Copyright © 2004 by The Journal of Bone and Joint Surgery, Incorporated

Functional Outcomes Following Trauma-Related Lower-Extremity Amputation

By Ellen J. MacKenzie, PhD, Michael J. Bosse, MD, Renan C. Castillo, MS, Douglas G. Smith, MD, Lawrence X. Webb, MD, James F. Kellam, MD, Andrew R. Burgess, MD, Marc F. Swiontkowski, MD, Roy W. Sanders, MD, Alan L. Jones, MD, Mark P. McAndrew, MD, Brendan M. Patterson, MD, Thomas G. Travison, PhD, and Melissa L. McCarthy, ScD

Background: The principal aims of this study were to examine functional outcomes following trauma-related lower-extremity amputation and to compare outcomes according to the amputation levels. We hypothesized that above-the-knee amputations would result in less favorable outcomes than would through-the-knee or below-the-knee amputations. A secondary aim was to examine the factors, in addition to amputation level, that influence outcome, including the type of soft-tissue coverage, selected patient characteristics, and the technological sophistication of the prosthetic device.

Methods: A cohort of 161 patients who had undergone an above-the-ankle amputation at a trauma center within three months following the injury was followed prospectively at three, six, twelve, and twenty-four months after the injury. The Sickness Impact Profile, a self-reported measure of functional status, was used as the principal measure of outcome. Secondary outcomes included pain; degree of independence in transfers, walking, and climbing stairs; self-selected walking speed; and the physician's satisfaction with the clinical, functional, and cosmetic recovery of the limb. Longitudinal multivariate regression techniques were used to determine whether outcomes differed according to the level of amputation after we controlled for covariates.

Results: There was no significant difference in the scores on the Sickness Impact Profile between the patients treated with above-the-knee and those treated with below-the-knee amputation. However, patients with a below-the-knee amputation performed better than did patients with an above-the-knee amputation on the timed test for walking speed ($p = 0.04$). Patients with a through-the-knee amputation had worse regression-adjusted Sickness Impact Profile scores ($p = 0.05$) and slower self-selected walking speeds ($p = 0.004$) than did patients with either a below-the-knee or an above-the-knee amputation. Differences according to the level of amputation were most pronounced for physical function. In general, physicians were less satisfied with the clinical, cosmetic, and functional recovery of the patients with a through-the-knee amputation. Except for problems encountered with insufficient gastrocnemius coverage of the stump in many patients with a through-the-knee amputation, neither the soft-tissue coverage nor the technological sophistication of the prosthesis correlated with outcome.

Conclusions: Severe disability accompanies above-the-ankle lower-extremity amputation following trauma, regardless of the level of amputation. Clinicians should critically evaluate the need for a through-the-knee amputation in patients with a traumatic injury. The results of this study also underscore the need for controlled studies that examine the relationship between the type and fit of prosthetic devices and functional outcomes.

Level of Evidence: Prognostic study, Level I-1 (prospective study). See Instructions to Authors for a complete description of levels of evidence.

Lower-limb amputations secondary to trauma typically are performed in young patients without the medical comorbidities often associated with nontraumatic amputations. However, in order to preserve limb length, trauma-related amputations are often performed in or near the zone of injury, resulting in atypical wound closures, the use of skin grafts or flaps to achieve good coverage, and a residual limb that is often less than ideal. There is debate regarding the functional outcomes following amputation as few prospective studies have been conducted with the use of well-validated and broadly based measures of outcome. The few studies that have been performed have largely focused on return to work as the single metric[1-13].

The principal aim of the present study was to examine a range of two-year functional outcomes following trauma-related amputation and to compare outcomes according to the

level of amputation—i.e., above the knee, through the knee, and below the knee. We hypothesized that above-the-knee amputations would result in less favorable outcomes than would either through-the-knee or below-the-knee amputations. A secondary aim of the study was to examine the factors, in addition to the level of amputation, that influence outcome, including the type of soft-tissue coverage, characteristics of the patient, and the technological sophistication of the prosthetic device being used at the time of the outcome assessment.

Materials and Methods

Study Population

The study population consisted of 161 patients treated with an above-the-ankle amputation within three months after sustaining high-energy trauma below the distal femoral level. These individuals were participants in the Lower Extremity Assessment Project (LEAP), a multi-institutional, prospective study designed to examine the differences in outcome following reconstruction or amputation[14]. Previous publications have described the overall similarity between the outcomes following reconstruction and those following amputation[15]. The present analysis was conducted to determine whether outcomes differed among subgroups of patients with an amputation. To be eligible for participation in the parent LEAP study, a patient had to be between eighteen and sixty-nine years of age and have one or more of the following injuries to the lower extremity: a Gustilo[16] Grade-IIIB or IIIC fracture, a Grade-IIIA fracture with certain characteristics (Grade-IIIA fracture requiring a hospital stay of more than four days, requiring two or more surgical procedures, and associated with two or more of the following: severe muscle damage, associated nerve injury, or major bone loss or bone injury), a dysvascular limb (a knee dislocation, a closed tibial fracture with a pulseless foot, or a penetrating wound with vascular injury), a major soft-tissue injury to the tibia (a degloving or severe crush/avulsion injury), or a severe foot or ankle injury (an open pilon or Grade-IIIB ankle fracture or a severe hindfoot or midfoot injury). Criteria for exclusion included a moderate-to-severe brain injury (a score of <15 on the Glasgow Coma Scale[17] at twenty-one days after the lower-limb injury or at the time of discharge), a spinal cord deficit, a prior amputation of the leg or foot, or a third-degree burn on the injured lower limb. Also excluded were patients who had been transferred to the participating center more than twenty-four hours after the injury, those who did not speak English or Spanish, those with a documented psychiatric disorder or mental retardation, and those who were on active military duty or who lived outside the hospital's catchment area and for whom follow-up was deemed impossible. Patients were recruited into the study from eight level-I trauma centers over a forty-month period (March 1994 through June 1997).

