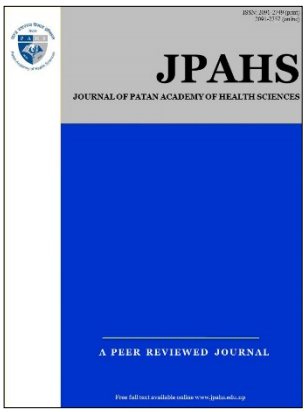


ISSN: 2091-2749 (Print)
2091-2757 (Online)

# Evaluation of effectiveness of locking compression plates in internal fixation of proximal humerus fractures: a prospective study

Shreel Koirala

Lecturer, Dept. of Orthopaedics, Birat Medical College, Biratnagar, Morang, Nepal

**Correspondence**
Dr. Shreel Koirala
Dept. of Orthopaedics
Birat Medical college,
Biratnagar, Morang, Nepal
Email: shreelkoirala@gmail.com

**Submitted**
25 Mar 2023

**Accepted**
30 April 2023

**How to cite this article**
Koirala S. Evaluation of effectiveness of locking compression plates in internal fixation of proximal humerus fractures: a prospective study. Journal of Patan Academy of Health Sciences. 2023Aug;10(2):20-27.

https://doi.org/10.3126/jpahs.v10i2.59125

## Abstract

**Introduction:** Locking compression plate (LCP) provides significant biological and biomechanical advantages in the management of proximal humerus fracture (PHF) by providing greater stability, vascular preservation, superior healing, and fewer complications. However, the translation of these properties to functional benefits for patients remains to be elucidated. The objective of the study was to evaluate the effectiveness of LCP in internal fixation of PHF in terms of rate of healing and functional outcomes.

**Method:** This prospective study enrolled 30 Proximal Humerus Fracture patients aged >18 years, from both genders, and treated them with LCP. They were followed up regularly for 1 year and assessed clinically and radiologically using Neer's criteria and Constant-Murray score. Results were analysed using Chi-square test, p≤0.05 indicated statistical significance.

**Result:** With a mean age of 45.20±15.02 y and M:F ratio of 2.3:1, most patients showed right-sided injuries 18(60%) and Neer 4-part injuries 13(43.33%), predominantly due to road traffic accidents 19(60%), with a satisfactory Neer's score 26(86.67%) and a good Constant-Murray score 16(53.33%). The mode of injury showed significant association with age (p=0.013) but not with gender (p=0.866). Over follow up, 27(90%) patients maintained humeral head height and 24(80%) patients showed good humeral neck-shaft angle. Radiological union of PHF took 12 weeks in 12(43.33%) of patients with no dislocation in 27(90%) of patients. However, 1(3.3%) patient showed no union.

**Conclusion:** LCP is associated with favorable clinical, functional and radiological outcomes in PHF patients by providing rapid healing and good rigidity, angular stability, and torsional strength.

**Keywords:** fracture fixation, fracture healing, shoulder fractures

## Introduction

Proximal humerus fracture (PHF) is the commonest fracture affecting the shoulder girdle in adults, comprising 4-5% of all fractures.[1] It accounts for over 10% of fractures among elderly and predisposes elderly women to a 2.5 times higher risk of hip fracture.[2,3]

Management of PHF requires accurate diagnosis and options which have long been subject to various controversies.[3,4] Operative treatment goals include anatomical reduction of the articular surface, early postoperative shoulder range of motion, and early patient mobilization.[3,4]

The recent evolution of locking compression plates (LCP) has revolutionized extremity fracture treatment.[5-7] LCP has a unique biomechanical function as it provided flexible stabilization, avoids stress shielding, and induces callus formation. LCP can also be used in minimally invasive techniques where it allows for prompt healing, lower infection rates, and reduced bone resorption by preservation of blood supply.[6-10] Consequently, LCP provides an effective solution to overcome age-old complications associated with PHF treatment with traditional fixed angle plates resulting from their inherent lack of rigidity such as postoperative loss of reduction, malalignment, and implant failure.[6-10] Proximal humerus inter-locking osteosynthesis system (PHILOS), based on the firm principles of locked plating, has yielded tremendous success in the treatment of such fractures over the years.[11]

However, the translation of these mechanical and biological properties to clinical and functional benefits for the patients, especially with indigenous LCP, remains to be elucidated. Therefore, the present study was conducted to evaluate the effectiveness of LCP in internal fixation of PHF in terms of rate of healing and functional outcomes.

