Comparative Effectiveness Review
Number 213

Lower Limb Prostheses: Measurement Instruments, Comparison of Component Effects by Subgroups, and Long-Term Outcomes

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Key Messages

Purpose of Review
To assess validity of instruments used in adult lower limb amputees, whether patient characteristics can predict relative effectiveness of different lower limb prosthesis (LLP) components, and long-term LLP use.

Key Messages

- Thirty of 50 evaluated instruments (ambulatory/functional outcomes and other measures) have evidence of validity and reliability. Many studies use nonvalidated instruments.
- Based on a small number of studies, patient characteristics do not predict who would most benefit from a given LLP component. Half of studies used nonvalidated instruments and analyses were inadequate.
- Only a few studies assessed long-term LLP use; 11 to 22 percent of patients abandon their LLP after 1 year; people with above-the-knee amputations are more likely to abandon their prostheses than people with below-the-knee amputations; 24 to 29 percent of people with LLPs use them only indoors 1 year after they first receive the prostheses. The studies, though, had important methodological issues.

This report is based on research conducted by the Brown Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2015-00002-I). 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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This report may periodically be assessed for the currency of conclusions. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program Web site at www.effectivehealthcare.ahrq.gov. Search on the title of the report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

If you have comments on this systematic review, they may be sent by mail to the Task Order Officers named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Key Informants

In designing the study questions, the EPC consulted a panel of Key Informants who represent subject experts and end-users of research including clinicians, allied health professionals, and patient representatives. Key Informant input can inform key issues related to the topic. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest identified.

The list of Key Informants who provided input to this report follows:

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest identified.

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Peer Reviewers

Prior to publication of the final evidence report, we sought 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 $5,000 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

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Lower Limb Prostheses: Measurement Instruments, Comparison of Component Effects by Subgroups, and Long-Term Outcomes

Structured Abstract

Background. Lower limb prosthesis (LLP) candidates are a heterogeneous group. Many LLP options exist. How to best match an amputee with an LLP is unclear. Optimal selection of devices should be guided by evidence on which amputees would do best with which LLP component or configuration, and which evaluation instruments are valid and reliable in this population.

Methods. We addressed questions pertaining to: assessing validity, reliability, and related psychometric properties for assessment techniques, predictor tools, and outcome measures in lower limb amputees; determining which patient and other characteristics may predict which LLP configuration or component would result in better clinical and patient-centered outcomes for different lower limb amputees (i.e., heterogeneity of treatment effect); determining whether patient expectations align with outcomes; evaluating whether patients are satisfied with the process of obtaining their LLPs; and describing long-term use of LLPs. The review does not evaluate overall comparative effectiveness among LLP components, nor does it include assessment of biomechanical outcomes. We searched six databases and other sources through October 2017 for eligible studies.

Results. We found eligible studies that assessed the psychometric properties of 50 instruments (classified as assessment techniques, prediction tools, and outcome measures). Of these, 30 have evidence for both validity and reliability, but only 17 of these have evidence that was deemed generalizable to the Medicare population. Most of the remaining instruments have evidence of either validity or reliability, but not both. Of 13 studies reporting data or analyses to allow assessment of heterogeneity of treatment effect, 7 used both predictor and outcome measures with evidence of validity. 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 benefit most or least from a given component (low strength of evidence); the studies were almost all underpowered to address this Key Question. Two studies provide low strength of evidence that people are satisfied with their encounters with their prosthetists. No eligible study addressed how study participants' preprescription expectations of ambulation align with outcomes. Based on eight eligible studies, there is low strength of evidence that (1) about 11 to 22 percent of lower limb amputees who receive an LLP prescription stop using the prosthesis at about 1 year and (2) people with unilateral transfemoral amputations are about twice as likely to abandon their LLP than those with transtibial amputations. There is low strength of evidence that 24 to 29 percent of LLP recipients use their prostheses only indoors at 1 year.

Conclusions. Numerous instruments assessing ambulation, function, quality of life, and other patient-centered outcomes have evidence of validity and reliability for people with lower limb amputations. The literature does not provide adequate evidence regarding whether specific characteristics or preprescription instruments are predictive of which specific LLP component

individuals should receive 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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Introduction

Background

An estimated 1.9 million people in the United States are living with limb loss, a number expected to double by 2050, mostly due to the rising prevalence of diabetes.[1, 2] However, fewer than half of amputees ever receive a prescription for a prosthetic device.[3, 4] The management of lower limb amputees with respect to lower limb prostheses (LLPs) is complicated. 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, in some instances, wearable monitoring technologies that record patient activity;[5] although prosthetists and treating clinicians often rely on clinical judgment to match patients to prostheses. Insurance coverage policies often dictate which prostheses and components are selected for a given patient. Numerous instruments 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 LLP components to patients pertain to the large heterogeneity in patient characteristics and attributes of LLPs; the lack of data on patient characteristics and LLP attributes that 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 matching.

Objectives

This review's Key Questions and study eligibility criteria were designed to assist Centers for Medicare & Medicaid Services 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 cover all aspects of LLP evaluation. Specifically, it excludes from evaluation biomechanical and other nonpatient-centered intermediate outcomes. It also does not attempt to review all evidence comparing specific components. Instead, it largely focuses on those comparisons that provide within-study data to allow assessment of heterogeneity of treatment effects (i.e., whether outcomes with specific devices vary across individuals based on different characteristics such as age or health status). The review also focuses on people who may be eligible for Medicare coverage, whether due to age or disability. Thus, we categorize studies based on their likely generalizability to amputees with Medicare. Based on discussions with our Technical Expert Panel, this includes studies with a mean age at least 65 years and those in which the percentage of participants with dysvascular disease (including diabetes) is broadly similar to the Medicare amputee population (i.e., at least 50%). Furthermore, the review excludes studies of exclusively military amputees with battle-related trauma (who are generally covered by Department of Defense and/or Veterans Health Administration insurance); however, we do include studies of veterans with multiple etiologies

of amputation. Furthermore, the review excludes studies from low-income or low-resource settings not applicable to the United States.

Key Questions

The following summarized Key Questions (KQs) are 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?

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

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

KQ 4. In adults who use a lower limb prosthesis, how do ambulatory, functional, and patient-centered **outcomes** with **different prosthetic components vary** based on study **participant characteristics**?

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

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

KQ 7. **At 6 months, 1 year, and 5 years after receipt of an 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

Methods

The Brown Evidence-based Practice Center conducted 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.[6] The review was registered with PROSPERO (CRD42017058488).

The searches were conducted on October 30, 2017. Study eligibility criteria are described in the full report.

Results

Summary of Studies

The literature searches yielded 10,765 citations and an additional 357 references were screened from review articles, existing systematic reviews, and from reviewers of the draft report. Of these, 425 articles were retrieved in full text. We excluded 348 articles. Of note, 89 studies compared lower limb prosthesis (LLP) components or configurations but did not report either subgroup analyses, regression analyses, or individual patient data which would allow subgroup analyses. Overall, we found 80 eligible studies (in 77 articles), of which 55 studies evaluated psychometric properties addressing Key Questions (KQ) 1 to 3, 14 studies provided data relevant to KQ 4, no studies for KQ 5, two studies for KQ 6, and eight studies for KQ 7.

Key Questions 1 to 3. Assessment Techniques, Prediction Tools, Functional Outcome Measurement Tools

Studies provided evidence regarding psychometric properties of 50 instruments for people with lower limb amputations. In total, 55 studies in 52 articles met criteria to provide evidence regarding instrument psychometrics in people with lower limb amputations. The evidence is summarized for each instrument in the main report.

We categorized instruments (or subscales, etc. of instruments) by whether studies that evaluated them were generalizable to the Medicare population (i.e., study mean age ≥65 years or ≥50% of participants had dysvascular disease) and by whether there is supporting evidence for validity and/or reliability.

The instruments evaluated are:

- 1 Leg Standing Balance
- 180 Degree Turn Test
- 2MWT (2 Minute Walk Test)
- 6MWT (6 Minute Walk Test)
- AAS (Amputee Activity Survey)
- ABC (Activities-specific Balance Confidence)
- ADAPT (Assessment of Daily Activity Performance in Transfemoral Amputees)
- AMP (Amputee Mobility Predictor with, AMPPRO, or without prosthesis, AMPnoPRO)
- AMPSIMM (Amputee Single Item Mobility Measure)
- Barthel Index
- BBS (Berg Balance Scale)
- Climbing Stairs Questionnaire

- Employment Questionnaire
- FAC (Functional Ambulation Categories)
- FAI (Frenchay Activities Index)
- FIM (Functional Independence Measure)
- FSST (Four Square Step Test)
- Functional Reach Test
- Houghton Scale
- L Test (L Test of Functional Mobility)
- LCI (Locomotor Capabilities Index)
- LEMOCOT (Lower-Extremity Motor Coordination Test)
- NQ-ACGC (Quality of Life in Neurological Conditions – Applied Cognition/General Concerns)
- OPCS (Office of Population Censuses and Surveys Scale)
- OPUS (Orthotics Prosthetics Users Survey)
- Patient Activity Monitor
- PEQ, PEQ-MS (Prosthetic Evaluation Questionnaire, Mobility Subscale)
- PFI (Physical Function Index)
- PGI (Patient Generated Index)
- PLUS-M (Prosthetic Limb Users Survey of Mobility)
- PPA (Prosthetic Profile of the Amputee)
- 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)
- Rising and Sitting Down Questionnaire
- RMI (Rivermead Mobility Index)
- SAT-PRO (Satisfaction with Prosthesis Questionnaire)
- SCS (Socket Comfort Score)
- SF-12/SF-36/SF-36V (Short Form Health Surveys 12, 36, and 36V)
- SIGAM (Special Interest Group of Amputation Medicine)
- Single beam test
- SIP-PD (Sickness Impact Profile-Physical Dimension)
- Tandem Test
- TAPES (Trinity Amputation and Prosthesis Experience Scales)
- TFP (Transfemoral Fitting Predictor)
- TUG (Timed Up and Go)
- TWT (Timed Walking Test)
- Walking Questionnaire
- WHOQOL-BREF (World Health Organization Quality-of-Life Scale – Brief Version)

Key Question 1. Assessment Techniques

Based on explicit reporting within articles that instruments were evaluated at the time of initial assessment or prosthesis fitting, 10 studies evaluated 12 instruments as initial assessment tools.

Eleven of the instruments have evidence of test validity from studies generalizable to the Medicare population. These include 1 Leg Standing Balance, 2MWT, AMPnoPRO, FAC, FAI, FIM, LEMOCOT, OPCS, PROS, SF, and TFP. For SF, more specifically, test validity has been found for SF-12 Physical Component Score, SF-12 Role Physical, SF-12 Bodily Pain, SF-36 Physical Functioning (where a modified 15-item version performed better than the original 10-item version). Three of the 11 instruments were also reported to have evidence of test reliability when evaluated at initial assessment: AMPnoPRO, TMP, and for SF-12 the subscales for Role Emotional, Role Physical, Bodily Pain, and Mental Health.

One instrument, LCI, was evaluated at initial assessment only in a study that is not generalizable to the Medicare population. Both the LCI-4 and LCI-5 versions of the instrument were found to have evidence of test validity, reliability, and responsiveness. Floor and ceiling percentages were reported for LCI-4, and no such effects were found.

Key Question 2. Prediction Tools

Based on reporting of metrics relevant to predictive validity, eight studies evaluated 13 instruments as prediction tools. However, all but one study reported only correlations of the instrument results with occurrence or test scores at a future time point. Thus, these are not true evaluations of the predictive accuracy of these instruments. Only one study reported on diagnostic test accuracy (sensitivity and specificity) for several instruments.

Twelve instruments have been reported to have predictive validity in whole or in part in studies that are generalizable to the Medicare population. These include the 1 Leg Standing Balance, 180 Degree Turn Test, 2MWT, AMPnoPRO, FAC, FAI, FIM, FSST, LCI-4 Advanced, LEMOCOT, OPCS, and TUG. Two instruments were evaluated for predictive validity only in studies that were not generalizable to the Medicare population. Both AMPSIMM and LCI-5 were reported to be correlated with future functional status.

One study evaluated four of these instruments in a study deemed generalizable to the Medicare population for test accuracy to predict two or more falls during a 6-month followup period.[7] The Turn Time and Turn Test components of the 180 Degree Turn Test, FSST and TUG all had high sensitivity (85% to 100%) and specificity (74% to 93%) to predict falls. The Advanced components portion of LCI-4 had high specificity (91%) but low sensitivity (43%) to predict falls, which overall was reported to be statistically significant ($P<0.01$). The Turn Steadiness component of the 180 Degree Turn Test also had high sensitivity (85%) but low sensitivity (31%) to predict falls, but this test overall was not statistically significant ($P=0.22$).

Key Question 3. Functional Outcome Measurement Tools

All 50 evaluated instruments were deemed to be relevant functional outcome measurement tools. The findings are summarized in Tables A to D. In brief, 34 instruments (in whole or in part) had supporting evidence generalizable to the Medicare population, of which, in Table A, 17 instruments (or parts thereof) have evidence to support validity and reliability, and in Table B, 13 instruments have evidence of validity alone and 7 instruments have evidence of reliability alone. As noted in the tables, two of the instruments (PEQ and SF-12/36/36V), specific instrument

items have supporting evidence for both validity and reliability, or for either validity or reliability alone. There are also 19 instruments (in whole or in part) that have supporting evidence only from studies not generalizable to the Medicare population. Of these, in Table C, 13 instruments (or parts thereof) have evidence to support validity and reliability, and in Table D, four instruments have evidence of validity only, three more have evidence of validity but explicitly not reliability, and 4 have evidence of reliability only. As noted in the tables, five of these instruments with evidence not generalizable to the Medicare population also have evidence for specific items that was generalizable to the Medicare population. Also, as noted in the tables, five other instruments have evidence for both validity and reliability for some subscales not only validity or reliability for others.

Table A. Instruments with evidence of both validity and reliability generalizable to the Medicare population

Rep*	Instrument	MCare	Validity	Reliability
	2MWT (2 Minute Walk Test)	Gen	Valid	Reliable
	6MWT (6 Minute Walk Test)	Gen	Valid	Reliable
	ABC (Activities-specific Balance Confidence)	Gen	Valid	Reliable
	AMP (Amputee Mobility Predictor) Both AMPnoPRO (without prosthesis) and AMPPRO (with prosthesis)	Gen	Valid	Reliable
	Climbing Stairs Questionnaire	Gen	Valid	Reliable
	Functional Reach Test	Gen	Valid	Reliable
	Houghton Scale Both total Scale score and a subscale of items 1 to 3 (on prosthesis wear and use)	Gen	Valid	Reliable
1	LCI (Locomotor Capabilities Index)† Specifically: LCI-4 (LCI with a 4-point ordinal scale)	Gen	Valid	Reliable
2	PEQ (Prosthetic Evaluation Questionnaire)‡ Specifically, the PEQ-MS 13/11 (the Mobility Subscale with 13 items and 11 categories)	Gen	Valid	Reliable
	PPA (Prosthetic Profile of the Amputee)§ Specifically: Prosthesis use (outdoors), and Acceptance / Adaptation	Gen	Valid	Reliable
	Rising and Sitting Down Questionnaire	Gen	Valid	Reliable
	RMI (Rivermead Mobility Index)	Gen	Valid	Reliable
	SCS (Socket Comfort Score)	Gen	Valid	Reliable
3	SF-12 (Short Form Health Survey 12) Specifically: SF-12 PCS (Physical Component Score), SF-12 RP-2 (Role Physical), and SF-12 BP-2 (Bodily Pain)	Gen	Valid	Reliable
	TFP (Transfemoral Fitting Predictor)	Gen	Valid	Reliable
	TUG (Timed Up and Go)	Gen	Valid	Reliable
	Walking Questionnaire	Gen	Valid	Reliable

Abbreviations: Gen = generalizable to the Medicare population, MCare = Medicare (generalizability), Rep = repeated (see note for explanation).

Note: Instruments are organized across Tables A to D by whether the studies that evaluated them were generalizable to the Medicare (MCare) population (indicated by "Gen" in the MCare column) and by whether there was evidence of both validity and reliability, validity only, reliability only, and evidence of lack of reliability (indicated by "No" in the Reliability column of the relevant tables). Across tables, blank cells in the Validity or Reliability columns indicate that there was not evidence to support validity or reliability (not that the studies were found to be not valid or not reliable). In the Rep column, instruments that had parts that were variably generalizable, validated, or found to be reliable, and are thus repeated in different tables (or sections of tables), are noted with unique indicators (unique numbers) for each instrument. Instruments with blank cells in the Rep column are presented only in this table.

*Instruments that are included in multiple sections (repeated [Rep]) are indicated by unique numbers.

†LCI-4 (the total instrument) has been reported to be both valid and reliable in studies generalizable to the Medicare population. LCI-4 Basic, LCI-5, and LCI1-4 were not evaluated among studies generalizable to the Medicare population.

‡PEQ MS 13/11 has been reported to be both valid and reliable in studies generalizable to the Medicare population. The overall PEQ scale and each of the items, except shower and bathe safely (version with seven categories, 1 to 7) were reported to have reliability but were not evaluated for test validity in a study generalizable to the Medicare population.

§Also see listings for LCI, which is included in the PPA, but is evaluated separately in this table.

Table B. Instruments with evidence of either validity or reliability generalizable to the Medicare population

	Rep*	Instrument	MCare	Validity	Reliability
Instruments With Evidence of Validity (Only) Generalizable to the Medicare Population		1 Leg Standing Balance	Gen	Valid	
		180 Degree Turn Test Specifically: Turn Time and Turn Steps components	Gen	Valid	
		AAS (Amputee Activity Survey)	Gen	Valid	
	4	BBS (Berg Balance Scale)†	Gen	Valid	
		FAC (Functional Ambulation Categories)	Gen	Valid	
	5	FAI (Frenchay Activities Index)†	Gen	Valid	
		FIM (Functional Independence Measure), total score	Gen	Valid	
		FSST (Four Square Step Test)	Gen	Valid	
		LEMOCOT (Lower-Extremity Motor Coordination Test)	Gen	Valid	
		OPCS (Office of Population Censuses and Surveys Scale)	Gen	Valid	
		PROS (Prosthetist's Perception of Client's Ambulatory Abilities)	Gen	Valid	
	6	SIGAM (Special Interest Group of Amputation Medicine)†	Gen	Valid	
	3	SF-12 and SF-36 (Short Form Health Surveys 12 and 36) Specifically: SF-12 total score and SF-36 PF (Physical Functioning subscale, PF 15 performed better than PF-10)	Gen	Valid	
Instruments with Evidence of Reliability (Only) Generalizable to the Medicare Population		OPUS (Office of Population Censuses and Surveys Scale) Specifically: subscales Quality of Life, Lower Limb Function, and Satisfaction	Gen		Reliable
	2	PEQ (Prosthetic Evaluation Questionnaire)‡ Specifically: the overall scale and each of the items, including PEQ-MS 13/7, except the items shower and bathe safely (version with 7 categories, 1 to 7)	Gen		Reliable
		PGI (Patient Generated Index)	Gen		Reliable
		PSFS (Patient-Specific Functional Scale)	Gen		Reliable
		SAT-PRO (Satisfaction with Prosthesis Questionnaire)	Gen		Reliable
	3	SF-36V (Short Form Health Survey 36 for use with veterans) Specifically: SF-36V subscales General Health, Physical Functioning, and Role Physical	Gen		Reliable
		Walking Speed, 10 meters	Gen		Reliable

Abbreviations: Gen = generalizable to the Medicare population, MCare = Medicare (generalizability), Rep = repeated (see note for explanation).

Note: Instruments are organized across Tables A to D by whether the studies that evaluated them were generalizable to the Medicare (MCare) population (indicated by "Gen" in the MCare column) and by whether there was evidence of both validity and reliability, validity only, reliability only, and evidence of lack of reliability (indicated by "No" in the Reliability column of the relevant tables). Across tables, blank cells in the Validity or Reliability columns indicate that there was not evidence to support validity or reliability (not that the studies were found to be not valid or not reliable). In the Rep column, instruments that had parts that were variably generalizable, validated, or found to be reliable, and are thus repeated in different tables (or sections of tables), are noted with unique indicators (unique numbers) for each instrument. Instruments with blank cells in the Rep column are presented only in this table.

*Instruments that are included in multiple sections (repeated [Rep]) are indicated by unique numbers.

†BBS, FAI, and SIGAM have evidence of validity among studies generalizable to the Medicare population, but evidence of both validity and reliability among studies *not* generalizable to the Medicare population.

‡PEQ MS 13/11 has been reported to be both valid and reliable in studies generalizable to the Medicare population. The overall PEQ scale and each of the items, except shower and bathe safely (version with seven categories, 1 to 7) were reported to have reliability but were not evaluated for test validity in a study generalizable to the Medicare population.

Table C. Instruments with evidence of both validity and reliability not generalizable to the Medicare population

Rep*	Instrument	MCare	Validity	Reliability
4	BBS (Berg Balance Scale)†	No	Valid	Reliable
5	FAI (Frenchay Activities Index)†	No	Valid	Reliable
	L Test (L Test of Functional Mobility)	No	Valid	Reliable
1	LCI (Locomotor Capabilities Index)‡ Specifically: LCI-4 Basic and Advanced (Basic and Advanced components, separately, with a 4-point ordinal scale), LCI-5 (LCI with a 5-point ordinal scale), and LCI10-4 (10-item scale which combined two of the response levels from LCI-5)	No	Valid	Reliable
7	Patient Activity Monitor Specifically: Walking Velocity	No	Valid	Reliable
2	PEQ (Prosthetic Evaluation Questionnaire) § Specifically: the Function subscale Residual limb health, the Mobility subscale Ambulation, the Psychosocial subscales Frustration and Social Burden, and the Global subscale Well-Being; and PEQ MS 12/5 (the Mobility Subscale with 12 items and 5 categories)	No	Valid	Reliable
	PFI (Physical Function Index) Including the overall instrument and the four subscales Squat to Pick Up Object, Walk at Steady Pace, Run at Steady Pace, and Climb Stairs	No	Valid	Reliable
8	PLUS-M (Prosthetic Limb Users Survey of Mobility) Specifically: the form version SF-12#	No	Valid	Reliable
9	PROMIS-29 (Patient-Reported Outcomes Measurement Information System 29-Item Profile) Specifically: the Physical Function subscale	No	Valid	Reliable
10	Q-TFA (Questionnaire for Persons with a Transfemoral Amputation) Specifically: the subscales Prosthetic Use, Prosthetic Mobility, and Problem	No	Valid	Reliable
6	SIGAM (Special Interest Group of Amputation Medicine)†	No	Valid	Reliable
	SIP-PD (Sickness Impact Profile-Physical Dimension) Including the overall instrument and the three subscales Ambulation, Body Care and Movement, and Mobility	No	Valid	Reliable
11	TAPES (Trinity Amputation and Prosthesis Experience Scales) All subscales of TAPES and TAPES-R except Weight Satisfaction (from the original TAPES) and Satisfaction with Prosthesis Subscale 1 (esthetics, from TAPES-R)	No	Valid	Reliable

Abbreviations: Gen = generalizable to the Medicare population, MCare = Medicare (generalizability), Rep = repeated (see note for explanation).

Note: Instruments are organized across Tables A to D by whether the studies that evaluated them were generalizable to the Medicare (MCare) population (indicated by "Gen" in the MCare column) and by whether there was evidence of both validity and reliability, validity only, reliability only, and evidence of lack of reliability (indicated by "No" in the Reliability column of the relevant tables). Across tables, blank cells in the Validity or Reliability columns indicate that there was not evidence to support validity or reliability (not that the studies were found to be not valid or not reliable). In the Rep column, instruments that had parts that were variably generalizable, validated, or found to be reliable, and are thus repeated in different tables (or sections of tables), are noted with unique indicators (unique numbers) for each instrument. Instruments with blank cells in the Rep column are presented only in this table.

*****Instruments that are included in multiple sections (repeated [Rep]) are indicated by unique numbers.

†BBS, FAI, and SIGAM have evidence of validity among studies generalizable to the Medicare population, but evidence of both validity and reliability among studies *not* generalizable to the Medicare population.

‡LCI-4 (the total instrument) has been reported to be both valid and reliable in studies generalizable to the Medicare population. LCI-4 Basic, LCI-5, and LCI1-4 were not evaluated among studies generalizable to the Medicare population.

§PEQ MS 13/11 has been reported to be both valid and reliable in studies generalizable to the Medicare population. The overall PEQ scale and each of the items, except shower and bathe safely (version with seven categories, 1 to 7) were reported to have reliability but were not evaluated for test validity in a study generalizable to the Medicare population.

#The form version SF-12 (not to be confused with the Short Form Health Survey SF-12) has evidence for both test validity and reliability.

Table D. Instruments with evidence of either validity or reliability not generalizable to the Medicare population

	Rep*	Instrument	MCare	Validity	Reliability
Instruments With Evidence of Validity (Only) Not Generalizable to the Medicare Population		AMPSIMM (Amputee Single Item Mobility Measure)	No	Valid	
		Employment Questionnaire	No	Valid	
		TWT (Timed Walking Test)	No	Valid	
		WHOQOL-BREF (World Health Organization Quality of Life-Brief Version) Specifically: the Physical Health, Psychological Health, Social Relations, and Environmental subscales	No	Valid	
Instruments With Evidence of Validity But Not Reliability Not Generalizable to the Medicare Population	7	Patient Activity Monitor Specifically: Step Count and Step Length	No	Valid	No
	10	Q-TFA (Questionnaire for Persons with a Transfemoral Amputation) Specifically: Global Health subscale	No	Valid	No
	11	TAPES (Trinity Amputation and Prosthesis Experience Scales) Specifically: the Satisfaction with Prosthesis Subscale 1 (esthetics) from TAPES R	No	Valid	No
Instruments With Evidence of Reliability (Only) Not Generalizable to the Medicare Population		ADAPT (Assessment of Daily Activity Performance in Transfemoral Amputees) Specifically: Items 10 to 18; items 1 to 9 were not evaluated	No		Reliable
		NQ-ACGC (Quality of Life in Neurological Conditions – Applied Cognition / General Concerns)	No		Reliable
	8	PLUS-M (Prosthetic Limb Users Survey of Mobility) Specifically: the form versions CAT (Computer Adaptive Test) and SF-7 (a short form version)	No		Reliable
	9	PROMIS-29 (Patient-Reported Outcomes Measurement Information System 29-Item Profile) Specifically: the Anxiety, Depression, Fatigue, Pain Intensity, Pain Interference, Physical Function, Sleep Disturbance, and Social Role Satisfaction subscales	No		Reliable

Abbreviations: Gen = generalizable to the Medicare population, MCare = Medicare (generalizability), Rep = repeated (see note for explanation).

Note: Instruments are organized across Tables A to D by whether the studies that evaluated them were generalizable to the Medicare (MCare) population (indicated by "Gen" in the MCare column) and by whether there was evidence of both validity and reliability, validity only, reliability only, and evidence of lack of reliability (indicated by "No" in the Reliability column of the relevant tables). Across tables, blank cells in the Validity or Reliability columns indicate that there was not evidence to support validity or reliability (not that the studies were found to be not valid or not reliable). In the Rep column, instruments that had parts that were variably generalizable, validated, or found to be reliable, and are thus repeated in different tables (or sections of tables), are noted with unique indicators (unique numbers) for each instrument. Instruments with blank cells in the Rep column are presented only in this table.

*Instruments that are included in multiple sections (repeated [Rep]) are indicated by unique numbers.

Key Question 4. LLP Comparative Effectiveness by Subgroup

It should be noted that this review makes no attempt to make conclusions about the overall effects of different LLP components or configurations. Key Question 4 addressed whether there is evidence regarding heterogeneity of treatment effects (whether outcomes with specific devices vary across individuals based on different characteristics such as age or health status) in the field of LLP research and whether studies used validated measures.

A relatively small percentage of comparative studies report sufficient data to allow subgroup analysis and evaluation of heterogeneity of treatment effect (14%, 15 of 104 otherwise eligible articles). These studies either address or provide sufficient data that allowed us to address the focused question of whether the relative effect of different components or configurations differs across different subgroups of lower limb amputees.

Twelve of the 14 studies included between 5 and 168 users of LLPs, one included 899 amputees, and one 1013. Seven studies evaluated microprocessor knees (compared to mechanical knees), two evaluated other knee components, three evaluated ankle/foot components, and one each evaluated pylons or sockets. One large study developed a regression model to evaluate the predictive ability of a wide range of participant characteristics. Another study (Hahn 2015) conducted correlation and regression analyses but did not fully report the results of these analyses. Overall, studies that investigated subgroup effects did not identify participant characteristics that predict which lower limb amputees would benefit most or least from any given component (low strength of evidence).

Of the 13 studies, only seven used validated predictor and outcome measures. Only one of the eligible studies was a randomized trial, but it evaluated atypical, nonvalidated predictor variables (subgroups of the Medicare Functional Classification Level K2). Only two studies explicitly evaluated heterogeneity of treatment effect; others 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 findings were not consistent across, and often within, studies. Only one study, which compared a specific microprocessor knee (Genium™) to any prior used knee (mostly another microprocessor knee, C-Leg™), analyzed the most important aspect of the KQ, namely whether any study participant characteristics (or set of characteristics) could accurately and effectively predict which patients would benefit most or least from a given component. However, there were methodological and analytic concerns with this study. Despite finding numerous statistically significant associations between participant characteristics and functional outcomes, the study concluded that no model accurately predicted relative effect (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 benefit most or least from a given LLP component or configuration. Based on the methodology used to assess strength of evidence, the studies warrant a low strength of evidence that patient characteristics evaluated in the studies do not predict which patients would benefit most or least from a given LLP component or configuration (Table E). Although one large study attempted to develop a model to predict success with microprocessor knees, the study did not use a validated outcome and had several methodological and analytic issues. It, therefore, provided insufficient additional evidence regarding who would be more likely or less likely to benefit from a microprocessor knee. An additional issue across almost all studies was that 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.

Key Question 5. Expectations of Ambulation

We found no study that addressed this key question.

Key Question 6. Patient Satisfaction With Process

Two studies addressed this Key Question. Note that this Key Question did not address satisfaction with the LLP itself. Studies addressing satisfaction with LLPs (or function with the prosthesis) would have been eligible for Key Question 4 if they reported subgroup analyses. One study surveyed individuals about satisfaction with upper or lower prosthetic limbs and related services. The second study, designed to assess the reliability and construct validity of the Orthotics and Prosthetics National Office Outcomes Tool in clients with LLPs, reported data about satisfaction with the prosthetist appointments.

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 an 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 F).

Table E. Key Question 4 evidence profile

Outcome	No. Studies (N)	Study Limitations	Consistency	Precision	Reporting Bias	Directness*	Other Issues	Findings	SoE Grade
Validated predictors and outcomes (univariable)	8 (1096, 1013 in 1 study)	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	Some trends of differences in relative effect based on participant characteristics, however, none statistically significant after correcting for multiple testing	Low
All outcomes (univariable)	13 (1328, 1013 in one study)	Medium†	Consistent	Imprecise	Undetected	Indirect‡	Nonvalidated outcomes, high degree of multiple testing; mostly K2 to K4 level, unilateral transfemoral amputations due to traumatic etiologies	Some trends of differences in relative effect based on participant characteristics, however, none statistically significant after correcting for multiple testing	Low
Ambulatory and functional outcomes, nonvalidated (multivariable model)	1 (899)	High§	NA	Precise	Undetected	Indirect#	K2 to K4 (mostly K3) level, mostly traumatic etiologies. Study does not directly address Key Question.	A large set of variables individually were associated with better outcomes with the microprocessor knee. No model predicted who would most benefit from knee.	Insufficient

Abbreviations: 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. 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.

Table F. 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. Long-Term Outcomes

We found eight studies with at least 100 participants who were followed for at least 6 months after prescription of an LLP. The studies analyzed data from 109 to 555 participants followed for 1 to 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. Studies did not explicitly account for intervening mortality or subsequent surgeries or injuries.

Table G summarizes the strength of evidence for each outcome and subgroup analysis with data. For all outcomes of interest, there is low or insufficient strength of evidence because evidence is sparse, most studies were conducted in the 1990s or earlier, and only one of the studies was conducted in the United States, with its unique healthcare system and standards for prosthesis prescription. Also, most studies had methodological limitations, most populations analyzed were not directly applicable to the Medicare population, and some study findings were inconsistent with each other. Subgroup analyses in single studies tended to be underpowered to detect differences, mostly leading to determinations that the evidence was insufficient.

We found a low strength of evidence, based on six studies, that about 11 to 22 percent of lower limb amputees who receive an 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. However, only one of the studies was conducted in the United States and it used hospital data as of 1998; most other studies were also old. 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.

Based primarily on two generally representative studies, there is low strength of evidence that 24 to 29 percent of LLP recipients use their prostheses only indoors at 1 year. 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 the rates of failure to maintain bipedal ambulation (1 study, 7% at 7 years), use of prostheses only for transfer (1 study, 4% at 1 year), and why people abandon their prostheses. No study reported on “major problems” with prostheses.

Table G. 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, old study	7% at 7 years	Insufficient
Use of prosthesis only for transfers	All participants	1 (196)	High	NA	Precise	Undetected	Indirect	Single 25 year old study	4% at 1 year	Insufficient
	TF vs. TT	1 (196)	High	NA	Precise	Undetected	Indirect	see above	No significant difference	Insufficient
	Age	1 (196)	High	NA	Precise	Undetected	Indirect	see above	Nonsignificantly higher limited used with older age	Insufficient
Use of prosthesis only indoors	All participants	4 (1040)	Medium	Inconsistent	Imprecise	Undetected	Direct	Mostly old, non-U.S.	24-29% at 1 year	Low
	TF vs. TT	2 (337)	High	Inconsistent	Precise	Undetected	Direct	see above	Twice as many TF use only indoors (1 study, P=0.008)), no difference (1 study)	Insufficient
	Age	1 (196)	High	NA	Precise	Undetected	Direct	see above	Older more likely to use only indoors (P=0.042)	Insufficient
	Bilateral vs. unilateral	1 (141)	High	NA	Precise	Undetected	Direct	see above	Bilateral more than twice as likely to use only indoors (P=0.0006)	Insufficient

Outcome	Subgroup	No. Studies (N)	Study Limitations	Consistency	Precision	Reporting Bias	Directness*	Other Issues	Findings	SoE Grade
Abandonment of prosthesis	All participants	6 (1153)	Medium	Consistent †	Precise	Undetected	Direct	Mostly old, non-U.S.	11-22% at 1 year (or undefined)†	Low
	TF vs. TT	3 (538)	High	Consistent	Precise	Undetected	Direct	see above	TF more likely to abandon prosthesis than TT	Low
	Bilateral vs. unilateral	3 (452)	High	Inconsistent	Precise	Undetected	Direct	see above	Nonsignificant, but conflicting directionality	Insufficient
	Age	2 (397)	High	Inconsistent	Precise	Undetected	Direct	see above	Older nonsignificantly more likely to abandon (1 study), no difference in age (1 study)	Insufficient
	Multiple	1 (201)	High	NA	Precise	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	Single non-U.S. study	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 LLP for people with major lower limb amputations. We found over 100 studies that compared at least two LLP components or configurations that reported ambulatory, functional, or other patient-centered outcomes. We found many additional studies that evaluated only biomechanical properties of the components (which this review does not evaluate) 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 us to evaluate) heterogeneity of treatment effect. Overall, the evidence is currently sparse and fails to adequately address whether different subgroups of amputees are more likely or less likely to benefit from specific LLP components or configurations. We also found generally sparse evidence regarding patient expectations, patient satisfaction with care, and long-term outcomes.

From the amputee's and the clinician's perspective, among the most important questions is which LLP configuration (comprised of which prosthetic components) would best enable maximal health, function, and quality of life for a given individual. Given the large number of component types (knee, foot/ankle, socket, liner, etc.) and the range of features for each of these, the process of determining which LLP component or configuration is best for individuals is quite complex. However, the majority of the evidence addresses the question of which LLP component or configuration maximizes ambulation and function in the average patient, as opposed to which LLP component or configuration would best suit the needs of a given individual. In other words, few studies address the issue of heterogeneity of treatment effect. 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 prosthesis, and unnecessarily increase health care expenditures.

We found evidence to enable the evaluation of the psychometric properties of 50 instruments (many containing evaluated subscales and items) in people with lower limb amputations. Many of the studies that evaluated instrument psychometric properties, however, were conducted in samples of participants who were arguably different than typical lower limb amputees with Medicare insurance, many of whom have 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 that 39 of the 50 instruments have been evaluated in studies deemed generalizable to the Medicare population. Seventeen of these instruments were found, as a whole or in part, to have evidence supporting both reliability and validity. However, we recommend that researchers who are using this report to determine which instruments to use for their own studies also review the primary studies to determine whether the instruments have been sufficiently validated for their needs, are responsive to clinically important change, and have been evaluated in a sample of people representative of their study population.

Notably, no study has evaluated psychometric properties of the Medicare Functional Classification Level (MFCL or K level) system. Furthermore, the reader is reminded that lack of evidence regarding the psychometric properties of instruments does not imply that these measures are not valid or reliable, only that they have not been (adequately) evaluated. Standards for psychometric testing have changed over the years, so older instruments, evaluated by earlier studies, may not have psychometric property evaluations more commonly reported now.

Nevertheless, we strongly encourage future researchers to maximize the use of instruments with evidence of validity and reliability in the population of interest. Where such measures are

lacking, the validity of the instruments being used as pivotal outcomes should be examined before use in future studies. We also encourage journal editors to require use of validated and reliable instruments when appropriate and feasible. However, we recognize that it will remain common that unvalidated measures may be appropriate in select instances (e.g., when measures to assess a particular trait or construct do not exist).

Evidence 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.

