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Minimally Invasive Intramedullary Fixation of Middle third clavicular Fractures Through the Medial Entry by Titanium Elastic Nailing System (TENS)

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ORIGINAL ARTICLE

Minimally Invasive Intramedullary Fixation of Middle third clavicular Fractures Through the Medial Entry by Titanium Elastic Nailing System (TENS)

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Abstract

Background: In the past, nonoperative management was employed to address clavicle fractures; however, recent evidencebased updates from high-quality randomized studies are starting to alter this approach. A minimally invasive titanium elastic nailing system (TENS) Establishes a 3-point stabilization in the curved clavicle.

Objectives: To evaluate the radiological and clinical findings of the surgical fixation of midclavicular fractures utilizing the TENS.

Patients and Methods: The prospective case series involved thirty people who presented to Al-Azhar University Hospitals in Cairo with dislocated middle 3rd clavicle fracture. Individuals were monitored for six months after receiving percutaneous elastic intramedullary nails.

Results: The final Constant score was 89.13 ± 13.91 . Excellent findings in 20 cases (67%), good in 6, middling in 2, and poor in 2. Union duration ranged from 8-12 weeks, with a mean of 10.0 ± 1.33 weeks, except for one case of hypertrophic non-union. The final score was significantly associated with patients' age and medical problems. Patients had one infection (3.3%), two medial skin irritations (6.66%), and one hypertrophic non-union (3.3%).

Conclusion: **TENS** is a method that relies on imaging and is most suitable for young patients without medical conditions who have acute, uncomplicated clavicle fractures in the middle 3rdof the bone.

Keywords: Titanium Elastic Nailing System ; Intramedullary Fixation; Middle third clavicular Fractures

1. Introduction

T he clavicle, a long bone with two curves, is the only direct connection between the axial and appendicular skeletons (sternoclavicular joint. ¹

The midshaft of the clavicle is the thinnest and least medullous region, making it the most susceptible to fractures. Its superficial subcutaneous location and the absence of muscular and ligamentous support contribute to its vulnerability. Additionally, the midshaft lacks ligamentous attachments and is subjected to various forces from ligaments and muscles, further increasing the risk of injury. It is the most susceptible area to fractures.²

Several factors, including the rise in popularity of contact sports and high-velocity vehicle collisions, appear to contribute to the rising incidence of clavicle fractures among adults.³

2.6% of all fractures observed in emergency department visits to the hospital are clavicle fractures, the most frequent type of bone fracture in the human body. Commonly correlated with direct or indirect clavicle trauma, these injuries are most prevalent in younger patients. ⁴

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Depicting the site of the fracture, the clavicle is conventionally segmented into thirds. Approximately 80% of all clavicle fractures happen in the middle 3rd, also known as the midshaft. Lateral third fractures represent 12%to 15% of the total, while medial third fractures represent 5% to 6%. ⁵

Regarding treatment, it is critical to consider the fracture site, the extent of displacement, and the correlation between adjacent nonoperative In structures. the past, management was the standard approach for clavicle fractures; however, recent evidencebased management has been revolutionized by high-quality randomized studies.

Surgical intervention is obligatory in cases where there is imminent skin perforation, existing or impending neurovascular compromise, or a floating shoulder. Surgical fixation is considered necessary in cases where there is a large displacement of fracture fragments or non-unions. The conventional operative approach is plate osteosynthesis; nevertheless, there have been reports of increased rates of complications associated with this method. ⁶

Implants such as Knowles pins, Kirschner wires, Hagie pins, Rockwood pins, and titanium nails that are minimally invasive have been utilized.

One method of intramedullary stabilization that differs from Kirschner wire fixation is the titanium elastic nailing system or TENS. Ligiers' three-point fixation concept is used to attach the flexible titanium nail to the S-shaped clavicle securely. ^{7,8}

This method makes use of a smaller incision, minimizes dissection of soft tissues, and provides relative stability that promotes callus formation to provide an excellent cosmetic result with minimal invasiveness. Within the Sshaped clavicle, a 3-point fixation system is utilized in this procedure. The goal is to get the clavicle back to its average length as soon as possible so that you can get back to your normal activities. Thanks to TENS, this is made possible. ⁹

We set out to evaluate the radiological and clinical results of TENS to fix midclavicular fractures surgically.

2. Patients and methods

In this prospective case series, Al-Azhar University Hospitals in Cairo treated thirty individuals with dislocated middle third clavicle fractures with percutaneous elastic intramedullary nails by the medial entrance and followed them for six months.

Inclusion criteria included Patients with

dislocated midclavicular Fractures, people between 15 and 60 years old, both genders and closed fractures.

