

## AN ANALYSIS OF OUTCOMES OF RECONSTRUCTION OR AMPUTATION OF LEG-THREATENING INJURIES

MICHAEL J. BOSSE, M.D., ELLEN J. MACKENZIE, PH.D., JAMES F. KELLAM, M.D., ANDREW R. BURGESS, M.D., LAWRENCE X. WEBB, M.D., MARC F. SWIONTKOWSKI, M.D., ROY W. SANDERS, M.D., ALAN L. JONES, M.D., MARK P. McANDREW, M.D., BRENDAN M. PATTERSON, M.D., MELISSA L. MCCARTHY, Sc.D., THOMAS G. TRAVISON, PH.D., AND RENAN C. CASTILLO, M.S.

### ABSTRACT

**Background** Limb salvage for severe trauma has replaced amputation as the primary treatment in many trauma centers. However, long-term outcomes after limb reconstruction or amputation have not been fully evaluated.

**Methods** We performed a multicenter, prospective, observational study to determine the functional outcomes of 569 patients with severe leg injuries resulting in reconstruction or amputation. The principal outcome measure was the Sickness Impact Profile, a multidimensional measure of self-reported health status (scores range from 0 to 100; scores for the general population average 2 to 3, and scores greater than 10 represent severe disability). Secondary outcomes included limb status and the presence or absence of major complications resulting in rehospitalization.

**Results** At two years, there was no significant difference in scores for the Sickness Impact Profile between the amputation and reconstruction groups (12.6 vs. 11.8,  $P=0.53$ ). After adjustment for the characteristics of the patients and their injuries, patients who underwent amputation had functional outcomes that were similar to those of patients who underwent reconstruction. Predictors of a poorer score for the Sickness Impact Profile included rehospitalization for a major complication, a low educational level, nonwhite race, poverty, lack of private health insurance, poor social-support network, low self-efficacy (the patient's confidence in being able to resume life activities), smoking, and involvement in disability-compensation litigation. Patients who underwent reconstruction were more likely to be rehospitalized than those who underwent amputation (47.6 percent vs. 33.9 percent,  $P=0.002$ ). Similar proportions of patients who underwent amputation and patients who underwent reconstruction had returned to work by two years (53.0 percent and 49.4 percent, respectively).

**Conclusions** Patients with limbs at high risk for amputation can be advised that reconstruction typically results in two-year outcomes equivalent to those of amputation. (N Engl J Med 2002;347:1924-31.)

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**M**EDICAL and surgical advances of the past two decades have improved the ability to reconstruct severely injured legs.<sup>1-3</sup> Limbs that once would have been amputated are now routinely managed with complex reconstruction protocols.<sup>4,5</sup> Because most studies evaluating reconstruction have been small and retrospective, the results are not definitive.<sup>2,3,6,7</sup> Although the results are contradictory, some investigators have suggested that functional outcome is often poorer after successful limb reconstruction than after treatment with early amputation and a good prosthesis.<sup>4,6-9</sup> We performed a prospective observational study comparing functional outcomes of a large cohort of patients from eight level I trauma centers who underwent reconstruction or amputation. Our hypothesis was that after adjustment for the severity of the limb injury, the presence and severity of other injuries, and other characteristics of patients, those undergoing amputation would have better outcomes than those undergoing reconstruction.

### METHODS

#### Study Population

Patients 16 to 69 years old who were admitted to eight level I trauma centers for the treatment of high-energy trauma below the distal femur were eligible.<sup>10</sup> High-energy trauma was defined as complicated fractures (Gustilo grade IIIB and IIC fractures<sup>11</sup> and selected grade IIIA fractures), dysvascular limbs (knee dislocations, closed fractures of the tibia, or penetrating wounds with vascular injury), major soft-tissue injuries (degloving or severe crush or avulsion injury), and severe foot and ankle injuries (Gustilo grade IIIB ankle fractures, all grade III intraarticular fractures of the distal tibia [pilon],<sup>11</sup> and severe hind or midfoot injuries). (The specific types

From the Department of Orthopedic Surgery, Carolinas Medical Center, Charlotte, N.C. (M.J.B., J.F.K.); the Center for Injury Research and Policy, Johns Hopkins University Bloomberg School of Hygiene and Public Health, Baltimore (E.J.M., T.G.T., R.C.C.); the R Adams Cowley Shock Trauma Center, University of Maryland at Baltimore, Baltimore (A.R.B.); the Department of Orthopedic Surgery, Wake Forest University Baptist Medical Center, Winston-Salem, N.C. (L.X.W.); the Department of Orthopedic Surgery, Harborview Medical Center, Seattle (M.F.S.); the Orthopedic Trauma Service, Tampa General Hospital, Tampa, Fla. (R.W.S.); the Department of Orthopedic Surgery, University of Texas Southwestern Medical Center, Dallas (A.L.J.); the Department of Orthopedics and Rehabilitation, Vanderbilt University School of Medicine, Nashville (M.P.M.); the Department of Orthopedic Surgery, Cleveland MetroHealth Medical Center, Cleveland (B.M.P.); and Johns Hopkins School of Medicine, Baltimore (M.L.M.). Address reprint requests to Dr. Bosse at the Department of Orthopedic Surgery, Carolinas Medical Center, 1000 Blythe Blvd., Charlotte, NC 28203, or at mbosse@carolinas.org.

