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Investigating the functional outcomes and complications associated with open reduction and internal fixation in proximal humeral fractures locking plate: A prospective study

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Abstract-

Objective: The aim of the study is to assess the functional and radiological outcomes in 2, 3, and 4-parts proximal humerus fractures treated using the proximal humerus locking plate.

Methods: From January 2016 to December 2016, total 31 patients with displaced 2, 3 or 4-parts proximal humerus fractures included. The functional outcomes were assessed using Constant scores, and radiological assessments were also done over 6 weeks, 3months, and 6 months. The data was analysed for significance using 't' test or ANOVA (analysis of variance) test (statistics calculators version 3.0 Beta). The significance was set at value $P < 0.05$.

Results: Twenty patients (3 excellent, 17 good) had satisfactory results. Though the average Constant score was relatively lesser among the 4-part fractures (67) as compared to 2, and 3-part fractures (79, and 75) at final follow up, it did not reach the desired statistical significance due to inadequate sample sizes. The two most common complications were screw perforation of the head of humerus, and sub-acromial impingement in three patients (9.67%) each respectively. One patient developed osteonecrosis of head in four part fracture.

Conclusion: Locking plate can be a promising implant for fixation of proximal humerus fractures, and due to locking screws, it can work satisfactorily in elderly with osteoporotic fractures with augmentation like cement or bone graft. Although, significant proportion of patients can predictable functional outcomes, complications do occur in some patients. Level of evidence: Type IV.

Keywords: Proximal humerus fractures, shoulder, ORIF, internal fixation

Introduction

Proximal humerus fractures (PHF) appears to be a common musculoskeletal injuries and also a major complication among the aging population as the prevalence/rate of injuries and falls increase with creeping age along with other co-morbidities and complications like osteoporosis worsens the overall risks of humeral fracture [1]. PHF account for approximately 5% of all fractures [2]. More than 70% of patients with these fractures are older than sixty years of age, and 75% are women. Besides such fractures tends to cause severe and prolonged disability which is quite often underestimated, compared to that of hip fractures [1, 2].

For majority of PHF cases are treated using non operative management showing satisfactory function [3]. More than 20% PHF cases are classified as displaced and according to Neer (1970) [13] the treatment for such cases remains still disputed. Open reduction and internal fixation (ORIF) is the most frequently performed operative procedure for treatment of displaced proximal humeral fractures [4, 5, 6]. Non-operative method is advocated for minimally displaced fractures, whereas, vast operative methods have been recommended over the course of time by various studies like polarus nail [7], percutaneous pinings [8], locking plates [9], hemiarthroplasty [10], and reverse shoulder arthroplasty [11]. Till date, there is no single effective method which proved to be effective for application for all fracture types. Results tend to vary significantly among the researchers as there has been reports indicated high complication rates observed in each modality.

Considering the underlying complications associated with ORIF for displaced PHF which still account for up to 30% and numerous studies investigated factors associated with poor outcome.

Meier *et al.*,^[12] reported that this method results in an additional disturbance and hindrance to the blood supply for humeral head, which is caused as a result of extensive surgical approaches.

Until now, the disagreement remains on how effectively such fractures can be treated in elderly patients. However, reports on whether or not ORIF patients show higher signs of complication rate and also to assess the functional outcomes and the overall impact of co-morbidities and their negative impact determined at the post-operative follow-ups are quite rare. This study intends to evaluate the functional outcomes and determine the underlying complications associated with ORIF in patients with PHF.

Materials and Method

From January 2016 to December 2016, 35 patients older than 20 years who underwent ORIF of PHF were included.

All fractures were classified according to Neers classification^[13]. Radiographs with true AP view of gleno-humeral joint perpendicular to the plane of the scapula and the axillary view parallel to the plane of scapula and perpendicular to the acromion, was done to assess the type of fractures, displacement and plan the treatment. Also CT (computerized tomography) scan of humerus and shoulder with 3-D reconstruction was done in selected cases in order to exactly determine the fracture pattern and associated dislocation or extent of articular surface involvement and the amount of tuberosity displacement in comminuted fractures.

Surgery was done under general anesthesia or brachial block. Patient was kept in beach chair position. Deltopectoral approach^[14] was used to expose the fracture and humeral head. By making a deltopectoral groove through a 10 to 15 cm longitudinal cutaneous incision the proximal humerus was approached. The incision should begin just above the coracoid process and extend till proximal humeral shaft. After achieving appropriate hemostasis in subcutaneous tissue, deltopectoral interval and cephalic vein were identified.

