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### Functional outcome of management of open fractures both bones of leg with primary intramedullary interlocking nailing

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#### Abstract

**Background:** Open fractures of the tibia pose complex challenges in orthopaedic treatment. Primary intramedullary nailing with simultaneous soft tissue reconstruction has gained recognition as an aggressive approach to achieve faster bone healing and lower infection rates. However, there is a need to evaluate its effectiveness and impact on outcomes.

**Aim:** This prospective study to assess the functional and radiological outcomes of locking intramedullary nailing and primary soft tissue reconstruction in open fractures of both bones of the leg.

**Materials and Methods:** The study included 30 patients with high-grade open tibial diaphyseal fractures who underwent primary intramedullary interlocking nailing with soft tissue reconstruction. The study included patients who were aged 20 years or older, presented within 24 hours of the injury, had high-grade open tibial diaphyseal fractures (Gustilo Anderson Grade I, II IIIA, III B), had primarily reconstruct able soft tissue injuries, and were willing to undergo treatment and follow-up. Patients with an immature skeleton, fractures with intra-articular extension, Gustilo Anderson Grade III C fractures, grossly contaminated and damaged wounds, or those who refused to participate were excluded from the study. Standardized management protocols were followed, including thorough wound irrigation and debridement, skeletal stabilization, and soft tissue reconstruction. Patients were followed up at regular intervals to assess outcomes such as fracture union, infection rates, and functional parameters.

**Results:** This prospective study evaluated 30 cases of open tibial fractures treated with primary intramedullary interlocking (IMIL) nails. The patients had a mean age of 43.8 years, with 19 males and 11 females. Road traffic accidents were the most common cause of injury. Fractures were classified according to the Gustilo and Anderson grading system, out of the thirty cases, thirteen were grade I, nine were grade II, four were grade IIIA, and seven were grade IIIB. Primary closure, secondary closure with various techniques, and flap reconstruction were used for wound closure. No perioperative complications were observed, and the average surgery duration was 118 minutes. The average time to bone union varied based on fracture grade, with an overall average of 20.7 weeks. Dynamization was performed in cases with delayed union. Infection occurred in four cases, all of which were successfully managed with debridement and antibiotics. One case developed deep infection and osteomyelitis. The functional outcomes were assessed using modified Ketenjian, *et al.* criteria, with 25 patients achieving excellent or good results. Some patients experienced reduced range of motion, anterior knee pain, and limb length discrepancy, but overall, the results were favourable.

**Conclusion:** In conclusion, un-reamed intramedullary nailing with early soft tissue coverage for open fractures of the tibia results in faster healing of both soft tissues and bone, easier soft tissue coverage, improved biomechanical stability, early rehabilitation, and infection rates comparable to other methods.

Keywords: Tibia fracture, leg both bone fracture, primary IMIL nailing, soft tissue reconstruction.

#### Introduction

The occurrence of open fractures in long bones varies at a rate of approximately 11.5 cases per 100,000 people per year. Specifically, open fractures of the tibia account for around 23.5% of all tibial fractures per year and make up 0.2% of all injuries annually <sup>[1]</sup>. The specific methods of skeletal stabilization and soft tissue treatment of open fractures continue to be topics of debate in the orthopaedic traumatology <sup>[2]</sup>.

All the open fractures, 63% are seen in the tibia alone <sup>[3]</sup>. The risk of infection in an open fracture increases as the severity of the injury on the Gustilo and Anderson<sup>[2, 3]</sup> grading system worsens, ranging from less than 2% in grade 1 to nearly 50% in grade III. Severe open tibial fractures result from highenergy acts of violence and their surgical management is complex, time-consuming, and often associated with significant morbidity <sup>[4]</sup>. Many challenges arise due to the unique anatomy of the tibia and its vulnerable soft tissue envelope. The choice of treatment depends on the specific characteristics of the fracture and associated soft tissue damage, requiring experience and clinical judgment as crucial components of the overall treatment approach. The established management for severe open tibial fractures follows a philosophy of initial wound debridement and cleansing, fracture stabilization using external fixation, immediate intravenous antibiotics, prophylactic bone grafting and delayed wound closure <sup>[5, 6]</sup>. Debridement may need to be repeated due to difficulties in assessing tissue viability. Soft tissue coverage is delayed ensuring a healthy wound bed. Although external fixation <sup>[7]</sup> is relatively easy to apply and has minimal impact on the blood supply to the tibia, the high incidence of pin tract infections, challenges in managing soft tissue such as flap mobilization, and the potential for malunion and non-union have overshadowed these advantages.

