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A comparative study of functional outcome of distal tibial extra-articular fracture fixed with intramedullary interlocking nail versus locking compression plate

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Abstract
Background: Distal metaphysical fracture of the tibia has been a challenging situation when mostly treated with Plaster of Paris casts, resulting in ankle and knee stiffness and prolonged immobilization. This affecting quality of life of the patient. For the past decade, nailing and plating for fracture reduction has been successful in treating fractures of lower extremity especially distal tibia
Objectives: To compare the functional and radiological results of locking compression plate osteosynthesis over intramedullary nailing.
Methods: Patients with closed extra articular distal tibial fractures admitted under orthopedics in KIMS hospital will be randomly divided into 2 groups of 10 patients each. Group-1 was operated by Closed reduction and internal fixation with Intramedullary interlocking nail and Group-2 was operated by Locking compression plate done using MIPPO technique. Patients was followed up at regular intervals of 6 weeks for 6 to 10 months and assessed clinically, functionally and radiologically based in IOWA knee evaluation and ankle evaluation rating system.
Conclusion: All fractures united well. Rate of union in patients who underwent plate fixation with LCP had lesser average union time (26 weeks) compared to IMIL nailing (27 weeks). In our study valgus union of >5degrees in two patients and varus union of >5 degrees in two patient in IMIL nail group. But in plating group no malunion was noted. In both groups we achieved good anatomical reduction, stable internal fixation and early mobilization and functional outcome in both groups are comparable with statistically significant difference.

Keywords: Distal tibial fracture, LCP plate, MIPPO, IMIL nail, IOWA knee and ankle evaluation

1. Introduction
The difficulty in treating the fractures of distal tibial end is exemplified by orthopedicians, who in the first half of twentieth century believed these injuries were so severe and fraught with so many complications that the fracture was deemed not amenable for surgical reconstruction [1]. Distal tibial fractures represent a significant challenge to most of the surgeons today. They are only 1-10% of lower extremity fractures [2].
Conservative treatment by cast application leads to prolonged immobilization, leading to ankle and knee stiffness affecting quality of life of the patient [3]. Introduction of locking compression plate was a revolution in the evolution of management of fractures where prolonged bed rest is avoided and return to work is satisfactorily helpful.
For the recent decade, nailing and plating for fracture reduction has been successful in treating fractures of lower extremity especially distal tibia. The goal of the techniques is to apply stable fixation while maintaining the fracture biology and minimizing the soft tissue problems [4, 5, 6]. Compared to conventional plates, locking plates impart a higher degree of stability and provides better protection against primary and secondary loss of reduction. Intramedullary nailing has the advantage of a shorter operating and radiation time and easier removal of the implant [7]. But delayed union, malunion and secondary procedures were more frequent after nailing [8].
Our objective of this study was to compare the functional and radiological results of locking compression plate osteosynthesis over intramedullary nailing.

2. Materials and Methods

2.1 Source of Data

The study was conducted on 20 patients admitted with extra articular distal tibial fracture during June 2013 to February 2017, in Department of Orthopaedics, Kempegowda institute of medical sciences and research centre, Bangalore.

2.2 Inclusion Criteria

1. Age: Above 18 years up to 70 years of either sex
2. Closed Distal Tibial extra articular fractures (as per AO Classification [1] 43A1 , 43A2,43A3)

2.3 Exclusion Criteria

1. Pathological fractures
2. Old neglected fractures
3. Old fractures with implant failure

2.4 Clinical Assessment

On admission of the patient, a careful history was elicited from the patient and/or attenders to reveal the mechanism of injury and the severity of the trauma.

The patients were then assessed clinically to evaluate their general condition and the local injury. Methodical examination was done to rule out fractures at other sites.

2.5 Radiographic Assessment

Standard guidelines were utilized to get radiographs –Antero-posterior and lateral radiographs of the affected leg along with ankle were taken and the fracture patterns were classified based on the AO/OTA classification of fractures of distal tibia.

2.6 Pre-Operative Evaluation

Inpatients meeting the inclusion and exclusion criteria are selected for the study. All the patients were explained about the aims of the study, the methods involved and an informed written consent was obtained before being included in the study. The patient were randomly divided into 2 groups of 10 patients each

2.7 Operative Procedure

Group-1 was operated by closed reduction and internal fixation with intramedullary interlocking nail.