## Method

This hospital-based, prospective study was conducted at a tertiary care hospital in Bengaluru, India, from May 2015 to December 2016, after obtaining ethical clearance from the Institutional Review Board.

The study included 30 skeletally mature PHF patients aged >18 years, irrespective of their gender, presenting with displaced PHF diagnosed according to NEER two, three, and four parts, PHF with shoulder dislocation, and those with failure of implants undergoing revision surgery with LCP. An informed consent form was obtained from all the study participants.[12] The study excluded patients <18 years of age, NEER four-part fractures in the elderly, patients with open fractures, pathological fractures from primary or metastatic tumors, and poly-trauma.

After a thorough history and examination as per advanced trauma life support (ATLS) guidelines, a detailed musculoskeletal and neurovascular examination of the injured limb was performed.[13] The patients were stabilized with intravenous (IV) fluids, oxygen, blood transfusion, antibiotics, and analgesics, as needed. The involved limb was immobilized using a shoulder immobilizer. Pre-operative routine investigations included hemogram, blood sugar/urea/creatinine levels, liver function tests, blood grouping, bleeding time, clotting time, chest X-ray postero-anterior view, shoulder X-ray antero-posterior view, doppler, electro- and echocardiography, and pre-anesthetic evaluations. Fractures were radiologically classified as per Neer's classification.[14] Preoperative radiographic calculations were done to ascertain the size of the plate, and screws. One gram of third-generation cephalosporin was injected intravenously 10 min before surgery.

With the patient supine on a radiolucent table, head end elevated, and a sandbag below the same scapula, the entire injured extremity and ipsilateral axilla were prepared. An incision was made from the lateral edge of the coracoid process tip, paralleling the anterior deltoid

border, to the deltoid insertion. The deltopectoral interval was identified, the cephalic vein reflected medially, and sub-deltoid dissections were performed with an elevator and a finger guiding the fracture fragments. Reduction was performed with a heavy non-absorbable suture passed through the rotator cuff where it attached to the greater tuberosity (tendon-bone junction), thus controlling the head fragment. If the head was in varus, inferiorly pulling this suture brought it to an anatomic position. In NEER two-part fractures, the shaft was mobilized to align with the head. The plate was then slid along the anterolateral cortex of the proximal humerus with its proximal part against greater tuberosity and its inferior portion against the shaft. After reduction, clamp A was placed to hold the plate against the shaft with its tip below the greater tuberosity tip to prevent the postoperative decrease in elevation/abduction and enable the correct placement of calcar screws. Repeated C-arm checking was mandatorily performed to confirm appropriate fracture reduction and plate position.

The plates and screws used were manufactured from 316L stainless alloy with gun drilling technique or titanium. The LCP used was PHILOS (proximal humerus internal locking Osteosynthesis) in the current study. The LCP used had 3.5 mm thickness, 3-5 holes, an anatomically pre-contoured plate head with soft edges, and locking screws for secure support. The head of the locking screw was threaded and locked to the plate. LCP combi-holes in the plate shaft provided an intraoperative choice between angular stability and compression. The plate has small holes to temporarily pass wires through it into the head preventing plate shifting. Under fluoroscopic guidance, a drill was passed through the plate into the head to a depth of 8-10 mm from the articular surface followed by insertion of 5-6 locking screws into the head and 2-3 additional screws along the calcar, under c-arm guidance. Bicortical screws secured the plate distally. The clasps were then removed. These screws could be locking or non-locking according to the bone quality.

For three-part fractures, long head of the biceps was used to guide fragments positioning. If the head was in valgus, it was gently brought up to face the glenoid, without disturbing its stable medial periosteal cortical hinge. The greater tuberosity was placed behind the plate and temporarily stabilized to the head with K-wires. This position was confirmed under the c-arm with its 6-10 mm below the reduced head and the plate tip below the greater tuberosity tip. The shaft was reduced such that its medial cortex aligned with the medial inferior edge of the head and its lateral cortex with the inferior edge of the greater tuberosity. The shaft was clamped to the plate and screws were placed into the head through the plate, tuberosity, and into the shaft. A final C-arm assessment was always done before routine closure.

