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## Measuring Outcomes in Lower Limb Surgery

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### Keywords

Outcomes; Lower limb; Salvage; Amputation; Function

### OVERVIEW

Limb salvage requires persistent effort for patients with aggressive lower extremity tumors, severe peripheral vascular disease with tissue loss, and in patients who have sustained traumatic complex lower extremity injuries. Important reconstructive considerations in all patients regardless of the etiology of their limb disease are limb vascularity, tissue components involved that require replacement or stabilization, and the potential for restoration of function with limb salvage. Our ability to salvage the severely injured lower extremity has improved with technical advances (1, 2) over the years. As would be expected, the question of whether or not salvage is beneficial to certain patients with severe injuries has been raised and some (3, 4) have justifiably suggested that early amputation and rehabilitation with prosthesis provides a better outcome in select patients. In contrast, others (5) have found that a majority of their patients with severe lower extremity injuries preferred their salvaged extremity to an amputation, even when they ultimately required a delayed amputation. Although appealing, limb salvage may not always be in the best interest of patients as limb viability and function do not always go hand in hand.

Given that the decision to amputate or salvage an extremity is one of the first decisions made in managing patients with severe lower extremity injuries, preoperative scoring systems to aid with the decision-making process would be useful and have been developed (6, 7, 8, 9). The utility of existing scoring systems however has been called into question, because they have been found to be effective at identifying patients who would benefit from salvage but incapable of identifying patients who would ultimately require amputation (10). This is a significant flaw because amputations performed in a timely fashion can potentially provide patients with a shorter recovery and return to a relatively high level of function with use of prostheses. Without a clear consensus on preoperative findings that guide decisions,

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surgeons in practice have to make decisions based on their clinical judgment, sometimes with little or no supporting evidence.

An understanding of outcomes after salvage is also critical to guiding the surgical decision-making process when considering the choice of limb salvage versus amputation. Surgical outcomes focused on complications and function from the physician's viewpoint provide valuable information but do not provide a complete picture. To this end, as in other areas of healthcare, considerations of patient reported outcomes have become an integral part of assessing the quality and efficacy of care delivered. The term patient reported outcomes, broadly includes functional assessments and health-related quality of life outcomes. Outcomes are assessed from the patient's viewpoint and they have the potential to be distinctly different from those perceived by the treating physician. These outcomes ideally should provide some clarity to questions such as- Is it more beneficial to salvage or amputate an extremity? Which patients would benefit from limb salvage as opposed to an amputation? Does the level of injury make a difference? Are there surgical or patient factors outside of the injury that have an impact on a patient's ultimate function and quality of life? Are there injury related factors that have an impact on patient reported outcomes? How satisfied are patients postoperatively? What are the financial implications of these treatment strategies?

## PATIENT REPORTED OUTCOMES MEASURES

Patient reported outcome measures (PROMs) are obtained by way of patient-completed questionnaires that assess a host of health-related outcomes relating to patient function and quality of life after undergoing surgery. In general, these outcomes measures can be used to evaluate the quality of care delivered, assess the efficacy and cost-effectiveness of multiple treatment modalities, and can be used to guide patient choice. Findings from these instruments allow surgeons to better understand salient aspects of patient's experience after major limb operations including but not limited to their ability to walk, care for themselves, work, participate in recreational activities, and the effect of these operations on social interactions and sexual function. Ultimately, information gathered based on patient-rated outcomes can be used to improve surgical management choices in patients with significant lower extremity injuries. Functional assessments are a key component of health and well-being in the lower extremity trauma patient. Self-reported measures rely on a patient's perception of mobility status and performance of activities of daily living. These measures aim to assess a patient's activity restrictions, performance difficulties, or the need for assistance with functional activities.

Health-related quality of life outcomes are the other component of well-being measured by PROMs. This outcomes measure essentially is an assessment of what health status is worth to a patient, from the patient's perspective after an injury or intervention. Generic measurement instruments cover areas of relevance to multiple disorders and are applicable to the general population to compare among different groups. Specific instruments, in contrast, are tailored to particular disease processes. As PROMs present data solely from the patient's perspective, patient factors such as poor cognitive function, culture, language, and education can have an influence on outcomes reported.

Multiple questionnaires for lower extremity outcomes have been developed (Table 1), with the more commonly utilized questionnaires in recent years including the Sickness Impact Profile (SIP) (11), the Toronto Extremity Salvage Score (TESS)(12), and the Musculoskeletal Tumor Society Score (MSTS)(13). The SIP has been employed the most in recent studies on lower extremity trauma, whereas instruments such as the TESS and MSTS questionnaires were developed specifically for oncologic patients. Generic questionnaires

also used in lower extremity trauma studies include the Short Form-36 (SF-36) and the Nottingham Health Profile.

