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Original Research Article

Assessing Functional Outcome and Complications Associated with open Reduction and Internal Fixation using a Platefor Displaced Midshaft Clavicle Fractures

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Abstract:

Aim: The purpose of the present study was to evaluate functional outcomes and complications associated with open reduction and internal fixation (ORIF) with plates for displaced midshaft clavicle fractures.

Material & Methods: A retrospective study was conducted using a hospital database to analyse patients who underwent open reduction and internal fixation with a plate for displaced mid-shaft clavicle fractures. The study was conducted at the Department of Orthopaedics. The study period ranged from October 2019 to September 2021. A total of 50 patients who presented with midshaft fracture of the clavicle underwent surgical intervention using open reduction and plate fixation.

Results: Among the individuals surveyed, a majority of 84% (n=42) were identified as male, while the remaining 16% were identified as female. The average age of the patient population was 36 years, with a range of 18 to 65 years and a standard deviation of 12.96. The most prevalent cause of damage, accounting for 72% of cases, was high energy trauma. The common cause of low energy trauma in a group of patients was a domestic fall on the shoulder. Based on the Robinson categorization, it was seen that 42% of the fractures fell under the category of type 2B1, while the remaining 58% were classified as type 2B2. The plate that was most frequently utilized was the 3.5 mm pre-contoured locking plate, accounting for 40% of cases. This was followed by the 3.5 mm reconstruction plate, which was used in 38% of cases, and the 3.5 mm dynamic compression plate, which was used in 22% of cases. All patients who had open reduction and plate fixation achieved fracture union with a success rate of 100%. The average time for fracture union was 7.3 weeks, with a range of 6 to 20 weeks and a standard deviation of 3.32. Three patients, including 6% of the sample, experienced mechanical failure of the implant in the form of plate breaking around two months after the surgical procedure. Twenty percent of the patients experienced symptoms associated to hardware, such as plate discomfort and plate prominence. All of the patients included in the study underwent implant removal within a time frame ranging from 12 to 18 months following the first surgical procedure. During the perioperative phase, two patients experienced a superficial infection, accounting for 4% of the total cases. These infections were managed by administering antibiotics specific to the causative organisms and using daily dressings. A reoperation rate of 30% was documented.

Conclusion: The utilization of open reduction and internal fixation as a treatment method for displaced, midshaft clavicle fractures has demonstrated notable success in terms of achieving union, satisfying patients, and enhancing functional outcomes. The most frequent reason for reoperation continues to be the removal of hardware due to symptoms.

Keywords: Clavicle fracture, Mid-shaft, Plate fixation, Functional outcome, Union, Reoperations, Complications

Introduction

The clavicle is a bone that is commonly subject to fractures. [1] The mid-shaft fracture of the clavicle is the most prevalent type, accounting for approximately 80% of all clavicular fractures. This particular fracture occurs at the thinnest region of the bone, which lacks any muscle or ligamentous connections. [2,3] Clavicle fractures constitute around 2.6% of all fractures and account for 44% to 66% of fractures involving the shoulder. Middle third fractures constitute around 80% of all clavicle fractures, while fractures occurring in the lateral and medial thirds of the clavicle account for approximately 15% and 5% respectively. Approximately 70 to 80% of these fractures occur in the middle third of the bone, where the application of typical compressive pressures to the shoulder, combined with the thin cross section of the bone, leads to bony failure. Fractures of the shaft are most frequently observed in individuals within the early adult age group. [4]

The occurrence of midshaft clavicle fractures is prevalent among adults below the age of 50, making it one of the most frequently observed injuries in the vicinity of the shoulder girdle. Displaced fractures have been managed by both conservative and surgical approaches. [4,5] Historically, conservative methods such as the use of arm slings, clavicular braces, or figure of eight bandages have been employed for the care of mid-shaft clavicular fractures. However, these approaches have yielded suboptimal results, characterized by non-union and symptomatic malunion. Consequently, there has been a shift towards the adoption of operational interventions. [6]