A total of 161 patients met the LEAP study criteria and had had a unilateral amputation within three months after the injury. (Ten LEAP patients who had undergone bilateral amputation were excluded from this analysis.) Of the 161 patients with a unilateral amputation, thirteen had an intact lower limb at the time of discharge from the hospital where they had received their initial acute care but were readmitted for a delayed amputation within three months after the injury. Within three months after the injury, 109 study patients had an amputation below the knee; thirty-four, above the knee; and eighteen, through the knee. One patient had a revision to a higher level subsequent to the three-month evaluation. Most injuries had resulted from a motor-vehicle (20%), motorcycle (25%), or pedestrian-motor vehicle (17%) collision. The majority of the patients were men (84%); the mean age (and standard deviation) of the entire group of patients was 35.2 ± 13.3 years, with a range of eighteen to sixty-eight years.

Procedures

The study participants were evaluated at baseline (before hospital discharge) and at three, six, twelve, and twenty-four months after the injury. At each time-point, the patients were evaluated by an orthopaedic surgeon to ascertain complications and limb status, by a physical therapist to ascertain impairment and functional performance, and by a research nurse to assess the patient's perception of the functional outcome. At twelve and twenty-four months after the injury, permission was obtained from the patient to contact his or her prosthetist or prosthetists for detailed information about the type of prosthesis. Of the 161 study patients, 143 (88.8%) were followed at three months; 141 (87.6%), at six months; 139 (86.3%), at twelve months; and 124 (77.0%), at twenty-four months. Patients with incomplete follow-up were more likely to be male, nonwhite, and without a high-school education ($p < 0.05$). The study was approved by the institutional review boards at the coordinating center and at each study site. Written informed consent was obtained from all study participants.

Measures of Outcome

Functional outcome was measured with use of the Sickness Impact Profile (SIP)[18]. The SIP is a multidimensional measure of self-reported health status, consisting of 136 statements about limitations in twelve categories of function: (1) walking, (2) mobility, (3) body care and movement, (4) social interaction, (5) alertness, (6) emotional behavior, (7) communication, (8) sleep and rest, (9) eating, (10) work, (11) home management, and (12) recreation and pastimes. Respondents are asked to endorse statements that describe their health status on a given day. Scores were calculated for the overall instrument, for each of the twelve categories listed above, and for two major dimensions of health (physical health summarizing limitations in the first three categories, and psychosocial health summarizing limitations in the second four categories). The SIP has been well tested for reliability and validity[19], including with regard to the assessment of postinjury outcomes[20]. Overall SIP scores range from 0 to 100 points. An SIP of >10 points represents substantial disability, and differences of 2 or 3 points reflect meaningful differences in function. Overall SIP scores range between 2 and 3 points for the general population[21].

Secondary outcomes included two performance measures: degree of independence in transfers, walking, and climbing stairs (defined by the Functional Independence Measure [FIM][22]) and walking speed as measured with a 100-ft (30.48-m) timed test[23]. Both performance measures were administered by a physical therapist at each follow-up visit. Intensity of pain was measured with use of a visual analogue scale[24]. Before the examination by the physical therapist, patients were asked to place a mark on a 100-mm line that best described their present level of pain. The line was anchored with the descriptors "no pain at all" on one end (0) and "unbearable pain" on the other end (100). A continuous score was derived by measuring the distance of the mark (in millimeters) from the lower end of the scale. Finally, because of concerns that the Sickness Impact Profile may not adequately capture difficulties in performing tasks requiring advanced functional capabilities, three questions were added to the interview to assess the respondent's ability to walk without help on uneven ground or a slope, outdoors in bad weather, and while carrying an object. The physician's satisfaction with the clinical, functional, and cosmetic recovery of the lower limb was recorded at each visit with use of a 10-point scale ranging from 1 (not at all satisfied) to 10 (completely satisfied).

Factors Influencing Outcome

Factors, in addition to the level of amputation, that were hypothesized to influence outcome included (1) characteristics of the injury leading to the amputation as well as injuries sustained in association with the specific limb injury, (2) characteristics of the amputation and post-acute-care complications, (3) characteristics of the patient including preexisting medical conditions and health habits, and (4) the technological sophistication of the prosthetic device being used at two years after the injury.

All injuries were prospectively characterized according to the type and extent of osseous damage, extent of soft-tissue injury, initial pulse assessment, and plantar sensation[25]. Associated injuries were classified with use of the Abbreviated Injury Scale (AIS)[26], the Injury Severity Score (ISS)[27], and two scores denoting the maximum AIS severity of contralateral and ipsilateral (non-study) lower-limb and pelvic injuries. Shock was defined as systolic blood pressure of <90 mm Hg prior to the initiation of resuscitation[28].

Amputations were classified according to their timing (immediate, not immediate but during the initial hospitalization, and postdischarge but within the first three months after the injury) and the type of closure (either a typical elective amputation skin flap or an atypical, best possible skin coverage, including the use of split-thickness skin grafts and free tissue transfers). Also recorded at the time of the amputation was whether a myodesis or myoplasty was performed, whether the joint above the amputation was immobilized, the number of days from the amputation to the wound closure, and whether a temporary prosthesis was fitted following the amputation. To account for the impact of complications on recovery, a variable was constructed to indicate rehospitalization because of a complication associated with the lower-limb injury and/or amputation and included the need for a stump revision and treatment of a major infection.

