Delay in Initial Debridement for Open Tibial Fractures and Its Possible Impact on Patient Outcomes

A Single-Center Prospective Cohort Study

Muhammad Tahir, MBBS, MRCS(Eng), Nadeem Ahmed, MBBS, FCPS, Saeed Ahmad Shaikh, MBBS, FCPS, Allah Rakhio Jamali, FCPS, Usama Khalid Choudry, MBBS, and Shoaib Khan, MBBS, MRCSEd

Investigation performed at the Jinnah Postgraduate Medical Centre, Karachi, Pakistan

Background: The current consensus regarding the management of open fracture indicates that the initial debridement should be performed within the first 6 hours after injury. Unfortunately, in Pakistan, the emergency medical services are not well-established and patient arrival at the hospital is delayed the majority of the time. In this study, we present our experience with delayed surgical management of open tibial fractures.

Methods: A prospective study of patients who presented to the accident and emergency department of the authors’ institution was performed. The duration of the study was 4 years. All patients ≥18 years of age with an isolated open fracture of the tibia were included in the study. Open fractures were graded using the Gustilo-Anderson (GA) classification. The study participants were divided into 3 groups based on the timing of the surgery. Infection and nonunion rates were compared using chi-square analysis. P < 0.05 was considered significant.

Results: A total of 1,896 patients were included in the study. There was no significant difference between the results of surgery performed before 48 hours and those of surgery performed after 48 hours with regard to the infection rates associated with GA type-I (p = 0.48), type-II (p = 0.70), or type-III (p = 0.87) fractures or the nonunion rates associated with type-I (p = 0.6338), type-II (p = 0.4030), or type-III (p = 0.4808) fractures. A higher GA classification was associated with higher rates of infection and nonunion independent of the timing of the surgery (95% confidence interval [CI] = 1.24 to 1.89, p < 0.01).

Conclusions: Our study indicates that the risks of infection and nonunion remain acceptable despite delays in the management of open tibial fractures within a 24 to 96-hour window. A delay in the initial time to debridement is acceptable only when early care cannot be provided. Prompt initial debridement remains the best possible treatment for open tibial fractures.

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

The majority of open fractures of the tibia are the result of a high-energy impact to the lower extremity (most commonly sustained in road traffic accidents) resulting in extensive soft-tissue damage, periosteal stripping, comminution, and contamination.

There is a multitude of literature that classifies open fractures. However, the most widely accepted classification is the one proposed by Gustilo and Anderson. Despite interobserver variation, the Gustilo-Anderson (GA) classification guides management strategies very effectively. Open fractures pose a greater challenge than closed fractures in a similar area. They are associated with higher rates of nonunion and infection. The yearly incidence of open fractures of long bones has been reported to be 11.5 per 100,000 individuals. The most common site by far is the tibial shaft.

As the soft-tissue coverage of the tibia is provided only by skin, about 24% of tibial shaft fractures are open injuries and 60% of these are GA type III. Acknowledgment of the importance of combined plastic surgery and orthopaedic efforts led to the publication of management strategies by the British
Orthopaedic Association (BOA) and British Association of Plastic Surgeons (BAPS). The management of open fractures encompasses early stabilization, intravenous antibiotics, wound debridement, and definitive surgery.

The current consensus regarding the management of open fractures indicates that the initial debridement should be performed within the first 6 hours after injury. In developing countries, there are many obstacles to providing optimal care to patients, including a shortage of well-trained staff, scarce resources, a lack of training and education, and an inadequate number of designated trauma centers.

In Pakistan, the emergency medical services are not well-established; therefore, most patients arrive several hours after the initial injury and have not received adequate treatment even if they have visited a primary care center. In the literature, there is still debate regarding the actual impact of the timing of surgery on outcomes, particularly in patients with lower-extremity trauma. A recent retrospective study of 227 open tibial shaft fractures showed no significant difference in the rate of infection between those receiving initial debridement within 24 to 48 hours and those treated 49 to 96 hours after injury. A national survey from India revealed that a substantial proportion of patients with open tibial fractures undergo initial debridement and irrigation >6 hours after presentation to the emergency department because of other injuries or presentation in the evening. Most of the available evidence on the effect of the timing of surgery for open tibial fractures is from retrospective studies, and there is a need for a higher level of evidence regarding this subject.

