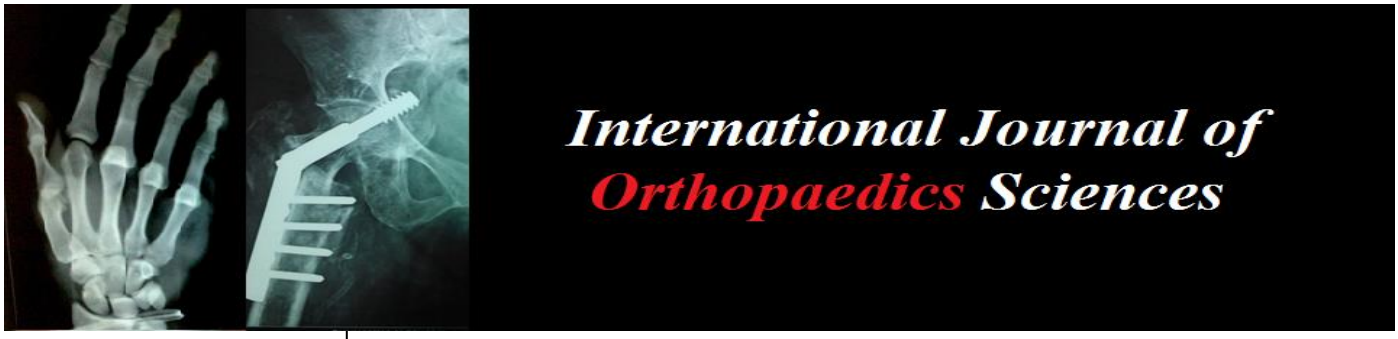

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Dr. K Hari Krishna Reddy
Associate Professor, Department of Orthopaedics, Narayana Medical College and Hospital, Nellore, Andhra Pradesh, India

Dr. Shaik Nawaz Shareef
Postgraduate Resident, Department of Orthopaedics Narayana Medical College and Hospital, Nellore, Andhra Pradesh, India

Corresponding Author:
Dr. K Hari Krishna Reddy
Associate Professor, Department of Orthopaedics, Narayana Medical College and Hospital, Nellore, Andhra Pradesh, India

Randomised prospective comparison of intramedullary nailing V/S plating in distal tibial metaphyseal fractures

Dr. K Hari Krishna Reddy and Dr. Shaik Nawaz Shareef

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Abstract
Background: Tibial fractures are the most common long bone fractures, while distal tibial fractures are even more complicated due to their proximity to the ankle and the close relationship with thin, soft tissue envelope and severe comminution.
Objectives: To assess and compare fractures' functional outcomes in Group A (treated with plating) versus Group B (treated with intramedullary nailing). To assess the efficacy, advantages, and disadvantages of the treatment modalities and their complications.
Materials and Methods: This is a comparative study done from October 2019 to March 2021 in the Department of Orthopaedics, Narayana general hospital, attached to Narayana Medical College, Nellore. In this study period total of 40 patients were taken for study as per inclusion criteria. The patients are randomized into two groups of 20 cases each. Group A treated with plating, and Group B was treated with intramedullary nailing.
Results: In our study, good results were observed in Intramedullary nailing groups (51.43%) when compared with the plating group (40.3%). These differences were statically significant with a p-value (p<0.05). The mean Olerud and Molander functional score at the end of 1 year was higher for the intramedullary interlocking nail group (81.6) as compared to that for the plating group (74.4). The average duration for the radiological union in the intramedullary interlocking nail group was 20.1 ± 1.14 weeks (range 18-22 weeks), and in the plating group, it was 24.1 ± 1.16 weeks (range 22-30 weeks). Thus, the union occurred significantly faster in the nailing group (P-value 0.001). Three patients from the plating group had delayed union. In this study, a significantly better ankle range of motion was noticed in the intramedullary interlocking nail group as compared to that of the distal tibia plating group. Average dorsiflexion at the final follow-up (12 months) was 11.8 degrees and 8.7 degrees in the intramedullary interlocking nail group and the distal tibia plating group, respectively(P value<0.025). The average plantar flexion was 30.6 degrees and 23.7 degrees in the intramedullary interlocking nail group and the distal tibia plating group, respectively (P value< 0.001).
Conclusion: Intramedullary nailing has the advantages of shortened operating time, early weight-bearing (partial and full), decreased wound problems, an early union of the fracture, decreased implant-related problems, and overall reduced morbidity. Intra-medullary interlocking nail is a good and satisfactory method for the treatment of AO 43 a type distal tibia fractures.