The use of reamed intramedullary nails in the management of open tibial fractures is contentious. While reamed nails offer an improved stability to the fractures, their use carries the theoretical risks of increasing infections and nonunions as a consequence of the disturbed endosteal blood supply <sup>[8]</sup>. The use of unreamed intramedullary nails may compromise the stability at the site of the fractures <sup>[9, 10]</sup>. The numerous methods which are used for treating open fractures of the tibia are evidence of the ongoing efforts which are being made to improve the outcomes of the treatment of these fractures and of the continuing pursuit of more efficient and advanced methods for treating these fractures <sup>[11]</sup>.

With the use of potent antibiotics, advancements in fracture stabilization techniques, soft tissue reconstruction procedures, and improved wound care, the approach of primary skeletal stabilization through interlocking intramedullary nailing and simultaneous soft tissue reconstruction has gained recognition <sup>[12]</sup>. Early reports of this aggressive "fix and flap" protocol <sup>[13]</sup> suggest faster bone healing and lower infection rates, as the vascularized flap tissues swiftly and reliably convert the severe open fracture into a closed injury in a single stage. The flap acts as a biological dressing, safeguarding the exposed tibia, which lacks periosteum, against harmful nosocomial strains. Therefore, we conducted a prospective study to assess the functional and radiological outcomes of locking intramedullary nailing and primary soft tissue reconstruction.

#### **Materials and Methods**

This prospective study involved 30 patients with open fractures of both bones of the leg who underwent primary intramedullary interlocking nailing with soft tissue reconstruction at the Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam. Prior to the investigation, approval from the hospital ethics committee was obtained, and the informed consent was obtained. The study included patients who were aged 20 years or older, presented within 24 hours of the injury, had high-grade open tibial diaphyseal fractures (Gustilo Anderson Grade I, II IIIA, III B), had primarily reconstruct able soft tissue injuries, and

were willing to undergo treatment and follow-up. Patients with an immature skeleton, fractures with intra-articular extension, Gustilo Anderson Grade III C fractures, grossly contaminated and damaged wounds, or those who refused to participate were excluded from the study. All patients were initially evaluated either at the outpatient department or the emergency department. Upon admission, a detailed history was taken, including information about the time elapsed since the injury, mode of injury, and a physical examination was conducted. Local examination of the affected limb was performed. A standardized management protocol was followed for all patients. Upon admission, resuscitation and patient assessment were prioritized in accordance with advanced trauma life support guidelines. Other potential injuries, such as pulmonary, abdominal, and head injuries, as well as concomitant fractures of long bones or the pelvis, were ruled out. Thorough inspection and palpation of the limb were conducted, and any neurovascular deficits were identified. Intravenous antibiotics, such as cephalosporins and aminoglycosides, were administered immediately upon admission. When there was a suspicion of infection with clostridia, penicillin or metronidazole was given for anaerobic organism coverage. Tetanus prophylaxis was also provided. The wound was thoroughly washed with sterile saline solution, and the plastic surgeon's opinion was sought to meticulously analyse the soft tissue status of the wound. Only wounds with primarily reconstruct able soft tissue status were included in the study. Subsequently, the patients underwent radiological evaluation, including standard chest anteroposterior view and leg AP and lateral views. Routine blood investigations were performed. After obtaining informed consent and ensuring anaesthesia fitness for surgery, the patients underwent surgery. In the operating room, thorough wound irrigation and debridement were performed in collaboration with the plastic surgeon. Following skeletal stabilization, the plastic surgeon proceeded with soft tissue reconstruction (immediate reconstruction). If immediate reconstruction was not feasible, reinspection was conducted within 24-72 hours, and reconstruction was performed (early reconstruction). The surgery was performed with the patient in the supine position under anaesthesia. An incision was made 2 cm above the tibial tuberosity from inferior pole of patella to tibial tuberosity, and with the assistance of an image intensifier, the fracture site was visualized. An entry was made with AWL, and a guide wire was passed. Fracture reduction was done, which was confirmed using the image intensifier. Serial hand reaming was conducted, and a nail of appropriate size was inserted and fixed with 1 or 2 proximal screws based on the fracture pattern and comminution, as well as 2 distal screws. Fracture reduction was confirmed with the image intensifier, and the wound was closed in layers. Sterile wound dressing and crepe bandage were applied.

