Comparison of two different locking plates for two-, three- and four-part proximal humeral fractures—results of an international multicentre study

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Abstract

Purpose The aim of this study was to compare the functional outcome, quality of restoration, and complication rate after open reduction and internal fixation (ORIF) of displaced or unstable 2-, 3- and 4-part humeral fractures using two different locking plates.

Methods The data used in this analysis was prospectively collected in two large multicentre studies in 15 European Level 1 trauma centres. A total of 318 patients with

proximal humeral fractures were treated with ORIF using either the locking proximal humerus plate (LPHP) or proximal humeral internal locking system (PHILOS). Outcome measurements included Constant and Neer scores, evaluation of local pain at the fracture site and complications, and radiographic assessment at one year.

Results At one year, the mean Constant scores (relative to the contralateral shoulder) improved significantly for both groups and were above 80% for 2-, 3-, and 4-part fractures. A significantly shorter surgical time, less pain at the fracture site, and better functional outcome was achieved by PHILOS-treated patients with 2-part fractures throughout the one-year follow-up month and with 3-part fractures at three months ($p < 0.05$). There was no difference between the treatment outcomes for 4-part fractures, and no difference in the complication rates ($p > 0.05$).

Conclusions PHILOS and LPHP can be considered as useful implants for ORIF of displaced and unstable proximal humeral fractures. There was a slight advantage of the PHILOS system with regard to operative time and functional outcome, especially for the treatment of 2- and 3-part fractures.

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Introduction

Proximal humeral fractures are common injuries in the elderly population [1, 2]. While non-displaced fractures can be treated nonoperatively, surgical treatment is recommended for displaced fractures and commonly involves open reduction and internal plate fixation. Clinically relevant complications such as loss of reduction, screw loosening, and osteonecrosis of the humeral head are frequently observed after surgery, especially in association with poor bone quality [3–6]. In order to reduce the complication rate,

anatomically shaped locking plates have been developed (proximal humeral Internal locking system [PHILOS] and locking proximal humeral plate [LPHP]; Synthes GmbH, Switzerland). These plates provide angular stability which is especially useful in osteoporotic bone [7].

Locking Proximal Humerus Plate (LPHP)

Proximal Humeral Internal Locking System (PHILOS)

Both of the implants have been investigated in prospective clinical trials [5, 8–11]. None of these studies

distinguish between the different fracture types, although this factor is assumed to have an essential influence on final clinical outcome [3]. A direct outcome comparison between these two implants is warranted [12]. The aim of this analysis was to compare the functional outcome, anatomical restoration, and complication rate of patients with 2-, 3- and 4-part proximal humeral fractures treated either with a LPHP or PHILOS plate.

Patients and methods

Data collection

The data used in this analysis was prospectively collected in two large multicentre case series with similar protocols after obtaining Institutional Review Board approval [5–9]. Patients included in the two groups were enrolled from a total of 15 centres with each clinic using only one of the nominated implants. Patients with a proximal humeral fracture that either met the indications for operative treatment as outlined by Neer [13] or was unstable when tested with passive motion using an image intensifier were included if they were aged at least 18 years of age, required operative treatment within ten days of sustaining their fracture, and provided informed consent prior to enrollment. Exclusion criteria included open fractures, pathological fractures or refractures, concomitant ipsilateral fractures of the distal humerus and/or elbow joint, and plexus and/or nerve injuries. Pregnant or polytraumatised patients, those with known alcohol or drug dependency, existing medical disorders having an impact on bone healing (e.g. multiple sclerosis, paraplegia, and relevant neurological disorders), and those who knew that they would be unable to attend all scheduled study visits were also excluded.

A total of 318 patients with an equal number of fractures were included in the analysis; 87 (27%) had 2-part fractures, 153 (48%) had 3-part fractures and 78 (25%) had 4-part fractures according to Neer. Thirty-three, 49, and 48 patients were lost at the respective three-, six-, and 12-month follow-ups, leaving 285 (90%), 269 (85%), and 270 (85%) patients and fractures available at the respective time points (Fig. 1). For all analysis groups categorised according to treatment and fracture type, the average age of the patients ranged between 60.8 to 65.6 years and mostly included women ($\geq 68\%$) (Table 1).

