if necessary) among lower limb amputees.

In two studies of 372 lower limb amputees, at least half of whom had dysvascular conditions, the SIGAM/WAP overall score was found to have adequate reliability.<sup>48, 99</sup> Convergent validity of the SIGAM/WAP was also supported. Evidence for construct validity was mixed.

### **Step Activity Monitors**

Step Activity Monitors are commercially available walking activity monitors. The evaluated monitors are specifically targeted towards evaluation of amputee gait patterns. Three separate items were assessed in two studies with 74 mostly younger (mean age 54 years), mostly unilateral lower limb amputees, of whom about one-quarter had dysvascular conditions.<sup>33, 100</sup> One study evaluated the Patient Activity Monitor (PAM, Ossur, Reykjavik, Iceland).<sup>100</sup> One study evaluated the StepWatch 3 Activity Monitor (Orthocare Innovations, Mountlake Terrace, Washington, U.S.).<sup>33</sup>

### **PAM: Total Step Count**

PAM step counts were found to be higher than those quantified by simultaneous 3-dimensional motion assessment. The item displayed convergent validity with multiple measures.

### **PAM: Medium Step Length**

PAM step length was strongly correlated with measures of step length measured by motion capture ( $r = 0.77-0.95$ ).

### **PAM: Walking Velocity**

PAM walking velocity was strongly correlated with velocity determined by motion capture ( $r = 0.95-0.99$ ).

### **SAM: Steps Per Day**

The SAM measure of steps/day correlated with the 2 MWT ( $r = 0.78$ ).

## **Trinity Amputation and Prosthesis Experience Scales**

The TAPES is a multidimensional self-report instrument that evaluates the experience of amputation and adjustment to a lower limb prosthesis. The TAPES is divided into multiple subscales to assess various aspects of amputation experience and lower limb prosthesis adjustment. In total, 26 domains and domain-subscales (Activity Restriction, Activity Restriction Item 10, Activity Restriction Item 9, Adjustment to Limitation, Age, Aesthetic Satisfaction, Athletic Activity Restriction, Functional Activity Restriction, Functional Satisfaction, Gender, General Adjustment, Health Rating, Length of Time Living with Prosthesis, Level of Amputation, Other Medical Problems, Phantom Limb Pain, Physical Capabilities, Prosthetic Use, Psychosocial Adjustment, Residual Limb Pain, Satisfaction with the Prosthesis, Satisfaction Items 1-4, Satisfaction Items 5-9, Social Adjustment, Social Restriction, Weight Satisfaction) as well as the TAPES Total Overall Score have been evaluated.

The six studies included almost 1000 mostly unilateral lower limb amputees, of whom about one-third had dysvascular conditions.<sup>33, 39, 53, 101-103</sup>

### **Total Overall Score**

The TAPES Total Overall Score was only evaluated for and displayed convergent validity. Therefore TAPES regarded as a Total Overall Score demonstrated only weak evidence of validity.

### **Activity Restriction**

This domain displayed reliability, convergent validity, construct validity and structural validity. This domain was found to be valid.

### **Activity Restriction Item 9**

This domain subscale displayed was evaluated for and displayed structural validity. Therefore, this domain subscale demonstrated weak evidence of validity.

### **Activity Restriction Item 10**

This domain subscale displayed was evaluated for and displayed structural validity. Therefore, this domain subscale demonstrated weak evidence of validity.

### **Adjustment to Limitation**

This domain displayed reliability, convergent validity, divergent validity, construct validity and structural validity. This domain was found to be valid.

### **Age**

This domain displayed was evaluated for and displayed convergent validity. Therefore, this domain demonstrated weak evidence of validity.

### **Athletic Activity Restriction**

This domain displayed reliability, convergent validity and structural validity. This domain was found to be valid.

### **Esthetic Satisfaction**

This domain displayed was evaluated for and displayed convergent validity. Therefore, this domain demonstrated weak evidence of validity.

### **Functional Activity Restriction**

This domain displayed reliability, convergent validity, content validity and structural validity. This domain was found to be valid.

### **Functional Satisfaction**

This domain displayed reliability, convergent validity and structural validity. This domain was found to be valid.

### **Gender**

This domain displayed was evaluated for convergent validity. There was no evidence of validity for this domain.

### **General Adjustment**

This domain displayed reliability, convergent validity and structural validity. This domain was found to be valid.

### **Health Rating**

This domain displayed was evaluated for and displayed convergent validity. Therefore, this domain demonstrated weak evidence of validity.

### **Length of Time Living with Prosthesis**

This domain displayed was evaluated for and displayed convergent validity. Therefore, this domain demonstrated weak evidence of validity.

### **Level of Amputation**

This domain displayed was evaluated for and displayed convergent validity. Therefore, this domain demonstrated weak evidence of validity.



### **Other Medical Problems**

This domain displayed was evaluated for and displayed convergent validity. Therefore, this domain demonstrated weak evidence of validity.

### **Phantom Limb Pain**

This domain displayed was evaluated for convergent validity. There was no evidence of validity for this domain.

### **Physical Capabilities**

This domain displayed was evaluated for and displayed convergent validity. Therefore, this domain demonstrated weak evidence of validity.

### **Prosthetic Use**

This domain displayed was evaluated for and displayed convergent validity. Therefore, this domain demonstrated weak evidence of validity.

### **Psychosocial Adjustment**

This domain displayed reliability and structural validity. Therefore, this domain demonstrated weak evidence of validity.

### **Residual Limb Pain**

This domain displayed was evaluated for and displayed convergent validity. Therefore, this domain demonstrated weak evidence of validity.

### **Satisfaction Items 1 to 4**

This domain subscale displayed reliability and structural validity. Therefore, this domain subscale demonstrated weak evidence of validity.

### **Satisfaction Items 5 to 9**

This domain subscale displayed reliability and structural validity. Therefore, this domain subscale demonstrated weak evidence of validity.

### **Satisfaction With the Prosthesis**

This domain displayed reliability and structural validity. Therefore, this domain demonstrated weak evidence of validity.

### **Social Adjustment**

This domain displayed reliability, convergent validity and structural validity. This domain was found to be valid.

### **Social Restriction**

This domain displayed reliability, convergent validity and structural validity. This domain was found to be valid.

## **Weight Satisfaction**

This domain displayed reliability, convergent validity and structural validity. This domain was found to be valid.

## **Trait Meta Mood Scale**

The TMMS is a measure of individual differences in the ability to reflect on and manage one's emotions. Two subdomains of the TMMS were evaluated, the Clarity of Feelings and the Mood Repair domains. Items in the clarity of feelings domain refer to the ability to understand one's mood, while items on the mood repair domain evaluate ability to counteract unpleasant moods or maintain pleasant ones.

One study of 60 mostly younger (mean age 47 years) unilateral lower limb amputees, few of whom had dysvascular conditions, evaluated both TMMS subdomains.<sup>53</sup> Both Clarity of Feelings and Repair domains of the TMMS demonstrated evidence of convergent validity, but no other aspect of validity was evaluated. Therefore, there is weak evidence of validity for the TMMS subdomains.

## **Timed Up and Go**

The TUG test measures the amount of time it takes an amputee to get up from an armless chair.

Seven studies have evaluated TUG among 292 lower limb amputees, mostly with unilateral transtibial amputations, at least 40 percent of whom had dysvascular conditions.<sup>20, 29, 32-34, 60, 104</sup> The TUG displayed reliability, convergent validity, and construct validity. The MDC90 was 3.6.

## **Walking Speed, 10 Meters**

Walking speed is measured on a 10 meter walkway.

In two studies of 163 lower limb amputees, almost half with dysvascular conditions,<sup>79, 105</sup> 10 meter walking speed displayed reliability with an ICC of 0.83 to 0.98. The test was inversely correlated with the Rivermead Mobility Index (Spearman  $r = -0.70$ ,  $P < 0.0001$ ).

## **Walking Speed, 15.2 Meters**

Walking speed is measured on a 15.2 meter (50 foot) walkway.

In one study of 30 participants with diabetes and transmetatarsal amputations,<sup>106</sup> 15.2 meter walking speed was correlated with lower extremity strength.

## **Walking Questionnaire**

The Walking Questionnaire is a self-report measure of activity limitations when walking inside and outside the house.

In three studies of 389 lower limb amputees, mostly with dysvascular conditions (75%),<sup>47-49</sup> the questionnaire has demonstrated evidence of reliability, convergent, and construct validity. There were mixed evidence of the questionnaire's convergent validity. Overall, the Walking Questionnaire was found to be reliable and valid.

## **World Health Organization Disability Assessment Schedule 2.0**

The WHODAS 2 is a standardized measure that measures the extent of activity limitation experienced by an individual.

One study of 65 lower limb amputees, without further description,<sup>107</sup> evaluated three of the WHODAS 2 subscales: Getting Around, Participation in Society, and Self Care. Only the construct validity of these scales was evaluated in this study. All three subscales displayed evidence of construct validity. Therefore there was weak evidence that the WHODAS 2 subscales were valid.

### **World Health Organization Quality-of-Life Scale (WHOQOL-BREF)**

The WHOQOL-BREF is an instrument containing 26 items that measure the quality of life of amputees. The instrument has several subscales, such as environment, physical health, psychological, social relationships, and General Health and Overall Quality-of-Life.

These measures have been studied by four studies with 257 lower limb amputees, of whom only about 10 percent had dysvascular conditions.<sup>53, 59, 103, 108, 109</sup>

### **Overall QoL and General Health**

The overall score was evaluated together with the General Health subscale. It displayed reliability and convergent validity. No other aspect of validity was evaluated. There was no evidence of floor or ceiling effects. In one study the subscales (environment, physical health, psychological, and social relationships) each displayed convergent validity.

**Table 3.1. Outcome Measures: Studies, and Participant Characteristics**

Instrument: Subscale	Studies, n	Studies	Total N	Bi	Uni	TF	Kn	TT	TM	Trau	Vasc	CA	Other	NR	Age
2MWT*	9	Newton 2016 0; Brooks 2002 12422326; Gremeaux 2012 22389424; Resnik 2011 21310896; Brooks 2001 11588757; Major 2013 23856150; Miller 2004 15180125; Devlin 2004; Parker 2010 2010632385	468 (33-290)	51	417	109	2	306	0	16	352	3	13	84	64.7 (21-94)
6MWT	3	Reid 2015 25588644; Gailey 2002 11994800; Resnik 2011 21310896	297 (44-167)	3	294	103	12	164	6	102	30	29	92	44	58 (18-100)
AAS	2	Gailey 2002 11994800; Panesar 2001 11330761	201 (34-167)	2	199	85	7	97	0	61	34	24	82	0	56.9 (18-100)
ABC*	9	Hafner 2016 28273329; Kelly 2016 27756174; Sakakibara 2011 21704978; Miller 2003 12736877 (sample 1 & sample 2); Major 2013 23856150; Miller 2004 15180125; Asano 2008 18569891; Hafner 2017; Wong 2016	2319 (209-1291)	205	2114	721	0	1341	0	909	1052	28	330	0	58.4 (18-nd)
ABIS	1	Gallagher 2007 17314705	145	17	128	52	3	73	0	37	78	7	23	0	60.5 (nd)
ABIS-R	2	Coffey 2009 19900240, Gallagher 2007 17314705	183 (38-145)	26	157	56	3	96	0	37	78	7	61	0	63.5 (18-nd)
AMP	2	Gailey 2002 11994800; Resnik 2011	211	6	205	90	9	101	2	61	nd	24	82	44	60 (18-100)
AMPSIMM	1	Norvell 2016 27496697	113	0	113	28	0	59	26	0	81	0	32	0	63.5 (18-nd)
ADAPT	1	Theeven 2010 20809056	20	0	20	20	0	0	0	12	6	2	0	0	50.3 (18-75)
AQoL	1	Miller 2008 <sup>43</sup>	58	0	58	21	0	37	0	13	29	nd	16	0	66.4 (21-91)
Barthel Index*	1	Brunelli 2006 16813789	45	0	45	45	0	0	0	0	45	0	0	0	69 (38-87)
BBS*	2	Major 2013 23856150; Gremeaux 2012 22389424; Wong, 2016	94 (30-64)	3	91	31	0	60	0	30	49	2	10	3	56.7 (21-87)
BIQ	1	Fisher 1998	107	nd	nd	32	4	64	2	37	43	5	22	0	55.5 (40-88)
Climbing Stairs Questionnaire	4	de Laat 2010, de Laat 2011, de Laat 2012, Yari 2008	561 (46-172)	36	525	164	24	279	9	45	435	45	41	0	60.4 (18-nd)
Frenchay Activities Index (& Index-18)	2	Miller 2004 15180125; Asano 2008 18569891	499 (84-415)	0	499	136	0	363	0	50	254	0	195	0	61 (20-nd)
FIM*	3	Cyril 2001; Leung 1996 8831480; Panesar 2001 11330761	269 (34-107)	5	264	73	12	185	0	nd	57	nd	87	125	43.7 (35-89)
Harold Wood/Stanmore Mobility Grade	2	Fisher 1998, Hanspal 1991	307 (100-107)	nd	nd	126	4	163	9	102	66	0	39	100	58.4 (17-88)
HADS	1	Coffey 2009 19900240	38	9	29	6	0	23	0	0	38	0	0	0	66.4 (18-nd)
Houghton*	5	Devlin 2004 15295762; Houghton 1992 1393461; Miller 2000 0; Miller 2001 11552197, Wong 2016 26874230, Brooks 2001	793 (76-435)	160	630	421	6	296	4	91	381	nd	nd	321	60.7 (23-91)
IES (various)	1	Gallagher 2000	60	1	59	20	3	29	2	27	7	13	13	0	47.1 (18-nd)
IPAQ	1	da Silva 2011	22	nd	nd	7	1	13	0	15	2	0	6	0	nd (18-69)

Instrument: Subscale	Studies, n	Studies	Total N	Bi	Uni	TF	Kn	TT	TM	Trau	Vasc	CA	Other	NR	Age
LCI* (various)	13	Arwert 2007 17943683, Brunelli 2006 16813789; Callaghan 2002 12227445; Cyril 2001 0; de Laat 2011 0; Dite 2007 0; Franchignoni 2007 18050010; Gauthier-Gagnon 1994 7993169; Miller 2001 11588750 (sample 1); Miller 2001 11588750 (sample 2); Norvell 2011 21531528; Panesar 2001 11330761; Traballesi 2007 16955063; Treweek 1998 0	1447 (23-329)	58	1194	352	47	858	56	205	618	17	209	539	58.8 (18-80)
L-Test	3	Rushton 2015 25134533; Deathe 2005 15982169, Major 2013 23856150	126 (33-93)	0	33	30	0	96	0	8	44	2	4	68	57 (55.9-60)
OPCS	1	Panesar 2001	34	2	32	17	0	14	0	0	0	0	0	34	67 (44-85)
OPUS (various)	1	Resnik 2011	44	0	44	23	2	19	0	0	0	0	0	44	66 (31-85)
PGI	1	Callaghan 2003 14682557	42	0	42	42	0	0	0	0	38	0	0	4	69 (36-87)
PROMIS-29 (various)	2	Amtmann 2015 25917819; Hafner 2016 28273329	1292 (201-1091)	0	1292	456	0	836	0	725	533	8	26	0	55.8 (18-nd)
PSFS	1	Resnik 2011	44	0	44	23	2	19	0	0	0	0	0	44	66 (31-85)
PFI (various)	1	Cyril 2001 0	107	0	107	24	12	82	0	0	0	0	0	107	35 (nd)
PEQ (various)	2	Legro 1998 9710165; Resnik 2011 21310896	159 (23-92)	0	159	81	5	65	8	62	23	1	22	44	67.3 (20-85)
PEQ	5	Resnik 2011 21310896; Miller 2000 0 & Miller 2001 11588750 (sample 1); Miller 2000 0 & Miller 2001 11588750 (sample 2); Hafner 2016 28273329; Miller 2001 11552197	1507 (23-435)	0	1507	424	2	1081	0	121	726	8	409	44	61.4 (31-85)
PEQ Mobility (Likert 5)	1	Franchignoni 2007 17351696	123	14	109	65	0	44	0	69	43	nd	11	0	54 (36-65)
PEQ (Modified)	1	Van de Weg 2005 16466153	220	0	220	0	0	220	0	0	0	0	0	220	62.1 (nd)
PLUS-M (various)	4	Kelly 2016 27756174; Hafner 2017 27590443; Hafner 2016 25944625; Hafner 2016 28273329	1728 (37-1291)	214	1514	551	1	1128	4	842	753	10	150	4	55 (19.3-88.7)
Quality of Life NQ-ACGC	2	Hafner 2016 28273329; Morgan 2016 26836953	1287 (201-1086)	0	1287	413	52	822	0	723	530	32	26	2	55.7 (18-88.7)
Q-TFA (various)	1	Hagberg 2004 15558399	156	0	156	156	0	0	0	86	13	48	9	0	51 (20-70)
Rising and Sitting Down Questionnaire	3	de Laat 2011, de Laat 2012, Yari 2008	389 (46-172)	24	365	109	16	186	6	28	292	42	28	0	60.4 (37-92)
RMDQ	1	Hammarlund 2011 21515895	46	nd	nd	19	9	18	0	33	0	13	0	0	48 (19-78)
RMI	2	Franchignoni 2003 12809197, Ryall 2003 12648004	340 (140-200)	25	175	161	8	175	7	69	92	34	20	0	54.9 (19-78)
Russek's Code	1	Treweek 1998	772	nd	nd	201	0	571	0	0	0	0	0	772	nd
SAT-PRO	1	Bilodeau 1999 10462879	55	0	55	nd	0	nd	0	0	55	0	0	0	71.3 (60-nd)
SF-12 † (various)	2	Happich 2008, Hoffman 2002 11833020	106 (35-71)	nd	nd	35	nd	nd	nd	0	0	35	71	0	43.3 (34-89)
SF-36 † (various)	14	Aksnes 2008 18539673, Boutoille 2008 18026199, Davidson 2010, Hagberg 2001, Hammarlund 2011 21515895, Pezzin 2000, Sinha 2011 21515894, Smith 1995 7745656, van der Slius 2009, Willrich 2005, Schoppen 2001 11239317, van der Schans 2002, Remes 2010, Resnik 2011	2315 (25-652)	38	845	777	131	1226	25	1203	393	212	405	98	49.1 (19-85)
SF36V	1	Resnik 2011	44	0	44	23	2	19	0	0	0	0	0	44	66 (31-85)

Instrument: Subscale	Studies, n	Studies	Total N	Bi	Uni	TF	Kn	TT	TM	Trau	Vasc	CA	Other	NR	Age
SIP (various)	4	Cyril 2001 0; Greive 1996 8876000; Mackenzie 2005 16085622; Yari 2008 19052251	290 (20-107)	0	173	53	31	164	7	2	6	36	2	244	43.8 (16-nd)
SSQN6	1	Remes 2010	59	nd	nd	nd	nd	nd	nd	0	59	0	0	0	75.2 (nd)
SCS	3	Hafner 2016 28273329; Fisher 2003 12601268; Hanspal 2003 14617445	345 (44-201)	7	338	129	0	207	0	195	99	16	43	0	57.3 (17-88)
SIGAM/WAP	2	Ryall 2002 12851094, de Laat 2012	372 (172-200)	25	175	55	8	93	1	32	192	19	69	0	61.1 (18-nd)
Step Activity Monitor (various)	2	Ramstrand 2007 17520493; Parker 2010 2010632385	74 (22-52)	6	68	28	0	46	0	26	20	0	6	22	53.7 (20.1-88.7)
TAPES (various)	6	Desmond 2008 18569892, Gallagher 2000, Gallagher 2004 15129396, Gallagher 2007 17314705, Gallagher 2010 20489393, Parker 2010 2010632385	951 (63-498)	46	679	317	26	509	2	318	298	89	195	6	54 (18-nd)
TMMS	1	Gallagher 2000	60	1	59	20	3	29	2	27	7	13	13	0	47.1 (18-nd)
TUG*	7	Schoppen 1999 10414769; Newton 2016 0; Arwert 2007 17943683; Dite 2007 17207685; Gremeaux 2012 22389424; Parker 2010 2010632385; Resnik 2011 21310896	292 (23-37)	6	286	70	2	220	0	42	117	2	7	121	62.4 (18-69)
Walking Speed, 10 meters	2	Boonstra 1993 8233772; Franchignoni 2003 12809197	163 (23-140)	0	118	87	0	61	0	45	44	17	4	53	30, 57
Walking Speed, 15.2 meters	1	Salsich 1997 9065361	30	0	30	0	0	0	30	0	30	0	0	0	61.7
Walking Questionnaire	3	de Laat 2011, de Laat 2012, Yari 2008	389 (46-172)	nd	nd	109	16	186	2	28	291	42	28	0	60.4 (18-nd)
WHODAS 2 (various)	1	Gallagher 2011	65	nd	nd	nd	nd	nd	nd	0	0	0	0	65	nd
WHOQOL-BREF (various)	4	da Silva 2011, Deans 2008, Gallagher 2000, Gallagher 2004	257 (22-87)	1	59	78	4	194	2	69	34	27	128	0	60.4 (18-69)

Abbreviations: 180 Degree Turn Test, 2MWT = 2 minute walk test, 6MWT = 6 minute walk test, AAS = Amputees activity survey, ABC = Activities-specific Balance Confidence, ABIS(-R) = Amputee Body Image Scale (revised), ADAPT = Assessment of Daily Activity Performance in Transfemoral amputees, AIMS = Arthritis Impact Measurement Scale, AMP = Amputee Mobility Predictor, AMPSIMM = Amputee Single Item Mobility Measure, AqoL = Assessment of Quality of Life, BBS = Berg Balance Scale, BIQ = Body Image Questionnaire, CAPE = Clifton Assessment Procedures for the Elderly, Census and Surveys, FAI = Frenchay Activities Index, FIM = Functional Independence Measure, HADS = Hospital Anxiety and Depression Scale, IES = Impact of Event Scale, IPAQ = International Physical Activity Questionnaire, L Test = L Test of Functional Mobility, LCI = Locomotor Capabilities Index, MDC = minimal detectable change, MIC = minimal (clinical) important difference, Neuro-QoL ACGC = Neurological Disorders Applied Cognition General Concerns Short Form, NQ- ACGC = Quality of Life in Neurological Conditions – Applied Cognition/General Concerns, OPCS = Office of Population, OPUS = Orthotic Prosthetic User's Survey, PAM = Patient activity monitor, PEQ = Prosthesis Evaluation Questionnaire, PFI = Physical Function Index, PGI = Patient Generated Index, PLUS-M = Prosthetic Limb Users Survey of Mobility, PROMIS- 29 = Patient-Reported Outcomes Measurement Information System 29-item profile, PROS = Prosthetist's Perception of Client's Ambulatory Abilities, PSFS = Patient Specific Functional Scale, Q-TFA = Questionnaire for Persons with a Transfemoral Amputation, QoL = Quality of Life, RMDQ = Roland Morris Disability Questionnaire, RMI = Rivermead Mobility Index, SAT-PRO = Satisfaction with Prosthesis, SCS = Socket Comfort Score, SF = Short Form Health Survey, SIGAM = Special Interest Group in Amputee Medicine, SIP = Sickness Impact Profile, SSQN6 = Saranson's 6-item Social Support Questionnaire, TAPES = Trinity Amputation and Prosthesis Experience Scales, TFP = Transfemoral Fitting Predictor, TMMS = Trait Meta Mood Scale, TUG = Timed Up and Go, WHODAS 2 = World Health Organization Disability Assessment Schedule version 2, WHOQOL-BREF = World Health Organization Quality of Life abbreviated.

\* Also evaluated for Key Question 2.

† Also evaluated for Key Question 1.

**Table 3.2. Outcome Measures: Reliability, Validity, and Other Characteristics**

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
2MWT*		Yes: ICC 0.83 to 0.99	Yes	nr	nr	Yes: Pearson r 0.22 to 0.48	nr	Yes	nr	MDC90 112.5	nr	nr	nr	nr
6MWT		Yes: ICC 0.97	Yes	nr	nr	Yes: Pearson r -0.72 to 0.95; R <sup>2</sup> 0.79 to 0.89	nr	Yes	nr	MDC90 147.5	nr	nr	nr	nr
AAS		nr	Yes	nr	nr	Yes (p<0.0001)	nr	Yes	nr	nr	nr	Unclear	nr	nr
ABC*		Yes: ICC 0.91-0.95; Cronbach's $\alpha$ 0.93	Yes	Yes	nr	Yes: Pearson r -0.72 to 0.72	nr	Yes	nr	MDC90 0.49; MDC95 0.58	nr	nr	No (<10% implied)	No (<10% implied)
ABIS		Yes: Cronbach's $\alpha$ 0.90; Spearman r 0.30 to 0.74; Kaiser-Meyer-Olkin measure 0.87	No	nr	nr	No	nr	nr	No	nr	nr	nr	nr	nr
ABIS-R	Depression	Yes: Item-separation index 4.59; Item-separation reliability 0.95; Person-separation index 2.33; Person-separation reliability 0.84	Yes	nr	nr	Yes: Spearman r -0.51 to -0.36	nr	nr	nr	nr	nr	nr	nr	nr
AMP	noPRO	Yes: ICC 0.86 to 0.99	Yes	nr	nr	Yes: Pearson r -0.433 to 0.818	nr	Yes: Pearson r -0.378 to 0.263; P=0.001	nr	nr	nr	nr	nr	nr
	PRO	Yes: ICC 0.97 to 0.99	Yes	nr	nr	Yes: Pearson r -0.594 to 0.818	nr	Yes: Pearson r -0.433 to 0.292; P=0.001	nr	nr	nr	nr	nr	nr

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
	Total	Yes: ICC 0.88	Yes	nr	nr	nr	nr	nr	nr	MDC90 3.4	nr	nr	nr	nr
AMPSIMM		nr	Yes	nr		Yes: Spearman r 0.72 to 0.86	nr	Yes	nr	nr	nr	SRM 1	No	No
ADAPT		Yes: Pearson r 0.69 to 0.96	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr
AQoL		nr	Yes (weak)	nr	nr	Yes (P<0.05)	nr	nr	nr	nr	nr	nr	nr	nr
Barthel Index*		nr	Yes (weak)	nr	nr	nr	nr	Mixed	nr	nr	nr	nr	nr	nr
BBS*		Yes: ICC 0.945; Cronbach's $\alpha$ 0.827	Yes	nr	nr	Yes: Spearman r -0.8 to 0.675; AUC 0.88	nr	Yes	nr	nr	nr	nr	No	No
BIQ		Yes: Cronbach's $\alpha$ 0.90	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr
Climbing Stairs Questionnaire		Yes: ICC 0.79	Yes	nr	nr	Yes: Spearman r 0.42 to 0.60	nr	Yes	nr	nr	nr	nr	nr	nr
FAI-15		Yes: Cronbach's $\alpha$ 0.81; ICC 0.79	Yes	nr	nr	Yes: Pearson r -0.49 to 0.526; Beta 0.19	nr	Mixed	nr	nr	nr	nr	nr	nr
FAI-18		Yes: Cronbach's $\alpha$ 0.84; ICC 0.78	Yes	nr	nr	Yes: Pearson r -0.46 to 0.548	nr	Mixed	nr	nr	nr	nr	nr	nr
FIM*	Overall Score	nr	No	nr	nr	No: Pearson r -0.06 to 0.13; p<0.00001	No: Pearson r -0.12	Yes	nr	nr	nr	SRM -0.49; Kazis ES -0.51; p<0.00001	No	No
	Amputation Function	No: Cronbach's $\alpha$ 0.55	No	nr	nr	No: Pearson r -0.03 to 0.13	nr	No	nr	nr	nr	SRM -0.20-0.52; Kazis ES -0.23-0.52	No	Chair transfer Yes (53%)
	Discharge motor subscore	nr	Yes (weak)	nr	nr	Yes: Spearman r 0.58	nr	nr	nr	nr	nr	nr	nr	nr
Harold Wood/Stanmore Mobility Grade		nr	No	nr	nr	No: Kendall tau -0.04 to 0.21, P>0.05	nr	nr	nr	nr	nr	nr	nr	nr
HADS	Anxiety	nr	Yes	nr	nr	Yes: Spearman r -0.58 to 0.77	nr	nr	nr	nr	nr	nr	nr	nr
	Depression	nr	Yes	nr	nr	Yes: Spearman r -0.49 to 0.75	nr	nr	nr	nr	nr	nr	nr	nr



Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
Houghton*		Yes: Cronbach $\alpha$ 0.68 to 0.71; ICC 0.85 to 0.96	Yes	nr	Yes	Yes: Pearson r -0.6 to 0.67; undefined r 0.235 to 0.653; Spearman r -0.76 to 0.73	nr	Yes: ES 0.29 to 1.62	nr	nr	nr	ES 0.6	No	No
IES	Avoidance	nr	Yes	nr	nr	Yes: Correlation r -0.453 to -0.266	nr	nr	nr	nr	nr	nr	nr	nr
	Intrusion	nr	Yes	nr	nr	Yes: Correlation r -0.623 to -0.265	nr	nr	nr	nr	nr	nr	nr	nr
IPAQ		Poor to adequate: Cronbach $\alpha$ 0.55 to 0.63	No	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr
LCI*	Advanced	Yes: Cronbach $\alpha$ 0.95	Yes	nr	nr	Yes: Pearson r -0.48 to 0.54	nr	No	nr	nr	nr	nr	Yes (nr)	No
	Basic	Yes: Cronbach's $\alpha$ 0.97	No	nr	nr	Mixed: Pearson r -0.24 to 0.31	nr	No	nr	nr	nr	nr	Yes (nr)	No
		Yes: Cronbach's $\alpha$ 0.89; ICC 0.88	Yes	nr	nr	Yes: Pearson r -0.64 to 0.83	nr	Yes: ES 0.13 to 1.66	nr	nr	nr	nr	No	Yes (nd)
	Overall Score	Yes: Cronbach's $\alpha$ 0.83	Yes	nr	nr	Yes: Pearson r -0.15 to 0.59	Yes: Pearson r -0.08	No	nr	nr	nr	nr	Yes (23-50%)	No
	LCI10-4	Yes: Item separation 0.98 Person separation 0.94	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr
	LCI-4	Yes: Cronbach's $\alpha$ 0.95; ICC 0.74-0.8	Yes	Yes	nr	Yes	nr	Yes	nr	nr	nr	nr	No	Yes (nd)
	LCI-5	nr	Yes	nr	nr	Yes: Spearman r -0.84 to 0.50	nr	Yes	Yes	nr	nr	nr	No	Yes (50%)
L Test of Functional Mobility		Yes: ICC 0.96-0.97	Yes	nr	nr	Yes: Spearman r 0.27 to 0.28 Pearson r -0.86 to 0.97	nr	Yes	nr	nr	4.5	Yes: AUROC 0.67	nr	nr
OPCS		nr	Yes	nr	nr	Yes: P<0.001	nr	nr	nr	nr	nr	nr	nr	nr

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
OPUS	Lower Limb Function	Yes: ICC 0.67	No	nr	nr	nr	nr	nr	nr	nr	nr	MDC90 10.3	No	No
	Quality of Life	Yes: ICC 0.85	No	nr	nr	nr	nr	nr	nr	nr	nr	MDC90 9.2	No	No
	Satisfaction	No: ICC 0.50	No	nr	nr	nr	nr	nr	nr	nr	nr	MDC90 15.7	No	No
PGI		No: ICC 0.48	No	nr	nr	Mixed: Pearson r 0.11 to 0.56	nr	nr	nr	nr	nr	nr	nr	nr
PROMIS-29	Anxiety	Yes: ICC 0.86	No	nr	nr	nr	nr	Mixed	nr	MDC90 7.81; MDC95 9.31	nr	nr	Yes (34%)	nr
	Depression	Yes: ICC 0.88	Yes	nr	nr	nr	nr	Yes	nr	MDC90 6.71; MDC95 8.00	nr	nr	Yes (42%)	nr
	Fatigue	Yes: ICC 0.84	No	nr	nr	nr	nr	Mixed	nr	MDC90 7.74; MDC95 9.22	nr	nr	nr	nr
	Pain Interference	Yes; ICC 0.82	No	nr	nr	nr	nr	Mixed	nr	MDC90 8.51; MDC95 10.1	nr	nr	Yes (28%)	nr
	Physical Function	Yes: ICC 0.88	Yes	nr	nr	nr	nr	Yes	nr	MDC90 6.13; MDC95 7.31	nr	nr	nr	No (14%)
	Sleep Disturbance	Yes: ICC 0.85	No	nr	nr	nr	nr	Mixed	nr	MDC90 7.61; MDC95 9.07	nr	nr	nr	nr
	Social Role Satisfaction	Yes: ICC 0.79	Yes	nr	nr	nr	nr	Yes	nr	MDC90 9.53; MDC95 0.79	nr	nr	nr	Yes (16%)
	Pain Intensity	Yes: ICC 0.87	nr	nr	nr	nr	nr	nr	nr	MDC90 1.97; MDC95 2.35	nr	nr	No (12%)	nr
PSFS	Item 1	Yes: ICC 0.82	nr	nr	nr	nr	nr	nr	nr	MDC90 3.3	nr	nr	No	No
	Item 2	Yes: ICC 0.66	nr	nr	nr	nr	nr	nr	nr	MDC90 4.2	nr	nr	No	No
	Item 3	Yes: ICC 0.79	nr	nr	nr	nr	nr	nr	nr	MDC90 3.1	nr	nr	No	No
	Item 4	Yes: ICC 0.56	nr	nr	nr	nr	nr	nr	nr	MDC90 4.5	nr	nr	No	No

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
	Item 5	Yes: ICC 0.77	nr	nr	nr	nr	nr	nr	nr	MDC90 3.1	nr	nr	No	No
	Total	Yes: ICC 0.83	nr	nr	nr	nr	nr	nr	nr	MDC90 11	nr	nr	No	No
PFI	Overall score	Yes: Cronbach's $\alpha$ 0.71	Yes	nr	nr	Yes: Pearson r -0.55 to 0.57	nr	No	nr	nr	nr	SRM 0.89; Kazis ES 1.06	No	No
	Climb Stairs	Yes: Cronbach's $\alpha$ 0.78	Yes	nr	nr	Yes: Pearson r -0.15 to 0.41	nr	No	nr	nr	nr	SRM 0.74; Kazis ES 0.79	Yes (41%)	Yes (17%)
	Run at steady pace	Yes: Cronbach's $\alpha$ 0.87	Yes	nr	nr	Yes: Pearson r -0.3 to 0.37	nr	No	nr	nr	nr	SRM 0.36	No	No
	Squat to pick up object	Yes: Cronbach's $\alpha$ 0.82	Yes	nr	nr	Yes: Pearson r -0.53 to 0.46	nr	No	nr	nr	nr	SRM 0.55; Kazis ES 0.67	No	Yes (36%)
	Walk at steady pace	Yes: Cronbach's $\alpha$ 0.74	Yes	nr	nr	Yes: Pearson r -0.41 to 0.45	nr	No	nr	nr	nr	SRM 0.65; Kazis ES 0.98	Yes (18%)	Yes (32%)
PEQ (Likert 5)	Mobility	Yes: Cronbach $\alpha$ 0.96; Rasch Person separation 0.95; Rasch Item separation 0.98	Yes	nr	nr	Yes: Spearman r 0.77	nr	nr	nr	nr	nr	nr	nr	nr
	Mobility modified (MS12/5)	Yes: Cronbach $\alpha$ 0.96; Rasch Person separation 0.95; Rasch Item separation 0.98	Yes	nr	nr	Yes: Spearman r 0.78	nr	nr	nr	nr	nr	nr	nr	nr
PEQ	Ambulation	Yes: Cronbach's $\alpha$ 0.89; ICC 0.81 to 0.90	Yes	nr	nr	Yes: Pearson r 0.61	nr	Yes: Spearman r 0.61 to 0.81; P<0.05	nr	MDC90 1.1	nr	nr	No	No
	Appearance	Yes: Cronbach's $\alpha$ 0.73; ICC 0.70 to 0.84	No	nr	nr	nr	nr	No	nr	MDC90 1.4	nr	nr	nr	nr

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
	Frustration	Yes: Cronbach's $\alpha$ 0.82; ICC 0.64 to 0.82	No	nr	nr	nr	nr	No	nr	MDC90 1.6	nr	nr	nr	nr
	Mobility	Yes: Cronbach's $\alpha$ 0.95; ICC 0.77 to 0.99	Yes	nr	nr	Yes: Pearson r -0.5 to 0.85; Beta -0.31	nr	Yes: ES 0.11 to 1.57	nr	MDC90 0.3 to 0.55; MDC95 0.65	nr	nr	No (<10% implied)	No (<10% implied)
	Perceived responses	No: Cronbach's $\alpha$ 0.89; ICC 0.41 to 0.56	No	nr	nr	nr	nr	No	nr	MDC90 0.9	nr	nr	nr	nr
	Prosthesis utility	Yes: ICC 0.79	nr	nr	nr	nr	nr	nr	nr	MDC90 1.2	nr	nr	nr	nr
	Residual limb health	Yes: Cronbach's $\alpha$ 0.8; ICC 0.79 to 0.80	No	nr	nr	nr	nr	No	nr	MDC90 0.8	nr	nr	nr	nr
	Social burden	Yes: Cronbach's $\alpha$ 0.83; ICC 0.64 to 0.81	Yes	nr	nr	Yes: Pearson r -0.52 to 0.59	nr	No	nr	MDC90 1.4	nr	nr	nr	nr
	Sounds	Yes: Cronbach's $\alpha$ 0.78; ICC 0.79 to 0.84	No	nr	nr	nr	nr	No	nr	MDC90 1.7	nr	nr	nr	nr
	Transfer	Yes: Cronbach's $\alpha$ 0.47; ICC 0.73 to 0.75	No	nr	nr	nr	nr	No	nr	MDC90 1.3	nr	nr	No	Yes (25%)
	Usefulness	Yes: Cronbach's $\alpha$ 0.89; ICC 0.86	No	nr	nr	nr	nr	No	nr	nr	nr	nr	No	No
	Wellbeing	Yes: Cronbach's $\alpha$ 0.87; ICC 0.70-0.87	Yes	nr	nr	Yes: Pearson r -0.49	nr	No	nr	MDC90 1.4	nr	nr	No	Yes (strong)
PEQ (Modified)	Problems	Yes: Cronbach's $\alpha$ 0.76	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr
	Satisfaction	Yes: Cronbach's $\alpha$ 0.88	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr	nr

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
PLUS-M	12-item short form	Yes: ICC 0.96	nr	nr	nr	nr	nr	nr	nr	MDC90 4.50; MDC95 5.36	nr	nr	No (<10% implied)	No (<10% implied)
	7-item short form	Yes: ICC 0.95	nr	nr	nr	nr	nr	nr	nr	MDC90 4.69; MDC95 5.59	nr	nr	No (<10% implied)	No (<10% implied)
	CAT	Yes: ICC 0.92	nr	nr	nr	nr	nr	nr	nr	MDC90 6.42; MDC95 7.65	nr	nr	No (<10% implied)	No (<10% implied)
Quality of life NQ-ACGC		Yes: ICC 0.88-0.90	Yes	nr	nr	nr	nr	Yes: nr	nr	MDC90 6.67; MDC95 7.94	nr	nr	nr	Yes (17%)
Q-TFA	Global	Yes: ICC 0.89	Yes	nr	nr	Yes: Spearman's r 0.27 to 0.62	nr	nr	nr	nr	nr	nr	No	No
	Problem	Yes: ICC 0.89	Yes	nr	nr	Yes: Spearman's r -0.65 to -0.30	nr	nr	nr	nr	nr	nr	nr	nr
	Prosthetic Mobility	Yes: ICC 0.97	Yes	Yes	nr	Yes: Spearman's r 0.10 to 0.79	nr	nr	nr	nr	nr	nr	No	No
	Prosthetic Use	Yes: ICC 0.94	Yes	nr	nr	Yes: Spearman r 0.11 to 0.36	nr	nr	nr	nr	nr	nr	No	Yes (31%)
Rising and Sitting Down Questionnaire		Yes: ICC 0.83	Yes	nr	nr	Yes: Spearman r 0.40 to 0.57	nr	Yes	nr	nr	nr	nr	nr	nr
RMDQ		nr	No	nr	nr	Yes: Spearman r -0.74 to -0.05	nr	nr	nr	nr	nr	nr	nr	nr
RMI		Yes: Cronbach's $\alpha$ 0.85	Yes	nr	nr	Yes: Spearman r -0.58 to 0.85	nr	nr	nr	nr	nr	ES 0.35	nr	No (11%)
Russek's Code		nr	No	nr	nr	nr	nr	Weak	nr	nr	nr	nr	nr	nr
SAT-PRO		Yes: Cronbach $\alpha$ 0.90; ICC 0.87	Yes	Yes	nr	nr	nr	Yes	nr	nr	nr	nr	nr	nr
SF-12 †	MCS	nr	Yes	nr	nr	nr	nr	Yes	nr	nr	nr	nr	nr	nr
	PCS	nr	Yes	nr	nr	nr	nr	Yes	nr	nr	nr	nr	nr	nr
SF-36 †	Bodily Pain	nr	Yes	nr	nr	nr	nr	Yes	nr	nr	nr	nr	nr	nr
	Emotional Problems	nr	No	nr	nr	nr	nr	No	nr	nr	nr	nr	nr	nr
	Emotional Role Limitations	nr	No	nr	nr	nr	nr	No	nr	nr	nr	nr	nr	nr
	Emotional Wellbeing													
	Energy/Fatigue	nr	No	nr	nr	nr	nr	No	nr	nr	nr	nr	nr	nr

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
	General Health	nr	Yes	nr	nr	Yes: P<0.05	nr	Yes	nr	nr	nr	nr	nr	nr
	MCS	nr	No	nr	nr	nr	nr	No	nr	nr	nr	nr	nr	nr
	Mental Health	nr	Yes	nr	nr	nr	nr	Mixed	nr	nr	nr	nr	nr	nr
	Overall	nr	Yes	nr	nr	nr	nr	Mixed	nr	nr	nr	nr	nr	nr
	PCS	nr	Yes	nr	nr	nr	nr	Mixed	nr	nr	nr	nr	nr	nr
	Physical Functioning	nr	Yes	nr	nr	nr	nr	Mixed	nr	nr	nr	Yes: P<0.05	nr	nr
	Physical Role Limitations	nr	Yes	nr	nr	nr	nr	Mixed	nr	nr	nr	nr	nr	nr
	Social Functioning	nr	Yes	nr	nr	nr	nr	Mixed	nr	nr	nr	nr	nr	nr
	Vitality	nr	Yes	nr	nr	nr	nr	Mixed	nr	nr	nr	nr	nr	nr
SF-36V	General Health	Yes: ICC 0.80	Yes	nr	nr	nr	nr	nr	nr	MDC90 17.1	nr	nr	No	No
	Physical Functioning	Yes: ICC 0.61	Yes	nr	nr	nr	nr	nr	nr	MDC90 34.2	nr	nr	No	No
	Role Physical	Yes: ICC 0.81	Yes	nr	nr	nr	nr	nr	nr	MDC90 26.3	nr	nr	No	No
SIP	Overall Score	Yes: Cronbach's $\alpha$ 0.76	Yes	nr	nr	Yes: Pearson r -0.53 to 0.58	Yes: Pearson r 0.004	No	nr	nr	nr	SRM 0.80; Kazis ES 0.77	No	No
	Ambulation	Yes: Cronbach's $\alpha$ 0.88	Yes	nr	nr	Yes: Pearson r -0.54 to 0.49	nr	No	nr	nr	nr	SRM 0.81; Kazis ES 0.95	No	No
	Body care and movement	Yes: Cronbach's $\alpha$ 0.81	Yes	nr	nr	Yes: Pearson r -0.45 to 0.32	nr	No	nr	nr	nr	SRM 0.69; Kazis ES 0.95	Yes	No
	Physical Dimension	nr	Mixed	nr	nr	nr	nr	Mixed	nr	nr	nr	nr	nr	nr
	Emotional stability	nr	Yes	nr	nr	nr	nr	Yes	nr	nr	nr	nr	nr	nr
	Psychological autonomy and communication	nr	No	nr	nr	nr	nr	No	nr	nr	nr	nr	nr	nr
	Social behavior	nr	No	nr	nr	nr	nr	No	nr	nr	nr	nr	nr	nr
	Somatic autonomy	nr	No	nr	nr	nr	nr	No	nr	nr	nr	nr	nr	nr
	Mobility Control	nr	No	nr	nr	nr	nr	No	nr	nr	nr	nr	nr	nr
	Mobility Range	nr	No	nr	nr	nr	nr	No	nr	nr	nr	nr	nr	nr
	Mobility	Yes: Cronbach's $\alpha$ 0.91	No	nr	nr	Mixed: Pearson r -0.4 to 0.3	nr	No	nr	nr	nr	SRM 0.42; Kazis ES 0.48	Yes	No
SSQN6		nr	No	nr	nr	Yes: P<0.05	nr	No	nr	nr	nr	nr	nr	nr
SCS	All modes	Yes: ICC 0.0.63-0.79	nr	nr	nr	nr	nr	nr	nr	MDC90 2.73; MDC95 3.26	nr	nr	nr	No (14%)

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
	Electronic mode only	Yes: ICC 0.79	nr	nr	nr	nr	nr	nr	nr	MDC90 2.31; MDC95 2.75	nr	nr	nr	nr
	Mixed mode	Yes: ICC 0.63	nr	nr	nr	nr	nr	nr	nr	MDC90 3.03; MDC95 3.61	nr	nr	nr	nr
		Yes: Kendall's tau 0.97 to 0.99	Yes	nr	nr	Yes: Kendall's tau 0.48 to 0.51	nr	nr	nr	nr	nr	nr	nr	nr
	Paper mode only	Yes: ICC 0.77	nr	nr	nr	nr	nr	nr	nr	MDC90 2.82; MDC95 3.36	nr	nr	nr	nr
SIGAM/WAP	Total Overall Score	Yes: ICC 0.79; Rasch Item Separation Index 0.98; Rasch Person Separation Index 0.87	Yes	nr	nr	Yes: Spearman r 0.37; P<0.001	nr	Mixed	nr	nr	nr	nr	nr	nr
Step Activity Monitors	PAM: Step count, total	nr	Yes	nr	nr	Yes: Pearson r 0.90 to 0.98	nr	nr	nr	nr	nr	nr	nr	nr
	PAM: Step length (medium)	nr	Yes	nr	nr	Yes: Pearson r 0.36 to 0.99	nr	nr	nr	nr	nr	nr	nr	nr
	PAM: Walking velocity	nr	Yes	nr	nr	Yes: Pearson r 0.95 to 0.99	nr	nr	nr	nr	nr	nr	nr	nr
	SAM: Steps/day	nr	Yes	nr	nr	Yes: Spearman r 0.718-0.966	nr	No	nr	nr	nr	nr	nr	nr
TAPES	Total Overall Score	nr	Yes	nr	nr	Yes: Spearman r 0.42 to 0.84	nr	nr	nr	nr	nr	nr	nr	nr

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
	Activity Restriction	Yes: Cronbach's $\alpha$ 0.89; Person separation index 2.51; Person separation reliability 0.86; Item separation index 18.48; Item separation reliability 1	Yes	nr	nr	Yes: Spearman $r$ - 0.663 to 0.424; $P < 0.001$	nr	Yes	Yes: Rasch MnSQ 0.6 to 1.4; CFI 0.98; MNFI 0.97; RMSEA 0.1; SRMR	nr	nr	nr	nr	nr
	Activity Restriction Item 10	nr	Yes	nr	nr	nr	nr	nr	Yes: Rasch outfit MnSq 1.84	nr	nr	nr	nr	nr
	Activity Restriction Item 9	nr	Yes	nr	nr	nr	nr	nr	Yes: Rasch outfit MnSq 3.13	nr	nr	nr	nr	nr
	Adjustment to Limitation	Yes: Cronbach's $\alpha$ 0.86; Person separation index 1.98; Person separation reliability 0.80; Item separation index 6.91; Item separation reliability 0.98	Yes	nr	nr	Yes: Spearman $r$ 0.14 to 0.62; $P < 0.001$	Yes: $P < 0.001$	Yes: $P < 0.05$	Yes: Factor analysis 25.3%	nr	nr	nr	nr	nr
	Age	nr	Yes	nr	nr	Yes: Pearson $r$ - 0.22 to 0.1	nr	nr	nr	nr	nr	nr	nr	nr
	Athletic Activity Restriction	Yes: Cronbach's $\alpha$ 0.76	Yes	nr	nr	Yes: Pearson $r$ - 0.63 to -0.18	nr	nr	Yes: Factor analysis 21.3%	nr	nr	nr	nr	nr



Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
	Esthetic Satisfaction	nr	Yes	nr	nr	Yes: Pearson r 0.28 to 0.47; Spearman r -0.27 to 0.22	nr	nr	nr	nr	nr	nr	nr	nr
	Functional Activity Restriction	Yes: Cronbach's $\alpha$ 0.87	Yes	Yes	nr	Yes: Spearman r 0.30 to 0.31	nr	nr	Yes: Factor analysis 25.1%	nr	nr	nr	nr	nr
	Functional Satisfaction	Yes: Cronbach's $\alpha$ 0.85	Yes	nr	nr	Yes: Pearson r -0.64 to -0.24	nr	nr	Yes: Factor analysis 30.1%	nr	nr	nr	nr	nr
	Gender	nr	No	nr	nr	No: Pearson r -0.11 to 0.13	nr	nr	nr	nr	nr	nr	nr	nr
	General Adjustment	Yes: Cronbach's $\alpha$ 0.90; Person separation index 2.17; Person separation reliability 0.82; Item separation index 6.0; Item separation reliability 0.97	Yes	nr	nr	Yes: Pearson r 0.46 to 0.79; Spearman r -0.57 to -0.54; $P < 0.001$	nr	nr	Yes: Factor analysis 23.6%	nr	nr	nr	nr	nr
	Health Rating	nr	Yes	nr	nr	Yes: Pearson r 0.35 to 0.67	nr	nr	nr	nr	nr	nr	nr	nr
	Length of Time Living with Prosthesis	nr	Yes	nr	nr	Yes: Pearson r 0.19 to 0.33	nr	nr	nr	nr	nr	nr	nr	nr
	Level of Amputation	nr	Yes	nr	nr	Yes: Pearson r -0.14 to 0.17	nr	nr	nr	nr	nr	nr	nr	nr
	Other Medical Problems	nr	Yes	nr	nr	Yes: Pearson r -0.33 to -0.15	nr	nr	nr	nr	nr	nr	nr	nr
	Phantom Limb Pain	nr	No	nr	nr	Yes: Pearson r 0.07 to 0.08	nr	nr	nr	nr	nr	nr	nr	nr
	Physical Capabilities	nr	Yes	nr	nr	Yes: Pearson r 0.33 to 0.69	nr	nr	nr	nr	nr	nr	nr	nr
	Prosthetic Use	nr	Yes	nr	nr	Yes: Pearson r 0.21 to 0.50	nr	nr	nr	nr	nr	nr	nr	nr

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
	Psychosocial Adjustment	Yes: Cronbach's $\alpha$ 0.89	Yes	nr	nr	nr	nr	nr	Yes: Rasch MnSQ 0.6 to 1.4; CFI 0.99; MNFI 0.98; RMSEA 0.057; SRMR 0.059	nr	nr	nr	nr	nr
	Residual limb pain	nr	Yes	nr	nr	Yes: Pearson r - 0.25 to -0.11	nr	nr	nr	nr	nr	nr	nr	nr
	Satisfaction Items 1-4	Yes: Cronbach's $\alpha$ 0.85; Person separation index 1.61; Person separation reliability 0.72; Item separation index 0.91; Item separation reliability 0.46	Yes	nr	nr	nr	nr	nr	Yes: Factor analysis 19%	nr	nr	nr	nr	nr
	Satisfaction Items 5-9	Yes: Cronbach's $\alpha$ 0.86; Person separation index 1.83; Person separation reliability 0.77; Item separation index 8.32; Item separation reliability 0.99	Yes	nr	nr	nr	nr	nr	Yes: Factor analysis 13%	nr	nr	nr	nr	nr

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
	Satisfaction with the Prosthesis	Yes: Cronbach's $\alpha$ 0.95	Yes	nr	nr	nr	nr	nr	Yes: Rasch MnSQ 0.6 to 1.4; CFI 0.98; MNFI 0.97; RMSEA 0.089; SRMR 0.057	nr	nr	nr	nr	nr
	Social Adjustment	Yes: Cronbach's $\alpha$ 0.89; Person separation index 1.92; Person separation reliability 0.79; Item separation index 5.43; Item separation reliability 3.97	Yes	nr	nr	Yes: Pearson r 0.33 to 0.69; Spearman r -0.44 to -0.40	nr	No	Yes: Factor analysis 13%; Rasch infit MnSq 1.94	nr	nr	nr	nr	nr
	Social Restriction	Yes: Cronbach $\alpha$ 0.84	Yes	nr	nr	Yes; Spearman r 0.40 to 0.43	nr	nr	Yes: Factor analysis 23.7%	nr	nr	nr	nr	nr
	Weight Satisfaction	nr	Yes	nr	nr	Yes; Spearman r -0.23; Pearson 0.26 to 0.44	nr	nr	Yes: Factor analysis 13.7%	nr	nr	nr	nr	nr
TMMS	Clarity of Feelings	nr	Weak	nr	nr	Yes; Correlation r 0.41 to 0.56	nr	nr	nr	nr	nr	nr	nr	nr
	Repair	nr	Weak	nr	nr	Yes; Correlation r 0.34 to 0.55	nr	nr	nr	nr	nr	nr	nr	nr
TUG*		Yes: Spearman r 0.93 to 0.96; ICC 0.88	Yes	nr	nr	Yes: Spearman r -0.841 to 0.46; Pearson r 0.35 to 0.80	nr	Yes: Spearman LCI-5=-0.65; P-value<0.05	nr	MDC90 3.6	nr	nr	nr	nr
Walking speed, 10 meters		Yes: ICC 0.83 to 0.98	Yes	nr	nr	Yes: Spearman r -0.70	nr	nr	nr	nr	nr	nr	nr	nr

Instrument	Subscale	Reliability	Overall Valid?	Content Validity	Criterion Validity	Convergent Validity	Divergent Validity	Construct Validity	Structural Validity	MDC	MID	Responsive-ness	Floor Effect	Ceiling Effect
Walking speed, 15.2 meters		nr	Yes	nr	nr	Yes: Pearson r -0.47 to 0.77	nr	nr	nr	nr	nr	nr	nr	nr
Walking Questionnaire		Yes: ICC 0.73	Yes	nr	nr	Yes: Spearman r -0.47 to 0.57		Mixed	nr	nr	nr	nr	nr	nr
WHODAS 2	Getting Around	nr	Weak	nr	nr	nr	nr	Yes: P<0.05	nr	nr	nr	nr	nr	nr
	Participation in Society	nr	Weak	nr	nr	nr	nr	Yes: P<0.05	nr	nr	nr	nr	nr	nr
	Self Care	nr	Weak	nr	nr	nr	nr	Yes: P<0.05	nr	nr	nr	nr	nr	nr
WHOQOL-BREF	Overall QoL and General Health	Yes: Cronbach $\alpha$ 0.84 to 0.89	Yes	nr	nr	Yes: P<0.01	nr	nr	nr	nr	nr	nr	No	No
	Environment		Yes	nr	nr	Yes: P<0.01	nr	nr	nr	nr	nr	nr	No	No
	Physical Health		Yes	nr	nr	Yes: Correlation r -0.62 to 0.63; P<0.01	nr	nr	nr	nr	nr	nr	No	No
	Psychological		Yes	nr	nr	Yes: P<0.01	nr	nr	nr	nr	nr	nr	No	No
	Social Relationships		Yes	nr	nr	Yes: Correlation r -0.62 to 0.73; P<0.01	nr	nr	nr	nr	nr	nr	No	No

Abbreviations: 180 Degree Turn Test, 2MWT = 2 minute walk test, 6MWT = 6 minute walk test, AAS = Amputees activity survey, ABC = Activities-specific Balance Confidence, ABIS(-R) = Amputee Body Image Scale (revised), ADAPT = Assessment of Daily Activity Performance in Transfemoral amputees, AIMS = Arthritis Impact Measurement Scale, AMP = Amputee Mobility Predictor, AMPSIMM = Amputee Single Item Mobility Measure, AQoL = Assessment of Quality of Life, BBS = Berg Balance Scale, BIQ = Body Image Questionnaire, CAPE = Clifton Assessment Procedures for the Elderly, Census and Surveys, ES = effect size, FAI = Frenchay Activities Index, FIM = Functional Independence Measure, HADS = Hospital Anxiety and Depression Scale, IES = Impact of Event Scale, IPAQ = International Physical Activity Questionnaire, L Test = L Test of Functional Mobility, LCI = Locomotor Capabilities Index, MDC = minimal detectable change, MIC = minimal (clinical) important difference, Neuro-QoL ACGC = Neurological Disorders Applied Cognition General Concerns Short Form, NQ- ACGC = Quality of Life in Neurological Conditions – Applied Cognition/General Concerns, nr = not reported, OPCS = Office of Population, OPUS = Orthotic Prosthetic User's Survey, PAM = Patient activity monitor, PEQ = Prosthesis Evaluation Questionnaire, PFI = Physical Function Index, PGI = Patient Generated Index, PLUS-M = Prosthetic Limb Users Survey of Mobility, PROMIS- 29 = Patient-Reported Outcomes Measurement Information System 29-item profile, PROS = Prosthetist's Perception of Client's Ambulatory Abilities, PSFS = Patient Specific Functional Scale, Q-TFA = Questionnaire for Persons with a Transfemoral Amputation, QoL = Quality of Life, RMDQ = Roland Morris Disability Questionnaire, RMI = Rivermead Mobility Index, SAT-PRO = Satisfaction with Prosthesis, SCS = Socket Comfort Score, SF = Short Form Health Survey, SIGAM/WAP = Special Interest Group in Amputee Medicine/Dutch Working Group on Amputations and Prosthetics, SIP = Sickness Impact Profile, SRM = standardized response mean, SSQN6 = Saranson's 6-item Social Support Questionnaire, TAPES = Trinity Amputation and Prosthesis Experience Scales, TFP = Transfemoral Fitting Predictor, TMMS = Trait Meta Mood Scale, TUG = Timed Up and Go, WHODAS 2 = World Health Organization Disability Assessment Schedule version 2, WHOQOL-BREF = World Health Organization Quality of Life abbreviated.

\* Also evaluated for Key Question 2.

† Also evaluated for Key Question 1.

## Key Questions 1 to 3 Summary

In total, we have summarized the evidence on the performance characteristics of 61 measures (assessment techniques, prediction tools, and outcome measures) and subscales of many of these. As discussed above, the distinctions among these categories was, to a degree, arbitrary, based on interpretation of the original purpose of the measure, the hypotheses of the studies, and the analyses reported. Here we summarize them together. Here we also group together assessments of scales, their subscales, and variations.

Table 1-3.1 summarizes the findings regarding reliability, (overall) validity, the minimal detectable change (MDC), the minimal (clinical) important difference (MID), the responsiveness, and floor or ceiling effects. Most notable is that while some measure of validity has been assessed for most measures (n=53), other characteristics are less frequently evaluated. Reliability has been assessed for 40 measures and the MID was estimated for only one measure (the L test of Functional Mobility).

All 40 measures that have been assessed for reliability were found to be reliable (at least to an adequate extent). Of the 53 measures assessed for validity, 47 have been validated (either as a single measure, or for all or most of their subscales); although four of these were found to be only weakly validated. Among the 47 validated measures, seven have been validated for only some or most of their subscales (marked as “mixed” in Table 1-3.1, or with footnotes). Furthermore, only 29 measures have evidence to support both reliability and validity; seven of these, though, have been found to have either floor or ceiling effects in whole or in part.

