

ORIGINAL RESEARCH**A Comparative Study on Functional and Radiological Outcome of Distal Tibial Fractures Managed with Intramedullary Interlocking Nail and Locking Compression Plate****Avinash Kumar¹, Gnanesh V.², Prasad M. S³**

¹Assistant Professor, Department of Orthopaedics, Kanachur Medical College, Mangalore, Karnataka, India.

²Senior Resident, Department of Orthopedics, Srinivasa Medical College, Surathkal, Mangalore, Karnataka, India.

³Final Year DNB Resident, Department of Orthopaedics, People Tree Hospitals, Yashawanthapur, Bengaluru, Karnataka, India.

ABSTRACT

Background: Intramedullary interlocking nailing (IMIL) allows minimally invasive, symmetric, and dynamic fracture fixation by following the principles of biological fracture fixation. This technique is also used widely for distal tibial shaft fractures, with good results⁶. Presently, there is no clear consensus on optimal method of managing these fractures. Various surgical modalities used for these fractures include closed intramedullary nailing, plating by open or closed methods, and various types of external fixators. **AIM:** To compare the functional and radiological outcome of surgical modalities for distal tibia fracture, i.e. Minimally Invasive Percutaneous Plate Osteosynthesis (MIPPO) vs. Intra medullary Interlocking nail (IMIL) with respect to following parameters: Time to full weight bearing, Time to radiological union, Functional outcome and Complications.

Materials and Methods: Study Design: Prospective interventional study. Study area: The study was done in Department of Orthopaedics, KVG Medical College, Sullia, Dakshina Kannada, Karnataka, India. Study Period: October 2017 to September 2020. Study population: Adult patients with fractures of lower third tibia admitted in department of Orthopaedics KVG Medical College, Sullia, Dakshina Kannada, Karnataka, India. Sample size: 52. Sampling method: By universal sampling method. All patients with distal tibia fractures who satisfy the inclusion criteria have been included in the study. Patients will be allocated randomly into two groups using computer generated random numbers i.e., IMIL group and MIPPO group each with 26 patients. **Statistical Analysis:** The data were analysed using statistical software MS (Microsoft) Excel and SPSS (statistical package for social science) version 20. Data was presented as percentages or mean \pm SD (standard deviation) as deemed appropriate for qualitative and quantitative variables, respectively. The chi-square test and Mann Whitney U test were applied to evaluate the statistical significance between the two groups. A P-value of < 0.05 was considered as statistically significant. All P-values reported are two-tailed.

Results: A total of 52 patients with extra articular distal tibial fractures were taken in our study and divided into two groups based on their mode of treatment. The most common mode of injury was found to be Road Traffic Accident (RTA), seen in 59.61% of the patients, followed by sports injury 25% (e.g., football), falls 09.6%, and direct blow 05.7%.

Conclusion: In this study average time taken for surgery and fracture union in patients treated by nailing is significantly lower when compared to the ones treated by plating.

Time taken for full weight bearing and mobilization was significantly lower in nailing group than plating group.

Keywords: Intramedullary interlocking nailing, Minimally Invasive Percutaneous Plate Osteosynthesis.

Corresponding Author: Dr Gnanesh V, Senior resident, Department of Orthopedics, Srinivasa Medical College, Surathkal, Mangalore, Karnataka, India. E-mail Id: vg.gnanesh@gmail.com

INTRODUCTION

High speed motor vehicle accidents are on the rise over past few years. These are responsible for most of the fractures of tibia. As tibial fractures are commonly associated with soft tissue injury, if not treated properly, these can cause substantial disability to the patient. High energy motor vehicle trauma constitutes the commonest cause followed by falls, direct blow, and sports injury.^[1,2] The incidence of distal tibia fractures in most series is 0.6%, and it constitutes to about 10%–13% of all tibial fractures.^[1,2]

Because of its subcutaneous location, poor blood supply and decreased muscular cover anteriorly, complications such as delayed union, non-union, wound infection, and wound dehiscence are often seen as a great challenge to the surgeon. The goals of managing distal tibial fracture are to obtain a healed, well-aligned fracture; pain free weight bearing; and functional range of motion in ankle joint. Non-operative treatment of closed comminuted fractures with cast usually leads to problems like prolonged immobilization, malunion, shortening and joint stiffness.^[3-5]

Open reduction and internal fixation with conventional plate frequently leads to complications like non-union, delayed union, infection and implant failure. The most important factor in the treatment of these fractures is the management of overlying soft tissues. So, while using the technique of internal fixation, emphasis must be put on the vascular support of bone and soft tissue by doing minimum exposure, indirect reduction and in particular least possible damage to the periosteum.

