

# Study of Functional Outcome in Midshaft Clavicle Fracture Treated With Titanium Elastic Nailing System

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## Abstract

**Purpose:** Conservative methods were commonly used for midshaft clavicle fracture treatment, but with complications such as non-union, malunion, and shoulder asymmetry. Early surgical treatment for midshaft clavicular fractures could greatly reduce the same. Open reduction and internal fixation with plate and intramedullary fixation are the commonly used surgical techniques. Plating was considered as the gold standard in view of firm fixation and early rehabilitation, but with larger incision and soft-tissue exposure. Intramedullary fixation has been favored for its small incision, less periosteal stripping, faster union, and less operating time. Here, we assess the functional outcome following titanium elastic nailing system (TENS) application.

**Methodology:** It is a prospective cohort study (evidence level II), 60 patients fitting as per inclusion and exclusion criteria presenting to our orthopedic department from July 2017 to May 2019 are included in the study after obtaining informed consent.

**Results:** Among 60 patients treated with TENS, excellent functional outcome was seen in 50 patients (83.3%) by the 3rd month and 54 (90%) by the 6th month using Constant and Murley scoring system. In our study, 66.6% of cases had union by the 3rd month and rest all by 6 months.

**Conclusion:** TENS should be considered as primary option for midshaft clavicle fracture with mild-to-moderate comminution.

**Keywords:** Midshaft clavicle fracture, Locking compression plate, Titanium elastic nailing system, Intramedullary nailing, Closed reduction and nailing, Mini-open incision.

## Introduction

Clavicle fractures account approximately 2.6% of all fractures and are the commonest injuries in active individuals who participate in activities such as sports and high-speed falls or violent collisions [1]. Clavicle fractures most frequently result from a direct axial blow on shoulder, fall with an outstretched arm, road traffic accidents, sports accidents, or a fall from height [2, 3].

“Midclavicular fractures will heal without, with, or even despite the doctor!” [4] since long time conservative treatment has been the treatment of choice. This treatment policy was based on two studies conducted in the 1960s,

which stated non-union percentages of less than 1% after conservative treatment, regardless of the degree of displacement [5, 6]. In such studies, children were included, and they are known to recover faster because of their greater potential to remodel; moreover, these data were not adequately classified regarding patient age and fracture displacement. According to recent data based on the classification of fractures, the incidence of displaced midshaft clavicular fractures going into non-union in adults is 10–15% [7]. In a meta-analysis of literatures from 1975 to 2005, Zlowodzki et al. found that the non-union rate for non-surgically treated displaced midshaft clavicle fractures was 15.1% and is higher than that previously described [8].

Thus, surgical management is getting accepted mainly because the results of conservative management are inferior both functionally and clinically and that

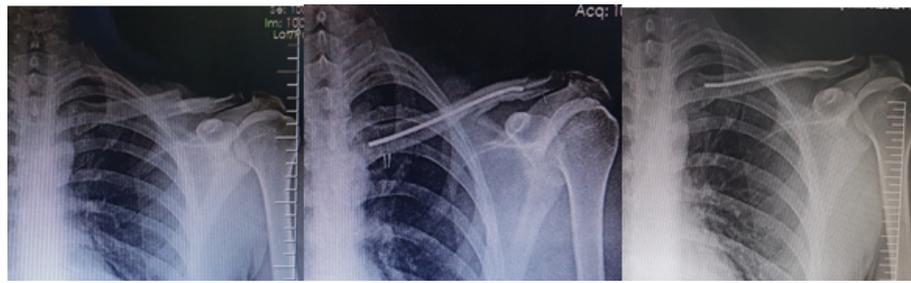
all recent studies show fractures with displacement and initial shortening of more than 2 cm resulted in non-union [9]. Safety and efficacy of primary open reduction and internal fixation for these fractures are proved by many studies and have also showed high rate of union with a low complication rate, thereby helping in early return to function [10, 11].

At present, patients desire best functional outcome along with rapid and pain-free functional recovery following a fracture. In contrast to conservative treatment, minimally invasive techniques are fulfilling these objectives with a reduced rate of complications [12]. Various methods of treating clavicle midshaft fractures have been described. In particular, plate fixation and nailing can help obtain firm anatomical reduction in severe displaced or segmental fracture, but the indication for both for a particular type of fracture is still in debate.

