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Functional and radiological outcome of antibiotic coated intramedullary interlocking nail in the management of open tibial shaft fractures

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Abstract

Background: Open tibial shaft fractures are common high-energy injuries frequently associated with soft tissue damage and contamination, leading to a high risk of infection, delayed union, and nonunion. Achieving stable fixation and infection control remains a major challenge in their management. Antibioticcoated intramedullary interlocking nails have emerged as an effective solution, providing both mechanical stability and localized high antibiotic concentrations at the fracture site.

Aim: To evaluate the functional and radiological outcomes of antibiotic-coated intramedullary interlocking nails in the management of open tibial shaft fractures. Materials and Methods: This prospective study was conducted in the Postgraduate Department of Orthopaedics, Government Hospital for Bone and Joint Surgery, Government Medical College Srinagar, from May 2021 to January 2024. Twenty-one skeletally mature patients (>18 years) with Gustilo-Anderson type I, II, and IIIA open tibial fractures were included. All patients underwent early debridement, antibiotic-coated intramedullary interlocking nailing, and standardized postoperative care. Patients were followed for 9 months with clinical and radiological evaluation. Functional assessment was done using the Modified Johner-Wruhs criteria.

Results:Out of 21 patients, 18 (85.7%) were males and 3 (14.3%) females, with a mean age of 33.9 years. Road traffic accidents were the most common cause of injury (71.4%), followed by falls (19.0%) and sports-related injuries (9.6%). According to the Gustilo-Anderson classification, 7 cases (33.3%) were type I, 10 (47.6%) type II, and 4 (19.1%) type IIIA. The average time to radiological union was 18.3 weeks. Superficial infection was observed in 2 patients (9.6%) and deep infection in 1 patient (4.8%), all of which resolved with appropriate treatment. No cases of nonunion or implant failure were reported. At the final follow-up, 12 patients (57.1%) achieved excellent, 6 (28.6%) good, and 3 (14.3%) fair functional outcomes according to the Modified Johner-Wruhs criteria.

Conclusion: Antibiotic-coated intramedullary interlocking nailing provides a reliable method for managing open tibial shaft fractures, combining stable fixation with local antibiotic delivery. It significantly reduces infection rates, promotes faster union, and achieves excellent to good functional outcomes in the majority of patients. This technique is safe and effective for Gustilo type I to IIIA fractures and can be considered a preferred approach in similar clinical scenarios.

Keywords: Open tibial fractures, antibiotic-coated intramedullary nail, infection control, radiological union, functional outcome

Introduction

Open fractures are orthopedic emergencies in which the fracture and associated hematoma communicate with the external environment through a traumatic breach in the surrounding soft tissues and skin. The defect may not always lie directly over the fracture site but may be located at a distance due to the injury mechanism. Among long bones, the tibia is the most commonly fractured owing to its subcutaneous anteromedial surface and limited soft tissue envelope, making it highly susceptible to trauma and subsequent complications such as malunion and nonunion [1].

The tibial diaphysis is the most frequently involved site, and approximately 80% of these fractures are accompanied by fibular fractures [2, 3]. Tibial shaft fractures demonstrate a bimodal age distribution, with low-energy spiral injuries predominating in older patients, whereas highenergy transverse or comminuted fractures are more common in younger individuals. Lowenergy injuries typically occur from falls or sports activities, while high-energy trauma, such as road traffic accidents, remains the leading cause of open tibial fractures [4]. Owing to its subcutaneous location, the reported incidence of open fractures of the tibia ranges from 12% to

47% ^[5], with motorcycle accidents showing rates as high as 63% ^[6]. When open fractures involve the tibia, Gustilo-Anderson Type IIIB injuries are especially prevalent, often requiring soft tissue reconstruction and flap coverage ^[7].

The management of open tibial fractures poses significant challenges due to contamination, bone exposure, and high infection risk. The Gustilo-Anderson classification remains the cornerstone for grading open fractures, guiding both surgical and antibiotic strategies. It categorizes injuries into Types I, II, and III (subdivided into IIIA, IIIB, and IIIC) based on wound size, contamination level, and the extent of soft tissue and vascular injury [8, 9].

