*https://doi.org/10.48047/AFJBS.6.14.2024.9632-9645*

African Journal of Biological Sciences

Journal homepage: http://www.afjbs.com

Research Paper Open Access

# TIP LOCKING IM TIBIAL NAIL VERSUS LCP IN FIXATION OF DISTAL TIBIA FRACTURES - A RANDOMIZED CONTROLLED TRIAL

**Ketaki Mohite[1], Nilesh Joshi[2], Yash Shewale[3], Himanshu Deshmukh[4], Harsh Thakkar[5], Satyajit Deshpande[6]**

Department Of Orthopaedics, NKPSIMS and Lata Mangeshkar hospital, Nagpur, Maharashtra, INDIA.

**Corresponding Author:** Dr.Yash Shewale, Department Of Orthopaedics, NKPSIMS and Lata Mangeshkar hospital, Nagpur, Maharashtra, INDIA.
**Email:** yashshewale1995@gmail.com

Article History

Received: 03 June 2024

Accepted: 20 July 2024

Published: 21 August 2024

*doi: 10.48047/AFJBS.6.14.2024.9632-9645*

**ABSTRACT**

**Background-** Distal Tibia Fractures make an overall fewer part, 10 percentage of total lower limb fractures and 7% of all Tibia bone Fractures. The management of these fractures is challenging and its location near the ankle makes the management by IM IL nail or locking compression is very complicated. IM IL nail is an accepted treatment for distal tibia and tibial shaft fractures. Another widely accepted method is the LCP that has gained a lot of traction. Plates and intra-medullary nails are both effective methods, but also have their own complications. We projected that randomized selection and management of meta-diaphyseal fractures of distal tibia which was extra articular would evaluate the success of IM IL nail versus LCP treatment and improve patient care and evaluate the functional outcome. **Materials and Methods:** The present study was conducted between 1st November 2019 to 31st October 2021 in a tertiary care hospital. All patient with distal tibia fracture getting admitted in orthopaedics ward and fulfilling the inclusion criteria. We calculated sample size by using epi info software referencing the study by Balakrishna Pinnaka et al.(2018). the required sample size was 15 in each group and total 30 cases of distal tibial fracture. Convenient Sampling Technique was used, in the light of the ongoing pandemic, as it suited our study. Patients participated in the study once inclusion criteria was met. **Results:** There was statistical difference between IM nail and LCP in terms of time of union, radiation exposure and ankle range of movements with IM nail having superior results than LCP.

Conclusion: IM IL nailing is better in management of distal tibia fractures than LCP Osteosynthesis, in terms of early fracture union rates, early weight bearing, ease of procedure, functional outcome of lower limb and less complication rates.

## INTRODUCTION

Distal Tibia Fractures make an overall fewer part, 10 percentage of total lower limb fractures and 7% of all Tibia bone Fractures [1-3]. It is more common in males [4]. They are usually caused by two forces, the axial type of force and the rotational type of force [5]. The predominant reasons are road traffic accident, twisting of ankle and fall, usually from a considerable height. Distal Tibia fractures most commonly present linked with soft tissue injury, owing to its subcutaneous location. Due to its peculiar vasculature and subcutaneous location, distal tibia fractures are a challenge to manage It is of utmost importance that the soft tissue be repaired and preserved along with the fixation of the underlying bone fracture or it can lead to disability to the patient [6]. Around 85 % of fractures of distal tibia are associated with fibula fractures [7].

The management of these fractures is challenging and its location near the ankle makes the management by IM IL nail or locking compression is very complicated. Various management methods are put forward, such as IM nailing, plate fixation and even non-operative management and external fixation. However, every one of these options are associated with their own challenges. External fixation of distal tibia fractures may cause complications like improper reduction of the fracture, malunion, non-union and even infection of the pin tracts [8]. For medically unfit patients or patients refusing surgical managements, Nonsurgical treatment has a role, though limited [9]. Conservative treatment by cast application is effective till certain extent but has disadvantages like Immobilization for a longer period, knee stiffness which affects quality of life of the patient [10].

