

## Original research article

## Retrospective assessment of the outcome and associated complications of open reduction and internal fixation with plate for displaced midshaft clavicle fractures

Dr. Kumar Gaurav<sup>1</sup>, Dr. Amit Kumar<sup>2</sup>, Dr. Manish Kumar<sup>3</sup>, Dr. Rajeev Anand<sup>4</sup>

<sup>1</sup>Senior Resident, Department of Orthopaedics, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India.

<sup>2</sup>Consultant, kalyani Hospital, Patna, Bihar, India

<sup>3</sup>Senior Resident, Department of Orthopaedics, Nalanda Medical College and Hospital, Patna, Bihar, India

<sup>4</sup>Assistant professor, Department of Orthopaedics, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India.

Corresponding Author: Dr. Kumar Gaurav

### Abstract

**Background:** Displaced mid-shaft clavicular fractures are treated by conservative methods which shows higher rate of malunion and non-union with suboptimal outcomes. Fracture fixation by pre-counteracted anatomical clavicular locking plate avoids these complications.

**Aim:** to determine the functional outcome and complications of open reduction and internal fixation with plate for displaced midshaft clavicle fractures.

**Materials and Methods:** This retrospective study was carried out in the Department of Orthopaedics, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India, for 1 year. 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 were included in this study. 50 who were treated with open reduction and plate fixation and fulfilled above inclusion criteria; were selected as study population. 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.

**Results:** 50 patients who had midshaft fracture clavicle were operated with open reduction and plate fixation. Out of them, 84% were male and 16% were female with male: female ratio of 4:1. Mean age of the patient was 36.5 years (range 20-60 years; SD 13.17). High energy trauma was the commonest (74%) cause of injury. Domestic fall on shoulder was the common cause in low energy trauma group of patients. According to Robinson classification, 34% of fractures were type 2B1 and 66% were type 2B2. The most commonly used plate was 3.5mm pre-contoured locking plate (46%) followed by 3.5mm reconstruction plate (38%) and 3.5 mm dynamic compression plate (16%).

**Conclusion:** We concluded that the 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.

**Keywords:** Middle third clavicle fracture, Open reduction, Internal fixation

## Introduction

Fracture of clavicle is a common traumatic injury around shoulder due to its subcutaneous position and it accounts for approximately 2.6% to 12% of all fractures and 44% to 66% of fractures about the shoulder region. Middle third fractures account for 80% of all clavicle fractures this is because the junction between the two cross-sectional configurations occurs in the middle third and is a vulnerable area to break for fracture, especially with axial loading. Moreover, the middle third lacks reinforcement by muscles or ligaments distal to the subclavius insertion, resulting in additional vulnerability.<sup>1,2</sup> There are many methods described to treat clavicle fractures.<sup>3</sup> Roughly these methods can be divided into conservative and surgical methods. Conservative methods consist of applying a simple sling, clavicular brace or figure of eight bandage. Conservative management has the advantages of being cheap, affordable and is devoid of the risks of anesthesia. But there are certain disadvantages that conservative methods are associated with risk of non-union, residual deformity and patient dissatisfaction.<sup>4,5</sup> Recent studies shows non-union rates up to 15% and patient dissatisfaction of up to 31% following conservative management.<sup>6</sup> Treating those with shortening of more than two cm by simple splint age is now believed to produce a considerable risk of symptomatic mal-union mainly pain and lack of power during shoulder movements and an increased incidence of non-union therefore operative methods have evolved as a better option and there is improved patient-oriented outcomes compared to that of operative treatment that is considering incidence of nonunion, functional outcome, pain scores, quality of life, cosmetic aspect and complication. The goals of treatment of mid-shaft clavicle fracture are to restore normal anatomy, limit pain and promote quick return to activity or play.<sup>7,8</sup> The surgical indication for mid-shaft clavicle fractures is controversial and has been changing recently. The accepted indications for operative treatment of clavicular fracture are open fracture, associated neurovascular compromise and skin tenting with potential for progression to open fracture along with substantial displacement, comminution (Z deformity) and shortening greater than one to two cm.<sup>9</sup> There are various operative methods for treatment of mid-shaft clavicle fracture which includes intramedullary devices, plates, and external fixators. Plating of mid-shaft clavicle fracture is preferred method of fixation by many authors. Biomechanically, plate fixation is superior to intramedullary fixation because it better resists the bending and torsional forces that occur during elevation of the upper extremity above shoulder level. Patient can be allowed full range of motion once their soft tissue have healed. Disadvantages of plate fixation include the necessity for increased exposure and soft tissue stripping, potential injury to the supraclavicular nerves, higher infection rates and the refracture after plate removal these complications can be reduced by careful soft tissue handling, minimal periosteal stripping and meticulous plate fixation.<sup>3</sup> In our study we used the locking plate which provide stiffer constructs and are useful in patients with osteoporotic bone and severely comminuted fractures and also this plate also provides rigid fixation, rotational control over the fracture, and ability for cortical compression at the site. The surgeon also doesn't need to contour the plate which retrains mechanical strength and has less soft tissue related problems. This plate has less hardware prominence and there is no need of implant removal after fracture healing as compared to traditional plate.<sup>10-12</sup> The aim of the present study was to determine the functional outcome and complications of open reduction and internal fixation with plate for displaced midshaft clavicle fractures.

