

THE INSENSATE FOOT FOLLOWING SEVERE LOWER EXTREMITY TRAUMA: AN INDICATION FOR AMPUTATION?

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Background: Plantar sensation is considered to be a critical factor in the evaluation of limb-threatening lower extremity trauma. The present study was designed to determine the long-term outcomes following the treatment of severe lower extremity injuries in patients who had had absent plantar sensation at the time of the initial presentation.

Methods: We examined the outcomes for a subset of fifty-five subjects who had had an insensate extremity at the time of presentation. The patients were divided into two groups on the basis of the treatment in the hospital: an insensate amputation group (twenty-six patients) and an insensate salvage group (twenty-nine patients), the latter of which was the group of primary interest. In addition, a control group was constructed from the parent cohort so that the patients in the study groups could be compared with patients in whom plantar sensation was present and in whom the limb was reconstructed. Patient and injury characteristics as well as functional and health-related quality-of-life outcomes at twelve and twenty-four months after the injury were compared between the subjects in the insensate salvage group and those in the other two groups.

Results: The patients in the insensate salvage group did not report or demonstrate significantly worse outcomes at twelve or twenty-four months after the injury compared with subjects in the insensate amputation or sensate control groups. Among the patients in whom the limb was salvaged (that is, those in the insensate salvage and sensate control groups), an equal proportion (approximately 55%) had normal plantar sensation at two years after the injury, regardless of whether plantar sensation had been reported to be intact at the time of admission. No significant differences were noted among the three groups with regard to the overall, physical, or psychosocial scores. At two years after the injury, only one patient in the insensate salvage group had absent plantar sensation.

Conclusions: Outcome was not adversely affected by limb salvage, despite the presence of an insensate foot at the time of presentation. More than one-half of the patients who had presented with an insensate foot that was treated with limb reconstruction ultimately regained sensation at two years. Initial plantar sensation is not prognostic of long-term plantar sensory status or functional outcomes and should not be a component of a limb-salvage decision algorithm.

Level of Evidence: Prognostic Level I. See Instructions to Authors for a complete description of levels of evidence.

The treatment of severe, leg-threatening injuries often necessitates an immediate or early decision between limb reconstruction and amputation. This initial decision requires a prediction of treatment outcomes on the basis of patient and injury characteristics. Although a multitude of guidelines and scoring systems have been devised to assist with this decision¹⁻⁵, recent work by Bosse et al.⁶ has challenged their usefulness. Of the five systems that were

evaluated, three included plantar sensation as a limb-scoring element. In a recent analysis of the factors that were identified by treating surgeons as having affected the decision to amputate a severely injured extremity, Swiontkowski et al.⁷ identified the absence of plantar sensation as one of the most important variables used in the decision process.

In the current investigation, we sought to determine whether an insensate foot is an accurate indicator of the need for amputation. More specifically, we hypothesized that the outcomes associated with amputation and reconstruction would be no different among patients who had an insensate foot at the time of admission.



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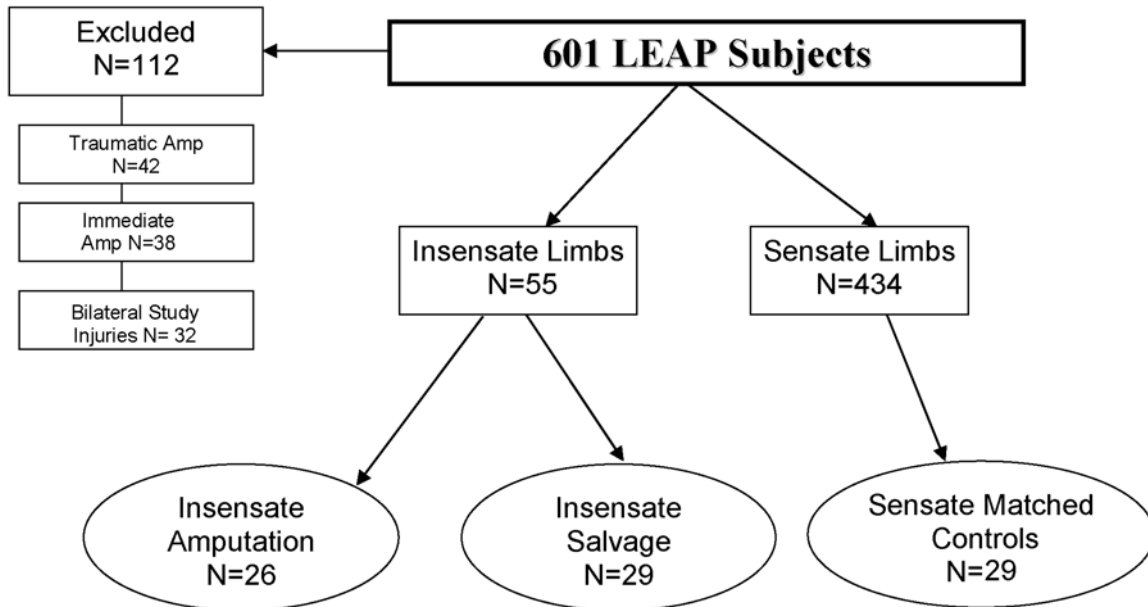


