"ONE YEAR HOSPITAL BASED PROSPECTIVE STUDY OF TENS INTRA-MEDULLARY NAILING IN MIDSHAFT CLAVICLE FRACTURES"

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IN

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LIST OF ABBREVIATIONS	
AC	Acromio-clavicular
ADL	Activities of daily living
AO	Association of osteosynthesis
DASH	Disabilities of the arm, shoulder and hand
ECG	Electrocardiogram
ER	External rotation
ESIN	Elastic stable intra-medullary nailing
EX-FIX	External fixation
FFH	Fall from height
FOOSH	Fall on out stretched hand
HIV	Human immunodeficiency virus
IR	Internal rotation
LCP	Locking compression plate
ORIF	Open reduction internal fixation
OSS	Oxford shoulder score
OTA	Orthopaedic trauma association
ROM	Range of motion
RTA	Road traffic accident
SCM	Sternocleidomastoid
SD	Standard deviation
TEN	Titanium elastic nailing
TENS	Titanium elastic nailing system

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“ONE YEAR HOSPITAL BASED PROSPECTIVE STUDY OF TENS INTRA-MEDULLARY NAILING IN MID SHAFT CLAVICLE FRACTURES”

ABSTRACT

BACKGROUND: Clavicle fractures are common injuries in young and active individuals, especially those who participate in sports where high-speed falls (e.g., bicycling, motorcycles) or violent collisions (e.g., Football, hockey) are frequent, whereas in children and elderly they are related to falls, and they account for approximately 2.6% of all fractures. The most common site of fracture in the clavicle occurs at the middle third and which accounts for almost 80% of all clavicle fractures.

AIM: To explain the faster pain relief, early return of function and restitution of clavicle length with the help of reduction and internal fixation of clavicle fracture creating an elastic stability at the fracture gap.

MATERIALS AND METHODS: 32 patients presenting with mid shaft clavicle fractures in department of orthopaedics, KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre and Charitable Hospital, were included in this study after taking their consent and fracture was stabilized using TENS nail.

RESULTS: In this study, it was noted that males were predominantly involved, maximum incidence between 20-30 years. Most of the cases had RTA as a mode of injury with right clavicle fracture predominance. Post operatively, patients were followed up and OSS score was calculated at 4, 8, 16 weeks and the improvement in OSS score was found to be statistically significant.

CONCLUSION: We concluded that intramedullary fixation of displaced mid shaft clavicle fractures is a safe minimally invasive technique and is recommended in view of faster union, lesser morbidity, earlier rehabilitation and fewer complications.

Keywords: mid shaft clavicle, TENS nail, intramedullary fixation.

INTRODUCTION

Clavicle fractures are commonly seen in young population, notably in those who are more active in sports, on the contrary, in elderly and children they are attributed mostly to falls, accounting for around 2.6% of all the fractures. [1,2,3].

Previous studies were of the opinion that displaced clavicle shaft fractures were a typically benign injury with an intrinsically good prognosis even on conservative treatment. [4,5]

Neer et al, in a study described a 0.1% non-union rates during conservative management[4] , whereas in 1968 Rowe mentioned 0.8% non-union in non-surgically treated patients.[6] Afterwards, different other studies were not able to conclude similar satisfactory results with fractures managed conservatively. [7,8]

Zlowodzki et al, in his meta-analytical study of literature over a period of 30 years from 1975 to 2005, observed 15.1% rate of non-union in conservatively managed patients with displaced fracture of midshaft clavicle.[9]

15% rates of non-union and > 2cms of shortening was reported by Hill et al when treated conservatively, whereas 31% of the patients in his study were not convinced with the outcomes. [10]

High tricortical union with low uneventful post operative period have been described after using various methods of fixation in displaced fractures, intra-medullary methods being the preferred one.

To avoid the rates of non-union, delayed union or any other complications per se, titanium elastic nailing system has been advocated for displaced fractures of middle 1/3rd of clavicle.

AIM OF THE STUDY

To explain the faster pain relief, early return of function and restitution of clavicle length with the help of reduction and internal fixation of clavicle fracture creating an elastic stability at the fracture gap.

REVIEW OF LITERATURE

In a study done by Hill et al., 52 cases of middle 1/3rd clavicle fractures were treated conservatively out of which 16 cases were not satisfied with results. Fractures with 2 cm of initial shortening revealed significantly high non-union rates with unsatisfactory results. Final outcomes were not affected by any other factors like fracture pattern, patient and treatment related factors. [7]

Fracture related factors like complete displacement, skin tenting and more than 2 cm of shortening were indicative of surgical intervention. Other factors for surgery included associated injuries to the adjacent neurovascular structures, floating shoulder. Open reduction with clavicle plate fixation has been considered as mainstay of treatment. [11]

In 1950, Peronei described intramedullary fixation for the first time for fracture of the clavicle. 72% and 57% respective reduction in relative risk for non-union was seen during a systematic review when compared between surgical and non-surgical management groups. [9]

Certain merits have been identified with intra-medullary implant usage such as small incision with minimal dissection of the soft tissues, relative stability encouraging copious formation of callus.[12]

An added benefit of this implant is that it provides 3-point fixation within the bone. [11,13]

Chen et al studied 2 groups of patients with clavicular fractures managed surgically using extra and intra-medullary implants, which significantly showed lesser union time in nailing group but insignificant association in respect to malunion and non-union rates.

Significantly good outcomes, with respect to union, cosmesis, function, were seen in cases managed with TENS. [14]

Smekal et al. showed excellent results in his trial, which included patients treated with nail, with respect to union rate (100%), and good DASH and constant scores. [10]

ANATOMY

SURGICAL ANATOMY

Clavicle, being one of the thinnest bones in human body, is wider at its lateral and medial ends. Medial and lateral articulation includes sternum and acromion process, respectively.

Two definite curves seen in clavicle are, the convex medial curve and the concave lateral curve, giving the bone its unique S shape.

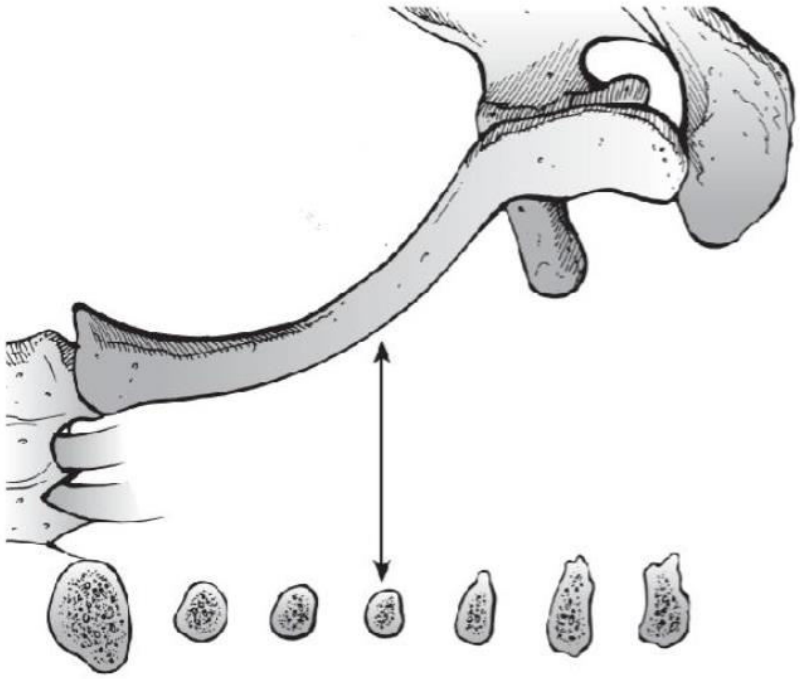

FIG-1: Gross anatomy

ANATOMY OF LIGAMENTS:

MEDIALLY:

Sterno-clavicular capsule- binds clavicle to the sternum owing to the medial stability. Antero-posterior stability to the bone is primarily given by the thickened posterior capsule.

Inferior stability of bone is provided by inter-clavicular ligamentous structures, which runs between the medial ends of the bone on either side.

Additional support is provided by the strong ligaments holding the first rib and clavicle together.

Translation of the sternal end of the bone is additionally prevented by rhomboid fossa infero-medially, which acts as an insertional point of the above mentioned ligaments.

LATERALLY:

Conoid and Trapezoid are the two ligaments, medial and lateral respectively, anchoring the clavicle to the coracoid process by inserting into their respective tubercles.

Primary function of these two soft tissue structures is to prevent superior migration of the clavicle.

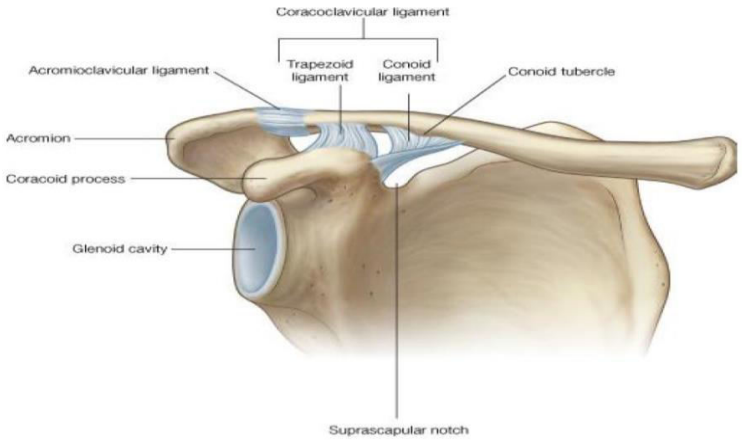

FIG-2: Lateral ligamentous complex

MUSCULATURE AROUND CLAVICLE:

Pectoralis major muscle originates from the antero-inferior border of this bone while the superior border gives origin to sternocleidomastoid muscle.

Pectoralis major fibers merges with the anterior part of deltoid fibers at the lateral part and superiorly, the fibers of trapezius blends with the deltoid fibers origin.

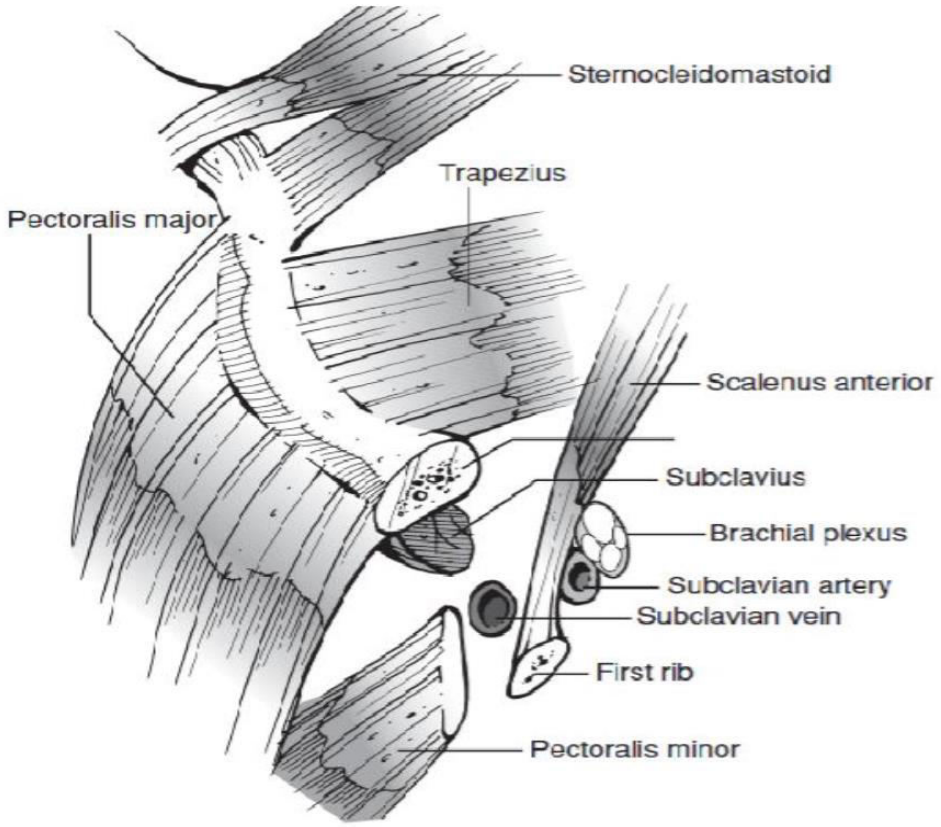

FIG-3: Musculature around clavicle

Subclavius muscle inserts at the inferior border of the clavicle giving a cushioning effect in the sub-clavicular space. Brachial plexus and subclavian vessels lies inferior to the subclavius muscle.

