



COMPARISON OF MINIMALLY INVASIVE PERCUTANEOUS PLATE OSTEOSYNTHESIS (MIPPO) TECHNIQUE AND CONVENTIONAL OPEN REDUCTION WITH LOCKING COMPRESSION PLATE (LCP) FOR THE TREATMENT OF CLAVICLE MIDSHAFT FRACTURES IN ADULTS: A RANDOMIZED CONTROLLED CLINICAL TRIAL (RCT)

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Conflicts of Interest: Nil

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Abstract:

Background: The present study investigated operative treatment of clavicle midshaft fractures in adults by comparing minimally invasive percutaneous plate osteosynthesis (MIPPO) technique and conventional open reduction using locking compression plate(LCP) in a randomized, controlled, clinical trial with a minimum of 1-year follow-up.

Materials and methods: Between June 2015 and May 2018, 40 cases of open reduction and internal plate fixation were performed at Department of Orthopaedics, Gandaki Medical College, Pokhara, Nepal; for clavicle midshaft fractures. The inclusion criteria for the operation included complete displacement, severe comminution and marked shortening of more than 2cm of the clavicle. MIPPO and conventional open reduction surgery procedures with LCP were used in 20 and 20 cases, respectively.

Results: The mean time to union was 14 weeks in the open reduction group compared to 12 weeks in MIPPO group ($P > 0.05$). The MIPPO group had no significantly superior Constant shoulder scores or DASH scores at all time-points ($P > 0.05$). However, the open reduction group showed associated complications as dysesthesia in the area of the incision and directly below which was reported in 6 cases, hypertrophic scarring reported in 3 cases, painful shoulder in 2 cases and a limitation of shoulder motion in one case ($P > 0.05$). The complications in the MIPPO group were dysesthesia in two cases, no hypertrophic scarring, no painful shoulder, and no limitation of shoulder motion were noted ($P < 0.05$). Patients in this operative group were more satisfied with cosmetic appearance and overall outcome than those in the conventional open reduction group.

Conclusions: The stable fixation can be achieved through operative treatment with a locking compression plate for clavicle shaft fractures. Particularly, MIPPO of displaced midshaft clavicular fractures resulted in a lower rate of dysesthesia, hypertrophic scarring, and a better cosmetic than conventional open reduction, although the functional outcomes (Constant and DASH) were no different between the two groups. Overall satisfaction was higher in the MIPPO group than conventional open reduction group. MIPPO group was aesthetically more acceptable compared to the open reduction group.

INTRODUCTION

The clavicle is easily fractured because of its subcutaneous, relatively anterior location and frequent exposure to transmitted forces. The middle third, or midshaft, is the thinnest, least medullous area of the clavicle, and thus the most easily fractured; the lack of muscular and ligamentous support makes it vulnerable to injury. The acromioclavicular (AC) and sternoclavicular joints have robust ligamentous and capsular support. The sternal ossification center of the clavicle completes ossification and fuses with the shaft by age 30 years.

This medial ossification center contributes to 80 percent of the longitudinal growth of the bone. Physeal injuries should be considered in adolescents with open growth plates.

Clavicle fractures constitute 5 to 10 percent of all fractures.[1] Mostly occur in men younger than 25 years; however, they are also more common in men older than 55 and in women older than 75.[2] The anatomic site of the fracture is typically described using the Allman classification, which divides the clavicle into thirds.[3] Group I (midshaft) fractures occur on the middle third of the clavicle, group II

fractures on the lateral (distal) third, and group III fractures on the medial (proximal) third.[4] Midshaft fractures account for approximately 75 to 80 percent of all clavicle fractures and typically occur in younger persons. Distal third fractures represent about 15 to 25 percent of clavicle fractures. Medial third fractures are least common, accounting for less than 5 percent of clavicle fractures.[1,4,5] Most clavicle fractures occur in the midshaft and can be treated nonoperatively. Furthermore, there is an increasing incidence of complex fracture patterns after high-energy trauma [4,5]. However, factors including severity of displacement, degree of comminution, and greater than 2 cm of shortening have been reported in the literature to predispose patients to unsatisfactory outcomes with non-operative treatment [6,7]. Because of these factors, there has been a trend toward operative treatment of clavicle midshaft fractures. There are various methods for treating clavicle midshaft fractures, such as intramedullary K-wires or elastic stable intramedullary nailing and plate fixation [6,8-12]. In particular, plate fixation can provide stable anatomical fixation and locking compression plate (LCP), which can be bent to the S-shaped curvature of the clavicle, are the most preferred [13]. The goal of the present study was to assess operative treatment of clavicle midshaft fractures in adults by comparing minimally invasive percutaneous plate osteosynthesis (MIPPO) technique and conventional open reduction using locking compression plate (LCP) in a randomized, controlled, clinical trial with a minimum of 1-year follow-up.