Antibiotic-coated intramedullary interlocking nails have emerged as an innovative solution for managing open and infected tibial fractures. These implants are impregnated with heat-stable antibiotics—most commonly gentamicin—embedded in polymethyl methacrylate (PMMA) or absorbable carriers, enabling sustained local drug release at bactericidal concentrations while maintaining fracture stability [10, 11]. The use of such nails minimizes systemic antibiotic toxicity, enhances bone healing by stimulating osteoblastic activity, and permits early mobilization and weight bearing [12].

Initially described in 2002 for infected nonunions, antibiotic-coated nails have since evolved from simple cement-coated wires providing minimal stability to mechanically robust, interlocking systems offering both rotational and axial control [13]. Their clinical indications include open tibial fractures (Gustilo Types I-IIIA), infected nonunions, and fractures managed previously with external fixation for more than two weeks. Contraindications include skeletal immaturity, pregnancy, and hypersensitivity to aminoglycosides [14].

Gentamicin remains the most commonly used antibiotic due to its broad-spectrum activity against both Gram-negative and Gram-positive organisms, including Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, and Klebsiella species [15]. Vancomycin and tobramycin are also used in resistant infections or in cases involving methicillin-resistant Staphylococcus aureus (MRSA).

The tibia's blood supply, derived from nutrient, periosteal, and metaphyseal arteries, plays a critical role in fracture healing. Compromised vascularity, often due to soft tissue stripping or infection, increases the risk of delayed union or nonunion, underscoring the importance of stable fixation with local infection control. Hence, antibiotic-coated intramedullary nails provide a dual advantage of mechanical stability and sustained local antimicrobial activity, leading to improved functional and radiological outcomes in open tibial shaft fractures.

Aims and Objectives

The aim of the present study was to evaluate the functional and radiological outcomes of antibiotic-coated intramedullary interlocking nailing in the management of open tibial shaft fractures.

Materials and Methods

This prospective study was conducted in the Postgraduate Department of Orthopaedics, Government Hospital for Bone and Joint Surgery, an associated hospital of Government Medical College, Srinagar, after obtaining approval from the Institutional Ethical Committee. The study period extended from May 2021 to January 2024. Patients diagnosed with open tibial fractures who met the inclusion criteria were enrolled after obtaining informed consent.

Inclusion Criteria

- 1. Skeletally mature patients (age >18 years)
- 2. Gustilo type I, II, and IIIA fractures
- 3. Fractures distal to the tibial tuberosity
- 4. Fractures up to 4 cm proximal to the ankle joint
- 5. Time since injury to surgery less than 24 hours

Exclusion Criteria

- 1. Intra-articular tibial fractures around the knee
- 2. Gustilo type IIIB and IIIC fractures
- 3. Pathological fractures, fracture nonunion, and delayed union
- 4. Patients with neurovascular injury
- 5. Patients with malignancy (primary or secondary)
- 6. Intra-articular fractures of the distal one-third of the tibia near the ankle joint
- 7. Closed tibial fractures
- 8. Patients medically unfit for surgery
- 9. Pregnant or breastfeeding patients, or those with a known allergy to aminoglycosides
- 10. Patients with head injury
- 11. Polytrauma patients
- 12. Time since injury to surgery exceeding 24 hours

Preoperative Assessment

Patients were admitted and managed following Advanced Trauma Life Support (ATLS) protocols. A detailed history was recorded, including mechanism of injury, associated injuries, drug and personal history. General and local examinations were performed to assess the limb involved, swelling, tenderness, deformity, and distal neurovascular status. Radiographic evaluation included standard anteroposterior and lateral views of the leg, including knee and ankle joints. Fractures were classified according to the Gustilo and Anderson classification. Wound documentation and photography were carried out in the emergency department. Initial wound irrigation with sterile normal saline and provisional fracture stabilization using splints

normal saline and provisional fracture stabilization using splints or traction were performed. Triple antibiotic therapy was initiated with intravenous cefuroxime (1.5 g twice daily), amikacin (500 mg twice daily), and metronidazole (100 mg thrice daily). Tetanus prophylaxis was also administered. Routine investigations included complete blood count,

coagulation profile, blood grouping and serology, blood sugar, renal and liver function tests, ECG, and chest X-ray. Patients were immobilized with a long leg splint and given analgesics. Surgery was performed after anesthetic clearance and informed consent.

