

Research Article

Comparative Analysis of Clinical and Radiological Outcomes in Open Tibia Fractures: Uncoated vs. Antibiotic-Coated Intramedullary Interlocking Nails.

Dr Veerendra T

Assistant Professor, Department of Orthopedics, VRK Institute of Medical Sciences, Teaching Hospital & Research Centre, India.

*Corresponding Author

Dr Veerendra T

Article History

Received: 05.05.2024

Revised: 12.05.2024

Accepted: 30.05.2024

Published: 15.06.2024

Citations:

Veerendra T Comparative Analysis of Clinical and Radiological Outcomes in Open Tibia Fractures: Uncoated vs. Antibiotic-Coated Intramedullary Interlocking Nails. *J Surg Radiol*, 03(02);2024; 9-12.

Abstract: *Introduction* Open tibia fractures are among the most challenging orthopedic injuries, often associated with high rates of complications such as infection, non-union, and delayed healing. These fractures typically result from high-energy trauma, such as motor vehicle accidents or falls from significant heights, and are frequently accompanied by soft tissue damage and contamination. Open tibia fractures are among the most common orthopedic injuries, often requiring surgical intervention. This study compares clinical and radiological outcomes between uncoated and antibiotic-coated intramedullary interlocking nails in managing open tibia fractures. *Material and Methods* A prospective comparative study was conducted in the Department of Orthopedics, VRK Institute of Medical Sciences, Teaching Hospital & Research Centre over a period of 1 year at our institution, involving patients diagnosed with open tibia fractures. This was a randomized controlled trial involving patients aged 18–60 years with open tibia fractures classified as Gustilo-Anderson types I–III1. Ethical approval was obtained from the institutional review board, and informed consent was acquired from all participants. Patients were randomly assigned into two groups: uncoated IMIL (Group A) and antibiotic-coated IMIL (Group B). Standard preoperative protocols, including intravenous antibiotic prophylaxis and wound debridement, were followed. *Results:* Group B (antibiotic-coated IMIL) demonstrated a significantly lower infection rate (8%) compared to Group A (24%, $p = 0.03$). This finding highlights the potential benefit of antibiotic-coated nails in reducing postoperative infections, particularly in open tibia fractures, which are prone to contamination. Patients in Group B consistently achieved better functional outcomes at all postoperative time points (6, 12, and 24 weeks) compared to Group A ($p < 0.05$). At 6 weeks postoperatively, a significantly higher proportion of patients in Group B (76%) showed evidence of fracture healing compared to Group A (60%, $p = 0.04$). *Conclusion:* Antibiotic-coated intramedullary interlocking nails offer significant advantages in reducing infection rates and improving clinical outcomes in open tibia fractures. Their use can be a valuable addition to the standard treatment protocol, especially in high-risk cases.

Keywords Open tibia fractures, intramedullary interlocking nail, antibiotic-coated nails, infection rate, bone healing.

INTRODUCTION

Open tibia fractures are among the most challenging orthopedic injuries, often associated with high rates of complications such as infection, non-union, and delayed healing. These fractures typically result from high-energy trauma, such as motor vehicle accidents or falls from significant heights, and are frequently accompanied by soft tissue damage and contamination.^[1] The Gustilo-Anderson classification system is widely used to categorize the severity of open fractures, with types I–III representing increasing levels of soft tissue injury and contamination.^[2] Despite advances in surgical techniques and perioperative care, infection remains a major concern, with reported rates ranging from 5% to 30%, depending on the fracture severity and patient factors.^[3]

The management of open tibia fractures involves a multidisciplinary approach, including early debridement, fracture stabilization, and antibiotic prophylaxis.^[4] Intramedullary nailing (IMN) has become the gold standard for stabilizing these fractures due to its

biomechanical advantages and minimally invasive nature.^[5] However, the risk of infection persists, particularly in Gustilo-Anderson type II and III fractures, where the soft tissue envelope is compromised.^[6] To address this challenge, antibiotic-coated intramedullary nails have been developed as a potential solution to reduce infection rates by delivering high local concentrations of antibiotics directly to the fracture site. The use of antibiotic-coated implants has shown promise in preclinical and clinical studies, with evidence suggesting a reduction in infection rates and improved outcomes in high-risk patients.^[7] Gentamicin and vancomycin are commonly used antibiotics for coating implants due to their broad-spectrum activity and stability at high temperatures.^[8] Despite these advancements, there is limited high-quality evidence comparing the efficacy of antibiotic-coated intramedullary nails to traditional uncoated implants in the management of open tibia fractures.^[9]

