Patient-reported Outcome Instruments in Lower Extremity Trauma: A Systematic Review of the Literature

Lily R. Mundy, MD*
A. Jordan Grier, MD†
E. Hope Weissler, MD‡
Matthew J. Carty, MD§
Andrea L. Pusic, MD, MHS§
Scott T. Hollenbeck, MD*
Mark J. Gage, MD†

Background: Advances in fracture fixation and soft tissue coverage continue to improve the care of patients after limb-threatening lower extremity (LE) trauma. However, debate continues regarding which treatment option—reconstruction or amputation—is most appropriate. Many authors have attempted to quantify the patient experience in this treatment paradigm; however, they have not used patient-reported outcome (PRO) instruments specific to this population. Our aim was to identify and evaluate PRO instruments developed specifically for LE trauma, applicable to reconstruction and amputation, using established PRO instrument development and validation guidelines.

Methods: A multidisciplinary team used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses method to query PubMed, Medline Ovid, EMBASE, Cochrane, Medline Web of Science, and Psych Info databases from inception to November 2016. Publications were included that described the development and/or validation of a PRO instrument assessing satisfaction and/or quality of life in LE trauma, applicable to both amputation and reconstruction. Two authors independently reviewed each full-text citation.

Results: After removing duplicates, 6,290 abstracts were identified via the database query. Following a preliminary title and abstract screen, 657 full-text citations were reviewed. Of these references, none satisfied the previously established inclusion criteria.

Conclusions: No studies were identified that described a PRO instrument developed to assess outcomes in LE trauma patients applicable to both reconstruction and amputation. There is thus a need for a PRO instrument designed specifically for patients who have sustained limb-threatening LE trauma to guide treatment decisions. (Plast Reconstr Surg Glob Open 2019;7:e2218; doi: 10.1097/GOX.0000000000002218; Published online 3 May 2019.)

INTRODUCTION

Severe lower extremity (LE) traumatic injuries are life-changing events. Treatment options include early amputation, limb reconstruction, or delayed amputation after reconstructive attempts; however, there is a no consensus regarding the best treatment modality.1–7 Successful reconstruction may involve numerous operations with a high rate of complications and long-term disability.3,8 However, amputation has its own limitations, including lifelong reliance on a prosthesis for ambulation. In the setting of modern reconstructive microsurgery and orthopaedic trauma care, the optimal treatment has not yet been established.

The impact of severe LE trauma is multidimensional. Traditional metrics including infection rates, postoperative complications, and pure functional assessments only capture a small portion of the experience borne by this patient population, neglecting outcomes such as return to work status, social integration, and substance abuse. A thorough assessment of the utility of amputation versus

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METHODS

Search Strategy
A comprehensive search was designed with the assistance of a medical librarian using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines to identify PRO instruments assessing quality of life and/or satisfaction for patients with LE traumatic injuries, applicable to both patients undergoing reconstruction and/or amputation.12 The search was conducted in PubMed, Medline Ovid, EMBASE, Cochrane, Medline Web of Science, and Psych Info, from inception to November 2016. Search terms were developed for LE trauma and outcome instruments, as listed in Table 1. The search terms were searched as text words and mapped to medical subject headings when applicable. Terms within each search category were combined with the Boolean operator OR, and the 3 categories were combined with AND.

Selection Criteria
Publications were included if they were published in English and if they described the development and/or validation of a PRO instrument designed to measure satisfaction and/or quality of life in LE trauma patients, applicable to both amputation and reconstruction cohorts. Conference abstracts, theses, letters to the editor, editorials, and review articles were excluded. Secondary searching, including a citation review of applicable publications, was performed to identify additional instruments. Corresponding authors were contacted to obtain additional information if necessary.

Data Extraction
One author (L.R.M.) reviewed all titles and abstracts. All potentially applicable publications were reviewed as full-text by 2 authors (A.J.G. and L.R.M.). Any disagreements between A.J.G. and L.R.M. were resolved by consensus with the senior author (M.J.G.). All publications utilizing a PRO instrument that was not applicable to both amputation and reconstruction patients were excluded. Excluded citations were sorted into the following categories: ad hoc instruments, non-MSK PRO instruments, MSK PRO instruments not developed for LE trauma, MSK PRO instruments assessing functional outcomes only, PRO instruments specific to amputation patients only, LE PRO instruments specific to reconstruction only, and trauma PRO instruments not specific to the LE. Utilization frequencies of each PRO instrument in each category were also recorded.

