

**“A CLINICAL STUDY OF MID SHAFT CLAVICLE FRACTURE
TREATED WITH ANATOMICAL LOCKING
COMPRESSION PLATE”**

By

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Dissertation submitted to

BLDE UNIVERSITY, VIJAYAPUR, KARNATAKA.



In partial fulfillment of the requirements for the degree of

MASTER OF SURGERY

IN

ORTHOPAEDICS

Under the guidance of

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LIST OF ABBREVIATIONS USED

#	Fracture
AO	Association for osteosynthesis
AP	Arm pouch
ASIF	Association for the study of internal fixation
C	Comminution
D	Displacement
FB	Fall from bike
FOH	Fall on outstretched hand
FS	Fall on shoulder
GA	General Anaesthesia
LT	Left side
LCP	Locking compression plate
M	Male
MID	Middle third clavicle fracture
RT	Right side
B/L	Bilateral
RTA	Road traffic accident

ABSTRACT

Background and objectives:

Fractures of the clavicle is one of the most common injures of human skeleton. It has been traditionally treated non-operatively. The present study was undertaken to study the functional outcome and duration of unoin in midshaft clavicle fractures treated with anatomical locking compression plate

Methods:

Fifty patients with clavicle fractures treated surgically between December 2014 to January 2016 were included for this study. 50 middle third clavicle fractures were treated with Anatomical locking compression plate and screws.

Results:

Among 50 patients with middle third clavicle fracture treated with Anatomical locking compression plate and screws, 44 fractures united at an average of 11.13 weeks. 1 patient had plate loosening, 1 patient had plate breakage 3 patients had plate prominence. The functional outcome according to Constant and Murley score after fracture union in surgically treated middle third clavicle fractures were excellent in 38 patients, good in 8 patients and fair in 2 Patient and poor in 2 patient.

Conclusion:

This study shows rigid fixation with Anatomical locking compression plate and screws for fresh displaced or comminuted middle third clavicle fracture gives immediate pain relief and prevents the development of shoulder stiffness and non union.

Key words: Clavicle – Injuries, Fractures- Fixation, Internal –Methods, Anatomical Locking Compression Plate.

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INTRODUCTION

Midclavicle fracture is one of the most common injuries of the skeleton, representing 3% to 5% of all fractures and 45% of shoulder injuries. The annual incidence of midclavicle fracture is 64 per 100 000 population. Fractures of mid shaft contribute 70% to 80% of all clavicle fractures; lateral fractures contribute 15% to 30%, and medial fractures, at 3%, are relatively rare. Open clavicle fracture is an absolute rarity, found in only 0.1% to 1% of cases. The rate of midclavicle fractures is more than twice as high in men as in women. The peak incidence occurs in the third decade of life.¹

The clavicle is an S-shaped bone that acts as a strut between the sternum and the glenohumeral joint. It also has a suspensory function to the shoulder girdle. The shoulder hangs from the clavicle by the coracoclavicular ligament.²

The most commonly used system of classification of clavicle fractures is that of Allman. It is divided into 3 groups.²

- Group I: Middle-third fractures.
- Group II: Lateral-third fractures.
- Group III: Medial- third fractures.

A weak spot in the clavicle is present at the midclavicle region, which accounts for most fractures occurring in this region. Numerous muscular and ligamentous forces act on the clavicle, and knowledge of these differing forces is necessary to understand the nature of displacement of clavicle fractures and why certain fracture patterns tend to cause problems if not reduced and surgically stabilized.

The incidence of nonunion of midclavicle fractures is usually quoted as being from 0.1 to 0.8%, and the mainstay of treatment has long been nonoperative. These data, however, are based on studies in which clavicle fractures were not adequately classified regarding patient age and fracture displacement. More recent data, based on detailed classification of fractures, suggest that the incidence of nonunion in displaced comminuted midshaft clavicle fractures in adults is between 10 and 15%.³

Midshaft fractures have traditionally been treated non-operatively. Surgical treatment of acute midshaft clavicle fractures was not favoured due to relatively frequent and serious complications. However, the prevalence of non-union or mal-union in displaced midshaft clavicle fractures after conservative treatment is higher than previously presumed and fixation methods have evolved. Surgery is accepted more and more as primary treatment for displaced midshaft clavicle fractures, mainly because the results of non-operative treatment are interpreted as inferior to operative treatment both clinically and functionally.

Also persistent wide separation of fragments with interposition of soft tissue may lead to failure of closed reduction. There is 15% nonunion rate in widely displaced fracture of middle-third of the clavicle treated without surgery. And all fractures with initial shortening of more than 2cm resulted in nonunion.⁴

Several studies have examined the safety and efficacy of primary open reduction and internal fixation for completely displaced midshaft clavicle fractures and have noted high union rate with a low complication rate.⁵ In a large number of complex clavicle fractures a satisfactory outcome is possible with a low complication rate using a locked compression plate.⁶ Primary internal fixation of

displaced comminuted mid-shaft clavicle fractures leads to predictable and early return to function.⁷

While the overwhelming majority of clavicle fractures are benign, associated life-threatening intrathoracic injuries are possible. Complications vary based on location of fracture. Early complication likes brachial plexus compression , laceration of the great vessels, trachea, or esophagus, injuries to the neurovascular bundle and the pleural dome, poor cosmetic appearance, pneumothorax and intrathoracic injury. Late complication likes delayed union or nonunion resulting from hypertrophic callus formation.

The present consensus that great majority of clavicle fractures heal with non operative treatment is no longer valid. The amount of pain and disability during the first three weeks of conservative treatment has been underrated and the common view that non-union does not occur is wrong. Pressure from a displaced fragment on the retroclavicular part of the brachial plexus may cause symptoms after conservative treatment. Recent studies have shown that higher rate of non union and specific deficits of shoulder function in subgroups of patients with these injuries. Hence they can be treated as a spectrum of injuries requiring careful assessment and individualized treatment. Nonunion after a clavicular fracture is an uncommon occurrence, although the prevalence is higher than previously reported. There are subgroups of individuals who appear to be predisposed to the development of this complication either from intrinsic factors such as age or gender, or from the type of injury sustained.

There are various methods for treating clavicle midshaft fractures, such as intramedullary K-wires or Steinmann pins fixation and plate fixation. In particular, plate fixation can help obtain firm anatomical reduction in severe displaced or comminuted fracture.

There are various plates including Sherman plates, Dynamic compression plates and Semitubular plates, reconstruction plate and Anatomical locking compression plate (LCP). We have taken up this study to gain a deeper understanding of results and problems associated with this procedure, to evaluate the functional outcome after fixation of displaced midshaft clavicle fractures with Anatomical locking compression plate.

AIMS AND OBJECTIVES

To study the functional outcome and duration for union in midshaft clavicle fractures treated with anatomical locking compression plate.

REVIEW OF LITERATURE

In 1981, Zenni EJ Jr, Krieg JK and Rosen MJ concluded that the indications for open reduction and internal fixation should be: (1) neurovascular compromise due to posterior displacement and impingement of the bone fragments on the brachial plexus, subclavian vessels, and even the common carotid artery; (2) fracture of the distal third of the clavicle with disruption of the coracoclavicular ligament; (3) severe angulations or comminution of a fracture in the middle third of the clavicle; (4) the patient's inability to tolerate prolonged immobilization and (5) symptomatic non-union following treatment by closed methods.⁸

In 1987, JB Jupiter and RD Leffert reported that of all the etiological factors that were reviewed the extent of displacement of the original fracture was the most significant cause of non-union. Associated complications were limited mobility of the shoulder, neurovascular symptoms, and thoracic outlet syndrome.⁹

In 2002, Iannotti MR et al., concluded that clavicles plated at the superior aspect exhibit significantly greater biomechanical stability than those plated at the anterior aspect. Also concluded that the LCDC plate offers significantly greater biomechanical stability than the reconstruction and DC plates.¹⁰

In 2003 Michael McKee et al., reported that malunion following clavicle fracture may be associated with orthopedic, neurologic, and cosmetic complications. They concluded that in selected cases, corrective osteotomy results in a high degree of patient satisfaction and improves patient-based upper-extremity scores.¹¹

In 2006 Michael McKee et al., concluded that although good results with minimal functional deficits have been reported following nonoperative treatment of clavicle fractures, surgeon-based methods of evaluation may be insensitive to loss of muscle strength. They detected residual deficits in shoulder strength and endurance in this patient population, which may be related to the significant level of dysfunction detected by the patient-based outcome measures.¹²

2007- In a multicenter, prospective trial by the Canadian Orthopedic Trauma Society of displaced midshaft fracture, outcome and complication rates were compared for nonoperative treatment and plate fixation. Constant Shoulder scores and Disability of the Arm, Shoulder and Hand (DASH) scores were greatly improved in the operative fixation group. Mean time to radiographic union was faster in the operative group than in the nonoperative group. There were lower rates of nonunion in the operative group than in the nonoperative group. Symptomatic malunion was present in none of the operative group. At 1 year after injury, the operative-group patients were more likely to be satisfied with the appearance of the shoulder and with the shoulder in general than the nonoperative group patients.¹³

In 2007, Huang et al. concluded apex of the superior bow of the clavicle is typically located along the lateral aspect of the bone, whereas the medial aspect of the superior surface of the clavicle remains relatively flat, making it an ideal plating surface. They also opined that displaced midshaft clavicle fractures that are treated with plate fixation have better functional outcomes than those that are treated non operatively.¹⁴

In 2008, Wg Cdr V Kulshrestha reviewed the results of twenty cases of displaced/ comminuted midclavicle fractures, which were treated with primary open

reduction and internal fixation with a reconstruction plate placed over the superior surface of clavicle. All the fractures clinically united by eight weeks. As per Rowe criterion 12 had excellent, six good and two fair results. On an average patients had fully functional recovery in four months. Primary internal fixation of displaced comminuted mid-shaft clavicular fractures leads to predictable and early return to function thus preventing unacceptably high complication rates of nonoperative management of these fractures.⁷

In 2008, Wun-Jer Shen M.D.et al., operated on 251 fresh completely displaced mid- third clavicle fractures in adult. The fractures were plated with a Mizuho C-type plate or an AO/ASIF 3.5 mm reconstruction plate. The mean time to radiographic union was 10 weeks. Seven patients (3%) developed nonunion. Healing with angulation occurred in 14 patients. Deep infection developed in one patient, and superficial infection in four cases; 21 patients reported soreness with changes in the weather and activity; 28 patients had residual skin numbness caudal to the incision. No patient had shoulder droop, and none had impairment of range of motion or shoulder strength. None developed new or late neurovascular impairment; 171 patients eventually had the hardware removed at an average 401 days postoperatively. Overall, 94% were satisfied with the procedure. For completely displaced clavicle fractures in adults, plating is a reliable procedure.³

Between April 2003 and October 2009, N.Modi et al operated on 62 clavicle fractures using LCP plates through infraclavicular approach. All patients were followed up until clinical and radiological union was achieved (radiological union was determined by the presence of bridging callus and absence of fracture lines). At the final follow-up 53 patients were available for review. There were 42 male and 11 female patients with an average age of 45 years. The fractures were classified using

the system described by CM Robinson (28Type B1 fractures and 25Type B2 fractures). The average union time was 4.6 months. There was 1 superficial infection treated with oral antibiotics. There was 1 stress fracture medial to the plate which was treated non-operatively and the fracture united. There were 2 plate failures which required revision, one at 8 days post-op and other at 6weeks.⁶

In 2010, Gereon Schiffer et al presented and evaluated the current treatment options on the basis of a selective review of the literature. They confirmed some long-held concepts and refuted others. The risk of non-union after conservative treatment was previously reported as 1% to 2% but has turned out to be much higher in selected subgroups such as in patients with severe displacement, female patients, and patients of advanced age. Furthermore, new implants and techniques have made surgery safer and more likely to result in bony union.²

In 2010, Cho et al did a comparative study of reconstruction plate and reconstruction locking compression plate for the treatment of midshaft clavicle fractures. Forty one patients with a clavicle midshaft fracture were treated by internal fixation with a reconstruction plate (19 patients) or reconstruction LCP (22 patients). The mean time to union was 14.6 weeks in the reconstruction plate group compared to 13.2 weeks in the reconstruction LCP group ($p > 0.05$). The mean score to Quick DASH was 33.85 points in the reconstruction plate group compared to 34.81 points in the reconstruction LCP group ($p > 0.05$). The complications in the reconstruction plate were hypertrophic scarring in 2 cases, painful shoulder in 2 cases, limitation of shoulder motion in 2 cases, and screw loosening in 3 cases. In addition, the complications in the reconstruction LCP group was hypertrophic scarring in 4 cases, painful shoulder in 1 case and a limitation of shoulder motion in 1case ($p > 0.05$). This study showed radiologically and clinically satisfactory results in both groups.

Overall, operative treatment with a Reconstruction plate or reconstruction LCP for clavicle shaft fractures can be used to obtain stable fixation.¹⁵

In 2011, Darren S. Drosdowech et al in a biomechanical study compared four different techniques of fixation of middle third clavicle fractures. Twenty fresh-frozen clavicles were randomized into four groups. Each group used a different fixation device (3.5 Synthes reconstruction plate, 3.5 Synthes limited contact dynamic compression plate, 3.5 Synthes locking compression plate, and 4.5 DePuy Rockwood clavicular pin). All constructs were mechanically tested in bending and torque modes both with and without a simulated inferior cortical defect. Bending load to failure was also conducted. The four groups were compared using an analysis of variance test. The plate constructs were stiffer than the pin during both pure bending and torque loads with or without an inferior cortical defect.

