

**“STUDY OF FUNCTIONAL OUTCOME IN MIDSHAFT CLAVICLE
FRACTURE TREATED WITH TITANIUM ELASTIC NAILING SYSTEM”**

By

Dr. SREEJITH THAMPY J



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

In partial fulfilment of the requirements for the degree of

MASTER OF SURGERY IN ORTHOPAEDICS

UNDER THE GUIDANCE OF

DR. ARUN H.S MBBS., M.S. (ORTHO)

PROFESSOR & HOD



**DEPARTMENT OF ORTHOPAEDICS,
SRI DEVARAJ URS MEDICAL COLLEGE, TAMAKA,**

KOLAR-563101

2019

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

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation/thesis entitled “**STUDY OF FUNCTIONAL OUTCOME IN MIDSHAFT CLAVICLE FRACTURE TREATED WITH TITANIUM ELASTIC NAILING SYSTEM**” is a bonafide and genuine research work carried out under the guidance of **Dr. ARUN H.S**, Professor& HOD, Department of Orthopedics, Sri Devaraj Urs Medical College, Tamaka, and Kolar.

Date: 05/12/2018

Place: Kolar

Signature of the candidate

Dr. SREEJITH THAMPY J

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

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled “**STUDY OF FUNCTIONAL OUTCOME IN MIDSHAFT CLAVICLE FRACTURE TREATED WITH TITANIUM ELASTIC NAILING SYSTEM**” is a bonafide research work done by **Dr. SREEJITH THAMPY J** in partial fulfilment of the requirement for the Degree of MASTER OF SURGERY in Orthopedics.

Date: 05/12/2018

Place: Kolar

Signature of the Guide

Dr. ARUN H.S,

Professor & HOD,

Department of Orthopedics,

Sri Devaraj Urs Medical College,

Tamaka, Kolar

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

**ENDORSEMENT BY THE HOD,
PRINCIPAL / HEAD OF THE INSTITUTION**

This is to certify that the dissertation entitled “**STUDY OF FUNCTIONAL OUTCOME IN MIDSHAFT CLAVICLE FRACTURE TREATED WITH TITANIUM ELASTIC NAILING SYSTEM**” is a bonafide research work done by **Dr. SREEJITH THAMPY J** under the guidance of **Dr. ARUN H.S**, Professor & HOD, Department Of Orthopedics.

Dr. ARUN. H.S

Professor & HOD

Department of Orthopedics,

Sri Devaraj Urs Medical College,

Tamaka, Kolar

Dr. HARENDRA KUMAR M.L

Principal,

Sri Devaraj Urs Medical College,

Tamaka, Kolar

Date: 05/12/2018

Place: Kolar

Date: 05/12/2018

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 Medical
College & Research Center, Tamaka, Kolar has unanimously approved

Dr. SREEJITH THAMPY J

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

**“STUDY OF FUNCTIONAL OUTCOME IN MIDSHAFT CLAVICLE
FRACTURE TREATED WITH TITANIUM ELASTIC NAILING SYSTEM”**

To be submitted to

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

Date: 05/12/2018

Place: Kolar

Member Secretary

Sri Devaraj Urs Medical College,
Tamaka, Kolar-563101

**SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION ANDRESEARCH
CENTER, TAMAKA, KOLAR, KARNATAKA**

COPYRIGHT

DECLARATION BY THE CANDIDATE

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

Date: 05/12/2018

Signature of the candidate

Place: Kolar

Dr. SREEJITH THAMPY J



Sri Devaraj Urs Academy of Higher Education and Research

Certificate of Plagiarism Check

Author Name	Dr.Sreejith Thampy.J
Course of Study	Synopsis / Thesis / Dissertation
Name of Supervisor	
Department	
Acceptable Maximum Limit	10%
Submitted By	librarian@sduu.ac.in
Paper Title	STUDY OF FUNCTIONAL OUTCOME IN MIDSHAFT CLAVICLE FRACTURE TREATED WITH TITANIUM ELASTIC NAILING SYSTEM
Similarity	07 %
Paper ID	181201015724
Submission Date	2018-12-01 01:57:24

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

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

Library and Information Centre
Sri Devaraj Urs Medical College
Banaski, 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 beloved teacher and guide **Dr. ARUN H.S**, M.S., (Ortho), Professor and H.O.D., SRI DEVARAJ URS MEDICAL COLLEGE, Tamaka, Kolar for his valuable suggestions, guidance, great care, constant help to undertake this study, and the support given for the preparation of this dissertation.

I owe a great deal of respect and gratitude to **Dr. SHAIKH NAZEER** the senior most faculty in our institute without whom this study wouldn't be possible. I also thank, **Dr. SIDDARAM N PATIL**, M.S (Ortho) Professor, **Dr. SATYARUP** M.S., (Ortho), Professor, **Dr. MANOHAR P.V**, M.S., Ortho, Professor Department of Orthopedics, SRI DEVRAJ URS MEDICAL COLLEGE, Tamaka, Kolar for their scholarly suggestions and all round encouragement.

I am also thankful to **Dr. NAGAKUMAR** M.S.,(Ortho) **Dr. HARI PRASAD** DNB (Ortho), **Dr. PRABHU. E**, M.S (Ortho), **Dr ASHIQ BARY** MS (Ortho), **Dr. PRABHULING PATIL** DNB (Ortho), **Dr. ANIL KUMAR S.V** DNB (Ortho), **Dr. MAHESH KUMAR** DNB (Ortho).

I am highly grateful to **Dr. HARENDRA KUMAR M.L** Principal, 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 Orthopedics, Sri Devaraj Urs Medical College, Tamaka, Kolar, have also made a significant contribution to this work, to which I express my humble gratitude

I am eternally grateful to my **PARENTS, Mr. R JAYAKUMARAN THAMPY, Mrs. SASEENDRA KUMARI I** and my beloved wife **Dr. ANJALI PK**, loving Sister **Dr. PARVATHY THAMPY S** for their love, perseverance and understanding. They have been my pillar of support and encouraged me in every step. This dissertation would have not been possible without their blessings.

I also thank my friends **Dr. PRADEEP, Dr. HARSHA, Dr. ABHIMANYU, Dr. ABHISHEK, Dr. SARATH, Dr. UMESH, Dr. AJAY, Dr. SAGAR, Dr. RONAK, Dr. MANSHEER, Dr. ARPITHA** and my beloved seniors **Dr. PRATAP, Dr. SACHINDRA NAYAK, Dr. AYANAKSHA, Dr. UTKARSH, Dr. VAIBHAV MITTAL, Dr. KARTHIK, Dr. JISHNU**, and my juniors **Dr. ABHIJITH, Dr. CECIL, Dr. ROGER, Dr. JOE PRADEEP, Dr. NEERAJ DESAI, Dr. SANDESH, Dr. SOURADEEP, Dr. ARJIT** for their love and support. They have contributed to the exchange of ideas resulting in the precise presentation of the collected information.

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

Date: 05/12/2018

Signature of candidate

Place: Kolar

Dr. SREEJITH THAMPY J

LIST OF ABBREVIATIONS USED

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

ABSTRACT

Back ground and objectives:

The clavicle is a frequently fractured bone, accounting for 2.6–5% of all skeletal fractures. Approximately 80% of clavicle fractures involve the midshaft and more than half of these fractures are displaced. Conservative methods were commonly used for midshaft clavicle fracture treatment, but with various unsatisfactory complications such as nonunion, malunion and shoulder asymmetry. The rate of malunion after conservative treatment for the midshaft clavicular fractures reached 15% and 30% of patients were unsatisfied.

Early surgical treatment for midshaft clavicular fractures could greatly reduce the incidence rate of nonunion and malunion. Open reduction and internal fixation with plate and intramedullary fixation are two of the most commonly used surgical techniques for treating displaced midshaft clavicular fractures. Open reduction and plate-screw fixation was considered as the gold standard with the advantages of firm fixation and earlier postoperative mobilization. But it has disadvantages like larger incision and soft tissue exposure, predisposing to many postoperative complications.

Intramedullary fixation technique for midclavicular fractures has been favored as it needs only small incision, less periosteal stripping, has better dispersion of stress with faster union and less operating time. Hence application of intramedullary devices seem to have more advantages than plate fixation for treatment of displaced midshaft clavicular fractures.⁷ Currently no such studies are present documenting the effectiveness of the TENS system in rural population in Kolar region. So this study aims to assess the functional outcome following TENS application and the complications associated with same in rural population in and around Kolar.

Methods:

30 patients with midshaft clavicle fractures presenting to the Orthopedic Department of R L Jalappa hospital from October 2017 till November 2018 are included in the study after obtaining informed consent.

Result:

Among 30 patients with middle third clavicle fracture treated with Titanium Elastic Nailing System, excellent functional outcome was seen in 25 patients (83.3 %) and good outcome in 4 patients (20 %) and 1 fair outcome (3.3%) by 3rd month of follow up. At 6th month 27(90%) cases showed excellent result and rest 3(10%) showed good result according to Constant and Murley scoring system for assessing functional outcome.⁵⁴ In our study 66.6% of cases had clinical and radiological union by 3rd month and by 6 months all the fracture were united. 3 cases showed delayed union and no case showed nonunion.

Conclusion:

This study proves that TENS should not only be considered a reliable secondary option for displaced midshaft clavicle fracture but also as a primary option for midshaft clavicle fracture with displacement more than 2mm, as well as in cases with mild to moderate comminuted fracture instead of conservative method or LCP fixation.

Key words: Midshaft clavicle fracture, fracture fixation, Titanium elastic nailing system, intramedullary nailing, closed reduction, internal fixators.

TABLE OF CONTENTS

SL NO	TITLE OF CONTENT	PAGE NO
1	INTRODUCTION	1-3
2	AIMS AND OBJECTIVES	4
3	REVIEW OF LITERATURE	
	• ANATOMY	5
	• MECHANISMS OF INJURY	23
	• FRACTURE BIOMECHANICS	24
	• CLASSIFICATION	25-28
	• TREATMENT	31-38
	• COMPLICATIONS	39-41
	• REHABILITATION	42
	• LITERATURE SURVEY	43-48
4	METHODOLOGY	49-64
5	RESULTS AND OBSERVATIONS	65-83
6	DISCUSSION	84-95
7	CONCLUSION	96-97
8	SUMMARY	98-99
9	LIMITATIONS OF STUDY	100
10	BIBLIOGRAPHY	101-109
11	ANNEXURE	
	ANNEXURE- I : PROFORMA	110-115
	ANNEXURE- II : CONSENT FORM	116-117
	ANNEXURE-III : MASTER CHART	118

LIST OF TABLES

SL NO	TITLE OF TABLES	PAGE NO
1	SEX INCIDENCE	65
2	AGE INCIDENCE	66
3	TIME INTERVAL	67
4	MODE OF INJURY	68
5	SIDE AFFECTED	69
6	FRACTURE PATTERN	70
7	NAIL SIZE	71
8	MODE OF REDUCTION	72
9	CLASSIFICATION	73
10	ASSOCIATED INJURY	74
11	STAY IN HOSPITAL	75
12	TIME OF UNION	76
13	COMPLICATIONS	77
14	FUNCTIONAL OUTCOME	78
15	COMPARISON OF DIFFERENT STUDIES ACCORDING TO AGE, SEX, SIDE, AFFECTED, TIME INTERVAL, MODE OF REDUCTION AND TIME OF UNION.	87
16	COMPARISON OF COMPLICATIONS IN DIFFERENT STUDIES	92

LIST OF FIGURES

SL NO	FIGURES	PAGE NO
1	CLAVICLE BONE	7
2	SHAPE AND CONFIGURATION OF CLAVICLE	10
3	OSSIFICATION CENTRE	10
4	LIGAMENTOUS ANATOMY	12
5	MUSCULAR ATTACHMENT	13
6	DEEP RELATIONS OF CLAVICLE	16
7	BRACHIAL PLEXUS AND CLAVICLE	17
8	CLAVICLE BIOMECHANICS(A & B)	19&20
9	MECHANISM OF INJURY	23
10	FRACTURE BIOMECHANICS	24
11	ALLMAN CLASSIFICATION	26
12	ROBINSON CLASSIFICATION	27
13	AO CLASSIFICATION	28
14	NAIL POSITION WITHIN CLAVICULAR CANAL	35
15	CLINICAL PRESENTATION	51
16	INSTRUMENTS (A & B)	52&53
17	OPERATIVE PHOTOGRAPHS-OPEN REDUCTION	55-56
18	OPERATIVE PHOTOGRAPHS-CLOSED REDUCTION	57
19	C-ARM PIC SHOWING CLOSED REDUCTION	58
20	POST-OP CLINICAL PIC (A & B)	59

LIST OF GRAPHS

SL NO	GRAPHS	PAGE NO
1.	SEX INCIDENCE	65
2.	AGE INCIDENCE	66
3.	TIME INTERVAL	67
4.	MODE OF INJURY	68
5.	SIDE AFFECTED	69
6.	FRACTURE PATTERN	70
7.	NAIL SIZE	71
8.	MODE OF REDUCTION	72
9.	CLASSIFICATION	73
10.	ASSOCIATED INJURIES	74
11.	STAY IN HOSPITAL	75
12.	TIME OF UNION	76
13.	COMPLICATIONS	77
14.	FUNCTIONAL OUTCOME I	78
15.	FUNCTIONAL OUTCOME II	78

CLINICAL AND X-RAY PHOTOGRAPHS

SL.NO	CONTENT	PAGE NO
1	CASE 1	79
2	CASE 2	80
3	CASE 3	81
4	CASE 4	82
5	COMPLICATIONS	83

INTRODUCTION

Clavicle fractures account approximately 2.6% of all fractures and are the commonest injuries in active individuals who participate in activities like sports and high-speed falls or violent collisions.¹

The clavicle bone is S-shaped, and name is derived from Latin word *clavicula* meaning- “little key”. Clavicle has a key shape and has the ability to rotate around its axis.² Clavicle fractures most frequently result from a direct axial blow on shoulder, fall with an outstretched arm, road traffic accidents, sports accidents, or a fall from height.^{3,4}

Midshaft fractures forms majority of clavicle fractures (80% to 85%), where a combination of typical compressive forces to the shoulder and the narrow cross section of the bone results in bony failure.¹

“Midclavicular fractures will heal without, with or even despite the doctor!”⁵

Traditionally, standard management was non-operative treatment for mid- shaft fractures regardless of displacement, expecting that even severe radiographic malalignment would not influence functional results.¹ Recently, relatively high incidence of complications, deficits in functional recovery in shoulder and disappointing cosmetic results in up to 30% of the patients as per increasing evidences has challenged this mode of treatment in patients sustaining mid- shaft clavicular fracture.⁶

Since long time Conservative treatment has been the treatment of choice. This treatment policy was based on two studies conducted in the 1960's, which stated non-union percentages of less than 1% after conservative treatment, regardless of the degree of displacement.^{7,8} In such studies children were included, and they are known to recover faster because of their greater potential to remodel moreover these data, were not adequately

classified regarding patient age and fracture displacement. According to recent data based on detailed classification of fractures, the incidence of displaced midshaft clavicular fractures going into non-union in adults is 10-15%.⁹ In a meta-analysis of literatures from 1975 to 2005, Zlowodzki et al. found that the non-union rate for non-surgically treated displaced midshaft clavicle fractures was 15.1% and is higher than that previously described.¹⁰

Mainstay of treatment for midshaft clavicle fractures has been non-operative. Because of relatively frequent occurrence of serious complications, operative treatment was not favored in midshaft fractures. But, the prevalence of non-union or mal-union following displaced midshaft fractures of clavicle is higher than known before after conservative treatment. Thus, surgical management is getting accepted more and more, mainly because the results of conservative management are inferior to operative treatment both functionally and clinically and that all recent studies shows fractures with wide displacement and more than 2cm of initial shortening resulted in non-union.² Safety and efficacy of primary open reduction and internal fixation for these fractures is proved by many studies and have also noted high rate of union with a low complication rate.¹¹ Hence primary internal fixation of these fractures helps in early return to function.¹²

Complications vary according to location of fracture and are associated with delayed union or non-union, brachial plexus compression by hypertrophic callus formation, compression or injury of the great vessels, trachea, and injuries to the neurovascular structures and the dome of pleura, poor cosmetic appearance, pneumothorax and intrathoracic injury.¹

At present, patients want best functional outcome along with rapid and pain-free functional recovery following a fracture. In contrast to conservative treatment, minimally invasive techniques are fulfilling these objectives with a reduced rate of complications.¹³

The theory that majority of clavicular fractures heal with non-operative treatment is no longer valid. The amount of disability and degree of pain during the first 3 weeks of conservative treatment has been underrated and the belief that non-union does not occur is wrong. Recent studies showed that conservative management can be followed with symptoms due to pressure by displaced fragment over the brachial plexus, higher rate of non-union and specific deficits of shoulder function. Hence these fractures can be treated as a spectrum of injuries requiring careful assessment and individualized treatment.^{8,14,15}

Various methods of treating clavicle midshaft fractures include intramedullary K-wires, Steinmann pin fixation, Locking compression plate fixation and intramedullary nailing with TENS. In particular, plate fixation and nailing can help obtain firm anatomical reduction in severe displaced or segmental fracture, but the indication for both for a particular type of fracture is still in debate. And this study aims in evaluating the effectiveness of TENS (TITANIUM ELASTIC NAILING SYSTEM) as an intramedullary fixation device in clavicle fracture treatment.

AIMS AND OBJECTIVES

- To assess the functional outcome of midshaft clavicle fracture treated with TENS using CONSTANT scoring system .¹⁶
- To document the advantages, disadvantages and complications of this procedure.
- To study the duration of bony union following fixation with intramedullary nailing.

REVIEW OF LITERATURE

ANATOMY

The clavicle (collar) bone connects upper limb to the trunk. Medial end which articulates with sternum is wider and thinner at its lateral third. The clavicle assumes a gentle S-shape, this resembles musical symbol the “clavicula” thus the name.

EVOLUTION:

When humans evolved into bipeds and assumed an upright posture, changes occurred in the shoulder girdle in order to comply with the demands of a non-weight bearing joint. Clavicle is present in animals including man who use their upper limb for holding, grasping and climbing.

Mammals adapted for running and swimming have lost their clavicle to further mobilize their shoulder girdle.¹⁷

PECULIARITIES OF CLAVICLE:

- only long bone in the body to lie horizontally
- only bone with membranous ossification
- first bone in the body to ossify
- It lacks a well-defined medullary cavity
- It is subcutaneous throughout its whole extent
- The shaft ossifies from two primary centres.¹⁷

CLAVICLE ANATOMY:

When discussing clavicle anatomy, we can divide the anatomical structures into following components, the osseous structures, the ligamentous structures, the muscular anatomy and the joints.¹⁷

OSSEOUS STRUCTURE AND SIDE DETERMINATION:

Clavicle is a relatively thin bone, medial and lateral expansions are wider where it articulates with the sternum and acromion, respectively (Fig: 1). It has two curves of which the larger curve in the coronal plane gives the bone its characteristic S shape (medial end convex anterior and lateral end concave anterior). The medial superior surface of the clavicle is flat. The clavicle lies almost horizontally at the root of the neck (Fig: 1). The lateral acromial end of the bone is flattened and articulates with the medial side of the acromion. The medial or sternal end is enlarged and articulates with the clavicular notch of the manubrium sterni and first costal cartilage. Inferior aspect of the intermediate two fifths is grooved in its long axis for the attachment of subclavius.

There is a medullary cavity in its medial two thirds. The cortical bone is thickest at the transition zone between the ante curve and retro curve. The female clavicle is shorter, thinner, less curved and smoother. The clavicle is subcutaneous throughout its whole length and accordingly can be palpated for its entire length; the medial (sternal) end forms an expanded, blunt faced margin of the jugular notch. The anterior border of lateral (acromial) end is not readily distinguished from the acromion; the attachment of deltoid obscures the anterior aspect of the acromioclavicular joint.

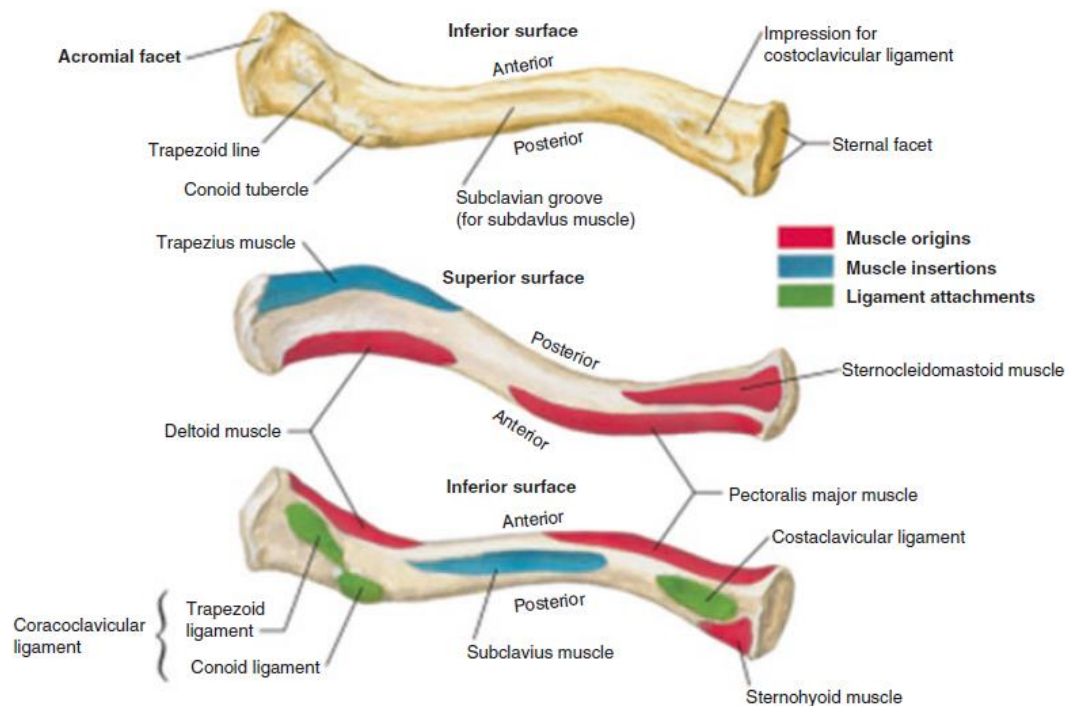


FIG. 1: Left clavicle anatomy

LATERAL TWO-FIFTHS

This part of the clavicle is flat and have superior and inferior surface, limited by an anterior and a posterior border. The anterior border of lateral end is concave, thin and roughened, and a small deltoid tubercle is occasionally seen. The posterior border is roughened by muscular attachments and is convex backwards. The superior surface is rough near its margins but smooth centrally, where it can be felt through the skin. The inferior surface presents two obvious markings a conoid tubercle and a groove. Close to the posterior border, a prominent conoid tubercle gives attachment to the conoid part of the coracoclavicular ligament, and the subclavius muscle is attached to the groove on the inferior surface. The groove edges give attachment to clavipectoral fascia which merges with conoid ligament at posterior edge of groove.