NEUROVASCULAR BUNDLES AROUND CLAVICLE:

One of the most important structures arising from the cervical plexus, anterior to clavicle, is the supra-clavicular nerves.

These structures are to be isolated by thorough dissection while operating on clavicle fractures, especially in the middle third shaft as evidenced by Jupiter and Ring et al. [15]

Inferior border of clavicle harbors some vital structures including the subclavian vein, over which lies the subclavius muscle and the 1st rib.

Medially lies scalenus anterior muscle which protects posteriorly lying structures, namely, brachial plexus and subclavian artery.

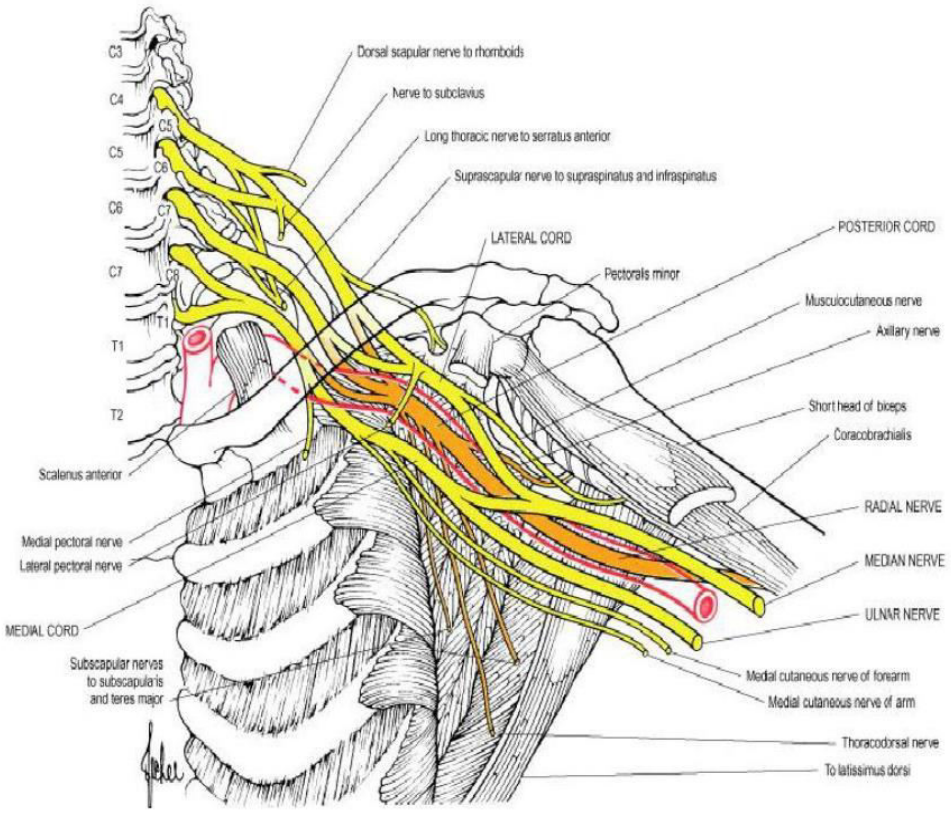

FIG-4: Neurovascular bundles around clavicle

MODES OF INJURY

The commonnest mode of injury responsible for these types of fractures is the direct impact on the shoulder area. [2]

Nevertheless, the commonest mechanism resulting in such fractures is FOOSH. [1]

Other mechanisms leading to such injuries are, road traffic accidents, secondary injuries sustained by riders or pillion riders, direct injury during sports or penetrating injuries. [2]

The deforming forces or the position of the upper limb whilst trauma is happening, does not affect the fracture site or pattern.

130 patients with fully displaced fractures of the clavicle were studied prospectively and was found that the most common modes of injuries included road traffic accidents, sports injuries, fall from heights and falls on outstretched hand.

Osteoporotic aged individuals are more prone to have these fractures with trivial trauma, such as fall from standing height, when compared to young individuals with good bone stock.

BIOMECHANICS OF FRACTURE

The classical deformity seen in clavicle fractures, is a result of combination of the muscular pull on the medial side and the gravitational pull on the lateral side of the fracture fragments.

The muscular pull is by the SCM muscle, pulling sternal fragment superiorly, whilst gravity along with deltoid and pectoralis major pulls acromial fragment inferiorly and medially.

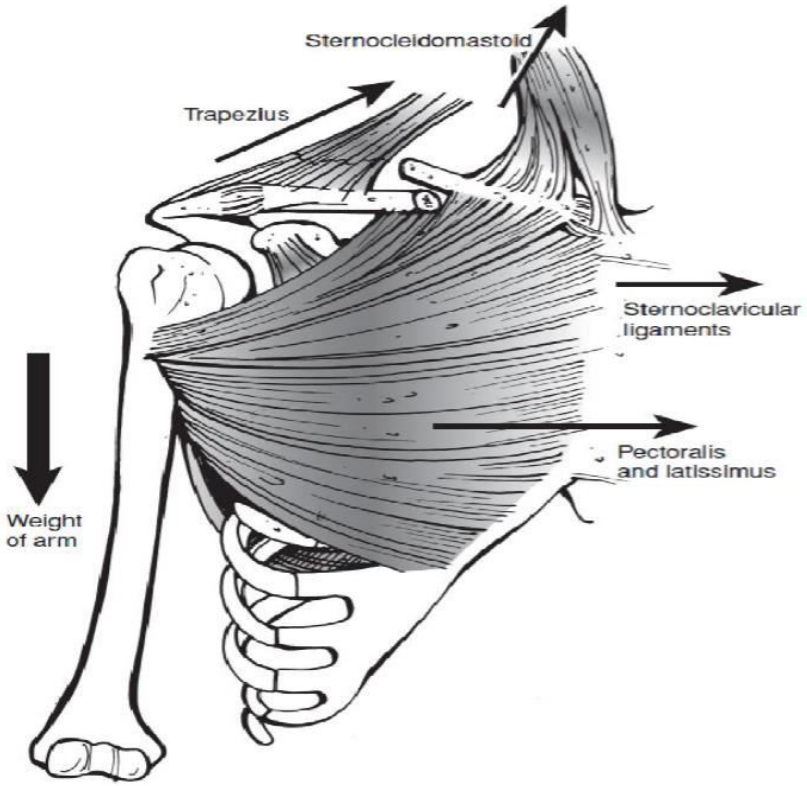

FIG-5 : Deforming forces acting on clavicle

CLASSIFICATION

On basis of fracture location, certain classification systems have been proposed :

ROBINSON'S CLASSIFICATION (Fig- 6)

GROUP I – MEDIAL 1/3rd OF CLAVICLE

A – Un-displaced fracture

A1 – fracture is extra-articular

A2 – fracture with intra-articular extension

B – Displaced fracture

B1 - fracture is extra-articular

B2 - fracture with intra-articular extension

GROUP II – MIDDLE 1/3rd OF CLAVICLE

A – fragment cortices are aligned

A1 – Un-displaced fracture

A2 – fragments are angulated

B- fragments are displaced

B1- single butterfly or simple fracture fragment

B2- segmental or comminuted type of fracture.

GROUP III- DISTAL THIRD OF CLAVICLE

A- Undisplaced fracture

A 1 - fracture is extra-articular

A 2 - fracture with intra-articular extension

B- Displaced fracture

B 1 - fracture is extra-articular

B 2 - fracture with intra-articular extension

ALLMAN'S CLASSIFICATION

Type 1 - Middle 1/3rd

Type 2 - Lateral 1/3rd

Type 3 - Medial 1/3rd

On the basis of lateral ligamentous complex involvement and displacement of fracture fragments, lateral 1/3rd clavicular fractures were further sub-classified into 3 groups by **NEER** :

GROUP 1 : Lateral clavicle fracture with intact coracoclavicular ligaments.

GROUP 2 : Conoid ligament disrupted from the sternal fragment whereas trapezoid not disrupted from lateral fragment.

IIa : Coracoclavicular ligaments not disrupted from acromial fragment.

IIb : Conoid disrupted from sternal end

GROUP 3 : lateral clavicle shaft fracture extending into intra-articular area

CRAIG'S CLASSIFICATION (Fig- 6)

TYPE I: Middle 1/3rd fracture.

TYPE II: Distal 1/3rd fracture; sub-divided into 5 types

I – displacement is minimal (inter ligamentous)

II – fracture line is medial to the conoid and trapezoid ligaments

IIa- both ligaments stays intact

IIb- Conoid gets torn whereas trapezoid stays intact.

