



Original Research Article

Functional outcome and complications of open reduction and internal fixation with plate for displaced midshaft clavicle fractures

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ABSTRACT

Introduction: The purpose of the present study is to evaluate functional outcomes and complications associated with open reduction and internal fixation (ORIF) with plates for displaced midshaft clavicle fractures.

Materials and Methods: A retrospective review was performed utilising hospital database for patients treated with ORIF with plate for displaced mid-shaft clavicle fracture from January 2016 to August 2018. The primary outcome measure was union. The secondary outcome measures were functional outcome (DASH), patient satisfaction with treatment and cosmetic appearance, pain, complications and reoperations. All selected patients were requested to attend out-patient department (OPD) for assessment of patient oriented functional outcome measures.

Results: Thirty patients were included in the study. Eighty percent were male patients with male female ratio of 4:1, with an average age of 35years. Forty percent fractures were Robinson type 2B1 and 60% were type 2B2. All patients treated with ORIF had fracture union (ie union rate of 100%) at an average time of 7.9 weeks. Patient satisfaction rate was 83%. Mean DASH Score was 14.63 ± 6.27 . The complication rate was 33.33%. The common complications were reoperation rate (30%), symptomatic hardware (23.33%), implant failure (6.66%) and superficial infection (3.33%).

Conclusion: Open reduction and internal fixation for displaced, midshaft clavicle fracture results in high rates of union and patient satisfaction, and improved functional outcome. Symptomatic hardware removal remains the most common cause of reoperation. Patients with complications reported significantly worst functional outcome scores than patients without complication.

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1. Introduction

The clavicle is the palpable, subcutaneous, horizontal long bone that connects the upper limb with axial skeleton. Fractures of clavicle are common accounting for approximately 5 to 10% of all adult fractures and up to 40% of injuries around shoulder girdle.¹⁻⁴ About 70 to 80% of these fractures are in middle third of bone where typical compressive forces applied to the shoulder and the narrow cross section of the bone combine and result in bony failure. Shaft fractures occur most commonly in young adults.⁵

Traditionally, displaced midshaft clavicle fractures have been treated conservatively with closed manipulation and various methods of immobilisation with the expectation of high probability of fracture union, good functional outcomes, and high level of patient satisfaction.^{6,7} However the outcomes of nonoperative treatment are not as favourable as once thought. Many studies have demonstrated high rates of non-union, symptomatic malunion and shoulder stiffness with nonoperative treatment.^{8,9}

Hill et al⁸ evaluated 242 fractures of clavicle which had been treated conservatively and found unsatisfactory results with initial shortening of 20mm or more. They recommended open reduction and internal fixation for

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severely displaced fracture of middle third of clavicle in adult patients.

Canadian Orthopaedic Trauma Society published the results of a multicentre randomised clinical trial comparing nonoperative treatment with plate fixation of displaced midshaft clavicular fractures showing improved functional outcome and a lower rate of malunion and non-union.¹⁰ Woltz et al¹¹ showed a significantly lower non-union rate after plate fixation of displaced midshaft fracture of clavicle compared with nonoperative treatment in a sling.

The aim of present study is to evaluate the functional outcome and complications of operative treatment of displaced midshaft clavicle fracture with plate fixation.

2. Materials and Methods

A retrospective review was performed utilising hospital database for patients treated with open reduction and internal fixation with plate for displaced mid-shaft clavicle fracture from January 2016 to August 2018.

Inclusion criteria were patients with acute, displaced mid-shaft clavicle fractures with significant shortening (>2cm) or displacement (>100% width of clavicle) or Z-type fracture pattern or significant comminution; impending skin compromise; age greater than 18 years and less than 65 years; a minimum of 12 months of follow-up after index surgery.

Exclusion criteria were: an open fracture; non-midshaft fracture; pathological fracture; surgical treatment other than plate fixation; delayed union and non-union; associated vascular and neurological injury.

From January 2016 to August 2018, fifty seven patients with clavicle fracture were operated in our institute, out of them, forty-one patients were having midshaft clavicle fractures treated with different modalities of fracture fixation. Thirty patients, who were treated with open reduction and plate fixation and fulfilled above inclusion criteria; were selected as study population. The medical records, treatment charts and radiographs of these selected patients were evaluated to identify patient's demographic information, mechanism of injury, classification of fracture, implant selection, intraoperative complications and reoperations. All the selected patients were telephonically contacted and called in outpatient department (OPD) for evaluation of pain (VAS score), cosmetic satisfaction (VAS score), assessment of overall treatment satisfaction (3-point Likert scale), functional outcome (DASH Score) and satisfaction with cosmetic appearance of shoulder (VAS score). All thirty patients attended OPD for final evaluation of these patient oriented functional outcome measures.

