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Original Research Article

Functional and Radiological Outcomes of Prophylactic Antibiotic-Loaded Absorbable Calcium Sulfate Beads Application during Definitive Fixation of Compound Tibia Fracture

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Conflict of interest: Nil

Abstract

Background: Open tibial fractures are associated with substantial risks of wound complications, infection and delayed union because of soft-tissue injury, contamination and limited local vascularity. Local antibiotic delivery using absorbable calcium sulfate beads may provide high antibiotic concentrations at the fracture site while avoiding later implant removal.

Objectives: This study evaluated functional and radiological outcomes, wound healing and infection-related complications following definitive fixation of selected open tibial fractures supplemented with antibiotic-loaded absorbable calcium sulfate beads.

Methods: This hospital-based prospective study was conducted in the Department of Orthopaedics, Silchar Medical College and Hospital, from October 2024 to September 2025. Forty patients aged >15 years with displaced Gustilo–Anderson type I, II or IIIA open tibial fractures and a planned minimum one-year follow-up were included. Patients with type IIIB/IIIC fractures, diabetes, immunocompromised states, relevant neurological conditions or inability to complete follow-up were excluded. Following standard wound debridement and definitive fracture fixation, antibiotic-loaded absorbable calcium sulfate beads containing vancomycin or gentamicin were placed in the wound/dead space when indicated. Patients were followed clinically and radiologically for one year. Functional outcome was assessed using the Johner and Wruhs criteria. Data were analysed using SPSS version 22.0.

Results: The mean age was 38.6 ± 12.4 years and 77.5% of patients were male. Road traffic accidents accounted for 70% of injuries. Gustilo–Anderson type II fractures constituted 50% of the cohort, followed by type IIIA (32.5%) and type I (17.5%). Intramedullary nailing was used in 62.5%, plate fixation in 22.5% and definitive external fixation in 15%. The overall postoperative infection rate was 7.5%, comprising 5% superficial and 2.5% deep infection. Primary wound healing occurred in 82.5% of patients. Mean radiological union time was 18.4 ± 3.2 weeks, with an overall union rate of 97.5%. Excellent and good functional outcomes were recorded in 57.5% and 30% of patients, respectively. Persistent sterile drainage was the most frequent complication (12.5%). On univariate analysis, smoking (p=0.041) and debridement performed after 6 hours (p=0.009) were significantly associated with infection.

Conclusion: In this prospective single-centre series of selected open tibial fractures, definitive fixation supplemented by antibiotic-loaded absorbable calcium sulfate beads was associated with a low observed infection rate, high union rate and predominantly excellent-to-good functional outcomes. Persistent sterile drainage was the commonest bead-related/wound complication observed. Because the study had a small sample and no control group, these findings support the use of calcium sulfate beads as an adjunct rather than establishing superiority over standard care.

Keywords: Open Tibial Fractures, Prophylactic Antibiotic, Calcium Sulfate, Superiority.

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Introduction

Open tibial fractures remain challenging injuries because the tibia has a relatively subcutaneous location and open injuries may combine high-energy trauma, contamination, soft-tissue

disruption and compromised vascularity. Infection, delayed union and nonunion can adversely affect limb function and may require additional procedures. Early systemic antibiotics, meticulous debridement, appropriate soft-tissue management and stable fracture fixation remain fundamental components of treatment [1-3].

Systemic antibiotics may not reliably achieve sustained concentrations at a contaminated fracture site, particularly when local vascularity is compromised. Local antibiotic-delivery systems have therefore been explored as adjuncts to conventional treatment. Absorbable calcium sulfate is a biodegradable carrier that can be loaded with antibiotics and placed directly into a wound or dead space. Compared with nonabsorbable polymethylmethacrylate beads, absorbable calcium sulfate does not require a second operation for routine removal and may provide sustained local antibiotic release [4, 5].

Previous studies have reported favorable infection-control and healing outcomes with antibiotic-loaded calcium sulfate in open fractures, osteomyelitis and fracture-related infection, although the available literature includes heterogeneous populations and study designs. The thesis underpinning the present work identified a need for additional prospective clinical data concerning prophylactic use during definitive fixation of open tibial fractures [6-9].

The primary aim of this study was to evaluate functional and radiological outcomes following definitive fixation of selected open tibial fractures supplemented with prophylactic antibiotic-loaded absorbable calcium sulfate beads. Secondary objectives were to assess wound healing, postoperative infection and associated complications.