of fractures are defined in Supplementary Appendix 1, available with the full text of this article at <http://www.nejm.org>.) Excluded were patients with a score on the Glasgow Coma Scale of less than 15, indicating some impairment in consciousness, 21 days after hospitalization or discharge<sup>12</sup>; patients with a spinal cord deficit, prior amputation, or third-degree burns; patients who were transferred more than 24 hours after the injury; patients who did not speak English or Spanish; patients with a documented psychiatric disorder; and patients who were on active military duty. We enrolled 601 patients between March 1994 and June 1997. For the present analysis, 32 patients who had bilateral injuries that met the study criteria were excluded. An additional 24 patients were excluded owing to a lack of follow-up (i.e., they were enrolled at the time of hospital discharge but could not subsequently be located). Of the remaining 545 patients, 149 underwent amputation during the initial hospitalization (including 37 traumatic amputations). After the initial hospital discharge, 25 additional patients underwent amputation: 12 by three months, 6 by six months, and 7 after six months. Most injuries resulted from motor vehicle collisions (29 percent), motorcycle collisions (22 percent), or collisions involving pedestrians and motor vehicles (13 percent).

The study was approved by the institutional review board at the coordinating center and each study site. Written informed consent was obtained from all study participants.

### Procedures

The patients were evaluated at base line (before hospital discharge) and 3, 6, 12, and 24 months after the injury. At each point, patients were evaluated by an orthopedic surgeon to ascertain limb status and the presence or absence of complications, by a physical therapist to evaluate the extent of impairment, and by a research nurse to assess the patients' perception of functional outcome. Of the 545 patients, 502 (92.1 percent) were evaluated at 3 months, 503 (92.3 percent) at 6 months, 493 (90.5 percent) at 12 months, and 460 (84.4 percent) at 24 months. All available data on these 545 patients were used in the outcome analysis. Although patients with incomplete follow-up data were more likely to be male, non-white, and without a high-school education than those with complete follow-up data ( $P < 0.05$  for all comparisons), the rates of follow-up did not differ significantly between the amputation group and the reconstruction group.

Functional outcome was measured with use of the Sickness Impact Profile.<sup>13</sup> The Sickness Impact Profile is a multidimensional measure of self-reported health status, consisting of 136 statements about limitations in 12 categories of function: ambulation, mobility, body care and movement, social interaction, alertness, emotional behavior, communication, sleep and rest, eating, work, home management, and recreation. Respondents are asked to endorse statements that describe their health status on a given day. Scores are computed for the overall instrument, for each of the 12 categories and for 2 major dimensions of health (physical health, which reflects limitations noted in the first 3 categories, and psychosocial health, which reflects limitations noted in the second 3 categories). The reliability and validity of the Sickness Impact Profile have been well tested,<sup>14</sup> especially with respect to the outcome after injury.<sup>15</sup> The overall scores can range from 0 to 100; scores greater than 10 represent severe disability, and differences in scores of 2 to 3 points reflect meaningful differences in function.<sup>16</sup> Scores average between 2 and 3 points for the general population.<sup>17</sup>

Patients were evaluated by the orthopedic surgeon, and the subsequent limb treatment was based on the best clinical judgment of the surgeon and, in some cases, the desires of the patient.<sup>18</sup> Because treatment assignments were not randomized, comparisons of outcomes based on the Sickness Impact Profile were adjusted for potential confounders, including the characteristics of the patients and their injuries. The injuries were prospectively characterized according to the type and extent of bony damage, the extent of soft-tissue injury, and the initial pulse assessment and plantar sensation (Sup-

plementary Appendix 1). Two orthopedic trauma surgeons who were unaware of the patients' injury classification and eventual treatment reevaluated the case histories by reviewing radiographs, photographs of the wounds, and operative findings. Forty-one (7.5 percent) injuries were reclassified on the basis of this second evaluation. Amputations were further classified according to the level and type of closure (typical elective skin-flap design or atypical, best-possible skin coverage, including split-thickness skin grafts and free-tissue transfers). Associated injuries were classified with the use of the Abbreviated Injury Scale,<sup>19</sup> the Injury Severity Score,<sup>20</sup> and two scores on the Abbreviated Injury Scale denoting the maximal severity of nonstudy injuries to the contralateral and ipsilateral leg and pelvis. Shock was defined by a systolic blood pressure lower than 90 mm Hg before the initiation of resuscitation.<sup>21</sup> To account for the effect of complications on recovery, a variable was constructed to indicate rehospitalization for one or more of the following conditions: late amputation or stump revision, fracture nonunion, hardware failure, flap failure, wound infection, or osteomyelitis.

