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Original Article

Operative Fixation of Displaced Midclavicular Fractures in Adult by Titanium Elastic Nailing System

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ABSTRACT

Introduction and aim: Clavicular fractures are very common, and it usually treated conservatively. However, recent shift to surgical intervention had been observed. The guidelines seem to be in its road to change. The aim of this work is to assess clinical and radiological results of surgical fixation of midshaft clavicle fractures by Titanium Elastic Nailing System.

Methodology: Fifteen patients with mid-shaft (middle third) displaced fractures of the clavicle were included. All were assessed in systematic manner (history, examination and investigations). Then, eligible patients provided an informed consent and underwent surgical treatment according to study protocol. All were followed up for 6 months and their outcome was ranged according to Constant and Murley Score.

Results: Ten patients (66.7%) had excellent, 3 patients (20%) had good, one patient (6.7%) had fair, and one patient (6.7%) had poor outcome. Pain was absent or mild in the majority of patients (93.3%). 86.7% of patients return to full work, and all had unaffected sleep. Union was achieved in 14 patients (93.3%). One patient had an infection, two had medial end skin irritation and one had hypertrophic non-union. Younger age and absence of any associated medical disease were associated with excellent outcome.

Conclusion: Titanium Elastic Nailing could be considered as a reasonable alternative approach to the management of displaced mid-shaft clavicular fractures, as it is associated with excellent outcome, low pain, and early return to normal daily activities.

Keywords: Clavicle; Mid shaft; Displaced fractures; Closed Reduction; Titanium Elastic Nailing.



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INTRODUCTION

The clavicle is a long, dual-curved bone that forms the only direct link between the axial (via the sternoclavicular joint) and appendicular (via the acromioclavicular joint) skeletons (1,2). 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 is vulnerable to injury (3). The clavicular fractures' incidence in adults appears to be increasing because of several factors, including high-velocity vehicular accidents and the increase of popularity of contact sports (4).

In the human body, the clavicular fractures accounting for 2.6% of all fractures, making it the most common broken bone seen in emergency departments. Younger subjects are more prone to these injuries, due to clavicular prone to direct or indirect trauma (2). The clavicle is classically divided into thirds when describing the location of the fracture. Middle third fractures (i.e., midshaft), representing about 80.0% of all fractures of the clavicle. Thus, these fractures are the most common, followed by lateral third fractures (12% to 15%) and lastly medial third fractures (5% to 6%) (5). The site of the fracture, the displacement degree, and injured surrounding structures, are the criteria to consider surgical treatment. The non-operative (conservative) intervention technique is the standard of care. However, this approach going to change and there was a recent shift to surgical intervention in recent studies with change of available treatment guidelines (6,7).

Imminent perforation of the skin, impending or injury to neurovascular structures and the floating shoulder are the absolute indications for surgery. However, gross displacement of bone fragments, as well as non-unions, are considered as relative indications for surgery. Plate osteosynthesis is the standard operative treatment, but higher complication rates had been described with this technique (8).

Elastic stable intramedullary nailing (ESIN) is a minimally invasive procedure that provide a three-point fixation within the characteristics S-shaped clavicle and it usually aims to restore the clavicular length to its original length and to ensure patient return to full activity as early as possible, with provision of good cosmeses because of the small incision, less soft tissue manipulations and relative stability which encourages callus formation (9).

THE AIM OF THE WORK

The aim of this work is to assess clinical and radiological results of surgical fixation of midshaft clavicle fractures by Titanium Elastic Nailing System.

PATIENTS AND METHODS

This study was a prospective case series carried out on fifteen patients with mid-shaft (middle third) displaced fractures of the clavicle. They were selected from Al-Azhar University Hospital (Damietta) and treated by percutaneous elastic intramedullary nails and followed up for six months. Patient was included in the study, if he/she signed a consent, had displaced midclavicular fractures, age between 18 and 55 years, with closed fractures. Otherwise, the patient was excluded if he/she had previous clavicular surgery in the same side, had pathological conditions such as tumors and/or infection, the age below 18 years or older than 55 years, had open fractures, Polly trauma patient or the patient had associated brachial plexus injury.

Ethical consideration: The study protocol had been approved by

the local research and ethics committee of Damietta Faculty of Medicine. Each patient signed an informed consent and the data reporting was in accordance with Helsinki declaration for research conduct and reporting.

