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Comparative evaluation of operative versus non-operative management of midshaft displaced clavicle fractures: A case series

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Abstract

Background and objectives: Clavicle fractures are common injuries in young individuals and they account for approximately 2.6% of all fractures. Various treatment modalities are available for the management of such fractures. Recent studies have suggested benefits following primary operative fixation of substantially displaced midshaft fractures of the clavicle

The objective of this study was to access the functional outcome and result of operative versus non-operative treatment of midshaft displaced clavicle fracture.

Method: This is a prospective comparative observational study of 50 cases of clavicle fracture with comparison between operative and non-operative management of midshaft displaced clavicle fractures assessed by DASH score.

Results: In majority of the operative patients, fractures were united within 14-16 weeks. Average dash score was around 18.00 at 6 weeks, 7.32 at 3 months and 5.16 at 6 months. In majority of the nonoperatively managed patients, fractures were united within 22-24 weeks with mean dash score of 30.77 at 6 weeks, 9.82 at 3 months and 6.36 at 6 months

Conclusion: DASH scores were significantly better for the operative group at 6 weeks, 3 months and 6 months follow-ups. In the present study, operative management by primary open reduction and internal plate fixation of acute displaced midshaft clavicle fracture has better result and functional outcome as compared to non-operative management for the same.

Keywords: Clavicle fractures, Robinson classification, DASH score, Allman classification, open reduction and internal fixation (ORIF)

1. Introduction

Clavicle fractures are common injuries in young, active individuals, especially those who participate in activities or sports where high speed falls (e.g., bicycling, motorcycles) or violent collisions (e.g, football, hockey) are frequent and they account for approximately 2.6% of all fractures [35-38, 39, 42, 44-47]

Robinson [50] reported in an epidemiologic study that the annual incidence was highest in the under-20 age group, decreasing with each subsequent age cohort.

Most clavicle fractures heal uneventfully without serious consequences with non-operative treatment. Treatment guidelines were based on Neer [43] and Rowe's [53] two large series that show non-union rates of less than 1% in conservatively managed fractures compared to nearly 4% in operatively treated patients. These results established the concept that union rates and function were excellent with conservative treatment and were better than those after operative treatment.

But more recent studies have questioned union rates, functional recovery and the morbidity of malunions after conservative management.

Thus, the present study is aimed at comparing the treatment outcomes following conservative management versus operatively treated midshaft clavicular displaced fractures. 50 patients were treated by open reduction and internal fixation and by conservative management alternatively at the Department of Orthopedics, New Civil hospital, Surat, between April 2015 to August 2016.

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2. Materials and Methods

A total of 50 subjects having midshaft displaced clavicular fracture were included in the study. Ethical committee approval was obtained before initiation of the study.

2.1 Patient Recruitment

Preliminary assessment of the patient entering casualty with clavicle fractured was done and primary treatment of any other associated injury was performed. X-ray Shoulder with Arm Anteroposterior View is usually done. A 20 degree cephalad view is preferred to eliminate the overlap of thoracic cage and to view the clavicle in profile.

Patients were included in the study if they had: 1) Age >16 years 2) Closed fractures 3) Robinson Classification [6] 2B1 and 2B2 (displaced fractures) 4) No medical contradictions to general anaesthesia.

Patients were excluded from the study if they had: 1) Age <16 years 2) Open fracture 3) Fracture in proximal or distal third of clavicle 4) Pathological fracture 5) Undisplaced fracture 6) Associated head injury 7) Associated with neurovascular injury 8) Established non-union from previous fracture 9) associated acromioclavicular joint dislocation 10) Patients not fit for anaesthesia

Once identified as eligible for the study, the patients were divided into 2 groups alternatively:

Group A: Patients treated operatively by open reduction and internal fixation

Group B: Patients treated conservatively

Patients received detailed information from the surgeon regarding the advantages and disadvantages of both operative and nonoperative care. Baseline demographics and injury characteristics were recorded. Preoperatively, routine blood investigations and radiographical assessment was performed. Fractures were classified according to Allman's classification as per proforma and the size of the plate was determined based on patient's x-ray. If the fracture was too comminuted or with shortening then plate size was calculated on X ray of the opposite extremity. After the patient was fit for surgery medically and anaesthetically, the patient was posted for surgery.