Materials and Methods

Study Design and Setting: A hospital-based prospective study was conducted in the Department of Orthopaedics, Silchar Medical College and Hospital (SMCH), from October 2024 to September 2025. Patients were evaluated, treated and followed within the department.

Participants: Forty patients were included after application of the predefined eligibility criteria. Inclusion criteria were displaced open tibial fractures classified as Gustilo–Anderson type I, II or IIIA; age >15 years; minimum one-year follow-up after definitive fixation; and willingness to provide written informed consent. Exclusion criteria were age below 15 years, associated head trauma likely to impair neurological assessment or recovery, Gustilo–Anderson type IIIB or IIIC fractures, immunocompromised status, diabetes mellitus, pre-trauma gait deficit, neurological pathology affecting lower-limb function, refusal of consent, or non-compliance with follow-up/treatment requirements.

Sample Size: The thesis reports use of Daniel's sample-size formula for prevalence studies, with Z=1.96, expected prevalence P=11% and desired precision d=0.1, yielding a calculated sample size of 40 patients.

Perioperative Management: Initial emergency management included haemodynamic stabilization, wound irrigation, sterile dressing, broad-spectrum intravenous antibiotics according to institutional protocol, analgesia and tetanus prophylaxis where indicated. Operative management consisted of thorough wound inspection and meticulous debridement of devitalized skin, contaminated foreign material, non-viable muscle and bone, followed by copious normal-saline lavage.

Definitive fixation was selected according to fracture pattern, soft-tissue condition and surgeon preference, with intramedullary interlocking nailing or plate osteosynthesis used in most cases and definitive external fixation in selected patients.

Calcium Sulfate Bead Application: After fracture stabilization, antibiotic-loaded absorbable calcium sulfate beads were prepared according to the manufacturer's guidelines. Vancomycin or gentamicin was mixed with calcium sulfate powder to form a uniform paste, which was moulded into beads and allowed to set.

The beads were placed directly into the wound bed, particularly within dead space or areas considered at increased risk of bacterial colonization, while avoiding interference with the fixation construct.

Figure 1: Calcium Sulfate Beads Prepared

Wound management and follow-up: Wound closure was based on soft-tissue status. Primary closure was attempted when satisfactory coverage was available; delayed closure or soft-tissue reconstruction was used when required. Postoperatively, systemic antibiotics were continued according to institutional protocol. Physiotherapy and progressive weight-bearing were individualized according to fixation stability and fracture pattern. Follow-up was performed at approximately 2 weeks, 6 weeks, 3 months, 6 months and 12 months, with assessment of pain, gait, and range of motion, wound condition, complications and functional recovery. Serial radiographs were used to assess callus formation, union, alignment and implant integrity.

Figure 2: Wound Debridement

Figure 3: Calcium sulfate beads applied

Figure 4: Preoperative X-ray.

Figure 5: Postoperative X-ray

Figure 6: Follow up X-ray

Figure 7: Post-Operative Range of Movement of Knee and Ankle.

Outcome Measures: The principal outcomes reported in the thesis were postoperative infection, wound healing, time to radiological union, overall union, functional outcome using the Johner and Wruhs criteria, and postoperative complications.

Infection was categorized as superficial or deep.

Complications recorded included persistent sterile drainage, deep infection, nonunion, malunion, and implant failure and compartment syndrome.

Statistical Analysis: Data were analysed using SPSS version 22.0. Frequencies, percentages, means and standard deviations were used for descriptive analysis. The Chi-square test was used for categorical comparisons, with Student's t-test or Mann–Whitney U test for continuous variables as appropriate to data distribution. A p-value <0.05 was considered statistically significant.

The risk-factor analysis reported in the thesis was univariate.

Ethical Considerations: Institutional Ethics Committee approval was obtained before initiation of data collection. Written informed consent was obtained from participants, confidentiality was maintained and the study was conducted in accordance with the ethical principles described in the thesis.

Results

Forty patients were included. The mean age was 38.6 ± 12.4 years, with an age range of 18–68 years. The cohort was predominantly male and road traffic accidents were the principal injury mechanism.

Table 1: Demographic and injury characteristics.

Characteristic	n	%
Age 18–30 years	12	30.0
Age 31–40 years	11	27.5
Age 41–50 years	9	22.5
Age 51–60 years	5	12.5
Age >60 years	3	7.5
Male	31	77.5
Female	9	22.5
Road traffic accident	28	70.0
Fall from height	7	17.5
Industrial injury	4	10.0
Sports injury	1	2.5
Smoker	12	30.0
Non-smoker	28	70.0

Table 2: Fracture characteristics and definitive fixation. The mean interval from injury to definitive fixation was approximately 3.2 ± 1.4 days.