Bending load to failure with an inferior cortical defect revealed that the reconstruction plate was weaker compared with the other three groups. The limited contact and locking plates were stiffer than the reconstruction plate but demonstrated statistical significance only with the cortical defect.¹⁶

In 2011 C VanBeek study concluded that Prominent hardware in 9 of 14 patients treated with noncontoured group and 9 of 28 treated with precontoured group. Hardware removal rates were 3 of 14 in noncontoured and 3 of 28 in the contoured group.¹⁷

In 2012 H. Jiang study concluded that union in 13 wks in conventional open reduction group and 12 wks in MIPPO group. operative treatment with a LCP for clavicle for clavicle shaft fractures can be used to obtain stable fixation. MIPPO of displaced midshaft clavicle fractures resulted in lower rate of dysesthesia, hypertrophic scarring, and a better cosmetic than conventional open reduction.¹⁸

In 2012 Yu-Cheng Lai et al., study concluded that 18 of 21 patients in dynamic compression plate group and 28 of 33 patients in locked compression plate group with an average follow-up of 19.9 and 18.1 months, respectively average hospital stay was 3.8 days in DCP group and 4.4 days in LCP groups. But more blood loss in DCP than LCP group.¹⁹

In 2013 Nathan Formaini study concluded that 138 patients underwent open reduction internal fixation with either a superior (n=82) or anteroinferior (n=56) plate for the treatment of an acute midshaft clavicle fracture. In orthopaedic trauma association clavicle fractures represented the majority of injuries in each group underwent treatment with an anteroinferior plate. But Largest difference between 2 groups was a significantly lower rate of patient reported implant prominence at long term follow up in patients treated with an anteroinferior plate.²⁰

In 2014 Juliann Kwak-Lee study concluded that in the Intramedullary pin group, there was a significant increased rate of implant failure compared to plate fixation. The pin group also demonstrated a significantly higher rate of infection than treated with plate fixation. But as plate fixation techniques included a larger incision and more dissection so complication of numbness and hypersensitivity over their incision sites which was not in pin fixation. Time of union in plate fixation with average 14.6 wks compared to pin fixation at 9.5wks. Fracture nonunion at 6 months was 6.0% in the plate group and 8.8% in pin group.²¹

In 2015 Ming Yang et al., study concluded that conventional plate fixation of comminuted midshaft fracture of the clavicle, wedge-shaped fragments often need to be fixed with lag screws. A new procedure, which included intramedullary K-wire assistance in reduction, binding fragments by suture, and eventually bridging plate fixation, was compared with conventional techniques. This new procedure is more

effective than the conventional techniques, and the fixation of free fragments using lag screws is not necessary. This was a retrospective study of 60 patients from August 2008 to March 2013 with comminuted midshaft clavicle fractures with wedge-shaped fragments. Seventeen patients were treated with conventional plate fixation, and the wedge-shaped fragments were fixed using lag screws. Another 43 patients were treated with the new procedure, including intramedullary K-wire assistance in reduction, binding of wedge-shaped fragments by suture, and bridging plate fixation. Patients were followed for an average of 13 months and radiographs were used to observe fracture healing. Shoulder function was assessed using the Constant Score System (CSS). There was no significant difference in bone healing time and shoulder function between the two study groups. The operating time for bridging plate fixation was significantly shorter than conventional plate fixation ($P=0.014$). Fractures healed in 14.9 ± 5.59 weeks for the conventional plate fixation (group) and in 13.6 ± 3.59 weeks for the bridging plate fixation group. One patient treated with conventional plate fixation had implant failure and underwent a second operation. Bridging plate fixation is a simple and effective procedure for comminuted midshaft clavicle fractures. The wedge-shaped fragments in comminuted midshaft clavicle fractures do not always need to be fixed by lag screws and the new procedure described is an effective treatment alternative.²²

In 2016 K. Ramkumar Reddy et al., study concluded that Fractures of the clavicle is one of the most common injuries of human skeleton. It has been traditionally treated non-operatively. Thirty adult patients with clavicle fractures treated surgically with locking compression plate and screws between September, 2013 to March, 2015. All thirty cases of clavicle midshaft fractures were treated with pre contoured locking plate under general anaesthesia. Passive range of motion stated

in third post op day. Average hospital stay was 10 days. The average time for fracture union is 9.3 weeks (8 – 12 weeks). The functional outcome according to Constant and Murley score is excellent in 19 patients (63.3%) and good in 11 patients (36.7%). Stable fixation with pre contoured locking compression plate and screws for fresh displaced or comminuted middle third clavicle fracture gives immediate pain relief and prevents the development of shoulder stiffness and non union.²³

In 2016 Raghu Kumar J study concluded that Clavicle fractures had been traditionally treated non operatively which resulted in high rates of non union, they reviewed the results of 20 cases of displaced middle third clavicle fractures (Robinson type 2B) which were treated with open reduction and internal fixation with pre-contoured locking compression plate at JJM Medical College. Out of 20 patients operated with Precontoured LCP, 12 were male and 8 were female patients. None of the patients developed superficial or deep wound infection. One patient had developed stiffness of the shoulder, One patient had implant prominence, one patient had delayed union and one patient had implant failure, none of them developed non union. Constant score was Excellent in 16, Good in 3 and Fair in 1 patients. Precontoured locking compression plate fixation has better functional outcome, results in early return to function and avoids complications of conservative methods.²⁴

ANATOMY

EVOLUTION:

- * As humans evolved into a biped and assumed an orthograde posture the shoulder girdle underwent changes in order to comply with the demands of a non weight bearing joint.
- * Clavicle is present in animals including man who use their upper limb for holding, grasping and climbing.
- * Mammals adapted for running and swimming have lost their clavicle to further mobilize their shoulder girdle.²⁵

PECULIARTIES OF CLAVICLE:

- * It is the only long bone to lie horizontally in the body
- * It is the only bone with membranous ossification
- * It is the first bone to ossify in the body
- * It lacks a well defined medullary cavity
- * It is subcutaneous throughout its whole extent
- * The shaft ossifies from two primary centres.²⁵

CLAVICLE ANATOMY:

The anatomical structures can be divided into following components, the osseous structures, the ligamentous structures, the muscular anatomy and the joints.²⁵

I) OSSEOUS STRUCTURE:

The clavicle is a relatively straight bone when viewed anteriorly where as in the transverse plane it resembles an italic S.

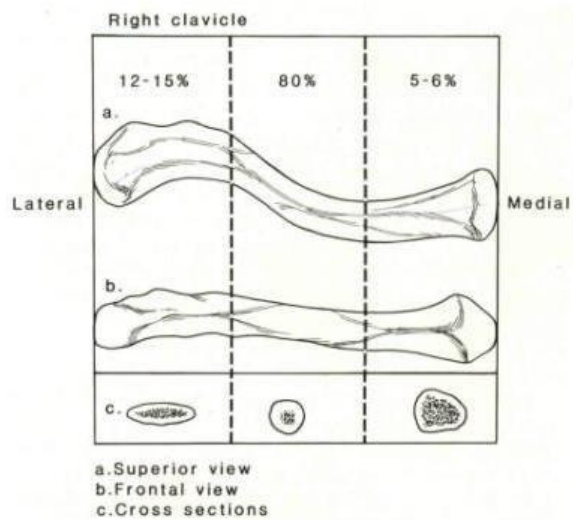
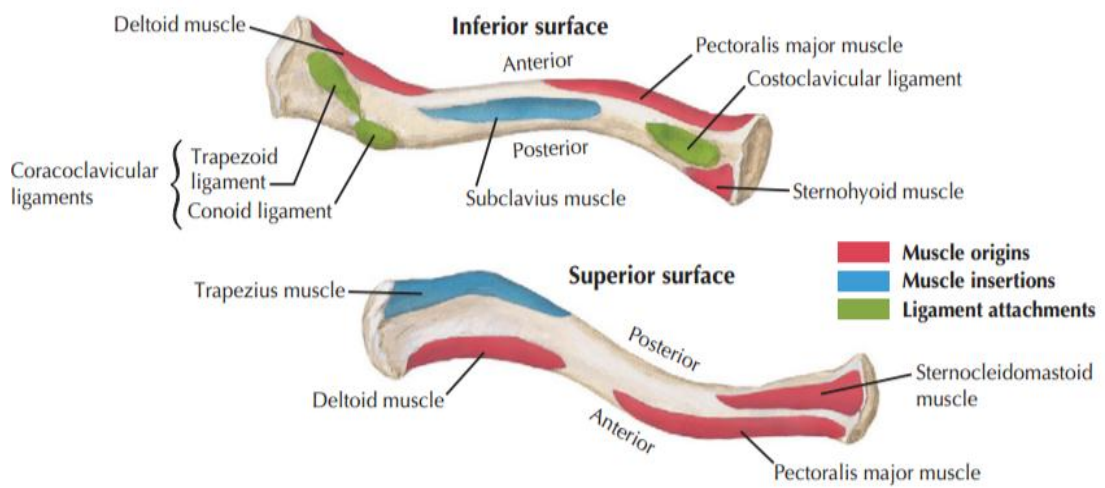
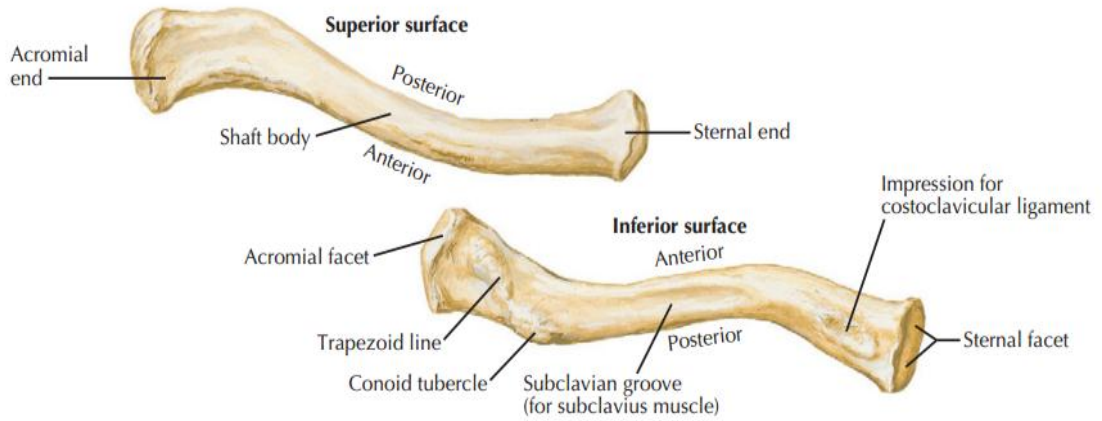
Its name is derived from latin word clavis; the diminutive of which is clavicula which refers to the musical symbol of similar shape. Greater radius of curvature occur at its medial curve which is convex anteriorly and smaller lateral curve which is convex posteriorly.

In cross section of the clavicle there is a gradual transition like flat lateral aspect, tubular middle portion and an expanded prismatic medial end.

The obvious process of the bone includes the lateral and medial articular surfaces.

The medial end of the bone has rhomboid fossa on its inferior surface where the costoclavicular ligament is inserted.

The mid portion of the clavicle contains the subclavian groove where the subclavius muscle has a fleshy insertion.



THE SHAPE AND CONFIGURATION OF THE CLAVICLE

At the lateral end of the bone is the conoid tubercle on the posterior portion of the lateral curve of the clavicle where conoid ligament is attached. The trapezoid line where trapezoid ligament is attached.²⁵

OSSIFICATION:

- It ossifies from two primary and one secondary centre.
- Primary centers (medial and lateral) appear in the shaft between 5-6 weeks of intrauterine period and fuse by about 45th day.
- A secondary centre for sternal end appears at 15th year in females and 17th years in males and unites with shaft at 21st year in females and 22nd year in males. A secondary centre sometimes develops in the cartilage at the acromial end at 18- 20 years and rapidly unites by 24th years.
- Medial clavicular epiphysis responsible for the majority (80%) of longitudinal growth.²⁵

II) LIGAMENTOUS ANATOMY:

A) Medial ligamentous anatomy:

a) Interclavicular ligament:

This ligamentous band spans from the medial clavicle to the superior sternum and to the contralateral clavicle. It loosens with shoulder elevation but serves as a support to prevent downward displacement of lateral end of the clavicle.

b) Costoclavicular ligament:

This ligament runs from the upper aspect of the first rib and adjacent aspect of the sternum to the clavicle. The anterior and posterior fibers of the costoclavicular ligament stabilize the medial clavicle during upward and down

ward rotation.

c) Capsular ligaments:

Specific thickenings of the sternoclavicular joint capsule are referred to as the capsular ligaments. The strongest and most important are the anterosuperior and posterior aspect of the capsule which are responsible for limiting superior displacement of medial end clavicle and inferior displacement of the lateral end of clavicle.²⁶

B) Lateral ligamentous anatomy

a) Coracoclavicular ligaments:

The trapezoid and conoid are thick strong ligaments travelling from the base of the coracoid process of the scapula to the inferior aspect of the lateral clavicle. These ligaments serve as the important function of suspension of the shoulder girdle from the clavicle and it provides vertical stability.

b) Acromioclavicular ligaments:

The capsule of the acromioclavicular joint forms the acromioclavicular ligaments. Posterosuperiorly the ligament serves to resist anteroposterior displacement of the distal clavicle. The coracoclavicular ligament also helps to stabilize the clavicle during rotation on its long axis in over head activities.²⁶

III) MUSCULAR ANATOMY:

Clavicle acts as a bony frame work for muscle origin and insertion.

i) Muscles that insert on the clavicle:

Upper third of trapezius inserts on to the superior surface of the outer third of the clavicle.

Subclavius muscle arises from first rib anteriorly at the costochondral junction. It proceeds obliquely and inserted into a groove on the under surface of the clavicle. This muscle appears to aid in depressing middle third of the clavicle.

ii) Muscles arising on the clavicle:

Clavicular head of deltoid arises from the outer third of clavicle opposite to the insertion of trapezius. Sternocleidomastoid muscle arises from the posterior edge of the medial third of the clavicle.

Pectoralis major arises from the anterior portion of medial two thirds of the clavicle.

Sternohyoid contrary to its name does have a small origin in the clavicle just medial to the origin of the sternocleidomastoid.

Platysma originates over the deltoid and pectoralis major. It crosses the superficial anterior surface of the clavicle.²⁶

IV) JOINTS:

The clavicle provides the connection between the upper limb and the thorax through its articulation at sternoclavicular and acromioclavicular joints.

i) Sternoclavicular joints:

The sternoclavicular joint is formed laterally by the proximal end of the clavicle and medially by clavicular notch of manubrium and cartilage of 1st rib. This joint is the only true articulation between the upper extremity and the axial skeleton.

The sternoclavicular joint is a diarthroidal type of plane synovial joint which allows 6 degrees of freedom.

