Do Transtibial Amputations Outperform Amputations of the Hind- and Midfoot Following Severe Limb Trauma?

A Secondary Analysis of the OUTLET Study

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Background: The purpose of this study was to compare 18-month clinical and patient-reported outcomes between patients with severe lower-limb injuries treated with a transtibial amputation or a hind- or midfoot amputation. Despite the theoretical benefits of hind- and midfoot-level amputation, we hypothesized that patients with transtibial amputations would report better function and have fewer complications.

Methods: The study included patients 18 to 60 years of age who were treated with a transtibial amputation (n = 77) or a distal amputation (n = 17) and who were enrolled in the prospective, multicenter Outcomes Following Severe Distal Tibial, Ankle, and/or Foot Trauma (OUTLET) study. The primary outcome was the difference in Short Musculoskeletal Function Assessment (SMFA) scores, and secondary outcomes included pain, complications, amputation revision, and amputation healing.

Results: There were no significant differences between patients with distal versus transtibial amputation in any of the domains of the SMFA: dysfunction index [distal versus transtibial], 31.2 versus 22.3 (p = 0.13); daily activities, 37.3 versus 26.0 (p = 0.17); emotional status, 41.4 versus 29.3 (p = 0.07); mobility, 36.5 versus 27.8 (p = 0.20); and bother index, 34.4 versus 23.6 (p = 0.14). Rates of complications requiring revision were higher for distal amputations but not significantly so (23.5% versus 13.3%; p = 0.28). One distal and no transtibial amputees required revision to a higher level (p = 0.18). A higher proportion of patients with distal compared with transtibial amputation required local surgical revision (17.7% versus 13.3%; p = 0.69). There was no significant difference between the distal and transtibial groups in scores on the Brief Pain Index at 18 months post-injury.

Conclusions: Surgical complication rates did not differ significantly between patients who underwent transtibial versus hind- or midfoot amputation for severe lower-extremity injury. The average SMFA scores were higher (worse), although not significantly different, for patients undergoing distal compared with transtibial amputation, and more patients with distal amputation had a complication requiring surgical revision. Of note, more patients with distal amputation required closure with an atypical flap, which likely contributed to less favorable outcomes.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

Traumatic injuries of the foot, ankle, and distal tibia are difficult to treat and often beset by poor patient outcomes. Several prospective multicenter studies have sought to elucidate differences in patient outcomes between those undergoing limb salvage and those undergoing amputation for these severe injuries, in both civilian and military populations[1-6]. These studies suggest situations in which treatment with amputation results in better outcomes than limb salvage does; however, questions remain about the optimal amputation level for these injuries.

*The members of The Major Extremity Trauma Research Consortium are included in a note at the end of the article.

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The ideal amputation level for a given patient, and injury, has increasing importance as prosthetic and orthotic technologies improve[7]. Established amputations distal to the knee include transtibial amputation, ankle disarticulation with leveling of the malleoli (Syme), talar resection with arthrodesis of the calcaneal remnant to the tibia (Boyd or modified Pirogoff), midtarsal disarticulation through the talonavicular and calcaneocuboid joints (Chopart), midtarsal disarticulation (Lisfranc), and transmetatarsal amputation[8,9]. Most information on these more distal amputations is from diabetic or peripheral vascular disease populations, or in the setting of active infection[10,11]. There are little data on hind- or midfoot amputations in posttraumatic populations[12]. These more distal amputations have the theoretical advantages of improved body image, short-distance ambulation without a prosthesis, and improved energy cost compared with more proximal amputations[9,11,13-15].

The purpose of the current study was to compare outcomes at 18 months post-injury of patients with severe lower-limb injuries participating in a large multi-institutional, prospective cohort study who received a transtibial amputation versus those who received a hind- or midfoot amputation. Despite the theoretical benefits of hind- or midfoot-level amputation, we hypothesized that patients with transtibial amputations would report better function and have fewer complications than those with hind- or midfoot amputations, given the more tenuous nature of the soft-tissue envelope about the foot and distal tibia compared with that around the diaphysis of the tibia.

