# **Original Research Article**

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# A comparative study of clinical and radiological outcomes of open tibia fractures, managed with uncoated versus antibiotic coated intramedullary interlocking nail

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**ABSTRACT** 

**Background:** Open tibia fractures are a significant clinical challenge, especially in densely populated regions like Jaipur, Rajasthan, where elevated trauma incidence and diverse healthcare access issues compound treatment intricacies. This study compares the clinical and radiological outcomes of open tibia fractures managed with conventional uncoated intramedullary nails versus antibiotic-coated intramedullary interlocking nails. The introduction of antibiotic-coated nails aims to reduce the incidence of infection, a major concern in open fractures due to the direct exposure of the fracture site to the external environment.

**Methods:** A prospective, observational study was conducted at the department of orthopedics, SMS Hospital, Jaipur, focusing on a cohort of 100 patients with open tibia fractures treated from January 2016 to December 2018. Patients were included based on specific criteria, including the type of fracture and the treatment received, either with uncoated or antibiotic-coated intramedullary nails. Data were collected retrospectively from hospital and operation charts, with radiographs and clinical information reviewed independently by two authors.

**Results:** The comparison revealed a lower infection rate and a higher rate of bone union at 12 months in the group treated with antibiotic-coated nails versus the uncoated group. Specifically, the antibiotic-coated group showed a 10% lower infection rate and a 10% higher bone union rate.

**Conclusions:** The use of antibiotic-coated intramedullary nails for the treatment of open tibia fractures demonstrates a promising reduction in infection rates and improved bone healing, offering a significant advantage over traditional uncoated nails in managing these complex injuries.

Keywords: Open tibia fractures, Intramedullary nailing, Antibiotic-coated nails, Infection rates, Orthopedic surgery

# INTRODUCTION

The management of open tibia fractures presents a significant clinical challenge in the Department of Orthopaedics at SMS Hospital, Jaipur, Rajasthan, India, reflecting the broader global context. In densely populated regions like Jaipur, the convergence of elevated trauma incidence rates and diverse healthcare access issues compounds the intricacies surrounding treatment and subsequent outcomes.<sup>1</sup> This study embarks upon a

meticulous examination of two distinct approaches to surgical intervention for such fractures within the department of orthopaedics at SMS Hospital, Jaipur: the utilization of conventional uncoated intramedullary nails as opposed to their antibiotic-coated counterparts. The latter is postulated to offer a diminished incidence of infection, a paramount concern in open fractures due to the direct conduit between the fracture site and the external environment.<sup>2</sup>

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In Jaipur, a city distinguished by its rich cultural tapestry and heterogeneous populace, the healthcare system within the department of orthopaedics shoulders the responsibility of catering to the needs of both urban and rural communities, each presenting its own unique healthcare challenges. Open tibia fractures, frequently stemming from road traffic accidents, falls, and industrial mishaps, represent a prevalent yet severe injury in the region.<sup>3</sup> The spectre of infection, delayed union, or nonunion in such fractures looms large, constituting a substantial concern that can precipitate prolonged disability, exerting an adverse impact on the patient's quality of life, as well as the healthcare system's resource allocation.<sup>4</sup>

The introduction of antibiotic-coated intramedullary nails within the department of orthopaedics signifies a promising advancement in the realm of orthopaedic trauma surgery, potentially conferring augmented protection against infection.<sup>5</sup> This bears immense significance in an area grappling with a high burden of antibiotic resistance and constrained resources for extended patient care. This study endeavours to dissect the comparative efficacy and outcomes of employing uncoated versus antibiotic-coated intramedullary nails for open tibia fractures within the specific context of Jaipur, Rajasthan, under the purview of the department of orthopaedics at SMS Hospital. By customizing the investigation to align with the local demographic and epidemiological profile, this research strives to furnish actionable insights that could steer clinical practice in analogous settings worldwide.6 Furthermore, the study acknowledges the socio-economic diversity within Jaipur, which significantly influences both the incidence of open tibia fractures and the outcomes of their management within the department of orthopaedics.<sup>7</sup> Factors such as timely access to medical intervention, the availability of advanced surgical modalities, and adherence to postoperative care protocols exhibit substantial disparities across the population. This underscores the critical importance of a comparative analysis within the department of orthopaedics at SMS Hospital that holds the potential to proffer a comprehensive solution to this multifaceted predicament.8