IM IL nail is an accepted treatment for distal tibia and tibial shaft fractures. They currently signify an effective treatment of simple as well as intricate fractures of tibia like distal tibial meta-diaphyseal fracture [11,12]. The tip locking Multidirectional IM nail is being accepted widely as a concrete choice, since it has advantages of decreased duration of operation, decrease of days of hospital stay, early complete weightbearing and decreased fracture union time. Another widely accepted method is the LCP that has gained a lot of traction. The locking plate gives a superior steadiness [13,14]. Minimally invasive percutaneous locking plate is being widely used with quite good outcomes [15,16]. However, this method has a long learning curve and anatomical reduction of the fracture is difficult.

Thus, Plates and intra-medullary nails are both effective methods, but also have their own complications. We projected that randomized selection and management of meta-diaphyseal fractures of distal tibia which was extra articular would evaluate the success of IM IL nail versus LCP treatment and improve patient care and evaluate the functional outcome.

**MATERIALS AND METHODS**

The present study was conducted between 1st November 2019 to 31st October 2021 in a tertiary care hospital.

Study design: A Randomized Controlled Trial.

Study setting: Department of Orthopaedics of Tertiary care centre.

Study population : All patient of distal tibia fracture getting admitted in orthopaedics ward and fulfilling the inclusion criteria.

Sample size: We calculated sample size by using epi info software referencing the study by Balakrishna Pinnaka *et al.*(2018).38 According to the study, average union duration was 19.6 and 20.71 weeks for nailing and plating respectively. The difference between these was statistically significant (p= 0.42).

The required sample size was 15 in each group and total 30 cases of distal tibial fracture.

Inclusion criteria:

· Distal tibia fractures amenable to osteosynthesis by tip locking IM tibial nail and LCP.
· Closed fractures
· Open fractures, (grade I and II) of distal tibia, without intra-articular extension
· Patient aged 18 years
· Consenting patients

Exclusion criteria:

· Patients with associated fractures in ipsilateral limb fracture
· Non consenting patients
· Compound fracture type III B and III C.
· Fractures with intra articular extension.

Withdrawal criteria: Patient could back out from the study anytime if they did not want to continue.

Methods of measurement: The functional outcomes will be measured by using Lower Extremity Functional Scale (LEFS).

Data collection tool:

1. X ray of affected knee with leg up to ankle joint, AP and lateral views taken at the radiology department of tertiary care hospital
2. Investigations namely CBC, LFT, KFT, HIV, HBSAG, HCV, RBS, Blood group and ECG, required for preoperative assessment of the patient will be sent to central pathology laboratory
3. Lower Extremity Functional Scale (LEFS) score was obtained at suture removal and subsequent follow up.

Method of data collection:

The ethics committee attached to medical college was asked for the permission and upon getting the approval, all the selected candidates for the study were randomly allocated to two groups. Written informed consent was taken. The study was carried out for 2 years, from 1st November 2019 to 31st October 2021. Appropriate intervention was done on patients from both groups.

Follow-up was done, and data was obtained:

· At 1 month: Clinical evaluation with Lower Extremity Functional Scale (LEFS) and X-ray of affected knee with leg up to ankle joint anteroposterior and lateral view.

