



# Assessment Measures for Evaluation of Outcomes in Transtibial Amputees resulting from Trauma: A Systematic Review

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## ABSTRACT

**Introduction:** Amputations secondary to high-energy open fractures and blast, ballistic, and crush injuries to the lower extremity are common challenges faced by military and civilian orthopaedic surgeons. A lack of consensus on domains to be measured and quality of prosthetic rendering pose methodological challenges to researchers and clinicians alike. We conducted a systematic review of the literature to summarize which domains of health, prosthetic fit, and prosthetic alignment are used to describe outcomes for lower extremity amputees secondary to trauma.

**Materials and methods:** A search of PubMed, Cochrane, and Embase was conducted including the keywords: Amputation, traumatic, transtibial, survey, and metric. Articles were selected based on whether the study assessed clinical outcomes following transtibial amputation following trauma. Experimental and observational comparative studies and case series were included. Study characteristics and results were extracted using standardized data forms. The number of unique measures recorded, the frequency of measure use, and the number outcome measures were validated and were compiled.

**Results:** Literature search ultimately resulted in 273 articles being included. A conceptual model was constructed to capture and organize the causal and temporal relationships between fit, alignment, and outcome. Of the 68 articles that used questionnaires to assess prosthetic fit, 37 used a questionnaire designed specifically for the study as opposed to a published or validated tool. Four validated tools were commonly used to capture patient satisfaction with a prosthesis: The OPUS, PEQ, TAPES, and the Socket Comfort Fit Score. Prosthetic alignment was assessed in 19 of 273 articles. One article validated the use of an alignment jig for quantification and prescription of prostheses. Totally, 8 of 19 articles assessing alignment used gait analysis and ground reaction forces to capture differences due to alterations in alignment.

**Discussion:** Choice of an appropriate outcome measure is critical in generating evidence to support treatment decisions for patients undergoing transtibial amputation after trauma. We found a large number of different tools being used across studies, making results difficult to compare. Prosthetic fit and comfort of the residual limb in the socket and the alignment of

the socket and the shank of the prosthesis make up the foundation for the proposed conceptual model. In order to distinguish effects attributable to an intervention of interest vs the impact of the quality of the socket fitting, validation of a clinically objective scoring system to assess socket fit is necessary.

**Conclusion:** A large number of different tools are currently being used across studies to assess outcomes for transtibial amputees resulting from trauma, and there is a need for development and validation of a clinically objective scoring system to assess socket fit.

**Keywords:** Assessment tool, Transtibial amputation, Traumatic.

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## INTRODUCTION

Traumatic amputations due to high-energy open fractures, blast, gunshot wound, and crush injuries to the lower extremity are common challenges to military and civilian orthopaedic trauma surgeons.<sup>1-5</sup> Numerous therapeutic controversies including the indications for limb salvage and tibia-fibula synostosis still require high-quality, multicenter clinical trials in order to guide clinical decision making. Furthermore, transtibial amputees secondary to trauma are a unique population within the lower extremity amputee population. This population is younger, with less chronic medical comorbidities; however, they often present with multiple acute injuries and the condition of the limb varies widely.

Advancements in prosthetic engineering have the potential to revolutionize treatments to vastly improve the quality of life (QOL) after life-altering injuries yet many are costly and untested. The compounding price of purchase and maintenance of prosthetic devices<sup>6</sup> and implementation of new technologies over the lifetime of the amputee demands attention to value.<sup>7</sup> Payers for health care services will increasingly pay attention to both quality and cost, requiring that new treatments and prosthetic technologies be evaluated through rigorous comparative research.

An essential component in conducting this research is a reliable assessment of the quality of prosthetic fitting.

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Although optimizing prosthetic fit and alignment is a goal of many new technologies and treatments in the care of traumatic amputees, adequate fit and alignment are poorly defined and rely primarily on the subjective assessment of the prosthetist.<sup>8,9</sup> Currently, there are no validated, objective measures to evaluate the fit and alignment of the prosthesis for the lower extremity amputee. Although there are acceptable measures regionally, these are not easily implemented in the context of large, multicenter studies that are needed to conduct the research to compare technologies and treatments. Uniform assessment of the condition of the residual limb is also important. In addition to the aforementioned limitations in outcome assessments, potential bias in measurement of treatment effects can be imposed by the quality of prosthetic rendering.