Fig. 1

Illustration demonstrating how the study cohort was constructed.

Materials and Methods

Study Population

The data for the current study were collected as part of the Lower Extremity Assessment Project (the LEAP study), a multicenter, prospective outcome study of 601 patients with severe, limb-threatening lower extremity injuries^{8,9}. Eligible study patients included individuals between the ages of sixteen and sixty-nine years who had been admitted to one of eight level-I trauma centers with an injury distal to the femur. The injuries that were studied included Gustilo and Anderson¹⁰ type-IIIB and type-IIIC fractures, selected type-IIIA fractures, injuries associated with dysvascular limbs (i.e., knee dislocations, closed tibial fractures, or penetrating wounds associated with vascular injury), major soft-tissue injuries (i.e., degloving or severe crush/avulsion injuries), or severe foot and ankle injuries (i.e., open pilon or type-IIIB ankle fractures or severe hindfoot or midfoot injuries). Patients were excluded if they had a substantial brain injury (as indicated by a Glasgow Coma Scale score of <15 at twenty-one days after the injury or at the time of discharge), spinal cord deficit, previous leg or foot amputation, or third-degree burns on the injured leg. Patients also were excluded if they had been transferred to the participating center more than twenty-four hours after the injury, if they did not speak English or Spanish, if they had documented psychiatric disorders or mental retardation, or if they were on active military duty or lived outside the catchment area and were unable to return for follow-up at the participating centers. Informed consent was obtained from all patients in accordance with each center's institutional review board.

The current study is based on a subset of fifty-five patients with a unilateral injury who did not have plantar sen-

sation at the time of hospital admission and on a matched subgroup of patients who did (Fig. 1). Although 601 patients were enrolled in the LEAP study, 112 were excluded from this analysis because the severity of the limb injury had resulted in traumatic amputation (forty-two patients) or had necessitated immediate amputation (thirty-eight patients) or because they had sustained a bilateral injury (thirty-two patients). Of the remaining 489 subjects, fifty-five had an insensate foot at the time of admission and were divided into two groups according to treatment. The first group (the insensate amputation group) comprised twenty-six patients with absent plantar sensation who underwent amputation after the first twenty-four hours (and after the initial operation on the limb) but during the primary hospital admission, and the second group (the insensate salvage group) comprised twenty-nine patients with absent plantar sensation in whom the limb was reconstructed.

A third group (the sensate control group), comprising twenty-nine subjects from the LEAP study in whom plantar sensation had been intact at the time of admission and in whom the limb was salvaged, was constructed so that we could compare the outcomes for subjects who had had an insensate extremity at the time of admission (the insensate salvage group) with those for patients who had had a sensate extremity at the time of admission (the sensate control group). The twenty-nine patients in the sensate control group were matched to the twenty-nine patients in the insensate salvage group on the basis of four injury characteristics: (1) the severity of the muscle damage, (2) the severity of the venous injury, (3) the severity of the tibial fracture, and (4) the presence of an associated foot injury. These four injury characteristics were selected because they were previously identified (in addition to

the absence of plantar sensation) as being the most important predictors (in that order) of whether an extremity was amputated or reconstructed during the initial hospitalization⁷. A table in the Appendix describes the criteria used to grade the severity of the selected characteristics.

