Expert tibial nail (ETN) versus minimally invasive plate osteosynthesis techniques in the treatment of distal tibia fractures in young adults: a randomized controlled trial

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Purpose
To compare anatomical locked plates inserted in a minimally invasive pattern (MIPO) versus expert tibial nailing (ETN) for fixation of extra-articular fractures of the distal tibia in young adults.
Patients and methods
The study included 120 patients, 84 males and 36 females. The mean follow-up time was 13.5 months, with at least 12 months of follow-up. Cases were equally divided and randomized by the closed-envelope technique into two groups, group A: fixed by anatomical locked plate through a minimally invasive approach, and group B: fixed by ETN.
Results
The average operative time was significantly higher in the MIPO group (94 min) compared with the ETN group (81.67 mins). Also, the radiological exposure time was also higher (87.6 secs) in group A versus 78.4 in group B. Although there was an incidence of deformity in few cases of the ETN group (eight patients), that was not significant enough to warrant correction by revision surgery. There were no significant differences in the union time (*P* value: 0.09) and American Orthopedic Foot and Ankle Society (AOFAS) scores (*P* value: 0.78) between the two groups. Furthermore, the infection and the need for further surgeries did not show significant differences among both groups.
Conclusion
Both MIPO and ETN are valid treatment options for distal tibia fractures, AO type 43 A. Both methods resulted in acceptable union time, and American Orthopedic Foot and Ankle Society scores, with no reported cases of nonunion.
Level of evidence.
Therapeutic study, level I

Keywords:
distal tibia fractures, expert tibial nails, locked plates, minimally invasive plate osteosynthesis

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Introduction

Distal meta-diaphyseal tibial fractures are a common consequence of high-energy trauma and are usually associated with variable degrees of soft-tissue injury [1,2]. In young adults, usually the management will be surgical by plate osteosynthesis, intramedullary nailing (IMN), or external fixation. Surgical treatment is still challenging despite innovations in fracture fixation [3,4].

Previously, open reduction and plate osteosynthesis was the standard technique to achieve a rigid fixation in distal tibial fractures. However, it usually requires excessive wound dissection that may represent a risk in the presence of a poor muscular envelope around the tibia. This may result in soft-tissue problems and nonunion. Standard-locked IMNs were used as a treatment option, but the fixation strength may not be adequate to allow for fracture union with higher rates of malunion or revision surgery [4,5].

Recently, closed reduction and minimally invasive plate osteosynthesis (MIPO) techniques were used to overcome the drawbacks of the traditional ORIF methods [6–8]. Furthermore, the interlocking system of expert tibial nail (ETN) was developed to increase the angular stability and the fixation strength, especially in fractures of the proximal or distal 1/3 of the tibia. This could be achieved by the presence of multiple multidirectional locking screws [1,9].

Several studies have compared open reduction and plate fixation with traditional nailing for distal tibial fractures with their known advantages and complications [10,11].

The aim of our study was to compare the anatomical locked plates applied by a minimally invasive technique (MIPO) versus expert tibial nailing (ETN) for the fixation of extra-articular fractures of the distal tibial in young adults. The hypothesis is that the plate group will result in better fracture reduction with less incidence of malalignment, but with more skin complications.

Patients and methods

This prospective randomized controlled trial was started in March 2020 in a level-1 trauma center. The study included 120 patients, 84 males and 36 females. The last case was operated upon on May 2022 and the mean follow-up time was 13.5 months, with at least 12 months of follow-up. The sample size was calculated using 'Clincalc sample size calculator', with 0.05 alpha error and power of the study was 0.80, for independent groups. A random sample of all patients presenting to the emergency department with distal tibial fractures during the study period has been included if they meet the inclusion and exclusion criteria till reaching the calculated sample size.

Approval from the scientific board and the ethical committee of the Trauma and Orthopaedic Department was obtained. We included all closed extra-articular fractures of the distal tibia (43 A1, 2, 3) according to the AO Classification. While we excluded skeletally immature patients, intra-articular fractures, ipsilateral fractures, open fractures, and pathological fractures.

The block-randomization method was used to create equal groups. The data were hidden using the closed-envelope technique. One hundred and twenty closed envelopes were prepared, every envelope had a card numbered from 1 to 120. In each case, the resident on call chose a closed envelope. The cases were then classified into each group by the odd/even technique. Group A (even numbers) was fixed by anatomical locked plate through a minimally invasive approach, and group B (odd numbers) was fixed by ETN. Both implants were made of titanium.