The factors that influence the quality of prosthetic fit are diverse and complex. They vary over time and cannot be considered in isolation. To our knowledge, there has not been a systematic review focusing on outcome measures for transtibial amputees secondary to trauma. We will attempt to establish the domains of health, prosthetic fit, and prosthetic alignment that are currently used to describe outcomes for lower extremity amputees secondary to trauma. We will also develop a model to understand and visualize the complex interactions contributing to prosthetic fit among transtibial amputees secondary to trauma.

## MATERIALS AND METHODS

### Eligibility Criteria

We conducted a systematic review of the literature to include studies with the following characteristics: (1) Randomized controlled trial, prospective, or retrospective observational study; (2) inclusion of patients with transtibial amputations secondary to trauma; (3) assessment of function, performance, or comfort outcomes following transtibial amputation. Only articles published in English were included.

### Search Strategy

The literature search was performed in consultation with a research librarian. Relevant studies were identified through a systematic, computerized search of MEDLINE, Cochrane, and EMBASE (from inception of the database to 2012). For the searches, terms related to "amputation" or "prosthesis," "tibia" or "transtibial," and "survey" or "metric" were included. Initial search results were screened by title and abstract for subsequent full-text review. The final set of included articles was selected based on whether the study assessed clinical outcomes in a population including patients with transtibial

amputation following trauma. Experimental and observational comparative studies, and case series were included. Only papers with human subjects were included.

### Data Abstraction

From the screened abstracts, articles were selected for inclusion by two reviewers. One reviewer extracted data from each eligible study using a standardized data extraction form. Data extracted included sample population demographics, assessment of amputee health, assessment of amputation tools used, and validation of tools used. Tools were considered validated if the accuracy and precision were being tested in the selected work or were referenced to have undergone such testing and found to be acceptable. The most common reason for exclusion of an abstract was that the sample population did not include any transtibial amputees following major limb trauma. Three articles were unavailable due to journals being out of print.

## RESULTS

The primary search yielding 1,885 studies were retrieved. Of these, 276 articles were identified that used a measure to capture an aspect of transtibial amputee outcomes after trauma. Three articles were unable to be retrieved. The full text of 273 articles was reviewed in detail (Fig. 1).

Given the heterogeneity of studies, descriptive statistics and qualitative summary were performed. A conceptual model was constructed to capture and organize the causal and temporal relationships between fit, alignment, and outcome (Fig. 2). The assessment measures used in the articles were classified based on how they fit into the conceptual model.

- Measures of socket fit (n = 68)
- Measures of socket relationship to foot (alignment) (n = 19)
- Measures of prosthetic componentry (n = 68)
- Gait: Biomechanical measures (n = 75)
- Pain measures (n = 17)
- Function: General QOL measures (n = 75); disease-specific QOL measures (n = 83)

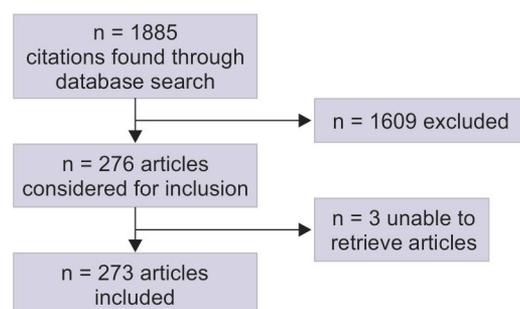


Fig. 1: Study eligibility

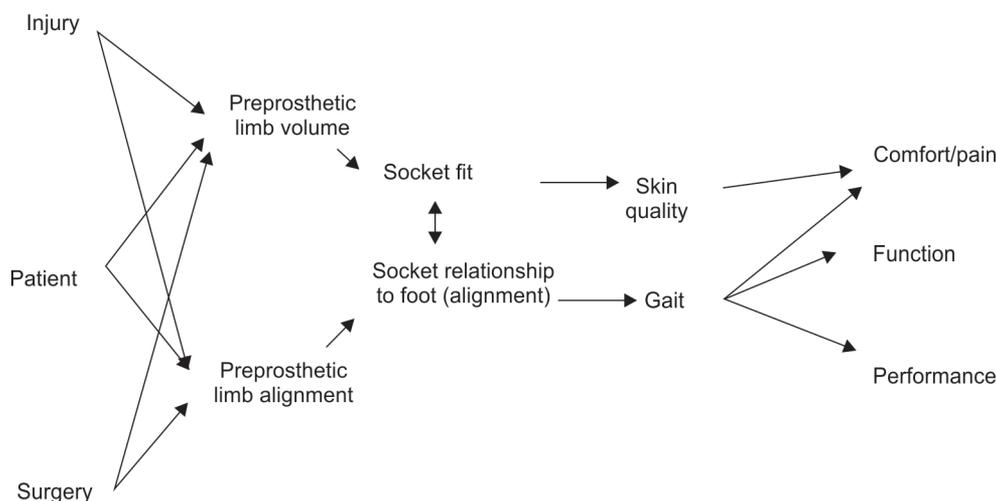


Fig. 2: Conceptual framework

- Performance: Performance measures (n = 59)
- Satisfaction/Other (n = 57)

Of the 273 articles, 32 assessed the validity of one or more measurement tools; 40 different assessments were validated in these 32 articles.

