Functional Outcome of Bilateral Limb Threatening
Lower Extremity Injuries at Two Years Postinjury

Joel J. Smith, MD, Julie Agel, MA, ATC,† Marc F. Swiontkowski, MD,† Renan Castillo, MS,‡ Ellen MacKenzie, PhD,‡ James F. Kellam, MD,§ and the LEAP Study Group*

Objectives: To describe the functional outcome of bilateral limb-threatening injuries at 2 years postinjury and to evaluate whether a different decision-making process should be used for these patients as opposed to patients with unilateral limb-threatening injury.

Design/Setting/Patients: This study population of 32 patients is a subset of 601 patients from a study of 8 level I trauma centers. The patients were prospectively followed through 24 months.

Main Outcome Measurements: The principle outcome measure at 2 years was the Sickness Impact Profile, designed to measure physical and psychosocial dimensions.

Results: The overall Sickness Impact Profile scores at 2 years demonstrate that all 3 bilateral injury groups (bilateral salvage [n = 14], unilateral salvage/amputation [n = 8], and bilateral amputation [n = 10]) were severely disabled (Sickness Impact Profile >10). The bilateral salvage group had the most dramatic improvement over the 24 months. The 2-year physical subscale Sickness Impact Profile data showed a similar trend. At the 2-year assessment, the bilateral amputation group was recording greater disability (Sickness Impact Profile = 16.3) compared to the bilateral salvage and unilateral amputation/salvage groups (Sickness Impact Profile = 8.5 and 12.6, respectively). The overall Psychosocial Dimension, which started off worst in the bilateral salvage group, ended up similar in all 3 groups (8 to 9). The percent of patients who returned to work was 66.7% in the unilateral salvage/amputation group versus 21.4 and 16% in the bilateral salvage and amputation groups, respectively.

Conclusions: The results indicate that treatment judgments should be based upon the results derived from the analysis of the larger unilateral limb cohort data. Patients with severe, bilateral lower extremity injuries should be counseled that regardless of treatment combinations, the function of each limb is similar at 24 months. The unilateral amputation/salvage group had a greater probability of going back to work. This is the major identifiable benefit to undergoing salvage versus amputation.

Key Words: bilateral injury, lower extremity trauma, sickness impact profile

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The management of traumatic, limb-threatening injuries to the lower extremity remains a controversial topic in the orthopaedic literature. Due to technical advances in the care of severe soft tissue and bony injuries, there is argument that many limbs are salvaged to the detriment of the patient.[1–3] These patients often suffer a protracted medical course that can leave them in a devastated social and financial position regardless of their surgical outcome.[4] To further complicate the decision-making process, it has remained arguable whether the outcome of a surgically salvaged limb is functionally better than a primary amputation.[5–8] The Lower Extremity Assessment Project (LEAP) was undertaken to address this question in a prospective, longitudinal study.[9,10] The purpose of LEAP was to examine these assertions made in smaller studies[1,2,11–14] in a large enough population to have statistical power. This project demonstrated that at 2 years, there was no functional difference, as measured by the Sickness Impact Profile (SIP), between patients with unilateral limb-threatening lower extremity injuries treated with amputation or salvage procedures. For purposes of analysis, all patients with bilateral limb-threatening injuries were excluded from this primary analysis. There were patients with bilateral injuries in this group, but with only 1 limb injury substantial enough to qualify as limb threatening. These remained in the unilateral cohort.

A subset of 32 patients who had bilateral, lower limb-threatening injuries underwent the same data collection process as the greater LEAP study cohort.[10] These patients present a treatment challenge due to the emotional and functional considerations of potentially amputating both lower extremities in a previously healthy person. The objective of this study is to describe the functional outcome of the subset of bilateral limb-threatening injuries at 2 years postinjury and evaluate whether a different decision-making process is indicated.

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From the *Department of Orthopaedic Surgery, University of California, San Diego, CA; †Department of Orthopaedic Surgery, University of Minnesota, Minneapolis, MN; ‡Center for Injury Research & Policy, Johns Hopkins University, Baltimore, MD; and §Department of Orthopaedic Surgery, Carolinas Medical Center, Charlotte, NC.

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Reprints: Julie Agel, MA, ATC, Department of Orthopaedic Surgery, University of Minnesota, 2450 Riverside Avenue, So., Suite R200, Minneapolis, MN 55454 (e-mail: agelx001@umn.edu).