In this study, we present our outcomes related to the infection and nonunion rates in patients with delayed surgical management of open tibial fractures.

**Materials and Methods**

This work has been reported in line with the STROCSS (Strengthening the Reporting of Cohort Studies in Surgery) criteria for prospective studies. Our prospective study consisted of patients who presented to the accident and emergency department of our institution. Written informed consent was obtained from all participants. The study was conducted from February 2015 to December 2018. All patients ≥18 years of age with an isolated open fracture of the tibia were included in the study. Open fractures were graded using the GA classification. Patients with >1 open fracture site in the lower extremity were excluded from the study. The study subjects were divided into 3 groups based on the timing of the initial surgery: 24 to 48 hours, 49 to 72 hours, or 73 to 96 hours after the injury. All patients fulfilling the study inclusion criteria initially underwent the Advanced Trauma Life Support protocol of management. After initial resuscitation, analgesia, tetanus prophylaxis, and an appropriate intravenous antibiotic were administered on the basis of the GA classification of the fracture. After optimization, patients were taken to the operating room for wound debridement and surgical fixation.

The methods of fixation employed at our institution included external fixation, intramedullary nailing with or without reaming, and plate application. The type of surgical procedure was entirely the operating surgeon’s choice. Patients were discharged from the hospital after recovery, and further evaluation was done in the outpatient department. All patients were followed for a period of 2 years. Data regarding infection and nonunion were recorded in the follow-up period. Clinical and laboratory parameters were used for the evaluation of deep tissue infection. These parameters included purulent wound discharge; persistent fever; and increased total leukocyte count, C-reactive protein level, and erythrocyte sedimentation rate. Nonunion was recorded as a failure to show any signs of callus or bone formation on serial radiographs by 9 months.

The Student t test was used for the analysis of continuous variables, and the Pearson chi-square test was used for categorical variables. Relative risk (RR) estimation was done, and the number needed to harm (NNH), which represents the number of patients needed to undergo an intervention to cause harm to 1 patient, was determined. The significance level was determined to be <0.05. The analysis was completed using SPSS software, version 22 (IBM).

**Results**

A total of 1,896 patients were included in the study. The mean age of the patients and standard deviation was 43.60 ± 13.65 years; 72.2% (1,368) were male and 27.8% (528) were female. According to the GA classification, 30.8% (584) of the fractures were type I, 39.7% (752) were type II, and 29.5% (560) were type III. Of the 1,896 patients, 702 (37.02%) were type III 29.5% (560). Of the 1,896 patients, 1,368 (72.2%) were male and 528 (27.8%) were female. According to the GA classification, 546 (32%) were type I, 1,064 (56.4%) were type II, and 246 (13.9%) were type III. The Student t test was used for the analysis of continuous variables, and the Pearson chi-square test was used for categorical variables. Relative risk (RR) estimation was done, and the number needed to harm (NNH), which represents the number of patients needed to undergo an intervention to cause harm to 1 patient, was determined. The significance level was determined to be <0.05. The analysis was completed using SPSS software, version 22 (IBM).

**TABLE I Study Population Characteristics**

| Patient characteristics | % (No.)* |
|-------------------------|----------|
| Age (yr)                | 43.60 ± 13.65 |
| Male                    | 72.2% (1,368)  |
| Female                  | 27.8% (528)   |
| Diabetes                | 8.7% (165)    |
| Hypertension            | 10.4% (198)   |
| Smoker                  | 23.9% (453)   |
| Mechanism of injury     |           |
| Road traffic accident   | 67.4% (1,278) |
| Gunshot wound           | 18.4% (348)   |
| Fall                    | 5.0% (95)     |
| Assault                 | 4.1% (77)     |
| Crush injury            | 3.2% (61)     |
| Animal bite             | 2.0% (37)     |
| GA type                 |            |
| I                       | 30.8% (584)   |
| II                      | 39.7% (752)   |
| III                     | 29.5% (560)   |

*Except for age, which is given as the mean and standard deviation.
underwent debridement at 24 to 48 hours after the injury; 608 patients (32.06%), at 49 to 72 hours; and 586 patients (30.90%), at 73 to 96 hours (Table I).

