Intramedullary Nailing of Open Tibial Fractures: Provisional Plate Fixation

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abstract

Tibia fracture is the most common type of long bone fracture, and intramedullary nailing is the preferred treatment. In open fractures, a provisional plate is often used to maintain reduction. It is unknown whether this practice increases the risk of infection or other complications. This study retrospectively compared patients who were treated at a level 1 trauma center with intramedullary nailing of an open tibia fracture. Patients who were included: (1) were 18 years or older; (2) were treated between January 1, 2005, and June 30, 2013; (3) had an open fracture of the tibia; and (4) were treated operatively with intramedullary nailing, with or without provisional plate fixation. Patient sex, history of diabetes, history of smoking, mechanism of injury, and side of injury were analyzed. Postoperative complications included infection, delayed union or nonunion, compartment syndrome, and death. After the authors controlled for age, Gustilo-Anderson type, and AO/Orthopaedic Trauma Association classification, they found that provisional plate use did not significantly increase the risk of infection (adjusted odds ratio, 1.64; 95% confidence interval, 0.51-5.32; *P*=.41) or any other complications (adjusted odds ratio, 1.24; 95% confidence interval, 0.46-3.35; *P*=.67). In the subgroup of patients who had a provisional plate (n=35), removal of the plate did not significantly decrease the risk of infection (adjusted odds ratio, 0.43; 95% confidence interval, 0.07-2.69; *P*=.36) or other complications (adjusted odds ratio, 0.55; 95% confidence interval, 0.12-2.46; *P*=.44). In open tibia fractures treated with intramedullary nailing, provisional plate stabilization, a valuable reduction aid, did not increase the risk of infection or other complications. Because of the small subgroup size, however, definitive conclusions cannot be drawn about removal of these provisional plates. [*Orthopedics*. 2016; 39(5):e931-e936.]

The tibia is the most commonly fractured long bone, with 24% of shaft fractures presenting as open injuries.[1] The traumatic opening introduces an extra layer of complexity, increasing the risk of infection and local wound complications. Open tibia fractures are more prone to infection than nontibia open fractures (10.5% vs 5.3%, respectively), probably because of the subcutaneous location of the bone and challenges associated with soft tissue management and muscular coverage.[2] To reduce these risks, management of open tibia shaft fractures requires timely antimicrobial therapy[2] and thorough surgical debridement.[3]

Previous studies showed that definitive plate fixation in open tibia shaft fractures is associated with a high rate of infection, particularly with increased Gustilo-Anderson types.[4,5] Plating has fallen out of favor because of the negative effects of the surgical dissection required for place-

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ment of appropriately sized surface implants. Intramedullary nailing has become the treatment of choice for open tibia fractures because it offers superior biomechanical properties and excellent clinical outcomes.[6,7]

To assist in maintaining fracture reduction during intramedullary nailing, several techniques have been used, including blocking screws, percutaneous clamping, manual reduction with an assistant, and adjunctive plate fixation.[8-10] A provisional plate (mini-fragment or small fragment plate) may be used after debridement of the traumatic wound, and the plate is either retained or removed before definitive closure.

The current study assessed whether the use of a provisional plate increased the risk of complications in open tibial shaft fractures. In addition, the study analyzed the subgroup of patients who were treated with a provisional plate to determine whether removal of the plate was associated with complications. Despite multiple studies describing the provisional plating technique, few studies have looked at its association with complications.[11]

Materials and Methods

A retrospective study was conducted of patients who were treated with intramedullary nailing for an open tibia fracture at a level 1 trauma center over an 8.5-year period. A list was compiled from the hospital surgical billing database, using *International Classification of Diseases, Ninth Revision* (823.30, 823.32), and Current Procedural Terminology (27759) codes. Patients were included if they met the following criteria: (1) 18 years or older; (2) treated between January 1, 2005, and June 30, 2013; (3) diagnosed with open diaphyseal fracture of the tibia; and (4) treated operatively with intramedullary nailing, with or without provisional plate fixation.

