Zagazig University Medical Journal
www.zumj.journals.ekb.eg

Comparative Study Between Conservative Management and Plate Fixation For The Mid-Shaft Clavicle Fractures in Adults

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Submit Date	**13-3-2019**
Revise Date	**11-4-2019**
Accept Date	**12-4-2019**

ABSTRACT

Introduction: Fracture clavicle used to be treated conservatively. But, risk of mal-union and shoulder dysfunction has raised many concerns regarding this way of treatment. Operative treatment for clavicle fracture gained popularity recently for displaced fracture clavicle. So, in our study we compared between the two methods of treatment.

Patients and methods: We conducted a prospective study for all adult patient presented to our hospital with unstable fracture clavicle from August 2016 to September 2017. Patients were divided in two groups A and B, with exclusion of poly-trauma patients. Group A treated conservatively and group B treated by open reduction and internal fixation with plate and screws on the superior surface of the clavicle. The patients were followed up and assessed by constant shoulder score. **Results:** The study included 20 patients in two group 10 patient for each group. The demographic data in both groups showed no significant differences. Follow up was 6.2 and 7.3 months in both groups respectively. Union occurred in 5.8 and 5.3 months in both groups respectively. The difference was insignificant for follow up and union; p value> 0.05. Functional outcome was excellent in 8 and good in 2 in group A, and excellent in 6, good in 4 in group B. This difference was found to be significant, p value < 0.05. **Conclusion:** From our study and supported by others we recommend that conservative treatment should be the first choice for most patients and operative fixation to be reserved for selected cases.

Keywords: Clavicle fracture; clavicle fixation; conservative clavicle treatment

INTRODUCTION

Optimal shoulder function is achieved by the interaction of four joints (sternoclavicular, acromioclavcular, glenohumeral and scapulothoracic) joints working in biomechanical harmony. It is impossible to intervene at one joint without affecting the efficiency of the other three joints [1] .

Fractures of the clavicle are common, comprising up to 5% of all skeletal lesions in adults and up to 44% of fractures of the shoulder girdle. Fractures of the middle third of the clavicle (midshaft) account for about 80% of all clavicular fractures [2] . These fractures also show a bimodal age distribution. Between different age groups, young male patients aged less than 30 years and elderly patients aged over 70 years appear to be the two distinct age groups at higher risk for clavicular fractures [3] .

Falls onto the affected shoulder account for most (87%) of clavicular fractures with direct impact accounting for only (7%), falls onto an outstretched hand accounting for (6%) and very rarely clavicular fractures occur secondary to muscle contractions during seizures or as stress fractures [(2)].

Treatment of clavicular fractures in adults can be done either by conservative or surgical methods. Many different methods of clavicle immobilization have been described and can be summarized as a sling, strapping, or a combination of both.

Although non surgical management may be optimal for many clavicularfractures, good outcomes of non-surgically treated fractures are not universal [4]. Recent evidence suggests that specific subsets of patients at high risk for non union, shoulder dysfunction or residual pain after non surgical management should have acute surgical intervention to minimize suboptimal outcomes[5] . Therefore, specific treatment of clavicular fractures should not be broadly applied but rather should be individualized based on fracture characteristics and patient expectations.

Undisplaced fractures of the clavicle have a high rate of union, and the functional outcomes are good after non-operative treatment. Non-operative treatment of displaced fractures may be associated with a higher rate of nonunion and functional deficits. However, it remains difficult to predict which patients will have these complications [6].

The aim of this work is to compare results of conservative treatment and operative treatment with plate and screws in treatment of mid-shaft clavicular fractures in adults.

PATIENTS AND METHODS

This is a prospective study done at the department of Orthopedic Surgery; Zagazig General Hospital for patients presented to ER with fracture clavicle from August 2016 to September 2017. These patients were subdivided into two groups, Group **A** for conservative treatment and Group **B** for operative treatment. The study included patients with displaced mid-shaft fractures; simple or wedge comminuted (Type 2 B1) and comminuted segmental (Type 2B2) according to Robinson's classification[(4)]. We excluded from the study patients with ipsilateral upper limb injury, patients with neurovascular injuries, floating shoulder, lateral and medial one fifth fractures, fracture of the clavicle with multiple ipsilateral rib fractures, and poly-trauma patients.

