Comparative study between Expert nail tibia and minimally invasive plate osteosynthesis (MIPO) fixation in lower fourth tibial Fracture

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Abstract
Background: Expert nail and MIPO techniques are two well-accepted and effective method in fixation lower fourth tibial fracture. Expert nail showed lower infection rate and faster time to healing but with more mal-alignment in reduction. While in MIPO technique less mal-alignment reduction could be achieved but with more infection problems and slower rate of union. Purpose: compare the results of fixation of extra-articular lower fourth tibial fractures in adults by Expert nail vs. distal tibial plate with MIPO technique. Patients and methods: The study included 20 patients their ages were between 20-52 years, they were 13 males and 7 females. The patients were 12 heavily active patients, 5 moderate active patients and 3 lightly active patients. 4 patients were hypertensive and one patient was diabetic. All 20 patients were with unilateral fracture, 9 patients had the right side affected and 11 patients had the left side affected. Results: There was insignificant difference (P>0.05) in the MIPO group, 8 fractures (80%) united and one fracture (10%) had delayed union and one (10%) failed to unite. In the Expert nail group, 10 fractures (100%) united. In MIPO group, one fracture united in rotational deformity (external rotation 25 degree). In Expert nail group 2 (20%) fractures united on coronal plane deformity. Mean time for union in Expert nail 14 ± 2.85 weeks, while in MIPO group 17.07 ± 4.01 weeks. This showed statically significant for Expert nail (P value: 0.041). Expert nail showed faster time of union while one developed resistant infection. In Expert nail group, 2 patients (20%) showed superficial infection. Antibiotics according to culture and sensitivity was administrated and the wounds become clean. In MIPO group, 3 patients (30%) needed secondary surgeries (2 debridement, 1 revision). While in Expert nail group, one patient needed to secondary operation (fibular revision). In MIPO group, 5 patients (50%) were graded as excellent, 4 patients (40%) good and one patient (10%) poor. In Expert nail group, 7 patients (70%) were graded as excellent, 2 patients (20%) good and one patient (10%) fair. Conclusion: both techniques can provide effective treatment and fixation for closed lower fourth extra-articular tibial fractures. Expert nail showing lower infection rate and faster time to healing but with more mal-alignment reduction. While in MIPO technique less mal-alignment reduction can achieve but with more infection problems and slower rate of union.

Keywords: Expert nail tibia, MIPO fixation, tibia Fracture.

1. Introduction
Tibia is the most common long bone involved in road traffic accidents due to its subcutaneous location. Shaft tibia fractures being the most common and distal tibia fractures being second most common location. Falls direct blows and sports injury being other causes of distal tibia fractures. The incidence of distal tibia fractures is 0.7% of all body fracture and it constitutes to about 10% of all tibial fractures. Road traffic accidents are the most common cause of tibia fractures [1]. Because of subcutaneous location of this area, 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. [2]. The patient's medical history should be reviewed because of systemic problems Patient characteristic such as smoking, alcoholism, peripheral vascular disease, diabetes, and metabolic bone disease may affect treatment planning [3]. Marked pain and swelling of the ankle, the inability to bear weight, in addition to a mechanism of axial loading and torsion force, should raise the suspicion for a fracture of the distal tibia. Deformity of the limb is often apparent on initial examination. Care must be taken to accurately assess the neurovascular status of the extremity, the degree of swelling, and the condition of the surrounding soft tissues[4]. It should be apparent that plain x-rays are essential to evaluate the ankle. They define the bony anatomy. Anteroposterior, lateral, and mortise (A-P view with the foot internally rotated 15°-20°) should be obtained. Radiographs should include the entire tibia and fibula, as well as the ankle. Computed tomography is used to evaluate complex or comminuted fractures, particularly of the distal tibia or when the injury pattern is not clearly delineated plain radiographs.[5]. Reports of complications secondary to aggressive internal fixation have caused more conservative forms of treatment to be reconsidered. Non-displaced fractures can be treated in non-weight bearing casts. These need to be long-leg casts for rotational stability. Weight bearing should be restricted for 4 to 6 weeks. In elderly or debilitated patients or in patients with metabolic bone disease, closed reduction and casting may be advisable, the Disadvantage of Casting prevents observation of swelling and the skin, and loss of reduction is common with progressive angular deformity and shortening, stiffness, and loss of ROM [6]. Disadvantage: Casting prevents observation of swelling and the skin, and loss of reduction is common with
progressive angular deformity and shortening, stiffness, and loss of ROM [7]. Minimally invasive plate osteosynthesis (MIPO) has been used to decrease development of these complications. MIPO respects the soft tissue envelope along with maintaining the biological environment needed for proper osseous healing [8]. This study aimed to compare the results of fixation of extra-articular lower fourth tibial fractures in adults by Expert nail vs. distal tibial plate with MIPO technique.

