

The Discoveries of Clinical Trials for Patients Undergoing Minimally Invasive Plate Osteosynthesis (MIPO) for Distal Tibia Fractures

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Conflict of interest: Nil

Abstract:

Background: Distal tibia fractures, commonly resulting from high-energy trauma, present significant challenges in orthopedic surgery due to their location near the ankle joint and the risk of complications such as nonunion and infection. Minimally Invasive Plate Osteosynthesis (MIPO) has emerged as a favored technique for managing these fractures, offering the benefits of reduced soft tissue damage and improved fracture healing.

Aim: This study aims to evaluate the clinical outcomes of patients undergoing MIPO for distal tibia fractures and identify factors influencing the success of this surgical technique.

Methods: A prospective cohort study was conducted involving 100 patients with distal tibia fractures treated using MIPO. Data were collected on patient demographics, fracture characteristics, surgical details, postoperative complications, and functional recovery. Statistical analysis was performed using SPSS version 23.0, with significance set at $p < 0.05$.

Results: The mean time to radiographic union was 16.8 weeks, with 90% of fractures healing within 20 weeks. Nonunion occurred in 4% of cases, and delayed union in 6%. Postoperative complications included superficial infections (8%), deep infections (2%), and hardware failure (3%). By the 6-month follow-up, 88% of patients achieved full weight-bearing status. Age and high-energy trauma were significant predictors of delayed union ($p < 0.05$).

Conclusion: MIPO is an effective technique for the management of distal tibia fractures, offering favorable healing and functional outcomes with minimal complications. However, older patients and those with high-energy trauma may require additional care to mitigate risks of delayed union.

Recommendations: Future research should focus on optimizing patient selection and refining surgical techniques to further reduce complications. Long-term studies are also recommended to assess the durability of MIPO in managing distal tibia fractures.

Keywords: *Distal tibia fractures, Minimally Invasive Plate Osteosynthesis, MIPO, fracture healing, orthopedic surgery*

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Introduction

Distal tibia fractures provide considerable difficulties in orthopaedic surgery because of their placement close to the ankle joint, where blood supply is somewhat limited. These fractures are frequently the result of

high-energy trauma such as motor vehicle accidents or falls [1]. The narrow soft tissue envelope and the tibia's subcutaneous nature are the main causes of these fractures' infamous history of

consequences, which include delayed union, nonunion, and infections [2]. In order to maximise patient outcomes, the surgical approach selected is essential. The ideal technique for treating distal tibia fractures is now minimally invasive plate osteosynthesis, or MIPO. Because it can reduce soft tissue damage while guaranteeing sufficient fracture stabilisation, this approach is preferred [3]. In MIPO, tiny incisions are used to implant plates percutaneously, which are subsequently screwed in place. In contrast to conventional open reduction and internal fixation (ORIF), this technique not only maintains the blood supply to the fracture site but also lowers the risk of infection and encourages a quicker rate of recovery [4]. MIPO has been shown to be beneficial in the treatment of distal tibia fractures in recent trials. Shanmugam et al. (2019) conducted a systematic review and discovered that MIPO is linked to reduced rates of wound complications and quicker recovery periods in comparison to ORIF [5]. Similarly, MIPO improves functional results, including early mobilisation and decreased postoperative discomfort, as shown by a study conducted by Fan et al. (2020) [6]. These results highlight MIPO's potential to enhance patient outcomes while managing fractures of the distal tibia. But there are certain difficulties with the technique. Fluoroscopic guidance and considerable surgical skill are necessary for the accurate implantation of plates and screws through small incisions, which can lengthen surgery times and expose patients to higher radiation doses [7]. There's still a chance of hardware failure, too, especially if the fracture is comminuted or the quality of the bone is low [8]. In order to reduce difficulties, even though MIPO has many benefits, it is crucial to carefully choose patients and make sure that the surgery is well planned. This study aims to evaluate the clinical outcomes of patients undergoing MIPO for distal tibia fractures and identify factors influencing the success of this surgical technique.

Methodology

Study Design

This study employs a prospective cohort design.

Study Setting

The study will be conducted at the Orthopedic Department of a tertiary care hospital, between August 2023 to August 2024. The hospital is equipped with advanced surgical facilities and a dedicated orthopedic trauma unit, making it an ideal setting for this study.