The patient's vitals were monitored. Antibiotics and analgesics were given as per the hospital protocol. Blood transfusion was given depending upon the preoperative general condition and intraoperative blood loss. The operated arm was elevated and placed in an immobilizer. Within a few days after the surgery, elbow, wrist, finger, and thumb motions were started. Shoulder motions were started 2-4 w postoperatively, allowing early healing and minimizing the risk of loss of reduction, screw penetration, and screw pull-out.

All patients were followed up at the $4^{th}$, $10^{th}$, $14^{th}$, and $18^{th}$ w followed by every 6 w thereafter until fracture union was noted, and subsequently at the $6^{th}$ and $9^{th}$ month and 1 y. Patients were assessed clinically, radiologically, and functionally using Neer's criteria and Constant-Murley scoring.[14,15] Post-operative radiological evaluations were done, Figure 1a-c. Humeral head height (HHH) was measured as the distance between two lines drawn perpendicular to the shaft of the plate, one placed at the top edge of the plate and the other at the superior edge of humeral head.[16] A difference of >3 mm in the HHH between immediate and final follow-up appointments, measured relative to the plate on AP radiographs, indicated a loss of reduction.

Humeral neck-shaft angle (HNSA) was measured on a true shoulder AP view as the angle between the line bisecting the humeral shaft and the line perpendicular to the line from the superior border to the inferior border of the articular surface. It was graded radiographically as 'good' (121°-140°), 'fair' (100°-120°), or 'poor' (<100°).[17] The last follow-up x-ray was used to evaluate the patients for avascular necrosis using Cruess classification, a system modified from Ficat & Arlet classification.[18-20]

Data was compiled & analyzed using statistical software R version 4.0.3 and Microsoft Excel. QQ plot/Shapiro-Wilk's test was used to check the normality of variables. Continuous variables are represented in mean±standard deviation (SD) form and categorical variables by a frequency table. Chi-square test was used to assess the association between two categorical variables. A p-value ≤ 0.05 indicated statistical significance.

## Result

The study consisted of 30 PHF patients with a mean age of 45.20±15.02 y and a M:F ratio of 2.3:1, Table 1 and 2. Most patients suffered from right-sided injury 18(60%), predominantly NEER 4-part injury 13(43.33%), most commonly due to road traffic accident 19(60%). Irrespective of poor radiological outcome, majority patient showed satisfactory NEER's score 26(86.67%) and a good Constant-Murley score 16(53.33%), Figure 1. On follow-up, HH was maintained in 27(90%) of the patients and 80% of patients showed good HNSA. Radiological union of PHF took 12 w in 12(43.33%) of patients with no dislocation in 27(90%) of patients. However, 1 patient showed no union. The chi-square test (Monte Carlo test) revealed that the mode of injury showed a significant association with age (p=0.013) but not with gender (p=0.866), Table 3 and 4.

**Table 1. Age, DASH Score and Working Capacity of patients treated for PHF**

| Variables | Mean (SD) | Median (IQR) |
|---|---|---|
| Age | 45.20 (15.02) | 45 (36, 59.25) |
| DASH | 33.28 (14.66) | 30.65 (25.05, 39.03) |
| WC | 8 (1.58) | 8 (8,8) |

DASH, Disabilities of the Arm, Shoulder and Hand Score; IQR = Interquartile range; SD = Standard deviation; WC, Working Capacity.

