Effect of Delayed Treatment on Open Tibial Shaft Fractures

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Abstract

Open tibial shaft fractures were analyzed retrospectively to determine the effect of treatment timing on infection and nonunion rates. The cases of 77 patients with 81 open tibial shaft fractures were reviewed.

Patients were treated with initial wound cleansing and splinting in the emergency department and then formally with operative irrigation and débridement and stabilization, which included intramedullary (IM) nailing, external fixation, open reduction and internal fixation, or splinting. All tibial shaft components ultimately were treated with IM nailing. Mean time to operative treatment was 12.97 hours (SD, 10.8 hours). There were 7 infections (8.6%) and 3 nonunions (3.7%).

Time was found not to be a significant factor in predicting either infection or nonunion. Increased severity of fracture was a significant factor in predicting infection rate. The infection rate for fractures treated first with external fixation and then with IM nailing was significantly higher than that for fractures treated with IM nailing alone. In addition, a relation was found between patients who received multiple débridements and development of infection.

These results show that infection and nonunion rates were not adversely affected by longer time to operative treatment (up to 48 hours) when adequate trauma department open fracture care and early initiation of antibiotics were coupled with standardized and thorough débridement in the operative theater.

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Although they are not emergent conditions (eg, compartment syndrome, pulseless extremity), open fractures require urgent treatment. Compared with open fractures in other areas of the body, open tibial shaft fractures pose a more difficult challenge because of their high infection rate. The infection rate reported in the literature has ranged from 2% to 47%,[1-15] with rates as high as 50% reported for Gustilo-Anderson grade 3b fractures.[16] These high rates are attributed to restricted soft-tissue coverage over the tibia and the relatively poor osseous blood supply. Treatment of open tibial shaft fractures is controversial in several areas, including fixation method, antibiotic choice, timing and method of soft-tissue coverage, role of early bone grafting, and even irrigation method. One area that has not been discussed much is time to operative irrigation and débridement and definitive treatment. It is often taught that open fractures should be treated with operative débridement and stabilization within 6 to 8 hours.[10,11,17-20] Although this principle has historical support, no investigators have demonstrated the scientific foundation for the 6- to 8-hour time frame.

In the study reported here, we sought to determine if time to operative débridement and stabilization of open tibial shaft fractures had a significant impact on infection and nonunion rates.

Materials and Methods

For this study, we reviewed the cases of 100 consecutive patients (>17 years old) with 104 open tibial shaft fractures (with and without concomitant articular involvement) evaluated and treated at our institution between September 1997 and January 2001. This series, specific to Dr. Cole, involved the consecutive series of patients admitted on his call days during this period. Open tibial shaft fractures transferred from other facilities were not included because of time inconsistencies in those emergency departments and in the transfers. Therefore, our series of patients included only those directly admitted to our emergency/trauma department (ED/TD) after the trauma. Our hospital is a level I trauma center with a catchment area of 100 nautical miles and 16 counties. Time from original dispatch to patient admission ranges from 12 minutes (by helicopter) to 45 minutes (longest average route from farthest county by ground transportation).

A retrospective review of patient data included age, fracture location, gender, smoking status, Gustilo-Anderson fracture grade, exact time of entry into ED/TD, exact surgery start time, hospital course (including all procedures), outpatient course (including all procedures), and follow-up time. Exclusion criteria included patient death during inpatient status (4 patients), charts with incomplete data (14 patients), and less than 5 weeks' follow-up (5 patients). Excluded patients were not significantly different from included patients with respect to age, gender, fracture grade, or fracture location. Seventy-seven patients with 81 open tibial shaft fractures remained for the study.

