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Comparison between conservative and surgical management of displaced mid-shaft clavicle fractures in adults

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Abstract

Clavicle fracture is a one of the most frequently fractured bones in the body with an incidence of 2.6-10% of all fractures due to its subcutaneous placement and relatively anterior position. Fractures affecting the middle third account for majority (approximately 80%) of all clavicular fractures and 50% of these are displaced. Both non-operative and surgical methods have been described for the management of clavicular fractures. However, it is not uniformly dictated on which treatment modality to opt for. Hence, this study was done in order to compare conservative approach with open reduction and internal fixation with plate in mid-shaft clavicular fractures in terms of subjective outcome, functional outcome, rates of non-union and mal-union and other local complications.

Patients of age between 20-50yrs were allocated into two groups, each including 15 patients on alternate basis. Group 1 patients were managed conservatively, consisting of a figure-of-eight bandage and a sling, whereas patients of group 2 were treated surgically by open reduction & internal fixation with plate & screws. Follow-up examination was done at every 2 weeks for 6 weeks and then 3, 6 and 9 months using patient's subjective evaluation, functional outcome, radiographic assessment and other complications.

The study showed that time to union was significantly shorter in patients treated surgically and this group also showed a favourable Constant shoulder score at all follow-ups. Though there was no statistically significant difference between the groups with regard to complication rate, subjective outcome or functional outcome, the surgical intervention group fared better especially when considering overall outcome results.

The present study showed that the time to union was lesser, rate of mal-union and non-union was lower, and Constant shoulder scores were higher in the surgical group. This affirms that while conservative treatment remains the treatment of choice for simple un-displaced mid-shaft clavicle fractures, for displaced and comminuted fractures the surgical intervention gives better outcomes and early functional recovery in young active adults.

Keywords: clavicle, fracture, mid-shaft, plating

Introduction

Clavicle fracture is one of the most common injuries around the shoulder girdle [1]. Fractures of the clavicle account for approximately 2.6%-10% of all fractures [2]. Incidence in males is usually highest in 2nd and 3rd decade which decreases thereafter as per age [3]. In females, it is usually bimodal, with peak incidence in young and elderly [4]. Allman [5] classified clavicle fractures into three groups based on their location along the clavicle. The middle-third fractures are most common and account for approximately 80-85% all clavicular fractures [6]. The narrow cross section of the bone in the middle shaft combined with typical muscle forces acting over it predispose to fracture the bone in this locality. Further, Robinson modified Allman classification based on the degree of displacement and comminution [3]. AO classification is also used for clavicular fractures widely.

Most mid-shaft clavicle fractures generally unite with any method of immobilization. Hence, non-operative treatment was the accepted modality of treatment. This was evident by extremely low non-union rates shown by various studies done earlier [7, 8]. However, certain recent studies have shown suboptimal outcomes and a very high non-union rates when displaced fractures are managed conservatively [9, 10]. Other poor outcomes of non-operative treatment were functional impairment of the shoulder and a non-cosmetic bump at the base of

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the neck possibly due to shortening of the clavicle and exuberant callus formation [9]. Restoration of normal length and alignment by surgical methods can prevent these drawbacks of conservative treatment. Clavicle acts as a strut, which keeps the upper limb away from the torso for efficient shoulder and upper limb function, while also transmitting forces from upper limb to trunk. Good outcome with high union rates and low complication rates has been reported with various surgical modalities of primary fixation of the displaced fractures [11-14]. However, operative treatment has also got its own disadvantages such as surgical site infection, hypertrophic scar, hardware prominence and a repeat surgery for implant removal at times. Since mid-shaft clavicular fractures generally unite with most of the treatment modalities, clinical trials performed to compare these therapeutic options are rare. In addition, there is no uniform consensus yet on the definite choice of treatment for displaced mid-shaft clavicular fractures.