However, among the 61 measures, only 35 have been evaluated in samples of lower limb amputees deemed to be generally applicable to the Medicare population, based primarily on either the percentage of participants with dysvascular conditions or their ages. These are highlighted in Table 1-3.1 by having bold text in the Population column. Among these 35, 27 have evidence of validity, in whole or in part, and 25 have evidence of reliability. In total, 19 measures have been found to have evidence of both reliability and validity in study participants generally applicable to the Medicare population. These include:

- 2 minute walk test (2MWT)
- Activities-specific Balance Confidence (ABC)
- Amputee Body Image Scale, revised (ABIS-R)
- Berg Balance Scale (BBS)
- Climbing Stairs Questionnaire
- Frenchay Activities Index, 15 item (FAI-15)
- Houghton Score
- Locomotor Capabilities Index (LCI)
- Patient-Reported Outcomes Measurement Information System 29-item profile (PROMIS-29)
- Prosthesis Evaluation Questionnaire (PEQ)
- Quality of Life in Neurological Conditions – Applied Cognition/General Concerns (NQ-ACGC)
- Rising and Sitting Down Questionnaire
- Satisfaction with Prosthesis (SAT-PRO)
- Special Interest Group of Amputation Medicine/Dutch Working Group on Amputations and Prosthetics (SIGAM/WAP)

- Trinity Amputation and Prosthesis Experience Scale (TAPES)
- Timed Up and Go (TUG)
- Transfemoral Fitting Predictor (TFP)
- Walking speed, 10 meters
- Walking Questionnaire

Of these 19 measures, only the Houghton Score has been evaluated for and found to demonstrate responsiveness. Floor or ceiling effects have been found for four of these measures (or their subscores): LCI, PROMIS-29, PEQ, and NQ-ACGC.

**Table 1-3.1. Summary of Performance of Measures in People With Lower Limb Amputations**

Measure	N <sup>A</sup>	Population <sup>B</sup>	Reliability	Validity <sup>C</sup>	MDC <sup>D</sup>	MID <sup>D</sup>	Responsiveness	Floor/Ceiling
180 Degree Turn Test	1	U, TT		Weak				
2MWT	5	B/U, TF, TT, Vasc	Yes	Yes	Yes <sup>D</sup>			
6MWT	3	U, TF, TT, Tr	Yes	Yes	Yes <sup>D</sup>			
AAS	2	U, TF, TT, Mix		Yes				
ABC	5	B/U, TF, TT, Mix	Yes	Yes	Yes <sup>D</sup>			No
ABIS	1	B/U, TF, TT, Vasc	Yes	No				
ABIS-R	2	B/U, TF, TT, Vasc	Yes	Yes				
AMP	2	U, TF, TT, Tr	Yes	Yes	Yes <sup>D</sup>			
AMPSIMM	1	U, TF, TT, TM, Vasc		Yes			Yes	No
ADAPT	1	U, TF, Tr	Yes					
AQoL	1	U, TF, TT, Mix		Weak				
Barthel Index	2	U, TF, Mix		Yes				
BBS	5	U, TF, TT, Vasc	Yes	Yes				No
BIQ	1	TF, TT, Vasc	Yes					
CAPE CAS	1	TF, TT		Yes				
Climbing Stairs Questionnaire	4	B/U, TF, TT, Vasc	Yes	Yes				
FAI-15	2	U, TF, TT, Vasc	Yes	Yes				
FAI-18	1	U, TF, TT, Mix	Yes	Yes				
FIM	5	U, TF, TT, Vasc	No	No			Yes	Yes <sup>F</sup>
FSST	1	U, TT		Yes				
Harold Wood/Stanmore Mobility Grade	3	TF, TT, Mix		No				
HADS	1	B/U, TF, TT		Yes				
Houghton Score	5	B/U, TF, TT, Vasc	Yes	Yes			Yes	No
IES subscales	1	U, TF, TT, Tr		Yes				
IPAQ	1	TF, TT, Mix	Adequate					
LCI (various)	15	B/U, TF, TT, Mix	Yes	Yes <sup>H</sup>				Yes
L test	2	TF, TT, Mix	Yes	Yes		Yes <sup>D</sup>	Yes	
OPCS	1	U, TF, TT		Yes				
OPUS	1	U, TF, TT	Yes				Yes	No
PGI	1	U, TF, Vasc	No	No				
PROMIS-29	2	U, TF, TT, Mix	Yes	Mix <sup>K</sup>	Yes <sup>D</sup>			Yes (most)
PSFS	1	U, TF, TT	Yes		Yes <sup>D</sup>			No
PFI	1	U, TF, TT	Yes	Yes			Yes	Yes (most)
PEQ (various)	8	B/U, TF, TT, Mix	Yes	Mix <sup>I</sup>	Yes <sup>D</sup>			Mix <sup>J</sup>
PLUS-M	4	B/U, TF, TT, Mix	Yes		Yes <sup>D</sup>			No
PROS	1	TF, TT, Vasc		Yes				
NQ-ACGC	2	U, TF, TT, Mix	Yes	Yes	Yes <sup>D</sup>			Yes
Q-TFA	1	U, TF, Tr	Yes	Yes				Mix <sup>L</sup>
Rising and Sitting Down Questionnaire	3	B/U, TF, TT, Vasc	Yes	Yes				

Measure	N <sup>A</sup>	Population <sup>B</sup>	Reliability	Validity <sup>C</sup>	MDC <sup>D</sup>	MID <sup>D</sup>	Responsiveness	Floor/Ceiling
RMDQ	1	TF, TT, Tr		Yes				
RMI	2	B/U, TF, TT, Mix	Yes	Yes			Yes	No
Russek's Code	1	TF, TT,		<b>No</b>				
SAT-PRO	1	<b>U, Vasc</b>	Yes	Yes				
SF-12	6	B/U, TF, TT, Mix		Yes				
SF-36	17	B/U, TF, TT, Mix		Mixed <sup>N</sup>			Yes (PF) <sup>O</sup>	
SF-36V	1	B/U, TF, TT	Yes		Yes <sup>D</sup>			No
SIP	4	U, TF, TT	Yes	Mix <sup>P</sup>			Yes	Yes <sup>Q</sup>
SSQN6	1	<b>Vasc</b>		<b>No</b>				
SCS	3	<b>U, TF, TT, Mix</b>	Yes		Yes <sup>D</sup>			No
SIGAM/WAP	2	<b>B/U, TF, TT, Vasc</b>	Yes	Yes				
Step Activity Monitors	2	U, TF, TT, Mix		Yes				
TAPES	6	<b>B/U, TF, TT, Mix</b>	Yes (various)	Yes <sup>R</sup>				
TMMS	1	U, TF, TT, Tr		Weak				
TUG	8	<b>U, TF, TT, Vasc</b>	Yes	Yes	Yes <sup>D</sup>			
TFP	1	<b>U, TF, Vasc</b>	Yes	Yes				
Walking speed, 10 meters	2	<b>U, TF, TT, Vasc</b>	Yes	Yes				
Walking speed, 15.2 meters (50 feet)	1	<b>U, TM, Vasc</b>		Yes				
Walking Questionnaire	3	<b>TF, TT, Vasc</b>	Yes	Yes				
WHODAS 2	1	nd		Weak				
WHOQOL-BREF subscales	5	U, TF, TT, Mix	Yes	Yes				No

Abbreviations: 180 Degree Turn Test, 2MWT = 2 minute walk test, 6MWT = 6 minute walk test, AAS = Amputees activity survey, ABC = Activities-specific Balance Confidence, ABIS(-R) = Amputee Body Image Scale (revised), ADAPT = Assessment of Daily Activity Performance in Transfemoral amputees, AIMS = Arthritis Impact Measurement Scale, AMP = Amputee Mobility Predictor, AMPSIMM = Amputee Single Item Mobility Measure, AQoL = Assessment of Quality of Life, BBS = Berg Balance Scale, CAPE = Clifton Assessment Procedures for the Elderly, Census and Surveys, FAI = Frenchay Activities Index, FIM = Functional Independence Measure, HADS = Hospital Anxiety and Depression Scale, IES = Impact of Event Scale, IPAQ = International Physical Activity Questionnaire, L Test = L Test of Functional Mobility, LCI = Locomotor Capabilities Index, MDC = minimal detectable change, MIC = minimal (clinical) important difference, Neuro-QoL ACGC = Neurological Disorders Applied Cognition General Concerns Short Form, NQ-ACGC = Quality of Life in Neurological Conditions – Applied Cognition/General Concerns, OPCS = Office of Population, OPUS = Orthotic Prosthetic User's Survey, PAM = Patient activity monitor, PEQ = Prosthesis Evaluation Questionnaire, PFI = Physical Function Index, PGI = Patient Generated Index, PLUS-M = Prosthetic Limb Users Survey of Mobility, PMQ = Prosthetic Mobility Questionnaire, PROMIS-29 = Patient-Reported Outcomes Measurement Information System 29-item profile, PROS = Prosthetist's Perception of Client's Ambulatory Abilities, PSFS = Patient Specific Functional Scale, Q-TFA = Questionnaire for Persons with a Transfemoral Amputation, QoL = Quality of Life, RMDQ = Roland Morris Disability Questionnaire, RMI = Rivermead Mobility Index, SAT-PRO = Satisfaction with Prosthesis, SCS = Socket Comfort Score, SF = Short Form Health Survey, SIGAM = Special Interest Group in Amputee Medicine, SIP = Sickness Impact Profile, SSQN6 = Saranson's 6-item Social Support Questionnaire, TAPES = Trinity Amputation and Prosthesis Experience Scales, TFP = Transfemoral Fitting Predictor, TMMS = Trait Meta Mood Scale, TUG = Timed Up and Go.15D HRQoL = 15D Health Related Quality of Life instrument, WHODAS 2 = World Health Organization Disability Assessment Schedule version 2, WHOQOL-BREF = World Health Organization Quality of Life abbreviated.



<sup>A</sup> Number of studies

<sup>B</sup> Bold text signifies that the study samples were deemed generally applicable to the Medicare population; text in italics if deemed not applicable. B = bilateral amputations, B/U = both bilateral and unilateral amputations, CA = cancer amputations, nd = no data reported describing participants, TF = transfemoral amputations, TM = transmetatarsal amputations, Tr = at least a plurality of trauma amputations, TT = transtibial amputations, Mix = a mix of amputation etiologies, nd = no data on amputation characteristics, U = unilateral amputations, Vasc = at least a plurality of dysvascular etiologies. If a category was omitted (i.e., unilateral vs. bilateral, amputation level, amputation etiology), there were insufficient data reported to summarize that category.

<sup>C</sup> Weak indicates that there is weak evidence of validity. Measures for which validity was assessed and no evidence was found to support validity are highlighted in bold.

<sup>D</sup> Yes indicates that and MDC or MID have been reported.

<sup>E</sup> Motor score validated at discharge from inpatient rehabilitation, but not at admission to rehabilitation. Subscales also not validated.

<sup>F</sup> Chair transfer subscale has a ceiling effect. Other subscales and total do not.

<sup>G</sup> Average prosthetic use per day validated; average falls per month and average prosthetic use per week were not validated.

<sup>H</sup> Most variations found to be valid; Basic LCI was not.

<sup>I</sup> Validated: Mobility, Mobility modified, Ambulation, Social burden, and Wellbeing subscales. Not validated: Appearance, Frustration, Perceived responses, Residual limb health, Sounds, Transfer, and Usefulness subscales.

<sup>J</sup> Ceiling effects found for Transfer and Wellbeing, but not for Ambulation, Mobility, or Usefulness subscales. These subscales did not have floor effects.

<sup>K</sup> Validated: Depression, Physical Function, and Social Role Satisfaction subscales. Not validated: Anxiety, Fatigue, Pain Interference, and Sleep Disturbance subscales.

<sup>L</sup> Ceiling effect for Prosthetic Use subscale, not for Global or Prosthetic Mobility subscales. No floor effects.

<sup>N</sup> Except Emotional Problems, Emotional Role Limitations, Energy/Fatigue subscales.

<sup>O</sup> Reported only for Physical Functioning (PF) subscale.

<sup>P</sup> Validated: Ambulation, Body Care and Movement, Emotional Stability subscales, and overall score. Inconsistent validation for Physical Scale subscale. Not validated: Physical Autonomy and Communication, Social Behavior, Somatic Autonomy, Mobility Control, Mobility Range, and Mobility subscales.

<sup>Q</sup> Floor effects for Bodily Care and Movement and Mobility subscales. No floor effects for Ambulation subscale and overall score. No ceiling effects for these measures.

<sup>R</sup> Except Gender subscale. Only weak evidence for total overall score validity.

## Key Question 4

In adults who use a lower limb prosthesis, how do the **relative effects** on ambulatory, functional, and patient-centered outcomes of **different prosthetic components** or levels of components/prostheses **vary based on study participant characteristics?**

### Overall Summary of Studies

In total, we found 11 studies (in 12 articles) that directly compared different LLP components and provided sufficient data to allow subgroup analyses based on participant characteristics.<sup>110-120</sup> Ten studies included between 5 and 168 users of LLP; one included 899 amputees. Five studies evaluated microprocessor knees (compared to mechanical knees), two evaluated other knee components, two evaluated ankle/foot components, and one each evaluated pylons or sockets. The largest study (Hahn 2016) developed a regression model to evaluate predictive ability of a wide range of participant characteristics.<sup>114</sup> An older study (Alaranta 1994) reported a correlation analysis between participant characteristics and outcomes and also subgroup analyses without statistical comparisons between subgroups.<sup>110</sup> One study (De Asha 2014) provided subgroup comparisons with statistical analyses<sup>111</sup>; three studies reported subgroup results but did not statistically compare subgroups (Gard 2003, Hafner 2009, Theeven 2011)<sup>112, 113, 117</sup>; and six studies reported individual patient data which allowed *post hoc* subgroup analyses (Gard 2003, Isakov 1985, Kahle 2008, Silver-Thorn 2009, Traballese 2011, Wong 2015).<sup>112, 115, 116, 119, 120</sup> Overall studies that investigated subgroup effects did not identify participant characteristics that predict which lower limb amputees would most benefit from a given component (low strength of evidence).

The following summary tables present summaries of all eligible studies for reference in the next sections. Detailed results summaries are tabulated separately for each study to improve formatting and readability. Table 4.1 summarizes the study design and participant characteristics of the 11 studies. In all studies, all patients were assessed with all components being compared either per a study design protocol or through the natural history of people being prescribed a new prosthesis. Among studies that reported prior prosthesis use history, people were all experienced LLP users, with at least 3 month, but generally longer, experience. The large majority of study participants were male (85% across studies with reported data) with unilateral amputations (100% in 8 of 11 studies). The level of amputation varied depending on the components being tested. The studies of knees, and the study of sockets, included almost all patients with transfemoral amputations. The study of pylons included only patients with transtibial amputations. The two ankle/foot studies included both patients with transtibial and transfemoral amputations. Nine of the 11 studies reported the K level of included patients. Except for two studies that included only K2 level patients, most study participants were at K3 (or K4) level. Only Wong 2015 explicitly included people at K1 level. The amputation etiologies across studies varied more widely, although with one exception at least about half of patients had trauma-related amputations. Isakov 1985 was the only study that included a majority of people with dysvascular disease-related amputations (14/17, 82%). The study participants were relatively young, with mean ages ranging from 34 to 61 years, suggesting that well over half the amputees were less than 65 years old.

Table 4.2 describes the components that were compared in the studies. Table 4.3 describes the risk of bias (study quality) of the studies. Six of the studies were deemed to be at moderate risk of bias overall and five studies at high risk of bias. Briefly, only one study was randomized; no study attempted to blind patients or providers (which may have been impossible for many components), but studies also did not blind outcome assessors (which may have been difficult for most studies); since all studies were one- or two-way crossover studies, by definition the groups of patients evaluating each component were equivalent; dropout rates were low across studies; only one study conducted multivariable analyses comparing subgroups; and only two studies statistically evaluated heterogeneity of treatment effect (differences among subgroups).

Table 4.4 provides an overall summary of subgroup comparisons across all studies and Tables 4.5-4.15 provide the summary results for each study individually. Narrative summaries follow the tables.

There is an important caveat about the determination of whether outcome measures have been validated (in Table 4.4 and for the text sections following the tables). We consider variations and modifications of measures to be separate measures that would each need to be validated. This applies both to modifications of existing measures (which, by definition, are no longer the same measure) and to variations such as walking and cadence tests conducted over different lengths of time or distance walked. Thus, the 2 minute walk test is distinct from the 6 minute walk test and from walking tests of other times or distances. In addition, when determining whether a measure used in a study has been validated we did not give the study the benefit of the doubt when measures were inadequately defined. For example, walk tests for which no time or distance was reported are, by definition, considered to be not validated.

**Table 4.1. Study Design and Participant Characteristics of Studies Comparing Components**

Study Year (PMID) Country	Study design	Funding Source	Components	Amputation and Prosthesis Use History	N enrolled	Mean Age (SD) [Range]	Male	K Level	Amputation Level	Unilateral	Etiology
Alaranta 1994 (7991366) Finland	NRCS, retrospective	Not reported / unclear	Foot/Ankle, energy-storing vs. conventional	Prosthesis ≥6 mo	208	58.4	93%	K3-4 100%	TT 84%, TF 16%	93%	Trauma 86%, dysvascular 5%, other 9%
De Asha 2014 (24997811) UK	NRCS, prospective	Industry provided materials	Foot/Ankle, hydraulic vs. rigid	Amputation ≥2 y prior, prosthesis ≥6 mo	19	44.5 (12.5)	nd	K3-4 100%	TT 58%, TF 42%	100%	Trauma 84%, dysvascular 0%, cancer 16%
Gard 2003 (15077637) USA	Pre-post, prospective	Nonindustry	Pylon, shock-absorbing vs. conventional	Prosthesis ≥6 mo	10	54 (17) [31-79]	90%	nd	TT 100%	100%	Trauma 70%, dysvascular 30%
Hafner 2009 (19675993) USA	RCT (crossover)	Industry funded	Knee, microprocessor vs. conventional	Amputation ≥2 y prior	17	49.1 (16.4)	76%	K2 47%, K3 53%	TF 100%	100%	Trauma 59%, dysvascular 6%, cancer 18%, infection 12%, other 6%
Hahn 2016 (27828871) Austria	Single group, retrospective	Industry provided materials	Knee, microprocessor, hydraulic vs. conventional	nd	899	49.0 (12.9)	83%	K2 13%, K3 64%, K4 23%	Knee 19%, TF 80%	nd	Trauma 69%, dysvascular 6%, cancer 16%, other 10%
Isakov 1985 (3868034) Israel	Pre-post, prospective	Not reported / unclear	Knee, locking vs. open	nd	17	55.6 (12.1)	94%	nd	TF 100%	100%	Trauma 18%, dysvascular 82%
Kahle 2008 (18566922) USA	Pre-post, prospective	Nonindustry	Knee, microprocessor vs. conventional	Prosthesis ≥90 d	15	51 (19)	nd	K2 60%,* K3 33%,* K4 7%	nd	100%	Trauma 47%, dysvascular 47%, other 6%
Silver-Thorn 2009 (none) USA	NRCS, prospective	Nonindustry	Knee, locking vs. hydraulic	nd	5	44.8 (9.3)	nd	K2 100%	TF 100%	100%	Trauma 80%, dysvascular 0%, cancer 20%
Theeven 2011 (21947182, 22549656) Netherlands and Belgium	RCT (crossover)	Nonindustry	Knee, microprocessor (2 types) vs. conventional	Amputation ≥1 y prior	41	59.1 (12.6)	73%	K2 100%	TF 100%	100%	Trauma 77%, dysvascular 20%, other 3%
Traballesi 2011 (21684165) Italy	Pre-post, prospective	Not reported / unclear	Socket, Marlo vs. ischial containment	Prosthesis ≥1 y	12	33.9 (9.4)	86%	K3-4 100%	TF 100%	100%	Trauma 86%, dysvascular 0%, cancer 14%
Wong 2015 (25768067) USA	NRCS, prospective	Industry funded	Knee, microprocessor vs. conventional	nd	8	60.8 (11.3)	nd	K1 25%, K2 25%, K3 50%	TF 100%	75%	nd

\* 4 of 9 patients who were K2 when evaluated with their conventional knee were K3 when evaluated with the microprocessor knee; 3 of 5 patients who were K3 when evaluated with their conventional knee were K4 when evaluated with the microprocessor knee.

Abbreviations: Knee = at level of knee amputation, nd = no data (not reported), NRCS = nonrandomized comparative study, RCT = randomized comparative study, SD = standard deviation, TF = transfemoral amputation, TT = transtibial amputation.

**Table 4.2. Comparative Study Components**

Study Year (PMID)	Component Type	Arm	Component Name/Description (Manufacturer)
Alaranta 1994 (7991366)	Foot/Ankle	Energy storing prostheses	Flexible plastic/carbon fiber leaf spring
		Conventional prostheses	Solid-ankle-cushion-heel
De Asha 2014 (24997811)	Foot/Ankle	Hydraulic	Echelon (Endolite)
		Rigid	Varied, habitual
Gard 2003 (15077637)	Pylon	Shock-absorbing pylon	Telescopic-Torsion Pylon (Endolite)
		Conventional pylon	Varied, habitual
Hafner 2009 (19675993)	Knee	Microprocessor	C-Leg Model 3C98 (Otto Bock)
		Nonmicroprocessor	Varied, habitual
Hahn 2016 (27828871)	Knee	Microprocessor, hydraulic	Genium (Otto Bock)
		Conventional prostheses	Varied, habitual
Isakov 1985 (3868034)	Knee	Locking system	3R17 (Otto Bock)
		Load-dependent brake ("open")	3R15 (Otto Bock)
Kahle 2008 (18566922)	Knee	Microprocessor	C-Leg (Otto Bock)
		Nonmicroprocessor	Varied, habitual*
Silver-Thorn 2009 (none)	Knee	Locking system	Total Knee 2000 (Össur)
		Hydraulic	3R80 (Otto Bock)
Theeven 2011 (21947182, 22549656)	Knee	Microprocessor (stance and swing phases)	C-Leg (Otto Bock)
		Microprocessor (stance phase)	C-Leg Compact (Otto Bock)
		Nonmicroprocessor	Varied, habitual†
Traballesi 2011 (21684165)	Socket	Marlo Anatomical Socket	Lower anterior and posterior trim lines
		Ischial Containment Socket	Typical socket shape
Wong 2015 (25768067)	Knee	Microprocessor	C-Leg (n=5) or C-Leg Compact (n=3) (Otto Bock)
		Nonmicroprocessor	Varied, habitual‡

\* 4-bar multiaxial knee joint with hydraulic swing-phase control (n=5), Total Knee 2000® Polycentric knee with geometric locking system (Össur) (n=5), Mauch Single axis hydraulic knee system with swing and stance control SNS® (Össur) (n=4), Weight-activated stance-phase brake mechanism with pneumatic swing-phase control (n=3), Single axis friction (n=1), Weight-activated stance-phase brake mechanism with friction swing-phase control (n=1).

† 3R80, 3R106, 3R60, 3R92 (Otto Bock); Acphapend (Proteval); Ultimate (Ortho Europe); Total Knee, Mauch Knee (Össur); Graph-Lite (Teh Lin); or manual locking knee.

‡ 3R60 or 3R80 (n=3), Mauch Knee (Össur) (n=2), Total Knee 1900 or 2000 (Össur) (n=2), or Locking 3R41 (Otto Bock) (n=1)

**Table 4.3. Comparative Study Risk of Bias / Study Quality**

Study Year (PMID)	Randomization	Allocation concealment	Blinding, Patients	Blinding, Providers	Blinding, Outcome Assessors	Outcome Assessment, Validation	Equivalent Groups	Dropouts	Multivariable	HTE Analyzed?	Overall Quality
Alaranta 1994 (7991366)	High RoB (nonrandomized)	NA (crossover)	High RoB	High RoB	High RoB	Low RoB, not validated	Low RoB (pre-post)	Low RoB	High RoB (no)	Partially*	High RoB
De Asha 2014 (24997811)	High RoB (nonrandomized)	NA (crossover)	High RoB	High RoB	High RoB	Low RoB, not validated	Low RoB (pre-post)	Low RoB	High RoB (no)	Yes (interaction)	High RoB
Gard 2003 (15077637)	High RoB (nonrandomized)	NA (crossover)	High RoB	High RoB	High RoB	Low RoB, not validated	Low RoB (pre-post)	Low RoB	High RoB (no)	No (IPD reported)	High RoB
Hafner 2009 (19675993)	High RoB (nonrandomized)	NA (crossover)	High RoB	High RoB	Unclear RoB	Low RoB, validated	Low RoB (crossover)	Low RoB	High RoB (no)	Indirectly†	Moderate RoB
Hahn 2016 (27828871)	High RoB (nonrandomized)	NA (crossover)	High RoB	High RoB	High RoB	Low RoB, not validated	Low RoB (pre-post)	Low RoB	Low RoB (yes)	Yes (model)	Moderate RoB
Isakov 1985 (3868034)	High RoB (nonrandomized)	NA (crossover)	High RoB	High RoB	Unclear RoB	Low RoB, validated	Low RoB (crossover)	Low RoB	High RoB (no)	No (IPD reported)	Moderate RoB
Kahle 2008 (18566922)	High RoB (nonrandomized)	NA (crossover)	High RoB	High RoB	High RoB	Low RoB, validated	Low RoB (pre-post)	Low RoB	High RoB (no)	No (IPD reported)	Moderate RoB
Silver-Thorn 2009 (none)	High RoB (nonrandomized)	NA (crossover)	High RoB	High RoB	High RoB	Low RoB, not validated	Low RoB (crossover)	Low RoB	High RoB (no)	No (IPD reported)	High RoB
Theeven 2011 (21947182, 22549656)	Low RoB	NA (crossover)	High RoB	High RoB	High RoB	High RoB (outcome definition unclear), not validated	Low RoB (crossover)	Low RoB	High RoB (no)	Indirectly†	High RoB
Traballesi 2011 (21684165)	High RoB (nonrandomized)	NA (crossover)	High RoB	High RoB	High RoB	Low RoB, validated	Low RoB (pre-post)	Low RoB	High RoB (no)	No (IPD reported)	Moderate RoB
Wong 2015 (25768067)	High RoB (nonrandomized)	NA (crossover)	High RoB	High RoB	High RoB	Low RoB, validated	Low RoB (pre-post)	Low RoB	High RoB (no)	No (IPD reported)	Moderate RoB

Abbreviations: HTE = heterogeneity of treatment effect (difference in effect/association between different subgroups of participants), IPD = individual participant data, NA = not applicable, RoB = risk of bias.

\* Reported transtibial and transfemoral analyses separately; did not report statistical analyses comparing subgroups; correlations of differences in effect of two components with other outcomes reported.

† Reported subgroup analyses separately; did not report statistical analyses comparing subgroups.

**Table 4.4. Summary of Subgroup Comparisons**

Study	Components	Total N	Subgroups	Subgroups Validated?	Outcomes	Outcomes Validated? §	Subgroup Comparison Findings (P value*)
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	168	TF vs. TT Age Age at amputation Body weight/BMI	Yes, all	Movement disability index subquestions and total	No	Younger age weakly correlated with favoring energy-storing for total movement disability (<0.01†). Lighter body weight weakly correlated with favoring energy-storing for total movement disability (<0.01†).
De Asha 2014 (PMID 24997811)	Hydraulic vs. rigid ankle/foot	19	TF vs. TT	Yes	Gait speed (8 meters) Cadence (8 meters)	No#	Nonsignificant
Gard 2003 (PMID 15077637)	Shock-absorbing vs. non-shock-absorbing pylon	10	Vascular vs. traumatic Sex Age Height Time since amputation	Yes, all	Walking speed (distance undefined) Fast walking speed (distance undefined)	No#	One woman favored the shock-absorbing pylon more than men did for self-selected walking speed (0.0002) and fast walking speed (<0.0001).
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	17	K2 vs. K3	Yes	PEQ subscales Falls & stumbles, reported Walking speeds, various Stair Assessment Index Hill Assessment Index Self-reported abilities/difficulties	Yes Yes No No No No	Nonsignificant
Hahn 2016 (PMID 27828871)	Microprocessor, hydraulic vs. mechanical knee	899	Multiple (not all explicitly listed)	Yes, mostly	Ambulatory, functional, other activities, and speed measures	No	"None of the variables and none of the regression models yield explanatory predictive power."
Isakov 1985 (PMID 3868034)	Locking vs. open knee	17	Vascular vs. nonvascular Sex Age	Yes, all	Gait speed (6 min)	Yes	Nonsignificant
Kahle 2008 (PMID 18566922)	Microprocessor (C-Leg) vs. mechanical knee	15	K level (2, 3, 4) Age Vascular vs. nonvascular Height Employment status Prosthesis use duration Residual limb firmness Residual limb length	Yes Yes Yes Yes Yes Yes No Yes	Falls & stumbles, reported Walking speeds, varied Montreal Rehabilitation Performance Profile	Yes No No	Nonsignificant



Study	Components	Total N	Subgroups	Subgroups Validated?	Outcomes	Outcomes Validated? §	Subgroup Comparison Findings (P value*)
Silver-Thorn 2009 (PMID none)	Locking (Total Knee 2000) vs. hydraulic knee	5	Age Time since amputation Height Residual limb length	Yes, all	Gait speed (distance undefined) Cadence (distance undefined) Comfort measures Confidence Stability, perceived Borg Rating of Perceived Exertion	No#	Nonsignificant
Theeven 2011 (PMID 21947182, 22549656)	Microprocessor (2 settings) vs. mechanical knee	30	K2 subgroups (high, intermediate, low)	No	Activity measures PEQ subscales Perceived difficulties Performance times	No Yes No No	Nonsignificant
Traballesi 2011 (PMID 21684165)	Marlo anatomic vs. ischial component socket	7	Sex Age Height Time since amputation	Yes, all	PEQ mobility subscale	Yes	Nonsignificant
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee	8	K level (1, 2, 3) Age Time since ambulation Bilateral vs. unilateral	Yes, all	ABC balance, Berg Balance Scale Houghton scale TUG walking Falls, reported Fear of falling	Yes	K2-3 favored microprocessor knee more than K1 did on TUG walking scale (0.0001)

Abbreviations: ABC = Activities-Specific Balance Confidence, PEQ = Prosthesis evaluation questionnaire, TF = transfemoral amputation, TT = transtibial amputation, TUG = timed up and go test.

\* Whether statistically significant difference in effect/association by subgroup, based on Bonferroni P-value.

† P value reported as <0.01; Bonferroni P value threshold = 0.0036.

§ The decisions in this column may change as additional studies are review during the literature search update process.

# For gait speed and cadence, we included the distance or time walked as an integral part of the measure. To be considered validated, the specific time or distance walk had to have evidence of validity. Walking tests without reported time or distance are considered to be nonvalidated.

**Table 4.5. Subgroup analyses. Alaranta 1994, Comparing Energy-Storing Versus Conventional Ankle/Foot Component**

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
Movement disability index: Indoors	ES (<0.001)	168	Transfemoral	27	Transtibial	141	1.00		
Movement disability index: Upstairs	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.59		
Movement disability index: Downstairs	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.86		
Movement disability index: Upstairs	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.59		
Movement disability index: Uneven ground	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.51		
Movement disability index: Upstairs	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.59		
Movement disability index: Uphill street	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.89		
Movement disability index: Upstairs	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.59		
Movement disability index: Swift walking	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.79		
Movement disability index: Upstairs	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.59		
Movement disability index: Total	no data	168	Age					<0.01	Younger age weakly correlated with favoring ES
		168	Age at amputation					NS	
		168	Body weight					<0.01	Lighter body weight weakly correlated with favoring ES
		168	Body mass index					NS	

Data for Alaranta 1994 (PMID 7991366).<sup>110</sup> Additional details in Appendix D.. P values <0.05 are bolded and associated "findings" are noted; however see footnote about Bonferroni P value threshold. *Italic bold* P values are statistically significant below the Bonferroni P value.

Abbreviations: ES = energy storing prosthesis

\* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

† Bonferroni P = 0.0036 (due to multiple testing, to be considered to be statistically significant, the P values for differences between subgroups had to be less than this value). A separate Bonferroni P value was calculated for each study based on the number of analyses (including subgroup analyses) analyzed by the study researchers and by this review.

**Table 4.6. Subgroup analyses. De Asha 2014, Comparing Hydraulic Versus Rigid Ankle/Foot Component**

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
Gait speed (m/s), 8 m	Hydraulic (0.005)	19	Transfemoral	8	Transtibial	11	0.12		
Cadence (steps/min), 8 m	Neither (0.84)	19	Transfemoral	8	Transtibial	11	0.53		

Data for De Asha 2014 (PMID 24997811).<sup>111</sup> Additional details in Appendix D. P values <0.05 are bolded and associated "findings" are noted; however see footnote about Bonferroni P value threshold. *Italic bold* P values are statistically significant below the Bonferroni P value.

\* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

† Bonferroni P = 0.005 (due to multiple testing, to be considered to be statistically significant, the P values for differences between subgroups had to be less than this value). A separate Bonferroni P value was calculated for each study based on the number of analyses (including subgroup analyses) analyzed by the study researchers and by this review.

**Table 4.7. Subgroup analyses. Gard 2003, Comparing Shock-Absorbing Versus Non-Shock-Absorbing Pylon**

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
Self-selected walking speed (m/s), distance undefined	Neither (NS)	10	Vascular	3	Traumatic	7	0.87		
		10	Male	9	Female	1	<i>0.0002</i>		One woman favored SAP more than men did
		10	Age 31-46 y	5	57-79 y	5	0.78	0.81	
		10	Height 1.73-1.81 m	5	1.82-1.88 m	5	0.022	0.010	Shorter favored SAP more than taller did
		10	Time since amputation 1-2 y	4	4-50 y	6	0.34	0.76	
Fast walking speed (m/s), distance undefined	Neither (NS)	10	Vascular	3	Traumatic	7	0.67		
		10	Male	9	Female	1	<i>&lt;0.0001</i>		One woman favored SAP more than men did
		10	Age 31-46 y	5	Age 57-79 y	5	0.64	0.84	
		10	Height 1.73-1.81 m	5	1.82-1.88 m	5	0.077	0.17	
		10	Time since amputation 1-2 y	4	4-50 y	6	0.045	0.096	More recent amputation favored SAP more than more distant did

Data for Gard 2003 (PMID 15077637).<sup>11,2</sup> Additional details in Appendix D. P values <0.05 are bolded and associated "findings" are noted; however see footnote about Bonferroni P value threshold.

Italic bold P values are statistically significant below the Bonferroni P value.

Abbreviations: NS = not statistically significant, SAP = shock-absorbing pylon

\* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

† Bonferroni P = 0.0028 (due to multiple testing, to be considered to be statistically significant, the P values for differences between subgroups had to be less than this value). A separate Bonferroni P value was calculated for each study based on the number of analyses (including subgroup analyses) analyzed by the study researchers and by this review.

**Table 4.8. Subgroup analyses. Hafner 2009, Comparing Microprocessor Versus Mechanical Knee Component**

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
Stair Assessment Index	Microprocessor (<0.001)	17	K level 2	8	K level 3	9	0.96		
Hill Assessment Index	Microprocessor (<0.001)	17	K level 2	8	K level 3	9	0.41		
Hill speed (m/s)	Microprocessor (<0.001)	17	K level 2	8	K level 3	9	0.24		
Obstacle course speed (m/s)	Microprocessor (<0.001)	17	K level 2	8	K level 3	9	0.65		
Attention speed (m/s)	Microprocessor (<0.001)	17	K level 2	8	K level 3	9	0.14		
Attention accuracy (% correct)	Neither (>0.05)	17	K level 2	8	K level 3	9	0.97		
PEQ Ambulation	Microprocessor (0.008)	17	K level 2	8	K level 3	9	0.14		
PEQ Appearance	Neither (0.50)	17	K level 2	8	K level 3	9	0.90		
PEQ Frustration	Neither (0.11)	17	K level 2	8	K level 3	9	0.16		
PEQ Perceived response	Neither (0.07)	17	K level 2	8	K level 3	9	0.75		
PEQ Residual limb health	Neither (0.50)	17	K level 2	8	K level 3	9	0.93		
PEQ Social burden	Neither (0.54)	17	K level 2	8	K level 3	9	1.00		
PEQ Sounds	Neither (0.07)	17	K level 2	8	K level 3	9	0.25		
PEQ Utility	Neither (0.07)	17	K level 2	8	K level 3	9	0.14		
PEQ Well-being	Microprocessor (0.016)	17	K level 2	8	K level 3	9	0.83		
Mental Energy expenditure (VAS)	Microprocessor (0.02)	17	K level 2	8	K level 3	9	0.43		
Confidence while walking (VAS)	Microprocessor (0.001)	17	K level 2	8	K level 3	9	0.47		
Multitasking while walking (VAS)	Microprocessor (0.002)	17	K level 2	8	K level 3	9	0.82		
Difficulty with concentration (VAS)	Neither (0.07)	17	K level 2	8	K level 3	9	0.98		
Activity avoidance (VAS)	Neither (0.10)	17	K level 2	8	K level 3	9	0.11		
Frustration with falls (VAS)	Microprocessor (0.005)	17	K level 2	8	K level 3	9	0.81		
Embarrassment with falls (VAS)	Neither (0.23)	17	K level 2	8	K level 3	9	0.87		
Stumbles (VAS)	Microprocessor (0.05)	17	K level 2	8	K level 3	9	0.49		
Stumbles (number, reported)	Microprocessor (0.003)	17	K level 2	8	K level 3	9	0.40		
Semiconrolled falls (VAS)	Neither (0.64)	17	K level 2	8	K level 3	9	0.91		
Semiconrolled falls (number, reported)	Microprocessor (0.03)	17	K level 2	8	K level 3	9	0.53		

Data for Hafner 2009 (PMID 19675993).<sup>113</sup> Additional details in Appendix D. P values <0.05 are bolded and associated "findings" are noted; however see footnote about Bonferroni P value threshold. Italic bold P values are statistically significant below the Bonferroni P value.

Abbreviations: PEQ = Prosthesis evaluation questionnaire, VAS = visual analogue scale.

\* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

† Bonferroni P = 0.0018 (due to multiple testing, to be considered to be statistically significant, the P values for differences between subgroups had to be less than this value). A separate Bonferroni P value was calculated for each study based on the number of analyses (including subgroup analyses) analyzed by the study researchers and by this review.

**Table 4.9. Subgroup analyses. Hahn 2016, Comparing Genium Microprocessor Versus Prior Knee Components (Mostly C-Leg Microprocessor Knee)**

Outcomes*	Overall Favor† (P value)	N Total	Study Conclusions‡
Functional benefits (safety, harmonization of gait pattern, relief of the contralateral limb, possibility to divide attention, capability to vary gait speed, reduction of overall effort, reduction in number of aids, and change of mobility grade) Perception (of safety) Advanced maneuvers (assessed by prosthetist) Variable gait speed (capability to vary speed) Toileting Walking stairs alternatingly (up/down)	Genium (implied <0.05)	899	Many variables were statistically significant in multivariable regression analyses for different outcomes (see text). However, "None of the variables and none of the regression models yield explanatory predictive power" regarding who would most benefit from a microprocessor knee. These variables included: age, years wearing prosthesis, distance walked per day, gender, vascular disease etiology, amputation level, bilateral amputation, no comorbidity, diabetes mellitus, cardiovascular disease, "distortion circulation leg", hip problem, "further disability", profession, residual limb condition, residual limb length, residual limb loading, adhesion, number of falls per year, mobility grade. In addition, these variables were determined to have no overall predictive value: body mass index, neuropathy, visual impairment, artificial hip, back pain, paresis lower extremity, paresis upper extremity, further amputation, malformation, contralateral joint instability/joint replacement/pain, osteoarthritis of the lower limb joints, hip contracture, scarred residual limb, and annual falls (yes/no).

Data for Hahn 2016 (PMID 27828871).<sup>114</sup> Additional details in Appendix D.

\* Listed outcomes. Unclear which outcomes were used in the final models.

† Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

‡ There were many important biases and other concerns with the study and analyses.

**Table 4.10. Subgroup analyses. Isakov 1985, Comparing Locking Versus Open Knee Component**

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
Gait speed (m/min), 6 minutes	Neither (0.060)	17	Vascular	14	Nonvascular	3	<b>0.016</b>		Nonvascular favored open knee more than vascular did
		17	Male	16	Female	1	0.59		
		17	Age 26-50 y	8	55-75 y	9	<b><i>0.004</i></b>	<b>0.014</b>	Younger favored open knee more than older did

Data for Isakov 1985 (PMID 3868034).<sup>115</sup> Additional details in Appendix D. P values <0.05 are bolded and associated "findings" are noted; however see footnote about Bonferroni P value threshold. Italic bold P values are statistically significant below the Bonferroni P value.

\* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

† Bonferroni P = 0.010 (due to multiple testing, to be considered to be statistically significant, the P values for differences between subgroups had to be less than this value). A separate Bonferroni P value was calculated for each study based on the number of analyses (including subgroup analyses) analyzed by the study researchers and by this review.

**Table 4.11. Subgroup analyses. Kahle 2008, Comparing Microprocessor (C-Leg) Versus Mechanical Knee Component**

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
Stumbles, reported	Microprocessor (0.006)	15	K level 2	10	K level 3-4	5	0.14		
		15	K level 2-3	4	K level 4	11	0.030		K2-3 favored C-Leg more than K4 did
		15	Age 28-57 y	8	58-83 y	7	0.53	0.38	
		15	Vascular	7	Nonvascular	8	0.056		
		15	Height 160-170 cm	5	173-188 cm	10	0.44	0.93	
		14	Employed	7	Not employed	7	0.75		
		15	Prosthesis use 6-12 mo	9	>12 mo	6	0.13		
		15	Residual limb "firm"	7	"soft" or "medium"	8	0.38		
		15	Residual limb "medium" or "firm"	13	"soft"	2	0.51		
		15	Residual limb length 32-43 cm	8	11-31 cm	7	0.19	0.71	
15	Residual limb as percent of femur 74-100%	8	27-73%	7	0.40	0.74			
Falls, reported	Microprocessor (0.03)	15	K level 2	10	K level 3-4	5	0.48		
		15	K level 2-3	4	K level 4	11	0.089		
		15	Age 28-57 y	8	58-83 y	7	0.48	0.10	
		15	Vascular	7	Nonvascular	8	0.24		
		15	Height 160-170 cm	5	173-188 cm	10	0.48	0.48	
		14	Employed	7	Not employed	7	0.15		
		15	Prosthesis use 6-12 mo	9	>12 mo	6	0.29		
		15	Residual limb "firm"	7	"soft" or "medium"	8	0.20		
		15	Residual limb "medium" or "firm"	13	"soft"	2	0.84		
		15	Residual limb length 32-43 cm	8	11-31 cm	7	0.37	0.68	
15	Residual limb as percent of femur 74-100%	8	27-73%	7	0.48	0.80			
Self-selected walking speed, 75 m	Microprocessor (0.03)	15	K level 2	10	K level 3-4	5	0.84		
		15	K level 2-3	4	K level 4	11	0.75		
		15	Age 28-57 y	8	58-83 y	7	0.82	0.80	
		15	Vascular	7	Nonvascular	8	0.27		
		15	Height 160-170 cm	5	173-188 cm	10	0.20	0.33	
		14	Employed	7	Not employed	7	0.67		



Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
		15	Prosthesis use 6-12 mo	9	>12 mo	6	0.46		
		15	Residual limb "firm"	7	"soft" or "medium"	8	0.51		
		15	Residual limb "medium" or "firm"	13	"soft"	2	0.70		
		15	Residual limb length 32-43 cm	8	11-31 cm	7	0.63	0.50	
		15	Residual limb as percent of femur 74-100%	8	27-73%	7	0.16	0.49	
Fastest walking on even terrain, 75 m	Microprocessor (0.005)	15	K level 2	10	K level 3-4	5	0.64		
		15	K level 2-3	4	K level 4	11	0.93		
		15	Age 28-57 y	8	58-83 y	7	0.75	0.41	
		15	Vascular	7	Nonvascular	8	0.41		
		15	Height 160-170 cm	5	173-188 cm	10	0.18	0.26	
		14	Employed	7	Not employed	7	0.76		
		15	Prosthesis use 6-12 mo	9	>12 mo	6	0.43		
		15	Residual limb "firm"	7	"soft" or "medium"	8	0.34		
		15	Residual limb "medium" or "firm"	13	"soft"	2	0.60		
		15	Residual limb length 32-43 cm	8	11-31 cm	7	0.34		
15	Residual limb as percent of femur 74-100%	8	27-73%	7	0.18	0.46			
Fastest walking on uneven terrain, 38 m	Microprocessor (<0.001)	15	K level 2	10	K level 3-4	5	0.76		
		15	K level 2-3	4	K level 4	11	0.068		
		15	Age 28-57 y	8	58-83 y	7	0.77	0.071	
		15	Vascular	7	Nonvascular	8	0.13		
		15	Height 160-170 cm	5	173-188 cm	10	0.44	0.41	
		14	Employed	7	Not employed	7	0.41		
		15	Prosthesis use 6-12 mo	9	>12 mo	6	0.94		
		15	Residual limb "firm"	7	"soft" or "medium"	8	0.12		
		15	Residual limb "medium" or "firm"	13	"soft"	2	0.052		
15	Residual limb length 32-43 cm	8	11-31 cm	7	0.30	0.17			
15	Residual limb as percent of femur 74-100%	8	27-73%	7	0.77	0.13			
Fastest walking on even terrain, 6 m	Microprocessor (0.001)	15	K level 2	10	K level 3-4	5	0.38		

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
		15	K level 2-3	4	K level 4	11	0.98		
		15	Age 28-57 y	8	58-83 y	7	0.71	0.48	
		15	Vascular	7	Nonvascular	8	0.65		
		15	Height 160-170 cm	5	173-188 cm	10	0.64	0.79	
		14	Employed	7	Not employed	7	0.030		Employed favored C-Leg more than not employed did
		15	Prosthesis use 6-12 mo	9	>12 mo	6	0.44		
		15	Residual limb "firm"	7	"soft" or "medium"	8	0.50		
		15	Residual limb "medium" or "firm"	13	"soft"	2	0.71		
		15	Residual limb length 32-43 cm	8	11-31 cm	7	0.14	0.72	
		15	Residual limb as percent of femur 74-100%	8	27-73%	7	0.36	0.78	
Montreal Rehabilitation Performance Profile	Microprocessor (<0.001)	15	K level 2	10	K level 3-4	5	0.15		
		15	K level 2-3	4	K level 4	11	0.38		
		15	Age 28-57 y	8	58-83 y	7	0.20		
		15	Vascular	7	Nonvascular	8	0.21		
		15	Height 160-170 cm	5	173-188 cm	10	0.44	0.88	
		14	Employed	7	Not employed	7	0.32		
		15	Prosthesis use 6-12 mo	9	>12 mo	6	0.37		
		15	Residual limb "firm"	7	"soft" or "medium"	8	0.16		
		15	Residual limb "medium" or "firm"	13	"soft"	2	0.30		
		15	Residual limb length 32-43 cm	8	11-31 cm	7	0.12	0.97	
15	Residual limb as percent of femur 74-100%	8	27-73%	7	0.19	0.998			

Data for Kahle 2008 (PMID 18566922).<sup>116</sup> Additional details in Appendix D. P values <0.05 are bolded and associated "findings" are noted; however see footnote about Bonferroni P value threshold. Italic bold P values are statistically significant below the Bonferroni P value.

\* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

† Bonferroni P = 0.00040 (due to multiple testing, to be considered to be statistically significant, the P values for differences between subgroups had to be less than this value). A separate Bonferroni P value was calculated for each study based on the number of analyses (including subgroup analyses) analyzed by the study researchers and by this review.

**Table 4.12. Subgroup analyses. Silver-Thorn 2009, Comparing Locking (Total Knee 2000) Versus Hydraulic Knee Component**

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
Borg Rating of Perceived Exertion test	Neither (1.00)	4	Age 33-41 y	2	43-58 y	2	0.47	0.91	
		4	Time since amputation 8-20 y	2	31-34 y	2	0.20	0.30	
		4	Height 171-173 cm	2	178-184 cm	2	0.47	0.15	
		4	Residual limb length 23-28 cm	2	43-58 y	2	0.20	0.029	Shorter residual limb favored Total Knee 2000 more than longer residual did
Confidence (Likert)	Neither (0.32)	4	Age 33-41 y	2	31-34 y	2	0.77	0.34	
		4	Time since amputation 8-20 y	2	178-184 cm	2	0.31	0.075	
		4	Height 171-173 cm	2	32-36 cm	2	0.77	0.80	
		4	Residual limb length 23-28 cm	2	43-58 y	2	0.31	0.46	
Perceived stability	Neither (0.32)	4	Age 33-41 y	2	31-34 y	2	0.77	0.34	
		4	Time since amputation 8-20 y	2	178-184 cm	2	0.31	0.075	
		4	Height 171-173 cm	2	32-36 cm	2	0.77	0.80	
		4	Residual limb length 23-28 cm	2	43-58 y	2	0.31	0.45	
Comfort on uneven terrain	Neither (0.19)	4	Age 33-41 y	2	31-34 y	2	0.81	0.56	
		4	Time since amputation 8-20 y	2	178-184 cm	2	0.037	0.1	More recent amputation favored Total Knee 2000 more than more distant amputation did
		4	Height 171-173 cm	2	32-36 cm	2	0.81	0.41	
		4	Residual limb length 23-28 cm	2	43-58 y	2	0.037	0.051	Longer residual limb favored Total Knee 2000 more than more shorter did
Comfort up stairs	Neither (0.092)	4	Age 33-41 y	2	31-34 y	2	0.29	0.88	
		4	Time since amputation 8-20 y	2	178-184 cm	2	0.29	0.52	

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
		4	Height 171-173 cm	2	32-36 cm	2	0.29	0.085	
		4	Residual limb length 23-28 cm	2	43-58 y	2	0.29	<b>0.046</b>	Shorter residual limb favored Total Knee 2000 more than more longer did
Comfort in a crowd	Neither (0.39)	4	Age 33-41 y	2	31-34 y	2	0.42	0.95	
		4	Time since amputation 8-20 y	2	178-184 cm	2	0.42	0.39	
		4	Height 171-173 cm	2	32-36 cm	2	0.42	0.14	
		4	Residual limb length 23-28 cm	2	43-58 y	2	0.42	0.19	
Gait speed (m/s), distance undefined	Neither (0.072)	5	Age 33-41 y	2	31-34 y	3	0.67	0.53	
		5	Time since amputation 8-20 y	3	178-184 cm	2	0.14	0.10	
		5	Height 171-173 cm	2	32-36 cm	3	0.50	0.87	
		5	Residual limb length 23-28 cm	3	43-58 y	2	0.071	0.20	
Cadence (steps/min), distance undefined	Neither (0.20)	5	Age 33-41 y	2	31-34 y	3	0.74	0.39	
		5	Time since amputation 8-20 y	3	178-184 cm	2	0.37	0.36	
		5	Height 171-173 cm	2	32-36 cm	3	0.16	0.48	
		5	Residual limb length 23-28 cm	3	43-58 y	2	0.30	0.28	

Data for Silver-Thorn 2009 (PMID none).<sup>120</sup> Additional details in Appendix D. P values <0.05 are bolded and associated "findings" are noted; however see footnote about Bonferroni P value threshold. Italic bold P values are statistically significant below the Bonferroni P value.

\* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

† Bonferroni P = 0.00078 (due to multiple testing, to be considered to be statistically significant, the P values for differences between subgroups had to be less than this value). A separate Bonferroni P value was calculated for each study based on the number of analyses (including subgroup analyses) analyzed by the study researchers and by this review.

**Table 4.13. Subgroup analyses. Theeven 2011, Comparing Microprocessor (2 Settings) Versus Mechanical Knee Component**

Outcome	Overall Favors*† (P value)	N Total	Subgroups	N Subgroups‡	Comparator	N Comparator	P Difference§ (Categorical)	P Difference# (Continuous)	Findings†
Activity time (% of up time)	Neither (0.86, 0.90)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.42 (all§)	
Bouts of activity (number)	Neither (0.99, 0.95)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.42 (all§)	
Daily activity "counts"	Neither (0.94, 0.89)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.31 (all§)	
PEQ Ambulation	Microprocessor A (0.01, 0.14)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.018 (all§)	High K2 favored microprocessor knee B more than low K2 subgroup; other comparisons P>0.13
PEQ Appearance	Neither (0.55, 0.33)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.69 (all§)	
PEQ Residual limb health	Microprocessors (0.003, <0.001)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.29 (all§)	
PEQ Satisfaction with prosthesis	Neither (0.05, 0.14)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.28 (all§)	
PEQ Satisfaction with walking	Microprocessor A (0.003, 0.19)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.006 (all§)	Intermediate K2 favored both microprocessor knees more than low K2 subgroup (P=0.28, 0.006), high K2 favored microprocessor knee B more than intermediate K2 subgroup (P=0.041); other comparisons P=0.066-0.44
PEQ Sounds	Neither (0.52, 0.33)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.33 (all§)	
PEQ Utility	Microprocessors (0.006, 0.02)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.25 (all§)	
PEQ Well-being	Neither (0.30, 0.93)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.54 (all§)	
Perceived difficulty ambulation requiring prosthesis skill	Neither (0.63, 0.72)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.48 (all§)	
Perceived difficulty balance	Neither (0.56, 0.60)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.69 (all§)	
Perceived difficulty sitting and standing	Neither (0.62, 0.57)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.54 (all§)	
Performance time ambulation requiring prosthesis skill (min)	Microprocessor B (NS, 0.023)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.68 (all§)	

Outcome	Overall Favors*† (P value)	N Total	Subgroups	N Subgroups‡	Comparator	N Comparator	P Difference§ (Categorical)	P Difference# (Continuous)	Findings†
Performance time requiring balance (min)	Microprocessors (<0.001, 0.002)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.31 (all§)	
Performance time requiring sitting and standing (min)	Neither (0.87, 1.00)	30	K2 High, Intermediate§	12, 12	K2 Low§	6		>0.51 (all§)	

Data for Theeven 2011 (PMID 21947182, 22549656).<sup>117, 118</sup> Additional details in Appendix D. P values <0.05 are bolded and associated "findings" are noted; however see footnote about Bonferroni P value threshold. *Italic bold* P values are statistically significant below the Bonferroni P value.

Abbreviations: PEQ = Prosthesis evaluation questionnaire.

\* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

† The two values for statistical significance indicate the separate analyses for the two microprocessor settings ("A" and "B").

‡ The numbers of participants in each of the two subgroups (high K2 and intermediate K2).

# Bonferroni P = 0.00037 (due to multiple testing, to be considered to be statistically significant, the P values for differences between subgroups had to be less than this value). A separate Bonferroni P value was calculated for each study based on the number of analyses (including subgroup analyses) analyzed by the study researchers and by this review.

§ 6 comparisons summarized: "High" vs. "intermediate" K2, "high" vs. "low" K2, and "intermediate" vs. "low" K2 for both microprocessor knees A and B vs. mechanical knee. "High," "intermediate," and "low" functional mobility levels were assigned by "three independent experts (a physical therapist, a rehabilitation physician and a prosthetist) based on participants' daily activity level, mean comfortable walking speed, past medical history, psychosocial status and current physical condition."

**Table 4.14. Subgroup analyses. Trallesi 2011, Comparing Marlo Anatomic vs. Ischial Component Socket Component**

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
PEQ Mobility	Marlo Anatomic Socket (0.018)	7	Male	6	Female	1	<b>0.022</b>		One woman favored Marlo Anatomic Socket more than men did
		7	Age 25-28 y	3	41-46 y	4	0.42	0.28	
		6	Height 174-180 cm	2	184-185 cm	4	0.074	<b>0.017</b>	Shorter favored Marlo Anatomic Socket more than taller did, among men
		7	Time since amputation 2-9 y	3	10-26 y	4	0.56	0.69	

Data for Trallesi 2011 (PMID 21684165).<sup>119</sup> Additional details in Appendix D. P values <0.05 are bolded and associated "findings" are noted; however see footnote about Bonferroni P value threshold. Italic bold P values are statistically significant below the Bonferroni P value.

Abbreviations: PEQ = Prosthesis evaluation questionnaire.

\* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

† Bonferroni P = 0.0071 (due to multiple testing, to be considered to be statistically significant, the P values for differences between subgroups had to be less than this value). A separate Bonferroni P value was calculated for each study based on the number of analyses (including subgroup analyses) analyzed by the study researchers and by this review.

**Table 4.15. Subgroup analyses. Wong 2015, Comparing Microprocessor Versus Mechanical Knee Component**

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
Falls, number	Microprocessor (0.020)	8	K level 1	6	K level 2-3	2	0.12		
		8	K level 1-2	4	K level 3	4	0.040		K1-2 favored microprocessor knee more than K3 did
		8	Age 43-61 y	4	63-74 y	4	0.040	0.027	Older favored microprocessor knee more than younger did
		8	Time since amputation 0.5-2 y	4	4-47 y	4	0.73	0.67	
		8	Bilateral	2	Unilateral	6	0.12		
ABC Balance	Microprocessor (0.012)	8	K level 1	6	K level 2-3	2	0.016		K2-3 favored microprocessor knee more than K1 did
		8	K level 1-2	4	K level 3	4	0.16		
		8	Age 43-61 y	4	63-74 y	4	0.10	0.021	Younger favored microprocessor knee more than older did
		8	Time since amputation 0.5-2 y	4	4-47 y	4	0.22	0.96	
		8	Bilateral	2	Unilateral	6	0.016		Bilateral favored microprocessor knee more than unilateral did
Houghton Scale	Neither (0.058)	8	K level 1	6	K level 2-3	2	0.61		
		8	K level 1-2	4	K level 3	4	0.37		
		8	Age 43-61 y	4	63-74 y	4	0.37	0.10	
		8	Time since amputation 0.5-2 y	4	4-47 y	4	0.13	0.47	
		8	Bilateral	2	Unilateral	6	0.61		
BBS Balance	Neither (0.11)	8	K level 1	6	K level 2-3	2	0.81		
		8	K level 1-2	4	K level 3	4	0.51		
		8	Age 43-61 y	4	63-74 y	4	0.95	0.93	
		8	Time since amputation 0.5-2 y	4	4-47 y	4	0.77	0.33	
		8	Bilateral	2	Unilateral	6	0.81		
TUG Walking	Microprocessor (0.043)	8	K level 1	6	K level 2-3	2	<i>0.0001</i>		K2-3 favored microprocessor knee more than K1 did
		8	K level 1-2	4	K level 3	4	0.24		
		8	Age 43-61 y	4	63-74 y	4	0.28	0.17	



Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
		8	Time since amputation 0.5-2 y	4	4-47 y	4	0.37	0.78	
		8	Bilateral	2	Unilateral	6	<i><b>0.0001</b></i>		Bilateral favored microprocessor knee more than unilateral did
Fear of falling	Microprocessor (0.042)	8	K level 1	6	K level 2-3	2	0.11		
		8	K level 1-2	4	K level 3	4	0.62		
		8	Age 43-61 y	4	63-74 y	4	0.35	0.24	
		8	Time since amputation 0.5-2 y	4	4-47 y	4	0.48	0.51	
		8	Bilateral	2	Unilateral	6	0.11		

Data for Wong 2015 (PMID 25768067).<sup>1,21</sup> Additional details in Appendix D. P values <0.05 are bolded and associated "findings" are noted; however see footnote about Bonferroni P value threshold. Italic bold P values are statistically significant below the Bonferroni P value.

Abbreviations: ABC = Activities-Specific Balance Confidence, BBS = Berg Balance Scale, TUG = timed up and go test.

\* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).

† Bonferroni P = 0.0010 (due to multiple testing, to be considered to be statistically significant, the P values for differences between subgroups had to be less than this value). A separate Bonferroni P value was calculated for each study based on the number of analyses (including subgroup analyses) analyzed by the study researchers and by this review.

## Studies That Evaluated Validated Outcomes

Of the 11 studies that directly compared different LLP components and provided sufficient data to allow subgroup analyses, nine reported on basic patient characteristics such as age, sex, limb length, amputation level, and amputation etiology. We considered these to be potentially important predictors and therefore handle them as if they were validated predictors. A tenth study (Hafner 2009) and two other studies (Kahle 2008, Wong 2015) evaluated K levels,<sup>113, 116, 121</sup> which we assumed to be equivalent to validated, although we found no studies assessing K level validity, per se. One study (Theeven 2011) evaluated only K2 level subgroups (“high,” “intermediate,” and “low”), which were unique to the study and we considered to be *not* validated.<sup>117, 118</sup> Likewise, here we omit evaluation of residual limb firmness (an *ad hoc* descriptor) as a validated outcome predictor as was reported by one study (Kahle 2008).<sup>116</sup> None of the validated assessment techniques or predictor tools were used to characterize subgroups.

Studies evaluated numerous outcomes, most of which have not been validated in lower limb amputees. Only five of the studies analyzed validated outcomes (Hafner 2009, Isakov 1985, Kahle 2008, Trallesi 2011, and Wong 2015). These five studies were all deemed to be at moderate risk of bias. Four of the five studies reported data on subgroups based on patient characteristics that we considered valid; the fifth studies reported subgroup results separately but did not statistically analyze between-group differences (we calculated these differences based on reported data). Studies also reported events (e.g., falls) that we considered to be valid, by definition. The validated outcomes among these studies include 6 minute walk test (6MWT, gait speed measured during 6 minutes), reported falls, the PEQ, ABC, BBS, Houghton scale, and TUG walking.