Material and methods

Inclusion criteria were:

- Only those patients who gave their informed written consent were included with
 - Complete displacement;
 - Severe comminution
 - Marked shortening of the clavicle (> 2 cm).

Exclusion criteria were:

- Pathological and open fracture;
- Fracture in the proximal or distal third of the clavicle;
- Inability to comply with follow-up;
- Contraindication for surgery in general anesthesia;
- Lack of consent.

Randomization Between June 2015 and May 2018, 40 cases of open reduction and internal plate fixation were performed at Department of Orthopaedics, Gandaki Medical College, Pokhara, Nepal; for clavicle midshaft fractures. The inclusion criteria for the operation included complete displacement, severe comminution and marked shortening of more than 2cm of the clavicle. MIPPO and conventional open reduction surgery procedures with LCP were used in 20 and 20 cases, respectively. The randomization schedule was done initially according to VinzenzSmekal’s methods [14]. Fractures were classified according to Robinson’s classification [11]. In the MIPPO group, the mean follow-up period was 15 months (range, 12 to 24 months). There were 12 males and 8 females with a mean age of 40 years (range, 20 to 70 years). The cause of the injury was a traffic accident in 10 cases, fall down in 6 cases, a sport injury in 4 cases. There were 12 B1 type and 8 B2 type fractures according to Robinson classification [11]. The mean interval from injury to surgery was 7 days (range, 1 to 15 days). In the conventional open reduction group, the mean follow up period was 15 months (range, 12 to 24 months). There were 12 males and 8 females with a mean age of 45 years (range, 18 to 68 years). The cause of the injury was a traffic accident in 12 cases, fall down in 5 cases, a sports injury in 3 case. There were 13 B1 type and 7 B2 type fractures. The mean interval from injury to surgery was 7 days (range, 1 to 15 days).

Table 1: Demographic data of the patients.

Parameter	MIPPO group (n =20)	Conventional group (n = 20)	P- value
Follow up, range (mo)	15 (12–24)	15 (12–24)	1
Age, range (years)	40 (20–70)	45 (18–68)	0.796
Case (%)			
Traffic accident			
Fall down	10	12	0.845
Sports injury	6	5	
Type of fractures	4	3	
Type B1			
Type B2	12	13	0.446
Interval from injury to operation, range (day)	8	7	
	7 (1–15)	7 (1–15)	1

Operative technique

Under general anesthesia, the patient was positioned in a beach-chair semi-sitting position. The involved shoulder was prepared and draped. In the MIPPO group, a small skin incision (approximately 3 cm) was centred over the fracture site. Larger branches of the identifiable supraclavicular nerves were identified and protected throughout the procedure; smaller branches were sacrificed at the surgeon's discretion. The fracture site was identified, and the fracture was reduced. Comminuted fragments were secured with lag screws if possible. Next, a distal incision (approximately 1 cm) and a proximal incision (approximately 1 cm) were made approximately 2 cm lateral of the fracture site respectively. Each plate was contoured to the shape of the clavicle and placed in the anterosuperior position. The distal incision was the insertion site. Fixation was performed following a reduction with minimal periosteal stripping. To obtain maximum fixation strength, three screws were used in the primary distal (in the distal incision) and proximal fragments (in the proximal incision), respectively. Bone-grafting was not performed. In the conventional open reduction group, an oblique incision (approximately 8–10 cm) was made over the fracture site. Larger branches of the identifiable supraclavicular nerves were identified and protected throughout the procedure; smaller branches were sacrificed at the surgeon's discretion. Each plate was contoured to the shape of the clavicle. Fixation was performed following a reduction with minimal periosteal stripping. Three screws were used in the proximal and distal areas, respectively. Bone-grafting was not performed. Postoperatively, the patients were given a simple sling for approximately 2 weeks, and pendulum exercise and active range of motion exercise were then started.

Main outcome measurements

For a radiological assessment, the bone union period was compared using radiographic evidence, such as callus formation and trabecular bridging across the fracture site. Radiographs were taken after 1 week, 3 weeks, 6 weeks, and again after 3 months and 6 months.

For the clinical assessment, standardized clinical evaluation and completion of the Constant shoulder score [15] and the Disability of the arm, shoulder and hand (DASH) score [16] were included.

Statistical analysis was performed using SPSS ver. 18.0 (SPSS Inc., Chicago, IL, USA). An independent t-test and Chi2 test were used. A P-value less than 0.05 was considered significant [17]. Postoperative complications were noted in both groups.

