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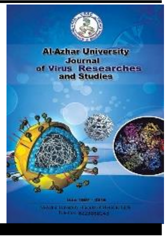

A Comparative Study of Intramedullary Interlocking Nail and Locked Plate Fixation in the Management of Extra Articular Distal Tibia Fractures

Abbas El-Sayed Abbas Ali Hamad*[1], Mahmoud Mabrouk Saeid[1] and Mohammed Ramadan El-Fishawy[1]

[1]Department of Orthopaedics Surgery, Faculty of Medicine for Girls, Al-Azhar University, Cairo, Egypt

***E-mail: drabbas725@gmail.com**

Abstract

Distal tibial fractures accounts for approximately 37.8% of all tibial injuries. Fractures of the distal tibia affecting all ages. Treatment of distal tibial fractures in skeletally mature patients without articular extension is challenging because of its unique anatomical characteristics of subcutaneous location with weak blood supply and proximity to the ankle joint. To compare clinical and radiological outcomes in extra articular fractures of distal tibia treated by interlocking intramedullary nails or locked plates. This study was done at *Al-Helal* Hospital, during the period of February 2021 to August 2021. A total of 20 patients were recruited for this study to compare ILN vs. distal tibial locked plate with open technique in fixation of extra-articular distal tibial fractures. Patients were assessed clinically using Olerud and Molander score and radiologically at 6months. The average time for union was 13.10 weeks (range, 12-16 weeks) in group A (looking intramedullary) and 16.78 weeks (range,12-24 weeks) in group B (distal tibia locked plate) malunion was found in 20% of patients in group A (looking intramedullary) and 10% of patients in group B (distal tibia locked plate). The overall results were comparable, and most patients were satisfied with the results. These results indicate that both modalities of treatment deserve a place in treating distal metaphyseal fractures of tibia. Both techniques can provide effective treatment and fixation for closed extraarticular fractures. ILN showed lower infection rate and faster time to healing but with more mal-alignment reduction. While in open reduction internal fixation technique less mal-alignment reduction could be achieved but with more infection problems and slower rate of union.

Keywords: Intramedullary Interlocking nail, locked plate fixation, Management extra articular distal tibia fractures.

1. Introduction

Fracture is the result of mechanical overload with important biological consequences. Proper understanding of mechanical and biological aspects of fracture repair is the key for selection of particular type of treatment modality for a given fracture [1]. Tibia is the most commonly broken long bone in the body. Injuries usually require hospital admission and frequently require surgery, resulting in prolonged periods (months) away from work and social activities. Tibial diaphysis is the most common site of fracture in the tibia and about 80% of these injuries have associated fibular fractures. Published data suggest an incidence of 17 per 100,000 person-years, although more recent data indicate that the incidence may be declining [2, 3]. Distal tibia shaft fractures account for approximately 37.8% of all tibial injuries. Fractures of the distal tibia affecting all ages. Treatment of distal tibial fractures in skeletally mature patients without articular extension is challenging because of its unique anatomical characteristics of subcutaneous location with week blood supply and proximity to the ankle joint. External fixation combined with limited open reduction and internal fixation (EF + LORIF) has been recommended by some authors, with minimal soft tissue complications, good functional results, and no local soft tissue irritation. With the development of locking plates and biological fixation for treating fractures of the extremities [4]. The aim of the work compares clinical and radiological outcomes in extra articular fractures of distal tibia treated by interlocking intramedullary nails or locked plates.

2. Patients and Methods

From February 2021 to August 2021, a prospective randomized study was conducted at *Al-Helal* Hospital including 20 patients to compare ILN vs. distal tibial locked plate in fixation of extra-articular distal tibial fractures.

2.1 Inclusion Criteria

Adults (aged more than 18 years) males and females and Complex extra articular meta-diaphyseal fractures of the lower third of tibia.

2.2 Exclusion Criteria

Open fractures, intra articular fractures, patients with vascular injury, patients aged below 18 years and pathological fractures. 20 patients who met the inclusion criteria were divided into 2 groups; 10 patients in each group**:** ***Group A:*** patients fixed by ILN and ***Group B:*** patients fixed by locked plate. The study was conducted after taking clearance from the scientific board and the ethical committee of our department.

2.3. Patients' evaluation includes:

2.3.1. Clinical evaluation:

- **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 and Pre-fracture level of activity.

- **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 and Local examination of the injured limb involved assessment of the vascular and neurological status with attention to wounds, abrasions and local soft tissue condition.

2.3.2. Investigations:

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

- **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.

• **Preoperative management:** Appropriate pain relief was provided by systemic analgesics, temporary stabilization by above knee slab in all patients was done, Proper control of blood sugar level was achieved in diabetic patients, Patients" co-morbidities were optimized, all patients were consented for surgery, possible complications, randomization, and the study and a prophylactic antibiotic, namely the first-generation antibiotic, was given to all patients 30-45 minutes prior to surgery.

