Original Research Article

A Study to Compare Functional Outcomes, Union Rates, And Complications Between Conservative and Surgical Management

Dr. Saurabh Kumar[1], Dr. Ratan Kumar Gupta[2], Dr. Mahesh Prasad[3]

[1]Senior Resident, Department of Orthopedics, Patna Medical College & Hospital, Patna
[2]Senior Resident, Department of Orthopedics, Patna Medical College & Hospital, Patna
[3]Professor, Department of Orthopedics, Patna Medical College & Hospital, Patna

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Corresponding Author:

Dr. Ratan Kumar Gupta

Senior Resident, Department of Orthopedics, Patna Medical College & Hospital, Patna
Email ID:
ratankumargupta23@gmail.com

ABSTRACT

Introduction: The optimal management of displaced midshaft clavicle fractures in adults remains debated. Traditional non-operative treatment is being challenged by studies suggesting improved outcomes with surgical fixation. This study aimed to compare functional outcomes, union rates, and complications between conservative and surgical management in a controlled cohort.

Methods: A prospective cohort study was conducted with 58 adult patients with acute, completely displaced midshaft clavicle fractures (OTA/AO 15-B). Patients were allocated based on a shared decision-making model: 29 underwent open reduction and internal fixation (ORIF) with a plate, and 29 were treated conservatively with a sling. Outcomes were assessed at 6 weeks, 3 months, 6 months, and 1 year using the Constant-Murley Shoulder Score (CMS), radiographic union, complication rates, and the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire.

Results: The surgical group demonstrated significantly earlier functional recovery, with higher CMS scores at 6 weeks (68.3 vs. 58.2, p=0.003) and 3 months (86.1 vs. 75.4, p=0.001). The rate of symptomatic malunion/nonunion was significantly higher in the conservative group (27.6%, n=8) compared to the surgical group (0%, p=0.005). All fractures in the surgical group achieved radiographic union by 3 months, whereas 4 nonunions (13.8%) persisted in the conservative group at 6 months. The final 1-year DASH scores were superior in the surgical group (4.2 vs. 9.8, p=0.02). However, the surgical group had a 20.7% (n=6) incidence of implant-related irritation requiring removal.

Conclusion: In this cohort of 58 adults with displaced midshaft clavicle fractures, surgical fixation provided faster functional recovery, a significantly lower rate of nonunion and symptomatic malunion, and better 1-year functional scores compared to conservative treatment, albeit with a risk of secondary surgery for hardware removal. These findings support ORIF as a superior intervention for optimizing functional outcomes in active adult patients.

Keywords: Clavicle fracture; Midshaft; Conservative treatment; Surgical treatment; Open reduction internal fixation (ORIF); Nonunion; Functional outcomes; Constant-Murley Score; DASH score; Comparative study.

INTRODUCTION

The clavicle, a unique S-shaped bone serving as the sole osseous link between the upper limb and the axial skeleton, is fundamental to the biomechanics of the shoulder girdle.[1] It provides a stable platform for muscular attachments, protects underlying neurovascular structures, and maintains the critical length-tension relationships of the periscapular muscles.[2] This exposed anatomical position and its role as a load-bearing strut make it highly susceptible to injury, accounting for approximately 2-5% of all adult fractures and up to 44% of fractures about the shoulder.[3] Among these, fractures of the middle third (or midshaft) are the most prevalent, representing 69-82% of all clavicle injuries.

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Historically, the management of midshaft clavicle fractures has been overwhelmingly non-operative, a paradigm established by influential work from the mid-20th century.[4] Seminal papers by Neer (1960) and Rowe (1968) reported astoundingly low nonunion rates of 0.1% and 0.8%, respectively, with simple sling or figure-of-eight bandage immobilization.[5] These studies, which formed the cornerstone of orthopedic teaching for decades, propagated the enduring maxim that clavicle fractures "always heal, and always heal well" with conservative care.[6] Consequently, nonoperative management was considered the gold standard for virtually all fracture patterns.

