Original Article

A comparative study of intramedullary interlocking nailing and minimally invasive plate osteosynthesis in extra articular distal tibial fractures

Arup K Daolagupu, Ashwani Mudgal, Vikash Agarwala, Kaushik K Dutta

Abstract

Background: Extraarticular distal tibial fractures are among the most challenging fractures encountered by an orthopedician for treatment because of its subcutaneous location, poor blood supply and decreased muscular cover anteriorly, complications such as delayed union, nonunion, wound infection, and wound dehiscence are often seen as a great challenge to the surgeon. Minimally invasive plate osteosynthesis (MIPO) and intramedullary interlocking nail (IMLN) are two well-accepted and effective methods, but each has been historically related to complications. This study compares clinical and radiological outcome in extraarticular distal tibia fractures treated by intramedullary interlocking nail (IMLN) and minimally invasive plate osteosynthesis (MIPO).

Materials and Methods: 42 patients included in this study, 21 underwent IMLN and 21 were treated with MIPO who met the inclusion criteria and operated between June 2014 and May 2015. Patients were followed up for clinical and radiological evaluation.

Results: In IMLN group, average union time was 18.26 weeks compared to 21.70 weeks in plating group which was significant ($P < 0.0001$). Average time required for partial and full weight bearing in the nailing group was 4.95 weeks and 10.09 weeks respectively which was significantly less ($P < 0.0001$) as compared to 6.90 weeks and 13.38 weeks in the plating group. Lesser complications in terms of implant irritation, ankle stiffness, and infection, were seen in interlocking group as compared to plating group. Average functional outcome according to American Orthopedic Foot and Ankle Society score was measured which came out to be 96.67.

Conclusion: IMLN group was associated with lesser duration of surgery, earlier weight bearing and union rate, lesser incidence of infection and implant irritation which makes it a preferable choice for fixation of extra-articular distal tibial fractures. However, larger randomized controlled trials are required for confirming the results.

Key words: Distal tibial fractures, interlocking nailing, locking plate, minimally invasive
MeSH terms: Nailing, intramedullary, minimal invasive surgical procedure, bone plates, tibial fractures

Introduction

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

Distal tibial metaphysis is defined as by constructing a square, with sides of length defined by widest portion of tibial plafond.[3] Because of its subcutaneous location, poor blood supply and decreased muscular cover anteriorly, complications such as delayed union, nonunion, wound infection, and wound dehiscence are often seen as a great challenge to the surgeon.

Department of Orthopaedics, Silchar Medical College, Silchar, Assam, India

Address for correspondence: Dr. Ashwani Mudgal,
T-289, Indira Colony, Narela, New Delhi - 110 040, India.
E-mail: drashwanimudgal@gmail.com

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Minimally invasive plate osteosynthesis (MIPO) and intramedullary interlocking nail (IMLN) are two well-accepted and effective methods, but each has been historically related to complications. Malalignment and knee pain are frequently reported after IMLN,[4,5] whereas wound complications, and implant prominence have been associated with tibial plating in some series.[6]

The present study compares IMLN and MIPO by locking compression plate in extra-articular distal tibial fractures. In this study we compared the functional outcome, the union rate and time, and the various complications associated with it.

Materials and Methods

42 skeletally matured patients with extra articular distal tibial fractures AO Type 43A1, 43A2, 43A3 were randomly selected using a computer generated plan from the site www.randomization.com (seed no. 22323) to allocate the patient into two groups, i.e., IMLN and MIPO groups (each with 21 patients). The study was of 1 year duration between June 2014 and May 2015. Informed consent was obtained from each patient before participation in the study. Inclusion criteria included fracture meeting the AO criteria, age more than 18 years, those who gave valid consent, presence of distal fragment of at least 3 cm in length without articular incongruity, duration of injury <2 weeks, competent neurological and vascular status of the affected limb and patients who met the medical standards for routine elective surgery. Patient with open fractures, intraarticular extension, pathological fractures, poor medical health or who did not give consent were excluded. The study was approved by the Local Ethical Committee and Institutional Review Board. Sample size was calculated with the assumption of at least of 30% possible difference between the two groups. Hence, 21 patients were allotted into each group to obtain an alpha error of 5% and statistical power of 80% and also to include the dropouts.

