eC **A commentary by William T. Obremskey, MD, MPH,** is linked to the online version of this article.

SCIENTIFIC ARTICLES
OBSERVATIONAL STUDIES

Clinical Outcomes Following Open Tibial Fractures in Latin America

A Multicenter Prospective Study

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Background: The study compared health-related quality of life and fracture-healing based on the fixation method following isolated open tibial fractures in Latin America.

Methods: A prospective study was conducted across 18 trauma centers in 8 countries. Adult patients with isolated open tibial diaphyseal fractures were included. The primary outcome measures were Physical Component Summary (PCS) and Mental Component Summary (MCS) scores of the 12-Item Short Form Health Survey (SF-12), which was administered at baseline and at follow-up at 6, 12, 26, and 52 weeks. The secondary outcome measure was the modified Radiographic Union Scale for Tibial Fractures (mRUST) score.

Results: Of 422 patients, 389 had a baseline evaluation, with 352 (83.4% of the 422) completing at least 1 SF-12 follow-up and 309 (73.2%) completing at least 1 SF-12 follow-up and having radiographic follow-up within 1 year postoperatively. Initial definitive intramedullary nailing and external fixation or casting followed by staged intramedullary nailing were the most common fixation strategies. Both fixation methods were performed with similar frequency for Gustilo-Anderson (GA) Type-I and II injuries. The majority of GA Type-IIIA and IIIB/C fractures were treated with staged fixation. The presence of minimal or superficial contamination did not influence whether fractures were treated with initial intramedullary nailing or staged intramedullary nailing, whereas the presence of deep contamination was associated with staged management. For all GA types combined, initial definitive intramedullary nailing was associated with significantly higher PCS and MCS scores at 1 year than staged fixation. The mRUST scores at 1 year for all GA types combined were higher with initial definitive intramedullary nailing than with staged intramedullary nailing.

Conclusions: Staged treatment remains common in Latin America, even for less severe injuries. Initial intramedullary nailing was associated with improved PCS and MCS scores and significantly higher mRUST scores relative to staged intramedullary nailing.

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

*Members of the Asociación de Cirujanos Traumatólogos de las Americas (ACTUAR) Study Group are included in a note at the end of the article.

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Trauma represents a major burden globally, with mortality and morbidity rates 2 to 5 times higher in low and middle-income countries (LMICs) compared with high-income countries (HICs)[1,2]. Notably, Latin America, a region comprising mostly LMICs, has the greatest proportion of road traffic fatalities per capita worldwide[3,4]. Road traffic accidents have contributed to a rise in the incidence of open tibial fractures, often associated with severe soft-tissue defects and increased rates of complications, including deep infection, chronic osteomyelitis, and nonunion[5].

Early management decisions for open tibial fractures can critically affect long-term outcomes. However, decision-making can be challenging in Latin America because of delayed patient presentation, lack of formal guidelines and protocols[6], and limited specialist availability[7]. Furthermore, long-term outcome data comparing treatment strategies, including fixation methods, are limited in this setting[8]. LMICs remain historically underrepresented in clinical trials[9,10], with significantly fewer collaborative multicenter publications originating from orthopaedic surgery than other specialties[11]. Surgeons in Latin America often have to rely on studies from higher-resourced regions, which may not be fully applicable to their patient populations. Recognizing the need to better understand open tibial fracture management in this region, this study sought to compare health-related quality of life and fracture healing based on fixation strategies following open tibial fractures in Latin America.

> *Initial intramedullary nailing was associated with improved PCS and MCS scores and significantly higher mRUST scores relative to staged intramedullary nailing.*

Materials and Methods

A multicenter prospective observational study was conducted across 18 trauma centers in 8 countries between 2018 and 2022 (see Appendix Supplementary Figs. 1 and 2 and Appendix 1.1). Inclusion criteria were patients who were ≥18 years of age and had isolated OTA/AO Type 42[12] open tibial diaphyseal fractures (see Appendix 1.2)[13]. Patients were treated at the discretion of the local surgeons' preferences. Demographic characteristics, medical history, injury characteristics, radiographs, and treatment patterns were collected during enrollment. Open tibial fractures were categorized using the Gustilo-Anderson (GA) classification.