Therefore, the concept of management of these fractures has been changed from absolute fixation to relative fixation by biological osteosynthesis with preservation of osseous and soft tissue vascularity. Biological plating provides relative stability and preserves vascularity around the fractures. The principle of this minimally invasive technique includes indirect closed reduction, extra periosteal dissection and relative stability which allows limited controlled motion at the fracture site with secondary bone healing and callus formation.^[3-5]

Intramedullary interlocking nailing (IMIL) allows minimally invasive, symmetric, and dynamic fracture fixation by following the principles of biological fracture fixation. This technique is also used widely for distal tibial shaft fractures, with good results.^[6] Presently, there is no clear consensus on optimal method of managing these fractures. Various surgical modalities used for these fractures include closed intramedullary nailing, plating by open or closed methods, and various types of external fixators. Despite all the advances that have been made in the available treatment options, fractures of the distal tibia still pose a challenge to the Orthopaedic surgeons.

The present was undertaken to compare the two primary modalities of treatment for these fractures: namely, distal tibial locking compression plate by Minimally Invasive Percutaneous Plate Osteosynthesis (MIPPO) and closed intra-medullary interlocking nailing (IMIL), and to know the efficacy of these techniques in the management of closed fractures of distal tibia.

AIM:

To compare the functional and radiological outcome of surgical modalities for distal tibia fracture, i.e. Minimally Invasive Percutaneous Plate Osteosynthesis (MIPPO) vs. Intra medullary Interlocking nail (IMIL) with respect to following parameters: Time to full weight bearing, Time to radiological union, Functional outcome and Complications.

MATERIALS & METHODS

Study Design: Prospective interventional study

Study area: The study was done in Department of Orthopaedics, KVG Medical College, Sullia, Dakshina Kannada, Karnataka, India.

Study Period: October 2017 to September 2020

Study population: Adult patients with fractures of lower third tibia admitted in department of Orthopaedics, KVG Medical College, Sullia, Dakshina Kannada, Karnataka, India.

Sample size: 52

The proportion of cases attending the hospital with distal tibia fracture was found to be 6.7 in a pilot study. Using this as a proportion (p) & q= 100-p, with an allowable error of 7% the minimum sample size was calculated using the formula.

$$n=4pq/e^2$$

n= sample size, p= proportion distal end tibia fracture in pilot study,

q=100-p e=allowable error

Substituting the values in the formula,

$$\text{Study size (n)} = 4 \times 6.7 \times 93.3 / 7^2$$

$$\text{Study size (n)} = 51.029$$

Study size (n) = 51~52

Total - minimum 52 study participants.

Minimum 26 study participants in each group.

Sampling method:

By universal sampling method. All patients with distal tibia fractures who satisfy the inclusion criteria have been included in the study. Patients will be allocated randomly into two groups using computer generated random numbers i.e., IMIL group and MIPPO group each with 26 patients.

Inclusion criteria

- Extra Articular distal tibial fractures AO Type 43A1, 43A2, 43A3
- Age more than 18 years
- Duration of injury within 15 days
- Intact neurological and vascular status of the affected limb
- Patients who met the medical standards for routine elective surgery.

Exclusion criteria:

- Patient with open fractures
- Intraarticular extension of fracture
- Pathological fractures
- Patients not willing to undergo surgery
- Patients medically unfit for surgery
- Patients with earlier fractures of distal metaphyseal tibia on the same side

Ethical consideration: Institutional Ethical committee permission was taken prior to the commencement of the study.