The overall infection rates for the GA type-I, II, and III fractures were 8.42%, 16.74%, and 26.57%, respectively, in the group debrided in the 24 to 48-hour period; 10.14%, 20.85%, and 29.60% for those debrided in the 49 to 72-hour period; and 12.32%, 16.98%, and 26.73% for those debrided in the 73 to 96-hour period.

The infection rates were comparable (no significant difference) between the fractures debrided before and those debrided after 48 hours. This was true for the GA type-I fractures (RR = 1.36, CI = 0.57 to 3.21, p = 0.48), type-II fractures (RR = 1.12, CI = 0.60 to 2.07, p = 0.70), and type-III fractures (RR = 1.03, CI = 0.65 to 1.64, p = 0.87).

The trends for the nonunion rates for GA type-I, II, and III fractures according to the timing of the surgery were similar to those observed for the infection rates. The overall nonunion rates for the type-I, II, and III injuries were 6.13%, 11.78%, and 18.46%, respectively, for those debrided in the 24 to 48-hour period; 8.53%, 15.61%, and 22.64% for those debrided in the 49 to 72-hour period; and 9.35%, 14.56%, and 23.44% for those debrided in the 73 to 96-hour period.

The nonunion rates were comparable (no significant difference) between the fractures debrided before and those debrided after 48 hours. This was the case for GA type-I fractures (RR = 1.28, CI = 0.46 to 3.56, p = 0.6338), type-II fractures (RR = 1.36, CI = 0.65 to 2.82, p = 0.4030), and type-III fractures (RR = 1.22, CI = 0.69 to 2.13, p = 0.4808) (Table II). Moreover, the RUST scores (radiographic union score for tibial fracture) demonstrated a significant relationship with the complexity of the open fracture that corresponded with the rate of nonunion (Table III).

The NNH values for infection when debridement was performed after 48 hours were very high: 34, 50, and 100 for type-I, II, and III fractures, respectively. They were also extremely high for nonunion: 50, 25, and 25, respectively. These high NNH values indicate minimal impact of delayed surgery on the outcomes of tibial fractures.

Overall, the data suggest that a higher GA classification is associated with higher rates of infection and nonunion independent of the timing of surgery (CI = 1.24 to 1.89, p < 0.01) (Fig. 1).

Additionally, our data suggested that a delay of >12 hours between the injury and the first administration of antibiotics was strongly associated with deep infection after surgery, independent of the delay before debridement and the GA classification (RR = 6.183, CI = 4.389 to 8.372, p < 0.05).

Our study showed a higher risk of wound infection in smokers than in non-smokers with an open fracture (RR = 1.893, CI = 1.776 to 2.017, p < 0.001, NNH = 2.382).

Furthermore, among the different types of surgery performed, external fixation was associated with the highest risk of

| TABLE III RUST Scores According to GA Fracture Type for Patients Treated with Initial Debridement Before and After 48 Hours |
|---------------------------------------------------------------|
| GA Type | Debridement Before 48 Hours | Debridement After 48 Hours | 95% CI of Difference | P Value |
|---------|-----------------------------|-----------------------------|---------------------|--------|
| I       | 5.1 ± 1.2                   | 5.2 ± 1.5                   | 0.013-0.18          | 0.02   |
| II      | 4.9 ± 1.6                   | 5.1 ± 1.4                   | 0.14-0.29           | <0.01  |
| III     | 4.7 ± 1.3                   | 4.8 ± 1.1                   | 0.02-0.17           | 0.01   |

*The values are given as the mean and standard deviation.
infection and open reduction and internal fixation, with the lowest risk (mean difference = 30.7%, p < 0.05) (Fig. 2).

Patients with debridement performed within a 48-hour time period had fewer nonunions, superficial infections, and amputations compared with patients who had the initial debridement between 49 and 96 hours. This finding suggests that early debridement is a key factor in limiting the rate of infection and subsequent amputation. Table IV lists the numbers of patients with various complications in the 3 groups defined by the timing of the debridement.