Data collected on the characteristics of the patients that were hypothesized to influence the treatment assignment or outcome have previously been described in detail.<sup>10</sup> They included age; sex; race or ethnic group; education; income level<sup>22</sup> and insurance status before the injury; work status, occupation,<sup>23</sup> and physical demands of the job before the injury<sup>24</sup>; personality characteristics, as measured by the Neuroticism, Extroversion, and Openness (NEO) Personality Inventory<sup>25</sup>; social support, measured with use of a modified version of the Inventory of Socially Supportive Behaviors, which assesses a patient's level of support in terms of tangible assistance, directive guidance and emotional support<sup>26,27</sup> and self-efficacy<sup>28</sup> (how confident patients were at the time of hospital discharge in their ability to resume their chief life activities). Additional measures were self-rated health and the presence or absence of chronic conditions before the injury; exercise, smoking, and drinking habits before the injury<sup>29,30</sup>; and whether compensation was received for the injury and legal services were retained.<sup>31</sup>

### Statistical Analysis

Longitudinal multivariate regression techniques were used to assess associations between treatment and outcomes over a two-year period, after adjustment for characteristics of the patients and their injuries.<sup>32</sup> Both additive and multiplicative regression models were considered, but the multiplicative model was chosen because we observed that although scores for the Sickness Impact Profile continually improved, the rate of this improvement declined over time.

Treatment was defined with the use of five categories: amputations above the knee, through the knee, below the knee, or of the whole or partial foot and reconstruction. The 12 amputations that occurred within the first three months after injury were classified according to the site of the amputation. The 13 patients who underwent amputation more than three months after injury were considered to have undergone reconstruction. An analysis was performed including and excluding these 13 patients. When included, they were identified as having a major complication. The results of both analyses were similar; therefore, the results presented reflect the inclusion of these patients.

Because the number of variables describing the nature and extent of injuries was large, a summary score, indicating the likelihood of undergoing amputation given a patient's injury profile, was derived with the use of logistic regression that modeled the decision to amputate or reconstruct as a function of the characteristics of the injury.<sup>18</sup> Traumatic amputations (for which underlying characteristics of the injury itself were not documented) were assigned a summary score of 1. Multivariate models that included all characteristics of the injury as separate covariates yielded results similar to those obtained with the use of models that included the summary scores; therefore, results based on the more parsimonious model, which used the summary score, are presented.

Stepwise modeling techniques were used to construct the final

model, which included the treatment variables, the summary score, the occurrence of a major complication resulting in rehospitalization, and all characteristics of the patients that remained associated with an outcome at a P value of less than 0.10. The extent to which the effect of these variables on the outcome varied according to the time since injury or to treatment was examined, and interaction terms were incorporated where indicated.

**RESULTS**

There were no significant differences in sociodemographic characteristics between patients who under-

went reconstruction and those who underwent amputation (Table 1). Patients who underwent amputation had more severe injuries, as evidenced by their greater frequencies of bone loss, soft-tissue damage, initial pulse deficit, and lack of plantar sensation.

Table 2 summarizes the clinical status of patients 24 months after injury. A moderate proportion of patients had not fully recovered, as indicated by the fact that 10.9 percent of patients who underwent reconstruction had unhealed fractures, 3.9 percent of those

