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CLINICAL RESEARCH

Similar Outcomes for Nail versus Plate Fixation of Three-part Proximal Humeral Fractures

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Abstract

Background There is a lack of consensus regarding optimal surgical management of displaced and unstable three-part proximal humeral fractures.

Questions/purposes The objective of this prospective observational study was to compare the clinical and radiologic outcomes of plate versus nail fixation of three-part proximal humeral fractures.

Patients and Methods Two hundred eleven patients with unstable three-part proximal humeral fractures were treated with ORIF using plate (PHILOS [proximal humeral interlocking system]/LPHP [locking proximal humerus plate]) or nail (PHN [proximal humeral nail]) osteosynthesis. Outcome measurements included pain, Constant and Murley and Neer scores, and the occurrence of complications at 3, 6, and 12 months postsurgery. Regression analysis and the likelihood ratio test were used to evaluate differences between the cohorts.

Results Throughout the 1-year followup period the Constant and Murley scores improved significantly for both cohorts; there was no significant difference between the nail group compared with the plate group. Also, 1-year Neer scores were similar between the two cohorts. Patients in the PHN group perceived significantly less pain compared with patients in the plate fixation group at 3, 6 and 12 months after surgery. We observed 79 local complications in 60 patients with no significant risk difference between the treatment groups; 35 intraoperative complications were directly related to the initial surgical procedure.

Conclusions The similar 1-year outcomes for nail versus plate fixation of three-part proximal humeral fractures suggest that both techniques may be useful for internal fixation of these fractures. Many complications were related to incorrect surgical technique and therefore can be avoided. Advanced surgical skills and experience are considered to be more critical for successful operative

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in accordance with the Declaration of Helsinki ethical standards, and that informed consent for participation in the study was obtained.
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treatment of three-part proximal humeral fractures than the selection of the implant.

Level of Evidence Level II, therapeutic study (prospective comparative study). See the Guidelines for Authors for a complete description of levels of evidence.

Introduction

Complex three- and four-part fractures of the proximal humerus occur in greater than 50% of patients older than 60 years [8]. The management of these fractures may be challenging owing to displacement by the rotator cuff, devascularization of the humeral head, and osteoporosis. Treatment options of displaced and unstable proximal humeral fractures vary widely, implying a lack of consensus regarding optimal management of these injuries [14, 30, 31]. The goals of surgery are to obtain anatomic fracture reduction and stable primary fixation to ensure rapid fracture healing and immediate postoperative functional therapy without prolonged immobilization [11, 12].

Although plate fixation offers high stability, an increased risk of avascular necrosis might result from extensive surgical exposure. Alternately, rotator cuff tears occurring after antegrade nailing might negatively influence a patient's functional outcome [12]. For both devices, implant-related complications such as nail or plate impingement and secondary screw perforation have been reported [9, 12, 25, 29]. Only a limited number of prospective clinical studies comparing the results after operative stabilization of proximal humeral fractures using different implants have been published and most of these studies included a small number of patients [13, 22, 28]. Furthermore, most studies do not distinguish between different fracture types, eg, three- and four-part fractures.

The objective of this prospective multicenter observational study was to compare plate versus nail fixation of three-part proximal humeral fractures regarding surgical duration, time for intraoperative fluoroscopy, functional assessment using the Constant Murley score and radiologic assessment of quality of reduction, presence of hardware-related complications, and the rate of local complications.

Patients and Methods

The patients included in this investigation are a subset of patients from a large prospective cohort study who were part of three case series with similar protocols [3, 4, 29], whereby each participating center used only one of the three investigated implants. Between 2002 and 2005, 384 consecutive patients from 25 European clinics treated with the implant of interest and meeting the inclusion criteria were enrolled; from this collective, all patients with an operatively treated three-part fracture of the proximal humerus (n = 211) were included in this analysis. The study was approved by institutional review boards at each of the 25 participating centers. Included patients were required to be at least 18 years of age, skeletally mature, and provide written informed consent before enrollment. All fractures either met the indications for operative treatment as outlined by Neer [24], or were unstable when tested with passive motion using an image intensifier. The exclusion criteria included pseudarthrosis, pathologic fractures and refractures, open fractures, or concomitant fractures of the ipsilateral elbow or distal radius. In addition, patients with existing disorders having an effect on the healing process and function such as multiple sclerosis, paraplegia or other relevant neurologic disorders, polytrauma with an Injury Severity Score greater than 16, and posttraumatic brachial plexus injury or peripheral nerve palsy were excluded.

