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Original Research Article

Prospective Evaluation of Surgical Management of Clavicle Fractures Using Anatomically Precontoured Locking Plates

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Abstract:

Background: Midclavicular fractures, especially midshaft fractures, are common injuries that affect functional use of the shoulder and anatomical plates and screws offer stable fixation and early mobilization, which may improve the outcome compared to conservative management.

Aim: To prospectively evaluate the outcomes, both functional and radiological, of surgically managed displaced mid-third clavicle fractures with anatomically precontoured locking plates.

Method: A prospective observational study involving 40 adult patients (between 18–60 years) that had displaced midshaft clavicle fractures were undertaken at Nalanda Medical College, Patna. The patients were surgically treated with open reduction and internal fixation with anatomically precontoured locking plates and were followed up until 6 months post-operatively. Functional recovery was evaluated using the Constant-Murley Score; and radiological union (maximum angles) were assessed on plain X-rays taken post-operatively.

Results: Most patients were young adults, aged 18–30 years (30%) and primarily sustained fractures due to road traffic accidents (65%). The right side was more commonly involved (60%); and for functional outcome, 28 patients (70%) were evaluated with excellent results, 8 patients (20%) had good results, whereas 4 patients (10%) were evaluated with fair recovery; there were no poor outcomes. All radiological unions were achieved without major complications.

Conclusion: Anatomically precontoured locking plates for fractures of the midshaft of the clavicle provided excellent fixation, successful early mobilization and sufficient functional recovery, which indicated an effective and reliable management modality.

Keywords: Clavicle Fracture, Midshaft Fracture, Precontoured Locking Plate, Open Reduction Internal Fixation, Functional Outcome.

Introduction

"The clavicle, characterized as a slender S-shaped bone, is integral to the biomechanics and structural stability of the shoulder girdle. It functions as a supportive strut connecting the sternum to the glenohumeral joint, facilitating an essential suspensory role that ensures proper alignment and mobility of the upper limb [1]. The relationship between the shoulder girdle and clavicle is largely maintained by the coracoacromial ligament, demonstrating its importance for upper extremity function and stability. The clavicle also provides the only bony linkage between the thorax and upper limb, establishing an important role in providing shoulder movement and mechanical forces during activities. Thus, any impairment to the structural integrity of the clavicle, such as a fracture, can significantly impact shoulder function and upper extremity biomechanics [2]. Clavicular fractures are very common injuries, generally because the bone is subcutaneous and so is vulnerable to trauma caused by both low-energy mechanisms such as falls, as well as high-energy mechanisms including road traffic accidents and sport injuries. Approximately 5% to 10% of fractures of the body will involve a clavicular fracture and shoulder girdle injuries will include up to 44% clavicular fractures. The mid-clavicle is the most common area and together involving approximately 70% to 80% of clavicular fractures, commonly followed by fracture of the lateral-third (12% to 15%) and medial-third (5% to 8%) [3].

The predominant system employed for the classification of clavicle fractures is Allman's classification, which divides these fractures into three distinct groups: Group I encompasses fractures occurring in the middle third, Group II comprises fractures

located in the lateral third, and Group III pertains to fractures situated in the medial third. Traditionally, clavicle fractures have been treated conservatively through non-operative treatment approaches, including the use of slings, figure-of-eight bandages, or other forms of immobilization [4]. Although several techniques for closed reduction have been documented, sustaining the reduction in adult patients has proven to be difficult due to the anatomical and biomechanical characteristics associated with the clavicle. This challenge frequently results in a certain level of residual deformity and functional limitations when treated non-operatively, particularly in adult populations [5].

