"STUDY OF PROXIMAL HUMERUS FRACTURES TREATED BY ANATOMICAL LOCKING PLATES"

By

DR. AMIT J. PATEL

Dissertation submitted to the

S.B.K.S. MEDICAL INSTITUTE & RESEARCH CENTRE

SUMANDEEPVIDYAPEETH, PIPARIA, VADODARA.

In the partial fulfilment

of the requirements for the degree of

M.S.

In

ORTHOPAEDICS

Under the guidance of

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The Sumandeep Vidyapeeth Institutional Ethics Committee (SV IEC) is in receipt of your above mentioned study document and as the research study classifies in the minimal risk category; as recommended by HRRP SBKS MI&RC. The SV IEC approves your study to be conducted in the presented form.

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We have received your application requesting the SVIEC to allow change in the title of your dissertation study. The same has been recommended by your guide and HRRP coordinator of your college.

The matter has been reviewed by SVIEC. We are pleased to allow change in the title of your dissertation from **"Study of Proximal Humerus Fractures Treated by Philos Plate."** to **"Study of Proximal Humerus Fractures Treated by Anatomical Locking Plates."** since there is no other change in your dissertation as per synopsis submitted by you earlier.

The other terms and conditions shall remain the same as contained in the original permission letter under above mentioned reference no. 2.

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STUDY COMPLETION CERTIFICATE

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"STUDY OF PROXIMAL HUMERUS FRACTURES TREATED BY ANATOMICAL LOCKING PLATES"** is a bonafide and genuine research work carried out by me under the guidance of Professor **DR. PARESH P. GOLWALA, M.S. (ORTHOPAEDICS)**.

Date: **Signature of the Candidate**

Place: Piparia, Vadodara. **Dr. Amit Patel**

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled **"STUDY OF PROXIMAL HUMERUS FRACTURES TREATED BY ANATOMICAL LOCKING PLATES"** is a bonafide research work done by **DR. AMIT PATEL** under my guidance and in partial fulfilment of the requirement for the degree of **"MASTER OF SURGERY" in ORTHOPAEDICS.**

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ENDORSEMENT BY THE HOD, DEAN / HEAD OF THE INSTITUTION

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I hereby declare that the SumandeepVidyapeeth, Piparia, Vadodara District, Gujarat, have the rights to preserve, use and disseminate this dissertation / thesis in print or electronic format for academic / research purpose.

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Dr. Amit Patel

ABSTRACT

Background and objectives:

Treatment of the proximal humerus fracture is controversial and various operative modalities have been tried in literatures. Difficulties in Open reduction and internal fixation have been multi-factorial including osteoporotic bone, angular instability, implant impingement, loss of reduction and backing out of screws. Anatomical plates are pre-shaped and pre-contoured with fixed angle relationship between the screws and plate. The locking screw, provide angular as well as axial stability. Thus objectives of our study were to evaluate the results of proximal humerus anatomical plate in various groups like young and old patients, Neer's type 2, 3 & 4 fractures with emphasis on fracture union, functional outcome and complications.

Methods:

The study analyzed 15 men and 10 women aged 26 to 75 (mean, 46.64) years with Neer's 2, 3 & 4 part proximal humerus fractures treated by anatomical locking plate. Patients were followed for a minimum period of 6 months. Functional outcomes and shoulder range of movements were assessed based on the Constant and Murley scoring system. At the final follow-up results were compared between 2-part, 3-part & 4-part fractures, between younger (≤60) and older (>60) and between different modes of injury.

Results:

In our study, 13 cases had 2 part fractures as per Neer's classification, while 11 cases had 3 part and 2 had four part fractures with the mean follow up of 11.8 (range 6-18) months. At final follow up the mean Constant score was 71.07 for 2 part fractures, 64.14 for 3 part fractures, 47.75 for 4 part fractures with the mean Constant score of 68.78. Out of 26 cases, 3 (11.54%) had excellent outcome, 12 (46.15%) had good outcome, 8 (30.77%) had fair outcome and 3 (10%) had poor outcome. Results were satisfactory in patients younger than 60 years, while unsatisfactory results were seen in more than 60 years of age. In our study, Right (56%) upper limb was more commonly involved than Left (40%) while 1 patient had bilateral involvement. Complications encountered in this study were shoulder stiffness in 5 (19.23%),

malunion in 3 (11.54%), infection in 1 (3.85%), impingement of implant in 1 (3.85%), implant loosening (failure of implant) in 1 (3.85%) and screw perforation in 1 (3.85%) case.

Conclusion:

Anatomical locking plate leads to satisfactory functional outcomes in 2 & 3 part fractures but results are unsatisfactory in 4 part fractures and in elderly people. This study teaches us that in fractures of proximal humerus, restoration of joint congruity is vital for restoration of joint function. Restriction of abduction and external rotation suggests that greater tuberosity fragment must be anatomically reduced well. Strict adherence to shoulder mobilisation protocols and part of patient compliance can improve the further results.

Keywords: Proximal humerus fractures, Anatomical locking plate, Constant and Murley score, Neer's classification

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INTRODUCTION

Trauma to proximal humerus usually presents an existent challenge to orthopedic surgeons (Peter S Rose et.al). Fractures of the proximal humerus signify roughly 4% of all fractures and 26% of humerus fractures.[1]

Proximal humeral fractures have a bimodal distribution occurring either in younger age group following high velocity injuries or in older people with low velocity injuries like simple fall.[2] In elderly individuals, fracture of the proximal humerus is the 3rd most common fracture, following hip fracture and Colles' fracture. 80 % of these are osteoporosis related, more common in females as compared to males (3:1)[3, 4]. The injury is of up most importance when it affects the young and middle age groups of the population as it leads to temporary disability and loss of working hours. Due to increased frequency of road traffic accidents in present era, the incidence of these fracture are increased.

Initially there was a common agreed conservative approach to proximal humerus fractures and internal fixation became more prominent after Neer's classification. Following which Neer's prosthesis was also used for comminuted fractures. However, with availability of modern plates like PHILOS the interest in osteosynthesis again came up. The present day treatment goal would be to achieve fracture union with painless shoulder and restoration of function.[5]

Open reduction and internal fixation have multiple complications like infection, osteoporotic bone, implant failure, impingement of implant, angular instability, loss of reduction and screw perforation, myositis ossificans, neuro-vascular deficits.

In order to decrease these difficulties, the AO/ASIF group (Synthes, Stratec Medical ltd, Mezzovico Switzerland); developed the **PHILOS (Proximal Humeral Internal Locking Osteosynthesis) plate** that provides angular as well as axial stability with multiple interlocking screws.

These anatomical plates are pre-shaped and pre-contoured locking compression plates, with an aiming device for insertion of the locking screws and positioning of the plate to prevent impingement. Fixed angle relationship between the

screws and plate is the key to this technology. The threaded screw heads are locked into the threaded plate holes to prevent screw toggle, slide and pull out, thus diminishing the possibility of primary or secondary loss of reduction. Locking the screw to the plate mechanically recreates a point of cortical bone contact,[6] which may be useful in the poor cancellous bone of the proximal humerus.

Multiple holes in the proximal part of the plate are also available for suture anchors passed through rotator cuff and soft tissue attached to tuberosities which gives additional stability.[7] The **anatomical locking plate** can therefore provides an excellent stable construct even in multi-fragmented osteoporotic proximal humerus fractures.

From the point of view of evidence-based medicine it is still not possible to define the **"gold standard"** for stabilization of fractures of the humeral head.[8,9] However, there are few prospective studies[10-18] available that actually evaluate the results of this technique or report on the treatment-related complications.

There may be special technical requirements for the success of such a plate which needs to be defined. Therefore, our study was planned to evaluate functional outcome of proximal humeral fractures treated with open reduction and internal fixation with **anatomical locking plate** with view to evaluate range of movement, possible return of functions around shoulder girdle, radiological outcome and remaining disability, to evaluate the complications and to identify the predictors of loss of fixation of such an implant, after approval by the Institutional Ethical Board.

AIM AND OBJECTIVES

The aim of the present study was:

1. To evaluate functional outcome after open reduction and internal fixation of displaced proximal humerus fractures by proximal humerus anatomical locking plate.

2. To determine the efficacy of proximal humerus anatomical locking plate.

3. To evaluate the complications and identify the predictors of loss of fixation of such an implant.

Thus objectives of our study was to evaluate the outcome of proximal humerus anatomical locking plate in various age groups like young and old patients, Neer's type 2, 3 & 4 fracures with emphasis on fracture union, functional outcome and complications.

RATIONALE OF THE STUDY

Displaced and comminuted fractures of the proximal humerus pose management problems for the orthopaedic surgeons.

Open reduction and internal fixation of displaced proximal humerus fractures is indicated in patients with 2 and 3 part fractures with significant displacement, and in some 4 part fracture. Many fixation techniques have been described like k wire fixation, tension band wiring, intramedullary nailing and plate fixation.

Previous studies have reported acceptable functional results after a conventional ORIF with a buttress-plate and non-locking screws of proximal humeral fractures, particularly in young patients. However, this method has also been associated with a high complication rate, both in elderly patients with comminuted fractures and in young patients, due to a failure in the stability of the osteosynthesis.

Initial results with plate fixation were promising, although there was a high incidence of avascular necrosis, axillary nerve lesions, and failure of the construct. In recent times, locking anatomical plate fixation for proximal humerus fractures has gained considerable popularity over the past decade. Angular stable implants have been suggested to have more reliable fixation of osteoporotic fractures in the shoulder. In biomechanical analysis, locking plates demonstrate significantly greater torsional stability in a cadaveric model, suggesting better clinical performance compared to non-locking plates. Clinically, many studies have shown that locking plates provide high rates of union for displaced proximal humerus fractures. However, there remain a significant number of complications from this technically demanding procedure, many of which occur intra-operatively, including screw cut out, varus positioning of the head, and poor position of the plate leading to impingement. In addition, there remain a small group of patients that develop non-unions.

Therefore, our study will test functional outcome of proximal humeral fractures treated with open reduction and internal fixation with locking plates with view to evaluate range of movement, possible returns of functions around shoulder girdle, radiological outcome, remaining disability and related complications.

REVIEW OF LITERATURE

HISTORICAL PERSPECTIVES

The management of fractures of the proximal humerus has challenged medical practitioners since the earliest recorded medical texts.[19] The recommendations established by the ancient Greek and Roman medical authorities remained remarkably unchanged throughout medieval and early modern medicine.[20]In the earliest known surgical text, *The Edwin Smith Papyrus* (copied circa 1600 BC), three cases of humeral fractures were described. Reduction by traction followed by bandaging with linen was recommended.

In *Corpus Hippocraticum* (circa 440–340 BC), the maneuver of reduction was fully described: bandages of linen soaked in cerate and oil were applied followed by splinting after a week (Fig.1).

Fig.1.The Hippocratic mode of reduction for fractures of the humerus

Celsus (25 BC–AD 50) distinguished shaft fractures from proximal and distal humeral fractures. In Late Antiquity, complications from powerful traction or tight bandaging were described by Paul of Aegina (circa AD 625–690). Illustrations from sixteenth and seventeenth century surgical texts are included to show the ancient methods of reduction and bandaging (Fig.2). The richness of written sources points toward a multifaceted approach to the diagnosis, reduction, and bandaging of humeral fracture in Ancient Egypt, Greece, and Rome.[21]

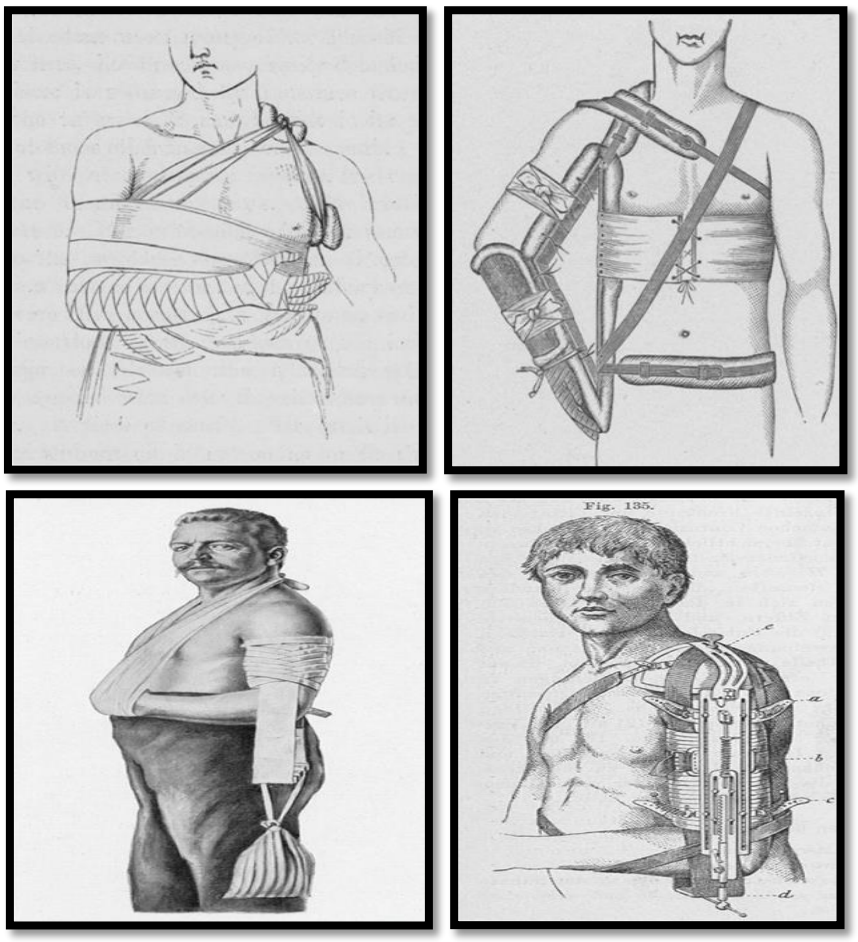


Fig.2.Robert Liston's bandage, Middledropf's triangle, Hamilton's bandage, Bardenheuer's apparatus

In 1851, Astley Cooper distinguished three patterns of proximal humeral fractures according to the anatomic segments involved (1) extra-articular fractures (surgical neck fractures); (2) fractures through the anatomic neck and tuberosities; and (3) fracture-dislocations.

In 1888, Albert Hoffa distinguished fractures of the surgical neck, the greater tuberosity, and the lesser tuberosity according to the surface characteristics. The Irish physician and pathologist Robert William Smith gave a thorough description of the pathoanatomic pattern of an impacted four- part fracture-dislocation of the proximal humerus.[21]

The French surgeon Joseph-François Malgaigne gave several descriptions of complex fractures of the proximal humerus. The German physician and pioneer in brain chemistry, Johann Ludwig Wilhelm Thudichum proposed a comprehensive

classification based on the anatomic level of the fracture lines at proximal end of humerus half a century before the radiographic era.[21]

With the introduction of ether anesthetics in 1846[22] and antiseptic surgical methods in 1867,[23] invasive procedures of reduction or resection of the humeral head became less hazardous. However, internal fixation for fractures of the proximal humerus was not considered until the early twentieth century[24] after Ro¨ntgen's discovery in 1895[25] profoundly changed operative orthopaedics and enabled preoperative planning.

Kocher in 1896 gave anatomical classification for proximal humerus fractures. It was Codman in 1934, who divided these fractures into four parts based on epiphyseal lines, but didn't distinguish between surgical neck and anatomical neck.[21,26,27]

In 1907, Lambotte introduced intramedullary pins to fix fresh fractures of surgical of humerus.[27]In1970's and 1980's conservative management was popular by mean of strapping and traction on Thomas splint. In 1970, Neer introduced the 4 part classification system based of displacement and angulation which is widely used even in present era. With invention of Neer's prosthesis type 3 & 4 fractures were treated with hemiarthroplasty. But this didn't work satisfactory enough.[19]In 1974, Kapandji proposed a "palm tree" technique for fixation.

In the years to follow, staples, intramedullary nails, angle blade plates, external fixation, osteo-sutures in form of tension band wiring, percutaneous fixation with wires and plates and screws (monoaxial and polyaxial) have been introduced and widely used.[27]

The latest addition in the implant list is the PHILOS (The Proximal Humeral Internal Locking Osteosynthesis) plate developed by the AO/ASIF group (Synthes, Stratec Medical ltd, Mezzovico Switzerland) in 2003; which is an anatomically contoured rounded plate with combined holes, which will allow a case specific adaptable treatment for fractures of the proximal humerus (Baker P N et.al).[28]

Similar anatomical plates are also now available that are manufactured by

local companies.

LITERATURE

In 1985, Young and Wallaceanalyzed 34 patients with minimally displaced fractures at 6 months and showed that 97% had good or acceptable results with conservative treatment.[29]

In the following year (1988), Kristiansen B andHakonKofoed published a comparative study performed in 30 patients with displaced 2, 3, 4 part proximal humerus fractures treated either by closed reduction and sling (group 1) or by transcutaneous reduction and external fixation (group 2). At final follow up patients treated with group 1(n=11) had mean Neer score of 60 while those treated with transcutaneous reduction and external fixation had mean score of 79, being much superior than the group 1.[30]

The proponents of open reduction and plate fixation like S. K. Moda et al. studied the result of AO T-plate and semitubular plate in 1990. 25 patients with displaced fractures of the proximal humerus or fracture-dislocations were treated by open reduction and internal fixation (excluding greater tuberosity fractures). In 15 fractures an AO T-plate was used and in other 10 cases a bent semitubular plate was employed as a blade plate. Overall results were excellent or satisfactory in 21 out of 25 cases (84%) and author emphasized on preservation or meticulous repair of rotator cuffs for better outcome.[31]

Jaberg et al. in 1992 promoted percutaneous pinning in his study. In a series, 54 unstable proximal humerus fractures were treated with closed reduction and percutaneous pining. Of the 48 patients available for final follow-up, 34 had a good or excellent result, 10 had a fair result, and 4 a poor result (loss of fixation).[32,33]

In 1997, Resch[34] demonstrated in his study the use and results of closed reduction and percutaneous cancellous screw fixation. A study of 27 patients, 9 with 3-part and 18 with 4-part fractures, treated by percutaneous reduction and screw fixation (Resch procedure)was performed. All the 3-part fractures showed good to very good functional results, with an average Constant score of 91% (84% to 100%),

and no signs of avascular necrosis. Avascular necrosis was seen in 11% of 4- part fractures. The average Constant score in patients with 4-part fractures who did not need further operation was 87% (75% to 100%).

Zyto et al.[35] in 1998 published his study on hemireplacement and found no statistical difference between three- and four-part fractures according to the Constant score and range of movement, but their series was small.

The advent of 21st century saw more and more studies performed on rigid fixation and replacement procedures for proximal humerus fractures.

A study performed by B. Hintermann published in 2000 A. D. , depicting the results of 42 elderly patients, with a mean age of 72 years, with displaced fractures of the proximal humerus (34 three-part, 8 four- part) treated using a blade plate and a standard deltopectoral approach. The final mean Constant score was 73. Thus author conclude that rigid fixation of displaced fractures of the proximal humerus with a blade plate in the elderly patient provides sufficient primary stability to allow early functional treatment.[36]

The advent of proximal humerus locking plates and PHILOS (proximal humerus internal locking osteosynthesis) was considered an important landmark in treatment of proximal humerus fracture treatment as many complex fractures with it showed promising results. This was supported by various studies like that of V. Quarz et al. in 2004 [37], P. Moonot et al in 2007 [38], Owsley KC et al. in 2008 [39], Mehmet et al. in 2008 [40], Darin M. Friess et al. in 2008 [41], K. N. Sharafeldin in 2008 [42], Solberg BD et al. in 2009 [43], AA Martinez et al. in 2009 [44], S¨udkamp et al in 2009 [45], MA Fazal et al. in 2009 [46], Leonard M et al. in 2009 [47], Xavier A et al in 2009 [48], Thyagarajan DS et al in 2009 [49], Mohamed M.H. El-Sayed in 2010 [50], Gerhard Konrad et al in 2010 [51], Sameer Aggarwal et al. in 2010 [52], J. M. Muthuuri in 2010 [53], Rajinder Singh Gaheer in 2010 [54], AtillaSancar et al in 2010 [55], Jonathan D. Barlow et al. in 2011 [56], Sproul RC et al in 2011 [57], D. Faraj et al. in 2011 [58], Mahantesh Y. Patil et al. in 2012 [59], Tingjun Ye et al in 2013 [60], and Chandan Kumar et al in 2013. [61]

In 2007P. Moonot et al. studied total of 32 patients, 23 women and nine men with a meanage of 59.9 years (18 to 87). Data were collected prospectively and the outcomes were assessed using the Constant score. The mean follow-up was for 11 months (3 to 24). In 31 patients (97%) the fracture united clinically and radiologically at a mean of 10 weeks (8 to 24). Mean Constant score at final review was 66.5 (30 to 92).[38]

In 2009 Solberg study, the mean Constant score (and standard deviation) at the time of final follow-up was significantly better in the locked-plate group (68.6 +/- 9.5 points) than in the hemiarthroplasty group (60.6 +/- 5.9 points) ($p < 0.001$). The Constant scores for the three-part fractures in the locked-plate and hemiarthroplasty groups were 71.6 and 60.4 points ($p < 0.001$), respectively, and the scores for the four-part fractures in those groups were 64.7 and 60.1 points ($p = 0.19$), respectively. Patients with an initial varus extension deformity in the locked-plate group had significantly worse outcomes than those with a valgus impacted pattern (Constant score, 63.8 compared with 74.6 points, respectively; $p < 0.001$). [43]

In 2009Martinez described Functional outcomes of 31 men and 27 women aged 36 to 73 (mean, 61) years who underwent Philos plate fixation for proximal humeral fractures retrospectively Patients were followed up for 12 to 18 (mean, 15) months. All fractures healed satisfactorily, except in one patient with a valgus 4-part fracture who had malunion. No wound infections, vascular injuries, avascular necrosis, or loss of fixation ensued. Two patients with axillary nerve palsy recovered spontaneously within 3 months. Functional outcome was excellent in 13 patients, good in 36, moderate in 8, and poor in 1. The mean Constant score was 80 (range, 40–100). [44]

In 2010 Rajinder Singh Gaheer observed 56 patients with Mean follow-up of 40 months (range, 18-62 months). A total of 55 fractures (98.2%) united clinically and radiologically, with a mean neck/shaft angle of 127.1°. One patient (1.8%) had revision for implant failure with a longer PHILOS plate and iliac crest bone graft. This went on to unite at 20 weeks. The mean time to union was 9 weeks (range, 7-20 weeks). The mean Constant score at final review was 72.1 (range, 36-96). A total of 28 patients (50%) had an excellent outcome, 22 (39.2%) had a satisfactory outcome, and 6 (10.82%) had a poor outcome. The mean score in patients older than 65 years

was 70.3 (range, 36-80) and in patients younger than 65 years was 72.5 (range, 42-96). The difference was not statistically significant (P=.09). [54]

In, 2010Mohamed M.H. El-Sayed[50]studied 59 patients ranged between 31 and 52 years, with a mean of 42 years. All the surgical wounds healed by first intention. Time of last follow-up ranged from 24 to 67 months with a mean of 42 months. According to the Neer classification system 12 fractures were type 3, 29 cases were type 4, 10 cases were type 3 or 4 fracture dislocation and 8 cases were of type 3 and 4 head splitting fractures. The mean Constant score for the 3 part fracture group was 75 (65-82), and 67 (55-72) in the 4 part fracture group. The mean score was 61 (44-69) in the fracture dislocation group and 61 (49-70) in the split head type fractures. An overall mean Constant score of 65 (44-82) was recorded at the final follow-up visit Based on the Neer scoring system, there were 14 excellent results (23.8%), 27 good results (45.7%), 15 fair results (25.5%), and only 3 patients had poor results (5%). Thus, 41 patients (69.5%), showed favourable results at the final follow-up visit.

In 2010 Aggrawal[52]studied total of 47 patients, 27 males while 20 females. Mean age of the patients 58.51 years (23-81 years). The average follow up period was 21.49 months (12-38 months). Out of a total of 47 patients, 27 were found to be older than 65 years of age suggesting a strong relation of proximal humerus with age related osteoporosis. Further, males 65 years or younger were more likely to sustain high energy fractures (n = 19/20, 95%) and female 65 years and older were more likely to sustain low energy fracture (n = 19/ 27, 70.37%) and this result was found to be statistically significant (p = 0.000). Falls accounted for 55% of fractures, road side accidents 42.5% and 1 fracture was caused by seizure. 13 cases were type 2, 23 cases were type 3 and 10 cases were type 4 fractures by Neer. All fractures united with an average union time of 20 (16-25) weeks. Mean Constant score at final follow up was 72.08. Outcomes were excellent in 17%, good in 38.5%, moderate in 34% while poor in 10.5%.

In 2009 Sudkamp[45] studied One hundred and eighty-seven patients (mean age, 62.9 ± 15.7 years) with an acute proximal humeral fracture were managed with open reduction and internal fixation with a locking proximal humeral plate. The patients included 135 women (72%) and fifty-two men (28%); the women were significantly older than the men (mean age, sixty seven compared with fifty-two years; $p < 0.05$).

The proximal humeral fracture was caused by a low-energy injury in 162 patients (87%) and by a high-energy injury in twenty-five patients (13%). the mean Constant score was 70.6 ± 13.7 points for the injured side. Sixty-two complications were encountered in fifty-two (34%) of 155 patients during the one-year follow-up period. Thirty seven complications (60%) occurred during the first three months after the operation, and thirty-four (55%) were directly related to the initial surgical procedure. Twenty-one patients (14%) had primary screw perforation of the humeral head that was unrecognized during surgery and four patients had subacromial impingement because the Locking Proximal Humerus Plate was positioned too far cranially. Three patients had a postoperative neurological lesion. Four patients had a deep wound infection. Two patients had a superficial infection. Because of a loss of reduction in eleven patients (7%) and humeral head necrosis in six patients (4%), eleven cases of delayed screw perforation of the humeral head were seen over the one-year follow-up period. There were seven implant-related complications: three patients had plate breakage, two patients had plate pullout, and two patients had screw loosening. After twelve months, four patients had a nonunion of the fracture.

In 2017 Sreen[52] studied Functional outcomes of 12 men and 18 women aged 22 to 78 (mean, 58) years who underwent PHILOS plate fixation for proximal humeral fractures were reviewed. Indications for surgery were 2 part (n=9), 3 part (n=14) or 4-part (n=7) closed proximal humeral fractures with angulation of more than 45 degrees or displacement of more than 1 cm. Functional outcomes and shoulder range of movement were assessed based on the Constant scoring system. All patients will be followed up at monthly intervals for 6 months. During this period patient, will be motivated for physiotherapy and gradual normal use of the affected limb. Fracture union will be assessed clinically and radiologically. The radiological union in most of the cases (24) occurring between 10-14 weeks. Range of union time was 8 to 18 weeks. Avascular necrosis of head occur in one case. In out of 30 cases excellent result in 7 cases, Good in16 cases Satisfactory in 5 cases and Poor in 2 cases were obtained.

In 2012 AnnamalaiRegupathy[62]analised total of 11 patients in which 9 were females and 2 were males. The age group in the study was from 18 years to 81 years with mean of 54.45 years. The maximum age incidence was between 41 years to 60

years. There were 8 patients with 2 part fractures and 3 patients with 3 part fractures. Ten patients had fracture on right side and one patient had fracture on left side. The commonest mechanism of injury was following trivial trauma like fall without stretched hand in old population and in younger group the mode of injury was following high velocity injury. The mean Constant score was 81.16 with minimum of 55 to maximum of 100. The results based on Constant score was classified as excellent of 50% cases, 16.6% of good result, 16.6% of moderate and 16.6% of poor results.