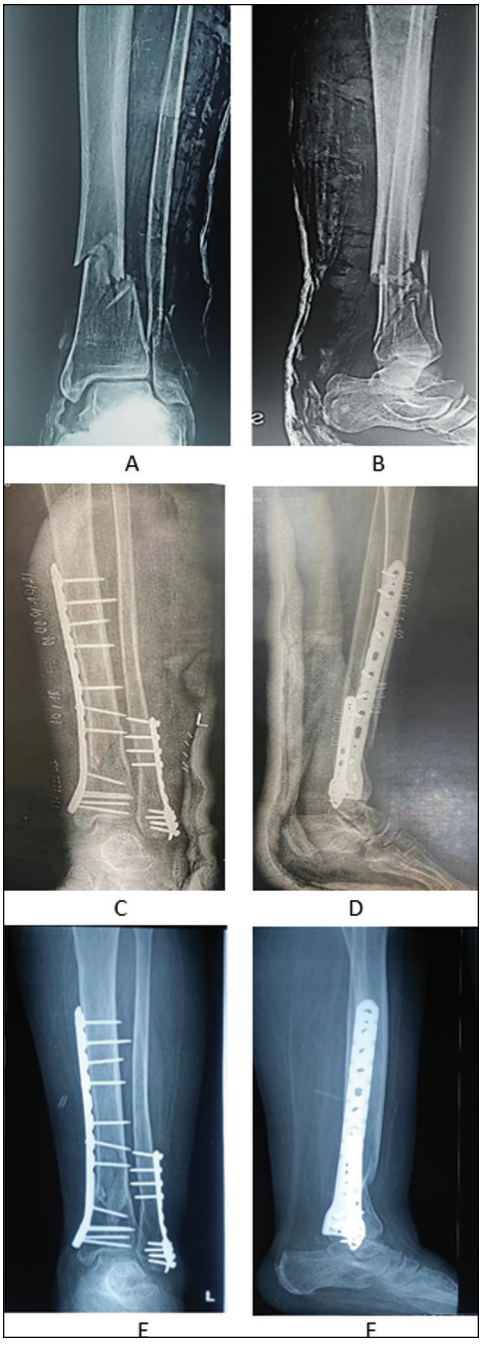
Preoperatively, the patients were medically optimized if needed, consented to randomization, and 1.5 gm of cefuroxime was given at anesthesia induction.

Group A: Distal tibia anatomical locked plate:

The patient was in a supine position with a thigh tourniquet. Two vertical incisions, 3 cm each, were made over the medial malleolus and proximal to the fracture site after restoring the tibial length and rotation guided by the image intensifier. Manual manipulation, percutaneous clamps, or fixator-assisted reduction were used to perform a percutaneous closed reduction of the fracture. Percutaneously, the anatomical distal tibia (titanium) locked plate was delivered submuscularly and fixed by screws.

In comminuted fracture patterns, the plate-span ratio was 3 times the fracture length with a plate screw density (SD) ratio between 0.4 and 0.5 (40–50%). While in simple fractures, the SD ratio was 0.3–0.4 (30–40%) [12,13] (Fig. 1).

