

Proximal humeral internal locking plate combined with a custom neutral-position shoulder and elbow sling for proximal humerus fractures

A randomized study

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Abstract

Objectives: The aim of this study was to investigate the effectiveness of the proximal humeral internal locking system (PHILOS) plate combined with a custom neutral-position shoulder and elbow sling for proximal humerus fractures.

Methods: A total of 112 patients with proximal humerus fractures were assigned randomly into 2 groups. Group A (n=56) was treated by open reduction and internal fixation (ORIF) with a PHILOS plate; group B (n=56) was treated by ORIF with a PHILOS plate in combination with the use of a custom neutral-position shoulder and elbow sling for 30 days after surgery. The incidence of internal fixation failure, the Constant–Murley shoulder assessment, and Visual Analogue Scale (VAS) score were recorded and analyzed.

Results: Patients included were followed up for an average of 15 months (range, 6–24 months). No significant differences were observed in mean VAS scores and mean Constant–Murley shoulder assessment scores at 1-day preoperative and postoperative day 3 between groups A and B. However, mean VAS scores and mean Constant–Murley shoulder assessment in group B were significantly improved when compared with group A at postoperative day 30 and the final follow-up. No cases of postoperative infection, loss of reduction, PHILOS break, or vascular nerve injury occurred in either group.

Conclusions: Proximal humerus fractures treated with the combination of the PHILOS and custom neutral-position shoulder and elbow sling for 30 days after operation was associated with a lower incidence of internal fixation failure. There was no increase in adverse events compared with open reduction and internal fixation with a PHILOS plate alone.

Abbreviations: ORIF = open reduction and internal fixation, PHILOS = proximal humeral internal locking system, VAS = Visual Analogue Scale.

Keywords: custom neutral-position shoulder and elbow sling, humeral fractures, internal fixation, internal fixation failure, PHILOS plate

1. Introduction

Proximal humerus fractures, most of which are linked to osteoporosis,^[1,2] account for about 4% to 5% of all human fractures. In the past 3 decades, the incidence of proximal humerus fractures has increased by 13.7%.^[1–3] Nondisplaced proximal humerus fractures and those with adequate stability

and minimal displacement can be successfully managed with conservative treatment.^[4] Unstable and displaced proximal humerus fractures usually require surgical intervention; however, the optimal surgical approach remains a topic of debate.^[5,6]

In recent years, the proximal humeral internal locking system (PHILOS) has proved efficient for proximal humerus fractures. The PHILOS is an interlocking anatomically precontoured plate that is broader at its proximal than its distal end.^[7] Good functional outcomes have been reported after fixation with the PHILOS plate.^[8,9] However, some postoperative complications have been reported, including poor shoulder joint function, reduction loss, failure of the internal fixation, impingement syndrome, malunion or nonunion of the fracture, and humeral head osteonecrosis.^[10–13]

The main aim of our study was to investigate early clinical results in 112 cases with proximal humerus fractures who were treated by open reduction and internal fixation (ORIF) using the PHILOS plate alone or in combination with a custom neutral-position shoulder and elbow sling.

2. Patients and methods

2.1. Study population

The cases presented with proximal humerus fractures from a prospective cohort study, included in the present investigation,

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Figure 1. Postoperative routine suspension.

are a subset of patients who were part of 2 participating centers with similar protocols (The First Affiliated Hospital of Medical University of Anhui, Putian University Affiliated Hospital, and The First Affiliated Hospital of Fuzhou Military Region General Hospital) between January 2012 and June 2016. All cases with proximal humerus fractures for open reduction and internal fixation must meet the surgical indications, as outlined by Neer.^[14,15] Patients with pathological proximal humerus fractures, cleavage fractures of the humeral head, 4-part fractures, or clear contraindications to surgery were excluded. Patients were randomized into 2 groups according to the random number table produced by the computer, group A or group B. Group A received ORIF with a PHILOS plate combined with the use of a routine suspension for 30 days after surgery (Fig. 1), while group B received ORIF with a PHILOS plate combined with the use of a custom neutral-position shoulder and elbow sling for 30 days after surgery.

The present study was approved by the Institutional Research Committee of the Medical University of Anhui, Putian University Affiliated Hospital, and Fuzhou Military Region General Hospital. Informed written consent was obtained from all the participants.