In 2013 Chandan Kumar et al[61] studied 52 patients with displaced proximal humerus fractures treated with proximal humerus locking plate. 11 patients had 2‑part fractures, 22 patients had 3‑part fractures, and 19 patients had 4‑part fractures. The mean follow up period was 15.21 ± 2.59 months. 65.8% (n=27) patients had good to excellent result, 19.5% (n=8) had fair, and 14.7% (n=6) had poor result. Constant scores for 2‑part (79.83 ± 6.95) and 3‑part fractures (74.22 ± 12.53) were significantly superior to those of 4‑part fractures (61.09 ± 14.29) (P value = 0.002 and 0.018, respectively). Difference between 2‑part and 3‑part fractures was not significant (P value = 0.623). There was no significant difference between younger (≤60) and older patients (>60). Complications encountered in this series were varusmalreduction in 17% (n=7), screw perforation in 10% (n =4), plate impingement in 12% (n=5), infection in 2% (n =1), and nonunion in 2% (n =1) of cases.

In 2015Bansal V et al[63] studied 16 men and 9 women aged 19 to 82 (mean, 49.24) with an acute proximal humerus fracture were treated with PHILOS plate, 11 patients had 2-part fractures, 11 patients had 3-part fractures, and 3 patients had 4-part fractures. After 6 month follow up, a mean Constant score57.4 was achieved. Outcomes were excellent in 16%, good in 44%, fair in 16% while poor in 24%. The Constant score was poorer for Neer type IV fractures as compared to other types. The most frequently occurring complications in our patients were malreduction 20%, screw perforation 16%, infection 12%, avascular necrosis 8%, frozen shoulder 8%, impingement 4% and plate pull out 4%.

In 2017 Kulkarni S et al.[564]studied 60 patients, 44 patients were operated with PHILOS (proximal humerus interlocking system) and 16 patients were operated with

PHLP (proximal humeral locking plate). Patients were ranged from 21 to 76 years (mean age 52.5 years) with 38 males and 22 females. Mode of injury was high energy trauma (road traffic accidents) in 38 cases and low energy trauma (fall at home) in 22 cases. According to Neer's classification, out of 60, 4 (6.67%) were two part fractures, 44 (73.33%) were three part fractures, 12 (20.00%) were four part fractures. The mean Constant Murely score was 83.83. For two part fractures the mean constant Murely score was 91.0. For three part fractures the mean Constant Murely score was 84.5. For four part fractures the mean Constant Murely score was 76.0. The mean DASH score was 17.95.

ANATOMY

Embryology:

Embryonic period:

4th week: The upper limb bud is first seen as an elevation on ventrolateral body at end of 4th week of gestation.

5th week: The central core of humerus begins to chondrify , although shoulder joint is yet not formed .

7th week: The upper limb rotates 90 degree laterally on longitudinal axis. The shoulder joint is completely formed with increasing cavitations.

8th week: Shoulder joint has adult form.

Foetal period:

8-12 week: Primary centre arises.

13th week: Glenoid labrum starts forming.

Post natal period:

Proximal humerus develops from three ossification centres.

Humeral head: 4 – 5 months age

Greater tuberosity: 1-3 years age

Lesser tuberosity: 4-5 years age

The two tuberosities coalesce at around 5 to 7 years of age and subsequently fuse with the humeral head at 7 to 13 years of age. For girls, growth of proximal humerus physis continues until around 14 years of age, with subsequent fusion of the epiphysis to the shaft at 14 to 17 years of age. For boys, growth continues until about

age 16, when closure of the physis begins. For most boys, the proximal humeral physis is closed by about 18 years of age[65,66].

Bony Anatomy

The proximal humerus is uniquely adapted to allow for the large range of motion of the shoulder joint. The diaphysis expands into the surgical neck, which is just below the greater and lesser tuberosities of the metaphyseal flare. The anatomic neck is just above the tuberosities, and it is the region just below the humeral articular surface (Fig.3).

The humeral articular segment is almost spherical, with a diameter of curvature averaging 46 mm (ranging from 37 to 57 mm). The inclination of the humeral head relative to the shaft averages 130 degrees, and the geometric center of the humeral head is offset an average of 3 mm posteriorly and 7 mm medially from the axis of the humeral shaft.

Humeral retroversion, as measured with respect to the epicondyles of the distal humerus, averages about 35 degrees. However, it can be significantly variable among individuals, and the range has been reported to be between 10 degrees of anteversion and 60 degrees of retroversion.

The bone density of the proximal humerus just underneath the articular surface is strongest, while the bone of the central humeral head and neck is more porous[26, 27, 65].

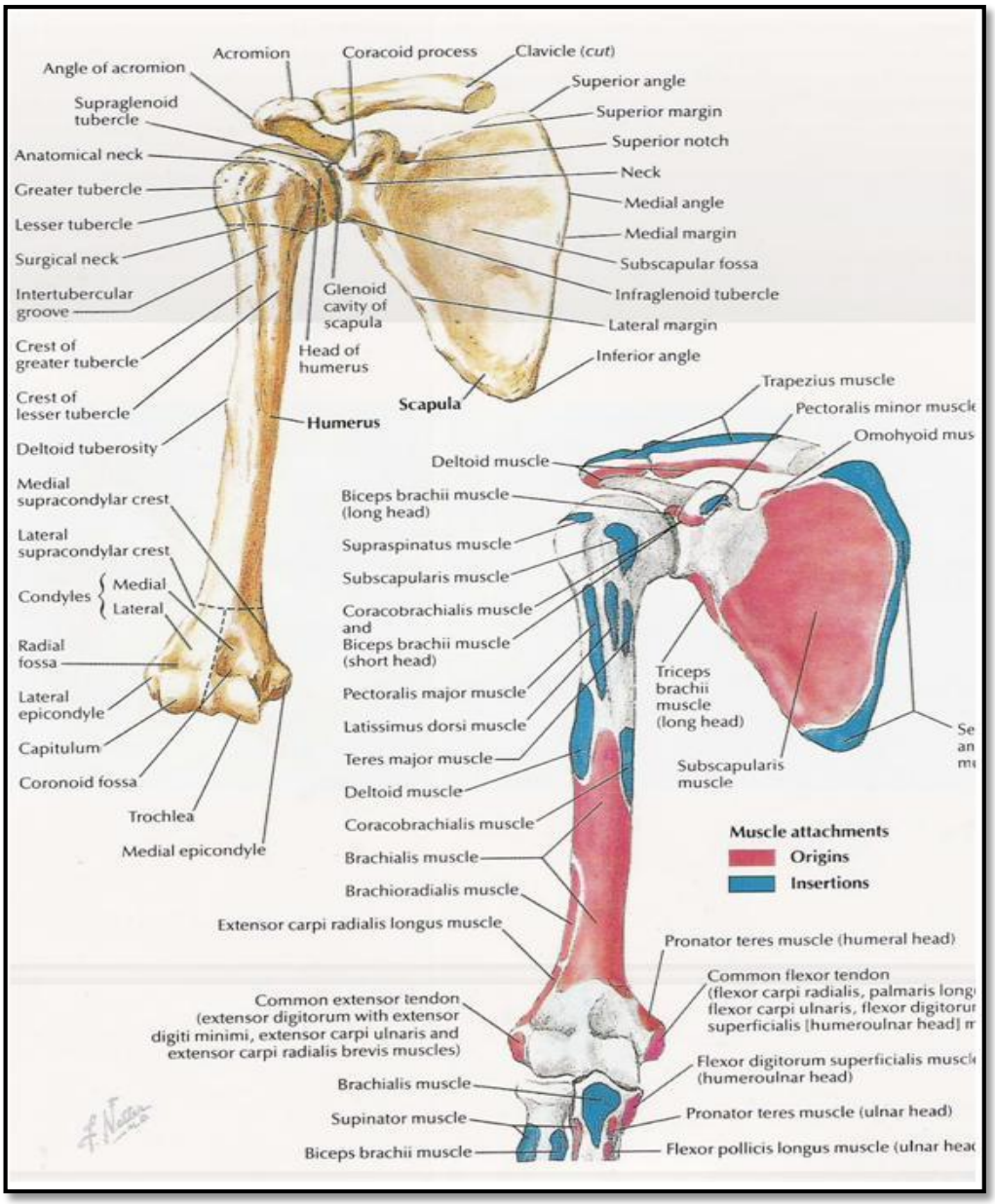


Fig. 3.Anatomy of humerus and its muscle attachments

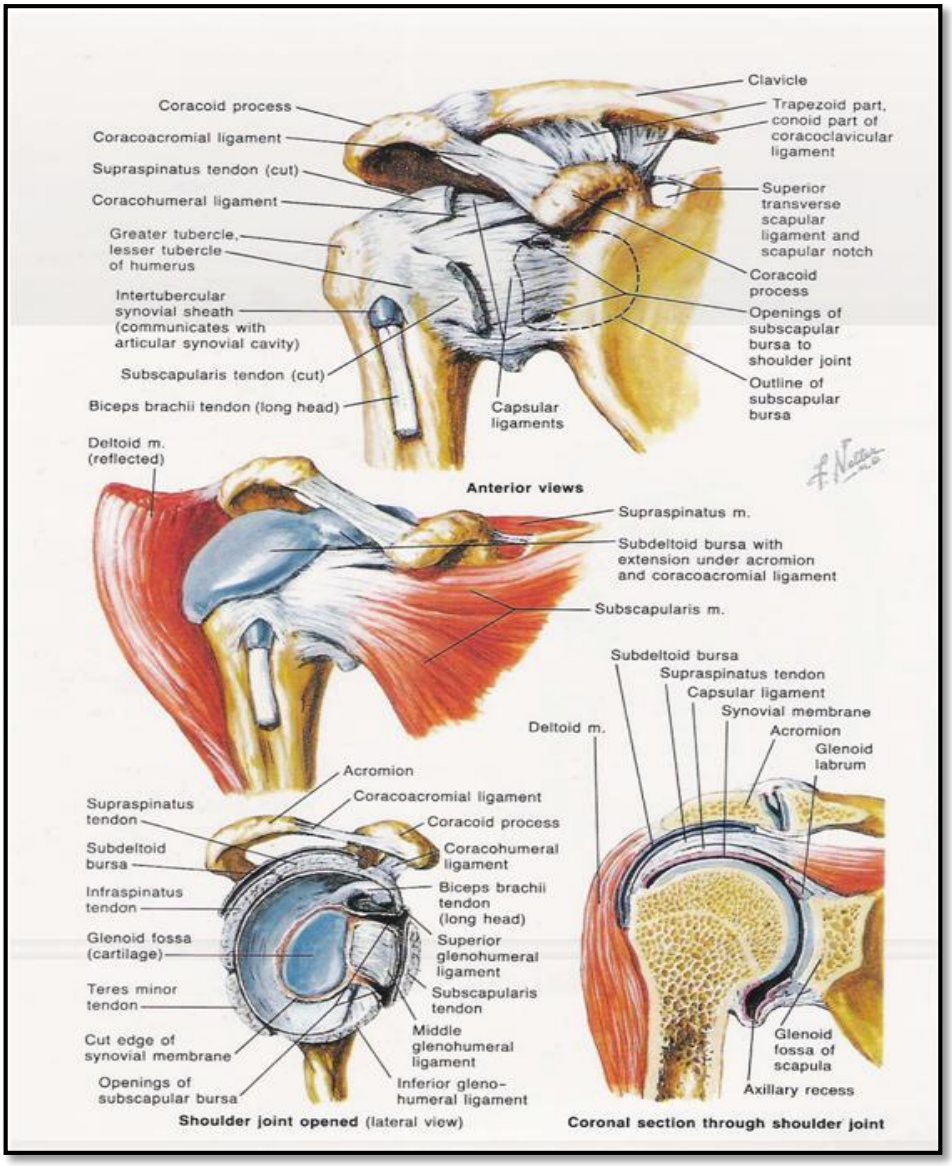


Fig.4. Anatomy of Glenohumeral joint

Rotator Cuff

The rotator cuff includes supraspinatus, infraspinatus, teres minor and subscapularis which act as dynamic stabilizers of shoulder joint. During abduction the rotator cuff maintains position of humerus head in relation to glenoid cavity and thus prevents proximal migration by pull of deltoid. The greater tuberosity has three regions from anterior to posterior into which the supraspinatus, infraspinatus, and teres minor insert (Fig 4, 5). Recognition of these three prominences may aid in determining which tendons are involved in the fracture. The subscapularis tendon inserts into the lesser tuberosity, which is separated from the greater tuberosity by the

bicipital groove (Fig 6). This groove in which courses the biceps tendon is a useful landmark for fixation of the tuberosities during fracture repair. The medial lip of bicipital groove has attachment of teres major, while the lateral lip has insertion of pectoralis major. Typically the tendon structure is stronger than the adjacent bone of the tuberosities, and this is the basis for a variety of suture fixation methods for proximal humerus fracture repairs. The deltoid inserts into deltoid tuberosity just inferior to greater tuberosity on lateral aspect, while the coracobrachialis inserts on medial aspect of shaft of humerus at level of deltoid tuberosity. [26,27,65]

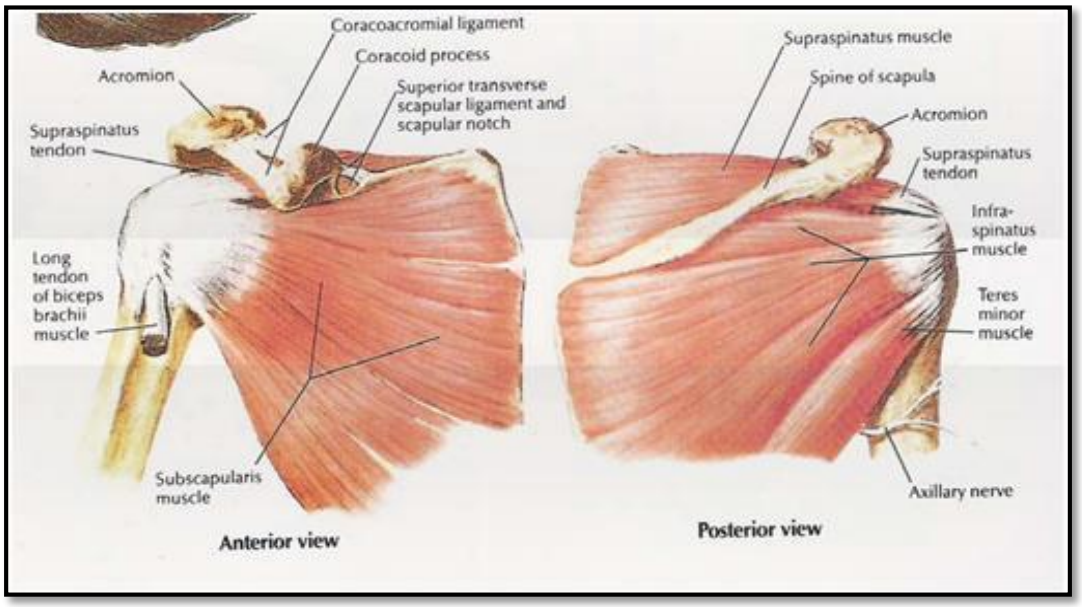


Fig.5. Anatomy of rotator cuff

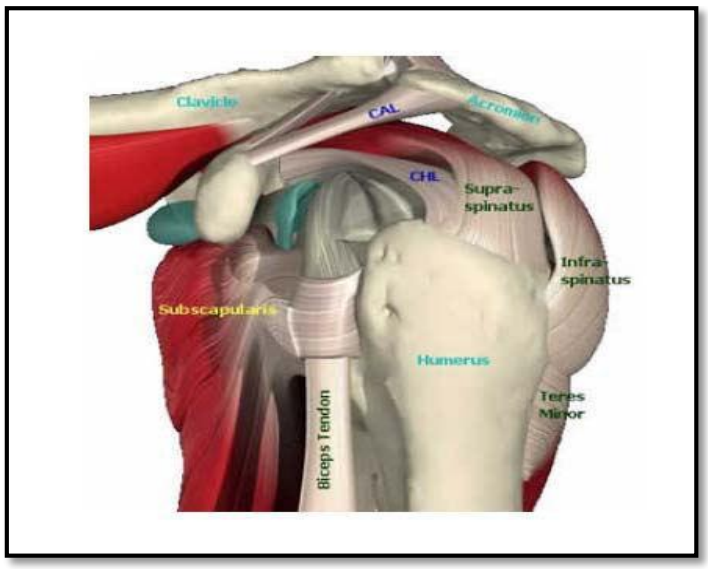


Fig.6. Pattern of arrangement of rotator cuff

Vascular Anatomy

The axillary artery and vein and the branches of the anterior and posterior humeral circumflex vessels are important to consider. The anterior humeral circumflex artery originates from the axillary artery at the inferior border of the subscapularis muscle. The anterior humeral circumflex artery courses around the proximal humeral metaphysis and anastomoses with the posterior humeral circumflex artery, which accompanies the axillary nerve through the quadrilateral space (Fig. 7).

The ascending branch of the anterior humeral circumflex artery courses immediately lateral to the bicipital groove and it is paramount in maintaining vascularity of the articular segment. This vessel enters the humeral head just below the articular surface to form the arcuate artery, which perfuses the majority of the humeral head. Loss of vascularity to the humeral head can occur if this vessel is disrupted in the setting of a fracture that involves the articular segment of the humerus at the anatomic neck level. Rarely, proximal humerus fractures with significant displacement of the humeral shaft can injure the axillary artery near the take-off of the circumflex vessels. Recent studies based on gadolinium enhanced MRI have shown that posterior humeral circumflex artery supplies 64% of blood supply to humeral head, while anterior humeral circumflex artery supplies 36% of humeral head[26, 27, 65, 67].

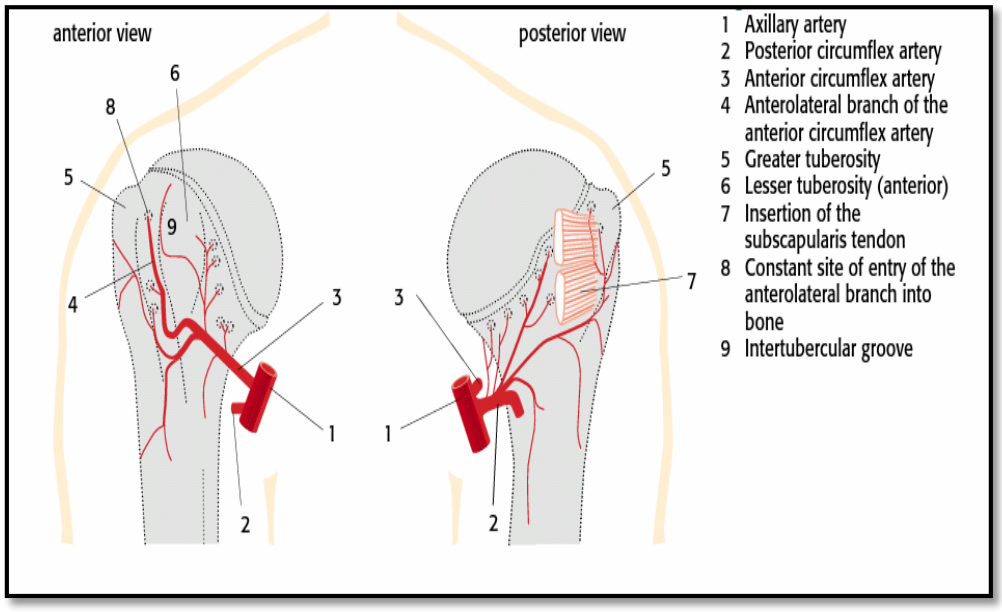


Fig.7. Blood supply of the proximal humerus

Nerves

The innervation of the shoulder joint is derived from the C5 - T1 contribution to the brachial plexus. The In the setting of displaced proximal humerus fractures and fracture-dislocations, the axillary nerve is the primary nerve at risk for injury ,as well as during operative treatment of the same. The axillary nerve arrives from posterior cord of the plexus and travels posterolaterally of the lower subscapularis to enter the quadrilateral space, where it lies immediately inferior to glenohumeral joint capsule. Its posterior branch supplies posterior deltoid and teres minor and provides sensation to "badge area" of proximal arm. Its anterior branch has variable course deep to deltoid and supplies its anterior and middle part[26, 27, 65].

Nerve supply and Action of Muscles

The deltoid is supplied by the axillary nerve. Acromial fibres help in abduction, anterior fibres in forward flexion and internal rotation and posterior fibres in extension and external rotation.

Pectoralis major acts according to site of origin of fibres. As a whole it helps in flexion, adduction and internal rotation, while fibres arising from the clavicular part help in flexion and internal rotation, and sterno-costal fibres help in extension of flexed arm but not beyond anatomical position. Clavicular part is supplied by lateral pectoral nerve, while medial pectoral nerve supplies rest of the muscle.

Supraspinatus initiates abduction and is supplied by suprascapular nerve. The same nerve supplies the Infraspinatus which helps in depression of humeral head and external rotation. Teres minor helps in external rotation and is supplied by axillary nerve[65].

Bursa

The subacromian and subdeltoidbursae lubricate the motion between the rotator cuff and overlying acromian and acromioclavicular joint. The subcoracoid and the subscapularisbursae are not of much importance.[65]

Biomechanics

The shoulder girdle is actually a complex of 4 different joints: 1) Glenohumeral joint 2) acromioclavicular 3) scapulothoracic and 4) sternoclavicular joint. The anatomy of glenohumeral joint is complex and proper function of joint depends upon the proper alignment and interaction of surrounding anatomical structures. The most important movement i.e. abduction occurs as result of combined motion at glenohumeral and scapulothoracic joint. For the initial 30 degree of abduction the glenohumeral to scapulothoacic ratio of contribution is 4:1, while for more than 30 degree of abduction it is 2:1. The abduction beyond 90 degree is hindered by the impingement of tuberosity against coraco-acromial arch. External rotation of the arm moves the tuberosity posteriorly and loosens the inferior ligaments of glenohumeral joint, which facilitates further abduction[26, 27, 65].

Most fractures of the proximal humerus are the result of an indirect force such as a fall onto the outstretched arm rather than a direct blow to the shoulder. The trauma is usually low energy in older osteoporotic individuals while it is high velocity trauma in younger individuals. The origin of a proximal humerus fracture is probably due to a combination of factors, which include relatively osteoporotic bone (in the elderly), direct contact against the adjacent acromion and glenoid rim, and forceful pull of the rotator cuff muscles and extrinsic muscles such as the pectoralis major.

The fracture configuration and displacement then depends on the position of the humerus at the time of the injury, the bone quality of the proximal humerus and level of fracture. The muscular pull of adjacent tendon attachments on humeral fracture fragments determines the patterns of displacement. This is especially true in nonimpacted situations.

The pectoralis major pulls the humeral shaft anteriorly and medially. The supraspinatus and infraspinatus pull the greater tuberosity posterosuperiorly, depending on the integrity of their tendinous insertion. The subscapularis pulls the lesser tuberosity medially.

A fracture proximal to pectoralis major insertion will result in abduction of the proximal fragment, while distal fragment is pulled medially by pectoralis major. For fracture distal to pectoralis major insertion and above the deltoid insertion, the distal

fragment is displaced laterally by deltoid, while pectoralis major, teres major and latissimusdorsi pull proximal fragment medially. For fracture distal to deltoid insertion, the proximal fragment is abducted and flexed, while the distal fragment migrates proximally (Fig 8).

In a three-part fracture with displacement of the lesser tuberosity, the humeral head will be externally rotated away from the glenoid by the pull of the greater tuberosity, which remains attached to the articular segment.

In a three-part fracture with the greater tuberosity pulled off the articular segment, the intact subscapularis and lesser tuberosity will pull the humeral head into internal rotation toward the glenoid[26, 27].

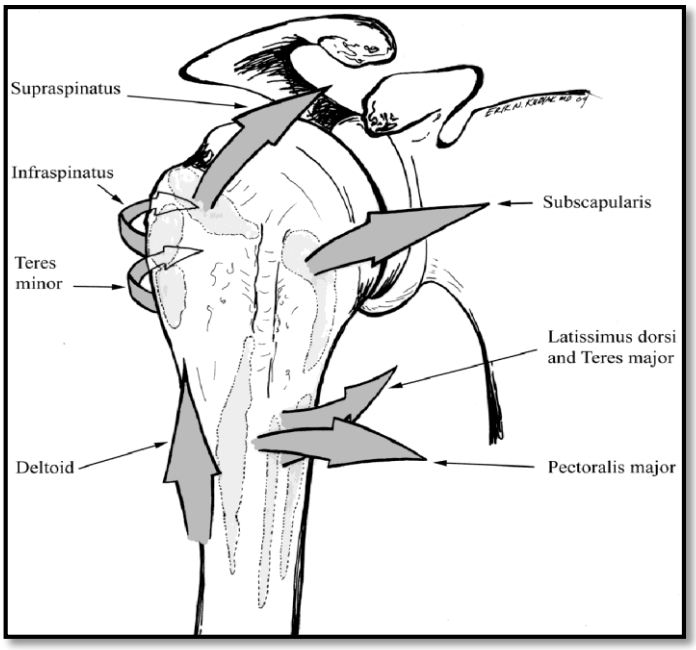


Fig.8. Deforming forces on the proximal humerus. Direction of arrows shows direction of deformity caused by each muscle

CLASSIFICATIONS

DePalma and Cautilli first emphasized the difference between fractures with and without dislocation of the joint surfaces. Neer subsequently modified and emphasized this fracture type in his classic fourpart classification scheme.

Codman in 1934 was the first to observe that there were four major fracture fragments when a proximal humerus fracture occurred, and that these occurred in varying combinations depending on the mechanism of injury . These fragments were the articular head, the greater and lesser tuberosities, and the humeral shaft (Fig.9) [26, 27, 69].

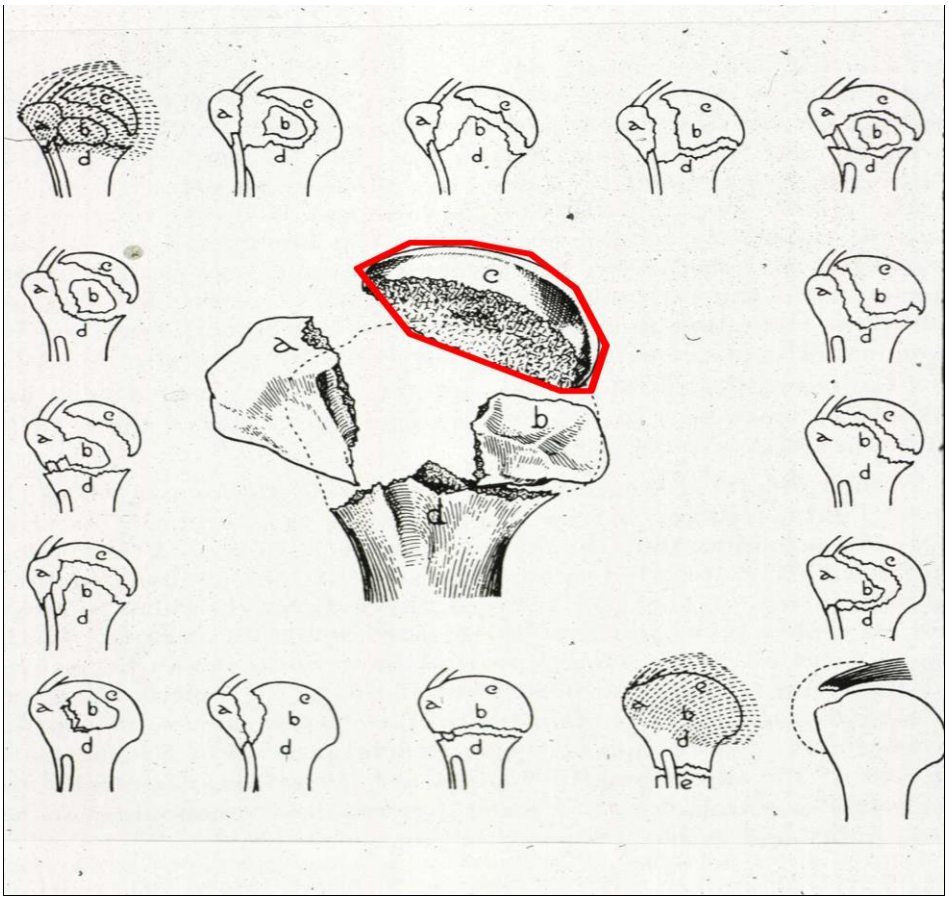


Fig.9. Codman's classification

Kocher's classification

He classified proximal humerus fractures based on anatomical level of fracture

- Anatomic neck
- Epiphyseal region
- Surgical neck

Disadvantage of this system is that it doesn't allow for multiple fractures at different level, nor does it differentiate displaced from undisplaced fractures, which require different management (Fig. 10).