Irrigation and Debridement

Early irrigation and debridement were performed under sterile conditions. Irrigation volume varied with fracture type: 3 L for Gustilo I, 6 L for Gustilo II, and 9 L for Gustilo III fractures. High-volume, low-pressure pulsatile lavage was used. Wounds were extended longitudinally for adequate exposure, and nonviable tissues were excised. Muscle viability was assessed using the "4Cs" criteria: color, consistency, contractility, and capacity to bleed. All avascular fascia and devitalized bone fragments without soft tissue attachments were removed.

Operative Technique

After anesthesia, patients were positioned supine on a radiolucent table, ensuring adequate knee flexion. Following wound wash and debridement, closed reduction was achieved under fluoroscopic guidance. Reduction was accepted as per Trafton's criteria (mediolateral angulation <5°, anteroposterior

angulation <10°, and rotation <10°). The entry point was made along the patellar tendon, aligned with the ventral edge of the tibial plateau. A ball-tipped guide wire was introduced, and the canal was reamed serially. An appropriately sized antibiotic-coated intramedullary interlocking nail was inserted, with blocking screws applied if necessary to correct malalignment. The nail was locked proximally and distally, and the wound was closed after thorough wash. Postoperative intravenous antibiotics (cefuroxime, metronidazole, and amikacin) were continued, and distal neurovascular status was checked.

Postoperative Care and Follow-Up

On the first postoperative day, patients were assessed for wound soakage, pain, and neurovascular status. Standard anteroposterior and lateral radiographs were taken. Quadriceps and range of motion exercises were initiated early, and patients were mobilized with toe-touch weight bearing using a walker. Patients were discharged on the third postoperative day and continued oral antibiotics for five days.

Follow-up was conducted at 2 weeks, 6 weeks, and monthly thereafter until the final follow-up at 9 months. At each visit, clinical and radiological assessments were performed. Clinically, residual pain, tenderness, deformity, and muscle atrophy were evaluated. Radiological assessment included fracture alignment, union status, and implant integrity.

Results

A total of 21 patients with open tibial shaft fractures treated with antibiotic-coated intramedullary interlocking nails were included in this prospective study. The patients were followed up

clinically and radiologically for a period of 9 months. The following observations were made during the study.

The majority of patients in this study were males (18 out of 21, 85.7%) while females accounted for 3 patients (14.3%). The most affected age group was between 21-40 years, comprising 12 patients (57.1%). The mean age of the patients was 33.9 years (range 19-58 years). Right side involvement was seen in 13 patients (61.9%), and left side in 8 patients (38.1%). The most common mode of injury was road traffic accidents (RTA), observed in 15 cases (71.4%) and followed by falls in 4 cases (19.0%) and sports-related injuries in 2 cases (9.6%).

Table 1: Demographic profile of patients

Parameter	Category	No. Of Patients (n=21)	Percentage (%)
Age (years)	18-20	3	14.3
	21-40	12	57.1
	41-60	6	28.6
Sex	Male	18	85.7
	Female	3	14.3
Side involved	Right	13	61.9
	Left	8	38.1
Mode of injury	RTA	15	71.4
	Fall	4	19.0
	Sports injury	2	9.6

Most patients in this study had Gustilo type II fractures (10 cases, 47.6%), followed by type I fractures in 7 patients (33.3%) and type IIIA fractures in 4 patients (19.1%). No patient with type IIIB or IIIC fracture was included, as per the study criteria.