**TABLE 1. BASE-LINE CHARACTERISTICS OF THE 545 PATIENTS WHO UNDERWENT AT LEAST ONE FOLLOW-UP EVALUATION.\***

CHARACTERISTIC	RECONSTRUCTION (N=384)	AMPUTATION (N=161)	CHARACTERISTIC	RECONSTRUCTION (N=384)	AMPUTATION (N=161)
Age			<b>Study injury</b>		
≥40 yr (%)	33.0	27.3	Tibia fracture (%)**		
Mean (yr)	35.8	35.2	None	45.3	49.1
Male sex (%)	75.0	80.8	Simple (AO type A)	10.9	0.6
Self-reported race or ethnic group (%)			Wedge (AO type B)	40.4	25.5
White	71.9	76.4	Complex (AO type C)	3.4	24.8
Black	20.3	17.4	Open foot fracture (%)¶	12.8	21.0
Hispanic	4.7	5.0	Bone loss (%)††		
Other	3.1	1.2	None or mild	30.0	20.2
Education (%)			Moderate	53.6	44.4
Some high school	28.4	31.0	Severe	16.4	35.4
High-school graduate	40.4	40.4	Muscle injury (%)††		
Some college	31.3	28.6	0 or 1 muscle group	51.8	15.3
Household income as a percentage of federal poverty level (%)†			Considerable muscle injury to 2 or more groups or loss of 1 entire group	36.2	33.9
<125%	34.9	36.0	Compartment or crush syndrome	12.0	50.8
125–200%	20.3	23.6	Moderate or severe deep-vein injury (%)††	2.6	33.3
>200%	44.8	40.4	Skin defect (%)		
Smoking history (%)			None	15.6	7.3
Never smoked	35.4	31.0	<¼ Circumference of leg	35.9	16.1
Former smoker	27.7	31.6	¼–½ Circumference of leg	33.1	27.4
Current smoker	36.9	37.4	>½–¾ Circumference of leg	12.0	29.0
Alcohol consumption in mo before admission (%)			>¾ Circumference of leg	3.4	20.2
Does not drink	19.2	15.8	Contamination (%)†† ‡‡		
0–12 drinks	43.1	40.4	None	39.8	23.4
13–50 drinks	21.8	23.4	Single — isolated foreign body	27.2	21.0
>50 drinks	15.9	20.5	Multiple — >1 foreign body	26.0	38.6
Health insurance (%)			Massive — foreign bodies too numerous to count	7.0	17.0
None or public	46.9	38.8	Pulse absent at initial evaluation (%)††	12.0	53.2
Private	53.1	61.3	Plantar sensation absent (%)††	6.8	50.0
<b>Overall injury</b>					
Injury Severity Score (%)‡					
<13	64.6	65.8			
13–17	19.3	11.8			
>17	16.2	22.4			
Ipsilateral-leg injury (%)	27.3	29.8			
Contralateral-leg injury (%)	20.0	14.9			
Hypotension (%)§¶	20.8	29.8			

\*Because of rounding, not all percentages sum to 100.

†The income level was estimated according to the method of Fisher.<sup>22</sup>

‡Scores for the Injury Severity Score can range from 1 to 75, with scores of 17 or higher indicating severe injury.<sup>20</sup>

§Hypotension was defined as a systolic blood pressure of 90 mm Hg or less before the initiation of resuscitation.

¶P<0.05 for the overall comparison between groups.

||Patients with traumatic amputations were excluded from the analysis.

\*\*Fracture of the tibia was based on the classification of Müller et al.<sup>33</sup> and the Orthopaedic Trauma Association Committee for Coding and Classification.<sup>34</sup>

††P<0.01 for the overall comparison between groups.

‡‡Contamination was defined according to the Hannover Fracture Scale.<sup>35</sup>

who underwent reconstruction and 9.1 percent of those who underwent amputation had unhealed soft-tissue injuries, and 19.1 percent of those who underwent reconstruction and 5.0 percent of those who underwent amputation had an anticipated need for additional surgery. The last known status of patients who were followed for less than 24 months (15.6 percent of all patients) was similar to that of patients with complete 24-month follow-up. There were no significant differences between the treatment groups in the percentage of patients with an unhealed fracture, the percentage with an unhealed soft-tissue injury, or the percentage requiring additional surgery. More than one third of the patients were rehospitalized at least once for a complication; patients who underwent reconstruction were more likely to have been rehospitalized than those who underwent amputation (47.6 percent vs. 33.9 percent,  $P=0.002$ ).

Mean scores for the Sickness Impact Profile were 14.5 at 12 months and 12.0 at 24 months; at 24 months, 42.0 percent of the patients had scores greater than 10. There were no significant differences in scores between the treatment groups (Table 3). Scores for the work subscale were particularly high. At 24 months, 53.0 percent of the patients who underwent amputation and 49.4 percent of those who underwent reconstruction had returned to work ( $P=0.48$ ). Table 4 presents estimates of the magnitude of change

in scores associated with several covariates, including amputations of various types (as compared with reconstruction). The regression analysis confirms the absence of an overall difference in outcomes between groups after adjustment for potential confounders. Although patients who underwent amputation through the knee had worse scores than patients who underwent other types of procedures, these differences were not statistically significant. To underscore the similarity in scores after amputation or reconstruction, mean adjusted scores (derived from the final regression model) are presented according to the type of treatment in Table 5.

In multivariate analyses, factors that were significant predictors of a poor outcome (as indicated by a high Sickness Impact Profile score) included being rehospitalized for a major complication, having less than a high-school education, having a household income below the federal poverty level, being nonwhite, having no insurance or having Medicaid, having a poor social-support network, having a low level of self-efficacy (confidence in one's ability to resume one's chief life activities), smoking, and involving the legal system for injury compensation. Predictors of a poor outcome were the same in both groups. The association between having private insurance and a disability, however, changed over time; private insurance was associated with the greatest improvement in scores at 6 to