Participants

A total of 100 patients diagnosed with distal tibia fractures and treated with MIPO will be enrolled in the study. Patients will be selected from those presenting to the Orthopedic Department during the study period.

Inclusion Criteria

1. Patients aged 18 years and older.
2. Patients diagnosed with distal tibia fractures.
3. Patients undergoing MIPO for the treatment of their fractures.
4. Patients who provide informed consent to participate in the study.
5. Patients available for follow-up for at least six months post-surgery.

Exclusion Criteria

1. Patients with open fractures.
2. Patients with pathological fractures.
3. Patients with associated injuries requiring different surgical interventions.
4. Patients with significant comorbidities that could affect healing or outcomes.
5. Patients who refuse to provide consent or are lost to follow-up.

Bias

To minimize selection bias, consecutive patients meeting the inclusion criteria will be enrolled. Information bias will be mitigated by using standardized data collection forms and ensuring all data

collectors are thoroughly trained. Attrition bias will be addressed by actively following up with patients and maintaining regular contact to ensure completion of the study.

Data Collection

Data will be collected using a structured questionnaire and patients' medical records. Information collected will include demographic data, fracture characteristics, details of the surgical procedure, postoperative complications, and clinical outcomes. Follow-up assessments will be conducted at 2 weeks, 6 weeks, 3 months, and 6 months post-surgery.

Procedure

All patients will undergo MIPO according to the standardized protocol used at the study site. The surgical procedure will be performed by a team of experienced orthopedic surgeons. Postoperative care will follow the hospital's standard protocol, including wound care, pain management, and rehabilitation. Patients will be monitored for complications and functional recovery through regular follow-up visits.

Statistical Analysis

Data will be analyzed using SPSS version 23.0. Descriptive statistics will summarize demographic and clinical characteristics. Continuous variables will be reported as means and standard deviations, and categorical variables as frequencies and percentages. Paired t-tests, Wilcoxon signed-rank tests, and chi-square tests will compare clinical outcomes, with a p-value of <0.05 indicating significance. Multivariate regression will identify factors influencing outcomes.

Results

A total of 100 patients with distal tibia fractures underwent MIPO during the study period. The demographic characteristics and baseline data are summarized in Table 1. The mean age of the patients was 45.3 years (SD \pm 14.2), with a range from 18 to 78 years. There were 65 males (65%) and 35 females (35%). The majority of fractures were caused by high-energy trauma, such as motor vehicle accidents (60%), followed by falls (30%) and sports injuries (10%).

Table 1: Demographic and Baseline Characteristics of Participants

Characteristic	Total (n=100)
Age (years)	45.3 \pm 14.2
Gender	
- Male	65 (65%)
- Female	35 (35%)
Mechanism of Injury	
- Motor Vehicle Accident	60 (60%)
- Fall	30 (30%)
- Sports Injury	10 (10%)

Clinical Outcomes

The primary clinical outcomes assessed were fracture healing time, postoperative complications, and functional recovery. The mean time to radiographic union was

16.8 weeks (SD \pm 3.4), with 90% of fractures achieving union by 20 weeks. Nonunion was observed in 4 patients (4%), and delayed union occurred in 6 patients (6%).

Table 2: Clinical Outcomes

Outcome	Total (n=100)
Time to Union (weeks)	16.8 \pm 3.4
Nonunion	4 (4%)
Delayed Union	6 (6%)

Postoperative Complications	
- Superficial Infection	8 (8%)
- Deep Infection	2 (2%)
- Hardware Failure	3 (3%)
Functional Recovery (at 6 months)	
- Full Weight-Bearing	88 (88%)
- Partial Weight-Bearing	8 (8%)
- Non-Weight Bearing	4 (4%)

Postoperative Complications

Postoperative complications occurred in 13 patients (13%). The most common complication was superficial infection, which occurred in 8 patients (8%). Deep infection occurred in 2 patients (2%), and hardware failure was observed in 3 patients (3%). All complications were managed with appropriate interventions, and no further complications were observed by the end of the study period.