Study tools and Data collection procedure:

Protocol for Collection of data of patients presenting with closed distal tibia fractures are follows.

- History
- Clinical examination both local and systemic.
- Radiological examination – Radiographs of Leg AP and Lateral, CT/MRI(if necessary)
- Investigations–which are necessary for anaesthetic fitness.
- Fracture anatomy assessed with radiographs. And classified according AO classification

Surgery Procedure - IMIL Group patients will undergo Multidirectional IMIL nailing.

MIPPO group patient will undergo LCP plating by MIPPO technique.

Evaluation of the Results

- Time taken for full weight bearing
- Time taken for radiological union of fracture
- Functional outcome assessment
- Complications

Teeny and WISS Clinical Assessment Score for Functional Evaluation of Ankle

Parameters	Score
1. Pain	
a) No pain, including long walks, running or sports	50
b) Slight or occasional pain, pain after long walk or sports, or mild pain at end of day	45
c) Mild pain with walking or running, but no change in activities of daily living. May have some pain going up or down stairs or walking on uneven ground. May require non-narcotic pain medicine several times a week.	40
d) Mild-moderate pain, tolerable, but requires some concessions to pain. May required daily non- narcotic pain medicine? No night pain	30
e) Moderate pain. Definite change in activities of daily living, pain at rest or at night, despite restriction of activities. Occasional weak narcotic needed.	20
f) Continuous pain, regardless of activities, most often not relieved with non-narcotic medication. Dependent on narcotic pain medicine for significant pain relief. Severe limitations of activities.	10
g) Disabled because of pain. Constant pain, no relief with medicines.	0
2. Distance	
a) Unlimited	8
b) Limited, but greater than 6 blocks	6
c) 4-6 blocks	4
d) 1-3 blocks	2
e) Indoors only	1
f) Bed-chair, or unable to walk	0
3. Supports or Orthosis	
a) None	8
b) Soft wrap needed for long walk	7
c) Cane or orthosis, only for long walks	6
d) Cane, single crutch or orthosis full time	4
e) Two canes or two crutches	2

f) Walker or unable to walk	0
4. Running	
a) Unlimited, as such as desired	5
b) Limited, but able to run	3
c) Unable to run	0
5. Toe raising	
a) Able to raise on toes x 10 repetitions	5
b) Able to raise on toes x 5 repetitions	3
c) Able to raise on toes x 1 repetitions	1
d) Unable to raise on toes	0
6. Hills (up or down)	
a) Up and down normally	3
b) Climbs and /or descends with foot externally rotated	2
c) Climbs and/or descends on toes or by side stepping	1
d) Unable to climb and/or descend hills	0
7. Stairs (up or down)	
a) Climbs and descends normally	3
b) Needs banister	2
c) Steps down and/or up with normal foot only	1
8. Limp	
a) None	8
b) Only when fatigued	6
c) Slight, constant	4
d) Moderate, constant	2
e) Marked	0
9. Swelling	
a) None	3
b) Only in the evening or after walking	2
c) Constant, mild (less than 1 cm difference around calf)	1
d) Marked	0
10. Plantar range of motion	
a) Greater than 30°	2
b) Greater than 10°	1
c) Less than 10°, or presence of equine s contracture	0
11. Dorsal range of motion	
a) Greater than or equal to 15°	5
b) Greater than or equal to 10°, less than 15°	4
c) Greater than or equal to 0°, less than 10°	3

Clinical Grading	Total score
Excellent	>92 points
Good	87-92 points
Fair	65-86 points
Poor	<65 points

Statistical Analysis

The data were analysed using statistical software MS (Microsoft) Excel and SPSS (statistical package for social science) version 20. Data was presented as percentages or mean _ SD

(standard deviation) as deemed appropriate for qualitative and quantitative variables, respectively. The chi-square test and Mann Whitney U test were applied to evaluate the statistical significance between the two groups. A P-value of < 0.05 was considered as statistically significant. All P-values reported are two-tailed.

RESULTS

A total of 52 patients with extra articular distal tibial fractures were taken in our study and divided into two groups based on their mode of treatment.