**Discussion**

The current guidelines indicate that early intervention for open fractures should be performed in <6 hours; however, this is not always possible in a developing country such as Pakistan. The probable causes of delay include difficulties with transportation from rural to urban areas; long distances to tertiary care centers; and availability of only a single theater in the evening session, which is mostly engaged with life-threatening emergencies requiring general surgery.

Another cause of the delays was the time required to obtain implants, which usually are not available in the hospital and are purchased by the patient’s family. Because of the low socioeconomic status of most of these families, it took time for them to arrange the finances for the purchase. Our study population represented a younger age group, and the majority of them were medically fit to undergo surgical intervention on presentation; therefore, in most instances, the delay was secondary to logistical issues. Sometimes other, life-threatening injuries took priority and the open lower-limb fracture was dealt with when the patient was optimized and family members had arranged to obtain the implant.

Our findings regarding infection and nonunion rates are similar to those in other studies on delayed management of open tibial fractures. A retrospective study of 58 patients with open tibial fractures in Malaysia showed that the time between injury and initial debridement was not related to infection (62.1 hours, p = 0.58); however, the time between injury and initial debridement was significantly related to nonunion (p = 0.02), in contrast to our study.

In a prospective cohort study of 736 patients with open fractures seen at 3 Canadian trauma centers, Westgeest et al. reported no association between nonunion and the time to surgery (p = 0.15). A recent study of the outcomes of type-IIIIB diaphyseal tibial fractures demonstrated that the timing of the initial debridement (performed at a mean of 19 ± 12.3 hours after the injury) or definitive reconstruction (performed at a mean of 65 ± 51.7 hours) was not associated with negative outcomes. In a retrospective review, Duyos et al. reported a statistically similar rate of infection between patients treated from 24 to 48 hours after injury and those treated from 49 to 96 hours after surgery (p = 0.984), with 9%, 15%, and 27% rates of infection for GA type-I, II, and III injuries, respectively, in the 24 to 48-hour period. These data were comparable with...
our infection rates of 8.4%, 16.7%, and 26.6% in the same time interval for these fracture types. Furthermore, the 10%, 15%, and 25% infection rates in the 73 to 96-hour period reported by Duyos et al. were similar to the infection rates of 12.3%, 17.0%, and 26.7% in the same period in our study. A national survey from India indicated that delays of >6 hours in the management of open fractures were more frequent in level-I trauma centers and large university-based hospitals. In our own country, which is a developing nation like India, we have seen a similar trend with regard to delayed surgical management of open tibial fractures in level-I trauma centers.

The results of our study, along with those of other published studies, support the idea that delayed initial debridement of open tibial fractures can be a safe option, although every effort should be made to operate on these patients earlier. In a 2016 meta-analysis on the outcomes of open tibial fractures with regard to the timing of surgical debridement, Prodromidis and Charalambous found no apparent difference in the deep infection and nonunion rates between open tibial fractures debrided within 6 hours and those managed after 6 hours. A large-scale study from the U.K. in 2018 challenged the updated NICE (National Institute for Health and Care Excellence) guidelines. The authors reported data from 4 major trauma centers in the U.K., which showed no difference in infection rates for open tibial fractures debrided before and those debrided after 12 hours (mean time to debridement, 13.6 hours). Additionally, the authors reported that, in order to achieve a target of 12 hours, “it is vital to ensure dedicated orthoplastic capacity is adequately resourced.” In a prospective study of 315 patients from Los Angeles, Srour et al. reported that the time to irrigation and debridement made no difference in wound complications, nonunion rates, or implant failure (adjusted odds ratio for <6 hours versus 19 to 24 hours = 1.1, CI = 0.2 to 6.2, p = 0.90). In their series, all patients underwent initial debridement within 24 hours.

