Original Article

Uncoated Versus Antibiotic Coated Intramedullary Interlocking Nail in Open Tibial Shaft Fractures –A Prospective Radndomised Study of Clinical Outcomes and Complications

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Abstract

Background: Open tibial shaft fractures are associated with a high risk of infection, delayed union, non-union, and repeated surgical procedures. Antibiotic-coated intramedullary nails provide stable fixation together with local antibiotic delivery and may improve treatment outcomes. The objective is to compare clinical outcomes, fracture healing, infection rates, secondary procedures, and functional recovery between uncoated and antibiotic-coated intramedullary interlocking nails in open tibial shaft fractures. **Material and Methods:** This prospective randomized study included 50 adults with open tibial shaft fractures treated at Basaveshwara Medical College Hospital and Research Centre from May 2023 to January 2025. Patients were allocated equally to uncoated and antibiotic-coated nail groups. The coated nails were prepared using polymethylmethacrylate cement containing vancomycin and gentamicin. Infection, wound complications, union time, delayed union, non-union, secondary procedures, hospital stay, SF-36 scores, and Lysholm scores were compared. **Results:** Infection occurred in 48% of the uncoated group and 12% of the coated group (p=0.007). No osteomyelitis occurred in the coated group. Mean union time was significantly shorter with coated nails (7.1 versus 9.2 months, p<0.0001). Delayed union occurred in 20% versus 60%, while non-union occurred in 4% versus 28% in the coated and uncoated groups, respectively. Repeat debridement, dynamization, bone grafting, and revision surgery were significantly less frequent in the coated group. Mean hospital stay was 15 days with coated nails and 26 days with uncoated nails. SF-36 and Lysholm scores were significantly better in the coated group at all follow-ups. **Conclusion:** Antibiotic-coated intramedullary nails significantly reduced infection and secondary procedures, promoted faster union, shortened hospitalization, and improved functional recovery compared with uncoated nails in open tibial shaft fractures.

Keywords: Open tibial fracture, antibiotic-coated nail, intramedullary nailing, gentamicin, vancomycin, and infection, non-union.

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Introduction

Open tibial shaft fractures are among the most challenging orthopedic injuries because of the subcutaneous location of the tibia, extensive soft tissue damage, and contamination at the time of injury. These fractures are associated with high rates of infection, delayed union, non-union, prolonged hospitalization, and repeated surgical interventions, making their management a significant clinical challenge.[1]

Intramedullary interlocking nailing (IMIL) is considered the standard treatment for most open tibial shaft fractures as it provides stable fixation, preserves fracture biology, and facilitates early mobilization. However, despite advances in surgical techniques and systemic antibiotic therapy, postoperative infection remains a major cause of treatment failure, particularly in Gustilo-Anderson type II and III open fractures.[2,3]

Local antibiotic delivery has emerged as an effective strategy to reduce bacterial colonization at the fracture site while minimizing systemic toxicity. A systematic review by Craig et al. demonstrated that the addition of local prophylactic antibiotics significantly decreases infection rates in open tibial fractures managed with intramedullary nailing.[4]

Antibiotic-coated intramedullary nails combine mechanical stabilization with sustained local antibiotic release, thereby preventing biofilm formation and reducing deep infection. Fuchs et al. first reported encouraging clinical outcomes using gentamicin-coated tibial nails, with low infection rates and satisfactory fracture healing.[5] Similarly, Metsemakers et al. demonstrated that antibiotic-coated nails are particularly beneficial in complex open fractures and revision procedures by reducing implant-related infections without compromising

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fracture union.[6]

Comparative clinical studies have further supported the advantages of antibiotic-coated nails. Pinto et al. observed lower infection rates and improved fracture healing in Gustilo type I and II open tibial fractures treated with antibiotic-coated nails compared with conventional uncoated nails.[7] More recently, Perisano et al. also reported favorable clinical and radiological outcomes with antibiotic-coated intramedullary nails, emphasizing their role in reducing postoperative complications and improving functional recovery in open tibial fractures.[8]

Although encouraging evidence exists regarding antibiotic-coated intramedullary nails, comparative prospective randomized studies evaluating their effectiveness against conventional uncoated nails remain limited. Therefore, the present study was undertaken to compare the clinical outcomes, fracture healing, infection rates, functional recovery, and complications between antibiotic-coated and uncoated intramedullary interlocking nails in patients with open tibial shaft fractures.