· At 3 months: Clinical evaluation with Lower Extremity Functional Scale (LEFS) and X-ray of affected knee with leg up to ankle joint anteroposterior and lateral view.
· At 6 months: Clinical evaluation with Lower Extremity Functional Scale (LEFS) and X-ray of affected knee with leg up to ankle joint anteroposterior and lateral view.
Clinical and radiological evaluation and functional evaluation will be done at 1, 3 and 6 months by Lower Extremity Functional Score (LEFS).
Data management:
All data was added in Microsoft Excel. Data backup was maintained. Patient's identity and information was kept confidential, validity of the data was checked periodically by guides and experts.
Method of randomization:
Randomization of patients was done using a computer-based randomization software sealed envelope Ltd. 2017 ver. 1.13.3. Patients operated with Tip locking IM multidirectional nail - Group A (CASE). Patients operated with LCP- Group B (CONTROL). Blocked randomization list was generated by the statistician using above software.
BLINDING:
Open label trial.
ALLOTMENT CONCEALMENT:
Sealed opaque envelope was used for allotment concealment.
Implants and Instruments used for nailing:
· A set of IL nails from 28-38cm length in 7 to 10 mm width.
· A diamond - tip bone awl
· A canulated awl
· Nail removal set
· Hand drill and drill bit of 3.2mm
· Depth gauge and 4.5 mm cortical screw set
· Screw driver
· Reamer
· Guide wire
Instruments and Implants for Plating:
· Anatomical contour medial LCP.
· 5mm locking compression cortical screws.
· 3.2 mm loc king cancellous screws.
· 4mm and 2.7 mm drill bits.
· 5mm and 3.2 mm drill sleeves.
· 2mm K-wires.
· 5mm and 3.2 screw drivers.
· Pneumatic/Electric/Hand drill
· T-handle
· Reduction clamps
· Plate holding forceps
Description of Tip Locking IM IL-Nail:
The nail used for our procedures was a commercially available Multidirectional IL IM Nail. The nail is a hollow metallic rod with a 200 bent at the proximal end, similar to the tibial bent, for the ease of procedure. The locking holes are present at the proximal and distal end. The Tip locking IM nail has distal locking 0.5cm above the tip, thus making it ideal for the fracture of distal tibia.
Description of LCP:
A LCP has an anatomical shape. There are K wire holes to assist in placing the plate at appropriate position. For support at the articular surface, the distal part of the head has three diverging locking screws. Also, there are two combination holes and eight Distal locking holes in the plate.
Surgical Intervention:
The patient was operated as soon as the skin condition improved, and it took place in the orthopaedic modular operation theatre.
Operative Technique for nailing:
Patient was taken in the Orthopaedic Operation Theatre, on the operating table. Spinal anaesthesia given. Torniquet applied. Under all aseptic precautions, Cleaning, painting and draping was done. Limb exsanguination for 1 minute and torniquet inflated to 300mmhg.
After this, operation was started. The anteromedial bony prominence of tibial tuberosity was palpated and incision of length

1-2 cm taken. Patellar tendon was split vertically after knee was kept in full flexion. Entry was made with a curved awl just above and medial to tibial tuberosity.

i. Passing of Guide Wire.

A guide wire was passed once the entry was made. The wire tip was furthered till it reaches the fracture location with further passing into the distal fragment was done with further manipulation or by rotating the tip of the wire or both. Location was checked under C arm.

ii. Insertion of Nail.

Nail length determined pre-operatively by taking the measurement from highest point of tibial tuberosity to medial malleolar tip. The appropriate nail length checked by keeping the nail over the tibia and assessed under the C-arm shoot. The nail was fit with bolt to insertion handle. Sequential reaming of canal is done up to appropriate sizes. Over the guidewire, the nail was passed, further in the bone canal.

iii. Insertion of the proximal IL Screw.

Proximal IL was done using the sleeves. 4.5 mm IL bolt inserted and checked under C arm.

iv. Insertion of distal IL screw.

Distal locking done with C arm guidance, 4.5 mm IL bolt of adequate length is used.

Closure was done in layers. Sterile dressing was done. Compression bandage was applied and the tourniquet was released.

Operative technique for plating:

The LCPs are available in many configurations and sizes. Patient was taken in the Orthopaedic operation theatre, on the operation table. Spinal anaesthesia was given. Tourniquet applied. Under all aseptic precautions, Cleaning, painting and draping was done. Limb exsanguination done for 1 minute and tourniquet inflated to 300mmhg. After this, operation was started. Reduction was achieved by traction and manipulation. A 2-3cm long incision was taken on medial malleolus. Sub muscular plane was made by passing periosteum. The plate was slid along the tibia through the incision. The Plate was held in position. Plate was checked under C-arm in both required views for positioning the plate. Temporary fixation was performed with K-wires to check final plate position before the first screw was inserted. Once accurate restoration of length, alignment and rotation was achieved, provisional stabilization of the plate was performed with a single conventional "positioning" screw inserted through the plate. Reduction is finalized by pulling the distal segment against the plate with a non-locking screw or other instrument.

Screw insertion:

Further proximal and distal screw insertion was completed. The number and position was dependent on the individual fracture anatomy and bone quality.

Locking head screws (LHS) improved fixation. Cortical screws can be used first to reduce fracture against the plate. They may be sufficient for definitive fixation in the diaphysis. Adequate wash was given. Incision closed in layers. Sterile dressing was done and compressive bandage was applied. Tourniquet was released.

Post operative regimen:

· Intravenous antibiotic regimen with Third generation cephalosporin and aminoglycoside was completed till 3 days post the operation. Further 9 days of oral antibiotics were given.