There is a growing preference among surgeons to perform surgical procedures due to the perceived clinical and functional limitations of nonoperative interventions. Multiple research projects have conducted an analysis on the safety and effectiveness of primary open reduction and internal fixation in treating fully displaced mid-shaft clavicular fractures. These studies have seen a significant rate of successful bone union, along with a minimal occurrence of complications. [7] There are several modalities of fixations that can be utilized, such as elastic stable intra-medullary nailing, intramedullary K-wires, and plate fixation. [2] The utilization of intramedullary fixing has been found to be a comparatively less intrusive surgical procedure, resulting in reduced blood loss and shorter hospitalization periods. There are several drawbacks associated with this procedure, including malrotation, overriding of pieces, discomfort at the entry site, implant migration, and the requirement for implant removal. Plate osteosynthesis fixation is considered to be a comparatively more stable surgical treatment, exhibiting reduced likelihood of malrotation and overriding. However, it is important to acknowledge several drawbacks associated with this technique, such as the potential for a larger scar, prominence of the plate which may result in skin necrosis, and an increased risk of infection. [8]

Therefore, the purpose of this investigation was to examine the outcomes of clavicle fractures treated with plate osteosynthesis and intramedullary fixation. Specifically, the study aimed to evaluate the time required for consolidated union, pain scores, comorbidities associated with each treatment approach, and functional outcomes.

Material & Methods

A retrospective study was conducted using a hospital database to analyze patients who underwent open reduction and internal fixation with a plate for displaced mid-shaft clavicle fractures. The study was conducted at the Department of Orthopaedics, Indira Gandhi Institute of Medical Sciences, located in Patna, Bihar, India. The study period spanned from October 2019 to September 2021. A total of 50 patients who presented with midshaft fracture of the clavicle underwent surgical intervention using open reduction and plate fixation.

Inclusion Criteria:

- Patients with acute, displaced mid-shaft clavicle fractures with significant shortening (>2cm) or displacement (>100% width of clavicle) or Z-type fracture pattern or significant comminution; impending skin compromise;
- Age greater than 18 years and less than 65 years;
- A minimum of 12 months of follow-up after index surgery.

Exclusion Criteria:

An open fracture; non-midshaft fracture; pathological fracture; surgical treatment other than plate fixation; delayed union and non-union; associated vascular and neurological injury.

Methodology

Between October 2019 and September 2021 a total of 50 patients diagnosed with clavicle fractures had surgical intervention at our institution. Among these patients, seventy-five individuals presented with midshaft clavicle fractures and were managed using various methods of fracture fixation. A total of 50 patients who met the inclusion criteria and underwent open reduction and plate fixation were chosen as the study population.

The researchers analyzed the medical records, treatment charts, and radiographs of the chosen patients in order to identify their demographic information, the mechanism of damage, the classification of the fracture, the selection of the

implant, any intraoperative problems, and any subsequent reoperations. All the patients who were chosen for the study were contacted via telephone and asked to come to the outpatient department (OPD) for the purpose of evaluating their pain levels (measured using the Visual Analog Scale or VAS), their satisfaction with the cosmetic outcome of the treatment (also measured using VAS), their overall satisfaction with the treatment (measured using a 3-point Likert scale), their functional outcome (measured using the Disabilities of the Arm, Shoulder, and Hand or DASH Score), and their satisfaction with the cosmetic appearance of their shoulder (measured using VAS). All thirty patients presented themselves at the outpatient department (OPD) for the purpose of undergoing a final evaluation of the patient-oriented functional outcome measures.

The aim of operative treatment was to achieve stable fixation of both the fragments, restore the length and curvature of the clavicle to allow early mobilisation of shoulder. Patients underwent surgery within two weeks of injury after pre-anaesthetic evaluation. Prophylactic antibiotics were given before incision. Under general anaesthesia, patient was given a beach chair semi-sitting position. A curvilinear incision was made over the clavicle to expose the fracture. The fracture was reduced and fixed with plate placed on superior surface, with the goal being minimum of three screws in the main proximal and distal fragments. Oblique fractures were fixed with a lag screw and neutralisation plate. In transverse fracture, axial compression was achieved while in comminuted fractures, bridge plate technique was used. Deltopectoral fascia was closed as distinct layer, followed by skin closure. A collar cuff sling was given for two weeks. Stitches were removed on 14th postoperative day.

Outcome Measures

The primary outcome measure was union. The secondary outcome measures were functional outcome (DASH), patient satisfaction with treatment and cosmetic appearance, complications and reoperations. Fracture union was defined as complete cortical bridging between proximal and distal fragments on radiological evaluation. Fracture non-union was defined as absence of complete osseous bridging between the fragments on radiograph after ≥ 6 months of operative treatment. Thirty points DASH score (Disability of Arm Shoulder and Hand Score) was used to assess the functional evaluation of patients. DASH is a 30 item; self-report questionnaire designed to help describe the disability experienced by people with upper limb disorders. The care was taken that the patients has answered at least 27 questions of DASH questionnaire. Pain was scored by the patient on visual analogue scale (VAS) from 0 (no pain) to 10 (extreme pain). Satisfaction with cosmetic appearance of incision and shoulder was rated on 10 point VAS Scale where higher score indicates high rate of satisfaction. Overall satisfaction with treatment was recorded on 3-point Likert Scale as unsatisfied, partially satisfied and fully satisfied.