Materials and Methods

Study Design and Setting: This prospective randomized controlled study was conducted in the Department of Orthopaedics, Basaveshwara Medical College Hospital and Research Centre over a period of 21 months (May 2023–January 2025).

Sample Size

A total of 50 patients with open tibial shaft fractures fulfilling the eligibility criteria were enrolled. Patients were randomized into two equal groups:

- **Group A:** Uncoated intramedullary interlocking nail (n=25)
- **Group B:** Antibiotic-coated intramedullary interlocking nail (n=25)

Inclusion Criteria

- Patients aged 18 years or older.
- AO/OTA type 42-A1, A2, A3, B1, B2, B3, C1, C2, and C3 open tibial shaft fractures.
- Gustilo-Anderson Type I, II, IIIA, IIIB, and IIIC open fractures.
- Patients willing to provide written informed consent.

Exclusion Criteria

- Closed tibial shaft fractures.
- Pathological fractures.
- Patients younger than 18 years.
- Open fractures treated with external fixation or plate osteosynthesis.

Preoperative Assessment

All patients underwent detailed clinical examination and radiographic evaluation. Standard anteroposterior and lateral radiographs of the knee, tibia, and ankle were obtained. Fractures were classified according to the AO/OTA and Gustilo-Anderson classification systems.

Randomization and Surgical Procedure: Patients were randomized using computer-generated random numbers into either the uncoated or antibiotic-coated nail group. Thorough wound debridement and irrigation were performed before fracture fixation.

Both groups underwent closed or open reduction with intramedullary interlocking nailing under spinal anesthesia using standard surgical techniques. In the antibiotic-coated group, the nail was coated intraoperatively with 40 g polymethylmethacrylate (PMMA) bone cement containing 2 g vancomycin and 0.5 g gentamicin before implantation.

Postoperative Care: All patients received intravenous antibiotics, analgesics, limb elevation, and early rehabilitation. Progressive weight-bearing was initiated according to fracture stability and radiological evidence of healing. Patients were followed at 6 weeks, 3 months, 6 months, and 12 months.

Outcome Measures

Patients were evaluated for:

- Superficial and deep infection.
- Osteomyelitis.
- Time to fracture union.
- Delayed union and non-union.
- Secondary procedures (debridement, dynamization, bone grafting, revision surgery).
- Functional outcome using the SF-36 and Lysholm Knee Scale.
- Postoperative complications and duration of hospital stay.

Statistical Analysis

Data were analyzed using SPSS version 25.0. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Student's *t*-test, Chi-square test, and Fisher's exact test were used for comparisons between groups. A p-value <0.05 was considered statistically significant.

Results

A total of 50 patients with open tibial shaft fractures were included and randomized equally into the uncoated intramedullary interlocking nail group and antibiotic-coated nail group, with 25 patients in each group. The mean follow-up duration was approximately 14.7 months, ranging from 6 to 18 months.

Table 1: Baseline Demographic and Clinical Characteristics

Parameter	Uncoated nail (n=25)	Antibiotic-coated nail (n=25)	p-value
Mean age, years (range)	33 (20–50)	36 (19–60)	0.33
Male	22 (88.0%)	24 (96.0%)	0.21
Female	3 (12.0%)	1 (4.0%)	
Mean BMI, kg/m²	25	27	0.201
Road traffic accident	21 (84.0%)	23 (92.0%)	0.525
Fall from height	3 (12.0%)	2 (8.0%)	
Sports injury	1 (4.0%)	0	
AO/OTA fracture type			0.89