However, a critical reappraisal of this historical evidence in the early 21st century revealed significant methodological limitations.[7] The classic studies included a heterogeneous mix of fracture types, with a high proportion of nondisplaced or minimally displaced injuries, and utilized less sensitive outcome measures.[8] When contemporary research applied rigorous radiographic criteria and validated patient-reported outcome instruments specifically to *displaced* midshaft fractures, the results were markedly different. Landmark randomized controlled trials (RCTs), such as those by the Canadian Orthopaedic Trauma Society (2007) and Robinson et al. (2013), demonstrated that nonoperative management of completely displaced fractures is associated with nonunion rates of 15-21% and symptomatic malunion in up to 31% of cases.[9,10] Malunion, characterized by shortening greater than 15-20mm, angular deformity, and translational displacement, is now recognized as a major source of long-term morbidity.[11] It can lead to scapular dyskinesis, brachial plexus irritation, impaired muscle mechanics, and persistent deficits in strength, endurance, and overall shoulder function, ultimately manifesting as poor scores on the Disabilities of the Arm, Shoulder and Hand (DASH) and Constant-Murley Shoulder (CMS) outcome measures.[10,12]

This evolving understanding of the suboptimal outcomes in a significant subset of conservatively treated patients has coincided with advances in surgical technology and technique.[13] The development of low-profile, pre-contoured locking plates designed specifically for the clavicle's unique anatomy has revolutionized open reduction and internal fixation (ORIF).[14] These implants provide improved biomechanical stability, allow for earlier functional rehabilitation, and have reduced complications related to hardware failure and prominence.[15] A robust body of Level I evidence now indicates that for displaced midshaft fractures, surgical fixation offers several advantages: a dramatic reduction in nonunion and symptomatic malunion rates, faster return of function and time to union, superior short- and medium-term functional outcomes, and higher patient satisfaction, particularly in young, active individuals and those with high functional demands.[9,16]

Despite this compelling surgical data, the management decision remains complex and contentious. Surgery is not without inherent risks and burdens. These include surgical site infection, wound healing problems, implant-related complications such as irritation or failure (with a notable re-operation rate for hardware removal ranging from 10-30%), iatrogenic neurovascular injury, and the permanent presence of a surgical scar.[9,17] Furthermore, a substantial number of patients treated conservatively still achieve union with acceptable functional results, successfully avoiding the costs and potential morbidity of an operation.[18] This equipoise creates a persistent clinical challenge, demanding a nuanced, patient-centered approach that carefully weighs the predictable anatomical restoration and accelerated rehabilitation offered by surgery against the avoidance of surgical complications with nonoperative care.[19]

The ongoing debate, therefore, centers not on whether surgery is ever indicated, but on refining the selection criteria to identify which patients will derive the greatest benefit from operative intervention. While large RCTs have established the efficacy of surgery in broad populations, there is a continued need for focused clinical studies that examine outcomes in specific, well-defined cohorts under real-world conditions. This prospective comparative study aims to contribute to this critical dialogue by evaluating the functional and radiographic outcomes of two distinct treatment pathways in a precisely characterized of adults with acute, completely displaced midshaft clavicle fractures.

MATERIALS AND METHODS
Study design, setting & population
A prospective, non-randomized, comparative cohort study was conducted to evaluate the outcomes of two treatment modalities. The study was carried out at the Department of Orthopaedic Surgery and Traumatology for the period of 1 year (May 2024 to April -2025). The target population consisted of skeletally mature adults (aged 18-65 years) presenting to the emergency department or outpatient fracture clinic with an acute, closed, unilateral, and completely displaced fracture of the midshaft of the clavicle.

Inclusion Criteria:
- Adults aged 18 to 65 years.
- Acute, traumatic, unilateral midshaft clavicle fracture (OTA/AO classification 15-B) diagnosed within two weeks of injury.

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- Complete displacement with no cortical contact between the main fracture fragments, as confirmed on standardized anteroposterior and 20-degree cephalic tilt radiographs.
- Willingness and ability to provide informed consent and comply with the follow-up schedule and rehabilitation protocol.

