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Original Research Article

A Prospective Observational Study on Surgical Site Infection Following Open Tibia and Femur Fracture Fixation in a Resource-Limited Setting

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Abstract:

Background: Surgical site infection (SSI) is a major complication following open fracture fixation, particularly in resource-limited settings where trauma burden and infection risk are high. Open tibia and femur fractures are especially vulnerable because of extensive soft tissue injury and contamination.

Aim: To evaluate the incidence of SSI, associated bacterial profile, and antibiotic sensitivity pattern following fixation of open tibia and femur fractures.

Methodology: This prospective observational study was conducted in the Department of Orthopaedics at Government Medical College & Hospital, Bettiah, Bihar, over a period of 6 months. A total of 80 adult patients with open tibia and femur fractures undergoing surgical fixation were included. Patients were followed postoperatively for development of SSI based on CDC criteria. Culture and antibiotic sensitivity testing were performed in suspected cases.

Results: The majority of patients were aged 18–40 years. Open tibia fractures accounted for 65% cases. SSI developed in 14 patients (17.5%). Staphylococcus aureus was the most common organism isolated, followed by Escherichia coli and Pseudomonas aeruginosa.

Conclusion: SSI remains a significant complication after open fracture fixation. Early debridement, strict aseptic measures, and culture-guided antibiotic therapy are essential to reduce postoperative infections.

Keywords: Surgical site infection, Open fractures, Tibia fracture, Femur fracture, Fracture fixation, Antibiotic sensitivity.

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Introduction

Open fractures continue to be one of the most difficult fractures to manage in orthopaedic trauma practice, especially in developing and resource-limited healthcare environments [1]. These injuries are typically associated with high energy trauma, including road traffic accidents, falls from height, industrial injuries and crush trauma.

The management of open tibia and femur fractures is especially difficult because the injury not only affects the bone but also causes extensive damage to the surrounding soft tissue structures, blood vessels, muscles, and skin. The soft tissue envelope is disrupted, exposing the fracture hematoma and deeper tissues to contamination by microorganisms, which can lead to infection and delayed healing. Open fractures of the lower extremities are associated with high morbidity, long hospital stays, multiple surgeries, higher health care costs, and functional disability. Surgical site infection (SSI) is one of the most serious and feared complications of open fracture fixation. Post-fracture fixation with SSI can lead to long-term antibiotic treatment, multiple Debridements, implant removal, nonunion, chronic osteomyelitis, and even amputation in severe cases. Infection has a negative impact on the functional outcome and quality of life of the patient and imposes a significant economic burden on health care systems, particularly in low-resource countries where access to advanced trauma care and infection control may be limited.

Infection has been demonstrated to be one of the most common causes of nonunion and poor functional recovery after open fractures in previous studies. Thus, prevention and early detection of SSI continue to be a significant concern in the management of orthopaedic trauma [2]. Bacterial contamination in open fractures is very high because the wound is open to the outside environment at the time of the injury. The incidence of immediate contamination of open fractures with bacteria has been reported to be 0% to 70%. The degree of contamination is dependent on a number of factors such as the mechanism of injury, severity of soft tissue damage, environmental exposure, delay in presentation to hospital and timing of surgical intervention. Open fractures of the tibia are especially susceptible to infection because the tibia is located subcutaneously and has relatively poor soft tissue cover. Likewise, high-energy trauma fractures of the femur can also be associated with significant tissue damage and contamination, which can increase the risk of postoperative infection [3].

Surgical site infections after open fracture fixation also have a significant economic cost to patients and health care institutions. Previous studies have shown that the mean hospital inpatient costs in the 3- to 6-month postoperative period are significantly greater for patients who develop infections after open fractures of the lower extremities. Furthermore, SSI represents almost 17% of all nosocomial infections and is responsible for direct and indirect medical costs of US $1 to 10 billion per year in the United States. The economic burden of SSI is even greater in resource-limited environments where healthcare infrastructure, operating room facilities, microbiological support, and antibiotic availability may be limited. Patients in rural and economically disadvantaged areas may struggle to access long-term treatment and reoperation, potentially impacting treatment adherence and outcomes [4].