III – fractures with intra articular extension

IV – fractures in paediatric age group; both ligaments remains attached to the periosteal sleeve

V – fracture with comminution

TYPE III: Medial 1/3rd fracture

Type 1 – displacement minimal

Type 2 – displacement significant

Type 3 - fracture with intra articular extension

Type 4 – fracture involving the physis; as seen in paediatric population

Type 5 – fracture comminution is present

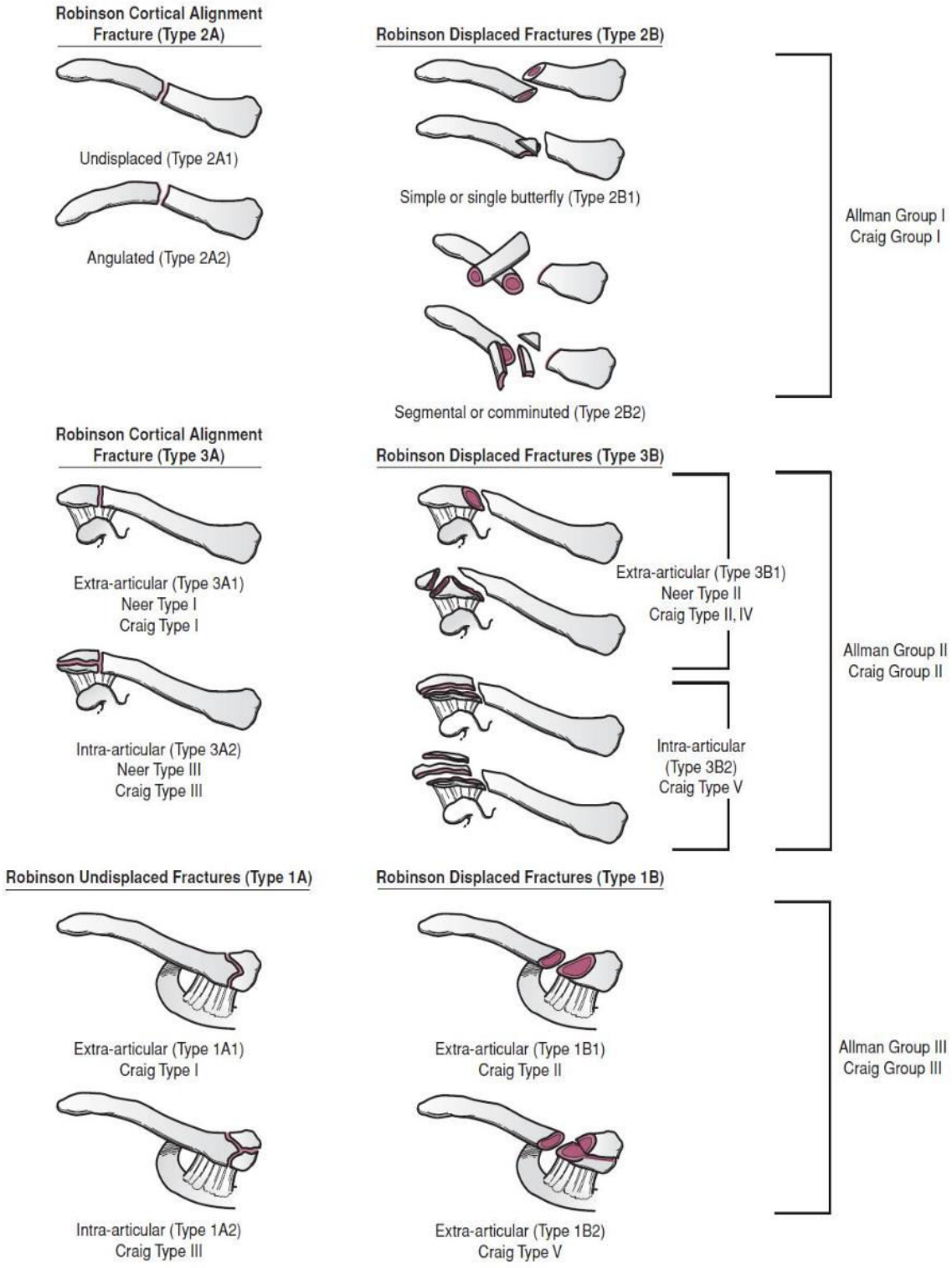

FIG-6: Robinson, Allman and Craig's system of classification.

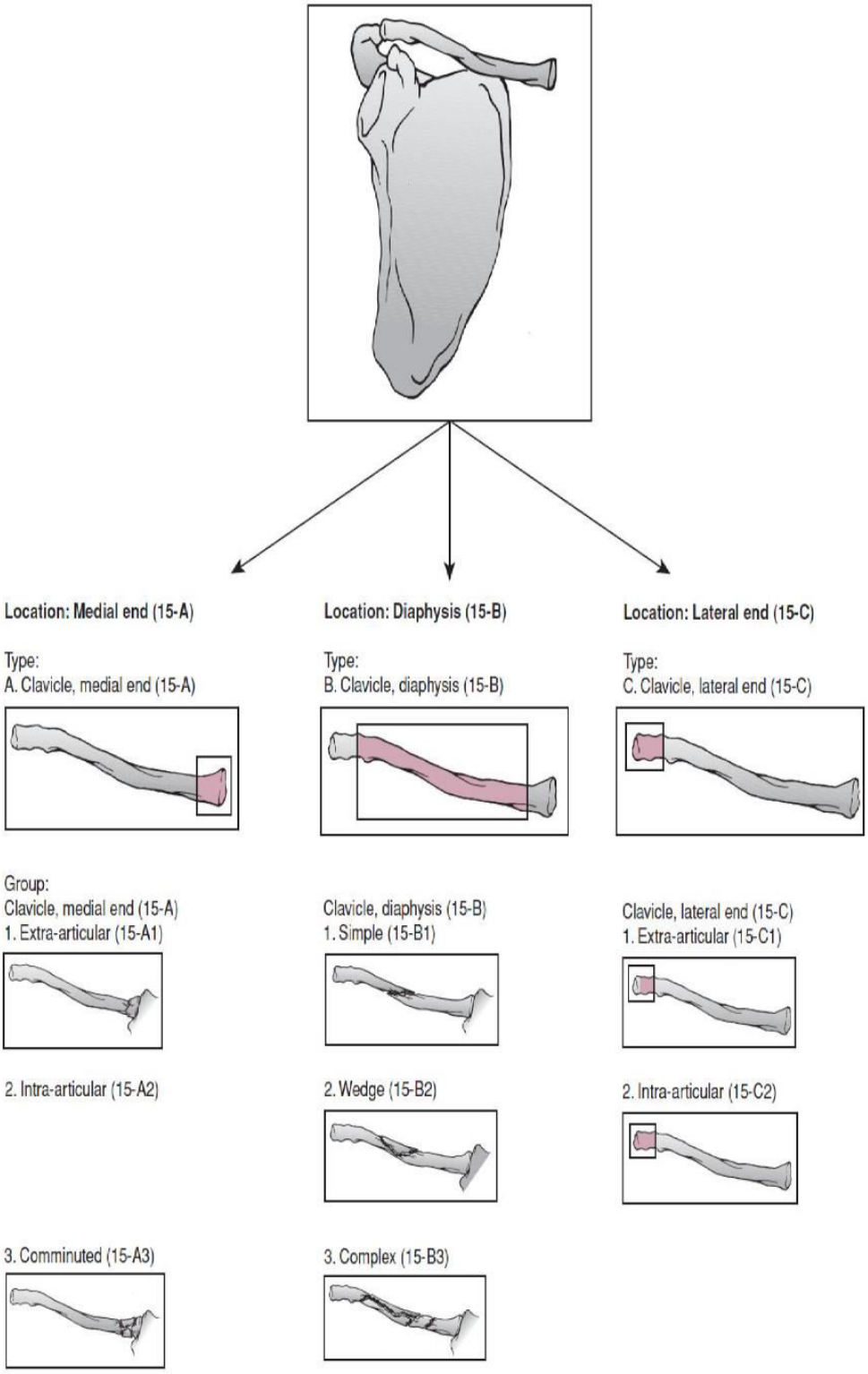

FIG-7: AO/OTA Classification

TREATMENT MODALITIES

NON-SURGICAL MANAGEMENT:

In 30th century BC, "Edwin Smith" papyrus reported, closed reduction of a middle 1/3rd shaft of clavicle fracture with significant displacement, for the first time.

The classical deformity seen in these types of fractures and the significant need to correct them was first defined by Hippocrates. (16)

The fracture can be reduced effectively intra-operatively with a maneuver which includes putting the patient supine on operation table with lifting of shoulder girdle by placing a sandbag under the ipsilateral scapula. This facilitates the lateral fragment to translate antero-superiorly, thus causing the fracture to reduce. However, holding this position intra-operatively is very cumbersome because it includes supporting the ipsilateral arm in the reduced manner.

Over a period of thousand years, many other modalities of conservative management have been documented in the form of splints, braces and casts, to facilitate and maintain the fracture reduction. (16,17,18)

Currently, the evidences reported in favor of these equipments that are used for fracture reduction have not been very promising as confirmed clinically, radiologically or functionally.

In addition to all these methods, affected arm immobilization using an arm pouch sling or figure of 8 bandage has been shown as mainstay of conservative treatment.

OUTCOMES:

The rate of union in patients with middle 1/3rd clavicular fractures have not been very supportive as per the newer studies.

868 patients, diagnosed with middle 1/3rd clavicular fractures, were studied prospectively for a span of time by Robinson et al. They showed that in comminuted fractures, there is a non-union rate of 21% which was found to be statistically significant.

A 4 year long observation by McKee et al, cases with displaced fracture patterns were not satisfied with the results on being treated conservatively. They reported reduced muscle strength around the index shoulder joint despite radiological confirmation of bony union. (20)

SURGICAL MANAGEMENT:

Following are the surgical indications for fixation -

FRACTURE RELATED FACTORS:

1. Displaced fractures more than 20mm
2. Shortening of clavicle by more than 20mm
3. Comminuted fracture pattern (more than 3 fragments)
4. Clavicle with fracture at 2 places
5. Compound fractures
6. Skin tenting
7. Scapulo-thoracic dissociation
8. Winging of scapula on preliminary examination

INJURIES ASSOCIATED WITH CLAVICLE FRACTURES:

1. Injury to adjacent vasulature

2. Progressing neurological deficit

3. Fractures of the same sided upper limb

4. Rib fractures on the same side at multiple levels

5. Floating shoulder

6. Both sided clavicle fractures

FACTORS RELATED TO PATIENTS:

1. Patients with multiple fractures requiring early mobilization of upper limb.

2. Patients involved in sports activities requiring early return of upper extremity function.

MODALITIES OF SURGICAL MANAGEMENT:

ORIF WITH PLATING -

Advantages:

- Absolute stability without any micro movement at site of fracture
- Cortices can get effectively compressed
- Rotational stability can be achieved

  Shortening can be corrected along with alignment

Disadvantages:

Bigger scar length

- Implant prominence
- Damage to the supraclavicular nerves
- Risk of infection

VARIOUS IMPLANTS USED FOR FIXATION:

1. Anatomical LCP

2. Non-locking reconstruction plate

3. LCP

CLOSED REDUCTION INTERNAL FIXATION WITH NAILING

Advantages:

- No disruption of fracture haematoma
- Less soft tissue injury
- Implant removal can be done under local anaesthesia

Disadvantages

- Risk of infection
- Nail can get prominent and move medially or laterally
- Rotational stability cannot be acheived
- Risk of non-union is high

VARIOUS IMPLANTS USED FOR INTRAMEDULLARY FIXATION:

- Hagie pin
- TENS
- Intramedullary compression clavicular nail

EX – FIX :

External fixator can be used for infected fractures of the clavicle, as described by **COOK T.W** in 1954, however their use is very limited as per the available evidences Some of the indications of fixing the fractures with an externally applied implant includes compound fractures and soft tissue disruption.

MATERIALS AND METHODS

A prospective study of functional outcome of TENS intra-medullary nailing in mid shaft clavicle fractures was done in KLE's, Dr. Prabhakar Kore Charitable Hospital and MRC, at Orthopaedics Department, Belagavi over a period of one year from June 2022 to June 2023.

INCLUSION CRITERIA:

- Cases with marked displacement of fracture radiographically
- Patients with clavicle shortening of >2 cm
- Age between 16 and 70 years
- Polytrauma
- Associated injury of one or both lower limbs
- Floating shoulder injury
- Medically fit for general anaesthesia
- Given informed consent and motivation for follow up.

EXCLUSION CRITERIA:

- Fractures other than middle 1/3rd shaft fractures
- Open fractures
- Age <16 years or >70 years
- Pathological fractures
- Non-union

- Medically unfit for surgery or anesthesia.
- Unmotivated patients for follow up.
- Inability to give consent.

