



A Comparative Study of Non-Operative versus Operative Management with Locking Compression Plate of Displaced Mid-Shaft Clavicle Fractures in Adults

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ABSTRACT

Introduction: For a long time, all mid-shaft fractures of the clavicle were treated conservatively; however, this is starting to change as a more operative approach is becoming more popular. While some studies support conservative care, some support surgical intervention. Given that both conservative and surgical management have drawbacks and benefits of their own, there is a lack of agreement regarding the optimal course of care.

Aims/ objective: To compare time for union, mal-union rate and function outcomes after conservative management and surgical management with locking compression plate (LCP) in patients with mid-shaft clavicular fracture.

Materials and Method: 28 patients received conservative treatment and 20 patients received surgical treatment. A figure of eight clavicular brace was fitted and adjusted to preserve clavicle reduction for those who chose conservative therapy. Patients in operative group received standard pre-operative testing and had a pre-contoured LCP placed during the procedure. At every follow-up, x-ray scans were obtained to look for implant position, malunion, and radiological union while evaluating non-union, and the time taken for the union was noted. The functional assessment was based on scores determined with the aid of a Fast DASH questionnaire and UCLA to evaluate the function of the shoulder.

Results: Healing and union were faster in patients who were operated with locking compression plates as compared to non-operative group with statistically significant difference ($p < 0.05$). Frequency of non-union was only 4.55% in operative group as compared to 10.71% cases of non-union in non-operative group. Functional outcomes were comparatively better in patients who received conservative management than the patients managed operatively with respect to UCLA and DASH score.

Conclusion: The surgical technique of treatment resulted in noticeably faster healing. There should be trial and research aimed at improving functional outcome after surgery with locking compression plate in clavicular fracture.

Keywords: Clavicle Fracture, Conservative Management, Locking Compression Plate, Union, Functional Outcome.

INTRODUCTION

Approximately 2-5 percent of all fractures are clavicle fractures. Due to the shoulder's excessive compressive pressures and the bone's limited cross-section, over eighty percent of clavicle fractures occur in the mid-shaft.^{1,2} Conservative treatment for these fractures involves immobilization in an arm sling and clavicular brace; surgical treatment involves fixation using intramedullary screws or locking compression plate (LCP). For a long time, all mid-shaft fractures of the clavicle were treated conservatively; however, this is starting to change as a more operative approach is becoming more popular. While some studies support conservative care, some support surgical intervention.

Given that both conservative and surgical management have drawbacks and benefits of their own, there is a lack of agreement regarding the optimal course of care.^{3, 4} According to the literature, there are not many recognized grounds for surgical intervention in cases of midshaft clavicle fractures. These indications include open fractures, patients with multiple injuries, and fractures involving

neurovascular impairments, which are typically omitted from studies. Operative intervention is performed in cases of mid-shaft clavicle fractures in order to reduce the risk of non-union, improve early functional outcomes, and get early mobility in patients who are active.⁵

The move towards surgical management has been prompted by the side effects of non-operative intervention, such as non-union, malunion, changed shoulder mechanics, sluggish healing, and pressure consequences of protrusion on brachial plexus. Enhanced early functional outcomes and a decreased likelihood of non-union are two benefits of surgical management. Even while surgical therapy seems like a wonderful alternative, there are drawbacks to this kind of care as well, the most prevalent of which is the need for a second procedure to remove the implant.³⁻⁷ So, the recommendation to do surgery on every patient is still up for debate.

When compared to conservative care, displaced mid-shaft clavicle fractures managed surgically with LCP had better fracture union and functional results.⁸ This was demonstrated by a multi-center randomised controlled



trial. Furthermore, a higher functional outcome and a faster return to work had been achieved with surgical therapy of a mid-shaft clavicle fracture.^{9,10}

Open fracture reduction and internal fixation using wires, pins, or plates fastened with screws are the two primary operational fixation techniques for midshaft clavicle fractures.¹¹⁻¹³ The surgeon faces difficulties while placing implants and performing reduction procedures because of the clavicle's distinct anatomical configuration. Because it offers more stability and convenience of plate installation, the pre-contoured locking plate is currently the implant of choice for these kinds of clavicle fractures.¹⁴ The issue of fixing it with a mechanically better 3.5-millimeters locking compression plate (LCP) was brought up, nevertheless, because it is not a weight-bearing bone.