### Socket Fit, Alignment, and Components

Socket fit and alignment form the foundation of the conceptual model. Two approaches were used to assess fit and alignment: Questionnaires and technology-based assessments. Prosthetic componentry is intricately related to the fit and alignment of a prosthesis and evaluation outcomes measures assessing prosthetic componentry, alignment, and the fit was less straightforward than for other outcome measures. Often the assessment of componentry, alignment, or fit was included in outcomes measures that also assessed another measure classification.

### Fit

Socket fit or comfort was addressed in 68 of the 273 articles. Four measures of prosthetic fit were validated: The OPUS, PEQ,<sup>10-13</sup> Socket Comfort Score,<sup>14</sup> and TAPES.<sup>15,16</sup> Of the 68 articles related to prosthetic fit, 37 used a unique questionnaire; the most commonly used standard questionnaire was the PEQ (n = 10). Seventeen articles offered methods other than or in addition to patient assessment of the quality of fit. Six of these articles suggest measurements of pistoning or residual limb socket contact using radiographic methods. Six additional articles incorporated physician or prosthetist assessment of the quality of fit.

### Alignment

Prosthetic alignment was assessed in 19 of 273 articles. One article validated the use of an alignment jig for

quantification and prescription of prostheses.<sup>17</sup> Eight of 19 articles assessing alignment used gait analysis and ground reaction forces to capture differences due to alterations in alignment.

### Components

Out of 273 articles, 68 addressed different prosthetic components. No tools were specifically validated to measure componentry. Thirty-seven of 68 articles pertaining to components evaluated gait analysis and ground reaction forces to capture differences due to alterations in components.

### Gait Biomechanics

Biomechanical measures are an intermediary stage in the conceptual model that demonstrate how fit and alignment are affecting the amputee but are not direct outcome measures that patients perceive affecting their health. The ultimate purpose of prostheses is to enable the amputee to regain functional and recreational abilities. The ideal lower extremity prosthesis would allow the amputee to use biomechanically normal gait. Although this ideal has yet to be fulfilled, biomechanical markers provide valuable information relating prosthetic function to normal biomechanics. Biomechanical measures, similar to performance measures, are quantitative, objective, and repeatable. They also allow for precise, real-time adjustments to alignment or components to potentially alter gait characteristics.

Biomechanical measures were included in 75 of the 273 studies. Three tools were used to record biomechanical parameters: Force platforms, pressure sensors, and motion analysis camera systems. Forty-one studies used force platforms to measure ground reaction forces and 15 studies used various forms of pressure sensor. Over

50 studies used motion analysis cameras to capture spatio-temporal variables, such as speed, cadence, or step length. Thirty-seven of the 75 studies that used biomechanical measures did so to evaluate componentry. Eight articles used biomechanical measures to determine alignment and 16 used biomechanical methods to evaluate socket fit.

### **Pain, Function, Performance**

Pain, function, and performance are the final temporal stage of the conceptual model. These outcomes mostly concern patients because they reflect and impact the daily QOL.

#### **Pain**

Measures to report pain were used in 17 of the 273 studies. This was the lowest frequency among the measure domains; only measures that exclusively captured pain characteristics were included in this domain. Eleven metrics to evaluate pain were used, but were not specifically validated in a population including trauma-related transtibial amputees in these studies. The most commonly used pain metrics were the McGill Pain Questionnaire (n = 5) and the Visual Analog Scale (n = 5).

#### **Function**

The QOL assessments provide a multidimensional approach to the measurement of patients' perception of their personal health outcomes. Consideration of patients' QOL in treatment decisions is imperative. Most of the QOL, disease-specific QOL, and pain measures were subjective, qualitative, and self-reported measures completed by the amputee. General health and disease-specific QOL outcomes were commonly assessed in trauma-related transtibial amputees. However, many different general health QOL outcome measures were used and few were specifically validated for amputees secondary to trauma. Although QOL measures are commonly incorporated into amputation outcome studies, standardized use of reliable, responsive, and valid QOL measures remains critical in establishing the validity and comparability of results from clinical research involving this population.