The applicability of these studies to the general population of people with LLPs may be somewhat limited, as the studies mostly evaluated prosthetic 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) device. 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. Studies evaluating heterogeneity of treatment effect also evaluated a limited set of patient characteristics such as age, amputation level, or amputation etiology. None analyzed differences in treatment effect by subgroups based on any assessment techniques, prediction tools, or outcome measures. Eligible studies reporting long-term LLP use after prescription were almost all conducted outside the United States and were mostly more than an decade old. Additional evidence limitations are discussed in the full report.

Analysis Limitations

Assessment of reliability, validity, and other psychometric properties is open to interpretation. By the strictest definition, an instrument 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 an instrument 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 an instrument has predictive validity regarding one outcome, such as future successful use of an 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 an instrument to have evidence of validity if there was evidence of any type of validity (other than face/content). We, thus, categorized the evidence and dichotomized data so that instruments were classified as valid or not. It is incumbent on each study's researchers to determine whether given instruments and measures have sufficient evidence of validity and are appropriate for their study purposes. Additional evidence limitations are discussed in the full report.

Future Research Recommendations

Future research is needed to adequately address most of the questions in this review. While numerous instruments have evidence of validity, at least in part, additional studies are needed to

confirm their psychometric properties and to better understand specific aspects of validity. Well-conducted studies, using validated predictors and outcomes, are needed to evaluate which devices would be most effective to achieve successful outcomes for which patients. 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 that incorporate the perspectives of patient and other key stakeholders (a core outcome set); in addition, studies may measure other specific outcomes, as needed. This would allow comparability across studies and pooling of study findings (e.g., meta-analysis). Creation of such a core outcome set would likely require a consensus development process among a range of stakeholders. More specific recommendations for studies of heterogeneity of treatment effect and studies on expectations, satisfaction with services, and long-term followup are provided in the full report.

Conclusions and Clinical Implications

Numerous instruments that assess ambulation, function, quality of life, and other patient-centered outcomes exist for people with lower limb amputations and LLPs. Researchers should minimize the use of nonvalidated or *ad hoc* measures. Those who wish to use new or previously unvalidated instruments should validate these measures before using them. Researchers with an interest in assessing LLPs for the Medicare population would be best served to focus on those instruments with evidence of reliability and validity for this population or validate the measures in this population. The majority of the evidence on LLPs addresses the question of which LLP component or configuration maximizes ambulation and function in the average patient, as opposed to which LLP would best suit the needs of a given individual. In other words, few studies address the issue of heterogeneity of treatment effect. A small evidence base does not provide data to guide LLP selection for a specific patient to maximize their ambulation, function, and quality of life or to minimize abandonment or limited use. However, this does not imply that the evidence suggests patient characteristics cannot effectively predict which patients would benefit most or least from one or another specific component; only that the current evidence does not support use of any given predictor. There is low strength of evidence that patients are generally satisfied with the prosthetic services they receive. Further high-quality research is needed to better assess the psychometric properties of instruments (whether assessment techniques, prediction tools, or outcome measures) and to answer the Key Questions addressed in this systematic review.

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Introduction

Background

An estimated 1.9 million people in the United States are living with limb loss, a number expected to double by 2050 mostly due to the rising prevalence of diabetes.[1, 2] However, fewer than half of amputees ever receive a prescription for a prosthetic device.[3, 4] Prescription rates are even lower among older amputees, African Americans, and Americans living in the southern United States[4] 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 prostheses, 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,[8] anxiety, and depression[9]) and higher mortality (estimated 5-year mortality rates for amputees range between 50[10] and 74 percent[11]; estimated 1-year mortality is 36% for amputees >65 years old[12]). However, in a study of Medicare beneficiaries, amputees who received an LLP were significantly more likely to remain in the home and less likely to have an emergency room admission.[13]

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.[2] Trauma accounts for about 17 percent of major lower limb amputation. Cancer is a relatively uncommon cause of lower limb amputation in adults (2%). However, individuals who lost their limb from etiologies other than dysvascular disease are disproportionately represented in the total limb loss community.[2] This is likely due to the relatively high mortality rate among those with dysvascular conditions. About two-thirds or all amputees are men; although among older adults (≥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.[14]

The current standard approach for matching patients to prostheses relies heavily on performance-based assessments, self-assessments, and, in some instances, wearable monitoring technologies that record patient activity;[5] although prosthetists and treating clinicians often rely on clinical judgment to match patients to prostheses. Insurance coverage policies often dictate which prostheses and components are selected for a given patient. Numerous instruments 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 outcome measurement tools (OMTs), assessment techniques, and prediction tools have been evaluated in the amputee population for the most frequently used instruments.[15] 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, ideally, to as great a degree as possible. Medicare covers custom fabricated LLPs in accordance with Local Coverage Determination (LCD): Lower Limb Prostheses (L33787).[16] 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. An 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 prosthesis components are limited to beneficiaries with a functional ability at or above a certain level.

As indicated by Medicare coverage guidance,[16] 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 potential value of certain componentry, and thus to match the most appropriate LLP to fit the beneficiary's clinical needs.

Table 1. Lower limb extremity prosthesis Medicare Functional Classification Levels (K levels)

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.

Note: Definitions per Centers for Medicare & Medicaid Services.[16]

In practice it is difficult for clinicians to determine the most appropriate component for a given patient (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.[17] This can occur if a person receives an LLP allowed for lower K levels when an LLP allowed only for higher K levels would enable better function, or if a person receives an 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 LLP components to patients pertain to the large heterogeneity in patient characteristics and attributes of the LLPs; the lack of data on patient characteristics and LLP attributes that 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 matching. 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.[8,16]

Objectives

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 the Centers for Medicare & Medicaid Services 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 all aspects of LLP evaluation. Specifically, it excludes from evaluation biomechanical and other nonpatient-centered intermediate outcomes. It also does not attempt to review all evidence comparing specific components. Instead, it largely focuses on those comparisons that provide assessment of heterogeneity of treatment effects (i.e., whether outcomes with specific devices vary across individuals based on different characteristics such as age or health status). The review also focuses on people who may be eligible for Medicare coverage, whether due to age or disability. Thus, we categorize studies based on their likely generalizability to amputees with Medicare. Based on discussions with our Technical Expert Panel, this includes studies with a mean age at least 65 years and those in which the percentage of participants with dysvascular disease (including diabetes) is broadly similar to the Medicare amputee population (i.e., at least 50%). Furthermore, the review excludes studies of exclusively military amputees with battle-related trauma (who are generally covered by Department of Defense and/or Veterans Health Administration insurance); however, we do include studies of veterans with multiple etiologies of amputation. Furthermore, the review excludes studies from low-income or low-resource settings not applicable to the United States.

Key Questions

Preliminary Key Questions (KQs) 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 KQs (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 KQs 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 an 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 ambulatory, functional, and patient-centered **outcomes** with **different prosthesis components vary** based on study **participant characteristics**?

Prosthesis components include:

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

Study participant characteristics of interest include:

- Medicare Functional Classification Level (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
- Periamputation 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 an 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 an 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)

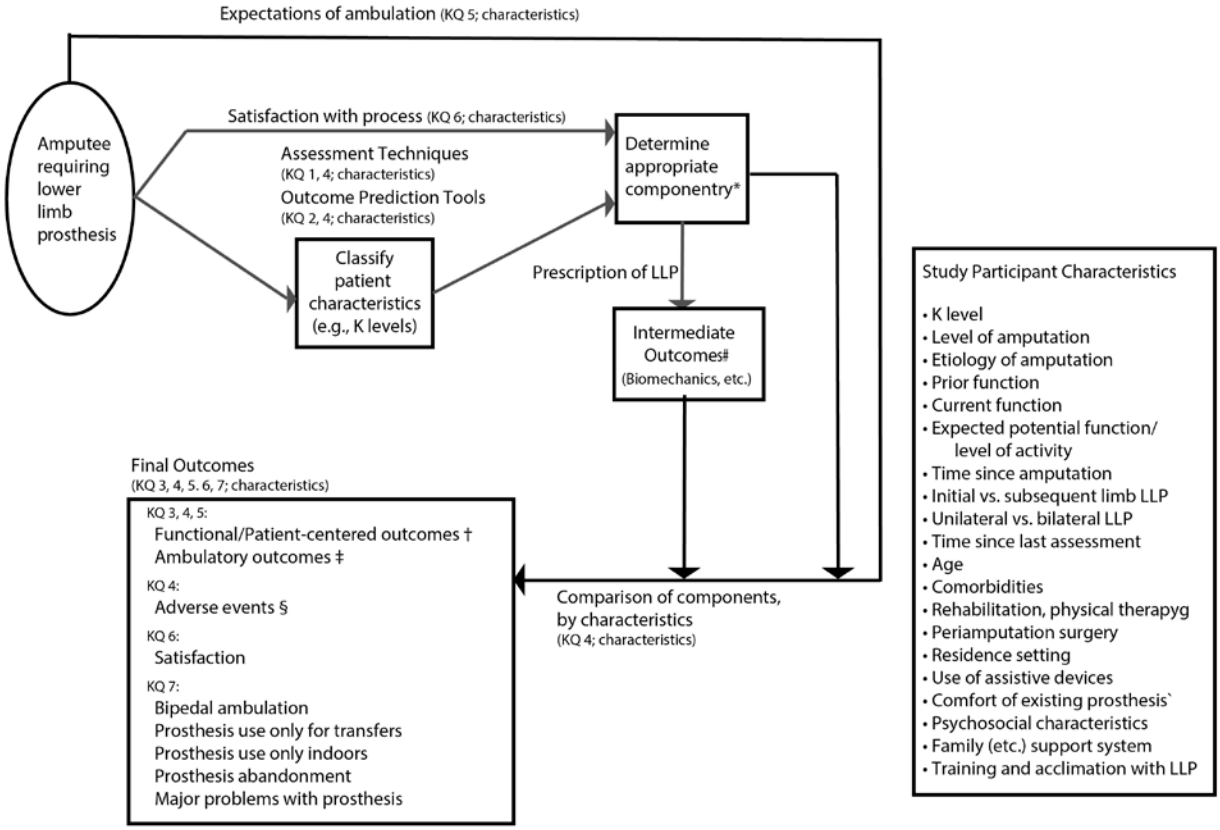
- Patient characteristics
  - Age
  - Level of amputation
  - Number of lower limbs amputated (unilateral vs. bilateral)
  - Prior level of function (prior to onset of extremity disability)
  - Current level of function
  - Etiology of amputation
  - Time since amputation
  - Comorbidities (e.g., diabetes, cardiovascular or peripheral vascular disease)
  - Operative treatment
  - Use of assistive device
  - Cosmesis of the prosthesis
  - Comfort of the prosthesis
  - Cognitive function
  - Other
- Prosthesis componentry

7b. What were the reasons for suboptimal use of the prosthesis 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



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.

#Biomechanical outcomes are not included among the outcomes of interest in this review.

Methods

The Brown Evidence-based Practice Center conducted 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.[6] The review was registered with PROSPERO (CRD42017058488).

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 October 30, 2017. 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 for additional primary studies. Peer and public review provided 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 clearly and explicitly includes *only* participants with battle-related trauma (this does not apply to studies of veterans with multiple amputation etiologies)
  - ***Exclude*** if study includes *only* congenital amputations
  - ***Exclude*** if study includes *only* children ≤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 the indirectness of the population.
  - ***Exclude*** if study conducted in low- or middle-income country, per the World Bank[18] (the interventions, management, and characteristics of people in low-income countries (such as Haiti) or middle-income countries (such as Cambodia or Iraq) are too different to be applicable to the U.S. population)

KQ 1-2:

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

Interventions or Predictors of Interest (and Instruments for KQ 1-3)

All KQ:

- Custom fabricated lower limb prosthesis
- Specific prosthesis components, 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 prostheses
  - ***Exclude*** immediate postoperative prostheses (used temporarily prior to definitive or replacement prostheses immediately after amputation surgery)
  - ***Exclude*** evaluation of orthotics and of implanted devices

KQ 1-3 Instruments:

- 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)
- Prediction 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:

- Report data to support assessments of reliability, validity, responsiveness, minimal detectable change, minimal important difference, or 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, which is not a functional or related outcome specific to a given LLP component or configuration
- 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 instruments (e.g., evaluation of the French translation of a scale designed in English).
- Any study design
- N≥20 lower limb amputees (an arbitrary threshold chosen to ensure a sufficient number of study participants for statistically meaningful correlation and comparison analyses within each study)
- 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
  - ≥6 month followup from time of LLP prescription, or
  - ≥1 year followup from time of amputation, if no data reported about time since LLP prescription

- Minimum sample size: N≥100 (smaller studies are numerous but lack precision)

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, instrument(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 instruments 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), instrument type (assessment techniques, prediction tools, and outcome measures), instrument name, instrument subscale/item as appropriate, instrument description or definition, evaluated property (validity, reliability, responsiveness, minimal detectable change, minimal important difference, and floor/ceiling effect), aspect of the instrument (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 instrument is being compared to), the metric used to assess the instrument (e.g., Spearman r or effect size), the value of the metric, and

the strength of the property (if relevant). There is no universal standard for how to evaluate and summarize psychometric properties; however, the measurement properties were scored based on overall results using methods adapted from others.[19-24] Based on criteria summarized in Table 2, we determined whether each aspect is supported within each study.

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

Validity addresses whether an instrument 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 instrument (e.g., that steps per day measures walking activity). Criterion validity addresses the extent to which an instrument 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 instruments hypothesized to be related are actually statistically related. Predictive validity refers to the comparison with a future outcome (e.g., current health status, physical function or ambulation, independent living, and future mortality). Divergent (or discriminant) validity tests whether instruments 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 an instrument measures 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 convergent, construct, structural, or predictive validity. For KQ 2 (prediction tools), if an instrument was evaluated for predictive validity, this instrument was included.

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

Minimal detectible 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 instruments being evaluated were assessment techniques, prediction tools, or outcome measures. Although conceptually these categories of instruments are distinct, in practice distinguishing which category a study and instrument belongs in is open to interpretation. To categorize outcomes, we used the following approach: For KQ 1 (assessment techniques), we included instruments 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 instruments for which predictive validity was assessed. For KQ 3 (outcome measures), we included other instruments, 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 psychometric properties

- Reliability
  - Internal consistency
    - Cronbach alpha
      - Excellent ≥0.80
      - Adequate 0.60-0.79
      - Poor ("not reliable") <0.60
    - Rasch analysis person-separation reliability index
      - Excellent ≥0.90
      - Good 0.80-0.89
  - Test-retest, interrater, intrarater
    - Intraclass correlation coefficient (ICC) for continuous data
    - Kappa for categorical data
      - Excellent ≥0.80
      - Good 0.60-0.79
      - Poor ("not reliable") <0.60
    - Require: Test-interval be defined, large enough, and well justified
    - Require: Defined training of testers and test administration
- Validity
  - (If an *a priori* hypothesis is reported, describe that and whether valid based on the hypothesis; otherwise use criteria below)
  - Content validity
    - Content of instrument 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
    - Not sufficient for "overall" validity
  - Criterion validity*
    - Criterion standard scores (for norm-based scores, cited age-matched normative values, etc.)
    - Well defined and justified criterion standard ("gold standard")
  - Convergent (concurrent) validity
    - Strength and direction of *a priori* correlation (r or r_s [standardized])
      - Large ≥0.5
      - Moderate 0.3-0.5
      - Small 0.1 to 0.29
    - Intraclass correlation coefficient for continuous data
      - Excellent ≥0.80
      - Good 0.60-0.79
      - Poor ("not reliable") <0.60
    - Statistical significant association of *a priori* hypothesis in regression analysis
      - Would be weak evidence, if only this analysis is reported
  - Divergent (discriminant) validity
    - Low correlation (<0.1) in testing different constructs
  - Predictive validity (only for Key Question 2)
    - Diagnostic test accuracy (e.g., sensitivity, specificity, area under the receiver operating characteristics curve)†
    - Correlation or regression strength with future outcome (with prosthesis)†
  - Construct validity
    - Differences between known groups hypothesized to be different in the key construct
    - Diagnostic test measures (e.g., compared to concurrent controls, nonamputees)
    - Factor analysis or principal component analysis
      - N ≥10 per item
      - Root mean square error of approximation ≤0.05-0.08
      - Standardized response means ≤0.08
      - Model fit measures ≥0.95
  - Structural validity (Rasch testing)
    - Evidence from factor analysis
    - Fit statistics are between 0.05 and 1.5 (i.e., items fit the model)
- Responsiveness
  - Whether responsiveness statistics have been reported
    - Effect size with pooled standard deviation
    - Effect size with baseline standard deviation
    - Standardized response mean

Guyatt responsiveness index Receiver operating characteristic curve
Minimal detectable change / Minimum (clinical) important difference Record values reported derived from Test-retest analyses 90% or 95% confidence interval
Floor/ceiling effect ≥15% of sample within the margin of error of the minimum or maximum value

*Criterion validity is largely theoretical for the instruments of interest since there are not "gold standards" to compare with.

†Correlations with future events is a weaker form of evidence for predictive validity than diagnostic test accuracy.

For KQs 4 and 7, data were extracted into the Systematic Review Data Repository (SRDR, https://srdr.ahrq.gov/projects/1091) 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.

Study Generalizability Categorization

For KQs 1-3, we categorized studies regarding their generalizability to the Medicare population. Studies *were not* excluded based on this categorization, but instead descriptions of each instrument's psychometric properties and summaries across instruments were categorized based on likely generalizability to the Medicare population. The two primary reasons people are eligible for Medicare are being at least 65 years of age or being certified to have a disability based on Medicare criteria. Lower limb amputation alone is an insufficient criterion to meet Medicare eligibility criteria. Based on the age criterion for Medicare coverage, we determined that studies with an average age of 65 years or higher (where at least half the study sample are likely to be over age 65 years) are generalizable to the Medicare population. Considering the age and disability requirements for eligibility, the most prevalent amputation etiology among Medicare recipients are dysvascular conditions. In discussion with Centers for Medicard & Medicaid Services representatives and our Technical Expert Panel we determined that an additional reasonable determinant for studies being generalizable to the Medicare population (when average age is less than 65 years) is whether at least half the sample are reported to have dysvascular conditions as their amputation etiology. We recognize that these criteria are arbitrary and imperfect, but they were necessary to allow us to categorize studies for the purposes of this review.

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[25, 26]—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. Specific and overall risk of bias assessments were made by at least two experience systematic reviewers and where there were discrepancies these were discussed and finalized by the team as a whole.

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.

For KQ 1 to 3, each instrument assessed by the eligible studies is described in terms of its validity, reliability, and other psychometric properties.

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 D 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 or configuration. Where $P\geq0.05$, 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. We did not attempt to further correct for analyses conducted but not reported by the study authors. 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 1 to 3, each instrument was categorized by whether relevant studies were generalizable to the Medicare population and then whether these studies provided evidence of test validity and reliability (within the generalizable or not categories). For each KQ, we created

and present lists of instruments with evidence for both validity and reliability, for validity only, for reliability only, and for "not reliability." We did not create lists of instruments that were evaluated for but did not display evidence of validity. Given that research in this area is continually advancing, it is likely that additional evidence on measurement properties of instruments will be generated. We did not weigh the strength of evidence or create a composite score comparing measures to identify the best measure.

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:

- studies found a statistically significant difference in the same direction, and/or
- 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 favoring one intervention 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 studies' effect sizes were between 0.80 and 1.25, 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.[27] 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. SoE determinations were made by at least two experience systematic reviewers and where there were discrepancies these were discussed and finalized by the team as a whole.

We did not grade the SoE for KQ 1 to 3 regarding instrument/measure psychometrics. The SoE rubric does not fit evaluation of whether studies have assessed validity, reliability, and related concepts. Instead, we categorized instruments by whether studies that assessed them were generalizable to the Medicare population and whether they provided evidence of test validity and reliability.

Peer Review

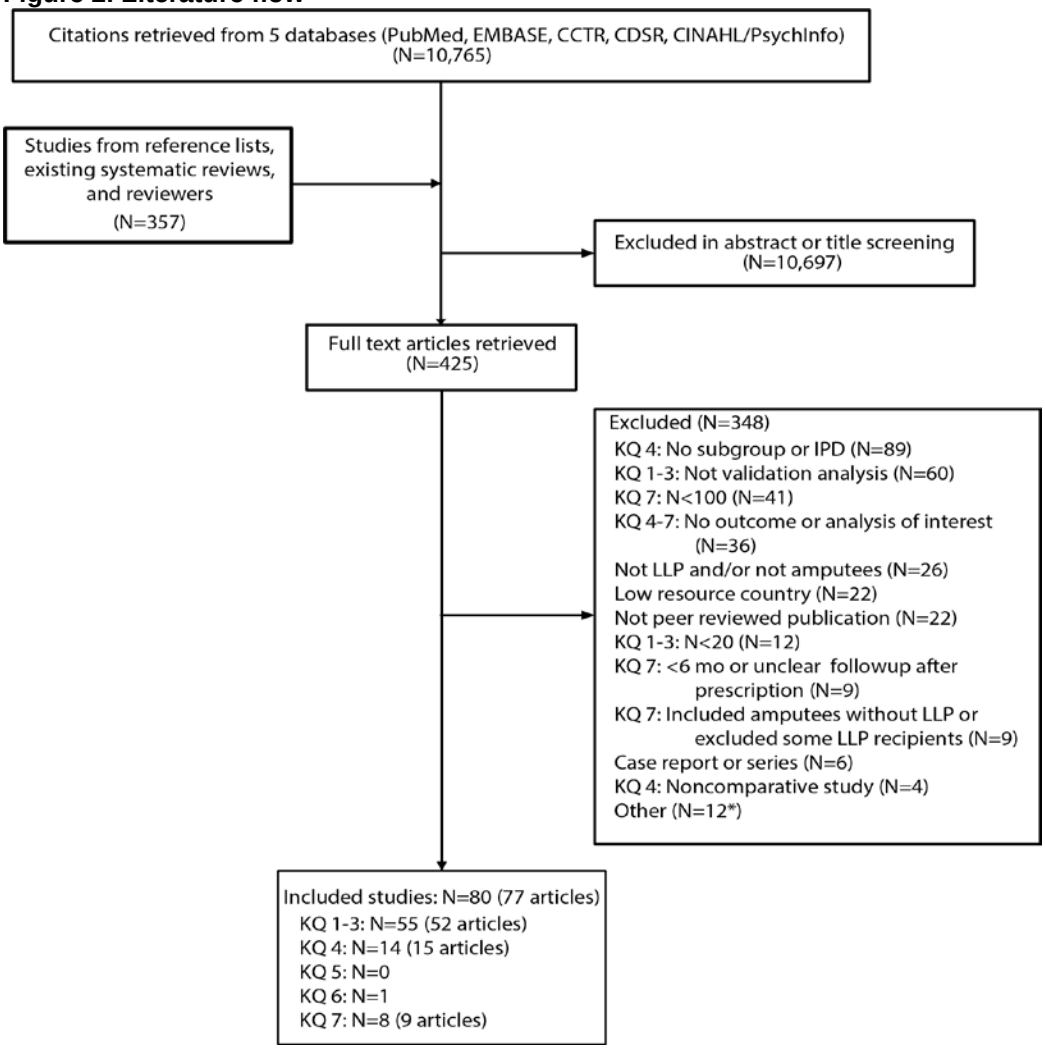
A draft version of this report was reviewed from October 24 to November 21, 2017 by invited and public reviewers. The reviewers were either directly invited by the Evidence-based Practice Center or they offered comments through a public review process. Extensive revisions of the draft were made based on their comments. The draft and final reports were 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 10,765 citations and an additional 357 references were screened from review articles, existing systematic reviews, and from reviewers of the draft report (Figure 2). Of these, 425 articles were retrieved in full text. We excluded 348 articles for the reasons listed in Figure 2 (see Appendix B). Of note, 89 studies compared lower limb prosthesis (LLP) components or configurations but did not report either subgroup analyses, regression analyses, or individual patient data which would allow subgroup analyses. Overall, we found 80 eligible studies (in 77 articles), of which 55 studies evaluated psychometric properties addressing Key Questions (KQ) 1 to 3, 14 studies provided data relevant to KQ 4, no studies for KQ 5, two studies for KQ 6, and eight studies relevant to KQ 7.

Figure 2. Literature flow



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

*Duplicate publication: N = 4; Not available: N=2; Pediatric population: N=2; Battle injuries only: N=1; Not primary study: N=1; Retracted publication: N=1; Unclear technology: N=1.

Key Questions 1 to 3. Assessment Techniques, Prediction Tools, Functional Outcome Measurement Tools

Studies provided evidence regarding psychometric properties of 50 instruments for people with lower limb amputations. In total, 55 studies in 52 articles met criteria to provide evidence regarding instrument psychometrics in people with lower limb amputations. The evidence is summarized for each instrument as listed below, followed by an overall summary across instruments. Following this, are summaries of the evidence pertaining to each specific Key Question (1 to 3). Upon review of the instruments, it became evident that determination of whether instruments should be classified as "assessment techniques" or "prediction tools" depended largely on our judgment. We also found that presentation of instruments first by Key Question (assessment techniques, prediction tools, functional outcome measurement tools) resulted in confusion and misleading duplication of findings in regards to the overall state of the evidence. Therefore, the entirety of evidence regarding all instruments is presented first, followed by descriptions of evidence pertaining to each Key Question.

The instruments evaluated are:

- 1 Leg Standing Balance
- 180 Degree Turn Test
- 2MWT (2 Minute Walk Test)
- 6MWT (6 Minute Walk Test)
- AAS (Amputee Activity Survey)
- ABC (Activities-specific Balance Confidence)
- ADAPT (Assessment of Daily Activity Performance in Transfemoral Amputees)
- AMP (Amputee Mobility Predictor with, AMPPRO, or without prosthesis, AMPnoPRO)
- AMPSIMM (Amputee Single Item Mobility Measure)
- Barthel Index
- BBS (Berg Balance Scale)
- Climbing Stairs Questionnaire
- Employment Questionnaire
- FAC (Functional Ambulation Categories)
- FAI (Frenchay Activities Index)
- FIM (Functional Independence Measure)
- FSST (Four Square Step Test)
- Functional Reach Test
- Houghton Scale
- L Test (L Test of Functional Mobility)
- LCI (Locomotor Capabilities Index)
- LEMOCOT (Lower-Extremity Motor Coordination Test)
- NQ-ACGC (Quality of Life in Neurological Conditions – Applied Cognition/General Concerns)
- OPCS (Office of Population Censuses and Surveys Scale)
- OPUS (Orthotics Prosthetics Users Survey)
- Patient Activity Monitor

- PEQ, PEQ-MS (Prosthetic Evaluation Questionnaire, Mobility Subscale)
- PFI (Physical Function Index)
- PGI (Patient Generated Index)
- PLUS-M (Prosthetic Limb Users Survey of Mobility)
- PPA (Prosthetic Profile of the Amputee)
- 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)
- Rising and Sitting Down Questionnaire
- RMI (Rivermead Mobility Index)
- SAT-PRO (Satisfaction with Prosthesis Questionnaire)
- SCS (Socket Comfort Score)
- SF-12/SF-36/SF-36V (Short Form Health Surveys 12, 36, and 36V)
- SIGAM (Special Interest Group of Amputation Medicine)
- Single beam test
- SIP-PD (Sickness Impact Profile-Physical Dimension)
- Tandem Test
- TAPES (Trinity Amputation and Prosthesis Experience Scales)
- TFP (Transfemoral Fitting Predictor)
- TUG (Timed Up and Go)
- TWT (Timed Walking Test)
- Walking Questionnaire
- WHOQOL-BREF (World Health Organization Quality-of-Life Scale – Brief Version)

1 Leg Standing Balance

The 1 Leg Standing Balance test measures the time the amputee can stay balanced on their unaffected leg. Studies used various names for the same test, including One-Leg Balance and just Balance Test. Three studies[28-30] reported on the psychometric properties of the 1 Leg Standing Balance test in 194 people, total, with lower limb amputations (see Tables 3 to 5). The studies were deemed to be generalizable to the Medicare population based either on the average age of study participants (75 years old in one study) or the high percentage of study participants with dysvascular disease (63% and 66% in the other studies) (Table 3).

Two studies provided information on predictive validity (Table 4). The 1 Leg Standing Balance test, as an initial assessment at the start of rehabilitation or prefitting, was correlated with the Barthel Index, 2MWT, TUG, and K level (the Medicare Functional Classification Level) at discharge from rehabilitation, but it did not predict admission to a skilled nursing facility. One study found that the test did not discriminate between people in different Houghton Scale categories. This latter study also found high floor (0 seconds: 34%) and ceiling (20 seconds: 42%) effects (Table 5).

Overall, for the 1 Leg Standing Balance test, there is evidence of predictive validity, but with a floor and ceiling effect (when conducted for 20 seconds). These findings are generalizable to the Medicare population.

180 Degree Turn Test

The 180 Degree Turn Test is a video evaluation of the 180 degree turn of the Timed Up and Go test, evaluating number of steps, time to complete, and turn steadiness. One study[7] evaluated the psychometric properties of the 180 Degree Turn Test in 40 people with lower limb amputations (see Tables 3 to 5). The study was deemed to be generalizable to the Medicare population based on the high percentage of study participants with dysvascular disease (65%); although the average age was under 65 years old.

Items of the 180 Degree Turn Test, specifically "Turn Time" and "Turn Steps" were predictive of the likelihood of falling at least twice over the following 6 months with 85 percent sensitivity and 78 percent specificity (Turn Time) and 100 percent sensitivity and 74 percent specificity (Turn Steps). "Turn Steadiness" had low sensitivity for two or more falls at 6 months (31%), but relatively high specificity (85%); overall the accuracy was not statistically significant (P=0.22).

Overall, for the 180 Degree Turn Test, there is evidence of predictive validity for the three items (or parts) turn time and turn steps (but no evidence to support validity of turn steadiness). These findings are generalizable to the Medicare population.

2MWT

The 2 Minute Walk Test measures the distance walked along a straight, uncarpeted hallway for a 2-minute time period. Nine studies[29, 31-38] evaluated the psychometric properties of the 2MWT in 814 people, total, with lower limb amputations (see Tables 3 to 5). Five of the studies were deemed to be generalizable to the Medicare population based on either average age greater than 65 years[32, 37] or at least have the study participants having dysvascular disease.[29, 31, 34]

Among studies generalizable to the Medicare population (with 481 participants), studies provided evidence that the 2MWT had convergent validity when compared with ABC, divergent validity when compared with the Houghton Scale, and predictive validity as an initial assessment to predict Houghton Scale at discharge from rehabilitation, 2MWT at 2 months, and SF-36 PF at 3 months. The test was also found to have reliability with no floor or ceiling effects. The minimal detectable change at 90% confidence—MDC(90)—was 34.3 meters.

Among the remaining studies (with 333 participants), there was evidence that the 2MWT had convergent validity when compared with several other tests and divergent validity based on contrasts by amputation level, age, time with prosthesis, and Houghton Scale.

Overall, for the 2MWT, there is evidence of test validity and reliability, without floor or ceiling effects. These findings are generalizable to the Medicare population.

6MWT

The 6 Minute Walk Test measures the distance walked along a straight, uncarpeted hallway for a 6-minute time period. Three studies[17, 36, 37] evaluated the psychometric properties of the 6MWT in 297 people, total, with lower limb amputations (see Tables 3 to 5). Two of the studies were deemed to be generalizable to the Medicare population based on average age greater than 65 years.[17, 37]

Among the two studies generalizable to the Medicare population (with 211 participants), studies provided evidence that the 6MWT has convergent validity when compared with the Amputee Mobility Predictor (AMP) with or without a prosthesis, divergent validity based on contrasts by K level, and reliability. The MDC(90) was 45 meters.

In the study not deemed generalizable to the Medicare population (with 86 participants), the 6MWT had convergent validity when compared with several other tests and divergent validity based on contrasts by amputation etiology, age, K level, and Houghton Scale.

Overall, for the 6MWT, there is evidence of test validity and reliability. These findings are generalizable to the Medicare population.

Table 3. Study descriptive data: 1 Leg Stand through 6MWT

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
1 Leg Standing Balance		Eijk 2012 21958418	48	75.2 (8.6)	46	nd	35	48	nd	nd
		Gremeaux 2012 22389424	64	58 (16)	66	25	27	73	100	0
		Spaan 2017 27770064	82	59.2 (13.3)	63	nd	nd	55	100	0
180 Degree Turn Test	Turn time Turn steps Turn steadiness	Dite 2007 17207685	40	61.7 (nd)	65	nd	0	100	100	0
2MWT		Brooks 2001 11588757	290	66.3 (13.1)	67	nd	21	62	82	18
		Brooks 2002 12422326	33	63.6 [42-80]	79	nd	0	100	100	0
		Gremeaux 2012 22389424	64	58 (16)	66	25	27	73	100	0
		Major 2013 23856150	30	54 (12)	23	47	50	53	90	10
		Miller 2003 12736877	50	58.0 (15.8)	58	nd	24	76	100	0
		Newton 2016 (Eur J Physiother)	37	57.6 (7.6)	nd	nd	24	76	100	0
		Reid 2015 25588644	86	60 (15.3)	35	48	15	73	97	3
		Resnik 2011 21310896	44	66 (13)	nd	nd	52	43	100	0
		Wong 2016 26874230	180	55.5 (16.0)	49	51	44	56	81	13
6MWT		Gailey 2002 11994800	167	68.3 (18.0)	46	37	40	49	100	0
		Reid 2015 25588644	86	60 (15.3)	35	48	15	73	97	3
		Resnik 2011 21310896	44	66 (13)	nd	nd	52	43	100	0

Abbreviations: 2MWT = 2 Minute Walk Test, 6MWT = 6 Minute Walk Test, Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), nd = no data/not reported, PMID = PubMed identifier (or journal), TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 4. Summary of instrument psychometric validity properties: 1 Leg Stand through 6MWT

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
1 Leg Standing Balance		Eijk 2012 21958418	Yes					Yes (BI at rehab discharge) No (SNF status at rehab discharge)
		Gremeaux 2012 22389424	Yes		No (Houghton)			
		Spaan 2017 27770064	Yes					Prefitting test Yes (2MWT, TUG, K level at end of rehab)
180 Degree Turn Test	Turn time	Dite 2007 17207685	Yes					Yes (falls at 6 mo)
	Turn steps							Yes (falls at 6 mo)
	Turn steadiness							No (falls at 6 mo)
2MWT		Brooks 2001 11588757	Yes					Initial fitting test Yes (2MWT at 2 mo, SF-36 PF at 3 mo, Houghton at hospital discharge)
		Brooks 2002 12422326	Yes					
		Gremeaux 2012 22389424	Yes		Yes (Houghton)			
		Major 2013 23856150	No	Yes (BBS)				
		Miller 2003 12736877	Yes	Yes (ABC)				
		Newton 2016 (Eur J Physiother)	No	No (TAPES)	Yes (TT vs. TF, age, time with prosthesis)			
		Reid 2015 25588644	No	Yes (6MWT)				
		Resnik 2011 21310896	Yes					

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
		Wong 2016 26874230	No	Yes (PEQ-MS, ABC, 3-BBS, TUG)	Yes (Houghton)			
6MWT		Gailey 2002 11994800	Yes	Yes (AMPnoPRO, AMPPRO)	Yes (K levels)			
		Reid 2015 25588644	No	Yes (2MWT, TUG, LCI-5, ABC)	Yes (Houghton, K levels, amputation etiology, age)			
		Resnik 2011 21310896	Yes					

Abbreviations: 2MWT = 2 Minute Walk Test, 6MWT = 6 Minute Walk Test, ABC = Activities-specific Balance Confidence scale, AMP(no)PRO = Amputee Mobility Predictor with (without) Prosthesis, BBS = Berg Balance Scale, BI = Barthel Index, K level = Medicare Functional Classification Level, LCI = Locomotor Capabilities Index, MC = Medicare, mo = months, PEQ-MS = Prosthesis Evaluation Questionnaire motor score, PMID = PubMed identifier (or journal), SF-36 PF = Short Form Health Survey 36 physical function subscale, SNF = skilled nursing facility, TAPES = Trinity Amputation and Prosthesis Experience Scales, TF = transfemoral amputation, TT = transtibial amputation, TUG = Timed Up and Go test.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 5. Summary of other instrument psychometric properties: 1 Leg Stand through 6MWT

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
1 Leg Standing Balance		Eijk 2012 21958418	Yes						
		Gremeaux 2012 22389424	Yes					34%	42%
		Spaan 2017 27770064	Yes						
180 Degree Turn Test		Dite 2007 17207685	Yes						
		Brooks 2001 11588757	Yes						
		Brooks 2002 12422326	Yes	Yes					
		Gremeaux 2012 22389424	Yes					0%	0%
		Major 2013 23856150	No						
		Miller 2003 12736877	Yes						
		Newton 2016 (Eur J Physiother)	No						
		Reid 2015 25588644	No						
		Resnik 2011 21310896	Yes	Yes	MDC(90) 34.3 m	.	.		
		Wong 2016 26874230	No						
6MWT		Gailey 2002 11994800	Yes						
		Reid 2015 25588644	No						
		Resnik 2011 21310896	Yes	Yes	MDC(90) 45 m				

Abbreviations: 2MWT = 2 Minute Walk Test, 6MWT = 6 Minute Walk Test, MC = Medicare, MDC(90) = minimal detectable change at 90% confidence, MID = minimum (clinical) important difference, PMID = PubMed identifier (or journal).

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

AAS

The Amputee Activity Survey is a 20-item questionnaire that allows amputee subjects to describe their average daily activity level. Two studies[17, 39] evaluated the psychometric properties of the AAS in 201 people, total, with lower limb amputations (see Tables 6 to 8). Both studies were deemed to be generalizable to the Medicare population based on average age greater than 65 years, and in one study all participants had dysvascular disease.

The studies provided evidence that AAS has convergent validity with AMPPRO and AMPnoPRO , correlates with duration of rehabilitation stay, and discriminates between people with different K levels.