Whiting et al. found no association between the infection rate and the mean time from injury to debridement, although,

### TABLE IV Complications in the 3 Debridement-Delay Groups

| Outcome                     | 24-48-Hr Delay | 48-72-Hr Delay | 72-96-Hr Delay |
|-----------------------------|----------------|----------------|----------------|
| Superficial infection       | 132            | 175            | 155            |
| Deep infection              | 99             | 122            | 106            |
| Osteomyelitis               | 27             | 32             | 38             |
| Osteomyelitis resolved      | 20             | 23             | 28             |
| Recurrent osteomyelitis     | 7              | 11             | 10             |
| Nonunion                    | 47             | 105            | 125            |
| Graft or flap failure       | 23             | 27             | 28             |
| Amputation                  | 12             | 37             | 25             |
| Unplanned surgery           | 62             | 75             | 69             |
| Death                       | 3              | 7              | 5              |
in our study, the infection rate increased gradually when the delay to debridement increased. It increased gradually for type-I fractures, but for type-II and III fractures it increased when a delay of 24 to 48 hours was increased to 49 to 72 hours and then dropped slightly when the debridement was performed past 72 hours. However, the numbers of cases of osteomyelitis increased as the time to initial debridement was delayed. With regard to the severity of the injury, Whiting et al. reported that the higher the GA type, the higher the rate of infection. Similarly, we noted a higher infection rate in our study population when the GA type was higher.

Overall, it can be concluded that delayed management of open tibial fractures can be considered when logistical issues prevent earlier debridement, but every effort should be made to prioritize these cases on an urgent basis. This conclusion has been supported by numerous studies conducted across the Western world.

In developing countries such as Pakistan, which has limited resources and infrastructure and a lack of dedicated trauma centers, complying with widely accepted guidelines can be challenging. However, open lower-limb fractures should be dealt with as a matter of surgical emergency, with the patient placed on the next available trauma surgery list; there should also be input from a plastic surgeon.

Our study is the first of its kind from the region, to our knowledge. The prospective nature of the study in light of the fact that the majority of the available literature is retrospective warrants its publication as Level-II evidence.

Limitations and Recommendations

We cannot comment on perioperative and patient-related risk factors that might affect the outcomes of surgery for open tibial fractures. Also, our study did not include a control group of patients who underwent debridement <24 hours after injury for comparison. It should be noted that smoking may have been underreported in our data, as patients might have felt that they would be treated differently if that information was disclosed; this could have created bias. In addition, the method of fixation was not standardized among the GA types, possibly leading to inhomogeneity of the findings and perhaps explaining why more infections were reported among the external fixation group.

We recommend a study of multiple cohorts at multiple centers to obtain a bigger sample with post-stratification for patient-associated risk factors. It would be difficult to conduct a prospective randomized controlled trial as it would not be ethical to randomize patients into early and late-treatment groups, being that delaying treatment is not sound clinical practice. Therefore, we need to rely on Level-II evidence to support our clinical decisions.

Conclusions

Our study indicates that the risks of infection and nonunion remain acceptable despite a delay in the management of open tibial fractures within a 24 to 96-hour window. However, a delay in the initial debridement is acceptable only when it is unavoidable. Prompt initial debridement is still the best possible treatment for open tibial fractures.

