EVALUATION OF FUNCTIONAL OUTCOME OF INTRAMEDULLARY INTERLOCKING NAIL FIXATION FOR HUMERAL SHAFT FRACTURE

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Under the Guidance of

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The Institutional Ethics Committee of Sri Devaraj Urs Medical College, Tamaka, Kolar has examined and unanimously approved the Synopsis entitled **"Evaluation of Functional Outcome of Intramedullary Interlocking Nail Fixation for Humeral Shaft Fracture"** being investigated by Dr.PATEL DARSHANKUMAR ATULBHAI & Dr. Nagakumar J S in the Department of Orthopaedics at Sri Devaraj Urs Medical College, Tamaka, Kolar. **Permission is granted by the Ethics Committee to start the study.**

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GLOSSARY	ABBREVIATIONS
IMIL	Intramedullary interlocking
UCLA	University of California Los Angeles
IM	Intramedullary
DCP	Dynamic compression plate
SF	Short form
ASES SCORE	American shoulder and elbow surgeons shoulder score
RR	Relative Risk
CI	Confidence Interval
AO/ ASIF	Arbeitsgemeinschafy fur Osteosynthesefragen/Association of study of internal fixation
AO	Arbeitsgemeinschafy fur osteosynthesefragen
IEC	Institutional Ethics Committee
SD	Standard Deviation
RTA	Road Traffic Accident
L	Lower
M	Middle
U	Upper
IMN	Intramedullary Nailing
ORIF	Open reduction and internal fixation

ABSTRACT

BACKGROUND AND OBJECTIVE: -

Fractures of shaft of humerus are commonly encountered, which accounts for approximately 3% of all fractures. Treatment methods for such injuries continue to progress as advances are made in both non-operative and operative methods of management. Antegrade interlocked humerus nailing for stabilization of humerus fractures was introduced many years ago and is a valid treatment option for stabilization of shaft of humerus fractures. Avoidance of complications like non-union, malunion, fracture disease, excessive soft tissue dissection and difficulty in nursing and rehabilitation in polytrauma cases allows intramedullary interlocking (IMIL) nails to successfully bridge the gap between functional bracing and plating.

The objective of study is to assess the functional outcomes of intramedullary interlocking nailing in case of humerus shaft fractures by University of California Los Angeles (UCLA) scoring system and the associated complications of above mentioned procedure.

METHOD: -

30 patients of age between 18-65 years admitted in orthopaedics department in R.L Jalappa hospital attached to Sri Devaraj Urs Medical College with fracture of shaft of humerus meeting inclusion and exclusion criteria were taken up for the study. Their demographic data, history, clinical examination, and details of investigations were recorded in study proforma, and then were taken for antegrade IMIL nailing. Time for recovery, ambulation time for the patient and complications of the procedure like pain, infection, joint stiffness, iatrogenic fractures, radial nerve palsy etc were documented and the patients were followed up at 1st, 3rd, and 6th month after surgery.

RESULT: -

In this study patients age ranging from 18-65 years with mean age of 43.1±14.8 were assessed of which 22 were male and 8 were females. Fracture of middle third was most common accounting to 56.7% of the humerus shaft fractures. Most common mode of injury was RTA which was 66.7% and 60% of patients sustained injury to right side. In 83.4% patients, duration between trauma and surgery was 1-5 days and U-slab was the most common method of preliminary immobilization used in this study. Among 30 patients treated with IMIL nailing 2 cases had complication of shoulder stiffness and delayed union, one case had surgical site infection and shoulder stiffness, one case had only shoulder stiffness, one case had iatrogenic fracture of medial epicondyle of humerus, one case had implant breakage secondary to trauma post fixation. Functional outcomes were evaluated using UCLA scoring in which mean score of present study was 31.73±3.609 indicating excellent functional outcome following intramedullary interlocking nail fixation at 6-month follow-up.

CONCLUSION: -

Intramedullary interlocking nailing is safe and effective modality of treatment for the humerus shaft fracture with excellent functional outcome with mean UCLA score of 31.73±3.609 at 6-month follow-up. At the follow up from 1 month to 6 month UCLA score improves from fair to good and excellent in majority of participants. Further IMIL nailing is associated with less complications (maximum of which was shoulder stiffness).

Keywords: Diaphyseal humerus fracture, humerus, Intramedullary interlocking nail, UCLA score.

INTRODUCTION

INTRODUCTION

Acute humerus fractures have a good healing tendency with non-operative methods thanks to the blood supply of surrounding muscles which is excellent. Thus, functional bracing is still the main modality of treatment in many trauma centres.[1,2] The humerus is the second most common bone affected by metastatic disease in the appendicular skeleton (ranging from 16 to 20% of the cases), followed by the femur. Humeral shaft fractures are commonly encountered by orthopaedic surgeons, accounting for approximately 3% of all fractures.[3,4,5]

Most of the shaft of humerus fractures could be treated by non-operative methods satisfactorily and it unites rapidly in 10-12 weeks. But it is associated with a notable risk of non-union, malunion, fracture disease, and difficulty in nursing and rehabilitation in polytrauma cases. Treatment methods for these injuries continue to evolve as advances are made in both non-operative and operative management. The encouraging results that have been reported with recent advances in internal fixation techniques and instrumentation led to an expansion of surgical indications for such fractures and a dilemma about the procedure of choice.[1]

When surgical treatment is needed, screws and plates osteosynthesis has been the main modality of treatment in many places.[6,7] Although dynamic compression plating has traditionally been considered the "gold standard" in humeral surgery, intramedullary fixation has certain advantages like being closer to the normal mechanical axis of a bone and it acts as the load sharing device. Bending forces and consequent fatigue failure are less. Since the fracture is not exposed directly (haematoma at the fracture site is preserved) and soft tissue dissection is less, the fixation is more biological and with less stress shielding and chances of iatrogenic nerve injury are also reduced. Intramedullary nail (IM) fixation is an established

method of treatment of high-energy long bone fractures especially in polytrauma setting, as well as osteoporotic, impending and pathological fractures. Locked IM nails can be inserted usually by using closed techniques by keeping the soft tissue dissection minimal in contrary to what is required for plating. Interlocking nails give rotational stability, decreases the need for post-operative bracing and allowing early mobilization of the extremity while preserving fracture haematoma.[8,9]

However, the procedure has its own pitfalls. Failed closed reduction, failed locking, iatrogenic fractures and nerve injuries in the intraoperative period and adhesive capsulitis, non-union, nail protrusion and impingement in post-operative period has been reported.[10]

AIMS & OBJECTIVES

AIMS AND OBJECTIVES

- To study the functional outcome of intramedullary interlocking nailing in case of humerus shaft fractures by UCLA scoring system.
- To study the complications encountered with intramedullary interlocking nailing.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Ummat A et al[10] observed that Superficial wound infection occurred in four cases (8%). Shortening of one cm was observed in one case (2%) and troublesome shoulder pain remained in two patients (4%). Persistent restriction of shoulder movements remained in twelve patients (24%) at 6 months, non-union occurred in two patients (4%), iatrogenic transient radial nerve palsy occurred in four patients (8%). Two patients (8%) developed myositis ossificans of shoulder joint and two patients (8%) developed hypertrophy of scar. Several technical errors and complications, which this study consider technique specific, were registered. The analysis and avoidance of these complications, related to intramedullary nailing of the humerus, will allow intramedullary nails to successfully bridge the gap between bracing and plating.

Baltov A et al[11] registered 52 (46.85%) intra-operative complications in 40 (36.04%) patients, on average 1.3 per patient. The most common were distraction n=5 (4.5%), long proximal locking screws n=9 (8.1%), additional diaphyseal fracture n=7 (6.3%) and countersinking of nail in humeral head n=8 (7.2%). The number of postoperative complications were 40 (36.0%) related to 19 (17.1%) patients. When first generation nails were used, the intra-operative complications related risk increases to 1.58 times, and the postoperative complications related risk was 1.67 times higher compared to second generation nails. They registered several technical errors and complications, which they considered as technique specific. The analysis and avoidance of these complications, related only to IM nailing of the humerus, will allow IM nails to successfully bridge the gap between functional bracing and plating.

Demirel M et al[12] found in 109 fractures, primary union was observed. In the other five patients union attained after removal of a nail and fixation with DCP and bone grafting.

Average time of union was 13 weeks (range, 10-36 weeks). One hundred-five patients had excellent or satisfactory recovery of shoulder and elbow function. Complications included impingement due to proximal locking screws in two patients and prominent nail in three patients, transient postoperative radial nerve palsy in four patients. This study shows that antegrade locked nailing in humeral shaft fractures are reliable as well as effective in multiply injured patients.

Sheriff F et al[13] found that at 12-months follow-up, bone consolidation was present in 30 cases; in 1 case complications developed. Constant shoulder score, mean Morrey elbow score, SF-12 physical score or SF-12 mental score was assessed. Antegrade inter-locking nailing of humerus shaft fractures can result in good functional outcome and unimpaired quality of life. Compression interlocking can minimize the fracture gap and increase the biomechanical stiffness. Potential disadvantages of compression interlocking include possible bending or loosening of the locking screw in the dynamic oblong hole.

Rajagopal HP et al[14] observed patients with age ranging from 20 to 74 years (average, 36 years) and average follow-up was 30.7 months (range, 12–48 months). There were 13 male patients and 7 were females. Fracture at middle third of shaft was most common accounting to 80% (16/20) of fractures. Fracture union was attained in 90% (18/20) of their cases. 2 patients had non-union for which additional surgeries were needed. According to Constant–Murley score, excellent shoulder function was achieved in 70% (14/20) while good in 25% (5/20). Average ASES score was 93.3%. No patients had radial nerve palsy postoperatively. Correct entry point, minimizing injury to rotator cuff, gentle and adequate reaming, embedding nail tip, static locking and good approximation of fracture fragments will help make antegrade intramedullary nailing, a reliable solution for the treatment of shaft of humerus fractures and in attaining successful union with good elbow and shoulder function.

Ganji P et al[15] found that humeral interlocking nail is an effective means of fixation of acute humeral fractures. It is also of special value in open humeral fractures due to lower incidence of infections. Distraction at the fracture site should be avoided. Shoulder stiffness is a significant problem in antegrade nailing, which can be minimized if taken care in preventing proximal protrusion of the nail and repairing the rotator cuff properly and early institution of physiotherapy.

Cox MA et al[16] found that there were four established nonunions and four cases of delayed union (time to union > four months). Age of patient was the only predictor of nonunion. There was one case of intraoperative fracture and one case of infection. Two prominent proximal screws required removal, and one nail was removed after union because of impingement. Three patients required manipulation under anesthesia to improve shoulder movement. At review, six patients had residual poor shoulder function as per Constant score, four attributable to shoulder stiffness and two to residual pain. The author`s findings shows significant rate of non-union or delayed union in elderly patients. Rationale and indications for humerus nailing should be distinctly defined, when increased rate of union is considered with conservative treatment.

Pestatodes G et al[17] found that cases of locked humeral nailing have offered a reliable solution for the treatment of humeral diaphysis fractures, giving a satisfactory functional outcome and high rate of union, allowing early use of the limb, which is of great importance, especially in multiple trauma patients and those having a pathological fractures. Reservations must be raised, however, as regards use of humeral nailing in comminuted proximal third fractures, especially in osteoporotic patients. Certain technical aspects, such as proper countersinking of proximal end of the nail, avoidance of overdistraction at the fracture site, and achievement of adequate fixation stability, must be given adequate attention in their effort to reduce delayed union and nonunion rates and to obtain better functional results.

Jinn L et al[18] observed that total 30 patients had 31 significant complications. Nine of them were persistent non-unions, six from acute fractures and three from non-unions. Fracture gap was associated with a significantly higher risk of non-union. The risk of operative comminution was significantly increased in retrograde nailing, and operative comminution resulted in a significantly higher risk of nonunion. Seven of the nine nonunions underwent revisional nailing and achieved eventual union. Removal of the protruded screws was performed in two cases. Other complications included shoulder impairment, elbow impairment, angular mal-union, and radial nerve palsy post nailing. Many complications of humerus nailing can be prevented by improving design of the implant or surgical techniques. The patients with persistent nonunion can be reliably treated by revisional nailing and bone grafting.

Blyth MJG et al[19] in his study, first consecutive 51 shaft of humerus fractures treated with Russell-Taylor intramedullary nail at Glasgow Royal Infirmary were reviewed in a retrospective study. There were eight iatrogenic nerve injuries- three to the radial nerve which settled spontaneously and five to the lateral cutaneous nerve of forearm of which three had failed to recover completely. The authors feels that the insertion of distal interlocking screws in the antero-posterior direction puts this nerve at risk. They believe that iatrogenic injury to lateral cutaneous nerve of forearm during humeral nailing has not been previously reported.

Garnavos C et al[20] found that while intramedullary nailing has been considered as gold standard treatment for diaphyseal fractures of femur and tibia, its role in the management of diaphyseal humeral fractures remains controversial. The reasons include not only the complicated anatomy and unique biomechanical characteristics of arm but also the fact that surgical technique and nail designs devised for the treatment of femur and tibia fractures are being transposed to the humerus. As a result, there is no unanimity on many aspects of the

humeral nailing procedure, e.g., the basic nail design, nail selection criteria, timing of the procedure, and the fundamental principles of the surgical technique (e.g., antegrade/retrograde, reamed/unreamed, and static/dynamic). Proposals aiming to improve outcomes include the categorization of humeral nails in two distinct groups: "fixed" and "bio", avoidance of reaming for the antegrade technique and utilization of "semi-reaming" for the retrograde technique, guidelines for reducing complications, setting the best "timing" for nailing and criteria for selecting the most appropriate surgical technique (antegrade or retrograde).

Bhandari M et al[21] did meta-analysis on comparison of Compression plating versus intra-medullary nailing of humerus shaft fractures from which 3 studies (involving 155 patients) were pooled, since they were homogeneous ($p > 0.1$) found that plate fixation gave a lower relative risk of reoperation than intramedullary nailing (RR = 0.26, 95% CI 0.007-0.9, $p = 0.03$). This translated to a risk reduction of 74% for reoperation when plate fixation was employed. Thus, 1 reoperation could be prevented for every 10 patients treated with plates. Plate fixation also reduces the risk of shoulder problems in comparison to intramedullary nails (RR = 0.10, 95% CI 0.03-0.4, $p = 0.002$). Plate fixation for humerus shaft fractures may reduce the risk of reoperation and impingement of shoulder. The cumulative evidence remains inconclusive, and a larger trial is needed in order to confirm these findings.

Stannard JP et al[22] found that Forty-one patients with forty-two fractures had an adequate duration of clinical follow-up (a mean of twenty-two months) for analysis. Thirty-nine fractures healed, with a mean time to union clinically of twelve weeks. Thirty-eight of the forty-two shoulders had minimal or no pain. Thirty-six shoulders had a full range of motion. The mean Constant shoulder score was 90 points. Four patients had five complications, which included two nonunions, two hardware failures, and one wound infection. All four patients had been managed with a 7.5-mm nail. A multivariate analysis demonstrated that age

of more than fifty years was associated with lower Constant score and that the occurrence of a complication was associated with a lower physical component score on the Short Form-36 (SF-36). The flexible humeral nail allows both retrograde and antegrade implantation and static locking. Nail insertion can be accomplished without violating the rotator cuff or damaging the articular surface of the humerus head. Although the nail functioned well for most of their patients, the use of small-diameter (7.5-mm) nail was associated with increased complication rate. This implant should be handled with precaution in any subject with a medullary canal diameter of <or=8 mm.

The treatment of shaft of humerus fractures has a long history. In the past 75 years, after World War two, however, surgeons started using plates, intramedullary nails, external skeletal fixation implants and many more fixation methods when managing humeral diaphyseal fractures. The history of non-operative management of humeral diaphyseal fractures shows that a multiplicity of different treatment methods has been employed. As with non-operatively treated fractures, the surgeon must expect to encounter some cases of malunion. However, in the humerus minor degrees of malunion rarely present a problem because shoulder girdle compensates for the alteration of humeral length along with rotatory and angular deformities. In addition, simple humeral diaphyseal fractures are distinguished from more complex fractures by the absence of static strain and the presence of normal functioning antagonistic muscle groups. This tends to minimize the incidence of significant malunion. Treatment methods employed in the past included the sling and swathe method. In addition, reversed sugar tong splints, thoracobrachial spica casts and plaster Velpeau dressings were also employed. Surgeons also made use of adduction splints or casts and, if the humeral fracture was associated with multiple queries, lateral or overhead traction was occasionally employed. These treatment methods often immobilizes elbow and shoulder

joints for considerable periods and which consequently ends up with joint stiffness and impaired function for an extended period.

In **350BC, Hippocrates** utilized bandages embedded with resins and waxes to treat various fractures.[23] In **860 AD, Rhaze** for treating various fractures utilized lime and egg white in Arabia.[23] In **1852, Matthysen** a military surgeon in Dutch utilized plaster of paris for treatment of fractures for the very first time.[23] In **1897, Nicolaysen** described Medullary fixation principles for fixation of fracture of long bones.[24] In **1918, Hey Groves** demonstrated Intramedullary nailing techniques for diaphyseal fractures of the long bones.[24] In **1933, Caldwell** discovered and popularized the **"Hanging Cast Technique"** which utilizes cast`s weight to provide traction and helps in reduction of the fracture.[25] In **1939, Kuntscher** of Hamburg utilized V-shaped nail, which was inserted from the long bone end passing through the fracture site with the help of guide wire and under fluoroscopic control.[24] In **1939, Rush** utilized Steinman pin for intramedullary fixation of humerus, ulna and femur. Later they altered the pin ends to hook and introduced the techniques for treating extremities fractures.[26] In **1958, Muller** with various other surgeons from Swiss made AO/ASIF group. Internal fixation principles were formulated by AO.[26]

Fracture shaft of the humerus account for 3 % of all the fractures.[3,4,5] The concept for treatment of Shaft fractures has been evolving over the period. Historically closed modality of management for humerus shaft fractures have centered around any one of the below mentioned two principles:

1. Thoracobrachial immobilization
2. Dependency traction

Thoracobrachial immobilization utilized body as splint. This was attained by utilizing shoulder arm spica casting or by body strapping. This treatment modality was not reliable for either maintaining the alignment of the bone or promotion of bone healing.[27]

Caldwell promoted **hanging arm cast** as a treatment option for management of humeral shaft fractures. These are above elbow casts. They are stipulated to weigh less than 2lbs., in order to avoid distraction. These casts are provided with series of loops, which are used to correct angulation deformities. U slabs or co-aptation splints were devised based on dependency traction. These are effective methods of treatment but functionally inferior to bracing. Treatment for shaft of humerus fractures was revolutionized by the **functional bracing** introduced by **Sarmiento.** This is a fracture treatment orthosis made up of lightweight plastic brace fitted with Velcro straps. This has provided magnificent long-term outcome with 100% union rate with minimal rate of complications like malalignment, infections, and iatrogenic nerve injury. Various studies found bracing to be a much superior modality of fracture treatment in an otherwise normal individual.[25,27,28]

Intramedullary interlocking (IMIL) nailing was the obvious sequel for this and first nail to be introduced was the Seidal's nail. Here the distal locking is achieved by expandable fins, which are opened from within the barrel. This fell into dispute because of the complications associated with flange failure.[29]

❖ SURGICAL ANATOMY:-

Humerus as one of the long bone constitute the appendicular skeleton of our body. Humerus forms the single bone scaffold of the arm segment. Humerus is the long tubular bone with a diaphysis and globular metaphysis proximally and a flattened and widened metaphysis

distally. It is surrounded by a thick sleeve of muscles both anterior and posterior, which enhances the vascularity of the bone.[30]

❖ ANATOMY OF THE HUMERUS

Humeral diaphysis constitutes the middle three – fifth of the bone expanding from pectoralis major attachment proximally to supracondylar region distally. The cross-section of diaphysis is circular in its proximal half and in the distal half it gradually becomes triangular. This transition occurs near the insertion of the deltoid at the mid diaphysis.[30]

▪ DIAPHYSIS

The proximal third of shaft is broad and rounded in cross section. It is grooved anteriorly by the long head of biceps. In the distal half the diaphysis flattens out into a triangular cross section. It has an anteromedial and an anterolateral surface flanked by medial and lateral supracondylar ridges. It also has a posterior surface. The lower end of humerus in its juxtaarticular region is marked by the fossae to accommodate the olecranon in posterior aspect and the radial head and coronoid in the anterior aspect. The medullary canal follows the contour of the humeral shaft. It is rounded in proximal third and is triangular in distal half. It is broad proximally and tapers down distally. The medullary canal is straight and has an anterior offset in the distal end.[30]

▪ PROXIMAL HUMERAL METAPHYSIS

Proximal humeral metaphysis is the broad and globular end of the bone. It has a spherical head, which engages with glenoid of scapula. Apart from this, in proximal part of humerus there are two bony prominences, the greater and lesser tuberosity isolated from each other by bicipital groove. The shallow constriction forms anatomical neck of humerus separates the

two tuberosities from the articulating surface. This is a significant landmark for the entry point for the interlocking nail in antegrade insertion technique.[30]

- **DISTAL HUMERAL METAPHYSIS**

Distal humeral metaphysis flattens anteroposteriorly and broadens mediolaterally. It is made up of the medial epicondyle, trochlea, capitulum, and lateral epicondyle from medially to laterally. In between distal articulating surface and diaphysis there is olecranon fossa located posteriorly and the coronoid and the radial head fossa situated anteriorly.[30]

