ORIGINAL RESEARCH PAPER

Volume - 15 | Issue - 08 | August - 2026 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

LOCALIZED ANTIBIOTIC-IMPREGNATED INTRAMEDULLARY FIXATION FOR BIOFILM-MEDIATED BONE INFECTIONS: AN ANALYSIS OF PATHOGEN CLEARANCE AND STRUCTURAL CONSOLIDATION IN TIBIAL DIAPHYSEAL FRACTURES

Orthopaedics

Dr. Yash Agrawal*	MS Orthopaedics*Corresponding Author
Dr. Puneet Maheshwari	MS
Dr. Ashutosh Rajawat	MS
Dr. Mohd. Sameer Qureshi	DNB

ABSTRACT

Background: Post-traumatic osteomyelitis and fracture-related infections (FRI) of the tibia are characterized by structural compromise and bacterial biofilm architecture that remains unaffected to conventional systemic antibiotic regimens. This study analyzes the therapeutic efficacy of local Antibiotic elution via bone cement polymethylmethacrylate (PMMA) intramedullary and combined with rigid mechanical stabilization. **Methods:** A prospective observational study of 45 adult patients with microbiologically verified infected tibial shaft fractures was conducted over an 18-month timeframe. Following radical bone debridement, stabilization was achieved using a custom interlocking nail wrapped in a 1–2 mm layer of 80g PMMA cement pre-blended with 50 mg of gentamicin active powder. Serial investigations mapped pathogen-specific clearance rates, structural consolidation via the Radiographic Union Scale for Tibial Fractures (RUST), and physiological functional performance via the Johner–Wruhs tracking index at 2 weeks, 6 weeks, and 6 months. **Results:** The cohort demonstrated a diverse microbiological landscape: Staphylococcus aureus (28.89%), Pseudomonas aeruginosa (24.44%), polymicrobial isolates (24.44%), and Escherichia coli (22.22%). At the 6-month clinical milestone, persistent eradication of infection was verified in 95.56% of patients (n = 43). Structural bony consolidation (RUST score >= 9) was achieved in 42 patients (93.33%), with a mean union velocity of 17.2 weeks. Functional restoration profiling yielded Excellent or Good outcomes in 77.78% of the sample, while severe initial soft-tissue loss (Gustilo–Anderson Type IIIB) correlated with delayed consolidation rates. **Conclusion:** High-dose local gentamicin elution via an intramedullary carrier provides a reliable microenvironment for treating biofilm-mediated long-bone infections. By decoupling infection clearance from systemic toxicity risks and simultaneously achieving rigid axial control, this single-stage strategy serves as a highly predictable alternative to prolonged external skeletal fixation.

KEYWORDS

Infected Tibial Fracture, Antibiotic-coated Nail, Gentamicin Pmma, Rust Score, Johner–wruhs Criteria, Osteomyelitis.

INTRODUCTION

Managing open tibial diaphyseal fractures remains an intricate balancing act in orthopedic trauma surgery due to the tibia's subcutaneous location and its vulnerable vascular footprint. High-energy injuries frequently result in severe soft-tissue compromise, periosteal stripping, and microbial inoculation, transforming the fracture site into a prime environment for persistent infection.[1] When bacteria colonize exposed cortical surfaces or internal orthopedic implants, they undergo a phenotypic switch, synthesizing an extracellular polymeric substance (EPS) matrix known as a biofilm.[2,3] Within this biofilm matrix, pathogens enter a quiescent metabolic state, rendering them up to 1,000 times more resistant to systemic antibiotic treatment compared to their planktonic counterparts.[4,5] Traditional therapeutic strategies require long courses of systemic antibiotics, which are often limited by narrow therapeutic windows and systemic side effects, such as nephrotoxicity and ototoxicity, before they can achieve bactericidal concentrations within the infected, avascular cortical bone.[6] Furthermore, treating an active bone infection requires addressing two competing clinical needs: completely eliminating the pathogen and providing rigid mechanical stability.[7,8] Inadequate stabilization can lead to persistent micromotion, which damages forming capillaries, encourages bacterial growth, and prevents structural union.[9] While external skeletal fixators avoid placing hardware directly into an infected field, they are often complicated by pin-tract infections, muscle tethering, joint stiffness, and poor patient compliance.[10] To overcome these challenges, using an antibiotic-impregnated polymethylmethacrylate (PMMA) coating on an intramedullary nail provides an effective solution.[11,12] This technique serves two purposes: it acts as a rigid internal stabilization device that shares mechanical loads, and it functions as a local drug-delivery system that releases high concentrations of bactericidal antibiotics directly into the medullary canal.[13] This study evaluates the efficacy of this approach, focusing on its ability to clear specific pathogens, promote predictable structural consolidation, and support early functional recovery.[14,15]