The applicability of these studies to the overall population of people receiving LLPs varies. Most patients in the studies were on the younger side (less than about 50 years old), particularly in the Trallesi 2011 study comparing sockets, in which the average age was 34 years. Most included study participants were men; however, the percentage of men varied from 76 to 94 percent (among the three studies that reported patient sex). Among four studies that characterized patients K levels at baseline, only one study (Wong 2015) included people at K1 level (25%), three studies included people at K2 level (25-60%), one study (Trallesi 2011) included people at either K3 or K4 level, three additional studies included people at K3 level (33-53%), and one additional study included one additional patient (7%) at K4 level. These studies all evaluated knees or sockets; thus all patients had undergone transfemoral amputations. The four studies that reported amputation etiologies displayed wide heterogeneity across studies. In three studies, trauma accounted for about half or more of amputations (47-86%). In one study (Isakov 1985), 82 percent had dysvascular causes and only 18 percent trauma. In contrast, in Trallesi 2011, 86% had trauma as an etiology and the remainder cancer (none had dysvascular disease). Similarly, Hafner 2009 had a majority of people with trauma (59%), but only 6 percent with dysvascular etiologies. On the other hand, in Kahle 2008, about half each had trauma or dysvascular etiologies (excluding patients with congenital amputations).

## Microprocessor Knees

Hafner 2009 (Table 4.8) compared the C-Leg microprocessor knee and mechanical knees in 17 people with unilateral transfemoral amputations, 59 percent due to trauma (and only 6 percent due to dysvascular disease). The participants were split approximately equally between K2 and K3. The study reported subgroup analyses by K level, but did not report statistical analyses

comparing the subgroups. Among the outcomes reported, they reported PEQ subscales, which have been validated, and the numbers of reported stumbles and falls. Overall, people using the microprocessor knee had fewer stumbles and falls and also scored better on PEQ Ambulation and Well-being subscales, compared to mechanical knees, but no differences were found between knees on the other PEQ subscales. Post hoc analyses comparing the K2 and K3 subgroups found no differences in effect (microprocessor vs. mechanical knee) between the subgroups. Overall, the study does not support differences in benefit of the microprocessor between people classified as K2 or K3.

Kahle 2008 (Table 4.11) compared a microprocessor knee (C-Leg) with a mechanical knee in 15 people with unilateral amputations (amputation level not described), excluding four people with congenital amputations. The participants had with K2 or greater function, but half of them moved up a K level when using the microprocessor knee. About one-third each had dysvascular and traumatic causes of their amputations. Overall, people reported fewer stumbles and falls (as separate outcomes) with the microprocessor knee. Other nonvalidated outcomes were also assessed. The article reported individual participant data which allowed multiple subgroup analyses based on K level, amputation etiology, age, height, employment status, and residual limb length. The study also reported on a nonvalidated measure of residual limb firmness. After accounting for multiple testing, no statistically significant differences were found between subgroups regarding relative benefit of the microprocessor knee to prevent stumbles and falls. While not statistically significant after accounting for multiple testing, K2 or K3 participants tended to have relatively fewer stumbles with the microprocessor knee than K4 amputees did. Overall, however, the study does not support any differences in benefit of microprocessor knees based on patient or residual limb characteristics.

Wong 2015 (Table 4.15) compared the C-Leg microprocessor and mechanical knees in 8 people classified as K1 to K3 with transfemoral amputations, three-quarters of which were unilateral. Overall, the study found mostly better outcomes with the microprocessor knee. The article reported individual participant data which allowed multiple subgroup analyses based on K levels, age, time since amputation, and bilateral versus unilateral amputation. The study analyzed several validated outcomes along with reported falls. For the TUG Walking outcome, the study found that those classified as K2 or K3 did relatively better with the microprocessor knee compared to mechanical knees than those classified as K1. People with bilateral amputations also did relatively better with the microprocessor knees compared to those with unilateral amputations. No differences were found in effect between older and younger patients or based on time since amputation. Across the other validated outcomes (reported falls, ABC Balance, BBS, fear of falling, and Houghton scale) no statistically significant differences were found between subgroups after accounting for multiple testing. For several subgroup comparisons, there was a tendency for one subgroup to perform relatively better with the microprocessor knee than another subgroup (i.e.,  $P < 0.05$ , but not significant after accounting for multiple testing); however, there was not consistency across subgroups or outcomes (see Table 4.15). Overall, there was evidence of subgroup differences in the effect of microprocessor knees on TUG walking based on K level and bilateral versus unilateral amputation, but no consistent patterns were found across subgroups and outcomes.

## **Other Components**

Isakov 1985 (Table 4.10) compared two Otto Bock prostheses with a locking system knee (model 3R17) and with an “open” load-dependent brake knee (model 3R15) in 17 people with

unilateral transfemoral amputations, 82 percent of which were due to dysvascular disease. Overall, people had similar gait speeds with both knees. They reported gait speed averaged over 6 minutes and provided individual participant data that allowed subgroup analyses based on amputation etiology, sex, and age. Those 50 years or younger were more likely to have faster walking speed with the open knee, in contrast to those who were 55 years and older ( $P=0.004$ ); however linear regression failed to find a significant association (after accounting for multiple testing). Participants with nonvascular amputation etiologies also tended to walk faster with the open knee, in contrast to those with vascular amputations; however, this finding was not statistically significant after accounting for multiple testing. Differences in gait speed between the two prostheses were similar in the one woman and the 16 men in the study. Overall, younger lower limb amputees favored the open knee over the locking knee significantly more than older amputees.

Traballesi 2011 (Table 4.14) compared the Marlo Anatomic Socket with an ischial component socket in 7 people with unilateral transfemoral amputations with K3 to K4 function; the large majority (86%) had amputations due to trauma. Overall, people had better mobility, per the PEQ mobility subscale, with the Marlo Anatomic Socket. The article reported individual participant data, which allowed multiple subgroup analyses based on patient characteristics and time since amputation. After accounting for multiple testing, no statistically significant differences were found between subgroups regarding relative benefit of the Marlo Anatomic Socket. The single woman in the study did tend to have even better mobility with the Marlo Anatomic Socket than the ischial component socket than the six men did; but the woman differed from the men in more ways than just her sex and the clinical significance of this finding is questionable. Shorter men also tended to have relatively better mobility with the Marlo Anatomic Socket than taller men, but this finding was also not statistically significant after accounting for multiple testing. Overall, the study does not support any differences in benefit of the Marlo Anatomic Socket over the ischial component socket based on patient characteristics.

## Studies Using Nonvalidated Measures

### All studies

Six studies reported analyses based only on nonvalidated measures (Alaranta 1994, De Asha 2014, Gard 2003, Hahn 2016, Silver-Thorn 2009, and Theeven 2011); two other studies reported subgroup analyses with some nonvalidated measures in addition to the validated measures discussed above (Hafner 2009, Kahle 2008). Theeven 2011 reported subgroup data only for *ad hoc* subclassifications of the K2 level (high, intermediate, and low). Kahle 2008 categorized patients based on firmness of their residual limb. These nine studies all used nonvalidated outcomes.

As summarized in Table 4.4, studies generally found no significant differences in the relative effectiveness of different components based on subgroup classification.

### Study With Regression Analysis

Hahn 2016 was the largest eligible study, which conducted the most comprehensive analysis.<sup>114</sup> It was the only eligible study to attempt to assess heterogeneity of treatment effect (how effects may differ in different people). The study created multivariable regression models with the goal of predicting which patients would most benefit from a Genium® microprocessor

knee compared to people's prior knee (mostly an alternative microprocessor knee, the C-Leg; both from Otto Bock Healthcare Products Austria).

Given the large size of the study (899 people with knee or higher amputations, mostly due to trauma (69%) who were classified as K2 to K4) and the use of regression analyses to investigate heterogeneity of treatment effect, the study was included for review. However, because of the imprecise comparison among LLP components used, strictly speaking, an argument could have been made to reject the study from the review. The study did not compare distinct components (or even types of components). Instead, they compared newly-prescribed Genium knees to participants' prior knee prosthetics. Among the 899 participants, 689 (76.6%) had used the C-Leg (a similar microprocessor knee), 38 (4.2%) used mechanical hydraulic knees, 22 (2.4%) pneumatic knees, 15 (1.7%) 4-axis polycentric knees, 19 (2.1%) other polycentric knees, 9 (1.0%) brake knees, and 3 (0.3%) locked knees. The article failed to report anything regarding the other 104 (11.7%) of the prior knees. Thus, the analysis is mostly a comparison of two different microprocessor knees, but in reality is an evaluation of just the Genium knee without a specific comparator. Of note, a somewhat similar study was conducted by the same group analyzing the C-Leg (or C-Leg compact) in 1223 participants, but this study was rejected since there was no description of, or clear comparison with, the prior knees.

The participants in the Genium study were all considered to be candidates most likely to benefit from the Genium prosthesis by their prosthetist's assessment. Thus, these people were deemed more likely to respond to the Genium prosthesis than other amputees. As noted, 77 percent were already users of microprocessor knees (the C-Leg or C-Leg compact). Furthermore, the analytic method used further limited the number of people included in the model. The researchers required complete datasets for all selected variables and did not impute missing data. Thus, at most the 425 people with data about their residual limb condition were included in the model; likely the actual number included was much smaller because of missing data for other variables. The final numbers analyzed in the models were not reported.

The study outcomes were based primarily on prosthetists' and participants' ratings/assessments as indicated in an existing database. (NB. The outcomes reported in this paper were assessed by a 2008 thesis conducted at the Universitätsklinikum Münster in Germany, which is not available). However, the authors state that "the data do not rely on validated outcomes as recommended in controlled trials. This limits the accuracy of the findings specifically with respect to magnitude of the effects."

Across the various specific outcomes evaluated, the total responsiveness ranged from 67 to 96 percent. Total responsiveness ranged from 95 to 97 percent, suggesting that few people failed to have some improvement with the Genium prosthesis. For inclusion in their models, the researchers chose the most responsive items within each of the performance areas: safety, harmonization of gait pattern, relief of contralateral limb, possibility to divide attention, capability to vary gait speed, reduction of overall effort, reduction in number of aids, change of mobility grade, perceived safety on stairs and slopes, variation of gait speed, walking with small steps, more difficult walking requirements, and more difficult walking environments. However, the study does not report the percentage of patients who were responsive for each modeled outcome; in part this is due to the fact that the actual outcome(s) used in the final model are unclear. If the percentage was indeed high, there may be "class imbalance" where the proportion of failures is so small, there is little room for a model to improve over an intercept-only model that simply classifies everyone as a responder. In other words, the "best" model may not differentiate people as likely responders and nonresponders much better than an assumption that

all will respond, since in reality almost all did respond. However, it is not clear which “responsiveness” outcome(s) were used in their final model(s).

A very large set of variables related to patient characteristics, amputation and residual limb characteristics, and current type of prosthesis used, among others were tested for inclusion as predictors in the models. The analyses found numerous highly statistically significant predictors of the outcomes. However, overall, the authors reported that “none of the variables and none of the regression models yield[ed] explanatory predictive power.” They were also not able to determine a coherent, stable, reproducible variable set.

The paper, though, does not, in fact, perform an analysis of the predictive performance of logistic regression models to identify people with better or clearly better outcomes with a Genium knee. The only metric of predictive performance reported was an  $R^2$  value, which is not sufficient to make conclusions for several reasons. While the  $R^2$  value can be considered as a metric of global predictive performance, it is not generally a very informative one. For logistic regression there are several pseudo- $R^2$  statistics. These statistics have different interpretations, and not all of them have a maximum of 1 (i.e., 100%) in a given dataset. The various pseudo- $R^2$  from the same logistic regression can differ greatly because each is calculated differently. For example, it is possible for a logistic regression to have a e.g., Nagelkerke pseudo  $R^2$  of 0.99, and a McFadden pseudo- $R^2$  of 0.40. The studies does not report which  $R^2$  was used, so one cannot determine if it really indicates that there is no predictive ability at all. It is conceivable that the reported  $R^2$  values of 0.263 indicates that the model is explanatory. Finally, the study does not report a thorough evaluation of the discriminatory performance (ability of a model to correctly discriminate those at higher risk from those at lower risk) and calibration performance (among those predicted to have a given probability of response — x per 100 — do around x per 100 actually respond?). For these reasons, the study does not provide compelling evidence that their model has no predictive performance.

The article does not report the actual final model(s), and as noted, it is not abundantly clear which outcomes were used in the final models. However, they report linear regressions between a long list of participant and component variables and outcomes. It is implied that the outcomes are the differential response to the Genium knee (whether there was a relative difference with the Genium and the prior prostheses—mostly C-Leg). In addition, many of the associations were highly statistically significant. Among these, for the outcome “variable gait speed”, younger age, longer distance walked per day (presumably on their old knee), nonvascular etiology, amputation level (unclear how defined), unilateral amputation, no comorbidities, no diabetes, no cardiovascular disease, no leg peripheral vascular disease, no further disability, profession (not defined), better residual limb condition, longer residual limb length, greater residual limb loading, greater number of falls per year, and higher mobility grade were all statistically significantly associated with better variable gait speed with the Genium knee (than people with the opposite states). P values for these variables ranged from  $10^{-26}$  (mobility grade) to 0.025 (further disability). Similar findings were reported for toileting and walking up stairs alternatingly.

In brief, while relative effectiveness of the Genium microprocessor knee was highly statistically significantly different for many subgroups versus prior knee prostheses (mostly the C-Leg microprocessor knee), the study reported that no set of variables were found to accurately predict which patients would most benefit from the microprocessor knee. However, there are numerous concerns about a number of critical issues. There was likely selection bias: the included subpopulation was chosen based on their assessed likelihood of succeeding with the

microprocessor knee, and analyzed participants had to have available data for all included variables. The primary comparison was between newly prescribed microprocessor Genium knees and a mix of prior prosthetic knees, mostly another microprocessor knee, the C-Leg, but also various mechanical knees and a large number of unknown prosthetic types. The average participant may have been too likely to respond well to the microprocessor knee to allow for the possibility of determining who, on average, would be likely to fail with the knee. The study's analytic methodology and findings were too incompletely reported to assess how the model fared and if correct methodologies were used.

## Summary

Table 4.16 summarizes the study findings. A relatively small percentage of comparative studies report sufficient data to allow subgroup analysis and evaluation of heterogeneity of treatment effect (12%, 11 of 90 otherwise eligible studies). Of these 11 studies, only five used validated measures. Only one of the eligible studies was a randomized trial (Theeven 2011), but it did not evaluate validated subgroups. Only two studies (De Asha 2014, Hahn 2016) evaluated heterogeneity of treatment effect (analysis of differences in effect across subgroups); most reported individual participant level data without conducting their own subgroup analyses. Across studies, a scattering of statistically significant differences in relative effects of different components were found based on different subgroup comparisons. However, these were not consistent across, and often within, studies. Only one study (Hahn 2016) analyzed the most important aspect of the KQ, namely whether any study participant characteristics (or set of characteristics) can accurately and effectively predict which patients will most benefit from a given component. However, the study was methodologically and analytically flawed and compared a specific microprocessor knee (Genium) to any prior used knee (mostly another microprocessor knee, C-Leg). This study was conducted in largely younger men (average age 49 years, 83% men) two-thirds of whom had traumatic etiologies for their amputations. Despite finding numerous statistically significant associations between participant characteristics and functional outcomes, the study concluded that no model accurately predicted relative outcome (between the Genium microprocessor knee and, mostly, the C-Leg microprocessor knee).

Overall studies that investigated subgroup effects did not identify participant characteristics that predict which lower limb amputees would most benefit from a given component. Based on the methodology used to assess strength of evidence, the studies warrant a low strength of evidence that evaluated patient characteristics do not predict which patients would most benefit from a given LLP component. However, it may be more accurate to conclude that the evidence is currently sparse and fails to adequately address whether different subgroups of amputees are more or less likely to benefit from given specific components. Most studies were very underpowered to find statistically significant evidence of differences among subgroups, with on average only about 30 participants per study (excepting one larger regression analysis). Only five of the 11 studies used validated outcomes. Similar conclusions are reached for this subset of studies. In fact, these studies were even smaller, with on average only about 12 participants each. One large study attempted to develop a model to predict success with microprocessor knees; however the study failed to use a validated outcome and had several methodological and analytic flaws, and thus provides insufficient additional evidence regarding who would most benefit from a microprocessor knee. Furthermore, across all studies, study participants were in general not likely to be representative of the Medicare population, being both mostly young and with amputations due to trauma, with relatively few people with dysvascular disease.

**Table 4.16. Key Question 4 Evidence Profile**

Outcome	No. Studies (N)	Study Limitations	Consistency	Precision	Reporting Bias	Directness*	Other Issues	Findings	SoE Grade
Validated outcomes (univariable)	5 (64)	Medium †	Consistent	Imprecise	Undetected	Indirect ‡	High degree of multiple testing; mostly evaluations of knee components; mostly K2 or K3 level, unilateral transfemoral amputations due to traumatic etiologies	Mostly no significant differences in relative effect based on participant characteristics	Low
All outcomes (univariable)	10 (296)	Medium †	Consistent	Imprecise	Undetected	Indirect ‡	Nonvalidated outcomes, high degree of multiple testing; mostly K2 to K4 level, unilateral transfemoral amputations due to traumatic etiologies	Mostly no significant differences in relative effect based on participant characteristics	Low
Ambulatory and functional outcomes, nonvalidated (multivariable model)	1 (899)	High §	NA	Precise	Undetected	Indirect #	K2 to K4 (mostly K3) level, mostly traumatic etiologies	Flawed study concluded no model accurately predicted relative outcomes. A large set of variables individually were associated with better outcomes with the microprocessor knee.	Insufficient

Abbreviations: KQ = Key Question, NA = not applicable, RoB = risk of bias, SoE = strength of evidence.

\* Representative of either (or both) older adults (≥65 years old) or those with dysvascular amputations.

† Nonrandomized studies, univariable analyses (mostly individual participant data reports), generally lack of evaluation of heterogeneity of treatment effect, mostly small studies.

‡ Both relatively young age amputees and primarily people with amputations due to trauma in most studies. Almost all (that reported) had unilateral transfemoral amputations.

§ Nonrandomized, likely biased sample of participants, nonvalidated outcomes, unclear which outcome(s) used in final models, unclear and possibly flawed analytic methods. See text.

# Highly selected participants who had been assessed as likely to benefit from a microprocessor knee, possibly biased dropouts, relatively young and two-thirds had trauma etiology.



## Key Question 5

How do study participants' preprescription **expectations of ambulation** align with their functional outcomes?

KQ 5 asked how study participants' preprescription expectations of ambulation align with their functional outcomes. We found no study that addressed this issue.

## Key Question 6

What is the level of patient **satisfaction with the process** of accessing a LLP (including experiences with both providers and payers)?

We found two studies that addressed this question. Pezzin 2004 surveyed individuals about satisfaction with upper or lower prosthetic limbs and related services.<sup>122</sup> Hart 1999 reported data about satisfaction with the prosthetist appointments in a study designed to assess the reliability and construct validity of the OPOT in clients with LLPs.<sup>18</sup>

In the more recent study (Pezzin 2004) study participants were asked 12 questions about the prosthetist from whom they received care in the past 12 months.<sup>122</sup> Based on their responses, 3 dimensions of prosthetist quality assessment were examined: technical skills, information giving, and interpersonal manner. These questions were answered by approximately 823 study participants who had seen a prosthetist in the past 12 months. Participant descriptive data were given for 935 adults in the U.S., including the 12 percent who had not recently seen a prosthetist. Overall, the study was deemed to be at moderate risk of bias. Approximately 30 percent of potentially eligible patients could not be reached or refused to participate; no assessment of whether they were systematically different than respondents. However, multivariable analyses were conducted where appropriate.

Study participants were 18 to 84 years old (mean 50.5 years) who had either a lower limb amputation ( $\geq 78.9\%$ ) or upper limb amputation ( $\geq 10.0\%$ ); the 10.8 percent of participants with bilateral amputations were not further categorized as having upper or lower limb amputations (but people with both upper and lower limb amputations were excluded). Amputation was due to dysvascular diseases (37.8%), trauma (38.7%), or cancer (23.4%). Lower limb amputees were almost evenly split between above-knee (38.5%) and below-knee (40.4%) amputations. Amputation occurred during childhood in 12.5 percent and after age 64 years in 8.8 percent of participants. Among participants, 20.7 percent had Medicare insurance and 15.4 percent Medicaid (participants were categorized as having only a single type of insurance). Most participants (94.6%) were currently using a prosthesis. They used their prostheses for an average of 71 (SD 41) hours per week and had a mean 9 (SD 11) visits to a prosthetist in the past 12 months, but a median of 5 visits; 12 percent did not visit a prosthetist in the past year.

The study found that more than 75 percent consistently agreed or strongly agreed with positive statements across all items related to prosthetist technical skills, information giving, and interpersonal manner. Participants were most satisfied with prosthetist's technical skills: they agreed or strongly agreed that prosthetists check everything (93%), are competent (95%), understand patients' medical history (89%), understand what is wrong (86%), and are current on technology (90%). Participants were also mostly satisfied with prosthetists' information giving:

they agreed or strongly agreed that prosthetists tell them all they want to know (88%), answer all questions (93%), have the patients' confidence (88%), and, to a lesser extent, can be depended on (75%). Regarding interpersonal skills, participants agreed or strongly agreed that prosthetists were not in a hurry (83%), explained things (87%), and discussed things (85%). Less favorable ratings related to being able to depend on the prosthetist for the individual's physical wellbeing (26% disagreed or strongly disagreed).

Multivariable regression models were used to examine the correlates of positive perceptions of a prosthetist's quality for the three summary dimensions of provider care (technical skills, information giving, and interpersonal manner); however, numerical data regarding the models were not reported. Females, whites, those with higher levels of education, those with above-knee amputation or bilateral amputation, and those who had undergone an amputation more recently were more likely to have favorable perceptions about their prosthetist ( $P < 0.05$ ). Patients with Medicaid insurance had lower satisfaction ( $P < 0.05$ , implied) than those with private or commercial insurance, but no differences were found among those with Medicare, other public insurance, or the uninsured. No differences in satisfaction were found based on amputation etiology or geographic region of residence (in the U.S.). The study did not evaluate satisfaction with payers.

In the older study validating OPOT, Hart 1999 surveyed 840 adults requiring LLP who were seen in 56 practices in the U.S.<sup>18</sup> Almost half had Medicare (43.6%) or Medicaid (7.2%) as a primary payer. The clients were on average about 56 years old (men  $55.6 \pm 16.2$  years, women  $58.1 \pm 17.9$  years), ranging from K0 (0.4%) to K4 (14.0%) K level; about half were classified as K3 (47.6%) and about one-quarter K2 (29.8%). Seventy percent were men. About three-quarters (73.4%) had transtibial or below-knee amputations and most of the rest (19.2%) had transfemoral amputations. Nearly two-thirds had dysvascular causes of amputation (58.2%) and nearly one-third trauma (29.2%). About two-thirds were being evaluated for a replacement prosthesis (67.6%), as opposed to first prosthesis (32.4%).

Clients were surveyed at initial fitting (of their first or new prosthesis) and at followup on average 82 days later (SD 44). Clients were asked five questions covering receiving an appointment within a reasonable time period, location of office, courtesy from staff, waiting room staff, and ability to express client concerns about the limb; other questions pertained to satisfaction with their LLP and function. These questions were transformed into a single client satisfaction with prosthetist performance score ranging from 0 to 100 (best). The average scores were similar at both visits at  $81.9 \pm 12.3$  and  $84.6 \pm 10.8$ . Of note, client satisfaction was not correlated with SF-12, SF-12 subscales, or a measure of overall health status. Also of note, the clients mostly found the question of satisfaction to be important (mean  $86 \pm 16$ , also on a scale of 0-100).

A limitation of this study was that a high percentage of clients did not answer the survey questions at both initial and followup visits. Of 840 included clients, only 417 (50%) gave answers at the initial visit and only 348 (41%) at followup; only 203 (24%) answered both surveys. Overall, the study was deemed to be at high risk of bias due to nonresponse without an assessment or full description of who did not answer the survey. No analyses were conducted to assess which clients were satisfied or dissatisfied, or why.

In summary, a moderate risk of bias study (of generally younger adults about one-third of whom had dysvascular disease) found that at least three-quarters of people receiving a LLP were satisfied with the process of accessing their LLP and a high risk of bias study (in which about half had Medicare or Medicaid insurance) found that on average clients were satisfied with their

visits to their prosthetists' offices (average score about 83 of 100). Together, the study provides low strength evidence that people are satisfied with their encounters with their prosthetists (Table 5-6.1).

**Table 5-6.1. Key Questions 5 and 6 Evidence Profile**

Outcome	No. Studies (N)	Study Limitations	Consistency	Precision	Reporting Bias	Directness*	Other Issues	Findings	SoE Grade
Alignment of outcomes with expectations (KQ 5)	0	NA	NA	NA	NA	NA	NA	None	Insufficient
Satisfaction with process (KQ 6)	2 (~1663)	Medium	Consistent	Precise	Undetected	Direct †	Nonvalidated outcomes	Clients generally satisfied with their encounters with their prosthetists	Low

Abbreviations: KQ = Key Question, NA = not applicable, SoE = strength of evidence.

\* Representative of either (or both) older adults (≥65 years old) or those with dysvascular amputations.

† One study included a wide range of prosthetics practices; about half the participants had Medicare or Medicaid as a primary payer. The other study was less representative.

## Key Question 7

**At 6 months, 1 year, and 5 years after receipt of a LLP, (accounting for intervening mortality, subsequent surgeries or injuries) what percentage of individuals...?**

- i. Maintain bipedal ambulation
- ii. Use their prostheses only for transfers
- iii. Use prostheses only indoors
- iv. Have abandoned their prostheses
- v. Have major problems with prosthesis

## Overall Summary of Studies

We found eight studies (in nine articles) with at least 100 participants who were followed for at least 6 months after prescription of a LLP.<sup>123-131</sup> Most studies of amputees with outcomes of interest were rejected because the analyses were not restricted to people with prescribed prostheses and were thus mostly analyses of predictors for not receiving a prescription for LLP. The studies analyzed between 109 and 555 participants for between 1 and 7 years (except for two studies that implied long-term followup, but did not report a timeframe.<sup>125, 127</sup> The studies only sparsely covered the subquestions pertaining to specific outcomes, particularly related to questions about different outcomes in different subgroups of amputees.

Table 7.1 summarizes the study design and participant characteristics of the eight studies. The studies mostly included older adults, 65 to 80 percent of whom were men. However, they were each representative of different cohorts of lower limb amputees as indicated by their amputation level and etiologies. Four studies were restricted to all (or almost all) unilateral amputees,<sup>123-126</sup> while four included about 10 to 20 percent bilateral amputees.<sup>127-129, 131</sup> Three of the studies included approximately similar percentages of people classified as having transfemoral and transtibial amputations (and no amputations at other levels).<sup>124, 126, 127</sup> One study was restricted to people with transtibial amputations.<sup>125</sup> Four studies included at least twice as many people with transtibial than transfemoral amputations.<sup>127-129, 131</sup> One of these latter studies included a small percentage of people with amputations at the hip and 11 percent with foot or ankle amputations.<sup>128</sup> This study (Matsen 2000) also included 12 percent of people who had congenital amputations. Five of the studies evaluated people who mostly (about 80-95%) had diabetes or other vascular diseases as the etiology of their amputation.<sup>123-126, 129</sup> In addition to congenital amputations, Matsen 2000 also included an atypically large percentage of people with traumatic (50%) and infectious (21%) etiologies.<sup>128</sup> Roffman 2016 similarly had large percentages with traumatic (57%) and infectious (43%) etiologies.<sup>130, 131</sup> Marmann 1994 did not report amputation etiologies.<sup>127</sup>

Table 7.2 describes the risk of bias (study quality) of the studies. In addition to the studies each being representative of different types of amputees, most studies failed to include between about 25 and 85 percent of potentially eligible participants, mostly due to failure of people to respond to surveys. These studies did not attempt to demonstrate that the included participants were representative of their populations and were deemed to have high risk of sample bias. This was the primary concern for three studies, which were deemed to be at moderate risk of bias

(Davies 2003, Gauthier-Gagnon 1999, and Roffman 2016).<sup>124, 126, 131</sup> Notably, Matsen 2000 had a very low survey response rate and self-described their population as nonrepresentative; the study also poorly defined its outcomes and did not clearly report the results for the outcomes of interest; this study was deemed to have high overall risk of bias.<sup>128</sup> Dudkiewicz 2011 and Marmann 1994 did not report when their surveys were done in relation to LLP prescription, and were deemed to have high overall risk of bias.<sup>125, 127</sup> Only two studies were deemed to be at overall low risk of bias (Chen 2008 and Pohjolainen 1990).<sup>123, 129</sup> However, only four studies reported subgroup (predictor) analyses (Davies 2003, Marmann 1994, Pohjolainen 1990, and Roffman 2016); none of them reported multivariable analyses for the predictors and outcomes of interest. Thus, the four subgroup analyses were all deemed to be subject to high risk of bias.

Table 7.3 provides the outcome results of interest across studies.

**Table 7.1. Study Design and Participant Characteristics of Studies Reporting Long-Term Followup After Prosthesis Prescription**

Study Year (PMID) Country	Study design*	N Surveyed (Eligible)	Population	Mean Age (SD) [Range]	Male	K level	Amputation Level	Unilateral	Etiology
Chen 2008 (18724135) Taiwan	Retrospective	109 (120)	Major lower limb amputation, received prosthesis	64.3 (12.9) [28-85]	65%	nd	TF 14%, TT 86%	97%	Vascular 94%, trauma 6%
Davies 2003 (14727699) UK	Retrospective	281 (357)	Unilateral lower limb amputation with prosthesis	68	70%	nd	TF 49%, TT 51%	100%	Vascular 88%, other 12%
Dudkiewicz 2011 (21303214) Israel	Retrospective	557 (717)	Below knee amputation with prosthesis	64.2	75%	nd	TT 100%	94%	Vascular/DM 83%, trauma 3%, infection 11%, other 3%
Gauthier-Gagnon 1999 (10378500) Canada	Retrospective	396 (nd)	Unilateral lower limb amputation, completed 1 y prosthetic training	62.6 (15.9)	74%	nd	TF 42%, TT 58%	100%	Vascular/DM 78%, trauma 17%, other 5%
Marmann 1994 (none) Germany	Retrospective	110 (399)	Lower limb prosthesis able to walk	73	nd	nd	TF 60%, TT 40%	90%	nd
Matsen 2000 (10954097) USA	Retrospective	148 (1035)	Lower limb amputation, with prosthesis (implied)	50.1 (16.2)	72%	nd	Hip 3%, TF 23%, Knee 9%, TT 55%, Foot/ankle 11%	87%	Vascular/DM 21%, trauma 50%, infection 21%, cancer 2%, congenital 12%†
Pohjolainen 1990 (2235304) Finland	Retrospective	175 (175)	Lower limb amputation, with prosthesis	62.2 [14-87]	73%	nd	TF 36%, TT 64%	89%	Vascular 81%, trauma 10%, cancer 6%, other 3%
Roffman 2016 (26637652, 25450484) Australia	Prospective (n=66), retrospective (n=135)	201 (nd)	Lower limb amputation, previously ambulatory, prosthesis rehab	55	80%	1-4	TF 27%, Knee 3%, TT 70%	85%	Vascular 26%, trauma 27%, infection 43%, cancer 4%

Abbreviations: DM = diabetes mellitus, TF = transfemoral amputation, TT = transtibial amputation.

\* Funding source for all studies was nonindustry.

† Some patients listed more than one reason for amputation.

**Table 7.2. Long-Term Followup Study Risk of Bias / Study Quality**

Study Year (PMID)	Sample Bias	Outcome Assessment	Predictors/Variables Definitions	Multivariable Analysis	Other	Overall Quality
Chen 2008 (18724135)	Low RoB	Low RoB	NA*	NA*		Low RoB (no subgroup analyses)
Davies 2003 (14727699)	High RoB	Low RoB	Low RoB	High RoB (no)		Moderate RoB, except high RoB for subgroup analyses
Dudkiewicz 2011 (21303214)	High RoB	Low RoB	NA*	NA*	Followup time not reported	High RoB (no subgroup analyses)
Gauthier-Gagnon 1999 (10378500)	Unclear RoB	Low RoB	NA*	NA*		Moderate RoB (no subgroup analyses)
Marmann 1994 (none)	High RoB	Low RoB	Low RoB	High RoB (no)	Followup time not reported	High RoB
Matsen 2000 (10954097)	High RoB	High RoB (outcomes poorly described)	NA*	NA*	Incomplete reporting of results; 12% congenital amputees	High RoB (no subgroup analyses)
Pohjolainen 1990 (2235304)	Low RoB	Low RoB	Low RoB	High (no)		Low RoB, except high RoB for subgroup analyses
Roffman 2016 (26637652, 25450484)	Unclear RoB	Low RoB	Low RoB	High (no)		Moderate RoB, except high RoB for subgroup analyses

Abbreviations: NA = not applicable, RoB = risk of bias.

\* No predictor/subgroup analyses reported; only overall rate reported.



**Table 7.3. Long-Term Followup Results**

Author	Outcome	Outcome Description	Subgroup	Timepoint	% (n/N)	P Subgroups	
Chen 2008 (18724135)	Abandoned prostheses		All Participants	28.3 mo	0.9% (1/109)		
Davies 2003 (14727699)	Abandoned prostheses	Stanmore Harold Wood Mobility Grade 1 ("has abandoned limb wearing or uses only a cosmetic limb)	All Participants	1 y	12.2% (24/196)	0.19	
			Transfemoral		15.7% (14/89)		
			Transtibial		9.3% (10/107)		
			Age <50 y		0% (0/16)		
			50-64 y		14.2% (7/49)		
			65-79 y		11.3% (13/115)		
			>80 y		25% (4/16)		
	Only use for transfers	Stanmore Harold Wood Mobility Grade 2 (wears a prosthesis only for transfers or to help with nursing; walks only with a therapist or carer)	All Participants		4% (8/196)	0.47	
			Transfemoral		5.6% (5/89)		
			Transtibial		2.8% (3/107)		
			Age <50 y		0% (0/16)		
			50-64 y		2% (1/49)		
			65-79 y		5.2% (6/115)		
	Indoor use only of prosthesis	Stanmore Harold Wood Mobility Grade 3 (Walks indoors only, using walking aids; negligible walking outdoors)	All Participants		24.4% (48/196)	0.0076	
			Transfemoral		33.7% (30/89)		
Transtibial				16.8% (18/107)			
Age <50 y				6.2% (1/16)			
50-64 y				14.2% (7/49)			
65-79 y				30.4% (35/115)			
>80 y				31.2% (5/16)			
Dudkiewicz 2011 (21303214)	Indoor use only of prosthesis	Functional Usage at home	All Participants§	nd	37.1% (75/555)		
Gauthier-Gagnon 1999 (10378500)	Abandoned prostheses		All Participants	5 y	15% (~58/396)*		
Marmann 1994 (none)	Abandoned prostheses		All Participants	nd	22% (24/110)	0.70	
			Bilateral		27% (3/11)		
			Unilateral		21% (21/99)		
	Only use for transfers			All Participants		15% (16/110)	0.66
				Bilateral		18% (2/11)	
				Unilateral		14% (14/99)	
Matsen 2000 (10954097)	Unable to walk		All Participants	7 y after surgery	7% (10/148)		
	Indoor use only of prosthesis		All Participants		11% (16/148)		
Pohjolainen 1990 (2235304)	Abandoned prostheses		All Participants	1 y	10.6% (15/141)	0.22	
			Bilateral		0% (0/16)		
			Unilateral		12.0% (15/125)		
			Transfemoral unilateral		23.9% (11/46)		

Author	Outcome	Outcome Description	Subgroup	Timepoint	% (n/N)	P Subgroups
	Indoor use only of prosthesis		Transtibial, unilateral		5.0% (4/79)	0.0032
			All Participants		29% (41/141)	
			Bilateral		68.7% (11/16)	
			Unilateral		24.0% (30/125)	0.0006
			Transfemoral unilateral		23.9% (11/46)	
			Transtibial, unilateral		24.1% (19/79)	1.00
Roffman 2016 (26637652, 25450484)	Abandoned prostheses		All Participants	1 y	17.9% (36/201)	
			Sex			0.19 †
			Age at amputation (continuous)			0.98 †
			Home vs. residential care			0.19 †
			Charlson Comorbidity Index (continuous)			0.24 †
			Diabetes, types 1/2			0.15/0.45 †
			Peripheral artery disease			0.46 †
			Cardiac condition		28.0% (21/75)	
			No cardiac condition		11.9% (15/126)	0.04 †, ‡
			Renal failure			0.25 †
			Stroke			0.98 †
			Arthritis			0.80 †
			Remaining limb pathology			0.055 †
			Amputation cause			0.26 †
			Bilateral		29.0% (9/31)	
			Unilateral		15.9% (27/170)	0.08 †
			Transfemoral unilateral		33.9% (21/62)	
Transtibial or knee, unilateral		14.1% (24/170)	0.0013 †, ‡			

\* Data not clearly reported.

† Univariable analyses.

‡ Bonferonni P value =0.0020

§ Analyzed predictors pertain to time of survey, not to status at time of amputation or prosthesis prescription and are therefore omitted here.

## **Failure to Maintain Bipedal Ambulation**

No study explicitly reported maintenance of bipedal ambulation, per se. Matsen 2000 reported, for only the full sample, that 7 percent (10/148) were “not able to walk” at a mean of 7 years after surgery.<sup>128</sup> The estimated exact 95 percent confidence interval about this estimate is 4 to 12 percent. This study was potentially not fully representative of typical adult amputees in the U.S. given that half the amputations occurred due to trauma, one-fifth due to infection, and only one-fifth due to vascular disease or diabetes. The study was deemed to be at high risk of bias, primarily due to inclusion of only a small percentage (14%) of potentially eligible patients being included and for poor description of their outcome. The authors note that their institution predominantly serves individuals in poor health and with a low economic status. In addition, only 14% of potentially eligible amputees responded to their survey, which required completing a five-page self-assessment packet.

## **Use of Prostheses Only for Transfers**

Two studies, Davies 2003 and Marmann 1994,<sup>124, 127</sup> reported on use of prostheses only for transfers in a total of 316 study participants. One study included only people with unilateral amputations; the second study included 11 people (10%) with bilateral amputations; roughly half of patients had transtibial and half transfemoral amputations. In the study of only unilateral amputees, the cause of amputation was vascular or diabetes in 88 percent of the amputees; etiology was not reported in the second study. Davies 2003 was deemed to be at overall moderate risk of bias and Marmann 1994 at high risk of bias. Both studies had high percentages of potentially eligible patients who were not included and neither demonstrated that the survey respondents were representative of their populations; Marmann 1994 also did not report when the survey was conducted in relation to either amputation date or first LLP prescription. Neither study performed multivariable analyses to compare subgroups.

The more recent study conducted in the UK, Davies 2003, found that at 1 year eight participants (4%; estimated exact 95% confidence interval 2% to 8%) used their prostheses only for transfers (and walked only with a therapist or carer). The earlier study conducted in Germany, Marmann 1994, found a higher percentage of patients used their prostheses only for transfers (22%, 24/110; estimated exact 95% confidence interval 15% to 30%) at an unreported time after LLP prescription. Neither study found significant differences in rates of use of prostheses only for transfers based on level of amputation (transtibial vs. transfemoral), unilateral or bilateral amputation, or by age; however, the studies were greatly underpowered for subgroup analyses.

## **Use of Prostheses Only Indoors**

Four studies reported on rates of prosthesis use only indoors.<sup>124, 125, 128, 129</sup> The studies were deemed to be of low (Pohjolainen 1990), moderate (Davies 2003) and high risk of bias (Dudkiewicz 2011, Matsen 2000), primarily due to failure to include a large or demonstrably representative proportion of their eligible population), failure to describe their outcomes poorly (Matsen 2000), and failure to report timing in relation to LLP prescription (Dudkiewicz 2011). Overall, about 90 percent of included patients had unilateral amputations. In three of the studies about 80 to 90 percent of patients had vascular etiologies for their amputations, but Matsen 2000 had a less typical population in whom half of amputations were due to trauma, and only about 20

percent were due to diabetes or other dysvascular diseases. The distribution of levels of amputations varied widely across the four studies.

Three of the four studies reported that between 24 and 37 percent of amputees used their prostheses only indoors; Matsen 2000 (described above under *Maintenance of Bipedal Ambulation*) reported a substantially lower rate of use only indoors at 11 percent.<sup>128</sup> The major difference between Matsen 2000 and the other three studies (Davies 2003, Dudkiewicz 2011, and Pohjolainen 1990) is that participants in Matsen 2000 were much less likely to have had a vascular or diabetes amputation etiology (21% vs. 81-88%). Two of the studies provided within-study subgroup data to allow univariable analyses. Davies 2003 (described above under *Use of Prostheses Only for Transfers*) found that significantly more people with transfemoral amputations (34%) were restricted to indoor use than those with transtibial amputations (17%,  $P=0.008$ ).<sup>124</sup> The study also found that restriction to indoor use increased with amputees' age (<50 years 6%, 50-64 years 14%,  $\geq 65$  years 31%;  $P=0.042$  across age groups). Pohjolainen 1990, in contrast, found no difference in indoor restriction between unilateral transfemoral and transtibial amputees (both 24%), but it found that almost three times as many people with bilateral amputations (69%) were restricted to indoor use than those with unilateral amputations (24%,  $P=0.0006$ ).<sup>129</sup>

## Abandonment of Prostheses

Six studies reported on rates of prosthesis abandonment (no longer using).<sup>123, 124, 126, 127, 129-131</sup> Among these studies, between 85 and 100 percent of study participants had unilateral amputations. The patients' amputation levels varied widely across studies, with between 14 and 60 percent with transfemoral amputations and between 40 to 86 percent with transtibial amputations. Among four of five studies that reported amputation etiologies, the large majority (78-94%) had amputations due to dysvascular conditions; Roffman 2016 had an atypical population in which about one-quarter of amputations were due to dysvascular etiologies and one-quarter due to trauma; 43 percent had infectious etiologies. Half the studies were deemed to have moderate risk of bias, primarily due to high or unclear percentage of potentially eligible patients not being included (and no demonstration that included participants were representative of the eligible population). One study was at high risk of bias; Marmann 1994 also did not report when the study was conducted in relation to LLP prescription. Two studies were at low risk of bias.

All but one study were relatively consistent, reporting that between 11 and 22 percent of amputees had stopped using their prosthesis at 1 year in 3 studies and 5 years in one study (15%). The highest rate of abandonment (22%) was reported in an older, high risk of bias study from Germany with no information about how long people had been using LLPs. A low risk of bias outlier study from Taiwan (Chen 2008) reported only a single person (0.9%) who abandoned their prosthesis.

Four of the studies reported subgroup data. Three compared unilateral transfemoral and transtibial amputees, finding that people with transfemoral amputations were more likely to abandon their prostheses (16-34%) than people with transtibial amputations (5-14%). Two of the analyses (Pohjolainen 1990, Roffman 2016) were statistically significant ( $P=0.0013$  and  $0.003$ ). The nonsignificant study, Davies 2003, ( $P=0.22$ ) was hampered by the small number of bilateral amputees in the study ( $n=16$ ).

Three studies found no significant difference in likelihood of abandonment between unilateral and bilateral amputees; although their findings were conflicting. Pohjolainen 1990

found many more unilateral amputees (12%) had abandoned their prostheses than bilateral amputees (0%), but the difference was nonsignificant ( $P=0.22$ ). Roffman 2016 found about twice as many people with bilateral amputation abandoned their prostheses (29%) than people with unilateral amputation (16%), but again the difference was nonsignificant ( $P=0.08$ ). Marmann 1994 found similar percentages of people abandoned their prostheses among unilateral (21%) and bilateral (27%) amputees ( $P=0.70$ ).

Two studies also found no significant differences based on age. Davies 2003 found that the rate of abandonment did rise with age from 0 percent of those under age 50 years to 25 percent of those over age 80 years, but was nonsignificant ( $P=0.18$ ). Roffman 2016 found no significant association with age at amputation in linear regression ( $P=0.98$ ).

Roffman 2016 reported a large number of subgroup analyses in addition to the analyses described above, although all were univariable for this outcome.<sup>131</sup> This study included amputees who were more likely to have transtibial amputations and were more likely to have infection or trauma as an amputation etiology, compared to most studies. Most analyses found no significant difference between subgroups (see Table 7.3). People with a history of a “cardiac condition” were more likely (28%) to have abandoned their prosthesis than those with no such history (12%,  $P=0.04$ ); however the study evaluated many comparisons and after applying the Bonferroni correction ( $P$  value threshold 0.002), this difference was not statistically significant. The only statistically significant finding was the difference between unilateral transfemoral amputation and transtibial or at-knee amputation, described above.

## Major Problems with Prostheses

None of the studies reported outcomes that could be construed as having “major problems” with their prostheses.

## Reasons for Abandoning Prostheses

Only Roffman 2016 reported reasons for prosthetic nonuse (or other outcomes of interest).<sup>131</sup> Study participants were able to list multiple reasons for nonuse; however, the reported reasons were summarized in general categories lacking precise definitions. Among the 36 of 201 amputees who abandoned their prostheses, reasons for abandonment included “issues with residual limb” (36%,  $n=13$ ), “prosthetic issues” (28%,  $n=10$ ), “medical comorbidities” (28%,  $n=10$ ), “issues with remaining lower limb” (25%,  $n=9$ ), “pain issues” (25%,  $n=9$ ), falls or fear of falling (14%,  $n=5$ ), “high energy cost” (8%,  $n=3$ ), “unmotivated” (8%,  $n=3$ ), unable to don prosthesis (6%,  $n=2$ ), and “balance issues” (6%,  $n=2$ ).

## Summary

Table 7.4 summarizes the strength of evidence for each outcome and subgroup analysis with data. For most outcomes of interest, there is low strength of evidence because studies mostly had methodological limitations, the populations analyzed were often not directly applicable to the Medicare population, some studies were inconsistent with each other, and few studies reported the outcomes of interest. Subgroup analyses in single studies tended to be underpowered to detect differences, mostly leading to determinations that the evidence was insufficient. However, we found a moderate strength of evidence, based on six studies, that about 11 to 22 percent of lower limb amputees who receive a LLP prescription abandon the prosthesis

(stop using it) at about 1 year; these studies are generally representative of people with LLP, in particular older adults and those with dysvascular etiologies. Three of these studies provide low strength of evidence that people with unilateral transfemoral amputations are about twice as likely to abandon their LLP than those with unilateral transtibial amputations. Potential differences among other subgroups had insufficient evidence due to conflicting results among three studies or only a single, imprecise study with data. Also based on four, generally representative studies, there is low strength of evidence that 11 to 37 percent of LLP recipients use their prostheses only indoors; however, these studies are somewhat inconsistent and imprecise. There is low strength of evidence about how likely different subgroups of people use their prostheses only indoors, suggesting that people with transfemoral amputations, or who are older, or with bilateral amputations are more likely to be limited to indoor use. There is insufficient evidence about why people abandon their prostheses.

**Table 7.4. Key Question 7 Evidence Profile**

Outcome	Subgroup	No. Studies (N)	Study Limitations	Consistency	Precision	Reporting Bias	Directness*	Other Issues	Findings	SoE Grade
Failure to maintain bipedal ambulation	All participants	1 (148)	High	NA	Precise	Undetected	Indirect	Unclear outcome,	7% (95% CI 4, 12) at 7 years	Low
Use of prosthesis only for transfers	All participants	2 (316)	High	Inconsistent	Precise	Undetected	Indirect	Old studies	4% (95% CI 2, 8) at 1 year, 22% (95% CI 15, 30) at unknown time	Low
	TF vs. TT	1 (196)	High	NA	Imprecise	Undetected	Indirect	25 years old	No significant difference	Insufficient
	Bilateral vs. unilateral	1 (110)	High	NA	Imprecise	Undetected	Indirect	None	No significant difference	Insufficient
	Age	1 (196)	High	NA	Imprecise	Undetected	Indirect	25 years old	Nonsignificantly higher limited used with older age	Insufficient
Use of prosthesis only indoors	All participants	4 (1040)	Medium	Inconsistent	Imprecise	Undetected	Direct	None	24-37% at 1 to 7 years	Low
	TF vs. TT	2 (337)	High	Inconsistent	Precise	Undetected	Direct	None	Twice as many TF use only indoors (1 study, P=0.008), no difference (1 study)	Low
	Age	1 (196)	High	NA	Precise	Undetected	Direct	None	Older more likely to use only indoors (P=0.042)	Low
	Bilateral vs. unilateral	1 (141)	High	NA	Precise	Undetected	Direct	None	Bilateral more than twice as likely to use only indoors (P=0.0006)	Low
Abandonment of prosthesis	All participants	6 (1153)	Medium	Consistent †	Precise	Undetected	Direct	None	11-22% at 1 year (or undefined)†	Moderate
	TF vs. TT	3 (538)	High	Consistent	Precise	Undetected	Direct	None	TF more likely to abandon prosthesis than TT	Low
	Bilateral vs. unilateral	3 (452)	High	Inconsistent	Imprecise	Undetected	Direct	None	Nonsignificant, but conflicting directionality	Insufficient
	Age	2 (397)	High	Inconsistent	Imprecise	Undetected	Direct	None	Older nonsignificantly more likely to abandon (1 study), no difference in age (1 study)	Insufficient
	Multiple	1 (201)	High	NA	Imprecise	Undetected	Indirect	Multiple testing	No significant associations	Insufficient
Major problems with prosthesis	All participants	0	NA	NA	NA	NA	NA	NA	None	Insufficient
Reasons for poor outcomes	All participants	1 (201)	High	NA	Imprecise	Undetected	Indirect	None	Various general categories of reasons reported	Insufficient

Abbreviations: NA = not applicable, RoB = risk of bias, SoE = strength of evidence, TF = transfemoral amputation, TT = transtibial amputation.

\* Representative of either (or both) older adults (≥65 years old) or those with dysvascular amputations.

† Except that one outlier study from Taiwan found that only 0.9% of study participants abandoned their prostheses at a mean of 28 months.



## Discussion

A large number of studies have evaluated lower limb prostheses (LLP) for people with major lower limb amputations. We found nearly 100 studies that compare at least two prostheses or components that likely report ambulatory, functional, or other patient-centered outcomes. There are many additional studies that evaluated only biomechanical properties of the components and likely several hundred studies that evaluate just a single component. However, we found few studies that evaluated (or at least provided data to allow evaluation of) heterogeneity of treatment effect. From the amputee's and the clinician's perspective, among the most important questions is which prosthesis (comprised of which prosthetic components) would best enable maximal function for a given individual? Given the large number of component types (knee, foot/ankle, socket, etc.) and the range of features for each of these, the process of determining which LLP configuration is best for individuals is quite complex. The majority of the evidence addresses the question of which components maximize ambulation and function in the average patient, as opposed to which component would best suit the needs of a given individual. Suboptimal matching of patients to LLPs may unnecessarily increase health care utilization, prevent attainment of maximal patient function, and defer realization of improved quality of life attainable with an appropriate prosthetic.

Further limiting and complicating the evidence base, there are a very large number of measures that are used in the surgical, rehabilitation, and prosthesis literature to assess overall patient function, predict future outcomes, and measure various aspects of ambulation, function, quality of life issues, and other patient-centered outcomes. While some of the scales and scores used in these studies were developed specifically to assess lower limb amputees, many were designed for other populations. Many of the measures used in LLP research studies have either not been validated in the population of interest or were created *ad hoc* for each study. This review found that among the small number of comparative studies that provided heterogeneity of treatment effects data, fewer than half used both validated predictors (or subgroups based on basic participant characteristics) and validated outcomes.

We found that a large number of measures that have been validated (to a lesser or greater extent), 29 of which have, in whole or in part, been found to be both reliable and validated in lower limb amputees. Many of the studies that evaluated measure properties, however, were conducted in samples of participants who were not well-applicable to the large number of amputees with dysvascular conditions, including diabetes and peripheral vascular disease, or who are older and are, thus, more typical of lower limb amputees with Medicare insurance. We found only 35 of the 61 measures have been evaluated in studies deemed generally generalizable to the Medicare population, of which 19 were found to have evidence of both reliability and validity.

These measures address many aspects of patients' function, ambulation, and quality of life. To improve the accuracy, interpretability, and, importantly, the reproducibility of the literature, we would strongly encourage future researchers to maximize the use of validated measures. Where validated measures of interest are lacking, proposed research measures should first be validated before use in future studies. We would also encourage journal editors to require use of validated measures.

However, the studies were highly variable in who was analyzed and how instruments and measures were validated, etc. We, therefore, recommend that researchers who are using this report to determine which measures to use for their own studies also review the primary studies

to determine whether the measures have been sufficiently validated for their needs and have been evaluated in a sample of people representative to their study population.

## Evidence Summary

- In practice, it is difficult to cleanly make the distinction between assessment techniques (to evaluate function etc. prior to LLP prescription), prediction tools (to predict likelihood of a future outcome, such as ambulation with a prosthesis), and outcome measures (to determine actual or change in ambulation, function, etc.). Many specific measures can be used for at all stages of evaluation of function.
- Among 61 measures for which we found assessments of measurement characteristics, we found 40 to be reliable, 47 validated in whole or in part, and 29 both reliable and validated. However, seven of these have evidence of floor or ceiling effects. Responsiveness, minimal detectable change, and minimal (clinical) important difference have relatively infrequently been assessed.
- Restricting to studies deemed to be generally generalizable to the Medicare population, 35 measures have been evaluated. Of these, 27 have evidence of validity, in whole or in part, and 25 have evidence of reliability. In total, 19 measures have been found to have evidence of both reliability and validity.
- We found 11 studies that compared LLP components and provided data to compare differences in effect among different subgroups (i.e., heterogeneity of treatment effect). However, most were small, underpowered studies, reported only participant-level data, were nonrandomized, and did not evaluate heterogeneity of treatment effect. These studies mostly evaluated knee components and mostly included younger men at K2 or K3 level, with unilateral transfemoral amputations with traumatic etiologies; populations not highly applicable to the Medicare population. In addition, only five of the studies reported on both validated predictors (or basic patient characteristic subgroups) and validated outcomes. Only a single study, using nonvalidated outcomes, attempted to comprehensively evaluate whether any or a set of patient characteristics predicted which component would yield best function for individual patients. In summary,
  - Studies that used validated measures mostly evaluated knee components and were conducted in mostly younger men, at K2 or K3 level, unilateral transfemoral amputations due to trauma. These studies did not identify participant characteristics that predict which lower limb amputees would most benefit from a given component. There is low strength of evidence that evaluated patient characteristics do not predict which patients would most benefit from a given LLP component based on validated outcomes. However, it may be more accurate to conclude that the evidence is currently sparse and fails to adequately address whether different subgroups of amputees are more or less likely to benefit from given specific components.
  - Overall, studies did not identify participant characteristics that predict which lower limb amputees would most benefit from a given component, regardless of whether validated measures were used. There is low strength of evidence that evaluated patient characteristics do not predict which patients would most benefit from a given LLP component. However, it may again be more accurate to conclude that the evidence is currently sparse and fails to adequately address

whether different subgroups of amputees are more or less likely to benefit from given specific components.

- One large study of highly selected, mostly younger men with mostly trauma-related amputations, evaluated multivariable prediction models to determine who would most benefit from a microprocessor knee based on nonvalidated outcomes. The study concluded that they failed to identify participant characteristics that predict whether individual patients would have better function with a microprocessor or mechanical knee; however, they did report numerous patient characteristics that were statistically significantly associated with differential effects between knee components. The study had several methodological and analytic flaws, and thus provides insufficient additional evidence regarding who would most benefit from a microprocessor knee.
- We found no evidence regarding how study participants' preprescription expectations of ambulation align with their functional outcomes.
- Two studies provided low strength of evidence that people are satisfied with their encounters with their prosthetists. This conclusion is applicable to people who have Medicare or Medicaid as their primary payers, based principally on one of the two studies.
- Based on six eligible studies of long-term followup at least 1 year after LLP prescription,
  - There is insufficient evidence regarding failure to maintain bipedal ambulation
  - There is insufficient evidence regarding how many people use LLP only for transfers
  - There is low strength of evidence that 11 to 37 percent of people use their LLP only indoors at 1 to 7 years after prescription, but insufficient evidence to assess differences in indoor-only use in different subpopulations
  - There is moderate strength of evidence that 11 to 18 percent of people have abandoned their prostheses (no longer used them) at 1 year.
    - There is also moderate strength of evidence that people with transfemoral amputations are more likely to abandon their prostheses than those with transtibial prostheses, but still the majority of amputees continue to use their prostheses, regardless of level of amputation
    - There is insufficient evidence to assess differences in abandonment in other subgroups of patients
  - There is insufficient evidence regarding reported major problems with LLP
  - There is insufficient evidence regarding reasons why people with LLP have poor outcomes (in terms of use of prostheses).

## Evidence and Analysis Limitations

Despite the large literature base for research on LLP, relatively few studies address the questions of interest for this review, particularly related to heterogeneity of treatment effect, patient expectations and satisfaction, and long-term use of LLP after prescription.

Assessment of reliability, validity, and other measure properties is open to interpretation. By the strictest definition, a measure would be considered to be valid and appropriate for use in a given study, only if there is good evidence regarding the multiple aspects of validity for the specific population, conditions, and outcomes under evaluation. That a measure demonstrates convergent validity with a given related measure does not imply that it also can distinguish

differences related to subgroups of patients or an intervention effect. That a measure has predictive validity regarding one outcome, such as future successful use of a LLP, does not imply predictive validity for other ambulatory outcomes, such as speed of walking or community ambulation. Despite these challenges, and the lack of a universal gold standard for determining absolute validity, we took a liberal approach in our literature synthesis. We considered a measure to be validated if there was evidence of any type of validity (other than face/content). We, thus, categorized the evidence and dichotomized data so that measures were classified as valid or not valid. We made no attempt to rank or compare measures. Some measures may be better than others (e.g., because they have less error associated with repeat administration or they are more responsive to change), but the relative importance of these issues will be study-dependent. The overall logic for our approach was that the question of interest for this general review of all measures used in LLP research is whether a measure has been validated for any purpose. Since the actual validity of a measure for use in a specific study may vary based on the study question, eligibility criteria, and hypotheses, we could not address all levels of validity. It is incumbent on each study's researchers to determine whether given measures are valid—and appropriate—for their study purposes.

As discussed above, the distinction between assessment techniques, prediction tools, and outcome measures is arguably somewhat artificial in actual application. Most, if not all, measures can be used for any of these contexts. Readers may disagree with how the measures were categorized across Key Questions 1 to 3.

This review attempts to particularly highlight the evidence applicable to the Medicare population. This is a challenge to do and requires judgment, which many may disagree with. Very few of the studies were limited to participants over the age of 65 years. None was limited to people with disabilities, at least in terms of what would allow them to qualify for Medicare. Extremely few studies reported the type of medical insurance study participants had (although, many of the studies were conducted in Europe and other countries other than U.S.). We categorized studies to be likely generalizable to the Medicare population based on having a relatively large percentage of participants with dysvascular etiologies for their lower limb amputations (also including diabetes) and/or likely including about half or more of participants over age 65 years. This system, though, is imperfect.

Although not a limitation, per se, it should be noted that this review makes no attempt to make conclusions about the overall effects of different LLP components. Key Question 4 addressed whether there is evidence regarding heterogeneity of treatment effects, particularly with validated measures, in the field of LLP research. As previously described, the evidence base addressing heterogeneity of treatment effect, particularly with validated measures, is quite small. Only a single study attempted to truly address the question at hand, but did not use a validated outcome measure, and was methodologically and analytically flawed. The applicability of these studies to the general population of people with LLPs may be somewhat limited, as the studies mostly evaluated knees and were mostly conducted in younger men with unilateral transfemoral amputations due to trauma. Furthermore, implicitly or explicitly, most of these studies included only people who were deemed (by their prosthetists) to be likely to benefit from their new (generally more complex) component. This may bias these studies toward finding no difference between subgroups of individuals in relative effect of the compared components since everyone was more likely than average to do better with the new component. In all of these studies, all patients used all evaluated LLPs. However, most of the studies that analyzed heterogeneity of treatment effect or provided data to allow subgroup analyses were observational and did not

control for underlying differences during use of one component or the other. For example, studies did not describe or control for rehabilitation, training, or acclimation with each of the components. In particular, in the pre-post studies (where everyone switched from an old (simpler) to a new (more complex) LLP, one would expect that patient characteristics such as age, strength, and mobility will also have changed. These are important issues for the underlying analyses comparing the components; although, the effect of this limitation of the comparative studies on assessing heterogeneity of treatment effect is unclear. If the bias is similar in different subgroups (e.g., the new component is favored in part due to bias equally among transtibial and transfemoral amputees), then the bias would cancel out when assessing differences in relative effect (of the two components) between the two subgroups (transtibial versus transfemoral). As discussed, the single large study with regression modeling is likely highly biased and may be analytically flawed, so it is insufficient to provide reliable evidence.