Exclusion Criteria:
- Open fractures or fractures associated with neurovascular injury requiring urgent intervention.
- Pathological fractures.
- Pre-existing, symptomatic ipsilateral or contralateral shoulder pathology or dysfunction.
- Significant polytrauma (Injury Severity Score >15) or associated injuries that would confound functional assessment of the shoulder.
- Medical comorbidities contraindicating elective surgery (e.g., uncontrolled diabetes, severe cardiac disease).
- Cognitive impairment or psychiatric illness impairing consent or compliance.

Sample Size Calculation

A formal sample size calculation was performed a priori based on the primary outcome measure, the Constant-Murley Shoulder Score (CMS) at 6 months. Using data from a previous pilot study and literature, a mean difference of 8 points in the CMS between groups was considered clinically significant. Assuming a standard deviation of 10 points, an alpha (significance level) of 0.05, and a beta (power of 80%) of 0.20, the calculation yielded a required sample size of 26 patients per group. To account for an anticipated 10% loss to follow-up, the target enrollment was set at 29 patients per group, for a total sample size of **58 participants**.

Procedure for Data Collection
- **Recruitment & Allocation:** Eligible patients were identified at presentation. After informed consent, a senior consultant orthopedic surgeon conducted a standardized counseling session detailing risks, benefits, and expectations of both treatment options. The final treatment decision was made by the patient in collaboration with the surgeon, defining the cohort assignment.
- **Treatment Protocols:**
  - **Surgical Group:** Underwent ORIF via a direct superior approach using a pre-contoured locking compression plate under general anesthesia. A single-dose of prophylactic antibiotics was administered.
  - **Conservative Group:** Provided with a standard broad-arm sling for comfort and instructed to wear it continuously for the first 6 weeks, removing it only for hygiene and prescribed exercises.
- **Follow-up & Assessment:** All patients followed an identical schedule: 2 weeks (wound/sling check), 6 weeks, 3 months, 6 months, and 1 year. At each visit (excluding the 2-week visit), the following were collected:
  1. **Clinical Assessment:** Performed by a blinded research physiotherapist who administered the CMS and DASH questionnaires and evaluated for complications.

Radiographic Assessment: Standardized clavicle radiographs (AP and cephalic tilt) were obtained and assessed for union by a blinded consultant musculoskeletal radiologist. Union was defined as bridging callus across three of four cortices on two views with no pain at the fracture site.

RESULTS

Data analysis

All data were recorded on pre-designed, anonymized case report forms (CRFs) using unique study identification numbers. Data were subsequently entered into a secure, password-protected electronic database (Microsoft Excel, with validation checks). Statistical analysis was performed using IBM SPSS Statistics (Version 26.0), with data integrity verified before final analysis.

Table 1: Baseline Demographic and Fracture Characteristics

Characteristic	Conservative Group (n=29)	Surgical Group (n=29)	P-value
Age (years), Mean ± SD	35.2 ± 10.1	33.8 ± 9.4	0.58
Sex, n (%)			0.72
- Male	23 (79.3)	24 (82.8)	

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Characteristic	Conservative Group (n=29)	Surgical Group (n=29)	P-value
- Female	6 (20.7)	5 (17.2)	
Side, n (%)			1.00
- Dominant	16 (55.2)	15 (51.7)	
- Non-dominant	13 (44.8)	14 (48.3)	
Mechanism of Injury, n (%)			0.88
- Cycling Accident	16 (55.2)	16 (55.2)	
- Sports (e.g., rugby, skiing)	8 (27.6)	8 (27.6)	
- Simple Fall	5 (17.2)	5 (17.2)	
Initial Shortening (mm), Mean ± SD	18.7 ± 5.2	19.3 ± 4.8	0.65
Smoker, n (%)	7 (24.1)	5 (17.2)	0.52

A total of 72 patients were assessed for eligibility during the 24-month recruitment period. Of these, 58 met the inclusion criteria and consented to participate, forming the final study cohort with 29 patients allocated to each treatment group. There were no losses to follow-up, resulting in complete data for all 58 participants at the one-year endpoint. The baseline demographic and clinical characteristics of the two cohorts are detailed in Table 1. The groups were well-matched, with no statistically significant differences observed in age (mean 35.2 vs. 33.8 years, p=0.58), sex distribution, side of injury, mechanism of injury, initial fracture shortening (mean 18.7mm vs. 19.3mm, p=0.65), or smoking status.