There is a laterally inclined nutrient foramen lateral to the groove. Deltoid (anterior) and trapezius (posterior) are attached to the lateral two fifths of the shaft; both muscles are directly inserted into the clavicle but are also indirectly inserted into the periosteum. The coracoclavicular ligaments, attached to the conoid tubercle and trapezoid line (Fig. 4), transmit the weight of the upper limb to the clavicle, and are counteracted by the cervical part of trapezius, which supports its lateral part.¹⁷

MEDIAL THREE-FIFTHS

The medial three fifths of the shaft of the clavicle are cylindrical or prismoid in form and have four surfaces, the inferior surface is often reduced to a mere ridge.

The anterior surface is mostly rough but laterally is smooth and rounded, where it forms the upper boundary of the infra-clavicular fossa. The upper surface is roughened medially and smooth laterally. The smooth posterior surface bears a groove in its lateral half and devoid of muscular attachments, except at its lower part adjoining the sternal end, where sternohyoid is attached. The inferior surface is marked by a roughened oval depression below the surface. Margins of medial 3/5th attaches to the costoclavicular ligament, connecting clavicle to the upper surface of the first rib. Anteriorly the medial three fifths provide attachment for the clavicular head of pectoralis major.

The medial half of superior surface gives attachment to clavicular head of sternocleidomastoid. Medially, this surface is related to the lower end of the internal jugular vein (separated by sternohyoid), termination of the subclavian vein, and the start of brachiocephalic vein. Laterally, the clavicle arches in front of the trunks and divisions of the brachial plexus and the third part of the subclavian artery. The thyrocervical trunk and its branches, the suprascapular and transverse cervical vessels, are just behind and above the

upper aspect of this surface. Subclavius is inserted in the subclavian groove on the inferior surface; the clavipectoral fascia is attached to the edges of the groove. The posterior lip of the groove is continuous with the conoid tubercle laterally and brings the clavipectoral fascia into continuity with the conoid ligament. A nutrient foramen is found in the lateral end of the groove and the nutrient artery is derived from the suprascapular artery.¹⁷

STERNAL END

The sternal end is directed medially, downwards and forwards, and articulates with the clavicular notch of the manubrium sterni. The sternal surface is usually irregular and quadrangular, and its upper part gives attachment to the interclavicular ligament, sternoclavicular capsule and articular disc.

This part of clavicle projects upwards beyond the manubrium sterni and can be felt and seen easily, forming the lateral wall of the jugular notch, behind which are the cricoid cartilage, cricothyroid membrane, the lower part of the thyroid cartilage of the larynx and the brachiocephalic vein. The sternal ends of each clavicle thus form a guide to the jugular notch.¹⁷ The clavicle is narrowest in its mid-portion, explaining the high incidence of fractures in this area.

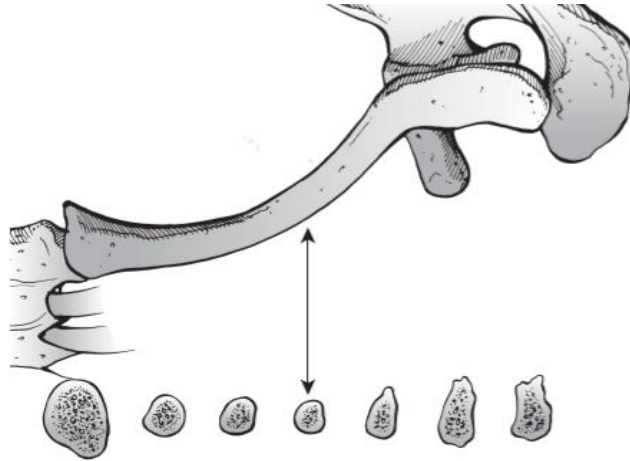


FIG 2: The cross-sectional and topographic anatomy of the clavicle.¹

OSSIFICATION:

The clavicle begins to ossify before any other bone in the body. It ossifies from two primary and one secondary centre (fig 3). During intrauterine period of 5-6 weeks Primary centres (medial and lateral) appear in the shaft and by about 45th day they fuse and cartilage then develops at both the clavicular ends. At 15th year in females and 17th year in males another secondary centre appears for the sternal end which unites at 21st year in females and 22nd year in males with the shaft. Whereas for the acromial end secondary centre sometimes develops in the cartilage at 18- 20 years and by 24th years it rapidly unites with shaft. Majority of longitudinal growth (80%) is caused by medial clavicular epiphysis.²⁹ The two centres of ossification meet between the medial three fifths and lateral two fifths of the clavicle.¹⁷

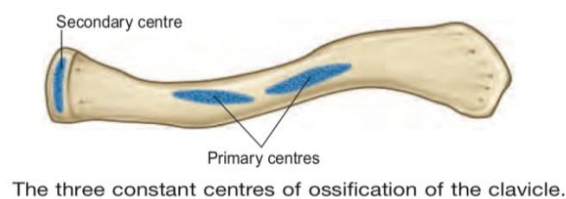


FIG. 3⁶¹

II) LIGAMENTOUS ANATOMY:

A) Medial ligamentous anatomy:

a) Costoclavicular ligament:

It extends from the upper aspect of first rib and sternum to the clavicle. This ligament stabilizes the upward and downward rotation of the medial clavicle with its anterior and posterior fibers.

b) Interclavicular ligament:

It is a ligamentous band which runs from medial end of clavicle to superior aspect of sternum, further it extends to the clavicle on other side. Shoulder elevation loosens the ligament. It acts as a support to prevent downward movement of lateral end of the clavicle.

c) Capsular ligaments:

Sternoclavicular joint capsule has specific thickenings which are called as capsular ligaments. The anterosuperior and posterior aspect of the capsule are the strongest and limits superior displacement of medial clavicle end and inferior displacement of the lateral clavicle end.¹

B) Lateral ligamentous anatomy

a) Coracoclavicular ligaments:

Thick strong ligaments joining the base of the coracoid process of scapula to the inferior aspect of lateral clavicle are called trapezoid and conoid ligaments. These ligaments provide vertical stability by assisting in shoulder girdle suspension from the clavicle and help to stabilize the clavicle during rotation on its long axis in overhead activities.¹

b) Acromioclavicular ligaments:

These are formed from the capsule of the acromioclavicular joint. These ligaments resist anteroposterior displacement of the distal end of clavicle.

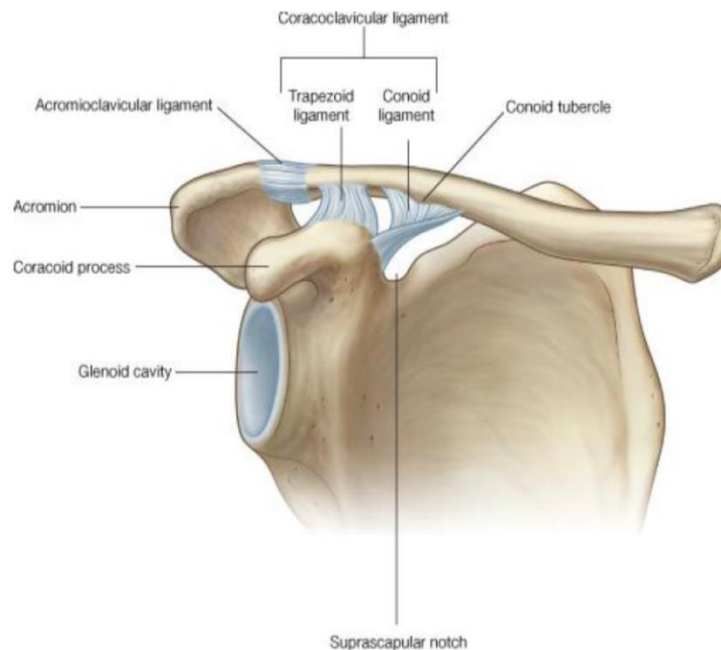


FIG. 4: Ligamentous anatomy

III) MUSCULAR ANATOMY:

Clavicle is not as important as the scapula in terms of muscle origin, but still serves as the attachment site of several large muscles.

From medial aspect, the pectoralis major muscle originates from the clavicular shaft anteroinferiorly, and the sternocleidomastoid originates superiorly.

The pectoralis origin merges with the origin of the anterior deltoid laterally, while the trapezius insertion blends superiorly with the deltoid origin at the lateral margin (Fig. 5).

Muscle attachment plays a significant role in the deformity which results after fracture.

The medial clavicular fragment is elevated by the unopposed pull of the sternocleidomastoid muscle, while the distal fragment is held inferiorly by the deltoid and medially by pectoralis major. Clavicular undersurface is the insertion site of the subclavius muscle and serves as a soft tissue buffer in the sub clavicular space superior to the brachial plexus and subclavian vessels.

The platysma or “shaving muscle” is variable in terms of thickness and extent, but usually envelopes the anterior and superior aspect of the clavicle and lies in the subcutaneous tissue, extending to the mandible and the deeper facial muscle.¹

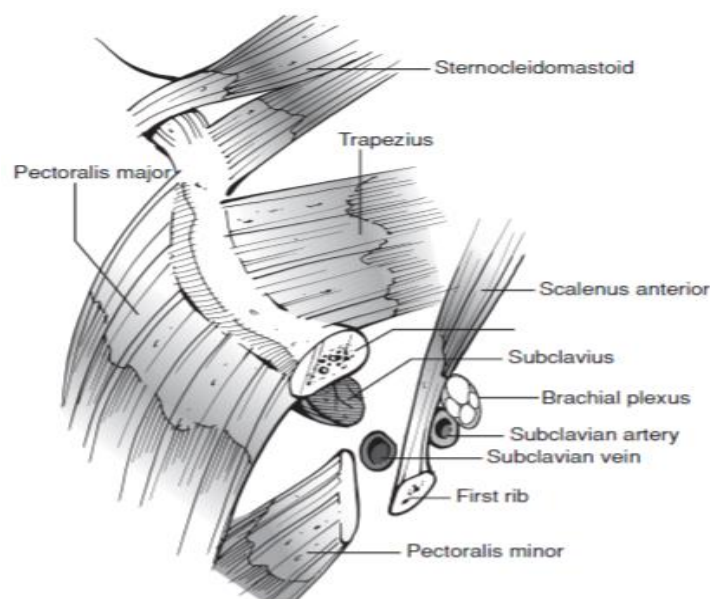


FIG. 5: Muscular attachments.¹

IV) JOINTS:

The upper limb and the thorax are connected by clavicle through its articulation at sternoclavicular and acromioclavicular joints.

i) Sternoclavicular joints:

This joint is formed laterally by proximal end of clavicle and medially by clavicular notch of manubrium and cartilage of 1st rib. This joint provides the only true articulation between the axial skeleton and the upper extremity. Elevation and depression occur in this joint with approximate range of motion of 30-35 degrees of upward elevation and about 35 degrees in anteroposterior direction and rotation along long axis is about 44-50 degrees.

Majority of sternoclavicular elevation occurs between 30-90 degrees of arm elevation and rotation occurs at 70-80 degrees of elevation of arm. Fusion of Sternoclavicular joint limits abduction to 90 degrees.^{18,19}

ii) Acromioclavicular joint:

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

It is a plane synovial joint with relatively flat articulating surfaces and allows a freedom of 3 degrees of movement.

Rotation of about 20 degrees occurs between the acromion and clavicle during superior and inferior movements and happens especially during the first 40 degrees and last 20 degrees of elevation.

Motion of the acromioclavicular joint is significantly less than at the sternoclavicular joint, but it does play a critical role in allowing full arm motion.¹⁸

RELATIONSHIP:

Costoclavicular space:

It is the space between medial clavicle and the first rib.¹⁸

Superficial infraclavicular space:

It is formed by pectoralis major and deltoid portion of the clavicle.¹⁸

Grants space:

It is formed by investing layer of cervical fascia anteriorly and omohyoid fascia posteriorly. External jugular vein and subclavian vein join here at its confluence with internal jugular vein.¹⁸

Blood supply:

Main nutrient artery enters just medial to the attachment of coracoclavicular ligament.¹⁸

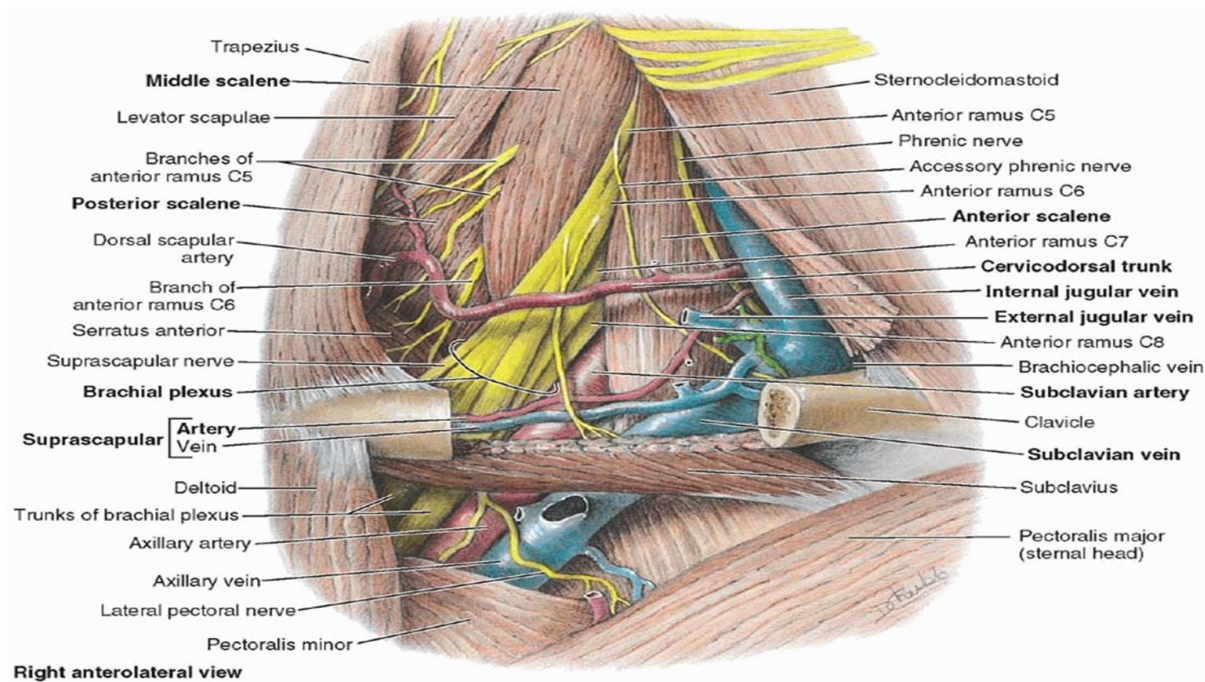


FIG. 6: Deep relations of clavicle.

Neurovascular Anatomy of the Clavicle

They originate from cervical roots C3 and C4 gives origin to supraclavicular nerve which exit from a common trunk behind posterior border of the sternocleidomastoid muscle.

There are 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 divided causes an area of numbness felt inferior to the surgical incision, but this tends to improve with time. The subclavian vein runs between the first rib and subclavius muscle.

Subclavian artery and brachial plexus lie more posteriorly and is separated from the vein and clavicle by an additional layer of the scalenus anterior muscle medially. We should be careful not to violate the sub clavicular space with drills, screws, or instruments as plexus is closest to the clavicle in its mid-portion.¹

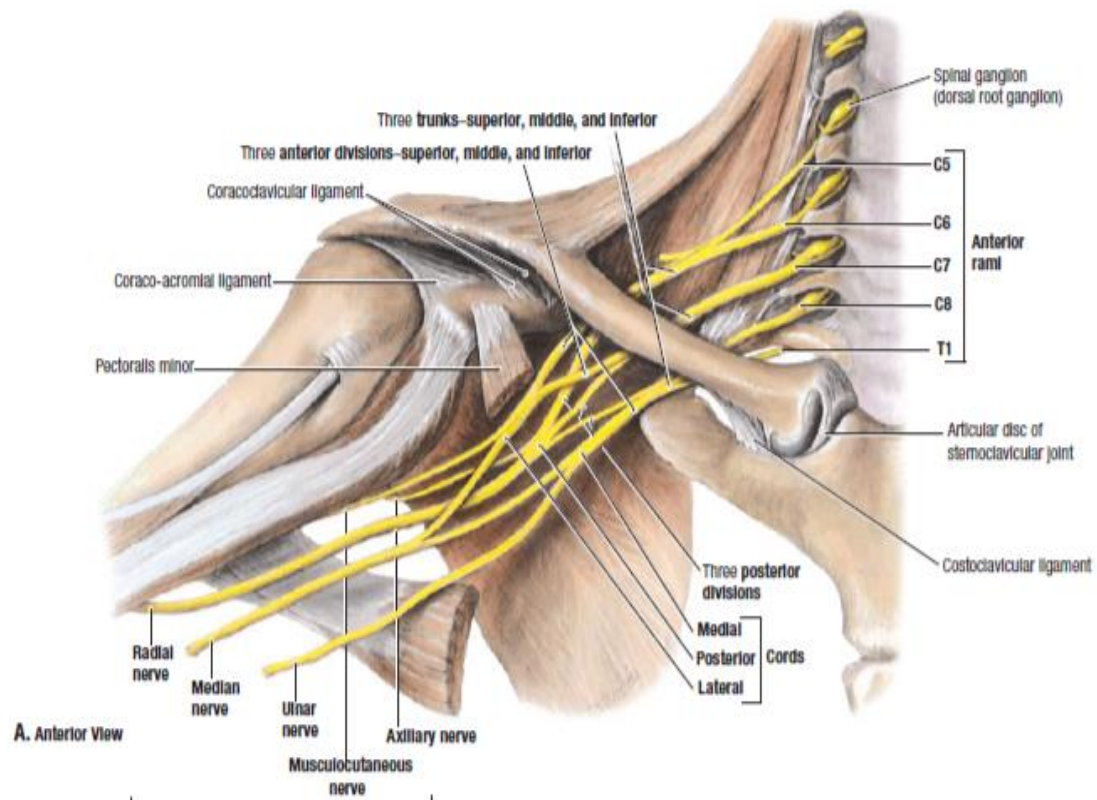


FIG. 7: Brachial plexus and clavicle.

CLAVICULAR BIOMECHANICS

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

There are three axis of clavicular motion.

a) Anteroposterior

b)Superoinferior

c)Rotational

Shoulder girdle functions with help of delicate interaction of almost 30 muscles and integrated motion of the sternoclavicular, acromioclavicular, glenohumeral and scapulothoracic joints.

It is generally accepted that scapulohumeral rhythm occur in a 2:1 ratio with the humerus moving 2 degrees for every 1 degree of scapular motion. The clavicle must elevate during arm elevation to allow the scapula to rotate upwards and it rotates totally 70 degrees in an upward fashion during arm elevation.

During the extremity elevation, clavicular elevation of about 30 degrees occurs with maximum elevation occurring at 130 degrees of arm elevation and depression at around 5 degrees in sagittal plane. During the first 40 degree of arm elevation, clavicle rotates approximately 10 degrees forwards. No rotation takes place during the next 90 degrees but an additional 15 to 20 degrees of forward rotation occur during the terminal arc. Without clavicular rotation, elevation of arm is possible only to about 110 degrees. In the frontal plane approximately 15 degrees of clavicular retraction and protraction occurs.^{18,19}

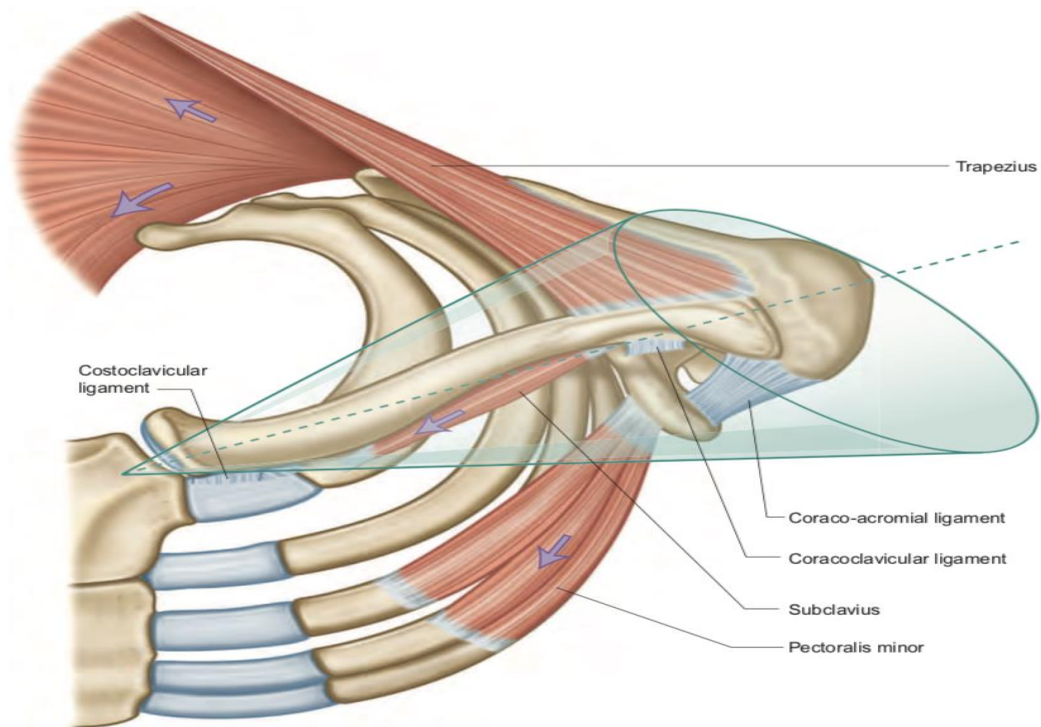


FIG 8 A.¹⁷

Fig.8 A 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.¹⁷

A maximum range of 30° rotation of clavicle occurs at sternoclavicular joint; the maximal range of rotation of the scapula i.e. by combining sternoclavicular and acromioclavicular joints, is about 60° with respect to the sternum.¹⁷

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 acromioclavicular capsule and ligaments).