No or very few studies were found to address questions about patient expectations and satisfaction with care.

Few studies met eligibility criteria regarding long-term LLP use after prescription. The primary reason why potentially relevant studies were excluded was that they evaluated long-term ambulation and function after surgery including patients who never received an LLP. We also restricted the studies to those with at least 100 people to allow for some degree of precision in estimates. Smaller studies may have provided additional data, but their estimates would have been less precise (and subgroup analyses in these studies would be even less likely to be statistically significant due to lack of power). Among the eligible studies, the most common outcome of interest was LLP abandonment (or lack of use). Studies generally failed to report on indoor-only use of LLPs and other outcomes. Studies also mostly did not report information on why people limited or stopped their use of LLPs.

## **Future Research Recommendations**

### **General Recommendations**

Future research is needed to adequately address most of the questions in this review. While numerous measures have been validated, at least in part, additional studies are needed to confirm the measurement properties and to better generalize their validity (etc.) to more scenarios of people with lower limb amputations. For example, additional studies are needed that compare responsiveness of validated measures to specific prosthetic interventions. Some metrics may be better choices because they are more responsive to the types of changes provided by specific components. For microprocessor knees, for example, metrics that include items related to walking on uneven surfaces, stairs, balance confidence, stumbles and/or falls, would likely be more responsive than metrics that focus on specific physical performance such as distance walked or speed of ambulation. These latter metrics may be more responsive in assessment of foot, ankle, and powered componentry.

To as great an extent as possible, studies should assess validated, patient-centered outcomes related to ambulation, function, quality of life, and related outcomes. Continued use of *ad hoc* and nonvalidated measures greatly limits the interpretability, usability, representativeness, and overall value of the studies. Ideally, studies should use a core set of validated, patient-centered outcomes (in addition to other study-specific outcomes, as needed). This would allow comparability across studies and pooling of study findings (e.g., meta-analysis). A large body of individual, one-off analyses with unique outcomes will provide a much weaker evidence base

than a smaller body of comparable studies. Noncomparable studies will continue to be more likely to be of little use to prosthetists, treating physicians, patients, policymakers, and other decisionmakers, and therefore will more likely be ignored. Similarly, researchers should emphasize trying to include a well-representative sample of patients with LLPs, so that their studies will be applicable to the population at large.

## **Studies of Heterogeneity of Treatment Effect**

Particularly for a clinical field as varied as lower limb prosthetics, there is a great need to understand how best to choose among the myriad LLP and component choices for an individual patient. Lower limb amputees are clearly a highly heterogeneous group with distinct needs dependent upon age, etiology of limb loss, level of amputation, comorbidities and health status, postoperative stage, and rehabilitation status. Better understanding of which component would be best for which patient could both maximize individual's ambulation, function, and quality of life and minimize waste due to either abandonment or due to "over-prescription," where people are given LLPs with specific capabilities that they cannot benefit from. Therefore, many more studies are needed to adequately assess heterogeneity of treatment effect. The goal of these studies should not be to simply find subgroup differences, but instead should be to predict which set of characteristics best predicts which component is best for which patient. This will require generally larger studies to allow for meaningful regression analyses. As with all studies, these should take care to include a representative and unbiased sample of lower limb amputees. Eligibility criteria and analytic methods should be employed to maximize participation and inclusion in final models. Robust analytic methods and complete and transparent reporting are essential. Appropriate, and clear, measures of model performance should be used and reported. We recommend the following specific metrics, although others may be more appropriate based on specific analyses conducted.<sup>132, 133</sup> The most useful metrics of global performance are the (root) mean square error or Brier score. Less useful metrics are global statistics of fit, and the various pseudo-R<sup>2</sup> metrics. These global metrics are difficult to interpret correctly, particularly if there is class imbalance when a small percentage of participants experience a given outcome. Metrics of discrimination should also be reported, including the receiver operating characteristics (ROC) curve, area under the ROC curve (AUC), and accuracy measures (e.g., sensitivity and specificity). It is also important to report analyses of calibration. Assessments of calibration are numerous, but the most common is a simple calibration plot that orders observations in percentiles of increased predicted risk, and plots the observed percent of responders in each percentile. Conclusions about predictive performance require a thorough evaluation of the performance itself.

We recommend that consideration be given to reanalyze the dataset evaluated by either or both of the studies by Hahn et al. (2015 and 2016).<sup>114, 134</sup> However, the value of these datasets may still be highly limited, as they appear to have relatively few comparisons between microprocessor and mechanical knees, but instead, at least in the case of Hahn 2016, are comparisons of different microprocessor knees, a question of less generalizable interest. Nevertheless, ideally the largest, least biased sample of participants available should be included, minimizing exclusions based on strict eligibility criteria and analytic methods. The selected outcome (or outcomes) should be clearly stated and defined; it should clearly represent a difference in effect between the two components and should occur in a low enough percentage of participants to avoid class imbalance. Ideally, it should also be validated. Full reporting of the model and its predictive performance are necessary. However, if the available sample for

reanalysis remains highly biased and it is in fact the case that the large majority of participants performed better with the microprocessor knee in part because they were preselected based on their high likelihood of succeeding with the new knee, then a reanalysis may not be warranted as it would still represent a biased, nonrepresentative group of lower limb amputees. Study conclusions would still not be applicable to the average person considering which type of knee prosthesis to use.

## **Studies on Expectations, Satisfaction With Services, and Long-Term Followup**

Studies on the relationship between patient expectations and outcomes are needed, as are additional studies of patient satisfaction with prosthetic services (and how to improve prosthetic services to improve satisfaction).

Additional large, long-term followup studies are needed to understand problems and limitations people are having with their prostheses, rates of abandonment or limited use, and reasons for these limitations and abandonment. Explanations of the prevalence of abandonment and limited use of LLPs and of why this occurs can yield further research in how to minimize underuse of LLP and resultant limited ambulation.

## **Conclusions and Clinical Implications**

Numerous measures of ambulation, function, quality of life, and other patient-centered outcomes exist for people with lower limb amputations and LLPs. Those that have been validated should be used to form a core set of measures for use in future research studies of LLP. This would enhance the value, interpretability, reproducibility, and comparability of the future studies, and would allow more coherent summarization of the evidence. Researchers should minimize the use of nonvalidated or *ad hoc* measures, but instead should validate the new measures before their use. In particular, researchers with an interest in assessing LLPs for the Medicare population would be best served to focus on those measures with evidence of reliability and validity for this population. The majority of the evidence addresses the question of which components maximize ambulation and function in the average patient, as opposed to which component would best suit the needs of a given individual. A small evidence base does not support which components should be selected for which patient to maximize their ambulation, function, and quality of life or to minimize abandonment or limited use. However, this does not imply that there is evidence that no patient characteristics could effectively predict which patients would most benefit from one or another specific component. There is low strength of evidence that patients are generally satisfied with the prosthetic services they receive. However, further high quality research is needed to better assess the properties of measures (assessment techniques, prediction tools, and outcome measures), particularly for the Medicare population, and to answer all these questions and to assess patient expectations.

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# Appendix A

## PUBMED

("Recovery of Function"[Mesh]  
OR "functional assessment"  
OR "functional status"  
OR "Mobility Limitation"[Mesh]  
OR function  
OR mobility  
OR ambulation  
OR stair\*  
OR locomotion  
OR "treatment outcome"  
OR walking  
OR (abandonment and prosth\*)  
OR (rejection\* and prosth\*)  
OR Quality of Life  
OR Health Status)

AND

("Artificial limb"  
OR "Artificial limbs"  
OR "Artificial Limbs"[Mesh]  
OR prosth\* [text term]  
OR Artificial Limbs)

AND

("lower limb"[Mesh] OR "leg"[Mesh] or lower extremity or foot or ankle or tibia or fibula or femur or thigh or  
"Membrum inferius" or leg or lower limb)

NOT

("Arthroplasty"[Mesh] or "Prosthesis Implantation"[Mesh] or "Vascular Surgical Procedures"[Mesh] or  
"Osteotomy"[Mesh]) OR Aneurysm\*[tiab] OR Aorta\*[tiab] OR Aortic\*[tiab] OR Arthroplast\*[tiab] OR "avascular  
necrosis"[tiab] OR Bypass\*[tiab] OR Cement\*[tiab] OR endoprost\*[tiab] OR fixat\*[tiab] OR fracture\*[tiab] OR  
Graft\*[tiab] OR Implant\*[tiab] OR total hip replacement\*[tiab] OR total knee replacement\*[tiab] OR  
((Orthot\*[tiab] OR Orthos\*[tiab]) NOT (amput\*[tiab] OR prosth\*[tiab])) OR "addresses"[pt] OR  
"autobiography"[pt] OR "bibliography"[pt] OR "biography"[pt] OR "case reports"[pt] OR "comment"[pt] OR  
"congresses"[pt] OR "dictionary"[pt] OR "directory"[pt] OR "editorial"[pt] OR "festschrift"[pt] OR "government  
publications"[pt] OR "historical article"[pt] OR "interview"[pt] OR "lectures"[pt] OR "legal cases"[pt] OR  
"legislation"[pt] OR "letter"[pt] OR "news"[pt] OR "newspaper article"[pt] OR "patient education handout"[pt] OR  
"periodical index"[pt] OR "comment on" OR ("Animals"[Mesh] NOT "Humans"[Mesh]) OR rats[tw] OR cow[tw]  
OR cows[tw] OR chicken\*[tw] OR horse[tw] OR horses[tw] OR mice[tw] OR mouse[tw] OR bovine[tw] OR sheep  
OR ovine OR murine

PUBMED: 2757 on 11/30/16



## EMBASE

	<b>#39</b>
#31 NOT #38	<a href="#">4,449</a>
	#38
#32 OR #33 OR #34 OR #35 OR #36 OR #37	<a href="#">561,702</a>
	#37
orthot* OR orthos* NOT (amput* OR prosth*)	<a href="#">79,418</a>
	#36
aneurysm* OR aorta* OR aortic* OR arthroplast* OR 'avascular necrosis' OR bypass* OR cement* OR endoprosth* OR fixat* OR fracture* OR graft* OR implant* OR total AND hip AND replacement* OR totalAND knee AND replacement*	<a href="#">25,573</a>
	#35
'osteotomy'/exp	<a href="#">37,235</a>
	#34
'vascular surgery'/exp	<a href="#">384,960</a>
	#33
'prosthesis implantation'/exp	<a href="#">2,151</a>
	#32
'arthroplasty'/exp	<a href="#">63,011</a>
	#31
#24 AND #27 AND #30	<a href="#">6,991</a>
	#30
#28 OR #29	<a href="#">377,525</a>
	#29
lower AND extremity OR foot OR ankle OR tibia OR fibula OR femur OR thigh OR 'membrum inferius' OR leg OR lower AND limb	<a href="#">83,740</a>
	#28
'leg'/exp OR 'leg'	<a href="#">341,178</a>
	#27
#25 OR #26	<a href="#">287,601</a>
	#26
artificial AND limb* OR prosth*	<a href="#">287,569</a>
	#25
'limb prosthesis'/exp OR 'limb prosthesis'	<a href="#">7,731</a>
	#24
#17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23	<a href="#">4,097,920</a>
	#23
quality AND of AND life OR health AND status	<a href="#">474,604</a>
	#22
rejection* AND prosth*	<a href="#">1,092</a>
	#21
abandonment AND prosth*	<a href="#">80</a>
	#20
function OR mobility OR ambulation OR stair* OR locomotion OR 'treatment outcome' OR walking	<a href="#">3,662,274</a>

'walking difficulty'/exp OR 'walking difficulty' OR 'mobility'/exp OR mobility AND limitation	#19
	<a href="#">2,685</a>
'functional assessment'/exp OR 'functional assessment' OR 'functional status'/exp OR 'functional status'	#18
	<a href="#">103,884</a>
'convalescence'/exp OR 'convalescence' OR 'recovery'/exp OR recovery AND of AND ('function'/exp OR function)	#17
	<a href="#">92,026</a>

**Cochrane**

Recovery of Function OR functional assessment OR functional status OR Mobility Limitation OR function OR mobility OR ambulation OR stair OR stairs OR locomotion OR treatment outcome OR walking OR (abandonment and prosthesis) OR (rejection and prosthesis) OR Quality of Life OR Health Status

AND

Artificial limb or Artificial limbs or prosthesis or prosthetic

AND

lower limb OR leg or lower extremity or foot or ankle or tibia or fibula or femur or thigh or “Membrum inferius”

NOT (Arthroplasty or Prosthesis Implantation or Vascular Surgical Procedures or Osteotomy OR Aneurysm OR Aorta OR Aortic OR Arthroplast OR avascular necrosis OR Bypass OR Cement OR endoprosth OR fixat OR fracture OR Graft OR Implant OR total hip replacement OR total knee replacement)

**CINAHL/PSYCInfo**

( Recovery of Function OR functional assessment OR functional status OR Mobility Limitation OR function OR mobility OR ambulation OR stair OR stairs OR locomotion OR treatment outcome OR walking OR (abandonment and prosthesis) OR (rejection and prosthesis) OR Quality of Life OR Health Status )

AND

( Artificial limb or Artificial limbs or prosthesis or prosthetic )

AND

( lower limb OR leg or lower extremity or foot or ankle or tibia or fibula or femur or thigh or “Membrum inferius” )

## Appendix B

authors	journal	Title	pubmed id	Rejection Reason
Agrawal V and Gailey R and O'Toole C and Gaunaud I and Finnieston A	Influence of gait training and prosthetic foot category on external work symmetry during unilateral transtibial amputee gait.	Prosthetics and orthotics international	23364890	KQ 4-7: No outcome of interest
Agrawal V and Gailey RS and Gaunaud IA and O'Toole C and Finnieston A and Tolchin R.	Comparison of four different categories of prosthetic feet during ramp ambulation in unilateral transtibial amputees	Prosthet Orthot Int	24925671	KQ 4-7: No outcome of interest
Agrawal V and Gailey RS and Gaunaud IA and O'Toole C and Finnieston AA.	J Rehabil Res Dev	Comparison between microprocessor-controlled ankle/foot and conventional prosthetic feet during stair negotiation in people with unilateral transtibial amputation	24301431	KQ 4-7: No outcome of interest
Agrawal Veena R and Skrabek Ryan Q and Embil John M and Gross Patrick and Trepman Elly			107899203. Language:	KQ 7: N<100
Agrawal Vibhor Ramchandra		A comparison of gait kinetics between prosthetic feet during functional activities -- Symmetry in External Work (SEW) approach	2011-99080-196	KQ 1-3: N<20
Akkaya N and Akkaya S and ĩġ½_imĩġ½ĩġ½ir Atalay N and Findikoĩġ½ĩġ½lu G and Alkan H and Ardil F.		Demographic and clinical features of our lower limb amputee patients		Low resource country
Albert MV and Deeny S and McCarthy C and Valentin J and Jayaraman A.		Monitoring daily function in persons with transfemoral amputations using a commercial activity monitor: a feasibility study	24954402	KQ 1-3: N<20
Albert MV and McCarthy C and Valentin J and Herrmann M and Kording K and Jayaraman A.		Monitoring functional capability of individuals with lower limb amputations using mobile phones	23750254	KQ 1-3: N<20
Ali S and Abu Osman NA and Arifin N and Gholizadeh H and Abd Razak NA and Wan Abas WAB.	Comparative study between Dermo, Pelite, and seal-in X5 liners: Effect on patient's satisfaction and perceived problems	Scientific World Journal	25184154	Low resource country

Ali S and Abu Osman NA and Eshraghi A and Gholizadeh H and Abd Razak NA and Wan Abas WA.	Clin Biomech (Bristol, Avon)	Interface pressure in transtibial socket during ascent and descent on stairs and its effect on patient satisfaction	24161521	Low resource country
Ali S and Osman NA and Mortaza N and Eshraghi A and Gholizadeh H and Wan Abas WA.	Clin Biomech (Bristol, Avon)	Clinical investigation of the interface pressure in the trans-tibial socket with Dermo and Seal-In X5 liner during walking and their effect on patient satisfaction	22795863	Low resource country
Ali S and Osman NA and Razak A and Hussain S and Wan Abas WA.	The effect of Dermo and Seal-In X5 prosthetic liners on pressure distributions and reported satisfaction during ramp ambulation in persons with transtibial limb loss	Eur J Phys Rehabil Med	24963603	Low resource country
Altner PC and Rusin JJ and DeBoer A.			7369844	KQ 7: N<100
Azuma Y and Chin T and Takase I and Tezuka Y and Nakatsuka A and Fujie H and Fujiwara Y and Kurokawa M and Ochi T and Hara M and Oyabu H and Miura Y.	Relation between balance function evaluated using berg balance scale and walking ability in transfemoral amputees	Physiotherapy (United Kingdom)		Not peer reviewed publication
Baker R and McGinley JL and Schwartz MH and Beynon S and Rozumalski A and Graham HK and Tirosh O.	The Gait Profile Score and Movement Analysis Profile	Gait and Posture		Pediatric
Barr JB and Wutzke CJ and Threlkeld AJ.	Physiotherapy theory and practice	Longitudinal gait analysis of a person with a transfemoral amputation using three different prosthetic knee/foot pairs	22191438	Case report/series
Berg KO, Maki BE, Williams JI, Holliday PJ, Wood-Dauphinee SL		Clinical and laboratory measures of postural balance in an elderly population	1444775	Not amputees
Bilodeau S and Hebert R and Desrosiers J.			11061199	KQ 7: N<100
Bischoff HA and Stahelin HB and Monsch AU and Iversen MD and Weyh A and von Dechend M and Akos R and Conzelmann M and Dick W and Theiler R		Identifying a cut-off point for normal mobility: a comparison of the timed 'up and go' test in community-dwelling and institutionalised elderly women.	12720619	Not amputees
Blum C and Ehrlie S and Isner ME.	Ann Phys Rehabil Med	Assessment of therapeutic education in 135 lower limb	27676838	Not peer reviewed

		amputees		publication
Brunelli S and Fusco A and Iosa M and Delussu AS and Paolucci S and Trallesi M.			23072255	KQ 7: N<100
Burger H and Marincek C and Isakov E.	Mobility of persons after traumatic lower limb amputation	Disabil Rehabil	9246543	Low resource country
Buttenshaw P and Dolman J.				KQ 7: N<100
Callaghan B and Condie E and Johnston M.		Using the common sense self-regulation model to determine psychological predictors of prosthetic use and activity limitations in lower limb amputees	18825576	KQ 7: Included amputees without LLP
Callaghan BG and Johnston M and Condie ME.		Using the theory of planned behaviour to develop an assessment of attitudes and beliefs towards prosthetic use in amputees	15497923	KQ 4-7: No outcome of interest
Campbell WB and Ridler BM.			8896478	KQ 7: N<100
Chamlian TR.	Einstein (Sao Paulo)	Use of prostheses in lower limb amputee patients due to peripheral arterial disease	25628194	KQ 7: Unclear followup time
Chan KM and Tan ES.			2130743	KQ 7: N<100
Chan T and Wu J and Bowring G.	Functional outcomes of major lower limb amputation 1994-2006: A modern series	Internal Medicine Journal		KQ 7: <6 mo f/up post-prescription
Chou TGR and Webster JB and Shahrebani M and Roberts TL and Bloebaum RD.		Characterization of step count accuracy of actigraph activity monitor in persons with lower limb amputation	105317621	KQ 1-3: N<20
Chou YL and Shi SS and Huang GF and Lin TS.	Interface pressure and gait analysis in different walking speeds and on the below-knee amputees with multiple axis prosthetic foot prosthesis	Biomedical Engineering - Applications, Basis and Communications		KQ 4: Noncomparative
Coelho A and Espanha M and Bruno PM.		Six-minute walk test and timed up & go test in persons with transfemoral amputations		Not peer reviewed publication
Coffey L and Gallagher P and Desmond D and Ryall N and Wegener ST			24907639	KQ 7: N<100
Cohen E and Dickstien R and Schwarz V and Pillar T.	Harefuah	Evaluation of the rehabilitation of geriatric amputees		Not primary study
Coleman KL and		Step activity monitor: long-	10659890	Not amputees

Smith DG and Boone DA and Joseph AW and del Aguila MA		term, continuous recording of ambulatory function.		
Collin C and Wade DT and Cochrane GM.				KQ 7: N<100
Corey MR and St Julien J and Miller C and Fisher B and Cederstrand SL and Nylander WA and Guzman RJ and Dattilo JB	Am J Surg. 2012 Nov;204(5):626-30	Patient education level affects functionality and long term mortality after major lower extremity amputation.	22906244	KQ 7: Included amputees without LLP
Crea S and Cipriani C and Donati M and Carrozza MC and Vitiello N.	Providing time-discrete gait information by wearable feedback apparatus for lower-limb amputees: usability and functional validation	IEEE Trans Neural Syst Rehabil Eng	25373108	Not amputees
Cull DL and Taylor SM and Hamontree SE and Langan EM and Snyder BA and Sullivan TM and Youkey JR.	Am J Surg	A reappraisal of a modified through-knee amputation in patients with peripheral vascular disease	11532414	KQ 7: Excluded some LLP recipients
Cutti AG and Raggi M and Parel I.	Assessment of Transtibial Amputees walking in real-life environments: Inter-rater reliability of a protocol based on inertial and magnetic sensors	Gait and Posture		Not peer reviewed publication
Davie-Smith F and Scott H.	The scottish physiotherapy amputee research group (SPARG)	Physiotherapy (United Kingdom)		Not peer reviewed publication
De Luccia N and Pinto MA and Guedes JP and Albers MT	Rehabilitation after amputation for vascular disease: a follow-up study.	Prosthetics & Orthotics International. 16(2):124-8, 1992 Aug.	1408671	Low resource country
Dillingham TR and Pezzin LE and MacKenzie EJ and Burgess AR.			11475475	KQ 7: N<100
Diogo MJ	[Functional evaluation of elderly patients with lower limb amputation followed at a university hospital].	Revista latino-americana de enfermagem	12733244	Low resource country
Dite W and Temple VA		A clinical test of stepping and change of direction to identify multiple falling older adults.	12422327	Not amputees
Dolezal Jeanette M and Vernick Sanford H and Khan Nusrat and Lutz David and	Factors associated with use and nonuse of an AK prosthesis in a rural, southern,	International Journal of Rehabilitation & Health	2001-06721-005	KQ 7: Unclear followup time

Tyndall Carl	geriatric population			
Duff L and Jarvis H.	Walking speed and oxygen consumption of a unilateral hip disarticulation amputee during level walking using a C-leg vs a Genium	Prosthetics and Orthotics International		Case report/series
Ehrler S and Blum-Demans C and Coulon S and Isner-Horobeti ME.	Assessment of therapeutic education in lower-limb amputees	Prosthetics and Orthotics International		Not peer reviewed publication
Ehrler S and Coulon S.	Under limb amputation for people with mobility 1 or 2; choice of fitting with prosthetic	Annals of Physical and Rehabilitation Medicine		Not peer reviewed publication
Eshraghi A and Abu Osman NA and Karimi MT and Gholizadeh H and Ali S and Wan Abas WA	American journal of physical medicine & rehabilitation / Association of Academic Physiatrists	Quantitative and qualitative comparison of a new prosthetic suspension system with two existing suspension systems for lower limb amputees.	23168378	Low resource country
Fernandez A and Formigo J.			16281726	KQ 7: N<100
Fisher K and Hanspal R.		Body image and patients with amputations: does the prosthesis maintain the balance?	9926350	KQ 7: No outcome of interest
Fisher K and Hanspal RS and Marks L		Return to work after lower limb amputation.	12601268	KQ 7: No outcome of interest
Frlan-Vrgoc L and Vrbancic TS and Kraguljac D and Kovacevic M.	Functional outcome assessment of lower limb amputees and prosthetic users with a 2-minute walk test	Coll Antropol	22397262	Low resource country
Fusetti C and Senechaud C and Merlini M	[Quality of life of vascular disease patients following amputation].	Annales de chirurgie	11447794	KQ 7: Unclear followup time
Gardiner MD and Faux S and Jones LE		Inter-observer reliability of clinical outcome measures in a lower limb amputee population.	11926262	KQ 1-3: N<20
Gatt A and Chockalingam N.	Validity and reliability of a new ankle dorsiflexion measurement device	Prosthetics and Orthotics International	23211471	Not amputees
Gaunard I and Gailey R and Salem R and Hafner B.	Construct validity of the Prosthetic Limb Users Survey of Mobility (PLUS-M)	Prosthetics and Orthotics International		Duplicate publication
Gaunard I, Spaulding S, Amtmann D, Salem R, Gailey R, Morgan S, Hafner B		Use of and Confidence Administering Outcome Measures among Clinical Prosthetists: Results from a National Survey and Mixed-Methods Training Program	24827935	Not amputees
Gholizadeh H and Abu Osman NA and	PLoS One	The effects of suction and pin/lock suspension	24827560	Low resource country

Eshraghi A and Ali S.		systems on transtibial amputees' gait performance		
Gong SY and Yang P and Liu QD and Song L.	Application of intelligent lower limb prostheses sensor	Journal of Clinical Rehabilitative Tissue Engineering Research		Low resource country
Guarita ML and Gaspar AP and Inghan S.	Long-term prosthetic outcome of bilateral lower limb amputees: A case series	PM and R		Not peer reviewed publication
Hafner B and Morgan S and Askew R.	Reliability of self-reported outcome measures in people with lower limb loss: Implications to clinical care and research	Prosthetics and Orthotics International		Not peer reviewed publication
Hafner BJ and Morgan SJ and Abrahamson DC and Amtmann D	Characterizing mobility from the prosthetic limb user's perspective: Use of focus groups to guide development of the Prosthetic Limb Users Survey of Mobility.	Prosthetics and orthotics international	25944625	KQ 1-3: Not validation
Hafner BJ, Spaulding SE, Salem R, Morgan SJ, Gaunaud IA, Gailey RS		Prosthetists' perceptions and use of outcome measures in clinical practice: long-term effects of focused continuing education	27638012	Not amputees
Hagberg K and Branemark R.			11860092	KQ 7: N<100 **INCLUDED FOR KQ 3**
Hahn Andreas and Lang Michael	Effects of Mobility Grade, Age, and Etiology on Functional Benefit and Safety of Subjects Evaluated in More Than 1200 C-Leg Trial Fittings in Germany	Journal of Prosthetics & Orthotics (JPO)	103452300. Language:	KQ 4: Noncomparative
Ham R and de Trafford J and Van de Ven C.	Patterns of recovery for lower limb amputation	Clinical Rehabilitation	107397632. Language:	KQ 7: <6 mo f/up post-prescription
Hansen SE.	Ugeskrift for Laeger	A follow-up examination of elderly amputees fitted with prostheses	695031	Unclear technology
Harness N and Pinzur MS.			11210955	KQ 7: N<100
Harris KA and van Schie L and Carroll SE and Deathe A and Maryniak O and Meads GE and Sweeney JP.		Rehabilitation potential of elderly patients with major amputations	1864873	KQ 7: N<100
Hatfield AG.		Beyond the 10-m time: a pilot study of timed walks in lower limb amputees	11911519	KQ 1-3: N<20
Hefferman GM and Zhang F and Nunnery MJ and Huang H.	Integration of surface electromyographic sensors with the	Prosthet Orthot Int	24469430	Case report/series



	transfemoral amputee socket: a comparison of four differing configurations			
Hellstrand Tang U and Zigelgner R and Lisovskaja V and Karlsson J and Hagberg K and Tranberg R.	Comparison of plantar pressure in three types of insole given to patients with diabetes at risk of developing foot ulcers - A two-year, randomized trial	Journal of Clinical and Translational Endocrinology		Not LLP
Hermudsson Y and Ekdahl C and Persson BM.	Outcome after trans-tibial amputation for vascular disease. A follow-up after eight years	Scand J Caring Sci	9801627	KQ 7: N<100
Herskovitz A and Dudkiewicz I and Brill S.		Rehabilitation outcome of post-acute lower limb geriatric amputees	22686166	KQ 7: N<100
Highsmith Michael Jason	Comparative outcomes assessment of the C-Leg and X2 knee prosthesis		2013-99220-100	Not peer reviewed publication
Highsmith Mj and Kahle Jt	Functional effects of the genu knee in transfemoral amputees measured with the continuous scale physical functional performance-10 (CS-PFP10) assessment	Prosthetics and orthotics international	CN-01131588	Not peer reviewed publication
Holden JM and Fernie GR.		Extent of artificial limb use following rehabilitation	3681530	KQ 7: No outcome of interest
Houghton AD and Taylor PR and Thurlow S and Rootes E and McColl I	The British journal of surgery	Success rates for rehabilitation of vascular amputees: implications for preoperative assessment and amputation level.	1393461	KQ 7: Unclear followup time **INCLUDED FOR KQ 3**
Howard C and Wallace C and Stokic D.	Mechanical knee users improve motor function with rheo3 knee: Single-subject design	Prosthetics and Orthotics International		Not peer reviewed publication
Huang GF and Chou YL and Su FC.	Gait analysis and energy consumption of below-knee amputees wearing three different prosthetic feet	Gait Posture	10998614	Retracted publication
Inderbitzi R and Buettiker M and Enzler M.			12819649	KQ 7: N<100
Jarl G and Heinemann AW and Lindner HY and Norling Hermansson LM.		Cross-Cultural Validity and Differential Item Functioning of the Orthotics and Prosthetics Users' Survey With Swedish and	25804528	KQ 1-3: Not validation

		United States Users of Lower-Limb Prosthesis		
Jayakaran P and Johnson GM and Sullivan SJ		Concurrent validity of the Sensory Organization Test measures in unilateral transtibial amputees.	22760518	KQ 1-3: N<20
Jayakaran P and Johnson GM and Sullivan SJ.		Reliability and concurrent validity of the step quick turn test in older persons with a unilateral transtibial amputation	21862909	KQ 1-3: N<20
Johannesson A and Larsson GU and Ramstrand N and Lauge-Pedersen H and Wagner P and Atroshi I.		Outcomes of a standardized surgical and rehabilitation program in transtibial amputation for peripheral vascular disease: a prospective cohort study	20134308	KQ 7: No outcome of interest
Johansson JL and Sherrill DM and Riley PO and Bonato P and Herr H.	A clinical comparison of variable-damping and mechanically passive prosthetic knee devices	Am J Phys Med Rehabil	16034225	KQ 4-7: No outcome of interest
Jones L and Hall M and Schuld W			8219247	KQ 7: N<100
Jordan RW and Marks A and Higman D.		The cost of major lower limb amputation: a 12-year experience	22440579	KQ 7: No outcome of interest
Kark L and Vickers D and McIntosh A and Simmons A.		Use of gait summary measures with lower limb amputees	22000790	KQ 1-3: N<20
Kent JA and Stergiou N and Wurdeman SR		Step activity and stride-to-stride fluctuations are negatively correlated in individuals with transtibial amputation.	26319219	KQ 1-3: Not validation
Kuntze Ferreira AE and Neves EB.	Gait Posture	A comparison of vacuum and KBM prosthetic fitting for unilateral transtibial amputees using the Gait Profile Score	25684145	Low resource country
Kurichi JE and Kwong P and Vogel WB and Xie D and Cowper Ripley D and Bates BE	Effects of prosthetic limb prescription on 3-year mortality among Veterans with lower-limb amputation.	Journal of Rehabilitation Research & Development. 52(4):385-96, 2015.	26348602	KQ 4-7: No outcome of interest
Lacruz A and Turcot K and Sagawa Y and Lenoir J and Carmona G and Armand S and Assal M.	Swiss Medical Weekly	CR-EQUIPEMENTS SACH foot versus otto BOCK SACH foot		Duplicate publication
Larsson J and Agardh CD and Apelqvist J and Stenstrom A.		Long term prognosis after healed amputation in patients with diabetes	9602814	KQ 7: N<100
Lee WC and Zhang M and Chan PP and Boone DA	Gait analysis of low-cost flexible-shank transtibial prostheses.	IEEE transactions on neural systems and rehabilitation engineering : a publication of the IEEE	17009497	KQ 4-7: No outcome of interest

		Engineering in Medicine and Biology Society		
Leung HB and Wong WC and Wu FC and Guerin JS.	J Orthop Surg (Hong Kong)	Perioperative and rehabilitation outcome after lower-limb amputation in elderly Chinese patients in Hong Kong	15237131	KQ 7: Unclear followup time
Lim TS and Finlayson A and Thorpe JM and Sieunarine K and Mwiapatayi BP and Brady A and Abbas M and Angel D			16768686	KQ 7: N<100
Lindberg K and Kristensen MT.	Construct validity and responsiveness of functional measures used in lower limb amputees following an outpatient prosthetic rehabilitation program	Prosthetics and Orthotics International		Not peer reviewed publication
Major MJ and Johnson WB and Gard SA		Interrater reliability of mechanical tests for functional classification of transtibial prosthesis components distal to the socket.	26360815	KQ 1-3: Not validation
Mateos Torres E and Claris A and Muniesa-Portolà JM and Vidal-Barraquer F.	The natural history of ischaemic patients who undergo below-knee amputation: A long way to autonomous walking	Angiologia		KQ 4-7: No outcome of interest
McWhinnie DL and Gordon AC and Collin J and Gray DW and Morrison JD.			7827880	KQ 7: N<100
Met R and Janssen LI and Wille J and Langezaal AE and van de Mortel RW and van de Pavoordt ED and de Vries JP.			18458050	KQ 7: N<100
Meulenbelt HE and Geertzen JH and Jonkman MF and Dijkstra PU.	Arch Phys Med Rehabil	Determinants of skin problems of the stump in lower-limb amputees	19154832	No analyses of interest
Miller WC and Deathe AB and Speechley M and Koval J.	The influence of falling, fear of falling, and balance confidence on prosthetic mobility and social activity among individuals with a lower extremity amputation	Arch Phys Med Rehabil	11552197	KQ 7: Excluded some LLP recipients **INCLUDED FOR KQ 3**
Miyazaki S.		Long-term unrestrained measurement of stride length and walking velocity utilizing a piezoelectric gyroscope	9254988	Unclear technology

Mizuno N and Aoyama T and Nakajima A and Kasahara T and Takami K.		Functional evaluation by gait analysis of various ankle-foot assemblies used by below-knee amputees	1491951	No analyses of interest
Monteiro RP and Pfeifer LI and Soares I and Dos Santos Ade A and Sousa N.	Validation of the functional and social performance - DSF-84 checklist: preliminary study	Disabil Rehabil	23323959	Low resource country
Moore TJ and Barron J and Hutchinson F3rd and Golden C and Ellis C and Humphries D.	Prosthetic usage following major lower extremity amputation	Clin Orthop Relat Res	2910604	KQ 7: Excluded some LLP recipients
Morgan S and Askew R and Hafner B.	Equivalence of electronic and paper administration for four self-report instruments used in prosthetic clinical care	Prosthetics and Orthotics International		Not peer reviewed publication
Morgan SJ, Amtmann D, Abrahamson DC, Kajlich AJ, Hafner BJ		Use of cognitive interviews in the development of the PLUS-M item bank	24442531	KQ 1-3: Not validation
Morgan SJ, Friedly JL, Amtmann D, Salem R, Hafner BJ		A cross-sectional assessment of factors related to pain intensity and pain interference in lower limb prosthesis users	27742450	KQ 1-3: Not validation
Moustapha A and Sagawa Junior Y and Watelain E and Thevenon A.	Epidemiological cross-sectional survey of outcome in lower-limb amputees in the Nord-Pas de Calais region	Annals of Physical and Rehabilitation Medicine		Not peer reviewed publication
Muniesa JM and Pou M and Marco E and Boza R and Guillón A and Duarte E and Escalada F and Belmontey R and Tejero M.	Health-related quality of life in patients with lower limb amputations	Rehabilitacion	105502435. Language:	KQ 4-7: No outcome of interest
Naylor H and Russell P.	A scoring tool to predict functional outcome in lower limb amputees (BLARt)-a pilot study	Prosthetics and Orthotics International		Not peer reviewed publication
Nehler MR and Coll JR and Hiatt WR and Regensteiner JG and Schnickel GT and Klenke WA and Strecker PK and Anderson MW and Jones DN and Whitehill TA and Moskowitz S and Krupski WC.		Functional outcome in a contemporary series of major lower extremity amputations	12844082	KQ 7: N<100
O'Neill BF and Evans JJ.			19280435	KQ 7: N<100

OConnell PG and Gnatz S	Hemiplegia and amputation: rehabilitation in the dual disability.	Archives of physical medicine and rehabilitation	2730308	KQ 7: Excluded some LLP recipients
Pernot HF and Winnubst GM and Cluitmans JJ and De Witte LP.			11061195	KQ 7: N<100
Pinzur MS and Littooy F and Daniels J and Arney C and Reddy NK and Graham G and Osterman H.			1499219	KQ 7: N<100
Pohjolainen T and Alaranta H.		Predictive factors of functional ability after lower-limb amputation	1888111	KQ 4-7: No outcome of interest
Popielarz S and Lacroix J and Munoz M and Fargeas-Gluck MA and Salle JY and Mandigout S.	Science and Sports	Shock absorbers for vascular trans-tibial amputees in environmental situations seem more efficient on comfort than on oxygen consumption		KQ 4: Noncomparative
Powell LE, Myers AM	The Activities-specific Balance Confidence (ABC) Scale	J Gerontol		Not amputees
Raya MA and Gailey RS and Gaunard IA and Ganyard H and Knapp-Wood J and McDonough K and Palmisano T.		Amputee mobility predictor-bilateral: a performance-based measure of mobility for people with bilateral lower-limb loss	24301433	Battle injury
Redfield MT and Cagle JC and Hafner BJ and Sanders JE.		Classifying prosthetic use via accelerometry in persons with transtibial amputations	24458961	KQ 1-3: N<20
Remes L and Isoaho R and Vahlberg T and Viitanen M and Rautava P.		Predictors for institutionalization and prosthetic ambulation after major lower extremity amputation during an eight-year follow-up	19448384	KQ 7: N<100
Rispin K and Wright V and Andrysek J.	Assessing the test-retest reliability of the lower limb function questionnaire (LLFQ)	Prosthetics and Orthotics International		Pediatric
Roffman CE and Buchanan J and Allison GT.	Long term locomotor function in individuals with lower limb amputation following discharge from rehabilitation	Prosthetics and Orthotics International		Not peer reviewed publication
Rosenberg DE and Turner AP and Littman AJ and Williams RM and Norvell DC and Hakimi KM and Czerniecki JM			23094934	KQ 7: N<100
Rushton PW and Miller WC.		Goal attainment scaling in the rehabilitation of patients	12048654	KQ 1-3: N<20

		with lower-extremity amputations: a pilot study		
Saraf A.	Mobilization status of diabetics versus non-diabetics after below knee amputation: A comparison	Prosthetics and Orthotics International		Not peer reviewed publication
Schaffalitzky E and Gallagher P and Maclachlan M and Ryall N.	Understanding the benefits of prosthetic prescription: exploring the experiences of practitioners and lower limb prosthetic users	Disabil Rehabil	21050130	KQ 1-3: Not validation
Schoppen T and Boonstra A and Groothoff JW and van Sonderen E and Goeken LN and Eisma WH.		Factors related to successful job reintegration of people with a lower limb amputation	11588749	KQ 7: No outcome of interest
Schoppen T, Boonstra A, Groothoff JW, de Vries J, Göeken LN, Eisma WH		Physical, mental, and social predictors of functional outcome in unilateral lower-limb amputees	12808530	KQ 7: N<100
Scopes J and Van Der Linden M and Gleeson N.	Minimal detectable change values of common outcome measures used in lower limb prosthetic rehabilitation in the UK	Physiotherapy (United Kingdom)		Not peer reviewed publication
Seker A and Kara A and Camur S and Malkoc M and Sonmez MM and Mahirogullari M.	Int J Surg	Comparison of mortality rates and functional results after transtibial and transfemoral amputations due to diabetes in elderly patients-a retrospective study	27475745	Low resource country
Singh R and Venkateshwara G.		Effect of fluid collections on long-term outcome after lower limb amputation	22244246	KQ 7: N<100
Sinha R and van den Heuvel WJ and Arokiasamy P	Adjustments to amputation and an artificial limb in lower limb amputees.	Prosthetics and orthotics international	23722600	Low resource country
Sinha R and van den Heuvel WJ and Arokiasamy P and van Dijk JP.	Influence of adjustments to amputation and artificial limb on quality of life in patients following lower limb amputation	Int J Rehabil Res	24157864	Duplicate publication
Siriwardena GJ and Bertrand PV.	Factors influencing rehabilitation of arteriosclerotic lower limb amputees	J Rehabil Res Dev	1880748	KQ 4-7: No outcome of interest
Steinberg FU and Garcia WJ and Roettger RF and Shelton DJ.			0 (PMID:4810416)	KQ 7: N<100

Steinberg FU and Sunwoo I and Roettger RF.		Prosthetic rehabilitation of geriatric amputee patients: a follow-up study	4062526	KQ 7: N<100
Tang KT, Spence WD, Maxwell D, Stansfield BW.		Validity of method to quantify transtibial amputees' free-living prosthetic wearing times and physical activity levels when using suction suspension sockets	22773201	KQ 1-3: N<20
Taylor SM and Kalbaugh CA and Blackhurst DW and Hamontree SE and Cull DL and Messich HS and Robertson RT and Langan EM3rd and York JW and Carsten CG3rd and Snyder BA and Jackson MR and Youkey JR.		Preoperative clinical factors predict postoperative functional outcomes after major lower limb amputation: an analysis of 553 consecutive patients	16102618	KQ 7: Included amputees without LLP
Taylor SM and Kalbaugh CA and Cass AL and Buzzell NM and Daly CA and Cull DL and Youkey JR		'Successful outcome' after below-knee amputation: an objective definition and influence of clinical variables.	18646478	KQ 7: Included amputees without LLP
Tezuka Y and Chin T and Takase I and Azuma Y and Nakatsuka A and Fujie H and Kurokawa M and Fujiwara Y and Ochi T and Oyabu H and Honda Y and Kohno H and Miura Y.				KQ 7: N<100
Topuz Semra and Ulcer Ozlem and Sener Gul	Effects of different prosthetic feet on the ambulation activities and gait in transtibial amputees	Turkish Journal of Physiotherapy Rehabilitation	104947410. Language:	Low resource country
Ulger O and Topuz S and Bayramlar K.	Turkish Journal of Physiotherapy Rehabilitation	Effects of a hydraulic knee joint on energy consumption, gait and patient satisfaction in trans-femoral amputees	105160169. Language:	Low resource country
van der Water GJ and De Vries J and Mulder MA.	Comparison of the lightweight Camp Normal Activity Foot with other prosthetic feet in trans-tibial amputees: a pilot study	Prosthet Orthot Int	9747994	Case report/series
van Eijk MS and van der Linde H and Buijck B and Geurts A and Zuidema S and Koopmans R.	Predicting prosthetic use in elderly patients after major lower limb amputation	Prosthet Orthot Int	22252778	KQ 7: <6 mo f/up post-prescription
Wan Hazmy CH and Chia WYE and Fong		Functional outcome after major lower extremity	17042220	Low resource country

TS and Ganendra P.		amputation: A survey on lower extremity amputees		
Webster JB and Hakimi KN and Williams RM and Turner AP and Norvell DC and Czerniecki JM.			23516053	KQ 7: N<100
Williams RM and Turner AP and Green M and Norvell DC and Henderson AW and Hakimi KN and Blake DJ and Czerniecki JM.			25357146	KQ 7: N<100
Wong A and Heinemann A and Ehrlich-Jones L and Connelly L and Semik P and Fatone S.	Comparison of the opus and FOTO's functional status measures for persons with lower limb amputation	Archives of Physical Medicine and Rehabilitation		Not peer reviewed publication
Wong CK and Chen CC and Blackwell WM and Rahal RT and Benoy SA.		Balance ability measured with the Berg balance scale: a determinant of fall history in community-dwelling adults with leg amputation	25223891	KQ 1-3: Not validation
Wong CK and Chen CC.		A prognostic clinical prediction rule to identify adults with lower limb loss not likely to achieve successful prosthetic function within one year		Duplicate publication
Yigiter K and Bayar K and Ulger OG and Akdogan S and Erbahceci F and Yakut Y and Sener G.	The effect of flexible and hard sockets on the ambulation of above knee amputees	Fizyoterapi Rehabilitasyon		Low resource country
Yiğiter K, Sener G, Bayar K.	Comparison of the effects of patellar tendon bearing and total surface bearing sockets on prosthetic fitting and rehabilitation	Prosthetics and Orthotics International	12562067	Low resource country
Zidarov D and Swaine B and Gauthier-Gagnon C.	Arch Phys Med Rehabil	Life habits and prosthetic profile of persons with lower-limb amputation during rehabilitation and at 3-month follow-up	19887223	KQ 7: <6 mo f/up post-prescription



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Franchignoni,	2003		Transfemoral (n=79), Transtibial (n=61)	peripheral vascular diseases (52.9%), trauma (32.1%), tumour (12.1%) infective diseases (2.9%)	57	nd	140	10 Meter Walk Test	Total Overall Score		Validity	Convergent
Mazari	2010							10 Meter Walk Test	Total Overall Score		Validity	Known group/Discriminant
Mazari	2010							10 Meter Walk Test	Total Overall Score		Ability to measure change	Responsiveness
Ryall et al,	2002							10 Meter Walk Test	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Ryall et al,	2003							10 Meter Walk Test	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Remes et al,	2010		nd	peripheral artery disease	75.17	nd	59	15D HRQoL	nd		Validity	Known group/Discriminant
Remes	2010		nd	peripheral artery disease	75.17		59	15D HRQoL			Validity	Known group/Discriminant
Dite	2007		Transtibial	nd	61.6	Unilateral	40	180 degree turn test			Validity	Known group/Discriminant
Brooks	2001		Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2 min walk test			Validity	Concurrent/convergent
Brooks	2001		Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2 min walk test			Validity	Concurrent/convergent
Brooks	2001		Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2 min walk test			Validity	Concurrent/convergent
Brooks	2001		Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2 min walk test			Validity	Predictive
Brooks	2001		Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2 min walk test			Validity	Predictive
Brooks	2001		Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2 min walk test			Validity	Concurrent/convergent
Brooks	2001		Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2 min walk test			Validity	
Brooks	2001		Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2 min walk test			Validity	Predictive
Brooks	2001		Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2 min walk test			Validity	Construct
Brooks	2001		Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2 min walk test			Validity	Construct
Rau et al,	2007							2 Minute Walk Test	Total Overall Scale		Ability to measure change	Responsiveness
Frlan-Vrgoc	2011							2 Minute Walk Test	Total Overall Score		Validity	Known group/Discriminant
Gremeaux	2012							2 Minute Walk Test	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Resnik and Borgia	2011							2 Minute Walk Test	Total Overall Score		Reliability	Test-retest
Salavati et al,	2011							2 Minute Walk Test	Total Overall Score		Validity	Construct
Brooks	2001	11588757	Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2MWT			Validity	Concurrent/convergent
Brooks	2001	11588757	Transtibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2MWT			Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Franchignoni,	2003		Rivermead Mobility Index (RIM)		Spearman r	0.69				Spearman's: RIM=0.69
Mazari	2010									significant differences between articulated and non articulated walking aid users at visit 1
Mazari	2010									significant improvements over time with EWA use
Ryall et al,	2002									grades of SIGAM were significantly different
Ryall et al,	2003									Spearman: RMI=-0.58
Remes et al,	2010		amputees vs control group		P value	<0.001				
Remes	2010		amputees vs control group		P value	<0.001				
Dite	2007				Multiple Fallers vs nonmultiple Fallers P Value	<0.001				differentiated between multiple and nonmultiple fallers
Brooks	2001		PF of SF-36 at rehab discharge		Pearson r	0.22	Small	Yes		Hypothesis: moderate correlation; p=0.008
Brooks	2001		PF of SF-36 at 3 month follow-up		Pearson r	0.479	Moderate	Yes		Hypothesis: moderate correlation; p<0.001
Brooks	2001		Houghton		Pearson r	0.493	Moderate	Yes		Hypothesis of moderate correlation; Houghton measured at discharge only; p<0.001; n=56
Brooks	2001		distance walked at discharge		Pearson r	0.72	Large	Yes		n=197
Brooks	2001		distance walked at follow up		Pearson r	0.568	Large	Yes		n=69
Brooks	2001									
Brooks	2001									
Brooks	2001		distance walked at follow up		Pearson r	0.568	Large	Yes		
Brooks	2001		Transtibial vs total group							
Brooks	2001									
Rau et al,	2007									significant improvement after intervention
Frlan-Vrgoc	2011									significant differences between age groups, amputation level, cause of amputation, and prosthetic experience
Gremeaux	2012									All scores were highly correlated with eachother: Pearsons 0.35-0.80
Resnik and Borgia	2011									ICC=0.83
Salavati et al,	2011									Spearman: LCI-5=0.71
Brooks	2001	11588757	Houghton		Pearson r	0.493	Moderate	Yes		Hypothesis: moderate correlation; Houghton measured at discharge only; p<0.001; n=56. For subgroup of unilateral transtibial: r = .53, p=0.02
Brooks	2001	11588757	Age		Pearson r	-0.289	Small	Yes		Change in distance walked baseline to discharge, p<0.001. For transtibial group, r = -.358, p<0.001

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Brooks	2001	11588757	Trans tibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2MWT			Validity	Convergent
Brooks	2001	11588757	Trans tibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2MWT			Validity	Convergent
Brooks	2001	11588757	Trans tibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2MWT			Validity	Known group
Brooks	2001	11588757	Trans tibial (n=179), Transfemoral (n=60), Bilateral (n=51)	Vascular (n=194, n=165 DM)	66.3	Able to walk, had been fit with prosthesis	290	2MWT			Validity	Predictive
Brooks	2002	12422326	Trans tibial	Peripheral vascular disease (n=20), diabetes (n=11), osteomyelitis (n=1), sarcoma (n=1)	63.6	A minimum of 2 weeks of rehabilitation; tolerate 2 minutes of walking; no prosthetic modifications planned; no other medical restrictions preventing them from participating in the test	33	2MWT			Reliability	Interrater
Brooks	2002	12422326	Trans tibial	Peripheral vascular disease (n=20), diabetes (n=11), osteomyelitis (n=1), sarcoma (n=1)	63.6	A minimum of 2 weeks of rehabilitation; tolerate 2 minutes of walking; no prosthetic modifications planned; no other medical restrictions preventing them from participating in the test	33	2MWT			Reliability	Intrater
Gremeaux	2012	22389424	Transfemoral (n=17), trans tibial (n=47)	Vascular (n=42), trauma (n=16), cancer (n=2), other (n=1)	58 (22-87)	unilateral	64	2MWT			Validity	Convergent
Gremeaux	2012	22389424	Transfemoral (n=17), trans tibial (n=47)	Vascular (n=42), trauma (n=16), cancer (n=2), other (n=1)	58	unilateral	64	2MWT			Validity	Convergent
Newton	2016		Trans tibial (n=28), Transfemoral (n=9)	nd	40-69	comfortable and well fitted prosthesis for at least 12 mo	37	2MWT			Validity	Construct
Parker	2010	2010632385	Transfemoral (n=16), Trans tibial (n=30), Bilateral trans tibial (n=6)	Vascular (n=20), Trauma (n=26), Other (n=6)	55.2		52	2MWT			Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Trans tibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	2MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Trans tibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	2MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Trans tibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	2MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Trans tibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	2MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Resnik	2011		Transfemoral (52%); through knee (5%); trans tibial (43%)		66	unilateral	44	2MWT			Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); trans tibial (43%)		66	unilateral	44	2MWT			Reliability	Test-retest
Gailey, Roach et. Al.	2002							6 Minute Walk Test	Total Overall Score		Validity	Known group/Discriminant

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Brooks	2001	11588757	PF of SF-36		Pearson r	0.479	Moderate	Yes		Hypothesis: moderate correlation; p<0.001. For subgroup of unilateral transtibial: r = .29, p=0.005
Brooks	2001	11588757	Age, Gender (using stepwise regression)		Pearson r	0.369	Moderate	Yes		p<0.001
Brooks	2001	11588757	transtibial men vs transtibial women		p	<0.001		Yes		change in distance walked also significantly greater in men p=0.001
Brooks	2001	11588757	2 min walk test	3 months	Pearson r	0.568	Large	Yes		n=69
Brooks	2002	12422326	nd		ICC	0.98 to 0.99	Excellent	Yes	The 2MWT exhibits good within- and between-rater reliability in individuals with transtibial amputation	
Brooks	2002	12422326	nd		ICC	0.9 to 0.96	Excellent	Yes	The 2MWT exhibits good within- and between-rater reliability in individuals with transtibial amputation	
Gremeaux	2012	22389424	nd			AUC	0.93			
Gremeaux	2012	22389424	TUG, BBS, Modified Houghton		Pearson r	0.35-0.8				All scores were highly correlated with each other: Pearsons 0.35-0.80
Newton	2016		Transfemoral vs. Transtibial		P, univariate	0.11		No		known group
Parker	2010	2010632385	LCI-5		Spearman's r	0.819	Large			
Reid	2015	25588644	6-minute walk test		Pearson r	0.95	Large	Yes	The 2MWT was strongly predictive of the 6MWT	
Reid	2015	25588644	6-minute walk test		correlation strength (R squared)	0.79	Large	Yes	The 2MWT was strongly predictive of the 6MWT	K1 and K2 amputee level (n=30)
Reid	2015	25588644	6-minute walk test		correlation strength (R squared)	0.87	Large	Yes	The 2MWT was strongly predictive of the 6MWT	K3 and K4 amputee level (n=56)
Reid	2015	25588644	6-minute walk test		correlation strength (R squared)	0.82	Large	Yes	The 2MWT was strongly predictive of the 6MWT	Amputation aetiology: Vascular (n=21)
Reid	2015	25588644	6-minute walk test		correlation strength (R squared)	0.89	Large	Yes	The 2MWT was strongly predictive of the 6MWT	Amputation aetiology: Trauma (n=41)
Resnik	2011		NA		MDC90	112.5				
Resnik	2011		NA		ICC (95% CI)	0.83 (0.71, 0.90)				
Gailey, Roach et. Al.	2002									differentiated between MFCL Medicare comon procedure coding system groups

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Gailey, Roach et. Al.	2002							6 Minute Walk Test	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Kark and Simmons	2011							6 Minute Walk Test	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Raya et al	2010							6 Minute Walk Test	Total Overall Score		Validity	Construct
Resnik and Borgia	2011							6 Minute Walk Test	Total Overall Score		Reliability	Test-retest
Remes et al,	2010		nd	peripheral artery disease	75.17	nd	59	6-item Brief Social Support Questionnaire, and Self-reported Life Satisfaction score (SSQN6)	nd		Validity	Known group/Discriminant
Remes et al,	2010		nd	peripheral artery disease	75.17	nd	59	6-item Brief Social Support Questionnaire, and Self-reported Life Satisfaction score (SSQN6)	nd		Validity	Concurrent/convergent criterion
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Construct
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Construct
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Construct
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Construct
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Gailey, Roach et. Al.	2002									Pearsons: AMPPRO=0.69, AMPnoPRO=0.82
Kark and Simmons	2011									no significant correlation with PEQ items
Raya et al	2010									Pearsons: Hip Extension=0.69, Hip Aduction=0.66, plantarflexion=0.61, grip=0.54
Resnik and Borgia	2011									ICC=0.97
Remes et al,	2010		amputees vs control group		P value	0.071				
Remes et al,	2010									All the QoL scores had a significant corelation with the SSQ6N score
Reid	2015	25588644	Two minute walk test		Pearson r	0.95	Large	Yes	The 2MWt was strongly predictive of the 6MWt	
Reid	2015	25588644	Timed up and go		Pearson r	-0.72	Large	Yes	Adequate to excellent correlation between the 6MWt and previously validated measures of ambulation in lower extremity amputees	
Reid	2015	25588644	Locomotor Capabilities Index version 5		Pearson r	0.61	Large	Yes	Adequate to excellent correlation between the 6MWt and previously validated measures of ambulation in lower extremity amputees	
Reid	2015	25588644	Houghton		Pearson r	0.57	Large	Yes	Adequate to excellent correlation between the 6MWt and previously validated measures of ambulation in lower extremity amputees	
Reid	2015	25588644	Activity-Specific Balance Confidence scale		Pearson r	0.6	Large	Yes	Adequate to excellent correlation between the 6MWt and previously validated measures of ambulation in lower extremity amputees	
Reid	2015	25588644	Level of Amputation (K1+K2 vs K3 vs K4)		P	<0.0001		Yes	the results of the study also suggest that the 6MWt has good discriminative validity.	P-value based on ANOVA
Reid	2015	25588644	Aetiology of amputation (Diabetes vs Infection not related to diabetes vs Vascular disease vs Cancer vs Trauma and congenital)		P	<0.0001		Yes	the results of the study also suggest that the 6MWt has good discriminative validity.	P-value based on ANOVA
Reid	2015	25588644	Age >=50 vs <50		P	<0.0001		Yes	the results of the study also suggest that the 6MWt has good discriminative validity.	
Reid	2015	25588644	Male vs female		P	0.24		No	As has been shown in previous examinations of the 6MWt, men walked further than women. this result was not statistically signifcant in the present study.	
Reid	2015	25588644	Two minute walk test		correlation strength (R squared)	0.79	Large	Yes	The 2MWt was strongly predictive of the 6MWt	K1 and K2 amputee level (n=30)
Reid	2015	25588644	Two minute walk test		correlation strength (R squared)	0.87	Large	Yes	The 2MWt was strongly predictive of the 6MWt	K3 and K4 amputee level (n=56)

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60	nd	86	6-minute walk test	nd	Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	6MWT			Validity	Known group
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	At peak of prosthetic independence, no longer in rehab	167	6MWT			validity	construct
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	6MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Construct
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	6MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Construct
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	6MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Construct
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	6MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	6MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	6MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Reid	2015	25588644	Transfemoral (n=13), Transtibial (n=63), Syme (n=4), Knee disarticulation (n=3), Bilateral (n=3)	Multiple	60		86	6MWT		Use the 6MWT in LEAs to assess longer walking distance ability, since 6 min allow LEAs to achieve distances greater than 300 m	Validity	Convergent
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	6MWT			Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	6MWT			Reliability	Test-retest
Ginsberg, Rai...Marchese	2007				Adolescents and Young Adults			9 minute run walk	Total Overall Score		Validity	Known group/Discriminant

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Reid	2015	25588644	Two minute walk test		correlation strength (R squared)	0.82	Large	Yes	The 2MWt was strongly predictive of the 6MWt	Amputation aetiology: Vascular (n=21)
Reid	2015	25588644	Two minute walk test		correlation strength (R squared)	0.89	Large	Yes	The 2MWt was strongly predictive of the 6MWt	Amputation aetiology: Trauma (n=41)
Gailey	2002	11994800			MFCL levels in ability to ambulate	P value	0.001			
Gailey	2002	11994800			known groups b/w k level	p, 1 way anova	0.0001		Yes	
Reid	2015	25588644	Level of Amputation (K1+K2 vs K3 vs K4)		P	<0.0001		Yes	the results of the study also suggest that the 6MWt has good discriminative validity.	P-value based on ANOVA
Reid	2015	25588644	Aetiology of amputation (Diabetes vs Infection not related to diabetes vs Vascular disease vs Cancer vs Trauma and congenital)		P	<0.0001		Yes	the results of the study also suggest that the 6MWt has good discriminative validity.	P-value based on ANOVA
Reid	2015	25588644	Age >=50 vs <50		P	<0.0001		Yes	the results of the study also suggest that the 6MWt has good discriminative validity.	
Reid	2015	25588644	Male vs female		P	0.24		No	As has been shown in previous examinations of the 6MWt, men walked further than women, this result was not statistically significant in the present study.	
Reid	2015	25588644	Timed up and go		Pearson r	-0.72	Large	Yes	Adequate to excellent correlation between the 6MWt and previously validated measures of ambulation in lower extremity amputees	
Reid	2015	25588644	Locomotor Capabilities Index version 5		Pearson r	0.61	Large	Yes	Adequate to excellent correlation between the 6MWt and previously validated measures of ambulation in lower extremity amputees	
Reid	2015	25588644	Houghton		Pearson r	0.57	Large	Yes	Adequate to excellent correlation between the 6MWt and previously validated measures of ambulation in lower extremity amputees	
Reid	2015	25588644	Activity-Specific Balance Confidence scale		Pearson r	0.6	Large	Yes	Adequate to excellent correlation between the 6MWt and previously validated measures of ambulation in lower extremity amputees	
Resnik	2011		NA		MDC90	147.5				
Resnik	2011		NA		ICC (95% CI)	0.97 (0.95, 0.99)				
Ginsberg, Rai...Marchese	2007									AK amputees had lower scores than BK amputees (no statistical analyses).