The operative approaches have previously been described for LPHP [5] and PHILOS [9]. The duration of surgery was documented for the comparative analysis. Surgeons involved in the care of these patients had to have prior experience in at least five osteosyntheses with the chosen implant before their patients were included in the study. All operating or supervising surgeons also were required to be fellowship-trained trauma surgeons.

Fig. 1 Patient recruitment and follow-up rates**Patient groups**

Follow-up assessments of clinical outcome and complications were performed at three, six and 12 months after surgery. Patients were examined to assess their shoulder function based on the Constant [14] and Neer [13] scores, and local pain at the fracture site according to a "yes/no"

answer; the latter is assessed as part of the Constant scoring system. All local intra- and postoperative complications were documented up to one year. Plain radiographs were taken in two planes (i.e. anteroposterior and axillary view) at the designated time points and were reviewed by the

Table 1 Patient demographics and fracture characteristics

Factors		2-part fractures				3-part fractures				4-part fractures			
		PHILOS		LPHP		PHILOS		LPHP		PHILOS		LPHP	
		n	Mean (SD) or %	n	Mean (SD) or %	n	Mean (SD) or %	n	Mean (SD) or %	n	Mean (SD) or %	n	Mean (SD) or %
Age (years)		43	60.8 (19.2)	44	62.8 (14.9)	70	67.0 (15.3)	83	64.1 (15.9)	38	63.4 (13.7)	40	65.6 (13.3)
Gender	Male	11	26%	14	32%	17	24%	23	28%	15	39%	8	20%
	Female	32		30		53		60		23		32	
Smoking	Yes	6	15%	9	20%	10	17%	18	22%	8	24%	6	15%
	No	34		35		49		65		26		34	
Concurrent general disease	Yes	16	37%	22	50%	44	63%	52	63%	25	66%	24	60%
	No	27		22		26		31		13		16	
Energy trauma	High	14	33%	6	14%*	12	18%	9	11%	13	34%	5	13%
	Low	29		38		56		74		25		35	
Dominant arm injured	Yes	16	37%	23	53%	35	50%	45	54%	24	63%	23	58%
	No	27		20		35		38		14		17	

PHILOS proximal humeral interlocking system, *LPHP* locking proximal humerus plate, *SD* standard deviation

n corresponds to the actual number of patients with baseline data

* $p < 0.05$

primary author to evaluate fracture healing, the incidence of avascular necrosis of the humeral head, and assess the reconstruction of the humeral head axis. Loss of reduction was determined by comparing the immediate postoperative radiographs with those taken at one year, and final radiological axis was categorised as varus $>45^\circ$, varus $>30\text{--}45^\circ$, varus $>15\text{--}30^\circ$, anatomical $\pm 15^\circ$, or valgus $>15^\circ$.

Statistical analysis

Data management and analyses were implemented separately for the 2-, 3-, and 4-part fracture subgroups using Intercooled Stata version 11 (StataCorp LP, TX, USA). Continuous variables were described using means, standard deviations, and ranges, and categorical variables were tabulated with absolute and relative frequencies. Logistic, binomial and random-effects linear regression models were used to evaluate differences between the two groups at three, six, and 12 months after surgery. The null hypothesis that there would be no difference between the two groups was tested at the 0.05 significance level.

A sample size estimation or power analysis was not conducted prior to this explorative analysis. A post-hoc power analysis using the Constant score at one year indicated a power of 73% and 94% considering a sample size of 30 (for both 2- and 4-part fractures) and 55 patients

(for 3-part fractures) per group, respectively. This was based on a minimum detectable Constant score difference of ten points, a common standard deviation of 15 (effect size 0.67), and an alpha error level set at 0.05.

Results

The mean operative time was 85 (SD 34) minutes for 2-part fractures, 87 (SD 33) minutes for 3-part fractures, and 108 (SD 46) minutes for 4-part fractures. PHILOS surgery was generally faster than fixing fractures with LPHP (73 vs. 96 min for 2-part fractures, 86 vs. 87 min for 3-part fractures, and 101 vs. 116 min for 4-part fractures). A significant difference could be detected only for the 2-part fractures ($p < 0.01$).

Patients treated with a LPHP were 1.2–2.1 times more likely to perceive pain at any follow-up evaluations compared to those treated with PHILOS (Table 2).

