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### **Comparison of functional outcome between expert tibial nail and distal tibial medial locking plate by mippo technique for closed extra articular distal tibial fracture**

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#### **Abstract**

**Background:** Distal tibial fractures account for approximately 7% of all tibial fractures and can present a management challenge because of their inherent instability, scarcity of soft tissues, subcutaneous nature and poor vascularity of bone. Despite the availability of various modern techniques, there is either no or insufficient evidence to draw definitive conclusions on the best surgical intervention.

**Materials and Methods:** The study was an open labelled randomized control trial conducted over a period of one year from January to December 2017. Patients with extra-articular distal tibia fracture attending the Department of Orthopaedics, in tertiary care hospital through casualty or outpatient basis fulfilling the inclusion and exclusion criteria were the study participants. After obtaining necessary permissions and consent, the patients were randomized into two groups for IMIL nailing and plating. Data on socio-demographic characteristics, surgery details and complications were obtained. The functional outcomes were measured at 1, 3, 4, and 6 months by using Olreud & Molander scale and RUST scale. The data obtained were entered into excel and analyzed using SPSS v16.

**Results:** A total of 32 patients (16 in each group) participated. The mean age of participants were 44.1 ( $\pm 16.95$ ) years and majority were males (56.3%). Majority (81.3%) patients had an associated fracture in the distal fibula. The time of surgery and fracture union for intramedullary nail was significantly less when compared to plating. The Olreud & Molander scores and RUST scores were significantly higher in patients with IMIL nail. Malunion and anterior knee pain were more frequent after IM interlocking nail. Non-union and infection were found only in the plating group.

**Conclusion:** The study found intra-medullary inter-locking (IMIL) nailing was more successful and effective in terms of achieving good union with optimal functional outcomes compared to the extra medullary plating for closed extra-articular distal third tibial fractures. A larger sample size with equal representation in both groups is required for a p value with higher significance.

**Keywords:** Extra articular, distal tibia, plating, nailing, compare

#### **Introduction**

Distal tibial fractures are one of the most complex injuries around the ankle joint, accounting for approximately 7% of all tibial fractures [1]. Fractures of the distal tibial metaphysis with or without intra-articular extension can present a management challenge because of their inherent instability, scarcity of soft tissues, subcutaneous nature and poor vascularity of bone. Treatment modality is dictated by the fracture displacement, comminution, intra-articular extension and injury to the soft-tissue envelope [2]. Soft-tissue management has been seen to play a vital role in the management alongside the bony reconstruction [3].

Open reduction and plating is a popular method that can result in good fixation. The technique is used widely, but it usually requires a relatively extensive wound exposure and soft-tissue dissection and is often associated with delayed healing, infection, and hardware problems [4]. Recently, minimally invasive percutaneous medial locked plating has been described in the literature with promising results. However, this method is technically demanding, and it is often difficult to achieve anatomic reduction [5, 9].

Expert tibia nails currently represent an effective approach to the treatment of complex extra-articular distal tibial fractures. The low multidirectional locked nailing may represent a

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superior surgical option, since it offers advantages in terms of full weight-bearing, union rate, short operating time and hospital stay [6, 8].

Despite the availability of various modern techniques, there is either no or insufficient evidence to draw definitive conclusions on the best surgical intervention for distal tibial metaphyseal fractures in adults. Hence, our study aims to compare the functional outcomes of distal metaphyseal fractures of tibia managed with Minimally Invasive Percutaneous Plate Osteosynthesis (MIPPO) and expert tibial intramedullary nailing.