2.2. Surgical procedures

All patients were managed with similar protocols for ORIF using the PHILOS plate. Under brachial plexus block or general anesthesia, patients on a radiolucent table were operated in supine position. The involved extremity was abducted, placed on a 4 to 6 cm cushion, and operated using a deltopectoral approach. Following retraction of the deltoid muscle at the intertubercular groove, the cephalic vein, axillary nerve, and musculocutaneous nerve were exposed and protected. Displaced fractures were provisionally reduced. Subsequently, the reduced fracture fragments were stabilized in an anatomical position using K-wires under the guidance of intraoperative fluoroscopy. The PHILOS was positioned, assisted by a mounted aiming device, ≥ 10 mm

distal to the proximal end of the greater tuberosity and 5 to 10 mm posterior to the intertubercular groove, during which careful attentions were paid for ensuring that a sufficient gap was maintained between the tendon of the long head of the biceps and the PHILOS plate. If necessary, the tendon of the long head of the biceps should be reconstructed. The PHILOS plate was placed and fixed firmly with the aid of inserting stable screws into the injured humeral head when adequate reduction of the fracture and subsequent positioning of the screw was confirmed, a final fluoroscopy for verifying the correct placement of the PHILOS was conducted at the discretion of the orthopedic surgeon.

Postoperatively, group B was treated with a custom neutral-position shoulder and elbow sling for 30 days after the surgery (Fig. 2). The injured extremity in a sling was immobilized and passive exercise was also initiated within 2 days after the operation. Controlled active mobilization with abduction, lifts, arm swings, and flexion beyond 90 degrees was initiated during postoperative day 7 to day 21 on the basis of bone quality and stability of the PHILOS plate.

2.3. Outcome measurements

Baseline demographic and clinical characteristics of each patient were recorded upon admission to hospital. Follow-up appointments were scheduled for 3 and 30 days postsurgery, along with a final follow-up appointment. At each follow-up visit, the patient was assessed for internal fixation failure, using X-ray, and defined as the loosening or breakage of the hardware. The Constant–Murley shoulder assessment score and the Visual Analogue Scale (VAS) pain score were recorded. Shoulders were rated using the Constant–Murley shoulder function assessment score as excellent (86–100 points), good (71–85 points), fair (56–70 points), or poor (≤ 55 points) based on quality of daily life (20 points), pain (15 points), mobility (40 points), and strength (25 points).^[16] Patients evaluated pain intensity using the VAS with 0 as no pain and 10 as the worst possible pain.^[17] The primary outcome was set as constant shoulder function score at 30 days postsurgery.

2.4. Statistical analysis

Sample size was calculated using the primary end outcome. According to our preliminary experiment, mean score was 80 and standard deviation was set 9. We set a difference of 5 between 2 groups, $\alpha=0.05$, $\beta=0.2$, the sample size should be 102. Considering 10% dropout rate, we finally enrolled 102 patients.

Statistical analyses were conducted using SPSS 17.0 software (SPSS Inc., Chicago, IL). Pre- and postoperative Constant–Murley shoulder assessment scores, VAS scores, and the incidence of postoperative complications in each group were analyzed using χ^2 test or Student *t* test. Any $P < .05$ was considered statistically significant.

3. Results

A total of 112 cases with proximal humerus fractures, including 52 two-part fractures and 60 three-part fractures based on the Neer classification, were included in this study. Group A ($n=56$) included 17 males and 39 females with a mean age of 64.29 ± 6.61 years (range 41–72 years). In this group, 2 patients were classified as American Society of Anesthesiologists (ASA) I, 52 patients were classified as ASA II, and 2 cases were classified as ASA III. Group B ($n=56$) included 20 males and 36 females with



Figure 2. Postoperative use of a custom neutral-position shoulder and elbow sling.

an average age of 64.18 ± 6.76 years (range 42–70 years). In this group, 3 cases were categorized as ASA I, 51 cases were categorized as ASA II, and 2 cases were categorized as ASA III. There was no significant difference in terms of baseline demographic and clinical characteristics between groups, including the degree of osteoporosis (Table 1).

All operations were performed successfully in both groups. Patients included were followed up for an average time of 15 months (range, 6–24 months). No significant differences were observed in the mean Constant–Murley shoulder assessment score

and mean VAS score at 1-day preoperative or postoperative day 3 between groups A and B. However, the mean Constant–Murley shoulder assessment scores and mean VAS scores in group B were significantly improved at postoperative day 30 and the final follow-up visit when compared with group A (Tables 2 and 3).