2.2 Operative Technique

Patients were treated under general anesthesia. After anesthesia, the patient was positioned in beach chair semi-sitting position with a pillow in the inter-scapular region which will allow the shoulder to drop back which helps to restore the length and increase exposure of the clavicle. Local parts (including same upperlimb) were prepared, painted and draped. The fracture was approached with an incision centered over the fracture medially from the sternal end to laterally upto the anterior edge of acromion.

The fracture was reduced and fragments held with bone clamps or K wire. If possible as an alternative a mini fragment screw can be used for provisional fixation to allow perfect contouring of the plate. A 3.5mm precontoured anatomical locking clavicle plate was placed either superiorly or inferiorly. Typically, an eight hole plate fits well as per the S-shape of clavicle. For superior plate placement, screws were aimed from superior to inferior taking care to avoid injury to the neurovascular structures while for anterior plate placement; screws were aimed posteriorly and superiorly. If an oblique fracture was present, a lag screw placed either through the plate or directly in the bone at roughly a 90-degree angle to the fracture line.

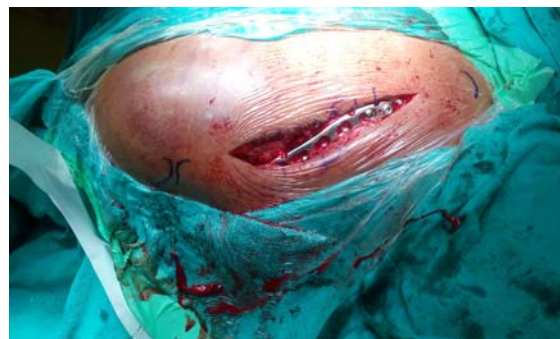


Fig 1: Photograph showing fixation of the fracture with anatomical locking plate.

2.2.1 Post-Operative Management

The operated extremity was placed in a collar- cuff sling or a shoulder immobilizer for comfort. The pendulum exercises were taught and patients were encouraged to use the arm avoiding heavy weight lifting, pushing or pulling. Patients were discharged on the 3rd or 6th post-operative day according to the dressing status. The suture removal was done on the 10th to 12th post- operative day and patients were called for 6 weekly follow – up

At the time of follow-up patients were assessed clinically and radiographically. Once early callus formation was present on x-ray, patients were advised progressive weight lifting, till patients were mobilized with full weight lifting. At 3 months, patients were allowed preinjury levels of activity (excluding all contact sports) and at 6 months, patients were allowed unrestricted activities.



Fig 2: Clinical photographs of operated case of clavicle fracture on 3 months of follow up.



Fig 3: Clinical photograph of patient on follow up after 2 weeks after removal of implant due to impingement.



Fig 4: Preoperative and postoperative radiographs of clavicle fracture operated with anterior plating

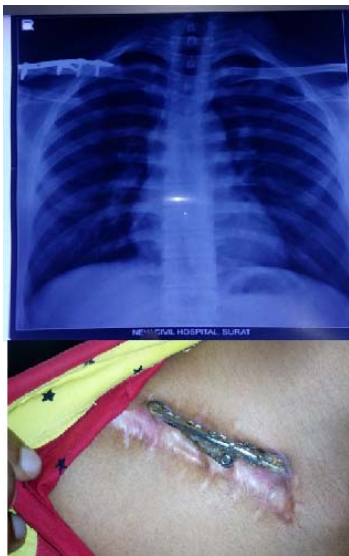


Fig 5: Post-operative complication of non-infective wound complication in an operated case of clavicle plating with implant exposed, patient had a good DASH score of 8 at 6 months of follow up and after 12 months underwent implant removal.

2.3 Non-operative Care

Patients allocated to group B, that is nonoperative care, received a standard sling for 6 weeks. Most of the patients were advised to begin “out of sling” activities after 3 weeks and at the 6-week time point, all underwent a rehabilitation schedule depending on the status of fracture healing. At 3 months, patients were allowed pre-injury levels of activity (excluding all contact sports) and at six months, patients were allowed unrestricted activities.



