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

COMPARATIVE STUDY OF SURGICAL MANAGEMENT VERSUS CONSERVATIVE MANAGEMENT OF DISPLACED FRACTURES OF THE CLAVICLE

BY,

DR. ABHIJEET S. SALUNKHE, M.B.B.S.

POST GRADUATE (M.S. ORTHOPAEDICS)

UNDER THE GUIDANCE OF

Dr. MANOHAR P.V.

Professor,

DEPARTMENT OF ORTHOPAEDICS

SRI DEVARAJ URS MEDICAL COLLEGE, TAMAKA, KOLAR

APRIL/ MAY-2020

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, CENTRE, TAMAKA, KOLAR, KARNATAKA

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"COMPARATIVE STUDY OF SURGICAL MANAGEMENT VERSUS CONSERVATIVE MANAGEMENT OF DISPLACED FRACTURES OF THE CLAVICLE"** is a bonafide and genuine research work carried out under theguidance of **Dr.MANOHAR P.V.,** Professor, Department of Orthopaedics, Sri Devaraj UrsMedical College, Tamaka, and Kolar.

Date:

Place: Kolar

Signature of the candidate

Dr. ABHIJEET S SALUNKHE

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCHCENTRE, TAMAKA, KOLAR, KARNATAKA

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled **"COMPARATIVE STUDY OF SURGICAL MANAGEMENT VERSUS CONSERVATIVE MANAGEMENT OF DISPLACED FRACTURES OF THE CLAVICLE"** is a bonafide research work done by **Dr. ABHIJEET S SALUNKHE** in partial fulfilment of the requirement for the Degree of MASTER OF SURGERY in Orthopaedics.

Date:

Place: Kolar

Signature of the Guide

Dr.MANOHAR P.V.,

Professor,

Department of Orthopaedics,

Sri Devaraj Urs Medical College,Tamaka, Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCHCENTER, TAMAKA, KOLAR, KARNATAKA

ENDORSEMENT BY THE HOD,PRINCIPAL / HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled **"COMPARATIVE STUDY OF SURGICAL MANAGEMENT VERSUS CONSERVATIVE MANAGEMENT OF DISPLACED FRACTURES OF THE CLAVICLE"** is a bonafide research work done by**Dr. ABHIJEET S SALUNKHE** under the guidance of **Dr.MANOHAR P.V.,** Professor, Department Of Orthopaedics.

Dr. ARUN. H.S
Professor & HOD
Department of Orthopaedics,
Sri Devaraj Urs Medical College,
Tamaka, Kolar

Date:
Place: Kolar

Dr. SREERAMULU P.N.
Principal and Dean
Sri Devaraj Urs Medical College,
Tamaka, Kolar

Date:
Place: Kolar

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION

AND

RESEARCHCENTER, TAMAKA, KOLAR, KARNATAKA

ETHICAL COMMITTEE CERTIFICATE

This is to certify that the Ethical committee of Sri Devaraj Urs MedicalCollege &Research Center, Tamaka, Kolar has unanimously approved

Dr. ABHIJEET S SALUNKHE

Post-Graduate student in the subject of ORTHOPAEDICS at Sri Devaraj UrsMedical College, Kolar to take up the dissertation work entitled

"COMPARATIVE STUDY OF SURGICAL MANAGEMENT VERSUS CONSERVATIVE MANAGEMENT OF DISPLACED FRACTURES OF THE CLAVICLE"

To be submitted to

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION ANDRESEARCHCENTER, TAMAKA, KOLAR, KARNATAKA,

Date:

Place: Kolar

Member Secretary

Sri Devaraj Urs Medical College,

Tamaka, Kolar-563101

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION ANDRESEARCHCENTER, TAMAKA, KOLAR, KARNATAKA

COPYRIGHT

DECLARATION BY THE CANDIDATE

I hereby declare that the Sri Devaraj Urs Academy of Higher Education and Research Center, Kolar, Karnataka shall have the rights to preserve, use and disseminate this dissertation/thesis in print or electronic format for academic /research purpose.

Date: Signature of the candidate

Place: Kolar **Dr. ABHIJEET S SALUNKHE**

SDUAHER

Sri Devaraj Urs Academy of Higher Education and Research

Certificate of Plagiarism Check for Thesis/Dissertation

Author Name	Dr. Abhijeet S Salunkhe
Course of Study	M.S. Orthopaedics
Name of Supervisor	Dr. Manohar P.V.
Department	Orthopaedics
Acceptable Maximum Limit	
Submitted By	librarian@sduu.ac.in
Paper Title	COMPARATIVE STUDY OF SURGICAL MANAGEMENT VERSUS CONSERVATIVE MANAGEMENT OF DISPLACED FRACTURES OF THE CLAVICLE
Similarity	7 %
Paper ID	191125021657
Submission Date	2019-11-25 02:16:57

* This report has been generated by DrillBit Anti-Plagiarism Software

Signature of Student	Signature of Supervisor
Head of the Department	
University Librarian	Director Of Post Graduate Studies

Senior Librarian,
Library and Information Centre
Sri Devaraj Urs Medical College
Tamaka, KOLAR-563 101.

Director
P.G. STUDIES
Sri Devaraj Urs Medical College
Tamaka, KOLAR-563 101

ACKNOWLEDGEMENT

At the outset I thank the Lord, **ALMIGHTY**, for giving me the strength to perform all my duties.

It is indeed a great pleasure to recall the people who have helped me in completion of dissertation. Naming all the people who have helped me in achieving this goal would be impossible, yet I attempt to thank few, who have helped me in diverse ways.

I acknowledge and express my humble gratitude and sincere thanks to my belovedteacher**Dr. ARUN H.S**, M.S., (Ortho), Professor and H.O.D. and to my beloved guide **Dr. MANOHAR P.V,** M.S., (Ortho), Professor Department of Orthopaedics, SRI DEVARAJ URS MEDICAL COLLEGE, Tamaka, Kolar for their valuable suggestions, guidance, great care,constant help to undertake this study, and the support given for the preparation of thisdissertation.

I owe a great deal of respect and gratitude to **Dr. SHEIKH NAZEER** the senior most faculty in our institute without whom this study wouldn't be possible. I also thank, **Dr. SATYARUP D.** Professor, **Dr. NAGAKUMAR J.** Professor, SRI DEVRAJ URSMEDICAL COLLEGE, Tamaka, Kolar, for their scholarly suggestions and all roundencouragement.

I am also thankful to our beloved Associate Professors **Dr. HARI PRASAD**, **Dr. PRABHU. E,** and **Dr. ESWARA REDDY** for their valuable contribution in my thesis and constant motivation to complete my thesis in time.

I also want to thank our departments senior residents without whom this study wouldn't have completed. **Dr. AJAY KURAHATTI, Dr. ABHISHEK YADAV**, **Dr. SREEJITH THAMPY**, **Dr. HARSHA M, Dr. SREEHARSHA**, Senior Resident Department of Orthopedics, SRI DEVARAJ URS MEDICAL COLLEGE, Tamaka, Kolar,

I am highly grateful to **Dr. SREERAMULU P.N,** Principal and Dean, Sri Devaraj Urs Medical College, Tamaka, Kolar, for permitting me to conduct this study.

I am thankful to the Department of Anesthesia, Sri Devaraj Urs Medical College, Tamaka, Kolar, for their valuable co-operation. All the non-medical staff of Department of Orthopaedics, Sri Devaraj Urs Medical College, Tamaka, Kolar, have also made a significantcontribution to this work, to which I express my humble gratitude.

I am eternally grateful to my parents, **Mr. SUNIL G SALUNKHE and Dr. SANDHYA S SALUNKHE** and my beloved brother **Dr. SHUBHAM SALUNKHE** for their love, perseverance and understanding. They have been mypillar of support and encouraged me in every step. This dissertation would have not beenpossible without their blessings.

I also thank my friends Dr. CECIL, Dr. SACHIN ANGADI, Dr. ROGER, Dr.RAM MANOHAR, Dr. SAKTHI, my beloved seniors **Dr. SACHINDRANAYAK, Dr. AYANAKSHA, Dr. UTKARSH, Dr. VAIBHAV MITTAL, Dr. KARTHIK,Dr. JISHNU,** and my juniors **Dr. JOEPRADEEP, Dr. NEERAJ DESAI, Dr. SANDESH, Dr. SOURADEEP, Dr. ARJIT, Dr. NANDINI BHATIA , Dr. DARSHAN PATEL** for their love and support. They have contributed to the exchange of ideas resulting in the precisepresentation of the collected information.

Finally, I thank all my patients who formed the back bone of this study, without them thisstudy would not have been possible.

Date: Signature of candidate

Place: Kolar **Dr. Abhijeet S Salunkhe**

LIST OF ABBREVATIONS USED

AO	Association for the study of internal fixation
CRIF	Closed reduction and internal fixation
DMCF	Displaced middle third clavicle fracture
GA	General Anesthesia
IM nail	Intra medullary nail
IMF	Intra medullary fixation
LCDCP	Limited contact dynamic compression plate
LCP	Locking compression plate
LT	Left side
MCF	Middle third clavicle fracture
ORIF	Open reduction and internal fixation
OTA	Orthopedic Trauma Association
PF	Plate fixation
ROM	Range of movement
RT	Right side
RTA	Road traffic accident
TEN	Titanium elastic nail
TENS	Titanium elastic nailing system

ABSTRACT

Back ground and objectives:

Clavicle fracture accounts for approximately 2.6% of all the skeletal fractures.These fractures are often associated with shoulder girdle injuries in approximately 44% of cases. Non operative treatment has been a mainstay of a modality of treatment, and irrespective of the type of fracture and amount of comminution, all these fractures were treated non-operatively. Newly published results conclude that, in non-operatively managed cases of displaced fractures of clavicle in adults, nonunion rates are around 10-15%. Meta-analysis of literatures from 1975 to 2005, showed that non-union rate for non-operatively treated displaced midshaft clavicle fractures was 15.1% and this is higher than that previously described studies. With different studies being conducted the fact that clavicularmalunion is a distinct clinical entity with cosmetic, neurologic, orthopedic, and radiographic characteristics and its association with complications like symptomatic malunion, shortening, droopy shoulder, has encouraged surgeons to treat these fractures operatively.

Different surgical methods for clavicle midshaft fractures have been described and these are locking compression plate fixation, intramedullary K-wires, Steinmann pin fixation, and intramedullary nailing with TENS.

Internal fixation with intramedullary device helps to restores the normal anatomy and also has advantage of early return to functional activity, the shorter period of immobilization, and less complications. Open reduction and internal fixation with LCP has advantage of stable fracture fixation with fewer non-union rates and better functional outcome.

Therefore in this study we have compared the functional outcome of displaced clavicle fractures treated by non-surgical management with that of surgical management by TENS and by open reduction and internal fixation with clavicular locking compression plate.

Methods:

60 patients with clavicle fractures presenting to the Orthopaedic Department of R L Jalappa hospital from Nov. 2017 to April 2019 are included in the study after obtaining informed consent.

Result:

Among 60 patients with clavicle fractures, majority of the injury occurred in male patients- 45 cases (75%), whereas a total of 15 cases (25%) were seen in females. Majority of these fractures 21 cases (35%) and 13 cases (21%) occurred between 21-30 years and 31-40 years of age groups. Majority of the cases i.e. 33 cases (55%) occurred as a result of road traffic accidents, 14 cases (23.33%) as a result of fall on an outstretched hand, 8 cases (13.33%) due to direct trauma and 5 cases (8.33%) due to self fall. According to Robinson classification, there were 47 cases (78.3%) under 2B1 and 13 (21.6 %) cases under 2B2 type. The functional outcome at the end of 6 months in 30 conservatively managed cases showed, 4 cases (13.3%) with excellent outcome; 6 cases (20%) had good outcome. 16 cases (53.3%) had fair and 4 cases (13.3%) had poor outcome. While in surgically managed 30 cases, the functional outcome at the end of 6 months showed a total of 23(76.6%) cases with excellent outcome, 4 cases (13.3%) had good outcome 2 cases (6.6%) had a fair, and 1 case (3.33%) had poor outcome. At the end of 6 months, functional outcome of both the groups were compared by applying chi square test, the p value was <0.001, showing the results, statistically significant. Thus, in our study operative group had fewer complications, early bony union and better functional outcome as compared to the conservative group.

Conclusion:

This study concludes that irrespective of surgical modalities of management used, surgically treated cases have better functional outcome, fewer complications, early bony union and better overall patient satisfaction. But treatment has to be individualized for every patient of displaced midshaft clavicle fracture and routine use of operative procedure is not advisable, especially in a rural set up like ours where main concern of patients is cost of operative treatment.

Key words: Midshaft clavicle fracture, conservative management of clavicle fracture, Titanium elastic nailing system, intramedullary nailing, closed reduction, internal fixators, open reduction, clavicle LCP fixation.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF GRAPHS

CLINICAL AND X-RAY PHOTOGRAPHS

INTRODUCTION

INTRODUCTION

The clavicle is the only long bone which lies horizontally and is subcutaneous in its whole extent.[1] Clavicle is present at the root of the neck and it helps to transfer the weight of upper limb to the axial skeleton. Clavicle also contributes to movements of shoulder girdle. [1]

The shape of shaft of clavicle is gently curved so that it resembles the italic letter *f*, and is convex forwards in its medial two-thirds and concave forwards in its lateral third. [1] Clavicle derived its name from Latin word clavicula which means - "little key". The shape of clavicle is similar to that of a key and it also has an ability to rotate around its axis.[3] Most common mode of fractures of clavicle include direct axial blow to shoulder, fall on outstretched arm, or a fall from height, sports injuries, and road traffic accidents. [2,3]

Acromial end of clavicle is flat, which articulates with acromion, while the relatively large medial or sternal end has articulation with manubrium sterni and first costal cartilage.[1]

Clavicle fractures are common injuries in young, active individuals, especially those who participate in activities or sports where high-speed falls (bicycling, motorcycles) or violent collisions (football, hockey) are frequent, and they account for approximately 2.6% of all fractures.[4] These fractures are often associated with shoulder girdle injuries in approximately 44% of cases.[2] Attributed to its S shape and thinner bone at the middle curvature, clavicle most commonly gets fractured at its middle third and hence is the most common site of fracture in approximately 70% to

80% of cases; while approximately 12% to 15% of fractures occur at lateral 1/3 rd and 5% to 8% occur at medial third 1/3rd of clavicle. [2]

Fractures occurring at the middle 1/3rd show maximum amount of displacement as compared to fractures located in the medial and lateral 1/3rd of clavicle.[5] Many methods of treatment of clavicle fractures have been described in literature. Roughly, all the methods of treatment can be divided into operative and non-operative methods. [6]

For many years, irrespective of the type of fracture and amount of comminution, non-operative treatment has been a mainstay of management for fracture clavicle. This treatment protocol was based on two major studies conducted in 1960, on outcome of conservative management of fracture clavicle.[7,8] These studies showed that after conservative treatment of fracture clavicle, non-union rates were <1%, regardless of degree of displacement. But drawback of these studies was, that study sample constituted of children, which affected the final results as children recover faster because of their greater potential to remodel. Also the data in these studies was not properly classified with respect to patient age and fracture displacement. [7,8]

Newly published results of studies conclude that in non-operatively managed cases of displaced fractures of clavicle in adults, nonunion rates are around 10 to 15%.[9]Meta-analysis of literature from 1975 to 2005, showed that the non-union rate for non-operatively treated displaced midshaft clavicle fractures was 15.1% and this is higher than that of previously described studies.[10]

After non-operative treatment, particularly in displaced fractures with some amount of shortening, will have some degree of disability at shoulder girdle. Therefore there is increasing trend to operate all displaced clavicle fracture.[2]

Different surgical methods for clavicle midshaft fractures have been described, which include locking compression plate fixation, intramedullary K-wires, Steinmann pin fixation and intramedullary nailing with TENS. Internal fixation with intramedullary device helps to restore normal anatomy and have advantage of early return to functional activity, the shorter period of immobilization, and less complications.[11-13]

Thus, it is necessary to arrive at conclusion and define indications for surgical or conservative management for displaced midshaft clavicle fractures.

In this study we have compared the functional outcome of displaced midshaft clavicle fractures treated by non surgical management with shoulder arm pouch and clavicular brace, to that of surgical management by closed or open reduction and internal fixation with TENS and by open reduction and internal fixation with clavicular locking compression plate.

AIMS & OBJECTIVES

AIMS AND OBJECTIVES

- To study functional outcome of midshaft clavicle fracture managed with conservative management and with surgical management using CONSTANT scoring system.
- To study the complications, advantages and disadvantages of both treatment modalities.
- To study the duration of bony union following conservative management and surgical management.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

There are number of methods described to reduce the clavicle fracture and to immobilize the shoulder as a part of non-surgical treatment, it is now being realized that it is difficult to maintain the fracture in reduced position and with period of time, some degree of malunion and shoulder joint disability is likely. [13]

In one of the comparative study,patients in non-operative group were dissatisfied with the final outcome and patient dissatisfaction rate was up to 31% and the nonunion rate was > 15% in non-surgical group as compared to 2.2% in surgical group. [10]

In a systematic review carried out on non-surgical management of displaced clavicle fractures, all possible predictors were analyzed and nonunion incidence was studied, displacement was the most likely predictor for nonunion. [14] Smoking, fracture comminution, shortening, advancing age and female gender were identified to be doubtful risk factors, whereas fracture angulations, a vertical fragment, the presence of associated injuries and other factors did not demonstrate any effect over incidence of a nonunion.[14]

McKee et al in his meta-analysis of randomized clinical trials of non surgical treatment versus surgical management in displaced midshaft clavicle fractures, reported 15% of nonunion rate for non surgical treatment group versus 1% in surgical group.[15] Though functional outcome was good in surgically treated cases it was mainly attributed to prevention of nonunion because functional outcome of united fractures was comparable in both groups.[15]

In study conducted by Pearson et al, the cost aspect of operative fixation surpassed the poor functional outcome after non-surgical management.[16]

Randomizedclinical trial conducted in 2013 upon surgical verses non surgical management of fracture clavicle showed decreased rates of complications like neurovascular deficits, non-union and malunion, in surgical group as compared with conservative group.[17]

Study of review of the literature on the current treatment modalities for clavicle fractures concluded that patients with severe displacement, female patients and old age, percentage of non-union after non operative management is much higher than previously reported. It also concluded that with development of newer operative techniques and newer implants, surgery for fracture clavicle has become safer and also has higher rates of bony union.[18]

Many studies have given the indications for surgical intervention in clavicle fracture and these include; 1) injuries caused by fracture fragments to vital neurovascular structures like brachial plexus, subclavian vessels, the common carotid artery causing neurovascular deficits; (2) fracture involving lateral 1/3rd as it is always associated with disruption of coracoclavicular ligament; (3) the noncompliance of patients for prolonged immobilization; (4) comminuted fractures involving middle 1/3rd or fractures causing tenting of the skin;
(5) symptomatic non-union after conservative management; (6) open fractures; (7) bilateral clavicle fractures and (8) floating shoulder fractures.[19]

Huang et al, studied anatomical characteristics of clavicle and ideal surface for plating in cases of fracture clavicle. They found out that superior surface of the medial 1/3rd of clavicle is relatively flat, making it ideal for plating. In the same study functional outcome of plating group was superior to conservative group. [20]

N. Modi et al treated 62 patients of clavicle fracture using Locking Compression Plate with infraclavicular approach. Follow up of cases was done tillradiological union and results showed that average time of fracture union was 4.6 months. Out of 62 patients, one patient had superficial infection; one had stress fracture which later on treated non-operatively. [21]

A prospective, randomized controlled trial with 59 patients with midshaft clavicular fracture, compared final outcome after plate fixation and after intramedullary nail fixation. Final results showed better outcome for nail group.[22] When stress distribution across fracture site was studied with TENS in situ and with reconstruction plate in situ, the results showed that, in TENS, stress distribution was more anatomical in both loading configurations, whereas stress distribution in reconstruction plate was non-physiological. Fracture stabilized with a reconstruction plate had stress shielding effect. They also found out that TENS have higher chance of implant failure than reconstruction plate as TENS have more bone and implant stresses. [23] In a similar study by Smith et al, on stress generation across fracture site with implants in situ, showed failure torque after removal of an intramedullary device was significantly greater than failure torque after plate removal. This finding was important as chances of re-fracture are high after plate removal as compared to TENS. [24]

Meta-analysis conducted in 2016 suggested that intramedullary nailing and plating provides equivalent long-term functional outcomes, and plating may lead to a higher risk of implant failure and post operative complications. In the conclusion, intramedullary nailing provides a better alternative to plating and though plating is considered standard treatment among many orthopedic surgeons, intramedullary

nailing can be more cost effective when taken into consideration the implant removal costs.[25]

Wang et al states in treatment of midshaft clavicle fractures although there is no significant differences in constant scores in plate and nail group, intramedullary TENS fixation has good clinical outcome as compared to plate fixation.[26] As long as radiological union is taken into account TENS is effective than plate technique.[27] Due to a smaller incision, nail fixation have better cosmetics. Complications associated with intramedullary devices include migration of the nail and implant irritation documented in many studies.[28-29]

When compared to elastic stable nail, plating has been associated with complications like re-fracture, major revision surgery and implant failure.It is also associated with need for increased exposure and stripping of soft-tissue, increased risk of damaging supraclavicular nerve, higher infection rates and risk of re-fracture after plate removal.[28-30]

In a meta-analysis, it was found out that intramedullary fixation method has advantage over plate fixation group with reduced surgery time, smaller incision, less blood loss and better functional recovery with better shoulder range of movements at 6-months postoperative follow up. Among postoperative complications, intramedullary fixation was associated with lower incidence of superficial infection, symptomatic hardware, hypertrophic scar and re-fracture after implant removal and it does not increase the risk of implant failure, non-union, malunion, and brachial plexus injury.[31]

ANATOMY

INTRODUCTION

Clavicle is the bony link between the axial skeleton and upper limb. It forms important part of shoulder girdle. Basic knowledge of its anatomy is necessary to understand fracture healing, fracture biomechanics and aids in treatment of fracture. [1]

EVOLUTION:

With evolution of humans to bipeds to assume upright position majority of musculoskeletal changes occurred in pelvis, spine and in shoulder girdle. Clavicle also underwent many changes and now plays a vital role in all the animals who use their upper limbs for functions like climbing, holding and grasping.

SIDE DETERMINATION

It is based on following characteristics:

1. The sternal end of clavicle is more robust and quadrangular in shape while acromial end is flat. The lateral end of the clavicle has small oval facetover surface for its articulation with medial surface of the acromion of the scapula.[1]
2. Medial end of clavicle has much larger facet for articulation mainly with the manubrium of the sternum, and to a first costal cartilage. [1]
3. On its acromial end, clavicle has a distinct tubercle known as conoid tubercle and also a lateral roughening known as the trapezoidline which gives attachment to coracoclavicular ligament. [1]

I] OSSEOUS STRUCTURE:

A) SHAFT OF CLAVICLE

Shaft of clavicle is somewhat of italic letter '*f* ' fashion curvature. The inferior surface of clavicle has a groove for attachment of subclavius muscle. Clavicle is trabecular internally, with a shell of much compact bone in its shaft unlike all other long bones clavicle usually has no medullary cavity .[1]

In females clavicle is less curved, is shorter and thinner than in male. Apart from this, circumference of midshaft is considered more reliable measurement for sex determination.[1]

B) LATERAL THIRD

Lateral third of clavicle is flat and has superior and inferior surfaces. Both surfaces are limited by anterior and posterior borders. Anterior border of lateral end is concave in shape and is roughened by muscle attachment. Lateral third of clavicle has deltoid tubercle. Superior surface of lateral end of clavicle is subcutaneous and is palpable while inferior surface has conoid tubercle and trapezoidal line which give attachments to coracoclavicular ligaments.

Conoid tubercle gives attachment to conoid part of coracoclavicular ligament, while trapezoid line, gives attachment to the trapezoidal part of coracoclavicular ligament. These coracoclavicular ligaments transmit the weight of the upper limb to the clavicle.[1]

The sternal end of clavicle gives attachments to deltoid muscle anteriorly and to trapezius posteriorly. The transmitted weight from ligaments is counteracted by the two muscles and is transmitted to shaft and to the central skeleton.[1]

C) MEDIAL TWO-THIRDS

Medial two thirds of clavicle is cylindrical and has four surfaces; the anterior, posterior, inferior and superior. Anteriorly, it is rough in most of its part but is smooth laterally and forms superior surface of infraclavicular fossa.

Clavicular head of pectoralis major muscle attaches to the anterior surface; while superiorly there is attachment of clavicular head of sternocleidomastoid muscle. The posterior surface is smooth, and has no attachments except in the lower sternal end where the lateral fibers of sternohyoid are attached. Subclavius is inserted into inferior surface in the subclavian groove, which is covered by a clavipectoral fascia which is attached to the edges of subclavian grooves. Suprascapular artery gives branch to form a nutrient artery for clavicle that enters into the subclavian groove through nutrient foramen.

A: 1. Sternocleidomastoid
2. Sternal end.
3. Pectoralis major.
4. Trapezius.
5. Acromial end.
6. Deltoid.

Fig. No.1: ANATOMY OF LEFT CLAVICLE (SUPERIOR VIEW)[1]

B: 1. Pectoralis major.
2. For costoclavicular ligament.
3. For first costalcartilage.
4. For sternum.
5. Sternohyoid.
6. Subclavius.
7. Deltoid.
8. For acromion.
9. Trapezoid line.
10. Trapezius.
11. Conoid tubercle.

Fig. No.2:ANATOMY OF LEFT CLAVICLE(INFERIOR VIEW) [1]

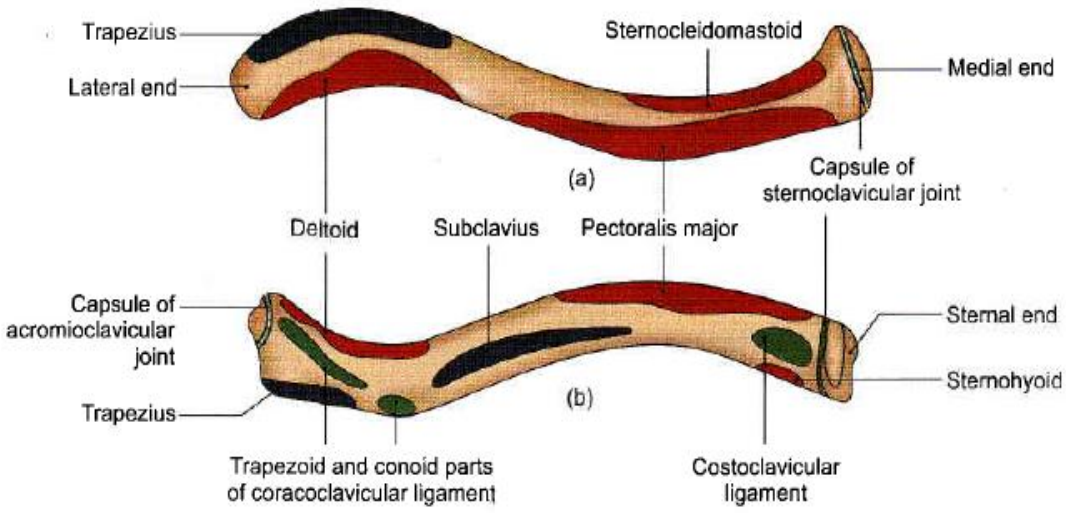


Fig. No.3: MUSCULAR ATTACHMENTS OF CLAVICLE[32]

II] OSSIFICATION

The ossification of clavicle starts first and it is the first bone to ossify. There are three ossification centers. The shaft of the bone is ossified from two primary centers, medial and lateral, which appear between the fifth and sixth weeks of intrauterine life, and fuse about the 45th day. On both ends, cartilage is developed. [1]

There are two secondary centers, one for sternal end which appears in late teens and one for acromial end which appears around 18 to 20 years. Ossification of clavicle is not exclusively by intramembranous ossification. In 14 mm embryos, clavicle is nothing but a band of condensed mesenchyme between the acromion and apex of the first rib. Medial and lateral zones of early cartilage transformation ('precartilage') occur within this band, and intramembranous centres of ossification appear, and soon fuse, in the mesenchyme between them.[1] Sternal and acromial zones soon become true cartilage into which ossification extends from the shaft.

Length increases by interstitial growth of these terminal cartilages; the latter develop zones of hypertrophy, calcification and advancing endochondral ossification like other growth cartilages. Diameter increases by subperichondral deposition in the extremities and subperiosteal deposition in the shaft. [1]

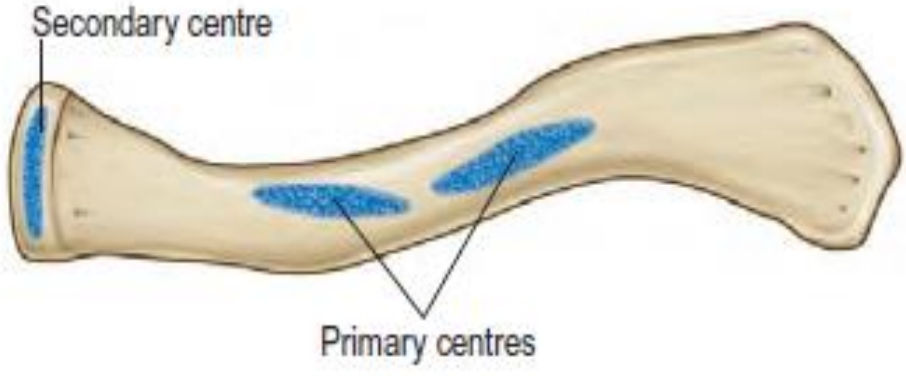


Fig. No.4: **THE THREE CENTERS OF OSSIFICATION IN CLAVICLE**[1]

III] JOINTS AND LIGAMENTS:

A) STERNOCLAVICULAR JOINT

It is a synovial type of joint of sellar variety. It is of great significance as it represents the only skeletal articulation which connects the upper limb with central skeleton.

i) Articulating surfaces: Sternal end of clavicle along with clavicular notch of sternum forms the articulating surfaces, along with superior surface of first costal cartilage (Fig.5).