The surgical approaches have been described for LPHP [29], PHILOS [4], and PHN [3]. Fixation of the greater tuberosity was achieved with the use of additional nonabsorbable sutures which were tagged through the rotator cuff or the tuberosity fragment and fixed at the blade's base or through holes in the plate. With these tagging sutures, the tuberosity fragments can be brought in continuity with the lateral cortex of the shaft fragment, even if the nail was inserted in the tuberosity fracture line. Surgeons involved in the care of these patients had to have prior experience in at least five osteosyntheses with the applied implant before their patients were included in the study. All operating or supervising surgeons also were required to be fellowship-trained trauma surgeons. Postoperative treatment involved immobilizing the arm in a sling and performing passive ROM exercises within 2 days postsurgery. Controlled active mobilization with abduction and flexion beyond 90° was started 1 to 3 weeks postoperatively, depending on the stability of the osteosynthesis and bone quality.

The patient series treated with LPHP included 60 women and 23 men with an average age of 64 years. This was similar to the PHILOS cohort including 53 women and 17 men with an average age of 67 years. The majority of LPHP- (89%) and PHILOS- (82%) treated fractures resulted from a low-energy injury that occurred at home (LPHP = 36% versus PHILOS = 41%). The dominant shoulder was involved in 45 (54%) patients treated with the LPHP and in 35 (50%) patients treated with the PHILOS. Most of the fractures treated with the LPHP (81%) and PHILOS (69%) were classified as AO Type B. All fractures from both cohorts were closed with the majority (90%) localized to the greater tuberosity. Since there was no significant difference between the PHILOS and the LPHP groups, both were analyzed together and compared with the PHN group.

Table 1. Patient demographics

Factors	PHN		Plate		Significance
	Number	Mean ± SD/%	Number	Mean ± SD/%	
Age (years)	58	64.8 ± 13.0	153	65.4 ± 15.6	p = 0.44
Gender					
Male	11	19%	40	26%	p = 0.37
Female	47		113		
Smoking*					
Yes	8	14%	28	20%	p = 0.22
No	50		114		
Concurrent general disease					
Yes	36	62%	96	63%	p = 1.00
No	22		57		
Energy trauma*					
High	6	11%	21	14%	p = 0.64
Low	51		130		
Dominant arm injured					
Yes	31	53%	80	52%	p = 1.00
No	27		73		

PHN = proximal humeral nail; Plate = proximal humeral interlocking system (PHILOS) and locking proximal humerus plate (LPHP); SD = standard deviation; * actual number of patients with baseline data.

Among patients treated with PHN, there were 47 women and 11 men with an average age of 65 years (Table 1). Eighty-nine percent of the fractures were low-energy injuries and 53% of the injuries occurred at home. The dominant shoulder was involved in 53% of the patients. Most of the fractures (93%) were classified as AO Type B. All fractures were closed and 57 (98%) were localized to the greater tuberosity.

Among the 211 patients treated with a PHN or PHILOS/LPHP implant, 192 (51 versus 63/78) had a 3-month evaluation, 182 (52 versus 60/70) had a 6-month evaluation, and 178 (47 versus 59/72) had a 1-year evaluation. Thirty-three patients were lost by the 1-year followup: two patients died of unrelated causes, and the remaining 31 could not be contacted or refused to come to the treating clinic for further examination.

The duration of surgery and radiographic screening time were documented. Each patient was examined and interviewed regarding pain at each followup. Mobility, strength, and the Constant and Murley score for the injured and contralateral shoulders were determined as previously described [7]. In addition, the Neer score was calculated at the 1-year followup [24].