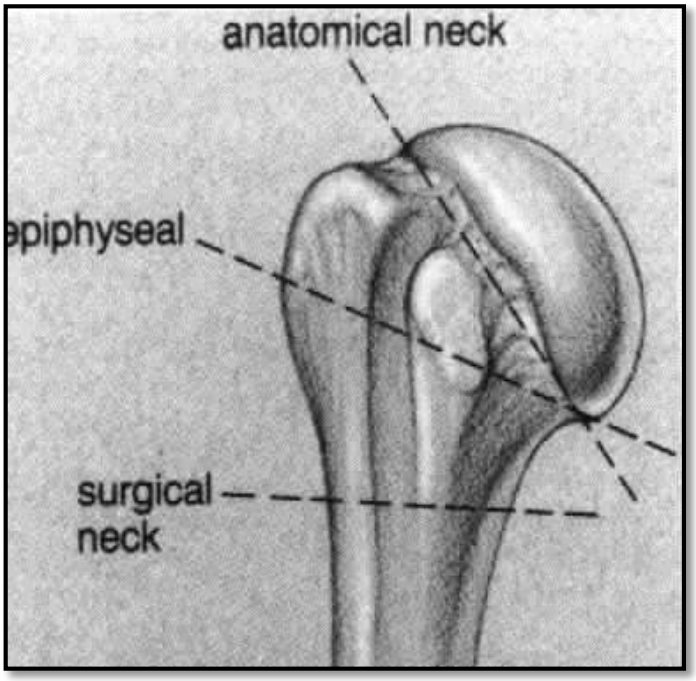


Fig.10 Kocher's classification

Watson and Jones Classification

It is based on mechanism of injury mainly for surgical neck fractures.

1. Abduction type

2. Adduction type

The deformity in these fracture type is anterior angulation.

Disadvantage of this classification system is that it is dependent on method in which radiograph is obtained.

Neer's classification

Neer's classification was first published in 1975. He modified and improved on Codman's classification by emphasizing patterns and degree of displacement rather than the location of fracture lines. He believed this gave important insight into humeral articular segment He emphasized the prognostic importance of fracture dislocations, which he felt had a high likelihood of osteonecrosis due to loss of soft tissue attachments to the humeral head. According to Neer, a fracture fragment is considered displaced if there is more than 1 centimetre of separation or a fragment is angulated more than 45 degrees from the adjacent fragment. If displacement is less than this, then the fracture is considered to be "minimally displaced" regardless of the number of fracture lines (Fig 11).

A two part fracture means that only one segment is displaced, and the most common type is a surgical neck fracture. Greater tuberosity displacement is another common form of two part fracture. Two part fractures that involve the lesser tuberosity or the anatomic neck are rare.

A three part fracture involves displacement of the shaft and humeral head from either the greater tuberosity (more common) or the lesser tuberosity. The pattern of deformity is then based on the pull upon each segment, as previously described.

A fourpart fracture isolates the humeral articular segment from the tuberosities and the shaft. The typical scenario is dislocation of the humeral segment out of the glenoid with no remaining soft tissue attachments. The so called valgus impacted four part fracture was described after Neer's original classification and is an important variant, since it may have a better prognosis than the classic four part Fracture.

In this fracture, residual vascularity may be maintained through an intact medial soft tissue sleeve despite more than 45 degrees of angulation of the humeral head segment as well as greater and lesser tuberosity displacement. Thus, the risk for osteonecrosis is less than in the case of a classic four part fracture.

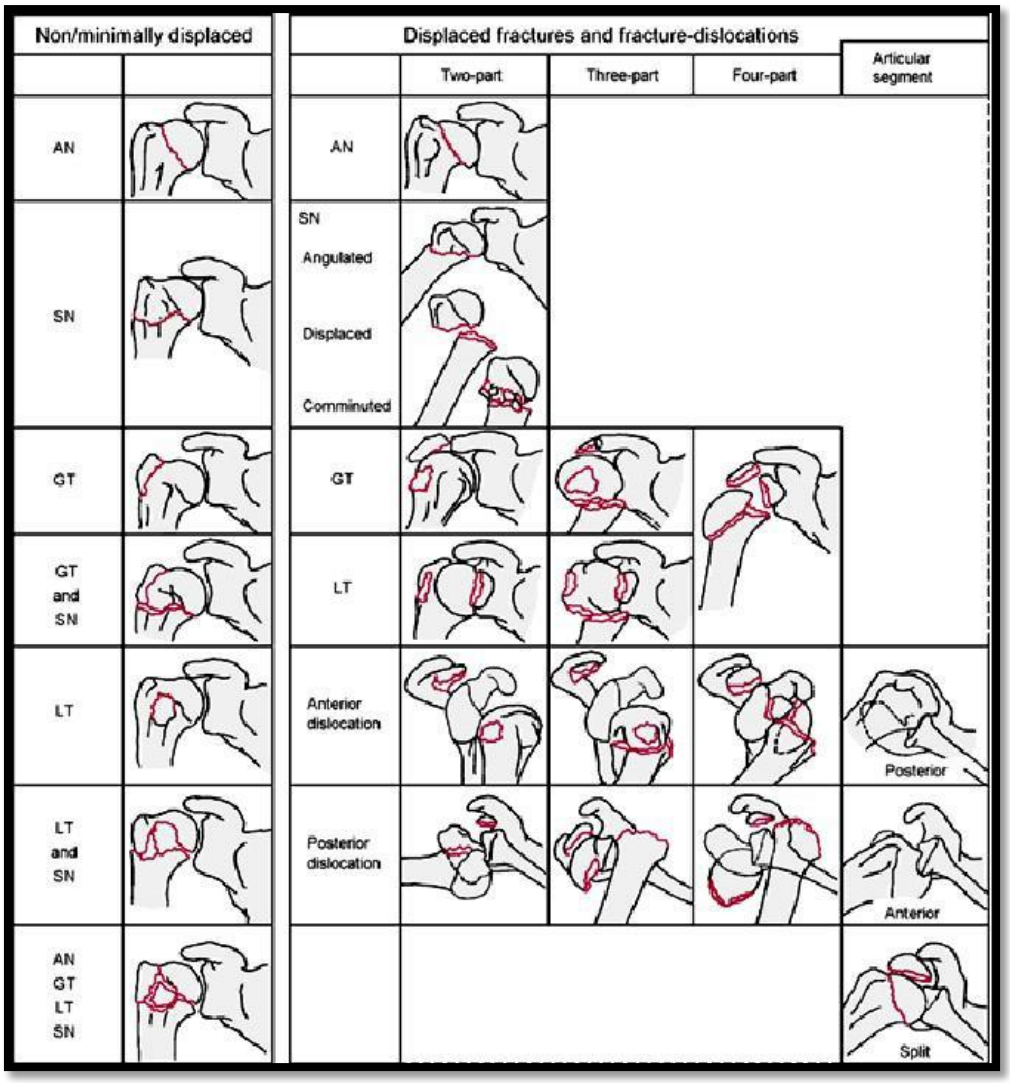


Fig.11. Neer's classification

AO Classification

Jakob et al proposed the AO Group classification of proximal humerus fractures. This system creates subgroups of fractures according to the degree of displacement, resulting in 27 subgroups and emphasizes on vascular supply to articular surface (Fig.12). Its complexity has resulted in limited use. Concerns for reliability of these classification schemes have been raised, and several studies have documented poor interobserver reliability.

A = Extra articular unifocal fracture

A1 Extra articular unifocal fracture,tuberosity

1. Greater tuberosity,not displaced
2. Greater tuberosity, displaced
3. with a glenohumeral dislocation

A2 Extraarticular unifocal fracture, impacted metaphyseal

1. Without frontal malalignment
2. With varus malalignment
3. With valgus malalignment

A3 Extra articular unifocal fracture,non impacted metaphyseal

1. Simple, with angulation
2. Simple, with translation,
3. Multifragmentary

B =Extra articular bifocal fracture

B1 Extra articular bifocal fracture, with metaphyseal impaction

1. Lateral + greater tuberosity
2. Medial + lesser tuberosity
3. Posterior + greater tuberosity

B2 Extra articular bifocal fracture, without metaphyseal impaction

1. Without rotator displacement of epiphyseal fragment
2. With rotator displacement of epiphyseal fragment.
3. Multifragmentary metaphyseal + one of the tuberosities

B3 Extra articular bifocal fracture, with glenohumeral dislocation

1. "vertical" cervical line + greater tuberosity intact + anterior and medial dislocation.

2. "vertical" cervical line + greater tuberosity fractured + anterior and medial dislocation.

3. lesser tuberosity fractured + posterior dislocation

C = Articular fracture

C1 – Articular fracture, with slight displacement

1. Cephalotubercular, with valgus malalignment.
2. Cephalotubercular, with varus malalignment
3. Anatomical neck

C2 – Articular fracture, impacted with marked displacement

1. Cephalotubercular, with valgus malalignment
2. Cephalotubercular, with varus malalignment
3. Transcephalic and tubercular, with varus malalignment

C3 – Articular fracture, dislocated

1. Anatomical neck
2. Anatomical neck and tuberosities
3. cephalotubercular fragmentation

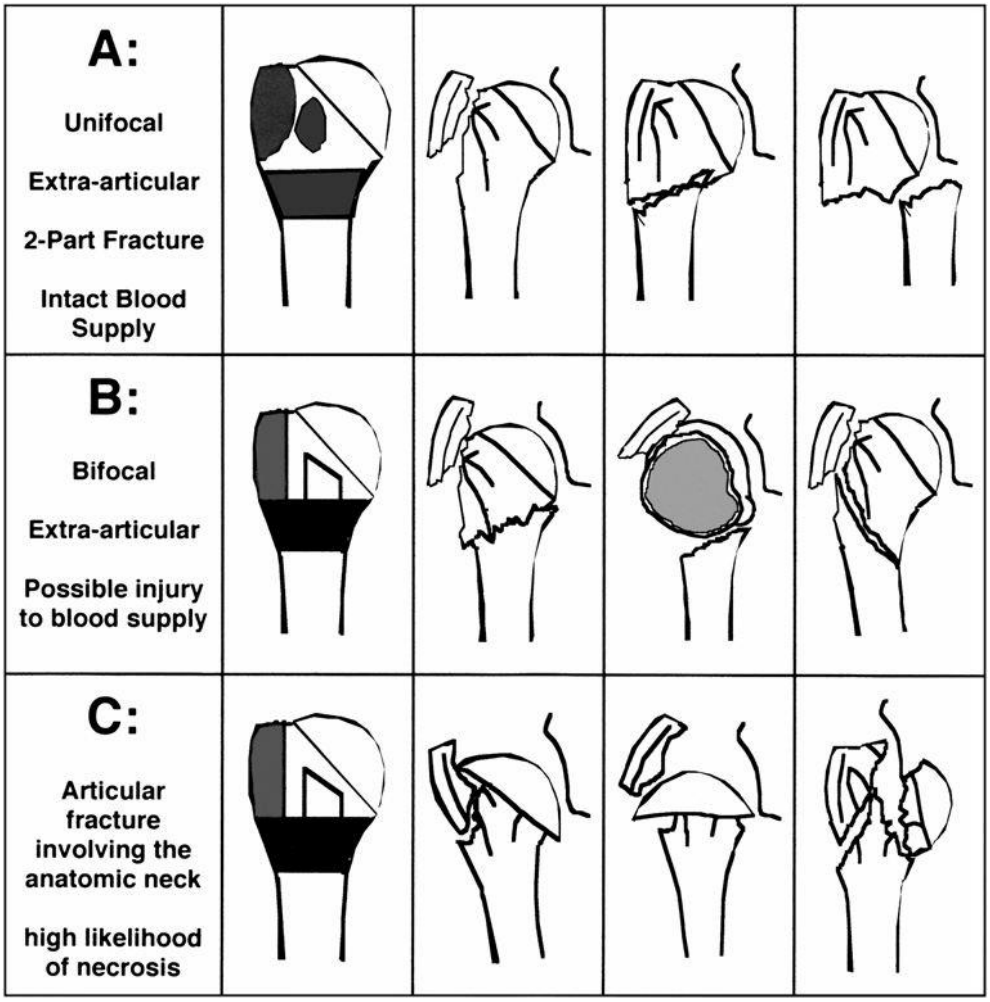


Fig.12. AO classification

Edelson et al. in 2004[70] proposed classification based on CT scan 3D reconstruction of fracture configuration. The 3D CT reconstructions were presented in what we term a "Fracture Wheel" format. The fracture are classified as

1. Two part
2. Three part
3. Shield fracture

The above mentioned types may be in varus or valgus or neutral angulation.

4. Shield variant: a) 4 part b) Shattered shield c) Head split

5. Isolated greater tuberosity

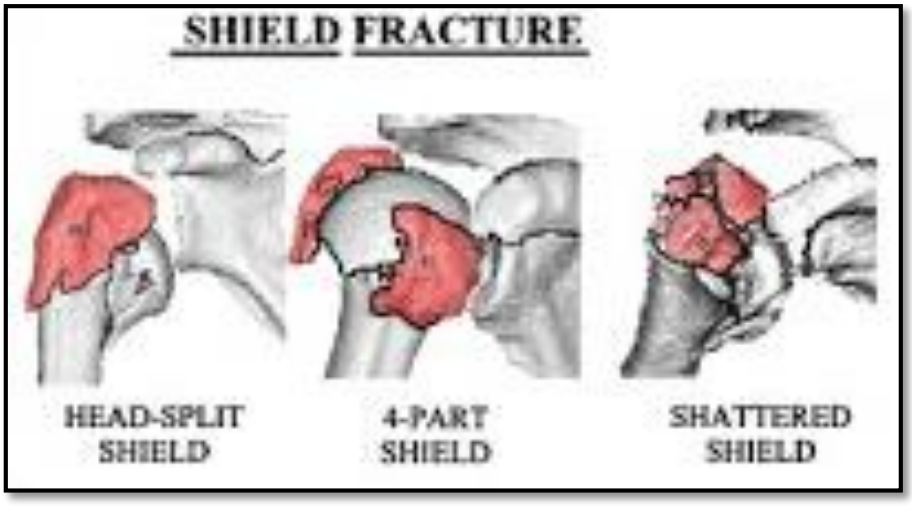


Fig.13.Shield fracture

The above mentioned fractures may be associated with anterior or posterior dislocation. The Shield is a section of bone circling around the head fragment comprised of the greater and lesser tuberosities held together by the bicipital groove. The 'Shield' fracture is most easily understood as a worsening and a progression of three part Fracture pattern as the head segment continues to be driven down and back (Fig.13).[26,27,70]

CLINICAL EVALUATION

The patients usually present with pain and swelling. Ecchymosis is usual finding which spreads up to elbow and surrounding chest region. On palpation tenderness and crepitus may be present; loss of shoulder contour if associated with dislocation may be noted. Shoulder range of motion is painful and restricted. Associated neurovascular injuries like brachial plexus, axillary nerve or vessel injury may be present and carefully sort after.[26,27]

Radiographs

Adequate radiographic evaluation is essential for accurate fracture classification and treatment decisions. A trauma series is mandatory, and this consists of an anteroposterior (AP) view of the scapula, which is a true AP view of the shoulder joint, an axillary view, and a lateral Y view of the scapula. If abduction of the shoulder for an axillary view cannot be performed due to pain, a Velpeau axillary view can be substituted while the patient's arm remains in the sling.

For scapular A P view, the posterior aspect of affected shoulder is kept on xray plate and opposite shoulder is tilted forward to approximately 35 degrees (Fig 14, 15).

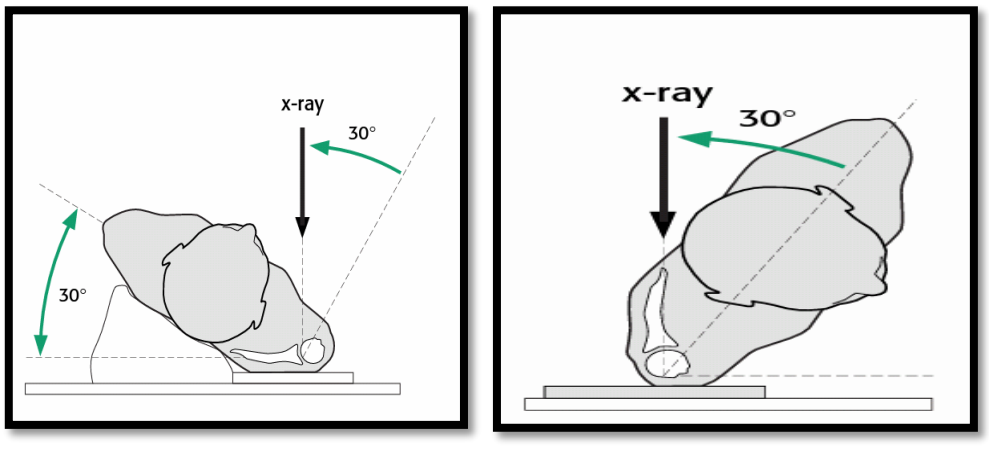


Fig.14. Positioning for Scapular AP and lateral view

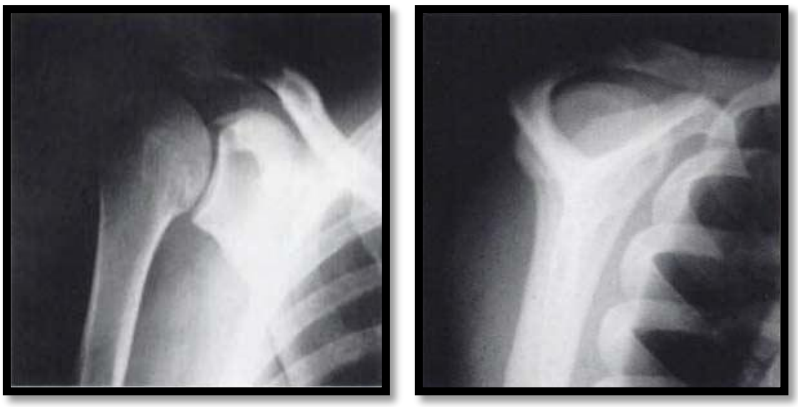


Fig.15. Radiograph Scapular AP and lateral view

For Lateral 'Y' scapular view, the anterior part of affected shoulder is placed on X ray plate and opposite shoulder is tilted backwards by about 35 degrees (Fig 14, 15).

Axillary view is taken with affected shoulder abducted with Xray plate on top of affected shoulder and X ray beam directed from below upwards (Fig 16).

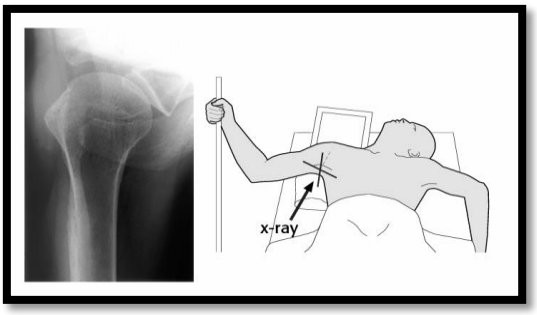


Fig.16.Axillary view

Velpeau view is done with patients arm rested in a sling. The patient leans back and beam is aimed down through the shoulder .This may be preferred after trauma as shoulder remains immobilized and avoids further displacement of fracture(Fig 17).

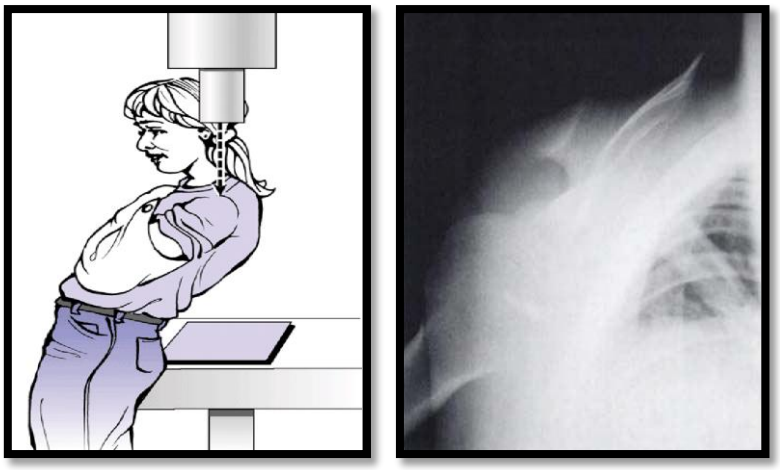


Fig.17.Velpeau view

A CT scan may be helpful when plain xrays fail to clearly show the fracture or if there is concern for concomitant glenoid or scapular injury. MRI studies are rarely needed and do not usually give the osseous detail of a CT scan.

The Hertel radiographic criteria[5] for perfusion of the humeral head can be used to predict ischemia (Fig 18). The metaphyseal extension of the humeral head of less than 8 mm and medial hinge disruption of more than 2 mm are predictive of ischemia. The combination of metaphyseal extension of the humeral head, medial hinge disruption of more than 2 mm, and an anatomical neck fracture pattern has a 97% positive predictive value for humeral head ischemia.[26,27]

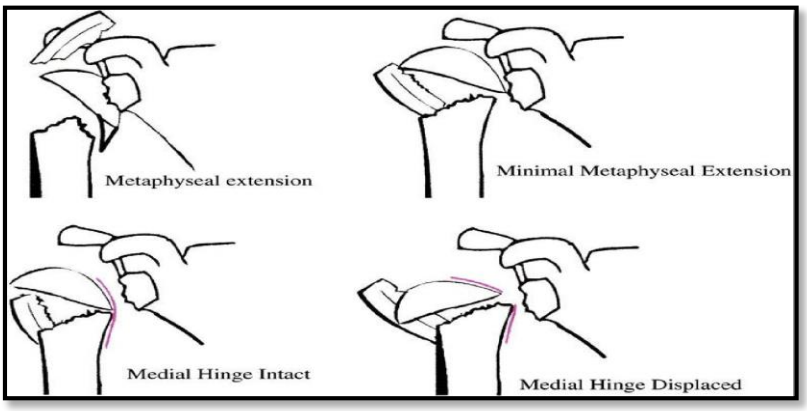


Fig.18.Hertel radiographic criteria, Predictors of humeral head ischemia after intracapsular fracture of the proximal humerus

Tingart et al.[68] suggested that cortical thickness of the humeral diaphysis to be a reliable and reproducible predictor of bone mineral density and the success of internal fixation. The combined cortical thickness (Fig 19) is the average of the medial and lateral cortical thickness at two levels.

Generally, a cortical thickness of less than 4 mm precludes internal fixation because adequate screw purchase cannot be obtained.[26,27,68]

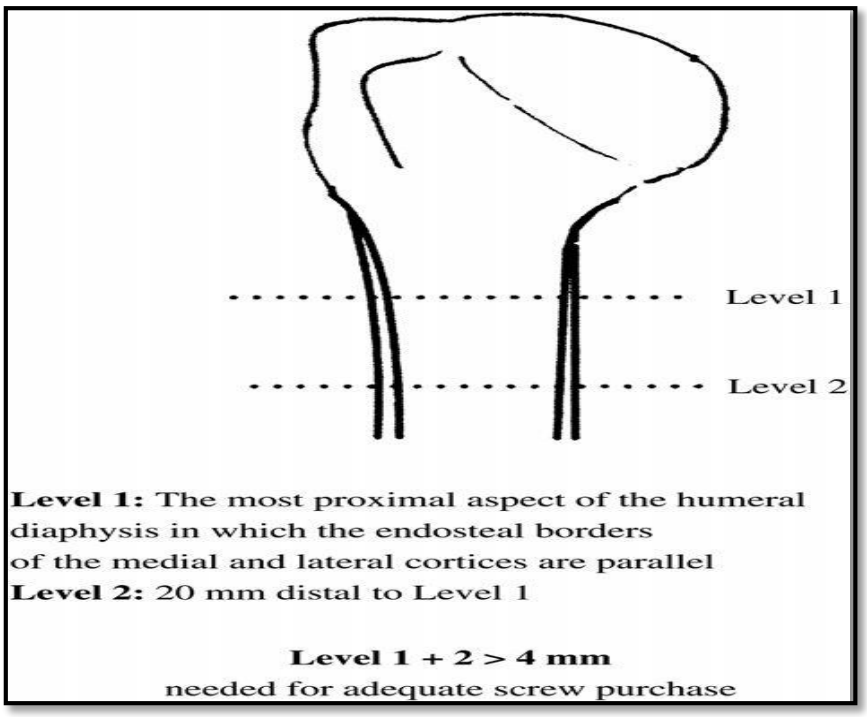


Fig.19. Combined cortical thickness

The cortical thickness of the proximal humerus diaphysis predicts bone mineral density of the proximal humerus.

MATERIAL AND METHODS

The study was conducted in our institute on a consecutive series of patients for the treatment of displaced (angulation of the articular surface of >45 degrees or displacement of more than 1 cm between the major fracture segments) 2-part, 3-part, and 4-part proximal humerus fractures (as defined by Neer's criteria) from April 2015 to September 2017 were enrolled in the study. Written and informed consent was obtained from all the patients.

The study was approved by the Ethical and Research Committee of Sumandeep vidyapeeth, Pipariya, Vadodara. After finding the suitability as per inclusion and exclusion criteria, patients were selected for the study and briefed about the nature of the study, the intervention if any to be carried out and written, informed consent was obtained. History was obtained through verbal communication, clinical examination both local and systemic was done.

Antero-posterior and axillary views of shoulder were obtained in all patients. 3-D CT reconstruction was used only in those patients in whom head splitting fracture is suspected. Fractures were classified according to Neer's classification into 2-part, 3-part, and 4-part. Once diagnosis was confirmed, patient was given shoulder immobilizer and analgesics.

Those patients who were selected for operative treatment underwent routine pre operative investigations

1) Complete Blood count
2) Serum creatinine
3) Blood grouping and cross matching
4) Bleeding time and clotting time
5) SGPT levels
6) RBS

7) HIV and HBsAg antibody detection and titres

8) Urine routine analysis

9) X-ray Chest PA view

After physician's cardio-respiratory assessment and anaesthetic fitness, patients were posted for planned operative procedure.

METHOD

Standard deltopectoral approach was used with the patient in the beech-chair position on a radiolucent table with access for image intensifier in a view to obtain intraoperative anteroposterior and axillary views. Fracture was reduced by manual traction and abduction to neutralize pull of the deltoid muscle. Incision was made starting from the coracoids process into the delto pectoral groove about 8 to 12 cm long. After making a plane between deltoid laterally and pectoralis major medially, the conjoint tendon was retracted medially.