The distal articulating surface is angulated anteriorly by an angle of 40 degrees to the diaphyseal axis of humerus in sagittal plane. The shaft is supplied by single nutrient artery arising from the brachial artery at the mid diaphyseal level.[30]

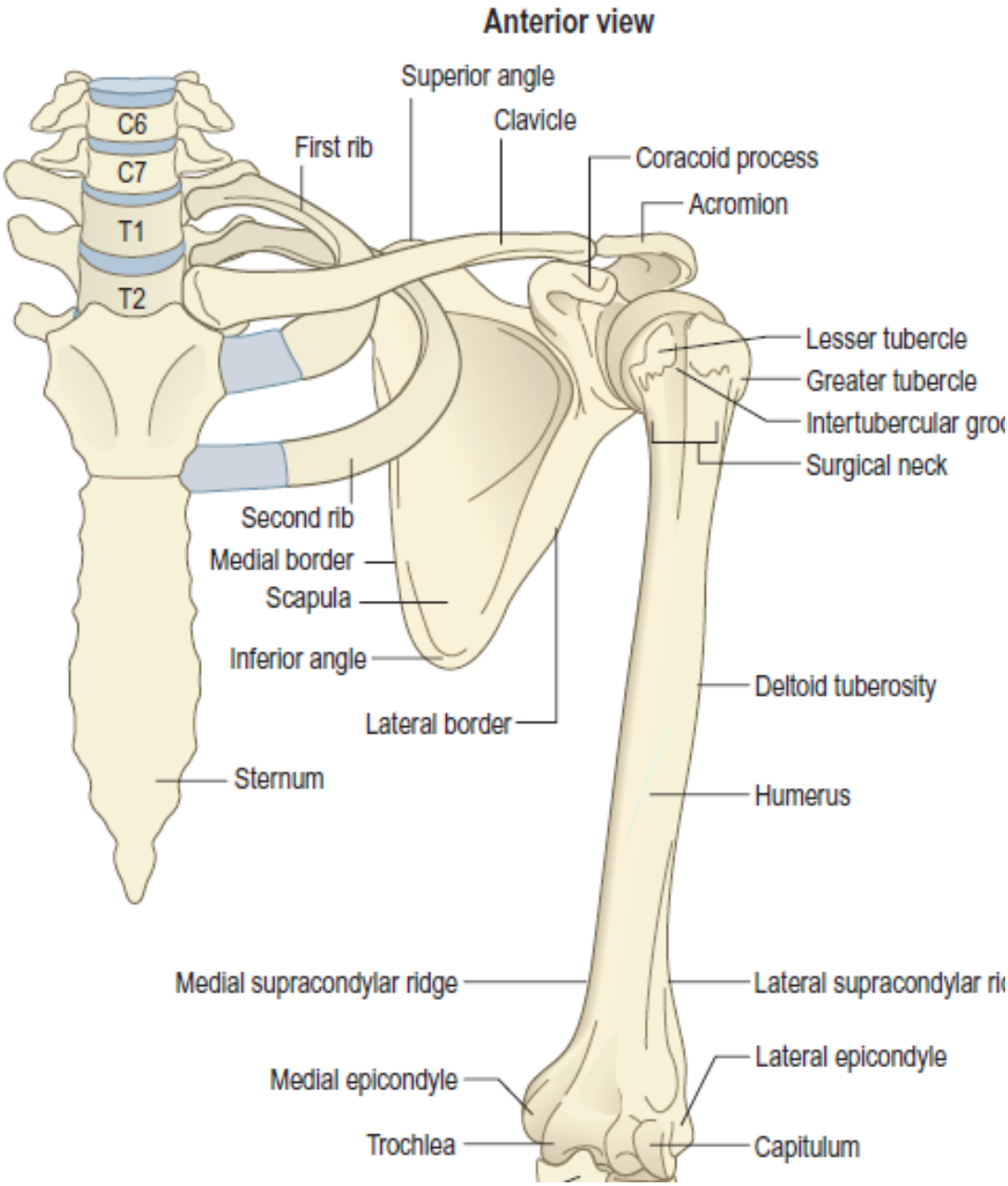

Figure 1: Bony anatomy of humerus anterior view[30]

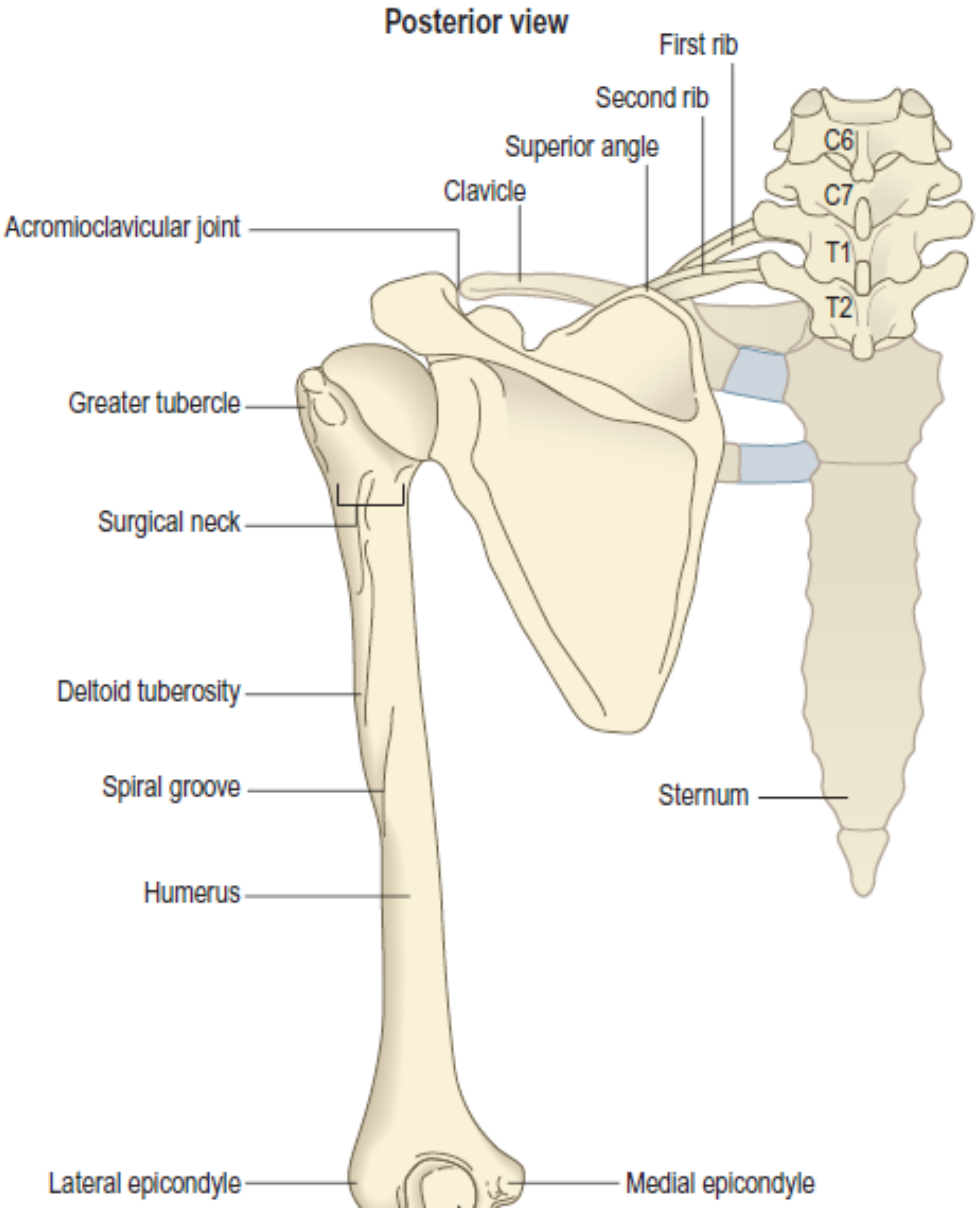

Figure 2: Bony anatomy of humerus posterior view[30]

- **SOFT TISSUE RELATIONS**

The humerus is surrounded by rich sleeve of muscles, which provides increased vascularity for the bone. Neurovascular bundles around the humerus are protected from damage by the surrounding soft tissue during exposure of bone.[30]

- **MUSCULAR RELATIONS**

Triceps lies over the posterior surface of humerus, two of its heads, lateral and medial, originates from posterior surface of the bone on both side of radial groove. Biceps brachii is related to bone anteriorly but it does not have any attachment on the humerus, and the brachialis arises from anterior surface of distal third of the bone. The deltoid envelops lateral, anterior and posterior portions of the proximal third of humerus shaft.[30]

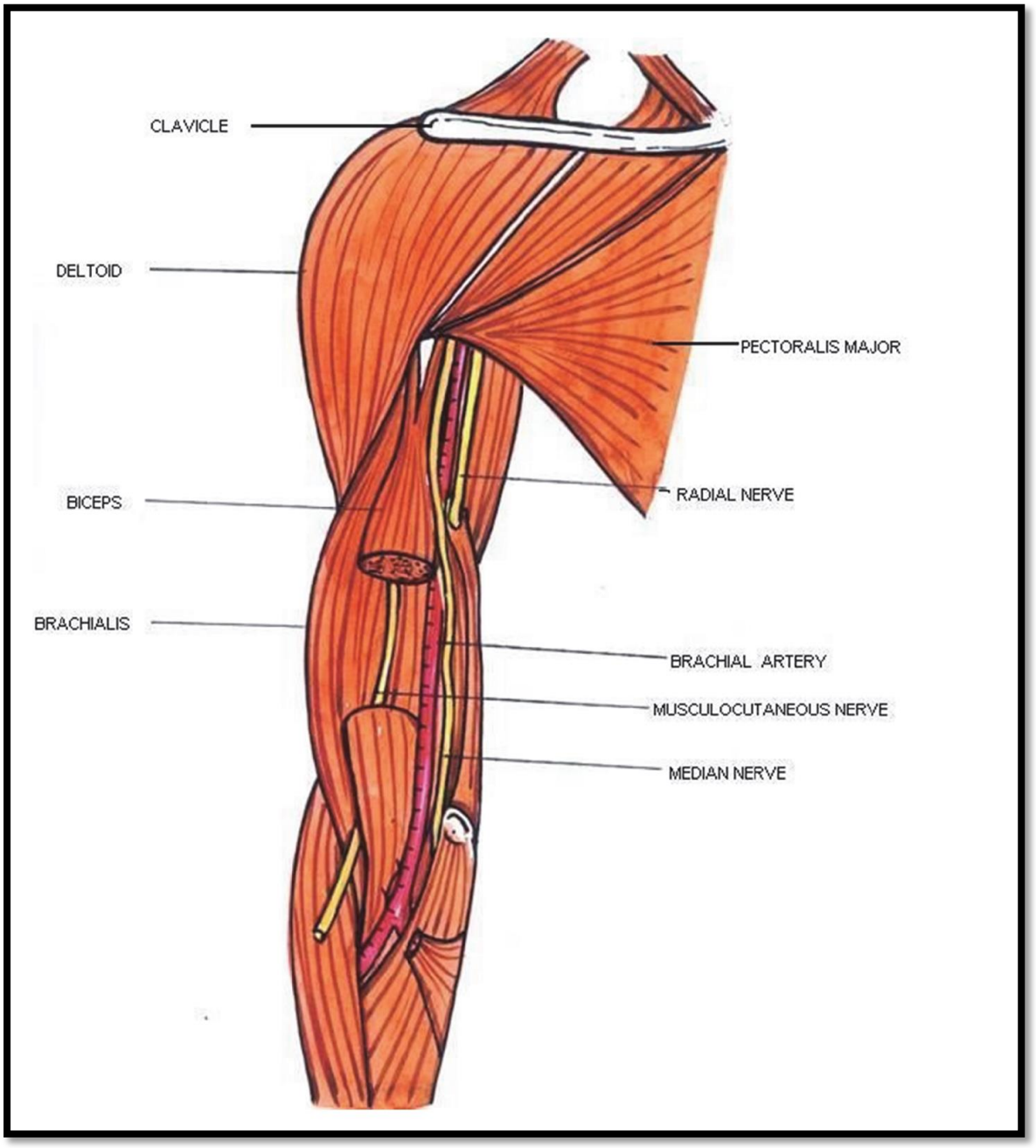

Figure 3:- Muscles of anterior Compartment of arm[30]

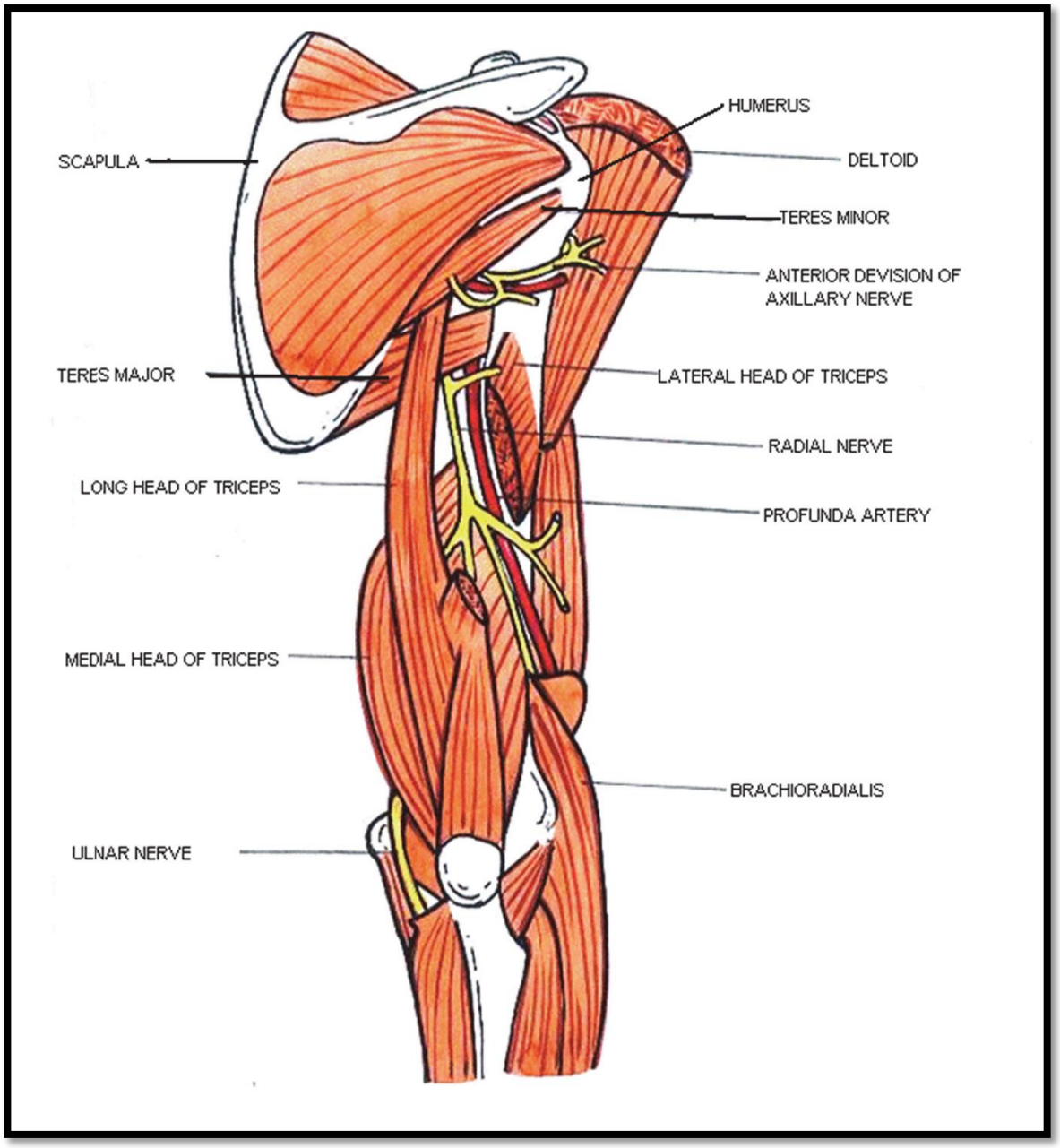

Figure 4: - Muscles of posterior Compartment of arm[30]

- **MUSCULAR ATTACHMENTS**

The anatomical neck of humerus has the attachment of shoulder joint capsule and various ligaments. The rotator cuff muscles insert on the greater tuberosity. From superior to inferior greater tuberosity has attachment of supraspinatus, infraspinatus and teres minor. Lesser tuberosity has attachment of subscapularis muscle. Latissimus dorsi, pectoralis major and

teres major insert into the bicipital groove. The deltoid attaches to the deltoid tuberosity which is located on lateral aspect of the humeral midshaft. Coracobrachialis inserts on the medial aspect correlating to insertion of the deltoid. The anteromedial and anterolateral surfaces in distal third of humerus gives brachialis muscle origin. Lateral and medial heads of triceps originate above and below of the bicipital groove on the posterior surface of humerus. Common extensor and flexor origin arise from lateral and medial epicondyles respectively. Extensor carpi radialis longus, extensor carpi radialis brevis and brachioradialis originates from lateral supracondylar ridge of humerus.[30]

- **NEURO VASCULAR RELATIONS**

Three important neurovascular bundles surround the humerus in its anatomical association. Axillary nerve winds around the proximal metaphysis of humerus innervating the deltoid. On an average it lies 4.56cm distal to lateral border of acromion. This is the important landmark while inserting proximal locking screw. Radial nerve is accompanied by profunda brachii vessels. It goes around posterior aspect of humerus in radial groove bounded by lateral and medial head of triceps. It is important in exposure of posterior humerus shaft for plating. Occasionally radial nerve gets trapped in the humerus shaft fracture which ends up with radial nerve palsy. Brachial vessels, ulnar and median nerve and the medial cutaneous nerves of arm and forearm runs between the brachialis and biceps brachi.[30]

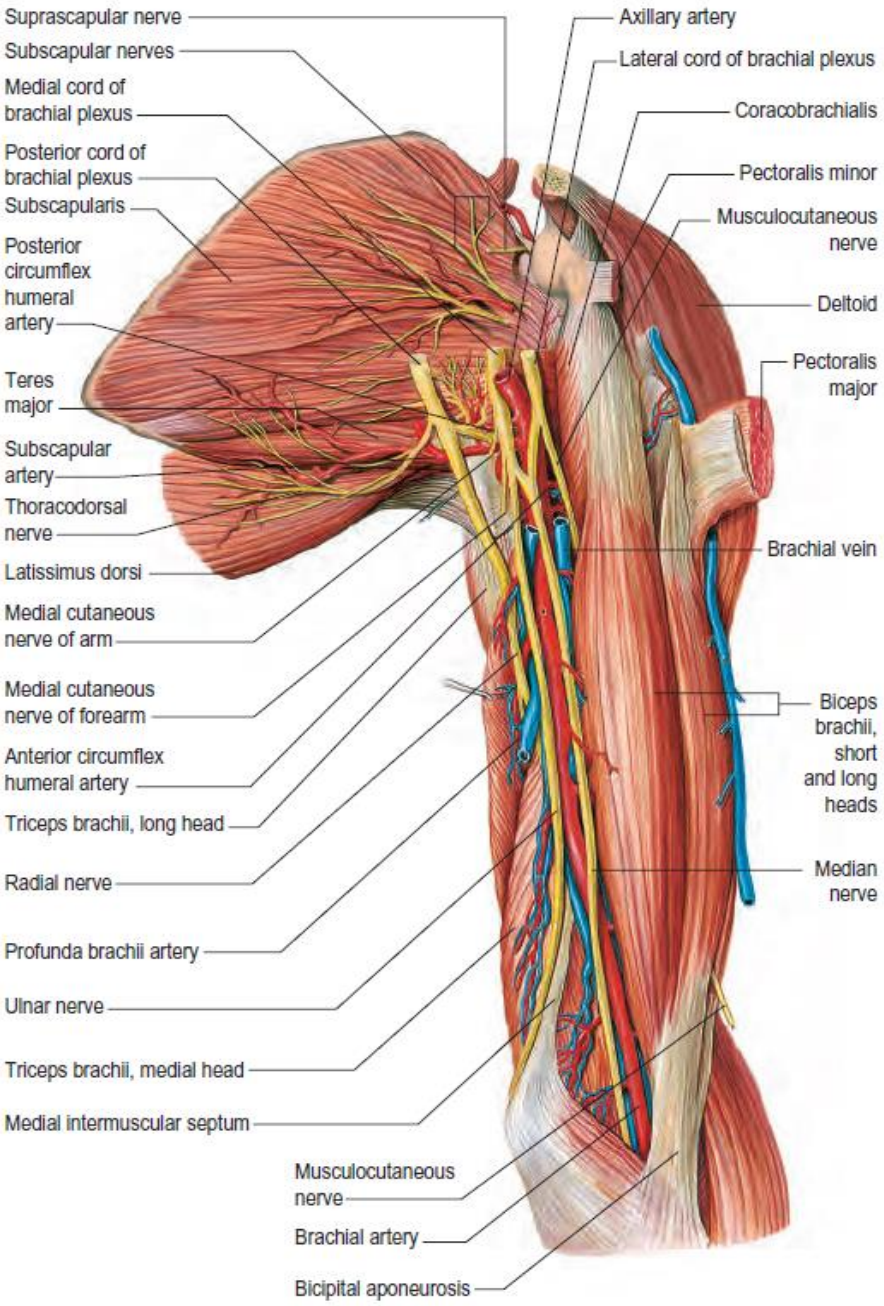

Figure 5: Neurovascular anatomy of arm[30]

❖ APPLIED SURGICAL ANATOMY

- Entry point for humerus nailing is nearer to the bicipital tendon which might get irritated if nail projects out.
- While exposing the entry point, dissection of the rotator cuff must be done, and it must be carefully repaired at the end.
- Entry point is intraarticular and there is often a increased risk of shoulder stiffness.
- The axillary nerve lies at distance of 4.56 cm from acromion tip distally. It might get injured while applying the lower of the proximal locking bolts.
- The radial nerve runs very close to middle two thirds of bone in the radial groove. It may be injured by the fracture, during reduction, or during exposure by posterior approach.
- The brachialis has a dual nerve supply which is by radial and musculocutaneous nerve. This information is used at time of developing the plane during anterolateral approach.
- The canal is almost straight, and the entry point is eccentric. This determines the angle in proximal end of nail.[30]

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▪ CLASSIFICTION

AO/AISF has a detailed system of classification of fractures based on site and morphology of fracture. The comprehensive classification is of good prognostic value, in that higher the fracture grades, greater is the impact of injury implying the higher chances of occurrence of complications while treatment.