This study was done to compare time for union, mal-union rate and function outcomes after conservative management and surgical management with locking compression plate in patients with mid-shaft clavicular fracture.

MATERIALS AND METHODS

This was comparative observational prospective study carried out in patients of displaced midclavicular fracture in Department of Orthopaedics of SKMCH, Muzaffarpur, Bihar (a tertiary care centre of eastern India) from July 2022 to June 2023. The study was started after getting approval from institutional ethics committee and the patients were recruited after screening for inclusion and exclusion criteria and after taking written informed consent from them. Rights and safety of patients were taken care of as per guidelines of Good Clinical Practice and declaration of Helsinki.

Inclusion Criteria: Patients of either sex of age between 18 to 60 years with displaced (greater than 1.5cm) mid-clavicular shaft fracture i.e., type 2b Robinson were included in our study.

Exclusion Criteria: Patients with un-displaced clavicular fracture or fracture of medial or lateral end of clavicle or open clavicular fracture or pathological fracture or associated fracture of scapula or humerus or fracture leading to neurological deficit were excluded from our study.

Based on findings from earlier research, the treating surgeon discussed with patients the various treatment options and the benefits and drawbacks of both conservative and operative method. The non-surgical group of patients consisted of those who were willing to receive conservative care, while the operative group included individuals who were willing to undergo surgery. There was no randomization. The research was prospective and observational in nature.

Consecutive sampling was done and all patients fulfilling our eligibility criteria and giving written informed consent during the study period were recruited. 28 patients

received conservative treatment and 20 patients received surgical treatment.

A figure of eight clavicular brace was fitted and adjusted to preserve clavicle reduction for those who chose conservative therapy. The patient was instructed to wear a brace for four weeks and not to lift any weights while their limb was restrained in a sling. After being informed of all available treatment options, those who gave their permission for surgery received standard pre-operative testing and had a pre-contoured LCP placed during the procedure.

In order to examine the positioning of fracture fragments, post-operative scans were obtained. At the conclusion of one-week, mild shoulder pendulum exercises, elbow, and wrist mobilization were initiated. Following a period between two and three weeks, a mildly aided shoulder range of motion was permitted, with an 80° limit on abduction. According to the degree of union at the site of the fracture, a functional range of motion was initiated in all planes after six weeks.

There were follow-ups at six weeks, three months, six months, nine months, and 12 months. At every follow-up, x-ray scans were obtained to look for implant position, malunion, and radiological union while evaluating non-union, and the time taken for the union was noted. The functional assessment was based on scores determined with the aid of a Fast DASH questionnaire and UCLA to evaluate the function of the shoulder.^{15,16} Based on the clinical findings (no discomfort at the fracture site, good functional mobility and range of movement) and radiographic observation of a bridging callus at the fracture site, the fracture was deemed united.

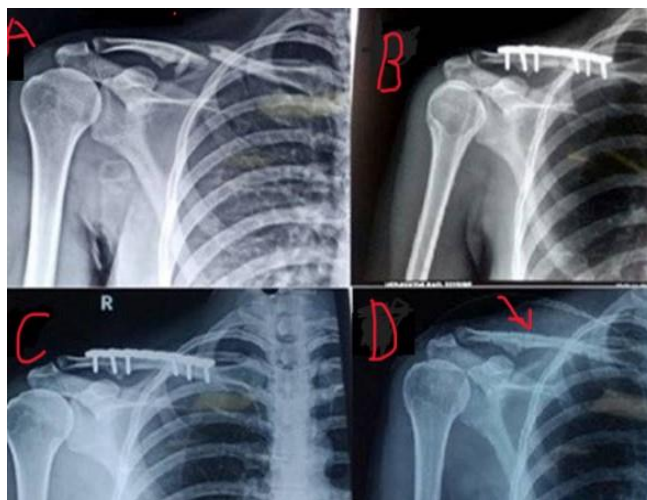


Figure 1: A) Clavicular Fracture B) Pos-operative X-Ray after application of Locking Compression Plate C) Fracture union with LCP in position D) Good union after removal of implant