Exclusion criteria included Patients with a history of previous ipsilateral clavicular surgery, pathological fractures caused by infection or malignancies, Individuals younger than 15 or older than 60 years, open fractures, Patients with associated nearby fractures (such as lateral third fracture or A.C joint disruption), and patients with correlated brachial plexus injury.

Informed consent: For this study, we obtained informed permission from every participant.

METHODS

Methods of diagnosis: Information has been gathered that is consistent with the following sheet: history, clinical examination, and radiological evaluation.

Methods of treatment: Percutaneous (TENS) was utilized in clavicular fracture fixation in an antegrade manner in all patients (Anesthesia, positioning, Skin incision, Procedure, and Closure).

Surgical technique

General anaesthesia was administered to the patient before surgery. Using an image intensifier to pinpoint the exact location, a small skin incision was made directly across from the sternoclavicular joint, directly above the medial aspect of the clavicle, and antibiotics were administered as a preventative measure.

The clavicle's medullary chamber was accessed with the help of an awl. The awl was positioned laterally in line with the clavicle and inclined at an estimated thirty-degree angle to the coronal plane. Thorough care was taken to avoid severe consequences by preventing perforation of the dorsal cortex.

After the medullary cavity had been accessed, a flexible intramedullary nail was introduced. The diameters of the implanted nail (TENS) varied from 2.0 to 3.0 mm, as determined by the medullary cavity. Before it arrived at the fracture location, the nail was advanced, utilizing oscillating motions while secured in a universal chuck with a T-T handle. In conjunction with arm manipulation and direct pressure on the fragments, closed reduction was executed once the nail had reached the fracture site—subcutaneous insertion of tiny, pointed reduction or bone-retaining forceps allowed for fracture reduction in most cases.

Thirteen people were unable to achieve a close decrease. The fracture was minimized by making a small vertical incision (two centimetres) across the location of the fracture and carefully preserving the supraclavicular nerve with little dissection.

After that, the nail was hammered into the side of the clavicle, about a centimetre away from the side of the arm. Careful precautions were taken to ensure that the dorsolateral cortex of the lateral clavicle would not be perforated.

After the wound was closed, the nail's protruding medial end was clipped near its entry point into the bone, away from the cortex.



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Figure 1. showed the surgical technique as followed a) skin incision for medial nail entry, b) anterior cortex perforated with awl, c) Awl directed by image intensifier, d) (TENS) inserted using T-handle, e) reduction using a Hohmann bone lever, f) mini open incision over fracture and g) medial end of TENS cut.

Follow up: All cases were followed up clinically & radiologically for six months and assessed according to the modified Constant and Murley shoulder score.

Methods of statistical analysis: For numerical data, the collected information was displayed statistically using mean, SD, minimum, &maximum; for qualitative data, it was displayed using frequency with percentage. A p value less than 0.05 was deemed statistically significant when comparing groups using chi-square or Fisher exact tests.

3. Results

Table 1. patients' demographic data

		VALUES
AGE	<35years	26 (86.7%)
	≥35years	4 (13.3%)
	Mean±SD;	27.73±11.28;1
	MinMax.	8-55
SEX	Male	21 (70%)
	Female	9 (30%)
OCCUPATION	Hard worker	16 (53.3%)
	LIGHT WORKER	14 (46.7%)

The Mean±SD of age was 27.73 ± 11.28 with a range 18-55. 70% of the Cases were Men (21 patients) & 30% were women (9 patients). 53.3% of the cases were hard duty workers (16 cases), while 46.7% (14 cases) were lightworkers.

 Table 2. Outcome among studied populations

 VARIABLE
 RESULTS

VARIADLE	RESULIS	
FINAL SCORE	Excellent (91-	20 (66.7%)
	100)	
	Good (75-90)	6 (20.0%)
	Fair (60-74)	2 (6.7%)
	Poor (<60)	2 (6.7%)
	Mean±SD (Min.–	89.13±13.91;50.
	Max.)	0-100.0
PAIN	Absent to mild	28 (93.3%)
	Moderate	2 (6.7%)
	Mean±SD (Min.–	14.50±2.24;5.0-
	Max.)	15.0
ACTIVITY	Full work	26 (86.7%)
	Full	26 (86.7%)
	recreation/sport	
	Unaffected sleep	30 (100.0%)
POSITIONING	Up to neck	4 (13.3%)
(CONSTANT	Above head	26 (86.7%)
SCORE)	MEAN±SD(MIN	18.80±3.69(8.0-
,	MAX.)	20.0)

The final score was determined by utilizing the modified Constant and Murley shoulder score, which indicated that the mean score was 89.13±13.91 at the conclusion of the follow-up period. This score ranged from fifty to one hundred. Twenty cases, or 66.7 percent of the total, had excellent results, six cases, or twenty percent, had good results, two patients, or 6.7 percent, had fair results, and two patients, or 6.7 percent, had bad results. The majority of patients (93.3 percent of them) did not experience any pain, or it was just light, &only two patients (6.7 reported experiencing percent) moderate discomfort.