## Materials and Methods

This retrospective study was carried out in the Department of Orthopaedics, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India, for 1 year. after taking the approval of the protocol review committee and institutional ethics committee.

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 were included in this study.

Patients with open fracture; non-midshaft fracture; pathological fracture; surgical treatment other than plate fixation; delayed union and non-union; associated vascular and neurological injury were excluded from this study.

#### Methodology

During the study period 70 patients with clavicle fracture were operated in our institute, out of them, 60 patients were having midshaft clavicle fractures treated with different modalities of fracture fixation. 50 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 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 25 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.

#### 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  $p < 0.05$ .

### Results

50 patients who had midshaft fracture clavicle were operated with open reduction and plate fixation. Out of them, 84% were male and 16% were female with male: female ratio of 4:1. Mean age of the patient was 36.5 years (range 20-60 years; SD 13.17). High energy trauma was the commonest (74%) cause of injury. Domestic fall on shoulder was the common cause in low energy trauma group of patients. According to Robinson classification, 34% of fractures were type 2B1 and 66% were type 2B2. Table 1 shows demographic characters of selected cohort. The most commonly used plate was 3.5mm pre-contoured locking plate (46%) followed by 3.5mm reconstruction plate (38%) and 3.5 mm dynamic compression plate (16%) (Table 2).

**Table 1: Demographic profile of the patients**

Gender	Number of patients	Percentage
Male	42	84
Female	8	16
<b>Age</b>		
Below 25	17	34
25-50	28	56
Above 50	5	10
<b>Mechanism</b>		
Low energy trauma	13	26
High energy trauma	37	74
Robinson 2B1	17	34
Classification2B2	33	66

**Table 2: Type of plate used for internal fixation**

Type of plate	Frequency (n)	Percentage(%)
3.5mm reconstruction	19	38
3.5mm Dynamic Compression Plate	8	16
3.5mm Pre-contoured Locking Plate	23	46

All patients treated with open reduction and plate fixation had fracture union (100%) at an average time of 8.1 weeks (range 5-22 weeks; SD 4.12). 4 patients (8%) had mechanical failure of implant in the form of plate breakage at about 2 months of operation. Out of these 4 broken plates, 2 was reconstruction plate (3.5mm) and the others locking plate. all patients were treated with implant removal, fixation with plate and iliac crest bone graft. all cases had union of fracture between 17-20 weeks. 20 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 10 symptomatic hardware, 6 were DCP, 3 LCP and 1 was reconstruction plate. 2 patients had superficial infection (4%) during perioperative period which was treated with organism specific antibiotics and daily dressings. Reoperation rate of 34% was reported which included 4 patients with plate breakage and 10 patients with symptomatic hardware. In all 50 patients, surgery was uneventful without any intraoperative complications. (Table 3)