In the younger age group, apart from isolated clavicle fractures poly-traumatic injuries are also very common and clavicular mid-shaft fracture is an associated finding. In such situations, the choice of treatment remains a constant dilemma for achieving maximum pre-fracture functional status. Hence, in this study we endeavoured to find an evidence-based answer to select the better approach for the management of acute displaced mid-shaft clavicular fractures. The aim of this study was to compare 30 patients with mid-shaft clavicular

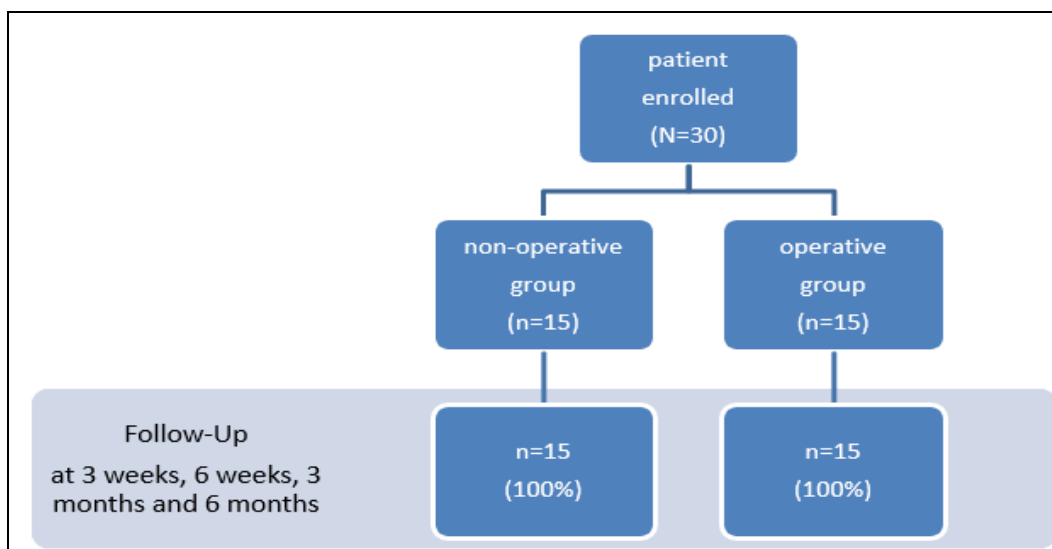
fractures treated either by conservative approach or primary internal plate fixation in terms of functional outcome, the rate of non-union, malunion and overall local complications up to 6 months after treatment. In addition, it was also intended to study the clinical response in terms of subjective outcome and the advantages and disadvantages of both the treatment modalities.

Materials and Methods

A non randomised comparative study with equal allocation of management of mid-shaft clavicle fractures (AO Type 15.2A, B, C fractures and Allman Type 1 fractures) was carried out at a tertiary care teaching hospital between Dec 2016 and Dec 2018. Study population included patients in age group of 20 and 50 years with completely displaced fracture of the mid-shaft clavicle. Patients with severe brain injury, intubated patients, open fractures or ipsilateral limb fracture and those with injury precluding operative fixation within 10 days of admission were excluded from the study.

It is a non-randomized comparative trial with equal allocation, consisting of 30 patients with freshly (newly) diagnosed mid-shaft clavicular fractures. Group 1 included 15 patients who were managed conservatively and group 2 had 15 patients who were treated surgically. Patients were allocated into both the treatment groups on alternate basis, i.e., group 1 followed by group 2 (Table 1).

Table 1: Patient allocation Methodology



Patient's eligible for the study was identified in the outpatient department of the hospital and the study protocol was instituted. Patients were informed in detail by the treating surgeon regarding the advantages and disadvantages of both operative and non-operative management. The nature of the study was explained in their own language that they understand and necessary consent was obtained after the patients gave their willingness to participate in the study. According to the treatment option preferred by the patients were allocated in either operative or non-operative group. Allocation of the patients were made till there were 15 patients in both groups.

Group 1 patients were managed conservatively, consisting of a figure-of-eight bandage (Fig. 1) and a sling, whereas patients of group 2 were treated surgically by plate osteosynthesis (Fig. 2).

In the non operative group patients were treated with

clavicular brace and arm sling for 3 weeks. Rehabilitation is started from 3 weeks onwards.

Patients allocated to plate fixation group underwent the operation within 10 days after the injury. An 8–10 cm skin incision was placed on the line joining sternal notch to anterior edge of acromion centred over fracture site on the affected side. Platysma was released from lateral side and supraclavicular nerves protected wherever possible. Subsequently the clavipectoral fascia was incised and elevated. Fractures fragments identified and reduced under vision. The plate (3.5 mm DCP with proper contouring, recon plates, anatomical locking/non-locking clavicular plates) was applied over the superior aspect of the clavicle taking care not to injure the underlying neurovascular structures. Comminuted fragments secured with lag screws wherever possible. Rehabilitation started just after pain tolerance.