2. Patients and methods
This study has been conducted at the orthopedic department, faculty of medicine, Benha university hospitals on twenty patients, 13 males and 7 females to compare Expert nail vs. distal tibial plate with MIPO technique in fixation of extra-articular lower fourth tibial fractures.

- **Inclusion criteria:**
  - Fracture lower fourth tibia
  - Non-pathological origin
  - Closed fracture
  - Recent fracture

- **Exclusion criteria:**
  - open fracture
  - intraarticular fracture
  - senile patient
  - premature epiphyseal closure patient.

- **Sample size and randomization:**
20 patients who met the inclusion criteria were randomized by closed envelope technique to 2 groups; 10 patients in each group:
  - Group A: 10 patients were fixed by distal tibial plate with MIPO technique.
  - Group B: 10 patients were fixed by Expert nail.

- **Preoperative Evaluation:**
- **Clinical evaluation:**
  1- **History:**
  - Personal data: Name, age, sex, occupation, address, telephone number, and special habits of medial importance including smoking.
  - Mode of trauma and time of trauma.
  - Medical history with special attention to co-morbidities as diabetes, hypertension and renal failure.
  - Pre-fracture level of activity.
  2-Examination:
  - In cases involved in high energy trauma, patients were managed according to the ATLS protocol with attention to possible life-threatening conditions and other injuries.
  - Local examination of the injured limb involved assessment of the vascular and neurological status with attention to wounds, abrasions and local soft tissue condition.

- **Investigations:**
  1-**Radiological:**
  - Plain X-rays AP and Lat views of the affected leg showing whole tibia with the knee and ankle joints.
  - CT scan in cases where the involvement of articular surface is suspected.

 2-**Laboratory:**
The following labs were routinely ordered for all patients on presentation: Complete blood count (CBC), prothrombin time (PT), prothrombin concentration (PC), international normalized ratio (INR), aspartate aminotransferase (AST), alanine aminotransferase (ALT), random blood sugar (RBS), urea, and creatinine. Other labs were ordered according to the patients’ co-morbidities.

- **Operative Technique:**
  - **Group A: Distal tibial locked plate with MIPO technique:**
    1- **Patient Positioning:**
    Patients were positioned supine on a radiolucent operative table with elevation of the contralateral iliac crest. This permits rotation for better access to the medial side. Under spinal anaesthesia and ceftriaxone is given at induction of anaesthesia. A pneumatic tourniquet was applied to the thigh. Fibula was fixed if fractured within 7 cm from the tip of lateral malleolus or if it will help in reduction of tibia, this was left to surgeon discretion. Open reduction and internal fixation of fibular fracture, (if decided) was initially performed with the use of a 1/3rd tubular plate through the lateral approach. Establishment of correct tibial length was accomplished by reducing and stabilizing the fibular fracture.
    2-Incision:
    A 2-3 cm incision was made along the antero-medial aspect of the tibia distally at the level of the medial malleolus and proximally about 2-3 cm incision proximal to the end of fracture line.
    3-Introduction of plate:
    A subcutaneous extra periosteal tunnel was created using periosteal elevator, through which a plate was then introduced taking care not to damage the periosteum and choosing an appropriate plate size and determine the level of the plate with the aid of the image intensifier.
    4-Reduction and Fixation:
    Percutaneous closed reduction of the fracture was done by manual manipulation, percutaneous clamps or fixator assisting reduction.
    The distal screws were then inserted, two screws were usually inserted one over the medial malleolus and one right below the fracture site, the later screw helps in bony reduction, taking advantage of the anatomical configuration of the plate.
    With preservation of reduction, proximal screws were taken through small incisions, then the remaining distal screws.
    Care must be taken during closure of subcutaneous tissue to cover the plate properly, and skin not to be under tension.
  - **Group B: Fixation by Expert nail:**
1- Positioning:
Patients under spinal anaesthesia and ceftriaxone is given at induction of anaesthesia. A pneumatic tourniquet was applied to the thigh. Patients were placed supine with the knee flexed 90 degrees on a radiolucent table that provides wide access for an image intensifier that is typically brought in from the opposite side. A bolster under the thigh to allow for up to 110 degrees of knee flexion.