For each subject in the insensate salvage group, we identified all possible controls with the same level of severity in terms of each of the four selected injury characteristics. In all but three cases, at least one control who was exactly matched in terms of all four injury criteria was found. In the remaining three cases, one control was matched exactly in terms of the first three criteria (i.e., severity of the muscle damage, venous injury, and tibial fracture) and two controls were matched exactly in terms of the first two criteria (i.e., severity of the muscle damage and venous injury). Whenever more than one possible control was found, one was randomly selected. The total study population consisted of eighty-four subjects who were divided into three study groups, depending on the status of plantar sensation at the time of the initial presentation and the type of limb treatment received during the hospital stay (Fig. 1).

Data Collection

Subjects were enrolled in the study during the initial hospitalization and were asked to return to the trauma center for a follow-up evaluation at three, six, twelve, and twenty-four months after the injury. Prior to discharge from the hospital, subjects were interviewed to obtain background sociodemographic data and preinjury health-status information⁹. At the time of hospital admission, the attending orthopaedic surgeon documented the nature and severity of the index injury according to several classifications and/or scoring systems: (1) the Gustilo and Anderson¹⁰ and Tscherny and Gotzen¹¹ classifications of all tibial and foot fractures, (2) the Orthopaedic Trauma Association¹² and AO¹³ classifications of long-bone fractures and soft-tissue tibial injuries, and (3) all components of the Mangled Extremity Severity Score (MESS)³, the Hannover Fracture Scale (HFS)¹⁴, the Limb Salvage Index (LSI)⁵, and the Predictive Salvage Index (PSI)².

Different components of these systems were used to classify the severity of each index injury according to three dimensions: (1) osseous injury, (2) soft-tissue injury, and (3) neurovascular injury (see Appendix). Plantar sensation was recorded as a dichotomous variable as either present (but not necessarily normal) or absent. The presence or absence of plantar sensation was determined on the basis of a clinical evaluation by the attending orthopaedic surgeon and not on the basis of surgical exploration and evaluation of the posterior tibial nerve.

The attending orthopaedic surgeon also recorded the primary treatment that was received during the initial hospitalization (i.e., immediate or delayed amputation as opposed to reconstruction) and whether the limb was initially reconstructed and was subsequently amputated after discharge (i.e., late amputation). The medical records for each patient and the trauma registries at each site were used to obtain informa-

tion on associated injuries, the mechanism of injury, and the length of the hospital stay. All injuries were classified according to the Abbreviated Injury Scale¹⁵ and the Injury Severity Score¹⁶.

At twelve and twenty-four months after the injury, subjects underwent a clinical evaluation (performed by the attending orthopaedic surgeon), a functional status evaluation (performed by a physical therapist), and an interview. The orthopaedic surgeon documented the clinical recovery in relation to the index injury in terms of osseous and soft-tissue healing, any limb complications that had occurred, and all treatment that had been received in relation to the index injury. The physical therapy assessment included an evaluation of leg impairment and function. Leg impairment was measured in terms of range-of-motion limitations, pain, and impaired or absent plantar sensation. Summary active range-of-motion scores were derived according to the American Medical Association's *Guides to the Evaluation of Permanent Impairment*¹⁷. Pain was assessed with use of a visual analog scale. Patients were asked to mark an X on a 100-mm line at the point that best described the pain that they felt in the leg during a typical day (with 0 mm indicating no pain and 100 mm indicating unbearable pain)¹⁸. The physical therapists also documented the subjects' current weight-bearing status, use of orthoses or walking aids, and ability to ascend and descend a flight of stairs reciprocally.

Sensation was evaluated at twenty-four months after the injury. Subjects were examined and were asked if they had normal sensation in each leg. Subjects who demonstrated or reported any type of abnormal sensation were further examined with an assessment of their sensitivity to pinprick. For the purposes of the current study, we report the results of sensation testing on the plantar surface of the salvaged foot in three areas: the first metatarsophalangeal joint, the middle part of the heel, and the middle part of the lateral aspect of the foot. The physical therapist rated the sensation of each of these areas as normal, impaired, or absent. If the sensation varied among the three areas of the foot in a particular subject, the sensation of the foot was classified as impaired.

Finally, health-related quality of life was assessed by asking subjects to complete the Sickness Impact Profile (SIP)^{19,20}. The SIP is a general health-status questionnaire that is used to evaluate 136 limitations in physical and psychosocial health across twelve health domains: sleep and rest, eating, work, home management, recreation and pastimes, walking ability, mobility, body care and movement, social interaction, alertness, emotional behavior, and communication. SIP scores range from 0 to 100; the higher the score, the greater the dysfunction. The SIP has been validated across different demographic and cultural groups and across different types of injury and illness^{8,19,21-28}.

