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Antibiotic Eluting Tibial Nailing System are Effective in Improving fracture union rates and Reducing Infection in Open Gade II & IIIa Injuries.

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ABSTRACT

Background: *A one-step therapy option for problematic infections is antibiotic-impregnated nailing, which provides stability. Unlike cement beads, it offers stability across the fracture site.The present study aimed to study compound fractures of the shaft of the tibia managed with an antibiotic-eluting tibial nailing system.* ***Material and Methods:****The current investigation was single-center, prospective, observational research, performed in patients over 18 years of either sex, who had open (complex Grade II, Grade IIIA) shaft of tibia fracture. Commercially available cytocompatible Gentamicin eluting tibial nail was employed.* ***Results:*** *In the present study, 50 cases were studied. Mostofthesurgeriesare donelessthan6hoursfromthetimeofinjury.The averagetimeisabout8.05hours +/- 3.45 hours. 48patientsachievedunion (96 %).In the current study, a 96% union rate was attained, with 96% achieving excellent to good scores on the Lysholm scale, 4% achieving a fair result at the 6-month follow-up, and 100% achieving an excellent score at the 1-year follow-up.* ***Conclusion:****Antibiotic eluting nailing is a very successful one-stage treatment that reduces problems and achieves early bone union with less morbidity.*

Keywords: *Antibiotic eluting nailing, Gustilo type, compound fractures of tibia, union*

INTRODUCTION

These days, polytrauma patients frequently have open lengthy bone fractures that cause significant soft tissue damage and wound contamination, which puts orthopaedic surgeons' skills to the test[1].An environment that is mutually antagonistic to fracture healing is produced by the combination of mechanical instability and infection. Intramedullary (IM) nails have been advised for certain open fractures since modern surgical methods and medicines have effectively treated the infection even in open fractures [2,3]

Grade II and IIIA open fractures are treated with delayed interlocking nailing once the wound has healed [4].After

injury, patients with an open tibial fracture are far more likely to become infected [5].Consequently, a high dose of intravenous (IV) antibiotics must be administered after surgery for compound tibial shaft fractures (Gustilo types II, and IIIA) that are treated with conventional Stainless Steel Intramedullary (SSIM) nails. This might lead to systemic side effects and higher morbidity in patients who are already compromised. Some compound fractures require external fixation, initially with simultaneous wound management followed by delayed conversion to interlocking nailing.
The literature reports the application of antibiotic-impregnated IM nailing for compound tibia fractures [6]One stage of treatment to get rid of a persistent infection while ensuring stability is antibiotic-impregnated nailing .Unlike cement beads, it offers stability across the fracture site [7]. Second, there are fewer side effects and a greater concentration of antibiotics at the local site—encompassing avascular bone fragments—when antibiotics are impregnated into the nail.The present study aimed to study compound fractures of the shaft of the tibia managed with an antibiotic-eluting tibial nailing system.

MATERIAL AND METHODS
This was a prospective, single-center investigationperformed in the orthopedics department of Saveetha Medical College & Hospital in Chennai, India. The October 2020–December 2021 study period and the December 2022 follow-up were conducted. The institutional ethics committee (126/06/2019/IEC/SMCH) granted study approval. Patients of either sex who are more than 18 years old, have an open (complex grade 2, Grade IIIA) shaft of tibia fracture, and are willing to engage in the current study are the inclusion criteria for this research. Exclusion criteria are Patients aged below 18 years, Gustilo type I,IIIB, and type IIIC, Fractures with intra-articular extensions, Patients medically unfit for surgery, Pathological fractures other than osteoporosis, Associated head injury, and Associated neurovascular injury.
The maingoal of the investigationwas to identify the radiological union rates and infection rates in CompoundGrade II and Grade IIIA fracture subtypes. The secondary goal is to evaluate the functional result of these fracture subtypes at three-month, six-month, and one-year follow-ups.

Patient recruitment and Surgical Technique:
The normal emergency evaluation, radiograph and investigations were conducted after recording the history of the injury, including its mechanism and method. Debridement and primary suturing were carried out, when possible, along with wound irrigation using three liters of normal saline for open fractures.In cases when patients failed to arrive at the hospital within the specified 6-hour period or whose wound edges were unclean due to traffic accidents, early procedures such as plaster of Paris (POP) back splintage and culture collection were performed.
Under spinal anesthesia, a standard nailing procedure was carried out on all patients. Gentamicin-eluting tibial nails that are commercially available and cytocompatible were employed (figure 1).
Figure 1-Antibiotic Eluting Nail