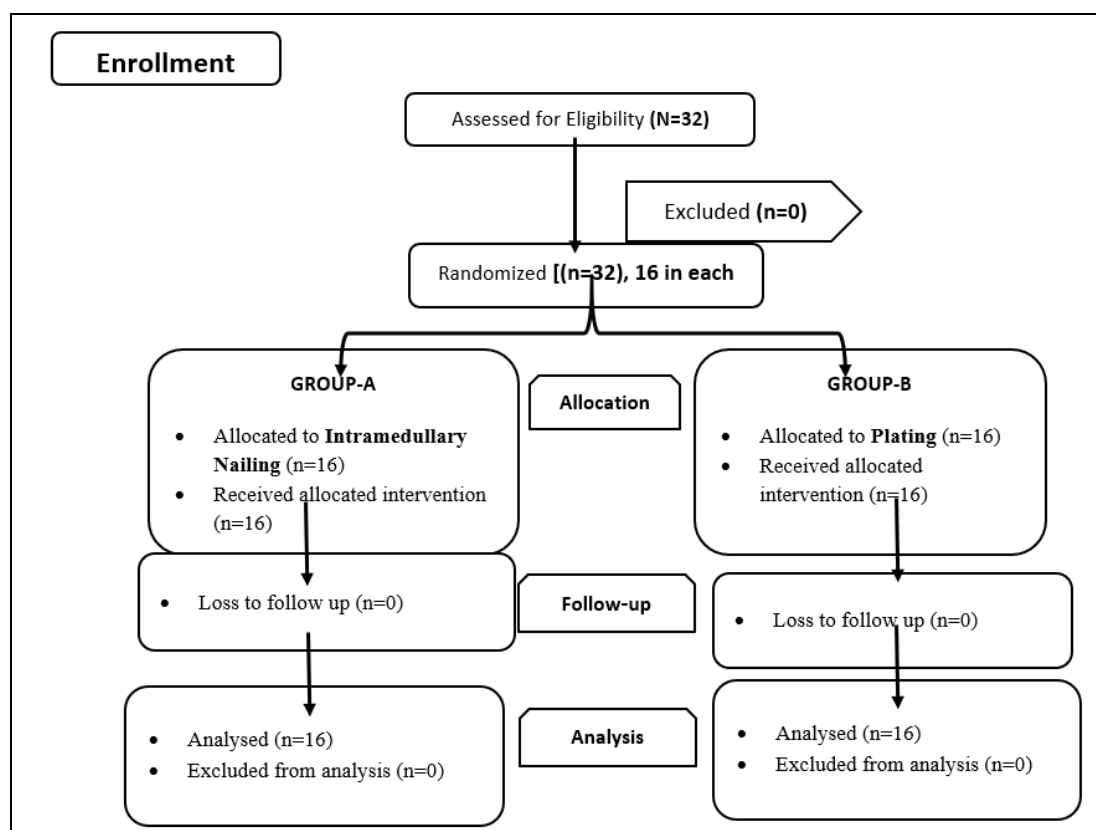
### Materials and subjects

The study was a randomized control trial conducted in the Department of Orthopaedics, in a tertiary care hospital between the periods from January 2017 to July 2018 after obtaining ethical clearance from the Institutional Human Ethical Committee (IHEC) project no.

Skeletally matured patients with fracture involving distal 1/3rd of tibia (AO type A1, A2, A3) were included in the study. Skeletally immature patients, Pilon fractures (AO type B,C) All open fractures, Associated fractures in ipsilateral limb excluding fibula and mentally ill patients were excluded from the study.

### Sampling Procedure

The 32 patients with extra-articular distal tibial fracture and fulfilling the inclusion criteria were selected and verified. Informed and written consent were obtained. The patients were numbered sequentially at the time of admission and were randomized into two groups. Group one underwent expert tibial nail and group two underwent distal medial tibial locking plate for distal tibial fracture. The cost, pros and cons of both the procedures were explained prior to the surgery to the respective groups. Computer generated random numbers were used for randomizing the patients.



### Post-operative protocol

Patient who were in nailing group was made to full weight bear as soon as possible, were as in plating group patient Clinical and radiological follow-up was done at end of 1month, 3 months, 6months and 12 months after the surgery. Standard antero-posterior and lateral view radiographs of the leg with knee and ankle joint were taken. All patients were covered with 3 doses of intravenous broad spectrum antibiotics. Dressing was removed and the wound was inspected on the 2 and 5 day after surgery and subsequently the sutures were removed on the 12 post-operative day.