Group-2 was operated by locking compression plate done using MIPPO technique.

2.8 Post-Operative Period

Immediate post-operative complications like fat embolism, compartment syndrome, neurological damage and vascular injury is looked for. Intravenous antibiotic regimen was continued for 5-7 days after the surgery. Another 5 days of oral antibiotics were advised. Suture or staple removal was done at 10-12th post-operative day.

Group-1: Non-weight bearing of the patient using standard walking frame was done from the first post-operative day under the supervision.

Group-2: Active quadriceps exercises are restarted on the 1st post-operative day with active ankle and toe movements with knee mobilization as far as the patient is comfortable and free of pain. The patient is made to ambulate from the 3rd post-operative day without bearing weight on the operated leg with crutches or walker.

2.9 Follow Up

The Patients were followed up at regular intervals of 6 weeks for up to 6-10 months to assess clinically, functionally and radiologically based on IOWA knee evaluation and ankle evaluation rating system [9]. Partial and full weight-bearing were allowed based on radiological and consolidation of the fractures. The fracture was designated as united, when there was periosteal bridging callus at the fracture site at least in three cortices in the anteroposterior and lateral views. Trabeculations extending across the fracture site was also taken into consideration.

2.10 Statistical Methods

Descriptive and inferential statistical analysis has been carried out in the present study.

Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven1s test for homogeneity of variance has been performed to assess the homogeneity of variance. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

2.11 Statistical software

The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs & tables

3. Results

Table 1: Age distribution of patients studied

Age in years	Nail Group		Plate Group	
	No.	%	No.	%
<20	1	10.0	0	0.0
20-30	0	0.0	2	20.0
31-40	4	40.0	1	10.0
41-50	1	10.0	3	30.0
51-60	2	20.0	3	30.0
61-70	2	20.0	1	10.0
Total	10	100.0	10	100.0
Mean ± SD	46.00±14.76		45.60±13.26	

Samples are age matched with Student t test P=0.950

Table 2: Gender distribution of patients studied

Gender	Nail Group		Plate Group	
	No	%	No	%
Female	3	30.0	1	10.0
Male	7	70.0	9	90.0
Total	10	100.0	10	100.0

Table 3: Occupation distribution in two groups of patients studied

Occupation	Nail Group		Plate Group	
	No	%	No	%
Farmer	3	30.0	3	30.0
Housewife	3	30.0	1	10.0
Businessman	2	20.0	1	10.0
Government officer	0	0.0	2	20.0
Labourer	0	0.0	1	10.0
Lawyer	0	0.0	1	10.0
Student	1	10.0	0	0.0
Teacher	1	10.0	0	0.0
Truck driver	0	0.0	1	10.0
Total	10	100.0	10	100.0

Table 4: Mode of Injury distribution in two groups of patients studied

Mode of Injury	Nail Group		Plate Group	
	No	%	No	%
Road-traffic accident	9	90.0	5	50.0
Self-fall	1	10.0	2	20.0
Fall from height	0	0.0	2	20.0
Contact sport	0	0.0	1	10.0
Total	10	100.0	10	100.0

Table 5: Duration of surgery (in minutes) distribution in two groups of patients studied

Duration of surgery (in minutes)	Nail Group		Plate Group	
	No	%	No	%
1-60	0	0.0	0	0.0
61-90	8	80	4	40.0
91-120	2	20	6	60.0
121-150	0	0.0	0	0.0
Total	10	100.0	10	100.0
Mean ± SD	83.00±11.60		98.80±11.09	

P=0.006**, Significant, Student t test

Table 6: Knee activity in two groups of patients studied

Knee Activity	Nail Group	Plate Group	P Value
6 weeks	8.00±0.00	7.00±0.00	-
12 weeks	14.60±1.26	17.00±0.00	<0.001**
24 weeks	31.00±2.11	31.50±1.58	0.556

Table 7: Knee Pain in two groups of patients studied

Knee Pain	Nail Group	Plate Group	P value
6 weeks	26.00±8.43	35.00±0.00	0.003**
12 weeks	35.00±0.00	35.00±0.00	-
24 weeks	35.00±0.00	35.00±0.00	-