Materials and Methods

Study Population

The study included patients 18 to 60 years of age who were surgically treated for a severe injury of the distal tibia, ankle, and/or foot and enrolled in the OUTLET study (Outcomes Following Severe Distal Tibia, Ankle, and/or Foot Trauma: Comparison of Limb Salvage Versus Transtibial Amputation Protocol; ClinicalTrials.gov number NCT01606501). OUTLET was an observational study conducted at 31 U.S. Level-I trauma centers and 3 military treatment facilities and designed to answer critical questions regarding the recovery trajectories and outcomes among patients with severe distal tibia, ankle, and/or foot trauma. Inclusion criteria and study management were previously described, with the following injuries included: Gustilo type-III pilon fractures (AO/OTA 43B1.3, 43B2-B3, or 43C[16]), Gustilo type-IIIB or IIIC ankle fractures (AO/OTA 44), Gustilo type-III mid- and/or hindfoot fractures (AO/OTA 81B2-B3, 82B, or 82C), open foot crush or blast injuries from a high-energy mechanism involving the mid- and/or hindfoot with substantial soft-tissue damage, or other severe foot injuries, including closed foot crush or blast injuries[17]. This secondary analysis was restricted to patients who received an amputation at the transtibial, ankle, or hind- or midfoot level, including transmetatarsal amputation.

Details regarding the study's institutional review board approval and implementation of the study protocol were previously published[17].

Data Collection

Patient and Injury Characteristics

Participant demographics, self-reported pre-injury health, employment and marital status, social support, tobacco use, and previous leg injury were collected during the index hospitalization by interviewing the patient. All injuries sustained in the index trauma were documented. Major comorbidities including diabetes, cardiac disease, vascular disease, pulmonary disease, or psychiatric conditions; health insurance; injury classification; amputation level; and type of soft-tissue closure were collected from the medical record and verified by the treating surgeon and prospectively documented at each clinic visit.

Outcomes

Outcomes were assessed at 18 months after injury and at a minimum of 15 months after definitive amputation with use of the Short Musculoskeletal Function Assessment instrument (SMFA) and the Brief Pain Inventory (BPI)[18,19]. The SMFA is a validated, 46-item questionnaire that includes 2 indices: the dysfunction index, with subdomains of daily activities, arm/hand function, mobility, and emotional status, and the bother index[18]. Revision of amputation at the local level or to a higher level and amputation healing as assessed by the treating surgeon were documented at each study visit.

Statistical Analysis

For the primary analysis in the current study, we compared 18-month SMFA scores of patients with transtibial amputations to those of patients with more distal amputations, employing a minimum clinically important difference (MCID) of 7 or more, in line with previous reports of these data[20]. We performed comparative analyses of the cohorts, evaluating baseline demographic and injury characteristics as well as secondary outcomes, including revision surgeries. Nominal variables (sex, race/ethnicity, marital status, education level, social and emotional support, health insurance status, self-evaluation of health, tobacco use, comorbidities, concomitant injury, injury location, flap type, prior injury, need for revision, reason for revision) were compared using Fisher exact tests, while numeric variables (age, time to amputation, number of operating room [OR] trips prior to definitive amputation, body mass index [BMI], SMFA, and BPI scores) were compared using Wilcoxon rank sum tests. Because of the small sample size, comparisons were unadjusted and the focus of the analysis was to characterize outcomes for the 2 amputation levels. Significance was defined as $p \leq 0.05$.