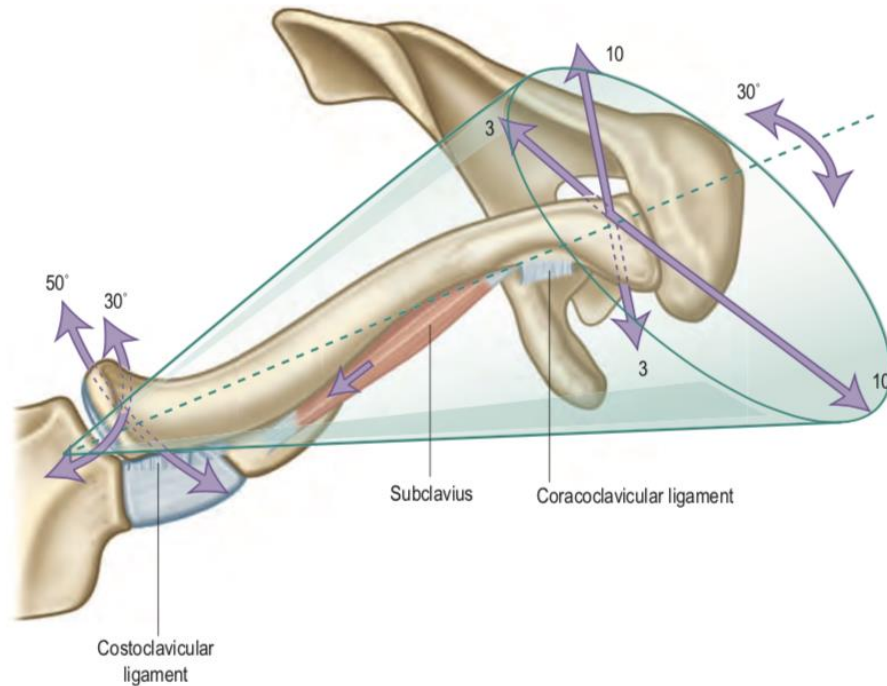


FIG 8 B.¹⁷

The upward displacement of the distal clavicle is resisted by the action of subclavius, or to decelerate the clavicle moving into elevation.¹⁷ (Fig.8 B) The distal clavicle is moved by trapezius, which has an extensive attachment along the spine of the scapula and the medial aspect of the distal third of clavicle.⁶¹

The antagonist of trapezial power is pectoralis minor, which, rarely, has an extension or slip of tendon that joins the coracoacromial ligament. The latter acts as a tension band between the ‘outriggers’ of the coracoid and acromion. Shortening or tightness of pectoralis minor will create fixed protraction of the scapula, which then rotates ventrally around the chest wall.¹⁷

FUNCTIONS OF CLAVICLE

Codman stated that-Human beings should be proud that our brains are more developed than the animals and that we can also boast of our clavicles. He also stated that the clavicle is one of the man's greatest skeletal inheritances as he depends on it to a greater extent than most animals except the apes and monkeys on the use of his hands and arms.²⁰

1) Strut Function

Clavicle braces the shoulder girdle and keeps it away from the sternum and thoracic cage. Strut allows shoulder to reach into cross-body and allows the thoraco-humeral muscles to maintain their optimal working distance. There by increasing the strength of shoulder girdle movements.²⁰

2) Stability and power:

It acts as a bony link between shoulder girdle and thorax and contributes to the stability and power of the shoulder especially in movement above the shoulder level. The long clavicle facilitates placement of shoulder in a lateral position so that the upper limb can be positioned more effectively to deal with the three-dimensional environment.²¹

3) Cosmosis:

It has a Smooth surface and lies subcutaneously providing a graceful curve to the base of the neck.²⁰

4) Motion of the shoulder girdle:

Lateral curvature of clavicle permits it to act as a crank shaft and allows half of the scapular movements. This crank shaft mechanism on shoulder abduction provides 30 degrees of the total 60 degrees contribution from scapulothoracic motion.²¹

5) Muscle attachments:

It provides a bony base for muscle origin and insertion.²¹

6) Protection of neurovascular structures:

The tubular cross section of clavicular medial third increases its strength along with it the subclavius muscle adds protection to the subclavian vessels, brachial plexus and lungs which are directly behind the clavicular medial third. Loss of clavicle can cause shoulder drooping which further cause exacerbation of thoracic outlet symptoms and resultant draping of brachial plexus over the first rib.²¹

7) Respiratory function:

Elevation of the shoulder girdle brings about a cephalad motion of the thorax corresponding to inspiration due to its connection with the first rib.²¹

8) Protection to lungs:

It protects the superior aspect of the lungs.²¹

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

MECHANISM OF INJURY

The primary mechanism of clavicular failure is by compression caused by low or high energy impact like.

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

Clavicles when axially loaded, middle third tend to fracture more as it's the region where the lateral curve of clavicle changes to medial curve of clavicle. Another mechanism of fracture is when a direct force when applied to the top of shoulder and when clavicle is forced against the first rib, a middle third spiral fracture is produced. One more mechanism is referred to as "seat belt fractures". The forward force on the clavicle by the shoulder strap of seat belt acts as a fulcrum at the midpoint of the clavicle and causes the bone to fracture in an oblique or transverse pattern with little comminution. Stress fractures of the clavicle has been reported in athletes involved in a variety of sports like baseball, diving, gymnastics.²²

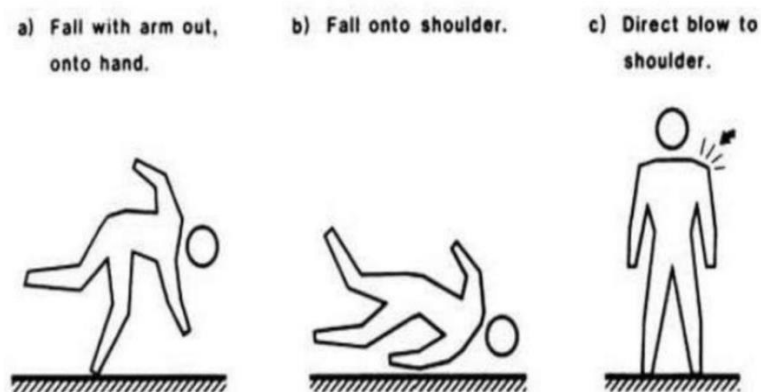


FIG 9

FRACTURE BIOMECHANICS

For mid shaft fracture the displacing forces are:

- a) superior displacement of medial segment - by pull of sternocleidomastoid
- b) Stabilizing on the medial segment by the sternoclavicular ligaments.
- c) inferior and medial displacement on the lateral segment through the pectoralis major and latissimus muscles
- d) Inferior on the lateral segment through the weight of the arm pulling through the coracoclavicular ligaments.
- e) Inferior displacement of lateral segment - stabilized by trapezius

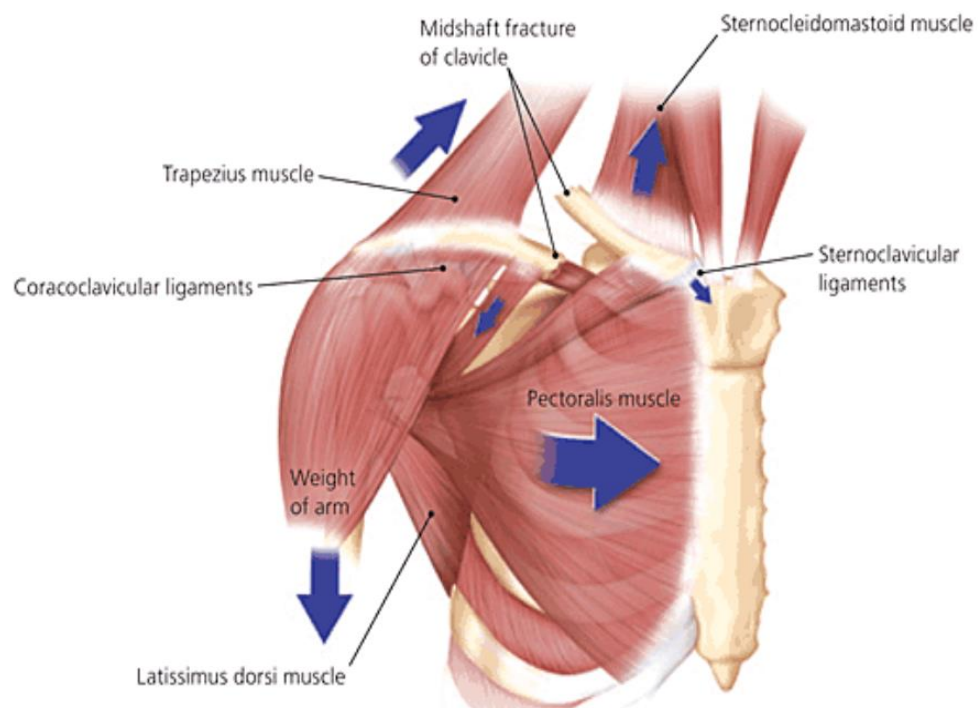


FIG 10

CLASSIFICATION

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.¹⁸

The unique features of distal clavicle fracture were recognized by Neer and he proposed a separate classification system for this group. He divided Allman's group II into three distinct types:

Type-I Coracoclavicular ligament intact

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

Type –III Intraarticular extension into acromioclavicular joint.^{18,22}

In 1990 Craig introduced a more detailed classification scheme that combines the Allman and Neer classification (fig 11).¹⁸

ALLMAN CLASSIFICATION

Group 1- Fracture of middle third (80%), the most common type.

Group 2 - Fracture of distal third (15%), subclassified according to the location of the coracoclavicular ligaments.

Type I: Minimal displacement, interligamentous fracture between the conoid and trapezoid, ligaments still intact.

Type II: Displaced secondary to a fracture medial to the coracoclavicular ligaments, higher incidence of nonunion.

Type IIA: Conoid and trapezoid attached to the distal fragment.

Type IIB: Conoid torn, trapezoid attached to the distal fragment.

Type III: Fracture involving the articular surface of the AC joint.

Group III: Fracture of proximal third(5%), minimal displacement if costoclavicular ligament remain intact.

Type I: Minimal displacement.

Type II: Displaced.

Type III: Intra articular.

Type IV: Epiphyseal separation.

Type V: Comminuted.

FIG 11

Robinson classification of clavicular fractures

The classification proposed by Robinson was based on anatomical site, extent of displacement, articular extension, comminution, and stability of fracture (fig 12).^{1, 23} We have used this system of classification.

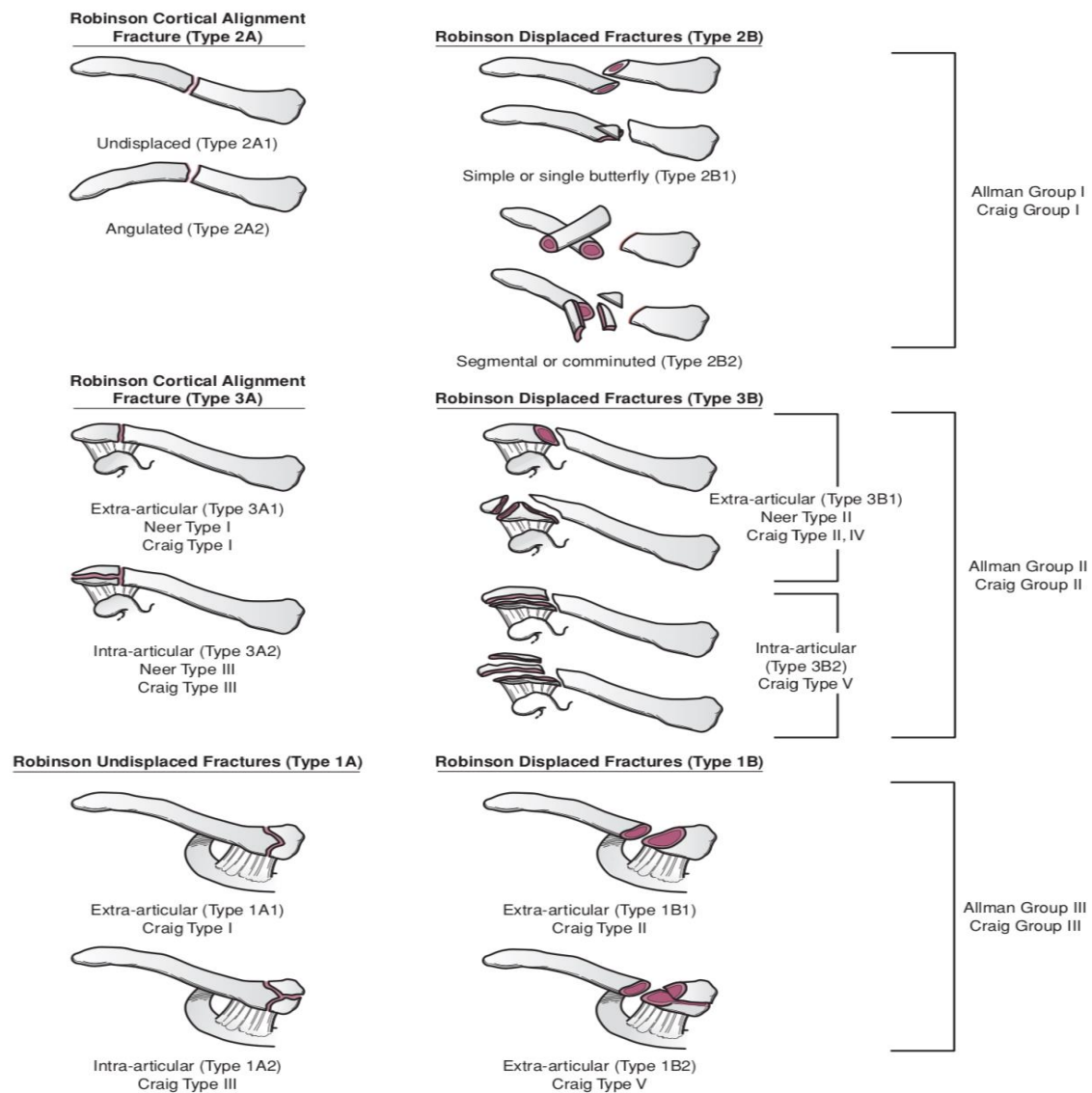


FIG 12.¹

AO/OTA Fracture and Dislocation Classification Compendium¹

It was updated in 2007 to include recent developments like unified numbering scheme and measures to improve inter-observer reliability (Fig. 13).

The clavicle is designated as segment 15 and divided into the standard medial metaphyseal, diaphyseal, and lateral metaphyseal fractures. Here it is divided according to the AO “rule of squares” into shorter segments and not like one-third of the length of the bone. Diaphyseal fracture further divided into simple (15-B1), wedge (15-B2), and complex (15-B3) subtypes.

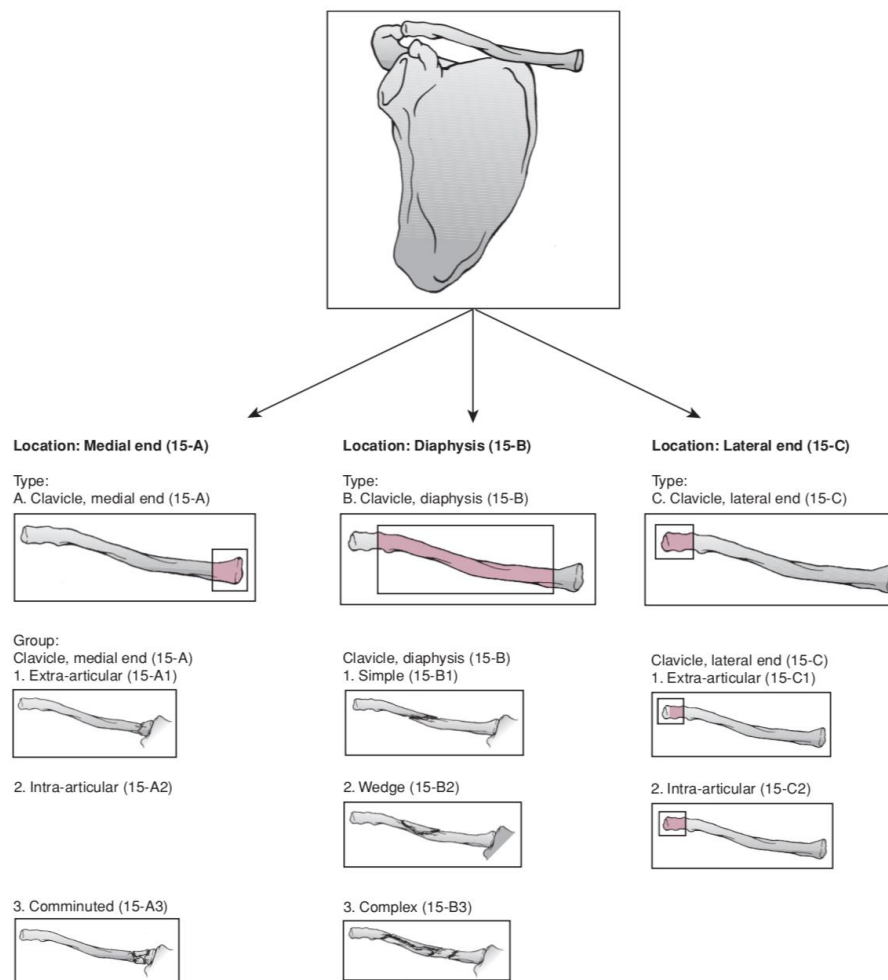


FIG 13.¹

CLINICAL FINDINGS

Clinical Presentation: The affected extremity was held close to the trunk across the chest and supported by opposite hand. Patient may angle their head towards the side of injury in an attempt to relax the pull of trapezius muscle on the fragment, because any movements of affected extremity will elicit pain.

History: Patient usually provides history of either direct or indirect injury to the shoulder and present with their affected limb held with unaffected limb. The major causes include simple fall, fall from height, fall during sport activity or road traffic accident.

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 (fig. 14). Gentle palpation and manipulation will usually produce crepitus. All arm movements are painful.⁶² Abnormal mobility, bony deformity 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.

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.

The involved arm droops forwards and downwards because of the pull of the pectoralis minor muscle and weight of the arm.

ASSOCIATED INJURIES:

Injuries accompanying acute clavicular fractures may be divided into –

- 1) Skeletal injuries - sternoclavicular or acromioclavicular dislocation or fracture dislocation, Head and neck injuries, first rib fracture, Associated with dislocation – disruption of scapulothoracic articulation.
- 2) Injury to lung and pleura -Pneumothorax, hemothorax
- 3) Vascular injuries -, occlusion, laceration, spasm or acute compression. Most commonly injured vessels are the subclavian artery and vein and internal jugular vein
- 4) Brachial plexus injuries.¹⁸
- 5) Fracture of both the clavicle and the scapula i.e. floating shoulder are associated with an extremely unstable shoulder girdle.

RADIOGRAPHIC EVALUATION

Evaluation of middle third clavicle fractures:

The clavicle not only shortens but also gets inferiorly angulated and medially rotated and the deformity is truly in 2 planes. For accurate evaluation of fragment position at least two projections are required – 1. An anteroposterior view, 2. 45 degrees cephalic tilt view.

TREATMENT

The main goal in treating clavicle fractures are to achieve bone healing with minimal morbidity, residual deformity, loss of function along with pain relief and comfort. General methods of clavicle fracture treatment can be broadly grouped into:

A) NON-OPERATIVE TREATMENT OF CLAVICLE FRACTURES:

The earliest attempt reported for closed reduction of a displaced midshaft fracture of clavicle was dating from the 30th century BC, recorded in the “Edwin Smith” papyrus. Typical deformity caused was described by Hippocrates, he further emphasized about the importance of trying to correct the deformity. The first description of treatment of clavicle fracture had hundreds of descriptions of different devices designed to maintain the reduction, including splints, body jackets, casts, braces, slings, swathes, and wraps. At the present time, there is no evidence that any of these devices maintains 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.⁶

B) OPERATIVE TREATMENT:

Mainstay of treatment for clavicle fractures have been non-operative, but in view of recent studies showing decrease in union rate, operative treatment is recommended by most surgeons.

Main aim of operative treatment is to achieve a healed clavicular strut in normal anatomical position as best as possible to provide shoulder girdle stability. 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.^{24,25}

Indications for operative treatment are:

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 weight-bearing/arm use in case of poly trauma.
2. Patient motivation for rapid return of function (e.g., elite sports or the self-employed professional)

Available methods broadly divided into:

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

I INTRAMEDULLARY DEVICES:

It includes fixation with smooth or threaded Kirschner wires, Steinman pins, Knowles pins, Hagie pins, cannulated screws, and currently Elastic nails and its modifications.²⁶

INTRAMEDULLARY FIXATION WITH K-WIRES: Kirshner wire size of 2.5 to 3mm used for intramedullary fixation, usually not recommended because of danger of migration of wires into the thorax.

INTRAMEDULLARY FIXATION WITH TENS

The TENS stands for titanium elastic nailing system. In contrast to Kirschner wire fixation, ESIN (Elastic stable intramedullary nailing) using TENS is a truly intramedullary stabilization technique. The flexible Titanium nail is firmly anchored in the S-shaped clavicle according to the principles described by Ligier et al.²⁷ The largest series of ESIN for midclavicular fractures so far was published by Jubel et al in 2002.⁵

Why Titanium?

Titanium has a good record of 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. 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 for intraosseous applications. The implant used in this study is made of titanium alloy (Ti-6Al-7Nb).^{28, 29}

Usual size of 2 to 3 mm nails is used (Size of nail was measured using the formula = $0.4 \times \text{canal diameter in mm}$).³⁰ With the help of image intensifier entry point made 1.5 to 2 cm lateral to sternoclavicular joint is the preferred entry point, posterolateral entry can be made 2 to 3cm medial to AC joint but is not preferred as there is increased risk of nail migrating into intrathoracic structures. In case of difficulty in negotiating the nail through site of fracture during closed reduction, aid of towel clip or Allis forceps can be used percutaneously to pass the nail through site of fracture into lateral fragment. Still if not able to reduce a small incision can be made over the fracture site and nail passed after fracture reduction under direct vision. The final nail position inside the clavicle is as shown below (fig 14).

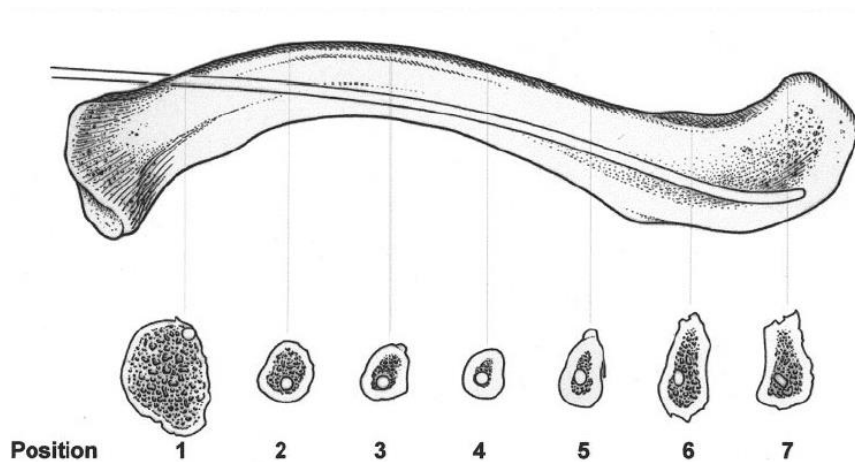


FIG 14-Position of the TENS within the clavicular canal.⁶⁹

Advantages of TENS implant:

TENS has a curved tip which 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 TENS to mildly and moderately comminuted fractures. From the biomechanical point of view, intramedullary positioning of the implant is ideal as direction of rotation and the loading of the arm determines the tension side of clavicle.