This nail uses two coats of the antibiotic—measured by scanning electron microscopy (SEM) at a thickness of 50 microns—to improve adherence over dip coating. The producer utilized a high-velocity spray coating technique to apply an even layer of antibiotic on the nail. There is an Inadequate concentration of antibiotics when administered systemically due to Compromised local vascularity and non-perfusing necrotic tissues. Gentamycin IM 80mg delivers 4 to 8 µg/ml in healthy tissue and very minimal in unhealthy tissue. Local concentration is important in antibiotic-eluting nailing Up to 200 µg/ml of unhealthy, less vascularized tissues are administered, which both stopped and eliminated the bacterial colonies that were invading the body [8].It contained one milligram of the medication per square centimeter.On a nail of average size, 100 mg of medication was used. The

medication was administered postoperatively with an initial burst of thirty to forty percent in the first three to four days and an initial maximum concentration locally of up to 200microgram/ml. This treatment stopped and eradicated the encroaching bacterial colonies.
The antibiotic was then continuously released for a further 4–8 weeks, which is the most susceptible time after surgery for infections. As a result, the local medication concentrations remain high enough to have a bactericidal effect. Postoperative X-rays were taken to verify the effectiveness of reduction. The patients were introduced to oral antibiotics for a further seven days following the initial seven days of parenteral broad-spectrum antibiotic therapy (cefuroxime (1.5gm)BD+amikacin (25mg/kg)BD).
From the first day following the procedure, active toe, ankle, and knee joint movements were advised. As soon as the fracture is stable and shows indications of healing, weight bearing (from the toe touch to partial weight bearing to full weight bearing) should be increased.Five days of IV antibiotics were administered; a wound swab was obtained from both superficial and deep tissue locations for culturing, and the medications were changed out correspondingly. Patients underwent follow-up at three-, six-, nine-, and one-year intervals. At 9 months post-op follow-up (FIGURE-2) we looked for the union of bone radiologically.
Figure 2A - preoperative xray, 2B- Immediate post-operative xray, 2C- 9 months followupxray

SPSS 23.0 was employed for data analysis and Microsoft Excel was employed for data collection and compilation. The expression n (%) was employed to display discrete categorical data.If applicable, the median and interquartile range were reported for continuous data, alternatively, the mean ± SD and range were utilized. Rates of time to union and infections are given as percentages. The student t-test was utilized to tabulate the functional outcome at three, six, and twelve months and assess its statistical significance. When comparing categorical data between two groups, the appropriate Fisher's exact test or Pearson Chi-square test had been utilized. Every statistical test was conducted with a significance level of α=0.05 and was two-sided.

RESULTS

In the present study, 50 cases were studied. 28 (65%) were Male and22 (35%)were Female. The patients' ages ranged from between the ages of 20 and 60, with a mean of 35.7(Table 1).
Table 1-General Characteristic

Demographics	
Age-Years (mean ± SD)	35.7 ± 9.8
Gender (N/50)	
Male	28/50
Female	22/50

The mode of injury among males was more commonly due tovehicleaccidents and for females, it was byself-fall.

Mostoftheinjuries were frommotorvehicleaccidents, and others were fallsfromheight or self-fall (Table 2).

Table 2-Mode Of Injury

Mode of injury (N/50)	No. of patients
Motorvehicleaccident	35/50
Fall of HeavyObject	5/50
Fallfromheight	10/50

Sixty-six percent of the patients had surgery performed within six hours of the accident, while the remainder of patients had surgery performed between six and twenty-four hours after the injury[Table 3].The averagetime since the injury to the operation theatre was8.05hours +/- 3.45 hours.

Table 3-Timing Of Surgery

Timing of surgery (N %)	
Lessthan6hours	33 (66%)
6to24hours	17 (34%)

Among the 50 patients, the majority of cases were GustilotypeII (68%), and the remaining were Grade IIIA (Table 4).

Table 4-Type of Injury

Type Of Injury (N %)	
GustilotypeII	34(68%)
GustilotypeIIIA	16 (32%)

48 patients exhibited radiological union (i.e., bridging of at least three out of four cortices on orthogonal views) at the nine-month follow-up. Thirty-three patients with open Grade II tibia fractures and fifteen patients with open Grade IIIA tibia fractures were among the patients.

As a result, the study's total union rate at nine months was 96% (Table 5), with open Grade II and Grade IIIA groups having union rates of 97% and 94%, respectively.

Table 5-Time of Union

Time Of Union	No.ofPatients (n%)
9 months	48/50 (96%)
Morethan9 months	2/50 (4%) 1 from Grade II 1 from Grade IIIA

One instance of a Gustilo type IIIA fracture revealed delayed union (more than nine months). Superficialinfections [figure 3]were reported in 2 patients[Table 6],out of which one case required flap coverage.The Grade IIIA open tibia fractures that all of these patients (2/16, 12.5%) experienced. Patients with open Grade II tibia fractures did not develop any infections.The deepinfectionhasbeenreportedinNONEofthepatients. Delayedunions were reportedin2patients.