Throughout the one-year follow-up, the absolute mean Constant score of the injured shoulder improved significantly for all groups ($p < 0.001$) and reached 73.2 (SD 14.1) points, 71.7 (SD 13.4) points, and 68.3 (SD 16.6) points for the 2-, 3-, and 4-part fracture groups at the final examination, respectively. A similar trend was observed for the Constant score relative to the uninjured contralateral side (Fig. 2a–c); a Constant score (relative to the contralateral arm) of over 80%

Table 2 Pain assessment of PHILOS and LPHP treated patients categorized according to Neer fracture type

Follow-up	Treatment	Pain at fracture site ^a		%	RR	95%CI	P-value ^b
		No	Yes				
2-part fractures							
Three months	LPHP	9	30	77%	0.65	(0.45;0.93)	0.019
	PHILOS	21	20	49%			
Six months	LPHP	9	29	76%	0.59	(0.39;0.89)	0.012
	PHILOS	21	16	43%			
One year	LPHP	15	20	57%	0.44	(0.24;0.82)	0.009
	PHILOS	28	15	35%			
3-part fractures							
Three months	LPHP	21	56	73%	0.93	(0.72;1.2)	0.574
	PHILOS	24	39	62%			
Six months	LPHP	29	40	58%	0.67	(0.48;0.93)	0.017
	PHILOS	31	29	48%			
One year	LPHP	37	33	47%	0.54	(0.37;0.79)	0.001
	PHILOS	38	21	36%			
4-part fractures							
Three months	LPHP	6	27	82%	0.42	(0.26;0.67)	<0.001
	PHILOS	19	12	39%			
Six months	LPHP	12	23	66%	0.42	(0.25;0.71)	0.001
	PHILOS	19	10	34%			
One year	LPHP	14	19	58%	0.67	(0.38;1.16)	0.152
	PHILOS	20	13	39%			

PHILOS proximal humeral interlocking system, LPHP locking proximal humerus plate, CI confidence interval, RR adjusted relative risk

n corresponds to the actual number of patients with follow-up data at the nominated time point

^a Assessed according to the Constant score pain component

^b Based on the Wald test

Fig. 2 Constant scores (relative to the contralateral shoulder) over the one-year follow-up period. For each box plot, the ends of the rectangle correspond to the upper and lower quartiles of the data values. The line drawn through the rectangle corresponds to the median value. The whiskers, starting at the ends of the rectangle (or points representing extreme values), indicate minimum and maximum values. **a** Patients with 2-part fractures. **b** Patients with 3-part fractures. **c** Patients with 4-part fractures

was achieved for all fractures by one year. PHILOS treated 2-part fractures had significantly higher mean Constant scores at all follow-up visits (Table 3), whereas PHILOS treated 3-part fractures had significantly higher mean Constant scores only at the three-month visit. There was no significant difference in the mean Constant score for 4-part fracture patients treated with either PHILOS or LPHP. The one-year Neer scores of the injured shoulder were not significantly different between the LPHP- and PHILOS-treated patients for all fracture types (Fig. 3).

Based on the radiographic assessment of fracture alignment, there was no difference in varus or valgus deviations between the cohorts (Table 4).

Complications

A total of 55 intraoperative and 64 postoperative complications were reported for 29% patients (92/318) during the one-year follow-up. The risk of experiencing at least one local complication did not significantly differ between the PHILOS- and LPHP-treated patients with 2-, 3- or 4-part fractures ($p=0.15$, 0.64 , or 0.61 , respectively).

There were 42 primary screw perforations (13.2%) of the humeral head that were unrecognised during surgery, and five patients experienced subacromial impingement (1.6%) because the plate was positioned too far cranially. In two patients, a postoperative neurological lesion was diagnosed. There were four deep (1.3%) and three superficial wound infections (0.9%).

The most common postoperative complications were secondary screw perforation ($n=26$, 8.2%) and secondary loss of reduction/impaction ($n=25$, 7.9%). With regard to implant-related and bone/fracture-related postoperative complications, no significant difference between the treatment groups was found.

Discussion

To our knowledge, this study is the first prospective case series comparing different types of locking plates used for internal stabilisation of proximal humeral fractures. The aim of the paper was to compare the functional outcome, anatomical restoration, and complication rate of patients with 2-, 3- and 4-part proximal humeral fractures treated either with a LPHP or PHILOS plate.