Overall, for the AAS, there is evidence of test validity. This finding is generalizable to the Medicare population.

ABC

The Activities-specific Balance Confidence scale assesses self-reported balance confidence. Seven studies[33, 34, 36, 38, 40-42] evaluated the psychometric properties of ABC in 1194 people, total, with lower limb amputations (see Tables 6 to 8). However, only two studies,[34, 42] with 120 people, were deemed to be generalizable to the Medicare population based on average age greater than 65 years in one study and high percentage of people with dysvascular disease (58%, 62%) in both studies.

The studies found convergent validity with several other instruments, including the 2MWT, 6MWT, the BBS, PEQ-MS, and TUG. The instrument discriminated between several patient characteristics, including K level, amputation etiology, use of mobility device, walking distance, and automatic stepping, but not amputation level. One of the studies that is generalizable to the Medicare population[42] conducted a Rasch analysis resulting in a simplified 5-option response format. The analysis concluded that two items in the full ABC (Item 5: Reaching while standing on your tiptoes; Item 13: Walking in a crowd or getting bumped) should be removed or reworded. Studies also found evidence of reliability. Two studies,[38, 41] not generalizable to the Medicare population found no floor or ceiling effect.

Overall, for the ABC scale, there is evidence of test validity and reliability, from studies generalizable to the Medicare population. Other studies also found no floor or ceiling effect.

ADAPT

The Assessment of Daily Activity Performance in Transfemoral Amputees test measures the functional ability of transfemoral amputees in regard to daily activities. One study[43] evaluated ADAPT in 20 people, not generalizable to the Medicare population (see Tables 6 to 8).

Regarding psychometric properties, the study reported only reliability for half the study items (items 10 to 18); reliability was not assessed in the other items. In addition, no ceiling effect was found.

Overall, for the ADAPT test, there is evidence that it has, in part, reliability and no ceiling effect, from a study not generalizable to the Medicare population.

AMP

The Amputee Mobility Predictor measures functional capabilities of an amputee either with a prosthesis (AMPPRO) or without a prosthesis (AMPnoPRO).

Four studies[17, 30, 37, 40] evaluated the psychometric properties of AMP (see Tables 6 to 8).

AMPnoPRO

Two studies[17, 30] evaluated AMPnoPRO (without a prosthesis) in 249 people with lower limb amputations, both generalizable to the Medicare population based on their average age (68 years in one study) or with a high percentage of people with dysvascular disease (63%).

One study reported evidence of convergent validity between AMPnoPRO and both the 6MWT and AAS, and that AMPnoPRO discriminated between people based on their K levels. The other study reported that AMPnoPRO had predictive validity, when conducted prefitting as an initial assessment for the 2MWT, TUG, and K level at the end of rehabilitation. One study provided evidence of reliability.

AMPPRO

Three of the studies[17, 37, 40] evaluated AMPPRO (with a prosthesis) in 410 people, total, with lower limb amputations. Two of these studies[17, 37] were deemed generalizable to the Medicare population based on the average age of the included study participants (66 and 68 years).

As for AMPnoPRO, one study reported evidence of convergent validity between AMPnoPRO and both the 6MWT and AAS. AMPnoPRO also discriminated between people based on their K levels and was reported to have reliability.

Overall

Overall, for AMP—when used both with (AMPPRO) and without (AMPnoPRO) the patient's prosthesis—there is evidence of test validity and reliability, from studies generalizable to the Medicare population. In addition, AMPnoPRO, as an initial assessment tool, has been reported to have predictive validity, also in a population generalizable to the Medicare population.

AMPSIMM

The Amputee Single Item Mobility Measure is a single-item self-reported mobility measure wherein amputees select one statement about their level of mobility. One study[44] evaluated the psychometric properties of AMPSIMM in 113 people with lower limb amputations (see Tables 6 to 8). The study was deemed to *not* be generalizable to the Medicare population.

The study found convergent validity for AMPSIMM with LCI-5 and TAPES. It also found predictive validity for these same measures and both prosthesis use per day and satisfaction with mobility at 4 and 12 months followup. The study found evidence of responsiveness, with no floor or ceiling effect.

Overall, for AMPSIMM, there is evidence of test validity and responsiveness, without floor or ceiling effect. However, these findings are not generalizable to the Medicare population.

Table 6. Study descriptive data: AAS through AMPSIMM

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
AAS		Gailey 2002 11994800	167	68.3 (18.0)	46	37	40	49	100	0
		Panesar 2001 11330761	34	67 [44-85]	100	0	53	44	94	6
ABC		Hafner 2016 28273329	201	60.2 (11.4)	23	60	35	65	nd	nd
		Hafner 2017 27590443	199	55.4 (14.3)	44	41	18	76	100	0
		Major 2013 23856150	30	54 (12)	23	47	50	53	90	10
		Miller 2003 12736877	50	58.0 (15.8)	58	nd	24	76	100	0
		Reid 2015 25588644	86	60.0 (15.3)	35	48	15	73	97	3
	5-item	Sakakibara 2011 21704978	448	68.1 (10.3)	62	27	25	67	95	5
		Wong 2016 26874230	180	55.5 (16.0)	49	51	44	56	81	13
ADAPT		Theeven 2010 20809056	20	50.3 (10.7)	30	60	100	0	nd	nd
AMP	AMPnoPRO	Gailey 2002 11994800	167	68.3 (18.0)	46	37	40	49	100	0
		Spaan 2017 27770064	82	59.2 (13.3)	63	nd	nd	55	100	0
	AMPPRO	Gailey 2002 11994800	167	68.3 (18.0)	46	37	40	49	100	0
		Hafner 2017 27590443	199	55.4 (14.3)	44	41	18	76	100	0
		Resnik 2011 21310896	44	66 (13)	nd	nd	52	43	100	0
AMPSIMM		Norvell 2016 27496697	113	63.5 (8.1)	nd	nd	25	52	100	0

Abbreviations: AAS = Amputees Activity Survey, ABC = Activities-specific Balance Confidence, ADAPT = Assessment of Daily Activity Performance in Transfemoral amputees, AMP = Amputee Mobility Predictor, AMPnoPRO = Amputee Mobility Predictor without use of a prosthesis, AMPPRO = Amputee Mobility Predictor with use of a prosthesis, AMPSIMM = Amputee Single Item Mobility Measure, Dysvasc = dysvascular disease (including diabetes), nd = no data/not reported, PMID = PubMed identifier (or journal), TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 7. Summary of instrument psychometric validity properties: AAS through AMPSIMM

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
AAS		Gailey 2002 11994800	Yes	Yes (AMPnoPRO, AMPPRO)	Yes (K levels)			
		Panesar 2001 11330761	Yes			Yes (duration of rehab stay)		
ABC		Hafner 2016 28273329	No					
		Hafner 2017 27590443	No		Yes (K levels)			
		Major 2013 23856150	No	Yes (BBS)				
		Miller 2003 12736877	Yes	Yes (2MWT, TUG)	Yes (amputation etiology, use of mobility device, walking distance, automatic stepping), No (TT vs. TF)			
		Reid 2015 25588644	No	Yes (6MWT)				
	5-item	Sakakibara 2011 21704978	Yes				Rasch Exploratory factor analysis: items 5 and 13 problematic ‡	
		Wong 2016 26874230	No	Yes (PEQ-MS, 2MWT, 3-BBS, TUG)	Yes (Houghton)		.	
ADAPT		Theeven 2010 20809056	No					
AMP	AMPnoPRO	Gailey 2002 11994800	Yes	Yes (6MWT, AAS)	Yes (K levels)		.	
		Spaan 2017 27770064	Yes					Prefitting test Yes (2MWT, TUG, K level at end of rehab)

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
	AMPPRO	Gailey 2002 11994800	Yes	Yes (6MWT, AAS)	Yes (K levels)			
		Hafner 2017 27590443	No		Yes (K levels)			
		Resnik 2011 21310896	Yes					
AMPSIMM		Norvell 2016 27496697	No	Yes (LCI-5, TAPES)				Yes (prosthesis use per day, 4 & 12 mo; TAPES 4 & 12 mo; satisfaction with mobility 4 & 12 mo; LCI-5 4 mo)

Abbreviations: 2MWT = 2 Minute Walk Test, 6MWT = 6 Minute Walk Test, AAS = Amputees Activity Survey, ABC = Activities-specific Balance Confidence, ADAPT = Assessment of Daily Activity Performance in Transfemoral amputees, AMP = Amputee Mobility Predictor, AMPnoPRO = Amputee Mobility Predictor without use of a prosthesis, AMPPRO = Amputee Mobility Predictor with use of a prosthesis, AMPSIMM = Amputee Single Item Mobility Measure, BBS = Berg Balance Scale, Dysvasc = dysvascular disease (including diabetes), K level = Medicare Functional Classification Level, LCI = Locomotor Capabilities Index, MC = Medicare, mo = months, nd = no data/not reported, PEQ-MS = Prosthesis Evaluation Questionnaire – Mobility Subscale, PMID = PubMed identifier (or journal), TAPES = Trinity Amputation and Prosthesis Experience Scales, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, TUG = Timed Up and Go.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

‡Item 5: Reaching while standing on your tiptoes; Item 13: Walking in a crowd or getting bumped.

Table 8. Summary of other instrument psychometric properties: AAS through AMPSIMM

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
AAS		Gailey 2002 11994800	Yes						
		Panesar 2001 11330761	Yes						
ABC		Hafner 2016 28273329	No	Yes	MDC(90) 0.49 MDC(95) 0.58			0%	0%
		Hafner 2017 27590443	No						
		Major 2013 23856150	No						
		Miller 2003 12736877	Yes	Yes					
		Reid 2015 25588644	No						
	5-item	Sakakibara 2011 21704978	Yes	Yes					
		Wong 2016 26874230	No					"no floor effect"	"no ceiling effect"
ADAPT		Theeven 2010 20809056	No	Yes (items 10-18, items 1-9 nd)					"no ceiling effect"
AMP	AMPnoPRO	Gailey 2002 11994800	Yes	Yes					
		Spaan 2017 27770064	Yes						
	AMPPRO	Gailey 2002 11994800	Yes	Yes					
		Hafner 2017 27590443	No						
		Resnik 2011 21310896	Yes	Yes	MDC(90) 3.4	.	.	.	.
AMPSIMM	.	Norvell 2016 27496697	No				Yes (SMR "large effect")	2.2-6.5%	0-6.1%

Abbreviations: AAS = Amputees Activity Survey, ABC = Activities-specific Balance Confidence, ADAPT = Assessment of Daily Activity Performance in Transfemoral amputees, AMP = Amputee Mobility Predictor, AMPnoPRO = Amputee Mobility Predictor without use of a prosthesis, AMPPRO = Amputee Mobility Predictor with use of a prosthesis, AMPSIMM = Amputee Single Item Mobility Measure, MDC(90/95) = minimal detectable change at 90/95% confidence, MID = minimum (clinical) important difference, PMID = PubMed identifier (or journal), SMR = standardized mean response.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

Barthel Index

The Barthel Index measures independence in activities of daily living. One study[28] evaluated the psychometric properties of the Barthel Index in a relatively older sample of people with lower limb amputations (see Tables 9 to 11). Based on the study's average age (75 years), the study was deemed to be generalizable to the Medicare population.

The study found that the Barthel index as an assessment tool *did not* have predictive validity for discharge to a skilled nursing facility after rehabilitation. Other assessments of validity or other psychometric properties were not reported.

Overall, the evidence *does not* support validity of the Barthel Index for people with lower limb amputations in a study generalizable to the Medicare population. However, given that an instrument assessing independence in activities of daily living might not be expected to predict need for skilled nursing facility placement, it may be reasonable to conclude that the Barthel Index has not adequately had psychometric properties evaluated.

BBS

The Berg Balance Scale is a 14-item performance measure designed to assess balance. Three studies[29, 33, 38] evaluated the psychometric properties of BBS in 274 people, total, with lower limb amputations (see Tables 9 to 11). One of the studies[29] was deemed to be generalizable to the Medicare population based on a relatively high percentage of participants with dysvascular conditions (66%); the studies' average ages were all under 60 years.

The study generalizable to the Medicare population provided evidence of divergent validity based on the Houghton Scale. The other two studies, not generalizable to the Medicare population, reported convergent validity with the 2MWT, ABC, FAI, L Test, PEQ-MS, and TUG, and divergent validity to distinguish those with fear of falling, those who required daily use of a mobility aid, and the Houghton Scale; it did not distinguish by amputation level or etiology, or number of falls.

Overall, for BBS, there is evidence of test validity, including in a study generalizable to the Medicare population.

Climbing Stairs Questionnaire

The Climbing Stairs Questionnaire assesses perceived limitations in walking and climbing stairs among those with lower limb amputations who live at home. One study[45] evaluated the psychometric properties of this instrument in 172 people with lower limb amputations (see Tables 9 to 11). The study was deemed generalizable to the Medicare population based on the average age of the participants (65 years) and the relatively high percentage with dysvascular conditions (83%).

The study reported reliability of the measure as well as convergent validity with the LCI, the Rising and Sitting Down Questionnaire, and the Walking Questionnaire.

Overall, for the Climbing Stairs Questionnaire, there is evidence of test validity and reliability in a study generalizable to the Medicare population.

Employment Questionnaire

The Employment Questionnaire includes questions about employment status. One study[46] evaluated the psychometric properties of this instrument in 100 people with lower limb amputations (see Tables 9 to 11). The study was deemed not to be generalizable to the Medicare population based on a relatively low average age (47 years) and percentage with dysvascular conditions (47%).

The study reported convergent validity with the London Handicap Scale .

Overall, for the Employment Questionnaire, there is evidence of test validity, but in a population not generalizable to the Medicare population.

Table 9. Study descriptive data: Barthel Index through Employment Questionnaire

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
Barthel Index		Eijk 2012 21958418	48	75.2 (8.6)	46	nd	35	48	nd	nd
BBS		Gremeaux 2012 22389424	64	58 (16)	66	25	27	73	100	0
		Major 2013 23856150	30	54 (12)	23	47	50	53	90	10
		Wong 2016 26874230	180	55.5 (16.0)	49	51	44	56	81	13
Climbing Stairs Questionnaire		de Laat 2010 20801258	172	65 (11) [37-92]	83	8	32	54	93	7
Employment Questionnaire		Fisher 2003 12601268	100	47.4 (11.05)	24	64	43	50	100	0

Abbreviations: BBS = Berg Balance Scale, Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), nd = no data/not reported, PMID = PubMed identifier (or journal), TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 10. Summary of instrument psychometric validity properties: Barthel Index through Employment Questionnaire

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
Barthel Index		Eijk 2012 21958418	Yes					No (SNF status at rehab discharge)
BBS		Gremeaux 2012 22389424	Yes		Yes (Houghton)			
		Major 2013 23856150	No	Yes (ABC, PEQ-MS, FAI, 2MWT, L Test)	Yes (fear of falling, daily use of mobility aid), No (amputation level, amputation etiology, number of falls)			
		Wong 2016 26874230	No	Yes (PEQ-MS, ABC, 2MWT, TUG)	Yes (Houghton)			
Climbing Stairs Questionnaire		de Laat 2010 20801258	Yes	Yes (LCI, RSQ, WQ)				
Employment Questionnaire		Fisher 2003 12601268	No	Yes (LHS)				

Abbreviations: 2MWT = 2 Minute Walk Test, ABC = Activities-specific Balance Confidence scale, BBS = Berg Balance Scale, FAI = Frenchay Activities Index, LCI = Locomotor Capabilities Index, LHS = London Handicap Scale, L Test = L Test of Functional Mobility, MC = Medicare, PEQ-MS = Prosthesis Evaluation Questionnaire – Mobility Subscale, PMID = PubMed identifier (or journal), RSQ = Rising and Sitting Down Questionnaire, SNF = skilled nursing facility, TUG = Timed Up and Go, WQ = Walking Questionnaire.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 11. Summary of other instrument psychometric properties: Barthel Index through Employment Questionnaire

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
Barthel Index		Eijk 2012 21958418	Yes						
BBS		Gremeaux 2012 22389424	Yes					0%	0%
		Major 2013 23856150	No	Yes				0%	10%
		Wong 2016 26874230	No					"no floor effect"	"no ceiling effect"
Climbing Stairs Questionnaire		de Laat 2010 20801258	Yes	Yes					
Employment Questionnaire		Fisher 2003 12601268	No						

Abbreviations: BBS = Berg Balance Scale, MC = Medicare, MDC = minimal detectable change, MID = minimum (clinical) important difference, PMID = PubMed identifier (or journal).

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

FAC

The Functional Ambulation Categories instrument measures independence of gait from total dependency to independent walking on all surfaces. One study[28] evaluated the psychometric properties of FAC in 48 people with lower limb amputations (see Tables12 to 14). The study was deemed to be generalizable to the Medicare population based on the average age of study participants (75 years); although fewer than half had dysvascular etiologies for their amputations.

The study provided information on predictive validity. The FAC, as an initial assessment at the start of rehabilitation was correlated with the Barthel index at discharge from rehabilitation, but it did not predict admission to a skilled nursing facility.

Overall, for FAC, a study generalizable to the Medicare population provided evidence of predictive validity for future Barthel index, but not for admission to a skilled nursing facility.

FAI

The Frenchay Activities Index measures instrumental activities of daily living in patients recovering from stroke. Three studies[28, 33, 47] evaluated the psychometric properties of FAI in 162 people, total, with lower limb amputations (see Tables 12 to 14). One of the studies was deemed to be generalizable to the Medicare population based on the average age of the study participants (75 years); the other two studies included people of lower average age (54 and 57 years), but in all studies, fewer than half the participants had dysvascular conditions.

The study generalizable to the Medicare population provided information on predictive validity. The FAI as an initial assessment at the start of rehabilitation was correlated with the Barthel index at discharge from rehabilitation.

Among the other studies, there was evidence that FAI had convergent validity when compared with a number of other instruments including BBS, 2MWT, TUG, PEQ-MS, and ABC. One of the studies deemed to be not generalizable to the Medicare population provided information that FAI was reliable.

Overall, for FAI, there is evidence of test validity, including predictive validity for future Barthel index but not admission to a skilled nursing facility in a study generalizable to the Medicare population. There is also evidence of test reliability.

FIM

The Functional Independence Measure determines the level of disability of patients, as reflected by their need for assistance and/or aids during activities of daily living. Four studies[39, 48, 49] evaluated the psychometric properties of FIM in 224 people, total, with lower limb amputations (see Tables 12 to 14). While the instrument has subscales for motor and cognitive domains, it was evaluated as a total score and for the items Chair Transfer, Walk on Level Surface, and Climb Stairs. One of the studies was deemed to be generalizable to the Medicare population based on both the average age of the study participants (67 years) and the proportion of participants with dysvascular conditions (100); two studies included people of lower average age (35 and 51 years) and fewer than half had dysvascular conditions; and one study did not report age and proportion of participants with dysvascular conditions.

The study deemed to be generalizable to the Medicare population provided information on construct validity of FIM. The FIM total score as an initial assessment at the start of rehabilitation was correlated with the duration of stay. Among the other studies, one study

showed provided information on construct validity. Neither the individual items nor FIM overall were correlated with walking speed or return to usual activity. Two studies provided information on divergent validity. FIM score did not differ notably by amputation level, injury severity score, age, and comorbidities. FIM score did not differ by Houghton Scale categories. FIM as an initial assessment at the start of rehabilitation was found to *not* have predictive validity for a future Houghton Scale, but FIM at discharge from rehabilitation did have predictive validity for the Houghton Scale 3 to 12 months later.

One of the studies deemed to be not generalizable to the Medicare population provided information that the overall score and the three examined items were reliable. The same study also provided information that FIM, overall, was responsive to walking speed but not return to usual activity. Two of the items, Chair Transfer and Climb Stairs were also responsive to walking speed but not return to usual activity. The item Walk on Level Surface, however, was responsive to neither. The same study also provided information about floor and ceiling effects of FIM and the items. There was no evidence for a floor effect, but there was a ceiling effect (53%) for the Chair Transfer item.

Overall, for FIM, there is evidence of test validity in studies both generalizable and not generalizable to the Medicare population; although, one study evaluated the individual items but did not find evidence of their validity. In studies not generalizable to the Medicare population, there is evidence of predictive validity for FIM assessed at discharge from, but not for FIM assessed at initiation of, rehabilitation; there is also evidence of test reliability (both overall and for the evaluated items) and responsiveness of FIM. The Chair Transfer item was also found to have a ceiling effect.

FSST

The Four Square Step Test measures dynamic balance through assessment of the patient's ability to step over objects forward, sideways, and backwards. One study[7] evaluated the psychometric properties of FSST in 40 people with lower limb amputations (see Tables 12 to 141). The study was deemed to be generalizable to the Medicare population based on the proportion of study participants with dysvascular etiologies for their amputations (65%); participants' average age was 62 years.

The study provided information on predictive validity. The FSST at discharge from rehabilitation was predictive of two or more falls at 6 months after discharge (sensitivity 92% and specificity 93%).

Overall, for FSST, there is evidence of predictive validity in a study generalizable to the Medicare population.

Functional Reach Test

The Functional Reach Test assesses a patient's stability by measuring the maximum distance the patient reaches forward while standing in a fixed position. One study[29] evaluated the psychometric properties of the Functional Reach Test in 64 people with lower limb amputations (see Tables 12 to 14). The study was deemed to be generalizable to the Medicare population based on the proportion of study participants with dysvascular etiologies for their amputations (66%); participants' average age was 64 years. The study provided evidence of divergent validity for The Functional Reach Test to discriminate people based on the Houghton Scale.

Overall, for the Functional reach test, there is evidence of test validity from a study generalizable to the Medicare population.

Table 12. Study descriptive data: FAC through Functional Reach Test

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
FAC		Eijk 2012 21958418	48	75.2 (8.6)	46	nd	35	48	nd	nd
FAI		Eijk 2012 21958418	48	75.2 (8.6)	46	nd	35	48	nd	nd
		Major 2013 23856150	30	54 (12)	23	47	50	53	90	10
		Miller 2004 15180125	84	56.5 (13.0)	40	60	29	71	100	0
FIM		Franchignoni 2004 15129398	50	51 (nd [21-86]	32	58	60	40	100	0
		Leung 1996 8831480	33	nd	nd	nd	24	73	97	3
		Panesar 2001 11330761	34	67 [44-85]	100	0	53	44	94	6
	Chair transfer Walk on level surface Climb stairs Total (Overall)	Cyril 2001 (Johns Hopkins)	107	35 (12.5)	0	100	21	67	100	0
FSST		Dite 2007 17207685	40	61.7 (nd)	65	nd	0	100	100	0
Functional Reach Test		Gremeaux 2012 22389424	64	58 (16)	66	25	27	73	100	0

Abbreviations: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), FAC = Functional Ambulation Categories, FAI = Frenchay Activities Index, FIM = Functional Independence Measure, FSST = Four Square Step Test, nd = no data/not reported, PMID = PubMed identifier (or journal), TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 13. Summary of instrument psychometric validity properties: FAC through Functional Reach Test

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
FAC		Eijk 2012 21958418	Yes	.	.	.	.	Yes (BI at rehab discharge) No (SNF status at rehab discharge)
FAI		Eijk 2012 21958418	Yes	.	.	.	.	Yes (BI at rehab discharge) No (SNF status at rehab discharge)
		Major 2013 23856150	No	Yes (BBS)	.	.	.	.
		Miller 2004 15180125	No	Yes (2MWT, TUG, PEQ-MS, ABC)	Yes (amputation etiology, use of mobility device, age, years as amputee), No (TT vs. TF)	.	.	.
FIM		Franchignoni 2004 15129398	No	Yes (LCI, LCI-5, RMI)		.	.	.
		Leung 1996 8831480	No	.	Mixed (Houghton)	.	.	Mixed: Discharge FIM Yes (Houghton ≥9 at 3-12 mo), Admission FIM No (Houghton ≥9 at 3-12 mo)
		Panesar 2001 11330761	Yes	.	.	Yes (duration of stay)	.	.
		Cyril 2001 (Johns Hopkins)	No	.	No (amputation level, injury severity score, age, comorbidities)	No (walking speed, return to usual activity)	.	.

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
	Chair transfer	Cyril 2001 (Johns Hopkins)	No	.	No (same)	No (same)	.	.
	Walk on level surface		No	.	No (same)	No (same)	.	.
	Climb stairs		No	.	No (same)	No (same)	.	.
FSST		Dite 2007 17207685	Yes	.	.	.	.	Yes (falls at 6 mo)
Functional Reach Test		Gremeaux 2012 22389424	Yes	.	Yes (Houghton)	.	.	.

Abbreviations: 2MWT = 2 Minute Walk Test, ABC = Activities-specific Balance scale, BBS = Berg Balance Scale, BI = Barthel Index, Dysvasc = dysvascular disease (including diabetes), FAC = Functional Ambulation Categories, FAI = Frenchay Activities Index, FIM = Functional Independence Measure, FSST = Four Square Step Test, LCI = Locomotor Capabilities Index, MC = Medicare, mo = months, nd = no data/not reported, PEQ-MS = Prosthesis Evaluation Questionnaire motor score, PMID = PubMed identifier (or journal), RMI = Rivermead Mobility Index, SNF = skilled nursing facility, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, TUG = Timed Up and Go.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells (in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 14. Summary of instrument psychometric validity properties: FAC through Functional Reach Test

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
FAC		Eijk 2012 21958418	Yes						
FAI		Eijk 2012 21958418	Yes						
		Major 2013 23856150	No						
		Miller 2004 15180125	No	Yes					
FIM		Franchignoni 2004 15129398	No						
		Leung 1996 8831480	No						
		Panesar 2001 11330761	Yes						
		Cyril 2001 (Johns Hopkins)	No	Yes			Yes (walking speed), No (return to usual activity)	0%	0%
	Chair transfer	Cyril 2001 (Johns Hopkins)	No	Yes			Yes (walking speed), No (return to usual activity)	1.0%	53.3%
	Walk on level surface		No	Yes			No (walking speed, return to usual activity)	2.0%	0%
	Climb stairs		No	Yes			Yes (walking speed), No (return to usual activity)	4.7%	0%
FSST		Dite 2007 17207685	Yes						
Functional Reach Test		Gremeaux 2012 22389424	Yes					1.5%	3%

Abbreviations: FAC = Functional Ambulation Categories, FAI = Frenchay Activities Index, FIM = Functional Independence Measure, FSST = Four Square Step Test, MDC = minimal detectable change, MID = minimum (clinical) important difference, nd = no data/not reported, PMID = PubMed identifier (or journal).

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells n the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare (MC) population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

Houghton Scale

The Houghton Scale reflects a patient's perception of prosthesis use, including items for wearing and using prostheses, and stability walking in different settings. Eight studies (in seven articles)[29, 32, 36, 38, 50, 51] evaluated the psychometric properties of the Houghton Scale in 836 people, total, with lower limb amputations (see Tables 15 to 17). Six of the studies were deemed to be generalizable to the Medicare population, of which two studies were generalizable based on both the average age of the study participants (66 years) and the percentage of participants with dysvascular conditions (53% to 66%). The other two studies included people of lower average age and fewer than half with dysvascular conditions.

Among the studies deemed to be generalizable to the Medicare population, there was evidence that the Houghton Scale had convergent validity when compared with a number of other instruments including SF-36 PCS, 2MWT, TUG, PEQ-MS, ABC, and PPA-LCI. One of these studies also provided evidence of mixed divergent validity of a combined subset of items 1 to 3 in the Scale regarding wearing and using the prosthesis. When assessed at discharge from rehabilitation, The Houghton Scale successfully discriminated participants by their amputation level; however, when assessed at 3 month followup, it did not do so, nor did it discriminate between unilateral vs. bilateral amputation or by age at either time point.

Two of the studies deemed to be generalizable to the Medicare population provided information on reliability of the Houghton Scale. The Houghton Scale was found to be reliable overall and for items 1-3. The Houghton Scale was also reported to be responsive to change. One study reported floor and ceiling effects of the Houghton Scale and its items when measured both at discharge from rehabilitation and at 3 month followup. No floor or ceiling effect was found for the overall Scale, but each of the items had either a floor or ceiling effect at one or both time points. Three other studies also did not find floor or ceiling effects for the overall score, but one other study did find a ceiling effect of the overall Scale (in a French language version).

Overall, for the Houghton Scale, among studies generalizable to the Medicare population (and other studies), there is evidence of test validity, reliability, and responsiveness. Studies mostly found no floor or ceiling effect for the overall Scale. One study reported test validity and reliability for a subset of items related to prosthesis use, but floor or ceiling effects for individual items.

L Test

The L Test of Functional Mobility is a modified version of the TUG Test that incorporates two transfers and four turns, of which at least one would be to the opposite side. Three studies[33, 52, 53] evaluated the psychometric properties of the L Test in 156 people, total, with lower limb amputations (see Tables 15 to 17). One of the studies was deemed to be generalizable to the Medicare population based on the proportion of participants with dysvascular conditions (58%); the other two studies included a lower proportion of participants with dysvascular conditions (23% and 40%) and people of lower average age.

The studies not generalizable to the Medicare population reported evidence of convergent validity with BBS, TUG, 2MWT, 10 meter Walk Test, ABC, FAI, and PEQ-MS. Also, one of these studies reported that the L Test was able to discriminate between patients by amputation level, amputation cause, walking aid use, autowalk ("not having to consciously think about each step"), and age.

One of the studies deemed to be not generalizable to the Medicare population reported evidence that the L Test was reliable, had an MDC of 6.2 sec and an MIC of 4.5 sec. Thestudy that was generalizable to the Medicare population reported only that the L test was not responsive to Global Rating of Change scores.

Overall, for the L Test, there is evidence of test validity and reliability in studies not generalizable to the Medicare population, but the one study that was generalizable to the Medicare population suggests that it may lack responsiveness to change.

Table 15. Study descriptive data: Houghton Scale through L Test

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
Houghton		Brooks 2001 11588757	56	66.3 (13.1)	66	nd	21	63	82	18
		Devlin 2004 15295762 - Sample 1	49	60.9 (16.8)	53	nd	20	84	88	8
		Gremeaux 2012 22389424	64	58 (16)	66	25	27	73	100	0
		Miller 2001 11588750 (sample 1)	60	58.4 (15.5)	53	nd	28	72	100	0
		Miller 2001 11588750 (sample 2)	329	59.9 (16.7)	53	nd	26	74	100	0
		Reid 2015 25588644	86	60 (15.3)	35	48	15	73	97	3
		Wong 2016 26874230	180	55.5 (16.0)	49	51	44	56	81	13
	Total (overall) Wear prosthesis (item 1) Use prosthesis to walk (item 2) Flat surface walking stability (item 4a) Slope walking stability (item 4b) Rough ground stability (item 4c) Walking stability (item 4 total) Items 1-3	Devlin 2004 15295762 - Sample 2	76	65.5 (13.6)	82	nd	11	59	36	61
L Test		Major 2013 23856150	30	54 (12)	23	47	50	53	90	10
		Rushton 2015 25134533	33	60.0 (13.0)	58	nd	18	82	100	0
		Deathe 2005 15982169	93	55.9 (14.2)	40	60	26	74	100	0

Abbreviations: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), L Test = L Test of Functional Mobility, nd = no data/not reported, PMID = PubMed identifier (or journal), TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 16. Summary of instrument psychometric validity properties: Houghton Scale through L Test

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
Houghton		Brooks 2001 11588757	Yes					
		Devlin 2004 15295762 - Sample 1	Yes					
		Devlin 2004 15295762 - Sample 2	Yes	Yes (SF-36 PCS, 2MWT)	Mixed (TT vs. TF) ‡, No (uni vs. bi, age)			
		Gremeaux 2012 22389424	Yes					
		Miller 2001 11588750 (sample 1)	Yes	Yes (2MWT, TUG, ABC, PPA-LCI, PEQ-MS)				
		Miller 2001 11588750 (sample 2)	Yes	Yes (ABC, PPA-LCI, PEQ-MS)				
		Reid 2015 25588644	No	Yes (6MWT)				
		Wong 2016 26874230	No	Yes (2MWT, PEQ-MS, ABC, 3-BBS, 2MWT)				

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
	Wear prosthesis (item 1) Use prosthesis to walk (item 2) Use prosthesis outdoors (item 3) Flat surface walking stability (item 4a) Slope walking stability (item 4b) Rough ground stability (item 4c) Walking stability (item 4 total)	Devlin 2004 15295762 - Sample 2	Yes	.				
	Items 1-3		Yes	Yes (SF-36 PCS, MCS, 2MWT)	Mixed (TT vs. TF) ‡, No (uni vs. bi, age)			
L Test		Major 2013 23856150	No	Yes (BBS)				
		Rushton 2015 25134533	Yes					
		Deathe 2005 15982169	No	Yes (TUG, 2MWT, 10MWT, ABC, FAI, PEQ-MS)	Yes (amputation level, amputation cause, walking aid use, autowalk, age)			

Abbreviations: 10MWT = 10 meter walk test, 2MWT = 2 minute walk test, 6MWT = 6 minute walk test, ABC = Activities-specific Balance scale, BBS = Berg Balance Scale, Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), FAI = Frenchay Activities Index, L Test = L Test of Functional Mobility, MC = Medicare, MCS = Mental Component Score, nd = no data/not reported, PCS = Physical Component Score, PEQ-MS = Prosthesis Evaluation Questionnaire motor score, PMID = PubMed identifier (or journal), PPA-LCI = Prosthetic Profile of the Amputee – Locomotor Capabilities Index, SF-36 = Short Form Health Survey-36, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, TUG = Timed Up and Go, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

‡Discriminated when assessed at rehabilitation discharge, but not when assessed at 3 month followup.

Table 17. Summary of instrument psychometric validity properties: Houghton Scale through L Test

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
Houghton		Brooks 2001 11588757	Yes						
		Devlin 2004 15295762 - Sample 1	Yes	Yes					
	Total (Overall)	Devlin 2004 15295762 Sample 2	Yes	Yes			Yes (ES=0.60)	0/1.3%†	1.3/1.3†
	Wear prosthesis (item 1)		Yes					3.9/12%†	28/57%†
	Use prosthesis to walk (item 2)		Yes					2.6/2.6%†	22/78%†
	Use prosthesis outdoors (item 3)		Yes					29/18%†	1.3/6.6%†
	Flat surface walking stability (item 4a)		Yes					0/14.6%†	91/85%†
	Slope walking stability (item 4b)		Yes					47/62%†	53/38%†
	Rough ground stability (item 4c)		Yes					67/64%†	33/36%†
	Walking stability (item 4 total)		Yes					9.2/10.5%†	29/24%†
	Items 1-3	Devlin 2004 15295762 Sample 2	Yes	Yes				0/2.6%†	1.3/3.9%†
		Gremeaux 2012 22389424	Yes					0%	23%
		Miller 2001 11588750 (sample 1)	Yes					0%	12.9%
		Miller 2001 11588750 (sample 2)	Yes					0.3%	6.0%
		Reid 2015 25588644	No						
		Wong 2016 26874230	No						
L Test		Major 2013 23856150	No						
		Rushton 2015 25134533	Yes				No (GRC)		
		Deathe 2005 15982169	No	Yes	6.2 sec	4.5 sec			

Abbreviations: ES = effect size, GRC = Global Rating of Change score, L Test = L Test of Functional Mobility, MC = Medicare, MDC = minimal detectable change, MID = minimum (clinical) important difference, nd = no data/not reported, PMID = PubMed identifier (or journal), PMID = PubMed identifier (or journal), sec = seconds.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Floor or ceiling effects at rehabilitation discharge/at 3 month followup.

LCI

The Locomotor Capabilities Index assesses an individual's perceived independence in performing 14 activities while wearing a prosthesis. The entire LCI may be summed to provide a single score or two 7-item subscales: basic and advanced capabilities. 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 adding a fifth level to the response scale. The LCI10-4 is a 10-item scale which combined two of the response levels from LCI-5, as described below. Eleven studies, in 10 articles,[7, 36, 43, 48, 51, 54-58] evaluated the variations of LCI in 1182 people, total, with lower limb amputations (see Tables 18 to 20). Eight of the studies, in seven articles,[43, 48, 51, 54-56, 58] evaluated the original LCI-4 as an overall (total) score in 933 people. Two of these studies[48, 55] evaluated the basic subscale in 157 people. Three studies[7, 48, 55] evaluated the advanced subscale in 197 people. Three studies[36, 48, 57] evaluated LCI-5 in 259 people. One study[57] created and evaluated LCI10-4 in 123 people. Across these 11 studies, six were deemed generalizable to the Medicare population based on average age (65 and 68 years) and/or relatively high percentage of people with dysvascular conditions (53% to 83%). These studies all evaluated LCI-4. Evaluations of the basic subscale, LCI-5, and LCI10-4 have not been conducted in studies generalizable to the Medicare population.

LCI-4 and Subscales

The original LCI-4 has been reported to have convergent validity with various other instruments, including SIP-PD, PFI, the Rising and Sitting Down Questionnaire, RMI, FIM, the Reintegration to Normal Living Index daily activity subscale, 2MWT, TUG, ABC (and LCI-5). Two of three studies reported that LCI-4 discriminated people based on their amputation level, amputation etiology, use of mobility device, walking distance, and automatic walking, but the third study found that it did not discriminate based on amputation level, injury severity, age, or comorbidities. One study also found that LCI-4 correlated with walking speed but not return to usual activity. One study that was not generalizable to the Medicare Population reported that LCI-4 as in initial assessment at start of rehabilitation had predictive validity by correlation with TWT, RMI, and FIM at discharge from rehabilitation. LCI-4 was also reported to have reliability, responsiveness, but floor (54%) and ceiling effects (up to 70%) when measured at some time points (e.g., after rehabilitation).

The basic capabilities subscale of LCI-4, in studies not generalizable to the Medicare population, was reported to discriminate by amputation level in one study, but another found that it did not discriminate based on amputation level, injury severity, age, or comorbidities. One study also found that the basic subscale correlated with walking speed but not return to usual activity. The subscale was reported to have reliability, but a high floor effect (90%) in one study.