Patient characteristics that were hypothesized to influence treatment assignment or outcome were described in detail in a previous publication[14]. They include age, gender, race/ethnicity, education, preinjury poverty status (defined by relating total household income to household size)[29] and insurance status, work status and occupation[30], personality characteristics measured by the NEO Personality Inventory[31], social support measured by a modified version of the Inventory of Socially Supportive Behaviors (a tool that measures available support in terms of tangible assistance, directive guidance, and emotional support)[32,33], and self-efficacy[34,35] (a measurement of how confident patients are [at the time of hospital discharge] about their ability to resume their major life activity). Also hypothesized to influence recovery were self-rated preinjury health and preexisting chronic conditions; preinjury exercise, smoking[36], and drinking habits[37]; and compensation received for the injury and whether legal services were retained[38].

To determine the technical sophistication of the prostheses worn by the study participants, a panel of two prosthetists and of one orthopaedic surgeon with more than ten years' experience in amputation surgery and rehabilitation rated each device as low, medium, or high technology[39]. These ratings were based on information obtained from a mailed survey of the patients' prosthetists and included characteristics of the suspension system; sockets; knee, foot, and ankle components; exoskeletal and endoskeletal shank techniques; and whether CAD/CAM technology was used when the prosthesis was fitted. It should be noted that the sophistication of the device used at twenty-four months after the injury was known for only 119 (74%) of the patients. Patients were asked to estimate the number of days between the amputation and the fitting of their first definitive prosthesis.

Statistical Methods

Overall differences in outcome according to the level of amputation were initially tested with analysis-of-variance techniques and multiple-comparison tests for continuous measures (i.e., the SIP scores and the pain scores on the visual analogue scales) and chi-square analysis for categorical measures (self-selected walking speed of ≥4 ft (1.22 m)/sec, independence in activities, self-reported inability to perform certain activities, and physician-reported satisfaction with recovery). Longitudinal multivariate regression techniques[40] were then used to determine whether there were differences in SIP scores and the percentages of patients with a self-selected walking speed of ≥4 ft/sec after we controlled for other factors hypothesized to influence outcome. In modeling SIP outcomes, both additive and multiplicative regression models were considered, but the multiplicative model was chosen because we observed that, while SIP scores continuously improved, the rate of this improvement declined over time. Longitudinal logistic regression techniques were used to estimate the odds of walking at a speed ≥4 ft/sec after we controlled for potential

TABLE I Treatment and Clinical Status at Twenty-four Months Post-Injury According to Amputation Level at Three Months

	Patient Group*				
	All Patients (N = 161; 124)	Below-the-Knee Amputation (N = 109; 81)	Through-the-Knee Amputation (N = 18; 16)	Above-the-Knee Amputation (N = 34; 27)	P Value for Difference Between Groups†
Mean no. of days of initial hospital stay	17.7	16.9	23.7	16.9	0.08
% of patients with ≥1 rehospitalization					
For any major complication	29.8	30.3	27.8	29.4	0.72
For stump revision	14.5	11.9	11.1	23.5	0.23
For infection	16.2	16.5	22.2	11.8	0.61
Mean no. of surgical exposures over 2 yr (including initial hospital stay)	2.3	2.3	2.4	2.1	0.65
Mean total no. of hospital days for treatment of injury (including initial hospital stay)	20.5	19.6	27.2	19.7	0.09
% of patients treated with					
Atypical flap	38.2	40.2	20.0	40.6	0.32
Myodesis	28.7	22.8	14.3	53.3	0.01
Myoplasty	55.9	67.0	13.3	40.7	0.01
Temporary prosthesis	10.4	13.3	6.3	3.3	0.25
Mean no. of days from amputation to wound closure	4.8	3.7	10.6	5.3	0.01
% of patients in whom soft tissue not healed at 2 yr (as assessed by the surgeon)	6.5	9.3	0.0	0.0	0.16
% of patients likely to require additional surgery after 2 yr (as anticipated by the surgeon)	4.8	4.1	14.3	0.0	0.13

*N = total number of patients; number of patients followed at twenty-four months. †As determined with analysis of variance for continuous measures and chi-square analysis for categorical measures.

confounders. Stepwise modeling techniques were used to construct the final multivariate models that included the level of amputation and all patient, injury, and device characteristics that remained associated with outcome at $p < 0.20$. The extent to which the effect of these variables on outcome varied according to the time since the injury or the level of the amputation was examined, and interaction terms were incorporated where indicated. To examine the potential bias introduced by variable follow-up and incomplete data, two models were developed. The first model was based on data from only individuals for whom complete twenty-four-month follow-up data were available. The second model was based on data available on all patients who were followed for at least three months and used pairwise deletion to estimate the parameters of the model. Similar results were obtained with use of the two approaches; thus, the results based on all available data are reported.

Results

Course of Hospital Treatment and Clinical Status at Twenty-four Months

The average stay in the hospital for initial acute care was 17.7 days (Table I). The duration of the initial hospitalization was longest for the patients treated with a through-the-knee amputation (23.7 days) ($p = 0.08$). More than one-quarter (29.8%) of all patients were rehospitalized at least once because of a complication, with 14.5% requiring a stump revision. Rates of rehospitalization were similar across the subgroups. On the average, the patients spent a total of 20.5 days in the hospital as a result of their injury and had 2.3 surgical exposures (i.e., the number of times they received general anesthesia related to the LEAP injury). The percentage of patients who had a myodesis was significantly higher in the above-the-knee amputation group than it was in the below-the-knee or through-the-knee amputation group ($p = 0.01$), and the percentage of those who had a myoplasty was significantly lower in the through-the-knee amputation group than it was in the below-the-knee or above-the-knee amputation group ($p = 0.01$). The mean number of days until wound closure was significantly higher for the patients with a through-the-knee amputation than it was for those with a below-the-knee or above-the-knee amputation ($p = 0.01$).

