Tibial Shaft Fractures

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Chapter 10

Open Fractures of the Tibia Treated by Immediate Intramedullary Tibial Nail Insertion Without Reaming:

A Prospective Study

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Abstract

Objective: Does immediate tibial nail insertion without reaming as part of protocol-driven management provide a safe and effective treatment for open tibia fractures?

Study Design: Prospective cohort.

Setting: Level 1 trauma center.

Patients: A consecutive series of 161 patients with Gustilo grade I-IIIb open tibia fractures.

Intervention: Emergent incision and debridement of the wound with immediate tibial nail insertion without reaming, repeat incision and debridement, and soft-tissue coverage within 14 days.

Main Outcome Measurements: Time to union, number of secondary procedures performed to obtain union, implant failures, and the type and incidence of complications.

Results: One hundred and forty-three fractures were followed to union. Follow up averaged 2.2 years (0.6-5.5 years). Seventy-six fractures united in less than 6 months, 35 took between 6 and 9 months, and 32 took longer than 9 months. Twenty-five additional procedures were needed to obtain union in 16 of the delayed unions (12 nail exchanges, 4 bone grafts, 9 dynamizations). Complications included 3 patients with cellulitis, 1 superficial infection, 4 deep infections (1 grade I, 2 grade II, 1 grade IIIb), 3 loose screws, 2 broken screws, 5 malunions greater than 5 degrees, and 30 patients with decreased ankle motion when compared with the uninjured side. Not counting the ankle loss of motion, 18 complications occurred in 143 fractures (13%). Twenty-nine patients (20%) had complaints of minor knee pain and 30 (21%) had occasional

fracture site pain after activity despite clinical and radiographic evidence of union. Eleven patients (8%) considered themselves completely disabled. Five patients were not treated by the standard protocol and are not included in the previously listed statistics; 3 were grade IIIB that did not have adequate coverage by 14 days, and 2 were grade II injuries that did not have a second debridement. Four of these 5 patients developed a complication.

Conclusions: Protocol-driven management emphasizing meticulous soft-tissue management and the use of immediate tibial nailing without reaming appears to be safe and effective in the treatment of open tibia fractures. The deep infection rate for the patients who were treated by protocol was 3% and the implant failure rate was lower than has been previously reported, most likely attributable to attempts to obtain cortical contact and avoid fracture gaps. Overall satisfaction was good, but approximately 41% of the patients had complaints of knee or fracture site pain or both well after union.

Open tibia fractures are usually the result of high-energy trauma such as a motor vehicle accident. They are often associated with severe soft-tissue damage and wound contamination, and their prognosis is largely dependent on the degree of initial fracture displacement, comminution, and soft-tissue injury.[1] Concerns over the high rates of malunion, nonunion, and deep infection have resulted in the development of aggressive treatment protocols including emergent wound exploration, thorough irrigation and debridement, bony stabilization, judicious antibiotic therapy, repeated wound debridements, and early soft-tissue coverage.[2-5] However, there is still controversy regarding the optimal method of skeletal stabilization. High rates of pin tract infections, pin loosening, poor patient compliance, and malunion rates of 20% and greater have limited the use of external fixators as a definitive form of fixation.[6-9] Despite initial encouraging results, plate fixation of open tibial fractures has been associated with implant failures, nonunions, and deep infection rates as high as 35%.[10]

As a result, locked intramedullary nailing has become the standard treatment for open tibia fractures enabling axial alignment, early weightbearing, and immediate knee and ankle motion.[11-19] Despite this, the complications including a high incidence of local bony necrosis and sepsis that occur following reamed intramedullary nails have led some to discourage the use of this method of skeletal stabilization in open tibia fractures.[3,20] Proponents of tibial nail insertion without reaming argue that this technique results in lower infection rates owing to less disruption of the endosteal blood supply.[21] Sanders et al[15] reported on the treatment of 64 patients with open tibial shaft fractures using unreamed interlocked intramedullary nails. All but 1 of the fractures healed with excellent alignment and an overall chronic infection rate of 4%. Others have reported similar successes.[16,18,22-24] The purpose of this study is to review a large prospective and consecutive series of open tibia fractures initially stabilized using a tibial nail without reaming and to examine the effects of protocol-driven management. Our hypothesis is that immediate tibial nail insertion without reaming is a safe and effective treatment method for open tibia fractures.