2.4 Operative procedures:

2.4.1. Group A: Fixation by locking intramedullary nail:

1-Positioning: 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. The deep incision was medial 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 (Fig. 1).

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, using poller screws as blocking screws (two cases) helps to control deformity in the coronal plane by narrowing the medullary canal. we began with less invasive reduction techniques, and if they did not succeed, progresses to more invasive techniques (Fig. 2,3).

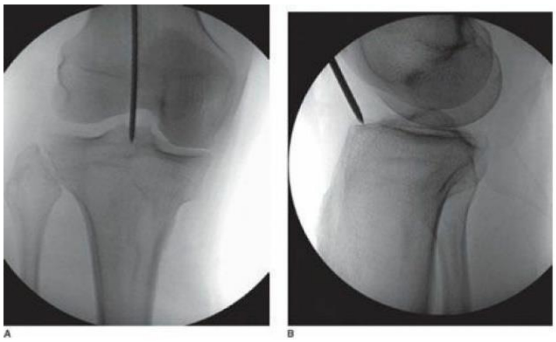

Figure (1): AP (A) and Lateral (B) views of the proximal tibia demonstrate the ideal starting point for a tibial nail. With either an awl or with a guide pin that can be enlarged with a cannulated drill or awl.

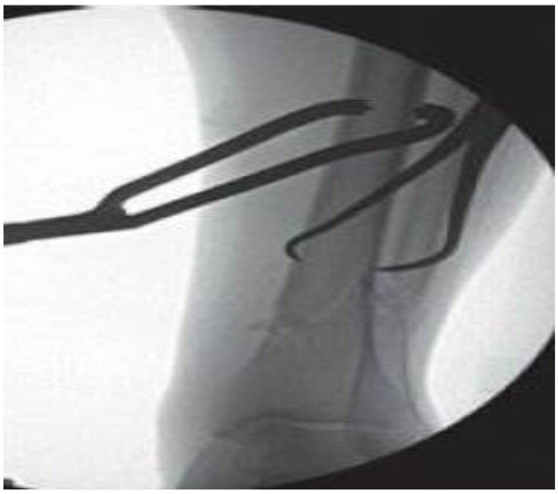

Figure (2): Reduction of spiral fracture by reduction clamp.

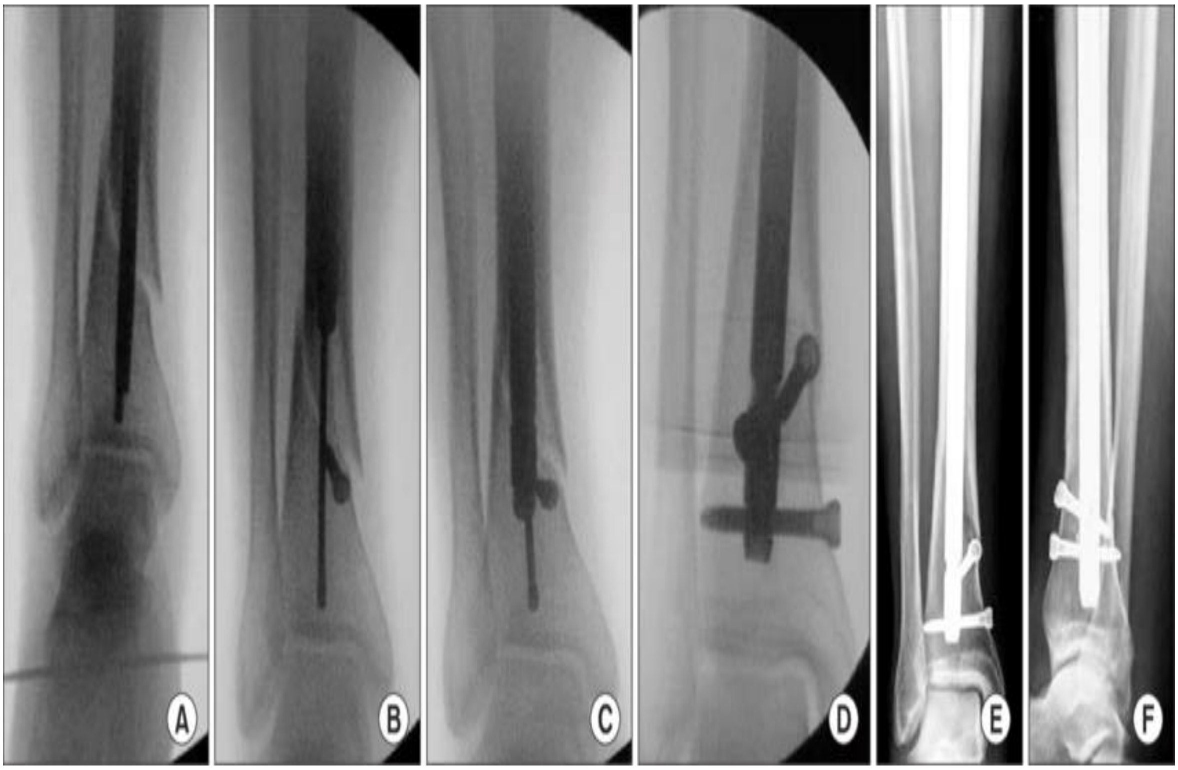

Figure (3): Using poller screws as blocking screws.