The sternoclavicular joint has relatively little bony stability and the bony

surfaces are somewhat flat. The ligamentous structures provide the stability to the joint. Anterior sternoclavicular ligament is covered anteriorly by sternomastoid and it blends posteriorly with Intraarticular disc. Posterior sternoclavicular ligament blends with the tendons of sternothyroid and sternohyoid muscle posteriorly. Joint surface is covered with hyaline cartilage. A complete disc is found to separate the joint into two compartments. Elevation and depression occur in the joint between the disc and the sternum. Range of motion is approximately 30 to 35 degrees of upward elevation about 35 degrees in anteroposterior direction and rotation along long axis is about 44 to 50degrees. Most sternoclavicular elevation occurs between 30 and 90 degrees of arm elevation. Rotation occurs at 70 to 80 degrees of arm elevation. Fusion of sternoclavicular joint limits abduction to 90 degrees.^{25,27}

ii) Acromioclavicular joint:

Acromioclavicular joint is the only articulation between the clavicle and scapula. It is formed medially by acromial end of clavicle and laterally by medial margin of acromion.

It is a plane synovial joint because the articulating surfaces are relatively flat and allows 3 degrees off freedom.

It is surrounded by a thin capsule that is reinforced by superior, inferior, anterior and posterior acromioclavicular ligaments and it contains a perforated disc.

The upward and downward movements allows rotation of about 20 degrees between the acromion and clavicle. It occurs during the first 40 degrees and last 20 degrees of elevation.

Motion of the acromioclavicular joint is significantly less than at the

sternoclavicular joint but it does play a critical role in allowing full arm motion.^{25,27}

RELATIONSHIP:

Anterior surface of the clavicle is essentially subcutaneous over its course with only the thin platysma and cervical fascia covering it. The supraclavicular nerves which provide sensation to the overlying skin are consistently found deep to the platysma muscle layer. The strong tubular portion of the clavicle is clothed on its underside by the subclavius muscle and it overlies these vital structures which may account for the low incidence of neurovascular injury associated with clavicular fractures.

Sometimes it may be entrapped within the fracture site and inhibit healing. Immediate relationships of the sternoclavicular joint are the origins of the sternocleidomastoid in front and sternohyoid and sternothyroid muscles behind the joint. Of prime importance however are the great vessels and the trachea which are endangered during posterior dislocation of the clavicle from the sternum. The Medial anterior curve is often described as an accommodation for subclavian vein, subclavian artery and brachial plexus and the curve is a land mark for finding the subclavian vein.²⁵

Costoclavicular space:

It is the space between medial clavicle and the first rib.²⁵

Superficial infraclavicular space:

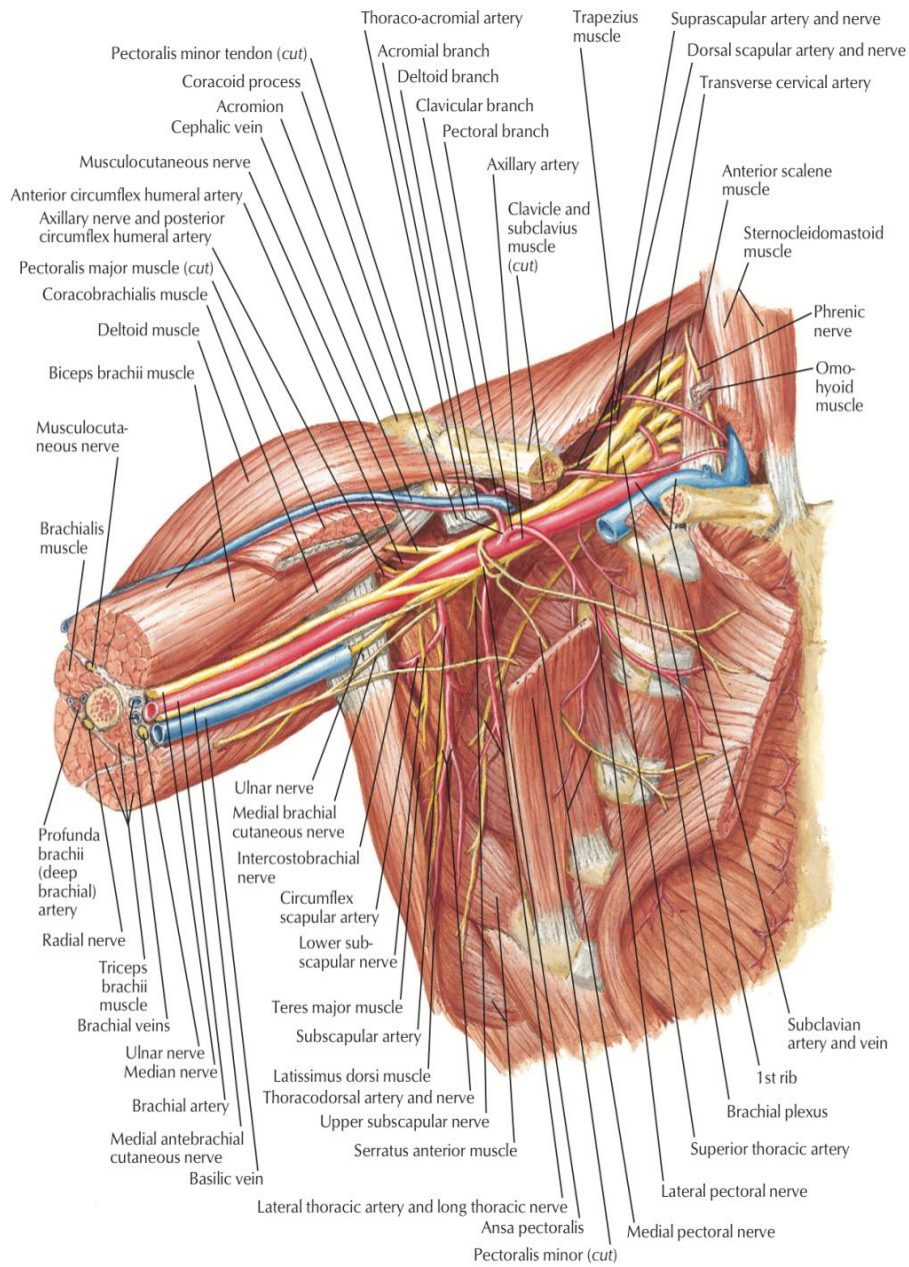
It is formed by pectoralis major and deltoid portion of the clavicle.²⁵

Grants space:

It is formed by investing layer of cervical fascia anteriorly and omohyoid fascia posteriorly. Here external jugular vein join subclavian vein at its confluence with internal jugular vein.²⁵

Blood supply:

Main nutrient artery enters just medial to the attachment of coracoclavicular ligament.²⁵



DEEP RELATION OF CLAVICLE

BIOMECHANICS

The study of biomechanics refers to the movement of joint through space and it attempts to explain both the quality and quantity of joint movement.

There are three axis of clavicular motion.

1. Anteroposterior
2. Superoinferior
3. Rotational

The function of the shoulder girdle requires the integrated motion of the sternoclavicular, acromioclavicular, glenohumeral and scapulothoracic joints.

This motion is created by the delicate interaction of almost 30 muscles.

It is generally accepted that scapulohumeral rhythm occur in a 2:1 ratio with the humerus moving 2 degrees for every 1 degree of scapular motion.

During arm elevation the clavicle must elevate to allow the scapula to rotate upwards.

Clavicle rotates totally 70 degrees in an upward fashion during arm elevation.

During abduction of the extremity clavicle abduction of about 30 degrees occur with maximum abduction occurring at about 130 degrees of arm abduction and depression occur approximately 5 degrees in saggital plane. The clavicle also rotates forwards approximately 10 degrees during the first 40 degree of arm abduction .

No change takesplace during the next 90 degrees of arm abduction but an additional 15 to 20 degrees of forward rotation subsequently occur during the terminal arc.

Approximately 15 degrees of clavicle protraction and retraction occurs in the frontal plane.^{25,27}

FUNCTIONS OF THE CLAVICLE

Codman stated that “We are proud that our brains are more developed than the animals we can also boast of our clavicles. It seems that the clavicle is one of the man’s greatest skeletal inheritances for he depends to a greater extent than most animals except the apes and monkeys on the use of his hands and arms”.

1) Power and stability of the arm:

The clavicle serves as a bony link from thorax to shoulder girdle. It contributes significantly to the power and stability of the shoulder especially in movement above the shoulder level.

The long clavicle may facilitate placement of the shoulder in a more lateral position so that the upper limb can be positioned more effectively to deal with the three dimensional environment.

2) Motion of the shoulder girdle:

Lateral curvature of clavicle permits it to act as a crank shaft, effectively allowing half of the scapular movements. This so called crank shaft mechanism on shoulder abduction provides 30 degrees of the total 60 degrees contribution from scapulothoracic motion.

3) Muscle attachments:

It provides a bony base for muscle origin and insertion.

4) Protection of neurovascular structures:

Subclavian vessels, brachial plexus and lungs are directly behind the medial third of the clavicle. The tubular cross section of the medial third of the clavicle increases its strength which along with subclavius muscle adds to its protective function at this level.

Loss of clavicle can cause exacerbation of thoracic outlet symptoms because of drooping of the shoulder and resultant drapping of brachial plexus over the first rib.

5) Respiratory function:

Because of the connection with the first rib elevation of the shoulder girdle brings about a cephalad motion of the thorax corresponding to inspiration. This relationship is used in some breathing exercises and in some form of artificial respiration.

6) Cosmesis:

Cosmetic function is served by the smooth subcutaneous bony clavicle by providing a graceful curve to the base of the neck.

7) Protection to lungs:

It protects the superior aspect of the lungs.²⁵

Thus the clavicle plays an important functional role in the shoulder girdle and every effort should be made to preserve the normal length and alignment during the treatment of clavicle disorders.

INCIDENCE OF INJURY

Fractures of the clavicle account for approximately 5 to 10% of all fractures and up to 44% of all injuries to the shoulder girdle. The site of fracture also depends upon the age of the patient and mechanism of injury.¹

Elderly men – medial third clavicle fracture
Children - middle third clavicle fracture, undisplaced
Adolescents - middle third clavicle fracture, displaced
Middle aged patient- lateral third clavicle fractures

The incidence of both lateral and medial clavicle fracture rose sharply after the age of 75 years suggesting that these areas become substantially more susceptible to fracture when osteoporotic.^{25,27}

MECHANISM OF INJURY

The primary mechanism of clavicle failure is by compression it may be caused by either low energy or high energy impact like.

- i) Fall on the shoulder-87%
- ii) Direct blow on to shoulder-7%
- iii) Fall on to an outstretched hand-6%

Clavicle when axially loaded they tended to fracture at the middle third in the region where the curve of the lateral aspect of the clavicle changes to the curve of the medial aspect of the clavicle. Another mechanism of fracture of the clavicle is a direct force when applied to the top of the shoulder the clavicle is forced against the first rib and a spiral fracture of the middle third is produced. Another variation in the mechanism which is seen more commonly in the past few years is referred to as “seat belt fractures”. The shoulder strap from the seat belt acts as a fulcrum typically at the midpoint of the clavicle and the forward force on the clavicle against this fulcrum causes the clavicle to fracture in a transverse or oblique pattern with little

comminution.

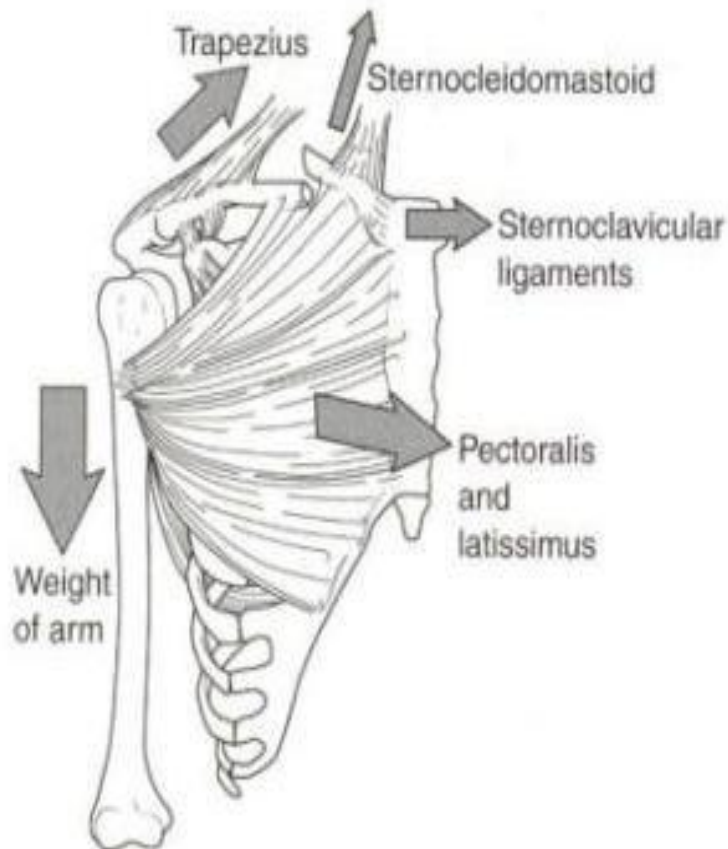
Stress fracture of the clavicle has been reported in athletes. It is seen in a variety of sports like baseball, diving, gymnastics etc.²⁶

FRACTURE BIOMECHANICS

For mid shaft fracture the displacing forces are

- a) Superior displacement of medial segment by sternocleidomastoid
- b) Inferior displacement of lateral segment by pectoralis major and latissimus muscles

The trapezius provides a stabilizing force against inferior displacement of the lateral segment.



DISPLACING FORCES ON MIDDLE THIRD CLAVICLE FRACTURE

CLASSIFICATION

There are several classification scheme for fractures of the clavicle ranging from the simple to complex. The most commonly used system is that of Allman. He separated clavicle fracture into three groups according to location in the bone because prognosis and treatment vary according to the type

Group-I - Middle third clavicle fractures

Group-II - Lateral third clavicle fractures

Group-III- Medial third clavicle fractures.^{25,26}

Neer recognized the unique behaviour of distal clavicle fracture and proposed a separate classification system for this group. He divided Allman's group II into three distinct types.

Type-I Coracoclavicular ligament intact

Type - II Coracoclavicular ligament detached form the medial segment but trapezoid part intact to distal segment

Type - III Intraarticular extension into the acromioclavicular joint.^{17,18}

In 1990 Craig introduced a more detailed classification scheme that combines the Allman and Neer classification.^{25,26}

Robinson's classification of clavicle fractures:

The classification proposed by Robinson was based on the observation on 1000 adult clavicle fracture and taken into the account the anatomical site, extent of displacement, comminution, articular extension and stability of the fracture.