#### **Quality of Life – General**

General QOL measures were used in 75 of the 273 included studies. Over 50 discrete general health QOL measures were documented and four of the measures were validated. The four general health QOL measures that were validated for use in a population including trauma-related transtibial amputees were: The Goal Attainment Scale,<sup>18</sup> the International Physical Activities Questionnaire,<sup>19</sup> the 36-Item Short-Form Health Survey

questionnaire (SF-36),<sup>10</sup> and the World Health Organization Quality of Life instrument.<sup>19</sup> The most frequently used general health QOL tools were the SF-36 (n = 20) and the Sickness Impact Profile (SIP) (n = 8). There were 27 general health QOL measures that were used by only one study and 15 studies designed their own unique general health QOL questionnaires.

#### **Quality of Life – Disease Specific**

Disease-specific QOL measures were used in 83 of the 273 included studies; this was the highest frequency of any measure domain. The use of over 20 disease-specific QOL measures was recorded. Twelve disease-specific QOL assessment tools were validated for use in a population including trauma-related transtibial amputees; this was the highest number of validated measures. The validated measures were: The Amputee Body Image Scale,<sup>20</sup> the Amputee Mobility Predictor with Prosthesis,<sup>10,21</sup> the Discomfort-Engagement in everyday activities involving revealing the body scale,<sup>22</sup> the Engagement in everyday activities involving revealing the body scale,<sup>22</sup> the Functional Measure for Amputees,<sup>23</sup> the Houghton Scale,<sup>11,24</sup> the Locomotor Capabilities Index (LCI),<sup>11,25</sup> the Lower Limb Amputee Measurement Scale,<sup>26</sup> the Orthotics and Prosthetics Users' Survey,<sup>10</sup> the Prosthetic Evaluation Questionnaire (PEQ),<sup>10-13</sup> the Prosthetic Profile of the Amputee (PPA),<sup>27</sup> and the Trinity Amputation and Prosthesis Experience Scales (TAPES).<sup>15,16</sup> Of the disease-specific QOL measures, the PEQ (n = 21) and the PPA (n = 19) were used most frequently. Additionally, 34 studies designed a unique questionnaire to address disease-specific QOL.

#### **Performance**

Performance metrics play an important role in amputee outcome assessments because the rehabilitation goals for lower extremity amputees are centered on improved mobility and function. Design and assessment of rehabilitation programs to be efficient and cost-effective depend on quantification of improvement through objective metrics. Physical performance measures provide quantitative and objective measurements which can be compared over time to track progress. Furthermore, physical performance metrics were relatively consistent across studies and were overall well validated among populations including transtibial amputees resulting from trauma.

Performance measures were used in 59 of the 273 studies. Two categories within this classification emerged: Objective performance measures and mobility grading scales. The objective performance tools measured precisely quantifiable values, such as the time to complete

a task or the number of steps taken during a defined time period. Fifteen objective performance metrics were identified. Among these, 6 were validated for use in a population including trauma-related transtibial amputees: The 2 Minute Walk Test,<sup>10,28</sup> 6 Minute Walk Test (6MWT),<sup>10,29</sup> the L Test,<sup>30</sup> the Prosthetic Activity Monitor,<sup>31</sup> the Step Quick Turn Test,<sup>32</sup> and the Timed "Up and Go" (TUG) test.<sup>10</sup> The TUG test was used most frequently (n = 11). Other commonly used measures were the 6MWT (n = 9) and a step counter (n = 9).

The grading scales are designed to measure mobility or balance as the patient performs specific tasks. Fifteen mobility indexes or grading scales were identified and seven of these were validated in a population including trauma-related transtibial amputees. These were the Activity-specific Balance Confidence Scale,<sup>33,34</sup> the Amputee Activity Score,<sup>35</sup> LCI,<sup>11</sup> the Patient Specific Functional Scale,<sup>10</sup> the Prosthetic Observational Gait Score,<sup>8</sup> the Rivermead Mobility Index,<sup>36,37</sup> and the Special Interest Group in Amputee Medicine mobility grades.<sup>38</sup> The most commonly used scales in this study were the LCI (n = 12) and the Harold Wood Stanmore Mobility Grading Scale (n = 6).

