

# The MangLE score: A novel simple tool to identify patients who are unlikely to require amputation following severe lower extremity injury

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<b>BACKGROUND:</b>	There are no validated and sensitive models that can guide the decision regarding amputation in patients with mangled lower extremities. We sought to describe a simple scoring model, the Mangled Lower Extremity (MangLE) score, which can predict those who are highly unlikely to need an amputation as a means to direct resources to this cohort.
<b>METHODS:</b>	This is a retrospective study using the 2013–2021 American College of Surgeons Trauma Quality Improvement Program data set. Adult patients with a mangled lower extremity, defined as a crush injury or a fracture of the femur or tibia combined with severe soft tissue injury, arterial injury, or nerve injury, were included. Patients who suffered a traumatic lower extremity amputation, underwent amputation within 24 hours of admission, or who died within 24 hours of admission were excluded. Patients were divided into those who did/did not undergo amputation during their hospital stay. Demographics, injury mechanism, Injury Severity Score, and Abbreviated Injury Scale score, initial vital signs, and comorbid conditions were abstracted. A logistic regression model was constructed and the top five most important variables were used to create the score.
<b>RESULTS:</b>	The study includes 107,620 patients, of whom 2,711 (2.5%) underwent amputation. The five variables with the highest predictive value for amputation were arterial injury, lower-extremity Abbreviated Injury Scale score of $\geq 3$ , crush injury, blunt mechanism, and shock index. The lowest possible MangLE score was 0, and the highest was 15. The model demonstrated an excellent predictive ability for lower extremity amputation in both the development and validation data set with an area under the receiver operating characteristic curve of 0.81 (95% confidence interval, 0.80–0.82) and 0.82 (95% confidence interval, 0.81–0.84), respectively. The negative predictive value for a score of $< 8$ is 99%.
<b>CONCLUSION:</b>	The MangLE score is able to identify patients who are unlikely to require amputation. Resources for limb salvage can be directed to this cohort. ( <i>J Trauma Acute Care Surg.</i> 2025;98: 160–166. Copyright © 2024 Wolters Kluwer Health, Inc. All rights reserved.)
<b>LEVEL OF EVIDENCE:</b>	Prognostic and Epidemiological; Level IV.
<b>KEY WORDS:</b>	Amputation; mangled extremity; crush.

Mangled lower extremity is a rare injury associated with significant lifelong morbidity. One of the most difficult decisions in the management of a mangled extremity is recommending for early amputation versus repeated operative interventions to include stabilization of bony structures, revascularization, nerve repair, and soft tissue debridement with final soft tissue coverage/reconstruction of the limb.<sup>1</sup> A recent study found that more than 50% of patients who sustain a mangled lower extremity ultimately undergo amputation during the index hospitalization and that ongoing attempts to salvage the limb are associated with acute kidney injury.<sup>2</sup> As well, ongoing attempts to salvage a limb that will ultimately be amputated are associated with increased cost, length of stay, and likely stress for the patient.

Several scores have been developed to predict which patients will most likely require amputation, the Mangled Extremity Severity Score (MESS) being the most commonly used.<sup>3</sup> However, the utility of this score has been called into question in the modern era, which allows for advanced revascularization techniques and soft tissue manipulation.<sup>4</sup> Currently, there is no consensus about the ideal method to predict favorable limb salvage outcomes. Ly et al.<sup>5</sup> performed an evaluation of the ability of current scores to predict limb salvage and found that none predicted functional outcomes accurately or reliably. A study

from 1990 using the MESS proposed a score of  $\geq 7$  as highly predictive of amputation.<sup>6</sup> Recent studies analyzed the validity of the MESS but were unable to replicate the results found in the original or in subsequent studies of this score.<sup>7</sup>

All scoring systems to date have attempted to predict who needs a lower extremity amputation, and there are no studies evaluating who does not need an amputation as the primary outcome. A scoring system that accurately predicts low likelihood of lower extremity amputation could guide patient counseling and direct multidisciplinary resources to appropriate patients. To address this need, we developed the Mangled Lower Extremity (MangLE) score based on contemporary data. Our objective was to identify the patients most likely to undergo successful limb salvage following severe lower extremity injury so that resources can be appropriately mobilized for their recovery.