After stabilization of the traumatized patient, standard anteroposterior, and lateral radiographs of the affected leg with knee and ankle joint were taken and the leg was immobilized in posterior splint till the surgery and routine preoperative investigations were done. After anesthetic clearance, the patient was taken up for surgery. A patient who presented within 6 h of injury without gross swelling of leg were operated on the same day or next available day. Limbs with gross swelling were splinted and elevated till swelling subsided, and wrinkles appeared over the ankle joint. Fracture blisters if present managed with puncturing with sterile needle and nonadhesive dressing and observed closely for any sign of secondary infection.

Operative procedure

Patients were operated under spinal anesthesia in supine position on a standard radiolucent table. Prophylactic intravenous antibiotics were administered 15 min before skin incision. An image intensifier was used in all the cases to provide fluoroscopic guidance. The patient was positioned supine with the hip flexed 45° and the knees flexed to 90° on radiolucent table. A 5-cm incision along the medial border of the patellar tendon was made, extending from the tibial tubercle in a proximal direction. The patellar tendon was retracted laterally to expose the insertion site and protect the tendon during insertion. Then the awl is inserted where the anterior tibia reaches the joint. Utmost care is taken to stay in the extra-articular area because back of the nail may impinge on the femoral condyle. Nailing was done using standard technique and all fractures were fixed with two proximal and two distal locking screws.

In MIPO, the leg was prepared circumferentially from the toes to mid thigh and draped free. A longitudinal incision of length 3–4 cm was made bone deep over the medial malleolus adequate enough to put screws in distal fragment. The saphenous nerve and vein were preserved and retracted anteriorly. Then an epiperiosteal space tunneling toward the diaphysis was made using the blunt tip of the plate. The reduction was achieved with manual traction and manipulation. Anatomically, precontoured plate was used and was positioned on anteromedial aspect of distal tibia by passing it through the subperiosteal tunnel. After insertion of plate and achieving the reduction, the plate was temporarily fixed to bone with K-wires and fixed proximal fragment with one locking screw. Distal fragment fixation was done with a combination of locking and cortical screws. Depending on fracture pattern and bone quality the decision of inserting the lag screw was made. Insertion of screws in the proximal fragment was done with small stab incisions.

Postoperative protocol

Radiograph with standard anteroposterior and lateral view of the involved leg was taken immediate postoperatively, at 6 weekly intervals till union and at 1 year followup [Figures 1 and 2]. Active range of movements of knee and ankle joint along with quadriceps strengthening exercises were started on the next day of surgery. Weight bearing was started after radiographic assessment showed signs of union as bridging callus in three out of four cortices and clinically as the absence of tenderness and movement at the fracture site.[7] This finding suggested the fracture site has sufficiently consolidated so as to allow partial weight bearing which usually occurs by 6–8 weeks. By the end of the 3rd month if there were no signs of callus formation in interlocking nailing group then dynamization was done and

Figure 1: X-ray leg bones with ankle anteroposterior and lateral views (a) Preoperative views showing fracture distal end tibia (b) immediate postoperative x-ray of IMIL nail group showing nail *in situ* (c) At 1-year followup showing sound union with intramedullary nail *in situ*

