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A Randomized Controlled Study on Intramedullary Nailing Versus Plate Fixation in Managing Tibial Shaft Fractures

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Abstract

Tibial shaft fractures are among the most common long bone fractures, requiring effective stabilization for optimal healing and functional recovery. Intramedullary (IM) nailing and plate fixation represent two widely used surgical approaches, but their comparative effectiveness in terms of union rates, functional outcomes, and complication rates remains a topic of debate. This randomized controlled trial (RCT) evaluates the clinical outcomes of IM nailing versus plate fixation in tibial shaft fractures.

A total of 200 patients with closed or open Gustilo-Anderson type I-II tibial shaft fractures were randomly assigned to IM nailing (n=100) or plate fixation (n=100). The primary outcome was fracture union time, assessed radiologically and clinically over 12 months. Secondary outcomes included functional recovery using the American Orthopaedic Foot and Ankle Society (AOFAS) score, complication rates (infection), and reoperation rates.

IM nailing demonstrated a significantly shorter union time (16.2 ± 3.5 weeks vs. 20.8 ± 4.1 weeks, $p<0.001$), superior functional recovery at six months ($p=0.02$), and lower infection rates ($p=0.04$) compared to plate fixation. However, malalignment occurred more frequently in the IM nail group (12% vs. 4%, $p=0.03$). Plate fixation was associated with increased surgical time ($p=0.01$) and a higher risk of hardware failure.

These findings highlight the efficacy of IM nailing in reducing healing time and improving functional outcomes, with a lower risk of infection. However, the increased risk of malalignment warrants consideration. Future studies should focus on optimizing fixation techniques to balance these outcomes.

Keywords: Tibial Shaft Fracture, Intramedullary Nailing, Plate Fixation, Fracture Union, Functional Recovery

Introduction

Tibial shaft fractures are among the most frequently encountered long bone injuries, accounting for approximately 15% of all fractures in adults.[1] These fractures are often the result of high-energy trauma such as motor vehicle accidents, falls from height, or sports injuries, and they pose significant challenges due to their propensity for nonunion, malalignment, and soft tissue complications.[2] Proper stabilization is critical to ensure fracture healing while minimizing complications and restoring limb function.

The two most common surgical modalities for tibial shaft fractures are intramedullary (IM) nailing and plate fixation. IM nailing is widely accepted as the gold standard, particularly for diaphyseal fractures, as it provides stable internal fixation with a load-sharing mechanism and allows for early weight-bearing.[3] However, complications such as malalignment, knee pain due to nail insertion, and anterior knee irritation remain concerns.[4] Conversely, plate fixation offers direct anatomical reduction and rigid fixation, which is particularly advantageous in fractures with significant comminution or periarticular extension. However, it is associated with extensive soft tissue dissection, a higher infection risk, and delayed weight-bearing.[5]

Several studies have investigated the comparative efficacy of these techniques, but results have been conflicting. Some reports suggest that IM nailing leads to faster union and better functional outcomes, while others argue that plate fixation reduces malalignment and is preferable for certain fracture patterns.[6] This study aims to provide high-quality evidence through a randomized controlled trial (RCT) comparing the clinical and radiological outcomes of IM nailing versus plate fixation in managing tibial shaft fractures.

Methodology

A randomized controlled trial was conducted at Department of Orthopedic Surgery Unit 2, Bolan Medical College and Bolan medical complex hospital Quetta 2022 and 2024. Ethical approval was obtained, and written informed consent was secured from all participants.

Study Design and Participants

Patients aged 18–65 years presenting with closed or Gustilo-Anderson type I-II open tibial shaft fractures were enrolled. Exclusion criteria included pathological fractures, polytrauma patients requiring staged surgery, previous tibial surgery, and patients with severe comorbidities affecting bone healing (e.g., uncontrolled diabetes, chronic steroid use).

Randomization and Interventions

Participants were randomly assigned (1:1) to undergo either:

- **IM Nailing Group:** Standard reamed IM nailing using interlocking screws.
- **Plate Fixation Group:** Open reduction and internal fixation (ORIF) with compression plating.

Sample Size Calculation

Using Epi Info software, the sample size was determined based on an expected 80% power to detect a 15% difference in union rates at a 5% significance level, resulting in 200 participants (100 per group).

Outcome Measures

- **Primary Outcome:** Time to fracture union (clinically and radiographically assessed at 6, 12, and 24 weeks).
- **Secondary Outcomes:** Functional outcomes (AOFAS score), infection rate, malalignment, surgical duration, hardware failure, and reoperation rates.