STUDY DESIGN: Prospective Study

SAMPLE SIZE: 32

SAMPLING TECHNIQUE: The formula for minimum sample size based on prevalence rate is as follows

$n = [z \alpha^2 P (1-P)] / d^2$

where,

P- percentage of mid third of clavicle

d- percentage likely difference in prevalence.

Zα- the level of significance.

For 5% level of significance $z\alpha = 1.96$.

Ref:

With P = 75% and,

d = 20% of P = 15.0%

Data collection procedure:

Chest x-rays with bilateral clavicle to be evaluated and studied over a period of 1 year in 32 selected patients at KLEs Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

All the patients were reviewed post operatively in the hospital at 4, 8 and 16 weeks or till roentgenographic and clinical evidence of union had been acheived.

Follow up roentgenographs were taken at subsequent visits at the hospital along with functional evaluation of the patients.

OSS was used as a clinical subjective parameter for evaluating patient's functional improvement in day to day activities where patients were asked a few relevant questions.

Radiologically, three cortical union was taken into consideration for assessment of patients.

DATA PROCESSING AND ANALYSIS/ STATISTICAL ANALYSIS:

Two quantitative assessment tools were calculated, which were mean and standard deviation. Student's unpaired t test was used as an evaluation variable for comparison of continuous variables, when the data was separated into 2 groups based on their quality.

Student's paired t test was helpful in quantifying pre and post intervention methods.

Median signified discrete variables.

Categorical data was measured in rates, ratios and percentages. Association amongst outcome, clinical and demographic data was tested using Chi-square test, test of proportion or Fisher's exact test.

Non-parametric tests were used to calculate discrete variables. Other suitable methods included ANOVA, correlation, regression etc.

Data which was compared between groups was documented graphically and p value of less than 5% (0.05) was taken into significant consideration for all the methods.

DETAILED STEPS OF THE STUDY:

All the patients underwent required examination and associated possible injuries were excluded. Till we proceeded for operation, affected limb was immobilized in an arm pouch.

Investigations done prior to surgery included –

1. Roentgenography of the injured shoulder – postero-anterior view along with apical oblique view.

2. Complete routine haemogram

3. Mini renal profile

4. Coagulation profile

5. Serological markers

6. ECG and X-ray chest

FIG-8: Instruments used in surgery

SURGICAL INSTRUMENTS

1. Bone awl
2. Mallet
3. T-handle
4. TENS (diameter - 2mm , 2.5mm , 3mm)
5. Hohmann's spikes
6. Nail cutter
7. Reduction clamps
8. Pliers

SURGERY: TENS FOR MIDDLE 1/3RD OF CLAVICLE FRACTURES.

Patient put supine on operating table after induction and a sandbag was kept under the ipsilateral scapula to aid in reduction. Parts were painted and draped under all sterile aseptic precautions. Sternal end of the clavicle was left exposed so as to facilitate the incision.

Preoperative marking and identification of fracture pattern was done under C-arm guidance.

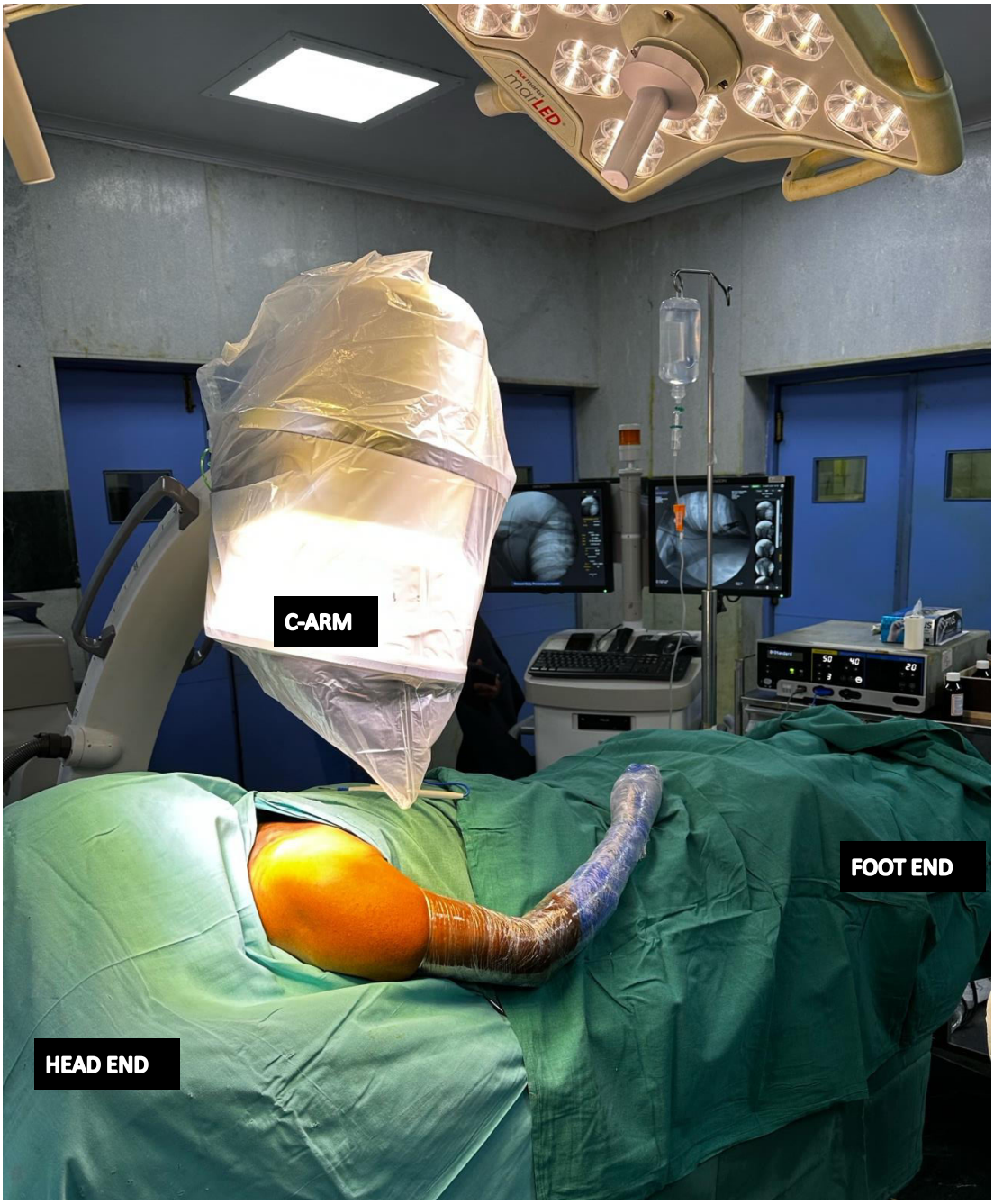

FIG-9: Operation theatre setup

SURGICAL APPROACH:

- Sternoclavicular joint was taken as a reference landmark, lateral to which, 1 cm long incision was taken horizontally. Superficial dissection including fat and platysma was done to clear the operative field.

- All the muscles covering the clavicle anteriorly were reflected subperiosteally along with pectoralis fascia.

- Bone entry was then taken using the bone awl. It can be done by 2 methods, either directly or after making an impression on the bone by a drill bit of 2.7mm.

- The nail was then introduced into the medullary cavity by using a T-handle through the originally made entry.

- Under fluoroscopic guidance, an attempt was made for closed reduction which could be aided by using reduction clamps in a percutaneous fashion.

- Even after all the attempts made at closed reduction, if the reduction could not be achieved, a small incision was then taken at the fracture site under radiographic guidance.

- This would help in direct visualization of the fracture and helped in reduction.

- Nail was inserted from the medial end of bone until just medial to the lateral end.

- The nail was kept a little short of the lateral endpoint, it was cut and punched inside so that it does not irritate the soft tissues. The incision was then closed in layers.

