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Original Article

Orthopaedics Section

Functional Outcomes and Complications of Open Reduction and Internal Fixation Using Precontoured Locking Plates for Displaced Midshaft Clavicle Fractures: A Prospective Interventional Study

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ABSTRACT

Introduction: Clavicle fractures are common injuries, with displaced midshaft fractures traditionally managed conservatively. However, recent evidence suggests that operative treatment may offer superior outcomes.

Aim: To evaluate the functional outcomes and complications of Open Reduction and Internal Fixation (ORIF) using precontoured locking plates for displaced midshaft clavicle fractures.

Materials and Methods: This prospective interventional study was conducted at the Post Graduate Institute of Swasthiyog Pratishthan from April 2021 to January 2023. Thirty five patients with displaced midshaft clavicle fractures underwent ORIF using precontoured locking plates. Demographic variables assessed included age, sex, mechanism of injury, fracture classification, and associated injuries. Functional outcomes were assessed using the Constant-Murley score at six weeks, three months, and six months postoperatively. Statistical analysis included descriptive statistics, paired t-tests for comparing functional scores, and one-way ANOVA with Bonferroni post-hoc analysis for multiple time-point comparisons. A p-value of <0.05 was considered statistically significant.

Results: The majority of patients were male (n=29, 82.86%) with a mean age of 38.7 years. All fractures achieved union, with no cases of non-union. The mean Constant-Murley score improved from 73.8±7.2 at six weeks to 89.7±3.9 at six months ($p<0.001$). At six months, excellent functional recovery was observed in the majority of patients. Complications occurred in three patients, including hardware irritation in one patient (2.86%) and superficial infection in one patient (2.86%). The majority of patients (48.57%) returned to work within 6-8 weeks.

Conclusion: ORIF using precontoured locking plates for displaced midshaft clavicle fractures provides excellent functional outcomes with a low complication rate.

Keywords: Constant-Murley score, Robinson classification, Shoulder function, Surgical timing, Union rates

INTRODUCTION

Clavicle fractures are among the most common fractures encountered in orthopaedic practice, accounting for approximately 5-10% of all fractures and 35-44% of shoulder girdle injuries [1,2]. The incidence of clavicle fractures in the general population is reported to be 30-60 per 100,000 annually, with the highest incidence observed in young males. Recent data from the United States indicate that sports-related injuries account for 45-50% of all clavicle fractures, with an annual incidence rate of 18.72 per 100,000 persons at risk [3].

Midshaft clavicle fractures represent approximately 80% of all clavicle fractures, with displaced fractures accounting for a significant proportion of these injuries [4]. The prevalence of midshaft clavicle fractures shows a bimodal distribution, with peaks in males younger than 25 years (due to sports injuries) and patients older than 55 years (due to falls), and males are affected approximately twice as often as females [5].

Historically, conservative treatment with figure-of-eight bandages or slings was the standard of care for midshaft clavicle fractures, based on early reports suggesting non-union rates of less than 1% [6]. However, recent literature has challenged this traditional approach to displaced midshaft clavicle fractures. Contemporary studies have reported non-union rates of 7-15% following conservative treatment of displaced midshaft clavicle fractures, with unsatisfactory functional outcomes in 15-31% of patients [7,8].

The shift toward operative management has been driven by several factors, including improved understanding of the biomechanical consequences of clavicle shortening, the development of specialized implants, and evidence from randomised controlled trials demonstrating superior outcomes with surgical fixation [9]. Modern studies indicate that surgical treatment leads to significantly improved functional outcomes, increased patient satisfaction, earlier return to activities, and lower rates of non-union compared with conservative treatment [10,11].

Precontoured locking plates have gained popularity as they offer several theoretical advantages over traditional reconstruction plates, including improved anatomical fit, reduced need for intraoperative contouring, lower profile design, and potentially fewer complications [12]. The biomechanical advantages of precontoured plates include better load distribution, reduced stress concentration, and superior stability compared to traditional plates [13,14].

The purpose of this study was to evaluate the functional outcomes and complications of ORIF using precontoured locking plates for displaced midshaft clavicle fractures.

MATERIALS AND METHODS

This prospective interventional, single-institution study was conducted at the Post Graduate Institute of Swasthiyog Pratishthan, Miraj, Maharashtra, from April 2021 to January 2023, after obtaining approval from the Institutional Ethics Committee (IEC No: PGISP/IEC/042021/02).