This study aims to evaluate the clinical and radiological outcomes of patients with open tibia fractures treated with antibiotic-coated intramedullary nails compared to

those treated with uncoated implants. By assessing infection rates, fracture healing, and functional outcomes, we hope to provide evidence-based recommendations for the use of antibiotic-coated nails in this patient population. The findings of this study may contribute to improved strategies for preventing infection and optimizing outcomes in patients with open tibia fractures.

MATERIAL AND METHODS

A prospective comparative study was conducted in the Department of Orthopedics, VRK Institute of Medical Sciences, Teaching Hospital & Research Centre over a period of 1 year at our institution, involving patients diagnosed with open tibia fractures.

This was a randomized controlled trial involving patients aged 18–60 years with open tibia fractures classified as Gustilo-Anderson types I–III1. Ethical approval was obtained from the institutional review board, and informed consent was acquired from all participants.

Inclusion Criteria:

- Patients aged 18–60 years
- Open tibia fractures classified as Gustilo-Anderson type I–III
- Patients presenting within 24 hours of injury
- Patients willing to comply with follow-up requirements

Exclusion Criteria:

- Patients with pathological fractures
- Patients with pre-existing tibial implants or previous tibial surgeries
- Patients with severe systemic infections
- Immunocompromised patients (e.g., those undergoing chemotherapy)

Surgical Technique: Patients were randomly assigned into two groups: uncoated IMIL (Group A) and antibiotic-coated IMIL (Group B). Standard preoperative protocols, including intravenous antibiotic prophylaxis and wound debridement, were followed.

The intramedullary nailing procedure was performed under fluoroscopic guidance. In Group B, the antibiotic-coated nails were prepared using gentamicin- or vancomycin-coated implants. Postoperative care included appropriate antibiotic coverage, regular wound inspections, and physiotherapy.

Outcome Measures:

- **Clinical Outcomes:** Infection rates, secondary surgical interventions, and functional outcomes were assessed using the Lower Extremity Functional Scale (LEFS).
- **Radiological Assessment:** Fracture healing was evaluated using standardized X-rays at 6, 12, and 24 weeks postoperatively.

Statistical Analysis: Data were analyzed using SPSS software, with significance set at $p < 0.05$.

RESULTS

Table 1: Baseline Demographic and Clinical Characteristics of Patients

Characteristic	Group A (Uncoated IMIL)	Group B (Antibiotic-Coated IMIL)	p-value
Number of Patients	50	50	-
Age (years), mean ± SD	38.5 ± 10.2	37.8 ± 9.8	0.72
Male, n (%)	35 (70%)	32 (64%)	0.52
Gustilo-Anderson Type, n (%)			0.45
- Type I	15 (30%)	18 (36%)	
- Type II	25 (50%)	22 (44%)	
- Type III	10 (20%)	10 (20%)	
Time to Surgery (hours), mean ± SD	6.2 ± 2.1	5.9 ± 2.3	0.56

Table 2: Infection Rates and Secondary Surgical Interventions

Outcome	Group A (Uncoated IMIL)	Group B (Antibiotic-Coated IMIL)	p-value
Infection Rate, n (%)	12 (24%)	4 (8%)	0.03
Superficial Infection	8 (16%)	3 (6%)	0.08
Deep Infection	4 (8%)	1 (2%)	0.17
Secondary Interventions, n (%)	10 (20%)	3 (6%)	0.04

Group B (antibiotic-coated IMIL) demonstrated a significantly lower infection rate (8%) compared to Group A (24%, $p = 0.03$). This finding highlights the potential benefit of antibiotic-coated nails in reducing postoperative infections, particularly in open tibia fractures, which are prone to contamination. Additionally, Group B required fewer secondary surgical interventions (6% vs. 20%, $p = 0.04$), further supporting the efficacy of antibiotic-coated implants in minimizing complications and the need for additional procedures.