The cephalic vein was left either with the deltoid muscle or with the pectoralis major muscle. The conjoint tendon was then retracted and a curved blunt retractor was placed under the deltoid muscle around the fragment of humeral head in the subacromial space after blood clots and bursal tissue was removed. The axillary nerve was identified and palpated by sliding the index finger under the conjoined tendons on to the anterior aspect of subscapularis.

The biceps tendon was located and used as a landmark to help to identify the fragments of greater and lesser tuberosities with their attached tendons. With two-part fractures involving the surgical neck, the alignment of biceps usually reflected the adequacy of the reduction. In a fracture in which lesser tuberosity is not detached but where the surgeon wished to inspect the articular surface, a small incision through the interval was made and articular surface was observed. All the tendinous structures were then identified with stay sutures. Hematoma was removed and open reduction of main fracture fragments and the greater tuberosity, if present, was accomplished manually. Reduction of the intra articular fragments was done using linear bone clamps or Kirschner wires to temporarily hold reduction. Additionally, the rotator cuff was grasped using suture near the insertion at the tuberosities for correcting varus malalignment. After reduction, the fracture was fixed temporarily with Kirschner

wires and checked using image intensifier.

Lag screws were used to secure the intra-articular fragments and comminutions. The locking humerus plate was inserted along the humeral shaft

at least 1 cm distal to the upper end of greater tuberosity and also was fixed temporarily with K-wires. In certain cases, Standard locking, cortical or cancellous screws were employed for fixation. Before inserting the first locking screw, anatomical reduction of fracture was achieved and fixed with lag screw, if necessary. In the patient with indirect reduction of the shaft to the plate, a non locking screw first for fixation of the plate to the shaft was employed. In patient showing signs of primary and good reduction, the surgeons employed locking screw initially and then used plate as an internal fixator. K wires were removed after at least two screws (proximal and distal) were placed. The final construct was checked under fluoroscope and the wound was washed, drain inserted and closed in layers. Pouch arm sling was given for the patient. All patients wore restraining shoulder bandage postoperatively for at least 4 weeks. Active assisted shoulder mobilizing exercises were started on 1st post-operative day and active ROM exercises were started 2 weeks postoperatively, and active assisted exercises were started at 4 weeks. Muscle strengthening exercises were started after 10-12 weeks of surgery.

The active follow-up regimen constituted both clinical and radiological examination post-operative at regular intervals of 6 weeks, 12 weeks, 6 months, and at least 1 year after surgery. All radiographs were reevaluated for studying radiological evidence for complications including mal-union, avascular necrosis, non-union, and failure of the implant or not. Postoperatively, functional outcome of operated shoulder was assessed by Constant scoring system 1 and complications if any were noted.

The values for operated side were compared with that of contralateral side and were represented in absolute values in terms of percentage of contralateral side. The differences noted with respect to Constant scoring system the score results were checked for statistical significance using 't' test and ANOVA (analysis of variance) test (STATISTICS CALCULATORS VERSION 3.0 BETA) was used for continuous variables. The significance was set at value $P < 0.05$.

Results

Out of 35 patients four were lost in follow-up, hence we have compiled our data according to 31 patients. Maximum patients from the study group belonged to the age group 61-70 years (12 patients). Most of cases (23 patients, 74.19% cases) were operated upon within 3 days.

Around half of the patients had 3-part fractures. The improvement in constant scores (individual component, and total) was statistically significant over the course of 6 weeks, 3 months, and 6 months (Table 1, and Table 2). Though the average Constant score was relatively lesser among the 4-part fractures (67) as compared to 2, and 3-part fractures (79, and 75) at final follow up, it did not reach the desired statistical significance due to inadequate sample sizes. Total 31 patients, 20 patients (3 excellent, 17 good) had satisfactory results. Also, the average % percentage improvement in constant score at 6-months did not differ significantly between the cases aged less than 60 years and more than 60 years. The average time for fracture union was around 13 weeks.

The two most common complications were screw perforation of the head of humerus, and sub-acromial impingement in three patients (9.67%) each respectively. Out of three screw

perforations, one was diagnosed next post-operative day which was exchanged with smaller one. Two patients were diagnosed with screw perforation at 3 months of follow-up. One of those two had re-operated for screw exchange and other had screw removal. After reoperation one patient had improved his constant score at 6 months but another could not improve because the patient refused for surgery till six month of follow-up. One patient had superficial wound infection that healed with local wound treatment and oral antibiotics.

Non-union of proximal humerus was seen in one patient post fixation. It was 2-parts surgical neck fracture, and was not reduced well intra-operatively. The muscle forces weren't balanced and medial support wasn't restored. Hence, it went into varus non-union. Patient was counselled regarding

revision ORIF and bone graft versus Arthroplasty. Patient did not take decision to undergo surgery till last follow-up.