All patients underwent thorough debridement of the traumatic wound. The fracture was reduced, and in certain cases, a mini-fragment or low-profile small fragment (one-third tubular) provisional plate was used (off-label use) to maintain reduction at the discretion of the attending orthopedic trauma surgeon. Intramedullary nailing was the definitive method of fixation. Implants were either retained, with the wounds closed before nailing, or the provisional plate was removed after nailing and before definitive wound closure. Indications for provisional plate fixation included transverse or short oblique fractures that were not amenable to a distal clamp and simple segmental fractures with short working lengths. The authors' protocol is to administer intravenous antibiotics on arrival to the emergency department for all patients with open fractures.

The primary end point was to evaluate whether the use of a provisional plate before intramedullary nailing increases the risk of complications. Electronic medical records were reviewed for patient age, sex, body mass index, diabetes, smoking history, mechanism of injury, side of injury, Gustilo-Anderson type, and AO/Orthopaedic Trauma Association (OTA) fracture classification.[12,13] Operative reports and radiographs were reviewed to determine whether provisional plating was used, and all cases were categorized as either yes or no. Those who had a provisional plate were further stratified into 2 groups: plate removed vs plate retained at the time of definitive closure.

Because few patients had complications, outcome measures for postoperative complications were classified into the following groups: (1) infection (superficial or deep); (2) noninfectious complication (wound healing, delayed union, nonunion, or compartment syndrome); and (3) any complication (combination of infection and noninfectious complications). Patients with complications were independently compared with those who did not have complications. Potential confounders determined in the univariate analysis and added to the multivariate logistic regression model were age, Gustilo-Anderson type, and AO/OTA fracture classification. To minimize potential bias, data were collected and verified by 2 independent surgeons (M.L., R.A.H.). Data were also independently verified and checked for statistical validity (L.R.).

Statistical analysis included descriptive statistics and baseline comparisons of the provisional plate group. Chi-square statistics were used for categorical variables, and independent *t* tests were used for continuous variables. Multiple logistic regression analyses were conducted to answer the research questions, with adjustments for confounding variables. Results were considered significant at alpha=.05 (2-tailed). Statistical analysis was performed with SPSS version 18 software (IBM, Armonk, New York).

Results

During the study period, 143 patients were diagnosed with open diaphyseal tibia fracture. After exclusions for age (n=7), death (n=4), acute amputation (n=1), and insufficient follow-up (n=27), 104 patients remained in the analysis (4 bilateral tibia fractures, N=108 extremities). Of the 108 extremities that were treated with intramedullary nailing, 35 underwent provisional plating and 73 did not.

Average patient age was 37 years (±12.9) (SD), and most patients were male (75%) and nonsmokers (68.9%) (**Table 1**). Average body mass index was 26.9 kg/m^2 (±5.3), and 3.9% of patients had a history of diabetes mellitus. In most cases, the mechanism of injury was related to road traffic accidents (approximately 67% motor vehicle collision, motorcycle collision, or pedestrian struck) vs falls, crush injuries, and other mechanisms. Average follow-up was approximately 10 months. Overall, 27.8% of patients had a complication (16.7% superficial or deep infection; 11.1% other). Of the infections, 5 were associated with wound breakdown. A provisional plate was used in 32.4% of extremities (n=35), and of these, 57.1% (n=20) were retained permanently and 42.9% (n=15) were removed before definitive

Table 1

Demographic and Clinical Characteristics by Provisional Plate Use[a]