The functional outcome was assessed using the Olreud-Molander Ankle Score (OMAS) and the Radiographic Union Scale in Tibial fractures (RUST) score.

### Data analysis and statistical tools

The data obtained from the proforma were entered into

Microsoft excel 2016 software and analysed using Statistical Package for Social Sciences (SPSS) version 16. Mean and standard deviation were calculated to summarize continuous variables such as age, time of surgery and time of union. The Olerud and Molander scores were summarized as number and percentages while the RUST scores were summarized as Mean and Standard deviation. Independent t test was used to find the existence of significant differences in RUST scores among the two procedure groups.

### Results

The present study was a randomized control trial to compare the functional outcome of expert tibial nail and distal tibial medial locking plate by MIPPO technique for the treatment of extra articular distal tibial fracture.

### Variables

**Table 1:** Distribution of the socio-demographic variables, co-morbidities and surgery details among the two procedure groups

Variables	Group A (Intramedullary Nail) n (%)	Group B (Plating) n (%)	Total, n (%)	Chi-square (p value)
Age				
20-40 years	10 (66.7)	5 (33.3)	15 (46.9)	3.2 (0.257)
40 -60 years	4 (33.3)	8 (66.7)	12 (37.5)	
>60 years	2 (40)	3 (60)	5 (15.6)	
Gender				
Male	8 (44.4)	10 (55.6)	18 (56.3)	0.508 (0.722)
Female	8 (57.1)	6 (42.9)	14 (43.8)	
Diabetes Mellitus				
Yes	4 (44.4)	5 (55.6)	9 (28.1)	0.155 (0.694)
No	12 (52.2)	11 (47.8)	23 (71.9)	
Smoking status				
Smoker	3 (42.8)	4 (57.2)	7 (21.9)	0.183 (0.669)
Non-smoker	13 (52)	12 (48)	25 (78.1)	
Fibula Fracture				
Present	14 (53.8)	12 (46.2)	26 (81.3)	0.821 (0.654)
Absent	2 (33.3)	4 (66.7)	6 (18.7)	

Table 1 shows the distribution of the socio-demographic among the two procedure groups. The association between all the above independent variables and the procedure groups was found to be insignificant ( $p > 0.05$ ).

### Duration of surgery

**Table 2:** Association between the type of procedure and duration of surgery

Procedure	Duration of Surgery (minutes)		p value
	Mean	SD	
Intramedullary nail	72.19	10.483	<0.001
Plating	98.13	11.236	

Table 2 The mean duration of surgery among the patients who underwent intramedullary nail was 72.19 ( $\pm 10.483$ ) minutes while it was 98.13 ( $\pm 11.236$ ) minutes among the patients undergoing plate osteosynthesis by MIPPO technique. There was statistically significant difference ( $p < 0.001$ ) in the time of

surgery between the two procedure groups.

### Functional score

**Table 3:** Association of the Olreud-Molander Ankle score with the two procedure groups at the end of 6th month

Procedure	Olreud-Molander Ankle score, n (%)		p value
	Good	Excellent	
Intramedullary nail	2 (12.5)	14 (87.5)	0.019
Plating	8 (50)	8 (50)	

Table 3 There was statistically significant difference ( $p = 0.019$ ) in the Olreud-Molander Ankle score among the two procedure groups. The patients with intramedullary nail had higher proportions in excellent groups when compared to patients with plating.