It is as follows

Type- 1 Medial third

- A - Undisplaced
- A1 - Extraarticular
- A2 - Intraarticular
- B - Displaced
- B1 - Extraarticular
- B2 - Intraarticular

Type- 2 Middle third

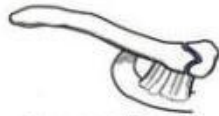
- A - Cortical alignment
- A1 - Undisplaced
- A2 - Angulated
- B - Displaced
- B1 - Simple or single butterfly fragment
- B2 - Comminuted or segmental

Type- 3 Distal third

- A - Nondisplaced
- A1 - Extraarticular
- A2 - Intraarticular
- B - Displaced
- B1 - Extraarticular
- B2 - Intraarticular

TYPE - 1 : MEDIAL THIRD CLAVICLE FRACTURE

Robinson Undisplaced Fractures (Type 1A)



Extra-articular (Type 1A1)



Intra-articular (Type 1A2)

Robinson Displaced Fractures (Type 1B)



Extra-articular (Type 1B1)



Extra-articular (Type 1B2)

TYPE - 2 : MIDDLE THIRD CLAVICLE FRACTURE

Robinson Cortical Alignment Fracture (Type 2A)



Undisplaced (Type 2A1)



Angulated (Type 2A2)

Robinson Displaced Fractures (Type 2B)



Simple or single butterfly (Type 2B1)



Segmental or comminuted (Type 2B2)

TYPE - 3 : DISTAL THIRD CLAVICLE FRACTURE

Robinson Cortical Alignment Fracture (Type 3A)



Extra-articular (Type 3A1)



Intra-articular (Type 3A2)

Robinson Displaced Fractures (Type 3B)



CLINICAL FINDINGS

Patient usually provides a clear history of some form of either direct or indirect injury to the shoulder.

The vast majority of fractures will result from a simple fall, a fall from a height, a fall during a sport activity or a motor vehicle accident.

Patient may angle their head towards the side of injury in an attempt to relax the pull of trapezius muscle on the fragment and splint the involved extremity because any movements of affected extremity will elicit pain.

The involved arm droops forwards and downwards because of the weight of the arm and pull of the pectoralis minor muscle. This drooping further accentuates the posterosuperior angulation seen in most clavicle fracture.

Ecchymosis may be noted over the fracture site and severe displacement of bone fragments will produce tenting of the skin. Physical examination reveals tenderness directly over the fracture site.

Gentle palpation and manipulation will usually produce crepitus. All movement of the arm is painful.^{25,26}

ASSOCIATED INJURIES:

Associated injuries accompany acute fracture of the clavicle. It may be divided into—

- 1) Associated skeletal injuries
- 2) Injury to lung and pleura
- 3) Vascular injuries
- 4) Brachial plexus injuries

Skeletal injuries may include sternoclavicular or acromioclavicular dislocation or fracture dislocation of these joints.

Head and neck injuries

Fracture of the first rib

Associated with dislocation – disruption of scapulothoracic articulation. Fracture of both the clavicle and the scapula are associated with an extremely unstable shoulder girdle – floating shoulder. Pneumothorax, hemothorax with fractures of the clavicle because the apical pleura and upper lung lobes lie adjacent to this bone. Vascular injuries include laceration, occlusion, spasm or acute compression. The vessels most commonly injured are the subclavian artery, subclavian vein and internal jugular vein. Injury to brachial plexus is often associated with subclavian vascular injury.¹⁷

RADIOGRAPHIC EVALUATION

Evaluation of middle third clavicle fractures:

The clavicle not only shortens but also become angulated inferiorly and rotated medially and the deformity is truly in two planes. To obtain an accurate evaluation of fragment position at least two projections of the clavicle should always be obtained – An anteroposterior view and a 45 degrees cephalic tilt view.

For evaluation of internally fixed clavicle the abduction lordotic view with the arm abducted 135 degrees and beam angled 25 degrees cephalad is extremely helpful.

In patients with minimal displacement of the fracture fragments and with no gross motion tomography or even bone scan may be useful to demonstrate the presence of non-union in asymptomatic patients.^{25,26,28}

TREATMENT

The exact method of treatment of a fractured clavicle depends on several factors including the age, medical condition of the patient, the location of the fracture and associated injuries. It is important to achieve anteroposterior and lateral alignment of the fracture because the clavicle is a curvilinear bone.²⁵

In adults with clavicle fractures the goal of treatment as with other fractures is to achieve healing of bone with minimal morbidity, loss of function and residual deformity. General methods of treatment of fractures of the clavicle can be broadly grouped into the following ways–

Conservative treatment

Operative treatment

OPERATIVE TREATMENT:

The chief goal in this method of treatment is to achieve a healed clavicle strut in an normal anatomical position as possible. The healed clavicle bone in good position provides stability to the shoulder girdle.

It may be by any of these methods:

- i) Intramedullary fixation
- ii) Internal fixation with plates and screw
- iii) External fixation.

Indication:

Indications for operative treatment of clavicle fractures are:

1. Severe displacement caused by comminution with resultant angulation and tenting of the skin severe enough to threaten its integrity and that fails to respond to closed reduction.
2. Symptomatic non-union like shoulder girdle dysfunction neurovascular

compromise.

3. Neurovascular injury or compromise that is progressive or that fails to reverse after the closed reduction of the fracture.
4. Open fracture.
5. Type II distal clavicle fracture (displaced).
6. Multiple trauma, when mobility of the patients is desirable and closed methods of immobilization are impractical.
7. Floating shoulder.
8. Inability to tolerate closed immobilization such as neurological problems of parkinsonism, seizure disorders.
9. Cosmetic reasons.

Relative indications include shortening of more than 15 to 20mm and displacement more than the width of the clavicle.^{25,26,28,29}

I INTRAMEDULLARY DEVICES:

Before the advent of AO/ASIF techniques, the smaller thin plates that were used gave poor results leading many to prefer intramedullary fixation with smooth or threaded Kirschner wires, Steinman pins, Knowles pins, Hagie pins, or Cannulated screws, Wires or Screws.

Advantages:

It can be performed through a small skin incision in Langer's lines. It requires minimal soft tissue stripping and can be removed under local anaesthesia.

In setting of comminution the cantilever effect for a pin extends to medial most portion of the pin there by providing better fixation in bending loads. It allows axial compression so it enhances healing.

Disadvantages:

Intramedullary fixation of the clavicle is technically very difficult owing to the curvature, high density and poorly defined intramedullary canal of the bone. And also intramedullary fixation does not have control over the rotational forces making postoperative immobilization necessary in vast majority of cases so plate fixation is used now.²⁵

II PLATE AND SCREWS:

Biomechanically plate fixation is superior to intramedullary fixation because it better resists the bending and torsional forces that occur during abduction of the upper extremity above shoulder level.

Types of plate used:

- i) AO Reconstruction plate
- ii) Dynamic compression plate
- iii) Low-contact dynamic compression plate
- iv) One third semitubular plate
- v) Locking compression plate
- vi) Anatomical Locking compression plate

In relatively simple fractures standard 3.5mm dynamic compression plates are used. The 3.5mm AO reconstruction plate with its lower profile and its ability to be contoured in two planes to fit the S-shaped clavicle more easily is the preferred implant. However it provides no compression and is weaker than a dynamic compression plate in terms of bending.

The low-contact dynamic compression plate allows ease of contouring with uniform plate bending. Smaller contact area with the underlying bone leading to less disruption of the underlying blood supply.

One third tubular plate has a high rate of fatigue failure because it does not provide strong enough fixation.^{26,28,30,31}

Advantages:

- 1) For transverse fractures, compression across the fracture site is achieved.
- 2) For oblique fractures or butterfly fragments, lag screw fixation is possible with the plate functioning in a neutralization mode.
- 3) Rotational control of the fracture is achieved.
- 4) Fixation is rigid enough to allow the patient to bear weight minimally on the extremity or to use the arm for activities of daily living.²⁶

Disadvantages:

It includes the necessity for increased exposure and soft tissue stripping.

Potential damage to the supraclavicular nerves which cross through the surgical field. The plate itself sits subcutaneous and can be the source of irritation and poor cosmesis.

For plate removal another procedure is required and the patient is left with multiple stress rises in the clavicle and to prevent refracture removal of plate is done at 12 to 18 months. Despite these short comings plate fixation utilizing careful surgical techniques is an excellent method of treatment for mid clavicle fractures.^{26,28,31,32}

I EXTERNAL FIXATION:

External fixation of clavicle is mentioned for the sake of completeness, and the indications are few. It may be indicated for severe open fracture with poor quality of the overlying skin and infected non union after plate removal.³³

COMPLICATIONS

a) Malunion:

Adults have no remodeling potential so shortening or angulation may occur after displaced clavicular fractures. Patients with shortening of the clavicular segment of more than 15mm at follow-up examination had significantly more pain than those without these findings. So it is recommended not to accept shortened clavicle.

b) Nonunion:

Clavicle non-union is defined as failure to show clinical or radiographic progression of healing at 4 to 6 months.

At 16 weeks period as long as some potential for healing was present it is called delayed union.

The incidence of non-union probably much higher than previously thought with an incidence of 15% to 25%.

Factors predispose to non-union of the clavicle are—

- i. Inadequate immobilization: Clavicle is one of the most difficult bones to immobilize properly and completely after fracture.
- ii. Severity of trauma: Since clavicle being subcutaneous bone it is subjected to severe soft-tissue injury so upto half of this fractures result in non-union.
- iii. Refracture: Because the vascular anatomy of a fractured bone remains altered for a long period even after fracture union, reinjury might in some way prevent this altered blood supply from reaching to the new fracture.

- iv. Location of fracture: The fractures of the distal third of the clavicle are more susceptible for nonunion because–
 - a) They are unstable and the muscle forces and weight of the arm tend to displace the fracture fragments.
 - b) It is difficult to secure adequate external immobilization.
 - c) These fractures usually result from severe trauma and usually associated with soft tissue injury.
- v. Degree of displacement: 91% of delayed unions and nonunions had initial shortening of atleast 2cm. Marked displacement is often associated with other factors like soft tissue damage, open fracture and soft tissue interposition that will interfere with healing.
- vi. Primary open reduction: Extensive soft tissue dissection, periosteal stripping and infection have been attributed to high rate of non-union in fractures treated with internal fixation. But it is probable that the operative fractures also included difficult cases (those associated with severe trauma, soft tissue damage and associated injuries) thus contributing to the poor results.

One cannot overlook the fact that most of the surgical complications are related to poor fixation techniques and it is not the concept of surgical treatment that is the problem but rather the choice of fixation.

c) Neurovascular sequelae:

In adults late neurovascular sequelae can follow both united and ununited fractures. Abundant callus or significant fracture deformity in some patients may narrow the costoclavicular space sufficiently to cause symptoms which most frequently involve the subclavian and axillary vessels or the brachial plexus (especially the ulnar nerve). The ulnar nerve crosses the first rib directly under

the medial third of the clavicle and the other two cords are further to the lateral side. Therefore the ulnar nerve is more frequently involved in complications arising from fractures of the medial third of the clavicle.

d) Post traumatic arthritis:

It may follow after intraarticular injuries to both the sternoclavicular and acromioclavicular joints. Often this is a result of an unrecognized intraarticular fracture.^{26,30,33}

Complications of surgery and its treatment:

1) Hard ware problems:

As with fresh fracture fixation inadequate purchase or plate size, collapse of the intercallary graft are important predictors of failures like plate loosening, plate angulation, plate breakage which may be treated by replating.

In the case of perfect transverse fracture the point of fixation of the cantilever is the sternoclavicular joint and the plate acts to compress the fracture with bending. In most high energy clavicle fractures are comminuted and in this setting the fixation point of the cantilever moves laterally to the fracture site and putting significant force on the lateral most screws so the plate fails by pullout of the lateral most screws.

2) Infection:

Infection after operative treatment for fracture or non-union can be a devastating complication.

Reconstruction for deep infection or osteomyelitis particularly in the non-union situation where bone loss may be extensive is often difficult. Initial treatment should include operative debridement. Although consideration can be given for retaining a stable graft. If hardware configuration is unstable treatment

should include removal of all graft and hardware followed by 6 weeks of intravenous antibiotics.

Revision surgery can be undertaken once clinically apparent infection subsides.

If there is a major bone loss vascularized graft may be needed.

3) Hypertrophic scar:

The potential for a hypertrophic uncosmetic scar after open plating is common.

The remedy is scar excision at the time of plate removal.

4) Refracture:

Initial comminuted fracture is a risk factor for subsequent refracture.

5) Non union, delayed union and malunion:

It can be treated by replating and bone grafting.^{26,33,34}

REHABILITATION:

Objectives:

Improve and restore the function of the shoulder for activities of daily living, vocational and sports activities.

Duration:

The expected duration of rehabilitation is for 10 to 12weeks.

Rehabilitation protocol:

- i. Day one to one week : Limb is immobilized in universal shoulder immobilizer in adduction and internal rotation. Elbow is maintained at 90° of flexion with no range of motion at shoulder.
- ii. At two weeks: After suture removal gentle pendulum exercises to the shoulder in the sling as pain permits is allowed.

At four to six weeks: At the end of 6 weeks gentle active range of motion of the shoulder is allowed. Abduction is limited to 80°.

- i. At six to eight weeks: Active to active – assistive range of motion in all planes is allowed.
- ii. At eight to 12 weeks: Isometric and Isotonic exercises are prescribed to the shoulder girdle muscles.³⁴

METHODOLOGY

The present study was carried out from 1st December 2014 to 31st January 2016 at Orthopaedic Department in Shri B.M.Patil Medical College Hospital and Research Center, Vijayapur. During this period 50 patients of mid shaft clavicle fractures were treated surgically.

INCLUSION CRITERIA

1. Adults above 18 years.
2. Robinson's type 2B1(Mid shaft simple displaced and single butterfly fragment fracture), Robinson's type 2B2(Mid shaft segmental fracture) classification will be included for this study.
3. Patients willing for treatment and giving informed and written consent.

EXCLUSION CRITERIA

- 1) Patient is below 18 years.
- 2) Fracture of medial third clavicle.
- 3) Fracture of lateral third clavicle.
- 4) Patients not fit for surgery, managed conservatively for other medical reasons.
- 5) All open fractures of clavicle.
- 6) Immunocompromised status.