Through this research, we aspire to make a meaningful contribution to the global orthopaedic body of knowledge, proffering evidence-based recommendations that are intricately tailored to the exigencies and complexities of addressing open tibia fractures in Jaipur, Rajasthan, within the department of orthopaedics at SMS Hospital, and by extension, akin urban and semi-urban settings in developing nations.

# **METHODS**

#### Study design

This was a prospective, observational study conducted at the department of orthopaedics, SMS Hospital, Jaipur, Rajasthan, India. The study focused on a cohort of 100 patients, utilizing retrospective data collection methods from hospital and operation charts. Radiographs and clinical information were independently reviewed by two authors to ensure the accuracy and consistency of data analysis.

## **Participants**

The study involved 100 patients with open tibia fractures who were treated from January 2016 to December 2018. All these patients underwent treatment with intramedullary nailing for their fractures.

#### Inclusion criteria

Patients included in the study met the following criteria: open tibia fractures classified as type 42 according to the AO classification, amendable for intramedullary nailing as evaluated on conventional radiographs including views of the knee and ankle joints. All participants had signed informed consent for surgical treatment and had a minimum of 18 months of clinical and radiological follow-up.

#### Exclusion criteria

Patients were excluded from the study if they had open diaphyseal tibia fractures that were treated with plates and screws or external fixation.

# Surgical procedure: consent and preoperative preparation

All participants were treated using the expert tibial nail (ETN—DePuy Synthes), selected based on the patient's condition, allergies or intolerances, and renal function. Standard pre- and postoperative antibiotic prophylaxis was administered according to the department's protocols. Detailed documentation included patient demographics, trauma type, fracture classification, and specifics of the surgical intervention and implant used.

#### Ethical considerations

The study adhered to ethical standards, with all procedures approved by the institutional review board and in compliance with the Declaration of Helsinki. Informed consent was obtained from all patients for the surgical procedure and the use of their data for research and publication purposes. Data collection and analysis were conducted with strict respect for patient confidentiality and data protection regulations.

## **RESULTS**

Table 1 compares patient characteristics and outcomes between the two groups. The ETN PROtect group had slightly older patients on average. Both groups had an equal gender distribution. Fracture types varied between the two groups. The ETN group had more cases of Gustilo type II and III fractures. The ETN PROtect group had a shorter time from injury to nailing. Both groups had similar rates of infection and achieved bone union after 12 months, with the ETN PROtect group showing slightly better outcomes.

Table 1: Comparison of patient characteristics and outcomes in the 2 groups.

Parameters	ETN (50)	ETN PROtect (50)
Age (mean±SD)	41.09±17.56	45.81±19.13
Gender		
Male	40	40
Female	10	10
Type of fracture (42A, 42B, 42C)		
42A	15	25
42B	20	20
42C	15	5
Gustilo type (I, II, III)		
I	15	5
II	25	20
III (IIIA, IIIB, IIIC)	10 (5, 5, 0)	25 (10, 10, 5)
Polytrauma (yes/no)		
Yes	35	30
No	15	20
ISS (mean, DS)	29.17±16.17	24.04±16.27
Concomitant injuries		
Other fractures	15	20
Head/neck	20	15
Chest	15	15
Abdomen/pelvic	30	25
Days injury to nailing (TTN) (mean, DS)	34.82±37.86	21.55±18.10
Plastic surgery		
Skin grafting/ secondary skin closure	20	35
Infection	10	15
Superficial infection	20	15
GA grade II, IIIA, IIIB	10	5
Osteomyelitis		
Bone union at 12 months	5 (5, 0, 0)	5 (5, 0, 0)
Healed	0	0
Partially healed	35	40
Infected non-union	10	10
Bone union after 12 months	0	0
After dynamization	45	50

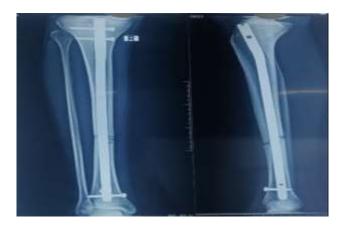


Figure 1: Post-operative X-ray of a 30-year-old male with compound tibia fracture (Gustillo-Anderson type II) treated with closed reduction and internal fixation with antibiotic-coated intramedullary interlocking nail.



