

DOI: <https://doi.org/10.33314/jnhrc.v19i2.3234>

Comparative Study between the Precontoured Anatomical Locking Plate and Clavicle Brace for Displaced Mid-Shaft Clavicle Fractures

Kapil Mani KC,¹ Parimal Acharya,¹ Dirgha Raj RC,¹ Suman Babu Marahatta,¹ Ankit Niroula,¹ Amuda KC²

ABSTRACT

Background: Most of the midshaft clavicle fractures heal conservatively without further complications with union rate of 94 to 99.7%. Several recent studies recommend surgery for displaced midshaft fracture, to reduce risk of non-union malunion and clavicle shortening. So there is still dilemma for the optimal treatment for displaced midshaft clavicle fracture.

Methods: This was the prospective comparative study performed in Civil Service Hospital, Nepal. Patients were divided into the two groups each containing 40 patients and were treated with figure of eight brace for group 1 while group 2 patients were treated surgically.

Results: Mean time to unite the fracture was 11.87 ± 1.78 versus 11.55 ± 1.46 weeks (P value 0.37). There were 14 (35%) cases of malunion more than 10 degree in group 1 and 1 (2.5%) malunion in group 2 (P value 0.001). Twenty nine (72.5%) patients in group 1 and 35 (87.5%) in group 2 were fully satisfied one year after treatment Constant and Murley score in group 1 were 75.22 ± 2.85 , 90.87 ± 3.39 and 96.30 ± 1.80 at the time of fracture union, six month and one year after surgery while that score in group 2 were 81.67 ± 2.86 , 93.87 ± 2.17 , 98.20 ± 1.20 respectively (P value <0.001).

Conclusions: There is higher incidence of nonunion, symptomatic malunion and inferior perception of satisfaction in conservatively treated patients. Functional outcomes are comparable one year after surgery, however it is significantly better in operative group before that.

Keywords: Figure of eight bandage; midshaft clavicle fractures; non-operative treatment; precontoured locking plate

INTRODUCTION

Clavicle fracture has been considered as one of the commonest fractures in the body which accounts for 4 to 12% of whole fractures and 44 to 66% of shoulder girdle fractures.^{1,2} Most of the midshaft clavicle fractures heal conservatively without further complications with union rate of 94 to 99.7%.³

Several clinical trials have recommended the surgical treatment for displaced midshaft clavicle fractures to reduce risk of nonunion, malunion, shortening and improve the patient satisfaction, however it is associated with surgical scar, paraesthesia, surgical site infection, implant prominence, second surgery for removal of implant.⁴⁻¹¹ There is still dilemma for the optimal treatment for displaced midshaft clavicle fracture unless it is associated with neurovascular compromise, floating shoulder, compound fracture, polytrauma, head injury.

The aim of this study is to compare the functional

outcome, malunion, rate of nonunion and overall complications between clavicle brace and plate osteosynthesis for displaced midshaft clavicle fractures.

METHODS

This was the prospective comparative study performed in the department of orthopedics, Civil Service Hospital, Kathmandu, Nepal from 2013 to 2018. Permission for the study was taken from the Institutional Review Board in our hospital. Altogether 80 patients were eligible for the study during this 5 years period. All the patients of age range 20 to 70 years with displaced midshaft clavicle fractures within 7 days of injury were included in the study while patients with multiple injuries or ipsi-lateral upper limb fractures, head injury, open fractures, associated neurovascular injury, bilateral clavicle fractures were excluded from the study. Patients were divided into the two groups (Group 1 and Group 2) each containing 40 patients. Group 1 patients were treated conservatively with figure of eight brace and arm sling

Correspondence: Dr Kapil Mani KC, Civil Service Hospital, Minbhawan, Kathmandu, Nepal. Email: drkapil2007.kmcc@gmail.com, Phone: +9779851114502.

while group 2 patients were treated with open reduction and internal fixation (ORIF) with precountered locking compression plate. Clavicle fractures with absolute indications for surgical treatment like open fractures, those with neurovascular injury, head injury and floating shoulder were excluded from the study while those with severe skin tenting were directly allocated into the group 2. Allocation of patients into the two treatment groups were decided by alternative methods i.e. group 1 followed by group 2. Patients attending either in OPD or emergency department were first assessed by orthopedic resident or registrar and those eligible for the study were fully explained regarding the study protocol as well as advantages and disadvantages of both treatment options. Patients who want to choose either conservative or operative treatment, were again allocated into the respective group. Surgery was performed by consultant orthopedic surgeons in our hospital. The necessary consent was taken for those willing to enroll in the study. The other demographic parameters like sex, side, mode of injury, types of fracture based on Robinson classification between two groups were demonstrated in table 1.