The age of included patients ranged between 18 and 55 years, 86.7% of them were less than 35 years and 13.3% were 35 years or older. Males were predominant, representing 86.7%, and 53.3% of them were hard workers (table 1). Clinically, 66.7% had injury of the right side, 13.3% had associated ipsilateral fractures and 13.3% had associated chronic medical conditions. The mechanism of injury was road traffic accident (60.0%), falling down (26.7%) and direct trauma (13.3%); the fracture pattern was B1 (80.0%), B2 (13.3%) and A2 (6.7%). Twenty percent of patients underwent to surgical intervention after 7 days, while 80.0% had intervention within one week. The closed reduction was successful for 66.7% and open reduction was necessary for 33.3% (Table 2).

Table (1): Patient characteristics

		Values
Age	<35years	13(86.7%)
	≥ 35 years	2(13.3%)
	Mean±SD; Min. - Max.	27.73±11.28; 18-55
Sex	Male	13(86.7%)
	Female	2(13.3%)
Occupation	Hard worker	8(53.3%)
	Light worker	7(46.7%)

Table (2): Clinical data of studied patients

		Values
Affected side	Right	10(66.7%)
	Left	5(33.3%)
Associated conditions	Associated ipsilateral fractures	2(13.3%)
	Associated medical conditions	2(13.3%)
Mechanism of injury	Road traffic accident	9(60.0%)
	Falling down	4(26.7%)
	Direct trauma	2(13.3%)
Fracture pattern Robinson classification	2B1	12(80.0%)
	2B2	2(13.3%)
	2A2	1 (6.7%)
Time lapse before surgery (days)	≤ 7 days	12(80.0%)
	> 7 days	3(20.0%)
	Mean±SD (min-max)	4.60±2.93;1-10
Reduction	Open	5(33.3%)
	Closed	10(66.7%)

Data were collected by a pre-prepared systematic sheet, which divided into sections; the first for history (personal data and present history), the second for clinical examination (affected side, tenderness, skin condition and associated injuries); and the third for radiological investigations (antero-posterior radiograph of the shoulder was obtained for all patients to assess the fracture type).

All patients were treated using percutaneous elastic stable intramedullary nails. Surgery was performed with the patient under general anaesthesia. Prophylactic antibiotic prophylaxis (third generation cephalosporin) was given before surgery about 30 minutes. The patient was put in the semi setting (beach-chair) position on operative table. To ensure extension of the shoulder girdle, a small towel roll placed between the two scapulae. It is important to scrub the whole ipsilateral upper extremity to allow free manipulation of the shoulder and arm during surgery and to scrub the chest till the midline for the entry point. An image intensifier was used for the operation (Figure 1). A short skin incision (1cm) was created just lateral to the sternoclavicular joint centred above the medial end of the clavicle localised by image intensifier (Figures 2-4).

Technique: An awl was used to open the medullary cavity, 1cm lateral to the sternoclavicular joint. The awl was pointed laterally in-line with the clavicle and angled at about 30° to the coronal plane. Care was expressed to preserve the dorsal cortex in order to avoid major complications (Figure 5).

Once the medullary cavity was opened, an intramedullary nail was carefully inserted. The implanted nail (FSIN) had diameters between 2.0 and 3.0 mm according to the patient's dimensions. The nail was fixed in a universal chuck with a T handle and advanced with oscillating movements till it reached the fracture site (Figure 6).

Once the nail reached the site of the fracture, a closed reduction was done by direct pressure on the fragments combined with arm manipulation. Usually reduction was facilitated when small pointed reduction forceps was applied percutaneously to reduce the fracture (Figure 7). In 5 patients closed reduction could not be accomplished. In these patients, a short incision directly over the fracture site (2 cm) with minimal dissection (to avoid the supraclavicular nerve injury) was performed to reduce the fracture (figure 8).

The nail was then pushed into the lateral part of the clavicle close to about 1 cm. Care to prevent perforation of the dorsolateral cortex of the lateral clavicle was considered (figure 9). 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 (figure 10).

Closure of skin was performed by simple interrupted sutures using 3-0 proline. In case of open reduction, a standard closure of the other wound was then performed in layers using 2-0 absorbable sutures for the myofascia and subcutaneous tissue then subcuticular stitch for the skin. After the surgery, patient was placed in a sling. All patients were followed up clinically and radiologically for at least six months. Patients were discharged with their arm immobilized in a sling. The sutures were removed after 2 weeks. The shoulder sling was discarded at 2 weeks and active-assisted exercises were started. Early gentle mobilization when pain allows, with no overhead abduction for first six weeks. The nail was removed after complete radiological union (after 6 months) to avoid any further skin irritation. Results were assessed at the end of this period according to A modified **Constant and Murley Score (CMS)**⁽¹⁰⁾.