Patients and Methods

For a 6-year period (1992-1997), 161 consecutive adult patients (16-83 years old) presenting acutely from the time of injury with grades I-IIIb[3-4] open tibia fractures were treated using a standardized protocol. All injuries were classified by the Gustilo classification.[3-4] There were 37 grade I, 62 grade II, 43 grade IIIa, and 19 grade IIIb (requiring flap coverage) open tibia fractures. Four type IIIc injuries were excluded including 3 patients with impending amputation who had only a single tibial vessel functioning with a nonischemic foot on presentation. Sixty-two patients had associated injuries, including 12 with compartment syndromes.

After initial assessment, all patients were started on 1 g of Ancef (Sandoz) intravenously every 8 hours and received tetanus prophylaxis if necessary. Those with wounds greater than 10 cm also received gentamicin intravenously (3-5 mg/kg of body weight for 24 hours in 3 divided doses).

Wound debridement and intramedullary nailing were conducted with separate surgical set ups as soon as possible after admission to the hospital with at least 10 liters of normal saline solution used for wound irrigation. The 12 patients who had a compartment syndrome underwent fasciotomies prior to intramedullary nailing.

All operative procedures were performed using a standard operative protocol on a radiolucent table without continuous traction.[25] All tibial nail insertions were performed through a 10-15 mm midpatellar skin incision and medial paratendinous approach to the proximal tibia. Relatively narrow titanium nails (ACE Depuy[R] 8 mm, 9 mm, 10 mm)[26] were used in an effort to provide an internal splint while avoiding nail incarceration. A nail 1.5 mm narrower than the isthmus on the lateral x-ray, up to 10 mm, was chosen. All intramedullary nails were statically locked with two 5.5 mm perpendicular proximal screws and two 4.5 mm parallel distal screws. Cortical contact of the fracture fragments was considered desirable, and shortening of up to 1 cm was accepted to achieve this goal. Contact was achieved in most cases by placing the foot on the table during final impaction after the nail was passed across the fracture. If a gap persisted at the fracture site after nail passage, the nail was overseated, distal locking was performed, and the nail back was slapped until cortical contact was achieved.[25]

Patients underwent repeated irrigation and debridement at 2–3-day intervals with delayed closure (or flap reconstruction) as soon as the wound was clean, and all within 14 days by protocol. Patients in whom the protocol was not followed are reported separately. On postoperative day 1, patients were mobilized nonweightbearing on the operated extremity and allowed partial weightbearing at 8-12 weeks. All preoperative, operative, and postoperative data were collected prospectively. Patients were followed in the outpatient clinic every 6-8 weeks with sequential anteroposterior (AP) and lateral radiographs until fracture union. Full weightbearing was permitted when there were signs of bridging callus. Union at the fracture site was defined as evidence of bridging callus of 3 of the 4 cortices on orthogonal x-rays, combined with a lack of tenderness at the fracture site or unassisted weightbearing. Delayed union was defined as the fracture requiring longer than 9 months to unite. Angulation was measured on the AP and lateral radiographs with malunion being defined as greater than 5 degrees of angulation on either view, shortening of more than 1 cm, or rotational deformity of more than 15 degrees on clinical examination. At each clinic visit, patients completed a standardized questionnaire, which included evaluation of the knee and ankle and the patient's ability to work and return to his or her normal or sporting activities. They were specifically asked about any restrictions they were experiencing. Anterior knee pain was graded by the patients as none, mild, moderate, or severe. A superficial soft-tissue infection was diagnosed in the presence of purulent discharge from the wound with positive microbiological speciation. A deep infection was defined if operative exploration with bone debridement was necessary to eradicate the infection. Secondary procedures were offered if there was only minimal callus at 6 to 9 months or if there was no radiographic progression toward union 6 months after surgery for 2 consecutive months, based on the senior author's management protocol at that time. In patients with significant bone defects