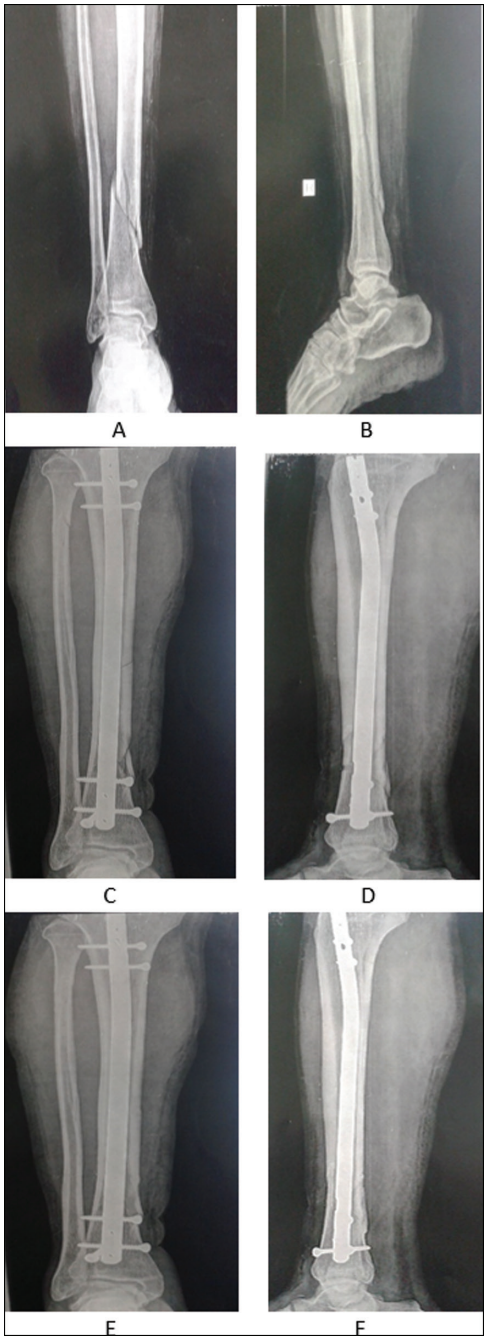
Figure 1



Minimally invasive plate osteosynthesisgroup, (a, b) preoperative radiograph AP, lateral views, (c, d) postoperative radiograph AP, lateral views, and (e, F) AP, lateral views after union.

Group B: Fixation by an expert tibial nail (ETN):
The patient was in supine position with no tourniquet. A bolster was put beneath the thigh. A midline skin incision was followed by a medial parapatellar incision in the retinaculum and the patellar tendon was laterally retracted. An awl was used to make the standard entry that was aligned with the medullary canal and the lateral tubercle of the intercondylar eminence, slightly distal to the angle between the tibial plateau and anterior metaphysis. Restoration of length, angulation, and rotation was essential with occasional use of blocking (Poller) screws (Fig. 2). In 5 (8.3%) cases of this group, a minimal incision (1–2 cm) was done at the fracture site to align the bony ends before passing the guidewire.

Figure 2



Nail group, (a, b) preoperative x-ray AP, lateral views, (c, d) postoperative x-ray AP, lateral views, and (e, f) AP, lateral views after union.

In both groups, the fibula was fixed if it was associated with syndesmotic instability tested by cotton test intraoperatively [14]. In all the fixed cases, the fibula was fractured within 7 cm of the tip of the lateral malleolus. Temporary alignment of the tibia was achieved first, followed by definitive fibular and then tibial fixation. In case of doubt about the rotation of the leg, the cable of the diathermy was used to confirm alignment of the anterior superior iliac spine, center of the knee, tibial crest, and second ray [15].

Follow-up and rehabilitation

In both groups, postoperatively, the patients were assessed by a physiotherapist. Knee and ankle range of motion was started on the second day postoperatively. The patients were allowed toe-touch weight-bearing using crutches. Full weight-bearing was started after the clinical and radiological union.

All patients were followed-up after 2 weeks for suture removal, and then at 1.5, 3, 6, and 12 months. At the final follow-up visit, the American Orthopedic Foot and Ankle Society Score (AOFAS) was used for functional assessment [16]. All patients were observed for any possible complications, signs of infection, or failure.

Statistical analysis

Data were analyzed using SPSS v21. We summarized the quantitative data using the mean, median, and standard deviation. Count and percentage were used for categorical data. The Mann–Whitney test was used for comparisons. Parametric and nonparametric tests of significance have been done according to data type. *P*-value less than 0.05 was considered as statistically significant.

Results

One hundred twenty cases with extra-articular fractures of the distal tibia met the inclusion criteria. They were divided into two groups, with 60 patients in each group: group A was fixed using an anatomical locked plate, while group B was fixed using ETN. The mean age for group A was 24.37 ± 6.17 years (range: 18–30) compared with 22.93 ± 5.24 years (range: 17–28) in group B. There was no statistically significant difference in comparing demographic data between the two groups apart from the age that was significantly higher in group A (Table 1).

Table 1 Demographic data

	Group (A) Plate		Group (B) Nail		*P*-value
	Count	%	Count	%	
Age	24.37 ± 6.17		22.93 ± 5.24		0.003
Sex					
Male	44	73.3%	40	66.7%	0.58
Female	16	26.7%	20	33.3%	
Occupation					
Heavy	28	46.7%	28	46.7%	
Moderate	22	36.7%	22	36.7%	
Light	6	10%	10	16.6%	0.31
Extreme	4	6.6%			
Comorbidities					
Diabetic	4	6.6%	0		0.16
Hypertensive	8	13.3%	8	13.3%	1
Mode of trauma					
Direct	22	36.7%	4	6.6%	
RTA	18	30%	32	53.3%	
FFH	0		8	13.3%	0.31
FTG	20	33.3%	16		
Affected side					
Right	28	46.7%	36	60%	1
Left	32	53.3%	24	40%	
AO Classification					
43A1	20	33.3%	46	76.7%	0.28
43A2	36	60%	14	23.3%	
43A3	4	6.6%	0		

RTA: road traffic accident, FFH: fall from height, FTG: fall to the ground, AO: Arbeitsgemeinschart Osteosynthesisfragen.