The advanced capabilities subscale of LCI-4 was reported to discriminate by amputation level in one study, but another found that it did not discriminate based on amputation level,

injury severity, age, or comorbidities. One study also found that the basic subscale correlated with walking speed but not return to usual activity. These two studies were not generalizable to the Medicare population. A third study, generalizable to the Medicare population reported predictive validity with low sensitivity (43%) but high specificity (91%) for two or more falls at 6 months after testing; overall the accuracy was reported to be statistically significant ($P<0.01$). One study reported reliability but a high floor effect (54%).

LCI-5

In studies not generalizable to the Medicare population, LCI-5 was reported to have convergent validity with several other instruments, including RMI, FIM, PEQ-MS, PPA, the 6MWT (and LCI-4). One study reported that LCI-5 administered in the initial assessment at start of rehabilitation had predictive validity by correlation with TWT, RMI, and FIM at discharge from rehabilitation. This study also reported reliability, responsiveness, but a high ceiling effect at the end of rehabilitation (22%). One study conducted a Rasch analysis of LCI-5 and concluded that it lacked structural validity with four of the 14 items having poor fit.

LCI10-4

Based on the above-mentioned Rasch analysis, four items were dropped from the instrument and two of the intermediate response options ("yes, if someone helps me" and "yes, if someone is near me"). The study, which was not generalizable to the Medicare population, reported there were similar statistically significant correlations with PEQ-MS and PPA as LCI-5 and reliability, but was better fitting by Rasch analysis.

Overall

Overall, for the various versions and subscales of LCI, there is evidence of test validity and reliability for each version, but with floor and ceiling effects, depending when the instrument was used (in relation to rehabilitation). These conclusions are generalizable to the Medicare population only for LCI-4. LCI-4 and LCI-5 were reported to also have predictive validity at 6 months, in a study not generalizable to the Medicare population. The advanced capabilities subscale was reported to have low sensitivity, but high specificity, for falls at 6 months in a study generalizable to the Medicare population.

Table 18. Study descriptive data: LCI

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
LCI	LCI-4	Callaghan 2002 12227445	133	67.8 (16.1) [16-101]	83	11	0	100	100	0
	LCI-4 (total) Basic Advanced	Cyril 2001 (Johns Hopkins)	107	35 (12.5)	0	100	21	67	100	0
	LCI-4	de Laat 2011 21807151	164	65 (11) [37-92]	83	8	33	57	97	7
	Advanced	Dite 2007 17207685	40	61.7 (nd)	65	nd	0	100	100	0
	LCI-4 (total) Basic Advanced LCI-5	Franchignoni 2004 15129398	50	51 [21-86]	32	58	60	40	100	0
	LCI-5 LCI10-4	Franchignoni 2007 18050010	123	54 [IQR 36-65]	35	56	64	41	89	11
	LCI-4	Gauthier-Gagnon 1994 7993169	70	60.6 (16.8)	70	23	50	50	100	0
	LCI-4	Miller 2001 11588750 (sample 1)	60	58.4 (15.5)	53	nd	28	72	100	0
	LCI-4	Miller 2001 11588750 (sample 2)	329	59.9 (16.7)	53	nd	26	74	100	0
	LCI-5	Reid 2015 25588644	86	60 (15.3)	35	48	15	73	97	3
	LCI-4	Theeven 2010 20809056	20	50.3 (10.7)	30	60	100	0	nd	nd

Abbreviations: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), IQR = interquartile range, LCI = Locomotor Capabilities Index, nd = no data/not reported, PMID = PubMed identifier (or journal), TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 19. Summary of instrument psychometric validity properties: LCI

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
LCI	LCI-4	Callaghan 2002 12227445	Yes					
		Cyril 2001 (Johns Hopkins)	No	Moderate (SIP-PD, PFI)	No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed), No (return to usual activity)		
		de Laat 2011 21807151	Yes	Yes (Rising and Sitting Down Questionnaire)				
		Franchignoni 2004 15129398	No	Yes (LCI-5, RMI, FIM)	Yes (TT vs. TF)			Yes (TWT, RMI, FIM at rehab discharge)
		Gauthier-Gagnon 1994 7993169	Yes	Yes (RNL daily activity), No (RNL perception of self)				
		Miller 2001 11588750 (sample 1)	Yes	Yes (2MWT, TUG, ABC)				
		Miller 2001 11588750 (sample 2)	Yes	Yes (ABC)	Yes (TT vs. TF, amputation etiology, use of mobility device, walking distance, automatic walking)			
		Theeven 2010 20809056	No					
	Basic	Cyril 2001 (Johns Hopkins)	No		No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed), No (return to usual activity)		
		Franchignoni 2004 15129398	No		Yes (TT vs. TF)			

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
	Advanced	Cyril 2001 (Johns Hopkins)	No		No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed), No (return to usual activity)		
		Dite 2007 17207685	Yes					Mixed (Sn 43%, Sp 91% for falls at 6 mo)
		Franchignoni 2004 15129398	No		Yes (TT vs. TF)			
	LCI-5	Franchignoni 2004 15129398	No	Yes (LCI-4, RMI, FIM)				Yes (TWT, RMI, FIM at rehab discharge)
		Franchignoni 2007 18050010	No	Yes (PEQ-MS, PPA)			Rasch: Lacks structural validity, 4/14 items with poor fit	
		Reid 2015 25588644	No	Yes (6MWT)			.	
	LCI 10-4	Franchignoni 2007 18050010	No	Similar significant correlations as LCI-5			Rasch: good fit	

Abbreviations: 6MWT = 6 minute walk test, FIM = Functional Independence Measure, LCI = Locomotor Capabilities Index, mo = months, MC = Medicare, PEQ-MS = Prosthesis Evaluation Questionnaire – Mobility Subscale, PFI = Physical Function Index, PMID = PubMed identifier (or journal), PPA = Prosthetic Profile of the Amputee, RMI = Rivermead Mobility Index, RNL = Reintegration to Normal Living Index, SIP-PD = Sickness Impact Profile-Physical Dimension, Sn = sensitivity, Sp = specificity, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, TWT = Timed Walk Test.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 20. Summary of other instrument psychometric properties: LCI

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
LCI	LCI-4	Callaghan 2002 12227445	Yes	Yes					
		Cyril 2001 (Johns Hopkins)	No					54.2%	0%
		de Laat 2011 21807151	Yes						
		Franchignoni 2004 15129398	No	Yes			Yes (ES = 1.09)		2% at beginning; 46% at end of program
		Gauthier-Gagnon 1994 7993169	Yes	Yes			.		
		Miller 2001 11588750 (sample 1)	Yes	Yes			.	1.7%	36.7%
		Miller 2001 11588750 (sample 2)	Yes				.	0.3%	40.4%
		Theeven 2010 20809056	No				.		70%
	Basic	Cyril 2001 (Johns Hopkins)	No	Yes			.	89.7%	1.0%
		Franchignoni 2004 15129398	No				.		
	Advanced	Cyril 2001 (Johns Hopkins)	No	Yes			.	54.2%	1.0%
		Dite 2007 17207685	Yes				.		
		Franchignoni 2004 15129398	No				.		
	LCI-5	Franchignoni 2004 15129398	No	Yes			Yes (ES = 1.40)		22% at end of program
		Franchignoni 2007 18050010	No				.	0%	5%
		Reid 2015 25588644	No				.		
	LCI 10-4	Franchignoni 2007 18050010	No	Yes			.		

Abbreviations: ES = effect size, LCI = Locomotor Capabilities Index, MC = Medicare, MDC = minimal detectable change, MID = minimum (clinical) important difference, PMID = PubMed identifier (or journal).

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

LEMOCOT

The Lower-Extremity Motor Coordination Test measures unaffected lower limb motor coordination from a seated position. One study[30] evaluated the psychometric properties of LEMOCOT in 82 people with lower limb amputations (see Tables 21 to 23). The study was deemed to be generalizable to the Medicare population based on the high percentage of study participants with dysvascular disease (63%); although the average age was under 65 years old.

The study reported predictive validity with correlations with of the initial assessment scores with 2MWT, TUG, and K levels at the end of rehabilitation.

Overall, for LEMOCOT there is evidence of predictive validity from a study generalizable to the Medicare population.

NQ-ACGC

The Quality of Life in Neurological Conditions – Applied Cognition/General Concerns is a short form of a larger item bank that measures general cognitive abilities, including memory, attention, and decision making. One study[41] evaluated the psychometric properties of NQ-ACGC in 201 people with lower limb amputations (see Tables 21 to 23). The study was not deemed to be generalizable to the Medicare population due to their relatively low average ages (60 years) and low percentage of study participants with dysvascular conditions (23%).

The study found evidence of good reliability. The study reported MDC(90) to be 6.67 and MDC(95) to be 7.94. Ceiling effects were observed at 17%; no floor effects were observed. The study did not report on test validity.

Overall, for NQ-ACGC, there is evidence of test reliability, but with a ceiling effect in a study not generalizable to the Medicare population.

OPCS

The Office of Population Censuses and Surveys Scale assesses disability and impairment in the community. One study[39] evaluated the psychometric properties of SIP-PD in 34 people with lower limb amputations (see Tables 21 to 23). The study was deemed to be generalizable to the Medicare population based on average age (66 years) and that all study participants had dysvascular disease.

The study provided evidence that OPCS administered at initial assessment had predictive validity in that it correlated with duration of stay in a postoperative rehabilitation unit.

Overall, for OPCS, there is evidence of test validity from a study generalizable to the Medicare population.

OPUS

The Orthotics Prosthetics Users Survey is a self-report survey that contains separate subscales measuring 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. The OPUS also contains a subscale relevant only to users of upper extremity prostheses/orthoses, which is not summarized here. One study[37] evaluated the psychometric properties of the three lower limb relevant OPUS subscales in 44 people with lower limb amputations (see Tables 21 to 23). The study was deemed to be generalizable to the Medicare population based on the average

age of participants (66 years); although the number of people with dysvascular conditions was not reported.

The study provided evidence of reliability for all three subscales, and the study reported the MDC(90) to range from 9.2 to 15.7. No floor effects or ceiling effects were observed for any of the subscales. The study did not assess test validity, per se.

Overall, for OPUS, there is evidence of test reliability without a floor or ceiling effect in a study generalizable to the Medicare population.

Patient Activity Monitor

The Patient Activity Monitor is a small walking activity monitor that was designed for the evaluation of lower limb amputee gait patterns. One study[59] evaluated the psychometric properties of the Patient Activity Monitor in 22 people with lower limb amputations (see Tables 21 to 23). The study was not deemed to be generalizable to the Medicare population; the average age of participants was 50 years old, and the study did not report the number of participants with dysvascular etiologies for their amputations.

The study provided evidence of convergent validity for the measures of walking velocity and step length when compared to the Qualisys motion analysis system for fast, medium, and slow walk; the study also provided evidence of convergent validity for walking velocity and manual count of steps. Regarding reliability, the Patient Activity Monitor on average underestimated the step count by 11 (standard deviation [SD] 16) steps, with a wide Bland-Altman limits of agreement. Measures of walking velocity were reliable. For step length, average estimates were accurate, but the Patient Activity Monitor recorded lower values that Qualisys with shorter step lengths and higher values with longer step lengths.

Overall, for the Patient Activity Monitor, from a study not generalizable to the Medicare population, there is evidence of test validity and good reliability for walking velocity, but not step count or step length.

Table 21. Study descriptive data: LEMOCOT through Patient Activity Monitor

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
LEMOCOT		Spaan 2017 27770064	82	59.2 (13.3)	63	nd	nd	55	100	nd
NQ-ACGC		Hafner 2016 28273329	201	60.2 (11.4)	23	60	35	65	nd	nd
OPCS		Panesar 2001 11330761	34	67 [44-85]	100	0	53	44	94	6
OPUS	Quality of life Lower limb function Satisfaction	Resnik 2011 21310896	44	66 (13)	nd	nd	52	43	100	0
Patient Activity Monitor	Step count Walking velocity Step length	Ramstrand 2007 17520493	22	50 (nd)	nd	nd	55	45	nd	nd

Abbreviations: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), LEMOCOT = Lower-Extremity Motor Coordination Test, nd = no data/not reported, NQ-ACGC = Quality of Life in Neurological Conditions – Applied Cognition/General Concerns, OPCS = Office of Population Censuses and Surveys Scale, OPUS = Orthotics Prosthetics Users Survey, PMID = PubMed identifier (or journal), TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 22. Summary of instrument psychometric validity properties: LEMOCOT through Patient Activity Monitor

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
LEMOCOT		Spaan 2017 27770064	Yes					Prefitting test Yes (2MWT, TUG, K level at end of rehab)
NQ-ACGC		Hafner 2016 28273329	No					.
OPCS		Panesar 2001 11330761	Yes					Yes (duration of stay)
OPUS	Quality of life Lower limb function Satisfaction	Resnik 2011 21310896	Yes					
Patient Activity Monitor	Step count	Ramstrand 2007 17520493	No	Yes (Hand count, Qualisys motion analysis system) for fast, medium, slow walk				
	Walking velocity		No	Yes (Qualisys motion analysis system) for fast, medium, slow walk				
	Step length		No	Yes (Qualisys motion analysis system) for fast, medium walk; Moderate for, slow walk				

Abbreviations: 2MWT = 2 minute walk test, K level = Medicare Functional Classification Level, LEMOCOT = Lower-Extremity Motor Coordination Test, MC = Medicare, NQ-ACGC = Quality of Life in Neurological Conditions – Applied Cognition/General Concerns, OPCS = Office of Population Censuses and Surveys Scale, OPUS = Orthotics Prosthetics Users Survey, PMID = PubMed identifier (or journal), TUG = Timed Up and Go.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 23. Summary of other instrument psychometric properties: LEMOCOT through Patient Activity Monitor

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
LEMOCOT		Spaan 2017 27770064	Yes						
NQ-ACGC		Hafner 2016 28273329	No	Yes	MDC(90) 6.67, MDC(95) 7.94			nd	17%
OPCS		Panesar 2001 11330761	Yes						
OPUS	Quality of life	Resnik 2011 21310896	Yes	Yes	MDC(90) 9.2			No effect	No effect
	Lower limb function		Yes	Yes	MDC(90) 10.3			No effect	No effect
	Satisfaction		Yes	Yes	MDC(90) 15.7			No effect	No effect
Patient Activity Monitor	Step count	Ramstrand 2007 17520493	No	No (BA LOA -43.1 to 21.3 steps in 5 min (vs. Qualisys)					
	Walking velocity		No	Yes (BA LOA -0.11 to 0.09 m/sec)					
	Step length		No	No (BA LOA -0.07 to 0.14 m, bias)					

Abbreviations: BA LOA = Bland-Altman limits of agreement, LEMOCOT = Lower-Extremity Motor Coordination Test, MC = Medicare, MDC(90) = minimal detectable change (at 90% confidence), MID = minimum (clinical) important difference, m = meters, min = minutes, nd = no data/not reported, NQ-ACGC = Quality of Life in Neurological Conditions – Applied Cognition/General Concerns, OPCS = Office of Population Censuses and Surveys Scale, OPUS = Orthotics Prosthetics Users Survey, PMID = PubMed identifier (or journal), sec = seconds.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

PEQ

The Prosthetic Evaluation Questionnaire measures perceived ability to perform a range of ambulation and transfer tasks with a lower limb prosthesis. Its original version had 82 items organized into 9 validated scales related to prosthesis function (4 scales), mobility (1 scale), psychosocial issues (3 scales), and well-being (1 scale), and individual items. The items each had a 100 mm visual analog scale (VAS). The scoring was subsequently modified to an 11-category (0 to 10) numeric scale and then, in a further modification, a 7-category (1 to 7) numeric scale. The ambulation scale and individual items related to transfer were combined into a Mobility Subscale (PEQ-MS) with 13 items and 11 categories ("13/11"). A subsequent modification, described below, simplified the PEQ-MS to a 12-item scale each with 5 categories (0 to 4) dubbed PEQ-MS 12/5. A further modification used 8 categories (0 to 7). Overall, nine studies (in eight articles evaluated the variations of PEQ in a total of 1258 people with lower limb amputations.[33, 37, 38, 40, 41, 51, 60, 61] Tables 24 to 26 summarize studies of all versions of PEQ.

PEQ, Original (9 Scales)

Two studies evaluated the psychometric properties of all scales of the PEQ in 136 people, total, with lower limb amputations. The original study reporting PEQ, which used a 100 mm VAS was not generalizable to the Medicare population (age and etiology data not reported.[60]) An evaluation that used a 7-category (1 to 7) numeric scale was generalizable to the Medicare population (average age 66 years).[37]

For the version with VAS scoring, the study reported convergent validity of the Ambulation subscale with the SF-36 physical function scale, of the Social Burden subscale with both SF-36 social function and SIP social interaction, and of the Well-Being subscale with the Profile of Mood States (POMS-SF) scale. Most of the subscales did not discriminate between people based on amputation level, comorbidities, years since amputation, or age. However, the Residual Limb Health and Frustration subscales discriminated by age and the Ambulation subscale discriminated by comorbidities. Both studies found that all subscales (and the overall scale) had reliability. One study provided MDC(90) estimates for each subscale. Both studies found ceiling effects for Transfers (25% and 27%) and one study each (but not the other) found a floor effect for Frustration (22%, "no effect") and ceiling effects for Perceived Responses (17%, "no effect") and Well-Being (34% and 8%).

PEQ-MS 13/11

Four studies, in three articles, evaluated the psychometric properties of the original version of PEQ-MS with all original 13 items, scored 0 to 10 (11 categories) in 498 people, total.[33, 51, 61] Two of the studies were generalizable to the Medicare population based on more than half the sample having dysvascular conditions (53%); average ages of the studies ranged from 54 to 60 years. Four of the studies reported convergent validity with a variety of other instruments, including LCI, PPA, BBS, 2MWT, TUG, and ABC. One study reported that the PEQ-MS 13/11 had similar but slightly lower correlations with LCI and PPI than the PEQ-MS 12/5 (see below).[61] This study found a misfit of the bathing item by Rasch analysis. One study found that the PEQ-MS 13/11 discriminated people based on amputation etiology, use of mobility device, walking distance, and automatic walking, but not by amputation level.

Two studies, one generalizable to the Medicare population, reported good reliability of the instrument and no floor or ceiling effects were found in three studies.

PEQ-MS 12/5

Four studies evaluated the psychometric properties of a modification of the PEQ 13/11 in which the bathing item was dropped based on Rasch analysis and the scoring had five categories (0 to 4).[38, 40, 41, 61] The studies evaluated 703 people, total. None of the studies was generalizable to the Medicare population (average ages 54 to 60 years, 23% to 49% with dysvascular conditions).

Rasch analysis found better structural validity than the PEQ-MS 13/11 instrument. Two studies reported convergent validity with LCI, PPA, 2MWT, ABC, BBS, and TUG. Two studies also found that PEQ0MS 12/5 discriminated among people by K level and Houghton Scale. Two studies reported good reliability and one study reported MDC(90) and MDC(95) estimates. No floor or ceiling effects were found.

PEQ-MS 13/7

One study that is generalizable to the Medicare population (average age 66 years) evaluated a modified version of PEQ-MS in which there were 7 categories (1 to 7).[37]. The study did not evaluate test validity, but found the subscale to be reliable without floor or ceiling effect. An MDC(90) estimate was reported.

Overall

Overall, for PEQ scales and variations, there is evidence of reliability for each of the scales and the overall instrument in a study generalizable to the Medicare population, but with ceiling effects for Transfers and Well-Being. There is also evidence of test validity for PEQ-MS 13/11 and PEQ-MS 12/5, and test reliability without floor or ceiling effects for all three variations of PEQ-MS (13/11, 12/5, and 13/7) in studies generalizable to the Medicare population.

There is corroborating evidence in studies *not* generalizable to the Medicare population of test validity (of the original versions) of the PEQ items individually, but with floor or ceiling effects for Transfers, Perceived Responses, and Frustration. Also in studies not generalizable to the Medicare population, there is evidence of better structural validity of PEQ-MS 12/5 than PEQ-MS 13/11 with test validity, reliability, and no floor or ceiling effect.

Table 24. Study descriptive data: PEQ

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
PEQ	MS 13/11 (original) MS 12/5	Franchignoni 2007 17351696	123	54 [IQR 36-65]	35	56	64	41	89	11
	MS 12/5	Hafner 2016 28273329	201	60.2 (11.4)	23	60	35	65	nd	nd
	MS 12/5	Hafner 2017 27590443	199	55.4 (14.3)	44	41	18	76	100	0
	Function: Usefulness (VAS) Function: Residual limb health (VAS) Function: Appearance (VAS) Function: Sounds (VAS) Mobility: Ambulation (VAS) Mobility: Transfers (VAS) Psychosocial: Perceived responses (VAS) Psychosocial: Frustration (VAS) Psychosocial: Social burden (VAS) Global: Well-being (VAS)	Legro 1998 9710165	92	nd	nd	66	25	63	nd	nd
	MS 13/11	Major 2013 23856150	30	54 (12)	23	47	50	53	90	10
	MS 13/11	Miller 2001 11588750 (sample 1)	60	58.4 (15.5)	53	nd	28	72	100	0
	MS 13/11	Miller 2001 11588750 (sample 2)	329	59.9 (16.7)	53	nd	26	74	100	0
	Overall scale (all modified to 7 categories) Function: Usefulness Function: Residual limb health Function: Appearance Function: Sounds Mobility: Ambulation Mobility: Transfers Psychosocial: Perceived responses Psychosocial: Frustration Psychosocial: Social burden Global: Well-being MS 13/7	Resnik 2011 21310896	44	66 (13)	nd	nd	52	43	100	0
	MS 12/5	Wong 2016 26874230	180	55.5 (16.0)	49	51	44	56	81	13

Abbreviations: Bi = bilateral amputation, IQR = interquartile range, MS = Mobility Scales, nd = no data/not reported, PEQ = Prosthesis Evaluation Questionnaire, PMID = PubMed identifier (or journal), TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation, VAS = Visual Analog Scale.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 25. Summary of instrument psychometric validity properties: PEQ

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
PEQ	Function: Usefulness (VAS)	Legro 1998 9710165	No		No (amputation level, comorbidities, years since amputation, age)			
	Function: Residual limb health (VAS)		No		Yes (age) No (amputation level, comorbidities, years since amputation)			
	Function: Appearance (VAS)		No		No (amputation level, comorbidities, years since amputation, age)			
	Function: Sounds (VAS)		No		No (amputation level, comorbidities, years since amputation, age)			
	Mobility: Ambulation (VAS)		No	Yes (SF-36 physical function)	Yes (comorbidities) No (amputation level, years since amputation, age)			
	Mobility: Transfers (VAS)		No		No (amputation level, comorbidities, years since amputation, age)			
	Psychosocial: Perceived responses (VAS)		No		No (amputation level, comorbidities, years since amputation, age)			
	Psychosocial: Frustration (VAS)		No		Yes (age) No (amputation level, comorbidities, years since amputation)			
	Psychosocial: Social burden (VAS)		No	Yes (SF-36 social function, SIP social interaction)	No (amputation level, years since amputation, comorbidities, age)			

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
	Global: Well-being (VAS)		No	Yes (POMS-SF)	No (amputation level, years since amputation, comorbidities, age)			
	Overall and subscales	Resnik 2011 21310896	Yes					
	MS 13/11	Franchignoni 2007 17351696	No	Similar but slightly lower correlations than PEQ-MS 12/5			Rasch: Misfit of one item (bathing)	
		Major 2013 23856150	No	Yes (BBS)				
		Miller 2001 11588750 (sample 1)	Yes	Yes (2MWT, TUG, ABC, PPA-LCI)				
		Miller 2001 11588750 (sample 2)	Yes	Yes (ABC, PPA-LCI)	Yes (amputation etiology, use of mobility device, walking distance, automatic walking) No (TT vs. TF)			
	MS 12/5	Franchignoni 2007 17351696	No	Yes (LCI, PPA)			Rasch: Better structural validity than 13/11	
		Hafner 2016 28273329	No					
		Hafner 2017 27590443	No		Yes (K levels)			
		Wong 2016 26874230	No	Yes (2MWT, ABC, 3-BBS, TUG)	Yes (Houghton)			

Abbreviations: 2MWT = 2 minute walk test, 3-BBS = total sum score of 3 Berg Balance Scale items, ABC = Activities-Specific Balance Confidence scale, BBS = Berg Balance Scale, Bi = bilateral amputation, IQR = interquartile range, K level = Medicare Functional Classification Level, LCI = Locomotor Capabilities Index, MC = Medicare, MS = Mobility Scales, nd = no data/not reported, PEQ = Prosthesis Evaluation Questionnaire, PEQ-MS = Prosthesis Evaluation Questionnaire motor score, PMID = PubMed identifier (or journal), PPA = Prosthetic Profile of the Amputee, PPA-LCI = Prosthetic Profile of the Amputee – Locomotor Capabilities, SF-36 = Short Form Health Survey-36, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, TUG = Timed Up and Go, Uni = unilateral amputation, VAS = Visual Analog Scale.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 26. Summary of other instrument psychometric properties: PEQ

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
PEQ	Function: Usefulness (VAS)	Legro 1998 9710165	No	Yes				0%	2%
	Function: Residual limb health (VAS)		No	Yes				0%	2%
	Function: Appearance (VAS)		No	Yes				0%	7%
	Function: Sounds (VAS)		No	Yes				1%	10%
	Mobility: Ambulation (VAS)		No	Yes				0%	2%
	Mobility: Transfers (VAS)		No	Yes				0%	25%
	Psychosocial: Perceived responses (VAS)		No	Yes				0%	17%
	Psychosocial: Frustration (VAS)		No	Yes				22%	1%
	Psychosocial: Social burden (VAS)		No	Yes				10%	0%
	Global: Well-being (VAS)		No	Yes				0%	8%
	Overall scale (modified 7 categories)	Resnik 2011 21310896	Yes	Yes (except shower and bathe safely)				No effect	No effect
	Function: Usefulness (7 categories)		Yes	Yes	MDC(90) 1.2			No effect	No effect
	Function: Residual limb health (7 categories)		Yes	Yes	MDC(90) 0.8			No effect	No effect
	Function: Appearance (7 categories)		Yes	Yes	MDC(90) 1.4			No effect	No effect
	Function: Sounds (7 categories)		Yes	Yes	MDC(90) 1.7			No effect	No effect
	Mobility: Ambulation (7 categories)		Yes	Yes	MDC(90) 1.1			No effect	No effect
	Mobility: Transfers (7 categories)		Yes	Yes	MDC(90) 1.3			0%	27%
	Psychosocial: Perceived responses (7 categories)		Yes	Yes	MDC(90) 0.9			No effect	No effect
	Psychosocial: Frustration (7 categories)		Yes	Yes	MDC(90) 1.6			No effect	No effect
	Psychosocial: Social burden (7 categories)		Yes	Yes	MDC(90) 1.4			No effect	No effect
	Global: Well-being (7 categories)		Yes	Yes	MDC(90) 1.4			0%	34%
	MS 13/7		Yes	Yes	MDC(90) 0.8			No effect	No effect

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
	MS 13/11	Franchignoni 2007 17351696	No	Yes				0%	4%
		Major 2013 23856150	No						
		Miller 2001 11588750 (sample 1)	Yes	Yes				0.6%	8.1%
		Miller 2001 11588750 (sample 2)	Yes					0.3%	10.0%
	MS 12/5	Franchignoni 2007 17351696	No	Yes					
		Hafner 2016 28273329	No	Yes	MDC(90) 0.55, MDC(95) 0.65			0%	0%
		Hafner 2017 27590443	No						
		Wong 2016 26874230	No					"no floor effect"	5.8%

Abbreviations: MC = Medicare, MDC(90/95) = minimal detectable change (at 90/95% confidence), MID = minimum (clinical) important difference, MS = Mobility Scales, PEQ = Prosthesis Evaluation Questionnaire, PMID = PubMed identifier (or journal), VAS = Visual Analog Scale.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

PFI

The Physical Function Index is a generic measure of ability to perform various physical tasks. One study[55] evaluated the psychometric properties of the PFI in 107 people with lower limb amputations (see Tables 27 to 29). The study evaluated the instrument scored in total and also the individual items Squat to pick up object, Walk at steady pace, Run at steady pace, and Climb stairs. The study was not deemed generalizable to the Medicare population based on the young age of the participants (average 35 years) and that none had dysvascular conditions.

The study provided moderate evidence of convergent validity for the PFI instrument as a whole when compared with LCI and SIP-PD. The study found that the PFI did not discriminate participants by amputation level, injury severity score, age, or comorbidities for any of the subscales, including the overall instrument. All subscales were found to have construct validity when compared to walking speed, and the subscales of Walk at a steady pace and Run at a steady pace were additionally found to have construct validity with return to usual activity. The remaining subscales were not found to have construct validity with return to usual activity.

The study reported good reliability for all subscales and the total instrument. Responsiveness of the subscales was mixed, as the items of Squat to pick up object, Climb stairs, and the overall instrument were not found to have significance changes from 3 to 12 months in correlation with Return to walking speed or Usual activity, but the remaining subscales were found to have responsiveness correlated with Walking speed alone. Large ceiling effects were observed for each of the subscales and large floor effects were observed for Walk at steady pace and Climb stairs. Neither floor nor ceiling effects were observed for the overall instrument.

Overall, for PFI, in a study not generalizable to the Medicare population, there is evidence of test validity and reliability for the instrument as a whole and its subscales. Two of the subscales demonstrate responsiveness. The subscales, but not the instrument as a whole have floor and ceiling effects.

PGI

Patient-centered quality of life is assessed through the Patient Generated Index, 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. One study[62] evaluated the psychometric properties of the PGI in 42 people with lower limb amputations (see Tables 27 to 29). The study was deemed to be generalizable to the Medicare population based on the relatively high percentage of study participants with dysvascular disease (86%) although the average age in all three studies was not reported.

The study did not assess test validity, but it provided evidence of reliability for the PGI.

Overall, there is evidence of reliability of the PGI in a study generalizable to the Medicare population.

PLUS-M

The Prosthetic Limb Users Survey of Mobility is a self-reported instrument that assesses perceived mobility in people with lower limb amputation. Three studies[40, 41, 63] evaluated the psychometric properties of the PLUS-M in 599 people, total, with lower limb amputations (see Tables 27 to 29). The instrument was evaluated in two different short-form lengths (SF-7 and SF-12, which should not be confused with the Short Form Health Survey instrument SF-12) as

well as by Computer Adaptive Test (CAT). The studies were not deemed generalizable to the Medicare population based on average age less than 65 years (55 to 60 years) and the low percentage of study participants with dysvascular disease (23% to 44%).

One of the studies reported convergent validity of the PLUS-M SF-12 (compared with the PEQ-MS, ABC, PROMIS-PF, AMP, TUG, and MFCL) and found that it discriminated people based on K levels. The other two studies reported evidence of reliability for the PLUS-M CAT, SF-7, and SF-12; although for SF-7, the reliability was rated as poor in one study. One study reported MDC(90) and MDC(95) estimates for the three instrument forms. No floor or ceiling effects were observed across all versions of the PLUS-M.

Overall, for PLUS-M, from studies not generalizable to the Medicare population there is evidence of test validity and reliability (with mixed evidence), without floor or ceiling effects for all three instrument forms.

PPA

The Prosthetic Profile of the Amputee assesses frequency of wear and the use of lower limb prosthesis, along with factors potentially associated with prosthesis use. The instrument includes the LCI instrument, which has been described above. This section includes only other items from PPA that were assessed separately from LCI. One study[58] evaluated the psychometric properties of PPA items other than LCI in 70 people with lower limb amputations (see Tables 27 to 29). The study evaluated psychometric properties of the Prosthetic Use outdoor and indoor, and Acceptance/Adaptation. The study was deemed to be generalizable to the Medicare population based on the relatively high percentage of study participants with dysvascular disease (0%); although the average age was less than 65 years (61 years).

The study reported convergent validity of the Prosthesis Use (Outdoor Use) subscale with Reintegration to Normal Living Index daily activity subscale and the Acceptance/Adaptation subscale with the Reintegration to Normal Living Index, overall. Prosthetic Use (Indoor Use) did not correlate with the Reintegration to Normal Living Index. The study also reported that each of the items had test reliability.

Overall, for the PPA items (other than LCI), from a study generalizable to the Medicare population, there is evidence of test validity for Prosthetic Use (outdoor use), and Acceptance/Adaptation, but not the Prosthetic Use (indoor use). All items have evidence of reliability.

Table 27. Study descriptive data: PFI through PPA

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
PFI	Squat to pick up object Walk at a steady pace Run at a steady pace Climb stairs Total (Overall)	Cyril 2001 (Johns Hopkins)	107	35 (12.5)	0	100	21	67	100	0
PGI		Callaghan 2003 14682557	42	nd	86	nd	100	0	100	0
PLUS-M	CAT SF-7 SF-12	Amtmann 2017 28866959	199	55.2 (14.4)	42	41	17	73	100	0
	CAT SF-7 SF-12	Hafner 2016 28273329	201	60.2 (11.4)	23	60	35	65	nd	nd
	SF-12	Hafner 2017 27590443	199	55.4 (14.3)	44	41	18	76	100	0
PPA‡	Prosthesis use, outdoor use Prosthesis use, indoor use Acceptance/adaptation	Gauthier-Gagnon 1994 7993169	70	60.6 (16.8)	70	23	50	50	100	0

Abbreviations: Bi = bilateral amputation, CAT = Computer Adaptive Test, Dysvasc = dysvascular disease (including diabetes), nd = no data/not reported, PFI = Physical Function Index, PGI = Patient Generated Index, PLUS-M = Prosthetic Limb Users Survey of Mobility, PMID = PubMed identifier (or journal), PPA = Prosthetic Profile of the Amputee, SF-12 = short form-12 item (PLUS-M), SF-7 = short form-7 item (PLUS-M), TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

‡The Locomotor capabilities portion of the PPA has been incorporated in together with the Locomotor Capabilities Index (LCI) instrument and is not repeated here.

Table 28. Summary of instrument psychometric validity properties: PFI through PPA

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
PFI		Cyril 2001 (Johns Hopkins)	No	Moderate (LCI, SIP-PD)	No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed), No (return to usual activity)		
	Squat to pick up object		No		No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed), No (return to usual activity)		
	Walk at steady pace		No		No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed, return to usual activity)		
	Run at steady pace		No		No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed, return to usual activity)		
	Climb stairs		No		No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed), No (return to usual activity)		
PGI		Callaghan 2003 14682557	Yes					
PLUS-M	CAT SF-7 SF-12	Amtmann 2017 28866959	No					
	CAT SF-7 SF-12	Hafner 2016 28273329	No					
	SF-12	Hafner 2017 27590443	No	Yes (PEQ-MS, ABC, PROMIS-PF, AMP, TUG, MFCL)	Yes (K levels)			
PPA	Prosthesis use, outdoor use	Gauthier-Gagnon 1994 7993169	Yes	Yes (RNL daily activity), No (RNL perception of self)				
	Prosthesis use, indoor use		Yes	No (RNL)				
	Acceptance/adaptation		Yes	Yes (RNL)				

Abbreviations: 2MWT = 2 minute walk test, ABC = Activities-specific Balance scale, AMP = Amputee Mobility Predictor, CAT = computer adaptive test, K level = Medicare Functional Classification Level, LCI = Locomotor Capabilities Index, MC = Medicare, MFCL = Medicare Functional Classification Level, PCS = Physical Component Score,

PEQ-MS = Prosthesis Evaluation Questionnaire-Mobility Scale, PFI = Physical Function Index, PGI = Patient Generated Index, PLUS-M = Prosthetic Limb Users Survey of Mobility, PMID = PubMed identifier (or journal), RNL = Reintegration to Normal Living Index, SF-12 = short form 12 item (PLUS-M), SF-7 = short form 7 item (PLUS-M), SIP-PD = Sickness Impact Profile-Physical Dimension, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, TUG = Timed Up and Go.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 29. Summary of other instrument psychometric properties: PFI through PPA

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
PFI	Squat to pick up object	Cyril 2001 (Johns Hopkins)	No	Yes			No (walking speed, return to usual activity)	8.4%	36.4%
	Walk at steady pace		No	Yes			Yes (walking speed), No (return to usual activity)	17.8%	31.8%
	Run at steady pace		No	Yes			Yes (walking speed), No (return to usual activity)	2.8%	85.0%
	Climb stairs		No	Yes			No (walking speed, return to usual activity)	41.1%	16.8%
	Total (Overall)		No	Yes			No (walking speed, return to usual activity)	0%	12.1%
PGI		Callaghan 2003 14682557	Yes	Yes					
PLUS-M	CAT	Amtmann 2017 28866959	No	Yes					
	SF-12		No	Yes					
	SF-7		No	Poor					
	CAT	Hafner 2016 28273329	No	Yes	MDC(90) 6.67, MDC(95) 7.94			0%	0%
	SF-12		No	Yes	MDC(90) 6.67, MDC(95) 7.94			0%	0%
	SF-7		No	Yes	MDC(90) 4.69, MDC(95) 5.59			0%	0%
	SF-12	Hafner 2017 27590443	No					0%	1%
PPA	Prosthesis use, outdoor use	Gauthier-Gagnon 1994 7993169	Yes	Yes					
	Prosthesis use, indoor use		Yes	Yes					
	Acceptance/adaptation		Yes	Yes					

Abbreviations: CAT = computer adaptive test, MC = Medicare, MDC(90/95) = minimal detectable change (at 90/95% confidence), MID = minimum (clinical) important difference, PFI = Physical Function Index, PGI = Patient Generated Index, PLUS-M = Prosthetic Limb Users Survey of Mobility, PMID = PubMed identifier (or journal), PPA = Prosthetic Profile of the Amputee, SF-12 = short form 12 item (PLUS-M), SF-7 = short form 7 item (PLUS-M).

