# " COMPARATIVE STUDY OF CLINICAL AND FUNCTIONAL OUTCOME IN MIDDLE THIRD CLAVICULAR FRACTURES TREATED WITH RECONSTRUCTION PLATE VERSUS LOCKING COMPRESSION PLATE "

**BY**

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**DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA**

**In partial fulfillment of the requirements for the degree of**

**MASTER OF SURGERY**
**IN**
**ORTHOPAEDICS**

**Under the Guidance of**

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**SRI DEVARAJ URS MEDICAL COLLEGE,**
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**2025**

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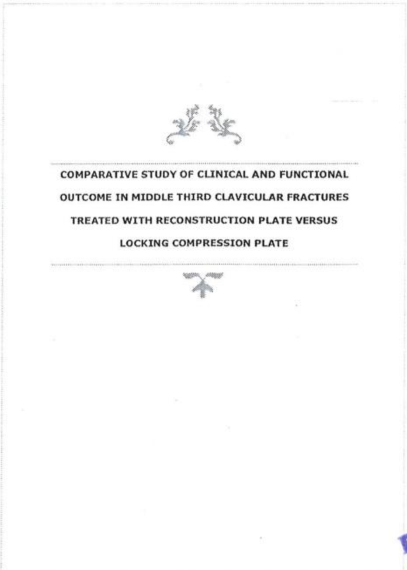
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COMPARATIVE STUDY OF CLINICAL AND FUNCTIONAL OUTCOME IN MIDDLE THIRD CLAVICULAR FRACTURES TREATED WITH RECONSTRUCTION PLATE VERSUS LOCKING COMPRESSION PLATE ABSTRACT Background and Objective MCF represent a significant proportion of appendicular skeletal injuries, with ongoing debate regarding optimal fixation modalities. Despite advances in orthopaedic implant technology, comparative evidence evaluating RPs versus LCPs remains limited, particularly regarding clinical with functional status. This prospective interventional study aimed to compare the clinical and functional outcomes in MCF treated with RPs versus LCPs, evaluating pain scores, functional disability, radiological union rates, and complication profiles over a 24-week follow-up period. Methodology This comparative prospective interventional study was conducted at R.L. Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College. Forty-eight patients with displaced (>2 cm) middle third clavicle fractures were enrolled and divided into two equal groups (n=24 each) using simple random sampling. Group A underwent surgical fixation with RPs, while Group B received LCPs. Patients aged 18-60 years with displaced middle third clavicle fractures, skin tenting, or bilateral involvement were included. Exclusion criteria encompassed previous clavicular injuries, pathological fractures, non-union cases, medical contraindications to surgery, and bleeding disorders. All patients underwent comprehensive clinical assessment, radiographic evaluation, and standardized surgical protocols. Post-operatively, patients were evaluated at 6 weeks, 3 months, and 6 months using VAS for pain assessment, DASH score for functional evaluation, and radiographic examination for union assessment. Results Both treatment groups demonstrated comparable baseline characteristics, with mean ages of 37.88 years (SD=12.47) in the LCP group and 36.54 years (SD=11.455) in the RP group. Male predominance (83.3%) was observed in both groups. The LCP group exhibited consistently lower pain scores at all assessment intervals: 6 weeks (mean=3.46 vs. 4.45, p<0.0001), 12 weeks (mean=2.51 vs. 3.00, p<0.0001), and 24 weeks (mean=1.49 vs. 1.96, p≤0.0001). Similarly, operative status measured by DASH scores were significantly better in the LCP group at 6 weeks (mean=34.73 vs. 44.49, p<0.0001), 12 weeks (mean=25.03 vs. 29.96, p<0.0001), and 24 weeks (mean=10.98 vs. 16.04, p<0.0001). Radiological union rates at 12 weeks were comparable (75.0% vs. 70.8%, p=0.745), but by 24 weeks, the LCP group achieved 100% union compared to 87.5% in the RP group (p=0.07). Notably, the LCP group demonstrated no implant failures (0% vs. 4.2%, p=1.000) or delayed unions (0% vs. 12.5%, p=0.234), and lower infection rates (12.5% vs. 20.8%, p=0.701) compared to the RP group, though these differences did not reach statistical significance. Conclusion 3 This prospective comparative study provides evidence supporting the clinical and functional superiority of LCPs over RPs

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# COMPARATIVE STUDY OF CLINICAL AND FUNCTIONAL OUTCOME IN MIDDLE THIRD CLAVICULAR FRACTURES TREATED WITH RECONSTRUCTION PLATE VERSUS LOCKING COMPRESSION PLATE

## ABSTRACT

**Background and Objective**

MCF represent a significant proportion of appendicular skeletal injuries, with ongoing debate regarding optimal fixation modalities. Despite advances in orthopaedic implant technology, comparative evidence evaluating RPs versus LCPs remains limited, particularly regarding clinical with functional status. This prospective interventional study aimed to compare the clinical and functional outcomes in MCF treated with RPs versus LCPs, evaluating pain scores, functional disability, radiological union rates, and complication profiles over a 24-week follow-up period.

**Methodology**

This comparative prospective interventional study was conducted at R.L. Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College. Forty-eight patients with displaced (>2 cm) middle third clavicle fractures were enrolled and divided into two equal groups (n=24 each) using simple random sampling. Group A underwent surgical fixation with RPs, while Group B received LCPs. Patients aged 18-60 years with displaced middle third clavicle fractures, skin tenting, or bilateral involvement were included. Exclusion criteria encompassed previous clavicular injuries, pathological fractures, non-union cases, medical contraindications to surgery, and bleeding disorders. All patients underwent comprehensive clinical assessment, radiographic evaluation, and standardized surgical protocols. Post-operatively, patients were evaluated at 6 weeks, 3 months, and 6 months using VAS for pain assessment, DASH score for functional evaluation, and radiographic examination for union assessment.

**Results**

Both treatment groups demonstrated comparable baseline characteristics, with mean ages of 37.88 years (SD=12.47) in the LCP group and 36.54 years (SD=11.455) in the RP group. Male predominance (83.3%) was observed in both groups. The LCP group exhibited consistently lower pain scores at all assessment intervals: 6 weeks (mean=3.46 vs. 4.45, p<0.0001), 12 weeks (mean=2.51 vs. 3.00, p<0.0001), and 24 weeks (mean=1.49 vs. 1.96, p<0.0001). Similarly, operative status measured by DASH scores were significantly better in the LCP group at 6 weeks (mean=34.73 vs. 44.49, p<0.0001), 12 weeks (mean=25.03 vs.

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**Conclusion**

This prospective comparative study provides evidence supporting the clinical and functional superiority of LCPs over RPs in the management of MCF. The statistically significant advantages in pain reduction and functional outcomes, coupled with the trend toward reduced complications and enhanced union rates, suggest that LCPs offer clinically meaningful benefits throughout the recovery period. These findings align with contemporary biomechanical principles of locking plate systems and contribute valuable evidence to inform implant selection in the surgical management of DMCF, though individualized decision-making considering patient factors, fracture characteristics, and resource availability remains essential in clinical practice.

**Keywords:** Visual Analogue Scale, Disability of Arm, Shoulder and Hand, LCPs, reconstruction plates, clavicle

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# ABBREVIATION

| Abbreviation | Explanation |
|---|---|
| COTS | Canadian Orthopaedic Trauma Society |
| DMCF | Displaced Middle Third Clavicular Fractures |
| MCF | Middle Third Clavicular Fractures |
| CF | Clavicular Fractures |
| IM | Intramedullary |
| LCP | Locking Compression Plates |
| RP | Reconstruction Plates |
| MIPO | Minimally Invasive Plate Osteosynthesis |
| ORIF | Open Reduction and Internal Fixation |
| PLP | Precontoured Locking Plate |
| DCP | Dynamic Compression Plates |
| DASH | Disabilities of the Arm, Shoulder and Hand |
| VAS | Visual Analog Scale |
| CMS | Constant-Murley Score |
| CRPS | Complex Regional Pain Syndrome |
| PROM | Patient-Reported Outcome Measures |
| QOL | Quality Of Life |
| RCT | Randomized Controlled Trials |
| SD | Standard Deviation |
| CI | Confidence Interval |
| RR | Relative Risk |

# INTRODUCTION

About 2.6-4% among all adult breakages are caused by CF, and 35% of shoulder girdle injuries are CF as well. Of all CF, 80% are middle third fractures.[1,2] These fractures typically result from direct trauma to the shoulder during falls, sports injuries, or motor vehicle accidents.[2] Historically, non-operative management of MCF was the norm due to the widespread perception that non-union was uncommon and that functional outcomes were good irrespective of the extent of displacement or shortening. [3,4]

However, recent evidence challenges this traditional approach, particularly for DMCF. Research has shown that when severely displaced fractures are not surgically repaired, there is a greater chance of non-union and malunion, as well as patient discontent with the aesthetic and functional results. [3,5] Operative fixation enhanced functional results, decreased incidence of malunion as well as non-union, and shortened time to radiographic union, according to a multicenter, RCTs comparing plate fixation with non-operative therapies for DMCF. The trial was done by the COTS. [5]

The evolution of surgical management for MCF has seen the development of various fixation techniques, including IMF with Knowles pins and plate osteosynthesis with different plate designs.[6–8] Among these, plate fixation has gained widespread acceptance due to its ability to provide rigid fixation, rotational stability, and early functional rehabilitation.[9,10] The two most commonly used plates for MCF are RPs and LCPs, each with its own biomechanical advantages and potential complications.[9,11,12]

The RPs' ability to be easily molded to meet the clavicle's S-shaped structure makes them a great choice for bone surface attachment. [12] Individuals with low bone density are more likely to experience plate bending or breakage, and they may not have the mechanical strength necessary for comminuted fractures. [13,14] On the other hand, LCPs provide angular stability through the threaded connection between the screw heads and the plate, resulting in a fixed-angle construct that may better resist bending forces and provide more stable fixation, particularly in osteoporotic bone.[9,11,15]

Several studies have compared the outcomes of these two plate types with varying results. Cho et al. reported no significant differences in union rates, complications, or operational status between RPs and LCPs.[12] Conversely, Kingsly et al. found better functional outcomes with anatomical pre-contoured locking plates compared to RPs.[10] Likewise, Lai et al. showed that LCPs yielded better outcomes with regard to union rates as well as functional recovery.[11]

The choice of plate type may also influence the rate of implant-related complications and the need for implant removal. Fridberg et al. reported a complication rate of 12.4% and a reoperation rate of 11.4% following locking plate osteosynthesis, with the majority of reoperations performed for implant removal due to localized discomfort.[16] Wijdicks et al., in a systematic review of plate fixation complications, identified implant-related irritation, infection, implant failure, and nonunion as the most common complications, with irritation being the predominant reason for implant removal.[14]

More recently, MIPO techniques have been introduced with the aim of preserving soft tissue attachments and potentially reducing the risk of neurovascular injury and infection.[17,18] Jiang et al. compared conventional ORIF with MIPO techniques using LCPs and found comparable functional outcomes with lower complication rates in the MIPO group.[17]

Despite advances in operative approaches and implant variations, the optimal plate choice for MCF remains debated, with the decision often based on surgeon preference, fracture pattern, bone quality, and cost considerations.[9,19,20] This study aims to compare the clinical and functional outcomes of MCF treated with RPs versus LCPs to provide evidence-based guidance for implant selection.

# OBJECTIVES

To assess and compare the clinical and functional outcome in MCF treated with RP versus LCP in the study participants.

# REVIEW OF LITERATURE

## Anatomy

### Anatomical Characteristics and Regional Divisions

As a stabilizing strut for the shoulder, the clavicle extends from the sternum to the scapula. There is just one bony link between the upper limb and the axial skeleton, and it is an S-shaped double-curved long bone. Thirds, medial, middle, and lateral, are the three anatomical divisions of the bone. [21] The middle third, comprising approximately 60% of the bone's length, represents the thinnest segment with a transition from the tubular medial portion to the flattened lateral end.

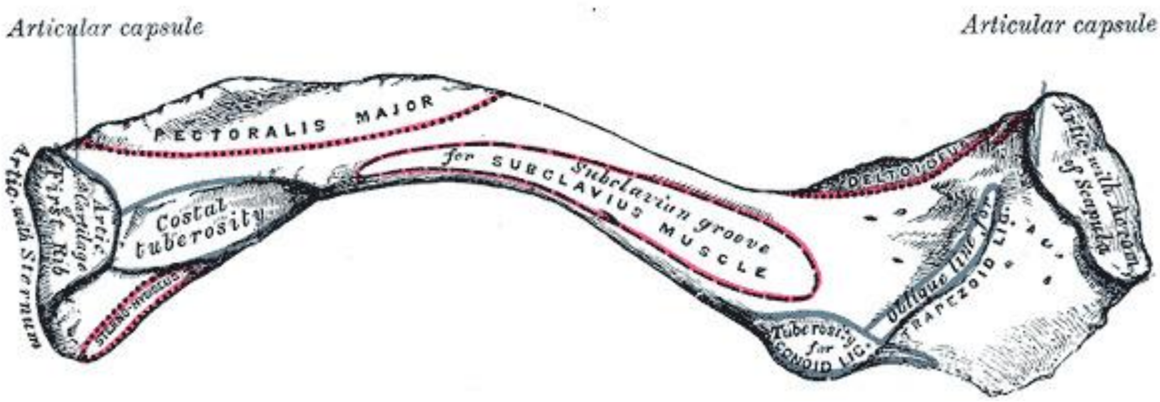



***Figure 1:* Clavicle**[22]

The cross-sectional morphology varies considerably, transitioning from a triangular shape medially to a flattened oval configuration laterally. This anatomical variation influences fracture patterns and fixation strategies.[2] The clavicle's unique contour presents challenges for implant design and application, necessitating either the use of malleable plates that can be contoured intraoperatively or pre-contoured anatomical plates that match the bone's natural shape.[23]

## Ossification and Development

In embryology, solidification of the clavicle begins at around 5 or 6 weeks of conception and, unexpectedly, does not finish until around 18 or 25 years of age, when the medial epiphysis fuses. [24] Unlike most long bones, the clavicle develops through intramembranous ossification rather than endochondral ossification. This developmental process contributes to the bone's distinctive morphology and may influence its healing potential. The clavicle continues to develop and remodel throughout adolescence, which has implications for fracture management in skeletally immature patients.[2]

## Biomechanical Properties and Function

Biomechanically, the clavicle functions as a strut that transmits forces between the upper extremity and the axial skeleton while maintaining the shoulder in its functional position lateral to the thorax. It acts as a rigid support for the glenohumeral joint, enabling proper positioning for optimal upper extremity function. The clavicle also serves as a site for muscular attachment and protects vital neurovascular structures passing beneath it. During arm elevation, the clavicle rotates posteriorly and superiorly, facilitating scapular rotation and maintaining the glenohumeral relationship.[25,26] These complex movements subject the clavicle to various forces, including bending, rotation, and axial loading, which influence fracture patterns and healing potential.

## Vascular Supply and Innervation

The clavicle is mostly supplied with blood by the suprascapular artery, which is a branch of the thyrocervical trunk. It is also supplied by the thoraco-acromial artery and the internal thoracic artery. The periosteal blood supply is particularly important for fracture healing, with the middle third being relatively less vascularized compared to the medial and lateral segments. This comparative hypo vascularity may contribute to the higher rates of delayed union and non-union observed in middle third fractures. Innervation around the clavicle includes the supraclavicular nerves anteriorly and the suprascapular nerve posteriorly, with the brachial plexus passing in close proximity to the inferomedial aspect of the bone.[27] This anatomical relationship necessitates careful surgical technique to avoid iatrogenic neurovascular injury during fixation procedures.[2,20]

**Muscular and Ligamentous Attachments**

Several muscles attach to the clavicle, including the deltoid and pectoralis major anterolaterally, the trapezius superiorly, and the sternocleidomastoid medially. These muscular attachments create deforming forces that influence fracture displacement patterns.

Typically, the medial fragment is pulled superiorly and posteriorly by the sternocleidomastoid, while the lateral fragment is displaced inferiorly and anteriorly by the weight of the arm and the pull of the pectoralis major.

The coracoclavicular as well as acromioclavicular ligaments stabilize the lateral end, while the costoclavicular ligament anchors the medial end. The robust periosteal sleeve provides additional stability and enhances healing potential when preserved during surgical approaches.[28]

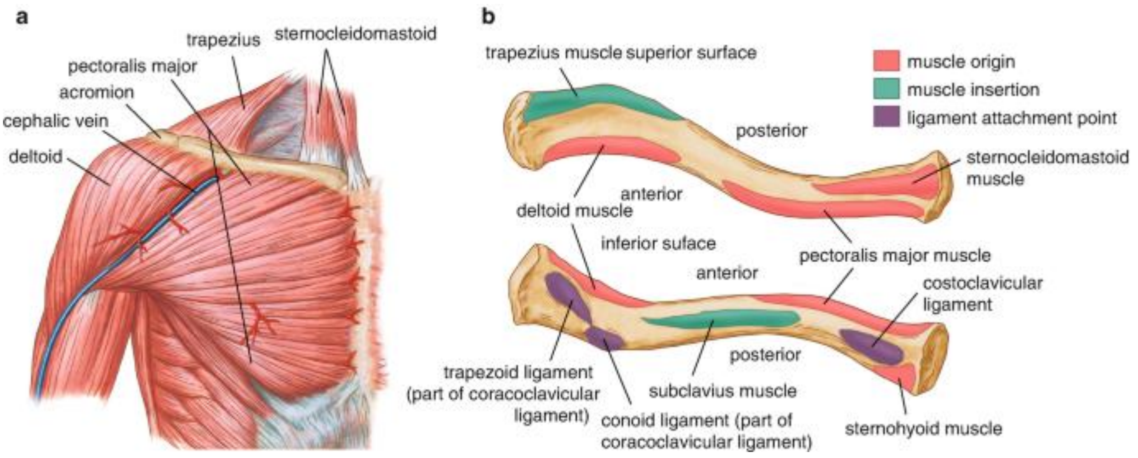



***Figure 2:* Muscular attachments of clavicle**[29]

**Biomechanical Forces Acting on the Clavicle**

During normal function, the clavicle experiences complex loading patterns. Axial compression occurs through the sternoclavicular and acromioclavicular joints during weight-bearing activities. Bending forces are applied superiorly and inferiorly, while torsional forces occur during rotational movements of the shoulder girdle. The middle third, being the thinnest segment with the least surrounding soft tissue support, represents a biomechanical vulnerability zone. It is explained by the preponderance of fractures in the middle third of the body, according to computational models, because this area undergoes the greatest stress concentration when the hand is outstretched or when the shoulder is hit directly. [1,19] These biomechanical considerations are essential for understanding fracture patterns and developing optimal fixation strategies.