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 (Fig.4).

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 cortical chatter is encountered.

8- Nail insertion: Attaching the insertion device and proximal locking screw guide to the nail. Directing the apex of the proximal bend in the nail posteriorly Inserting the nail with the knee in flexion to avoid impingement on the patella. Evaluating rotational alignment by aligning the iliac crest, patella, and second ray of the foot. 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 should lie 0.5 to 2.0 cm from the subchondral bone of the ankle joint.

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. In our study we use 8 expert nails and 2 conventional nails. Expert nail costs double of ordinary nail system.

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

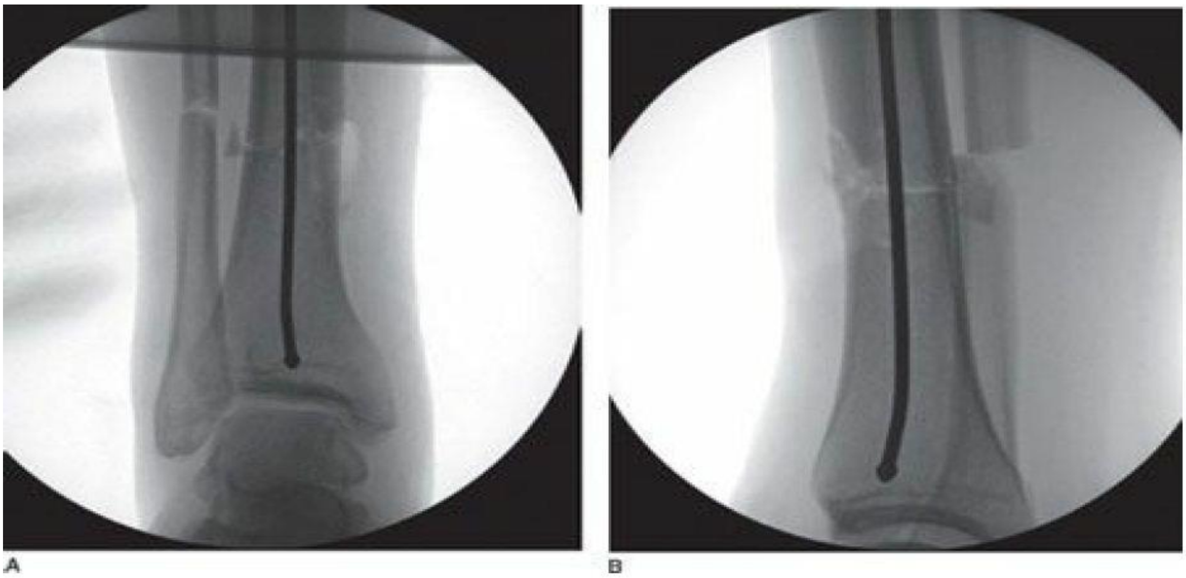

Figure (4): Guide wire must be in the central portion of the distal fragment in both the AP and lateral views to avoid a translational or angular deformity.

2.4.2. Group B: Distal tibial locked plate:

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. 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 (7 cases), 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 (Fig.5).

2- Incision: 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 (Fig. 6).

3-Reduction and Fixation: Open reduction internal fixation of the fracture was done by manual manipulation or clamps (Fig. 7).

2.5 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 and 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 except those provided with back slab, but not allowed to weight bear.

2.6 Follow-up program: At 2 weeks: stitches were removed. Weight bearing was restricted to the injured side with crutches held on the other side, 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 to start weight bearing and exclude fixation failure and at 24 weeks (6 months): Follow-up X-rays were obtained. If full union occurred, patients were instructed to start full weight bearing.

2.7 Evaluation: Union: Fracture union is defined as the absence of pain at fracture site and the presence of bridging callus in 3 of the 4 cortices seen on the AP and lateral radiographs of the tibia. Time to union was recorded and Alignment of the bone: Malalignment was defined as greater than 5° ante-/ recurvation, greater than 5° varus/valgus deformity, or greater than 15° rotation difference. Rotational deformity was measured with the patient supine with both patellae facing forward. The angles were measured between the lateral edge of the feet and the surface of the bed. The left and right sides will be compared.

2.8 Functional Score [6]: The functional outcome will be calculated using a standard set of questions. Olerud-Molander Ankle Score (OMAS)6 was used.