### Time of Union of fracture

**Table 4:** Association between the type of procedure for distal tibial fracture and time of union of the fracture

Procedure	Time of Union (weeks)		t value	p value
	Mean	SD		
Intramedullary nail	19.25	3.642	2.639	0.013
Plating	24.13	6.428		

Table 4 shows the distribution and association of the time for fracture union (In weeks) post-surgery and the type of procedure. The mean time for fracture union among the patients who underwent intramedullary nail was 19.25 ( $\pm 3.642$ ) weeks while it was 24.13 ( $\pm 6.428$ ) weeks among the patients undergoing plate osteosynthesis by MIPPO

technique. The time for fracture union among patients who underwent intramedullary nail was significantly less when compared to plating

### Complication

**Table 5:** Distribution of Complications among the two procedure groups

Complications	Type of Procedure n, (%)	
	Intramedullary Nail, (n=16)	Plating, (n=16)
Malunion	1 (6.3%)	0
Non-union	0	3 (18.8%)
Delayed Union	2 (12.5%)	2 (12.5%)
Infection	0	3 (18.8%)
Anterior knee pain	4 (25%)	0

Table 5 shows the distribution of the complications following surgery among the two procedure groups. Compared to the participants who underwent intramedullary nail fixation for

distal tibial fracture, those with plating had higher proportions of complications such as non-union (18.8%) and infections (18.8%) respectively. The proportion of patients with delayed

union of fracture was equal in both the procedure groups [2(50%)]. Patients who underwent intramedullary nail for distal tibial fracture had higher proportions of malunion (6.3%) and anterior knee pain (25%) when compared to plating.

### Discussion

In our study, we compared the two techniques (expert tibial nail and distal tibial medial locking plate fixation) with various parameters like union rate, duration of surgery, rate of complications, and functional outcome using Olreud and Molander score, and RUST score. The time of surgery and fracture union for intramedullary nail was significantly lesser when compared to plating. The Olreud & Molander scores and RUST scores were significantly higher in patients with IMIL nail. Malunion and anterior knee pain were more frequent after IM interlocking nail. Non-union and infection were found only in the plating group.

In the present study, the mean average age incidence was 44.1 years. The youngest individual was 18 years, and oldest was

80 years. The average age of the patients with distal tibial fracture were similar to the studies done by Kumar YC *et al.* [13] and Natarajan *et al.* [14] among similar target population. Hence, distal tibial fractures commonly occur in the age group of 40-50 years.

The functional outcome as assessed by the Olreud-Molander Ankle score were significantly higher in the patients who underwent Intramedullary nailing when compared to the group with plating. More number of patients were in the excellent group (87.5%) in the patients with nailing when compared to patients with plating (50%). The findings were similar to studies by Vallier HA *et al.* [7] and Singh A *et al.* [15]. Similarly, Nandakumar *et al.* concluded that intramedullary interlocking nailing is a reliable method of treatment for distal metaphyseal tibial fractures with a high union rate and low complication rate [11, 12, 10].

In the present study, the average period of radiological union was found to be significantly faster in the nailing group which is comparable to Yang *et al.* [16] existing studies (Table-6).

**Table 6:** Comparison of radiological union -nailing versus plating

Authors	Time of Union	
	Nailing	Plating
Vallier HA, Le TT, Bedi A [7]	22.6 weeks	27.8 weeks
Singh A, Kumar R, Ummat V, Pandey PK [15]	22.6 weeks	23 weeks
Im GI, Tae SK [17]	18 weeks	20 weeks
Janssen KW, Biert J, kampen A [18]	21 weeks	19 weeks
Natarajan GB, Srinivasan DK, Vijayaraghavan PV [14]	24.9 weeks	24.2 weeks
Our study	19.25 weeks	24.13 weeks

The comparison of the complications of nailing and plating in the current study with the previous studies have been

represented in table 7 and table 8 respectively.