A modest proportion of patients had not fully recovered by the time of the twenty-four-month assessment, as indicated by unhealed soft-tissue injuries (in 6.5% of the patients) and an anticipated need for additional surgery (in 4.8% of the patients). There were no significant differences between groups with regard to the percentage of patients with an unhealed

TABLE II Outcomes at Twenty-four Months Post-Injury According to Amputation Level at Three Months

	Patient Group*				
	All Patients (N = 161; 124)	Below-the-Knee Amputation (N = 109; 81)	Through-the-Knee Amputation (N = 18; 16)	Above-the-Knee Amputation (N = 34; 27)	P Value for Difference Between Groups†
SIP scores‡					
Overall	12.5 ± 11.9	12.7 ± 12.8	15.9 ± 12.9	10.2 ± 7.8	0.34
Physical function	10.1 ± 9.8	9.8 ± 10.6	13.9 ± 9.0	9.0 ± 7.2	0.26
Psychosocial function	11.2 ± 15.7	12.1 ± 16.4	15.0 ± 20.2	6.6 ± 8.6	0.17
Pain score on visual analogue scale‡	24.2 ± 24.3	24.7 ± 23.7	14.4 ± 20.7	27.0 ± 27.4	0.25
% of patients able to perform activity independently or partially independently					
Transfers	100.0	100.0	100.0	100.0	
Walking	96.8	98.8	87.5	96.3	0.05
Stair-climbing	96.8	98.8	87.5	96.3	0.05
% of patients with self-selected walking speed of ≥4 ft/sec	52.4	62.0	21.4	43.5	0.01
% of patients unable to perform activity without help					
Walking on uneven ground or slope	20.2	11.3	62.5	23.1	0.00
Walking outdoors in bad weather	35.5	30.0	75.0	30.8	0.04
Walking while carrying an object	12.1	6.3	31.3	19.2	0.07
% of cases for which physician is satisfied with:					
Clinical recovery	78.2	77.3	50.0	95.7	0.02
Cosmetic recovery	56.5	54.1	38.5	72.7	0.05
Functional recovery	68.6	72.0	50.0	69.6	0.36

*N = total number of patients; number of patients followed at twenty-four months. †As determined with analysis of variance for continuous measures and chi-square analysis for categorical measures. ‡The values are given as the mean and the standard deviation. SIP = Sickness Impact Profile[18].

soft-tissue injury (p = 0.16) or the percentage requiring additional surgery (p = 0.13).

The mean number of days from the amputation to the fitting of the first prosthesis (excluding the temporary prosthesis) was 101 days, with no difference among the three groups of patients (see Appendix). Approximately three-quarters of the prostheses worn at twenty-four months after the injury were judged to be of medium technological sophistication (53.8% of the prostheses) or high technological sophistication (17.7%).

Outcomes by Level of Amputation

Overall, and across most dimensions of the SIP, patients with a through-the-knee amputation had the highest SIP scores (Table II and Appendix). Those with a below-the-knee amputation had somewhat higher mean scores than those with an above-the-knee amputation, although the differences were more modest. However, none of the differences among the three amputation groups was significant at the $p < 0.05$ level.

The mean overall SIP scores for all three amputation groups indicated substantial disability. Forty-three percent of all patients, 44.4% of those with an above-the-knee amputation, 60.0% of those with a through-the-knee amputation, and 39.2% of those with a below-the-knee amputation had an overall SIP score of ≥10 points. For all dimensions except eating and communication, the SIP scores at twenty-four months after the injury were significantly higher than published population norms or preinjury scores (mean, 2.6 points) ($p < 0.01$)[20,21]. Subscores that reflected limitations in the amount and kind of work that could be performed (including the inability to work at all) were particularly high; only 54.4% of patients who were working prior to the injury had returned to work by two years after the injury.

Poorer outcomes following through-the-knee amputation compared with those following below-the-knee or above-the-knee amputation were reflected by the secondary measures examined in this study (Table II). Patients with a through-the-knee amputation had significantly worse scores for the objective performance measures of self-selected walking speed (p = 0.01) and independence in transfers, walking, and stair-climbing (p = 0.05). A higher percentage of patients with a through-the-knee amputation also reported needing help with two of the three physically demanding tasks (walking on uneven

TABLE III Longitudinal Regression Results for Sickness Impact Profile[18] (SIP) Scores and Walking Speed of Four Feet or More per Second

	SIP Scores*						Walking speed of ≥4 ft/sec†	
	Overall		Physical Function		Psychosocial Function			
	Percent Increase (Decrease)	P Value	Percent Increase (Decrease)	P Value	Percent Increase (Decrease)	P Value	Odds Ratio	P Value
Above-the-knee amputation (compared with below-the-knee amputation)	(8.3)	0.50	9.3	0.94	(12.3)	0.48	0.22	0.04
Through-the-knee amputation (compared with below-the-knee amputation)	37.0	0.05	41.5	0.03	61.2	0.15	0.03	0.004
Female (compared with male)	17.1	0.31	20.2	0.25	42.6	0.12	0.16	0.02
Nonwhite race (compared with white race)	59.8	0.001	55.8	0.001	99.5	0.001	0.27	0.08
Age <55 yr (compared with age ≥55 yr)	38.7	0.06	0.40	0.97	46.6	0.01	4.69	0.16
No college education (compared with some college education)	31.6	0.02	17.3	0.19	59.0	0.00	0.38	0.13
No health insurance or public health insurance (compared with private health insurance)	(1.1)	0.94	14.7	0.15	32.8	0.17	0.70	0.61
Income level at or below poverty level (compared with near or above poverty level)	21.4	0.10	15.2	0.34	37.6	0.08	0.86	0.83
Smoking before injury (compared with not smoking before injury)	32.3	0.02	31.9	0.02	53.4	0.001	0.37	0.11
Chronic preinjury medical condition (compared with no preinjury condition)	28.5	0.01	26.1	0.03	32.9	0.10	0.48	0.22
Injury Severity Score (ISS) >13 points (compared with ISS ≤ 13 points)	19.5	0.13	16.9	0.16	29.7	0.12	0.39	0.12
Ipsilateral injury (compared with no ipsilateral injury)	24.2	0.05	31.3	0.01	22.8	0.87	0.49	0.25
Self-efficacy score (for each point increase on a 100-point scale)	(0.2)	0.001	(0.1)	0.02	(0.3)	0.001	1.01	0.34