Patients enrolled for Conservative treatment were treated by support for the arm by arm sling.

Written informed consent had been obtained from all participants in the study in both groups. The study was approved by the research ethical committee of Faculty of Medicine, Zagazig University.

Surgical Techniques:

Surgery was performed with the patient under general anesthesia; the patient was placed in semi-sitting position with a small pad behind the shoulder. The entire shoulder girdle, including the sternum, was prepared and draped so that the upper extremity can be used to mobilize the lateral fragment to aid in reduction.

The proximal and distal ends of the clavicle are marked on the skin and an incision centered over the fracture site. An oblique incision was made along the superior surface of the clavicle. The skin and subcutaneous tissue were raised as a flap, protecting any obvious cutaneous nerve branches and reflected upward allowing the underlying myofascia to be identified. This layer, including the delto-pectoral muscle attachment, was raised as contiguous flaps and was preserved so that a two-layered closure can be achieved over the plate.

Next, the fracture site was identified by fully exposing the proximal and distal fragments, the fracture ends were held with reduction forceps, and the clavicle was realigned.

With the fracture reduced, the plate was applied to the superior surface of clavicle and was secured to the medial and lateral fragments with bone reduction forceps, the plate was bent to follow the contour of the clavicle. A drill-and-tap preparation sized to the screw was then used to fix the plate to the clavicle, A minimum of three screws were placed on either side of the fracture such that purchase was achieved through all six cortices of bone. The plate used in the study was 3.5 sized reconstruction plates.

Once all of the screws have been inserted, the field was copiously irrigated with normal saline. Standard closure was then performed in layers with use of no. 0 absorbable sutures for the myofascia and for the subcutaneous

tissue, and no. 1 non absorbable sutures for the skin.After the surgery, the arm was placed in a sling.

Post-operative care:

Patients were discharged on the 2nd day with arm sling and instruction for pendulum exercises in the first week.

Follow up visits for all patients were 6-10 visits with a mean of 8 visits; every 2 weeks for the first 2 months (i.e. 4 visits) then every month for the following four months (i.e. 4 visits) and every 2 months for the last 4 months (i.e. 2 visits). In the first visit review of wounds and removal of sutures was done for patients in group B. The patients in group B were instructed to start active-assisted shoulder motion, range of motion exercises of the elbow and shoulder to improve function and to restore patient independence. At six week the sling was removed and start carful full range of motion for group A. X-ray was done in each visit to check union. When radiographic union was evident, full active use of the arm was permitted for all patients, and follow-up ended.

Methods of patient assessment:

Functional outcome was assessed using the Constant Shoulder Score (CSS), in table-1, adopted by the European Society for Shoulder and Elbow Surgery (ESSES)[7,8]. This scoring system consists of four variables that are used to assess each shoulder separately. The subjective variables are pain and ADL (sleep, work, recreation / sport) which give a total of 35 points. The objective variables are range of motion and strength which give a total of 65 points.

Grading of the Constant Shoulder Score:

A difference between normal and abnormal side more than 30 is considered "poor", from 21-30 is considered "fair", from 11-20 is considered "good" and less than 11 is considered "excellent" Constant Shoulder Score [7,8]

Statistical analysis:

Statistical analysis was done using SPSS v.19 software (SSPS Inc., Chicago, IL, USA). The t-test was used for the paired analysis of preoperative and final results. A *p* value < 0.05 was considered to be significant.

