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Original Article

THE CLINICAL AND RADIOLOGICAL OUTCOMES OF THE USE OF ELASTIC INTRA-MEDULLARY NAILS IN THE FIXATION OF FRESH NON-COMMINUTED MID-SHAFT CLAVICLE FRACTURES IN ADULTS.

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Abstract

Aim: *Clavicular fractures make up 5% to 10% of all fractures and 35% to 45% of injuries to the shoulder girdle. About 80% of all clavicular fractures are mid-shaft fractures, with lateral third fractures coming in second (12%-15%) and medial third fractures coming in third (5%–6%). Conservative treatment, such as a figure-of-eight bandage, is typically used to treat non-displaced mid-clavicular fractures. Absolute indications for surgical treatment include the floating shoulder, impending or existing neurovascular impairment, and imminent skin perforation. Relative indications for surgical fixing include non-unions and severe displacement of fracture fragments. The most common surgical procedure is plate osteosynthesis, but this method has been linked to increased rates of complications. This study's objective is to assess the clinical and radiological results of employing elastic intra-medullary nails to treat adults with fresh, non-comminuted mid-shaft Clavicle fractures.* ***Patients and Methods****: A prospective study was conducted on 20 adult patients treated with an elastic intra-medullary nail for non-comminuted mid-shaft clavicle fractures between August 2021 and August 2022.* ***Results****: According to the Constant and Murley shoulder score, the mean score at the conclusion of the follow-up period was 93, with a range of 58 to 100. 13 of the patients (or 65%) had great results, 4 (20%) had good results, 2 (10%) had fair results, and 1 (or 5%) had subpar results.* ***Conclusion****: Using an intramedullary elastic nail to fixe non-comminuted mid-shaft clavicular fractures is a successful course of treatment in some circumstances. All of the cases included in the study experienced complete union over the follow-up period, and most of them had good range of motion, strength and cosmetically accepted scar.*

Keywords: *Mid-shaft, Clavicle fracture, Screw fixation, Intramedullary.*

1. Introduction

The clavicle is the main connection between the axial (via the sternoclavicular joint) and the appendicular (via the acromioclavicular joint) skeleton. Any force absorbed by the upper extremity is transmitted to the thorax through the clavicle. This fact, in addition to its superficial location, explains why it's vulnerable to injury [1]. The incidence of fractures of the clavicle in adults appears to be increasing because of several factors, including high-velocity vehicular accidents and the increase of popularity of contact sports [2]. Clavicular fractures account for 5% to 10% of all fractures and 35% to 45% of shoulder girdle injuries. Most commonly mid-shaft fractures account for about 80% of all clavicular fractures, followed by lateral third fractures (12% to 15%) and lastly medial third fractures (5% to

6%) [3]. Conservative treatment, such as a figure-of-eight bandage, is typically used to treat non-displaced mid-clavicular fractures. Absolute indications for surgical treatment include the floating shoulder, impending or existing neurovascular impairment, and imminent skin perforation. Relative indications for surgical fixing include non-unions and severe displacement of fracture fragments. The most common surgical procedure is plate osteosynthesis, but this method has been linked to increased rates of complications [4].

2. Patients and Methods

This study involved 20 adult patients who underwent percutaneous elastic intramedullary nail therapy for displaced fractures of the middle section of the clavicle between August 2021 and August 2022.

2.1. *Ethical consent*

An approval of the study was obtained from Institutional Review Board and Ethical Committee. Every patient signed an informed written consent for acceptance of the operation.

2.2. *Inclusion criteria*

According to the Robinson classification [4]. Adults between the ages of 16 and 60 having fresh unilateral midshaft clavicular fractures of type IIA2 (angulation >45) or IIB1 (shortening or overlapping displacement >2 cm).

2.3. *Exclusion criteria*

1) Proximal and distal clavicular fractures. **2)** Comminuted clavicular fractures. **3)** Open fractures. **4)** Multiple injuries of upper limbs. **5)** Pathological fractures. **6)** Combined with injuries of blood vessels or nerves. **7)** Other diseases which affected the functions of upper limbs. **8)** Patient with underlying diseases such as primary hypertension and cardiac diseases.

2.4. *Preoperative assessment*

1) Clinical assessment, which looks for symptoms such as pain, soreness, deformity, shortening, skin tethering, and loss of function. **2)** Radiological evaluation: The cornerstone for diagnosing clavicular fractures is plain X-ray imaging, fig. (1).