Inclusion and Exclusion criteria: The study included patients aged over 18 years with closed, displaced midshaft clavicle fractures (Robinson type 2B) [3], displacement >2 cm or shortening >2 cm, comminution with >3 fragments, no medical contraindications for surgery, and with written consent. Exclusion criteria were patients aged under 18 years, open fractures, pathological fractures, active infection at the operative site, medical contraindications to surgery, undisplaced fractures, and previous clavicle fractures.

Sample size calculation: Sample size was calculated using the formula: n= $(Z\alpha/2)^2\times(PQ)/E^2$. Where P=90% (expected good outcome rate) [15], Q= 10%, $Z\alpha/2$= 1.96 (95% confidence level), E= 0.12 (12% allowable error). n= $(1.96)^2\times0.9\times0.1/(0.12)^2$= 30. Considering 15% loss to follow-up, final sample size= 35 patients.

Study Procedure

Data were collected for demographic variables, including age, sex, mechanism of injury, fracture classification, associated injuries, time to surgery, duration of surgery, plate specifications, complications, and functional outcomes. Patients were assessed with a detailed history regarding mode of injury and severity of trauma. Clinical examination included evaluation of deformity, swelling, ecchymosis, and neurovascular status. Associated injuries were documented. Standard anteroposterior and 30-degree cephalad tilt radiographs were obtained to assess fracture configuration and comminution. Fractures were classified using Robinson's classification system [4].

Surgical technique: All surgeries were performed under general anaesthesia with the patient in a beach-chair position. A horizontal incision was made over the fracture site, and the fracture was reduced and fixed with a precontoured locking clavicle plate. The time interval between injury and surgery was recorded for analysis.

Outcome assessment: Functional outcomes were assessed using the Constant-Murley score [16] at six weeks, three months, and six months postoperatively. Return to work was evaluated and documented. Early complications (within six weeks) included wound infection, hardware irritation, and wound dehiscence. Late complications (after six weeks) included non-union, implant failure, and persistent pain. The Constant-Murley scoring system grades functional outcomes as: Excellent (90-100 points), Good (80-89 points), Moderate (65-79 points), and Poor (<65 points).

STATISTICAL ANALYSIS

Data were analysed using EPI software version 7.0 and Microsoft Excel. Descriptive statistics were presented as mean ± standard deviation for continuous variables and frequencies/percentages for categorical variables. Paired t-test was used to compare functional scores at different time points. One-way ANOVA with Bonferroni post-hoc analysis was performed to compare mean scores across multiple time points. A p-value <0.05 was considered statistically significant.

RESULTS

Demographics: Thirty-five patients with displaced midshaft clavicle fractures were included in the study. The mean age of the study population was 38.7 years (range 18-65 years). Twenty-nine patients (82.86%) were male, and six (17.14%) were female. The oldest patient was 65 years, and the youngest was 18 years. The maximum number of patients belonged to the age groups 18-27 years (n=4, 11.43%) and 48-57 years (n=9, 25.71%), showing a bimodal age distribution. Fracture classification and associated injuries are shown in [Table/Fig-1]. The left-side was involved in 18 patients (51.43%) and the right-side in 17 patients (48.57%). Road traffic accidents were the most common mechanism of injury, accounting for 29 patients (82.86%), while six patients (17.14%) sustained fractures due to falls [Table/Fig-1].

Parameter	Number (%)
Mode of injury	
Road traffic accident	29 (82.86%)
Fall	6 (17.14%)
Side affected	
Right	17 (48.57%)
Left	18 (51.43%)
Robinson Classification [4]	
Type 2B1a	20 (57.14%)
Type 2B1b	13 (37.14%)
Type 2B2b	2 (5.71%)
Associated injuries (total n=6)	
Scapula fracture	3 (8.57%)
Chest trauma	2 (5.71%)
Wrist fracture	1 (2.86%)

[Table/Fig-1]: Distribution of fracture characteristics including mechanism of injury, affected side, Robinson classification subtypes, and associated injuries in 35 patients with displaced midshaft clavicle fractures.