2.9 Olerud-Molander Ankle Score (OMAS) [6]: Is a self-administered patient questionnaire. The least possible score was 0 (totally impaired) to a maximum possible score of 100(completely normal). It is based on nine different aspects: 1. Pain 2. Stiffness 3. Swelling, 4. Stair climbing 5. Running 6. Jumping 7. Squatting 8. Supports 9. Activities of daily life.

Figure (5): Positioning and draping of distal tibial locked plate.

(A) (B)

Figure (6): (A) Choosing an appropriate plate size (B) Determine the level of the plate with the aid of the image intensifier which show fracture medial malleolus.

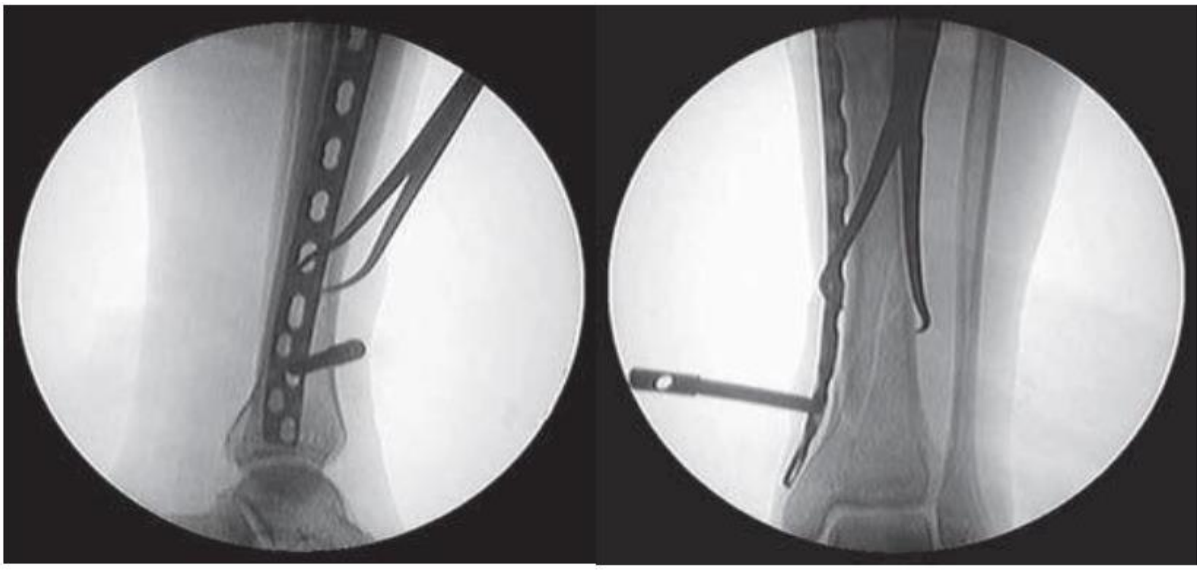

Figure (7): The plate correctly positioned so that the plate itself acts as a reduction mould.

Table (1): Olerud-Molander Ankle Score [6].

Parameter	Degree	Score
I. Pain	None	25
	While walking on uneven surface	20
	While walking on even surface outdoors	10
	While walking indoors	5
	Constant and severe	0
II. Stiffness	None	10
	Stiffness	0
III. Swelling	None	10
	Only evenings	5
	Constant	0
IV. Stair-climbing	No problems	10
	Impaired	5
	Impossible	0
V. Running	Possible	5
	Impossible	0
VI. Jumping	Possible	5
	Impossible	0
VII. Squatting	No problems	5
	Impossible	0
VIII. Supports	None	10
	Taping, wrapping	5
	Stick or crutch	0
IX. Work, activities of daily life	Same as before injury	20
	Loss of tempo	15
	Change to a simpler job/ part-time work	10
	Severely impaired work capacity	0

Table (2): Score Grade [6].

91-100	Excellent
61-90	Good
31-60	Fair
0-30	Poor

3. Results

From February 2021 to Augast 2021, 20 patients with extra-articular distal tibial fractures met the inclusion criteria. They were divided into two groups; 10 patients in each group:

- Group A was fixed using ILN.
- Group B was fixed using locked plate.

The 20 patients were followed-up for at least 6 months and up to 9 months. The mean follow-up period was 7.13 months. Table. 3 shows that there was no statistically significant difference found between nail group and plate group regarding demographic data and characteristics of the studied cases. Table. 4 shows that there was no statistically significant difference found between the two studied groups regarding mode of trauma and fracture side while there was statistically significant difference found between them regarding fibular fracture. Table. 5 shows that there was no statistically significant difference found between the two studied groups regarding AO classification of the fracture.

Table (3): Demographic data and characteristics of the studied cases.

		Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
Age	Mean ± SD	33.10 ± 10.90	36.30 ± 13.43	-0.585•	0.566	NS
	Range	20 – 57	20 – 55			
Sex	Male	7 (70.0%)	7 (70.0%)	0.000*	1.000	NS
	Female	3 (30.0%)	3 (30.0%)			
Occupation	Light Activity	1 (10.0%)	0 (0.0%)	3.818*	0.148	NS
	Moderate	2 (20.0%)	6 (60.0%)			
	Heavy	7 (70.0%)	4 (40.0%)			
HTN	No	9 (90.0%)	9 (90.0%)	0.000*	1.000	NS
	Yes	1 (10.0%)	1 (10.0%)			
DM	No	10 (100.0%)	9 (90.0%)	1.053*	0.305	NS
	Yes	0 (0.0%)	1 (10.0%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

Table (4): Mode of trauma, fracture side and fibular fracture in the two studied groups.

		Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
Mode of trauma	Direct	2 (20.0%)	4 (40.0%)	1.167*	0.558	NS
	RTA	5 (50.0%)	3 (30.0%)			
	FFH	0 (0.0%)	0 (0.0%)			
	FTG	3 (30.0%)	3 (30.0%)			
Fracture side	Rt	4 (40.0%)	4 (40.0%)	0.000*	1.000	NS
	Lt	6 (60.0%)	6 (60.0%)			
Fibular fracture	Intact	1 (10.0%)	1(10.0%)	0.000	1.000	NS
	Fractured	9 (90.0%)	9 (90.0%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

Table (5): AO classification of the fracture in the two studied groups.

Classification	Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
43A1.1	5 (50.0%)	1 (10.0%)	5.867*	0.319	NS
43A1.2	2 (20.0%)	3 (30.0%)			
43A1.3	1 (10.0%)	1 (10.0%)			
43A2.1	0 (0.0%)	1 (10.0%)			
43A2.3	2 (20.0%)	2 (20.0%)			
43A3.3	0 (0.0%)	2 (20.0%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

Table. 6 shows that there was no statistically significant difference found between the nail group and plate group regarding operative time. Table. 7 shows that there was statistically significant difference found in fibular fixation between nail group and plate group. Table. 8 shows that there was no statistically significant difference found between nail group and plate group regarding malnunion.

Table (6): Comparison between nail group and plate group regarding operative time.

Operative time	Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
Mean ± SD	116.00 ± 16.47	127.00 ± 18.89	-1.388•	0.182	NS
Range	100 – 150	100 – 150			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

Table (7): Comparison between nail group and plate group regarding fibular fixation.

		Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
Fibular fixation	Intact	2 (20.0%)	1 (10.0%)	7.611*	0.022	S
	Fixed	1 (10.0%)	7 (70.0%)			
	Not fixed	7 (70.0%)	2 (20.0%)			

Table (8): Comparison between nail group and plate group regarding malnunion.

Malunion	Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
No	8 (80.0%)	8 (80.0%)	4.000*	0.261	NS
Sagittal plane deformity	0 (0.0%)	0 (0.0%)			
Coronal plane deformity	2 (20.0%)	0 (0.0%)			
Rotation	0 (0.0%)	1 (10.0%)			
Nonunion	0 (0.0%)	1 (10.0%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

Table. 9 shows that there was statistically significant difference found between nail group and plate group regarding time for union. Table. 10 shows that there was no statistically significant difference found between nail group and plate group regarding infection. Table. 11 shows that there was no statistically significant difference found between nail group and plate group regarding need for secondary procedure.

Table (9): Comparison between nail group and plate group regarding time for union.

Time for union	Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
Mean ± SD	13.10 ± 1.52	16.78 ± 4.06	-2.673•	0.016	S
Range	12 – 16	12 – 24			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

Table (10): Comparison between nail group and plate group regarding infection.

Infection	Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
Non	10 (100.0%)	9 (90.0%)	1.053*	0.305	NS
Superficial infection	0 (0.0%)	0 (0.0%)			
Deep infection	0 (0.0%)	1 (10.0%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

Table (11): Comparison between nail group and plate group regarding need for secondary procedure.

Need for secondary procedure	Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
No	10 (100.0%)	9 (90.0%)	1.053*	0.305	NS
Dynamization	0 (0.0%)	0 (0.0%)			
Debridement	0 (0.0%)	0 (0.0%)			
Revision	0 (0.0%)	1 (10.0%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

Table. 12 shows that there was no statistically significant difference found between nail group and plate group regarding Olerud and Molander score. Table. 13 shows that there was no statistically significant difference found between nail group and plate group regarding complications. Table. 14 shows that there was no statistically significant relation found between classification and Olderud – Molander Ankle Score in nail group. Table. 15 shows that there was no statistically significant relation found between classification and Olderud – Molander Ankle Score in plate group.

Table (12): Comparison between nail group and plate group regarding Olerud and Molander score.

Score	Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
Excellent	8 (80.0%)	5 (50.0%)	2.359*	0.307	NS
Good	2 (20.0%)	4 (40.0%)			
Fair	0 (0.0%)	0 (0.0%)			
Poor	0 (0.0%)	1 (10.0%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

Table (13): Comparison between nail group and plate group regarding complications.