Fig 1: Conservative treatment with figure of 8 bandage with shoulder Arm Pouch

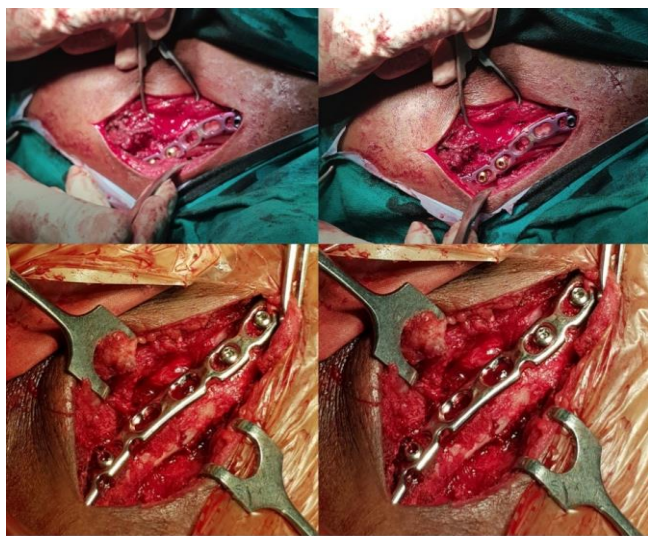


Fig 2: Intra operative fracture reduction and fixation with anatomical plate

A rehabilitation protocol was started after removal of the bandage in group 1 and just after pain tolerance in group 2. Gentle pendulum exercises of the shoulder in the sling/arm pouch were allowed as per pain tolerance immediately after surgery in surgical treated group and after 3 weeks in conservative group. At 3 weeks, gentle active range of motion of the shoulder was allowed with abduction limiting to 90°. Subsequently, active range of motion exercises that are to be performed at home is advised. At four to 6 weeks, active to active assisted range of motion in all planes was allowed. When fracture union (defined as radiographic union with no pain or motion with manual stressing of the fracture) was evident, muscle strengthening exercises were also allowed. At eight to 12 weeks, isometric and isotonic exercises were prescribed to the shoulder girdle muscles with a return to full activities (including sports) at 3 months.

Regular follow-up was done every 2 weeks for initial 6 weeks, then at 3, 6 and 9 months using patient's subjective evaluation, functional outcome and radiographic assessment. Patients' subjective evaluation was investigated by direct interview at the follow-up visits. Functional outcome was graded on the standardized clinical evaluation and completion of the Constant and Murley score [15]. Fracture healing was monitored by periodic radiographic examinations on two planes. The fracture was considered to be united when there was no tenderness at the fracture site with full function of the limb clinically and when the bridging callus and obliteration of fracture gap in X-Ray. Both the clinical and radiologic unions were assessed by an independent surgeon. An adverse

event or complication was defined as any event that necessitated another operative procedure or additional medical treatment.

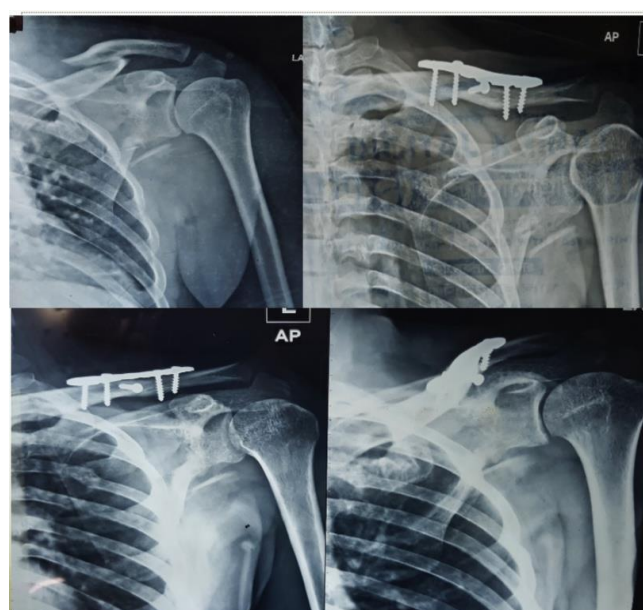


Fig 3: a) Displaced Mid Shaft Clavicle Fracture b) Immediate Post Op Xray c) and d) 3 months post op showing radiological fracture site consolidation and union