MATERIALS AND METHODS

The LEAP study involved 601 patients from 8 level I trauma centers. This study population, as a subset of the LEAP study, was subject to the data collection methods described in earlier publications.[9,11] Eligible for participation in the LEAP study were patients between the ages of 16 and 69 years who were admitted to 1 of 8 level I trauma centers with high-energy, lower-extremity trauma below the distal femur, including Gustilo level IIIB and IIIC fractures, selected level IIIA fractures, dysvascular limbs (ie, knee dislocations, closed tibia fractures, or penetrating wounds with vascular injury), major soft-tissue injuries to the tibia (ie, degloving or severe/crush/avulsion injury), and open pilon or level IIIB ankle fractures or open hindfoot or midfoot injuries. The patients were followed-up at 3-, 6-, 12-, and 24-month intervals. The principle outcome measure at 2 years was the Sickness Impact Profile (SIP), an instrument designed to measure physical and psychosocial dimensions.[15] This instrument was self-administered. The lower the SIP score, the better the patient outcome. A change of 2 to 3 points is believed to represent a meaningful difference in function.[16] Secondary outcomes were divided into 2 groups: patient variables (return to work, time to full weight bearing, and number of rehospitalizations) and limb variables (final status of the limb, late amputation or stump revision, presence of nonunion, status of soft tissue, need for additional surgery, rehospitalization for any complication). Rehospitalization is both a patient and treatment variable because the limb variable is based on the complications associated with each limb's treatment. The patient variable rehospitalization addresses the issue of the patient and their overall return to work.

The subset of 32 patients had bilateral limb-threatening injuries that would have individually qualified the patient for the study. Four patients were lost to follow-up over the 2-year follow-up period. Analysis was performed either by patient variables or leg variables based on whether or not we were looking at the effect of specific treatment or overall patient return to function. The bilateral injury study population was divided into 3 groups based on initial treatment decisions: bilateral salvage (n = 14), unilateral salvage/amputation (n = 8), and bilateral amputation (n = 10). Table 1 summarizes these injuries by outcome groups (salvaged or amputated limb). Because these combinations of injuries are rare, the patients reported here represent a small patient population with a nonhomogeneous complement of injuries, thus the descriptive nature of the paper. It was not possible to break down the treatment outcome groups any further. This would have subdivided the cohort too much to allow reasonable groups for statistical analysis.

TABLE 1. Injury Outcomes by Patient

Injury	No. Patients
Bilateral salvage	14
Bilateral below-knee amputations	4
Bilateral above-knee amputations	3
Above-knee amputations/below-knee amputation	2
Above-knee amputation/salvage	5
Below-knee amputation/salvage	3
Below-knee amputation/through-knee amputation	1

This table demonstrates the combination of injury patterns that were seen in this study population by patient.

RESULTS

Patient Variables

The overall SIP scores at 2 years demonstrate that all 3 bilateral injury groups were severely disabled (SIP >10) (Fig. 1). Observing the trends in recovery measured by the overall SIP scores, the bilateral salvage group had the most dramatic recovery (improvement) from 26.97 to 9.8 over the 24 months. The unilateral amputation/salvage group started off with the lowest (18.6) (best) scores; at 1 year, all 3 groups are similar overall, then the unilateral (12.69) and bilateral amputation (14.73) groups show less improvement than the bilateral salvage group (9.8). The 2-year physical subscale SIP data showed a similar trend. At the 3-month assessment, the bilateral amputation and bilateral salvage groups were recording more disability than the unilateral amputation/salvage group (SIP = 24 versus 20). By the 2-year assessment, this had reversed and the bilateral amputation group was recording greater disability (SIP = 16.3) compared to the bilateral salvage and unilateral amputation/salvage groups (SIP = 8.5 and 12.6, respectively). Mobility is within 1 standard deviation from the norm in all groups. The Ambulation and Body Care and Movement categories shifted the overall Physical Dimension to a lower (better) score. The overall Psychosocial Dimension, which started off worse in the bilateral salvage group, ended up similar in all 3 groups (8 to 9) and is within 1 standard deviation from the normal scores.