Characteristic	Provisional Plate Use		Total	*P*
	Yes	No		
Age, mean (SD), y	41.5 (±13.0)	34.3 (±12.3)	36.6 (±12.9)	.007[b]
Body mass index, mean (SD), kg/m^2	26.2 (±5.3)	27.2 (±5.3)	26.9 (±5.3)	.38
Sex, No. (%)				
Female	8 (23.5)	18 (25.7)	26 (25)	.81
Male	26 (76.5)	52 (74.3)	78 (75)	
Diabetes mellitus, No. (%)				
Yes	2 (5.9)	2 (2.9)	4 (3.9)	.47
No	32 (94.1)	66 (97.1)	98 (96.1)	
Smoking status, No. (%)				
Yes	12 (35.3)	20 (29)	32 (31.1)	.52
No	22 (64.7)	49 (71)	71 (68.9)	
Mechanism of injury, No. (%)				
Motor vehicle collision	7 (20.6)	11 (15.7)	18 (17.3)	.12
Motorcycle collision	11 (32.4)	23 (32.9)	34 (32.7)	
Pedestrian struck	4 (11.8)	14 (20)	18 (17.3)	
Fall (standing)	1 (2.9)	3 (4.3)	4 (3.8)	
Fall (height)	3 (8.8)	9 (12.9)	12 (11.5)	
Crush	7 (20.6)	2 (2.9)	9 (8.7)	
Other	1 (2.9)	8 (11.3)	9 (8.7)	
Side of injury, No. (%)				
Left	18 (51.4)	29 (39.7)	47 (43.5)	.25
Right	17 (48.6)	44 (60.3)	61 (56.5)	
Gustilo-Anderson type, No. (%)				
I and II	15 (42.9)	45 (61.6)	60 (55.6)	.066
III (A and B)	20 (57.1)	28 (38.4)	48 (44.4)	
AO/OTA classification, No. (%)				
42-A	13 (37.1)	49 (67.1)	62 (57.4)	.01[b]
42-B	12 (34.3)	14 (19.2)	26 (24.1)	
42-C	10 (28.6)	10 (13.7)	20 (18.5)	

Abbreviation: AO/OTA classification, AO/Orthopaedic Trauma Association Fracture and Dislocation Classification Compendium.
[a]*N=108 extremities (35 provisional plate used, 73 no provisional plate used, 4 bilateral extremities).*
[b]*Significant* (P<.05).

wound closure. In a subgroup analysis of noninfectious complications, particularly delayed union (n=1) and nonunion (n=8), only 2 cases of nonunion had a provisional plate (n=1 removed; n=1 retained).

Comparison of patients with and without a provisional plate showed no significant differences with respect to body mass index, smoking status, history of diabetes, mechanism of injury, or side of injury (**Table 1**). However, those with a provisional plate were significantly older (t=2.74, df=102, P=.007), and fewer were classified as AO/OTA 42-A (37.1% vs 67.1%, P=.01) compared with the nonplated group. Therefore, age and AO/OTA classification were added as confounding variables in the overall analysis. Additionally, because Gustilo-Anderson type approached statistical significance at baseline by provisional plate use (P=.066, greater percentage of provisional plate use with more complex fractures) and was associated with having a complication (odds

Table 2

Logistic Regression Analysis: Risk of Infection and Any Complication[a]

Demographic	Univariate Odds Ratio (95% Confidence Interval)	Multivariate Odds Ratio (95% Confidence Interval)
Infection		
Age	0.98 (0.94-1.02)	-
AO/OTA type 42-C	1.10 (0.28-4.39)	-
Gustilo type III	1.28 (0.45-3.61)	-
Provisional plate used	1.52 (0.52-4.42)	1.64 (0.51-5.32)
Any		
Age	0.98 (0.94-1.01)	-
AO/OTA type 42-C	2.00 (0.72-5.53)	-
Gustilo type III	2.40 (1.01-5.68)[b]	-
Provisional plate used	1.59 (0.66-3.84)	1.24 (0.46-3.35)

Abbreviation: AO/OTA Classification, Orthopaedic Trauma Association Fracture and Dislocation Classification Compendium.
[a]N=108 extremities. Reference groups: AO/OTA types 42-A and 42-B; Gustilo-Anderson types I and II; no provisional plate.
[b]Significant (P<.05).