A. AO/AISF CLASSIFICTION OF THE HUMERAL DIAPHYSEAL FRACTURES[31]

Type A: Simple fractures circumferential break in the bone

- A1 = Spiral fractures
  - a -in the proximal zone
  - b -in the middle zone
  - c -in the distal zone

- A2. = Oblique fractures - fracture lies at 30 degree or more to the diaphysis
  - a -in the proximal zone
  - b -in the middle zone
  - c -in the distal zone

- A3. = transverse fractures- fracture lies at < 30 degree to the diaphysis
  - a -in the proximal zone
  - b -in the middle zone
  - c -in the distal zone

Type B: Wedge fractures

Separate fragment but the fractures reduce with contact between the main fracture fragments

- B1. = spiral wedge as a result of torsional force
  - a -in the proximal zone
  - b -in the middle zone
  - c -in the distal zone

- B2. = bending wedge as a result of bending stress
  - a -in the proximal zone

- b -in the middle zone
- c -in the distal zone

- B3. = bending wedge where the wedge is comminuted
  - a -in the proximal zone
  - b -in the middle zone
  - c -in the distal zone

Type C: complex fractures

There are more than two fracture fragments, and even after reduction the two main fragments do not come in contact.

- C1. = spiral
  - a -in the proximal zone
  - b -in the middle zone
  - c -in the distal zone

- C2. = segmental
  - a -in the proximal zone
  - b -in the middle zone
  - c -in the distal zone

- C3. = irregular fractures
  - a -in the proximal zone
  - b -in the middle zone
  - c -in the distal zone

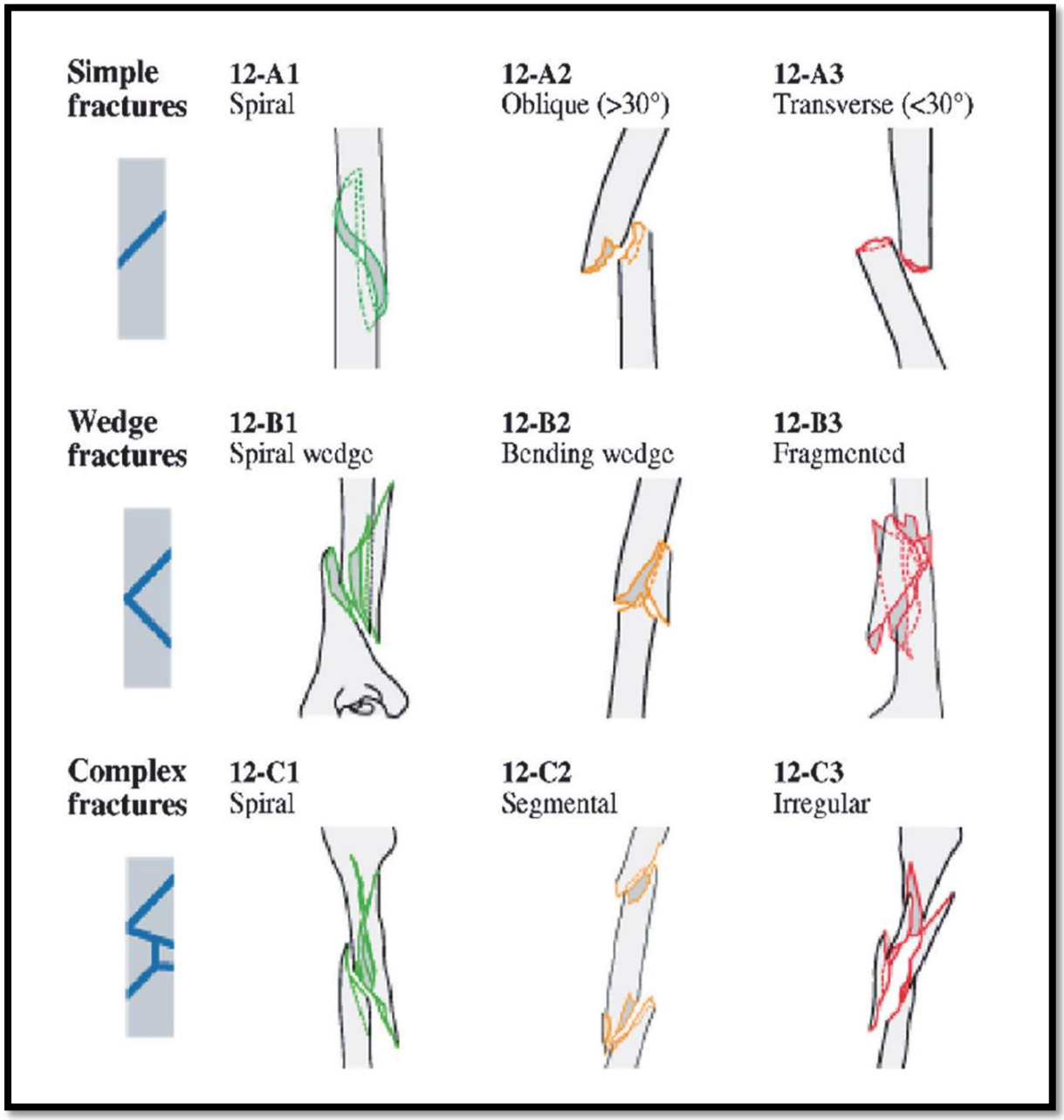


Figure 6: - AO/AISF classification of the humeral diaphyseal fractures[31]

❖ MECHANISM OF INJURY

Shaft of humerus fracture occurs usually due to direct trauma, but indirect trauma might also be the cause of fracture. Direct blow over arm, fall and road traffic accidents all constitutes direct trauma. Direct trauma usually causes comminuted or transverse fracture.[32,33]

Indirect trauma includes violent contraction of muscle, fall on outstretched hand and twisting injuries, which usually causes an oblique or spiral fractures. Humerus shaft fractures due to violent muscle contractions are uncommon. However, these fractures can occur following throwing baseball, hand grenades and arm wrestling. Indirect trauma usually causes fracture at middle and distal third junction of shaft of humerus.[32,33]

Compressive and bending forces leads to transverse fractures in general. While tortional forces causes spiral fractures. A wedge or oblique fractures can be caused due to combination of tortional and bending forces or compressive and bending forces. Elderly patients with history of fall usually sustains less comminution of bone. Greater degree of soft tissue injury and comminution is seen with high energy trauma. Fracture fragment displacement is mainly based on relationship of muscle insertion at the fracture site. The proximal fragment of humerus goes into external rotation and abduction if fracture occurs above pectoralis major insertion, this is due to unopposed action of external rotators (infraspinatus and teres minor) and supraspinatus.[32,33]

Proximal fragment will go into adduction while distal fragment will have proximal and lateral displacement if fracture occurs between pectoralis major and deltoid insertion. If fracture occurs distal to deltoid insertion, there will be abduction of proximal fragment by deltoid and there will be proximal displacement of distal fragment.[32,33]

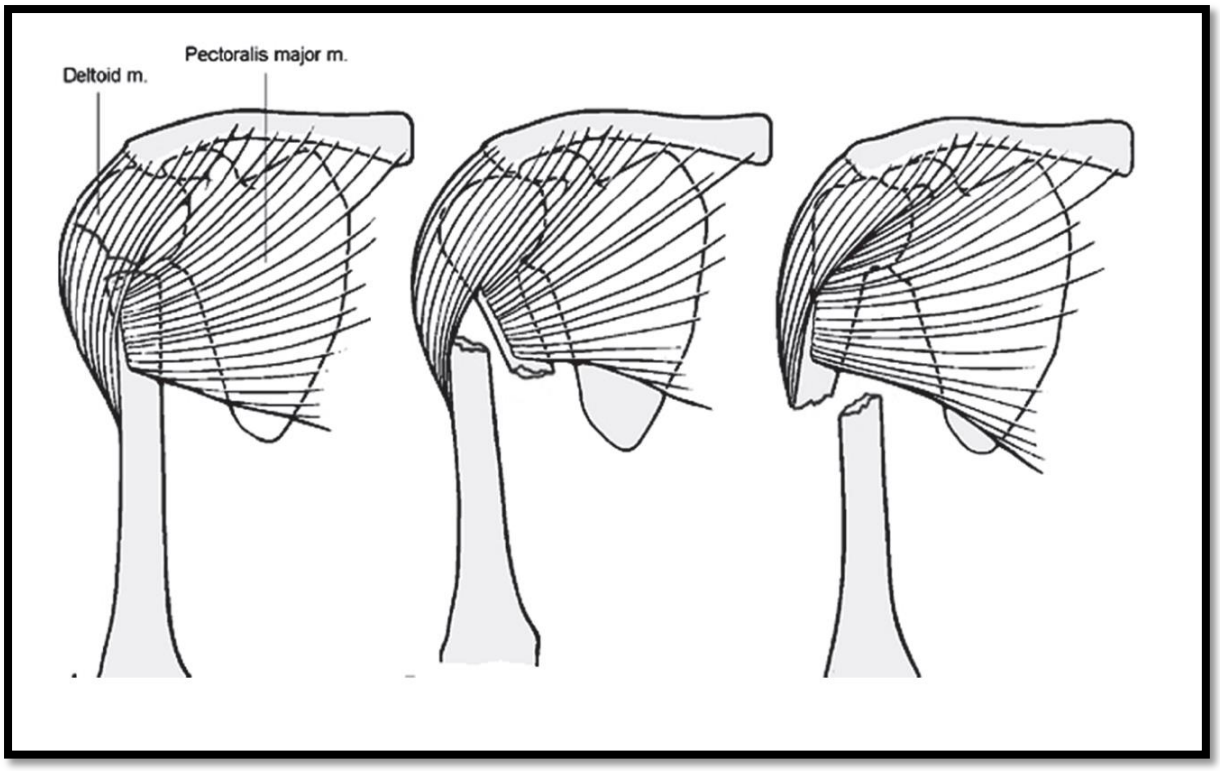


Figure 7: Mechanism of displacement of proximal shaft fracture of humerus[32,33]

❖ GENERAL PRINCIPLES OF MANAGEMENT

In almost 60 % of the patients, humerus shaft fractures are associated with polytrauma. Hence these systemic problems must be sought after and treated before the definitive management of the humeral fractures.

- AVAILABLE TREATMENT OPTIONS

1. Thoracobrachial immobilization
2. Closed reduction and hanging cast
3. Closed reduction and coaptation splint
4. Open reduction internal fixation with
    a) Plate osteosynthesis
    B) Intramedullary nailing

I. Multiple nails

II. Flexible nails

III. Solid nails

5. Closed reduction internal fixation with intramedullary interlocking nailing

6. External fixator application with

a. AO external fixator

b. Ilizarov ring fixator

AO/AISF formulated the following treatment guidelines based on Lambotte's principles of surgical management of fractures.

- Anatomical reduction especially in intraarticular fractures
- Stable internal fixation to fulfill local biomechanical demands
- Preservation of blood supply
- Active painless mobilization of the limb to prevent development of joint disease.[34]

❖ INTRA- MEDULLARY INTERLOCKING (IMIL) NAIL FIXATION[31,34]

Closed intramedullary nailing for humerus shaft fractures is becoming the main modality of treatment in case of polytrauma patients, fractures associated with overlying burns injury, patients having osteoporotic bone, patients with segmental and pathological fractures. IMIL nail fixation can be used to fix any humerus fractures which are 3cm proximal to olecranon and 2cm distal to surgical neck of humerus. IMIL nail can be passed antegrade or retrograde and it is designed for reamed and unreamed insertion.

INSTRUMENTS AND IMPLANTS USED FOR NAILING

1- Drill bit of 3.2 mm and 2.7mm

2- Double drill sleeve

3- Hexagonal screwdriver

4- Depth gauge

5- Wrench

6- Slotted hammer

7- Bone awl

8- Protection sleeve

9- Drill sleeve

10- Trocar

11- Insertion handle

12- Connecting screws for un-reamed humerus nail

13- Reamed and un-reamed humerus nails

14- 3.4 mm locking bolts

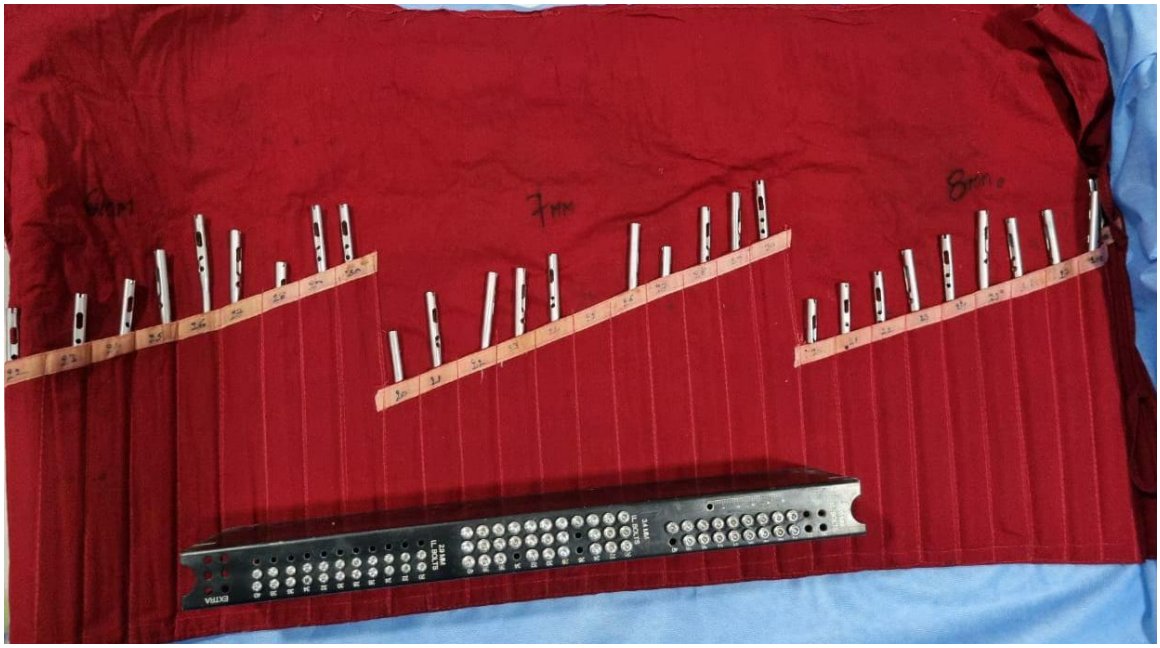


Figure 8: - Interlocking instrumentation set

Figure 8: - Interlocking instrumentation set

- Antegrade Nailing

Nail length and diameter can be estimated from the preoperative X-rays of un-injured humerus.

- Preoperative planning

Proper alignment and length of humerus must be achieved with traction before inserting antegrade nail. To avoid brachial plexus palsy, open reduction might be required in case of late displaced fractures. The inserted nail should be restricted approximately 1 to 2 cm proximal to olecranon fossa.

- Patient`s position and preparation

Patient to be placed in supine position with head turned to opposite side for better exposure of shoulder. Traction might be applied either by assistant or through a skeletal traction pin placed in olecranon which in turn attached to traction bow. Rotational alignment is achieved by putting shoulder in anatomical position and manipulating the distal fragment such that arm, and hand is directing towards the ceiling and elbow is flexed to 90°.

- Approach and preparation of humerus

Longitudinal skin incision centering the tip of greater tuberosity is made from most lateral point of acromion and extending distally. Deltoid fascia is incised, and greater tuberosity palpated. Entry point of nail is just medial to tip of greater tuberosity which is approximately 0.5 cm posterior to bicipital grove (to reduce risk of damage to rotator cuff), and tip of nail should be buried in bone proximally, to minimize sub-acromial impingement. Small straight bone awl is used to make entry in bone just medial to tip of greater tuberosity.

Entry point of nail is confirmed under image intensifier. Entry point should be at the center on both anteroposterior and lateral views to secure the nail in midplane of humerus.

- Guide wire insertion

Bone awl is withdrawn and 2.4mm guide wire is inserted. The position of guide wire at the medullary canal center is confirmed with the image intensifier. Guidewire is inserted through the fracture site into distal fragment till its tip reaches 1 to 2 cm proximal to olecranon fossa.

- Determination of nail length

1. Using a guide wire method, with distal end of wire 1 to 2 cm proximal to olecranon fossa, overlap another guide wire extending proximally from humerus entry point. Length of overlapped guide wire is subtracted from the total length to get the correct nail length.

2. Gauge method for nail length- gauge is placed anteriorly to humerus, pre- operatively 1 to 2 cm proximal to olecranon fossa. Now bring the C-arm to proximal end of humerus and read correct length of nail directly from stamped measurement on the nail length gauge.

- Reamed method

Humerus is reamed along its entire length over 2.4 mm guide wire in 0.5 mm increments until the required diameter is achieved. Medullary canal is reamed 1 mm greater than the selected diameter of nail.

- Un-reamed method

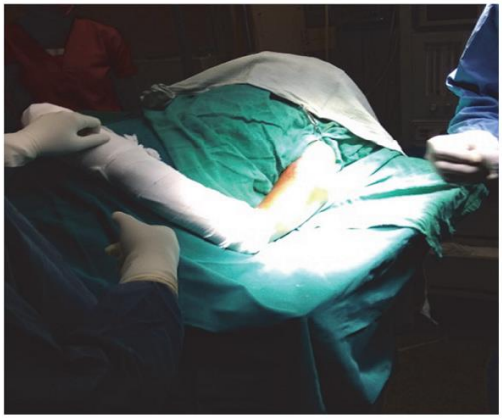
With the help of 10 mm diameter reamer proximal humerus metaphysis is reamed for about 4 cm, to open medullary canal. T handle Jacobs's chuck is mounted with sounds and is inserted manually. The biggest diameter sound which passes through the isthmus easily is the correct nail diameter.

- Humeral nail insertion

After removal of guide wire, non-cannulated humerus nail is inserted under c-arm guidance. Proximal drill guide is attached to the selected nail. The guide is grabbed with outrigger handle pointing away from patient and proximal nail curvature is pointed laterally. Nail is inserted distally till 1 to 2 cm proximal to olecranon fossa is reached, during which care must be taken to avoid risk of splintering of distal humerus. Nail position at distal fragment is checked by lateral and antero-posterior image intensification.

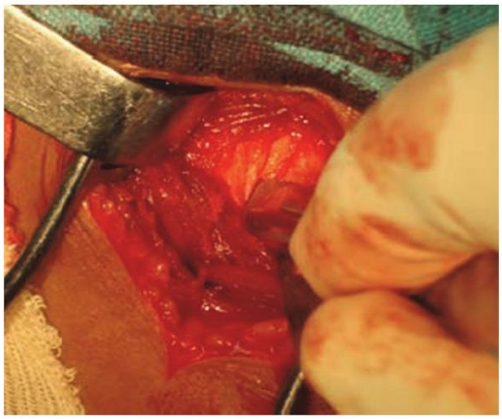
- Proximal and distal locking of humeral nail

A 3.4 mm locking screws are used for proximal and distal locking. Proximal screws are inserted using the zig and sleeves which is attached to nail. For placement of distal interlocking screw, with antero-posterior orientation of oval distal screw hole in nail, antero-posterior insertion portal is made. Using free hand technique screw is inserted under C-arm guidance.