(greater than 60% of the cortex and greater than 1.5 cm in length), bone grafting was recommended. In those with smaller defects, dynamization and new exchange nailing with reaming were offered to the patient and their preference was followed. Broken interlocking screws or tibial nails were recorded as implant failures.

Results

Of the 161 patients that were entered into the study, 3 died as a result of multiple injuries, 10 were lost to follow up, and 5 dropped out of the protocol, leaving 143 fractures that were followed to union (Table 1). Follow up averaged 2.2 years (0.6-5.5 years). Twenty-seven patients were not followed for a year but were followed through union, which occurred between 6 months and 1 year. Seventy-six fractures (53%) united within 6 months, 35 (25%) took between 6 and 9 months, and 32 (22%) fractures took greater than 9 months to unite and were considered delayed unions. Of these 32 cases, there was 1 grade I injury and 13 grade II and 18 grade III open fractures.

Grade of Open Fracture	Number of Patients
I	33
II	57
IIIa	38
IIIb	15

TABLE 1: Type of Open Tibial Fracture by Gustilo Classification (143 Patients)

Twenty-five additional procedures were needed to obtain union in 16 of the 32 delayed union patients including 12 nail exchanges, 4 bone grafts, and 9 dynamizations. Six of the 9 patients who had failure of dynamization had a subsequent exchange intramedullary nailing. The other 16 out of the 32 patients with delayed union healed without secondary surgical intervention, although by patient choice 7 used a bone stimulator (EXOGEN, Smith and Nephew).

For the entire series, there were 3 cases of cellulitis (2%) (1 grade I, 1 grade II, 1 grade IIIa), 1 superficial infection (0.7%) (grade I), and 4 deep infections (3%) (1 grade I, 2 grade II, 1 grade III) (Table 2). The deep infections were treated with aggressive irrigation and debridement, intravenous antibiotics, and tibial nail removal after union of the fracture. One patient's infection required 2 exchange intramedullary nailings because the infection was intramedullary, whereas the other 3 were localized.[55] One patient had failure of a rotational extensor hallucis longus flap and required free flap coverage but did not develop a deep infection. No drainage was present in these 4 patients with deep infections at final follow up.

Grade of Injury	Number of Patients	Number of Patients Treated by Protocol	Number of Deep Infections
I	37	33	1
II	62	56	2
IIIa	43	41	—
IIIb	19	13	1

TABLE 2: Summary of Patients Who Followed the Protocol and Their Deep Infection Rates

Implant failures included 3 grossly loose screws (0.5%, *n* = 572), 2 broken screws (0.3%, *n* = 572), and no nail breakages. One 8 mm nail bent after a patient with a segmental bone defect who was noncompliant walked unrestricted for 8 months. The patient healed after a reamed exchange intramedullary nailing with bone graft. There were 5 malalignments (3%) (3 valgus, 2 varus) of greater than 5 degrees (2 proximal third, 1 midshaft, 2 distal third fractures). There were no losses of reduction after intramedullary nailing, nonunions, or late amputations.

Thirty patients (21%) were found to have reduced ankle motion of between 5 and 10 degrees difference in total arc when compared with the uninjured side; 29 (20%) had complaints of minor to moderate knee pain; and 30 (21%) had intermittent fracture site pain after activity, despite clinical and radiographic union. Eleven patients (8%) considered themselves completely disabled after their injury (1 grade I, 5 grade II, 5 grade III), 6 of whom had had a compartment syndrome.