Data analysis: the collected data were presented statistically by mean, standard deviation, minimum and maximum for numerical data, and frequency with percentage for qualitative data. Chi square or Fisher Exact tests were used for comparison between groups, and p value < 0.05 was considered statistically significant

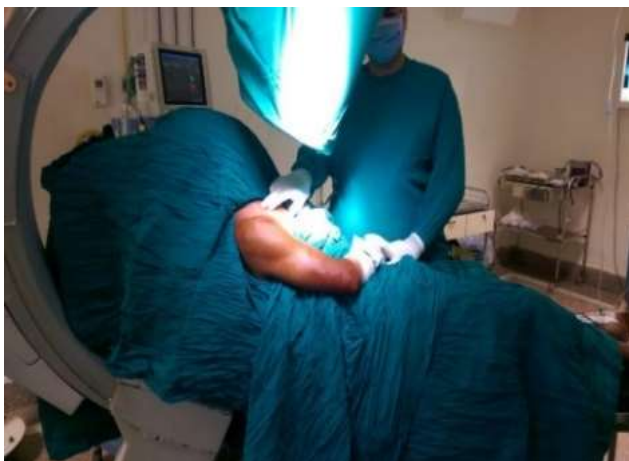


Figure (1): The patient is placed on a radiolucent operating table in the beach-chair position with an image intensifier from behind



Figure (2): Skin incision was localised about one-centimetre lateral to the sternoclavicular joint.



Figure (3): Skin incision localised by image intensifier.



Figure (4): Short skin incision

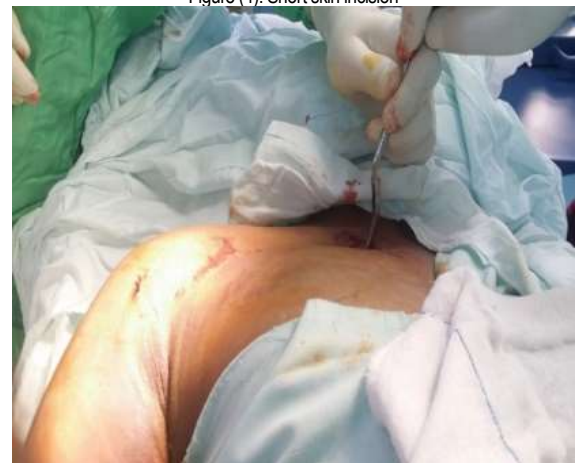


Figure (5): The medullary cavity of the clavicle was opened using an awl



Figure (6): ESIN reached the fracture site



Figure (7): Reduction the fracture by reduction forceps



Figure (8): A 2 cm incision over fracture site showing supraclavicular nerve



Figure (9): The nail was then pushed into the lateral part of the clavicle close to its extremity



Figure (10): Medial end of nail cut close to its entry point into the bone

RESULTS

The final Score: At the end of the follow up period, the mean score was 89.13 ± 13.91 ranging from 50 to 100 according to the modified Constant and Murley shoulder score. 10 patients (66.7%) had excellent results, 3 patients (20%) had good results, one patient (6.7%) had fair result, and one patient (6.7%) had poor result. Pain was absent or mild in the majority of patients (93.3%) and only one patient (6.7%) had moderate pain. The activity scoring revealed that, 86.7% of patients return to full work, and all had unaffected sleep. The positioning was up to the neck in 13.3%, and above the head in 86.7% (Table 3).

Table (4): presented the range of active motions in forward flexion, abduction, external rotation, internal rotation and overall rate of union. The union was achieved in 14 patients (93.3%).

Strength: At the end of the follow up period, the mean final constant score for strength was 24.0 ± 3.08 ranging from 15 to 25.

When searching for factors affecting final score, only younger age and absence of any associated medical disease were associated with excellent outcome (Table 5).

Complications: One patient (6.7 %) had an **infection** at the entry after removal of the sutures with minimal serous discharge. Intravenous antibiotic was given with daily dressing until subsided after about 1 week. In addition, two patients (13.33%) developed **medial end skin irritation** due to medial migration of the intramedullary nail, one patient had to remove the nail while the other resolved within 2 weeks of medical treatment with anti-inflammatory drugs. Furthermore, one patient (6.7%) had **hypertrophic non-union**, so the nail was removed and the fracture was fixed by plate and screws with bone graft.