Variable	n	%
Gustilo–Anderson type I	7	17.5
Gustilo–Anderson type II	20	50.0
Gustilo–Anderson type IIIA	13	32.5
Proximal-third fracture	8	20.0
Middle-third fracture	21	52.5
Distal-third fracture	11	27.5
Intramedullary nail	25	62.5
Locking compression plate	9	22.5
Definitive external fixation	6	15.0

Table 3: Wound-healing and infection outcomes.

Outcome	n	%
No postoperative infection	37	92.5
Superficial infection	2	5.0
Deep infection	1	2.5
Primary wound healing	33	82.5
Delayed wound healing (>3 weeks)	5	12.5
Persistent sterile drainage (>2 weeks)	5	12.5
Flap coverage required	7	17.5

Table 4: Time to radiological union. Mean union time was 18.4 ± 3.2 weeks and overall union was 97.5%.

Radiological outcome	n	%
Union <16 weeks	12	30.0
Union 16–20 weeks	23	57.5
Union >20 weeks	4	10.0
Nonunion	1	2.5

Table 5: Functional outcome according to Johner and Wruhs criteria.

Johner & Wruhs category	n	%
Excellent	23	57.5
Good	12	30.0
Fair	4	10.0
Poor	1	2.5

Table 6: Reported complications. Categories are not necessarily mutually exclusive.

Complication	n	%
Persistent sterile drainage	5	12.5
Deep infection	1	2.5
Nonunion	1	2.5
Malunion	1	2.5
Implant failure	1	2.5
Compartment syndrome	1	2.5

Risk-factor Analysis: On univariate Chi-square analysis, smoking and delayed debridement were significantly associated with postoperative infection. Infection occurred in 16.7% of smokers compared with 3.6% of non-smokers (p=0.041). Infection occurred in 4.0% of patients debrided within 6 hours compared with 13.3% when debridement was delayed beyond 6 hours (p=0.009). Age (p=0.421), gender (p=0.882), Gustilo–Anderson grade (p=0.854) and fixation method (p=0.338) were not statistically significant in the reported univariate analysis

Table 7: Univariate risk-factor analysis for postoperative infection.

Risk factor	Category	Infection rate	p value
Age	≤40 years: 1/23; >40 years: 2/17	4.3% vs 11.8%	0.421
Gender	Male: 2/31; Female: 1/9	6.5% vs 11.1%	0.882
Smoking	Smoker: 2/12; Non-smoker: 1/28	16.7% vs 3.6%	0.041
Gustilo grade	Type I–II: 2/27; Type IIIA: 1/13	7.4% vs 7.7%	0.854
Time to debridement	≤6 h: 1/25; >6 h: 2/15	4.0% vs 13.3%	0.009
Fixation method	IM nail: 1/25; plate: 1/9; ex-fix: 1/6	4.0%, 11.1%, 16.7%	0.338

Discussion

This prospective single-centre study evaluated 40 selected open tibial fractures managed with definitive fixation supplemented by antibiotic-loaded absorbable calcium sulfate beads. The principal findings were a 7.5% overall postoperative infection rate, 97.5% radiological union, a mean union time of 18.4 ± 3.2 weeks, and excellent or good Johner and Wruhs functional outcomes in 87.5% of patients. Persistent sterile drainage was the most frequent recorded complication.

The demographic profile was consistent with the trauma-heavy epidemiology of open tibial fractures. The mean age was 38.6 ± 12.4 years and 57.5% of patients were aged ≤40 years. Men constituted 77.5% of the cohort and road traffic accidents accounted for 70% of injuries. These findings are broadly comparable with the patterns discussed in the thesis literature review, including the prospective series of Ajayakumar et al. [10] and the combat-related series reported by Helgeson et al. [11].

Gustilo–Anderson type II injuries were the largest subgroup (50%), followed by type IIIA (32.5%) and type I (17.5%). The exclusion of type IIIB and IIIC injuries is important when interpreting the observed infection and union rates because the cohort represents a selected subset of open tibial fractures rather than the full spectrum of severe open injuries [1].