One patient was diagnosed with osteonecrosis of humeral head at 6 month of follow up and partial collapse of humeral head, the fracture was 4-part according to Neer's classification. The patient had poor constant score in initial follow-up, and improved a little only in next visits. Hence, the result was poor according to constant score grading system. The fracture was united in timely fashion. Surprisingly, patient had mild pain at 6 months. Patient was advised that he would require reoperation with hemiarthroplasty of humeral head but the elderly patient continued the same and regular follow up.

Table 1: Statistically significant over the course of 6 weeks, 3months, and 6 months

Component	Follow-up			P-values		
	6 Week (n = 31)	3 Month (n = 31)	1 Year (n = 31)	6 Week v/s 3 Month	6 Week v/s 1 Year	3 Month v/s 1 Year
Pain	5.48 ± 1.50	9.35 ± 2.50	13.71 ± 2.22	0.001 (S)	0.001 (S)	0.001 (S)
ADL	5.74 ± 1.34	9.29 ± 1.9	15.35 ± 2.09	0.001 (S)	0.001 (S)	0.001 (S)
Power	6.45 ± 1.84	12.48 ± 3.15	19.32 ± 3.23	0.001 (S)	0.001 (S)	0.001 (S)
Abduction	2.62 ± 0.94	4.29 ± 1.44	6.65 ± 1.40	0.001 (S)	0.001 (S)	0.001 (S)
Forward Flexion	3.55 ± 0.85	5.61 ± 0.95	7.81 ± 1.19	0.001 (S)	0.001 (S)	0.001 (S)
Internal Rotation	3.35 ± 1.08	4.97 ± 1.02	7.10 ± 1.01	0.001 (S)	0.001 (S)	0.001 (S)
External Rotation	2.13 ± 0.5	3.55 ± 1.23	6.06 ± 1.21	0.001 (S)	0.001 (S)	0.001 (S)
Total Score	29.29 ± 5.49	49.58 ± 7.32	76.0 ± 7.98	0.001 (S)	0.001 (S)	0.001 (S)

Table 2: Statistically significant over the course of 6 weeks, 3months, and 6 months

% Improvement in Constant Score	Follow-up				P-values		
	Normal Shoulder (n=31)	6-Weeks (n=31)	3-Months (n=31)	1-year (n=31)	Normal v/s 6-Weeks	Normal v/s 3-Months	Normal v/s 1-year
Mean ± Standard Deviation	0.0%	-69.98% ± 5.03%	-48.89% ± 6.83%	-21.67% ± 6.50%	0.0001 (S)	0.0001 (S)	0.0001 (S)

Discussion

This study supports the use of locking plate for fixation of 2, 3, and 4-parts fracture (Fig.1, Fig.2) of proximal humerus. Using this modality can yield satisfactory functional results in significant number of patients, and locking construct helps in early mobilization of shoulder, hence, it can reduce post-operative stiffness.

According to the Finnish study, proximal humeral fractures represent an increasing challenge for the health-care system especially in the increasing proportion of elderly population and also in increasing number of Road Traffic Accidents [15].

Open reduction and internal fixation of proximal humeral fractures with non-locking plates and screws has been shown to provide the strongest fixation in non-osteoporotic bone. For displaced fracture, traditional treatment with conventional plates and screws has been associated with high rates of unsatisfactory results and complications in osteoporotic bones [16].

As the stability of the osteosynthesis with non-locking plates and screws relies on the friction between the plate and bone, the effectiveness of traditional plate-and-screw fixation decreases with bone quality. Complications such as screw loosening and secondary loss of reduction resulting from the insufficient purchase of screws in osteoporotic bone lead to high failure rates, especially among patients with three and four-part fractures.

In the year 2000, Ruedi TP *et al.*, [17] explained that by following conventional AO techniques, locking screw provide the ability to create a fixed angle construct. Such construct supersedes in osteoporotic bone or multi-fragmentary fractures where traditional screw purchase is compromised.

Locking plates are angular stable plates which has advantage of secure fixation in metaphyseal and osteoporotic bones. There are biomechanical studies which suggest that locking plates resist physiological loads more effectively. Locking plates give the possibility of early exercise and a short period of immobilization [18].

There was a study conducted by Moonot P *et al.*, [19] in 2007 about the functional outcomes in proximal humerus fractures using PHILOS, but he only used 3, and 4-parts fractures. The study was conducted on 32 patients out of which 23 were men, and nine were men. The mean Constant score at final follow-up was 66.5 whilst in our study it was 76 as there has been improved understanding over the course of years in surgical method, and rehabilitation protocol for patients treated by ORIF with locking compression plates.

