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Comparative study between distal fibular locked plate and other conventional plates for fixation of lateral malleolar fracture

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Abstract

Background: Conservative therapy is suitable for stable isolated lateral malleolus fractures (LMF), but surgical fixation is the preferred approach for displaced, unstable LMF. This work aimed to contrast the findings of fixation of lateral malleolus fracture by using locked or conventional plates at least for 6 months.

Methods: This prospective comparative work had been conducted on 30 participants aged from 18 to 65 years old, both genders, with ankle fractures. Participants had been categorised into two groups equally in a parallel manner: Group 1: Participants with ankle fracture that had been managed with conventional methods band Group 2: Participants with ankle fracture that had been managed with distal fibular locked plate.

Results: American orthopaedic foot and ankle society (AOFAS) score had been significantly greater at 6 m and 12 m in group 2 compared to group 1 (p<0.05). Range of motion (ROM) (extension and flexion) were significantly higher at 1 m, 2 m, 3 m, 6 m and 12 m in group 2 compared to group 1 (p<0.05). Radiography union was significantly higher at 2 m, 3 m and 12 m in group 2 compared to group 1 (p<0.05). Healing time was significantly decreased in group 2 compared to group 1 (p=0.001). Superficial infection delayed wound healing and plate removal were insignificantly different between two groups.

Conclusion: In patients with ankle fracture, fixation of lateral malleolus fracture by using locked plate had higher AOFAS score, ROM (Extension and flexion), Radiography union and lower healing time than conventional plate at least for 6 months.

Keywords: Distal fibular locked plate, conventional plates, fixation, lateral malleolar fracture, AOFAS score

Introduction

Fractures of the ankle are the third most frequent fractures in older patients, occurring after fractures of hip and wrist, with an incidence rate of 184 occurrences/100,000 individuals/year ^[1]. With the ongoing growth in life expectancy, it is projected that these injuries will see a 25% surge by 2050. Consequently, they will become more prevalent in the everyday practice of most orthopaedic departments ^[2].

The treatment of these fractures in older people remains complicated due to a relatively high risk of wound-associated complications, hardware failures, and sepsis ^[3].

Surgical management using open reduction alongside internal fixation is recognized to be the preferred practice for displaced and unstable lateral malleolar fractures (LMF). This is because it is associated with better outcomes in terms of regaining the alignment and length of the fibula along with preserving the lateral malleolus stability ^[4].

While surgical intervention offers improved anatomical alignment and functional outcome, it is sometimes accompanied by problems like mal-union, nonunion, posttraumatic osteoarthritis, and infections of the wounds, especially in older individuals ^[5].

Conservative therapy is suitable for stable isolated LMF, but surgical fixation is considered the most effective management for displaced, unstable LMF^[6].

From a theoretical standpoint, fixing the fibula can potentially improve patients' ability to

control limb rotation and anatomical alignment. However, surgical interventions involving the distal fibula often led to adverse effects like mal-union, nonunion, post-traumatic osteoarthritis, and infections due to the anatomical characteristics of the fibula ^[7].

Currently, the locking compression plates (LCPs) are being utilised for the management of several fractures, including distal fibular fractures, owing to their solid fixations and ability to apply minimally intrusive plate osteosynthesis (MIPO) approach. There are two commonly utilised types of LCPs: the LCP distal fibula plate.

And the LCP metaphyseal plate [8].

This work aimed to contrast the results of fixation of lateral malleolus fracture by using locked or conventional plates at least for 6 months.

Patients and Methods

This prospective comparative work had been conducted on 30 participants aged from 18 to 65 years old, both genders, with ankle fractures (closed fractures, bimalleolar and trimalleolar fractures, and displaced lateral malleolus fractures). The work had been performed following approval from the Ethics Committee Al-Azhar University Hospitals, Cairo, Egypt. All participants provided well-informed written consent.

The criteria for exclusion were open fractures and fractures with a fracture line located > 9 cm away from the tip of the fibula and pathological fractures.

Randomization

Computer-generated randomization numbers were used for random allocation and each patients' code was kept in an opaque sealed envelope. Patients were randomly allocated with 1:1 allocation ratio into two equal groups in a parallel manner: Group 1: Participants with ankle fractures that had been managed with conventional methods band Group 2: Participants with ankle fractures that had been managed with distal fibular locked plate.

Each participant had been exposed to taking of history, general and local examination, laboratory investigations and radiological examination.