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**Figure 1:** Case 1. (a) Pre-operative, (b) post-operative, (c) union at the 2nd month.



**Figure 2:** Case 2. (a) Pre-operative, (b) post-operative, (c) post-implant removal.

Moreover, this study aims in evaluating the effectiveness of titanium elastic nailing system (TENS) as an intramedullary fixation device in clavicle fracture treatment.

### Methodology

It is a prospective cohort study with level of evidence II, 60 patients of midshaft clavicle fractures who underwent treatment with TENS as an intramedullary device from July 2017 to May 2019 in the Department of Orthopedics, R.L. Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar were selected according to inclusion and exclusion criteria. Clinical, functional, and radiological outcome was assessed following TENS application. Functional outcome was determined using Constant

scoring system [13]. Ethical clearance and approval was obtained from our Institutional Review Board before performing the study.

### Inclusion and exclusion criteria

Our study includes those of age 18 years and above with middle third clavicle fractures with the displacement of more than shaft width and duration of fracture <3 weeks. We excluded patients with severe comminution/bone loss, pre-existent morbidity concerning ipsilateral arm, shoulder or hand, head injury (Glasgow Coma Scale <12), open fractures, and pathological fractures, associated with neurovascular injury.

### Operative technique

Patient under general anesthesia was positioned in a radiolucent table with a

sandbag under interscapular region. A small horizontal incision in line with clavicle of 1–1.5 cm is made lateral to the sternal end of the clavicle. Skin, subcutaneous tissue, and platysma were divided. The anterior cortex is opened at an angle of 30° to horizontal plane after soft-tissue dissection with an awl or a drill bit. A flexible titanium nail of appropriate size was advanced into the medullary canal manually using Jacobs chuck. With image intensification, the implant is advanced to the fracture site and reduction is performed by means of a reduction clamp percutaneously and negotiating the nail into the lateral fragment. If this does not succeed, the tip of the nail was maneuvered from one fragment to another under direct vision after performing a second small transverse (2–3 cm) skin incision directly over the fracture site. The nail is then advanced manually or gently tapped with a mallet until it is just medial to the AC joint [12]. Medially, nail tip was bent and/or buried into nearby soft tissue to prevent nail prominence.

### Post-operative protocol

A sling is given for a few days. Nail position and reduction confirmed with check X-rays. Wound was inspected on the 2nd post-operative day and on the 14th post-operative day suture/staple removed. Shoulder movements other than overhead abduction and flexion initiated from the 2nd post-operative day. A minimum of 3 days of IV antibiotics was kept mandatory before patients were discharged. They were discharged at request or post-suture removal with the arm pouch. Rehabilitation of the affected limb was started immediately postoperatively according to patient's pain tolerance except for those with comminution for whom we started the same after 2 weeks. Gentle shoulder pendulum exercises were allowed first. At 3 weeks, gentle active shoulder range of movements was allowed but abduction



**Figure 3:** Clinical picture showing minimal scar.



**Figure 4:** Medial ulceration.



**Figure 5:** (a) Lateral nail protrusion, (b) post-implant removal.

was limited to 90°. At 4 weeks, active shoulder ROM was allowed in all planes. Regular follow-up was done every 4 weeks and examined clinically and radiologically to know implant position and fracture union. We examined for tenderness, implant loosening, deformity, signs of infection, and shoulder movements. Follow-up was continued till radiological union. Implant removal done was after union is confirmed and as per patients request (Figure 1 and 2). Constant and Murley scoring system was used to assess functional outcome [13].

### Results and Observations

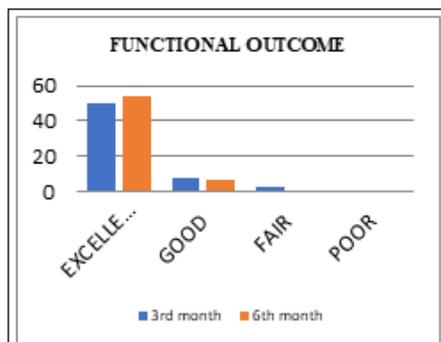
Males formed the majority (83.3%). The distribution of age reveals that 4 cases (6.6%) lie between 18 and 20 years, 20 cases (33.3%) lie between 21 and 30 years, 22 cases (36.6%) lie between 31 and 40 years, 4 cases (6.6%) lie between 41 and 50 years, 6 (10%) between 50 and 60 years, and 4 cases (6.6%) above 60. In 26 cases (43.3%), the time interval from fracture to surgery was <3 days, 20 cases