Table 1. Showing demography of fracture in both groups.

Demographic parameters	Group 1	Group2	P value
Age (years)	41.45±10.76	34.37±9.88	0.37
Sex			
Male	26	25	
Female	14	15	
Side			
Right	17	18	
Left	23	22	
Mode of injury			
RTA	16	22	
Fall from height	14	13	
Sports injury	8	4	
Direct injury	2	1	
Robinson Classification			
Type B1	24	19	
Type B2	16	21	

Patients enrolled in the conservative treatment were stabilized with figure of eight bandage in moderately tight condition and arm pouch sling. All necessary investigations were performed and pre-anesthetic evaluation was done for patients enrolled in the surgical

treatment. After appropriately positioned the patients in operative table, around 8 to 10 cm longitudinal incision was given over subcutaneous border of clavicle. Now superficial fascia and deep clavi-pectoral fascia were dissected with precaution to preserve the subcutaneous nerve and fractured ends were exposed. Usually clavicle fractures were associated with comminuted fragments. After minimal periosteal dissection, fracture was reduced along with comminuted fragments and fixed with precountered anatomical locking plate. Depending on the intraoperative situation, one or two inter-fragmentary screws can be added separately from the plate to enhance fracture fixation. Wound was closed after approximation of muscle and deep fascia. Postoperative radiograph was performed on same day of surgery. Antibiotic was continued for 3 days. Wound was observed on third postoperative day with exchange of dressing. Suture was removed 2 weeks after surgery.

Conservatively treated patients were followed up in OPD every week for three weeks to assess any displacement off fracture and then every two months until the union of fracture. X-ray was performed in each follow up visit. Intermittent elbow mobilization was started next day after application of bandage while pendulum and passive mobilization exercise of shoulder were started 3 weeks after injury. Active shoulder mobilization and isometric exercises of peri-scapular muscles were started after removal of clavicular brace.

For operated patients, pendulum exercise of shoulder and elbow mobilization exercise were started next day after surgery. Patients were advised to support the operated limb in arm pouch sling for 2 weeks and then advised to use intermittently until six weeks. Passive mobilization of shoulder was started after 10 days followed by active assisted mobilization on three weeks until six weeks after that full active mobilization and isometric peri-scapular muscle strengthening exercises were started. Patients were followed up in OPD in 2 weeks, 6 weeks and then every 6 weeks thereafter until fracture union. Last two follow up visits were 6 months and one year after surgery. Radiograph was taken during each visit to assess the fracture union. Fracture union was considered when definitive callus was visible in three out of four quadrants in both AP and cephalic tilt view along with clinical evidence of no pain and mobility on fracture site in group 1 patients. A clinical evaluation for the functional assessment of the shoulder and upper limb was performed at the time of fracture union, six month and one year after surgery using Constant and Murley score system in both groups.

Statistical analyses were performed using the SPSS software (version16.0). Quantitative variables were documented as mean ± standard deviation. Quantitative variables between the two groups were assessed by independent student's t-test while qualitative data between two groups were assessed by either chi-square test or Fisher exact test. P values <0.05 were considered statistically significant.

RESULTS

The mean age of the patients in group 1 was 41.45±10.76 years as compared to the 34.37±9.88 years in group 2. There were 14 (35%) cases of malunion more than 10 degree in group 1 and 1 (2.5%) malunion in group 2. Similarly nonunion, terminal restriction of movement, implant prominence, paraesthesia over surgical site were 2 (5%) versus 0, 5 (12.5%) versus 2 (5%), 6 (15%) versus 0, 10 (25%) versus 0 (table 2). Mean time to unite the fracture in group 1 was 11.87±1.78 weeks and that in group 2 was 11.55±1.46 weeks. Twenty nine (72.5%) patients in group 1 and 35 (87.5%) in group 2 were fully satisfied one year after surgery. Constant and Murley score in group 1 were 75.22±2.85, 90.87±3.39 and 96.30±1.80 at the time of fracture union, six month and one year after surgery while that score in group 2 were 81.67±2.86, 93.87±2.17, 98.20±1.20 respectively (Table 3).