Table 2: Distribution of patients according to Gustilo-Anderson classification

Gustilo Type	No. Of Patients	Percentage (%)
Type I	7	33.3
Type II	10	47.6
Type IIIA	4	19.1

All patients were operated within 24 hours of injury as per the inclusion criteria. Most surgeries were performed between 6-12 hours after trauma (12 patients, 57.1%), while 6 patients (28.6%) were operated within 6 hours and 3 patients (14.3%) after 12 hours but within 24 hours.

Table 3: Time interval between injury and surgery

Time interval (hours)	No. Of Patients	Percentage (%)
<6	6	28.6
6-12	12	57.1
12-24	3	14.3

The mean time for radiological union was 18.3 weeks. The majority of fractures united between 16-20 weeks (12 patients, 57.1%), followed by 6 patients (28.6%) achieving union within 15 weeks and 3 patients (14.3%) showing delayed union (>20 weeks). No case of nonunion was reported.

Table 4: Time to radiological union

Time to Union (weeks)	No. Of Patients	Percentage (%)
≤15	6	28.6
16-20	12	57.1
>20	3	14.3

Superficial infection was observed in 2 patients (9.6%) which responded to local wound care and oral antibiotics. Deep

infection occurred in 1 patient (4.8%) and was managed with debridement and intravenous antibiotics. No implant failure or chronic osteomyelitis was noted during the follow-up period.

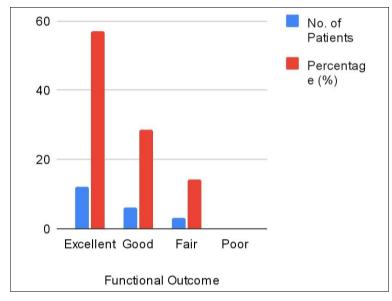
Table 5: Postoperative complications

Complication	No. Of Patients	Percentage (%)
Superficial infection	2	9.6
Deep infection	1	4.8
Delayed union	3	14.3
Nonunion	0	0
Implant failure	0	0

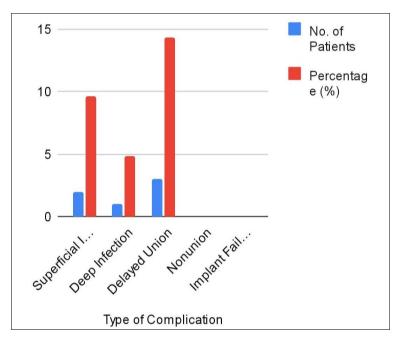
At final follow-up (9 months), 12 patients (57.1%) showed excellent functional results, 6 patients (28.6%) had good outcomes, and 3 patients (14.3%) had fair results. None had poor outcomes. Most patients were able to return to their pre-injury activities within 5-6 months.

Table 6: Functional outcome according to modified Johner-Wruhs criteria

Functional Outcome	No. Of Patients	Percentage (%)
Excellent	12	57.1
Good	6	28.6
Fair	3	14.3
Poor	0	0



Bar Graph 1: Functional outcomes according to modified Johner -Wruhs criteria.



Bar Graph 2: Distribution of Post-operative complications.

Discussion

Open fractures of the tibial shaft are among the most frequent long bone injuries due to the subcutaneous location of the tibia and its limited soft tissue envelope. These injuries are often caused by high-energy trauma such as road traffic accidents and are associated with significant complications including infection, delayed union, and nonunion if not managed appropriately [16]. The management of open tibial fractures aims to achieve fracture stabilization, infection control, and soft tissue healing in the shortest possible time. In this context, antibiotic-coated intramedullary nails have gained attention for their dual role in mechanical stabilization and local antibiotic delivery.

