

## A Prospective Study to Assess the Impact of the Prophylactic Use of Antibiotic Coated Intramedullary Nail in Treatment of Open Tibia Fractures

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Received: 03-01-2022 / Revised: 18-02-2022 / Accepted: 20-03-2022

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Conflict of interest: Nil

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### Abstract

**Aim:** To estimate the impact in the clinical setting, this study models whether the use of Gentamicin-coated implants is one of the methods which provide mechanical stability, effectively prevent infection and promote bony union by simple one stage procedure.

**Material & Method:** This prospective study was conducted in the Department of Orthopaedics, where a total of 50 patients were treated over a period of 15 months with gentamicin coated tibia interlocking nail after taking written and informed consent.

**Results:** The most common cause of injury was found to be road traffic accident and accounted for 87% of cases. Fibula fracture was associated with 91% of patients. Time taken in wound healing in majority of patients was less than 5 weeks (52%). Majority of patents (58%) had RUST score 8 at six months of duration.

**Conclusion:** At six months, the antibiotic-coated nail had a satisfactory clinical and radiological outcome, and early findings suggest the use of antibiotic-coated implants as a novel possible therapeutic option for infection prevention in open tibia fractures.

**Keywords:** open tibial fracture; antibiotic-coated nails; diaphyseal infections; intramedullary nails; long-bone infection

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### Introduction

Implant-associated infections still represent a problem for Orthopaedic and Trauma surgery. Elective orthopaedic surgery usually has a low infection rate

(0.7–4.2%) [1]. In Trauma surgery this rate is higher with incidence rates between 3.6 and 8.1% in patients with closed fractures and between 5 and 33% in cases of open

fractures [2, 3]. Risk factors for infection are traumatic mechanism, severity of soft tissue injury (up to 30% in Gustilo-Anderson grade III fracture), comorbidities such as diabetes mellitus and chronic inflammatory diseases, smoking and obesity [4–7].

Implant-associated infections impair fracture healing and often involve implant removal and prolonged antibiotic therapy, often intravenously, resulting in both socioeconomic and patient quality of life impact.[8]

The annual incidence of open injuries is 11.5 per 100,000 with 40% occurring in the lower limb, commonly in the tibia shaft.[9, 10]

Bacteria can adhere to the surfaces of invasive devices such as implants by forming a biofilm. This causes difficulties in treating infections as the biofilm significantly reduces the impact of systemic antibiotics. Eradication of the bacterial biofilm requires up to 10 0 0 times higher antibiotic concentrations than those required for “free-floating” bacteria [11]. Implant coatings have gained attention due to their potential to prevent implant-related infections by delivering high local concentrations [12].

Intramedullary nailing is the gold standard for tibial shaft fracture, with lower infection rate compared to external fixation or internal fixation with plate and screws [13].

Gustilo grade III open fractures, rate of deep infection is about 80%.9 [14] According to other studies, on increasing grades of Gustilo the chances of infection increases. The effectiveness of systemic antibiotics is limited in reducing risk of infection with use of prosthesis and osteosynthetic devices. [15, 16]Once implant gets infected, then it requires implant removal, debridement and long term antibiotic therapy. This implant related infection is prevented by delivering

the antibiotics locally acting on tissue implant interface. One of such method is using a polylactic acid (PLA) coated intramedullary nail releasing gentamicin.[16]

### Material & Method:

This prospective study was conducted in the Department of Orthopaedics, where a total of 50 patients were treated over a period of 15 months

Patients included in study were adults (>18years of age) having Gustilo type I, II and type III A compound tibia shaft fractures manageable with intramedullary nailing and excluded were:

1. Gustilo type III B, III C
2. Females who were pregnant, breast-feeding or planning to become pregnant during the study
3. Patients with consumptive or malignant primary disease
4. Vascular compromised patients
5. Patients suffering from neuropathy
6. A known allergy to used antibiotic.

### Methodology

In this study antibiotic coated tibia interlocking nail with property of sustained release of gentamicin was used. The coating contains combination of gentamicin and biodegradable polymeric carrier Poly (D, L-Lactide). An average size nail carries 100 mg (1 mg/cm<sup>2</sup>) gentamicin drug. Protocols given by ethical committee were strictly followed.

Patient followed post-operatively at 1, 2, 3 and 6 months for outcome assessment.

### Results:

All 50 patients (43 males and 7 females) were followed up for minimum of six months duration. The radiological Union was assessed using RUST Score (Table 1) and clinical assessment results were graded as excellent, good, fair and poor (Table 2).

The study comprised 70% of the patients between 18-40 years of age and 30% of the patients between 41-60 years of age. In this study, there was predominance of male population. Males were 86 % against females 14% (Table 3).