The mean time interval between injury and surgery was 3 ± 3.7 days for group A versus 2 ± 2.1 for group B. Although the interval was longer in the plate group because of waiting for favorable skin conditions, there was no statistical difference (*P* value=0.57). The range of hospital stay postoperatively was nearly the same for both groups around 1–3 days.

The mean operative time for group A was 94.0 ± 17.29 min, while it was 81.67 ± 16.26 min for group B with a *P*-value of 0.03.

In both groups, the fibula was fractured in 52 patients. The fibula was fixed by plate and screws in 34 cases in group A, compared with 20 cases in group B. The average radiological exposure time was recorded on the image intensifier screen (in seconds) after each case and documented. In group A, the radiological exposure time was 87.6 s (range: 66–102) versus 78.4 in group B (range: 65–93). The results were statistically significant (*P*-value = 0.01).

Mean union time in group A was 16.73 ± 3.61 weeks versus 14 ± 2.8 weeks in group B with a *P* value of 0.09 indicating a nonstatistically significant difference between both groups.

Eight (13.3%) patients in group B showed coronal plan deformity during the follow-up with no incidence in group A. However, the varus deformity was less than 5º, and no revision surgery was required. The results were statistically significant with a *P*-value of 0.02 (Table 2).

Regarding the AOFAS score in group A, 40 (66.67%) patients were graded as excellent, and 20 (33.33%) patients were good. In group B, 46 (76.67%) patients were graded as excellent, 10 (16.67%) patients were good, and 4 (6.67%) patients were fair (*P* value=0.78). The mean score of group A was 89.9%, and in group B was 90.26% (Table 3).

In group A, 8 (13.33%) patients sustained superficial infection versus 6 patients in group B (10%). All cases were treated by antibiotics according to culture and sensitivity with repeated dressings. In group A, removal of the plate was done in 2 cases after 1 year, because of skin irritation, while in group B, dynamization was performed in 4 (6.67%) patients to facilitate healing. There were no incidences of deep infection or wound dehiscence.

Discussion

Tibial fractures are common, and effective treatment can be accomplished using a variety of surgical techniques. Since the soft-tissue sleeve in the distal one-third of the tibia is thinner in comparison to

Table 2 Results

	Group (A) Plate		Group (B) Nail		*P*-value
	Count	%	Count	%	
Operative time	94 min		81.6 min		0.03
Fluoroscopic time	87.6 s		78.4 s		0.01
Fibula situation					
-Fixed	34	56.7%	20	33.3%	0.2
-Not fixed	18	30%	32	53.3%	
-Intact	8	13.3%	8	13.3%	
Coronal plane deformity	0		8	13.3%	< 0.01
Union time	16.7 weeks		14 weeks		0.09
Superficial infection	8	13.3%	6	10%	0.35
Secondary procedure					
-Dynamization	-	-	4	6.6%	<0.02
-Removal	2	3.3%	-	-	

Table 3 American orthopedic foot and ankle society score

AOFAS score	Group (A) Plate		Group (B) Nail		*P*-value
	Count	%	Count	%	
Excellent	40	66.7%	46	76.7%	
Good	20	33.3%	10	16.6%	0.78
Fair	0	0%	4	6.7%	

the proximal one-third and has low vascularization, distal tibial fractures are much more difficult to treat. Several studies compared distal tibial locked plates and intramedullary nails. Although the minimally invasive locked plates and the ETN are reliable and widely accepted treatments for distal tibial fractures, there is a scarcity of comparative studies available to enhance the selection of the optimal treatment approach [17,18].

In our study, 120 cases were divided into two groups. The preoperative data, including mode of injury, AO classification, and associated fibular fracture, showed no statistically significant differences between the two groups. Both groups were evaluated and compared in terms of operative time, superficial infection, deep infection, union, alignment, the need for secondary operations (dynamization, debridement, and revision), and AOFAS scores.

Fixation of the fibula associated with distal tibial fractures is highly controversial and there are no clear indications of which fractures should be fixed. Vallier and colleagues, Li and colleagues, and Guo and colleagues performed fibular fixation at the discretion of the surgeon. Proper reduction of the lateral malleolus with strong fixation facilitates tibial reduction and reduces the risk of malalignment [17–19].

However, fixation of the fibula may reduce the strain over the tibial fracture site increasing the risk of delayed union or nonunion [20]. Torino D and Mehta S recommended fixing the fibula in case it was combined with unstable syndesmosis [21].

Ruedi and Allgower stated that a fractured fibula within ten cm of the ankle joint should be fixed [22,23]. Kumar *et al.* performed a cadaveric biomechanical study and found that fixation of fibula fractures within 7 cm from the ankle improved the rotational stability and reduced the axial rotation [24].