Our study population comprised of mostly elderly females who had sustained their fractures during a low energy trauma, which is comparable to previous studies on proximal humerus fractures [12–15]. Follow-up rates of between 85% and 90% were completed throughout the one-year assessment period, which can be considered satisfactory considering the mean age of the patients. Furthermore, there was no significant difference in the loss to follow-up rates between the two treatment groups.

The overall results showed good to very good functional outcomes one year after surgery in the majority of patients. The mean Constant score improved significantly up to 12 months, and the relative Constant scores of 87% for 2- and 3-part fractures, and 81% for 4-part fractures are in agreement with previous studies on angular stable locking plates [16, 17]; these studies confirm that locking plates are useful implants for ORIF, even complex and multiple-fragment fractures. For 2-part fractures, patients treated with PHILOS showed lower pain levels and a better Constant score at three, six and 12 months after surgery. This somewhat unexpected result might at least

Table 3 Absolute mean Constant scores for PHILOS and LPHP patients

	Follow-up	PHILOS		LPHP		Effect ^a	95%CI	P-value ^b	LR
		<i>n</i>	Mean (SD)	<i>n</i>	Mean (SD)				
<i>PHILOS</i> proximal humeral interlocking system, <i>LPHP</i> locking proximal humerus plate, <i>SD</i> standard deviation, <i>CI</i> confidence interval, <i>LR</i> overall likelihood ratio test for group effect <i>n</i> corresponds to the actual number of patients with follow-up data at the nominated time point ^a Adjusted group difference (PHILOS vs. LPHP) ^b Based on the Wald test	2-part fractures								
	Three months	36	60.2 (12.6)	30	53.6 (12.5)	10.93	(5.39;16.47)	<0.001	0.002
	Six months	37	67.0 (15.7)	37	62.3 (14.4)	8.49	(3.11;13.87)	0.002	
	One year	35	74.8 (12.6)	34	71.6 (15.6)	6.45	(0.96;11.94)	0.021	
	3-part fractures								
	Three months	54	52.9 (17.7)	64	50.7 (13.5)	6.01	(0.85;11.16)	0.022	0.025
	Six months	54	62.0 (16.8)	64	66.1 (13.2)	0.03	(−5.12;5.18)	0.991	
	One year	54	72.3 (13.8)	63	71.2 (13.0)	3.84	(−1.35;9.02)	0.147	
	4-part fractures								
	Three months	26	56.3 (12.8)	25	52.5 (11.7)	1.75	(−5.56;9.06)	0.640	0.920
	Six months	27	65.8 (13.6)	28	62.7 (11.2)	−0.03	(−7.17;7.11)	0.994	
	One year	29	67.7 (18.5)	26	68.7 (14.7)	−0.32	(−7.45;6.81)	0.930	

in part be accounted for by the shorter operation time using the PHILOS plate. Longer surgery time may lead to soft tissue injury including local ischemia, muscle damage and neurological impairment. This might be followed by increased reactive hyperemia and neuromuscular deficits associated with increased postoperative pain, a more difficult rehabilitation process, and an inferior functional outcome.

The reason for the different outcome of PHILOS versus LPHP is unclear. It can be speculated that the implant's design is at least partly responsible. In fact, the proximal part of the PHILOS plate is slightly larger and longer than that of the LPHP and has additional angular stable and oblique screws. Therefore, positioning of the plate and fixation of the humeral head may be easier. The additional oblique screws might offer better fixation of the head fragment. Better fixation might explain reduced postoperative pain and facilitated early functional rehabilitation,

Fig. 3 Comparison of one-year Neer scores for fracture subgroups. For each box plot, the ends of the rectangle correspond to the upper and lower quartiles of the data values. The line drawn through the rectangle corresponds to the median value. The whiskers, starting at the ends of the rectangle (or points representing extreme values), indicate minimum and maximum values

which might lead to better outcomes. The length of the PHILOS might be an advantage when indirect reduction manoeuvres are performed. This consideration is supported by the fact that a varus deviation of more than 15° was only