Figure (1) Preoperative X-ray showing a clavicular fracture.

2.5. *Surgical technique*

2.5.1. Anesthesia and positioning

Under general anesthesia, the patient was positioned supine on a radiolucent surgical table with a tiny towel roll between the scapulae to provide shoulder girdle extension. Additionally, a pad was positioned directly behind the shoulder to raise the lateral third of the clavicle to a position that facilitates an effortless reduction of the fracture. The procedure involved the use of an image intensifier, fig. (2).

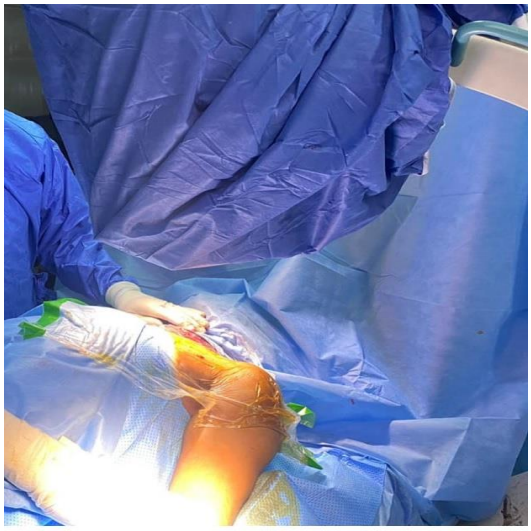

Figure (2) The patient is placed on a radiolucent operating table in a supine position with an image intensifier from the opposite side of the operation table.

2.5.2. Skin incision

Just laterally to the sterno-clavicular joint, above the medial end of the clavicle, an

image intensifier-guided short skin incision of about an inch was performed

Figure (3) Skin incision localised by image intensifier.

2.5.3. Procedure

The entry point was made using a 3.2 drill bit guided by a sleeve to avoid slipping of the drill bit. The awl was directed toward the coronal plane at roughly a 30% angle and pointed laterally in line with the collarbone. The dorsal cortex was avoided at all costs to prevent serious problems. An elastic nail was then placed after the medullary cavity had been punctured (the nail's size was calculated using the formula = 0.4 canal diameter in mm). Depending on the patient's size, the implanted nails had diameters between 2.0 and 3.5 mm. The nail was placed in a T handle and moved gradually until it reached the fracture site after being shaped in a S shape to match the anatomical shape of the clavicle, fig. (4).

Figure (4) The elastic nail reached the fracture site.

Once the nail had reached the fracture site, the shoulder was tractioned while the fragments were directly approximated. Typically, the lateral piece was percutaneously reduced with a tiny, pointed reduction forceps, fig. (5).

Figure (5) Reduction was done using a pointed forceps applied percutaneously to the lateral fragment.

In some cases, closed reduction may not be accomplished. In these cases, a short incision directly over the fracture site is done to reduce the fracture. The nail was then pushed into the lateral part of the clavicle. Care was taken to avoid perforation of the dorsolateral cortex of the lateral clavicle, fig. (6).

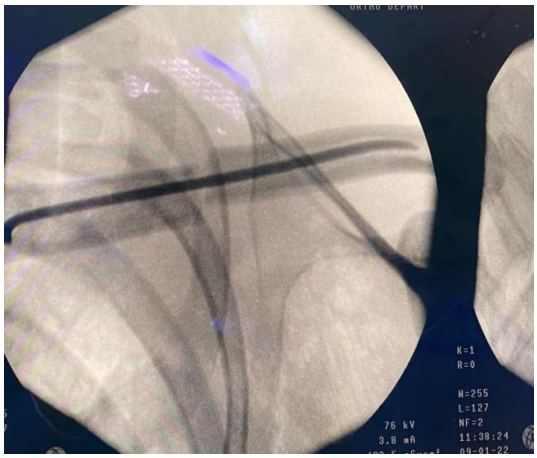

Figure (6) The nail was then pushed into the distal part of the clavicle close to its extremity.