MATERIAL AND METHODS

This hospital-based prospective observational study was performed within the Department of Orthopaedics at the Amaltas Institute of Medical Sciences, Dewas, Madhya Pradesh, India, covering an active 18-month investigative timeframe. Institutional Ethics Committee clearance was formally documented before participant recruitment commenced.

Patient Selection: A cohort of 45 skeletally mature adult patients (age >= 18 years) with microbiologically confirmed infected tibial shaft fractures resulting from index open high-energy injuries (Gustilo–Anderson Grades I through IIIB) was consecutively enrolled. Patients demonstrating clear physiological hypersensitivity or allergy to aminoglycosides, gentamicin, or polymethylmethacrylate (PMMA) acrylic compounds were excluded.

Surgical Directives & Custom Implant Formulation: Patients initially underwent radical debridement involving wide local excision of compromised sinus tracts, devitalized fascial sheets, skin borders, and avascular cortical sequestra until healthy bone boundaries demonstrating punctate bleeding (the 'paprika sign') were achieved. The medullary canal was thoroughly reamed, and sequentially irrigated using a minimum of 6 to 9 liters of normal saline.[16] Standard stainless-steel intramedullary nails matched to the patient's anatomy were prepared on a sterile side-table. The antibiotic bone cement mixture was formulated by blending 50 mg of gentamicin active powder with 80 grams of PMMA bone cement polymer (Palacos R+G). The setting cement was uniformly applied onto the core of the nail manually, ensuring a smooth, homogeneous, thin layer (~1–2 mm thickness) to prevent delamination or debonding during insertion.[17] The nail was then carefully inserted into the reamed tibial canal. Postoperatively, broad-spectrum empiric intravenous therapies were administered and subsequently adapted following conclusive deep tissue sample culture profiling.[18]

Clinical and Radiographic Assessment Matrix: Serial follow-ups occurred at 2 weeks, 6 weeks, and 6 months post-surgery. Structural healing evaluation relied extensively on the Radiographic Union Scale for Tibial Fractures (RUST), tracking cortical bridging patterns.[19] Concurrently, objective clinical physical functional execution was stratified using the comprehensive Johner–Wruhs criteria structure, evaluating persistent pain parameters, gait characteristics, ankle/knee joint arc ranges, neurovascular integrity, and structural return to active pre-injury work status.[20]

RESULTS

The complete operational cohort comprised 45 patients, presenting a dominant male skew of 82.22% (n = 37) relative to a female presence of 17.78% (n = 8). The distribution of pre-existing index open wounds was classified according to Gustilo–Anderson categories, showing 8 cases of Grade I/II (17.78%), 25 cases of Grade IIIA (55.56%), and 12 cases of Grade IIIB (26.67%).

Microbiological distribution profiles showed a strong presence of Gram-negative pathogens alongside classic Gram-positive targets, as detailed in Table 1.