**Epidemiology and Classification of CF**

**Incidence and Prevalence**

CF is responsible with 35% of shoulder girdle injuries and 2.6-4 percent of all adult cracks.[2,30] MCFs account for around 80% of all CF cases, and the overall incidence is estimated to be 64-71 per 100,000 population per year. The incidence is most common among the elderly and young adults, respectively, and it follows a bimodal distribution. Recent epidemiological trends suggest an increasing incidence, particularly in active populations participating in high-energy sports and recreational activities.[28]

**Demographic Distribution**

Age, gender, and occupational factors significantly influence the epidemiology of CF. Most often, injuries caused by extremely powerful processes, such as those in sports or car accidents, disproportionately affect young adult males. In the elderly population, there is a female predominance, with fractures often resulting from low energy falls in the context of osteoporosis.

Occupational factors play a role, with higher incidence rates observed in individuals engaged in contact sports, cycling, and certain industrial occupations involving fall risks.[31] Military personnel and athletes demonstrate particularly high rates of CF, reflecting exposure to high-energy trauma and repetitive loading.[2,4]

***Figure 3: Radiograph of displaced midshaft clavicle fracture.***[32]

## Mechanisms of Injury

Direct damage to the shoulder, landings on a hand reaching out or, less frequently, direct impact to the clavicle itself are the three main causes that can cause CF.[33] The leading cause is a fall that presses on the shoulder's side, which causes a bending moment greater than the mechanical threshold of the bone. Direct impact pressures may produce greater comminuted pattern of fracture in high-energy trauma cases, including car collisions. Sports-related injuries often involve either collision forces or falls, with cycling, football, rugby, and skiing being associated with higher incidence rates. The mechanism of injury influences fracture patterns, displacement, and comminution, which in turn affects treatment decisions and prognosis.[19,28]

## Classification Systems

Several classification systems exist for CF, each with distinct clinical implications.

### The Allman classification

It is one of the earliest systems, divides fractures into three groups based on anatomical location: Group I (middle third), Group II (lateral third), and Group III (medial third).

**The Robinson classification,** an expansion of the Edinburgh classification, further subdivides these groups based on displacement, comminution, and articular involvement. For middle third fractures specifically, Robinson Type 2B fractures (displaced, comminuted middle third fractures) demonstrate the highest rates of non-union and functional deficit when treated non-operatively.

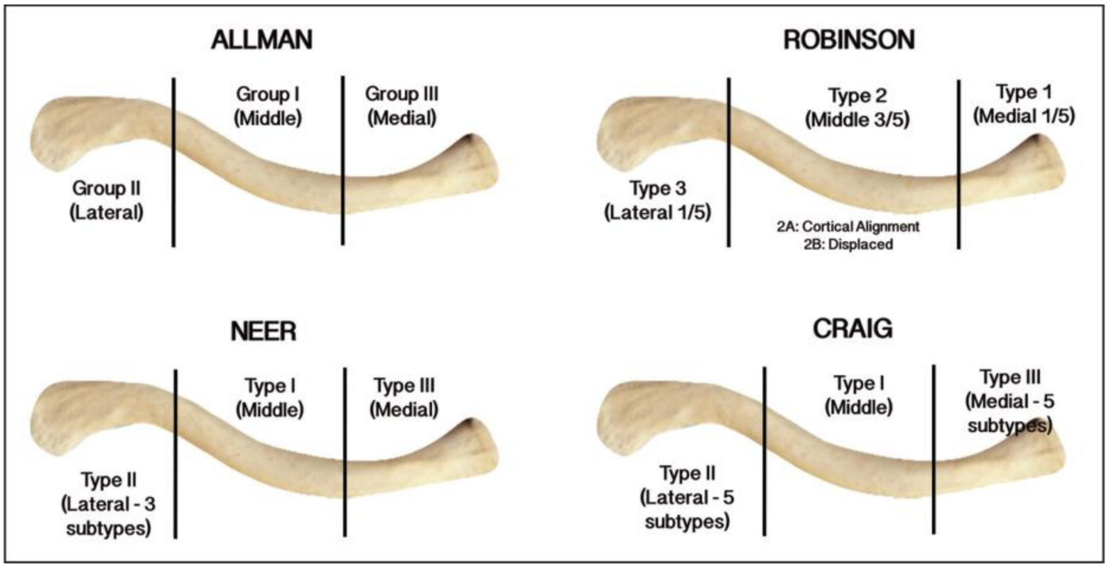
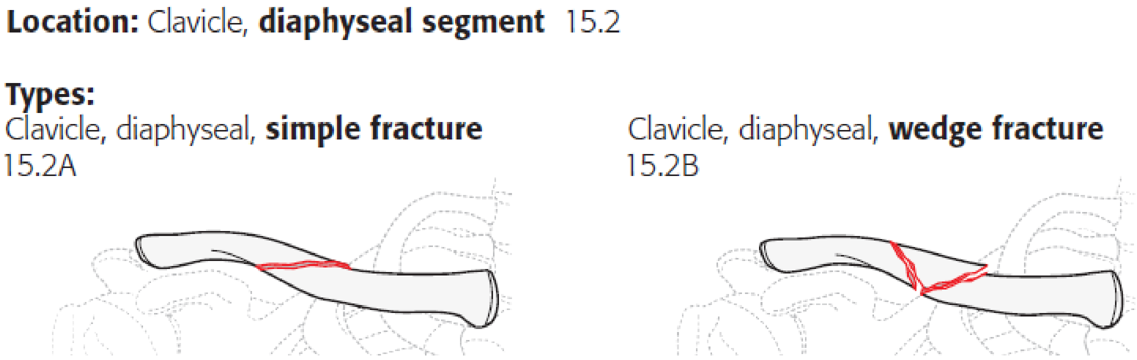



*Figure 4: Allman, Craig, Robinson, and Neer also Craig classification systems*[34]

**AO/OTA classification**

The AO/OTA classification provides additional detail regarding fracture morphology, with types A, B, and C denoting simple, wedge, and complex fracture patterns, respectively.[35] These classification systems guide treatment algorithms and prognostic discussions, with higher complexity fractures generally warranting more aggressive management strategies.[2,36]



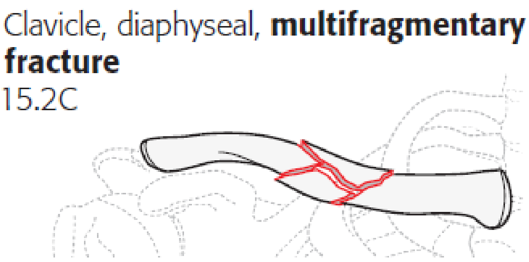



*Figure 5: AO/OTA classification of diaphyseal segment of clavicle[37]*

**Distribution of Fracture Patterns**

Among MCF, approximately 48% demonstrate significant displacement, with displacement defined as no cortical contact between the main fragments. Comminution is present in approximately 30-40% of cases, with the "butterfly fragment" pattern being particularly common.[38] The presence of displacement and comminution adversely affects healing potential and functional outcomes, particularly when treated non-operatively. Shortening of greater than 1-2 cm occurs in approximately 15-20% of middle third fractures and has been associated with poorer functional outcomes and patient dissatisfaction.

Segmental fractures, though uncommon, present particular challenges for fixation and demonstrate higher non-union rates when treated conservatively. These fracture pattern distributions have informed the evolution of treatment approaches, with more complex patterns increasingly managed surgically.[5,36]

## Evolution of Treatment Approaches for MCF

### Historical Perspective on Non-operative Management

Neer and Rowe's seminal studies from the 1960s and 1970s, which found non-union rates of just under one percent with conservative therapy, led to the historical trend of non-operative management of MCF. For four to six weeks, the conventional method included keeping the patient immobile with a figure-of-eight bandage or a basic sling, and then gradually increasing the patient's range of motion with exercises. This approach was predicated on the excellent healing potential of the clavicle and the perception that even malunited fractures resulted in acceptable functional outcomes. The axiom that "CF always heal" and that "there is no malunion of the clavicle, only cosmetic issues" guided clinical practice for decades. This conservative approach was reinforced by reports of high complication rates associated with early fixation techniques, particularly pin migration and hardware failure.[4,5]

### Indications for Surgical Versus Non-Operative Management

Surgical intervention is now indicated by a more refined set of criteria in modern practice. These include relocation bigger than 2 cm, shortening bigger than 2 cm, significant comminution, segmental fractures, open fractures, gliding shoulder, neurovascular negotiation, skin tenting with impending open fracture, polytrauma requiring early mobilization, patient preference in high-demand individuals, and so on.

Non-operative management remains appropriate for non-displaced or minimally displaced fractures, low-demand patients with significant comorbidities, and patients who prioritize avoiding surgical risks over potential functional benefits[39] This evolution reflects a more nuanced understanding of fracture biomechanics and healing potential, as well as improvements in surgical techniques and implant design[3,4,23]

## Shifting Paradigms in Treatment Approaches

The paradigm shift in middle third clavicular fracture management has been driven by several high-quality studies challenging the traditional non-operative approach. The landmark multicentre RCT by the COTS in 2007 demonstrated improved functional status, lower non-union rates, and faster return to function with plate fixation compared to non-operative treatment for displaced fractures. Similarly, Althausen et al. found improved clinical outcomes and cost-effectiveness with surgical management when accounting for productivity losses and long-term disability. These findings, corroborated by subsequent meta-analyses, have led to a progressive shift toward surgical management for displaced middle third fractures, particularly in young, active patients. This evolution represents a move away from a "one-size-fits-all" approach toward more individualized treatment decisions based on fracture characteristics, patient factors, and functional demands.[3,5]

## Evidence Challenging Traditional Non-Operative Management

Literatures have identified 15-20% for displaced middle third fractures treated non-operatively than previously reported. Factors associated with non-union include displacement, comminution, advanced age, female gender, and tobacco use. Beyond non-union, functional deficits have been increasingly recognized even in fractures that achieve union.[40]

Malunited fractures with shortening >1-2 cm have been associated with decreased strength, reduced endurance, altered scapulothoracic kinematics, and lower patient satisfaction. These findings have prompted a re-evaluation of the traditional belief that cosmetic deformity is the only significant sequela of malunited CF. PROM have further demonstrated persistent deficits in overhead activities, heavy lifting, and contact sports following conservative management of displaced fractures.[3,4,23]

**Current Treatment Algorithms and Decision-Making Processes**

Contemporary decision-making for MCF involves a multifactorial assessment including fracture characteristics, patient factors, and shared decision-making. Current algorithms generally recommend surgical fixation for fractures with complete displacement, shortening >2 cm, severe comminution, or significant soft tissue compromise. Patient-specific factors influencing treatment selection include age, activity level, occupational demands, and comorbidities. The timing of intervention is also critical, with acute fixation (within 2 weeks) associated with better outcomes than delayed intervention. These algorithms emphasize the importance of high-quality radiographic assessment, including standardized anteroposterior and 20° cephalic tilt views to accurately characterize displacement and shortening.

Three-dimensional CT reconstruction may provide additional information in complex cases or for preoperative planning. The decision-making process has evolved to incorporate not only fracture healing as the primary endpoint but also patient-reported outcomes, satisfaction, and return to pre-injury activities.[19,23,36,41]

## Surgical Techniques and Approaches

### Surgical Approaches

Two primary approaches are utilized for plate fixation of MCF: the superior approach and the anteroinferior approach. The superior approach, traditionally more common, involves an incision along the upper part of clavicle, providing direct access to the place of injury. This approach facilitates plate placement on the tension side of the bone, theoretically optimizing biomechanical stability. However, it may result in prominent hardware and higher rates of irritation, particularly in thin patients. The anteroinferior approach has gained popularity for its potential to reduce hardware prominence and irritation. This approach involves plate placement on the lower part, which may provide comparable stability with less soft tissue disruption and hardware prominence. Nourian et al., in their study compared the anteroinferior with superior plating, found lower reoperation rates and hardware irritation with anteroinferior plate placement. The choice between approaches should consider fracture pattern, patient body habitus, and surgeon experience.[36]

### ORIF Techniques

ORIF techniques for MCF have evolved substantially. After appropriate exposure, the fracture is reduced under direct visualization, with care taken to preserve the periosteal sleeve when possible. Temporary fixation can be achieved with reduction clamps or K-wires. For simple fractures, compression techniques using lag screws may enhance stability. In comminuted fractures, an indirect reduction technique preserving the soft tissue attachments to fracture fragments may be preferable to maintain vascularity. Plate application follows, with screw placement ideally achieving at least six cortices of fixation on either side of the fracture. Technical considerations include plate contours matching the clavicular anatomy, avoiding excessive periosteal stripping, and protecting the underlying neurovascular structures. Fluoroscopic confirmation of reduction and implant position is standard practice.[8,19]

## MIPO

MIPO represents an evolution in surgical technique aimed at preserving soft tissue attachments while achieving stable fixation. The MIPO technique involves two small incisions, one medial and one lateral to the fracture site, through which a pre-contoured plate is inserted in a submuscular or epi-periosteal tunnel. Indirect reduction techniques are employed, often using the plate as a reduction tool. Jiang et al. compared conventional ORIF with MIPO techniques using LCPs and found comparable union rates but significantly minimal surgical duration, decreased blood loss, and with minimal length of incision with MIPO. Kundangar et al. demonstrated better early functional outcomes with MIPO compared to conventional open techniques, though final outcomes were similar. The MIPO approach may be particularly advantageous for complex fractures where preservation of biological factors is critical for healing. However, the technique requires advanced surgical skills and is associated with a learning curve.[17,18]

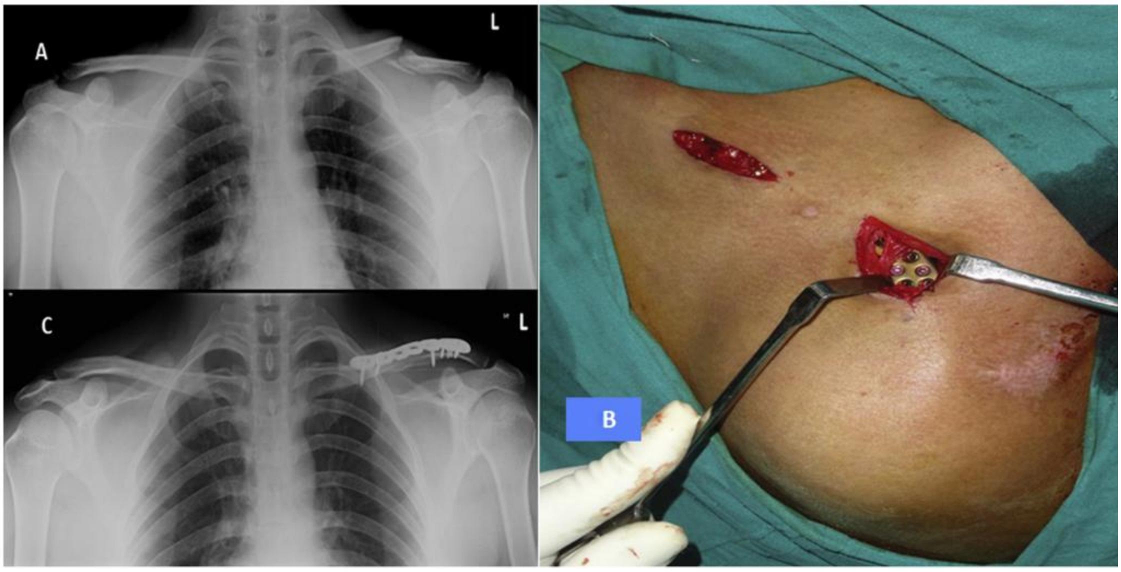



*Figure 6: MCF treated by IF: MIPO using PLP[18]*

## IMFs

IMF represents an alternative to plate fixation for MCF. Various devices have been employed, including Knowles pins, titanium elastic nails, and threaded Steinmann pins. The theoretical advantages include less soft tissue disruption, smaller incisions, and less prominent hardware. Chu et al. reported good outcomes with Knowles pins, with union rates exceeding 90% and low complication rates. However, IMF techniques have limitations, including less rotational stability, risk of hardware migration, and limited applicability in comminuted fractures. A comparative long-term analysis by Chan et al. found that while both plate and IMF achieved satisfactory union rates, plate fixation provided better maintenance of reduction in comminuted fractures. IMF may be most appropriate for simple, transverse fractures in patients concerned about scar appearance or hardware prominence.[6,8]

## Positioning, Draping, and Intraoperative Considerations

Proper positioning is crucial for successful clavicular fracture fixation. Supine positioning with a hump between the scapulae allows for posterior retraction of the shoulder girdle, which in turn allows access to the clavicle. It is possible to adopt a modified beach-chair posture by turning the head away from the side that is being operated on. Draping should allow access to the entire clavicle and shoulder girdle, with consideration for extension into the deltopectoral region if expanded exposure becomes necessary. Critical intraoperative considerations include protection of the subclavian vessels and brachial plexus, preservation of periosteal attachments when possible, and meticulous soft tissue handling. For complex fractures, preoperative CT imaging may assist with planning. Intraoperative fluoroscopy is essential for confirming reduction quality and implant position. The use of locking screws may be particularly advantageous in osteoporotic bone or comminuted regions where bicortical fixation may not be achievable.[19,36]

## Post-operative Protocols and Rehabilitation Strategies

Preoperative care usually includes immobilizing the arm with a sling to alleviate discomfort, followed by early range of motion exercises within pain constraints. Passive range of motion may begin immediately for simple fractures with stable fixation, while more complex fractures may require a more protected protocol for 2-3 weeks. After 6-8 weeks, you can start to gradually strengthen your muscles again. You should be able to resume to full activities, including contact sports, within 3-4 months, as long as there is radiographic confirmation of the union. In order to avoid stiffness after surgery, it is recommended to start doing pendulum exercises and increasing the range of motion in the elbow as soon as possible.