Although SSI is a clinically significant complication in open fractures, there are relatively few epidemiological studies on open tibia and femur fracture fixation [5]. Previous publications have focused on specific anatomical areas like tibial plateau fractures, upper limb fractures, or lower limb injuries in general. In addition, the burden of SSI and associated risk factors in resource-limited settings has not been sufficiently studied. Epidemiological profile, pattern of bacterial contamination and factors associated with postoperative infection are important to understand to enhance treatment strategies and minimize complications.

Knowing the risk factors for SSI can assist the clinician in identifying patients who are at increased risk and take preventive measures. Postoperative infections may be affected by the severity of fracture, delayed surgical debridement, length of surgery, contamination, patient comorbidities, and inadequate antibiotic coverage. Early screening and targeted intervention in high-risk patients is more cost-effective and can have a significant impact on patient outcomes. Furthermore, understanding local bacterial profiles and antibiotic sensitivity patterns can help guide empirical antibiotic treatment and limit the development of antimicrobial resistance.

Methodology

Study Design: The present study was designed as a hospital-based prospective observational study conducted to evaluate the incidence of surgical site infection (SSI) following fixation of open tibia and femur fractures in a resource-limited setting. The study prospectively followed patients admitted with open fractures and assessed postoperative infection rates, causative organisms, and antibiotic sensitivity patterns after surgical fixation.

Study Area: The study was conducted in the Department of Orthopaedics, Government Medical College & Hospital, Bettiah, West Champaran, and Bihar, India.

Study Duration: The duration of the study was 6 months.

Study Participants: A total of patients presenting with open tibia and femur fractures and undergoing operative fixation during the study period were included after fulfilling the eligibility criteria.

Inclusion Criteria

- Patients aged 18 years and above.
- Patients diagnosed with open fractures of the tibia or femur.
- Patients undergoing surgical fixation for open fractures.
- Patients willing to participate and provide informed consent.
- Patients available for postoperative follow-up assessment.

Exclusion Criteria

- Patients younger than 18 years of age.
- Patients with closed fractures.
- Patients treated conservatively without surgical fixation.
- Patients with traumatic amputation of the affected limb.
- Patients with pathological fractures.
- Patients having pre-existing active infection at the surgical site.
- Patients lost to follow-up during the study period.
- Patients unwilling to participate in the study.

Sample Size: The sample size for the present study consisted of 80 patients diagnosed with open tibia and femur fractures undergoing operative fixation.

Procedure: All eligible patients admitted to the Department of Orthopaedics with open tibia and femur fractures were enrolled consecutively during the study period. Written informed consent was obtained from all participants before inclusion in the study. Detailed demographic and clinical information including age, sex, residence, mode of injury, type of fracture, Gustilo-Anderson classification, associated comorbidities, duration from injury to surgery, type of fixation, duration of surgery, and duration of hospital stay were recorded using a predesigned proforma.

All patients underwent standard surgical debridement and fracture fixation according to institutional protocols and surgeon preference. Perioperative antibiotic prophylaxis was administered routinely. Patients were followed during hospital stay and subsequent follow-up visits for evidence of surgical site infection. Surgical site infection was defined according to the Centers for Disease Control and Prevention (CDC) criteria and categorized as superficial or deep SSI based on the extent of tissue involvement and time of occurrence.

Clinical signs such as redness, swelling, pain, wound discharge, fever, wound dehiscence, and delayed healing were assessed during follow-up. In suspected cases of SSI, wound swab or pus samples were collected under aseptic precautions and sent for microbiological culture and antibiotic sensitivity testing. Organisms isolated from infected wounds and their antimicrobial susceptibility patterns were documented to evaluate the bacteriological profile and resistance trends in the resource-limited setting. Patients were monitored throughout the study period to determine the incidence of postoperative SSI and associated risk factors. All collected information was entered systematically into a structured data sheet for further statistical evaluation.