Surgery and postoperative care

The recipients had surgery while positioned supine, using a pneumatic tourniquet. Throughout the procedure, all participants were assessed for potential syndesmotic injuries. A syndesmotic injury was defined as a widening of the medial clear space greater than 5 mm, and if present, it was repaired. Following the completion of fracture reduction, interfragmentary screws were utilised in a suitable manner wherever feasible. Subsequently, the fracture was stabilised using a locking tubular (1/3 Tubular LCPs ©Xrbest Jiangsu. China) or a locking anatomical plate (Distal Fibula LCPs ©Xrbest Jiangsu. China). Following the operation, the individuals were initially sent to the anaesthesia recovery unit for a duration of 2 hours, and subsequently transferred to the in-patient's unit. After being transferred to the inpatient's unit, the surgical sites were treated with cold packs for a duration of 12 hours. Celecoxib was orally taken at a standard dosage of 200 mg twice daily for regular pain management following the surgery, provided there were no contraindications. Subsequently, it was administered in accordance with the given instructions. Every patient was administered antibiotic prophylaxis in the form of a single dosage of 2 grammes of the 2nd generation cephalosporin. If a patient had an allergy,

they were administered either levofloxacin or teicoplanin in accordance with the hospital's procedure. Every patient was administered low molecular-weight heparin as a preventive measure against blood clot formation starting 6 hours after the surgery and continuing until the patient was no longer immobilised, which lasted for a period of 30 days. A brief leg cast was put for the purpose of managing soft tissue on the initial three days. Participants were instructed to schedule follow-up appointments on the 15th day post-surgery and then monthly thereafter. Complete weight-bearing was prohibited until 2 months post-surgery. Participants were monitored in the clinic at regular intervals of 1-, 2-, 3-, 6-months, and 1 year after the procedure. A surgeon evaluated the soft tissue and ankle functioning through clinical evaluation. Weightbearing with a brace was permitted either 4- or 6-weeks postsurgery, relying on the radiographical outcome. Weightbearing without a brace was permitted approximately 8- or 10-weeks following operation.

Measurement

Each ankle ROM was assessed twice while the patient was lying supine, using a conventional (60-cm) goniometer, both at the time of discharge as well as each subsequent follow-up appointment. The American Orthopaedic Foot & Ankle Society (AOFAS) underwent clinical score evaluations at 6and 12-months post-surgery. The AOFAS score possess a maximum value of 100 points, which is divided into 50 points for functioning, 40 points for discomfort, and 10 points for alignment^[9]. At 4 weeks after the operation, radiographs were taken from the lateral, anterior posterior, and at a mortise to check the progress. This was repeated at 8, 12, 16, 20, and 24 weeks until the bones had fully healed. The healing of a fracture is determined by the presence of visible callus on Xray examination, which bridges three out of the four cortices. The term "bone healing" has been described in the following manner: (1) The patient did not experience any pain at the site of the fracture; (2) Visible callus was observed on the lateral and anterio-posterior (AP) views, bridging three out of the four cortices. Preoperative, postoperative, and follow-up radiographs were taken of the affected ankle from the anterior-posterior, lateral, and mortise views. Consequences were documented during each clinical and radiological follow-up.

Statistical analysis

The statistical analysis was conducted using SPSS v26 software (IBM Inc., Chicago, IL, USA). The quantitative variables were displayed as the mean and standard deviation (SD) and had been contrasted between the two groups using an unpaired Student's t-test. The qualitative variables were displayed as frequencies and percentages (%) and have been analysed utilising the Chi-square test or Fisher's exact test, as appropriate. A two tailed P value < 0.05 was considered statistically significant.

Results

forty- one individuals were evaluated for their eligibility, out of which seven patients did not match the requirements and four patients declined from participating in the work. The remaining individuals were randomly assigned to two equal groups, with 50 individuals in each group. Statistical analysis was conducted on each participant who were assigned to the study. Figure 1.



Fig 1: CONSORT flowchart of the enrolled patients

Age, sex, weight, height and BMI were insignificantly different between two groups. Total screws used for plate

fixation was significantly decreased in group 1 contrasted to group 2 (P=0.009). Table 1.