Analysis

The outcomes for subjects with absent plantar sensation at the time of the initial evaluation who were managed with limb reconstruction (the insensate salvage group) were compared

TABLE I Differences in Impairment and Functional Outcomes by Group*†‡

Impairment and Function	Insensate Amputation Group	Insensate Salvage Group	Sensate Control Group
Foot sensation at 24 months§			
Normal	NA	55.6% (10)	55.0% (11)
Impaired	NA	22.2% (4)	25.0% (5)
Absent	NA	5.6% (1)	0.0% (0)
Amputated	NA	16.7% (3)	20.0% (4)
Mean visual pain score§			
12 months	24.0 (21.2)	24.5 (22.1)	25.9 (22.0)
24 months	38.3 (27.3)	30.5 (28.6)	31.7 (23.2)
Mean AMA range-of-motion score			
12 months	NA	0.34 (0.27)	0.30 (0.27)
24 months	NA	0.27 (0.25)	0.28 (0.29)
Percentage of patients fully weight-bearing§			
12 months	64.7% (11)	87.5% (21)	68.0% (17)**
24 months	94.1% (16)	100.0% (18)	90.9% (20)
Percentage of patients with immobilization device			
12 months	76.5% (13)#	29.2% (7)	60.0% (15)#
24 months	88.2% (15)#	21.1% (4)	45.5% (10)**
Percentage of patients using walking aid			
12 months	70.6% (12)#	37.5% (9)	40.0% (10)
24 months	23.5% (4)	15.8% (3)	27.3% (6)
Percentage of patients able to climb and descend stairs reciprocally§			
12 months	17.6% (3)#	54.2% (13)	40.0% (10)
24 months	33.3% (5)	57.9% (11)	72.7% (16)

*AMA = American Medical Association. †At twelve months after the injury, physical therapy assessments were completed for seventeen subjects in the insensate amputation group, twenty-four subjects in the insensate salvage group, and twenty-five subjects in the sensate control group. ‡At twenty-four months after the injury, physical therapy assessments were completed for seventeen subjects in the insensate amputation group, nineteen subjects in the insensate salvage group, and twenty-two subjects in the sensate control group. ‡The numbers in parentheses indicate the sample sizes (for categorical variables) or the standard deviation (for continuous variables). §Missing data. #The characteristic differs significantly ($p \leq 0.05$) compared with the insensate salvage group. **The characteristic differs ($0.05 \leq p \leq 0.10$) compared with the insensate salvage group.

with those for other patients with severe lower limb injuries, specifically, subjects without plantar sensation who underwent amputation during admission (the insensate amputation group) and subjects with plantar sensation in whom the limb was salvaged (the sensate control group). To ensure that differences in outcome were not due to differences in patient characteristics or injury severity, we compared the patient characteristics and injury severity in the insensate salvage group with those in the insensate amputation and sensate control groups. For groups that had similar patient and injury severity characteristics, functional and health-related quality-of-life outcomes were compared. When one group was compared with another, a chi-square statistic was used when the characteristic or outcome was categorical and a Student *t* test was used when the variable of interest was continuous. For all analyses, differences were considered to be significant if $p < 0.05$. However, because of the small sample sizes within each group, differences were also noted if $p \leq 0.10$.

Results

With the numbers available, there were no significant differences in sociodemographic or preinjury health characteristics between subjects without plantar sensation who underwent reconstruction (the insensate salvage group) and those in the other two study groups (see Appendix). No significant differences in the length of hospital stay were noted among the study groups (mean range, 13.7 to 19.7 days; $p = 0.16$).

The comparison of injury characteristics according to treatment group revealed few differences in injury severity between subjects in the insensate salvage group and those in the insensate amputation and sensate control groups, with a few exceptions (see Appendix). First, subjects in the insensate amputation group were more likely to have sustained substantial bone loss compared with subjects in the insensate salvage group (23% compared with 3%; $p = 0.04$). Second, subjects in the sensate control group were significantly more likely to