Regular radiographic follow-up is recommended at 2 weeks, 6 weeks, 3 months, and 6 months to monitor union progression and implant integrity. Early identification of fixation failure or delayed union allows for timely intervention and management strategy adjustments. Rehabilitation protocols should be individualized based on fracture stability, bone quality, patient compliance, and concomitant injuries. Return to high-demand activities requires both radiographic evidence of union and restoration of functional capacity, including strength and endurance.[24,42]

## Types of Plates Used in Clavicular Fracture Fixation

### Evolution of Plate Designs

Plate designs for clavicular fracture fixation have evolved from simple, flat plates to more sophisticated, anatomically contoured options. The initial designs focused on providing stability to the fracture site, but advancements in materials and biomechanics have led to the development of plates that cater to specific anatomical and mechanical requirements. Modern plates offer improved fixation, reduced implant-related complications, and a better fit to the bone's natural contour.[43]


A. **Middle third fracture of the left clavicle**


B. **Radiograph after ORIF with a Recon plate.**

***Figure 7: Middle third fracture of clavicle treated by RP[44]***

**RPs**

RPs are versatile and can be bent to fit the unique contour of the clavicle. These plates are often used for complex fracture patterns and provide adequate fixation due to their ability to conform to the bone's surface. Biomechanically, they offer satisfactory stability but may require careful bending to ensure proper alignment. Technical considerations include ensuring the plate's contour matches the clavicle's natural shape to avoid soft tissue irritation and promote healing. [45]

**LCPs**

The distinctive design of LCPs is characterized by a fixed-angle construction achieved by screwing into the plate. Especially in cases with degenerative bones or comminuted fractures, this shape improves stability. The biomechanical advantage of LCPs lies in their ability to distribute stress uniformly across the plate, reducing the risk of implant failure. Technical considerations include selecting the appropriate plate length and screw configuration to optimize fixation and minimize soft tissue irritation.[46]

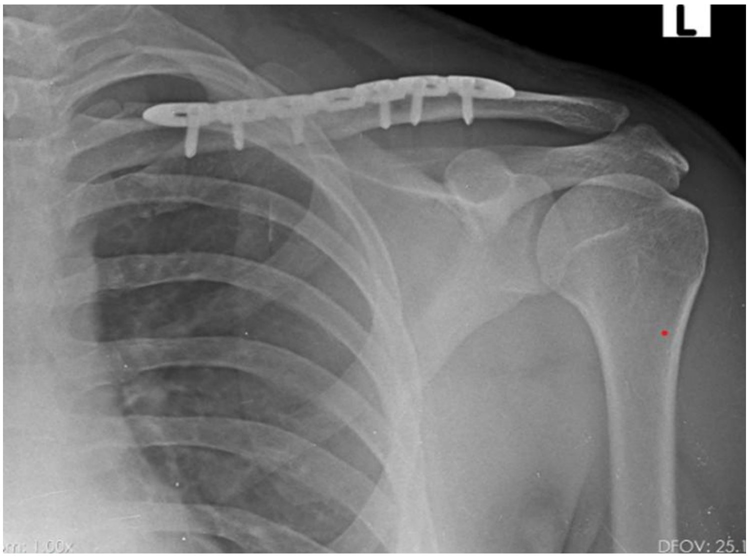



***Figure 8: Mid-shaft clavicle fracture treated with open reduction with internal fixation using a locked superior plate***[47]

## Pre-Contoured Anatomical Plates Versus Standard Plates

Pre-contoured anatomical plates are designed to match the natural curvature, providing a more precise fit and reducing the need for intraoperative bending. These plates are beneficial in minimizing soft tissue irritation and improving patient comfort. However, the anatomical variability among patients can pose challenges, as not all pre-contoured plates fit perfectly, potentially leading to suboptimal fixation. Standard plates, while less specific, offer greater versatility in adaptation to various fracture patterns.[48]

## Biomechanical Studies Comparing Different Plate Types

Biomechanical studies have compared the stability and performance of different plate types in clavicular fracture fixation. Research indicates that locking plates generally provide superior mechanical stability compared to non-locking plates, particularly in the presence of comminution. The results of these studies highlight the significance of optimizing results by choosing the right plate type according to fracture features and patient-specific variables.[49]

## Material Considerations

There are few considerations when deciding between titanium as well as stainless steel for clavicular plates. Because of its resilience and longevity, stainless steel is ideal for demanding uses. Titanium, is safer and less prone to trigger allergic responses because it is biocompatible. The reduced stress shielding and improved integration are further benefits of titanium because to its lower modulus of elasticity, which looks like bone. Factors unique to each patient, such as their allergy history and the necessity of postoperative imaging compatibility, are major factors in determining which of these materials to use.[50]

## Comparative Studies of RPs and LCPs in treatment of MCF

1. In a retrospective study of 41 patients with midshaft CF treated with either RPs (n=19) or reconstruction LCPs (n=22). The study evaluated union time, complications, and functional outcomes. The mean follow-up was 13.6 months. No significant differences were found in union rates (100% in both groups) or mean union time (14.6 weeks for RP vs. 13.4 weeks for LCP, $p>0.05$). PRFO were similar, with excellent and good results in 89.5% of RP cases and 90.9% of LCP cases. The authors concluded that both plates provide satisfactory outcomes with no significant clinical differences.[12]
2. In a prospective study that compared anatomical PLPs (n=30) with RPs (n=30) for displaced midshaft CF. Patients were evaluated using the CMS and radiographs till one year. The LCP group had a noticeably shorter mean time to union compared to the other group (11.9 weeks vs. 14.1 weeks, $p<0.05$). The PRFO were better in the group using the locking plates, with an average Constant score of 93.7, compared to 85.3 in the group using the RPs ($p<0.05$). The group that had the LCPs had a lower rate of complications (10% vs. 23.3%). In comparison to RPs, the scientists found that anatomical PLPs result in more favourable functional outcomes with less problems.[10]
3. Lai et al., (Taiwan, 2012) compared 24 patients treated with DCP and 39 patients treated with LCP for DMCF. Mean follow-up was 24 months. The researchers assessed union rates, time to union, PRFO using the CMS, and complications. The LCP group demonstrated significantly shorter time to union and better functional outcomes (mean Constant score 95.2 vs. 89.7, $p<0.05$). Complication rates were lower in the LCP group (5.1% vs. 16.7%). The authors concluded that LCPs provide

superior clinical outcomes compared to DCPs for midshaft clavicle fractures, particularly in comminuted fractures or osteoporotic bone.[11]

4. Gan et al., (Malaysia, 2020) conducted a cohort study comparing LCPs (n=26) with RPs (n=20) for MCFs. Patients were assessed using the DASH score, VAS for pain, and radiographic union till six months. Mean follow-up was 11.6 months. Union rates were comparable (96.2% vs. 95.0%), but the locked compression plate group showed better DASH scores at 3 months and 6 months. The study also analysed operative costs, finding locked compression plates to be 2.3 times more expensive. The authors concluded that locked compression plates provide better early functional outcomes but at higher cost.[9]
5. Kariya et al., (India, 2019) compared precontoured LCPs (n=19) with RPs (n=21) in a prospective study of MCF. PRFO were assessed using the CMS and DASH scores, while complications were documented over a mean follow-up of 12 months. The LCP groups demonstrated notable better MCS scores (94.7 vs. 81.9, $p<0.05$) and lower DASH scores (6.3 vs. 12.8, $p<0.05$). Bony reunion time was shorter in the LCP (11.2 weeks vs. 14.1 weeks, $p<0.05$). Excellent results were reported in 94.7% of locking plate cases versus 66.6% of RP cases. The authors concluded that PLPs provide superior functional outcomes with fewer complications.[20]
6. Fang et al., (Hong Kong, 2020) conducted a observational study comparing 53 patients with anatomically PLPs to 53 patients with RPs for clavicle fractures. After a follow-up of 12 months, there were no significant differences in union rate (98.1% vs. 96.2%, $p>0.05$) or time to union (12.8 vs. 13.5 weeks, $p>0.05$). However, the PLPs group demonstrated significantly fewer complications (17.0% vs. 35.8%, $p<0.05$) and lower implant removal rates (11.3% vs. 30.2%, $p<0.05$). The authors concluded that while both plate types achieve satisfactory radiological outcomes, anatomically pre-

contoured plates result in fewer complications and lower implant removal rates than RPs.[15]

7. Jiang et al., (China, 2012) compared conventional ORIF with MIPO techniques using LCPs for midshaft CF. Outcomes were assessed using the CMS and union rates at a mean follow-up. The MIPO group demonstrated comparable union rates (100% vs. 96.9%) but significantly shorter union time (12 weeks vs. 14 weeks, $p<0.05$), less blood loss, shorter operation time, and smaller incisions. Functional outcomes were similar between groups (Constant scores 96.1 vs. 94.3, $p>0.05$). The authors concluded that the MIPO technique provides comparable functional outcomes with less surgical trauma and may be a viable alternative to conventional ORIF.[17]
8. Fridberg et al., (Denmark, 2013) conducted a study of 105 consecutive patients treated with LCPs for CF. The study focused on complication and reoperation rates rather than comparative outcomes. There was a 94% bony union rate, and the average time it took to union was 16 weeks. Complications occurred in 13 patients (12.4%), including non-union (6), deep infection (3), and mechanical failure (4). The authors concluded that LCPs is better one with acceptable complication rates, though patients should be informed about the potential need for implant removal.[16]
9. Kundangar et al., (India, 2019) compared open plating (n=28) with MIPO (MIPO, n=28) using LCPs for middle third clavicle fractures. Outcomes were assessed using the CMS, DASH score, and radiographic union at 6 weeks, 3 and 6 months. At 6 weeks (77.6 vs. 69.4, $p<0.05$) and 3 months (92.1 vs. 86.3, $p<0.05$), the MIPO group had considerably greater early Constant scores, albeit by 6 months, the scores had leveled out. There was less blood loss, a shorter operation duration, and superior cosmetic results in the MIPO group. Union rates were 96.4% for both methods. The study's authors found that compared to traditional open plating, MIPO leads to greater early functional recovery and similar long-term results.[18]

10. Meeuwis et al., (Netherlands, 2017) retrospectively analysed 97 patients treated with ORIF for DMCF, focusing on construct failure. The study included both RPs (n=41) and LCPs (n=56) with a mean follow-up more 3 years. Construct failure occurred in 8 patients (8.2%), with a significantly higher rate in the RPs group compared to the LCPs (14.6% vs. 3.6%, $p<0.05$). Risk factors for failure included comminuted fractures and plate positioning. The authors concluded that LCPs provide more stable fixation with lower failure rates than RPs, particularly in comminuted fractures, and recommended superior plate positioning to reduce failure risk.[13]
11. Wijdicks et al., (Netherlands, 2012) conducted a systematic review of 11 studies comprising 635 patients to evaluate complications of plate fixation for CF. The overall complication rate was 34%. Major complications included non-union (2.2%), infection (2.4%), and implant failure (1.9%). The most common complication was implant-related irritation (38.8% of complications), leading to implant removal in 13.7% of patients. The review found no significant differences in complication rates between RPs and locking plates, though hardware irritation appeared less frequent with anatomically contoured plates. The authors concluded that while plate fixation is effective, patients should be informed about the high rate of irritation symptoms and potential need for implant removal.[14]

## Complications Associated with Plate Fixation in CF

### Hardware-Related Complications

The commonly seen complications encountered in this fixation is hardware-related issues such as irritation and prominence. Patients often report discomfort due to the plate protruding under the skin, especially in those with less subcutaneous tissue. This can lead to requests for hardware removal, which, while generally straightforward, presents its own risks and costs.[51]

**Implant Failure**

Implant failure, including plate bending, breakage, and screw pullout, is a significant concern in clavicular fixation. These failures can occur due to inadequate fixation, excessive stress on the implant, or patient-specific factors such as bone quality. RPs, in particular, are more prone to bending and breakage compared to LCPs.[52]

**Infection Rates**

Infections, both superficial and deep, are potential complications following clavicular plate fixation. While the overall infection rate is low, deep infections can lead to severe complications, necessitating implant removal and further surgical intervention. The risk of infection is influenced by surgical technique, post-operative care, and patient factors such as diabetes or immunosuppression.[14]

**Non-union and Malunion**

Non-union and malunion represent failures of bone healing, where the fracture does not unite correctly or at all. Factors contributing to these complications include inadequate fixation, infection, and patient non-compliance with post-operative protocols. Malunion can result in functional impairment and persistent pain, often requiring corrective osteotomy and re-fixation.[53]

**Neurovascular Injuries**

Neurovascular injuries, although rare, are serious complications that can occur during clavicular surgery. The proximity of the clavicle to major neurovascular structures places them at risk during dissection and plate placement. Careful surgical technique and an understanding of clavicular anatomy are essential to minimize these risks.[54]

### CRPS

CRPS is a chronic pain condition that can develop after surgery or trauma. While rare, it can occur following clavicular fracture fixation, leading to prolonged rehabilitation and significant functional impairment. Early diagnosis and multidisciplinary management are crucial in mitigating the effects of CRPS.[14]

### Hypertrophic Scarring

Hypertrophic scarring is a cosmetic and sometimes functional complication of surgical incisions. In some patients, the incision site may develop excessive scar tissue, which can be uncomfortable and aesthetically displeasing. Treatment options include scar massage, silicone sheeting, and in severe cases, surgical revision.[12]

### Risk Factors for Complications

Several risk factors have been identified for complications following clavicular plate fixation. These include fracture type (e.g., comminuted or Z-type fractures), patient factors (e.g., smoking, diabetes), and technical aspects (e.g., plate selection, surgical technique). To reduce the occurrence of problems, it is helpful to be aware of these risk factors so that surgical the making of choices and patient counselling can be more informed. [55]

## Outcome Assessment Tools for CF

Several assessment tools are employed, each with unique strengths and limitations.

### CMS

The CMS is used in research for assessing shoulder function, including in patients with CF. It evaluates pain, daily activities, range of motion, and strength, providing a comprehensive overview of shoulder function. CMS is particularly useful for comparing pre- and post-treatment outcomes in clinical studies. Although not specifically designed for CF, its applicability to shoulder-related assessments makes it a valuable tool in this context.[56]

**DASH Score**

The DASH score is an end measure that looks at how well patients say their upper limbs work and what symptoms they are having. It talks about how function affects daily life and quality of life, which makes it very important for people with CF. Because it looks at how your body changes over time, the DASH score is a great way to keep track of your progress, compare treatments, and find places where you can improve. [57]

**VAS for Pain**

The VAS is a simple way to figure out how much pain someone is feeling. Patients rate their amount of pain on a range from 0 (no pain) to 10 (worst pain possible). The VAS is a popular tool in therapy because it can record how people feel about their pain and is pretty easy to use. It's a good way to figure out how well pain treatments for CF are working. [58]

**PROM**

To find out what the patient thinks about their health as well as how well their care is working, PROMs are important in fracture fixation. There aren't many PROMs that are specifically for CF, but tools like the DASH and also CMSs measure the condition's clinical and functional effects in a similar way. These measurements are very important for finding out how the treatment affected the patient.[59]

**Radiological Assessment Parameters**

Radiological exams are necessary to see how the bone is aligned, how it heals, and what effects it might have. Imaging techniques like X-rays and CT scans are often used to look at things like fracture narrowing, angulation, and callus growth. You might find out a lot about the clavicle's structure and how it heals from these tests.[60]

**Reliability and Validity of Different Assessment Tools**

We need true and reliable review tools if we want results that are always the same. The Constant-Murley and DASH scores are used in clinical and study settings because they have been shown to be very reliable and effective in many studies. Using imaging data to accurately check how fractures heal and how they are aligned requires careful method and analysis, even though the results are reliable.[61]

## Long-term Outcomes and QOL in CF

**Long-term Functional Results**

The kind of technique used to treat a clavicular fracture determines the patient's long-term functional prognosis. Surgical fixation, whether with RPs or LCPs, is associated with good functional results for patients, according to studies. The QOL and ability to carry out daily tasks may be negatively impacted for certain patients due to persistent functional deficiencies, such as decreased shoulder strength or endurance.[62]

**Implant Removal Rates and Indications**

After clavicular implant surgery, patients often wonder whether they should keep the implants or get rid of them because of the prominence, pain, or personal choice. Plates often result in a greater incidence of implant removal than other fixation systems. Hardware discomfort, infection, or a patient's desire for lifestyle reasons are common indications for removal. Consider all of the advantages and hazards, including the likelihood of refracture, before deciding to remove an implant.[63]

**Return to Work and Sports**

A lot of people with CF, especially sports, worry about not being able to do their favourite things and work out again. What the patient does for a living, how the fracture is being treated, and how bad it is are some of the things that affect when the patient can expect to return to work. Fracture refixation often lets people get back to high-level tasks faster than conventional treatments. However, healing times depend on a determinant of each patient's case.[64]

**Patient Satisfaction**

As a key sign of how well treatment is working, how happy the patient is very important. Three things that add to satisfaction of outcomes are the relief of symptoms, the return of function, and also the improvement in appearance. Even though everyone's experiences are different, surgery tends to make patients happier than preventative treatment because it speeds up healing and leaves less disability behind. [65]

**QOL Measures**

There is quality of life measures that we need to know how CF affects people in the big picture. A lot of the time, these kinds of exams include tests of psychological, bodily, and social performance. Studies show that after surgery, patients often say their QoL, pain levels, and daily skills get better over time. Long-term problems, like pain or limited movement, can still have a big effect on quality of life.[66]

**Economic Impact of Different Treatment Strategies**

People as well as healthcare systems should carefully consider how different ways of treating CF would affect their budgets in routine life. Surgical surgery may seem more expensive at first, but it saves money in the long run because it lowers the risk of problems and speeds up healing so that the person can go back to work. Cost-effectiveness analyses show that surgery may be a good choice for busy people who could lose a lot of money if they have problems or need to take time off.[67]

## Gaps in Current Literature and Future Directions in Clavicular Fracture Treatment

### Limitations of Existing Comparative Studies

Some of the research problems that CF comparison studies are now currently facing are small sample sizes, varied patient demographics, as well as different surgery procedures. Several studies done after the fact, which makes it hard to draw conclusions about cause and effect. Also, it's hard to compare studies because there aren't clear result metrics. These problems show that more thorough study methods are needed to get good results on the best ways to treat people.[68]

### Need for High-Quality RCTs

Good RCTs are needed to help us learn more about how to treat clavicular injuries. Recently not many RCTs that meet the standards for power and scientific rigor. These kinds of studies are needed to compare different surgery ways, look at long-term results, and find out how well new treatments work. RCTs might be able to give us the high-quality data we need to change professional standards and make care for patients better.[69]

### Developments in Implant Design and Materials

As new materials and techniques are used to make clavicular fracture devices work better, it's good to see improvement. New ways of making things, like 3D printing, have made it easier to make plates and devices that are already shaped to fit each patient. The goals of these improvements are better structural stability, less pain, and better fit and function of implants. New material research, like that into safe alloys, holds a lot of promise for the future.[44]

### Emerging Biological Augmentation Techniques

Two biological methods that show promise for helping fractures heal faster are the use of growth factors and bone grafts. When there is a difficult or non-union fracture, these methods try to speed up biological processes that make the bone heal faster and better in the end. More study is needed to find out how well and safely they work in everyday clinical practice. At the same time, research is still going on to find ways to combine these methods with standard fixing procedures.[70]

**Role of 3D Printing and Patient-Specific Implants**

3D printing has totally changed how implants are made to fit each patient. This has made it possible for more personalized treatment plans that take into account each person's unique anatomy. Surgery may take less time, implants may fit better, and effects may be better with this method. Researchers are also exploring the idea of using 3D-printed medical tools and instructions to boost accuracy and lower the risk of issues happening during surgery. More research needs to be done to make these methods better and figure out what long-term benefits they might have.[71]

**Areas Requiring Further Research**

More study is needed in a number of areas relating to how to treat clavicular fractures. Some of these questions are about how age and other health problems can affect treatment outcomes. Others are about the best ways to recover and the long-term effects of various fixing methods. It's important for healthcare systems to think about how different treatment choices affect their budgets, like how well they work and how many resources they need. To make full treatment suggestions, these study gaps will need to be filled.[72]

# MATERIALS AND METHODS

**Study Design and Study Setting**

A comparative prospective interventional study was conducted at the outpatient department of orthopaedics and emergency department of R.L. Jalappa Hospital and Research Centre, which is affiliated with SDUAHER.