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Marchese, Rai, Carlson et al	2007					Both Children and adult amputees together		9 minute run walk	Total Overall Score		Reliability	Intra-rater
Marchese, Rai, Carlson et al	2007					Both Children and adult amputees together		9 minute run walk	Total Overall Score		Reliability	Inter-rater
Marchese, Rai, Carlson et al	2007					Both Children and adult amputees together		9 minute run walk	Total Overall Score		Validity	Construct
Marchese, Rai, Carlson et al	2007					Both Children and adult amputees together		9 minute run walk	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Walker	2009		Syme or Boyd amputation	fibular deficiency	32.5		36	AAOS Lower Limb Module			Validity	Known group
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AAS			Validity	Known group
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AAS			validity	construct
Panesar	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67		34	AAS		Amputee Activity Score: Ability to measure change	Responsiveness	nd
Panesar	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67		34	AAS		Amputee Activity Score: Ability to measure change	Responsiveness	nd
Panesar	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67		34	AAS		Amputee Activity Score	Validity	Convergent
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	ABC	nd	16-item instrument that measures respondents' confidence in performing basic ambulatory activities	Reliability	test-retest
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	ABC	nd	16-item instrument that measures respondents' confidence in performing basic ambulatory activities	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	ABC	nd	16-item instrument that measures respondents' confidence in performing basic ambulatory activities	MDC	
Kelly	2016	27756174	U below knee 703, B below knee 135, U above knee 383, B above knee 70	dysvas 546, trauma 666, infection 44, congenital 20, multiple 15	54.3 (13.7)	nd	1291	ABC	nd	16-item self-report measure that asks people to rate their confidence in performing various ambulatory activities	validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Marchese, Rai, Carlson et al	2007									ICCs between 0.93 and 1.00 for healthy sample and 0.97 and 0.99 for patients
Marchese, Rai, Carlson et al	2007									ICCs between 0.93 and 1.00 for healthy sample and 0.97 and 0.99 for patients
Marchese, Rai, Carlson et al	2007									walk distance increased over time (6, 12, 18 months) for small group with limb sparing surgery
Marchese, Rai, Carlson et al	2007									Spearman: MSTS function=0.45, MSTS walking=0.44, MSTS gait=0.52. Pearsons: SF36 PF=0.49, SF36 RP=0.43, TESS=0.50
Walker	2009		amputees vs lengthening for fibular deficiency				provided in the appendix (not retrieved)			no significant differences between the amputation and limb-lengthening groups
Gailey	2002	11994800			MFCL levels in ability to ambulate	P value	0.001			
Gailey	2002	11994800	known groups b/w k level			p, 1 way anova	0.0001		yes	
Panesar	2001					P value	<0.00001			significant changes between admission and discharge
Panesar	2001					P value	<0.0001			significant changes between discharge and follow-up
Panesar	2001		OPCS, AAS, FIM			P value	<0.0001			significant kendal correlations coefficients between each of the measures
Hafner	2016	28273329				ICC	0.95			retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329				MDC 90	0.49			retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329				MDC 95	0.58			retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Kelly	2016	27756174	number of co-morbidities			P val, multiple linear regression	0.0002	Yes	The ABC shows construct validity for co-morbidities	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Kelly	2016	27756174	U below knee 703, B below knee 135, U above knee 383, B above knee 70	dysvas 546, trauma 666, infection 44, congenital 20, multiple 15	54.3 (13.7)	nd	1291	ABC	nd	16-item self-report measure that asks people to rate their confidence in performing various ambulatory activities	validity	Construct
Kelly	2016	27756174	U below knee 703, B below knee 135, U above knee 383, B above knee 70	dysvas 546, trauma 666, infection 44, congenital 20, multiple 15	54.3 (13.7)	nd	1291	ABC	nd	16-item self-report measure that asks people to rate their confidence in performing various ambulatory activities	validity	Construct
Kelly	2016	27756174	U below knee 703, B below knee 135, U above knee 383, B above knee 70	dysvas 546, trauma 666, infection 44, congenital 20, multiple 15	54.3 (13.7)	nd	1291	ABC	nd	16-item self-report measure that asks people to rate their confidence in performing various ambulatory activities	validity	Construct
Sakakibara	2011	21704978	Trans tibial (n=1299), Transfemoral (n=112), Bilateral (n=121), Other (n=16)	Vascular (n=276), Trauma (n=122), Cancer (n=20), Other (n=30)	68.1	At least 19 years old, had a major unilateral amputation, used their prosthesis on a daily basis for at least 6 months, and lived in the community	448	ABC	nd	Modified response scale (Four-, 5-, and 6-response formats). Response options from the original 101-point format were grouped so that each revised response option was chosen by at least 10 participants	Validity	Content
Wong	2016	26390393	TT (n=22), TF (n=13), BTT (n=2), BTT/BFT (n=2), BFT/BTT (n=1)	vascular (28), nonvascular (12)	57.0 +- 11.9	nd	40	ABC	nd	The Activities-specific Balance Confidence (ABC) scale assessed balance confidence as self-reported by the prosthetic user. The ABC reports percentage values describing the individual's subjective confidence in maintaining balance when performing 16 activities that represent a hierarchy of difficulty without redundancy	Validity	predictive
Wong	2016	26390393	TT (n=22), TF (n=13), BTT (n=2), BTT/BFT (n=2), BFT/BTT (n=1)	vascular (28), nonvascular (12)	57.0 +- 11.9	nd	40	ABC	nd		Validity	predictive
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	ABC		16-item instrument that measures respondents' confidence in performing basic ambulatory activities	Reliability	test-retest
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	ABC		16-item instrument that measures respondents' confidence in performing basic ambulatory activities	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	ABC		16-item instrument that measures respondents' confidence in performing basic ambulatory activities	MDC	
Kelly	2016	27756174	U below knee 703, B below knee 135, U above knee 383, B above knee 70	dysvas 546, trauma 666, infection 44, congenital 20, multiple 15	54.3 (13.7)	nd	1291	ABC		16-item self-report measure that asks people to rate their confidence in performing various ambulatory activities	validity	Construct
Kelly	2016	27756174	U below knee 703, B below knee 135, U above knee 383, B above knee 70	dysvas 546, trauma 666, infection 44, congenital 20, multiple 15	54.3 (13.7)	nd	1291	ABC		16-item self-report measure that asks people to rate their confidence in performing various ambulatory activities	validity	Construct
Kelly	2016	27756174	U below knee 703, B below knee 135, U above knee 383, B above knee 70	dysvas 546, trauma 666, infection 44, congenital 20, multiple 15	54.3 (13.7)	nd	1291	ABC		16-item self-report measure that asks people to rate their confidence in performing various ambulatory activities	validity	Construct
Kelly	2016	27756174	U below knee 703, B below knee 135, U above knee 383, B above knee 70	dysvas 546, trauma 666, infection 44, congenital 20, multiple 15	54.3 (13.7)	nd	1291	ABC		16-item self-report measure that asks people to rate their confidence in performing various ambulatory activities	validity	Construct
Miller	2003	12736877	Transfemoral (n=12), Transtibial (n=38)	Vascular (n=29), Nonvascular (n=21)	58		50	ABC			Reliability	internal consistency
Miller	2003	12736877	Transfemoral (n=12), Transtibial (n=38)	Vascular (n=29), Nonvascular (n=21)	58		50	ABC			Reliability	Test-retest

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Kelly	2016	27756174	bilat or unilat		P val, multiple linear regression	0.0002		Yes	the ABC shows construct validity for the number of amputated limbs	
Kelly	2016	27756174	amp level		P val, multiple linear regression	<0.0001		Yes	The ABC shows construct validity for the level of amputation	
Kelly	2016	27756174	etiology		P val, multiple linear regression	<0.0001		Yes	the ABC shows construct validity for amp etiology	
Sakakibara	2011	21704978	nd		nd	nd		Yes	The findings in this study support the internal consistency reliability and validity of the ABC Scale with a 5-option response format	
Wong	2016	26390393	predict community ambulation		AUC	0.927		y		
Wong	2016	26390393	predict failure to reach community ambulation	12 months	AUC	0.927		y	cut off score 65%	The Activities-specific Balance Confidence (ABC) scale assessed balance confidence as selfreported by the prosthetic user. The ABC reports percentage values describing the individual's subjective confidence in maintaining balance when performing 16 activities that represent a hierarchy of difficulty without redundancy
Hafner	2016	28273329			ICC	0.95				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			MDC 90	0.49				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			MDC 95	0.58				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Kelly	2016	27756174	number of co-morbidities		P val, multiple linear regression	0.0002		Yes	The ABC shows construct validity for co-morbidities	
Kelly	2016	27756174	bilat or unilat		P val, multiple linear regression	0.0002		Yes	the ABC shows construct validity for the number of amputated limbs	
Kelly	2016	27756174	amp level		P val, multiple linear regression	<0.0001		Yes	The ABC shows construct validity for the level of amputation	
Kelly	2016	27756174	etiology		P val, multiple linear regression	<0.0001		Yes	the ABC shows construct validity for amp etiology	
Miller	2003	12736877	nd		Chronbach Alpha	0.93		Yes		
Miller	2003	12736877	nd		ICC	0.91		Yes		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Miller	2003	12736877	Transfemoral (n=86), Transtibial (n=243)	Nonvascular (n=174)	59.9		329	ABC			Validity	Construct
Miller	2003	12736877	Transfemoral (n=86), Transtibial (n=243)	Nonvascular (n=174)	59.9		329	ABC			Validity	Construct
Miller	2003	12736877	Transfemoral (n=86), Transtibial (n=243)	Nonvascular (n=174)	59.9		329	ABC			Validity	Construct
Miller	2003	12736877	Transfemoral (n=86), Transtibial (n=243)	Nonvascular (n=174)	59.9		329	ABC			Validity	Construct
Miller	2003	12736877	Transfemoral (n=86), Transtibial (n=243)	Nonvascular (n=174)	59.9		329	ABC			Validity	Convergent
Miller	2003	12736877	Transfemoral (n=86), Transtibial (n=243)	Nonvascular (n=174)	59.9		329	ABC			Validity	Convergent
Sakakibara	2011	21704978	Transtibial (n=1299), Transfemoral (n=112), Bilateral (n=121), Other (n=16)	Vascular (n=276), Trauma (n=122), Cancer (n=20), Other (n=30)	68.1	At least 19 years old, had a major unilateral amputation, used their prosthesis on a daily basis for at least 6 months, and lived in the community	448	ABC		Modified response scale (Four-, 5-, and 6-response formats ). Response options from the original 101-point format were grouped so that each revised response option was chosen by at least 10 participants	Validity	Content
Gallagher	2007	17314705	Below knee (n=73), Through knee (n=3), Above knee (n=52), Bilateral (n=17)	PVD (n=40), Diabetes/PVD (n=38), Accident/trauma (n=37), Infection (n=8), Cancer (n=7), Clot (n=4), Other (n=11)	60.5		145	ABIS			Reliability	Internal consistency
Gallagher	2007	17314705	Below knee (n=73), Through knee (n=3), Above knee (n=52), Bilateral (n=17)	PVD (n=40), Diabetes/PVD (n=38), Accident/trauma (n=37), Infection (n=8), Cancer (n=7), Clot (n=4), Other (n=11)	60.5		145	ABIS			Reliability	Internal consistency
Gallagher	2007	17314705	Below knee (n=73), Through knee (n=3), Above knee (n=52), Bilateral (n=17)	PVD (n=40), Diabetes/PVD (n=38), Accident/trauma (n=37), Infection (n=8), Cancer (n=7), Clot (n=4), Other (n=11)	60.5		145	ABIS			Reliability	Internal consistency
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)	nd	38	ABIS-R	depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)	nd	38	ABIS-R	depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)	nd	38	ABIS-R	depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)	nd	38	ABIS-R	depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)	nd	38	ABIS-R	depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)	nd	38	ABIS-R	depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	66.4		38	ABIS-R	Depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	66.4		38	ABIS-R	Depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	66.4		38	ABIS-R	Depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	66.4		38	ABIS-R	Depression		Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Miller	2003	12736877	Transtibial vs Transfemoral		ttest p	>=0.05		No		
Miller	2003	12736877	Vascular vs Other		ttest p	<0.05		Yes		
Miller	2003	12736877	Mobility device use yes vs no		ttest p	<0.05		Yes		
Miller	2003	12736877	Automatic stepping yes vs no		ttest p	<0.05		Yes		
Miller	2003	12736877	2MWT		Pearson r	0.72		Yes		
Miller	2003	12736877	TUG		Pearson r	-0.72		Yes		
Sakakibara	2011	21704978	nd		nd	nd		Yes	The findings in this study support the internal consistency reliability and validity of the ABC Scale with a 5-option response format	
Gallagher	2007	17314705				Cronbach's alpha	0.9	Large		
Gallagher	2007	17314705				Spearman's r	0.3-0.74	Moderate to large		
Gallagher	2007	17314705				Kaiser-Meyer-Okin measure	0.87	Large		
Coffey	2009	19900240	TAPES general adjustment		Spearman r	-0.48				
Coffey	2009	19900240	TAPES social adjustment		Spearman r	-0.51				
Coffey	2009	19900240	TAPES adjustment to limmitations		Spearman r	-0.45				
Coffey	2009	19900240	TAPES social restriction		Spearman r	0.44				
Coffey	2009	19900240	TAPES weight satisfaction		Spearman r	-0.36				
Coffey	2009	19900240	TAPES functional satisfaction		Spearman r	-0.46				
Coffey	2009	19900240	TAPES general adjustment		Spearman r	-0.48				
Coffey	2009	19900240	TAPES social adjustment		Spearman r	-0.51				
Coffey	2009	19900240	TAPES adjustment to limmitations		Spearman r	-0.45				
Coffey	2009	19900240	TAPES social restriction		Spearman r	0.44				

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	66.4		38	ABIS-R	Depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	66.4		38	ABIS-R	Depression		Validity	Convergent
Gallagher	2007	17314705	Below knee (n=73), Through knee (n=3), Above knee (n=52), Bilateral (n=17)	PVD (n=40), Diabetes/PVD (n=38), Accident/trauma (n=37), Infection (n=8), Cancer (n=7), Clot (n=4), Other (n=11)	60.5		145	ABIS-R			Reliability	Internal consistency
Gallagher	2007	17314705	Below knee (n=73), Through knee (n=3), Above knee (n=52), Bilateral (n=17)	PVD (n=40), Diabetes/PVD (n=38), Accident/trauma (n=37), Infection (n=8), Cancer (n=7), Clot (n=4), Other (n=11)	60.5		145	ABIS-R			Reliability	Internal consistency
Gallagher	2007	17314705	Below knee (n=73), Through knee (n=3), Above knee (n=52), Bilateral (n=17)	PVD (n=40), Diabetes/PVD (n=38), Accident/trauma (n=37), Infection (n=8), Cancer (n=7), Clot (n=4), Other (n=11)	60.5		145	ABIS-R			Reliability	Internal consistency
Gallagher	2007	17314705	Below knee (n=73), Through knee (n=3), Above knee (n=52), Bilateral (n=17)	PVD (n=40), Diabetes/PVD (n=38), Accident/trauma (n=37), Infection (n=8), Cancer (n=7), Clot (n=4), Other (n=11)	60.5		145	ABIS-R			Reliability	Internal consistency
Theeven	2010	20809056	Unilateral transfemoral (n=20)	Trauma (n=12), Vascular (n=6), cancer (n=2)	50.3	Age 18–75 years; use of an upper leg prosthesis; completion of the rehabilitation programme; ability to walk at least 500 m	20	ADAPT	nd	A test involving a selection of those circuit stations that best simulate daily life situations.	Reliability	Test-retest
Theeven	2010	20809056	Unilateral transfemoral (n=20)	Trauma (n=12), Vascular (n=6), cancer (n=2)	50.3	Age 18–75 years; use of an upper leg prosthesis; completion of the rehabilitation programme; ability to walk at least 500 m	20	ADAPT		A test involving a selection of those circuit stations that best simulate daily life situations.	Reliability	Test-retest
Lerner	1991		Transtibial	Trauma	41.5	nd	20	AIMS-modified	Health perception		Validity	Known group
Lerner et al.	1991		Transtibial	Trauma	41.5	nd	20	AIMS-modified	Health perception		Validity	Known group
Lerner	1991		Transtibial	Trauma	41.5	nd	20	AIMS-modified	Pain		Validity	Known group
Lerner et al.	1991		Transtibial	Trauma	41.5	nd	20	AIMS-modified	Pain		Validity	Known group

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Coffey	2009	19900240	TAPES weight satisfaction		Spearman r	-0.36				
Coffey	2009	19900240	TAPES functional satisfaction		Spearman r	-0.46				
Gallagher	2007	17314705				item separation index	4.59			
Gallagher	2007	17314705				item separation reliability	0.95			
Gallagher	2007	17314705				person separation index	2.33			
Gallagher	2007	17314705				person separation reliability	0.84			
Theeven	2010	20809056	nd		Pearson r	0.69 to 0.96		Yes	The results of this study indicate that it is feasible to objectively measure functional abilities in daily life in transfemoral amputees using the concept of simulated daily life situations. Further research is necessary to establish the psychometric properties of the final ADAPT test.	All correlation coefficients (Pearson's r) exceeded 0.80, except for activity 13c (r = 0.69)
Theeven	2010	20809056	nd		Pearson r	0.69 to 0.96		Yes	The results of this study indicate that it is feasible to objectively measure functional abilities in daily life in transfemoral amputees using the concept of simulated daily life situations. Further research is necessary to establish the psychometric properties of the final ADAPT test.	All correlation coefficients (Pearson's r) exceeded 0.80, except for activity 13c (r = 0.69)
Lerner	1991				P	<0.05				Persons with osteomyelitis had worse perceived health than those with fracture non-union and amputation.
Lerner et al.	1991									Persons with osteomyelitis had worse perceived health than those with fracture non-union and amputation.
Lerner	1991				P	<0.05				Higher pain scores observed for patients with fracture non-union and osteomyelitis as compared to amputees.
Lerner et al.	1991									Higher pain scores observed for patients with fracture non-union and osteomyelitis as compared to amputees.



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Walker et al,	2009		Syme or Boyd amputation	fibular deficiency	32.5	nd	36	American Academy of Orthopaedic Surgeons Lower Limb Module	nd		Validity	Known group
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		Validity	Convergent
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		validity	construct
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		validity	construct
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		validity	construct
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		validity	convergent
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		validity	convergent
Gailey	2002	11994800	UTT (10), UTF (8), Bi (6)	disease (19), trauma (5)	68.3 +- 17.8	18-100	24	AMP	AMPnoPRO		reliability	interrater
Gailey	2002	11994800	UTT (10), UTF (8), Bi (6)	disease (19), trauma (5)	68.3 +- 17.8	18-100	24	AMP	AMPnoPRO		reliability	intrater
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPnoPRO	Without Prosthesis	Validity	Concurrent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPnoPRO	Without Prosthesis	Validity	Concurrent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPnoPRO	Without Prosthesis	Validity	Concurrent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPnoPRO	Without Prosthesis	Validity	Concurrent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPnoPRO	Without Prosthesis	Validity	Known group

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Walker et al,	2009		amputees vs lengthening for fibular deficiency			p[rovided in the appendix (not retrieved)				no significant differences between the amputation and limb-lengthening groups
Gailey	2002	11994800	6MWT		Pearson product moment correlation	0.694		yes		multiple regression
Gailey	2002	11994800	known groups b/w k level			p, 1 way anova	0.0001		Yes	
Gailey	2002	11994800	time since amp			pearson r	0.263	small	unclear	
Gailey	2002	11994800	comorbidities			pearson r	-0.378	moderate	yes	
Gailey	2002	11994800	6MWT			pearson r	0.818	large	yes	
Gailey	2002	11994800	AAS			pearson r	0.768	large	yes	
Gailey	2002	11994800				ICC	0.99		Yes	The AMPnoPRO shows excellent interrater reliability
Gailey	2002	11994800				ICC	0.86 - 0.97		Yes	The AMPnoPRO shows excellent intrarater reliability
Gailey	2002	11994800			AAS	Pearson r	0.667			
Gailey	2002	11994800			Comorbidity index	Pearson r	-0.433			
Gailey	2002	11994800			Age	Pearson r	-0.686			
Gailey	2002	11994800			Time since amputation	Pearson r	0.292			
Gailey	2002	11994800			MFCL levels in ability to ambulate	Pearson r	0.001			

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPnoPRO		Reliability	Inter-rater
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPnoPRO		Reliability	Intra-rater
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPnoPRO		Validity	Concurrent
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		Validity	Convergent
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		validity	construct
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		validity	construct
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		validity	construct
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		validity	convergent
Gailey	2002	11994800	ankle (2), TT (82), KD (7), TF (67), hip disarticulation (7), transpelvic (2)	disease (76), trauma (61), tumor (24), congenital (6)	54.84 +- 18.6	18-100	167	AMP	AMPnoPRO		validity	convergent
Gailey	2002	11994800	UTT (10), UTF (8), Bi (6)	disease (19), trauma (5)	68.3 +- 17.8	18-100	24	AMP	AMPnoPRO		Reliability	interrater
Gailey	2002	11994800	UTT (10), UTF (8), Bi (6)	disease (19), trauma (5)	68.3 +- 17.8	18-100	24	AMP	AMPnoPRO		Reliability	intrarater
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPnoPRO		Reliability	Inter-rater
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPnoPRO		Reliability	Intra-rater

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Gailey	2002	11994800			ICC	0.99	Excellent			Among subgroup of n=26
Gailey	2002	11994800			ICC	0.97	Excellent			Among subgroup of n=27
Gailey	2002	11994800			6-min walk test	Pearson r	0.694			
Gailey	2002	11994800	6MWT		Pearson product moment correlation	0.818		yes		multiple regression
Gailey	2002	11994800	known groups b/w k level			p, 1 way anova	0.0001		Yes	
Gailey	2002	11994800	time since amp			pearson r	0.292	small	unclear	
Gailey	2002	11994800	comorbidities			pearson r	-0.433	moderate	yes	
Gailey	2002	11994800	6MWT			pearson r	0.694	large	yes	
Gailey	2002	11994800	AAS			pearson r	0.667	large	yes	
Gailey	2002	11994800			ICC	0.99			Yes	The AMPPRO shows excellent interrater reliability
Gailey	2002	11994800			ICC	0.96 - 0.98			Yes	The AMPPRO shows excellent intrarater reliability
Gailey	2002	11994800			ICC	0.99	Excellent			Among subgroup of n=24
Gailey	2002	11994800			ICC	0.96	Excellent			Among subgroup of n=25

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPPRO		Validity	Concurrent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPPRO		Validity	Concurrent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPPRO		Validity	Concurrent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPPRO		Validity	Concurrent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPPRO		Validity	Concurrent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPPRO		Validity	Concurrent
Gailey	2002	11994800	Ankle disarticulation (n=2) Transtibial (n=82), Knee disarticulation (n=7), Transfemoral (n=67), Hip disarticulation (n=7), Transpelvic (n=2)	Disease (n=76), Trauma (n=61), Tumor (n=24), Congenital (n=6)	54.8	At peak of prosthetic independence, no longer in rehab	167	AMP	AMPPRO		Validity	Known group
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	AMP	Total		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	AMP	Total		Reliability	Test-retest
Norvell	2016	27496697	transmetatarsal (26), transtibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM	nd	Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Criterion validity (concurrent)
Norvell	2016	27496697	transmetatarsal (26), transtibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM	nd	Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Criterion validity (concurrent)
Norvell	2016	27496697	transmetatarsal (26), transtibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM	nd	Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Criterion validity (concurrent)

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Gailey	2002	11994800			6-min walk test	Pearson r	0.818			
Gailey	2002	11994800			AAS	Pearson r	0.768			
Gailey	2002	11994800			Comorbidity index	Pearson r	-0.378			
Gailey	2002	11994800			Age	Pearson r	-0.594			
Gailey	2002	11994800			Time since amputation	Pearson r	0.263			
Gailey	2002	11994800			MFCL levels in ability to ambulate	P value	0.001			
Resnik	2011		NA		MDC90	3.4				
Resnik	2011		NA		ICC (95% CI)	0.88 (0.79, 0.93)				
Norvell	2016	27496697	LCI-5		Spearman r	0.72	large	Yes	AMPSIMM is concurrently valid with LCI-5	6 weeks, total sample included transmetatarsal
Norvell	2016	27496697	LCI-5		Spearman r	0.81	large	Yes	AMPSIMM is concurrently valid with LCI-5	4 months, total sample included transmetatarsal
Norvell	2016	27496697	LCI-5		Spearman r	0.86	large	Yes	AMPSIMM is concurrently valid with LCI-5	12 months, total sample included transmetatarsal



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Norvell	2016	27496697	6 week AMPSIMM vs 12 month LCI-5		Spearman r	0.07	<small	no (p = 0.56)	6 week AMPSIMM scores are not predictive of 12 month LCI-5 scores	total sample included transmetatarsal
Norvell	2016	27496697	4 month AMPSIMM vs 12 month LCI-5		Spearman r	0.4	Moderate	yes (p = 0.004)	4 month AMPSIMM scores are moderately predictive of LCI-5 score at 12 months	
Norvell	2016	27496697	AMPSIMM vs prosthetic use @ 4 months		P. spearman r	<0.001		y	There is sufficient evidence of construct validity of the AMPSIMM with prosthetic use at 4 months	
Norvell	2016	27496697	AMPSIMM vs prosthetic use @ 12 months		P. spearman r	<0.001		y	There is sufficient evidence of construct validity of the AMPSIMM with prosthetic use at 12 months	
Norvell	2016	27496697	AMPSIMM vs TAPES @ 4 months		P. spearman r	0.003		y	There is sufficient evidence of construct validity of the AMPSIMM with TAPES at 4 months	
Norvell	2016	27496697	AMPSIMM vs TAPES @ 12 months		P. spearman r	<0.001		y	There is sufficient evidence of construct validity of the AMPSIMM with TAPES at 12 months	
Norvell	2016	27496697	AMPSIMM vs Satisfaction w/ mobility @ 4 months		P. spearman r	<0.001		y	There is sufficient evidence of construct validity of the AMPSIMM with "satisfaction with mobility" at 4 months	
Norvell	2016	27496697	AMPSIMM vs Satisfaction w/ mobility @ 12 months		P. spearman r	<0.001		y	There is sufficient evidence of construct validity of the AMPSIMM with "satisfaction with mobility" at 12 months	
Norvell	2016	27496697	known groups (metatarsal vs tibial vs femoral)		SRM	1	large	yes		no actual p but authors present different means for each level of amputation
Norvell	2016	27496697			nd	nd		No	Two subjects (2.4%) achieved a minimum score and five (6.1%) achieved a maximum score at 12 months post-amputation, indicating neither a floor or ceiling.	
Norvell	2016	27496697	AMPSIMM vs prosthetic use @ 4 months		P. spearman r	<0.001		y	There is sufficient evidence of construct validity of the AMPSIMM with prosthetic use at 4 months	
Norvell	2016	27496697	AMPSIMM vs prosthetic use @ 12 months		P. spearman r	<0.001		y	There is sufficient evidence of construct validity of the AMPSIMM with prosthetic use at 12 months	
Norvell	2016	27496697	AMPSIMM vs TAPES @ 4 months		P. spearman r	0.003		y	There is sufficient evidence of construct validity of the AMPSIMM with TAPES at 4 months	
Norvell	2016	27496697	AMPSIMM vs TAPES @ 12 months		P. spearman r	<0.001		y	There is sufficient evidence of construct validity of the AMPSIMM with TAPES at 12 months	



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Norvell	2016	27496697	transmetatarsal (26), transibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	27	AMPSIMM		Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Construct
Norvell	2016	27496697	transmetatarsal (26), transibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	47	AMPSIMM		Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Construct
Norvell	2016	27496697	transmetatarsal (26), transibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM		Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Construct
Norvell	2016	27496697	transmetatarsal (26), transibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM		Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Criterion validity (concurrent)
Norvell	2016	27496697	transmetatarsal (26), transibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM		Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Criterion validity (concurrent)
Norvell	2016	27496697	transmetatarsal (26), transibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM		Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Criterion validity (concurrent)
Norvell	2016	27496697	transmetatarsal (26), transibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM		Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Criterion validity (predictive)
Norvell	2016	27496697	transmetatarsal (26), transibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM		Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	Criterion validity (predictive)
Norvell	2016	27496697	transmetatarsal (26), transibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM		Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Validity	floor/ceiling
Norvell	2016	27496697	transmetatarsal (26), transibial (59), transfemoral (28)	nd	63.5 +- 8.1	>=18, awaiting/underwent amp in last week, primary cause of amp diabetes or peripheral arterial disease	113	AMPSIMM		Amputee Single Item Mobility Measure is a single item measure with scores ranging from 0-6 and is concurrently administered with the LCI-5 other outcome measures at 6 weeks, 4 months, and 12 months post-amputation	Responsiveness	
Panesar et al.	2001		Transfemoral (n=17), transibial (n=14), hindquarter (n=1), bilateral transibial (n=1), bilateral transfemoral (n=1)	nd	67	nd	34	Amputee Activity Score (AAS)	Total Overall Scale		Validity	Convergent
Panesar et al.	2001		Transfemoral (n=17), transibial (n=14), hindquarter (n=1), bilateral transibial (n=1), bilateral transfemoral (n=1)	nd	67	nd	34	Amputee Activity Score (AAS)	Total Overall Scale		Ability to measure change	Responsiveness
Panesar et al.	2001		Transfemoral (n=17), transibial (n=14), hindquarter (n=1), bilateral transibial (n=1), bilateral transfemoral (n=1)	nd	67	nd	34	Amputee Activity Score (AAS)	Total Overall Scale		Ability to measure change	Responsiveness
Gailey, Roach et. Al.	2002							Amputee Mobility Predictor (AMP)	AMPnoPRO		Reliability	Test-retest
Gailey, Roach et. Al.	2002							Amputee Mobility Predictor (AMP)	AMPnoPRO		Reliability	Inter-rater



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Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Gailey, Roach et. Al.	2002							Amputee Mobility Predictor (AMP)	AMPnoPRO		Validity	Known group/Discriminant
Gailey, Roach et. Al.	2002							Amputee Mobility Predictor (AMP)	AMPnoPRO		Validity	Concurrent/convergent/criteria Validity criterion
Gailey, Roach et. Al.	2002							Amputee Mobility Predictor (AMP)	AMPnoPRO		Validity	Predictive
Hafner	2007						17	Amputee Mobility Predictor (AMP)	Total Overall Score		Ability to measure change	Responsiveness
Topuz	2011							Amputee Mobility Predictor (AMP)	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Gailey, Roach et. Al.	2002							Amputee Mobility Predictor (AMP)	with prosthesis (AMPPRO)		Reliability	Test-retest
Gailey, Roach et. Al.	2002							Amputee Mobility Predictor (AMP)	with prosthesis (AMPPRO)		Reliability	Inter-rater
Gailey, Roach et. Al.	2002							Amputee Mobility Predictor (AMP)	with prosthesis (AMPPRO)		Validity	Known group/Discriminant
Gailey, Roach et. Al.	2002							Amputee Mobility Predictor (AMP)	with prosthesis (AMPPRO)		Validity	Concurrent/convergent/criteria Validity criterion
Gailey, Roach et. Al.	2002							Amputee Mobility Predictor (AMP)	with prosthesis (AMPPRO)		Validity	Predictive
Resnik and Borgia	2011							Amputee Mobility Predictor (AMP)	with prosthesis (AMPPRO)		Reliability	Test-retest
Miller et al	2008		Transfemoral (n=21), Transtibial (n=37)	cardiovascular or diabetic complications (n=29), trauma (n=13), infection (n=8), other (n=8)	66.4	Unilateral	58	AQoL	Total Overall Score		Validity	Concurrent/convergent criterion
Brunelli	2006	16813789	Unilateral transfemoral	Amputation for vascular disease and mild or moderate hemiparesis	69	nd	45	Barthel Index	Total Overall Score		Validity	Known group/Discriminant
Brunelli	2006	16813789	Unilateral transfemoral	Amputation for vascular disease and mild or moderate hemiparesis	69	nd	45	Barthel Index	Total Overall Score		Validity	Known group/Discriminant
Treweek	1998		Transfemoral (26%), transtibial (74%)	nd	67 (nd for Barthel Index)	nd	938 (n=546 for Barthel Index)	Barthel Index	Total Overall Score		Validity	Known group
Brunelli	2006	16813789	Unilateral transfemoral	Amputation for vascular disease and mild or moderate hemiparesis	69		45	Barthel Index			Validity	Known group/Discriminant
Brunelli	2006	16813789	Unilateral transfemoral	Amputation for vascular disease and mild or moderate hemiparesis	69		45	Barthel Index			Validity	Known group/Discriminant
Eijk	2012	21958418	Transfemoral (n=17), Transtibial (n=23), transgenual (n=5), hip disarticulation (n=1), minor amputation (n=2)	PAD (n=45), astreomyelitis (n=1), tumour (n=1), trauma (n=1)	75.2		48	Barthel index			Validity	Predictive
Treweek	1998		Transfemoral (26%), transtibial (74%)	nd	67 (nd for Barthel Index)		938 (n=546 for Barthel Index)	Barthel Index			Validity	Known group
Wong	2016	26390393	TT (n=22), TF (n=13), BTT (n=2), BTT/BFT (n=2), BFT/BTT (n=1)	vascular (28), nonvascular (12)	57.0 +- 11.9	nd	40	BBS	item 10: look behind/over shoulder	The BBS was used to measure physical balance ability. The BBS challenges static and dynamic balance in 14 tasks, each scored from 0 to 4 with the total score reported	Validity	predictive

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Gailey, Roach et. Al.	2002									differentiated between MFCL Medicare comon procedure coding system groups
Gailey, Roach et. Al.	2002									Pearsons: Age=-0.56, Time since Amputation=0.26, Comorb=-0.38, 6 min walk=0.82, AAS=0.77, pack years smoked=0.21
Gailey, Roach et. Al.	2002									significantly predicts 6 minute walk test in regression model.
Hafner	2007		Mechanical control prosthetic knee versus microprocessor control prosthetic knee							no significant differences between control technology
Topuz	2011									Spearman's: TAPES Activity=-0.30
Gailey, Roach et. Al.	2002									ICC 0.96-0.98
Gailey, Roach et. Al.	2002									ICC: 0.99
Gailey, Roach et. Al.	2002									differentiated between MFCL Medicare comon procedure coding system groups
Gailey, Roach et. Al.	2002									Pearsons: Age=-0.69, Time since Amputation=0.29, Comorb=-0.43, 6 min walk=0.69, AAS=0.67, pack years smoked=0.25
Gailey, Roach et. Al.	2002									significantly predicts 6 minute walk test in regression model
Resnik and Borgia	2011									ICC=0.88
Miller et al	2008									Overall scores were associated with a mini-nutritional assessment (which included questions on well-being), findings from multiple linear regression..
Brunelli	2006	16813789	Laterality of impairment: Ipsilateral vs Contralateral		P value	<0.001				
Brunelli	2006	16813789	Cause of amputation: Atherosclerosis vs Diabetes		P value	>0.05				
Treweek	1998									did not discriminate patients (mann-Whitney test) by amputation level (transtibial and transfemoral)
Brunelli	2006	16813789	Laterality of impairment: Ipsilateral vs Contralateral		P value	<0.001				
Brunelli	2006	16813789	Cause of amputation: Atherosclerosis vs Diabetes		P value	>0.05				
Eijk	2012	21958418	Successful rehabilitation	12 months	P value	<0.001				significantly correlated with Barthel index (Mannwhitney U); beta = .53
Treweek	1998									did not discriminate patients (mann-Whitney test) by amputation level (transtibial and transfemoral)
Wong	2016	26390393	predict community ambulation		AUC	0.875		y		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Wong	2016	26390393	TT (n=22), TF (n=13), BTT (n=2), BTT/BFT (n=2), BFT/BTT (n=1)	vascular (28), nonvascular (12)	57.0 +- 11.9		40	BBS	item 10: look behind/over shoulder		Validity	predictive
Wong	2016	26390393	TT (n=22), TF (n=13), BTT (n=2), BTT/BFT (n=2), BFT/BTT (n=1)	vascular (28), nonvascular (12)	57.0 +- 11.9	nd	40	BBS	item 9: retrieve object from floor	The BBS was used to measure physical balance ability. The BBS challenges static and dynamic balance in 14 tasks, each scored from 0 to 4 with the total score reported	Validity	predictive
Wong	2016	26390393	TT (n=22), TF (n=13), BTT (n=2), BTT/BFT (n=2), BFT/BTT (n=1)	vascular (28), nonvascular (12)	57.0 +- 11.9		40	BBS	item 9: retrieve object from floor		Validity	predictive
Gremeaux	2012	22389424	Transfemoral (n=17, transtibial (n=47)	Vascular (n=42), trauma (n=16), cancer (n=2), other (n=1)	58	unilateral	64	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Convergent
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Floor/ceiling effect	Ceiling
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Construct
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Construct
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Convergent
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Convergent
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Wong	2016	26390393	predict failure to reach community ambulation	12 months	AUC	0.875		y	cut off score <=3	The BBS was used to measure physical balance ability. The BBS challenges static and dynamic balance in 14 tasks, each scored from 0 to 4 with the total score reported
Wong	2016	26390393	predict community ambulation		AUC	0.771		y		
Wong	2016	26390393	predict failure to reach community ambulation	12 months	AUC	0.771		y	cut off score <=3	The BBS was used to measure physical balance ability. The BBS challenges static and dynamic balance in 14 tasks, each scored from 0 to 4 with the total score reported
Gremeaux	2012	22389424	nd			AUC	0.88			
Major	2013	23856150	nd		%	10		No	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	Transfemoral vs transtibial		P	0.325		No	The BBS was also unable to discriminate between groups on the basis of amputation etiology and level	Mann-Whitney U p-value
Major	2013	23856150	Dysvascular vs other		P	0.061		No	The BBS was also unable to discriminate between groups on the basis of amputation etiology and level	Mann-Whitney U p-value
Major	2013	23856150	ABC Scale		Spearman r	0.634	Large	Yes	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	PEQ-MS		Spearman r	0.584	Large	Yes	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	FAI		Spearman r	0.607	Large	Yes	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	2MWT		Spearman r	0.675	Large	Yes	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Convergent
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Floor/ceiling effect	Floor
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Internal Consistency
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	BBS		The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Reliability	Interrater
Walker et al,	2009		Syme or Boyd amputation	fibular deficiency	32.5	nd	36	Beck Depression Inventory-II	nd		Validity	Known group
Walker	2009		Syme or Boyd amputation	fibular deficiency	32.5		36	Beck Depression Inventory-II			Validity	Known group
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Convergent
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Convergent
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Convergent
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Convergent

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Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Major	2013	23856150	L Test		Spearman r	-0.802	Large	Yes	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	nd		%	0		No	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	nd		Cronbach's alpha	0.827		Yes	The BBS appears to be a valid and reliable clinical instrument for assessing balance in individuals with lower-limb amputation	
Major	2013	23856150	nd		ICC	0.945		Yes	The BBS appears to be a valid and reliable clinical instrument for assessing balance in individuals with lower-limb amputation	
Walker et al,	2009		amputees vs lengthening for fibular deficiency			p[rovided in the appendix (not retrieved)				no significant difference between the amputees and the patients treated with lengthening.
Walker	2009		amputees vs lengthening for fibular deficiency			p[rovided in the appendix (not retrieved)				no significant difference between the amputees and the patients treated with lengthening.
Major	2013	23856150	ABC Scale		Spearman r	0.634	Large	Yes	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	PEQ-MS		Spearman r	0.584	Large	Yes	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	FAI		Spearman r	0.607	Large	Yes	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	2MWT		Spearman r	0.675	Large	Yes	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	



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Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Convergent
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Floor/ceiling effect	Floor
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Floor/ceiling effect	Ceiling
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Construct
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Construct
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Reliability	Interrater
Major	2013	23856150	Unilateral transtibial (n=13), unilateral transfemoral (n=14), or bilateral (n=3)	Dysvascular (n=7), traumatic (n=14), infectious (n=6), congenital (n=3)	54	Used a prosthesis for ambulation with or without an additional mobility aid; did not have an upper-extremity amputation; had a residual limb in good condition	30	Berg Balance Scale	nd	The Berg Balance Scale (BBS) is a well-established clinical outcome measure originally designed to assess the balance of elderly individuals	Validity	Internal Consistency
Berry	2009		Unilateral transfemoral		54.7	K3	368	Berry 50-question survey	Gait/ maneuverability	Ability to measure change	Responsiveness	
Berry	2009		Unilateral transfemoral	in article	54.7	K3	368	Berry 50-question survey	Gait/ maneuverability		Reliability	Test-retest
Berry, Olson and Lartzt	2009	0	Unilateral transfemoral	nd	54.7	K3	368	Berry 50-question survey	gait/ maneuverability		Reliability	Test-retest
Berry, Olson and Lartzt	2009	0	Unilateral transfemoral	nd	54.7	K3	368	Berry 50-question survey	gait/ maneuverability		Ability to measure change	Responsiveness
Hanspal	1997	9331580	Transfemoral (n=17), Transtibial (n=15)	nd	66.4		32	CAPE			Validity	Predictive
Hanspal	1997	9331580	Transfemoral (n=17), Transtibial (n=15)	nd	66.4		32	CAS			Validity	Predictive

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Major	2013	23856150	L Test		Spearman r	-0.802	Large	Yes	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	nd		%	0		No	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	nd		%	10		No	The BBS demonstrated monotonic relationships with the other outcome measures that assess constructs related to balance and mobility, providing evidence that the BBS does assess balance in persons with LLA	
Major	2013	23856150	Transfemoral vs transtibial		P	0.325		No	The BBS was also unable to discriminate between groups on the basis of amputation etiology and level	Mann-Whitney U p-value
Major	2013	23856150	Dysvascular vs other		P	0.061		No	The BBS was also unable to discriminate between groups on the basis of amputation etiology and level	Mann-Whitney U p-value
Major	2013	23856150	nd		ICC	0.945		Yes	The BBS appears to be a valid and reliable clinical instrument for assessing balance in individuals with lower-limb amputation	
Major	2013	23856150	nd		Cronbach's alpha	0.827		Yes	The BBS appears to be a valid and reliable clinical instrument for assessing balance in individuals with lower-limb amputation	
Berry	2009								significantly better scores with C-Leg then past nonmicroprocessor controlled device	
Berry	2009									94% of questions were answered with identical scores on both surveys, and 6% of questions had a 1 point difference in response (scale of 1-5)
Berry, Olson and Lartz	2009	0								94% of questions were answered with identical scores on both surveys, and 6% of questions had a 1 point difference in response (scale of 1-5)
Berry, Olson and Lartz	2009	0								significantly better scores with C-Leg then past nonmicroprocessor controlled device
Hanspal	1997	9331580	Clifton Assessment Procedures for the Elderly	8-14 months		Pearson r	0.93	Large		Clifton Assessment Procedures for the Elderly
Hanspal	1997	9331580	Grade of mobility	8-14 months	Pearson r	0.81	Large			

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
de Laat	2010		Transfemoral (n=55), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=143), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	172	Climbing Stairs Questionnaire			Reliability	Test-retest
de Laat	2010		Transfemoral (n=55), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=143), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	172	Climbing Stairs Questionnaire			Validity	Convergent
de Laat	2010		Transfemoral (n=55), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=143), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	172	Climbing Stairs Questionnaire			Validity	Convergent
de Laat	2010		Transfemoral (n=55), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=143), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	172	Climbing Stairs Questionnaire			Validity	Convergent
de Laat	2010		Transfemoral (n=55), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=143), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	172	Climbing Stairs Questionnaire			Validity	Known group
de Laat	2010		Transfemoral (n=55), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=143), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	172	Climbing Stairs Questionnaire			Validity	Known group

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
de Laat	2010				nd	ICC	0.79			data from 33 participants
de Laat	2010				Locomotor Capabilities Index (LCI-4)	Spearman r	0.52			
de Laat	2010				The Rising and Sitting down Questionnaire	Spearman r	0.52			
de Laat	2010				The Walking Questionnaire	Spearman r	0.42			
de Laat	2010				Vascular vs Nonvascular	Mann-Whitney U P value	0.6			
de Laat	2010				Bilateral vs Unilateral	Mann-Whitney U P value	0.09			

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
de Laat	2010		Transfemoral (n=55), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=143), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	172	Climbing Stairs Questionnaire			Validity	Known group
de Laat	2011		Transfemoral (n=54), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=142), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	171	Climbing Stairs Questionnaire			Validity	Convergent
de Laat	2012		Transfemoral (n=55), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=143), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	172	Climbing Stairs Questionnaire			Validity	Convergent
Yari	2008		Hip disarticulation (n=31, hemipelvectomy (n=15)	Tumour (n=36), Vascular (n=6), Trauma (n=2), Other (n=2)	55.8		46	Climbing Stairs Questionnaire			Validity	Known group
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	Home Integration		Reliability	Internal consistency
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	Home Integration		Validity	Structural
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	Home Integration		Validity	Known group
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	Home Integration		Validity	Concurrent/convergent criterion
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	Productivity		Reliability	Internal consistency
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	Productivity		Validity	Structural
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	Productivity		Validity	Known group
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	Productivity		Validity	Concurrent/convergent criterion
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	social integration		Reliability	Internal consistency
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	social integration		Validity	Structural
Hirsh, et al	2011		Amputees and non- amputees grouped together					Community Integration Questionnaire	social integration		Validity	Known group

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
de Laat	2010				Higher (transfemoral or knee disarticulation) vs Lower (transtibial or Syme amputation)	Mann-Whitney U P value	0.256			
de Laat	2011		The Rising and Sitting down Questionnaire		Spearman r	0.42				Spearman: Rising and Sitting=0.42
de Laat	2012		The Walking Questionnaire		Spearman r	0.6				Spearman: Walking=0.60
Yari	2008		hip disarticulation group vs hemipelvectomy group		ttest P	0.16				no significant difference
Hirsh, et al	2011				Cronbach Alpha	0.84				for all disabilities
Hirsh, et al	2011									EFA and CFA suggested that modification of scales and scoring be made
Hirsh, et al	2011									Scores for persons with limb loss were compared to scores of persons with SCI, MS and MD, no significant differences were found.
Hirsh, et al	2011									Correlation with SF 36 General health: original scoring: .152
Hirsh, et al	2011				Cronbach Alpha	0.45				a = .45 (for all disabilities)
Hirsh, et al	2011									EFA and CFA suggested that modification of scales and scoring be made
Hirsh, et al	2011									Scores for persons with limb loss were compared to scores of persons with SCI, MS and MD, no significant differences were found.
Hirsh, et al	2011									Correlation with SF 36 General health: original scoring: .341
Hirsh, et al	2011				Cronbach Alpha	0.51				a = .51 (for all disabilities)
Hirsh, et al	2011									EFA and CFA suggested that modification of scales and scoring be made
Hirsh, et al	2011									Scores for persons with limb loss were compared to scores of persons with SCI, MS and MD, no significant differences were found.

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire	social integration		Validity	Concurrent/convergent criterion
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire	Total Overall Score		Reliability	Internal consistency
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire- REVISED SCORING	Home Integration		Validity	Structural
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire- REVISED SCORING	Home Integration		Validity	Known group
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire- REVISED SCORING	Home Integration		Validity	Concurrent/convergent criterion
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire-REVISED SCORING	Productivity		Validity	Structural
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire-REVISED SCORING	Productivity		Validity	Known group
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire-REVISED SCORING	Productivity		Validity	Concurrent/convergent criterion
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire-REVISED SCORING	social integration		Validity	Structural
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire-REVISED SCORING	social integration		Validity	Known group
Hirsh, et al	2011		Amputees and non-amputees grouped together					Community Integration Questionnaire-REVISED SCORING	social integration		Validity	Concurrent/convergent criterion
Resnik, et al	2011							Craig Handicap Assessment and Reporting Technique (CHART)	Occupation		Validity	Concurrent/convergent criterion
Resnik, et al	2011							Craig Handicap Assessment and Reporting Technique (CHART)	Occupation		Ability to measure change	Responsiveness
Resnik, et al	2011							Craig Handicap Assessment and Reporting Technique (CHART)	social integration		Validity	Concurrent/convergent criterion
Resnik, et al	2011							Craig Handicap Assessment and Reporting Technique (CHART)	social integration		Ability to measure change	Responsiveness
Resnik, et al	2011							CRIS	Extent of Limitation		Reliability	Test-retest
Resnik, et al	2011							CRIS	Extent of Limitation		Validity	Known group

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Hirsh, et al	2011									Correlation with SF 36 General health: original scoring: .300
Hirsh, et al	2011				Cronbach Alpha	0.75				$\alpha = .75$ (for all disabilities)
Hirsh, et al	2011									Confirmatory factor analysis showed that a 3 factor solution using the revised scoring fit the data well. The goodness-of-fit indices include: (df 50; RMSEA .05; 90% confidence interval for RMSEA, .04 – .06; P for test of close fit [RMSEA .05] .23; NNFI .95; Goodness of Fit Index 0.97; and Adjusted Goodness of Fit Index .95).
Hirsh, et al	2011									Scores for persons with limb loss were compared to scores of persons with SCI, MS and MD, no significant differences were found.
Hirsh, et al	2011									Correlation with SF 36 General Health and CIQ Revised scoring: .151,
Hirsh, et al	2011									Confirmatory factor analysis showed that a 3 factor solution using the revised scoring fit the data well. The goodness-of-fit indices include: (df 50; RMSEA .05; 90% confidence interval for RMSEA, .04 – .06; P for test of close fit [RMSEA .05] .23; NNFI .95; Goodness of Fit Index 0.97; and Adjusted Goodness of Fit Index .95).
Hirsh, et al	2011									Scores for persons with limb loss were compared to scores of persons with SCI, MS and MD, no significant differences were found.
Hirsh, et al	2011									Correlation with SF 36 General Health and CIQ Revised scoring: .306
Hirsh, et al	2011									Confirmatory factor analysis showed that a 3 factor solution using the revised scoring fit the data well. The goodness-of-fit indices include: (df 50; RMSEA .05; 90% confidence interval for RMSEA, .04 – .06; P for test of close fit [RMSEA .05] .23; NNFI .95; Goodness of Fit Index 0.97; and Adjusted Goodness of Fit Index .95).
Hirsh, et al	2011									Scores for persons with limb loss were compared to scores of persons with SCI, MS and MD, no significant differences were found.
Hirsh, et al	2011									Correlation with SF 36 General Health and CIQ Revised scoring: .341
Resnik, et al	2011									No correlation between the CHART Occupational Function subscale and any CRIS scale
Resnik, et al	2011									Resnik reported that the ES for persons undergoing 3 months of outpatient rehabilitation was non-significant.
Resnik, et al	2011									Correlation between the CHART social integration scale and the CRIS satisfaction with participation scale was $R=0.26$ .
Resnik, et al	2011									Resnik reported that the ES for persons undergoing 3 months of outpatient rehabilitation was non-significant.
Resnik, et al	2011									0.91 MDC 95% 5.7
Resnik, et al	2011									Extent scores lower in persons with PTSD TBI, and depression



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Resnik, et al	2011							CRIS	Extent of Limitation		Validity	Concurrent/convergent criterion
Resnik, et al	2011							CRIS	Extent of Limitation		Ability to measure change	Responsiveness
Resnik, et al	2011							CRIS	Extent of Limitation		Ability to measure change	Floor/ceiling effects
Resnik, et	2011							CRIS	Perceived Limitation		Reliability	Test-retest
Resnik, et al	2011							CRIS	Perceived Limitation		Validity	Known group
Resnik, et al	2011							CRIS	Perceived Limitation		Validity	Concurrent/convergent criterion
Resnik, et al	2011							CRIS	Perceived Limitation		Ability to measure change	Responsiveness
Resnik, et al	2011							CRIS	Perceived Limitation		Ability to measure change	Floor/ceiling effects
Resnik, et al	2011							CRIS	Satisfaction with Limitation		Reliability	Test-retest
Resnik, et al	2011							CRIS	Satisfaction with Limitation		Validity	Known group
Resnik, et al	2011							CRIS	Satisfaction with Limitation		Validity	Concurrent/convergent criterion
Resnik, et al	2011							CRIS	Satisfaction with Limitation		Ability to measure change	Responsiveness
Resnik, et al	2011							CRIS	Satisfaction with Limitation		Ability to measure change	Floor/ceiling effects
Zahiten-Hinguranage et al,	2004		nd	malignant lower extremity sarcoma	68.6	nd	22	EORTC QLQ-C30 core v3	3 somatic scale		Validity	Known group
Zahiten-Hinguranage	2004		nd	malignant lower extremity sarcoma	68.6		22	EORTC QLQ-C30 core v3	3 somatic scales		Validity	Known group
Zahiten-Hinguranage	2004		nd	malignant lower extremity sarcoma	68.6		22	EORTC QLQ-C30 core v3	Behavioral (role)		Validity	Known group
Zahiten-Hinguranage et al,	2004		nd	malignant lower extremity sarcoma	68.6	nd	22	EORTC QLQ-C30 core v3	Behavioural (role)		Validity	Known group
Zahiten-Hinguranage	2004		nd	malignant lower extremity sarcoma	68.6		22	EORTC QLQ-C30 core v3	Cognitive		Validity	Known group

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Resnik, et al	2011									Correlations between: Quality of Life Scale (QOL) 0.5739; Occupation (CHART) - 0.0422; Correlations with Social Integration (CHART) 0.1690; Role Physical (SF-36) 0.3247; Role Emotional (SF-36) 0.5432; Social Functional (SF-36) 0.4843; Physical Function (SF-36) 0.3305; Activities of Daily Living (ADL) -0.1834
Resnik, et al	2011									Small effect after 3 months of rehab, approximately equivalent to change in QOL and Role Physical
Resnik, et al	2011									The ceiling effect using the MDC 90% was acceptable (<15%) for Extent of Participation
Resnik, et	2011									0.9 MDC 95% 6.93
Resnik, et al	2011									Perceived scores lower in persons with PTSD TBI
Resnik, et al	2011									Correlations with Quality of Life Scale (QOL) 0.6661 Occupation (CHART) -0.1186 Social Integration (CHART) 0.2168; Role Physical (SF-36) 0.2558; Role Emotional (SF-36) 0.3552; Social Functional (SF-36) 0.5009; Physical Function (SF-36) 0.4038; Activities of Daily Living (ADL) -0.2367
Resnik, et al	2011									Small effect after 3 months of rehab, approximately equivalent to change in QOL and Role Physical
Resnik, et al	2011									The ceiling effect using the MDC 90% was acceptable (<15%) for Perceived
Resnik, et al	2011									0.9 MDC 95% 5.81
Resnik, et al	2011									Satisfaction scores lower in persons with PTSD TBI, and depression
Resnik, et al	2011									Correlations with Quality of Life Scale (QOL) 0.7946; Occupation (CHART) - 0.1197; Social Integration (CHART) 0.2607; Role Physical (SF-36) 0.3645; Role Emotional (SF-36) 0.4511; Social Functional (SF-36) 0.5352; Physical Function (SF-36) 0.3709; Activities of Daily Living (ADL) -0.2471
Resnik, et al	2011									Small effect after 3 months of rehab, approximately equivalent to change in QOL and Role Physical
Resnik, et al	2011									The ceiling effect was 16.2 percent for the Satisfaction with Participation subscale.
Zahlten-Hinguranage et al,	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage et al,	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Zahiten-Hinguranage et al,	2004		nd	malignant lower extremity sarcoma	68.6	nd	22	EORTC QLQ-C30 core v3	Cognitive		Validity	Known group
Zahiten-Hinguranage	2004		nd	malignant lower extremity sarcoma	68.6		22	EORTC QLQ-C30 core v3	Emotional		Validity	Known group
Zahiten-Hinguranage et al,	2004		nd	malignant lower extremity sarcoma	68.6	nd	22	EORTC QLQ-C30 core v3	Emotional		Validity	Known group
Zahiten-Hinguranage	2004		nd	malignant lower extremity sarcoma	68.6		22	EORTC QLQ-C30 core v3	Global health and QoL scale		Validity	Known group
Zahiten-Hinguranage et al,	2004		nd	malignant lower extremity sarcoma	68.6	nd	22	EORTC QLQ-C30 core v3	Global health and QoL scale		Validity	Known group
Zahiten-Hinguranage	2004		nd	malignant lower extremity sarcoma	68.6		22	EORTC QLQ-C30 core v3	Physical		Validity	Known group
Zahiten-Hinguranage et al,	2004		nd	malignant lower extremity sarcoma	68.6	nd	22	EORTC QLQ-C30 core v3	Physical		Validity	Known group
Zahiten-Hinguranage	2004		nd	malignant lower extremity sarcoma	68.6		22	EORTC QLQ-C30 core v3	Single item symptom measures		Validity	Known group
Zahiten-Hinguranage et al,	2004		nd	malignant lower extremity sarcoma	68.6	nd	22	EORTC QLQ-C30 core v3	Single item symptom measures		Validity	Known group
Zahiten-Hinguranage	2004		nd	malignant lower extremity sarcoma	68.6		22	EORTC QLQ-C30 core v3	Social		Validity	Known group
Zahiten-Hinguranage et al,	2004		nd	malignant lower extremity sarcoma	68.6	nd	22	EORTC QLQ-C30 core v3	Social		Validity	Known group
Giannoudis	2009		below knee	trauma	46.8	nd	22	EQ-5D	Anxiety and depression		Validity	Known group
Giannoudis et al,	2009		below knee	trauma	46.8	nd	22	EQ-5D	Anxiety and depression		Validity	Known group
Giannoudis	2009		below knee	trauma	46.8	nd	22	EQ-5D	Mobility		Validity	Known group
Giannoudis et al,	2009		below knee	trauma	46.8	nd	22	EQ-5D	Mobility		Validity	Known group

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Zahlten-Hinguranage et al,	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage et al,	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage et al,	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage et al,	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage et al,	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage et al,	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Zahlten-Hinguranage et al,	2004		Comparisons between limb salvage and amputee patients, but no statistical testing					Unclear		Comparisons between limb salvage and amputee patients, but no statistical testing
Giannoudis	2009									Patients in the IIIB, IIIC and amputation groups reported more problems with ongoing anxiety and depression than those in the tibial fracture and fasciotomy groups (p < 0.05)
Giannoudis et al,	2009									Patients in the IIIB, IIIC and amputation groups reported more problems with ongoing anxiety and depression than those in the tibial fracture and fasciotomy groups (p < 0.05)
Giannoudis	2009									Patients with amputations and IIIB fractures reported problems with mobility most frequently. IIIC fracture patients reported problems less frequently p < 0.05
Giannoudis et al,	2009									Patients with amputations and IIIB fractures reported problems with mobility most frequently. IIIC fracture patients reported problems less frequently p < 0.05

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Giannoudis	2009		below knee	trauma	46.8	nd	22	EQ-5D	Pain and discomfort		Validity	Known group
Giannoudis et al.	2009		below knee	trauma	46.8	nd	22	EQ-5D	Pain and discomfort		Validity	Known group
Giannoudis	2009		below knee	trauma	46.8	nd	22	EQ-5D	Usual activity		Validity	Known group
Giannoudis et al.	2009		below knee	trauma	46.8	nd	22	EQ-5D	Usual activity		Validity	Known group
Eijk	2012	21958418	Transfemoral (n=17), Transtibial (n=23), transgenual (n=5), hip disarticulation (n=1), minor amputation (n=2)	PAD (n=45), astreomyelitis (n=1), tumour (n=1), trauma (n=1)	75.2		48	FAC	Total Overall Score		Validity	Predictive
Asano	2008	18569891	Transfemoral (n=112), Transtibial (303)	vascular (220), nonvascular (195)	61.9	Unilateral	415	FAI			Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24), Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI		The Frenchay Activities Index is a 15-item self-report measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Construct
Miller	2004	15180125	Transfemoral (n=24), Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI		The FAI is a 15-item self-report measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Giannoudis	2009									Patients with IIIB and IIIC fractures reported ongoing problems with pain most frequently, with positive responses in just over 80% and just over 70%, respectively. Patients having undergone fasciotomy reported pain as frequently as those with amputations with positive responses in around 50% of cases and closed fracture patients in 20% of cases. The differences between responses from the amputees and both the IIIB and IIIC groups were statistically significant ( $p < 0.01$ ) as were those between the simple tibial fracture and all other groups ( $p < 0.01$ ).
Giannoudis et al.	2009									Patients with IIIB and IIIC fractures reported ongoing problems with pain most frequently, with positive responses in just over 80% and just over 70%, respectively. Patients having undergone fasciotomy reported pain as frequently as those with amputations with positive responses in around 50% of cases and closed fracture patients in 20% of cases. The differences between responses from the amputees and both the IIIB and IIIC groups were statistically significant ( $p < 0.01$ ) as were those between the simple tibial fracture and all other groups ( $p < 0.01$ ).
Giannoudis	2009									Patients with IIIB fractures reported problems with undertaking their usual activities most frequently (80% of respondents) ( $p < 0.05$ compared with all other groups). Those with IIIC fractures, fasciotomies and amputations reported problems with similar frequency at 47%, 37% and 32%, respectively (no statistical significance when compared with each other). Those who had suffered closed tibial fracture recorded problems least frequently at 20% of respondents ( $p < 0.05$ compared with all other groups).
Giannoudis et al.	2009									Patients with IIIB fractures reported problems with undertaking their usual activities most frequently (80% of respondents) ( $p < 0.05$ compared with all other groups). Those with IIIC fractures, fasciotomies and amputations reported problems with similar frequency at 47%, 37% and 32%, respectively (no statistical significance when compared with each other). Those who had suffered closed tibial fracture recorded problems least frequently at 20% of respondents ( $p < 0.05$ compared with all other groups).
Eijk	2012	21958418	Barthel index	12 months	P value	0.003			significantly correlated with Barthel index (Mannwhitney U);	Functional Ambulation Categories (FAC)
Asano	2008	18569891	QoL, single item question		Beta	0.19				Multivariate regression
Miller	2004	15180125	Transfemoral vs transtibial		P	$\geq 0.05$		No	The FAI did not discriminate between Transfemoral and transtibial	
Miller	2004	15180125	Vascular vs trauma		P	$< 0.05$		Yes	The FAI discriminated between Transfemoral and transtibial Vascular and trauma	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI		The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI		The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI		The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI		The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI		The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Reliability	Internal Consistency
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI		The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Reliability	Test-retest
Miller et al	2001							FAI Modified	no subscale		Reliability	Test-retest
Miller et al	2001							FAI Modified	no subscale		Reliability	Internal consistency
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI-18		To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Construct
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI-18		To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Construct
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI-18		To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI-18		To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Miller	2004	15180125	Two-minute walk		Pearson r	0.526	Large	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	Timed up and go		Pearson r	-0.486	Moderate	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	PEQ-MS		Pearson r	0.386	Moderate	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	ABC		Pearson r	0.505	Large	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	nd		Cronbach's alpha	0.81	Excellent	Yes	Good internal consistency	
Miller	2004	15180125	nd		ICC	0.79	Good	Yes	Strong test-retest reliability.	
Miller et al	2001									in this paper
Miller et al	2001				Cronbach Alpha	0.87				Alpha 0.87
Miller	2004	15180125	Transfemoral vs transtibial		P	>=0.05		No	The FAI-18 did not discriminate between Transfemoral and transtibial	
Miller	2004	15180125	Vascular vs trauma		P	<0.05		Yes	The FAI-18 discriminated between Transfemoral and transtibial Vascular and trauma	
Miller	2004	15180125	Two-minute walk		Pearson r	0.548	Large	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	Timed up and go		Pearson r	-0.462	Moderate	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Miller	2004	15180125	Transfemoral (n=24), Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI-18		To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24), Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI-18		To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24), Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI-18		To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Reliability	Internal Consistency
Miller	2004	15180125	Transfemoral (n=24), Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5		84	FAI-18		To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Reliability	Test-retest
Kahle	2008						19	Fastest Possible Walking Speed 38m on uneven terrain (FPWS38 uneven)	Total Overall Score		Ability to measure change	Responsiveness
Kahle	2008						19	Fastest Possible Walking Speed 6m on even terrain (FPWS6)	Total Overall Score		Ability to measure change	Responsiveness
Kahle	2008						19	Fastest Possible Walking Speed 75m on even terrain (FPWS75)	Total Overall Score		Ability to measure change	Responsiveness
Leung	1996	8831480	Transfemoral (n=8), Transtibial (n=24), Bilateral (n=1)	nd	nd		33	FIM	Admission motor subscore		Validity	Predictive
Leung	1996	8831480	Transfemoral (n=8), Transtibial (n=24), Bilateral (n=1)	nd	nd		33	FIM	Admission motor subscore		Validity	Predictive
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Ceiling
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Miller	2004	15180125	PEQ-MS		Pearson r	0.404	Moderate	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	ABC		Pearson r	0.518	Large	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	nd		Cronbach's alpha	0.84	Excellent	Yes	Good internal consistency	
Miller	2004	15180125	nd		ICC	0.78	Good	Yes	Strong test-retest reliability.	
Kahle	2008									significant improvement after using C-Leg
Kahle	2008									significant improvement after using C-Leg
Kahle	2008									significant improvement after using C-Leg
Leung	1996	8831480	Houghton score >=9 vs. Houghton score <9	3-12 months	P	0.42		No	The admission FIM score is not useful in predicting successful prosthetic rehabilitation in lower extremity amputee patients	
Leung	1996	8831480	DMERC functional level	3-12 months	Spearman r	0.18	Small	No	The admission FIM score is not useful in predicting successful prosthetic rehabilitation in lower extremity amputee patients	
Cyril	2001		nd		%	0		No		
Cyril	2001		Transibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Normal Walking Speed (Yes vs No)		Pearson r	-0.06	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Walking Speed (continuous score)		Pearson r	0.13	Small	Unclear		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Divergent
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Floor
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Reliability	Internal Consistency
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore, overall	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Ceiling
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Return to Usual Activity (Yes vs No)		Pearson r	0.02	None	No		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001		Physical Function Index		Pearson r	-0.12		Unclear		
Cyril	2001		nd		%	0		No		
Cyril	2001		nd		Cronbach's alpha	0.55	Poor	Unclear		
Cyril	2001		nd		SRM	-0.49				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		Effect size with baseline SD	-0.51				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		%	53.3		Yes		
Cyril	2001		Transibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyrl	2001		Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyrl	2001		Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyrl	2001		Transibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyrl	2001		ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyrl	2001		Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyrl	2001		Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyrl	2001		Normal Walking Speed (Yes vs No)		Pearson r	-0.04	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Floor
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Reliability	Internal Consistency
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Ceiling
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Walking Speed (continuous score)		Pearson r	0.1	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Return to Usual Activity (Yes vs No)		Pearson r	-0.01	None	No		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001		nd		%	1		No		
Cyril	2001		nd		Cronbach's alpha	0.85	Excellent	Yes		
Cyril	2001		nd		SRM	-0.2				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		Effect size with baseline SD	-0.23				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		%	0		No		
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Normal Walking Speed (Yes vs No)		Pearson r	0.03	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.