## PATIENTS AND METHODS

### Source of Data

Data were retrieved from the 2013–2021 American College of Surgeons Trauma Quality Improvement Program (TQIP) data set. We adhered to the Declaration of Helsinki and the Transparent Reporting of a Multivariable Prediction Model for individual prognosis or diagnosis guidelines (Supplemental Digital Content, Supplementary Table 1, <http://links.lww.com/TA/D993>). Need for institutional review board approval was waived for this study.

### Participants

The study included all adult patients (18 years or older) who were admitted with a mangled lower extremity. Consistent with previous studies,<sup>2,8</sup> a mangled lower extremity was defined as a crush injury or a fracture of the femur or tibia combined with severe soft tissue injury, arterial injury, or nerve injury. The injury codes used for the query are noted in Supplemental Digital Content (Supplementary Table 2, <http://links.lww.com/TA/D993>). Patients who suffered a traumatic lower extremity amputation, underwent a surgical lower extremity amputation

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within 24 hours of admission, or died within 24 hours of admission were excluded. A random sample consisting of 80% of the patients in the data set was used for developing the MangLE score, while the remaining 20% were used for validation.

### Outcomes

The primary outcome of interest was lower extremity amputation.

### Descriptive and Inferential Statistical Analyses

Patients were grouped based on if they did or did not undergo a lower extremity amputation. Continuous variables were summarized as means and SDs or medians and interquartile ranges based on the individual variable's distributions. Correspondingly, the Student's *t* test and Mann-Whitney *U* test were used to determine the statistical significance of differences between the cohorts. For categorical variables, counts and percentages were used instead, while significance testing was performed using the  $\chi^2$  test or Fisher's exact test, as appropriate.

Statistical significance was defined as a two-sided *p* value of  $\leq 0.05$ . Missing data were managed using multiple imputations by chained equations. Analyses were performed using the statistical programming language R (R Foundation for Statistical Computing, Vienna, Austria) using the *tidyverse*, *DALEX*, *parallel*, *pROC*, *mice*, and *cowplot* packages.

### Variable Importance Determination

Potentially relevant variables for developing the MangLE score were extracted from the TQIP database. These included age, sex, race, Injury Severity Score (categorized as  $\leq 9$ , 10–15, 16–25, and  $>25$ ), body region Abbreviated Injury Scale (AIS) score (dichotomized as 0–2 vs.  $\geq 3$ ), presence of a femur or tibia fracture, severe soft tissue injury, arterial injury, nerve injury, crush injury, shock index (categorized as  $\leq 0.7$ , 0.7–0.9, and  $>0.9$ ), admission systolic blood pressure of  $<90$  mm Hg, admission pulse  $>100$  beats per minute, admission temperature  $<35^\circ\text{C}$  or  $\geq 38.5^\circ\text{C}$ , admission oxygen saturation  $<90\%$ , admission respiratory rate  $>20$  or  $<12$  breaths per minute, admission Glasgow Coma Scale (categorized as 3–8, 9–13, and 14–15), steroid use, comorbidity count, history of myocardial infarction, history of angina, history of peripheral vascular disease, hypertension, cerebrovascular disease, diabetes mellitus, chronic renal failure, dementia, chronic obstructive pulmonary disease, current smoker, cirrhosis, major psychiatric illness, coagulopathy, and type of trauma (blunt or penetrating).

A logistic regression (LR) model was constructed using these candidate variables as predictors and lower extremity amputation as the response variable. The relative importance of each candidate variable within the model was determined using permutation importance, which assessed the impact on a predefined value (1 – area under the receiver operating characteristic curve [AUROC]) when a specific variable was omitted.<sup>9</sup> Instead of just removing the variable from the data set, this method replaced it with random variables from other cases by shifting the values of the variable, effectively concealing the variable's information during the evaluation. This process was repeated 10 times to account for the inherent uncertainty linked to permutations. The relative importance of each variable in the model was then presented as the average increase in 1 – AUROC

compared with the AUROC in a model containing all variables without masking. The top five most important variables, based on their relative importance, were subsequently chosen for inclusion in the MangLE score.