**Study Period**

18 months (1 year and 6 months),

**Inclusion Criteria**

1. 18 to 60 years of age
2. DMCF of >2cm
3. Skin tenting in MCF
4. Bilateral MCF

The inclusion of displaced fractures (>2 cm) was based on evidence from previous studies suggesting higher non-union rates and suboptimal functional outcomes with non-operative management of such fractures (COTS, 2007).

**Exclusion Criteria**

1. History of previous fracture or injury over the clavicle
2. Non-union of MCFs
3. Pathological fractures
4. Contraindications to surgery by prevailing medical conditions
5. Bleeding disorders

**Sample Size Estimation**

The sample size was calculated based on the study by Avinash Kumar Katukam

et al., which evaluated outcomes in MCF treated with RPs versus LCPs. In their study population, the proportion of excellent and good outcomes was 66.6% in the RP group and 94.73% in the LCP group.[73] Using these values, the sample size was calculated using the formula:

$$N = 2\,(Z\alpha/2 + Z\beta)^2\,P(1-P)/(p1-p2)^2$$

Based on this calculation, we got a minimum required sample size of 24 patients in each group, for a total of 48 participants.

**Sampling Method**

Eligible patients who provided informed consent were randomized into two groups using simple random sampling through a computer-generated random number sequence to ensure unbiased allocation and minimize selection bias. This randomization process assigned 24 patients to Group A (RP) and 24 patients to Group B (LCP).

**Intervention**

All participants undergone an evaluation before surgery including detailed medical history, clinical examination, and radiographic evaluation with anteroposterior chest radiographs showing bilateral shoulder joints. Pre-anaesthetic evaluation and routine laboratory investigations were performed to assess medical fitness for surgery.

Surgical procedures were performed under appropriate anaesthesia using a standardized approach. The surgical procedure involved making a curved incision at the top of the clavicle, precisely where the fracture was located. Reduction was accomplished and kept in place for the time being with reduction clamps after meticulous dissection and exposure of the fracture site. The first group had RP contouring and application to the clavicle's upper surface. The upper part of the clavicle in Group B was covered by a pre-shaped LCP. In both groups, a minimum of six cortices of fixation was obtained on either side of the fracture. Wound closure was performed in layers, and a standard postoperative protocol was followed.

Postoperatively, all patients received intravenous antibiotics according to the departmental antibiotic policy. Sutures were removed on the 14th postoperative day, and patients were discharged with instructions for gradual mobilization and rehabilitation.

**Data Collection Procedure**

Patients were followed up at 6 weeks, 12 weeks, and 24 weeks postoperatively.

At each follow-up visit, the following parameters were assessed:

Pain was evaluated using the VAS, a validated, unidimensional measure of pain intensity widely used in diverse adult populations. The scale consists of a 10-cm line with anchors representing "no pain" (score 0) and "worst possible pain" (score 10), with higher scores indicating greater pain intensity.[74]

Functional outcome was assessed using the DASH score, a 30-item self-reported questionnaire designed to measure physical function and symptoms in patients with musculoskeletal disorders of the upper limb.[75] The DASH has demonstrated high test-retest reliability (ICC=0.96) and internal consistency(Cronbach's alpha=0.96) in previous validation studies (Beaton et al., 2001).[76]

Scores range from 0 (no disability) to 100 (severe disability), with lower

scores indicating better functional outcomes. Radiological union was evaluated using standardized anteroposterior radiographs. Fracture union was defined as the absence of subjective complaints and radiological invisibility of the fracture line, characterized by periosteal callus bridging the fracture site and extensions of trabeculations across the fracture line. Fractures that healed after 6 months without additional operative procedures were classified as delayed union, while those that did not unite after 6 months or required additional operative procedures were categorized as non-union.

Complications including implant failure, infection, and delayed union were systematically recorded at each follow-up visit.

All assessments were performed by the same investigators to minimize inter-observer variability and enhance reliability of the measurements.

**Data Analysis**

Statistical analysis was performed using IBM SPSS Statistics software version 22.0. Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as means with SD. For comparing the means of continuous variables between the two intervention groups, independent t-tests were applied. Chi-square tests or Fisher's exact tests (when expected cell countswere less than 5) were used for comparing categorical variables between groups.

Specifically, VAS scores and DASH scores were compared between the two groups at 6, 12, and 24 weeks using independent t-tests, while radiological union rates, implant failure, and infection rates were compared using chi-square or Fisher's exact tests. A p-value less than 0.05 was considered statistically significant for all analyses.

# RESULTS

***Table 1: Age distribution***

| Age in years | LCP | RP |
|---|---|---|
| Mean | 37.88 | 36.54 |
| Median | 39.5 | 33 |
| Std. Deviation | 12.47 | 11.455 |
| Minimum | 18 | 18 |
| Maximum | 58 | 58 |

The LCP group had a mean age of 37.88 years and the RP group demonstrated a slightly younger population with a mean age of 36.54 years.

***Table 2: Distribution according to fracture displacement in centimetres***

| Fracture displacement in centimetres | LCP | RP |
|---|---|---|
| Mean | 2.91 | 2.75 |
| Median | 3 | 2.75 |
| Std. Deviation | 0.418 | 0.416 |
| Minimum | 2 | 2 |
| Maximum | 4 | 4 |

The LCP group exhibited a mean displacement of 2.91 cm (SD=0.418), with a median of 3 cm and displacement range from 2 to 4 cm. The RP group showed a slightly lower mean displacement of 2.75 cm (SD=0.416), with an identical median (2.75 cm) and the same range of displacement (2-4 cm).

Table 3: Distribution according to VAS score

| Group | | 6 weeks | 12 weeks | 24 weeks |
|---|---|---|---|---|
| LCP | Mean | 3.46 | 2.51 | 1.49 |
| | Median | 3.50 | 2.60 | 1.40 |
| | Mode | 4 | 2 | 1 |
| | Std. Deviation | .302 | .286 | .308 |
| | Minimum | 3 | 2 | 1 |
| | Maximum | 4 | 3 | 2 |
| RP | Mean | 4.45 | 3.00 | 1.96 |
| | Median | 4.40 | 2.95 | 1.95 |
| | Mode | 4 | 3 | 2 |
| | Std. Deviation | .292 | .329 | .308 |
| | Minimum | 4 | 3 | 2 |
| | Maximum | 5 | 4 | 2 |

The LCP group demonstrated progressive improvement in VAS pain scores from 6 weeks (mean=3.46, SD=0.302) to 12 weeks (mean=2.51, SD=0.286) to 24 weeks (mean=1.49, SD=0.308). The RP group consistently showed higher pain scores at all timepoints: 6 weeks (mean=4.45, SD=0.292), 12 weeks (mean=3.00, SD=0.329), and 24 weeks (mean=1.96, SD=0.308). The data suggests that while both treatment modalities resulted in progressive pain reduction over time, the LCP was associated with lower pain scores throughout the recovery period, indicating potentially superior pain management outcomes.

*Table 4: DASH score*

| Group | | 6 weeks | 12 weeks | 24 weeks |
|---|---|---|---|---|
| LCP | Mean | 34.73 | 25.03 | 10.98 |
| | Median | 35.20 | 25.35 | 11.75 |
| | Mode | 30 | 27 | 12 |
| | Std. Deviation | 3.040 | 2.643 | 2.497 |
| | Minimum | 30 | 20 | 5 |
| | Maximum | 39 | 30 | 14 |
| RP | Mean | 44.49 | 29.96 | 16.04 |
| | Median | 44.30 | 31.20 | 15.95 |
| | Mode | 42 | 34 | 19 |
| | Std. Deviation | 2.810 | 3.082 | 3.233 |
| | Minimum | 40 | 25 | 10 |
| | Maximum | 50 | 34 | 20 |

The LCP group showed consistent improvement in functional outcomes with DASH scores decreasing from 6 weeks (mean=34.73, SD=3.040) to 12 weeks (mean=25.03, SD=2.643) to 24 weeks (mean=10.98, SD=2.497). The RP group demonstrated higher initial DASH scores at 6 weeks (mean=44.49, SD=2.810) and maintained higher scores at 12 weeks (mean=29.96, SD=3.082) and 24 weeks (mean=16.04, SD=3.233). The consistently lower DASH scores in the LCP group suggest better functional outcomes throughout the recovery period, with both groups showing substantial functional improvement by 24 weeks.

*Table 5: Gender differences*

| Group | Gender | Frequency | Percent |
|---|---|---|---|
| LCP | Female | 4 | 16.7 |
| | Male | 20 | 83.3 |
| | Total | 24 | 100.0 |
| RP | Female | 4 | 16.7 |
| | Male | 20 | 83.3 |
| | Total | 24 | 100.0 |

Among the study participants, in both groups 83.3 percent were males and 16.7 percent were females. There is no difference in proportion between both groups regarding gender.

*Figure 9: Gender differences*

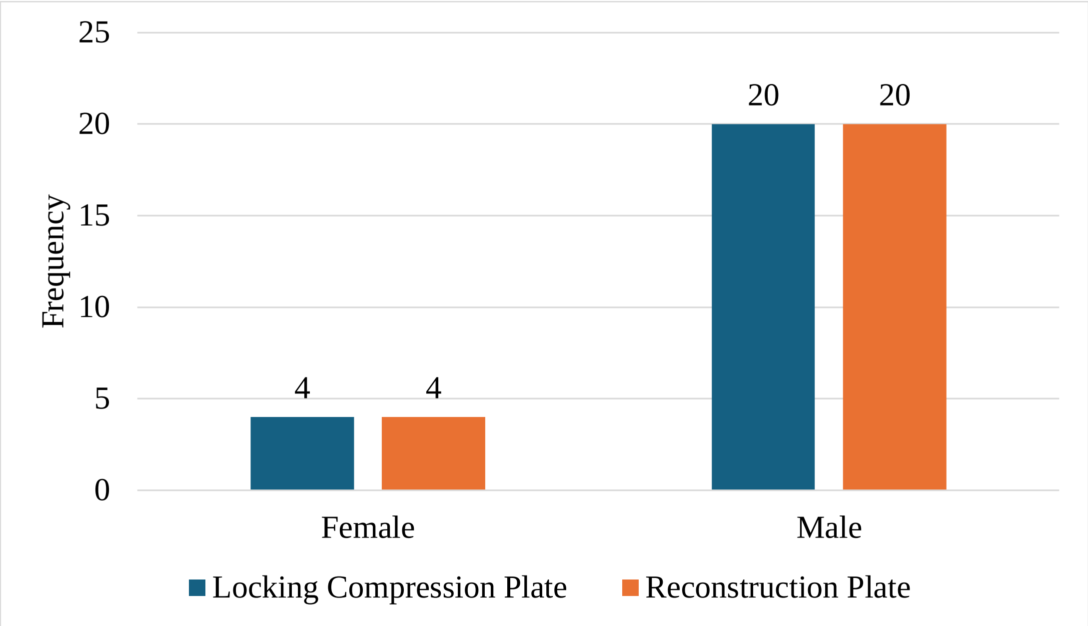


*Table 6: Radiological union at 12 weeks*

| Group | Radiological union at 12 weeks | Frequency | Percent |
|---|---|---|---|
| LCP | No | 6 | 25.0 |
| | Yes | 18 | 75.0 |
| | Total | 24 | 100.0 |
| RP | No | 7 | 29.2 |
| | Yes | 17 | 70.8 |
| | Total | 24 | 100.0 |

Among the study population in the LCP, 75 percent of them had radiological union at 6 weeks. People in the RP group, about 70.8 percent of them, had radiological union at 12 weeks. Thus, the LCP is better than the RP in terms of radiological union at 12 weeks.

*Figure 10: Radiological union at 12 weeks*

*Table 7: Radiological union at 24 weeks*

| Group | Radiological union at 24 weeks | Frequency | Percent |
|---|---|---|---|
| LCP | No | 0 | 0.0 |
| | Yes | 24 | 100.0 |
| | Total | 24 | 100.0 |
| RP | No | 3 | 12.5 |
| | Yes | 21 | 87.5 |
| | Total | 24 | 100.0 |

Among the study population in the LCP, 100 percent of them had radiological union at 24 weeks. People in the RP group, about 87.5 percent of them, had radiological union at 24 weeks.

*Figure 11: Radiological union at 24 weeks*

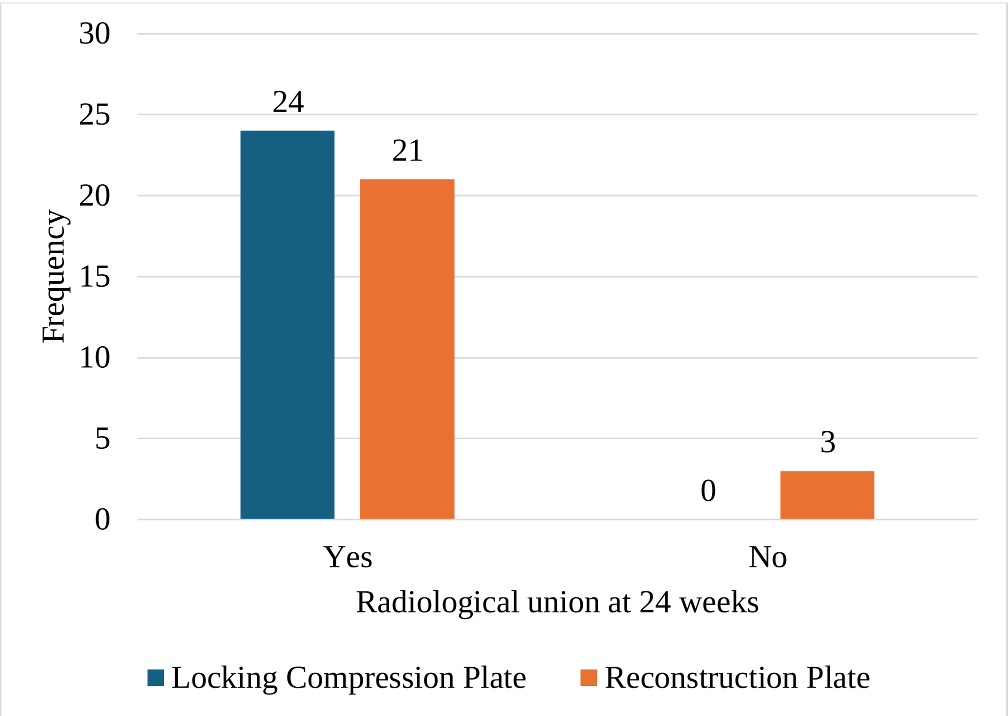


*Table 8: Implant failure*

| Group | Implant Failure | Frequency | Percent |
|---|---|---|---|
| LCP | No | 24 | 100.0 |
| RP | No | 23 | 95.8 |
| | Yes | 1 | 4.2 |
| | Total | 24 | 100.0 |

Among the study population in the LCP, 100 percent of them had no implant failure. People in the RP group, about 4.2 percent of them, had implant failure. Thus, the LCP is better than the RP in terms of implant failure.

*Figure 12: Implant failure*

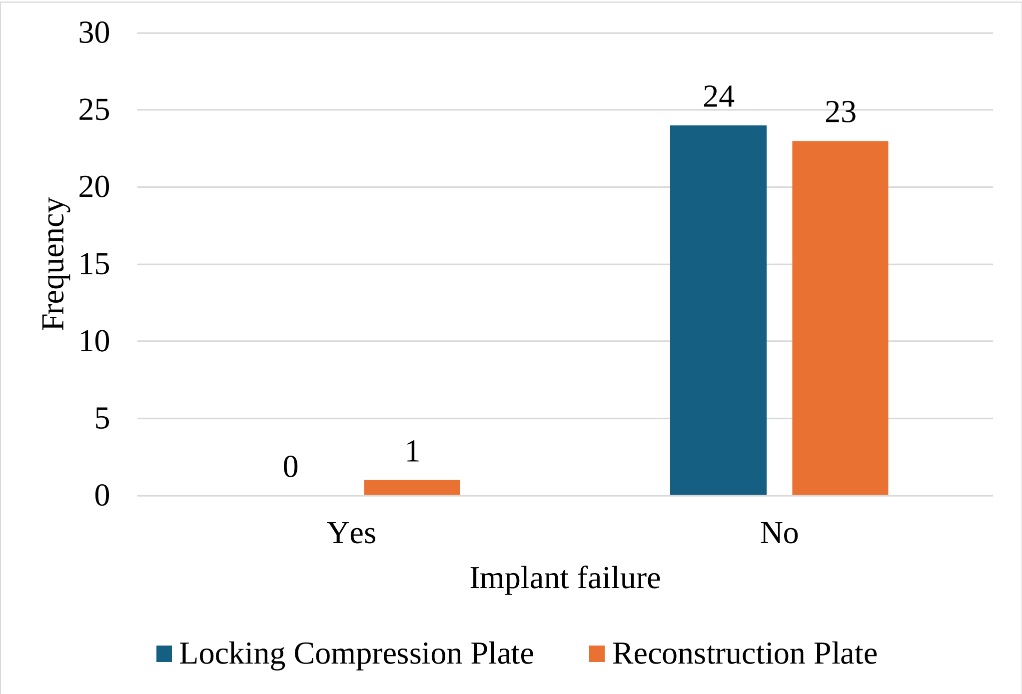


***Table 9: Delayed union***

| Group | Delayed union | Frequency | Percent |
|---|---|---|---|
| LCP | No | 24 | 100.0 |
| RP | No | 21 | 87.5 |
| | Yes | 3 | 12.5 |
| | Total | 24 | 100.0 |

Among the study population in the LCP, 100 percent of them had fracture union. People in the RP group, about 12.5 percent of them, had delayed union. Thus, the LCP is better than the RP in terms of assessing delayed union.

