

## Outcome of Prophylactic Use of Antibiotic Coated Intramedullary Nail in Treatment of Open Tibia Fractures

Hardik R Patel<sup>1</sup>, Nilay Pavan Kumar<sup>2</sup>

<sup>1</sup>Associate Professor, Department of Orthopedics, Zydus Medical College and Hospital, Dahod, Gujarat

<sup>2</sup>Senior Resident, Department of Orthopedics, Zydus Medical College and Hospital, Dahod, Gujarat

---

Received: 19-12-2022 / Revised: 15-01-2023 / Accepted: 02-02-2023

Corresponding author: Dr Hardik R Patel

Conflict of interest: Nil

---

### Abstract

**Background and Aim:** The most frequent long-bone fractures in both adults and children are tibia shaft fractures. Treatment options range from plaster immobilisation to debridement and surgical stabilisation, among others. It has been demonstrated that implants with an antibiotic coating lower the likelihood of implant-related infection. Thus, the goal of the current study was to evaluate the effectiveness of using an antibiotic-coated intramedullary nail as a preventative measure for treating open tibia fractures.

**Material and Methods:** A prospective study was conducted on 140 patients with infected non-union of lower limb long bones treated with antibiotic cement laden nails and beads. The experiment in this study used a tibia interlocking nail coated with an antibiotic that could release gentamicin over time. The appropriate size of an antibiotic-coated nail is inserted into the medullary canal. After surgery, the patients were observed for up to six months to assess their healing.

**Results:** Road traffic collisions were shown to be the most frequent cause of injury, accounting for 110 patients out of the total cases. At the end of the six-month period, the majority of patients had RUST scores of 9, 21.43% had RUST scores of 11, and 8.57% had RUST scores of 6. Out of a total of 140 patients, 16 patients had great outcomes, 30 patients had good results, 82 patients had medium results, and only 12 patients had poor results.

**Conclusion:** Infected non-union of the femur and tibia have traditionally been treated with several surgical methods that have proven ineffective and have received low patient participation and compliance. But the single-stage antibiotic cemented nailing approach has successfully achieved the objectives of infection control and fracture union with good patient compliance. It delivers high concentrations of local antibiotics, eliminates repeated surgeries, and reduces the systemic toxicity of antibiotics. The patients also comply well with the treatment.

**Keyword:** Antibiotic-coated implants, Gentamicin, Open fracture, Tibia shaft fractures

---

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

---

## Introduction

Long bone ununion fractures are not only a challenging surgical issue, but also a persistent and occasionally life-limiting condition. Infected long bone non-union causes not only physical disability but also financial difficulty and a loss of self-worth. According to one definition, infected non-union is when there is a chronic infection at the fracture site and there has been a failure to heal for 6–8 months. The most frequent long-bone fractures in both adults and children are tibia shaft fractures [1,2].

They have a significant socioeconomic impact because they cause roughly 26 fractures per 100,000 people and 569,000 hospital days annually. The risk of fracture is three times higher in men than in women. The annual incidence of open injuries is 11.5 per 100,000 with 40% occurring in the lower limb, commonly in the tibia shaft [3-5].

These typically come from high-energy accidents and are frequently accompanied by polytrauma, high rates of infection, and other consequences that could endanger the limb and, on rare occasions, life. They present a therapeutic challenge for orthopaedic surgeons. The main reason for non-union is injury to the surrounding soft tissue and vascular system [6-8].

Treatment options range from plaster immobilisation to debridement and surgical stabilisation, among others. The incidence of malunion in comminuted fractures was reduced by locking intramedullary nails. The majority of interlocking intramedullary nails used to be created by reaming, which results in the thermal necrosis of the tibia and the destruction of the endosteal blood supply [9,10]. Most surgeons advise against utilising intramedullary nailing with reaming for Type III open tibial fractures due to the relatively high infection rate following treatment. There are less possibilities of wound infection and osteomyelitis following the use of cutting-edge surgical procedures and medications [11].

Osteomyelitis, osteoporosis, numerous sinuses in soft tissue, and systemic antibiotic resistance all make therapy and recovery more difficult. These elements create an environment that is unfavourable to fracture union. Even after extensive treatment and multiple surgeries to address this issue, the prognosis is uncertain, and amputation might be the only remaining option [12].