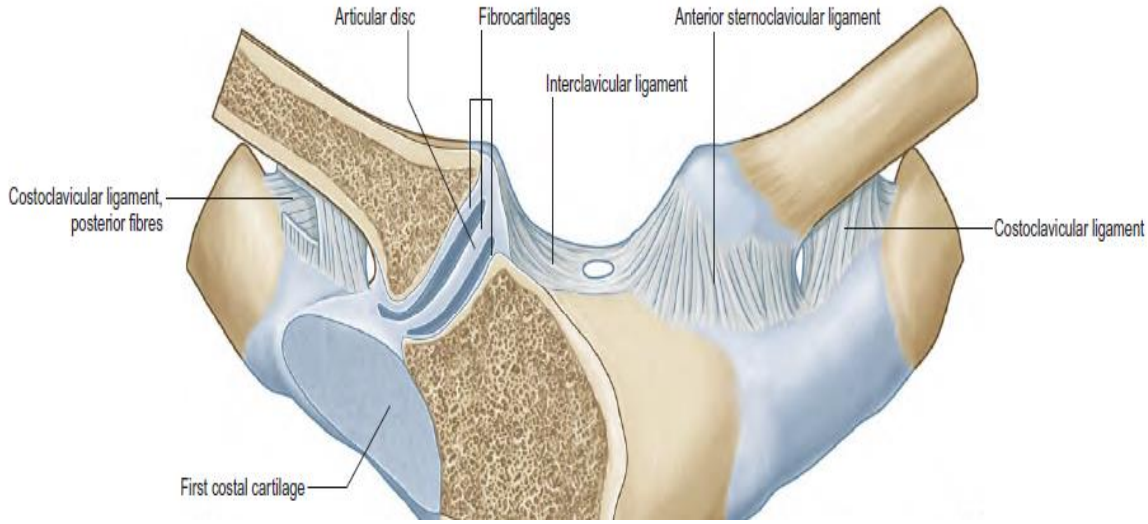


Fig. No.5: ARTICULATING SURFACES OF STERNOCLAVICULAR JOINT[1]

Articular surface is covered by fibrocartilage. The joint is convex vertically. The clavicular notch of the sternum is reciprocally curved to articulate with clavicular end, but they both are not fully congruent. An articular disc divides the joint.[1]

ii) Fibrous capsule: On anterior and posterior aspect capsule is thick while it is more of a loose areolar tissue on superior aspect and inferior aspect.

iii) Ligaments: These include anterior and posterior sternoclavicular and the costoclavicular ligaments on each side and interclavicular ligaments.

a) **Anterior sternoclavicular ligament:** It is a broad ligament and has attachment to the anterosuperior aspect of the sternal end of the clavicle. It passes inferomedially to the upper anterior aspect of the manubrium, giving its fibers to first costal cartilage.

b) **Posterior sternoclavicular ligament:** It is a weaker band of ligament present in the posterior aspect of joint. It passes inferomedially to attach to posterior aspect of manubrium.

c) **Interclavicular ligament:** It the continuation of deep cervical fascia, and attaches to sternal ends of both clavicles.

d) **Costoclavicular ligament:** It is a short and flat cone shaped ligament which is attached to superior surface of first rib and inferior surface of medial end of clavicle. This ligament has anterior and posterior lamina and which ascend laterally and medially respectively; to fuse with capsule.

iv) Articular disc: It is a flat and circular in shape and is present, between the sternal and clavicular surfaces. It has attachment to the posterosuperior border of the articular surface of the clavicle superiorly and to the first costal cartilage near its sternal junction inferiorly. Articular disc is thicker peripherally. It is more lax on clavicular side and facilitates movements between the clavicle and the disc.

v) Vascular supply: It receives vascular supply from branches of internal thoracic artery and suprascapular artery.

vi) Nerve supply: The sternoclavicular joint receives innervations from the medial supraclavicular nerve and the nerve to subclavius.

vii) Factors maintaining stability: In sternoclavicular joint the articular surfaces are less congruent. But strength of its ligament attachment especially articular disc

makeit very stable. These factors and the usual transmission of force along the clavicle make dislocations very rare. [1]

B) ACROMIOCLAVICULAR JOINT

It is a synovial plane joint.

i) Articulating surfaces: These are formed by acromial end of clavicle and medial margin of acromion. The clavicular surface is oval in shape and is narrow. It overlaps the corresponding facet on the medial acromial border. The long axis of articular surfaces is anteroposterior.

ii) Fibrous capsule: Articular margins are completely surrounded by the capsule. Capsule is strengthened superiorly by the acromioclavicular ligament. It is lined by synovial membrane in its whole extent.

iii) Ligaments: There are two ligaments thatsupports the joint and these are acromioclavicular ligament and coracoclavicular ligament.

a. **Acromioclavicular ligament:** It is quadrilateral in shape and extends between superior surface of lateral third of clavicle and acromion.

b. Coracoclavicular ligament: It is considered the most important accessory ligament to keep clavicle and acromion in opposition. Coracoclavicular ligament possesses two parts trapezoid and conoid which are separated by a bursa or fat.

iv) Articular disc: The articular disc often occurs in the upper part of the joint, partially separating the articular surfaces.

v) Vascular supply: The acromioclavicular joint receives its arterial supply from branches from the suprascapular and thoracoacromial arteries.

vi) **Innervation:** The acromioclavicular joint is innervated by branches from the suprascapular and lateral pectoral nerves.

vii) **Factors maintaining stability:** The coracoclavicular ligament stabilizes the acromioclavicular joint. In acromioclavicular dislocation, the ligament is torn and the scapula falls away from the clavicle, which may be slightly elevated by the unopposed pull of trapezius. Dislocation can occur because of the flatness and orientation of the joint surfaces; once the acromioclavicular joint dislocates it never reduces.

viii) **Movements:** At the joint are like those of the sternoclavicular joint. These are passive, i.e. no muscle directly moves the joint, but muscles which move the scapula indirectly move the clavicle. Axial rotation of the clavicle is about 30°, the two joints together therefore; permit about 60° of scapular rotation. Angulation with the scapula occurs in any direction.[1]

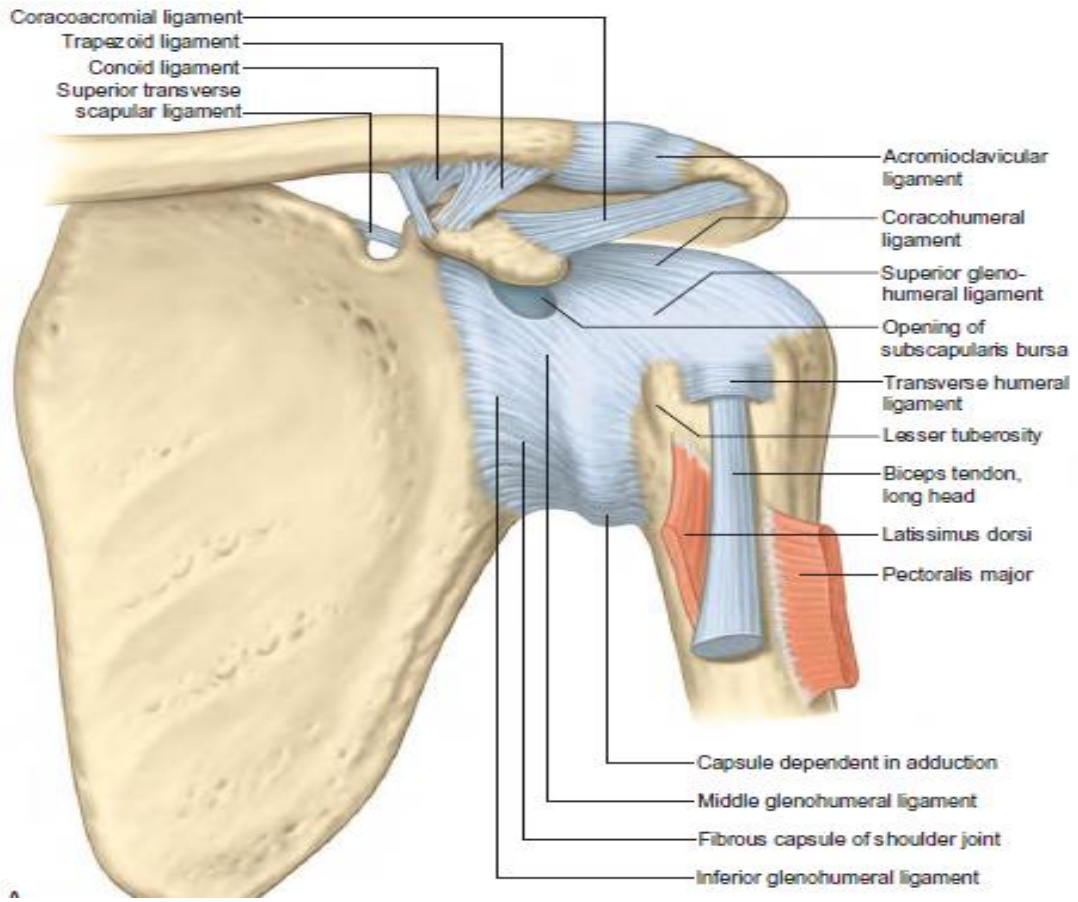


Fig. No. 6A: LIGAMENTOUS ANATOMY[1]

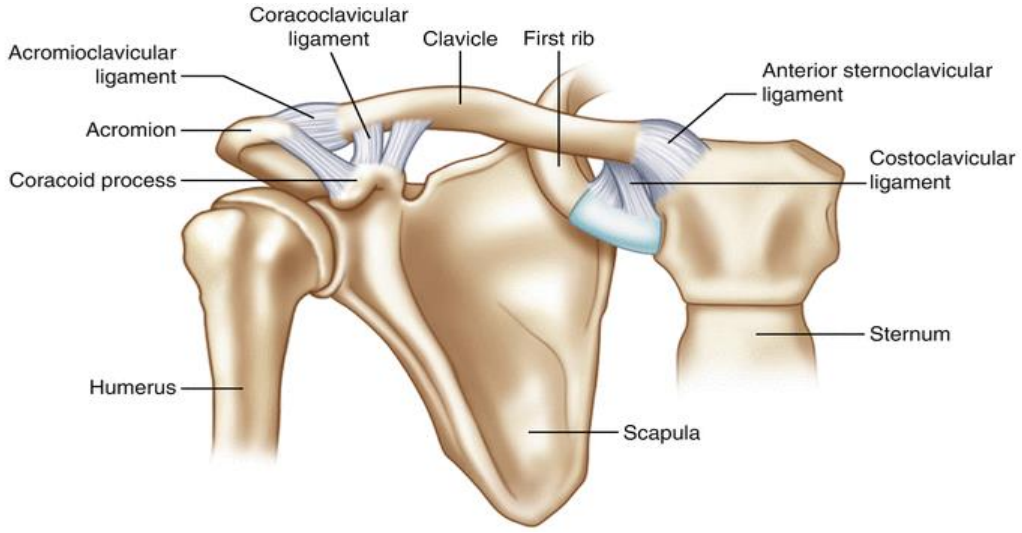


Fig. No. 6B: LIGAMENTOUS ANATOMY

IV) MUSCULAR ANATOMY:

From medial aspect, the pectoralis major muscle originates from the clavicular shaft anteroinferiorly, and the sternocleidomastoid originates superiorly. The pectoralis origin merges with deltoid laterally, while the trapezius insertion blends superiorly with the deltoid. (Fig. No.7)[33]

This muscular attachment knowledge is important as they play the important deforming forces after fracture. In fracture shaft of clavicle medial third fragment is elevated by the sternocleidomastoid muscle pull and the distal fragment is held inferiorly by the deltoid muscle pull and held medially by pectoralis major muscle pull. Subclavius muscle which is attached at the undersurface of clavicle act as a soft tissue buffer in sub clavicular space which is above the brachial plexus and subclavian vessels.[33]

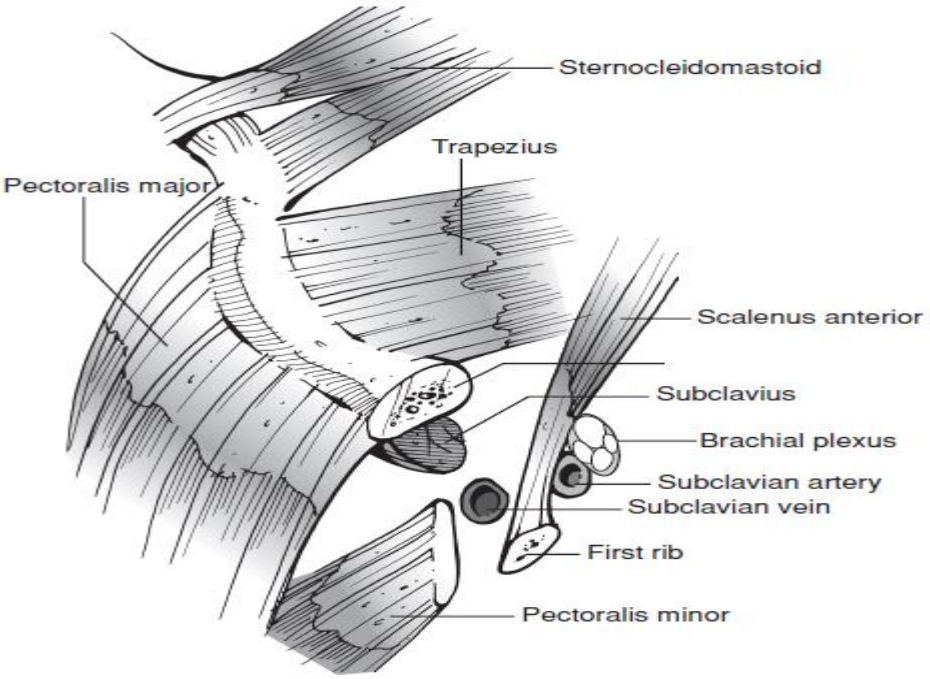


Fig. No.7.: MUSCULAR ATTACHMENTS AND RELATIONS OF CLAVICLE[33]

V) BLOOD SUPPLY OF CLAVICLE

Nutrient artery to clavicle is a branch of suprascapular artery, which enters the shaft, medial to attachment of coracoclavicular ligament.[34]

VI) NEUROVASCULAR STRUCTURES IN RELATION TO CLAVICLE:

Cervical roots C3 and C4 gives origin to supraclavicular nerve which exit from a common trunk behind sternocleidomastoid muscle. It gives three major branches called anterior, middle, and posterior that cross the clavicle superficially from medial to lateral and are at risk during surgical approaches which when injured leads to loss of sensations inferior to the surgical incision, but this tends to improve with time. The subclavian vein passes in between first rib and subclavius muscle. While brachial plexus and subclavian artery remain posteriorly and are separated from subclavian vein and clavicle by scalenus anterior muscle medially. One should be careful and cautious not to enter the subclavius space during operative procedure as these vitals structure lie at great proximity to clavicle.[33]

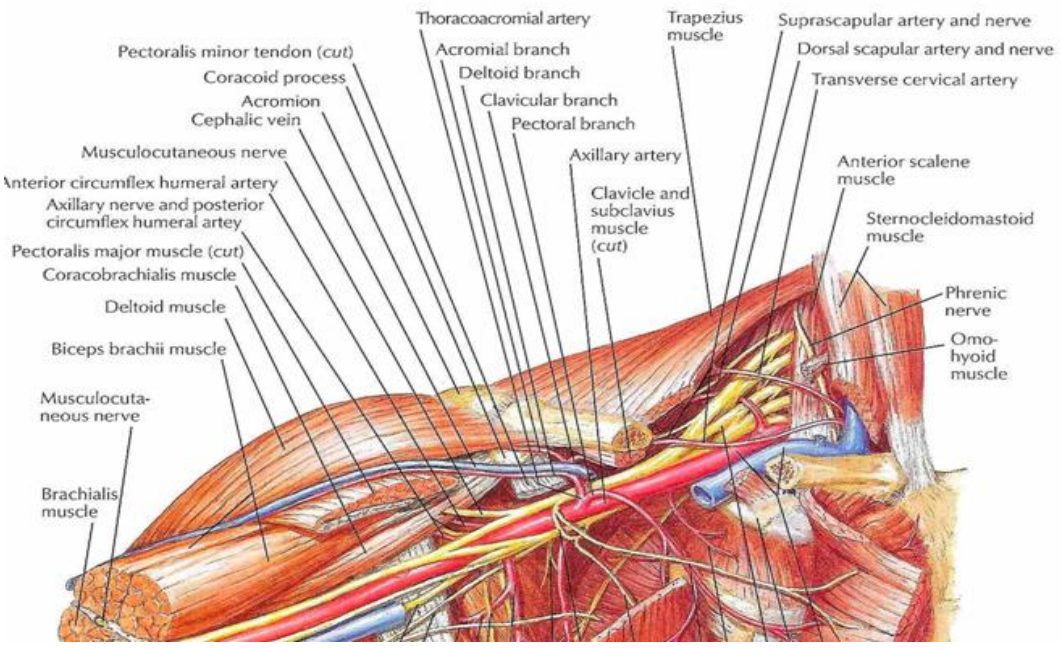


Fig. No.8:NEUROVASCULAR STRUCTURES DEEP TO CLAVICLE[3]

CLAVICULAR BIOMECHANICS

Clavicular motion occurs through following axis:

A. Anteroposterior
B. Superoinferior
C. Rotational

All the movements occurring at shoulder girdle are result of integration of almost 30 muscles surrounding it and 4 joints viz.acromioclavicular, scapulo -thoracic, sternoclavicular and glenohumeral joints. [34,36]

For every 1 degree motion of scapula, humerus moves 2 degrees; this is called as scapulohumeral rhythm which occurs in 2:1 ratio. To allow scapula to rotate upwards during arm elevation clavicle has to be elevated and rotate around its axis by around 70 degree in upward direction during arm abduction. [34,36]

Clavicle rotates by about 10 degrees forward when there is 40 degrees of arm abduction, while there is no rotation at clavicle during next 90 degrees. During the last terminal arc final 15 to 20 degrees of rotation occurs. Without clavicular rotations only 110 degrees of arm abduction is possible.[1]

During the motion of upper limb, lateral 1/3rd clavicle forms an asymmetric conical path where sternoclavicular joint act as a fulcrum. A maximum range of 30° rotation of clavicle occurs at sternoclavicular joint and maximal range of movement of scapula i.e. by combining sternoclavicular and acromioclavicular joints, is about 60° with respect to the sternum.[1]

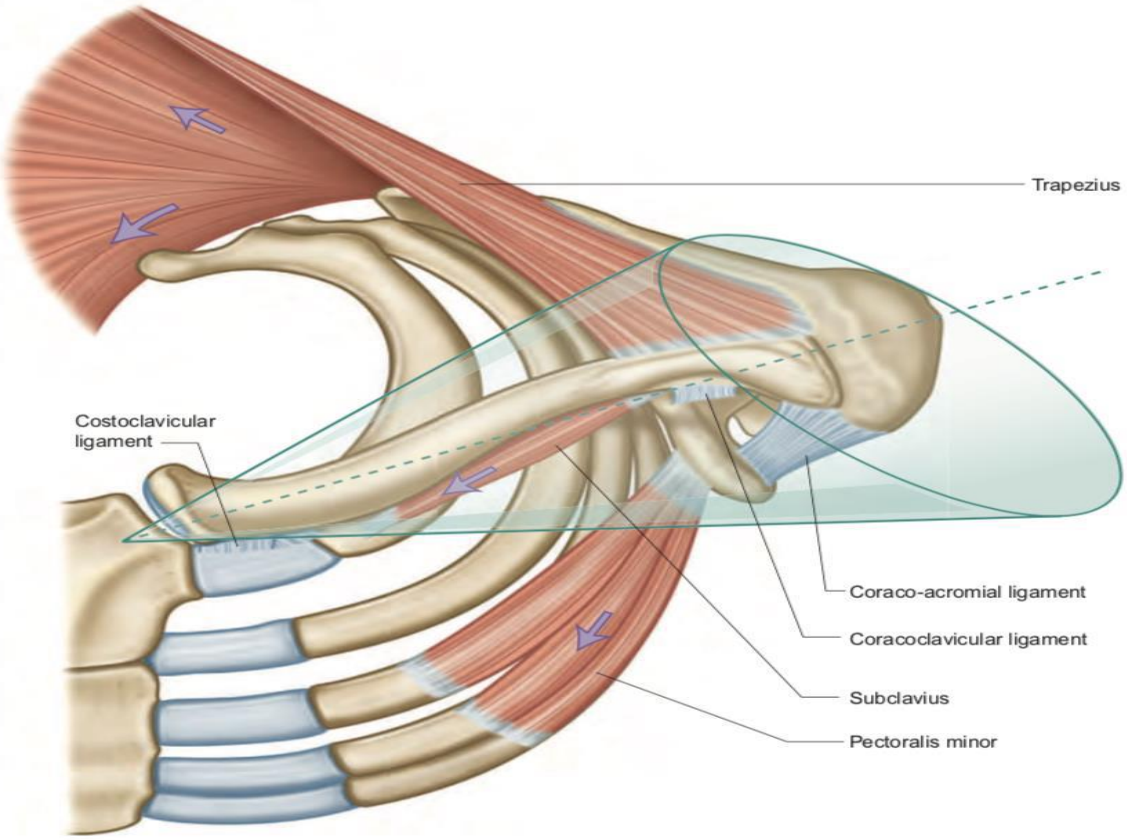


Fig. No.9A:CLAVICULAR BIOMECHANICS[1]

Fig. No.9A shows the movements of clavicle with the sternoclavicular joint as the medial fulcrum. The lateral end of clavicle forms an asymmetric conical path during motion of the upper extremity.[1]

The scapula is suspended from the distal clavicle at the acromioclavicular joint, which can be considered as the true joint (the cavity bounded by the acromio clavicular capsule and ligaments). [1]

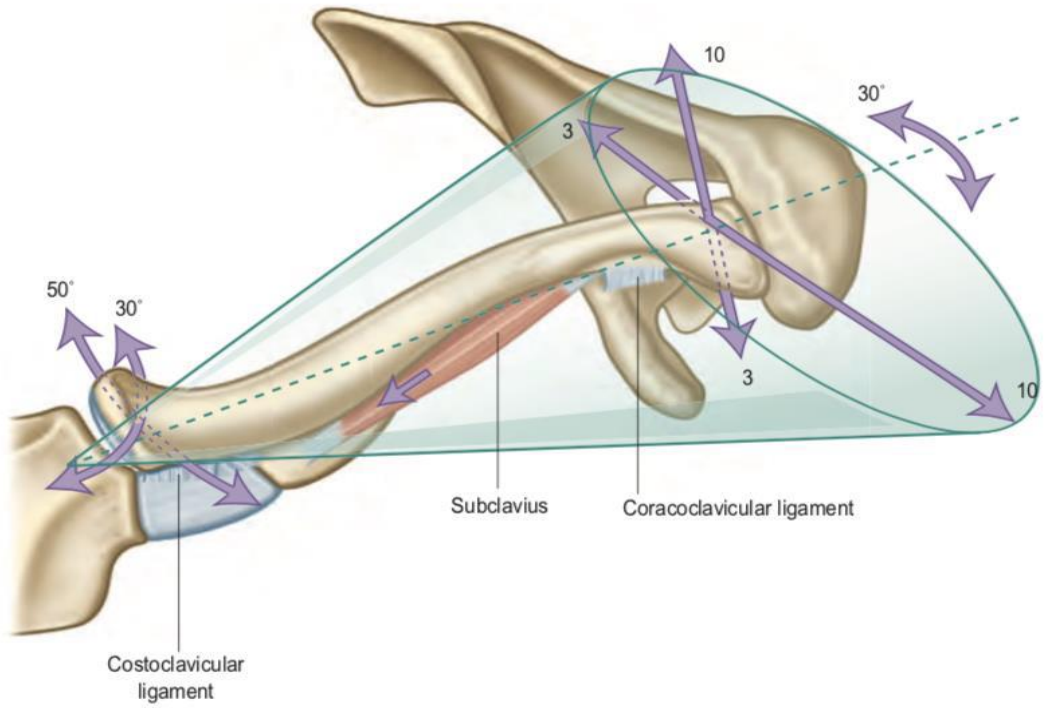


Fig. No.9B: BIOMECHANICS OF CLAVICLE[1]

Subclavius prevents excessive upward displacement of clavicle during all movements of shoulder.Trapezium attaches to spine of scapula and to medial aspect of lateral third of clavicle, there by contribute to the stability of shoulder girdle.

The antagonist of trapezial power is pectoralis minor, which, rarely, has an extension or slip of tendon that joins the coracoacromial ligament. Pectoralis minor contraction will create protraction of scapula, which then rotates ventrally around the chest wall.[1]

FUNCTIONS OF CLAVICLE

Clavicle has following important functions:

1) Strut Function

Clavicle act as a brace to the shoulder girdle. Clavicle allows shoulder to reach into cross-body and allows the thoraco-humeral muscles to maintain their optimal working distance. Thereby increasing strength in shoulder movements.[37]

2) Stability and power:

Clavicle plays a key role in providing stability and power specifically when the arm is in more than 90 degrees of abduction. Because of position of clavicle and shoulder girdle the entire upper limb can have effective movement in all the 3 dimensions and subsequently better range of movement.[38]

3) Cosmetic aspects:

Clavicle being the subcutaneous in its entire aspect and has smooth surface; it provides the graceful curve to base of neck, hence also called as beauty bone.[37]

4) Contribution to shoulder girdle:

Clavicle act as a crank shaft helping in movements of shoulder joint especially in abduction, as it maintains the scapulohumeral rhythm.[38]

5) Muscular attachments:

Clavicle is a important bony base for origin and insertion of muscles.[38]

6) Neurovascular structure protection:

Many important neurovascular structures like brachial plexus, subclavian vessels, and apex of lungs are in close proximity of clavicle. Clavicle along with its muscular attachments forms important protector of these structures.

Absence of clavicle or its fracture can make these structures vulnerable to direct trauma injury. Also absence of clavicle causes drooping of shoulder which exacerbates the thoracic outlet syndrome.[38]

7) Respiratory function:

Owing to its ligamentous attachments to first rib, elevation of clavicle causes cephaled movement of rib cage during inspiratory movements.[3]

MECHANISM OF INJURY:

The most common mechanism of clavicle fracture is direct trauma to shoulder joint due to variety of reasons like during road traffic accidents or during sports activity or by fall from height. (Fig.10).

When the compression forces to the shoulder joint are directed from its lateral end clavicle function as a strut owing to its muscular attachments and articulations. (Fig.11).

Fig.No.10: MECHANISM OF INJURY IN CLAVICULAR FRACTURE[33]

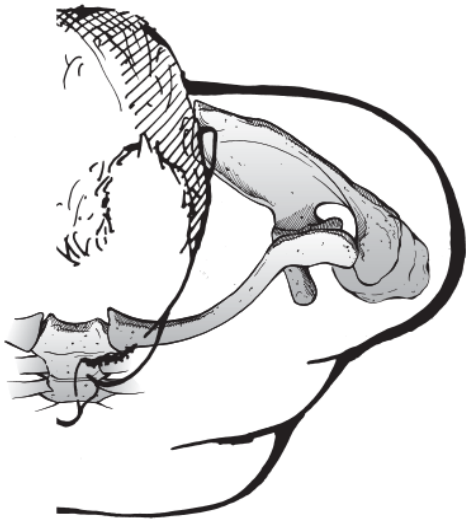


Fig. No.11: THE STRUT FUNCTION OF THE CLAVICLE[33]

When the deforming forces exceeds beyond certain limit there may be disruption of acromioclavicular (AC) joint or sternoclavicular (SC) joint or fracture clavicle. Posteriorly directed forces over sternal end results in sternoclavicular joint injuries.

Most (85%) clavicle fractures occur in the midshaft where clavicle is narrowest and surrounding soft tissue structures are least in this area. (Fig12)

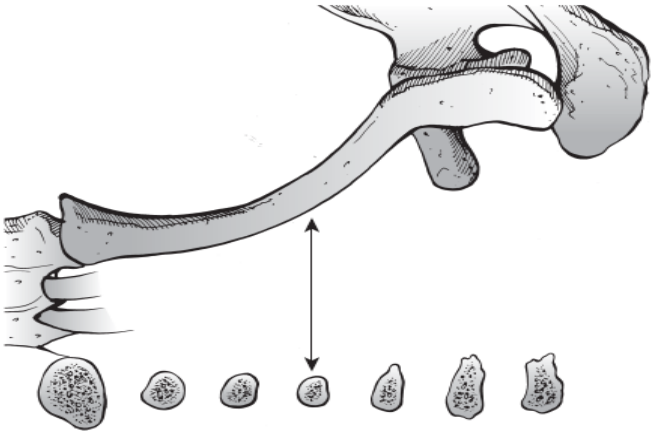


Fig. No.12: CROSS SECTION OF CLAVICLE AT DIFFERENT LEVEL[33]

The typical deformity is a result of both gravitational pull as well as distraction forces created by muscle pull. This deformity includes lateral third fragment displaced inferiorly, anteriorly and medially with rotational componant. (Fig No.13).

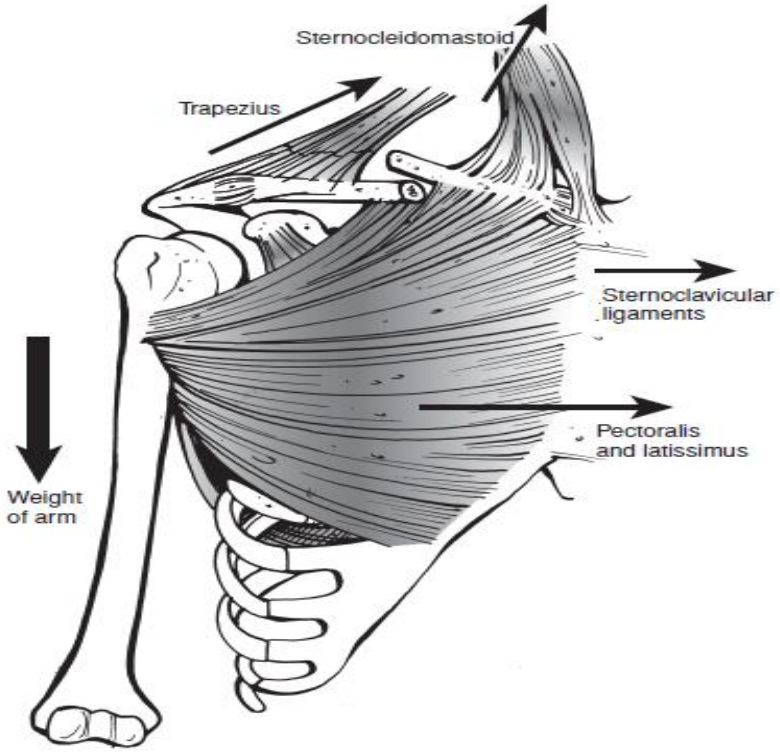


Fig. No.13:VARIOUS DEFORMING FORCES FOR DISPLACEMENT OF CLAVICLE[33]

In young healthy individuals, simple self fall from a standing height will not produce displaced clavicle fracture, but likely to produce one in elderly person. Such fractures are most commonly lateral third fractures.[33]

BIOMECHANICS OF FRACTURE CLAVICLE:

Various deforming forces for displacement of clavicle after its fracture are as below:

a) Sternocleidomastoid causes superior displacement of medial third segment
b) Pectoralis major and latissimus dorsi muscle causes inferior and medial displacement of lateral third segment
c) Weight of the arm also causes inferior displacement of lateral third segment of clavicle

CLASSIFICATION OF CLAVICULAR FRACTURES:

Several classification schemes exist for clavicular fractures, but the most commonly used system is that of Allman. According to location of fracture in the bone, he separated clavicle fractures into 3 groups. This is important because prognosis and treatment vary according to the type. These include:

Group-I - middle third clavicle fractures

Group-II - lateral third clavicle fractures

Group-III- medial third clavicle fracture.[34]

This classification has advantage of being the simplest classification and is used by most of the surgeons.

Drawback of this classification is that,it does not consider many factors like fracture pattern, displacement, shortening and amount of comminution which ultimately influence the overall management.

NEER CLASSIIFCATION:

Based on ligamentous attachment and degree of displacement, Neer described following types of fractures:

Type I: Fracture of lateral 1/3rd with intact coracoclavicular ligaments

Type II: Disruption of coracoclavicular ligaments from the medial fragment, with the trapezoidal ligament attached to the distal fragment

IIA: Both conoid and trapezoid attached to the distal fragment

IIB: Conoid detached from the medial fragment

Type III: lateral 1/3rd clavicle fracture with extension into the acromioclavicular joint. [34,39]

ROBBINSON CLASSIFICATION

This classification classifies clavicle fracture by considering displacement of fracture, intra-articular extension of fracture, anatomical site of fracture, and fracture stability.[34,40] This system of classification has been used in this study.

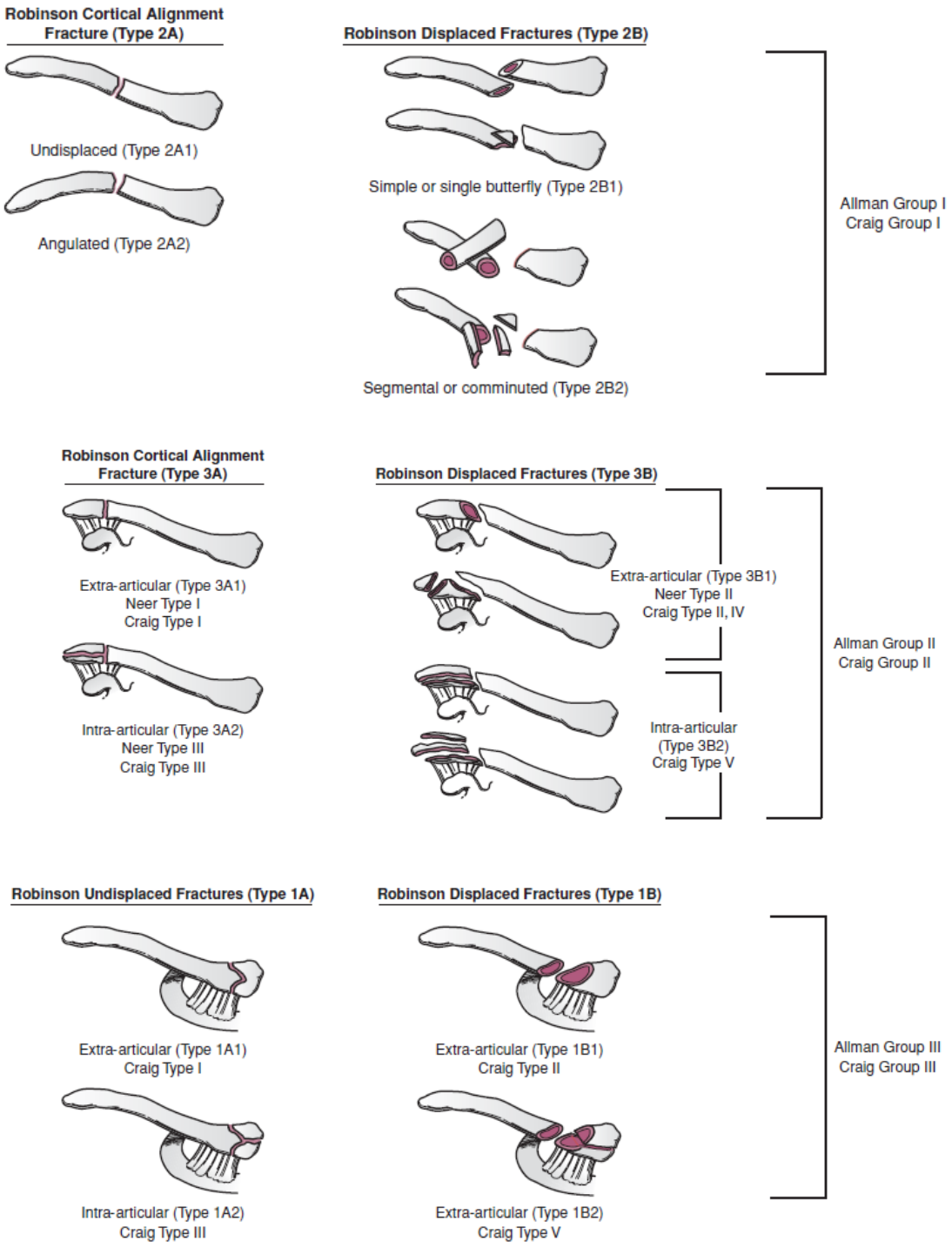


Fig. No.14: ROBBINSON CLASSIFICATION [34]

AO/OTA FRACTURE AND DISLOCATION CLASSIFICATION

This classification was updated in 2007 to include recent developments like unified numbering scheme and measures to improve inter-observer reliability. The clavicle is designated as segment 15 and divided into the standard medial metaphyseal, diaphyseal, and lateral metaphyseal fractures. They have used AO rule of squares to divide clavicle into shorter segments instead of one third of bone length.[34] (Fig. No.15)

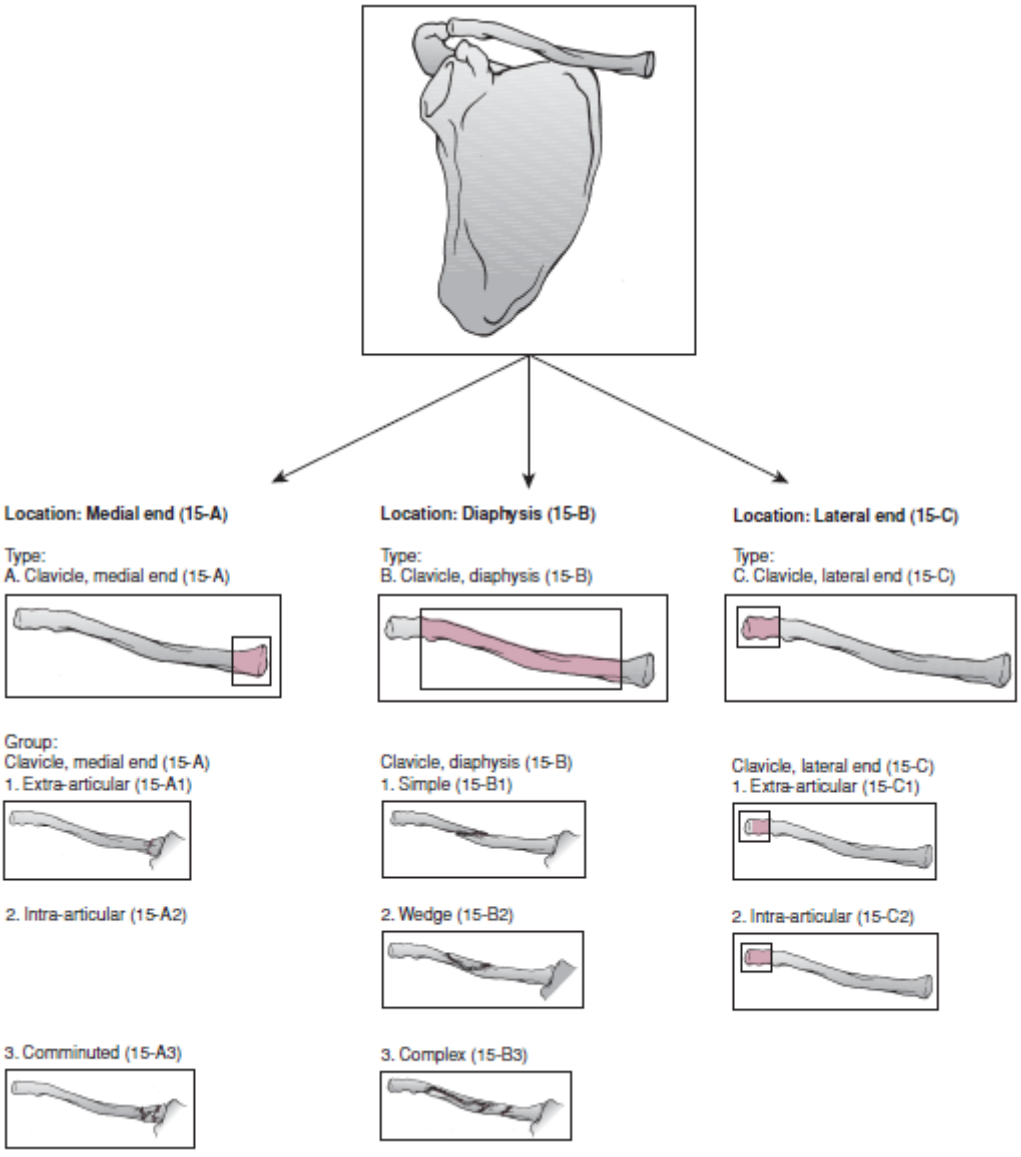


Fig. No.15**:AO / OTA CLASSIFICATION**[34]

CLINICAL FINDINGS

HISTORY AND CLINICAL PRESENTATION:

Patient with clavicle fracture will present with history of direct blow to shoulder joint caused by self fall on shoulder, or by any sports injury, or during road traffic accidents. Patient will complain of pain, swelling, ecchymosis around the affected clavicular area. Abrasions will be present in most of the cases of self fall over shoulder. Patient will be holding the affected extremity close to his trunk across the chest and supported by opposite hand. To decrease the pain of fracture patient may tilt his head towards affected side. This will relax the trapezium muscle pull and will reduce any distraction at fracture site.