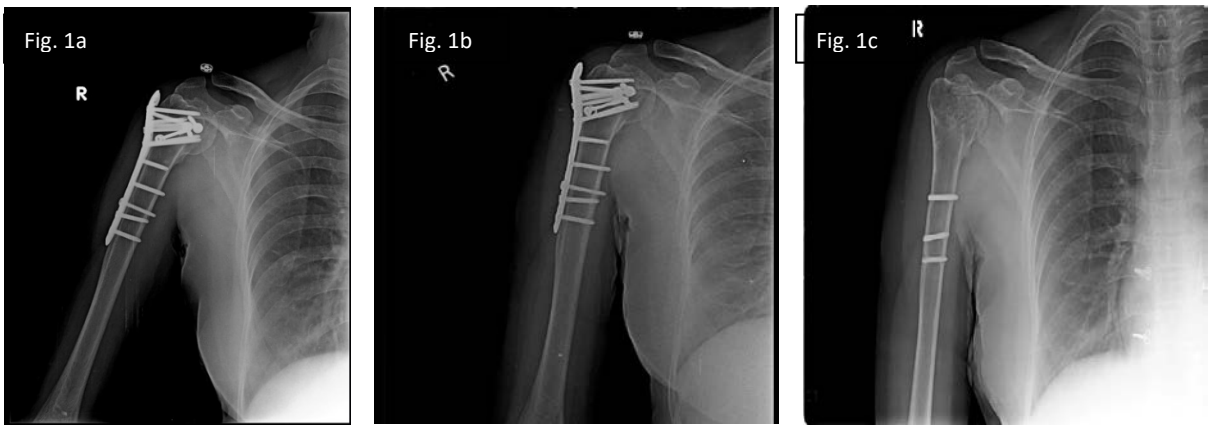


**Figure 1. The plane radiographs (AP views) of a case of self-fall, treated with Proximal Humerus internal locking system (PHILOS) a) immediate postoperative view b) 6 months follow up c) 12 months follow up (PHILOS removed)**

**Table 2. Categorical variables of patients treated for PHF**

| Variables | Subcategory | N (%) | Variables | Subcategory | N (%) |
|---|---|---|---|---|---|
| Gender | Female | 9(30%) | Constant-Murley score | Excellent | 1(3.33%) |
| | Male | 21(70%) | | Fair | (40.00%) |
| Age groups (years) | <20 | 2(6.67%) | | Good | 16(53.33%) |
| | 20-30 | 5(16.67%) | | Poor | 1(3.33%) |
| | 31-40 | 4(13.33%) | NEERS score | Excellent | 2(6.67%) |
| | 41-50 | 8(26.67%) | | Failure | 1(3.33%) |
| | 51-60 | 5(16.67%) | | Satisfactory | 26(86.67%) |
| | >60 | 6(20.00%) | | Unsatisfactory | 1(3.33%) |
| DASH score | <30 | 14(46.67%) | Humeral height | Maintained | 27(90%) |
| | 30-40 | (36.67%) | | Not maintained | 3(10%) |
| | >40 | (16.67%) | Humeral neck shaft angle | Fair | 5(16.67%) |
| CM | DM | 5(16.67%) | | Good | 24(80.00%) |
| | DM, HTN | 2(6.67%) | | Poor | 1(3.33%) |
| | DN, HTN | 1(3.33%) | Time taken for radiological union (weeks) | 10 weeks | 7(23.33%) |
| | HTN | 4(13.33%) | | 11 weeks | 1(3.33%) |
| | N | (56.67%) | | 12 weeks | 13(43.33%) |
| | SD | 1(3.33%) | | 8 weeks | (26.67%) |
| Mode of injury | Direct blow | 2(6.67%) | | No union | 1(3.33%) |
| | RTA | 18(60.00%) | RS | Fair | 13(43.33%) |
| | Self-fall | 10(33.33%) | | Good | 16(53.33%) |
| Side of injury | Left | 12(40%) | | Poor | 1(3.33%) |
| | Right | 18(60%) | Dislocation | No | 27(90%) |
| NEER | 2-part | 7(23.33%) | | Yes | 3(10%) |
| | 3-part | 10(33.33%) | | | |
| | 4-part | 13(43.33%) | | | |

DASH: Disabilities of the Arm, Shoulder and Hand Score; CM: co-morbidities; DM: Diabetes mellitus; DN: Diabetic neuropathy; HNT: Hypertension; N: Sample size; RTA: Road traffic accident; RS: Radiological score; SD: Standard deviation

**Table 3. Association between age and mode of injuries in patients with PHF**

| Mode of Injuries | Age (in y) | | p-value |
|---|---|---|---|
| | ≤50 | >50 | |
| Road traffic accident | 14(73.68%) | 4(36.36%) | 0.013*[MC] |
| Self-Fall | 3(15.79%) | 7(63.64%) | |
| Direct Blow | 2(10.53%) | 0 | |