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Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Floor
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Reliability	Internal Consistency
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Ceiling
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Walking Speed (continuous score)		Pearson r	0.06	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Return to Usual Activity (Yes vs No)		Pearson r	0.1	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001		nd		%	4.7		No		
Cyril	2001		nd		Cronbach's alpha	0.62	Adequate	Yes		
Cyril	2001		nd		SRM	-0.52				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		Effect size with baseline SD	-0.52				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		%	0		No		
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Normal Walking Speed (Yes vs No)		Pearson r	0.13	Small	Unclear		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Floor
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Reliability	Internal Consistency
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	FIM	Amputation function subscore: Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Leung	1996	8831480	Transfemoral (n=8), Transtibial (n=24), Bilateral (n=1)	nd	nd	NR-89	33	FIM	Discharge motor subscore		Validity	Convergent
Leung	1996	8831480	Transfemoral (n=8), Transtibial (n=24), Bilateral (n=1)	nd	nd		33	FIM	Discharge motor subscore		Validity	Predictive
Cox, Williams & Weaver,	2011		Transfemoral (n=23), Transtibial (n=64)	Diabetes	62	nd	87	FIM	Overall		Validity	Known group
Cox	2011		Transfemoral (n=23), Transtibial (n=64)	Diabetes	62		87	FIM	Total Overall Scale		Validity	Known group
Panesar	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67		34	FIM	Total Overall Scale	Ability to measure change	Responsiveness	nd

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Walking Speed (continuous score)		Pearson r	0	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Return to Usual Activity (Yes vs No)		Pearson r	0.13	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001		nd		%	2		No		
Cyril	2001		nd		Cronbach's alpha	0.75	Adequate	Yes		
Cyril	2001		nd		SRM	-0.25				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		Effect size with baseline SD	-0.27				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Leung	1996	8831480	Houghton score		45 days (mean)	Spearman r	0.58	Large	Yes	The motor subscore at discharge correlates with the use of prosthesis
Leung	1996	8831480	Houghton score >=9 vs. Houghton score <9	3-12 months	P	0.0015		Yes	The motor subscore at discharge correlates with the use of prosthesis	
Cox, Williams & Weaver,	2011		below vs above knee		P value	<0.0001				
Cox	2011		below vs above knee		P value	<0.0001				
Panesar	2001		P value			<0.00001			significant changes between admission and discharge	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Panesar	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67		34	FIM	Total Overall Scale		Validity	Convergent
Dite	2007		Transtibial	nd	61.6	Unilateral	40	Four Square Step Test			Validity	Known group/Discriminant
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index	nd	The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Reliability	Internal Consistency
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index	nd	The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Reliability	Test-retest
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index	nd	The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Construct
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index	nd	The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Construct
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index	nd	The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index	nd	The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index	nd	The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index	nd	The FAI is a 15-item self-repor-t measure that assesses frequency of participation in domestic chores, work/leisure and outdoor activities. Scores ranging from 0 (no activity) to 45 (very high participation).	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index- 18	nd	To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Reliability	Internal Consistency
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index- 18	nd	To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Reliability	Test-retest
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index- 18	nd	To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Construct
Miller	2004	15180125	Transfemoral (n=24) , Transtibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index- 18	nd	To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Panesar	2001		OPCS, AAS, FIM		P value	<0.0001				significant kendal correlations coefficients between each of the measures
Dite	2007				Multiple Fallers vs nonmultiple Fallers	P Value	<0.001			
Miller	2004	15180125	nd		Cronbach's alpha	0.81	Excellent	Yes	Good internal consistency	
Miller	2004	15180125	nd		ICC	0.79	Good	Yes	Strong test-retest reliability.	
Miller	2004	15180125	Transfemoral vs transtibial		P	>=0.05		No	The FAI did not discriminate between Transfemoral and transtibial	
Miller	2004	15180125	Vascular vs trauma		P	<0.05		Yes	The FAI discriminated between Transfemoral and transtibial Vascular and trauma	
Miller	2004	15180125	Two-minute walk		Pearson r	0.526	Large	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	Timed up and go		Pearson r	-0.486	Moderate	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	PEQ-MS		Pearson r	0.386	Moderate	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	ABC		Pearson r	0.505	Large	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	nd		Cronbach's alpha	0.84	Excellent	Yes	Good internal consistency	
Miller	2004	15180125	nd		ICC	0.78	Good	Yes	Strong test-retest reliability.	
Miller	2004	15180125	Transfemoral vs transtibial		P	>=0.05		No	The FAI-18 did not discriminate between Transfemoral and transtibial	
Miller	2004	15180125	Vascular vs trauma		P	<0.05		Yes	The FAI-18 discriminated between Transfemoral and transtibial Vascular and trauma	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Miller	2004	15180125	Transfemoral (n=24), Trans tibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index-18	nd	To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24), Trans tibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index-18	nd	To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24), Trans tibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index-18	nd	To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Convergent
Miller	2004	15180125	Transfemoral (n=24), Trans tibial (n=60)	Vascular (n=34), Trauma (n=50)	56.5	nd	84	Frenchay Activities Index-18	nd	To broaden the range of activities we added three items to the existing FAI. The total score of the FAI- 1 8 ranges from 0 to 54	Validity	Convergent
Eijk	2012		Transfemoral (n=17), Trans tibial (n=23), transgenual (n=5), hip disarticulation (n=1), minor amputation (n=2)	PAD (n=45), astromyelitis (n=1), tumour (n=1), trauma (n=1)	75.2		48	Functional Ambulation Categories (FAC)	Total Overall Score		Validity	Construct
Cyril	2001	0	Transfemoral (22%), Trans tibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms o f need for assistance and level o f independence. Developed as part o f the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Reliability	Internal Consistency
Cyril	2001	0	Transfemoral (22%), Trans tibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms o f need for assistance and level o f independence. Developed as part o f the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Ceiling
Cyril	2001	0	Transfemoral (22%), Trans tibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms o f need for assistance and level o f independence. Developed as part o f the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Floor

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Miller	2004	15180125	Two-minute walk		Pearson r	0.548	Large	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	Timed up and go		Pearson r	-0.462	Moderate	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	PEQ-MS		Pearson r	0.404	Moderate	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Miller	2004	15180125	ABC		Pearson r	0.518	Large	Yes	Hypothesized relationships (p <00001) between both FAI versions and the Activity-specific Balance Confidence Scale, Prosthetic Evaluation Questionnaire - Mobility Scale, 2-minute walk and timed up and go test were observed.	
Eijk	2012		Barthel index		P Value	0.003				significantly correlated with Barthel index (Mannwhitney U)
Cyril	2001	0	nd		Cronbach's alpha	0.85	Excellent	Yes		
Cyril	2001	0	nd		%	53.3		Yes		
Cyril	2001	0	nd		%	1		No		

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Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
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Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Normal Walking Speed (Yes vs No)		Pearson r	-0.04	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Walking Speed (continuous score)		Pearson r	0.1	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Return to Usual Activity (Yes vs No)		Pearson r	-0.01	None	No		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001	0	Transibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Chair transfer	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Reliability	Internal Consistency
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Ceiling
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Floor

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	nd		SRM	-0.2				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Effect size with baseline SD	-0.23				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Cronbach's alpha	0.62	Adequate	Yes		
Cyril	2001	0	nd		%	0		No		
Cyril	2001	0	nd		%	4.7		No		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
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Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Normal Walking Speed (Yes vs No)		Pearson r	0.03	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Walking Speed (continuous score)		Pearson r	0.06	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Return to Usual Activity (Yes vs No)		Pearson r	0.1	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001	0	Transibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Climb stairs	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Reliability	Internal Consistency
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Ceiling
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Floor

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	nd		SRM	-0.52				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Effect size with baseline SD	-0.52				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Cronbach's alpha	0.55	Poor	Unclear		
Cyril	2001	0	nd		%	0		No		
Cyril	2001	0	nd		%	0		No		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Divergent
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Normal Walking Speed (Yes vs No)		Pearson r	-0.06	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Walking Speed (continuous score)		Pearson r	0.13	Small	Unclear		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Return to Usual Activity (Yes vs No)		Pearson r	0.02	None	No		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001	0	Physical Function Index		Pearson r	-0.12		Unclear		
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
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Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Overall FIM-AFS	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Reliability	Internal Consistency
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Ceiling

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	nd		SRM	-0.49				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Effect size with baseline SD	-0.51				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Cronbach's alpha	0.75	Adequate	Yes		
Cyril	2001	0	nd		%	0		No		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Floor/ceiling effect	Floor
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	nd		%	2		No		
Cyril	2001	0	Normal Walking Speed (Yes vs No)		Pearson r	0.13	Small	Unclear		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Walking Speed (continuous score)		Pearson r	0	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Return to Usual Activity (Yes vs No)		Pearson r	0.13	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Functional Independence Measure - Amputation function subscore	Walk on level surface	The Functional Independence Measure (FIM) is an 18-item instrument that assesses function in terms of need for assistance and level of independence. Developed as part of the Uniform Data System for Medical Rehabilitation, the measure was specifically designed to evaluate functional outcomes following rehabilitation	Responsiveness	nd
Panesar et al.	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67	nd	34	Functional Independence Measure (FIM)	Total Overall Scale		Validity	Convergent
Panesar et al.	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67	nd	34	Functional Independence Measure (FIM)	Total Overall Scale		Ability to measure change	Responsiveness
Leung	1996	8831480	Transfemoral (n=8), Transtibial (n=24), Bilateral (n=1)	nd	NR-89	nd	33	Functional Independent Measure	Admission motor subscore	In the most recent version of FIM, the 18 items that make up the whole FIM score have been subdivided into a motor subscore and a cognitive subscore	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	nd		SRM	-0.25				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Effect size with baseline SD	-0.27				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Panesar et al.	2001		OPCS, AAS, FIM		P value	<0.0001				significant kendal correlations coefficients between each of the measures
Panesar et al.	2001		nd		P value	<0.00001				significant changes between admission and discharge
Leung	1996	8831480	Houghton score>=9 vs. Houghton score<9		P	0.42		No	The admission FIM score is not useful in predicting successful prosthetic rehabilitation in lower extremity amputee patients	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Leung	1996	8831480	Transfemoral (n=8), Transtibial (n=24), Bilateral (n=1)	nd	NR-89	nd	33	Functional Independent Measure	Admission motor subscore	In the most recent version of FIM, the 18 items that make up the whole FIM score have been subdivided into a motor snbscore and a cognitive subscore	Validity	Convergent
Leung	1996	8831480	Transfemoral (n=8), Transtibial (n=24), Bilateral (n=1)	nd	NR-89	nd	33	Functional Independent Measure	Discharge motor subscore	In the most recent version of FIM, the 18 items that make up the whole FIM score have been subdivided into a motor snbscore and a cognitive subscore	Validity	Construct
Leung	1996	8831480	Transfemoral (n=8), Transtibial (n=24), Bilateral (n=1)	nd	NR-89	nd	33	Functional Independent Measure	Discharge motor subscore	In the most recent version of FIM, the 18 items that make up the whole FIM score have been subdivided into a motor snbscore and a cognitive subscore	Validity	Convergent
Callaghan	2002	12227445	Unilateral transtibial	nd	nd		133	Functional Measure for Amputees	Average number of falls over 1 month		Reliability	Test-retest
Callaghan, Sockalingam, Treweek and Condie	2002	12227445	Unilateral transtibial	nd	nd	nd	133	Functional Measure for Amputees	Average number of falls over 1 month		Reliability	Test-retest
Callaghan	2002	12227445	Unilateral transtibial	nd	nd		133	Functional Measure for Amputees	Average prosthetic use per day in hours		Reliability	Test-retest
Callaghan, Sockalingam, Treweek and Condie	2002	12227445	Unilateral transtibial	nd	nd	nd	133	Functional Measure for Amputees	Average prosthetic use per day in hours		Reliability	Test-retest
Gallagher	2000	study 2	Partial foot (n=2), below knee (n=29), through knee (n=3), above knee (n=20), hip disarticulation (n=4), bilateral (n=1), not specified (n=1)	Congenital (n=7), cancer (n=13), Accident (n=27), peripheral vascular disorder (n=7), other (n=6; not described further)	47.1	18+ years old	60	Functional Measure for Amputees	Average prosthetic use per day in hours		Validity	Convergent
Gallagher	2000	study 2	Partial foot (n=2), below knee (n=29), through knee (n=3), above knee (n=20), hip disarticulation (n=4), bilateral (n=1), not specified (n=1)	Congenital (n=7), cancer (n=13), Accident (n=27), peripheral vascular disorder (n=7), other (n=6; not described further)	47.1	18+ years old	60	Functional Measure for Amputees	Average prosthetic use per day in hours	Average per day	Validity	Convergent
Gallagher	2000	study 2	Partial foot (n=2), below knee (n=29), through knee (n=3), above knee (n=20), hip disarticulation (n=4), bilateral (n=1), not specified (n=1)	Congenital (n=7), cancer (n=13), Accident (n=27), peripheral vascular disorder (n=7), other (n=6; not described further)	47.1	18+ years old	60	Functional Measure for Amputees	Average prosthetic use per day in hours	Average per day	Validity	Convergent
Callaghan	2002	12227445	Unilateral transtibial	nd	nd		133	Functional Measure for Amputees	Average prosthetic use per weeks in days		Reliability	Test-retest
Callaghan, Sockalingam, Treweek and Condie	2002	12227445	Unilateral transtibial	nd	nd	nd	133	Functional Measure for Amputees	Average prosthetic use per weeks in days		Reliability	Test-retest
Remes et al,	2010		nd	peripheral artery disease	75.17	nd	59	Geriatric Depression Scale	nd		Validity	Known group/Discriminant
Remes	2010		nd	peripheral artery disease	75.17		59	Geriatric Depression Scale			Validity	Known group/Discriminant
Hanspal	1997	9331580	Transfemoral (n=17), Transtibial (n=15)	nd	66.4		32	Grade of mobility			Validity	Predictive
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)	nd	38	HADS	Anxiety		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)	nd	38	HADS	Anxiety		Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Leung	1996	8831480	Houghton score		Spearman r	0.18	Small	No	The admission FIM score is not useful in predicting successful prosthetic rehabilitation in lower extremity amputee patients	
Leung	1996	8831480	Houghton score >=9 vs. Houghton score <9		P	0.0015		Yes	The motor subscore at discharge correlates with the use of prosthesis	
Leung	1996	8831480	Houghton score		Spearman r	0.58	Large	Yes	The motor subscore at discharge correlates with the use of prosthesis	
Callaghan	2002	12227445			ICC	0.64				
Callaghan, Sockalingam, Treweek and Condie	2002	12227445			ICC	0.64				
Callaghan	2002	12227445			ICC	0.85				
Callaghan, Sockalingam, Treweek and Condie	2002	12227445			ICC	0.85				
Gallagher	2000	study 2	TAPES Functional restriction		Correlation r	-0.313	Moderate	Yes		p<0.02
Gallagher	2000	study 2	TAPES Social restriction		Correlation r	-0.376	Moderate	Yes		p<0.005
Gallagher	2000	study 2	TAPES Athletic activity restriction		Correlation r	-0.366	Moderate	Yes		p<0.05
Callaghan	2002	12227445			ICC	0.96				
Callaghan, Sockalingam, Treweek and Condie	2002	12227445			ICC	0.96				
Remes et al,	2010		amputees vs control group		P value	0.071				
Remes	2010		amputees vs control group		P value	0.071				
Hanspal	1997	9331580	Cognitive ability	8-14 months	Pearson r	0.45		Moderate		
Coffey	2009	19900240	HADS Depression		Spearman r	0.62				
Coffey	2009	19900240	ABIS-R		Spearman r	0.77				





Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Coffey	2009	19900240	TAPES social restriction		Spearman r	0.41				
Coffey	2009	19900240	TAPES weight satisfaction		Spearman r	-0.39				
Coffey	2009	19900240	TAPES functional satisfaction		Spearman r	-0.36				
Coffey	2009	19900240	TAPES general adjustment		Spearman r	-0.48				
Coffey	2009	19900240	TAPES social adjustment		Spearman r	-0.58				
Coffey	2009	19900240	HADS Depression		Spearman r	0.62				
Coffey	2009	19900240	ABIS-R		Spearman r	0.77				
Coffey	2009	19900240	TAPES social restriction		Spearman r	0.41				
Coffey	2009	19900240	TAPES weight satisfaction		Spearman r	-0.39				
Coffey	2009	19900240	TAPES functional satisfaction		Spearman r	-0.36				
Coffey	2009	19900240	TAPES general adjustment		Spearman r	-0.48				
Coffey	2009	19900240	TAPES social adjustment		Spearman r	-0.58				
Coffey	2009	19900240	ABIS-R		Spearman r	0.75				
Coffey	2009	19900240	TAPES functional restriction		Spearman r	0.39				
Coffey	2009	19900240	TAPES social restriction		Spearman r	0.54				
Coffey	2009	19900240	TAPES weight satisfaction		Spearman r	-0.43				
Coffey	2009	19900240	TAPES functional satisfaction		Spearman r	-0.4				
Coffey	2009	19900240	TAPES general adjustment		Spearman r	-0.49				
Coffey	2009	19900240	TAPES social adjustment		Spearman r	-0.49				
Coffey	2009	19900240	TAPES adjustment to limitations		Spearman r	-0.44				
Coffey	2009	19900240	ABIS-R		Spearman r	0.75				
Coffey	2009	19900240	TAPES functional restriction		Spearman r	0.39				
Coffey	2009	19900240	TAPES social restriction		Spearman r	0.54				
Coffey	2009	19900240	TAPES weight satisfaction		Spearman r	-0.43				

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)		38	HADS	Depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)		38	HADS	Depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)		38	HADS	Depression		Validity	Convergent
Coffey	2009	19900240	Transfemoral (n=6), Transtibial (n=23), bilateral (n=9)	Diabetes-related	68 (median)		38	HADS	Depression		Validity	Convergent
Fisher and Hanspal	1998		Transfemoral (30%), Transtibial (60%), knee disarticulation (4%), hip disarticulation (4%), partial foot amputation (2%)	dysvascular or diabetes (40%), trauma (35%), infection (8%), congenital (8%), neoplasm (5%), other (4%)	55.5	nd	107	Harold Wood/Stammore mobility grade	Total Overall Score		Validity	Construct
Fisher and Hanspal	1998		Transfemoral (30%), Transtibial (60%), knee disarticulation (4%), hip disarticulation (4%), pariyial foot amputation (2%)	dysvascular or diabetes (40%), trauma (35%), infection (8%), congenital (8%), neoplasm (5), other (4%)	55.5	nd	107	Harold Wood/Stammore mobility grade	Total Overall Score		Validity	Convergent
Fisher and Hanspal	1998		Transfemoral (30%), Transtibial (60%), knee disarticulation (4%), hip disarticulation (4%), pariyial foot amputation (2%)	dysvascular or diabetes (40%), trauma (35%), infection (8%), congenital (8%), neoplasm (5), other (4%)	55.5	nd	107	Harold Wood/Stammore mobility grade	Total Overall Score		Validity	Convergent
Fisher and Hanspal	1998		Transfemoral (30%), Transtibial (60%), knee disarticulation (4%), hip disarticulation (4%), pariyial foot amputation (2%)	dysvascular or diabetes (40%), trauma (35%), infection (8%), congenital (8%), neoplasm (5), other (4%)	55.5	nd	107	Harold Wood/Stammore mobility grade	Total Overall Score		Validity	Convergent
Fisher and Hanspal	1998		Transfemoral (30%), Transtibial (60%), knee disarticulation (4%), hip disarticulation (4%), partial foot amputation (2%)	dysvascular or diabetes (40%), trauma (35%), infection (8%), congenital (8%), neoplasm (5%), other (4%)	55.5	nd	107	Harold Wood/Stammore mobility grade	Total Overall Score		Validity	Convergent
Fisher, Hanspal and Marks	2003		Transfemoral (43%), Transtibial (50%), hip or partial foot amputation (7%)	vascular or diabetes (24%), trauma (64%), neoplasm (8%), other (4%)	47.4	normal or near normal cognitive ability, aged 17-65, amputation between 16-64 years, established prosthesis wearer, amputation at least 1 year previously	100	Harold Wood/Stammore Mobility Grade	Total Overall Score		Validity	Convergent
Hanspal	1991		Transfemoral (n=51), Transtibial (n=49)	nd	72.4	nd	100	Harold Wood/Stammore mobility grade	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Fisher	1998		Transfemoral (30%), Transtibial (60%), knee disarticulation (4%), hip disarticulation (4%), pariyial foot amputation (2%)	dysvascular or diabetes (40%), trauma (35%), infection (8%), congenital (8%), neoplasm (5), other (4%)	55.5		107	Harold Wood/Stammore mobility grade			Validity	Convergent
Fisher	1998		Transfemoral (30%), Transtibial (60%), knee disarticulation (4%), hip disarticulation (4%), pariyial foot amputation (2%)	dysvascular or diabetes (40%), trauma (35%), infection (8%), congenital (8%), neoplasm (5), other (4%)	55.5		107	Harold Wood/Stammore mobility grade			Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Coffey	2009	19900240	TAPES functional satisfaction		Spearman r	-0.4				
Coffey	2009	19900240	TAPES general adjustment		Spearman r	-0.49				
Coffey	2009	19900240	TAPES social adjustment		Spearman r	-0.49				
Coffey	2009	19900240	TAPES adjustment to limitations		Spearman r	-0.44				
Fisher and Hanspal	1998									significant correlation with age
Fisher and Hanspal	1998		AALQ (attitude to artificial limbs questionnaire)		Kendall tau	-0.04				not statistically significant
Fisher and Hanspal	1998		BIQ (Body image questionnaire)			0.02				not statistically significant
Fisher and Hanspal	1998		HADS anxiety (hospital anxiety depression scale)			0.21				not statistically significant
Fisher and Hanspal	1998		HADS depression (hospital anxiety depression scale)			0.16				not statistically significant
Fisher, Hanspal and Marks	2003		Employment questionnaire		nonparametric correlation	nd				correlation with Employment questionnaire P<.001
Hanspal	1991									significant correlation with cognitive assessment scale
Fisher	1998		AALQ (attitude to artificial limbs questionnaire)		Kendall tau	-0.04				not statistically significant
Fisher	1998		BIQ (Body image questionnaire)		Kendall tau	0.02				not statistically significant

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Fisher	1998		Transfemoral (30%), Transtibial (60%), knee disarticulation (4%), hip disarticulation (4%), pariyal foot amputation (2%)	dysvascular or diabetes (40%), trauma (35%), infection (8%), congenital (8%), neoplasm (5%), other (4%)	55.5		107	Harold Wood/Stanmore mobility grade			Validity	Convergent
Fisher	1998		Transfemoral (30%), Transtibial (60%), knee disarticulation (4%), hip disarticulation (4%), partial foot amputation (2%)	dysvascular or diabetes (40%), trauma (35%), infection (8%), congenital (8%), neoplasm (5%), other (4%)	55.5		107	Harold Wood/Stanmore mobility grade			Validity	Convergent
Fisher	1998		Transfemoral (30%), Transtibial (60%), knee disarticulation (4%), hip disarticulation (4%), partial foot amputation (2%)	dysvascular or diabetes (40%), trauma (35%), infection (8%), congenital (8%), neoplasm (5%), other (4%)	55.5		107	Harold Wood/Stanmore mobility grade			Validity	Construct
Fisher	2003		Transfemoral (43%), Transtibial (50%), hip or partial foot amputation (7%)	vascular or diabetes (24%), trauma (64%), neoplasm (8%), other (4%)	47.4	normal or near normal cognitive ability, aged 17-65, amputation between 16-64 years, established prosthesis wearer, amputation at least 1 year previously	100	Harold Wood/Stanmore Mobility Grade			Validity	Convergent
Hanspal	1991		Transfemoral (n=51), Transtibial (n=49)	nd	72.4	nd	100	Harold Wood/Stanmore mobility grade			Validity	Concurrent/convergent/criteria Validity criterion
Hafner	2007						17	Hill Assessment Index (HAI)	Total Overall Score		Ability to measure change	Responsiveness
Wong	2016	26390393	TT (n=22), TF (n=13), BTT (n=2), BTT/BFT (n=2), BFT/BTT (n=1)	vascular (28), nonvascular (12)	57.0 +- 11.9	nd	40	Houghton	mobility	Houghton scale quantifies duration of daily prosthesis wear, use of prosthesis, use of assistive devices, and perceived stability when using the prosthesis on various terrains. The four questions are summated with the total score reported in a range from 0 to 12, with higher scores indicating better function. Scores of 9 or higher have been suggested to represent prosthetic use for community walking	Validity	predictive
Delvin	2004	15295762	Multiple	Multiple	60.9	nd	49	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Reliability	Test-retest
Delvin	2004	15295762	Multiple	Multiple	60.9	nd	49	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Reliability	Internal Consistency
Delvin	2004	15295762	Multiple	Multiple	65.5	nd	76	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Floor/ceiling effect	Floor
Delvin	2004	15295762	Multiple	Multiple	65.5	nd	76	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Floor/ceiling effect	Ceiling
Delvin	2004	15295762	Multiple	Multiple	65.5	nd	76	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Responsiveness	nd

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Fisher	1998		HADS anxiety (hospital anxiety depression scale)		Kendall tau	0.21				not statistically significant
Fisher	1998		HADS depression (hospital anxiety depression scale)		Kendall tau	0.16				not statistically significant
Fisher	1998									significant correlation with age
Fisher	2003				Employment questionnaire	nonparametric correlation	nd			correlation with Employment questionnaire P<.001
Hanspal	1991									significant correlation with cognitive assessment scale
Hafner	2007		Mechanical control prosthetic knee versus microprocessor control prosthetic knee							significant differences between control technology
Wong	2016	26390393	predict community ambulation, initial score <7		AUC	0.885		Yes		
Delvin	2004	15295762	nd		ICC	0.96	Excellent	Yes	The Houghton Scale showed good test-retest reliability over a 1-week span	
Delvin	2004	15295762	nd		Cronbach's alpha	0.71	Adequate	Yes	The internal consistency was moderate at discharge and follow-up	Values at discharge time (.7 at follow up)
Delvin	2004	15295762	nd		%	0		No	Floor and ceiling effects on the individual items were notable (as expected), although nearly absent for the overall score	
Delvin	2004	15295762	nd		%	1.3		No	Floor and ceiling effects on the individual items were notable (as expected), although nearly absent for the overall score	
Delvin	2004	15295762	nd		Effect size	0.6		Yes	The effect size calculated for this change was .60, indicating a moderate difference	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Delvin	2004	15295762	Multiple	Multiple	65.5	nd	76	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Convergent
Delvin	2004	15295762	Multiple	Multiple	65.5	nd	76	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Convergent
Delvin	2004	15295762	Multiple	Multiple	65.5	nd	76	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Convergent
Delvin	2004	15295762	Multiple	Multiple	65.5	nd	76	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Convergent
Delvin	2004	15295762	Multiple	Multiple	65.5	nd	76	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Construct
Delvin	2004	15295762	Multiple	Multiple	65.5	nd	76	Houghton	nd	The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Construct
Houghton	1992	1393461	Transfemoral (n=31), Transtibial (n=56), Gritti-Stokes (n=3), Through-knee (n=1), Bilateral (n=11)	nd	Range 50-88	nd	102	Houghton	nd	Rehabilitation was assessed by the answers to four standard questions. A score of 9 was accepted as satisfactory rehabilitation and one of 6 as indicating mobility on the prosthesis around the home	Validity	Construct
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	60	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Reliability	Test-retest
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	60	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Reliability	Internal Consistency
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	60	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Floor/ceiling effect	Floor
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	329	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Floor/ceiling effect	Floor

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Delvin	2004	15295762	PCS		r (not defined)	0.393	Moderate	Yes	At discharge, there was correlation with the PCS	Convergent validity (at discharge time)
Delvin	2004	15295762	MCS		r (not defined)	0.235	Small	No	At discharge, there was no correlation with the MCS	Convergent validity (at discharge time)
Delvin	2004	15295762	2MWT		r (not defined)	0.62	Large	Yes	At both discharge and follow-up, the Houghton Scale correlated significantly with the 2MWT	Convergent validity (at discharge time)
Delvin	2004	15295762	2MWT		r (not defined)	0.653	Large	Yes	At both discharge and follow-up, the Houghton Scale correlated significantly with the 2MWT	Convergent validity (at follow-up)
Delvin	2004	15295762	Transfemoral vs transtibial		P	<0.05		Yes	The Houghton Scale successfully discriminated between transfemoral versus transtibial participants	Construct validity (at both discharge and follow-up: p>0.05)
Delvin	2004	15295762	Unilateral vs bilateral		P	>=0.05		No	There was no difference between unilateral and bilateral transtibial participants	Construct validity (at discharge; at follow-up: p>0.05)
Houghton	1992	1393461	Transfemoral vs transtibial		nd	nd		Yes	BK amputees performed better than AK ones. The remaining 15 per cent comprised bilateral (11 per cent), GS (3 per cent) and TK (1 per cent). The numbers of these amputation types were too small to assess comparative rehabilitation.	
Miller	2000	0	nd		ICC	0.85	Excellent	Yes	The Houghton score displayed an excellent Test-retest reliability based on the ICC value	
Miller	2000	0	nd		Cronbach's alpha	0.68	Adequate	Yes	The score displayed an adequate Internal Consistency based on Cronbach's alpha value	
Miller	2000	0	nd		%	0		No	There was no indication of floor effect	
Miller	2000	0	nd		%	0.3		No	There was no indication of floor effect	



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	60	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Floor/ceiling effect	Ceiling
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	329	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Floor/ceiling effect	Ceiling
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Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	60	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	60	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	329	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	60	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	329	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	60	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	329	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	329	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Construct
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	329	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Miller	2000	0	nd		%	12.9		No	There was no indication of floor effect	
Miller	2000	0	nd		%	6		No	There was no indication of ceiling effect	
Miller	2000	0	Two minute walk test		Pearson r	0.64	Large	Yes	The Houghton displayed Large correlation with the Two minute walk test	
Miller	2000	0	Timed up and go		Pearson r	-0.6	Large	Yes	The Houghton displayed Large correlation with the Timed up and go	
Miller	2000	0	Activities-specific Balance Confidence		Pearson r	0.67	Large	Yes	The Houghton displayed Large correlation with the Activities-specific Balance Confidence	
Miller	2000	0	Activities-specific Balance Confidence		Pearson r	0.63	Large	Yes	The Houghton displayed Large correlation with the Activities-specific Balance Confidence	
Miller	2000	0	Prosthetic Profile of the Amputee - Locomotor Capabilities Index		Pearson r	0.6	Large	Yes	The Houghton displayed Large correlation with the Prosthetic Profile of the Amputee - Locomotor Capabilities Index	
Miller	2000	0	Prosthetic Profile of the Amputee - Locomotor Capabilities Index		Pearson r	0.59	Large	Yes	The Houghton displayed Large correlation with the Prosthetic Profile of the Amputee - Locomotor Capabilities Index	
Miller	2000	0	Prosthetic Evaluation Questionnaire - Mobility		Pearson r	0.59	Large	Yes	The Houghton displayed Large correlation with the Prosthetic Evaluation Questionnaire - Mobility	
Miller	2000	0	Prosthetic Evaluation Questionnaire - Mobility		Pearson r	0.55	Large	Yes	The Houghton displayed Large correlation with the Prosthetic Evaluation Questionnaire - Mobility	
Miller	2000	0	Transtibial vs Transfemoral		Effect size	0.29		Yes	The Houghton differed between Transtibial and Transfemoral	
Miller	2000	0	Vascular vs non-vascular		Effect size	0.63		Yes	The Houghton differed between Vascular and non-vascular	

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Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	329	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Construct
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	329	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Construct
Miller	2000	0	Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9	University associated outpatient amputee clinic that serves the region of southwestern Ontario, Canada	329	Houghton	nd	This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Construct
Wong	2016	26874230	Multiple	Multiple	55.5	nd	180	Houghton	nd	The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function. 3 Houghton Scale (range 0-12) categories: >=9 vs 6-8 vs <=5	Validity	Criterion
Wong	2016	26874230	Multiple	Multiple	55.5	nd	180	Houghton	nd	The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function. 3 Houghton Scale (range 0-12) categories: >=9 vs 6-8 vs <=5	Validity	Criterion
Wong	2016	26874230	Multiple	Multiple	55.5	nd	180	Houghton	nd	The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function. 3 Houghton Scale (range 0-12) categories: >=9 vs 6-8 vs <=5	Validity	Criterion
Wong	2016	26874230	Multiple	Multiple	55.5	nd	180	Houghton	nd	The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function. 3 Houghton Scale (range 0-12) categories: >=9 vs 6-8 vs <=5	Validity	Criterion
Wong	2016	26874230	Multiple	Multiple	55.5	nd	180	Houghton	nd	The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function. 3 Houghton Scale (range 0-12) categories: >=9 vs 6-8 vs <=5	Validity	Criterion
Wong	2016	26874230	Multiple	Multiple	55.5	nd	180	Houghton	nd	The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function.	Validity	Criterion (convergent)
Wong	2016	26874230	Multiple	Multiple	55.5	nd	180	Houghton	nd	The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function.	Validity	Criterion (convergent)
Wong	2016	26874230	Multiple	Multiple	55.5	nd	180	Houghton	nd	The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function.	Validity	Criterion (convergent)

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

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Miller	2000	0	Mobility device used vs no device		Effect size	1.62		Yes	The Houghton differed between Mobility device used and no device use	Mobility device use is an item of Houghton scale
Miller	2000	0	Walking distance <1 block vs unlimited		Effect size	0.54		Yes	The Houghton differed between Walking distance <1 block and unlimited	
Miller	2000	0	Automatic walking yes vs no		Effect size	0.78		Yes	The Houghton differed between Automatic walking and no automatic walking	
Wong	2016	26874230	Activities-specific Balance Confidence		P	<0.05		Yes	The 3 Houghton Scale ability categories differed significantly from each other (P<.05) for all outcome measures: Prosthetic Evaluation Questionnaire mobility subscale, ABC Scale, balance ability, TUG test, and 2MWT	Based on the ANOVA-Tukey test
Wong	2016	26874230	Timed up and go		P	<0.05		Yes	The 3 Houghton Scale ability categories differed significantly from each other (P<.05) for all outcome measures: Prosthetic Evaluation Questionnaire mobility subscale, ABC Scale, balance ability, TUG test, and 2MWT	Based on the ANOVA-Tukey test
Wong	2016	26874230	Two minute walk test		P	<0.05		Yes	The 3 Houghton Scale ability categories differed significantly from each other (P<.05) for all outcome measures: Prosthetic Evaluation Questionnaire mobility subscale, ABC Scale, balance ability, TUG test, and 2MWT	Based on the ANOVA-Tukey test
Wong	2016	26874230	3-Berg Balance Scale		P	<0.05		Yes	The 3 Houghton Scale ability categories differed significantly from each other (P<.05) for all outcome measures: Prosthetic Evaluation Questionnaire mobility subscale, ABC Scale, balance ability, TUG test, and 2MWT	Based on the ANOVA-Tukey test
Wong	2016	26874230	Prosthetic Evaluation Questionnaire - Mobility subscale		P	<0.05		Yes	The 3 Houghton Scale ability categories differed significantly from each other (P<.05) for all outcome measures: Prosthetic Evaluation Questionnaire mobility subscale, ABC Scale, balance ability, TUG test, and 2MWT	Based on the ANOVA-Tukey test
Wong	2016	26874230	Prosthetic Evaluation Questionnaire - Mobility subscale		Spearman r	0.73	Large	Yes	The Houghton Scale scores correlated with performance-based balance and walking ability measures	
Wong	2016	26874230	Activities-specific Balance Confidence		Spearman r	-0.76	Large	Yes	The Houghton Scale scores correlated with performance-based balance and walking ability measures	
Wong	2016	26874230	3-Berg Balance Scale		Spearman r	0.67	Large	Yes	The Houghton Scale scores correlated with performance-based balance and walking ability measures	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Wong	2016	26874230	Multiple	Multiple	55.5	nd	180	Houghton	nd	The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function.	Validity	Criterion (convergent)
Wong	2016	26874230	Multiple	Multiple	55.5	nd	180	Houghton	nd	The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function.	Validity	Criterion (convergent)
Wong	2016	26390393	TT (n=22), TF (n=13), BTT (n=2), BTT/BFT (n=2), BFT/BTT (n=1)	vascular (28), nonvascular (12)	57.0 +- 11.9		40	Houghton Scale	mobility		Validity	predictive
Devlin	2004	15295762	Multiple	Multiple	65.5		76	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Floor/ceiling effect	Ceiling
Devlin	2004	15295762	Multiple	Multiple	65.5		76	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Construct
Devlin	2004	15295762	Multiple	Multiple	65.5		76	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Construct
Devlin	2004	15295762	Multiple	Multiple	65.5		76	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Convergent
Devlin	2004	15295762	Multiple	Multiple	65.5		76	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Convergent
Devlin	2004	15295762	Multiple	Multiple	65.5		76	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Convergent
Devlin	2004	15295762	Multiple	Multiple	65.5		76	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Validity	Convergent
Devlin	2004	15295762	Multiple	Multiple	65.5		76	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Floor/ceiling effect	Floor

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Wong	2016	26874230	Timed up and go		Spearman r	0.67	Large	Yes	The Houghton Scale scores correlated with performance-based balance and walking ability measures	
Wong	2016	26874230	Two minute walk test		Spearman r	0.73	Large	Yes	The Houghton Scale scores correlated with performance-based balance and walking ability measures	
Wong	2016	26390393	predict failure to reach community ambulation	12 months	AUC	0.885		y	cut off score <=7	Houghton scale quantifies duration of daily prosthesis wear, use of prosthesis, use of assistive devices, and perceived stability when using the prosthesis on various terrains. The four questions are summated with the total score reported in a range from 0 to 12, with higher scores indicating better function. Scores of 9 or higher have been suggested to represent prosthetic use for community walking
Devlin	2004	15295762	nd		%	1.3		No	Floor and ceiling effects on the individual items were notable (as expected), although nearly absent for the overall score	
Devlin	2004	15295762	Transfemoral vs transtibial		P	<0.05		Yes	The Houghton Scale successfully discriminated between transfemoral versus transtibial participants	Construct validity (at both discharge and follow-up: p>0.05)
Devlin	2004	15295762	Unilateral vs bilateral		P	>=0.05		No	There was no difference between unilateral and bilateral transtibial participants	Construct validity (at discharge; at follow-up: p>0.05)
Devlin	2004	15295762	PCS		r (not defined)	0.393	Moderate	Yes	At discharge, there was correlation with the PCS	Convergent validity (at discharge time)
Devlin	2004	15295762	MCS		r (not defined)	0.235	Small	No	At discharge, there was no correlation with the MCS	Convergent validity (at discharge time)
Devlin	2004	15295762	2MWT		r (not defined)	0.62	Large	Yes	At both discharge and follow-up, the Houghton Scale correlated significantly with the 2MWT	Convergent validity (at discharge time)
Devlin	2004	15295762	2MWT		r (not defined)	0.653	Large	Yes	At both discharge and follow-up, the Houghton Scale correlated significantly with the 2MWT	Convergent validity (at follow-up)
Devlin	2004	15295762	nd		%	0		No	Floor and ceiling effects on the individual items were notable (as expected), although nearly absent for the overall score	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Devlin	2004	15295762	Multiple	Multiple	60.9		49	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Reliability	Internal Consistency
Devlin	2004	15295762	Multiple	Multiple	65.5		76	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Responsiveness	nd
Devlin	2004	15295762	Multiple	Multiple	60.9		49	Houghton Scale		The Houghton Scale1, is an instrument that looks solely at prosthetic use in people with lower-extremity amputations; it reflects a person's perception of prosthetic use, rather than a health care provider's viewpoint, and it consists of 4 questions	Reliability	Test-retest
Houghton	1992	1393461	Transfemoral (n=31), Transtibial (n=56), Gritti-Stokes (n=3), Through-knee (n=1), Bilateral (n=11)	nd	Range 50-88	nd	102	Houghton Scale		Rehabilitation was assessed by the answers to four standard questions. A score of 9 was accepted as satisfactory rehabilitation and one of 6 as indicating mobility on the prosthesis around the home	Validity	Construct
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Floor/ceiling effect	Ceiling
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Floor/ceiling effect	Ceiling
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Construct
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Construct
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Construct
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Construct
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Devlin	2004	15295762	nd		Cronbach's alpha	0.71	Adequate	Yes	The internal consistency was moderate at discharge and follow-up	Values at discharge time (.7 at follow up)
Devlin	2004	15295762	nd		Effect size	0.6		Yes	The effect size calculated for this change was .60, indicating a moderate difference	
Devlin	2004	15295762	nd		ICC	0.96	Excellent	Yes	The Houghton Scale showed good test-retest reliability over a 1-week span	
Houghton	1992	1393461	Transfemoral vs transtibial		nd	nd		Yes	BK amputees performed better than AK ones. The remaining 15 per cent comprised bilateral (11 per cent), GS (3 per cent) and TK (1 per cent). The numbers of these amputation types were too small to assess comparative rehabilitation.	
Miller	2000		nd		%	12.9		No	There was no indication of floor effect	
Miller	2000		nd		%	6		No	There was no indication of ceiling effect	
Miller	2000		Transtibial vs Transfemoral		Effect size	0.29		Yes	The Houghton differed between Transtibial and Transfemoral	
Miller	2000		Vascular vs non-vascular		Effect size	0.63		Yes	The Houghton differed between Vascular and non-vascular	
Miller	2000		Mobility device used vs no device		Effect size	1.62		Yes	The Houghton differed between Mobility device used and no device use	Mobility device use is an item of Houghton scale
Miller	2000		Walking distance <1 block vs unlimited		Effect size	0.54		Yes	The Houghton differed between Walking distance <1 block and unlimited	
Miller	2000		Automatic walking yes vs no		Effect size	0.78		Yes	The Houghton differed between Automatic walking and no automatic walking	



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Floor/ceiling effect	Floor
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Floor/ceiling effect	Floor
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Reliability	Internal Consistency
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	Houghton Scale		This measure assesses the amount of time the prosthesis is used, the manner in which the prosthesis is used, whether a mobility device is used when ambulating outside and the perception of stability when walking over a variety of terrains.	Reliability	Test-retest

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Miller	2000		Two minute walk test		Pearson r	0.64	Large	Yes	The Houghton displayed Large correlation with the Two minute walk test	
Miller	2000		Timed up and go		Pearson r	-0.6	Large	Yes	The Houghton displayed Large correlation with the Timed up and go	
Miller	2000		Activities-specific Balance Confidence		Pearson r	0.67	Large	Yes	The Houghton displayed Large correlation with the Activities-specific Balance Confidence	
Miller	2000		Activities-specific Balance Confidence		Pearson r	0.63	Large	Yes	The Houghton displayed Large correlation with the Activities-specific Balance Confidence	
Miller	2000		Prosthetic Profile of the Amputee - Locomotor Capabilities Index		Pearson r	0.6	Large	Yes	The Houghton displayed Large correlation with the Prosthetic Profile of the Amputee - Locomotor Capabilities Index	
Miller	2000		Prosthetic Profile of the Amputee - Locomotor Capabilities Index		Pearson r	0.59	Large	Yes	The Houghton displayed Large correlation with the Prosthetic Profile of the Amputee - Locomotor Capabilities Index	
Miller	2000		Prosthetic Evaluation Questionnaire - Mobility		Pearson r	0.59	Large	Yes	The Houghton displayed Large correlation with the Prosthetic Evaluation Questionnaire - Mobility	
Miller	2000		Prosthetic Evaluation Questionnaire - Mobility		Pearson r	0.55	Large	Yes	The Houghton displayed Large correlation with the Prosthetic Evaluation Questionnaire - Mobility	
Miller	2000		nd		%	0		No	There was no indication of floor effect	
Miller	2000		nd		%	0.3		No	There was no indication of floor effect	
Miller	2000		nd		Cronbach's alpha	0.68	Adequate	Yes	The score displayed an adequate Internal Consistency based on Cronbach's alpha value	
Miller	2000		nd		ICC	0.85	Excellent	Yes	The Houghton score displayed an excelent Test-retest reliability based on the ICC value	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Miller	2001	11552197	below knee (73%)	Vascular (53%)	62	23-91	435	Houghton Scale			Validity	Convergent
Miller	2001	11552197	below knee (73%)	Vascular (53%)	62	23-91	435	Houghton Scale			Validity	Convergent
Miller	2001	11552197	below knee (73%)	Vascular (53%)	62	23-91	435	Houghton Scale			Validity	Convergent
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	Houghton Scale		Ability to measure change	Floor/ceiling effects (appropriateness)	
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		55	Houghton Scale			Reliability	Internal consistency
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		55	Houghton Scale			Reliability	Test-retest
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	Houghton Scale			Validity	Convergent validity
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	Houghton Scale			Validity	Convergent validity
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	Houghton Scale			Validity	Convergent validity
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	Houghton Scale			Validity	Convergent validity
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	Houghton Scale			Validity	Convergent validity
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%	60		329	Houghton Scale		Ability to measure change	Floor/ceiling effects (appropriateness)	
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%	60		329	Houghton Scale			Validity	Construct (discriminant)
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%	60		329	Houghton Scale			Validity	Convergent validity
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%	60		329	Houghton Scale			Validity	Convergent validity
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%	60		329	Houghton Scale			Validity	Convergent validity
Wong	2016	26874230	Multiple	Multiple	55.5		180	Houghton Scale		The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function.	Validity	Criterion (convergent)
Wong	2016	26874230	Multiple	Multiple	55.5		180	Houghton Scale		The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function.	Validity	Criterion (convergent)
Wong	2016	26874230	Multiple	Multiple	55.5		180	Houghton Scale		The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function.	Validity	Criterion (convergent)
Wong	2016	26874230	Multiple	Multiple	55.5		180	Houghton Scale		The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function.	Validity	Criterion (convergent)
Wong	2016	26874230	Multiple	Multiple	55.5		180	Houghton Scale		The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function.	Validity	Criterion (convergent)

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Miller	2001	11552197	Falling		standardized regression coefficient	0.021				not statistically significant
Miller	2001	11552197	fear of falling		standardized regression coefficient	0.058				not statistically significant
Miller	2001	11552197	ABC scale (balance confidence)		standardized regression coefficient	0.804				statistically significant
Miller	2001	11588750 (sample 1)	NA		% at floor or ceiling	13		Yes		Ceiling effect (negligible floor effects)
Miller	2001	11588750 (sample 1)			Cronbach Alpha	0.68	adequate			55/60 were stable
Miller	2001	11588750 (sample 1)			ICC (95% CI)	0.85 (0.74, 0.90)				55/60 were stable
Miller	2001	11588750 (sample 1)			2 minute walk test	correlation	0.64			
Miller	2001	11588750 (sample 1)			Timed up and go (TUG)	correlation	-0.6			
Miller	2001	11588750 (sample 1)			ABC scale	correlation	0.67			
Miller	2001	11588750 (sample 1)			LCI	correlation	0.6			
Miller	2001	11588750 (sample 1)			PEQ mobility	correlation	0.59			
Miller	2001	11588750 (sample 2)	NA		% at floor or ceiling	6		Yes		Ceiling effect (negligible floor effects)
Miller	2001	11588750 (sample 2)	by: amputation level;; amputation cause; mobility device; walking distance; automatic walking		differences between levels of factors	Statistically significant differences in scores across all examined factors				
Miller	2001	11588750 (sample 2)			ABC scale	correlation	0.63			
Miller	2001	11588750 (sample 2)			LCI	correlation	0.59			
Miller	2001	11588750 (sample 2)			PEQ mobility	correlation	0.55			
Wong	2016	26874230	Prosthetic Evaluation Questionnaire - Mobility subscale		Spearman r	0.73	Large	Yes	The Houghton Scale scores correlated with performance-based balance and walking ability measures	
Wong	2016	26874230	Activities-specific Balance Confidence		Spearman r	-0.76	Large	Yes	The Houghton Scale scores correlated with performance-based balance and walking ability measures	
Wong	2016	26874230	3-Berg Balance Scale		Spearman r	0.67	Large	Yes	The Houghton Scale scores correlated with performance-based balance and walking ability measures	
Wong	2016	26874230	Timed up and go		Spearman r	0.67	Large	Yes	The Houghton Scale scores correlated with performance-based balance and walking ability measures	
Wong	2016	26874230	Two minute walk test		Spearman r	0.73	Large	Yes	The Houghton Scale scores correlated with performance-based balance and walking ability measures	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Wong	2016	26874230	Multiple	Multiple	55.5		180	Houghton Scale		The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function. 3 Houghton Scale (range 0-12) categories: >=9 vs 6-8 vs <=5	Validity	Criterion
Wong	2016	26874230	Multiple	Multiple	55.5		180	Houghton Scale		The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function. 3 Houghton Scale (range 0-12) categories: >=9 vs 6-8 vs <=5	Validity	Criterion
Wong	2016	26874230	Multiple	Multiple	55.5		180	Houghton Scale		The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function. 3 Houghton Scale (range 0-12) categories: >=9 vs 6-8 vs <=5	Validity	Criterion
Wong	2016	26874230	Multiple	Multiple	55.5		180	Houghton Scale		The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function. 3 Houghton Scale (range 0-12) categories: >=9 vs 6-8 vs <=5	Validity	Criterion
Wong	2016	26874230	Multiple	Multiple	55.5		180	Houghton Scale		The 4-question self-reported Houghton Scale quantifies daily prosthetic use and function in various walking conditions. Total scores range from 0 to 12 without ceiling or floor effects, with higher scores indicating better function. 3 Houghton Scale (range 0-12) categories: >=9 vs 6-8 vs <=5	Validity	Criterion
Gallagher	2000	study 2	Partial foot (n=2), below knee (n=29), through knee (n=3), above knee (n=20), hip disarticulation (n=4), bilateral (n=1), not specified (n=1)	Congenital (n=7), cancer (n=13), Accident (n=27), peripheral vascular disorder (n=7), other (n=6; not described further)	47.1	18+ years old	60	IES	Avoidance		Validity	Convergent
Gallagher	2000	study 2	Partial foot (n=2), below knee (n=29), through knee (n=3), above knee (n=20), hip disarticulation (n=4), bilateral (n=1), not specified (n=1)	Congenital (n=7), cancer (n=13), Accident (n=27), peripheral vascular disorder (n=7), other (n=6; not described further)	47.1	18+ years old	60	IES	Avoidance		Validity	Convergent
Gallagher	2000	study 2	Partial foot (n=2), below knee (n=29), through knee (n=3), above knee (n=20), hip disarticulation (n=4), bilateral (n=1), not specified (n=1)	Congenital (n=7), cancer (n=13), Accident (n=27), peripheral vascular disorder (n=7), other (n=6; not described further)	47.1	18+ years old	60	IES	Avoidance		Validity	Convergent
Gallagher	2000	study 2	Partial foot (n=2), below knee (n=29), through knee (n=3), above knee (n=20), hip disarticulation (n=4), bilateral (n=1), not specified (n=1)	Congenital (n=7), cancer (n=13), Accident (n=27), peripheral vascular disorder (n=7), other (n=6; not described further)	47.1	18+ years old	60	IES	Intrusion		Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Wong	2016	26874230	Activities-specific Balance Confidence		P	<0.05		Yes	The 3 Houghton Scale ability categories differed significantly from each other (P<.05) for all outcome measures: Prosthetic Evaluation Questionnaire mobility subscale, ABC Scale, balance ability, TUG test, and 2MWT	Based on the ANOVA-Tukey test
Wong	2016	26874230	Timed up and go		P	<0.05		Yes	The 3 Houghton Scale ability categories differed significantly from each other (P<.05) for all outcome measures: Prosthetic Evaluation Questionnaire mobility subscale, ABC Scale, balance ability, TUG test, and 2MWT	Based on the ANOVA-Tukey test
Wong	2016	26874230	Two minute walk test		P	<0.05		Yes	The 3 Houghton Scale ability categories differed significantly from each other (P<.05) for all outcome measures: Prosthetic Evaluation Questionnaire mobility subscale, ABC Scale, balance ability, TUG test, and 2MWT	Based on the ANOVA-Tukey test
Wong	2016	26874230	3-Berg Balance Scale		P	<0.05		Yes	The 3 Houghton Scale ability categories differed significantly from each other (P<.05) for all outcome measures: Prosthetic Evaluation Questionnaire mobility subscale, ABC Scale, balance ability, TUG test, and 2MWT	Based on the ANOVA-Tukey test
Wong	2016	26874230	Prosthetic Evaluation Questionnaire - Mobility subscale		P	<0.05		Yes	The 3 Houghton Scale ability categories differed significantly from each other (P<.05) for all outcome measures: Prosthetic Evaluation Questionnaire mobility subscale, ABC Scale, balance ability, TUG test, and 2MWT	Based on the ANOVA-Tukey test
Gallagher	2000	study 2	TAPES General adjustment		Correlation r	-0.455	Moderate	Yes		p<0.001
Gallagher	2000	study 2	TAPES Social adjustment		Correlation r	-0.462	Moderate	Yes		p<0.05
Gallagher	2000	study 2	TAPES Adjustment to limitation		Correlation r	-0.266	Small	Yes		p<0.05
Gallagher	2000	study 2	TAPES General adjustment		Correlation r	-0.623	Large	Yes		p<0.001