TABLE II Differences in Health-Related Quality-of-Life Activities by Group*†‡

Outcomes	Insensate Amputation Group	Insensate Salvage Group	Sensate Control Group
Mean SIP score			
Overall			
12 months	14.9 (14.7)	12.3 (11.8)	11.9 (9.0)
24 months	12.3 (13.2)	11.6 (11.4)	9.6 (7.6)
Physical			
12 months	14.2 (13.8)	9.7 (8.9)	10.2 (9.4)
24 months	9.1 (10.3)	8.8 (9.5)	8.6 (7.8)
Psychosocial			
12 months	12.1 (20.5)	10.7 (15.1)	8.5 (9.6)
24 months	12.3 (20.4)	10.9 (15.6)	5.8 (6.9)
Work			
12 months	37.5 (35.2)	34.8 (32.7)	44.2 (31.0)
24 months	45.2 (33.6)	38.1 (31.4)	41.6 (33.7)
Percentage of patients returning to work (among those working before injury)§			
12 months	60.0% (9)	31.6% (6)	34.8% (8)
24 months	60.0% (9)	55.6% (10)	52.4% (11)

*SIP = Sickness Impact Profile. †At twelve months after the injury, SIP scores and interviews were completed for twenty-one and twenty-four subjects in the insensate amputation group, twenty-six and twenty-seven subjects in the insensate salvage group, and twenty-six subjects (both) in the sensate control group. At twenty-four months after the injury, SIP scores and interviews were completed for nineteen subjects in the insensate amputation group, twenty subjects in the insensate salvage group, and twenty-six subjects in the sensate control group. ‡The numbers in parentheses indicate the sample size (for categorical variables) or the standard deviation (for continuous variables). §Missing data.

have normal limb perfusion compared with subjects in the insensate salvage group (72% compared with 41%; $p = 0.02$).

We found no significant difference between the patients managed with reconstruction (that is, between the insensate salvage and sensate control groups) in terms of the rate of late amputation at two years after the injury (15.8% [three of nineteen patients] and 18.2% [four of twenty-two patients], respectively). With the numbers available, no significant differences were noted between subjects in the insensate salvage group and those in the insensate amputation and sensate control groups in terms of physical impairment. Among subjects in whom the limb was salvaged (the insensate salvage and sensate control groups), an equal proportion (approximately 55%) either reported normal foot sensation or tested normally for pinprick sensation, regardless of whether they had had intact or absent plantar sensation at the time of hospital admission. Five (25%) of the patients in the sensate cohort had development of plantar sensory dysfunction over the course of the limb reconstruction. Only one patient who underwent limb reconstruction after presenting with absent sensation remained insensate at two years. Similarly, with the numbers available, no significant differences were noted between subjects in the insensate salvage group and those in the insensate amputation and sensate control groups in terms of pain or range-of-motion scores at twelve or twenty-four months after the injury.

Functionally, subjects in the insensate amputation and sensate control groups were significantly more likely to wear

an immobilization device (cast, splint and orthosis, or prosthesis) compared with subjects in the insensate salvage group ($p < 0.05$). Subjects in the insensate amputation group also were significantly more likely to use a walking aid (crutches, walker, or cane) at twelve months compared with subjects in the insensate salvage group (71% compared with 38%; $p = 0.04$). Finally, at twelve months, subjects without plantar sensation who had undergone amputation (the insensate amputation group) also were significantly less likely to be able to climb and descend stairs reciprocally compared with subjects without plantar sensation in whom the limb was salvaged (the insensate salvage group) (18% compared with 54%; $p = 0.02$).

We found no significant differences among the treatment groups with regard to the proportion of subjects who completed the twelve-month (range, 90% to 93%; $p = 0.88$) or twenty-four-month follow-up evaluation (range, 69% to 90%; $p = 0.14$) (Table I). With the numbers available, we found no significant differences between the subjects in the insensate salvage group and those in the insensate amputation and sensate control groups with regard to health-related quality-of-life activities at twelve or twenty-four months. Overall, the physical, psychosocial, and work SIP scores were similar between the groups (Table II). All study groups reported poorer health-related quality of life at twelve and twenty-four months after the injury as compared with a preinjury sample of patients with similar but less severe injuries²⁹. Among subjects who had been working before the injury, we found no significant differences between those in the insensate salvage group

and those in the other study groups with regard to percentage of subjects who had returned to work at twelve or twenty-four months after the injury.

Although excluded from this study design, the thirty-eight patients who were managed with immediate amputation (that is, those in whom amputation was the index procedure) were reviewed to determine the status of plantar sensation at the time when the limb-treatment decision was made. All of these patients had had absent plantar sensation.