Table 4 Fracture alignment of PHILOS- and LPHP-treated patients at one year

Fracture deviation categories	PHILOS		LPHP	
	<i>n</i>	%	<i>n</i>	%
2-part fractures				
Varus >45°	2	5%	2	5%
Varus >30–45°	6	14%	4	9%
Varus >15–30°	7	16%	16	36%
Anatomical ± 15°	26	60%	22	50%
Valgus >15°	2	5%	0	0%
Total	43	100%	44	100%
3-part fractures				
Varus >45°	3	4%	6	7%
Varus >30–45°	11	16%	8	10%
Varus >15–30°	21	30%	13	16%
Anatomical ± 15°	31	44%	54	65%
Valgus >15°	4	6%	2	2%
Total	70	100%	83	100%
4-part fractures				
Varus >45°	6	16%	5	13%
Varus >30–45°	8	21%	4	10%
Varus >15–30°	4	10%	9	22%
Anatomical ± 15°	19	50%	17	42%
Valgus >15°	1	3%	5	13%
Total	38	100%	40	100%

PHILOS proximal humeral interlocking system, *LPHP* locking proximal humerus plate

n corresponds to the actual number of patients with radiographs at the immediate postoperative period and at one year

seen in 35% of PHILOS treated 2-part fracture patients compared to 50% LPHP patients, although this difference was not significant.

There is, to our knowledge, only one other published study comparing the outcome of ORIF using LPHP and PHILOS [12]. In this study, no significant difference was found between the two implants concerning pain (determined using the visual analogue scale) or function (based on the Oxford shoulder score). In comparison with our study, the study by Faraj et al. is limited by its retrospective design using a telephone survey for the assessment of pain and function. Additionally, the measured outcomes were not separately analysed for the different fracture types, so that our observed significant differences in outcome after treatment of 2- and 3-part fractures with PHILOS and LPHP could not have been detected by Faraj et al.

In our study, complications were recorded in 29% of the patients with screw perforation of the humeral head being the most frequent event. This is also noted in recent earlier studies using angular stable locking plates [8–10, 17–20]. Yang et al. found an overall complication rate of 35.9% with a screw cut-out rate of 7.6% [8]. Helwig et al reported screw penetration of the humeral head in 11 of 87 patients (12.6%) and Thanasis et al. showed a screw cut-out rate of 11.6% in their review of 791 patients [10–17]. These previous studies agree that screw perforation of fixed-angle implants has replaced the complications of secondary displacement and implant loosening as the main implant related complication of non-fixed-angle implants.

Some limitations of the study need to be discussed. Although general surgical technique and postoperative rehabilitation were standardised among the involved trauma centres, an influence of individual preferences cannot be excluded. This applies to surgical aspects including the approach, the use of additional suture wires for the fixation of the greater or lesser tuberosity, and the number of screws positioned as well as to technical issues including the quality of the fluoroscopy and postoperative radiographs. The Neer classification cannot describe all the anatomical variants of the fractures that were fixed using one system or the other. However, if we had subdivided our patients according to other anatomical variants of the fractures (e.g. valgus, varus, head rotation, etc.) the groups would have been too small for a statistical analysis.

Another limitation of the study is the lack of randomisation associated with a higher level of evidence, as we cannot exclude the possibility that the groups compared differed in other respects. This limitation may have been diminished by fact that statistical adjustment for factors showing differences among the groups were used to minimise potential treatment allocation bias.

Inherent to the study design is the fact that not the implant but the whole treatment process is compared. On a larger perspective, this study compares centres of care that use PHILOS to those that use LPHP. It might well be that the measured differences are not related to the implant but rather some of the many other outcome determining factors. On the other hand, the multicentre design of the study is pragmatic and results are more representative of everyday practice where many differently equipped hospitals and differently experienced surgeons are treating these common fractures. Finally, the follow-up period of one year may be too short to draw final conclusions on long-term outcome and complications such as avascular necrosis of the humeral head.

In conclusion, PHILOS and LPHP can be considered useful implants for ORIF of displaced and unstable proximal humeral fractures. Both implants allow secure fracture fixation and early postoperative shoulder mobilisation. Attention needs to be paid to the anatomical reconstruction as well as the correct positioning of the head screws to avoid complications related to incorrect surgical technique. We observed a slight advantage of the PHILOS with regard to operative time and functional outcome in simple fracture patterns and no difference in complex fracture patterns.

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