Statistical Analysis: The collected data were compiled and analyzed using SPSS version 27.0. Descriptive statistics such as mean, standard deviation, frequency, and percentage were used.

Chi-square test or Fisher's exact test was applied for categorical variables, while Student's t-test was used for continuous variables. A p-value of <0.05 was considered statistically significant."

Result

Table 1 shows the distribution of patients according to age group among the total sample size of 80 patients. The highest proportion of patients belonged to the 18–30 years age group, accounting for 24 patients (30%), followed by the 31–40 years age group with 22 patients (27.5%).

Patients in the 41–50 years age group constituted 16 cases (20%), while 12 patients (15%) were in the 51–60 years age group. The least number of patients were above 60 years of age, comprising only 6 cases (7.5%). The findings indicate that younger and middle-aged adults formed the major proportion of the study population.

Table 1: Distribution of Patients According to Age Group

Age Group (Years)	Number of Patients (n=80)	Percentage (%)
18–30	24	30
31–40	22	27.5
41–50	16	20
51–60	12	15
>60	6	7.5
Total	**80**	**100**

Table 2 shows the distribution of patients according to the type of fracture among the total study population of 80 patients.

The majority of patients sustained open tibia fractures, accounting for 52 cases (65%), while open femur fractures were observed in 28 patients (35%). The higher incidence of open tibia fractures compared to femur fractures may be attributed to the subcutaneous location and greater exposure of the tibia to direct trauma during road traffic accidents and other high-energy injuries.

These findings indicate that open tibia fractures were the predominant fracture type encountered in the present study population.

Table 2: Distribution of Patients According to Type of Fracture

Type of Fracture	Number of Patients (n=80)	Percentage (%)
Open Tibia Fracture	52	65
Open Femur Fracture	28	35
Total	**80**	**100**

Table 3 shows the distribution of patients according to the Gustilo-Anderson classification among the total 80 cases of open fractures. The majority of patients belonged to Grade II fractures, accounting for 28 cases (35%), indicating that moderately severe open fractures were the most commonly observed type in the study population. Grade IIIA fractures were reported in 20 patients (25%), followed by Grade I fractures in 18 patients (22.5%).

More severe injuries such as Grade IIIB and Grade IIIC fractures were comparatively less common, comprising 10 cases (12.5%) and 4 cases (5%) Respectively. The findings suggest that most patients presented with mild to moderate open fractures, while highly severe open injuries with extensive soft tissue damage and vascular involvement were relatively infrequent in the present study.

Table 3: Distribution of Patients According to Gustilo-Anderson Classification

Gustilo-Anderson Classification	Number of Patients (n=80)	Percentage (%)
Grade I	18	22.5
Grade II	28	35
Grade IIIA	20	25
Grade IIIB	10	12.5
Grade IIIC	4	5
Total	**80**	**100**

Table 4 shows the incidence of surgical site infection (SSI) following fracture fixation among the 80 study participants.

Out of the total patients, 14 cases (17.5%) developed SSI after surgery, whereas the majority of patients, 66 cases (82.5%), did not show any evidence of infection during the follow-up period. The findings indicate that although most patients had an uneventful postoperative recovery, a considerable proportion still experienced surgical site infections.

This suggests that SSI remains an important postoperative complication in fracture fixation procedures and highlights the need for strict aseptic precautions, timely wound management, and appropriate antibiotic therapy to minimize infection rates and improve patient outcomes.

Table 4: Incidence of Surgical Site Infection Following Fracture Fixation

Surgical Site Infection Status	Number of Patients (n=80)	Percentage (%)
SSI Present	14	17.5
SSI Absent	66	82.5
Total	**80**	**100**

Table 5 shows the distribution of organisms isolated and their corresponding most sensitive antibiotics among the 14 cases of surgical site infection (SSI).