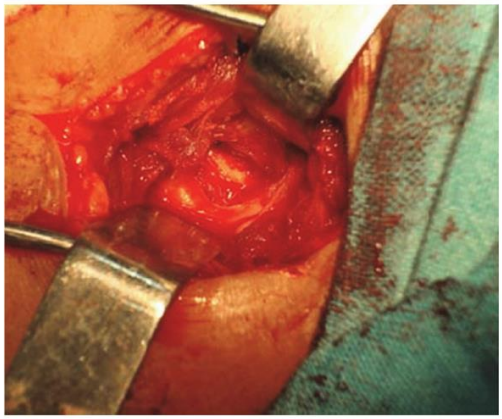


Patient positioning and draping

Skin incisions



Supraspinatus



Proximal humerus exposed

Awl entry

Nail inserted using zig

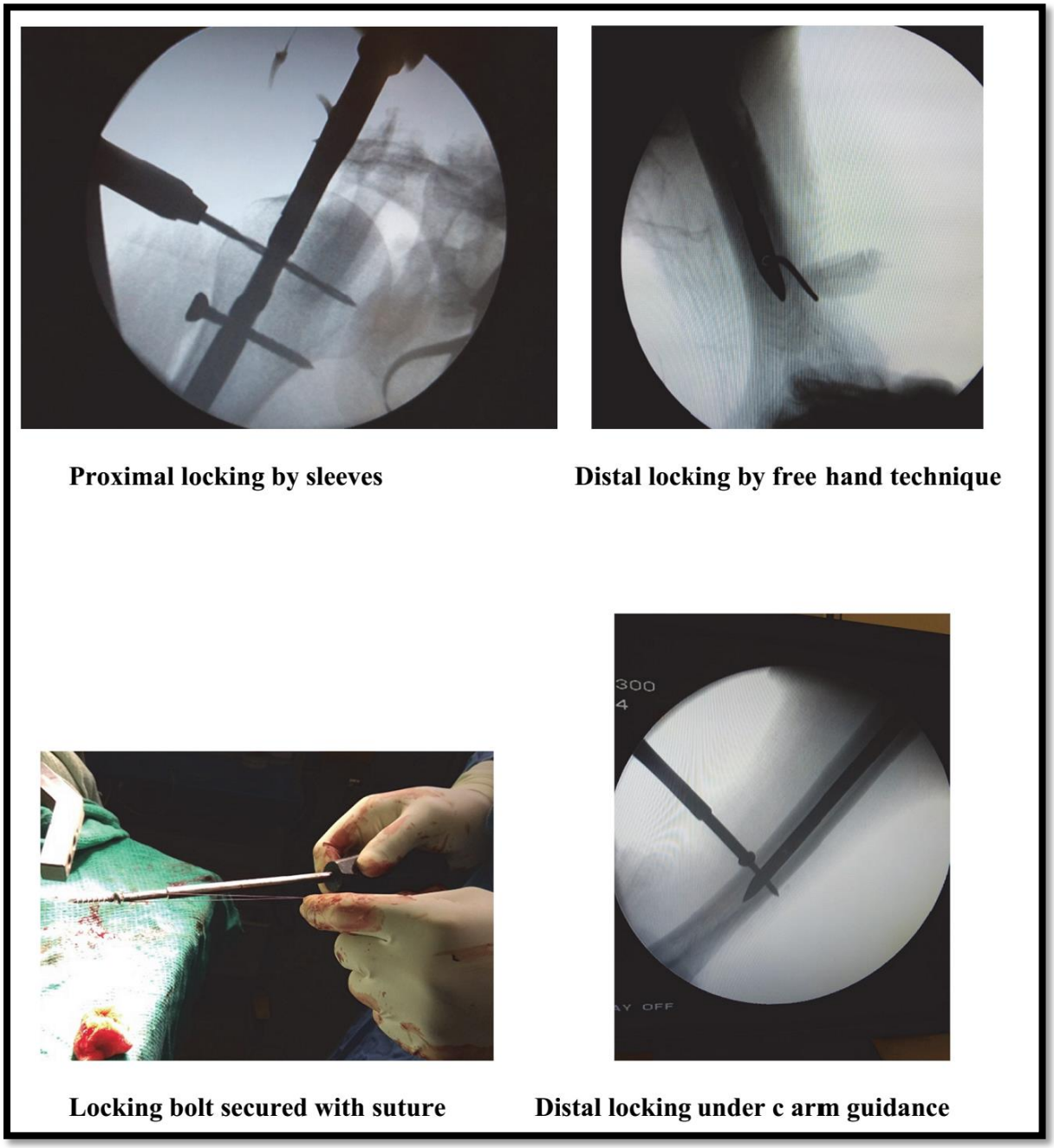


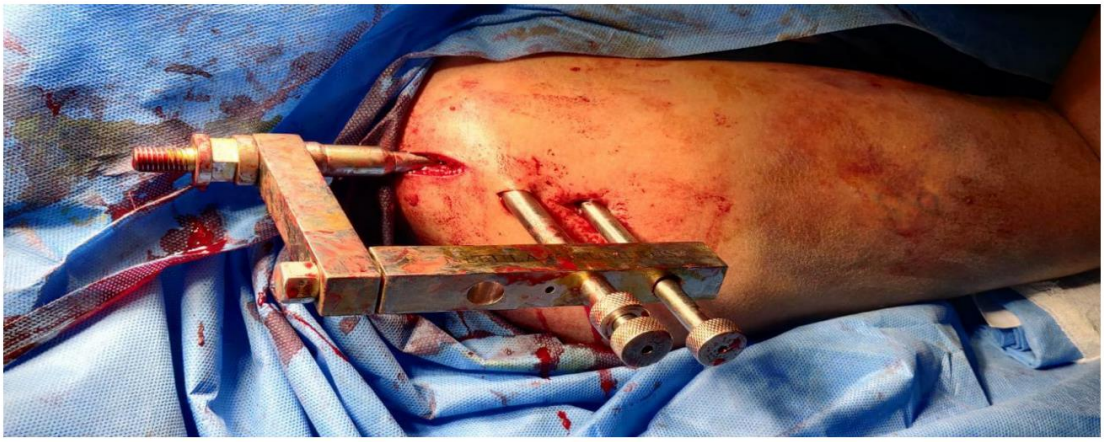
Figure 9: - Antegrade Humerus Nailing Technique

Skin marking for humerus fracture

Incision

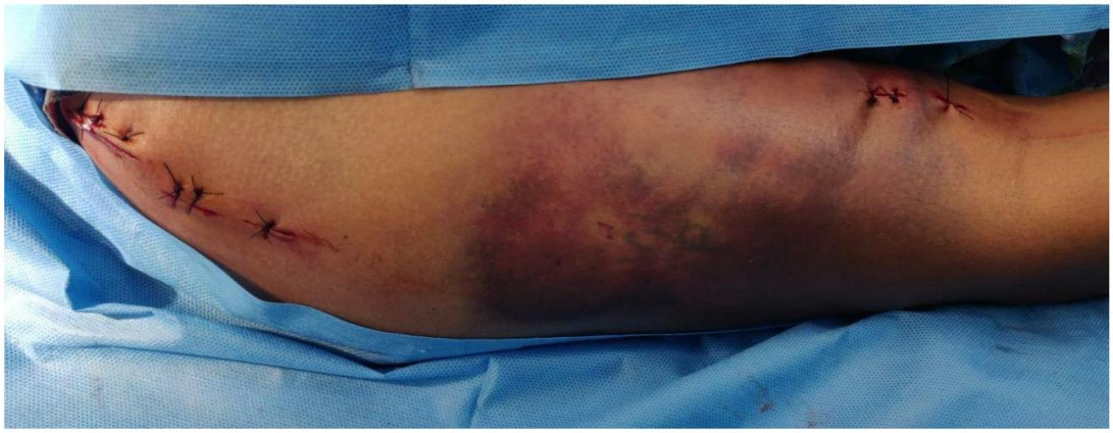
Entry point

Guide wire insertion



Proximal locking

Distal locking



Skin closure

C-arm image of entry point

C-arm image of proximal locking

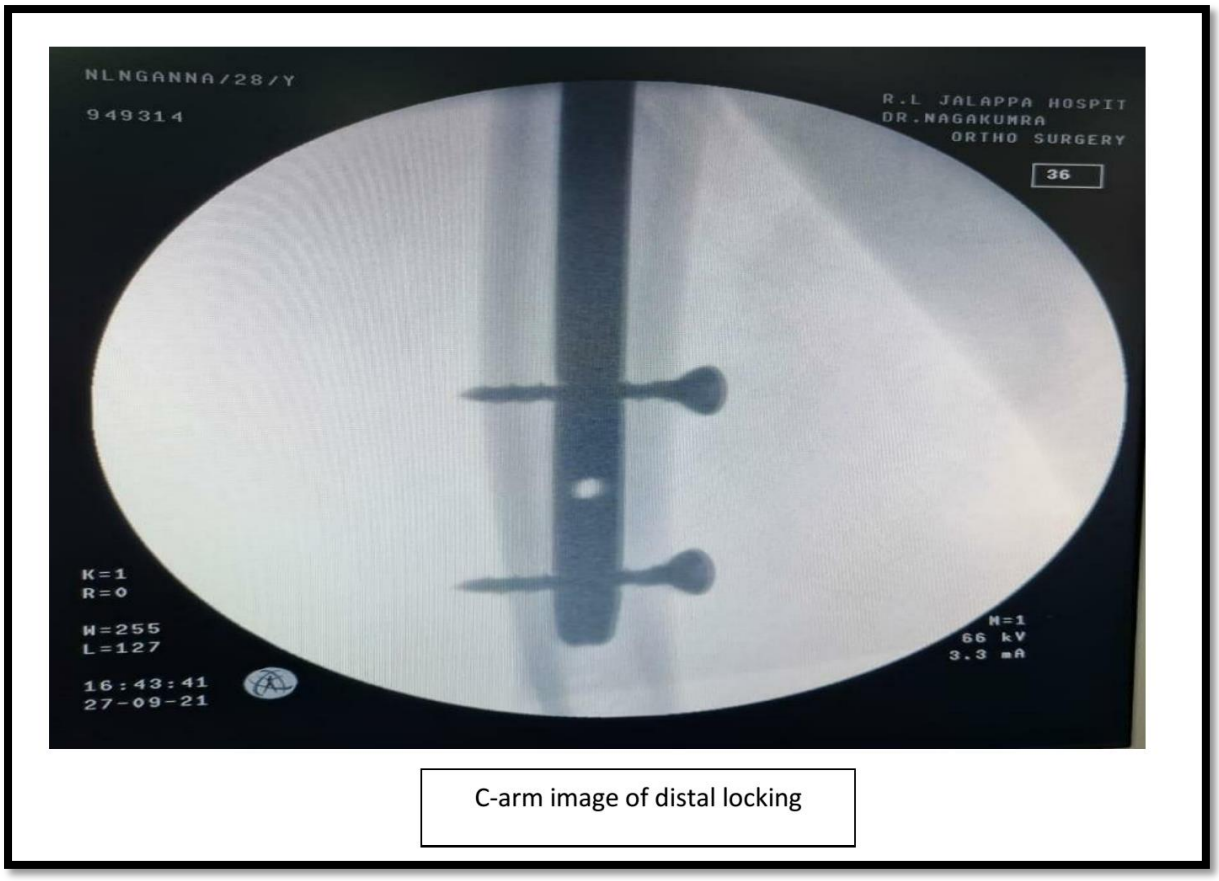


Figure 10: Intraoperative images of IMIL nailing for humerus

- Retrograde humeral interlocking nailing

  Retrograde humerus nailing can be used for mid-shaft and proximal third fractures without damaging sub-acromial space or rotator cuff. Contraindications for retrograde humeral nailing are fractures of osteoporotic bone, medullary canal with diameter less than 10 mm and distal third humerus fractures.

- Positioning of patient

  With patient in prone or lateral decubitus position retrograde humerus nailing can be performed. Radiolucent arm board is used for fractured extremity if patient is placed in prone position. While using lateral decubitus position, fractured limb is suspended, and care must be taken to avoid distraction of fracture site and to avoid risk of neurovascular compromise.

- Approach and preparation of humerus

  A longitudinal incision from tip of olecranon process to 6 cm proximally is made and along the fibers of triceps it is split. Olecranon fossa along with the region proximal to it is located. Using a drill posterior cortex of humerus shaft, 2.5 cm proximal to most proximal extent of olecranon fossa is opened, and hole is extended with small, curved awl.

- Guide wire Insertion

  Ball tipped guide wire of size 2.4 mm is inserted. Guide wire is inserted proximally through fracture site into proximal fragment using image intensifier. Guide wire position in proximal fragment is confirmed with the help of image intensifier by internally and externally rotating the arm. Guide wire is passed into humerus head if it is situated properly in medullary canal.

- Nail length determination

  The nail length can be obtained either by using nail length gauge or by using guide wire.

- Humeral nail insertion

  It must be ensured that the guide wire is removed before inserting the humeral nail. Care must be taken during nail insertion, to avoid fracture of the bone proximal to entry point or piercing of nail through anterior cortex. Prominence of distal end of nail outside the medullary canal should not be more than 1 cm. Proximal end of nail should not be closer to subchondral bone more than 2 cm, as closer placement of nail to subchondral bone will leads to placement of proximal locking screws where it might extend into sub-acromial space.

- Proximal and distal locking of humeral nail

  With the help of zig attached to the nail, distal screws are inserted. By using free hand technique, proximal screws are placed from lateral to medial direction.

- Post-operative period

  Application of compression bandage with arm pouch immobilization is given post-operatively. On post-operative day two, surgical site inspection should be done, and parenteral antibiotics should be continued for 3 days period. Suture removal should be done on post-operative day 12.

- After treatment:

  Arm sling immobilization should be done for period of 2 to 3 days, following which active shoulder and elbow range of motion exercises should be started at 4^{th} to 7^{th} post-operative day.

❖ BIOMECHANICS OF INTRAMEDULLARY NAILING

The concept introduced by Kuntscher of elastic intra-medullary nailing is based on the principle of elastic impingement (i.e., radial compliance). The nail with a slot, while insertion can be compressed. The nail would expand and occupy the entire medullary canal, once the insertion is complete. This was used in fixation of femur, tibia and the humerus. Even though his concept was successful in treatment of the lower limb fractures, it was found not to be effective in treating the humeral diaphyseal fractures.[35]

Further mechanical testing shows that these nails are stable based on three-point fixation rather than radial compliance. Multiple flexible nails have been used in fixation of humeral diaphyseal fractures as they are found to provide rotational stability because of their multiple entry points and because of multiple nails providing a greater strength.[35]

Significant deforming mechanical stress is exerted on the bone by the muscles getting attached on to it. These stresses may be bending stress, compression stress, rotational stress and distraction stress. As intra-medullary nail is placed at the Centre of bone, it gives temporary stiffness to bone and acts as internal splint and works as load sharing device. It permits load transmission at fracture site and hence aiding fracture healing. Translational and bending stresses are best controlled by these nails. Since it shares the center of rotation of the bone it does not controls rotational stresses acting on bone. This can be achieved by additional fixations like derotation plates, interlocking screws or pins.[35]

❖ INTERLOCKING NAILS

The introduction of interlocking nail has made the use of unlocked nails obsolete.

- STATIC LOCKING & BRIDGING FIXATION

  Screw insertion at both the ends of the humerus nail gives rotational stability by interlocking the nail with proximal and distal fragment. Interlocking essentially, maintains bone length and it also controls rotational stability at fracture site. As stresses at humerus are much more of rotational type than compression and distraction type, interlocking is very important. Bridging fixation could be achieved by static locking. In case of bridging fixation implant crosses the fracture, location and is engaged to distal and proximal bone fragment by locking screws situated at a distance from fracture site. Static locking is efficacious in treating fractures with severe comminution, spiral or long oblique fractures, frail soft tissue coverage. In these conditions it is undesirable to open the fracture site and devascularize the fracture ends.[35]

- NAIL LENGTH AND WORKING LENGTH

In working with interlocking nailing, three lengths of nail become significant

- Total nail length
- Length of nail bone contact
- Working length

Total length of nail is purely anatomical. Too long nail can protrude at a point of insertion and thus be intraarticular. It may cause distraction at fracture site and ends up with non-union. Too short a nail length can compromise the fracture fixation. Length of nail bone contact reflects the total surface area of contact between bone and nail. This may provide for the rigidity of nail fixation.[35]

The success of fixation can be determined by the working length of nail. Working length is defined as length of nail traversing fracture site from distal most point of fixation in proximal fragment. This explains the bone length carrying load across the fracture place. Bending stiffness of nail is in inverse proportional relation with square of nail`s working length. Torsional stiffness is in inverse proportional relation with working length. Therefore, shorter the working length, stronger the fixation.[35]

- LOCKING SCREWS

Strength of the locking screws depends upon root diameter and span of the screws between the support points. The screw ends are supported by the two cortices, while the longitudinal load is applied by the nail. Hence the locking screw is loaded at four points. Screws which have threaded portion at one end and solid shaft at other end have better strength. Obliquely oriented locking holes prevent mediolateral translation on varus or valgus load.[35]

❖ MATERIAL PROPERTIES

Material which is used in nail preparation should have sufficient strength to bear varied stresses and it should have anti-corrosive properties. Properties of material depends upon porosity of material, grain size, composition of material and the processing involved. Distinct materials have distinct elastic modulus thus have distinct tensile strengths. Titanium alloy and 316 L stainless steel are best suited material for fracture fixation.[35,36]

The composition of 316 L stainless steel is iron, 17% chromium, 12% nickel, 2% molybdenum along with 0.03% carbon and 3% manganese. It has an excellent resistance to corrosion. Compared to human bone it has modulus elasticity. Composition of titanium alloy are aluminum, vanadium and titanium composite. Titanium alloy has property of modulus of elasticity very similar to human bone and it also has anti-corrosive property because of its ability to form oxide films. Because of its ability of cyclical loading, it has very good resistance to fatigue.[35,36]

❖ PRINCIPLES OF FRACTURE FIXATION BY INTERLOCKING NAILING

Intramedullary interlocking nailing is safe and effective method of fracture fixation. Early mobilization of nearby joint and soft tissue is enough proof for the adequate stability provided by the fixation. This is the biological means of fixation and aims at providing early useful movements of the arm.

Basic concepts associated with interlocking nailing are:

1. It can be used to fix any fractures between a point 3 cm from surgical neck of the humerus to a point 4 cm proximal to the upper limit of the olecranon fossa.
2. Closed nailing must be attempted whenever possible. This is more scientific and biological way of fixing the fracture.

3. Bony union is the primary objective of surgical procedure. Nail is in no way a good substitute for bony union.
4. Proper dimensions of instrumentation and nail are essential. Image intensifier control is mandatory.
5. Intramedullary fixation may be complemented with reaming. Use of reaming is based upon the concept of providing a uniform bone implant interface.[35]

❖ **INTERLOCKING NAILING VS PLATING**

- ADVANTAGES
  - ➢ No periosteal stripping
  - ➢ Fracture hematoma not disturbed
  - ➢ Minimal incision, so chances of infection less

- DISADVANTAGES
  - ➢ Insertion site is intra articular so chances of impingement
  - ➢ Chances of injury to rotator cuff
  - ➢ Incidence of non-union

- UNREAMED NAILS
  - ➢ Rush nails, Enders nails, and Hacketh nail.
  - ➢ Unreamed humeral nail AO (Synthes)

- ADVANTAGES
  - ➢ Lesser operating time.
  - ➢ Lesser disruption of endosteal blood supply

- Lesser infection rate
- Lesser disruption of the fragments of comminution.

- DISADVANTAGES
  - Only small sized nail can be used

- REAMED NAILS
  - Cannulated nail system

- ADVANTAGES
  - Allows use of larger sized implants
  - Allows for a better bone implant interface
  - The osteogenic potential in the osteoprogenitor cells present in the reaming debris and morselized bone fragments promote bony union.

- DISADVANTAGES
  - Improperly reduced eccentric reaming results in splintering and malreduction
  - Loss of endosteal blood supply may result in delayed union.
  - Increases the risk of fat embolism
  - Higher infection rates
  - Need for a flexible and cannulated reaming system is essential
  - Costly equipments and inventory.[35]

EFFECTS OF REAMING ON DIAPHYSIAL CIRCULATION

Rhenlander et al. studied the consequences of reaming on diaphyseal blood flow and bony union. Theoretically, the endosteal vessels supply two-thirds of the diaphyseal cortex. By destroying this blood source, reaming delays osteosynthesis.[37,38]

Cylindrical tubular bones, which fill the medullary canal further, jeopardize the vascularity by entirely filling the canal. Moreover, reaming leaves, a layer of necrotic bone material, which fills space inbetween the bone and the implant creating a large potential sequestrum. Till the revascularization is complete this is potentially a disastrous region for infection. However, the intramedullary position of the nail does not hamper the restoration of the endosteal flow.[37,38]

MATERIAL & METHODS

MATERIALS AND METHODS

- **Study Setting**: Study was done at orthopaedic department R.L.Jalappa Hospital attached to Sri Devaraj Urs Medical College, Tamaka, Karnataka, India.
- **Study design: -** The current study was prospective, observational and hospital-based study
- **Study subject: -** Study has included 30 cases with fracture shaft of humerus admitted at orthopaedic department R.L.Jalappa Hospital attached to Sri Devaraj Urs Medical College, Tamaka.
- **Inclusion criteria: -**
    - Patients between 18 years and 65 years with humeral shaft fracture.
    - Fracture of humerus >2cm distal to surgical neck and 3 cm proximal to olecranon fossa.
    - Closed/Open (type 1) fractures of humerus shaft.
- **Exclusion criteria: -**
    - Humerus shaft fractures associated with neurovascular injury
    - History of previous humeral fracture of the same side
    - Pathological fractures
- **Study period: -** October 2019 to June 2021.