The primary outcome measures were the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores of the 12-Item Short Form Health Survey (SF-12). This health-related questionnaire measures patients' physical and mental health status and has previously been validated in a Spanish-speaking country[14,15]. The SF-12 scores range from 0 to 100, with higher scores indicating better physical and mental health conditions[16]. A preoperative SF-12 was administered at enrollment (asking for pre-injury health status) and subsequently at 6, 12, 26, and 52 weeks after definitive fixation. At each time point, patients were evaluated by an orthopaedic trauma surgeon to assess the injury, the presence or absence of any complications, orthogonal radiographs, and the patients' physical and mental health using the SF-12.

The secondary outcome measure was the modified Radiographic Union Scale for Tibial Fractures (mRUST) score. Individuals at the central coordinating center at the University of California San Francisco (UCSF) independently reviewed radiographs and assigned mRUST scores, with disagreements adjudicated by the Steering Committee (10 North American and Latin American orthopaedic surgeons). A union was defined as an mRUST score of ≥14 at 1 year[17-19].

Statistical Analysis

Descriptive statistics summarized demographic characteristics, fracture patterns, and treatment variables using Stata SE (version 18; StataCorp). Missing data were addressed using multiple imputation, generating 50 imputed data sets. Predictive mean matching was used to impute continuous variables, including the PCS, MCS, and mRUST, measured at each time point. Following imputation, each of these 3 outcome variables was analyzed using generalized estimating equations to account for repeated measures. Because of the strong association between injury severity and fixation strategies, comparisons were stratified by the GA classification (see Appendix 1.3).

Results

Demographic Characteristics

A total of 422 patients provided consent and were enrolled. Of these patients, 389 had a baseline evaluation, with 352 (83.4% of the 422 patients) completing at least 1 SF-12 follow-up (93.0% at 6 weeks, 86.0% at 12 weeks, 82.0% at 26 weeks, and 80.0% at 52 weeks) and 309 (73.2%) having at least 1 SF-12 and radiographic follow-up (78.0% at 6 weeks, 70.9% at 12 weeks, 68.3% at 26 weeks, and 78.0% at 52 weeks). Mexico had the highest proportion of the 389 patients enrolled (131 [33.7%]). The median age was 31 years (interquartile range, 23 to 41 years). The majority of patients were male (84.6%) and did not have diabetes (94.6%) or a smoking history (60.9%). There was no significant relationship between smoking and infection or smoking and nonunion. One-half of the patients (49.9%) had government insurance, more than one-fourth (27.2%) had no insurance, and a smaller proportion (20.1%) had private insurance.

The most common fractures were GA Type II (222 [57.1%]) and Type IIIA (99 [25.4%]), and road traffic accidents

Table 1. Patient Demographic Characteristics and Management (N = 389)*

Age *(yr)*	31 (23 to 41)
Male sex	329 (84.6%)
Insurance status	
Government	194 (49.9%)
Uninsured	106 (27.2%)
Private	78 (20.1%)
Not reported	11 (2.8%)
Diabetes status	
Yes	14 (3.6%)
No	368 (94.6%)
Unknown	6 (1.5%)
Not reported	1 (0.3%)
Smoking history	
Never	237 (60.9%)
Current	86 (22.1%)
Former	65 (16.7%)
Not reported	1 (0.3%)
Mechanism of injury	
Road traffic accident	318 (81.7%)
Fall	30 (7.7%)
Firearm	17 (4.4%)
Crush	11 (2.8%)
Other	12 (3.1%)
Not reported	1 (0.3%)
Hospital distance	
<25 km	283 (72.8%)
25 to 50 km	62 (15.9%)
>50 to 75 km	24 (6.2%)
>75 to 100 km	7 (1.8%)
>100 km	11 (2.8%)
Not reported	2 (0.5%)
GA fracture classification	
GA Type I	47 (12.1%)
GA Type II	222 (57.1%)
GA Type IIIA	99 (25.4%)
GA Type IIIB/C	21 (5.4%)
Time from injury to antibiotic administration *(hr)*	
GA Type I	2.98 (1.5 to 5.4)
GA Type II	2.05 (1.25 to 4)
GA Type IIIA	3.0 (2.0 to 6.97)
GA Type IIIB/C	2.48 (1.92 to 3.75)
Time from injury to initial surgery *(hr)*	
GA Type I	7.10 (7.1 to 17.7)
GA Type II	7.45 (7.45 to 14)
GA Type IIIA	7.26 (3.5 to 13)
GA Type IIIB/C	5.75 (4.32 to 9.6)
Operative treatment approach for all GA types combined	
External fixation or casting followed by staged intramedullary nailing	178 (45.8%)
Initial definitive intramedullary nailing	127 (32.7%)
Definitive casting	40 (10.3%)
Definitive external fixation	20 (5.1%)
External fixation or casting followed by staged plating	17 (4.4%)
Definitive plating	7 (1.8%)