Surgical details: The time interval between injury and surgery ranged from 1 to 25 days, with the majority of patients (n=22, 62.85%) undergoing surgery within one to three days of trauma [Table/Fig-2]. The mean duration of surgery was 74.3±10.2 minutes (range 60–100 minutes). Plate specifications used were as follows: 6-hole plates in 2 patients (5.71%), 7-hole plates in 16 patients (45.71%), 8-hole plates in 12 patients (34.28%), and 9-hole plates in 5 patients (14.28%).

Duration	Number of patients	Percentage	Mean±SD
1-3 days	22	62.85%	3.74±2.1 days
4-6 days	6	17.14%	
7-9 days	5	14.28%	
10-12 days	1	2.86%	
>12 days	1	2.86%	

[Table/Fig-2]: Distribution of time interval from injury to surgical intervention showing majority of patients (62.85%) underwent surgery within 1-3 days of trauma.

Union rates: All patients (100%) achieved clinical union by 12 weeks (3 months) and radiological union by 24 weeks (6 months). No cases of non-union, delayed union, or malunion were observed [Table/Fig-3].

Time period	Clinical union n (%)	Radiological union n (%)
6 weeks	25 (71.42%)	5 (14.29%)
3 months	35 (100%)	28 (80%)
6 months	35 (100%)	35 (100%)

[Table/Fig-3]: Temporal progression of clinical and radiological union rates at 6 weeks, 3 months and 6 months postoperatively showing 100% union by final follow-up.

Functional outcomes: According to the Constant -Murley functional outcome grade, the progressive improvement observed from moderate-good outcome at 6 weeks to excellent outcome in 82.85% of patients at 6 month [Table/Fig-4]. The mean±SD Constant-Murley scores at six weeks, three months, and six months were 73.8±7.2, 85.2±5.8, and 89.7±3.9, respectively, showing progressive improvement. One-way ANOVA revealed significant differences in Constant-Murley scores across the three time points (F=89.23, p <0.001) [Table/Fig-5]. Post-hoc Bonferroni analysis showed significant improvements between all time-point comparisons: six weeks to three months (mean difference=11.4, p<0.001), three months to six months (mean difference=4.5, p<0.001), and six weeks to six months (mean difference=15.9, p<0.001) [Table/Fig-6]. Seventeen patients (48.57%) returned to work within 6-8 weeks, seven patients (20%) within 9-11 weeks, and 11 patients (31.42%) within 12-15 weeks.

Grade	6 weeks n (%)	3 months n (%)	6 months n (%)
Excellent	2 (5.71%)	25 (71.42%)	29 (82.85%)
Good	19 (54.28%)	9 (25.71%)	6 (17.14%)
Moderate	13 (37.14%)	1 (2.85%)	0
Poor	1 (2.85%)	0	0

[Table/Fig-4]: Distribution of Constant-Murley functional outcome grades.

Follow-up period	Mean Constant-Murley Score (±SD)
6 weeks	73.8±7.2
3 months	85.2±5.8
6 months	89.7±3.9

[Table/Fig-5]: Progression of functional outcomes using Constant-murley score.
One-way ANOVA; F= 89.23; p<0.001

Comparison	Mean difference	95% CI	p-value
6 weeks vs 3 months	+11.4	9.9-12.9	<0.001
3 months vs 6 months	+4.5	3.5-5.5	<0.001
6 weeks vs 6 months	+15.9	14.1-17.7	<0.001

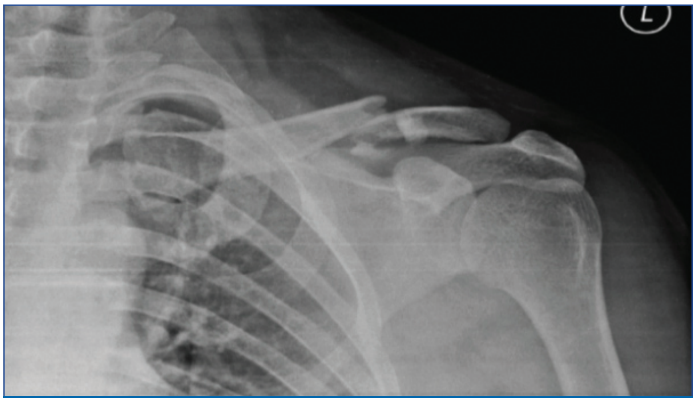
[Table/Fig-6]: Post-hoc Bonferroni pairwise comparisons showing improvements in Constant-Murley scores between all-time points with mean differences and 95% confidence intervals.