References

1. Johnson EN, Bums TC, Hayda RA, Hospenthal DR, Murray CK. Infectious complications of open type III tibial fractures among combat casualties. Clin Infect Dis. 2007 Aug 15;45(4):409-15. Epub 2007 Jul 5.
2. Thakore RV, Francois EL, Nwosu SK, Attum B, Whiting PS, Siuta MA, Venuti MA, Smith AK, Shen MS, Mousavi I, Obremkowy WT, Sethi MK. The Gustilo-Anderson classification system as predictor of nonunion and infection in open tibia fractures. Eur J Trauma Emerg Surg. 2017 Oct;43(5):651-6. Epub 2017 Sep 22.
3. Zalavras CG, Marcus RE, Levin LS, Patzakis MJ. Management of open fractures and subsequent complications. J Bone Joint Surg Am. 2007 Apr;89(4):894-95.
4. Court-Brown CM, Rimmer S, Prakash U, McQueen MM. The epidemiology of open long bone fractures. Injury. 1998 Sep;29(7):529-34.
5. Howard M, Court-Brown CM. Epidemiology and management of open fractures of the lower limb. Br J Hosp Med. 1997 Jun 4-17;57(11):562-7.
6. Naique SB, Pearse M, Nanchahal J. Management of severe open tibial fractures: the need for combined orthopaedic and plastic surgical treatment in specialist centres. J Bone Joint Surg Br. 2006 Mar;88(3):351-7.
7. Lee C, Porter KM. Prehospital management of lower limb fractures. Emerg Med J. 2005 Sep;22(9):680-3.
8. Giannoudis PV, Papakostidis C, Roberts C. A review of the management of open fractures of the tibia and femur. J Bone Joint Surg Br. 2006 Mar;88(3):281-9.
9. Spiegel DA, Gosselin RA, Coughlin RR, Joshimura P, Browner BD, Dornans JP. The burden of musculoskeletal injury in low and middle-income countries: challenges and opportunities. J Bone Joint Surg Am. 2008 Apr;90(4):915-23.
10. Choudhry UK, Mahwish A, Areeba N. Emergency patient transportation in South Asia-call for a proper pre-hospital care system. J Surg Emerg Med. 2017;1(1):1-3.
11. Duyos OA, Beaton-Comulada D, Davila-Parrilla A, Perez-Lopez JC, Ortiz K, Foy-Parrilla C, Lopez-Gonzalez F. Management of open tibial shaft fractures: does the timing of surgery affect outcomes? J Am Acad Orthop Surg. 2017 Mar;25(3):230-8.
Delay in Initial Debridement for Open Tibial Fractures: Possible Impact on Patient Outcomes

12. Namdari S, Baldwin KD, Matuszewski P, Esterhai JL, Mehta S. Delay in surgical débridement of open tibia fractures: an analysis of national practice trends. J Orthop Trauma. 2011 Mar;25(3):140-4.

13. Agha RA, Borrelli MR, Vella-Baldacchino M, Thavayogan R, Orgill DP; STROCSS Group. The STROCSS statement: strengthening the reporting of cohort studies in surgery. Int J Surg. 2017 Oct;46:198-202. Epub 2017 Sep 7.

14. Razaq IA, Hyder AA, Akhtar T, Khan M, Khan UR. Assessing emergency medical care in low income countries: a pilot study from Pakistan. BMC Emerg Med. 2008 Jul 3;8:8.

15. Yusof NM, Khalid KA, Zulkifli AH, Zakaria Z, Amin MAM, Awang MS, Ahmad AC, Alter SF. Factors associated with the outcome of open tibial fractures. Malays J Med Sci. 2013 Oct;20(5):47-53.

16. Westgeest J, Weber D, Dulai SK, Bergman JW, Buckley R, Beaupre LA. Factors associated with development of nonunion or delayed healing after an open long bone fracture: a prospective cohort study of 736 subjects. J Orthop Trauma. 2016 Mar;30(3):149-55.

17. Al-Hourani K, Fowler T, Whitehouse MR, Khan U, Kelly M. Two-stage combined ortho-plastic management of type IIIB open diaphyseal tibial fractures requiring flap coverage: is the timing of debridement and coverage associated with outcomes? J Orthop Trauma. 2019 Dec;33(12):591-7.

18. Prodromidis AD, Charalambous CP. The 6-hour rule for surgical debridement of open tibial fractures: a systematic review and meta-analysis of infection and non-union rates. J Orthop Trauma. 2016 Jul;30(7):397-402.

19. Hendrickson SA, Wall RA, Manley O, Gibson W, Toher D, Wallis K, Ward J, Wallace DL, Lamymann M, Giblin AV, Wright TC, Khan U. Time to Initial Debridement and wound Excision (TIDE) in severe open tibial fractures and related clinical outcome: a multi-centre study. Injury. 2018 Oct;49(10):1922-6. Epub 2018 Jul 27.

20. Srour M, Inaba K, Okoye O, Chan C, Skiada D, Schnüriger B, Trump M, Lam L, Demetriades D. Prospective evaluation of treatment of open fractures: effect of time to irrigation and debridement. JAMA Surg. 2015 Apr;150(4):332-6.

21. Whiting PS, Galat DD, Zirkle LG, Shaw MK, Galat JD. Risk factors for infection after intramedullary nailing of open tibia shaft fractures in low- and middle-income countries. J Orthop Trauma. 2019 Jun;33(6):e234-9.