Key words: Distal tibial, metaphyseal fractures, intramedullary nailing

1. Introduction
The tibia is a long bone with a triangular cross-section, and it has a subcutaneous anteromedial border. The tibia is bounded by four tight fascial compartments (anterior, posterior, lateral, and deep posterior). Fractures of the distal tibia account for less than 10% of all fractures of the lower extremities. These fractures are more frequently seen in men than women and aged between 35-40 years. Additionally, distal tibial fractures are associated with posterior malleolus fractures. The management of distal tibial fractures remained challenging in orthopaedic traumatology. Under its location and subcutaneous position in the leg, the tibia is exposed to the risk of injury and open fractures. High energy trauma and poor blood supply at the lower one-third shaft of the tibia pose difficulties in bringing out optimal results.
Most of the controversy revolves around the treatment techniques regarding the choice of implants, as the indication for surgery is fairly clear.

Fractures of the tibia traditionally have been managed with closed reduction and casting. Since the late 1950s, in which an adequate reduction was not obtained or maintained by conservative methods, open reduction and internal fixation (ORIF) was tried. During ORIF, excessive tissue dissection and devitalization are seen, which creates problems in wound healing and can lead to infection. Due to this, other less invasive methods were developed to treat fractures of the distal tibia. A briefer period of disability and early return to regular activates, with a shorter time to the union, can be attained by accurate closed intramedullary (IM) nailing compared to patients managed by locking plate.

This study compare the radiographic and clinical results of patients with extra-articular distal one-third tibial shaft fracture, treated with intramedullary interlocking nailing and those treated by distal tibia locking plate and assess the complications in both the treatment modalities [2, 3]

Aims And Objectives

1. To assess and compare the functional outcomes of fractures in Group A (treated with plating) versus Group B (treated with intramedullary nailing).
2. To assess the complications of both procedures

Methodology

Study design: Prospective randomized control trial.

Study subjects: 40 cases will be studied

Inclusion criteria:

1. Age of the patients: 21 to 60 years
2. Closed displaced fracture of the distal tibia
3. Open fractures of the distal tibia (Gustilloanderson grade I&II)

Exclusion criteria

1. Age of the patients <21 and>60 years
2. Pathological fractures
3. Presence of infection at the fracture site.
4. Patient unfit for surgery due to various medical reasons
5. Gustillo Anderson type III
6. Associated fractures of talus, calcaneum
7. Intra-articular fractures
8. An associated proximal tibia fracture
9. Segmental fracture of the tibia
10. The patients who are not willing to give consent to participate in the study

Study setting

Department of Orthopaedics, Narayana general hospital attached to Narayana Medical College, Nellore. Ethical clearance was received before the beginning of the study from the Ethical Clearance Committee.

Study period: 18 months duration (Oct 2019 to March 2021)

Study procedure

A total of 40 patients will be taken for study as per inclusion criteria.

The patients will be divided into two groups 20 cases each.

Group A will be treated with plating and group B will be treated with intramedullary nailing.

The plating group include patients managed by distal tibia medial locking plate by minimally invasive method, and the Nailing group include patients managed with closed reduction and reamed intramedullary nailing.

A detailed questionnaire shall be duly completed for each case.

The questionnaire shall include information on the age, occupation, smoking status, etc. Detailed history, general physical examination, systemic and local examination and tests will be recorded as per the proforma.

Complications include preoperative, intraoperative, immediate& late stage.

All fibula fractures within 7-8 cms of ankle joint are fixed with plating. Postoperatively, the operated limb was immobilized in plaster splint in all the cases for two weeks till soft tissue oedema was settled. Static quadriceps exercises were started within a slab. After 2 weeks plaster splint was removed and patients were instructed strict non-weight-bearing walking with a crutch or walker. At the end of six weeks, radiographs were taken and weight-bearing was initiated only after signs of callus are seen on radiographs.

Patients are followed on 6th week and then every 3 monthly till 1 year. Mal-alignment was described as >5° varus/valgus deformity, >5° ante-/recurvation or >15° rotation. Delayed union was described as radiographic union >24 weeks. Functional outcome was done by Olerud and Molander functional evaluation score (% of normal) [4]

Results

A total of 40 patients are included in this study, 20 patients were operated on with a distal tibia locking plate (Plating group) and 20 operated with Intramedullary interlocking nail (Nailing group).