Limb Variables

Two years postinjury, the bilateral salvage patients had a mean number of rehospitalizations for treatment of complications of 2 versus 1.7 in the unilateral salvage/amputation patients and 1 in the bilateral amputation patients. The mean time to full weight bearing for patients was similar in the bilateral amputation and salvage groups (18.8 and 15.3 weeks) and higher in the unilateral salvage/amputation group (24.8 weeks). The percent of patients who returned to work was 66.7% in the unilateral salvage/amputation group versus 21.4% and 16% in the bilateral salvage and amputation groups, respectively (Table 2). Self selected walking speed for patients with bilateral salvage was 36.8 seconds, 38 seconds for patients with bilateral amputations, and 29.7 seconds for patients in the unilateral salvage/amputation group.

The results as grouped by final status of the limb at 24 months are as follows (Table 3). The percent with late amputation or stump revision was 0 in both groups. The percent of nonunions at 2 years was 0 in both groups. All of the soft tissues healed in the amputated limbs. There were 2 unhealed soft tissue wounds in the salvaged limbs (5.6%). The percent requiring additional surgery was 8.7 in the salvaged limb and 7.4 in the amputated limbs. All of the patients who presented with a vascular injury underwent an initial amputation on that side.

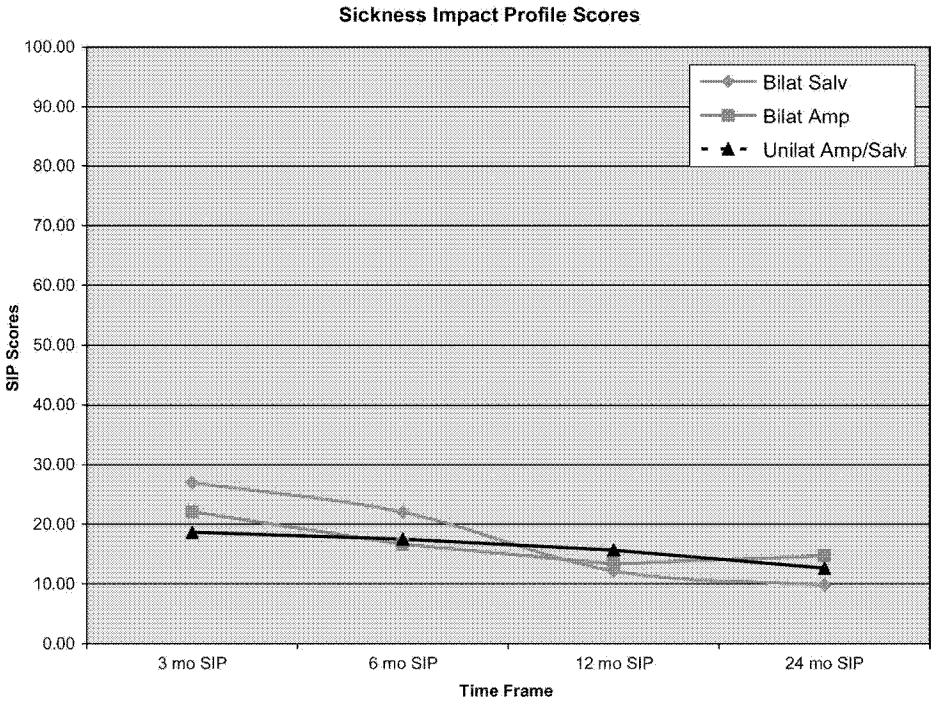

FIGURE 1. Graph showing Sickness Impact Profile at 3, 6, 12, and 24 months for bilateral salvage (♦), bilateral amputation (■), and unilateral amputation and unilateral salvage (▲) groups.

DISCUSSION

Literature searches on the topic of bilateral, lower-extremity, limb-threatening injuries revealed no other papers or case reports. Ovid search strategies of bilateral lower extremity amputation, bilateral lower extremity trauma, and bilateral lower extremity limb salvage were used. The small size of the study groups makes it difficult to say how specific injury combinations relate to the overall final outcome. Applying statistics to this population would potentially create type II errors due to the small power.

The 3 treatment groups showed similar trends found in the larger cohort of the unilateral population. Disability levels remained high in the overall, physical, and psychosocial dimensions of the SIP at 2 years. An overall SIP score of 10 is considered to represent severe disability. Forty-six percent of our patient population had scores over 10. This compares to 42% of the unilateral injury population. The psychosocial subscale of the SIP showed only minimal improvement over the 24-month period. This may indicate that there is a need to assist these patients with psychologic rehabilitation with at least the same vigor given to their physical recovery. Although the physical subscales improved dramatically, all of the study groups reported similar levels of physical subscore disability. Patients showed continuous improvement over the 2-year interval, and it is possible that they might have continued improving after the time of the last reporting.