· Sutures were removed on post-operative day 12. Patients were made to do strict non weight bearing mobilization with the help of crutches from post operative day 1 or 2 itself.

· Above knee slab was given to all patients of Plating group till stitches were removed, after which cast (below knee) was given for 1 month.

· All patients of both groups were advised strict non weight bearing on the operated leg, till instructed to.

· For plating group, Knee ROM and strengthening exercises were advised.

· For nailing group, Knee as well as Ankle ROM and strengthening exercises were advised.

Follow up:

It was done post operatively at 1, 3 and 6 months.

· For the plating group, the cast was removed after 4 weeks and ankle ROM was started. Weight bearing, even toe touch weight bearing allowed only if there were signs of fracture union on radiological assessment after 6 weeks. Thus weight bearing is delayed in plating group. It is started at 8 weeks or more post operatively

· For nailing group, on 4 week follow up, radiological assessment is done and on seeing the evidence of callous formation, weight bearing can be initiated. First toe touch is done and it is followed by full weight bearing.

· Upon achieving proof of callus formation, the fracture was said to be united.

The final outcomes were measured with respect to :

· Union time

· Weight bearing

· Ease of procedure

· Blood loss

· Infection rates
· Radiological exposure
· Functional outcomes measured by the Lower Extremity Functional Scale.
The above parameters were measured for a duration of 6 months. Results were analysed by using appropriate statistical tests.