1. Age distribution

Out of 20 who have undergone plating procedure, the majority were from 41-50 years age i.e. 8 (40%) followed by 7 (35%) from 31-40 years age group. Out of 20 who have undergone Intramedullary nailing procedure, the majority were from 31-40 years age, i.e. 9 (45%) followed by 6(30%) from 41-50 years age group

The mean age of patients from the plating group was 36.42± 12.72 years, while the mean age of patients from IM nailing was 42.56± 11.93 years.

2. Sex distribution: In both the study groups, the majority were males (85% in plating and 90% in Intramedullary nailing)
3. Mode of injury: Commonest cause of injury was road traffic accidents in 15 (75%) and 14(70%) in the plating and Intramedullary nailing group respectively.
4. Concomitant Fibula Fracture was observed in both the intervention groups approximately similar in number. i.e. 90% and 75%.

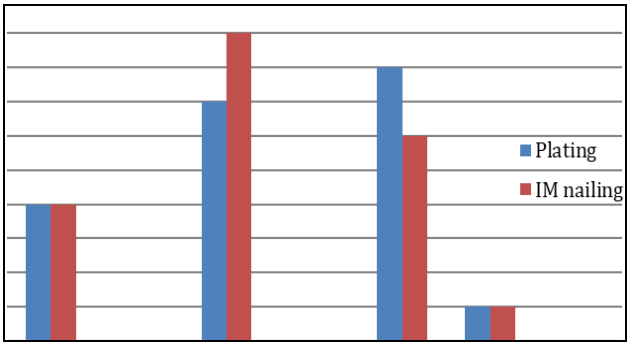
   Both the groups did not vary significantly concerning the age group of patients, mode of injury, sex distribution, type of fracture or associated fibula fracture.
5. In our study in the plating group, 80% of patients had closed fractures, 15% had Gustilo Anderson type I fracture. In the Intramedullary nailing group, 75% of patients had closed fractures, 20% had Gustilo Anderson type I fracture
6. Mean operative time in surgery of patients from Intramedullary nailing was 75.21 ± 9.9 minutes while in patients from the plating group was 90.02 ± 10.5 minutes
7. Mean hospitalization days in patients from Intramedullary nailing was 6.21 ± 2.3 days while in patients from the plating group was 8.66 ± 3.2 days
8. Time to full weight bear: The average duration following which patients could be allowed to bear full weight on the operated leg was 13.7 ± 1.12 weeks (range, 13-18

weeks) in the nailing group and 17.8 ± 0.94 weeks(range 16-21 weeks) in plating group. The patients in the intramedullary interlocking nail group were able to bear weight on the operated limb in a significantly lesser time (P-value <0.005).

9. Time to union: The average duration for the radiological union in the intramedullary interlocking nail group was 20.1 ± 1.14 weeks(range 18-22 weeks) and in the plating group it was 25.1 ± 1.16 weeks (range 22-30 weeks). Thus, the union occurred significantly faster in the nailing group (P-value 0.001). Three patients from the plating group had delayed union.
10. Ankle range of motion: In the present study, a significantly better ankle range of motion was noticed in the intramedullary interlocking nail group as compared to that of the distal tibia plating group. Average dorsiflexion at the final follow-up (12 months) was 11.8 degrees and 8.7 degrees in the intramedullary interlocking nail group and the distal tibia plating group respectively (P value<0.025). The average plantar flexion was 30.6 degrees and 23.7 degrees in the intramedullary interlocking nail group and the distal tibia plating group, respectively (P value< 0.001).
11. Functional outcome assessment: The mean Olerud and Molander functional score at the end of 1 year was higher for the intramedullary interlocking nail group (82.6) as compared to that for the plating group (75.4). Both the groups had good results with a slightly better outcome in the intramedullary interlocking nail group, though not significantly different.
12. Five cases from Intramedullary nailing and 1 case from the plating group had significant valgus (6˚-10˚). Other patients either had no varus/valgus or had acceptable 5˚ varus /valgus
13. Complications: The only postoperative complication seen in this study was an infection at the operative site in 2 patients (10%), all in the plating group. No infection noted in the nailing group.
14. Secondary procedures: In this study, one patient required vacuum-assisted closure of the wound and one patient had fibula plate removal due to persistent wound problems. All two patients belong to the plating group.