Titanium nail is blunt at its entry side and intramedullary advancement of the blunt nail makes an injury to the neurovascular structures very unlikely. No such complication has been described in the literature using this technique. Other fatal complications like implant migration into the chest cavity have not been observed either.

Advantages of TENS procedure:

- It can be performed closed or through small skin incision.
- It can be removed under local anesthesia.
- It requires minimal soft tissue stripping.
- Decreased hardware prominence.
- Lower incidence of re-fracture.³¹
- In setting of comminution, the cantilever effect for a pin extends to medial most portion of the pin there by providing better fixation in bending loads.
- It allows axial compression so it enhances healing.

Disadvantages:

- Failure to control axial length and rotation especially with increasing fracture comminution.³¹
- Technically difficult due to the curvature, high density and poorly defined intramedullary canal of the bone.

PLATE AND SCREWS:

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

LCDCP of 3.5mm or low-profile reconstruction plates are commonly used. Pre-contoured clavicle locking plates are commercially available. Plates are positioned on

anterior or superior surface of clavicle (Tension site). 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 the arm should not be raised above the head until union.³²

Advantages:

1. Compression across site of fracture for transverse fractures.
2. By making the plate function in neutralization mode, lag screw fixation can be used for oblique fractures or butterfly fragments.
3. Control of fracture rotation.
4. It achieves a rigid fixation and allows minimal weight bearing on the extremity for using the arm for daily living activities.³³

Disadvantages:

1. Need for increased soft tissue stripping and exposure.
2. Risk of damage to supraclavicular nerves which cross through the surgical field.
3. The plate itself sits subcutaneous and can be the source of irritation and poor cosmesis.
4. For plate removal another procedure is required, and the patient is left with multiple stress risers in the clavicle along with risk of re-fracture following removal.

III EXTERNAL FIXATION:

Indications for external fixation of clavicle are very few and are mentioned here for the sake of completeness. Usually indicated for severe open fracture with unfavorable skin

condition for surgical management and infected non-union post plate removal.^{34,35} This method 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.³⁶

PLATE VS NAIL

If decided to treat a clavicle fracture surgically, open reduction and Plate fixation has gained recognition as an effective treatment and is often considered the gold standard. Two different surgical approaches for clavicle plating have been described, in which the position of plate is either on the anteroinferior or superior surface of clavicle.³⁷ Implant-related irritation has been reported in both plating techniques; therefore, the best approach from a patient's perspective is yet to be determined. Intramedullary fixation especially that with TENS is a promising alternative to traditional open reduction and internal PF for completely DMCF's.³⁸ The advantages of using an IM pin include smaller incision, less soft tissue dissection, and load-sharing fixation with relative stability that encourages copious callus formation.³⁹ In contrast, technique-specific complications like medial implant protrusion and irritation are reported in several studies.^{25,33,40} Selection of optimal surgical treatment can be facilitated by identifying patients at risk of developing implant-related irritation preoperatively.

Implant-related irritation after IMF using a pin or nail could have several causes, one of which is technical. IMF may cause nuisance when the IM nail is left too long. Most of the time, however, implant-related irritation is from protrusion of the implant after medial migration.^{25,38} A possible solution for implant-related irritation that was recently proposed was the application of an end cap at the medial end of the TEN.⁴¹

COMPLICATIONS OF FRACTURE OF CLAVICLE

a) Malunion:

Following displaced clavicular fractures chance of shortening or angulation is 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.¹⁴

b) Non-union:

Non-union of clavicle is defined as absence of clinical or radiographic signs of progression of healing at 4 to 6 months. At 16 weeks period as long as some potential for healing was present it is called delayed union. The incidence of non-union probably much higher than previously thought with an incidence of 15% to 25%.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 $\geq 20\text{mm}$.³⁵
- iv) Marked displacement $>20\text{mm}$ - muscle forces and weight of the arm tend to displace the fracture fragments.³⁵
- v) Soft tissue interposition that will interfere with healing.
- vi) Re-fracture.

- vii) Primary open reduction: Extensive soft tissue dissection, periosteal stripping and infection have been attributed to high rate of non-union in fractures treated with internal fixation.

c) Post traumatic arthritis:

Intra-articular injuries to both the sternoclavicular and acromioclavicular joints can predispose to it and most often it occurs as a result of missed intra-articular fracture.¹

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 subclavian and axillary vessels or the brachial plexus (mainly ulnar nerve). Ulnar nerve crosses the first rib under the medial third of clavicle; hence ulnar nerve is more frequently involved in complications arising from fractures of the medial third of the clavicle.

COMPLICATIONS FOLLOWING SURGICAL MANAGEMENT:

1) Hard ware problems:

In elastic nailing, medial end protrusion is the main concern. Even lateral migration of nail is seen in comminuted fractures during fracture collapse especially if lateral end is reamed.

As far as plate fixation is concerned inadequate purchase or plate size, collapse of the intercalary graft are the important predictors of failures like plate loosening, plate breakage, plate angulation, which may be treated by re-plating. Significant force on the lateral most screws can cause pullout of the lateral most screws.

2) Infection:

Infection after operative treatment for fracture or non-union can be a devastating complication. Plate fixation due to its need for large incision and soft tissue damage are more prone for infection compared to elastic nailing even if open reduction was done in the later. Reconstruction for deep infection or osteomyelitis particularly in the non-union situation with bone loss maybe extensive is often difficult. Initial treatment 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 especially in case of plating due to uneven stress risers.

7) Non-union, delayed union and malunion.^{19,36,42}

8) Shoulder stiffness.^{3,20}

REHABILITATION:

Rehabilitation helps to restore and improve the shoulder functions for activities of daily living, vocational and sports activities.

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

Rehabilitation protocol:

- i) Day 1 to 1 week: Limb is kept in a sling or shoulder arm pouch with shoulder held in adduction and internal rotation. Elbow is maintained at 90° of flexion with only shoulder pendulum exercises started according to patient's tolerance.
- ii) At 2 weeks: suture removal along with shoulder pendulum exercises and arm still on sling or shoulder arm pouch.
- iii) At 3 weeks gentle active shoulder range of movements were allowed but abduction was limited to 90 degrees.
- iv) At 4 weeks active ROM of shoulder in all planes were allowed.
- v) At 6 to 8 weeks: Active to active – started on assisted ROM in all planes.
- vi) At 8 to 12 weeks: Isometric and isotonic exercises are started for the shoulder girdle muscles.⁴³

LITERATURE SURVEY

The extent of displacement of the original fracture was the most significant cause for non-union of clavicle.⁴⁴

Malunion following clavicular fracture may be associated with neurologic, orthopedic, and cosmetic complications. In selected cases, corrective osteotomy results in a high degree of patient satisfaction and improves patient-based upper-extremity scores, and hence showed the importance of proper management of clavicle fracture. The same study also shows that even though good results with minimal functional deficits have been reported following non-operative treatment of clavicular fractures, surgical modality appears to be better than conservative. The associated short comes in surgical modality which were documented previously may be due to surgeon-based methods of evaluation which may be insensitive to loss of muscle strength as the author also detected residual deficits in shoulder strength and endurance which was related to the significant dysfunction detected by the patient based outcome measures.^{11,15}

Evaluation of selective review of the literature on the current treatment options confirmed some long-held concepts and refused others especially that in patients with severe displacement, females, old age, the risk of non-union after conservative treatment is much higher than previously reported and that new developments in implants and techniques have made surgery safer as well as increased the rate of bony union.⁵

A computer tomography assisted cadaveric study conducted by Ledger. M in 2005 concluded that shortening of clavicle by 15mm led to an upward angulation at the sternoclavicular end and an increase in anterior scapular version which leads to shoulder

girdle function limitations. Pearson in 2010 showed that the cost effectiveness of surgical fixation outweighed that of non-surgical management with poor functional outcomes.⁴⁵

In a multicenter, prospective trial by the Canadian Orthopedic Trauma Society of displaced midshaft fracture, outcome and complication rates were compared for non-operative treatment and plate fixation. In their study both Constant Shoulder scores and Disability of the Arm, Shoulder and Hand (DASH) scores were greatly improved in the operative fixation group. They also found that the mean time to radiographic union was faster and non-union rate is lower in the operative group, than in the non-operative group. Among operative group none had symptomatic malunion and at 1 year after injury, the operative-group patients were more satisfied with their shoulder appearance than the non-operative group patients.⁷

Clinical trials in 2013 conducted on operative vs. non operative treatment of clavicle fracture also showed reduced rate of non-union, malunion, neuro-vascular deficits in operative cases when compared to non-operative treatment.⁴⁶ Even randomized control analysis done on same year on operative versus non operative treatment for midshaft displaced clavicular fractures shows better functional outcome and reduced rate of non-union in fractures fixed with operative treatment when compared to non-operative treatment.³⁷

The optimal treatment strategy of midshaft clavicle fractures is an ongoing topic of debate.⁴⁷⁻⁴⁹ A study in 2014, assessed functional outcome of mid 1/3rd clavicle fractures after open reduction and internal fixation, which showed in certain selected patients and certain fracture configuration there is better outcome in terms of union rate, cosmesis and functional ability.⁵⁰

A prospective, randomized controlled trial with 59 patients with midshaft clavicular fracture, randomly received fixation with either a reconstruction plate, known as the plate

group or elastic stable intramedullary nailing known as the nail group concluded that the mean six-month DASH score was found to be more in the plate group than in the nail group indicating better outcome for nail group.⁵¹

In a comparative study between Titanium elastic nail (TENS) and reconstruction plate about loading configurations, TENS led to a stress distribution like that of the intact clavicle in both loading configurations, whereas stress distribution in cantilever bending with the reconstruction plate was non-physiological. Fixation with a reconstruction plate showed obvious stress shielding more stable but was more stable. But TEN generated the highest displacement of the distal clavicle, followed by the intact clavicle and the reconstruction plate. TENS have higher peak bone and implant stresses and have more chance to fail in both loading configurations compared with the reconstruction plate. Thus, they recommend reconstruction plate fixation for patients with demand for early return to activity.⁵² Interestingly, Smith et al. reported that the failure torque after removal of an IM device was significantly greater than after plate removal and remained strong as the innate clavicle.⁵³

Another meta-analysis in 2016 suggests that intramedullary nailing and plating provides equivalent long-term functional outcomes, and plating may lead to a higher risk of failure and non-operative complications. Although plating appears to be the standard of care amongst orthopedic surgeons, they believe that intramedullary nailing can provide a viable alternative that is more cost effective due to significantly reduced operative times.⁵⁴

In certain studies, implant irritation or failure which require revision was consistently reported following open reduction and plate fixation of displaced mid- shaft clavicle fractures.⁵⁵ Additionally, this procedure was associated with other minor complications like superficial infections and plate loosening.⁵⁶ Although better cosmetic

results have been reported after intramedullary fixation due to a smaller incision, there have also been complications of migration of the nail and implant irritation documented in many studies.^{33,57}

Plating is associated with higher re-fracture, major revision surgery and implant failure when compared to elastic stable nail.⁴⁰ 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.⁵⁸ In contrast TENS overcomes several disadvantages of plate fixation.

In a meta-analysis, intramedullary fixation advantaged over plate fixation group with reduced surgery time, smaller incision, less blood loss and better functional recovery at 6-months postoperative follow-up. This study also showed no significant difference in shoulder range of motion in terms of forward flexion, abduction, external rotation and internal rotation between the two groups. Meanwhile 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, delayed union, revision surgery and brachial plexus injury.³⁴

It is notable that, the re-fracture after hardware removal occurred only in plate fixation with the incidence rate of 6.3% (10/158) but none intramedullary fixation.³⁴ Biomechanical data have shown increased weakness of the clavicle after plate removal compared with IM device removal.⁵⁹ ESIN is a safe and effective method for midclavicular fractures with a low complication rate once potential technical pitfalls are appreciated. It provides reliable restoration of clavicular length, excellent cosmetic and functional results and a quick recovery to training is possible.³¹

TENS acts as an internal splint at the fracture site. It has significantly shorter operation time, smaller wound incision, minimal scarring, less pain level, less analgesic use, less symptomatic hardware, less stress shielding, and the ability to remove the implant under local anesthesia with minimal dissection.³⁹ Moreover, it provides biological fixation while preserving soft tissue and the periosteal blood supply. The healing process involves external bridging callus through intramembranous bone formation.⁶⁰

Although TEN fixations may lead to a higher degree of length shortening after bony union especially in fractures with comminution, no significant statistical difference was observed in objective functional results as compared to other subgroups. Therefore, Titanium Elastic nail is useful in fixation of displaced midshaft clavicle fracture even in cases of comminuted fracture pattern, which overall is an effective and less surgically invasive procedure.⁶¹

Plate and intramedullary devices are the two major types of implants currently used for internal fixation of clavicle fractures. Even though Plate fixation is the standard surgical method for fixing displaced midshaft clavicle fractures, no obvious strong evidence supports this practice. Wang et al states that intramedullary TEN fixation has good clinical results when compared to plate fixation for displaced fractures of midshaft of clavicle, without any significant difference even in terms of Constant score.⁶¹ As per Radiological Union TENS Technique of treatment is more effective than Plate technique.⁶²

TEN fixation allows for earlier relief of shoulder pain and a more cosmetically satisfactory appearance than plate fixation.⁵⁷ Many other studies recommends the use of minimally invasive Titanium elastic nailing system for midshaft clavicle fracture fixation in view of faster union, lesser morbidity, easier implant removal and fewer complications; with exception to comminuted fractures where plating remains the procedure of choice.⁶³

Thus, expectations of patients with high demand on shoulder function can be met with TENS, as it is a minimally invasive procedure which restore clavicle length and allows early resumption of training, faster functional recovery and good cosmetic result.³¹

METHODOLOGY

This is a prospective study with 30 patients of mid shaft clavicle fractures satisfying the inclusion and exclusion criteria, who underwent treatment with Titanium elastic nailing system as an intramedullary device in the Department of Orthopedics from October 2017 to November 2018, R.L. Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

INCLUSION CRITERIA:

- 1) Age > 18 years
- 2) Middle third clavicle fractures
- 3) Simple fractures
- 4) Displacement of more than shaft width
- 5) Shortening by over 2 cm
- 6) Risk of perforation of skin by fracture ends

EXCLUSION CRITERIA:

- 1) Patients with pre-existent morbidity concerning arm, shoulder or hand
- 2) Moderate to severe head injury (Glasgow coma scale <12)
- 3) Open fractures

- 4) Pathological fractures
- 5) Fractures associated with neurovascular injury
- 6) Severely comminuted fractures

Preliminary evaluation:

Patient's information like name, sex, age, address and occupation were documented.

Detailed history was taken regarding the time and mode of injury like direct shoulder injury, fall on shoulder, fall on outstretched hand or road traffic accident.

Patient was asked his major complaint like site of pain, swelling, and side of clavicle. Past family history and medical illness were documented.

General examination and vitals of the patient was noted. 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:

Local examination

1. INSPECTION:

- Patients with clavicle fracture usually presents with ipsilateral elbow flexed and supported with the other hand.
- Skin over the clavicle was inspected for any abrasion, laceration, contusion, ecchymosis, swelling and skin indentation by fracture fragments.



FIG 15

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 distal neurological and vascular status of the affected upper limb was examined, and patient screened for other injuries..
- Plain X Ray of clavicle with shoulder –anteroposterior view was taken. (To assess pattern, site of fracture and to classify according to Robinson classification)
- 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 as preoperative workup. All

patients were operated once they are clinically stable and fit for surgery as assessed by the physician.

PRE-OPERATIVE PREPARATION OF PATIENTS:

- Patients were kept 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.
- Tranquilizers were given as advised by the anesthetist. A systemic antibiotic usually Inj. Amoxicillin clavulanic acid 1gm intravenously were administered 30 minutes before surgery to all patients.

INSTRUMENTS USED IN OUR INSTITUTE

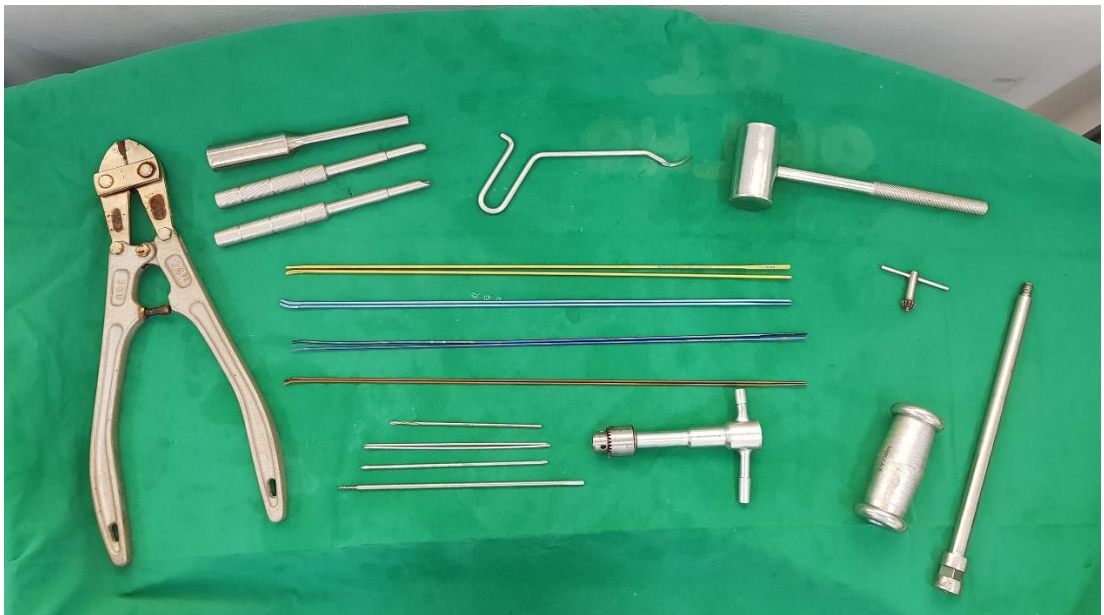


FIG 16 A

FULL 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	

Hammer Guide for TEN	
Insertor for TEN	
Combined Hammer for TEN	
Universal Chuck with T-Handle	
Double Drill Guide 4.5/3.2	
Drill Bit Ø 2.7 mm, length 125/100 mm, 3-flute, for Quick Coupling	
Bolt Cutter	
Impactor for TEN, straight	
Impactor for TEN, bevelled	
Impactor, bevelled, small, for TEN Ø 1.5 to 3.0 mm	
Awl for TEN	
Extraction Pliers for TEN	

FIG 16 B

SURGICAL TECHNIQUE

- Patient was positioned in supine position under General Anesthesia (GA) with sandbag under interscapular region in a radiolucent table. Entire upper limb from base of neck to hand were prepared and draped allowing free movements of the arm.
- Small horizontal incision in line with clavicle, of 1-1.5 cm is made lateral to the sternal end of the clavicle. Skin, subcutaneous tissue and platysma were divided (Step-1).
- The anterior 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 and was advanced into the medullary canal manually (Step-3).
- With image intensification, the implant is advanced to the 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 does not succeed, the tip of the nail was maneuvered from one fragment to another under direct vision after performing a second small transverse (2–3cm) skin incision directly over the fracture site. The nail is then advanced manually or gently tapped with a mallet until it is just medial to the AC joint.¹³

OPERATIVE PHOTOGRAPHS

OPEN REDUCTION (FIG: 17)



A) MAKING ENTRY WITH AWL



B) INSERTING TENS THROUGH ENTRY POINT



**C) PASSING THE NAIL TO
FRACTURE SITE WITH
TWISTING MOTION**

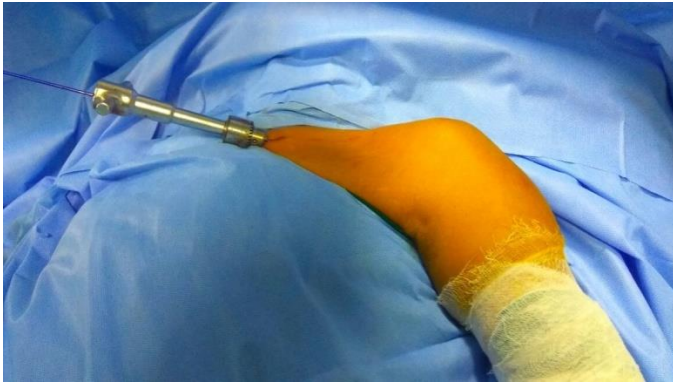


**D) OPENING THE
FRACTURE SITE WITH
MINIMAL INCISION**



**E) OPEN REDUCTION OF
FRACTURE AND NAIL
PASSED**

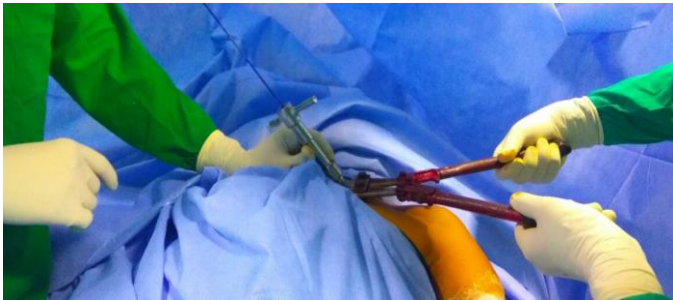
CLOSED REDUCTION (FIG 18)