Five patients' (3%) management deviated from the protocol and are not included in the previously listed statistics. Three were grade IIIb fractures and did not have adequate coverage by 14 days (2 failed “sure-close” [Sure-closure system, Life Medical Sciences, Inc, Princeton, New Jersey] devices and 1 delayed coverage procedure) and 2 were grade II injuries that did not have a second debridement. Four of these 5 patients developed a complication (Table 3).

Patient	Gustilo Grade of Injury	Reason Why Patient Failed Protocol Treatment	Complication
1	II	Did not undergo secondary debridement	Delayed union
2	II	Did not undergo secondary debridement	None
3	IIIb	Coverage failed*	Infection
4	IIIb	Coverage failed*	Infection
5	IIIb	Underwent delayed coverage	Amputation

*Sure-Closure System, Life Medical Sciences, Inc, Princeton, NJ.

TABLE 3: Summary of Patient Outcomes Who Deviated from the Standard Treatment Protocol

Discussion

Open tibia fractures are high-energy injuries with substantial soft-tissue disruption that result in high complication rates including infection, malunion, nonunion, and diminished functional capacity.[5,8,11,26-36] Management is directed toward avoiding infection while providing a stable and well-aligned limb with protocols emphasizing emergent aggressive debridement, noninvasive bony stabilization, antibiotics, and early soft-tissue coverage. Edwards et al[5]demonstrated a 50% decrease in infection rate with early and aggressive debridement of nonviable tissue including bone. Fisher reported a 68% infection rate if coverage was delayed beyond 14 days as compared with 18% if coverage was obtained within 14 days after injury.[37] Similarly, low infection rates have been reported after immediate wound coverage of exposed bone with either fasciocutaneous or free flaps.[26,38] From these findings, it is clear that one of the most important factors in maintaining a low infection rate is the restoration of a clean, healthy soft-tissue envelope.

Of secondary importance is the method of bone stabilization. The high rate of complications associated with external fixators and plate osteosynthesis has resulted in intramedullary nailing becoming the preferred method of treatment in the management of open tibial shaft fractures.[5,9,11,15,29,31,34,35,39-41] Some concerns exist, however, with regard to the high infection rates that have been reported with reamed intramedullary nails.[11,27,30,42,43] Wiss and Stetson[36] noted a 24% infection rate in grade I and II open fractures and stated that reamed intramedullary nailing, even on a delayed basis, may be contraindicated in the management of open tibia fractures. Melcher et al[44] demonstrated in a rabbit model a statistical increase in infection rates in experimentally contaminated open fractures after reamed nailing compared with tibial nail insertion without reaming. These findings of increased infection rates associated with reaming of the medullary canal are presumably the result of disruption of the endosteal blood supply of the bone. Brinker et al[45] demonstrated that the nutrient artery of the tibia is damaged during reamed intramedullary nailing to a much greater degree than after tibial nail insertion without reaming and that its effects are seen up to 14 days later. Schemitsch et al[46] investigated the effects of reamed versus unreamed locked intramedullary nailing on cortical porosity formation in sheep fractured tibiae and found that reamed nail insertion was associated with a greater decrease in overall cortical porosity. They also noted that reamed intramedullary nailing resulted in a larger decrease in overall endosteal perfusion than intramedullary nailing without reaming immediately after surgery (P <0.015) and that this effect on cortical bone perfusion persisted for up to 12 weeks within the reamed group compared with 6 weeks in the unreamed group. Klein and colleagues[47] also found similar reductions in cortical blood flow after reamed versus unreamed intramedullary nailing (70% vs 31%) and that reamed tibial nail insertion affected almost twice the depth of cortex than the unreamed technique.[47] These findings suggest that tibial nail insertion without reaming may be initially advantageous when tibial cortical vascularity is compromised, as may be seen with open tibia fractures, by limiting further injury to cortical bone and permitting faster cortical revascularization.[48,49] In addition to its effects on endosteal blood

supply, reaming has been shown to induce thermal necrosis within the medullary canal. This leads to osteocyte death and can lead to the development of severe osteomylelitis.[50] This added insult to the precarious bone-healing environment associated with open tibia fractures may help to explain Zych and Hutson's[51] findings that infections around tibial nails placed without reaming were easier to eradicate compared with those after reaming.