Table 1: Age distribution of patients

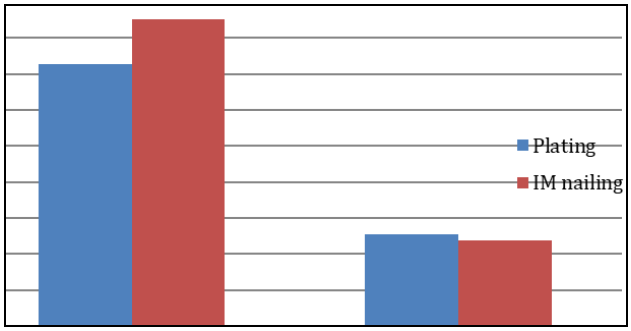
Age group in years	Plating	IM nailing
21-30	4	4
31-40	7	9
41-50	8	6
>50	1	1
Total	20	20



Graph 1: Bar diagram showing Distribution according to age group

Table 2: Distribution according to the comparison of mean age between two groups

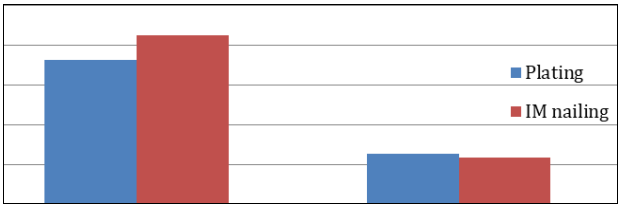
Comparison of mean age	Mean	SD
Plating	36.42	12.72
IM nailing	42.56	11.93



Graph 2: Bar diagram showing Distribution according to the comparison of the mean age between two groups

Table 3: Distribution according to gender

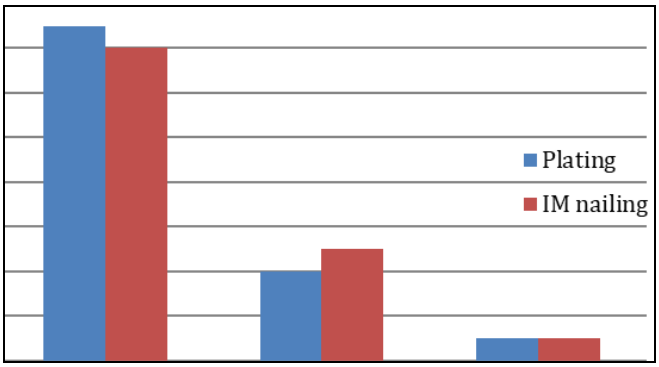
Gender	Plating	IM nailing
Female	3	2
Male	17	18
Total	20	20



Graph 3: Bar diagram showing Distribution according to gender

Table 4: Distribution according to the mode of injury

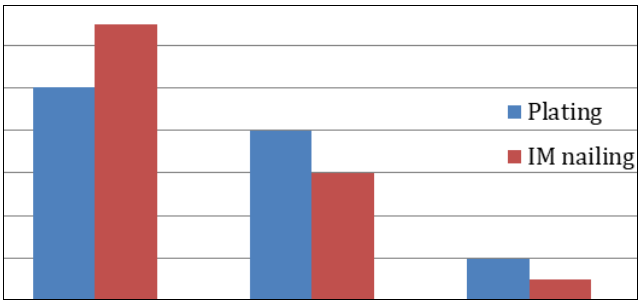
Type of injury	Plating	IM nailing
RTA	15	14
Fall	4	5
Assault	1	1
Total	20	20



Graph 4: Bar diagram showing Distribution according to the mode of injury

Table 5: Distribution according to the type of fracture

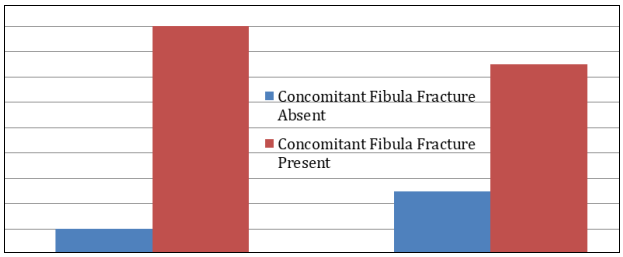
Type of Fracture	Plating	IM nailing
43 A1	10	13
43 A2	8	6
43 A3	2	1
Total	20	20