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

PROMIS-29

The Patient-Reported Outcomes Measurement Information System 29-Item Profile is a compilation of self-report instruments that measure symptom and quality of life constructs: physical function, anxiety, depression, fatigue, sleep disturbance, social role satisfaction, pain interference, and pain intensity. Three studies[40, 41, 64] evaluated the psychometric properties of the PROMIS-29 subscales in 1491 people, total, with lower limb amputations (see Tables 30 to32). The studies were not deemed generalizable to the Medicare population based on average age less than 65 years (55 to 60 years) and the low percentage of study participants with dysvascular disease (23% to 45%).

One study reported that the Physical Function subscale discriminated participants by K levels. Another study reported MDC(90) and MDC(95) estimates for each subscale and that each had reliability. For the Physical Function subscale, one study found the minimum (clinical) important difference, MID, to be 8 (of 100 points). Large floor effects were found for the subscales of Anxiety, Depression, and Pain Interference, but not for Pain Intensity, in one study, and a large ceiling effect was also reported for Social Role Satisfaction, but not Physical Function. Data for the floor or ceiling effects of remaining subscales were not reported.

Overall, for the PROMIS-29 subscales, among studies not generalizable to the Medicare population, there is evidence of test validity for the Physical Function subscale, reliability for all subscales, but large floor or ceiling effects for the Anxiety, Depression, Pain Interference, and Social Role Satisfaction subscales.

PROS

The Prosthetist's Perception of Client's Ambulatory Abilities 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. One study[65] evaluated the psychometric properties of the PROS in 840 people with lower limb amputations who were being evaluated for their first or replacement prosthesis (see Tables 30 to 32). The study was deemed to be generalizable to the Medicare population based on the relatively high percentage of study participants with dysvascular disease (58%) although the average age of participants was less than 65 years.

The study reported that the PROS did not have convergent validity when compared with the SF-36 PF-10 or PCS. The PROS was, however, found to discriminate by K levels.

Overall, for PROS, there is evidence of test validity from a study generalizable to the Medicare population.

Table 30. Study descriptive data: PROMIS through PROS

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
PROMIS-29	Physical function	Amtmann 2015 25917819	1091	55.0 (13.4)	45	55	35	65	100	0
	Anxiety Depression Fatigue Pain intensity Pain interference Physical function Sleep disturbance Social role satisfaction	Hafner 2016 28273329	201	60.2 (11.4)	23	60	35	65	nd	nd
	Physical function	Hafner 2017 27590443	199	55.4 (14.3)	44	41	18	76	100	0
PROS		Hart 1999 (J Prosthet Orthot)	840	56.3 (~17)	58	29	19	73	nd	nd

Abbreviations: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), nd = no data/not reported, PMID = PubMed identifier (or journal), PROMIS = Patient-Reported Outcomes Measurement Information System, PROS = Prosthetist's Perception of Client's Ambulatory Abilities, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 31. Summary of instrument psychometric validity properties: PROMIS through PROS

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
PROMIS-29	Physical function	Amtmann 2015 25917819	No					
	Anxiety Depression Fatigue Pain intensity Pain interference Physical function Sleep disturbance Social role satisfaction	Hafner 2016 28273329	No					
	Physical function	Hafner 2017 27590443	No		Yes (K levels)			
PROS		Hart 1999 (J Prosthet Orthot)	Yes	No (PF-10, PCS)	Yes (K levels)			

Abbreviations: K level = Medicare Functional Classification Level, MC = Medicare, PCS = Physical Component Score, PF-10 = Physical Functioning (10-item), PMID = PubMed identifier (or journal), PMID = PubMed identifier (or journal), PROMIS = Patient-Reported Outcomes Measurement Information System, PROS = Prosthetist's Perception of Client's Ambulatory Abilities.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 32. Summary of other instrument psychometric properties: PROMIS through PROS

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsive-ness	Floor	Ceiling
PROMIS-29	Physical function	Amtmann 2015 25917819	No			8 (of 100) points			
	Anxiety	Hafner 2016 28273329	No	Yes	MDC(90) 1.97-9.53, MDC(95) 2.35-11.36			34%	nd
	Depression		No	Yes	MDC(90) 1.97-9.53, MDC(95) 2.35-11.36			42%	nd
	Fatigue		No	Yes	MDC(90) 1.97-9.53, MDC(95) 2.35-11.36			nd	nd
	Pain intensity		No	Yes	MDC(90) 1.97-9.53, MDC(95) 2.35-11.36			12%	nd
	Pain interference		No	Yes	MDC(90) 1.97-9.53, MDC(95) 2.35-11.36			28%	nd
	Physical function		No	Yes	MDC(90) 1.97-9.53, MDC(95) 2.35-11.36			nd	14%
	Sleep disturbance		No	Yes	MDC(90) 1.97-9.53, MDC(95) 2.35-11.36			nd	nd
	Social role satisfaction		No	Yes	MDC(90) 1.97-9.53, MDC(95) 2.35-11.36			nd	16%
	Physical function	Hafner 2017 27590443	No						
PROS		Hart 1999 (J Prosthet Orthot)	Yes						

Abbreviations: MC = Medicare, MDC(90/95) = minimal detectable change (at 90/95% confidence), MID = minimum (clinical) important difference, nd = no data/not reported, PMID = PubMed identifier (or journal), PROMIS = Patient-Reported Outcomes Measurement Information System, PROS = Prosthetist's Perception of Client's Ambulatory Abilities.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

PSFS

The Patient-Specific Functional Scale is an individualized assessment of patient-specific activities that they find difficult to perform due to their amputation and how they would rate their current abilities to complete those activities. One study[37] evaluated the psychometric properties of the PSFS in 44 people with lower limb amputations (see Tables 33 to 35). The study was deemed to be generalizable to the Medicare population for the average age of participants (66 years) although the percentage of study participants with dysvascular disease not reported.

The study provided evidence of reliability, an MDC(90) of 11.2, and no floor nor ceiling effects.

Overall, for PSFS, in a study generalizable to the Medicare population there is evidence of reliability without a floor or ceiling effect.

Q-TFA

The Questionnaire for Persons with a Transfemoral Amputation measures Prosthetic Use, Prosthetic Mobility, Problem, and Global Health as separate scores for nonelderly transfemoral amputees. One study[66] evaluated the psychometric properties of the Q-TFA in 156 people with lower limb amputations (see Tables 33 to 35). The study was not deemed to be generalizable to the Medicare population based on average age less than 65 years and the percentage of study participants with dysvascular disease not being reported.

The study reported convergent validity compared with the SF-36 and the PCS. As predicted, the SF-36 MCS did not have convergent validity with Q-TFA. The subscales Prosthetic Use, Prosthetic Mobility, and Problem were found to be reliable, but not Global Health. A ceiling effect was found for the Prosthetic Use subscale (31%), but not the other subscales.

Overall, for Q-TFA, from a study not generalizable to the Medicare population, there is evidence of test validity, reliability for the subscales Prosthetic Use, Prosthetic Mobility, and Problems, but not Global Health, and a ceiling effect for just the Prosthetic Use subscale.

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. One study[56] evaluated the psychometric properties of the Rising and Sitting Down Questionnaire in 171 people with lower limb amputations (see Tables 33 to 35). The study was deemed to be generalizable to the Medicare population for the average age of participants (65 years) and the relatively high percentage of study participants with dysvascular disease (83%).

The study reported convergent validity compared with the LCI, the Climbing Stairs Questionnaire, and the Walking Questionnaire. The study also provided evidence of reliability.

Overall, for the Rising and Sitting Down Questionnaire, from a study generalizable to the Medicare population, there is evidence of test validity and reliability.

RMI

The Rivermead Mobility Index assesses mobility as a cumulative index. Three studies[48, 67, 68] evaluated the psychometric properties of the RMI in 390, total, people with lower limb amputations (see Tables 33 to 35). One of the studies was deemed to be generalizable to the

Medicare population based on the relatively high percentage of study participants with dysvascular disease (53%) although the average age in all three studies was less than 65 years.

The studies reported convergent validity compared with the FIM Motor subscale, TWT, LCI and LCI-5, and the RMI. Structural validity of the RMI was supported in one of the studies through Rasch analysis; most items fit the model, but some redundancy was observed. Two of the studies provided evidence of reliability for RMI, and evidence of responsiveness was found in one (effect size of 1.35). No floor or ceiling effects were observed.

Overall, for RMI, there is evidence, including from a study generalizable to the Medicare population, of test validity, reliability, responsiveness, and no floor or ceiling effect.

SAT-PRO

The Satisfaction with Prosthesis Questionnaire is a self-report tool measuring satisfaction with a prosthesis. One study[69] evaluated the psychometric properties of the SAT-PRO in 61 people with lower limb amputations (see Tables 33 to 35). The study was deemed to be generalizable to the Medicare population based on the average age of participants (71 years) and that all participants had dysvascular disease (100%).

The study reported evidence of reliability for the SAT-PRO.

Overall, for SAT-PRO, from a study generalizable to the Medicare population, there is evidence of reliability.

SCS

The Socket Comfort Score is a one-item measure of prosthetic socket comfort. Two studies[41, 70] evaluated the psychometric properties of the SCS in 93 people with lower limb amputations (see Tables 33 to 35). One study was deemed to be generalizable to the Medicare population for the average age of participants (67 years) and the relatively high percentage of study participants with dysvascular disease (66%); the other study was not deemed generalizable to the Medicare population based on average age less than 65 years and the relatively low percentage of study participants with dysvascular disease (23%).

The study generalizable to the Medicare population reported construct validity between the SCS and a prosthesis fit assessment conducted by a prosthetist or physician. Both studies provided evidence of reliability. One of the studies reported the minimal detectable change at 90% confidence, MDC(90), for ranging from 2.31 to 3.03; the MDC(95) ranged from 2.75 to 3.61. Neither floor nor ceiling effects were observed.

Overall, for the SCS, there is evidence of test validity and reliability from a study generalizable to the Medicare population. Another study provided evidence of a lack of floor or ceiling effect.

Table 33. Study descriptive data: PSFS through SCS

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
PSFS		Resnik 2011 21310896	44	66 (13)	nd	nd	52	43	100	0
Q-TFA	Global health Prosthetic use Prosthetic mobility Problem	Hagberg 2004 15558399	156	51 (13.1)	8	55	100	0	100	0
Rising and Sitting Down Questionnaire		de Laat 2011 21807151	171	65 (11) [37-92]	83	8	32	54	93	7
RMI		Franchignoni 2003 12809197	140	57 (18)	53	32	56	44	100	0
		Franchignoni 2004 15129398	50	51 [21-86]	32	58	60	40	100	0
		Ryall 2003 12648004	200	57.2 (17.7) [13-90]	32	40	41	57	88	13
SAT-PRO		Bilodeau 1999 10462879	61	71.3 (6.3)	100	0	44	56	100	0
SCS		Hafner 2016 28273329	201	60.2 (11.4)	23	60	35	65	nd	nd
		Hanspal 2003 14617445	44	66.8 (13.0)	66	23	41	73	84	16

Abbreviations: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), nd = no data/not reported, PMID = PubMed identifier (or journal), PSFS = Patient-Specific Functional Scale, Q-TFA = Questionnaire for Person with a Transfemoral Amputation, RMI = Rivermead Mobility Index, SAT-PRO = Satisfaction with Prosthesis Questionnaire, SCS = Socket Comfort Score, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoraland transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 34. Summary of instrument psychometric validity properties: PSFS through SCS

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
PSFS		Resnik 2011 21310896	Yes					
Q-TFA	Global health	Hagberg 2004 15558399	No	Yes (SF-36)				
	Prosthetic use		No	Yes (PCS), Mixed (MCS), as predicted				
	Prosthetic mobility		No	Yes (PCS), Mixed (MCS), as predicted				
	Problem		No	Yes (SF-36)				
Rising and Sitting Down Questionnaire		de Laat 2011 21807151	Yes	Yes (LCI, Climbing Stairs Questionnaire, Walking Questionnaire)				
RMI		Franchignoni 2003 12809197	Yes	Yes (FIM motor, TWT)				
		Franchignoni 2004 15129398	No	Yes (LCI, LCI-5, RMI)				
		Ryall 2003 12648004	No	Yes (TWT)			Rasch: Most items fit model but some redundancy	
SAT-PRO		Bilodeau 1999 10462879	Yes	.			.	
SCS		Hafner 2016 28273329	No					
		Hanspal 2003 14617445	Yes			Yes (Prosthetist/Physician fit assessment)		

Abbreviations: FIM = Functional Independence Measure, LCI = Locomotor Capabilities Index, MC = Medicare, MCS = Mental Component Score, PCS = Physical Component Score, PMID = PubMed identifier (or journal), PSFS = Patient-Specific Functional Scale, Q-TFA = Questionnaire for Person with a Transfemoral Amputation, RMI = Rivermead Mobility Index, SAT-PRO = Satisfaction with Prosthesis Questionnaire, SCS = Socket Comfort Score, SF-36 = Short Form Health Survey-36, TWT = Timed Walk Test.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 35. Summary of other instrument psychometric properties: PSFS through SCS

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
PSFS	.	Resnik 2011 21310896	Yes	Yes	MDC(90) 11.2			No effect	No effect
Q-TFA	Global health	Hagberg 2004 15558399	No	No				1%	5%
	Prosthetic use		No	Yes				0%	31%
	Prosthetic mobility		No	Yes				0%	0%
	Problem		No	Yes				0%	0%
Rising and Sitting Down Questionnaire		de Laat 2011 21807151	Yes	Yes					
RMI		Franchignoni 2003 12809197	Yes	Yes			Yes (ES = 1.35)	0%	0%
		Franchignoni 2004 15129398	No						
		Ryall 2003 12648004	No	Yes				0% (implied)	11%
SAT-PRO		Bilodeau 1999 10462879	Yes	Yes				.	.
SCS		Hafner 2016 28273329	No	Yes	MDC(90) 2.31-3.03, MDC(95) 2.75-3.61			nd	14%
		Hanspal 2003 14617445	Yes	Yes					

Abbreviations: ES = effect size, MC = Medicare, MDC(90/95) = minimal detectable change (at 90/95% confidence), MID = minimum (clinical) important difference, nd = no data/not reported, PMID = PubMed identifier (or journal), PSFS = Patient-Specific Functional Scale, Q-TFA = Questionnaire for Person with a Transfemoral Amputation, RMI = Rivermead Mobility Index, SAT-PRO = Satisfaction with Prosthesis Questionnaire, SCS = Socket Comfort Score.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

SF-12/SF-36/SF-36V

The Short Form Health Surveys (SF-12 and SF-36) are generic measures of health-related quality of life (QoL) designed originally for the general population; the Short Form Health Survey-36 for use with veterans (SF-36V, also known as VR-36) is an adaptation designed for assessing the health status among the veteran population. The SF instruments can be scored as two summary measures, called the physical component score (PCS) and the mental component score (MCS) and include subscales (including 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, as subscales, and parsed into numerous components subsets (from pairs of specific questions to the whole score). Two studies[37, 65] evaluated the psychometric properties of the SF-12, SF-36, and SF-36V in 884 people with lower limb amputations (see Tables 36 to 38). Both studies were deemed to be generalizable to the Medicare population either for the average age of participants (66 years) or a relatively high percentage of study participants with dysvascular conditions (58%).

SF-12

One study provided evidence that the SF-12 subscale PCS did not have convergent validity with PROS in people who were being evaluated for their first or replacement prosthesis.[65] Rasch analysis of the SF-12 PCS supported clinically logical hierarchical ordering of the items within the subscale. The other subscales were not evaluated for convergent validity or by Rasch analysis. The SF-12 PCS, Role Physical (RP-2), and Bodily Pain (BP-2) discriminated among people by K level. The other evaluated scales did not (MCS, Role Emotional, and Mental Health). Test reliability was reported for RE-2, RP-2, BP-2, and MH-2.

SF-36

One study provided evidence that the SF-36 subscale PF-10 (10-item Physical Functioning score) did not have convergent validity with the PROS in people who were being evaluated for their first or replacement prosthesis.[65]) There was mixed evidence of divergent validity in discrimination by K levels for SF-36, such that the instrument differentiated three of the six possible pairs of K levels. One study provided evidence of structural validity for both. Rasch analysis supporting clinically logical hierarchical ordering of the items for PF-10 and PF-15 (a newly created15-item Physical Functioning score), but better fit was observed for PF-15 than PF-10.

SF-36V

One study provided evidence of reliability for all three subscales of the SF-36V. The study reported MDC(90) estimates for the subscales. Neither floor nor ceiling effects were observed for General Health or for Physical Function, but there was a ceiling effect for Role Physical (18%).

Overall

The evidence supporting test validity of the SF instruments in the lower limb amputee population is mixed in studies generalizable to the Medicare population. There is evidence of test

validity for: SF-12 PCS, Role Physical, Bodily Pain, and PF-15. There was also test validity for PF-10, but it performed poorer than a newly created PF-15. Studies have not provided evidence of test validity for Role Emotional or Mental Health. SF-36V has not been assessed for test validity. Evidence of reliability has been reported for PCS, Role Emotional, Role Physical, Bodily Pain, Mental Health, and three aspects of SF-36V. A ceiling effect has been reported for SF-36V Role Physical; the General Health, and Physical Functioning subscales did not have floor or ceiling effects.

SIGAM

The Special Interest Group of Amputation Medicine scale measures ambulation mobility (with walking aids if necessary) among lower limb amputees. Three studies (in two articles)[71, 72] evaluated the psychometric properties of the SIGAM in 267 people, total, with lower limb amputations (see Tables 36 to 38). One of the studies was deemed to be generalizable to the Medicare population due to the average age of participants (66 years); although the study did not report the number of participants with dysvascular etiologies for their amputations. The remaining two studies were not deemed to be generalizable to the Medicare population due to their relatively low average ages (57 and 61 years) and low percentages of study participants with dysvascular conditions (32% and 17%).

The one study deemed generalizable to the Medicare population provided evidence that the SIGAM had convergent validity with the Walking Questionnaire. One study provided evidence of structural validity through Rasch analysis supporting calibration between the SIGAM and RMI and an acceptable infit and outfit for the SIGAM. Two studies provided evidence of reliability and one study provided evidence of responsiveness with an effect size of 10.66. No floor or ceiling effect were reported.

Overall, for SIGAM, there is evidence of test validity, including from a study generalizable to the Medicare population. From a study not generalizable to the Medicare population, there is also evidence of test reliability, responsiveness, and no floor or ceiling effect.

Single Beam Test

The Single Beam Test is measure of balance performance on three beams each 5.5 meters long. The three beams are narrow, intermediate width, or wide. One study[69] evaluated the psychometric properties of the Single Beam Test in 93 people with lower limb amputations (see Tables 36 to 38). The study was not deemed to be generalizable to the Medicare population based on average age less than 65 years (47 years); the percentage of study participants with dysvascular disease was not reported.

The study provided evidence of a large floor effect (“too easy”) for the wide (87%) and intermediate (40%) beams. The narrow beam had a large ceiling effect (32% “too hard”), but no ceiling effect was observed for the wide or intermediate beams. Of note, the study reported that “each participant had at least one beam that was appropriately challenging to assess his or her balance ability."

Overall, for the Single Beam Test, from a study not generalizable to the Medicare population, across the three beams there is no floor or ceiling effect.

Table 36. Study descriptive data: Short Form Health Surveys through Single Beam Test

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
Short Form Health Surveys	SF-12: MCS PCS Role emotional (RE-2) Role Physical (RP-2) Bodily Pain (BP-2) Mental Health (MH-2)	Hart 1999 (J Prosthet Orthot)	840	56.3 (~17)	58	19	73	nd	nd	19
	SF-36: Physical functioning (PF-15) Physical functioning (PF-10)	Hart 1999 (J Prosthet Orthot)	840	56.3 (~17)	58	19	73	nd	nd	19
	SF-36V: General health Physical functioning Role physical	Resnik 2011 21310896	44	66 (13)	nd	nd	52	43	100	0
SIGAM		de Laat 2012 22424695	34	65 (11) [37-92]	nd	nd	nd	nd	nd	nd
		Ryall 2002 12851094 - Study 1	200	57.2 (17.7) [13-90]	32	40	41	57	88	13
		Ryall 2002 12851094 - Study 2	33	60.7 (14.5)	17	12	48	48	100	0
Single Beam Test	Wide Beam Intermediate Beam Narrow Beam	Sawers 2017 28948848	30	47.0 (14.4)	nd	nd	37	63	100	0

Abbreviations: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), MCS = Mental Component Score, nd = no data/not reported, PCS = Physical Component Score, PMID = PubMed identifier (or journal), SF-12 = Short Form Health Survey-12, SF-36 = Short Form Health Survey-36, SF-36V = Short Form Health Survey-36 adapted for veterans, SIGAM = Special Interest Group of Amputation Medicine scale, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 37. Summary of instrument psychometric validity properties: Short Form Health Surveys through Single Beam Test

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
Short Form Health Surveys	SF-12: MCS	Hart 1999 (J Prosthet Orthot)	Yes		No (K levels)			
	SF-12: PCS		Yes		Yes (K levels)		Rasch: Clinically logical hierarchical ordering	
	SF-12: Role emotional (RE-2)		Yes		No (K levels)		.	
	SF-12: Role physical (RP-2)		Yes		Yes (K levels)		.	
	SF-12: Bodily pain (BP-2)		Yes		Yes (K levels)		.	
	SF-12: Mental Health (MH-2)		Yes		No (K levels)		.	
	SF-36: Physical functioning (PF-15)		Yes		.		Rasch: Clinically logical hierarchical ordering, better fit than PF-10	
	SF-36: Physical functioning (PF-10)	.	Yes	No (PROS)	Mixed (K levels)		Rasch: Clinically logical hierarchical ordering	
	SF-36V: General health Physical functioning Role physical	Resnik 2011 21310896	Yes	.				
SIGAM		de Laat 2012 22424695	Yes	Yes (Walking Questionnaire)				
		Ryall 2002 12851094 - Study 1	No				Rasch: Calibrates to RMI, acceptable infit and outfit	
		Ryall 2002 12851094 - Study 2	No				.	

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
Single Beam Test	Wide Beam Intermediate Beam Narrow Beam	Sawers 2017 28948848	No					

Abbreviations: K level = Medicare Functional Classification Level, MC = Medicare, MCS = Mental Component Score, PCS = Physical Component Score, PMID = PubMed identifier (or journal), PROS = prosthetist's perception of client's functional abilities, RMI = Rivermead Mobility Index, SF-12 = Short Form Health Survey-12, SF-36 = Short Form Health Survey-36, SF-36V = Short Form Health Survey-36 adapted for veterans, SIGAM = Special Interest Group of Amputation Medicine scale.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells (with ".") in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 38. Summary of other instrument psychometric properties: Short Form Health Surveys through Single Beam Test

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
Short Form Health Surveys	SF-12: MCS	Hart 1999 (J Prosthet Orthot)	Yes						
	SF-12: PCS	.	Yes	Yes					
	SF-12: Role emotional (RE-2)	.	Yes	Yes					
	SF-12: Role physical (RP-2)	.	Yes	Yes					
	SF-12: Bodily pain (BP-2)	.	Yes	Yes					
	SF-12: Mental Health (MH-2)	.	Yes	Yes					
	SF-36: Physical functioning (PF-15) Physical functioning (PF-10)		Yes	.					
	SF-36V: General health	Resnik 2011 21310896	Yes	Yes	MDC(90) 17.1			No effect	No effect
	SF-36V: Physical functioning		Yes	Yes	MDC(90) 34.2			No effect	No effect
	SF-36V: Role physical		Yes	Yes	MDC(90) 26.3			3%	18%
SIGAM	.	de Laat 2012 22424695	Yes						
	.	Ryall 2002 12851094 - Study 1	No	Yes				6.5% floor or ceiling	
	.	Ryall 2002 12851094 - Study 2	No	Yes			Yes (ES = 10.66)		
Single Beam Test	Wide Beam	Sawers 2017 28948848	No					87%	0%
	Intermediate Beam		No					40%	10%
	Narrow Beam		No					3%	32%

Abbreviations: ES = effect size, MC = Medicare, MDC(90) = minimal detectable change (at 90% confidence), MID = minimum (clinical) important difference, PMID = PubMed identifier (or journal), SF-12 = Short Form Health Survey-12, SF-36 = Short Form Health Survey-36, SF-36V = Short Form Health Survey-36 adapted for veterans, SIGAM = Special Interest Group of Amputation Medicine scale.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

SIP-PD

The Sickness Impact Profile-Physical Dimension is a generic, self-report measure used to assess the impact of illness on health-related functional status. The instrument can be scored in total and has three subscales: Ambulation, Body Care and Movement, and Mobility. One study[55] evaluated the psychometric properties of the SIP-PD in 107 people with lower limb amputations (see Tables 39 to 41). The study was not deemed to be generalizable to the Medicare population; the average age of participants was 35 years old and no participants had dysvascular etiologies for their amputations.

The study provided evidence of moderate convergent validity between the overall SIP-PD instrument and both LCI and PFI. The overall instrument and the subscales of Ambulation, Body care and movement, and Mobility did not discriminate based on amputation level, injury severity score, age, or comorbidities. There was evidence of construct validity for the three subscales and the overall instrument when compared to walking speed and return to usual activity (except that the Ambulation subscale did not correlate with return to usual activity). The total instrument and the three subscales were found to have reliability, but not responsiveness for walking speed or return to usual activity. Floor effects were observed for the subscales of Ambulation (16%), Body care and movement (36%), and Mobility (64%), but not for the overall instrument; no ceiling effects were observed.

Overall, for SIP-PD, there is evidence of test validity and reliability, but not responsiveness, for the overall instrument and its three subscales. The three subscales, but not the overall instrument, were reported to have floor effects. However, these findings are not generalizable to the Medicare population.

Tandem Test

The Tandem Test measures duration of maintaining a full-tandem stance without support, with the amputated limb placed behind the unaffected limb. One study[29] evaluated the psychometric properties of the Tandem Test in 64 people with lower limb amputations (see Tables 39 to 41). The study was deemed to be generalizable to the Medicare population based on the high percentage of study participants with dysvascular disease (66%); although the average age was under 65 years old.

The study reported that the Tandem Test did not have divergent validity to discriminate people based on the Houghton Scale. Large floor and ceiling effects were observed (each 44%).

Overall, for the Tandem Test, there is *not* evidence of test validity and the instrument has large floor and ceiling effects in a study generalizable to the Medicare population.

Table 39. Study descriptive data: SIP-PD through Tandem Test

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
SIP-PD	Ambulation Body care and movement Mobility Total (Overall)	Cyril 2001 (Johns Hopkins)	107	35 (12.5)	0	100	21	67	100	0
Tandem Test	.	Gremeaux 2012 22389424	64	58 (16)	66	25	27	73	100	0

Abbreviation: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), nd = no data/not reported, PMID = PubMed identifier (or journal), SIP-PD = Sickness Impact Profile-Physical Dimension, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 40. Summary of instrument psychometric validity properties: SIP-PD through Tandem Test

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
SIP-PD		Cyril 2001 (Johns Hopkins)	No	Moderate (LCI, PFI)	No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed, return to usual activity)		
	Ambulation		No		No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed), No (return to usual activity)		
	Body care and movement		No		No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed, return to usual activity)		
	Mobility		No		No (amputation level, injury severity score, age, comorbidities)	Yes (walking speed, return to usual activity)		
Tandem Test		Gremeaux 2012 22389424	Yes		No (Houghton)			

Abbreviations: LCI = Locomotor Capabilities Index, MC = Medicare, PFI = Physical Function Index, PMID = PubMed identifier (or journal), SIP-PD = Sickness Impact Profile-Physical Dimension.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells (with ".") in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 41. Summary of other instrument psychometric properties: SIP-PD through Tandem Test

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
SIP-PD	Ambulation	Cyril 2001 (Johns Hopkins)	No	Yes			No (walking speed, return to usual activity)	16.0%	0%
	Body care and movement		No	Yes			No (walking speed, return to usual activity)	36.4%	0%
	Mobility		No	Yes			No (walking speed, return to usual activity)	63.6%	0%
	Total (Overall)		No	Yes			No (walking speed, return to usual activity)	12.1%	0%
Tandem Test		Gremeaux 2012 22389424	Yes	.				44%	44%

Abbreviations: MC = Medicare, MDC = minimal detectable change, MID = minimum (clinical) important difference, PMID = PubMed identifier (or journal), SIP-PD = Sickness Impact Profile-Physical Dimension.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare\ population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

TAPES

The Trinity Amputation and Prosthesis Experience Scales is a multidimensional self-report instrument that evaluates the experience of amputation and adjustment to a lower limb prosthesis. Two studies[73, 74] the psychometric properties of the TAPES in 123 people, total, with lower limb amputations and a third study[75] evaluated the revised version of the TAPES (TAPES-R) in 359 people with lower limb amputations (see Tables 42 to 44). The original TAPES has three main sections: Psychomotor, Activity Restriction, and Prosthesis Satisfaction. Each of these has three different aspects, as listed in the tables. The revised version had items divided somewhat differently, as listed in the tables. The three studies were not deemed to be generalizable to the Medicare population due to their relatively low average ages (47-55 years) and low percentage of study participants with dysvascular conditions (<50%).

TAPES (Original)

The studies provided evidence that the TAPES subscales mostly had convergent validity with several other tests (WHOQOL-BREF, Impact of Events Scale, TMMS), in at least one study. Satisfaction with weight was evaluated only in one study and was not reported to have convergent validity with WHOQOL-BREF. Several subscales had construct validity in regards to the number of hours per day of prosthesis worn , including General adjustment, Functional restriction, Social restriction, Athletic restriction, and Functional satisfaction. One study reported evidence of reliability for each of the TAPES subscales.

TAPES-R

The revised version of the Trinity Amputation and Prosthesis Experience Scales (TAPES-R), like the original TAPES, evaluates the experience of amputation and adjustment to a lower limb prosthesis; the TAPES-R uses a simplified structure including reworded or removed items and changes to rating scales. The study of TAPES-R[75] provided evidence of structural validity for each of the subscales by Rasch analysis and of reliability for all the subscales except Satisfaction with Prostheses Subscale 1, which included four items about esthetics (color, shape, and appearance).

Overall

Overall, for both the original TAPES and the revised TAPES-R, there is evidence of test validity and reliability for the various subscales except Weight Satisfaction (which was reported to have reliability but not test validity) and the esthetic portion of the TAPES-R Satisfaction with Prosthesis Subscale (which lacked reliability). These findings are not generalizable to the Medicare population.

Table 42. Study descriptive data: TAPES

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
TAPES	Psychosocial: General Adjustment Psychosocial: Social Adjustment Psychosocial: Adjustment to Limitation Activity: Functional Restriction Activity: Social Restriction Activity: Athletic Restriction Satisfaction: Functional Satisfaction Satisfaction: Aesthetic Satisfaction	Gallagher 2000 (Rehab Psychol)	60	47.1 [19-84]	12	45	33	48	98	2
	Same as Gallagher 2000	Gallagher 2004 15129396	63	47.5 (18.4)	nd	43	40	57	100	0
	Revised (TAPES-R)	Gallagher 2010 20489393	359	54.8 (18.6)	49	47	47	80	94	6

Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

Abbreviations: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), nd = no data/not reported, PMID = PubMed identifier (or journal), TAPES = Trinity Amputation and Prosthesis Experience Scales, TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, Uni = unilateral amputation.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 43. Summary of instrument psychometric validity properties: TAPES

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
TAPES	Psychosocial: General Adjustment	Gallagher 2000 (Rehab Psychol)	No	Yes (WHOQOL-BREF psychological; IES intrusion, avoidance; TMMS clarity of feelings, repair)		Yes (hours worn per day)		
	Psychosocial: Social Adjustment		No	Yes (WHOQOL-BREF social relationships; IES intrusion, avoidance; TMMS clarity of feelings, repair)				
	Psychosocial: Adjustment to Limitation		No	Yes (WHOQOL-BREF physical health; IES intrusion, avoidance; TMMS clarity of feelings, repair)				
	Activity: Functional Restriction		No	Yes (WHOQOL-BREF physical health)		Yes (hours worn/day)		
	Activity: Social Restriction		No	Yes (WHOQOL-BREF social relationships)		Yes (hours worn/day)		
	Activity: Athletic Restriction		No	Yes (WHOQOL-BREF physical health)		Yes (hours worn/day)		
	Satisfaction: Functional Satisfaction		No	Yes (WHOQOL-BREF social relationships)		Yes (hours worn/day)		
	Satisfaction: Aesthetic Satisfaction		No	Yes (WHOQOL-BREF social relationships)				
	Satisfaction: Weight Satisfaction							
	Psychosocial: General Adjustment	Gallagher 2004 15129396	No	Yes (WHOQOL-BREF Physical health, Psychological health, Social relations, Environment)				
	Psychosocial: Social Adjustment		No	Yes (WHOQOL-BREF Psychological health, Social relations)				
	Psychosocial: Adjustment to Limitation		No	Yes (WHOQOL-BREF Physical health)				
	Activity: Functional Restriction		No	Yes (WHOQOL-BREF Physical health)				

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
	Activity: Social Restriction		No	No (WHOQOL-BREF subscales)				
	Activity: Athletic Restriction		No	No (WHOQOL-BREF subscales)				
	Satisfaction: Functional Satisfaction		No	No (WHOQOL-BREF subscales)				
	Satisfaction: Aesthetic Satisfaction		No	Yes (WHOQOL-BREF Psychological health)				
	Satisfaction: Weight Satisfaction		No	No (WHOQOL-BREF subscales)				
TAPES-R	Psychomotor Adjustment Subscale 1 (General Adjustment)	Gallagher 2010 20489393	No				Variance explained (Rasch) 65%	
	Psychomotor Adjustment Subscale 2 (Social Adjustment)		No				Variance explained (Rasch) 60%	
	Psychomotor Adjustment Subscale 3 (Adjustment to Limitation)		No				Variance explained (Rasch) 64%	
	Activity Restriction		No				Variance explained (Rasch) 95%	
	Satisfaction with Prosthesis Subscale 1		No				Variance explained (Rasch) 55%	
	Satisfaction with Prosthesis Subscale 2		No				Variance explained (Rasch) 62%	

Abbreviations: IES = Impact of Events Scale, MC = Medicare, PMID = PubMed identifier (or journal), TAPES = Trinity Amputation and Prosthesis Experience Scales, TAPES-R = Trinity Amputation and Prosthesis Experience Scales-Revised, TMMS =Trait Meta Mood Scale, WHOQOL-BREF = World Health Organization Quality of Life-Brief Version.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells (with ".") in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 44. Summary of other instrument psychometric properties: TAPES

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
TAPES	Psychosocial: General Adjustment	Gallagher 2000 (Rehab Psychol)	No	Yes					
	Psychosocial: Social Adjustment		No	Yes					
	Psychosocial: Adjustment to Limitation		No	Yes					
	Activity: Functional Restriction		No	Yes					
	Activity: Social Restriction		No	Yes					
	Activity: Athletic Restriction		No	Yes					
	Satisfaction: Functional Satisfaction		No	Yes					
	Satisfaction: Aesthetic Satisfaction		No	Yes					
	Satisfaction: Weight Satisfaction		No	Yes					
		Gallagher 2004 15129396	No						
TAPES-R	Psychomotor Adjustment Subscale 1 (General Adjustment)	Gallagher 2010 20489393	No	Yes					
	Psychomotor Adjustment Subscale 2 (Social Adjustment)		No	Yes					
	Psychomotor Adjustment Subscale 3 (Adjustment to Limitation)		No	Yes					
	Activity Restriction		No	Yes					
	Satisfaction with Prosthesis Subscale 1 (items 1-4)		No	No					
	Satisfaction with Prosthesis Subscale 2 (items 5-9)		No	Yes					

Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells (with ".") in the psychometric properties columns indicate no evidence regarding this construct.

Abbreviations: MC = Medicare, MDC = minimal detectable change, MID = minimum (clinical) important difference, PMID = PubMed identifier (or journal), TAPES = Trinity Amputation and Prosthesis Experience Scales, TAPES-R = Trinity Amputation and Prosthesis Experience Scales-Revised.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

TFP

The Transfemoral Fitting Predictor is a 9-item instrument with two subscales that describes graded tasks and aims to assess the prosthetic potential of transfemoral amputees. One study[69] evaluated the psychometric properties of the TFP in 93 people with lower limb amputations (see Tables 45 to 47). The study was deemed to be generalizable to the Medicare population based on average age greater than 65 years and a high percentage of study participants with dysvascular disease (94%).

The study provided evidence of construct validity as the TFP at initial assessment correctly classified 90% of those who went on to LLP or not. The study also found evidence of structural validity for the TFP with 74% of the variance explained by principal component analysis (PCA), and excellent reliability.

Overall, for TFP, from a study generalizable to the Medicare population, there is evidence of test validity and reliability.

TUG

The Timed Up and Go test measures the amount of time it takes an amputee to get up from an armless chair. Ten studies[7, 29, 34-38, 40, 76, 77] evaluated the psychometric properties of the TUG in 850 people, total, with lower limb amputations (see Tables 45 to 47). Five of the studies were deemed to be generalizable to the Medicare population based on average age greater than 65 years or high percentage of study participants with dysvascular disease.[7, 29, 34, 37, 77]

The studies reported evidence of convergent validity when compared with several other instruments, including ABC, PLUS-M, the 2MWT and 6MWT, the Groningen Activity Restriction Scale, PEQ-MS, BBS, and the mobility control subscale of SIP. There was not convergent validity with TAPES or other subscales of SIP. TUG discriminated among people based on Houghton Scale (in one of two studies), K level, age, and time with prosthesis. Two studies had different findings related to whether TUG discriminated people based on amputation level. One study, generalizable to the Medicare population, reported predictive validity when predicting the number of falls (≥2 falls) at 6 months after testing (sensitivity 85% and specificity 74%). Studies found evidence of reliability and two studies reported MDC(90) to be 1.3 or 3.6 seconds No floor or ceiling effects were reported in a single study generalizable to the Medicare population.