After the surgery, active movements of the toes, ankle, and knee joint were encouraged from the first day. Weightbearing was gradually increased depending on the fracture stability, comminuted and signs of healing, ranging from toe touch to partial weight-bearing to full weight-bearing. Intravenous antibiotics were administered for five days, and wound swabs were taken from superficial and deep tissues for culture, with antibiotics adjusted accordingly. The scores were also analysed between patients who had primary union of the fracture and those that required secondary procedures and between patients who had an early flap cover compared with those whose cover was delayed more than 72 hours. Other parameters relevant to outcome status were also recorded. These included vas score, gait, the use of walking aids, limb length discrepancy, the range of movement of the knee and ankle joint, muscle wasting and strength, and comments about the cosmetic appearance of the injured limb. All patients were followed up every 2 weeks for 6 weeks, and then monthly. Fracture union was determined when the patient could bear full weight without pain at the fracture site, and there was radiographic evidence of bridging of 3/4 cortices in anteroposterior and lateral views. Non-union was defined as a fracture that remained unhealed nine months after surgery or showed no progressive signs of healing for three months. Secondary bone stimulating procedures were performed when non-union was anticipated. The collected data were analysed using IBM SPSS Version 22.0, with a Pvalue of less than 0.05 considered statistically significant.

#### Results

This prospective study examined 30 cases of open tibial fractures treated with primary intramedullary interlocking (IMIL) nails between April 2022 and April 2023. The study included 30 patients, aged 18 to 75 years, with an average age of 43.8. Among them, 19 were male and 11 were female. The most common cause of injury was road traffic accidents (RTAs) with 22 patients, followed by falls from height and self-falls with 4 cases each. According to the Gustilo and Anderson classification, the fractures were classified as grade I (8 cases), grade II (6 cases), grade IIIA (5 cases), grade IIIB (8 cases) (Figure 1). The right side was more frequently affected, accounting for 66.7% (n=20) of the cases. The time interval between injury and surgery varied, with 10 cases operated on within less than 8 hours, 7 cases within 8-16 hours, 3 cases within 16-24 hours, and 10 cases within 24-48 hours, with an average interval of 11.966 hours. Wound closure was achieved through primary closure in 14 cases, secondary closure with a lateral skin release in 2 cases, secondary closure with a split-thickness skin graft in 8 cases, and secondary closure with muscle pedicle rotation flaps and split-thickness skin grafting in 6 cases. No perioperative complications were observed, and the average duration of surgery was 118 +/- 28 minutes. Three cases experienced marginal flap necrosis but were successfully managed with debridement and re-suturing. The average time to bone union varied according to fracture grade, with 16.0 weeks for grade I, 18.3 weeks for grade II, 23.6 weeks for grade IIIA, 28.4 weeks for grade IIIB, and 32 weeks for grade IIIC. The overall average time to union was 20.7 weeks. Dynamization was performed in 9 cases where no signs of union were present at 6-10 weeks. Out of these cases, 4 showed union at 6 months of follow-up, 4 were classified as delayed unions at 6 months and were treated with autogenous cortico-cancellous bone grafting, resulting in union at 12 months of follow-up. One case (Grade IIIB) was labelled as an infected non-union at 6 months and was managed with repeated debridement. Infection was the main complication, occurring in four cases. Two cases of grade IIIB had infections (Coagulase Negative Staphylococcus and Pseudomonas aeruginosa), both of which were successfully treated with repeated debridement and antibiotics. One case of grade IIIA had an infection with Escherichia coli, which was also managed with debridement and antibiotics. One case of grade IIIB had deep infection and osteomyelitis. One case of grade IIIB presented with malunion, while no cases experienced implant failure or deep vein thrombosis. The functional results were evaluated using modified Ketenjian<sup>[15]</sup> et al. criteria (Figure 2) (Table 2). Out of the 30 patients, 25 achieved excellent or good functional

outcomes. Satisfactory results were obtained for type I and II fractures. In severe type III injuries, 11 (72%) patients showed excellent or good functional results. The five patients who achieved fair results shared the common factor of the fracture site being close to a joint. Reduced range of motion was observed in 7 cases at the knee and 4 cases at the ankle (Table 3). Anterior knee pain was reported in 7 cases, and one case of type IIIB exhibited a limb length discrepancy of less than 1cm. None of patients were lost to follow-up (Table 4).