continued

Table 1. (*continued*)

*The values are given either as the median, with the interquartile range in parentheses, or as the number of patients, with the percentage in parentheses.

were the most common mechanism of injury (81.8%). Most patients (72.8%) traveled <25 km for definitive care. The median time from the injury to the initial surgery was approximately 7 hours for GA Type-I, II, and IIIA fractures and 5.8 hours for GA Type-IIIB/C fractures, although this difference was not significant. For all GA types combined, the most common methods of fixation were external fixation or casting followed by staged intramedullary nailing (178 [45.8%]) and initial definitive intramedullary nailing (127 [32.7%]) (Table 1).

Of the 269 patients with GA Type-I or II fractures, 116 (43.1%) were treated with initial intramedullary nailing and 100 (37.2%) were treated with staged management (external fixation or casting followed by planned intramedullary nailing) at the initial surgery. For the 120 patients with GA Type-IIIA or IIIB/C fractures, staged fixation followed by intramedullary nailing was the most frequently performed management pathway (78 [65.0%]) (Table 2).

Outcomes

External fixation and casting before conversion to staged intramedullary nailing were both used as temporizing modalities and were associated with similar 1-year scores for the PCS (52.7 for external fixation and 53.0 for casting; $p = 0.77$) and MCS (51.3 for external fixation and 52.1 for casting; $p = 0.50$). Therefore, these 2 groups were combined to compare initial and staged intramedullary nailing. Initial intramedullary nailing, compared with staged intramedullary nailing, was associated with higher scores for the PCS (56.5 compared with 52.7; $p < 0.001$) and MCS (54.4 compared with 51.7; $p < 0.006$) for all fracture types at 1 year (Figs. 1-A and 1-B). Notably, definitive casting was associated with the highest PCS (57.9) and MCS (57.6) scores at 1 year for all GA types combined.

Because fracture severity influenced the fixation method, initial intramedullary nailing and staged intramedullary nailing were compared within the GA Type-II and IIIA fracture groups (the greatest number of fracture types in this study). For GA Type-II fractures, initial intramedullary nailing, relative to staged intramedullary nailing, was associated with significantly higher scores for the PCS (56.5 compared with 54.3; $p = 0.027$) and MCS

Table 2. Operative Approach by GA Type

Operative Approach	GA Type I (N = 47)	GA Type II (N = 222)	GA Type IIIA (N = 99)	GA Type IIIB/C (N = 21)	Total (N = 389)
External fixation or casting followed by staged intramedullary nailing	19 (40.4%)	81 (36.5%)	62 (62.6%)	16 (76.2%)	178 (45.8%)
Initial definitive intramedullary nailing	20 (42.6%)	96 (43.2%)	11 (11.1%)	0 (0%)	127 (32.7%)
Definitive casting	5 (10.6%)	27 (12.2%)	8 (8.1%)	0 (0%)	40 (10.3%)
Definitive external fixation	0 (0%)	5 (2.3%)	11 (11.1%)	4 (19.1%)	20 (5.1%)
External fixation or casting followed by staged plating	1 (2.1%)	9 (4.1%)	6 (6.1%)	1 (4.8%)	17 (4.4%)
Definitive plating	2 (4.3%)	4 (1.8%)	1 (1.0%)	0 (0%)	7 (1.8%)

(55.6 compared with 51.8; p = 0.004) (see Appendix Supplementary Figs. 3-A and 3-B). Similarly, for GA Type-IIIA fractures, initial intramedullary nailing, relative to staged intramedullary nailing, also was associated with significantly higher PCS scores (58.0 compared with 52.0; p < 0.001) and higher MCS scores (53.5 compared with 51.5; p = 0.53) (see Appendix Supplementary Figs. 4-A and 4-B).