Table 1: Demographic data and total screw	s used for plate fixation of the studied group	ups
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Age (years)		Group 1 (n=15)	Group 2 (n=15)	Р
		39.27±12.81	44.73±12.39	0.245
Sov	Male	9 (60%)	11 (73.33%)	0,600
Sex	Female	6 (40%)	4 (26.67%)	0.099
Weight (kg)		78.13±12.38	81.27±14.6	0.531
Height (cm)		Height (cm) 169.07±7.81 167.6±6.59		0.583
BMI (kg/m ²)		BMI (kg/m ²) 27.4±4.42 28.97±5.05		0.372
Total screws used for plate fixation		6.07±1.58	7.47±1.13	0.009*

Data are presented as mean ± SD or frequency (%). *Significant as P value ≤0.05, BMI: Body mass index

AOFAS score was significantly higher at 6 m and 12 m in group 2 compared to group 1 (p<0.05). ROM (Extension and flexion) was insignificantly various at discharger between the

two groups and was significantly higher at 1 m, 2 m, 3 m, 6 m and 12 m in group 2 contrasted to group 1 (p<0.05). Table 2.

		Group 1 (n=15)	Group 2 (n=15)	Р
AOFAS score	6 m	73.47±4.81	79.93±4.68	0.001*
	12 m	81.13±4.45	92.4±4.98	< 0.001*
	At discharge	2.67±1.18	2.53±1.19	0.760
	1 m	3.33±1.05	4.87±1.3	0.001*
DOM (Extension)	2 m	4.13±1.19	8.6±2.75	< 0.001*
ROM (Extension)	3 m	5.87±1.25	11.4±2.64	< 0.001*
	6 m	8.33±1.45	14.73±2.02	< 0.001*
	12 m	12.13±2.03	19.07±2.12	< 0.001*
ROM (Flexion)	At discharge	11.33±2.29	10.33±1.88	0.201
	1 m	15.6±1.96	19.2±3.43	0.001*
	2 m	18.93±2.37	22.27±4.01	0.010*
	3 m	23.47±2.42	27.2±4.04	0.005*
	6 m	27.13±2.67	34.8 <u>+</u> 4.44	< 0.001*
	12 m	29.33+2.79	36.8+4.49	< 0.001*

Data are presented as mean ± SD. *Significant as P value ≤0.05. AOFAS: American Orthopaedic Foot & Ankle Society, ROM: Range of motion

Radiography union was insignificantly different at 1 m and 6 m between both groups and was significantly higher at 2m, 3

m and 12 m in group 2 contrasted to group 1 (p<0.05). Table 3.

Table 3: Radiography union of the studied groups					
	Group 1 (n=15)	Group 2 (n=15)	Р		
1 m	2 (13.3%)	5 (33.3%)	0.389		
2 m	3 (20%)	10 (66.7%)	0.025*		
3 m	5 (33.3%)	12 (80%)	0.025*		
6 m	8 (53.3%)	13 (86.7%)	0.108		
12 m	11 (73.3%)	14 (93.3%)	0.046*		

Data are presented as frequency (%). *Significant as P value ≤0.05

Healing time was significantly decreased in group 2 compared to group 1 (P=0.001). Superficial infection delayed wound

healing and plate removal were insignificantly various among two groups. Table 4.

Table	4:	Healing	time	of	the	studied	group	s
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		Group 1 (n=15)	Group 2 (n=15)	Р
Healing time (weeks)		13.87±1.51	11.87±1.6	0.001*
Complications	Superficial infection	1 (6.67%)	0 (0%)	1
	Delayed wound healing	2 (13.33%)	1 (6.67%)	1
	Plate removal	2 (13.33%)	0 (0%)	0.482

Data are presented as mean ± SD or frequency (%). *Significant as P value ≤0.05

Case 1: Cases with ankle fracture that were treated with distal

fibular locked plate. Figure 2.



Fig 2: (A) Pre x ray, (B) Intra operative x rays, (C)Immediate post-operative, (D) After 1 month, (E) After 3 months and (F) After 6 months

Case 2: Cases with ankle fracture were treated with conventional methods. Figure 3.





Fig 3: (A) Day of fracture, (B) After 2 weeks, (C) After 2 months and (D) After 6 months

Discussion

Ankle fractures are a prevalent type of injury, constituting around 9% of all fractures. These fractures, typically caused by minor force injuries, occur at a rate of 122-184 per 100,000 individuals per year and rank as the 3rd most frequent type of fracture, following fractures of the hip and wrist ^[10].