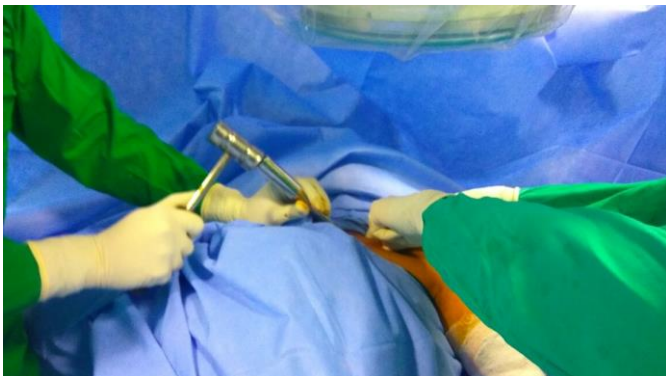
A) NAIL ENTRY



B) NEGOTIATING FRACTURE SITE

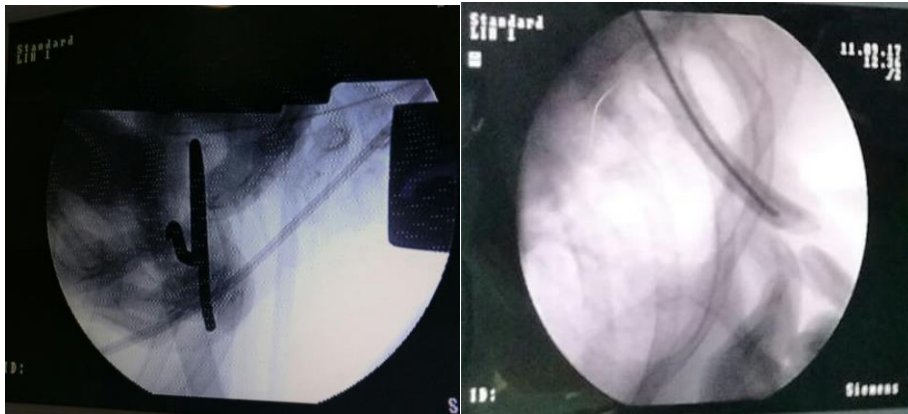


C) CUTTING THE NAIL

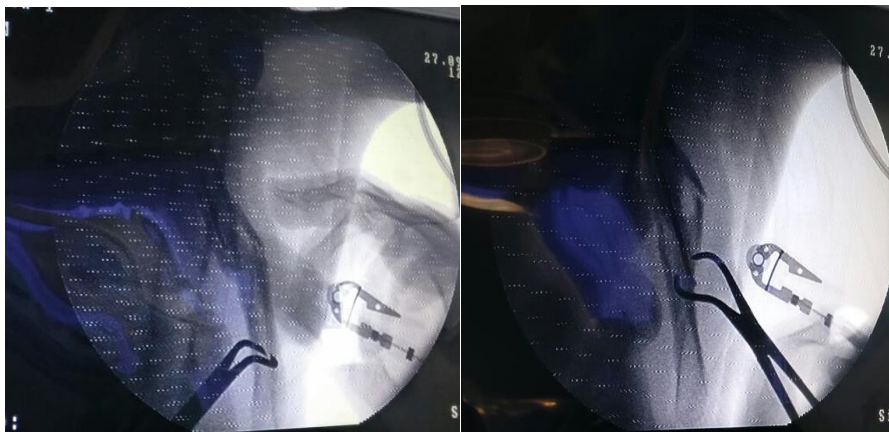


D) USING IMPACTOR TO SMOOTHEN THE CUT SITE AND TO PASS FURTHER TO REDUCE NAIL PROMINENCE

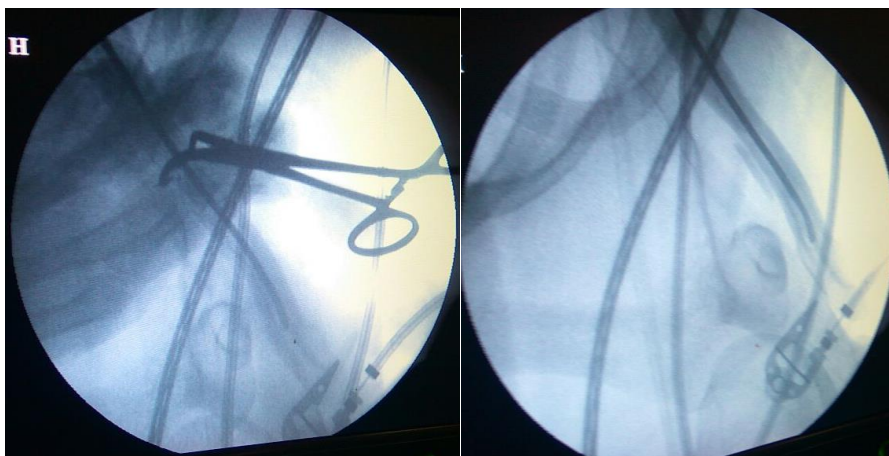
FLUOROSCOPY PICTURES OF CLOSED REDUCTION (FIG 19)



A) Entry with awl and passing nail till fracture site



B) Negotiating fracture using towel clip and nail passed to lateral fragment



C) Final nail

POSTOPERATIVE PROTOCOL

- Patients were kept nil by mouth for 6 hours post operatively and Intravenous fluids and antibiotics were given as needed and for postoperative pain control, a sling is given for a few days.
- Post operatively nail 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 other than overhead abduction and flexion initiated from 2nd post-operative day.
- A minimum of 3 days of IV antibiotics was kept mandatory before patients were discharged. They were discharged at request or post suture removal with the arm pouch. Active shoulder movements i.e. over 90° abduction or flexion, was limited for 4 weeks.



Fig: 20 A- Free ROM in an immediate postop patient following closed reduction and TENS application.



Fig: 20 B- Second post op dressing in a case with open reduction and TENS application.

FOLLOW UP

- Rehabilitation of the affected limb was started immediately post op according to patient's pain tolerance except for those with comminution for whom we started the same after 2 weeks. Gentle shoulder pendulum exercises were allowed first.
- At 3 weeks gentle active shoulder range of movements were allowed but abduction was limited to 90 degrees.
- At 4 weeks active shoulder ROM was allowed in all planes.
- Regular follow up for every 4 weeks was done where affected clavicle examined clinically and radiologically to know about implant position and fracture union. During local examination, we looked for tenderness, implant loosening, deformity, signs of infection and shoulder movements of affected clavicle were assessed.
- Depending on the stage of fracture union and time duration from day of surgery rehabilitation of the limb was done.
- Follow up was continued till radiological union.
- Constant and Murley scoring system was used to assess functional outcome.¹⁶

CONSTANT AND MURLEY SCORING:

In the current study, we chose the Constant scoring system being 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.¹⁶ 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
31-60 Degrees	2
61-90 Degrees	4
91-120 Degrees	6
121-150 Degrees	8
> 151 Degrees	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 of discussion. According to The European Society for Shoulder and Elbow Surgery following method is used:⁶⁴

- 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 the scapula (30 degrees in front of the coronal plane) with a straight elbow.
- Palm of the 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
90-100	Excellent
80-89	Good
70-79	Fair
0-70	Poor

RESULTS AND OBSERVATIONS

In this series, 30 patients with mid shaft clavicle fracture were admitted and operated with TENS and followed up for a period of 6 months between October 2017 to November 2018 in R.L. Jalappa Hospital of Sri Devaraj Urs Medical College . The observations are as given below:

TABLE 1: - DISTRIBUTION OF CASES ACCORDING TO SEX

SEX	NUMBER OF CASES	PERCENT
FEMALE	5	16.6
MALE	25	83.3
TOTAL	30	100.0

Majority of the injury occurred in male patients- 25 cases (83.3%), whereas a total of 5 cases (16.6%) were seen in females.

GRAPH: 1 -Distribution of cases according to sex

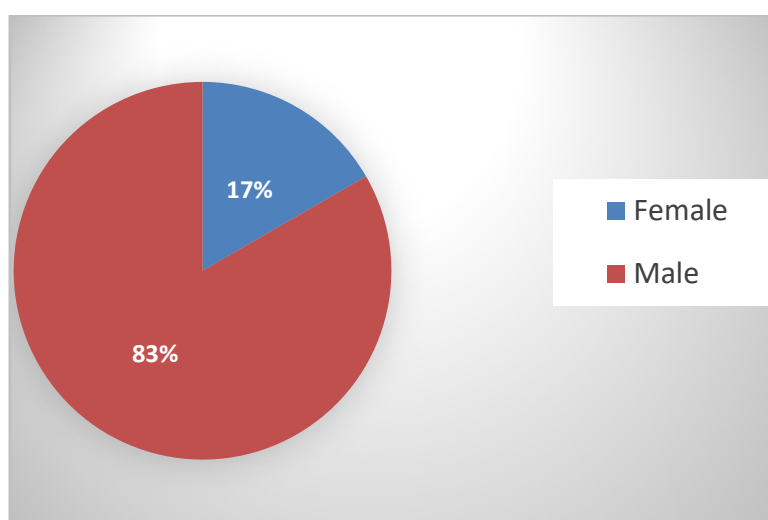


TABLE 2: - DISTRIBUTION OF CASES ACCORDING TO AGE GROUP

AGE GROUP (IN YEARS)	NO OF CASES	PERCENT
18-20	2	6.6
21-30	10	33.3
31-40	11	36.6
41-50	2	6.6
51-60	3	10
61-70	2	6.6

The distribution of age reveals that 2 cases (6.6%) lie between 18-20years, 10 cases (33.3%) lie between 21-30years, 11cases (36.6%) lie between 31-40years, 2 cases (6.6%) lie between 41-50 years and 2cases (6.6%) from 60 and above.

GRAPH 2: -Distribution of cases according to Age group

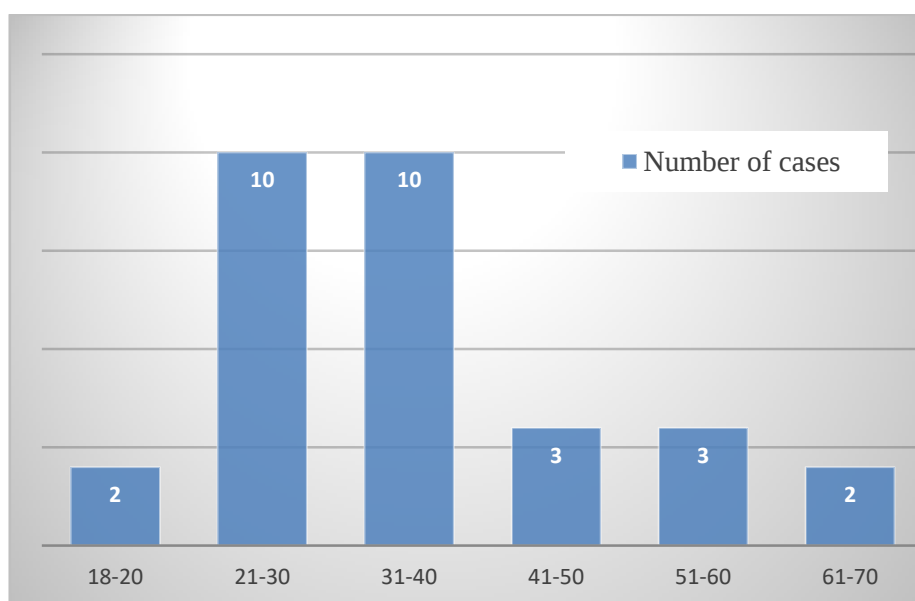


TABLE 3: - DISTRIBUTION OF CASES ACCORDING TIME INTERVAL BETWEEN TRAUMA & SURGERY

Time interval between trauma & surgery	Number of cases	Percent
<3Days	13	43.3
3-7 Days	10	33.3
7-14 Days	5	16.6
>14 days	2	6.6
Total	30	100

In 13cases (43.3%), the time interval was less than 3 days, 10 cases (33.3%) happened between 3-7 days, whereas in 5 cases (16.6%), surgery was conducted between 7 to 14 days, and 2 cases (6.6%) after 14 days.

GRAPH: 3- Distribution of cases according to time interval between trauma & surgery

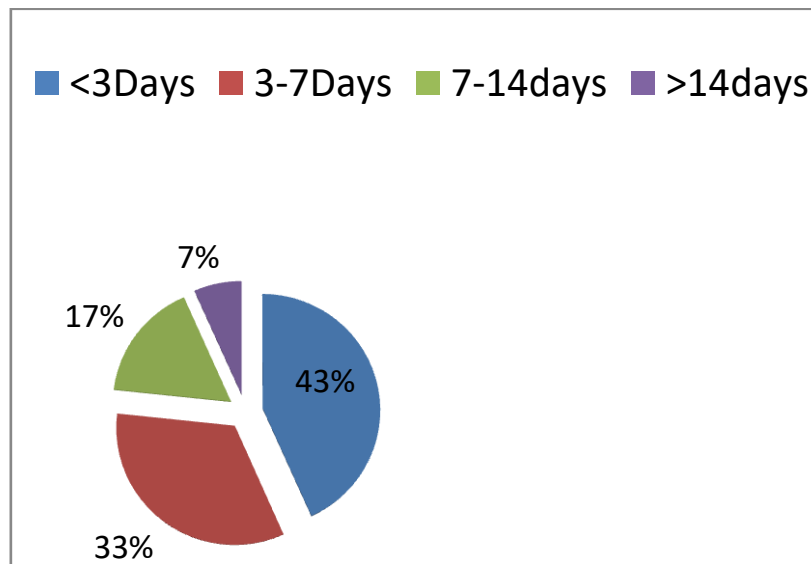


TABLE 4: - DISTRIBUTION OF CASES ACCORDING TO MODE OF INJURY

Mode of injury	Number of cases	Percent
Fall	3	10
Direct trauma	3	10
FOOH	6	20
RTA	18	60
Total	30	100.0

Majority of the cases i.e. 18 cases (60%) occurred as a result of road traffic accidents, 6cases (20%) as a result of fall on an outstretched hand, 3 cases (10.0%) due to fall and 3cases (10%) due to direct trauma.

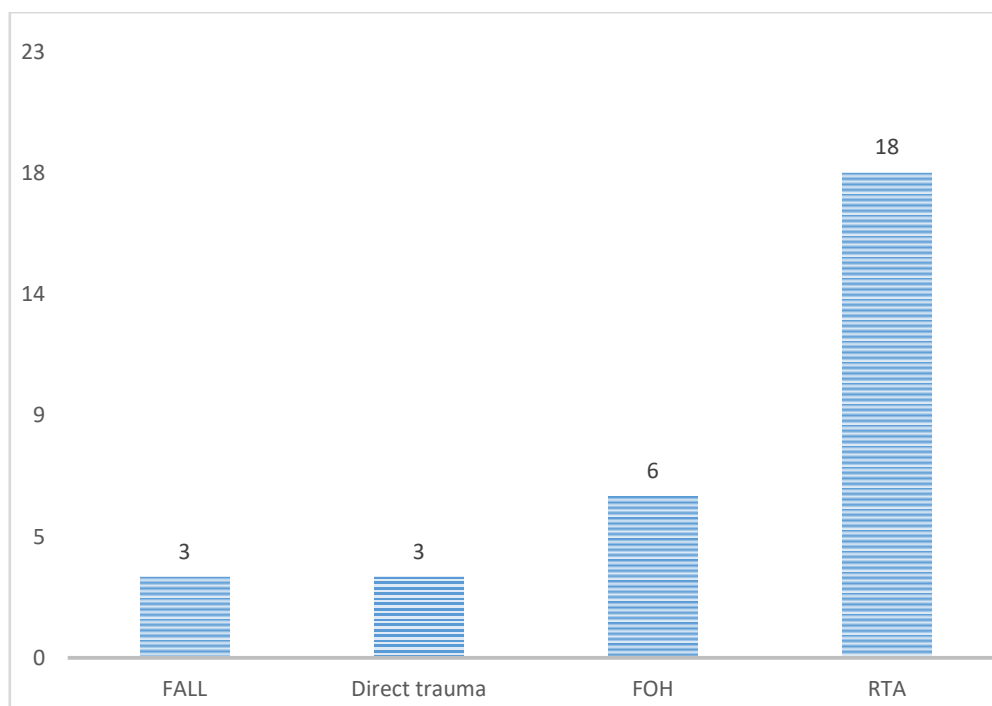
GRAPH: 4- Distribution of cases according to Mode of injury

TABLE 5: - DISTRIBUTION OF CASES ACCORDING TO SIDE AFFECTED

Side affected	Number of cases	Percent
LEFT	14	46.6
RIGHT	16	53.3
Total	30	100.0

In this study, there were a total of 16 cases (53.3%) of right sided fracture, and left side was affected in 14 cases (46.6%).

GRAPH: 5- Distribution of cases according to Side affected

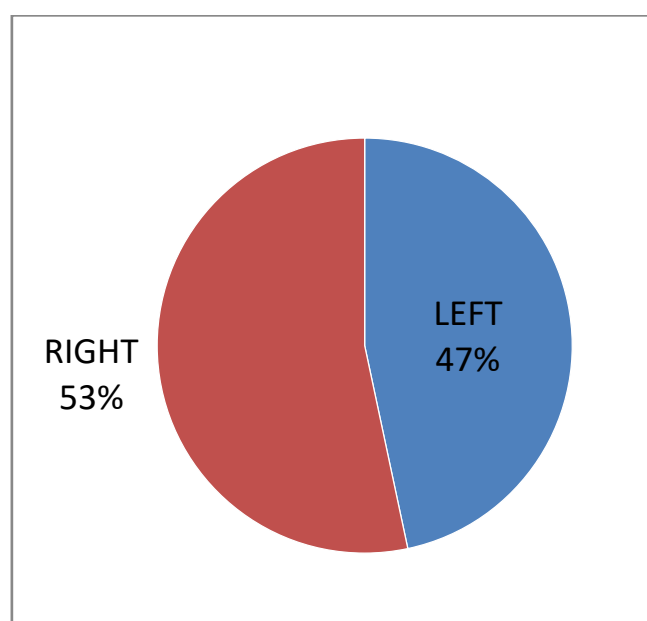


TABLE 6: - DISTRIBUTION OF CASES ACCORDING TO FRACTURE PATTERN

Fracture pattern	Simple transverse	Simple oblique	Simple spiral	Wedge	Segmental	Comminuted	Total
Number of cases	10	6	3	4	2	5	30
Percent	33.3	20	10	13.3	6.6	16.6	100

10 cases (33.3%) were simple transverse fractures, 6(20%) were simple oblique fractures, 3(10%) were simple spiral fractures, 4(13.3%) were wedge type, 2(6.6%) were segmental and 5(16.6%) were comminuted fractures.

GRAPH: 6- Distribution according to fracture pattern

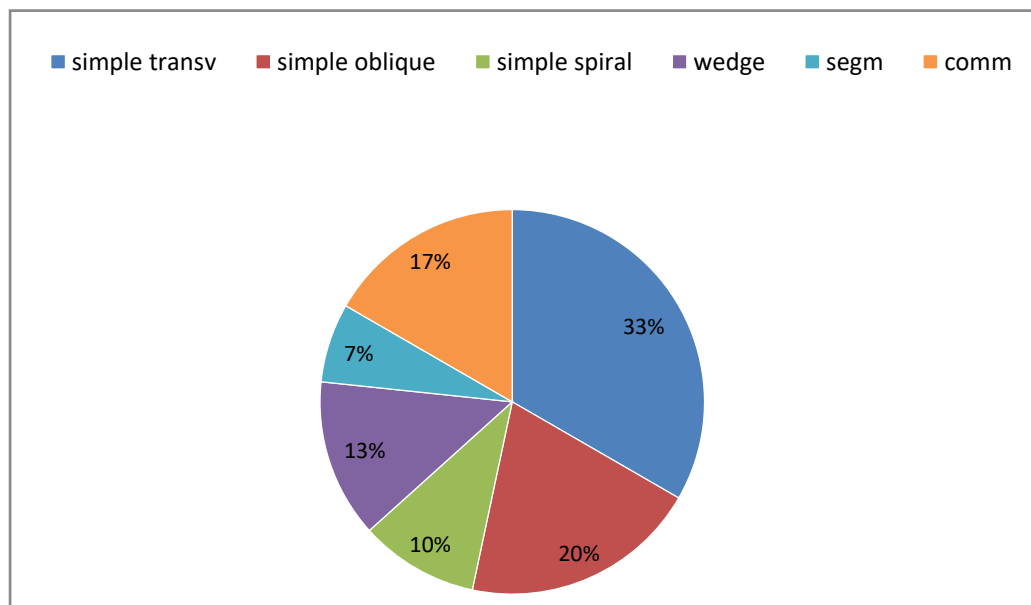


TABLE 7: - DISTRIBUTION OF CASES ACCORDING TO NAIL SIZE USED

Nail size(diameter in mm)	Number of cases	Percent
3	2	6.6
2.5	16	53.3
2	12	40
Total	30	100

Majority of nail size used was of size 2.5mm in 16(53.3%) cases, followed by 2mm for 12 cases (40%), 3mm size were used for 2(6.6%) cases.

GRAPH: 7- Distribution according to nail size

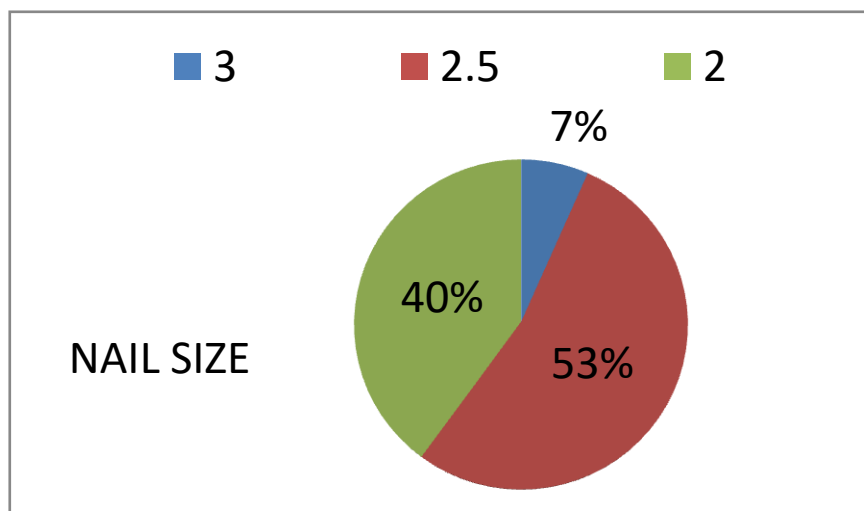


TABLE 8: - DISTRIBUTION OF CASES ACCORDING TO MODE OF REDUCTION

Side affected	Number of cases	Percent
Closed	6	20
Open	24	80
Total	30	100.0

Majority of surgery needed open reduction in 24(80%) of cases rest of 6cases (20%) was able to do closed reduction

GRAPH: 8- Distribution according to mode of reduction

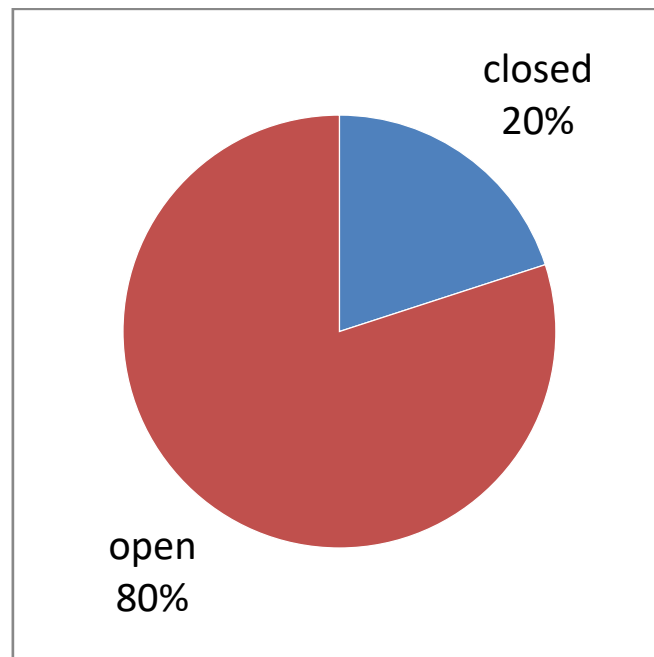


TABLE 9: - DISTRIBUTION OF CASES ACCORDING TO ROBINSON CLASSIFICATION

Robinson classification (type)	Number of cases	Percent
2A1	1	3.3
2A2	3	10
2B1	19	63.3
2B2	7	23.3
Total	30	100.0

According to Robinson classification, there were 19 cases (63.3%) under 2B1 and 7(23.3%) cases under 2B2, 3 cases (10%) under 2A2 and 1case (3.3%) under 2A1.