Type A	8 (32.0%)	11 (44.0%)	
Type B	12 (48.0%)	11 (44.0%)	
Type C	5 (20.0%)	3 (12.0%)	
Gustilo-Anderson type			0.46
Type I	5 (20.0%)	1 (4.0%)	
Type II	12 (48.0%)	15 (60.0%)	
Type IIIA–IIIC	8 (32.0%)	9 (36.0%)	
Associated injuries	7 (28.0%)	8 (32.0%)	0.47
Comorbidities present	12 (48.0%)	9 (36.0%)	0.32

The two groups were comparable regarding age, sex, BMI, mechanism of injury, fracture classification, associated injuries, and comorbidities. Road traffic accidents were the predominant mechanism, and Gustilo-Anderson Type II fractures were most frequent in both groups.

Table 2: Comparison of Infection, Wound Healing and Fracture Union

Outcome	Uncoated nail (n=25)	Antibiotic-coated nail (n=25)	p-value
Any surgical-site infection	12 (48.0%)	3 (12.0%)	0.007
Superficial infection	8 (32.0%)	3 (12.0%)	—
Deep infection/osteomyelitis	4 (16.0%)	0	—
Wound-healing complications	14 (56.0%)	6 (24.0%)	0.021
Mean time to union, months	9.2	7.1	<0.0001
Delayed union	15 (60.0%)	5 (20.0%)	0.0039
Non-union	7 (28.0%)	1 (4.0%)	0.025
Successful fracture union	18 (72.0%)	24 (96.0%)	0.025
Gentamicin-related systemic toxicity	—	0	—

Antibiotic-coated nails were associated with significantly lower infection and wound-healing complication rates. No case of osteomyelitis occurred in the coated group. Fracture union was faster and more frequent in the coated group, with significantly lower delayed-union and non-union rates.

Table 3: Secondary Procedures and Hospital Stay

Outcome	Uncoated nail (n=25)	Antibiotic-coated nail (n=25)	p-value
Repeat debridement	12 (48.0%)	5 (20.0%)	0.037
Dynamization	8 (32.0%)	2 (8.0%)	0.033
Bone marrow aspiration	8 (32.0%)	2 (8.0%)	0.033
Bone grafting	6 (24.0%)	1 (4.0%)	0.045
Revision surgery	6 (24.0%)	1 (4.0%)	0.045
Amputation	1 (4.0%)	0	0.321
Plastic surgical coverage	6 (24.0%)	5 (20.0%)	0.70
Hospital stay, days, mean ± SD	26.0 ± 7.36	15.0 ± 5.10	<0.0001

Patients treated with antibiotic-coated nails required significantly fewer repeat debridements, dynamization procedures, bone grafts, and revision surgeries. The mean hospital stay was also substantially shorter in the coated group. The need for plastic surgical coverage and the amputation rate did not differ significantly.

Table 4: Functional Outcomes During Follow-up

Functional score	Follow-up	Uncoated nail Mean ± SD	Antibiotic-coated nail Mean ± SD	p-value
SF-36	3 months	48 ± 6.45	54 ± 4.52	<0.0001
	6 months	59 ± 7.14	72 ± 3.46	<0.00001
	12 months	73 ± 4.97	86 ± 4.38	<0.0000001
Lysholm Knee Score	3 months	44 ± 4.07	52 ± 5.68	<0.00001
	6 months	62 ± 7.31	86 ± 3.87	<0.0000001
	12 months	79 ± 4.91	92 ± 3.86	<0.0000001

Functional recovery improved progressively in both groups; however, SF-36 and Lysholm scores were significantly higher in the antibiotic-coated nail group at every follow-up. At 12 months, the coated group demonstrated superior quality of life and knee function.

Overall, antibiotic-coated intramedullary nails significantly reduced infection, delayed union, non-union, secondary interventions, and hospitalization while accelerating fracture healing and improving functional outcomes compared with uncoated nails.