Table 6-Superficial Infection

Types of fracture	No. of patients affected with superficial infection
Grade II(n=34)	0
Grade IIIA n=16	2

Figure 3- Superficial infection

According to the Lysholm scale, a union rate of 96% with 96% excellent to good results was attained in the current investigation (Table 7). The average recovery time from surgery was 4.32 weeks for partial weight bearing and 6.52 weeks for complete weight bearing.

Based on the Lysholm criteria [9], the knee joint's postoperative functionality was rated as excellent, good, fair, and bad. When the score fell between 90 and 100, it was rated as Excellent; from 84 to 89, it was rated as Good; and from 83 to 64, it was rated as Fair. Excellenttogoodoutcomeswereachievedin96%ofpatientsandfairoutcomeswere attainedin4 % ofpatients at 6 months follow-up. 100 percent achieved excellent results at 1 year follow-up.

The complete range of flexion was always restored with consistent physical treatment and active knee movements. After approximately five weeks of active ankle movements, every patient showed a near-normal or normal range of movement.

Table 7-Functional Outcome

	3 months	6 months	12 months	p value
Grade II (n=34)	69	91	98	0.002
Grade III(n=16)	68	92	99	0.003

Out of fifty cases, only two required the use of systemic antibiotics to eliminate the infection (superficial infection) for longer than the prescribed duration, thus extending the duration of the union. The patients were encouraged to schedule follow-up appointments for three, six, nine, and twelve months later to evaluate the union's radiological development, the state of their wounds, and any implant failure that may have occurred (Table 8). The Gustilo type II injury had the shortest time to union—six months—while the Gustilo type IIIa fracture had the longest—twelve months.

Table 8-Complications

Complications	No.ofPatients	PERCENTAGE
JointStiffness	1	2 %
SuperficialInfection	2	4 %
Delayedunion	2	4 %

DISCUSSION

After an open fracture, infection is a reasonably common consequence that can occur at rates as high as 52% [10]. Amputation and, in extreme circumstances, death are among the consequences of infection following an open fracture, as are prolonged hospital stays and non-union. Therefore, strategies to lessen the likelihood of infection following open fractures are essential to the general treatment of these wounds.

A positive and crucial role in refractory infection is played by the antibiotic-impregnated nail which continues to elute antibiotics at the fracture site for up to 3 years [11].As a result, early solid fixation and localized antibiotic release at the fracture site greatly decrease the risk of non-union, postoperative infection, and fracture end necrosis, which accelerates bone union and minimizes morbidity. Research on eluting has been reported less frequently than that on antibiotic-coated s.Very few of the studies that have been published in the literature have been compared.

In 2021, S Vignesh et al.,[12] showed that all the fractures reached union status by the end of one year. At the conclusion of the year, there was no discernible difference in the RUST score between Grade II and Grade IIIA injuries. These findings were comparable to that of the present study.
In a study by periasano et al.,[13], total of 38 cases had undergone surgery with Antibiotic coated nailing for compound tibial fracture . There were 13 cases with complications: there was delayed union in 5 cases, followed by 4 superficial wound and surgical site infections and 4 nonunion .
In a study by Rohilla et al.,[14], which has 32 patients with compound fracture type II and type IIIA. In this study , 16 were managed with Antibiitic coated nail and showed good Union 13 cases (81.2%). The results obtained in our study were better when compared to this study.
In another study by Verma et al.,[15], total of 20 cases were present in the study , and Antibiotic coated nailing was done in 10 patients . Superficial infection was noted in one patient at 2 weeks . These findings were comparable to that of the present study .
The complications of this antibiotic eluting nailing arethe same as that of regular intramedullary nailing, which includesfrequentmedical problems—such as pseudarthrosis, neurological impairments, fat embolism, malrotation, infection, disorders of the venous andarterial system, and compartment-syndrome as well as into particularproblems—such asissues with nail insertion and with the locking bolts,malpositioning of the guide wire, malreduction of the fracture, and splitting fragments [16]
When compared to the previously mentioned research, the current study's findings were superior, with a 96% union rate at 9 months follow-up and a 4% overall infection rate. The infection didn't hinder the union and was treated by concurrently administering systemic antibiotics and releasing local antibiotics through the nail.
The current study's shortcomings included the implant's low cost, small sample size, and lack of randomization. Further research utilizing a more extensive dataset is required to validate the results of this investigation.
CONCLUSION
A particularly successful single-stage procedure for the treatment of Gustilo type II, IIIA complex tibial fractures is the antibiotic tibial eluting nailing device. Because there is constant antibiotic elution at the fracture site, there is less need for IV or oral administration, which reduces overall systemic side effects. It also lessens problems like deep infection and persistent osteomyelitis and assists in accomplishing early bony union with reduced morbidity. Furthermore, because the fixation is strong in the absence of infection, it lowers the non-union percentage and increases the rate of eventual early fracture union and bone growth. Additionally, early weight-bearing and joint range-of-motion exercises are allowed because load sharing makes implant fracture extremely rare.

Conflict of Interest: None
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