Table 8: ROM ankle in two groups of patients studied

Rom ANKLE	Nail Group	Plate Group	P VALUE
6 weeks	13.40±1.90	12.40±1.58	0.216
12 weeks	17.40±1.35	17.80±1.48	0.535
24 weeks	19.00±1.05	19.40±0.97	0.388

Table 9: Fracture union grade in two groups of patients studied: A Comparative assessment

Fracture union grade	6 weeks	12 weeks	24 weeks
Nail group (n=10)			
• 1	0(0%)	0(0%)	0(0%)
• 2	0(0%)	2(20%)	4(40%)
• 3	2(20%)	7(70%)	6(60%)
• 4	8(80%)	1(10%)	0(0%)
• 5	0(00%)	0(0%)	0(0%)
Plate group (n=10)			
• 1	0(0%)	0(0%)	4(40%)
• 2	0(0%)	3 (30%)	6(60%)
• 3	4(40%)	7(70%)	0(0%)
• 4	6(60%)	0(0%)	0(0%)
• 5	0(0%)	0(0%)	0(0%)

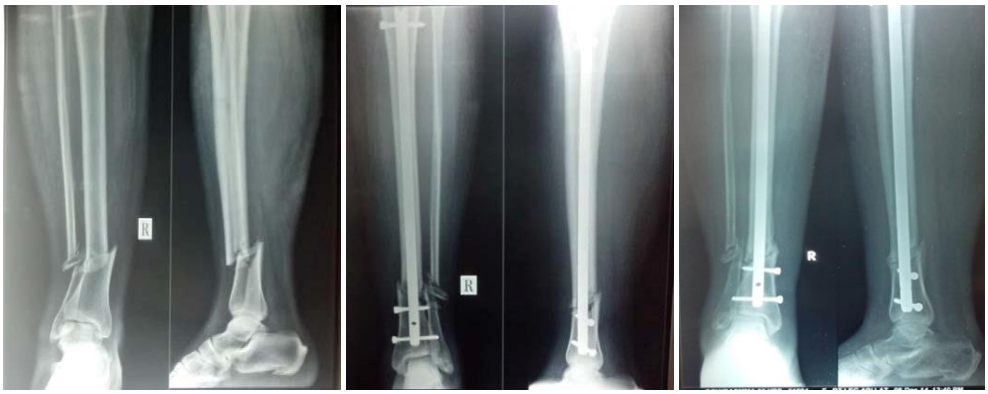
Table 10: Coronal deformity in two groups of patients studied: A Comparative assessment

Coronal Angulation	6 weeks	12 weeks	24 weeks
Nail group (n=10)			
• Valgus (<50)	2(20%)	2(20%)	2(20%)
• Valgus(>50)	2(20%)	2(20%)	2(20%)
• No Deformity	6(60%)	6(60%)	6(60%)
Plate group (n=10)			
• Valgus (<50)	NIL	NIL	NIL
• Valgus (>50)	NIL	NIL	NIL
• No Deformity	10(100%)	10(100%)	10(100%)
P value	0.474	0.474	0.474

Table 11: Post op Infections

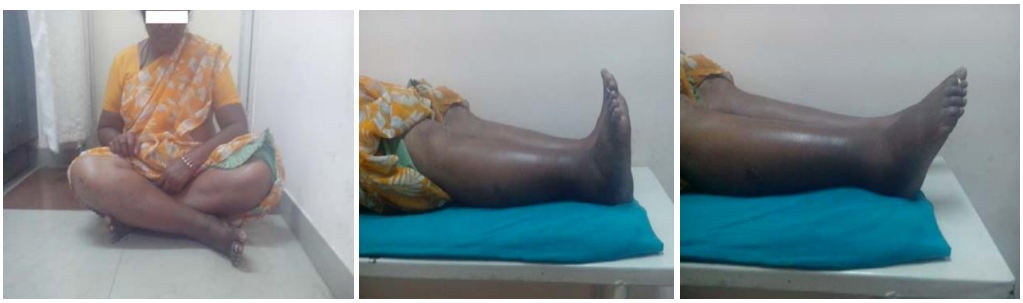
Post op Infections	Nail Group		Plate Group	
	No	%	No	%
No	10	100.0	8	80.0
Yes	0	0.0	2	20.0
Total	10	100.0	10	100.0