The aim of operative treatment was to achieve stable fixation of both the fragments, restore the length and curvature of the clavicle to allow early mobilisation of shoulder. Patients underwent surgery within two weeks

of injury after pre-anaesthetic evaluation. Prophylactic antibiotics were given before incision. Under general anaesthesia, patient was given a beach chair semi-sitting position. A curvilinear incision was made over the clavicle to expose the fracture. The fracture was reduced and fixed with plate placed on superior surface, with the goal being minimum of three screws in the main proximal and distal fragments. Oblique fractures were fixed with a lag screw and neutralisation plate. In transverse fracture, axial compression was achieved while in comminuted fractures, bridge plate technique was used. Deltopectoral fascia was closed as distinct layer, followed by skin closure. A collar-cuff sling was given for two weeks. Stitches were removed on 14th postoperative day.

2.1. Outcome measures

The primary outcome measure was union. The secondary outcome measures were functional outcome (DASH), patient satisfaction with treatment and cosmetic appearance, complications and reoperations.

Fracture union was defined as complete cortical bridging between proximal and distal fragments on radiological evaluation. Fracture non-union was defined as absence of complete osseous bridging between the fragments on radiograph after ≥ 6 months of operative treatment.

Thirty points DASH score (Disability of Arm Shoulder and Hand Score) was used to assess the functional evaluation of patients. DASH is a 30 item; self-report questionnaire designed to help describe the disability experienced by people with upper limb disorders. The care was taken that the patients has answered at least 27 questions of DASH questionnaire. Pain was scored by the patient on visual analogue scale (VAS) from 0 (no pain) to 10 (extreme pain). Satisfaction with cosmetic appearance of incision and shoulder was rated on 10 point VAS Scale where higher score indicates high rate of satisfaction. Overall satisfaction with treatment was recorded on 3-point Likert Scale as unsatisfied, partially satisfied and fully satisfied.

2.2. Statistical analysis

Data analysis was done by using statistical software SPSS, version 16. Student's t test for two samples assuming unequal variance was used to compare functional outcome of patients with and without complication. The test was two sided. The results were considered significant at $p < 0.05$.

3. Results

Thirty patients who had midshaft fracture clavicle were operated with open reduction and plate fixation. Out of them, 80% (n=24) were male and 20% were female with male : female ratio of 4:1. Mean age of the patient was 35 years (range 18-65 years; SD 12.96). High energy trauma

was the commonest (70%) cause of injury. Domestic fall on shoulder was the common cause in low energy trauma group of patients. According to Robinson classification, 40% of fractures were type 2B1 and 60% were type 2B2. Table 1 shows demographic characters of selected cohort. The most commonly used plate was 3.5mm pre-contoured locking plate (43.33%) followed by 3.5mm reconstruction plate (36.66%) and 3.5 mm dynamic compression plate (20%) (Table 2).

Table 1: Demographic characters of cohort

Parameters		Numbers (n)	Percent (%)
Sex	Male	24	80
	Female	06	20
	<30	12	40
Age (years)	31-50	14	46.66
	>50	4	13.33
Mechanism	High energy trauma	21	70
	Low energy trauma	9	30
Robinson Classification	2B1	12	40
	2B2	18	60

Table 2: Type of plate used for internal fixation

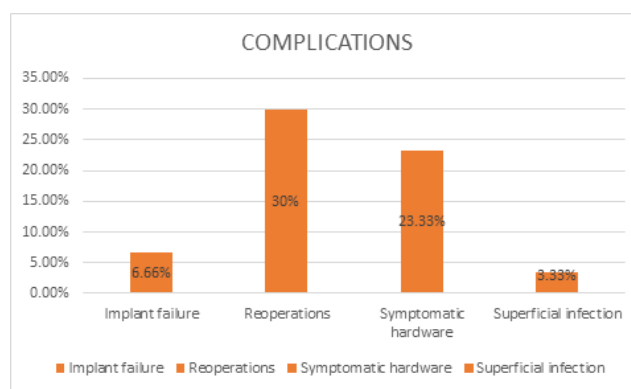
Type of plate	Frequency (n)	Percentage (%)
3.5mm reconstruction	11	36.66
3.5mm Dynamic Compression Plate	6	20.00
3.5mm Pre-contoured Locking Plate	13	43.33