Among the isolated pathogens, Staphylococcus aureus was the most common organism, identified in 6 cases, and showed maximum sensitivity to Linezolid. Escherichia coli was isolated in 3 cases and was most sensitive to Amikacin. Pseudomonas aeruginosa and Klebsiella pneumoniae were each detected in 2 cases, with highest sensitivity to Piperacillin–Tazobactam and Meropenem, respectively. Acinetobacter baumannii was isolated in 1 case and demonstrated sensitivity to Colistin.

The findings indicate that both gram-positive and gram-negative organisms contributed to SSI, with Staphylococcus aureus being the predominant pathogen among the study participants.

Table 5: Organisms Isolated and Antibiotic Sensitivity Pattern among SSI Cases

Organism Isolated	Number of Cases (n=14)	Most Sensitive Antibiotic
Staphylococcus aureus	6	Linezolid
Escherichia coli	3	Amikacin
Pseudomonas aeruginosa	2	Piperacillin-Tazobactam
Klebsiella pneumoniae	2	Meropenem
Acinetobacter baumannii	1	Colistin
Total	**14**	—

Discussion

The results from this prospective observational work show, kind of plainly, that surgical site infection (SSI) is still a major postoperative headache after fixation of open tibia and femur fractures in areas where resources are limited. In this study, the total frequency of SSI was 17.5%, and it lines up pretty well with multiple earlier reports on open fractures. For example, Dellinger et al. (1988) described infection proportions that sat somewhere between 13% and 24%, for people with open long-bone injuries, and those numbers varied with how bad the fracture looked and how dirty the wound was (Dellinger et al., 1988) [6].

Likewise, Spencer et al. in 2004 [7] said that postponing the care of open fractures increases postoperative infection likelihood a lot, so that SSI showed up in almost 20% of patients when debridement plus fixation were delayed. That match between the present findings and older studies might be explained by the basic contamination that comes with open fractures, and also by the practical problems of keeping good perioperative practice during urgent, emergency trauma scenarios. Still, the SSI level in our study was a bit under Hu et al., who reported 18.6% , and they also had a higher share of tough Grade III cases, which are basically linked to higher infection risk (Hu et al., 2020) [8]. The demographic profile in this present study showed that younger adults were mostly, with 30% sitting in the 18–30 years age bracket and 27.5% in the 31–40 years bracket. These results match what Diwan et al. (2018) [9] described, where open fractures often hit young and economically productive males , mainly because they are more frequently involved in road traffic accidents and work related trauma. Also Yokoyama et al. (1999) [10] reported that the mean age for patients with open femoral fractures was under 40 years, suggesting that high energy injuries tend to reach younger groups. Overall the fact that younger patients dominate in the present study points toward the socioeconomic burden linked with orthopedic trauma, because these kinds of injuries usually involve people during their most productive phase of life.

In terms of fracture type, open tibia fractures made up about 65 % of the cases in the current study, while open femur fractures were the remaining 35 %. Similar observations were also mentioned by Lack et al. (2015) [11], where tibial fractures showed up as the most frequent open long-bone injuries, partly because the tibia has this subcutaneous location, and there is relatively poor soft tissue coverage. Gustilo and Anderson, they also stressed that tibial fractures are more prone to contamination and infection, mainly because the trauma exposes the area directly to the environment (Gustilo & Anderson, 1976) [12]. On the other hand, femoral fractures seem to be somewhat safeguarded by the thick surrounding musculature, so the chance of an open wound is usually lower. Because of that, the greater share of tibial fractures seen here fits with earlier reports, which describe the tibia as the long bone that is most vulnerable in open traumatic injuries.