There were no cases that showed loss of reduction, postoperative infection, PHILOS breaking, or vascular nerve injury occurred in either group. In group A, internal fixation failure occurred in 5 patients (8.92%) during the day 3 to day 30 postoperative period (Table 4). Of these cases, 2 patients (40%)

Table 1
Baseline characteristics of the patients.

	Group A (n=56)	Group B (n=56)	χ^2 or <i>t</i>	<i>P</i>
Sex (male/female)	17/39	20/36	0.363	.547
Age, y	64.29 ± 6.61	64.18 ± 6.76	0.087	.931
ASA (n, %)			0.210	.901
I	2 (3.57%)	3 (5.36%)		
II	52 (92.86%)	51 (91.07%)		
III	2 (3.57%)	2 (3.57%)		

Table 2
Constant shoulder function score ($\bar{x} \pm s$).

Group	N	Constant shoulder function score			
		Day 1 preoperative	Day 3 post operative	Day 30 post operative	Final follow-up
A	56	1.52 ± 0.69	80.73 ± 5.52	76.04 ± 18.97	85.98 ± 4.99
B	56	1.59 ± 0.83	81.07 ± 4.84	86.39 ± 4.70	88.27 ± 4.10
<i>t</i>		-0.497	-0.346	-3.966	-2.650
<i>P</i>		.620	.730	<.0001	.009
		>.05	>.05	<.05	<.05

Table 3
Visual Analogue Scale ($\bar{x} \pm s$).

Group	N	Visual Analogue Scale			
		Day 1 pre operative	Day 3 post operative	Day 30 post operative	Final follow-up
A	56	8.50 ± 0.66	2.27 ± 0.65	2.71 ± 1.57	1.84 ± 0.60
B	56	8.50 ± 0.71	2.25 ± 0.67	1.73 ± 0.59	1.52 ± 0.50
<i>t</i>		0.000	0.144	4.386	0.000
<i>P</i>		1.000	.886	<.0001	1.000
		>.05	>.05	<.05	>.05

Table 4
Postoperative dysfunction and failure of internal fixation ($\bar{x} \pm s$).

Group	N	Postoperative dysfunction and failure of internal fixation (%)		
		Day 3 post operative	Day 30 post operative	Final follow-up
A	56	0	8.92% (5 cases)	0
B	56	0	0 (0 cases)	0
χ^2			7.165	
<i>P</i>			.07	
			>.05	

with total failure of the internal fixation underwent a second operation within 30 days after the initial operation. The remaining 3 patients (60%) had partial failure of the internal fixation and were treated conservatively, which resulted in malunion. Notably, the Constant–Murley shoulder assessment score and VAS score were significantly different at postoperative day 3, day 30, and at the final follow-up when compared with preoperative values in these 5 patients.

4. Discussion

Proximal humerus fractures represent a tremendous challenge for internal fixation due to the complexity of the shoulder joint, such that failure of internal fixation and postoperative shoulder dysfunction occurs in an estimated 3% to 23% of patients.^[18–20] The majority of proximal humerus fractures are related to osteoporosis,^[21–24] and patients with these fractures are often >60 years of age. Nevertheless, stable reduction is essential to achieve early functional recovery and healing of the fracture. Therefore, the present study evaluated the clinical effectiveness of ORIF with a PHILOS plate combined with the aid of a custom neutral-position shoulder and elbow sling in decreasing the incidence of internal fixation failure and allowing for early functional rehabilitation in patients presented with proximal humerus fractures. Patients wore the custom neutral-position shoulder and elbow sling for 30 days after surgery to provide support to the shoulder joint during postoperative controlled active mobilization. Our findings showed that the Constant–Murley shoulder assessment scores and VAS scores were significantly improved at postoperative day 30 and the final follow-up in patients that used the neutral-position shoulder and elbow sling (group B), in comparison with the patients that did not use the sling (group A). Importantly, patients should be provided appropriate immobilization and informed not to participate in excessive or improper functional exercise during the healing process. This will improve joint function and the overall prognosis while decreasing the possibility of internal fixation failure.