Illustration 1: Group 1 (Imil Nail Group) Radiographs



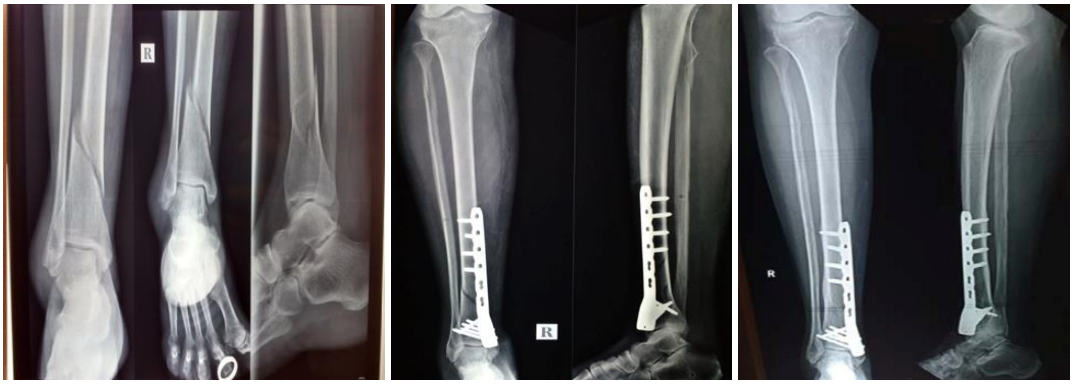
Pre Op Immediate Post Op 28 Weeks Follow Up

Clinical Photos



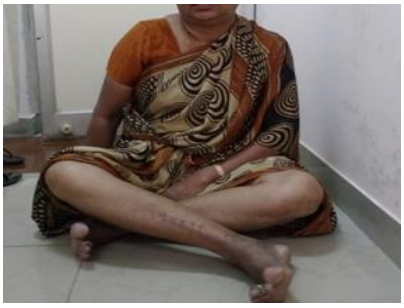
Sitting Cross Legged **Dorsiflexion** **Plantar Flextion**

Lustration 2: Group 2 (Lcp Plate Group) Radiographs



Pre Op **Immediate Post Op** **24 Weeks Follow Up**

Clinical Photos



Sitting Cross Legged

Doriflexion

Plantarflexion

Fractures of distal tibia are among the most difficult fractures to treat effectively. The status of the soft tissue, degree of comminution sustained at the time of injury affects the long term clinical results. The goal of the operative treatment is to obtain anatomical alignment of the joint surface by providing enough stability to allow early movement this should be accomplished using techniques that minimize osseous and soft tissue devascularization in the hopes of decreasing the complications resultingfrom treatment [4, 5, 6]. The present study was undertaken to compare the functional and radiological outcome of plate osteosynthesis versus intramedullary nailing for distal tibia fractures.We evaluated our results and compared them to those obtained by various other studies utilizing similar modalities of treatment. Our analysis as follows:

3.1 Age distribution: Our study revealed the average age of patients with such injuries to be 46 years
(19-68). It is comparable to a study on similar fractures conducted by below authors.

Table 12

Study	Minimum age (years)	Maximum age (years)	Average
TT Guo *et al.* [10]	23	70	42
C Mauffry *et al.* [11]	23	70	46
Present study	19	68	46

3.2 Sex distribution
In our study, the male predominance for such kind of injuries was high compared to other studies due to the fact that male dominance over females in travelling, occupational injuries etc. in India.

Table 13

Study	Male percentage	Female percentage
TT Guo *et al.* [10]	50	35
C Mauffery *et al.* [11]	66	34
Present study	80	20

3.3 Occupation: Majority of our patients are from the rural background and hardworking.

3.4 Mode of injury: Most common mode of injury was Road traffic accident.

3.5 Duration of surgery: It was significantly more in patients who underwent plate osteosynthesis because a minimally invasive plate osteosynthesis need high precision, traction that is not fixed, and repeated c-arm exposures for insertion of screws.

3.6 Knee activity and knee pain
Knee movements never get impaired in plate osteosynthesis and knee pain is unheard of in plate group. These are specific complications of IMIL nailing, if it occurs.

3.7 Range of motion
The difference of ROM at ankle in our study in both the groups was not statistically significant.Active knee and ankle movements were started immediately after surgery on post op day 1. Non weight bearing mobilization was done till 4-6 weeks after surgery. Partial weight bearing was started at 6-8 weeks. As the union progressed total weight-bearing was allowed by 12 weeks depending on radiological union. At around 26-28 weeks radiological consolidation was achieved.