Table 2. Complications in both groups.

Parameters	Group 1	Group 2	Total	P value
Malunion > 10 degree angulation	14(35%)	1(2.5%)	15	0.001
Nonunion	2(5%)	0	2	0.04
Terminal restriction of ROM	5(12.5%)	2(5%)	7	0.462
Paraesthesia over scar site	10(25%)	0	10	0.001

Table 3. Constant and Murley score one year after surgery.

Constant and Murley score	Group 1	Group 2	P value
At the time of fracture union	75.22±2.85	81.67±2.86	<0.001
Six month	90.87±3.39	93.87±2.17	<0.001
One year	96.30±1.80	98.20±1.20	<0.001

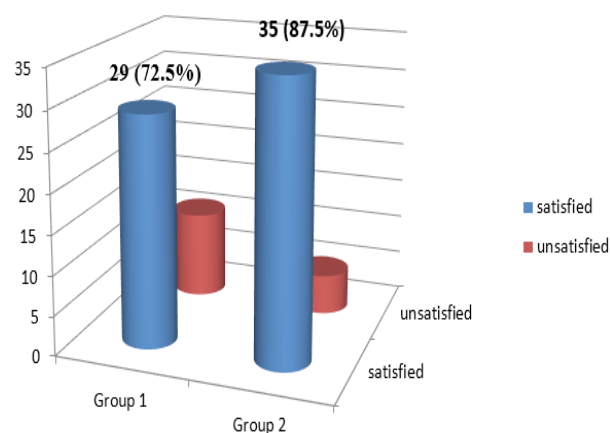


Figure 3. Level of satisfaction between the two groups.

DISCUSSION

Non-operative treatment was considered as gold standard method in the previous decade for the clavicle fracture of whatever displacement and comminution because of its excellent remodeling potential. Conservative treatment with figure of eight (FOE) bandage and/or arm sling maintains good alignment of fracture resulting reasonably good outcomes.³ Ersen et al¹² performed prospective randomized study between the FOE and arm sling for non-displaced or non-complicated displaced clavicle fractures in 60 patients and found that there are no significant functional difference with regard to type of immobilization, however patients feel more comfortable while using the sling.

However, recent meta-analysis mentioned that nonunion rate for non-operatively treated displaced clavicle fractures is relatively higher (15%) as compared to surgically treated fractures with recent implants.⁷ Other recent trials also revealed higher nonunion, malunion, residual pain, decreased shoulder power and endurance activity, inferior overall functional score of shoulder with conservatively treated patients.⁵⁻⁷ Ropars et al¹⁰ have indicated that surgery is particularly reserved for the fractures with more than 2 cm of displacement including open fractures, associated neurovascular insult and floating shoulder. Similarly Lazarrides¹³ in his retrospective series reported that clavicle shortening more than 18 mm in male and 14 mm in female has been closely associated with functional dissatisfaction related to lack of strength and resistance to effort (P <0.01). Regarding the intramedullary flexible nailing which

is assumed a good alternative for displaced clavicle fractures, Andrade-Silva, in a prospective randomized study of 59 cases, found no significant difference ($P > 0.05$) in DASH or Constant score, consolidation time or postoperative pain. The surgeon should therefore choose the technique in which he or she is more experienced.¹⁴

In the current study, demographic parameters including age, sex, site of injury, mechanism of injury, fracture patterns in both groups are comparable. The mean age of the patients in group 1 was 41.45 ± 10.76 years as compared to the 34.37 ± 9.88 years in group 2. The incidence of fracture has been found to be more in male, more common in left side, mainly because of road traffic accidents like in other type of trauma. Robinson B2 type fracture was slightly more common in group 2 while B1 type fracture seemed slightly more in group 1. However, both mean age and fracture pattern in two groups are not significantly different.