RESULTS

This study included 20 adult patients in two equal groups, the age in group A ranges from 22-55 years with a mean of 37.7 years and in group B it ranges from 21-41 years with a mean of 30.3 years with no statistically significant difference, p value> 0.05. Group A included 9 males (90 %) and 1 female (10 %), group B included 7 males (70 %) and 3 females (30%) with no statistically significant difference; p value> 0.05. In group A five patients had dominant side injury (50 %) and five patients had non-dominant side injury (50 %). In group B four patients had dominant side injury (40 %) and six patients had non-dominant side injury (60 %) with no statistically significant difference; p value > 0.05. In group A direct fall on the shoulder occurred in six patients (60 %), direct impact in three patients (30 %) and fall on outstretched hand in one patient (10 %). In group B direct fall on the shoulder occurred in nine patients (90%),and fall on outstretched hand in one patients (10 %). Only two patients in group B had associated injuries; one had ipsilateral one rib fracture and one had contralateral distal radius fracture. Group A included five patients with 2B1 (50%), and five patients with type 2B2 (50%). Group B had three patients with type 2B1 (30%), and seven patients with type 2B2 (70%), with no statistically significant difference; p value > 0.05.

Follow up period of patients in group A ranged from 5 months to 8 months with mean of 6.2 months, in group B it varied between 5 months to 10 months with mean of 7.3 months, and the difference was statistically insignificant; p value > 0.05.

Patients in group A achieved union in 5.8 months; range 4 to 8 months. Figure 1 shows patient of group A after injury and figure 2 shows the same patient after union of the clavicle fracture. In group B union occurred in 5.3 months; range 4 to 12 months. Figure 3 shows patient of group B after injury, and figure 4 shows the same patient after plate fixation of the clavicle fracture. Figure 5 of the same patient after complete union. The difference was statistically insignificant with p value >0.05.

Patient outcome in group A according to constant shoulder score was excellent in 8 patients and good in 2 patients, in group B it was excellent in 6 patients, good in 4 patients. This difference was found to be statistically significant as p value < 0.05.

Patients in group A showed ability to return to pre-injury daily activities in 10.2 weeks with range 8 to 14 weeks. In group B patients returned to pre-injury daily activities in 11.8 weeks with range of 7 to 15 weeks. There was no statistically significant difference as p value > 0.05.

One patient in group B developed surgical site infection. It was noted after operation by 6 weeks with discharge from the surgical site and local inflammation. The plate was removed as the infection was deep and debridement and irrigation was done and followed by antibiotic according to culture sensitivity results. The patient achieved healing 3 months afterwards.

Malunion occurred in five patients in group A and it didn't occur in group B. The results are summarized in table 2.

Table-1. Constant Shoulder Score (CSS)

1. Pain	**2. Activity Level (check all that apply)**	
Severe…….0	Unaffected Sleep……2	
Moderate……....5	Full Recreation/Sport……..4	
Mild……10	Full Work……4	
None……...15		
3. Arm Positioning	**4. Strength of Abduction [kg.]**	
Up to Waist……2	0……0	6……14
Up to Xiphoid……4	1……....2	8……17
Up to Neck……6	3…….5	9……20
Up to Top of Head……8	4…….....8	10……23
Above Head……..10	5…….....11	>10……..25
5. Forward Flexion	**6. Lateral Elevation**	
31-60 degrees……2	31-60 degrees……2	
61-90 degrees……4	61-90 degrees……4	
91-120 degrees……...6	91-120 degrees……..6	
121-150 degrees…….8	121-150 degrees……8	
151-180 degrees……10	151-180 degrees……10	
7. External Rotation	**8. Internal Rotation**	
Hand behind Head, Elbow forward…2	Lateral Thigh……..0	
Hand behind Head, Elbow back……4	Buttock……2	
Hand to top of Head, Elbow forward..6	Lumbosacral Junction……4	
Hand to top of Head, Elbow back…..8	Waist (L3)……..6	
Full Elevation……10	T12 Vertebra…….8	
	Interscapular(T7)……..10	

Table-2. Summary of results and complication.