### Development of the MangLE Score

A new LR model was fitted to the development data set with lower extremity amputation as the outcome and only the top five variables as predictors. The shock index was converted into two binary dummy variables, and therefore, there were six variables in the model. The MangLE score for each patient was calculated as follows. First, multiply the value (0 or 1) of each variable by two times its coefficient obtained from the LR model mentioned previously and then round the result to the nearest integer. Second, calculate the MangLE score by summing up these rounded integers. The calculation can be expressed using the following formula and is illustrated in Table 1:

$$\text{MangLE} = \sum_{i=1}^6 [2\beta_i x_i - 0.5]$$

where  $\beta_i$  is the LR model coefficient of a variable and  $x_i$  is 0 or 1.<sup>10</sup>

### Validation of the MangLE Score

The MangLE score was computed for each patient in the validation data set to assess its ability to predict lower extremity amputation. Using a new LR model, its performance was evaluated based on the AUROC as well as the sensitivity and specificity that maximized Youden's index (sensitivity + specificity – 1). This same cutoff was used to calculate the positive and negative predictive values. The confidence intervals (CIs) for the AUROCs were determined using the variance of the AUROC as outlined by DeLong et al.<sup>11</sup> using the algorithm proposed by Xu and Xu.<sup>12</sup> The remaining CIs were estimated using a stratified bootstrapping method with 2,000 replicates.

**TABLE 1.** Mangled Lower Extremity Score

Variable	Value	Points*
Arterial injury	False	0
	True	4
Lower extremity AIS score $\geq 3$ **	False	0
	True	3
Crush injury	False	0
	True	3
Type of trauma	Penetrating	0
	Blunt	3
Shock index	$\leq 0.7$	0
	0.7–0.9	1
	$>0.9$	2
Total score:		0–15

\*Points are calculated using  $[2\beta_i x_i - 0.5]$ , where  $\beta_i$  is the LR model coefficient of a variable and  $x_i$  is 0 or 1.<sup>10</sup>

\*\*See Table 5 for specific injuries.

## RESULTS

After applying the inclusion and exclusion criteria, 107,620 patients remained for further analysis (Table 2). Furthermore, 2.5% (n = 2,711) underwent amputation >24 hours after admission, and the median time to amputation was 6.8 days (interquartile range, 3–13 days). There was no significant age difference between those who did and did not undergo amputation. The majority of patients in both cohorts were male and non-Hispanic White. There was no significant difference in the number of comorbidities between the two groups; however, peripheral vascular disease (1.4% vs. 0.4%,  $p < 0.001$ ), diabetes mellitus (11.1% vs. 9.8%,  $p = 0.022$ ), active smoking (29.3% vs. 26.3%,  $p < 0.001$ ), and cirrhosis (1.0% vs. 0.6%,  $p = 0.003$ ) were significantly more common among those who were amputated.

Patients who underwent amputation had a significantly higher median Injury Severity Score (14 vs. 10,  $p < 0.001$ ), incidence of crush injury (15.3% vs. 4.5%,  $p < 0.001$ ), presence of arterial injury (56.1% vs. 15.0%,  $p < 0.001$ ), and presence of nerve injury (8.6% vs. 4.6%,  $p < 0.001$ ). Conversely, there was a significantly higher rate of severe soft tissue injury in the nonamputated group than in the amputated group (82.4% vs. 53.0%,  $p < 0.001$ ). Amputated patients had a significantly higher shock index on arrival, although the median shock index was less than one in both cohorts (0.83 vs. 0.68,  $p < 0.001$ ) (Table 3). Other injury characteristics of each cohort are noted in Supplemental Digital Content (Supplementary Table 3, <http://links.lww.com/TA/D994>).

Unadjusted outcomes for patients with lower extremity amputation differed significantly in all categories. Patients who underwent amputation had significantly higher risk of in-hospital mortality (5.5% vs. 1.7%,  $p < 0.001$ ), intensive care unit

admission (80.3% vs. 35.8%,  $p < 0.001$ ), and median intensive care unit length of stay (8.0 days vs. 4.0 days,  $p < 0.001$ ). In addition, the amputated group had significantly higher rates of mechanical ventilation (54.7% vs. 18.7%,  $p < 0.001$ ) and longer median ventilator duration (5.0 days vs. 4.0 days,  $p < 0.001$ ) (Table 4).

Based on the permutation importance estimated using the development data set, the top five most important variables included in the LR model were arterial injury, lower extremity AIS score of  $\geq 3$ , crush injury, mechanism of injury, and shock index (Table 1). Arterial injury, lower extremity AIS score of  $\geq 3$ , presence of crush injury, and blunt trauma were scored as either present or absent. Presence of arterial injury contributed 4 points, while lower extremity AIS score of  $\geq 3$ , crush injury, and blunt trauma each contributed 3 points if present. Specific injuries that have an AIS score of 3 are noted in Table 5. Initial shock index was graded with shock index of  $\leq 0.7$  contributing 0 points, shock index of 0.7 to 0.9 contributing 1 point, and shock index of  $>0.9$  contributing a maximum of 2 points (Table 1).