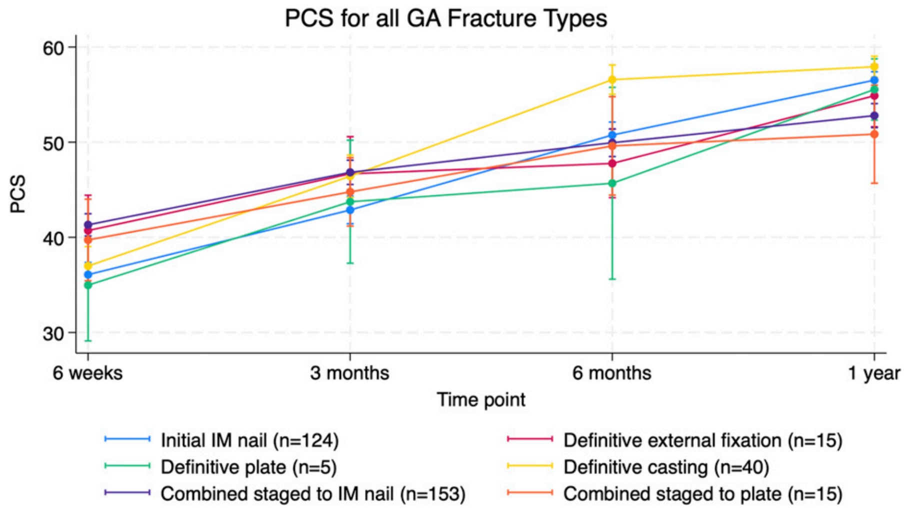

Fig. 1-A

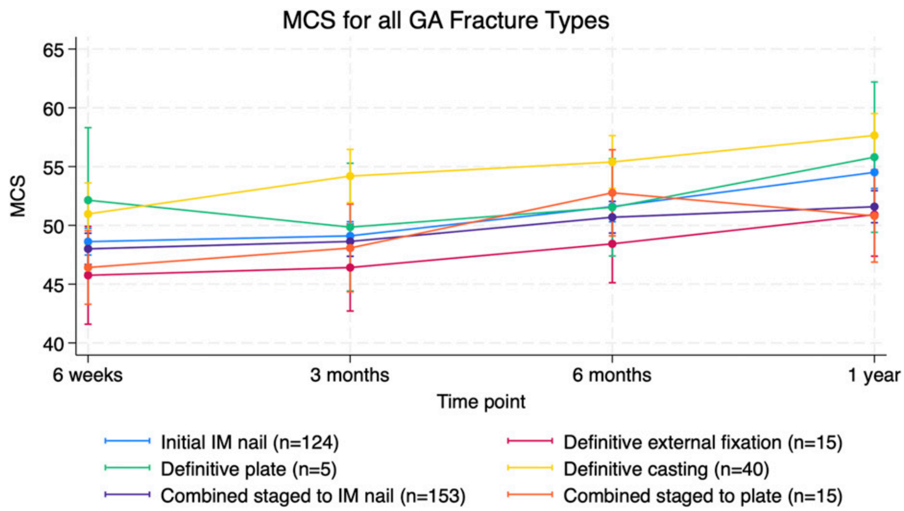

Fig. 1-B

Fig. 1-A PCS at up to 1 year for all GA fracture types. IM = intramedullary. **Fig. 1-B** MCS at up to 1 year for all GA fracture types. IM = intramedullary.