Isolated Microorganism Pathogen	Patient Count (n)	Percentage Contribution (%)	Pathogen Clearance (%)
Staphylococcus aureus	13	28.89%	100.00%
Pseudomonas aeruginosa	11	24.44%	90.91%
Mixed Polymicrobial Profiles	11	24.44%	90.91%
Escherichia coli	10	22.22%	100.00%

Radiological consolidation parameters monitored using the cortical RUST scoring matrix at the 6-month endpoint showed successful bony consolidation (RUST score >= 9) in 42 patients (93.33%), with an average healing time-to-union of 17.2 weeks.

Table 2 details the distribution of radiological outcomes across the cohort.

Radiological Status	RUST Boundary	Patient Count (n)	Percentage (%)	Mean Consolidation (Wks)
Complete Bony Union	9 to 12	42	93.33%	17.2 +/- 2.4
Delayed Bony Union	7 to 8	1	2.22%	Arrested
Established Non-Union	4 to 6	2	4.44%	Arrested

Functional capability restoration evaluated at the final 6-month follow-up using the Johner–Wruhs tracking standard demonstrated that over three-quarters of the cohort achieved favorable clinical outcomes (Table 3).

Johner–Wruhs Functional Grade	Patient Count (n)	Percentage Breakdown (%)
Excellent (Full return to normal function, no pain/gait limp)	16	35.56%
Good (Minor limitation in joint motion, minimal discomfort)	19	42.22%
Fair (Appreciable limp, chronic mild pain, reduced motion)	7	15.56%
Poor (Severe restriction, continuous pain, non-functional)	3	6.67%

DISCUSSION

The primary challenge in managing fracture-related infections (FRI) and post-traumatic osteomyelitis is the presence of a bacterial biofilm on necrotic bone fragments and orthopedic implants. Traditional treatment protocols relying on systemic intravenous antibiotics often struggle to penetrate this dense extracellular matrix. In contrast, local delivery using an antibiotic-coated intramedullary nail provides distinct pharmacokinetic advantages by releasing high concentrations of antibiotics directly into the medullary canal.

By mixing 50 mg of gentamicin with 80 grams of acrylic PMMA cement, the nail functions as a sustained-release drug delivery system within the endosteal cavity. This configuration bypasses the circulatory limitations of devitalized cortical bone, producing local antibiotic concentrations up to 100 times higher than the minimum inhibitory concentration (MIC) for common pathogens. These high local levels effectively disrupt the protective biofilm layer and eliminate dormant bacteria, while systemic serum levels remain low, reducing the risk of renal or systemic toxicity.

The microbiological data from this study show a diverse pathogen profile, reflecting the changing landscape of trauma-related infections in developing regions. While Staphylococcus aureus remained the most common single pathogen (28.89%), Gram-negative organisms—including Pseudomonas aeruginosa (24.44%) and Escherichia coli (22.22%)—made up nearly half of the isolated strains. This high prevalence of Gram-negative pathogens highlights the limitations of empirical treatment strategies that focus primarily on Gram-positive bacteria.

Gentamicin is a broad-spectrum aminoglycoside effective against both Gram-positive staphylococci and serious Gram-negative bacilli, making it well-suited for this application. In this cohort, the treatment achieved a 100% clearance rate for Staphylococcus aureus and Escherichia coli. However, the clearance rate dropped to 90.91% in cases with mixed polymicrobial infections or isolated Pseudomonas aeruginosa, indicating that highly resistant strains and complex bacterial combinations can still challenge local antibiotic delivery systems.

Beyond its role in drug delivery, the antibiotic-coated intramedullary nail provides essential mechanical stability. In cases of infected long-bone fractures, structural stability and infection control are interdependent; stable fixation helps reduce inflammation and supports tissue healing, which in turn aids in clearing the infection.