Statistical Analysis

Data analysis was done by using statistical software SPSS, version 16. Student's t test for two samples assuming unequal variance was used to compare functional outcome of patients with and without complication. The test was two sided. The results were considered significant at $p < 0.05$.

Results

Table 1: Demographic characters

Parameters	N	%
Gender		
Male	42	84
Female	8	16
Age (years)		
<30	19	38
31-50	24	48
>50	7	14
Mechanism		
High energy trauma	36	72
Low energy trauma	14	28
Robinson classification		
2B1	21	42
2B2	29	58

Out of them, 84% (n=42) were male and 16% were female. Mean age of the patient was 36 years (range 18-65 years; SD 12.96). High energy trauma was the commonest (72%) cause of injury. Domestic fall on shoulder was the common cause in low energy trauma group of patients. According to Robinson classification, 42% of fractures were type 2B1 and 58% were type 2B2.

Table 2: Type of plate used for internal fixation

Type of plate	N	%
3.5 mm reconstruction	19	38
3.5 mm Dynamic Compression Plate	11	22
3.5mm Pre-contoured Locking Plate	20	40

The most commonly used plate was 3.5 mm pre-contoured locking plate (40%) followed by 3.5 mm reconstruction plate (38%) and 3.5 mm dynamic compression plate (22%).

Table 3: Outcomes and complications

Outcomes	N	%
Union of fracture	50	100
Complications		
Implant failure	3	6
Reoperation	15	30
Symptomatic hardware	10	20
Superficial infection	2	4

All patients treated with open reduction and plate fixation had fracture union (100%) at an average time of 7.3 weeks (range 6-20 weeks; SD 3.32). 3 patients (6%) had mechanical failure of implant in the form of plate breakage at about 2 months of operation. Twenty percent patients had hardware related symptoms like plate irritation and plate prominence. All these patients had implant removal between 12 to 18 months of index surgery. 2 patients had superficial infection (4%) during perioperative period which was treated with organism specific antibiotics and daily dressings. Reoperation rate of 30% was documented.

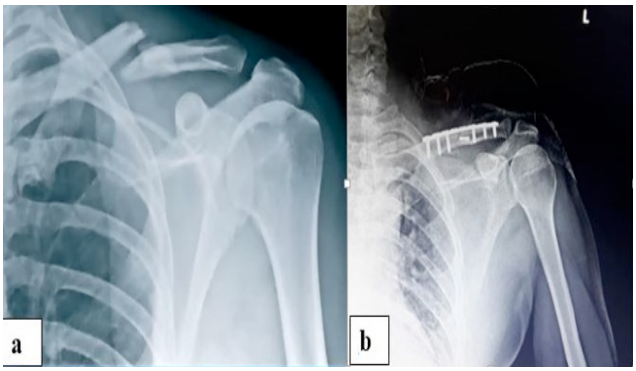

Figure 1: a: X-ray showing fracture left clavicle with displacement; b: Immediate post-op x ray showing reduction and internal fixation with plate.

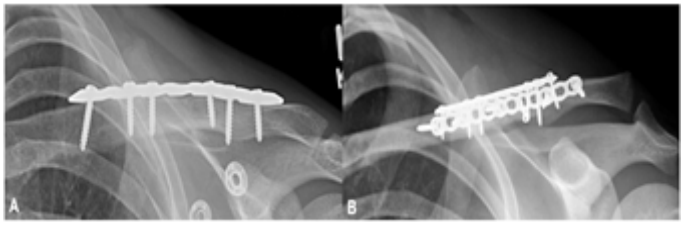

Figure 2: Post-operative radiographs demonstrating: A) superiorly placed 3.5 mm pre-contoured plate fixation for displaced mid-shaft clavicle fractures and; B) dual plate technique with a 2.4-mm LCP superior plate and 2.7-mm reconstruction anterior plate.