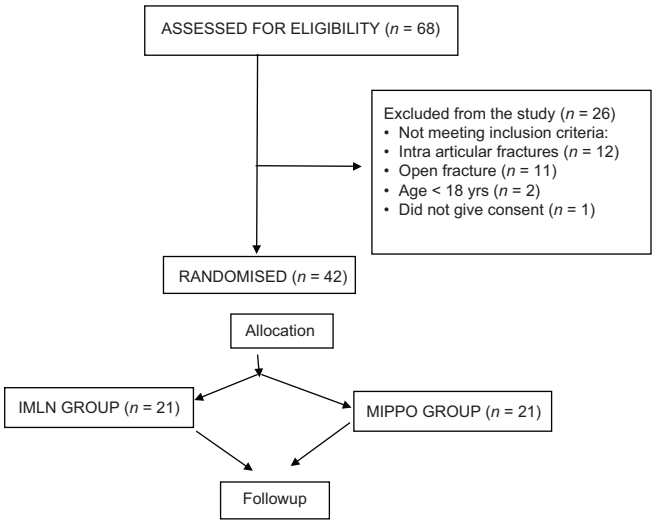
Figure 2: (a) X-ray of leg bones with ankle anteroposterior and lateral views showing distal tibial fracture (b) X-ray anteroposterior and lateral views immediate postoperative after minimally invasive plate osteosynthesis group showing plate *in situ*, fracture well reduced (c) X-ray anteroposterior and lateral views at 20 weeks followup showing union

advised partial weight bearing and patient was called after 6 weeks for radiological followup.

A clinical evaluation for the functional assessment of the ankle was obtained at each visit using the American Orthopedic Foot and Ankle Society (AOFAS) score. The final results at the end of 1 year followup were evaluated using the "Johner and Wruhs' Criteria" as excellent, good, fair, and poor.[8]

Statistical analysis

Statistical analysis was performed to test the associations between positive predictive variables and clinical outcomes Chi-square test or Fisher exact test was used for comparison of qualitative data. Unpaired Student's *t*-test was used to compare demographic variables and fracture classification between treatment groups. In all cases, $P < 0.05$ was considered statistically significant. Statistical analysis was done with GraphPad InStat 3 statistical software (GraphPad Software, Inc. California.USA). The sample size was calculated with the assumption of at least of 5% possible difference between the two groups. Hence, 21 patients were allotted into each group to obtain an alpha error of 5% and statistical power of 80% and also to include the dropouts [Flow Chart 1].



Flow Chart 1: Consort flow chart

Results

In this study, 42 patients of extra-articular distal tibial fractures were randomly selected using a computer-generated plan to allocate the patient into two groups of treatment out of which 21 were in IMLN group, and 21 were in MIPO group. The mean age of the patients was 37.14 years with range from 19 to 59 years. Of the 21 patients in IMLN group, the age ranged from 19 to 50 years (mean 35.19 ± 9.22 years). Of the 21 patients in MIPO group, the age ranged from 20 to 59 years (mean 39.09 ± 10.13 years) [Table 1].

There were 32 males and 10 females in the study with 57.14% having right tibia involvement.

Extra-articular distal tibial fractures were classified according to AO classification; the most common type was 43A1 with 21 patients (50%) whereas 15 (35.71%) were in Type 43A2 and 6 (14.28%) in Type 43A3. There were 11 Type 43A1, 6 Type 43A2, and 4 Type 43A3 in IMLN group whereas in MIPO group there were 10 Type 43A1, 9 Type 43A2, and 2 Type 43A3.

The most common mode of injury was road traffic accident (RTA) seen in 66.67% patients followed by falls, sports injury (e.g., football) and assault. More than half (57.14%) were operated within 3–7 days of injury.

The operating duration in IMLN group ranged from 45 to 70 min (mean 57.14 ± 8.30 min) whereas in case of MIPO it ranged from 60 to 80 min (mean 66.67 ± 5.55 min). P <0.0001 showed it to be statistically significant.

The mean time for starting partial weight bearing in IMLN group was 4.95 ± 1.07 weeks as compared to 6.90 ± 1.33 weeks in MIPO group which was statistically significant ($P < 0.0001$) [Table 2].