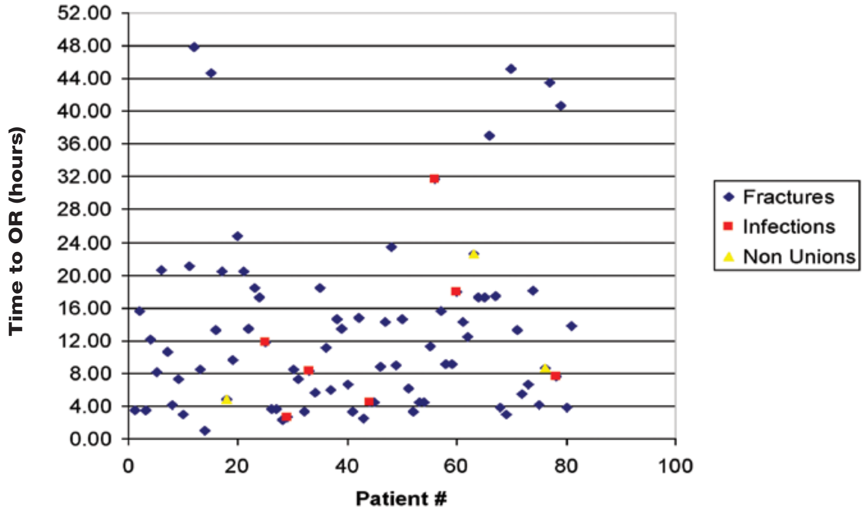

Figure. Scatter plot of all cases with infections and nonunions.

All patients underwent wound cleansing and splinting by the resident who was on call in the ED/TD on admission. Cleansing involved removing gross debris and contaminants and irrigating with normal saline (2 L). All patients were ultimately treated by Dr. Cole in standard fashion. He performed thorough operative irrigation and débridement and then tibia and/or fibula stabilization—consistent with strategies (described by Cole and colleagues[4]) based on soft-tissue condition and fracture pattern. Ultimately, all patients included in this study underwent reamed ACE/Depuy (Johnson & Johnson, New Brunswick, NJ) proximal and distal interlocking IM nailing for the shaft components of their fractures. All fractures were either 41-, 42-, or 43- by AO (Arbeitsgemeinschaft für Osteosynthesefragen) classification. The "center" of each of the 81 fractures was within the diaphysis. We did not exclude fractures with an intra-articular extension or a fracture "remote" from the "central" shaft component. None of the 7 infections involved the intra-articular portions, and none of the 3 nonunions was involved with the joint. Fractures treated with delayed fixation (ie, external fixation exchanged to IM) involved severe crushes, ground-in dirt or debris, or vascular compromise. Decisions to perform repeat irrigation and débridement were based on degree of contamination and soft-tissue injury; thus, there was a separate subset of patients who received "multiple débridements." Soft-tissue coverage strategies outlined by Cole and colleagues[4]—including tensionless primary closure (rare cases), judicious use of fasciocutaneous flaps to cover exposed bone, and bone shortening to allow for acute wound coverage—were followed. Antibiotics, administered on patients' arrival in the ED/TD, were selected on the basis of fracture grade, soft-tissue appearance, and patient allergy status. All patients were treated with a first-generation cephalosporin (cefazolin) for 36 hours; an aminoglycoside was added for highly contaminated wounds in which the contaminants were soaked or abraded into the tissues.[4] Antibiotic coverage was extended for an additional 24 to 36 hours after subsequent débridements. Any deviation from this protocol was undertaken with the Infectious Disease team on the basis of intraoperative cultures.

Infections were defined as osteomyelitis or deep infection by clinical examination after definitive closure procedures that required operative intervention, including irrigation and débridement with or without hardware removal. Nonunions were defined as fractures that required operative intervention and that showed radiographic evidence of nonunion more than 6 months after ultimate fixation. Two cases that required intravenous (IV) antibiotics without operative intervention were not included as infections. One of these cases was that of a homeless man admitted 7 months after surgery for cellulitis of the operative leg caused by insect bites; the other was that of a man admitted 1 month after surgery for IV antibiotics for a superficial infection of the skin graft donor site. Cases of repeat débridements performed during inpatient care before definitive closure procedures were not included as infections. However, these repeat débridements were analyzed for their relation to infection and time to treatment.

Statistical Analysis

The data set consisted of 81 observations from 77 subjects. Because the focus of this study was on using infection and nonunion as primary variables, each subject and its variables were used as independent observations. The variables used were gender, smoking status, fracture location, fracture grade, multiple débridements (≥2), fixation method, infection (yes, no), union (yes, no), and time (the only continuous variable used in the analysis). Logistic regression models were analyzed and χ^2 tests conducted. Correction for low observed infection numbers (no infections in grade 1 and 2 fractures) involved combining fracture grade into a binary value of grades 1 and 2 versus grade 3 (A, B, C) for χ^2 analysis. One categorical variable was generated from time of surgery (<8 hours vs >8 hours). SPSS software was used for all analysis, and $P = .05$ was used for significance.