EXAMINATION FINDINGS:

Proximal fracture ends are usually prominent and may tent the skin. Ecchymosis of skin over clavicle, shoulder or nearby areas may be found. Swelling, tenderness is classically seen. All arm movements will be painful.[41] Abnormal mobility, bony deformity and crepitus may be felt. Neurovascular examination of affected limb should be done. Chest injury should be ruled out, patient presenting with abnormal asymmetrical breath sounds, tachypnea may indicate ipsilateral underlying pneumothorax.

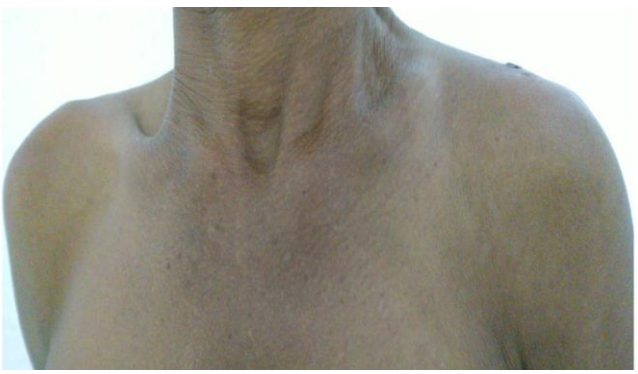


Fig.No.16: SKIN TENTING SEEN IN CLAVICLE FRACTURE

Shortening of clavicle may be present, measured by mark made in the midline of suprasternal notch and another at the palpable acromioclavicular joint ridge, measuring the length gives the difference between involved and uninvolved side.

ASSOCIATED INJURIES:

Following are injuries most commonly associated with clavicle fractures

1) Skeletal injuries – dislocation or fracture dislocation of acramioclavicular or sternoclavicular joint, head and neck injuries, first rib fracture, associated with dislocation or disruption of scapulothoracic articulation.
2) Blunt trauma to chest - pneumothorax, hemothorax
3) Vascular injuries - occlusion, laceration, spasm or acute compression of major vessels
4) Brachial plexus injuries.[34]
5) Clavicle fracture along with fracture of scapula. This kind of injury results in floating shoulder. [34]

RADIOGRAPHIC EVALUATION

The medial end gets superiorly displaced while lateral end gets inferiorly displaced in most of the cases of clavicle fracture with some amount of shortening. To know the exact configuration of deformity, one should always get at least 2 standard radiographs as 1) An anteroposterior view, 2) 45 degrees cephalic tilt view.

TREATMENT OF CLAVICLE FRACTURES

Primary goal of any modality of treatment is to achieve bony union; along with least complication rate which are associated with fracture itself and with the treatment undertaken. Like all other fracture treatment modalities these fractures can be treated conservatively or surgically.

A) CONSERVATIVE MANAGEMENT OF CLAVICLE FRACTURES:

Since the ancient times of 30th century BC, attempts to reduce the clavicle fracture have been made and its record is found in the "Edwin Smith" papyrus. Typical deformity caused was described by Hippocrates, he further emphasized about the importance of trying to correct the deformity. [42]

There are about hundreds of descriptions of different devices designed to maintain the reduction, including splints, body jackets, casts, braces, slings, swathes, and wraps. Now with period of time its been evident that none of these methods helps to maintain the fracture reduction or improves clinical, functional or radiographic outcomes. Current non-operative care is to apply a simple, conventional sling with a padded neckpiece, and no reduction is attempted. A sling has been shown to provide the same results as a figure-of-eight bandage, providing more comfort and fewer skin problems.[42,43]

So irrespective of type of treatment, main aim is to restore normal range of movements at shoulder joint with minimal deformity and pain.[45] Clavicle fractures with minimal displacement or no displacement should be treated non operatively as conservative modality of treatment will result in better outcome.[40] This is the reason why many authors recommend non surgical treatment in clavicle fractures with shortening up to 2 cm. [46]

However, in open fractures, compromised skin conditions, neurological deficiencies, vascular injury, ipsilateral serial rib fractures or floating shoulder surgical modality of treatment has to be considered. [47]

Complications of non-operative treatment mainly include malunion with shortening. This alters the biomechanics of shoulder girdle, in fact a shortening >10% affects scapular kinematics. [48]

In a long-term period, there will be consequences such as acromioclavicular degeneration, rotator cuff dysfunction and furthermore reduction of force. Therefore, patients with a functional shorter clavicle may benefit by undergoing a surgical procedure [49]. Thus after considering this it is clear that conservative type of modality of treatment can be used in most of the fracture clavicle but correct identification of patients which will be benefited from either of the treatment modalities is more important. Patients with persisting pain or a delayed course under conservative treatment may be candidates for early secondary surgery.

PRACTICAL CONSIDERATIONS AND TECHNIQUES OF NON-OPERATIVE MANAGEMENT

Based on the distraction forces acting at clavicle fracture ends, the frequent changes of position during day and night, and the constant respiratory excursions, there is always some motion in the fractured clavicle.[50]

In line with these observations, former techniques like painful closed reduction techniques are neither successful regarding enduring alignment nor recommended anymore.[51]

The most basic and common conservative treatment is to immobilize the affected shoulder with simple sling. Figure-of-eight brace is thought to prevent or reduce secondary fracture shortening while healing is going on. Stepwise tightening brace is recommended to counteract the shortening forces. Among all these treatment option, its not clear that which one is more effective and regarding period of immobilization. [52] Many studies have shown that the figure of- eight brace causes more discomfort and pain with no added advantage in fracture healing and preventing complication. Its complications include nerve compression with temporary brachial plexus palsies and restriction of venous blood return have been reported in the literature. [53]

B) OPERATIVE TREATMENT:

With increasing evidence that conservative treatment of displaced clavicle fractures is associated with increased morbidity to patient and also has long term effects on shoulder girdle biomechanics; operative treatment is being increasingly favored by many orthopedic surgeons**.**

Thus main aim in surgical management is to achieve early bone healing and to minimize the complications. Residual clavicle bone strength following implant removal may also be affected by implant characteristics and the fixation method due to differences in stress shielding and bone remodelling.[43,44]

OPERATIVE MANAGEMENT IS INDICATED IN:[4]

A) Fracture-Specific

1. Displacement >2 cm

2. Shortening >2 cm

3. Increasing comminution (>3 fragments)

4. Segmental fractures

5. Open fractures

6. Impending open fractures with soft tissue compromise

7. Obvious clinical deformity

8. Scapular malposition and winging on initial examination

B) Associated Injuries

1. Vascular injury requiring repair

2. Progressive neurologic deficit

3. Ipsilateral upper extremity injuries/fractures

4. Multiple ipsilateral upper rib fractures

5. "Floating shoulder"

6. Bilateral clavicle fractures

C) Patient Factors

1. Requirement for early upper extremity function as in poly trauma patients.

2. Patient motivation for rapid return of function (e.g., elite sports or the self-employed professional)

AVAILABLE METHODS BROADLY DIVIDED INTO:

i) Intramedullary device

ii) Open reduction and internal fixation with plates and screw

iii) Fixation using external device

I] INTRAMEDULLARY DEVICES:

Intramedullary devices consists of methods of fixation using K-wires, Knowles pins, Hagie pins, Steinman pins, cannulated screws, and newly introduced Elastic nails and their modifications.[54]

a)INTRAMEDULLARY FIXATION WITH K-WIRES:

Kirschner wire size of 2.5 to 3mm used for intramedullary fixation, usually not recommended because of danger of migration of wires into the thorax.

b)INTRAMEDULLARY FIXATION WITH TENS

The TENS stands for titanium elastic nailing system. In contrast to Kirschner wire fixation, ESIN (Elastic stable intramedullary nailing) is a truly intramedullary stabilization technique. According to the principles written by Ligier et al the flexible Titanium nail is firmly anchored in the S-shaped clavicle.[55]

Advantages of Titanium over other alloys:

i) Titanium is being used successfully as an implant material and this success with titanium implants is credited to its excellent biocompatibility due to the formation of stable oxide layer on its surface.

ii) Its osseo-integration property, high corrosive resistance, high specific strength, non-magnetic property, ability to repair itself instantaneously if damaged,

and modulus of elasticity compatible with that of bone, titanium is the material of choice. In this study the implant used is made of titanium alloy (Ti-6Al-7Nb).[56,57]

iii) Usual size of 2 to 3 mm nails is used (Size of nail was measured using the formula = 0.4 × canal diameter in mm).[58] Under c arm guidance entry point made 1.5 to 2 cm lateral to sternoclavicular joint. Alternatively posterolateral entry can be made 2 to 3cm medial to acromioclavicular joint but is not preferred as there are high chances of nail migrating into intrathoracic structures. During the closed reduction towel clip or Allis forceps can be used percutaneously to pass the nail into lateral fragment. Despite the best effort if the nail is not able to pass through fracture site to distal fragment, with small incision fracture site can be opened and nail is passed under direct vision.

Advantages of TENS implant:

A curved tip of TENS helps to facilitates nail passage within the medullary cavity. It blocks itself in the bone, thus improving fixation stability by providing intramedullary three point stabilization of the S-shaped clavicle using support within the medullary canal to effectively control rotation, angulation, and shortening. Clavicle has a unique anatomy which may allow the surgeon to extend the indications of using the TEN to moderately comminuted fractures. From the biomechanical point of view, intramedullarypositioning of the implant is ideal as direction of rotation as well as weight of arm determines the tension side of clavicle.

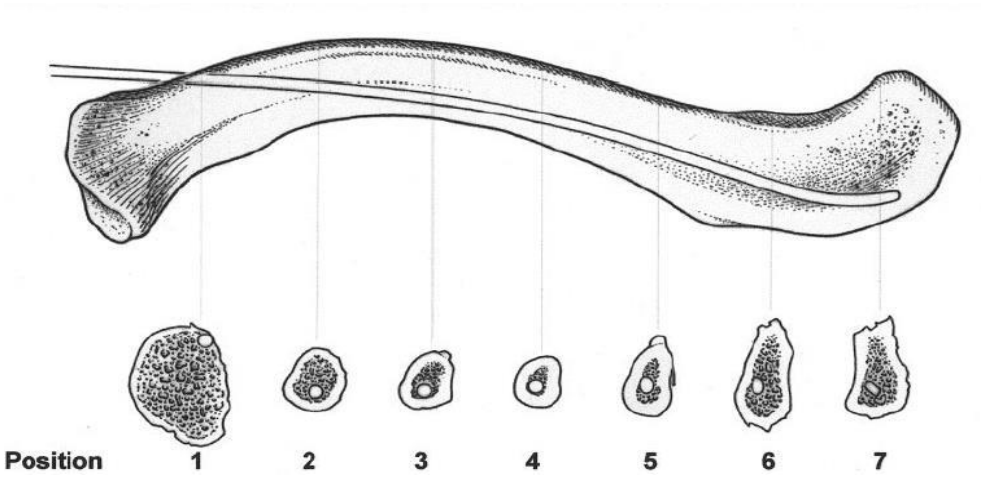


Fig. No. 17-Position of the TEN within the clavicular canal.[59]

Titanium nail has blunt entry side making it highly unlikely that it will cause injury to any of neurovascular structures. No such complication has been observed in literature using this technique. Other fatal complications like implant migration into the chest cavity have not been observed either. [60]

ADVANTAGES OF TENS PROCEDURE:

• Incision site for nail entry is very small, minimal soft tissue trauma

• Nail removal after fracture union can be done under local anesthesia.

• No or minimal soft tissue stripping.

• Decreased hardware prominence.

• Least or minimal incidence of re-fracture.[61]

• Fracture healing is enhanced by axial compression effect.

DISADVANTAGES OF TENS :

• Failure to control axial length and rotation especially with increasing fracture communition.[61]

• Technical expertise are required to some extent, attributed to inherent characteristics of clavicle like poorly defined medullary cavity, rotations of the lateral third fragment, and degree of curvature.

II) FIXATION USING PLATES AND SCREW:

Extramedullary fixation technique like plating is more rigid and is considered more stable than intramedullary devises like TENS as they resists the torsional and bending forces which are frequently produced during range of movements movements.

Fixation with plate and screws continues to evolve. Limited Contact Dynamic Compression Plate (LCDCP) of 3.5mm or low-profile reconstruction plates are being used recently. Locking precontoured plates are available which allow more anatomical fitting and also helps to maintain the bone strength. Usually plate is fixed over superior aspect of clavicle. But if fracture configuration allows anteroinferior plate placement is preferred as passage of screw is safer in this case and also post operatively less hardware prominance.[20]

TYPES OF PLATE USED:

i) AO Reconstruction plate

ii) Dynamic compression plate

iii) Locking compression plate

iv) One third semitubular plate

v) Low-contact dynamic compression plate

BIOMECHANICS OF LCP

The principle of locking compression plate is represented by the combination of two completely different anchorage technologies and two opposed principals of osteosynthesis in one implant. It combines the principles of conventional plate osteosynthesis for direct anatomical reduction with those of bridging plate osteosynthesis. Since the LCP can be used as a conventional plate using only dynamic compression, it provides the surgeon with multiple variations. Nevertheless, these new possibilities mean that pre-operative planning and understanding of the different biomechanical principals of osteosynthesis are essential if good clinical outcome are to be achieved and maximum benefit is to be attained from options offered by the LCP system.[66] Fig No.18A and 18B

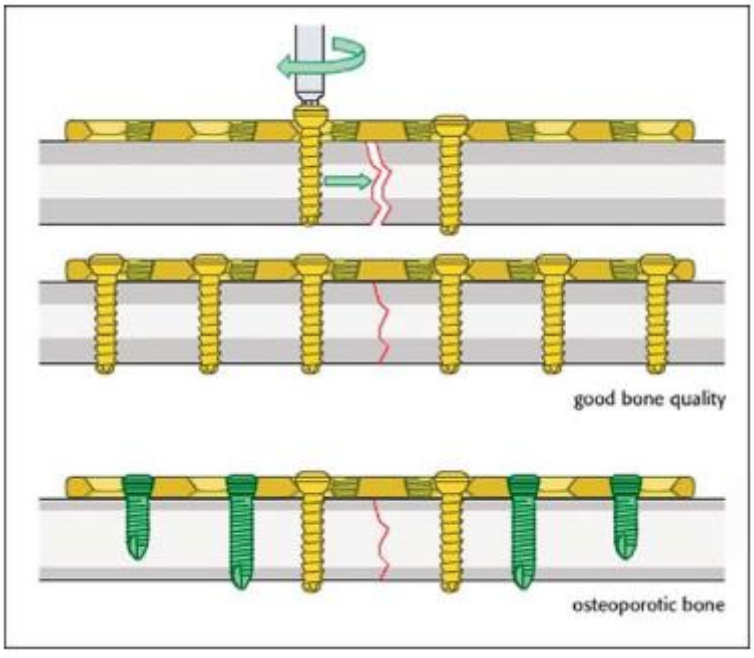


Fig. No.18A: BIOMECHANICS OF LCP: If the LCP is used in a compression mode, two cortex screws (placed eccentrically in the DC part of the combination hole) are used to compress the fracture.[66]

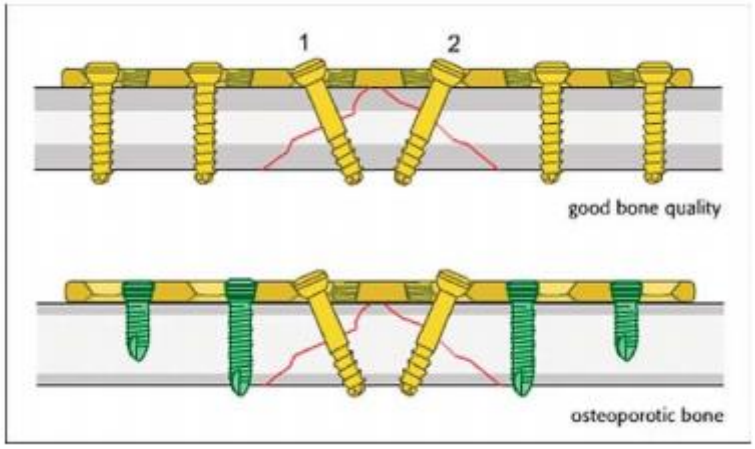


Fig No.18B: If the LCP is used as a neutralization plate, fracture reduction and interfragmentary compression are achieved by the lag screws (1 & 2).[66]

In case of good bone quality, the additional cortical screws add to the stability by increasing the friction between plate and bone. In osteoporotic bone, additional stability is achieved by inserting locking head screws. [66]Post operatively the arm is supported in sling for 1 to 2 weeks, solid union possible by 8 to 10 weeks. Activities involving light weight are allowed in daily living, but overhead abduction is not allowed until bony union is evident.

ADVANTAGES OF OPEN REDUCTION AND INTERNAL FIXATION WITH PLATE AND SCREWS FIXATION:

1. In transverse fracture cases, plate and screws achieve better compression across fracture site.
2. In cases of oblique fractures or butterfly fragments lag screw fixation can be used.
3. Better control of rotations of fractures owing to stable construct.
4. Stable construct also allows minimal weight lifting during daily living activities.[62]

DISADVANTAGES OF OPEN REDUCTION AND INTERNAL FIXATION WITH PLATE AND SCREWS FIXATION:

1. Major disadvantage is open reduction with subsequent soft tissue and periosteal stripping.
2. Supraclavicular nerves are at risk of injury during the soft tissue dissection as they cross through the surgical field.
3. Hardware prominence is common complication in thin patients owing to subcutaneous superior border of clavicle.
4. For plate removal another procedure is required, and the patient is left with higher chances of re-fracture following implant removal.

III) EXTERNAL FIXATION:

External fixation is rarely used for clavicle fracture. Usually it is indicated for severe open fracture with unfavorable skin conditions and infected non-union post plate removal.[63,34] External fixation involves many practical disadvantages which include: - difficulties with the position, prominence of the fixation pins and poor patient acceptance which lead to its minimal use.[65]

MATERIALS & METHODS

METHODOLOGY

A) CALCULATION OF SAMPLE SIZE:

It is estimated based on the difference between functional outcome between the two methods of treatment in a similar comparative study with 5% of alfa error, a effect size of 62%(11.25), with 95% confidence interval, with 80% power, calculated sample size per group is 27. With 10% of dropout rate, final sample size per group was 30.

Sample size(n) = $\frac{2\,\sigma^2(Z_{1-\alpha}+ Z_{1-\beta})}{d}$

$\sigma = 1.4$

$Z_{1-\alpha} = 1.96$ (95% confidence interval)

$Z_{1-\beta} = 0.842$ (80% power)

d = effect size 11.5% difference in mean score

B) SAMPLING METHOD:

With Sample size of 60, systematic random sampling method was used, and patients were randomized into 2 groups using block randomized technique, with block size of 4. Group A patients received non-operative treatment with arm pouch and clavicular brace (30 patients). Group B received surgical management (30 patients). All patients were evaluated by detailed history about the trauma and mode of injury, and detailed physical and radiological examination.

C) METHOD OF COLLECTION OF DATA:

This study will be conducted on patients attending the orthopedic outpatient section and inpatient of R.L.Jalappa hospital and research centre Tamaka, Kolar. It is a prospective and comparative study of 60 cases of displaced diaphyseal fractures of the clavicle carried out from Nov. 2017 to April 2019. All the cases satisfying the inclusion and exclusion criteria were included in the study. Cases in the surgical group were managed either with intramedullery device like TENS or extramedullary device like plate and screw and cases in conservative group will be managed with shoulder arm pouch andclavicular brace. Functional outcome of both the methods will be assessed using the objective and subjective parameters of the *Constant and Murley score.*[67]

D) INCLUSION CRITERIA:

- Patients with displaced midshaft clavicle fracture aged between 18 years to 65 years

E) EXCLUSION CRITERIA:

- Compound fractures of the clavicle.
- Severely comminuted fractures of the clavicle.
- Patients with neurovascular deficits

F) PRELIMINARY EVALUATION:

Patient's information like name, sex, age, address and occupation were documented. For all the cases admitted and included in this study have been thoroughly examined including history, mode of injury, time of injury and place of injury were documented.

Patient was asked about their major complaints like site of pain, swelling and side affected. Past family history and medical illness were documented.

General examination and primary and secondary surveys also were documented. Systemic examination was done and after ruling out any other co-morbidities or vital organ injuries and once patient's vitals are confirmed to be stable, local examination was done and recorded as given below:

G) LOCAL EXAMINATION

1. INSPECTION**:**

• Patients with clavicle fracture usually presents with ipsilateral elbow flexed and forearm supported with the other hand.

• Skin around the clavicle was inspected for any abrasion, laceration, contusion, ecchymosis, swelling and skin indentation by fracture fragments.

Fig. No. 19: LOCAL EXAMINATION OF CLAVICLE FRACTURE

2. PALPATION:

• The affected clavicle was palpated gently for crepitus.

• Entire length of clavicle was palpated to check for site of tenderness, bony crepitus, and abnormal mobility.

3. MOVEMENTS:

• There was painful restriction of shoulder movements on the affected side.

• The affected upper limb was examined for distal vascular and neurological status, and patient screened for other injuries.

• Immobilization was done with arm pouch or sling for affected limb.

• Routine investigations like hemoglobin along with total count, differential count, ESR, blood sugar, renal function test, HBsAg, HIV and ECG were done. All patients in operative group were taken for surgery only after they were clinically stable and fit for surgery as assessed by the physician.

G) FRACTURE MANAGEMENT

1) Conservative management :

All selected patients were immobilized with help of clavicular brace and shoulder arm pouch for maximum three weeks. No method of reduction of fracture was used. Serial tightening of brace was done as tolerated by patient.

They were encouraged to discontinue the sling when they no longer felt it was necessary and to use the arm and shoulder within the limits of pain. No physiotherapy was instituted.

Fig. No. 20: CONSERVATIVE MANAGMENT OF PATEINT

Patients with symptomatic radiological nonunion six months after the injury were offered surgical treatment, consisting of debridement, reaming of the medullary cavity, followed by fixation with clavicular LCP fixation. Bone graft was used from iliac crest if necessary.

2) OPERATIVE MANAGEMENT:

Selected cases were managed with eitherintramedullery device like TENS or extramedullary device like plate and screw.

No randomization was done in this group. First 15 patients were treated with open reduction and internal fixation with clavicular locking compression plate and screws and next 15 patients were treated with open reduction and internal fixation or closed reduction and internal fixation by TENS.

PRE-OPERATIVE PREPARATION OF PATIENTS:

• All patients maintained nil per oral for 6 hours before surgery.

• Patient was taken for surgery after taking written informed consent.

• The neck, chest, axilla shoulders and arm were prepared.

• A systemic antibiotic usually Inj. Amoxicillin clavulanic acid 1gm intravenou- sly was administered 30 minutes before surgery to all patients.

I] OPERATIVE TREATMENT WITH TENS:

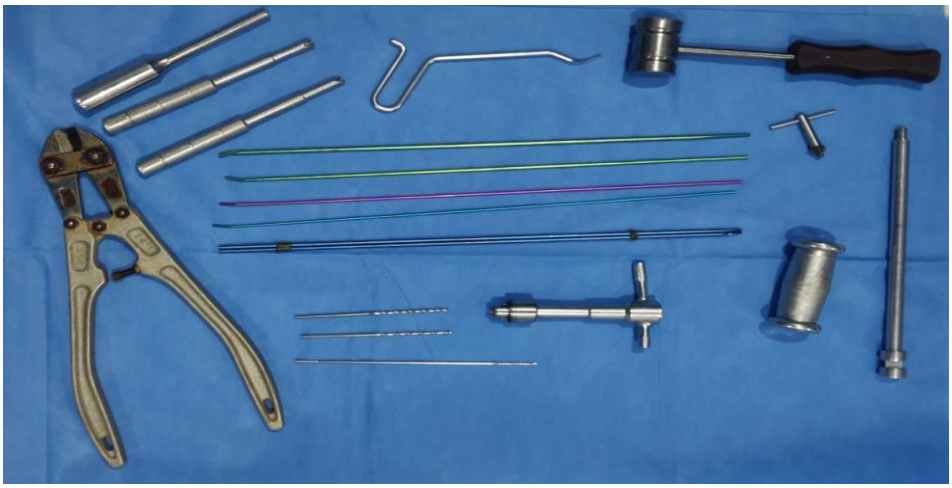


Fig. No. 21 : TENS INSTRUMENT SET

Nail diameter	Length (mm)	Color of Ti version	
1.5	300	purple	
2.0	440	green	
2.5	440	rose red	
3.0	440	gold	
3.5	440	light blue	
4.0	440	purple	

Fig. No. 22: TENS INSTUMENTS SET

SURGICAL TECHNIQUE OF TENS

• Patient positioned in supine position under general anaesthesia over a radiolucent table with sandbag under interscapular region and was draped under sterile conditions in such a way that free range of movements is possible at shoulder.

• A small horizontal incision in line with clavicle, of 1-1.5 cm; approximately 2 cm lateral to the sternoclavicular joint. Underlying soft tissue was divided in layers with blunt dissection to reach the bone. (Step-1).

• The cortex is opened at an angle of 30 degree to horizontal plane after soft tissue dissection with an awl or a drill bit (Step-2).

• A flexible titanium nail of appropriate size was put on a Jacobs chuck with T-handle and was advanced into the medullary canal manually (Step-3).

• With image intensification, the implant is passed gradually till fracture site. When the tip reaches the fracture, reduction is performed by means of a reduction clamp percutaneously and negotiating the nail into the lateral fragment.

• If this fails, tip of the nail was maneuvered from one fragment to another under direct vision after performing a second small transverse (2–3cm) incision over fracture site. The nail is then advanced manually or gently tapped with a mallet to the AC joint.[68]

OPERATIVE PHOTOGRAPHS

1) OPEN REDUCTION

Fig. No.23: PATEINT POSITIONED AND DRAPED

Fig. No.24: MAKING ENTRY WITH AWL

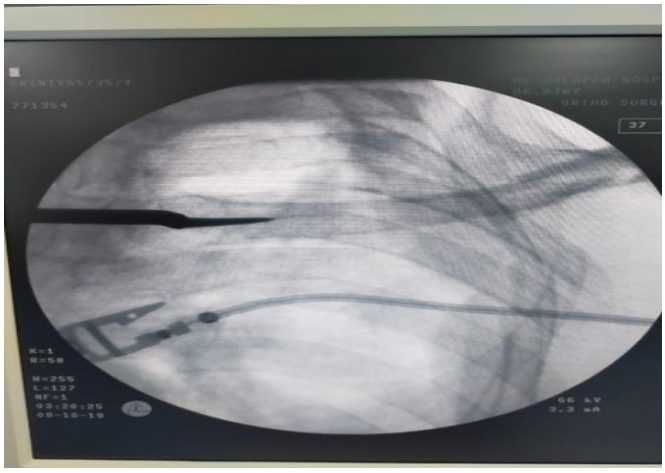


Fig. No.25: INTRAOPERATIVE C-ARM IMAGE OF ENTRY BEING MADE WITH AWL

Fig. No.26: INSERTING TENS THROUGH ENTRY POINT

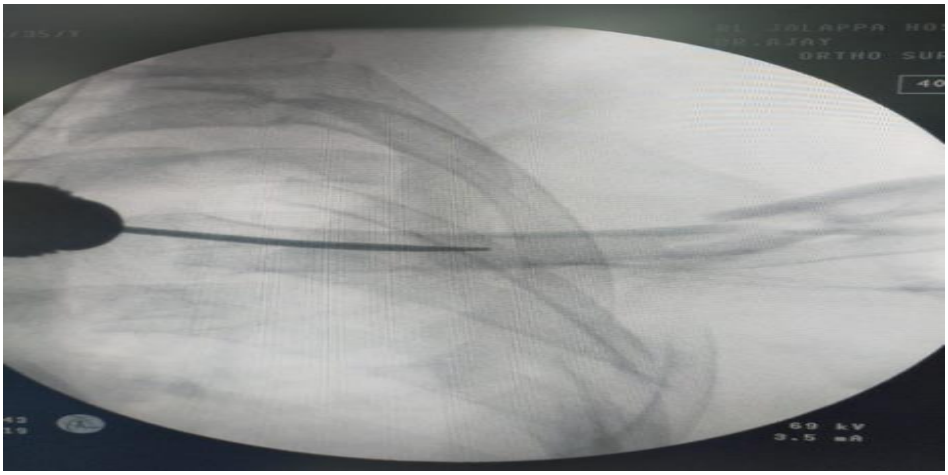


Fig. No.27: INTRAOPERATIVE C-ARM IMAGE : PASSING TENS THROUGH FRACTURE SITE

Fig. No.28: FRACTURE OPENED WITH MINIMAL INCISION

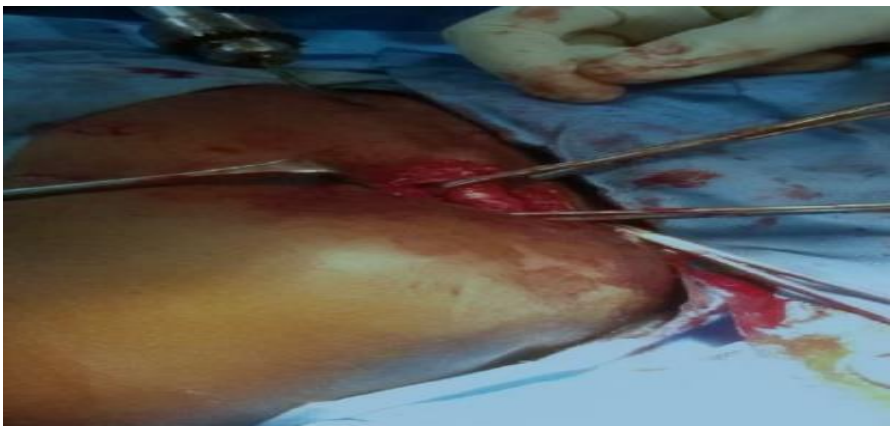


Fig. No.29: NAIL PASSED UNDER DIRECT VISION

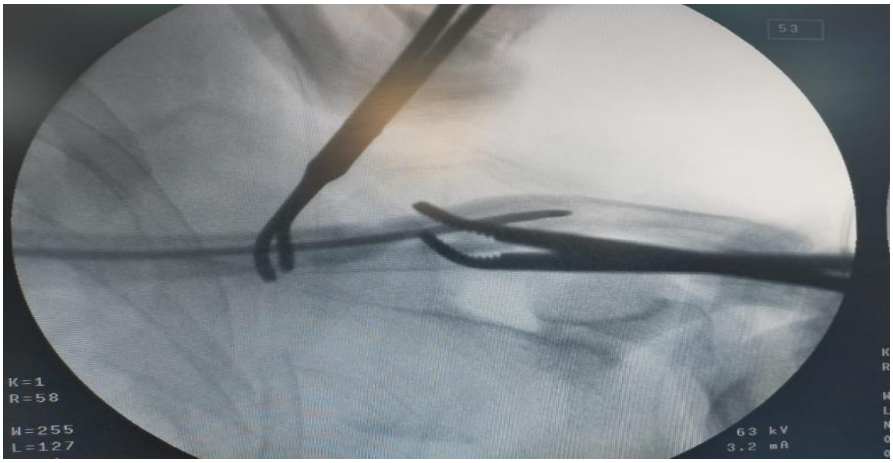


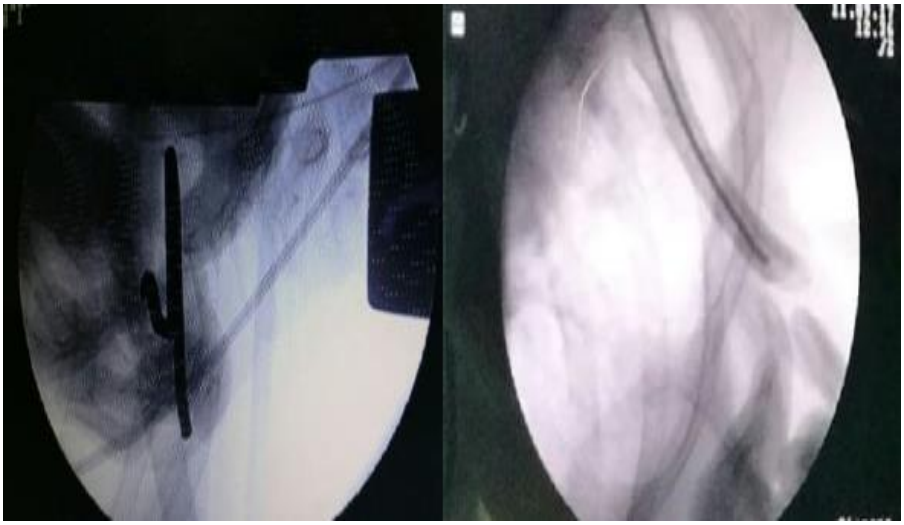
Fig. No.30: INTRAOPERATIVE C-ARM IMAGE OF NEGOTIATING NAIL THROUGH FRACTURE SITE