Graph 5: Bar diagram showing Distribution according to the type of fracture

Table 6: Distribution according to Concomitant Fibula Fracture

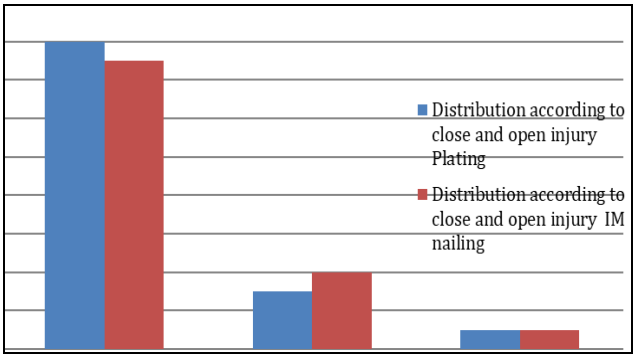
Concomitant Fibula Fracture	Plating	IM nailing
Absent	2	5
Present	18	15
Total	20	20



Graph 6: Bar diagram showing Distribution according to Concomitant Fibula Fracture

Table 7: Distribution according to a close and open injury

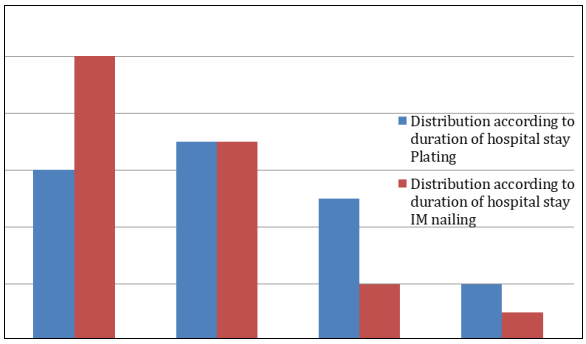
Fracture Type	Plating	IM nailing
Closed	16	15
Gustilo Anderson type I	3	4
Gustilo Anderson type II	1	1
Total	20	20



Graph 7: Bar diagram showing Distribution according to a close and open injury

Table 8: Distribution according to the duration of hospital stay

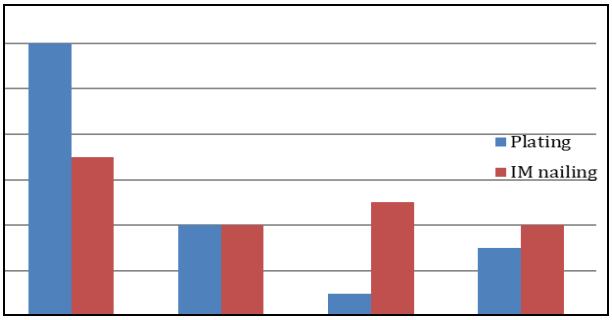
Duration (in days)	Plating	IM nailing
4 to 7	6	10
8 to 9	7	7
10 to 11	5	2
> 11	2	1
	20	20



Graph 8: Bar diagram showing Distribution according to the duration of hospital stay

Table 9: Distribution according to valgus/varus deformity

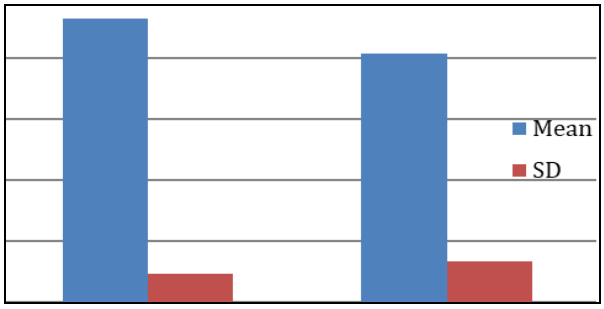
	Plating	IM nailing
None	12	7
0 to 5 Valgus	4	4
> 5 Valgus	1	5
0-5 Varus	3	4



Graph 9: Bar diagram showing Distribution according to valgus/varus deformity

Table 10: Distribution according to a comparison of mean weeks for bone union between two groups

	Mean	SD
Plating	23.21	2.26
IM nailing	20.33	3.27



Graph 10: Bar diagram showing Distribution according to a comparison of mean weeks for bone union between two groups

Table 11: Outcome of patients in both groups Dorsiflexion Plantar flexion Functional evaluation

Ankle range of motion	Nailing Group(degrees)	Plating Group(degrees)
Dorsiflexion	11.8	8.7
Plantar flexion	30.6	23.7