The groups where salvage procedures were performed had higher rehospitalization rates for complications than the bilateral amputation group. This may be due to the complexity of the initial surgical procedures performed on a salvaged limb. In descending order, the bilateral salvage group has the highest mean number of rehospitalizations followed by the

TABLE 2. Patient Variables At 24 Months Postinjury

	Total* (n = 464)	Amputees (n = 133)	All (n = 331)	Total Bilateral Injury, All (n = 32)	Bilateral Salvage (n = 14)	Unilateral Amputation (n = 8)	Salvage Bilateral Amputation (n = 10)
Mean no. rehospitalizations for complication (of those with any rehospitalization)	1.7	1.4	1.8	1.8	2	1.7	1
Mean time to full weight bearing	26.6	22.2	28.4	22.2	18.8	24.8	15.3
Mean overal SIP score	12.0	12.6	11.8	11.9	9.8	14.7	12.7
% with overall SIP ≥10	42.2	43.9	41.5	46.4	38.5	62.5	42.9
% return to work	51.0	53.0	49.4	34.5	21.4	66.7	16.7

*Overall study cohort followed at 2 years.

TABLE 3. Limb Variables At 24 Months Postinjury

	Total* (n = 464)	Amputees (n = 133)	All (n = 331)	Total Bilateral Injury, All (n = 64)	Total 1 (n = 36) Salvage	Total 2 (n = 28) Amputations
% with late amputation or stump revision	3.9	5.2	3.3	0	0	0
% fractures not healed (of those with fractures)	10.6	NA	10.8	0	0	0
% soft tissue not healed (of those with soft-tissue injury)	4.7	8.9	3.8	6.7	0	3.5
% requiring additional surgery (as assessed by surgeon)	15.0	5.0	19.0	6.5	8.7	7.4
% rehospitalized for any complication	40.8	30.5	45.3	20.3	25	14.3

NA, not applicable.
*Overall study cohort followed at 2 years.

unilateral amputation/salvage group and the bilateral amputation group. Based upon this, it seems that the salvaged limb increases the risk for rehospitalization. The return to work rate was much better in the unilateral amputation/salvage group. This may be due to the degree of injury in that group, but it is not explainable based upon the other data examined. The self-selected walking speed variable was variably collected. This may have been due to the fact that some of these patients were not ambulatory. The data show that the patient with bilateral salvaged limbs had a more rapid gait followed by the bilateral amputation group. The unilaterial amputation group had the fastest speed.

The evidence suggests that disability is severe with bilateral limb-threatening injuries, but no more severe than for those patients with severe unilateral lower-extremity injuries.[9] The SIP scores, whether the treatment is amputation, salvage, or both, continue to improve over time. The results indicate that treatment judgments should be based upon the results derived from the analysis of the larger unilateral limb cohort data.

At 2 years, we are not sure if we have seen the full extent of the possible recovery because, at least in this group, the population norms had not been reached in the SIP. Patients were still under clinical care beyond routine prosthetic maintenance. There is evidence in other severe lower-extremity fractures series that the recovery period may be many years.[17,18] In this study, all combinations of treatment of bilateral limb-threatening injuries yielded similar outcomes at 2 years. This is demonstrated by the comparison of the measured outcomes of the unilateral amputation/salvage group with the other 2 groups. The outcomes tools used in this study could not detect overall levels of disability greater in the bilateral injuries versus the unilateral injuries treated in the same institutions by the same physicians.

An inherent limitation of this study is that all patients were seen at level I trauma centers where this severity of injury is not uncommon, and there were multiple resources available for treatment. The level of results achieved in this patient population might not be achievable in smaller hospitals that do not have available the full range of resources.

CONCLUSION

The unilateral amputation/salvage group had a greater probability of going back to work. This is the major identifiable benefit to undergoing salvage versus amputation. Based upon this analysis, patients with severe bilateral lower-extremity injuries should be counseled that regardless of treatment combinations, the functional outcomes are similar at 24 months across the 3 groups.

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