Results

40 patients volunteered to participate and signed written informed consent. All of them completed the study. 20 patients were randomized to both the MIPPO and the conventional open reduction treatment groups, respectively. Demographic data are shown in (Table 1). The patients' age, gender, cause of injury, fracture pattern, interval from injury to operation were not statistically different in the two groups ($P > 0.05$). The mean operative time was 60 min (range, 45 to 90 min) in the MIPPO group and 60 min (range, 45 to 90 min) in the conventional open reduction group, showing no notable intergroup differences ($P > 0.05$). Bony union was achieved in all cases after surgery at an average of 12 weeks (range, 8 to 20 weeks) in the MIPPO group and 14 weeks (range, 8 to 24 weeks) in the conventional open reduction group, respectively, indicating no significant intergroup difference ($P > 0.05$). Patients returned to activity from injury on average at 14 weeks in the MIPPO group and 16 weeks (range, 8 to 24 weeks) in the conventional open reduction group, indicating no significant intergroup difference ($P > 0.05$). There were no non-unions or malunions. In the clinical assessment, the MIPPO group had no significantly superior Constant shoulder scores or DASH scores at all time-points ($P > 0.05$). However, postoperative complications were noted in both groups. The open reduction group showed relatively higher complications such as dysesthesia in the area of the incision and directly below which was reported in 6 cases, hypertrophic scarring reported in 3 cases, painful shoulder in 2 cases and a limitation of shoulder motion in one case ($P > 0.05$). The complications in the MIPPO group were dysesthesia in two cases, no hypertrophic scarring, no painful shoulder, and no limitation of shoulder motion were noted ($P < 0.05$). Patients were specifically questioned about their satisfaction or dissatisfaction regarding the appearance of the shoulder (and incision, if applicable) at 1-year following the injury. Patients in the MIPPO group were more likely to be satisfied with the appearance of the shoulder ($P < 0.005$) (Table 2).

Table 2: Results of patients treated with fixation via (MIPPO- Minimally invasive percutaneous plate osteosynthesis) vs open reduction.

Parameter	MIPPO group (n =20)	Conventional group (n = 20)	P- value
OP time, range (min)	60 (45—90)	60 (45—90)	1
Bone union period range (wk)	12 (8—20)	14 (18—69)	0.432
Returned to activity range (wk)			
Complication (%)	14	16	0.322
Dysesthesia			
Hypertrophic scarring			
Painful shoulder	2	6	
Motion limitation	0	3	
Satisfaction with appearance	0	2	
	0	1	
	18	11	0.00389*

Reasons for dissatisfaction in the MIPPO group included dysesthesia and the three incisions, while reasons for dissatisfaction in the conventional open reduction group included dysesthesia and hypertrophic scarring.

Discussion

Fractures of the clavicular shaft were considered to be a domain of non-operative treatment for a long time. This dogma was based on the studies conducted by NEER CS and Rowe CR in the 1960s [18,19]. However, recent studies have shown that the rate of malunion and non-union after non-operative treatment might well be much higher than previously shown. Subjective contentment with the results of non-operative treatment is not uniformly high [20,21]. In 2007, the Canadian Orthopaedic Trauma Society reported that internal fixation with plates resulted in more rapid union, excellent clinical outcomes, and lower complication rates in 132 patients with displaced clavicle fractures than non-operative treatments [22]. Hence, there has been increasing interest in surgical treatments with open reduction and internal fixation. The operative methods for the treatment of clavicle midshaft fractures involve intramedullary K-wire fixation or Steinmann pin fixation or elastic stable intramedullary nailing and plate fixation. The procedures using the former two materials result in low resistance to torque, carry risks of pin loosening and infection, and require a long-term fixation period. In addition, Elastic stable intramedullary nailing leads to good cosmetic and functional results. Patients profit from marked postoperative pain reduction and a rapid recovery of range of motion in the shoulder joint. However, multifragmentary

fractures or oblique fractures can lead to a telescoping of the fracture site. This leads to a postoperative length reduction. To prevent this complication, Elastic stable intramedullary nailing is only recommended for simple or displaced wedge fractures. Open reduction and internal fixation with plates (plate osteosynthesis) is still the standard method for the surgical treatment of clavicular shaft fractures. The goal of surgical treatment is the anatomic reduction with reconstruction of clavicular length and alignment of the shoulder girdle. To prevent early stress fracture of the implant, a fairly strong implant in comparison to the bone strength should be chosen. LCP have been preferred for plate osteosynthesis of the clavicle. The advantages of LCP include strong fixation due to locking between the screw and plate, and blood supply preservation due to minimal contact between plate and cortical bone. When LCP are used to treat clavicle midshaft fractures, the risks of injury to the subclavicular artery or brachial plexus could potentially be reduced because fixation can be achieved without the tip of the screw reaching the opposite bone cortex and periosteal stripping can be minimized to promote rapid union.