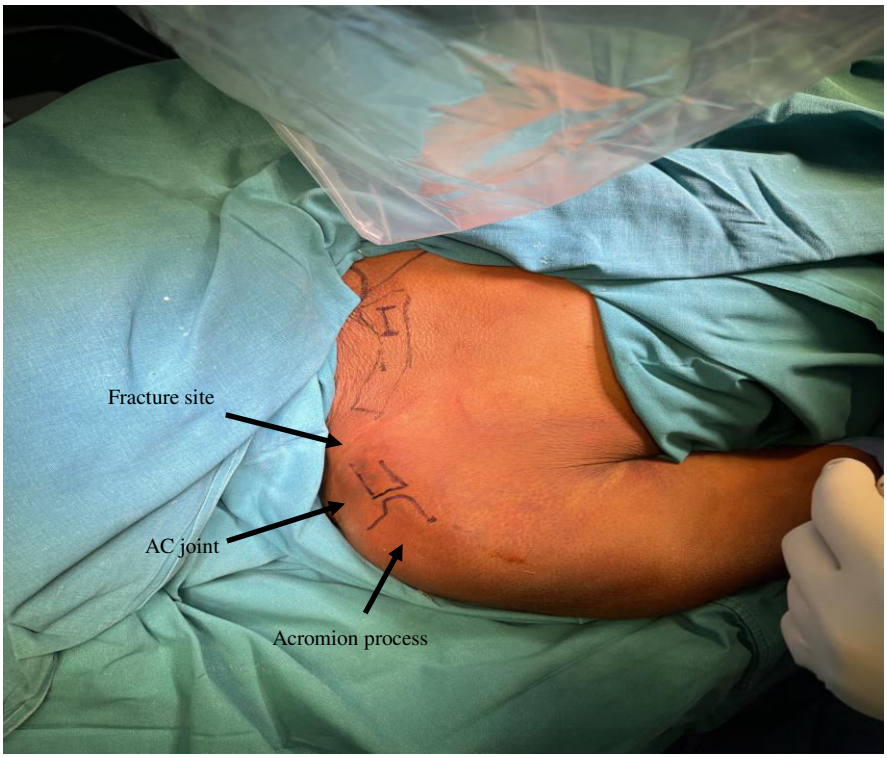

FIG-10: Skin marking for the incision site

FIG-11: Bone entry

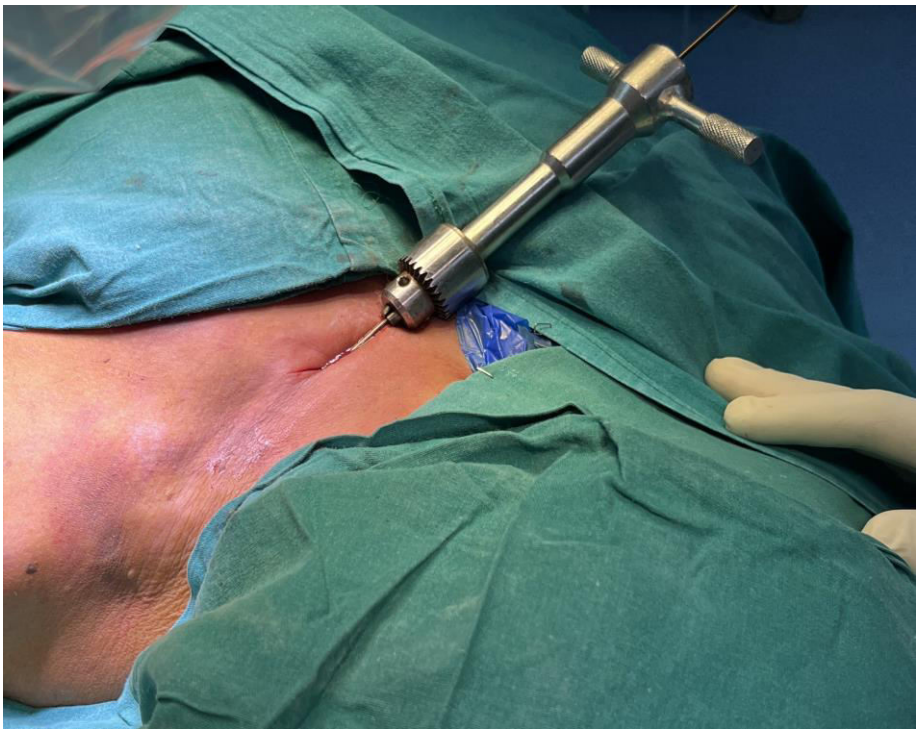

FIG-12: Introduction of nail

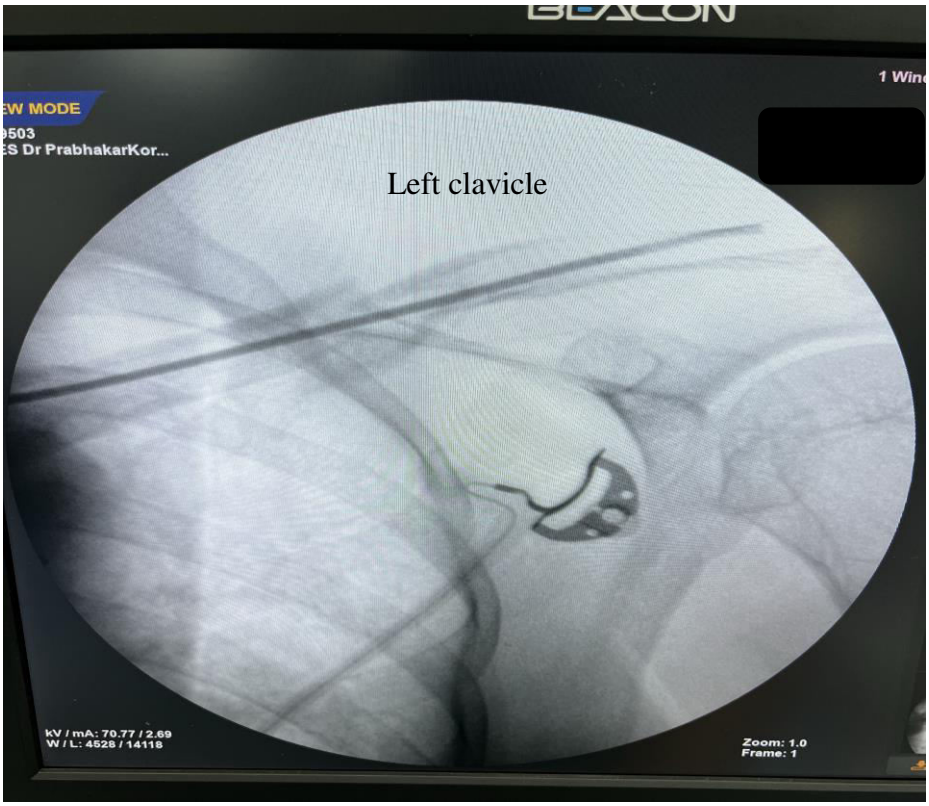

FIG-13: C-arm image (peri-operative)

FIG-14: Post closure

POST SURGICAL REHABILITATION:

Post-op Day-2 : Patients were started with early range of motion exercises i.e. pendulum movements, for the shoulder joint after initial immobilization in an arm pouch.

Post-op Day-7 : Overhead abduction was encouraged after 2 weeks of surgery with initial active ROM exercises.

Post-op Day-14 : Removal of arm pouch sling was done along with motivation to start with all day to day activities except heavy weight lifting till union was confirmed on follow-up xrays.

Follow up of patients was advised at post intervention 4, 8 and 16 weeks for repeat roentgenographic studies and clinical assessment with the help of Oxford shoulder score.

POST-SURGICAL ASSESSMENT:

Patients were assessed for improvement in function with the help of 2 methods, namely, OSS questionnaire and roentgenographic evidence of new callus formation over the fracture site.

Certain parameters were taken into consideration to document it as a clinically united fracture, namely, non-tender fracture site along with union as seen in plain xrays. Time taken from injury to union was documented in weeks.

Other post surgical assessment included intra-operative data i.e., duration of surgery, number of mops soaked in blood, length of the surgical scar and post-operative complications. These complications were an indirect method of assessment of surgical outcome.

RESULTS

Table-1: Age Distribution (in years)

Age (in years)	Frequency	Percentage (%)
20-30	12	37.5
31-40	8	25
41-50	3	9.5
51-60	7	22
61-70	2	6
Total	32	100

Mean age of patients was 39.19±13.243 with a minimum age of 20 and maximum age of 63.

FIG-15: AGE DISTRIBUTION

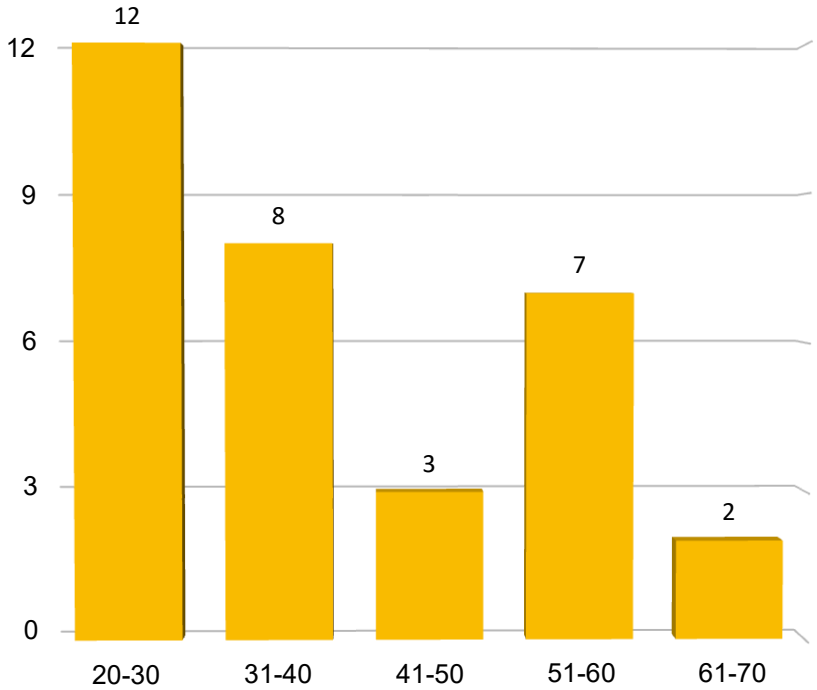

Table-2: Gender Distribution

Gender	Frequency	Percentage (%)
Male	27	84.4
Female	5	15.6
Total	32	100

FIG-16: GENDER DISTRIBUTION

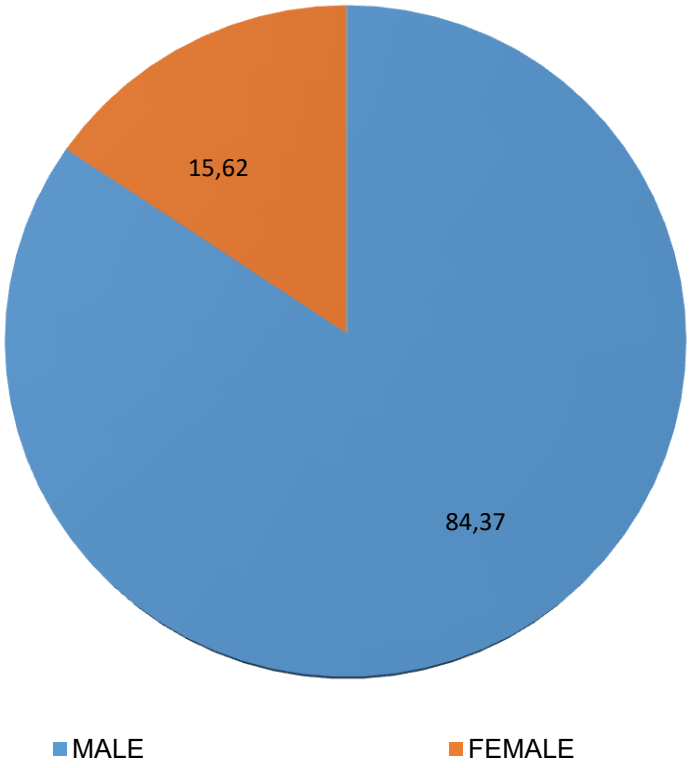

Table-3 : Modes of injury

Mode of injury	Frequency	Percentage (%)
RTA	24	75
FOOSH	5	15.6
FFH	3	9.4
TOTAL	32	100