Overall, for TUG, there is evidence in studies generalizable to the Medicare population of test validity, including predictive validity for falls 6 months after testing, and reliability without a floor or ceiling effect.

Table 45. Study descriptive data: TFP through TUG

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
TFP		Condie 2011 21807149	93	68.8 (10.6)	94	nd	100	0	100	0
TUG		Clemens 2017 28862042	118	48 (13.7)	nd	nd	53	47	100	0
		Dite 2007 17207685	40	61.7 (nd)	65	nd	0	100	100	0
		Gremeaux 2012 22389424	64	58 (16)	66	25	27	73	100	0
		Hafner 2017 27590443	199	55.4 (14.3)	44	41	18	76	100	0
		Miller 2003 12736877	50	58.0 (15.8)	58	nd	24	76	100	0
		Newton 2016 (Eur J Physiother)	37	57.6 (7.6)	nd	nd	24	76	100	0
		Reid 2015 25588644	86	60 (15.3)	35	48	15	73	97	3
		Resnik 2011 21310896	44	66 (13)	nd	nd	52	43	100	0
		Schoppen 1999 10414769	32	73.3 (nd)	nd	nd	16	84	100	0
		Wong 2016 26874230	180	55.5 (16.0)	49	51	44	56	81	13

Abbreviations: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), nd = no data/not reported, PMID = PubMed identifier (or journal), TF = transfemoral (above the knee) amputation, TFP = Transfemoral Fitting Predictor, TT = transtibial (below the knee) amputation, TUG = Timed Up and Go, Uni = unilateral amputation.

*Mean or median with standard deviation in parentheses and range in square brackets.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 46. Summary of instrument psychometric validity properties: TFP through TUG

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
TFP		Condie 2011 21807149	Yes			Correctly classifies those who went on to LLP or not LLP 90.3%	Yes (PCA)	
TUG		Clemens 2017 28862042	No	Yes (PLUS-M, ABC)	Yes (TT vs. TF)			
		Dite 200717207685	Yes		.			Yes (falls at 6 mo)
		Gremeaux 2012 22389424	Yes		No (Houghton)			
		Hafner 2017 27590443	No		Yes (K levels)			
		Miller 2003 12736877	Yes	Yes (ABC)				
		Newton 2016 (Eur J Physiother)	No	No (TAPES)	Yes (age, time with prosthesis), No TT vs. TF)			
		Reid 2015 25588644	No	Yes (6MWT)				
		Resnik 2011 21310896	Yes					
		Schoppen 1999 10414769	Yes	Yes (GARS, SIP mobility control), No SIP other subscales				
		Wong 2016 26874230	No	Yes (PEQ-MS, ABC, 3-BBS, 2MWT)	Yes (Houghton)			

Abbreviations: 2MWT = 2 minute walk test, 3-BBS = total sum score of 3 Berg Balance Scale items, 6MWT = 6 minute walk test, ABC = Activities-Specific Balance Confidence scale, GARS = Groningen Activity Restriction Scale, K level = Medicare Functional Classification Level, LLP = lower limb prosthesis, MC= Medicare, mo = months, PCA = Principal Component Analysis, PEQ-MS = Prosthesis Evaluation Questionnaire motor score, PLUS-M = Prosthetic Limb Users Survey of Mobility, PMID = PubMed identifier (or journal), SIP = Sickness Impact Profile, TAPES = Trinity Amputation and Prosthesis Experience Scales, TF = transfemoral (above the knee) amputation, TFP = Transfemoral Fitting Predictor, TT = transtibial (below the knee) amputation, TUG = Timed Up and Go test, TWT = Timed Walk Test.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 47. Summary of other instrument psychometric properties: TFP through TUG

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
TFP		Condie 2011 21807149	Yes	Yes					
TUG		Clemens 2017 28862042	No	Yes	MDC(90) 1.28 sec				
		Dite 2007 17207685	Yes						
		Gremeaux 2012 22389424	Yes					0%	0%
		Hafner 2017 27590443	No						
		Miller 2003 12736877	Yes						
		Newton 2016 (Eur J Physiother)	No						
		Reid 2015 25588644	No						
		Resnik 2011 21310896	Yes	Yes	MDC(90) 3.6 sec				
		Schoppen 1999 10414769	Yes	Yes					
		Wong 2016 26874230	No						

Abbreviations: MC = Medicare, MDC(90) = minimal detectable change (at 90% confidence), MID = minimum (clinical) important difference, PMID = PubMed identifier (or journal), sec = seconds, TFP = Transfemoral Fitting Predictor, TUG = Timed Up and Go test.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells (with ".") in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

TWT

The Timed Walking Test measures the time to walk 5 meters forward, turn 180 degrees, and walk 5 meters back to the starting point, with the use of any usual walking aids necessary. Two studies[68, 72] evaluated the psychometric properties of the TWT in 233 people, total, with lower limb amputations (see Tables 48 to 50). The studies were not deemed to be generalizable to the Medicare population due to relatively low average age (57 and 61 years) and relatively few people with dysvascular conditions (27% and 32%).

One study provided evidence that the TWT had good convergent validity when compared with RMI. Evidence of responsiveness was found in one study with an effect size of 8.56.

Overall, for TWT, there is evidence of test validity and responsiveness from studies not generalizable to the Medicare population.

Walking Questionnaire

The Walking Questionnaire is a self-report measure of activity limitations when walking inside and outside the house. One study[71] evaluated the psychometric properties of the Walking Questionnaire in 172 people with lower limb amputations (see Tables 48 to 50). The study was deemed to be generalizable to the Medicare population based on average age of 65 years and a high percentage of study participants with dysvascular disease (83%).

The study found evidence of moderate convergent validity when compared with several other tests including LCI, PPA, RSQ, and CSQ. The study found the Walking Questionnaire to have good reliability.

Overall, for the Walking Questionnaire there is evidence from a study generalizable to the Medicare population of test validity and reliability.

WHOQOL-BREF

The World Health Organization Quality-of-Life Scale – Brief Version is an instrument measuring the quality of life of amputees. The instrument has several subscales, including: environment, physical health, psychological, social relationships, and general health and overall quality of life. One study[73] evaluated the psychometric properties of the WHOQOL-BREF in 63 people with lower limb amputations (see Tables 48 to 50). The study not deemed to be generalizable to the Medicare population, with a relatively low average age (47 years) and an unreported percentage of people with dysvascular conditions.

The study found all WHOQOL-BREF subscales had convergent validity when compared to TAPES.

Overall, for WHOQOL-BREF, from a study not generalizable to the Medicare population, there is evidence of test validity for the individual subscales.

Table 48. Study descriptive data: TWT through WHOQOL-BREF

Instrument	Item/Subscale	Study, PMID	N	Age*	Dysvasc†, %	Trauma†, %	TF†, %	TT†, %	Uni†, %	Bi†, %
TWT		Ryall 2002 12851094 - Study 2	33	60.7 (14.5)	27	12	48	48	100	0
		Ryall 2003 12648004	200	57.2 (17.7) [13-90]	32	40	41	57	88	13
Walking Questionnaire		de Laat 2012 22424695	172	65 (11) [37-92]	83	8	32	54	93	7
WHOQOL-BREF	Physical Health Psychological Health Social Relations Environmental	Gallagher 2004 15129396	63	47.5 (18.4)	nd	43	40	57	100	0

Abbreviations: Bi = bilateral amputation, Dysvasc = dysvascular disease (including diabetes), nd = no data/not reported, PMID = PubMed identifier (or journal), TF = transfemoral (above the knee) amputation, TT = transtibial (below the knee) amputation, TWT = Timed Walking Test, Uni = unilateral amputation, WHOQOL-BREF = World Health Organization Quality of Life-Brief Version.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated.

*Mean or median with standard deviation in parentheses and range in square brackets.

†Percentages of study participants with other amputation etiologies, amputation levels, and unreported etiologies, levels, or unilateral versus bilateral amputation are omitted from this summary table. See Appendix C for further details. Transfemoral and transtibial data may sum to more than 100% because of double counting of participants with bilateral amputations.

Table 49. Summary of instrument psychometric validity properties: TWT through WHOQOL-BREF

Instrument	Item/Subscale	Study, PMID	MC*	Convergent Validity (Concurrent)	Divergent Validity (Discriminant)	Construct Validity	Structural Validity	Predictive Validity †
TWT		Ryall 2002 12851094 - Study 2	No					
		Ryall 2003 12648004	No	Yes (RMI)	.	.	.	.
Walking Questionnaire		de Laat 2012 22424695	Yes	Yes (LCI, PPA, RSQ, CSQ)				
WHOQOL-BREF	Physical Health	Gallagher 2004 15129396	No	Yes (TAPES)				
	Psychological Health		No	Yes (TAPES)				
	Social Relations		No	Yes (TAPES)				
	Environmental		No	Yes (TAPES)				

Abbreviations: CSQ = Climbing Stairs Questionnaire, LCI = Locomotor Capabilities Index, MC = Medicare, PMID = PubMed identifier (or journal), PPA = Prosthetic Profile of the Amputee, RMI = Rivermead Mobility Index, RSQ = Questionnaire Rising and Sitting Down, TAPES = Trinity Amputation and Prosthesis Experience Scales, TWT = Timed Walk Test, WHOQOL-BREF = World Health Organization Quality of Life-Brief Version.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the validity columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Studies evaluated for predictive validity were assessed for Key Question 2.

Table 50. Summary of other instrument psychometric properties: TWT through WHOQOL-BREF

Instrument	Item/Subscale	Study, PMID	MC*	Reliability	MDC	MID	Responsiveness	Floor	Ceiling
TWT		Ryall 2002 12851094 - Study 2	No				Yes (ES 8.56)		
		Ryall 2003 12648004	No						
Walking Questionnaire		de Laat 2012 22424695	Yes	Yes					
WHOQOL-BREF		Gallagher 2004 15129396	No						

Abbreviations: ES = effect size, MC = Medicare, MDC = minimal detectable change, MID = minimum (clinical) important difference, PMID = PubMed identifier (or journal), TWT = Timed Walk Test, WHOQOL-BREF = World Health Organization Quality of Life-Brief Version.

Note: Shading included only to more clearly distinguish separate instruments. Empty cells under Item/Subscale indicate that there are no instrument items or subscales or they were not evaluated. Empty cells in the psychometric properties columns indicate no evidence regarding this construct.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

Key Question 1. Assessment Techniques

Key Points

- Twelve instruments have been evaluated as initial assessment tools
  - Eleven of the instruments have evidence of test validity from studies generalizable to the Medicare population
  - One instrument had evidence of test validity in a study not generalizable to the Medicare population

Based on explicit reporting within articles that instruments were evaluated at the time of initial assessment or prosthesis fitting, 10 studies evaluated 12 instruments as initial assessment tools (Table 51).[17, 28, 30, 32, 39, 48, 49, 65, 69] The evaluated instruments are:

- 1 Leg Standing Balance
- 2MWT (2 Minute Walk Test)
- AMPnoPRO (Amputee Mobility Predictor without use of prosthesis)
- FAC (Functional Ambulation Categories)
- FAI (Frenchay Activities Index)
- FIM (Functional Independence Measure)
- LCI (Locomotor Capabilities Index)
- LEMOCOT (Lower-Extremity Motor Coordination Test)
- OPCS (Office of Population Censuses and Surveys Scale)
- PROS (Prosthetist's Perception of Client's Ambulatory Abilities)
- SF-12 (Short Form Health Survey 12)
- TFP (Transfemoral Fitting Predictor)

Findings

Studies Generalizable to Medicare Population

Eleven of the instruments have evidence of test validity from studies generalizable to the Medicare population (i.e., study mean age ≥65 years or ≥50% of participants had dysvascular disease). These include 1 Leg Standing Balance, 2MWT, AMPnoPRO, FAC, FAI, FIM, LEMOCOT, OPCS, PROS, SF, and TFP. For SF, more specifically, test validity has been found for SF-12 Physical Component Score, SF-12 Role Physical, SF-12 Bodily Pain, SF-36 Physical Functioning (where a modified 15-item version performed better than the original 10-item version). Three of the 11 instruments were also reported to have evidence of test reliability when evaluated at initial assessment: AMPnoPRO, TMP, and for SF-12 the subscales for Role Emotional, Role Physical, Bodily Pain, and Mental Health.

Studies Not Generalizable to Medicare Population

One instrument, LCI, was evaluated at initial assessment only in a study that is not generalizable to the Medicare population. Both the LCI-4 and LCI-5 versions of the instrument were reported to have test validity, reliability, and responsiveness. Floor and ceiling percentages were reported for LCI-4, and no such effects were found.

Table 51. Summary of psychometric properties of instruments evaluated as initial assessment tools

Instrument	Study, PMID	MC*	Test Validity	Reliability	Responsiveness	Floor/Ceiling Effect
1 Leg Standing Balance	Eijk 2012 21958418 Spaan 2017 27770064	Yes	Yes			
2MWT	Brooks 2001 11588757	Yes	Yes			
AMPnoPRO	Gailey 2002 11994800	Yes	Yes	Yes		
FAC	Eijk 2012 21958418	Yes	Yes			
FAI	Eijk 2012 21958418	Yes	Yes			
FIM	Leung 1996 8831480 Panesar 2001 11330761	Yes	Yes			
LCI	Franchignoni 2004 15129398	No	Yes (LCI-4, LCI-5)	Yes (LCI-4, LCI-5)	Yes (LCI-4, LCI-5)	No (LCI-4)
LEMOCOT	Spaan 2017 27770064	Yes	Yes			
OPCS	Panesar 2001 11330761	Yes	Yes			
PROS	Hart 1999 (J Prosthet Orthot)	Yes	Yes			
SF-12 and SF-36	Hart 1999 (J Prosthet Orthot)	Yes	Mixed†	Yes‡		
TFP	Condie 2011 21807149	Yes	Yes	Yes		

Abbreviations: 2MWT = 2 minute walk test, AMPnoPRO = Amputee Mobility Predictor without use of a prosthesis, FAC = Functional Ambulation Categories, FAI = Frenchay Activities Index, FIM = Functional Independence Measure, LCI = Locomotor Capabilities Index, LEMOCOT = Lower-Extremity Motor Coordination Test, MC = Medicare, OPCS = Office of Population Censuses and Surveys Scale, PMID = PubMed identifier (or journal), PROS = prosthetist's perception of client's functional abilities, SF = Short Form Health Survey, TFP = Transfemoral Fitting Predictor.

Note: These assessments are specific to the studies that evaluated the instruments as initial assessment tools. The findings may differ from the overall findings among all studies that evaluated the instruments. Empty cells indicate no data.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†Evidence of test validity for SF-12 Physical Component Score, SF-12 Role Physical, SF-12 Bodily Pain, SF-36 Physical Functioning (15-item version performed better than 10-item version). Evidence of lack of test validity for SF-12 Mental Component Score, SF-12 Role Emotional, and SF-12 Mental Health.

‡SF-12 Role Emotional, Role Physical, Bodily Pain, and Mental Health. No data for other versions and subscales.

Key Question 2. Prediction Tools

Key Points

- Thirteen instruments have been evaluated as prediction tools
  - Twelve of the instruments have evidence of predictive validity from studies generalizable to the Medicare population
  - One instrument (and a variation of one of the other 12 instruments) had evidence of predictive validity studies not generalizable to the Medicare population

Findings

Based on reporting of metrics relevant to predictive validity, eight studies evaluated 13 instruments as prediction tools (Table 52).[7, 28, 30, 32, 39, 44, 48, 49] However, all but one study reported only correlations of the instrument results with occurrence or test scores at a future time point. Thus, these are not truly evaluations of the predictive accuracy of these instruments. One study, as described below, reported on diagnostic test accuracy (sensitivity and specificity) for several instruments. The evaluated instruments are:

- 1 Leg Standing Balance
- 180 Degree Turn Test
- 2MWT (2 Minute Walk Test)
- AMPnoPRO (Amputee Mobility Predictor without Prosthesis)
- AMPSIMM (Amputee Single Item Mobility Measure)
- FAC (Functional Ambulation Categories)
- FAI (Frenchay Activities Index)
- FIM (Functional Independence Measure)
- FSST (Four Square Step Test)
- LCI (Locomotor Capabilities Index)
- LEMOCOT (Lower-Extremity Motor Coordination Test)
- OPCS (Office of Population Censuses and Surveys Scale)
- TUG (Timed Up and Go)

Studies Generalizable to Medicare Population

Twelve instruments have been reported to have predictive validity in whole or in part in studies that are generalizable to the Medicare population (i.e., study mean age ≥65 years or ≥50% of participants had dysvascular disease). These include the 1 Leg Standing Balance, 180 Degree Turn Test, 2MWT, AMPnoPRO, FAC, FAI, FIM, FSST, LCI-4 Advanced, LEMOCOT, OPCS, and TUG.

One study evaluated four of these instruments for test accuracy to predict two or more falls during a 6 month followup period.[7] The Turn Time and Turn Test components of the 180 Degree Turn Test, FSST and TUG all had high sensitivity (85% to 100%) and specificity (74% to 93%) to predict falls. The Advanced components portion of LCI-4 had high specificity (91%) but low sensitivity (43%) to predict falls, which overall was reported to be statistically significant ($P<0.01$). The Turn Steadiness component of the 180 Degree Turn Test also had high sensitivity (85%) but low sensitivity (31%) to predict falls, but this test overall was not statistically significant ($P=0.22$).

Six instruments—1 Leg Standing Balance, 2MWT, AMPnoPRO, FAC, FAI, and LEMOCOT—were reported to have predictive validity based on correlations with functional status (measured by different instruments) at either discharge from rehabilitation or 3 month followup.

FIM was reported to be correlated with a high Houghton Scale score (≥9) at 3 to 12 months follow up when assessed at discharge from, but not admission to, rehabilitation.

OPCS was reported to be correlated with duration of stay in a rehabilitation unit.

Studies Not Generalizable to Medicare Population

Two instruments were evaluated for predictive validity only in studies that were not generalizable to the Medicare population. Both AMPSIMM and LCI-5 were reported to be correlated with future functional status.

Table 52. Summary of predictive validity of instruments.

Instrument	Study, PMID	MC*	Predictive Validity	Predicted Variable
1 Leg Standing Balance	Eijk 2012 21958418 Spaan 2017 27770064	Yes	Yes	BI, 2MWT, TUG, K level at discharge
			No	SNF at discharge
180 Degree Turn Test	Dite 2007 17207685	Yes	Turn time (≥3.7 sec): Sn 85%, Sp 78% Turn steps (≥6): Sn 100%, Sp 74% Turn steadiness (No): Sn 31%, Sp 85%†	≥2 Falls at 6 mo
2MWT	Brooks 2001 11588757	Yes	Yes	Houghton at discharge SF-36 PF at 3 mo
AMPnoPRO	Spaan 2017 27770064	Yes	Yes	2MWT, TUG, K level at discharge
AMPSIMM	Norvell 2016 27496697	No	Yes	Prosthesis use, TAPES, Mobility satisfaction at 4 and 12 mo LCI-5 at 4 mo
FAC	Eijk 2012 21958418	Yes	Yes	BI at discharge
			No	SNF at discharge
FAI	Eijk 2012 21958418	Yes	Yes	BI at discharge
			No	SNF at discharge
FIM	Leung 1996 8831480	Yes	At admission: No	Houghton ≥9 at 3-12 mo
			At discharge: Yes	Houghton ≥9 at 3-12 mo
FSST	Dite 2007 17207685	Yes	≥24 sec: Sn 92%, Sp 93%	≥2 Falls at 6 mo
LCI-4 Advanced	Dite 2007 17207685	Yes	≤15: Sn 43%, Sp 91%‡	≥2 Falls at 6 mo
LCI-5	Franchignoni 2004 15129398	No	Yes	TWT, RMI, FMI at discharge
LEMOCOT	Spaan 2017 27770064	Yes	Yes	2MWT, TUG, K level at discharge
OPCS	Panesar 2001 11330761	Yes	Yes	Duration of rehabilitation
TUG	Dite 2007 17207685	Yes	≥19 sec: Sn 85%, Sp 74%	≥2 Falls at 6 mo

Abbreviations: 2MWT = 2 minute walk test, AMPnoPRO = Amputee Mobility Predictor without use of a prosthesis, AMPSIMM = Amputee Single Item Mobility Measure, BI = Barthel Index, FAC = Functional Ambulation Categories, FAI = Frenchay Activities Index, FIM = Functional Independence Measure, FSST = Four Square Step Test, K level = Medicare Functional Classification Level, LCI = Locomotor Capabilities Index, LCI = Locomotor Capabilities Index, LEMOCOT = Lower-Extremity Motor Coordination Test, MC = Medicare, mo = months, OPCS = Office of Population Censuses and Surveys Scale, PMID = PubMed identifier (or journal), RMI = Rivermead Mobility Index, sec = seconds, Sn = sensitivity, SNF = skilled nursing facility, Sp = specificity, TAPES = Trinity Amputation and Prosthesis Experience Scale, TUG = Timed Up and Go, TWT = Timed Walk Test.

Note: These assessments are specific to the studies that evaluated the instruments as prediction tools. The findings may differ from the overall findings among all studies that evaluated the instruments.

*Whether study was deemed generalizable to the Medicare population based on average age greater than 65 years and/or at least 50% of participants with dysvascular etiologies for their amputations.

†P=0.22.

‡P<0.01.

Key Question 3. Functional Outcome Measurement Tools

Key Points

- Fifty instruments have been evaluated as functional outcome measurement tools
  - There are 34 instruments (in whole or in part) that have supporting evidence generalizable to the Medicare population
    - Seventeen instruments (or parts thereof) have evidence to support validity and reliability
    - Thirteen instruments have evidence of validity alone
    - Seven instruments have evidence of reliability alone
  - There are 19 instruments (in whole or in part) that have supporting evidence only from studies not generalizable to the Medicare population
    - Thirteen instruments (or parts thereof) have evidence to support validity and reliability
    - Four instruments have evidence to support validity (without evidence regarding reliability)
    - Three instruments have evidence of validity but explicitly not reliability
    - Four instruments have evidence of reliability alone

Findings

All 50 evaluated instruments were deemed to be relevant functional outcome measurement tools. Here we first focus on summarizing instruments with generalizability to the Medicare population (i.e., study mean age ≥65 years or ≥50% of participants had dysvascular disease), test validity, and reliability; this is followed by summaries of instruments with evidence only from studies not generalizable to the Medicare population. Descriptions about other psychometric properties can be found in the descriptions of each instrument, above.

Studies Generalizable to Medicare Population

Instruments With Evidence of Validity and Reliability

Seventeen instruments have, in whole or in part, been reported to have both test validity and reliability in studies generalizable to the Medicare population. These include:

- 2MWT (2 Minute Walk Test)
- 6MWT (6 Minute Walk Test)
- ABC (Activities-specific Balance Confidence)
- AMP (Amputee Mobility Predictor)
  - Both AMPnoPRO (without prosthesis) and AMPPRO (with prosthesis)
- Climbing Stairs Questionnaire
- Functional Reach Test
- Houghton Scale
  - Both total Scale score and a subscale of items 1 to 3 (on prosthesis wear and use)
- LCI (Locomotor Capabilities Index)
  - Specifically: LCI-4 (LCI with a 4-point ordinal scale)
- PEQ (Prosthetic Evaluation Questionnaire)

    - Specifically the PEQ-MS 13/11 (the Mobility Subscale with 13 items and 11 categories)
- PPA (Prosthetic Profile of the Amputee)
    - Specifically: Prosthesis use (outdoors), and Acceptance/Adaptation; also see listings for LCI, which is included in the PPA, but evaluated separately here.
- Rising and Sitting Down Questionnaire
- RMI (Rivermead Mobility Index)
- SCS (Socket Comfort Score)
- SF-12 (Short Form Health Survey 12)
    - Specifically: SF-12 PCS (Physical Component Score), SF-12 RP-2 (Role Physical), and SF-12 BP-2 (Bodily Pain)
- TFP (Transfemoral Fitting Predictor)
- TUG (Timed Up and Go)
- Walking Questionnaire

Instruments With Evidence of Validity (Only)

Thirteen instruments have, in whole or in part, been reported to have test validity but have not been reported to have reliability in studies generalizable to the Medicare population. None of the studies explicitly reported a lack of reliability, instead evaluations of reliability were not reported. In some instances reliability was reported among other studies not generalizable to the Medicare population; these are listed below in the appropriate section. The instruments with evidence of test validity, but not reported reliability in studies generalizable to the Medicare population include:

- 1 Leg Standing Balance
- 180 Degree Turn Test
    - Specifically: Turn Time and Turn Steps components
- AAS (Amputee Activity Survey)
- BBS (Berg Balance Scale)
- FAC (Functional Ambulation Categories)
- FAI (Frenchay Activities Index)
- FIM (Functional Independence Measure), total score
- FSST (Four Square Step Test)
- LEMOCOT (Lower-Extremity Motor Coordination Test)
- OPCS (Office of Population Censuses and Surveys Scale)
- PROS (Prosthetist's Perception of Client's Ambulatory Abilities)
- SIGAM (Special Interest Group of Amputation Medicine)
- SF-12 and SF-36 (Short Form Health Surveys 12 and 36)
    - Specifically: SF-12 total score and SF-36 PF (Physical Functioning subscale, PF-15 performed better than PF-10)

Instruments With Evidence of Reliability (Only)

Seven instruments have, in whole or in part, been reported to have reliability but have not been reported to have test validity in studies generalizable to the Medicare population. This list includes only those instruments for which test validity was not assessed. The instruments with

evidence of test reliability, but no report about test validity in studies generalizable to the Medicare population include:

- OPUS (Office of Population Censuses and Surveys Scale)
  - Specifically: subscales Quality of Life, Lower Limb Function, and Satisfaction
- PEQ (Prosthetic Evaluation Questionnaire)
  - Specifically: the overall scale and each of the items, including PEQ-MS 13/7, except the items shower and bathe safely (version with 7 categories, 1 to 7)
- PGI (Patient Generated Index)
- PSFS (Patient-Specific Functional Scale)
- SAT-PRO (Satisfaction with Prosthesis Questionnaire)
- SF-36V (Short Form Health Survey 36 for use with veterans)
  - Specifically: SF-36V subscales General Health, Physical Functioning, and Role Physical
- Walking Speed, 10 meters

Studies Not Generalizable to Medicare Population

Instruments With Evidence of Validity and Reliability

Thirteen instruments have, in whole or in part, been reported to have both test validity and reliability only in studies *not* generalizable to the Medicare population. A number of these instruments have evidence for either test validity or reliability, but not both, in studies generalizable to the Medicare population; these are further discussed in the notes under the bullet list. The instruments with evidence of test validity and reliability only from studies not generalizable to the Medicare population include:

- BBS (Berg Balance Scale), see note below
- FAI (Frenchay Activities Index), see note below
- L Test (L Test of Functional Mobility)
- LCI (Locomotor Capabilities Index), see note below
  - Specifically: LCI-4 Basic and Advanced (Basic and Advanced components, separately, with a 4-point ordinal scale), LCI-5 (LCI with a 5-point ordinal scale), and LCI10-4 (10-item scale which combined two of the response levels from LCI-5)
- Patient Activity Monitor
  - Specifically: Walking Velocity
- PEQ (Prosthetic Evaluation Questionnaire), see note below
  - Specifically: the Function subscale Residual limb health, the Mobility subscale Ambulation, the Psychosocial subscales Frustration and Social Burden, and the Global subscale Well-Being; and PEQ MS 12/5 (the Mobility Subscale with 12 items and 5 categories)
- PFI (Physical Function Index)
  - Including the overall instrument and the four subscales Squat to Pick Up Object, Walk at Steady Pace, Run at Steady Pace, and Climb Stairs
- PLUS-M (Prosthetic Limb Users Survey of Mobility)
  - Specifically: the form version SF-12
- PROMIS-29 (Patient-Reported Outcomes Measurement Information System 29-Item Profile)
  - Specifically: the Physical Function subscale

- Q-TFA (Questionnaire for Persons with a Transfemoral Amputation)
  - Specifically: the subscales Prosthetic Use, Prosthetic Mobility, and Problem
- SIGAM (Special Interest Group of Amputation Medicine), see note below
- SIP-PD (Sickness Impact Profile-Physical Dimension)
  - Including the overall instrument and the three subscales Ambulation, Body Care and Movement, and Mobility
- TAPES (Trinity Amputation and Prosthesis Experience Scales)
  - All subscales of TAPES and TAPES-R except Weight Satisfaction (from the original TAPES) and Satisfaction with Prosthesis Subscale 1 (esthetics, from TAPES-R)

Supporting Evidence From Medicare-Generalizable Studies

Note that BBS, FAI, and SIGAM have been reported to be validated among studies generalizable to the Medicare population, but were not assessed for reliability.

Note that LCI-4 (the total instrument) has been reported to be both valid and reliable in studies generalizable to the Medicare population. LCI-4 Basic, LCI-5, and LCI1-4 were not evaluated among studies generalizable to the Medicare population.

Note that PEQ MS 13/11 has been reported to be both valid and reliable in studies generalizable to the Medicare population. The overall PEQ scale and each of the items, except shower and bathe safely (version with seven categories, 1 to 7) were reported to have reliability but were not evaluated for test validity in a study generalizable to the Medicare population.

Instruments With Evidence of Validity (Only)

Four instruments have, in whole or in part, been reported to have test validity but have not been reported to have reliability in studies *not* generalizable to the Medicare population. These include:

- AMPSIMM (Amputee Single Item Mobility Measure)
- Employment Questionnaire
- TWT (Timed Walking Test)
- WHOQOL-BREF (World Health Organization Quality of Life-Brief Version)
  - Specifically: the Physical Health, Psychological Health, Social Relations, and Environmental subscales.

Instruments With Evidence of Validity But Not Reliability

Subscales from three instruments have been reported to have test validity but *not* reliability in studies *not* generalizable to the Medicare population. This instrument is:

- Patient Activity Monitor
  - Specifically: Step Count and Step Length
- Q-TFA (Questionnaire for Persons with a Transfemoral Amputation)
  - Specifically: the Global Health score
- TAPES (Trinity Amputation and Prosthesis Experience Scales)
  - Specifically: the Satisfaction with Prosthesis Subscale 1 (esthetics) from TAPES-R

Instruments With Evidence of Reliability (Only)

Four instruments have, in whole or in part, been reported to have reliability but have not been reported to have test validity in studies *not* generalizable to the Medicare population. This list includes only those instruments for which test validity was not assessed. The instruments with

evidence of test reliability, but no report about test validity in studies not generalizable to the Medicare population include:

- ADAPT (Assessment of Daily Activity Performance in Transfemoral Amputees)
  - Specifically: Items 10 to 18; items 1 to 9 were not evaluated
- NQ-ACGC (Quality of Life in Neurological Conditions – Applied Cognition/General Concerns)
- PLUS-M (Prosthetic Limb Users Survey of Mobility)
  - Specifically: the form versions CAT (Computer Adaptive Test) and SF-7 (a short form version); the form version SF-12 (not to be confused with the Short Form Health Survey SF-12) has evidence for both test validity and reliability
- PROMIS-29 (Patient-Reported Outcomes Measurement Information System 29-Item Profile)
  - Specifically: the Anxiety, Depression, Fatigue, Pain Intensity, Pain Interference, Physical Function, Sleep Disturbance, and Social Role Satisfaction subscales

Note that the Single Beam Test was evaluated for only floor and ceiling effects, in a study not generalizable to the Medicare population, and thus is not in any of the above lists of instruments with evidence of validity or reliability. The Barthel Index was also omitted from these lists because it has only been reported that it failed to predict skilled nursing home placement, which does not adequately address whether the instrument has test validity.

Key Question 4. LLP Comparative Effectiveness by Subgroup

Key Points

- Fourteen studies provided sufficient data to evaluate Key Question 4
  - Eight studies evaluated validated predictors and outcomes
  - Six studies evaluated nonvalidated predictors and/or outcomes
  - Only one study specifically analyzed whether any study participant characteristics could accurately and effectively predict which patients will benefit most or least from a given component, but with nonvalidated outcomes
- Overall, studies that investigated subgroup effects did not identify participant characteristics that predict which lower limb amputees would benefit most or least from a given component or configuration (low strength of evidence)

Comments on Key Question and Evidence Base

It should be noted that this review makes no attempt to make conclusions about the overall effects of different LLP components or configurations. Key Question 4 addressed whether there is evidence regarding heterogeneity of treatment effects (whether outcomes with specific devices vary across individuals based on different characteristics such as age or health status) in the field of LLP research and whether studies used validated measures.

A relatively small percentage of comparative studies report sufficient data to allow subgroup analysis and evaluation of heterogeneity of treatment effect (14%, 15 of 104 otherwise eligible articles). It is also important to note that this Key Question (and the entire review) evaluates clinical and patient-centered outcomes only. This focus does not diminish the vital importance of biomechanical testing that is used develop and evaluate LLP components or configurations.

Although not all will agree, the decision was made to focus on only the outcomes important to LLP recipients, prosthetists, and providers.

Overall Summary of Studies

In total, we found 14 studies (in 15 articles) that directly compared different LLP components or configurations and provided sufficient data to allow subgroup analyses based on participant characteristics.[78-91] These studies either address or provide sufficient data to allow us to address the focused question of whether the relative effect of different components differs across different subgroups of lower limb amputees. The following summary does not focus on the relative effect of different components nor does it include the majority of studies that compare components (but do not provide subgroup analyses). Nor does it evaluate components based on biomechanical or other nonpatient-centered intermediate outcomes. Of the 104 articles we screened that potentially reported clinical outcomes in comparisons of different LLP components, 89 articles did not report subgroup analyses, evaluations of heterogeneity of treatment effect, predictor models, or sufficient patient-level data to allow *post hoc* subgroup analyses. These studies were excluded.

Twelve of the 14 studies included between 5 and 168 users of LLP, one included 899 amputees, and one 1013. Seven studies evaluated microprocessor knees (compared to mechanical knees), two evaluated other knee components, three evaluated ankle/foot components, and one each evaluated pylons or sockets. One large study (Hahn 2016) developed a regression model to evaluate the predictive ability of a wide range of participant characteristics.[83] Another study (Hahn 2015) conducted correlation and regression analyses but did not fully report the results of these analyses.[78] An older study (Alaranta 1994) reported a correlation analysis between participant characteristics and outcomes and also performed subgroup analyses without statistical comparisons between subgroups.[79] One study (De Asha 2014) provided subgroup comparisons with statistical analyses[80]; four studies reported subgroup results but did not statistically compare subgroups (Gard 2003, Hafner 2009, Moore 2017, Theeven 2011)[81, 82, 86, 91]; and seven studies reported individual patient data which allowed *post hoc* subgroup analyses (Gard 2003, Hasenoehrl 2017, Isakov 1985, Kahle 2008, Silver-Thorn 2009, Traballesi 2011, Wong 2015).[81, 84, 85, 88-90] Overall, studies that investigated subgroup effects did not identify participant characteristics that predict which lower limb amputees would benefit most or least from any 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 53 summarizes the study design and participant characteristics of the 14 studies. In each of the studies, all patients were assessed with all components compared, either per 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 months, but generally longer, of experience. The large majority of study participants were male (85% across studies with reported data) with unilateral amputations (100% in 9 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 three ankle/foot studies included both patients with transtibial and transfemoral amputations. Twelve of the 14 studies reported the K level (the Medicare Functional Classification Level) of included patients. Except for four studies that included only

K2 level patients, most study participants were at K3 (or K4) level, except for the Hahn 2015 study of C-Leg in which 93 percent were MOBIS level 2 or 3 (equivalent to K2 or K3).[78] Only Wong 2015 explicitly included people at K1 level. The amputation etiologies across studies varied more widely, although with three exceptions, at least about half of patients had trauma-related amputations. Only Isakov 1985 and Moore 2017 included a majority of people with dysvascular disease-related amputations (14/17, 82%). The study participants were relatively young in 11 studies, with mean ages ranging from 34 to 61 years, suggesting that well over half the amputees were less than 65 years old. One small study (Hasenoehrl 2017) included mostly people over age 65 years (mean 68, range 56 to 75).

Table 54 describes the components that were compared in the studies. Table 55 describes the risk of bias (study quality) of the studies. Eight of the studies were deemed to be at moderate risk of bias overall and six 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. Two studies conducted multivariable analyses comparing subgroups, but only one reported details of the analysis. Only three studies statistically evaluated heterogeneity of treatment effect (differences among subgroups).

Table 56 provides an overall summary of subgroup comparisons across all studies and Tables 57 to 70 provide the summary results for each study individually. Narrative summaries follow the tables.