An apical oblique view is taken with the image intensifier to ensure that the lateral end of the elastic nail didn’t penetrate the posterior cortex of the lateral one third of the Clavicle. The protruding medial end of the nail was left out of the cortex and shortened close to its entry point into the bone followed by wound closure, fig. (7)

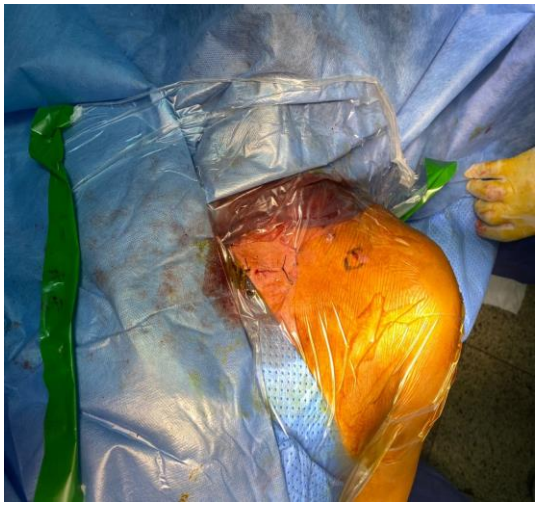

Figure (7) Medial end of nail cut close to its entry point into the bone.

2.5.4. Follow-up

Clinical and radiological monitoring of all patients was done for a minimum of six months. With their arm in a sling, patients were released from the hospital. In the first six weeks, there should be no overhead abduction and only early, mild mobilezation when pain permits. Active-assisted activities were begun once the shoulder sling was removed after 4 weeks, although the patients were cautioned about lifting anything heavy for 6 weeks. Exercises for passive and active relaxation were started at that time. After a week, the sutures were taken out. Following Constant and Murley Score [5], results were evaluated at the end of this period (CMS). The CMS system is employed globally as a tool for determi-ning normal shoulder function levels suited for various age groups and for determin-ing what constitutes impairment in healthy individuals. Additionally, variable rates of recovery from injury or treatment have been established using it. Higher scores on the CMS, a 100-point functional shoulder evaluation test, indicate greater function. Subjective pain (15 points), activity of daily living (20 points), objective clinical assessment of range of motion (40 points), and strength are the four different subscales that make up this scale (25 points), figs. (8, 9)

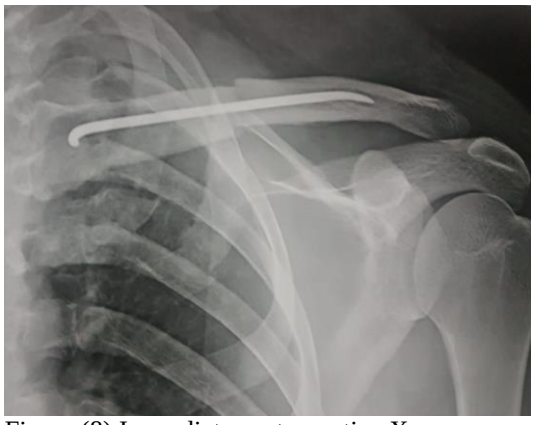

Figure (8) Immediate postoperative X- ray.

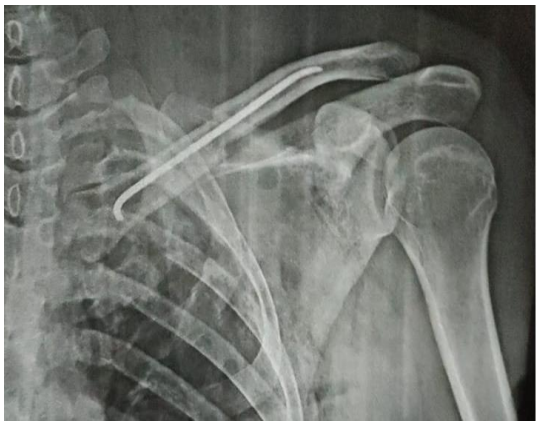

Figure (9) Follow up X-ray.

2.5.5. Statistical analysis

Statistical Package for Social Sciences (SPSS) version 22 for Windows was used to code, process, and analyse the obtained data (IBM SPSS Inc., Chicago, IL, USA). Using the Shapiro Walk test, the distribution of the data was examined for normality. Frequencies and relative percentages were used to depict qualitative data. To determine differences between two or more sets of qualitative variables, use the chi square test (2). Quantitative information was presented as mean SD (Standard deviation). Two independent groups of normally distributed variables were compared using the independent samples t-test (parametric data). P value less than 0.05 was regarded as significant.