Complications: A total of three patients (8.57%) experienced complications: superficial infection in one patient (2.86%), hypertrophic scar in one patient (2.86%), and hardware irritation in one patient (2.86%). No cases of non-union, implant failure, plate breakage, screw loosening, delayed union, or neurovascular injury were observed in this study [Table/Fig-7].

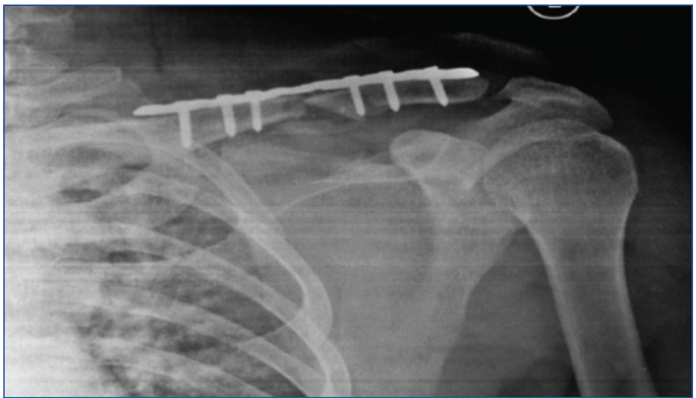
Complications	Number (%)	Time of occurrence
Early (<48 hours)		
None	35 (100%)	-
Late (>48 hours)		
Superficial infection	1 (2.85%)	5 days
Hardware irritation	1 (2.85%)	3 months
Hypertrophic scar	1 (2.85%)	6 weeks
Non-union	0	-
Implant failure	0	-

[Table/Fig-7]: Distribution of early (<48 hours) and late (>48 hours) postoperative complications showing low overall complication rate of 8.57% with no major complications requiring reoperation.

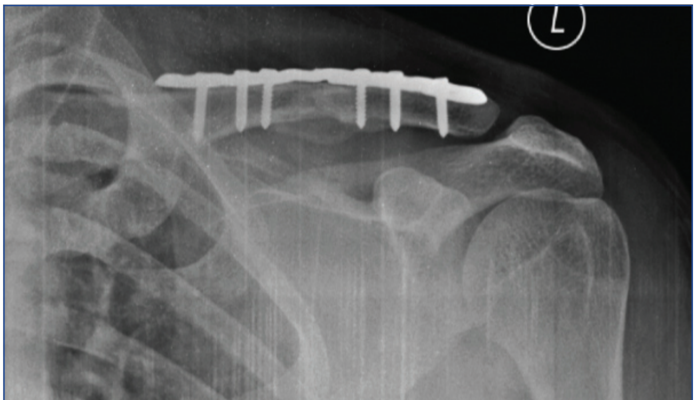
Case Illustration: A 32-year-old male presented with a left displaced comminuted midshaft clavicle fracture (Robinson type 2B1b) following a road traffic accident. The preoperative radiograph [Table/Fig-8] demonstrated displaced midshaft clavicle fractures with varying degrees of comminution and shortening. ORIF was performed using an 8-hole precontoured plate. The postoperative radiograph confirmed anatomical reduction and stable fixation with the precontoured plate [Table/Fig-9]. Follow-up radiographs at six months showed complete union with callus formation in all cases [Table/Fig-10]. Clinical examination at the final follow-up demonstrated excellent range of motion and functional recovery in the majority of patients [Table/Fig-11].



[Table/Fig-8]: Representative preoperative anteroposterior radiograph demonstrating displaced comminuted midshaft clavicle fracture with >2cm shortening (Robinson type 2B classification).



[Table/Fig-9]: Immediate postoperative anteroposterior radiograph showing anatomical reduction and stable fixation with precontoured locking plate.



[Table/Fig-10]: Six-month follow-up anteroposterior radiograph demonstrating complete union with mature callus formation and maintained reduction.

[Table/Fig-11]: Clinical photographs at 6-month follow-up showing excellent range of motion including: (a) forward elevation; (b) lateral elevation; (c) internal rotation; and (d) external rotation..