There were 14 (35%) cases of malunion more than 10 degree in group 1 and 1 (2.5%) malunion in group 2 (P value 0.001) while 2 (5%) cases of nonunion in group 1 and no single case of nonunion in group 2 (P value 0.04) were noted which is statistically significant. No single case of surgical site infection, which is assumed to be a devastating complication, is present in operated group in our study. The current study is similar to study by Canadian Orthopedic Society who mentioned that symptomatic malunion and nonunion were more common in non-operative group as compared to operative group (7 of 49 in conservative versus 2 of 62 in operative for nonunion and 9 of 49 versus 0 for malunion with $P < 0.001$ and $P = 0.042$ respectively).⁵ Shetty et al¹⁵ and Paul Toogood et al¹⁶ in their recent studies had reported that open reduction and internal fixation has shown superior results with rare nonunion and malunion in compared to conservative management of displaced fractures. However, report of Judd et al is somehow contradictory with higher incidence of complications in operated group (48%) in comparison to conservative group (7%) with even similar rate of nonunion.¹⁷

Constant and Murley score in group 1 were 75.22 ± 2.85 , 90.87 ± 3.39 and 96.30 ± 1.80 at the time of fracture union, six month and one year after surgery while that score in group 2 were 81.67 ± 2.86 , 93.87 ± 2.17 , 98.20 ± 1.20 respectively (P value < 0.001 in all three stages). This shows that difference of functional score between the two groups is more significant at the time of fracture union and six month after surgery while it is comparable one year after surgery. A study was done by Canadian

Orthopaedic Trauma Society, Wang et al have shown better functional scoring with a patient undergoing operative management compared to conservative management.^{5,6}

In the current study mean time to unite the fracture in group 1 was 11.87 ± 1.78 weeks and that in group 2 was 11.55 ± 1.46 weeks which is not statistically significant (p value 0.37). Study of Jian-Yuan et al¹⁷ and Altamimi et al¹⁸ reported that average time to unite the fracture is significantly earlier in operated groups in comparison to conservative groups. However, Sarah et al¹⁹ had reported that plate fixation significantly reduces the risk of nonunion, but does not have a clinically relevant advantage regarding final functional outcome. Clavicular nonunion which is not uncommon after either of treatment methods can be managed by re-surgery with plates and bone grafting. Overall, there is not enough evidence to support routine operative treatment for all patients with a displaced midshaft clavicular fracture. Preservation of biological environment in conservative treatment cannot be underestimated which is responsible for faster healing even though it is affected by overlap of fracture fragments to some extent. In our study, Twenty nine (72.5%) patients in group 1 and 35 (87.5%) in group 2 were fully satisfied one year after surgery. Satisfaction of patients between two groups in our study is comparable to the study of Canadian Orthopedic Trauma Society and BM Naveen et al.¹¹

Vascular complications after surgical treatment, even though rare, are life threatening conditions. Vascular structures are quite close to the medial half of clavicle¹⁰. In the current study, there was no case of vascular injury. Ideally plate should be placed superiorly on most medial part and anteriorly on the middle segment. In addition, drill bit should be directed more vertically in the medial segment and more horizontally as we shift more laterally.²⁰

CONCLUSIONS

There is higher incidence of nonunion, symptomatic malunion and inferior perception of satisfaction in conservatively treated patients. Functional outcome based on Constant and Murley score is significantly better in operatively treated patients at the time of fracture union and six months after surgery in comparison to non-operative patients, however functional outcomes are somehow similar on year after surgery.

Author Affiliations

¹Civil Service Hospital, Minbhawan, Kathmandu, Nepal

²Nepalese Army Institute of Health Sciences, Kathmandu, Nepal.