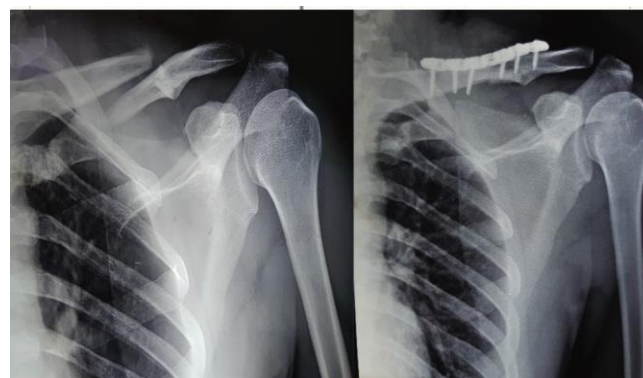


Fig 4: a) Displaced Mid Shaft Clavicle Fracture b) At 3months post op showing fracture union

Statistics

The data analysis was done using SPSS software version 17. Fisher's exact test, Chi-square test and 2 independent sample t-tests to find the association/significance between group 1 and group 2 were used. The observed results were determined to be significant if the *P* value was <0.05.

The institute’s ethics committee approval was taken before the commencement of study.

group 1 and group 2 with regard to demographic parameters such as mode of injury, age and sex of patients, side affected, presence of associated injuries and type of fracture as per Robinson’s classification (Table 2).

Results

There was no statistically significant difference between the

Table 2: Type of fracture as per Robinson’s classification

Demographic parameters	Group 1 (Conservative)	Group 2 (Operative)	P value (<0.05 is taken as significant)
Age (mean)	32	29.2	0.33
	S.D.-7.051	S.D.-8.453	
Sex			0.68
Male	10	12	
Female	5	3	
Mode of Injury			0.75
RTA	6	5	
Fall	5	7	
Sports Injury	4	3	
Side Affected			0.71
Dominant	8	10	
Non-Dominant	7	5	
Associated Injury			0.69
Present	6	4	
Absent	9	11	
AO Classification			0.62
AO 15.2A	8	6	
AO 15.2B	5	5	
AO 15.2C	2	4	

The fracture united in 93% of the patients in group 1, whereas 100% patients had fracture union in group 2. Fracture union was early and seen in a greater number of patients in group 2 as compared to group 1. Mean (SD) duration for “Time to Union” for Operative group (Group-1) was 9.53 weeks (1.885 weeks) compared to Non-Operative Group

11.07 Weeks (1.438 weeks). So, the average duration for “Time to Union” was significantly (P value 0.02) shorter in operative group. Around 67% of patients were fully satisfied, with the treatment at the end of 6 months in group 1, as compared to 87% in group 2 with the treatment.

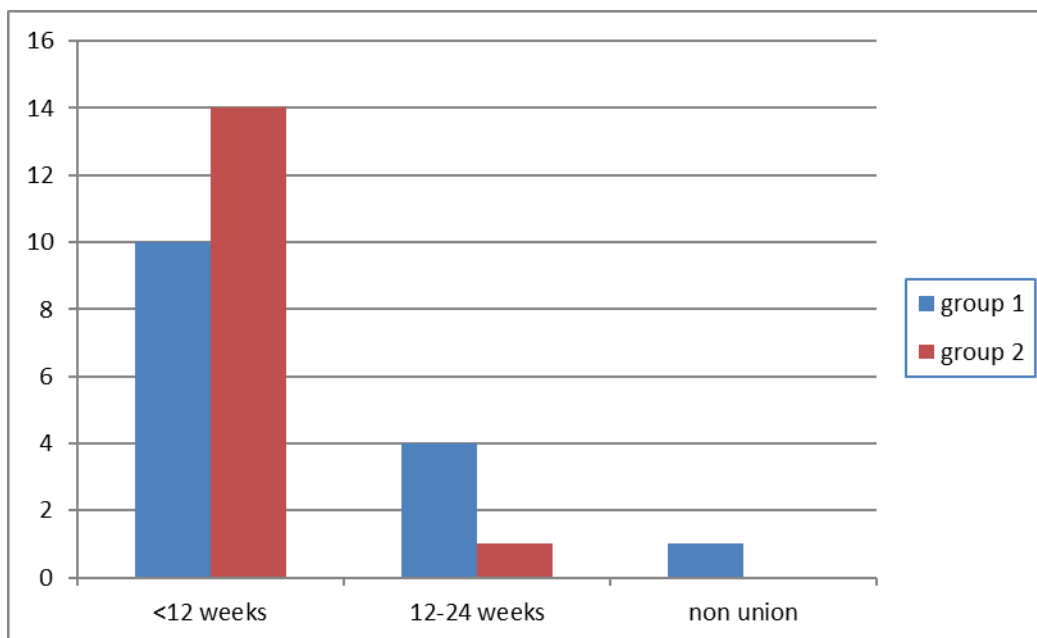


Fig 5: Time of Union with respect to treatment group

Table 3: Comparison of Constant Shoulder Score between 2 groups at 6 weeks, 3 months and 6 months