2- Incision
The skin incision had to be in line with the central axis of the medullary canal. Depending on the anatomy of the patient and surgical preference, the deep incision was transpatellar, medial or even lateral parapatellar extending from the inferior pole of the patella to the tibial tuberosity.

3- Starting point
The correct entry point was important for the alignment of the nail. In the A.P. view the entry point was in line with the axis of the intramedullary canal and with the lateral tubercle of the intercondylar eminence. In lateral view the entry point was at the ventral edge of the tibial plateau.

4- Creation of nail entry site:
A solid awl was used. Before the full opening was created, confirmation of correct entry by image intensifier was done.

5- Fracture reduction
Reduction was an essential part of intramedullary nailing. The fracture was reduced to allow guide-wire placement, during reaming, and during nail insertion. Length, angulation, and rotation were all important to restore. Even after guide-wire insertion, further correction of alignment was needed to avoid deformity. Sometimes only mild traction and rotational adjustment were required. Percutaneous reduction aids (pointed reduction forceps or ball-spike pusher) may allow reduction without opening the fracture. With other fractures, blocking (pollar) screw was necessary, we began with less invasive reduction techniques, and if they did not succeed, progressed to more invasive techniques.

6- Insertion of the guide wire
A ball-tipped guidewire was inserted through the entry portal into the tibial canal and passed it across the fracture site into the tibia under fluoroscopic guidance. The guide rod should be centered within the distal fragment on anteroposterior and lateral views and advanced to within 1.0 cm to 0.5 cm of the ankle joint.

7- Reaming
Reaming was performed with deep fluted, small core diameter sharp reamers. They were advanced slowly at high speed, increasing the diameter by 0.5-mm until characteristic cortical sound was encountered.

8- Nail insertion
The insertion device and proximal locking screw guide was attached to the nail. The apex of the proximal bend in the nail was directed posteriorly, the nail was inserted with the knee in flexion to avoid impingement on the patella. Rotational alignment by aligning the iliac crest, patella, and second ray of the foot was evaluated.

Moderate manual pressure with a gentle back- and-forth twisting motion usually was sufficient for nail insertion. When the nail was fully inserted the proximal end should lie 0.5 to 1.0 cm below the cortical opening of the entry portal. This position was best seen on a lateral fluoroscopic view. The distal tip of the nail was lied 0.5 to 2.0 cm from the subchondral bone of the ankle joint. Very distal fractures require nail insertion near the more distal end of this range.

9- Interlocking screws:
Some nail systems use oblique proximal locking screws that are directed anteromedial to posterolateral and anterolateral to posteromedial. Expert nail has multidirectional interlocking screws.

10- Closure
The surgical wounds were closed in layers with interrupted absorbable sutures. The paratenon of the patellar tendon sheath was repaired if was opened as part of the approach.

Postoperative management:
- Patients with fibular fracture and not fixed were put in posterior slab.
- Immediate postoperative X-rays were obtained: whole leg AP and Lat.
- Neurovascular status was examined.
- Intravenous broad-spectrum antibiotics were prescribed for two days.
- Low molecular weight heparin was given every 24 hours postoperative to all patients till mobilization as prophylaxis against DVT and pulmonary embolism.
- Patients were discharged from the hospital on the third postoperative day on oral broad-spectrum antibiotics for one week, analgesics and anti-edematous medications, and instructions for knee and ankle ROM and quadriceps muscle exercise, but not allowed to weight bear.