*These estimates are based on the results of a longitudinal multiplicative regression model and indicate the percent increase or decrease in scores associated with each covariate in comparison with the reference group (shown in parentheses). †These estimates are based on a longitudinal logistic regression and indicate the adjusted odds of achieving a walking speed of ≥4 ft/sec relative to the reference group (shown in parentheses).

ground and walking outdoors in bad weather) ($p < 0.05$). Although patients with a through-the-knee amputation reported a lower average level of pain, it was not significantly different from the pain levels reported by the other two groups. Patients with a below-the-knee amputation had a faster walking speed than those with an above-the-knee amputation, and a smaller percentage of patients with a below-the-knee amputation indicated that they needed help with walking on uneven ground or while carrying an object. These differences between the below-the-knee and above-the-knee amputation groups did not achieve significance.

The relatively poor twenty-four-month outcomes of through-the-knee amputations compared with the outcomes of below-the-knee and above-the-knee amputations is underscored by the differences in the percentage of cases in which the physician was satisfied or very satisfied with the recovery. Although subjective in nature, these ratings suggest that physicians were less satisfied with both the clinical and the cosmetic recovery of the patients with a through-the-knee amputation ($p \leq 0.05$). They were also less satisfied with their functional recovery, although this difference was not as large and was not significant (Table II).

Adjusted Differences in Outcomes by Potential Confounders

The differences observed in the SIP scores according to the level of amputation persisted after we controlled for selected potential confounders. Specifically, the regression-adjusted SIP scores for patients with a through-the-knee amputation were 37.0% higher than those for patients with a below-the-knee amputation ($p = 0.05$) (Table III). These differences in scores were largely due to differences in physical, as opposed to psychosocial, function. There were no measurable differences in the SIP scores between the below-the-knee and above-the-knee amputation groups. Differences in walking

speed also persisted after controlling for potential confounders. Specifically, the adjusted relative odds of having a walking speed of ≥4 ft/sec was 0.03 for the through-the-knee amputation group compared with the below-the-knee amputation group (p = 0.004) and 0.22 for the above-the-knee amputation group compared with the below-the-knee amputation group (p = 0.04). Thus, when compared with the patients who had a below-the-knee amputation, those who had a through-the-knee amputation had significantly worse outcomes as demonstrated by both a self-reported measure of disability and a performance-based measure of walking speed. Furthermore, although the SIP scores did not differ significantly between the below-the-knee and above-the-knee amputation groups, the walking speed of the patients with a below-the-knee amputation was significantly faster than that of the patients with an above-the-knee amputation.

In addition to the level of amputation, factors that were significant (p ≤ 0.05) predictors of a poor overall SIP score included a preexisting medical condition, smoking, an ipsilateral limb injury, less than a college education, low self-efficacy, and nonwhite race (Table III). The effect of an ipsilateral injury and a previous medical condition on the overall SIP scores was largely due to their impact on physical, as opposed to psychosocial, function, whereas a higher educational level appeared to affect psychosocial function more than physical function. Marginally significant predictors of a poor SIP score (p < 0.15) include poverty, an age of less than fifty-five years, and an ISS score of >13 points. Predictors of poor outcome were the same for all levels of amputation. We found no significant differences in outcome on the basis of the timing of the amputation, the type of soft-tissue coverage, the muscle-anchoring techniques, or the technological sophistication of the prosthetic device. The only significant predictor of walking speed (in addition to the level of the amputation) was gender; women were 0.16 times as likely as men to achieve a speed of ≥4 ft/sec (p = 0.02).

To better understand why patients with a through-the-knee amputation had poorer outcomes, three of us reviewed the operative reports, the anteroposterior and lateral radiographs, and the appearance of the wound on admission and at the time of soft-tissue coverage for all eighteen patients who had undergone a through-the-knee amputation. The through-the-knee amputation was in the zone of injury in all but one patient. Twelve of the eighteen patients did not have gastrocnemius muscle coverage over the femoral condyles, as this tissue was not available. Management of the distal part of the femur varied. The condyles were contoured in ten of the patients. The patella was removed in nine of the patients, and it was fused to the distal end of the femur in one.

Discussion

Although rates of major lower-limb amputation secondary to trauma have declined in recent years, the annual number of hospital discharges following trauma-related amputation in the United States remains high, at approximately 3500[41,42]. Most of the amputations are performed in adolescents and young adults, yet little is known about the impact of the amputations on functional outcomes and quality of life. Even less is known about the factors associated with post-amputation recovery. With very few exceptions, the outcome studies that have been published were limited by their retrospective design, small sample size, and lack of standardized measures of outcomes[1-13]. Clinical experience suggests, however, that the type and quality of the soft-tissue coverage, preservation of the knee joint, residual limb length, and design of the prosthesis are important factors leading to good outcomes[43].

In this study, the functional outcomes at twenty-four months were poor. These results are generally in agreement with those of others[1-13] who have reported high rates of physical disability following amputation despite substantial advances in amputation surgery and in the development of prostheses made of lightweight and strong materials that incorporate technologically sophisticated energy-returning foot and ankle modifications. However, to our knowledge, the high rates of psychosocial (in addition to physical) disability have not been reported before. The two studies in which this aspect of outcome was evaluated with standardized assessment techniques[1,3] showed no significant deficits in scores measuring mental health and emotional function. Both of those studies, however, were retrospective, with assessments made at variable points in time ranging from two to ten years after the injury. In the present study, the rates of psychosocial disability were high at three months and remained high, with little improvement, over the twenty-four-month follow-up period.