Results

There were 77 transtibial and 17 distal amputations (5 Syme, 7 midtarsal [through the joint], and 5 transmetatarsal [through the metatarsal bone]). The average patient age was 39.8 years, 86.2% of the patients were male, and 51.1% were active tobacco users at baseline. Patients with transtibial and distal amputations were similar with respect to pre-injury demographics (Table I). Compared with transtibial amputation, a significantly higher proportion of patients with distal amputation presented with foot crush or blast injuries (94% versus 52%; p =

TABLE I Pre-Injury Patient Characteristics*

	Overall	Distal, N = 17	Transtibial, N = 77	P Value†
Age‡	39.83 ± 13.1	41.82 ± 11.8	39.39 ± 13.4	0.5390§
BMI‡	29.17 ± 5.83	28.09 ± 4.14	29.41 ± 6.14	0.6163§
Male sex	81 (86.17)	14 (82.35)	67 (87.01)	0.6983
Race/ethnicity				0.96
Hispanic	7 (7.45)	1 (5.88)	6 (7.79)	
Non-Hispanic non-White	17 (18.09)	3 (17.65)	14 (18.18)	
Non-Hispanic White	70 (74.47)	13 (76.47)	57 (74.03)	
Education				0.9818
No college	50 (53.19)	9 (53.19)	41 (53.24)	
Some college	44 (46.81)	8 (47.06)	36 (46.75)	
Marital status				0.3261
Married, living with partner	44 (48.35)	11 (64.71)	33 (44.60)	
Never married	24 (26.37)	3 (17.65)	21 (28.38)	
Separated/divorced/widowed	23 (25.27)	3 (17.65)	20 (27.03)	
Social and emotional support				0.6995 (3 categories); 0.8989 (binary)
Always	70 (75.27)	13 (76.47)	57 (75)	
Usually, sometimes	20 (21.51)	4 (23.53)	16 (21.05)	
Rarely, never, don't know	3 (3.23)	0 (0)	3 (3.95)	
No health insurance	15 (15.96)	2 (11.76)	13 (16.88)	0.602
Self-evaluation of health				0.5983
Excellent	29 (31.18)	8 (47.06)	21 (27.63)	
Very good	39 (41.94)	5 (29.41)	34 (44.74)	
Good, fair, poor	25 (26.88)	4 (23.53)	21 (27.63)	
No. of major comorbidities#				0.2157
0	53 (56.38)	12 (70.59)	41 (53.25)	
1	20 (21.28)	1 (5.88)	19 (24.68)	
>1	21 (22.34)	4 (23.53)	17 (22.08)	
Current tobacco use	48 (51.06)	9 (52.94)	39 (50.65)	0.8642
Previous leg injury	15 (16.48)	2 (11.76)	13 (17.57)	0.8492

*The values are given as the number, with the percentage in parentheses, except where otherwise noted. †Fisher exact test for all except as noted for age and BMI. ‡The values are given as the mean and standard deviation. §Wilcoxon test. #Major comorbidities included diabetes, cardiac disease, vascular disease, pulmonary disease, or psychiatric conditions.

0.02) and were treated with an atypical residual limb closure (requiring split-thickness skin grant and/or modulation of remaining skin to obtain coverage, often employing fasciocutaneous techniques) (35% versus 17%; p = 0.007). Patients with transtibial amputation underwent a median of 2 OR trips prior to definitive amputation versus a median of 1 trip for those with distal amputation (p = 0.052) (Table II).

At 18 months of follow-up, the distal and transtibial amputation groups did not differ significantly in terms of mean SMFA scores for the dysfunction index (distal versus transtibial, 31.2 versus 22.3; difference, 8.9); daily activities (37.3 versus 26.0; difference, 11.3); emotional status (41.4 versus 29.3; difference, 12.1); mobility (36.5 versus 27.8; difference, 8.7), and the bother index (34.4 versus 23.6; difference, 10.8). While not significant, these differences exceeded the MCID thresholds for 5 of 6 domains. Arm/hand scores are not reported, but were normal in both groups. BPI scores did not differ significantly between the groups at 18 months post-injury (3.2 versus 2.6 for pain severity, p = 0.35; 4.3 versus 2.9 for pain interference, p = 0.17) (Table III).