Complication	Nail group No. = 10	Plate group No. = 10	Test value	P-value	Sig.
Non	8 (80.0%)	7 (70.0%)	0.267	0.605	NS
Infection	0 (0.0%)	1 (10.0%)	1.053	0.304	NS
Malunion	2 (20.0%)	1 (10.0%)	0.392	0.531	NS
Delayed union	0 (0.0%)	1 (10.0%)	1.053	0.304	NS
DVT	0 (0.0%)	1 (10.0%)	1.053	0.304	NS
Failure of implant	0 (0.0%)	0 (0.0%)	0.000	1.000	NS

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test.

Table (14): Relation between classification in nail group and Olerud – Molander Ankle Score.

Score	Classification in Nail group			Test value	P-value	Sig.
	43A1	43A2	43A3			
	No. = 8	No. = 0	No. = 2			
Excellent	7 (87.5%)	0 (0.0%)	1 (50.0%)	1.406*	0.236	NS
Good	1 (12.5%)	0 (0.0%)	1 (50.0%)			
Fair	0 (0.0%)	0 (0.0%)	0 (0.0%)			
Poor	0 (0.0%)	0 (0.0%)	0 (0.0%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

Table (15): Relation between classification in plate group and Olerud – Molander Ankle Score.

Score	Classification in Plate group			Test value	P-value	Sig.
	43A1	43A2	43A3			
	No. = 8	No. = 0	No. = 2			
Excellent	2 (40.0%)	1 (100.0%)	2 (50.0%)	2.100*	0.717	NS
Good	2 (40.0%)	0 (0.0%)	2 (50.0%)			
Fair	0 (0.0%)	0 (0.0%)	0 (0.0%)			
Poor	1 (20.0%)	0 (0.0%)	0 (0.0%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant *: Chi-square test; •: Independent t-test

3.1 Case Presentation

3.1.1 Case 1: Preoperative data: Female patient, 38 years old, nonsmoker, housewife, co-morbidities: -ve, mode of Trauma: Falls to ground, fracture side: right and AO classification: 43 A1.

Figure (8): Preoperative x-ray.

Figure (9): Immediate post-operative x-ray.

Figure (10): 12 weeks follow up x-rays.

3.1.2 Case 2: Preoperative data: Female patient 50 years old, nonsmoker, housewife, co-morbidities: -ve, mode of trauma: RTA, fracture side: Left, AO classification: 43A1, closed Fracture and associated proximal fibular fracture.

Figure (11): pre-operative x-rays.

Figure (12): Immediate postoperative X-rays.

Figure (13): Follow-up after 12 weeks X-rays showed full union of the fracture by callus.

4. Discussion

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 locked plate and ILN have proven to be effective widely accepted treatment options for distal tibial fractures, limited comparative literature exists to optimize treatment decision [7,8]. Five randomized controlled trials have been published comparing plate versus intramedullary nail fixation of the distal tibia (Table 16). Two have studied locking plates on the tibia, one has used standard anterolateral tibia plates and two have reported on standard medial plates on the tibia. In performing a meta-analysis of these studies, variability in plating type and technique warrants consideration, as implications for soft tissue irritation and wound complications are related. Further difficulty in comparing these studies arises when the management of soft tissues, open reduction is not usually explained in those studies. Associated fibula fractures are considered, also. Patients with an intact fibula or with fibula fixation in combination with intramedullary nailing of the tibia have increased the risk of delayed union or nonunion in some studies. Three of 5 randomized controlled trials to date have performed fibula fixation at surgeon discretion, accounting for fixation of up to 30% of the associated fibula fractures in those studies. It has also been suggested that reduction and fixation of the fibula will aid in obtaining accurate reduction of the tibia, and that fixation of the fibula will reduce risk for later tibia malalignment, although supporting data are limited. In our study, fibula was fixed if within 7 cm from the tip of lateral malleolus or if it will help in reduction of tibia, and this was left to surgeon discretion. Several recent meta-analyses have reviewed comparative studies. In prospective trials, methodological flaws have been noted, including selection bias, small sample sizes, and patient attrition. [9,10,11,12,13].

Table (16): Five randomized prospective trials and 3 retrospective studies comparing plate vs ILN for distal tibial fractures [13].