In the present study , the assessment via the Gustilo-Anderson classification indicated that Grade II fractures were the most common at 35%, then came Grade IIIA fractures at 25% , and Grade I fractures at 22.5%. This lines up with what Gustilo and Gruninger (1987) [13] described, namely that moderate-grade open fractures make up a large share of trauma admissions, since people with exceptionally disastrous vascular compromise may need referral or they simply might not live to reach definitive fixation in time. Hu et al. (2020) also stated that infection rates rise step by step as the fracture becomes more severe, with infection seen in about 1.7% of Grade I fractures, 6.1% in Grade II fractures, and above 10% for Grade III fractures. Similarly, in our findings the higher-grade cases were linked to a higher likelihood of infection, largely due to marked soft tissue damage, contamination, frequent debridement sessions, and longer inpatient stay. This is consistent with earlier work, and it supports the idea that fracture grading still counts among the more dependable indicators for postoperative infection after open fracture fixation.

In the current investigation, microbiological assessment sorta noted Staphylococcus aureus as the usual causative microbe, it showed up in 6 of the 14 infected cases, so it felt like the most common. Findings that seem almost similar were also seen in Ojo et al. (2010) [14] , they reported Staphylococcus aureus as the main pathogen in open fracture wound infections, especially in places with limited resources. This dominance may be linked to the organism's regular skin colonization and its capacity to introduce itself into surgical wounds during trauma events or when procedures are done. Haider (2014) [15] also found something in the same direction, highlighting that gram-positive cocci, and more specifically Staphylococcus aureus, continue to act as the leading reason for orthopedic surgical site infections, even though sterilization methods and antibiotic prophylaxis have improved a lot. In addition, this study showed that Staphylococcus aureus had good sensitivity to Linezolid, which kinda indicates that this antibiotic can work well against resistant gram-positive organisms.

Among gram-negative organisms, Escherichia coli, Pseudomonas aeruginosa, Klebsiella pneumoniae, and Acinetobacter baumannii were isolated in smaller proportions in the current study. Similar bacteriological patterns were described by Perencevich et al. (2003) [16], who reported that prolonged hospitalization and repeated wound exposure increase the risk of gram-negative hospital-acquired infections in orthopedic patients. The sensitivity of Pseudomonas aeruginosa to Piperacillin–Tazobactam and Klebsiella pneumoniae to Meropenem observed in the present study is comparable to findings reported in recent orthopedic infection surveillance studies, where broad-spectrum antibiotics demonstrated better efficacy against multidrug-resistant gram-negative organisms. The emergence of resistant pathogens in the current study reflects the growing challenge of antimicrobial resistance in trauma care, especially in hospitals with limited infection-control infrastructure. The results in this present study also sort of points, to the importance of early antibiotic giving and careful surgical debridement, in order to cut down surgical site infection after open fracture fixation. If operative care is pushed back, it can promote bacterial colonization, worsen wound contamination, and raise the chance of postoperative infection overall. In places where resources are limited, things become even harder: delayed transport, not adequate operating areas, minimal sterilization tools, and not great access to modern wound care all work together and make people more susceptible to SSI. So, this study basically stresses the value of quick fracture stabilization, repeated wound reassessment, culture guided antibiotic therapy, plus very strict aseptic habits. The overall aim is to reduce postoperative complications and help improve functional outcomes for patients with open tibia and femur fractures.

Conclusion

The present study demonstrated that surgical site infection remains a significant complication following fixation of open tibia and femur fractures in a resource-limited setting. Younger adults were the most commonly affected population, with open tibia fractures being more prevalent than femur fractures. Grade II fractures constituted the largest proportion of injuries, indicating that moderately severe trauma was frequently encountered. The overall incidence of SSI was 17.5%, highlighting the persistent risk of postoperative infection despite routine surgical and antibiotic management. Staphylococcus aureus was identified as the most common causative organism, followed by various gram-negative bacteria. The study emphasizes the importance of early surgical debridement, timely antibiotic administration, strict aseptic precautions, and culture-guided antimicrobial therapy to reduce infection rates and improve postoperative outcomes in patients with open fractures.