Statistical Analysis

Data collected from patients of mid-shaft clavicular fracture were recorded in a tabular form using Microsoft Excel 365 and transferred to graph pad version 8.3 for

further statistical analysis. Categorical data such as age, sex, side of fracture, mode of injury, time for union and frequency of non-union were expressed as frequency and percentage and chi-square test or fisher's exact test was used to test for statistical significance of difference between operative and non-operative group. Continuous data such as UCLA and DASH score were expressed as mean and standard deviation (SD) and unpaired t-test was used to test for statistical significance of difference between operative and non-operative group with a p-value of less than 0.05 as a measure of statistical significance.

OBSERVATIONS AND RESULTS

Most of the patients with mid-shaft clavicular fracture belonged to 31-50 years of age group and most of them were males. Road traffic accident was major cause of clavicular fracture followed by fall on outstretched hand. Most of the clavicular fracture were left sided. Both non-operative and operative groups were similar with respect to age, sex, cause of injury or side of fracture with no statistically significant difference ($p>0.05$) [Table 1].

Table 1: Comparison of baseline demographic and clinical characteristics between operative and non operative group

| Variables | Non-operative group (%, n=28) | Operative Group (%, n = 22) | P-Value |
|---------------------------|----------------------------------|--------------------------------|---------|
| Age | | | |
| 18-30 | 8 (28.57) | 4 (18.18) | 0.59 |
| 31-40 | 9 (32.14) | 10 (45.45) | |
| 41-50 | 10 (35.71) | 8 (36.36) | |
| >50 | 1 (3.57) | 0 (0.00) | |
| Gender | | | |
| Male | 17 (60.71) | 16 (72.73) | 0.37 |
| Female | 11 (39.29) | 6 (27.27) | |
| Cause of Fracture | | | |
| Road Traffic Accident | 15 (53.57) | 13 (59.09) | 0.98 |
| Fall on outstretched hand | 9 (32.14) | 7 (31.82) | |
| Sports Injury | 4 (14.29) | 3 (13.64) | |
| Side of Fracture | | | |
| Right | 9 (32.14) | 7 (31.82) | 0.98 |
| Left | 19 (67.86) | 15 (68.18) | |

Table 2: Comparison of fracture union time and no-union rate between operative and non-operative groups

| Variables | Non-operative group (%, n=28) | Operative Group (%, n = 22) | P-Value |
|-----------------------|----------------------------------|--------------------------------|---------|
| Time for union | | | |
| 2-3 months | 8 (28.57) | 13 (59.09) | 0.04 |
| Greater than 3 months | 20 (71.43) | 9 (40.91) | |
| Non-union | | | |
| Yes | 3 (10.71) | 1 (4.55) | 0.62 |
| No | 25 (89.29) | 21 (95.45) | |

Table 3: Comparison of UCLA score at each follow-up between operative and non-operative groups

| Variables | UCLA score in mean \pm SD | | P-Value |
|-----------|-----------------------------|------------------|---------|
| | Non-operative group | Operative Group | |
| 3 months | 21.87 \pm 4.46 | 19.98 \pm 4.36 | 0.14 |
| 6 months | 26.87 \pm 4.56 | 26.11 \pm 4.08 | 0.54 |
| 9 months | 31.23 \pm 4.78 | 29.91 \pm 4.17 | 0.31 |
| 12 months | 34.27 \pm 2.21 | 32.71 \pm 3.84 | 0.08 |