IMIL group-26 patients were treated with multi directional intramedullary interlocking nail.

MIPPO group- 26 patients were treated with Minimally Invasive Percutaneous Locking Compression Plate Osteosynthesis (MIPPO).

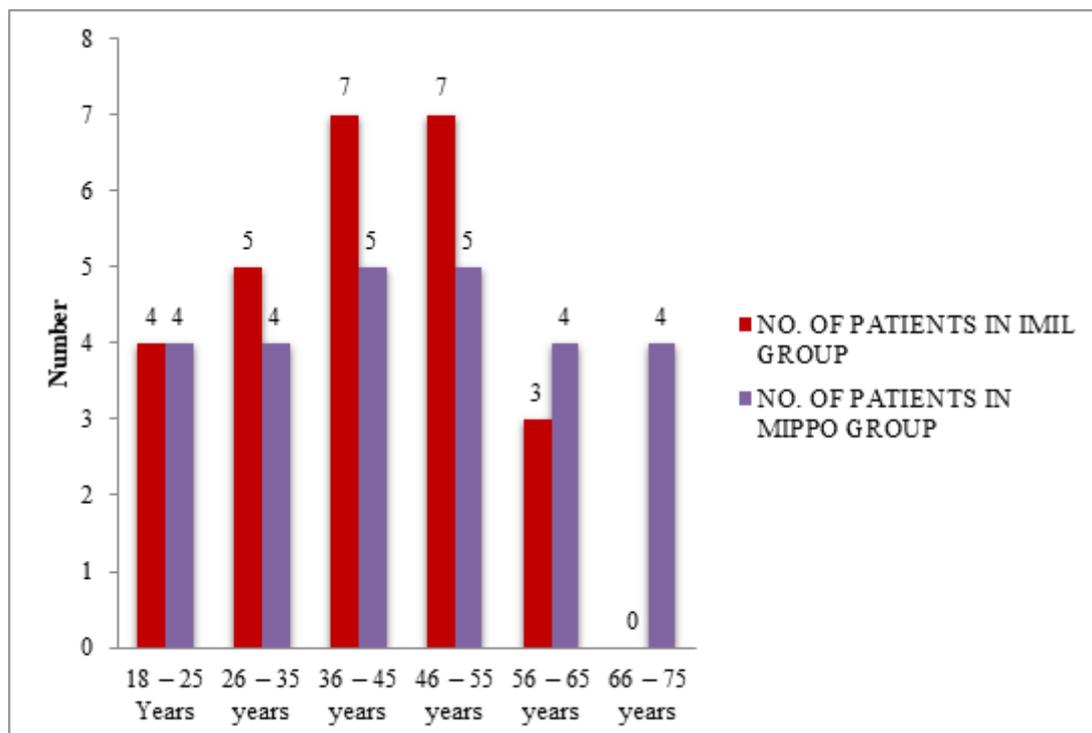


Figure 1: Age Distribution of Patients in the Study Population

Table 1: Gender Distribution in the Study Population

S. No.	Gender	no of Patients in IMIL Group	Percentage	No. Of patients in MIPPO group	Percentage
1	MALE	21	80.76 %	17	65.38 %
2	FEMALE	5	19.23 %	9	34.61 %

IMIL group consisted of 4 patients in the age group of 18-25 years, i.e 15.38%, 5 from the age group of 26-35 years (19.23%), 7 from the age group of 36-45 years (26.92%), 7 from the age group 46-55 years (26.92%), 3 belonging to the age group of 56-65 years (11.53%) and none of the age >66 years. MIPPO consisted of 4 patients in the age group of 18-25 years, i.e 15.38%, 4 from the age group of 26-35 years (15.38%), 5 from the age group of 36-45years (19.23%), 5 in the age group of 46-55 years (19.23%), 4 belonging to the age group of 56-65 years (15.38%) and 4 belonging to the age group of 66-75 years, i.e 15.38%.