Table (3): Outcome among studied populations

	Variable	Results
Final score	Excellent (91 - 100)	10(66.7%)
	Good (75 - 90)	3(20.0%)
	Fair (60 - 74)	1(6.7%)
	Poor (< 60)	1(6.7%)
	Mean \pm SD (Min. – Max.)	89.13 ± 13.91 ; 50.0 – 100.0
Pain	Absent or mild	14 (93.3%)
	Moderate	1(6.7%)
	Mean \pm SD (Min. – Max.)	14.50 ± 2.24 ; 5.0- 15.0
Activity	Full work	13(86.7%)
	Full recreation/sport	13(86.7%)
	Unaffected sleep	15(100.0%)
Positioning (constant score)	Up to neck	2(13.3%)
	Above head	13(86.7%)
	Mean \pm SD (Min. – Max.)	18.80 ± 3.69 (8.0- 20.0)

Table (3): Outcome among studied populations

Variable	Results	
Final score	Excellent (91 - 100)	10(66.7%)
	Good (75 - 90)	3(20.0%)
	Fair (60 - 74)	1(6.7%)
	Poor (< 60)	1(6.7%)
	Mean ± SD (Min. – Max.)	89.13±13.91; 50.0 – 100.0
Pain	Absent or mild	14 (93.3%)
	Moderate	1(6.7%)
	Mean ± SD (Min. – Max.)	14.50±2.24; 5.0- 15.0
Activity	Full work	13(86.7%)
	Full recreation/sport	13(86.7%)
	Unaffected sleep	15(100.0%)
Positioning (constant score)	Up to neck	2(13.3%)
	Above head	13(86.7%)
	Mean ± SD (Min. – Max.)	18.80±3.69 (8.0- 20.0)

Table (4): Range of motion among studied populations

Variable	Results	
Active forward flexion	61-90°	1(6.7%)
	121-150°	1(6.7%)
	151-180°	13(86.7%)
	Mean±SD(min.- max.)	9.60 ± 1.39 (4.0 – 10.0)
Active abduction	61-90°	1(6.7%)
	121-150°	1(6.7%)
	151-180°	13(86.7%)
	Mean±SD(min.- max.)	9.60 ± 1.39 (4.0 – 10.0)
Active external rotation	Hand on top of head with elbow held forward	2(13.3%)
	Full elevation from on top of head	13(86.7%)
	Mean±SD(min.- max.)	9.60 ± 1.23 (6.0 – 10.0)
Active internal Rotation	Dorsum of hand to waist (3rd lumbar vertebra)	2(13.3%)
	Dorsum of hand to interscapular region (DV 7)	13(86.7%)
	Mean±SD(min.- max.)	9.60 ± 1.23 (6.0 – 10.0)
Union	Non union	1(6.7%)
	Union	14(93.3%)
	Mean±SD(min.- max.)	10.0 ± 1.33 (8.0 – 12.0)

Table (5): Factors affecting final score

		Final score								P- Value
		Excellent (n = 10)		Good (n = 3)		Fair (n = 1)		Poor(n = 1)		
		No.	%	No.	%	No.	%	No.	%	
Age	<35	9	90	3	100.0	0	0.0	0	0.0	w
	≥35	1	10	0	0.0	1	100.0	1	100.0	
Sex	Male	8	80	3	100.0	1	100.0	1	100.0	0.410
	Female	2	20	0	0.0	0	0.0	0	0.0	
Associated Injuries	Free	9	90	3	100.0	0	0.0	1	100.0	0.066
	Positive	1	10	0	0.0	1	100.0	0	0.0	
Lapse before surgery	≤ 7	8	83.3	3	100.0	0	0.0	1	100.0	0.847
	>7	2	16.7	0	0.0	1	100.0	0	0.0	
Associated medical conditions	Free	10	90	3	100.0	0	0.0	0	0.0	0.021*
	Positive	0	10	0	0.0	1	100.0	1	100.0	
Fracture pattern	2A2	0	0.0	0	0.0	1	100.0	0	0.0	0.669
	2B1	9	90	2	66.7	0	0.0	1	100.0	
	2B2	1	10	1	33.3	0	0.0	0	0.0	
Open reduction	No	8	80	1	33.3	1	100.0	0	0.0	0.51
	Yes	2	20	2	66.7	0	0.0	1	100.0	

