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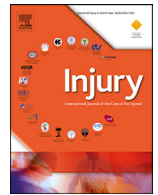
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Modern treatment of tibial shaft fractures: Is there a role today for closed treatment?

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ABSTRACT

Purpose: The decision to attempt closed treatment on tibial shaft fractures can be challenging. At our institution, we attempt treatment of nearly all closed, isolated tibial shaft fractures. The purpose of this study was to report the results of 10 years of experience to develop a tool to identify patients for whom non-operative treatment of tibial shaft fractures may be a viable option

Method: This was a retrospective review of patients with tibial shaft fracture seen at a level 1 trauma center over 10 years. Patients with closed, isolated injuries underwent sedation, closed reduction, long-leg casting, and outpatient follow-up. Patients were converted to surgery for inability to obtain or maintain acceptable alignment or patient intolerance. Radiographic characteristics and patient demographics were extracted. Logistic regression analysis was used to develop a model to predict which patient and injury characteristics determined success of nonoperative treatment.

Results: 334 patients were identified with isolated, closed tibial shaft fractures, who were reduced and treated in a long leg cast. 234 patients (70%) converted to surgical treatment due to inability to maintain alignment, patient intolerance, and nonunion. In a regression model, coronal/sagittal translation, sagittal angulation, fracture morphology, and smoking status were shown to be significant predictors of success of nonoperative treatment ($p < 0.05$). We developed a Tibial Operative Outcome Likelihood (TOOL) score designed to help predict success or failure of closed treatment. The TOOL score can be used to identify a subgroup of patients with injuries amenable to closed treatment (38% of injuries) with a nonoperative success rate over 60%.

Conclusion: Non-operative treatment of tibial shaft fractures is feasible, although there is a relatively high conversion rate to operative treatment. However, it is possible to use injury characteristics to identify a cohort of patients with a higher chance of success with closed treatment, which is potentially useful in a resource-constrained setting or for patients who wish to avoid surgery.

Level of Evidence: Prognostic Level 3

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Introduction

Tibial shaft fractures are common injuries and can be sustained via both high and low energy mechanisms in patients of all ages [1]. In skeletally mature patients with displaced tibial shaft fracture, the most common treatment is intramedullary nail fixation [2,3], as operative treatment allows earlier definitive stabilization, avoids prolonged cast/brace treatment, and may allow for more rapid mobilization as well as faster time to union [4].

Although less commonly practiced, closed treatment is a potentially viable option, and typically involves reduction and casting followed transition to functional bracing [5-8]. The largest case series to date of closed treatment of tibial fractures is by Sarmiento [5-8], and shows that in the right practice environment, non-operative treatment can achieve excellent radiographic results in some patients. However, these results were obtained at a specialty clinic in a relatively unique organization, and the generalizability and reproducibility of that system to other orthopedic surgeons is not well-established [9,10]. Additionally, those case series do not describe the number of patients for whom non-operative treatment was attempted and failed, so it is difficult to assess the suc-

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cess rate of closed treatment or identify factors that would predispose patients to successful or unsuccessful closed treatment.

At our institution, a tertiary referral and Level 1 trauma center, we have been employing a standardized approach with a uniform initial attempt to treat tibia fractures nonoperatively for the past 10 years. We maintain a prospective registry of all consultations seen in the Emergency Department and have a stable local population with a relatively high follow-up rate, which enables us to longitudinally evaluate the outcomes resulting from our approach.

The purpose of this paper is to describe the results of this standardized treatment protocol over a 10-year period to see if it is possible to identify a sub-set of patients with tibial shaft fractures for whom non-operative treatment may have a higher success rate, and hence be a more viable option in situations where surgeons or patients may want to avoid surgery.

Methods

This was a retrospective, observational study conducted with approval of the local Institutional Review Board. This was a sample size of convenience and utilized a prospectively maintained trauma database to identify all patients with acute tibial shaft fractures seen in the emergency department over a 10-year period. Inclusion criteria were patients with an extra articular tibia fracture (AO-OTA type 41A, 42A-C, 43A), seen in the ED with an acute fracture. Exclusion criteria was skeletal immaturity defined as age < 18 years at time of injury.