Discussion

The findings of the present study do not support the belief that the initial plantar sensory status in patients who have a leg-threatening injury is correlated with poor late outcome if limb salvage is attempted. The current analysis demonstrated that although patients with severe injuries and absent plantar sensation at the time of presentation had substantial impairment at twelve and twenty-four months, the patients managed with limb salvage did not have worse outcomes than those managed with amputation. Of importance was the finding that the group of patients who had had absent plantar sensation at the time of presentation and who were managed with limb salvage (the insensate salvage group) was not significantly different from a control group of patients with similar injuries in whom plantar sensation had been intact at the time of presentation (the sensate control group) in terms of outcome, final plantar sensory status, or the need for late amputation.

Our results suggest that tibial nerve dysfunction on clinical examination cannot be assumed to be equivalent to nerve disruption. Ten (67%) of fifteen subjects in the insensate salvage group (excluding three patients in whom the limb was later amputated) had normal foot sensation at two years after the injury. It is likely that a substantial number of these cases were the result of reversible ischemia or neurapraxic injuries of peripheral nerves rather than permanent loss of tibial nerve function.

Absent plantar sensation has been identified as a critical element in the decision-making process when selecting amputation or limb reconstruction for patients with a severe injury of the lower extremity. The current treatment of a severely injured lower limb may be influenced by the belief that plantar sensation dysfunction and late outcomes are related. Swiontkowski et al.⁷ studied the decision-making process in order to determine the critical elements used by the surgeon to make the initial treatment decision between amputation and limb salvage. At the time of the initial presentation, the treating surgeon rank-ordered critical injury and patient characteristics that were hypothesized to impact the treatment decision. Tibial nerve dysfunction was identified as the most important clinical finding, ranking even higher than limb ischemia. At the conclusion of patient enrollment, the surgeons who had managed the patients were surveyed to determine the limb injury characteristics that had driven the decision process. Plantar sensation was considered to be the most important physical finding directing treatment. The

Mangled Extremity Severity Score (MESS)³; the Nerve Injury, Ischemia, Soft-Tissue Injury, Skeletal Injury, Shock, and Age (NISSSA) score⁴; and the Hannover Fracture Scale¹⁴ heavily weight the results of the initial plantar sensory examination, with the assumption that a sensory impairment correlates with diminished limb-salvage capacity and that the initial examination represents the final deficit. Bosse et al.⁶ prospectively evaluated the clinical utility of the lower-extremity injury severity scores and were unable to validate the scores as useful clinical tools for the amputation decision-making process. Three of the five scores that were evaluated contained elements that included plantar sensation. The origin of the relative importance of tibial nerve function in this patient group is difficult to trace. The long-term outcomes for patients with tibial nerve dysfunction following extremity trauma are unknown. Despite the belief among some investigators that an insensate foot precludes successful treatment of an injured lower extremity, the insensate foot is routinely treated without amputation in patients with other conditions, including diabetes and spinal cord injury³⁰⁻³³.

Lange et al.³⁴ suggested a decision-making protocol based on absolute and relative indications for immediate amputation. The presence of one of two absolute indications (either complete tibial nerve disruption or a crush injury with warm ischemia of more than six hours' duration) or of two of three relative indications (serious associated polytrauma, severe ipsilateral foot trauma, or a projected long course to full recovery) was suggested as an indication for immediate amputation. One of the limitations of this protocol is that, in most cases, complete tibial nerve disruption is difficult to confirm at the time of decision-making, and in many cases it is inferred by examination of sensory function on the plantar surface of the foot. Surgical exploration of the nerve within the zone of injury is usually contraindicated as it causes additional soft-tissue injury.

The employment of the initial plantar sensory examination in the decision-making process may yield a self-fulfilling prophecy. It is possible that orthopaedic surgeons are performing early limb amputation on the basis of the plantar sensory examination of extremities that have the potential to perform as well, if reconstructed. In the parent study, thirty-eight patients were managed with immediate limb amputation; all of those patients lacked plantar sensation. It is difficult to determine the extent to which this finding influenced the decision to amputate the limb, if at all. Bosse et al.⁸ found that the two-year outcomes for patients with severe lower extremity injuries who had been managed with amputation were no different from those who had been managed with reconstruction and concluded that limb reconstruction efforts should continue. In the present study, the subanalysis comparing the insensate salvage group with the sensate control group and the insensate amputation group led to the same conclusion.