The fractured tuberosities were identified and nonabsorbable suture were passed at the tendoosseous junction. The bicipital groove acts as good landmark for tuberosity position as well as plate placement. The greater tuberosity always lies lateral and slightly superior to bicipital groove, whereas the lesser tuberosity lies medial to it. After adequate soft tissue dissection, once reduction is achieved, it was temporarily fixed with 2 mm K wires. Then adequate sized PHILOS plate was placed onto the lateral surface. Ideally it should lie at least 5mm inferior to greater tuberosity and lateral to the bicipital groove.

Once plate was in position, screws were inserted accordingly with help of jig at different predetermined angles in locking fashion in head of humerus and cortical screws in shaft. Final reduction was confirmed and after thorough wash with Normal saline; closure was done in layers.

Postoperatively shoulder arm sling with immobilizer was applied and continued till fracture union.

The dressing was done on post op days 2^{nd}, 5^{th}, 9^{th} and stitches were removed by 12th post op day. As per bone quality and type of fixation, post operative rehabilitation was carried out. Pendulum exercises were begun usually on 3rd to 5th post op day along with passive forward elevation upto 90 degree. Later at 3 to 4 weeks, active assisted abduction and further forward elevation with external rotation with sticks was allowed. After radiological signs of union, usually at 10 to 12 weeks, full active and strengthening exercise were taught by trained physiotherapist.

All the Patients were called for follow up at 6 weeks, 3 months, 6 months and further yearly follow up with x-rays. At each visit, functional evaluation was done according to Constant-Murley scoring system.

INCLUSION CRITERIA

1. Proximal humerus fractures due to trauma (excluding pathologic fractures).
2. Patients greater than 18 years of age.
3. Closed two part fracture with a major displacement of the humeral diaphysis or three or four part fracture.
4. Patients with a minimum follow up period of 6 months.

EXCLUSION CRITERIA

1. Skeletally immature patients (fractures occurring in children less than 18 years).
2. Patients with open fractures
3. Pathological fractures,
4. Patients with distal neurovascular deficit
5. Patients with nonunions, malunions or delay in surgery (>10 days),
6. Displaced three or four part fractures with significant bone loss (as seen on CT scan) suggesting insufficient screw purchase and thus treated by humeral arthroplasty.
7. Concomitant ipsilateral fracture of distal humerus or elbow joint
8. Patients with head splitting fractures.

Functional assessment

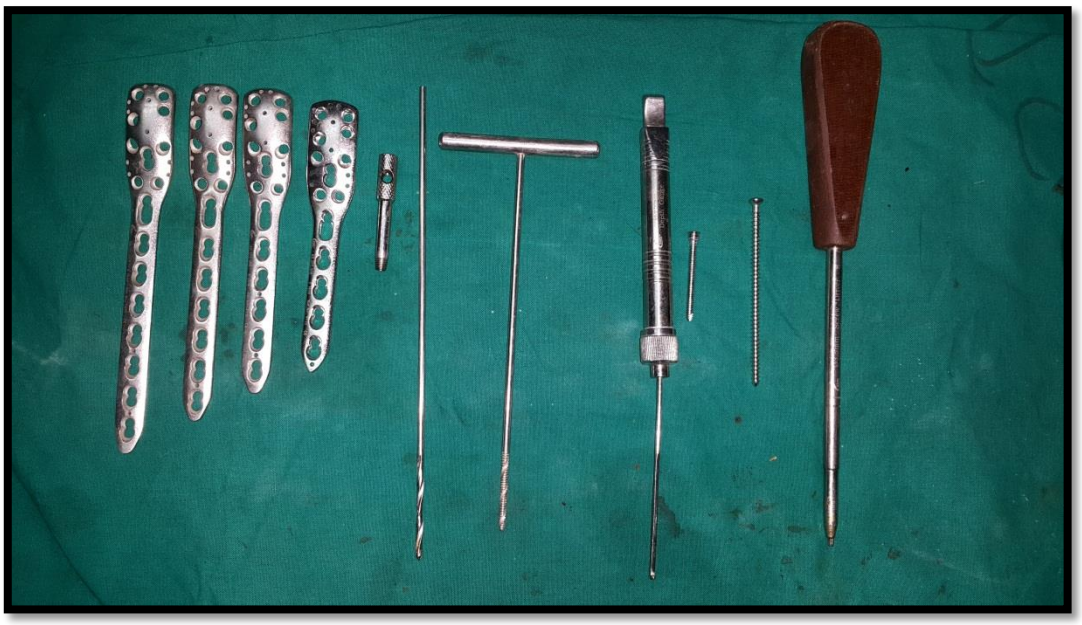
The functional assessment was done using **Constant and Murley scoring system** devised in 1985 and published in 1987. It has four basic parameters to be assessed.

1) Pain (15 points)
2) Activities of daily living (20 points)
3) Range of motion (40 points)
4) Power (25 points)

Total score is 100 for each shoulder.

Final evaluation was graded as follow:

Grade	Points range
Poor	0-55
Fair	56-70
Good	71-85
Excellent	86-100



PROXIMAL HUMURUS ANATOMICAL

LOCKING PLATES INSRUMENTS

OBSERVATIONS AND RESULTS

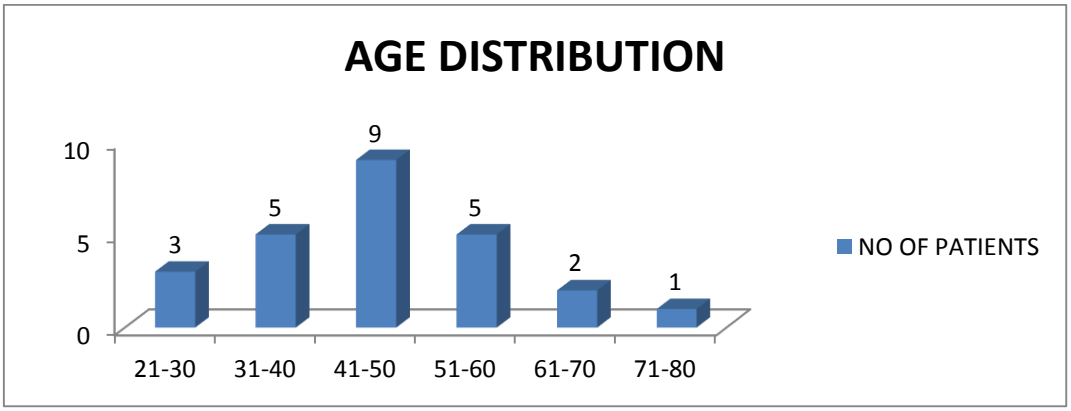
This study was carried out in Dhiraj Hospital, SBKS Medical Institute and Research Centre, from April 2015 to September 2017. The patients were followed up post-operatively at 6 weeks, 3 months and 6 months. The assessment of union, movements at shoulder, constant score and complications were done during each follow-up. There were total no of 25 patients out of whom 1 patient had bilateral fractures, so there were total 26 fractures.

Our Observations & Results are as follow:

TABLE.1. AGE DISTRIBUTION

AGE GROUP IN YEARS	NO. OF PATIENTS	PERCENTAGE (%)
21-30	3	12
31-40	5	20
41-50	9	36
51-60	5	20
61-70	2	8
71-80	1	4
TOTAL	25	100

CHART.1.AGE DISTRIBUTION



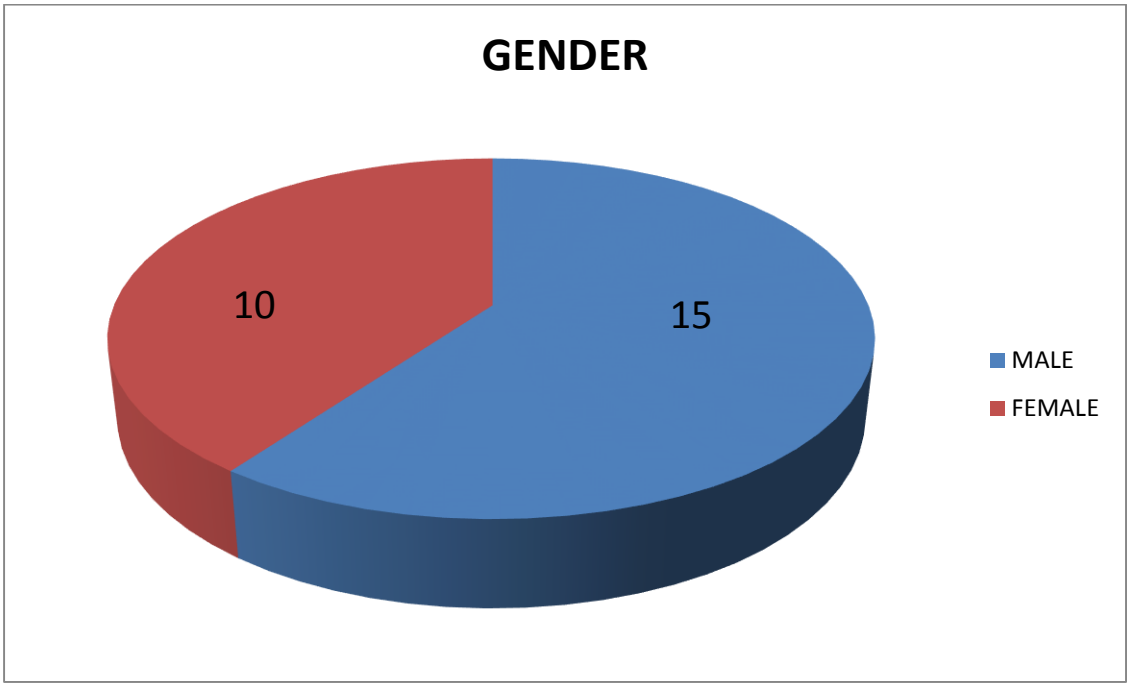
In age group of 21-30 years and above 60 years there were only 6 patients. However, majority of the patients were between 31-60 years. Mean age for male was 42 years & for female was 53.6 yearsThe mean age in our study was 46.64 years.

Most common age group in male was 41-50 years (46.67% of males), while in female most common age group was 51-60 years (30% of females).

TABLE.2.SEX DISTRIBUTION

SEX	NO OF PATIENTS	PERCENTAGE OF PATIENTS
MALE	15	60
FEMALE	10	40
TOTAL	25	100

CHART.2. SEX DISTRIBUTION

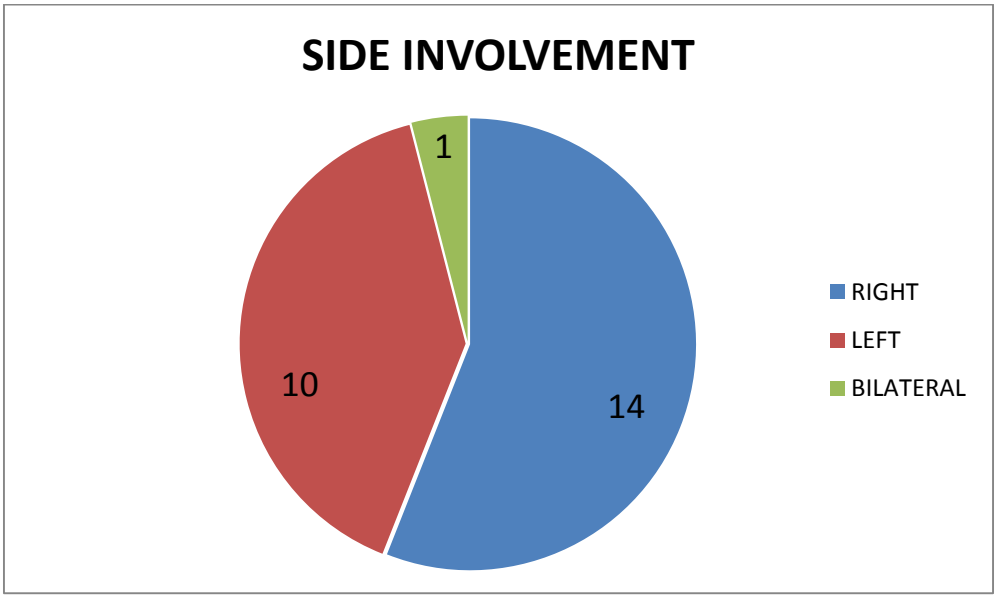


In the present study, 15(60%) patients were male while 10(40%) patients were female, with male and female ratio of 1.5:1.

TABLE.3.SIDE INVOLVEMENT

SIDE INVOLVED	NO OF PATIENTS	PERCENTAGE OF PATIENTS
RIGHT	14	56
LEFT	10	40
BILATERAL	1	4
TOTAL	25	100

CHART.3.SIDE INVOLVEMENT



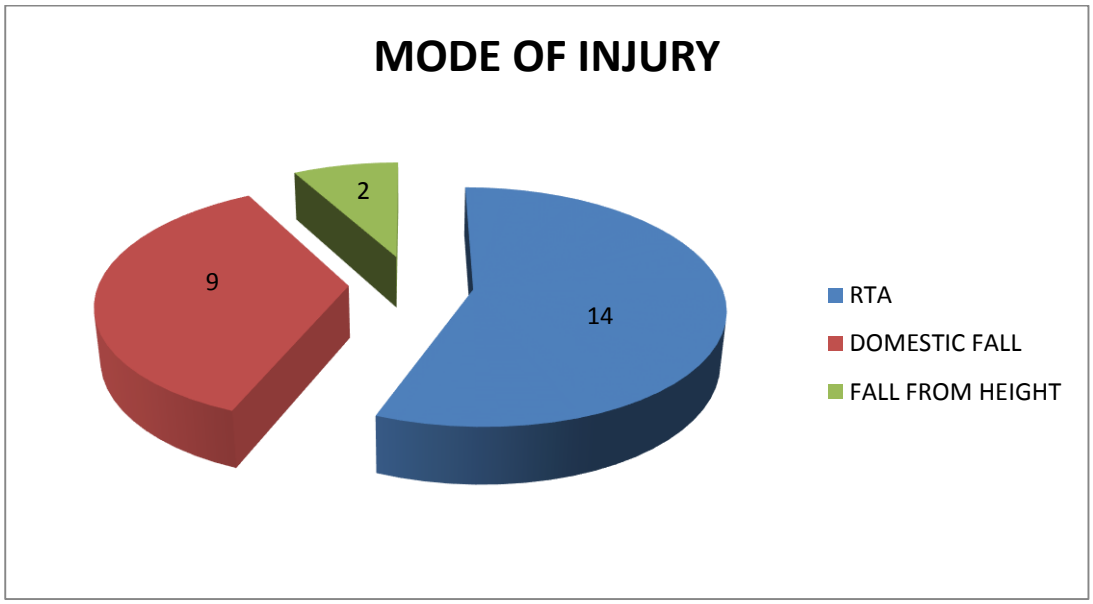
In the present study 14 (56%) patients had right proximal humerus fracture, while 10 (40%) patients had injured left side proximal humerus and there was bilateral involvement in 1 case (4%).

The lady who had bilateral fracture was having history of fall at home while walking, sustained bilateral fracture.

TABLE.4.1. MODE OF INJURY

MODE OF INJURY	NO OF PATIENTS	PERCENTAGE OF PATIENTS
RTA	14	56
DOMESTIC FALL	9	36
FALL FROM HEIGHT	2	8
TOTAL	25	100

CHART.4.1.MODE OF INJURY

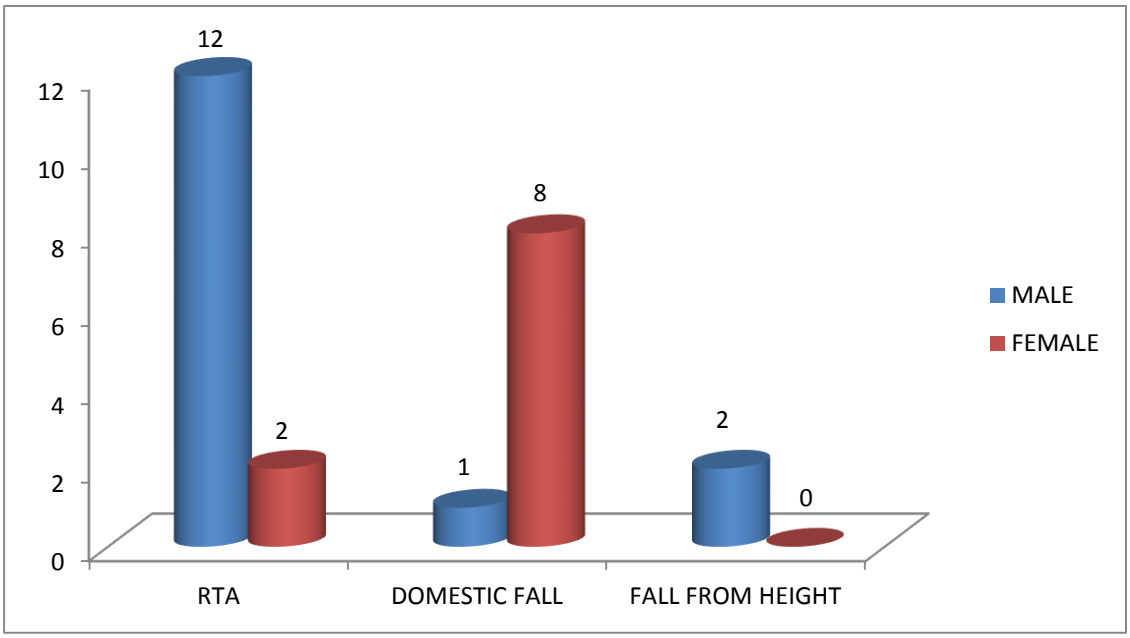


In the present study, 14(56%) patients had road traffic accident as mode of injury. 9(36%) patients were injured by domestic fall while 2(8%) patients had history of fall from height.

TABLE.4.2. MODE OF INJURY ACCORDING TO SEX

MODE OF INJURY	TOTAL NO OF PATIENTS	NO OF MALE PATIENTS	NO OF FEMALE PATIENTS
RTA	14	12	2
DOMESTIC FALL	9	1	8
FALL FROM HEIGHT	2	2	0
TOTAL	25	15	10

CHART.4.2. MODE OF INJURY ACCORDING TO SEX

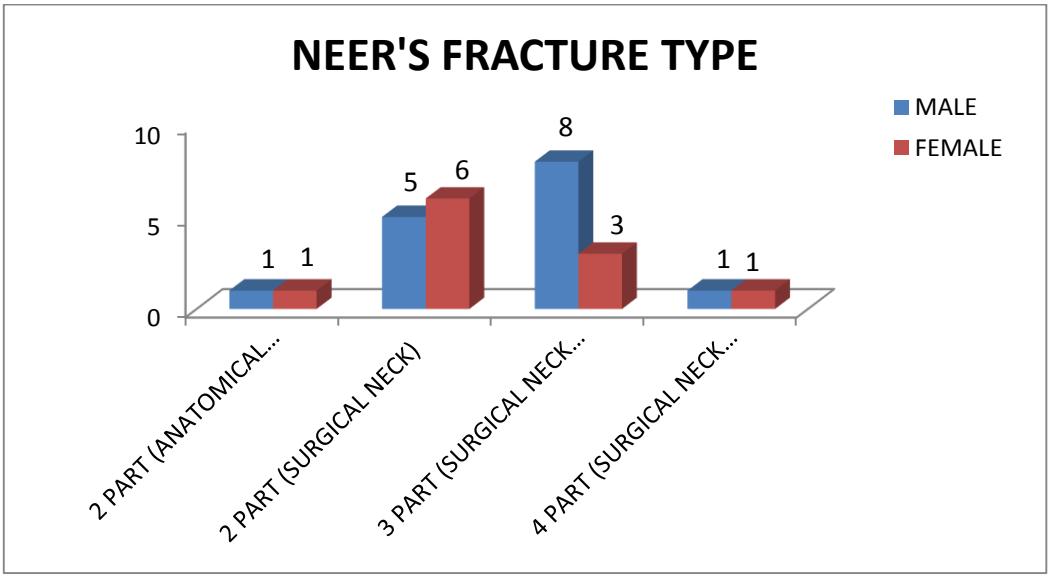


In male most common mode of trauma was RTA while in female domestic fall was more commonly observed. Mean age for RTA patient was 39.07 years, while for domestic fall was 58.22 years.

TABLE.5. NEER'S FRACTURE TYPE

NEER'S TYPE	NO OF CASES			PERCENTAGE OF PATIENTS	
	OVERALL	MALE	FEMALE	MALE	FEMALE
2 PART (ANATOMICAL NECK)	2	1	1	3.85	3.85
2 PART (SURGICAL NECK)	11	5	6	19.23	23.07
3 PART (SURGICAL NECK + GREATER TUBEROSITY)	11	8	3	30.77	11.53
4 PART (SURGICAL NECK + GREATER TUBEROSITY + LESSER TUBEROSITY)	2	1	1	3.85	3.85
TOTAL	26	15	11		

CHART.5. NEER'S FRACTURE TYPE

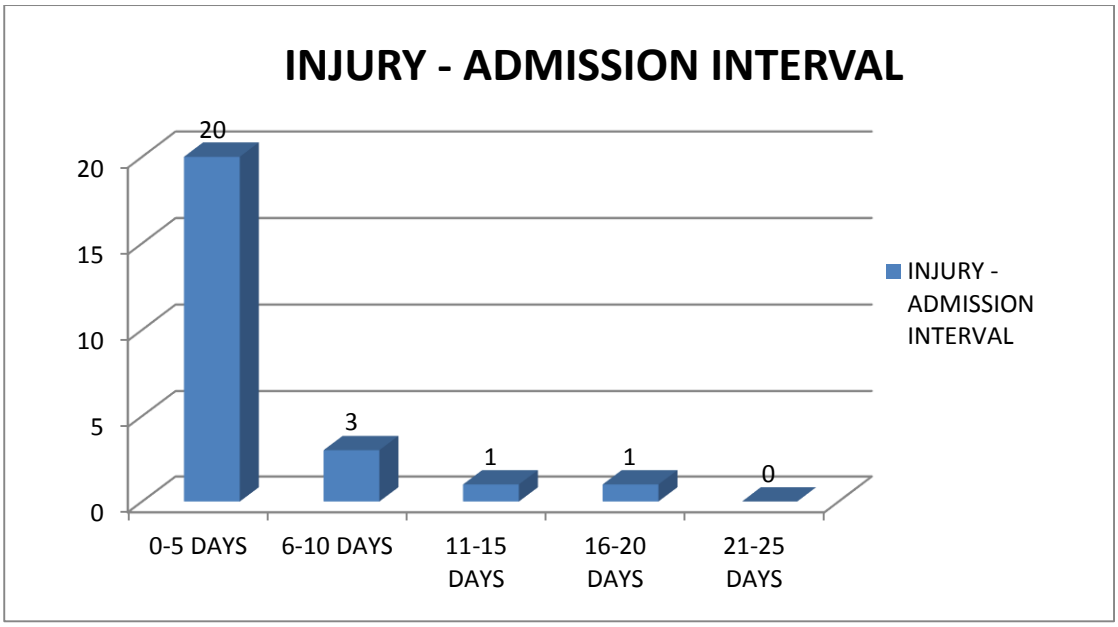


The most common type of fracture encountered in the present study were 2 part surgical neck fracture (11 patients, 42.3%) and 3 part fracture (Surgical Neck + Greater tuberosity) (11 patients, 42.3%) with equal incidence. 2 (7.7%)patients had 2 part Anatomical Neck fracture, while 2 (7.7%) patients had 4 part fracture(Surgical Neck + Greater tuberosity + Lesser tuberosity).

TABLE.6.INJURY ADMISSION INTERVAL

IN DAYS	NO. OF PATIENTS	PERCENTAGE
0-5	20	80
6-10	3	12
11-15	1	4
16-20	1	4
21-25	0	0
TOTAL	25	100

CHART.6. INJURY ADMISSION INTERVAL

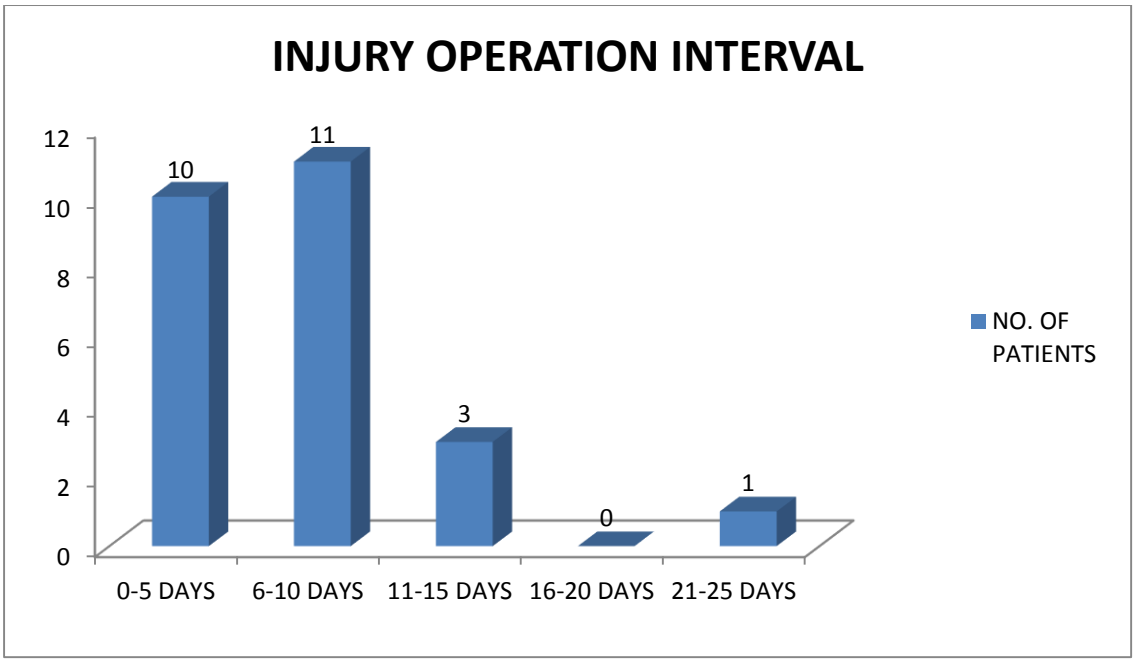


Most of the patients were presented within 5 days of injury with an average injury admission interval of 3.72 days.

TABLE.7. INJURY OPERATION INTREVAL

IN DAYS	NO. OF PATIENTS	PERCENTAGE
0-5	10	40
6-10	11	44
11-15	3	12
16-20	0	0
21-25	1	4
TOTAL	25	100

CHART.7. INJURY OPERATION INTREVAL

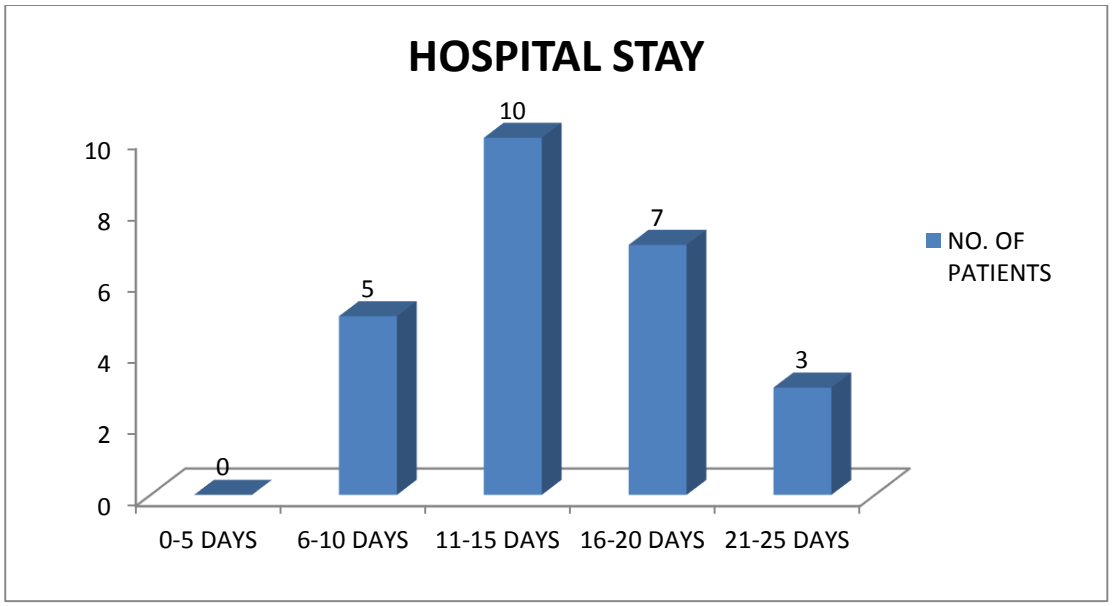


Most of the patients were operated within 10 days of injury with an average injury operation interval of 6.96 days.