In the current study, the fibula was fixed if it was associated with syndesmotic instability that was found in fractures within 7 cm of the tip of the lateral malleolus.

Guo and colleague. made a study in which 85 patients with fractures of the distal tibia were included. They were fixed by plate or nail. Regarding the operative time, there was a statistically significant difference between both groups with a larger operative time in the plate group than in the nail group. (97.9 vs. 81.2 min) [19].

In the study made by Li and colleagues, 46 cases with fractures of the distal tibia were treated with an anatomical locked plate and expert nail. The mean operative time in the plate group was 90 ± 20.3 min versus 76 ± 16.6 min in the nail group [18].

Guo and colleagues and Mauffrey and colleagues reported less fluoroscopic time in the nail group with a *P* value less than 0.05 [19,25].

The current study concurs with the literature, as the ETN has a shorter operative time and radiological

exposure time with statistically significant differences (*P*-value = 0.03, 0.01, respectively).

Regarding the postoperative union time, a meta-analysis that included 354 patients treated by interlocking nails (177 cases) and plates (177 cases) showed no statistically significant difference with a *P* value of 0.3 [26].

Li and colleagues showed that the union time was significantly higher in cases treated by locked plate than in expert nail (23.1 ± 3.6 vs 21.3 ± 3.5 weeks) with a *P* value of 0.047 [18]. In the 'Guo and colleagues' study, plating or nailing did not have any significant difference in the union time (IMN, 17.66, LCP 17.59 weeks) [19].

Vallier and colleagues reported a significant malalignment reduction in thirteen cases in the nail group and 4 cases in the plate group with a *P* value of 0.02 [17]. Other studies showed no significant difference in malalignment in both groups with a slight increase in the rate of malalignment in the ETN [27].

In the current study, there was no statistically significant difference in time to union (*P*- value of 0.09). However, in the nail group only, coronal plane malalignment (<5°) occurred with a highly significant difference (*P* value < 0.01). Fortunately, no cases needed revision.

A meta-analysis, including 482 cases in eight studies, was evaluated. In the nail group (245 cases), wound complications were found in 13 cases versus 39 cases in the plate group (237 cases). This showed that the nail group had significantly less incidence of wound complications than the plate group with a *P* value of 0.0003 [26].

Li and colleagues showed a significant increase in superficial infection with the plate group, and this goes with the results in our study with no significant difference [18].

Guo and colleagues reported that the mean AOFAS score in the plate group was 84, and in the nail, group was 86 with a *P* value less than 0.05. Li Y and colleagues used the OMAS score as a functional outcome, in the plate group was 89.0 ± 7.1, while in the nail group was 87.6 ± 8.4 with a *P* value of 0.478. Li Yand colleagues used the Mazur ankle score (Evaluation grading system for assessment of ankle function), in the plate group, 90% of patients got excellent or good and in the ILN group, 87% got excellent or good [18,19].

The current study found that all patients in the plate group received excellent and good scores on the AOFAS scale. In the nail group, 56 patients received excellent and good scores, and 4 cases had fair scores. The *P* value for the AOFAS score comparison between the two groups was 0.78, which was statistically insignificant.

Being a randomized controlled trial with a large number of cases included are among the strengths of our study. However, the short follow-up period represents a limitation in the current study. Further studies with longer periods of follow-up are recommended to support our results.

Conclusion

Although ETN had shorter operative time and radiological exposure than locked plates, it had a higher rate of malunion, but the angle of deformity was less than 5 degrees, and no revisions were required.

When analyzing the results of our study, it is apparent that both MIPO and ETN are viable treatment options for distal tibial fractures, AO type-43 A in young adults. Both options resulted in acceptable union time and AOFAS scores with no cases of nonunion or deep infection (wound dehiscence). Both methods had a lower incidence of complications compared with traditional nailing and plating in prior studies. However, more technical expertise is warranted for the ETN as blocking screws may be used to avoid malalignment.

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Ethical approval

This study was approved by our Institutional Ethics Review Board.

Consent to participate

All patients provided informed consent to participate in this study.

Consent to publish

All participants provided informed consent for the publication of this study.

Availability of data and materials

Not available.

Code availability

Not available.

Conflicts of interest

The authors declare that they have no conflict of interest.

Authors' contributions

All authors whose names appear on the submission.

(1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work;
(2) drafted the work or revised it critically for important intellectual content;
(3) approved the version to be published; and
(4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Registration data
Registration number: MS-203-2020
Registration date: 3-2020

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