Interestingly, and contrary to our hypothesis, patients who had undergone an above-the-knee amputation reported functional outcomes (as measured with the SIP) that were similar to those reported by patients with a below-the-knee amputation. However, the walking speeds of the patients with a below-the-knee amputation were significantly better than those of the patients with an above-the-knee amputation. Other studies have shown below-the-knee amputation to have an advantage over above-the-knee amputation with regard to measures of energy consumption involved in walking[24,44]. The results of the present study suggest that better lower-limb function per se (as measured by walking speed) may not necessarily translate into overall improvement in daily life (as perceived by the individual and measured with the SIP). As discussed below, several factors influence SIP scores; the extent of impairment of lower-limb function is only one of these factors. Regardless of the level of the amputation, all patients experienced similar frustrations and challenges that may overwhelm the actual degree of impairment of lower-limb function.

Through-the-knee amputations, however, resulted in two-year outcomes, as measured by both walking speed and self-reported measures of disability, that were significantly worse than those following either below-the knee or above-the-knee amputation. These results stand in contrast to those found in the amputation literature. Studies have shown improved self-selected walking velocity and maximum walking velocity as well as extended durations of prosthetic wear for persons with a through-the-knee amputation compared with those with an above-the-knee amputation[44-48]. Those studies,

however, were based primarily on the experience of elderly persons who had undergone elective amputation because of dysvascular disorders. In the performance of an elective through-the-knee amputation, the gastrocnemius muscles are employed to form a well-padded layer over the end of the femur. In the case of a trauma-related through-the-knee amputation, long posterior flaps containing the gastrocnemius muscles are often not available, as the amputation is being performed in or near the zone of injury[49]. Of our eighteen patients with a through-the-knee amputation, seventeen underwent the amputation in the zone of injury and twelve had no remaining gastrocnemius muscle. We believe that our data bring into question the wisdom of performing a through-the-knee amputation in patients who have sustained high-energy trauma, especially when the knee is included in the zone of injury.

Only 10.4% of our patients were fitted for a prosthesis immediately postoperatively. This probably reflects the management of the soft tissues in the zone of injury. The use of skin grafts or free tissue transfer does not appear to affect the outcomes of below-the-knee amputations. The mean SIP scores (and standard deviation) were 13.2 ± 12.7 and 13.5 ± 13.6 points for patients with typical and atypical flaps, respectively.

We also found that the technological sophistication of the prosthetic device did not appear to have an impact on outcome. The results of our analyses do not support the contention that outcomes measured in the first two years following amputation are improved by the provision of a more technologically sophisticated and expensive device. Given the subjective nature of the assessments of the devices used in this study, these findings must be interpreted with considerable caution. At a minimum, however, they underscore the need for controlled trials to better delineate the relationship between device characteristics and functional outcomes. It will be important to measure not only the component characteristics of the device but also the quality of the fit, alignment, and extent to which the specifications of the device match the needs of the patient.

Several factors in addition to the level of the amputation were significantly associated with poor SIP scores. There were particularly strong correlations between race and outcome. Nonwhites had overall SIP scores that were 60% higher than those of whites. Although race appears to correlate with outcome over and above socioeconomic status, it is likely that it is measuring an aspect that is not captured by educational level, poverty status, and insurance coverage alone. These relationships between race and functional outcome have been documented for other conditions[50]. It will be important in future studies to investigate the reasons for these large disparities in outcome.

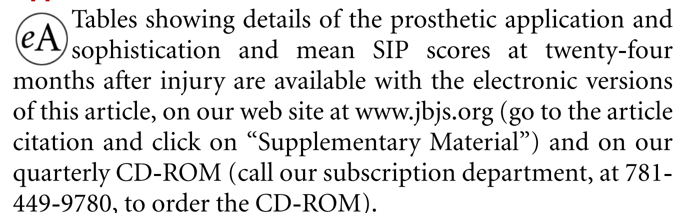
Our study also confirms the previous observation that low self-efficacy is an important determinant of poor outcome. Self-efficacy is the belief that one is able to perform specific tasks or activities. Persons with low self-efficacy are more likely to disengage from the coping process because they expect to fail[51]. These patients often feel a strong desire to resume activities that they enjoyed prior to the injury but hesitate to do so out of fear they will be unable to perform component tasks. Self-efficacy can be both taught and improved[52], and modification of self-efficacy through cognitive-behavioral interventions has been demonstrated[53]. More research is needed to develop and evaluate these interventions for individuals facing the challenges of postinjury recovery.

The results of this study must be interpreted in light of its limitations. Although it is one of the larger prospective studies of post-amputation outcomes, the numbers of through-the-knee amputations and above-the-knee amputations were relatively small. Follow-up rates were high, although complete twenty-four-month outcome data were missing for 23% of the patients initially enrolled in the study. Patients with missing data tend to be of lower socioeconomic status, suggesting that our results regarding poor overall levels of functional recovery may underestimate the extent of the problem. In addition, the generalizability of the results beyond level-I trauma centers is uncertain. The clinical outcomes observed in this study may well represent better-than-average results, given the injury volume and experience at the participating clinical centers.

It is also important to emphasize that the results presented here are based on functional outcomes observed at two years. A small number of patients had not recovered completely by this point in time, as evidenced by the percentage in whom the soft tissue had not healed and the percentage requiring additional surgery. Continued modification of the fit of the prosthesis and increasing comfort with and confidence in the prosthetic device could also improve the long-term function of patients with an amputation. Long-term follow-up of these patients is imperative, and a seven-year outcome assessment is under way.