FIG-17: MODE OF INJURY

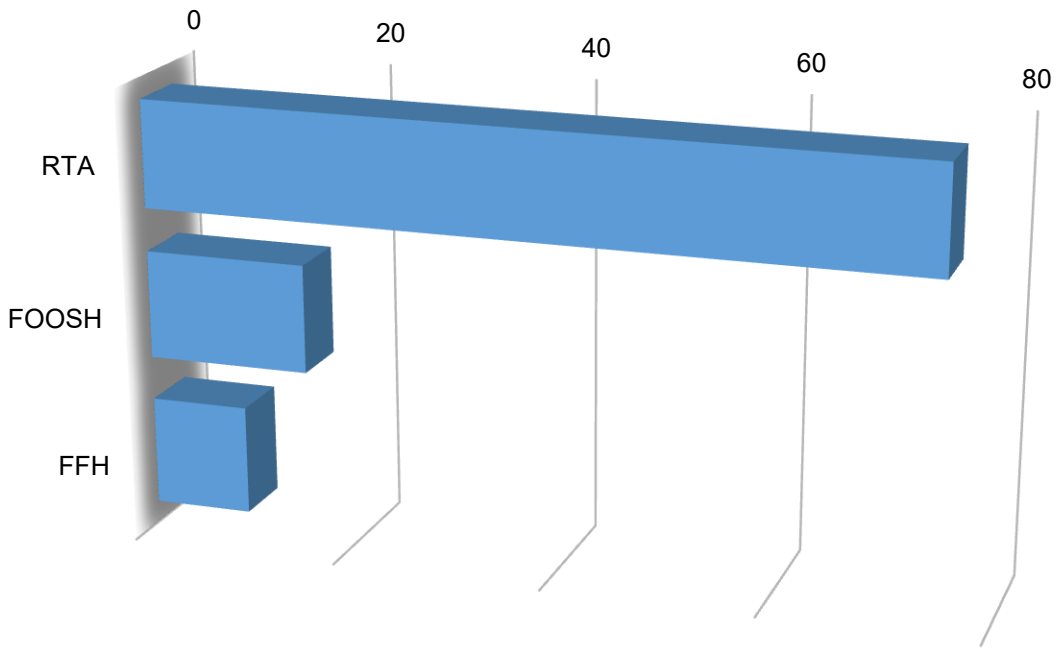

Table-4: Sidedness of injury

Side involved	Frequency	Percentage (%)
Right	21	65.6
Left	11	34.4
Total	32	100

FIG-18: SIDEDNESS OF INJURY

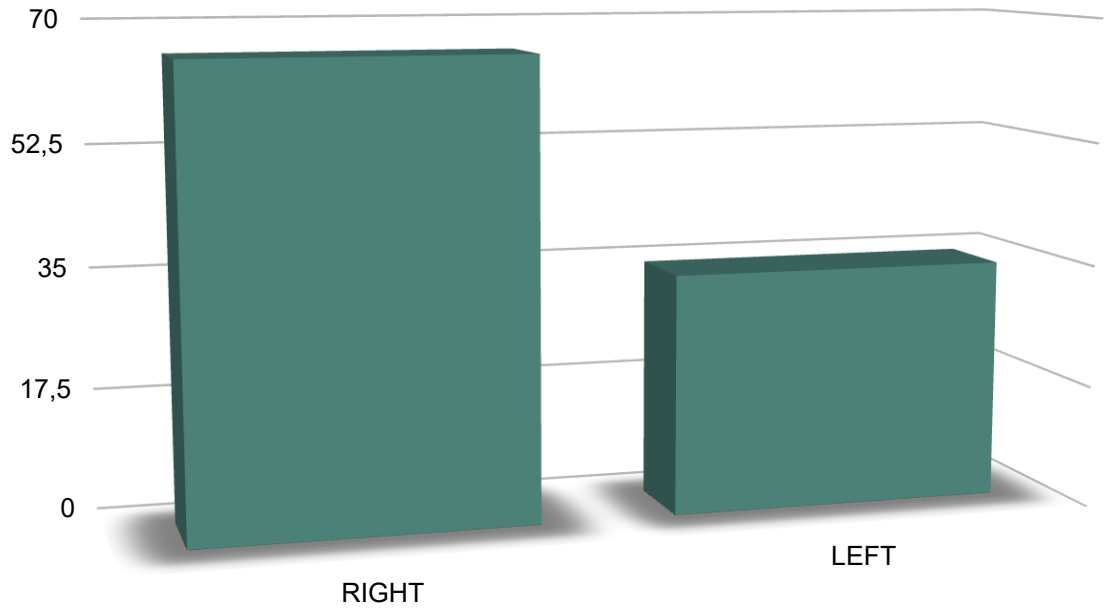

Table-5: Associated injury

ASSOCIATED INJURY	FREQUENCY	PERCENTAGE (%)
HEAD INJURY	8	25
RIGHT FIBULA FRACTURE	1	3.1
THORACIC INJURIES	1	3.1
TOTAL	10	31.2

Time of surgical intervention

Patients included in this study were taken for surgery in less than 10 days of injury, out of which maximum of them were operated within 48 hours.

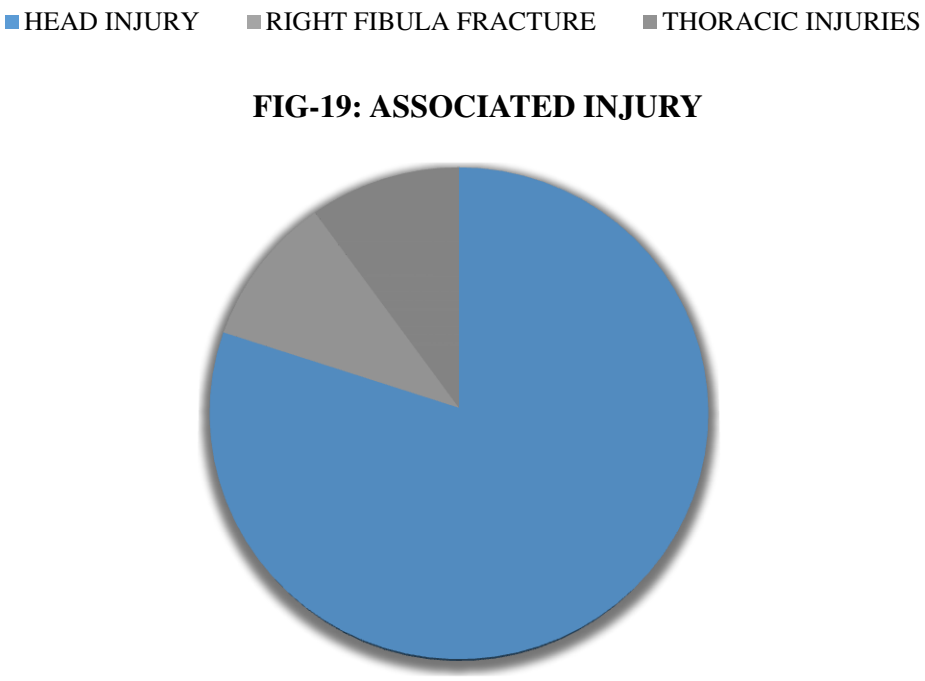

FIG-19: ASSOCIATED INJURY

FIG-20: TIMING OF SURGERY (POST INJURY)

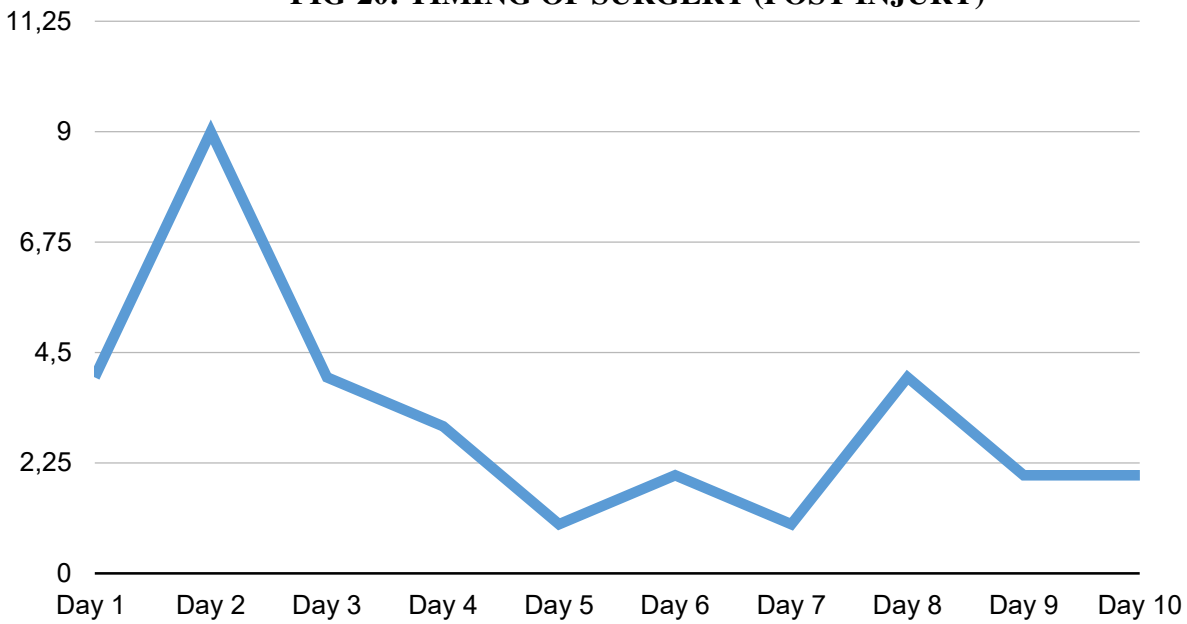

Table - 6: Time for union

TIME FOR UNION (WEEKS)			
MINIMUM	**MAXIMUM**	**MEAN**	**SD**
6	12	9.13	1.963

Table-7: OSS at follow ups

OSS	MINIMUM	MAXIMUM	MEAN	SD
4 WEEKS	16	28	21.47	3.048
8 WEEKS	28	39	34.19	3.095
16 WEEKS	38	50	42.69	3.095

The mean OSS score at 4 weeks, 8 weeks and 16 weeks of the study participants was found to be, 21.47±3.048, 34.19±3.095 and 42.69±3.095 respectively.

FIG 21: OSS at follow- ups

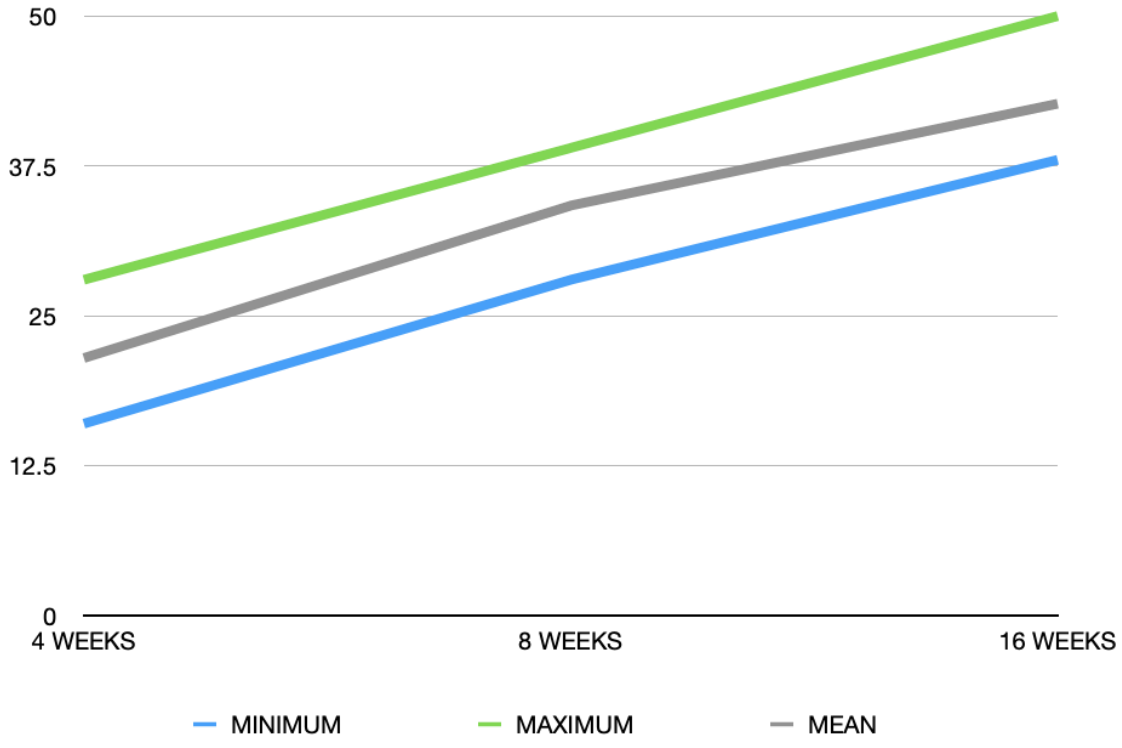

Table-8: Improvement in OSS

OSS	MEAN	SD	CORRELATION	P VALUE
4 WEEKS	21.47	3.048	0.526	0.002
16 WEEKS	42.69	3.095		

Improvement in OSS score was statistically significant (P = 0.002).