General information like name, age, sex, occupation and address were noted. Then a detailed history was elicited regarding mode of injury like self fall and motor vehicle accidents. Enquiry was made to note site of pain and swelling over the affected clavicle. Past medical illness and family history were also recorded.

General condition of the patients was examined for pallor, pulse rate and blood pressure. Respiratory and cardio vascular system were examined for any abnormalities.

Local examination was done in the following steps:

1. On inspection the following points were noted:

Patients with fracture clavicle often support the flexed elbow of the injured side with the other hand. Abnormal swelling was present in the middle third for middle third clavicle fracture. The condition of the skin over the clavicle was noted for any abrasion, laceration and contusion.

2. On palpation the following points were noted:

Palpation of the entire length of the affected clavicle for tenderness in the medial middle third or in the lateral third fracture. The fractured clavicle was also palpated for any abnormal mobility and crepitus.

3. Movements:

- The movement of the affected side shoulder was restricted due to pain.
- The distal neurovascular status of the affected upper limb was examined and also the associated injuries along with fractured clavicle were noted.
- Plain radiograph of clavicle with shoulder in anteroposterior view was taken to assess the site of fracture and the fracture type (displacement and comminution). The fractures were classified according to Robinson's classification.
- The affected upper limb was immobilized in an arm pouch.
- Routine investigation like Hb%, Total count, Differential count, ESR, Blood urea, Sugar, Serum creatinine and ECG were done. HBsAg and HIV test were done before surgery on all patients.
- All patients were operated as early as possible once the general condition of the patients were stable and the patients were fit for surgery as assessed by the physician.

Preoperative preparation of patients:

- Patients were kept fasting for 6 hours before surgery.
- A written informed consent for surgery was taken.
- The neck, chest, axilla shoulders and arm were prepared. Transquilizers were given as advised by the anesthetist.
- A systemic antibiotics usually Inj. Ceftriaxone with Salbactam 1.5gm intravenously were administered 30 minutes before surgery to all patients.
- All patients were operated under general anaesthesia .

INSTRUMENTS



Anatomical locking compression plate



Instruments and Implants

INSTRUMENTS

- 1) 3.5 mm 6 to 8 hole Clavicle anatomical locking compression plate
- 2) 3.0 mm drill bit
- 3) 3.5mm universal drill guide
- 4) Hand drill/ pneumatic drill
- 5) Depth gauge
- 6) 4.0 mm locking screw of varying sizes (12-20mm)
- 7) 3.5mm cortical screw of varying sizes (12-20mm)
- 8) Hexagonal screwdriver
- 9) General instruments like retractor, periosteal elevator, reduction clamps and bone lever

SURGICAL TECHNIQUE

- i. Patient in supine position with one towel in between the scapula. Entire upper limb from base of neck to hand were prepared and draped.
- ii. About 5 to 7cms, incision was made in the anterior aspect centering of clavicle over the fracture site.
- iii. The skin subcutaneous tissue and platysma were divided without undermining the edges.
- iv. The overlying fascia and periosteum were next divided. The osseous ends were freed from surrounding tissue.
- v. Minimal soft tissue and periosteum dissection was done.
- vi. Fracture fragments were reduced and plate was applied over the superior aspect of the clavicle.
- vii. At the junction of the medial and middle third of the clavicle, the inferior surface is exposed so that a protective instrument can be inserted during drilling to prevent injury to neurovascular structure underneath it.
- viii. The Anatomical locking compression plate was fixed to the medial and lateral fragment with locking screws/ cortical screws and atleast three screws in medial and lateral fragment were applied.
- ix. Wound was closed in layers after ensuring meticulous hemostasis and sterile dressing was applied.

Operative Photographs



Patients position after painting and draping.



Exposure of fracture site after incision of skin, subcutaneous tissue and fascia.



Osseous ends are freed from surrounding tissue and fracture ends reduced.



Plate fixation with screws



Skin closure

Post Operative care:

Patients were kept nil orally for 4 to 6 hours post-operatively. Intravenous fluids were given as needed.

Antibiotics were given 3days injectable and followed by 5 days oral.

Analgesics and tranquilizers were given according to the needs of the patient.

The operated upper limb was immobilized in an arm pouch.



Check X- rays were taken to study the alignment of fracture fragments.

The wound was inspected at 2nd postoperative day.

Suture/ staple removal was done on 10th postoperative day. Patients were discharged with the arm pouch.

Rehabilitation of the affected arm was started at the end of 2 weeks. Gentle pendulum exercises to the shoulder in the arm pouch were allowed. At 4 to 6 weeks gentle active range of motion of the shoulder was allowed but abduction in limited to 80 degrees.

At 6 to 8 weeks active range of motion in all planes were allowed.

Follow up:

- Regular follow up for every 4 weeks was done.
- Local examination of the affected clavicle for tenderness, instability deformity and shoulder movements were assessed.
- X-rays were taken at each follow up visits to known about progressive fracture union and implant position.
- Rehabilitation of the affected extremity were done according to the stage of fracture union and time duration from day of surgery.
- Patients were followed up till radiological union.

The functional outcome were assessed by Constant and Murley score.^{35,36,38}

CONSTANT AND MURLEY SCORING:

The patients are graded as follows

CATEGORY:

A) SUBJECTIVE:

1)	Pain	-	15Points
	No pain	-	15
	Bearable pain	-	10
	Disabling pain	-	5
2)	Activities of daily living: -		20Points
	Ability to perform full work -		04
	Ability to perform Leisure activities/Sports-		04
	Unaffected sleep -		02

Level at which work can be done:

Upto Waist	-	02
Upto Xyphoid	-	04
Upto Neck	-	06
Upto Head	-	08
Above head	-	10

B) OBJECTIVE:

RANGE OF MOVEMENTS: 40 POINTS:

a) Active flexion without pain

00 – 30	Degrees	:	00
31-60	Degrees	:	2
61-90	Degrees	:	4
91-120	Degrees	:	6
121-150	Degrees	:	8
>151	Degrees	:	10

b) Functional external rotation:

Hand behind head with elbow forwards	-	2
Hand behind head with elbow backwards	-	4
Hand above head with elbow forwards	-	6
Hand above head with elbow backwards	-	8
Full elevation from on top of head	-	10

c) Active abduction without pain:

With dorsum of hand on back, head of third metacarpal reaches

00 – 30	Degrees	:	00
31-60	Degrees	:	2
61-90	Degrees	:	4
91-120	Degrees	:	6
121-150	Degrees	:	8
>151	Degrees	:	10

d) Functional internal rotation:

Ipsilateral buttock	:	2
S1 spinous process	:	4
L3 spinous process	:	6
T12 spinous process	:	8
T7 spinous process	:	

e) Strength of abduction: 25Points

A normal shoulder in a 25 year old man resists 25 pounds without difficulty. The score given for normal power is 25 points, with proportionately less for less power.

Patients were graded as below with a maximum of 100points.

Total score	Result
90-100	Excellent
80-89	Good
70-79	Fair
0-70	Poor

RESULTS AND OBSERVATIONS

The present study consists of 50 patients of fresh fracture of the clavicle which were treated surgically with Anatomical locking compression plate & screws for middle third clavicle fracture between 1ST DECEMBER 2014 TO 31ST JANUARY 2016 in SHRI B.M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, VIJAYPUR . All the patients were available for follow-up and they were followed at 1st month, 2nd month, 3rd month. Results were analyzed both clinically and radiologically.

Statistical analysis

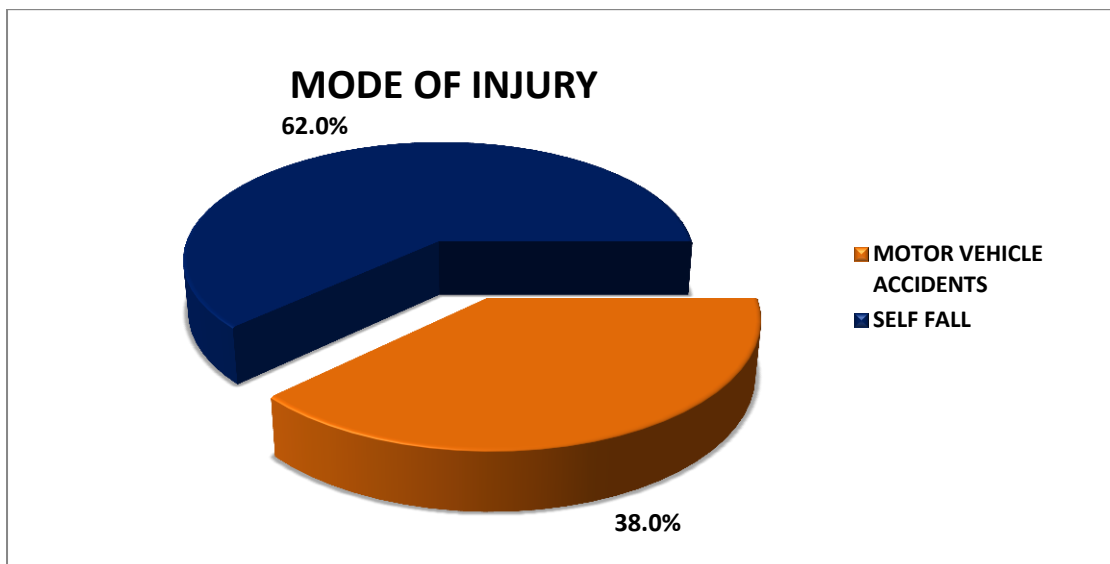
All characteristics were summarized descriptively. For continuous variables, the summary statistics of N, mean, standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries. Chi-square (χ^2)/Fisher exact test was employed to determine the significance of differences between groups for categorical data. The difference of the means of analysis variables was tested with the unpaired t-test. If the p-value was < 0.05, then the results were considered to be significant. Data were analyzed using SPSS software v.23.0.

MODE OF INJURY:

Table 1: Mode of Injury among patients

MODE OF INJURY	N	Percent
MOTOR VEHICLE ACCIDENTS	19	38
SELF FALL	31	62
Total	50	100

Figure 1: Mode of Injury among patients



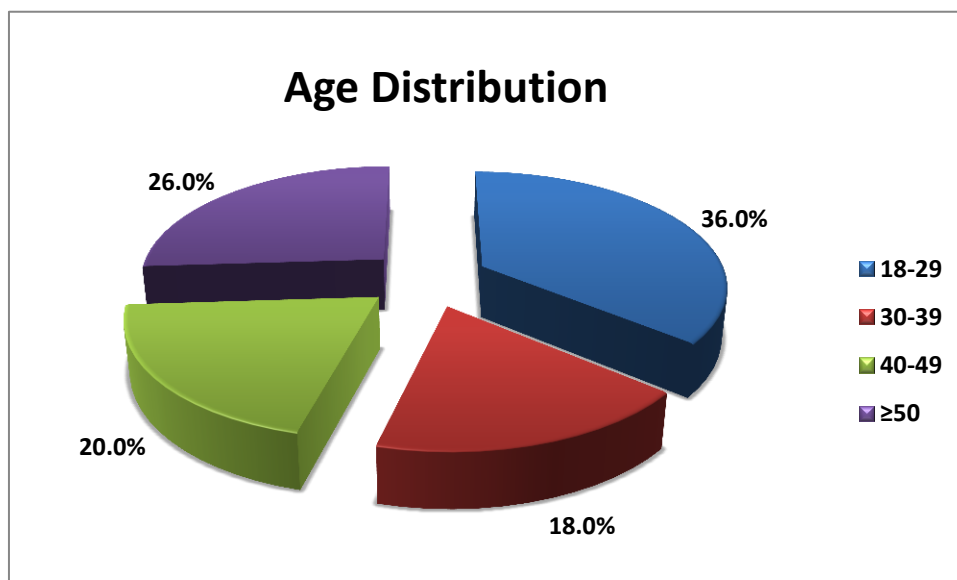
Direct injury occurred in 50 patients among them 19 patients (38 %) were due to motor vehicle accidents. 31 patients (62 %) were due to self fall.

AGE INCIDENCE:

Table 2: Age distribution of patients

Age Groups(Yrs)	N	Percent
18-29	18	36
30-39	9	18
40-49	10	20
≥50	13	26
Total	50	100

Figure 2: Age distribution of patients



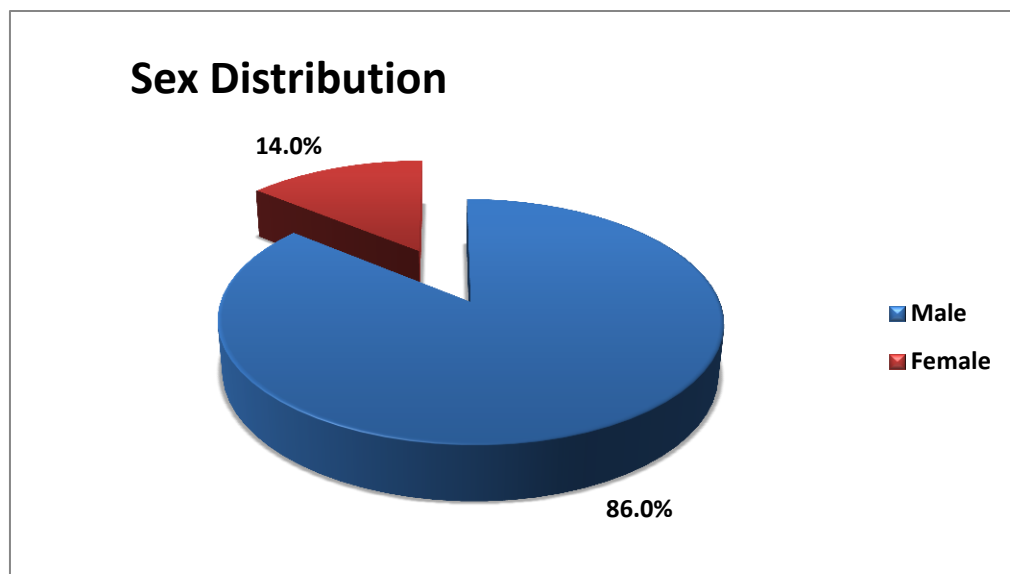
Majority of the patients were with middle third clavicle fracture i.e. 18 patients (36%) were in the age group of 18-29 years. The average patient age was 34 years.