## CONCLUSION

Choice of an appropriate outcome measure is critical in generating evidence to support treatment decisions for patients undergoing transtibial amputation after trauma and demonstrating treatment effects that matter to patients. A primary finding of this systematic review is the abundance of different tools being used across studies, rendering results difficult to compare. A recent example of the importance of selecting an appropriate outcome measure is the Lower Extremity Assessment Project (LEAP); LEAP was a National Institutes of Health-funded, multicenter, prospective observational study designed to provide a definitive assessment of limb salvage *vs* amputation, yet controversy and criticism remain.<sup>39</sup> In LEAP, the SIP was the primary outcome measure used to compare the salvage *vs* amputation groups. However, perhaps due to overrepresentation of patient characteristics that correlate with low SIP scores, such as lower educational level, poverty, and lack of health insurance, the SIP scores did not differ between the two groups.<sup>39</sup>

### Defining Fit and Alignment and their Impact on Outcome

The prosthetic fit is a complex and dynamic concept that includes two primary considerations that provide the foundation for the proposed conceptual model: The fit and comfort of the residual limb in the socket

and the alignment of the socket and the shank of the prosthesis. Measurement of the quality of prosthetic fit and alignment is less well established than measurement of the other domains of the conceptual model.

Prosthetic fit relates to residual limb volume and how it is accommodated by the prosthesis. It has a direct impact on skin quality and comfort through which function and performance can ultimately be affected. Board et al<sup>40</sup> state that good prosthetic fit effectively transfers forces between the limb and socket while providing a comfortable environment by minimizing local areas of high pressure and shear stress.<sup>21</sup> Amputees consistently report the importance of prosthetic fit and comfort in their level of function and QOL.<sup>11,22-24</sup> Poor prosthetic fit can lead to pressure sores, bleeding, bruising, chafing, and pain. If a socket fits poorly, it can significantly decrease the ability of the amputee to function and maintain good health and independence, leading to increased societal costs.<sup>25</sup> Proper alignment influences how the weight-bearing load is distributed over the residual limb and is, therefore, important for adequate prosthetic function and comfort.<sup>9,41</sup>

Alignment refers to how the weight-bearing load is distributed over the residual limb and is important for good prosthetic function and comfort.<sup>12,26</sup> It is determined by socket spatial relationship to the foot. In addition to prosthetic fit, proper alignment of the prosthesis is essential for comfort.<sup>10,13,27</sup>

Berke et al<sup>42</sup> found that pain related to the fit of the prosthesis is so common that it has become not only tolerated but at times considered normal or acceptable. They further identify that the absence of standardized guidelines for fitting the prosthesis may contribute to the idea that pain should be tolerated by the amputee. Other studies suggest that reproducible and objective assessments would be preferable to current alignment processes, which are time consuming and depend on the years of experience of the prosthetist and on the ability of the amputee to give feedback.<sup>43</sup> Multiple studies suggest that reproducible and objective assessments would be preferable to current comfort and alignment processes that are time-consuming and depend on the years of experience of the prosthetist and on the ability of the amputee to give feedback.

Patient satisfaction with a prosthesis and his/her report of socket fit is a critical aspect of amputee outcomes. Four validated tools are available to capture this outcome: The OPUS, PEQ, the Socket Comfort Fit Score, and the TAPES. However, with the exclusive availability of these tools, there is a significant gap in current amputee and prosthesis literature. There lacks a quantitative and replicable assessment of prosthesis fit and alignment, completed by a trained prosthetist. This measure could

provide a quantified measure of fit and alignment, i.e., applicable for transtibial amputees secondary to trauma without dependence on expensive technology. Such a tool could prove to be invaluable to the progression of prosthetic science.

This systematic review has multiple limitations. One limitation is the inclusion of only articles and assessment measures available in English. Due to exclusion of non-English articles, it is possible that concepts uniquely related to amputation outcomes in developing countries were underrepresented in this study. Another limitation is related to the search terms used for the systematic review. The search methodology and terms were designed with the guidance of a research librarian. However, due to the diversity of terms used to describe amputation, transtibial, and particularly survey, metric, or outcome, it is possible that some relevant articles were not captured.

Transtibial amputees secondary to trauma is a population with unique challenges and prosthetic issues. Accurate measurement of specific outcomes is important to guide clinical decision making and structure treatment and rehabilitation recommendations. Furthermore, distinguishing between effects attributable to an intervention of interest *vs* the impact of the quality of the socket fitting is essential as large-scale clinical trials are undertaken. Using the articles identified through this review, a conceptual model was designed to help organize outcomes among transtibial amputees secondary to trauma. In considering both the conceptual model and the outcome measures currently in use, there exists a significant gap in the quantitative and reproducible measurement of prosthetic fit. Further research and development of such a tool could significantly improve the measurement of outcomes for transtibial amputees secondary to trauma.

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