RESULTS
The results of the electronic search are shown in Figure 1. There were 9,113 publications identified in the search, with 6,290 publications after removal of duplicates. After the initial title and abstract screen, there were 657 articles remaining, all of which were reviewed in full text and assessed for eligibility. There were no articles meeting inclusion criteria; none described a PRO instrument assessing outcomes in LE trauma patients that were applicable to both reconstruction patients and amputation patients. There were no additional articles added via secondary searching. Table 2 reports the most frequently

Table 1. Search Strategy

| Category          | Terms                                                                 |
|-------------------|-----------------------------------------------------------------------|
| LE trauma         | LE trauma, limb salvage, limb reconstruction, limb threaten*, amputation |
| Quality of life   | Quality of life, health-related quality of life, functional status, function, well-being, health status, health status disparity, quality-adjusted life years, patient satisfaction |
| and/or patient    |                                                                        |
| satisfaction      |                                                                        |
| Outcome           | Patient-reported outcome, questionnaire, survey, instrument, measure, scale, assessment, treatment outcome, consumer satisfaction, psychometric*, data collection |

*LE, lower extremity.
utilized PRO instruments that are used to assess outcomes in LE trauma patients. The majority of studies utilized multiple PRO measures, with a combination of ad hoc measures, generic PRO instruments, and disease-specific PRO instruments. These instruments were most commonly designed for nontrauma MSK injuries and/or disease processes. Table 3 lists the proposed domains for a novel PRO instrument for LE trauma patients, based on the topics covered in the instruments listed here and expert opinion.

**DISCUSSION**

The decision to pursue reconstruction or amputation in the setting of limb-threatening LE trauma represents a significant challenge to both surgeons and patients. These injuries are often the result of high-energy mechanisms and patients present with extensive soft tissue loss, periosteal stripping, concomitant damage to neurovascular structures, and varying degrees of contamination. Early initiation of broad-spectrum antibiotic therapy, wound debridement, rigid fracture stabilization, and soft tissue coverage has revolutionized the treatment of these injuries and led to increased rates of limb salvage. However, debate continues concerning who should undergo reconstruction versus amputation. Although each treatment group faces unique challenges, both groups have worse clinical and functional outcomes compared with the general population due to persistent wounds, multiple procedures, depression, pain, posttraumatic stress disorder, and, in the setting of amputees, difficulties with prostheses.

The LE Assessment Project (LEAP) is the most comprehensive civilian study to date. This study attempted to determine whether amputated or salvaged patients had superior clinical, functional, and health-related quality of life outcomes using the Sickness Impact Profile. This prospective observational trial of 601 patients enrolled from 1994 to 1997 found no difference in clinical and

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**Fig. 1.** Flow diagram of systematic review. *Publications with multiple instruments were counted in each associated group.

| n = 9113 identified through database searching | n = 2623 duplicates removed |
| n = 6290 articles screened via title | n = 3813 excluded using title |
| n = 2477 articles screened via abstract | n = 1820 excluded using abstract |
| n = 657 full-text articles assessed for eligibility |
| n = 657 articles excluded: |
| No PRO Instrument and/or not LE Trauma Patients |
| - Foreign language (n=3) |
| - Review article (n=7) |
| - Study design (n=1) |
| - Not LE trauma patient population (n=64) |
| - No PRO instrument (n=93) |
| PRO Instrument in LE Trauma Patients* |
| - Ad hoc instrument as only instrument (n=53) |
| - Ad hoc instrument in addition to other PRO instrument (n=42) |
| - Non-MSK PRO instrument (n=263) |
| - MSK PRO instrument, not LE trauma (n=108) |
| - MSK PRO assessing functional outcomes only (n=71) |
| - Amputation-specific PRO instrument (n=108) |
| - Trauma PRO instrument, not LE-specific (n=2) |
| - LE Trauma PRO instrument, limb-salvage specific (n=1) |