- **Data Collection: -**

The study has been presented to the Institutional Ethics Committee (IEC) for ethical clearance. After getting clearance from IEC, the study has been started. All selected subjects has been approached and personally met & briefed about the study. After taking informed consent, a detailed questionnaire has been administered to the selected patients, according to their convenience. Strict confidentiality has been employed in conducting

the survey and use of information provided by each respondent. If study participants were not available due to some reasons, they have been re-approached after few days. Even after two trials, if they were not available or not ready to give information, they have been considered under non-responsive.

❖ **Measurement Tool: -**

- UCLA Scoring System

The UCLA outcome measure was developed at a time when little information was available on the appropriate methodology for instrument development. It was also a time when modern psychometric development was not routinely implemented. Inevitably, the methodology used for development of this tool is not explained, and the reasoning behind the question development and its weighting is not understood. Despite this, the UCLA SCORE is still widely used for specific situations, such as following treatment of shoulder instability or rotator cuff disease.[39]

The questionnaire is a combined objective and subjective survey that requires completion by both the doctor and patient. It has five sub-scales made up of: active forward elevation and strength (physician reported), pain, satisfaction, and function (patient reported). A maximum score of 35 is possible with higher scores indicating better outcomes. The UCLA score can then be converted to a 100-point scale for comparison with other shoulder outcome tools.[39]

UCLA Shoulder Rating Scale

	Score
Pain	
Present always and unbearable; strong medication frequently	1
Present always but bearable; strong medication occasionally	2
None or little at rest, present during light activities; salicylates frequently	4
Present during heavy or particular activities only; salicylates frequently	6
Occasional and slight	8
None	10
Function	
Unable to use limb	1
Only light activities possible	2
Able to do housework or most activities of daily living	4
Most housework, shopping and driving possible; able to do hair and to dress and undress, including fastening brassiere	6
Slight restriction only; able to work above shoulder level	8
Normal activities	10
Active forward flexion	
> 150°	5
120°–150°	4
90°–120°	3
45°–90°	2
30°–45°	1
< 30°	0
Strength of forward flexion (manual muscle testing)	
Grade 5 (normal)	5
Grade 4 (good)	4
Grade 3 (fair)	3
Grade 2 (poor)	2
Grade 1 (poor muscle contraction)	1
Grade 0 (nothing)	0
Satisfaction of the patient	
Satisfied and better	5
Not satisfied	0

Maximum Score = 35 points
Excellent = 30–35 points
Good = 28–33 points
Fair = 21–27 points
Poor = 0–20 points

Figure 11: UCLA shoulder rating scale[39]

- **Ethical issue: -** The study has been presented to Institutional Ethics Committee for ethical clearance. Written informed consent has been acquired from the subjects after a full explanation of the requirement of the study. There were no interference or influence of the research process on the treatment of the patient. The treating team has been free to administer the treatment as it considers relevant based on the clinical requirement of the patient. All information collected has been strictly used for study purposes, and confidentiality has been strictly maintained. This was also ensured to study participants before starting the study. The Consent Form and Participant Information Sheet are attached as annexure.

- **Sampling Method:**

  All eligible patients with humerus shaft fracture who has been fulfilling the inclusion criteria has been approached & assessed in the following phase.

  1. Informed consent from the patient has been obtained.
  2. Inclusion and exclusion criteria have been applied to the patient.
  3. Sociodemographic data has been obtained from patients.
  4. Patients has been followed up at 1^{st}, 3^{rd} & 6^{th} month after surgery. Serial x-rays were done at each follow-up. Radiological and clinical union of fracture site was assessed along with shoulder range of movement assessment.

  Final assessment was done at 6^{th} month.

- **Data analysis:** Collected data has been entered in excel data sheet and data analysis done with the help of IBM SPSS software 22.

❖ **Statistical method:**

Descriptive analysis has been carried out by mean and standard deviation for quantitative variables, frequency, and proportion for categorical variables. Data also be represented using appropriate diagrams like bar diagram and pie diagram.

The relationship between explanatory variables and categorical outcomes has been assessed by comparison of percentages. IBM SPSS version 22 has been used for statistical analysis.

RESULTS

RESULT

Table 1: Descriptive analysis of age distribution in the study population (N=30)

Age Group [in year]	Number	%
<20	1	3.3
20-40	13	43.3
41-60	12	40
>60	4	13.3
Mean ± SD	43.1 ± 14.8	

In this study number of patients with age group <20 years are 1 (3.3%), 20-40 years are 13 (43.3%), 41-60 years are 12 (40%), >60 years are 4 (13.3%).

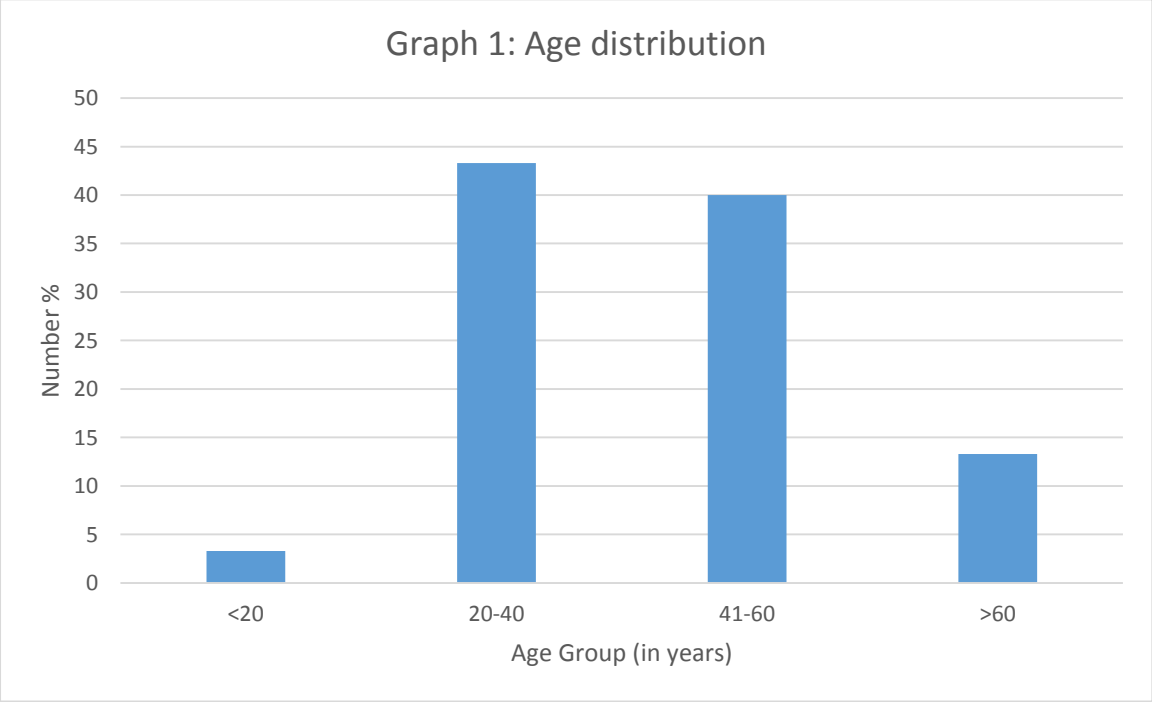


Table 2: Descriptive analysis gender distribution in the study population (N=30)

Gender	Number	%
Male	22	73.3
Female	8	26.7

In this study number of male patients are 22 (73.3%), while number of females are 8 (26.7%).

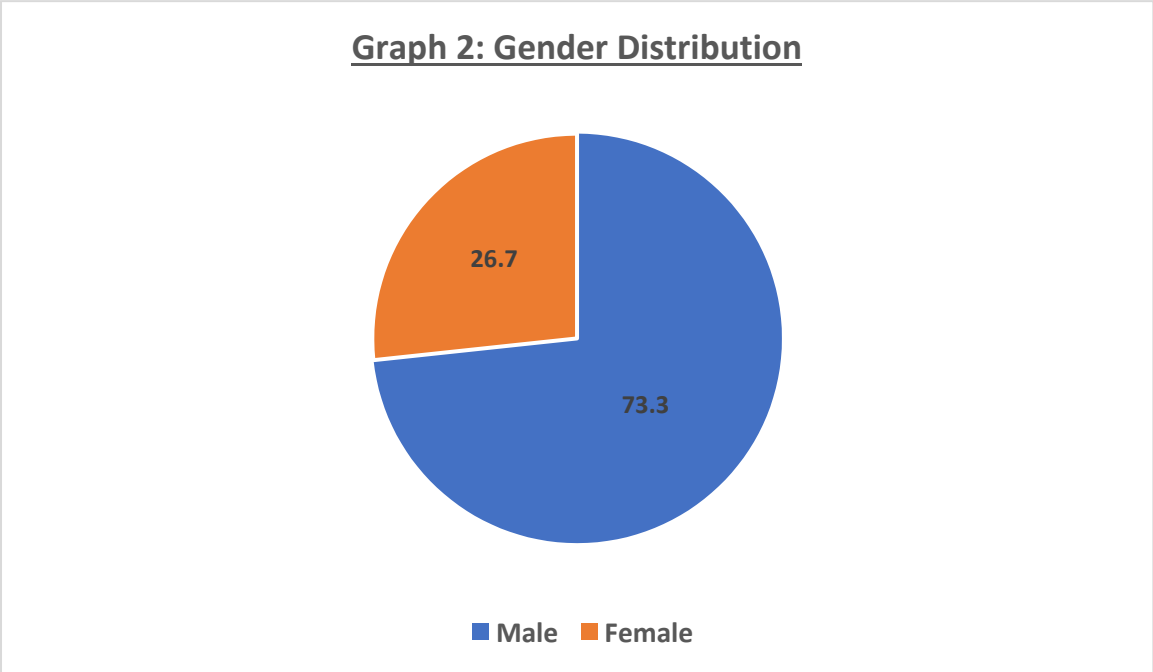


Table 3: Descriptive analysis 'mode of injury' in the study population (N=30)

Mode of Injury	Number	%
Assault	3	10
RTA	20	66.7
Slip & fall	7	23.3

In this study number of patients who had humerus shaft fracture following assault are 3 (10%), RTA are 20 (66.7%) and slip and fall are 7 (23.3%).

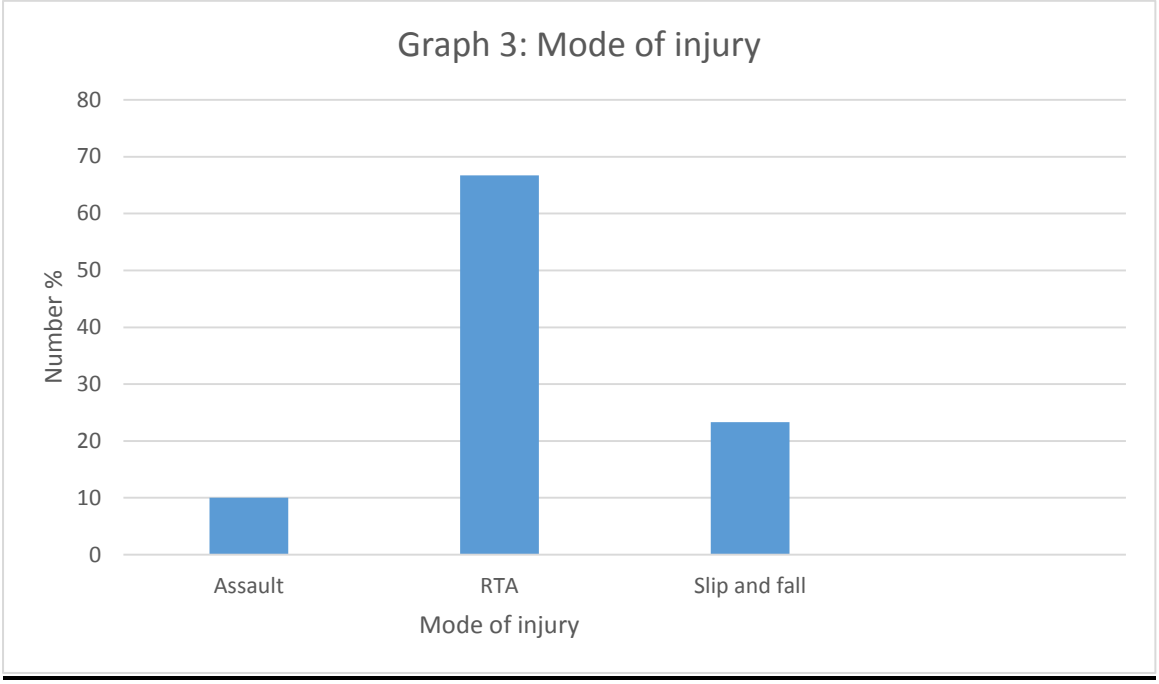


Table 4: Descriptive analysis mechanism of injury in the study population (N=30)

Mechanism of Injury	Number	%
Direct	28	93.3
Indirect	2	6.7

In this study number of patients having direct injury are 28 (93.3%) and indirect injury are 2 (6.7%).

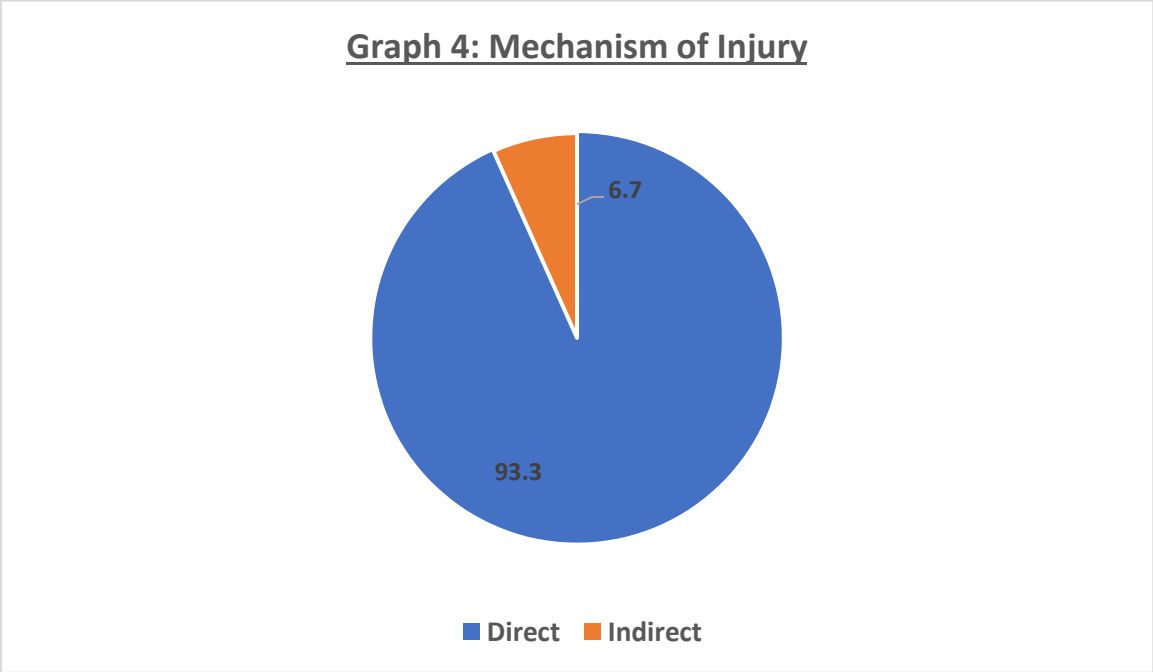


Table 5: Descriptive analysis side of injury in the study population (N=30)

Side of Injury	Number	%
Right	18	60
Left	12	40

In this study 18 (60%) patients had injury to right side while 12 (40%) patients had injury to left side.

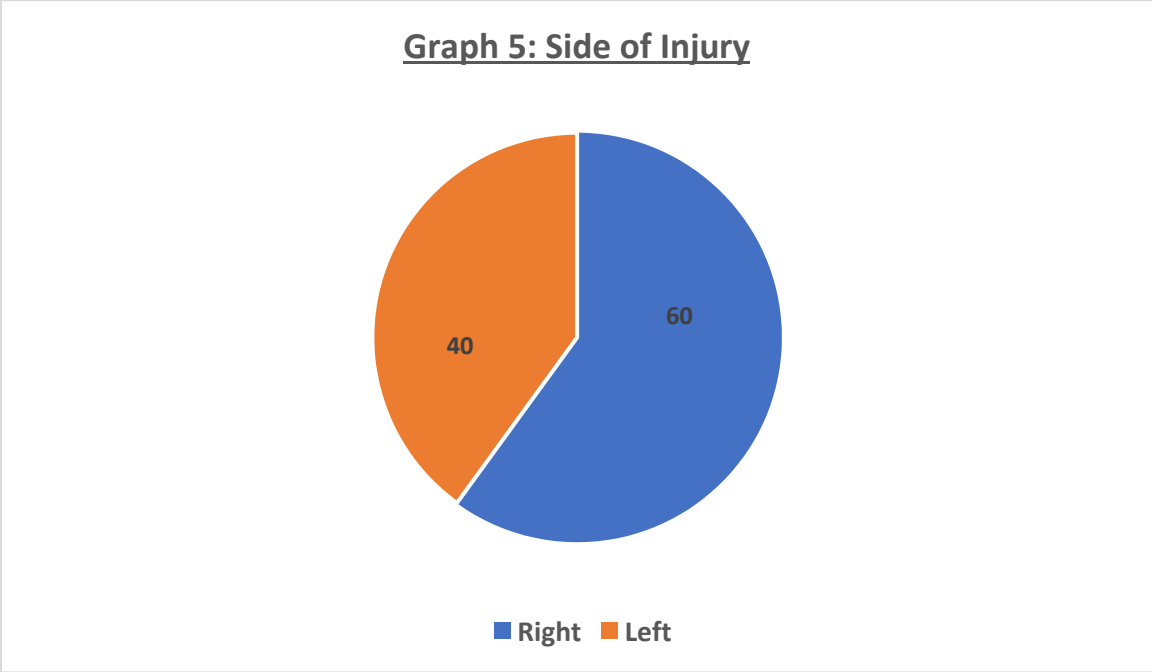


Table 6: Descriptive analysis site of injury in the study population (N=30)

Site of Injury	Number	%
L/3	7	23.3
M/3	17	56.7
U/3	6	20.0

In this study 7 (23.3%) patients had fracture to lower 3rd of humerus, 17 (56.7%) patients had middle third fracture, while 6 (20%) patients had upper 3rd fracture of humerus shaft.

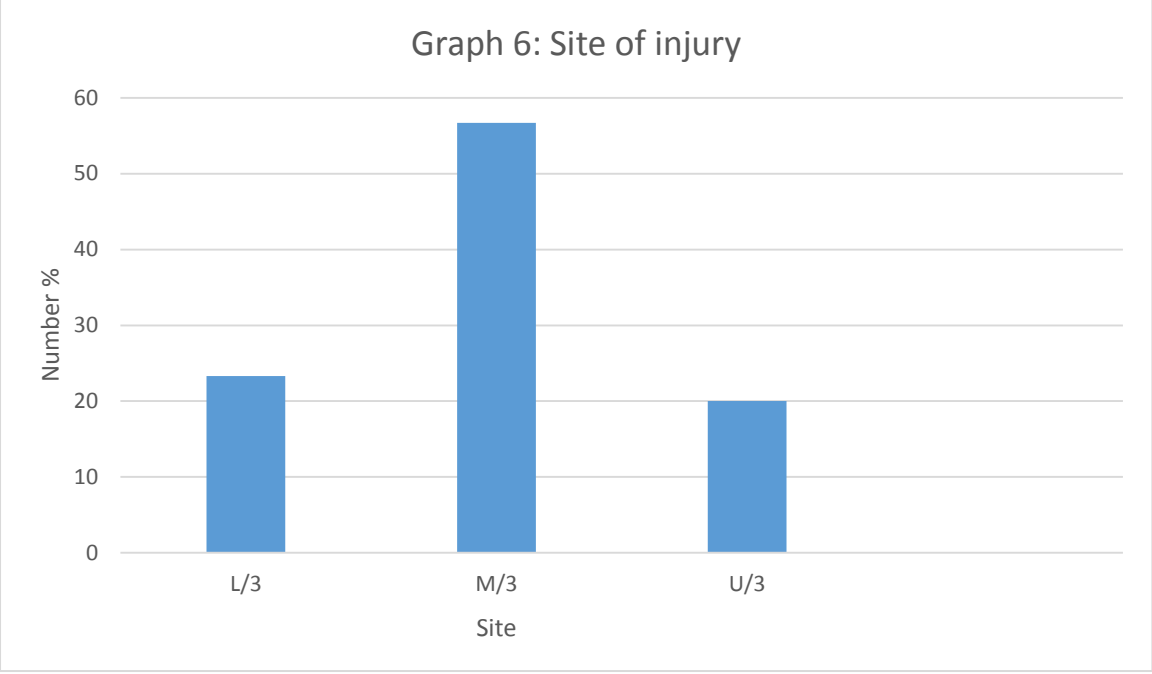


Table 7: Descriptive analysis of type of fracture in the study population (N=30)

Type of Fracture	Number	%
Open	1	3.3
Close	29	96.7

In this study 1 (3.3%) patient had open fracture, while 29 (96.7%) patients had closed fracture

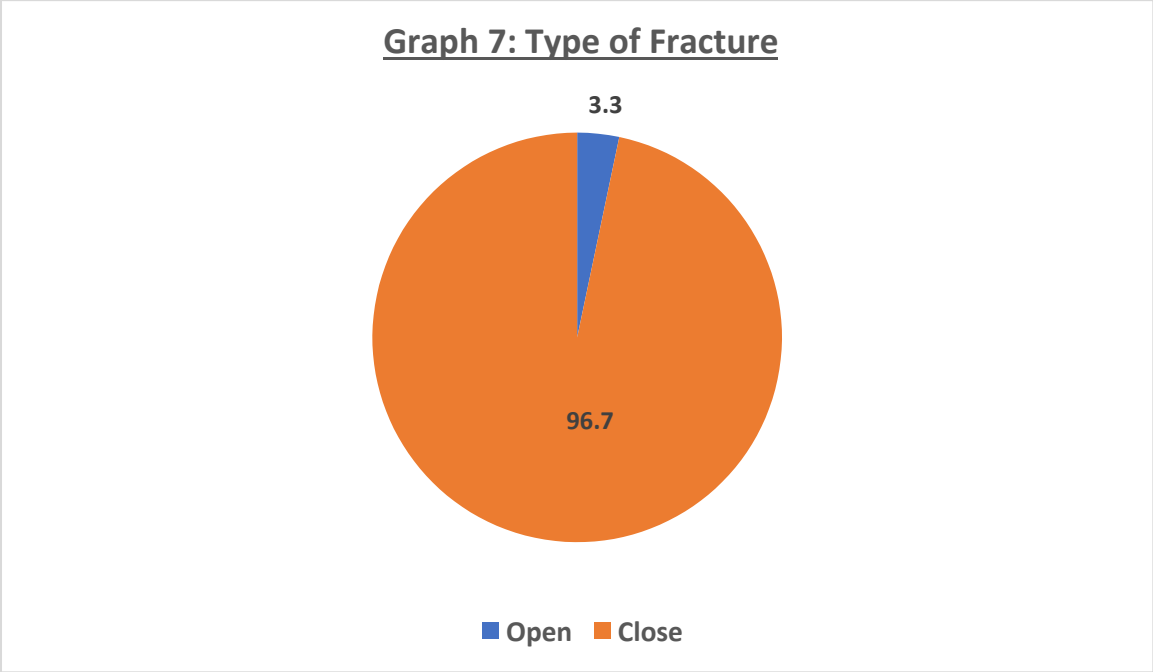


Table 8: Descriptive analysis of duration between trauma and surgery in study population (N=30)

Duration [in day]	Number	%
1-5	25	83.4
5-10	1	3.3
>10	4	13.3
Mean ± SD	3.6 ± 3.2 days	

In this study duration between trauma and surgery is between 1-5 days in 25 (83.4%) patients, 5-10 days (about 1 and a half weeks) in 1 (3.3%) patient and >10 days (about 1 and a half weeks) in 4 (13.3%) patients.