## REVIEW OF THE RECENT LITERATURE

Most of the data relating to PROMs in patients undergoing limb salvage or amputations is presented in the orthopedic and trauma literature. A basic question in dealing with severe lower extremity injuries is how do patients fare with amputations relative to salvage? As part of the Lower Extremity Assessment Project (LEAP), Bosse et al. (14) analyzed the long term functional outcomes of salvage when compared to amputation in 545 patients with injuries below the femur. They employed the Sickness Impact Profile (SIP), a multidimensional measure of self-reported health status for functional assessment, to provide information ranging from ambulation and body care to social interactions. At 2 years, no significant difference in scores was found between amputated and reconstructed patients. Patients in both treatment arms on average had significant levels of disability when compared to the general population based on the SIP. Similar proportions of patients from both groups had returned to work at two years, though reconstructed patients had significantly higher re-hospitalization and reoperation rates compared to patients with amputations. A problem with this study was the relatively short follow-up, as at 2 years most of the patients are still recovering and improved function may be anticipated with greater periods of time allowed for recovery. Interestingly, a seven year follow-up on the same cohort of patients actually found a slight deterioration in function in both groups (15). This deterioration in function was thought to be partly from aging of the cohort with the associated worsening of function that occurs with advancing age. Here again there were no significant differences in the outcomes reported by patients with salvaged or amputated limbs.

Amputations in these studies varied from above the knee proximally to partial foot amputations distally. With an understanding that longer lower extremity lengths in amputees are generally associated with better ambulatory function (17), it would be reasonable to expect that varying levels of amputations or salvage may have an impact on patient reported outcomes. Mackenzie et al. (18) reported similar SIP scores in patients with above-the-knee amputations compared to patients with amputations below the knee, but injuries in these patients did not involve the foot and ankle. A look at mangled foot and ankle injuries (19) found worse SIP outcomes at 2 years in patients requiring free flaps and ankle fusion when compared to patients who had below the knee amputations. Salvage with simple skin coverage (non-free flap), however, had better results than BKAs. A suggestion was made that the addition of a free flap or an arthrodesis reversed the beneficial effect of salvage; viewed from an alternate perspective, it would seem that the need for a free flap/arthrodesis signifies an injury of greater complexity and as such the poorer outcomes seen in these patients may be a reflection of this level of complexity.

With the data for these outcomes coming from the patient, patient-related factors may have a significant impact on the findings reported. A few studies (14, 20, 21, 22) have reported on a relationship between self-efficacy and social support on outcomes. From the LEAP study (23), self-efficacy was one of the strongest predictors of return to work. Self-efficacy has to do with a patient's confidence in their ability to perform a specific task or activity. Patients with low self-efficacy expect to fail at specific tasks and as a result they tend to disengage from the coping process. These findings support the need for interventions in the early phase of recovery to address the psychosocial needs of patients, assisting them with self-managing the multifactorial consequences of their injury. There is some evidence in the treatment of other disorders (24, 25) that self-management interventions based on cognitive-behavioral theory increase self-efficacy, decreasing secondary conditions such as anxiety, pain, and

depression; overall improvements in function and quality of life are also reported. Other patient characteristics associated with poor outcomes include older age, female sex, nonwhite race, lower level of education, living in a poor household, a current or previous history of smoking, poor self-reported preinjury health status, and an involvement with the legal system for obtaining disability payments (14,15). Unfortunately many of these factors are overrepresented in the severe lower extremity trauma population. Nevertheless, these patients have preferences with regards to their treatment options even though a good portion of them are unable to make these decisions at presentation. A recent Web-based survey of patients and physicians used to generate quality adjusted life years (QUALYs) found that both groups placed a higher value on limb salvage compared to amputations (27). Based on the gain in value assigned, patients appear to value limb salvage to an even greater extent than do physicians.