3. Results

Final Score according to the Constant and Murley shoulder score, the mean score at the conclusion of the follow-up period was 93, with a range of 58 to 100. (5) Of the 13 patients, or 65%, who had

results, four (20%) had good results, four (20%) had good results, two (10%) had fair results, and one (5%), had poor results, tab. (1), fig. (10).

Table (1) Distribution of the studied patient's regarding the net result according to Constant and Murley score

Valuation	Number	Percent
Satisfactory	**17**	**85.0**
Excellent	13	65.0
Good	4	20.0
Unsatisfactory	**3**	**15.0**
Fair	2	10.0
Poor	1	5.0

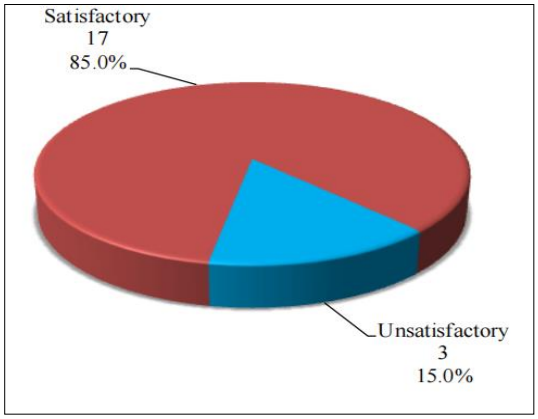

Figure (10) Distribution of the studied patients regarding the net result according to Constant and Murley score.

3.1. *Pain*

The mean final constant score for pain at the end of the follow-up period was 13.752.75 and ranged from 5 to 15, tab. (2).

Table (2) Distribution of the studied patients regarding pain according to Constant and Murley Score

Pain	Number	Percent
No	16	80.0
Mild	3	15.0
Moderate	1	5.0
Severe	0	0.0

3.2. *Activity of daily living*

At the end of the follow up period, the mean final Constant score for activity of daily living was 18.5±2.66 ranging from 14 to 20.

3.3. *Range of motion*

3.3.1. Active forward flexion

The mean final Constant score for active forward flexion at the conclusion of the follow-up period was 9.31.174, ranging from 6 to 10, tab. (3).

Table (3) Distribution of the studied patients regarding active forward flexion.

3.3.2. Active Abduction

Forward flexion	Number	Percent
91 – 120	1	5%
121 – 150	5	25%
151 – 180	14	70%

At the end of the follow up period, the mean final Constant score for active abduction was 9.0±1.522 ranging from 6 to 10, tab. (4).

Table (4) Distribution of the studied patients regarding active abduction.

Abduction	Number	Percent
91 – 120°	3	15%
121 – 150	4	20%
151 – 180	13	65%

3.3.3. Active external rotation

At the end of the follow up period, the mean final Constant score for active external rotation was 9.20± 1.96 ranging from 6 to 10, tab. (5).

Table (5) Distribution of the studied patients regarding active external rotation.

External rotation	Number	Percent
Hand above head with elbow forward	1	5%
Hand above head with elbow back	6	30%
Full elevation	13	65%

3.3.4. Active internal rotation

At the end of the follow up period, the mean final Constant score for active internal rotation was 9.0±1.522 ranging from 6 to 10, tab. (6).

Table (6) Distribution of the studied patients regarding active internal rotation.

Internal rotation	Number	Percent
Waist l3	3	15%
T12 vertebra	4	20%
Interscapular T7	13	65%

3.4. *Strength*

The mean final constant score for strength at the conclusion of the follow-up period was 24.02.616, with a range of 15 to 25. By the sixth month, 17 patients had regained their shoulder's normal strength as compared to the normal side; two patients had good strength, and one had a decent result on the spring balancing test.

3.5. *Factors affecting the final outcome*

3.5.1. Age

The association between age and the outcome was not statistically significant, tab. (7), fig. (11).

Table (7) Relation between final outcome and age of the patients.