**Table 7:** Comparison of studies-complications of nailing

Authors	Rate (%)		
	Infection	Non-Union	Mal-union
Vallier HA, Le TT, Bedi A [7]	5.3%	7.1%	23%
Singh A, Kumar R, Ummat V, Pandey PK [15]	0	0	15%
Im GI, Tae SK [17]	2.9%	0	11.7%
Janssen KW, Biert J, kampen A [18]	1	0	20.85%
Natarajan GB, Srinivasan DK, Vijayaraghavan PV [14]	0	6.7%	16.65%
Our study	0	0	6.3%

**Table 8:** Comparison of studies- complications of plating

Authors	Rate (%)		
	Infection	Non-Union	Mal-union
Vallier HA, Le TT, Bedi A [7]	2.7%	4.2%	8.3%
Singh A, Kumar R, Ummat V, Pandey PK [15]	10%	0	0
Im GI, Tae SK [17]	20%	6%	0
Janssen KW, Biert J, kampen A [18]	0	0	16.7%
Natarajan GB, Srinivasan DK, Vijayaraghavan PV [14]	6.6%	0	13.3%
Our study	18.8%	18.8%	0

Boos N *et al.* [20] in 51 cases of distal tibial fracture with interlocking nail, there was incidence of 16% malunion. In our comparative study has also described more malalignment after nailing than plating

In our study, delayed union of the fracture was found in equal proportion in both the nailing and plating group. This is comparable to studies conducted by Fan CY *et al.* [21] and Aso Mohammad *et al.* [22].

The infection rate was higher in the plating group when compared to nailing. About one fifth of the patients in the

plating group had developed infection post-surgery while there was no incidence of infection in the nailing group. Among these patients, two were superficial and were treated with antibiotics. The third infection was deep exposing the plate and was managed by placing a skin flap over the area. The findings were in line with the study done by Kumar YC *et al.* [13] and Redfern DJ *et al.* [19].

There were three cases of non-union (18.8%) in this study. The findings were present only in patients who underwent plating. Two patients with non-union underwent bone marrow

injection over the fracture site while the third patient underwent iliac bone grafting.

Smokers had higher proportions of non-union, delayed union when compared to non-smokers. Similarly, patients with diabetes mellitus had higher proportions of non-union and infection rates when compared to those without diabetes mellitus.

According to the results in our study, the fracture union rate is faster and malunion rate is higher in the nail group and the infection rate is higher in the plate group leads to complication like wound dehiscence, tendon exposed, implant exposed and implant failure and non-union. Therefore, the multidirectional intramedullary nail is superior to the plate.

### Conclusion

The study found intra-medullary inter-locking (IMIL) nailing was more successful and effective in terms of achieving good union with optimal functional outcomes compared to the extra medullary plating for closed extra-articular distal third tibial fractures. A larger sample size with equal representation in both groups is required for a p value with higher significance.

### Limitations

The study was done only among a smaller group of patients with distal tibial fracture.

The findings of the study can be applied only to the closed extra-articular type of distal tibial fracture AO type A1, A2 and A3. The findings cannot be generalized to other type of distal tibial fractures AO type B, C, Pilon fractures and open fractures.

### Recommendations for future research

Current results are influenced by selection bias because more severe fractures are often treated differently than less severe ones. Future studies could benefit from any of the following design improvements or additions:

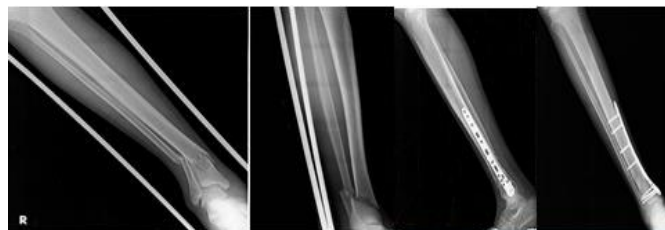
- Comparisons of IM nailing and plate fixation on patients with same fracture type and similar prognostic factors.
- Use of validated outcome measures, including patient reported outcomes that measure function and quality of life.
- Use of clinical outcome assessors who are blinded to treatment.
- Use of studies with sufficient statistical power that are designed to limit bias.
- Well-designed studies of long-term outcomes and impact of rehabilitation programs.

### Radiograph for nailing



**Fig 1:** Pre op radiograph shows distal tibia fracture and post op radiograph showing united fracture with nail in situ at end of 5th month

### Radiograph for plating



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