Constant Score at	Group 1		Group 2		P value
	Mean	S.D.	Mean	S.D.	
6 weeks	62.56	5.61	73.45	4.78	0.0000039
3 months	74.72	5.89	85.79	4.55	0.0000034
6 months	89.93	6.21	95.23	2.64	0.0051

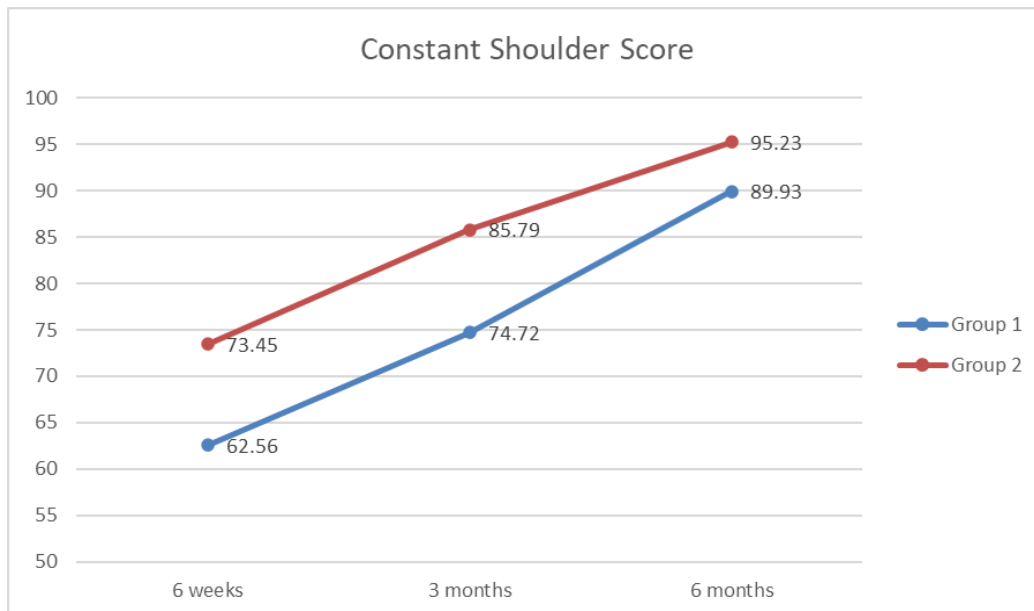


Fig 6: Constant shoulder score

Table 4: Shows table in parameters and group-1, and group-2

Parameters	Group-1	Group-2
Union Rate	93%	100%
Time to Union (Average)	11.07 weeks S.D.-1.438	9.53 weeks S.D.-1.885
Fully satisfied at 6 months	67%	87%
Mean Constant Score at 6weeks, 3 months & 6 months		Significantly Higher
Complications	33.33% Malunion Non-union Cosmetic deformity Stiff shoulder	13.33% Scar Hardware prominence

Five patients (33.33%) in group 1 had various complications such as malunion with cosmetic deformity, non-union and restriction of shoulder movements, as compared to 2 patients (13.33%) in group 2 who had scar-related problems and hardware prominence along with the one malunion (Table 5).

Malunion and non-union rates were higher in conservative group in comparison with the surgical group. However, complications of surgical group were generally related to surgical technique and the implant. Overall, the complication rate in the conservative group was relatively higher.