TABLE.8. AVERAGE HOSPITAL STAY

HOSPITAL STAY IN DAYS	NO. OF PATIENTS	PERCENTAGE
0-5	0	0
6-10	5	20
11-15	10	40
16-20	7	28
21-25	3	12
TOTAL	25	100

CHART.8. AVERAGE HOSPITAL STAY

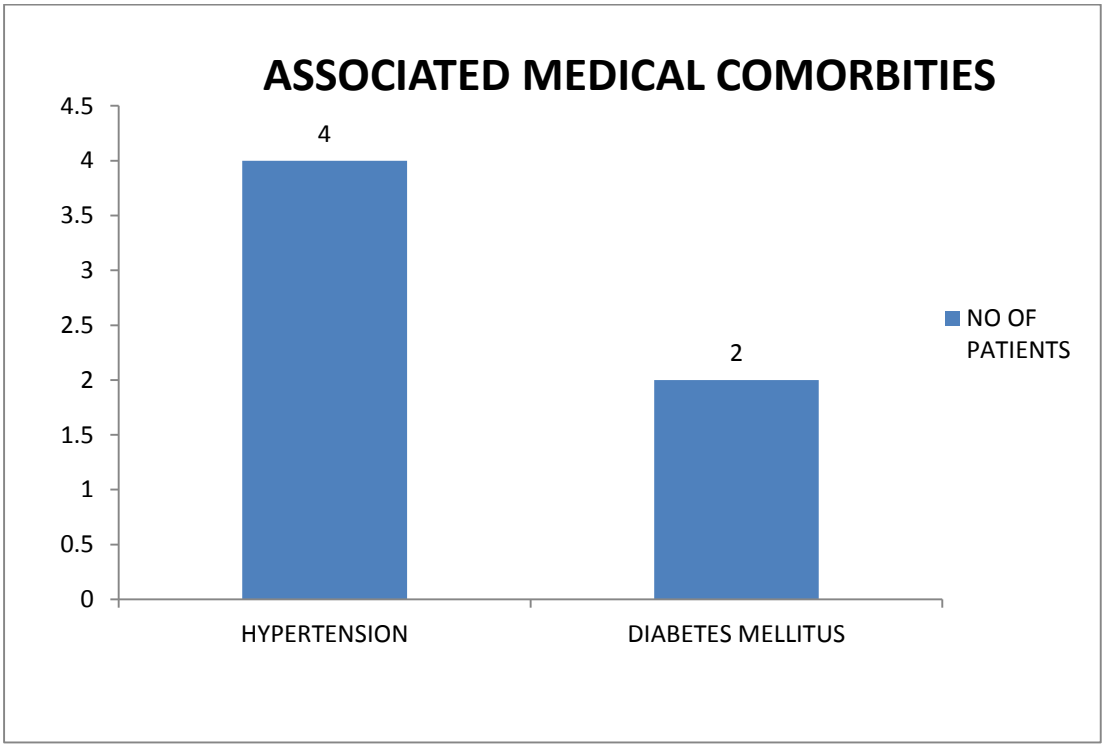


In our study, most of patients were hospitalised up to period of 15 days with an average hospital stay of 14.6 days.

TABLE.9. ASSOCIATED MEDCAL COMORBIDITIES

COMORBIDITIES	NO OF PATIENTS	PERCENTAGE
HYPERTENSION	4	16
DIABETES MELLITUS	2	8

CHART.10. ASSOCIATED COMORBIDITIES

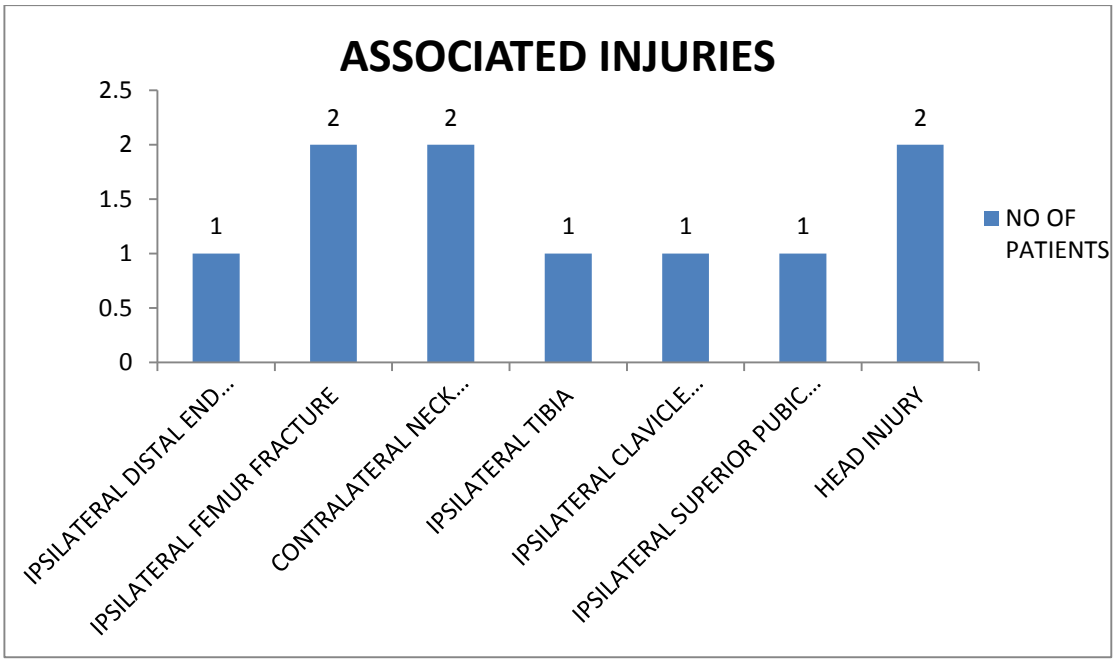


Hypertension and Diabetes Mellitus were most commonly associated medical comorbities.

TABLE.10. ASSOCIATED INJURIES

INJURY	NO OF PATIENTS	MODE OF TRAUMA		
		RTA	DOMESTIC FALL	FALL FROM HEIGHT
IPSILATERAL DISTAL END RADIUS FRACTURE	1		1	
IPSILATERAL FEMUR FRACTURE	2	2		
CONTRALATERAL NECK OFFEMUR	2	1		1
IPSILATERAL TIBIA	1	1		
IPSILATERAL CLAVICLE FRACTURE	1		1	
IPSILATERAL SUPERIOR PUBIC RAMI FRACTURE	1	1		
HEAD INJURY	2	2		
TOTAL	10	7	2	1

CHART.10. ASSOCIATED INJURIES

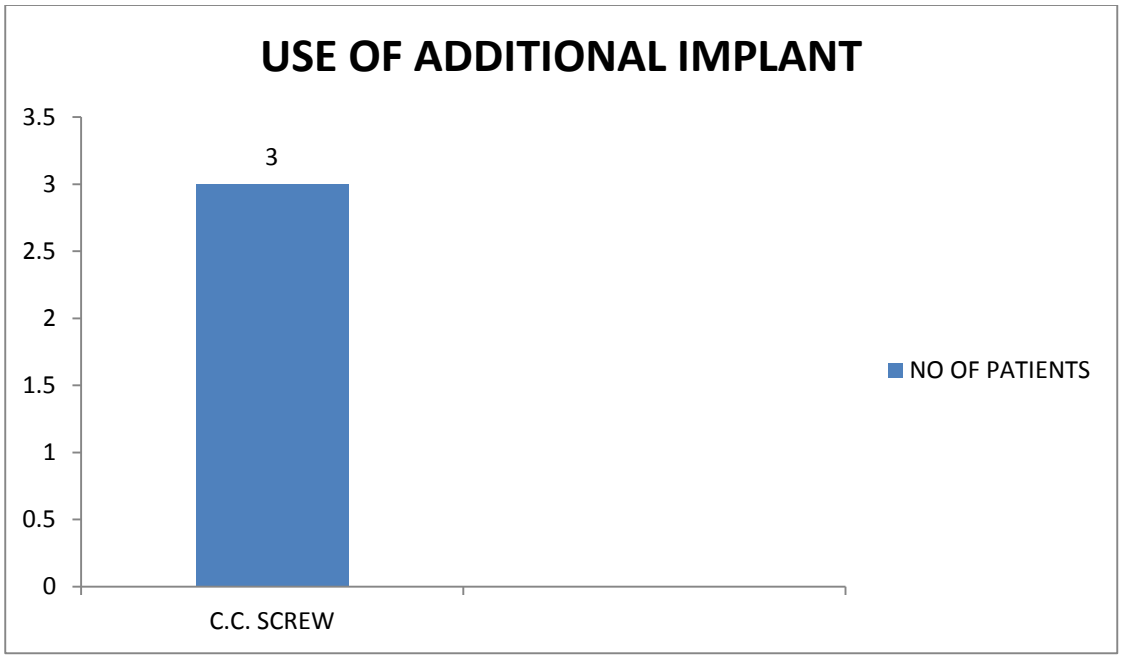


In case of RTA associated injuries were lower limb injuries and head injuries, while in case of domestic fall lower end radius and clavicle fracture were commonly associated injuries.

TABLE.13. ADDITIONAL FIXATION OF GREATER TUBEROSITY REQUIRED

ADDITIONAL IMPLANT	NO OF PATIENTS
C.C. SCREW	3
OTHERS	0

CHART.13. ADDITIONAL FIXATION OF GREATER TUBEROSITY REQUIRED

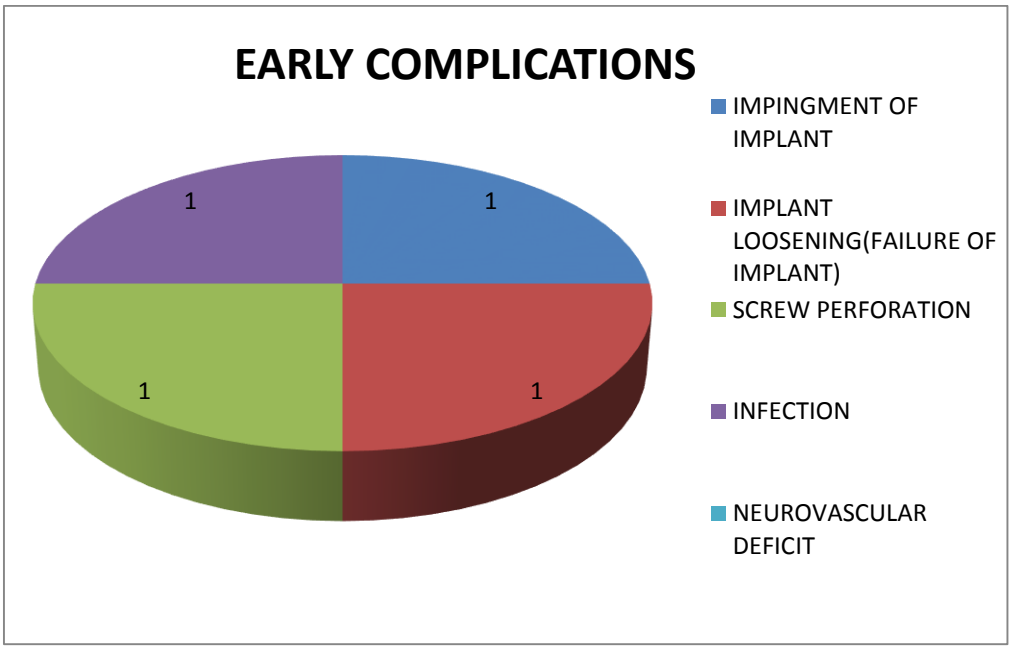


Addition 4 mm c.c. screws were used in three patients for fixation of Greater tuberosity fracture in type 3 fractures.

TABLE.11. EARLY COMPLICATIONS

COMPLICATIONS	NO OF FRACTURES	PERCENTAGE
IMPINGMENT OF IMPLANT	1	3.85
IMPLANT LOOSENING(FAILURE OF IMPLANT)	1	3.85
SCREW PERFORATION	1	3.85
INFECTION	1	3.85
NEUROVASCULAR DEFICIT	0	-
TOTAL	4	15.4

CHART.11. EARLY COMPLICATIONS

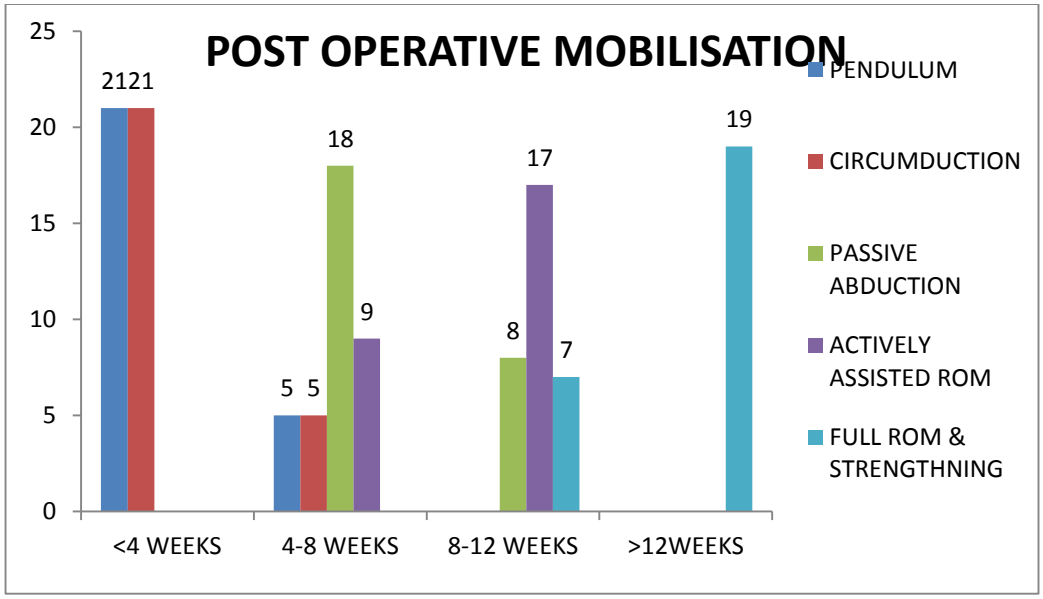


In our study, 1 (3.85%) patient had infection, 1 (3.85%) patients had impingement of implant, one patient (3.85%) had implant loosening(failure of implant) and one (3.85%) had screw perforation into head. There was no incidence of neurovascular deficit.

TABLE.14. POST OPERATIVE MOBILISATION

DURATION	EXERCISES				
	PENDULUM	CIRCUMDUCTION	PASSIVE ABDUCTION	ACTIVELY ASSISTED ROM	FULL ROM & STRENGTHNING
<4 WEEKS	21	21			
4-8 WEEKS	5	5	18	9	
8-12 WEEKS			8	17	7
>12WEEKS					19

CHART.14.POST OPERATIVE MOBILISATION

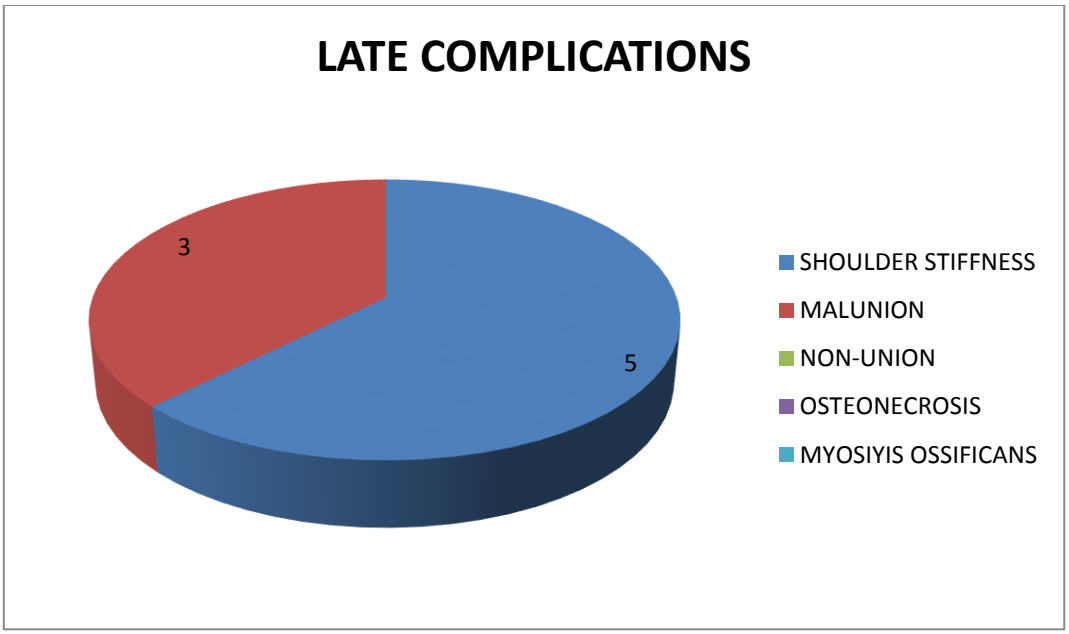


Elbow and wrist range of movements were startedin all the patients within 7 days of surgery. Pendulum and circumduction exercises were started at0-4 weeks while passive abduction exercises were started at 4-8 weeks.Assisted ROM was started at 8-12 weeks, while full range of movements and strengthening exercises were allowed only after 12 weeks in most of the cases.

TABLE.11. LATE COMPLICATIONS

COMPLICATIONS	NO OF FRACTURES	PERCENTAGE
SHOULDER STIFFNESS	5	19.23
MALUNION	3	11.53
NON-UNION	0	-
OSTEONECROSIS	0	-
MYOSIYIS OSSIFICANS	0	-
TOTAL	8	30.6

CHART.11. LATE COMPLICATIONS

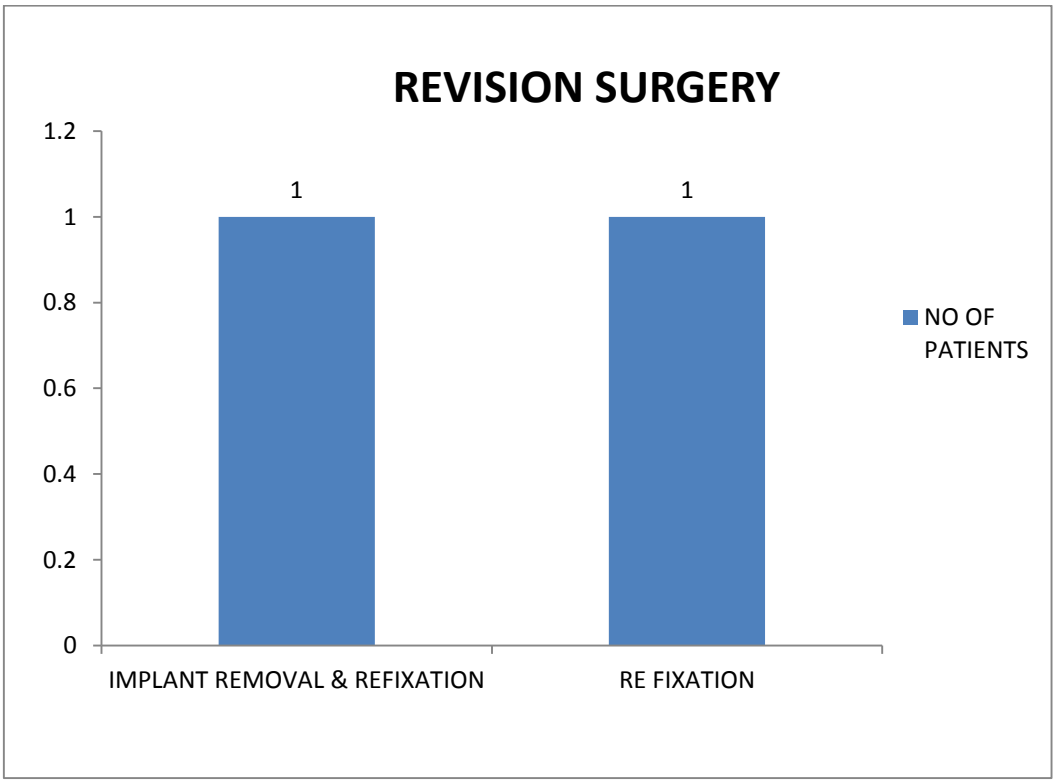


During the follow up period 5 patients had shoulder stiffness (19.23%), 3(11.54%) patients had malunion, There were no incidences of non-union, osteonecrosis of the proximal humerus, myositis ossificans.

TABLE.12. REVISION SURGERY REQUIRED

REVISION SURGERY	NO OF PATIENTS
IMPLANT REMOVAL	1
RE FIXATION OF PLATE & RUSH PIN	1

CHART.12.REVISION SURGERY REQUIRED

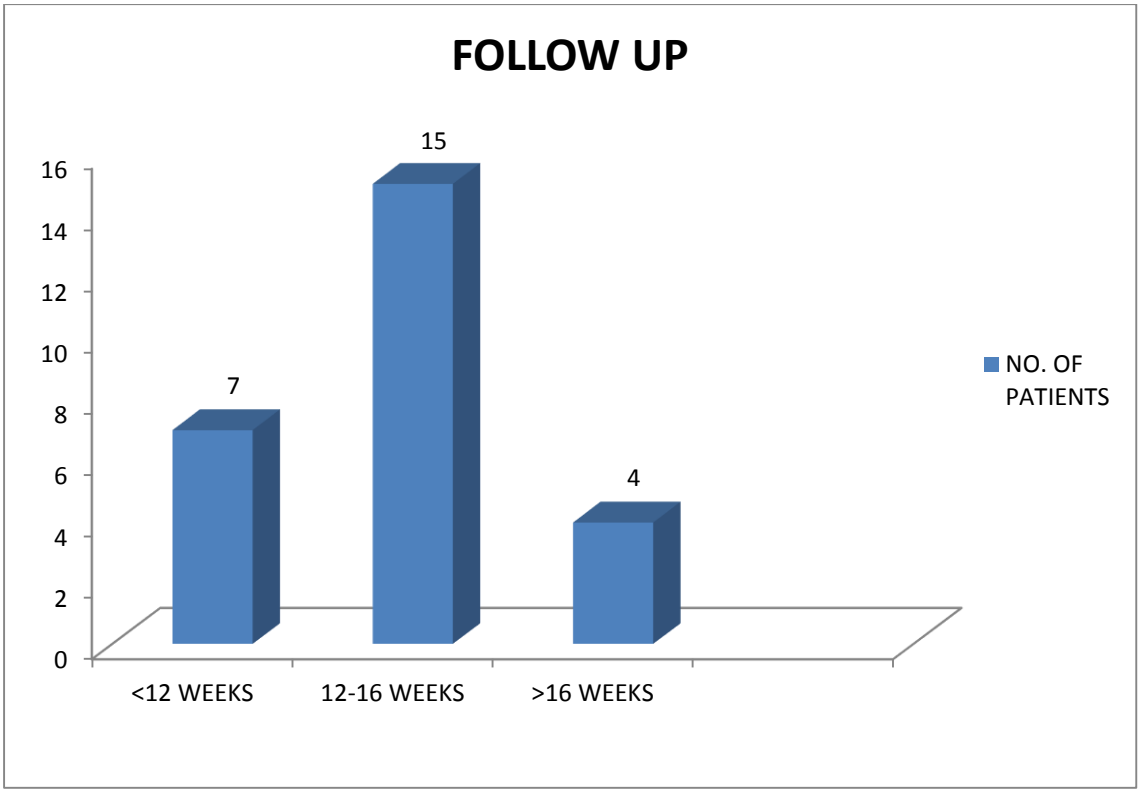


Revision surgery was required in two patients. In 1 patient there was implant failure, so implant removal and re fixation with intramedullary rush pin and tension band wiring was done. While in other patient loosening of implant was treated by refixation of plate and additional insertion of intramedullary rush pin.

TABLE.16. FOLLOW UP IN MONTHS

FOLLOW UP	NO. OF PATIENTS	PERCENTAGE
6-10 MONTHS	11	44
11-15 MONTHS	12	36
>15 MONTHS	2	8
TOTAL	25	100

CHART.16. FOLLOW UP IN MONTHS

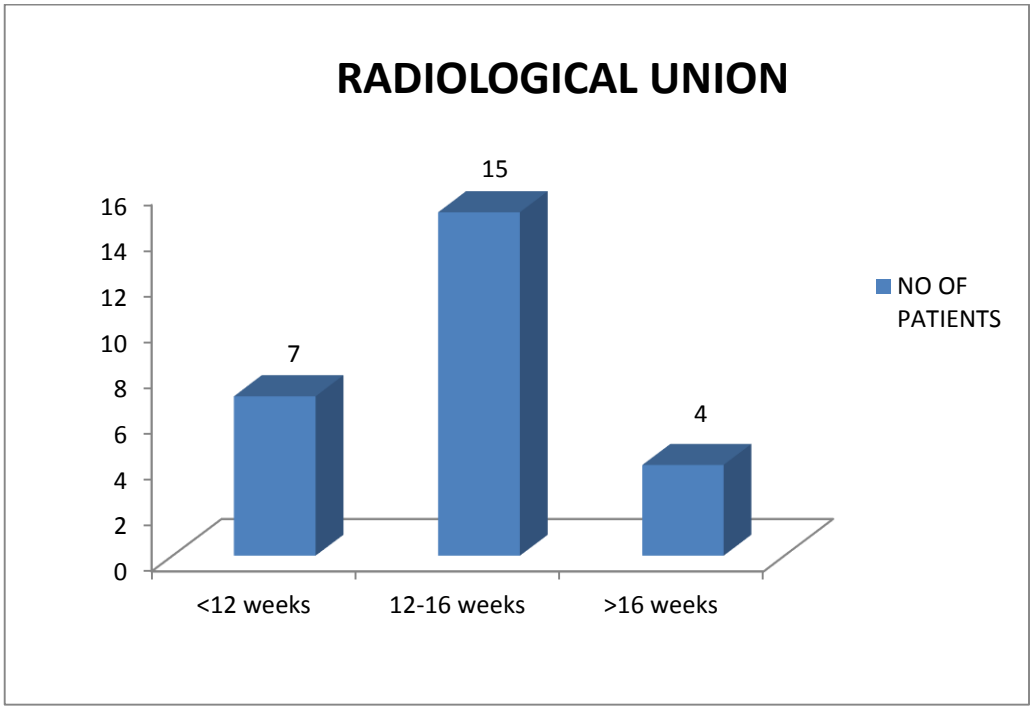


The minimum follow up was of 6 months and maximum of 17 months with the mean duration of 10.6 months.