Follow-up program:
- At 2 weeks: stitches were removed. Weight bearing was restricted to the injured side with crutches held on both sides.
- At 6 weeks: the patients were screened for any infection and follow-up AP and Lat whole leg X-rays were done. Range of motion and strengthening of the muscles were assessed. Patients were allowed toe-touch weight bearing.
- At 12 weeks (3 months): X-rays were done to check for signs of union or fixation failure. If full union occurred, patients were instructed to start full weight bearing. If the fracture showed callus formation but not fully united, patient was instructed to partially weight bearing.
- At 24 weeks (6 months): Follow-up X-rays were obtained. If full union occurred, patients were instructed to start full weight bearing and return to the work.

3. Results
From February 2021 to December 2021, a prospective randomized study was conducted at orthopedic surgery department of Benha University hospital to compare Expert nail vs. distal tibial plate with MIPPO technique.
in fixation of extra-articular lower fourth tibial fractures. The study included 20 patients their ages were between 20-52 years, they were 13 males and 7 females. The patients were 12 heavily active patients, 5 moderate active patients and 3 lightly active patients. 4 patients were hypertensive and one patient was diabetic. All 20 patients were with unilateral fracture, 9 patients had the right side affected and 11 patients had the left side affected. There was insignificant difference (P>0.05) in the MIPPO group, 8 fractures (80%) united and one fracture (10%) had delayed union and one (10%) failed to unite. In the Expert nail group, 10 fractures (100%) united (Figure 1).

In MIPPO group, one fracture united in rotational deformity (external rotation 25 degree). In Expert nail group 2 (20%) fractures united on coronal plane deformity. No statistical significance was found when the two groups were compared (P value 0.261) (Figure 2).

Mean time for union in Expert nail 14 ± 2.85 weeks, while in MIPPO group 17.07 ± 4.01 weeks. This showed statically significant for Expert nail (P value: 0.041). Expert nail showed faster time of union. (Figure 3).
In MIPPO group, 3 patients (30%) sustained deep infection. Debridement was done for the 3 patients, 2 of them became clean and united, while one developed resistant infection. In Expert nail group, 2 patients (20%) showed superficial infection. Antibiotics according to culture and sensitivity was administrated and the wounds become clean. No statistical significance was found when the two groups were compared (P value 0.079). (Figure 4).

In MIPPO group, 3 patients (30%) needed secondary surgeries (2 debridement, 1 revision). While in Expert nail group, one patient needed to secondary operation (fibular revision). Statically this showed no significance (P value 0.381). (Figure 5).

In MIPPO group, 5 patients (50%) were graded as excellent, 4 patients (40%) good and one patient (10%) poor. In Expert nail group, 7 patients (70%) were graded as excellent, 2 patients (20%) good and one patient (10%) fair. No statistical significance was found when the two groups were compared. (Figure 6).
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Fig. (6) AOFAS Score in both groups

4. Discussion
Tibial fractures are seen often, and successful results may be achieved with various surgical techniques. Distal tibial fractures are much more problematic because of the surrounding soft tissues being thinner than the proximal tissues and the poor vascularization. Although distal tibial plate with MIPO technique and Expert nail have proven to be effective widely accepted treatment options for distal tibial fractures. [9]

A total of 20 patients were included in this study (males 13, females 7) with mean age of 34.67 years and standard deviation 15.19. 10 patients in group A: fixed by distal tibial plate with MIPO technique, and 10 patients in group B: fixed by Expert nail. Epidemiological (Age, sex, Occupation and comorbidities) and preoperative data (MOT, associated fibular fracture) were not statistically significant in both groups. Follow up for 6 months. Our assessment measurements include: operative time, superficial infection, deep infection, union (united, delayed union, non-union), Alignment, need for secondary operations (dynamization, debridement, revision) and AOFAS score after 6 months.

A randomized controlled trial has been published comparing between expert tibial nail and distal tibial medial locking plate by MIPO technique for closed extra articular distal tibial fracture Roshan Raj KM, Nanda Kumar R, Manoharan M. (2019) [10].

Regarding time of surgery: in our study, in MIPO group mean operative time was 118.00 minutes with standard deviation 22.01. Expert nail group mean operative time was 114 minutes with standard deviation 21.18 (P value 0.082) which is not significant in this study.

In Roshan Raj KM, Nanda Kumar R, Manoharan M. (2019) [10] the mean duration of surgery among the patients who underwent expert nail was 72.19 (±10.483) minutes while it was 98.13 (±11.236) minutes among the patients undergoing plate osteosynthesis by MIPO technique. There was statistically significant difference (p<0.001).