A higher proportion of patients who had a distal amputation required reoperation compared with those who had a transtibial amputation (distal, 23.5% [4 of 17] versus transtibial, 13.3% [10 of 75]). Of the 4 patients with distal amputation needing a reoperation, 1 patient underwent a revision to a higher amputation level (transtibial), while the remaining 3 patients had local surgery without a change in level. The 10 patients with transtibial amputation who required reoperation remained at the same level but required operative interventions for wound

TABLE II Injury and Treatment Characteristics*

		Definitive Amputation Level		
	Overall	Distal†	Transtibial	P Value
Total	94	17 (18.09)	77 (81.91)	NA
Injury				0.0163‡
Pilon	21 (22.34)	1 (5.88)	20 (25.97)	
Talus/calcaneus	13 (13.83)	0 (0)	13 (16.88)	
Other foot injury (crush, blast)	56 (59.57)	16 (94.12)	40 (51.95)	
Traumatic amputation	4 (4.46)	0 (0)	4 (5.19)	
Ipsilateral injury (pelvis or below)	15 (15.96)	2 (11.76)	13 (16.88)	0.99‡
Contralateral limb injury	12 (12.77)	2 (11.76)	10 (12.99)	0.99‡
Flap				0.0072‡
Standard	70 (74.47)	8 (47.06)	62 (80.52)	
Atypical	19 (20.21)	6 (35.29)	13 (16.88)	
Other	5 (5.32)	3 (17.65)	2 (2.6)	
Time from injury to definitive amputation§ *(days)*	9.31 ± 9.11	7.29 ± 6.16	9.75 ± 9.62	0.5546#
No. of OR trips prior to definitive amputation**	2 [1-3]	1 [1-2]	2 [1-3]	0.052#

*The values are given as the number, with the percentage in parentheses, except where otherwise noted. NA = not applicable. †The distal group consisted of 5 Syme, 7 midtarsal, and 5 transmetatarsal amputations. ‡Fisher exact test. §The values are given as the mean and standard deviation. #Wilcoxon test. **The values are given as the median, with the range in square brackets.

issues or infection (8), neuroma (1), and heterotopic ossification (1) (Table IV).

Discussion

With this study, we aimed to compare patient-reported and clinical outcomes following severe lower-extremity injuries treated with either transtibial amputation or more distal hind- or midfoot amputation. Patient-reported SMFA scores for those with transtibial amputation were not significantly different from, but were superior to, the scores of those with distal amputation by more than the MCID for all 5 domains of the SMFA relevant to the study population (excluding arm/hand function). The MCID is defined as the smallest amount by which a score must change to reflect a clinically relevant difference[21]. Recent studies established 7 or greater as the MCID for the SMFA[20,21]. The authors of those studies did not find consistent differences in the MCID between the analysis techniques when stratifying by injury severity, with severe injuries defined as needing delayed fixation or being limb-threatening. They concluded that an MCID of 7 to 10 is defensible for the dysfunction index of the SMFA. Using the upper bound of 10 for our results, SMFA scores still differed by more than the MCID in 3 of the 6 unadjusted subscores (daily activities, emotional status, and bother). Furthermore, our analysis did not find significant

TABLE III Patient-Reported Pain and Function at 18 Months Following Injury*

	Overall, N = 94	Distal, N = 17	Transtibial, N = 77	P Value
Brief Pain Index				
Pain severity	2.68 (2.22)	3.21 (2.44)	2.55 (2.17)	0.3465
Pain interference	3.21 (3.17)	4.33 (3.54)	2.94 (3.04)	0.1678
SMFA				
Dysfunction index	24.07 (18.74)	31.23 (21.08)	22.25 (17.84)	0.1269
Daily activities	28.22 (26.44)	37.33 (30.49)	25.97 (25.12)	0.1738
Emotional status	31.72 (23.24)	41.43 (23.9)	29.33 (22.63)	0.0701
Mobility	29.5 (21.66)	36.49 (23.87)	27.79 (20.93)	0.1977
Arm/hand function	4.6 (10.3)	8.74 (14.61)	3.59 (8.8)	0.035
Bother index	25.75 (23.16)	34.44 (26.96)	23.58 (21.82)	0.1369

*The values are given as the mean, with the standard deviation in parentheses.