Age group	Net result				Total
	Satisfactory		Unsatisfactory		
	No.	%	No.	%	
<20	3	100%	0	0%	3
20 – 30	7	100%	0	0%	7
31 – 40	4	80%	1	20%	5
41 – 50	2	66.7%	1	33.3%	3
>50	1	50%	1	50%	2
Total	17		3		20
P	0.318				

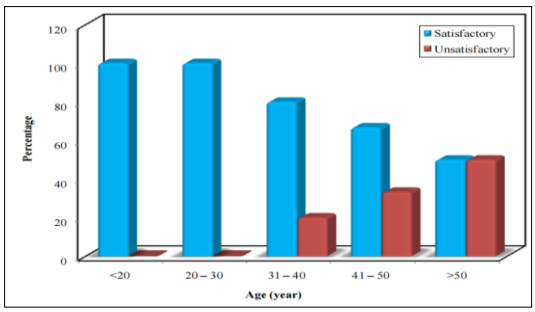

Figure (11) Relation between final outcome and age of the patients.

3.5.2. Sex

The association between sex and the outcome was not statistically significant. The mean final score for males ranged from 74 to 58 and was 94.928.54; for females, it was 89.437, from 58 to 100, tab. (8), fig. (12).

Table (8) Relation between final outcome and sex of the patients

Sex	Net result				Total
	Satisfactory		Unsatisfactory		
	No.	%	No.	%	
Male	12	92.3%	1	7.7%	13
Female	5	71.4%	2	28.6%	7
Total	17		3		20
P	0.27				

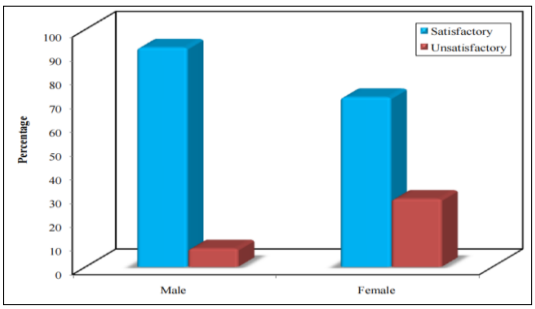

Figure (12) Relation between final outcome and sex of the patients.

3.5.3. Side

In terms of the final score, there was no statistically significant difference between the dominant and non-dominant side. The mean final score for the dominant side was 92.8312, ranging from 58 to 100, and for the non-dominant side was 93.258, ranging from 74 to 100.

3.5.4. Time lapse before surgery

There was no statistically significant relationship between final outcome and the time interval between trauma and the time of surgery, tab. (9), fig. (13).

Table (9) Relation between final outcome and time lapse before surgery.

Time lapse	Net result				Total
	Satisfactory		Unsatisfactory		
	No.	%	No.	%	
<3 days	10	90.9%	1	9.1%	11
3 – 7 days	5	83.3%	1	16.7%	6
>7 days	2	66.7%	1	33.3%	3
Total	17		3		20
P	0.575				

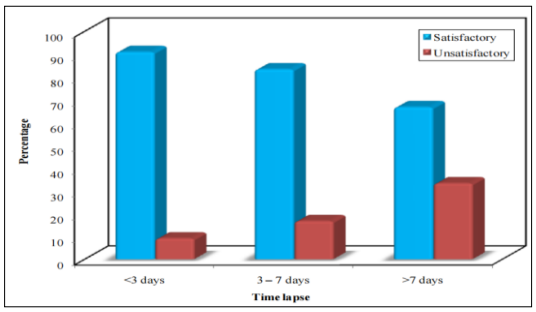

Figure (13) Relation between final outcome and time lapse before surgery.

3.5.5. Associated medical conditions

There was no statistically significant relationship between the associated medical condition and the final score, as the mean final score for patients without medical comorbidity was 92.82, whereas the mean final score for those with hypertension was 95, and finally the final score for that patient with diabetes mellitus was 92.

3.5.6. Union

The mean time for clinical union, which is defined as the absence of pain, restoration of functional range of motion, and improvement in shoulder strength, was 7.801.43 weeks, ranging from 6 weeks to 10 weeks, and the mean time for radiological union, which is defined as the absence of the fracture gap in the bone trabeculae, was 10.401.39 weeks, ranging from 8 weeks to 12 weeks.

3.5.7. Complications

Five patients (25%) complained of soft tissue irritation caused by prominent tip of the elastic nail medially at the site of the entry point which was resolved following the removal of the elastic nail after complete union had been achieved. Only one 33 years old patient showed migration of the elastic nail medially. No complications regarding damage to nerves or vessels were encountered.