GRAPH:9- Distribution of cases according to Robinson classification

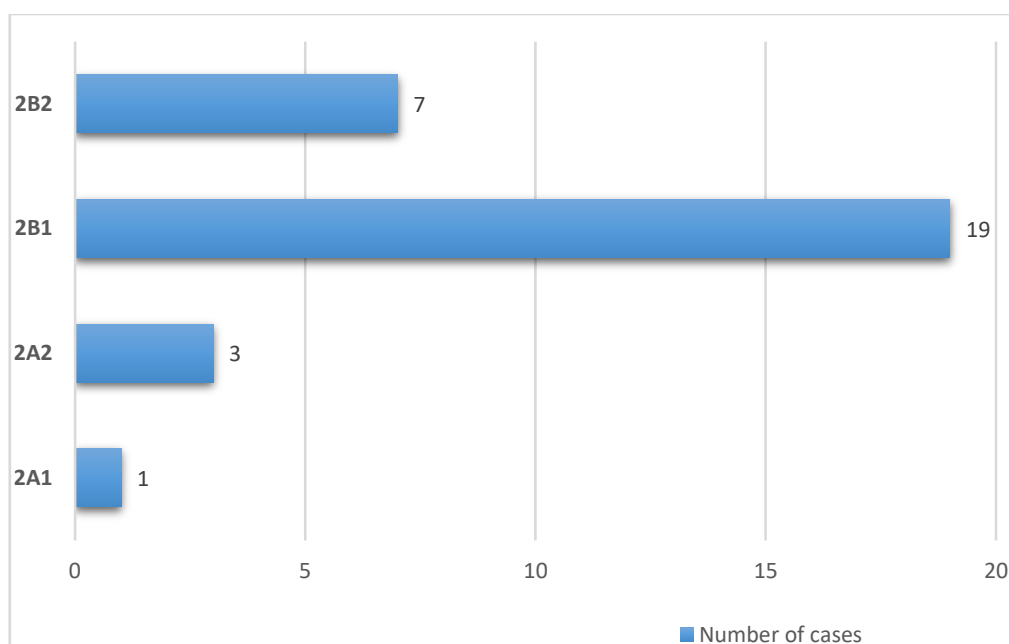


TABLE 10: - DISTRIBUTION OF CASES ACCORDING TO ASSOCIATED INJURY

Associated Injury	No of cases	Percent
NIL	21	70
Ipsilateral lower limb injuries	6	20
Facial injuries	3	10
Total	30	100.0

Most of the cases that is 21 (70%) did not have any associated injury. 6cases (20%) had ipsilateral lower limb fracture and 3cases (10%) had facial injury as an associated injury.

GRAPH: 10- Distribution of cases according to associated INJURY

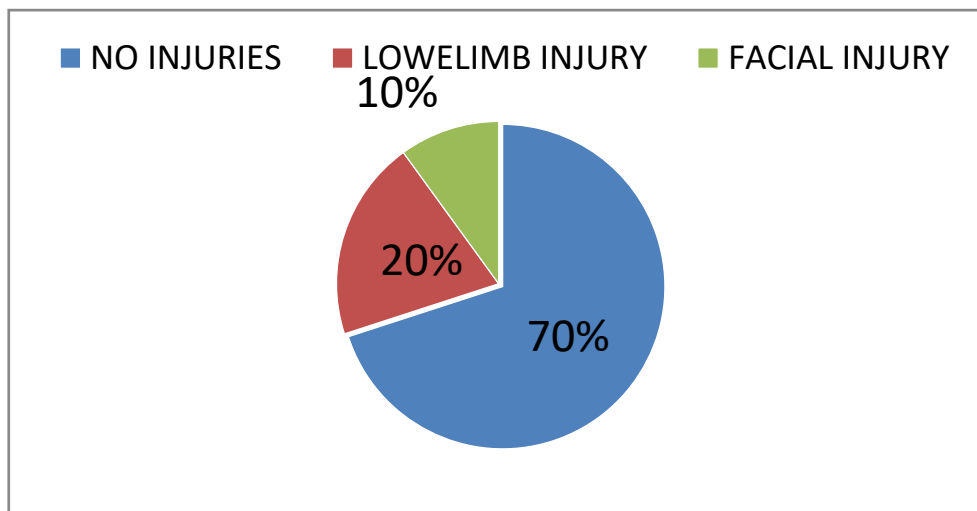


TABLE 11: - DISTRIBUTION OF CASES ACCORDING TO DURATION OF STAY IN HOSPITAL

Duration of stay in hospital	No of cases	Percent
3days	5	16.6
4-7 days	16	53.3
8-14 days	8	26.6
>14 Days	1	3.3
Total	30	100.0

5 cases (16.6%) had to stay in hospital for 3days, 16 cases (53.3%) for 7days, 8cases (26.6%) till 14days and 1 case (3.3%) had to stay for more than 2 weeks due to associated injury(bilateral bell's palsy).

GRAPH: 11- Distribution of cases according to Duration of stay in hospital

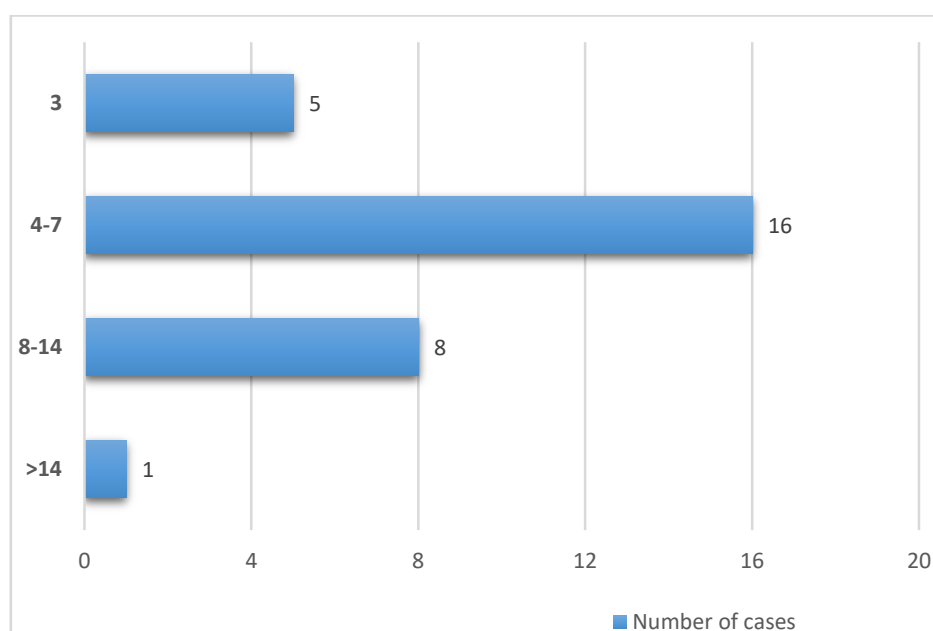


TABLE 12: - DISTRIBUTION OF CASES ACCORDING TO TIME OF UNION

Time of union	No of cases	Percent
0-6 weeks	8	26.6
6-12 weeks	16	53.3
12-16 weeks	3	10
16-20 weeks	2	6.6
20-24 weeks	1	3.3
Total	30	100.0

In 8 cases (26.6%), fracture united by the end of 8weeks, majority cases that is 16(53.3%) united by end of 12weeks, 3 (10%) cases took till 16 weeks, 2 (6.6%) cases took 20weeks whereas for 1 (3.3%) case the union took longer than 20 weeks.

GRAPH: 12- Distribution of cases according to time of union

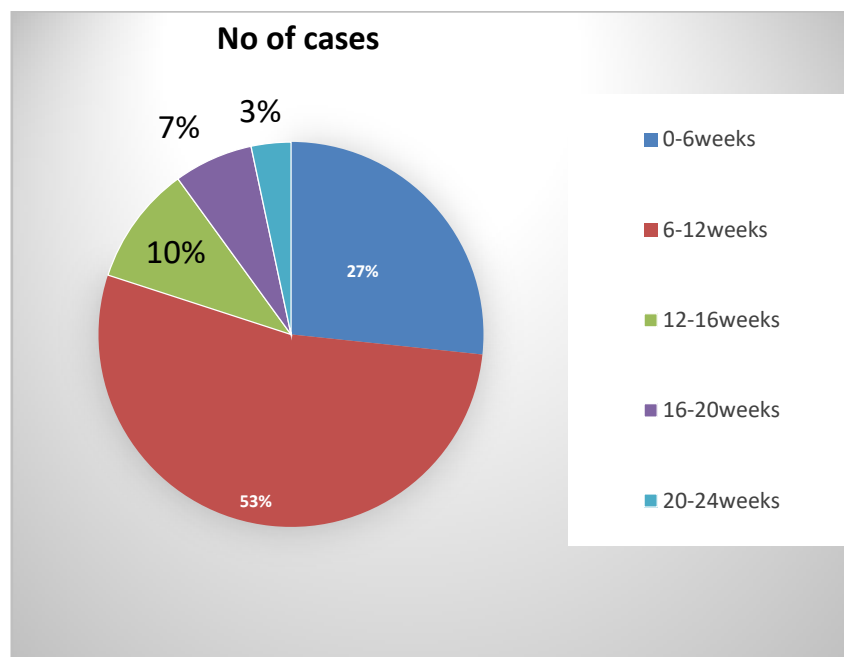


TABLE 13: - DISTRIBUTION OF CASES ACCORDING TO COMPLICATION

COMPLICATION	NO OF CASES	PERCENT
Nail entry point Infection	3	10
nail loosening	2	6.6
Delayed union	3	10
Lateral protrusion	2	6.6
Medial protrusion	4	13.3

Complications encountered in our study include: 3 cases (10%) each of delayed union and infection at nail entry site. 2 cases (6.6%) each of nail loosening and lateral protrusion of nail, 4 cases (13.3%) of medial protrusion of nail. 8(26.6%) cases complained of medial entry site skin irritation. There were no complications of malunion, non-union, nail breakage, hypertrophic scar or shoulder stiffness.

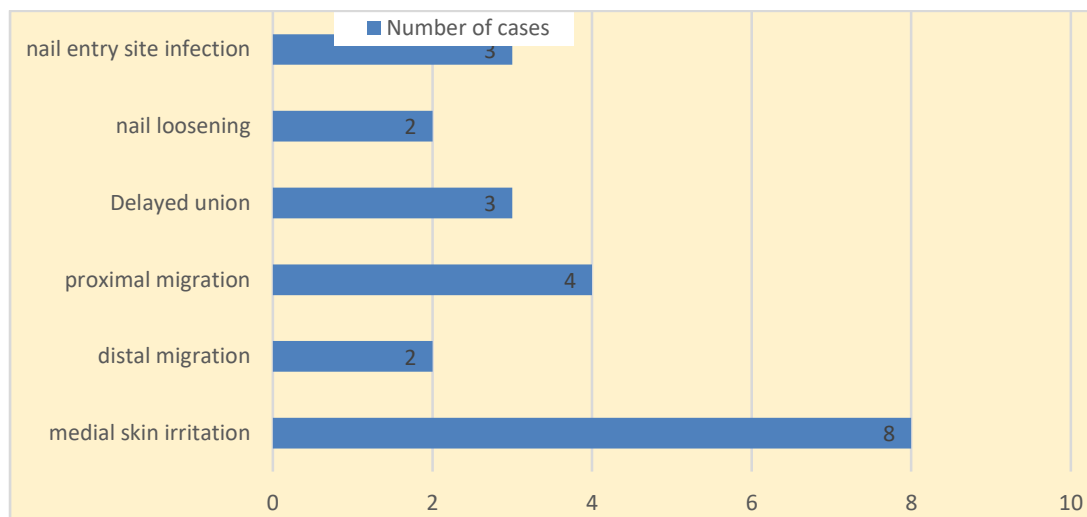
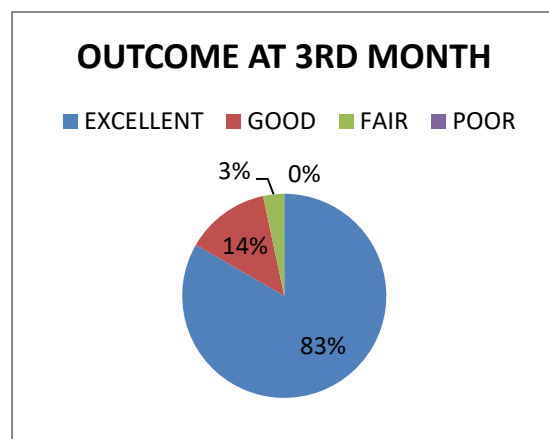
GRAPH: 13- Distribution of cases according to complication

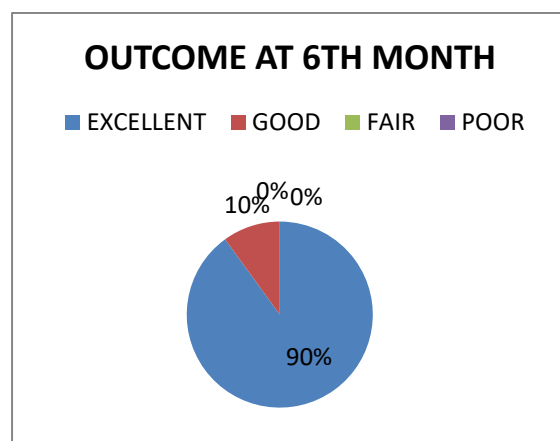
TABLE 14: - DISTRIBUTION OF CASES ACCORDING TO FINAL OUTCOME

Final Outcome by 3 months	Number of cases	Percent
Excellent	25	86.6
Good	4	13.3
Fair	1	0
Poor	0	0
Total	30	100.0

Out of 30 cases, a total of 25(83.3%) showed excellent outcome, 4 cases (13.3%) had good outcome and 1 case (3.3%) had a fair outcome, no case had poor outcome. And by end of 6 months 27(90%) cases showed excellent result and rest 3(10%) cases showed good result.

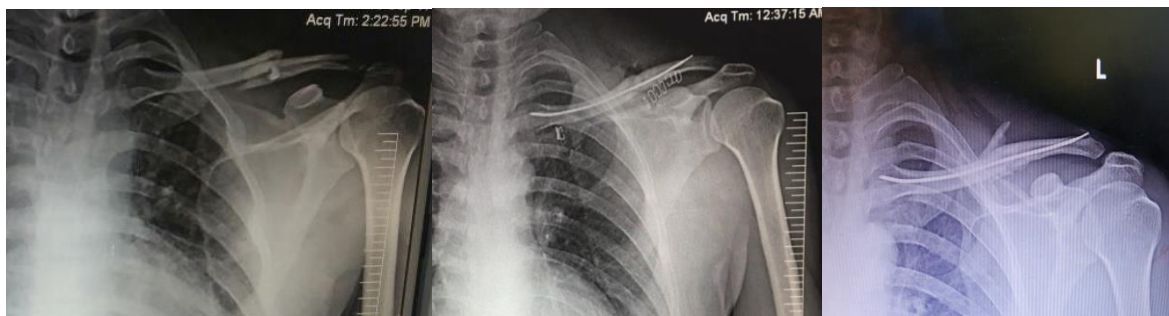


GRAPH: 14- Distribution of cases according to final outcome at 3rd month.



GRAPH: 15- Distribution of cases according to final outcome at 6 months

CASE 1



PRE-OP XRAY

POST-OP XRAY

AFTER 1 MONTH



GOOD UNION AFTER 12 WEEKS

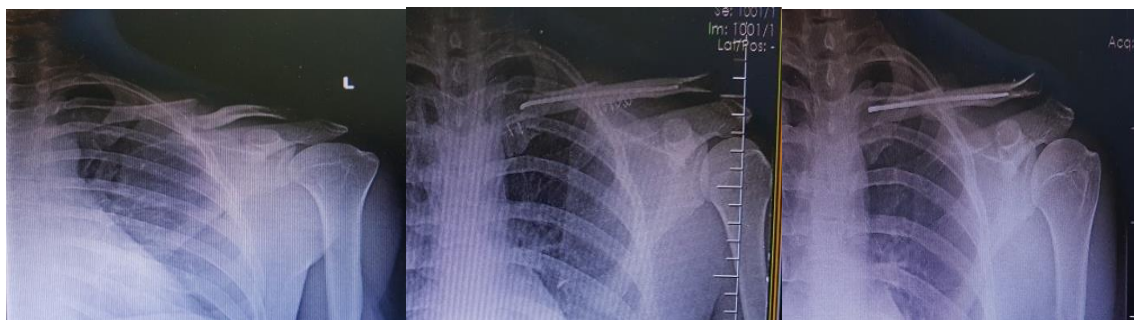
POST IMPLANT REMOVAL

3 MONTHS POST REMOVAL



Fig 22(a) clinical photographs showing shoulder abduction, adduction, flexion, extension, internal and external rotation by 3months, post implant removal without scar.

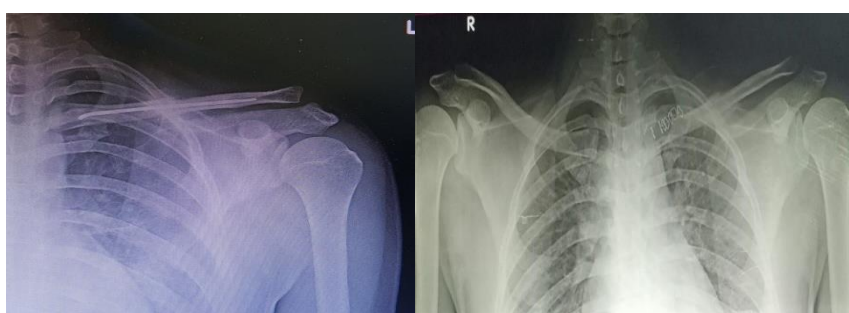
CASE 2



PRE-OP

POST-OP

AFTER 1 MONTH



AFTER 10 WEEKS

POST IMPLANT REMOVAL

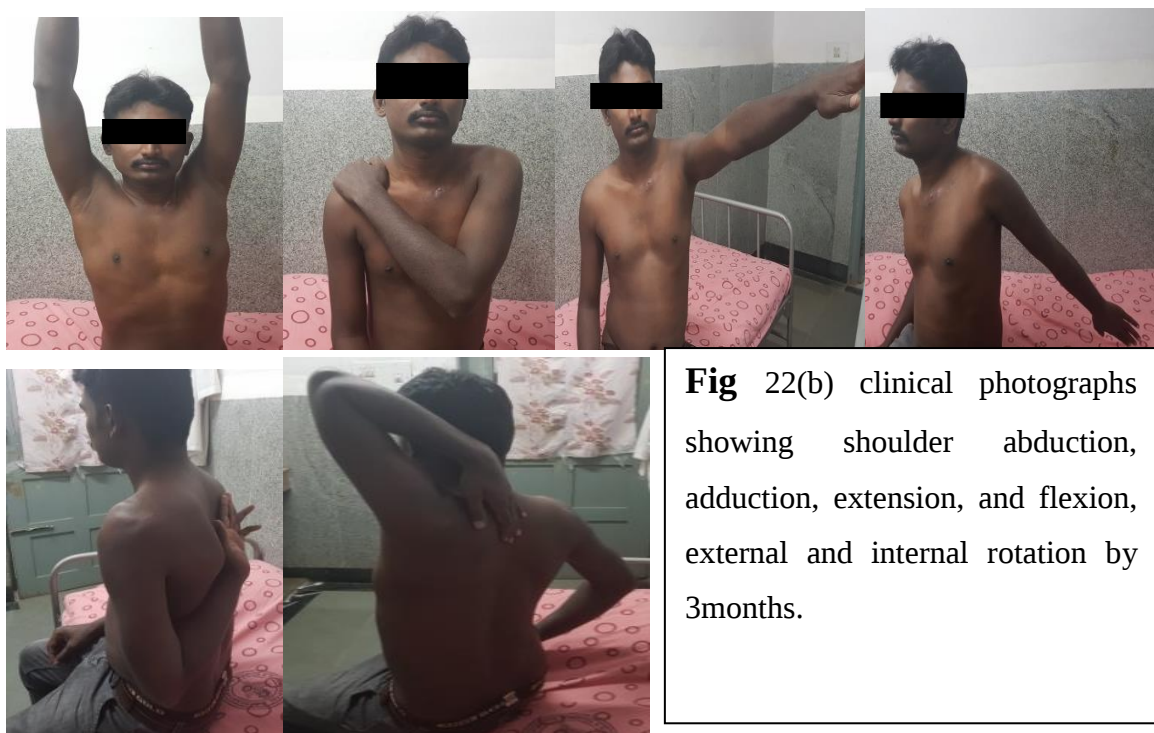
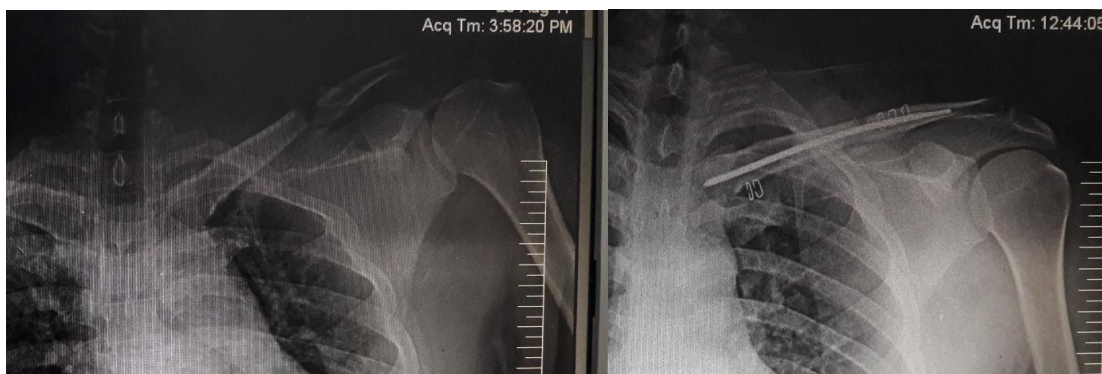


Fig 22(b) clinical photographs showing shoulder abduction, adduction, extension, and flexion, external and internal rotation by 3months.