LE = lower extremity, MSK = musculoskeletal
*Publications with multiple instruments were counted in each associated group.
| Title | Year | Country                  | Specialty Population | Domains                                                                 | No. Citations |
|-------|------|--------------------------|----------------------|--------------------------------------------------------------------------|---------------|
| **Non-MSK instruments** |      |                          |                      |                                                                          |               |
| SF-36: Short Form 36 Health Survey2,3 | 1992 | United States            | General population   | Vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, mental health | 117           |
| Sickness Impact Profile4,26 | 1975 | United States            | General population   | Social interaction, ambulation and locomotion, sleep and rest, taking nutrition, usual daily work, household management, mobility and confinement, movement of the body, communication activity, leisure pastimes and recreation, intellectual functioning, interaction with family members, emotions, feelings and sensations, personal hygiene | 34            |
| SF-12: 12 Item Short Form Survey5,33 | 1996 | United States            | General population   | Vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, mental health | 18            |
| HADS: Hospital Anxiety and Depression Scale6,34 | 1983 | United Kingdom           | General population   | Anxiety, depression                                                     | 13            |
| EQ-5D: EuroQOL 5D7,35 | 1990 | United Kingdom, The Netherlands, Sweden | General population | Mobility, self-care, usual activities, pain/discomfort, anxiety/depression, overall health status | 12            |
| WHOQOL: World Health Organization Quality of Life Questionnaire, BREF and 1008,36 | 1995, 1998 | Switzerland            | General population, global use | Quality of life domains for: physical, psychological, social, environmental, level of independence, spirituality, religion and personal beliefs, overall | 8             |
| PROMIS: Patient-Reported Outcomes Measurement Information System9–11,37–39 | 2005 | United States            | General population   | Physical functioning, fatigue, pain, emotional distress, social role participation | 3             |
| **MSK instruments, not LE trauma** |      |                          |                      |                                                                          |               |
| American Orthopaedic Foot and Ankle Society Ankle-Hindfoot and Midfoot Rating Scales12,40 | 1994 | United States            | Ankle and foot pathology | Clinician and PROs for function, pain, alignment | 32           |
| SMFA: Short Musculoskeletal Function Assessment Questionnaire13,27 | 1999 | United States            | MSK disease          | Dysfunction index, Bother index                                         | 13            |
| ABC: Activities-specific Balance Confidence Scale14,15 | 1995 | Canada                   | Elderly outpatients  | Confidence in mobility and balance                                      | 12            |
| WOMAC: Western Ontario42 McMaster University Osteoarthritis Index15 | 1988 | Canada                   | Osteoarthritis       | Stiffness, pain, physical function                                     | 7             |
| Musculoskeletal Tumor43 Society Scoring System16 | 1993 | United States            | Limb salvage in MSK oncology | LE Scales: pain, function, emotional acceptance, supports, walking and gait | 6             |
| OPUS: Orthotics and Prosthetics Users’ Survey47,48 | 2003 | United States            | Users of orthotics and prosthetics (upper and lower limbs) | Functional status, quality of life, satisfaction with prosthetics and orthotics | 6             |

(Continued)
Table 2. Continued

| Title                                                                 | Year | Country             | Specialty Population          | Domains                                                                 | No. Citations |
|----------------------------------------------------------------------|------|---------------------|-------------------------------|------------------------------------------------------------------------|---------------|
| MSK physical function outcome instruments                             |      |                     |                               |                                                                        |               |
| LCI: Locomotor Capabilities Index†‡‡                               | 1998 | Canada              | LE amputees                   | Patient perceived capability to complete locomotor activities          | 21            |
| LEFS: LE Functional Scale                                          | 1999 | United States, Canada| LE MSK diseases requiring physical therapy | Patient perceived difficulty with physical activities               | 16            |
| Houghton Scale                                                      | 1992 | United Kingdom      | LE amputation prosthetic users | Use of prosthetic and mobility                                          | 14            |
| Amputation-specific instruments                                     |      |                     |                               |                                                                        |               |
| PEQ: Prosthesis Evaluation Questionnaire                            | 1998 | United States       | LE amputation prosthetic users | Prosthetic function (usefulness, residual limb health, appearance, sounds), mobility (ambulation, transfers), psychosocial (perceived responses, frustration, social burden), well-being | 37            |
| TAPES: Trinity Amputation and Prosthesis Experience Scales          | 2000 | Ireland             | LE amputation prosthetic users | Psychosocial adjustment (general, social, limitations), activity restriction (functional, social, athletic), prosthesis satisfaction (function, aesthetic, weight), pain (residual, phantom), general health, overall physical capabilities | 21            |
| Prosthetic Profile of the Amputee                                   | 1994 | Canada              | LE amputees                   | Physical condition, prosthesis use, environment, leisure activities, general information | 7             |
| Q-TFA: Questionnaire for Persons With a Transfemoral Amputation     | 2004 | Sweden              | Nonelderly transfemoral amputation prosthetic users | Prosthetic use, mobility, problems, global health | 7             |
| Amputee Body Image Scale                                            | 2007 | Ireland             | LE amputation prosthetic users | Body image disturbances                                               | 6             |
| Limb salvage-specific instruments                                  |      |                     |                               |                                                                        |               |
| Wulterkens Telephone Questionnaire                                  | 2015 | The Netherlands, France| Trauma, limb salvage          | Function, daily life, psychology                                       | 1             |
| Hannover Score for Polytrauma Outcome                               | 2001 | Germany             | Trauma                        | PRO‡: General information, social relations, profession, status of pension, sports and hobbies, medications for orthopedic problems, medications in daily life, treatment during rehabilitation, financial, ability to remember hospital stay, daily problems, SF-12, questions from the musculoskeletal function assessment | 3             |