Table 53. Study design and participant characteristics of studies comparing components

Study Year (PMID) Country	Study Design	Funding Source	Components	Amputation and Prosthesis Use History	N Analyzed	Mean Age (SD)	Male	K Level	Amputation Level	Uni-lateral	Etiology
Alaranta 1994 (7991366) Finland	NRCS, retrospective	Not reported / unclear	Foot/Ankle, energy-storing vs. conventional	Prosthesis ≥6 mo	168	58.4	93%	K3-4 100%	TT 84%, TF 16%	93%	Tr 86%, Dysv 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%	Tr 84%, Dysv 0%, CA 16%
Gard 2003 (15077637) USA	Pre-post, prospective	Nonindustry	Pylon, shock-absorbing vs. conventional	Prosthesis ≥6 mo	10	54 (17) [32-79]	90%	nd	TT 100%	100%	Tr 70%, Dysv 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%	Tr 59%, Dysv 6%, CA 18%, Inf 12%, other 6%
Hahn 2015 (J Prosthet Orthot) Germany	NRCS, retrospective	None (employees of Otto Bock Healthcare)	Knee, microprocessor vs. conventional	Prosthesis ≥12 mo (implied) Amputation 17.5 yr (mean)	1013	55.6 (15.1)	83%	MG2 46%, MG3 47%, MG4 8%	TF 100%	nd	Tr 43%, Dysv 26%, CA 13%, Inf 6%, other 12%
Hahn 2016 (27828871) Germany	Single group, retrospective	Industry provided materials (employees of Otto Bock Healthcare)	Knee, microprocessor, hydraulic vs. conventional	nd	899	49.0 (12.9)	83%	K2 13%, K3 64%, K4 23%	Knee 19%, TF 80%	nd	Tr 69%, Dysv 6%, CA 16%, other 10%
Hasenoehrl 2017 (28399722) Austria	Pre-post, prospective	Industry provided materials	Knee, microprocessor vs. conventional	Prosthesis ≥12 mo	5	68.2 (7.6)	80%	K2: 100%	TF: 100%	100%	Tr 20%, Dysv 20%, other 60%
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%	Tr 18%, Dysv 82%

Study Year (PMID) Country	Study Design	Funding Source	Components	Amputation and Prosthesis Use History	N Analyzed	Mean Age (SD)	Male	K Level	Amputation Level	Uni-lateral	Etiology
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%	Tr 47%, Dysv 47%, other 6%
Moore 2017 (J Prosth Orthot) UK	Pre-post, prospective	Not reported / unclear	Foot/ankle, hydraulic vs. conventional	nd	14	38-84	86%	K2 100%	TT 86% TF 14%	93%	Tr14%, Dysv 71%, Inf 14%
Silver-Thorn 2009 (J Prosth Orthot) USA	NRCS, prospective	Nonindustry	Knee, locking vs. hydraulic	nd	5	44.8 (9.3)	nd	K2 100%	TF 100%	100%	Tr 80%, Dysv 0%, CA 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%	Tr 77%, Dysv 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%	Tr 86%, Dysv 0%, CA 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

Abbreviations: Dysv = dysvascular disease, Inf = infection, Knee = at level of knee amputation, MG = MOBIS grade (per article, equivalent to K level [Medicare Functional Classification Level]), nd = no data (not reported), NRCS = nonrandomized comparative study, PMID = PubMed identifier (or journal), RCT = randomized comparative study, SD = standard deviation, TF = transfemoral amputation, Tr = trauma, TT = transtibial amputation.

*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.

Table 54. Components evaluated in eligible comparative studies

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 2015 (J Prosthet Orthot)	Knee	Microprocessor	C-Leg or C-Leg Compact (Otto Bock)
		Conventional prostheses	Varied, habitual
Hahn 2016 (27828871)	Knee	Microprocessor, hydraulic	Genium (Otto Bock)
		Conventional prostheses	Varied, habitual
Hasenoehrl 2017 (28399722)	Knee	Microprocessor (swing phase)	Genium with Cenior-Leg ruleset (Otto Bock)
		Nonmicroprocessor	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*
Moore 2017 (J Prosth Orthot)	Foot/Ankle	Hydraulic	Avalon (Endolite)
		Multiaxial, nonhydraulic	Multiflex (Endolite)
Silver-Thorn 2009 (J Prosth Orthot)	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‡

Abbreviation: PMID = PubMed identifier (or journal).

*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 55. Comparative study risk of bias/study quality

Study Year (PMID)	Random-ization	Allocation Conceal-ment	Blinding, Patients	Blinding, Providers	Blinding, Outcome Assessors	Outcome Assess-ment, Validation	Equivalent Groups	Dropouts	Multi-variable	HTE Analyzed?	Overall Quality
Alaranta 1994 (7991366)	High RoB (non-randomized)	NA (cross-over)	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 (non-randomized)	NA (cross-over)	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 (non-randomized)	NA (cross-over)	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 (non-randomized)	NA (cross-over)	High RoB	High RoB	Unclear RoB	Low RoB, validated	Low RoB (crossover)	Low RoB	High RoB (no)	Indirectly†	Moderate RoB
Hahn 2015 (J Prosthet Orthot)	High RoB (non-randomized)	NA (cross-over)	High RoB	High RoB	High RoB	Low RoB, validated	Low RoB (crossover)	Low RoB	Low RoB (yes)	Yes (model)	Moderate RoB
Hahn 2016 (27828871)	High RoB (non-randomized)	NA (cross-over)	High RoB	High RoB	High RoB	Low RoB, not validated	Low RoB (pre-post)	Low RoB	Low RoB (yes)	Yes (model)	Moderate RoB
Hasenoehrl 2017 (28399722)	High RoB (non-randomized)	NA (cross-over)	High RoB	High RoB	High RoB	Low RoB, validated	Low RoB (crossover)	Low RoB	High RoB (no)	Indirectly†	Moderate RoB
Isakov 1985 (3868034)	High RoB (non-randomized)	NA (cross-over)	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 (non-randomized)	NA (cross-over)	High RoB	High RoB	High RoB	Low RoB, validated	Low RoB (pre-post)	Low RoB	High RoB (no)	No (IPD reported)	Moderate RoB
Moore 2017 (J Prosth Orthot)	High RoB (non-randomized)	NA (cross-over)	High RoB	High RoB	High RoB	Low RoB, validated	Low RoB (pre-post)	Low RoB	High RoB (no)	Partially*	Moderate RoB
Silver-Thorn 2009 (J Prosth Orthot)	High RoB (non-randomized)	NA (cross-over)	High RoB	High RoB	High RoB	Low RoB, not validated	Low RoB (crossover)	Low RoB	High RoB (no)	No (IPD reported)	High RoB

Study Year (PMID)	Random-ization	Allocation Conceal-ment	Blinding, Patients	Blinding, Providers	Blinding, Outcome Assessors	Outcome Assess-ment, Validation	Equivalent Groups	Dropouts	Multi-variable	HTE Analyzed?	Overall Quality
Theeven 2011 (21947182, 22549656)	Low RoB	NA (cross-over)	High RoB	High RoB	High RoB	High RoB (some outcome unclear), validated	Low RoB (crossover)	Low RoB	High RoB (no)	Indirectly†	High RoB
Traballesi 2011 (21684165)	High RoB (non-randomized)	NA (cross-over)	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 (non-randomized)	NA (cross-over)	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, PMID = PubMed identifier (or journal), 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 56. Summary of subgroup comparisons

Study Year (PMID)	Components	Total N	Subgroup Comparison Findings (P value*)	Subgroups	Subgroups Validated?	Outcomes	Outcomes Validated?
Alaranta 1994 (7991366)	Energy-storing vs. conventional ankle/foot	168	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†). Other analyses NS.	TF vs. TT Age Age at amputation Body weight/BMI	Yes, all	Movement disability index subquestions and total	No
De Asha 2014 (24997811)	Hydraulic vs. rigid ankle/foot	19	NS for both outcomes	TF vs. TT	Yes	Gait speed (8 meters) Cadence (8 meters)	No‡

Study Year (PMID)	Components	Total N	Subgroup Comparison Findings (P value*)	Subgroups	Subgroups Validated?	Outcomes	Outcomes Validated?
Gard 2003 (15077637)	Shock-absorbing vs. non-shock-absorbing pylon	10	One woman favored the shock-absorbing pylon more than men did for self-selected walking speed (0.0002) and fast walking speed (<0.0001). Other analyses NS.	Vascular vs. traumatic Sex Age Height Time since amputation	Yes, all	Walking speed (distance undefined) Fast walking speed (distance undefined)	No‡
Hafner 2009 (19675993)	Microprocessor vs. mechanical knee	17	NS, for all outcomes	K2 vs. K3	Yes	PEQ subscales: Ambulation	Yes
						Appearance	No
						Frustration	Yes
						Perceived Response	No
						Residual Limb	Yes
						Social Burden	Yes
						Sounds	No
						Utility	No
						Well-being	Yes
						Falls & stumbles, reported	Yes
						Walking speeds, various	No
						Stair Assessment Index	No
						Self-reported abilities/difficulties	No
Hahn 2015 (J Prosthet Orthot)	Microprocessor vs. mechanical knee	1013	NS, for all analyses‡	Age Vascular vs. other K2 vs. K3 vs. K4	Yes	Fear of falling (undefined)	No
						Safety (10 point scale)	No
						Use of walking aids	Yes
Hahn 2016 (27828871)	Microprocessor, hydraulic vs. mechanical knee	899	"None of the variables and none of the regression models yield explanatory predictive power."	Multiple (not all explicitly listed)	Yes, mostly	Ambulatory, functional, other activities, and speed measures	No
Hasenoehrl 2017 (28399722)	Microprocessor vs. mechanical knee	5	NS, for all analyses	Vascular vs. nonvascular Sex Age BMI Time since amputation	Yes, all	TUG	Yes
						2MWT	Yes
						10 meter walk	No
						AMPPRO	Yes
						BBS	Yes

Study Year (PMID)	Components	Total N	Subgroup Comparison Findings (P value*)	Subgroups	Subgroups Validated?	Outcomes	Outcomes Validated?
Isakov 1985 (3868034)	Locking vs. open knee	17	NS, for all subgroups	Vascular vs. nonvascular Sex Age	Yes, all	6MWT	Yes

Study Year (PMID)	Components	Total N	Subgroup Comparison Findings (P value*)	Subgroups	Subgroups Validated?	Outcomes	Outcomes Validated?
Kahle 2008 (18566922)	Microprocessor (C-Leg) vs. mechanical knee	15	NS, for all analyses	K level (2, 3, 4) Age Vascular vs. nonvascular Height Employment status Prosthesis use duration Residual limb firmness Residual limb length	Yes, all except residual limb firmness	Falls & stumbles, reported	Yes
						Walking speeds, varied	No
						Montreal Rehabilitation Performance Profile	No
Moore 2017 (J Prosth Orthot)	Hydraulic (Avalon) vs. nonhydraulic (Multiflex) ankle/foot	14	NS, for all outcomes	TF vs. TT	Yes	PEQ subscales: Ambulation	Yes
						Transferring	No
						Utility	No
						Well-being	Yes
						Prosthesis satisfaction	No
						Gait satisfaction	No
Silver-Thorn 2009 (J Prosth Orthot)	Locking (Total Knee 2000) vs. hydraulic knee	5	NS, for all analyses	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, all#
Theeven 2011 (21947182, 22549656)	Microprocessor (2 settings) vs. mechanical knee	30	NS, for all outcomes	K2 subgroups (high, intermediate, low)	No	Activity measures	No
						PEQ subscales: Ambulation	Yes
						Appearance	No
						Residual limb health	Yes
						Sounds	No
						Utility	No
						Well-being	Yes
						Prosthesis satisfaction	No
						Gait satisfaction	No
						Perceived difficulties	No
Traballesi 2011 (21684165)	Marlo anatomic vs. ischial component socket	7	NS, for all subgrous	Sex Age Height Time since amputation	Yes, all	PEQ MS 13/11	Yes

Study Year (PMID)	Components	Total N	Subgroup Comparison Findings (P value*)	Subgroups	Subgroups Validated?	Outcomes	Outcomes Validated?
Wong 2015 (25768067)	Microprocessor vs. mechanical knee	8	K2-3 favored microprocessor knee more than K1 did on TUG walking scale (0.0001). Other analyses NS.	K level (1, 2, 3) Age Time since ambulation Bilateral vs. unilateral	Yes, all	ABC balance,	Yes
						BBS	Yes
						Houghton scale	Yes
						TUG	Yes
						Falls, reported	Yes
						Fear of falling	No

Abbreviations: 2MWT = 2 Minute Walk Test, 6MWT = 6 Minute Walk Test, ABC = Activities-Specific Balance Confidence, AMPPRO = Amputee Mobility Predictor with use of a prosthesis, BBS = Berg Balance Scale, K level = Medicare Functional Classification Level (also indicated by K1, K2, K3, and K4), NS = not statistically significant, PEQ = Prosthesis evaluation questionnaire, PEQ MS 13/11 = PEQ Mobility Subscale with 13 items and 11 categories, PMID = PubMed identifier (or journal), 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.

‡By unadjusted comparisons, implicit, or based on correlation analysis

#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 57. Subgroup analyses: Alaranta, 1994, comparing energy-storing versus conventional ankle/foot components

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: Uneven ground	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.51		
Movement disability index: Uphill street	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.89		
Movement disability index: Swift walking	ES (<0.001)	168	Transfemoral	27	Transtibial	141	0.79		
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	

Abbreviation: ES = energy storing prosthesis

Note: Data for Alaranta 1994 (PMID 7991366).[79] Additional details in Appendix D. Across Tables 57 to 70, 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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*Statistically significant difference favoring listed component over comparator.

†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 58. Subgroup analyses: De Asha, 2014, comparing hydraulic versus rigid ankle/foot components

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).[80] Additional details in Appendix D. Across Tables 57 to 70, 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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*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 59. Subgroup analyses: Gard, 2003, comparing shock-absorbing versus non-shock-absorbing pylons

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	***0.0002***		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	***<0.0001***		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

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

Note: Data for Gard 2003 (PMID 15077637).[81] Additional details in Appendix D. Across Tables 57 to 70, 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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*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 60. Subgroup analyses: Hafner, 2009, comparing microprocessor versus mechanical knee components

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		

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
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		
Semicontrolled falls (VAS)	Neither (0.64)	17	K level 2	8	K level 3	9	0.91		
Semicontrolled falls (number, reported)	Microprocessor (0.03)	17	K level 2	8	K level 3	9	0.53		

Abbreviations: K level = Medicare Functional Classification Level, PEQ = Prosthesis evaluation questionnaire, VAS = visual analogue scale.

Data for Hafner 2009 (PMID 19675993).[82] Additional details in Appendix D. Across Tables 57 to 70, P values of differences (comparisons) <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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*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 61. Subgroup analyses: Hahn, 2015, comparing C-Leg™ or C-Leg Compact™ versus prior mechanical knees

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
Fear of falling (not described)	Microprocessor (86% said reduced)	1013	Age 21-40 41-60	~143 ~465	Age >60	~406	NS (implied)		
		1013	K level 2	~463	K level 3 K level 4	~472 ~78	NS (implied)		
Safety (10 point scale)	Microprocessor (83% said safer)	1013	Age 21-40 41-60	~143 ~465	Age >60	~406	NS (by correlation analysis)		
		1013	K level 2	~463	K level 3 K level 4	~472 ~78	NS (by correlation analysis)		
		1013	Vascular	~263	Other etiology	~750	NS (by correlation analysis)		
Use of walking aids (use/nonuse) †	Microprocessor (46% stopped using)	nd	Age 21-40 41-60	nd	Age >60	nd	NS (implied): Decline with age group: 67% vs. 51% vs. 38%		
		nd	K level 2	nd	K level 3 K level 4	nd	NS (implied): 41% vs. 57% vs. 0%		
		nd	Vascular	nd	Other etiology	nd	NS (implied)		

Abbreviations: K level = Medicare Functional Classification Level, nd = no data, NS = not statistically .signficant.

Note: Data for Hahn 2015.[78] Additional details in Appendix D. Additional details in Appendix D. Across Tables 57 to 70, P values of differences (comparisons) <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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*Statistically significant difference favoring listed component over comparator.

†Analysis included here is of people using walking aids with mechanical aids. Article also reports use of walking aids across all participants.

Table 62. Subgroup analyses: Hahn, 2016, comparing Genium™ microprocessor versus prior knee components (mostly C-Leg™ microprocessor knee)

Outcomes*	Overall Favors† (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).

Note: Data for Hahn 2016 (PMID 27828871).[83] Additional details in Appendix D.

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

†Statistically significant difference favoring listed component over comparator.

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

Table 63. Subgroup analyses: Hasenoehrl, 2017, comparing microprocessor versus mechanical knees

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
TUG	Neither (P=0.09)	5	Female	1	Male	4	0.46		
		5	Age 56-66 y	2	71-75 y	3	0.54	0.77	
		5	BMI 26.6-29.9 kg/m^2	2	30.0-38.7 kg/m^2	3	0.54	0.081	
		5	Time since amputation 3-4 y	3	5 y	2	0.49	0.55	
		5	Dysvascular	1	Other etiology	4	0.38		
2MWT	Neither (P=0.32)	5	Female	1	Male	4	0.64		
		5	Age 56-66 y	2	71-75 y	3	0.49	0.81	
		5	BMI 26.6-29.9 kg/m^2	2	30.0-38.7 kg/m^2	3	0.49	0.93	
		5	Time since amputation 3-4 y	3	5 y	2	0.50	0.85	
		5	Dysvascular	1	Other etiology	4	**0.045**		Dysvascular favored microprocessor knee more than other etiology did
10 meter walk, self-selected speed	Neither (P=0.10)	5	Female	1	Male	4	**0.006**		Men favored microprocessor knee more than woman did
		5	Age 56-66 y	2	71-75 y	3	0.69	0.71	
		5	BMI 26.6-29.9 kg/m^2	2	30.0-38.7 kg/m^2	3	0.69	0.88	
		5	Time since amputation 3-4 y	3	5 y	2	0.31	0.082	
		5	Dysvascular	1	Other etiology	4	0.068		
10 meter walk, fast	Non-mechanical (P=0.008)	5	Female	1	Male	4	0.97		
		5	Age 56-66 y	2	71-75 y	3	0.25	0.23	
		5	BMI 26.6-29.9 kg/m^2	2	30.0-38.7 kg/m^2	3	0.25	0.053	
		5	Time since amputation 3-4 y	3	5 y	2	0.45	0.78	
		5	Dysvascular	1	Other etiology	4	0.48		

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
AMPPRO	Neither (P=0.06)	5	Female	1	Male	4	0.57		
		5	Age 56-66 y	2	71-75 y	3	0.32	0.68	
		5	BMI 26.6-29.9 kg/m^2	2	30.0-38.7 kg/m^2	3	0.32	**0.027**	Higher BMI favored microprocessor more than lower BMI did (continuous BMI)
		5	Time since amputation 3-4 y	3	5 y	2	0.53	0.57	
		5	Dysvascular	1	Other etiology	4	0.42		
BBS	Neither (P=0.63)	5	Female	1	Male	4	0.29		
		5	Age 56-66 y	2	71-75 y	3	0.58	0.68	
		5	BMI 26.6-29.9 kg/m^2	2	30.0-38.7 kg/m^2	3	0.58	0.12	
		5	Time since amputation 3-4 y	3	5 y	2	0.15	0.37	
		5	Dysvascular	1	Other etiology	4	0.46	0.84	

Abbreviations: 2MWT = 2 Minute Walk Test, AMPPRO = Amputee Mobility Predictor with use of a prosthesis, BBS = Berg Balance Score, BMI = body mass index, TUG = Timed Up and Go.

Note: Data for Hasenoehrl 2017 (PMID 28399722).[90] Additional details in Appendix D. Across Tables 57 to 70, P values of differences (comparisons) <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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*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 = 0.001 (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 64. Subgroup analyses: Isakov, 1985, comparing locking versus open knee components

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	**0.016**		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	***0.004***	0.014	Younger favored open knee more than older did

Note: Data for Isakov 1985 (PMID 3868034).[84] Additional details in Appendix D. Across Tables 57 to 70, P values <0.05 of differences (comparisons) 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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*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 65. Subgroup analyses: Kahle, 2008, comparing microprocessor (C-Leg™) versus mechanical knee components

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		

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
		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		
		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	

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
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	

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
		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		
		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	

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
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	

Abbreviation: K level = Medicare Functional Classification Level.

Note: Data for Kahle 2008 (PMID 18566922).[85] Additional details in Appendix D. Across Tables 57 to 70, P values of differences (comparisons) <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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*Statistically significant difference favoring listed component over comparator.

†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 66. Subgroup analyses: Moore, 2017, comparing hydraulic versus nonhydraulic foot/ankle components

Outcome	Overall Favors*, (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	Findings
PEQ Ambulation	Hydraulic (0.005)	14	Transtibial	12	Transfemoral	2	0.26	
PEQ Transfer	Hydraulic (0.02)	14	Transtibial	12	Transfemoral	2	0.37	
PEQ Utility	Hydraulic (0.005)	14	Transtibial	12	Transfemoral	2	0.35	
PEQ Wellbeing	Neither (0.08)	14	Transtibial	12	Transfemoral	2	0.10	
PEQ Satisfaction, prosthesis	Hydraulic (0.0003)	14	Transtibial	12	Transfemoral	2	***0.011***	Transtibial amputees favored hydraulic more than transfemoral did
PEQ Satisfaction, gait	Hydraulic (0.0007)	14	Transtibial	12	Transfemoral	2	***0.022***	Transtibial amputees favored hydraulic more than transfemoral did

Abbreviation: PEQ = Prosthesis Evaluation Questionnaire.

Note: Data for Moore 2017[91] (J Prosthet Orthot) Additional details in Appendix D. Across Tables 57 to 70, P values of differences (comparisons) <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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*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 = 0.0083 (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 67. Subgroup analyses: Silver-Thorn, 2009, comparing locking (Total Knee 2000™) versus hydraulic knee components

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	

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
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**	0.10	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	
		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	**0.046**	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	

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
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	

Note: Data for Silver-Thorn 2009 (no PMID).[89] Additional details in Appendix D. Across Tables 57 to 70, P values of differences (comparisons) <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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*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 68. Subgroup analyses: Theeven, 2011, comparing microprocessor (2 settings) versus mechanical knee components

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 micro-processor 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

Outcome	Overall Favors*,† (P value)	N Total	Subgroups	N Subgroups‡	Comparator	N Comparator	P Difference§ (Categorical)	P Difference# (Continuous)	Findings†
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§)	
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§)	

Abbreviation: K level = Medicare Functional Classification Level, PEQ = Prosthesis Evaluation Questionnaire.

Note: Data for Theeven 2011 (PMID 21947182, 22549656).[86, 87] Additional details in Appendix D. Across Tables 57 to 70, P values of differences (comparisons) <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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*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.

§Six 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 69. Subgroup analyses: Traballesi, 2011, comparing Marlo anatomic versus ischial component socket components

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	**0.022**		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	**0.017**	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	

Abbreviation: PEQ = Prosthesis evaluation questionnaire.

Note: Data for Traballesi 2011 (PMID 21684165).[88] Additional details in Appendix D. Across Tables 57 to 70, P values of differences (comparisons) <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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*Statistically significant difference favoring listed component over comparator.

†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 70. Subgroup analyses: Wong, 2015, comparing microprocessor versus mechanical knee components

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		

Outcome	Overall Favors* (P value)	N Total	Subgroup	N Subgroup	Comparator	N Comparator	P Difference† (Categorical)	P Difference† (Continuous)	Findings
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	***0.0001***		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	
		8	Time since amputation 0.5-2 y	4	4-47 y	4	0.37	0.78	
		8	Bilateral	2	Unilateral	6	***0.0001***		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		

Abbreviations: ABC = Activities-Specific Balance Confidence, BBS = Berg Balance Scale, K level = Medicare Functional Classification Level, TUG = timed up and go test.

Note: Data for Wong 2015 (PMID 25768067).[92] Additional details in Appendix D. Across Tables 57 to 70, P values of differences (comparisons) <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. Empty cells indicate either not applicable (e.g., categorical data for continuous outcomes or "no findings" if the association was not statistically significant).

*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.

Evaluated Predictors

Of the 14 studies that directly compared different LLP components or configurations and provided sufficient data to allow subgroup analyses, 12 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. Four studies (Hafner 2009, Hahn 2015 Kahle 2008, Wong 2015) evaluated K levels,[78, 82, 85, 92] which we also 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.[86, 87] We omit evaluation of residual limb firmness (an *ad hoc* descriptor) as a nonvalidated outcome predictor as was reported by one study (Kahle 2008).[85] None of the validated assessment techniques or prediction tools were used to characterize subgroups.

Studies That Evaluated Validated Predictors and Outcomes

Studies evaluated numerous outcomes, most of which have not been validated in lower limb amputees. Only eight of the studies, at least in part, analyzed validated outcomes with validated predictors (Hafner 2009, Hahn 2015, Hasenoehrl 2017, Isakov 1985, Kahle 2008, Moore 2017, Traballesi 2011, and Wong 2015). These eight studies were all deemed to be at moderate risk of bias. Five of these studies reported data on subgroups based on patient characteristics that we considered valid; three 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 included the 2 and 6 minute walk tests (2MWT, 6MWT), reported falls, ABC, BBS, Houghton scale, TUG, and PEQ. Of note, the PEQ MS 13/11, evaluated by Trabellesi 2011, has been validated in studies generalizable to the Medicare population. The PEQ subscales, evaluated by Hafner 2009, Moore 2017, and Theeven 2011 have been validated only in studies not generalizable to the Medicare population; in addition, only some of the subscales have demonstrated test validity.

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 Traballesi 2011 study comparing sockets, in which the average age was 34 years. Only one study included mostly people over age 65 years (Hasenoehrl 2017). Most study participants were men; however, the percentage of men varied from 76 to 94 percent (among the five studies that reported patient sex). Among six studies that characterized patients K levels at baseline, only one study (Wong 2015) included people at K1 level (25%), five studies included people at K2 level (25 to 100%), one study (Traballesi 2011) included people at either K3 or K4 level, four additional studies included people at K3 level (33 to 53%), and one additional study included one additional patient (7%) at K4 level. The five studies that reported amputation etiologies displayed wide heterogeneity across studies. In three studies, trauma accounted for about half or more of amputations (47 to 86%). In one study (Isakov 1985), 82 percent had dysvascular causes and only 18 percent trauma. In contrast, in Traballesi 2011, 86 percent 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 60) 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, some of 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.

Hahn 2015 (Table 61) compared the C-Leg or C-Leg compact microprocessor knee and prior mechanical knees in 1013 people, 43 due to trauma and 26 percent due to dysvascular disease. The participants were split approximately equally between MOBIS grade 2 and 3 (equivalent to K2 and K3), with 8 percent at grade 4. The study outcomes were generally poorly defined (in terms of what the actual questions being asked were). Most study outcomes did not appear to be comparisons between when people were using the C-Leg or their prior leg. We considered only the objective question of whether people were using a walking aid to be validated. Among the unreported number of those people who had been using walking aids with their mechanical knees, younger people were more likely to stop using the walking aids than older, and possibly those at K3 were more likely to stop using the walking aids than those at K2; however, no significant differences by age, K level, or amputation etiology were reported. Among the unvalidated outcomes, no significant differences in reduction in fear of falling were observed based on age or K level, and by correlation analysis no significant differences in changes in rating of safety were found based on age, K level, or etiology.

Hasenoehrl 2017 (Table 63) compared a microprocessor knee (Genium with Cenior Leg ruleset, which was designed for people at K level 1 or 2 function) and their own no microprocessor knee in five people with unilateral transfemoral amputation who were at K level 2 at the start of the study. The participants were mostly over age 65 years; only one had dysvascular conditions. Overall, functional performance was similar with the two sets of knees; although participants walked 10 meters faster at fast speed with the nonmechanical knee. The article reported individual participant data which allowed multiple subgroup analyses based on amputation etiology, sex, age, BMI, and time since amputation. After accounting for multiple testing, no statistically significant differences were found between subgroups regarding relative benefit of the microprocessor knee to improve several validated walking and function instruments, including TUG, 2MWT, 10 meter walk (at self-selected or fast speed), AMPPRO, and BBS. However, the one participant with a dysvascular condition walked significantly farther with the microprocessor knee than the mechanical knee compared with the other participants. Similarly, the one woman walked 10 meters (at self-selected speed) slower with the microprocessor knee than the mechanical knee, compared with the men. In addition, by regression analysis, those with higher BMI favored microprocessor knees by the AMPPRO instrument more than those with lower BMI. However, these findings did not persist after correcting for multiple testing. Overall, the study does not support any differences in benefit of microprocessor knees based on patient characteristics.

Kahle 2008 (Table 65) 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 K level 2 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 70) 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 study 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 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 70). 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

Locking Knee

Isakov 1985 (Table 64) 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 (6MWT) 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.

Hydraulic Ankle/Foot Prosthesis

Moore 2017 (Table 66) compared a hydraulic to a nonhydraulic ankle/foot prosthesis in 14 people with K2 function; most had amputations due to dysvascular conditions. Overall, people had better function, as measured by most of the PEQ subscales, with the hydraulic foot. The study reported subgroup data for the 12 people with transtibial amputations and the two people with transfemoral amputations, but did not formally compare the subgroups. Based on satisfaction with prosthesis and gait, transtibial amputees tended to favor the hydraulic foot more than transfemoral amputees did. But these findings were not statistically significant after accounting for multiple testing. Overall, the study does not support any differences in benefit of hydraulic ankle/foot prostheses over nonhydraulic components based on amputation level.

Ischial Containment Socket

Traballesi 2011 (Table 69) compared the Marlo Anatomic Socket with an ischial containment 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-MS 13/11, 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 Only Nonvalidated Measures

All Studies

Six studies reported analyses based only on nonvalidated outcome measures (Alaranta 1994, De Asha 2014, Gard 2003, Hahn 2016, Silver-Thorn 2009) or based on nonvalidated predictors (Theeven 2011). Theeven 2011 reported subgroup data only for *ad hoc* subclassifications of the K2 level (high, intermediate, and low; and it can also be noted that K levels overall have not been validated), but used validated and nonvalidated outcome measures (Table 68). Other studies are summarized in Tables 58, 59, 62, and 67.

As summarized in Table 56, studies found no significant differences in the relative effectiveness of different components based on subgroup classifications, after adjustment for multiple comparisons.

Study With Regression Analysis: Genium Knee Versus C-Leg

Hahn 2016 was the largest eligible study, which conducted the most comprehensive analysis (Table 62).[83] 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 benefit most 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 this review, which is asking what patient characteristics (or functional status measures) differentiate who are most likely to have better functional outcomes with which *specific* component. Hahn 2016, however, did not compare distinct components (or types of components). Instead, they compared newly-prescribed Genium knees to participants' prior knee prostheses. 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 did not report on the other 104 (11.7%) prior knees. Thus, the analysis is partially 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.[78]

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. It is unclear exactly how the prosthetists made the assessments. The study participants were probably selected because they 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). Ideally, a comparison of a component to evaluate heterogeneity of treatment effect would have included all potential users of the component, not only those deemed most likely to benefit. 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 report having imputed missing data. Thus, at most the 425 people with data about their residual limb condition could have been included in a multivariate model with all predictors listed in the study. 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 related to subject perception ranged from 67 to 96 percent. Total responsiveness rated by the prosthetists ranged from 95 to 97 percent, suggesting that most people had some improvement with the Genium prosthesis according to the prosthetist's assessment. 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; furthermore, the actual outcome(s) used in the final model are unclear. If the percentage was indeed high (as is the total responsiveness rated by the prosthetist), 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" possible 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. Thus, based on the chosen outcome, it may have been inevitable that no factors successfully predicted which people did better with one prosthesis or the other. However, it is not clear which "responsiveness" outcome(s) were used in their final model(s). These issues may have been a direct consequence of the prosthetists' abilities to successfully select patients to receive the Genium knee.

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 outcomes with a Genium knee. The only metric of predictive performance reported was a Nagelkerke's 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.[93, 94] For this and related reasons, the study does not provide compelling evidence about the predictive performance of the analyzed variables.

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 benefit most 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 prosthesis knees, mostly another microprocessor knee, the C-Leg, but also various mechanical knees and a large number of unknown prosthesis 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 71 provides an overall summary the study findings and the evidence. Be reminded that this review does not make conclusions about the overall effectiveness of different LLP components and configurations. Key Question 4 addressed whether there is evidence regarding heterogeneity of treatment effects, particularly with validated measures, in the field of LLP research. A relatively small percentage of comparative studies report sufficient data to allow subgroup analysis and evaluation of heterogeneity of treatment effect (14%, 15 of 104 otherwise eligible articles).

Of these 14 studies, only eight used validated predictor and outcome measures. Only one of the eligible studies was a randomized trial (Theeven 2011), but it did not evaluate validated subgroups. Only three studies (De Asha 2014, Hahn 2015, Hahn 2016) evaluated heterogeneity of treatment effect (analysis of differences in effect across subgroups); others 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 findings 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) could accurately and effectively predict which patients will benefit most or least from a given component. However, there were methodological and analytical issues with this study, which compared a specific microprocessor knee (Genium) to any prior used knee (mostly another microprocessor knee, C-Leg). Despite finding numerous statistically significant associations between participant characteristics and functional outcomes, the study concluded that no model accurately predicted relative effect (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 benefit most or least from a given component or configuration. Based on the methodology used to assess strength of evidence, the studies warrant a low strength of evidence that patient characteristics evaluated in the studies do not predict which patients would benefit most or least from a given LLP component or configuration. However, it may be more accurate to conclude that the evidence is currently too sparse and, thus, fails to adequately address whether different subgroups of amputees are more likely or less likely

to benefit from given specific LLP components or configurations. Most studies were very underpowered to find statistically significant evidence of differences among subgroups, with on average only about 30 participants per study (excepting two larger studies). Only eight of the 14 studies used validated predictors and outcomes. Similar conclusions are reached for this subset of studies. One large study attempted to develop a model to predict success with microprocessor knees; however, the study did not use a validated outcome and had several methodological and analytic concerns. It, therefore, provided insufficient additional evidence regarding who would benefit most from a microprocessor knee. An additional issue across almost all studies was that 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 71. Key Question 4 evidence profile

Outcome	No. Studies (N)	Study Limitations	Consistency	Precision	Reporting Bias	Directness*	Other Issues	Findings	SoE Grade
Validated predictors and outcomes (univariable)	8 (1096, 1013 in 1 study)	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	Some trends of differences in relative effect based on participant characteristics, however, none statistically significant after correcting for multiple testing	Low
All outcomes (univariable)	13 (1328, 1013 in one study)	Medium†	Consistent	Imprecise	Undetected	Indirect‡	Nonvalidated outcomes, high degree of multiple testing; mostly K2 to K4 level, unilateral transfemoral amputations due to traumatic etiologies	Some trends of differences in relative effect based on participant characteristics, however, none statistically significant after correcting for multiple testing	Low
Ambulatory and functional outcomes, nonvalidated (multivariable model)	1 (899)	High§	NA	Precise	Undetected	Indirect#	K2 to K4 (mostly K3) level, mostly traumatic etiologies. Study does not directly address Key Question.	A large set of variables individually were associated with better outcomes with the microprocessor knee. No model predicted who would most benefit from knee.	Insufficient

Abbreviations: 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. 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. Expectations of Ambulation

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. Patient Satisfaction With Process

Key Points

- Two studies evaluated patient satisfaction with the process of accessing an LLP
- The studies suggest that people are satisfied with their encounters with their prosthetists (low strength of evidence)

Findings

We found two studies that addressed this question. Note that this Key Question did not address satisfaction with the LLP. Studies addressing satisfaction with the LLP (or function with the prosthesis) would have been eligible for Key Question 4 if they reported subgroup analyses. Pezzin 2004 surveyed individuals about satisfaction with upper or lower prosthetic limbs and related services.[95] 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.[65]

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.[95] 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 United States, 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 (≥78.9%) or upper limb amputation (≥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%). As reported, "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 United States). 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 United States.[65] 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 [SD 16.2] years, women 58.1 [SD 17.9] years), with K levels (Medicare Functional Classification Levels) ranging from K0 (0.4%) to K4 (14.0%); 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 (SD 12.3) and 84.6 (SD 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 [SD 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 follow-up visits. Of 840 included clients, only 417 (50%) gave answers at the initial visit and only 348 (41%) at follow-up; 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 an 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 provides low strength evidence that people are satisfied with their encounters with their prosthetists (Table 72).

Table 72. 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. Long-Term Outcomes

Key Points

- Eight studies with at least 100 participants followed patients at least 6 months after prescription of an LLP; however, studies suffered from high risk of bias, incomplete reporting, and limited applicability to current lower limb amputees in the United States.
- Among lower limb amputees who receive an LLP prescription, 11 to 22 percent abandon the prosthesis at about 1 year (low strength of evidence)
  - People with unilateral transfemoral amputations are about twice as likely to abandon their LLP than those with unilateral transtibial amputations (low strength of evidence)
- Among LLP recipients, 24 to 29 percent use their prostheses only indoors at 1 year (low strength of evidence)
  - People with transfemoral amputations, or who are older, or with bilateral amputations are more likely to be limited to indoor use (low strength of evidence)
- There is insufficient evidence regarding other long-term outcomes of interest

Findings

We found eight studies (in nine articles) with at least 100 participants who were followed for at least 6 months after prescription of an LLP.[96-104] 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 data from 109 to 555 participants followed for 1 to 7 years (except for two studies that implied long-term followup, but did not report a timeframe.[98, 100] The studies only sparsely covered the subquestions pertaining to specific outcomes, particularly related to different subgroups of amputees. Studies did not explicitly account for intervening mortality or subsequent surgeries or injuries.

Table 73 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,[96-99] while four included about 10 to 20 percent bilateral amputees.[100-102, 104] Three of the studies included approximately similar percentages of people classified as having transfemoral and transtibial amputations (and no amputations at other levels).[97, 99, 100] One study was restricted to people with transtibial amputations.[98] Four studies included at least twice as many people with transtibial than transfemoral amputations.[100-102, 104] One of these latter studies included a small percentage of people with amputations at the hip and 11 percent with foot or ankle amputations.[101] 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.[96-99, 102] In addition to congenital amputations, Matsen 2000 also included an atypically large percentage of people with traumatic (50%) and infectious (21%) etiologies.[101] Roffman 2016 similarly had large percentages with traumatic (57%) and infectious (43%) etiologies.[103, 104] Marmann 1994 did not report amputation etiologies.[100] Dudkiewicz 2011 stated that 537 of 557 (96%) of participants had solid ankle cushion heel static prosthetic feet and suggested (or unclearly stated) that these people were at

Medicare Functional Classification Level 1 (K level 1, indoor ambulation) at the time of LLP prosthesis.[98]

Table 74 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).[97, 99, 104] 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.[101] 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.[98, 100] Only two studies were deemed to be at overall low risk of bias (Chen 2008 and Pohjolainen 1990).[96, 102] 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 75 provides the outcome results of interest across studies. The summarized data represent the proportion of study participants who had the outcome of interest at the time of follow-up in the studies (e.g., the percentage of people failed to ambulate bipedally at time of followup). Except as noted, studies generally were not explicit about how many people had the outcomes at the time of LLP prescription (e.g., how many people were able to walk bipedally when they received their prostheses).