The observed overall infection rate was 7.5%, including one deep infection. This is lower than some historical reports of infection in severe open tibial injuries and is directionally consistent with literature describing local antibiotic carriers as useful adjuncts to systemic antibiotics and debridement. Ajayakumar et al. [10] reported very low infection in a prospective open-fracture series using antibiotic-loaded absorbable calcium sulfate beads, while Pavan et al. [12] reported lower infection with local antibiotic therapy than with systemic therapy alone in a comparative study. However, direct comparison is limited by differences in patient selection, fracture severity, treatment protocols and study design.

Wound healing was satisfactory in most patients, with primary healing in 82.5%. Persistent sterile drainage occurred in 12.5% and was the most common complication. Sterile wound drainage is a recognized issue with calcium sulfate products and should be distinguished from infection where clinical findings and investigations support a sterile process. The present study did not identify the need for bead removal as a routine intervention.

The mean radiological union time was 18.4 ± 3.2 weeks and 39 of 40 fractures united. The thesis discussion compares this result with Ajayakumar et al., [10] who reported a mean union time of 16.8 ± 2.9 weeks. The high union rate in the present cohort may reflect appropriate debridement, stable fixation, soft-tissue management, early rehabilitation and the selected fracture population. Because there was no untreated comparison group, the independent contribution of calcium sulfate beads to union cannot be determined.

Functional recovery was favorable: 57.5% of patients had an excellent result and 30% a good result according to the Johner and Wruhs criteria. Only one patient had a poor result. These outcomes are consistent with the high union rate and generally satisfactory wound status observed in the cohort, but functional outcomes are influenced by fracture pattern, soft-tissue injury, rehabilitation and other patient factors in addition to infection control.

Smoking and delayed debridement beyond 6 hours were the only statistically significant factors associated with infection in the univariate analysis. Infection occurred in 16.7% of smokers versus 3.6% of non-smokers (p=0.041), and in 13.3% of patients with delayed debridement versus 4.0% with debridement within 6 hours (p=0.009). These findings reinforce the importance of modifiable risk factors and timely surgical management. The analysis was univariate and the sample was small; therefore, these associations should not be interpreted as independent causal effects.

The study has several limitations. It included only 40 patients at a single tertiary-care centre and had no control group. The cohort was restricted to Gustilo–Anderson types I, II and IIIA and excluded diabetes and several other comorbidities, limiting generalizability. Although follow-up extended to one year, longer-term outcomes such as chronic osteomyelitis or late implant-related infection were not evaluated. The use of different fixation methods and local antibiotic choices also introduces clinical heterogeneity. Larger controlled studies are required to determine whether prophylactic calcium sulfate beads provide benefit beyond meticulous debridement, systemic antibiotics, soft-tissue management and stable fixation.

Despite these limitations, the study provides prospective clinical data from a real-world orthopaedic trauma setting and supports the feasibility of using absorbable antibiotic-loaded calcium sulfate beads as an adjunct during definitive fixation of selected open tibial fractures.

Conclusion

In this prospective series of 40 selected open tibial fractures, definitive fixation supplemented by prophylactic antibiotic-loaded absorbable calcium sulfate beads was associated with a 7.5%

postoperative infection rate, 97.5% fracture union, mean radiological union at 18.4 ± 3.2 weeks, and excellent-to-good functional outcomes in 87.5% of patients. Persistent sterile drainage was the most frequent complication. Smoking and debridement delayed beyond 6 hours were significantly associated with infection on univariate analysis. These findings support calcium sulfate beads as a potentially useful adjunct to established principles of open-fracture management, while larger comparative studies are needed to establish their independent prophylactic efficacy.

Declarations

Ethics Approval and Consent to Participate: Institutional Ethics Committee approval was obtained from Silchar Medical College and Hospital before commencement of data collection. Written informed consent was obtained from all participants, as stated in the thesis.

IHEC/IAEC Approval number and date: SMC/ETHICS/M3/2024/56.

Authors' contributions

Dr. Shamim Ahmed Barbhuiya

- Conceptualization.
- Study Design.
- Methodology.
- Supervision.
- Critical Review and editing of manuscript
- Final approval of the version to be published

Dr. Kironjyoti Nath

- Data Collection.
- Patient recruitment.
- Literature Review
- Data curation.
- Formal analysis.
- Manuscript drafting
- Preparation of tables and figures.
- Incorporation of revisions.

Dr. Vikash Agarwala

- Methodology.
- Supervision.
- Data interpretation.
- Critical revision of manuscript for important intellectual content.

Dr. Arijit Dhar

- Methodology.
- Supervision.
- Data interpretation.
- Critical Revision of manuscript for important intellectual content.

Data Availability: The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

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