2A2: Angulated; 2B1: Simple fracture or single butterfly; 2B2: Comminuted or segmental

DISCUSSION

Many authors advocated primary surgical treatment of displaced injuries. Imminent perforation of the skin, impending or existing

neurovascular compromise and the floating shoulder represent absolute indications for operative treatment. Gross displacement of fracture fragments, as well as non-unions, are seen as relative indications for surgical fixation. Plate osteosynthesis is the standard operative treatment. Currently, the implants most commonly used are

either dynamic compression or locking plates. Reconstruction plates have fallen into disfavor, since they are susceptible to deformity at the fracture site, leading to mal-union. Site-specific precontoured locking plates have recently been introduced, and they are less prominent after healing, leading to lower rates of hardware removal after union⁽¹¹⁾. The complications related to the use of plate fixation are infection, plate failure, hypertrophic or dysesthetic scars, implant loosening, non-union, refracture after plate removal, and very rarely intraoperative vascular injury⁽¹²⁾.

A variety of intramedullary devices including Knowles pins, Kirschner wires, Hagie pins and Rockwood pins have been used. Implant migration with fatal complications, implant failure and mal- and non-unions have been mentioned as complications⁽¹³⁾.

To overcome the disadvantages of previously described methods minimally invasive ESIN was recognized to replace plate fixation. **Jubel et al.**⁽¹⁴⁾ showed that to obtain good functional outcome, it is mandatory to correct clavicular shortening. They did not find nonunion or poor final postoperative outcome. In addition, intramedullary nailing was associated with good and early functional recovery for all patients. Nowadays, patient's expectations for functional outcomes are high. They expect rapid and pain-free functional recovery following a fracture. In **Narsaria et al.**⁽¹⁵⁾ study patients were divided in two groups (treatment by elastic intramedullary nail (EIN) or plate). Constant Shoulder score was significantly higher in the plating than the EIN group directly in postoperative period and preserved for the first two months, which is absent at the end of the second year of follow up. They concluded that, EIN is a safe, and minimally invasive intervention with a reduced rate of complication, excellent cosmetic outcome and comparable functional outcomes. It can be used as an equal and effective alternative to plate fixation in clavicular displaced, non-comminuted midshaft fractures.

Assobhi⁽¹⁶⁾ treated 38 patients randomly by either plating (plate group) or nailing (TEN group). Results were similar between the two groups after the 12th week. However, earlier union and function recovery were achieved at the 6th week for patients of the TEN group. The complications rate was significantly higher (15.8%) in the plate when compared to TEN group (0%). They reach to the conclusion that the TEN maneuver is more advantageous than plating with lower rate of complications; making its use more reasonable. **Jubel et al.**⁽¹⁴⁾ carried a prospective research on intramedullary fixation maneuvers by the use of elastic stable Ti nail to treat displaced mid-shaft clavicular fractures. Radiological evaluation confirmed the fracture healing, and clinical outcomes was assessed by different scores. All fractures were of transverse or oblique types. They finally said that, intramedullary fixation was successful on the clinical basis with rapid return to full sport activities. They advocated such treatment to athletes as an alternative to conservative treatment.

Hartmann et al.⁽¹⁷⁾ studied 15 cases with clavicular fractures, managed by elastic intramedullary nailing, and followed up for one year. All fractures yielded good healing on the clinical and radiological basis. No cases had non-union or infections. Functional results were excellent. As a conclusion, surgical treatment of displaced mid-shaft clavicular fractures with ESIN had an excellent functional outcome. This technique provides early free shoulder movement and associated with earlier return to normal daily activities, when compared to conservative, non-surgical treatment. **Meier et al.**⁽¹⁸⁾ case series was conducted to assess indications, technical and functional outcome of elastic stable intramedullary nailing of displaced midclavicular fractures in 14 patients. With delay more than 7 days, the closed reduction was never achieved suggesting that early intervention provides better chance for successful treatment. The

dorsolateral cortex was perforated (one patient) when the TEN was advanced to the clavicle lateral end using a force of the hammer. As this complication was realized during the maneuver, the Ti nail was withdrawn a few centimetres and the repositioned again. They do not advocate the use of the hammer anymore in the future. A smaller implant must be considered if it is not possible to advance the nail using only oscillatory movements.