As a result, treating long bone nonunion caused by infection presents a tremendous challenge to orthopaedic surgeons. Typically, bony union cannot occur until the infection has been totally eliminated [13].

Furthermore, high systemic dosages and their associated side effects are not necessary to achieve high antibiotic concentrations in the targeted area. The effectiveness of systemic antibiotics to prevent infections from prosthetic and osteosynthetic devices is poor. It has been demonstrated that implants with an antibiotic coating lower the likelihood of implant-related infection. Thus, the goal of the current study was to evaluate the effectiveness of using an antibiotic-coated intramedullary nail as a preventative measure for treating open tibia fractures.

## Material and Methods

A prospective study was conducted on 140 patients with infected non-union of lower limb long bones treated with antibiotic cement laden nails and beads. The study and follow-up phase lasts for two years in the orthopaedics department of the medical college and affiliated hospital. All treatments were carried out after receiving written informed consent from the patient and in line with the 1964 Helsinki Declaration, institutional and national research committee ethical standards, and other applicable laws and regulations. For the processing of their personal data and for the publication of this case series, all patients have given their written approval.

Adults (>18 years of age) with compound tibia shaft fractures of Gustilo types I, II, and III A that could be treated with intramedullary nailing were included in the study.

Patients with Gustilo type III B or III C, females who were or planned to become pregnant during the study, patients with consumptive or malignant primary diseases, patients with vascular compromise, patients with neuropathy, and patients with known antibiotic allergies were all excluded from the study. The experiment in this study used a tibia interlocking nail coated with an antibiotic that could release gentamicin over time. The appropriate size of an antibiotic-coated nail is inserted into the medullary canal. Flap grafts were applied to patients who needed them. Patients were administered intravenous antibiotics for five days following surgery. After surgery, the patients were observed for up to six months to assess their healing.

### Results

A total of 140 patients were included in the study. There were 102 men and 38 females included in the study. All the patients were followed up for minimum of 3 months period. RUST score was use to analyze the

radiological analysis of the union of fracture. The clinical findings are evaluated as excellent, acceptable, fair and bad. Maximum numbers of patients were from age group of 31 – 40 years. Minimum numbers of patients were of age below 30 years. There were overwhelmingly more men than women in this study, which found the mean age of these fractures to be 35.65 years. In comparison to females, the highest percentage was made up of men. Road traffic collisions were shown to be the most frequent cause of injury, accounting for 110 patients out of the total cases. In the current study's analysis, there were 140 patients; 82 of them had grade I compounding, 46 had grade II compounding, and 12 had grade III compounding.

At the end of the six-month period, the majority of patients had RUST scores of 9, 21.43% had RUST scores of 11, and 8.57% had RUST scores of 6. In around 12 patients; infection developed on later stage whereas in 8 there was non-union of the fractures ends. Out of the total 140 patients, excellent results were obtained in 16 patients, good result were obtained in 30 patients, 82 patients had fair results and only in 12 patients the outcome was found to be bad

**Table 1: Clinical outcome assessment**

Functional outcome	No. of patients
Excellent	16
Good	30
Fair	82
Bad	12
Total	140

### Discussion

A significant portion of all long bone injuries treated in emergency departments involve the tibia's shaft. There is no one-size-fits-all treatment for an open tibial shaft injury, and this could be detrimental. tibia fractures are more likely to be open and infectious because of how close they are to the skin [14-16].

Pieces often relocate themselves when swelling goes down, especially in spiral and oblique fractures. Infection caused by hip arthroplasty was first treated using antibiotic-impregnated cement in the early 1970s. The use of antibiotic bead chains in established bone and soft tissue infections has since

Klemm's introduction of them in 1974. The frequency of infection in the therapy of open fractures has decreased as a result of their proposed usage as a prophylaxis against infection in the introduction of the antibiotic bead pouch approach [17,18].

Antibiotics must be administered locally or systemically to the infection site in order to control infection. Excessive fibrosis forms around the nonunion site as a result of persistent infection and recurrent debridement, which impairs antibiotic penetration. Therefore, local antibiotic distribution is far more advantageous than systemic antibiotic therapy.

In this study, there were 140 patients; 82 of them had compounding of grade I, 46 of degree II, and 12 of grade III. 13 cases (52%) of grade-I fractures and 12 cases (48%) of other fractures were found in a study by Bhanu Pratap *et al.* Another study by Khaled Hamed *et al.* revealed that three (27.27%) patients had type II fractures, while eight (72.72%) patients had Gustilo type I fractures. Of the 70 patients, 68 (97.14%) underwent successful fracture union, and the other two (2.86%) underwent nonunion.