3.8 Duration of time to radiological consolidation
The average time for fracture consolidation in various studies conducted using similar methods was between 16-22 weeks. Our study had average radiological consolidation at 26 weeks.

Table 14

Study	Mean time to union (in weeks)
Ajay Krishnan *et al.* [12]	20
Kasper W *et al.* [13]	19
TT Guo *et al.* [10]	17.6
Present study	26

Patients who underwent plating with LCP for distal tibia fractures had faster union with an average time for union of 26 weeks as compared to 27 weeks in patients who underwent IMIL nailing.
In our study we found there is no statistically significant difference in plating and nailing for distal tibia fractures with respect to range of motion.In our study we found there is no statistically significant difference in plating and nailing for distal tibia fractures with respect to functional and radiological out come when evaluated with IOWA knee and ankle evaluation scoring system

3.9 Complications
In a study conducted by C. Mauffrey *et al.* [11], a randomized pilot trial of “locking plate” fixation versus intramedullary nailing for extra-articular fractures of the distal tibia, three patients (6.8%) in the IM nail group and six (14.6%) in the locking-plate group had wound problems. Compartment syndrome was noted in one patient in each group.
In a study conducted by J. J. Guo [10], wound complications were more common in the LCP Group, 14.6% compared with 6.8% in the IMN group. All were delayed wound healing.In a study by Kasper *et al.* [13], 2 patients (16.7%) of IM nailing group had varus/valgus malalignment of>5°, two (16.7%)

patients had rotational malalignment of >15° after ORIF versus 3 (25%) after IM nailing. Lau *et al.* [14] reported a rate of late infection of 15% in MIPO fixation of a locking plate in distal tibial fractures and 52% of their patients had the implant removed because of skin impingement. In a study by Sayed Abbas *et al.* [15], assessment of the treatment outcome of closed extra-articular distal tibia fracture: IM nailing vs plating, non-union occurred in thirteen patients, 8 patients had non-union in plating group and 5 of 27 patients in IM nailing group. 11 of twenty seven patients in IM nailing group suffered from malunion while only 4 patients in the other group had this complication.

3.10 Infection needing implant removal

Only one case of plate fixation needed implant removal after fracture union at 9 months because of non-healing ulcer. Patient was a 68 year old diabetic man on treatment for 13 years. However minimally invasive, incidence of infection in plate osteosynthesis is expected in plate osteosynthesis than closed intremedullary nailing in distal tibia fractures because of subcutaneous bone, lack of soft tissue, cortical bone and precarious blood supply. Wound healed well after implant removal

In our study, all fractures united. Delayed wound healing was seen in one case in plate group. In nailing group no infection or delayed wound healing were noted. 2 patient had valgus deformity in coronal plane of more than 5 degrees and two patients less than 5 degrees in the IMIL nail group. In plating group no deformities were observed. No other complications like compartment syndrome, non-union or implant failure were seen in our study.

5. Conclusion

According to this study, 20 patients with extra articular fracture of distal tibia have undergone plate osteosynthesis and IMIL nailing (10 in each group). The age of the patients in this study ranged from 19 to 68 years, average being 46 years. Most patients were of a rural background. Most patients (14 out of 20) sustained fracture following road traffic accident (High-energy trauma). Average operating time was 83 minutes for IMIL nailing and 99 minutes for distal tibia plating. Post operatively physiotherapy was started and partial weight bearing was started within 6-8 weeks, full weigh bearing at 12 weeks depending on the radiological union. In plating group no malalignment was seen (varus / valgus/rotational) compared to IMIL nailing group. In plate group two patients had delayed wound healing, No wound healing complication noted in IMIL nail group. In plating group one case needed implant removal after union of the fracture due to infection. Knee pain and knee movement restriction is specific only to nail group. In both groups we achieved early mobilization and functional outcome in both groups are comparable with no statistically significant difference

Radiological assessment showed that bony union (radiological consolidation) occurred in all patients. Rate of union in patients who underwent plate fixation with LCP had lesser average union time (26 weeks) compared to IMIL nailing (27 weeks).In both the groups we achieved good bony union and good functional outcome which was comparable in both the groups with no statistically significant differences.

5.1 Declarations

Funding: None
Conflict of interest: None declared

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