Table-9: Range of movements

RANGE OF MOVEMENTS	MINIMUM	MAXIMUM	MEAN	SD
FLEXION	130	180	158.59	11.376
ABDUCTION	135	180	157.50	13.259
ER	30	70	51.09	12.555
IR	30	70	51.25	11.288

Minimum flexion achieved was 130 while the maximum being 180. Minimum abduction achieved was 135 whereas maximum being 180. The minimum and maximum external rotation achieved was 30 and 70 respectively. The minimum and maximum internal rotation achieved was 30 and 70 respectively.

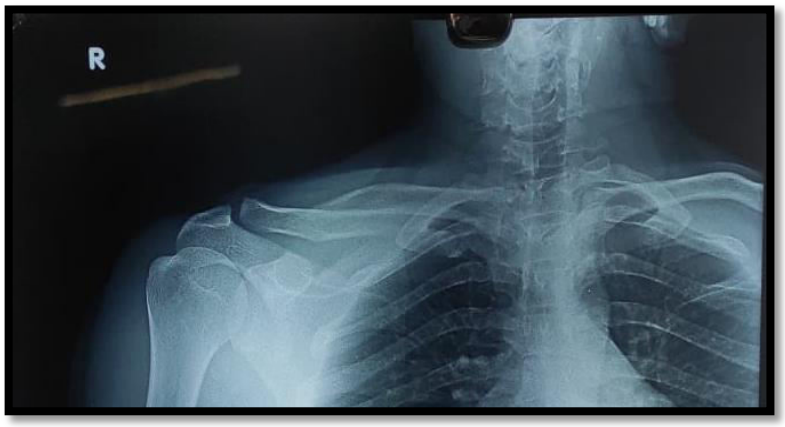

FIG-22: PRE-OP X-RAY

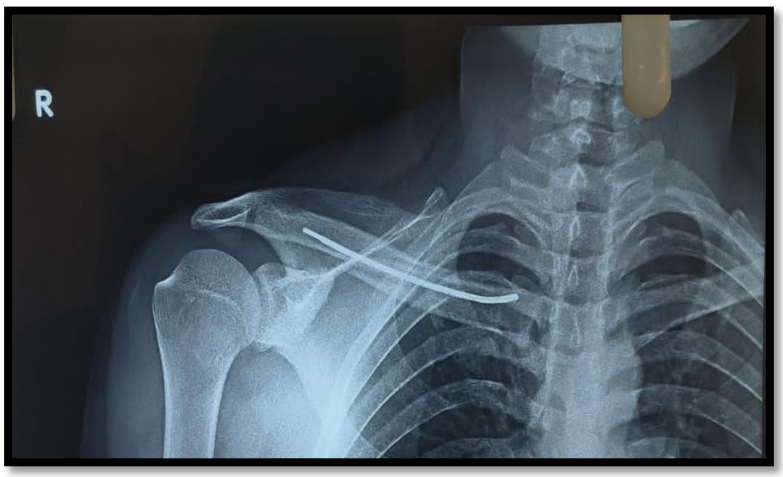

FIG -23: POST-OP X-RAY

FIG-24: 16wks POST -OP X-RAY

FIG - 25: POST OPERATIVE ROM

Case 2

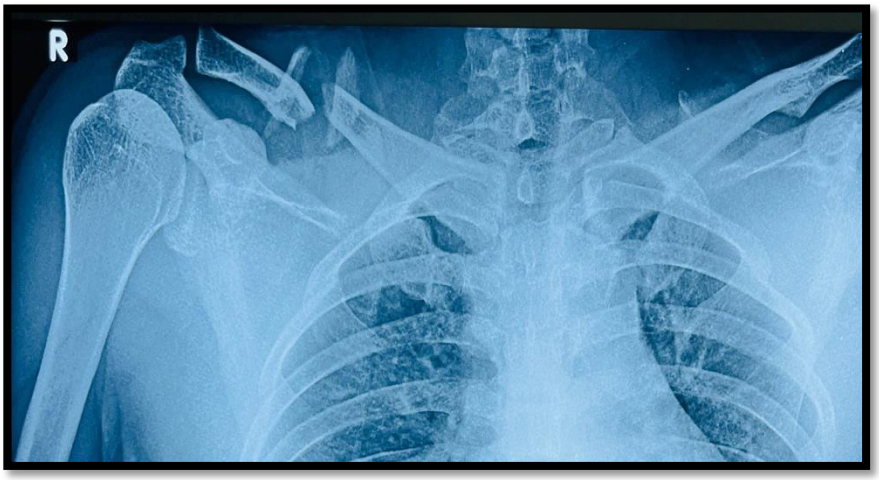

FIG-26: PRE-OP X-RAY

FIG-27: POST-OP X-RAY

FIG-28: 8wks POST-OP X-RAY

FIG-29: POST OPERATIVE ROM

Case 3

FIG-30: PRE-OP X-RAY

FIG-31: POST-OP X-RAY

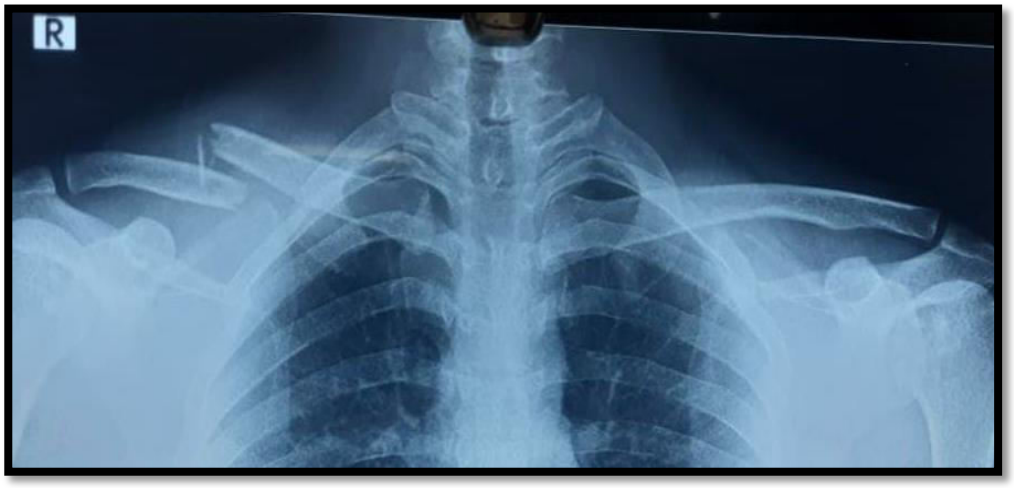

FIG-32: PRE-OP X-RAY

FIG-33: POST-OP X-RAY

DISCUSSION

Surgical intervention for midshaft clavicle fractures can be done in the following ways i.e., open reduction with plate fixation,[21,22] fixation with external fixator,[23] and closed/open reduction with nailing.[24,13,25,26,27] Although, the gold standard method of fixation is plating. Plating offers the added advantage of absolute stability with good inter-fragmentary compression at the fracture site.

Though plating has certain disadvantages, in a study conducted between 2 groups of patients with clavicle fractures, plating had better results as compared to non-surgical intervention as evidenced by increased union rates and better functional recovery.[21]

Another method of fracture fixation is through intra-medullary implants as they offer better biomechanical stability in relation to movements and loading at the shoulder joint. [10,13]

Small scar, lesser soft tissue disruption and good amount of callus formation makes intra-medullary nail a better implant of choice than a plate.[12]

With certain advantages, nail offers some specific disadvantages as well, namely, soft tissue irritation on the sternal end, implant prominence which often leads to implant removal before complete remodelling of the bone.[28]

In this study, 32 patients with middle 1/3rd clavicle fractures were operated using TENS nail.

Age and sex distribution:

Out of 32 cases, maximum number of cases i.e., 12 cases (37.5%) belonged to 20-30 years of age group. Youngest patient was 20 years old and eldest being 63 years old. There were 27 males (84.4%) and 5 females (15.6%) in this study.

Mode of injury:

75% of the cases had RTA as the mode of injury while other mode of injuries were FOOSH (15.6%) and FFH (9.4%).

Side of injury:

In our study, 21 patients (65.6%) had right side involvement whereas 11 patients (34.4%) presented with left clavicular fracture.

Associated injury:

Out of 32 patients,10 patients (31.2%) had associated injury out of which 8 patients (25%) had head injury while 1 patient (3.1%) had right fibula fracture and 1 patient (3.1%) had thoracic injury.

Time for union:

The mean time of union after injury of the study participants was found to be 9.13$\pm$1.963 with 6 weeks as minimum time duration and 12 weeks being maximum.

OSS score:

Patients were followed up post-operatively and OSS score was calculated at 4, 8 and 16 wks. Mean OSS score at 4, 8 and 16 wks of the study participants was found to be, 21.47$\pm$3.048, 34.19$\pm$3.095 and 42.69$\pm$3.095 respectively and the improvement in OSS score was statistically significant in this study (P=0.002).

Attaining a good intra-operative closed reduction was challenging in certain patients who had AO B2 type of fracture pattern and in some over-weight patients.

Percutaneous clamps had to be used to aid in reduction, but this method also failed in some patients. To counter this difficulty, small incision had to be taken over the fracture site so as to directly manipulate the fragments under vision.

In this study, good post-surgical functional results along with better cosmesis was achieved in displaced middle 1/3rd clavicle fractures when intra-medullary implant was used.

Minor complications like- medial protrusion of the nail in 2 patients, lateral protrusion in 1 patient and local skin irritation in 1 patient was seen.

SUMMARY

It is a prospective study done on 32 patients in the age group of 16-70 years. The mean age of the study participants was found to be 39.19±13.243 with a minimum age of 20 and maximum age of 63.

There were 27 males (84.4%) and 5 females (15.6%) in this study.

75% of the cases had RTA as the mode of injury. Right clavicle was involved in 21 patients (65.6%).

Out of 32 patients,10 patients had associated injuries (31.2%).

The mean time of union after injury of the study participants was found to be 9.13±1.963 with a minimum of 6 and maximum of 12 weeks. Average size of nail used was 2mm.

Patients were followed up post operatively and OSS score was calculated at 4, 8, and 16 weeks. The improvement in OSS score was statistically significant in our study (P=0.002).

Minor complications like- medial protrusion of the nail in 2 patients, lateral protrusion in 1 patient and local skin irritation in 1 patient was seen.

Major complications like non-union at the fracture site, scar neuromas, posterior cortex penetration by the nail were not seen

Certain patients had to undergo second surgery in the form of removal of nail but none of them had an incidence of repeat fracture at the same site.

CONCLUSION

Based on our prospective study done on 32 patients, the following can be concluded-

- TENS nailing is found to be a safe alternative for fixing middle 1/3rd claviclular fractures.
- It's a lesser invasive technique with less soft tissue injury.
- Intra-medullary fixation of middle 1/3rd clavicle fractures is found to be a better method as evidenced by faster union rates, early post-operative return of shoulder movements, and lesser intra, peri and post-operative complications.
- Nevertheless, plating stays the gold standard treatment in cases with comminuted clavicle fractures.

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ANNEXURE - I

ETHICAL CLEARANCE

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A+' Grade by NAAC in (3rd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC INSTITUTIONAL ETHICS COMMITTEE
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref No.MDC/JNMCIEC/ 42 **Date: 27/09/2022**

REG.NO: BL0121008

PG Student in Orthopaedics,
J. N. Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"ONE YEAR HOSPITAL BASED PROSPECTIVE STUDY OF TENS INTRA-MEDULLARY NAILING IN MIDSHAFT CLAVICLE FRACTURES."**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

(Dr. Smita Sonoli)
Member Secretary
JNMC Institutional Ethics Committee
J.N.Medical College, Belagavi.