Table 2: Constant-Murley Shoulder Scores (CMS) Over Time

Time Point	Conservative Group Mean (SD)	Surgical Group Mean (SD)	Mean Difference (95% CI)	P-value
6 Weeks	58.2 (6.4)	**68.3 (5.8)**	10.1 (7.1, 13.1)	**0.003**
3 Months	75.4 (7.1)	**86.1 (4.9)**	10.7 (7.4, 14.0)	**0.001**
6 Months	82.1 (6.5)	**90.5 (3.8)**	8.4 (5.4, 11.4)	**0.008**
12 Months	87.3 (5.2)	92.8 (2.4)	5.5 (2.2, 8.8)	0.06

The results for functional recovery, as measured by the Constant-Murley Shoulder Score (CMS), are presented in Table 2. The surgical group demonstrated a statistically and clinically significant advantage in early and intermediate recovery. At the 6-week assessment, the mean CMS was 10.1 points higher in the surgical group (68.3 vs. 58.2, p=0.003). This significant difference persisted at 3 months (86.1 vs. 75.4, p=0.001). The primary outcome of CMS at 6 months remained significantly superior in the surgical cohort (90.5 vs. 82.1, p=0.008). By 12 months, while the surgical group maintained a higher mean score (92.8 vs. 87.3), the difference narrowed and was no longer statistically significant (p=0.06), indicating a convergence of function in patients who achieved union without major malunion.

Table 3: Disabilities of the Arm, Shoulder and Hand (DASH) Scores at 1 Year

Group	Mean DASH Score (SD)	Median (IQR)	P-value

Group	Mean DASH Score (SD)	Median (IQR)	P-value
Conservative	**9.8 (6.2)**	8.5 (5-14)	**0.02**
Surgical	**4.2 (3.1)**	4.0 (2-6)	

Patient-reported disability at one year, measured by the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, showed a persistent and significant benefit for the surgically managed group. As shown in Table 3, the mean DASH score in the surgical group was 4.2 (SD 3.1), compared to 9.8 (SD 6.2) in the conservative group (p=0.02), reflecting less residual disability.

Table 4: Fracture Healing Outcomes

Outcome	Conservative Group (n=29) n (%)	Surgical Group (n=29) n (%)	P-value
Radiographic Union at 3 Mos	25 (86.2)	**29 (100)**	0.11
Nonunion at 6 Months	**4 (13.8)**	0 (0.0)	**0.04**
Symptomatic Malunion	**8 (27.6)**	0 (0.0)	**0.005**
Composite of Nonunion/Malunion	**8 (27.6)**	0 (0.0)	**0.005**

Radiographic and clinical healing outcomes revealed a stark contrast between the two treatment strategies, as summarized in Table 4. All 29 fractures (100%) in the surgical group achieved radiographic union by the 3-month follow-up. In the conservative group, 25 patients (86.2%) were united at 3 months, with 4 cases (13.8%) progressing to established nonunion at 6 months (p=0.04). Furthermore, a total of 8 patients in the conservative group (27.6%) developed a symptomatic malunion, contributing to functional deficits. The composite endpoint of major fracture-healing complications (nonunion or symptomatic malunion) occurred in 8 patients (27.6%) in the conservative group and in none of the surgical patients, yielding a statistically significant relative risk of 8.0 (95% CI 1.1 to 58.6, p=0.005).

Table 5: Treatment-Related Complications

Complication Type	Conservative Group (n=29) n (%)	Surgical Group (n=29) n (%)
Major Complications		
- Symptomatic Nonunion/Malunion	8 (27.6)	0 (0.0)
- Deep Infection	0 (0.0)	0 (0.0)
- Neurovascular Injury	0 (0.0)	0 (0.0)
Minor Complications		
- Superficial Infection	0 (0.0)	1 (3.4)
- Hardware Irritation	N/A	11 (37.9)
- *Required Hardware Removal*	N/A	**6 (20.7)**

Complication Type	Conservative Group (n=29) n (%)	Surgical Group (n=29) n (%)
- Skin/Nerve Hypersensitivity	2 (6.9)	3 (10.3)
- Shoulder Stiffness (transient)	5 (17.2)	2 (6.9)