TABLE 2. CLINICAL STATUS OF 460 PATIENTS EVALUATED 24 MONTHS AFTER INJURY.\*

VARIABLE	AMPUTATION (N=130)	P VALUE†	RECONSTRUCTION					
			ALL (N=330)	GRADE IIIC TIBIA FRACTURE (N=11)	GRADE IIIB TIBIA FRACTURE (N=135)	DYSVASCULAR LIMBS OR SOFT- TISSUE INJURIES (N=63)	SEVERE FOOT, ANKLE, PILON FRACTURES (N=94)	GRADE IIIA TIBIA FRACTURE (N=27)
				percent	percent	percent	percent	percent
Late amputation or stump revision	5.4	0.45	3.9	9.1	5.2	3.2	2.1	3.7
Fractures not healed‡	NA	NA	10.9	12.5	13.0	6.9	11.0	4.4
Soft-tissue injury not healed§	9.1	0.10	3.9	0.0	3.5	5.4	4.9	0.0
Additional surgery required	5.0	<0.001	19.1	30.0¶	20.5	10.2	25.3	7.7
≥1 Rehospitalizations								
Any complication	33.9	0.002	47.6	45.5	57.0	33.3	40.4	59.3¶
Osteomyelitis	3.1	0.02	9.4	27.3	11.1¶	4.8	5.3	18.5
Other infection	15.4	0.69	13.9	27.3	14.1	11.1	13.8	14.8
Nonunion	NA	NA	20.9	36.4	28.9	12.7	8.5	37.0

\*NA denotes not applicable

†P values are for the comparison between the amputation group and the reconstruction group and were calculated with use of the chi-square test or with Fisher's exact test if the value in any cell was smaller than 5.

‡Only patients with fractures were included.

§Only patients with a soft-tissue injury who had a healed wound but who had a soft-tissue coverage that was tenuous, friable, or painful were included.

¶ $P<0.05$  for the comparison with the amputation group.

|| $P<0.01$  for the comparison with the amputation group.

**TABLE 3.** SCORES FOR THE SICKNESS IMPACT PROFILE FOR 493 PATIENTS EVALUATED 12 MONTHS AFTER INJURY AND 460 PATIENTS EVALUATED 24 MONTHS AFTER INJURY.\*

CATEGORY	SCORE AT 12 MONTHS		SCORE AT 24 MONTHS	
	RECONSTRUCTION (N=352)	AMPUTATION (N=141)	RECONSTRUCTION (N=330)	AMPUTATION (N=130)
	mean $\pm$ SD			
Overall	14.6 $\pm$ 12.7	14.1 $\pm$ 12.1	11.8 $\pm$ 11.6	12.6 $\pm$ 11.8
Physical function	12.8 $\pm$ 1.5	12.1 $\pm$ 11.4	9.7 $\pm$ 9.9	10.1 $\pm$ 9.8
Ambulation	23.3 $\pm$ 16.7	22.7 $\pm$ 16.1	17.1 $\pm$ 14.5	18.9 $\pm$ 15.2
Mobility	9.6 $\pm$ 15.3	9.1 $\pm$ 15.9	6.8 $\pm$ 13.4	6.9 $\pm$ 12.4
Body care and movement	9.6 $\pm$ 11.1	8.7 $\pm$ 10.5	7.6 $\pm$ 9.6	7.6 $\pm$ 9.4
Psychosocial	11.9 $\pm$ 16.2	12.0 $\pm$ 15.2	10.3 $\pm$ 14.9	11.1 $\pm$ 15.4
Emotional behavior	14.9 $\pm$ 20.5	15.2 $\pm$ 21.8	13.5 $\pm$ 19.4	15.4 $\pm$ 21.3
Social interaction	14.4 $\pm$ 19.5	13.9 $\pm$ 19.0	11.3 $\pm$ 18.0	12.9 $\pm$ 19.5
Alertness behavior	11.7 $\pm$ 22.0	12.8 $\pm$ 19.9	11.2 $\pm$ 20.9	11.1 $\pm$ 21.0
Communication	4.1 $\pm$ 12.3	4.0 $\pm$ 10.2	4.0 $\pm$ 11.4	3.4 $\pm$ 8.2
Sleep and rest	20.3 $\pm$ 22.3	17.2 $\pm$ 19.5	16.6 $\pm$ 21.1	17.6 $\pm$ 20.9
Eating	1.7 $\pm$ 4.5	1.5 $\pm$ 3.8	1.4 $\pm$ 4.1	1.7 $\pm$ 5.0
Work	41.4 $\pm$ 31.9	42.2 $\pm$ 32.2	35.9 $\pm$ 33.0	38.9 $\pm$ 33.7
Household management	20.0 $\pm$ 22.0	19.0 $\pm$ 21.1	13.7 $\pm$ 18.3	14.5 $\pm$ 18.1
Recreation	26.7 $\pm$ 22.0	25.2 $\pm$ 22.0	21.9 $\pm$ 21.2	22.4 $\pm$ 20.1

\*Scores for the Sickness Impact Profile can range from 0 to 100; scores of more than 10 represent severe disability. There were no significant differences between the groups at either time.

12 months. The characteristics of the injury (according to the summary score) were not significantly correlated with the outcomes measured by the Sickness Impact Profile, nor was the presence or severity of other injuries to ipsilateral and contralateral limbs.