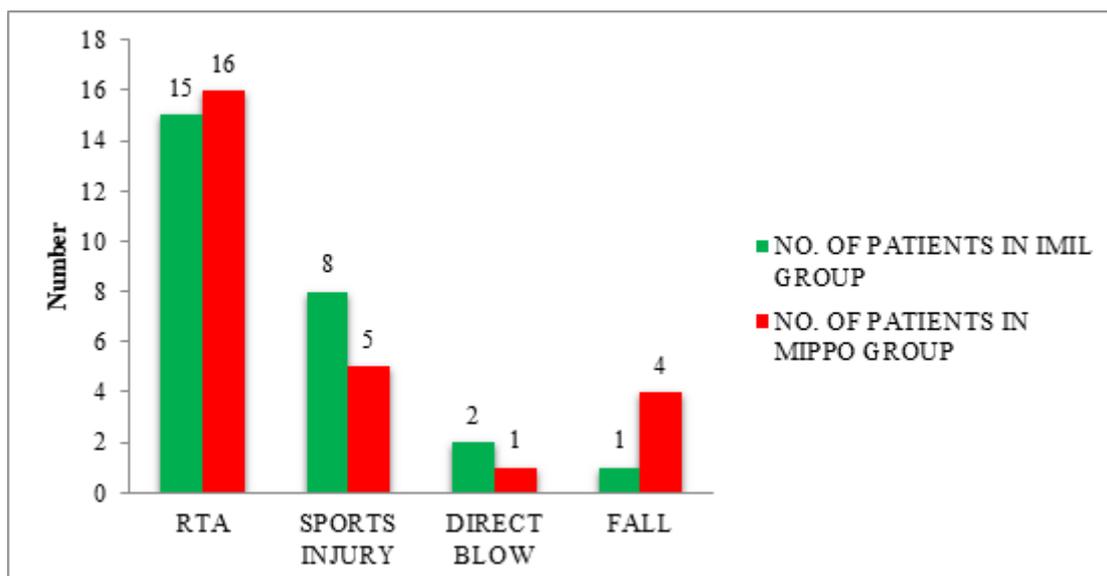


Figure 2: Mode of Injury in Both the Groups

The most common mode of injury was found to be Road Traffic Accident (RTA), seen in 59.61% of the patients, followed by sports injury 25% (e.g., football), falls 9.6%, and direct blow 05.7%.

Table 2: Type of Fracture Operated

S. NO.	Type Of Fracture	NO. OF Patients in IMIL Group	Percentage	NO. OF Patients in MIPPO Group	Percentage
1	DISTAL 1/3RD OF TIBIA -43 A1	10	38.46 %	9	34.61 %
2	DISTAL 1/3RD OF TIBIA -43 A2	2	7.69 %	8	30.76 %
3	DISTAL 1/3RD OF TIBIA -43 A3	5	19.23 %	2	7.69 %
4	DISTAL 1/3RD OF TIBIA + LATERAL MALLEOLI – 43 A1	3	11.53 %	1	3.84 %
5	DISTAL 1/3RD OF TIBIA + LATERAL MALLEOLI – 43 A2	5	19.23 %	2	7.69 %
6	DISTAL 1/3RD OF TIBIA + LATERAL MALLEOLI – 43 A3	1	3.84 %	4	15.38 %

Fracture type was based on AO classification- 19 cases belonged to 43-A1(10 in IMIL group and 9 in MIPPO group), 10 cases belonged to 43-A2 (2 in IMIL group and 8 in MIPPO group), 7 cases were classified under 43-A3 (5 in IMIL group and only 2 cases in MIPPO group). Based on additional fibular distal third fracture, 4 cases were classified under 43-A1(3 in IMIL group and 1 in MIPPO group), 7 cases as 43-A2 (5 in IMIL group and 2 in MIPPO group), 5 cases as 43-A3 (1 in IMIL group and 4 cases in MIPPO group).