Midshaft clavicle fractures are particularly common because the middle third of the clavicle is a site of biomechanical weakness. At this site, the bone's cross-sectional width is at its minimum, and the surrounding soft tissue sleeve, which would normally act to absorb and distribute external stresses, is relatively thin. In addition, a number of muscular and ligamentous attachments pull on the clavicle to provide counteracting stresses. For example, the sternocleidomastoid muscle generates an upward moment on the medial fragment while the weight of the arm and the action of the pectoralis major generate a downward and medial displacement of the lateral fragment. Understanding biomechanical stress is important in terms of predicting both the direction of displacement and possible complications that may arise if the fracture is unreduced or inadequately stabilized [6].

Epidemiologic research finds that mid-clavicular fractures constitute about 3% to 5% of the total skeletal trauma and cause almost 45% of the shoulder girdle-associated injuries. The annual incidence rate is about 64 per 100,000 population. Midshaft fractures are the cause of 70% to 80% of the total clavicular fractures, while 15% to 30% are fractures of the lateral third, with medial-third fractures being exceptional, occurring in only about 3% of the cases. Open clavicle fractures are rarely encountered, representing only 0.1% to 1% of the cases. These types of traumas are more prevalent in males in comparison with females, with the highest incidence being reported in persons in their third decade of life, when the physical activity is at its highest and the susceptibility to trauma is greatest among adults."

In the past, clavicle fractures were considered insignificant injuries with an excellent prognosis in the absence of surgical intervention. However, current research challenges this long-held mindset. Earlier beliefs minimized the magnitude of pain and functional distress experienced during the initial phase of nonsurgical care and incorrectly assumed that the occurrence of nonunion was rare. Today, it is recognized that there are certain subgroups of patients, particularly with displaced or comminuted fractures, who are at significant risk for complications like nonunion, malunion, and recurrent shoulder dysfunction. Beyond this, displaced fragments may impinge upon neurovascular structures, particularly the retro clavicular portion of the brachial plexus, with ensuing neurologic symptoms if appropriately controlled. Studies have demonstrated high incidences of nonunion and functional deficits with conservative management in such situations, emphasizing the place of custom-tailored evaluation and therapeutic approaches [7].

Nonunion, although quite rare, is presently known to happen more often than initially documented and can seriously affect a patient's quality of life. A number of factors are responsible for this complication. Intrinsically, they are patient age advancing, female sex, and deficient bone stock. Extrinsic factors are severity, grade, and fracture shape. Therefore, surgical treatment is increasingly deemed acceptable, particularly in fractures appreciably displaced, comminuted, or shortened.

Several surgical methods are utilized for the management of midshaft clavicular fractures, such as intramedullary fixation (e.g., Steinmann pins or K-wires), and plate osteosynthesis. Plate fixation is the most favored among the aforementioned methods, as it provides stable fixation and facilitates anatomical reduction, a feature very valuable in displaced or comminuted fractures. It permits early movement, obtains correct alignment, and avoids malunion or nonunion.

Anatomically precontoured locking plates have been a notable improvement over historic plate methods in the past few years. Anatomically precontoured plates are contoured to match the inherent curve of the clavicle themselves, thereby decreasing the necessity for contouring in the operating room and soft tissue disruption. Angular stability is offered through a locking system, thereby rendering them very useful in difficult situations such as osteoporotic bone or complicated fracture patterns. Clinical studies indicate that functional recovery is superior, recovery is rapid, and complications are fewer in the case of locking plates compared to standard plates. A prospective evaluation of surgical management for acute displaced mid-third clavicle fractures utilizing anatomically precontoured locking plates in both functional and radiological outcomes is proposed in the present study. Through a systematic evaluation of the outcome and potential complications, the present study provides insightful evidence on the safety and efficacy of such a therapeutic regimen. Such evidence shall lead towards the implementation of standardized management procedures, ultimately optimizing patient care as well as ensuring optimal functional recovery in the long-term aftermath of clavicular fracture.

Methodology

Study Design: This study was a prospective observational trial aimed at assessing functional and radiological outcomes after surgical treatment of mid third diaphyseal clavicle fractures using anatomically precontoured locking plates.