Table 3. Complications

Complication	GA Type I (N = 47)	GA Type II (N = 222)	GA Type IIIA (N = 99)	GA Type IIIB/C (N = 21)	Total (N = 389)
Delayed union or nonunion	1	10	9	4	24
Superficial infection		16	2		18
Deep infection		2	3	5	10
Delayed wound healing		2	4	4	10
Malunion		7	2		9
Implant failure			2		2
Compartment syndrome			1		1
Other		1	3		4
Total	1 (2%)	38 (17%)	26 (26%)	13 (62%)	77 (20%)

The mean 1-year mRUST scores decreased with increasing fracture severity as indicated by the GA type: 15.4 ± 0.25 for Type I, 15.2 ± 0.15 for Type II, 14.6 ± 0.32 for Type IIIA, and 13.6 ± 0.96 for Type IIIB/C. The mRUST score indicated union (≥14) for the majority of fractures that were GA Type I (88.8%), Type II (87.2%), Type IIIA (79.2%), and Type IIIB/C (59.8%) at 1 year, with a significantly (29%) lower union rate ($p = 0.04$) for the most severe fractures (GA Type IIIB/C) compared with the least severe fractures (GA Type I). Overall, mRUST scores for all GA types were significantly higher ($p < 0.001$) with initial intramedullary nailing (15.4) compared with staged intramedullary nailing (14.4) at 1 year. Specifically, 1-year mRUST scores for GA Type-II fractures were significantly higher ($p = 0.05$) after initial intramedullary nailing (15.4) compared with staged intramedullary nailing (14.6), and mRUST scores for GA Type-IIIA fractures were nonsignificantly higher ($p = 0.21$) after initial intramedullary nailing (15.1) compared with staged intramedullary nailing (14.1). Furthermore, for every 1-point increase in mRUST at 1 year, the PCS increased by 1.13 (95% confidence interval, 0.74 to 1.52) and the MCS increased by 0.41 (95% confidence interval, −0.03 to 0.87).

Table 4. Antibiotic Administration for all GA Types Combined

Characteristic	No. of Patients (N = 389)
Antibiotic regimen	
First-generation cephalosporin only	231 (59.4%)
First-generation cephalosporin and aminoglycoside	49 (12.6%)
Third-generation cephalosporin and other	38 (9.8%)
Third-generation cephalosporin only	38 (9.8%)
Third-generation cephalosporin and aminoglycoside	17 (4.4%)
First-generation cephalosporin and other	4 (1.0%)
Other	12 (3.1%)
Antibiotic duration after wound closure for all GA types combined	
<24 hours	32 (8.2%)
24 to 48 hours	31 (8.0%)
49 to 72 hours	56 (14.4%)
>72 hours	264 (67.9%)
Not reported	6 (1.5%)

Contamination and Complications

To establish whether the degree of contamination influenced the decision to perform initial intramedullary nailing compared with staged intramedullary nailing, the severity of contamination was determined for GA Type-II and IIIA fractures and then the prevalences of the 2 management methods were compared between the fracture types. The results showed that 175 (78.8%) of 222 GA Type-II fractures had a reported degree of contamination. These cases all had minimal or superficial contamination, with no reported deep contamination (see Appendix Supplementary Table 1). For these fractures, there was no clear preference for either operative approach, with similar percentages of patients undergoing initial intramedullary nailing (43.2%) and staged intramedullary nailing (36.5%) (Table 2). Seventy-two (72.7%) of 99 GA Type-IIIA fractures had a reported degree of contamination. Sixty-four (88.9%) of these cases had minimal or superficial contamination, and 8 (11.1%) had deep contamination. In contrast to GA Type-II fractures, most GA Type-IIIA fractures (62.6%) were treated with staged intramedullary nailing ($p < 0.001$), and all cases with deep contamination underwent staged treatment (Table 2).

There were a total of 77 complications, with the most common being delayed union or nonunion, followed by minimal or superficial and deep infections (Table 3). The proportion of complications increased with GA severity (with GA Type-IIIB/C being associated with the highest percentage of complications).