Study	Wound Complications or superficial infection, %	Deep Infection, %	Malalignment, %	Nonunion, %	Functional Outcomes
Guo et al,5 RCT					AOFAS
n = 41 locked plate	15	0	Not reported	0	84
n = 44 nail	6.8	0		0	86
Im et al,6 RCT					OM
n = 30 anterior plate	23*	3.3	0	6.7	88% of normal
n = 34 nail	2.9	0	12*	8.8	89% of normal
Janssen et al,7 2007					KS
n = 12 plate	0	8.3	17	17	146
n = 12 nail	0	8.3	50*	25*	139
Li et al,8 RCT					Mazur ankle score
n = 42 plate	17*	2.4	7.1	2.4	90% excellent or good
n = 40 nail	2.5	5.0	10	2.5	87% excellent or good
Mauffrey et al,9 RCT					OM: plots show trend for nail to improve faster over 12 mo
n = 12 locked plate	0	8.3	0	17*	
n = 12 nail	25*	0	8.3	0	
Vallier et al10					
n = 37 plate	0	2.7	5.4	2.7	
n = 76 nail	0	5.3	29*	6.6	Not reported
Vallier et al,11 RCT					
n = 48 plate	0	6.3	8.3	4.2	MFA 28; FFI 0.23
n = 56 nail	0	5.4	23*	7.1	MFA 27; FFI 0.29
Yang et al12					OM
n = 14 plate	0	0	7.1	0	84
n = 13 nail	0	0	23*	0	86

Another 3 comparative studies are listed in Table 19, all of which are retrospective, and one of which is case matched with 12 patients each treated with plate or nail. When analyzing the composite of these studies, several points are noteworthy. Deep infection and wound-healing complications are frequent and occur with similar rates after plate or nail fixation, even in patients with high-energy fractures with associated open wounds and severe soft tissue injury [13,14,15,16,17]. Five randomized prospective trials and 3 retrospective studies are included. Plates are specified as locking (vs. standard) and when applied anteriorly (vs. medially). *P, 0.05. AOFAS, American Orthopaedic Foot and Ankle Surgery score; FFI, Foot Function Index; KS, Knee Society rating; MFA, Musculoskeletal Function Assessment; OM, Olerud and Molander Ankle Score; RCT, randomized controlled trial. In recent publications, most patients returned to employment with no limitations once their tibia fracture healed. Previous comparative work has described similar functional outcome scores after distal tibia fracture, whether treated with plate or intramedullary nail fixation [18]. One study demonstrated a trend for patients with a nail to improve quicker than those with locking plates; however, these data were not controlled for a high rate of nonunion in the locking plate group. Historically, anterior knee pain has been noted commonly after tibia nailing. More recent studies have suggested that nails which are not prominent, and which are placed with meticulous surgical technique, minimizing trauma to the patellar tendon and knee joint, do not have a higher frequency of late knee pain, when compared with plates [19, 20]. Our study compared surgical and functional results of two methods, ILN and

ORIF with locked plate. This is a prospective comparative study, performed on all patients with distal tibial extra articular fractures who met the inclusion criteria. We compared our results with the results of the studies in literature which compared the two techniques in management of distal tibial extra articular fracture. We found 5 studies: A prospective, randomized trial comparing closed intramedullary nailing with percutaneous plating in the treatment of distal metaphyseal fractures of the tibia.10. They compared the outcome of closed intramedullary nailing with minimally invasive plate osteosynthesis using a percutaneous locked compression plate in patients with a distal metaphyseal fracture in a prospective study. A total of 85 patients were randomized to operative stabilization either by a closed intramedullary nail (44) or by minimally invasive osteosynthesis with a compression plate (41). Pre-operative variables included the patients' age, the side and pattern of the fracture. Peri-operative variables were the operating time and the radiation time. Postoperative variables were wound problems, the time to union of the fracture, the functional American Orthopedic Foot and Ankle surgery score and removal of hardware. Treatment of distal tibial shaft fractures by three different surgical methods: a randomized, prospective study [10]. In that randomized, prospective study, they aimed to compare ORIF, ILN stabilization and external fixation combined with limited open reduction and absorbable internal fixation for distal tibial shaft fractures by assessing complications and secondary procedures. From November 2002 to June 2012, 137 skeletally mature patients with displaced distal tibial shaft fractures with or without fibula fracture were randomized to be treated by ORIF (group A, n=46), ILN (group B, n=46) or external fixation combined with limited open reduction and absorbable internal fixation (group C, n=45). Age, gender, mechanism of injury, fracture pattern and presence of open fracture were equally distributed among the three groups. Indexes for evaluation included hospital stay, operative time, time to radiographic union, union status, infection and the incidence of re-operation. Mazur ankle score was introduced for functional evaluation. Statistics Analysis System (SAS) 9.2 was used for analysis. A randomized pilot trial of “locking plate” fixation versus intramedullary nailing for extra-articular fractures of the distal tibia. [11]. They performed a pragmatic, randomized, pilot trial to compare intramedullary nailing with 'locking-plate' fixation for extraarticular fracture of the distal tibia. Patients presenting with a closed or Gustillo1, extra articular fracture of the distal tibia were offered the opportunity to participate. post operatively. Mal-union, infection, rate of re-operation and non-union were recorded. The study recruited 12 patients into each group. Randomized, prospective comparison of plate versus intramedullary nail fixation for distal tibia shaft fractures [10]. Randomized, prospective study. One hundred four skeletally mature patients with extra-articular distal tibia shaft fractures with a mean age of 38 years. The majority had high-energy injuries. Patients were randomized to a reamed intramedullary nail (n = 56) or a large fragment medial plate (n = 48). Forty fractures (39%) were open. Twenty-eight (27%) had concomitant fibula fractures that were stabilized. Main outcome measurements: Malunion, nonunion, infection, and secondary operations. Comparison of intramedullary nail and plate fixation in distal tibia diaphyseal fractures close to the mortise [21]. In that study, they aimed to compare the functional and radiological results of intramedullary nailing and plate fixation techniques in the surgical treatment of distal tibia diaphyseal fractures close to the ankle joint. Between 2005 and 2011, 55 patients (32 males, 23 females; mean age 42 years; range 15 to 72 years) who were treated with intramedullary nailing (21 patients) or plate fixation (34 patients) due to distal tibia diaphyseal fracture were included in the study. The average follow-up period was 27.6 months (range, 12-82 months). The patients were evaluated with regard to nonunion, malunion, infection, and implant irritation. The AOFAS (American Orthopedic Foot and Ankle Society) scale was used for the clinical evaluation.