Fig. No.31: INTRAOPERATIVE C-ARM IMAGE OF FINAL NAIL PLACEMENT

Fig. No.32: SURGICAL WOUND CLOSED WITH STAPLES

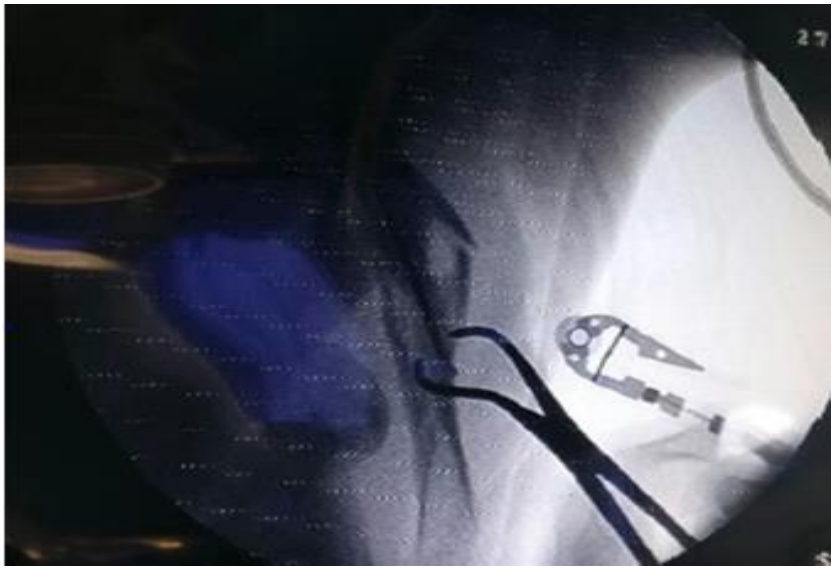
2) CLOSED REDUCTION INTRAOPERATIVE PHOTOGRAPHS

i) Fig. No.33: MAKING NAIL ENTRY

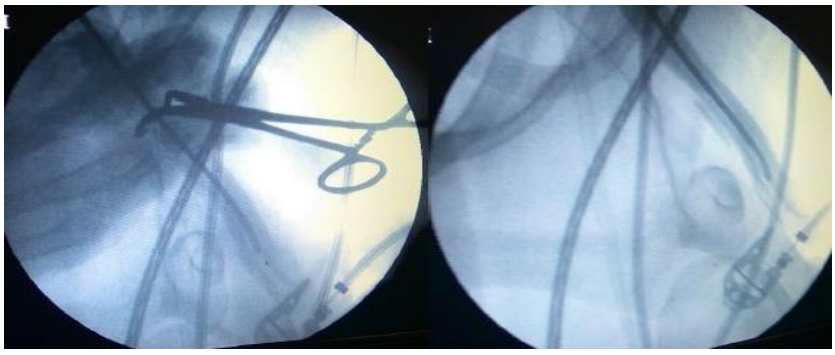


ii) Fig. No.34: INTRAOPERATIVE C-ARM IMAGE

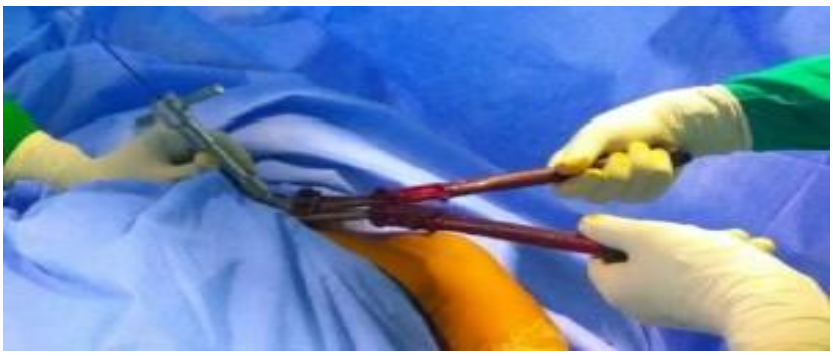
iii) Fig. No.35: PASSING NAIL THROUGH FRACTURE SITE



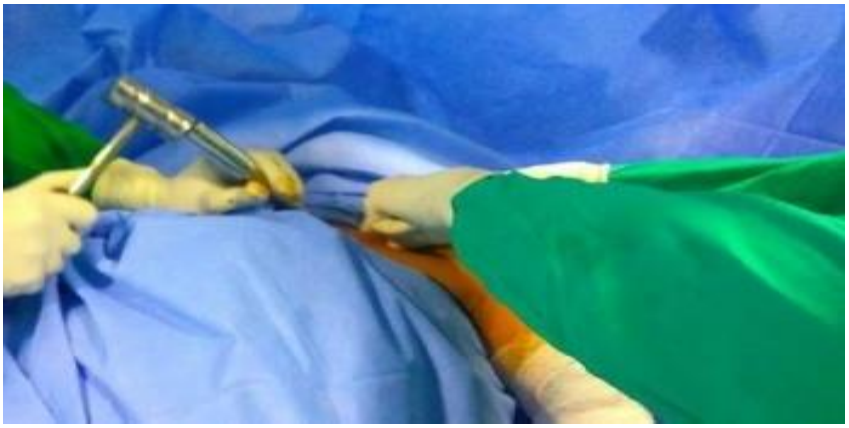
iv) Fig. No.36: NEGOTIATING FRACTURE USING TOWEL CLIP AND NAIL PASSED TO LATERAL FRAGMENT



v) Fig. No.37: FINAL NAIL POSITION



vi) Fig. No.38: CUTTING THE TENS



vii) Fig. No.39: IMPACTION OF TENS

II) OPERATIVE TREATMENT WITH LCP:

INSTRUMENTS

1. Clavicle locking compression plate of 3.5 mm and 7 to 9 hole
2. Universal drill guide 3.5mm
3. Drill bit 3.0 mm
4. Depth gauge
5. Power drill
6. Cortical screw of varying sizes 3.5mm (12-20 mm)
7. Locking screw of varying sizes 4.0 mm (12-20 mm)
8. General instruments like retractor, periosteal elevator,
9. Reduction clamps and bone lever.
10. Hexagonal screw driver

Fig. No.40A: LCP SET OF INSTUMRNTS

Fig. No.40B: LCP SET OF INSTUMRNTS

SURGICAL TECHNIQUE

i) Patient positioned in supine position under general anesthesia (GA) over a radiolucent table with sandbag under interscapular region and was draped under sterile conditions.

ii) About 6 to 8 cms, incision centered over fracture site was made in the anterosuperior aspect of clavicle.

iii) The underlying soft tissue was dissected with blunt dissection and platysma was identified and divided to reach the bone.

iv) The clavipectoral fascia was released from its attachment to anterior clavicle and is reflected inferiorly.

v) First medial fragment dissection is done. Minimal soft dissection was done.

vi) Both fracture fragments were held with fracture holding forceps and fracture was reduced. Plate was placed over superior aspect of clavicle

vii) This locking compression plate was fixed with locking and cortical screws with 6 cortexes on either side of fracture.

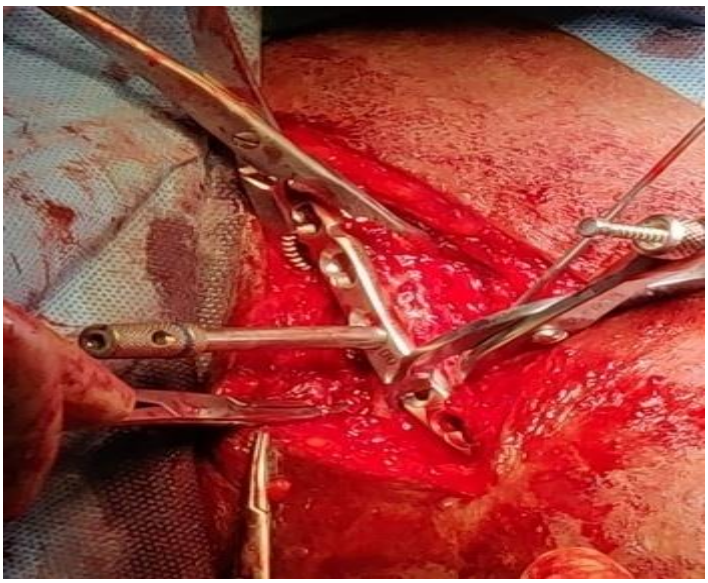
viii) Care was taken while drilling for screws not to go beyond the bone as all vital structure are in vicinity and a protective instrument was held over inferior aspect of clavicle.

ix) After hemostasis is assured wound wash was given thoroughly and wound was closed and sterile dressing was applied.

OPERATIVE PHOTOGRAPHS:

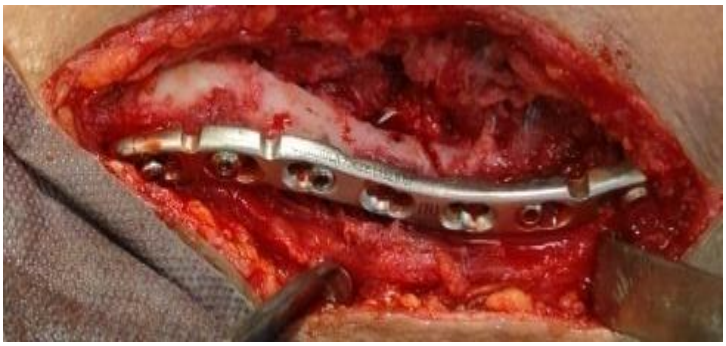
i) Fig. No.41:Patient positioning and draping

ii) Fig. No.42:Fracture exposure and reduction

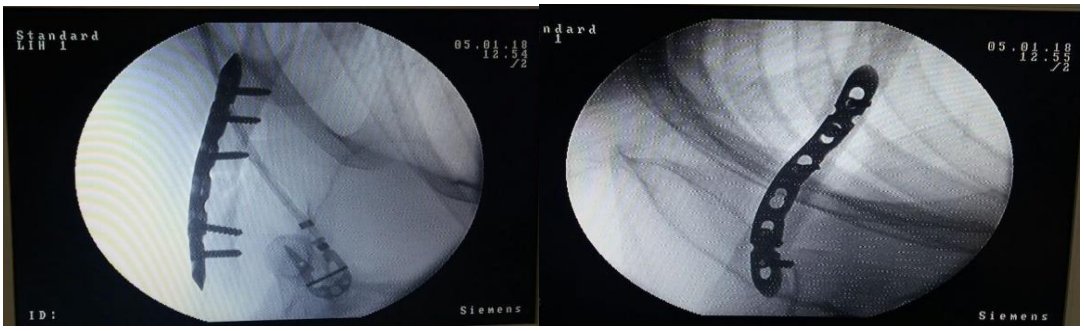


iii) Fig. No.43:Fracture exposure and reduction

Plate fixation



iv) Fig. No.44:Final screw fixation



v) Fig. No.45:Intraop Carm pics

vi) Fig. No.46:Wound closure and skin closure with staples

FOLLOW UP OF CONSERVATIVE CASES:

Affected shoulder was immobilized is shoulder arm pouch and clavicular brace for at least 3 weeks. Self-mobilization of the elbow out of the sling is encouraged several times a day to avoid elbow stiffening. The shoulder range of motion should be encouraged as tolerated by patient after 3weeks. For next 4 weeks patient is allowed to do range of movements in horizontal plane. Free range of motion is usually allowed after 6 weeks.[69] Weight bearing should be avoided until clinical fracture consolidation.

Many clinicians allow their patients to begin with isometric physiotherapy and resistance exercises depending on residual pain and discomfort. Sporting activities and work, are usually suspended until the patient is free of pain with radiographic signs of progressing fracture consolidation, usually after 6-12 weeks. [70] Contact sports should be avoided for 3-4 months. [71]

All cases were followed up, upto 6 months. Regular clinical follow-up examinations including radiographs were taken to monitor fracture healing. Non surgically treated cases normally unite during18 and 28 weeks post injury.[71-72]

FOLLOW UP OF OPERATIVE PROCEDURE:

POSTOPERATIVE PROTOCOL FOR TENS AND LCP:

- Till 6 hours post operatively all patients were kept nil per oral. Antibiotics and intravenous fluids were given as needed and for postoperative pain control, a sling is given for a few days.
- Post operatively implant position and reduction confirmed with check x-rays. Wound was inspected on second postoperative day and on 14th postoperative day suture/staple removed.
- Shoulder movements initiated from 2nd postoperative day.
- A minimum of 3 days of IV antibiotics was kept mandatory before patients were discharged. They were discharged at request or after sutures have been removed.
- Active shoulder movements i.e. over 90° abduction or flexion, was limited for 4 weeks. Gradual shoulder pendulum exercise and wall climbing exercises started as tolerated by patient.

COMPLICATIONS:

A) COMPLICATIONS OF NON-OPERATIVE TREATMENT

a) Malunion:

Chance of shortening or angulation are high as remodeling potential is low in adults. Patients had significantly more pain when clavicular segment is shortened more than 15mm at follow-up examination than those without this finding, indicating shortened clavicle is undesirable.[73]

b) Non-union:

Non-union of clavicle is defined as absence of clinical or radiographic signs of fracture healing at 4 to 6 months. At 16 weeks period as long as some potential for healing was present it is called delayed union. Non-union after conservative treatment is higher than actual thought with an incidence upto 15% to 25%.[10]

Factors predisposing to clavicular non-union are –

i. Inadequate immobilization.
ii. Severity of trauma: clavicle being subcutaneous bone, and if it is subjected to severe soft-tissue injury, half of this fractures result in non-union. Open fractures are even more prone for non-union.
iii. Marked shortening ≥20mm.[74]
iv. Marked displacement >20mm as caused by distracting muscle forces and by weight of the arm.[74]
v. Interposition caused by soft tissue that will interfere with healing.
vi. Re-fracture.

vii. Primary open reduction: Extensive soft tissue dissection, periosteal stripping and infection are attributed to cause nonunion in fractures treated with internal fixation.

c) Post traumatic arthritis:

Post traumatic arthritis is sequelae of missed intra-articular fracture in most of the cases. It can also occur a result of prolonged immobilization after clavicle fracture.[2]

d) Neurovascular sequelae:

It can occur following both united and non-united fractures in adults. Costoclavicular space may be significantly narrowed by the abundant callus or fracture deformity causing symptoms which involve the brachial plexus (mainly ulnar nerve) or subclavian and axillary vessels.

Ulnar nerve passes in between the first rib and the medial third of clavicle; hence ulnar nerve is more frequently involved in medial 1/3rd clavicle fracture complications.

COMPLICATIONS FOLLOWING SURGICAL MANAGEMENT:

1) Hard ware problems:

Protrusion of medial tip of elastic nail being most common complication associated with TENS nailing. Even lateral migration of nail has been observed in cases where lateral third fragment has been reamed and in comminuted fractures. In all cases of LCP fixation for clavicular fractures inadequate purchase or plate size, collapse of the intercalary graft are the important predictors of failures.

Hardware prominence in post op cases of LCP fixation is very common complication in thin built patients.

2**) Infection:**

Infection is devastating complication in cases of fracture clavicle treated by surgery or especially in cases of non-union which have been treated conservatively. Surgical treatment with LCP fixation demands for large incision, and soft tissue damage is more; making it more prone for infection. When compared to elastic nailing, infection rates are less even if open reduction is done.

Initial treatment of infections should include operative debridement. If hardware configuration is unstable, treatment should include 6 weeks of intravenous antibiotics after removal of all hardware.

Once infection subsided clinically, revision surgery can be undertaken. Vascularized graft may be needed if there is major loss of bone.

3) **Neurovascular injury.**

4) **Pneumothorax.**

5) **Hypertrophic scar:**

The risk of hypertrophic scar after open plating is high for which treatment option is to excise the scar at the time of plate removal.

6**) Re-fracture:**

Initial fracture comminution increases the risk for subsequent re-fracture.

7**) Malunion , delayed union and non-union.**[36,65,75]

8) **Shoulder stiffness**. [6,37]

CONSTANT AND MURLEY SCORING[67]:

In the current study, we chose the Constant scoring system as it is simple, practical, easy to apply, and they target the effect of the procedure on the overall daily function. Moreover, being universally accepted scoring systems, this helped to standardize the results in comparison with those of other studies reported in the literature.[67]The scoring system is as below:

CATEGORY:

A) SUBJECTIVE:

1) Pain- 15 points

No pain	15
Bearable pain	10
Disabling pain	5

2) Activities of daily living: - 10 Points

Ability to perform full work	4
Ability to perform Leisure activities/ Sports	4
Unaffected sleep	2

3**) Level at which work can be done: 10 Points**

Up to Waist	2
Up to Xiphoid	4
Up to Neck	6
Up to Head	8
Above head	10

B) OBJECTIVE:

(RANGE OF MOVEMENTS: 40 POINTS)

a) Active painless flexion: 10 Points

00 – 30 Degrees 0	0
31-60 Degrees 2	2
61-90 Degrees 4	4
91-120 Degrees 6	6
121-150 Degrees 8	8
> 151 Degrees 10	10

b) Functional external rotation: 10 Points

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 painless abduction: 10 Points

With dorsum of hand on back, head of 3rd metacarpal reaches

00 – 30 Degrees	0
31-60 Degrees	2
61-90 Degrees	4
91-120 Degrees	6
121-150 Degrees	8
> 151 Degrees	10

d)Functional internal rotation: 10 Points

Ipsilateral buttock	2
S1 spinous process	4
L3 spinous process	6
T12 spinous process	8
T7 spinous process	10

e) Strength of abduction: 25 Points

A shoulder of normal 25year old man resists 25 pounds (~12kg) without difficulty and for such a shoulder is 25 points was given. The technique of measurement of strength is still a subject to controversy. The European Society for Shoulder and Elbow Surgery recommends following method:

- A spring balance is attached to distal part of forearm.

- Strength is measured by keeping arm in 90 degrees of elevation from the plane of scapula with a straight elbow.
- Palm of hand facing the floor (pronation).
- The patient should maintain the resisted elevation for at least 5 seconds.
- It should be repeated one after another for 3 times immediately.
- The average in pound/kilogram (lb. / kg) is documented.
- There should be painless movement during measurement. Patient gets 0 points if pain is present and if unable to reach 90 degrees of elevation in the scapula plane.

Weight Points

Less than 1 kg	0
1 KG - 2 KG	3
2 KG - 3 KG	5
3 KG - 4 KG	7
4 KG - 5 KG	9
5 KG - 6 KG	11
6 KG - 7 KG	13
7 KG - 8 KG	15
8 KG - 9 KG	17
9 KG - 10 KG	19
10 KG - 11 KG	21
11 KG - 12 KG	23
>12kg	25

FINAL OUTCOME:

Maximum total point is 100. Patients were graded as given below:

Total score Result

SCORE GRADE

SCORE	**GRADE**
90-100	Excellent
80-89	Good
70-79	Fair
0-69	Poor

RESULTS

RESULTS AND OBSERVATIONS

In this series, 60 patients with mid shaft clavicle fracture were included. Out of total 60 cases; 30 were treated non-operatively and remaining 30 cases were treated with surgical management.

All 60 patients followed up for 6months from Nov. 2017 to April 2019. The observations are as given below:

TABLE 1: - DISTRIBUTION OF CASES ACCORDING TO SEX

Sex	Number of cases	Percent
Female	15	25%
Male	45	75%
Total	60	100%

Majority of the injury occurred in male patients- 45 cases (75%), whereas a total of 15 cases (25%) were seen in females.

GRAPH: 1 -DISTRIBUTION OF CASES ACCORDING TO SEX

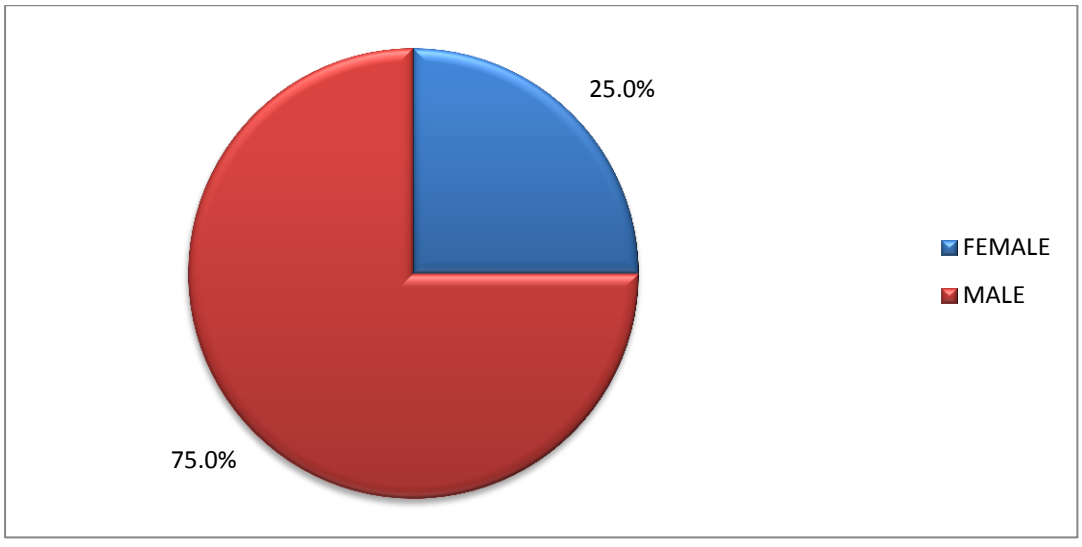


TABLE 2: - DISTRIBUTION OF CASES ACCORDING TO AGE GROUP

Age group (in years)	Number of cases	Percentage
Up to 20	3	5.0%
21-30	21	35.0%
31-40	13	21.7%
41-50	9	15.0%
51-60	8	13.3%
>60	6	10.0%

The distribution of age reveals that 3 cases (5%) lie between 18-20years, 21 cases (35%) lie between 21-30years, 13cases (21%) lie between 31-40years, 9 cases (15%) lie between41-50 years, 8 cases(13%) lie between51-60 years and 6 cases (10%) from >60 years.

GRAPH 2: -DISTRIBUTION OF CASES ACCORDING TO AGE GROUP

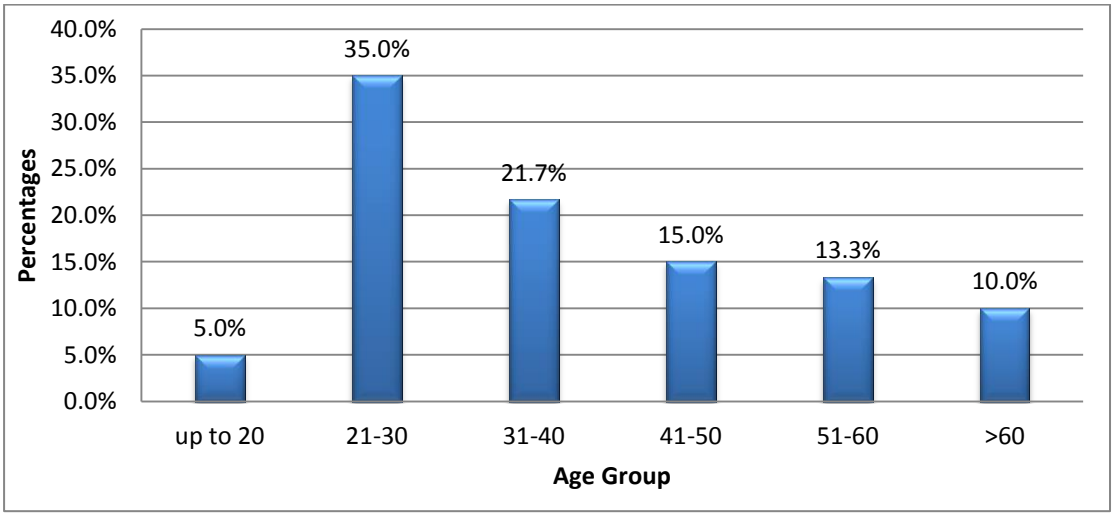


TABLE 3: - DISTRIBUTION OF SURGICALLY MANAGED CASES ACCORDING TIME INTERVAL BETWEEN TRAUMA & SURGERY

Time interval between injury and treatment	Number of cases	Percentage
< 3 days	19	63.3%
3-7 days	6	20%
8-14 days	2	6.6%
>14 days	3	10%
Total	30	100%

In 30 cases that were managed surgically, time interval between between trauma and surgical intervention was recorded. Majority of cases, 19 (63.3%) were operated within less than 3 days,6 cases(20%) were operated between 3 to 7 days, 2 cases (6.6%) surgery was done between 8 to 14 days, and in 3 cases (10%) after 14 days.

GRAPH: 3- DISTRIBUTION OF CASES ACCORDING TO TIME INTERVAL BETWEEN TRAUMA & SURGERY

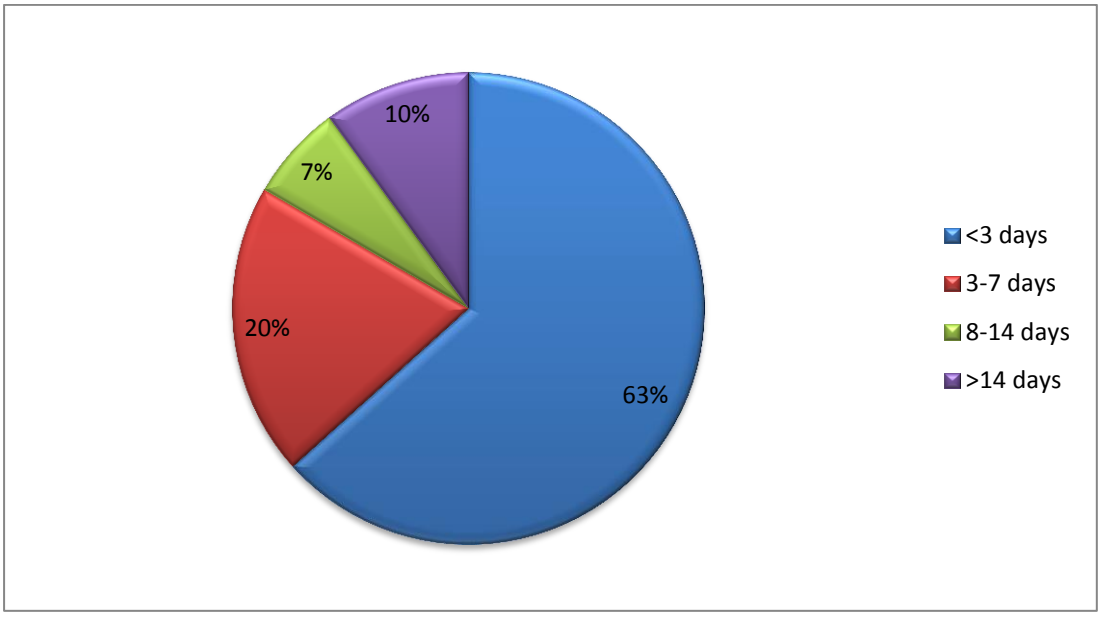


TABLE 4: - DISTRIBUTION OF CASES ACCORDING TO MODE OF INJURY

Mode of Injury	Frequency	Percentages
RTA	29	48.3%
FOOH	18	30.0%
Direct trauma	8	13.3%
Self-fall	5	8.3%

Majority of patients i.e. 29 cases (48.3%) had clavicle fracture as a result of road traffic accidents, 18 cases (30%) as a result of fall on an outstretched hand, 8 cases (13.33%) due to direct trauma and 5 cases (8.33%) due to self fall.

GRAPH: 4- DISTRIBUTION OF CASES ACCORDING TO MODE OF INJURY

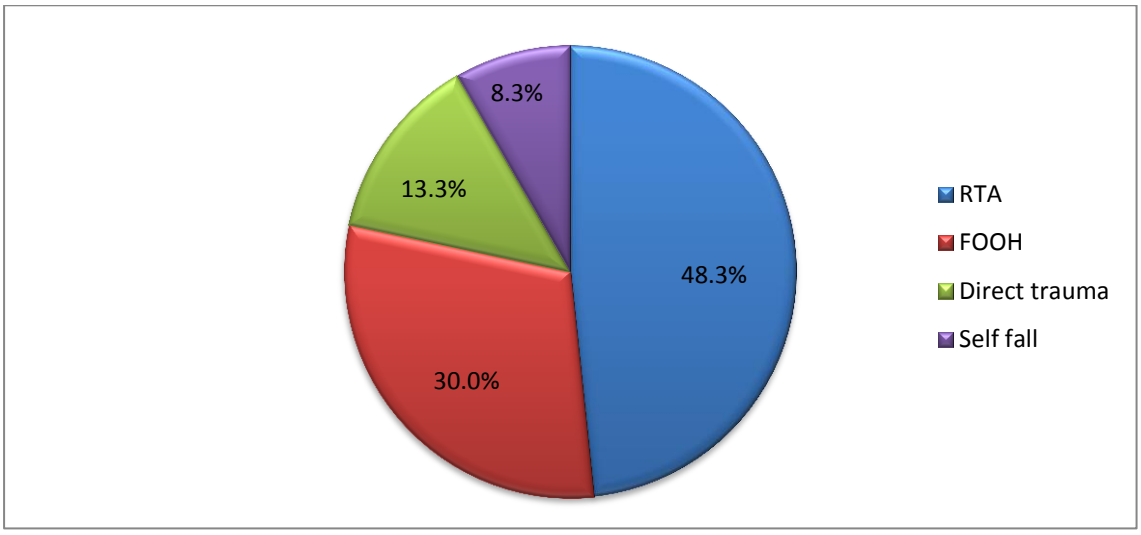


TABLE 5: - DISTRIBUTION OF CASES ACCORDING TO SIDE AFFECTED

Side affected	Number of cases	Percent
Left	24	40%
Right	36	60%
Total	60	100%

GRAPH: 5- DISTRIBUTION OF CASES ACCORDING TO SIDE AFFECTED

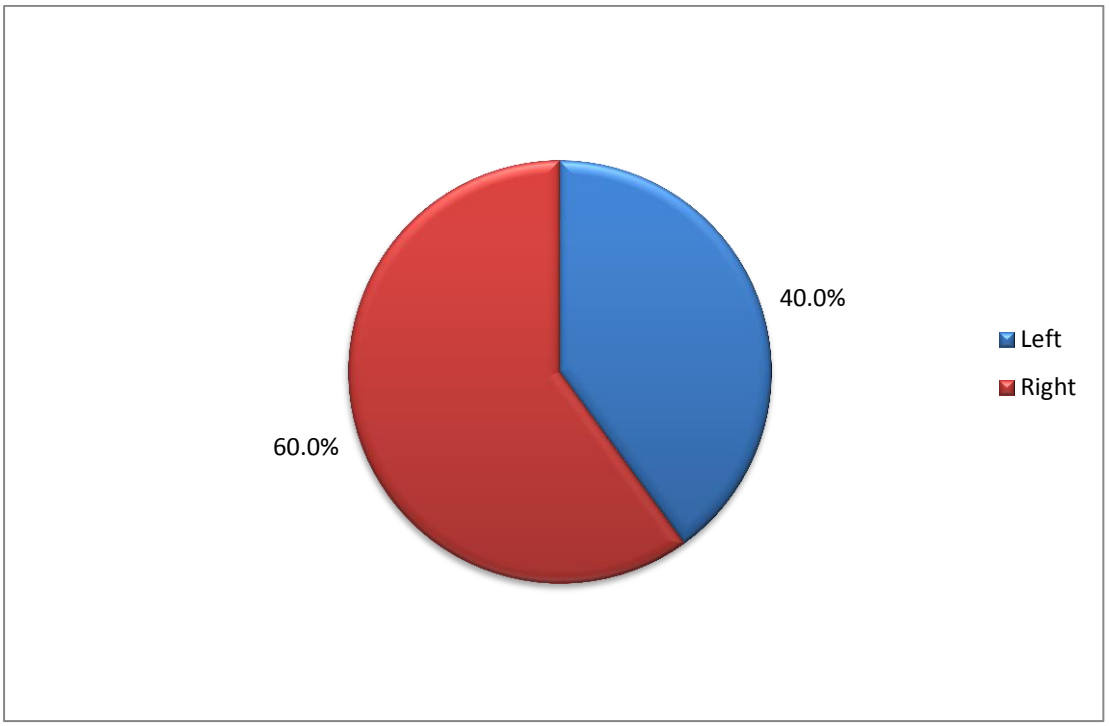


TABLE 6: - DISTRIBUTION OF CASES ACCORDING TO FRACTURE PATTERN

Fracture pattern	Simple transverse	Simple oblique	Simple spiral	Wedge	Segmental	comminuted	Total
Number of cases	23	16	7	8	1	5	60
Percent	38.3%	26.6%	11.6%	13.3%	1.6%	8.3%	100%

Out of total 60 cases 23 cases (38.3%) were simple transverse fractures, 16 (26.6%) were simple oblique Fractures, 7 (11.6%) were simple spiral fractures, 8 (13.3%) were wedge type, 1case (1.6%) was segmental and 5 (8.3%) were comminuted fractures.

GRAPH: 6- DISTRIBUTION ACCORDING TO FRACTURE PATTERN

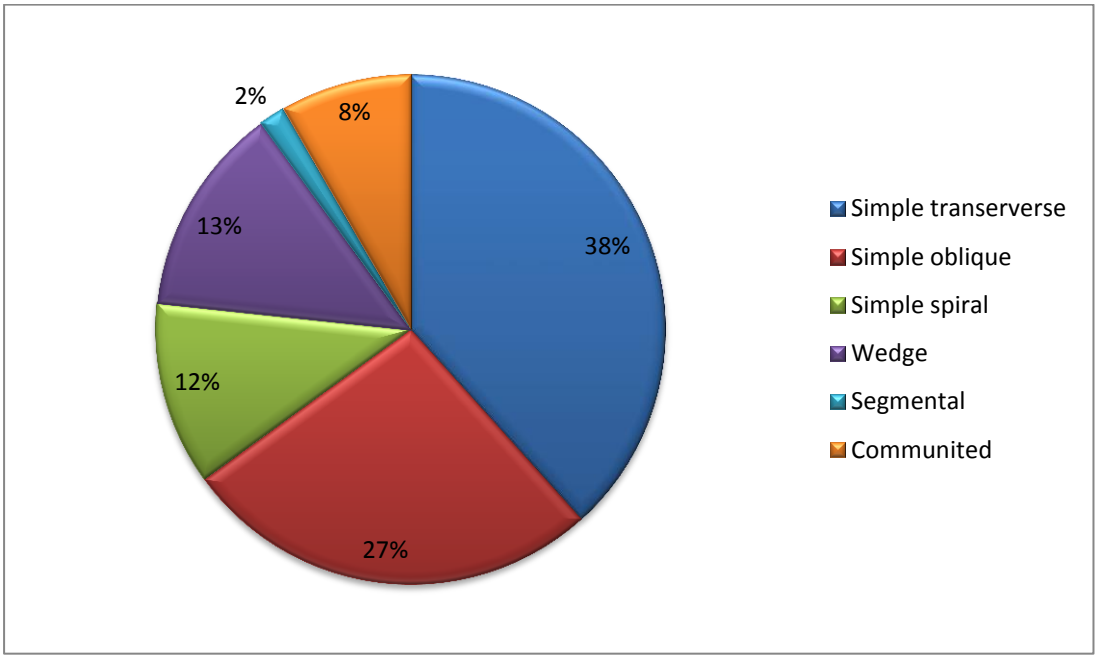


TABLE 7: - DISTRIBUTION OF CASES ACCORDING TO ROBINSON CLASSIFICATION

Robinson classification

Robinson Classification	Frequency	Percentages
2B1	47	78.3%
2B2	13	21.6%

According to Robinson classification, there were 47 cases (78.3%) under 2B1 and 13 (21.6 %) cases under 2B2.