Due to the high incidence of implant failure and the unfavorable prognosis, there is no consensus on the optimal treatment approach for proximal humerus fractures. As described by Gardner et al,^[25] fractures of the proximal humerus are supported by the medial cortical bone, which has been widely acknowledged. Robinson et al^[26] described a Plate-Joystick technique to assist in the reduction and stabilization of proximal humerus fractures and nonunion with a varus deformity. Konrad et al^[27] described that complications accompanied by plate and nail treatment of unstable three-part proximal humerus fractures are often due to avoidable incorrect surgical techniques. In addition, Wong et al^[28] found that the application of intramedullary nail in the near-end humerus can attain specific effects, but the possibility of second surgery and complication were still high. However, Lekic et al^[29] showed that there was no significant difference in complication rates between those patients receiving locking plates with screws when compared with intramedullary nailing for two-part proximal humerus fractures.

Currently, the use of the PHILOS plate for proximal humerus fractures is controversial. This approach has been associated with the risk for early shoulder joint dysfunction and implant failure, which may compromise clinical outcomes and represent an economic burden to the healthcare system. However, the use of a combination of internal fixation and a custom neutral-position shoulder and elbow sling provides anatomic fracture reduction

and fixation. This allows for early rehabilitation of patients and offsets the inability of osteoporotic bone to hold implants, considering the lack of strength of internal fixation due to osteoporosis. In addition, this ensures that the rotator cuff and shoulder muscles are relaxed, reducing the stress on the PHILOS plate during functional rehabilitation of the greater tuberosity and inferomedial region of the proximal humerus.

This study was associated with several limitations. First, X-ray scans were used to assess failure of internal fixation, which is vulnerable to measurement error. As imaging capabilities varied between sites, the scans were reviewed by the treating surgeon and coauthors to diminish bias with respect to classification of the fracture, healing of the fracture, and the potential occurrence of associated complications. Second, shoulder joint function was assessed using patient reported outcomes, which can be subjective. To mitigate this concern, the study included widely employed and highly validated instrumentation, which contributes to the robustness of the findings. Third, surgical procedures and postoperative management varied between study sites and among different surgeons at each study site. Despite the innate differences, all surgeons were experienced in the management of proximal humerus fractures with ORIF using the PHILOS plate. Lastly, a mean follow-up of 15 months is insufficient to draw comprehensive conclusions about the functional outcomes of a shoulder after a challenging fracture, especially when functional recovery is prolonged by postoperative complications. As such, the difference in clinical results between 2 groups may change over a longer follow-up, especially when considering the higher incidence of internal fixation failure and reoperation in group A.

In conclusion, ORIF with a PHILOS plate with or without the aid of a custom neutral-position shoulder and elbow sling is a safe and effective method for proximal humerus fractures. However, ORIF with a PHILOS plate combined with the aid of a custom neutral-position shoulder and elbow sling for 30 days after surgery was associated with a lower incidence of internal fixation failure and decreased number of adverse events, in comparison to ORIF with a PHILOS plate alone.