MC, Chi-square test Monte Carlo test, * indicates statistical significance

**Table 4. Association between gender and mode of injuries in patients with PHF**

| Mode of Injuries | Gender | | p-value |
|---|---|---|---|
| | Female | Male | |
| Road traffic accident | 1(11.11%) | 1(4.76%) | 0.866[MC] |
| Self-Fall | 6(66.67%) | 12(57.14%) | |
| Direct Blow | 2(22.22%) | 8(38.10%) | |

MC, Chi-square test Monte Carlo test

## Discussion

Considering the high incidence of PHF, especially among the elderly, exploring the most reliable and appropriate management strategies for these fractures becomes of utmost importance. The locking plates have been widely used in recent years because of their biomechanical and biological advantages over conventional plates. However, the effective and successful use of locking plates remains challenging and requires a learning

curve.[1-4] In view of this, the present study was conducted to evaluate the effectiveness of LCP in internal fixation of PHF in terms of rate of healing and functional outcomes.

The study used an Indian-made, pre-bent fixed angle plate with the dual function of achieving compression at the fracture site when required and obtaining rigid fixation by locking the screw to the plate, in turn reducing the plate back out, thus providing angular stability. The locking screws were self-tapping available in 4 mm and 4.5 mm thickness.

The epidemiology of the study cohort and outcomes observed are consistent with previous literature. A study among 13 male and 9 female PHF patients, with a mean age of 57 years (age distribution 35-83 years), using PHILOS plates observed a high fracture union rate with this technique that is nearly ideal to LCP.[21] The rate of union noted in the present study (96.7%) using LCP is also similar to two other studies whereby the union rates were 97.2% and 80% respectively.[22,23] This is most likely owing to the rigid stable fixation and vascular preservation offered by the locking principle.[6-10]

However, other two studies have reported problems with implant failure, screw protrusion, and backing out at rates of 3% (2/72) and 16% (4/25) respectively, while only 1 patient (3.33%) experienced implant failure and eventual non-union in the present study.[22,23]

While conventional plate osteosynthesis has been associated with frequent hardware impingement, no such complication with the PHILOS plate have been found in a study.[22] It was seen that the PHILOS plate were most beneficial in elderly patients, as no failure of internal fixation was seen in this particular group, besides attainment of an activity level sufficient for fulfilling independent daily living needs.[22] Thus, LCP used in the current study was PHILOS. These plates could even withstand a new fall.[22] A study reported good anatomical reduction with LCP in the majority of the patients with near anatomic fixation being achieved in the remainder.[10]

In another research, among 10 patients treated with minimally invasive bone grafting and suturing found the average disabilities of the arm, shoulder, and hand (DASH) score to be 23.0, while the present study showed a mean DASH score of 33.28.[24] However, it appears that they were more selective in their inclusion criteria, choosing to exclude comminuted humeral head fractures in patients that could not be reconstructed properly.[24]

It has been difficult to compare the results of the present study with those of other studies, owing to differing inclusion/exclusion criteria and the variety of shoulder scoring systems used. Nevertheless, the present study establishes that LCP is associated with significant clinical, functional, and radiological improvements with hastening of fracture union rate in PHF patients. LCP provides rigid fixation in the region of the proximal humerus, especially for fractures in three or four parts, epiphyseal fractures in young patients, and fractures in fragile bones that pose greater technical difficulty in fixation. However careful understanding of basic principles and identification of appropriate fracture patterns for use of LCP is essential to avoid complications like non-union. Further comprehensive, multicentric studies with a larger sample size and longer follow-up periods are encouraged to explore these and other fracture fixation systems, in order to facilitate better outcomes.

## Conclusion

LCP is associated with favorable clinical, functional, and radiological outcomes in PHF patients by providing rapid healing and good rigidity, angular stability, and torsional strength. Sound knowledge of principles and indications for LCP use is essential to achieve beneficial results.

## Acknowledgement
None

## Conflict of Interest
None

## Funding
None

## Author contribution
All: SK.

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