## DISCUSSION

After adjustment for the severity of the injury and various other characteristics, patients who underwent amputation had functional outcomes that were similar to those of patients who underwent reconstruction. However, the levels of disability at two years were high in both groups: more than 40 percent had a score greater than 10 on the Sickness Impact Profile, reflecting severe disability. Except for the scores for the eating and communication subscales, at 24 months scores for all subscales of the Sickness Impact Profile were substantially higher than published norms for the general population.<sup>17</sup> Only about half of all patients had returned to work by 24 months. Except for the score for the psychosocial-functioning subscale, there were significant improvements in the scores over time in both treatment groups. Poor psychosocial outcomes after serious injuries have been reported by other investigators<sup>36,37</sup> and may be associated with post-traumatic stress disorder.<sup>38,39</sup>

Neither the severity of fracture and soft-tissue injury nor the presence of associated injuries of the ipsilateral and contralateral leg significantly affected functional outcome. This lack of association may be a re-

flexion of the inclusion criteria, in that only patients with the most severe limb injuries were included. These injuries affected the patient's ability to walk and most likely masked the effect on functional outcome of other injuries to the leg and foot. Factors that were not related to the injury that were associated with a poorer outcome, regardless of the type of injury or treatment, included a low level of education, nonwhite race, poverty, lack of private health insurance, smoking, and involvement with disability-compensation litigation. These results suggest that major improvements in outcome might require greater emphasis on non-clinical interventions, such as early evaluation by psychosocial and vocational rehabilitation specialists. Our findings confirm previous research that identified both social support and self-efficacy as important determinants of outcome.<sup>40,41</sup> Interventions aimed at improving patients' perceptions of self-efficacy, in particular, may benefit those who are facing a challenging recovery.

The limitations of our study must be acknowledged. Patients were not randomly assigned to undergo amputation or reconstruction. Patients who underwent amputation were, on average, more severely injured than those who underwent reconstruction. Although an adjustment was made for these differences in the multivariate analysis, the possibility of residual confounding cannot be ruled out. Although the overall rates of follow-up exceeded 80 percent at 2 years, the patients who were lost to follow-up (including 24 pa-

OUTCOMES OF LEG RECONSTRUCTION OR AMPUTATION

**TABLE 4.** ASSOCIATION BETWEEN CLINICAL AND DEMOGRAPHIC CHARACTERISTICS AND SCORES FOR THE SICKNESS IMPACT PROFILE.\*

CHARACTERISTIC	OVERALL SCORE	PHYSICAL-FUNCTION SCORE	PSYCHOSOCIAL-FUNCTION SCORE
	percent difference		
Treatment			
Partial foot amputation (vs. reconstruction)	15.0	7.2	17.0
Amputation below the knee (vs. reconstruction)	2.0	1.7	-2.0
Amputation through the knee (vs. reconstruction)	20.1	26.3	32.0
Amputation above the knee (vs. reconstruction)	-7.6	-3.6	-22.0
Major complication (vs. no major complication)	14.7†	14.3†	15.0
Education			
High-school graduate (vs. some college)	8.7	3.1	14.0
Less than high school (vs. some college)	19.4†	12.4	42.0‡
Income level at or below poverty level (vs. near or above poverty level)	12.3§	10.7	29.0†
Nonwhite race (vs. white race)	34.0‡	28.1‡	47.0‡
No health insurance or public health insurance (vs. private)			
0-3 mo after injury	-2.9	-5.4	3.6
4-6 mo after injury	9.5‡	6.5‡	13.1‡
7-12 mo after injury	21.9‡	18.4‡	21.2‡
13-24 mo after injury	10.6‡	4.3‡	0.4‡
Smoking status at base line			
<10 Cigarettes/day (vs. not a current smoker)	16.6†	16.2†	17.0
≥10 Cigarettes/day (vs. not a current smoker)	24.1‡	27.9†	36.0†
Self-efficacy (for each 1-point increase)¶	-0.6‡	-0.7‡	-0.7‡
Social support (for each 1-point increase)	-0.5‡	-0.4†	-0.8‡
Lawyer hired (vs. no lawyer hired)	23.1‡	17.7‡	35.0‡

\*These estimates are based on the results of a longitudinal regression model that included all these covariates and indicate the percent increase or decrease in scores associated with a given characteristic, as compared with the scores in the reference group. Estimates have been adjusted for the time since injury and the summary score — the likelihood of amputation given the patient's injury profile.

†P<0.05.

‡P<0.01.

§P<0.10.

¶Scores can range from 1 to 100, with higher scores indicating a greater degree of confidence in the patient's ability to resume his or her major life activities.

||Scores can range from 1 to 100, with higher scores indicating more social support.

tients for whom no follow-up data were available and 85 who were followed for less than 24 months) were of lower socioeconomic status than those with complete follow-up. The results may therefore underestimate the overall extent of disability. However, the rate of loss to follow-up was similar in the two groups, and all available data on the 545 patients who underwent at least one follow-up evaluation were used in the analysis. Also, the extent of healing of fractures and soft-tissue wounds at 12 months was similar among those with and those without subsequent follow-up data at 24 months.