According to the research by Thomas Fuchs *et al.* and Bhanu Pratap *et al.*, none of the patients experienced non-union in their study. Out of 140 patients in this study, 16 had great outcomes, 30 had good outcomes, 82 had fair outcomes, and only 12 had bad outcomes.

### Conclusion

The treatment of infected non-union of the femur and tibia has typically used a number of surgical methods that have been shown to be ineffective, with poor patient participation and compliance. However, with good patient compliance, the single-stage treatment of antibiotic-cemented nailing has successfully achieved the objectives of infection control and fracture union. It gives high concentrations of local antibiotics, prevents the systemic toxicity of antibiotics, and reduces the need for

several operations with high patient compliance.

### References

1. Vijayanth, K. Management of infected Non Union of Long Bones by Antibiotic Loaded PMMA Cement Coated Nail and Beads. Madurai Medical College, Madurai, 2009.
2. Vijayanand Thambiah, M. Analysis of the Treatment of Infected Nonunion of Long Bones using Monolateral External Fixator: A Prospective study. Kilpauk Medical College, Chennai, 2006.
3. Atlas A., List L. L. O. Principles of Nonunion and Bone Defect Treatment.
4. Larsen P., Elsoe R., Hansen S. H., Graven-Nielsen T., Laessoe U., Rasmussen S. J. I. Incidence and epidemiology of tibial shaft fractures. 2015; 46: 746-750.
5. De Meo D., Cannari F. M., Petriello L., Persiani P., Villani C. J. M. Gentamicin-coated tibia nail in fractures and nonunion to reduce fracture-related infections: A systematic review. 2020; 25: 5471.
6. Wascher D. C. J. C. I. S. M. High-velocity knee dislocation with vascular injury: treatment principles. 2000; 19: 457-477.
7. Zelle B. A., Dang K. H., Ornell S. S. J. I. O. High-energy tibial pilon fractures: an instructional review. 2019; 43, 1939-1950.
8. Hegyes M. S.; Richardson M. W.; Miller M. D. J. C. I. S. M. Knee dislocation: complications of nonoperative and operative management. 2000; 19: 519-543.
9. Gaur A., Joshi B. J. I. J. O. O. Functional outcome of antibiotic coated interlocking intramedullary nail in open tibia diaphyseal fracture. 2019; 5: 803-807.
10. Dwivedi A. Prospective observational assessment of the prophylactic use of antibiotic coated intramedullary nail in treatment of open tibia fractures.
11. Hogue G. D., Wilkins K. E., Kim I. S. J. J.J. O. T. A. A. O. O. S. Management of pediatric tibial shaft fractures. 2019; 27: 769-778.

12. Jain A. K., Sinha S. J. C. O., Research R. Infected nonunion of the long bones. 2005; 431: 57-65.
13. Paley D., Catagni M. A., Argnani F., Villa A., Bijnedetti G. B., Cattaneo R. J. C. O., Research R. Ilizarov treatment of tibial nonunions with bone loss. 1989; 241: 146-165.
14. O'Malley O., Trompeter A., Krishnanandan S., Vesely M., Holt P., Goh G., Papadacos N., Bhatia V., Hing C. J. E. J. O. O. S., Traumatology. How common are vascular injuries in open tibial fractures? A prospective longitudinal cohort study. 2019; 29: 1119-1124.
15. Metgud R., Khajuria N., Patel S., Lerra S. J. J. O. C. R., therapeutics. Nuclear anomalies in exfoliated buccal epithelial cells of petrol station attendants in Udaipur, Rajasthan. 2015; 11: 868-873.
16. Brinker M. R., Bailey D. E. J. J. O. T., Surgery A. C. Fracture healing in tibia fractures with an associated vascular injury. 1997; 42: 11-19.
17. Gogia J. S., Meehan J. P., Di Cesare P. E., Jamali A. A. In Tilte. 2009; Thieme Medical Publishers.
18. Van Vugt T. A., Arts J. J., Geurts J. A. J. F. I. M. Antibiotic-loaded polymethylmethacrylate beads and spacers in treatment of orthopedic infections and the role of biofilm formation. 2019; 10: 1626.