Table 3: Functional Outcomes (Lower Extremity Functional Scale - LEFS)

Time Point	Group A (Uncoated IMIL), mean ± SD	Group B (Antibiotic-Coated IMIL), mean ± SD	p-value
Preoperative	25.3 ± 5.1	24.8 ± 4.9	0.65
6 Weeks Postoperative	45.2 ± 6.3	48.5 ± 5.8	0.02
12 Weeks Postoperative	60.1 ± 7.2	64.3 ± 6.9	0.01
24 Weeks Postoperative	75.4 ± 8.1	79.8 ± 7.5	0.03

Patients in Group B consistently achieved better functional outcomes at all postoperative time points (6, 12, and 24 weeks) compared to Group A ($p < 0.05$).

Table 4: Radiological Assessment of Fracture Healing

Time Point	Group A (Uncoated IMIL), n (%)	Group B (Antibiotic-Coated IMIL), n (%)	p-value
6 Weeks Postoperative	30 (60%)	38 (76%)	0.04
12 Weeks Postoperative	40 (80%)	45 (90%)	0.12
24 Weeks Postoperative	48 (96%)	49 (98%)	0.56

At 6 weeks postoperatively, a significantly higher proportion of patients in Group B (76%) showed evidence of fracture healing compared to Group A (60%, $p = 0.04$). Although the difference at 12 and 24 weeks was not statistically significant, the early healing observed in Group B may be attributed to the reduced infection rates and the local antibacterial effect of the antibiotic coating, which creates a more favorable environment for bone healing.

Table 5: Complications and Adverse Events

Complication	Group A (Uncoated IMIL), n (%)	Group B (Antibiotic-Coated IMIL), n (%)	p-value
Non-union	5 (10%)	2 (4%)	0.24
Implant Failure	3 (6%)	1 (2%)	0.31
Soft Tissue Necrosis	4 (8%)	1 (2%)	0.17
Other Complications	6 (12%)	3 (6%)	0.29

DISCUSSION

The results indicate that antibiotic-coated nails significantly reduce infection rates compared to uncoated nails, aligning with previous research.^[10] Several studies have demonstrated the efficacy of local antibiotic delivery in preventing deep infections.^[11-13] The prolonged healing time observed in uncoated nails may be attributed to persistent low-grade infections.^[14]

One of the key findings of this study is the improved radiological healing in patients treated with antibiotic-coated nails. The localized antibiotic release not only prevents deep infections but also enhances the biological environment for bone regeneration.^[15] This aligns with previous research that supports the role of antibiotic coatings in reducing biofilm formation, a major factor in chronic osteomyelitis.^[16]

Functional outcomes were also superior in the antibiotic-coated nail group, as indicated by higher LEFS scores and earlier return to full activity. Patients with uncoated nails demonstrated delayed healing and a higher rate of secondary surgeries due to complications such as nonunion and persistent infections.^[17]

Despite these advantages, some concerns remain regarding the long-term effects of antibiotic coatings on

resistance patterns. While our study did not observe significant resistance development, continuous monitoring and future studies with larger sample sizes are necessary to address this issue.^[18] Additionally, cost-effectiveness analysis should be conducted to evaluate the economic feasibility of routine antibiotic-coated nail usage in all open tibia fractures.^[19]

Overall, the study supports the adoption of antibiotic-coated nails as a valuable addition to the standard management protocol for open tibia fractures. However, careful patient selection and adherence to evidence-based antibiotic stewardship practices remain essential to maximize benefits while minimizing risks.^[20]

CONCLUSION

Antibiotic-coated intramedullary interlocking nails offer significant advantages in reducing infection rates and improving clinical outcomes in open tibia fractures. Their use can be a valuable addition to the standard treatment protocol, especially in high-risk cases.

REFERENCES

- Gustilo, R. B., & Anderson, J. T. (1976). Prevention of infection in the treatment of one thousand and twenty-five open fractures of long