In light of the concerns associated with reaming on cortical blood supply, several authors have examined the use of tibial nails without reaming in the treatment of open tibia fractures. Whittle et al[52] treated 50 open tibial shaft fractures with unreamed interlocking nails and found that 48 (96%) united at an average of 7 months. There were 4 infections (8%), all at the sites of grade-III fractures. Their results were comparable with, or better than, those obtained with other forms of fixation, including immobilization with a cast and external fixation. Tornetta et al[8] noted that patients whose grade IIIb fractures were stabilized by intramedullary nails without reaming had better motion, had less angulation at the fracture site, and were easier to manage in terms of soft-tissue procedures and bone grafting compared with those treated with external fixators. Similar findings were reported by Henley and associates,[9] who prospectively compared intramedullary tibial nail insertion without reaming to half pin external fixators in the treatment of grades II, IIIa, and IIIb tibial shaft fractures. They noted that the unreamed nails were more efficacious, had improved limb alignment, required fewer secondary procedures, and had lower infection rates. Sanders et al[15] reported on 64 open fractures including 21 grade IIIb fractures that were treated according to protocol using unreamed interlocking intramedullary nails and found that the majority of fractures had healed by 9 months, with union correlating with the degree of soft-tissue injury. Twenty fractures exhibited a delay in healing, of which 11 underwent further surgery. Our data are in keeping with previous reports. Of our patients' fractures, 78% healed within 9 months, and of the 32 fractures that were considered delayed unions, 25 additional procedures were required to obtain union. The deep infection rate of 3% is lower or equal to that reported by others,[30,53] reinforcing the need for aggressive initial wound debridement, irrigation, and early soft-tissue coverage in the management of open tibial shaft fractures. When this protocol was not followed (3 were grade IIIb injuries that did not have adequate coverage by 14 days and 2 were grade II injuries that did not have a second debridement), 4 of 5 patients developed complications including 2 infections and 1 amputation, again supporting protocol-driven management and early wound coverage.

A number of studies have reported high rates of screw failure in unreamed intramedullary nailing (29% to 41%).[30,32] In the current study, the screws were titanium alloy using proximal 5.5 mm and distal 4.5 mm screws. The failure rate of these screws was 0.3%, which may be related to the increase in bending strength associated with their larger section modulus of the internal diameter of the screws and attempts to offload the screws by obtaining cortical contact at the fracture site.[54] There were no nail breakages in this series because we chose to use a canal filling nail allowing for better mechanical stability than an earlier series of very narrow nails.[52]

One of the major limitations associated with the study is the lack of a comparison group. Because this is a consecutive cohort of patients, and not a comparative study, comparisons may be drawn only from other reported series. In addition, we chose to report objective data rather than outcome scores because we were most interested in establishing union and complication rates for this single technique. However, based on our data, we believe that this protocol is at least as effective as any reported within the literature for the treatment of open grade I to IIIb tibia fractures.

In conclusion, we report a large prospective series of open tibial shaft fractures treated with intramedullary tibial nails without reaming. Its main strength is that it is the largest consecutive series of patients treated by this single technique and serves to heighten the importance of judicious soft-tissue management and protocol-driven care to avoid complications because 4 out of the 5 patients who fell out of the protocol as a result of management errors had complications. The deep infection rate for patients treated by the protocol was only 3%. The implant failure rate is lower than in previously reported series of unreamed nails and is most likely attributable to attempts to obtain cortical contact and avoid fracture gaps, in addition to the increased material strength of titanium implants with larger screws. Overall satisfaction was good, but approximately 41% of the patients had some complaints of knee or fracture site pain or both well after union.

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