In the development data set, the MangLE score exhibited an excellent predictive ability with an AUROC of 0.81 (AUROC [95% CI], 0.81 [0.80–0.82]). In the validation data set, the MangLE score still retained an excellent predictive ability with an AUROC of 0.82 (AUROC [95% CI], 0.82 [0.81–0.84]) (Supplemental Digital Content, Supplementary Table 4, <http://links.lww.com/TA/D995>).<sup>13</sup> The cutoff that maximized Youden's index was a MangLE score of  $\geq 8$ . This resulted in a positive predictive value of 7.4% for predicting the need for amputation and a negative predictive value of 99.2% for predicting that an amputation is not needed. A cutoff at the maximum MangLE score of 15 results in a positive predictive value of 34.3% and a

**TABLE 2.** Demographics of Patients With a Mangled Lower Extremity

	Nonamputated (n = 104,909)	Amputated (n = 2,711)	<i>p</i>
Age, median (IQR), y	41 (28–57)	43 (29–56)	0.366
Sex, n (%)			<0.001
Female	35,436 (33.8)	507 (18.7)	
Male	69,280 (66.0)	2,198 (81.1)	
Missing	193 (0.2)	6 (0.2)	
Race, n (%)			0.007
Non-Hispanic White	59,633 (56.8)	1,636 (60.3)	
Hispanic or Latino	5,683 (5.4)	135 (5.0)	
Black	20,769 (19.8)	481 (17.7)	
Other	11,952 (11.4)	306 (11.3)	
Missing	6,872 (6.6)	153 (5.6)	
Comorbidity count, n (%)			0.086
0	47,927 (45.7)	1,181 (43.6)	
1–2	48,883 (46.6)	1,308 (48.2)	
$\geq 3$	8,099 (7.7)	222 (8.2)	
History of peripheral vascular disease, n (%)	442 (0.4)	39 (1.4)	<0.001
Diabetes mellitus, n (%)	10,239 (9.8)	301 (11.1)	0.022
Current smoker, n (%)	27,548 (26.3)	795 (29.3)	<0.001

IQR, interquartile range.

**TABLE 3.** Clinical Characteristics of Patients With a Mangled Lower Extremity

	Nonamputated (n = 104,909)	Amputated (n = 2,711)	p
Injury Severity Score, median (IQR)	10 (5–17)	14 (9–22)	<0.001
Injury Severity Score, n (%)			<0.001
≤9	47,792 (45.6)	693 (25.6)	
10–15	26,741 (25.5)	768 (28.3)	
16–25	18,381 (17.5)	687 (25.3)	
26–75	11,995 (11.4)	563 (20.8)	
Lower extremity AIS, n (%)			<0.001
2	41,796 (39.8)	264 (9.7)	
3	58,048 (55.3)	2,062 (76.1)	
4	4,086 (3.9)	294 (10.8)	
5	978 (0.9)	91 (3.4)	
Missing	1 (0.0)	0 (0.0)	
Crush injury, n (%)	4,751 (4.5)	415 (15.3)	<0.001
Femur or tibia fracture, n (%)	101,671 (96.9)	2,519 (92.9)	<0.001
Severe soft tissue injury, n (%)	86,482 (82.4)	1,437 (53.0)	<0.001
Arterial injury, n (%)	15,777 (15.0)	1,520 (56.1)	<0.001
Nerve injury, n (%)	4,785 (4.6)	234 (8.6)	<0.001
Mechanism of injury, n (%)			<0.001
Motor vehicle collision	39,750 (37.9)	984 (36.3)	
Motorcycle crash	15,326 (14.6)	843 (31.1)	
Pedestrian/cyclist struck	2,796 (2.7)	110 (4.1)	
Machinery	1,475 (1.4)	92 (3.4)	
Other blunt mechanism	27,638 (26.3)	207 (7.6)	
Penetrating	9,875 (9.4)	242 (8.9)	
Other	7,050 (6.7)	216 (8.0)	
Missing	999 (1.0)	17 (0.6)	
Shock index, median (IQR)	0.68 (0.56–0.84)	0.83 (0.64–1.1)	<0.001
Missing, n (%)	2309 (2.2)	69 (2.5)	
Glasgow Coma Scale, n (%)			<0.001
Mild (14–15)	89,357 (85.2)	2,039 (75.2)	
Moderate (9–13)	4,116 (3.9)	208 (7.7)	
Severe (3–8)	7,208 (6.9)	385 (14.2)	
Missing	4,228 (4.0)	79 (2.9)	

IQR, interquartile range.

negative predictive value of 97.5% for amputation (Table 6). The probability of amputation ranges from 0% for patients with a MangLE score between 0 and 2 and more than 34% for those with a MangLE score of 15.