In this study 15 patients were included. The final Constant score after 6 months was 89.15 ± 13.91 . 10 patients had excellent results, 3 patients had good results, 1 patient had fair result and 1 patient had poor results. In comparison with **Narsaria et al.**⁽¹⁵⁾ study showed higher score for the plating group, while **Assobhi**⁽¹⁶⁾ study showed higher score with the nailing group. However, both studies reported a non-significant difference between groups as regard to outcome, either functional or radiological at the end of the second follow up year.

Keihan Shokouh et al.⁽¹⁹⁾ case study showed that 10 patients out of 13 had a Constant score of 100, two patients were 90 and one patients was 95. After 6 months and after nail removal, all patients (n = 13) presented with normal shoulder function (mean: 98, range: 93 to 100).

Pain was moderate in one patient (6.67%) and no pain in 14 patients (93.33%). Similar results were reported in **Assobhi**⁽¹⁶⁾ study (TEN) group in the first 6 weeks of follow up while pain was equal in both groups (plate and TEN) after 12 weeks. Time of union in the studied patients ranged from 8 weeks to 12 weeks with a mean 10.0 ± 1.33 weeks with an exception of one case which started hard work after 2 weeks. He presented with hypertrophic non-union and went through revision by nail removal and fixation by plate and screws. **Hartmann et al.**⁽¹⁷⁾ study fracture healing was assessed with a mean follow-up time of one year. All fractures healed clinically and radiologically between 8-11 weeks. Non-union was not observed. **Kettler et al.**⁽²⁰⁾ case study (95 patients) showed that the bone healing was judged as optimal in 81 patients by the end of the 12th week, while in 4 patients a hypertrophic callus formation but without neurological symptoms. In 2 patients a nonunion persisted. An atrophic non-union was seen in a 42-year-old smoker with the nail in situ for 12 months; however, she remained clinically asymptomatic. A second patient with a nonunion after premature implant removal had a plate fixation after 6 months. In **Keihan Shokouh et al.**⁽¹⁹⁾ case study clinical union was accomplished in about 3-5 weeks and radiographic healing attained in 6-12 weeks.

Regarding the age and sex, there was statistically significant relationship between age and the final score. In comparison to **Jubel et al.**⁽¹⁴⁾ study was

all their patients are young athletes, the mean age in this study for the excellent results was 25.7 years and that for good results was 30.0 years, while that for the fair results was 53.0 and for the poor results was 35.0. This concludes that the outcome of young is better than elderly patients. On the other hand there was no statistically significant relationship between sex and final score neither in this study, **Hartmann et al.**⁽¹⁷⁾ study nor in **Meier et al.**⁽¹⁸⁾ case series.

Also, the associated medical condition showed statistically significant relationship with the final score. In comparison to the other studies were the patients were athletic with no mentioned medical morbidity, patients in this study showed associated medical conditions; the patient with poor result was uncontrolled diabetic, while that with fair result was hypertensive. As a result, the medical condition has an effect on final score of patients.

There were 4 patients with complications in this study; one patient

(6.67%) developed incisional infection, 2 patients (13.33%) developed medial end skin irritation, one of them had to remove the nail, while the other improved within 2 weeks of medical treatment. Lastly one patient (6.67%) presented with hypertrophic non-union and had to be revised by plating. In **Mark Kettler et al.** (20) case study only 6 patients out of 87 complained of irritation or scar formation at the medial entry point. In 2 cases, the protruding end of the nail at the medial side caused irritation.

Frigg et al. (21) reported 34 patients treated with intramedullary nailing. They reach to the conclusion that intramedullary nailing for midclavicular fractures by TEN had different postoperative complications with technical difficulty. They also reported that complications were reported in 70% of the patients (medial perforations (7), lateral perforations (7), nail breakage (1), nail dislocation (1), and hardware irritation (7). Lastly, Hartmann's (17) study showed 5 patients with complications, four patients suffered from skin irritation and pain at the sternal end of the clavicle 1 to 4 months after the operation. In three cases the prominent medial end of the TEN was shortened, in one case the TEN was removed early (5 months after the operative treatment).

The study had some limitations, one of them is the small number of included subjects, which is inevitable as many of our colleagues still stick to the conservative approach and surgical approach is confined to selected patients. This small number was not enough to give a big evaluation picture of such technique. A wide scale studies in the future are thus warranted.

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