Treatment protocol

Our protocol involved immediate admission and urgent surgery for patients with open fractures and polytrauma (defined as multi-extremity injury or chest, abdominal, or head injury severe enough to require admission to the general surgery trauma team).

All other patients (i.e. those with isolated tibial shaft fractures who are able to mobilize independently with crutches) underwent sedation in the ED with immediate closed reduction and long leg casting, followed by discharge home after evaluation by physical therapy. For those who maintained acceptable alignment, they were converted as outpatients to a patellar tendon bearing cast and allowed to bear weight as tolerated, and later transitioned into a functional fracture brace until radiographic union.

Acceptable alignment was defined using established parameters which included coronal angulation less than 5°, sagittal angulation less than 10°, rotation less than 5°, shortening less than 1 cm, displacement less than 50% [11]. During the casting phase, the cast would be wedged if alignment was outside of those parameters. If the alignment was unable to be obtained or maintained in a cast, it was converted to surgical treatment. Additionally, the patient would be converted to surgical treatment if unable to tolerate cast treatment or if they had nonunion defined by pain and lack of radiographic progression on serial radiographs at least 6 months after injury.

Data extraction

The electronic medical record was reviewed to extract pertinent clinical information. Demographic information extracted included age, gender, BMI, smoking status, and laterality. Injury characteristics extracted included high vs low energy injury (defined using the same criteria as the case series by Sarmiento et al. [5]), AO/OTA classification, fracture morphology (transverse, oblique/spiral, comminuted, segmental), fracture location (proximal third, middle third, distal third), and radiographic alignment parameters (sagittal angulation/translation, coronal angulation/translation, shortening).

All x-ray classifications and measurements were performed independently by two blinded reviewers (a trained research assistant and a chief resident). When angulation measurements differed by more than 5°, or when translation/shortening measurements were more than 10% different, they were additionally reviewed by the principal investigator (a fellowship trained traumatologist), and the average of the two closest numbers was used.

Data was extracted from subsequent outpatient follow-up visits, which included the number of visits, number of cast manipulations/wedges required, when conversion to a patellar tendon bearing cast was performed, when the patient was advanced to full weight-bearing, and when they were walking without an assistive device/aid. For those patients that failed nonoperative treatment, the reason for conversion to surgical fixation and the timing of that decision was recorded.

Statistical methods

A multivariable logistic regression analysis was performed to evaluate for magnitude of association and statistical significance between injury characteristics and success or failure of non-operative treatment. The analysis was run iteratively. First, we included all potential predictors of success or failure based on previous research. Next, we restricted the model to variables where the Odds Ratio (OR) measure of association was ≥ 1.30 or ≤ 0.76 indicating possible clinical relevance, or if p value was ≤ 0.08 . Finally, we included only variables where p value was ≤ 0.08 . Once the significant predictors of failure were identified, a simplified model was developed to incorporate an individual patient's injury characteristics and predict their chance of success vs. failure of nonoperative treatment.

Source of funding

There were no external sources of funding for this study.

Results

Non-operative success rate and clinic follow-up

Over a 10-year period, a total of 632 patients were identified with tibial shaft fractures. 58% of the patients were male, and the average age was 45 years (range 18–99 years). 49% of the injuries were categorized as high energy mechanisms. Of the 632 patients, immediate surgery was indicated in 228 patients (36%) due to open fracture and in 72 patients (11%) for polytrauma.

The remaining 332 patients with isolated tibial shaft fractures were reduced in the ED and treated in a long leg cast per the protocol described above. Of those 332 patients, 233 of them (70.2%) were converted to surgical treatment, typically within the first 3 weeks after injury (Kaplan Meier curve shown in Fig. 1); 96 patients were converted due to inability to obtain or maintain alignment, 127 patients were converted due to intolerance of closed treatment, and 10 patients were converted to surgical treatment for nonunion (Fig. 2).