(33.3%) took 3–7 days, 10 cases (16.6%) in the 2nd week, and 4 cases (6.6%) after 2 weeks. Majority of the cases, i.e., 36 cases (60%) occurred as a result of road traffic accidents, 12 cases (20%) as a result of fall on an outstretched hand, 6 cases (10.0%) due to fall, and 6 cases (10%) due to direct trauma. There were a total of 32 cases (53.3%) of the right-sided fracture and the rest left sided. Twenty cases (33.3%) were simple transverse fractures, 12 (20%) were simple oblique fractures, 6 (10%) were simple spiral fractures, 8 (13.3%) were wedge type, 4 (6.6%) were segmental, and 10 (16.6%) were comminuted fractures. Majority of nail size used was of size 2.5 mm in 32 (53.3%) cases followed by 2 mm for 24 cases (40%) and 3 mm size for 4 (6.6%) cases. Majority of surgery needed open reduction 48 (80%). According to Robinson classification, there were 38 cases (63.3%) under 2B1 and 14 (23.3%) cases under 2B2, 6 cases (10%) under 2A2, and 2 cases (3.3%) under 2A1. Most of the cases are 42 (70%) did not have any associated injury, 12 (20%) cases had ipsilateral lower limb fracture, and 6 cases (10%) had head/facial injury as an associated injury. Eleven cases (18.3%) had to stay in hospital for 3 days, 32 cases (53.3%) for 7 days, 16 cases (26.6%) till 14 days, and 1 case had to stay for more than 2 weeks due to bilateral Bell's palsy. Mean operating time was 35 min in cases done by closed reduction and 66 min if required open reduction. In 16 cases (26.6%), fracture united by the end of 8

weeks, majority cases are 32 (53.3%) united by end of 12 weeks, 6 (10%) cases took till 16 weeks, 4 cases took 20 weeks, whereas for 2 cases, the union took longer than 20 weeks. Complications encountered in our study include: Six cases (10%) of delayed union, 3 (5%) cases of infection at nail entry site, 4 cases (6.6%) each of nail loosening, 2 (3.3%) lateral protrusion of nail, and 4 (6.6%) cases of medial protrusion of nail. Twelve (20%) cases complained of medial entry site skin irritation. There were no complications of malunion, non-union, nail breakage, hypertrophic scar, or shoulder stiffness. Out of 60 cases, a total of 50 (83.3%) showed excellent outcome, 8 cases (13.3%) had good outcome, and 2 had a fair outcome by the end of the 3rd month of follow-up. Moreover, by 6 months, 54 (90%) cases showed excellent result and rest showed good result (Graph 1). The results in our study was compared to other studies with similar demographic pattern and all shows similar observation (Table 1 & 2).

### Discussion

Clavicle fractures were usually treated conservatively. Rowe states that midclavicular fractures are underrated regarding disability and pain, especially during the 1st week [6]. Studies conducted by Suhail et al., Robinson et al., Hill et al., and Nordqvist et al. found poor results following conservative treatment [11, 14, 15, 16]. At present, locking compression plating is the main stay of treatment among surgical management. However, disadvantages of plating include – increased soft-tissue stripping and exposure, supraclavicular nerve damage, and slightly higher infection rates along with risk of refracture after plate removal [11]. Intramedullary nailing with various implants such as Rockwood pin, Steinman pin, and Knowles pin has been tried but was not effective enough to replace the LCP due to their inferior biomechanical properties. The newest



**Graph 1:** Graph showing outcome at the 3rd and 6th months of follow-up.

**Table 1: Comparison of different studies according to age, sex, and side effect time interval, mode of reduction, and time of union**

Study	Avg. age (years)	Sex (M/F)	Side (R/L)	Avg. time till surgery (days)	Reduction (open/closed)	Avg. time of union (weeks)
Present study (n=30)	37	25/5	16/14	4.8	24/6	11.1
Mueller et al. (n=31)	37.5	24/7	14/17	14.5	15/16	-
Meier et al. (n=14)	28	2-Dec	-	6	7-Jul	7.7
Radwan et al. (n=46)	40	15/31	23/23	4.5	21/25	11.6

intramedullary device showing similar biomechanical properties to a clavicle is an elastic nail made of titanium.