GRAPH 7: - GRAPH SHOWING DISTRIBUTION OF CASES ACCORDING TO ROBINSON CLASSIFICATION

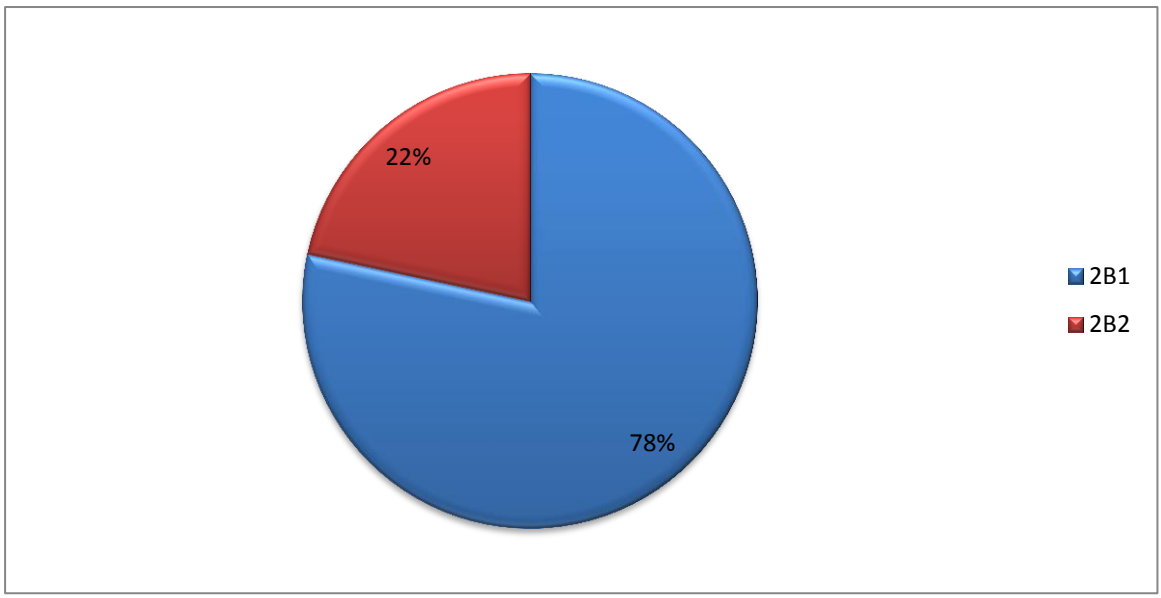


TABLE 8: - DISTRIBUTION OF CASES ACCORDING TO ASSOCIATED INJURY

Associated Injury	No. of cases	Percentages
Nil	35	58.3%
Head injury	10	16.7%
Blunt trauma to Chest	5	8.3%
Associated upper limb fracture	6	10%
Associated lower limb fracture	4	6.6%

35cases (58.3%) did not have any associated injury. 10 cases (16.7%) had head injury. 5 (8.3%) cases had blunt trauma to chest. 6 (10%) cases had upper limb injury. 4 (6.66%) cases had lower limb injuries.

GRAPH: 8- DISTRIBUTION OF CASES ACCORDING TO ASSOCIATED INJURY

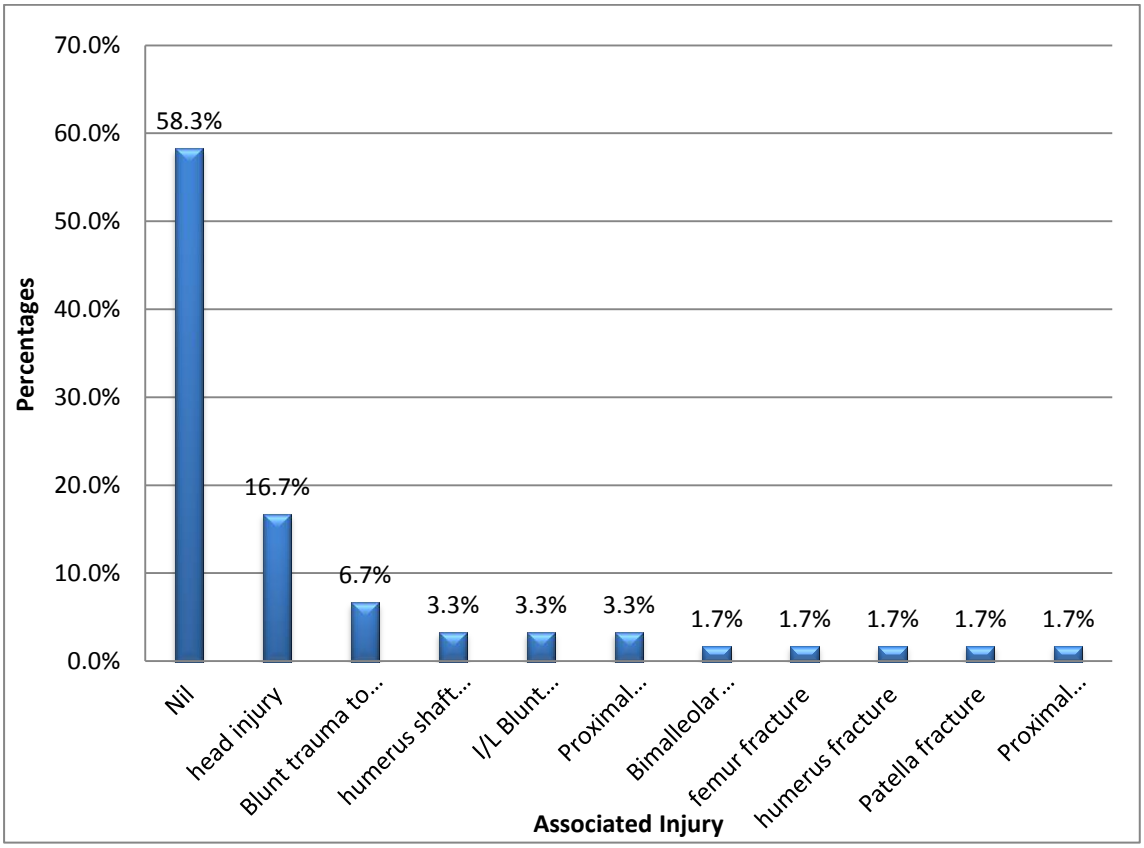


TABLE 9: COMPARISON OF DURATION OF STAY IN HOSPITAL BETWEEN GROUP (N=60)

Duration of Stay in hospital	Group		Chi square	P value
	Conservative (N=30)	Surgical (N=30)		
≤3 Days	17 (56.67%)	2 (6.67%)	26.337	<0.001
4 To 7 Days	2 (6.67%)	16 (53.33%)		
8 To 14 Days	3 (10%)	8 (26.67%)		
> 14 Days	8 (26.67%)	4 (13.33%)		

Among the patients in conservative group, 17 (56.67%) cases were admitted in hospital for ≤3 days, 2 (6.67%) cases for 4 to 7 days, 3 (10%) cases for 8 to 14 days and 8 (26.67%) cases for >14 days.

Among the patients in operative group, 2 (6.67%) cases stayed in hospital for ≤3 days, 16 (53.33%) cases for 4 to 7 days, 8 (26.67%) cases for 8 to 14 days and 4 (13.33%) cases for >14 days. The difference in the proportion of duration of hospital stay between group was statistically significant (P value <0.001).

GRAPH 9: COMPARISON OF DURATION OF STAY IN HOSPITAL BETWEEN GROUP (N=60)

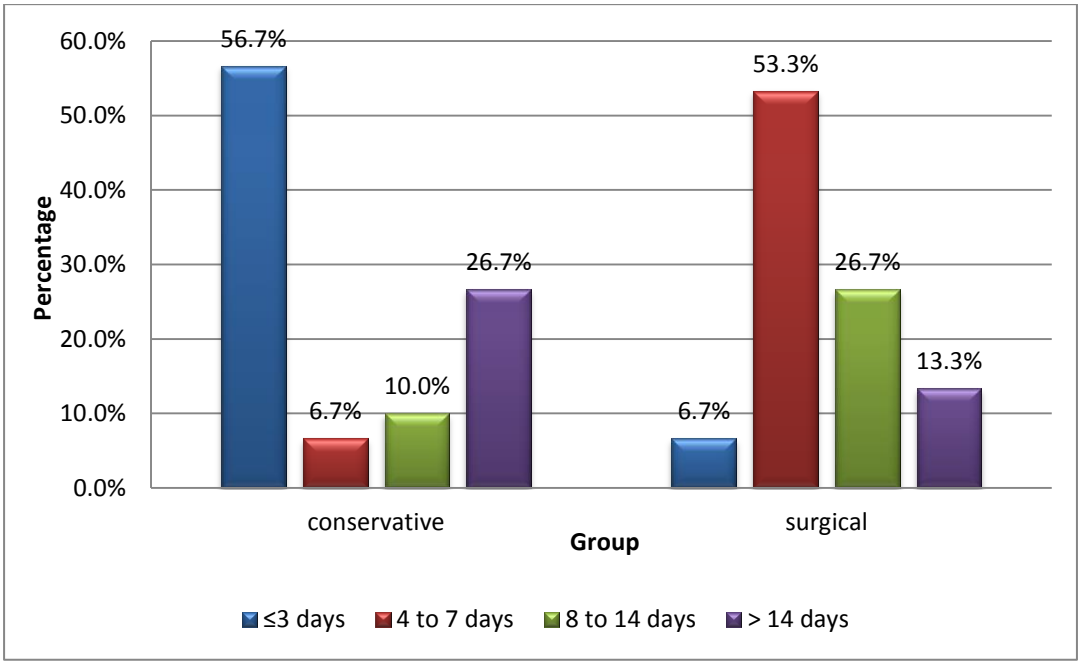


TABLE 10: COMPARISON OF TIME OF UNION (IN WEEKS) BETWEEN GROUP (N=56)

Time of Union (In Weeks)	Group		Chi square	P value
	Conservative (N=26)	Surgical (N=30)		
<8	1 (3.8%)	8 (26.6%)	17.7636	<0.001
9 To 16	9 (34.6%)	19 (63.3%)		
17 To 20	12 (46.15%)	2 (6.6%)		
21 To 24	4 (15.3%)	1 (3.3%)		

Among the people with conservative group, only 1 (3.85%) case had bony union at <8 weeks, 9 (34.6%) cases had bony union between 9 to 16 weeks, 12 (46.15%) cases had bony union between 17 to 20 weeks and 4 (15.3%) cases had bony union between 21 to 24 weeks. 4 cases (13.3%) had non union at the end of 6 months.

Among the people with surgical group, 8 (26.6%) cases had bony union in <8 weeks, 19 (63.33%) cases had bony union between 9 to 16 weeks, 2 (6.6%) cases had bony union between 17 to 20 weeks and 1 (3.3%) case had bony union between 21 to 24 weeks. The difference in the proportion of time of union (in weeks) between groups was statistically significant (P value <0.001)

GRAPH 10: COMPARISON OF TIME OF UNION (IN WEEKS) BETWEEN GROUP (N=56)

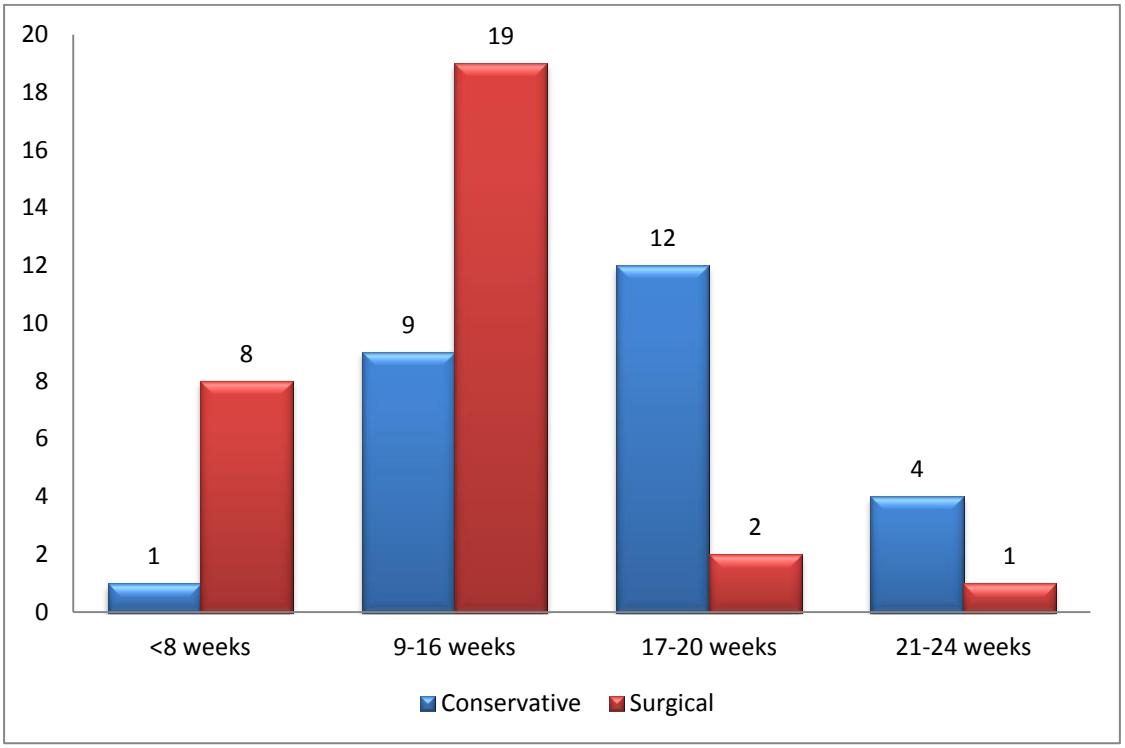


TABLE 11: COMPARISON OF MEAN OF UNION TIME IN WEEKS BETWEEN THE GROUPS

Parameter	Group	
	Conservative (Mean± SD)	Surgical (Mean± SD)
Union time in weeks(N=56)	16.61 ± 4.20	12.36 ± 4.05
Hospital stay in days(N=60)	8.2 ± 7.35	9.77 ± 5.63

The mean union time (in weeks) of conservative group was 16.61 ± 4.20 and it was 12.36 ± 4.05in surgical group. The mean hospital stay (in days) of conservative group was 8.2 ± 7.48and it was 9.77 ± 5.63 in surgical group.

TABLE 12: - COMPLICATION IN CONSERVATIVELY MANAGED CASES (N=30)

COMPLICATION	NO. OF CASES	PERCENT
Nil	7	23.33%
Malunion and Shortening	11	36.66%
Delayed union	8	26.66%
Non union	4	13.33%
Shoulder stiffness	1	3.33%
Total	30	100%

Out of 30 cases managed conservatively 7 cases did not showed any complications. While 11 cases (36.66%) showed Malunion along with some degree of shortening, 4 cases (13.33%) showed nonunion, shoulder stiffness was seen in 1 cases (1.66%), 8 cases (26.66%) showed delayed union.

GRAPH 11: DISTRIBUTION OF CONSERVATIVELY CASES ACCORDING TO COMPLICATION (N=30)

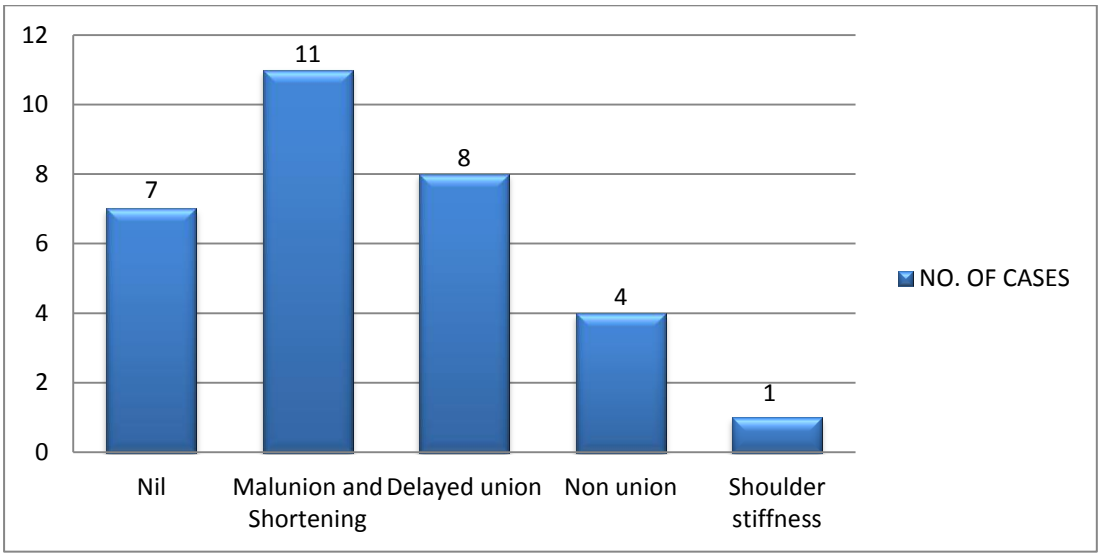


TABLE 13: - COMPLICATION IN SURGICALLY MANAGED CASES (N=30)

COMPLICATION	NO. OF CASES	PERCENTAGES
Nil	22	73.3%
Delayed union	2	6.7%
Implant prominence	2	6.7%
Implant failure and delayed union	1	3.3%
Distal nail migration	1	3.3%
Hypertrophic scar	1	3.3%
Proximal nail migration	1	3.3%
Total	30	100%

Out of 30 cases treated surgically 22 patients did not had any complication. While 2 cases (6.7%) had delayed union.1 case (3.33%) showed implant failure and subsequent delayed union. Implant prominence was seen in 2 cases (6.7%). 1 case had hypertrophic scar at surgical incision site. 1 (3.3%) case each of nail loosening and lateral and medial migration of nail respectively.

GRAPH: 12- DISTRIBUTION OF SURGICALLY MANAGED CASES ACCORDING TO COMPLICATION

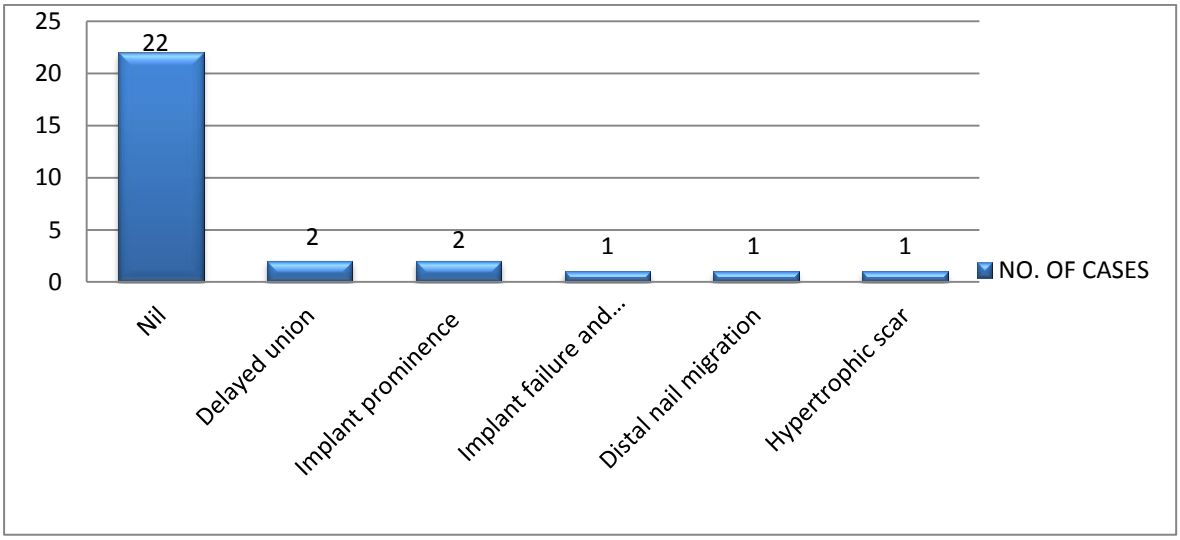


TABLE 14: COMPARISON OF COMPLICATION BETWEEN GROUP (N=60)

Complication	Group	
	Conservative (N=30)	Surgical (N=30)
Delayed Union	8 (26.6%)	2 (6.66%)
Distal Nail Migration	0 (0%)	1 (3.33%)
Hypertrophic Scar	0 (0%)	1 (3.33%)
Implant Failure	0 (0%)	1 (3.33%)
Implant Prominence	0 (0%)	2 (6.67%)
Malunion And Shortening	11 (36.6%)	0 (0%)
Non Union	4 (13.33%)	0 (0%)
Proximal Nail Migration	0 (0%)	1 (3.33%)
Shoulder Stiffness	1 (3.33%)	0 (0%)
Nil	7 (23.33%)	22 (73.33%)

TABLE 15: COMPARISON OF COMPLICATION BETWEEN GROUP (N=60)

Complication	Group		Chi square	P value
	Conservative (N=30)	Surgical (N=30)		
Yes	23 (86.66%)	8 (26.67%)	15.016	<0.001
No	7 (23.33%)	22 (73.33%)		

Among the patient with conservative group, 23 (76.67%) patienthad complications. Among the patient with surgical group, 8 (26.67%) patienthad complications. The difference in the proportion of complication between group was statistically significant (P value <0.001).

TABLE 16: - FINAL OUTCOME OF CONSERVATIVELY MANAGED CASES ACCORDING TO CONSTANT MURLEY SCORE(N=30)

Final Outcome by 6 months	Number of cases	Percent
Excellent	4	13.3%
Good	6	20.0%
Fair	16	53.3%
Poor	4	13.3%
Total	30	100%

Out of 30 conservatively managed cases, 4 cases (13.3%) showed excellent outcome; 6 cases (20%) showed good outcome. 16 cases (53.3%) showed fair outcome and 4 cases (13.3%) showed poor outcome.

GRAPH: 13-FINAL OUTCOME OF CONSERVATIVELY MANAGED CASES

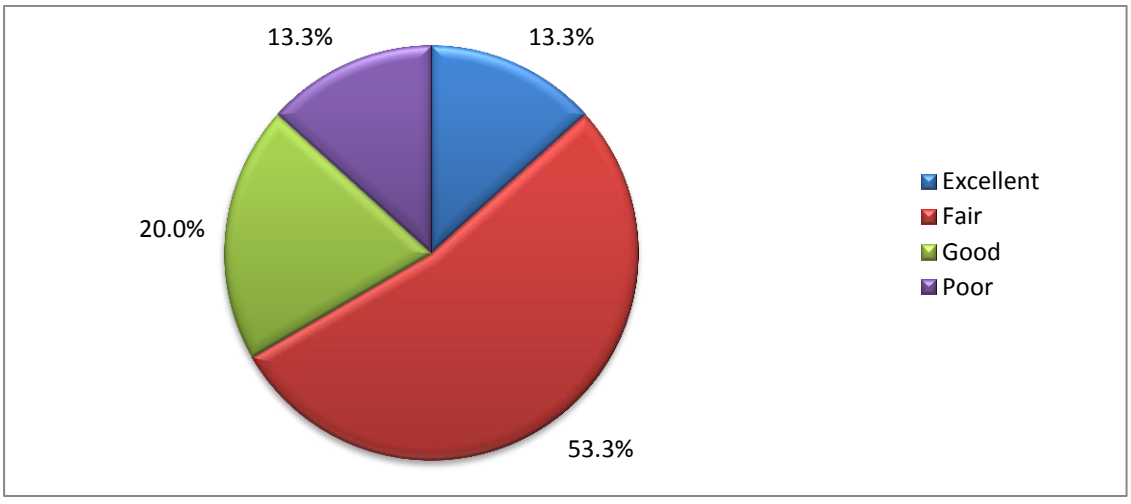


TABLE 17: FINAL OUTCOME OF SURGICALLY MANAGED CASES ACCORDING TO CONSTANT MURLEY SCORE (N=30)

Final Outcome by 6 months	Number of cases	Percent
Excellent	23	76.6%
Good	4	13.3%
Fair	2	6.6%
Poor	1	3.3%
Total	30	100%

Out of 30 cases which were managed surgically, a total of 23(76.6%) showed excellent outcome, 4 cases (13.3%) had good outcome 2 cases (6.6%) had a fair outcome, and 1 case (3.33%) had poor outcome.

GRAPH: 14-FINAL OUTCOME OF SURGICALLY MANAGED CASES

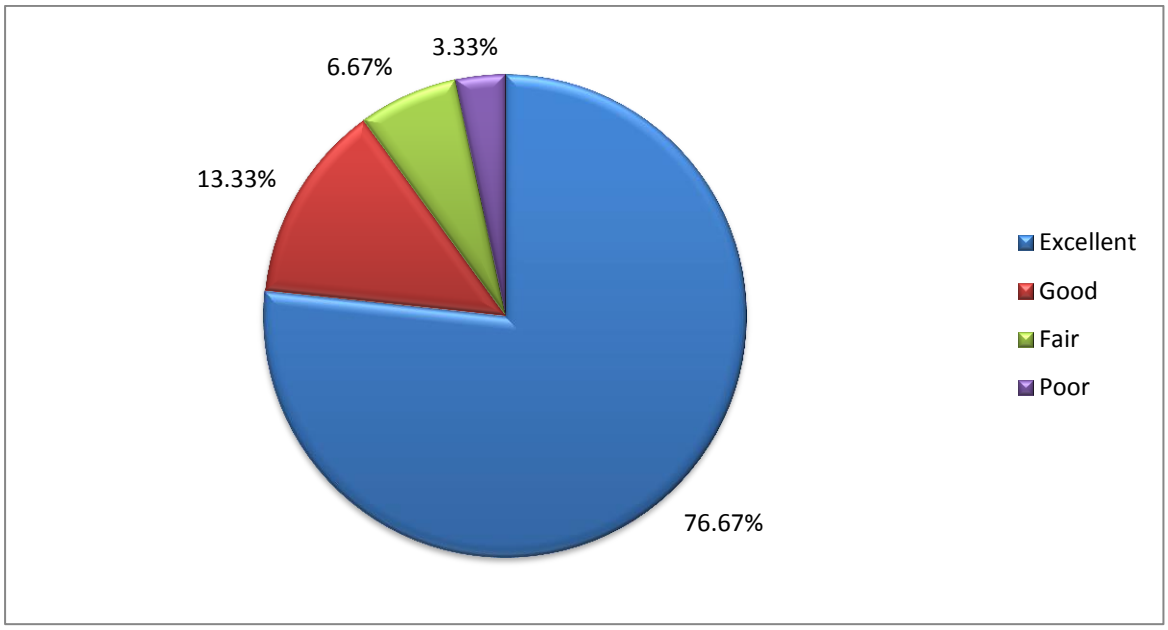
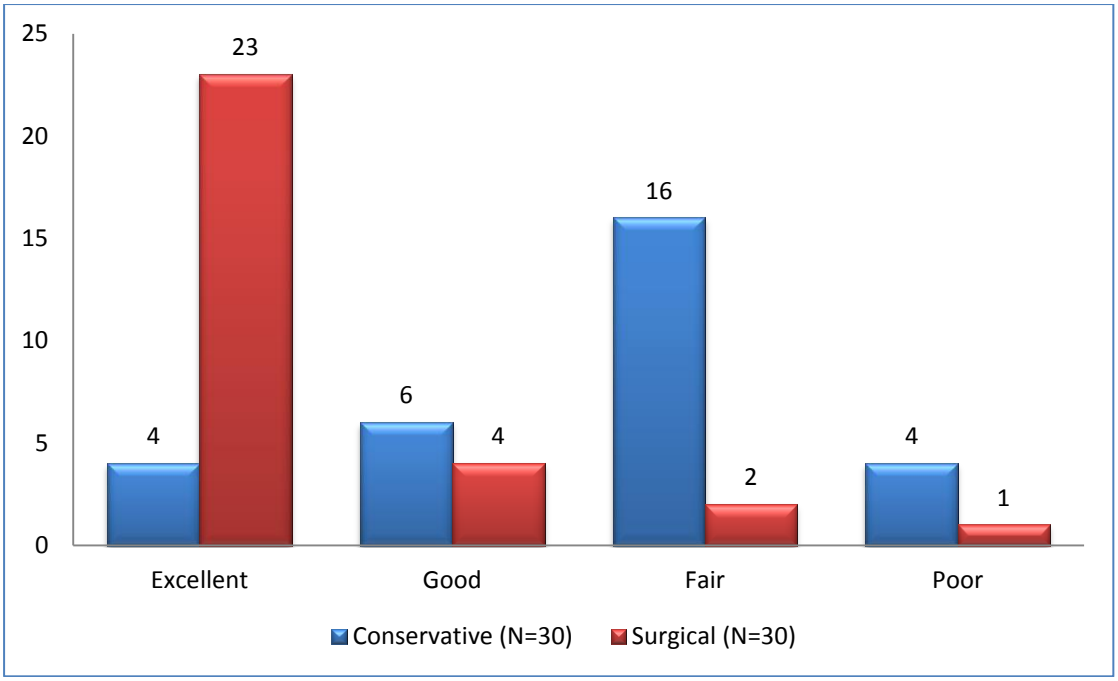


TABLE 18: COMPARISON OF FINAL OUTCOME AT 6 MONTHS BETWEEN GROUP (N=60)

Final Outcome At 6 Month	Group		Chisquare	P value
	Conservative (N=30)	Surgical (N=30)		
Excellent	4 (13.33%)	23 (76.66%)	24.45	<0.001
Good	6 (20%)	4 (13.33%)		
Fair	16 (53.33%)	2 (6.66%)		
Poor	4 (13.33%)	1 (3.33%)		

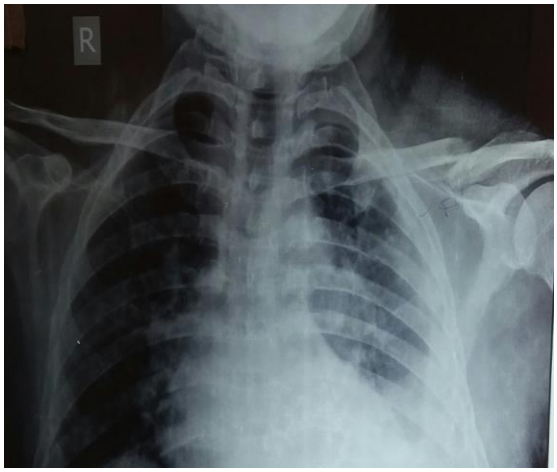
After comparison of the final outcome at the end of 6 months of both the groups by applying chi square test the p value was <0.001 showing the results statistically significant.

GRAPH 15: COMPARISON OF FINAL OUTCOME AT 6 MONTH BETWEEN GROUP (N=60)

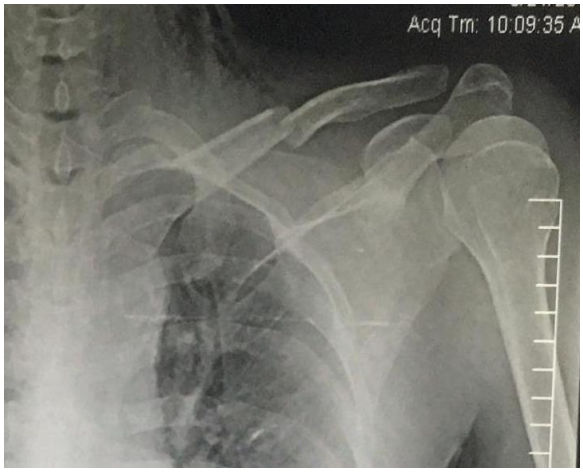


CONSERVATIVELY MANAGED CASES

CASE 1 : Fig.No. 47A

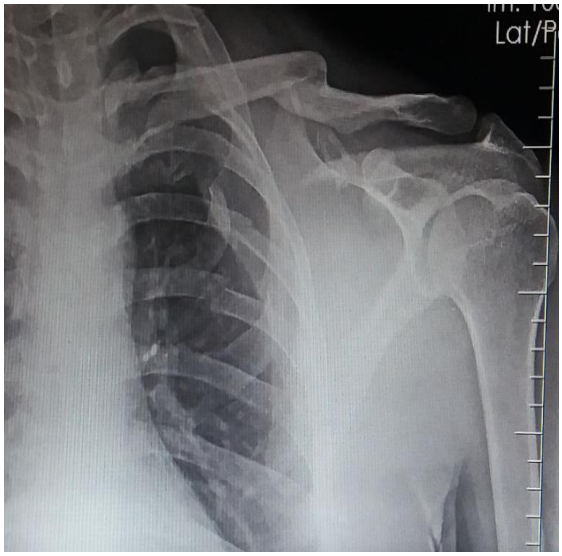


X-RAY ON DAY OF ADMISSION



1MONTH FOLLOW UP X-RAY

2 MONTH FOLLOW UP X RAY

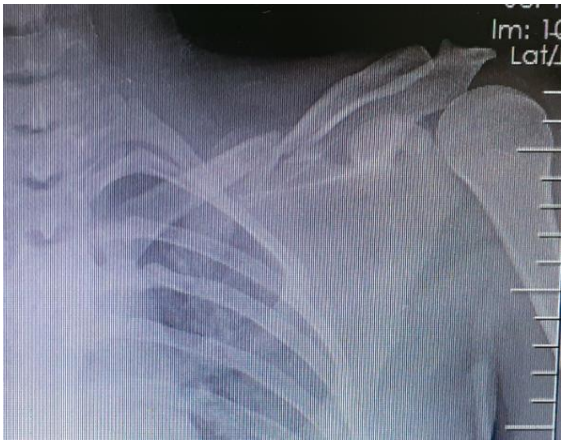


6 MONTH FOLLOW UP

CASE 1: ROM AT 2 WEEKS FOLLOW UP:

Fig.No. 47B: Clinical photographs showing shoulder flexion, abduction, external and internal rotation at 2 weeks follow up.

CASE 2 :Fig.No. 48A



X-RAY ON DAY OF ADMISSION

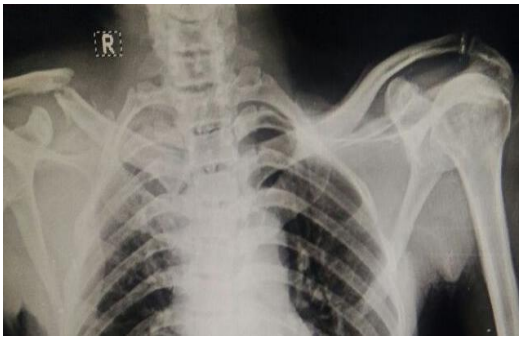
X-RAY2ND MONTH FOLLOW UP

4 MONTH FOLLOW UP X-RAY

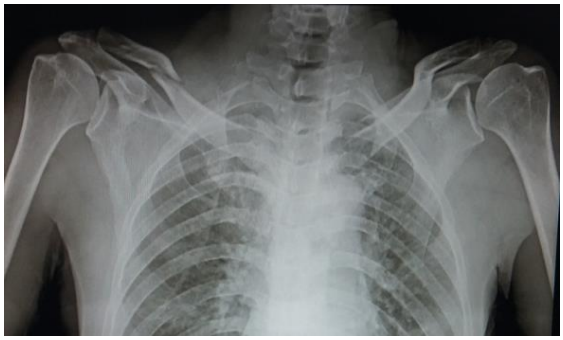
ROM AT 4 MONTH FOLLOW UP

Fig.No. 48B: Clinical photographs showing shoulder flexion, abduction, external and internal rotation and extension at 4 month follow up.