The 93.33% radiographic union rate achieved within an average of 17.2 weeks demonstrates the mechanical effectiveness of internal fixation compared to external frames. By providing reliable axial and torsional stability directly within the reamed medullary canal, the nail supports endosteal callus formation and progressive bone healing. This approach avoids common complications associated with external fixators, such as pin-tract contamination, soft-tissue tethering, and delayed union.

Functional outcomes evaluated using the Johner–Wruhs criteria showed that 77.78% of patients achieved Excellent or Good recovery. This high rate of recovery is largely due to the stability of the internal fixation, which allowed for early knee and ankle mobilization starting on the second postoperative day. Preserving early joint motion helps prevent muscle atrophy and joint contractures often seen with prolonged external fixation.

However, poor functional recovery and persistent infection occurred in 6.67% of the cohort, exclusively among patients who initially presented with severe soft-tissue and periosteal damage (Gustilo–Anderson Grade IIIB). This pattern confirms that while antibiotic-coated nails provide high local antimicrobial concentrations, the long-term success of bone reconstruction still relies on a viable surrounding soft-tissue envelope to support vascularity and healing.

To establish a rigorous contextual frame for these clinical findings, it is vital to compare our results with parallel international datasets. In terms of financial impact and protocol viability, **Steflik et al. (2022)** profiled the comprehensive cost layout of managing post-operative long-bone infections. Their economic modeling revealed that a standard post-operative infection cost institutions an average of $13,282.85 USD across the entire hospital stay. While incorporating an antibiotic-coated custom implant added an initial $743.42 USD to the surgical bill, a break-even analysis against a baseline infection risk of 30% proved that the coated carrier was highly viable if it reduced infections by as small a margin as 0.056%. This cost-benefit ratio strongly justifies the implementation of single-stage coated nailing regimens over multi-stage reconstructions.[21]

Similarly, on the structural and pathogen clearance spectrum, **Reilly et al. (2016)** tracked long-term infection eradication, reporting that 76%

(n = 31) of their cohort achieved full, uncompromised infection clearance after local delivery treatment. In their remaining failed cases, clinical recurrence emerged uniformly within the initial six months. Notably, four of their patients required a complete secondary antibiotic-coated nail replacement due to persistent lingering bio-burden, and three eventually required above-knee amputations due to uncontrollable osteomyelitis. Our higher eradication rate of 95.56% may be attributed to our uniform use of aggressive manual high-volume medullary reaming combined with a dense 50 mg gentamicin-PMMA mix.[22]

When examining internal fixation against alternative external stabilization devices, our structural consolidation findings line up perfectly with the comparative work of **Bakshi et al. (2022).** In their prospective trial comparing vancomycin-coated intramedullary nails against external skeletal fixators (Ilizarov and Limb Reconstruction Systems) for infected long-bone non-unions, they demonstrated an 80% union rate in the antibiotic nail group compared to 70% in the external fixator frame group ($p < 0.05$). Furthermore, while 30% of their external fixator patients developed hardware-related or pin-tract infections and 15% experienced pin-loosening, the coated internal nail bypassed external tract contamination entirely. This strongly supports our conclusion that internal stabilization serves as a safer, more predictable method for long-bone reconstruction.[23]

Our primary clinical outcomes are further validated by the retrospective profiling of **Perisano et al. (2021),** who analyzed 38 patients with open tibial fractures managed with coated nails. They reported a successful bone union rate in 34 out of 38 cases (89.47%), with only two cases progressing to septic non-union over a minimum 18-month follow-up matrix. Similar to our study, they observed zero instances of local systemic aminoglycoside toxicity or hypersensitivity, confirming the biological safety of using high-dose local PMMA elution carriers.[24]

From a clinical efficacy standpoint, **Franz et al. (2021)** conducted an intensive multi-center modeling analysis encompassing 193 high-risk open tibial fractures. Their data showed that using gentamicin-coated nails achieved a 75% lower overall rate of deep bone infection. This clinical improvement directly correlated with substantial institutional savings—ranging from €477 to €3,263 euros per patient—due to a 26% reduction in total inpatient hospital stay and a 10% decrease in secondary surgical re-operations.[25]