Study Area: The study took place in the Department of Orthopedics at Nalanda Medical College and Hospital, Patna, Bihar, India.

Study Duration: The total time frame of the study was one year, which included patient recruitment, surgical intervention, and at least six months of postoperative follow-up.

Sample Size: The study had 40 patients in total. The sample size was calculated according to the hospital data for displaced mid-third diaphyseal clavicle fractures in patients aged 18 years and older. The initial sample size calculation was conducted in a convenience sample procedure, where the minimum sample size used was estimated to be 25, determined at a 95% confidence interval, an alpha error of 5%, and an expected prevalence of 2–5%. To enhance the reliability and robustness of the results, the sample size was increased to 40 patients.

Study Population: The study population consisted of adult patients (>18 years) with displaced mid-third diaphyseal clavicle fractures admitted to the orthopedic department during the study period and treated surgically with open reduction and internal fixation using anatomically precontoured locking plates.

Inclusion Criteria

Patients were included in the study if they met the following criteria:

- Age 18–60 years.
- Acute, closed fractures of the mid-third diaphyseal clavicle (Allman Type 1).
- Displaced fractures require surgical intervention.
- Patients who were willing to participate and provided written informed consent.

Exclusion Criteria

Patients were excluded if they had:

- Age <18 years.
- Open clavicle fractures.
- Fractures located in the proximal or distal third of the clavicle.
- Pathological fractures.
- Undisplaced fractures managed conservatively.
- Associated head injury or neurovascular injury.
- Established non-union from a previous fracture.

Data Collection: Demographic and baseline information such as the name of the patient, age, sex, occupation, and address were elicited at the time of hospital admission. A detailed clinical history was elicited with special reference to the mechanism of injury, that is, road traffic accidents, falls onto the shoulder, falls from motorbikes, indirect trauma to the shoulder, or falls onto an outstretched hand. Each patient was carefully examined physically, that is, examination of the fracture site for the presence of tenderness, swelling, crepitus, and abnormal mobility. The neurovascular status distally of the limb was carefully assessed, and associated injury was observed.

Radiological evaluation consisted of two plain anteroposterior (AP) view radiographs of the clavicle and shoulder to determine the type and location of the fracture. The fractures were categorized based on Robinson's classification. Preoperative laboratory investigations were hemoglobin level, total and differential leukocyte counts, ESR, blood glucose, blood urea, serum creatinine and ECG. The routine screening for infectious diseases was HBsAg and HIV to protect the surgical team and patient.

Procedure

After the overall condition of the patient was stabilized and was medically cleared for surgery, a surgical intervention plan was initiated. All patients underwent open reduction and internal fixation (ORIF) utilizing anatomically precontoured locking plates. The patients underwent regional anesthesia via a brachial plexus block, which provided effective intraoperative anesthesia and postoperative analgesia. Following appropriate exposure of the fracture, the clavicle was restored anatomically, and fixation was achieved with the locking plate. This technique enables stable fixation, restores the anatomical integrity of the clavicle, and supports early postoperative mobilization facilitating improved functional recovery.

Postoperatively, the patients were immobilized with a sling, and standard rehabilitation protocol was followed. Sutures were removed 10-14 days after surgery after checking the status of the wound. The patients were mobilized stepwise with gradual active exercises across the shoulder in order to gain recovery of function and strength. Follow-up was done at two weeks, six weeks, three months, and six months after surgery. During each follow-up review, local examination of the clavicle was done in order to assess tenderness, deformity, instability, and range of movement across the shoulder. Progression towards fractured union was assessed with the assistance of radiographers.

Outcome Assessment: The main outcome measure was the functional recovery of the injured shoulder, assessed with the Constant-Murley Score (CMS) at the end of six months. The score comprised both the subjective parameters like pain and function in daily activities and the objective parameters like the range of movement and muscular strength. Depending

upon the total score, the outcome was graded as excellent (90–100 points), good (80–89 points), fair (70–79 points), and poor (<70 points). The other secondary measures were the time taken for the radiological union, which was the presence of bridging calluses over at least three out of four cortices, and the detection of any postoperative complication, like non-union, malunion, hardware irritation, infection, or neurovascular compromise.