4. Discussion

The most frequent fracture, accounting for 44% of fractures to the shoulder girdle and 5% of all bone injuries, is the clavicle fracture. According to Allman's clavicular fractures are categorised as middle, lateral, and medial third fractures. The middle third fracture, which accounts for 80% of all clavicular fractures, is the most common kind, followed by lateral and medial third fractures (12% to 15%). Mid-shaft displacement is induced by forces from the arm's weight and the muscles of the shoulder girdle, especially the latissimus dorsi, pectoralis minor, and pectoralis major. Following conservative therapy of clavicle fractures, a high delayed or non-union rate of about 50% emerges from the fractures' impairment of union [6]. Recent research suggests that displaced mid-shaft clavicular fractures are best treated surgically. Surgical fixation techniques include plating [7,8], intramedullary fixation employing a range of tools, including Knowles pins, Kirschener wires, Hagie pins, and Rockwood pins, as well as less invasive titanium nails [9] and external fixators [10]. But several of these techniques have been linked to a variety of side effects, including pin migration, screw breakage, rotator cuff irritation and rupture, infection, osteomyelitis, refracture, and osteoarthritic alterations, with no technique proving to be the best method of fixation [9,10]. It has been demonstrated that plate fixation enables early post-operative mobilization while providing firm stability and pain alleviation. For mid-shaft Clavicular fractures [7,8]. The most popular technique for plating was the superior approach and it has proven to be biomechanically beneficial, particularly when there is inferior cortical comminution [11,12]. The method, however, carries a higher risk of damaging the neurovascular pathways beneath the skin during fracture fixation, and the prominence of the plate directly beneath the skin may cause substantial skin irritation and call for plate removal. An alternative strategy that was created to get around this issue is the anterior strategy. Although this method was biomechanically inferior to the superior location of the plate, which gave more stable fixation, it had a low rate of complications [11,12]. Infection, metal failure, hypertrophic or unattractive scarring, implant loosening, non-union, re-fracture following plate removal, and neurovascular damage are the problems associated with the use of plate fixation [13]. We suggested a new fixation strategy to get over the limitations of plate fixation. This study's goal is to explain a novel surgical approach for fixing mid-shaft Clavicular fractures using elastic nails. 20 patients with a mean age of 32.2011.6 years were included in this study; 13 patients (65%) were men, and 7 patients (35%) were women. Only one patient had a poor result, whereas 13 patients had great results, 4 patients had good results, 2 patients had fair results, and 3 patients had average results. Constant's ultimate score of 93 was comparable to other publications in the literature. In our current study, intramedullary elastic nails were used to heal displaced fractures in the middle part of the clavicle. The tension side of the clavicle changes in relation to the rotation of the arm and the direction of

loading, making intramedullary implants ideal from a biomechanical standpoint. This procedure may have advantages like a smaller incision, low periosteal stripping, and load-sharing device characteristics. Its relative stability enables extensive callus growth during the healing process. Skin irritability caused by the nail's large medial end is a common problem that frequently necessitates either nail trimming or premature removal. A multifragmentary fracture may cause the clavicle to shorten and the nail to telescope. We did not include comminuted fractures because we think that under these conditions, the fixation method cannot preserve the length of the clavicle. Kadakia, et al. [14] favored placing the patient on a beach chair in a semi-setting position. In our study we favored placing the patient in a flat supine position to ensure a better access to the operative field. Also, a pad was placed directly underneath the shoulder to elevate the lateral one third of the Clavicle allowing for easier reduction of the fracture. Vishwanathan et al. [15] used an owl to make the entry point in the anterior cortex of the Clavicle. In our study a 3.2 drill bit introduced using a sleeve was first used to make the entry point prior to using the owl to avoid injuring any of the surrounding vital structures. With a mean follow-up duration of a year, Hartmann et al. [16] evaluated 15 instances of clavicle fractures treated with elastic intramedullary nailing. Clinical and radiological union was visible in all fractures. Infection or non-union were not noted. The Constant score indicated that the functional outcomes were outstanding. Conclusion: A satisfactory functional outcome is achieved when displaced midclavicular fractures are surgically treated with ESIN. Compared to conservative treatment, this method allows for the shoulder to regain freedom of motion more quickly and allows for an earlier return to normal activities. The rehabilitation protocol in our study was that the patient was placed in a broad arm sling for 4 weeks and began pendulum exercises during the first post-operative week and active-assisted motion at 2 weeks while still being placed in the broad arm sling. At 4 weeks, if radiographs showed no loss of reduction, the broad arm sling was discarded, and full active and passive motion were initiated. Resistance and strengthening activities were allowed when radiographs revealed union. Kadakia, et al. [14] immobilized the patients in a sling for 2 weeks and after that he initiated gradual physiotherapy which we believe was a very long period of immobilization and there was a delay in return to full activities in contrast to our study as we started pendulum exercises immediately in the first post-operative week. In this study, the average time for clinical union shown by the disappearance of pain, restoration of functional range of motion, and improvement in shoulder strength was 7.8 weeks, and the average time for radiological union shown by the obliteration of the fracture gap by bone trabeculae was 10.4 weeks. The patients in Kadakia's, et al. [14] trial were clinically and radiologically united at a mean time of 11.3 weeks (Range, 6-20 weeks). Fracture healing was evaluated with a one-year mean follow-up period in the study by Hartmann et al. [16]. Between 8 and 11 weeks, all fractures showed clinical and radiological healing. No non-union was seen. In contrast, 2 patients in a case series by Kettler et al. [17] had nonunion. In the case study by Keihan et al. [18], clinical union was attained in 3-5 weeks, and radiographic union manifested in 6-12 weeks. 38 patients were randomly assigned to one of two treatment groups in Assobhi's [19] trial and received either plating or titanium elastic nails.