Fig 6. 6 month old conservatively treated clavicle fracture with malunion

2.4 Statistical analysis

Statistical analysis was done using a computer aided software and DASH score was calculated at 6 weeks, 3 months and 6 months respectively for both groups and was then compared within the same group at different time intervals as well as in between 2 groups at same time interval using t-test.

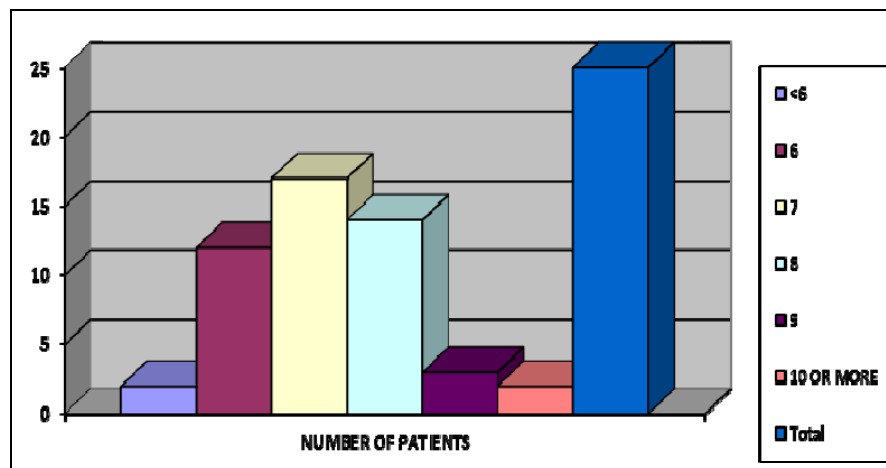
3. Results

Between April 2015 to August 2016, 50 patients with clavicle fractures with age between 19 to 60 years were treated out of which 25(50%) with open reduction and internal fixation with plate and 25(50%) with conservative management.

All patients in the study had midshaft displaced clavicle fractures. Among those who were operated, use of interfragmentary lag screw in 6(12%) patients having segmental fractures resulted in faster bone union and better functional results. Intra-Operatively, no major complications like bleeding or neurovascular injury were encountered in any patients. The patients were in the age group of 19 to 60 years with mean average age of 33 years. There was male predominance Male Female ratio was 4: 1. Commonest mode of injury was fall from height (37) and vehicular accident (23). Majority of patients were operated within 7 days from injury. Right side was affected in majority of patients (60%). Two patients had associated medical illness. Inter-fragmentary screw was used in 6(15%) patients. Intra-Operatively, no major complications were encountered in any patients. In postoperative period, complications include- two cases of infection both were debrided and with one followed up without infection thereafter and another had sustained infection who was allowed for delayed primary closure but had discharging sinus, infection subsided only after the implant was removed after 4 months. Patient had satisfying DASH score after the implant was removed. In spite of this event patient had good DASH score as compared to conservatively treated patient. Six cases of hypoaesthesia over supraclavicular region postoperatively. Four cases demanded removal of implant after bony union due to impingement. All 50 patients had full range of motion at final follow up without any limitation. Out of all 50 patients, majority 45 had a GOOD result. Conservatively treated displaced non comminuted clavicle fractures had increased rates of non-union and poor functional outcomes compared to operatively treated patients. All fractures in the operative group united compared with six non-unions in the nonoperative group. Eight symptomatic malunions occurred in the nonoperative group, whereas only two were reported for the operative group. In majority of the operative patients, fractures were united within 14-16 weeks. Average dash score was around 18.00 at 6 weeks, 7.32 at 3 months and 5.16 at 6 months. In majority of the non- operatively managed patients, fractures were united within 22-24 weeks with mean dash score of 30.77 at 6 weeks, 9.82 at 3 months and 6.36 at 6 months