DISCUSSION

The present study demonstrates excellent functional outcomes, with a 100% union rate following ORIF of displaced midshaft clavicle fractures using precontoured locking plates. The mean Constant-Murley score was 89.7±3.9 at six months, and the majority of patients achieved excellent functional recovery, which compares favourably with the published literature [16,17]. Reisch T et al., in their study of 100 patients treated with anatomical pre-contoured locking plates, reported a mean Constant-Murley score of 93.5±6.2, with 85.4% achieving excellent outcomes [16]. Similarly, Fang et al., in their propensity score–matched study of 106 patients comparing anatomically pre-contoured versus reconstruction plates, found that 90.6% of ALCP patients achieved full range of motion compared to 88.7% in the RLCP group (p=0.751), demonstrating comparable functional outcomes between the two plate types, though they observed significantly higher implant deformity rates in the RLCP group (11.3% vs 0%, p=0.012) [17].

The shift from conservative to operative management of displaced midshaft clavicle fractures has been one of the most significant changes in orthopaedic practice over the past two decades. Our findings support the current evidence favouring surgical treatment for displaced midshaft clavicle fractures, particularly in young, active patients [18].

The superior outcomes in our study may be attributed to meticulous surgical technique, appropriate patient selection, and a structured rehabilitation protocol. The precontoured design eliminated the need for intraoperative plate contouring, potentially reducing surgical time and preserving plate integrity [19,20]. The biomechanical advantages of precontoured plates include better load distribution and reduced stress concentration compared to traditional plates [21,22].

The complete union rate achieved in our study is consistent with recent meta-analyses and systematic reviews showing superior union rates with operative treatment compared to conservative management [14,23]. Frima H et al., in their comprehensive review, reported that surgical treatment of displaced midshaft clavicle fractures results in union rates of 94-100%, significantly higher than the 77-86% union rates seen with conservative treatment [14]. McKee RC et al., in their meta-analysis of randomised trials, found a non-union rate of 15.1% with conservative treatment versus 2.2% with operative treatment (relative risk 0.14, 95% CI 0.05-0.34), and a malunion rate of 31.3% versus 4.1%, respectively [23].

The low complication rate in our study compares favourably with recent systematic reviews reporting 15-25% complications with plate fixation [24]. The absence of non-union, implant failure, or neurovascular injury in our study highlights the safety of this technique when performed with careful soft-tissue handling and appropriate patient selection.

The functional outcomes in our study are consistent with contemporary literature. Recent studies have reported excellent outcomes ranging from 76.7% to 85.4% using various plate configurations. The mean Constant-Murley score of 89.7 at six months in our study is comparable to the 89.23-93.48 range reported in recent meta-analyses.

In the present study, an early return to work was observed, with 48.57% of patients resuming activities within 6-8 weeks, demonstrating the advantage of stable fixation in allowing early mobilisation. This finding aligns with the documented benefits of operative treatment in facilitating earlier return to function and activities [18,25].

Our study findings are similar to existing literature, showing that precontoured plates provide equivalent or superior stability compared to traditional reconstruction plates while maintaining a lower profile. Several biomechanical studies have demonstrated that precontoured plates offer better load distribution and reduced stress shielding, potentially contributing to improved healing and reduced complications [22,26].

The present study adds to the growing evidence supporting the use of precontoured locking plates for displaced midshaft clavicle fractures, demonstrating that appropriately selected patients can achieve excellent functional outcomes with high union rates and low complication rates.

Limitation(s)

The study has several limitations, including a relatively small sample size, short follow-up period (6 months), single-center design, absence of a control group for comparison with conservative treatment, and potential selection bias in patient recruitment. Future multicenter randomised controlled trials with longer follow-up periods are needed to validate these findings and provide more robust evidence for clinical decision-making.

CONCLUSION(S)

ORIF using precontoured locking plates for displaced midshaft clavicle fractures in the present study demonstrated excellent functional outcomes with 100% union rates and low complication rates. The technique enabled early return to work, with 48.57% of patients resuming activities within 6-8 weeks. The majority of patients (82.85%) achieved excellent functional outcomes at six months follow-up. This study supports the use of precontoured locking plates as an effective treatment option for displaced midshaft clavicle fractures in appropriately selected patients.

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