Table 3: Time for full Weight Bearing in Both the Groups

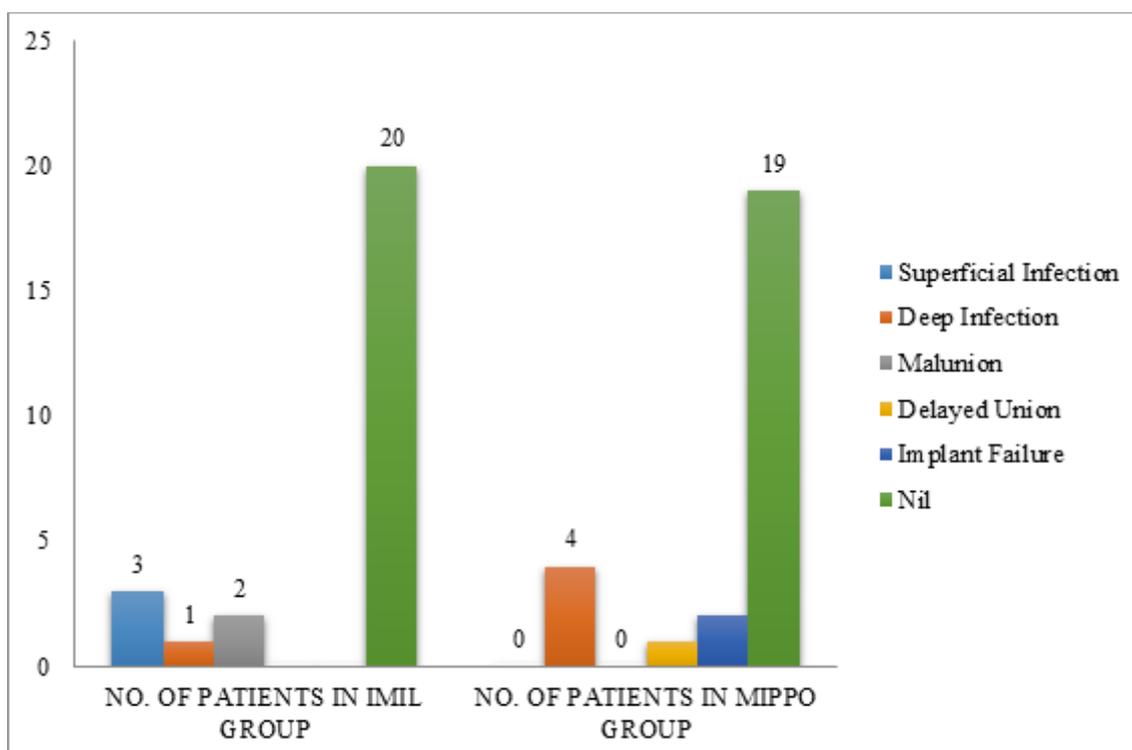
Groups	No of patients	Mean in percentage	P value
IMIL group	25	11.48	.001 HS
MIPPO group	24	12.96	
Total	49	12.20	

Time taken to start full weight bearing in patients treated with multidirectional locked nailing i.e, IMIL group is 11.48 weeks and in MIPPO group is 12.96 weeks. With 3 patients having delayed weight bearing, as they had complications.

Table 4: Difference in Functional Outcome Between the two Groups

SNO.	Groups	Mean score	U value	Z score	P value
1	IMIL GROUP	84.84 ± 9.66	320.5	0.31112	0.75656
2	MIPPO GROUP	84.26 ± 11.79			

The functional results, as assessed by Teeny And Weiss Criteria (Functional Evaluation Of Ankle), showed that majority (59.61%) of the patients in the study had good functional results (IMILN: 65.38%; MIPPO: 53.84%) and 36.53% had excellent results (IMILN: 30.76%;MIPPO: 42.30%). The difference in functional outcome showed mean score of 84.84 ± 9.66 in IMIL group where as in MIPPO group it is 84.26 ± 11.79. Using Chi-square test, these differences were not found to be statistically significant (P = 0.75656).

**Figure 3: Complications Noted in Both the Groups**

DISCUSSION

Extra articular distal tibia fractures management is still controversial, surgeon main aim is to get decent reduction with minimum postoperative complications. To get these results minimal invasive plating and multidirectional locked intramedullary nailing are the two viable options. When compared to minimal invasive plating multidirectional locked nailing technique has

exhibited many advantages in terms of time taken for surgery, union time, complications like wound infection, early weight bearing capacity and range of motion at ankle joint. In our study maximum number of patients who undergone for nailing or plating return back to full weight bearing capacity and good functional outcome.