**INTRA-OPERATIVE PHOTOGRAPHS DURING NAILING:**

Figure 1: POSITION

Figure 2: EXPOSURE

Figure 3: INSERTION OF NAIL

Figure 4: DRILLING FOR PROXIMAL INTERLOCK BOLT

Figure 5: GUIDE WIRE SHOWING ENTRY POINT

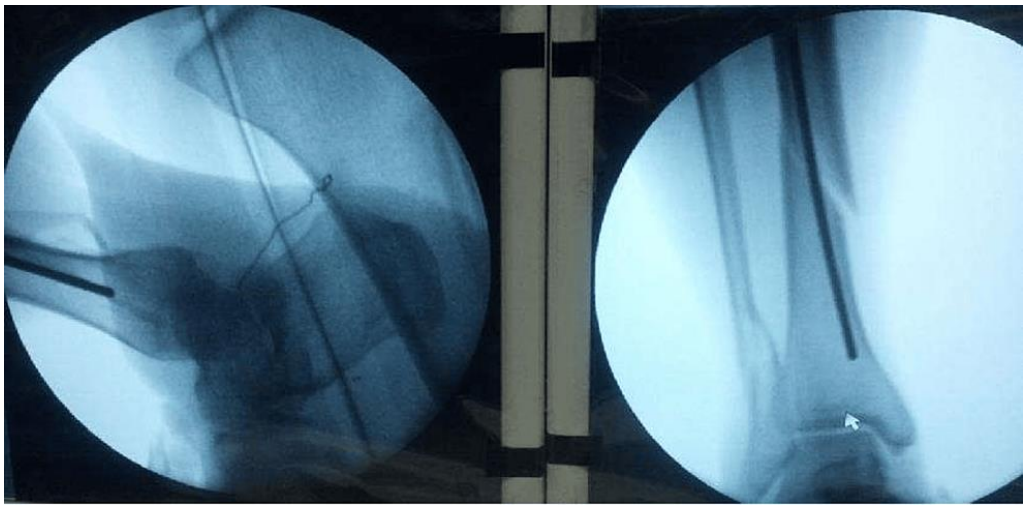

Figure 6: AP and LATERAL VIEW SHOWING GUIDEWIRE POSITION DISTAL TO FRACTURE

Figure 7: FINAL LATERAL FLUOROSCOPY VIEW

Figure 8: FINAL AP FLUOROSCOPY VIEW

**OPERATIVE PHOTOGRAPHS OF PLATING:**

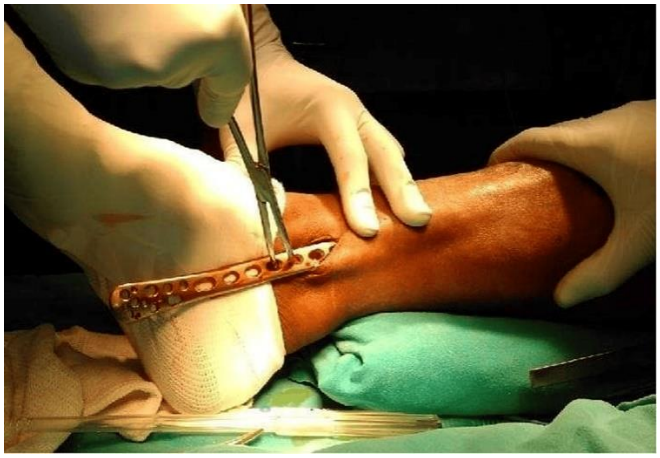

Figure 9: POSITIONING OF PLATE AND GLIDING OVER PERIOSTEUM

Figure 10: PLACING PLATE OVER MEDIAL MALLEOLUS

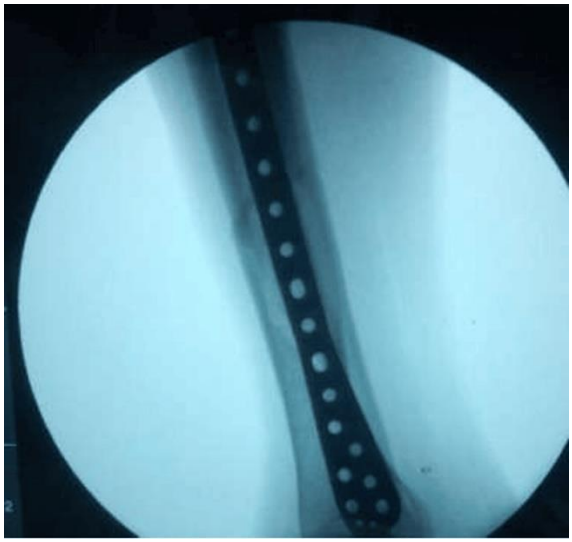

Figure 11: POSITION OF PLATE IN LATERAL VIEW

Figure 12: PLATE POSITION IN AP VIEW

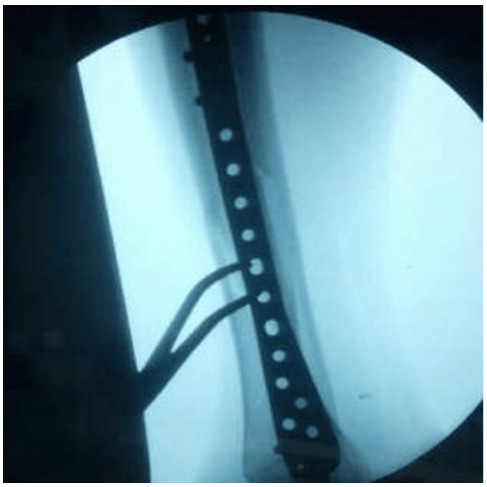

Figure 13: LATERAL VIEW AFTER SCREW FIXATION

**IM IL NAILING:**


Figure 14: RIGHT DISTAL TIBIA FRACTURE

Figure 15: IMMEDIATE POST OPERATIVE RADIOGRAPH


Figure 16: 6 MONTHS POST OPERATIVE RADIOGRAPH

**LCP:**


Figure 17: LEFT DISTAL TIBIA FRACTURE


Figure 18: IMMEDIATE POST OPERATIVE RADIOGRAPH


Figure 19: 6 MONTHS POST OPERATIVE RADIOGRAPH

**RESULTS**

**STATISTICAL ANALYSIS**

The data collection, compilation and analysis was done using EPI info (version 7.2). Expression of the qualitative variables was done in percentages and that of quantitative was done in terms of mean and standard deviation and in terms of percentages. Chi-square test and Fischer test were used for analysis of difference between the qualitative and quantitative variables. Student t test was used to differentiate between two means. The analysis of all parameters was two tailed and 0.05 was set as the significance level.

Table 1: Subject distribution based on the time of starting of weight bearing

| Weight bearing | Nailing | | Plating | | P value |
|---|---|---|---|---|---|
| | Number | % | Number | % | |
| Delayed | 0 | 0 | 15 | 100.00 | ----- |
| Early | 15 | 100.00 | 0 | 0 | |
| Total | 15 | 100.00 | 15 | 100.00 | |

Among nailing group, none had delayed weight bearing and 100% had early weight bearing. Among plating group 100% had delayed weight bearing and none had early weight bearing. There was significant difference between the weight bearings among the two groups.