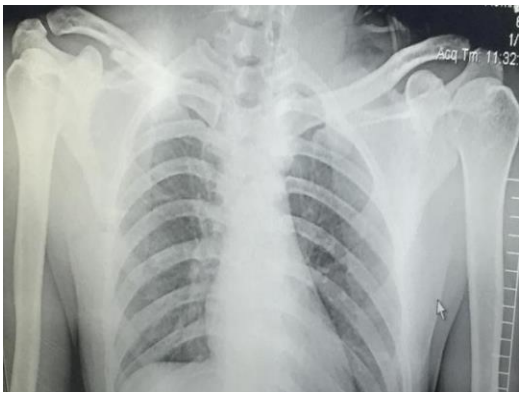
CASE 3 Fig.No. 49



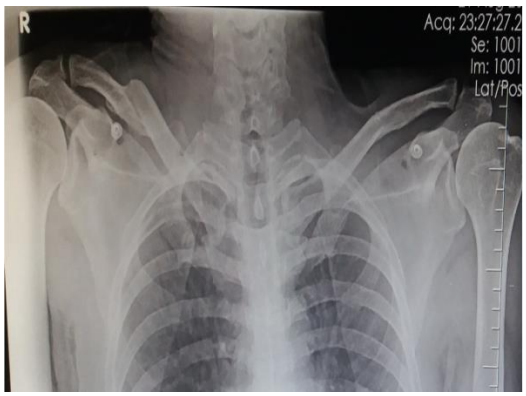
X-RAY ON DAY OF ADMISSION



1 MONTH FOLLOW UP X RAY



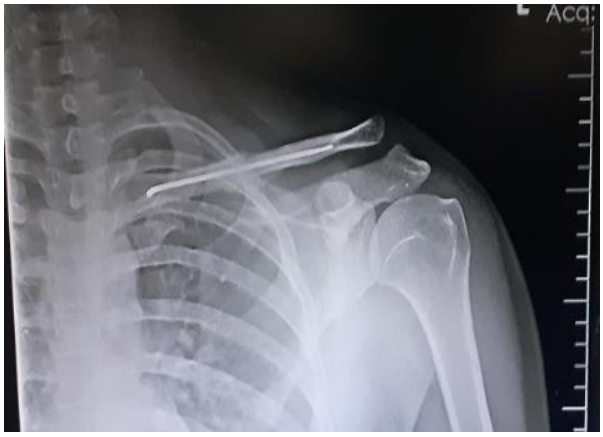
2 MONTH FOLLOW X-RAY



6TH MONTH FOLLOW UPX-RAY

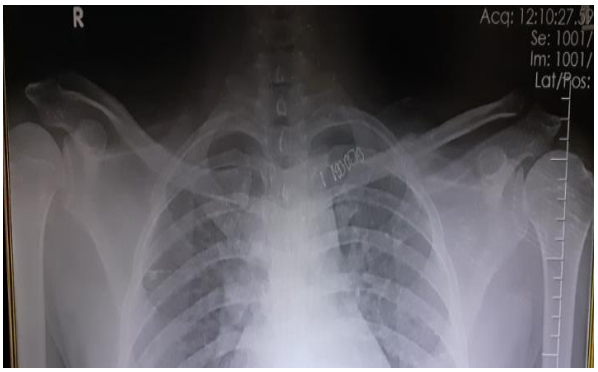
SURGICALLY MANAGED CASES WITH TENS

Case 1 :Fig.No. 50A



PRE OP X RAY **1 MONTH POST OP**

3RD MONTH POST OP **6TH MONTH POST OP**



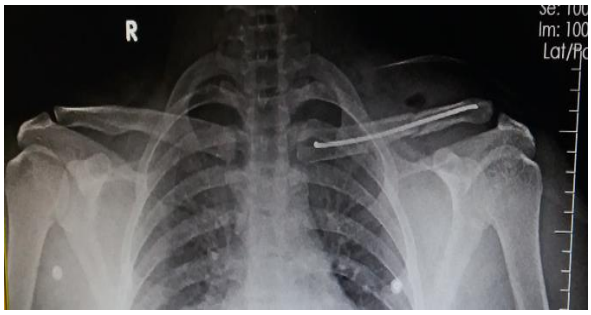
POST IMPLANT REMOVAL X RAY

ROM AFTER IMPLANT REMOVAL

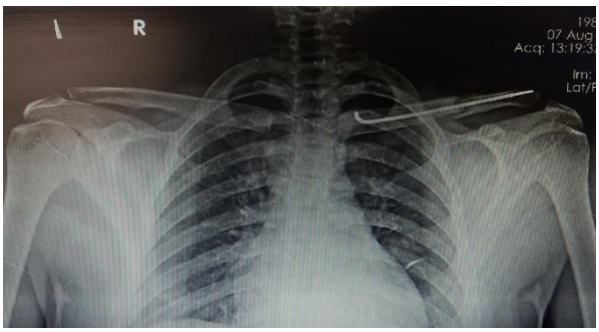
Fig.No. 50B: Clinical photographs showing shoulder flexion, abduction, internal rotation and external rotation after implant removal.

CASE 2 : Fig. No. 51

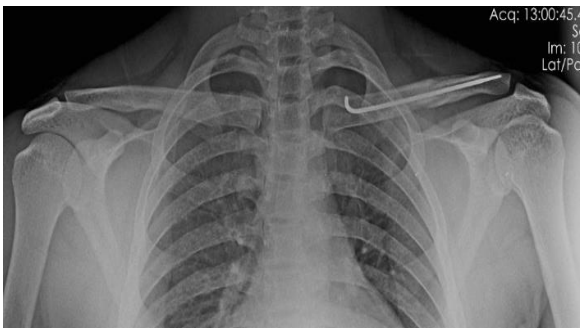
PRE OP X-RAY



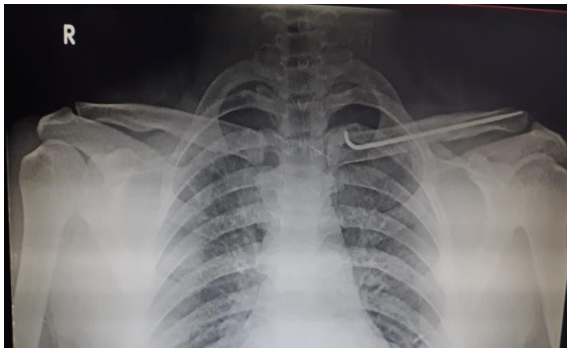
1 MONTH POST OP X-RAY



2 MONTH POST OP X-RAY



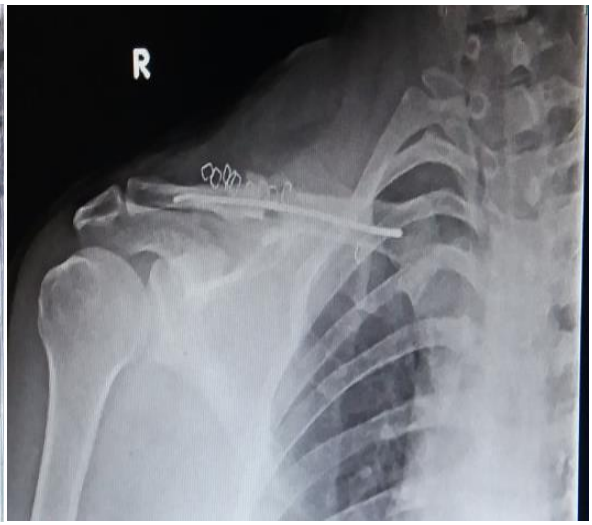
3 MONTH POST OP X-RAY



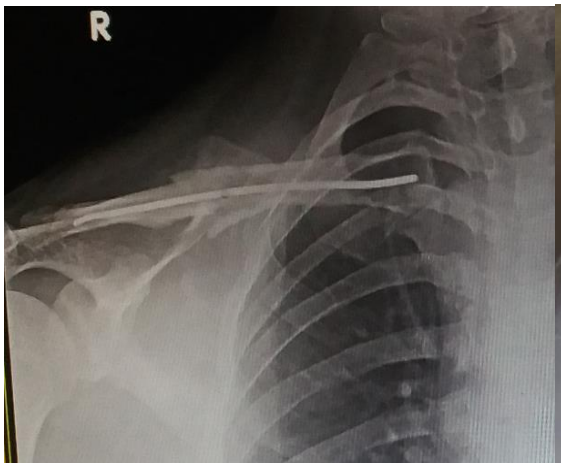
6TH MONTH GOOD UNION X-RAY

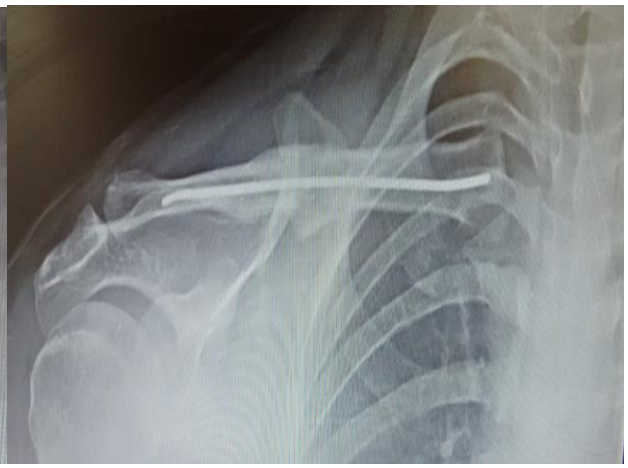
IMPLANT REMOVAL X RAY

CASE 3:Fig.No. 52

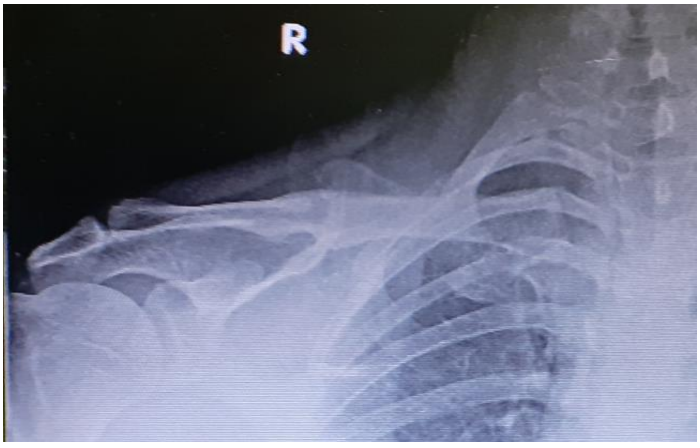


PRE OP X-RAY **POST OP DAY 1 X-RAY**





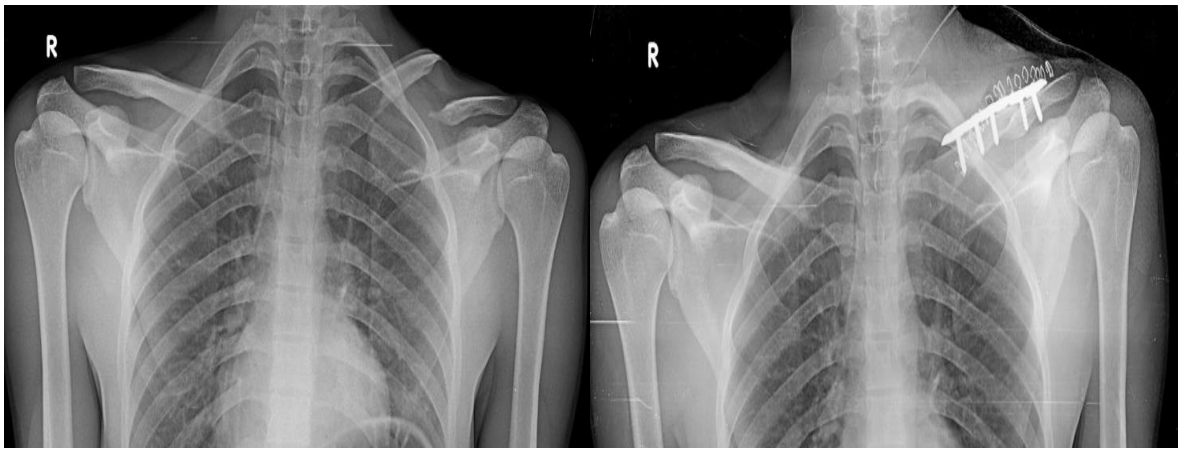
1 MONTH POST OP X-RAY **6TH MONTH POST OPX-RAY**



IMPLANT REMOVAL XRAY

SURGICALLY MANAGED CASES WITH PLATE AND SCREWS

CASE1 :Fig.No. 53A



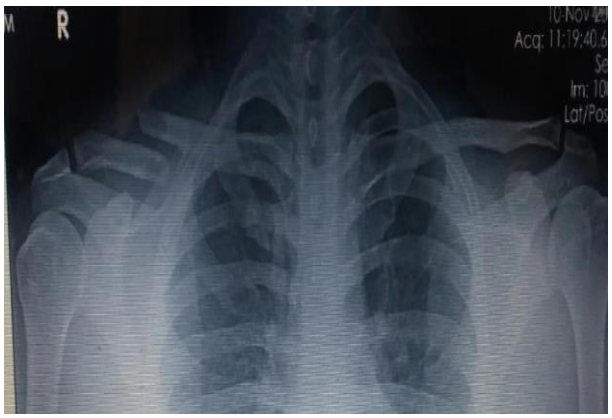
PRE OP X-RAY **IMMIDIATE POST OP X-RAY**

3RD MONTH POST OP X-RAY **6TH MONTH POST OP X-RAY**

RANGE OF MOVEMENTS AT SHOULDER AT 3 MONTH POST OP:Fig.No. 53B

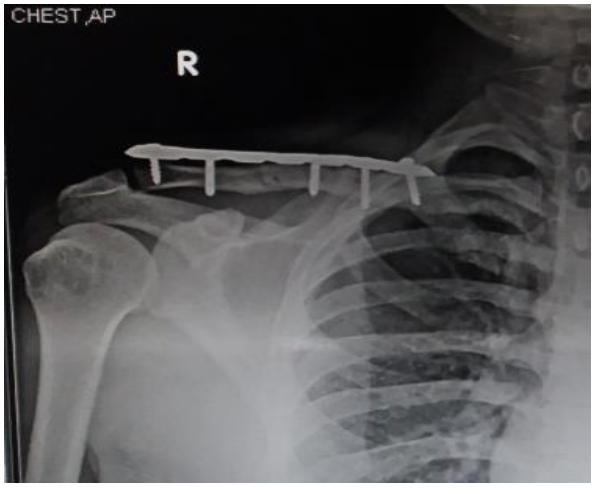
Fig.No. 53 B: Clinical photographs showing healed surgical scar, shoulder flexion, abduction, adduction, internal rotation and external rotation at 3 month post op.

CASE 2 Fig.No. 54A

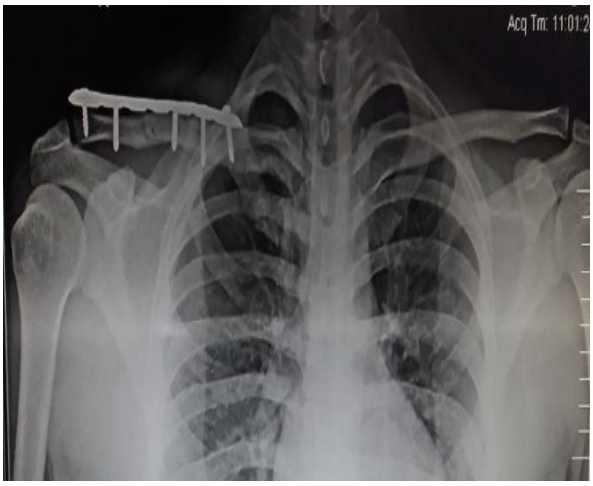


PRE OP X-RAY

IMMIDIATE POST OP X-RAY



1 MONTH POST OP X-RAY

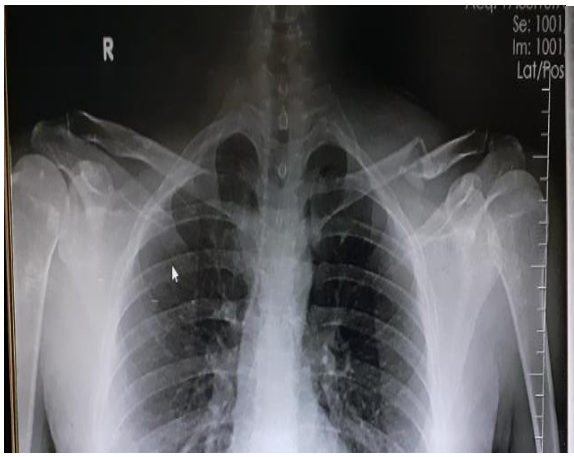


6TH MONTH POST OP

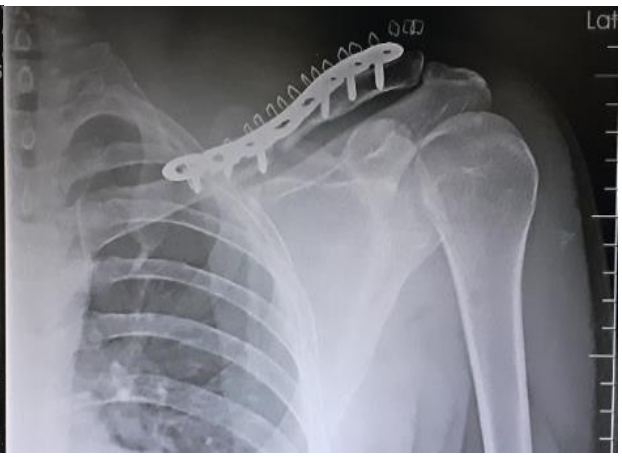
POST OP 3RD MOTH ROM: Fig.No. 55B

Fig.No. 55B: Clinical photographs showing shoulder flexion, abduction, internal rotation, external rotation and extension at 3rd month post op.

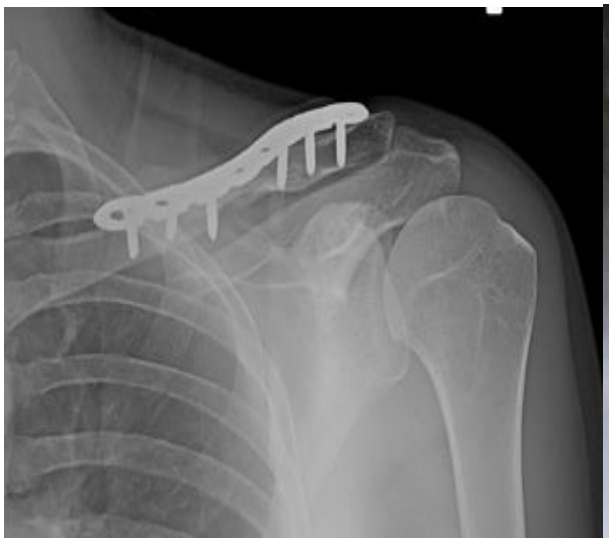
CASE 3 Fig.No. 55



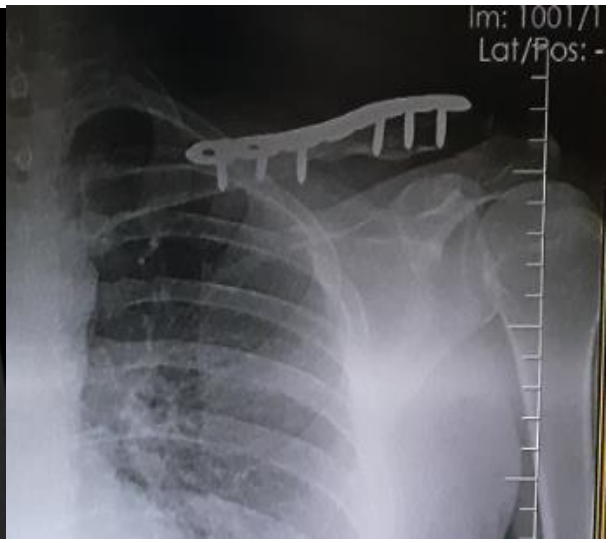
PRE OP X-RAY



IMMIDIATE POST OP X-RAY



3RD MONTH POST OP X-RAY

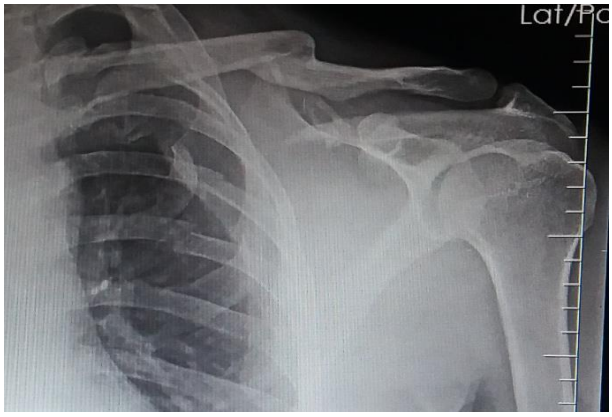


6TH MONTH POST OP X-RAY

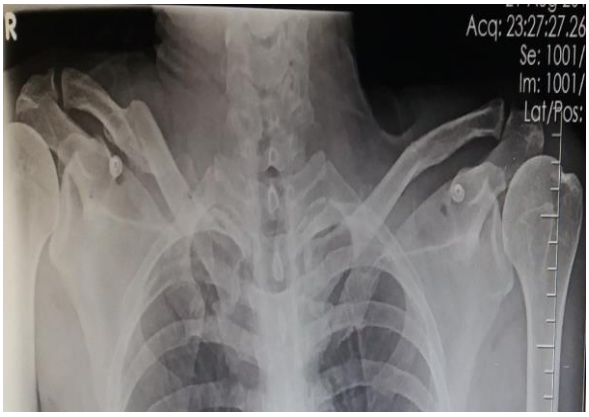
COMPLICATIONS ENCOUNTERED DURING STUDY

A) CONSERVATIVE MANAGEMENT:

i) MALUNION: Fig .No. 56A



Case 1



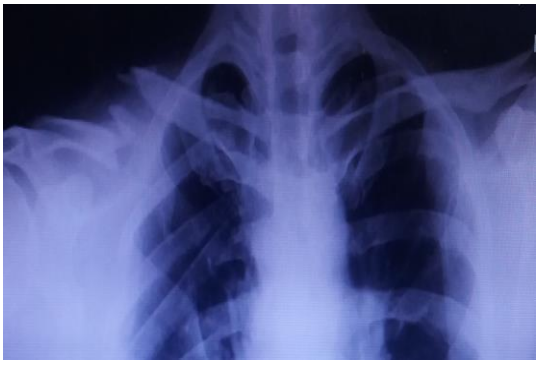
Case 2

Case 3

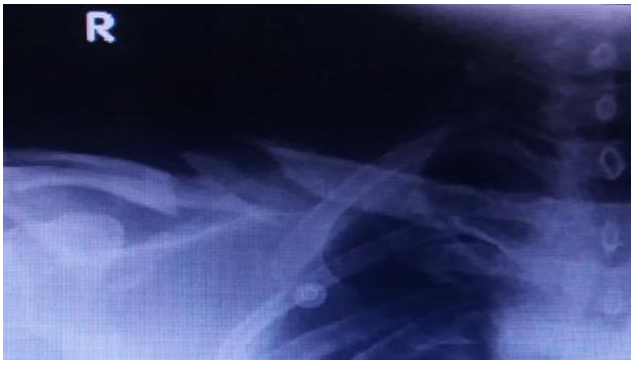
Case 4

ii) NON UNION: Fig.No. 56B

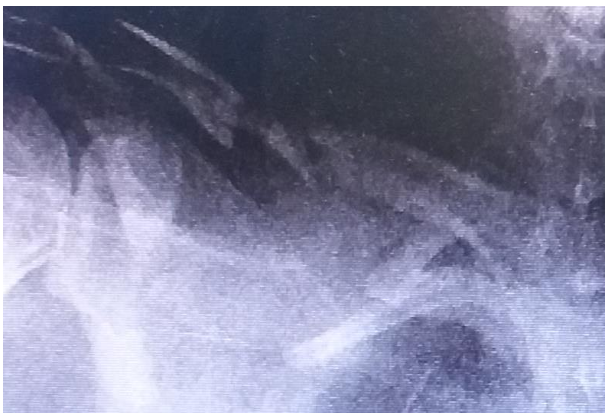
CASE 1:



X-RAY ON DAY 1

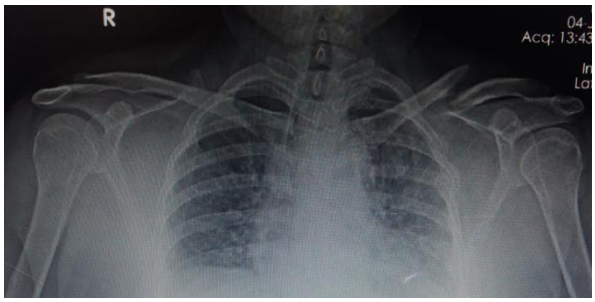


1 MONTH FOLLOW UP X-RAY



6TH MONTH FOLLOW UP X-RAY

CASE 2: Fig.No. 56C



X-RAY ON DAY OF ADMISSION **1 MONTH FOLLOW UP X-RAY**

6TH MONTH FOLLOW UP X-RAY

iii) POST TRAUMATIC ARTHRITIS: Fig.No. 56D

B) SURGICAL MANAGEMENT TENS :

CASE 1: Medial protrusion of nail:

Fig.No. 57A

CASE 2 : Lateral protrusion of nail and ulceration:

Fig.No. 57B

C) SURGICAL MANAGEMENT BY PLATING :

CASE 1 : IMPLANT FAILURE:

Fig.No. 57C

CASE 2 : HARDWARE PROMINENCE :

Fig.No. 57D

CASE 4 : HYPERTROPHIC SCAR:

Fig.No. 57E

DISCUSSION

DISCUSSION

Considering the excellent remodeling of clavicle, irrespective of displacement, amount of comminution, in the past, every fracture clavicle was treated non-operatively. The surgical treatment was only reserved for cases with neurological deficits, open fractures, clavicle fractures causing skin tenting. Many recent studies have showed increased incidence of nonunion, residual pain, malunion, decreased shoulder endurance, shoulder weakness, inferior patient and surgeon-oriented outcome scores, and lower overall patient satisfaction rate following conservative treatment. [5]

Our study compares functional outcome of displaced midshaft clavicle fracture managed with conservative management versus surgical management. The results of our study have been compared with:

A) Open reduction and plate fixation versus non-operative treatment for displaced midshaft clavicular fractures by C.M. Robinson et al.[71]

B) Estimating the risk of nonunion following non-operative treatment of a clavicular fracture by Robinson et al. [42]

C) A comparative study by Luke D. Jones et al on comparative study on titanium elastic nails, open reduction internal fixation and non-operative management for middle third clavicle fractures. [76]

D) A comparative study conducted by B. M. Naveen G et al on management of mid-shaft clavicular fractures between non-operative treatment and plate fixation in 60 patients. [77]

E) Prospective comparative analysis of functional outcome of titanium elastic nailing system versus non-operative treatment of midshaft clavicle fractures done by vishwanath g shettaret al. [78]

MECHANISM OF INJURY:

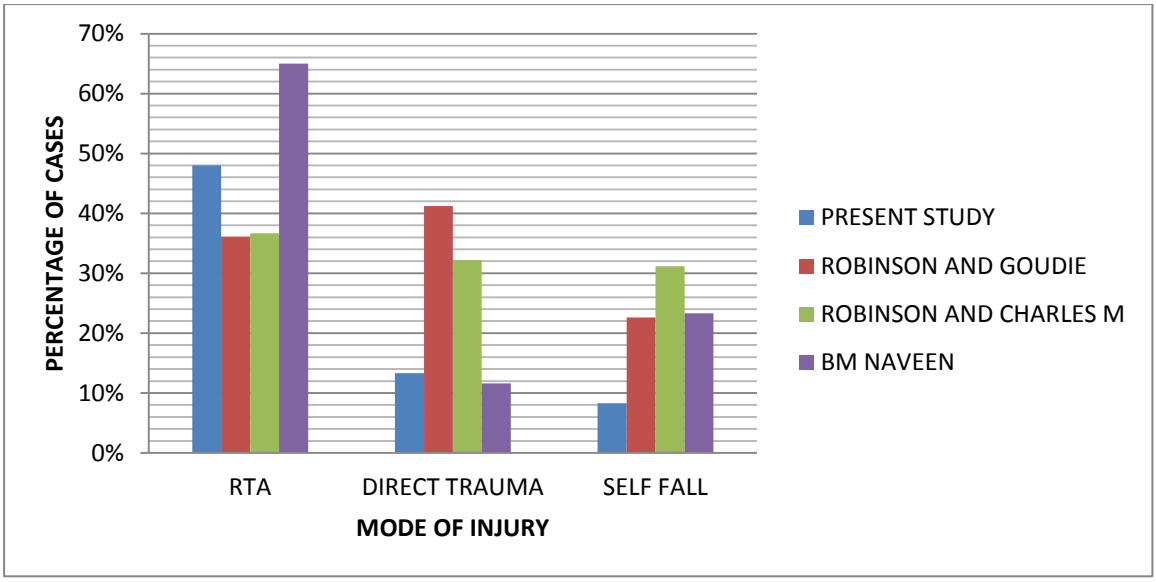
In our study, majority of clavicle fractures 29 cases (48.3%) occurred as a result of road traffic accidents, 18 cases (30%) as a result of fall on an outstretched hand, 8 cases (13.33%) due to direct trauma and 5 cases (8.33%) due to self fall.

When compared the results with below mentioned studies road traffic accidents and direct injuries secondary to sports activity are the most common causes of clavicle fractures.

TABLE NO. 19: COMPARISON OF MECHANISM OF INJURY

Mode of Injury	PRESENT STUDY	C.M. Robinson, E.B. Goudie et al [71]	C.M. Robinson, Charles M et al[42]	B. M. Naveen G et al [77]
RTA	48.3%	36.1%	36.67%	65%
Direct trauma	13.3%	41.23%	32.17%	11.6%
Self-fall	8.3%	22.6%	31.17%	23.33%

GRAPH NO. 16: COMPARISON OF MODE OF INJURY IN DIFFERENT STUDIES WITH PRESENT STUDY



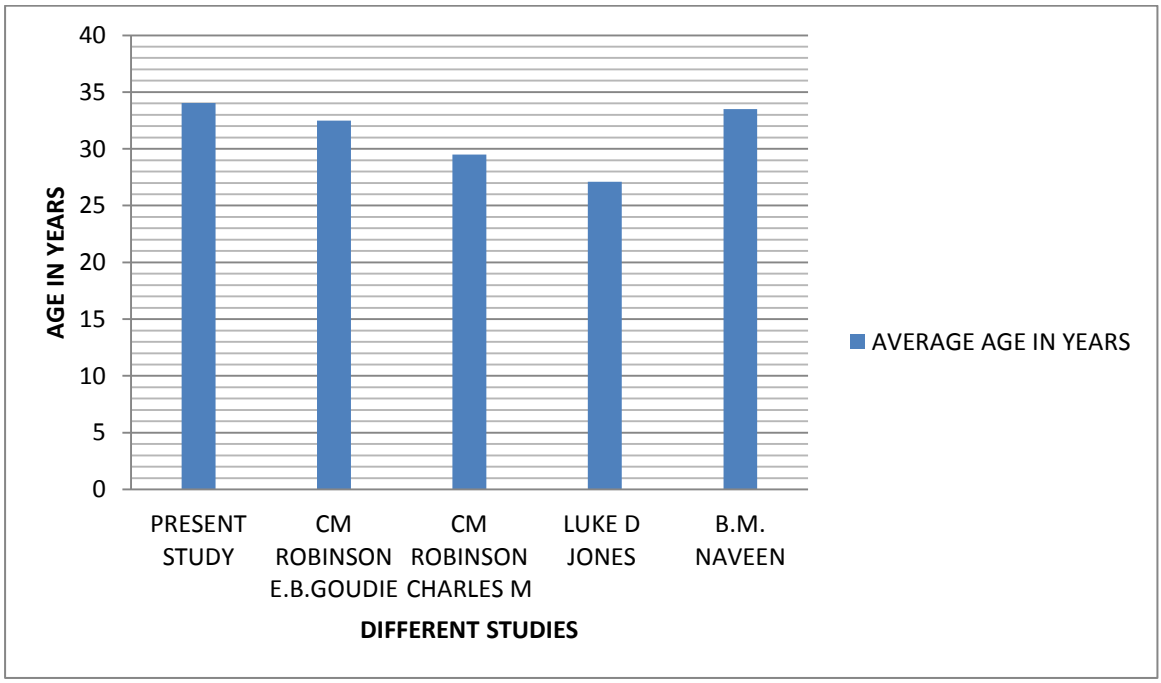
AGE INCIDENCE

The average age in our study is 34.05 years. In C.M. Robinson, E.B. Goudie et al [71] study 32.5 years was the mean age in non operative group and 32.3 years in operative group. In a study of C.M. Robinson, Charles M et al[42] of non operative treatment of clavicle fracture mean age of patients was 29.5 (19.25-46.75) years. In study by Luke D. Jones[76] mean age of all 90 patients was 27.1 year.Hence, it is clear that most of the clavicle fracture occurs in young and active individuals.

TABLE NO.20 COMPARISON OF AVERAGE AGE OF STUDY POPULATION

STUDY	AVERAGE AGE
Present study	34.05 years
C.M. Robinson, E.B. Goudie et al [71]	32.5 years in non -operative group32.3 years in operative group
C.M. Robinson, Charles M et al[42]	29.5 years
Luke D. Jones[76]	27.1 years
B. M. Naveen G et al [77]	35.02 years years in non -operative group 32.43 years in operative group

GRAPH NO.17 COMPARISON OF AVERAGE AGE OF STUDY POPULATION



SEX DISTRIBUTION

Male patients formed the majority of 45 cases (75%) and 15 cases (25%) were seen in females. In C.M. Robinson, E.B. Goudie et al [71] series male to female ration was 92:13in conservative group and 83:12 in operative group. In C.M. Robinson, Charles M etal[42] series 636 were male and 232 were female. In L.D. Jones[76] study 76(84.44%) patients were male and 14(15.55%) patients were female. In a study by B.M. Naveen[77] 53(88.33%) patients were male while only 7(11.66%) patients were female. After these comparisons we can conclude that most of the clavicle fracture occurs in male population attributed to their active lifestyle.

SIDE OF INJURY

Densitometry of clavicle shows that, the clavicle on the non-dominant side is denser than the clavicle on the dominant side. The middle third of the clavicles, irrespective of dominance is denser than the distal third. Some studies show that the greater bone mineral density on the non-dominant side, would diminish bone flexibility and hypothetically, increase the propensity to fractures.

In our study, there were a total of 36 cases (60%) of right sided fracture, and left side was affected in 24 cases (40%). In C.M. Robinson, E.B. Goudie et al [71] series 104 (52%) patients had right and 96% (48%) had left-sided injuries. Similarly, in LD Jones[76] series 44 patients (48.88%) had left side while 46 patients (51.11%) had right side clavicle fracture.This shows that clavicle fracture is not affected by hand predominance even though fall on outstretched hand is a major mechanism of injury.

DURATION OF UNION:

We have recorded time of union separately for both the groups. Among the people with conservative group, only 1 (3.85%) case had bony union in <8 weeks, 9 (34.6%) cases had bony union between 9 to 16 weeks, 12 (46.15%) cases had bony union between 17 to 20 weeks and 4 (15.3%) cases had bony union between 21 to 24 weeks.

Among the people with surgical group, 8 (26.6%) cases had bony union in <8 weeks, 19 (63.33%) cases had bony union between 9 to 16 weeks, 2 (6.6%) cases had bony union between 17 to 20 weeks and 1 (3.3%) case had bony union between 21 to 24 weeks. The difference in the proportion of time of union (in weeks) between groups was statistically significant (P value <0.001)

Average bony union in our study in conservative group was 16.61 weeks and was 12.36 weeks in operative group.

In a comparative study of conservative management versus plating by B.M. Naveen et al[77], the average duration for union in conservative group was 11.29 weeks as compared to 9.27 weeks in surgical group. In the same study, out of 60 patients, 2 patients in conservative group had symptomatic nonunion and no patient had nonunion in surgical group.

In a comparative study of conservative management versus TENS nailing by Shettar et al[78] mean union rate of TENS group was 13.16 weeks. In the same study they had nonunion rate of 5.26% in conservative group and none of the patient of surgical group had non union.