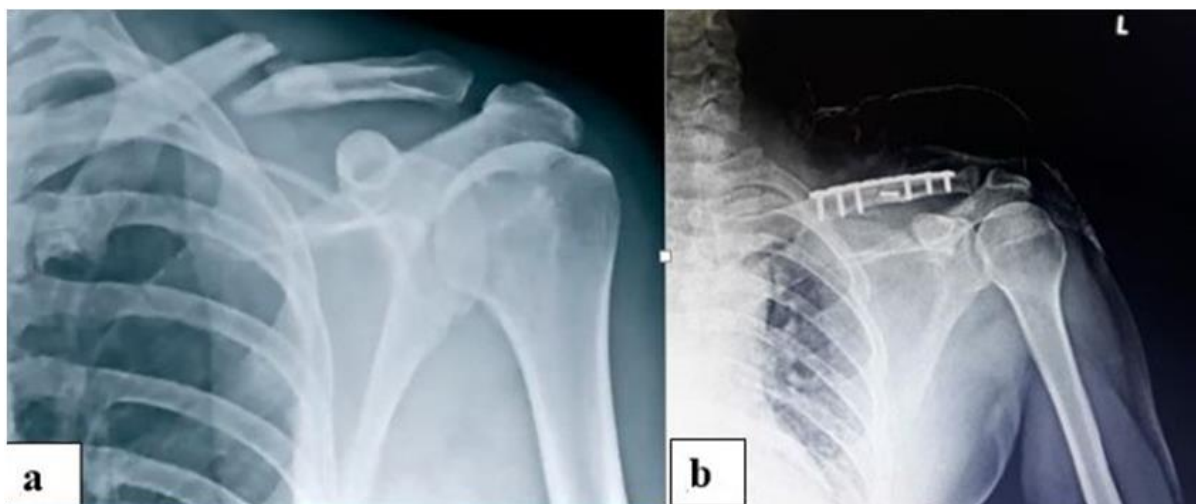
**Table 3: Outcomes and complications**

Outcomes	Number (n)	Percent (%)
Union of fracture	50	100
Implant failure	4	8
Reoperation	17	34
Symptomatic hardware	10	20
Superficial infection	2	4

By Likart 3-point scale, 86% patients were fully satisfied with the treatment. Mean satisfaction with cosmetic appearance using 10-point VAS was  $8.12 \pm 1.94$ . A good functional outcome with a mean DASH Score of  $15.12 \pm 5.88$  was reported. Patients reported very little pain at final follow-up with pain score using VAS Scale was  $0.8 \pm 1.3$ . 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.

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

	Without Complication=35	With complication n=15	df	p- Value
DASH	11.95	20.11	13	0.017
Cosmetic appearance	9.12	6.7	14	0.0003
Pain	0.5	2.5	15	0.0003

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

### 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.<sup>13</sup> Shortening of 20 mm is an independent risk factor for patient dissatisfaction and poor functional outcome.<sup>14,15</sup> 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%.<sup>16,17</sup> Robinson et al<sup>18</sup> in a randomised controlled trial (RCT) comparing the open reduction and plate fixation verses 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.<sup>19</sup> in a RCT found a non-union rate of 2.4% (2/86) in primary plate fixation group. The Canadian Orthopaedic Trauma Society<sup>16</sup> 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 8.1 weeks.

The overall satisfaction rate with treatment was 86% 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.<sup>16,18,19</sup>

Shortening of clavicle (>2cm) 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.<sup>15</sup> Studies have shown negative effect of shortening on abduction and forward elevation of shoulder, causal relationship with shoulder dyskinesia and altered position of scapula.<sup>20-22</sup> 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<sup>15,22</sup> 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 30% with 4 patients (8%) had mechanical failure of implant in the form of plate breakage at about 2 months of operation. Out of these 4 broken plates, 2 was reconstruction plate (3.5mm) and the others locking plate. all patients were treated with implant removal, fixation with plate and iliac crest bone graft. all cases had union of fracture between 17-20 weeks. 20 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 10 symptomatic hardware, 6 were DCP, 3 LCP and 1 was reconstruction plate. 2 patients had superficial infection (4%) during perioperative period which was treated with organism specific antibiotics and daily dressings. Reoperation rate of 34% was reported which included 4 patients with plate breakage and 10 patients with symptomatic hardware. In all 50 patients, surgery was uneventful without any intraoperative complications. Leroux et al<sup>23</sup> 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 al<sup>24</sup> 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.

### 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.

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