TABLE.15. RADIOLOGICAL UINION

RADIOLOGICAL UNION	NO OF PATIENTS	PERCENTAGE OF PATIENTS
<12 WEEKS	7	26.93
12-16 WEEKS	15	57.69
>16 WEEKS	4	15.38
TOTAL	26	100

CHART.15.1 .RADIOLOGICAL UINION

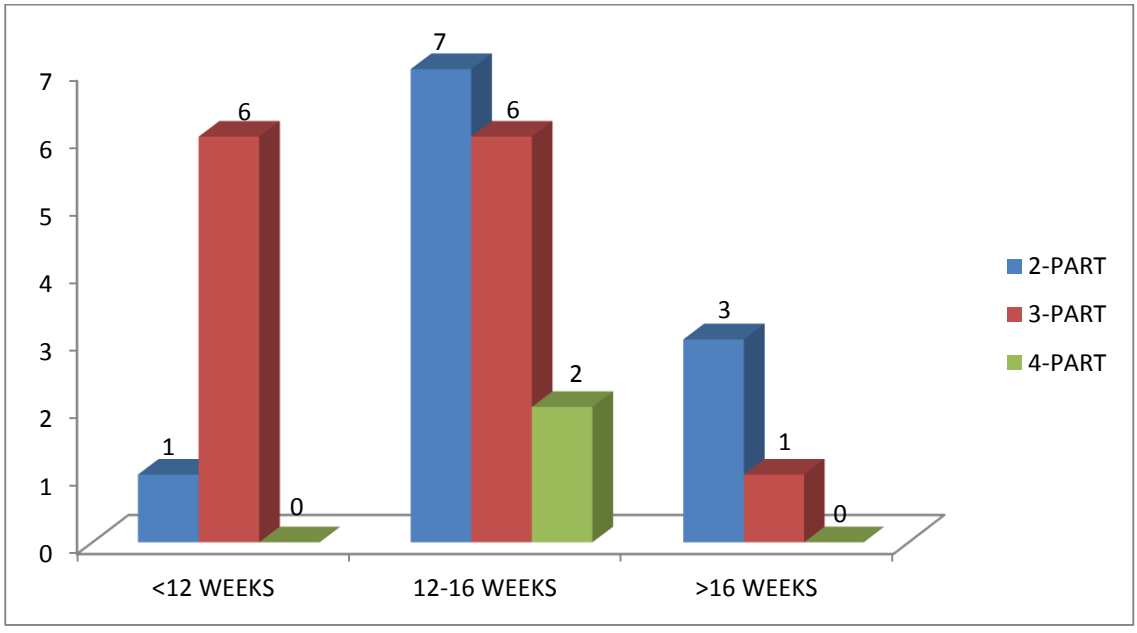


Most of the fractures were united by 12-14 weeks post operatively. The mean time for union was 13.69 weeks.

TABLE.15.2. RADIOLOGICAL UINION ACCORDING TO FRACTURE TYPES

RADIOLOGICAL UNION	NEER'S FRACTURE TYPE		
	2-PART	3-PART	4-PART
<12 WEEKS	1	6	0
12-16 WEEKS	7	6	2
>16 WEEKS	3	1	0
TOTAL	11	13	2

CHART.15.2 .RADIOLOGICAL UINION ACCORDING TO FRACTURE TYPES



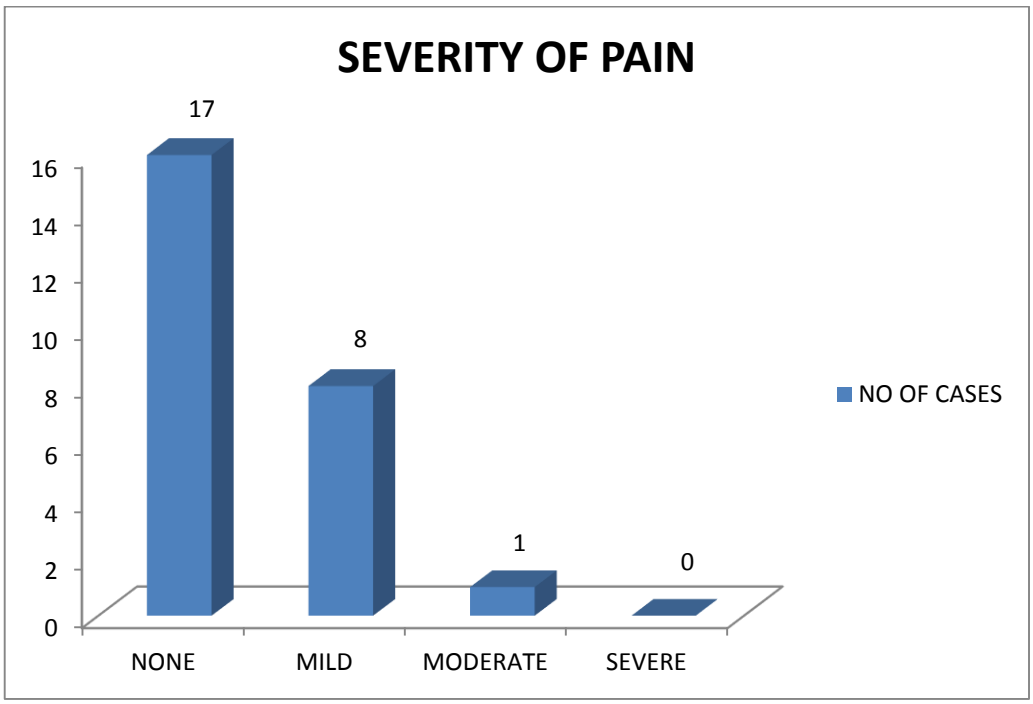
The average union time for two part fracture was 13.54 weeks, three part fracture was12.36 weeks and 14 weeks for four part fractures with overall average union time of 13.07 weeks.

FOLLOW -UP EVALUATION ACCORDING TO CONSTANT AND MURLEY SCORING SYSTEM

TABLE.17.1 .EVALUTION OF PAIN

PAIN	NO. OF CASES	PERCENTAGE (%)
NONE	17	65.38
MILD	8	30.77
MODERATE	1	3.85
SEVERE	0	0
TOTAL	26	100

CHART.17.2 .EVALUTION OF PAIN

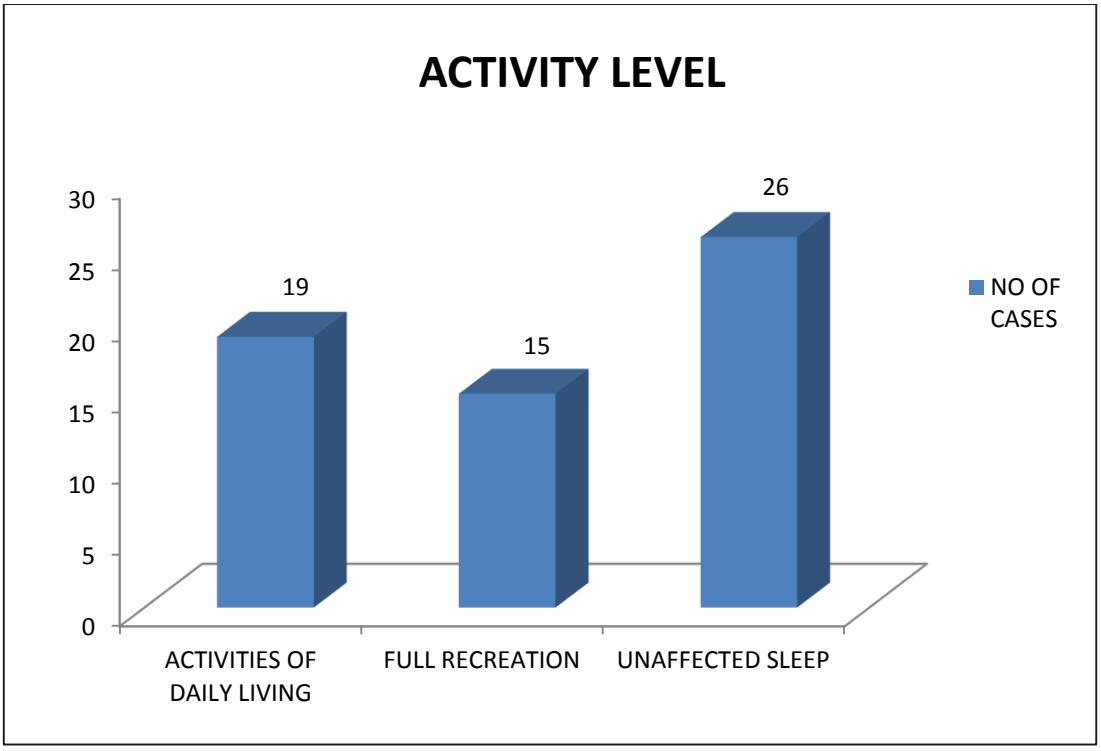


In most of the patients (65%) pain was relieved by the end of 1 month, while some patient (35%) had mild to moderate pain.

TABLE.17.2 .EVALUTION OF ACTIVITY LEVEL

ACTIVITY LEVEL	ACTIVITIES OF DAILY LIVING	FULL RECREATION/ SPORT ACTIVITY	UNAFFECTED SLEEP
NO OF CASES	19	15	26
PERCENTAGE	73.07	57.69	100

CHART.17.2. EVALUTION OF ACTIVITY LEVEL

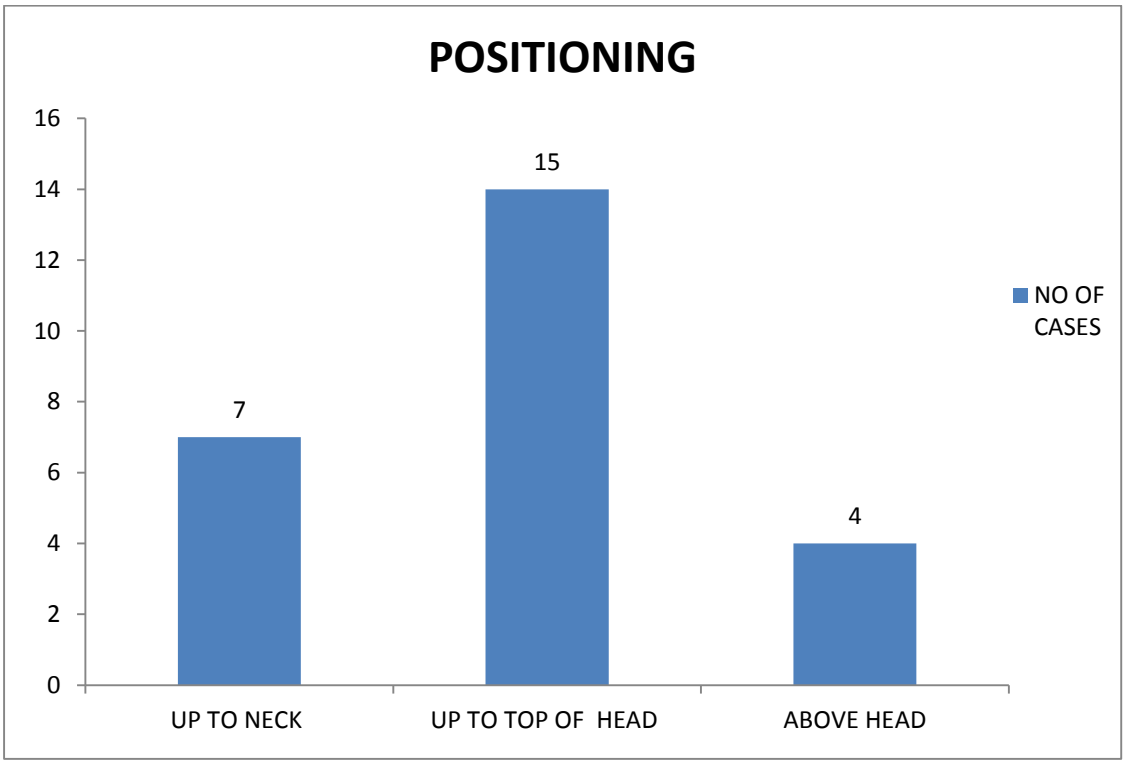


In our study, 19 (73.07%) cases were able to perform their daily work, but Full recreation was possible in only 15 (57.69%) fractures. Sleep was unaffected in all the cases.

TABLE.17.3. EVALUTION OF POSITIONING

LEVEL	UP TO NECK	UP TO TOP OF HEAD	ABOVE HEAD
NO. OF CASES	7	15	4
PERCENTAGE	26.92	57.69	15.39

CHART.17.3. EVALUTION OF POSITIONING



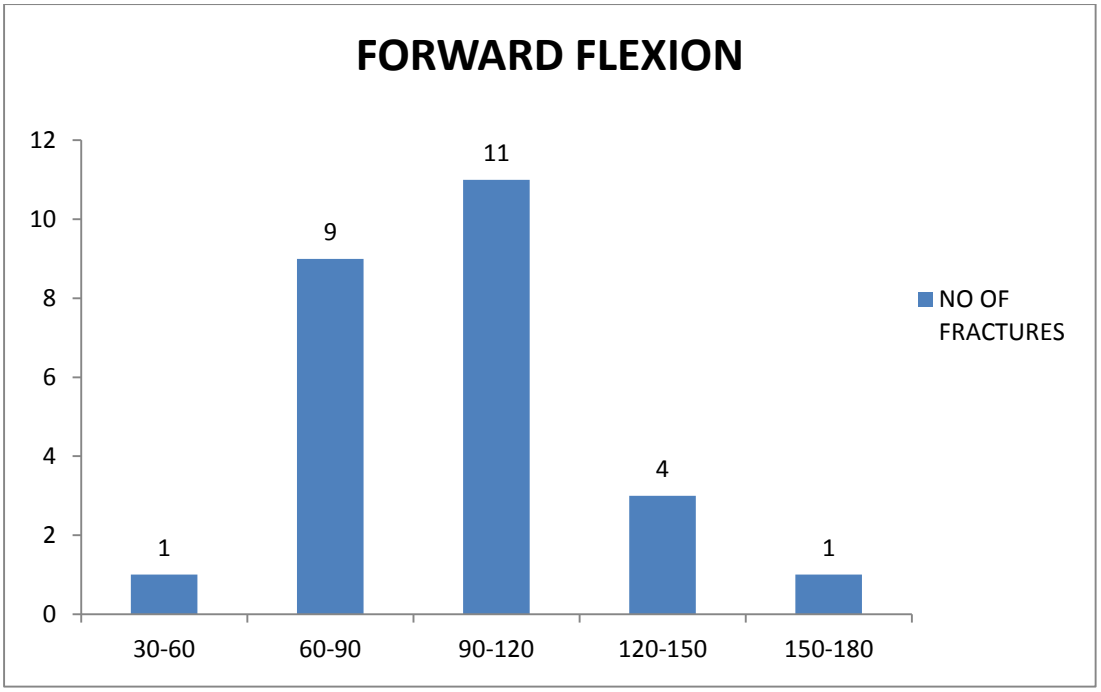
Most of the patients were able to position the hand up to top of the head. Above head movement was possible in 4 cases.

EVALUTION OF ROM

TABLE.17.4-A. EVALUTION OF FORWARD ELEVATION

IN DEGREE	NO OF CASES	PERCENTAGE
30-60	1	3.85
60-90	9	35.61
90-120	11	42.31
120-150	4	15.38
150-180	1	3.85
TOTAL	26	100

CHART.17.4-A. EVALUTION OF FORWARD ELEVATION

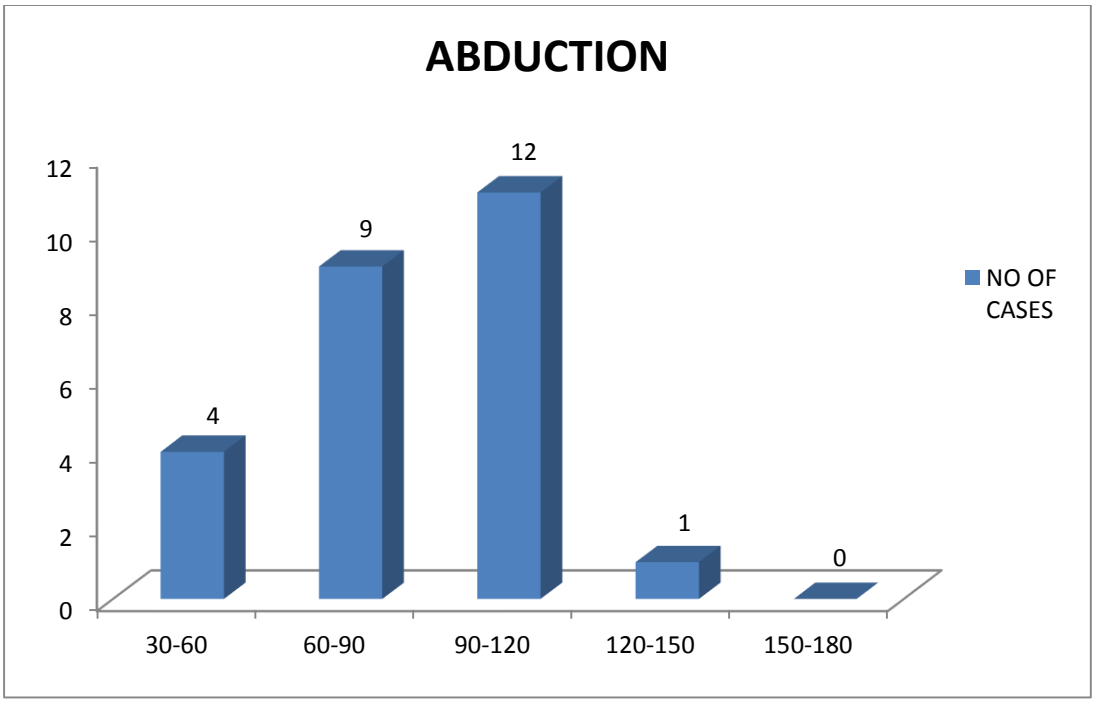


In present study, 9 cases (34.61%) were able to elevate shoulder up to 90 degree while 11 cases (42.31%) were able to elevate shoulder up to 120 degree.

TABLE.17.4-B. EVALUTION OF ABDUCTION

IN DEGREE	NO OF CASES	PERCENTAGE
30-60	4	15.38
60-90	9	34.62
90-120	12	46.15
120-150	1	3.85
150-180	0	0
TOTAL	26	100

CHART.17.4-B. EVALUTION OF ABDUCTION

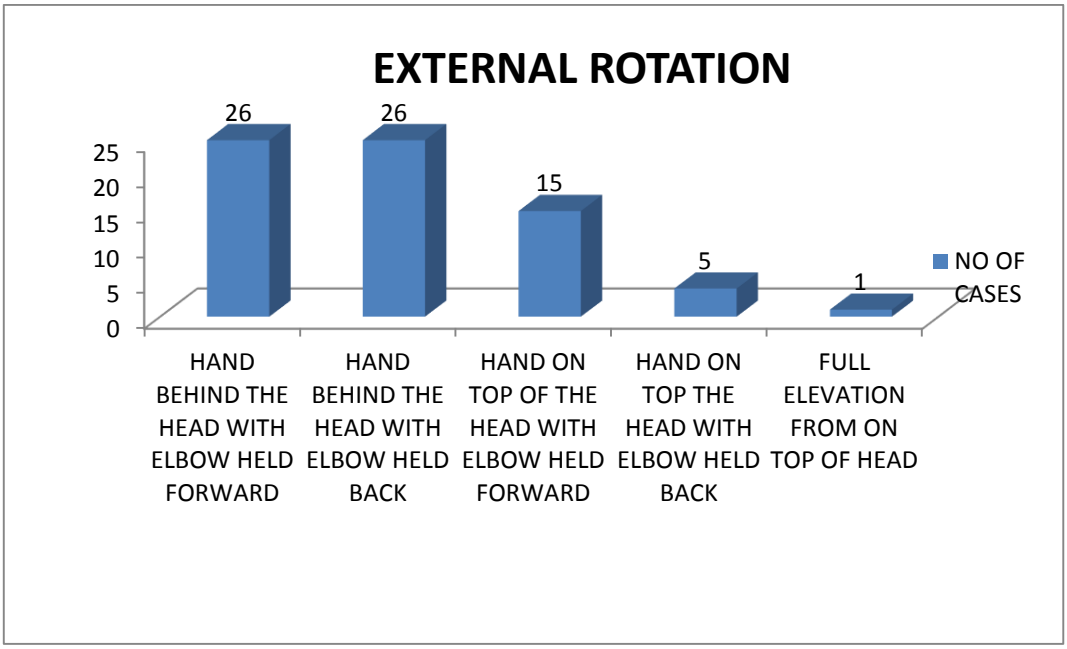


In present study, 13 cases (50%) were able to abduct shoulder more than 90 degree while 9 cases (34.62%) were able to abduct shoulder up to 60-90 degree and 4 cases (15.38%) were able to abduct the shoulder less than 60 degree.

TABLE.17.4-C. EVALUTION OF EXTERNAL ROTATION

Movements	Hand behind the head with elbow held forward	Hand behind the head with elbow held back	Hand on top of the head with elbow held forward	Hand on top the head with elbow held back	Full elevation from on top of head
NO. OF CASES	26	26	15	5	1
PERCENTAGE	100	100	57.69	19.23	3.85

CHART.17.4-C. EVALUTION OF EXTERNAL ROTATION

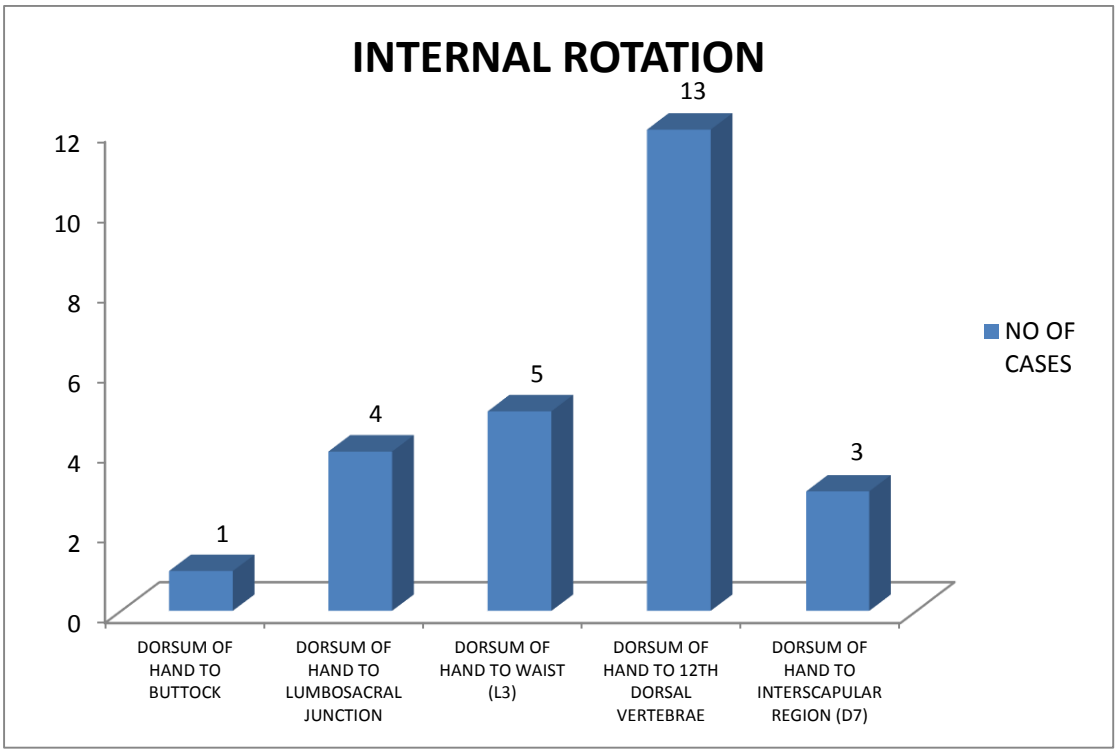


In our study almost all the cases were able to place the hand behind the head with elbow held forward and elbow held back. 15 cases (57.69%) were able to place the hand on the top of the head with elbow held forward while 5 cases (19.23%) were able to place the hand on top of the head with elbow held back.

TABLE.17.4-D. EVALUTION OF INTERNAL ROTATION

Movements	Dorsum of hand to lateral thigh	Dorsum of hand to buttock	Dorsum of hand to lumbosacral junction	Dorsum of hand to waist (l3)	Dorsum of hand to 12th dorsal vertebrae	Dorsum of hand to interscaoular region (d7)
NO. OF CASES	0	1	4	5	13	3
PERCENTAGE	0	3.85	15.38	19.23	50	11.54

CHART.17.4-D. EVALUTION OF INTERNAL ROTATION



In our study almost 13 cases (50%) were able to place the dorsum of the hand up to 12th dorsal vertebrae, while 3 cases (11.54%) were able to place the dorsum of hand up to interscapular region.

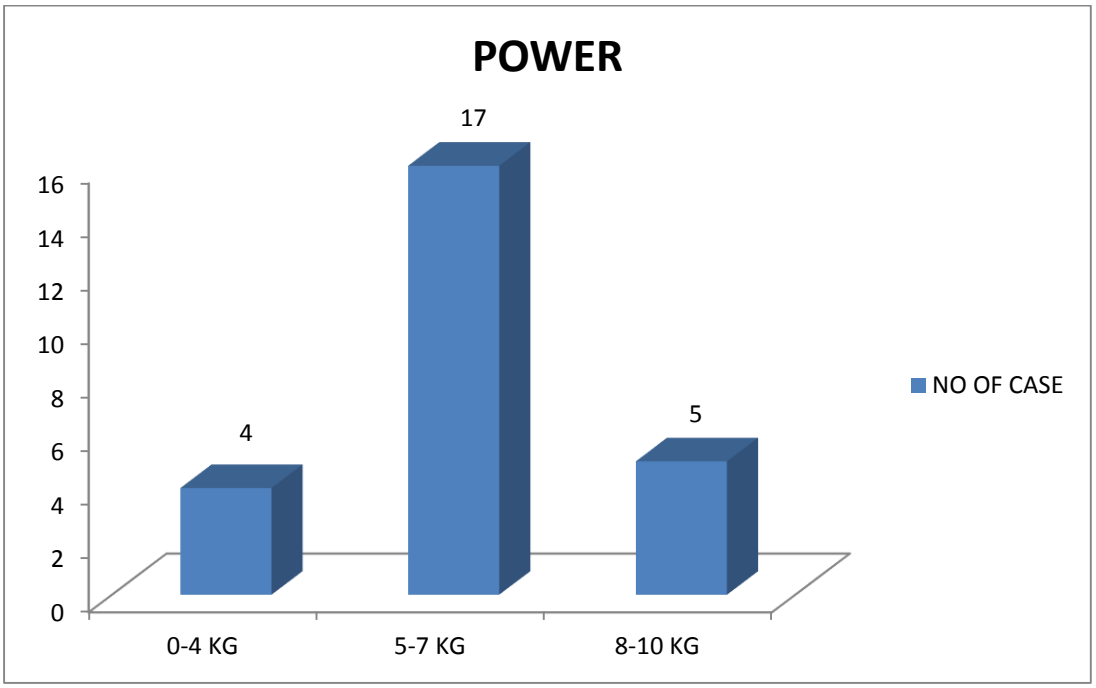
POWER

The assessment of power was done by using weights in increasing order and the number kilograms of pull the patient could resist at 90 degree of abduction or maximum abduction patient could achieve for minimum of 3 seconds and scored accordingly.