In our study, the patients were in the range of 18–75 years, with mean age being 41.42 ± 12.87 years in IMIL group and 45.34 ± 16.34 years in MIPPO group. Of the 52 patients, 38 were males and 14 were females. Predominant male involvement in our study was probably due to more outdoor activities and heavier labour undertaken by males as compared to females in this part of hilly area. The result were comparable to that of Kumar et al, Ram et al., Li et al and Vallier et al.^[7-10]

In our study, most common cause for these fractures was RTA followed by fall and sports injury, especially football. Our results were comparable to other studies by Kumar et al, Ram et al., Pawar et al.^[7,8,11] which also showed that RTA is the most common mode of injury as modernization and industrialization have intruded our lives.

A meta-analysis study of 354 patients managed with intramedullary nailing versus plating were analysed which shows, six studies containing 177 patients in both groups stated the operative time, and the significant heterogeneity among studies. The meta-analysis showed less operative time in the IMN group compared with plate group (MD=-13.37, 95%CI -19.34 to -7.40, $P < 0.0001$; [Figure 3]).^[12]

Guo JJ¹³ and others have done a study in 85 patients with distal metaphyseal tibia fractures treated with either plating or nailing and they had significant difference in time taken for surgery in patients treated with MIPO than nailing (97.9 vs 81.2 minutes).

Yong Li,^[14] and others have done a study in 46 patients with distal tibia metaphyseal fractures and they found average operating time 90 ± 20.3 (plating) vs 76 ± 16.6 (nailing) minutes, which is significantly high in patients treated with MIPO than multidirectional locked nailing.

Our study results can be compare with above study, where the average operating time in the intramedullary nailing group is around 81.14 ± 6.30 min, while in case of locking plate by MIPPO is Around 87.67 ± 5.55 min suggests there is significant difference in both groups. This was also comparable to studies done by Guo et al., Li et al, Pawar et al.^[11,13,14]

A meta-analysis study of 354 patients managed with intramedullary nailing versus plating were analysed which shows Six of the 8 studies, reported postoperative union time with using the different units of time; therefore, the standard mean difference (SMD) was used.⁵⁹ Of the 354 patients, 177 were treated with intramedullary nailing and the other 177 were treated with distal tibial plate. Random-effect analysis, with an I² of 67%, showed the difference between two groups did not differ significantly

(SMD=-0.20, 95%CI -0.58 to 0.18, $P=0.3$) [Figure 5].¹³

Yong Li,^[14] and others have done a study in 46 patients with distal tibia metaphyseal fractures and they found average operating time, full weight bearing and fracture union time is significantly high in patients treated with MIPO than multidirectional locked nailing(90 ± 20.3 vs 76 ± 16.6 minutes; 11.1 ± 1.7 vs 9.0 ± 1.4 weeks; 23.1 ± 3.6 vs 21.3 ± 3.5 weeks respectively).

Guo JJ,^[13] and others have done a study in 85 patients with distal metaphyseal tibia fractures treated with either plating or nailing and they have not found any significance difference in union time but time taken for surgery is significantly high in patients treated with MIPO than nailing (97.9 vs 81.2 minutes).

The mean time of union in our study was 23 ± 5.35 weeks for IMIL nail and 23.69 ± 7.20 weeks for MIPO. In our study, 22 fractures (42.30%) united between 14- 20 weeks. Of these 22 fractures, 9 cases were treated with IMIL nail and 13 with MIPPO. And 17 fractures (32.69%) united between 21 to 25 weeks. Of these 17 fractures, 11cases were treated with

IMIL nail and 6 with MIPO. Our study showed that intramedullary nailing led to faster average time for union compared to locking plate by MIPPO, which can be compared with above study. Other studies done by Li et al,^[9] Pawar et al,^[11] Yao et al.^[15] also are comparable to the results found in our study regarding faster union in IMLN.