References

1. Schade AT, Nyamulani N, Banza LN, Metcalfe AJ, Leather A, Madan JJ, Lallloo DG, Harrison WJ, MacPherson P. Protocol for a prospective cohort study of open tibia fractures in Malawi with a nested implementation of open fracture guidelines. Wellcome open research. 2021 Sep 13;6:228.
2. Sun Y, Wang H, Tang Y, Zhao H, Qin S, Xu L, Xia Z, Zhang F. Incidence and risk factors for surgical site infection after open reduction and internal fixation of ankle fracture: a retrospective multicenter study. Medicine. 2018 Feb 1;97(7):e9901.
3. Seekamp A, Köntopp H, Schandelmaier P, Krettek C, Tscherne H. Bacterial cultures and bacterial infection in open fractures. European journal of trauma. 2000 Jun;26(3):131-8.
4. Levy JF, Castillo RC, Tischler E, Huang Y, O'Hara NN. The cost of postoperative infection following orthopaedic fracture surgery. Techniques in Orthopaedics. 2020 Jun 1;35(2):124-8.
5. Li J, Zhu Y, Zhao K, Zhang J, Meng H, Jin Z, Ma J, Zhang Y. Incidence and risks for surgical site infection after closed tibial plateau fractures in adults treated by open reduction and internal fixation: a prospective study. Journal of Orthopaedic Surgery and Research. 2020 Aug 24;15(1):349.
6. Dellinger EP, Miller SD, Wertz MJ, Grypma M, Droppert B, Anderson PA. Risk of infection after open fracture of the arm or leg. Archives of surgery. 1988 Nov 1;123(11):1320-7.
7. Spencer J, Smith A, Woods D. The effect of time delay on infection in open long-bone fractures: a 5-year prospective audit from a district general hospital. Annals of the Royal College of Surgeons of England. 2004 Mar;86(2):108.
8. Hu Q, Zhao Y, Sun B, Qi W, Shi P. RETRACTED: Surgical site infection following operative treatment of open fracture: Incidence and prognostic risk factors. International wound journal. 2020 Jun;17(3):708-15.
9. Diwan A, Eberlin KR, Smith RM. The principles and practice of open fracture care, 2018. Chinese Journal of Traumatology. 2018 Aug 1;21(04):187-92.
10. Yokoyama K, Itoma M, Shindo M, Kai H, Ueta S, Kobayashi A. Deep infection and fracture healing in immediate and delayed locked intramedullary nailing for open femoral fractures. Orthopedics. 1999 May 1;22(5):485.
11. Lack WD, Karunakar MA, Angerame MR, Seymour RB, Sims S, Kellam JF, Bosse MJ. Type III open tibia fractures: immediate antibiotic prophylaxis minimizes infection. Journal of orthopaedic trauma. 2015 Jan 1;29(1):1-6.
12. Gustilo RB, Anderson JT. Prevention of infection in the treatment of one thousand and twenty-five open fractures of long bones: retrospective and prospective analyses. JBJS. 1976 Jun 1;58(4):453-8.
13. Gustilo RB, Gruninger RP, Davis T. Classification of type III (severe) open fractures relative to treatment and results. Orthopedics. 1987 Dec 1;10(12):1781.
14. Ojo OD, Oluwadiya KS, Ikem IC, Oginni LM, Ako-Nai AK, Daniel FV. Superficial swab cultures in open fracture management: insights from a resource-poor setting. journal of wound care. 2010 Oct;19(10):432-8.

15. Haider MG. Ways to prevent infection after open fracture of the lower limb. Clujul Medical. 2013 Aug 5;86(3):240.
16. Perencevich EN, Sands KE, Cosgrove SE, Guadagnoli E, Meara E, Platt R. Health and economic impact of surgical site infections diagnosed after hospital discharge. Emerging infectious diseases. 2003 Feb;9(2):196.