TABLE.17.5. EVALUTION OF POWER

WEIGHT	0-4 KG	5-7 KG	8-10 KG
NO. OF CASES	4	17	5
PERCENTAGE	15.38	65.38	19.24

CHART.17.5. EVALUTION OF POWER



In present study 17 cases (65.38%) were able to lift up to 5-7 kg weight while 5 cases (19.24%) were able to lift up to 8-10 kg weight.

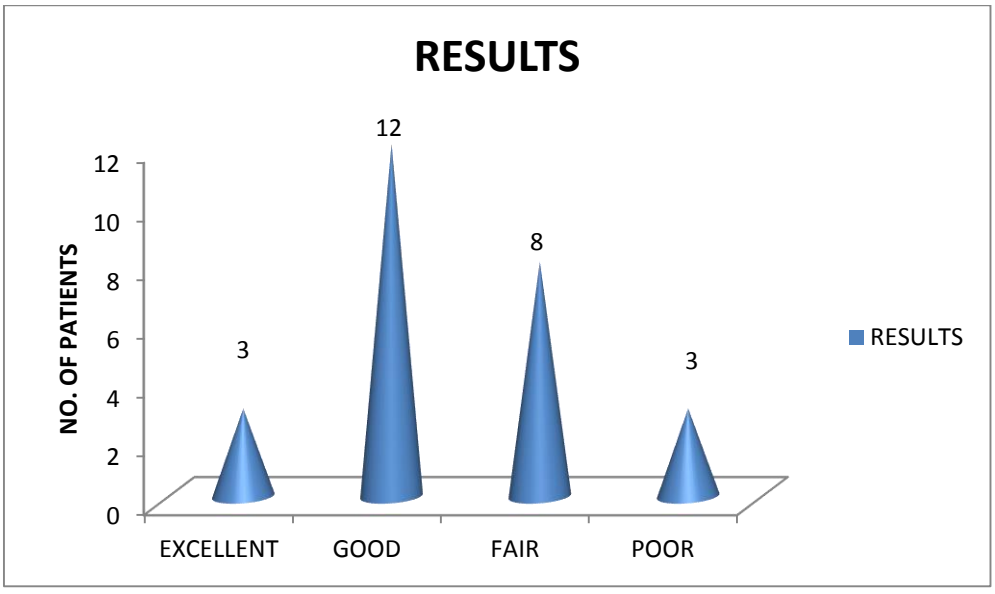
RESULTS

As per the final outcome decided by the **Constant Murley score**, the functional outcome of all the treated patients were graded into excellent (score 86 - 100), good (score 71-85),fair (score 56-70) and poor (0-55).

TABLE.19. FINAL RESULTS

RESULTS	NO. OF CASES	PERCENTAGE
EXCELLENT	3	11.54
GOOD	12	46.15
FAIR	8	30.77
POOR	3	11.54
TOTAL	26	100

CHART.19. FINAL RESULTS

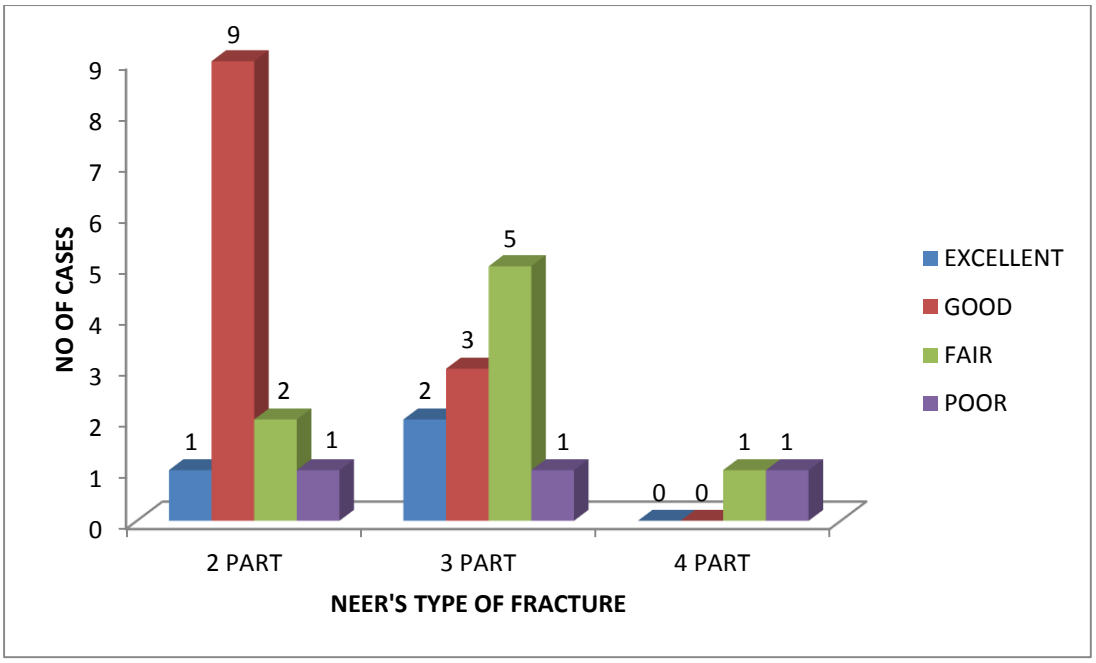


Out of 25 patients (26 shoulders) 3 (11.54%) had excellent outcome, 12 (46.15%) cases had good outcome, 8 (30.77%) cases had fair outcome and 3 (10%) cases had poor outcome.

TABLE.20. RESULTS ACCORDING TO TYPE OF FRACTURES

TYPE OF FRACTURE	RESULT			
	EXCELLENT	GOOD	FAIR	POOR
2 PART	1	9	2	1
3 PART	2	3	5	1
4 PART	0	0	1	1
TOTAL	3	12	8	3

CHART.20.RESULTS ACCORDING TO TYPE OF FRACTURES

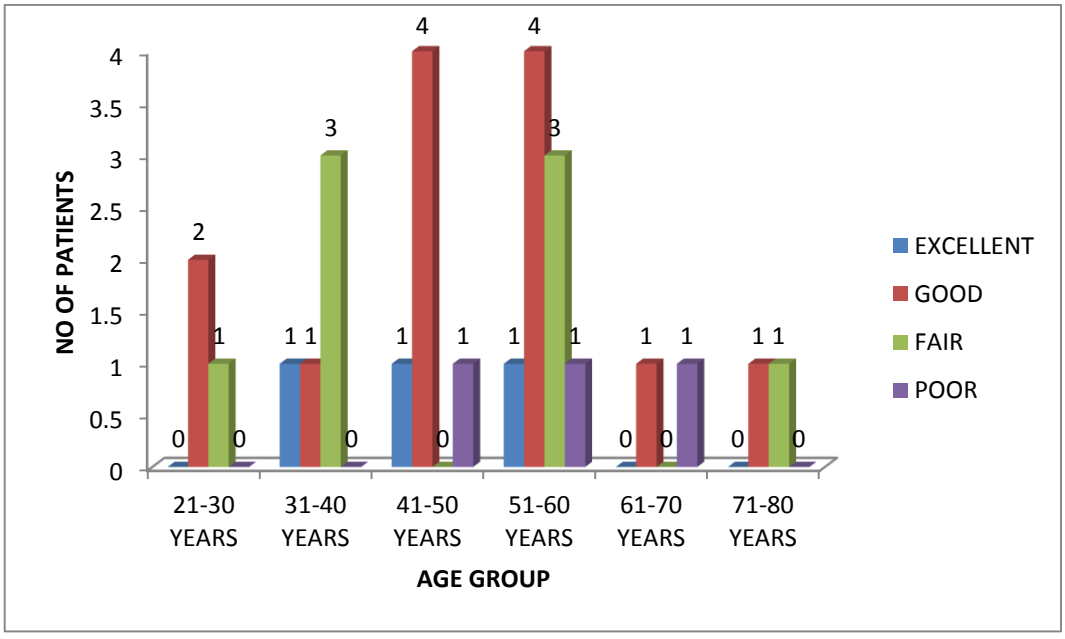


In our study in type 2 fractures results were good to excellent, in type 3 fractures results were fair to good, while 4 part fractures had poor to fair results.

TABLE.21. RESULTS ACCORDING TO AGE OF PATIENTS

AGE	RESULT			
	EXCELLENT	GOOD	FAIR	POOR
21-30	0	2	1	0
31-40	1	1	3	0
41-50	1	4	0	1
51-60	1	4	3	1
61-70	0	1	0	1
71-80	0	1	1	0
TOTAL	3	13	8	3

CHART.21.RESULTS ACCORDING TO AGE OF PATIENTS

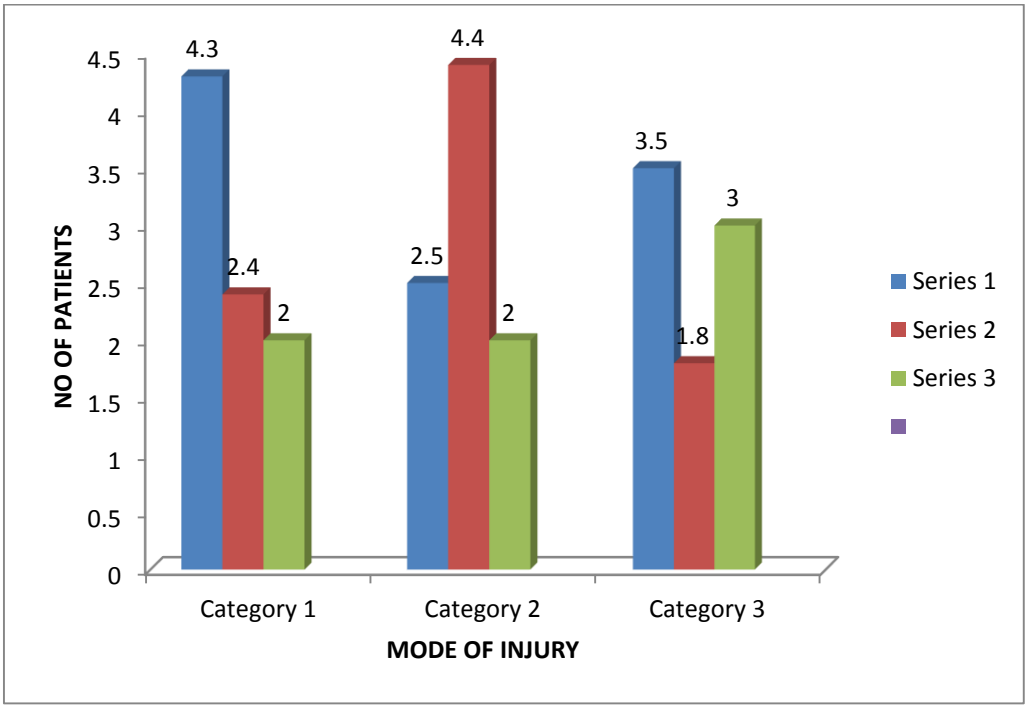


In our study good to excellent results were seen in most of the patients younger than 60 years, while in patients elder than 60 results were fair to poor in most of the cases.

TABLE.22. RESULTS ACCORDING TO MODE OF INJURY

MODE OF INJURY	RESULT			
	EXCELLENT	GOOD	FAIR	POOR
RTA	1	5	6	1
DOMESTIC FALL	1	7	1	2
FALL FROM HEIGHT	1	0	1	1
TOTAL	3	12	8	3

CHART.22. RESULTS ACCORDING TO MODE OF INJURY



In our study, we found that the patients who had domestic fall as mode of injury had good results, while the results were fair in those who had RTA as mode of injury.

DISCUSSION

Management of proximal humerus fractures remains a difficult problem for the orthopaedic surgeon. Several techniques and devices have been used for the fixation of these fractures. In the setting of displaced fractures, there is no consensus on the best treatment option, with some studies favouring prosthetic replacement[35,72,73] and other studies favouring reduction and plate fixation.[74,75] The main goal of treatment is restoration of limb function.

The use of locking plates confers greater stability to the fixation of fracture. Rose et al. encountered 75% of consolidation and excellent results in their casuistry, considering the fixations stable and performing early rehabilitation.[76] Open reduction, in spite of the morbidity of surgical access, allows perfect anatomicalreduction of the fracture.

The elderly patients who come with this type of fractures have osteoporotic bone & it makes the surgeon's task difficult in achieving a perfect osteosynthesis. Rigid fixation with locking plate favours immediate assisted mobility, avoiding stiffness and pain as sequel of the fracture.

Successful osteosynthesis of the proximal humerus can be difficult to achieve, especially in metaphyseal bone of the humeral head that has been described as an egg shell as there is little bone in the centre of the head.[77] The use of locking plates for osteoporotic fractures has increased greatly in the past decade and has changed management of many fracture types particularly in the proximal humerus. Locking plates allows rigid fixation of proximal humerus fractures that has been suggested to improve mechanical stability and therefore potentially result in better outcomes.[78]

Biomechanical evaluation of proximal humeral locking plates has demonstrated better biomechanical characteristics compared with a locked proximal humeral nail in varus bending and torsion.[78] Similar studies have shown that fixed angle devices perform better in a cadaveric setting compared to traditional plate fixation without locking.[79] For these reasons, locking plate fixation has become the treatment of choice.

The heterogeneity of multiple factors in the literature, including patient population, fracture type, and outcome measures reported, makes it difficult to determine the best treatment option for a given fracture pattern. The purpose of this study was to critically evaluate the proximal humerus fractures managed with an anatomical locking plate in our set up and review our observations with those available in literature.

In the present study of 25 patients with 26 fractures of proximal humerus were managed by open reduction and internal fixation with proximal humerus anatomical locking plate. (One patient had bilateral fracture.)

AGE INCIDENCE

In the present study there were only 6 patients in age group of 21-30 years and above 60 years. However, majority of the patients were between 31-60 years. Mean age for male patients was 42 years and for female patients it was 53.6 years. The average age of patients was 46.64 years, ranges from 26 to 75 years, which was consistent with the age incidence in studies done by Kulkarni S et al[64] 52.5 (21-76), Annamalai Regupathy[62] 54.45 (18-81), Sreen S. Et al[13] 58 (22-78) and Bansal V et al[63] 49.24 (19-82).

SEX INCIDENCE

Regarding sex incidence, most of western literature[43,45] reveals predominance of proximal humeral fractures in females in an elderly age group.The prevalence of proximal humerus fracture increases in males as they are venerable to more high energy trauma.In our study, the ratio ofmale to female is 1.5:1, these can be compared with other Indian studies[61,63]. So, this suggests that most of the male patient had sustained this trauma.

Our study shows that most of the proximal humerus fractures are osteoporotic fractures in women over the age of 50. The risk of fracture begins to increase linearly in women in their fifties, this is due to lack of postmenopausal treatment and its awareness as is evident by average age of female is 53.6 years. There are two main types of risk factors for osteoporotic fractures, first risk is fragile bones and the second is the risk of falling due to co morbidities.

The Male: Female ratio in Indian studies as compared to western studies is contradictory. We have high male preponderance though less than other fractures. However, western studies have a high female preponderance that is for 1 male to female are 2.14 to 2.59.

SIDE INVOLVEMENT

In our study right humerus (56%) was involved more often than the left (40%). More number of right side, merely reflects coincidence depending upon the position of the limb at the time of injury. Similar statistics are unavailable in the literature.

MODE OF INJURY

In the present study, 56% patients had history of road traffic accident, 9 (36%) patients were injured by domestic fall, 2 (8%) patients had history of fall from height.

Western literature[34,45] has shown proximal humerus fractures to be more common in elderly females. In contrast to majority of western studies that consider low energy falls as a more common cause, road traffic accidents were more common in Indian studies[63,64].

As reported by world health organization, India has the worst road traffic accident rate worldwide because of no traffic sense, which could be a reason for such a difference. Moreover our hospital being tertiary care hospital had a greater proportion of patients with high-energy polytrauma as compared to low energy isolated fractures of the proximal humerus.

This finding corresponded with the incidence rate in literature.

TABLE.25.COMPARISION OF MODE OF INJURY

STUDY	Domestic Fall	Road traffic accident	Fall from height	Total
Sudkamp et al[45]	162(86.63%)	25(13.37%)	0	187
Resch et al[34]	20(74.08%)	4(14.81%)	3(11.11%)	27
Kulkarni S et al[64]	22(36.67%)	38(63.33%)	-	60
Bansal V et al[63]	5(20%)	17(68%)	3(12%)	25
Present Study	9(36%)	14(56%)	2(8%)	25

In our study, mean age for patients who had RTA was 39.07 yearswhere as patients who had domestic fall was 58.22 years.

TYPE OF FRACTURE

The most common type of fracture encountered in the present study was 2 part fracture (13 patients, 50%), 3 part fracture was observed in 11 patients (42.3%), while 2 (7.7%) patients had 4 part fracture according to Neer.

As per literature,[13,43,61,63] the average age distribution of 2-part & 3-part fracture is 35-45%. Where as 4-part fracture incidence is lesser than other fractures.

TABLE.26.COMPARISION OF TYPE OF FRACTURE

Study	2 part	3 part	4 part	Total
Solberget al[43]	48(46.2%)	38(36.5%)	18(17.3%)	104
Bansal V et al[63]	11(44%)	11(44%)	3(12%)	25
Sreen S et al[13]	11(34.4%)	16(50%)	5(15.6%)	32
Kumar et al[61]	12(29.27%)	18(43.9%)	11(26.8%)	41
Present Study	13(50%)	11(42.3%)	2(7.7%)	26

INJURY OPERATION INTERVAL

In our study, average injury-operation interval was 6.96 days (range 2-24). The delay in surgery in a teaching institute could be due to multiple reasons. Late reporting of patients (average injury-admission interval of 3.72 days) is the main cause, where as associated comorbid conditions or associated trauma are being other major causes.

HOSPITAL STAY

Average hospital stay in our study was 14.6 days (range 8-24). Longer hospital stay was observed in polytrauma patients.

ASSOCIATED MEDICAL COMORBITIES

In total 6 patients had associated medical ailments; 4 patients were hypertensive, 3 were known case on medication and the other one was diagnosed after admission to the hospital; two cases in this study were known case of diabetes mellitus on admission. These associated medical conditions are known to affect the healing of fracture and have an impact on its outcome, especially in case of diabetes mellitus. Postoperatively out of this two diabetic patients one (case no. 4) presented superficial infection which was managed by antibiotics and antiseptic dressings.

ASSOCIATED INJURIES

In our study 10 patients had associated injury out of which 8 had history of RTA, 1 patient had domestic fall while 1 patient had history of fall from height. Lower limb injuries were commonly associated in case of RTA while distal end radius fracture was seen in domestic fall. However similar data are unavailable in literature to compare.

COMPLICATIONS

TABLE.27.COMPARISION OF COMPLATIONS

Study	Stiffness	Infection	Malunion	Implant Impingement	Osteonecrosis	Implant Loosening	Nonunion	Screw Perforation
Aggarwal et al[52]	0	9 (19.1%)	0	55 (10.6%)	2 (4.26%)	5 (10.6%)	0	6 (12.7%)
Sudkamp et al[45]	0	6 (3.8%)	0	4 (2.5%)	6 (3.8%)	4 (2.5%)	4 (2.5%)	21 (14%)
Rajinder et al[54]	4 (7.1%)	1 (1.8%)	0	1 (1.8%)	0	1 (1.8%)	0	1 (1.8%)
Bansal V et al[63]	0	2 (8%)	5(20%)	1 (4%)	2 (8%)	1 (4%)	0	4 (16%)
Kumar et al[61]	0	1 (2%)	0	5 (12%)	0	7 (17%)	1 (2%)	4 (10%)
Moonot etal[38]	0	1 (3%)	2(6%)	3 (9%)	1 (3%)	1 (3%)	1 (3%)	0
Present Study	**5 (19.2%)**	**1 (3.9%)**	**3 (11.5%)**	**1 (3.9%)**	**0**	**1 (3.9%)**	**0**	**1 (3.9%)**

Various complications seen in our study have been shown in table above. In our study, during the follow up period we found 12 (46%) patients with a total of 12 complications, requiring a total of 2 (7.7%) revision surgeries.

Shoulderstiffness observed in 5 (19.23%) patients (case no. 2,3,5,14,22) who were elderly and unwilling to undergo vigorous rehabilitation program. 3(11.54%) patients had malunion (case no. 4,11), 1 (3.85%) patient had screw perforation into head (case no. 11), 1 (3.85%) patient had superficial infection(case no.4) which was treated by antibiotic coverage and regular dressing.

Implantloosening (failure of implant) was seen in 1 (3.85%)patient (case no. 17)that required refixation of plate and intramedullary rush pin.

Postoperatively impingement was observed in 1 (3.85%) patient (case no. 2), whohad severe limitation of overhead abduction initially associated with severe pain. He got his plate removed at 5 months postoperatively with re-fixation by intramedullary rush pin and tension band wiring and good functional score was seen.

Though we are fortunate enough by not to have non-union, osteonecrosis of the proximal humerus, myositis ossificans or neurovascular deficit.

Resurgeries were required in 2 (7.7%) patients, comparable to 10% revision surgery rate in Wright et al.[76]

POST OPERATIVE REHABILITATION

In our study, pendulum and circumduction exercises were started 2-3 weeks post operatively, passive abduction and actively assisted ROM was started after 6-8 weeks while full range of movements and strengthening exercises were allowed after 10-12 weeks, which was similar to Post-operative rehabilitation protocol by Lake Cook Orthopaedics.

FRACTURE UNION

In our study the average radiological union time was 13.07 weeks. Similarly union time observed in Kumar et al[61] was 12 weeks and in Bansal V et al[63] was 11.2 weeks. Average union time for 2 part (13.54 weeks) & 4 part fracture (14 weeks) was longer compared to 3 part (12.36 weeks) fractures.

FOLLOW UP

The minimum follow up duration planned in our study was 6 months. The average follow up duration in our study was 10.6 months ranging from 6 months to 18 months.

EVALUATION

PAIN

At the time of final follow up one patient had moderate pain (case no. 2) and 8 patients had occasional pain.

ACTIVITY LEVEL

According to Constant criteria, we had noted activities of daily living, sleep disturbance & recreational sports activity if any.

We found that sleep was not disturbed due to shoulder pain in any of the patients. For their day to day activities like putting on clothes, eating, etc. 7 patients had some restrictions. Similarly 7 patients had complaint of some restrictions in recreational sports activity especially in throwing of objects.

HAND USAGE LEVEL

Following shoulder trauma, if patient is able to work overhead, he has achieved full function of shoulder.

In our study, according to Constant criteria almost 90% of the patients could position the hand up to the head or top of the head. However, 7 patients did have some restrictions.

ROM

For ROM, the following criteria were considered forward flexion, abduction, internal & external rotation.

If we analyse all the patients put to gather, it has been observed that forward flexion or elevation are usually satisfactory in all the patients following proximal humerus fracture in our study, only 1 patient had unsatisfactory result.

Abduction is one of the prime importance and all the functional disabilities are mainly due to restriction of this movement. Almost 50% shoulders had abduction less than 90 degree, at the time of final follow up.

External rotation is another prime function, following proximal humerus fractures, especially in 3 part fractures associated with greater tuberosity fractures. Almost 21 shoulders did not have full external rotation.15 cases (57.69%) were able to place the hand on the top of the head with elbow held forward while 5 cases (19.23%) were able to place the hand on top of the head with elbow held back.

Equally the internal rotation restriction is also seen in good number of patients. (21 fractures) Almost 13 cases (50%) were able to place the dorsum of the hand up to 12^{th} dorsal vertebrae, while 3 cases (11.54%) were able to place the dorsum of hand up to interscapular region.

In present study, 17 cases (65.38%) were able to lift up to 5-7 kg weight while 5 cases (19.24%) were able to lift up to 8-10 kg weight.

RESULTS

The mean constant score at final follow-up in our study was 68.78 that is comparable to72.08 in Aggarwal et al[52] and 72.3 in Kumar et al.[61]

We found that the highest constant score was 91.5 (case no.7) for Neer's type 3 fracture and the lowest constant score that was 40 (case no.2), a 63 years old female with history of domestic fall with type 4 fracture.

In our study also the mean Constant score for 4-part fractures was 47.75 which were inferior as compared to 2-part and 3-part fractures (71.07 and 64.14 respectively). These results are comparable to other studies like Aggarwal et al[52] and Kumar et al[61] in which the mean Constant score for 4-part fractures was significantly inferior to other types. These results were expected as these fractures are more complex and open reduction and internal fixation is tougher.

From all the above findings, there were 15 fractures (57.7%) had either excellent or good results & 11 fractures (42.3%) who had unsatisfactory results.

TABLE.29. COMPARISION OF RESULTS

STUDY	EXCELLENT	GOOD	FAIR	POOR
Bansal V et al[63]	4(16%)	11(44%)	4(16%)	6(24%)
Tingjun Ye et al[60]	2(2.2%)	32(36%)	40(44%)	15(16.9%)
M.H. El Sayed et al[50]	14(23.8%)	27(45.7%)	15(25.5%)	3(16.9%)
Aggarwal et al[52]	8(17.2%)	18(38.3%)	16(34.04%)	5(10.64%)
Present Study	3(11.54%)	12(46.15%)	8(30.77%)	3(11.54%)

Out of 25 patients (26 shoulders) treated by open reduction and internal fixation with anatomical locking plate, 3 (11.54%) had excellent outcome, 12 (46.15%) had good outcome, 8 (30.77%) patients had fair outcome and 3 (11.54%) had poor outcome.

If we compare across the available literature,[50,52,60,63] our findings of unsatisfactory results concur with 42.3%.

We found difference in outcome between patients of age group less than or more than 60 years of age. Patients more than 60 years of age group showed more unsatisfactory results. Similar findings have been reported by Aggarwal et al[52] who found the Constant scores to be higher in younger patients as compared to older patients (>65). Irrespective of type of fracture, old age with or without morbidities, the results are poor. This may be due to secondary degenerative changes as well as age related osteoporosis.

In this way our study is comparable to results available in literature and implies that in displaced 2, 3 and 4 part fracture this modality provides good outcome if anatomical reduction and stable fixation is achieved, along with appropriate rehabilitation.

In our study, there were 10 satisfactory results and 3 unsatisfactory results in 2 part fractures. In 3 part fractures, 5 results were satisfactory and 6 were unsatisfactory. While in 4 part fractures, both the results were unsatisfactory.

Finally, although this is a study with relatively small number of patients included, and based on the results recorded, it is suggested that fixation of 3 and 4 part high energy fractures using the anatomical locking plate is preferred method of treatment, and when well performed is expected to give relatively favourable results. It should be mentioned that this type of treatment was found to be of special value in young active patients because of the early rehabilitation.

This study teaches us that in fractures of proximal humerus, restoration of joint congruity is vital for restoration of joint function.Restriction of abduction and external rotation suggests that greater tuberosity fragment must be anatomically reduced well.

Infection and union related problems are minimum with this type of implant.Some limitation of the movements or unsatisfactory result is seen in elderly patients.

Strict adherence to shoulder mobilisation protocols and part of patient compliance can improve the further results.

SUMMARY AND CONCLUSION

The present study was conducted at The Department of Orthopaedics, Dhiraj Hospital, SBKS Medical Institute & Research Centre, Pipariya between December 2015 to September 2017. There were 25 patients in our study, 1 patient had bilateral fracture so the total number of 26 fractures of two part, three part and four part proximal humems treated with open reduction and internal fixation using anatomical locking plate have been included in the study. The follow up results were analyzed and discussed on the basis of Constant score.