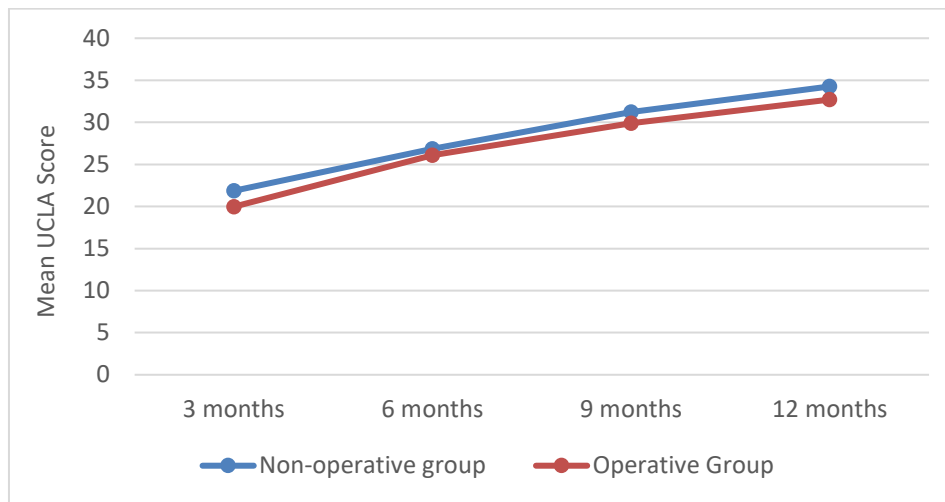


Figure 2: Comparison of UCLA Score between Two Groups

Table 4: Comparison of DASH score at each follow-up between operative and non-operative groups

| Variables | DASH score in mean ± SD | | P-Value |
|-----------|------------------------------|----------------------------|---------|
| | Non-operative group (% n=28) | Operative Group (% n = 22) | |
| 3 months | 35.29 ± 5.12 | 38.05 ± 6.31 | 0.09 |
| 6 months | 21.27 ± 4.26 | 25.22 ± 5.30 | 0.005 |
| 9 months | 4.74 ± 0.96 | 9.29 ± 1.08 | <0.0001 |
| 12 months | 0.87 ± 0.17 | 1.48 ± 0.40 | <0.0001 |

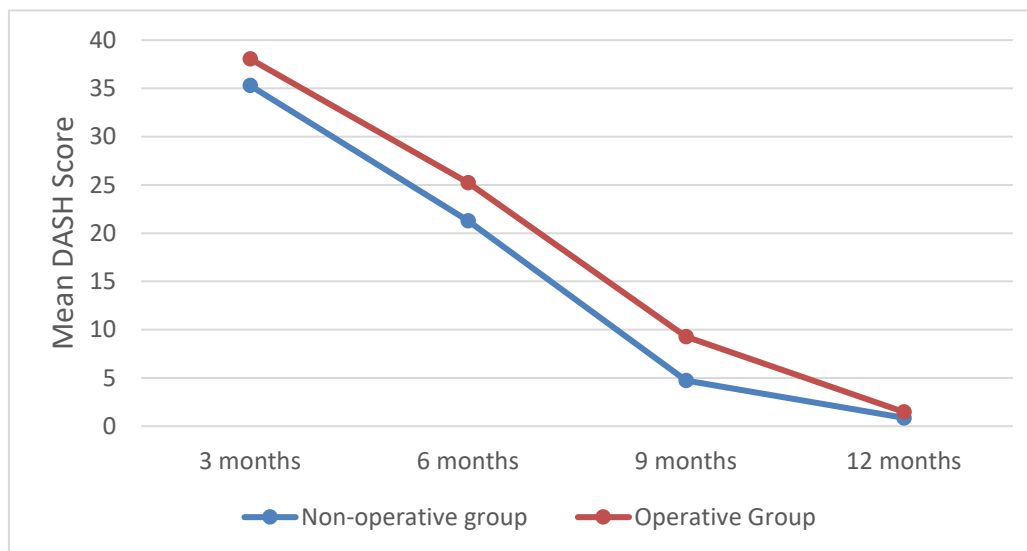


Figure 3: Comparison of DASH Score between Two Groups

Healing and union were faster in patients who were operated with locking compression plates as compared to non-operative group with statistically significant difference ($p < 0.05$). Frequency of non-union was only 4.55% in operative group as compared to 10.71% cases of non-union in non-operative group.

Functional outcomes were comparatively better in patients who received conservative management than the patients managed operatively with respect to UCLA and DASH score.