***Figure 13: Delayed union***

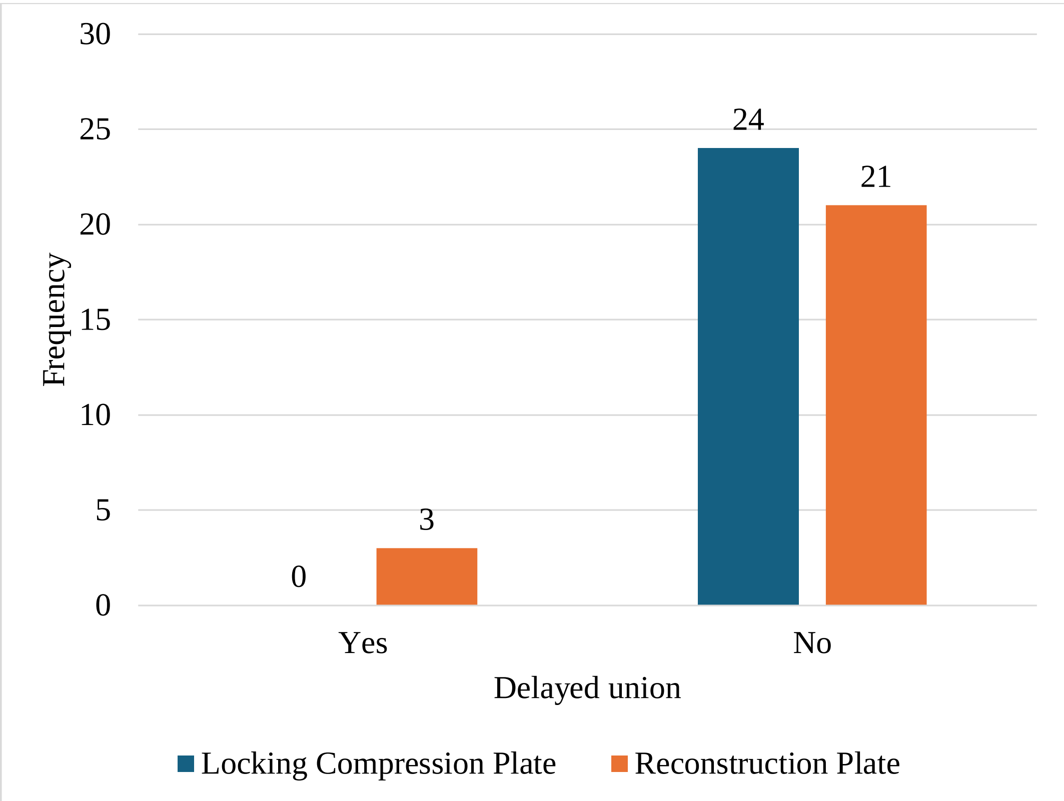


*Table 10: Infection acquired*

| Group | Infection | Frequency | Percent |
|---|---|---|---|
| LCP | No | 21 | 87.5 |
| | Yes | 3 | 12.5 |
| | Total | 24 | 100.0 |
| RP | No | 19 | 79.2 |
| | Yes | 5 | 20.8 |
| | Total | 24 | 100.0 |

Among the study population in the LCP, 12.5 percent of them had infection. People in the RP group, about 20.8 percent of them, had infection. Thus, the LCP is better than the RP in terms of infection acquired in post-surgical period.

*Figure 14: Infection acquired*

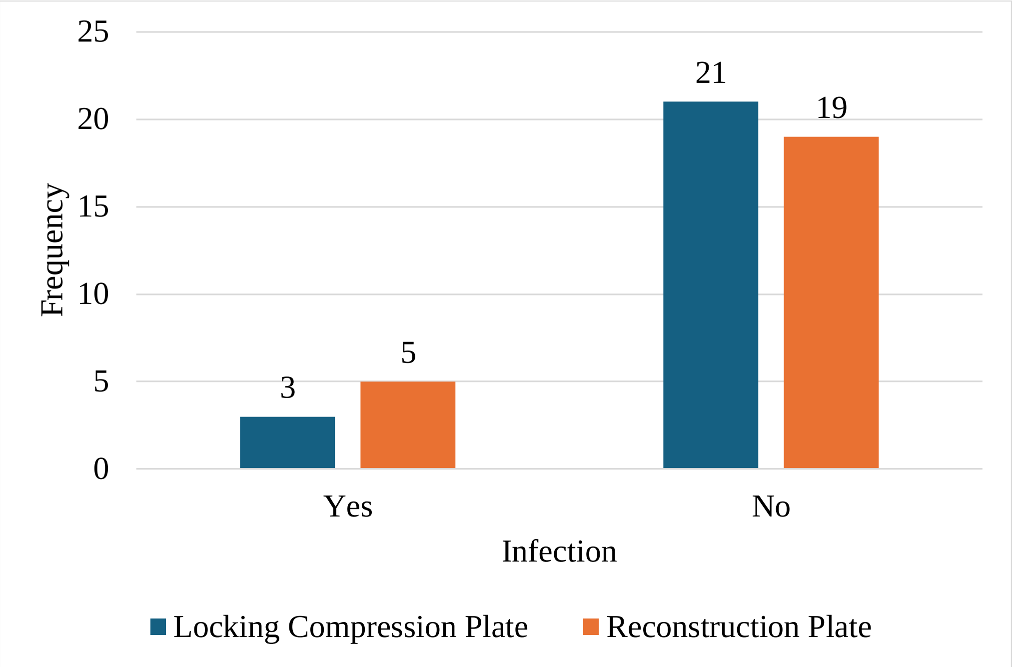


***Table 11: Association between LCP and RP according to fracture displacement among the study participants***

| Variable | Group | Mean | Std. Dev | Mean diff | P-Value |
|---|---|---|---|---|---|
| Fracture displacement in centimetres | LCP | 2.91 | .418 | 0.167 | 0.173 |
| | RP | 2.75 | .416 | | |

Among the study population in the LCP, the mean fracture displacement in centimetres was 2.91. People in the RP group, the mean fracture displacement in centimetres was 2.75. The difference in the mean between the above groups is not statistically significant (P – value = 0.173) according to independent T-test. Thus, there is no difference in both groups regarding fracture displacement.

***Table 12: Association between LCP and RP according to VAS score among the study participants***

| Variable | Group | Mean | Std. Dev | Mean diff | P-Value |
|---|---|---|---|---|---|
| 6 weeks | LCP | 3.46 | .302 | - 0.998 | < 0.0001 |
| | RP | 4.45 | .292 | | |
| 12 weeks | LCP | 2.51 | .286 | - 0.492 | < 0.0001 |
| | RP | 3.00 | .329 | | |
| 24 weeks | LCP | 1.49 | .308 | - 0.471 | < 0.0001 |
| | RP | 1.96 | .308 | | |

Among the study population in the LCP, the mean VAS score at 6 weeks was 3.46. For people in the RP group, the mean VAS score at 6 weeks was 4.45. The difference in the mean between the above groups is statistically significant according to an independent T-test. Thus, there is an association between VAS score and operating procedure. LCP have less VAS score than RP therefore LCPs are better than RPs.

***Table 13: Association between LCP and RP according to DASH score among the study participants***

| Variable | Group | Mean | Std. Dev | Mean diff | P-Value |
|---|---|---|---|---|---|
| 6 weeks | LCP | 34.73 | 3.040 | - 9.758 | < 0.0001 |
| | RP | 44.49 | 2.810 | | |
| 12 weeks | LCP | 25.03 | 2.643 | - 4.933 | < 0.0001 |
| | RP | 29.96 | 3.082 | | |
| 24 weeks | LCP | 10.98 | 2.497 | - 5.054 | < 0.0001 |
| | RP | 16.04 | 3.233 | | |

At 6 weeks, a notable variations was observed between the LCP group (mean=34.73, SD=3.040) and the RP group (mean=44.49, SD=2.810). This statistically significant difference persisted at 12 weeks (-4.933 points, p<0.0001) and 24 weeks (-5.054 points, p<0.0001). The consistent statistical significance across all timepoints provides strong evidence that the LCP offers superior functional outcomes throughout the recovery period compared to the RP.

*Table 14: Radiological Union Rates at 12 Weeks Post-Surgery by Treatment Group*

| Group | | Radiological union at 12 weeks | | Total | $\chi^2$ | P – Value |
|---|---|---|---|---|---|---|
| | | No | Yes | | | |
| LCP | Count | 6 | 18 | 24 | 0.105 | 0.745 |
| | % | 25.0% | 75.0% | 100.0% | | |
| LCP | Count | 7 | 17 | 24 | | |
| | % | 29.2% | 70.8% | 100.0% | | |

At 12 weeks, the LCP group demonstrated a 75.0% (18/24) union rate compared to 70.8% (17/24) in the RP group, though this difference was not statistically significant ($\chi^2$=0.105, p=0.745).

*Table 15: Radiological Union Rates at 24 Weeks Post-Surgery by Treatment Group*

| Group | | Radiological union at 24 weeks | | Total | $\chi^2$ | P – Value |
|---|---|---|---|---|---|---|
| | | No | Yes | | | |
| LCP | Count | 0 | 24 | 24 | 3.2 | 0.07 |
| | % | 12.5% | 87.5% | 100.0% | | |
| LCP | Count | 3 | 21 | 24 | | |
| | % | 12.5% | 87.5% | 100.0% | | |

By 24 weeks, the union rates improved to 87.5% (21/24) in both treatment groups, with no statistically significant difference between modalities ($\chi^2$=3.2, p=0.07). The data indicates similar radiological healing trajectories regardless of fixation method, with both approaches achieving comparable union rates by the final follow-up assessment, suggesting that either plate design provides adequate stability for fracture healing in the middle third clavicular region.

*Table 16: Comparison of Implant Failure Rates Between Treatment Groups*

| Group | | Implant Failure | | Total | Fischer exact test value | P – Value |
|---|---|---|---|---|---|---|
| | | No | Yes | | | |
| LCP | Count | 24 | 0 | 24 | 1.021 | 1.000 |
| | % | 100.0% | 0.0% | 100.0% | | |
| RP | Count | 23 | 1 | 24 | | |
| | % | 95.8% | 4.2% | 100.0% | | |

No implant failures occurred in the LCP group (0%, 0/24) over the course of the research. Although there was a single instance of implant failure in the RP group (4.2%, 1/24), Fisher's exact test (p=1.000) did not find a statistically significant difference between the two groups. There may be some mechanical benefits to using this fixation method for MCF, probably because to the increased stability provided by the locking mechanism between the screws and plate, as there were no implant failures in the LCP group, even though the results were not statistically significant.

*Table 17: Comparison of Delayed Union Rates Between Treatment Groups*

| Group | | Delayed union | | Total | Fischer exact test value | P – Value |
|---|---|---|---|---|---|---|
| | | No | Yes | | | |
| LCP | Count | 24 | 0 | 24 | 3.200 | 0.234 |
| | % | 100.0% | 0.0% | 100.0% | | |
| RP | Count | 21 | 3 | 24 | | |
| | % | 87.5% | 12.5% | 100.0% | | |

There were no instances of delayed union in the LCP group (0%, 0/24), but 12.5%, 3/24, occurred in the RP group. There was no statistically significant difference between the two groups, even after accounting for the numerical difference (p=0.234, Fisher's exact test). Even though it was not statistically significant, the fact that the LCP group did not have delayed union shows that there may be physiologic or biomechanical benefits to using LCP instead of standard RPs in MCF, which might lead to more predictable healing times.

*Table 18: Incidence of Post-Surgical Infection by Treatment Group*

| Group | | Infection | | Total | Fischer exact test value | P – Value |
|---|---|---|---|---|---|---|
| | | No | Yes | | | |
| LCP | Count | 21 | 3 | 24 | 0.600 | 0.701 |
| | % | 87.5% | 12.5% | 100.0% | | |
| RP | Count | 19 | 5 | 24 | | |
| | % | 79.2% | 20.8% | 100.0% | | |

The infection rate in the RP group was 20.8% (5/24), significantly greater than the 12.5% (3/24) in the LCP group. Nonetheless, the Fisher exact test yielded a p-value of just 0.701. It is important to take into account the somewhat high infection rates in both groups when practicing clinical medicine. This indicates that strict wound care procedures are necessary regardless of the implant type chosen for fixing middle third clavicular fractures.

# DISCUSSION

Using clinical as well as functional outcomes as the aim of this thesis, this study assessed at how well RPs and LCPs treated MCF. The two intervention methods are very different in terms of how much pain they have felt subjectively and objectively, how well they have worked, how often the bones were fused on x-ray, and any problems that have happened.

In a study of 512,187 people, Chen and their colleagues found in their study that CF was much more common in men compared to women ($p<0.001$). This is in line with the demographic profile of patients in this study, which showed that most of the patients (83.3%) were men in both treatment groups on comparison to females.[31] The increased risk of clavicular injuries in males may be linked to their greater involvement in contact sports and other high-energy activities .[33] In a study showed a peak incidence in the young to middle-aged adult population, which is consistent with the present study's patient mean age of 37.88 and 36.54 years, respectively, in the LCP and RP groups.[30]

Pain management outcomes, as assessed by VAS scores, demonstrated a consistent and statistically significant advantage for the LCP group at all time points. The mean VAS score at 6 weeks was significantly lower in the LCP group compared to the RP group. This finding aligns with the results reported by in a study. Who also observed superior pain relief with LCPs compared to RPs in the management of DMCF[20] The enhanced stability provided by the LCP, as described in the study biomechanical analysis of locking plate systems, may contribute to reduced micromotion at the fracture site, thereby diminishing pain during the healing process.[46]

Functional outcomes, as measured by the DASH score, similarly favoured the LCP group across all assessment intervals. The statistically significant mean difference of -9.758 points (p<0.0001) at 6 weeks, -4.933 points (p<0.0001) at 12 weeks, and -5.054 points (p<0.0001) at 24 weeks underscores the superior functional recovery associated with LCP fixation. This observation is consistent with the findings reported significantly better Constant shoulder scores in patients treated with LCPs (88.8±10.2) compared to RPs (80.2±12.7) (p=0.021).[12] Similarly, there is documente superior functional outcomes with anatomical PLPs compared to RPs, with mean DASH scores of 5.83±5.97 and 12.36±10.6 respectively (p=0.016).[10]

The biomechanical advantages of LCPs, particularly their enhanced resistance to torsional forces and improved fixation in osteopenic bone, as elucidated by Miller and Goswami (2007), may contribute to the observed functional benefits.[53] The anatomical precontouring of LCPs, which reduces the need for intraoperative plate manipulation, may also be a contributing factor to improved functional outcomes, as suggested in the studies.[48,51]

Radiological union is a critical parameter in assessing the efficacy of fracture fixation methodologies. In the present study, although the LCP group demonstrated higher union rates at 6 weeks (75.0% versus 70.8%) and 24 weeks (100% versus 87.5%) compared to the RP group, these differences did not reach statistical significance (p=0.745 and p=0.07, respectively). This finding is partially concordant with the observations of Cho et al. (2010, n=41, South Korea), who reported comparable union rates between LCPs and RPs (95.2% versus 95.0%) but with significantly shorter union times in the LCP group (13.2±2.8 weeks versus 16.8±4.2 weeks) (p=0.017).[12]

The absence of delayed union cases in the LCP group (0%) compared to the RP group (12.5%), although not statistically significant (p=0.234), suggests a potential biological or biomechanical advantage that may facilitate more predictable healing timeframes. Kingsly et al. (2019, n=40, India) found no instances of delayed union with LCPs, whereas Shahid et al. (2007, n=30, Pakistan) found a delayed union rate of 13.3% with RPs, therefore these tendencies are in line with each other.[10,44]

A major problem with CF surgery is implant failure, which often requires a second operation and extensive rehabilitation. The present research found that although the RP group did have one instance of implant failure (4.2%), there were no instances in the LCP group (0%). However, this difference was not statistically significant (p=1.000). This result is in line with what Wijdicks et al. found in their 2012 systematic evaluation of eleven research on the topic of CF plate attachment, which found implant failure rates between zero to twelve percent.[14] The lower incidence of implant failure with LCPs observed in the present study aligns with the biomechanical principles elucidated by Miller and Goswami (2007), particularly the enhanced stability provided by the locked interface between the screw and plate, which functions as a single unit, thereby distributing stress over a larger area and reducing the likelihood of failure.[46]

Post-operative infection represents another significant complication that can adversely affect healing and functional outcomes. The current study observed infection rates of 12.5% and 20.8% in the LCP and RP groups, respectively, though this difference did not reach statistical significance (p=0.701). These infection rates are somewhat higher than those reported in the literature, with Wijdicks et al. (2012) documenting infection rates ranging from 0% to 18% in their systematic review.[14] The relatively high infection rates observed in both groups of our study warrant consideration in clinical practice and suggest the need for rigorous wound care protocols regardless of the implant type selected.

Economic considerations play an increasingly important role in implant selection, particularly in resource-constrained healthcare environments. Although the current study did not specifically evaluate cost-effectiveness, it is worth noting that Gan et al. (2020, n=34, Malaysia) found no significant difference in total operative cost between locked compression plates and RPs (p=0.69), despite the higher unit cost of LCPs, attributable to shorter operative time and reduced need for implant removal with LCPs.[9]

Comparative studies evaluating different fixation modalities for MCF have yielded variable results, reflecting the complexity of implant selection and the multifactorial nature of clinical outcomes. Chiu et al. (2019, n=114, Taiwan) reported significantly lower implant failure rates with locking plates (0%) compared to RPs (14.3%) in their retrospective analysis, which is consistent with the trend observed in our study.[52] Conversely, Cho et al. (2010, n=41, South Korea) found comparable implant-related complication rates between LCPs and RPs but noted significantly shorter time to union and better functional outcomes with LCPs, aligning with our findings.[12]

The anatomical and biomechanical characteristics of the clavicle, as described by Harrington et al. (1993) in their analysis of the geometric properties of adult human clavicles, present unique challenges for fixation.[26] The S-shaped morphology, thin cortices, and predominantly cancellous bone in the middle third make it particularly susceptible to fixation failures. The variable cross-sectional geometry, with a flattened lateral portion and cylindrical medial portion, further complicates the achievement of optimal fixation. The LCP, with its fixed-angle stability, may better accommodate these anatomical peculiarities compared to the RP, as suggested by the findings of the current study.

The decision between operative and non-operative management of MCF remains contentious, with multiple RCTs and meta-analyses yielding conflicting results. The COTS (2007, n=132, Canada) demonstrated significantly better functional outcomes, lower non-union rates, and higher patient satisfaction with plate fixation compared to non-operative treatment in DMCF.[5] Similarly, Devji et al. (2015, n=15 studies) in their meta-analysis reported lower rates of malunion (RR 0.16, 95% CI 0.09-0.30) and non-union (RR 0.20, 95% CI 0.10-0.40) with operative intervention.[40] However, Lenza and Faloppa (2016, n=14 studies) in their Cochrane review concluded that while surgical intervention reduced the risk of non-union and symptomatic malunion, it was associated with a higher risk of adverse events and hardware removal.[4]

Within the surgical domain, the optimal implant for middle third clavicular fracture fixation remains debated. The introduction of LCPs has expanded the armamentarium available to orthopaedic surgeons, offering theoretical biomechanical advantages over traditional RPs. The present study contributes to this discourse by providing comparative data on clinical and functional outcomes with these two widely used implant systems.

**Clinical Significance**

The findings of this prospective interventional study comparing RPs versus LCPs for MCF have several clinically significant implications for orthopaedic practice. The statistically significant differences observed in pain scores and functional outcomes consistently favour the LCP, providing an evidence-based rationale for implant selection in this common orthopaedic injury.

The reduced pain scores associated with LCP fixation, as demonstrated by the significantly lower VAS scores at all assessment intervals (6, 12, and 24 weeks), may translate to enhanced patient comfort, reduced analgesic requirements, and potentially earlier mobilization. This has practical implications for post-operative pain management protocols and rehabilitation strategies. As Eden et al. (2015, n=86, Germany) demonstrated, pain reduction is a primary determinant of patient satisfaction following surgical treatment of DMCF.[54]

The superior functional outcomes observed with LCPs, evidenced by significantly lower DASH scores throughout the follow-up period, may facilitate earlier return to activities of daily living and occupational responsibilities. This has substantial socioeconomic implications, particularly for the predominantly young, economically active patient demographic affected by these injuries. Robertson and Wood (2016, n=10 studies) in their systematic review reported that return to sport following CF ranged from 0 to 12 weeks, with surgical fixation potentially allowing earlier return[64] The enhanced functional recovery associated with LCP fixation, as observed in our study, may further expedite this timeline.