	Group A	Group B
Union in months	5.8; (4 to 8)	5.3; (4 to 12)
Excellent constant shoulder score	8	6
Good constant shoulder score	2	4
Return to pre-injury daily activities	10.2 weeks	11.8 weeks
Malunion	5	0
Infection	0	1

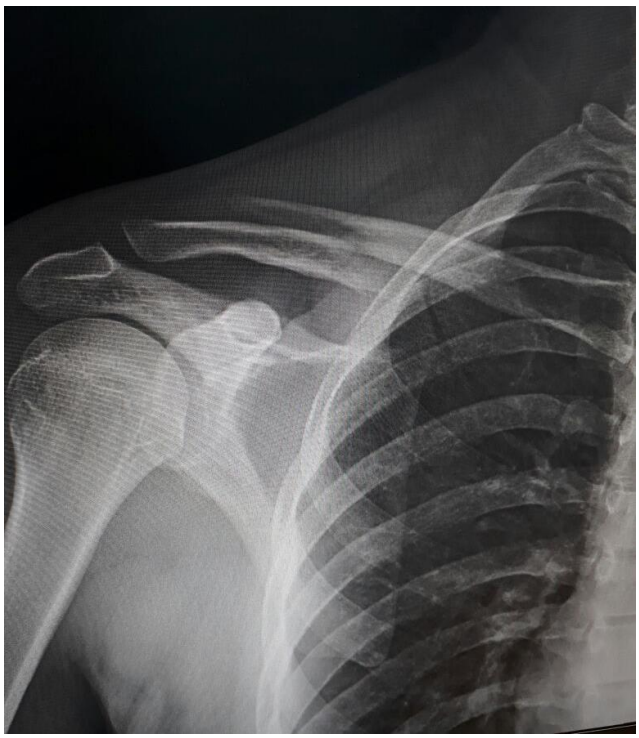

Figure-1: Patient 32 years old with right fracture clavicle at first presentation.

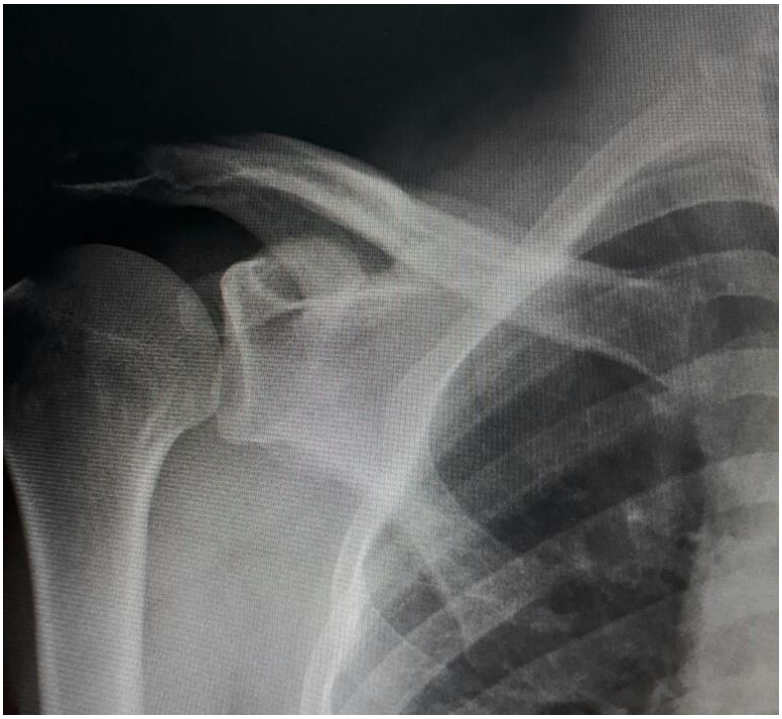

Figure-2: Same patient in figure-I after 10 weeks.

Figure-3: Patient of 35 years old at first presentation.

Figure-4: Same patient in figure-3 post-operative.

Figure-5: Same patient in figure-3 three months post-operative.

DISCUSSION

The outcomes following non-operative treatment for clavicle fractures are being increasingly doubted by researchers [9]. The available literature reports nonunion rates of up to 15% when non-operative treatment was used for displaced mid-shaft clavicle fractures[5,10] . However, this does not mean that surgery is definitely better than conservative treatment; it is still not confirmed whether all adult displaced mid-shaft clavicle fractures should be treated by operative fixation [5] .