All patients treated with open reduction and plate fixation had fracture union (100%) at an average time of 7.9 weeks (range 6-20 weeks; SD 3.38). Two patients (6.66%) had mechanical failure of implant in the form of plate breakage at about 2 months of operation. Out of these two broken plates, one was reconstruction plate (3.5mm) and the other locking plate. Both patients were treated with implant removal, fixation with plate and iliac crest bone graft. Both cases had union of fracture between 18-20 weeks. Twenty three percent patients had hardware related symptoms like plate irritation and plate prominence. All these patients had implant removal between 12 to 18 months of index surgery. Out of seven symptomatic hardware, 4 were DCP, 2 LCP and 1 was reconstruction plate. One patient had superficial infection (3.33%) during perioperative period which was treated with organism specific antibiotics and daily dressings. Reoperation rate of 30% was reported which included 2 patients with plate breakage and 7 patients with symptomatic hardware. In all thirty patients, surgery was uneventful without any intraoperative complications. (Table 3)

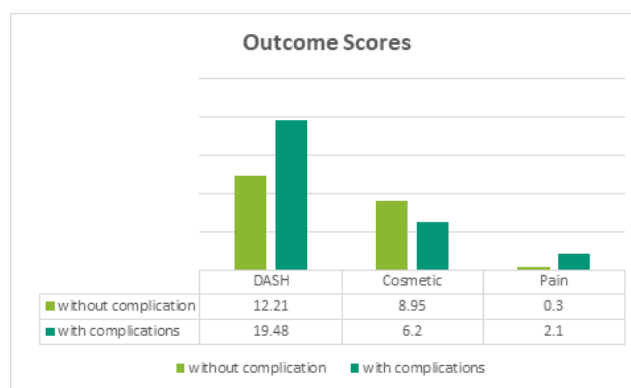
Table 3: Outcomes and complications

Outcomes	Number (n)	Percent (%)
Union of fracture	30	100
Implant failure	02	6.66
Reoperation	09	30
Symptomatic hardware	07	23.33
Superficial infection	01	3.33

By Likart 3-point scale, 83% patients were fully satisfied with the treatment. Mean satisfaction with cosmetic appearance using 10-point VAS was 8.03 ± 1.84 . A good functional outcome with a mean DASH Score of 14.63 ± 6.27 was reported. Patients reported very little pain at final follow-up with pain score using VAS Scale was 0.9 ± 1.2 . Patients with and without complications were compared using Student t - test and the results are summarised in Table 4. Patients with complications scored significantly worst results on the outcome measure of pain, cosmetic appearance and functional outcome DASH.



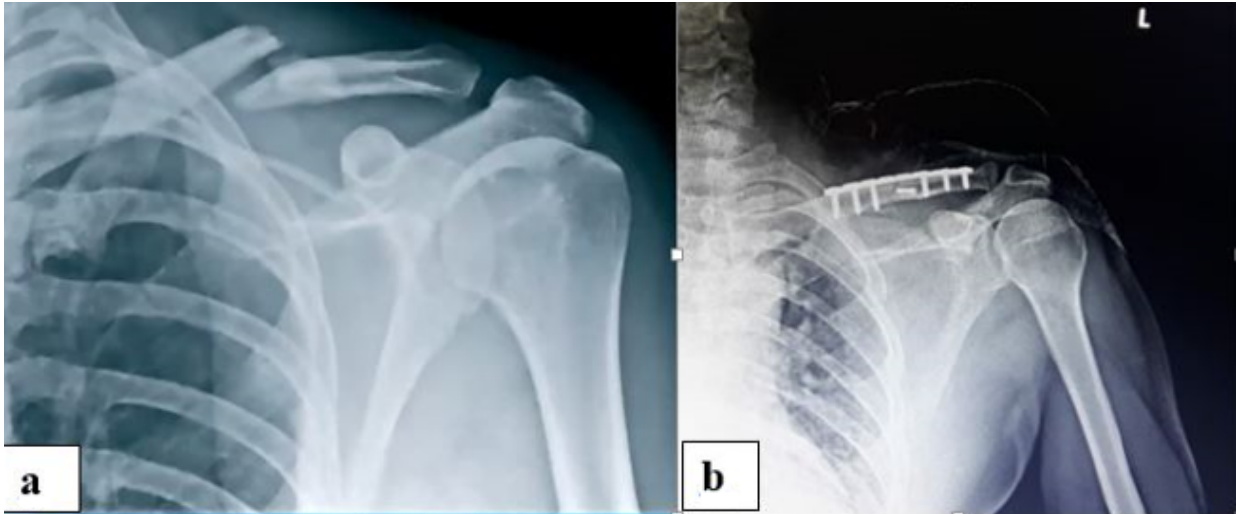
Graph 1:



Graph 2:

Table 4: Comparison of functional outcomes between patients with and without complications

	Without Complication n=20	With complication n=10	df	p- Value
DASH	12.21	19.48	12	0.012
Cosmetic appearance	8.95	6.2	13	0.0004
Pain	0.3	2.1	13	0.0004

**Fig. 1:** a: X-ray showing fracture left clavicle with displacement; b: Immediate post-op x ray showing reduction and internal fixation with plate

4. Discussion

Fractures of the clavicle are more common injuries and those occurring in middle third of the shaft are the most common. Although nonsurgical treatment is a reliable method, the recent data suggest that displacement of fracture and comminution are associated with high risk of non-union, if treated conservatively.¹¹ Shortening of ≥ 20 mm is an independent risk factor for patient dissatisfaction and poor functional outcome.^{8,9} This retrospective study evaluates fracture union, patient reported functional outcome, patient satisfaction with treatment and cosmetic appearance, complications and reoperation rate after open reduction and internal fixation using plate fixation for Robinson type 2B1 and 2B2 clavicle fractures.

Modern studies on primary plate fixation of acute midshaft clavicular fractures have described union rates ranging from 94 to 100%.^{10,12} Robinson et al.¹³ in a randomised controlled trial (RCT) comparing the open reduction and plate fixation versus nonoperative treatment for displaced midshaft clavicular fracture reported 1.2% non-union rate in open reduction and plate fixation group (ie. one out of 86 patients). Woltz et al.¹⁴ in a RCT found a non-union rate of 2.4% (2/86) in primary plate fixation group. The Canadian Orthopaedic Trauma Society¹⁰ performed a first RCT comparing ORIF and conservative treatment and found lower rates of non-

union (3%) and shorter time to union (16.4 weeks). The present study found comparable or even better result than these studies. All patients showed evidence of union on retrospective radiological evaluation and mean time to union was 7.9 weeks.

The overall satisfaction rate with treatment was 83% and most of the patients were happy with cosmetic appearance of shoulder. Patient oriented functional outcome score DASH shows good results. All these parameters were comparable with previously mentioned RCTs.^{10,13,14} Shortening of clavicle (>2 cm) after non-union or malunion is a major cause of patient dissatisfaction. Shortening in medial-lateral direction decreases the lever arm and strength of those muscles whose action is primarily in the plane of shortening ie abduction.⁹ Studies have shown negative effect of shortening on abduction and forward elevation of shoulder, causal relationship with shoulder dyskinesia and altered position of scapula.^{15–17} Studies have shown that shortening greater than 14mm in women and 18 mm in men are associated with worst functional outcome scores and decreased strength of shoulder.^{9,17} In our opinion, open reduction and plate fixation restores length and curvature of clavicle, prevents non-union and shortening, and indirectly results in increasing patient satisfaction and functional outcome measure scores.

The present study reports complication rate of 33.33% with most common complication being reoperation rate (30%) for implant removal (23.33%) and implant failure (6.66%). We had one case of superficial infection (3.33%) during perioperative period. Most common cause of implant removal was implant prominence and irritation. Rate of implant removal was higher in female patients. Among reoperations, mandatory cause of reoperation was two cases of implant failure ie 6.66%. Both failures occurred within two months of index surgery. Leroux et al¹⁸ retrospectively evaluated rate and risk of reoperation of a cohort of 1350 patients who had undergone open reduction and internal fixation with at least two years of follow-up. They reported 24.6% reoperation rate. Isolated implant removal was the most common cause of reoperation accounting for 18.8% reoperations. They reported lower rates of other complications such as non-union (2.6%), deep infection (2.6%), pneumothorax (1.2%) and malunion (1.1%). Naimark et al¹⁹ in a cohort of 7826 patients, reported 12.7% hardware removal rate. Reoperation rate in present study is comparable with that of Leroux study but much higher than Naimark study. The patients with complication reported worst DASH Score and more dissatisfaction for cosmetic appearance than patients without complication.

5. Conclusion

Open reduction and internal fixation with plate for displaced midshaft fracture clavicle results in high rates of fracture union and patient satisfaction, and improves patient-oriented functional outcome. Most common complication of the procedure was reoperation for symptomatic hardware. Patients with complication reported significantly worst score on patient oriented outcome measures than patients without complication.

6. Source of Funding

None.

7. Conflict of Interest

None.

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