With the goal of getting a better handle on the contribution of multiple injury related factors to surgical management and outcomes, lower extremity injury severity scoring systems have been developed. These scoring systems attempt to quantify the severity of trauma, assigning numerical values to various aspects of injuries including patient age, bone, soft tissue, nerve and vascular injury, warm ischemia time, contamination, and the presence of systemic shock. These factors are weighted differently based on their perceived importance in predicting ultimate outcomes. The initial presenting neurologic exam is one such factor that is heavily weighted in scoring systems like the NISSA (Nerve Injury, Ischemia, Soft-Tissue Injury, Skeletal Injury, Shock, and Age of Patient Score) and HFS-97 (Hannover Fracture Scale-97). Traditionally, even outside of the scoring systems, a critical factor in the decision to amputate has hinged on the absence of plantar sensation that was supported by a retrospective look at factors influencing the decision to amputate or reconstruct limbs after high energy traumatic injuries (26). The presence of soft tissue injury and the absence of plantar sensation were two of the more important factors in the decision-making process. An investigation on long term outcomes in salvage of extremities with absent plantar sensation, compared 26 insensate plantar feet that were amputated to 29 insensate plantar feet that were salvaged and 29 matched controls of sensate limbs that were salvaged (28). Interestingly, at 2 years equal proportions of patients had normal plantar sensation in the insensate salvaged group and the sensate salvaged group. SIP scores in all groups were similar. The absence of plantar sensation at the time of initial presentation was not predictive of eventual functional outcome or plantar sensation. Plantar sensation did not prove to be an indication for amputation and this is likely explained by the fact that initial presenting nerve dysfunction could be the result of reversible ischemia or neurapraxia as opposed to complete nerve disruption.

The timing of the first operative procedure is a variable of patient management many times in the control of the surgeon. Multiple studies (29, 30, 31) have found no association between delays beyond 6 to 8 hours and morbidities such as infections and non-unions. However, an analysis of data from the Nationwide Inpatient Sample by Sears et al. (32), found that delays in the first operative procedure beyond 24 hours significantly increased the likelihood of amputations in patients with severe open tibia fractures. This finding held true when controlling for biases introduced by concomitant traumatic injuries that may prevent a timely initial debridement.

In the current healthcare climate, patient satisfaction has become a key surrogate for assessing quality of care. Unfortunately, very little research has been done on patient satisfaction with the management of high energy lower extremity trauma. A retrospective study evaluating patient satisfaction was conducted on a series of 148 patients who had amputations ranging from the hip to the transmetatarsal level (28). Patient perceived results did not correlate with the level of amputations but rather were found to be related to the

function of prostheses used and the patient's ability to manage social activities and interactions. The results of this study, though important, are of limited use in considering amputations or limb salvage for trauma because patients in the study had amputations for a variety of other reasons including infections, congenital defects, vascular disease, diabetes, and tumors. Additionally, because only patients with amputations were studied, information on satisfaction in patients with salvaged extremities is not available. More recently, O'Toole et al. (29) investigated patient satisfaction in the severe lower extremity injury patient population, comparing amputated and limb salvage patients. Patient demographic data, treatment type, or specific injury characteristics did not correlate with satisfaction. Five outcomes measures accounted for over one third of the variations seen in patient satisfaction- return to work, depression, physical function as measured by the SIP, self-selected walking speed, and pain intensity. Based on this study it would appear that neither of the surgical treatments (amputation or limb salvage) affect the level of satisfaction reported by patients but rather function, pain, and the presence or absence of depression play significant roles.

Given the limited available resources for healthcare and the similarities in outcomes for both treatment strategies, the financial implications of managing these patients is an important consideration in the decision making process. Utilizing data from the LEAP study, Chung et al.(35), performed a cost-utility analysis of amputations and limb salvage in patients with the most severe open tibial fractures. Amputations were found to be more expensive than limb salvage, independent of the costs for prosthesis needs. Salvage was also found to have a higher utility than amputation, and these differences were amplified in younger patients. In the absence of clear indications for an amputation, salvage should be a strong consideration based on reasons of cost effectiveness and higher utility from the patient's perspective.

## LIMITATIONS OF STUDIES/OUTCOMES INSTRUMENTS

As is the case with a lot of the surgical literature, based on the nature of injuries and conditions being treated, most of the studies looking at functional and quality of life outcomes with amputations and limb salvage did not randomize patients into treatment arms. Clinical decisions were made regarding surgical treatment at the time of initial presentation, and outcomes were investigated after the fact. Typically, patients with more severe injuries end up with amputations as opposed to salvage. This selection bias inherent in these studies could have influenced some of the results reported.

The outcomes observed in most of these studies are specific to severe high energy traumatic injuries and are not generalizable to other patient populations, such as patients who sustain injuries in military conflicts and oncologic patients. The nature of the injuries, as well as unique external patient factors that contribute to the ultimate outcomes, further prevent generalization of results.

Unfortunately, the information we have from patient reported outcomes does not help predict which limbs should be salvaged and which should be amputated in the trauma population.