- Out of 25 patients, there were 15 males and 10 females with ratio of 1.5:1.
- Majority of the patients were between 31-60 years with an average age of 46.64 years. Mean age for male patients was 42 years and for female patients it was 53.6 years. Patients more than 60 years of age group showed more unsatisfactory results.
- In our study, Right (56%) upper limb was more commonly involved than Left (40%) while 1 patient had bilateral involvement.
- Road traffic accident (56%) was the most common mode of injury followed by domestic fall (36%) and fall from height (8%). In male most common mode of trauma was RTA while in female domestic fall was more common.
- The mean age for patients who had RTA was 39.07 years where as patients who had domestic fall was 58.22 years.
- In our study, 2 part surgical neck fractures (11) and 3 part fractures (11) were more common than other fractures. We had more number of patients of 2 part fracture & less number of 3 part fractures as compare to other studies.
- All the fractures were united with an average union time of 13 week, ranging from 10 to 18 weeks. We observed that 3 part fractures united earlier compared to 2 & 4 part fractures.
- We observed following complications, shoulder stiffness in 5 (19.23%) fractures, malunion in 3 (11.54%) fractures, screw perforation in 1 (3.85%) fracture, and

superficial infection in 1 (3.85%) fracture, failure of implant in 1 (3.85%) fracture and impingement of implant in 1 (3.85%) fracture. Re surgeries were required in 2 (7.7%) patients.

- The minimum follow up criteria was 6 months, however our average follow up was 11.8 months.
- At the time of final follow up there were 8 patients had occasional pain and 1 had moderate pain.
- Restriction of function for their activities of daily living was observed in 7 patients
- Following this fracture fixation we have observed that 3 movements are compromised to a large extent, that are abduction, external rotation & internal rotation.
- On assessment of results we had 3 (11.54%) excellent, 12 (46.15%) good outcomes. However, there were 8 (30.77%) fractures with fair and 3 (10%) fractures with poor outcome.
- There were 10 satisfactory results and 3 unsatisfactory results in 2 part fractures. In 3 part fractures, 5 results were satisfactory and 6 were unsatisfactory. While in 4 part fractures, both the results were unsatisfactory.
- The average age of the patients with unsatisfactory outcome was 44.81.
- The common fracture type associated with unsatisfactory outcome was type 3.

Finally, although this is a study with relatively small number of patient included, and based on the results recorded, it is suggested that fixation of 2, 3 and 4 part fractures using the anatomical locking plate is preferred method of treatment, and when well performed is expected to give relatively favourable results.

We have observed that shoulder protocol exercises, if applied correctly can give good outcomes in any type of fractures and compliance on patient's part is necessary.

Though this observation could not be validated by scientific observations, we found that all those patients who were noncompliant had unsatisfactory outcome.

This study teaches us that in fractures of proximal humerus, restoration of joint congruity with rotator cuff stability is vital for restoration of joint function. Restriction of abduction and external rotation suggests that greater tuberosity fragment must be anatomically reduced well. Infection and union related problems are with this type of implant are minimal.

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ANNEXURE - 1

STUDY OF PROXIMAL

HUMERUS FRACTURES TREATE

D BY PHILOS PLATE

PROFORMA

Name :

Age :

Sex :

Occupation :

OPD no. :

IPD no. :

Date of Admission :

Date of Operation:

Date of Discharge :

Address :

Phone no. :

History :

Mechanism of injury : Direct / Indirect

Side of injury :

Mode of trauma :

- domestics fall
- Road traffic accident
- Fall from height
- Assault injury
- Industrial injury
- Sports injury

Type of fracture : Closed /Compound

Duration since injury :

Associated injury : Pelvic / head injury / lower limb /opposite upper limb

Any SECONDARY diseases : hypertension / diabetes mellitus / COPD / asthma

/ CHD / TB

General physical examination : Temperature Pulse

Bp Respiratory rate

Jaundice/ pallor /cyanosis /clubbing /oedemafeet /lymphadenopathy

Systemic examination :

CVS

RS

CNS

Local examination :

Side of trauma : Right / Left/ Both

Local Temperature :

Swelling : present/absent

Tenderness : present/absent

Ecchymosis : present/absent

Crepitation : present/absent

Abnormal mobility : present/absent

Dnvd : present/absent

Local skin condition(abrasion ,scar ,sinus) : present/absent

Local wound(if present) :

Deformity : present/absent

Range Of movement : Shoulder :

Elbow :

Investigation

X ray : Shoulder :- AP , Axillary

Laboratory Investigations:

Complete blood count

Sr.Creatine

SGPT

BT/CT

HIV status :reactive / non reactive

HbsAg status :reactive / nonreactive

Urine Routine/micro:

CT scan

Treatment modality :

Fracture type according to NEER's classification :

->

Type of Anaesthesia :

Complication

Intra op:

Difficulty in anatomical reduction : present/absent

Improper placement of implant : present/absent

Difficulty in closure : present/absent

Immediate post op:

bleeding

Pain : no /mild /moderate /severe

Infection : present/absent

Skin necrosis : present/absent

Neurovascular deficit : present/absent

Delayed complication:

Stiffness : present/absent

Malunion : present/absent

Nonunion : present/absent

Impingement of implant : present/absent

Failure of implant : present/absent

Myositis ossificans : present/absent

Pain : no /mild /moderate /severe

Neurovascular deficit : present/absent

Avascular necrosis of humeral head : present/absent

Clinical and Functional Evaluation*:*

Constant and Murley Shoulder Scoring System	6 Weeks	3 Months	1 Year
1.Pain			
2.Activity of daily life			
A. Work			
B Recreation/sport			
C.Sleep			
3.Positioning			
4.Range of motion			
A.Abduction			
B.Flexion			
C.External Rotation			
D.Internal Rotation			
5.Power			
TOTAL			

Final Assesment (poor (0-55 points), fair (56-70), good (71-85), or excellent (86-100)) :_____

Secondary procedure required:

1. Infection
2. Arthroplasty

Pain relief:

Daily activities affected:

Return to occupation:

Patient's satisfaction:

Surgeon's comments:

ANNEXURE - 2

FOLLOW UP CRITERIA ACCORDING TO CONSTANT AND MURLEY SCORE

Category Score	
Pain	(15 Points)
None	15
Mild	10
Moderate	5
Severe	0
Activities of daily living	
Activity Level	(10 points)
Full work	4
Full recreation/sport	4
Unaffected sleep	2
Positioning	(10 points)
Up to waist	2
Up to xiphoid	4
Up to neck	6
Up to top of head	8
Above head	10
Range of Motion	(40 points)
Forward elevation	(10 points)
0-30	0
31-60	2
61-90	4
91-120	6
121-150	8
151-180	10
Abduction/ Lateral elevation	(10 points)
0-30	0
31-60	2
61-90	4
91-120	6
121-150	8
151-180	10
External Rotation scoring	(10 points)
Hand behind the head with elbow held forward	2
Hand behind the head with elbow held back	2
Hand on top of the head with elbow held forward	2
Hand on top the head with elbow held back	2

Full elevation from on top of head	2
Internal Rotation scoring	(10 points)
Dorsum of hand to lateral thigh	0
Dorsum of hand to buttock	2
Dorsum of hand to lumbosacral junction	4
Dorsum of hand to waist (L3)	6
Dorsum of hand to 12^{th} dorsal vertebrae	8
Dorsum of hand to interscaoular region (D7)	10
Power (Number kgs of pull the patient could resist at 90 degree of abduction or maximum abduction patient could achieve for minimum of 3 seconds**)**	(25 points)
Weight in Kg	
1	2.5
2	5
3	7.5
4	10
5	12.5
6	15
7	17.5
8	20
9	22.5
10	25

Final evaluation

0-55 : Poor

56-70 : Fair

71-85 : Good

86-100 : Excellent

ANNEXURE - 3

PARTICIPANT INFORMATION SHEET

Study Title: -"STUDY OF PROXIMAL HUMERUS FRACTURES TREATED BY ANATOMICAL LOCKING PLATES"

DATE:

You are being cordially invited to participate in the above titled study. The proposed study is a scientific endeavor to generate data on treatment of proximal humerus fracture treated with anatomical locking plates in our hospital.

1. Purpose & nature of the study: -

To study the results "STUDY OF PROXIMAL HUMERUS FRACTURES TREATED BY ANATOMICAL LOCKING PLATES"

2. Voluntary nature of participation: -

Your participation in this study is voluntary and at your free will. You can refuse to participate in the study. More over you are also free to withdraw at any time without having to give a reason. Despite this, you will continue to receive your standard medical care and treatment.

3. Study methods: -

The study is interventional and the investigator will not intervene in any part of the treatment. The treatment will be decided by the treating doctor, and only the treatment and the investigations will be observed and noted by the investigator. The investigator may ask questions relevant to your history, your disease, drug treatment and may enter the information in

4. Participant's responsibility: -

You will share information regarding the health problem with the investigator as required. You will co-operate with the investigator with regard to followup visits.

5. Expected adverse events, risks and solution: -

This is an interventional study only. Treatment of your disease will be decided by senior consultant only and not by the investigator. There is no question of adverse effects or risk to you on account of the study.

6. Benefits of participation: -

Your disease will be diagnosed easily and fast, there will be better chances of accurate diagnosis and treatment. So the treatment will be started as early as possible. Your treatment will become more appropriate and effective.

7. **Confidentiality**: -

Your information will remain strictly confidential and will not be revealed to any third party and will not be published anywhere without your prior permission.

8. **Investigator's Contact Information: -**

This interventional study, no additional problem will expect to arise. However if you need to share any information or seek advice with regard to the study, you can contact – Dr. Amit Patel, resident doctor, department of orthopaedics, SBKS MI & RC, Sumandeep Vidyapeeth University, Pipariya, Tal. Waghodia, Dist. Vadodara.

9. **Financial consideration**: -

You will not have to bear any extra cost purely for the purpose of the study. However, if the investigator desires to carry out any additional investigation, other than the ones suggested by your treating doctor or the ones which are a part of treating protocols for your disease condition, the cost of the same will be borne by the investigator. You will not get any financial incentives for participating.

10. **Protection and security**: -

It is an interventional study and no new drugs/procedure/technique is being tested, so this does not apply.

11. **Obtaining additional information**: -

If you need any additional information with regard to the study, or if you require any clarification, or in case of any doubt, you are free to ask questions to the Investigator. You will be given a copy of this participant information sheet for your information and record. If you need more information at a later date, you may call the investigator or meet him.

પરિશિષ્ટ-૩

પક્ષકાર માહિતી શીટ

અભ્યાસનું શિર્ષક: - "સ્ટડી ઓફ પ્રોક્ઝીમલ હ્યુમરસ ફ્રેક્ચર ટ્રીટેડ બાય એનાટોમીકલ લોકીંગ પ્લેટસ"

તારીખ:

ઉપરોક્ત શિર્ષક અભ્યાસમાં ભાગ લેવા માટે તમે સદ્ભાગ્યે આમંત્રિત છો. પ્રસ્તાવિત અભ્યાસે આપણા હૉસ્પિટલમાં પ્રોક્ઝીમલ હ્યુમરસ ફ્રેક્ચર માટે એનાટોમિકલ લોકીંગ પ્લેટ્સ અંગેનો અભ્યાસ.

1. અભ્યાસનો હેતુ અને સ્વભાવ: -

પ્રસ્તાવિત અભ્યાસે આપણા હૉસ્પિટલમાં પ્રોક્ઝીમલ હ્યુમરસ ફ્રેક્ચર માટે એનાટોમિકલ લોકીંગ પ્લેટ્સ અંગેનો અભ્યાસ.

2. સહભાગીની સ્વૈચ્છિક પ્રકૃતિ: -

આ અભ્યાસમાં તમારી સહભાગી સ્વૈચ્છિક છે અને તમારી સ્વતંત્ર ઇચ્છા પર તમે અભ્યાસમાં ભાગ લેવાનો ઇન્કાર કરી શકો છો. કોઈ પણ કારણ આપ્યા વગર તમે કોઈપણ સમયે પાછી ખેંચી શકો છો. આમ છતાં, તમે તમારી પ્રમાણભૂત તબીબી સંભાળ અને સારવાર મેળવશો.

અભ્યાસ પદ્ધતિ: -

આ અભ્યાસ આંતરવૈયક્તિક છે અને તપાસ કરનાર કોઇ પણ સારવારમાં દરમિયાનગીરી કરશે નહીં. આ સારવારનો નિર્ણય ડૉક્ટર દ્વારા લેવામાં આવશે, અને માત્ર સારવાર અને તપાસ જ તપાસકર્તા દ્વારા અવલોકન અને નોંધવામાં આવશે. તપાસકર્તા તમારા ઇતિહાસ, તમારી રોગ, ડ્રગ ટ્રીટમેન્ટ સાથે સંબંધિત પ્રશ્નો પૂછી શકે છે અને આમાં માહિતી દાખલ કરી શકે છે

4. સહભાગીની જવાબદારી: -

આવશ્યકતા મુજબ તપાસકર્તા સાથે સ્વાસ્થ્ય સમસ્યા અંગેની માહિતી તમે વહેંચશો. ફોલોઅપ મુલાકાતોના સંદર્ભમાં તમે તપાસનીસ સાથે સહકાર કરશો.

5. અપેક્ષિત પ્રતિકૂળ ઘટનાઓ, જોખમો અને ઉકેલ: -

આ માત્ર એક હસ્તક્ષેપ અભ્યાસ છે તમારી બિમારીની સારવાર માત્ર વરિષ્ઠ સલાહકાર દ્વારા નક્કી કરવામાં આવશે, તપાસકર્તા દ્વારા નહીં. અભ્યાસના લીધે તમને કોઈ પ્રતિકૂળ અસરો અથવા જોખમ વિશે કોઈ પ્રશ્ન નથી.

6. ભાગીદારીના લાભ: -

તમારી બિમારીને સરળતાથી અને ઝડપી નિદાન કરવામાં આવશે, સચોટ નિદાન અને સારવારની સારી તકો હશે. તેથી સારવાર શક્ય તેટલી વહેલી શરૂ થશે. તમારી સારવાર વધુ યોગ્ય અને અસરકારક બની જશે.

7. ગુપ્તતા: -

તમારી માહિતી સખત ગોપનીય રહેશે અને કોઈપણ તૃતીય પક્ષને જાહેર કરવામાં આવશે નહીં અને તમારી પૂર્વ પરવાનગી વગર પણ તે પ્રકાશિત થશે નહીં.

8. તપાસ કરનારની સંપર્ક માહિતી: -

આ આંતરિક અભ્યાસ, કોઈ વધારાની સમસ્યા ઊભી થવાની અપેક્ષા રાખવામાં આવશે નહીં. જો તમને કોઈપણ માહિતી શેર કરવા અથવા અભ્યાસના સંદર્ભમાં સલાહ લેવાની જરૂર હોય તો, તમે સંપર્ક કરી શકો છો –

ડૉ. અમીત પટેલ, નિવાસી ડૉક્ટર,

વિકલાંગ વિજ્ઞાન વિભાગ, એસબીકેએસ એમઆઇ અને આરસી,

સુમનંદી વિદ્યાપીઠ યુનિવર્સિટી, પિપરિયા, તાલ. વાઘોડિયા, જિ. વડોદરા

9. નાણાકીય વિચારણા: -

અભ્યાસના ઉદ્દેશ્ય માટે તમારે કોઈ પણ વધારાની ખર્ચ સહન કરવો પડશે નહીં. જો કે, જો તપાસકર્તા તમારી સારવારની ડોકટર દ્વારા ભલામણ કરેલા અને તમારી બીમારીની હાલત માટે પ્રોટોકોલનો ઉપયોગ કરવાના ભાગો સિવાય કોઈ પણ વધારાની તપાસ કરવા ઇચ્છે છે, તો તેની કિંમત તપાસકર્તા દ્વારા લેવામાં આવશે. ભાગ લેવા માટે તમને કોઈ નાણાકીય પ્રોત્સાહનો નહીં મળે.

10. રક્ષણ અને સલામતી: -

તે એક આદર્શ અભ્યાસ છે અને કોઈ નવી દવાઓ / પ્રક્રિયા / તકનીકની ચકાસણી કરવામાં આવી રહી નથી, તેથી તે લાગુ પડતું નથી.

11. વધારાની માહિતી મેળવી: -

જો તમને અભ્યાસ અંગે કોઈ વધારાની માહિતીની જરૂર હોય, અથવા જો તમને કોઈ સ્પષ્ટતાની જરૂર હોય અથવા કોઈ શંકા હોય તો, તમે તપાસ કરનારને પ્રશ્નો પૂછી શકો છો. તમને તમારી માહિતી અને રેકોર્ડ માટે આ પ્રતિભાગી માહિતી શીટની એક નકલ આપવામાં આવશે. જો તમને પછીની તારીખે વધુ માહિતીની જરૂર હોય, તો તમે તપાસનીસને બોલાવી શકો છો અથવા તેને મળો.

ANNEXURE - IV

Sumandeep Vidyapeeth

Piparia, Ta. Waghodia, Dist. Vadodara- 391760

Informed Consent Form (ICF) for Participants in Research Programes

Involving studies on human beings

Study Title: -"STUDY OF PROXIMAL HUMERUS FRACTURES TREATED BY ANATOMICAL LOCKING PLATES"

Study Number: SVIEC/GN/Medi/BNPG14/D15255

Participant's Initials: _____

Participant's Name: _____

Date of Birth (Age) _____ (Years)

1. I confirm that I have read and understood the information sheet dated _____for the above study and have had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that the investigator of this study, others working on the investigator's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records, both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information related to third party or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I agree to take part in the above study.

Signature (or left thumb impression) of the participant

Legally acceptable representative _____

Signatory's Name _____ Date _____

Signature of the investigator _____ Date _____

Study Investigator's Name _____

Signature of the impartial witness _____ Date _____

Name of the witness _____

પરિશિષ્ટ-૪

સુમનદીપવિદ્યાપીઠ

પીપરીયા. તા. વાઘોડિયા, જીલ્લોવડોદરા૩૯૧૭૬૦

માનવીઓમાં થતા સંશોધન માટેનું ઇન્ફોર્મડકન્સેન્ટફોર્મ

અભ્યાસનુંશીર્ષક: - "સ્ટડી ઓફ પ્રોક્ઝીમલ હ્યુમરસ ફ્રેક્ચર ટ્રીટેડ બાય એનાટોમીકલ લોકીંગ પ્લેટસ"

અભ્યાસ નંબર:

વિષયનો પ્રારંભ: વિષયનું નામ:
જન્મ તારીખ / ઉંમર:

વિષયનું સરનામું:

લાયકાત:

વ્યવસાય: વિદ્યાર્થી / સ્વ રોજગારી / સેવા / ઘરની પત્ની / અન્ય :(કૃપા કરીને યોગ્ય તરીકે નિશાની કરો)

આ વિષયની વાર્ષિક આવક:

નોમિની (ઓ) ની વિગતો:
નોમિની નામ:

નોમીનીનું સરનામું:

વિષય સાથે સંબંધ:

કૃપા કરી પ્રારંભિક બોક્સ (વિષય)

(i) હું પુષ્ટિ કરું છું કે મેં માહિતીપત્રની તારીખ વાંચી અને સમજી લીધી .... ઉપરના અભ્યાસ માટે અને પ્રશ્નો પૂછવાની તક મળી છે. ☐

(ii) હું સમજી શકું છું કે અભ્યાસમાં મારો સહભાગિંહ સ્વૈચ્છિક છે અને તે કોઈપણ તબીબી કાળજી અથવા કાયદાકીય અધિકારોને પ્રભાવિત કર્યા વિના, કોઈપણ કારણ વગર, કોઈપણ સમયે હું પાછી ખેંચી શકું છું.

(iii) હું સમજું છું કે ક્લિનિકલ ટ્રાયલના પ્રાયોજક, અન્યો ☐

પ્રાયોજકની વતી કાર્યરત, એથિક્સ કમિટી અને નિયમનકારી સત્તાવાળાઓએ વર્તમાન અભ્યાસના સંદર્ભમાં અને અન્ય કોઈ સંશોધનમાં તેનો સંદર્ભ આપવા માટે મારી સ્વાસ્થ્યના વિક્રમોને જોવાની મારી પરવાનગીની જરૂર નથી,
જો હું ટ્રાયલમાંથી પાછો ખેંચી લો તો પણ હું આ ઍક્સેસ માટે સંમત છું, પણ હું સમજું છું કે તૃતીય પક્ષો દ્વારા પ્રકાશિત અથવા પ્રકાશિત થયેલા કોઈપણ માહિતીમાં મારી ઓળખ જાહેર કરવામાં આવશે નહીં.

(iv) હું કોઈપણ અન્ય માહિતી અથવા પરિણામોના ઉપયોગને પ્રતિબંધિત કરવા માટે સંમત થતો નથી.

(v) હું ઉપરના અભ્યાસમાં ભાગ લેવા માટે સંમત છું. ☐

વિષય / LAR ની હસ્તાક્ષર (અથવા અંગૂઠા છાપ):

તારીખ: / /

હસ્તાક્ષરનું નામ:

તપાસકર્તાના હસ્તાક્ષર:

તારીખ: / /

અભ્યાસ તપાસ કરનારનું નામ:

સાક્ષીની હસ્તાક્ષર

તારીખ: / _ /

સાક્ષીનું નામ:

પેશન્ટ ઈન્ફર્મેશન શીટની નકલ અને ભરવામાં આવશે ઈન્ફોર્મ્ડ કોન્સન્ટ ફોર્મ વિષય અથવા તેના / તેણીના પરિચરને આપવામાં આવશે.

ANNEXURE - 5

ABBREVIATIONS

AP	-	ANTEROPOSTERIOR
K WIRE	-	KRISCHNER WIRE
MOI	-	MODE OF INJURY
CR&IF	-	CLOSED REDUCTION & INTERNAL FIXATION
OR&IF	-	OPEN REDUCTION & INTERNAL FIXATION
OPD	-	OUT PATIENT DEPARTMENT
PHILOS	-	PROXIMAL HUMERUS INTERNAL LOCKING OSTEOSYNTHESES
RTA	-	ROAD TRAFFIC ACCIDENT
ROM	-	RANGE OF MOVEMENTS

MASTER CHART

SR NO	PATIENT'S IDENTITY	AGE (YEARS)	SEX	SIDE OF INJURY	MECHANISM OF INJURY	INJURY ADMISSION INTERVAL (DAYS)	INJURY OPERATION INTERVAL (DAYS)	ASSOCIATED INJURY (DAYS)	ASSOCIATED COMORBIDITIES	ADDITIONAL IMPLANTS	HOSPITAL STAY (DAYS)	TYPE OF FRACTURE (NEER'S)	ASSOCIATED DISLOCATION	FOLLOW UP IN MONTHS	RADIOLOGICAL UNION IN WEEKS	COMPLICATION	RESURGERY REQUIRED	CONSTANT SCOREAT FINAL FOLLOW UP						RESULT
																		PAIN (15)	ACTIVITIES OF DAILY LIFE (10)	POSITIONING (10)	ROM (40)	POWER (25)	TOTAL SCORE	
1	AM	26	M	RIGHT	RTA	10	13	IPSILATERALLATERAL CONDYLE FEMUR AVULSION FRACTURE			15	3 PART		6	10			15	10	8	34	12.5	87	FAIR
2	AP	55	M	RIGHT	DOMESTIC FALL	5	6		HTN	4 MM C.C. SCREW	8	2 PART		18	12	IMPLANT IMPINGMENT,STIFFNESS	IMPLANT REMOVAL AND INTRAMEDULLARY RUSH PIN WIRH TBW	5	4	6	18	5	40	POOR
3	BD	63	F	LEFT	DOMESTIC FALL	2	8				12	4 PART		16	14	STIFFNESS		10	6	6	16	7.5	45.5	POOR
4	IF	50	M	RIGHT	RTA	4	7	IPSILATERAL DISTAL END RADIUS FRACTURE WITH ULNAR STYLOID #	DM		12	3 PART	ANTERIOR	16	14	INFECTION, MALUNION	IMPLANT REMOVALL	10	6	8	22	15	61	FAIR
5	JV	45	M	LEFT	RTA	0	2	IPSILATERAL SHAFT TIBIA - FIBULA #			6	3 PART		14	14	STIFFNESS		10	6	6	14	5	41	POOR
6	JG	55	F	LEFT	DOMESTIC FALL	11	13				10	2 PART	POSTERIOR	12	18			15	10	8	30	15	76	GOOD
7	JP-A	58	F	(B/L) RIGHT	DOMESTIC FALL	0	5	MID SHAFT C;AVICLE FRACTURE			22	3 PART		17	12			15	10	10	36	20	91.5	EXCELLENT
	JP-B			LEFT								2 PART			12			10	8	30	17.5	80.5	84.5	GOOD
8	KG	75	F	RIGHT	DOMESTIC FALL	10	12		HTN		8	3 PART		15	18	MAL-UNION		15	6	8	26	17.5	72.5	GOOD
9	LGP	46	M	LEFT	RTA	2	4				13	2 PART		12	12			10	6	8	24	10	58	FAIR
10	PPP	35	M	RIGHT	RTA	1	2				14	3 PART		12	10			15	10	10	32	20	87	EXCELLENT
11	RR	55	M	RIGHT	FALL FROM HEIGHT	3	9	CONTRALATERAL NOF #			21	3 PART		15	12	MAL-UNION		15	6	6	18	15	60	FAIR
12	PSY	60	F	LEFT	DOMESTIC FALL	20	24				16	2 PART		12	16			15	6	8	26	20	75	GOOD
13	PKK	45	M	RIGHT	RTA	1	7	CONTRALATERAL DISTAL FEMUR #			24	2 PART	ANTERIOR	11	16			15	10	8	26	15	74	GOOD
14	HCG	32	M	LEFT	RTA	2	4				14	3 PART	ANTERO-INFERIOR	12	10	STIFFNESS		10	6	8	20	15	59	FAIR
15	SP	30	F	RIGHT	RTA	1	3				15	2 PART		13	10			15	10	8	26	15	74	GOOD
16	RBK	49	M	LEFT	RTA	4	6			4 MM C.C. SCREW	18	3 PART		14	14			10	6	6	18	12.5	52.5	FAIR
17	SAM	37	F	LEFT	RTA	2	3	IPSILATERAL SUP. PUBIC RAMI #			14	2 PART		11	10	IMPLANT LOOSENING	INTRAMEDULLARY RUSH PIN	10	6	6	22	12.5	56.5	FAIR
18	RS	40	M	RIGHT	FALL FROM HEIGHT	1	4				12	2 PART		12	12			15	10	10	32	22.5	87.5	EXCELLENT
19	RHP	43	F	RIGHT	DOMESTIC FALL	2	5	IPSILATERAL RADIAL N PALSY	HTN		17	3 PART	ANTER-INFERIOR	14	12			15	6	8	26	17.5	74.5	GOOD
20	HR	50	F	LEFT	DOMESTIC FALL	0	2		DM		14	2 PART		6	16			15	10	8	28	12.5	73.5	GOOD
21	LB	42	M	RIGHT	RTA	4	6			4 MM C.C. SCREW	7	3 PART		6	10			15	6	10	28	15	72	GOOD
22	BR	35	M	RIGHT	RTA	3	8				20	4 PART		10	14	STIFFNESS		10	6	8	18	15	61	FAIR
23	BB	65	F	RIGHT	DOMESTIC FALL	1	7		HTN		16	2 PART		7	16			15	10	8	30	17.5	80.5	GOOD
24	RVV	45	M	RIGHT	RTA	2	8	IPSILATERAL IT FEMUR #			19	2 PART		6	14			15	6	8	28	15	72	GOOD
25	SLB	30	M	LEFT	RTA	2	6				18	2 PART		8	12			15	6	8	26	17.5	72.5	GOOD