Table 1: Demographic data

Parameters	Total	IMLN*	MIPO#
Male (%)	32 (76.19)	17 (80.95)	15 (71.42)
Female (%)	10 (23.80)	4 (19.04)	6 (28.57)
Mean age (years±SD)	37.14	35.19±9.22	39.09±10.13
Mechanism of injury (%)			
Road traffic accidents	28 (66.67)	14 (66.67)	14 (66.67)
Falls	5 (11.90)	2 (9.52)	3 (14.28)
Assault	4 (9.52)	1 (4.76)	3 (14.28)
Sports injury	5 (11.90)	4 (19.04)	1 (4.76)
AO classification (%)			
Type 43A1	21 (50)	11 (52.38)	10 (47.61)
Type 43A2	15 (35.71)	6 (28.57)	9 (42.85)
Type 43A3	6 (14.28)	4 (19.04)	2 (9.52)
Side involvement (%)			
Right	24 (57.14)	14 (66.67)	10 (47.61)
Left	18 (42.85)	7 (33.33)	11 (52.38)

*IMLN=Intramedullary interlocking nailing, #MIPO=Minimally invasive plate osteosynthesis, SD=Standard deviation

Table 2: Comparison between intramedullary interlocking nailing and minimally invasive plate osteosynthesis

Parameters	IMLN	MIPO	*P*
Duration of surgery (min)	57.14±8.30	66.67±5.55	<0.0001 (HS)
Weight bearing (weeks±SD)			
Partial weight bearing	4.95±1.07	6.90±1.33	<0.0001 (HS)
Full weight bearing	10.09±1.41	13.38±1.24	<0.0001 (HS)
Union time (weeks±SD)	18.26±2.49	21.70±2.67	<0.0001 (HS)

P=Probability value, HS=Highly significant, IMLN=Intramedullary interlocking nailing, MIPO=Minimally invasive plate osteosynthesis, SD=Standard deviation

The average time for full weight bearing was 10.09 ± 1.41 weeks in IMLN and 13.38 ± 1.24 weeks in MIPO group which was statistically significant ($P < 0.0001$).

The average time of union in the IMLN group was 18.26 ± 2.49 weeks (range 15–24 weeks). In the MIPO group, union occurred in an average of 21.70 ± 2.67 weeks (range 16–24 weeks). The statistical difference between the two groups comes out to be very significant ($P < 0.0001$).

In our study, IMLN group was associated with lesser duration of surgery, earlier weight bearing, and faster union rate when compared to MIPO group.

The functional results, as assessed by Johner and Wruh's criteria, showed that majority (54.76%) of the patients in the study had excellent functional results (IMLN: 57.14%; MIPO: 52.38%) and 21.42% had good results (IMLN: 14.28%; MIPO: 28.57%). Using Chi-square test, these differences were not found to be statistically significant ($P = 0.6723$).

Complications [Figure 3] were comparable among the two groups in regards with superficial infection, deep