CASE 3(Delayed Union)



PRE-OP

POST-OP



BY 1 MONTH

BY 3 MONTH

UNION BY 6 MONTHS

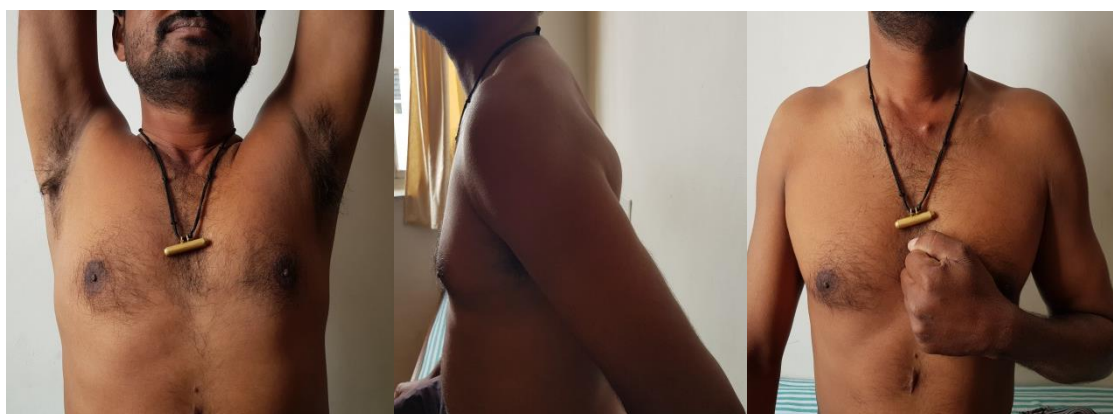
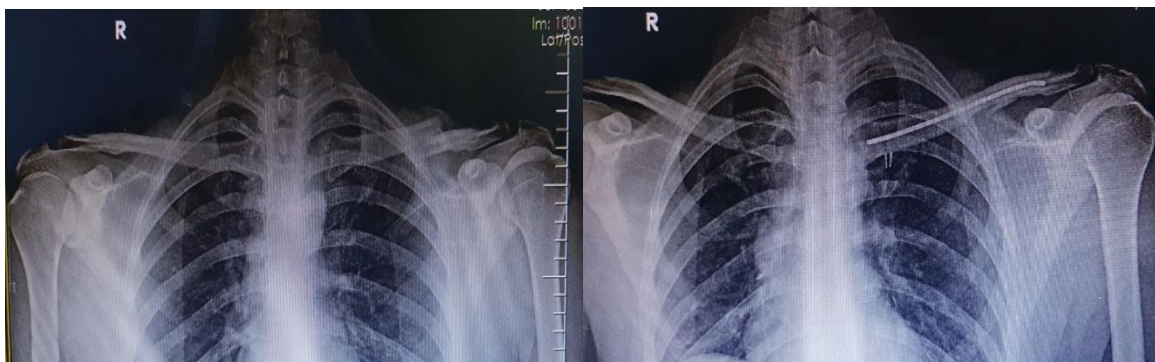


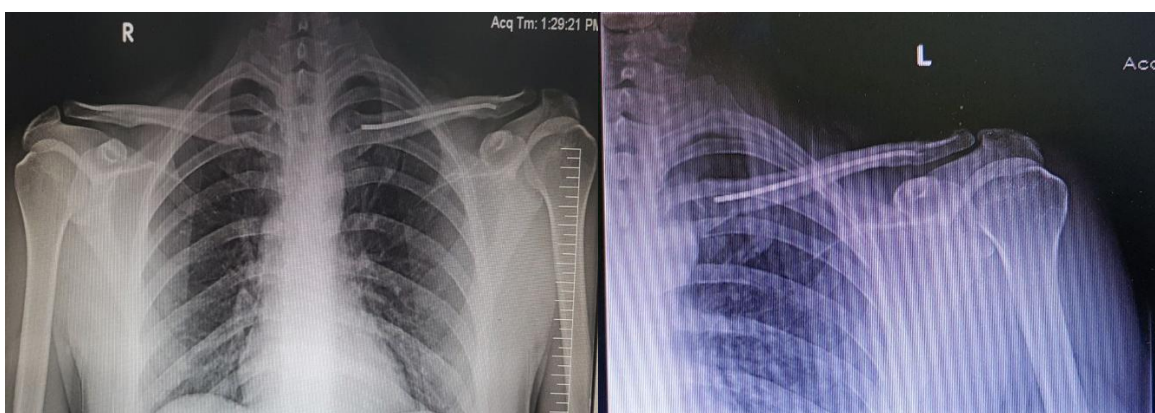
Fig 22(c) Clinical photographs showing shoulder abduction, internal and external rotation.

Case 4: (segmental fracture with fastest union)



Pre-operative x-ray

post-operative x-ray



UNION BY 1 MONTH

FOLLOW UP X-RAY AT 3 MONTH

Fig 22 D

COMPLICATIONS



MEDIAL NAIL PROMINENCE



ENTRY SITE ULCERATION



MEDIAL PROTRUSION OF NAIL



LATERAL PROTRUSION OF NAIL



HEALED SCAR POST IMPLANT REMOVAL

Fig 22 E

DISCUSSION

Clavicle fractures were usually treated conservatively. Rowe et al states that midclavicular fractures are underrated regarding disability and pain especially during the first weeks.⁸ Studies conducted by Hill et al¹⁴, Nordqvist et al⁶⁵, Robinson et al⁶, Suhail Ahmad Bhat et al¹², found poor results following conservative treatment for midshaft clavicle fractures. Following which various methods of fixation methods gained attention and broadly can be divided into two mainly plating and intramedullary nailing techniques (external fixation technique is rarely used).

Currently Locking compression plating is the main stay of treatment among surgical management. However, disadvantages of plating include- need for increased soft tissue stripping and exposure, supraclavicular nerve damage, slightly higher infection rates along with risk of re-fracture after plate removal.¹² Intramedullary nailing with various implants like Rockwood pin, Steinman pin, Knowles pin have been tried but was not effective enough to replace the LCP due to their inferior biomechanical properties. The newest intramedullary device showing similar biomechanical properties to a clavicle is an elastic nail made of titanium. Present study aims to see the outcome following TENS nailing in mid shaft clavicle fractures clinically, radiologically and functionally.

This study with TENS for patients with midshaft clavicle fractures is compared with A) Meier C et al study with 14 cases treated with TENS.³¹ B) Mueller M et al study with 31 cases treated with TENS⁶⁶ and C) Radwan et al where 46 underwent TENS for mid shaft clavicle fractures.⁶⁰

Mechanism of injury:

In our study, majority cases 18 (60%) occurred due to road traffic accidents, 6 cases (20%) as a result of fall on an outstretched hand, 3 cases (10.0%) due to fall and 3 cases (10%) due to direct trauma, whereas in Meier et al study mechanism was a direct injury to the shoulder in 13 patients, 1 patient fell on his extended arm, Ten fractures were caused by road traffic accidents and 4 by sports injuries.³¹ In Mueller et al study, Nineteen patients sustained their fractures in high-energy impact traffic injuries such as car and motorcycle injuries. Eight patients performed sports, one patient attributed his injury to the direct impact of rolling trunks, and two patients fell after a vasovagal syncope.⁶⁶ Radwan et al had 32 cases due to RTA, work related activities was cause for 8, 3 during sport activity and 3 by other causes.⁶⁰

This shows indirect injury caused by road traffic accidents forms the commonest cause of these fractures.

Age Incidence

The average age in our study is 37 years in that 2 cases (6.6%) lie between 18-20 years, 10 cases (33.3%) lie between 21-30 years, 11 cases (36.6%) lie between 31-40 years, 2 cases (6.6%) lie between 41-50 years and 2 cases (6.6%) from 60 and above. In Radwan et al study patients the average patients' age at the time of operation was 36 ± 11 years for group I versus 39 ± 9 years for group II.⁶⁰ In Mueller et al mean age was 40 years (range, 19–66, group 1: 40.2 years, group 2: 39.9 years, group 3: 39.1 years).⁶⁶ Whereas Meier et al had mean age of 28 years (range: 16 to 40).³¹

Thus, we can infer that clavicle midshaft fractures occur in young and active individuals and fixation is better option than conservative method for returning to activity faster.

Sex Distribution:

Male patients formed the majority- 25 cases (83.3%) and only 5 cases (16.6%) were seen in females. In Mueller et al series also there were 24 men and 7 women.⁶⁶ In Meier et al 15 study, 12 men, 2 females.³¹ Whereas in Radwan et al 31 cases were female and 15 were male⁶⁰

Majority of study shows males are more affected and can be attributed to their active lifestyle including regular motor vehicle use.

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.⁶⁷

In this study, there were a total of 16 cases (53.3%) of right sided fracture, and left side was affected in 14 cases (46.6%). In Mueller et al series Fourteen patients had right-and 17 had left-sided injuries.⁶⁶ Similarly, Radwan et al had equal right and left clavicle involvement (23 each).⁶⁰

This shows that clavicle fracture is not affected by hand predominance even though fall on outstretched hand is a major mechanism of injury.

Time interval for surgery:

In 13 cases (43.3%), the time interval before surgery was less than 3 days, 10 (33.3%) cases happened between 3-7 days, whereas in 5 cases (16.6%), surgery was

conducted between 7 to 14 days, and 2 cases (6.6%) after 14 days. In Mueller et al study surgery was performed on average 14.5 days after trauma.⁶⁶ Meier et al conducted surgery on 6th day post trauma.³¹ Radwan et al had a mean time interval of 4.5 days post trauma.⁶⁰

Thus, the results of all four studies are comparable as majority of cases were intervened at similar time interval post trauma.

Associated injuries:

In our study Most of the cases, that is 21 (70%) did not have any associated injury. 6 cases (20%) had ipsilateral lower limb fracture and 3cases (10%) had facial injury as an associated injury. In Mueller et al series in 9 patients the clavicular fracture was an isolated injury.⁶⁶

TABLE 15: - COMPARISON OF DIFFERENT STUDIES ACCORDING TO AGE, SEX AND SIDEAFFECTED TIME INTERVAL, MODE OF REDUCTION AND TIME OF UNION.

	Avg Age (years)	Sex(M/F)	Side (R/L)	Avg. time till surgery (days)	reduction (open/close d)	Avg. time of union (Weeks)
Present study(N=30)	37	25/5	16/14	4.8	24/6	11.1
Mueller et al(N=31)	37.5	24/7	14/17	14.5	15/16	-
Meier et al(N=14)	28	12/2	-	6	7/7	7.7
Radwan et al(N=46)	40	15/31	23/23	4.5	21/25	11.6

Fifteen patients had additional injuries such as long-bone fractures, chest or spine injuries, seven patients had life-threatening injuries like cerebral contusion and/or severe chest, pelvic and blunt abdominal trauma.

Mueller et al suggested that patients with additional injuries of the lower extremity were able to use crutches after intramedullary splinting, enabling early mobilization. This was effective as costs associated with long-term immobilization were reduced. On the other hand, treatment of additional injuries including intensive care of those with multiple injuries and usage of crutches did not affect clavicular healing.⁶⁶

This emphasizes that clavicle fracture should be ruled out in routine and fixation of clavicle with TENS is advantageous in patients with other injuries especially lower limb injuries compared to plating as it can assist in immediate mobilization of patient.

Type of fracture pattern and classification:

All patients with midshaft clavicle fractures were of closed type. 10 cases (33.3%) were simple transverse fracture, 6 (20%) were simple oblique, 3 (10%) were simple spiral fractures, 4 (13.3%) were wedge type, 2 (6.6%) were segmental and 5 (16.6%) were comminuted fractures. According to Robinson classification, there were 19 cases (63.3%) under 2B1 and 7 (23.3%) cases under 2B2, 3 cases (10%) under 2A2 and 1 case (3.3%) under 2A1. Meier et al graded according to the Orthopedic Trauma Association classification (OTA). There were 1 06-A1, 4 06-A2 and 3 06-A3 fractures in our series. Wedge fractures were found in 6 patients (3 06-B2 and 3 06-B3 fractures).³¹

This indicates TENS nailing is successful not only in simple fractures but also in segmental fractures and fractures with mild to moderate comminution.

Nail size:

In this study, majority of nail size used was of size 2.5mm that is in 16 (53.3%) cases followed by 2mm for 12 cases (40%), 3mm size was used for 2 (6.6%) cases. In Meier et al study nail diameters of 2.0 (n = 1), 2.5 (n = 8) and 3.0 mm (n = 5) were used.³¹

Slongo suggests that nail diameter should be between one third and 40% of the medullary space diameter.⁶⁸ We used 2.5mm in majority of cases (53.3%) and 2mm in those in who had narrower canal. In our study there was no incidence of nail breakage like many others. Mueller et al had 2 incidence of nail breakage but had no functional consequence. They further state that the middle third of the clavicle is subjected to considerable tension, bending and torsional forces, and they think that the diameter of the nail should not be less than half of the medullar cavity as rapid pain relief as observed even in our study like theirs may result in premature use of the arm.⁶⁶

Mode of reduction

Majority of surgery needed open reduction. That is in 24(80%) of cases, rest of 6cases (20%) was able to do closed reduction. In Meier et al study closed reduction was possible in 7 cases. A short incision of about 2 cm above the fracture site was necessary to obtain fracture reduction in 7 patients.³¹ Mueller et al had successful closed reduction in 16 patients. In 15 patients, an accessory incision had to be made above the fracture.⁶⁶ For Radwan et al insertion of the TEN in the lateral fragment had to be performed through an additional incision at the fracture site in 21/46 patients.⁶⁰

This shows that achieving closed reduction is difficult and majority requires minimal opening to aid in reductions and is mainly attributed to varied comminution and the S shaped curve of the bone which demands technical expertise.

Hospital stay:

5 cases (16.6%) had to stay in hospital for 3days, 16 cases (53.3%) for 7 days, 8cases (26.6%) till 14days and 1 case (3.3%) had to stay for more than 2 weeks due to

associated injury (bilateral Bell's palsy). In Meier et al study, mean duration of hospital stay was 1.2 days (range: 1 to 3). Twelve patients were treated as day cases.³¹

This clearly shows that this method is minimally invasive and promises faster recovery and return to day to day activities.

Duration of union:

In 8 cases (26.6%), fracture united by the end of 8 weeks, majority cases that is 16 (53.3%) united by end of 12 weeks, 3 (10%) cases took till 16 weeks, 2 (6.6%) cases took 20 weeks whereas for 1 (3.3%) case the union took longer than 20 weeks. Radwan et al observed mean duration for osseous union was 11.6 ± 2 weeks in group I versus 12.8 ± 2.2 weeks in group II ($P=0.07$). All patients, except one patient, achieved adequate osseous union after a mean duration of 11.5 ± 1.8 weeks in group I and 12.8 ± 2.2 weeks in group II.⁶⁰

This indicates majority of cases achieved union within 3 months and hence long term follow up is not essential and thus less cumbersome for the patients.

Complications:

In our study 8 (26.6%) cases had skin irritation at entry site, among that 4 had medial protrusion of nail outside the skin. Of which 3 patients had superficial infection at entry point. Superficial infection resolved by itself with local wound care. 2 patients among the 4 who had medial prominence underwent nail trimming under local anesthesia, after which no further irritation occurred for 1 but the other had loosening of nail and was removed in outpatient department as clavicle was united by then. Incidence of nail loosening, and superficial infection at nail entry site was found in 10% (3 cases) of the cases each. Loosened nail was removed in outpatient department itself, as all cases showed union by the time of loosening. Of the 3 loosened cases, 2 had superficial entry site infection after it protruded

outside the skin and the other had aseptic loosening. All 3 patients who had loosening were those with comminuted fractures, which caused migration of nail medially during fracture consolidation and union. Reaming was done in 2 cases when there was difficulty in engaging the nail into lateral fragment due to narrow medullary canal in their lateral end. Both the cases (6.6%) eventually had lateral protrusion of nail as their lateral cortex was breached during reaming. With this observation, for further cases we used small tapping with impactor or a smaller nail instead of reaming, after which no further incidence of lateral migration of nail was reported. Clavicle is considered to undergo delayed union if no bridging callus was found by 3 months to 6 months post fracture and we had 3 such cases but all united by end of 6 months.

There were no complications of malunion, non-union, nail breakage, hypertrophic scar or shoulder stiffness.

In study by Meier et al also no infection or migration of the Ti nail was observed. All fractures healed, no non-union or delayed union was observed other than premature removal of nail after skin perforation by the protruding medial end due to sport injury. 2 patients had skin irritation above ipsilateral sternoclavicular joint for which medial end of the TEN was shortened under local anesthesia which relieved the skin irritation within days.³¹

Mueller et al had seven patients with medial TEN migration and associated local pain and skin irritation. The nail was shortened in 4 patients. 1 case of lateral migration was also noted which was attributed to cortical breach during surgery. 2 cases of nail breakage were observed in which the lateral part of the nail was left in situ in view of fracture healing. Eight patients had keloid scars, but none objected or underwent plastic surgery for cosmetic reasons, superficial skin infection developed in one patient. This problem was observed only in their first half of series. After appreciating its cause, the medial end of the nail was kept

shorter following which skin irritation was no longer an issue like in our study.⁶⁶ Radwan et al reported 15 cases with skin irritation due to nail prominence medially. Iatrogenic perforation of lateral cortex was reported in 5 cases. Hypertrophic scar, superficial infections were recorded in three patients and all were treated with local care. 1 patient had medial migration of the TEN with medial-prominence and impending skin perforation managed with nail trimming.⁶⁰

Table 16: - Comparison of complications in different studies.

Complication	Present study (%)	Meier et al (%)	Mueller et al(%)	Radwan et al(%)
Entry site skin irritation	26	14	22.5	32.6
Medial protrusion	13.3	-	12.9	2.1
Lateral protrusion	6.6	-	3.2	10.8
Superficial entry site Infection	6.6	-	3.2	6.5
Nail breakage	-	-	6.4	-
Nail loosening	10	-	-	-
Shoulder stiffness	-	-	-	-
Hypertrophic scar	-	-	25.8	6.5
Non-union	-	-	-	2.1
Malunion	-	-	-	-
Delayed union	10	-	-	-

Almost all complications observed were in first half of our study whereas rest half had very few. Similar findings were also observed in other studies as mentioned above and hence surgical technique and experience of surgeon plays an important role not only in fixing the fractures but also in identifying the right case for the procedure.

Functional outcome:

The functional outcome according to Constant score in this study of 30 patients of midshaft clavicle fracture fixed with titanium elastic nailing system showed a total of 25 (83.3%) showed excellent outcome, 4 cases (13.3%) had good outcome and 1 case (3.3%) had a fair outcome, no case had poor outcome by end of 3 months, And at 6 months 27(90%) cases showed excellent result and 3(10%) showed good result.

Meier et al showed that in his study Constant shoulder score averaged 81 (range: 37 to 96) after 7 days and was 96 (range: 85 to 100) after 6 weeks. After 6 months and after hardware removal, all patients (n = 13) presented with basically normal shoulder function (mean: 98, range: 93 to 100).³¹ Mueller et al had Constant Score in group 1 as 91.6 points, in group 2 as 99.0 and in group 3 as 88.6 points whereas Radwan et al at final follow-up, the median Constant score was 92.^{60,66}

Hence, including our study almost all studies compared here show consistently good shoulder scores from first week of postoperative period itself. Our study used simple displaced and mild to moderately comminuted clavicle fractures like other studies compared here and the results of functional outcome give promising evidence on the use of TENS as a surgical option. Thus, titanium elastic nailing system is a reliable and effective option in management of middle third clavicle fractures.

OTHER FINDINGS

Relation between time interval of surgery and mode of reduction

Open reduction was needed in majority of surgery that is 24 (80%) of our cases and other 6 cases (20%) had closed reduction. All 6 cases which underwent closed reduction were operated within 3 days post trauma and operative time increased with increase in delay for

surgery. Clavicle is inherently a bone with high union potential and significant fibrosis occurs even when there is a delay of 1 week necessitating open reduction.

Mode of reduction is also determined by the fracture pattern even though certain studies excluded it.³⁴ In some cases of clavicle fracture which were deemed to be simple based on initial radiographs, were found to be comminuted during surgery. Such incidences pose difficulties while attempting closed reduction as the intra-op fluoroscopic images cannot give a 3-dimensional image, and an inexperienced surgeon will have to struggle to attain closed reduction leading to increased surgery time and soft tissue injury. Hence, it is recommended to do a mini open reduction in case of difficulty in attaining closed reduction, as main advantage of this intramedullary fixation with TENS is to reduce soft tissue injury and surgical time.

In study conducted by Meier et al open reduction was necessary in 4 OTA 06-A fractures. For OTA 06-B fractures 3 open and 3 closed reductions were performed. They observed that when operation was delayed for more than 7 days closed reduction was never achieved suggesting that patients benefit from an early intervention with better chances for successful closed reduction. In their study mean operation time was 62 minutes. Operation time was much shorter when closed reduction was successful compared with the open technique 39 minutes vs. 84 minutes.³¹ Mueller et al observed that surgery performed a couple of days after trauma always required an additional incision because of soft callus tissue interposition and closed reduction was prevented.⁶⁶

Importance of lateral cortex

Our study had 2 occurrences of lateral protrusion of nail and in both cases; we did reaming with k-wire for the lateral end of clavicle which had very narrow canal. So, we attributed it to the same. Further no cases were reamed instead used either small tapping with

impactor or a smaller nail (2mm). Following which similar complication were never encountered.

In study conducted by Mueller al in one case the dorsolateral cortex was perforated when the TEN was advanced to the lateral clavicular end using a hammer with force. As this problem was realized during the procedure the Titanium nail was withdrawn a few centimeters and repositioned. Hence, they also do not recommend using a hammer anymore instead a smaller implant was chosen advanced using oscillating movements only.⁶⁶

Implant removal

Twelve patients in our study underwent implant removal and all were removed under local anesthesia except for 4 patients who needed no anesthesia as implant was protruding medially. No patient had any occurrence of re-fracture and all were able to continue their occupation and day to day activity. Radwan et al removed the nail in 11 patients within 18 to 56 weeks after implantation as day cases.⁶⁰ Mueller et al removed TENS in 29 patients. Both studies also didn't report any case of re-fracture.⁶⁶

Other complications:

None of our cases had non-union. In study by Mueller et al only one non-union was observed and one secondary shortening of 1.5 cm in a comminuted fracture case.⁶⁶ Radwan et al observed 5 cases of malunion which did not affect the functional outcome.⁶⁰ No case of implant failure was observed in any of these studies other than Mueller et al who had 2 cases of implant breakage.⁶⁶

CONCLUSION

TENS is a new and technically more demanding surgical technique, especially to achieve closed fracture reduction, which gives the advantage of maintaining an intact fracture hematoma, less soft tissue injury which speeds up fracture healing. Even when open reduction of fracture was performed, surgical incisions were smaller in comparison with plate fixation, resulting in improved cosmetic results, lower infection rates and minimal soft tissue and periosteal stripping thereby enhancing bony union. Our study results were identical to the results of other studies suggesting that intramedullary fixation using TEN is an effective and reliable method for the management of midshaft clavicular fractures which are displaced or even to fractures with mild to moderate comminution. It gives good cosmetic and functional results with minimal morbidity and complications.