In the present study involving 21 patients with open tibial shaft fractures treated with antibiotic-coated intramedullary interlocking nails, the majority of patients were young males (85.7%) with road traffic accidents being the predominant cause of injury (71.4%). Similar demographic trends have been reported by Court-Brown and McBirnie, who observed that tibial fractures are more common in young adult males involved in vehicular accidents [17]. The predominance of Gustilo type II

fractures (47.6%) in this study is consistent with the pattern of moderate soft tissue injury often seen in traffic-related trauma $_{[18]}$

All patients were operated within 24 hours of injury, following early irrigation and debridement protocols. Early intervention is known to reduce infection rates and improve outcomes, as emphasized by Patzakis *et al.*, who found that early debridement within 6-8 hours significantly decreased the risk of deep infection in open fractures ^[19]. The current study reported a superficial infection rate of 9.6% and a deep infection rate of 4.8%, which are notably lower than those historically observed in open tibial fractures treated without local antibiotic delivery systems ^[20]. The use of antibiotic-impregnated nails likely contributed to this reduction by providing sustained local antibiotic release, maintaining bactericidal concentrations at the fracture site while minimizing systemic toxicity ^[21].

The mean time to radiological union in this study was 18.3 weeks, with the majority (57.1%) achieving union between 16 and 20 weeks. This compares favorably with reports by Conway *et al.*, who observed an average union time of 20-24 weeks in

open tibial fractures managed by conventional nailing techniques ^[22]. The relatively shorter healing time in the current study may be attributed to reduced infection rates, preserved bone biology through early stabilization, and the osteoconductive effect of the antibiotic cement layer ^[23]. Moreover, the absence of nonunion in this series underscores the biological advantage of early fixation and local antibiotic therapy.

Functional outcomes were assessed using the modified Johner-Wruhs criteria, where 57.1% of patients achieved excellent and 28.6% good outcomes, reflecting satisfactory restoration of limb function. These results are comparable to those reported by Wasko and Borens, who found 83% satisfactory outcomes in their series using gentamicin-coated nails for open tibial fractures [24]. The promotion of early mobilization and reduction in hospital stay with antibiotic-coated nails have also been emphasized by other authors [25].

The low rate of implant-related complications in this study is in accordance with the findings of Schmidmaier *et al.*, who demonstrated that antibiotic-coated implants not only inhibit bacterial colonization but also enhance callus formation due to improved local biological conditions ^[26]. The cost of antibiotic-coated implants remains a limitation in low-resource settings; however, the reduced need for secondary surgeries and prolonged antibiotic therapy may offset initial expenses ^[27]. The main disadvantage noted in literature is the potential reduction in mechanical strength of the nail due to the cement coating, though no such failures were encountered in this study ^[28].

Infection control remains the cornerstone of successful management in open fractures. The introduction of antibiotic-coated intramedullary nails represents a significant advancement in orthopedic trauma care, providing stable fixation while effectively addressing infection risk. The results from the present study reinforce the clinical utility of this technique, demonstrating low infection rates, satisfactory union times, and favorable functional outcomes. Further multicentric studies with larger sample sizes and long-term follow-up are warranted to validate these findings and optimize the antibiotic formulations used for coating.

Conclusion

The management of open tibial shaft fractures remains a challenging aspect of orthopedic trauma care due to the inherent risk of infection, delayed healing, and soft tissue compromise. The present prospective study involving 21 patients treated with antibiotic-coated intramedullary interlocking nails demonstrates that this approach provides effective fracture stabilization and simultaneously delivers high local antibiotic concentrations, thereby minimizing postoperative infections.

The majority of patients in the study achieved excellent or good functional outcomes, with an overall infection rate markedly lower than that reported in historical controls. The mean time to union of 18.3 weeks reflects satisfactory healing kinetics compared to conventional methods. These results corroborate previous literature indicating that antibiotic-coated nails significantly reduce deep infection and promote earlier union in open tibial fractures.

The technique also offers the advantage of early mobilization, reduced hospital stay, and improved patient compliance. Despite the higher cost and limited mechanical reuse of coated implants, their clinical benefits in infection control and fracture healing justify their utilization, especially in high-risk cases.

In summary, antibiotic-coated intramedullary nailing is a safe, effective, and biologically favorable option for the management

of open tibial fractures. It combines the principles of stable fixation with local infection prophylaxis, contributing to optimal functional recovery and reduced complication rates. Further large-scale randomized studies are recommended to establish standardized protocols regarding antibiotic selection, coating thickness, and duration of implantation to maximize therapeutic outcomes.

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