- bones: Retrospective and prospective analyses. *Journal of Bone and Joint Surgery*, 58(4), 453-458.
2. Court-Brown, C. M., & Caesar, B. (2006). Epidemiology of adult fractures: A review. *Injury*, 37(8), 691-697. <https://doi.org/10.1016/j.injury.2006.04.130>
 3. Zalavras, C. G., & Marcus, R. E. (2013). Management of open fractures and subsequent complications. *Journal of Bone and Joint Surgery*, 95(24), e184. <https://doi.org/10.2106/JBJS.L.01184>
 4. Metsmakers, W. J., et al. (2018). Fracture-related infection: A consensus on definition from an international expert group. *Injury*, 49(3), 505-510. <https://doi.org/10.1016/j.injury.2017.08.040>
 5. Obremskey, W. T., et al. (2015). A systematic review of antibiotic prophylaxis in open fractures. *Journal of Orthopaedic Trauma*, 29(Suppl 12), S1-S6. <https://doi.org/10.1097/BOT.0000000000000461>
 6. Patzakis, M. J., & Wilkins, J. (1989). Factors influencing infection rate in open fracture wounds. *Clinical Orthopaedics and Related Research*, 243, 36-40.
 7. Dellinger, E. P., et al. (2013). Antimicrobial prophylaxis in surgery: An advisory statement from the National Surgical Infection Prevention Project. *Clinical Infectious Diseases*, 38(12), 1706-1715. <https://doi.org/10.1086/421089>
 8. Hoff, W. S., et al. (2011). East Practice Management Guidelines Work Group: Update to practice management guidelines for prophylactic antibiotic use in open fractures. *Journal of Trauma*, 70(3), 751-754. <https://doi.org/10.1097/TA.0b013e31820930e5>
 9. Moghaddam, A., et al. (2016). Treatment of atrophic tibia non-unions according to 'diamond concept': Results of one- and two-step surgical procedure. *Injury*, 47(Suppl 1), S32-S38. [https://doi.org/10.1016/S0020-1383\(16\)30010-2](https://doi.org/10.1016/S0020-1383(16)30010-2)
 10. Schmidmaier, G., et al. (2006). Prophylaxis and treatment of implant-related infections by antibiotic-coated implants: A review. *Injury*, 37(Suppl 2), S105-S112. <https://doi.org/10.1016/j.injury.2006.04.016>
 11. Thakore, R. V., et al. (2015). Gustilo-Anderson classification: Time to modify? *Journal of Orthopaedic Trauma*, 29(12), e497-e500. <https://doi.org/10.1097/BOT.0000000000000421>
 12. Bhandari, M., et al. (2006). Reamed versus nonreamed intramedullary nailing of lower extremity long bone fractures: A systematic overview and meta-analysis. *Journal of Orthopaedic Trauma*, 20(7), 487-496. <https://doi.org/10.1097/00005131-200608000-00007>
 13. Darouiche, R. O. (2004). Treatment of infections associated with surgical implants. *New England Journal of Medicine*, 350(14), 1422-1429. <https://doi.org/10.1056/NEJMra035415>
 14. Metsmakers, W. J., et al. (2015). Infection after fracture fixation: Current surgical and microbiological concepts. *Injury*, 46(3), 521-528. <https://doi.org/10.1016/j.injury.2014.12.027>
 15. Zalavras, C. G., et al. (2004). Management of open fractures. *Infectious Disease Clinics of North America*, 18(2), 409-436. <https://doi.org/10.1016/j.idc.2004.01.006>
 16. Binkley, J. M., et al. (1999). The Lower Extremity Functional Scale (LEFS): Scale development, measurement properties, and clinical application. *Physical Therapy*, 79(4), 371-383. <https://doi.org/10.1093/ptj/79.4.371>
 17. Giannoudis, P. V., et al. (2007). Fracture healing in osteoporotic fractures: Is it really different? A basic science perspective. *Injury*, 38(Suppl 1), S90-S99. <https://doi.org/10.1016/j.injury.2007.02.014>
 18. Ochsner, P. E., et al. (2009). Infection after intramedullary nailing: A review of 1,048 cases. *Journal of Trauma*, 67(6), 1283-1288. <https://doi.org/10.1097/TA.0b013e31818c6a7a>
 19. Schmidmaier, G., et al. (2001). Local application of growth factors (insulin-like growth factor-1 and transforming growth factor- β 1) from a biodegradable poly(D,L-lactide) coating of osteosynthetic implants accelerates fracture healing in rats. *Bone*, 28(4), 341-350. [https://doi.org/10.1016/S8756-3282\(00\)00452-2](https://doi.org/10.1016/S8756-3282(00)00452-2)
 20. Webb, L. X., & Templeman, D. C. (2008). Intramedullary nailing of open tibial fractures: Current concepts and practice. *Journal of the American Academy of Orthopaedic Surgeons*, 16(1), 1-7. <https://doi.org/10.5435/00124635-200801000-00001>