This shows that most of the surgically treated patients attend early union along with minimal chances of non union rates when compared with non surgical management.

ASSOCIATED INJURIES

In our study most of the cases that is 35 (58.3%) did not have any associated injury. 10 cases (16.7%) had head injury. 5 (8.3%) cases had blunt trauma to chest. 6 (10%) cases had upper limb injury. 4 (6.66%) cases had lower limb injuries.

TYPE OF FRACTURE PATTERN AND CLASSIFICATION:

All patients with midshaft clavicle fractures were of closed type. As this study is based on displaced clavicle fractures, all fractures included in this study were 2B1 and 2B2. 47(78.3%) fractures were 2B1 type and 13 (21.6%) patients were of 2B2 type. 23 cases (38.3%) were simple transverse fractures, 16 (26.6%) were simple oblique fractures, 7 (11.6%) were simple spiral fractures, 8 (13.3%) were wedge type, 1(1.6%) were segmental and 5 (8.3%) were comminuted fractures.

In C.M. Robinson, Charles M et al[71] series 56 patients had 2A1 type fracture, 97 had 2A2 type 330 had 2B1 and 98 patients had 2B2 type of fracture.

While in a study conducted by B.M. Naveen et al[77] 25 (41.6%) patients had 2B1 type of clavicle fracture and 35(58.3%) patients had 2B2 type of fracture.

Thus it is clear that type 2 fractures of clavicle are more common and in type 2 fractures, type 2B1 fractures are more frequent.

IMPLANT SIZE

A) TENS SIZE:

In this study, majority of nail size used was of size 2.5mm that is in 10 (66.6%) cases followed by 2mm for 3 cases (20%), 3mm size was used for 2 (13.33%) cases. In a series conducted by Vishwanath et al all of the 19 patients were treated by 2mm TENS nail.Slongo suggests that nail diameter should be between one third and 40% of

the medullary space diameter.[70]We used 2.5mm in majority of cases (66.6%) and 2mm in those in who had smaller canal.

B) LCP PLATE SIZE:

In this study we have used 3.5mm locking compression plate for all the cases treated with LCP plating group. Also in the study conducted by B.M. Naveen[77] all the 30 patients in plating group were treated by 3.5mm DCP plate.

HOSPITAL STAY:

In non-operative group 17 (56.6%) patients stayed for less than 3 days, 2 (6.67%) patients had hospital stay of 4 to 7 days, 3 (10%) patients had hospital stay of 8 to 14 days and 8 (26.67%) patients had hospital stay of >14 days. Among the people with surgical group, 2 (6.67%) patients had hospital stay of ≤3 days, 16 (53.33%) patients had hospital stay of 4 to 7 days, 8 (26.67%) patients had hospital stay of 8 to 14 days and 4 (13.33%) patients had hospital stay of >14 days. The difference in the proportion of duration of hospital stay between group was statistically significant (P value <0.001).

This indicates that conservatively treated patients had added advantage of getting discharge from hospital early.

COMPLICATIONS:

In our study, out of 30 cases managed conservatively 7 cases did not have any complications. While 11 cases (36.66%) showed malunion with shortening, 4 cases (13.33%) showed nonunion, shoulder stiffness was seen in 1 case (1.66%), 8 cases (26.66%) showed delayed union.

On the other hand out of 30 cases in surgical group 22 patients did not have any complications. While 2 cases (6.7%) had delayed union.1 case (3.33%) showed implant failure and subsequent delayed union. Implant prominence was seen in 2 cases (6.7%) that were treated with LCP. 1 case had hypertrophic scar at surgical incision site. 1 (3.3%) case each of nail loosening and lateral and medial migration of TENS nail respectively.

The most common complication in conservative group was malunion with shortening. This suggest that maintaining the fracture ends in reduced position is quite difficult because of distracting forces acting across fracture fragments.

Also we have noted that all patients who had malunion also had shortening as the displaced ends of fracture tend to malunite one above the other. It was also observed that prolonged immobilization of affected shoulder lead to shoulder stiffness in one patient. This patient did not come for follow up and came to follow up at end of 3 months.

Also 4 patients (13.33%) who had comminuted fracture pattern did not achieve bony union and had symptomatic non union. All were offered secondary procedure of ORIF and LCP plating. When we compared results of similar fracture fixed surgically had normal bony union and better functional outcome. This shows that surgical management should be preferred in all cases of comminuted and displaced clavicle fracture.

In conservative management group, 8 cases (26.6%) did not showed any signs of union by end of 3 months but had bony healing by 6 months, were labeled as delayed union. This rate of delayed union was still high when it was compared with surgical group cases where 2 patients had delayed union and 1 case had implant

failure in the form of LCP breakage which was removed. This patient also achieved delayed union.

Other complications in surgical group were development of hypertrophic scar after ORIF with LCP. TENS loosening and its either proximal or distal migration were also observed in 2 cases. This loosened nail was removed in OPD with small incision under local anesthesia as patient had bony union both clinically and radiologically.

Also 2 patients with ORIF and LCP fixation had hardware prominence in post operative period. Both the patients were thin built and were counseled regarding the condition. Implant removal was done for both cases after 8 months of bony union.

When we compared complications in surgical group, ORIF and LCP fixation group had more complication rate as compared to TENS group. This advantage to TENS group was because of its closed procedure pattern in most of the cases and also less soft tissue stripping.

When compared 23 (76.67%) patients in conservative group, had some complications. Among the people with surgical group, 8 (26.67%) participants had complications. When we applied chi square test the difference in the proportion of complication between group was statistically significant (P value <0.001) showing that complications rates in surgically managed cases were less as compared to conservative group.

None of the surgically treated case had non union or malunion or shortening and thus maximum patients had excellent functional outcome with early return to work and better satisfaction with the treatment as compared to conservative group.

In a comparative study conducted by C.M. Robinson, E.B. Goudie et al[71] 13 patients (14.13%) had nonunion in patients who were managed conservatively and 1 patient (1.1%) had nonunion in plating group.

In the same study, 3 patients in conservative group had osseous prominence. Also 2 cases that were treated with plating had refracture after plate removal and on case had sub acromial decompression.

In a study done by C.M. Robinson, Charles M et al[42] overall non union rate was 6.2% in cases managed conservatively.

Comparative study of conservative management versus TENS nailing vs. plating by Luke et al[76] reported that among conservatively managed cases 32 cases (78.04%) did not had any complications, 7cases (17.07%) reported non union, 1 case (2.4%) each had re-fracture and symptomatic bump at fracture site which required additional surgical procedure.

In the same study out of 24 cases, 21 cases (87.5%) did not had any complication,1 case (4.1%) had non union while 2 cases (8.3%) had painful hardware. While in TENS group of 25 cases, 23 cases(92%) did not had any complication, 1 case(4%) had painful hardware and infection each respectively. Hence, we conclude that results of our study are comparable with other similar studies, proving the fact that overall complications as well as nonunion rates are less in surgically treated groups. Also when we compare either of the surgical procedures, TENS group has less complications as compared to ORIF and plating group.

The results of our study have been compared with complications in the other comparative studies by I) C.M. Robinson, E.B. Goudie et al [71] II) B.M. Naveen et al[77] and III) Luke et al.[76]

From the comparison it is clear that a) non union rate are less with surgical groups, b) other complications like malunion and shortening are fewer with surgical group, c) early mobilization and early return to normal activity is possible with surgical techniques, d) in cases of comminuted or segmental fracture pattern surgical modalities have less rate of complications like delayed union or non union,

e) among the surgical group intramedullary fixation with TENShad less number of complications.

TABLE No.21: COMPARISON OF COMPLICATIONS IN DIFFERENT STUDIES.

Complications	Present study		C.M. Robinson and E.B. Goudie et al[71]		B.M. Naveen et al[77]		Luke et al[76]		
	Conservative (N=30)	**Surgical (N=30)**	**Conservative (N=92)**	**Surgical (N=86)**	**Conservative (N=30)**	**Surgical (N=30)**	**Conservative (N=41)**	**Surgical (N=49)**	
								LCP (N=24)	TENS (N=25)
Nil	7 (23.33%)	22(73.3%)	75(81.52%)	80(93.02%)	21(70%)	24(80%)	32(78.04%)	21(87.5%)	23(92%)
Delayed Union	8 (26.6%)	2 (6.66%)	-	-	-	-	7(17.07)	1(4.1%)	-
Distal Nail Migration	-	1 (3.33%)	-	-	-	-	-	-	-
Hypertrophic Scar	-	1 (3.33%)	-	-	-	3(10%)	-	-	-
Implant Failure	-	1 (3.33%)	-	4(4.6%)	-	-	-	-	-

Implant Prominence	-	2 (6.67%)	-	-	-	2(6.67 %)	-	2(8.3 %)	1(4. 1%)
Malunion And Shortening	11 (36.6%)	0 (0%)	3 (3.2%)	-	6(20%)	1(3.33 %)	-	-	-
Non Union	4 (13.33 %)	0 (0%)	13(14.13 %)	1(1.1 %)	2(6.67 %)	-	-	-	-
Proximal Nail Migration	0 (0%)	1 (3.33%)	-	-	-	-	-	-	-
Shoulder Stiffness	1 (3.33%)	0 (0%)	-	-	1(3.33 %)	-	-	-	-
Infection	-	-	-	-	-	-	-	-	1(4. 1%)

TABLE No.22: DEMOGRAPHIC COMPARISON OF DIFFERENT STUDIES

		Average age	Sex(M/F)	Side(R/L)	Average time of union	
					Conservative	Surgical
Present study (N=60)		34.05 years	45 (75%) / 15 (25%)	36(60%)/ 24 (40%)	16.61 ± 4.20	12.36 ± 4.05
C.M. Robinson, E.B. Goudie et al [71]		32.5 years	92:13	57 /48	-	-
		32.3 years	83:12	47/48		
Luke D. Jones[76]		27.1 year	76(84.44%)/14(15.55%)	46(51.11%)/ 44(48.88%)	-	-
B.M. Naveen et al[77]	Conservative	35.02 years	27/3	13/17	11.29 weeks	9.27 weeks
	Surgical	32.43 years	24/4	12/18		
Shettar et al[78]		-	13/6 15/4	11/8 14/5	-	13.16 weeks.

FUNCTIONAL OUTCOME

In our study, we have calculated the functional outcome of all the 60 cases with Constant score.[25] The functional outcome at the end of 6 months in 30 conservatively managed cases, 4 cases (13.3%) showed excellent outcome; 6 cases (20%) showed good outcome. 16 cases (53.3%) showed fair outcome and 4 cases (13.3%) showed poor outcome. While in surgically managed 30 cases, showed a total of 23(76.6%) with excellent outcome, 4 cases (13.3%) had good outcome 2 cases (6.6%) had a fair outcome, and 1 case (3.33%) had poor outcome. Final outcome was compared by applying chi square test the p value was <0.001 showing the results statistically significant.

C.M. Robinson, E.B. Goudie et al [71] showed that mean Constant score of 92 in all the patients who were managed surgically. While the mean Constant score was 87.8 in conservatively managed group.

B.M Naveen[77] In his comparative study showed mean constant score of 89.60 in conservative group at the end of 6 months of follow up. While Constant score was >90 in 93.33% of patients at the end of 6 months of follow up.

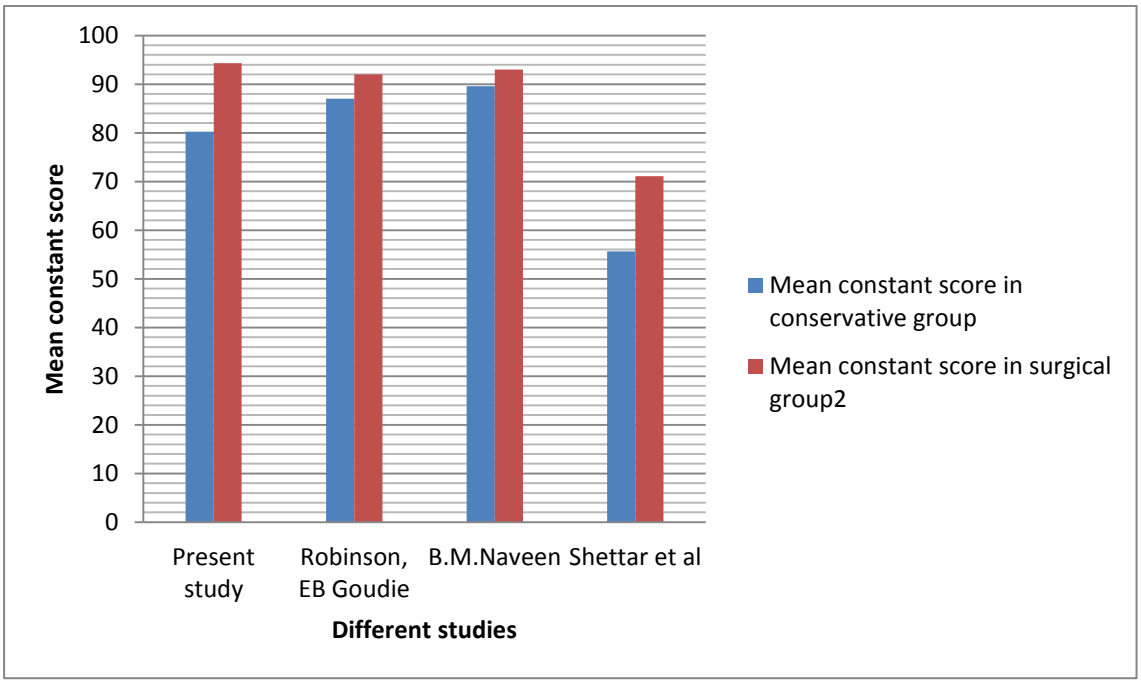
In a comparative study of conservative management versus TENS nailing by Shettar et al[78] mean constant score in conservative group was 55.63 and 71.16 in surgical group at the end of 6 months follow up.

Thus, after comparing functional outcome at the end of 6 months with above mentioned studies, our results are comparable, indicating that, functional outcomes are better after surgical management in cases of displaced clavicle fractures.

TABLE No.23:COMPARISON OF FUNCTIONAL OUTCOME

Study	Mean constant score in conservative group	Mean constant score in surgical group
Present study	80.23	94.3
C.M. Robinson, E.B. Goudie et al [71]	87	92
B.M Naveen[77]	89.6	93
Shettar et al[78]	55.63	71.16

GRAPH NO.18:COMPARISON OF FUNCTIONAL OUTCOME



IMPLANT REMOVAL

Out of 15 cases that were managed surgically with TENS, 10 patients underwent implant removal. All these implants were removed under local anesthesia and patient was discharged next day. Out of 15 cases that were managed with ORIF with LCP fixation 3 patients underwent LCP removal. All these cases were operated under general anesthesia. All the implant removals were done after confirmation of bony union both clinically and radio logically. None of the patient had incidence of re-fracture or surgical site infection or any other complication after implant removal.

CONCLUSION

CONCLUSION

Based on the results obtained during the study period and also considering the functional outcomes of both the groups of this prospective comparative study following conclusions were made.

The majority of complications in this study, were in conservative group.These complications were mainly attributed to the difficulty in maintaining fracture in anatomically aligned position. Presence of these many complications had a final effect on the functional outcome and majority of patients had good to fair outcome as compared to excellent outcome in the operative group. Non union rates were significantly high in the non-operative group as compared to operative group. All these complications lead finally to patient dissatisfaction to the treatment, prolonged period of absence from work, prolonged intake of analgesics and its subsequent complications.

Despite the method of operative intervention used, patients in this group had better functional outcome, less number of fracture related complications, early return to work. However, we would like to bring to the notice other aspect of this comparison, which most of the studies tend to forget. Most of the patients coming to our institution prefer conservative modalities of treatment despite of the counseling and explaining them regarding the possible outcome and complications that might occur. The only consideration patient has, is the financial constraints he is going to bear because of surgical procedure. Considering this aspect we do not support the routine protocol of operative management for all the displaced clavicle fracture, rather we recommend that, the treatment should be individualized according to patients age, his financial capabilities , his nature of work and his pain threshold.

In our institution, all the patients are counseled routinely, with all possible complications of both modalities, advantages and disadvantages of both treatment protocols and final decision is made after that. We also noted that young active male individuals opted for surgical modalities compared to older and middle age population. Female patients opted for TENS procedure as it has better cosmetic results in post procedure period.

Though this study was meant to compare the functional outcome of operative versus non-operative group, with larger number of cases, both the operative modalities could have been compared. TENS has fewer complications as compared to ORIF and plating group, owing to small incision, less soft tissue stripping and preservation of periosteal blood supply, and preservation of fracture hematoma. Also keeping in mind the implant removal after fracture union, TENS has advantage of removal as OPD procedure. When considering the cost of operative procedure TENS has less expenditure as compared to LCP. TENS has disadvantage of being a newer procedure which is technically more demanding, as being the closed reduction method of fixation. While LCP has advantages of being a familiar procedure to most of the orthopedic surgeons, a stable fixation, allowing early ROM at affected shoulder, early return of work as compared to TENS and less nonunion rates as compared to TENS in cases of comminuted and segmental fracture pattern.

Hence this study proves that, surgically managed displaced clavicle fractures have better functional outcome, fewer complications and early bony union when compared to non-operative treatment modality. But it isrecommend that, treatment has to be individualized for every case and routine use of operative procedure is not advisable especially in a rural set up like ours.

SUMMARY

SUMMARY

This is a prospective randomized comparative study of total 60 cases of displaced midshaft clavicle fractures. In this study, cases were divided into two groups , 30 cases were offered non-operative modality of treatment with shoulder arm pouch and clavicular brace and 30 cases were managed surgically.In surgical group 15 cases were managed by intramedullary device, Titanium Elastic Nailing System (TENS) and another 15 using open reduction and internal fixation with locking compression plate. No randomization was done among the operative group as the primary aim of the study was to compare the functional outcome between operative and non-operative groups. This study was carried out during period of Nov. 2017 to April 2019. Majority of the injury occurred in male patients- 45 cases (75%), whereas a total of 15 cases (25%) were seen in females. Majority of these fractures, 21 cases (35%) and 13cases (21%) occurred between 21-30 years and 31-40years of age groups. 33 cases (55%) occurred as a result of road traffic accidents, 14 cases (23.33%) as a result of fall on an outstretched hand, 8 cases (13.33%) due to direct trauma and 5 cases (8.33%) due to self fall. According to Robinson classification, there were 47 cases (78.3%) under 2B1 and 13 (21.6 %) cases under 2B2 type.

All the 30 cases in conservative group were managed with immobilization for at least 2 weeks in shoulder arm pouch and clavicular brace. Gradual range of movements was started as tolerated by patients at the end of 3rd week. Patients were followed up at 2nd and 6th week following discharge then at 3rd month and at 6th month. Constant score was calculated at every follow up.

All the 30 cases that were included in the operative group were divided into two subgroups. No method of randomization was done here.

1st 15 cases were operated with open reduction and internal fixation with LCP and next 15 cases were treated with intramedullary device, Titanium Elastic Nailing System (TENS).

All the patients in surgical group were immobilized for at least 5 days in post operative period and Range of motion exercise were instituted as tolerated by patient at the end of 1 week.The functional outcome at the end of 6 months in 30 conservatively managed cases showed, 4 cases (13.3%) with excellent outcome; 6 cases (20%) with good outcome. 16 cases (53.3%) showed fair outcome and 4 cases (13.3%) showed poor outcome. While in surgically managed 30 cases, the functional outcome at the end of 6months showed a total of 23(76.6%) with excellent outcome, 4 cases (13.3%) had good outcome 2 cases (6.6%) had a fair outcome, and 1 case (3.33%) had poor outcome. After comparison of the final outcome at the end of 6 months, of both the groups, by applying chi square test, the p value was <0.001, showing the results statistically significant. Thus, in our study operative group had fewer complications and better functional outcome as compared to the conservative group.

STUDY LIMITATIONS

• The conclusions drawn from this study cannot be generalized, because this study does not consider socioeconomic aspects of patients and also because of the small number of cases in both the groups.

• We have followed the patients in both the groups for 6 months, but whether the longer follow up period might affect the final outcome of the study or not remains unanswered.

BIBLIOGRAPHY

BIBLIOGRAPHY

1. Standring S, Gray H. Gray's anatomy. 40th ed. churchill livingstone elsevier; 2008:799-811p.61
2. Craig EV, Basamania CJ, Rockwood CA. Fractures of the clavicle. The shoulder. 3rd edition Philadelphia: Saunders, 2004; 455-519. |
3. Hulsmans MHJ. Operative treatment of displaced clavicle fractures: optimising implant choice: 509895-L-bw-Drukbedrijf, 2017.
4. Canale ST, Beaty JH. Campbell's Operative Orthopaedics. 11th Ed. Philadelphia:Elsevier; 2008.3371-3376p.
5. Nowak J, Mallmin H, Larsson S. The aetiology and epidemiology of clavicular fractures. A prospective study during a 2-year period in Uppsala, Sweden. Injury. 2000; 31(5):353– 358.
6. Stanley D, Trowbridge EA, Norris SH. The mechanism of clavicular fracture. A clinical and biomechanical analysis. J Bone Joint Surg Br. 1988; 70(3):461-464.
7. NEER CS. Nonunion of the clavicle. J Am Med Assoc. 1960; 172:1006-1011.
8. Rowe CR. An atlas of anatomy and treatment of midclavicular fractures. Clin Orthop Relat Res. 1968; 58:29-42. 102
9. Canale ST, Beaty JH. Campbell's Operative Orthopaedics. 11th Ed. Philadelphia:Elsevier; 2008.3371-3376p
10. Zlowodzki M, Zelle BA, Cole PA, et al. Treatment of acute midshaft clavicle fractures:Systematic review of 2144 fractures: On behalf of the Evidence-Based Orthopaedic Trauma Working Group. J Orthop Trauma.2005; 19(7):504–507.
11. Gille J, Schulz A, Wallstabe S, Unger A, Voigt C, Faschingbauer M. Hook plate for medial clavicle fracture. Indian J Orthop 2010;44:221‑3.

12. Thyagarajan DS, Day M, Dent C, Williams R, Evans R. Treatment of mid‐shaft clavicle fractures: A comparative study. Int J Shoulder Surg 2009;3:23‐7.
13. Canadian Orthopaedic Trauma Society. Non-operative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. J Bone Joint Surg Am 2007;89:1‐10.
14. Jørgensen A, Troelsen A, Ban I. Predictors associated with nonunion and symptomatic malunion following non-operative treatment of displaced midshaft clavicle fractures--A systematic review of the literature. Int Orthop 2014; 38(12): 2543-9. [http://dx.doi.org/10.1007/s00264-014-2450-7] [PMID: 25027978]
15. McKee MD, Pedersen EM, Jones C, Stephen DJ, Kreder HJ, Schemitsch EH, *et al.* Deficits following non-operative treatment of displaced midshaft clavicular fractures. J Bone Joint Surg Am 2006;88:35‐40.
16. Pearson AM, Tosteson AN, Koval KJ, et al. Is surgery for displaced, midshaft clavicle fractures in adults cost-effective? Results based on a multicenter randomized, controlled
trial. J Orthop Trauma. 2010; 24(7):426-33.
17. Liu GD, Tong SL, Ou S, Zhou LS, Fei J, NaN GX et al. Operative versus non-operative treatment for clavicle fracture. Int Orthop. 2013 Aug; 37(8): 1495–1500.
18. Schiffer G, Faymonville C, Skouras E, Andermahr J, Jubel A : Midclavicular fracture: Not just a trivial injury – current treatment options .Dtsch Arztebl Int. 2010;107(41);711-7.
19. Zenni EJ Jr, Krieg JK, Rosen MJ. Open reduction and internal fixation of clavicular fractures. J Bone Joint Surg Am. 1981; 63:147-51.
20. Huang JI, Toogood P, Chen MR, Wilber JH, Cooperman DR. Clavicular anatomy and the applicability of precontoured plates. J Bone Joint Surg Am. 2007; 89:2260-5.

21. N. Modi, A.D. Patel, P. Hallam Norfolk And Norwich University Hospital NHS Foundation Trust,Norwich,UK. Outcome Of 62 Clavicle Fracture Fixations With Locked Compression Plate: Is This The Right Way To Go? doi:10.1016/j.injury.2011.06.266.
22. Van der Meijden OA, Houwert RM, Hulsmans M, Wijdicks FJ, Dijkgraaf MG, Meylaerts SA et al. Operative Treatment of Dislocated Midshaft Clavicular Fractures: Plate or Intramedullary Nail Fixation. J Bone Joint Surg Am. 2015; 97:613-9.
23. Zeng L, Wei H, Liu Y, Zhang W, Pan Y, Zhang W, et al. Titanium Elastic Nail (TEN) versus Reconstruction Plate Repair of Midshaft Clavicular Fractures: A Finite Element Study. PLoS ONE.2015; 10(5): e0126131. Doi: 10.1371/journal. pone.0126131
24. Smith SD, Wijdicks CA, Jansson KS, Boykin RE, Martetschlaeger F, de Meijer PP, et al. Stability of mid-shaft clavicle fractures after plate fixation versus intramedullary repair and after hardware removal. Knee Surg Sports Traumatol Arthrosc. 2014; 22(2):448-55. doi: 10.1007/s00167-013-2411-5 [doi]
25. Hussain N, Sermer C, Prusick PJ, Banfield L, Atrey A, Bhandari M. Intramedullary Nailing Versus Plate Fixation for the Treatment Displaced Midshaft Clavicular Fractures: A Systematic Review and Meta-Analysis. Sci Rep. 2016;6:34912. Published 2016 Oct 20. doi:10.1038/srep34912
26. Wang Y C, Fu Y C, Chou S H, Liu P C, Tien Y C, Lu C C. Titanium Elastic Nail versus plate fixation of displaced midshaft clavicle fractures: A retrospective comparison study. *KJMS*.2015; 31, 473-479.
27. Kumareshwaran, Karthik V, Kumar D, Thanigai S.A study of patients with middle third clavicle fractures as per treatment given and radiological union. IJOS. 2017; 3(1): 240- 242.

28. Wijdicks FJ, Houwert RM, Millett PJ, Verleisdonk EJ, Van der Meijden OA. Systematic review of complications after intramedullary fixation for displaced midshaft clavicle fractures. Can J Surg. 2013; 56(1):58-64.
29. Chen YF, Wei HF, Zhang C, Zeng BF, Zhang CQ, Xue JF, et al. Retrospective comparison of titanium elastic nail (TEN) and reconstruction plate repair of displaced midshaft clavicular fractures. J Shoulder Elbow Surg. 2012; 21(4):495–501. doi: 10.1016/j.jse.2011.03.007 PMID: 21641826.
30. Canadian Orthopedic Trauma Society. Non-operative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter randomized clinical trial. J Bone Joint Surg Am. Jan 2007; 89(1):1-10.
31. Zhang B, Zhu Y, Zhang F, Chen W, Tian Y, Zhang Y. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine.2015;23:27.DOI 10.1186/s13049-015-0108-0
32. Garg Krishna, Mrudula Chandrupatla., Pragati Sheel MIttal. BD Chaurasia's Human Anatomy. NEW Delhi: CBS Publishers & Distributers; 2016.
33. Court-Brown CM, Heckman JD, McQueen MM, Ricci W, Tornetta P, McKee M.Rockwood and Green's fractures in adults.8th Ed. Philadelphia: WoltersKluwer;2015.1427-1470p..
34. Craig EV, Basamania CJ, Rockwood CA. Fractures of the clavicle. Chapter-11, In : Rockwood CA, Matsen FA, Wirth MA, Lippitt SB, editors, The shoulder. 3rd edition Philadelphia: Saunders, 2004; 455-519.
35. Netter F, Machado C, Hansen J, Benninger B, Brueckner J, Netter F. Atlas of human anatomy. 6th ed. saunders elsevier; 2014.

36. Wilk KE. The shoulder. Chapter-15, In Malone TR, McPoil TG, Nitz AJ, editors, Orthopaedics and sports physical therapy, 3rd edition, St.Louis : Mosby.1997; 401-409.
37. Moseley HF. Shoulder lesions. Edinburgh: Churchill Livingstone; 1972.207-235p.
38. Moore KL, Dalley AF, Agur AMR. Clinically oriented anatomy. 6th ed. Lippincott Williams & Wilkins; 2009.673-675p.
39. Lazarus MD. Fractures of the Clavicle. Chapter-26, In: Bucholz RW and Heckman JD, editors, Rockwood and Green‟s fractures in adults, 5th edition, Philadelphia: Lippincott Williams and Wilkins.2001; 1041-1078.
40. Robinson's CM. Fractures of the clavicle in the adult. Epidemiology and classification. J Bone Joint Surgery (Br).1998; 80: 476-484.
41. Kumareshwaran, Karthik V, Kumar D, Thanigai S.A study of patients with middle third clavicle fractures as per treatment given and radiological union. IJOS. 2017; 3(1): 240-242.
42. Robinson CM, Court Brown CM, McQueen MM, Walkefield AE. Estimating the risk of non-union following non operative treatment of a clavicular fracture. J Bone Joint Surg Am.2004; 86: 1359-1365.
43. Remiger AR, Miclau T, Lindsey RW. The torsional strength of bones with residual screw holes from plates with unicortical and bicortical purchase. Clin Biomech (Bristol, Avon). 1997; 12(1):71-73. Doi: S0268003396000629 [pii].
44. Andrade-Silva FB, Kojima KE, Joeris A, Santos Silva J, MattarR,Jr. Single, superiorly placed reconstruction plate compared with flexible intramedullary nailing for midshaft clavicular fractures: A prospective, randomized controlled trial. J Bone Joint Surg Am. 2015; 97(8):620-626. doi: 10.2106/JBJS.N.00497

45. Jeray KJ. Acute midshaft clavicular fracture. J Am Acad Orthop Surg 2007; 15(4): 239-48. [http://dx.doi.org/10.5435/00124635-200704000-00007] [PMID: 17426295]
46. Nordqvist A, Petersson CJ, Redlund-Johnell I. Mid-clavicle fractures in adults: End result study after conservative treatment. J Orthop Trauma 1998; 12(8): 572-6. [http://dx.doi.org/10.1097/00005131-199811000-00008] [PMID: 9840792]
47. Nowak J, Holgersson M, Larsson S. Can we predict long-term sequelae after fractures of the clavicle based on initial findings? A prospective study with nine to ten years of follow-up. J Shoulder Elbow Surg 2004; 13(5): 479-86. [http://dx.doi.org/10.1016/j.jse.2004.01.026] [PMID: 15383801]
48. Ban I, Branner U, Holck K, Krasheninnikoff M, Troelsen A. Clavicle fractures may be conservatively treated with acceptable results – A systematic review. Dan Med J 2012; 59(7): A4457. [PMID: 22759840]
49. DongWoo Lee, YoungHwan Jang, Jun Seop Yeom, Scott A. Banks. Effects of short malunion of clavicle on *in vivo* scapular kniematics. J Shoulder Elbow Surg 2017; 26: e286-92. [http://dx.doi.org/10.1016/j.jse.2017.03.013] [PMID: 28478902]
50. Stanley D, Trowbridge EA, Norris SH. The mechanism of clavicular fracture. A clinical and biomechanical analysis. J Bone Joint Surg Br 1988; 70(3): 461-4. [PMID: 3372571]
51. Lenza M, Belloti JC, Andriolo RB, Faloppa F. Conservative interventions for treating middle third clavicle fractures in adolescents and adults. Cochrane Database Syst Rev 2014; (5): CD007121 [PMID: 24879341]
52. Lenza M, Faloppa F. Surgical interventions for treating acute fractures or non-union of the middle third of the clavicle. Cochrane Database Syst Rev 2015; (5): CD007428. [PMID: 25950424]

53. DongWoo Lee, YoungHwan Jang, Jun Seop Yeom, Scott A. Banks. Effects of short malunion of clavicle on *in vivo* scapular kniematics. J Shoulder Elbow Surg 2017; 26: e286-92. [http://dx.doi.org/10.1016/j.jse.2017.03.013] [PMID: 28478902]
54. Khalil A. Intramedullary screw fixation for midshaft fractures of the clavicle. Int Orthop. 2009; 33:1421–4.
55. Ligier JN, Metaizeau JP, Prevot J. Closed flexible intramedullary nailing in paediatric traumatology. Chir Pédiatr. 1983; 24: 283-285.
56. Saini M, Singh Y, Arora P, Arora V, Jain K. Implant biomaterials: A comprehensive review. World J Clin Cases. 2015; 3(1):52-7.
57. Tschernitschek h, borchers l, geurtsen w. Non-alloyed Titanium as a bioinert metal—a review. Quintessence int.2005; 36: 523-530.
58. Kadakia AP, Rambani R, Qamar F, McCoy S, Koch L, Venkateswaran B. Titanium elastic stable intramedullary nailing of displaced midshaft clavicle fractures: A review of 38 cases. Int J Shoulder Surg. 2012; 6(3):82-5.
59. Andermahr J, Jubel A, Elsner A, Johann J, Prokop A, Rehm KE, et al. Anatomy of the clavicleand the intramedullary nailing of midclavicular fractures. Clin Anat (New York). 2007; 20(1):48–56.
60. Meier C, Grueninger P, PlatzA.Elastic stable intramedullary nailing for midclavicular fractures in athletes: Indications, technical pitfalls and early results. Acta Orthop. Belg., 2006; 72: 269-275.
61. Geel CW. Scapula and clavicle. Chapter-4 In Colton CL, Dell‟oca AF, Holz U, Kellam JF, Ochsner PE, editors. AO Principles of fracture management. New York: Thieme; 2000. 262-264.

62. Wijdicks FJ, Houwert RM, Millett PJ, Verleisdonk EJ, Van der Meijden OA. Systematic review of complications after intramedullary fixation for displaced midshaft clavicle fractures. Can J Surg. 2013; 56(1):58-64.
63. Zhang B, Zhu Y, Zhang F, Chen W, Tian Y, Zhang Y. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine.2015;23:27.DOI 10.1186/s13049-015-0108-0
64. Ruedi T, Duwelins PJ. Fractures and dislocations of the shoulder girdle and humerus. Chapter-15, In: Chapman MW, editor, Chapaman's orthopaedic Surgery.3rd ed. Philadelphia: Lippincott Williams and Wilkins; 2001. 444-450.
65. Jupiter JB, Ring D. Fractures of the clavicle. Chapter- 26, In: lannotti JP and Williams GR. editors. Disorders of the Shoulder diagnosis and Management. Philadelphia: Lippincott Williams and Wilkins; 1999.709-786.
66. Wagner, M. (2003). General principles for the clinical use of the LCP. Injury, 34, 31–42. doi:10.1016/j.injury.2003.09.023
67. Constant CR, Murley AHG. A clinical method of functional assessment of the shoulder. Clinical Orthopaedics and Related Research. 1987; 214: 160-164.
68. Kettler M, Schieker M, Braunstein , onig M, Mutschler W. Flexible intramedullary nailing for stabilization of displaced midshaft clavicle fractures: technique and results in 87 patients. Acta Orthop. 2007; 78:424-9.
69. Woltz S, Stegeman SA, Krijnen P, *et al.* Plate fixation compared with non-operative treatment for displaced midshaft clavicular fractures: A multicenter randomized controlled trial. J Bone Joint Surg Am 2017; 99(2): 106-12. [http://dx.doi.org/10.2106/JBJS.15.01394] [PMID: 28099300]

70. Non-operative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. J Bone Joint Surg Am 2007; 89(1): 1-10. [http://dx.doi.org/10.2106/JBJS.F.00020] [PMID: 17200303]
71. Robinson CM, Goudie EB, Murray IR, *et al.* Open reduction and plate fixation *versus* non-operative treatment for displaced midshaft clavicular fractures: A multicenter, randomized, controlled trial. J Bone Joint Surg Am 2013; 95(17): 1576-84. [http://dx.doi.org/10.2106/JBJS.L.00307] [PMID: 24005198]
72. Ersen A, Atalar AC, Birisik F, Saglam Y, Demirhan M. Comparison of simple arm sling and figure of eight clavicular bandage for midshaft clavicular fractures: A randomised controlled study. Bone Joint J 2015; 97-B(11): 1562-5. [http://dx.doi.org/10.1302/0301-620X.97B11.35588] [PMID: 26530661]
73. Hill JM, McGuire MH, Crosby LA. Closed treatment of displaced middle third fractures of the clavicle gives poor results. J Bone Joint Surgery (Br). 1997; 79:537-540.
74. Ruedi T, Duwelins PJ. Fractures and dislocations of the shoulder girdle and humerus. Chapter-15, In: Chapman MW, editor, Chapaman‟s orthopaedic Surgery.3rd ed. Philadelphia: Lippincott Williams and Wilkins; 2001. 444-450.
75. Creashaw AH. Fractures of shoulder arm and forearm. Chapter– 54, In: Canale ST, editor. Campbell‟s operative orthopedics. 10th ed. St. Louis: Mosby; 2003.2985-3071.
76. Jones L, Grammatopoulos G, Kambouroglou G. Titanium elastic nails, open reduction internal fixation and non-operative management for middle third clavicle fractures: a comparative study. European Journal of Orthopaedic Surgery & Traumatology. 2013;24(3):323-329.