The absence of implant failure cases in the LCP group, compared to 4.2% in the RP group, while not statistically significant, has practical implications for avoiding revision surgeries and the associated morbidity and healthcare costs. Meeuwis and their colleagues showed that lowering the failure rate of implants is important for therapy in the study patients. They found that 95% of the time, reconstruct failure after plate attachment of DMCF needed redo surgery among the participants. LCPs can help a lot of people who have weak bones or fractures that are hard to fix in these cases because they make the bones more biomechanically stable. This means that they can withstand rotational forces better and fixate better in osteopenic bone.[13]

There wasn't a big difference in the number of delayed union cases between the LCP and RP groups, but the fact that there weren't any in the LCP group suggests that LCP fixation makes recovery times more reliable. This changes how results are predicted as well as how doctors talk to patients about when they can expect to get better. Also, patients who had problems after having a CF repaired had much lower quality of life scores, as shown by van der Linde et al. (2017, n=97, Netherlands). This shows that delayed union and non-union can significantly lower QOL.[66]

The infection rates in both groups—12.5% in the LCP group and 20.8% in the RP group—are pretty high compared to what has been written, but they are not very different from each other. No matter what kind of implant is chosen, it is very important to be very careful with soft tissues, use the right antibiotics to prevent infections, and follow strict wound care steps while treating these injuries.

Even though there wasn't a statistically significant difference between the groups, the fact that the LCP group had a 100% rate of full imaging union at 24 weeks and the RP group had an 87.5% rate means that patients will be happier and more effective in the long run. Martetschläger et al. (2013, n=24 studies) talked about how important it is to get a stable union in their review of clavicular non-union and malunion treatment. The writers pointed out that these issues can cause a lot of harm, like long-lasting pain, limited function, and physical changes.[53]

In the end, this study is useful for therapy because it showed that LCP fixation for MCF worked better in terms of function and clinical outcomes. After looking at the data, doctors can make better decisions and choose the right implants, but more research is needed to find the best way to fix these injuries. This includes RCTs with a lot of people.

# CONCLUSION

The results of this prospective comparison study strongly suggest that LCP fixation is better for DMCF patients in terms of clinical and functional outcomes. The LCP group constantly had statistically significant improvements in pain scores and functional results at all evaluation points (6, 12, and 24 weeks), indicating that this fixing method made patients more comfortable and sped up their functional recovery. There were no statistically significant changes in the rates of imaging union, implant failure, or infection, but the total results are stronger because LCPs were found to be more likely to work in all of these areas. The absence of delayed union cases and implant failures in the LCP group, contrasted with 12.5% and 4.2% respectively in the RP group, suggests enhanced biomechanical and biological advantages with LCP fixation. These findings align with contemporary biomechanical understanding of locked plate systems, which provide enhanced stability through fixed-angle constructs and reduced plate-bone contact, potentially facilitating periosteal blood supply preservation. Based on these results, LCPs appear to offer clinically significant advantages for the surgical management of DMCF, though individualized decision-making considering patient factors, fracture characteristics, and resource availability remains paramount.

## STRENGTH OF THE STUDY

This prospective interventional study exhibits several notable methodological strengths that enhance the validity and reliability of its findings. The implementation of simple random sampling minimized selection bias and ensured equitable distribution of participants between treatment groups. The sample size calculation was methodologically sound, derived from previous research, with appropriate statistical parameters (10% type 1 error, 80% power), yielding a sufficiently powered study with 24 subjects per group. The prospective design with standardized follow-up intervals (6, 12, and 24 weeks) allowed for systematic evaluation of temporal changes in clinical and radiological parameters. The utilization of validated outcome measures—Visual Analogue Scale (VAS) for pain assessment and Disability of Arm, Shoulder and Hand (DASH) score for functional evaluation—ensured scientific rigor in outcome measurement. Additionally, the clear delineation of radiological union criteria enhanced objective assessment of fracture healing. The comprehensive assessment of complications (implant failure, delayed union, infection) provided valuable data on the safety profile of both fixation modalities. Finally, the study's focus on both clinical and functional outcomes offered a holistic evaluation of treatment efficacy, addressing patient-centered concerns beyond mere radiological healing.

# RECOMMENDATIONS

Future research should address the limitations identified in this study through several methodological enhancements. Larger, multi-centre RCTs with extended follow-up periods (minimum 2 years) would provide more robust evidence regarding long-term outcomes, including hardware-related complications necessitating implant removal. Studies incorporating patient-specific factors such as bone mineral density, smoking status, and compliance with rehabilitation protocols would help identify potential effect modifiers and refine patient selection criteria for specific implants. Cost-effectiveness analyses comparing different fixation modalities should be integrated into future research to inform evidence-based resource allocation in diverse healthcare settings. Investigation of MIPO techniques with both implant types could potentially further optimize outcomes by minimizing soft tissue disruption. Finally, studies evaluating PROM beyond DASH scores, including QOL assessments and return to specific activities (sports, occupation), would provide more comprehensive evaluation of patient-centered outcomes after surgical fixation of MCF.

# SUMMARY

This prospective interventional study was designed to compare the clinical and functional outcomes in MCF treated with RPs versus LCPs. The research was conducted at R.L. Jalappa Hospital and Research Centre, with 48 patients randomized into two equal groups: Group A receiving RPs and Group B receiving LCPs. In the study, standard measurement methods were used at set times (6, 12, and 24 weeks) to measure pain with the VAS and function with the DASH score. The study also used strict approaches to its methods.

The average age of patients in the LCP group was 37.88 years (SD=12.47) and the average age of patients in the RP group was 36.54 years (SD=11.455). In both groups, most of the people were guys (83.3%), which is in line with how CF is spread. At first, there wasn't a clear difference between the groups in the average amount of bone movement (2.91 cm vs. 2.75 cm, $p=0.173$).

The results demonstrated statistically significant differences in pain scores favoring the LCP group at all assessment intervals. At 6 weeks, the mean VAS score was 3.46 in the LCP group compared to 4.45 in the RP group ($p<0.0001$). This trend persisted at 12 weeks (2.51 versus 3.00) and 24 weeks (1.49 versus 1.96), indicating superior pain management with LCPs.

Functional outcomes, as measured by DASH scores, similarly favoured the LCP group across all time points. At 6 weeks, a significant mean difference of -9.758 points ($p<0.0001$) was observed between the LCP group (mean=34.73) and the RP group (mean=44.49). This statistically significant advantage persisted at 12 weeks (-4.933 points, $p<0.0001$) and 24 weeks (-5.054 points, $p<0.0001$), demonstrating enhanced functional recovery with LCPs.

Radiological union rates at 6 weeks (75.0% versus 70.8%, p=0.745) and 24 weeks (100% versus 87.5%, p=0.07) were higher in the LCP group, though not achieving statistical significance. Notable differences in complication rates were observed, with the LCP group demonstrating no cases of implant failure (0% versus 4.2%, p=1.000) or delayed union (0% versus 12.5%, p=0.234), and lower infection rates (12.5% versus 20.8%, p=0.701) compared to the RP group.

The study's strengths included its prospective design, randomized allocation, use of validated outcome measures, and comprehensive assessment of both clinical and functional parameters. Limitations encompassed the relatively small sample size, single-center design, and absence of long-term follow-up beyond 24 weeks.

The findings contribute significantly to the ongoing discourse regarding optimal fixation modalities for MCF, suggesting clinical and functional advantages with LCPs. The enhanced stability provided by the locking mechanism between screws and plate likely translates to reduced micromotion at the fracture site, diminishing pain and facilitating earlier functional recovery. These results align with biomechanical principles and previous comparative studies, providing evidence-based guidance for implant selection in the surgical management of this common orthopaedic injury.

# LIMITATION

The relatively small sample size (24 patients per group), while statistically justified, may limit the detection of significant differences in less frequent outcomes such as implant failure and delayed union. The follow-up period of 24 weeks, though sufficient for assessing initial union and early functional outcomes, precludes evaluation of long-term complications such as hardware-related discomfort necessitating implant removal, which has been reported to occur in 11-53% of cases in previous studies. The single-center design may limit generalizability to other healthcare settings with different surgical expertise, patient demographics, or post-operative protocols. The study did not account for potential confounding variables such as fracture complexity beyond displacement measurement, bone mineral density, or compliance with rehabilitation protocols, which may influence outcomes independently of implant selection. Additionally, the absence of blinding in outcome assessment introduces potential observer bias, particularly for subjective measures like VAS and DASH scores. Finally, the study did not include cost-effectiveness analysis, which is increasingly relevant in resource-constrained healthcare environments, considering the higher unit cost of LCPs compared to RPs, despite potentially lower complication rates.

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# ANNEXURE

## ANNEXURE - I

**SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR - 563101.**

**PATIENT INFORMATION SHEET**

**STUDY TITLE:"COMPARATIVE STUDY OF CLINICAL AND FUNCTIONAL OUTCOME IN MIDDLE THIRD CLAVICLE FRACTURES TREATED WITH RECONSTRUCTION PLATE VS LOCKING COMPRESSION PLATE ''**

**Study location:** R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

**Details-**Patients with suspected with middle third clavicle fractures presenting to Department of Orthopaedics of R.L.JALAPPA HOSPITAL AND RESEARCH CENTRE, attached to SRI DEVARAJ URS MEDICAL COLLEGE, TAMAKA, KOLAR

Patients in this study will have to undergo routine blood investigations (CBC, RFT, serum electrolytes, blood grouping, HIV & HBsAG), chest x ray AP view showing bilateral shoulder joint , ECG

You will undergo treatment with Reconstruction plate or Locking Compression Plate based on the group you were selected based on randomization

The following are the advantages of both the operations :

Good range of motion of shoulder , early return to work , reduce the risk of malunion and non union

The following are the complications with both the operations :

Pain,bleeding ,infection,iatrogenic fractures,neurovascular injuries

Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study we will collect information (as per proforma) from you or a person responsible for you or both. Relevant history will be taken. This information collected will be used only for dissertation and publication.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. This study has been reviewed by the Institutional Ethics Committee and you are free to contact the member of the Institutional Ethics Committee. There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

The expenses estimated for the patient for above procedure will be borne by the primary investigator.

**CONFIDENTIALITY**

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available. Your original records may be reviewed by your doctor or ethics review board. For further information/ clarification please contact

Dr. BORUSU SIVA NARAYANA (Post Graduate),

Department of ORTHOPAEDICS,

SDUMC, Kolar

CONTACT NO: 7660077564

ಶ್ರೀ ದೇವರಾಜ್ ಯುಆರ್ಎಸ್ ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತು ಸಂಶೋಧನೆ ಅಕಾಡೆಮಿ, ತಮಕ, ಕೋಲಾರ - 563101.

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ:“ಮಧ್ಯದ ಮೂರನೇ ಕ್ಲಾವಿಕಲ್ ಮುರಿತಗಳಲ್ಲಿ ಕ್ಲಿನಿಕಲ್ ಮತ್ತು ಕ್ರಿಯಾತ್ಮಕ ಫಲಿತಾಂಶದ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನವು ಮರುನಿರ್ಮಾಣ ಪ್ಲೇಟ್ ವಿರುದ್ಧ ಸಂಕೋಚನ ಪ್ಲೇಟ್ ಅನ್ನು ಲಾಕ್ ಮಾಡುವುದರೊಂದಿಗೆ ಚಿಕಿತ್ಸೆ ನೀಡಲಾಗುತ್ತದೆ.

ಅಧ್ಯಯನ ಸ್ಥಳ: ಆರ್ ಎಲ್ ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರವು ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಟಮಕ, ಕೋಲಾರ.

ವಿವರಗಳು-ಮಧ್ಯದ ಮೂರನೇ ಕ್ಲಾವಿಕಲ್ ಮುರಿತದ ಶಂಕಿತ ರೋಗಿಗಳು ಆರ್.ಎಲ್.ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರದ ಮೂಳೆಚಿಕಿತ್ಸಾ ವಿಭಾಗಕ್ಕೆ ಹಾಜರಾಗಿದ್ದಾರೆ, ಶ್ರೀ ದೇವರಾಜ್ ಯುಆರ್ಎಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ತಮಕ, ಕೋಲಾರ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ರೋಗಿಗಳು ವಾಡಿಕೆಯ ರಕ್ತ ಪರೀಕ್ಷೆಗಳಿಗೆ ಒಳಗಾಗಬೇಕಾಗುತ್ತದೆ (CBC, RFT, ಸೀರಮ್ ಎಲೆಕ್ಟ್ರೋಲೈಟ್‌ಗಳು, ರಕ್ತದ ಗುಂಪು, HIV ಮತ್ತು HBsAG), ದ್ವಿಪಕ್ಷೀಯ ಭುಜದ ಜಂಟಿ, ಇಸಿಜಿ ತೋರಿಸುವ ಎದೆಯ ಕ್ಷ ಕಿರಣ ಎಪಿ ವೀಕ್ಷಣೆಯಾದ್ಯಚ್ಛಿಕತೆಯ ಆಧಾರದ ಮೇಲೆ ನೀವು ಆಯ್ಕೆ ಮಾಡಿದ ಗುಂಪಿನ ಆಧಾರದ ಮೇಲೆ ನೀವು ಪುನರ್ನಿರ್ಮಾಣ ಪ್ಲೇಟ್ ಅಥವಾ ಲಾಕ್ ಕಂಪ್ರೆಷನ್ ಪ್ಲೇಟ್ನೊಂದಿಗೆ ಚಿಕಿತ್ಸೆಗೆ ಒಳಗಾಗುತ್ತೀರಿ

ಎರಡೂ ಕಾರ್ಯಾಚರಣೆಗಳ ಅನುಕೂಲಗಳು ಈ ಕೆಳಗಿನಂತಿವೆ:

ಭುಜದ ಚಲನೆಯ ಉತ್ತಮ ವ್ಯಾಪ್ತಿಯು, ಕೆಲಸಕ್ಕೆ ಬೇಗನೆ ಮರಳುವುದು, ಮಲ್ಯೂನಿಯನ್ ಮತ್ತು ಒಕ್ಕೂಟವಲ್ಲದ ಅಪಾಯವನ್ನು ಕಡಿಮೆ ಮಾಡುತ್ತದೆ

ಎರಡೂ ಕಾರ್ಯಾಚರಣೆಗಳ ತೊಡಕುಗಳು ಹೀಗಿವೆ:

ನೋವು, ರಕ್ತಸ್ರಾವ, ಸೋಂಕು, ಐಟ್ರೋಜೆನಿಕ್ ಮುರಿತಗಳು, ನ್ಯೂರೋವಾಸ್ಕುಲರ್ ಗಾಯಗಳು

ದಯವಿಟ್ಟು ಕೆಳಗಿನ ಮಾಹಿತಿಯನ್ನು ಓದಿ ಮತ್ತು ನಿಮ್ಮ ಕುಟುಂಬದ ಸದಸ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಿ. ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಬಹುದು. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸಮ್ಮತಿಸಿದರೆ ನಾವು ನಿಮ್ಮಿಂದ ಅಥವಾ ನಿಮ್ಮಿಂದ ಅಥವಾ ಇಬ್ಬರಿಗೂ ಜವಾಬ್ದಾರರಾಗಿರುವ ವ್ಯಕ್ತಿಯಿಂದ (ಪ್ರೊಫಾರ್ಮಾ ಪ್ರಕಾರ) ಮಾಹಿತಿಯನ್ನು ಸಂಗ್ರಹಿಸುತ್ತೇವೆ. ಸಂಬಂಧಿತ ಇತಿಹಾಸವನ್ನು ತೆಗೆದುಕೊಳ್ಳಲಾಗುವುದು. ಸಂಗ್ರಹಿಸಿದ ಈ ಮಾಹಿತಿಯನ್ನು ಪ್ರಬಂಧ ಮತ್ತು ಪ್ರಕಟಣೆಗೆ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ.

ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಲಾದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಯಾವುದೇ ಹೊರಗಿನವರಿಗೆ ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನವನ್ನು ಸಾಂಸ್ಥಿಕ ನೀತಿಶಾಸ್ತ್ರ ಸಮಿತಿಯು ಪರಿಶೀಲಿಸಿದೆ ಮತ್ತು ನೀವು ಸಾಂಸ್ಥಿಕ ನೀತಿಶಾಸ್ತ್ರ ಸಮಿತಿಯ ಸದಸ್ಯರನ್ನು ಸಂಪರ್ಕಿಸಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ. ಈ ಅಧ್ಯಯನವನ್ನು ಒಪ್ಪಿಕೊಳ್ಳಲು ಯಾವುದೇ ಒತ್ತಾಯವಿಲ್ಲ. ನೀವು ಭಾಗವಹಿಸಲು ಬಯಸದಿದ್ದರೆ ನೀವು ಪಡೆಯುವ ಕಾಳಜಿಯು ಬದಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸಿದರೆ ಮಾತ್ರ ನೀವು ಸಹಿ/ಹೆಬ್ಬೆರಳಿನ ಗುರುತನ್ನು ಒದಗಿಸಬೇಕಾಗುತ್ತದೆ.

ಮೇಲಿನ ಕಾರ್ಯವಿಧಾನಕ್ಕಾಗಿ ರೋಗಿಗೆ ಅಂದಾಜು ಮಾಡಲಾದ ವೆಚ್ಚಗಳನ್ನು ಪ್ರಾಥಮಿಕ ತನಿಖಾಧಿಕಾರಿಯು ಭರಿಸುತ್ತಾನೆ.

ಗೌಪ್ಯತೆ

ನಿಮ್ಮ ವೈದ್ಯಕೀಯ ಮಾಹಿತಿಯನ್ನು ಅಧ್ಯಯನ ವೈದ್ಯರು ಮತ್ತು ಸಿಬ್ಬಂದಿ ಗೌಪ್ಯವಾಗಿಡುತ್ತಾರೆ ಮತ್ತು ಸಾರ್ವಜನಿಕವಾಗಿ ಲಭ್ಯವಾಗುವಂತೆ ಮಾಡಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಮೂಲ ದಾಖಲೆಗಳನ್ನು ನಿಮ್ಮ ವೈದ್ಯರು ಅಥವಾ ಎಥಿಕ್ಸ್ ರಿವ್ಯೂ ಬೋರ್ಡ್ ಪರಿಶೀಲಿಸಬಹುದು. ಹೆಚ್ಚಿನ ಮಾಹಿತಿ / ಸ್ಪಷ್ಟೀಕರಣಕ್ಕಾಗಿ ದಯವಿಟ್ಟು ಸಂಪರ್ಕಿಸಿ

ಡಾ. ಬೋರುಸು ಶಿವ ನಾರಾಯಣ (ಸ್ನಾತಕೋತ್ತರ ಪದವೀಧರ),

ಆರ್ಥೋಪೆಡಿಕ್ಸ್ ವಿಭಾಗ,

SDUMC, ಕೋಲಾರ

ಸಂಪರ್ಕ ಸಂಖ್ಯೆ: 7660077564

# ANNEXURE - II

**SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR – 563101**

**INFORMED CONSENT FORM**

**Case no:**

**IP no:**

**TITLE:**

**COMPARATIVE STUDY OF CLINICAL AND FUNCTIONAL OUTCOME IN MIDDLE THIRD CLAVICLE FRACTURES TREATED WITH RECONSTRUCTION PLATE VS LOCKING COMPRESSION PLATE**

I, __________________________________________________ aged _____________ ,after being explained in my own vernacular language about the purpose of the study and the risks and complications of the procedure, hereby give my valid written informed consent without any force or prejudice for _which is a therapeutic procedure / open reduction and internal fixation with locking compression plate/reconstruction plate operation to be performed on me or _______ under any anaesthesia deemed fit. The nature and risks involved in the procedure (surgical and anaesthetical) have been explained to me to my satisfaction.