Our study:

A total of 20 patients were included in the study (males 14, females 6) with mean age of 33.10 years and standard deviation 10.90 of group A and mean age of 36.30 and standard deviation 13.43 of group B. 10 patients in group A: ILN, and 10 patients in group B: distal tibial locked plate with open reduction internal fixation technique. Epidemiological (Age, sex, Occupation and comorbidities), preoperative (MOT, AO classification, associated fibular fracture) data and operative time showing no statistically significant difference in both groups. Our assessment measurements include superficial infection, deep infection, union (united, delayed union, non-union), Alignment, need for secondary operations (dynamization, debridement, revision) and Olerud – Molander Ankle Score after 6 months. Regarding to time of surgery, in group A mean operative time was 116 min. with standard deviation16.47. Group B mean operative time was 127 with standard deviation 18.89. P value.182 which is not significant in this study. ***Guo et al.; Li et al.*** Showed significant decrease in operative time in ILN group. Time of surgery depends on many factors: presence of fibular fracture, difficulties in reduction, presence of good assistance and the the expert of surgeon. [8,11]. In our study, no patients in group A developed infection. While in group B, one patient developed deep infection which was resistance and ended with nonunion and need to revision. Delayed debridement time as the patient was uncooperative was most probably the cause of resistance infection. ***Li et al.*** showed significant increase in superficial infection with plate group, while ***Mauffrey et al.*** showed the opposite. The other studies showed no significant in both groups. Infection (deep and superficial) showed best outcome if detected early and aggressive intervention. So, patient follow up is very important to early detection of infection. Mode of trauma, good handling to soft tissues and skin coverage and general condition of the patient were also important factors in development of infection. [11,12]. Time to union in our study showed statistically significant decreased in ILN. In ILN group time to union was 13.10 weeks with SD 1.52, while in open reduction internal fixation 16.78 with SD 4.06.P value is 0.016 this is the main significant result in our study. Other studies showed no significant difference in both groups. ILNs are weight shearing devices while Plates are weight bearing. This may allow to decide partial weight bearing earlier in ILN group which create micromotions in fracture site and induce healing. In open reduction internal fixation group one patient showed rotational deformity (25-degree external rotation), and one patient show delayed union, In ILN 2 patients showed 17. coronal plane malalignment. ***Mauffrey et al.*** showed significant non-union rate in plate group, while other studies showed no significant differences in both groups in union rate. ***Vallier et al.*** showed significant mal-alignment reduction in ILN group [12,14]. ***Mauffrey et al.*** showed significant need for secondary surgeries in plate group, Debridement and removal of plate after short time of union due to skin irritation were the main secondary operations in plate group, while dynamization (removal of dynamic screw) is the majority in ILN group. Other studies showed no significant differences in need for secondary operation [12]. In our study, 5 patients in open reduction internal fixation group get excellent in **Olerud-Molander Ankle Score** and 4 get good while 1 was poor. Patient with poor score who develop infection nonunion. In ILN group, 8 patients get excellent, 2 patients were good. P value regarding to **Olerud-Molander Ankle Score** in both groups was 0.307 which is statistically insignificant. Each study used different outcome clinical scores at the end of follow up, no significant differences in clinical outcome comparing both groups.

Conclusion

Both techniques can provide effective treatment and fixation for closed extraarticular fractures. ILN showed lower infection rate and faster time to healing but with more mal-alignment reduction. While in open reduction internal fixation technique less mal-alignment reduction could be achieved but with more infection problems and slower rate of union. Good handling to soft tissues is an important factor to rapid healing of the fracture and to avoid complications. Good pre-operative planning for each patient to achieve good reduction with minimal soft tissue injury was an important as it reduce time of operation and the need for secondary surgeries.

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