

Lower Limb Prosthetic Outcome Measures: A Review of the Literature 1995 to 2005

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Background: Patient-based outcome measures, addressing constructs such as health-related quality of life, subjective health status, and functional status, are increasingly used as primary or secondary end points in clinical trials. In the field of amputee and prosthetic rehabilitation, there has been a parallel increase in the use of outcome measures but there are a multitude of measures currently being used by researchers and clinicians and currently there is no “golden standard.” Further, it is important to be able to distinguish between outcome measures that have adequate evidence and statistical estimates of validity and reliability and those that lack such evidence.

Objectives: The goal of this project was to conduct a structured review of the international literature on lower limb prosthetic outcome measures.

Criteria for selecting studies for this review:

Types of studies: The search identified 340 articles, of which 28 met all inclusion criteria and were included in the review.

Types of participants: Persons with lower limb amputations

Types of outcome measures: A total of 25 measures were used as primary outcome measures, with many more as comparators.

Mobility:

- Generic: Timed up and go (TUG) test measures mobility by assessing many of the basic components of mobility, Timed walk tests (TWTs) measure function in terms of mobility and have been used with a variety of clinical conditions,^{3,13} including lower limb amputees.
- Amputee specific: Amputee Mobility Predictor with Prosthesis. AMPPro is a predictive tool to assess the ambulatory potential of lower limb amputees, and it can also be used as an evaluative tool to measure function during or after rehabilitation. Locomotor Capabilities Index (LCI) measures a lower limb amputee’s locomotor capabilities with a prosthesis during and after rehabilitation. Russek’s Code measures mobility of lower limb amputees fitted with a prosthesis. Special Interest Group in Amputee Medicine (SIGAM) measures function of lower limb amputees fitted with a functional or cosmetic prosthesis in terms of mobility.
- Not generic or amputee specific: Rivermead Mobility Index (RMI) is a measure of function in terms of the capacity to perform a mobility activity and was developed and reported to be valid for use with stroke and various neurological conditions.

Function:

- Generic: The Barthel Index is a well-documented and recognized measure of function, The Functional Independence Measure (FIM) is a well documented and recognized multidimensional functional status tool designed originally for neurological patients and now for all rehabilitation diagnostic groups. The Office of Population Consensus and Surveys Scale (OPCS) measures functional capacity based on the World Health Organization (WHO) International Classification of Impairment, Disability and Handicap and was designed for use with disabled people in the community.

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- Amputee specific: The Amputee Activity Score (AAS) is a measure of function intended for outpatient lower limb amputees fitted with a prosthesis. The Functional Measure for Amputees (FMA) measures function of lower limb amputees in terms of prosthetic wear, use, and function with a prosthesis. The Houghton Scale measures function of lower limb amputees fitted with a prosthesis in terms of wear and use of the prosthesis. The Prosthetic Profile of the Amputee (PPA) measures function of adult unilateral lower limb amputees (prosthetic users and nonusers) in terms of predisposing, enabling, and facilitating factors related to prosthetic use after discharge from the hospital.
- Not generic or amputee specific: The Frenchay Activities Index (FAI) measures function in terms of participation in social activity and was developed for use with patients who have experienced stroke.

Quality of life:

- Generic: The Patient Generated Index (PGI) is a measure of quality of life designed to be used with a variety of clinical conditions and now lower limb amputees fitted with a prosthesis. The Short Form 36 (SF-36) and its abbreviated version, Short Form 12 (SF-12), are well documented and recognized measures of health related quality of life in the general population and all rehabilitation, severity of illness, and sociodemographic groups. The Sickness Impact Profile (SIP) is a well-documented and recognized measure of quality of life in functional and behavioral terms in all rehabilitation diagnostic groups for use on completion of rehabilitation.
- Amputee specific: The Attitude to Artificial Limb Questionnaire (AALQ) was specifically designed to measure quality of life of lower limb amputees fitted with a prosthesis. The Amputation Related Body Image Scale (ARBIS) measures quality of life of amputees in terms of body image disturbance. The Body Image Questionnaire (BIQ) measures quality of life in terms of body image and was amended from the body image questionnaire used in the treatment of eating disorders to be suitable for use with lower limb amputees fitted with a prostheses. The Orthotics and Prosthetics National Outcomes Tool (OPOT) measures three constructs (health-related quality of life, client satisfaction, and functional ability [prosthetist's perception]) and is a new tool developed for use with lower limb amputees. The Prosthesis Evaluation Questionnaire (PEQ) measures prosthetic-related quality of life. The Perceived Social Stigma Scale (PSSS) measures quality of life in terms of an amputee's perceived social stigma resulting from loss of limb(s). The Trinity Amputation and Prosthesis Experience Scales (TAPES) measures the health-related quality of life of lower limb amputees fitted with a prosthesis.

Search strategy for identification of studies: University of Strathclyde's RECAL database and Medline.

Conclusion: Several outcome measures are being utilized, but there is no gold standard and little agreement on which one should be used and when appropriate to use. However, there are some measures in this review that have proven reliability and validity and seem relatively easy to use. Given the complexity of many of the studies, it is unlikely that clinicians will use the research findings to assist in making an informed choice of outcome measures. They are simply too difficult to read. Terminology is inconsistent and can be confusing; a lexicon of terms is urgently required. For measuring mobility, the ease and objectivity of a timed walking test is appealing.

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Specifically for an elderly population, including amputees, a test that incorporates a sit-to-stand and a turn, such as the TUG, seems appropriate. Currently, we believe that the addition of the LCI5 would provide important information on community mobility. Generic, nonamputee-specific measures of function and quality of life are inappropriate for lower limb amputees. Amputee-specific measures such as the PPA, Houghton Scale, and PEQ have been shown to be valid and reliable tools; however, as with other measures, ease of use remains an issue with some.