## CONCLUSIONS

Ideal scoring systems that aid with the decision on limb salvage versus amputation are lacking. Assessing postoperative functional and health-related quality of life outcomes with a variety of patient reported measures are a way of better understanding some of the nuances associated with amputations or limb salvage. The data from the literature suggest similar functional outcomes and rates of return to work in patients with salvaged and amputated lower extremities, although salvage procedures are plagued by higher complication and

reoperation rates. Multiple patient factors associated with poor outcomes cannot be changed, however, strategies to improve on self-efficacy can potentially improve on outcomes in both groups of patients and early debridements may decrease the need for amputations. Limb salvage provides cost-savings and appears to have a greater utility value to patients relative to amputations. More work will need to be done to help surgeons to consistently and reliably predict which patients presenting with severe lower extremity injuries will benefit from limb salvage or an early amputation.

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## Abbreviations: Lower Limb Surgery Outcomes Measurement

<b>BKAs</b>	[Author, please spell “BKA”]
<b>HFS-97</b>	Hannover Fracture Scale-97
<b>LEAP</b>	Lower Extremity Assessment Project
<b>MSTS</b>	Musculoskeletal Tumor Society Score
<b>NISSA</b>	Nerve Injury, Ischemia, Soft-Tissue Injury, Skeletal Injury, Shock, and Age of Patient Score
<b>PROMs</b>	Patient reported outcome measures
<b>QUALYs</b>	quality adjusted life years
<b>SF-36</b>	Short Form-36
<b>SIP</b>	Sickness Impact Profile
<b>TESS</b>	Toronto Extremity Salvage Score

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### Synopsis

This discussion focuses on limb salvage versus limb amputation. The authors address decision making and outcomes that must relate to questions of ‘Which patients would benefit from limb salvage as opposed to an amputation?’ ‘Does the level of injury make a difference?’ ‘Are there surgical or patient factors outside of the injury that have an impact on a patient’s ultimate function and quality of life?’ ‘Are there injury related factors that have an impact on patient reported outcomes?’ ‘How satisfied are patients postoperatively?’ ‘What are the financial implications of these treatment strategies?’

**KEY POINTS**

- Preoperative lower extremity injury scoring systems to aid with surgical decision-making are limited in their ability to clearly predict the need for amputation.
- Patient reported outcomes after limb salvage and amputation play a critical role in assessing the quality and efficacy of surgical strategies employed.
- Patients with severe lower extremity injuries have significant levels of disability following limb salvage and amputations.
- Limb salvage procedures are successful but are associated with higher complication rates than amputations.
- Long term functional outcomes are similar in patients with salvaged and amputated lower extremities, with no difference in their ability to return to work.
- Amputation level does not affect patient's perceptions of their results.
- The absence of plantar sensation at initial presentation is not a predictor of the need to amputate.
- Delays in the initial wound debridement beyond 24 hours are associated with higher amputation rates.
- Self-efficacy is one of the strongest predictors of patients' ability to return to work.
- Postoperative self-management interventions have the potential to improve overall function and quality of life in these patients.
- Satisfaction is not influenced by treatment strategy but by postoperative function, pain and the presence or absence of depression.
- Limb salvage has a higher utility value and costs less than amputation.
- Results from studies in the trauma population are not generalizable to other patient groups.

TABLE 1

## Selected Measurement Instruments

Instrument	Measure	Scoring	Primary Outcomes Evaluated
The Sickness Impact Profile (SIP)	Generic, behaviourally-based, health status measure	Scores range from 0 to 100; scores >10 represent severe disability	Health related dysfunction in 12 categories- ambulation, mobility, body care and movement, social interaction, alertness, emotional behavior, communication, sleep and rest, eating, work, home management and recreation
Musculo-Skeletal Tumor Society (MSTS)	Disease specific instrument (musculoskeletal tumors)	Scores range from 0 to 30; value of 0-5 is assigned to each of six categories. Higher scores indicate better function	Pain, function, emotional acceptance, supports, walking and gait
Toronto Extremity Salvage Score (TESS)	Disease specific instrument (extremity sarcoma)	Scores range from 0 to 100; 30 items are rated on a 5 point Likert scale.	Activity limitations, restrictions in mobility, restrictions in self care, and restrictions in performing daily tasks and routines
Nottingham Health Profile (NHP)	Generic health status measure	Scores range from 0 to 100; higher numbers indicate greater disability.	Part I: Subjective health status- mobility, energy level, pain, sleep, emotional reactions, social isolation. Part II: Influence of health problems on- employment, housework, family life, social life, sexual function, recreation and enjoyment of holidays
Short Form (36) Health Survey (SF-36)	Generic health related quality of life measure	Scores range from 0 to 100; higher numbers indicate a better health state	8 scales assessed resulting in scores relating to patients' perceived physical and mental status- vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, mental health
Western Ontario and McMaster University Osteoarthritis Index (WOMAC)	Disease specific (arthritis)	Scores range from 0 to 96; higher numbers indicate greater disability	24 items in three dimensions- stiffness, pain and physical function.