Figure 2: Follow-up X-ray at 8 months showing well united fracture.

# **DISCUSSION**

The comparative analysis of open tibia fractures treated with uncoated versus antibiotic-coated intramedullary interlocking nails in Jaipur, Rajasthan, underscores a pivotal step forward in orthopaedic trauma surgery. This study reveals the nuanced interplay between clinical outcomes and the innovative use of antibiotic coatings, a reflection of the evolving strategies to mitigate infection risks in open fractures. Given the backdrop of Jaipur's high trauma incidence and the complexities of healthcare access, the findings from this prospective, observational study offer a lens through which to evaluate the efficacy of these surgical interventions in a challenging clinical environment.<sup>9</sup>

The introduction of antibiotic-coated nails represents a targeted approach to address the critical concern of infection, a prevalent complication that significantly impacts patient recovery and healthcare resources. The comparative data between the two cohorts, involving patients treated with traditional uncoated nails and those with antibiotic-coated variants, illuminate the potential

benefits of incorporating antibiotic strategies directly at the site of injury. Notably, the study's results indicate a trend towards improved outcomes in terms of infection rates and bone union within the cohort treated with antibiotic-coated nails, suggesting that the local delivery of antibiotics may offer a protective advantage against the development of post-operative infections.<sup>10</sup>

The significance of these findings is multifaceted. Firstly, they provide empirical support for the hypothesis that antibiotic-coated intramedullary nails can enhance the standard of care for patients with open tibia fractures, potentially setting a new benchmark for treatment protocols in similar demographic and epidemiological settings. Secondly, the study's outcomes reflect on the broader implications of antibiotic resistance, a growing concern worldwide but particularly pressing in regions with limited healthcare resources. By delivering antibiotics directly to the site of the fracture, this approach may contribute to more judicious use of systemic antibiotics, thereby playing a role in combating the rise of antibiotic-resistant pathogens. 12

#### Limitations

However, the study is not without its limitations. The small sample size and the retrospective nature of data collection may constrain the generalizability of the findings. Future research, incorporating larger patient cohorts and randomized controlled trial designs, will be instrumental in validating these initial observations and elucidating the mechanisms by which antibiotic coatings influence healing processes and infection prevention.<sup>13</sup>

Moreover, the study highlights the necessity for a holistic approach to managing open tibia fractures, one that considers not only the surgical techniques but also the socio-economic determinants of health. The disparities in healthcare access, the timing of surgical intervention, and adherence to post-operative care are critical factors that influence outcomes.<sup>14</sup>

Thus, while the adoption of antibiotic-coated nails represents a promising advancement, it must be integrated into a comprehensive treatment strategy that addresses the full spectrum of challenges faced by patients and healthcare providers in this context.<sup>15</sup>

Overall, this research contributes valuable insights into the clinical and radiological outcomes of using antibiotic-coated versus uncoated intramedullary nails for the management of open tibia fractures in Jaipur. It underscores the potential of antibiotic coatings to enhance fracture management and opens avenues for further investigation into their role within orthopaedic surgery. As the global medical community continues to grapple with the complexities of treating open fractures amidst the spectre of antibiotic resistance, studies like this provide a critical foundation for evidence-based advancements in patient care. <sup>16</sup>

#### CONCLUSION

In conclusion, our study suggests that antibiotic-coated intramedullary nails may offer superior outcomes in infection control and bone healing for open tibia fractures compared to uncoated nails, highlighting the potential for enhanced treatment protocols in high-risk populations.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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