I have been explained in detail about the Clinical Research"COMPARATIVE STUDY OF CLINICAL AND FUNCTIONAL OUTCOME IN MIDDLE THIRD CLAVICLE FRACTURES TREATED WITH RECONSTRUCTION PLATE VS LOCKING COMPRESSION PLATE being conducted. I have read the patient information sheet and I have had the opportunity to ask any question. Any question that I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. I hereby give consent to provide my history, undergo physical examination, undergo the surgical procedure, undergo investigations and provide its results and documents etc to the doctor / institute etc.

For study purpose the operation / procedure, etc may be video graphed or photographed. All the data may be published or used for any academic purpose. I will not hold the doctors / institute etc responsible for any untoward consequences during the procedure / study.

A copy of this Informed Consent Form and Patient Information Sheet has been provided to the participant

(Signature & Name of Pt. Attendant ) (Signature/Thumb impression & Name of patient)

(Relation with patient ) …………………………

Witness :…………………………………

(Signature & Name of Research person /doctor) …………………………………..

ಮಾಹಿತಿ ನೀಡಿದ ಒಪ್ಪಿಗೆ ನಮೂನೆ

ಪ್ರಕರಣ ಸಂಖ್ಯೆ :

IP ಸಂಖ್ಯೆ :

ಶೀರ್ಷಿಕೆ :

ಶೀರ್ಷಿಕೆ:

ಮಧ್ಯದಲ್ಲಿ ಮೂರನೇ ಕ್ಲಾವಿಕಲ್ ಮುರಿತಗಳಲ್ಲಿ ಕ್ಲಿನಿಕಲ್ ಮತ್ತು ಕ್ರಿಯಾತ್ಮಕ ಫಲಿತಾಂಶದ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನವು ಮರುನಿರ್ಮಾಣ ಪ್ಲೇಟ್ VS ಲಾಕ್ ಮಾಡುವ ಸಂಕೋಚನ ಫಲಕದೊಂದಿಗೆ ಚಿಕಿತ್ಸೆ ನೀಡಲಾಗುತ್ತದೆ

ನಾನು,

_______________________________________________________________________________

____________________________________ , ಅಧ್ಯಯನದ ಉದ್ದೇಶ ಮತ್ತು ಕಾರ್ಯವಿಧಾನದ ಅಪಾಯಗಳು ಮತ್ತು ತೊಡಕುಗಳ ಬಗ್ಗೆ ನನ್ನ ಸ್ವಂತ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಿದ ನಂತರ, ಈ ಮೂಲಕ ಯಾವುದೇ ಬಲ ಅಥವಾ ಪೂರ್ವಾಗ್ರಹವಿಲ್ಲದೆ ನನ್ನ ಮಾನ್ಯ ಲಿಖಿತ ತಿಳುವಳಿಕೆಯನ್ನು ನೀಡುತ್ತೇನೆ ಇದಕ್ಕಾಗಿ ಚಿಕಿತ್ಸಕ ವಿಧಾನ / ಮುಕ್ತ ಕಡಿತ ಮತ್ತು ಲಾಕಿಂಗ್ ಕಂಪ್ರೆಷನ್ ಪ್ಲೇಟ್/ಪುನರ್ನಿರ್ಮಾಣ ಪ್ಲೇಟ್ ಕಾರ್ಯಾಚರಣೆಯೊಂದಿಗೆ ಆಂತರಿಕ ಸ್ಥಿರೀಕರಣವನ್ನು ನನ್ನ ಮೇಲೆ ಅಥವಾ _______ ಯಾವುದೇ ಅರಿವಳಿಕೆ ಅಡಿಯಲ್ಲಿ ಫಿಟ್ ಎಂದು ಪರಿಗಣಿಸಲಾಗಿದೆ. ಕಾರ್ಯವಿಧಾನದಲ್ಲಿ ಒಳಗೊಂಡಿರುವ ಸ್ವಭಾವ ಮತ್ತು ಅಪಾಯಗಳು (ಶಸ್ತ್ರಚಿಕಿತ್ಸೆ ಮತ್ತು ಅರಿವಳಿಕೆ) ನನ್ನ ತೃಪ್ತಿಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಕ್ಲಿನಿಕಲ್ ರಿಸರ್ಚ್"ರಿಕನ್ಸ್ಟ್ರಕ್ಷನ್ ಪ್ಲೇಟ್ VS ಲಾಕಿಂಗ್ ಕಂಪ್ರೆಷನ್ ಪ್ಲೇಟ್‌ನೊಂದಿಗೆ ಚಿಕಿತ್ಸೆ ನೀಡಲಾದ ಮಧ್ಯದ ಮೂರನೇ ಕ್ಲಾವಿಕಲ್ ಮುರಿತಗಳಲ್ಲಿ ಕ್ಲಿನಿಕಲ್ ಮತ್ತು ಕ್ರಿಯಾತ್ಮಕ ಫಲಿತಾಂಶದ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನದ ಕುರಿತು ನನಗೆ ವಿವರವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ. ನಾನು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ. ನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವವನಾಗಿ ಭಾಗವಹಿಸಲು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸುತ್ತೇನೆ. ನನ್ನ ಇತಿಹಾಸವನ್ನು ಒದಗಿಸಲು, ದೈಹಿಕ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಲು, ಚುಚ್ಚುಮದ್ದಿನ ಕಾರ್ಯವಿಧಾನಕ್ಕೆ ಒಳಗಾಗಲು, ತನಿಖೆಗೆ ಒಳಗಾಗಲು ಮತ್ತು ಅದರ ಫಲಿತಾಂಶಗಳು ಮತ್ತು ದಾಖಲೆಗಳನ್ನು ಇತ್ಯಾದಿಗಳನ್ನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳಿಗೆ ಒದಗಿಸಲು ನಾನು ಈ ಮೂಲಕ ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ.

ಅಧ್ಯಯನದ ಉದ್ದೇಶಕ್ಕಾಗಿ ಕಾರ್ಯಾಚರಣೆ / ಕಾರ್ಯವಿಧಾನ, ಇತ್ಯಾದಿಗಳನ್ನು ವೀಡಿಯೊ ಗ್ರಾಫ್ ಅಥವಾ ಛಾಯಾಚಿತ್ರ ಮಾಡಬಹುದು. ಎಲ್ಲಾ ಡೇಟಾವನ್ನು ಪ್ರಕಟಿಸಬಹುದು ಅಥವಾ ಯಾವುದೇ ಶೈಕ್ಷಣಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಬಹುದು. ಕಾರ್ಯವಿಧಾನ / ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಅಹಿತಕರ ಪರಿಣಾಮಗಳಿಗೆ ನಾನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳನ್ನು ಜವಾಬ್ದಾರರನ್ನಾಗಿ ಮಾಡುವುದಿಲ್ಲ.

ಈ ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ ನಮೂನೆಯ ಪ್ರತಿಯನ್ನು ಮತ್ತು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಭಾಗವಹಿಸುವವರಿಗೆ ಒದಗಿಸಲಾಗಿದೆ

(ಪಿಟಿ. ಅಟೆಂಡೆಂಟ್‌ನ ಸಹಿ ಮತ್ತು ಹೆಸರು) (ಸಹಿ/ಹೆಬ್ಬೆರಳಿನ ಗುರುತು ಮತ್ತು ರೋಗಿಯ ಹೆಸರು)

(ರೋಗಿಯೊಂದಿಗಿನ ಸಂಬಂಧ) ………………………………

ಸಾಕ್ಷಿ :…………………………………

(ಸಂಶೋಧನಾ ವ್ಯಕ್ತಿ/ವೈದ್ಯರ ಸಹಿ ಮತ್ತು ಹೆಸರು) ………………………………………

## ANNEXURE - III

**SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR - 563101.**

**IP no:**

**TITLE:**

COMPARATIVE STUDY OF CLINICAL AND FUNCTIONAL OUTCOME IN MIDDLE THIRD CLAVICLE FRACTURES TREATED WITH RECONSTRUCTION PLATE VS LOCKING COMPRESSION PLATE

**1. BASIC DATA**

Name

Age/Sex

Address

Mobile No.

Date of operation

Date of Admission/OP

Date of Discharge

**History**:

**General physical examination:**

**Vitals:** Pulse- B.P-

RR- Temp-

**Systemic examination:**

CVS-

RS-

PA-

CNS-

**Preexisting systemic illness:**

Diabetes/Thyroid disorder/ Cervical Spine/ CVS/RS/ CNS/ TB/ Anemia/ Hypertension/ Malnutrition/others

**Local examination:**

IV) LOCAL EXAMINATION :

i) Inspection :

Attitude

Swelling

Deformity

Skin

ii) Palpation :

Local rise of temperature

Tenderness

Bony irregularity

Crepitus

iii) Movements :

iv) Neurovascular status :

v) Associated injuries

vi) Complications (if any)

2. **INVESTIGATIONS**:

- CBC
- BT, CT, Blood grouping , PT, INR ,APTT
- RBS
- RFT
- HIV, HBsAg and HCV status
- ECG
- Chest x ray
- RADIOLOGICAL INVESTIGATION:
    1. Antero posterior view of chest x-ray with bilateral shoulder .

**3. DIAGNOSIS**:

Middle Third Clavicle fractures

**4.OPERATIVE TREATMENT**:

- Operation date :
- Type of anesthesia:
- Approach used:

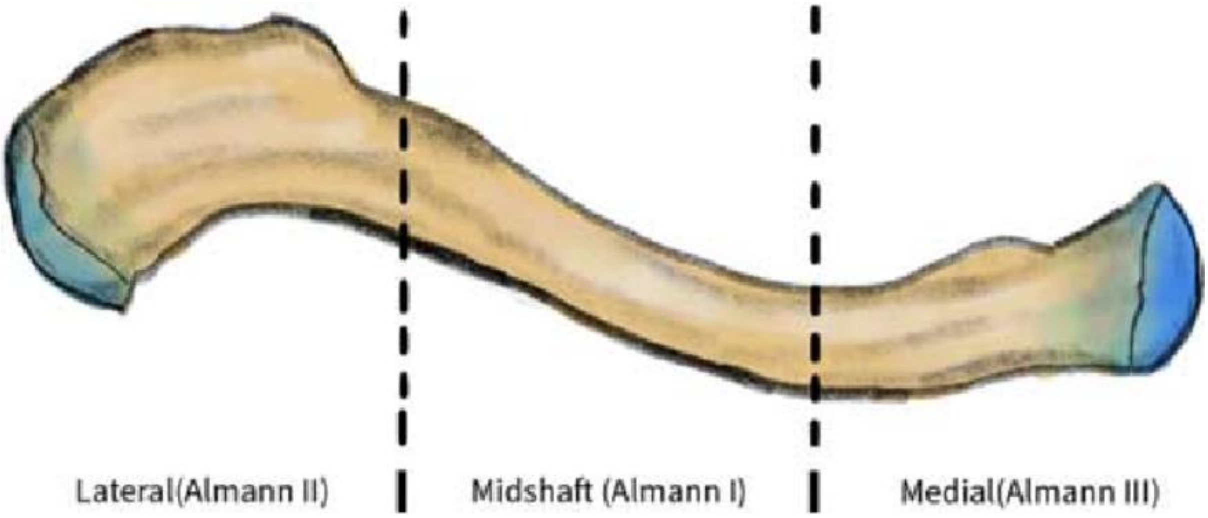
# ALLMAN CLASSIFICATION

Fractures of the clavicle is typically described using the Allman classification system, dividing the clavicle into 3 groups

Group I: Fractures of the middle third or midshaft fractures (the most common site),

Group II: Fractures of the distal or lateral third. A common site for non-union.

Group III: Fractures of the proximal or medial third.



# DASH SCORE

www.orthopaedicscores.com

Date of completion
May 21, 2014

## The Disabilities of the Arm, Shoulder and Hand (DASH) Score

Clinician's name (or ref) Marcus Chan

Patient's name (or ref A00001

**INSTRUCTIONS:** This questionnaire asks about your symptoms as well as your ability to perform certain activities. Please answer *every question* , based on your condition in the **last week**. If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate. It doesn't matter which hand or arm you use to perform the activity; please answer based on you ability regardless of how you perform the task.

**Please rate your ability to do the following activities in the last week.**

| Activity | No difficulty | Mild difficulty | Moderate difficulty | Severe difficulty | Unable |
|---|---|---|---|---|---|
| 1. Open a tight or new jar | ○ | ○ | ○ | ● | ○ |
| 2. Write | ○ | ○ | ● | ○ | ○ |
| 3. Turn a key | ○ | ● | ○ | ○ | ○ |
| 4. Prepare a meal | ○ | ○ | ● | ○ | ○ |
| 5. Push open a heavy door | ○ | ○ | ○ | ○ | ● |
| 6. Place an object on a shelf above your head | ○ | ○ | ○ | ○ | ● |
| 7. Do heavy household chores (eg wash walls, wash floors) | ○ | ○ | ○ | ● | ○ |
| 8. Garden or do yard work | ○ | ○ | ○ | ● | ○ |
| 9. Make a bed | ○ | ○ | ○ | ● | ○ |
| 10. Carry a shopping bag or briefcase | ○ | ● | ○ | ○ | ○ |
| 11. Carry a heavy object (over 10 lbs) | ○ | ○ | ● | ○ | ○ |
| 12. Change a lightbulb overhead | ○ | ○ | ○ | ● | ○ |
| 13. Wash or blow dry your hair | ○ | ○ | ○ | ● | ○ |
| 14. Wash your back | ○ | ○ | ○ | ○ | ● |
| 15. Put on a pullover sweater | ○ | ○ | ○ | ● | ○ |
| 16. Use a knife to cut food | ○ | ○ | ● | ○ | ○ |
| 17. Recreational activities which require little effort (eg cardplaying, knitting, etc) | ○ | ○ | ● | ○ | ○ |
| 18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (eg golf, hammering, tennis, etc) | ○ | ○ | ○ | ○ | ● |
| 19. Recreational activities in which you move your arm freely (eg playing frisbee, badminton, etc) | ○ | ○ | ○ | ○ | ● |
| 20. Manage transportation needs (getting from one place to another) | ● | ○ | ○ | ○ | ○ |
| 21. Sexual activities | ● | ○ | ○ | ○ | ○ |

| | | | | | | |
|---|---|---|---|---|---|---|
| 22. | During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? | ( ) Not at all | ( ) Slightly | ( ) Moderately | (•) Quite a bit | ( ) Extremely |
| 23. | During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? | ( ) Not limited at all | ( ) Slightly limited | ( ) Moderately limited | (•) Very limited | ( ) Unable |
| | **Please rate the severity of the following symptoms in the last week** | | | | | |
| 24. | Arm, shoulder or hand pain | ( ) None | (•) Mild | ( ) Moderate | ( ) Severe | ( ) Extreme |
| 25. | Arm, shoulder or hand pain when you performed any specific activity | ( ) None | ( ) Mild | ( ) Moderate | (•) Severe | ( ) Extreme |
| 26. | Tingling (pins and needles) in your arm, shoulder or hand | (•) None | ( ) Mild | ( ) Moderate | ( ) Severe | ( ) Extreme |
| 27. | Weakness in your arm, shoulder or hand | ( ) None | ( ) Mild | ( ) Moderate | ( ) Severe | (•) Extreme |
| 28. | Stiffness in your arm, shoulder or hand | (•) None | ( ) Mild | ( ) Moderate | ( ) Severe | ( ) Extreme |
| 29. | During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? | ( ) No difficulty | (•) Mild difficulty | ( ) Moderate difficulty | ( ) Severe difficulty | ( ) So much I can't sleep |
| 30. | I feel less capable, less confident or less useful because of my arm, shoulder or hand problem | ( ) Strongly disagree | ( ) Disagree | ( ) Neither agree nor disagree | ( ) Agree | (•) Strongly agree |

**Thank you very much for completing all the questions in this questionnaire.**

[Print page] [Close Window] [Reset]

To save this data please print or [Save As CSV]

Nb: This page cannot be saved due to patient data protection so please print the filled in form before closing the window.

**The Disabilies of the Arm, Shoulder and Hand (DASH) Score is** 60.0

( **NB.** A DASH score may not be calculated if there are greater than 3 missing items.)

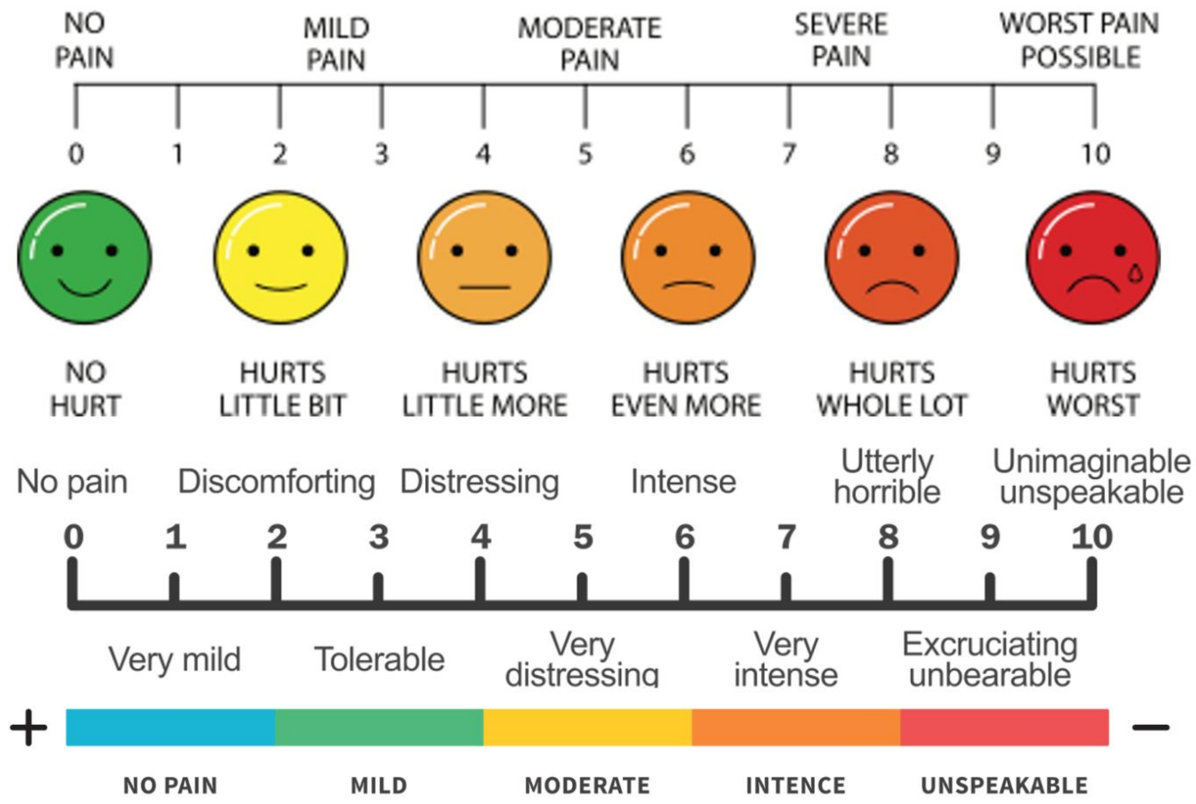
There are two further small sections to this score. They are both optional. Just click below to select

**WORK MODULE**

**SPORTS/PERFORMING ARTS MODULE**

**Reference for Score:** 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 Jun;29(6):602-8. Erratum in: Am J Ind Med 1996 Sep;30(3):372.