Conclusion

It is believed that the surgery time can be reduced using LCP because accurate plate contouring is not necessary and periosteal stripping could be minimized using self-tapping screws. Surgical treatment of displaced midclavicular fractures with locking compression plate, which can be shaped to match the shape of the clavicle, can be effective in the treatment of clavicle midshaft fractures. However, it remains some problem such as increased

soft tissue stripping, infections, extensive scars, supraclavicular nerve injury. Minimally invasive percutaneous plate osteosynthesis (MIPPO) has been widely applied to treat long bone shaft fractures in recent years because of its technical advantages and satisfactory clinical outcomes

References

1. Johnson EW, Collins HR. Non-union of the clavicle. *Arch Surg* 1963;87(6):963—6.
2. Paffen PJ, Jansen EW. Surgical treatment of clavicular fractures with Kirschner wires: a comparative study. *Arch ChirNeerl* 1978;30 (1):43—53.
3. Khan LA, Bradnock TJ, Scott C, et al. Fractures of the clavicle. *J Bone Joint Surg Am* 2009;91:447—60.
4. Nordqvist A, Petersson C. The incidence of fractures of the clavicle. *ClinOrthopRelat Res* 1994;300:127—32.
5. Postacchini F, Gumina S, De Santis P, et al. Epidemiology of clavicle fractures. *J Shoulder Elbow Surg* 2002;11:452—6.
6. 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;79:537—9.
7. Nowak J, Holgersson M, Larsson S. Sequelae from clavicular fractures are common. *ActaOrthop* 2005;76:496—502.
8. Chu CM, Wang SJ, Lin LC. Fixation of mid-third clavicular fractures with Knowles pins: 78 patients followed for 2-7 years. *Acta Orthop Scand* 2002;73:134—9.
9. Chuang TY, Ho WP, Hsieh PH, et al. Closed reduction and internal fixation for acute midshaft clavicular fractures using cannulated screws. *J Trauma* 2006;60:1315—20.
10. Shen WJ, Liu TJ, Shen YS. Plate fixation of fresh displaced midshaft clavicle fractures. *Injury* 1999; 30:497—500.
11. Robinson CM, Court-Brown CM, McQueen MM, et al. Estimating the risk of non-union following non-operative treatment of a clavicular fracture. *J Bone Joint Surg Am* 2004;86:1359—65.
12. Smekal V, Irenberger A, Struve P, et al. Elastic stable intramedullary nailing versus non-operative treatment of displaced midshaft clavicular fractures—a randomized, controlled, clinical trial. *J Orthop Trauma* 2009;23:106—12.
13. Chul CH, Song KS, Min BW, et al. Operative treatment of clavicle midshaft fractures: comparison between reconstruction plate and locking compression plate. *ClinOrthopSurg* 2010;2:154—9.
14. Smekal V, Irenberger A, Attal RE, et al. Elastic stable intramedullary nailing is best for mid-shaft clavicular fractures without comminution: results in 60 patients. *Injury* 2011;42:324—9.
15. Yian EH, Ramappa AJ, Arneberg O, et al. The Constant score in normal shoulders. *J Shoulder Elbow Surg* 2005;14:128—33.
16. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). *Am J Ind Med* 1996;29:602—8.
17. Beaton DE, Wright JG, Katz JN. Development of the QuickDASH: comparison of three item-reduction approaches. *J Bone Joint Surg Am* 2005;87:1038—46.
18. Neer 2nd CS. Non-union of the clavicle. *J Am Med Assoc* 1960;172:1006—11.
19. Rowe CR. An atlas of anatomy and treatment of midclavicular fractures. *ClinOrthopRelat Res* 1968;58: 29—42.
20. Zlowodzki M, Zelle BA, Cole PA, et al. Treatment of acute mid-shaft clavicle fractures: systematic review of 2144 fractures: on behalf of the Evidence-Based Orthopaedic Trauma Working Group. *J Orthop Trauma* 2005;19:504—7.
21. Kettler M, Schieker M, Braunstein V, et al. Flexible intramedullary nailing for stabilization of displaced midshaft clavicle fractures: technique and results in 87 patients. *ActaOrthop* 2007;78:424—9.
22. Canadian Orthopaedic Trauma Society. Non-operative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. *J Bone Joint Surg Am* 2007; 89:1—10.