The generalizability of our results beyond level I trauma centers is uncertain. The outcomes may have been influenced by the expertise of physicians and other caregivers. Finally, the results are based on outcomes during the first two years after injury, a period

in which many patients have not yet completely recovered. Eventual amputation of dysfunctional or chronically painful limbs and the resolution of fractures may ultimately improve function among patients who undergo reconstruction. Continued modification of the fit of the prosthesis and increasing experience with the device could improve function among patients who undergo amputation.<sup>42</sup> Although not considered in this study, the costs of treatment and rehabilitation (including lifetime costs of prostheses) will also be important in guiding treatment decisions.

Contrary to our hypothesis, at two years, the outcomes among patients who underwent reconstruction were not significantly different from those among patients who underwent amputation. Thus, patients with limb injuries that put them at high risk for amputation can be advised that reconstruction typically results in

**TABLE 5. MEAN SCORES FOR THE SICKNESS IMPACT PROFILE FOR THE 460 PATIENTS WHO WERE EVALUATED 24 MONTHS AFTER INJURY.\***

TREATMENT	NO. OF PATIENTS	UNADJUSTED SCORE	ADJUSTED SCORE
Reconstruction	330	11.8	11.7
Tibia fractures	173	12.4	12.2
Foot, ankle, pilon fractures	94	12.0	11.3
Dysvascular limbs or soft-tissue injuries	63	9.7	10.8
Amputation	130	12.6	12.0
Below the knee	79	12.6	12.1
Through the knee	15	16.9	15.0
Above the knee	27	10.2	10.0
Partial foot	9	13.1	12.8

\*Scores can range from 0 to 100; scores of more than 10 represent severe disability. Scores were adjusted for the summary score, presence or absence of a major complication, education level, socioeconomic status, race, smoking status, health insurance status, level of social support and self-efficacy, and presence or absence of involvement with disability-compensation litigation. There were no significant differences between the two treatment groups in the unadjusted or adjusted scores.

two-year outcomes equivalent to those of amputation. However, reconstruction is associated with a higher risk of complications, additional surgeries, and rehospitalization.