Statistical Analysis: All the data gathered were entered in Microsoft Excel 2007 and statistically analyzed using SPSS version 15.0 (SPSS Inc., Chicago, Illinois, USA). The continuous variables were presented as mean ± standard deviation (SD), whereas the categorical variables were presented as frequency and percentages. The Chi-square test was applied in comparing categorical variables, while the continuous variables were compared using paired t-test or ANOVA as the case may be. A p-value of <0.05 was considered significant, and the confidence limit was at the 95% level. The ultimate analysis was based on correlating the surgical outcomes, functional recovery, as well as complication rate in order to assess the effectiveness of using anatomically precontoured locking plates in the management of displaced mid-third clavicle fractures.

Result

Table 1 shows the demographic profile of the 40 patients included in the study. The majority of patients were in the 18–30 years age group (30%), followed by 31–40 years (25%), 41–50 years (20%), 51–60 years (15%), and those above 60 years (10%). The right clavicle was involved in 24 cases (60%), while the left clavicle was involved in 16 cases (40%). Regarding the mode of injury, road traffic accidents (RTA) were the most common cause, accounting for 26 cases (65%), followed by falls from height in 8 cases (20%), sports injuries in 4 cases (10%), and other causes in 2 cases (5%). This indicates that younger, active individuals are more prone to clavicle fractures, predominantly due to high-energy trauma such as RTAs.

Table 1: Demographic Profile of Patients (n = 40)

Parameter	Category	No. of Cases
Age Group (Years)	18 – 30	12
	31 – 40	10
	41 – 50	8
	51 – 60	6
	> 60	4
Side Involved	Right	24
	Left	16
Mode of Injury	Road Traffic Accident (RTA)	26
	Fall from Height	8
	Sports Injury	4
	Others	2

Table 2 represents the functional outcomes of patients treated with anatomically precontoured locking plates for clavicle fractures. Out of the 40 patients, the majority, 28 patients (70%), achieved an excellent functional outcome, while 8 patients (20%) had a good outcome. A smaller proportion, 4 patients (10%), showed a fair outcome, and no patients (0%) had a poor result. These findings suggest that surgical fixation with anatomically precontoured locking plates provides favorable results, with 90% of patients (excellent + good) achieving satisfactory functional recovery.

Table 2: Functional Outcome of the Study (n = 40)

S. No.	Functional Outcome	No. of Cases
1	Poor	0
2	Fair	4
3	Good	8
4	Excellent	28
Total	-	**40**

Discussion

Clavicle fracture is a common injury, with mid-third diaphyseal fracture being the cause of over 80% of the incidents. Traditionally, the fracture was often managed conservatively with an arm sling or figure-of-eight bandage. Although arm slings provided better satisfaction with the patients in terms of comfort and convenience, figure-of-eight bandages brought with them the complication of axillary pressure sores and neurovascular compression (Society of Orthopaedic Trauma, 2007) [9]. The majority of the patients in the present study were young adults, with 55% being under the age of 40, highlighting the

experience that this sort of injury involves predominantly the active population and agrees with the work of Robinson et al. (2004) [10], who reported similar high incidence among the younger, active population."

In terms of laterality of fracture, 60% of our cases occurred in the right clavicle. The slight prevalence of the right can be accounted for by the general population's greater prevalence of being right-handed, raising the risk of being injured on that side in falls or road traffic accidents (Hill et al., 1997) [11]. Road traffic accidents made up the most common mechanism of fracture in our series, responsible in 65% of cases, followed by falls from height (20%) and sport (10%). These findings are consistent with an urban based trauma study, where high energy mechanisms, such as RTA, were the main causal factor in the prevalence of clavicle fracture (Toogood et al., 2011) [12].