Table 2: Subject Distribution based on the time to union

| Time to union (in months) | Nailing | | Plating | | P value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| | 5.13 | 1.41 | 6.80 | 2.01 | 0.0136 |

The mean time to union (months) among nailing group was 5.13 months and among plating group was 6.81 months. There was significant difference between the averages of time for union among the two groups.

Table 3: Subject Distribution based on the image intensifier use (in seconds)

| Image intensifier use (in seconds) | Nailing | | Plating | | P value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| | 216.00 | 57.98 | 102.67 | 31.78 | <0.001 |

The average dose of image intensifier among nailing was 216 seconds and among plating group was 102.67 seconds and this difference was statistically significant.

Table 4: Subject distribution based on the Ankle ROM

| Ankle ROM | Nailing | | Plating | | P value |
|---|---|---|---|---|---|
| | Number | % | Number | % | |
| Full | 9 | 60.00 | 5 | 33.33 | 0.0103 |
| Mid range | 0 | 0 | 7 | 46.67 | |
| Near normal | 6 | 40.00 | 3 | 20.00 | |
| Total | 15 | 100.00 | 15 | 100.00 | |

The ankle range of movements among nailing group was full in 60% and 40% were near normal. Among plating group, 33.33% the range of movements was full, 46.67% was mid-range and 20% were near normal. There was significant difference in the ankle ROM among two groups.

Table 5: Based on the knee ROM

| Knee ROM | Nailing | | Plating | | P value |
|---|---|---|---|---|---|
| | Number | % | Number | % | |
| Full | 11 | 73.33 | 14 | 93.33 | 0.1416 |
| Near normal | 4 | 26.67 | 1 | 6.67 | |
| Total | 15 | 100.00 | 15 | 100.00 | |

Among the nailing group, 73.33% had full ROM and 26.67% had near normal ROM. Among plating group, 93.33% had full ROM and 6.67% had near normal ROM. There was no significant difference between the knee ROM among the two groups.

**DISCUSSION**

Distal tibia fracture is a complicated fracture to manage. The functional outcome is dependent on various factors like comminution of the fragments, the state of the surrounding soft tissues etc. If distal tibia fracture is extraarticular, then effective surgical management becomes furthermore complicated. Operative treatment has the goal of achievement of fracture reduction, with a fixation that will allow early ROM of the knee and ankle. Mode of treatment chosen should be such, so that tissue surrounding the fracture and periosteal blood supply is not damaged. Different methods are used for the management of these fractures. The two widely used fixation techniques are IM IL nailing and Locking compression plating. Plating, though being a very effective method, if done by open method, has the disadvantages of injuring the soft tissue and vascular system. The vascular supply and soft tissue of distal tibia is already critical and thus opening such fractures can lead to complications.

In our study of 30 cases, 15 patients were operated with IM IL Nail and 15 patients were treated with LCP.

The study was done in Orthopaedics department at our hospital, a tertiary care center from November 2019 to October 2021. A total sample size of 30 patients referred to the department OPD or casualty with extra-articular distal tibia fracture who underwent surgery were included. Patients less than 18 years of age, un consenting patients, patients with open fracture of grade 3 and patients with ipsilateral lower limb bone fracture were excluded from the study.

The study was done after taking ethical clearance from our institute and informed written consent taken from the patients. The various data was collected from patients regarding demographic profile of patients, spectrum of the patient, risk factors, mechanism of the injury and pre-operativeankle ROM and Knee ROM.

The bulk of patients in the nailing group were of the age group 31-40 years (46.67%), while the most bulk of patients in the plating group were of the age group 41-50 years (60%). The average age of the patient in the present study of all the patients involved is 43.23 years, while for studies we have compared with the average age as Kumar *et al.*, 39.4 years, Vallier *et al.*, 38.3 years and Salphale *et al.* 30.9 years. The results are comparable.

For the most important aspect of various studies, time of the fracture union is seen. The results for this in other studies was 24.9 weeks for nailing and 24.2 weeks for plating in the study by Kumar *et al.*, while it was 15.4 weeks for nailing in the study by Salphale *et al.* Vaza *et al.* conducted study with fracture union time at 23.45 weeks for nailing and 26 weeks for plating. In the present study, fracture union time for IL nails is 20.52 weeks and for plating was 27.2 weeks. Thus we can safely decipher from the present study that the IMN has a statistically significant better result in terms of fracture union as compared to the plating group.