Table 12: Olerud and Molander functional evaluation score
CASE: Distal one-third tibial fracture treated by intramedullary interlocking nail

Functional evaluation	Nailing Group	Plating Group
Excellent (91-100)	6	4
Good (61-90)	12	11
Fair (31-60)	2	5
Poor (0-30)	0	0

Preoperative


Immediate Post-op ray


After union at 17 weeks

CASE: Distal one-third tibial fracture treated by plating


Preoperative

Immediate Post-op x-ray


After union at 20 weeks

Discussion

Distal tibia fractures are the most common significant lower extremity injuries. A high percentage of good results were obtained with accurate open reduction or closed reduction techniques with stable internal fixation by using AO principles and methods for fixation of distal tibia fractures.

Since soft tissue and periosteum are commonly damaged in distal tibial fractures, large incisions could further increase this damage. Though plate fixation achieves rigid fixation and has been widely used in past years, the technique requires extensive wound exposure and soft tissue dissection, which limits its clinical application. With the advantage of minimally invasive, symmetric and dynamic fracture fixation, intramedullary nailing is a better choice for the management of distal tibial fractures. The fact that extraosseous soft tissue could not provide sufficient blood supply, is one of the major factors which supposed to cause delayed union or non-union in the fractured bones. In addition, the lack of arterial supply to the distal tibia contributes to the explanation for the more common incidence of delayed union or non-union in tibia fracture. Intramedullary nailing treatment could benefit the distal tibial fracture for it preserves the integrity of the surrounding soft tissue and vascular supply, and thus promotes biological bone healing. For this account, in the management of distal tibial fractures, intramedullary nailing might possess the advantages of saving operative time, decreased blood loss as well as reducing the incidence of infections. For instance, compared to the fixation with a cast, closed intramedullary nailing was associated with a shorter operative time. Meanwhile, static reamed Intramedullary nailing is reported to faster the radiographic union and shorter the time from trauma to surgery than minimally invasive plate

osteosynthesis (MIPO)Despite these desirable results of Intramedullary nailing in the above assessment indexes, Intramedullary nailing could also cause some unsatisfactory effects because Intramedullary nailing allows micro-motion, which induces callus formation. Biomechanically, even reamed intramedullary nailing could not match well to the lenient medullary canal of the tibia metaphysic, and the lack of adequate purchase of locking screws is apt to fail to gain or maintain the tibial alignment. This may contribute to the higher incidence of malunion with Intramedullary nailing than with plate. In the management of distal tibial metaphyseal fracture, intramedullary nailing is linked to many complications such as mal reduction and malunion. Moreover, intramedullary nailing is convinced to have a remarkable higher incidence of malunion than the percutaneous locked plate. Consistent with these results, our analysis showed that intramedullary nailing achieved a significantly higher incidence of malunion than the plate.

Age distribution

The mean age of patients from Intramedullary nailing was36.42± 12.72 years while the mean age of patients from the plating group was 42.56± 11.93years. The difference in mean age was found to be not significant ($p>0.05$)

Table 13: Comparision of different studies according to age-wise distribution

Author	Plating	IM nailing
Mayank Mahendra *et al.* [5]	41.90±15.27	41.04±14.07
Baral R *et al.* [6]	46.11±16. 116	37.38±12.18
Present study	36.42± 12.72	42.56± 11.93

Distribution according to the mode of injury

The commonest cause of injury was a road traffic accident in 15 (75%) and 14(70%) in the plating and Intramedullary nailing group respectively. The difference in the cause of injury was not significant ($p>0.05$).

Table 14: Comparision of different studies according to a mode of injury, RTA being the most common

Author	RTA
Pawar E D *et al.* [7]	60%
Holagundi L *et al.* [8]	73%
Mayank Mahendra *et al.* [5]	67%
Present study	73%

Mean surgery time

Mean operative time in surgery of patients from intramedullary nailing was 76.21 ± 9.9 minutes while in patients from the plating group was 91.02 ± 10.5 minutes. The difference in the meantime duration between both groups was found to be significant ($p<0.05$)

Table 15: Comparision of different studies according to the duration of surgery

Author	IL group	Plating group
Li Y *et al.* [9]	60 minutes	70 minutes
Guo *et al.* [10]	81.2 minutes	97.9 minutes
Mayank Mahendra *et al.* [5]	79.00±5.59 minutes	94.50±10.11 minutes
Present study	76.21 ± 9.9 minutes	91.02 ± 10.5 minutes