The evolution from conservative to surgical management, particularly since the development of anatomically precontoured locking plates (LCP), values for displaced midshaft clavicle fractures has improved our patients' outcomes. Traditional non-operative management has long been associated with high rates of nonunion. Neer (1960) [13] was the first to publish rates of 1%. However, recent literature suggests much higher rates of 4.5 - 9% (Robinson et al, 2004) [10], and as high as 15% (Hill et al, 1997) [11] in displaced fractures. Plate osteosynthesis, on the other hand, confers rigid stabilization, prompt pain relief, and early movement, and is associated with better functional recovery and lower malunion/nonunion rates. The present study verifies this, with excellent results in 70%, with the remaining 20% having good results, with only 10% having fair results. Importantly, no patients had poor results, reflecting an excellent rate of success with precontoured LCP fixation. Our findings are similar to the series reported by Mohammed et al., with a mean Constant score of 95.33 (3.4 SD) at one-year follow-up after plate fixation, that reported by Dhoju et al. with a mean Constant score of 97.45. The mean Constant score in the current study was marginally lower at 93.31% (6.72 SD) but remained in the excellent category. The slight variation may be due to differences in the population under study, patterns of fracture, or the timing of post-op rehabilitation. The high mean scores in all the series reflect the advantage of rigid fixation in restoring pre-injury function.

In surgical techniques comparison, superior plating is said to provide superior biomechanical stability compared to anterior plating, particularly with inferior cortical comminution. However, this is at the expense of the added danger of neurovascular injury and hardware prominence that may mandate plate removal (Toogood et al., 2011) [12]. No plate was removed during the early phase in any of the patients in this series, nor any significant neurovascular complications arose, so with due surgical care and appropriate selection of the patient, the danger may be mitigated.

Our analysis also reflects tendencies that are observed in similar prospective comparisons. For example, in one multicenter study published by the Society of Orthopaedic Trauma in 2007 [9], plate fixation was contrasted with nonoperative management and was found to be linked with better functional outcomes and more rapid return to pre-injury function. Similarly, Robinson et al. (2004) [10] concluded that displaced fractures in mobile adults yield significant advantages with operative fixation, similar to the population characteristics of our study wherein the overwhelming majority of the patients were active and relatively young.

In terms of limitations, although the functional results were excellent, long-term follow-up after more than one year would be beneficial in offering more information regarding late complications like implant-related irritation, refracture, or post-traumatic osteoarthritis. Prospective comparison of the results of precontoured locking plates with other forms of fixation like intramedullary nails would be useful in the future in order to find the best surgical strategy in various patterns of fracture.

Overall, the present study is consistent with the growing evidence that anatomically precontoured locking plate fixation is the most efficient in the treatment of displaced midshaft clavicle fractures. The majority of the patients had excellent or good function with an average Constant function score of 93.31%. The findings of the current study agree with the previous evidence, substantiating the benefit of surgical stabilization in young active adults, particularly in high-impact trauma cases, and highlighting that stringent surgical technique may decrease plate fixation-related complication.

Conclusion

The study on the surgical management of clavicle fractures using anatomically precontoured locking plates demonstrated favorable outcomes across the patient cohort. The procedure proved to be effective in providing stable fixation, facilitating early mobilization, and promoting fracture union without major complications. Most patients achieved excellent to good functional recovery, indicating that this method supports restoration of shoulder function and overall limb mobility. The approach was applicable across a wide age range and for various mechanisms of injury, including high-energy trauma, falls, and sports-related incidents, highlighting its versatility in clinical practice. Additionally, the absence of poor outcomes underscores the reliability and safety of anatomically precontoured locking plates in managing clavicle fractures. Overall, the study suggests that this surgical technique offers a

predictable and efficient solution for achieving optimal functional and anatomical results in patients with clavicular injuries.

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