The results of the present study should be interpreted in light of its limitations. The project was not a randomized, controlled trial, but every effort was made to enable compar-

isions among similarly injured groups. The sample size was small and approximately 30% of patients had been lost to follow-up by twenty-four months, thereby limiting our ability to detect small but potentially important differences between the groups. Likewise, the small sample size limited our ability to conduct multivariate analyses and to control for different patient and injury characteristics when evaluating outcomes among the three treatment groups. These differences have been shown to affect the final SIP score⁸. However, our bivariate analyses revealed few significant differences between the three treatment groups according to patient or injury characteristics.

The results of the present study demonstrated that patients with a severe lower extremity injury in whom plantar sensation had been absent at the time of initial presentation had substantial impairment at twelve and twenty-four months. This impairment appeared to be independent of treatment with either amputation or limb salvage. The outcome at two years did not appear to be adversely affected by limb salvage, despite the presence of an insensate foot at the time of admission. Surgeons employing limb-salvage scores to direct the decision-making process should critically assess the elements of these scores and the weight, if any, given to plantar sensation. The use of an insensate foot as an indicator of the need for amputation should be avoided.

Appendix

eA Tables showing the definition of leg injury characteristics used in this study and detailed patient and injury characteristics are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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References

- Gregory RT, Gould RJ, Pecllet M, Wagner JS, Gilbert DA, Wheeler JR, Snyder SO, Gayle RG, Schwab CW. The mangled extremity syndrome (M.E.S.): a severity grading system for multisystem injury of the extremity. *J Trauma*. 1985;25:1147-50.
- Howe HR Jr, Poole GV Jr, Hansen KJ, Clark T, Plonk GW, Koman LA, Pennell TC. Salvage of lower extremities following combined orthopaedic and vascular trauma. A predictive salvage index. *Am Surg*. 1987;53:205-8.
- Johansen K, Daines M, Howey T, Helfet D, Hansen ST Jr. Objective criteria accurately predict amputation following lower extremity trauma. *J Trauma*. 1990;30:568-73.
- McNamara MG, Heckman JD, Corley FG. Severe open fractures of the lower extremity: a retrospective evaluation of the Mangled Extremity Severity Score (MESS). *J Orthop Trauma*. 1994;8:81-7.
- Russell WL, Sailors DM, Whittle TB, Fisher DF Jr, Burns RP. Limb salvage versus traumatic amputation. A decision based on a seven-part predictive index. *Ann Surg*. 1991;213:473-81.
- Bosse MJ, MacKenzie EJ, Kellam JF, Burgess AR, Webb LX, Swiontkowski MF, Sanders RW, Jones AL, McAndrew MP, Patterson BM, McCarthy ML, Cyril JK. A prospective evaluation of the clinical utility of the lower-extremity injury-severity scores. *J Bone Joint Surg Am*. 2001;83:3-14.
- Swiontkowski MF, MacKenzie EJ, Bosse MJ, Jones AL, Trivison T; for the LEAP Study Group. Factors influencing the decision to amputate or reconstruct after high-energy lower extremity trauma. *J Trauma*. 2002;52:641-9. Erratum in: *J Trauma*. 2002;53:48.
- Bosse MJ, MacKenzie EJ, Kellam JF, Burgess AR, Webb LX, Swiontkowski MF, Sanders RW, Jones AL, McAndrew MP, Patterson BM, McCarthy ML, Trivison TG, Castillo RC. An analysis of outcomes of reconstruction or amputation after leg-threatening injuries. *N Engl J Med*. 2002;347:1924-31.
- MacKenzie EJ, Bosse MJ, Kellam JF, Burgess AR, Webb LX, Swiontkowski MF, Sanders RW, Jones AL, McAndrew MP, Patterson TM, McCarthy ML. Characterization of patients with high-energy lower extremity trauma. *J Orthop Trauma*. 2000;14:455-66.
- Gustilo RB, Anderson JT. Prevention of infection in the treatment of one thousand and twenty-five open fractures of long bones: retrospective and prospective analyses. *J Bone Joint Surg Am*. 1976;58:453-8.
- Tscherne H, Gotzen LE, editors. *Fractures with soft tissue injuries*. New York: Springer; 1984.
- Fracture and dislocation compendium. Orthopaedic Trauma Association Committee for Coding and Classification. *J Orthop Trauma*. 1996;10 Suppl 1:vix, 1-154.
- Muller ME, Nazarian S, Koch P, Schatzker J. *The comprehensive classification of fractures of long bones*. New York: Springer; 1990.
- Tscherne H, Oestern HJ. [A new classification of soft-tissue damage in open

and closed fractures (author's transl)]. *Unfallheilkunde*. 1982;85:111-5. German.