According to the activity scoring, 86.7 percent of patients are able to return to their full work schedules, and all of them had sleep that was unaffected. In 13.3 percent of cases, the location was up to the neck, while in 86.7 percent of cases, it was on top of the head. Table 2.

Table 3. Range of motion among studiedpopulations

VARIABLE		RESULTS
ACTIVE	61-90 0	2 (6.7%)
FORWARD	121-1500	2 (6.7%)
FLEXION	151-1800	26 (86.7%)
	Mean±SD	9.60±1.39(4.0
	(minmax.)	-10.0)
ACTIVEABDU	61-90 0	2 (6.7%)
CTION	121-1500	3 (10%)
	151-1800	25 (83.3%)
	Mean±SD	9.60±1.39
	(minmax.)	(4.0–10.0)
ACTIVE	Hand on top	4 (13.3%)
EXTERNAL	of head with	
ROTATION	elbow held	
	forward	
	Full elevation	26(86.7%)
	from on top	
	of head	
	Mean±SD	9.60±1.23(6.0
	(minmax.)	-10.0)
ACTIVE	Dorsumof	2 (6.7%)
INTERNAL	hand to waist	
ROTATION	(3rd lumbar	
	vertebra)	
	Dorsumof	28 (93.3%)
	hand to	
	interscapular	
	region (DV7)	
	Mean±SD(mi	9.60±1.23(6.0
	nmax.)	-10.0)
UNION	Nonunion	1 (3.3%)
	Union	29 (96.7%)
	MEAN±SD(MI	10.0±1.33(8.0
	NMAX.)	-12.0)

Table 3. The range of active motions that werepresented included forward flexion, externalrotation, abduction, internal rotation, & overallrate of union. twenty-eight patients, or 93.3percent, were successful in achieving the union.Table 4. complications among studied population.NUMBERPERCENTAGE

	OF	
	PATIENTS	
INFECTION	1	3.3%
MEDIAL END	2	6.6%
SKIN		
IRRITATION		
MEDIAL END	0	0%
SKIN		
PERFORATION		
NON UNION	1	3.3%
Following the	removal of the	sutures, one

patient (3.3 percent) experienced infection at the incision of entry, which was accompanied by a little amount of serous discharge. As a daily dressing, intravenous antibiotic was an administered until the symptoms decreased after approximately one week. Furthermore, two patients, which is 6.66 percent of the total, experienced medial end skin irritation as a of medial migration consequence of the intramedullary nail. One of the patients required nail removal, while the other patient experienced resolution within two weeks after receiving medical therapy with anti-inflammatory medicines. (3.33 percent) Furthermore, one patient hypertrophic experienced non-union, which necessitated the removal of the nail & the reconstruction of the fracture using a plate & screws in conjunction with bone transplant.

3.1.CASE PRESENTATION

Case1

The fracture was caused by a car accident that occurred to a man worker who was thirty-three years old. Complete active forward elevation, full external rotation ,full active abduction,There was no discomfort, complete active forward elevation, full active abduction, full external rotation, & full internal rotation. There was a total score of one hundred for the activities of daily living categories. After ten weeks, the union was finally reached. A rating of excellent was given to the patient.





Figure 2. showed that A) Preoperative x-ray, B) Postoperative x-ray and C) X-ray after six months.

Case 2

A 35-year-old men uncontrolled diabetic manual worker. The mechanism of injury was falling. Operation was done nine days after injury by mini open reduction after failed closed reduction trials. Time of operation was ninety minutes. The total score was 46 (ADL: 6, moderate pain, active forward flexion 61-90 o, active abduction 61-90o, External rotation: hand on head with elbow forward, internal rotation: hand dorsum to waist. The patient had hypertrophic non-union following 6 months. Poor patient. The nail was extracted & the fracture repaired utilizing plate, screws, and bone graft.