For the 99 patients successfully treated without surgery, 86 (86.9%) had complete follow-up (defined as radiographic and clinical union and discharge from clinic) with an average follow-up time of 27.1 weeks, while 13 (13.1%) were lost to follow-up. At time of union, the average absolute coronal and sagittal angulation was 2.4° and 3° respectively, coronal and sagittal translation was 16% and 17% respectively, and shortening of 2.7 mm. One patient was sent to prison and lost to follow up and re-presented to clinic 6 months after injury with a varus malunion requiring an osteotomy. The patients treated nonoperatively had an average of 6.7 (± 3.7) clinic visits, were transitioned to a patellar tendon bearing

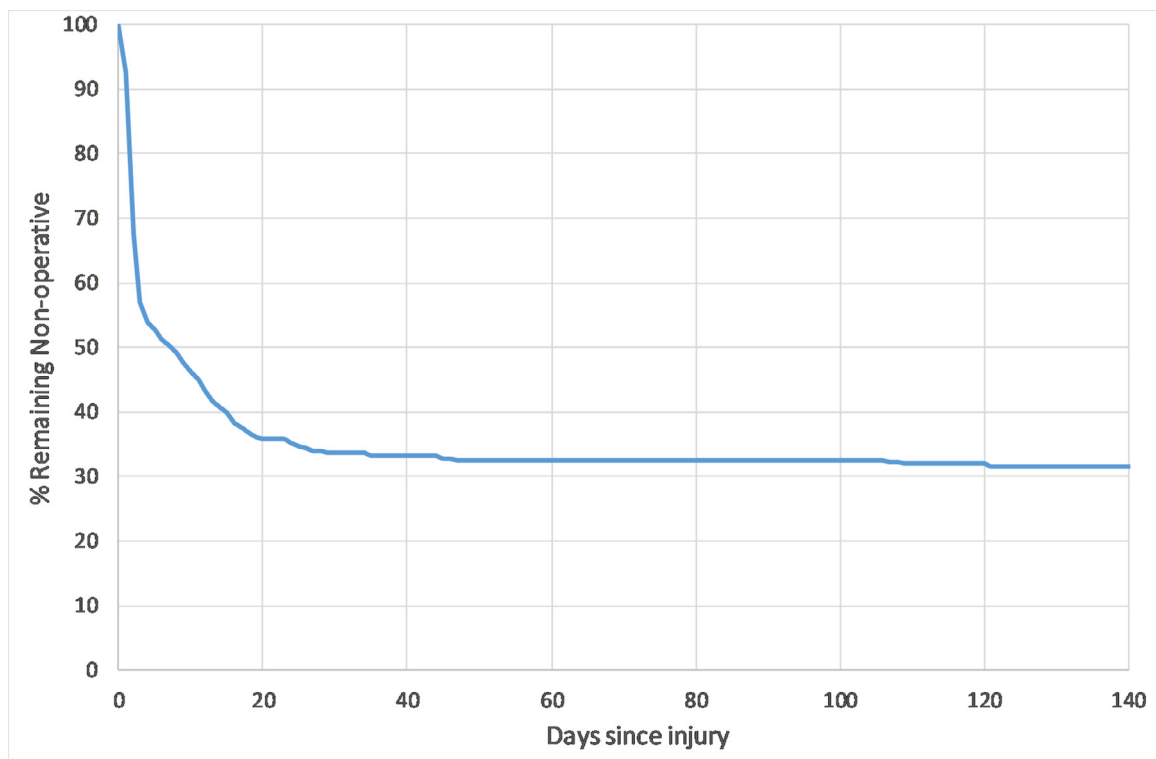


Fig. 1. Kaplan-Meier curve showing percentage of patients remaining in the non-operative group as a function of time from injury.

Table 1

Clinical Follow up for Non-Operatively and Operatively Treated Patients.

	Non-Operative		Failed - Alignment		Failed - Intolerance		Failed - Nonunion	
	Avg or%	SD	Avg or%	SD	Avg or%	SD	Avg or%	SD
Complete follow-up (%)	87	--	92	--	90	--	100	--
Number of clinic visits (#)	6.7	3.3	5.0	2.5	5.1	3.0	10.0	2.7
Average total follow-up [weeks]	27.1	16.1	37.4	40.9	36.0	33.4	101.5	109.8
Required cast adjustments (%)	22	--	--	--	--	--	--	--
Transitioned to PTB cast [weeks]	4.2	1.8	--	--	--	--	--	--
Advanced to WBAT [weeks]	9.6	5.1	5.6	5.0	5.1	6.4	22.7	9.9
Time to walking without aid [weeks]	13.7	7.1	--	--	--	--	--	--

cast at an average of 29 (\pm 13) days from injury. Patients treated with surgery had a 90.6% follow-up rate and had an average of 5.1 (\pm 2.8) clinic visits (Table 1).