#### Discussion

The management of open tibia fractures is challenging and complex. Factors such as contamination level, soft tissue and bone loss, fracture pattern, and comminution greatly influence the outcome. Infection risk is a key determinant in the treatment approach, with primary stabilization using an external fixator and wound management being the preferred method, followed by secondary definitive fixation based on the wound condition. However, external fixation is not without complications and drawbacks. Gustilo and Anderson <sup>[14]</sup> conducted a study on the prevention of infection in the treatment of 1,025 open fractures of long bones, reporting an infection incidence of 2-16%, mostly in type III compound injuries. Disruption of bony vascularity can significantly impede the normal healing process, leading to delayed unions and non-unions, which may require additional bone grafting. In our study, we achieved primary wound closure in 60% of cases, while 40% required secondary closure through procedures like lateral skin release, skin grafting, or flaps. These results were comparable to Yokoyama et al. <sup>[16]</sup>, who reported primary closures in 70.2% of cases and secondary closures using split skin grafts or flaps in 29.8% of cases. Performing soft tissue procedures was easier in our cases due to the absence of external fixator frames around the injured leg.

Routine dynamization was not performed in our study. Dynamization was done in 9 cases where no signs of union were observed at 6-10 weeks. The removal of locking bolts in un-reamed nailing for open tibial fractures should only be considered if minimal callus is present at the fracture site after 12-16 weeks, as emphasized by Whittle *et al.* <sup>[18]</sup>. Yokoyama *et al.* <sup>[11]</sup> reported a mean union time of 15 months in over 50% of type III fractures, with an overall mean union time of 6.6 months in their series, which is similar to our findings (5 months).

Sargeant *et al.* <sup>[17]</sup> studied the use of un-reamed tibial nails and suggested that loosely fitted intramedullary nails are less likely to cause cortical necrosis compared to snugly fitted reamed nails. Reaming of open fractures has been found to spread contamination from the wounds along the medullary canal and strip small bone fragments from soft tissue attachments <sup>[18]</sup>.

Court-Brown *et al.* <sup>[19]</sup> presented their results on 51 type III open tibial fractures treated with external fixators, reporting an average time to union of 36.7 weeks, a 17.6% incidence of osteomyelitis (71.4% caused by gram-negative organisms), and 35% of patients experiencing pin tract infections. In our series, type III cases achieved an average union time of 28.4 weeks and a 13.3% infection rate. These results suggest that nailing in open tibial fractures leads to faster union rates and lower infection rates compared to external fixation, which is supported by similar studies.

The most crucial factor in reducing infection rates is the early administration of antibiotics effective against both grampositive and gram-negative bacteria. However, it is widely acknowledged that antibiotics cannot replace adequate debridement. Delayed soft tissue reconstruction may result in contamination or infection despite the surgeon's best efforts. In the past, leaving the debrided wound open for healing by secondary intention was the standard treatment, but delayed primary closure or split-thickness skin grafting at five to seven days after initial debridement have proven to be safe and effective methods for wound management in both civilian and military injuries.

Blick *et al.* <sup>[22]</sup> reported a 9.1% incidence of compartment syndrome in open fractures treated with intramedullary nailing. We encountered one case that required fasciotomy due to high compartmental pressure. The low incidence of compartment syndrome in open fractures treated in our series may be attributed to the use of loose stitches for wound closure and avoiding closure of fascial compartments.

Anterior knee pain was observed in 23.3% of cases in our series. Court-Brown *et al.* <sup>[23]</sup> reported a 36% incidence of anterior knee pain and suggested techniques such as a more proximal and lateral entry point, hyperflexion of the knee during nail insertion, and knee extension during screw insertion to reduce irritation of overlying tendons. Restricted motion was observed in the knees of 7 cases (23.3%) and ankles of 4 cases (13.3%). A similar study by Joshi *et al.* <sup>[21]</sup> reported a 14.3% incidence of knee stiffness. Early mobilization of the knee and ankle with quadriceps drill exercises can further reduce the incidence of these

complications.