* *Included only in the WHOQOL-100, not the WHOQOL-BREF.
†A version of a scale within the Prosthetic Profile of the Amputee that is used independently.
‡Domains listed for PRO portion, also a clinician portion.
functional outcomes or with health-related quality of life, patient satisfaction with treatment, or rates of returning to work. Worse outcomes, based on the Sickness Impact Profile, were alternatively correlated with patient and environmental factors independent of treatment pathway, including lower socioeconomic status, non-white race, tobacco use, using the legal system for injury compensation, and low levels of self-efficacy.

The Military Extremity Trauma Amputation/Limb Salvage (METALS) study attempted to answer the same question in a military population. A retrospective cohort study from 2003 to 2007 was performed on 324 service members who served in either Afghanistan or Iraq and who had suffered limb-threatening trauma to the LE. In addition to outcome measures for depression, posttraumatic stress disorder, chronic pain, and daily activities, general MSK PROs were evaluated with the Short Musculoskeletal Function Assessment (SMFA). In contrast to the LEAP study, amputees had higher SMFA scores and engagement in vigorous sports in comparison to reconstruction patients. Amputation patients also had lower rates of posttraumatic stress disorder, although both groups had equivalent rates of employment and depression. These findings reflected the higher levels of intensive postinjury rehabilitation services and access to prostheses and support devices provided to the military amputees, in comparison with both civilian amputees and military reconstruction patients.

The LEAP and METALS studies have improved our understanding of treatment outcomes in high-energy LE trauma patients, but a major limitation to the above studies is the use of the Sickness Impact Profile, a generic PRO instrument, and the SMFA, a general MSK PRO instrument. These measures are appropriate tools to compare outcomes between LE trauma patients and either the general population or patients with various MSK diseases besides LE trauma. However, they do not have the sensitivity to evaluate LE trauma-specific COI that is critical to make comprehensive inferences about LE trauma treatment outcomes. Qualitative interviews of LE trauma patients have identified numerous COI that are of importance to this population, which are not captured in the above measures. Physical function and symptoms, appearance, psychosocial and sexual well-being, social support, impact on family, perceptions of recovery, coping, self-efficacy, medical decision-making, the impact on work and education, and impact on finances have all been identified as COI in qualitative research of LE trauma patients.

Although many of these COI may be addressed in various other PRO instruments or ad hoc measures, no instrument was found that comprehensively evaluates all COI relevant to LE trauma patients to allow for reproducible, rigorous comparisons between treatment outcomes. The most frequently observed paradigm was the use of a non-MSK-specific PRO instrument on patients with LE trauma (n = 266). It was also observed that authors often utilized an ad hoc instrument either alone (n = 61), or in addition to another PRO instrument (n = 44), in an attempt to describe the outcomes of their cohort. The frequency with which ad hoc instruments were employed further reinforces that there is a need for a metric capable of capturing and reporting severe LE trauma-relevant domains that are not adequately reflected in any of the currently available instruments.

With regards to study limitations, the results of this systematic review are dictated by the reliance upon the reviewed studies. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines were used to design our search query to reduce our risk of inadvertently omitting any studies that may be applicable to our hypothesis. However, missed relevant texts are possible. For those studies captured, the use of 2 separate reviewers reduced the possibility of selection bias from one reviewer.

CONCLUSIONS

The results of this systematic review highlight the need for a rigorously developed, reliable, and well-validated outcome instrument to better understand those with limb-threatening LE trauma. This tool would allow for the collection of more specific outcomes to this population. Additionally, it would provide a better understanding of the domains that are most important to limb-threatened patients and focus our clinical efforts to provide a greater impact on their outcomes.

Lily R. Mundy, MD
Division of Plastic and Reconstructive Surgery
Department of Surgery
Duke University
DUMC Box 3205
2301 Erwin Rd, Durham, NC 27710
E-mail: lily.mundy@duke.edu

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Table 3. LE PRO Instrument Proposed Conceptual Framework

| Appearance | Physical function | Psychosocial well-being | Sexual well-being | Employment | Prosthetics and orthotics | Satisfaction with experience | Satisfaction with outcome |
|------------|------------------|------------------------|-------------------|------------|--------------------------|-----------------------------|--------------------------|
for type III-B and III-C fractures of the tibia. Plast Reconstr Surg. 2008;122:1796–1805.
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