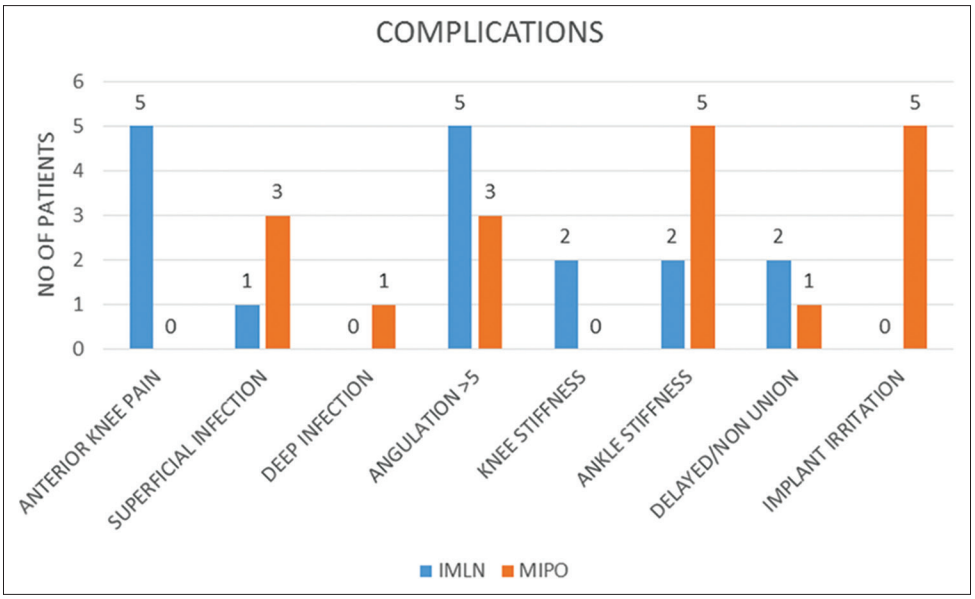


Figure 3: Bar diagram showing complications in both groups

infection, malalignment, knee, and ankle stiffness. However, statistically significant higher incidence of anterior knee pain was found in 23.80% patients IMLN group ($P = 0.0478$). Similarly, MIPO group was associated with higher rate of implant irritation which was found in 23.80% of patients ($P = 0.0478$) and also a higher rate of infection which was found in 19.04% of patients.

Discussion

Extra articular distal tibial fracture which are presented to the orthopedician, often poses a challenge to the surgeon as status of soft tissue and degree of comminution itself complicates the plan of management. The goal of operative treatment is to obtain anatomical alignment of the joint surface while providing enough stability to allow early motion. This should be accomplished using techniques that minimize osseous and soft tissue devascularization in the hopes of decreasing the complications resulting from treatment.

For years now, IMLN had an advantage over other methods because of its early weight bearing and union rate, lesser incidence of infections.

With the development of minimally invasive surgery, percutaneous plating has challenged interlocking nailing as locked plate designs act as fixed-angle devices whose stability is provided by the axial and angular stability at the screw-plate interface instead of relying on the frictional force between the plate and bone, which is thought to preserve the periosteal blood supply around the fracture site.[9]

In our study, the patients were in the range of 19–59 years, with mean age being 37.14 years. Of the 42 patients, 32 were males and 10 were females. IMLN group had 17 males; 4 females while MIPO group had 15 males; 6 females. Predominant male involvement in our study was probably due to more outdoor activities and heavier labor undertaken by males as compared to females in the Indian set up. The result were comparable to that of Kumar *et al.*,[10] Ram *et al.*,[11] Li *et al.*[12] and Vallier *et al.*[13]

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.*,[10] Ram *et al.*,[11] Pawar *et al.*[14] which also showed that RTA is the most common mode of injury as modernization and industrialization have intruded our lives.

In our study, the operating time in the intramedullary nailing group ranged from 45 to 70 min (mean 57.14 ± 8.30 min), while in case of lock plate it ranged from 60 to 80 min (mean 66.67 ± 5.55 min). This was comparable to studies done by Guo *et al.*,[15] Li *et al.*,[12] Pawar *et al.*,[14] Yao *et al.*[16]

The mean time for starting partial weight bearing in IMLN group was 4.95 ± 1.07 weeks as compared to 6.90 ± 1.33 weeks in MIPO group which was statistically highly significant. The *P* value using unpaired *t*-test is <0.0001. In our study, we allowed partial weight bearing only after signs of the union in form of bridging callus on at least three cortices out of four cortices on radiograph and clinically as the absence of tenderness and movement at the fracture site[7] which was usually by 6–8 weeks. The majority of the cases, having fulfilling above criteria around 6–8 weeks and were allowed partial weight-bearing on the affected limb.

The average time for full weight bearing was 10.09 ± 1.41 weeks in IMLN and 13.38 ± 1.24 weeks in MIPO group which was statistically highly significant as *P* value using unpaired *t*-test is <0.0001. The mean time of union in our study was 20.50 weeks (18.26 ± 2.49 weeks for IMIL nail and 22.75 ± 1.99 weeks for MIPO). In our study, 39 fractures (92.58%) united between 16 and 24 weeks. Of these 39 fractures, 19 cases were treated with IMIL nail and 20 with MIPO. Our study showed that intramedullary nailing led to faster average time for union compared to lock plate. Other studies done by Guo *et al.*,[15] Li *et al*.,[12] Pawar *et al*.,[14] Yao *et al*.[16] also are comparable to the results found in our study regarding faster union in IMLN.