Based on the functional scale developed by Ketenjian and Shelton <sup>[15]</sup> for primary internal fixation of open fractures, we had 1 poor result in a type I injury case with an associated femoral fracture that experienced delayed union and limited knee range of motion. In grade IIIB cases, 3 patients achieved fair results, but reduced ankle range of motion (75-50% of normal) and continued anterior knee pain were observed in some cases. Yokoyama *et al.* <sup>[16]</sup> reported 89% good to excellent results, which are comparable to our series (83.4% good to excellent results), (Table 1).

The prognosis of open tibial fractures after high-energy trauma is affected by the severity of soft tissue injury, contamination level, fracture configuration, and comminution extent. While the external fixator has been widely used in the past, it is associated with a high rate of pin tract infections (16%) and requires a secondary definitive procedure, making it cost-ineffective.

Overall, our study demonstrates that primary unreamed intramedullary nailing can be safely performed with minimal complications and excellent functional outcomes for grade I and II open tibial fractures. Modern management techniques, combined with the expertise of orthopaedic and plastic surgeons, can consistently restore excellent limb function in a high proportion of patients with grade III open fractures. Salvage and functional limbs can be achieved in severely injured cases, as demonstrated in our study.

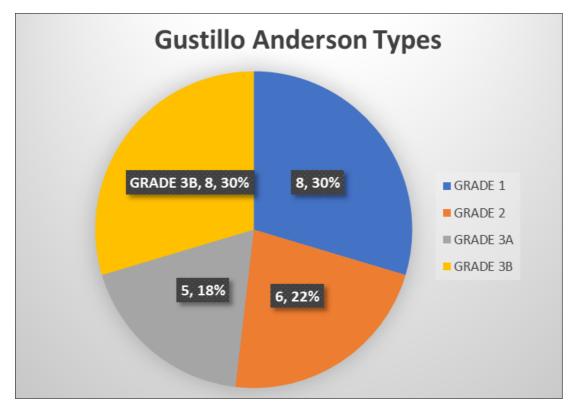


Fig 1: Distribution of grades of fracture according to gustillo Anderson classification

S. No.	Authors	Fixation Method	Union Time (Weeks)	Non-union %	Infection %	
1.	Davis	Plate & Screw	-	24	13	
2.	Lottes et al.,	Plate & Screw	-	35	35	
3.	Edwards et al., <sup>[20]</sup>	External Fixation	37	-	13.5	
4.	Blick et al., [21]	External Fixation	45.2	-	9.5	
5.	Joshi et al., <sup>[22]</sup>	Intramedullary Nailing	32	10.7	10.7	
6.	Our Study	Intramedullary Nailing	20.7	3.3%	10%	

**Table 1:** Comparative analysis of our results with other studies

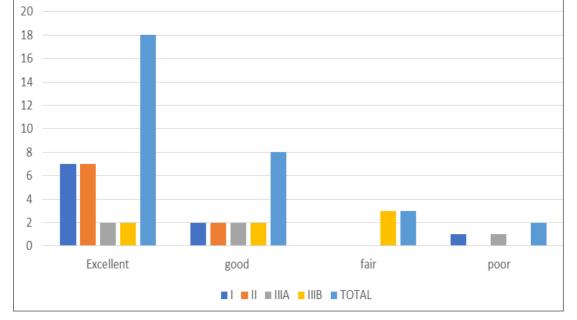


Fig 2: Outcome according to modified ketanjian criteria

Modified ketanjiian Criteria	Gustilo	and And	T . 4 . 1	percentage			
Mounicu Ketanjilali Criteria		II	IIIA	IIIB	Total	percentage	
<b>Excellent</b> • Normal	7	7	2	2	18	60	
Good Occasional pain with prolonged use Joint motion, 75% normal Trivial swelling Normal gait	2	2	1	2	7	23.4	
Fair Pain on ordinary activity Joint motion, 50% normal Small amount of swelling Slight limp	0	0	0	3	3	10	
<ul> <li>Poor</li> <li>Constant pain</li> <li>Joint motion, &lt; 50% normal</li> <li>Any visible deformity</li> <li>Limp, gait on cane or crutch</li> </ul>	1	0	1	0	2	6.6	

Complication	G	Gustilo and Anderson Grading						
Infection	0	0	0	2	1	3	10	
Delayed Union	0	0	0	3	1	4	13.3	
Non-Union	0	0	0	0	1	1	3.3	
Mal Union	0	0	0	1	0	1	3.3	
Nail / Screw Breakage	0	0	0	0	0			
Compartment Syndrome	0	0	0	0	1	1	3.3	
Deep Vein Thrombosis	0	0	0	0	0			
Anterior Knee Pain	1	0	0	4	2	7	23.3	
Limb Length Discrepancy	0	0	0	1	0	1	3.3	