SEX INCIDENCE:

Table 3 : Sex distribution of patients

SEX	N	Percent
Male	43	86
Female	7	14
Total	50	100

Figure 3: Sex distribution of patients



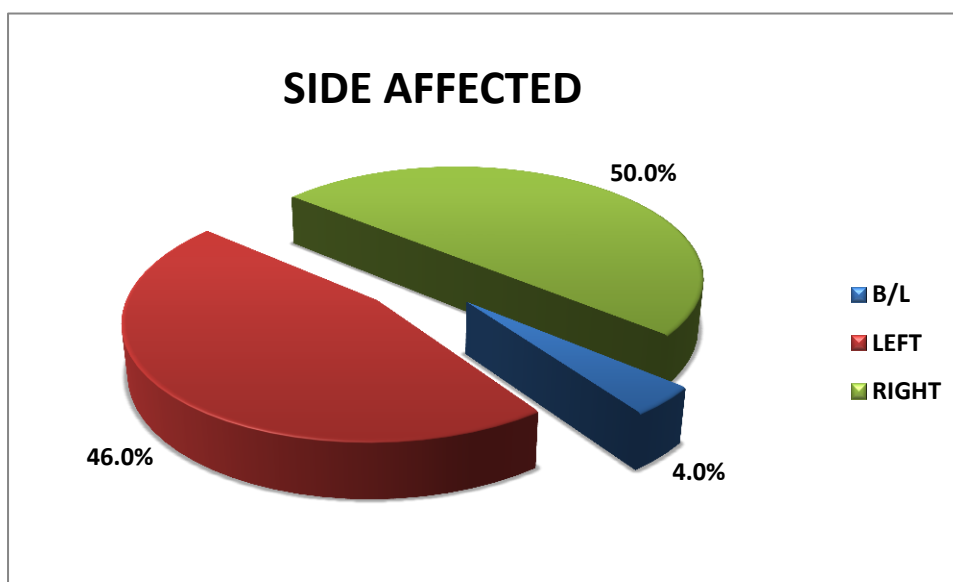
In this study 43 patients (86%) is male and 7 patients (14%) is female.

SIDE AFFECTED:

Table 4: Side Affected among patients

SIDE AFFECTED	N	Percent
B/L	2	4
LEFT	23	46
RIGHT	25	50
Total	50	100

Figure 4: Side Affected among patients



In this study, there were 23 patients (85 %) of Left sided fracture and 25 patients (46 %) of Right sided fracture and 2 patients (4%) of bilateral fracture.

ASSOCIATED INJURY:

NO

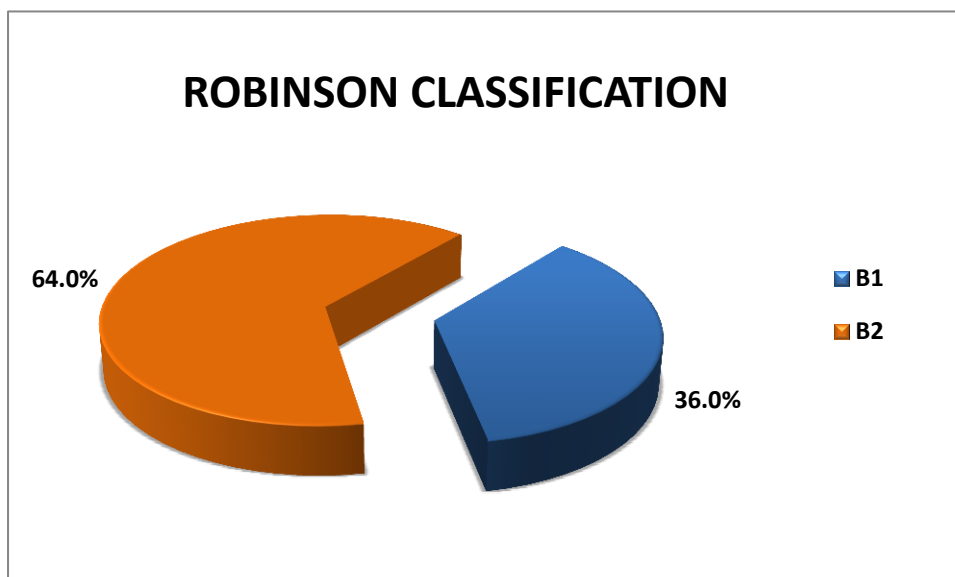
CLASSIFICATION:

Plain radiograph of clavicle with shoulder is taken in anteroposterior view to assess the site of fracture and the type of fracture (like Displacement, Angulation, Comminution). In this study Robinson classification was followed.

Table 5: Robinson Classification among patients

ROBINSON CLASSIFICATION	N	Percent
B1	18	36
B2	32	64
Total	50	100

Figure 5: Robinson Classification among patients



Type-2 middle third fracture type-2 B1 (displaced with simple or single butterfly fragment) occurred in 18 patients (36 %) and type-2 B2 (displaced with comminuted or segmental) fracture occurred in 32 patients (64%).

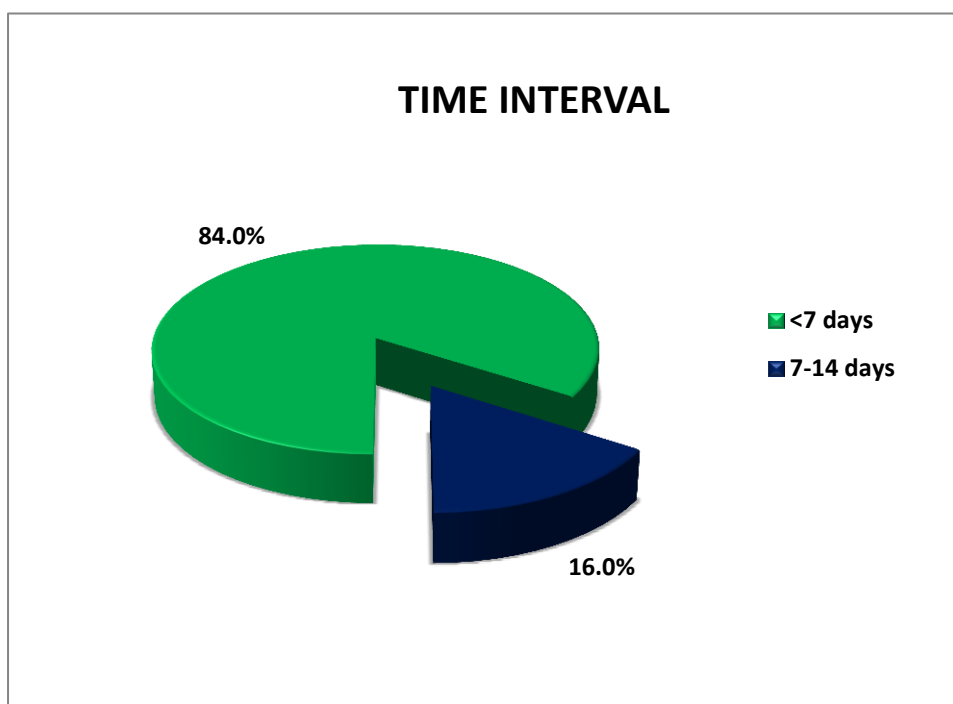
TIME INTERVAL FOR SURGERY:

All the patients were operated as early as possible once the general condition of the patients was stable.

Table 6: Time Interval between Trauma and Surgery among patients

TIME INTERVAL	N	Percent
<7 days	42	84
7-14 days	8	16
Total	50	100

Figure:6 Time Interval between Trauma and Surgery among patients



In this study, 42 patients (84 %) were operated in the first week and 8 patients (16%) were operated in the second week due to associated co-morbid conditions.

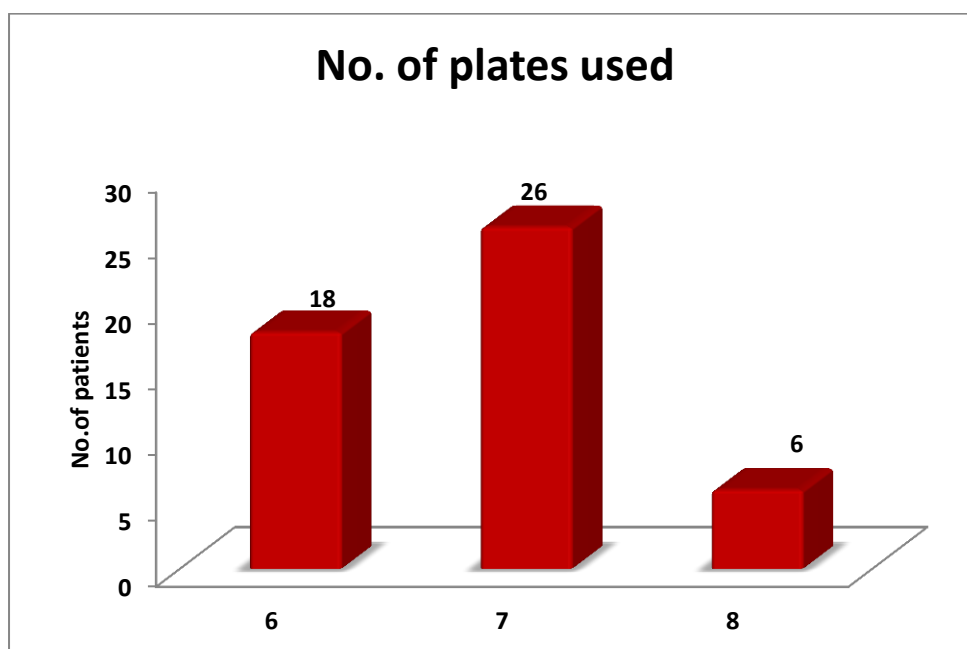
LENGTH OF PLATE

The length of the plate to be used was determined according to the extent of comminution at the fracture. The aim was to place at least three screws in the medial and lateral main fragments through both cortices of the bone.

Table: 7 Distribution of patients by No. of hole plates used

Length of Plate	No. of plates used	Percentage
6	18	36
7	26	52
8	6	12
Total	50	100

Figure:7 Distribution of patients by No. of hole plates used

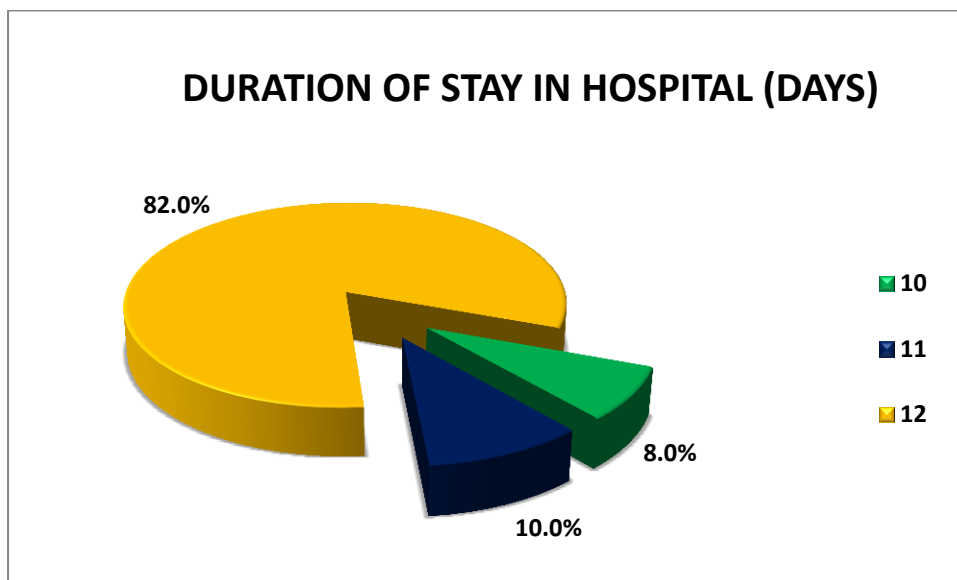


In 18 patients (36 %) 6 hole locking compression plates were used. In 26 patients (52 %) 7 hole compression plates were used and in 6 patients (12 %) 8 hole locking compression plates were used. Locking and cortical screws were used of following sizes from 12 to 20mm.

Table 8: Duration of Stay in Hospital (Days) of patients

DURATION OF STAY IN HOSPITAL (DAYS)	N	Percent
10	4	8
11	5	10
12	41	82
Total	50	100

Figure 8: Duration of Stay in Hospital (Days) of patients



41 patients (82%) discharge on 12th post of day, 5 patients (10%) discharge on 11th post of day, 4 patients(8%) discharge on 10th post of day.

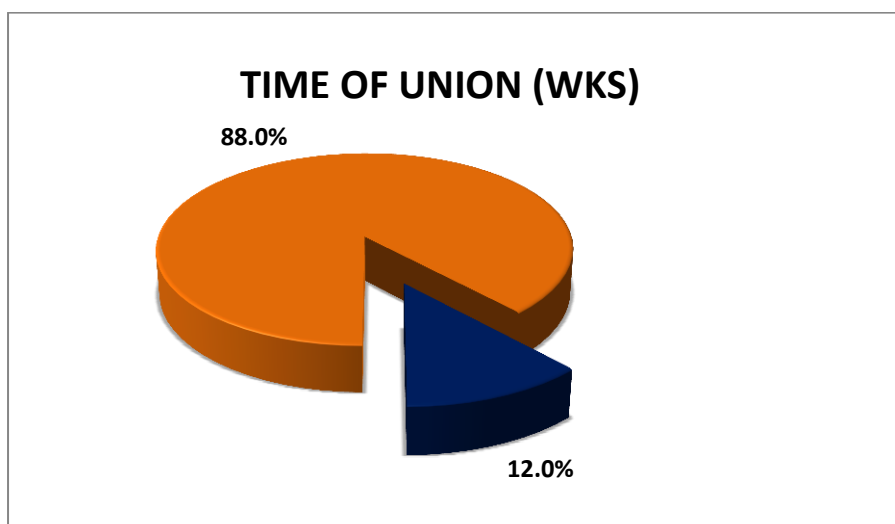
DURATION OF UNION

The fracture was considered to be united when clinically there was no tenderness, radiologically the fracture line was not visible and full unprotected function of the limb.