Our results are comparable with that of the other studies. We found that the preservation of blood supply surrounding the fracture is of utmost importance. Further soft tissue handling in the form of ORIF may result in compromise of vascular supply of distal tibia and may result the increased chances of infection or non-union. Understanding personality of fracture and skills of surgeons in fracture reduction and management with MIPPO or Nailing are equally important.

Conclusions

IM IL nailing is better in management of distal tibia fractures than LCP Osteosynthesis, in terms of early fracture union rates, early weight bearing, ease of procedure, functional outcome of lower limb.

**REFERENCES**


1. Bourne RB, Rorabeck CH: Macnab J (1983) Intra-articular fractures of the distal tibia: the pilon fracture. J Trauma 23: 591-596. https://journals.lww.com/jtrauma/abstract/1983/07000/intra_articular_fractures_of_the_distal_tibia__the.8.aspx.
2. Ovadia DN, Beals RK (1986: Fractures of the tibial plafond. J Bone Joint Surg Am. 68:543-551.
3. Marsh JL, Saltzman CL (2001: Ankle fractures. In: Bucholz RW, Heckman JD (eds) Rockwood and Green,,s fractures in adults. Lippincott Williams & Wilkins, Philadelphia, pp; 20012090.
4. Tyllianakis M, Megas P, Giannikas D, Lambiris E (2000: IL IM nailing in distal tibial fractures. Orthopedics. 23:805-808. 10.3928/0147-7447-20000801-13
5. Singer BR, McLauchlan GJ, Robinson CM (1998): Epidemiology of fractures in 15,000 adults: the influence of age and gender. J Bone Joint Surg Br. 80:243-8. 10.1302/0301-620X.80B2.0800243
6. Michael.W.Chapman ; Chapman‟s Orthopaedic Surgery S.Terry Canale, James.H.Beaty ; Campbells operative orthopaedics 11th edition: https://journals.lww.com/jbjsjournal/citation/2008/04000/campbell_s_operative_orthopaedics__11th_ed_.34.aspx.
7. Ruedi TP, Allgower M (1969: Fractures of the lower end of the tibia into the ankle-joint. Injury 5. 130:10.1016/S0020-1383(69)80066-5
8. Mosheiff R, Safran O, Segal D, Liebergall M (1999: The unreamedtibial nail in the treatment of distal metaphyseal fractures. Injury 30: 83-90. 10.1016/S0020-1383(98)00213-7

9. Helfet DL, Shonnard PY, Levine D(1997): Minimally invasive plate osteosynthesis of distal fractures of the tibia. Injury. 28:42-7. 10.1016/S0020-1383(97)90114-5
10. Whorton AM, Henley MB (1998: The role of fixation of the fibula in open fractures of the tibial shaft with fractures of the ipsilateral fibula: indications and outcomes. Orthopedics. 21:1101-1105. 10.3928/0147-7447-19981001-09
11. Kellam JF, Waddell JP: Fractures of the distal tibia metaphysis with intra-articular extension: the distal tibial explosion fractures. J Trauma. 1979, 19:593-609.
12. Martin JS, Marsh JL, Bonar SK, *et al.*: Assessment of the AO/ASIF fracture classification for the distal tibia. J Orthop Trauma. 1997, 11:477-483.
13. Leung F, Kwok HY, Pun TS (2004): Limited open reduction and Ilizarov external fixation in the treatment of distal tibial fractures. Injury. 35:278-83. 10.1016/S0020-1383(03)00172-4
14. Hasenboehler E, Rikli D: LCP with minimally invasive plate osteosynthesis in distal tibial fractures: a retrospective study of 32 patients. Injury. 2007, 38:365-370. 10.1016/j.injury.2006.10.024
15. Im GI, Tae SK (2005: Distalmetaphyseal fractures of tibia: a prospective randomized trial of closed reduction and IM nail versus open reduction and plate and screws fixation. J Trauma59:1219-1223 discussion 1223. 10.1097/01.ta.0000188936.79798.4e
16. Mosheiff R, Safran O, Segal D, Liebergall M (1999: Theunreamedtibial nail in the treatmentof distal metaphyseal fractures. Injury 30: 83-90. 10.1016/s0020-1383(98)00213-7