Table 1: Fracture Union in Operatively Treated

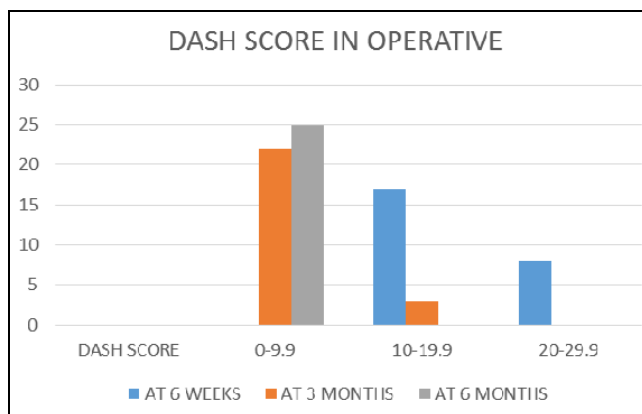
Union Time (In Weeks)	Number Of Patients
<6	2
6	12
7	17
8	14
9	3
10 Or More	2
Total	25

**Table 2:** Dash Score In Operative

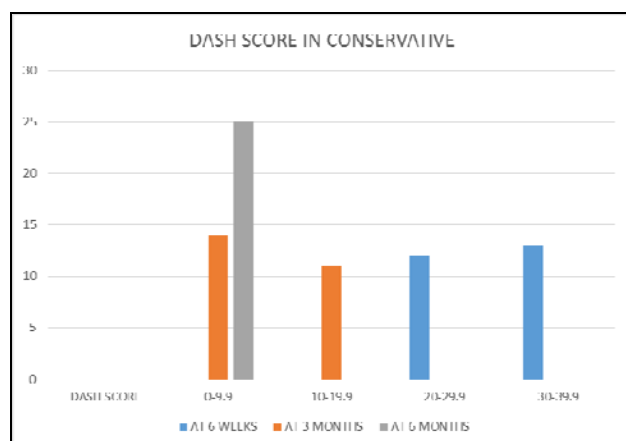
Dash Score	At 6 Weeks	At 3 Months	At 6 Months
0-9.9	0	22	25
10-19.9	17	3	0
20-29.9	8	0	0
30-39.9	0	0	0
40-49	0	0	0
Average	18.004	7.32	5.168

Table 4: Operative score paired sample statistics

	DASH score	Mean	N	Std. Deviation	P value
Pair 1	6 weeks	18.16	25	1.951	0.000
	3 months	7.68	25	1.626	
Pair 2	3 months	7.68	25	1.626	0.000
	6 months	5.16	25	1.864	
Pair 3	6 weeks	18.16	25	1.951	0.000
	6 months	5.16	25	1.864	

**Table 3:** Dash Score in Non-Operative

DASH SCORE	At 6 Weeks	At 3 Months	At 6 Months
0-9.9	0	14	25
10-19.9	0	11	0
20-29.9	12	0	0
30-39.9	13	0	0
40-49	0	0	0
Average	30.776	9.82	6.36

**Table 5:** Non-operative group paired sample statistics

	DASH score	Mean	N	Std. Deviation	P value
Pair 1	6 weeks	30.64	25	2.564	0.000
	3 months	9.80	25	1.658	
Pair 2	3 month	9.80	25	1.658	0.000
	6 month	6.52	25	1.686	
Pair 3	6 weeks	30.64	25	2.564	0.000
	6 months	6.52	25	1.686	

Table 6: Both Group Statistics (Independent sample test)

	Type of Management	N	Mean	Std. Deviation	P value
Dash 6 weeks	Conservative	25	30.77	2.564	0.000
	Operative	25	18.16	1.951	
Dash 3 month	Conservative	25	9.80	1.658	0.000
	Operative	25	7.68	1.626	
Dash 6 months	Conservative	25	6.52	1.686	0.009
	Operative	25	5.16	1.864	

4. Discussion

Clavicle fractures are common injuries in young, active individuals, especially those who participate in activities or sports where high speed falls (e.g., bicycling, motorcycles) or violent collisions (e.g., football, hockey) are frequent and they account for approximately 2.6% of all fractures [15-18, 19, 22, 24-27]. The majority of clavicle fractures (80-85%) occur in the midshaft of the bone where the typical compressive forces are applied to the shoulder and the narrow cross section of the bone combine and result in bony failure [4, 5-11, 12-18, 21, 30, 35, 39, 30-37]. Distal third fractures are the next common fractures (20%) and they tend to occur in more elderly individuals as a result of simple falls [20, 28, 29, 31, 32, 37]. Medial third fractures are rare (5%), perhaps because of difficulty in accurately imaging and identifying them [34, 36]. Motor vehicle accident is the usual mechanism of injury with a relatively high (20%) associated mortality rate from concomitant head and chest injuries. Most clavicle fractures heal uneventfully without serious consequences with non-operative treatment. Treatment guidelines were based on Neer23 and Rowe's [33].