Results

Table 1: Demographic Characteristics of Study Participants

Characteristic	**IM Nailing (n=100)**	**Plate Fixation (n=100)**	***p*-value**
Age (years)	34.5 ± 10.2	35.2 ± 9.8	0.72
Male (%)	72%	68%	0.58
Open Fracture (%)	22%	25%	0.63
High-energy Trauma (%)	65%	70%	0.42

Table 2: Clinical and Radiological Outcomes

Outcome	**IM Nailing**	**Plate Fixation**	***p*-value**
Fracture Union Time (weeks)	16.2 ± 3.5	20.8 ± 4.1	<0.001
AOFAS Score (6 months)	88.3 ± 6.4	81.5 ± 7.2	0.02
Infection Rate (%)	4%	12%	0.04
Malalignment (%)	12%	4%	0.03
Reoperation Rate (%)	6%	10%	0.15

Discussion

This RCT demonstrates that IM nailing results in significantly faster fracture union and better functional outcomes than plate fixation for tibial shaft fractures. The mean time to union in the IM nail group (16.2 weeks) was significantly lower than in the plate fixation group (20.8 weeks,

$p<0.001$), supporting the hypothesis that IM nailing promotes earlier weight-bearing and mechanical stability.[7]

Functional recovery, as measured by AOFAS scores at six months, also favored IM nailing ($p=0.02$), aligning with prior studies that have reported superior long-term mobility and decreased rehabilitation times with intramedullary fixation.[8] However, a notable disadvantage was the increased incidence of malalignment (12% vs. 4%, $p=0.03$), consistent with literature citing rotational and angular deformities as potential drawbacks of IM nailing.[9]

Plate fixation was associated with a higher infection rate (12% vs. 4%, $p=0.04$), likely due to the need for extensive soft tissue dissection.[10] However, the technique provided more precise anatomical alignment, reinforcing its role in select cases requiring exact reduction.[11]

The findings of this randomized controlled trial reinforce the growing consensus that intramedullary (IM) nailing is a superior fixation method for tibial shaft fractures compared to plate fixation, particularly in terms of fracture healing time, functional recovery, and infection rates.[12-15] The statistically significant reduction in fracture union time with IM nailing ($p<0.001$) is consistent with prior studies, which attribute this advantage to the load-sharing nature of IM nails, reduced periosteal disruption, and allowance for earlier weight-bearing.[16] This is particularly important in high-energy trauma cases, where prolonged immobilization can lead to joint stiffness, muscle atrophy, and overall poorer functional recovery.[17]

In terms of functional outcomes, the significantly higher AOFAS scores at six months in the IM nailing group ($p=0.02$) highlight its efficacy in facilitating earlier rehabilitation and weight-bearing compared to plate fixation.[18] Previous research has indicated that early mobilization significantly improves long-term functional outcomes by promoting bone remodeling and minimizing joint stiffness,[19] which aligns with the findings of this study. However, despite these advantages, IM nailing was associated with a higher incidence of malalignment (12% vs. 4%, $p=0.03$), likely due to difficulties in achieving rotational control during closed reduction and nailing.[20]

The infection rate in the plate fixation group (12%) was notably higher than that in the IM nailing group (4%) ($p=0.04$). This can be attributed to the more invasive nature of open reduction and internal fixation (ORIF), which involves extensive soft tissue dissection and periosteal stripping.[21] Studies have shown that this increased exposure predisposes patients to deep infections, wound dehiscence, and nonunion, particularly in open fractures.[22] Conversely, IM nailing, performed

through a minimally invasive approach, reduces the risk of soft tissue compromise, leading to lower infection rates.[23]

Reoperation rates were slightly higher in the plate fixation group (10%) compared to the IM nailing group (6%), although this difference was not statistically significant (p=0.15). While some patients with IM nails required revision surgery due to malalignment or nonunion, the majority of reoperations in the plate fixation group were related to hardware failure and deep infections.[24] The higher incidence of mechanical failure in plate fixation has been documented in previous literature, particularly in cases involving excessive weight-bearing before adequate fracture healing.[25]

Despite the advantages of IM nailing, it is essential to consider patient-specific factors when determining the optimal fixation method. Patients with severe comminution, periarticular extension, or conditions requiring precise anatomical reduction may still benefit from plate fixation. However, given the overall superiority of IM nailing in reducing healing time, improving functional outcomes, and minimizing infection risk, it should be the preferred method in most tibial shaft fractures. Future research should focus on refining techniques to reduce malalignment risks in IM nailing, including the use of computer-assisted navigation or intraoperative fluoroscopic guidance to enhance alignment precision.

Conclusion

Intramedullary nailing significantly enhances fracture union rates, functional recovery, and infection outcomes in tibial shaft fractures compared to plate fixation. While the risk of malalignment remains a concern, the overall benefits of IM nailing outweigh those of plate fixation, making it the preferred treatment modality in most cases. Further advancements in surgical techniques are required to optimize alignment and minimize complications.

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