The profile of treatment-related complications differed substantially between the groups, as detailed in Table 5. The predominant morbidity in the surgical cohort was related to the implant. Hardware irritation was reported in 11 patients (37.9%), and of these, 6 (20.7% of the surgical cohort) underwent a secondary elective procedure for plate removal following radiographic union. One superficial surgical site infection (3.4%) resolved with a course of oral antibiotics. There were no instances of deep infection, neurovascular injury, or mechanical failure. In the conservative group, minor complications included transient shoulder stiffness (n=5, 17.2%) and skin hypersensitivity (n=2, 6.9%). The major complications in this group were exclusively the healing failures previously described.

DISCUSSION

This prospective comparative study of 58 adults with displaced midshaft clavicle fractures provides robust clinical data supporting a paradigm shift towards surgical intervention for active individuals. Our findings demonstrate that surgical fixation with plate osteosynthesis offers a triad of key advantages: dramatically accelerated functional recovery in the critical first six months, a near-elimination of major fracture-healing complications, and superior patient-reported outcomes at one year. However, this benefit is counterbalanced by a defined surgical morbidity, predominantly in the form of symptomatic hardware.

The significantly higher Constant-Murley scores in the surgical group at 6 weeks and 3 months underscore the principal practical advantage of operative management: the restoration of stable skeletal anatomy that permits immediate, protected mobilization.[20] This rapid functional restitution is critical for patients whose occupational or recreational demands require an expedited return to shoulder girdle use.[21] Our findings align precisely with the landmark randomized controlled trial (RCT) by the Canadian Orthopaedic Trauma Society (COTS), which reported superior DASH scores at all time points up to one year in the surgical cohort, with the most marked difference observed in the first 3-6 months.[9] Similarly, a meta-analysis by McKee et al. consolidated evidence from multiple RCTs, concluding that operative management provides significantly better short- and medium-term functional outcomes.[16] Our cohort's trajectory—converging CMS scores at one year but a persistently better DASH score in the surgical group—reflects a nuanced reality: while many conservatively treated patients achieve good motion and strength, a subset is left with residual symptoms of fatigue, cosmetic deformity, or weakness during strenuous activity that are sensitively captured by patient-reported tools like the DASH.[10,22]

The most compelling argument for surgery in our study was its absolute prevention of nonunion and symptomatic malunion. The 27.6% rate of these complications in our conservative group is substantial and mirrors the results of Robinson et al., whose large prospective series reported a 21% nonunion rate and a 31% rate of patient dissatisfaction, primarily due to malunion, in nonoperatively treated displaced fractures.[10] Our 0% nonunion rate in the surgical group is consistent with modern fixation techniques and reinforces surgery as the most reliable path to predictable bony union.[16] Symptomatic malunion, characterized by shortening, is not merely a radiographic curiosity but a direct cause of compromised biomechanics, leading to scapular dyskinesia, muscle fatigue, and chronic pain—a sequelae effectively avoided by anatomical reduction and stable fixation.[11,23]

The trade-off for this reliability is a distinct complication profile. Our 20.7% re-operation rate for hardware removal is a recognized and consistent drawback of plate fixation, reported in 10-30% of cases across the literature, including the COTS trial.[9,17] This iatrogenic burden must be transparently discussed during shared decision-making.[24] It is noteworthy that in our study, as in most contemporary series, major surgical complications like deep infection or neurovascular injury were rare, suggesting that in experienced hands, the procedure is safe.

CONCLUSION

In conclusion, for the active adult with a displaced midshaft clavicle fracture, surgical management via plate osteosynthesis provides a faster, more predictable, and functionally superior recovery pathway compared to conservative treatment. It effectively trades the high risk of a poorly healed, symptomatic fracture for the lower, but definite, risk of a secondary procedure for hardware removal. These results, consistent with contemporary high-level evidence, strongly support offering surgical fixation as a first-line option to well-counseled patients for whom optimal functional recovery is a priority. Future research should focus on refining implant design to minimize removal rates and developing more precise criteria to identify patients who will do equally well with either approach.

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