Regarding time to union: in our study showed statistically significant decrease in Expert nail group. In Expert nail group time to union was 14.00 weeks with SD 2.85, while in MIPO group was 17.07 weeks with SD 4.01. One patient in MIPO group showed nonunion (P value 0.041). This is the main significant postoperative result in our study. In Roshan Raj KM, Nanda Kumar R, Manoharan M. (2019) [10], The mean time for fracture union among the patients who underwent intramedullary nail was 19.25 (±3.642) weeks while it was 24.13 (±6.428) weeks among the patients undergoing plate osteosynthesis by MIPO technique. The time for fracture union among patients who underwent intramedullary nail was significantly less when compared to plating (P value 0.013).

Regarding to malunion: in our study, in MIPO group one patient showed rotational deformity (25-degree external rotation). In expert nail 2 patients showed coronal plane malalignment which showed statistically insignificant (P value 0.261). In Roshan Raj KM, Nanda Kumar R, Manoharan M. (2019) [10], patients who underwent expert nail for distal tibial fracture had higher proportions of malunion (6.3%).

Regarding to delayed union: in our study, in MIPO group one patient showed delayed union of the fracture while there was no patient in expert nail group showed delayed union of the fracture which showed statistically insignificant (P value 0.426). In Roshan Raj KM, Nanda Kumar R, Manoharan M. (2019) [10], in MIPO group 2 patients showed delayed union of the fracture and 2 patients in expert nail group showed delayed union of the fracture.

Regarding to non-union: in our study, in MIPO group one patient showed non-union of the fracture while there was no patient in expert nail group showed non-union of the fracture which showed statistically insignificant (P value 0.426). In Roshan Raj KM, Nanda Kumar R, Manoharan M. (2019) [10], in MIPO group three patients showed non-union of the fracture (18.8) while there was no patient in expert nail group showed non-
union of the fracture. This means plating had higher proportions of non-union.

Regarding to infection: in our study, 3 patients in MIPPO group developed deep infection. Two of them become clean after debridement and the last one was resistant and ended with infected nonunion and needed revision. Delayed debridement time was most probably the cause of resistant infection. While in Expert nail group, 2 patients developed superficial infection which healed with antibiotics according to culture and sensitivity and repeated dressing. In Roshan Raj KM, Nanda Kumar R, Manoharan M. (2019) [10], two patients in MIPPO group developed superficial infection and one patient developed deep infection while there was no patient in expert nail group had developed infection. This means plating had higher proportions of infection.

In our study, 5 patients in MIPPO group got excellent in AOFAS score and 4 got good while 1 was graded as poor. Patient with poor score had developed infected non-union. In Expert nail group, 7 patients got excellent, 2 patients were good and one was fair. Patient who got fair score showed fibular non-union. P value regarding AOFAS score in both groups was 0.392 which was statistically insignificant. In Roshan Raj KM, Nanda Kumar R, Manoharan M. (2019) [10], according to the Olreud-Molander Ankle score in Expert nail group, 14 patients got excellent, 2 patients were good while in MIPPO group 8 patients got excellent score and 8 got good There was statistically significant difference (p=0.019) in the Olreud-Molander Ankle score among the two procedure groups. The patients with expert nail had higher proportions in excellent groups when compared to patients with plating.

In our study there was learning curve as the first operation in MIPPO group took longer time (160 min) than the last operation (100 min) and in expert nail group, the first operation took longer time (160 min) than the last operation (100 min).

The study was done only among a smaller group of patients with lower fourth tibial fracture and the duration of follow-up was short ranging from 6-9 months and there was leakage of control group

Although of this limitations, there was only one study comparing between expert nail and MIPPO in fixation distal tibial fracture as our study. Due to lower infection rate and faster time of healing, Expert nail will be used more than MIPPO technique in fixation lower fourth tibial fracture.

5. Conclusion

Both techniques can provide effective treatment and fixation for closed lower fourth extra-articular tibial fractures. Expert nail showing lower infection rate and faster time to healing but with more mal-alignment reduction. While in MIPO technique less mal-alignment reduction can achieve but with more infection problems and slower rate of union.

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Conflicts of interest:

There are no conflicts of interest.

References