DISCUSSION

Historically, nonoperative treatment was the norm for acute clavicle fractures. For a considerable amount of time, conservative therapy was the primary therapeutic approach; however, more recent research has shown that non-union rates are greater. Furthermore, those receiving nonoperative treatment bear a heightened chance of experiencing clinical manifestations like pain, weakness, and fast fatigue linked to clavicle fracture non-union and malunion.¹⁷



It is still debatable how to treat misplaced mid-shaft clavicle fractures.¹⁸ The primary goals of the surgeon are higher patient satisfaction, early union and a favourable functional outcome, and excellent reduction with few problems. After reviewing the literature, both conservative and surgical management have been suggested. We have discovered from this research on mid-shaft fractures of the clavicle that patients who underwent surgical reduction with LCP had a much shorter average time for fracture union than those who received conservative treatment. There were comparatively better functional outcomes in patients receiving conservative management. It was discovered that the non-surgical group had a greater satisfaction rate than the operational group.

The non-operative method has been the standard of care for all mid-shaft clavicular fractures. A greater likelihood of non-union and malunion were observed in clavicle fractures with displacements more than 2 cm, especially in cases where the fractures involved comminution. Additionally, because of patient discontent and diminished abduction strength, they had lower functional scores.¹⁹

Recent research indicates that compared to conservative treatment, surgically repaired mid-shaft clavicle fractures healed more quickly.²⁰ Even though clavicle fracture surgery is becoming more and more common, new problems are being discovered that require surgery. Common side effects include implant discomfort, cosmetic dissatisfaction, and tingling at the incision site from supraclavicular nerve injury sustained during plating and scarring.^{21, 22} A appropriate patient should be chosen for surgery in order to minimize problems and minimize the patient's burden while avoiding needless surgical intervention and achieving the greatest results. For better immediate functional outcomes and a quicker return to activities, surgical intervention is indicated in a person who is active.⁵

When displaced mid-shaft clavicular fractures were treated with plate fixation instead of sling immobilization, the incidence of malunion and non-union was reduced. Implant-related problems are relatively common (9–64%), despite the modest rates of non-union and malunion following surgical treatments. According to these research, the most frequent second surgery was for removal of implant.²³⁻²⁵

Ban et al. conducted a systematic evaluation of clavicle fractures and discovered that fractures managed surgically had a better functional outcome. The conservative group experienced a greater complication rate (47%) than the surgically managed group (30%). In contrast, 60% of patients who had surgery experienced problems, compared to only 20% of patients who received conservative treatment.²⁴

The Cochrane Collaboration proposed options for therapy for mid-shaft clavicular fractures. These alternatives were determined individually for each patient, with careful

consideration given to the specific advantages and hazards of each intervention as well as the patient's choice.²⁶

Conservative therapy entails no needless soft tissue and periosteal stripping; radiological fusion takes longer, but clinical functionality returns more quickly than in cases requiring surgery. Malunion was a problem in 98% of patients treated conservatively, but it had no neurological complaints, or pressure sensations. Additionally, the initially huge hump was not significant cosmetically because it gradually shrank due to remodelling. Patients should be informed about the expected outcomes and the necessity of revision surgery, particularly for implant removal, whenever a surgical modality is being considered for care. Patients should be informed about non-union rates and the challenges associated with conservative management.²⁷

These findings show that there is no discernible functional difference between the two groups, despite the fact that the operative group's union time was shorter. Given that conservative treatment produces comparable functional outcomes to the operational group, improves patient satisfaction, and avoids needless intervention especially in poor nations where cost is a concern, it may be preferable to surgical procedures. If appropriate bracing and tight immobilization are maintained, even fractures with displacements higher than 2 cm will fuse correctly.

Our study's limited sample size and short follow-up period were its main drawbacks.

CONCLUSION

Our study's findings indicate that while the two approaches were similar in terms of problems, the surgical technique of treatment resulted in noticeably faster healing; therefore, surgical management with locking compression plate is the better option, but patient-specific care should still be implemented. Better functional results and higher patient satisfaction are associated with conservative management. There should be trial and research aimed at improving functional outcome after surgery with locking compression plate in clavicular fracture.

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