Table 73. 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	196 (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. 96% K level 1 (unclear‡)	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, K level = Medicare Functional Classification Level, nd = no data, PMID = PubMed identifier (or journal), SD = standard deviation, TF = transfemoral amputation, TT = transtibial amputation.

*Funding source for all studies was nonindustry.

†Some patients listed more than one reason for amputation.

‡Almost all had solid ankle cushion heel prosthetic feet and had lower K level classification than 20 participants with single axis feet. It is likely that these people were at K level 1, but this is unclear.

Table 74. 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*	Follow-up 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)	Follow-up 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, PMID = PubMed identifier (or journal), RoB = risk of bias.

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

Table 75. Long-term followup results

Author	Outcome	Outcome Description	Timepoint	Comparison (P Value)	Subgroup	% (n/N)
Chen 2008 (18724135)	Abandoned prostheses	"No use"	28.3 mo		All participants††	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)	1 y		All participants	12.2% (24/196)
				Level (0.19)	Transfemoral	15.7% (14/89)
					Transtibial	9.3% (10/107)
				Age (0.18)	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)	1 y		All participants ††	4% (8/196)
				Level (0.47)	Transfemoral	5.6% (5/89)
					Transtibial	2.8% (3/107)
				Age (0.62)	Age <50 y	0% (0/16)
					50-64 y	2% (1/49)
					65-79 y	5.2% (6/115)
					>80 y	6.2% (1/16)
	Indoor use only of prosthesis	Stanmore Harold Wood Mobility Grade 3 (Walks indoors only, using walking aids; negligible walking outdoors)	1 y		All participants ††	24.4% (48/196)
				Level (**0.0076**)	Transfemoral	33.7% (30/89)
					Transtibial	16.8% (18/107)
				Age (**0.042**)	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	nd		All participants §	37.1% (75/555)**
Gauthier-Gagnon 1999 (10378500)	Abandoned prostheses	"Nonusers"	5 y		All participants	15% (~58/396)*

Author	Outcome	Outcome Description	Timepoint	Comparison (P Value)	Subgroup	% (n/N)
Marmann 1994 (none)	Abandoned prostheses	Using wheelchairs (exclusively)	nd		All participants	22% (24/110)
				Sides (0.70)	Bilateral	27% (3/11)
					Unilateral	21% (21/99)
Matsen 2000 (10954097)	Unable to walk	Not able to walk	7 y after surgery		All participants	7% (10/148)
	Indoor use only of prosthesis	Could walk only inside the house	7 y after surgery		All Participants	11% (16/148)
Pohjolainen 1990 (2235304)	Abandoned prostheses	Walking without prosthesis or nonambulatory	1 y		All participants	10.6% (15/141)
				Sides (0.22)	Bilateral	0% (0/16)
					Unilateral	12.0% (15/125)
				Level (**0.0032**)	Transfemoral unilateral	23.9% (11/46)
					Transtibial, unilateral	5.0% (4/79)
	Indoor use only of prosthesis	Walking indoors (including short distances only), requiring wheelchair outdoors	1 y		All participants	29% (41/141)
				Sides (**0.0006**)	Bilateral	68.7% (11/16)
					Unilateral	24.0% (30/125)
				Level (1.00)	Transfemoral unilateral	23.9% (11/46)
					Transtibial, unilateral	24.1% (19/79)

Author	Outcome	Outcome Description	Timepoint	Comparison (P Value)	Subgroup	% (n/N)
Roffman 2016 (26637652, 25450484)	Abandoned prostheses	Nonusers	1 y		All participants	17.9% (36/201)
				(0.19) †	Sex	
				(0.98) †	Age at amputation (continuous)	
				(0.19) †	Home vs. residential care	
				(0.24) †	Charlson Comorbidity Index (continuous)	
				(0.15/0.45) †	Diabetes, types 1/2	
				(0.46) †	Peripheral artery disease	
				Cardiac (**0.04**) †, ‡	Cardiac condition	28.0% (21/75)
					No cardiac condition	11.9% (15/126)
				(0.25) †	Renal failure	
				(0.98) †	Stroke	
				(0.80) †	Arthritis	
				(0.055) †	Remaining limb pathology	
				(0.26) †	Amputation cause	
				Sides (0.08) †	Bilateral	29.0% (9/31)
					Unilateral	15.9% (27/170)
				Level (**0.0013**) †, ‡	Transfemoral unilateral	33.9% (21/62)
					Transtibial or knee, unilateral	14.1% (24/170)

Abbreviation: nd = no data.

Note: P values <0.05 emphasized in bold font. Blank cells in % (n/N) column have no data reported. Where the "subgroup" is All participants, there is no comparison, thus, no P value and cell is left blank.

*Data not clearly reported.

†Univariable analyses.

‡Bonferroni 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.

**Most likely 96% of the participants were at Medicare Functional Classification Level 1 (K level 1) prior to prescription, suggesting an assessment they would be limited to indoor use.

††Excluding participants who were not prescribed prostheses, had died, or had bilateral amputations.

Failure To Maintain Bipedal Ambulation

No study explicitly reported maintenance of bipedal ambulation, per se. Matsen 2000, a study conducted in the United States, reported, for only the full sample, that 7 percent (10/148) were "not able to walk" at a mean of 7 years after surgery.[101] The estimated 95% confidence interval about this estimate is 4 to 12 percent. This study was potentially not fully representative of typical adult amputees in the United States 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

Only Davies 2003[97] reported on use of prostheses only for transfers in 196 study participants. Of note, this study is relatively old (published in 2003) and was conducted in the UK. The study reported this outcome for people with unilateral amputations, roughly half of patients had transtibial and half transfemoral amputations. The cause of amputation was vascular or diabetes in 88 percent of the amputees. The study was deemed to be at overall moderate risk of bias. The study had a high percentage of potentially eligible patients who were not included and neither demonstrated that the survey respondents were representative of their populations. It did not perform multivariable analyses to compare subgroups.

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 study found no significant differences in rates of use of prostheses only for transfers based on level of amputation (transtibial vs. transfemoral), or by age. However, the study was greatly underpowered for subgroup analyses.

Use of Prostheses Only Indoors

Four studies reported on rates of prosthesis use only indoors.[97, 98, 101, 102] 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). Notably only Dudkiewicz 2011 was published relatively recently and only Matsen 2000 was conducted in the United States.

Only Dudkiewicz 2011 reported on participants' K levels at the start of the study, suggesting that almost all had limited ambulation, possibly K level 1, at the time of prescription. For other studies it is unclear how many, if any people were homebound before LLP prescription. 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.

The four studies reported a wide range of rates of amputees using prostheses only indoors at followup. This likely is indicative of different study eligibility criteria. Matsen 2000 (described above under *Maintenance of Bipedal Ambulation*) reported a substantially lower rate of use only indoors than other studies at 11 percent.[101] 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%). At the other extreme, Dudkiewicz 2011 reported that 37 percent of people used prostheses indoors. However, the study (unclearly) reports that 96 percent of people were at K level 1 at the time of LLP prescription. This would suggest that 59 percent of the study participants (96 percent at K1 at initiation minus 37 percent at followup) exceeded their K level classification and improved to a higher K level. The remaining two studies, which both included mostly people with dysvascular etiologies for their amputations, had similar rates of indoor use only at 1 year followup (24% and 29%).

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).[97] The study also found that restriction to indoor use increased with amputees' age (<50 years 6%, 50-64 years 14%, ≥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).[102]

Abandonment of Prostheses

Six studies reported on rates of prosthesis abandonment (no longer using).[96, 97, 99, 100, 102-104] These included Chen 2008, Davies 2003, Gauthier-Gagnon 1999, Marmann 1994, Pohjolainen 1990, and Roffman 2016. Of note, none of these studies were conducted in the United States and only Roffman 2016 was published relatively recently. 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. Studies did not classify participants ambulation capabilities (i.e., K levels). 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. No clear differences were found across studies based on publication year.

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 statistically 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.[104] 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 75). 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, an Australian study, reported reasons for prosthesis nonuse (or other outcomes of interest).[104] 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 76 summarizes the strength of evidence for each outcome and subgroup analysis with data. For all outcomes of interest, there is low or insufficient strength of evidence because evidence is sparse, most studies were conducted in the 1990s or earlier, and only one of the studies was conducted in the United States, with its unique healthcare system and standards for prosthesis prescription. Also, most studies had methodological limitations, most populations analyzed were often not directly applicable to the Medicare population, some study findings were inconsistent with each other, and few studies clearly 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.

We found a low strength of evidence, based on six studies, that about 11 to 22 percent of lower limb amputees who receive an 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. However, only one of the studies was conducted in the United States and it used hospital data as of 1998; most other studies were also old. 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.

Based primarily on two generally representative studies, there is low strength of evidence that 24 to 29 percent of LLP recipients use their prostheses only indoors at 1 year. 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 the rates of failure to maintain bipedal ambulation (1 study, 7% at 7 years), use of prostheses only for transfer (1 study, 4% at 1 year), and why people abandon their prostheses. No study reported on “major problems” with prostheses.

Table 76. 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, old study	7% at 7 years	Insufficient
Use of prosthesis only for transfers	All participants	1 (196)	High	NA	Precise	Undetected	Indirect	Single 25 year old study	4% at 1 year	Insufficient
	TF vs. TT	1 (196)	High	NA	Precise	Undetected	Indirect	see above	No significant difference	Insufficient
	Age	1 (196)	High	NA	Precise	Undetected	Indirect	see above	Nonsignificantly higher limited used with older age	Insufficient
Use of prosthesis only indoors	All participants	4 (1040)	Medium	Inconsistent	Imprecise	Undetected	Direct	Mostly old, non-U.S.	24-29% at 1 year	Low
	TF vs. TT	2 (337)	High	Inconsistent	Precise	Undetected	Direct	see above	Twice as many TF use only indoors (1 study, P=0.008)), no difference (1 study)	Insufficient
	Age	1 (196)	High	NA	Precise	Undetected	Direct	see above	Older more likely to use only indoors (P=0.042)	Insufficient
	Bilateral vs. unilateral	1 (141)	High	NA	Precise	Undetected	Direct	see above	Bilateral more than twice as likely to use only indoors (P=0.0006)	Insufficient

Outcome	Subgroup	No. Studies (N)	Study Limitations	Consistency	Precision	Reporting Bias	Directness*	Other Issues	Findings	SoE Grade
Abandonment of prosthesis	All participants	6 (1153)	Medium	Consistent †	Precise	Undetected	Direct	Mostly old, non-U.S.	11-22% at 1 year (or undefined)†	Low
	TF vs. TT	3 (538)	High	Consistent	Precise	Undetected	Direct	see above	TF more likely to abandon prosthesis than TT	Low
	Bilateral vs. unilateral	3 (452)	High	Inconsistent	Precise	Undetected	Direct	see above	Nonsignificant, but conflicting directionality	Insufficient
	Age	2 (397)	High	Inconsistent	Precise	Undetected	Direct	see above	Older nonsignificantly more likely to abandon (1 study), no difference in age (1 study)	Insufficient
	Multiple	1 (201)	High	NA	Precise	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	Single non-U.S. study	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 over 100 studies that compared at least two LLP components or configurations that reported ambulatory, functional, or other patient-centered outcomes. We found many additional studies that evaluated only biomechanical properties of the components (which this review does not evaluate) 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 us to evaluate) heterogeneity of treatment effect. Overall, the evidence is currently sparse and fails to adequately address whether different subgroups of amputees are more likely or less likely to benefit from given specific LLP components or configurations. We also found generally sparse evidence regarding patient expectations, patient satisfaction with care, and long-term outcomes.

From the amputee's and the clinician's perspective, among the most important questions is which LLP configuration (comprised of which prosthesis components) would best enable maximal health, function, and quality of life for a given individual? Given the large number of component types (knee, foot/ankle, socket, liner, etc.) and the range of features for each of these, the process of determining which LLP component or configuration is best for individuals is quite complex. However, the majority of the evidence addresses the question of which LLP component or configuration maximizes ambulation and function in the average patient, as opposed to which LLP component or configuration of components would best suit the needs of a given individual. In other words, few studies address the issue of heterogeneity of treatment effect. 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 prosthesis, and unnecessarily increase health care expenditures.

Further limiting and complicating the evidence base, there are a very large number of instruments that are used in the surgical, rehabilitation, and prosthesis literature to assess overall patient function, predict future outcomes, and measure various aspects of mobility , function, quality of life issues, and other patient-centered outcomes. While some of the scales and items used in these studies were developed specifically to assess lower limb amputees, many were designed for other populations. Furthermore, many of the measures used in LLP research studies have either not been evaluated for validity in the population of interest or were created *ad hoc* for each study. Our review found that among the small number of comparative studies that provided heterogeneity of treatment effects data, fewer than half used both predictor and outcome measures with evidence of test validity. However, the studies were highly variable in terms of who was analyzed, how instruments were validated, etc. We, therefore, recommend development of a consensus set of core, validated and reliable instruments to be used in future research. However, it will remain important that researchers assess whether the instruments have sufficient evidence of validity for their needs and have been evaluated in a sample of people representative to their study population.

We found evidence to enable the evaluation of the psychometric properties of 50 instruments (many containing evaluated subscales and items) in people with lower limb amputations. Many of the studies that evaluated instrument psychometric properties, however, were conducted in samples of participants who were arguably different than typical lower limb amputees with Medicare insurance, many of whom have 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 that 39 of the 50 instruments have been evaluated in studies deemed generalizable to the Medicare population. Seventeen of these instruments, as a whole or in part, to have evidence supporting both reliability and validity. However, we recommend that researchers who are using this report to determine which instruments to use for their own studies also review the primary studies to determine whether the instruments have been sufficiently validated for their needs, are responsive to clinically important change, and have been evaluated in a sample of people representative of their study population.

Notably, no study has evaluated psychometric properties of the Medicare Functional Classification Level (MFCL or K level) system. Furthermore, the reader is reminded that lack of evidence regarding the psychometric properties of instruments does not imply that these measures are not valid or reliable, only that they have not been (adequately) evaluated. Standards for psychometric testing have changed over the years, so older instruments, evaluated by earlier studies, may not have psychometric property evaluations more commonly reported now.

These instruments address many aspects of patients' function, ambulation, and quality of life. To improve the accuracy, interpretability, and, importantly, the reproducibility of the literature, we strongly encourage future researchers to maximize the use of instruments with evidence of validity and reliability in the population of interest. Where such measures are lacking, the validity of the instruments being used as pivotal outcomes should be examined before use in future studies. We also encourage journal editors to require use of validated and reliable instruments when appropriate and feasible. However, we recognize that it will remain common that unvalidated measures may be appropriate in select instances (e.g., when measures to assess a particular trait or construct do not exist).

Summary of Evidence

- This review focuses on narrow research questions and does not attempt to address many of the "big picture" topics that may also be of interest to many readers.
  - The review summarizes the evidence supporting instrument psychometrics for all lower limb amputees, with a subfocus on studies likely generalizable to the Medicare population.
  - The review provides a gross assessment of validity, reliability, and other psychometric properties of instruments. It does not evaluate the strength of the evidence in support of those properties, rather it dichotomizes the evidence as present or absent. The review provides overall evidence summaries by instrument, but does not provide head-to-head comparisons of measurement properties of instruments.
  - The review evaluates the small subset of comparative studies that provide data to allow evaluation of heterogeneity of treatment effect of specific LLP components. It does not address the overall comparative effectiveness of different LLP components or configurations.
  - The review focuses on clinical and patient-centered outcomes. Despite the importance of biomechanical measures for the development and evaluation of LLP devices and components, this review focuses on outcomes that are important to people receiving LLPs and their healthcare providers.
  - The review addresses satisfaction with the process of accessing an LLP. Satisfaction with an LLP and overall satisfaction are covered only within the scope of Key Question 4 about heterogeneity of treatment effect.
  - The review evaluates specific long-term outcomes related to continued use of LLPs.

- 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 the 50 instruments for which we found assessments of psychometric properties, we found that (for the total instrument or for one or more of their subscales or items), 41 have evidence of test validity, 35 have evidence of reliability, and 28 have evidence of both test validity and reliability. However, floor or ceiling effects were common. 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, 39 instruments have been evaluated. Of these, 29 have evidence of validity, in whole or in part, and 23 have evidence of reliability. In total, 17 instruments have been found to have evidence of both reliability and validity, in whole or in part.
- We found 14 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. Only one study had a mean age greater than 65 years; only two other studies included a majority of participants with dysvascular conditions. In addition, only eight 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. Of note, this review did not directly address the question of average relative effect of different components; thus 89 comparative studies that did not provide subgroup analyses or patient-level data were excluded. 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 benefit most or least from a given component. There is low strength of evidence that evaluated patient characteristics do not predict which patients would benefit most 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 likely or less likely to benefit from given specific components.
  - Overall, studies did not identify participant characteristics that predict which lower limb amputees would benefit most or least from a given LLP component or configuration, regardless of whether validated measures were used. There is low strength of evidence that evaluated patient characteristics do not predict which patients would benefit most or least from a given LLP component or configuration. 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 likely 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 benefit most 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 limitations, including that it compared a specific microprocessor knee with a variety of other prosthetic knees (mostly including another microprocessor knee) in people selected based on the judgment of a prosthetist that they were likely to benefit from the test knee. The study, overall, provides insufficient additional evidence regarding who would benefit most or least 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.
- Regarding long-term followup, eight eligible studies of at least 100 participants with followup of at least 6 months after LLP prescription (or 1 year after amputation) reported outcomes of interest. However, only one of these studies was conducted in the United States and most (including the U.S. study) were published more than 10 years ago.
    - There is insufficient evidence regarding failure to maintain bipedal ambulation.
    - There is insufficient evidence regarding use of prostheses only for transfers.
    - There is low strength of evidence that 24 to 29 percent of people use their LLP only indoors at 1 to 7 years after prescription.
        - There is insufficient evidence to assess differences in indoor-only use in different subpopulations.
    - There is low strength of evidence that 11 to 22 percent of people have abandoned their prostheses (no longer used them) at 1 year.
        - There is low 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 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.

The applicability of these studies to the general population of people with LLPs may be somewhat limited, as the studies mostly evaluated prosthetic 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) device. 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 over a period of time, one would expect that patient characteristics such as age, strength, and mobility will also have changed. Analyses that controlled for differences in these and other potential confounders before versus after switching could account for some of the biases inherent in these studies. 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 has methodological concerns, so it is insufficient to provide evidence to address the Key Question. Overall, the studies suffered from the same methodological quality limitations described by Hafner and Sawers in their secondary analysis of a systematic review of microprocessor and nonmicroprocessor knees.[105] Namely, issues related to the complexity and variability of specific components used by participants; failure to use a specific, well-defined comparator component; information on how well the prosthetics were fit to the users or how adequately they were trained in use of each device; variability in experience with prior devices; lack of outcome assessor blinding; small sample size; possible bias in study eligibility criteria; and use of nonvalidated predictors and instruments.

Another limitation of the studies evaluating heterogeneity of treatment effect is that all studies evaluated only a limited set of patient characteristics such as age, amputation level, or amputation etiology. None analyzed differences in treatment effect by subgroups based on any assessment techniques, prediction tools, or outcome measures. In addition, studies of LLPs and other such devices will always have the difficulty that each LLP is matched to best fit and work for each individual. In most studies there is no “standard” intervention, but instead each LLP configuration is adjusted to best suit each individual. This inherent variability and complexity of the intervention (the LLP) will always confound analyses aiming to explain heterogeneity of treatment effects.

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). In addition, the eligible studies were almost all conducted outside the United States, in countries with very different healthcare systems and with different criteria for determining who is eligible for what type of prosthesis. The eligible studies were also mostly more than an decade old. 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 did not report on people's K levels or functional abilities at the time of LLP prescription or provide subgroup analyses based on K levels. Therefore, it is unknown to what degree the estimates of limited use varies by people's underlying functional abilities. Studies also mostly did not report information on why people limited or stopped their use of LLPs.

Analysis Limitations

Assessment of reliability, validity, and other psychometric properties is open to interpretation. By the strictest definition, an instrument 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 an instrument 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 an instrument has predictive validity regarding one outcome, such as future successful use of an 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 an instrument to have evidence of validity if there was evidence of any type of validity (other than face/content). We, thus, categorized the evidence and dichotomized data so that instruments were classified as valid or not. We made no attempt to rank or compare instruments. Some instruments 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 instruments used in LLP research is whether an instrument has been validated for any purpose. The actual appropriateness of an instrument for use in a specific study may vary based on the study question, eligibility criteria, and hypotheses.

As discussed above, the distinction between assessment techniques, prediction tools, and outcome measures is arguably somewhat artificial in actual application. Many of the instruments can be used for any of these contexts. Readers may disagree with how the instruments 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 United States). 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 or configurations. Key Question 4 addressed whether there is evidence regarding heterogeneity of treatment effects, particularly with validated measures, in the field of LLP research. 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 has methodological concerns.

Future Research Recommendations

General Recommendations

Future research is needed to adequately address most of the questions in this review. While numerous instruments have evidence of validity, at least in part, additional studies are needed to confirm their psychometric properties and to better understand specific aspects of validity. Additional studies are needed that compare responsiveness of validated instruments to specific prosthesis interventions. Some instruments, subscales, or specific items may be better choices because they are more responsive to the types of changes provided by specific components. For microprocessor knees, for example, instruments that include items related to walking on uneven surfaces, stairs, balance confidence, stumbles and/or falls, would likely be more responsive than instruments that focus on specific physical performance such as distance walked or speed of ambulation. These latter instruments may be more responsive in assessment of foot, ankle, and powered componentry.

As is the case for research in all clinical domains, studies should fully describe the participants' demographic information and other salient characteristics. For studies of LLPs, these include amputation level and etiology, baseline K level or equivalent, living situation, and other descriptions of people's functional status. In addition, at least for studies conducted in the United States, it would be informative to report people's insurance coverage, since insurance status may have important implications for access to prostheses and rehabilitation services.

Well-conducted studies, using validated predictors and outcomes, are needed to evaluate which LLP components and configurations would be most effective to achieve successful outcomes for which patients. 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 that incorporate the perspectives of patient and other key stakeholders (a core outcome set); in addition, studies that measure other specific outcomes, as needed (a core outcome set). This would allow comparability across studies and pooling of study findings (e.g., meta-analysis). A large body of individual, "one-off" analyses that use 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. Creation of such a core outcome set would likely require a consensus development process among a range of stakeholders. 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 prostheses, there is a great need to understand how best to choose among the myriad LLP component choices for an individual patient. However, currently the evidence is quite sparse related to differences in relative effect of different prostheses in different groups of people. 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 or "under-prescription," where people are given LLPs without capabilities they could benefit from. However, the evidence does not provide high, or even moderate, strength of evidence to support what patient (or other) characteristics could be used to accurately match patients with LLPs. 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.[93, 94, 106] 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.

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) to address many of the noted concerns.[78, 83] 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 more focused question that may be 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 follow-up 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. These studies should clearly include unbiased samples of people who have received LLPs. Currently many studies include only a subset of these people (e.g., those with a current LLP prescription) or also include amputees who never received an LLP. 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 instruments that assess ambulation, function, quality of life, and other patient-centered outcomes exist for people with lower limb amputations and LLPs. Researchers should minimize the use of nonvalidated or *ad hoc* measures. Those who wish to use new or previously unvalidated instruments should validate these measures before using them. Researchers with an interest in assessing LLPs for the Medicare population would be best served to focus on those instruments with evidence of reliability and validity for this population or validate the measures in this population. The majority of the evidence on LLPs addresses the question of which LLP component or configuration maximizes ambulation and function in the average patient, as opposed to which LLP would best suit the needs of a given individual. In other words, few studies address the issue of heterogeneity of treatment effect. A small evidence base does not provide data to guide LLP selection for a specific patient to maximize their ambulation, function, and quality of life or to minimize abandonment or limited use. However, this does not imply that the evidence suggests patient characteristics cannot effectively predict which patients would benefit most or least from one or another specific component; only that the current evidence does not support use of any given predictor. There is low strength of evidence that patients are generally satisfied with the prosthetic services they receive. Further high-quality research is needed to better assess the psychometric properties of instruments (whether assessment

techniques, prediction tools, or outcome measures) and to answer the Key Questions addressed in this systematic review.

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Abbreviations and Acronyms

2MWT:	2 Minute Walk Test
6MWT:	6 Minute Walk Test
AAS:	Amputee Activity Survey
ABC:	Activities-specific Balance Confidence
ADAPT:	Assessment of Daily Activity Performance in Transfemoral Amputees
AHRQ:	Agency for Healthcare Research and Quality
AMP:	Amputee Mobility Predictor
AMPnoPRO:	Amputee Mobility Predictor without use of a prosthesis
AMPPRO:	Amputee Mobility Predictor with use of a prosthesis
AMPSIMM:	Amputee Single Item Mobility Measure
BA LOA:	Bland-Altman limits of agreement
BBS:	Berg Balance Scale
Bi:	bilateral amputation
BMI:	body mass index
CAT:	computer adaptive test
CCTR:	Cochrane Central Trials Registry
CDSR:	Cochrane Database of Systematic Reviews
CSQ:	Climbing Stairs Questionnaire
Dysvasc:	dysvascular disease
FAC:	Functional Ambulation Categories
FAI:	Frenchay Activities Index
FIM:	Functional Independence Measure
FSST:	Four Square Step Test
IES:	Impact of Events Scale
IPD:	individual patient data
IQR:	interquartile range
K level:	Medicare Functional Classification Level
KQ:	Key Question
L Test:	L Test of Functional Mobility
LCD:	Local Coverage Determination
LCI:	Locomotor Capabilities Index
LEMOCOT:	Lower-Extremity Motor Coordination Test
LHS:	London Handicap Scale
LLP:	Lower limb prosthesis
MC:	Medicare
MCS:	Mental Component Score
MDC:	minimal detectable change
MFCL:	Medicare Functional Classification Level
MID:	minimum (clinical) important difference
nd:	no data/not reported
NQ-ACGC:	Quality of Life in Neurological Conditions – Applied Cognition/General Concerns
OMT:	Outcome Measurement Tool
OPCS:	Office of Population Censuses and Surveys Scale
OPOT:	Orthotics and Prosthetics National Office Outcomes Tool

OPUS:	Orthotics Prosthetics Users Survey
PCS:	Physical Component Score
PEQ:	Prosthesis Evaluation Questionnaire
PEQ-MS:	Prosthesis Evaluation Questionnaire-Mobility Scale
PFI:	Physical Function Index
PGI:	Patient Generated Index
PLUS-M:	Prosthetic Limb Users Survey of Mobility
PMID:	PubMed identifier
PPA:	Prosthetic Profile of the Amputee
PROMIS:	Patient-Reported Outcomes Measurement Information System
PROS:	Prosthetist's Perception of Client's Ambulatory Abilities
PSFS:	Patient-Specific Functional Scale
Q-TFA:	Questionnaire for Persons with a Transfemoral Amputation
RMI:	Rivermead Mobility Index
RNL:	Reintegration to Normal Living Index
RSQ:	Rising and Sitting Down Questionnaire
SAT-PRO:	Satisfaction with Prosthesis Questionnaire
SCS:	Socket Comfort Score
SF-12/SF-36/SF-36V:	Short Form Health Surveys 12, 36, and 36V
SIGAM:	Special Interest Group of Amputation Medicine
SIP:	Sickness Impact Profile
SIP-PD:	Sickness Impact Profile-Physical Dimension
Sn:	sensitivity
SNF:	skilled nursing facility
SoE:	Strength of Evidence
Sp:	specificity
TAPES:	Trinity Amputation and Prosthesis Experience Scales
TF:	transfemoral (above the knee) amputation
TFP:	Transfemoral Fitting Predictor
TMMS:	Trait Meta Mood Scale
TT:	transtibial (below the knee) amputation
TUG:	Timed Up and Go
TWT:	Timed Walk Test
Uni:	unilateral amputation
WHOQOL-BREF:	World Health Organization Quality-of-Life Scale – Brief Version
WQ:	Walking Questionnaire

Appendix A. Search Strategy

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 prosthe*)
OR (rejection* and prosthe*)
OR Quality of Life
OR Health Status)
AND
(“Artificial limb”
OR “Artificial limbs”
OR "Artificial Limbs"[Mesh]
OR prosthe* [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 endoprosth*[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

#39	#31 NOT #38	4,449
#38	#32 OR #33 OR #34 OR #35 OR #36 OR #37	561,702
#37	orthot* OR orthos* NOT (amput* OR prosth*)	79,418
#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*	25,573
#35	'osteotomy'/exp	37,235
#34	'vascular surgery'/exp	384,960
#33	'prosthesis implantation'/exp	2,151
#32	'arthroplasty'/exp	63,011
#31	#24 AND #27 AND #30	6,991
#30	#28 OR #29	377,525
#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	83,740
#28	'leg'/exp OR 'leg'	341,178
#27	#25 OR #26	287,601
#26	artificial AND limb* OR prosthe*	287,569
#25	'limb prosthesis'/exp OR 'limb prosthesis'	7,731
#24	#17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23	4,097,920
#23	quality AND of AND life OR health AND status	474,604
#22	rejection* AND prosthe*	1,092
#21	abandonment AND prosthe*	80
#20	function OR mobility OR ambulation OR stair* OR locomotion OR 'treatment outcome' OR walking	3,662,274
#19	'walking difficulty'/exp OR 'walking difficulty' OR 'mobility'/exp OR mobility AND limitation	2,685
#18	'functional assessment'/exp OR 'functional assessment' OR 'functional status'/exp OR 'functional status'	103,884
#17	'convalescence'/exp OR 'convalescence' OR 'recovery'/exp OR recovery AND ('function'/exp OR function)	92,026

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. Excluded Studies

Adamczyk PG, Roland M, Hahn ME. Sensitivity of biomechanical outcomes to independent variations of hindfoot and forefoot stiffness in foot prostheses. Hum Mov Sci. PMID: 28499159**.**
KQ 4-7: No outcome or analysis of interest

Agrawal V and Gailey R and O'Toole C and Gaunaurd 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. PMID: 23364890**.**
KQ 4-7: No outcome or analysis of interest

Agrawal V and Gailey RS and Gaunaurd 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. PMID: 24925671**.**
KQ 4-7: No outcome or analysis of interest

Agrawal V and Gailey RS and Gaunaurd IA and O'Toole C and Finnieston AA. Comparison between microprocessor-controlled ankle/foot and conventional prosthetic feet during stair negotiation in people with unilateral transtibial amputation. J Rehabil Res Dev. PMID: 24301431**.**
KQ 4-7: No outcome or analysis of interest

Agrawal Veena R and Skrabek Ryan Q and Embil John M and Gross Patrick and Trepman Elly. Effect of Socioeconomic and Health Factors on Prosthetic Use after Lower-Limb Amputation. Journal of Prosthetics & Orthotics (JPO).
KQ 7: N<100

Agrawal Vibhor Ramchandra. A comparison of gait kinetics between prosthetic feet during functional activities -- Symmetry in External Work (SEW) approach.
KQ 1-3: N<20

Akkaya N and Akkaya S and ï¿½_imï¿½ïï¿½ir Atalay N and Findikoï¿½ïï¿½lu G and Alkan H and ArdiÌ¤ F. Demographic and clinical features of our lower limb amputee patients. Journal of Rheumatology and Medical Rehabilitation.
Low resource country

Aksnes, L. H., Bauer, H. C. F., Jebsen, N. L., Follerås, G., Allert, C., Haugen, G. S. and Hall, K. S. Limb-sparing surgery preserves more function than amputation: a Scandinavian Sarcoma Group study of 118 patients. Journal of Bone & Joint Surgery, British Volume. PMID: 18539673**.**
KQ 1-3: Not validation

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. Pm r. PMID: 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. PLoS One. PMID: 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. PMID: 25184154**.**
Low resource country

Ali S and Abu Osman NA and Eshraghi A and Gholizadeh H and Abd Razak NA and Wan Abas WA. Interface pressure in transtibial socket during ascent and descent on stairs and its effect on patient satisfaction. Clin Biomech (Bristol, Avon). PMID: 24161521**.**
Low resource country

Ali S and Osman NA and Mortaza N and Eshraghi A and Gholizadeh H and Wan Abas WA. 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. Clin Biomech (Bristol, Avon). PMID: 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. PMID: 24963603**.**
Low resource country

Altner PC and Rusin JJ and DeBoer A. Rehabilitation of blind patients with lower extremity amputations. Arch Phys Med Rehabil. PMID: 7369844.
KQ 7: N<100

Andrysek J and Klejman S and Torres-Moreno R and Heim W and Steinnagel B and Glasford S. Mobility function of a prosthetic knee joint with an automatic stance phase lock. Prosthet Orthot Int. PMID: 21697198.
KQ 4: No subgroup

Andrysek J and Rotter K and Garcia D and Valdebenito R and Wright V and Moreno RT and Mitchell CA and Cubillos R. Clinical field trials of a new type of prosthetic knee joint utilizing the automatic stance-phase lock mechanism. Prosthetics and Orthotics International.
KQ 4: No subgroup

Andrysek J and Wright FV and Rotter K and Garcia D and Valdebenito R and Mitchell CA and Rozbaczylo C and Cubillos R. Long-term clinical evaluation of the automatic stance-phase lock-controlled prosthetic knee joint in young adults with unilateral above-knee amputation. Disabil Rehabil Assist Technol. PMID: 27376843.
KQ 4: No subgroup

Arwert HJ and van Doorn-Loogman MH and Koning J and Terburg M and Rol M and Roebroeck ME. Residual-limb quality and functional mobility 1 year after transtibial amputation caused by vascular insufficiency. Journal of rehabilitation research and development. PMID: 17943683.
KQ 7: N<100

Asano, M., Rushton, P., Miller, W. C. and Deathe, B. A. Predictors of quality of life among individuals who have a lower limb amputation. Prosthet Orthot Int. PMID: 18569891.
KQ 1-3: Not validation

Aström I, Stenström A. Effect on gait and socket comfort in unilateral trans-tibial amputees after exchange to a polyurethane concept. Prosthetics and Orthotics International. PMID: 15171575.
KQ 4: No subgroup

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

Bai X, Ewins D, Crocombe AD, Xu W. Kinematic and biomimetic assessment of a hydraulic ankle/foot in level ground and camber walking. PLoS One. PMID: 28704428.
KQ 4: No subgroup

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. Longitudinal gait analysis of a person with a transfemoral amputation using three different prosthetic knee/foot pairs. Physiotherapy theory and practice. PMID: 22191438.
Case report/series

Bateni H and Olney SJ. Effect of the weight of prosthetic components on the gait of transtibial amputees. Journal of Prosthetics & Orthotics (JPO).
KQ 4: No subgroup

Baum Brian S, Hiroaki Hobara, Yoon Hyuk Kim, Jae Kun Shim. Amputee Locomotion: Ground Reaction Forces During Submaximal Running With Running-Specific Prostheses. Journal of Applied Biomechanics. PMID: 26957365.
KQ 4: No subgroup

Beck ON, Taboga P, Grabowski AM. How do prosthetic stiffness, height and running speed affect the biomechanics of athletes with bilateral transtibial amputations?. J R Soc Interface. PMID: 28659414.
KQ 4: No subgroup

Beck ON, Taboga P, Grabowski AM. Prosthetic model, but not stiffness or height, affects the metabolic cost of running for athletes with unilateral transtibial amputations. J Appl Physiol (1985). PMID: 28360121.
KQ 4-7: No outcome or analysis of interest

Beck ON, Taboga P, Grabowski AM. Reduced prosthetic stiffness lowers the metabolic cost of running for athletes with bilateral transtibial amputations. J Appl Physiol (1985). PMID: 28104752.
KQ 4-7: No outcome or analysis of interest

Beekman CE and Axtell LA. Prosthetic use in elderly patients with dysvascular above-knee and through-knee amputations. Phys Ther. PMID: 3659135.
KQ 7: N<100

Bell EM and Pruziner AL and Wilken JM and Wolf EJ. Performance of conventional and X2(R) prosthetic knees during slope descent. Clinical biomechanics (Bristol, Avon). PMID: 26921583.
KQ 4: No subgroup

Berg KO, Maki BE, Williams JI, Holliday PJ, Wood-Dauphinee SL. Clinical and laboratory measures of postural balance in an elderly population. Arch Phys Med Rehabil. PMID: 1444775.
Not amputees

Berge JS and Czerniecki JM and Klute GK. Efficacy of shock-absorbing versus rigid pylons for impact reduction in transtibial amputees based on laboratory, field, and outcome metrics. J Rehabil Res Dev. PMID: 16680617.
KQ 4: No subgroup

Berry D and Olson MD and Larntz K. Perceived stability, function, and satisfaction among transfemoral amputees using microprocessor and nonmicroprocessor controlled prosthetic knees: a multicenter survey. Journal of Prosthetics & Orthotics (JPO).
KQ 4: No subgroup

Bilodeau S and Hebert R and Desrosiers J. [Questionnaire on the satisfaction of persons with lower-limb amputations towards their prosthesis: development and validation]. PMID: 10462879.
KQ 1-3: Not validation

Bilodeau S and Hebert R and Desrosiers J. Lower limb prosthesis utilisation by elderly amputees. Prosthet Orthot Int. PMID: 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. Age & Ageing. 32(3):315-20, 2003 May. PMID: 12720619.
Not amputees

Blum C and Ehrler S and Isner ME. Assessment of therapeutic education in 135 lower limb amputees. Ann Phys Rehabil Med. PMID: 27676838.
Not peer reviewed publication

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KQ 4: No subgroup

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Not LLP

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