### DISCUSSION

Determining whether to recommend amputation for a mangled lower extremity remains controversial with no contemporary, simple, and validated scoring systems to help guide this decision.<sup>1</sup> To date, all scoring systems have attempted to identify those likely to require amputation/fail attempts at limb salvage. The aim of this study was to develop and validate a simple yet accurate score to identify patients who are highly unlikely to require amputation following severe lower extremity trauma. Using a cutoff score of 8, the MangLE score achieved a negative predictive value of more than 99% for amputation with an overall AUROC of 0.82. Thus, the score may be useful in determining

**TABLE 4.** Unadjusted Outcomes Among Patients With a Mangled Lower Extremity

	Nonamputated (n = 104,909)	Amputated (n = 2,711)	p
In-hospital mortality, n (%)	1,781 (1.7)	149 (5.5)	<0.001
Sepsis, n (%)	578 (0.6)	138 (5.1)	<0.001
Acute kidney injury, n (%)	1,312 (1.3)	265 (9.8)	<0.001
Time to amputation, median (IQR), d	NA	6.8 (3.2–13)	NA
Length of stay, median (IQR), d	6.1 (3.0–13)	21 (13–34)	<0.001
Missing, n (%)	482 (0.5)	8 (0.3)	
ICU admission, n (%)	37,545 (35.8)	2,176 (80.3)	<0.001
ICU length of stay, median (IQR), d	4.0 (3.0–9.0)	8.0 (4.0–15)	<0.001
Mechanical ventilation, n (%)	19,575 (18.7)	1,483 (54.7)	<0.001
Length of ventilation, median (IQR), d	4.0 (2.0–9.0)	5.0 (2.0–12)	<0.001

ICU, intensive care unit; IQR, interquartile range; NA, not applicable.

**TABLE 5.** List of Injuries in the Lower Extremity That Result in an AIS score of  $\geq 3$

Compartment syndrome
Crush injury
Degloving injury, entire extremity
Penetrating injury, with blood loss $>20\%$ by volume (hip $\rightarrow$ ankle)
Femoral artery injury
Other named arterial or venous injury with blood loss $>20\%$ by volume
Sciatic nerve laceration (incomplete or complete)
Femur fracture
Open tibia fracture
Open ankle fracture (bimalleolar or trimalleolar)

who does not need an amputation, thereby allowing resources to be directed to such patients.

In regard to the model, the two factors that had the most impact on likelihood of limb salvage were absence of arterial injury and an AIS score of  $<3$ . As noted in Table 5, an AIS score of 3 or higher includes the presence of arterial injury, crush injury, and sciatic nerve injury, in addition to other injuries. This means that arterial injury and crush injury are double counted in the scoring model. This is intentional based on the analytic model used to create and validate the scoring system. Thus, the lowest score that a patient with a crush injury can have is 6, and the lowest score that a patient with an arterial injury can have is 7. Onto themselves, these injuries may be associated with successful limb salvage, but the probability of avoiding amputation decreases as other concomitant injuries in the limb are identified.

The scoring model is noteworthy about the differential impact of a severe sciatic nerve injury, which is included in the AIS score of 3, as compared with more distal nerves, such as the tibial or peroneal nerves, which have an AIS score of 2. This is logical in that it should be unusual for a patient to require amputation for a nerve injury located distal to the knee, whereas sciatic nerve injury portends much greater limb dysfunction.