In this study, majority cases 36 (60%) occurred due to road traffic accidents. The average age in our study is 37 years. Male patients formed the majority in our study – 50 cases (83.3%). Male predominance can be due to increased use of motor vehicles and the active lifestyle. Thus, we can infer that clavicle midshaft fractures occur in young and active individuals and fixation is better option than conservative method for faster return returning to activity. Densitometry of clavicle shows that the clavicle on the non-dominant side is denser than the clavicle on the dominant side. Some studies show that the greater bone mineral density on the non-dominant side would diminish bone flexibility and, hypothetically, increase the propensity to fractures [17]. In this study, there were a total of 32 cases (53.3%) of the right-sided fracture and rest left sided. We conclude that clavicle fracture is not affected by hand predominance.

In this study, 12 cases (20%) had ipsilateral lower limb fracture. Mueller et al. suggested that patients with additional injuries of the lower extremity were able to use crutches after intramedullary splinting, enabling early mobilization. This was effective as costs associated with long-term immobilization were reduced. On the other hand, treatment of additional injuries including intensive care of those with multiple injuries and usage of crutches did not affect clavicular healing [18]. This emphasizes that clavicle fracture should be ruled out in routine and fixation of clavicle with TENS is advantageous in patients with other injuries, especially lower limb injuries compared to plating as it can assist in immediate mobilization of patient.

All patients had closed fractures with majority (33.3%) being simple transverse fracture and 4 (6.6%) were segmental and 10 (16.6%) were comminuted fractures. According to Robinson classification, there were 38 cases (63.3%) under 2B1 and 14 (23.3%) cases under 2B2, 6 cases (10%) under

2A2, and 2 cases (3.3%) under 2A1. This indicates that TENS nailing is successful not only in simple fractures but also in segmental fractures and fractures with mild-to-moderate comminution.

Majority of nail size used was of size 2.5 mm that is in 32 (53.3%) cases followed by 2 mm for 24 cases (40%), 3 mm size was used for 4 (6.6%) cases. Slongo suggests that nail diameter should be between one-third and 40% of the medullary space diameter [19]. In our study, there was no incidence of nail breakage. Mueller et al. had two incidence of nail breakage but had no functional consequence. They further state that the middle third of clavicle is subjected to considerable tension, bending, and torsional forces, and they think that the diameter of the nail should not be <1/2 of the medullar cavity as rapid pain relief results in premature use of the arm, the latter of which was also observed in our study [17].

About 80% of our patients underwent open reduction with minimal incision giving better cosmetic outcome (Fig. 3). Difficulty encountered is mainly attributed to varied comminution and the S-shaped curve of the bone which demands technical expertise for negotiating the nail through fracture site and attaining closed reduction.

In 26 cases (43.3%), the time interval before surgery was <3 days. We observed that all 12 cases which underwent closed reduction were operated within 3 days post-trauma and operative time increased with increase in delay for surgery. Clavicle is inherently a bone with high union potential and significant fibrosis occurs even when there is a delay of 1 week necessitating open reduction. Mode of reduction is also determined by the fracture pattern even though certain studies excluded it [20]. Meier et al. observed that closed reduction was never achieved when delayed for more than 7 days, suggesting that an early intervention has better chances for successful closed reduction [21].

**Table 2: Comparison of complications in different studies**

Complication	Present study (%)	Meier et al. (%)	Mueller et al. (%)	Radwan et al. (%)
Entry site skin irritation	26	14	22.5	32.6
Medial protrusion	13.3	-	12.9	2.1
Lateral protrusion	6.6	-	3.2	10.8
Superficial entry site infection	6.6	-	3.2	6.5
Nail breakage	-	-	6.4	-
Nail loosening	10	-	-	-
Shoulder stiffness	-	-	-	-
Hypertrophic scar	-	-	25.8	6.5
Non-union	-	-	-	2.1
Malunion	-	-	-	-
Delayed union	10	-	-	-

Some cases of clavicle fracture which were deemed to be simple based on initial radiographs were found to be comminuted during surgery. Such incidences pose difficulties while attempting closed reduction as the intraoperative fluoroscopic images cannot give a three-dimensional image, and an inexperienced surgeon will have to struggle to attain closed reduction, leading to increased surgery time and soft-tissue injury. Hence, it is recommended to do a mini-open reduction in case of difficulty in attaining closed reduction, as the main advantage of this intramedullary fixation with TENS is to reduce soft-tissue injury and surgical time. Operation time was shorter with closed reduction compared to open reduction 35 min versus 66 min. In this study, 11 cases (18.3%) had to stay in hospital for 3 days and 16 cases (53.3%) for 7 days, this clearly shows that this method is minimally invasive and promises faster recovery and return to day-to-day activities.