Regression model

After the initial logistic regression model, smoking status, body mass index, energy of injury, fracture location and morphology, coronal translation, sagittal translation, and shortening all had an OR \geq 1.30 or \leq 0.76 and/or a p value \leq 0.08 (Table 2). When it was re-iterated using only these values, initial coronal and sagittal translation, shortening, fracture location and morphology, body mass index, and smoking status were all significant predictors of success of nonoperative treatment with a p value of \leq 0.08 (Table 2).

Based on the results of that, we developed a predictive model based on assigning point values for the significant factors. Point values were assigned based on the magnitude of the effect: for an OR of \sim 0.75, 1 point was assigned, for an OR of \sim 0.5, 2 points were assigned, and for an OR of \sim 0.1, 4 points were assigned. For continuous variables (translation), those points were assigned based on the average intra-quartile difference for that variable. Summing all the points created an average score which we named the Tibial Operative Outcome Likelihood (TOOL) score (Table 3).

When we applied the TOOL score retroactively to our cohort of patients, we were able to determine the effectiveness of predicting the likelihood of failure of closed treatment (Table 4). We were able to use this data to generate sensitivity and specificity of the various TOOL score thresholds for predicting success of closed treatment, and generate a corresponding ROC curve, which had an AUC of 0.830, which was comparable to the AUC of the final regression model (AUC 0.845, Fig. 3). A TOOL score cutoff of less than 7 included 121 of the patients with the least severe injuries (38% of total), while maintaining an overall success rate of 60% within that cohort. Conversely, the remaining 62% of patients with a TOOL score of 7 or higher had a success rate of only 13% (i.e. 87% rate of conversion to surgery).

Discussion

The results of this study show that nonoperative treatment of tibial shaft fractures is challenging but possible in some patients. While there is a high rate of conversion to surgery, there is a subset of patients with less severe injuries that have a relatively high success rate. Our analysis suggests the cohort of patients with low TOOL scores ($<$ 7, 38% of isolated fractures in this series) may have a success rate nearly fivefold higher than those with higher scores (60% vs 13%). In the subset of patients with lower TOOL scores,

Table 2
Results of Logistic Regression Analysis.

Full Model with Clinical Measures as Quartiles, others continuous where possible (age, BMI)																
		Age	BMI	Gender	Smoking	Injury Energy	Location (vs. Proximal)	Morphology (vs. Spiral)			Coronal Angulation	Coronal Translation	Sagittal Angulation	Sagittal Translation	Shortening	
		(per 5 yr)	(per 5 unit)	(Female)	(Yes)	High	Distal	Middle	ComSeg	Transverse	Oblique	Per quartile	Per quartile	Per quartile	Per quartile	Per quartile
Original Model	OR	0.93	0.74	1.18	0.44	0.64	0.9	0.21	0.19	1.57	0.79	0.87	0.6	0.79	0.74	0.71
	95% CI	0.96 - 1.01	0.52 - 1.04	0.53 - 2.61	0.21 - 0.94	0.25 - 1.65	0.29 - 2.81	0.06 - 0.76	0.05 - 0.74	0.46 - 5.37	0.28 - 2.25	0.63 - 1.22	0.41 - 0.89	0.57 - 1.1	0.52 - 1.07	0.50 - 1.02
	P-Value	0.209	0.081	0.688	0.033	0.352	0.854	0.017	0.016	0.472	0.66	0.429	0.012	0.181	0.112	0.066
Model restricted to variables where p value ≤ 0.08 or OR ≥ 1.30 or OR ≤ 0.76 - clinical measures as quartiles																
		Age	BMI	Gender	Smoking	Injury Energy	Location (vs. Proximal)	Morphology (vs. Spiral)			Coronal Angulation	Coronal Translation	Sagittal Angulation	Sagittal Translation	Shortening	
		(≥65)	(≥30)	(Female)	(Yes)	High	Distal	Mid	ComSeg	Transverse	Oblique	Per quartile	Per quartile	Per quartile	Per quartile	Per quartile
Revised Model	OR	-	0.73	-	0.46	0.74	0.84	0.23	0.15	1.64	0.89	-	0.59	-	0.73	0.71
	95% CI	-	0.52 - 1.01	-	0.22 - 0.96	0.30 - 1.82	0.28 - 2.52	0.07 - 0.74	0.04 - 0.57	0.51 - 5.28	0.32 - 2.47	-	0.41 - 0.86	-	0.51 - 1.04	0.50 - 1.01
	P-Value	-	0.058	-	0.037	0.51	0.76	0.014	0.005	0.41	0.83	-	0.006	-	0.077	0.058
Revised model restricted to variables where p value ≤ 0.08 (borderline significance) from Revised Model 1 - clinical measures as quartiles																
		Age	BMI	Gender	Smoking	Injury Energy	Location (vs. Proximal)	Morphology (vs. Spiral)			Coronal Angulation	Coronal Translation	Sagittal Angulation	Sagittal Translation	Shortening	
		(≥65)	(≥30)	(Female)	(Yes)	High	Distal	Mid	ComSeg	Transverse	Oblique	Per quartile	Per quartile	Per quartile	Per quartile	Per quartile
Final Model	OR	-	0.73	-	0.45	-	0.86	0.23	0.14	1.53	0.88	-	0.59	-	0.73	0.71
	95% CI	-	0.52 - 1.01	-	0.21 - 0.92	-	0.29 - 2.56	0.07 - 0.74	0.04 - 0.51	0.48 - 4.82	0.32 - 2.43	-	0.41 - 0.85	-	0.52 - 1.04	0.49 - 0.997
	P-Value	-	0.058	-	0.03	-	0.79	0.014	0.003	0.47	0.81	-	0.005	-	0.082	0.048