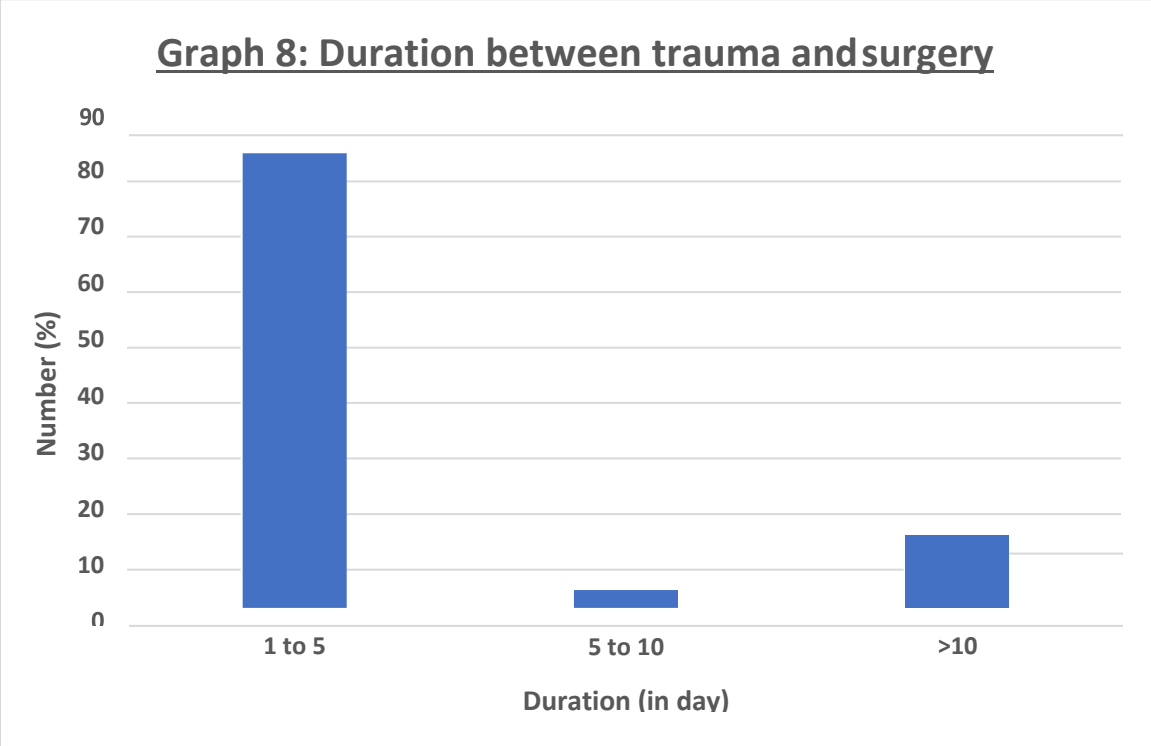


Table 9: Descriptive analysis of method of preliminary immobilization in study population (N=30)

Method	Number	%
Arm Pouch	6	20
U-slab	24	80

In this study preliminary immobilization with arm pouch is used in 6 (20%) patients and with U-slab in 24 (80%) patients

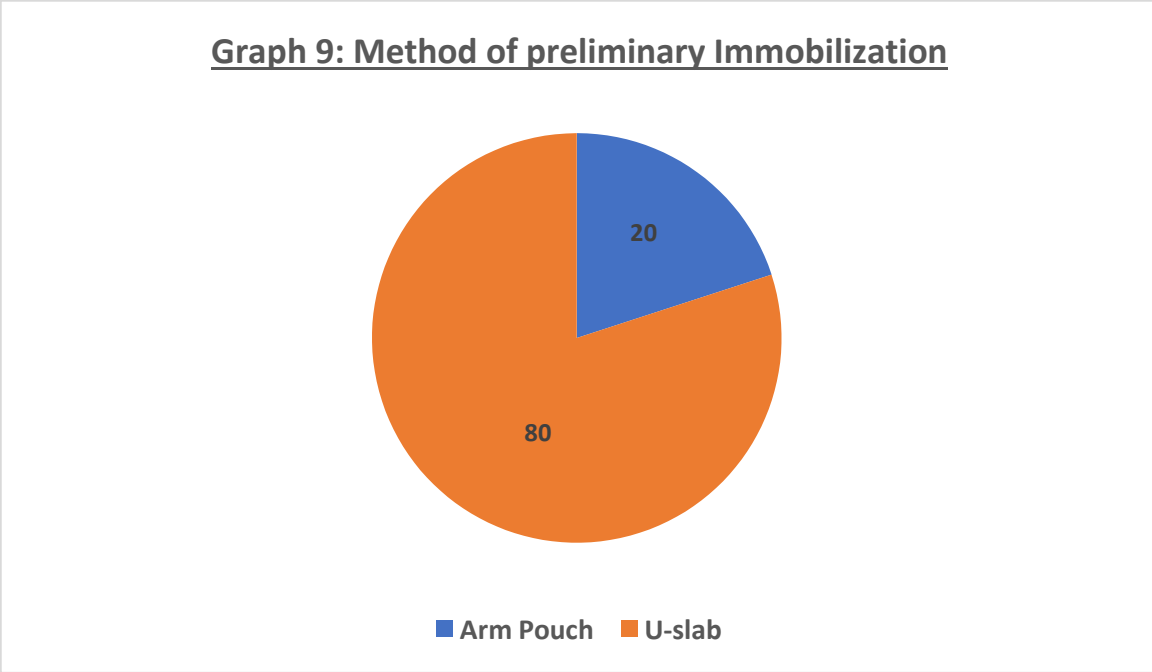


Table 10: Descriptive analysis of period of immobilization post-surgery in study population (N=30)

Period [in day]	Number	%
<5	3	10
5-10	26	86.7
>10	1	3.3

In this study, period of immobilization is <5 days in 3 (10%) patients, 5-10 days in 26 (86.7%) patients and >10 days in 1 (3.3%) patient.

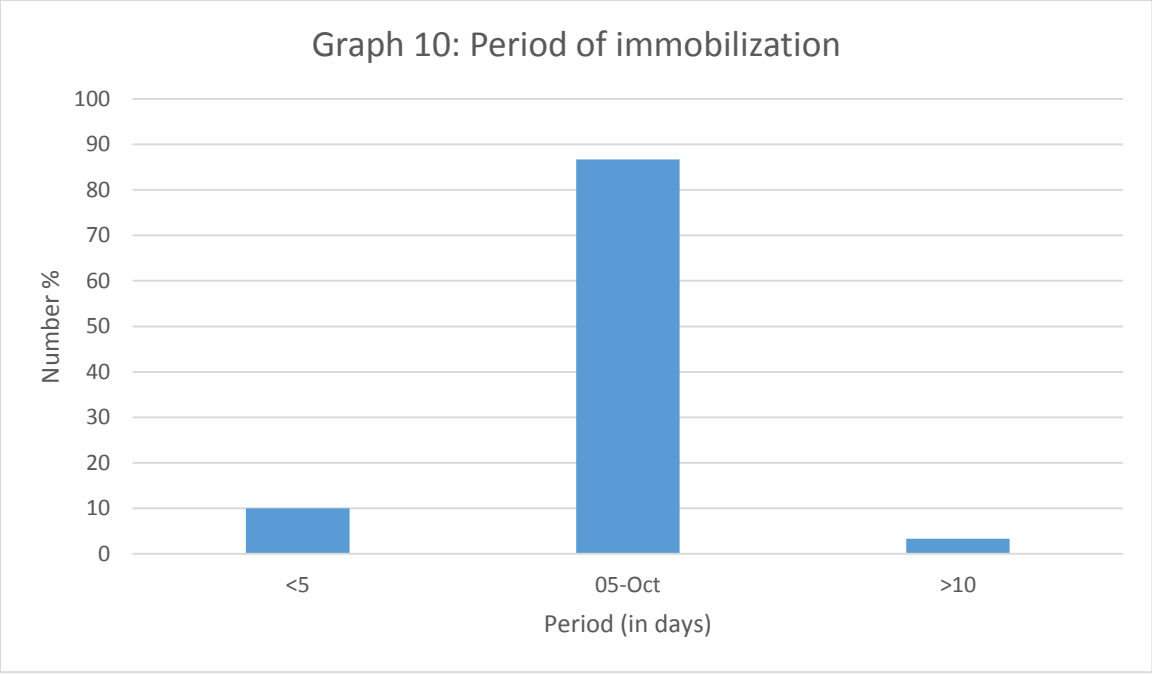


Table 11: Descriptive analysis of type of anaesthesia given in study population (N=30)

Type of anesthesia	Number	%
General	8	26.7
Regional	22	73.3

In this study 8 (26.7%) patients underwent surgical management under general anesthesia, while 22 (73.3%) patients under regional anesthesia.

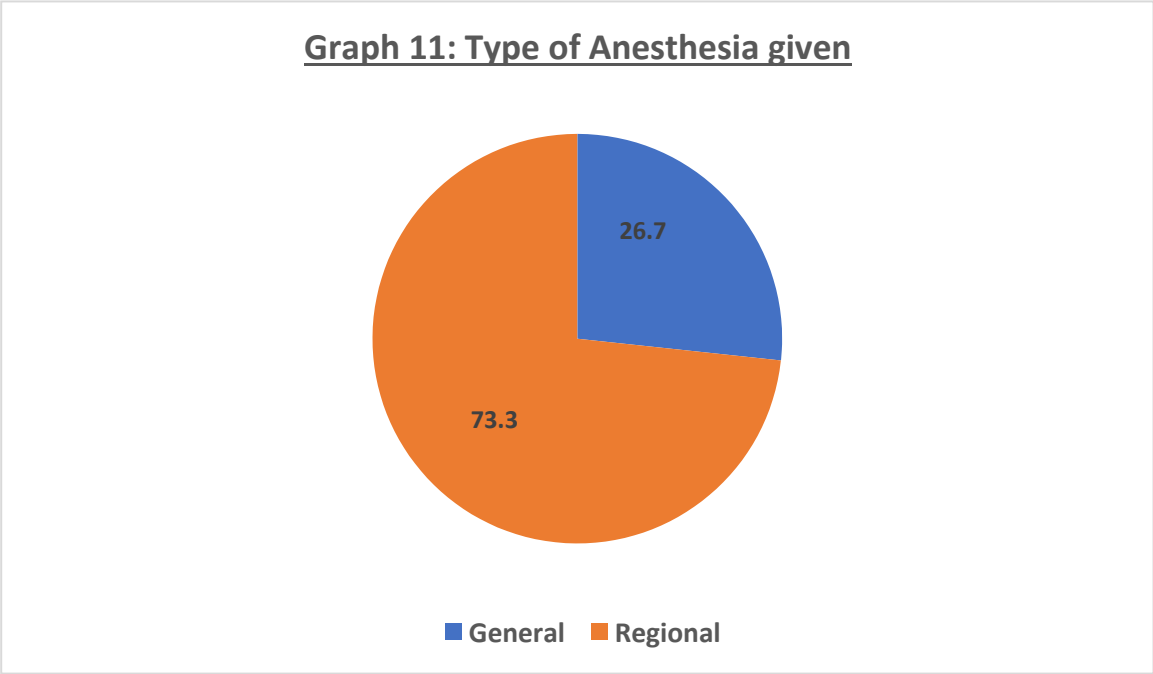


Table 12: Descriptive analysis of complication in study population (N=30)

Complication (n=6)	Number	%
S. Stiffness & Delayed Union	2	6.7
S. Stiffness	1	3.3
Implant Breakage	1	3.3
Iatrogenic Fracture	1	3.3
SSI & S. Stiffness	1	3.3

In this study post-operative complications like shoulder stiffness and delayed union seen in 2 (6.7%) patients, only shoulder stiffness in 1 (3.3%) patient, implant breakage in 1 (3.3%) patient, iatrogenic fracture in 1 (3.3%) patient and surgical site infection and shoulder stiffness in 1 (3.3%) patient. It was observed that 20% of the present study population developed complications post-surgery.

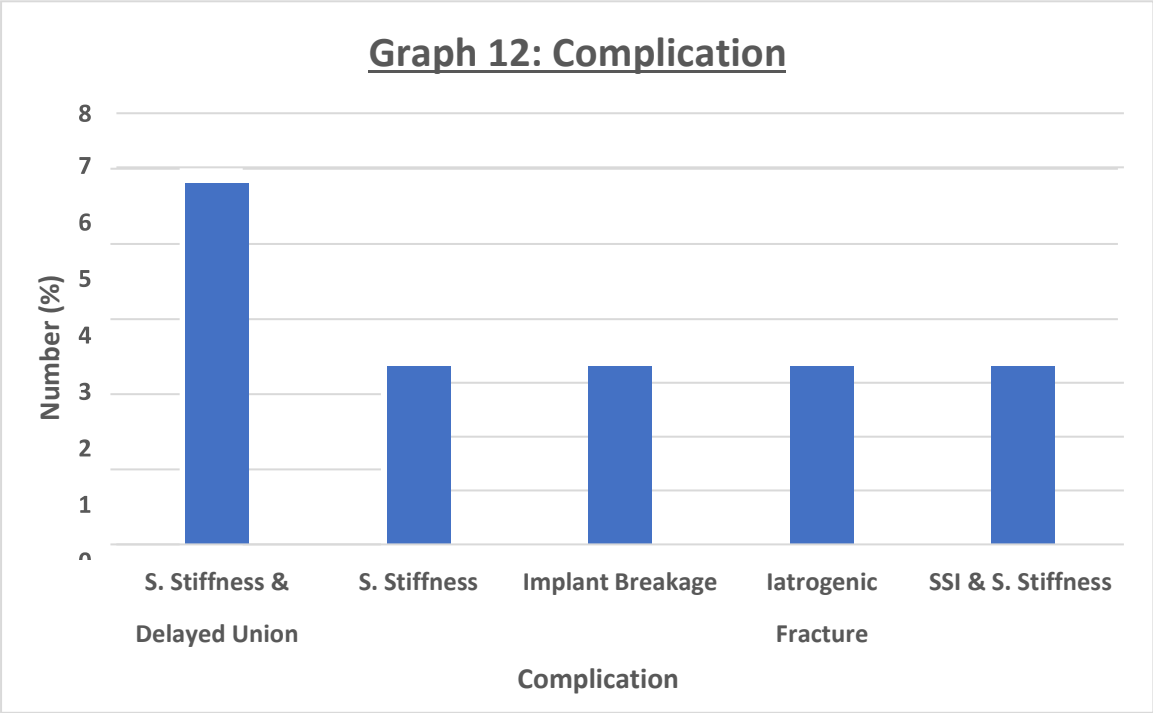


Table 13 (i): <u>Descriptive analysis of UCLA score</u>:

UCLA Parameter	Number	%
a). Pain		
4	1	3.3
5	2	6.7
8	24	80
10	3	10
b). Function		
4	1	3.3
8	5	16.7
10	24	80
c). Active forward flexion		
2	1	3.3
3	1	3.3
4	4	13.3
5	24	80
d). Strength of forward flexion		
2	1	3.3
3	1	3.3
4	4	13.3
5	24	80
e). Satisfaction		
5	30	100
Mean UCLA score	31.73±3.609	

According to UCLA scoring system,

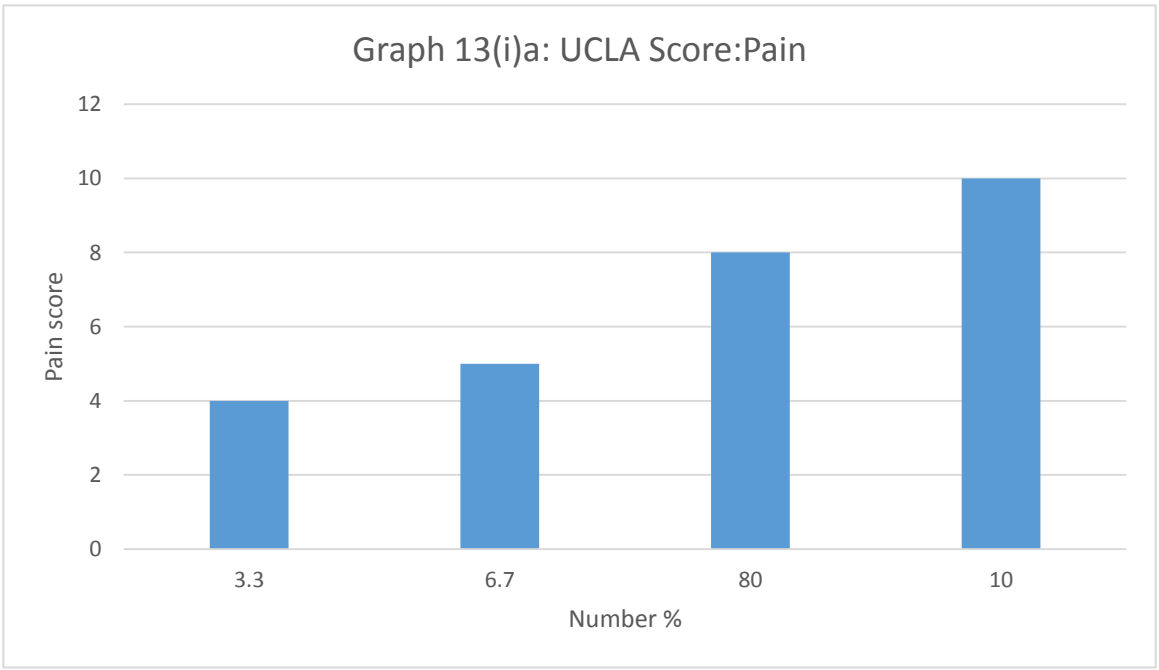
- Pain score 4,5,8,10 noted in 1 (3.3%), 2 (6.7%), 24 (80%) & 3 (10%) participants, respectively.
- Function score 4,8,10 noted in 1 (3.3%), 5 (16.7%) & 24 (80%) participants, respectively.
- Active forward flexion score and Strength of forward flexion score 2,3,4,5 noted in 1 (3.3%), 1 (3.3%), 4 (13.3%) and 24 (80%) participants, respectively.
- In all 30 (100%) patients satisfaction score was 5.