77. Naveen B, Joshi G, Harikrishnan B. Management of mid-shaft clavicular fractures: comparison between non-operative treatment and plate fixation in 60 patients. Strategies in Trauma and Limb Reconstruction. 2017;12(1):11-18.
78. Shettar V, Bhasme V, Battur M. Prospective Comparative Analysis of Functional Outcome of Operative – Titanium Elastic Nailing System (TENS) Versus Non Operative Treatment of Midshaft Clavicle Fractures. International Journal of Contemporary Medical Research [IJCMR]. 2018;5(9).

ANNEXURES

ANNEXURE-I

PROFORMA

1. BASIC DATA

Name: Age:

Sex:

Address:

Contact information:

Indoor No. : Out door No. :

Date of any previous Procedure:

Date of Admission/OP :

Date of Discharge:

HISTORY

Chief complaints:

History of presenting illness:

Duration of symptoms :

Exacerbating and relieving factors:

Involvement of other joints:

Previous conservative management

Physiotherapy

NSAID's / drugs

Mechanism of injury:

i) Fall on shoulder

ii) Direct injury to shoulder

iii) Fall on out stretched hand

iv) Road traffic accident

Mode of presentation: Nil:

Splint:

Past history: Medical:Pre existing systemic illness

Diabetes/Thyroid disorder/ Cervical Spine/ CVS/RS/

CNS/locomotor/ TB/ anaemia/ Hypertension/

malnutrition/others

: Surgical:

Family history:

Personal history:

Occupation:

Hand *dominance*: right / left

Level of activity/ sports:

Patient expectation:

General physical examination:

Vital signs		Systemic examination	
BP -	PR -	1. CVS	3.CNS
RR -	Temp -	2.RS	4.PA

LOCAL EXAMINATION:

- INSPECTION:

Side of injury:

Overlying skin:

Attitude of limb:

Deformity:

Swelling:

- PALPATION:

Local rise of temperature:

Tenderness:

Abnormal mobility:

Crepitus:

Bony irregularity:

Neurological deficit:

Vascular deficit:

- MOVEMENTS:

Associated injuries:

Details for *Constant and Murley score*:

2. DIAGNOSIS

Side right / left

Site medial/ mid / lateral 1/3rd

Displaced/ undisplaced

Tenderness : present / absent / tenderness at _____

Movements at shoulder joint:

Flexion:

Abduction:

Adduction:

External Rotation:

Internal Rotation:

Power:

Able to lift _____ lbs of sand bag/spring weight balance for 5 secs for 3 times with 90 deg abduction with extended elbow with no pain

Associated with rotator cuff tear, Drop arm sign - yes/no

Local disease

Congenital / Rheumatoid Arthritis/osteoarthritis/ osteoporosis / tumor /

Osteomyelitis / previous fracture / previous injection / previous operation

Other clinical findings

3. INVESTIGATIONS

Hb %, Total WBC count, differential count, ESR, BT, CT.

Blood urea, serum creatinine, RBS .

HIV, HBsAg status

X ray chest with b/l shoulder – AP view

4. MANAGEMENT

IMMEDIATE MANAGEMENT:

IV fluids:
Analgesics:
Blood transfusion:
Splintage:
Method:
Duration:

DEFINATIVE MANAGEMENT:

Shoulder arm pouch and clavicular brace

OR

CRIF + TENS

OR

ORIF + LCP Plating

Physiotherapy advised / or not

ONLY FOR SURGICAL MANAGEMENT:

- Observation in surgical ICU- yes/no
- Date of surgery:
- Duration of surgery: Anesthesia:
- Surgical approach:
- Reduction (open or closed):
- Implant used with exact dimensions:
- Intraoperative complications:
- Post op period:
- Antibiotics:
- Analgesics:
- Check x-rays:
- Splintage:
- Complications:
- Revision procedures:
- Secondary procedures:

ONLY FOR CONSERVATIVE MANAGEMENT:

- Analgesics:
- Check x-rays:
- Splintage:
- Complications:
- Secondary procedures:

5. POST PROCEDURE

- Immobilization of arm - yes/no
- NSAID's - yes/no
- Antibiotics:Prophylactic/therapeutic/Nil

Systemic complications

•Bleeding, infection, neurovascular injury, shock, ICU admission, malunion, non union

Local complications

1. necrosis of skin
2. infection : a)suspected/established

b)superficial/deep

c)mild/moderate/severe

3. hematoma
4. others

Further treatment of complications

None/Hematoma aspirated/open dressing/debridement/suction irrigation/plastic procedure/Physiotherapy/steroid injection/acromioplasty/rotator cuff repair

6. TIME OF DISCHARGE

Rom assesment

Overall functional assesment according to Constant Murley Score

Complications

1. Systemic :healed/improved/unchanged/dies/nil
2. local :healed/improved/unchanged/nil

7. FOLLOW UP:

		Discharge	3weeks	6weeks	3 months
PAIN					
CONSTANT SCORE					
MOVEMENTS OF SHOULDER GIRDLE	Abduction-				
	Adduction-				
	Flexion				
	Extension				
	IR				
	ER				
X-RAY FINDIGS	Union- Superior cortex Inferior cortex				
	Callus-				
	Implant failure i)TENS ii)LCP				
	Malunion-				
	Shortening-				
	Displacement-				
	Other findings:				

ANNEXURE-II
KANNADA CONSENT FORM

ತಿಳಿವಳಿಕೆಯಸಮ್ಮತಿನಮೂನೆ

ನಾನು, _____ ವಯಸ್ಸಿನ _____,

ನನ್ನಸ್ವಂತಭಾಷೆಯಲ್ಲಿವಿವರಿಸಲ್ಪಟ್ಟನಂತರಅಧ್ಯಯನದಉದ್ದೇಶಮತ್ತುಕಾರ್ಯವಿಧಾನದತೊಂದರೆಗಳುಮತ್ತುತೊಡಕುಗಳಬಗ್ಗೆವಿವರಿಸಿದನಂತರ, ಮುಚ್ಚಿದಕಡಿತಮತ್ತುಆಂತರಿಕಸ್ಥಿರೀಕರಣ /

ಓಪನ್ಗೆಯಾವುದೇಬಲದಅಥವಾಪೂರ್ವಾಗ್ರಹವಿಲ್ಲದೆನನ್ನಮಾನ್ಯವಾದಲಿಖಿತವಿರೋಧಿಸಮ್ಮತಿಯನ್ನುನೀಡಿನನ್ನಮೇಲೆನಡೆಸಬೇಕಾದರೋಗನಿದಾನಮತ್ತು / ಅಥವಾಚಿಕಿತ್ಸಕಪ್ರಕ್ರಿಯೆ / ವರ್ಗಾವಣೆ /

ಕಾರ್ಯಾಚರಣೆಅಥವಾಯಾವುದೇಅರಿವಳಿಕೆಅಡಿಯಲ್ಲಿ ಪ್ಲೇಟ್ನಂತಹ ಮತ್ತುತಿರುಪು /

ಸಂಪ್ರದಾಯವಾದಿನಿರ್ವಹಣೆಯೊಂದಿಗೆಪ್ಲೇಟ್ಮತ್ತುಸ್ಕ್ರೂ /

ಸಂಪ್ರದಾಯವಾದಿನಿರ್ವಹಣೆಗೆಒಳಪಡಿಸುವುದುಯೋಗ್ಯವಾದವು. ಕಾರ್ಯವಿಧಾನದಲ್ಲಿ

(ಶಸ್ತ್ರಚಿಕಿತ್ಸಾಮತ್ತುಅನಾಸ್ಥೆಟಿಕಲ್)

ಒಳಗೊಂಡಿರುವಸ್ವಭಾವಮತ್ತುಅಪಾಯಗಳುನನ್ನತೃಪ್ತಿಗೆನನಗೆವಿವರಿಸಲಾಗಿದೆ.

"ಕ್ವಾವಿಲ್ಲಲ್ನಸ್ಥಳಾಂತರಿತಡಯಾಫಿಸಿಯಲ್ಮುರಿತದಸಂಪ್ರದಾಯವಾದಿನಿರ್ವಹಣೆಮತ್ತುಕಾರ್ಯಾಚರಣೆಯನಿರ್ವಹಣೆಯಕಾರ್ಯಾತ್ಮಕಫಲಿತಾಂಶದನಿರೀಕ್ಷಿತಮತ್ತುತುಲನಾತ್ಮಕಅಧ್ಯಯನ"

ಕುರಿತುಕ್ಲಿನಿಕಲ್ರಿಸರ್ಚ್ಗೆರಿತುನಾನುವಿವರಿಸಿದ್ದೇನೆ.

ನಾನುರೋಗಿಯಮಾಹಿತಿಹಾಳೆಯನ್ನುಓದಿದ್ದೇನೆಮತ್ತುಯಾವುದೇಪ್ರಶ್ನೆಕೇಳಲುನನಗೆಅವಕಾಶವಿದೆ.ನಾನುಕೇಳಿದಯಾವುದೇಪ್ರಶ್ನೆಯನ್ನುನನ್ನತೃಪ್ತಿಗೆಉತ್ತರಮಾಡಲಾಗಿದೆ.ಈಸಂಶೋಧನೆಯಲ್ಲಿಪಾಲ್ಗೊಳ್ಳುವವರಾಗಿಭಾಗವಹಿಸಲುನಾನುಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದಸಮ್ಮತಿಸುತ್ತೇನೆ.ನನ್ನಇತಿಹಾಸವನ್ನುಒದಗಿಸಲು, ದೈಹಿಕಪರೀಕ್ಷೆಗೆಒಳಗಾಗಲು,

ಇಂಜೆಕ್ಷನ್ಪ್ರಕ್ರಿಯೆಗೆಒಳಗಾಗಲು,

ತನಿಖೆಗೆಒಳಗಾಗಬೇಕುಮತ್ತುಅದರಫಲಿತಾಂಶಗಳುಮತ್ತುದಾಖಲೆಗಳನ್ನುವೈದ್ಯರಿಗೆ /

ಇನ್ವೆಸ್ಟ್ಗೇಟರ್ಗೆನೀಡುವಂತೆನಾನುಒಪ್ಪಿಗೆನೀಡುತ್ತೇನೆ.

ಶೈಕ್ಷಣಿಕಮತ್ತುವೈಜ್ಞಾನಿಕಉದ್ದೇಶಕ್ಕಾಗಿಕಾರ್ಯಾಚರಣೆ / ವಿಧಾನ,

ಇತ್ಯಾದಿವೀಡಿಯೊವನ್ನುಅಥವಾಛಾಯಾಚಿತ್ರಮಾಡಬಹುದು.ಎಲ್ಲಾಡೇಟಾವನ್ನುಯಾವುದೇಶೈಕ್ಷಣಿಕಉದ್ದೇಶಕ್ಕಾಗಿ

ಪ್ರಕಟಿಸಬಹುದುಅಥವಾಬಳಸಬಹುದು.ಕಾರ್ಯವಿಧಾನ /

ಅಧ್ಯಯನದಸಮಯದಲ್ಲಿಯಾವುದೇಕೆಟ್ಟಪರಿಣಾಮಗಳಿಗೆನಾನುವೈದ್ಯರು /

ಇನ್ಸ್ಟಿಟ್ಯೂಟ್ಇತ್ಯಾದಿಗಳನ್ನುಹೊಂದುವುದಿಲ್ಲ.

ಈಮಾಹಿತಿಯುಕ್ತಸಮ್ಮತಿಯಫಾರ್ಮ್ಅತ್ತುರೋಗಿಯಮಾಹಿತಿಹಾಳೆಯನ್ನುಪ್ರತಿಸ್ಪರ್ಧಿಗೆಒದಗಿಸಲಾಗಿದೆ.

_____ _____ _____

(ರೋಗಿಯ ಪರಿಚಾರಕನ ಸಹಿ &ಹೆಸರು) (ರೋಗಿಯ / ಗಾರ್ಡಿಯನ್ನ ಸಹಿ /ಹೆಬ್ಬೆಟ್ಟಿನ ಗುರುತು &ಹೆಸರು)

(ರೋಗಿಯ ಸಂಬಂಧ)

(ಸಂಶೋಧಕನ /ವೈದ್ಯರ ಸಹಿ &ಹೆಸರು)

ANNEXURE-II
ENGLISH CONSENT FORM

I, _____ aged _____

,after being explained in my own vernacular language about the purpose of the study and the risks and complications of the procedure, hereby give my valid written inormed consent without any force or prejudice for Closed reduction and internal fixation / Open reduction and internal fixtion with plate and screw/ conservative management with shoulder arm pouch and clavicular brace or any other procedure deemed fit, which is a diagnostic & / or therapeutic procedure / biopsy / transfusion / operation to be performed on me or _____ under any anaesthesia deemed fit. The nature and risks involved in the procedure (surgical and anaesthetical) have been explained to me to my satisfaction.

I have been explained in detail about the Clinical Research on "comparative study of surgical management versus conservative management of displaced fractures of the clavicle." being conducted. I have read the patient information sheet and I have had the opportunity to ask any question. Any question that I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. I hereby give consent to provide my history, undergo physical examination, undergo the injection procedure, undergo investigations and provide its results and documents etc to the doctor / institute etc.

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

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

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

(Relation with patient)---------

Witness:----------

(Signature & Name of Research person /doctor)----------

ANNEXURE-III

PATIENT INFORMATION SHEET IN KANNADA

	SRI DEVARAJ URS MEDICAL COLLEGE, TAMAKA, KOLAR -563 101.	FORMAT NO. ISSUE NO.
	Information Sheet	REV. NO. DATE

ಮಾಹಿತಿಹಾಳೆ

ಸಂಸ್ಥೆಯಹೆಸರು: ಶ್ರೀದೇವರಾಜ್ ಅಂ□□ಮೆಡಿಕಲ್ಕಾಲೇಜ್, &ಶ್ರೀದೇವರಾಜ್ ಅರಸ್ ಅಕಾಡೆಮಿಆಫ್ ಉನ್ನತಶಿಕ್ಷಣ, ಟಮಾಕ, ಕೋಲಾರ, ಕರ್ನಾಟಕ, ಭಾರತ – 563101.

ಮೂಳೆ ವಿಭಾಗ.

ಪೀಠಿಕೆ:

"ಶಸ್ತ್ರಚಿಕಿತ್ಸೆ ನಿರ್ವಹಣೆಯವಿರುದ್ಧಹೋಲಿಕೆಯಅಧ್ಯಯನನಡೆಸುವುದುಮತ್ತುಕ್ಲಾವಿಕಲ್ನಸ್ಥಳಾಂತರಿತಡಯಾಫಿಸಿಯಲ್ಮುರಿತದಸಂಪ್ರದಾಯವಾದಿನಿರ್ವಹಣೆ".

ಕ್ರಿಯಾತ್ಮಕಪರಿಣಾಮಗಳವಿಷಯದಲ್ಲಿಡಯಾಪೈಸಿಯಲ್ ಕ್ಲಾವಿಕ್ಯುಲ್ ಮುರಿತದಸಂಪ್ರದಾಯವಾದಿನಿರ್ವಹಣೆಯಪರಿಣಾಮಕಾರಿತ್ವದಕ್ಲಿನಿಕಲ್ಅಧ್ಯಯನಮತ್ತುಡಯಾಪೈಸಿಯಲ್ಕ್ಲೈವಿಕ್ಯುಲ್ ಮುರಿತದಶಸ್ತ್ರಚಿಕಿತ್ಸಾನಿರ್ವಹಣೆಯಕ್ಲಿನಿಕಲ್ಅಧ್ಯಯನದಪರಿಣಾಮಕಾರಿತ್ವವಾಗಿದೆ.

ಸಂಶೋಧನೆಯಪ್ರಕಾರ: ನಿರೀಕ್ಷಿತವಿಶ್ಲೇಷಣಾತ್ಮಕಅಧ್ಯಾಯನ

ಭಾಗವಹಿಸುವಆಯ್ಕೆ: ಕ್ಲೈವಿಕ್ಯುಲ್ ಮುರಿತದೊಂದಿಗೆಎಲ್ಲಾರೋಗಿಗಳು

ಈಪಾಲ್ಗೊಳ್ಳುವವರುಏಕೆಆಯ್ಕೆಮಾಡುತ್ತಾರೆ? :
ಸೇರ್ಪಡೆಮತ್ತುಹೊರಗಿಡುವಮಾನದಂಡಗಳಪ್ರಕಾರಕ್ಲಾವಿಕ್ಯುಲ್ ಸ್ಥಳಾಂತರಿತಡಯಾಫಿಸಿಯಲ್ಮುರಿತಗಳೊಂದಿಗೆಎಲ್ಲಾರೋಗಿಗಳನ್ನುಆಯ್ಕೆಮಾಡಲಾಗುತ್ತದೆ.

ಸ್ವಯಂಪ್ರೇರಿತಭಾಗವಹಿಸುವಿಕೆ: ಹೌದು

ಪ್ರಯೋಜನಗಳುಮತ್ತುಶಸ್ತ್ರಕ್ರಿಯೆಯಅಪಾಯಗಳಅಪಾಯಗಳು: ಪ್ರಯೋಜನಗಳು:
ಭುಜದವ್ಯಾಪ್ತಿಯಚಲನೆಗಳಆರಂಭಿಕಲಾಭ,
ಮಲ್ಯೂಯುನಿಯನ್ನಾನ್ಒಕ್ಕೂಟಮತ್ತುಉತ್ತಮಕಾಸ್ಮೆಟಿಕ್ಫಲಿತಾಂಶಗಳಕನಿಷ್ಠಸಾಧ್ಯತೆಗಳು.

ಅಪಾಯಗಳು: ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯಸ್ಥಳದಲ್ಲಿಸೋಂಕು, ರಕ್ತಸ್ರಾವ, ನರನಾಳೀಯಗಾಯ, ಕಸಿವಿಫಲತೆ,
ಕಸಿತೆಗೆದುಹಾಕುವುದು.

ಸಂಪ್ರದಾಯವಾದಿನಿರ್ವಹಣೆಯಪ್ರಯೋಜನಗಳುಮತ್ತುಅಪಾಯಗಳು: ಪ್ರಯೋಜನಗಳು: ಕಡಿಮೆವೆಚ್ಚ,
ಪೋಸ್ಟ್ಆಪರೇಟಿವ್ತೊಡಕುಗಳು. ಅಪಾಯಗಳು: ಭುಜದರಾಮ್ನತಡವಾದಲಾಭ,
ಕಳಪೆಕಾಸ್ಮೆಟಿಕ್ಫಲಿತಾಂಶಗಳು, ಮಲ್ಯೂನಿಯನ್, ನಾನ್ಯೂನಿಯನ್.

ಗೌಪ್ಯತೆ: ಪಾಲ್ಗೊಳ್ಳುವವರಗೌಪ್ಯತೆಯನ್ನುಕಾಪಾಡಲಾಗುವುದು.

ಹಿಂತೆಗೆದುಕೊಳ್ಳಲುಸ್ವಾತಂತ್ರ್ಯ:
ಭಾಗವಹಿಸುವವರುಯಾವುದೇಸಮಯದಲ್ಲಿಭಯವಿಲ್ಲದೆಅಧ್ಯಯನದಹಿಂಪಡೆಯಲುಸ್ವತಂತ್ರರಾಗಿರುತ್ತಾರೆ
.

•ಯಾರನ್ನುಸಂಪರ್ಕಿಸಬೇಕು: ಡಾ.ಅಬಿಹಿತ್ಸಲಂಕೆ

•ರೂಮ್ ನಂಬರ್. 209, ಪಿಜಿಪುರುಷರ ಹಾಸ್ಟೆಲ್ ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ಮೆಡಿಕಲ್ಕಾಲೇಜ್, ಟಮಾಕ,
ಕೋಲಾರ

- Contact number : 9421955566 ; Email id: dr.abhijeetsalunkhe@gmail.com

ANNEXURE-III

PATIENT INFORMATION SHEET IN ENGLISH

	SRI DEVARAJ URS MEDICAL COLLEGE, TAMAKA, KOLAR -563 101.	FORMAT NO.	
		ISSUE NO.	
	Information Sheet	REV. NO.	
		DATE	

Information Sheet

Name of the Organisation: Sri Devaraj Urs Medical College, & Sri Devaraj Urs Academy of
Higher Education, Tamaka, Kolar, Karnataka, India – 563101.
Dept. of Orthopaedics.

Introduction:

I ,Dr. Abhijeet Salunkhe, Post Graduate, Dept. of Orthopaedics, Sri Devaraj Urs Medical College, Tamaka, Kolar, Karnataka, India – 563101, am conducting a " comparative study of surgical management versus conservative management of displaced diaphysial fractures of the clavicle".

The objective of our study is Clinical study of efficacy of conservative management of diaphysial clavicular fracture in terms of functional outcomes and Clinical study efficacy of operative management of diaphysial clavicular fracture in terms of functional outcomes.

Type of Research: Prospective Analytical Study

Participant Selection: All patients with clavicular fractures

Why this participant is chosen? : All patients withdisplaced diaphysial fractures of the clavicle are chosen as per the inclusion and exclusion criteria.

Voluntary Participation: Yes

Benefits and risks of surgical management : benefits : early gain of shoulder range of movements, minimal chances of malunion non union and good cosmetic results.

Risks : infection at site of surgery, bleeding, neurovascular injury, implant failure, resurgery to remove implant.

Benefits and risks of conservative management: benefits : low cost, no post operative complications. Risks : late gain of shoulder ROM, poor cosmetic results, malunion , non union.

Confidentiality: Confidentiality of participant will be maintained.

Freedom to withdraw: The participant is free to withdraw from the study at any time without fear.

- Whom to contact: Dr. ABHIJEET SALUNKHE
- ROOM NO. 209, PG MEN'S HOSTEL, SRI DEVARAJ URS MEDICAL COLLEGE,TAMAKA,KOLAR
- Contact number : 9421955566 ; Email id: dr.abhijeetsalunkhe@gmail.com

ANNEXURE-IV

CONSTANT AND MURLEY SCORING

CATEGORY:

A) SUBJECTIVE:

1) Pain- 15 points

No pain	15
Bearable pain	10
Disabling pain	5

2) Activities of daily living: - 10 Points

Ability to perform full work	4
Ability to perform Leisure activities/ Sports	4
Unaffected sleep	2

3**) Level at which work can be done: 10 Points**

Up to Waist	2
Up to Xiphoid	4
Up to Neck	6
Up to Head	8
Above head	10

B) OBJECTIVE:

(RANGE OF MOVEMENTS: 40 POINTS)

a) Active painless flexion: 10 Points

00 – 30 Degrees 0	0
31-60 Degrees 2	2
61-90 Degrees 4	4
91-120 Degrees 6	6
121-150 Degrees 8	8
> 151 Degrees 10	10

b) Functional external rotation: 10 Points

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 painless abduction: 10 Points

With dorsum of hand on back, head of 3rd metacarpal reaches

00 – 30 Degrees	0
31-60 Degrees	2
61-90 Degrees	4
91-120 Degrees	6
121-150 Degrees	8
> 151 Degrees	10

d)Functional internal rotation: 10 Points

Ipsilateral buttock	2
S1 spinous process	4
L3 spinous process	6
T12 spinous process	8
T7 spinous process	10

e) Strength of abduction: 25 Points

A shoulder of normal 25year old man resists 25 pounds (~12kg) without difficulty and for such a shoulder is 25 points was given. The technique of measurement of strength is still a subject to controversy. The European Society for Shoulder and Elbow Surgery recommends following method:

- A spring balance is attached to distal part of forearm.
- Strength is measured by keeping arm in 90 degrees of elevation from the plane of scapula with a straight elbow.
- Palm of hand facing the floor (pronation).

- The patient should maintain the resisted elevation for at least 5 seconds.
- It should be repeated one after another for 3 times immediately.
- The average in pound/kilogram (lb. / kg) is documented.
- There should be painless movement during measurement. Patient gets 0 points if pain is present and if unable to reach 90 degrees of elevation in the scapula plane.

Weight Points

Less than 1 kg	0
1 KG - 2 KG	3
2 KG - 3 KG	5
3 KG - 4 KG	7
4 KG - 5 KG	9
5 KG - 6 KG	11
6 KG - 7 KG	13
7 KG - 8 KG	15
8 KG - 9 KG	17
9 KG - 10 KG	19
10 KG - 11 KG	21
11 KG - 12 KG	23
>12kg	25

FINAL OUTCOME:

Maximum total point is 100. Patients were graded as given below:

Total score Result

SCORE GRADE

SCORE	**GRADE**
90-100	Excellent
80-89	Good
70-79	Fair
0-69	Poor

ANNEXURE-IV

KEY TO MASTER CHART

S. No.	-	Serial Number
UHID	-	Universal Hospital Identification Number
Sex	-	
M	-	Male
F	-	Female
MOI	-	Mechanism Of Injury
RTA	-	Road Traffic Accident
FOOH	-	Fall On Outstretched Hand
SF	-	Self Fall
DT	-	Direct trauma
SA	-	Side affected
L	-	Left
R	-	Right
RC	-	Robinson classification
FT	-	Fracture Type
SO	-	Simple oblique Fracture
ST	-	Simple transverse Fracture
SS	-	Simple spiral Fracture
SEG	-	Segmental Fracture
W	-	Wedge Fracture
COMM	-	CommunitedFracture

AI	-	Associated Injuries
HI	-	Head Injury
BTC	-	Blunt trauma to Chest
ULI	-	Associated Upper Limb Injury
LLI	-	Associated Lower Limb Injury
TI	-	Time interval since fracture
HS	-	Stay in Hospital in days
UT	-	Union Time in weeks
NU	-	Non-union
COMPL	-	Complications
MAS	-	Malunion and shortening
DU	-	Delayed Union
SHSTF	-	Shoulder stiffness
IF	-	Implant failure
IP	-	Implant prominence
HS	-	Hypertrophic scar
DNM	-	Distal Nail Migration
PNM	-	Proximal Nail Migration
SAD	-	Constant Murley Score at Discharge
SA1m up	-	Constant Murley Score at 1 month follow
SA3m up	-	Constant Murley Score at 3 month follow
SA6m	-	Constant Murley Score at 6 month follow up

FO6m	-	Functional outcome at 6 month follow up
EXC	-	Excellent outcome
GD	-	Good outcome
FR	-	Fair outcome
PR	-	Poor outcome

MASTER CHART

Sl.no.	UHID	Age	sex	MOI	SA	RC	FT	AI	TI	HS	UT	hospital stay in days	COMPL	SAD	SA1m	SA3m	SA6m	FO6m
1	564473	31	M	RTA	R	2B1	SO	HI	6	20	14	20	MAS	62	70	80	84	GD
2	588741	22	M	RTA	R	2B1	ST	Nill	1	3	12	3	MAS	68	75	82	86	GD
3	577287	65	M	RTA	L	2B1	W	ULI	7	14	NU	14	NU	60	68	72	76	FR
4	583585	30	M	RTA	R	2B1	ST	Nill	1	3	12	3	Nil	72	78	84	92	EXC
5	567538	46	F	FOOH	L	2B2	COMM	HI	1	20	20	20	DU	62	70	74	78	FR
6	561131	26	M	FOOH	R	2B1	SO	Nill	2	3	20	3	SHSTF	57	60	64	68	PR
7	675829	28	F	FOOH	L	2B1	ST	BTC	1	12	12	12	Nil	76	82	90	94	EXC
8	563700	40	F	RTA	L	2B1	ST	Nill	1	2	8	2	Nil	72	80	86	94	EXC
9	556778	43	M	RTA	R	2B1	ST	LLI	1	12	14	12	Nil	64	70	78	84	GD
10	579045	65	F	FOOH	L	2B2	COMM	Nill	10	3	NU	3	NU	54	60	64	68	PR
11	579226	39	F	RTA	R	2B1	ST	LLI	1	3	10	3	Nil	76	84	90	96	EXC
12	535969	35	F	FOOH	R	2B1	ST	Nill	1	1	21	1	DU	64	68	72	76	FR
13	655349	26	F	RTA	L	2B1	SS	HI	1	20	18	20	MAS	56	60	68	74	FR
14	742244	24	M	SF	R	2B1	ST	Nill	2	3	18	3	MAS	60	64	70	76	FR
15	657464	22	M	RTA	L	2B1	ST	ULI	6	16	14	16	Nil	70	76	80	86	GD
16	573232	60	M	SF	R	2B1	W	Nill	5	3	22	3	DU	62	68	72	78	FR
17	732936	24	M	RTA	L	2B1	ST	ULI	1	16	12	16	MAS	64	70	78	84	GD
18	588837	42	F	FOOH	R	2B1	ST	Nill	1	3	18	3	MAS	62	76	72	78	FR
19	524587	28	M	DT	L	2B1	W	Nill	1	3	20	3	DU	54	60	66	74	FR
20	617986	22	M	RTA	R	2B1	SS	HI	7	24	20	24	DU	58	62	68	76	FR
21	644890	33	M	SF	R	2B2	COMM	Nill	14	2	NU	2	NU	58	64	72	79	PR
22	597027	45	M	RTA	L	2B1	SO	Nill	1	1	21	1	MAS and DU	68	72	70	78	FR
23	561034	27	M	FOOH	L	2B1	ST	BTC	1	7	18	7	MAS	62	68	72	78	FR
24	601947	38	M	RTA	R	2B1	ST	Nill	1	3	10	3	Nil	66	70	76	82	GD
25	601054	36	M	FOOH	L	2B1	SS	Nill	1	3	24	3	DU	60	66	74	78	FR
26	607072	22	M	RTA	R	2B1	ST	HI	4	20	18	20	MAS	58	62	70	74	FR
27	550413	25	M	RTA	R	2B1	SO	Nill	1	1	18	1	MAS	64	72	78	88	FR
28	788521	28	F	FOOH	L	2B1	W	ULI	5	16	NU	16	NU	55	61	70	78	PR
29	693306	24	M	RTA	L	2B1	SS	ULI	1	7	20	7	DU	58	62	70	74	FR
30	720152	32	M	FOOH	R	2B1	ST	Nill	1	2	18	2	MAS	60	66	72	76	FR
31	530522	25	M	RTA	R	2B1	SO	Nill	1	7	8	7	Nil	72	80	90	94	EXC
32	650468	24	M	DT	L	2B1	W	LLI	1	12	15	12	Nil	70	78	88	92	EXC
33	628669	60	F	RTA	R	2B1	SO	Nill	2	6	24	6	IF	58	60	64	68	PR
34	670864	30	M	SF	R	2B2	SEG	HI	10	24	16	24	Nil	64	70	78	88	GD
35	660738	20	M	FOOH	R	2B1	W	Nill	2	7	16	7	IP	66	72	80	88	GD
36	658945	23	F	RTA	R	2B1	ST	Nill	2	12	12	12	Nil	76	82	92	100	EXC
37	666782	35	M	FOOH	L	2B1	ST	ULI	1	14	12	14	Nil	80	86	92	100	EXC

38	498106	27	M	RTA	L	2B1	SO	BTC	7	14	16	14	Nil	70	78	84	94	EXC
39	607141	46	M	RTA	R	2B1	ST	Nill	2	6	10	6	IP	72	82	90	100	EXC
40	623549	40	M	RTA	R	2B1	SS	Nill	2	5	12	5	Nil	76	84	92	98	EXC
41	602984	27	M	FOOH	L	2B1	SS	HI	17	18	14	18	Nil	72	80	90	100	EXC
42	628626	45	M	RTA	R	2B1	SO	Nill	7	5	20	5	DU	68	72	76	78	FR
43	622148	24	M	DT	R	2B1	ST	LLI	4	12	8	12	Nil	80	86	92	100	EXC
44	593425	45	M	DT	L	2B2	COMM	Nill	2	5	14	5	HS	72	80	88	100	EXC
45	733027	51	M	DT	R	2B1	SO	Nill	1	7	12	7	Nil	74	82	90	100	EXC
46	446182	30	M	RTA	R	2B1	SO	Nill	2	7	8	7	Nil	72	82	92	100	EXC
47	535969	28	F	SF	L	2B1	W	Nill	1	5	8	5	Nil	70	78	86	92	EXC
48	550413	55	M	FOOH	R	2B1	ST	HI	15	17	12	17	Nil	68	76	82	94	EXC
49	521115	36	M	RTA	L	2B1	SO	Nill	1	5	8	5	Nil	66	70	92	100	EXC
50	574940	30	F	DT	R	2B1	ST	Nill	2	7	10	7	Nil	64	74	90	100	EXC
51	571878	30	M	FOOH	R	2B2	COMM	HI	16	24	20	14	DU	58	62	70	78	FR
52	572377	40	M	DT	L	2B1	SO	Nill	5	7	8	7	Nil	66	72	80	88	GD
53	616399	24	F	FOOH	R	2B1	SO	Nill	4	7	12	7	DNM	70	78	86	92	EXC
54	579834	19	M	RTA	R	2B1	ST	BTC	4	12	10	12	Nil	62	72	90	100	EXC
55	573677	28	M	RTA	L	2B1	W	Nill	1	7	16	7	Nil	62	70	80	86	GD
56	587692	26	M	DT	R	2B1	SO	HI	12	14	12	14	Nil	64	74	86	100	EXC
57	622996	35	F	RTA	R	2B1	SO	Nill	1	7	12	7	Nil	70	80	88	100	EXC
58	612712	45	M	FOOH	R	2B1	ST	BTC	2	14	8	14	Nil	72	80	90	100	EXC
59	677282	47	M	FOOH	R	2B1	SO	Nill	2	3	8	3	PNM	68	78	92	100	EXC
60	733319	20	M	RTA	L	2B1	SS	Nill	1	3	10	3	Nil	74	80	84	100	EXC