Discussion

The clavicle is a discernible, superficial, horizontally-oriented osseous structure that serves to link the upper limb with the axial skeleton. Fractures of the clavicle are frequently observed, including roughly 5 to 10% of all fractures in adults and up to 40% of injuries in the vicinity of the shoulder girdle. [9-12] Approximately 70 to 80% of these fractures occur in the middle third of the bone, where the application of typical compressive pressures to the shoulder, along with the bone's thin cross section, leads to bony failure. Fractures of the shaft are predominantly observed in the demographic of young adults. [13] Historically, displaced midshaft clavicle fractures have been managed by conservative approaches involving closed manipulation and immobilization

techniques. This treatment modality has been associated with a favourable likelihood of fracture union, positive functional outcomes, and a high degree of patient satisfaction. [14,15]

Among the participants, a majority of 84% (n=42) were identified as male, while the remaining 16% were identified as female. The average age of the patient population was 36 years, with a range of 18 to 65 years. Previous research has consistently demonstrated that clavicular fractures are more prevalent among males as a result of high-energy trauma. [16-18] The most prevalent cause of damage, accounting for 72% of cases, was high energy trauma. The common cause of low energy trauma in a group of patients was a domestic fall on the shoulder. Based on the Robinson categorization, it was seen that 42% of the fractures fell under the category of type 2B1, while the remaining 58% were classified as type 2B2. The Robinson 2B1 mid shaft clavicular fracture demonstrated the highest prevalence in our sample, consistent with findings from earlier investigations. [16,17] The plate that was most frequently utilized in this study was the 3.5 mm pre-contoured locking plate, accounting for 40% of cases. Following closely behind were the 3.5 mm reconstruction plate, which accounted for 38% of cases, and the 3.5 mm dynamic compression plate, which accounted for 22% of cases. All patients who underwent open reduction and plate fixation demonstrated complete fracture union, with a 100% success rate. The average time for fracture union was 7.3 weeks, with a range of 6 to 20 weeks and a standard deviation of 3.32. A total of three patients, accounting for 6% of the sample, experienced mechanical failure of the implant in the form of plate breaking about two months after the operation.

A total of 20% of the patients experienced symptoms associated to hardware, such as plate discomfort and plate prominence. All of the patients included in the study underwent implant removal within a timeframe ranging from 12 to 18 months following the first surgical procedure. During the perioperative period, two patients experienced a superficial infection, accounting for 4% of the total cases. These infections were managed by administering antibiotics that specifically targeted the organisms involved, in addition to daily dressings. A reoperation rate of 30% was documented. [19] In a randomized controlled trial (RCT) conducted by Robinson et al. (2020), the authors compared the efficacy of open reduction and plate fixation with nonoperative treatment for displaced midshaft clavicular fractures. The study findings revealed a non-union rate of 1.2% in the open reduction and plate fixation group, specifically one out of 86 patients. [20] In a randomized controlled trial conducted by Woltz et al. (2021) [21], it was observed that the primary plate fixation group exhibited a non-union rate of 2.4% (2 out of 86 cases). The Canadian Orthopaedic Trauma Society conducted a randomized controlled trial (RCT) to compare the outcomes of open reduction internal fixation (ORIF) and conservative treatment. The study revealed a reduced incidence of non-union (3%) and a shorter duration for bone union (16.4 weeks) in the ORIF group. The current investigation yielded findings that were comparable to, or in some cases even superior than, those reported in previous investigations. All patients had signs of union upon retrospective radiological assessment, with an average time to union of 7.9 weeks. In a retrospective study conducted by Leroux et al. assessed the rate and risk of reoperation in a cohort of 1350 patients who had undergone open reduction and internal fixation. The patients were followed up for a minimum of two years. The researchers documented a reoperation rate of 24.6%. The most prevalent reason for reoperation, constituting 18.8% of all reoperations, was the removal of an isolated implant. The researchers documented decreased occurrences of additional problems, including non-union (2.6%), deep infection (2.6%), pneumothorax (1.2%), and malunion (1.1%). [22] In a study conducted by Naimark et al. among cohort of 7826 patients was examined, revealing a hardware removal rate of 12.7%. [23] The reoperation rate observed in the current study is similar to that reported in the Leroux study [22], but notably greater than the rate reported in the Naimark trial. [23]

Conclusion

The utilization of open reduction and internal fixation as a treatment method for displaced, midshaft clavicle fractures has demonstrated notable success in terms of achieving union, satisfying patients, and enhancing functional outcomes. The most frequent reason for reoperation is the removal of hardware due to symptoms.

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