Yong Li and others have done a study on distal tibia metaphyseal fractures in 46 patients and they found average full weight bearing is 11.1 ± 1.7 vs 9.0 ± 1.4 weeks which is significantly high in patients treated with MIPO than multidirectional locked nailing.

Our results showed similar to above study where There is a significant change seen in between two groups regarding full weight bearing mobilization. In patients operated with nailing, full weight bearing mobilization started at an average 11.48 weeks where as in plating group full weight bearing mobilization started at 12.96 weeks.

Guo et al,^[13] done a prospective randomized control study in 85 patients with distal tibia fractures treated with either MIPO or intramedullary nailing (41 patients with plating and 44 patients with nailing) and observed that all are united without any significant difference in functional score.

Im GI et al,^[16] study in distal tibia fractures shows a significantly better range of motion seen in patients treated with nailing than plating.

Yong Li et al,^[14] have done a study in 46 patients with distal tibia metaphyseal fractures treated with multidirectional locked nailing and MIPO and they found better functional score(Teeny And Weiss Criteria) in patients treated with nailing than MIPO.

Our study results are comparable with above study. There is a high significant change seen in functional outcome (Teeny And Weiss Criteria) between two groups, the mean is 84.84 ± 9.66 in patients treated with multidirectional locked nailing and 84.26 ± 11.79 in patients treated with minimal invasive percutaneous plate osteosynthesis ($p=0.75656$). The difference in functional outcome showed mean score of 84.84 ± 9.66 in IMIL group where as in MIPPO group it is 84.26 ± 11.79 , having p value $p = 0.75656$ these differences were not found to be statistically significant. Even though there is no statistical significance but clinically there is significant difference in the functional outcome comparatively which was similar to studies by Guo et al and Collinge et al.^[13,17]

In our study, most of the patients have no complications. In patients who had complications, In IMIL group most common complication is superficial infection (11.53%) followed by malunion (7.69%) and deep infection (3.84%). Whereas in MIPPO group most common complication is Deep infections (15.38%) followed by implant failure (7.69%) and delayed union (3.84%).

As RTA was the most common cause in our study, along with causing the fracture, it might also affect the soft tissue. This may lead to soft tissue disintegrity and infections. Both groups were comparable for complications which were comparable to studies by Guo et al,^[13] Ehlinger et al, Bahari et al, and Redfern et al.^[18-20]

Theoretically incidence of infection in the MIPO group should be less because technique itself promotes minimal handling of soft tissues. But a minimal incision cannot ensure minimal invasion because surgeons who are unfamiliar with the technique may repeatedly insert and pull out the plate, which will induce a dead space and increase infection risk or delayed union.

Im and Tae done a comparative study regarding wound complications in patients treated with intramedullary nailing and plating and observed significantly higher rate of wound complications in plating group than nailing group(7 out of 30 patients in plating group versus 1 out of 34 in nailing group; $p=0.03$).^[16]

Our results are comparable with above study, Postoperative complications are more seen in patients treated with plating (MIPPO group) when compared to nailing(IMIL group), four deep infection against one in IMIL group and only three superficial skin infection seen in

patients treated with intramedullary nailing against zero in MIPPO group. All these superficial skin infections are treated with regular dressing and antibiotics whereas for deep infections wound debridement was done followed by skin grafting.

CONCLUSION

In this study average time taken for surgery and fracture union in patients treated by nailing is significantly lower when compared to the ones treated by plating. Time taken for full weight bearing and mobilization was significantly lower in nailing group than plating group. Rate of malunion and wound infection is higher in patients treated with plating than nailing. At final follow up, the functional outcome is significantly higher in patients treated with multidirectional nailing than minimally invasive plating.

Finally, we consider multidirectional locked nailing is an efficient method for treating distal tibia fracture. Nevertheless, in a small sample paired comparison, no significant superiority of MIPO was found over IMIL nail. Furthermore, the MIPO technique is more challenging than IMIL as it requires closed reduction and management under X-ray control. Compared with MIPO and the IMN technique, IMIL nailing should still be considered the gold standard for distal tibia fracture management.

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