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Gallagher	2000	study 2	Partial foot (n=2), below knee (n=29), through knee (n=3), above knee (n=20), hip disarticulation (n=4), bilateral (n=1), not specified (n=1)	Congenital (n=7), cancer (n=13), Accident (n=27), peripheral vascular disorder (n=7), other (n=6; not described further)	47.1	18+ years old	60	IES	Intrusion		Validity	Convergent
Gallagher	2000	study 2	Partial foot (n=2), below knee (n=29), through knee (n=3), above knee (n=20), hip disarticulation (n=4), bilateral (n=1), not specified (n=1)	Congenital (n=7), cancer (n=13), Accident (n=27), peripheral vascular disorder (n=7), other (n=6; not described further)	47.1	18+ years old	60	IES	Intrusion		Validity	Convergent
da Silva	2011		Transfemoral (n=7), Transtibial (n=13), Hip (n=1), Knee (n=1)	Congenital (n=2), Metabolic (n=4), Vascular (n=2), Mechanical trauma (n=15)	18-69	nd	22	IPAQ	Overall		Reliability	Internal consistency
da Silva	2011		Transfemoral (n=7), Transtibial (n=13), Hip (n=1), Knee (n=1)	Congenital (n=2), Metabolic (n=4), Vascular (n=2), Mechanical trauma (n=15)	18-69		22	IPAQ			Reliability	Internal consistency
Deathe and Miller	2005		Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9	nd	93	L test	nd		Validity	Convergent
Deathe and Miller	2005		Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9	nd	93	L test	nd		Validity	Convergent
Deathe and Miller	2005		Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9	nd	93	L test	nd		Validity	Convergent
Deathe and Miller	2005		Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9	nd	93	L test	nd		Validity	Convergent
Deathe and Miller	2005		Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9	nd	93	L test	nd		Validity	Convergent
Deathe and Miller	2005		Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9	nd	93	L test	nd		Reliability	intrarater
Deathe and Miller	2005		Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9	nd	93	L test	nd		Reliability	interrater

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Gallagher	2000	study 2	TAPES Social adjustment		Correlation r	-0.265	Small	Yes		p<0.001
Gallagher	2000	study 2	TAPES Adjustment to limitation		Correlation r	-0.372	Moderate	Yes		p<0.01
da Silva	2011				Cronbach Alpha	0.55-0.63				
da Silva	2011				Cronbach Alpha	0.55-0.63				
Deathe and Miller	2005		Timed "Up & Go" Test		Pearson r	0.93				
Deathe and Miller	2005		2-Minute Walk Test		Pearson r	-0.86				
Deathe and Miller	2005		10-Meter Walk Test		Pearson r	0.97				
Deathe and Miller	2005		ABC		Pearson r	-0.48				
Deathe and Miller	2005		Frenchay Activities Index		Pearson r	-0.54				
Deathe and Miller	2005		PEQ-MS		Pearson r	-0.22				
Deathe and Miller	2005				ICC	0.97				
Deathe and Miller	2005				ICC	0.96				



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Deathe and Miller	2005		Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9	nd	93	L test	nd		Validity	Known group
Deathe and Miller	2005		Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9	nd	93	L test	nd		Validity	Known group
Deathe	2005	15982169	Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9		93	L test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Reliability	interrater
Deathe	2005	15982169	Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9		93	L test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Reliability	intrarater
Deathe	2005	15982169	Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9		93	L test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Convergent
Deathe	2005	15982169	Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9		93	L test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Convergent
Deathe	2005	15982169	Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9		93	L test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Convergent
Deathe	2005	15982169	Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9		93	L test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Convergent
Deathe	2005	15982169	Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9		93	L test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Convergent
Deathe	2005	15982169	Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9		93	L test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Deathe and Miller	2005		transfemoral vs transtibial		P value	<0.001				
Deathe and Miller	2005		traumatic vs vascular		P value	<0.001				
Deathe	2005	15982169				ICC	0.96			
Deathe	2005	15982169				ICC	0.97			
Deathe	2005	15982169			Timed "Up & Go" Test	Pearson r	0.93			
Deathe	2005	15982169			2-Minute Walk Test	Pearson r	-0.86			
Deathe	2005	15982169			10-Meter Walk Test	Pearson r	0.97			
Deathe	2005	15982169			ABC	Pearson r	-0.48			
Deathe	2005	15982169			Frenchay Activities Index	Pearson r	-0.54			
Deathe	2005	15982169			PEQ-MS	Pearson r	-0.22			

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Deathe	2005	15982169	Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9		93	L test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Known group
Deathe	2005	15982169	Transfemoral (n=24), Transtibial (n=69)	Trauma (n=8), Tumour (n=2), Infection (n=1), Vascular (n=25), Post-radiation (n=1), Congenital (n=2)	55.9		93	L test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Known group
Rushton	2015	25134533	Transfemoral (18.2%), Transtibial (81.8%)	Vascular (57.6%), Non-vascular (42.4%)	60	nd	33	L-test	nd	The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Criterion (convergent)
Rushton	2015	25134533	Transfemoral (18.2%), Transtibial (81.8%)	Vascular (57.6%), Non-vascular (42.4%)	60	nd	33	L-test	nd	The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Criterion (convergent)
Rushton	2015	25134533	Transfemoral (18.2%), Transtibial (81.8%)	Vascular (57.6%), Non-vascular (42.4%)	60	nd	33	L-test	nd	The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Criterion (convergent)
Rushton	2015	25134533	Transfemoral (18.2%), Transtibial (81.8%)	Vascular (57.6%), Non-vascular (42.4%)	60	nd	33	L-test	nd	The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Responsiveness	nd
Rushton	2015	25134533	Transfemoral (18.2%), Transtibial (81.8%)	Vascular (57.6%), Non-vascular (42.4%)	60	nd	33	L-test	nd	The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Responsiveness	nd
Rushton	2015	25134533	Transfemoral (18.2%), Transtibial (81.8%)	Vascular (57.6%), Non-vascular (42.4%)	60		33	L-test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Criterion (convergent)
Rushton	2015	25134533	Transfemoral (18.2%), Transtibial (81.8%)	Vascular (57.6%), Non-vascular (42.4%)	60		33	L-test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Criterion (convergent)
Rushton	2015	25134533	Transfemoral (18.2%), Transtibial (81.8%)	Vascular (57.6%), Non-vascular (42.4%)	60		33	L-test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Validity	Criterion (convergent)

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Deathe	2005	15982169			transfemoral vs transtibial	P value	<0.001			
Deathe	2005	15982169			traumatic vs vascular	P value	<0.001			
Rushton	2015	25134533	Global Rating of Change		Spearman r	0.28	Small	No	GRC was not a valid reference standard criterion for assessing important change in the ability of an individual with a LLA to get up and walk with a prosthesis.	
Rushton	2015	25134533	Global Rating of Change		Spearman r	0.27	Small	No	GRC was not a valid reference standard criterion for assessing important change in the ability of an individual with a LLA to get up and walk with a prosthesis.	Follow-up L Test
Rushton	2015	25134533	Global Rating of Change		Spearman r	0.27	Small	No	GRC was not a valid reference standard criterion for assessing important change in the ability of an individual with a LLA to get up and walk with a prosthesis.	L Test change between baseline and follow-up
Rushton	2015	25134533	Global Rating of Change		AUROC	0.67		No	The hypothesis that the L Test would correctly identify individuals who have and have not undergone an important change 80% of the time was not supported	
Rushton	2015	25134533	Global Rating of Change		Minimal clinically important difference	4.5		Yes	The study provides the first estimate of a MCID value for the L Test	
Rushton	2015	25134533	Global Rating of Change		Spearman r	0.28	Small	No	GRC was not a valid reference standard criterion for assessing important change in the ability of an individual with a LLA to get up and walk with a prosthesis.	
Rushton	2015	25134533	Global Rating of Change		Spearman r	0.27	Small	No	GRC was not a valid reference standard criterion for assessing important change in the ability of an individual with a LLA to get up and walk with a prosthesis.	Follow-up L Test
Rushton	2015	25134533	Global Rating of Change		Spearman r	0.27	Small	No	GRC was not a valid reference standard criterion for assessing important change in the ability of an individual with a LLA to get up and walk with a prosthesis.	L Test change between baseline and follow-up

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Rushton	2015	25134533	Transfemoral (18.2%), Trans tibial (81.8%)	Vascular (57.6%), Non-vascular (42.4%)	60		33	L-test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Responsiveness	nd
Rushton	2015	25134533	Transfemoral (18.2%), Trans tibial (81.8%)	Vascular (57.6%), Non-vascular (42.4%)	60		33	L-test		The L Test is a modified version of the Timed Up & Go (TUG) Test where the time it takes an individual to rise from an armless chair, walk 3 m, perform a right-angle turn, and continue walking 7 m before turning around 180° and walking back along the same path and sitting down is recorded in seconds	Responsiveness	nd
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	LCI	Total Overall Score	Ability to measure change	Floor/ceiling effects (appropriateness)	
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		55	LCI	Total Overall Score		Reliability	Internal consistency
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		55	LCI	Total Overall Score		Reliability	Test-retest
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	LCI	Total Overall Score		Validity	Convergent validity
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	LCI	Total Overall Score		Validity	Convergent validity
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	LCI	Total Overall Score		Validity	Convergent validity
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%	60		329	LCI	Total Overall Score	Ability to measure change	Floor/ceiling effects (appropriateness)	
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%	60		329	LCI	Total Overall Score		Validity	Construct (discriminant)
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%	60		329	LCI	Total Overall Score		Validity	Convergent validity
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Reliability	Test-Retest
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Validity	Convergent
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Validity	Convergent
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Validity	Convergent
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Validity	Known-group
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Validity	Known-group
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Validity	Predictive
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Validity	Predictive
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Validity	Predictive
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Validity	Predictive
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI			Validity	Responsiveness
Dite	2007		Trans tibial	nd	61.6	Unilateral	40	LCI-4	Advanced activity subscale		Validity	Known group/Discriminant
Treweek	1998		Transfemoral (26%), trans tibial (74%)	nd	67 (nd for Locomotor Index)		938 (n=195 for Locomotor Index)	LCI-4	Advanced activity subscale	Ability to measure change	Floor/ceiling effects (appropriateness)	
Treweek	1998		Transfemoral (26%), trans tibial (74%)	nd	67 (nd for Locomotor Index)		938 (n=195 for Locomotor Index)	LCI-4	Advanced activity subscale		Validity	Known group

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Rushton	2015	25134533	Global Rating of Change		AUROC	0.67		No	The hypothesis that the L Test would correctly identify individuals who have and have not undergone an important change 80% of the time was not supported	
Rushton	2015	25134533	Global Rating of Change		Minimal clinically important difference	4.5		Yes	The study provides the first estimate of a MCID value for the L Test	
Miller	2001	11588750 (sample 1)	NA		% at floor or ceiling	37		No		Ceiling effect (negligible floor effects)
Miller	2001	11588750 (sample 1)			Cronbach Alpha	0.89	excellent			55/60 were stable
Miller	2001	11588750 (sample 1)			ICC (95% CI)	0.88 (0.81, 0.93)				55/60 were stable
Miller	2001	11588750 (sample 1)			2 minute walk test	correlation	0.64			
Miller	2001	11588750 (sample 1)			Timed up and go (TUG)	correlation	-0.64			
Miller	2001	11588750 (sample 1)			ABC scale	correlation	0.82			
Miller	2001	11588750 (sample 2)	NA		% at floor or ceiling	40		No		Ceiling effect (negligible floor effects)
Miller	2001	11588750 (sample 2)	by: amputation level; amputation cause; mobility device; walking distance; automatic walking		differences between levels of factors	see notes				Only not statistically significant difference: between amputation level above or below the knee
Miller	2001	11588750 (sample 2)			ABC scale	correlation	0.81			
Franchignoni	2004	15129398			ICC	0.984				Among subgroup of n=37
Franchignoni	2004	15129398	RMI		Spearman's r	0.735				
Franchignoni	2004	15129398	FIM		Spearman's r	0.612				
Franchignoni	2004	15129398	LCI-5		Spearman's r	0.994				
Franchignoni	2004	15129398	Transtibial vs transfemoral		P-value	<0.001			Did not differ for RMI or FIM	
Franchignoni	2004	15129398	age		Spearman's r	-0.554				
Franchignoni	2004	15129398	TWT	9-19 days	Spearman's r	-0.667			10 meters	
Franchignoni	2004	15129398	RMI	9-19 days	Spearman's r	0.752				
Franchignoni	2004	15129398	FIM	9-19 days	Spearman's r	0.617				
Franchignoni	2004	15129398	LCI-5	9-19 days	Spearman's r	0.622				
Franchignoni	2004	15129398	LCI	9-19 days	Spearman's r	0.765				
Franchignoni	2004	15129398			Effect size	1.09				
Dite	2007				Multiple Fallers vs nonmultiple Fallers	P Value	0.04			differentiated between multiple and nonmultiple fallers
Treweek	1998								slightly less ceiling effect than whole Locomotor index	
Treweek	1998									discriminated patients (mann-Whitney test) by amputation level and age (greater or less than 40) for trans tibial patients

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Treweek	1998		Transfemoral (26%), transtibial (74%)	nd	67 (nd for Locomotor Index)		938 (n=195 for Locomotor Index)	LCI-4	Basic activity subscale		Validity	Known group
Arwert	2007	17943683	Unilateral transtibial	Vascular insufficiency	69.8	nd	23	LCI-4	Total Overall Score		Validity	Known group/Discriminant
Brunelli	2006	16813789	Unilateral transfemoral	Amputation for vascular disease and mild or moderate hemiparesis	69		45	LCI-4	Total Overall Score		Validity	Known group/Discriminant
Brunelli	2006	16813789	Unilateral transfemoral	Amputation for vascular disease and mild or moderate hemiparesis	69		45	LCI-4	Total Overall Score		Validity	Known group/Discriminant
Callaghan	2002	12227445	Unilateral transtibial	nd	nd		133	LCI-4	Total Overall Score		Reliability	Test-retest
Gauthier-Gagnon	1994	7993169	Transfemoral (n=35), transtibial(n=35)	Peripheral vascular disease/diabetes (70.6%), Trauma (22.8%), Tumor (4.3%), Other (4.3%)	60.6	Ulinateral	70	LCI-4	Total Overall Score		Reliability	Test-retest
Gauthier-Gagnon	1994	7993169	Transfemoral (n=35), transtibial(n=35)	Peripheral vascular disease/diabetes (70.6%), Trauma (22.8%), Tumor (4.3%), Other (4.3%)	60.6	Ulinateral	70	LCI-4	Total Overall Score		Validity	Construct
Gauthier-Gagnon	1994	107175246	Transfemoral (42%), nd(58%)	PVD (46%), diabetes (24%), nd(30%)	59.5	Ulinateral	70	LCI-4	Total Overall Score		Reliability	Internal consistency
Gauthier-Gagnon	1994	107175246	Transfemoral (42%), nd(58%)	PVD (46%), diabetes (24%), nd(30%)	59.5	Ulinateral	70	LCI-4	Total Overall Score		Validity	Content
Grise	1993	8347072	nd	nd	55.3	nd	26	LCI-4	Total Overall Score		Validity	Face/content
Panesar	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67		34	LCI-4	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Traballesi	2007	16955063	Transstibial	nd	65	Bilateral	30	LCI-4	Total Overall Score		Validity	Known group/Discriminant
Treweek	1998		Transfemoral (26%), transtibial (74%)	nd	67 (nd for Locomotor Index)		938 (n=195 for Locomotor Index)	LCI-4	Total Overall Score	Ability to measure change	Floor/ceiling effects (appropriateness)	
Treweek	1998		Transfemoral (26%), transtibial (74%)	nd	67 (nd for Locomotor Index)		938 (n=195 for Locomotor Index)	LCI-4	Total Overall Score		Validity	Known group
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 1		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 1		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 10		Validity	Structural

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Treweek	1998									Significant differences by age groups and amputation level
Arwert	2007	17943683	groups of different tibial length		ttest P	<0.05				differentiated between groups of different tibial length
Brunelli	2006	16813789	Laterality of impairment: Ipsilateral vs Contralateral		P value	<0.001				differentiated between laterality of impairment and severity of hemiparesis
Brunelli	2006	16813789	Cause of amputation: Atherosclerosis vs Diabetes		P value	>0.05				
Callaghan	2002	12227445			ICC	0.74				reliable on majority of questions and moderately reliable on remaining questions. ICC: 0.64-0.96, % agreement 20-90
Gauthier-Gagnon	1994	7993169			ICC	0.8				Locomotion index=0.80 (all items >0.75).
Gauthier-Gagnon	1994	7993169	Reintegration to Normal Living (RNL) index		Pearson r	0.53				Pearson RNL=0.53
Gauthier-Gagnon	1994	107175246			Cronbach alpha	0.95				
Gauthier-Gagnon	1994	107175246								The LCI retains unidimensionality
Grise	1993	8347072								Based on the comments from experts and LEA, the questionnaire was deemed to have face validity
Panesar	2001									significant kendal correlations coefficients between each of the measures
Traballesi	2007	16955063	patients with ideal stumps vs patients with combined stump pain and flexion deformities							LCI is significantly higher for patients with ideal stumps and lower for patients with combined stump pain and flexion deformities
Treweek	1998								ceiling effect evident	
Treweek	1998									discriminated patients (mann-Whitney test) by amputation level and age (greater or less than 40) for trans tibial patients
Franchignoni	2007	18050010				Rasch infit MnSq	1.04			
Franchignoni	2007	18050010				Rasch outfit MnSq	1			
Franchignoni	2007	18050010				Rasch infit MnSq	0.52			misfit



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 10		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 11		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 11		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 12		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 12		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 13		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 13		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 14		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 14		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 2		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 2		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 3		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 3		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 4		Validity	Structural

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Franchignoni	2007	18050010			Rasch outfit MnSq	0.46				misfit
Franchignoni	2007	18050010			Rasch infit MnSq	0.53				misfit
Franchignoni	2007	18050010			Rasch outfit MnSq	0.49				misfit
Franchignoni	2007	18050010			Rasch infit MnSq	0.76				
Franchignoni	2007	18050010			Rasch outfit MnSq	0.65				
Franchignoni	2007	18050010			Rasch infit MnSq	0.98				
Franchignoni	2007	18050010			Rasch outfit MnSq	1.11				
Franchignoni	2007	18050010			Rasch infit MnSq	1.18				
Franchignoni	2007	18050010			Rasch outfit MnSq	0.97				
Franchignoni	2007	18050010			Rasch outfit MnSq	1.16				misfit
Franchignoni	2007	18050010			Rasch infit MnSq	1.24				
Franchignoni	2007	18050010			Rasch infit MnSq	1.65				misfit
Franchignoni	2007	18050010			Rasch outfit MnSq	2.1				
Franchignoni	2007	18050010			Rasch infit MnSq	0.71				

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 4		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 5		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 5		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 6		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 6		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 7		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 7		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 8		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 8		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 9		Validity	Structural
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5	Item 9		Validity	Structural
de Laet	2011		Transfemoral (n=54), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=142), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	171	LCI-5	Total Overall Score		Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Franchignoni	2007	18050010				Rasch outfit MnSq	0.63			
Franchignoni	2007	18050010				Rasch infit MnSq	0.99			
Franchignoni	2007	18050010				Rasch outfit MnSq	0.81			
Franchignoni	2007	18050010				Rasch infit MnSq	1.02			
Franchignoni	2007	18050010				Rasch outfit MnSq	1.07			
Franchignoni	2007	18050010			Rasch infit MnSq	1.45				misfit
Franchignoni	2007	18050010				Rasch outfit MnSq	1.29			
Franchignoni	2007	18050010				Rasch infit MnSq	0.66			
Franchignoni	2007	18050010				Rasch outfit MnSq	0.67			
Franchignoni	2007	18050010				Rasch infit MnSq	0.76			
Franchignoni	2007	18050010				Rasch outfit MnSq	0.72			
de Laat	2011		The Rising and Sitting down Questionnaire		Spearman r	0.4				Spearman: Rising and Sitting=0.40

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
de Laat	2012		Transfemoral (n=55), Trans tibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and trans tibial (n=2), Trans tibial and trans tibial (n=7), Syme and trans tibial (n=3)	Vascular (n=143), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	172	LCI-5	Total Overall Score		Validity	Convergent
Franchignoni	2007	18050010					123	LCI-5	Total Overall Score		Reliability	Person separation reliability
Franchignoni	2007	18050010					123	LCI-5	Total Overall Score		Reliability	Item separation reliability
Franchignoni	2007	18050010					123	LCI-5	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Norvell	2011	21531528	Transfemoral (n=8), Trans tibial (n=52), transmetatarsal (n=27); unilateral	PVD or diabetes	62.06	55-65	87	LCI-5	Total Overall Score		Validity	Convergent
Norvell	2011	21531528	Transfemoral (n=8), Trans tibial (n=52), transmetatarsal (n=27); unilateral	PVD or diabetes	62.06	55-65	87	LCI-5	Total Overall Score		Validity	Known group
Parker	2010	2010632385	Transfemoral (n=16), Trans tibial (n=30), Bilateral trans tibial (n=6)	Vascular (n=20), Trauma (n=26), Other (n=6)	55.2		52	LCI-5	Total Overall Score	Ability to measure change	Floor/ceiling effects (appropriateness)	
Parker	2010	2010632385	Transfemoral (n=16), Trans tibial (n=30), Bilateral trans tibial (n=6)	Vascular (n=20), Trauma (n=26), Other (n=6)	55.2		52	LCI-5	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI-5			Validity	Convergent
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI-5			Validity	Convergent
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI-5			Validity	Known-group
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI-5			Validity	Known-group
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI-5			Validity	Predictive
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI-5			Validity	Predictive
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI-5			Validity	Predictive
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI-5			Validity	Predictive
Franchignoni	2004	15129398	Transfemoral (60%), Trans tibial (40%)	Trauma (58%), PVD (32%), Other (10%)	51	recent (<1 year) unilateral LLA	50	LCI-5			Validity	Responsiveness
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5			Floor/ceiling effect	Appropriateness
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5			Validity	Construct
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5			Validity	Construct
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5			Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
de Laat	2012		The Walking Questionnaire		Spearman r	0.5				Spearman: Walking=0.50
Franchignoni	2007	18050010			P value	0.94				
Franchignoni	2007	18050010			P value	0.98				
Franchignoni	2007	18050010								Spearman's: PEQ-MS=0.77
Norvell	2011	21531528	Satisfaction with mobility							significant associations with 12-month satisfaction with mobility
Norvell	2011	21531528								no difference between amputation level
Parker	2010	2010632385							half of participants obtained the highest score	
Parker	2010	2010632385								Spearman: TAPES activity=0.66, TUG--0.72, 2MWT=-0.84
Franchignoni	2004	15129398	RMI		Spearman's r	0.746				
Franchignoni	2004	15129398	FIM		Spearman's r	0.618				
Franchignoni	2004	15129398	Transfemoral vs transtibial		P-value	<0.001			Did not differ for RMI or FIM	
Franchignoni	2004	15129398	age		Spearman's r	-0.557				
Franchignoni	2004	15129398	TWT	9-19 days	Spearman's r	-0.708			10 meters	
Franchignoni	2004	15129398	RMI	9-19 days	Spearman's r	0.757				
Franchignoni	2004	15129398	FIM	9-19 days	Spearman's r	0.622				
Franchignoni	2004	15129398	LCI-5	9-19 days	Spearman's r	0.788				
Franchignoni	2004	15129398			Effect size	1.4				
Franchignoni	2007	18050010			%	5				showed maximum LCI-5, none showed floor effect
Franchignoni	2007	18050010	PEQ-MS		Spearman's r	0.77	Large	Yes		p<0.001
Franchignoni	2007	18050010	PPA item 12		Spearman's r	0.47	Moderate	Yes		p<0.001
Franchignoni	2007	18050010	PPA item 14b		Spearman's r	0.34	Moderate	Yes		p<0.001

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5			Validity	Construct
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI-5			Validity	Construct
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI10-4			Reliability	Internal consistency
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI10-4			Reliability	Internal consistency
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI10-4			Reliability	Internal consistency
Franchignoni	2007	18050010	Above knee (53%), Below knee (56%), Bilateral above knee (6%), Bilateral below knee (5%)	Peripheral vascular disease and/or DM (53%), Trauma (56%), Tumor/other (9%)	54	20-80 years old	123	LCI10-4			Reliability	Internal consistency
Zidarov, et al	2009						19	Life H Short Form 3.1	Community life		Ability to measure change	Responsiveness
Zidarov, et al	2009						19	Life H Short Form 3.1	Employment		Ability to measure change	Responsiveness
Zidarov, et al	2009						19	Life H Short Form 3.1	Interpersonal relations		Ability to measure change	Responsiveness
Zidarov, et al	2009						19	Life H Short Form 3.1	Recreation		Ability to measure change	Responsiveness
Zidarov, et al	2009						19	Life H Short Form 3.1	Responsibility		Ability to measure change	Responsiveness
Dite, Connor,Curtis	2007							Locomotor Capabilities Index (LCI-4 advanced)	Advanced activity subscale		Validity	Known group/Discriminant
Treweek	1998		Transfemoral (26%), transtibial (74%)	nd	67 (nd for Locomotor Index)	nd	938 (n=195 for Locomotor Index)	Locomotor Capabilities Index (LCI-4 advanced)	Advanced activity subscale		Validity	Known group
Treweek	1998		Transfemoral (26%), transtibial (74%)	nd	67 (nd for Locomotor Index)	nd	938 (n=195 for Locomotor Index)	Locomotor Capabilities Index (LCI-4 advanced)	Advanced activity subscale		Ability to measure change	Floor/ceiling effects (appropriateness)
Treweek	1998		Transfemoral (26%), transtibial (74%)	nd	67 (nd for Locomotor Index)	nd	938 (n=195 for Locomotor Index)	Locomotor Capabilities Index (LCI-4 basic)	Basic activity subscale		Validity	Known group
Arwert et al	2007	17943683	Unilateral transtibial	Vascular insufficiency	69.8	nd	23	Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Known group/Discriminant
Brunelli	2006	16813789	Unilateral transfemoral	Amputation for vascular disease and mild or moderate hemiparesis	69	nd	45	Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Known group/Discriminant

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Franchignoni	2007	18050010	PPA item 16b		Spearman's r	0.42	Moderate	Yes		p<0.001
Franchignoni	2007	18050010	PPA item 18		Spearman's r	0.51	Large	Yes		p<0.001
Franchignoni	2007	18050010				item separation index	7.39			
Franchignoni	2007	18050010				item separation reliability	0.98	Excellent		
Franchignoni	2007	18050010				person separation index	3.9			
Franchignoni	2007	18050010				person separation index	0.94	Excellent		
Zidarov, et al	2009									there were significant improvements in scores from admission to inpatient rehabilitation to 3 months after discharge P<.001
Zidarov, et al	2009									there were significant improvements in scores from admission to inpatient rehabilitation to 3 months after discharge P .014
Zidarov, et al	2009									there were significant improvements in scores from admission to inpatient rehabilitation to 3 months after discharge P .400
Zidarov, et al	2009									there were significant improvements in scores from admission to inpatient rehabilitation to 3 months after discharge P .001
Zidarov, et al	2009									there were significant improvements in scores from admission to inpatient rehabilitation to 3 months after discharge P .38
Dite, Connor,Curtis	2007									differentiated between multiple and nonmultiple fallers
Treweek	1998									discriminated patients (mann-Whittney test) by amputation level and age (greater or less than 40) for trans tibial patients
Treweek	1998									slightly less ceiling effect than whole Locomotor index
Treweek	1998									Significant differences by age groups and amputation level
Anwert et al	2007	17943683	groups of different tibial length		ttest P	<0.05				differentiated between groups of different tibial length
Brunelli	2006	16813789	Laterality of impairment: Ipsilateral vs Contralateral		P value	<0.001				differentiated between laterality of impairment and severity of hemiparesis



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Brunelli	2006	16813789	Unilateral transfemoral	Amputation for vascular disease and mild or moderate hemiparesis	69	nd	45	Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Known group/Discriminant
Callaghan, Sockalingam, Treweek and Condie	2002	12227445	Unilateral transtibial	nd	nd	nd	133	Locomotor Capabilities Index (LCI-4)	Total Overall Score		Reliability	Test-retest
Franchignoni, Orlandinim et al	2004							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Reliability	Test-retest
Franchignoni, Orlandinim et al	2004							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Reliability	Internal consistency
Franchignoni, Orlandinim et al	2004							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Known group/Discriminant
Franchignoni, Orlandinim et al	2004							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Franchignoni, Orlandinim et al	2004							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Ability to measure change	Responsiveness
Gauthier-Gagnon, Grise	1994							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Reliability	Test-retest
Gauthier-Gagnon, Grise	1994							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Construct
Grise	1993							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Face/content
Larsson, Johannesson et al	2009							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Reliability	Test-retest
Larsson, Johannesson et al	2009							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Reliability	Internal consistency
Larsson, Johannesson et al	2009							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Known group/Discriminant
Larsson, Johannesson et al	2009							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Larsson, Johannesson et al	2009							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Ability to measure change	Floor/ceiling effects (appropriateness)
Miller, Deathe and Speechley	2001							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Reliability	Test-retest
Miller, Deathe and Speechley	2001							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Reliability	Internal consistency
Miller, Deathe and Speechley	2001							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Known group/Discriminant
Miller, Deathe and Speechley	2001							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Miller, Deathe and Speechley	2001							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Ability to measure change	Floor/ceiling effects (appropriateness)
Panesar et al,	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67	nd	34	Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Traballesi	2007							Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Known group/Discriminant
Treweek	1998		Transfemoral (26%), transtibial (74%)	nd	67 (nd for Locomotor Index)	nd	938 (n=195 for Locomotor Index)	Locomotor Capabilities Index (LCI-4)	Total Overall Score		Validity	Known group
Treweek	1998		Transfemoral (26%), transtibial (74%)	nd	67 (nd for Locomotor Index)	nd	938 (n=195 for Locomotor Index)	Locomotor Capabilities Index (LCI-4)	Total Overall Score		Ability to measure change	Floor/ceiling effects (appropriateness)

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Brunelli	2006	16813789	Cause of amputation: Atherosclerosis vs Diabetes		P value	>0.05				
Callaghan, Sockalingam, Treweek and Condie	2002	12227445			ICC	0.74				reliable on majority of questions and moderately reliable on remaining questions. ICC: 0.64-0.96, % agreement 20-90
Franchignoni, Orlandinim et al	2004									repeated measures ANOVA did not reveal differences between scores at two time points, ICC=0.984
Franchignoni, Orlandinim et al	2004				Chronbach Alpha	0.95				
Franchignoni, Orlandinim et al	2004									differentiated between amputation level
Franchignoni, Orlandinim et al	2004									Spearman's: LCI-5=0.99, RMI=0.74, FIM=0.61
Franchignoni, Orlandinim et al	2004									significant increase during test period, effect size 1.09
Gauthier-Gagnon, Grise	1994									Locomotion index=0.80 (all items >0.75).
Gauthier-Gagnon, Grise	1994									Pearson RNL=0.53
Grise	1993									assumed to have content validity once all experts believed that questions reflected the specific objectives of the questionnaire
Larsson, Johannesson et al	2009									ICC=0.91
Larsson, Johannesson et al	2009				Chronbach Alpha	0.95				
Larsson, Johannesson et al	2009									differentiated between younger amputees and unilateral vs bilateral amputees. LCI scores >=36 were more common among men
Larsson, Johannesson et al	2009									Pearson: TUG=-0.75, EQ-5D (QOL)=0.84
Larsson, Johannesson et al	2009									23% had the maximum possible score, 0.7% had lowest possible score
Miller, Deathe and Speechley	2001									ICC= 0.77
Miller, Deathe and Speechley	2001				Chronbach Alpha	0.95				
Miller, Deathe and Speechley	2001									Significantly discriminant of Amputation cause(vascular/non), Mobility Device used (yes/no), Walking distance(unlimited,<1block) and Automatic Walking (yes/no)
Miller, Deathe and Speechley	2001									Pearsons: 2 min walk test=0.64, TUG=-0.64, ABC Scale=0.82, PEQ mobility=0.77, Houghton=0.60
Miller, Deathe and Speechley	2001									high ceiling effects
Panesar et al,	2001									significant kendal correlations coefficients between each of the measures
Traballesi	2007									LCI is significantly higher for patients with ideal stumps and lower for patients with combined stump pain and flexion deformities
Treweek	1998									discriminated patients (mann-Whittney test) by amputation level and age (greater or less than 40) for trans tibial patients
Treweek	1998									ceiling effect evident

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Czerniecki, J., Turner, A.,	2012		Transfemoral (n=7), Transtibial (n=38), Transmetatarsal (n=27)	peripheral vascular disease or diabetes	nd	nd	72	Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Known group/Discriminant
deLaat et al.	2011		Transfemoral (n=54), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=142), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	nd	171	Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Convergent
deLaat et al.	2012		Transfemoral (n=55), Transtibial (n=93), Hip disarticulation (n=3), Knee disarticulation (n=8), Syme (n=1), Transfemoral and transtibial (n=2), Transtibial and transtibial (n=7), Syme and transtibial (n=3)	Vascular (n=143), Infection (n=13), Traumatic (n=13), Oncologic (n=3)	65	18 years or older; they were wearing a prosthesis at the end of their rehabilitation treatment after a recent lower limb amputation; and they were able to understand and fill in the questionnaires	172	Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Convergent
Ferriero, Dughi, et al	1994							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Reliability	Internal consistency
Ferriero, Dughi, et al	1994							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Known group/Discriminant
Ferriero, Dughi, et al	1994							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Construct
Franchignoni, Giordnano, Ferriero et al	2007							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Reliability	Item separation reliability
Franchignoni, Giordnano, Ferriero et al	2007							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Reliability	Person separation reliability
Franchignoni, Giordnano, Ferriero et al	2007							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Franchignoni, Orlandinim et al	2004							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Reliability	Test-retest
Franchignoni, Orlandinim et al	2004							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Reliability	Internal consistency
Franchignoni, Orlandinim et al	2004							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Known group/Discriminant
Franchignoni, Orlandinim et al	2004							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Franchignoni, Orlandinim et al	2004							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Ability to measure change	Responsiveness
Norvell et al	2011							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Known group/Discriminant
Norvell et al	2011							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Predictive
Parker et al.,	2010							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Concurrent/convergent/criteria Validity criterion
Parker et al.,	2010							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Ability to measure change	Floor/ceiling effects (appropriateness)
Rau et al.,	2007							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Ability to measure change	Responsiveness
Salavati et al	2011							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Reliability	Test-retest
Salavati et al	2011							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Reliability	Internal consistency
Salavati et al.,	2011							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Face/content



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Salavati et al.	2011							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Known group/Discriminant
Salavati et al.	2011							Locomotor Capabilities Index (LCI-5)	Total Overall Score		Validity	Construct
Fisher, Hanspal and Marks	2003		Transfemoral (43%), Transtibial (50%), hip or partial foot amputation (7%)	vascular or diabetes (24%), trauma (64%), neoplasm (8%), other (4%)	47.4	normal or near normal cognitive ability, aged 17-65, amputation between 16-64 years, established prosthesis wearer, amputation at least 1 year previously	100	London Handicap Scale	No Subscales		Validity	Convergent
Fisher	2003		Transfemoral (43%), Transtibial (50%), hip or partial foot amputation (7%)	vascular or diabetes (24%), trauma (64%), neoplasm (8%), other (4%)	47.4	normal or near normal cognitive ability, aged 17-65, amputation between 16-64 years, established prosthesis wearer, amputation at least 1 year previously	100	London Handicap Scale			Validity	Convergent
Remes	2010		nd	peripheral artery disease	75.17		59	LS		Self-reported Life Satisfaction score	Validity	Concurrent/convergent criterion
Remes	2010		nd	peripheral artery disease	75.17		59	LS		Self-reported Life Satisfaction score	Validity	Known group/Discriminant
Van de Weg	2005	16466153	Transtibial	nd	62.1	nd	220	Modified PEQ	Problems	The questionnaire included questions on demographic variables (age, gender, marital status, level of education), reason for amputation, and time since first prosthesis. In addition, several questions concerned use, maintenance, and durability of the prosthesis	Reliability	Internal Consistency
Van de Weg	2005	16466153	Transtibial	nd	62.1	nd	220	Modified PEQ	Satisfaction	The questionnaire included questions on demographic variables (age, gender, marital status, level of education), reason for amputation, and time since first prosthesis. In addition, several questions concerned use, maintenance, and durability of the prosthesis	Reliability	Internal Consistency
Abdelgadir et al	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS	Role emotional, quality of life		Validity	Known group
Hart	1999							MOS questionnaire	Bodily pain		Reliability	Internal consistency
Hart,	1999							MOS questionnaire	Bodily pain		Validity	Known group
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Family satisfaction		Validity	Known group
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Family satisfaction		Validity	Concurrent/convergent criterion
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Negative feelings		Validity	Known group
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Physical functioning		Validity	Known group/Discriminant
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Physical functioning		Validity	Concurrent/convergent/criteria Validity criterion
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Physical functioning		Validity	Known group
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Physical functioning		Validity	Concurrent/convergent criterion
Boutoille	2008	19026199	Transtibial (n = 6), Toe-or-transmetatarsal (n = 19)	Diabetic amputees	68	nd	25	MOS questionnaire	Physical functioning		Validity	Known group/Discriminant
Boutoille	2008	19026199	Transtibial (n = 6), Toe-or-transmetatarsal (n = 19)	Diabetic amputees	68	nd	25	MOS questionnaire	Physical functioning		Validity	Known group/Discriminant
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Positive feelings		Validity	Concurrent/convergent criterion
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Role emotional		Validity	Known group
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Role physical		Validity	Known group

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Salavati et al.	2011									differentiated between amputation level and use of walking aids
Salavati et al.	2011									Spearman: TUG=-0.65, 2MWT=0.71
Fisher, Hanspal and Marks	2003		Employment questionnaire		nonparametric correlation	-0.52				correlation with Employment questionnaire P<.001
Fisher	2003				Employment questionnaire	nonparametric correlation	-0.52			correlation with Employment questionnaire P<.001
Remes	2010									All the QoL scores had a significant correlation with the LS score
Remes	2010		amputees vs control group		P value	0.448				
Van de Weg	2005	16466153	nd		Cronbach's alpha	0.76	Adequate	Yes	There is sufficient evidence of Internal Consistency for the PEQ-problems subscale	
Van de Weg	2005	16466153	nd		Cronbach's alpha	0.88	Excellent	Yes	There is sufficient evidence of Internal Consistency for the PEQ-satisfaction subscale	
Abdelgadir et al	2009	19155607	diabetic controls		P value	<0.01				It includes questions over the following domains: physical functioning, physical role, negative and positive feelings, emotional role, family satisfaction, sleep and general health; The questions within each domain were summed and linearly transformed into 0-100 scales such that a high score indicates better health
Hart	1999									$\alpha$ (at fitting)=0.89; $\alpha$ (at follow-up)=0.89
Hart,	1999									Younger(<60) patients demonstrated greater improvement in overall health status (p=.002)
Abdelgadir et al.	2009	19155607			P value	<0.01				
Abdelgadir et al.	2009	19155607			P value	<0.01				Significant positive correlation with sense of coherence (p<.0001)
Abdelgadir et al.	2009	19155607			P value	<0.01				
Abdelgadir et al.	2009	19155607			P value	<0.01				
Abdelgadir et al.	2009	19155607			P value	<0.01				Sense of coherence of LLA and physical function showed significant negative correlation (p<.0001)
Abdelgadir et al.	2009	19155607			P value	<0.01				
Abdelgadir et al.	2009	19155607			P value	<0.01				Sense of coherence of LLA and physical function showed significant negative correlation (p<.0001)
Boutoille	2008	19026199	amputee vs foot ulcer groups							no significant difference between amputee and foot ulcer groups
Boutoille	2008	19026199	amputee vs foot ulcer groups							no significant difference between amputee and foot ulcer groups
Abdelgadir et al.	2009	19155607			P value	<0.01				Significant positive correlation with sense of coherence (p<.0001)
Abdelgadir et al.	2009	19155607			P value	<0.01				
Abdelgadir et al.	2009	19155607			P value	<0.01				

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Role physical		Validity	Concurrent/convergent criterion
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Sleep		Validity	Known group
Abdelgadir et al.	2009	19155607	nd	nd	57.4	Diabetic Sudanese	60	MOS questionnaire	Sleep		Validity	Concurrent/convergent criterion
Morgan	2016	26836953	Transfemoral (n=343), Transtibial (n=691), Knee disarticulation (n=40), Symes (n=12)	Trauma (N=602), Dysvascular (N=484)	54.9	>18 years; unilateral LLL; no other amputations; use of a prosthesis to walk; ability to read, write, and understand English	1086	Neuro-QoL ACGC		The Quality of Life in Neurological Disorders Applied CognitionGeneral Concerns Short Form version 1.0 solicits information from respondents about the frequency with which they experience cognitive concerns over the prior 7 days. The Neuro-QoL ACGC is brief, has normative scores, and has demonstrated evidence of reliability and validity across a range of clinical populations	Validity	Construct
Morgan	2016	26836953	Transfemoral (n=343), Transtibial (n=691), Knee disarticulation (n=40), Symes (n=12)	Trauma (N=602), Dysvascular (N=484)	54.9	>18 years; unilateral LLL; no other amputations; use of a prosthesis to walk; ability to read, write, and understand English	1086	Neuro-QoL ACGC		The Quality of Life in Neurological Disorders Applied CognitionGeneral Concerns Short Form version 1.0 solicits information from respondents about the frequency with which they experience cognitive concerns over the prior 7 days. The Neuro-QoL ACGC is brief, has normative scores, and has demonstrated evidence of reliability and validity across a range of clinical populations	Validity	Construct
Morgan	2016	26836953	Transfemoral (n=343), Transtibial (n=691), Knee disarticulation (n=40), Symes (n=12)	Trauma (N=602), Dysvascular (N=484)	54.9	>18 years; unilateral LLL; no other amputations; use of a prosthesis to walk; ability to read, write, and understand English	1086	Neuro-QoL ACGC		The Quality of Life in Neurological Disorders Applied CognitionGeneral Concerns Short Form version 1.0 solicits information from respondents about the frequency with which they experience cognitive concerns over the prior 7 days. The Neuro-QoL ACGC is brief, has normative scores, and has demonstrated evidence of reliability and validity across a range of clinical populations	Validity	Construct
Morgan	2016	26836953	Transfemoral (n=343), Transtibial (n=691), Knee disarticulation (n=40), Symes (n=12)	Trauma (N=602), Dysvascular (N=484)	54.9	>18 years; unilateral LLL; no other amputations; use of a prosthesis to walk; ability to read, write, and understand English	1086	Neuro-QoL ACGC		The Quality of Life in Neurological Disorders Applied CognitionGeneral Concerns Short Form version 1.0 solicits information from respondents about the frequency with which they experience cognitive concerns over the prior 7 days. The Neuro-QoL ACGC is brief, has normative scores, and has demonstrated evidence of reliability and validity across a range of clinical populations	Validity	Construct
Demet et al	2002		Both upper and lower limb amputees grouped together					NHP	Emotional reactions		Reliability	Test-retest
Demet et al.	2003		Both upper and lower limb amputees grouped together					NHP	Emotional reactions		Validity	Known group
Demet et al	2002		Both upper and lower limb amputees grouped together					NHP	Energy		Reliability	Test-retest
Demet et al.	2003		Both upper and lower limb amputees grouped together					NHP	Energy		Validity	Known group
Demet et al	2002		Both upper and lower limb amputees grouped together					NHP	Mobility		Reliability	Test-retest
Demet et al.	2003		Both upper and lower limb amputees grouped together					NHP	Mobility		Validity	Known group
Demet et al	2002		Both upper and lower limb amputees grouped together					NHP	Pain		Reliability	Test-retest
Demet et al	2002		Both upper and lower limb amputees grouped together					NHP	Sleep		Reliability	Test-retest
Demet et al	2002		Both upper and lower limb amputees grouped together					NHP	Social isolation		Reliability	Test-retest

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Abdelgadir et al.	2009	19155607			P value	<0.01				Sense of coherence of LLA and role physical showed significant negative correlation (p<.0001)
Abdelgadir et al.	2009	19155607			P value	<0.01				
Abdelgadir et al.	2009	19155607			P value	<0.01				Significant positive correlation with sense of coherence (p<.0001)
Morgan	2016	26836953	Normative sample		P	<0.001		Yes	people with LLL, irrespective of etiology, report significantly greater cognitive concerns than the U.S. general population	Based on ttest; compared to the value of 50, the mean of the U.S. normative sample
Morgan	2016	26836953	Normative sample		P	<0.001		Yes	people with LLL, irrespective of etiology, report significantly greater cognitive concerns than the U.S. general population	Etiology group: Trauma, n=602
Morgan	2016	26836953	Normative sample		P	<0.001		Yes	people with LLL, irrespective of etiology, report significantly greater cognitive concerns than the U.S. general population	Etiology group: Dysvascular, n=484
Morgan	2016	26836953	Trauma (N=602) vs Dysvascular (N=484)		P	0.58		No	perceived cognitive concerns did not differ between people with traumatic and dysvascular etiologies	Based on an 1 sample, Bonferroni-adjusted ttest (p<0.01)
Demet et al	2002					0.84 (0.79-0.87)				
Demet et al.	2003				P Value	0.0212				Men had a better HRQL than women in t emotional reactions (p=0.0212)
Demet et al	2002					0.75 (0.69-0.8)				
Demet et al.	2003				P Value	0.026				Men had a better HRQL than womenenergy level (p=0.0260). Younger age at amputation was associated with greater energy level.
Demet et al	2002					0.81 (0.76-0.85)				
Demet et al.	2003				P Value	0.0017				Men had a better HRQL than women in physical disability (p=0.0017). Young age at the time of amputation was associated with less physical disability.
Demet et al	2002					0.84 (0.79-0.87)				
Demet et al	2002					0.76 (0.7-0.8)				
Demet et al	2002					0.64 (0.56-0.7)				



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Demet et al.	2003		Both upper and lower limb amputees grouped together					NHP	Social isolation		Validity	Known group
Happich et al.	2008		nd	neuropathy			71 (24 amputations in the year 2002 + 47 amputations before year 2002)	Norfolk QOL-DN	Overall QOL-DN		Validity	Known group
Happich	2008		nd	neuropathy			71	Norfolk QOL-DN			Validity	Known group
Demet et al	2002		Both upper and lower limb amputees grouped together					Nottingham Health Profile	Social isolation		Reliability	Test-retest
Demet et al	2003		Both upper and lower limb amputees grouped together					Nottingham Health Profile	Social isolation		Validity	Known group
Demet et al	2003		Both upper and lower limb amputees grouped together					Nottingham Health Profile	Social isolation		Validity	Construct
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	NQ-ACGC	nd	The Quality of Life in Neurological Conditions – Applied Cognition/General Concerns v1.0 (NQ-ACGC) is an item bank developed to measure general cognitive abilities, including memory, attention, and decision-making	Reliability	test-retest
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	NQ-ACGC	nd	The Quality of Life in Neurological Conditions – Applied Cognition/General Concerns v1.0 (NQ-ACGC) is an item bank developed to measure general cognitive abilities, including memory, attention, and decision-making	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	NQ-ACGC	nd	The Quality of Life in Neurological Conditions – Applied Cognition/General Concerns v1.0 (NQ-ACGC) is an item bank developed to measure general cognitive abilities, including memory, attention, and decision-making	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	NQ-ACGC		The Quality of Life in Neurological Conditions – Applied Cognition/General Concerns v1.0 (NQ-ACGC) is an item bank developed to measure general cognitive abilities, including memory, attention, and decision-making	Reliability	test-retest
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	NQ-ACGC		The Quality of Life in Neurological Conditions – Applied Cognition/General Concerns v1.0 (NQ-ACGC) is an item bank developed to measure general cognitive abilities, including memory, attention, and decision-making	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	NQ-ACGC		The Quality of Life in Neurological Conditions – Applied Cognition/General Concerns v1.0 (NQ-ACGC) is an item bank developed to measure general cognitive abilities, including memory, attention, and decision-making	MDC	
Panasar et al.	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67	nd	34	Office of Population Censuses and Surveys Scale (OPCS)	Total Overall Scale		Validity	Concurrent/convergent/criteria Validity criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Demet et al,	2003				P Value	0.0059				Men had a better HRQL than women in social isolation (p=0.0059). Younger age at amputation was associated with less social isolation. Vascular origin of amputation was associated with greater greater social isolation as compared to non-vascular etiology.
Happich et al,	2008									The Norfolk score increased with increasing DN severity, reaching the highest values (worse) in patients with lower extremity amputations.
Happich	2008									The Norfolk score increased with increasing DN severity, reaching the highest values (worse) in patients with lower extremity amputations.
Demet et al	2002					0.64 (0.56-0.7)				0.64 (0.56-0.7)
Demet et al	2003									Men scored significantly better than women (p=.0059)
Demet et al	2003									younger age, traumatic (vs. dysvascular) amputation were related to better scores of the social isolation
Hafner	2016	28273329			ICC	0.88				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			MDC 90	6.67				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			MDC 95	7.94				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			ICC	0.88				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			MDC 90	6.67				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			MDC 95	7.94				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Panesar et al,	2001		OPCS, AAS, FIM		P value	<0.0001				significant kendal correlations coefficients between each of the measures

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Panesar et al.	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67	nd	34	Office of Population Censuses and Surveys Scale (OPCS)	Total Overall Scale		Ability to measure change	Responsiveness
Panesar	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67		34	OPCS		Office of Population Censuses and Surveys Scale: Ability to measure change	Responsiveness	nd
Panesar	2001		Transfemoral (n=17), transtibial (n=14), hindquarter (n=1), bilateral transtibial (n=1), bilateral transfemoral (n=1)	nd	67		34	OPCS			Validity	Concurrent/convergent/criteria Validity criterion
Heinemann, Bode, O'Reilly	2003					Both Children and adult amputees together		OPUS	Health-related quality of life		Reliability	Internal consistency
Heinemann, Bode, O'Reilly,	2003					Both Children and adult amputees together		OPUS	Health-related quality of life		Validity	Structural
Resnik & Borgia	2011							OPUS	Health-related quality of life		Reliability	Test-retest
Resnik & Borgia,	2011							OPUS	Health-related quality of life		Ability to measure change	Floor/ceiling effects
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	OPUS	Lower limb function	Orthotics and Prosthetics Users' Survey	Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	OPUS	Lower limb function	Orthotics and Prosthetics Users' Survey	Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	OPUS	Lower limb function	Orthotics and Prosthetics Users' Survey	Reliability	Test-retest
Heinemann	2003					Both Children and adult amputees together		OPUS	Lower limb functional measure		Reliability	Internal consistency (chronbach alphas)
Resnik and Borgia	2011							OPUS	Lower limb functional measure		Reliability	Test-retest
Resnik and Borgia,	2011							OPUS	Lower limb functional measure		Ability to measure change	Floor/ceiling effects (appropriateness)
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	OPUS	Quality of life	Orthotics and Prosthetics Users' Survey	Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	OPUS	Quality of life	Orthotics and Prosthetics Users' Survey	Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	OPUS	Quality of life	Orthotics and Prosthetics Users' Survey	Reliability	Test-retest
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	OPUS	Satisfaction	Orthotics and Prosthetics Users' Survey	Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	OPUS	Satisfaction	Orthotics and Prosthetics Users' Survey	Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	OPUS	Satisfaction	Orthotics and Prosthetics Users' Survey	Reliability	Test-retest
Lerner	1991		Transtibial	Trauma	41.5	nd	20	PAIS	Domestic Environment	Psychosocial Adjustment to Illness Scale	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Panesar et al.	2001		nd		P value	<0.00001				significant changes between admission and discharge
Panesar	2001				P value	<0.00001			significant changes between admission and discharge	
Panesar	2001		OPCS, AAS, FIM		P value	<0.0001				significant kendal correlations coefficients between each of the measures
Heinemann, Bode, O'Reilly	2003									ICC of 0.88
Heinemann, Bode, O'Reilly,	2003									3 items slightly misfit; Person separation index: 2.74; Items separation index: 4.79
Resnik & Borgia	2011									0.85
Resnik & Borgia,	2011									No floor or ceiling effect observed
Resnik	2011		NA		% at the floor or ceiling	0		Yes		
Resnik	2011		NA		MDC90	10.3				
Resnik	2011		NA		ICC (95% CI)	0.67 (NR)				
Heinemann	2003									seperation index reliability=0.94
Resnik and Borgia	2011									ICC= 0.67
Resnik and Borgia,	2011									None observed
Resnik	2011		NA		% at the floor or ceiling	0		Yes		
Resnik	2011		NA		MDC90	9.2				
Resnik	2011		NA		ICC (95% CI)	0.85 (NR)				
Resnik	2011		NA		% at the floor or ceiling	0		Yes		
Resnik	2011		NA		MDC90	15.7				
Resnik	2011		NA		ICC (95% CI)	0.50 (NR)				
Lerner	1991		primary amputation vs delayed amutation		P value	<0.05				Among the amputee group, patients who underwent primary amputation scored worse on the PAIS than those who had delayed amputation (p< .05)

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Lerner	1991		Transfemoral	Trauma	41.5	nd	20	PAIS	Extended Family Relationships	Psychosocial Adjustment to Illness Scale	Validity	Construct
Lerner	1991		Transfemoral	Trauma	41.5	nd	20	PAIS	Sexual Relationships	Psychosocial Adjustment to Illness Scale	Validity	Construct
Lerner	1991		Transfemoral	Trauma	41.5	nd	20	PAIS	Social Environment	Psychosocial Adjustment to Illness Scale	Validity	Construct
Lerner	1991		Transfemoral	Trauma	41.5	nd	20	PAIS	Vocational Environment	Psychosocial Adjustment to Illness Scale	Validity	Construct
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Step length (fast)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Step length (fast)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Step length (fast)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Step length (medium)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Step length (medium)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Step length (medium)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Step length (slow)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Step length (slow)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Step length (slow)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Total step count	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Total step count	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Total step count	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Total step count	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transfemoral (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Total step count	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Lerner	1991		primary amputation vs delayed amputation		P value	<0.05				Among the amputee group, patients who underwent primary amputation scored worse on the PAIS than those who had delayed amputation (p< .05)
Lerner	1991		primary amputation vs delayed amputation		P value	<0.05				Among the amputee group, patients who underwent primary amputation scored worse on the PAIS than those who had delayed amputation (p< .05)
Lerner	1991		primary amputation vs delayed amputation		P value	<0.05				Among the amputee group, patients who underwent primary amputation scored worse on the PAIS than those who had delayed amputation (p< .05)
Lerner	1991		primary amputation vs delayed amputation		P value	<0.05				Among the amputee group, patients who underwent primary amputation scored worse on the PAIS than those who had delayed amputation (p< .05)
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.95	Large	Yes		
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.93	Large	Yes		Transfemoral
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.98	Large	Yes		Transtibial
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.95	Large	Yes		
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.95	Large	Yes		Transfemoral
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.99	Large	Yes		Transtibial
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.77	Large	Yes		
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.36	Moderate	Yes		Transfemoral
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.93	Large	Yes		Transtibial
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.97	Large	Yes		Transtibial
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.98	Large	Yes		Transfemoral
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.98	Large	Yes		
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.97	Large	Yes		
Ramstrand	2007	17520493	Qualisys motion analysis systems		Pearson r	0.91	Large	Yes		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Ramstrand	2007	17520493	Transfemoral (n=12), Transtibial (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Total step count	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transtibial (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Total step count	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transtibial (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Total step count	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transtibial (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Walking velocity	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transtibial (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Walking velocity	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transtibial (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Walking velocity (fast)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transtibial (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Walking velocity (medium)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Ramstrand	2007	17520493	Transfemoral (n=12), Transtibial (n=10)	nd	50	Capable of walking unaided for a five minute period without a pause	22	Patient Activity Monitor	Walking velocity (slow)	The Patient Activity Monitor (PAM) is a commercially available walking activity monitor and is specifically targeted towards evaluation of amputee gait patterns	Validity	Convergent
Anwert	2007	17943683	Unilateral transtibial	Vascular insufficiency	69.8	nd	23	PEQ	Ambulation		Validity	Known group/Discriminant
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Ambulation		Floor/ceiling effect	Appropriateness
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Ambulation		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Ambulation		Reliability	Internal consistency
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Ambulation		Validity	Construct (known groups / subgroups)
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Ambulation		Validity	Criterion
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Ambulation		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Ambulation		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Ambulation		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Apearance		Floor/ceiling effect	Appropriateness
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Apearance		Reliability	Test-retest

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Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Ramstrand	2007	17520493	Hand counter		Pearson r	0.98	Large	Yes		
Ramstrand	2007	17520493	Hand counter		Pearson r	0.97	Large	Yes		
Ramstrand	2007	17520493	Hand counter		Pearson r	0.9	Large	Yes		
Ramstrand	2007	17520493	Hand counter		Pearson r	0.98	Large	Yes		Transfemoral
Ramstrand	2007	17520493	Hand counter		Pearson r	0.99	Large	Yes		Transtibial
Ramstrand	2007	17520493	Hand counter		Pearson r	0.98	Large	Yes		
Ramstrand	2007	17520493	Hand counter		Pearson r	0.99	Large	Yes		
Ramstrand	2007	17520493	Hand counter		Pearson r	0.95	Large	Yes		
Arwert	2007	17943683	groups of different tibial length		ttest P	<0.05				differentiated between groups of different tibial length and Chakrabarty (residual limb quality) points
Legro	1998				% at the floor or ceiling	2		Yes		max of floor or ceiling proportion (not all scales in the same direction)
Legro	1998		NA		ICC (95% CI)	0.90 (0.84, 0.94)				among 61/92 people who did not have major change in health or prosthesis and did the retest
Legro	1998		NA		Chronbach Alpha	0.89	excellent			
Legro	1998		by: gender; age group; comorbidities (any); amputation level; years since amputation		difference in PEQ (subscale score)	see notes				statistically difference only by gender (men higher); by comorbidities (zero comorbidities higher)
Legro	1998		SF-36 physical function		correlation	0.61				
Resnik	2011				% at the floor or ceiling	0				
Resnik	2011		NA		MDC90	1.1				
Resnik	2011		NA		ICC (95% CI)	0.81 (0.68, 0.89)				
Legro	1998				% at the floor or ceiling	7		Yes		max of floor or ceiling proportion (not all scales in the same direction)
Legro	1998		NA		ICC (95% CI)	0.84 (0.76, 0.90)				among 61/92 people who did not have major change in health or prosthesis and did the retest



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Appearance		Reliability	Internal consistency
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Appearance		Validity	Construct (known groups / subgroups)
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Appearance		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Appearance		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Appearance		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Frustration		Floor/ceiling effect	Appropriateness
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Frustration		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Frustration		Reliability	Internal consistency
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Frustration		Validity	Construct (known groups / subgroups)
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Frustration		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Frustration		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Frustration		Reliability	Test-retest
Asano	2008	18569891	Transfemoral (n=112), Transtibial (303)	vascular (220), nonvascular (195)	61.9	Unilateral	415	PEQ	Mobility		Validity	Convergent
Franchignoni	2007	17351696	Unilateral transfemoral (53%), Unilateral transtibial (36%), Bilateral (11%)	Peripheral vascular disease and/or diabetes (35%), Trauma (56%), Tumour and other (9%)	54		123	PEQ	Mobility		Reliability	Internal consistency
Franchignoni	2007	17351696	Unilateral transfemoral (53%), Unilateral transtibial (36%), Bilateral (11%)	Peripheral vascular disease and/or diabetes (35%), Trauma (56%), Tumour and other (9%)	54		123	PEQ	Mobility		Reliability	Item separation reliability
Franchignoni	2007	17351696	Unilateral transfemoral (53%), Unilateral transtibial (36%), Bilateral (11%)	Peripheral vascular disease and/or diabetes (35%), Trauma (56%), Tumour and other (9%)	54		123	PEQ	Mobility		Reliability	Person separation reliability
Franchignoni	2007	17351696	Unilateral transfemoral (53%), Unilateral transtibial (36%), Bilateral (11%)	Peripheral vascular disease and/or diabetes (35%), Trauma (56%), Tumour and other (9%)	54		123	PEQ	Mobility		Validity	Convergent

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Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Legro	1998		NA		Chronbach Alpha	0.73	adequate			
Legro	1998		by: gender; age group; comorbidities (any); amputation level; years since amputation		difference in PEQ (subscale score)	see notes				no statistically significant differences in any factor
Resnik	2011				% at the floor or ceiling	0				
Resnik	2011		NA		MDC90	1.4				
Resnik	2011		NA		ICC (95% CI)	0.70 (0.51, 0.82)				
Legro	1998				% at the floor or ceiling	22		No		max of floor or ceiling proportion (not all scales in the same direction)
Legro	1998		NA		ICC (95% CI)	0.64 (0.47 0.77)				among 61/92 people who did not have major change in health or prosthesis and did the retest
Legro	1998		NA		Chronbach Alpha	0.82	excellent			
Legro	1998		by: gender; age group; comorbidities (any); amputation level; years since amputation		difference in PEQ (subscale score)	see notes				statistically significant difference only by age group (higher in younger people)
Resnik	2011				% at the floor or ceiling	0				
Resnik	2011		NA		MDC90	1.6				
Resnik	2011		NA		ICC (95% CI)	0.82 (0.69, 0.90)				
Asano	2008	18569891	QoL, single item question		Beta	-0.31				Multivariate regression
Franchignoni	2007	17351696			Chronbach Alpha	0.96				
Franchignoni	2007	17351696			Rasch Item separation	0.98				
Franchignoni	2007	17351696			Rasch Person separation	0.95				
Franchignoni	2007	17351696	LCI		Spearman r					similar (to PEQMS12/5) but slightly lower correlations with LCI (not shown)