Competing interests: None declared

REFERENCES

- Robinson CM. Fractures of the clavicle in the adult: Epidemiology and classification. *J Bone Joint Surg Br.* 1998; 80: 476–84. [\[Article\]](#)
- Nordqvist A, Petersson C. The incidence of fractures of the clavicle. *Clin Orthop Relat Res.* 1994; 300: 127-132. [\[PubMed\]](#)
- Robinson CM, Court-Brown CM, McQueen MM, Wakefield AE. Estimating the risk of nonunion following nonoperative treatment of a clavicular fracture. *J Bone Joint Surg Am.* 2004; 86-A (7): 1359-1365. [\[Article\]](#)
- Hill JM, McGuire MH, Crosby LA. Closed treatment of displaced middle-third fractures of the clavicle gives poor results. *J Bone Joint Surg Br.* 1997; 79(4): 537-539. [\[Article\]](#)
- Canadian orthopaedic trauma society. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. *J Bone Joint Surg Am.* 2007; 89: 1–10. [\[Article\]](#)
- Wang X-H, Guo W-J, Li A-B, Cheng G-J, Lei T, Zhao Y-M. Operative versus nonoperative treatment for displaced midshaft clavicle fractures: a meta-analysis based on current evidence. *Clinics.* 2015; 70(8): 584–92. [\[PubMed\]](#)
- Zlowodzki M, Zelle BA, Cole PA, Jeray K, McKee MD. Treatment of midshaft clavicle fractures: systemic review of 2144 fractures. *J Orthop Trauma.* 2005; 19:504–507. [\[PubMed\]](#)
- Assobhi JE. Reconstruction plate versus minimal invasive retrograde titanium elastic nail fixation for displaced midclavicular fractures. *J Orthop Traumatol.* 2011; 12: 185–92. [\[Article\]](#)
- Saha P, Datta P, Ayan S, Garg AK, Bandyopadhyay U, Kundu S. Plate versus titanium elastic nail in treatment of displaced midshaft clavicle fracture: a comparative study. *Indian J Orthop.* 2014; 48:567–93. [\[Article\]](#)
- Ropars M, Thomazeau H, Hutten D . Clavicle fractures . *Orthopaedics & Traumatology: Surgery & Research.* 2017; 103: S53–S59. [\[Article\]](#)
- Naveen BM, Joshi GR, Harikrishna B. Management of mid-shaft clavicular fractures: comparison between non-operative treatment and plate fixation in 60 patients. *Strat Traum Limb Recon.* 2017; 12: 11–18. [\[Article\]](#)
- Ersen A, Atalar AC, Birisik F, Saglam Y, Demirhan M. Comparison of simple arm sling and figure of eight clavicular bandage for midshaft clavicular fractures: a randomised controlled study. *Bone Joint J.* 2015; 97: 1562–5. [\[Article\]](#)
- Lazarides S, Zafiroopoulos G. Conservative treatment of fractures at the middle third of the clavicle: the relevance of shortening and clinical outcome. *J Shoulder Elbow Surg.* 2006; 15(2):191–4. [\[Article\]](#)
- Shetty SK, Chandran R, Ballal A, Mathias LJ, Hegde A, Shetty A. To operate or not to operate the mid-shaft fractures of the clavicle: a comparative study of functional outcomes of the two methods of management. *Journal of clinical and diagnostic research: JCDR.* 2017 Jan;11(1):RC01. [\[Article\]](#)
- Toogood P, Horst P, Samagh S, Feeley BT. Clavicle Fractures: A Review of the Literature and Update on Treatment. *Phys Sportsmed.* 2011; Sep;39(3): 142-50. [\[Article\]](#)
- Judd DB, Pallis MP, Smith E, Bottoni CR. Acute operative stabilization versus nonoperative management of clavicle fractures. *Am J Orthop.* 2009; 38(7): 341-345. [\[Article\]](#)
- Chu JY, Yeh KT, Lee RP, Yu TC, Chen H, Peng CH, Liu KL, Wang JH, Wu WT. Open reduction and internal fixation with plating is beneficial in the early recovery stage for displaced midshaft clavicular fractures in patients aged 30–65 years old. *Tzu-Chi Medical Journal.* 2018 Oct;30(4):242. [\[Article\]](#)
- Altamimi SA, McKee MD. Canadian Orthopaedic Society. Nonoperative treatment compared with plate fixation of displaced midshaft clavicle fractures. *Surgical technique.* *J Bone Joint Surg Am.* 2008; 90(90 Suppl 2 Pt 1):1–8. [\[Article\]](#)
- Woltz S, Krijnen P, Schipper IB. Plate fixation Versus Nonoperative Treatment for Displaced Midshaft Clavicular Fractures: A Meta-Analysis of Randomized Controlled Trials. *J Bone Joint Surg Am.* Jun 2017; 99(12):1051-1057. [\[Article\]](#)
- Galley IJ, Watts AC, Bain GI. The anatomic relationship of the axillary artery and vein to the clavicle: a cadaveric study. *J Shoulder Elbow Surg.* 2009; 18: e21–5. [\[Article\]](#)

-
21. Andrade-Silva FB, Kojima KE, Joeris A, Santos Silva J, Mattar Jr R. Single, superiorly placed reconstruction plate compared with flexible intramedullary nailing for midshaft clavicular fractures: a prospective, randomized controlled trial. *J Bone Joint Surg Am.* 2015; 97:620–6.[\[Article\]](#)