Discussion

The present prospective randomized study compared uncoated and antibiotic-coated intramedullary interlocking nails in 50 patients with open tibial shaft fractures. The groups were comparable with respect to demographic characteristics, mechanism of injury, fracture pattern, Gustilo-Anderson grade, associated injuries, and comorbidities. Antibiotic-coated nails were associated with significantly lower infection rates, faster fracture union, fewer secondary procedures, shorter

hospitalization, and better functional outcomes.

Local antibiotic delivery through a coated intramedullary nail provides high antibiotic concentrations at the fracture site while maintaining stable internal fixation. Schmidmaier et al. reported favorable clinical outcomes with gentamicin-coated tibial nails, particularly in fractures at increased risk of infection.[9] In the present study, the overall infection rate was significantly lower in the antibiotic-coated group than in the uncoated group, and no patient in the coated group developed deep infection or osteomyelitis.

The absence of gentamicin-related systemic toxicity in the present study supports the safety of local antibiotic delivery. Moghaddam et al. demonstrated that gentamicin-coated tibial nails did not produce clinically significant systemic gentamicin exposure, thereby reducing concerns regarding nephrotoxicity or ototoxicity.[10] This local delivery system may therefore provide effective antimicrobial activity without the adverse effects associated with prolonged systemic treatment.

Antibiotic-coated nails have also been used successfully in the management of infected fractures and tibial non-unions. Reilly et al. reported that antibiotic-coated nails can control infection while simultaneously providing mechanical stability.[11] Thonse and Conway similarly demonstrated satisfactory infection eradication and fracture stabilization with antibiotic cement-coated interlocking nails in infected non-unions and segmental defects.[12] These findings support the combined mechanical and antimicrobial role of antibiotic-coated implants.

The mean time to fracture union was significantly shorter in the coated group, while delayed union and non-union were more frequent in the uncoated group. Wasko and Borens reported satisfactory infection control and progressive fracture healing using antibiotic cement nails for post-traumatic tibial infections.[13] Reduced bacterial colonization and improved local infection control may preserve the biological environment required for fracture healing and explain the improved union observed in the present study.

Patients receiving coated nails required fewer repeat debridements, dynamization procedures, bone grafts, and revision surgeries. These reductions may lessen treatment burden and improve resource utilization. Franz et al. reported that antibiotic-coated intramedullary nails may reduce infection-related procedures and healthcare expenditure in open tibial fractures.[14] Similarly, Steflik et al. found antibiotic cement-coated nails to be cost-effective for the initial management of severe open tibial fractures because of the lower risk of infection and reoperation.[15]

The antibiotic-coated group also had a significantly shorter hospital stay. The reduced frequency of wound complications, infection, delayed union, and secondary surgery likely contributed to earlier discharge and recovery. A systematic review and meta-analysis by Vargas-Hernández et al. supported the effectiveness of antibiotic-coated nails in reducing infection following open tibial fractures, particularly in injuries with extensive contamination and soft-tissue damage.[16]

Functional recovery, assessed using SF-36 and Lysholm scores, was significantly better in the coated group at 3, 6, and 12 months. Improved function may be related to earlier fracture union, fewer complications, reduced hospitalization, and a lower requirement for additional procedures. Kalbas et al. emphasized that antibiotic-coated nails provide both local antimicrobial activity and stable fixation, making them useful in complex open fractures and fracture-related infections.[17]

Overall, the findings demonstrate that antibiotic-coated intramedullary nails provide important clinical advantages over uncoated nails in open tibial shaft fractures. However, the relatively small sample size, single-centre design, and limited follow-up should be considered while interpreting the results.

Conclusion

Antibiotic-coated intramedullary interlocking nails were more effective than uncoated nails in the management of open tibial shaft fractures. They significantly reduced surgical-site infection, osteomyelitis, delayed union, non-union, repeat debridement, dynamization, bone grafting, revision surgery, and duration of hospitalization. They also resulted in faster fracture union and superior functional outcomes without evidence of systemic gentamicin toxicity. Antibiotic-coated nails may therefore be considered a useful primary fixation option, particularly for Gustilo-Anderson type II and III open tibial fractures.

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Conflicts of interest

There are no conflicts of interest.

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