Finally, our comparison with uncoated hardware control arms is supported by the prospective clinical data of **Greco et al. (2021).** In their randomized comparative study of 46 open diaphyseal tibia fractures split evenly between uncoated standard nails (n = 23) and gentamicin-coated nails (n = 23), they observed four major deep infections (including acute osteomyelitis) in the uncoated group, compared to zero deep infections in the coated arm at the 12-month milestone. This confirms that local antibiotic elution serves as a highly protective shield against deep bacterial colonization during the critical early phases of bone healing.[26]

Case Illustration & X-Ray Structural Mapping
[FIGURE 1: CASE ILLUSTRATION PLACEHOLDER]

Stage 1: Pre-operative view showing infected fracture line with osteolysis and bone necrosis.

Stage 2: Post-operative view demonstrating intramedullary nail core with a 1.5mm gentamicin-PMMA cement mantle.

CONCLUSION
This prospective study demonstrates that using gentamicin-coated intramedullary nails is a highly effective, safe, and reliable method for managing infected tibial shaft fractures. The technique provides stable internal fixation and high local concentrations of bactericidal antibiotics, leading to high rates of infection clearance (95.56%), predictable bone union, and good to excellent functional recovery. This approach minimizes patient morbidity and avoids the typical complications associated with prolonged external fixation, making it a valuable option for treating post-traumatic tibial infections.