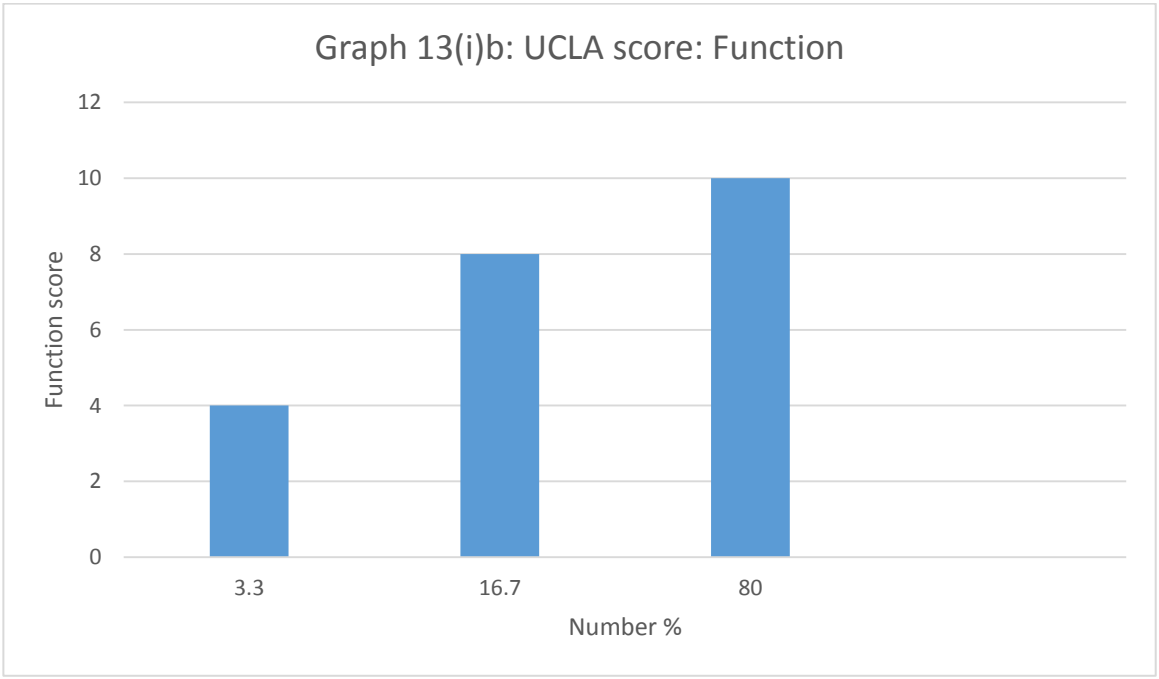
Mean UCLA score was 31.73 with 3.609 SD.

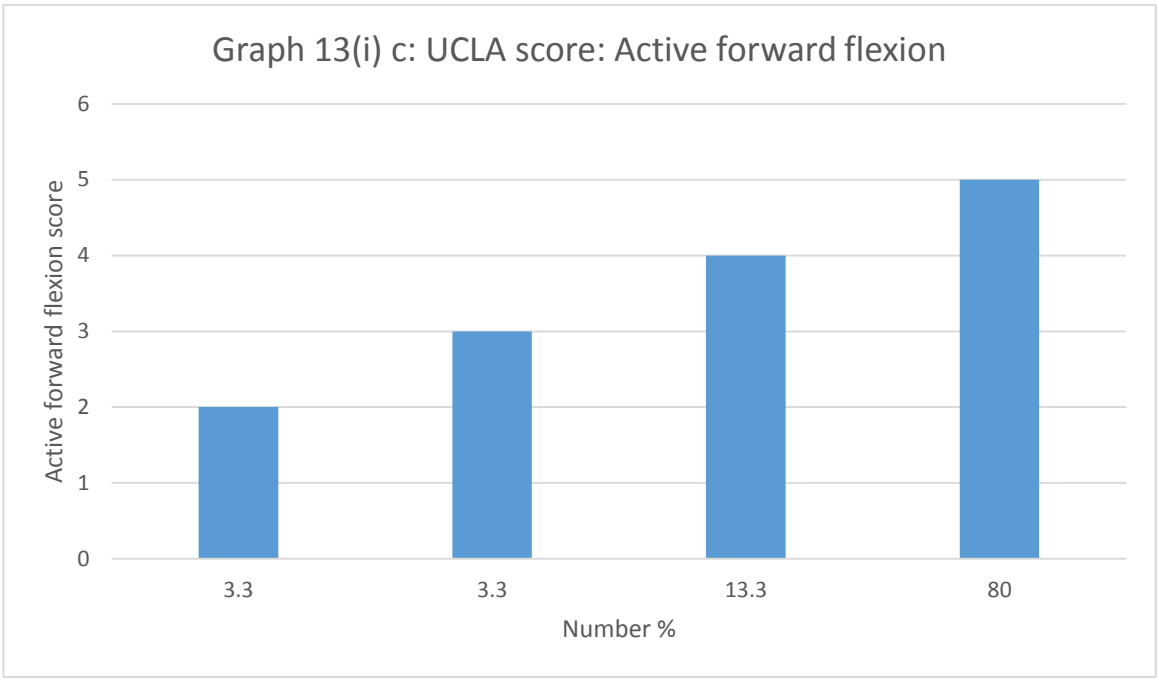
Table 13 (ii): Descriptive analysis of UCLA score at each follow-up (post-operative UCLA score at 1month, 3 months, 6 months) in study population (N=30):

	Good to excellent (28-35) (%)	Fair (21-27) (%)	Poor (0-20) (%)
At 1 month	**4 (13.33%)**	**25 (83.33%)**	**1 (3.33%)**
At 3 months	**26 (86.66%)**	**3 (10%)**	**1 (3.33%)**
At 6 months	**26 (86.66%)**	**3 (10%)**	**1 (3.33%)**

It shows that according to UCLA scoring system >27 points graded as good to excellent and < 27 as fair to poor. According to UCLA score, at 1 month 4 (13.33%) patients had good to excellent score, 25 (83.33%) patients had fair score and 1 (3.33%) patient had poor score in our study. At 3 months 26 (86.66%) had good to excellent, 3 (10%) had fair score and 1(3.33%) had poor score. At 6-month follow-up, 26 (86.66%) patients had good to excellent score, while 3 (10%) had fair and 1 (3.33%) had poor score.




Graph 13(i)b: UCLA score: Function
12
10
8
6
4
2
0
Function score
3.3
16.7
80
Number %


Graph 13(i) c: UCLA score: Active forward flexion
6
5
4
3
2
1
0
Active forward flexion score
3.3
3.3
13.3
80
Number %

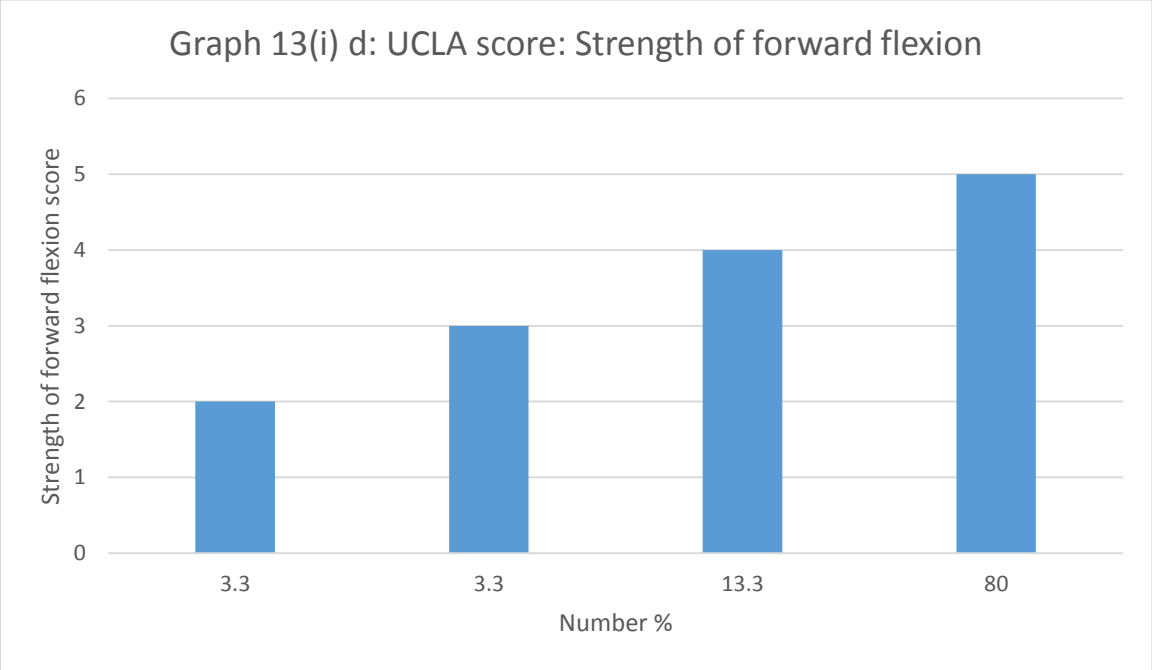


Table 14: Descriptive analysis of associated injury in study population (N=30)

Associated Injury	Number	%
➢ Open type 2 right both bone fracture of leg	1	3.3
➢ Left both bone fracture of forearm	1	3.3
➢ Left iliac wing fracture with ipsilateral anterior column fracture of hip	1	3.3
➢ 1st, 2nd, and 3rd Metatarsal fracture of right leg	1	3.3

In this study one (3.3%) patient had associated injury of open type 2 right both bone fracture of leg, one (3.3%) had left both bone fracture of forearm, one (3.3%) had left iliac wing fracture with ipsilateral anterior column fracture of hip and one (3.3%) had 1^{st},2^{nd} and 3^{rd} metatarsal fracture of right leg.

DISCUSSION

DISCUSSION

Present study was conducted among 30 cases with fracture of shaft of humerus admitted at orthopaedic department R.L. Jalappa Hospital attached to Sri Devaraj Urs Medical College, Tamaka during October 2019 to June 2021 with aim and objective of, to study the functional outcome of intramedullary interlocking nailing in case of humerus shaft fractures by UCLA scoring system & to assess the complications encountered with intramedullary interlocking nailing. Patients were selected according to inclusion and exclusion criteria.

The humeral shaft which is cylindrical in shape that expanse between the proximal insertion of the pectoralis major and the distal metaphyseal flare of the humerus, adds resistance to both torsional and bending forces and provides strength. Adequate soft tissue envelope favors good prognosis in healing of uncomplicated fractures.[14] Humeral shaft fractures constitute 5-8% of all extremity fractures with an annual incidence of 13/1,00,000. These fractures are managed with either conservative or surgical approaches.[40] While the former includes functional bracing, spica cast, Velpeau bandage, and coaptation splint; surgical approaches are plate and screw fixation, intramedullary nailing, and external fixator.[40]

Present study found that highest number of participants (83%) were from 20-60 years age group and mean age was 43.1 years. This finding correlates with the study done by Rajagopal HP et al[14], Cocco LF et al[43] and Patino JM et al[44] with mean age of 36, 49.8±20.1 and 41.9 years, respectively. While study done by Yuce A et al[45] observed higher mean age (70 years) in their study and Mahmoud HF et al[46] noted lower mean age (34 years).

Present study found that male: female ratio was 1:0.4. Study done by Yuce A et al[45], Rajagopal HP et al[14], Cocco LF et al[43] and Mahmoud HF et al[46] observed male: female ratio was 1:1, 1:0.5, 1:0.6 & 1:0.3 in their study, respectively.

In study done by Chun-Hao T et al[42], Rose SH et al[47] and Tytherleigh-Strong G et al[48] found that bi- modal age distribution with a minor peak in the third decade and consisting mainly of men resulting from high-energy trauma and a second major peak in the eighth decade, mostly women with osteoporotic fractures resulting from simple falls.

Present study found that highest number of participants (66.7%) were injured in 'road traffic accident' followed by 23.3% by slip & fall and most of participants (93.3%) were injured by direct injury, which is comparable to the study done by Rajagopal HP et al[14] Mahmoud HF et al[46] and Mehraj M et al[49] in which 75%, 52.4% and 67.5% of cases were injured in RTA, respectively. While 47.6% and 30% cases had trauma following fall in study done by Mahmoud HF et al[46] and Mehraj M et al[49] respectively.

Present study found that 3/5th participants (60%) had right sided injury and 40% had left sided injury, which is comparable to the study done by Cocco LF et al[43] in which 61.54% cases had right sided and 38.46% had left sided injury.

Present study shows that 23.3%, 56.7% & 20% participants had injury at lower third, middle third & upper third part of humerus, respectively. While in the study done by Rajagopal HP et al[14] 13.5%, 80% and 6.5% participants had injury at lower third, middle third & upper third part of humerus, respectively.

Direct fracture visualization allowing anatomical reduction and rigid fracture fixation are the cited advantages and an extensive open surgery with stripping of soft tissues from the bone, increased blood loss, disruption of the periosteal blood supply, a longer operating time, risk of injury to radial nerve, and difficulty with complex fracture patterns and in osteoporotic bones, the possible need for plate removal later is described as negative features for plate fixation.[50,51]

Present study shows that 3.3% participants had open fractures which is comparable to the study done by Jeyaraman M, et al[52] (7.56%). While in the study done by Rajagopal HP et al[14] all were closed fractures (100%).

Present study found that highest number of cases (83.4%) were operated within 5 days after injury. Mean 'duration between trauma and surgery' was 3.6 ± 3.2 days which correlate with the study done by Yuce A et al[45]. Study done by Mahmoud HF et al[46] noted mean duration was 1.9 days. Study done by Rajagopal HP et al[14] observed that 50% patients were operated on the same day, 40% after 2 days and 10% after 5 days.

Majority of shaft of humerus fracture which are non-complicated can be managed by non-operative method, with an anticipated union rate of >90%, continues to serve as main stay of management still.[50] Methods include hanging arm casts, functional bracing, coaptation splints, modified Velpeau dressings, abduction type splints and shoulder spica casts. Sarmiento et al in 1977 described moldable splint used as functional cast bracing permitting early return to daily activity, minimal morbidity and acceptable functional outcomes.[53] Westrick et al in a retrospective cohort study conducted on 296 patients with shaft of humerus fracture found non-union rate was remarkably higher in non-operative group (23.2% vs. 10.2%).[54]

Difficulty in affected limb immobilization due to extremely mobile scapulo-humerus joint and distraction at site of fracture by gravity effect leading to non-union and delayed union, extended immobilization leads to muscle weakness, joint stiffness, impatient patients eager to return to early function, less tolerance to acceptable deformity and surgeon`s reluctance to conservative management are the reasons for increasing trends for surgical management.[55,56]

Present study found that 'U slab' was the most common method (80%) used to preliminary immobilize the injured limb. Present study found that in most of cases (86.7%), period of immobilization post-surgery was for 5 to 10 days.

Present study found that highest number of participants 73.3% were operated under regional anesthesia and 26.7% were operated under general anaesthesia, while in the study conducted by Sahu RL et al[57] all cases were operated under general anaesthesia.

IMN stabilization offers an approach requiring less extensive dissection, minimal soft tissue disruption preserving the fracture hematoma, less blood loss, shorter operative times, and a lower incidence of serious complications such as radial nerve palsy. Recently many authors in prospective randomized studies, comparing IMN versus locking compression plates in treatment of humerus shaft fracture found intraoperative blood loss, operative time, hospital stay and average union time) were significantly lower in patients treated with IMN and no significant difference between two groups in terms of union rate, shoulder function or complications.[58-62]

Present study found that post-operative S. Stiffness & Delayed Union was the most common complication observed among the study participants. Chapman JR et al[63], Flinkkila T et al[64] and Reghavendra S et al[65] observed that Shoulder pain and restriction of shoulder movements and risk of delayed union has been suggested as disadvantages of antegrade intramedullary fixation.

Tsourvakas S et al[66] said that gap at the fracture site was considered as the cause of nonunion of fracture. Both healed with bone grafting. Good apposition of the fracture fragments, reaming where feasible, static locking to add initial high biomechanical stiffness of the osteosynthesis allowing early mobilization, are recommended to reduce healing related complications.

Bell MJ et al[67] reported 2.9% radial nerve palsy following plating of humerus shaft fractures where present study did not find any such incidence of radial nerve palsy.

Present study found that mean score UCLA score was 31.73±3.609 which indicate excellent functional outcome which is comparable with the study done by Mahmoud HF et al[46] (31.04±4.4), Brandao BL et al[68] and Benegas E et al[69]. Study done by Chun-Yan J et al[70] noted mean UCLA score was 31.2.

In our study	**Good to excellent (%)**	**Fair (%)**	**Poor (%)**
At 1 month	**13.33%**	**83.33%**	**3.33%**
At 3 months	**86.66%**	**10%**	**3.33%**
At 6 months	**86.66%**	**10%**	**3.33%**
Kumar et al study[71]			
At 1 month	**86.7%**	**13.3%**	**0**
At 3 months	**93.33%**	**6.66%**	**0**
At 6 months	**96.7%**	**3.33%**	**0**

Above table shows that there is improvement in UCLA score from 1st to 6th month follow-up period, which is comparable to the Kumar et al study.[71]

In our study, UCLA score was good to excellent in 26 cases (86.66%) and fair in 3 cases (10%), which is comparable to the study done by Mehraj M et al[49] in which 33 cases (82.5%) had good to excellent score and fair in 6 cases (15%).

Present study found associated injury in 13.3% participants while study done by Patino JM et al[44] noted associated injury in 26% participants in their study.

Primary surgical management of humerus shaft fracture include plate fixation (open reduction and internal fixation [ORIF]), intramedullary nailing (IMN) or by external fixation. Accepted indications for surgery include open, segmental, or pathological fractures, an adjacent floating joint, fractures with associated neurovascular injuries and inability to obtain and maintain adequate alignment. External fixation is utilized as temporary fixation of open fractures or poly-trauma patients.[72]

Isolated humerus shaft fractures can be managed satisfactorily with non-operative methods but operative stabilization of it is necessary for multiple injured patients, patients with acute, high energy humeral fractures to improve chances of healing, fracture alignment and functional results. With recent interest in biological fixation of fracture and because of biomechanical advantage of intramedullary nailing over dynamic compression plating, intramedullary nailing for fracture shaft humerus has gained a lot of popularity these days. Antegrade nailing is giving satisfactory results as it saves vital blood clot at fracture site, checks rotation, and axial alignment and telescoping along with early mobilization of patient. Moreover, it is especially useful in pathological and impending fractures.[73,74]

LIMITATIONS

The limitations of the study are small sample size, short term follow up period and further this study does not compare other modality of treatment like non-operative treatment or fixation with plates and screws. So further comparative studies with larger sample size and longer follow up period are recommended.

CONCLUSION

CONCLUSION

Intramedullary interlocking nailing is safe and effective modality of treatment for the humerus shaft fracture with excellent functional outcome with mean UCLA score of 31.73±3.609 at 6 month follow-up. At the follow up from 1 month to 6 month UCLA score improves from fair to good and excellent in majority of participants. Further, IMIL nailing is associated with less number of complications (maximum of which was shoulder stiffness).

SUMMARY

SUMMARY

Although dynamic compression plating has traditionally been considered the "gold standard" in humeral surgery, intra-medullary fixation has certain merits like being closer to normal mechanical axis of bone and acting as a load sharing device. Bending forces and consequent fatigue failures are less. Since the fracture is not directly exposed (fracture hematoma is preserved) and there is minimal soft tissue dissection, the fixation is more biological and with less stress shielding and chances of iatrogenic nerve injury are also reduced. Intramedullary nail (IM) fixation is an established method of treatment of high-energy long bone fractures especially in polytrauma setting, as well as osteoporotic, impending, and pathological fractures. Locked intramedullary nails usually can be inserted using closed techniques avoiding the extensive soft tissue dissection required for plating. Interlocking nails give rotational stability, decrease the need for post-operative bracing and allowing early mobilization of the extremity while preserving fracture hematoma.

Present study conducted with the aim and objectives of, to study the functional outcome of intramedullary interlocking nailing in case of humerus shaft fractures by UCLA scoring system & to study the complications encountered with intramedullary interlocking nailing.

Present study was conducted among 30 cases with fracture of shaft of humerus admitted at orthopaedic department R.L. Jalappa Hospital attached to Sri Devaraj Urs Medical College, Tamaka during October 2019 to June 2021 after ethical permission of IEC

patients were selected using inclusion and exclusion criteria. Collected data has been entered in the excel data sheet and data analysis done with the help of IBM SPSS software 22.

Highest number of participants (83%) were from 20-60 years age group and mean age was 43.1 years. Male: Female ratio was 1:0.4. Highest number of participants (66.7%) were injured in 'road traffic accident' and most of participants (93.3%) were injured by direct injury. Almost 3/5th participants (60%) had right sided injury. Middle third of the shaft of the humerus was the most common part injured among study participants. Most of the participants (97%) were noted with closed fracture. Highest number of cases (83.4%) were operated within 5 days after injury. Mean 'duration between trauma and surgery' was 3.6 days with 3.2 SD. 'U slab' was the most common method (80%) used to preliminary immobilize the injured part of humerus after injury. Present study found that in most of cases (86.7%), immobilization post surgery was given for 5 to 10 days. Highest number of participants (73.3%) were operated by regional anesthesia. Post-operative s. Stiffness & delayed union was the most common complication observed among the study participants. Mean UCLA score was 31.73 with 3.609 SD which is excellent. Associated injury noted in 13.3% participants.