Table 5: Complications in both groups

	Treatment Group		Total	Percentage	
	Group 1	Group 2		Group1	Group2
Malunion with Cosmetic deformity	3	0	3	20%	0%
Non-Union	1	0	1	6.66%	0%
Scar Problem	0	1	1	0%	6.66%
Hardware Problem	0	1	1	0%	6.66%
Restriction of ROM	1	0	1	6.66%	0%
Total	5	2	7	33.33%	13.33%

Discussion

Earlier, conservative management with brace & arm pouch was the treatment of choice for all clavicle fractures in middle as clavicle remodelled excellently. Conservative treatment with figure-of-8 bandage/brace aligns the displaced fragments in an acceptable position and results in a good functional outcome. But a recent meta-analysis revealed higher non-union rates for displaced fractures treated conservatively (15%) than operatively (2.2%) with modern internal fixation techniques [10]. Multiple recent trials & studies have also shown results that there is higher incidence of residual pain, non-union, malunion, shoulder weakness, shoulder stiffness, decreased shoulder endurance, inferior patient and surgeon-oriented outcome scores, and lower overall satisfaction after

non-operative management of mid-shaft clavicle fractures [12, 16]. The operative management of these fractures with plating or nailing was reserved only for a subset of population with open fractures or highly displaced fractures. The existing literature reports two sets of incidences of these fractures: The first is the largest and is associated with young active population (sports, motor vehicle accidents), whereas the second is associated with elderly individuals (osteoporotic fractures with simple falls) [4]. A direct blow to the shoulder is the most common mechanism of injury that produces a mid-shaft fracture of the clavicle. As the shoulder is subjected to a high compression force from lateral side, the clavicle and its articulations are the main areas to get affected as they resist these forces. Most (85%) clavicle fractures occur in the mid-

shaft as the bone is narrowest and enveloping soft tissue structures (which may help dissipate injury force) are most scarce^[17]. In our study, the age group was 20–50 years. The mean age was 36.40 years in group 1 and 38.50 years in group 2. The dominant side was affected in 18 cases (60%) out of 30 subjects, whereas remaining 12 cases (40%) had fracture on the non-dominant side which similar to the incidence reported in the literature. Functional impairment of the shoulder and the upper limb can be variable. A careful clinical & radiologic assessment is absolutely necessary to exclude associated chest injuries, such as pneumothorax or haemothorax, which are reported in the literature to occur at rates of up to 3%⁸. In the present study, 10 patients (33.33%) had associated injuries. However, none of these patients had pneumothorax or haemothorax or neurovascular injury.

Generally, the clavicle fractures undergo operative fixation within first 10–14 days from the time of injury. However, various studies report increased number of complications, if the primary fixation is delayed for more than 2 weeks^[20]. All patients underwent surgery within first 10 days in our study which might have contributed to higher rates of bony union. The advantages of plate fixation include immediate rigid stabilization, pain relief and helps in early mobilization. The rehabilitation protocol instituted in both the treatment groups has been discussed in the previous section. The early mobilization in the surgical group helped the patients to maintain their shoulder strength and early shoulder function, whereas conservatively treated patients had their shoulder immobilized for 3 weeks, which might have resulted in shoulder weakness, delayed shoulder function & stiffness. Hence, the functional outcome as measured by Constant shoulder score was higher in surgically treated patients at all follow-ups in comparison with non-surgical group. Moreover, the earlier rehabilitation might have contributed to higher rates of bony union and early functional recovery which is also evident from the results of this study.

The average duration required for union in conservative group was 11.07 weeks, as compared to 9.53 weeks in operative group. There is a statistically significant difference in the mean duration to union in both the groups similar to other studies^[20, 21]. Majority of the patients in conservative group returned to their pre-injury activity levels by around 4 months, whereas in the surgical group it was around 3 months.

Previous studies in adults have shown a higher rate of patient satisfaction after non-operative treatment of clavicle fractures^[16, 22]. But, patient-reported satisfaction scores may be superior with an early surgical stabilization in some circumstances. A multicentre trial reported better functional outcomes, lower malunion and non-union rates, and a shorter overall time to union in operatively treated clavicle fractures after plate fixation^[12]. In our study, the mean Constant shoulder score for group 1 was 62.56, 74.72 and 89.93 at 6 weeks, 3 and 6 months, respectively. However, for group 2, it was 73.45, 85.79 and 95.23 at 6 weeks, 3 and 6 months, respectively. There was a difference of 10.89 points in favour of surgical group at 6 weeks, 11.07 points at 3 months and 5.3 points at 6 months. At the end of 6 months, 94.55% patients achieved an excellent result (Constant score >90) in the surgically treated group as compared to 80% in the conservative group. 5.45% of the patients had a good score in surgical group (Constant score between 70 and 90) as compared to 13.33% in the conservative group. 6.66% patients had poor score in the conservative group (Constant score <70) as compared to none in the surgical group.