Results

Of the 81 open tibial shaft fractures, 18 were in females (22.2%), and 63 were in males (77.8%). Fifty-four of 81 fractures had data regarding the patient's smoking history. There were 20 smokers and 34 nonsmokers. All 3 nonunions were in nonsmokers. Of the 7 infections (discussed later), 4 were in smokers, and 3 were in nonsmokers (no significant difference, P = .237; Table I). With regard to the "center" of each fracture, 15 fractures involved the distal third (18.5%), 61 involved the middle third (75.3%), and 5 involved the proximal third (6.2%). Mechanism-of-injury data were available for 71 patients: 27 (38%) were in motor vehicle collisions, 20 (28%) were pedestrians hit by automobiles, 11 (15%) were in motorcycle crashes, 7 (10%) sustained their fractures in falls, 4 (5%) were struck by objects that caused the open tibia fracture, 1 received a gunshot wound, and 1 was injured playing soccer. Of the 81 fractures, 33 were treated with external fixation, exchanged later with IM nailing in a 1-stage procedure; 46 were treated with IM nailing alone; and 2 were treated with an alternative method (splint/open reduction and internal fixation), exchanged later with IM nailing. Mean follow-up was 14.4 months (range, 5 weeks to 61 months).

Mean time to operative treatment was 12 hours 58 minutes (range, 1 hour to 47 hours 48 minutes). Thirty-one fractures were treated within 8 hours (38.3%); 50 were treated after 8 hours (61.7%) (Table II). Seventy-three fractures were treated within 24 hours (90.1%); 8 were treated after 24 hours (9.9%). Reasons for delay included operating room availability, patient instability, and general or neurosurgical priority intervention. There was no statistically significant difference in the infection rate between fractures treated before and after 8 hours (P = .794). This finding was also true of nonunions (P = .858; Table I). Hourly rates of infection and union were compared from 1 hour after admission to 48 hours after admission, and thus conclusions are limited to this period. Increased time did not show a relation with increased rates of infection or union (P >.05). See Figure 1 for a scatter plot of all fractures, including those resulting in infection and nonunion. The variable of multiple débridements, also analyzed, was defined as 2 or more débridements before definitive closure. Of the 32 tibiae that received multiple débridements, 6 became infected (19%); of the 49 tibiae that did not receive multiple débridements, only 1 became infected (2%). A relation was found between patients who received multiple débridements and development of infection (P = .009). In addition, higher grade was associated with increased incidence of multiple débridements (P = .03). Of the 32 patients who received multiple débridements, 16 had their first one

Table I. Variable Cross-Tables

Variable*	χ^2	*P*	
Gender vs infection	0.279	.597	
Gender vs union	0.890	.345	
Location vs infection	2.512	.285	
Location vs union	0.592	.744	
Smoking vs infection	1.390	.237	
Grade vs infection	5.004	.025	Significant at P<.05
Grade vs union	0.050	.824	
Hours8 vs infection	0.068	.794	
Hours8 vs union	0.032	.858	
Union vs infection	0.295	.587	
Gender vs grade	4.834	.305	
Location vs grade	12.617	.126	
Hours8 vs multiple débridements	3.080	.079	
Location vs multiple débridements	1.119	.572	
Multiple débridements vs infection	6.846	.009	Significant at P<.05
Multiple débridements vs union	0.962	.327	
Multiple débridements vs grade	4.658	.031	Significant at P<.05
External fixation vs infection	6.090	.013	Significant at P<.05
External fixation vs nonunion	2.230	.134	

*Multiple débridements = 2 or more operative débridements; hours8 = time cutoff of 8 hours before operative débridement; external fixation = set of patients (n = 33) who had external fixation before nailing.

Table II. Frequency Table Comparing Patients Treated Within 8 Hours and After 8 Hours

Variable	<8 Hours	>8 Hours
n (%)	31 (38)	50 (62)
Gender		
Male	23 (74)	40 (80)
Female	8 (26)	10 (20)
Location		
Distal	3 (10)	12 (24)
Mid	27 (87)	34 (68)
Proximal	1 (03)	4 (08)
Grade		
1	5 (16)	9 (18)
2	5 (16)	14 (28)
3a	2 (06)	7 (14)
3b	15 (48)	19 (38)
3c	4 (13)	1 (02)
Infection		
No	28 (90)	46 (92)
Yes	3 (10)	4 (08)
Union		
No	1 (03)	2 (04)
Yes	30 (97)	48 (96)
Multiple débridements		
No	15 (48)	34 (68)
Yes	16 (52)	16 (32)

performed before 8 hours, and 16 had their first one performed after 8 hours. There was no relation between operative débridement time (>8 hours vs <8 hours) and need for repeat débridements (*P* = .08). There was also no significance found between gender and infection or nonunion or between fracture location and infection or nonunion. See Table I for cross-table variables.