According to UCLA scoring system >27 points graded as good to excellent and < 27 as fair to poor. According to UCLA score, at 1 month 4 (13.33%) patients had good to excellent score, 25 (83.33%) patients had fair score and 1 (3.33%) patient had poor score in our study. At 3 months 26 (86.366%) had good to excellent, 3 (10%) had fair score and 1(3.33%) had poor score. At 6-month follow-up, 26 (86.66%) patients had good to

excellent score, while 3 (10%) had fair and 1 (3.33%) had poor score.

This study concludes that humerus shaft fracture treated with IMIL nailing is safe and effective modality of management with excellent functional outcome with mean UCLA score of 31.73±3.609 at 6-month follow-up and it also has less number of complications (maximum of which is shoulder stiffness).

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CLINICAL IMAGE OF RANGE OF MOTION AT SHOULDER JOINT AT 6 MONTH FOLLOW UP

CASE 21

CASE 2

CASE 20

CASE 15

RADIOGRAPHS

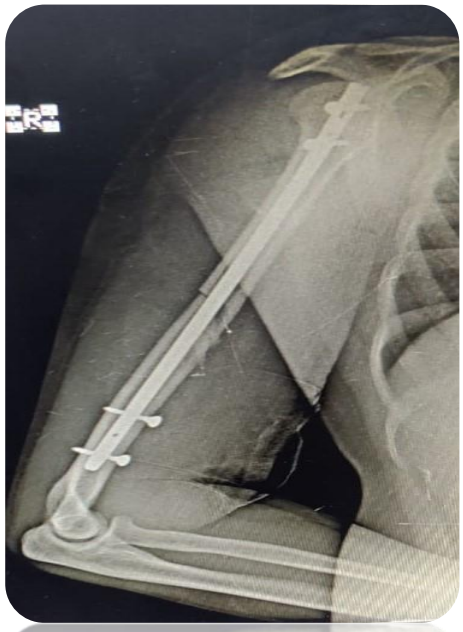
CASE 8

Pre-op Xray

Pre-op Xray

Immediate

Post-op Xray



Immediate

Post-op Xray

Post-op Xray at 6 month

Post-op Xray at 6 month

Xray after implant removal

Xray after implant removal

CASE 2

Pre-op Xray

Pre-op Xray

Post-op Xray

Post-op Xray

CASE 18

Pre-op Xray

Pre-op Xray

Post-op Xray

Post-op Xray

CASE 25 WITH IMPLANT BREAKAGE

CASE 16 WITH IATROGENIC FRACTURE

PROFORMA

NAME: I.P NO:

AGE: DATE OF ADMISSION:

SEX: DATE OF SURGERY:

DATE OF DISCHARGE:

ADDRESS:

1) PRESENTING COMPLAINTS:
2) HISTORY OF PRESENTING ILLNESS:

A) MODE OF INJURY

- MOTOR VEHICLE ACCIDENT
- MOTOR CYCLE ACCIDENT
- FALL FROM HEIGHT
- ASAULT
- OTHERS

B) MECHANISM OF INJURY

- DIRECT - INDIRECT

C) TYPE OF FRACTURE: OPEN/CLOSE

D) ASSOCIATED INJURIES

3) TREATMENT HISTORY: YES OR NO

IF YES

- OSTEOPATHS
- GENERAL PRACTITIONER
- ORTHOPAEDICIAN

4) PAST H/O INJURY / INJURIES

5) LOCAL EXAMINATION

A. INSPECTION

- SIDE INVOLVED: RT/LT
- OVERLYING SKIN
- ATTITUDE OF LIMB

- DEFORMITY
- SWELLING
- SHORTENING

B. PALPATION

- TEMPERATURE
- TENDERNESS
- ABNORMAL MOBILITY
- CREPITUS
- SITE OF INJURY: U/3, M/3, L/3
- BONY IRREGULARITY
- TRANSMITTED MOVEMENTS
- WOUND EXAMINATION
    a) PRESENCE OF FOREIGN BODY
    b) COLOUR OF MUSCLES
- DISTAL NVD

C. MEASUREMENTS:

	RT.	LT.
- LONGITUDINAL		

6) ASSOCIATED INJURIES:

- SHOULDER
- ELBOW
- RADIUS
- ULNA
- OTHERS

7) INVESTIGATIONS (PRE-OP ASSESSMENT)

- RADIOGRAPHY

8) CLINICAL DIAGNOSIS:

9) MANAGEMENT:

a) IMMEDIATE

- I.V FLUIDS

- PARENTERAL ANTIBIOTICS & ANALGESICS
- BLOOD TRANSFUSION
- PRELIMINARY IMMOBILIZITION

U- SLAB/ARM POUCH

- DURATION BETWEEN TRAUMA AND SURGERY

b) SURGICAL MANAGEMENT

- DOS:
- TYPE OF ANAESTHESIA
- POSITION OF PATIENT
- APPROACH
- METHOD: ANTEGRADE/RETROGRADE
- NAIL LENGTH: DIAMETER
- INTERLOCKING SCREWS- LENGTH
- IMMOBILIZATION AFTER SURGERY: YES/NO
- PERIOD OF IMMOBILIZATION

10) POST-OP PERIOD AND FOLLOW UP

a) 1 TO 10 POST-OP DAY

- ANTIBIOTICS & ANALGESICS
- RANGE OF MOTION
- CHECK X-RAY

b) 10 TO 14 POST-OP DAY

- SUTURE REMOVAL
- RANGE OF MOTION

c) 4 TO 6 WEEKS

- CHECK X-RAY
- ASSESSMENT OF RANGE OF MOTION

d) 12 TO 16 WEEKS

- CHECK X-RAY
- CLINICAL ASSESSMENT OF FRACTURE HEALING

e) 24 WEEKS

- CHECK X-RAY
- UCLA SCORE:

- PAIN
- FUNCTION
- ACTIVE FORWARD FLEXION
- STRENGTH OF FORWARD FLEXION
- SATISFACTION OF THE PATIENT

- RESULT/CONCLUSION: EXCELLENT/GOOD/FAIR/POOR

11) COMPLICATIONS IF ANY

INFORMED CONSENT FORM

I, _____ aged _____ ,after being explained in my own vernacular language about the purpose of the study and the risks and complications of the procedure, hereby give my valid written informed consent without any force or prejudice for Closed reduction and internal fixation / Open reduction and internal fixation with IMIL nail & screw which is a therapeutic procedure / biopsy / transfusion / operation to be performed on me or _____ under any anesthesia deemed fit. The nature and risks involved in the procedure (surgical and anaesthetical) have been explained to me to my satisfaction.

I have been explained in detail about the Clinical Research on "Evaluation of functional outcome of intramedullary interlocking nail fixation for humeral shaft fracture" being conducted. *I have read the patient information sheet and I have had the opportunity to ask any question. Any question that I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.* I hereby give consent to provide my history, undergo physical examination, undergo the injection procedure, undergo investigations, and provide its results and documents etc. to the doctor / institute etc.

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

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

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

(Relation with patient) ……

Witness:……

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

PATIENT INFORMATION SHEET

Study title: EVALUATION OF FUNCTIONAL OUTCOME OF INTRAMEDULLARY INTERLOCKING NAIL FIXATION FOR HUMERAL SHAFT FRACTURE

.

Study site: R.L Jalappa hospital, Tamaka, Kolar.

- Aim- To evaluate the functional outcome of intramedullary interlocking (IMIL) nailing in case of humerus shaft fractures by University of California Los Angeles (UCLA) scoring system.
- To study the complications encountered with this procedure.

Patient with facture of humerus 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 (CBC, CRP, Urine 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 get will not change if you do not 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. Darshan Patel

Mobile no: 9033906948

E-mail id: darshanpatel00962@gmail.com

ತಿಳಿವಳಿಕೆಯ ಸಮ್ಮತಿ ನಮೂನೆ

ನಾನು, _____ ವಯಸ್ಸಿನ _____,
ನನ್ನ ಸ್ವಂತ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲ್ಪಟ್ಟ ನಂತರ ಅಧ್ಯಯನದ ಉದ್ದೇಶ ಮತ್ತು ಕಾರ್ಯವಿಧಾನದ ತೊಂದರೆಗಳು ಮತ್ತು ತೊಡಕುಗಳ ಬಗ್ಗೆ ವಿವರಿಸಿದ ನಂತರ, ಮುಚ್ಚಿದ ಕಡಿತ ಮತ್ತು ಆಂತರಿಕ ಸ್ಥಿರೀಕರಣ / ಓಪನ್ಗೆ ಯಾವುದೇ ಬಲದ ಅಥವಾ ಪೂರ್ವಾಗ್ರಹವಿಲ್ಲದೆ ನನ್ನ ಮಾನ್ಯವಾದ ಲಿಖಿತ ವಿರೋಧಿ ಸಮ್ಮತಿಯನ್ನು ನೀಡಿ ನನ್ನ ಮೇಲೆ ನಡೆಸಬೇಕಾದ ರೋಗನಿದಾನ ಮತ್ತು / ಅಥವಾ ಚಿಕಿತ್ಸಕ ಪ್ರಕ್ರಿಯೆ / ವರ್ಗಾವಣೆ / ಕಾರ್ಯಾಚರಣೆ ಅಥವಾ ಯಾವುದೇ ಅರಿವಳಿಕೆ ಅಡಿಯಲ್ಲಿ _____ ನಂತಹ ಪ್ಲೇಟ್ ಮತ್ತು ತಿರುಪು / ಸಂಪ್ರದಾಯವಾದಿ ನಿರ್ವಹಣೆಯೊಂದಿಗೆ ಪ್ಲೇಟ್ ಮತ್ತು ಸ್ಕ್ರೂ / ಸಂಪ್ರದಾಯವಾದಿ ನಿರ್ವಹಣೆಗೆ ಒಳಪಡಿಸುವುದು ಯೋಗ್ಯವಾದವು. ಕಾರ್ಯವಿಧಾನದಲ್ಲಿ (ಶಸ್ತ್ರಚಿಕಿತ್ಸಾ ಮತ್ತು ಅನಾಸ್ಥೆಟಿಕಲ್) ಒಳಗೊಂಡಿರುವ ಸ್ವಭಾವ ಮತ್ತು ಅಪಾಯಗಳು ನನ್ನ ತೃಪ್ತಿಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

"ಕ್ಯಾವಿಲ್ಲನ್ನ ಸ್ಥಳಾಂತರಿತ ಡಯಾಫಿಸಿಯಲ್ ಮುರಿತದ ಸಂಪ್ರದಾಯವಾದಿ ನಿರ್ವಹಣೆ ಮತ್ತು ಕಾರ್ಯಾಚರಣೆಯ ನಿರ್ವಹಣೆಯ ಕಾರ್ಯಾತ್ಮಕ ಫಲಿತಾಂಶದ ನಿರೀಕ್ಷಿತ ಮತ್ತು ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ" ಕುರಿತು ಕ್ಲಿನಿಕಲ್ ರಿಸರ್ಚ್ ಕುರಿತು ನಾನು ವಿವರಿಸಿದ್ದೇನೆ. ನಾನು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಯಾವುದೇ ಪ್ರಶ್ನೆ ಕೇಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ. ನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರ ಮಾಡಲಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವವರಾಗಿ ಭಾಗವಹಿಸಲು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸುತ್ತೇನೆ. ನನ್ನ ಇತಿಹಾಸವನ್ನು ಒದಗಿಸಲು, ದೈಹಿಕ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಲು, ಇಂಜೆಕ್ಷನ್ ಪ್ರಕ್ರಿಯೆಗೆ ಒಳಗಾಗಲು, ತನಿಖೆಗೆ ಒಳಗಾಗಬೇಕು ಮತ್ತು ಅದರ ಫಲಿತಾಂಶಗಳು ಮತ್ತು ದಾಖಲೆಗಳನ್ನು ವೈದ್ಯರಿಗೆ / ಇನ್ಸ್ಟ್ಯೂಟ್ಗೆ ನೀಡುವಂತೆ ನಾನು ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ.

ಶೈಕ್ಷಣಿಕ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಕಾರ್ಯಾಚರಣೆ / ವಿಧಾನ, ಇತ್ಯಾದಿ ವೀಡಿಯೊವನ್ನು ಗ್ರಾಂಪ್ಡ್ ಅಥವಾ ಛಾಯಾಚಿತ್ರ ಮಾಡಬಹುದು. ಎಲ್ಲಾ ಡೇಟಾವನ್ನು ಯಾವುದೇ ಶೈಕ್ಷಣಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಪ್ರಕಟಿಸಬಹುದು ಅಥವಾ ಬಳಸಬಹುದು. ಕಾರ್ಯವಿಧಾನ / ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಕೆಟ್ಟ ಪರಿಣಾಮಗಳಿಗೆ ನಾನು ವೈದ್ಯರು / ಇನ್ಸ್ಟ್ಯೂಟ್ ಇತ್ಯಾದಿಗಳನ್ನು ಹೊಂದುವುದಿಲ್ಲ.

ಈ ಮಾಹಿತಿಯುಕ್ತ ಸಮ್ಮತಿಯ ಫಾರ್ಮ್ ಮತ್ತು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಪ್ರತಿಸ್ಪರ್ಧಿಗೆ ಒದಗಿಸಲಾಗಿದೆ.

_____ _____ _____

(ರೋಗಿಯಪರಿಚಾರಕನಸಹಿ&ಹೆಸರು) (ರೋಗಿಯ / ಗಾರ್ಡಿಯನ್ನಸಹಿ / ಹೆಬ್ಬೆಟ್ಟಿನಗುರುತು&ಹೆಸರು)

(ರೋಗಿಯಸಂಬಂಧ)

(ಸಂಶೋಧಕನ / ವೈದ್ಯರಸಹಿ&ಹೆಸರು)

KEY TO MASTER CHART

SR.NO	Serial number
M	Male
F	Female
UHID No	Unique hospital identification number
RTA	Road traffic accident
Lt.	Left
Rt.	Right
IT	Intertrochanteric
NOF	Neck of femur
#	Fracture
Abd	Abdomen
R	Right
L	Left
L/3	Lower third
M/3	Middle third
U/3	Upper third
C	Closed
O	Open
D	Days
RA	Regional anaesthesia
GA	General anaesthesia
CRIF	Closed reduction internal fixation
IMIL	Intramedullary interlocking
M	Months
S.stiffness	Shoulder stiffness
SSI	Surgical site infection
UCLA	University of California Los Angeles

MASTER CHART

																				UCLA score (6 MONTH)						
SR. NO.	NAME	AGE	GENDER	Uhid No.	MODE OF INJURY	ASSociated injuries	MECHANISM OF INJURY	Rt/Lt	SITE	TYPE OF FRACTURE	TRAUMA-SX INTERVAL IN DAYS	PRELIMINARY IMMOBILIZATION	ANAESTHESIA	TREATMENT GIVEN	PERIOD OF IMMOBILIZATION (DAYS)	FOLLOW UP	Complication	UCLA SCORE (1 MONTH)	UCLA SCORE (3 MONTH)	PAIN	FUNCTION	ACTIVE FORWARD FLEXION	STRENGTH OF FORWARD FLEXION	SATISFACTION OF PATIENTS	UCLA SCORE (6 MONTH)
1	Ashwathappa	65	M	937247	Slip & fall		Direct	R	L/3	C	1D	U-SLAB	RA	CRIF+IMIL	4D	6M	-	27	30	8	10	5	5	5	33
2	Sheela. S	40	F	939188	RTA	Lt.Distal radius fracture	Direct	R	M/3	C	3D	U-SLAB	GA	CRIF+IMIL	4D	6M	-	27	30	8	10	5	5	5	33
3	Hanumappa	65	M	936322	Slip & fall	Rt. IT fracture	Indirect	R	M/3	C	3D	U-SLAB	GA	CRIF+IMIL	7D	6M	-	27	30	8	10	5	5	5	33
4	Thilak kumar	24	M	862404	RTA		Direct	L	M/3	C	1D	U-SLAB	RA	CRIF+IMIL	5D	6M	-	28	32	10	10	5	5	5	35
5	Naveen kumar	19	M		RTA		Direct	L	U/3	C	5D	U-SLAB	RA	CRIF+IMIL	7D	6M	-	27	28	8	10	5	5	5	33
6	Arunachalam shetty	65	M	819464	RTA	Lt.Tibia shaft fracture	Direct	R	M/3	C	7D	U-SLAB	GA	CRIF+IMIL	11D	6M	S.stiffness & Delayed union	23	25	8	8	3	3	5	27
7	Venkatalakshmamma	55	F	885872	Slip & fall		Direct	R	L/3	C	3D	U-SLAB	RA	CRIF+IMIL	7D	6M	-	27	29	8	10	5	5	5	33
8	Sandeep	21	M	775239	RTA	Facial bone fracture with head injury	Direct	R	M/3	C	10D	U-SLAB	RA	CRIF+IMIL	5D	6M	-	26	30	8	10	5	5	5	33
9	Gangaiah	55	M	878776	Asault		Direct	L	M/3	C	2D	U-SLAB	RA	CRIF+IMIL	5D	6M	-	26	30	8	10	5	5	5	33
10	Ravindra babu	56	M	925205	RTA		Direct	L	L/3	C	1D	Arm Pouch	RA	CRIF+IMIL	7D	6M	-	27	30	8	10	5	5	5	33
11	Venkataswamy	65	M	925543	Slip & fall	Lt. NOF #	Direct	R	M/3	C	3D	U-SLAB	GA	CRIF+IMIL	7D	6M	S.stiffness	25	30	8	8	4	4	5	29
12	Manjula	38	F	887562	Slip & fall		Direct	L	M/3	C	4D	U-SLAB	RA	CRIF+IMIL	5D	6M	-	27	29	8	10	5	5	5	33
13	Hari kishore	21	M	939949	RTA		Direct	R	U/3	C	1D	Arm Pouch	RA	CRIF+IMIL	5D	6M	-	27	29	8	10	5	5	5	33
14	Srinivas	44	M	933681	RTA	Lt.2nd finger proximal phalanx#	Direct	L	L/3	O	4D	U-SLAB	RA	CRIF+IMIL	5D	6M	SSI & S.stiffness	24	25	5	8	4	4	5	26
15	Devaraj	40	M	651754	RTA		Direct	R	M/3	C	1D	Arm Pouch	RA	CRIF+IMIL	4D	6M	-	27	30	8	10	5	5	5	33
16	Seenappa	48	M	666458	RTA		Direct	R	M/3	C	1D	U-SLAB	RA	CRIF+IMIL	5D	6M	iatrogenic fracture	28	31	10	10	5	5	5	35
17	Rangadore	25	M	790353	Asault	Head injury	Direct	R	U/3	C	10D	U-SLAB	GA	CRIF+IMIL	5D	6M	-	27	30	8	10	5	5	5	33
18	Chandra bai	51	F	828670	RTA		Direct	R	M/3	C	2D	U-SLAB	RA	CRIF+IMIL	5D	6M	-	27	30	8	10	5	5	5	33
19	Altaf pasha	30	M	680723	RTA	Lt. tibia #	Direct	L	M/3	C	2D	U-SLAB	GA	CRIF+IMIL	7D	6M	-	26	29	8	10	5	5	5	33
20	Sudhindra hebbar	31	M	828570	RTA	Multiple rib #	Direct	L	U/3	C	5D	U-SLAB	RA	CRIF+IMIL	7D	6M	-	27	30	8	10	5	5	5	33
21	Lingamma	55	F	891449	Slip & fall	Rt. IT fracture	Indirect	L	U/3	C	5D	U-SLAB	GA	CRIF+IMIL	7D	6M	-	26	30	8	10	5	5	5	33
22	Rathnamma	60	F	829770	RTA	Abd injury	Direct	L	M/3	C	10D	U-SLAB	RA	CRIF+IMIL	7D	6M	-	25	29	8	10	4	4	5	31
23	Naveen	31	M	942073	RTA	Pubic diastesis,Lt.femur shaft #,Lt lateral malleolus	Direct	R	M/3	C	12D	U-SLAB	GA	CRIF+IMIL	7D	6M		27	32	10	10	5	5	5	35
24	Srinivas	51	M	852593	Slip & fall	Rt. Distal radius#	Direct	R	M/3	C	2D	U-SLAB	RA	CRIF+IMIL	5D	6M	-	27	30	8	10	5	5	5	33
25	Seenappa	48	M	880998	Asault		Direct	R	U/3	C	1D	Arm Pouch	RA	CRIF+IMIL	5D	6M	implant breakage	15	16	4	4	2	2	5	17
26	Manjula	41	F	748799	RTA		Direct	L	M/3	C	1D	Arm Pouch	RA	CRIF+IMIL	5D	6M	-	27	30	8	10	5	5	5	33
27	Venkatlakshmamma	50	F	767020	RTA		Direct	R	L/3	C	2D	U-SLAB	RA	CRIF+IMIL	5D	6M	-	26	29	8	8	5	5	5	31
28	Pavan	38	M	879787	RTA		Direct	R	M/3	C	2D	U-SLAB	RA	CRIF+IMIL	5D	6M	-	28	29	8	10	5	5	5	33
29	Sandeep	21	M	865021	RTA		Direct	R	L/3	C	1D	Arm Pouch	RA	CRIF+IMIL	5D	6M	S.STIFNESS & delayed	24	25	5	8	4	4	5	26
30	Yallappa	40	M	863556	RTA	Lt.distal radius #	Direct	L	L/3	C	2D	U-SLAB	RA	CRIF+IMIL	5D	6M		28	30	8	10	5	5	5	33