OR = Odds ratio. CI = confidence interval. BMI = body mass index. ComSeg = Comminuted or segmental pattern.

*(if OR > 1.0, means positively associated with success of non-operative treatment; OR < 1.0 means negatively associated with success—i.e., less likely to have success).

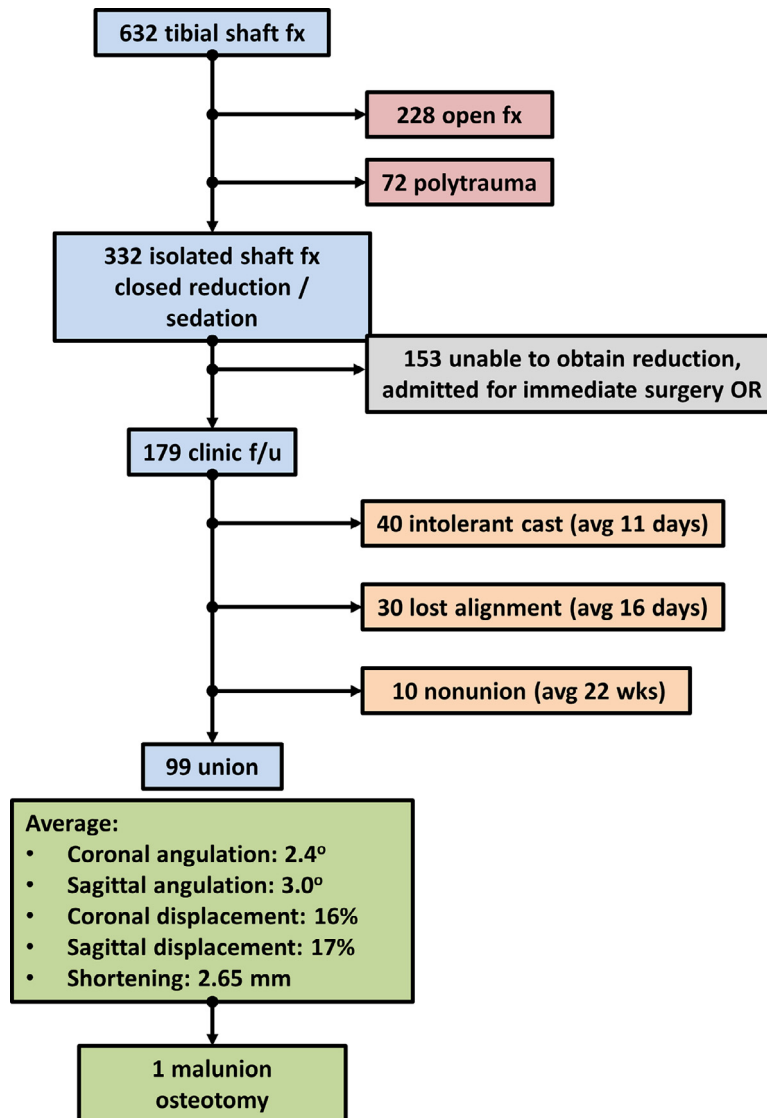


Fig. 2. Patient flow sheet.

Table 3
Methodology for Conversion of Logistic Regression Model to TOOL Score.

Measure	From Regression Model			Converted to TOOL scoring system	
	OR effect	Avg Quartile Size		Point value assigned	For every:
Coronal Translation	0.59	0.18	→	2 points	18% translation
Sagittal Translation	0.73	0.18		1 point	18% translation
Shortening	0.71	5	→	1 point	5 mm shortening