S. No.	Age	Mode of injury	Gustillo	Time since injury (hrs)	Timing		Soft tissue cover	Complication	Re-surgery	Union (Weeks)	Outcome
190.	_		Туре		(Hrs)	Surgical time		-			
1	56	RTA	IIIB	1	13	3	Fasciocutaneous flap +primary SSG	Flap necrosis	EXFIX	34	Fair
2	45	RTA	IIIB	5	17	4	Gastrocnemius flap +SSG	Deep infection + nonunion	EXFIX + MASQUELET	44	Poor
3	22	Fall from height	Ι	4	20	2		-	-	36	Good
4	28	RTA	II	1	12	2		-	-	32	Excellent
5	48	RTA	IIIA		12	2	Primary SSG	Superifial infection	EXFIX	52	Good
6	32	RTA	IIIB	5	16	2	Primary SSG	Non union	-	54	Fair

7	32	Fall from height	Ι	2	15	2		-	-	0.37	Excellent
8	34	RTA	IIIB	7	11	4	Gastrocnemius flap +SSG	Superficial infection	EXFIX	52	Good
9	47	Slip and fall	IIIA	3	17	2		-	-	40	Excellent
10	52	RTA	IIIB	2	22	2	Primary SSG	infection	Exchange nailing +ssg	36	Good
11	50	Slip and fall	II	6	11	2		malunion	-	44	Fair
12	45	RTA	IIIA	2	7	2	Primary SSG	-	-	36	Excellent
13	40	RTA	IIIB	1	8	4	Fasciocutaneous flap +primary SSG	Superficial infection	-	40	Good
14	23	RTA	IIIA	3	4	3	Gastrocnemius flap +SSG	-	-	36	Excellent
15	41	RTA	IIIB	4	11	2	Primary SSG	-	-	42	Excellent
16	43	RTA	IIIA	7	13	2	Primary SSG	-	-	38	Excellent
17	35	Fall from height	II	1	15	1		-	-	47	Excellent
18	59	Slip and fall	II	4	15	1		-	-	52	Excellent
19	42	RTA	IIIB	1	22	2	Primary SSG	-	-		Excellent
20	52	RTA	IIIA	3	9	4	Fasciocutaneous flap +primary SSG	Deep infection + chronic osteomyelitis	EXFIX + bone grafting	66	Poor
21	42	Slip and fall	II	1	7	1		-	-	48	Excellent
22	32	Fall from height	II	4	12	1		-	-	40	Excellent
23	44	RTA	IIIA	6	9	2	Primary SSG	-	-	43	Excellent
24	47	RTA	IIIB	1	6	3	Fasciocutaneous flap +primary SSG	Superficial infection	EXFIX	50	Good
25	54	RTA	IIIA	3	4	1		-	-	46	Excellent
26	50	RTA	IIIA	8	11	2	Primary SSG	Superficial infection	EXFIX	48	Good
27	24	RTA	II	1	7	1		-	-	37	Excellent
28	35	Slip and fall	Ι	3	13	1		-	-	36	Excellent
29	27	Fall from height	II	4	12	1		-	-	42	Excellent
30	30	RTA	IIIA	1	8	2	SSG	-	-	44	Excellent

#### Conclusion

The management of open tibia fractures is challenging, and various factors influence the outcomes. Primary stabilization using external fixation and wound management is commonly used, but it has limitations and complications. Our study showed that primary unreamed intramedullary nailing with early soft tissue coverage can lead to faster healing, easier soft tissue procedures, better stability, and good functional outcomes in grade I and II open tibial fractures. The union rates and infection rates were comparable or better than those reported in studies on external fixation. Early administration of appropriate antibiotics and timely soft tissue reconstruction are crucial in reducing infection rates. Complications such as compartment syndrome, anterior knee pain, and restricted motion were observed but could be minimized with proper techniques and early mobilization. Our findings support the effectiveness and safety of primary intramedullary nailing in open tibia fractures and highlight the importance of multidisciplinary approaches for achieving favourable outcomes in grade III fractures. Overall, this study demonstrates the potential of modern management techniques and surgical expertise in achieving successful limb salvage and functional recovery in severely injured cases.

#### Declarations

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**Conflict of Interest:** The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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