Surgical treatment of mid-shaft clavicle fracture is most commonly done using plates and intramedullary devices; studies have reported significant advantages using these surgical methods compared with non-operative treatment [11] . Although open reduction with internal fixation (ORIF) was associated with a lower rate of mal-union and nonunion, shorter time to union, and better functional recovery, the results from a multicenter trial showed that operative treatment had a complication rate of 34% and a reoperation rate of 18% [12]. A report of Timothy et al. at the 2014 American Academy Orthopedic Surgeon, analyzed 1,350 patients aged 16-60 years who were treated with internal fixation from 2002 to 2010, and found that the reoperation rate reached up to 25%.

Robinson et al. [13] performed a multicenter involving 200 patients and do not support the routine use of primary surgical fixation for displaced midshaftclavicular fractures in adults. Robinson et al. [13] found that open reduction and plate fixation

provides a lower rate of nonunion, but increased implant-related complications. When comparing with nonoperative treatment, routine primary surgical treatment not only exposed an unacceptably high number of patients to the risks of surgery, but also increased economic burden of hospital costs[14] .They think treatment should be chosen based on an individual patient, after consideration of expectations of treatment, each patient's age, and activity level [13].

A multicenter trial, initiated by Robinson et al., [14] comparing surgery with conservative treatment of fresh displaced mid-shaft clavicle fracture, suggest that conservative treatment should be the first choice for most patients, and ORIF is highly recommended for patients aged 16-30 years. In our study the overall results showed no significant difference between the two groups which support the idea of Robinson et al. which suggest conservative treatment as the first choice and choosing operative treatment reserved for selected cases.

In our study there was no significant difference between the two groups in achieving union.

Zlowodzki et al. [5] reported complication rates after plating in displaced acute midshaft clavicle fractures of 2.2% nonunion, 4.6% infection, and 2% fixation failure. Schiffer et al. [15] reported implant failure and refracture after implant removal in 10% of cases.

Many patients require later hardware removal. Shen et al. [16] reported that 171 of their 232 patients had their hardware removed, with two of these patients suffering a refracture after hardware removal.In our study one patient developed surgical site infection with hardware removal with no other cases of hardware failure.In their study of 103 patients, Bostman et al. [17] reported that only five patients developed deep infection requiring re-operation and removal of the hardware, and only three patients developed superficial infection, which subsided in each case with the use of antibiotic therapy. With similar results to Bostman[17], Shen et al. [16] reported only a single case of deep infection and four cases of superficial infection in their 232 patient population.

Functional outcome was assessed using the Constant Shoulder Score (CSS) [7,8] adopted by the European Society for Shoulder and Elbow Surgery (ESSES). This scoring system consists of four variables that are used to assess each shoulder separately. The subjective variables are pain and ADL (sleep, work, recreation / sport) which give a total of 35 points. The objective variables are range of motion and strength which give a total of 65 points.

The overall results were excellent in 14 cases (70%), good in 6 cases (30%). the functional results showed minimal superiority of conservative group over the operative one but overall results ranged from excellent to good. Also, the return of daily activities and pre-injury functional status was no statistically different between the two groups. A mean follow-up of 5 years, reported by van der Ven Denise et al. [18] comparing with conservation, significant superior outcome scores were seen at 6 weeks for the operative group, However, at 24-week and 5-year follow-up no difference was seen in functional outcome scores for both treatment groups.

CONCLUSION

From the results of our study and supported by others we recommend that conservative treatment should be the first choice for most patients and operative fixation to be reserved for selected cases.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Funding information: None declared

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To Cite This Article: Abu-zeid ME , Khairy HM, El-Adawy AM, Al-Malt A EL. Comparative Study Between Conservative Management and Plate Fixation For The Mid-Shaft Clavicle Fractures in Adults. Zumj 2020; 27(2)239-247: doi 10.21608/zumj.2019.10215.1105.