two large series that show nonunion rates of less than 1% in conservatively managed fractures with sling of Figure of Eight bandage compared to nearly 4% in operatively treated patients. These results established the concept that union rates and function were excellent with conservative treatment and were better than those after operative treatment. But more recent studies have questioned union rates, functional recovery and the morbidity of malunions after conservative management. A prospective observational study of 868 patients with clavicle fractures treated nonoperatively found a nonunion rate of 6.2%. A meta-analysis by Zlowodzki N, Zelle BA, Cole PA, *et al* [38], including 2144 fractures showed a nonunion rate of 15% for displaced clavicle fractures treated nonoperatively, whereas the nonunion rate of operative treatment was only 2%. Thus there appears to be a subgroup of patients those with displaced fractures who do not do as well as previously thought.

These concerns led the Canadian Orthopedic Trauma Society⁴ to initiate a multicenter prospective randomized controlled trial to compare non-operative treatment with a Figure of 8 clavicle bandage and operative plate fixation for displaced clavicle fractures. They concluded that operative treatment resulted in improved functional outcomes and lower rates of malunion and non-union. Complications occurred in 23 (37%) of 62 patients treated operatively compared to 31 (63%) of 49 treated nonoperatively.

In the present study, it was observed that all the 50 patients had full range of motion at final follow up without any limitation and out of all 50 patients, majority, that is, 45 had a GOOD result. In majority of the operative patients, fractures were united within 14-16 weeks. Average dash score was around 18.00 at 6 weeks, 7.32 at 3 months and 5.16 at 6 months.

In majority of the non-operatively managed patients, fractures were united within 22-24 weeks with mean dash score of 30.77 at 6 weeks, 9.82 at 3 months and 6.36 at 6 months. Hence, DASH scores were significantly better for the operative group when compared to non-operative group at every follow-up. ($p < 0.001$ at 6 weeks and 3 months and $p = 0.009$ at 6 months)

Two cases of infection were observed, both were debrided and with one followed up without infection thereafter and another had sustained infection who was allowed for delayed primary closure but had discharging sinus, infection subsided only after the implant was removed after 4 months. Patient had satisfying DASH score after the implant was removed. In spite of this event patient had good DASH score as compared to conservatively treated patient. Six cases of hypoesthesia over supraclavicular region postoperatively. Four cases demanded removal of implant after bony union due to impingement.

The conservative method of managing undisplaced or severely comminuted clavicular fracture with brace and sling gave good functional radiological results but conservatively treated displaced non-comminuted clavicle fractures had increased rates of non-union and poor functional outcomes compared to operatively treated patients.

Though better cosmetics, intramedullary fixation is not favored due to complications like difficulty technique, implant impingement or migration, need for implant extraction, etc. Reconstruction plates can be contoured according to the need and give stable construct predictable union and optimum functional outcome but have disadvantages of less implant strength, increased operative time and malalignment leading to mal union or non-union.

Open reduction and internal fixation using precontoured anatomical locking compression plate facilitated:

Anatomical reduction, Stable and rigid fixation, Better implant for all types of clavicle fractures as implant is anatomically contoured, Less operative time, Less implant failure rate, Less implant removal rate, Accurate screw placement that prevents neurovascular injury, Faster union, Better functional outcome and Faster return to day to day activity with minimal complications.

5. Conclusion

In this prospective cohort study, primary open reduction and internal plate fixation of acute displaced midshaft clavicular fractures resulted in improved outcomes and a decreased rate of nonunion and symptomatic malunion compared with nonoperative treatment. DASH scores were significantly better for the operative group when compared to nonoperative group at every follow-up ($p < 0.001$ at 6 weeks and 3 months and $p = 0.009$ at 6 months). So this study suggests operative management for midshaft displaced clavicle fractures is better than conservative management.

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