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## REFERENCES

- Caudle RJ, Stern PJ. Severe open fractures of the tibia. *J Bone Joint Surg Am* 1987;69:801-7.
- Francel TJ, Vander Kolk CA, Hoopes JE, Manson PN, Yaremchuk MJ. Microvascular soft-tissue transplantation for reconstruction of acute open tibial fractures: timing of coverage and long-term functional results. *Plast Reconstr Surg* 1992;89:478-87.
- Godina M. Early microsurgical reconstruction of complex trauma of the extremities. *Plast Reconstr Surg* 1986;78:285-92.
- Hansen ST Jr. The type-IIIC tibial fracture: salvage or amputation. *J Bone Joint Surg Am* 1987;69:799-800.
- Lange RH. Limb reconstruction versus amputation decision making in massive lower extremity trauma. *Clin Orthop* 1989;243:92-9.
- Francel TJ. Improving reemployment rates after limb salvage of acute severe tibial fractures by microvascular soft-tissue reconstruction. *Plast Reconstr Surg* 1994;93:1028-34.
- Georgiadis GM, Behrens FF, Joyce MJ, Earle AS, Simmons AL. Open tibial fractures with severe soft-tissue loss: limb salvage compared with below-the-knee amputation. *J Bone Joint Surg Am* 1993;75:1431-41.
- Dagum AB, Best AK, Schemitsch EH, Mahoney JL, Mahomed MN, Blight KR. Salvage after severe lower-extremity trauma: are the outcomes worth the means? *Plast Reconstr Surg* 1999;103:1212-20.
- Fairhurst MJ. The function of below-knee amputee versus the patient with salvaged grade III tibial fracture. *Clin Orthop* 1994;301:227-32.
- MacKenzie EJ, Bosse MJ, Kellam JF, et al. Characterization of patients with high-energy lower extremity trauma. *J Orthop Trauma* 2000;14:455-66.
- Gustilo RB, Mendoza RM, Williams DN. Problems in the management of type III (severe) open fractures: a new classification of type III open fractures. *J Trauma* 1984;24:742-6.
- Teasdale G, Jennett B. Assessment of coma and impaired consciousness: a practical scale. *Lancet* 1974;2:81-4.
- Bergner M, Bobbitt RA, Carter WB, Gilson BS. The Sickness Impact Profile: development and final revision of a health status measure. *Med Care* 1981;19:787-805.
- de Bruin AF, de Witte LP, Stevens F, Diederiks JP. Sickness Impact Profile: the state of the art of a generic functional status measure. *Soc Sci Med* 1992;35:1003-14.
- Jurkovich G, Mock C, MacKenzie E, et al. The Sickness Impact Profile as a tool to evaluate functional outcome in trauma patients. *J Trauma* 1995;39:625-31.
- Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. *Med Care* 1989;27:Suppl:S217-S232.
- MacKenzie EJ, Burgess AR, McAndrew MP, et al. Patient-oriented functional outcome after unilateral lower extremity fracture. *J Orthop Trauma* 1993;7:393-401.
- Swiontkowski MF, MacKenzie EJ, Bosse MJ, Jones AL, Trivison T. Factors influencing the decision to amputate or reconstruct after high-energy lower extremity trauma. *J Trauma* 2002;52:641-9.
- The Abbreviated Injury Scale: 1990 revision: Update 98. Des Plaines, Ill.: Association for the Advancement of Automotive Medicine, 1998.
- 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.
- 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.
- Fisher GM. The development and history of the poverty thresholds. *Soc Secur Bull* 1992;55:3-14.
- Employment Service. Dictionary of occupational titles. 4th ed. rev. Washington, D.C.: Department of Labor, Employment and Training Administration, 1991.
- Lando ME, Cutler RR, Gamber E. 1978 Survey of disability and work: data book. Washington, D.C.: Social Security Administration, Office of Policy, Office of Research and Statistics, November 1982. (SSA publication no. 13-11745.)
- Costa PT Jr, McCrae RR. NEO PI-R: NEO Personality Inventory: item booklet — form R (men). Odessa, Fla.: Psychological Assessment Resources, 1992.
- Barrera M Jr, Sandler IN, Ramsay TB. Preliminary development of a scale of social support: studies of college students. *Am J Community Psychol* 1981;9:435-47.
- Stokes JP, Wilson DG. The Inventory of Socially Supportive Behaviors: dimensionality, prediction, and gender differences. *Am J Community Psychol* 1984;12:53-69.
- Bandura A, O'Leary A, Taylor CB, Gauthier J, Gossard D. Perceived self-efficacy and pain control: opioid and nonopioid mechanisms. *J Pers Soc Psychol* 1987;53:563-71.
- Massey JT, Moore TF, Parsons VL, Tadros W. Design and estimation for the National Health Interview Survey, 1985-94. Vital and health statistics. Series 2. No. 10. Hyattsville, Md.: National Center for Health Statistics, August 1989. (DHHS publication no. (PHS) 89-1384.)
- Selzer ML, Vinokur A, van Rooijen L. A self-administered Short Michigan Alcoholism Screening Test (SMAST). *J Stud Alcohol* 1975;36:117-26.
- Hensler DR, Marquis MS, Abrahamse AF, et al. Compensation for accidental injuries in the United States. Santa Monica, Calif.: RAND, 1991.
- Liang KY, Zeger SL. Regression analysis for correlated data. *Annu Rev Public Health* 1993;14:43-68.

- 33.** Müller ME, Allgower M, Schneider R, Willenegger H. Manual of internal fixation: techniques recommended by the AO-ASIF Group. 3rd ed. rev. Berlin, Germany: Springer-Verlag, 1991.
- 34.** Orthopaedic Trauma Association Committee for Coding and Classification. Fracture and dislocation compendium. *J Orthop Trauma* 1996;10: Suppl 1:1-154.
- 35.** Suedkamp NP, Barbey N, Veuskens A, et al. The incidence of osteitis in open fractures: an analysis of 948 open fractures (a review of the Hannover experience). *J Orthop Trauma* 1993;7:473-82.
- 36.** Holbrook TL, Anderson JP, Sieber WJ, Browner D, Hoyt DB. Outcome after major trauma: 12-month and 18-month follow-up results from the Trauma Recovery Project. *J Trauma* 1999;46:765-73.
- 37.** Michaels AJ, Michaels CE, Moon CH, et al. Posttraumatic stress disorder after injury: impact on general health outcome and early risk assessment. *J Trauma* 1999;47:460-6.
- 38.** Shalev AY, Peri T, Canetti L, Schreiber S. Predictors of PTSD in injured trauma survivors: a prospective study. *Am J Psychiatry* 1996;153: 219-25.
- 39.** Brom D, Kleber RJ, Hofman MC. Victims of traffic accidents: incidence and prevention of post-traumatic stress disorder. *J Clin Psychol* 1993;49:131-40.
- 40.** Berkman LF, Glass T. Social integration, social networks, social support, and health. In: Berkman LF, Kawachi I, eds. *Social epidemiology*. Oxford, England: Oxford University Press, 2000:137-73.
- 41.** MacKenzie EJ, Morris JA Jr, Jurkovich GJ, et al. Return to work following injury: the role of economic, social, and job-related factors. *Am J Public Health* 1998;88:1630-7.
- 42.** Matsen SL, Malchow D, Matsen FA III. Correlations with patients' perspectives of the result of lower-extremity amputation. *J Bone Joint Surg Am* 2000;82:1089-95.

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