Table 3

Provisional Plate Use and Complications[a]

Complication	Provisional Plate Use, No.		Adjusted Odds Ratio[b] (95% Confidence Interval)
	Yes	No	
Infection	7 (20%)	11 (15.1%)	1.64 (0.51-5.32)
Any[c]	12 (34.3%)	18 (24.7%)	1.24 (0.46-3.35)

[a]Percentages are column percentages (denominator: yes, n=35; no, n=73).
[b]Adjusted for age, AO/OTA Classification (Orthopaedic Trauma Association Fracture and Dislocation Classification Compendium), Gustilo-Anderson type. Reference groups: AO/OTA types 42-A and 42-B; Gustilo-Anderson types I and II; no provisional plate.
[c]Includes infection and other complications.

ratio, 2.40; 95% confidence interval, 1.01-5.68; *P*=.046, **Table 2**), Gustilo-Anderson type was also controlled for in the overall multivariate analysis.

In the multiple logistic regression analysis (**Table 2**), after the authors controlled for age, AO/OTA classification, and Gustilo-Anderson type, provisional plate use did not significantly increase the risk of infection (adjusted odds ratio, 1.64; 95% confidence interval, 0.51-5.32; *P*=.41) or the risk of any type of complication (infection and noninfectious) (adjusted odds ratio, 1.24; 95% confidence interval, 0.46-3.35; *P*=.67) (**Table 3**).

In the provisional plate subgroup (n=35), after intramedullary nailing, the plate was retained in 20 extremities and removed in 15 extremities. Of those who had the plate retained, 60% did not have a complication (n=12) and 40% had a complication (n=8) (25% infection; 15% other complication). Compared with those who had the provisional plate removed, 73.3% did not have a complication (n=11) and 26.6% had a complication (n=4) (13.3% infection; 13.3% other complication). Plate removal did not significantly decrease the odds of infection (adjusted odds ratio, 0.43; 95% confidence interval, 0.07-2.69; *P*=.36) or any complication (adjusted odds ratio, 0.55; 95% confidence interval, 0.12-0.46; *P*=.44) compared with retention of the provisional implant (adjusted for AO/OTA classification and Gustilo-Anderson type) (**Table 4**).

Discussion

Intramedullary nailing of open tibial shaft fractures has been shown to be the most effective treatment option, with good clinical outcomes reported.[6,7] However, because of the high-energy mechanism of injury, significant comminution of the fracture, and high risk of complications, intramedullary nailing can pose a challenge. Because obtaining and maintaining fracture reduction can be difficult, surgeons have sought adjunct procedures to facilitate intramedullary nailing.

Provisional plating is an accepted technique to maintain alignment and facilitate internal fixation.[11,14,15] Archdeacon and Wyrick[11] described a technique known as as reduction plating, in which one-third tubular plates or mini-fragment plates are used. Plates with unicortical fixation were used to help to maintain reduction before definitive fixation, and the authors' preference was to retain the plate to assist with nailing.[11] Dunbar et al[14] described the technique with a thicker, 3.5-mm small fragment dynamic compression plate (DCP) or limited contact dynamic compression plate (LC-DCP) (Synthes, Paoli, Pennsylvania) to maintain fracture reduction during placement of intramedullary nails in 32 Gustilo-Anderson type III open tibial shaft fractures. They concluded that provisional plating provided stability and maintained accurate reduction during reaming and insertion of the nail. All plates were removed after insertion of the tibial nail before final wound closure. The

current authors consider this necessary because of concerns about soft tissue with thicker plates. Grimsrud and Siebler[15] described provisional plate fixation in both bone forearm fractures as a temporary internal external fixator. Although this technique is beyond the scope of the current study, it is another novel concept in provisional fixation.

In the current study, the overall complication rate for open tibia fractures was similar to that cited in the literature. The superficial and deep infection rate was 16.7% compared with a deep infection rate of 13.3% reported by Dunbar et al.[14] After the authors controlled for age, AO/OTA classification, and Gustilo-Anderson classification, use of a provisional plate did not significantly increase the odds of infection or any other measured complication (nonunion, delayed union, or compartment syndrome) compared with patients who did not have a provisional plate.