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Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	PEQ	Mobility	12-item self-report measure assessing the ability to perform mobility tasks while using a lower limb prosthesis	Reliability	test-retest
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	PEQ	Mobility	12-item self-report measure assessing the ability to perform mobility tasks while using a lower limb prosthesis	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	PEQ	Mobility	12-item self-report measure assessing the ability to perform mobility tasks while using a lower limb prosthesis	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	PEQ	Mobility	12-item self-report measure assessing the ability to perform mobility tasks while using a lower limb prosthesis	Reliability	test-retest
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	PEQ	Mobility	12-item self-report measure assessing the ability to perform mobility tasks while using a lower limb prosthesis	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	PEQ	Mobility	12-item self-report measure assessing the ability to perform mobility tasks while using a lower limb prosthesis	MDC	
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4	unilateral	60	PEQ	Mobility	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Floor/ceiling effect	Ceiling
Miller	2004	15180125						PEQ	mobility		Validity	Concurrent/convergent/criteria Validity criterion
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Mobility		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Mobility		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Mobility		Reliability	Test-retest
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Floor/ceiling effect	Ceiling
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Validity	Construct
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Validity	Construct
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Validity	Construct

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Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Hafner	2016	28273329			ICC	0.92				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			MDC 90	0.55				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			MDC 95	0.65				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			ICC	0.92				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			MDC 90	0.55				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			MDC 95	0.65				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Miller	2000		nd		%	8.1		No	There was no indication of ceiling effect	
Miller	2004	15180125								Pearsons: FAI=0.39, FAI-18=0.40
Resnik	2011				% at the floor or ceiling	0				
Resnik	2011		NA		MDC90	0.3				
Resnik	2011		NA		ICC (95% CI)	0.85 (0.74, 0.92)				
Miller	2000		nd		%	10		No	There was no indication of ceiling effect	
Miller	2000		Transtibial vs Transfemoral		Effect size	0.11		No	The Prosthetic Evaluation Questionnaire - Mobility did not differ between Transtibial and Transfemoral	p>0.05
Miller	2000		Vascular vs non-vascular		Effect size	0.81		Yes	The Prosthetic Evaluation Questionnaire - Mobility differed between Vascular and non-vascular	
Miller	2000		Mobility device used vs no device		Effect size	1.57		Yes	The Prosthetic Evaluation Questionnaire - Mobility differed between Mobility device used and no device use	

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Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Validity	Construct
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Validity	Construct
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Validity	Convergent
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Floor/ceiling effect	Floor
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (53%), Non-vascular (47%)	59.9		329	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Floor/ceiling effect	Floor
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Reliability	Internal Consistency
Miller	2000		Transfemoral (26%), Transtibial (74%)	Vascular (55%), Non-vascular (45%)	58.4		60	PEQ	Mobility (ambulation and transfer)	The Prosthetic Evaluation Questionnaire (PEQ) is composed of nine sub scales assessing emotional and social health, global well-being, prosthetic function including mobility over the past four weeks	Reliability	Test-retest
Miller	2001	11552197	below knee (73%)	Vascular (53%)	62	23-91	435	PEQ	Mobility (ambulation and transfer)		Validity	Convergent
Miller	2001	11552197	below knee (73%)	Vascular (53%)	62	23-91	435	PEQ	Mobility (ambulation and transfer)		Validity	Convergent
Miller	2001	11552197	below knee (73%)	Vascular (53%)	62	23-91	435	PEQ	Mobility (ambulation and transfer)		Validity	Convergent
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	PEQ	Mobility (ambulation and transfer)	Ability to measure change	Floor/ceiling effects (appropriateness)	
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		55	PEQ	Mobility (ambulation and transfer)		Reliability	Internal consistency
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		55	PEQ	Mobility (ambulation and transfer)		Reliability	Test-retest
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%	58		60	PEQ	Mobility (ambulation and transfer)		Validity	Convergent validity

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Miller	2000		Walking distance <1 block vs unlimited		Effect size	1.08		Yes	The Prosthetic Evaluation Questionnaire - Mobility differed between Walking distance <1 block and unlimited	
Miller	2000		Automatic walking yes vs no		Effect size	1.32		Yes	The Prosthetic Evaluation Questionnaire - Mobility differed between Automatic walking and no automatic walking	
Miller	2000		Two minute walk test		Pearson r	0.5	Moderate	Yes	The Prosthetic Evaluation Questionnaire - Mobility displayed Moderate correlation with the Two minute walk test	
Miller	2000		Timed up and go		Pearson r	-0.5	Moderate	Yes	The Prosthetic Evaluation Questionnaire - Mobility displayed Moderate correlation with the Timed up and go	
Miller	2000		Activities-specific Balance Confidence		Pearson r	0.82	Large	Yes	The Prosthetic Evaluation Questionnaire - Mobility displayed Large correlation with the Activities-specific Balance Confidence	
Miller	2000		Activities-specific Balance Confidence		Pearson r	0.85	Large	Yes	The Prosthetic Evaluation Questionnaire - Mobility displayed Large correlation with the Activities-specific Balance Confidence	
Miller	2000		nd		%	0.6		No	There was no indication of floor effect	
Miller	2000		nd		%	0.3		No	There was no indication of floor effect	
Miller	2000		nd		Cronbach's alpha	0.95	Excellent	Yes	The score displayed an excellent internal Consistency based on Cronbach's alpha value	
Miller	2000		nd		ICC	0.77	Good	Yes	The Prosthetic Evaluation Questionnaire score displayed an good Test-retest reliability based on the ICC value	
Miller	2001	11552197	Falling		standardized regression coefficient	-0.037				not statistically significant
Miller	2001	11552197	fear of falling		standardized regression coefficient	0.012				not statistically significant
Miller	2001	11552197	ABC scale (balance confidence)		standardized regression coefficient	0.723				statistically significant
Miller	2001	11588750 (sample 1)	NA		% at floor or ceiling	8		Yes		Ceiling effect (negligible floor effects)
Miller	2001	11588750 (sample 1)			Cronbach Alpha	0.95	excellent			55/60 were stable
Miller	2001	11588750 (sample 1)			ICC (95% CI)	0.77 (0.62, 0.85)				55/60 were stable
Miller	2001	11588750 (sample 1)			2 minute walk test correlation	0.5				

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%)	58		60	PEQ	Mobility (ambulation and transfer)		Validity	Convergent validity
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%)	58		60	PEQ	Mobility (ambulation and transfer)		Validity	Convergent validity
Miller	2001	11588750 (sample 1)	below knee (72%), above knee (28%)	Vascular (55%), nonvascular 45%)	58		60	PEQ	Mobility (ambulation and transfer)		Validity	Convergent validity
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%)	60		329	PEQ	Mobility (ambulation and transfer)	Ability to measure change	Floor/ceiling effects (appropriateness)	
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%)	60		329	PEQ	Mobility (ambulation and transfer)		Validity	Construct (discriminant)
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%)	60		329	PEQ	Mobility (ambulation and transfer)		Validity	Convergent validity
Miller	2001	11588750 (sample 2)	below knee (74%), above knee (26%)	Vascular (53%), nonvascular 47%)	60		329	PEQ	Mobility (ambulation and transfer)		Validity	Convergent validity
Franchignoni	2007	17351696	Unilateral transfemoral (53%), Unilateral transtibial (36%), Bilateral (11%)	Peripheral vascular disease and/or diabetes (35%), Trauma (56%), Tumour and other (9%)	54		123	PEQ	mobility modified (MS12/5)		Reliability	Internal consistency
Franchignoni	2007	17351696	Unilateral transfemoral (53%), Unilateral transtibial (36%), Bilateral (11%)	Peripheral vascular disease and/or diabetes (35%), Trauma (56%), Tumour and other (9%)	54		123	PEQ	mobility modified (MS12/5)		Reliability	Item separation reliability
Franchignoni	2007	17351696	Unilateral transfemoral (53%), Unilateral transtibial (36%), Bilateral (11%)	Peripheral vascular disease and/or diabetes (35%), Trauma (56%), Tumour and other (9%)	54		123	PEQ	mobility modified (MS12/5)		Reliability	Person separation reliability
Franchignoni	2007	17351696	Unilateral transfemoral (53%), Unilateral transtibial (36%), Bilateral (11%)	Peripheral vascular disease and/or diabetes (35%), Trauma (56%), Tumour and other (9%)	54		123	PEQ	mobility modified (MS12/5)		Validity	Convergent
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Perceived response		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Perceived response		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Perceived response		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Perceived responses		Floor/ceiling effect	Appropriateness
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Perceived responses		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Perceived responses		Reliability	Internal consistency
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Perceived responses		Validity	Construct (known groups / subgroups)

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Miller	2001	11588750 (sample 1)			Timed up and go (TUG)	correlation	-0.5			
Miller	2001	11588750 (sample 1)			ABC scale	correlation	0.82			
Miller	2001	11588750 (sample 1)			LCI	correlation	0.77			
Miller	2001	11588750 (sample 2)	NA		% at floor or ceiling	10		Yes		Ceiling effect (negligible floor effects)
Miller	2001	11588750 (sample 2)	by: amputation level; amputation cause; mobility device; walking distance; automatic walking		differences between levels of factors	see notes				Only not statistically significant difference: between amputation level above or below the knee
Miller	2001	11588750 (sample 2)	ABC scale		correlation	0.85				
Miller	2001	11588750 (sample 2)	LCI		correlation	0.83				
Franchignoni	2007	17351696				Chronbach Alpha	0.96			
Franchignoni	2007	17351696				Rasch Item separation	0.98			
Franchignoni	2007	17351696				Rasch Person separation	0.95			
Franchignoni	2007	17351696	LCI		Spearman r	0.78				Spearman's: LCI-5=0.78
Resnik	2011				% at the floor or ceiling	0				
Resnik	2011		NA		MDC90	0.9				
Resnik	2011		NA		ICC (95% CI)	0.41 (0.13, 0.63)				
Legro	1998				% at the floor or ceiling	17		No		max of floor or ceiling proportion (not all scales in the same direction)
Legro	1998		NA		ICC (95% CI)	0.56 (0.36, 0.71)				among 61/92 people who did not have major change in health or prosthesis and did the retest
Legro	1998		NA		Chronbach Alpha	0.89	excellent			
Legro	1998		by: gender; age group; comorbidities (any); amputation level; years since amputation		difference in PEQ (subscale score)	see notes				no statistically significant differences in any factor



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Prosthesis utility		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Prosthesis utility		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Prosthesis utility		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Residual limb health		Floor/ceiling effect	Appropriateness
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Residual limb health		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Residual limb health		Reliability	Internal consistency
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Residual limb health		Validity	Construct (known groups / subgroups)
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Residual limb health		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Residual limb health		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Residual limb health		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Social burden		Floor/ceiling effect	Appropriateness
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Social burden		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Social burden		Reliability	Internal consistency
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Social burden		Validity	Criterion
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Social burden		Validity	Construct (known groups / subgroups)
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Social burden		Validity	Criterion
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Social burden		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Social burden		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Social burden		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Sounds		Floor/ceiling effect	Appropriateness

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Resnik	2011				% at the floor or ceiling	0				
Resnik	2011		NA		MDC90	1.2				
Resnik	2011		NA		ICC (95% CI)	0.79 (0.64, 0.88)				
Legro	1998				% at the floor or ceiling	2		Yes		max of floor or ceiling proportion (not all scales in the same direction)
Legro	1998		NA		ICC (95% CI)	0.79 (0.68, 0.86)				among 61/92 people who did not have major change in health or prosthesis and did the retest
Legro	1998		NA		Chronbach Alpha	0.8	excellent			
Legro	1998		by: gender; age group; comorbidities (any); amputation level; years since amputation		difference in PEQ (subscale score)	see notes				statistically significant difference only by age group (older had higher PEQ scores)
Resnik	2011				% at the floor or ceiling	0				
Resnik	2011		NA		MDC90	0.8				
Resnik	2011		NA		ICC (95% CI)	0.93 (0.88, 0.96)				
Legro	1998				% at the floor or ceiling	10		Yes		max of floor or ceiling proportion (not all scales in the same direction)
Legro	1998		NA		ICC (95% CI)	0.81 (0.69, 0.88)				among 61/92 people who did not have major change in health or prosthesis and did the retest
Legro	1998		NA		Chronbach Alpha	0.83	excellent			
Legro	1998		SIP: social interaction		correlation	-0.52				negative correlation because the direction of the scales is opposite
Legro	1998		by: gender; age group; comorbidities (any); amputation level; years since amputation		difference in PEQ (subscale score)	see notes				statistically significant difference only by gender (higher in women)
Legro	1998		SF-36 social function		correlation	0.59				
Resnik	2011				% at the floor or ceiling	0				
Resnik	2011		NA		MDC90	1.4				
Resnik	2011		NA		ICC (95% CI)	0.64 (0.43, 0.79)				
Legro	1998				% at the floor or ceiling	10		Yes		max of floor or ceiling proportion (not all scales in the same direction)

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Sounds		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Sounds		Reliability	Internal consistency
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Sounds		Validity	Construct (known groups / subgroups)
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Sounds		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Sounds		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Sounds		Reliability	Test-retest
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Transfer		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Transfer		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Transfer		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Transfers		Floor/ceiling effect	Appropriateness
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Transfers		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Transfers		Reliability	Internal consistency
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Transfers		Validity	Construct (known groups / subgroups)
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Usefulness		Floor/ceiling effect	Appropriateness
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Usefulness		Reliability	Test-retest
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Usefulness		Reliability	Internal consistency
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Usefulness		Validity	Construct (known groups / subgroups)
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Well being		Floor/ceiling effect	Appropriateness
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Well being		Reliability	Test-retest

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Legro	1998		NA		ICC (95% CI)	0.84 (0.75, 0.90)				among 61/92 people who did no have major change in health or prosthesis and did the retest
Legro	1998		NA		Chronbach Alpha	0.78	adequate			
Legro	1998		by: gender; age group; comorbidities (any); amputation level; years since amputation		difference in PEQ (subscale score))	see notes				no statistically significant differences in any factor
Resnik	2011				% at the floor or ceiling	0				
Resnik	2011		NA		MDC90	1.7				
Resnik	2011		NA		ICC (95% CI)	0.79 (0.65, 0.88)				
Resnik	2011				% at the floor or ceiling	27				ceiling effect only
Resnik	2011		NA		MDC90	1.3				
Resnik	2011		NA		ICC (95% CI)	0.75 (0.59, 0.86)				
Legro	1998				% at the floor or ceiling	25		No		max of floor or ceiling proportion (not all scales in the same directin)
Legro	1998		NA		ICC (95% CI)	0.73 (0.58, 0.83)				among 61/92 people who did no have major change in health or prosthesis and did the retest
Legro	1998		NA		Chronbach Alpha	0.47	poor			
Legro	1998		by: gender; age group; comorbidities (any); amputation level; years since amputation		difference in PEQ (subscale score))	see notes				no statistically significant differences in any factor
Legro	1998				% at the floor or ceiling	2		Yes		max of floor or ceiling proportion (not all scales in the same directin)
Legro	1998		NA		ICC (95% CI)	0.86 (0.78, 0.91)				among 61/92 people who did no have major change in health or prosthesis and did the retest
Legro	1998		NA		Chronbach Alpha	0.89	excellent			
Legro	1998		by: gender; age group; comorbidities (any); amputation level; years since amputation		difference in PEQ (subscale score))	see notes				no statistically significant differences in any factor
Legro	1998				% at the floor or ceiling	8		Yes		max of floor or ceiling proportion (not all scales in the same directin)
Legro	1998		NA		ICC (95% CI)	0.89 (0.80, 0.93)				among 61/92 people who did no have major change in health or prosthesis and did the retest

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Well being		Reliability	Internal consistency
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Well being		Validity	Criterion
Legro	1998		Transfemoral (25%), transtibial (63%), through knee (3%), Symes (9%)	Trauma (67%), Chronic disease (41%), Congenital (3%), Tumor (1%)	40% over 60y		92	PEQ	Well being		Validity	Construct (known groups / subgroups)
Feneiro	1994							PEQ	Well-being		Reliability	Internal consistency
Legro et al	1998							PEQ	Well-being		Reliability	Test-retest
Legro et al	1998							PEQ	Well-being		Reliability	Internal consistency
Legro, et al	1998							PEQ	Well-being		Validity	Face/content
Legro, et al	1998							PEQ	Well-being		Validity	Concurrent/convergent criterion
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Well-being		Floor/ceiling effect	Appropriateness
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Well-being		Minimal Detectable Change	MDC90
Resnik	2011		Transfemoral (52%); through knee (5%); transtibial (43%)		66	unilateral	44	PEQ	Well-being		Reliability	Test-retest
Resnik & Borgia	2011							PEQ	Well-being		Reliability	Test-retest
Resnik & Borgia,	2011							PEQ	Well-being		Ability to measure change	Floor/ceiling effects
van de Weg	2005	16466153	Transtibial	nd	62.1		220	PEQ, modified	Problems	The questionnaire included questions on demographic variables (age, gender, marital status, level of education), reason for amputation, and time since first prosthesis. In addition, several questions concerned use, maintenance, and durability of the prosthesis.	Reliability	Internal Consistency
van de Weg	2005	16466153	Transtibial	nd	62.1		220	PEQ, modified	Satisfaction	The questionnaire included questions on demographic variables (age, gender, marital status, level of education), reason for amputation, and time since first prosthesis. In addition, several questions concerned use, maintenance, and durability of the prosthesis.	Reliability	Internal Consistency
Hart	1999							PF-10	Physical functioning		Reliability	Internal consistency
Hart	1999							PF-10	Physical functioning		Validity	Known group/Discriminant
Hart	1999							PF-10	Physical functioning		Validity	Concurrent/convergent/criteria Validity criterion
Hart	1999							PF-10	Physical functioning		Ability to measure change	Floor/ceiling effects (appropriateness)
Hart	1999							PF-15	Physical functioning		Reliability	Internal consistency
Hart	1999							PF-15	Physical functioning		Validity	Construct
Hart	1999							PF-15	Physical functioning		Ability to measure change	Floor/ceiling effects (appropriateness)

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Legro	1998		NA		Chronbach Alpha	0.87	excellent			
Legro	1998		POMS-sf: total score		correlation	-0.49				negative correlation because the direction of the scales is opposite
Legro	1998		by: gender; age group; comorbidities (any); amputation level; years since amputation		difference in PEQ (subscale score))	see notes				no statistically significant differences in any factor
Feneiro	1994				ICC	0.72				
Legro et al	1998									0.89
Legro et al	1998									0.87
Legro, et al	1998									Formative research supports content validity
Legro, et al	1998									moderate, negative correlation with Profile of mood state.
Resnik	2011				% at the floor or ceiling	34				ceiling effect only
Resnik	2011		NA		MDC90	1.4				
Resnik	2011		NA		ICC (95% CI)	0.70 (0.51, 0.82)				
Resnik & Borgia	2011									0.7
Resnik & Borgia,	2011									Strong ceiling effects, no floor effect
van de Weg	2005	16466153	nd		Cronbach's alpha	0.76	Adequate	Yes	There is sufficient evidence of Internal Consistency for the PEQ-problems subscale	
van de Weg	2005	16466153	nd		Cronbach's alpha	0.88	Excellent	Yes	There is sufficient evidence of Internal Consistency for the PEQ-satisfaction subscale	
Hart	1999				Chronbach Alpha					0.91
Hart	1999									differentiated between Durable medical equipment regional carriers (DMERC) functional levels, between AK and BK amputations, and between younger(<60) and older (>60) clients
Hart	1999									Pearsons with Role physical=0.50 and 0.63 at initial fitting and follow-up
Hart	1999									none or less ceiling effect compared to PF-15
Hart	1999				Chronbach Alpha					0.89
Hart	1999									demonstrated clinically logical hierarchical ordering.
Hart	1999									slight ceiling effect for PF-15 compared to PF=10

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Ceiling
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		nd		%	16.8		Yes		
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	<=0.05		Yes		3-Month Functional Scale Scores. P-value based on Mann-Whitney U



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Normal Walking Speed (Yes vs No)		Pearson r	-0.39	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Walking Speed (continuous score)		Pearson r	0.41	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Return to Usual Activity (Yes vs No)		Pearson r	-0.15	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Floor
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Reliability	Internal Consistency
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Climb stairs	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		nd		%	41.1		Yes		
Cyril	2001		nd		Cronbach's alpha	0.78	Adequate	Yes		
Cyril	2001		nd		SRM	0.74				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		Effect size with baseline SD	0.79				Effect Size Statistics for Change in Scores Between 3 and 12 Months

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyriel	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Ceiling
Cyriel	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyriel	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
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Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		nd		%	85		Yes		
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Normal Walking Speed (Yes vs No)		Pearson r	-0.3	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Walking Speed (continuous score)		Pearson r	0.37	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Return to Usual Activity (Yes vs No)		Pearson r	-0.26	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Floor
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Reliability	Internal Consistency
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Run at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Ceiling

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		nd		%	2.8		No		
Cyril	2001		nd		Cronbach's alpha	0.87	Excellent	Yes		
Cyril	2001		nd		SRM	0.36				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		%	36.4		Yes		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	<=0.05		Yes		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Transtibial vs Transfemoral		P	<=0.05		Yes		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Floor

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Normal Walking Speed (Yes vs No)		Pearson r	-0.53	Large	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Walking Speed (continuous score)		Pearson r	0.46	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Return to Usual Activity (Yes vs No)		Pearson r	-0.18	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001		nd		%	8.4		No		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Reliability	Internal Consistency
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Squat to pick up object	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Ceiling

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		nd		Cronbach's alpha	0.82	Excellent	Yes		
Cyril	2001		nd		SRM	0.55				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		Effect size with baseline SD	0.67				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		%	12.1		No		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyrl	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
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Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
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Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Floor

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Normal Walking Speed (Yes vs No)		Pearson r	-0.55	Large	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Walking Speed (continuous score)		Pearson r	0.57	Large	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Return to Usual Activity (Yes vs No)		Pearson r	-0.27	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001		nd		%	0		No		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Reliability	Internal Consistency
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Total Overall Score	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Walk at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Ceiling

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		nd		Cronbach's alpha	0.71	Adequate	Yes		
Cyril	2001		nd		SRM	0.89				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		Effect size with baseline SD	1.06				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		%	31.8		Yes		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Walk at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
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Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

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Cyril	2001		Age <35 vs >=35		P	<=0.05		Yes		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U



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Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

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Cyril	2001		ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001		Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Walk at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Walk at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Walk at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Walk at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Floor

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		Normal Walking Speed (Yes vs No)		Pearson r	-0.41	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Walking Speed (continuous score)		Pearson r	0.45	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001		Return to Usual Activity (Yes vs No)		Pearson r	-0.24	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001		nd		%	17.8		No		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Walk at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Reliability	Internal Consistency
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Walk at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001		Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	PFI	Walk at steady pace	Physical Function Index: Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Callaghan	2003	14682557	Transfemoral	Peripheral vascular disease (90%)	69	Unilateral	42	PGI			Reliability	Test-retest
Callaghan	2003	14682557	Transfemoral	Peripheral vascular disease (90%)	69	Unilateral	42	PGI			Validity	Convergent
Callaghan	2003	14682557	Transfemoral	Peripheral vascular disease (90%)	69	Unilateral	42	PGI			Validity	Convergent
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Climb stairs	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Reliability	Internal Consistency

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001		nd		Cronbach's alpha	0.74	Adequate	Yes		
Cyril	2001		nd		SRM	0.65				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001		nd		Effect size with baseline SD	0.98				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Callaghan	2003	14682557			ICC	0.48				
Callaghan	2003	14682557	SF-12 PCS		Pearson r	0.11				
Callaghan	2003	14682557	SF-12 MCS		Pearson r	0.56				
Cyril	2001	0	nd		Cronbach's alpha	0.78	Adequate	Yes		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Climb stairs	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Ceiling
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Climb stairs	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Floor
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Climb stairs	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Climb stairs	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	nd		%	16.8		Yes		
Cyril	2001	0	nd		%	41.1		Yes		
Cyril	2001	0	Normal Walking Speed (Yes vs No)		Pearson r	-0.39	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Walking Speed (continuous score)		Pearson r	0.41	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Climb stairs	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
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Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Climb stairs	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
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Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Return to Usual Activity (Yes vs No)		Pearson r	-0.15	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001	0	Transibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	<=0.05		Yes		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

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Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
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Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Climb stairs	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Climb stairs	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Reliability	Internal Consistency

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	nd		SRM	0.74				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Effect size with baseline SD	0.79				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Cronbach's alpha	0.71	Adequate	Yes		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Ceiling
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Floor
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	nd		%	12.1		No		
Cyril	2001	0	nd		%	0		No		
Cyril	2001	0	Normal Walking Speed (Yes vs No)		Pearson r	-0.55	Large	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Walking Speed (continuous score)		Pearson r	0.57	Large	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Return to Usual Activity (Yes vs No)		Pearson r	-0.27	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001	0	Transibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyrl	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyrl	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyrl	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Overall PFI	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyrl	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Reliability	Internal Consistency

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	nd		SRM	0.89				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Effect size with baseline SD	1.06				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Cronbach's alpha	0.87	Excellent	Yes		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Ceiling
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Floor
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	nd		%	85		Yes		
Cyril	2001	0	nd		%	2.8		No		
Cyril	2001	0	Normal Walking Speed (Yes vs No)		Pearson r	-0.3	None	No		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Walking Speed (continuous score)		Pearson r	0.37	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Return to Usual Activity (Yes vs No)		Pearson r	-0.26	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity
Cyril	2001	0	Transibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Run at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Reliability	Internal Consistency
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Ceiling

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	nd		SRM	0.36				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Cronbach's alpha	0.82	Excellent	Yes		
Cyril	2001	0	nd		%	36.4		Yes		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Floor
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	nd		%	8.4		No		
Cyril	2001	0	Normal Walking Speed (Yes vs No)		Pearson r	-0.53	Large	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Walking Speed (continuous score)		Pearson r	0.46	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Return to Usual Activity (Yes vs No)		Pearson r	-0.18	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
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Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	<=0.05		Yes		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
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Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Transtibial vs Transfemoral		P	<=0.05		Yes		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Squat to pick up object	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Reliability	Internal Consistency
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Ceiling

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	nd		SRM	0.55				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Effect size with baseline SD	0.67				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Cronbach's alpha	0.74	Adequate	Yes		
Cyril	2001	0	nd		%	31.8		Yes		

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, Vi mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Floor/ceiling effect	Floor
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, Vi mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, Vi mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, Vi mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Criterion

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	nd		%	17.8		No		
Cyril	2001	0	Normal Walking Speed (Yes vs No)		Pearson r	-0.41	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Walking Speed (continuous score)		Pearson r	0.45	Moderate	Yes		Walking speed at 12 months: Complete a 150 foot walk as fast as they could. Two measures of walking speed were used as criterion measures. First, a categorical variable that classified individuals as walking at a normal walking speed or not was constructed. Normal walking speed was defined as those who completed a 150-foot walk in 37.5 seconds or less, which is equivalent to the average time it takes to cross a normal street. Second, a continuous variable representing the number of seconds it took for individuals to walk 150 feet was used.
Cyril	2001	0	Return to Usual Activity (Yes vs No)		Pearson r	-0.24	Small	Unclear		Return to usual activity by 12 months after injury. Respondents reported their major activity at baseline and all subsequent follow-up periods (defined as working, laid off, looking for work, school, keeping house, retired, and other). Returning to one's usual activity was defined as resuming the same activity or to an activity of equal or greater productivity



Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	<=0.05		Yes		3-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		3-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Validity	Construct

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	Transtibial vs Transfemoral		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	ISS Score <13 vs >=13		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Age <35 vs >=35		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U
Cyril	2001	0	Comorbidities yes vs no		P	>0.05		No		12-Month Functional Scale Scores. P-value based on Mann-Whitney U

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Cyril	2001	0	Transfemoral (22%), Transtibial (77%), Through-knee (11%)	nd	35	High energy lower extremity trauma patients. Foot amputation or bilateral amputations were excluded	107	Physical Function Index	Walk at steady pace	Respondents were asked to respond about their ability to: (1) squat and pick up a 100 lb, 50 lb, 25 lb, and 10 lb object; (2) walk at a steady pace for 3 miles, 1 mile, and a quarter of a mile; (3) run at a steady pace without stopping for 3 miles, 1 mile, 1/2 mile, and 1 block; and (4) climb 5 flights, 3 flights, and 1 flight of stairs without stopping. Responses were coded as 1 (able to do without difficulty), 2 (able to do with difficulty) or 3 (unable to do at all). Four category scores (squat, walk, run and climb) were generated. Category scores ranged from 0 to 4 with lower scores indicating better function. A total score was constructed by summing all four category scores	Responsiveness	nd
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	PLUS-M	12- item short form	item bank developed to measure perceived mobility in people with lower limb amputation	Reliability	test-retest
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	PLUS-M	12- item short form	item bank developed to measure perceived mobility in people with lower limb amputation	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	PLUS-M	12- item short form	item bank developed to measure perceived mobility in people with lower limb amputation	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	PLUS-M	12- item short form	item bank developed to measure perceived mobility in people with lower limb amputation	Reliability	test-retest
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	PLUS-M	12- item short form	item bank developed to measure perceived mobility in people with lower limb amputation	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	PLUS-M	12- item short form	item bank developed to measure perceived mobility in people with lower limb amputation	MDC	

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Cyril	2001	0	nd		SRM	0.65				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Cyril	2001	0	nd		Effect size with baseline SD	0.98				Effect Size Statistics for Change in Scores Between 3 and 12 Months
Hafner	2016	28273329			ICC	0.96				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			MDC 90	4.5				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			MDC 95	5.36				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			ICC	0.96				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			MDC 90	4.5				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			MDC 95	5.36				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Amputation Level	Amputation Etiology	Age	Other Population Information	N	Instrument	Subscale	Description	Property	Aspect
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	PLUS-M	7-item short form	item bank developed to measure perceived mobility in people with lower limb amputation	Reliability	test-retest
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	PLUS-M	7-item short form	item bank developed to measure perceived mobility in people with lower limb amputation	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	PLUS-M	7-item short form	item bank developed to measure perceived mobility in people with lower limb amputation	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	PLUS-M	7-item short form	item bank developed to measure perceived mobility in people with lower limb amputation	Reliability	test-retest
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	PLUS-M	7-item short form	item bank developed to measure perceived mobility in people with lower limb amputation	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	unilateral	201	PLUS-M	7-item short form	item bank developed to measure perceived mobility in people with lower limb amputation	MDC	
Hafner	2016	28273329	above knee (70, 34.8%); below knee (131, 65.2 %)	dysvascular (46/22.9%); trauma (121/60.2%); infection (25/12.4%); tumor (8/4.0%); congenital (1/0.5%)	60.2 +-11.4	nd	201	PLUS-M	CAT	item bank developed to measure perceived mobility in people with lower limb amputation	Reliability	test-retest

Study Data for Key Questions 1-3, sorted by Instrument, Subscale, and Study

Author	Year	PMID	Comparator/Criterion/Outcome	Timepoint (predictive valid)	Metric Used	Value	Strength of Property	Is Aspect Supported?	Conclusion	Notes/Caveats
Hafner	2016	28273329			ICC	0.95				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			MDC 90	4.69				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			MDC 95	5.59				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant
Hafner	2016	28273329			ICC	0.95				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			MDC 90	4.69				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			MDC 95	5.59				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant.
Hafner	2016	28273329			ICC	0.92				retest on avg 48.9 (5.2) hrs after, presented separately by MoA when differences were observed. combined ICC, MoAs were statistically constant



Subgroup analyses for Key Question 4, sorted by Study

Study	Component Comparison	Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Diff (Categorical)
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Indoors	Energy storing (<0.001)	168	Transfemoral	27	Transtibial	141	1
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Upstairs	Energy storing (<0.001)	168	Transfemoral	27	Transtibial	141	0.59
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Downstairs	Energy storing (<0.001)	168	Transfemoral	27	Transtibial	141	0.86
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Upstairs	Energy storing (<0.001)	168	Transfemoral	27	Transtibial	141	0.59
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Uneven ground	Energy storing (<0.001)	168	Transfemoral	27	Transtibial	141	0.51
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Upstairs	Energy storing (<0.001)	168	Transfemoral	27	Transtibial	141	0.59
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Uphill street	Energy storing (<0.001)	168	Transfemoral	27	Transtibial	141	0.89
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Upstairs	Energy storing (<0.001)	168	Transfemoral	27	Transtibial	141	0.59
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Swift walking	Energy storing (<0.001)	168	Transfemoral	27	Transtibial	141	0.79
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Upstairs	Energy storing (<0.001)	168	Transfemoral	27	Transtibial	141	0.59
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot	Movement disability index: Total	nd	168	Age				
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot			168	Age at				
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot			168	Body weight				
Alaranta 1994 (PMID 7991366)	Energy-storing vs. conventional ankle/foot			168	Body mass index				
De Asha 2014 (PMID 24997811)	Hydraulic vs. rigid ankle/foot	Gait speed (m/s)	Hydraulic (0.005)	19	Transfemoral	8	Transtibial	11	0.12
De Asha 2014 (PMID 24997811)	Hydraulic vs. rigid ankle/foot	Cadence (steps/min)	Neither (0.84)	19	Transfemoral	8	Transtibial	11	0.53
Gard 2003 (PMID 15077637)	Shock absorbing vs. non-shock absorbing pylon	Self-selected walking speed (m/s)	Neither (NS)	10	Vascular	3	Traumatic	7	0.87
Gard 2003 (PMID 15077637)	Shock absorbing vs. non-shock absorbing pylon			10	Male	9	Female	1	0.0002
Gard 2003 (PMID 15077637)	Shock absorbing vs. non-shock absorbing pylon			10	Age 31-46 y	5	Age 57-79 y	5	0.78
Gard 2003 (PMID 15077637)	Shock absorbing vs. non-shock absorbing pylon			10	Height 1.73-1.81 m	5	Ht 1.82-1.88 m	5	0.022
Gard 2003 (PMID 15077637)	Shock absorbing vs. non-shock absorbing pylon			10	Time since amputation 1-2 y	4	Time since amputation 4-50 y	6	0.34
Gard 2003 (PMID 15077637)	Shock absorbing vs. non-shock absorbing pylon	Fast walking speed (m/s)	Neither (NS)	10	Vascular	3	Traumatic	7	0.67
Gard 2003 (PMID 15077637)	Shock absorbing vs. non-shock absorbing pylon			10	Male	9	Female	1	<0.0001
Gard 2003 (PMID 15077637)	Shock absorbing vs. non-shock absorbing pylon			10	Age 31-46 y	5	Age 57-79 y	5	0.64
Gard 2003 (PMID 15077637)	Shock absorbing vs. non-shock absorbing pylon			10	Height 1.73-1.81 m	5	Ht 1.82-1.88 m	5	0.077
Gard 2003 (PMID 15077637)	Shock absorbing vs. non-shock absorbing pylon			10	Time since amputation 1-2 y	4	Time since amputation 4-50 y	6	0.045
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Stair Assessment Index	Microprocessor (<0.001)	17	K level 2	8	K level 3	9	0.96
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Hill Assessment Index	Microprocessor (<0.001)	17	K level 2	8	K level 3	9	0.41
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Hill speed (m/s)	Microprocessor (<0.001)	17	K level 2	8	K level 3	9	0.24
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Obstacle course speed (m/s)	Microprocessor (<0.001)	17	K level 2	8	K level 3	9	0.65
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Attention speed (m/s)	Microprocessor (<0.001)	17	K level 2	8	K level 3	9	0.14
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Attention accuracy (% correct)	Neither (>0.05)	17	K level 2	8	K level 3	9	0.97
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	PEQ Ambulation	Microprocessor (0.008)	17	K level 2	8	K level 3	9	0.14
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	PEQ Appearance	Neither (0.50)	17	K level 2	8	K level 3	9	0.90
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	PEQ Frustration	Neither (0.11)	17	K level 2	8	K level 3	9	0.16
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	PEQ Perceived response	Neither (0.07)	17	K level 2	8	K level 3	9	0.75



Subgroup analyses for Key Question 4, sorted by Study

Study	Component Comparison	Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Diff (Categorical)
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	PEQ Residual limb health	Neither (0.50)	17	K level 2	8	K level 3	9	0.93
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	PEQ Social burden	Neither (0.54)	17	K level 2	8	K level 3	9	1.00
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	PEQ Sounds	Neither (0.07)	17	K level 2	8	K level 3	9	0.25
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	PEQ Utility	Neither (0.07)	17	K level 2	8	K level 3	9	0.14
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	PEQ Well-being	Microprocessor (0.016)	17	K level 2	8	K level 3	9	0.83
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Mental Energy expenditure (VAS)	Microprocessor (0.02)	17	K level 2	8	K level 3	9	0.43
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Confidence while walking (VAS)	Microprocessor (0.001)	17	K level 2	8	K level 3	9	0.47
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Multitasking while walking (VAS)	Microprocessor (0.002)	17	K level 2	8	K level 3	9	0.82
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Difficulty with concentration (VAS)	Neither (0.07)	17	K level 2	8	K level 3	9	0.98
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Activity avoidance (VAS)	Neither (0.10)	17	K level 2	8	K level 3	9	0.11
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Frustration with falls (VAS)	Microprocessor (0.005)	17	K level 2	8	K level 3	9	0.81
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Embarrassment with falls (VAS)	Neither (0.23)	17	K level 2	8	K level 3	9	0.87
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Stumbles (VAS)	Microprocessor (0.05)	17	K level 2	8	K level 3	9	0.49
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Stumbles (number)	Microprocessor (0.003)	17	K level 2	8	K level 3	9	0.40
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Semicontrolled falls (VAS)	Neither (0.64)	17	K level 2	8	K level 3	9	0.91
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Semicontrolled falls (number)	Microprocessor (0.03)	17	K level 2	8	K level 3	9	0.53
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Uncontrolled falls (VAS)	Neither (0.64)	17	K level 2	8	K level 3	9	0.90
Hafner 2009 (PMID 19675993)	Microprocessor vs. mechanical knee	Uncontrolled falls (number)	Microprocessor (0.006)	17	K level 2	8	K level 3	9	0.37
Hahn 2016 (PMID 27828871)	Genium microprocessor vs. prior knee (mostly C-Leg microprocessor)	Functional benefits (safety, harmonization of gait pattern, relief of the contralateral limb, possibility to divide attention, capability to vary gait speed, reduction of overall effort, reduction in number of aids, and change of mobility grade) Perception (of safety) Advanced maneuvers (assessed by prosthettist) Variable gait speed (capability to vary speed) Toileting Walking stairs alternatingly (up/down) HOWEVER, it is unclear which outcome(s) were used in the final models.	Genium	899	Many variables were statistically significant in multivariable regression analyses for different outcomes. variables and none of the regression models yield explanatory predictive power* regarding who would r microprocessor knee. These variables included: Age, Years wearing Prosthesis, Distance walked per da disease etiology, Amputation level, Bilateral amputation, No comorbidity, Diabetes mellitus, Cardiovascu circulation leg", Hip problem, Further disability, Profession, Residual limb condition, Residual limb length Adhesion, Number of falls per year, Mobility grade. Determined to have no overall predictive value: body mass index, neuropathy, visual impairment, artifici lower extremity, paresis upper extremity, further amputation, malformation, contralateral joint instability/j osteoarthritis of the lower limb joints, hip contracture, Scarred residual limb, and Annual falls (yes/no).				
Isakov 1985 (PMID 3868034)	Locking vs. open knee	Gait speed (m/min)	Neither (0.060)	17	Vascular	14	Nonvascular	3	0.016
Isakov 1985 (PMID 3868034)	Locking vs. open knee			17	Male	16	Female	1	0.59
Isakov 1985 (PMID 3868034)	Locking vs. open knee			17	Age 26-50 y	8	Age 55-75 y	9	0.004
				0					
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee	Stumbles	Microprocessor (0.006)	15	K level 2	10	K level 3-4	5	0.14
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	K level 2-3	4	K level 4	11	0.030
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Age 28-57	8	Age 58-83	7	0.53
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Vascular	7	Nonvascular	8	0.056
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Height 160-170 cm	5	Height 173-188 cm	10	0.44
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			14	Employed	7	Not employed	7	0.75



Subgroup analyses for Key Question 4, sorted by Study

Study	Component Comparison	Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Diff (Categorical)
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Prosthesis use 6-12 mo	9	Prosthesis use >12 mo	6	0.13
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "firm"	7	Stump "soft" or "medium"	8	0.38
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "medium" or "firm"	13	Stump "soft"	2	0.51
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump length 32-43 cm	8	Stump length 11-31 cm	7	0.19
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump as percent of femur 74-100%	8	27-73%	7	0.40
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee	Falls	Microprocessor (0.03)	15	K level 2	10	K level 3-4	5	0.48
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	K level 2-3	4	K level 4	11	0.089
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Age 28-57	8	Age 58-83	7	0.48
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Vascular	7	Nonvascular	8	0.24
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Height 160-170 cm	5	Height 173-188 cm	10	0.48
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			14	Employed	7	Not employed	7	0.15
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Prosthesis use 6-12 mo	9	Prosthesis use >12 mo	6	0.29
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "firm"	7	Stump "soft" or "medium"	8	0.20
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "medium" or "firm"	13	Stump "soft"	2	0.84
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump length 32-43 cm	8	Stump length 11-31 cm	7	0.37
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump as percent of femur 74-100%	8	27-73%	7	0.48
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee	Self-selected walking speed	Microprocessor (0.03)	15	K level 2	10	K level 3-4	5	0.84
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	K level 2-3	4	K level 4	11	0.75
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Age 28-57	8	Age 58-83	7	0.82
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Vascular	7	Nonvascular	8	0.27
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Height 160-170 cm	5	Height 173-188 cm	10	0.20
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			14	Employed	7	Not employed	7	0.67
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Prosthesis use 6-12 mo	9	Prosthesis use >12 mo	6	0.46
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "firm"	7	Stump "soft" or "medium"	8	0.51
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "medium" or "firm"	13	Stump "soft"	2	0.70
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump length 32-43 cm	8	Stump length 11-31 cm	7	0.63
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump as percent of femur 74-100%	8	27-73%	7	0.16
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee	Fastest walking on 75 m even terrain	Microprocessor (0.005)	15	K level 2	10	K level 3-4	5	0.64
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	K level 2-3	4	K level 4	11	0.93
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Age 28-57	8	Age 58-83	7	0.75

Subgroup analyses for Key Question 4, sorted by Study

Study	P Diff (Continuous)	Finding*	Difference Data*	Note	Within-Study Bonferroni P
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.71			Split at median	0.00040
Kahle 2008 (PMID 18566922)	0.74			Split at median, similar 100% vs. 27-79% or split at 67%	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.10			Split at median	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.48			Split at median, includes 1 woman	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.68			Split at median	0.00040
Kahle 2008 (PMID 18566922)	0.80			Split at median, similar 100% vs. 27-79% or split at 67%	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.80			Split at median	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.33			Split at median, includes 1 woman	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.50			Split at median	0.00040
Kahle 2008 (PMID 18566922)	0.49			Split at median, similar 100% vs. 27-79% or split at 67%	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.41			Split at median	0.00040

Subgroup analyses for Key Question 4, sorted by Study

Study	Component Comparison	Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Diff (Categorical)
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Vascular	7	Nonvascular	8	0.41
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Height 160-170 cm	5	Height 173-188 cm	10	0.18
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			14	Employed	7	Not employed	7	0.76
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Prosthesis use 6-12 mo	9	Prosthesis use >12 mo	6	0.43
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "firm"	7	Stump "soft" or "medium"	8	0.34
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "medium" or "firm"	13	Stump "soft"	2	0.60
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump length 32-43 cm	8	Stump length 11-31 cm	7	0.34
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump as percent of femur 74-100%	8	27-73%	7	0.18
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee	Fastest walking on uneven terrain	Microprocessor (<0.001)	15	K level 2	10	K level 3-4	5	0.76
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	K level 2-3	4	K level 4	11	0.068
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Age 28-57	8	Age 58-83	7	0.77
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Vascular	7	Nonvascular	8	0.13
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Height 160-170 cm	5	Height 173-188 cm	10	0.44
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			14	Employed	7	Not employed	7	0.41
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Prosthesis use 6-12 mo	9	Prosthesis use >12 mo	6	0.94
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "firm"	7	Stump "soft" or "medium"	8	0.12
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "medium" or "firm"	13	Stump "soft"	2	0.052
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump length 32-43 cm	8	Stump length 11-31 cm	7	0.30
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump as percent of femur 74-100%	8	27-73%	7	0.77
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee	Fastest walking on 6 m even terrain	Microprocessor (0.001)	15	K level 2	10	K level 3-4	5	0.38
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	K level 2-3	4	K level 4	11	0.98
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Age 28-57	8	Age 58-83	7	0.71
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Vascular	7	Nonvascular	8	0.65
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Height 160-170 cm	5	Height 173-188 cm	10	0.64
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			14	Employed	7	Not employed	7	0.030
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Prosthesis use 6-12 mo	9	Prosthesis use >12 mo	6	0.44
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "firm"	7	Stump "soft" or "medium"	8	0.50
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "medium" or "firm"	13	Stump "soft"	2	0.71
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump length 32-43 cm	8	Stump length 11-31 cm	7	0.14

Subgroup analyses for Key Question 4, sorted by Study

Study	P Diff (Continuous)	Finding*	Difference Data*	Note	Within-Study Bonferroni P
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.26			Split at median, includes 1 woman	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)				Split at median	0.00040
Kahle 2008 (PMID 18566922)	0.46			Split at median, similar 100% vs. 27-79% or split at 67%	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.071			Split at median	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.41			Split at median, includes 1 woman	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.17			Split at median	0.00040
Kahle 2008 (PMID 18566922)	0.13			Split at median, similar 100% vs. 27-79% or split at 67%	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.48			Split at median	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.79			Split at median, includes 1 woman	0.00040
Kahle 2008 (PMID 18566922)		Employed favored C-Leg more than not employed did	-2.0 vs. -0.5		0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.72			Split at median	0.00040



Subgroup analyses for Key Question 4, sorted by Study

Study	Component Comparison	Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Diff (Categorical)
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump as percent of femur 74-100%	8	27-73%	7	0.36
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee	Montreal Rehabilitation Performance Profile	Microprocessor (<0.001)	15	K level 2	10	K level 3-4	5	0.15
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	K level 2-3	4	K level 4	11	0.38
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Age 28-57	8	Age 58-83	7	0.20
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Vascular	7	Nonvascular	8	0.21
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Height 160-170 cm	5	Height 173-188 cm	10	0.44
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			14	Employed	7	Not employed	7	0.32
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Prosthesis use 6-12 mo	9	Prosthesis use >12 mo	6	0.37
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "firm"	7	Stump "soft" or "medium"	8	0.16
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump "medium" or "firm"	13	Stump "soft"	2	0.30
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump length 32-43 cm	8	Stump length 11-31 cm	7	0.12
Kahle 2008 (PMID 18566922)	Microprocessor vs. mechanical knee			15	Stump as percent of femur 74-100%	8	27-73%	7	0.19
<b>Silver-Thorn 2009 (PMID none)</b>	<b>Locking vs. hydraulic knee</b>	<b>Borg's Rating of Perceived Exertion test</b>	<b>Neither (1.00)</b>	<b>4</b>	<b>Age 33-41 y</b>	<b>2</b>	<b>Age 43-58</b>	<b>2</b>	<b>0.47</b>
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Time since amputation 8-20	2	31-34 y	2	0.20
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Height 171-173 cm	2	Height 178-184 cm	2	0.47
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Stump length 23-28 cm	2	32-36 cm	2	0.20
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee	Confidence (Likert)	Neither (0.32)	4	Age 33-41 y	2	Age 43-58	2	0.77
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Time since amputation 8-20	2	31-34 y	2	0.31
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Height 171-173 cm	2	Height 178-184 cm	2	0.77
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Stump length 23-28 cm	2	32-36 cm	2	0.31
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee	Perceived stability	Neither (0.32)	4	Age 33-41 y	2	Age 43-58	2	0.77
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Time since amputation 8-20	2	31-34 y	2	0.31
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Height 171-173 cm	2	Height 178-184 cm	2	0.77
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Stump length 23-28 cm	2	32-36 cm	2	0.31
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee	Comfort on uneven terrain	Neither (0.19)	4	Age 33-41 y	2	Age 43-58	2	0.81
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Time since amputation 8-20 y	2	31-34 y	2	0.037
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Height 171-173 cm	2	Height 178-184 cm	2	0.81

Subgroup analyses for Key Question 4, sorted by Study

Study	P Diff (Continuous)	Finding*	Difference Data*	Note	Within-Study Bonferroni P
Kahle 2008 (PMID 18566922)	0.78			Split at median, similar 100% vs. 27-79% or split at 67%	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)				Split at median	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.88			Split at median, includes 1 woman	0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)					0.00040
Kahle 2008 (PMID 18566922)	0.97			Split at median	0.00040
Kahle 2008 (PMID 18566922)	0.998			Split at median, similar 100% vs. 27-79% or split at 67%	0.00040
Silver-Thorn 2009 (PMID none)	0.91			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.30			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.15			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.029	Shorter stump favored Total Knee 2000 more than longer stump did	$\beta = 0.38 (0.10, 0.66)$	Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.34			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.075			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.80			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.46			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.34			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.075			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.80			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.45			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.56			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.1	More recent amputation favored Total Knee 2000 more than more distant amputation did	2.5 vs. 0	Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.41			Split at median	0.00078

Subgroup analyses for Key Question 4, sorted by Study

Study	Component Comparison	Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Diff (Categorical)
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Stump length 23-28 cm	2	32-36 cm	2	0.037
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee	Comfort up stairs	Neither (0.092)	4	Age 33-41 y	2	Age 43-58	2	0.29
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Time since amputation 8-20	2	31-34 y	2	0.29
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Height 171-173 cm	2	Height 178-184 cm	2	0.29
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Stump length 23-28 cm	2	32-36 cm	2	0.29
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee	Comfort in a crowd	Neither (0.39)	4	Age 33-41 y	2	Age 43-58	2	0.42
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Time since amputation 8-20	2	31-34 y	2	0.42
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Height 171-173 cm	2	Height 178-184 cm	2	0.42
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			4	Stump length 23-28 cm	2	32-36 cm	2	0.42
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee	Gait speed (m/s)	Neither (0.072)	5	Age 33-43 y	2	Age 49-58	3	0.67
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			5	Time since amputation 2-8 y	3	20-34 y	2	0.14
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			5	Height 171-178 cm	2	Height 184-185 cm	3	0.50
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			5	Stump length 23-28 cm	3	32-36 cm	2	0.071
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee	Cadence (steps/min)	Neither (0.20)	5	Age 33-43 y	2	Age 49-58	3	0.74
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			5	Time since amputation 2-8 y	3	20-34 y	2	0.37
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			5	Height 171-178 cm	2	Height 184-185 cm	3	0.16
Silver-Thorn 2009 (PMID none)	Locking vs. hydraulic knee			5	Stump length 23-28 cm	3	32-36 cm	2	0.30
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	Activity time (% of up time)	Neither (0.86, 0.90)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	Bouts of activity (number)	Neither (0.99, 0.95)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	Daily activity "counts"	Neither (0.94, 0.89)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	PEQ Ambulation	Microprocessor A (0.01, 0.14)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	PEQ Appearance	Neither (0.55, 0.33)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	PEQ Residual limb health	Microprocessors (0.003, <0.001)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	PEQ Satisfaction with prosthesis	Neither (0.05, 0.14)	30	K2 High, Intermediate	12, 12	K2 Low	6	

Subgroup analyses for Key Question 4, sorted by Study

Study	P Diff (Continuous)	Finding*	Difference Data*	Note	Within-Study Bonferroni P
Silver-Thorn 2009 (PMID none)	0.051	Longer stump favored Total Knee 2000 more than more shorter did	0 vs. 2.5	Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.88			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.52			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.085			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.046	Shorter stump favored Total Knee 2000 more than more longer did	$\beta = -0.14 (-0.27, -0.01)$	Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.95			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.39			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.14			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.19			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.53			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.10			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.87			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.20			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.39			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.36			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.48			Split at median	0.00078
Silver-Thorn 2009 (PMID none)	0.28			Split at median	0.00078
Theeven 2011 (PMID 21947182)	>0.42 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.42 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.31 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.018 (all†)	High K2 favored microprocessor knee B more than low K2 subgroup; other comparisons P>0.13			0.00037
Theeven 2011 (PMID 21947182)	>0.69 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.29 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.28 (all†)				0.00037

Subgroup analyses for Key Question 4, sorted by Study

Study	Component Comparison	Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Diff (Categorical)
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	PEQ Satisfaction with walking	Microprocessor A (0.003, 0.19)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	PEQ Sounds	Neither (0.52, 0.33)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	PEQ Utility	Microprocessors (0.006, 0.02)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	PEQ Well-being	Neither (0.30, 0.93)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	Perceived difficulty ambulation requiring prosthesis skill	Neither (0.63, 0.72)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	Perceived difficulty balance	Neither (0.56, 0.60)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	Perceived difficulty sitting and standing	Neither (0.62, 0.57)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	Performance time ambulation requiring prosthesis skill (min)	Microprocessor B (NS, 0.023)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	Performance time requiring balance (min)	Microprocessors (<0.001, 0.002)	30	K2 High, Intermediate	12, 12	K2 Low	6	
Theeven 2011 (PMID 21947182)	Microprocessor (2 settings) vs. mechanical knee	Performance time requiring sitting and standing (min)	Neither (0.87, 1.00)	30	K2 High, Intermediate	12, 12	K2 Low	6	
<b>Traballesi 2011 (PMID 21684165)</b>	<b>Marlo Anatomic vs. Ischial Component Socket</b>	<b>PEQ Mobility</b>	<b>Marlo Anatomic Socket (0.018)</b>	<b>7</b>	<b>Male</b>	<b>6</b>	<b>Female</b>	<b>1</b>	<b>0.022</b>
Traballesi 2011 (PMID 21684165)	Marlo Anatomic vs. Ischial Component Socket			7	Age 25-28 y	3	Age 41-46 y	4	0.42
Traballesi 2011 (PMID 21684165)	Marlo Anatomic vs. Ischial Component Socket			6	Height 174-180 cm	2	Height 184-185 cm	4	0.074
Traballesi 2011 (PMID 21684165)	Marlo Anatomic vs. Ischial Component Socket			7	Time since amputation 2-9 y	3	10-26 y	4	0.56
<b>Wong 2015 (PMID 25768067)</b>	<b>Microprocessor vs. mechanical knee</b>	<b>Falls, number</b>	<b>Microprocessor (0.020)</b>	<b>8</b>	<b>K level 1</b>	<b>6</b>	<b>K level 2-3</b>	<b>2</b>	<b>0.12</b>
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	K level 1-2	4	K level 3	4	0.040
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Age 43-61 y	4	Age 63-74	4	0.040
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Time since amputation 0.5-2 y	4	4-47 y	4	0.73
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Bilateral	2	Unilateral	6	0.12
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee	<b>ABC Balance</b>	<b>Microprocessor (0.012)</b>	<b>8</b>	<b>K level 1</b>	<b>6</b>	<b>K level 2-3</b>	<b>2</b>	<b>0.016</b>
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	K level 1-2	4	K level 3	4	0.16
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Age 43-61 y	4	Age 63-74	4	0.10
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Time since amputation 0.5-2 y	4	4-47 y	4	0.22

Subgroup analyses for Key Question 4, sorted by Study

Study	P Diff (Continuous)	Finding*	Difference Data*	Note	Within-Study Bonferroni P
Theeven 2011 (PMID 21947182)	>0.006 (all†)	Intermediate K2 favored both microprocessor knees more than low K2 subgroup (P=0.28, 0.006), high K2 favored microprocessor knee B more than intermediate K2 subgroup (P=0.041); other comparisons P=0.066-0.44			0.00037
Theeven 2011 (PMID 21947182)	>0.33 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.25 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.54 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.48 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.69 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.54 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.68 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.31 (all†)				0.00037
Theeven 2011 (PMID 21947182)	>0.51 (all†)				0.00037
<b>Traballesi 2011 (PMID 21684165)</b>					
Traballesi 2011 (PMID 21684165)		One woman favored Marlo Anatomical Socket more than men did	2.30 vs. 1.35		0.0071
Traballesi 2011 (PMID 21684165)	0.28			Split at median	0.0071
Traballesi 2011 (PMID 21684165)	0.017	Shorter favored Marlo Anatomical Socket more than taller did	$\beta = -0.14$ (-0.24, -0.04)	Split at median, men only	0.0071
Traballesi 2011 (PMID 21684165)	0.69			Split at median	0.0071
<b>Wong 2015 (PMID 25768067)</b>					
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)		K1-2 favored microprocessor knee more than K3 did	-2 vs. -0.75		0.0010
Wong 2015 (PMID 25768067)	0.027	Older favored microprocessor knee more than younger did	-0.75 vs. -2; $\beta = 0.06$ (0.01, 0.11)	Split at median	0.0010
Wong 2015 (PMID 25768067)	0.67			Split at median, similar split 0.5-4 vs. 17-47 y	0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)		K2-3 favored microprocessor knee more than K1 did	15.9 vs. 62.3		0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)	0.021	Younger favored microprocessor knee more than older did	$\beta = 1.9$ (0.4, 3.3)		0.0010
Wong 2015 (PMID 25768067)	0.96				0.0010

Subgroup analyses for Key Question 4, sorted by Study

Study	Component Comparison	Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Diff (Categorical)
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Bilateral	2	Unilateral	6	0.016
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee	Houghton Scale	Neither (0.058)	8	K level 1	6	K level 2-3	2	0.61
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	K level 1-2	4	K level 3	4	0.37
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Age 43-61 y	4	Age 63-74	4	0.37
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Time since amputation 0.5-2 y	4	4-47 y	4	0.13
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Bilateral	2	Unilateral	6	0.61
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee	BBS Balance	Neither (0.11)	8	K level 1	6	K level 2-3	2	0.81
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	K level 1-2	4	K level 3	4	0.51
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Age 43-61 y	4	Age 63-74	4	0.95
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Time since amputation 0.5-2 y	4	4-47 y	4	0.77
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Bilateral	2	Unilateral	6	0.81
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee	TUG Walking	Microprocessor (0.043)	8	K level 1	6	K level 2-3	2	0.0001
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	K level 1-2	4	K level 3	4	0.24
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Age 43-61 y	4	Age 63-74	4	0.28
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Time since amputation 0.5-2 y	4	4-47 y	4	0.37
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Bilateral	2	Unilateral	6	0.0001
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee	Fear of falling	Microprocessor (0.042)	8	K level 1	6	K level 2-3	2	0.11
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	K level 1-2	4	K level 3	4	0.62
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Age 43-61 y	4	Age 63-74	4	0.35
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Time since amputation 0.5-2 y	4	4-47 y	4	0.48
Wong 2015 (PMID 25768067)	Microprocessor vs. mechanical knee			8	Bilateral	2	Unilateral	6	0.11
		* Statistically significant difference favoring listed component over comparator. "Neither" does not distinguish between evidence of no difference and lack of statistical power to find a difference (due to imprecision).							
		† 6 comparisons summarized: High vs. intermediate K2, high vs. low K2, and intermediate vs. low K2 for both microprocessor knees A and B vs. mechanical knee.							

Subgroup analyses for Key Question 4, sorted by Study

Study	P Diff (Continuous)	Finding*	Difference Data*	Note	Within-Study Bonferroni P
Wong 2015 (PMID 25768067)		Bilateral favored microprocessor knee more than unilateral did	62.3 vs. 15.9		0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)	0.10				0.0010
Wong 2015 (PMID 25768067)	0.47				0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)	0.93				0.0010
Wong 2015 (PMID 25768067)	0.33				0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)		K2-3 favored microprocessor knee more than K1 did	-2.6 vs. -70		0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)	0.17				0.0010
Wong 2015 (PMID 25768067)	0.78				0.0010
Wong 2015 (PMID 25768067)		Bilateral favored microprocessor knee more than unilateral did	-70 vs. -2.6		0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)					0.0010
Wong 2015 (PMID 25768067)	0.24				0.0010
Wong 2015 (PMID 25768067)	0.51				0.0010
Wong 2015 (PMID 25768067)					0.0010