- 15.** The abbreviated injury scale. Des Plaines, IL: Association for the Advancement of Automotive Medicine; 1990.
- 16.** Baker SP, O'Neill B, Haddon W Jr, Long WB. The injury severity score: a method for describing patients with multiple injuries and evaluating emergency care. *J Trauma*. 1974;14:187-96.
- 17.** Guides to the evaluation of permanent impairment. 4th ed. Chicago: American Medical Association; 1993.
- 18.** Scott J, Huskisson EC. Graphic representation of pain. *Pain*. 1976;2:175-84.
- 19.** Bergner L, Hallstrom AP, Bergner M, Eisenberg MS, Cobb LA. Health status of survivors of cardiac arrest and of myocardial infarction controls. *Am J Public Health*. 1985;75:1321-3.
- 20.** Bergner M, Bobbitt RA, Carter WB, Gilson BS. The Sickness Impact Profile: development and final revisions of a health status measure. *Med Care*. 1981;19:787-805.
- 21.** Deyo RA, Inui TS, Leininger J, Overman S. Physical and psychosocial function in rheumatoid arthritis. Clinical use of a self-administered health status instrument. *Arch Intern Med*. 1982;142:879-82.
- 22.** Deyo RA, Diehl AK, Rosenthal M. How many days of bed rest for acute low back pain? A randomized clinical trial. *N Engl J Med*. 1986;315:1064-70.
- 23.** Drossman DA, Patrick DL, Mitchell CM, Zagami EA, Appelbaum MI. Health-related quality of life in inflammatory bowel disease. Functional status and patient worries and concerns. *Dig Dis Sci*. 1989;34:1379-86.
- 24.** Follick MJ, Smith TW, Ahern DK. The sickness impact profile: a global measure of disability in chronic low back pain. *Pain*. 1985;21:67-76.

- 25.** Hart LG, Evans RW. The functional status of ESRD patients as measured by the Sickness Impact Profile. *J Chronic Dis*. 1987;40 Suppl 1:117S-36S.
- 26.** Jurkovich G, Mock C, MacKenzie E, Burgess A, Cushing B, deLateur B, McAndrew M, Morris J, Swiontkowski M. The Sickness Impact Profile as a tool to evaluate functional outcome in trauma patients. *J Trauma*. 1995;39:625-31.
- 27.** McSweeney AJ, Grant I, Heaton RK, Adams KM, Timms RM. Life quality of patients with chronic obstructive pulmonary disease. *Arch Int Med*. 1982;142:473-8.
- 28.** Temkin N, McLean A Jr, Dikmen S, Gale J, Bergner M, Almes MJ. Development and evaluation of modifications to the Sickness Impact Profile for head injury. *J Clin Epidemiol*. 1988;41:47-57.
- 29.** MacKenzie EJ, Burgess AR, McAndrew MP, Swiontkowski M, Cushing BM, deLateur BJ, Jurkovich GJ, Morris JA Jr. Patient-oriented functional outcome after unilateral lower extremity fracture. *J Orthop Trauma*. 1993;7:393-401.
- 30.** Garland DE, Saucedo T, Reiser TV. The management of tibial fractures in acute spinal cord injury patients. *Clin Orthop Relat Res*. 1986;213:237-40.
- 31.** Nottage WM. A review of long-bone fractures in patients with spinal cord injuries. *Clin Orthop Relat Res*. 1981;155:65-70.
- 32.** Pinzur MS, Shields N, Trepman E, Dawson P, Evans A. Current practice patterns in the treatment of Charcot foot. *Foot Ankle Int*. 2000;21:916-20.
- 33.** Simon SR, Tejwani SG, Wilson DL, Santner TJ, Denniston NL. Arthrodesis as an early alternative to nonoperative management of Charcot arthropathy of the diabetic foot. *J Bone Joint Surg Am*. 2000;82:939-50.
- 34.** Lange RH, Bach AW, Hansen ST Jr, Johansen KH. Open tibial fractures with associated vascular injuries: prognosis for limb salvage. *J Trauma*. 1985;25:203-8.