This study was conducted to determine whether there was an increased risk of complications with retention vs removal of a provisional plate. Some surgeons consider plate removal important to decrease the mass effect of hardware in the region of a potentially tenuous wound. Other surgeons propose closing the wound over the provisional implant before intramedullary nailing to preserve the reamings. In the current study, removing the provisional plate was not associated with a decrease in infection or any complication. However, this study had a small subgroup sample size and the investigation would need to be replicated in a larger cohort. Nonetheless, local soft tissue may respond better with plate removal. The authors cannot comment on whether retention of the implant positively affected fracture union because that was not the focus of this study.

The benefits, risks, and costs of using a provisional plate must be weighed. Although the current study did not directly measure the fracture gap, provisional plating can be a valuable technique to decrease the fracture gap. In contrast, because provisional plating of tibia fractures is typically performed through the traumatic wound, there is concern that this technique causes additional trauma to the already compromised soft tissue envelope. However, an earlier report argued that a provisional plate actually required less soft tissue stripping than bone reduction clamps placed directly through a traumatic wound.[13] The current authors' technique is to be meticulous with soft tissue handling and work through the debridement wound. Further, a 2.0-mm or 2.7-mm, 4-hole plate plus cortical screws can cost approximately $550 to $840 retail (DePuy-Synthes, Paoli, Pennsylvania), but the cost is variable by facility type and contracted volume discounts. Because provisional plating can expedite intramedullary nailing, the cost of the provisional plate can be offset by shortened operating room time.[14,16,17] With operating room costs ranging from $22 per minute to $133 per minute, the time saved during nailing with a provisional plate to assist with reduction should be considered.[18]

Table 4

Provisional Plate Retained Versus Removed and Complications[a]

Complication	Provisional Plate, No.		Adjusted Odds Ratio[b] (95% Confidence Interval)
	Retained	Removed	
Infection	5 (25%)	2 (13.3%)	0.43 (0.07-2.69)
Any[c]	8 (40%)	4 (27%)	0.55 (0.12-2.46)

[a]Percentages are column percentages (denominator: retained, n=20; removed, n=15).
[b]Adjusted for AO/OTA Classification (Orthopaedic Trauma Association Fracture and Dislocation Classification Compendium), Gustilo-Anderson type. Reference groups: AO/OTA types 42-A and 42-B; Gustilo-Anderson types I and II.
[c]Includes infection and other complication category.

Limitations

This study had several limitations. First, this was a retrospective chart review and was restricted to the available data collected from electronic medical records. Second, the decision to use provisional plate fixation and the decision to retain or remove the implant were based on the surgeon's preference, which can introduce a selection bias. Third, the study did not account for the time interval between injury and initial dosage of antibiotics in the emergency department or the time interval between injury and initial operative debridement as confounding variables. Current data suggest that early administration of appropriate antibiotics is the most important variable for preventing wound infections in open fractures.[19] However, the authors' protocol for all open fractures is to administer intravenous antibiotics on arrival to the emergency department, with irrigation and debridement performed the same day or scheduled as the first case the next day. This study did not measure the biomechanical effect of using a provisional plate to aid intramedullary nailing. In a separate biomechanical study with synthetic long bone models, a provisional mini-fragment plate enhanced compressive forces for fixation with dynamic compression plates.[20] Further studies are needed to explore this effect with intramedullary nailing. However, based on the current findings, the effect is likely to be negligible, given the difference in size between the nail and the plates. Finally, the results of this study should be interpreted with caution. Because this study is underpowered (post hoc power, 0.15), with a sample size of 108, nonsignificant differences in results should not dictate a

change in practice until the findings are replicated in studies with larger sample sizes.

Conclusion

This study is the first to report on the use of provisional plate fixation (mini-fragment/small fragment plate) and the associated complications. Use of a provisional plate did not result in a significantly increased overall complication rate. Although this was not the focus of the study, the authors believe that provisional plate fixation facilitates the surgical procedure and improves fracture alignment, potentially improving outcomes. This technique is a viable option for the treatment of open tibia fractures. The question of removal vs retention of provisional plates remains unanswered, but the current study opens the door for higher-powered studies in the future.

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