Decisions to delay amputation in an attempt to salvage a limb are associated with recurrent operative soft tissue debridement, possible recurrent attempts at revascularization, and staged orthopedic repair and reconstruction, all of which lead to increased cost and prolongation of hospitalization. Thus, determining to whom such resources should be directed is critical to optimize patient expectations and resource utilization. In our study, a MangLE score up to 8 indicates that the chances of amputation are quite low and patients and clinicians can more confidently pursue maximal efforts toward limb salvage. However, even at its maximum, the positive predictive value of the score was low, meaning that a score greater than or equal to 8 does not necessarily mean that patients will need amputation. At its highest, a score of 15 was associated with a 34% incidence of amputation, suggesting that the majority of limbs can still be salvaged. As such, our findings support ongoing limb salvage efforts in patients with a score of less than 8 but cannot be used to guide decision making in those with a score of 8 or higher. However, as with all large database studies, prospective studies are now needed to validate our results.

While the MESS is the most common metric used when evaluating mangled extremities, surgical care has advanced such

that the ability for successful limb salvage has increased beyond what was possible when the score was first described. Johansen and Hansen<sup>4</sup> concluded that a MESS of 7 or higher does not accurately reflect the current advances in trauma care and have called for recalibration efforts. Unfortunately, limitations in the TQIP database and the retrospective nature of this study preclude us from being able to compare the MangLE score and the MESS.

Other scores guiding mangled lower extremity management have been developed. Howe et al.<sup>14</sup> created the Predictive Salvage Index (PSI), which showed a 78% sensitivity and 100% specificity for need for amputation. However, the same results could not be reproduced in a more recent larger analysis of several scoring systems based on 407 injured limbs.<sup>15</sup> This may be because the original PSI study was based on only 21 injured limbs. The Nerve Injury, Ischemia, Soft-Tissue Injury, Skeletal Injury, Shock and Age of Patient Score was developed to address nerve injuries in addition to the components of the MESS.<sup>16</sup> While initial results were encouraging (81% sensitivity and 92% specificity), as with the PSI score, this score also could not be replicated perhaps because of the inclusion of only 24 limbs in the original study.<sup>15</sup> In our report of the MangLE score, there was acceptable sensitivity of 76% and specificity of 75%, and the validation data set was consisted of more than 20,000 patients. In addition, the finding that the sensitivity and specificity are nearly equal despite there being much fewer cases requiring amputation suggests that the findings are accurate.

There are several limitations to application of the MangLE score. While PPV for amputation increased at scores of 8 and above, it plateaued at 34%. Therefore, the MangLE score cannot be used to predict patients absolutely requiring amputation during their index admission. Another limitation is that we are unable to account for all nuances of lower extremity injuries based on the innate limitations of the TQIP database. Specifically, the TQIP database does not include findings of the neurovascular examination or severity of crush injury/soft tissue injury present. We also are not able to determine what exact therapies the patients received or how care provided varied among the group. Future prospective studies are needed to assess this. In addition,

**TABLE 6.** Positive and Negative Predictive Values of the MangLE Score

Cutoff	Positive Predictive Value, %	Negative Predictive Value, %
$\geq 1$	2.6	100.0
$\geq 2$	2.6	100.0
$\geq 3$	2.6	100.0
$\geq 4$	3.3	99.8
$\geq 5$	3.7	99.6
$\geq 6$	3.9	99.6
$\geq 7$	5.4	99.4
$\geq 8$	7.4	99.2
$\geq 9$	10.6	98.9
$\geq 10$	12.6	98.6
$\geq 11$	14.7	98.3
$\geq 12$	16.2	98.0
$\geq 13$	29.5	97.6
$\geq 14$	28.6	97.5
15	34.3	97.5

the TQIP data set is subject to inaccuracies and data omission, which could impact the development of the MangLE score and does not capture patients who ultimately underwent amputation following discharge from their index hospitalization. Similarly, the data set does not allow us to determine limb function, chronic pain, or other complications of limb salvage.

## CONCLUSION

The MangLE score provides a simple method to identify patients who are highly unlikely to undergo lower extremity amputation. Clinicians can appropriately direct resources for limb salvage in these patients following injury, but prospective studies are needed to determine long-term outcome.

## AUTHORSHIP

M.P.F. contributed in the study design, data analysis and interpretation, and writing of the article. B.C. contributed in the writing of the article. M.M. contributed in the critical review. S.G. contributed in the writing of the article. Y.C. contributed in the data analysis and interpretation, and writing of the article. M.R. contributed in the writing of the article. S.M. contributed in the study design, data interpretation, and critical review. B.S. contributed in the study design, data interpretation, and writing of the article.

## DISCLOSURE

Conflicts of Interest: Author Disclosure forms have been supplied and are provided as Supplemental Digital Content (<http://links.lww.com/TA/D996>).

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