Earlier trials have analysed the risk of shoulder dysfunction

after conservative treatment, which generally was attributed to shortening of the bone segment, residual bone deformity, loss of force and persistent pain²³. Some studies showed lesser number of consolidation defects after surgical fixation as compared to conservative treatment, whereas others have demonstrated a 37% risk of adverse events after a surgical procedure possibly due to invasion of the periosteal structures that can lead to nerve damage, blood loss and post-traumatic hematoma, which can delay fracture healing^[19].

In our study, we had a total of 7 patients (23.33%) out of 30 with complications across both groups. Out of 7 patients with complications, 5 patients (16.66%) belonged to non-surgical group and 2 patients (6.66%) belonged to surgical group. Though the difference was not significant when total number of complications was taken into account in both the groups, symptomatic malunion and non-union was more common in conservative group than the surgical group. There was no surgical site infection, complex regional pain syndrome or neurovascular problems in any of our subjects. The study results are in line with more dated reports of outcomes of operative treatment of displaced mid-shaft clavicular fractures that show a complication rate of 23% and more. Some trials indicate that although clavicular deformities are complex and hard to analyse, shortening by 1.5–2 cm may result in an increased incidence of clinical symptoms. Shortening is one parameter which can be measured^[23]. In the present study, there were three patients (10%) with symptomatic malunion with a cosmetic deformity in conservative group as compared to no patient in the surgical group. This patient in the surgical group had premature loading of the injured extremity because of which the plate got bent and resulted in malunion.

Several recent studies have shown high union rates with surgical management using a variety of internal fixation devices, including plating and IM pin or rod fixation^[11]. In addition, there is also strong evidence that the non-union rate after conservative treatment may be higher than previously reported, particularly in certain patients and fracture types. In this study, we had 1 non-union (3.33%) out of 30 patients in conservative group as compared to none in surgical group. Patient with non-union underwent revision operative treatment at a later. Our results regarding to various complications compare well with the existing literature and the published studies on the subject.

This study has few strengths and limitations. Though the sample size is small and was not calculated prior to the study, the study has the sufficient power (>90%) to identify a standardized effect size in the Constant score of 0.5 at the final follow-up. It is a prospective non-randomized comparative trial, wherein there was no selection bias and the baseline demographic characteristics of the subjects in both the groups were almost similar, which reduced the chance of any other bias in the outcome. However, certain residual confounding factors in the results cannot be excluded as only a few were considered. The major strength of the study was the 100% follow-up in both the groups, though it was only 6 months.

From our study, we have noticed that in the surgical group, time to union was shorter with almost 100% union. The satisfaction level and subjective outcome was better in surgical group. The Constant shoulder scores were also significantly higher at all follow-ups in surgical group. The numbers of complications were lesser and many of them were implant related and surgical technique related. On the other side, patients treated conservatively took longer time to unite and had a greater number of malunions and non-union.

Subjective outcome was inferior as compared to surgical group, and Constant shoulder scores were also lower at all follow-ups. Hence, in a young, active patient, surgical fixation of an acute displaced mid-shaft clavicle fracture in the form of plating appears to result in improved outcome. Plate fixation in these individuals is a reasonable option to maintain anatomic reduction and achieve union with restoration of maximal shoulder function.

The limited complications of surgical group seen in the present study were implant and surgical technique related and can be minimized with better availability of modern implants and good surgical technique. Recently, with the advent of pre-contoured locking plates, the incidence of hardware prominence has decreased. These plates are particularly beneficial in osteoporotic and severely comminuted fractures. The usage of pre-contoured anatomic clavicle plates and an anteroinferior approach for the fixation may minimize many of these complications. The conservative treatment remains the gold standard in treatment of simple un-displaced mid-shaft clavicle fractures, but for displaced and comminuted fractures surgical intervention is appropriate especially in young active adults. If implants and expertise is available, with a good surgical technique operative treatment might give satisfactory and superior results over nonoperative treatment. Although certain multicentre trials support the use of primary operative fixation for diaphyseal fractures^[12], the quantum of this treatment effect on the outcome may not be sufficient enough to justify a surgical treatment to all patients.

In conclusion, anatomic reduction with plate fixation and early mobilization of displaced clavicle fractures is a viable treatment option, especially in young active adults with good outcomes and no major complications. There is also a need for further large multicentre prospective randomized controlled trials in order to generalize this preference of operative fixation over non-operative management in acute displaced mid-shaft clavicular fractures for all patients.

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