TABLE IV Complications*

	Overall, N = 92	Distal, N = 17	Transtibial, N = 75†	P Value‡
Overall revision (local level and higher level)	14 (15.22)	4 (23.53)	10 (13.33)	0.2828
Required surgical revision to higher level (infection)	1 (1.09)	1 (5.88)	0 (0)	0.18
Healing				0.074
Healed at intended level, uncomplicated	68 (73.91)	9 (52.94)	59 (78.67)	
Healed at intended level with wound care	10 (10.87)	4 (23.53)	6 (8)	
Healed at intended level with surgical revision	13 (14.13)	3 (17.65)	10 (13.33)	
Reason for local surgical revision				0.69
Infection	2 (2.12)	1 (5.88)	1 (1.33)	
Wound necrosis	4 (4.34)	1 (5.88)	3 (4.00)	
Aseptic	7 (7.61)	1 (5.88)	6 (8.00)	

*The values are given as the number, with the percentage in parentheses. †Two of the 77 transtibial amputees were missing complications data. ‡Fisher exact test.

differences in surgical complication rates between patients who underwent transtibial amputation and those with hind- or midfoot amputation. Distal amputations were more often performed following crush or blast injuries, required closure with an atypical flap, and needed local surgical revision.

This paper adds to the evidence guiding the counseling and treatment of patients presenting with lower-limb-threatening injuries. Prior studies have addressed outcomes between salvage and amputation for the mangled lower limb. These include the Lower Extremity Assessment Project (LEAP), including civilians, and the Military Extremity Trauma Amputation/Limb Salvage (METALS) study, including service members[2,22]. The current study compares outcomes of patients with different lower-extremity amputation levels.

Reports of outcomes after hind- and midfoot amputations for trauma are limited. Most reports on these amputation levels have focused on patients with diabetes, peripheral vascular disease, infections, or tumors. While there are several small series and case reports in the literature on hind- and midfoot amputations for trauma, the heterogeneous injury types, surgical techniques, and reported outcome measures, and the small patient numbers without comparison groups make it difficult to interpret prior reports[23-29]. Our study was an attempt to compare outcomes of patients undergoing hind- and midfoot versus transtibial amputations after traumatic injury.

This study has notable strengths. Given the limited published outcomes for patients undergoing hind- and midfoot amputations for trauma, the prospective nature and detailed follow-up information of this series add valuable information on this subject. Patients were followed for 18 months, exceeding the 12-month minimum typically required for follow-up in orthopaedic trauma. Castillo et al. found that extending the time of follow-up beyond 1 year adds little understanding of outcomes among orthopaedic trauma patients while adding cost[30]. Our findings are widely generalizable, given the study's multicenter nature. In terms of study limitations, the unbalanced group sample sizes, small sample sizes, and unequal variances between groups are related sources of bias that reduced the statistical power achieved at the 5% level of significance and limited our ability to conduct additional analyses to adjust for confounders that might have influenced the outcomes, including surgeon experience and preference, and injury characteristics. Despite this limitation, we believe that this study adds valuable information to the orthopaedic literature for the purposes of patient counseling and surgical decision-making. Specifically, our findings suggest that patients with lower-extremity, trauma-related amputations should be advised that additional surgeries, including local revision, may be necessary.

Conclusions

Rates of complications requiring surgery did not differ significantly between patients who underwent transtibial amputation and those who underwent hind- or midfoot amputation for severe lower-extremity injury. While limited by small numbers of distal amputations and not significantly different, the differences between transtibial and distal amputations in most (5 of 6) unadjusted SMFA scores were higher by more than the accepted MCID of 7 or more points. It is possible that factors such as soft-tissue coverage or the mechanism of injury drove differences between the groups and might have been detected with a larger sample size. Although the differences did not reach significance, average SMFA scores were higher (worse) for patients undergoing distal compared with transtibial amputation, and more patients with distal amputation had a complication requiring surgical revision. Of note, more patients with distal amputation required closure with an atypical flap, which likely contributed to less favorable outcomes. The small sample size limited statistical comparisons; however, these findings warrant further investigation, given the implications for treatment decision-making. ■

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