Morphology					
-Spiral	1.0*	n/a	→	0 points	if present
-Oblique	0.88	n/a		1 point	if present
-Transverse	1.53	n/a	→	-2 points	if present
-Comminuted	0.14	n/a		4 points	if present
-Segmental	0.14	n/a	→	4 points	if present
Location					
Proximal Third	1.0*	n/a		0 points	if present
Middle Third	0.23	n/a		4 points	if present
Distal Third	0.86	n/a		1 point	if present
BMI	0.73	per 5 units		1 point	per 5 points over 25
Smoking	0.45	n/a		2 points	if present

* Spiral morphology, proximal third shaft defined as reference morphology.

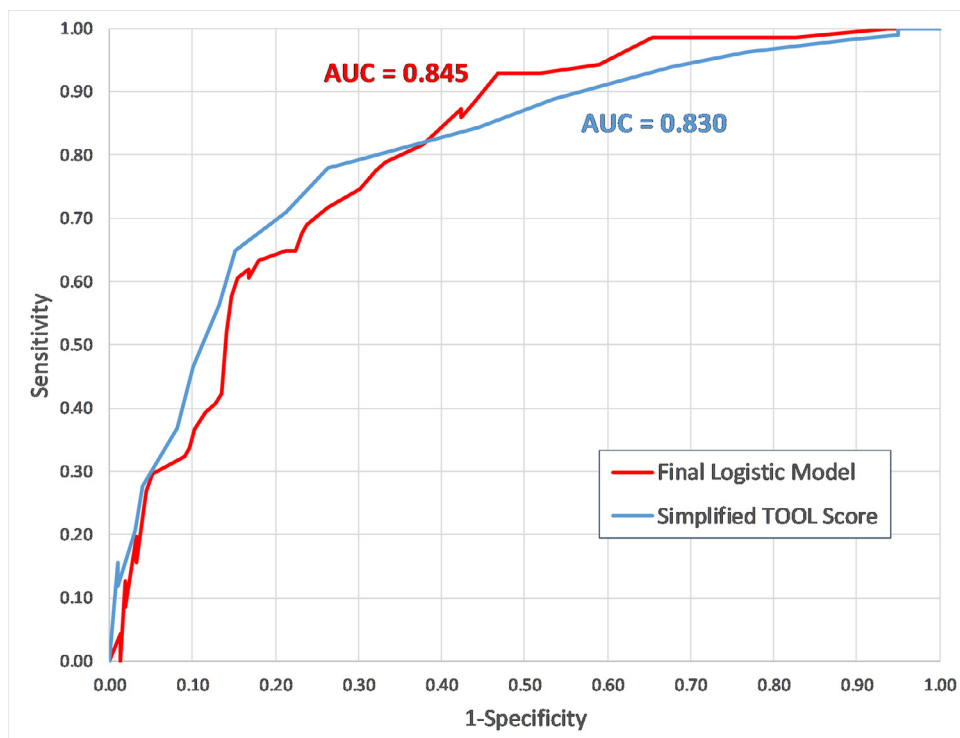


Fig. 3. Receiver operating characteristic (ROC) curve comparing the performance of the final logistic model against the simplified TOOL score.