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References

- [1] Okike K, Lee OC, Makanji H, et al. Comparison of locked plate fixation and nonoperative management for displaced proximal humerus fractures in elderly patients. *Am J Orthop (Belle Mead NJ)* 2015;44:E106–12.
- [2] Launonen AP, Lepola V, Flinkkila T, et al. Conservative treatment, plate fixation, or prosthesis for proximal humeral fracture. A prospective randomized study. *BMC Musculoskelet Disord* 2012;13:167.
- [3] Tamai K, Ishige N, Kuroda S, et al. Four-segment classification of proximal humeral fractures revisited: a multicenter study on 509 cases. *J Shoulder Elbow Surg* 2009;18:845–50.
- [4] Sudkamp N, Bayer J, Hepp P, et al. Open reduction and internal fixation of proximal humeral fractures with use of the locking proximal humerus plate. Results of a prospective, multicenter, observational study. *J Bone Joint Surg Am* 2009;91:1320–8.
- [5] Maier D, Jaeger M, Izadpanah K, et al. Proximal humeral fracture treatment in adults. *J Bone Joint Surg Am* 2014;96:251–61.
- [6] Ortmaier R, Filzmaier V, Hitzl W, et al. Comparison between minimally invasive, percutaneous osteosynthesis and locking plate osteosynthesis in 3-and 4-part proximal humerus fractures. *BMC Musculoskelet Disord* 2015;16:297.
- [7] Wu JW, Shen HL, Liu LM, et al. [Analysis of early failure of the PHILOS in proximal humerus fractures]. *Beijing Da Xue Xue Bao Yi Xue Ban* 2016;48:683–5.
- [8] Doshi C, Sharma GM, Naik LG, et al. Treatment of proximal humerus fractures using PHILOS plate. *J Clin Diagn Res* 2017;11:RC10–3.
- [9] Geiger EV, Maier M, Kelm A, et al. Functional outcome and complications following PHILOS plate fixation in proximal humeral fractures. *Acta Orthop Traumatol Turc* 2010;44:1–6.
- [10] Meier RA, Messmer P, Regazzoni P, et al. Unexpected high complication rate following internal fixation of unstable proximal humerus fractures with an angled blade plate. *J Orthop Trauma* 2006;20:253–60.
- [11] Wanner GA, Wanner-Schmid E, Romero J, et al. Internal fixation of displaced proximal humeral fractures with two one-third tubular plates. *J Trauma* 2003;54:536–44.
- [12] Gonc U, Atabek M, Teker K, et al. Minimally invasive plate osteosynthesis with PHILOS plate for proximal humerus fractures. *Acta Orthop Traumatol Turc* 2017;51:17–22.
- [13] Shukla DR, McAnany S, Pean C, et al. The results of tension band rotator cuff suture fixation of locked plating of displaced proximal humerus fractures. *Injury* 2017;48:474–80.
- [14] Neer CS2nd. Displaced proximal humeral fractures. II. Treatment of three-part and four-part displacement. *J Bone Joint Surg Am* 1970;52:1090–103.
- [15] Neer CS2nd. Displaced proximal humeral fractures. I. Classification and evaluation. *J Bone Joint Surg Am* 1970;52:1077–89.
- [16] Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res* 1987;160–4.
- [17] Burkhart KJ, Dietz SO, Bastian L, et al. The treatment of proximal humeral fracture in adults. *Dtsch Arztebl Int* 2013;110:591–7.
- [18] Ye T, Wang L, Zhuang C, et al. Functional outcomes following locking plate fixation of complex proximal humeral fractures. *Orthopedics* 2013;36:e715–22.
- [19] Roderer G, Erhardt J, Kuster M, et al. Second generation locked plating of proximal humerus fractures—a prospective multicentre observational study. *Int Orthop* 2011;35:425–32.
- [20] Russo R, Della Rotonda G, Cautiero F, et al. Reverse shoulder prosthesis to treat complex proximal humeral fractures in the elderly patients: results after 10-year experience. *Musculoskelet Surg* 2015;99(Suppl. 1):S17–23.
- [21] Wihlborg A, Akesson K, Gerdhem P. External validity of a population-based study on osteoporosis and fracture. *Acta Orthop* 2014;85:433–7.
- [22] Pawaskar AC, Lee KW, Kim JM, et al. Locking plate for proximal humeral fracture in the elderly population: serial change of neck shaft angle. *Clin Orthop Surg* 2012;4:209–15.
- [23] Carbone S, Razzano C, Albino P, et al. Immediate intensive mobilization compared with immediate conventional mobilization for the impacted osteoporotic conservatively treated proximal humeral fracture: a randomized controlled trial. *Musculoskelet Surg* 2017;101:137–43.
- [24] Jones G, Nguyen T, Sambrook P, et al. Progressive loss of bone in the femoral neck in elderly people: longitudinal findings from the Dubbo osteoporosis epidemiology study. *BMJ* 1994;309:691–5.
- [25] Gardner MJ, Weil Y, Barker JU, et al. The importance of medial support in locked plating of proximal humerus fractures. *J Orthop Trauma* 2007;21:185–91.
- [26] Robinson CM, Inman D, Phillips SA. The Plate-Joystick technique to reduce proximal humeral fractures and nonunions with a varus deformity through the extended deltoid-splitting approach. *J Orthop Trauma* 2011;25:634–40.
- [27] Konrad G, Audige L, Lambert S, et al. Similar outcomes for nail versus plate fixation of three-part proximal humeral fractures. *Clin Orthop Relat Res* 2012;470:602–9.
- [28] Wong J, Newman JM, Gruson KI. Outcomes of intramedullary nailing for acute proximal humerus fractures: a systematic review. *J Orthop Traumatol* 2016;17:113–22.
- [29] Lekic N, Montero NM, Takemoto RC, et al. Treatment of two-part proximal humerus fractures: intramedullary nail compared to locked plating. *HSS J* 2012;8:86–91.