Table: 9 Time of Union (Wks) among patients

TIME OF UNION (WKS)	N	Percent
8-12	44	88
>12	6	12
Total	50	100

Figure:9 Time of Union (Wks) among patients



In middle third clavicle fracture 44 patients (88%) united at the end of 12 weeks. In 6 (12%) patients out of 4 patients who had large butterfly fragment at fracture site which united at 16 weeks each and 1 patient implant loosening and 1 patient implant breakage.

We advise the patient for removal of the plate at the end of 1 year

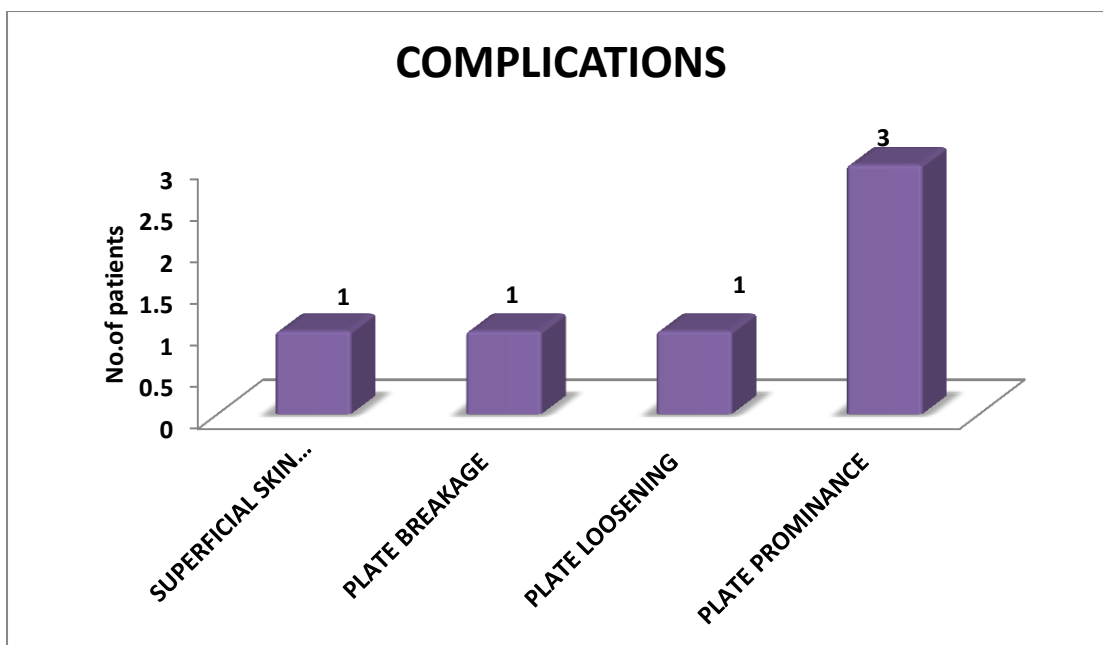
COMPLICATIONS:

Major complication: A complication requiring inpatient treatment and resulting in an additional morbidity of 2 months or more was regarded as a major complication.

Table 10: Complications among patients

COMPLICATIONS	N	Percent
SUPERFICIAL SKIN INFECTION	1	2
PLATE BREAKAGE	1	2
PLATE LOOSENING	1	2
PLATE PROMINANCE	3	6

Figure 10: Complications among patients



In this study 1 patient had superficial skin infection and in 3 patients had plate prominence and in another 1 patient had plate breakage, 1 patient had plate loosening.

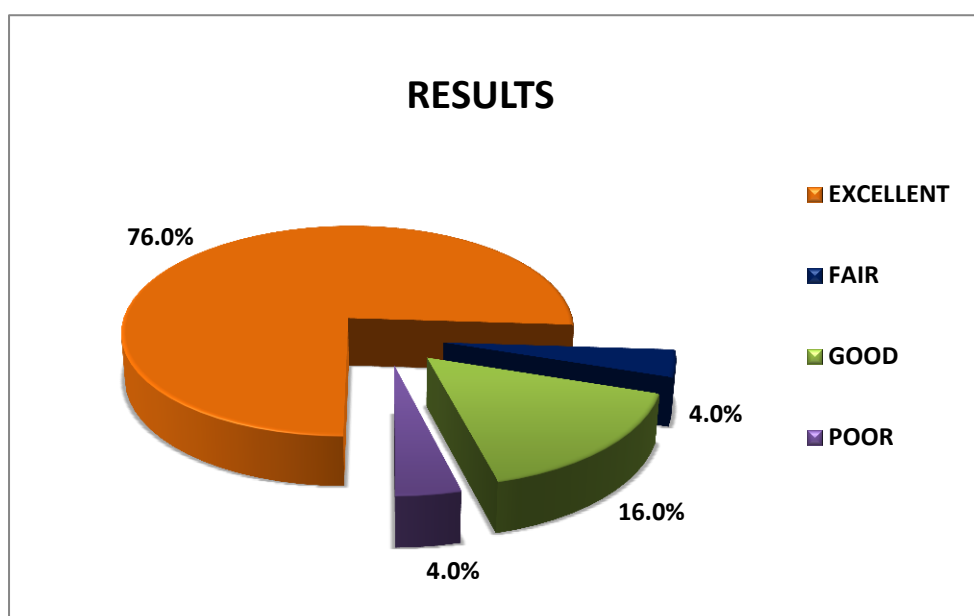
FUNCTIONAL OUTCOME:

The functional outcome is assessed by Constant and Murley score.

Table 11: Results after surgery among patients

RESULTS	N	Percent
EXCELLENT	38	76
FAIR	2	4
GOOD	8	16
POOR	2	4
Total	50	100

Figure 11: Results after surgery among patients



In this study 38 patients (76%) had excellent functional outcome, 2 patients (4%) fair outcomes, 8 patients (16%) good outcome, 2 patients (4%) poor outcomes

CASE -1



Pre operative xray



Immediate postoperative xray



1st follow up

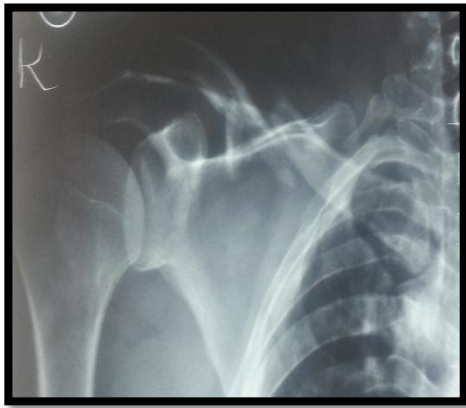


Final follow up



Range of Movements: Flexion, Extension, Abduction, Adduction, Internal Rotation, External Rotation

CASE 2



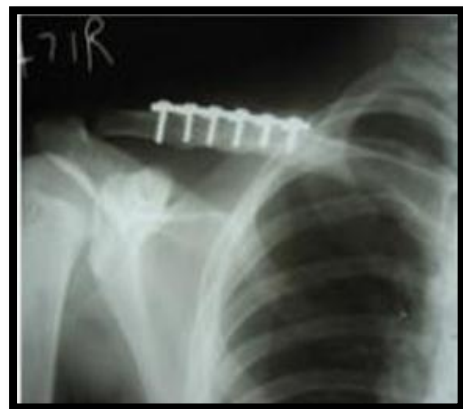
Pre operative xray



Immediate postoperative xray



1st follow up



Final follow up



Range of Movements: Flexion, Extension, Abduction, Adduction, Internal Rotation, External Rotation.

CASE – 3



Pre operative xray



Immediate postoperative xray



1st follow up

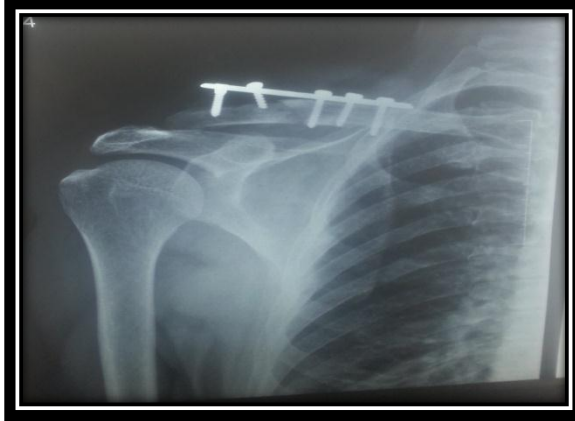


Final follow up

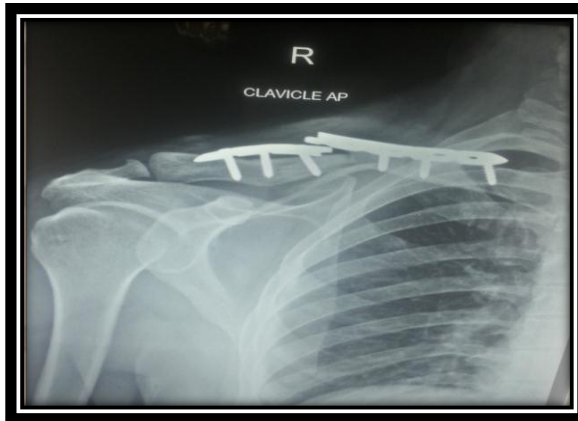


Range of Movements: Flexion, Extension, Abduction, Adduction, Internal Rotation, External Rotation

COMPLICATION



Implant loosening



Implant breakage

DISCUSSION

Clavicle fractures are usually treated conservatively. In a study conducted to analyze the results of conservative treatment by Hill et al³⁸ in 1997, Nordqvist et al³⁹ in 1998 and Robinson et al²⁹ in 2004 found poor results following conservative treatment of displaced middle third clavicle fracture. There are specific indications like displacement, with or without comminuted middle third clavicle fracture (Robinson Type-2B1, 2B2).

Our study of patients with middle third clavicle fractures is compared with Bostman et al³² study which treated middle third clavicle fractures. In their study totally 103 patients were treated by early open reduction and internal fixation with plate and screws. Cho et al¹⁵ study where 41 patients with a clavicle midshaft fracture were treated by internal fixation with a reconstruction plate (19 patients) or reconstruction LCP (22patients). Raghu K J et al²⁴ where 20 cases of displaced middle third clavicle fractures (Robinson type 2B) which were treated with open reduction and internal fixation with pre-contoured locking compression plate. Ramkumar et al²³ study where thirty adult patients with clavicle fractures treated surgically with Pre-contoured locking compression plate and screws. In Ming Yang et al²² study 60 patients with midshaft clavicle fracture were 17 patients were treated with conventional plate fixation and 43 patients were treated with intramedullary k wiring.

Mechanism of injury:

In our study the patients with middle third clavicle fracture the mechanism of injury was due to motor vehicle accidents in 19 patients (38 %), 31 patients (62 %) were due to self fall.

In Bostman et al³² study the mechanism of injury was due to fall from the two wheeler in 38 Patients (36.8%), slipping and fall in 24 Patients (23.30%), motorvehicle accident in 19 patients (18.45%) and sports in injury 22 patients (21.36%).

In Cho et al¹⁵ study, in reconstruction plate group there were 13 Patients who sustained Road Traffic Accident, 3 Patients with slip down, 1 Patient with sports injury, 1 Patient with fall down and 1 patient with miscellaneous mode of injury. In locking compression plate group there 7 Patients with Road Traffic Accident, 3 Patients with slip down, 1 Patient with fall down and 1 Patient with miscellaneous mode.

In Ramkumar et al²³ study , 17 cases were road traffic accident and 13 patients were due to fall on shoulder.

This shows that self fall is the common cause of this fracture.

Age Incidence:

Middle third clavicle fracture commonly occurred between the age group of 18 to 29 years in 18 patients (36%). The youngest patient age was 18 years and oldest patient age was 65 years. The average patients' age was 34 years.

In Bostman et al³² study patients average age was 33.4 years and the youngest patient age was 19 years and oldest patient age was 62 years.

In Cho et al¹⁵ study, in reconstruction plate group the mean age was 45 (range 22- 70) and that of the locking compression plate was 46 (range 19-69).

In Ramkumar et al²³ study patients average age was 33.8 years.

In Ming Yang et al²² study patients average was 41.7 years.

From our study we can infer that clavicle midshaft fractures occur in young and active patients.

Sex Incidence:

In our study 43 patients (86%) male and 7 patients (14%) female.

In Bostman et al³² series also commonly males are affected 76 Patients (73.79%) compared to females 27 Patients (26.21%).

In Cho et al¹⁵ study, the reconstruction plate group that 12 male and 7 female Patients and in the locking compression plate group it was 17 male and 5Patients.

Male predominance can be drawn from this inference.

In Raghu K J et al²⁴ study , 12 male and 8 female patients.

In Ramkumar et al²³ study , all 30 male patients.

Associated injuries:

In our study no associated injuries.

In Bostman et al³² series there was no associated injuries.

In Cho et al¹⁵ study, an associated injury was found in 16 Cases: hemothorax and rib fracture in 5 cases, scapular fracture in 3 cases (floating shoulder was observed in 2 of them) and rotator cuff tear in 1Case.

Type of fracture:

In our study all Patients with midshaft clavicle fractures were of closed type.

This is comparable to Bostman et al³², Cho et al¹⁵, Raghu K J et al²⁴ and Ramkumar et al²³ study which also showed all their patients were closed fractures.

Fracture classification:

In our study, Robinson Type-2 B1 (Displaced with simple or butterfly fragment) were more common and there were 18 Patients (36 %). Type-2 B2 (displaced with comminution) occurred in only 32 Patients (64%).

In Bostman et al³² study also Robinson type-2B1 was common in 81 patients (78.64%). Robinson type-2 B2 occurred only in 22 patients(21.36%).

In Cho et al¹⁵ study, in reconstruction plat group there were 7 Patients with B1 type and 12 Patients with B2 type and that of the locking compression group had 9 B1 type and 13 B2 type.

In Raghu K J et al²⁴ study, also Robinson type-2B1 was common in 3 patients. Robinson type-2 B2 occurred only in 17 patients.

In Ramkumar et al²³ study, also Robinson type-2B1 was common in 17 patients. Robinson type-2 B2 occurred only in 13 patients.

Time interval for surgery:

Most of the patient in our study were operated in the first week i.e. 42 patients (84%). 8 patients (16%) were operated in the second week due to associated comorbid condition.

In Bostman et al³² study all the patients were operated within 3 days of injury.

In Cho et al¹⁵ study the reconstruction plate group was operated by 4 days and that of locking compression plate was 9 days.