Table 4
Failure or success of closed treatment by TOOL score.

TOOL Score	n	Failed	Succeed	Success Rate
0	7	2	5	71%
1	8	2	6	75%
2	16	4	12	75%
3	14	5	9	64%
4	25	11	14	56%
5	19	10	9	47%
6	32	14	18	56%
7	20	15	5	25%
8	19	13	6	32%
9	21	19	2	10%
10	24	21	3	13%
11	23	21	2	9%
12	24	20	4	17%
13	16	15	1	6%
14	13	11	2	15%
15	8	8	0	0%
16+	27	26	1	4%

it may be reasonable to consider non-operative treatment based on other exigent circumstances. Logistic regression analysis identified initial coronal and sagittal translation, shortening, fracture morphology and location, body mass index, and smoking status to be significant predictors of success of non-operative treatment. Of note, attempting closed treatment is not appropriate for all patients. We reserve attempts for patients with isolated fractures (no other major injuries) who we anticipate will be able to mobilize safely with crutches and are amenable to the more intense follow-up and lower degree of certainty present in nonoperative treatment. In our experience, those who typically fail closed treatment are those with more severe injuries and thus higher TOOL scores (most significant is usually high degree of translation), have a body habitus that makes cast stabilization challenging, or a psychosocial situation not amenable to intensive follow-up. In those patients, expeditious surgical fixation may be the more reliable course.

Although treating surgeons know that non-operative treatment of tibial shaft fractures is possible, today these injuries are typically treated surgically due to the benefit of earlier mobilization as well as concerns over the uncertainty inherent in nonoperative treatment coupled with the logistical challenges required during clinic follow-up. However, there are situations where a treating surgeon may want to carefully consider non-operative treatment. Logistically, it may be difficult to guarantee early fixation at a busy trauma center with resource limitations, and an attempt at reduction, casting, and discharge may allow safe discharge to either temporize or definitively manage the problem. Additionally, as the recent COVID-19 outbreak has demonstrated, there are situations where physicians may want to minimize patient exposure to a potentially hazardous hospital environment [12]. Finally, some patients may simply have a strong preference to avoid surgery if it all possible, which should be entertained as part of a shared decision-making process. In that context, a tool that could help objectively identify which patients would have a higher success rate with nonoperative treatment would be valuable to help surgeons make challenging resource-allocation decisions.

In that light, our predictive model (TOOL score) performed well as a screening tool with an AUC of 0.83 and represents a simple score that practicing surgeons can use to determine which patients are more likely to fail or succeed with closed treatment. It can be used as concrete data to anchor an evidence-based approach to patient disposition and management in a resource-constrained setting.

There are several limitations to our study which warrant discussion. First, this study is retrospective, and is subject to the typical bias of retrospective data. However, at our institution we have been following a single treatment protocol for over 10 years, and, as part of the protocol, we attempted closed treatment in virtually all tibial shaft fractures (other than open fractures and polytrauma patients), hopefully minimizing the effect of selection bias. Although other centers may choose not to attempt non-operative treatment as aggressively, we feel that our organization's experi-

ence can establish a useful baseline of the “natural history” of attempted closed management of tibial shaft fractures in the modern practice environment. Additionally, the specific indication for conversion to surgery was surgeon and patient specific and can lead to heterogeneity in the primary outcome (failure of closed treatment). However, the surgical indications were applied relatively uniformly across surgeons, and are consistent with those typically found in the literature, and we believe that the factors that contribute to the decision to convert to surgery at our institution are likely roughly in line with current norms. Despite these issues, we feel that the uniform treatment algorithm and large sample size of patients can provide meaningful information to practicing surgeons, even those who do not frequently treat these injuries non-operatively.

This study takes 10 years of institutional experience with standardized non-operative treatment of tibial shaft fractures and synthesizes those results in a way that can help surgeons identify a cohort of patients who may potentially succeed with closed management. Although the mainstay of treatment will likely remain operative, this tool can help surgeons allocate scarce resources and make challenging logistic decisions during periods of crisis or heavy volume, while still achieving acceptable outcomes.

Declaration of competing interest

The authors of this study report no relevant financial or personal relationships that could inappropriately influence or bias the work presented in this manuscript.

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