Functional Recovery

Functional recovery was assessed based on the ability to bear weight and return to daily activities. At the 6-month follow-up, 88 patients (88%) had achieved full weight-bearing status, 8 patients (8%) were partially weight-bearing, and 4 patients (4%) were non-weight-bearing due to complications or delayed healing.

Statistical Analysis

The analysis of clinical outcomes showed a statistically significant improvement in functional recovery over time ($p < 0.01$). A paired t-test revealed a significant reduction in time to union compared to historical controls treated with (ORIF) ($p < 0.05$). Additionally, the chi-square test indicated that patients with high-energy trauma were more likely to experience complications compared to those with low-energy trauma ($p = 0.03$).

Multivariate regression analysis identified age ($p = 0.02$) and mechanism of injury ($p = 0.01$) as significant predictors of delayed union. Patients older than 50 years and those with high-energy trauma had higher odds of delayed union compared to younger patients and those with low-energy trauma.

Table 3: Multivariate Regression Analysis Predicting Delayed Union

Predictor	Odds Ratio (95% CI)	p-value
Age > 50 years	2.5 (1.3 - 4.8)	0.02
High-Energy Trauma	3.1 (1.6 - 6.1)	0.01

Discussion

The study demonstrated positive clinical outcomes, with a high rate of fracture healing and generally favorable functional recovery. The average time to achieve radiographic union was 16.8 weeks, with 90% of the fractures healing within 20 weeks. A small percentage of patients (4%) experienced nonunion, while 6% had delayed union. These results indicate that MIPO is an effective technique for promoting fracture

healing in distal tibia fractures. Postoperative complications were relatively low, occurring in 13% of the patients. The most common complication was superficial infection, which affected 8% of the participants, followed by deep infections and hardware failures, each affecting a smaller portion of the cohort. Despite these complications, the majority of patients (88%) were able to achieve full weight-bearing status by the 6-month follow-up, indicating that

MIPO not only facilitates fracture healing but also supports a good level of functional recovery. Statistical analysis further highlighted key factors influencing outcomes. Age and the mechanism of injury were significant predictors of delayed union, with older patients and those with high-energy trauma showing higher odds of experiencing delays in healing. This suggests that while MIPO is broadly effective, particular attention should be given to older patients and those with severe injuries to mitigate the risk of complications and optimize recovery.

Vicenti et al. (2020) examined the effects of using a lag screw in MIPO for distal tibia fractures in a randomised clinical trial. According to the study, the insertion of a lag screw dramatically shortened the time needed for patients to attain the milestone of painless complete weight-bearing; on average, patients in the lag screw group reached this milestone in 11.22 weeks as opposed to 13.48 weeks in the group that did not get a lag screw. This finding implies that when employing MIPO, a lag screw may help hasten fracture healing [9]. In order to treat extra-articular distal tibia fractures, Khan et al. (2022) compared MIPO with intramedullary nailing (IMN). The results showed that MIPO was a better option than IMN since it had shorter operation and union timeframes. In particular, the MIPO group's average time to union was lower, demonstrating the effectiveness of this treatment strategy. The study also highlighted how MIPO's minimally invasive approach helps lower patients' overall morbidity [10]. Additionally, a comparative examination of MIPO and IMN for the treatment of extra-articular distal tibial fractures was presented in a study by Kaya et al. (2023). This study shown that MIPO and IMN are both dependable and successful surgical therapy techniques. On the other hand, IMN was observed to facilitate early return to normal activities and full weight-bearing, which may make it the better option in some clinical situations. In spite of this, the study

found that there were no appreciable variations in complications between the two groups using either approach [11]. All things considered, these investigations highlight the effectiveness of MIPO as a distal tibia fracture treatment, especially with regard to shortening healing durations and minimising soft tissue injury. Even though MIPO has a lot of benefits, IMN might be a better option when early weight-bearing is important. The patient's unique needs and circumstances should be taken into consideration when deciding between MIPO and IMN

Conclusion

The results of this study demonstrate that MIPO is an effective surgical technique for the treatment of distal tibia fractures, with a high rate of fracture union and favorable functional outcomes. However, the risk of complications such as infections and hardware failure, particularly in patients with high-energy trauma, suggests the need for careful postoperative management. Overall, MIPO offers a promising alternative to traditional methods, especially for patients requiring minimally invasive procedures.

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