The fibula locking plate is utilised in the elderly people with osteoporotic bone or in younger people with comminuted and multi-fragmentary fractures. Biomechanical research has demonstrated that locking plates used in an osteoporotic fibula exhibit higher levels of torque and resistance to axial and angular forces at the point of failure compared to standard plates ^[11]. Using two distal unicortical screws had the same mechanical effectiveness as using three distal cortical screws from a normal plate [11, 12]. Traditional devices rely on the density of the bone mineral for the plate-bone construct, whereas locking devices are not affected by the quality of the bone. This is owing to the stability of the implant is achieved through a fixed-angle structure, eliminating the requirement for direct contact between the plate and the bone ^[13]. Locking plates don't provide any benefit in stable fractures with normal mineral density. Furthermore, the utilisation of a conventional plate for fixing the distal fibula may not be suitable due to its reliance on the mechanical integrity of a single cortical and cancellous bone in the distal fragment. The locking plates create a stable structure at a specific angle without requiring the screws to be anchored in both cortical bones. As a result, these plates are beneficial for treating complex fractures with many fragments and fractures located at the far end of the bone in young individuals. Consistent with our findings, Evola et al. [10] discovered that the AOFAS score had been substantially greater in the group treated with locking plates contrasted to those treated with non-locking plates. Shih et al. [14] assessed functional outcomes using the FAOS score and were the only researchers that concentrated on elderly patients. They observed significant variations between the two groups (locking group: 431.1±31.2; nonlocking group: 403.7 \pm 38.1, p< 0.002). Both publications provided information on the frequency of problems.

In the present study, ROM (Extension and Flexion) was significantly higher at 1m, 2m, 3m, 6m and 12m in group 2 than group 1. In disagreement with our results, Huang *et al.*^[15] revealed no statistically substantial variations existed in regards of ROM between the groups treated with the one-third tubular plate, locking compression (LCP) metaphyseal plate, and LCP distal fibula plate ($54.5\pm9.8^{\circ}vs$ $55.6\pm8.7^{\circ}vs$ $55.7\pm8.6^{\circ}$, p = 0.760). In their retrospective research, Bilgetekin *et al.*^[16] examined 62 orthopaedic individuals who

underwent surgery for lateral malleolus fracture. The study aimed to contrast the clinical and radiologic findings of using a locking one third tubular plate against an anatomical distal fibula locking plate in LMF. Both of the groups of locking plates in our investigation were likewise comparable in terms of ROM of the ankle.

In the current study, radiography union and healing time were significantly higher at 2m, 3m and 12m in group 2 than group 1. This outcome supported with work by Huang *et al.* ^[15] revealed that the participants who received treatment with an LCP distal fibula plate had a considerably shorter healing time (20.0±3.8 weeks) compared to those receiving therapy using an LCP metaphyseal plate (23.0±3.4 weeks, p < 0.0001) and a conventional one-third tubular plate (23.1±3.6 weeks, p < 0.0001). El Fatayri *et al.* ^[17] did not observe a statistically substantial variance in the rate of bone union among the NLP and LP groups at either 6 or 12 weeks after the surgery.

In the present study, regarding complication, superficial infection, delayed wound healing and plate removal were insignificantly variation among both groups. In agreement with our results, Evola *et al.* ^[10] revealed no variations in the rate of complications among the locking and non- locking plates. Supporting our results, Hasami *et al.* ^[18] revealed that utilising locking plates in surgically treated LMF didn't result in improved ankle functioning, reduced postoperative complications, or decreased need for hardware removal. Contrary to our findings, Shih *et al.* ^[14] observed a statistically significant distinction (P = .039) between the locking group, which had 6 instances of hardware removal (17.65%), and the nonlocking group, which had 16 removals (42.11%).

Limitations of the work involved that the relatively small sample size. The work was in a single center and the outcomes may vary elsewhere. The duration of patient followup was rather brief. The surgeon chose a certain plate depending on the quality of the bone and the form of the fracture. This expert view may contribute to the explanation for why these plates have comparable results in terms of functional outcomes, rate of complications, and hardware removal. The AOFAS score is an unvalidated functional outcome scoring system, and it was not able to analyse the different issues individually due to a low number of events.

Conclusion

In patients with ankle fracture, fixation of lateral malleolus fracture by using locked plate had higher AOFAS score, ROM (Extension and flexion), Radiography union and lower healing time than conventional plate at least for 6 months.

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Conflict of Interest: Nil.

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