(Dr. Harsha Hegde)
Chairman,
JNMC Institutional Ethics Committee
J.N.Medical College, Belagavi

ANNEXURES - II

INFORMED CONSENT

TITLE OF THE PROJECT/STUDY: "ONE YEAR HOSPITAL BASED PROSPECTIVE STUDY OF TENS INTRA-MEDULLARY NAILING IN MIDSHAFT CLAVICLE FRACTURES"

Name of Student/Principal Investigator: REG.NO: BL0121008

Name of Guide/Co Investigators: Dr. _____,

Objective: The aim of this study is to explain the faster pain relief , early return of function and restitution of clavicle length with the help of reduction and internal fixation of clavicle fracture creating an elastic stability at the fracture gap.

Introduction:

The clavicle fracture is one of the most frequent bony injuries. The mid third of the clavicle is involved in 70–80% and is known for its favorable prognosis in respect to consolidation and functional outcome. In adults, pain and injury associated limitation of activity during the first 3 weeks are frequently underestimated.

Recent reports stress the fact that 10-30% of conservatively treated patients have an unsatisfactory clinical, radiological and subjective result on account of shortening, nonunion or poor shoulder function.

The standard technique for surgical treatment of mid clavicle fractures is the internal plate fixation.

The problem of such a plate fixation is the fact that the tension side of the clavicle and, consequently, the optimal position of the plate change depending on the direc- tion of loading and the rotation of the arm. Whatever the plate position a moment of bending exerted on the implant cannot be prevented. Therefore, to avoid breakage of the plate, a rather large implant in relation to the size of the bone must be chosen. The use of such an implant, that is in general a small dynamic compression plate (DCP) or a small-fragment reconstruction plate, requires a secure screw purchase. This is often difficult to achieve. The resulting inadequate purchase increases the risk of plate avulsion. In addition, an extensive approach with detachment of soft tissues is necessary. Typical problems of internal plate fixation include: an ugly hypertrophic keloid, implant loosening, nonunion, and refracture after implant removal.

In contrast to these techniques our method consists of an extensive, intramedullary stabilization with a straight titanium nail in the S-shaped clavicle. In this study, we will show that this technique is safe, leads to faster pain relief, early use of the injured shoulder, and is associated with low incidence of non-union along with better functional and cosmetic results and shorter stay in hospital including day care surgeries.

Explanation of procedure: If you consent to be in this study, the relevant data will be done on X-Rays of chest with bilateral clavicle.

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact:

REG.NO: BL0121008

Post- graduate resident

Department of Orthopaedics,

J.N. Medical College,

K.A.H.E.R, Belagavi-10

Dr. _____

Department of

Orthopaedics

J.N. Medical College,

Belagavi-10

If you have any question or complaints with regard to your right as study participant, you may

contact

Dr Harsha Hegde,

Chairperson,

Ethical committee of JNMC,

0831-2473777

Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study "**ONE YEAR HOSPITAL BASED PROSPECTIVE STUDY OF TENS INTRA-MEDULLARY NAILING IN MIDSHAFT CLAVICLE FRACTURES**". My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

ANNEXURES - III

PROFORMA

CASE NO.:

Name :

Age / Sex :

IP number :

Address :

Contact Number :

Date of Admission :

Date of Surgery :

Date of Discharge :

Occupation :

Diagnosis :

HISTORY :

1. **Mode of injury:** Road traffic accident / Fall at home / Fall from height / Assault

2. **Presenting complaints:**

- Pain–site/duration
- Swelling – site / extent
- Deformity
- Disturbances in function – movements
- Other associated injuries – head injury / limb injuries / spine injuries

3. **Comorbidities:**

- Diabetes mellitus
- Hypertension
- Thyroid disorders
- Tuberculosis
- Bronchial asthma
- Epilepsy

4. **Drug history:** Steroids / Disease modifying anti-rheumatoid drugs / Immunosuppressants

5. **Past history:**

Any similar injuries

Previous surgeries or hospitalizations

Any major illnesses

6. **Personal history:**

Sleep:

Appetite:

Bowel/ Bladder:

Smoking:

Alcohol consumption:

7. **Family history:**

CLINICAL EXAMINATION:

General examination:

Built: Well/ Moderate/ Poor

Pallor/ Icterus/ Cyanosis/ Clubbing/ Lymphadenopathy/ Edema

Vitals:

1. Pulse :

2. BP :

3. Respiratory rate :

4. Temperature :

Systemic examination :

Cardiovascular system :

Respiratory system :

Per Abdomen :

Central Nervous System:

Local examination of shoulder :

Other injuries :

X – ray findings :

Final diagnosis:

Time interval between injury and surgery :

Procedure done :

Complications:

Post op period :

Follow up period :

Oxford shoulder score :

OXFORD SHOULDER SCORE (REVISED)

PROBLEMS WITH YOUR SHOULDER

Tick (✓) one box for every question.

1. During the past 4 weeks...

How would you describe the **worst** pain you had from your shoulder?

None	Mild	Moderate	Severe	Unbearable
☐	☐	☐	☐	☐

2. During the past 4 weeks...

Have you had any trouble dressing yourself because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

3. During the past 4 weeks...

Have you had any trouble getting in and out of a car or using public transport because of your shoulder?

No trouble at all	A little bit of trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

4. During the past 4 weeks...

Have you been able to use a knife and fork - at the same time?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

5. During the past 4 weeks...

Could you do the household shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

6. During the past 4 weeks...

Could you carry a tray containing a plate of food across a room?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

7. During the past 4 weeks...

Could you brush/comb your hair with the affected arm?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

8. During the past 4 weeks...

How would you describe the pain you usually had from your shoulder?

None	Very mild	Mild	Moderate	Severe
☐	☐	☐	☐	☐

9. During the past 4 weeks...

Could you hang your clothes up in a wardrobe, using the affected arm?

Yes, easily	With little difficulty	With moderate difficulty	With great difficulty	No, impossible
☐	☐	☐	☐	☐

10. During the past 4 weeks...

Have you been able to wash and dry yourself under both arms?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

11. During the past 4 weeks...

How much has pain from your shoulder interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally
☐	☐	☐	☐	☐

12. During the past 4 weeks...

Have you been troubled by pain from your shoulder in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
☐	☐	☐	☐	☐

SCORING:

0-19 Severe shoulder arthritis

20-29 Moderate to severe shoulder arthritis

30-39 Mild to moderate shoulder arthritis

40-48 Satisfactory joint function

KEY TO MASTER CHART

SL NO.	**Serial number**
OP NO.	Out patient number
IP NO.	In patient number
M	Male
F	Female
RTA	Road traffic accident
FOOSH	Fall on out stretched hand
FFH	Fall from height
ER	External rotation
IR	Internal rotation
OSS	Oxford shoulder score

MASTER CHART

Sl No.	NAME	AGE (YEARS)	SEX	IP/ OP NO.	MODE OF INJURY	LIMB INVOLVED	ASSOCIATED INJURIES	TIME OF SURGERY (days after injury)	FOLLOW UP			TIME FOR UNION (WEEKS)	SHOULDER MOVEMENTS			
									OSS after 4 weeks	OSS after 8 weeks	OSS after 16 weeks		FLEXION	ABDUCTION	ER	IR
1	JOTIBA PATIL	60	M	1098417	RTA	RIGHT	HEAD INJURY	8	20	33	41	6	145	150	65	60
2	GEETA GUMAJI	32	F	1106045	RTA	RIGHT	HEAD INJURY	9	24	35	43	10	160	180	70	60
3	SHANTAVVA	63	F	6514253	FOOSH	LEFT	-	6	18	35	41	8	165	170	70	70
4	SANKET	20	M	1105238	FOOSH	RIGHT	-	2	21	31	44	6	170	165	60	60
5	SHAMBAYYA	39	M	6589218	RTA	RIGHT	-	3	21	37	44	10	170	160	60	60
6	RAMESH	46	M	6578123	RTA	LEFT	-	5	26	34	41	8	160	150	70	70
7	PRAKASH	57	M	1137995	RTA	RIGHT	HEAD INJURY	8	23	36	40	8	170	160	60	65
8	VITTAL	58	M	1143073	RTA	RIGHT	RIGHT FIBULA FRACTURE	9	20	36	39	12	180	180	70	70
9	SHANTA	52	F	1150718	FOOSH	LEFT	-	1	18	35	42	6	170	160	60	60
10	SHIVANAND	51	M	1150756	RTA	RIGHT	-	2	19	33	42	10	180	180	55	50
11	SANTOSH	27	M	1163727	FFH	RIGHT	-	2	24	39	46	8	170	160	65	60
12	CHANDRAKANT	62	M	1167814	RTA	LEFT	-	3	20	39	41	12	165	160	60	60
13	IRANNA BASAPPA	25	M	1172348	RTA	RIGHT	-	2	22	38	42	8	170	160	50	60
14	BHARMAPPA	58	M	1176539	RTA	LEFT	-	2	20	32	40	8	160	170	50	50
15	MALLAPPA	32	M	1181533	RTA	RIGHT	HEAD INJURY	10	16	30	38	10	160	170	50	50
16	SHIVARAJ	30	M	1181673	RTA	RIGHT	HEAD INJURY	6	24	36	41	7	165	160	45	40
17	SAGAR N.	32	M	1187161	RTA	LEFT	-	4	23	38	44	12	150	160	40	40
18	NEHAL	29	M	1187951	FFH	RIGHT	-	2	18	30	42	11	160	170	50	50
19	SACHIN	28	M	1206724	RTA	RIGHT	HEAD INJURY	7	19	32	46	8	150	140	40	40
20	SAGAR B.	28	M	1208578	RTA	RIGHT	-	1	24	33	42	9	160	150	30	30
21	NINGAPPA	25	M	10003746	FOOSH	LEFT	-	3	24	32	41	12	160	140	40	40
22	UDAVVA	29	F	10007670	RTA	RIGHT	THORACIC INJURIES	10	28	38	50	12	130	140	30	30
23	VIJAY	47	M	10007715	RTA	LEFT	HEAD INJURY	8	26	36	48	11	135	140	40	40
24	SANTOSH G.	33	M	1167456	RTA	RIGHT	-	2	20	37	42	8	150	135	40	50
25	ARJUN	29	M	10006515	FOOSH	RIGHT	-	4	25	32	44	12	155	140	30	55
26	KALAGOUDA	44	M	1181529	RTA	RIGHT	-	1	27	38	47	10	150	150	35	40
27	SHANTAPPA	35	M	10032865	RTA	LEFT	-	1	20	33	38	8	150	170	40	40
28	PRAKASH	28	M	10032986	RTA	RIGHT	-	2	18	30	40	8	160	140	50	55
29	YALAPPA	58	M	10032984	FFH	LEFT	-	3	22	28	49	11	150	140	60	50
30	MAHANTESH	27	M	10032881	RTA	LEFT	HEAD INJURY	8	20	31	41	9	150	160	60	40
31	LAXMI	32	F	10032887	RTA	RIGHT	-	2	18	30	40	7	155	160	50	55
32	SHIVAPPA	38	M	10032884	RTA	RIGHT	-	4	19	37	47	7	150	170	40	40