Among the 81 fractures were 7 infections (8.6%) and 3 nonunions (3.7%). None of the 3 nonunions was complicated by infection. All the infections were in Gustilo grade 3a (n = 2) and 3b (n = 5) fractures. Two nonunions were in grade 3b fractures, and 1 nonunion was in a grade 2 fracture. Grade 3a, 3b, and 3c fractures were combined to form a category of grade 3 open fractures. Grade 3 fractures showed a statistically significant relation with infection, according to the χ^2 analysis (*P* = .025; Table I). Of the 33 fractures treated first with external fixation and later converted to IM nailing, 6 became infected (18%); of the 46 fractures treated with IM nailing alone, only 1 became infected (2%). This difference was significant (*P* = .013). All 3 nonunions were in the group treated with IM nailing alone; given the small numbers, no significant difference was found (*P* = .134). Although there was a trend toward higher grade and nonunion rate, the sample size was not large enough to show significance.

Discussion

Although there are hundreds of articles related to treatment issues of open tibia fractures—from Paré's description of his own open tibia fracture[21] to discussions of more contemporary issues, such as antibiotic therapy, fixation method, classification prognosis, and soft-tissue coverage options[1-8,11-16,18-20,22-30]—the topic of delay to operative treatment and its effect on infection and union rates is not often covered in the literature. In addition, the few studies dedicated to this topic have become dated.[18,22,29]

In one study, Kindsfater and Jonassen[10] found a significantly increased infection rate when grade 2 and 3 open tibia fractures were débrided after 5 hours. Clinical signs of infection were not used to determine infection status, but, rather, "only infections confirmed by a positive bone culture obtained in the operating room were recorded as true infections." However, this method for determining fracture infection was discredited earlier, in a prospective study in which 46% of open fractures had positive contaminated bone cultures from initial débridements but the wound infection rate was only 6.5%.[22] Even Kindsfater and Jonassen questioned their own method: They wrote that 10 of their 47 fractures had negative postdébridement cultures but still went on to osteomyelitis.

Although Kindsfater and Jonassen[10] made every effort to show scientific backing for the 6- to 8-hour time frame,[10] other investigators have quoted this time frame out of either opinion or recollection of historical data.[18,19,29] Some authors have written that there are published reports of evidence supporting the 6- to 8-hour rule when, in fact, those reports either do not mention the rule at all or show no significance with regard to timing of initial operative treatment.[17,20] In a study providing some meaningful insight into the issue of treatment delays for open tibia fractures, Khatod and colleagues[31] found "no significant increase in infection with respect to patients treated after 6 hours compared with those treated within 6 hours" and yet continued to "support the emergent treatment of open tibia fractures." Their conclusion and statement of support are not founded on the data they presented in their article. Ironically, they also stated, "The majority of literature does not find a correlation between timeliness of care for open fractures and rate of infectious outcome. The use of 6 hours as the cutoff for emergent treatment seems to be based more on historical precedence than on scientific evidence." Overall, the 6- to 8-hour rule continues to propagate in the literature despite its lack of solid scientific evidence.[10,11,17-20]

Several authors have been able to dilute the 6- to 8-hour rule by showing no significance between time to treatment and infection or nonunion rate. In a retrospective review of 241 open long bone fractures (not limited to tibiae), Harley and colleagues[9] reported no significant difference in infection or nonunion rate when waiting up to 13 hours before definitive treatment was initiated. They emphasized the importance of "prophylactic" antibiotics and open fracture first aid. Cellulitis not necessitating operative intervention was not considered a deep infection. Harley and colleagues also declared that infection was significantly related to the Gustilo grade of the fracture. Bednar and Parikh,[17] in a retrospective review of open fractures of the lower extremities, found that a delay within the first 24 hours "may not have a significant prognostic influence on the subsequent frequency of late deep infection in patients otherwise treated optimally." Patzakis and Wilkins[26] reported no significant difference between patients treated before 12 hours (6.8% infection rate) and patients treated after 12 hours (7.1% infection rate). They also found that Gustilo grade 3 fractures had an increased risk for infection "despite the use of broad-spectrum antibiotics and aggressive surgical débridement." Merritt[12] reported no significant relation between time to operative débridement and infection risk but a significant increase in infection related to longer than 121 minutes spent in the operating room. Similarly, Dellinger and colleagues[24] reported no significance in timing to operative treatment but a significant infection risk with increasing fracture grade. Others have also found a definitively increased infection risk in grade 3 fractures compared with lower grades.[3,7,8,15,30]

In our current retrospective review, we found no significant difference in infection rate or nonunion rate between open tibia fractures treated before or after 8 hours. Mean time to operative treatment was 13 hours. Up to 24 hours (by which point 90.1% of the fractures were treated), there was no significant increase in infection rate. Operative intervention was delayed because of neurosurgical or general surgical intervention in life-threatening situations, operative triage systems, and case load challenges. Results from this study are consistent with previously mentioned studies on this topic.