On the basis of the results of this study, we advise clinicians to critically evaluate the need for a through-the-knee amputation in a patient who has sustained a traumatic injury of the lower limb. The results also call into question the advisability of fitting patients with the more sophisticated (and expensive) prostheses, given that the low-tech devices appeared to yield equivalent outcomes. However, more research that takes into account the fit and alignment of the prosthesis must be conducted before definitive recommendations can be made.

Appendix



eA Tables showing details of the prosthetic application and sophistication and mean SIP scores at twenty-four months after injury are available with the electronic versions of this article, on our web site at www.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).

NOTE: The authors acknowledge the efforts of the coinvestigators, study coordinators, and physical therapists at each of the eight LEAP study sites. Their dedication to the study's objectives and their commitment to quality data collection were essential to the success of the study. They include Julie Agel, ATC; Jennifer Avery, PT; Denise Bailey, PT; Wendall Bryan; Debbie Bullard; Carla Carpenter, PT; Elizabeth Chaparro, RN; Kate Corbin; Denise Darnell, RN, BSN; Stephanie Dickason, PT; Thomas DiPasquale, DO; Betty Harkin, PT; Michael Harrington, PT; Dolfi Herscovici, DO; Amy Holdren, RNC, ANP, MSN; Linda Howard, PT; Sarah Hutchings, BS; Marie Johnson, LPN; Melissa Jurewicz, PT; Donna Lampke, PT; Karen Lee, RN; Marianne Mars, PT; Maxine Mendoza-Welch, PA; J. Wayne Meredith, MD; Nan Morris, PT; Karen Murdock, PT; Andrew Pollak, MD; Pat Radey, RN; Sandy Shelton, PT; Sherry Simpson, PT; Steven Sims, MD; Adam Star, MD; Celia Wiegman, RN; John Wilber, MD; Stephanie Williams, PA; Philip Wolinsky, MD; Mary Woodman, BA; and Michele Zimmerman, RN.

Ellen J. MacKenzie, PhD
Center for Injury Research and Policy, Johns Hopkins Bloomberg School of Public Health, 624 North Broadway, Room 554, Baltimore, MD 21205. E-mail address for E.J. MacKenzie: emackenz@jhsph.edu

Michael J. Bosse, MD
James F. Kellam, MD
Department of Orthopaedic Surgery, Carolinas Medical Center, 1000 Blythe Boulevard, Suite 306, Charlotte, NC 28232-2861

Renan C. Castillo, MS
Center for Injury Research and Policy, Johns Hopkins Bloomberg School of Public Health, 624 North Broadway, Room 545, Baltimore, MD 21205

Douglas G. Smith, MD
Department of Orthopaedics, Harborview Medical Center, 325 Ninth Avenue, ZA-48, Seattle, WA 98104

Lawrence X. Webb, MD
Wake Forest University, Bowman Gray School of Medicine, Medical Center Boulevard, Winston-Salem, NC 27157-1070

Andrew R. Burgess, MD
Orthopedics Associates of Portland, 33 Sewall Street, P.O. Box 1260, Portland, ME 04104

Marc F. Swiontkowski, MD
Department of Orthopaedic Surgery, University of Minnesota, 420 Delaware Street S.E., Box 492 Mayo, Minneapolis, MN 55455

Roy W. Sanders, MD
Florida Orthopedic Institute, 4175 East Fowler Avenue, Tampa, FL 33617-2011

Alan L. Jones, MD
University of Maryland at Baltimore, R Adams Cowley Shock Trauma Center, 22 South Greene Street, Baltimore, MD 21201

Mark P. McAndrew, MD
Vanderbilt University Hospital, 1161 21st Avenue South, Medical Center North, T-4311, Nashville, TN 37232-2550

Brendan M. Patterson, MD
Department of Orthopaedics, MetroHealth Medical Center, 2500 MetroHealth Drive, Cleveland, OH 44109-1998

Thomas G. Travison, PhD
Wyeth Research, 87 Cambridgepark Drive, MS 3100-60, Madison, NJ 02140

Melissa L. McCarthy, ScD
Department of Emergency Medicine, Johns Hopkins School of Medicine, 1830 East Monument Street, Suite 6-100, Baltimore, MD 21205

In support of their research or preparation of this manuscript, one or more of the authors received Grant ROI-AR42659 from the National Institutes of Health/National Institute of Arthritis and Musculoskeletal and Skin Diseases. None of the authors received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. Commercial entities (Zimmer and Synthes USA) paid or directed, or agreed to pay or direct, benefits to a research fund, foundation, educational institution, or other charitable or nonprofit organization with which one or more of the authors are affiliated or associated.