In 16 cases (26.6%), fracture united by 8 weeks and 32 (53.3%) united by 12 weeks. This indicates majority of cases achieved union within 3 months, and hence, long-term follow-up is not essential thereby less cumbersome for the patients. Twenty-four patients in our study underwent implant removal and under local anesthesia except for four patients who needed no anesthesia as implant were protruding medially. No patient had any occurrence of refracture and all were able to continue their occupation and day-to-day activity.

The complications encountered in our study are as follows: Twelve (20%) cases had skin irritation at entry site, among that four had medial protrusion of nail outside the skin and ulceration (Fig. 4). Three of latter had superficial infection at entry point which resolved by itself with local wound care. Two among the four with medial protrusion underwent nail trimming under local anesthesia which resolved the symptom. In this study, 4

cases (6.6%) had nail loosening. Loosened nails were removed in outpatient department itself, as all cases showed union by the time of loosening. Cause for loosening is attributed to superficial entry site infection after it protruded outside the skin in 3 of 4 and the other had aseptic loosening. We observed that all four patients who had loosening were those with comminuted fractures, which caused migration of nail medially during fracture consolidation and union.

Reaming with K-wire was done in two cases when there was difficulty in engaging the nail into lateral fragment due to narrow medullary canal in their lateral end. Both the cases (3.3%) eventually had lateral protrusion of nail (Fig. 5a) as their lateral cortex was breached during reaming. With this observation, for further cases, we used small tapping with impactor or a smaller nail (2 mm) instead of reaming, after which no further incidence of lateral migration of nail was reported. Lateral ulceration site healed by itself after implant removal (Fig. 5b). These problems were observed only in the first half of our study as after appreciating its cause, we kept medial end of the nail shorter or bent and buried into nearby soft tissue or muscle, which resolved the issue of medial prominence and irritation.

Clavicle is considered to undergo delayed union if no bridging callus was found by 3 months to 6 months post-fracture and we had six such cases but all united by the end of 6 months. There were no complications of malunion, non-union, nail breakage, hypertrophic scar, or shoulder stiffness. No case of implant failure was observed in our study.

Constant score by the end of 3 months showed excellent in 50 (83.3%) cases and by 6 months, 54 (90%) cases showed excellent and 3 (10%) showed good outcome. Hence, our study shows consistently good shoulder scores from the 1st week of post-operative period

itself. Our study used simple displaced and mild to moderately comminuted clavicle fractures and the results of functional outcome give promising evidence on the use of TENS as a surgical option.

### Conclusion

TENS in clavicle fracture is relatively a new and technically more demanding surgical technique, especially to achieve closed fracture reduction, which gives the advantage of maintaining an intact fracture hematoma, less soft-tissue injury, and less periosteal stripping which speeds up fracture healing. Even when open reduction of fracture was performed, surgical incisions were smaller in comparison with plate fixation, resulting in improved cosmetic results, lower infection rates, and minimal soft-tissue and periosteal stripping, thereby enhancing bony union.

We observed the following advantages: Shorter operative time, smaller wound incision, minimal scarring, early rehabilitation, early return to work, less pain level, less analgesic use, less symptomatic hardware, and the ability to remove the implant under local anesthesia, thereby reduce the need for another major surgery. Patient counseling is essential, and they must be informed about the following surgical risks and complications: Need for open reduction, migration of the nail, and secondary shortening. The complications incurred could be reduced by early surgery, advancing the nail by hand, proper case and nail selection, effective fluoroscopic use, limitation of the elevation of the arm to 90° up till 3rd post-operative week, and hardware removal 6 months after surgery.

During this study, it was observed that no literature has mentioned any complications such as intrathoracic migration, lung injury, and brachial plexus injury following this surgery even though general fear among the surgeons still exists. Hence, this study proves that

TENS should be used as a primary option for midshaft clavicle fracture with displacement more than 2 cm as well as in cases with mild-to-moderate comminution, especially in patients with high demand on shoulder function.