Tibial fractures are often associated with fibular fractures which might impact the treatment modality and ultimately the final reduction and union. Whether to fix the fibular fracture or not is the question of the hour. Fixation of fibula was done in 22/37 cases (59.45%) in our study. Eight cases were in IMLN group while 14 were in MIPO. Two cases of delayed union in IMLN group were noted in our study in which fibular fixation was done. With respect to secondary procedures to achieve union, we dynamized all 2 fractures (9.5%) that did not show signs of union by the end of 3 months in IMLN group. We achieved union in 1 and another required bone grafting at around 24 weeks. Nork *et al*. reported performing secondary surgical procedures (bone-grafting or dynamization by removal of the static proximal interlocking screw) to promote union in 19% of patients. Various studies[17-21] have hypothetized that fibula fixation may facilitate anatomic reduction of the tibia; however, it is possible that the fibula then reduces strain over the tibia fracture, which heightens the potential for delayed healing or nonunion.[17-20,22] This requests the need for larger randomized controlled trials (RCTs) for finalizing a protocol for associated fibular fractures.

In our study, we had acceptable alignment in 34 cases, i.e., 80.95%. Malalignment was found in 23.80% patients treated with IMLN whereas MIPO had 14.28% of patients. Of eight cases which had malalignment evident on immediate postoperative period healed in the same position at followup of 1 year and no significant change was noted. This finding suggests intraoperative error could be the prime cause for malunion and it also throws light on difficulty in reducing the distal fragment accurately. Four cases had valgus and one case had varus malunion which were primarily fixed with IMLN, and two had varus and one cases had valgus which belonged to MIPO group. This was comparable to studies by Kumar *et al.,*[10] Ram *et al.,*[11] Vallier *et al*.[13] and Pawar *et al.*[14]

In our study, anterior knee pain (23.80%) and valgus angulations (19.04%) were the most common complications seen in IMLN group, whereas implant irritation (23.80%) and ankle stiffness (23.80%) were the most common complications in plating group. Deep infection was seen in one patient (4.76%), superficial infection in three patients (14.28%) in plating group and one patient (4.76%) in interlocking group. 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 Nork *et al.,*[7] Guo *et al.*,[15] Ehlinger *et al*.,[23] Bahari *et al*.[24] and Redfern *et al*.[25]

Functional outcome according to AOFAS score was measured in our study which came out to mean score was 96.67, which was similar to studies by Guo *et al*.[15] and Collinge *et al*.[26]

Conclusion

Both procedures have shown a reliable method of fixation and preserving most of the osseous vascularity, fracture hematoma which provide biological repair and can be used safely to treat distal metaphyseal fractures of the tibia (OTA Type 43A). In our study, IMLN group was associated with lesser duration of surgery, earlier weight bearing and union rate, lesser incidence of infection and implant irritation and failure which makes it a preferable choice for fixation of extra-articular distal tibial fractures. The decision to fix the fibula was based on intraoperative reduction of tibia fracture. If significant malalignment was still persisting after fixation of tibia, only then the decision to fix fibula fracture was made. Thus, we do not recommend fibular fixation routinely because the essential benefit of closed IMLN and MIPO in the avoidance of soft tissue dissection might be compromised in this way and also reduces strain over the tibial fracture, which heightens the potential for delayed healing or nonunion but to support this, larger trial are needed. Dynamization, as a secondary procedure to achieve union, was simple, quick and effective in fracture slowly progressing to union treated with interlocking nails. The decision to dynamize the nail was taken at 12 weeks in our study.

We, acknowledge that with more number of cases in this study, the results and observations would have been more accurate and statistically significant. Number of the patient, duration and followup of our study was shorter due to limited time period. We think more time is required for proper assessment of final clinical and functional outcome. An RCT, possibly triple blinded or at least double blinded in nature, involving a large number of patients with long term followup is clearly needed to bring the differences between the two techniques.

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Conflicts of interest

There are no conflicts of interest.

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