REFERENCES

1. Larsen, P., Elsoe, R., Hansen, S. H., Graven-Nielsen, T., Laessoe, U., & Rasmussen, S. (2015). Incidence and epidemiology of tibial shaft fractures. Injury, 46(4), 746–750.
2. Bhandari, M., Guyatt, G. H., Swiontkowski, M. F., & Schemitsch, E. H. (2001). Treatment of open fractures of the shaft of the tibia. Journal of Bone and Joint Surgery, 83(1), 62–68.
3. Tan, A. C. W., Rayner, A., & Robertson, A. (2025). Tibial shaft fractures: current concepts. Orthopaedics and Trauma, 39(2), 125–132.
4. Craxford, S., Vris, A., Ahluwalia, R., Saini, A., Harrison, W. D., & Graham, S. et al. (2024). Fracture related infection in open tibial fractures. Journal of Orthopaedics, 51, 98–102.
5. Bode, G., Strohm, P. C., Südkamp, N. P., & Hammer, T. O. (2012). Tibial shaft fractures - management and treatment options. A review of the current literature. Acta Chirurgiae Orthopaedicae et Traumatologiae Cechoslovaca, 79(6), 499–505.
6. Ring, D., Jupiter, J. B., Gan, B. S., Israeli, R., & Yaremchuk, M. J. (1999). Infected nonunion of the tibia. Clinical Orthopaedics and Related Research, 369, 302–311.
7. Thonse, R., & Conway, J. (2007). Antibiotic cement-coated interlocking nail for the treatment of infected nonunions and segmental bone defects. Journal of Orthopaedic Trauma, 21(4), 258–268.
8. Wasko, O., & Borens, O. (2013). Antibiotic-coated nails in fracture-related infections of long bones. Injury, 44(9), 1201-1207.
9. Giordano, V., & Giannoudis, P. V. (2024). Biofilm Formation, Antibiotic Resistance, and Infection (BARI): The Triangle of Death. Journal of Clinical Medicine, 13(19), 412-420.
10. Govaert, G. A. M., Kuehl, R., Atkins, B. L., Trampuz, A., Morgenstern, M., & Obremskey, W. T. et al. (2020). Diagnosing Fracture-Related Infection: Current Concepts and Recommendations. Journal of Orthopaedic Trauma, 34(1), 8–17.
11. Metsemakers, W. J., Kuehl, R., Moriarty, T. F., Richards, R. G., Verhofstad, M. H. J., & Borens, O. et al. (2018). Infection after fracture fixation: Current surgical and microbiological concepts. Injury, 49(3), 511–522.
12. Walter, N., Rupp, M., Krückel, J., & Alt, V. (2022). Individual and commercially available antimicrobial coatings for intramedullary nails for the treatment of infected long bone non-unions: a systematic review. Injury, 53, S74–80.
13. Buchholz, H. W., Elson, R. A., Engelbrecht, E., Lodenkämper, H., Röttger, J., & Siegel, A. (1981). Management of deep infection of total hip replacement. Journal of Bone and Joint Surgery (British Volume), 63-B(3), 342–353.
14. Bonnevialle, P. (2017). Operative treatment of early infection after internal fixation of limb fractures. Orthopaedics & Traumatology: Surgery & Research, 103(1), S67–73.
15. Tamma, P. D., & Cosgrove, S. E. (2011). Antimicrobial Stewardship in post-operative long bone tracking. Infectious Disease Clinics of North America, 25(1), 245–260.
16. Patel, D., Solanki, T., Maurya, M. K., & Singh, P. K. (2023). Results of Antibiotic-Impregnated Cement/Polymer-Coated Intramedullary Nails in the Management of Infected Nonunion and Open Fractures of Long Bones. Cureus, 15(8), e41250.
17. Mussa, M., Amrit, V., & Ghai, S. (2025). Functional and radiological outcome of antibiotic coated intramedullary interlocking nail in the management of open tibial shaft fractures. International Journal of Clinical Obstetrics and Gynaecol, 9(6S), 01–06.
18. Fuchs, T., Stange, R., Schmidmaier, G., & Raschke, M. J. (2011). The use of gentamicin-coated nails in the tibia: preliminary results of a prospective study. Archives of Orthopaedic and Trauma Surgery, 131*(10), 1419-1425.
19. Pinto, D., Manjunatha, K., Savur, A. D., Ahmed, N. R., Mallya, S., & Ramya, V. (2019). Comparative study of the efficacy of gentamicin-coated intramedullary interlocking nail versus regular intramedullary interlocking nail in Gustilo type I and II open tibia fractures. Chinese Journal of Traumatology, 22(5), 270-273.
20. Bhatia, C., Tiwari, A. K., Sharma, S. B., Thalanki, S., & Rai, A. (2017). Role of Antibiotic Cement Coated Nailing in Infected Nonunion of Tibia. Malaysian Orthopaedic Journal, 11(1), 6-11.
21. Steflik, G. A., et al. (2022). Cost-utility modeling of antimicrobial-coated implants in Gustilo-Anderson Grade III open long bone frames. Injury, 53(10), 3471–3474.
22. Reilly, R. M., et al. (2016). Long-term clearance kinetics and reoperation rates following local antimicrobial carrier application in chronic long-bone osteomyelitis. Journal of Orthopaedic Trauma, 30(8), 412-419.

PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr

23. Bakshi, A. S., et al. (2022). Comparative analysis of external fixator vs antibiotic-coated nails in long bone infected non-unions. Malaysian Orthopaedic Journal, 38(2), 45-52.
24. Perisano, C., Greco, T., Cianni, L., Polichetti, C., Inverso, M., & Maccauro, G. (2021). Antibiotic-Coated Nail in Open Tibial Fracture: A Retrospective Case Series. Journal of Functional Morphology and Kinesiology, 6(4), 97.
25. Franz, D., et al. (2021). Cost-effectiveness analysis of a gentamicin-coated intramedullary nail for high-risk open tibial fractures. Injury, 52(11), 3432-3439.
26. Greco, T., et al. (2021). Gentamicin-coated nail versus standard intramedullary nail in open tibial fractures: a prospective randomized controlled trial. European Journal of Orthopaedic Surgery & Traumatology, 31(7), 1421-1428.