Antibiotics

For all GA types combined, the antibiotic regimen consisted of only a first-generation cephalosporin (in 59.4% of cases) (Table 4). A similar trend was observed for each GA type: 68.1% for Type I, 64.7% for Type II, 47.5% for Type IIIA, and 52.4% for Type IIIB/C. Most patients (67.9%) received postoperative antibiotics for >72 hours following definitive wound closure. All GA fracture types (63.8% for Type I, 64.0% for Type II, 76.8%

for Type IIIA, and 76.2% for Type IIIB/C) were predominantly treated with antibiotics for >72 hours. Although a longer duration of antibiotic administration was associated with a slightly higher infection rate, the sample size was not large enough to detect a significant difference.

Discussion

The current study found that patient-reported and radiographic outcomes of the treatment of open tibial fractures in Latin America were strongly associated with fixation strategies. Staged intramedullary nailing was nearly as common as initial intramedullary nailing for less severe fracture types. This contrasts with the literature from HICs, where lower-grade open fractures are predominantly treated with initial intramedullary nailing[20,21]. The difference in timing to intramedullary nailing may vary according to available resources and other circumstances (e.g., surgeon availability, implant accessibility and cost, insurance). The results suggest that, unless staged management is required (i.e., by a more severe fracture type or the presence of deep contamination), initial intramedullary nailing is favored over staged intramedullary nailing, as it is associated with improved clinical outcomes. For all GA types combined, initial definitive intramedullary nailing was associated with significantly higher 1-year PCS and MCS scores than staged intramedullary nailing. Although relatively few fractures were treated with definitive casting, these were associated with the highest PCS and MCS scores among all treatments for all GA types. Furthermore, the definitive casting group did not appear to have a greater proportion of lower-grade injuries compared with the initial and staged definitive intramedullary nailing groups as classified by GA type, warranting future evaluation.

Subanalyses demonstrated that injury severity and contamination degree can affect surgical decision-making. Compared with GA Type-II fractures, in which initial and staged intramedullary nailing were similarly employed, GA Type-IIIA fractures were largely treated with staged management. Similarly, minimal or superficial contamination did not influence whether fractures were treated with initial or staged fixation, whereas the presence of deep contamination was strongly associated with staged management. Collectively, these data further support that, unless deep contamination is present, surgeons should opt for initial intramedullary nailing.

The mRUST scores were associated with patients' quality-of-life PCS scores at 1 year post-injury. The mean mRUST scores approached the score that indicated healing at 26 weeks and was indicative of complete healing at 1 year for GA Type-I, II, and IIIA fractures. Less severe open tibial fractures were more likely to heal at 1 year compared with more severe fracture patterns. GA Type-IIIB/C fractures, on average, did not attain an mRUST score that reflected union by 1 year.

Most patients received antibiotics for >72 hours postoperatively, a treatment previously reported in Latin America. This differs from that recommended in the literature from HICs[22] and may be secondary to surgeons' efforts to compensate for delays in care before reaching the hospital and while in the hospital. The association of prolonged antibiotic administration with the rate of infection requires further investigation and represents a potential opportunity for practice improvement in the region.

The study's strengths included the number of participating sites and diversity of patient populations throughout the region; however, the study also had several limitations. First, there was a loss to follow-up. The study was conducted during the COVID-19 pandemic, limiting outpatient clinic availability and patients' willingness to follow up. This was addressed through telephone SF-12 interviews and imputation in the analysis. Second, the GA classification was used, even though the OTA Open Fracture Classification system is recognized as a potentially better predictor of outcomes and therefore might have more completely accounted for confounding by injury severity[23]. Third, it was not clear if the significant differences in PCS and MCS scores for initial intramedullary nailing compared with staged intramedullary nailing met the minimum clinically important difference; to date, the minimum clinically important difference in SF-12 scores has not been established for tibial shaft fractures[24]. Finally, direct comparisons of specific treatments were difficult because of the observational study design and confounding secondary to injury severity.

In summary, this study evaluated the effects of various factors on health-related quality of life and fracture-healing outcomes. Initial intramedullary nailing was associated with improved PCS and MCS scores and significantly higher mRUST scores relative to staged intramedullary nailing. Given the observed difference in management between the results in this study and those reported from higher-resourced regions, treatment timing (i.e., initial compared with staged intramedullary nailing) and antibiotic administration represent areas for further investigation and potential areas for improvement.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/J179). ■

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