Several of our findings merit further discussion. Of the 7 infections, all were in grade 3 fractures. This finding, evidence of a significant relation between increased grade of fracture and increased infection risk, is reported consistently.[3,7-9,11,13,20,24,29] Our reported infection rate is at the low end of rates reported for open tibia fractures—we think because of the meticulous care with débridements, judicious use of antibiotics, and careful attention to the principles of open fracture treatment in our study. These principles, thoroughly presented by Cole and colleagues,[4] include the importance of ED open fracture care, including early and appropriate antibiotic coverage along with initial gross contaminant cleansing with sterile splinting. Other principles outlined include thorough wound débridement, including copious irrigation and removal of small avascular bony fragments, early soft-tissue coverage, low threshold for repeat irrigations, and definitive fixation "only after an intact soft tissue sleeve is reconstructed."[4] These principles are mirrored elsewhere in the literature.[6,7,13,14,23,25]

Another interesting finding in our study is that 6 of the 7 infections developed in tibiae that were treated with external fixation exchanged to IM nailing. Nailing was performed 2 to 90 days after external fixation. In the literature, the infection rate for IM nailing of open tibia fractures performed after external fixation has been as high as 44% to 50%.[5,32] Some authors have confirmed this increased infection rate[8,15,25,30] and suggested nailing be done a certain amount of time after external fixator removal,[1,30] yet other authors have reported no significant difference in infection rate with regard to fixation method.[10,22,24] It is apparent that fractures with more soft-tissue loss and contamination receive external fixation initially over IM nailing. In our study, 26 (79%) of the 33 fractures treated with external fixation exchanged to IM nailing were grade 3. In the subset of patients treated with IM nailing alone, only 20 (43%) of the 46 were grade 3. These higher grade fractures also receive multiple débridements, which were found associated with a higher infection rate. As mentioned previously, fractures treated with delayed fixation were those "high-risk" injuries associated with severe crushes, ground-in dirt or debris, or vascular compromise. It is reasonable to assume that there is a selection bias toward fractures treated with external fixation and multiple débridements because of their "higher risk" category and elevated infection risk.

This study had several limitations. Although mean follow-up was 14.4 months, 47 patients were followed up for less than 1 year, and 10 of these had follow-up for less than 5 weeks. Gustilo and Anderson[6] stated in their series of 1025 open long bone fractures that "infections were usually evident during the first month after surgery," but obtaining longer follow-ups on our patients may have strengthened our results.

Another area of concern is lack of preadmission data. Timing was started when patients entered the ED/TD, before operative intervention was begun. Doing this allowed for accurate comparison of data points (patient's time to operative intervention) based on a reliable and reproducible starting point. Certainly, transportation times to the hospital differed because of locations of trauma incidents and transportation modes. As the exact injury times and transportation times reported by emergency medical technicians and patients were unreliable, we excluded these data for the sake of standardization. According to our institution's trauma administration, times from dispatch to ED/TD admission are consistently between 12 and 45 minutes. The importance of the preadmission time data is debatable.

Another weakness is the small number of nonunions (3). Further study on nonunions alone with a larger sample size would be beneficial.

In summary, we found that waiting longer than 8 hours for operative irrigation and débridement does not increase risk for infection or nonunion in open tibial shaft fractures treated with IM nailing. Data from this series of patients seem to show no evidence of a significant increase in infection rate or nonunion rate with delays in operative irrigation and débridement up to 48 hours. We also confirmed that increased fracture grade is associated with increased infection risk and need for multiple débridements. Careful attention to open fracture principles is paramount when urgent open fracture irrigation and débridement are delayed because of patient instability, triage situations, or operating room unavailability. Although there were no serious complications in this series of patients, it should be noted that open tibia fractures are at risk for devastating complications, such as necrotizing fasciitis, gas gangrene, and unrecognized compartment syndrome. The value of close clinical observation of these injuries is immeasurable when the patient's operation is delayed.

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