Figure 3. showed that A) Preoperative x-ray, B) Postoperative x-ray & C) X-ray after six months

4. Discussion

This long-held assumption that most displaced clavicular fractures heal well without surgery is now unfounded following non-operative therapy. According to recent research, subgroups of patients who sustained these injuries have a greater incidence of non-union and specific deficits in shoulder function. Hence, it is imperative to consider these fractures as a range of injuries that yield varied functional outcomes, necessitating meticulous evaluation and personalized therapy for each patient. ¹⁰

Proper intramedullary stabilization is achieved with TENS, as opposed to Kirschner wire fixation. Liggers' 3-point fixation principle securely fastens the flexible titanium nail within the S-shaped clavicle. ¹¹

The functional outcome is excellent when displaced midclavicular fractures are treated surgically with TENS. In contrast to the conservative treatment, this method facilitates an earlier resumption of daily activities and a more rapid shoulder range of motion. Compared with plate fixation, the procedure necessitates smaller incisions and is less invasive.¹² With a mean age of 36.73 ± 11.28 years, this study comprised 30 patients, of which 26 (87%) were male and 4 (13%) were female. There were six patients (29%) with concurrent medical conditions. The patients under study exhibited a time-lapse prior to surgery ranging from one to ten days, with an average of 4.60 ± 2.93 days. ¹³ cases (43.3%) out of 30 were treated with open reduction after closed reduction of the fracture failed. The patients under study exhibited a range of union times, from eight weeks to twelve weeks, with an average of 10.0 ± 1.33 weeks. An exception to this pattern was 1 case which exhibited a hypertrophic non-union.

After six months, the final Constant score was 89.15 ± 13.91 ; twenty cases achieved excellent findings, six achieved promising findings, two achieved fair findings, and two achieved poor findings. In contrast, Assobhi¹³ achieved a superior score in the nailing group. Nevertheless, at the two-year follow-up, neither study identified any statistically significant distinctions among the 2 groups in terms of functional or radiological Results.

Two patients (6.6%) reported moderate pain, while 28 patients (93.33%) reported no pain. Comparable outcomes were documented in the Assobhi,¹³ study (TEN) group during the initial six weeks of follow-up. However, following 12 weeks, the pain levels remained equivalent in both the plate and TEN groups.

The union duration among the patients under study varied from 8 to 12 weeks, with an average of 10.0 ± 1.33 weeks. However, there was one case in which intensive activity commenced after only two weeks. He was diagnosed with hypertrophic non-union, which was treated with plate, fasteners as well as nail removal for revision. In the study by Hartmann et al.¹⁴, fracture recovery was evaluated over a one-year mean follow-up period. Clinical and radiographic healing occurred on all fractures within eight to eleven weeks. The absence of non-union was not noted. Within 3-5 weeks, the clinical union was attained in the Keihan et al.¹⁵ case study, and the radiographic union was observed within 6-12 weeks. Concerning gender and age, the correlation between age and the final score was statistically significant.¹⁵ Comparatively, the mean age of cases in this research was 25.7 years for excellent results, 30.0 years for good results, 53.0 years for middling results, and 35.0 years for poor results. In contrast, in Jubel and Assobhi's¹³ studies, all of their patients were youthful athletes. It can be inferred that younger patients experience a more favourable outcome than their elderly counterparts. However, in contrast, neither this investigation nor Christoph Meier's case series⁹ found a statistically significant correlation between sex and final score.⁹

Statistically significant correlations between the final score and the associated medical condition were also observed. Patients in this study had concomitant medical conditions, as opposed to those in other studies where they were athletic and no medical morbidity was mentioned; the individual with the unfavourable outcome had uncontrolled diabetes, whereas the individual with the moderate outcome had hypertension. The medical condition consequently influences the ultimate score of patients.

In this study, four patients experienced complications: an incisional infection (3.3%), medial end skin irritation (6.66%) in two patients (one of whom required nail removal, while the other improved within two weeks of medical treatment), and hypertrophic non-union (3.3%) in one patient, which necessitated revision by plating.

Frigg et al.¹⁶ documented the intramedullary stapling of 34 patients. They concluded that intramedullary fixation of midshaft clavicular fractures with the TEN was technically demanding and resulted in a number of postoperative complications. Furthermore, they documented that those issues or complications arose in seventy per cent of the participants medial perforations, seven (seven lateral perforations, one nail fracture, one nail dislocation, and seven patients who experienced hardware irritation).

In Hartmann's¹⁴ study, five people had complications; four reported sternal clavicle cutaneous irritation and discomfort one to four months after the surgery. Three instances saw the conspicuous medial extremity of the TEN diminished, and one saw it prematurely removed five months after surgery.

Study limitations: The limited number of patients included in the study was unavoidable due to the prevailing conservative stance among our colleagues, resulting in a restricted selection of patients eligible for surgery. The small quantity needed to be sufficient to assess the technique comprehensively.

4. Conclusion

Intramedullary fixation of mid-shaft clavicular fractures with TENS is most appropriate for young patients who are medically free and have acute simple two-part middle 3rd clavicle fractures. The primary benefit of this methodology is that it is minimally invasive and has excellent functional outcomes; this method facilitates an earlier resumption of daily activities and a more rapid shoulder range of motion with protection of the supraclavicular nerve.

Disclosure

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Authorship

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