In cohort study conducted on 413 patients, Thorness *et al.*, [19] while Comparing ORIF with hemiarthroplasty for proximal humerus fractures found ORIF is better for younger patients, and have less operative complications and blood loss compared to the hemiarthroplasty cohort.

Although, hemiarthroplasty is another option for 4-parts proximal humerus fractures, in a meta-analysis conducted by Dai *et al.*, [20] for complex proximal humerus fractures it was concluded that ORIF with locking plate fixation could yield better functional outcomes than hemiarthroplasty provided the fundamentals of internal fixation followed to avoid the possibility of the implant failure and osteonecrosis of humeral head, and hence second surgery.

In our study, the male to female ratio is 17:14. In our country males are more involved in outdoor activities and predisposed to road traffic accident and high energy trauma which

explains our observation. Right side was more commonly involved, in 21 patients (67.74%) and left side in 10 patients (32, 26%) in our study. This is due to the right side dominance during reflex protective mechanism of the body. According to the Neers classification, 16 patients (51.61%) were having 3-parts fractures which was the most common. 11 patients (35.48%) and 4 patients (12.91%) were having 2-parts and 4-parts fractures respectively. Our patients had greatest limitation in abduction and external rotation of operated shoulder as compared to flexion and internal rotation movements in initial 6 weeks and 3 months. But after starting muscle strengthening exercise from 3 months, as according to rehabilitation program, abduction movement improved in 6 months.

The final outcome was evaluated by the difference between the operated shoulder Constant score and normal shoulder Constant score as excellent, good, fair and poor. 3 patients (9.68%) had excellent results, 17 patients (54.84%) had good results, 8 patients (25.80%) had fair results and 3 patients (9.68%) had poor results. The satisfactory results (excellent and good) were 64.51% and unsatisfactory (poor and fair) were 35.49%.

In spite of a short follow-up time, and the study being non randomized controlled trial, the results are still convincing about the usage of locking plate in proximal humerus fractures. The following are advantages of the plate—easy use, simple technique required, preformed contouring, biological fixation and angular screw fixation gives fixed angle stabilization. Furthermore, the complications recorded in this study almost similar to the previous study signifying its reproducibility. Many common complications of conventional plating can possibly be avoided. Careful proximal placement of the plate under vision and the x-ray machine, and divergent fixation of proximal screws along with adequate distal screws are essential to prevent impingement, and mal-union respectively. The study would justify the usage of PHILOS in displaced, and comminuted fractures of proximal humerus. However, a more randomized study is still needed to justify this promising method of fixation in future.



Fig 1A: 2-part PHF fracture

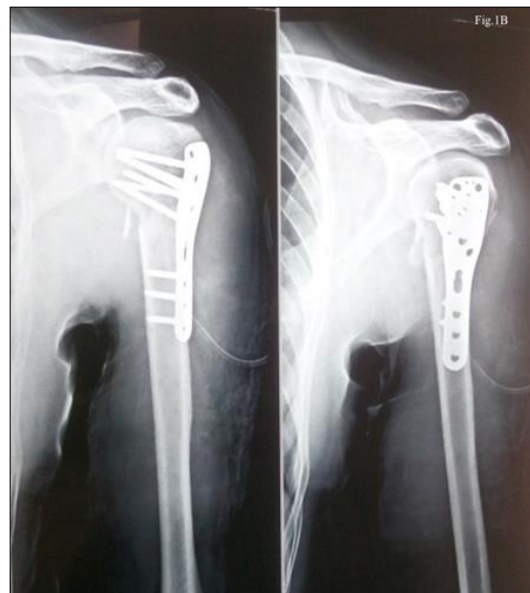


Fig 1B: Fracture healed at final follow up



Fig 2A: Shows 4-part PHF



Fig 2B: Shows screw perforation at 3 month

Conclusion

Locking plate can be a promising implant for fixation of proximal humerus fractures, and due to locking screws, it can work satisfactorily in elderly with osteoporotic fractures with augmentation like cement or bone graft. During surgery, careful proximal placement is crucial to prevent implant related complications which can hinder future functional outcomes to subnormal level, and re surgery. A careful planning is essential before surgery, and post-operative physiotherapy is very crucial in achieving the adequate functional outcomes. The patient needs to be followed regularly to achieve normal functional outcomes, and recognize the complications early. It is essential that a larger study with complete randomization is essential in future for further research.

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