### Study limitations

This study is not a comparative study, the conclusions drawn from this analysis cannot be generalized because of the small number of cases. Our patients were

followed up for 3–6 months, and a longer follow-up will throw more light on the long-term results and complications.

## References

1. Court-Brown CM, Heckman JD, McQueen MM, et al. *Rockwood and Green's Fractures in Adults*. 8th ed. Philadelphia, PA: Wolters Kluwer; 2015. p. 1427-70.
2. Stanley D, Trowbridge EA, Norris SH. The mechanism of clavicular fracture. A clinical and biomechanical analysis. *J Bone Joint Surg Br* 1988;70:461-4.
3. Nowak J, Mallmin H, Larsson S. The aetiology and epidemiology of clavicular fractures. A prospective study during a 2-year period in Uppsala, Sweden. *Injury* 2000;31:353-8.
4. Schiffer G, Faymonville C, Skouras E, Andermahr J, Jubel A. Midclavicular fracture: Not just a trivial injury-current treatment options. *Dtsch Arztebl Int* 2010;107:711-7.
5. Neer CS. Nonunion of the clavicle. *J Am Med Assoc* 1960;172:1006-11.
6. Rowe CR. An atlas of anatomy and treatment of midclavicular fractures. *Clin Orthop Relat Res* 1968;58:29-42.
7. Canale ST, Beatty JH. *Campbell's Operative Orthopaedics*. 11th ed. Philadelphia, PA: Elsevier; 2008. p. 3371-6.
8. Zlowodzki M, Zelle BA, Cole PA, Jeray K, McKee MD. Treatment of acute midshaft clavicle fractures: Systematic review of 2144 fractures: On behalf of the evidence-based orthopaedic trauma working group. *J Orthop Trauma* 2005;19:504-7.
9. University of Utrecht. (2017). Operative treatment of displaced clavicle fractures: optimising implant choice.
10. McKee MD, Wild LM, Schemitsch EH. Midshaft malunion of the clavicle. *J Bone Joint Surg Am* 2003;85:790-7.
11. Suhail AB, Khurshed AB, Sanjeev G, Lone MS, Bhat A, Ali N. Changing trends in management of adult clavicular fractures. *IJAR* 2014;6:843-9.
12. Kettler M, Schieker M, Braunstein V, König M, Mutschler W. Flexible intramedullary nailing for stabilization of displaced midshaft clavicle fractures: Technique and results in 87 patients. *Acta Orthop* 2007;78:424-9.
13. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res* 1987;214:160-4.
14. Robinson CM, Brown CM, McQueen MM, Walkefield AE. Estimating the risk of non-union following non operative treatment of a clavicular fracture. *J Bone Joint Surg Am* 2004;86:1359-65.
15. Hill JM, McGuire MH, Crosby LA. Closed treatment of displaced middle third fractures of the clavicle gives poor results. *J Bone Joint Surg Br* 1997;79:537-40.
16. Nordqvist A, Petersson CJ, Redlund-Johnell I. Mid clavicular fractures in adults: End result study after conservative treatment. *J Orthop Trauma* 1998;12:572-6.
17. Guerra TE, Pozzi IM, Busin G, Zanetti LC, Lopes JA, Orso V. Densitometric study of the clavicle: Bone mineral density explains the laterality of the fractures. *Rev Bras Ortop* 2014;49:468-72.
18. Mueller M, Rangger C, Striepens N, Burger C. Minimally invasive intramedullary nailing of midshaft clavicular fractures using titanium elastic nails. *J Trauma* 2008;64:1528-34.
19. Slongo TF. Complications and failures of the ESIN technique. *Injury* 2005;36:78-85.
20. Zhang B, Zhu Y, Zhang F, Chen W, Tian Y, Zhang Y. Meta-analysis of plate fixation versus intramedullary fixation for the treatment of mid-shaft clavicle fractures. *Scand J Trauma Resusc Emerg Med* 2015;23:27.
21. Meier C, Grueninger P, Platz A. Elastic stable intramedullary nailing for midclavicular fractures in athletes: Indications, technical pitfalls and early results. *Acta Orthop Belg* 2006;72:269-75.

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