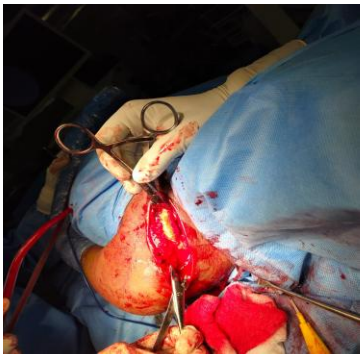
**VAS SCORE**


NO PAIN
MILD PAIN
MODERATE PAIN
SEVERE PAIN
WORST PAIN POSSIBLE
0 1 2 3 4 5 6 7 8 9 10
NO HURT
HURTS LITTLE BIT
HURTS LITTLE MORE
HURTS EVEN MORE
HURTS WHOLE LOT
HURTS WORST
No pain
Discomforting
Distressing
Intense
Utterly horrible
Unimaginable unspeakable
0 1 2 3 4 5 6 7 8 9 10
Very mild
Tolerable
Very distressing
Very intense
Excruciating unbearable
+
NO PAIN
MILD
MODERATE
INTENCE
UNSPEAKABLE

# IMPLANTS USED

## INTRA OP IMAGES

INCISION



FRACTURE REDUCTION

PL ACEMENT OF PLATE

FIXATION WITH SCREWS

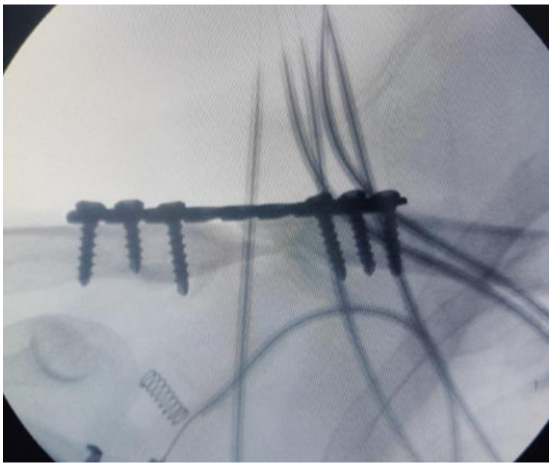
SKIN CLOSURE

SCAR IMAGE

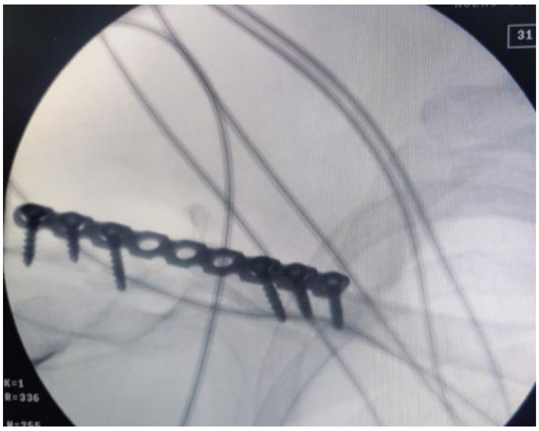
## C-ARM IMAGES

LCP PLATE

LCP PLATE



RECONSTRUCTION PLATE

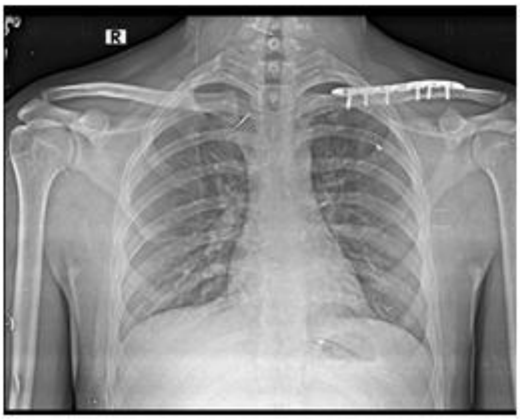


RECONSTRUCTION PLATE

PRE OP X-RAY

6 WEEKS

12 WEEKS



24 WEEKS

**LCP PLATE (CASE 1 X-RAYS)**

FLEXION

EXTENSION

ABDUCTION

EXTERNAL ROTATION

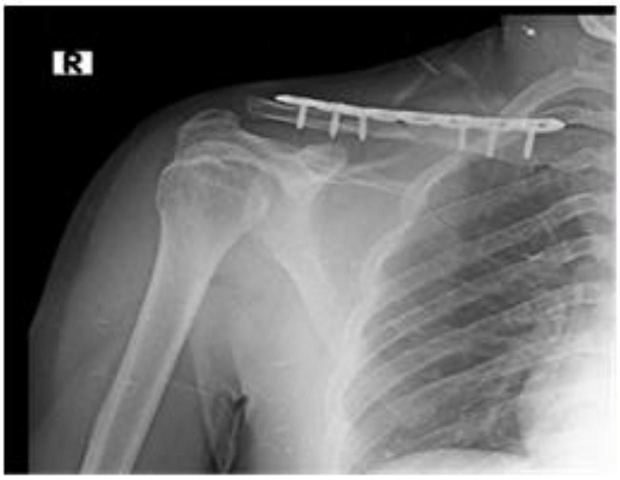
INTERNAL ROTATION



PRE OP X-RAY



6 WEEKS





12 WEEKS

24 WEEKS

**LCP PLATE (CASE 2 X-RAYS)**

FLEXION

EXTENSION

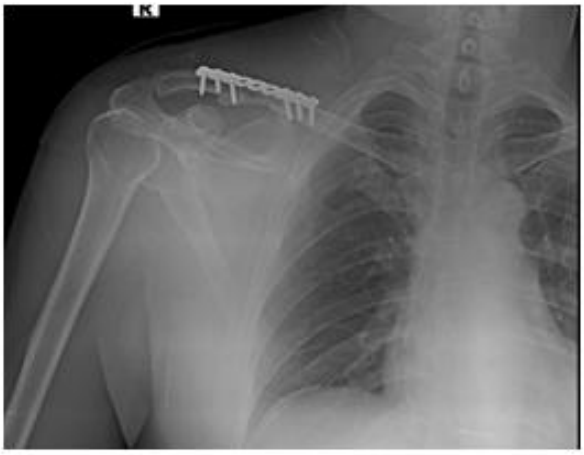
ABDUCTION

EXTERNAL ROTATION

INTERNAL ROTATION

**PRE OP X-RAY**

**6 WEEKS**



**12 WEEKS**

**24 WEEKS**

**RECONSTRUCTION PLATE (CASE 1 X-RAYS)**

**FLEXION**

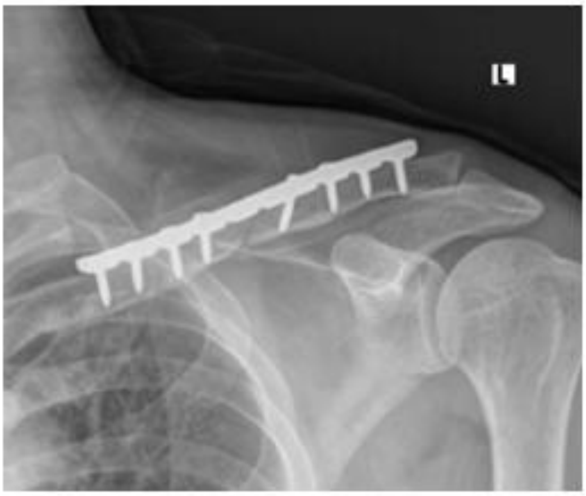
**EXTENSION**

**ABDUCTION**

**EXTERNAL ROTATION**

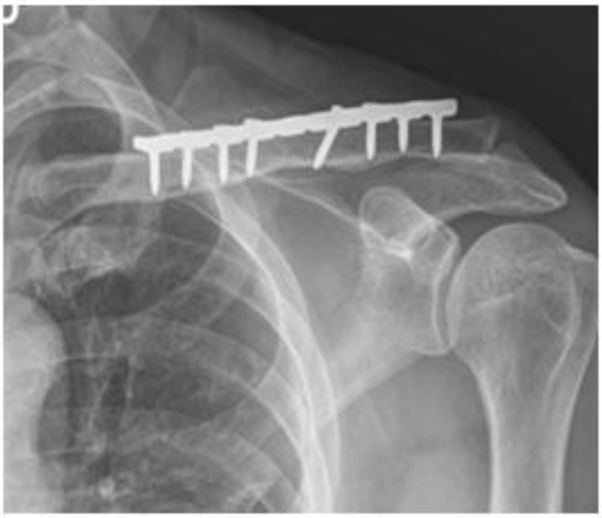
**INTERNAL ROTATION**


PRE OP X-RAY




1ST MONTH

3RD MONTH



6TH MONTH

**RECONSTRUCTION PLATE (CASE 2 X-RAYS)**

**FLEXION**

**EXTENSION**

**ABDUCTION**

**EXTERNAL ROTATION**

**INTERNAL ROTATION**

## KEY TO MASTER CHART

**M- MALE**

**F- FEMALE**

**RP - RECONSTRUCTION PLATE**

**LCP - LOCKING COMPRESSION PLATE**

**VAS - VIASUAL ANALOGUE SCORE**

**DASH SCORE - DISABILITY OF ARM SHOULDER AND HAND**

| Sl.No. | Age | Gender | Group | Displacement (cm) | VAS Score | | | DASH Score | | | Radiological Union | | | Implant Failure | Delayed union | Infection |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 6 WEEKS | 12 WEEKS | 24 WEEKS | 6 WEEKS | 12 WEEKS | 24 WEEKS | 6 WEEKS | 12 WEEKS | 24 WEEKS | | | |
| 1 | 58 | M | RP | 2.8 | 4 | 3 | 2 | 42 | 34 | 19 | 1 | 0 | 1 | NO | NO | NO |
| 2 | 31 | M | RP | 3.8 | 5 | 3 | 2 | 40 | 31 | 19 | 1 | 1 | 1 | NO | YES | NO |
| 3 | 32 | M | RP | 4.8 | 5 | 4 | 1 | 46 | 28 | 19 | 1 | 1 | 1 | NO | NO | YES |
| 4 | 48 | M | RP | 5.8 | 4 | 3 | 1 | 45 | 28 | 14 | 1 | 1 | 1 | NO | NO | NO |
| 5 | 18 | M | RP | 6.8 | 4 | 3 | 1 | 40 | 32 | 10 | 0 | 1 | 1 | NO | NO | YES |
| 6 | 20 | M | RP | 7.8 | 4 | 3 | 2 | 42 | 34 | 19 | 1 | 1 | 1 | NO | NO | NO |
| 7 | 33 | M | RP | 8.8 | 4 | 3 | 2 | 49 | 34 | 14 | 1 | 1 | 1 | NO | NO | NO |
| 8 | 40 | M | RP | 9.8 | 5 | 3 | 2 | 42 | 33 | 20 | 1 | 1 | 1 | NO | NO | YES |
| 9 | 28 | M | RP | 10.8 | 4 | 2 | 2 | 41 | 31 | 19 | 0 | 1 | 1 | NO | NO | YES |
| 10 | 29 | M | RP | 11.8 | 5 | 3 | 2 | 44 | 26 | 18 | 1 | 1 | 1 | NO | NO | NO |
| 11 | 27 | M | RP | 12.8 | 4 | 2 | 2 | 49 | 26 | 13 | 0 | 1 | 1 | NO | NO | NO |
| 12 | 49 | M | RP | 13.8 | 5 | 3 | 2 | 42 | 34 | 14 | 1 | 1 | 1 | NO | NO | NO |
| 13 | 33 | M | RP | 14.8 | 5 | 3 | 2 | 46 | 31 | 18 | 1 | 1 | 1 | NO | NO | NO |
| 14 | 25 | M | RP | 15.8 | 4 | 3 | 1 | 47 | 25 | 13 | 1 | 1 | 1 | NO | NO | NO |
| 15 | 55 | M | RP | 16.8 | 4 | 3 | 2 | 42 | 26 | 12 | 1 | 1 | 1 | NO | YES | NO |
| 16 | 29 | M | RP | 17.8 | 4 | 3 | 2 | 47 | 31 | 15 | 0 | 0 | 1 | NO | NO | NO |
| 17 | 41 | M | RP | 18.8 | 4 | 3 | 2 | 43 | 25 | 19 | 0 | 1 | 1 | NO | YES | NO |
| 18 | 45 | M | RP | 19.8 | 4 | 3 | 2 | 45 | 26 | 17 | 0 | 1 | 1 | NO | NO | YES |
| 19 | 25 | M | RP | 20.8 | 4 | 2 | 2 | 46 | 30 | 16 | 1 | 1 | 1 | NO | NO | NO |
| 20 | 45 | M | RP | 21.8 | 4 | 3 | 2 | 45 | 32 | 11 | 1 | 1 | 1 | NO | NO | NO |
| 21 | 53 | M | RP | 22.8 | 5 | 2 | 2 | 41 | 31 | 16 | 0 | 1 | 1 | NO | NO | NO |
| 22 | 43 | M | RP | 23.8 | 4 | 3 | 2 | 48 | 27 | 20 | 1 | 1 | 1 | NO | NO | NO |
| 23 | 25 | M | RP | 24.8 | 4 | 3 | 2 | 43 | 32 | 11 | 1 | 0 | 1 | NO | NO | NO |
| 24 | 45 | M | RP | 25.8 | 4 | 3 | 2 | 42 | 27 | 15 | 1 | 1 | 1 | YES | NO | NO |

| Sl.No. | Age | Gender | Group | Displacement (cm) | VAS Score | | | DASH Score | | | Radiological Union | | | Implant Failure | Delayed union | Infection |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 6 WEEKS | 12 WEEKS | 24 WEEKS | 6 WEEKS | 12 WEEKS | 24 WEEKS | 6 WEEKS | 12 WEEKS | 24 WEEKS | | | |
| 25 | 45 | M | LCP | 26.8 | 3 | 2 | 2 | 30 | 23 | 14 | 1 | 1 | 1 | NO | NO | YES |
| 26 | 54 | M | LCP | 27.8 | 4 | 3 | 2 | 36 | 27 | 12 | 0 | 1 | 1 | NO | NO | NO |
| 27 | 58 | M | LCP | 28.8 | 3 | 3 | 1 | 37 | 26 | 12 | 0 | 1 | 1 | NO | NO | NO |
| 28 | 53 | M | LCP | 29.8 | 3 | 3 | 1 | 30 | 28 | 12 | 1 | 1 | 1 | NO | NO | NO |
| 29 | 44 | M | LCP | 30.8 | 3 | 3 | 1 | 35 | 26 | 8 | 1 | 0 | 1 | NO | NO | NO |
| 30 | 34 | M | LCP | 31.8 | 3 | 2 | 1 | 32 | 26 | 8 | 1 | 1 | 1 | NO | NO | NO |
| 31 | 26 | M | LCP | 32.8 | 3 | 2 | 2 | 36 | 21 | 13 | 1 | 0 | 1 | NO | NO | NO |
| 32 | 50 | M | LCP | 33.8 | 3 | 2 | 2 | 32 | 24 | 13 | 1 | 0 | 1 | NO | NO | NO |
| 33 | 37 | M | LCP | 34.8 | 3 | 3 | 1 | 37 | 23 | 14 | 1 | 1 | 1 | NO | NO | NO |
| 34 | 30 | M | LCP | 35.8 | 4 | 2 | 1 | 34 | 22 | 14 | 0 | 1 | 1 | NO | NO | NO |
| 35 | 45 | M | LCP | 36.8 | 4 | 2 | 1 | 39 | 30 | 10 | 1 | 1 | 1 | NO | NO | NO |
| 36 | 46 | M | LCP | 37.8 | 4 | 2 | 1 | 31 | 24 | 10 | 1 | 1 | 1 | NO | NO | NO |
| 37 | 30 | M | LCP | 38.8 | 3 | 2 | 1 | 33 | 29 | 13 | 0 | 1 | 1 | NO | NO | NO |
| 38 | 52 | M | LCP | 39.8 | 3 | 2 | 1 | 31 | 26 | 11 | 0 | 1 | 1 | NO | NO | NO |
| 39 | 23 | M | LCP | 40.8 | 4 | 3 | 2 | 39 | 28 | 12 | 1 | 1 | 1 | NO | NO | YES |
| 40 | 35 | M | LCP | 41.8 | 3 | 2 | 1 | 39 | 25 | 13 | 1 | 1 | 1 | NO | NO | NO |
| 41 | 22 | M | LCP | 42.8 | 3 | 3 | 1 | 32 | 26 | 14 | 1 | 1 | 1 | NO | NO | YES |
| 42 | 42 | M | LCP | 43.8 | 4 | 2 | 2 | 36 | 25 | 8 | 1 | 1 | 1 | NO | NO | NO |
| 43 | 19 | M | LCP | 44.8 | 3 | 2 | 1 | 38 | 22 | 9 | 1 | 1 | 1 | NO | NO | NO |
| 44 | 27 | M | LCP | 45.8 | 4 | 3 | 2 | 35 | 27 | 6 | 0 | 1 | 1 | NO | NO | NO |
| 45 | 47 | M | LCP | 46.8 | 3 | 3 | 2 | 35 | 23 | 11 | 1 | 1 | 1 | NO | NO | NO |
| 46 | 22 | M | LCP | 47.8 | 4 | 2 | 1 | 32 | 20 | 5 | 1 | 1 | 1 | NO | NO | NO |
| 47 | 50 | M | LCP | 48.8 | 3 | 3 | 1 | 31 | 26 | 10 | 1 | 1 | 1 | NO | NO | NO |
| 48 | 18 | M | LCP | 49.8 | 4 | 2 | 1 | 39 | 22 | 10 | 1 | 1 | 1 | NO | NO | NO |