References

1. **Pezzin LE, Dillingham TR, MacKenzie EJ.** Rehabilitation and the long-term outcomes of persons with trauma-related amputations. *Arch Phys Med Rehabil.* 2000;81:292-300.
2. **Matsen SL, Malchow D, Matsen FA 3rd.** Correlations with patients' perspectives of the result of lower-extremity amputation. *J Bone Joint Surg Am.* 2000;82:1089-95.
3. **Smith DG, Horn P, Malchow D, Boone DA, Reiber GE, Hansen ST Jr.** Prosthetic history, prosthetic charges, and functional outcome of the isolated, traumatic below-knee amputee. *J Trauma.* 1995;38:44-7.
4. **Walker CR, Ingram RR, Hullin MG, McCreath SW.** Lower limb amputation following injury: a survey of long-term functional outcome. *Injury.* 1994;25:387-92.
5. **Millstein S, Bain D, Hunter GA.** A review of employment patterns of industrial amputees—factors influencing rehabilitation. *Prosthet Ortho Inst.* 1985;9:69-78.
6. **Legro MW, Reiber GD, Smith DG, del Aguila M, Larsen J, Boone D.** Prostheses evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. *Arch Phys Med Rehabil.* 1998; 79:931-8.
7. **Curley MD, Walsh JM, Triplett RG.** Some adjustment indices of oral-maxillofacial war casualties, limb amputees, and non-injured veterans. *Mil Med.* 1982;147:572-4.
8. **Kishbaugh D, Dillingham TR, Howard RS, Sinnot MW, Belandres PV.** Amputee soldiers and their return to active duty. *Mil Med.* 1995;160:82-4.
9. **Kegel B, Carpenter ML, Burgess EM.** Functional capacities of lower extremity amputees. *Arch Phys Med Rehabil.* 1978;59:109-20.
10. **Melchiorre PJ, Findley T, Boda W.** Functional outcome and comorbidity indexes in the rehabilitation of the traumatic versus the vascular unilateral lower limb amputee. *Am J Phys Med Rehabil.* 1996;75:9-14.
11. **Pierce RO Jr, Kernek CB, Ambrose TA 2nd.** The plight of the traumatic amputee. *Orthopedics.* 1993;16:793-7.
12. **Purry NA, Hannon MA.** How successful is below-knee amputation for injury? *Injury.* 1989;20:32-6.
13. **Pozo JL, Powell B, Andrews BG, Hutton PA, Clark J.** The timing of amputation for lower limb trauma. *J Bone Joint Surg Br.* 1990;72:288-92.
14. **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 undergoing amputation versus limb salvage for severe lower extremity trauma. *J Orthop Trauma.* 2000;14:455-66.
15. **Bosse MJ, MacKenzie EJ, Kellam JF, Burgess AR, Webb LX, Swiontkowski MF, Sanders RW, Jones AL, McAndrew MP, Patterson BM, McCarthy ML, Travison TG, Castillo RC.** An analysis of outcomes of reconstruction or amputation after leg-threatening injuries. *N Engl J Med.* 2002;347:1924-31.
16. **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;24:42-6.
17. **Teasdale G, Jennett B.** Assessment of coma and impaired consciousness. A practical scale. *Lancet.* 1974;2:81-4.
18. **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.
19. **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.
20. **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.
21. **Gilson BS, Bergner M, Bobbitt RA, Carter WB.** *The Sickness Impact Profile: final development and testing*. Seattle: Department of Health Services, University of Washington School of Public Health and Community Medicine; 1979.
22. **Granger CV.** The emerging science of functional assessment: our tool for outcomes analysis. *Arch Phys Med Rehabil.* 1998;79:235-40.
23. **Waters RL, Hislop HJ, Perry J , Thomas L, Campbell J.** Comparative cost of

walking in young and old adults. *J Orthop Res.* 1983;1:73-6.

24. **Scott J, Huskisson EC.** Graphic representation of pain. *Pain*. 1976;2:175-84.
25. **MacKenzie EJ, Bosse MJ, Kellam JF, Burgess AR, Webb LX, Swiontkowski MF, Sanders R, Jones AL, McAndrew MP, Patterson B, McCarthy ML, Rohde CA; 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.
26. **Association for the Advancement of Automotive Medicine.** *The abbreviated injury scale. 1990 revision.* Des Plaines, IL: Association for the Advancement of Automotive Medicine; 1990.
27. **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.
28. **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.
42. **Dillingham TR, Pezzin LE, MacKenzie EJ.** Limb amputation and limb deficiency: epidemiology and recent trends in the United States. *South Med J.* 2002;95:875-83.
43. **Pinzur MS.** Amputations in trauma. In: Browner BD, Jupiter JB, Levine AM, Trafton PG, editors. *Skeletal trauma: basic science, management and reconstruction.* 3rd ed, vol 2. New York: WB Saunders; 2003. p 2613-26.
44. **Pinzur MS, Gold J, Schwartz D, Gross N.** Energy demands for walking in dysvascular amputees as related to the level of amputation. *Orthopedics*. 1992; 15:1033-7.
45. **Hagberg E, Berlin OK, Renstrom P.** Function after through-knee compared with below-knee and above-knee amputation. *Prosthet Orthot Int*. 1992;16: 168-73.
46. **Bowker JH, San Giovanni TO, Pinzur MS.** North American experience with knee disarticulation with use of a posterior myofaciocutaneous flap: healing rate and functional results in seventy-seven patients. *J Bone Joint Surg Am.* 2000;82:1571-4.
47. **Pernot HF, Winnubst GM, Cluitmans JJ, De Witte LP.** Amputees in Limburg: incidence, morbidity and mortality, prosthetic supply, care utilisation and functional level after one year. *Prosthet Orthot Int.* 2000;24:90-6.
48. **Pinzur MS, Bowker JH.** Knee disarticulation. *Clin Orthop.* 1999;361:23-8.
49. **Yaremchuk MJ, Brumback RJ, Manson PN, Burgess AR, Poka A, Weiland AJ.** Acute and definitive management of traumatic osteocutaneous defects of the lower extremity. *Plast Reconstr Surg.* 1987;80:1-14.
50. **Smedley BD, Stith AY, Nelson AR, editors.** *Unequal treatment: confronting racial and ethnic disparities in health care.* Washington, DC: National Academies Press; 2002.
51. **Buckelew SP, Huyser B, Hewett JE, Parker JC, Johnson JC, Conway R, Kay DR.** Self-efficacy predicting outcome among fibromyalgia subjects. *Arthritis Care Res*. 1996;9:97-104.
52. **Bandura A.** *Social foundations of thought and action: a social cognitive theory.* Englewood Cliffs, NJ: Prentice-Hall; 1986.
53. **Lorig KR, Mazonson PD, Holman HR.** Evidence suggesting that health education for self-management in patients with chronic arthritis has sustained health benefits while reducing health care costs. *Arthritis Rheum*. 1993;36:439-46.