Compared with the current practice for plating, intramedullary fixation offers several advantages; it acts as an internal splint at the fracture site. We observed the following advantages: shorter operative time, smaller wound incision, minimal scarring, early rehabilitation, early return to work, less pain level, less analgesic use, less symptomatic hardware, and the ability to remove the implant under local anesthesia thereby reduce the need for another major surgery. Moreover, it provides biological fixation while preserving soft tissue and the periosteal blood supply. The healing process occurs through external bridging callus through intramembranous bone formation.

Patient counseling is essential, and they must be informed about the following surgical risks and complications: need for open reduction, migration of the nail, secondary shortening. The complications incurred could be reduced by: early surgery, advancing the nail by hand, proper case selection, proper nail selection, effective fluoroscopic use,

limitation of the elevation of the arm to 90 degree up till third postoperative week and hardware removal 6 months after surgery.

During this study it was observed that no literature has mentioned any complications like intrathoracic migration, lung injury, brachial plexus injury following this surgery even though general fear among the surgeons still exist.

Hence, this study proves that TENS should not only be considered a reliable secondary option for displaced midshaft clavicle fracture but also as a primary option for midshaft clavicle fracture with displacement more than 2cm as well as in cases with mild to moderate comminution instead of conservative method or current practice of LCP fixation especially in patients with high demand on shoulder function, as this is a minimally invasive procedure which can restore clavicle length along with early resumption of training, faster functional recovery and good cosmetic result.

SUMMARY

Thirty patients with middle third clavicular fractures were treated surgically with closed/open reduction and internal fixation with intramedullary nail using Titanium Elastic Nailing System (TENS) between October 2017 and November 2018.

Patients age ranged from 18 to 65 years and those above 18 years were excluded from this study and 18 to 40years is the commonest age group for middle third clavicle fracture. Majorities were males (83.3%) and the cause was RTA in most of the patients (60%). Majority of patients were under 2B1 group in Robinson classification and had simple transverse or oblique fractures (53.3%), 2(6.6%) were segmental and 5(16.6%) were comminuted fractures. Our study had almost equal number of right and left sided patients.

For all patients, surgery was done under general anesthesia with titanium elastic nailing system using closed or mini open reduction for middle third clavicular fractures. Almost 77% of cases were operated within 1-week post trauma. Majority of surgery needed open reduction in our study 24(80%) and rest had closed reduction. We used nail of size of 2.5mm in 16(53.3%) cases and 2mm for 12 cases(40%). 66.6% of case united clinically and radiologically by 3 months and all were united by 6 months. 3cases showed delayed union, no cases showed non-union. 70% of patients returned home within 1 week.

Rehabilitation of the affected limb was started immediately according to patient tolerance except for those with comminuted fracture for whom we started by second week. Gentle shoulder pendulum exercises with the limb supported by arm pouch were allowed first. By 3 weeks gentle active shoulder movements were allowed with abduction limited to 90 degrees. By 1-month full active shoulder movements were allowed in all planes, but not allowed to lift weight or do exertional activities with the affected arm.

The functional outcome assessment according to Constant and Murley score⁵⁴ showed excellent outcome in 25 patients (83.3 %) and good outcome in 4 patients (20 %) and 1 fair functional outcome (3.3%) by 3rd month end and by end of 6th month 27 (90%)cases showed excellent result and rest 3 (10%) showed good result.

In 3 cases (10%) superficial infection at nail entry site was noted. 2 cases (6.6%) of nail loosening, 2 cases (6.6%) of lateral protrusion of nail, 4 cases (13.3%) showed medial protrusion of nail. Most common complication like in all other studies was medial entry site skin irritation 8 (26.6%). There were no complications of malunion, non-union, nail breakage, hypertrophic scar or shoulder stiffness.

STUDY LIMITATIONS

- The conclusions drawn from this analysis cannot be generalized because of the small number of cases.
- This study is not a comparative study.
- Our patients were followed up for 3 to 6 months, and a longer follow up will throw more light on the long-term results and complications.

BIBLIOGRAPHY

1. Court-Brown CM, Heckman JD, McQueen MM, Ricci W, Tornetta P, McKee M. Rockwood and Green's fractures in adults. 8th Ed. Philadelphia: Wolters Kluwer; 2015. 1427-1470p.
2. Hulsmans MHJ. Operative treatment of displaced clavicle fractures: optimising implant choice: 509895-L-bw-Drukbedrijf, 2017.
3. 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.
4. 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. doi: 10.1016/S0020-1383(99)00312-5.
5. 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.
6. 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.
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.

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. McKee MD, Wild LM, Schemitsch EH. Midshaft malunion of the clavicle. J Bone Joint Surg Am. 2003; 85:790-7.
12. Suhail AB, Khursheed AB, Sanjeev G, Mohd SL, Abedullah B, Nadeem A. Changing Trends In Management Of Adult clavicular Fractures. IJAR. 2014; 6:843-849.
13. Kettler M, Schieker M, Braunstein V, König 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.
14. 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.
15. McKee MD, Pedersen EM, Jones C, Stephen DJ, Kreder HJ, Schemitsch EH, Wild LM, Potter J. Deficits following non-operative treatment of displaced midshaft clavicular fractures. J Bone Joint Surg Am. 2006; 88:35-40.
16. Constant CR, Murley AHG. A clinical method of functional assessment of the shoulder. Clinical Orthopaedics and Related Research. 1987; 214: 160-164.
17. Standring S. Gray's Anatomy: Elsevier; 2016 (41): 799-811p.

18. 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.
19. 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.
20. Moseley HF. Shoulder lesions. Edinburgh: Churchill Livingstone; 1972.207-235p.
21. Moore KL, Dalley AF, Agur AMR. Clinically oriented anatomy. 6th ed. Lippincott Williams & Wilkins; 2009.673-675p.
22. 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.
23. Robinson's CM. Fractures of the clavicle in the adult. Epidemiology and classification. J Bone Joint Surgery (Br).1998; 80: 476-484.
24. 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].
25. 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
26. Khalil A. Intramedullary screw fixation for midshaft fractures of the clavicle. Int Orthop. 2009; 33:1421–4.

27. Ligier JN, Metaizeau JP, Prevot J. Closed flexible intramedullary nailing in paediatric traumatology. *Chir Pédiatr.* 1983; 24: 283-285.
28. Saini M, Singh Y, Arora P, Arora V, Jain K. Implant biomaterials: A comprehensive review. *World J Clin Cases.* 2015; 3(1):52-7.
29. Tschernitschek h, borchers l, geurtsen w. Non-alloyed Titanium as a bioinert metal--a review. *Quintessence int.* 2005; 36: 523-530.
30. 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.
31. Meier C, Grueninger P, Platz A. Elastic stable intramedullary nailing for midclavicular fractures in athletes: Indications, technical pitfalls and early results. *Acta Orthop. Belg.,* 2006; 72: 269-275.
32. 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.
33. 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.
34. 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

35. Ruedi T, Duwelins PJ. Fractures and dislocations of the shoulder girdle and humerus. Chapter-15, In: Chapman MW, editor, Chapman's orthopaedic Surgery.3rd ed. Philadelphia: Lippincott Williams and Wilkins; 2001. 444-450.
36. Jupiter JB, Ring D. Fractures of the clavicle. Chapter- 26, In: Iannotti JP and Williams GR. editors. Disorders of the Shoulder diagnosis and Management. Philadelphia: Lippincott Williams and Wilkins; 1999.709-786.
37. Robinson CM, Goudie EB, Murray IR, Jenkins PJ, Ahktar MA, Read EO et al. Open Reduction and Plate Fixation Versus Non operative Treatment for Displaced Midshaft Clavicular Fractures,J Bone Joint Surg Am.2013;95:1576-84.
38. Smekal V, Irenberger A, Struve P, Wambacher M, Krappinger D, Kralinger FS. Elastic stable intramedullary nailing versus nonoperative treatment of displaced midshaft clavicular fractures-a randomized, controlled, clinical trial. J Orthop Trauma. 2009; 23(2):106-112. doi: 10.1097/BOT.0b013e318190cf88 [doi].
39. Millett PJ, Hurst JM, Horan MP, Hawkins RJ. Complications of clavicle fractures treated with intramedullary fixation. J Shoulder Elbow Surg. 2011; 20(1):86-91. doi: 10.1016/j.jse.2010.07.009 [doi].
40. Wijedicks FJ, Houwert M, Dijkgraaf M, de Lange D, Oosterhuis K, Clevers G, Verleisdonk EJ, "Complications after plate fixation and elastic stable intra- medullary nailing of dislocated midshaft clavicle fractures: a retrospective comparison". Int Orthop.2012; 36(10):2139-45.
41. Frigg A, Rillmann P, Ryf C, Glaab R, Reissner L. Can complications of titanium elastic nailing with end cap for clavicular fractures be reduced? Clin Orthop Relat Res. 2011; 469(12):3356-3363. doi: 10.1007/s11999-011- 1845-7 [doi].

42. 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.
43. Gaudinez RF, Hoppenfeld S. Clavicle fractures. Chapter-10 In: Hoppenfeld S, Murthy VL, editors. Treatment and Rehabilitation of fractures. Philadelphia: Lippincott Williams and Wilkins; 2000.73-84.
44. Jupiter JB, Leffert RD. Non-union of the clavicle. Associated complications and surgical management. J Bone Joint Surg Am. 1987; 69:753-60.
45. 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.
46. 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.
47. Houwert RM, Smeeing DP, Ahmed Ali U, Hietbrink F, Kruyt MC, van der Meijden OA. Plate fixation or intramedullary fixation for midshaft clavicle fractures: A systematic review and meta-analysis of randomized controlled trials and observational studies. J Shoulder Elbow Surg. 2016; 25(7):1195-1203. doi: 10.1016/j.jse.2016.01.018 [doi].
48. Smeeing DP, van der Ven DJ, Hietbrink F, et al. Surgical versus nonsurgical treatment for midshaft clavicle fractures in patients aged 16 years and older: A systematic review, meta-analysis, and comparison of randomized controlled trials and observational studies. Am J Sports Med. 2016. doi: 0363546516673615 [pii].

49. Woltz S, Stegeman SA, Krijnen P, et al. Plate fixation compared with nonoperative treatment for displaced midshaft clavicular fractures: A multicenter randomized controlled trial. *J Bone Joint Surg Am.* 2017; 99(2):106-112. doi: 10.2106/JBJS.15.01394 [doi].
50. Wajid MA, Sarwar MU. Out Come of Mid 1/3rd Clavicular Fractures after Open Reduction and Internal Fixation. 2014; 26:134-13.
51. 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.
52. 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
53. 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].
54. 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
55. Wijdicks FJ, Van der Meijden OA, Millett PJ, Verleisdonk EJ, Houwert RM. Systematic review of the complications of plate fixation of clavicle fractures. *Arch Orthop Trauma Surg.* 2012; 132(5):617-25.

56. Bostman O, Manninen M, Pihlajamaki M. Complications of plate fixation in fresh displaced midclavicular fractures. *J Trauma*.1997; 43(5), 778–783.
57. 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.
58. Canadian Orthopedic Trauma Society. Nonoperative 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.
59. 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; 22:448-55. [http://dx.doi.org/ 10.1007/s00167-013-2411-5](http://dx.doi.org/10.1007/s00167-013-2411-5).
60. Yasser R, Ali M, Walid B, NasefN. Outcome of elastic stable intramedullary nailing of displaced midshaft clavicular fracture: does the presence of fracture comminution differ? *Egypt Orthop J*.2017; 52:18–25.
61. 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.
62. 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.

63. Saha P, Datta P, Ayan S, Garg AK, Bandyopadhyay U, Kundu S. Plate versus titanium elastic nail in treatment of displaced midshaft clavicle fractures A comparative study. *Indian J Orthop.* 2014; 48:587-93.
64. Rocourt MH, Radlinger L, Kalberer F, Sanavi S, Schmid NS, Leunig M, Hertel R. Evaluation of intratester and intertester reliability of the Constant-Murley shoulder assessment. *J Shoulder Elbow Surg.* 2008 Mar-Apr;17(2):364-9.
65. Nordqvist A, Petersson CJ, Redlund-Johnell I. Mid clavicular fractures in adults: end result study after conservative treatment. *J Orthop Trauma.* 1998; 12: 572-576.
66. Mueller M, Rangger C, Striepen N, Burger C. Minimally Invasive Intramedullary Nailing of Midshaft Clavicular Fractures Using Titanium Elastic Nails. *J Trauma.* 2008; 64:1528–1534.
67. Teodoro Ezequiel Guerra M, Isabel Pozzi M, Busin G, Crestana Zanetti L, Antônio Lazzarotto Terra Lopes J, Orso V. Densitometric study of the clavicle: bone mineral density explains the laterality of the fractures. *Rev Bras Ortop.* 2014; 49(5):468-72. doi:10.1016/j.rboe.2014.07.002
68. Slongo TF. Complications and failures of the ESIN technique. *Injury.* 2005; 36:78–85.
69. Andermahr J, Jubel A, Elsner A, Johann J, Prokop A, Rehm KE, et al. Anatomy of the clavicle and the intramedullary nailing of midclavicular fractures. *Clin Anat (New York).* 2007; 20(1):48–56.

ANNEXURE-I

PROFOMA

DATE:

Name : Case no :

Age : Ip/op no :

Sex : Address :

Date of admission: Date of discharge:

Date of injury: Date of surgery:

Chief complaints :

History of presenting illness :

Mechanism of injury:

- i) Fall on shoulder
- ii) Direct injury to shoulder
- iii) Fall on out stretched hand
- iv) Road traffic accident

Duration of injury to surgery: days/months

Mode of presentation: Nil :
Splint:

Past history : Medical:

Surgical:

Family history:

Personal history:

General physical examination:

Vital signs

BP - PR -
RR - Temp -

Systemic examination

1. CVS 3.CNS
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:

Clinical Diagnosis:

INVESTIGATIONS

Hb: blood group: Serum urea: Creatinine:

Na+: K+: Cbc: hiv: Hbsag:

- X-ray examination:
 - Side of clavicle involved:
 - Type of fracture:

DIAGNOSIS:

MANAGEMENT

IMMEDIATE MANAGEMENT

IV fluids:

Analgesics:

Blood transfusion:

Splintage:

Method:

Duration:

SURGICAL MANAGEMENT:

- Surgery
- Duration of surgery:
- Surgical approach:
- Reduction (open or closed):
- Implant used with exact dimensions:

Date of surgery:

anesthesia:

Intraoperative complications:

Post op period:

Antibiotics:

Analgesics:

Check x-rays:

Splintage:

Complications:

Revision procedures:

Secondary procedures:

7) FOLLOW UP:

		Discharge	3weeks	6weeks	3 months
PAIN					
CONSTANT SCORE					
MOVEMENTS OF SHOULDER GIRDLE	Abduction-				
	Adduction-				
	Flexion-				
	Extension-				
	IR-				
	ER-				
X-RAY FINDINGS	Union- Superior cortex Inferior cortex				
	Callus-				
	Nail migration-				
	Nail breakage-				
	Malunion-				
	Shortening-				
	Displacement-				
	Other findings:				

ASSESSMENT OF RESULTS:

By Constant and Murley scoring grading is done as follows

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

ANNEXURE-II

CONSENT FORM

I/WE THE PATIENT ATTENDERS HAVE BEEN EXPLAINED ABOUT THE PATIENTS CONDITION AND THE NEED FOR THE PROCEDURE. THESE PROCEDURES AND COMPLICATIONS HAVE BEEN EXPLAINED TO ME IN MY OWN UNDERSTANDABLE LANGUAGE. I AM WILLING TO PAY FOR THE PROCEDURE AND THE TREATMENT. I/WE.....G/O..... IN MY FULL SENSES GIVE MY CONSENT TO TAKE PART IN ABOVE MENTIONED STUDY WHICH INCLUDES MONTHLY EVALUATION OF OPERATED SITE. I DON'T HOLD ANY TREATING DOCTOR, NURSING STAFF AND HOSPITAL MANAGEMENT FOR ANY UNTOWARD CONSEQUENCES. I HERE BY GIVE MY CONSENT FOR PARTICIPATING IN THE STUDY.

SIGNATURE OF THE PATIENT:

DATE:

Name :
Designation:

Guardian
Relationship
Full address

PATIENT INFORMATION SHEET

STUDY TITLE:

A Prospective study of Functional outcome of midshaft clavicle fracture treated with TENS

STUDY SITE:

R .L Jalappa hospital, Tamaka, Kolar.

AIM:

1. To determine the functional outcome of clavicle shaft fractures treated with open reduction internal fixation with TENS using CONSTANT scoring.
2. To study the technical difficulties and complications of Clavicle shaft fractures treated surgically with TENS.

SAMPLE SELECTION:

Skeletally mature patients with displaced midshaft clavicle fracture will be selected. Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in this study we will collect information (as per proforma) from you. Routine and relevant blood investigations, radiological investigation will be carried out if required. This information collected will be used for dissertation and publication only.

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

For any further clarification you can contact the study investigator:

Dr. SREEJITH THAMPY J
Mobile no: 9495915545
E-mail id: jsthampy@gmail.com

Sl no	Hosp no	age	sex	Mode of injury	Side	Robinson classification	fracture type	Associated injury	Time interval	Reduction	Size of nail	union time (in weeks)	hospital stay(days)	Supp. infection	mal union	Non union	Distal nail migration	proximal Nail migration	shoulder stiffness	Nail breakage	Nail loosening	Delayed union	nail removed	score at discharge	score at 1 month	score at 3 month	Outcome by 3 months	score at 6 month	Outcome by 6 months
1	431281	34	M	RTA	R	2B1	simple	nil	2	open	3.5	12	10	+	-	-	-	+	-	-	+	-	+	72	78	84	Good	92	Excellent
2	436694	55	M	RTA	R	2A2	spiral	nil	2	open	3	12	8	+	-	-	-	+	-	-	+	-	+	68	72	78	Fair	86	Good
3	445986	40	M	FALL	L	2B1	simple	L	19	open	2.5	8	14	-	-	-	+	-	-	-	-	+	78	84	92	Excellent	100	Excellent	
4	448302	40	M	FALL	L	2B1	simple	nil	1	open	2	20	5	-	-	-	-	-	-	-	+	+	82	86	94	Excellent	100	Excellent	
5	446182	24	M	FALL	L	2B1	spiral	L 5th	8	open	2.5	4	7	-	-	-	-	+	-	-	-	+	80	86	92	Excellent	100	Excellent	
6	465207	65	F	RTA	R	2B1	oblique	nil	1	open	2	8	5	-	-	-	-	-	-	-	-	-	74	82	90	Excellent	96	Excellent	
7	478436	33	M	RTA	L	2B2	commin	nil	1	open	2.5	16	10	+	-	-	-	+	-	-	-	-	+	72	76	82	Good	90	Excellent
8	486194	50	M	RTA	L	2B1	commin	nil	1	open	2.5	5	7	-	-	-	+	-	-	-	-	+	70	86	94	Excellent	100	Excellent	
9	503832	34	M	RTA	L	2B2	segment	nil	1	open	2.5	4	7	-	-	-	-	-	-	-	-	-	70	84	98	Excellent	100	Excellent	
10	524587	23	M	RTA	L	2B1	oblique	L	5	open	2.5	20	14	-	-	-	-	-	-	-	+	-	70	88	94	Excellent	100	Excellent	
11	50435	29	F	RTA	L	2B1	spiral	L	5	close	2	10	14	-	-	-	-	-	-	-	-	-	66	74	80	GOOD	88	Good	
12	533419	35	M	RTA	L	2B1	spiral	nil	5	close	2	12	3	-	-	-	-	-	-	-	-	+	80	88	92	Excellent	100	Excellent	
13	53396	39	M	RTA	R	2B2	oblique	nil	1	open	2.5	8	5	-	-	-	-	-	-	-	-	+	82	86	94	Excellent	100	Excellent	
14	535969	65	F	RTA	R	2B1	oblique	R TIB	3	open	2.5	24	14	-	-	-	-	-	-	-	+	-	68	74	82	Good	88	Good	
15	536303	25	M	FALL	R	2B1	Simpl	nil	6	open	2	12	5	-	-	-	-	-	-	-	-	-	78	90	96	Excellent	100	Excellent	
16	535955	55	M	RTA	R	2B1	Simpl	facial bone	9	open	2.5	16	7	-	-	-	-	-	-	-	-	-	74	90	94	Excellent	100	Excellent	
17	550413	55	M	RTA	R	2B2	segment	Metacarpal	9	open	2	12	7	-	-	-	-	-	-	-	-	+	88	88	94	Excellent	100	Excellent	
18	552104	18	M	FALL	R	2B1	simple	nil	17	open	2	12	3	-	-	-	-	-	-	-	-	-	84	92	96	Excellent	100	Excellent	
19	55548	28	M	RTA	R	2A1	simple	mand	6	open	2	8	7	-	-	-	-	-	-	-	-	-	78	90	94	Excellent	100	Excellent	
20	55391	45	M	RTA	R	2B1	commin	nil	12	open	2.5	4	5	-	-	-	-	-	-	-	-	+	76	88	92	Excellent	100	Excellent	
21	56447	31	M	RTA	R	2B1	Spiral	Nil	1	Close	2.5	12	5	-	-	-	-	-	-	-	-	-	84	90	96	Excellent	100	Excellent	
22	56983	23	M	RTA	L	2B1	Spiral	Nil	3	Open	2	4	3	-	-	-	-	-	-	-	+	+	82	92	96	Excellent	100	Excellent	
23	56961	35	F	RTA	R	2B2	Com	Nil	3	Open	2	16	7	-	-	-	-	-	-	-	-	-	74	86	90	Excellent	100	Excellent	
24	57187	48	M	FALL	L	2B2	Com	Nil	6	Open	2	12	10	-	-	-	-	-	-	-	-	-	74	84	92	Excellent	100	Excellent	
25	57367	28	M	RTA	R	2A2	Simpl	nil	1	Close	2.5	3	3	-	-	-	-	-	-	-	-	-	84	88	94	Excellent	100	Excellent	
26	572377	40	M	RTA	R	2B2	COMMIN	B/L Bel	10	Open	2.5	3	16	-	-	-	-	-	-	-	-	-	80	90	94	Excellent	100	Excellent	
27	57494	30	F	RTA	L	2A2	Simpl	Nil	1	Open	2	8	5	-	-	-	-	-	-	-	-	-	72	86	92	Excellent	100	Excellent	
28	57700	38	M	RTA	R	2B1	Oblique	Nil	1	Close	2.5	8	3	-	-	-	-	-	-	-	-	-	74	86	94	Excellent	100	Excellent	
29	57983	21	M	RTA	L	2B1	Simpl	Nil	3	Close	2.5	12	5	-	-	-	-	-	-	-	-	-	76	90	96	Excellent	100	Excellent	
30	58769	26	M	RTA	L	2B1	Simpl	Nil	2	Open	2.5	4	5	-	-	-	-	-	-	-	-	-	80	92	96	Excellent	100	Excellent	