Mean duration hospitalization

Mean hospitalization days in patients from intramedullary nailing was 7.21 ± 2.3 days while in patients from the plating group was 9.66 ± 3.2 days. The difference in mean time duration was found to be significant ($p<0.05$)

Table 16: Comparision of different studies according to mean hospitalization stay

Author	Plating group	IL group
Mayank Mahendra *et al.* [5]	9.86 ± 3.2 days	7.01 ± 2.3 days
Li Y *et al.* [9]	8.9 +/- 3.1days.	5.8 +/- 2.1 days
Present study	9.66 ± 3.2 days	7.21 ± 2.3 days

Duration of full weight-bearing

Full Weight-bearing initiation after surgery of patients from intramedullary nailing was 13.7 ± 1.12weeks while in patients from the plating group was 17.8 ± 0.94weeks. The difference in mean time duration was found to be significant ($p<0.05$). It means intramedullary group patients started early weight-bearing compared with plating method patients.

Table 17: Comparision of different studies according to full weight-bearing after surgery

Author	Interlocking(weeks)	Plating (weeks)
Present study	13.7 ± 1.12	17.8 ± 0.94
Mayank Mahendra *et al.* [5]	14.13 ± 2.22	17.2 ± 2.1
DV Prasad *et al.* [11]	10.09 ± 1.41	13.38 ± 1.24

Duration of bone union

In our study, we observed that mean weeks for the bone union after surgery of patients from intramedullary nailing was 20.11 ± 1.14 weeks while in patients from the plating group was 24.1±1.16 weeks. The difference in mean time duration was found to be significant ($p<0.05$)

Table 18: Comparision of different studies as per time taken for radiological union

Author	Interlocking(weeks)	Plating (weeks)
Mayank Mahendra *et al* [5]	20.33 ± 3.27 weeks	23.21±2.26 weeks
Li Y *et al.* [9]	21.3+/- 3.5	23.1+/- 3.6
Vaza J V *et al.* [12]	23.45 weeks	26 weeks
Pawar E D *et al* [7]	17.43 weeks	21.40 weeks
Mihir R Solanki *et al.* [13]	19.1 weeks	23.8 weeks
Kasper W *et al.* [14]	19 weeks	21 weeks
Present study	20.1 ± 1.14 weeks	24.1 ± 1.16 weeks

Range of movements

Significantly, lower mean range of dorsiflexion and plantar flexion observed in the plating group could be attributed to stripping of the muscles and tendons during an open reduction in those patients in which reduction was difficult by closed means while plating

Table 19: Comparision of different studies according to a range of movements

Author	Average dorsiflexion (In degrees)		Average plantar flexion (In degrees)	
	Interlocking	Plating	Interlocking	Plating
Mihir R Solanki *et al.* [13]	12.6	9.6	32.4	25.0
Present study	12.8	9.7	31.6	24.7

Olerud and Molander scoring system.

In our study, excellent results were more common in Intramedullary nailing groups (86%), compared to the plating group (71%). These differences were statically significant p-value <0.05.

Table 20: Comparision of different studies according to Olerud and Molander scoring system

Author	nailing group	plating group
Mihir R Solanki *et al.* [13]	88%	72%
GI *et al.* [15]	88.5%	88.2%
Present study	86%	71%

Postoperative complications

Postoperative complications like wound infection (10%), delayed union (20%) and deep infection as well as wound dehiscence(10%) were more in the plating group than in the Interlocking group. Mal-alignment (25%) and anterior knee pain (20%) was more common in the Interlocking group. (P>0.05)

Table 21: Comparision of different studies according to complications

Author	Total number of complications
Krishan A *et al.* [16]	2
Egol KA *et al.* [17]	2
Present study	2

Conclusion

1. Intramedullary nailing has the advantage of shortened operating time, early weight-bearing (both partial and full), decreased wound-related problems, an early union of the fracture, decreased implant-related problems and overall reduced morbidity
2. In osteosynthesis of displaced extra-articular distal tibia metaphyseal fractures OTA/AO Type 43-A both modalities nailing as well as plating deserve a place. However, in the present study IL nailing showed better outcomes as it offers an advantage in terms of mean operating time, less invasive surgery, hospital stay, partial & full weight-bearing time and union time.

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