Plate length:

In our study 7 hole plates were used in 26 Patients (52%), 6 hole plates were used in 18 Patients (36 %) and 8 hole plates were used in 6 patients (12%) depending upon type of fracture.

In Bostman et al³² study plate length was above 6 holes to place atleast three screws in each fragment. Plate length also depends upon the amount of comminution.

In Ramkumar et al²³ study 6, 7, 8, 9 hole plates were used to treat the fracture depending on the type and comminution. 6 hole plate in 3 patients (10%), 7 hole plate in 12 patients (40%), 8 hole plate in 12 patients (40%) and 9 hole plate in 3 patients (10%).

Duration of union:

In our study majority of the middle third clavicle fracture cases united between 8 to 12 weeks i.e. 18 Patients (90%). In 2 Patients (10%) delayed union occurred as there was a displaced butterfly fragment which united with the main fragment at the end of 16 weeks. There were no non-union.

Lazarus MD²⁶ stated radiological union occurred approximately between 6 to 12 weeks.

In Cho¹⁵ et al study, bony union for reconstruction plate was 14.6 weeks and that of locking compression plate was 13.2 weeks.

In Ramkumar et al²³ study, Majority of the cases are united by the end of 10 weeks (86.6) and between 10 – 12 weeks (13.4%). There were no delayed union or non union cases. Average time for union is 9.3 weeks.

Complications:

A. Major Complications:

Both Bostman et al³² and Cho et al¹⁵ didn't have any major complications either.

Plate loosening:

Plate loosening occurred in 1 Patient at the end of 6 weeks postoperatively. The cause in this patient was also due to non compliance with the post operative protocol. The patient went for farming in the field before the fracture union. With further advise of not to lift heavy weights in the affected limb clavicle fracture went to unite in mal position at end of 12 weeks and no reoperation was performed for this.

In Bostman et al³² study 7 patients (6.80 %) had implant loosening. In all the patients loosening occurred at 6 postoperative weeks. Malunion of varying degree followed in all of these patients and no reoperations were performed.

In Cho et al study¹⁵ only the reconstruction group that plate loosening in 3 Patients(15.8%)

In Raghu K J et al²⁴ study 1 patient had plate prominence.

Delayed union:

In Bostman et al³² study delayed union occurred in 3 Patients (2.91%).

In Raghu K J et al²⁴ study delayed union occurred in 1 Patient.

B. Minor complication:

Skin complications:

In our study 1 patient had superficial skin infection.

In Raghu K J et al²⁴ and Ramkumar²³ et al study and Cho et al¹⁵ study, no superficial skin complication.

The total complication rate of Bostman et al³² study was 23%.

Functional outcome:

The functional outcome according to Constant and Murley³⁵ in our study of total 50 Patients of fresh middle third clavicle fracture fixed with locking compression plate and screws showed excellent results in 36 Patients (72 %) and good functional outcome in patients 8 Patients (16 %). Fair functional outcome in 2 Patient (4%) & poor results in 2 patients (4%).

In Raghu K J et al²⁴ study of total 20 patients of fresh middle third clavicle fracture fixed with ORIF with pre contoured Locking compression plate and screws showed Constant score was excellent in 16, good in 3, fair in 1.

In Ramkumar et al²³ study of total 30 patients of fresh middle third clavicle fracture fixed with ORIF with pre contoured Locking compression plate and screws showed Constant score was excellent in 19, good in 11

The advantage of rigid internal fixation and early mobilization of fresh displaced clavicle fracture is that it (displaced comminuted middle third) gives immediate pain relief and prevents the development of shoulder stiffness and non-union.

CONCLUSION

The operative methods for the treatment of clavicle midshaft fractures involve intramedullary K-wire fixation or Steinmann pin fixation and plate fixation. The procedures using the former two materials result in low resistance to torque, carry risks of pin loosening and infection, and require a long-term fixation period. Open reduction and internal fixation with plates, such as Sherman plates, dynamic compression plates, and semitubular plates, can be effective in obtaining anatomical reduction, applying direct compression to the fracture site, and producing resistance to torque. However, it is disadvantageous in achieving firm fixation because it is difficult to hold the plates to the clavicle in severely comminuted fracture cases. In contrast, Anatomical locking compression plates fit the contour of the clavicle and fracture pattern to obtain firm fixation, are lighter and thinner than dynamic compression plates and are durable to multidirectional mechanical stress imposed on the fracture site. On the other hand, penetration of the opposite cortical bone for screw fixation may cause damage to the subclavian artery and firm fixation can be difficult to maintain in osteoporotic patients over 50 years of age. In our study, the use of Anatomical locking compression plates did not result in complications, such as subclavian artery injuries and brachial plexus injuries despite of piercing either cortex in a few badly comminuted cases, but there was 1 case of plate loosening & 1 case of implant breakage occurred during the follow-up period. Although nonunion, pain, or functional disabilities were not observed in these cases, it is believed that Anatomical locking compressions could be used as an alternative to LCP plates to reduce the number of complications. The advantages of Anatomical locking compression plate include strong fixation due to locking between the screw and plate, and blood supply preservation due to minimal contact between plate and cortical bone. With

conventional screws and plates, fracture site stability is provided by friction between the plate and bone cortex. Accordingly, screws need to be fixed onto both cortices. In contrast, when anatomical locking compression plate is used, an external force is transmitted from the cortical bone through the conically threaded plate hole to the plate because the screw head is locked firmly in the threaded plate hole. Therefore, the plate does not need to be compressed onto the cortical bone for stability, which results in good preservation of the blood supply, and the plate thread is also helpful in preventing screw loosening or instability. When anatomical locking compression plate are used to treat clavicle midshaft fractures, the risks of injury to the subclavicular artery or brachial plexus can be reduced because fixation can be achieved without the tip of the screw reaching the opposite bone cortex and periosteal stripping can be minimized to promote rapid union. It is believed that the surgery time can be reduced using anatomical locking compression plate because accurate plate contouring is not necessary and periosteal stripping could be minimized using self tapping screws. Nevertheless, Anatomical locking compression plate can be an effective replacement for a locking compression plate considering that complications, such as screw loosening and plate failure, were not observed in the anatomical locking compression plate group. Contour of the plates was performed with locking sleeves inserted into screw holes considering the problem of LCPs that screw fixation can be weakened if breakage of the screw holes occurs in the plate thread during plate contouring. Unfortunately, surgical treatments for clavicle fractures leave distinct scars on the shoulder. Surgical scars are currently considered major complications due to the increasing demand for aesthetics. However, the patients should be informed of the possible appearance of surgical scars preoperatively and surgical techniques should be improved to address the problem.

In conclusion, bony union could be achieved with anatomical locking compression plate clavicle and the clinical outcomes were satisfactory. Overall, operative procedures using anatomical locking compression plate, which can be shaped to match the contour of the clavicle, can be effective in the treatment of clavicle midshaft fractures. All the fractures united and there was no non union. Only 1 patient had plate breakage so implant removal was done till the end of this study. We were able to achieve excellent results in 38 patients.

SUMMARY

Fifty patients with midshaft clavicle fractures were treated surgically with anatomical locking compression plate and screws between 1ST DECEMBER 2014 TO 31ST JANUARY 2016 at Shri B M Patil Medical College Vijayapur.

Patients above 18 years were included in this study and the patients' age ranged from 18 to 65 years. Middle third clavicle fracture is common between 18 to 29 years. The average patients' age was 34 years.

Fall from two wheelers was the cause for this fracture in most of the patients and out of 50 patients, There were 86% patients males and 14% patients female. 50 % of the fractures were of the right side. 46 % of the fracture in left side and 4% of fracture bilateral. No patients had other associated injuries.

In 42 patients (84%) surgery was done within the 1st week. The indication for surgery in middle third clavicle fracture was Robinson type-2B1 in 36 patients (displacement with simple or single butterfly fragment) and type-2 B2 in 32 patients (displacement with comminution).

All our patients were operated under general anesthesia with Anatomical locking compression plate and screws for middle third clavicle fractures.

All our patients are immobilized in an arm pouch for 4 weeks. Average duration of stay in the hospital was 11.7 days. All the patients were mobilized at the end of 2nd week with the sling.

The duration of union range from 8-12 weeks (average 11.13 weeks) in 31 patients, 16weeks in 19 patients.

The functional outcome assessment according to Constant and Murley score showed excellent functional outcome in 38 patients (76 %) and good functional outcome in 8 patients (16 %) and 2 patients (4%) fair functional outcome in 2 patient(4%).

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ANNEXURES

ETHICAL CLEARANCE CERTIFICATE



B.L.D.E. UNIVERSITY'S
SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR-586 103
INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 22-11-2014 at 3-30pm to scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected & revised version synopsis of the Thesis has been accorded Ethical Clearance.

Title "A clinical Study of mid shaft clavicle -
- fracture treated with anatomical locking
- compression plate."

Name of P.G. student Dr. Patel, Amit. C.
Dept of Orthopaedics.

Name of Guide/Co-investigator Dr. Santosh S. Nandi
Associate professor of Orthopaedics

for

DR. TEJASWINI VALLABHA
CHAIRMAN
INSTITUTIONAL ETHICAL COMMITTEE
BLDEU'S, SHRI.B.M.PATIL
MEDICAL COLLEGE, BIJAPUR.

Following documents were placed before E.C. for Scrutinization

- 1) Copy of Synopsis/Research project.
- 2) Copy of informed consent form
- 3) Any other relevant documents.

CONSENT FORM

**BLDEU'S SHRI B. M. PATIL MEDICAL COLLEGE
HOSPITAL AND RESEARCH CENTRE, VIJAYAPUR-586 103**

TITLE OF RESEARCH :

Principle Investigator :

P.g. guide name :

All aspects of this consent form are explained to the patient in the language understood by him/her.

I, the undersigned, _____, s/o d/o w/o _____, aged _____ years, ordinarily resident of _____ do hereby state/declare that Dr Amit Patel of Shri. B. M. Patil Medical College Hospital And Research Centre has examined me thoroughly on _____ at _____ (place) and it has been explained to me in my own language that i am suffering from _____ disease (condition) and this disease/condition mimic following diseases. Further Dr Amit Patel i informed me that he/she is conducting dissertation/research titled **“a clinical study of mid shaft clavicle fracture treated with anatomical locking compression plate.** Under the guidance of Dr Santosh S. Nandi requesting my participation in the study. Apart from routine treatment procedure, the pre-operative, operative, post-operative and follow-up observations will be utilized for the study as reference data.

Doctor has also informed me that during conduct of this procedure like adverse results may be encountered. Among the above complications most of them are treatable but are not anticipated hence there is chance of aggravation of my condition and in rare circumstances it may prove fatal in spite of anticipated diagnosis

and best treatment made available. Further doctor has informed me that my participation in this study help in evaluation of the results of the study which is useful reference to treatment of other similar cases in near future, and also i may be benefited in getting relieved of suffering or cure of the disease i am suffering.

The doctor has also informed me that information given by me, observations made/ photographs/ video graphs taken upon me by the investigator will be kept secret and not assessed by the person other than me or my legal hirer except for academic purposes.

The doctor did inform me that though my participation is purely voluntary, based on information given by me, i can ask any clarification during the course of treatment / study related to diagnosis, procedure of treatment, result of treatment or prognosis. At the same time i have been informed that i can withdraw from my participation in this study at any time if i want or the investigator can terminate me from the study at any time from the study but not the procedure of treatment and follow-up unless i request to be discharged.

After understanding the nature of dissertation or research, diagnosis made, mode of treatment, i the undersigned shri/smt _____ under my full conscious state of mind agree to participate in the said research/dissertation.

Signature of patient:

Signature of doctor:

Witness: 1.

2.

Date:

Place

FOR OPERATION/ANAESTHESIA

I _____ Hosp. No. _____ in my full senses here by give my complete consent for _____ or any other procedure deemed fit which is a diagnostic procedure / biopsy / transfusion / operation to be performed on me / my son / my daughter / my ward _____ age under any anaesthesia deemed fit. The nature and risks involved in the procedure have been explained to me to my satisfaction. For academic and scientific purpose the operation/ procedure may be televised or photographed.

Date:

Signature/Thumb

Impression of Patient/GuardianName:

Author signature :

Designation:

PROFORMA

CaseNo: Hospital: Name:
I.P.No.: Age/ Sex:
D.O.A.: D.O.D.: Occupation:
Address:

DIAGNOSIS:

I) HISTORY:

Complaints: Pain/Swelling
Duration Side
Mode of injury: Fall on to the shoulder
Direct injury to the shoulder

PAST HISTORY:

II) FAMILY HISTORY:

III) GENERAL PHYSICAL EXAMINATION:

Pallor,

B.P.

P.R.,

Temp.

IV) SYSTEMIC EXAMINATION:

CVS

RS

P/A

CNS

V) LOCAL EXAMINATION:

i) Inspection:

Attitude

Swelling

Deformity

Skin

ii) Palpation:

Local rise of temperature

Tenderness

Bony irregularity

Crepitus

iii) Movement:

iv) Neurovascular status:

Associated injuries

v) Complications (if any)

VI) MANAGEMENT:

A) Investigations:

- 1) Blood: Hb% TC DC ESR
- 2) Urine: Albumin Sugar
- 3) Blood urea:
S.creatinine:

Blood sugar:
- 4) HIV, HBsAg
- 5) ECG
- 6) X-ray clavicle with shoulder AP view

B) Treatment:

- i) Surgical procedure
- ii) Indication
- iii) Date of surgery
- iv) Type of Anaesthesia
- v) Antibiotics used
- vi) Immobilization after surgery
 - Type
 - Duration

vii) Check x-ray:

viii) Rehabilitation:

VII) COMPLICATIONS:

VIII) FOLLOWUP:

	1 st month	2 nd month	3 rd month
Pain			
Deformity			
Movements of shoulder girdle			
X-ray findings			

IX) ASSESSMENT OF RESULTS:

By Constant and Murley scoring system grading is done as follows

Total score	Result
90-100	: Excellent
80-89	: Good
70-79	: Fair
0-70	: Poor

KEY FOR MASTER CHART

SL NO.	- Serial number
SBMPMC	- Shri B M Patil Medical College
M	- Male
F	- Female
MVA	- Motor vehicle accident
SF	- Self fall
PP	- Plate prominence
PB	- Plate breakage
PL	- Plate looseing
SSI	- Superficial skin infection
WK	- Week
CMS	- Constant murley score
IP.NO	- In patient No