The most common cause of injury was found to be road traffic accident and accounted for 87% of cases. Fibula fracture was associated with 91% of

patients. Time taken in wound healing in majority of patients was less than 5 weeks (52%) (Table 4).

Majority of patents (58%) had RUST score 8 at six months of duration (Table 5).

Four cases got infected in this study and in one case there was non union. Average duration of hospital stay was 16 days. Large numbers of patients had fair outcome- 62% (Table 6).

**Table 1: Radiological union scale in tibial (RUST) fractures**

Score per cortex	Callus	Fracture line
1	Absent	Visible
2	Present	Visible
3	Present	Invisible

**Table 2: Criteria for assessment of the result**

Variable	Excellent	Good	Fair	Poor
Infection at 4 weeks	Control	Control	Control	Not Control
Wound healed at	5 weeks	7 weeks	10 weeks	Not Healed
Radiological union at 6 month (RUST Score)	12 score	10 score	8 score	4 score
Weight bearing without pain at 6 months	Yes	Yes	No	No
Neurovascular complication	Absent	Absent	Absent	+/-
Patient compliance	Very good	Good	Fair	Poor

**Table 3: Sex distribution**

Sex	Frequency	%
Male	43	86 %
Female	7	14 %
Total	50	100 %

**Table 4: Time taken in wound healing**

Time taken in wound healing in weeks	Frequency	%
≤5 weeks	26	52%
5-7 weeks	12	24%
8-10 weeks	8	16%
Not healed	4	8%
Total	50	100%

**Table 5: Radiological union at six month (RUST score)**

Radiological union at 6 month(RUST score)	Frequency	Percentage
4	5	10%
8	29	58%
10	11	22%
12	5	10%
Total	50	100 %

**Table 6: Clinical outcome**

Functional outcome	Frequency	%
Excellent	4	8%
Good	12	24%
Fair	31	62%
Poor	3	6%
Total	50	100%

**Discussion:**

Despite the innovations and good results obtained in fractures treatment, infection rate, especially in open tibial fractures, is still high and is associated with a significant socioeconomic impact and a lengthening of hospital stay. A recent work demonstrated that infection rates and total costs for in-hospital treatment could be potentially reduced by 75% and up to 15% respectively, by using an antibiotic-coated nail in patients with high risk of infection [17, 18].

Meta-analysis made by Craig had underlined the role and effects of local antibiotics showing that patients with open shaft tibia fracture who received locally delivered antibiotics as prophylaxis, in addition to systemic antibiotics, had lower infection rates than those receiving standard systemic antibiotics [19].

Although the GA fracture classification is universally accepted, it has limitations including variable accuracy, dependent on the experience of the surgeon, and moderate-to-poor inter-observer agreement plus under estimation of damage to muscles and bone [19]. Results from the model showed that the usage of the gentamicin-coated nail in patients with

severe open fractures (GA III) which have high risk of infection, can potentially lead to substantial cost savings from avoided infections due to savings in in-patient days and procedures. These findings may be valid to other patient subgroups at higher risk of infection, for example immunocompromised patients, polytrauma, those with chronic disease, obese or smokers [19].

It is also important to note that compared to beads, by using a gentamicin-coated nail a second operation to remove the beads is not required. Although the use of gentamicin-loaded PMMA beads is accepted in clinical practice, the beads themselves can act as a biomaterial surface that microorganisms preferentially adhere to and grow on, and potentially develop antibiotic resistance [20].

Walter et al.[17]study on 13 patients with open tibial fractures treated with an antibiotic intramedullary nail; in their series 11 patients achieved bone consolidation without the need for additional surgical treatment, while 2 patients required nail removal and revision surgery for device-associated infection.

Wasko and Boren in their study too used antibiotic nails in 10 patients as revision surgery following previous intramedullary

nailing, with 6-year follow-up of infection eradication and bone consolidation, with no further treatment needed to control the infection. All this seems to show excellent results with these implants, considering the complexity of these patients and the severity of the local and general conditions.[21,22]

### Conclusion:

At six months, the antibiotic-coated nail had a satisfactory clinical and radiological outcome, and early findings suggest the use of antibiotic-coated implants as a novel possible therapeutic option for infection prevention in open tibia fractures.

Based on the findings of this study, antibiotic-coated nails appear to be a viable and safe treatment option for open tibial fractures, allowing fracture healing while reducing infection rates of internal fixation devices and the need for revision surgery, with a positive impact on patient quality of life and the socioeconomic system. Future large-scale randomized control studies will be required to generate statistically meaningful findings that will allow the usage of antibiotic-coated tibial nails to be standardized.

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