After the 12th week, the two groups' results were comparable. For the group treated with elastic nails, however, earlier union and functional recovery were attained in the sixth week. In comparison to the elastic nail group (0%), the plate group saw a higher incidence of problems (15.8%). The conclusion is that intra-medullary nailing has been shown to be more beneficial and linked with a lower incidence of problems than plating for mid-shaft Clavicle fractures. It is advised for athletes and young people who are active [19]. Meier et al. [20] performed a case series to assess the indications for and functional outcome of displaced midclavicular fractures in 14 athletes treated with elastic stable intramedullary nailing. Closed reduction was never achieved when the surgery was postponed for more than 7 days, indicating that early intervention is more beneficial to treated patients. In one instance, hammering the elastic nail into the lateral third of the clavicle caused the dorsolateral cortex to be punctured. A few centimeters were removed, and the titanium nail was then repositioned. They no longer advise using a hammer. If the nail cannot be advanced using merely oscillating movements, a smaller implant should be used. In terms of discomfort, there was no pain in 16 patients (80%), mild pain in 3 patients (15%), and moderate pain in one patient (5%). In Assobhi's [19] study, similar outcomes for the elastic nail group were recorded in the first six weeks of follow-up, but after 12 weeks, the pain was comparable in both groups (plate and elastic nails). Two complications were encountered in our study, the first was soft tissue irritation by the prominent medial tip of the elastic nail at the entry point which was resolved after removal of the elastic nail, the second was slight backing out of the elastic nail in one patient (5%) which we responded to by maintaining the broad arm sling for 6 weeks. In the case study by Kettler et al. [17], only 6 patients out of 87 reported discomfort or scarring at the medial entry location. In two instances, the medial side of the nail's projecting end caused irritation. In two patients, the nail on the lateral fragment missed the medullary canal. The fracture healed with a small malunion in one patient, who underwent a second procedure to reintroduce the nail. The other patient refused a subsequent treatment. According to Hartmann et al. [16], 4 patients experienced skin irritation and soreness near the sternal end of the clavicle 1 to 4 months after the procedure, and 5 patients experienced sequelae. In three cases, the TEN's conspicuous medial end was cut down, and in one case, the TEN was prematurely removed (5 months after the operative treatment). The primary benefit of our method is that it facilitates the start of early active motion. Additionally, because it makes it simple to remove the implant once full union is accomplished, it relieves the patient's complaint of pain at the implant site. But there were some limitations in this study: **1)** there were only 20 cases in the research. **2)** There was no control group, and the study was a randomized prospective study. **3)** Limited follow-up time.

5. Conclusion

Fixation of the mid shaft without comminutes in some circumstances, utilizing an intramedullary elastic nail to treat clavicular fractures is successful. Within the follow-up period, all of the study's cases had fully united, and the majority of them had scars that were both aesthetically pleasing and had good strength, range of motion, and scar acceptance. Low morbidity and positive overall outcomes characterize the procedure. In order to prevent damage to associated critical organs and structures, the procedure necessitates cautious planning and execution, especially when making the entry point medially. One common complaint among those who have been treated is soft tissue discomfort at the entrance place.

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