True AP and transscapular Y-view radiographs obtained postoperatively and at each followup were evaluated primarily by each treating surgeon to assess fracture healing, bone deviation (valgus/varus), and complication events. The primary author (GK) and senior author (NS) made a final review of all radiographic assessments.

Treatment groups were compared for baseline patient and injury. Factors considered to differ sufficiently between the groups and potentially confound the outcome comparison were taken into account in the regression models by making the appropriate statistical adjustments. For this investigation, the following factors were identified as potential confounders: age (continuous variable in years); gender; fracture classification (AO Type C versus A/B); and delay to surgery (continuous variable in days). The analysis of the absolute Constant and Murley score also was adjusted by the individual score documented from the contralateral uninjured side.

We made a post hoc power analysis using repeated-measures ANOVA and the Constant and Murley score. Group sizes of 45 and 120 patients respectively, provided greater than 99% power to detect a minimum difference of 10 points in the Constant and Murley score with a known standard deviation of 13; the correlations between contralateral and injured sides, and between followups were set to 0.50 and 0.80, respectively. For achieving a power of 90%, 16 and 44 patients in both groups would have been required.

Although two continuous surgical parameters (operation duration and C-arm time) were analyzed by linear regression, one continuous outcome parameter (Constant and Murley score) was investigated by repeated-measure linear regression, and four dichotomous outcome parameters (pain level at each followup and the occurrence of local complications within 1 year) were analyzed by logistic and binomial regressions. We tested the null hypothesis that there would be no difference when comparing the shoulder function and health status between patients treated with the nail with those treated with the plate at the nominated postoperative times.

In repeated-measure analyses, data were pooled and analyzed together in one overall linear regression model, while taking the repeated measurement of each patient into account; we regressed on the two indicator variables, implant type and followup time and the interaction term between implant type and time. The likelihood ratio test was used to study the overall effect of the implants and time on each outcome; a p value less than 0.05 was considered statistically significant. For each outcome showing an overall significant implant effect, the full regression model was used to estimate the effect size between the implant groups at each followup using the Wald test [2].

Using binomial regression, the effect sizes were reported as adjusted relative risks (RR), ie, the risk of experiencing an outcome in a plate group relative to the risk of experiencing the same outcome in the nail group (taken as the statistical reference).

Results

Throughout the 1-year followup period, the mean absolute Constant and Murley scores for the injured shoulders improved significantly for all cohorts ($p < 0.001$) (Fig. 1). There was a trend toward a lower Constant and Murley score for the plate group but the difference was not statistically significant ($p = 0.05$, 0.56, and 0.36 at the 3-, 6-, and 12-month examinations, respectively). A similar result pattern was observed when considering the Constant and Murley score relative to that recorded on the uninjured contralateral side. By the 1-year final evaluation, the mean relative Constant and Murley scores were 89% (SD, 11) for patients treated with the PHN and 87% (SD, 14) for patients treated with a plate osteosynthesis.

Nailing of three-part proximal humeral fractures (mean ± SD, 54 ± 21 minutes) was significantly faster than locking plate fixation (87 ± 34 minutes) ($p < 0.001$) (Fig. 2). However, a significantly longer median fluoroscopy time of 15 seconds was required for PHN surgery ($p < 0.001$).

Pain at the fracture site as rated by the patients during the Constant and Murley score assessment was significantly different between treatment groups at the 3-, 6-, and 12-month examinations (Table 2). Patients treated with a plate were two to three times more likely to perceive pain compared with those treated with the PHN.

The 1-year Neer scores for the injured shoulders were not significantly different between the patients treated with the PHN and those treated with a locking plate ($p = 0.39$) (Fig. 3).

The final radiologic outcomes at 1 year were classified as follows: anatomic ±15°; valgus > 15°; varus > 15°–30°; varus > 30°–45°; varus > 45° (Table 3). There was no

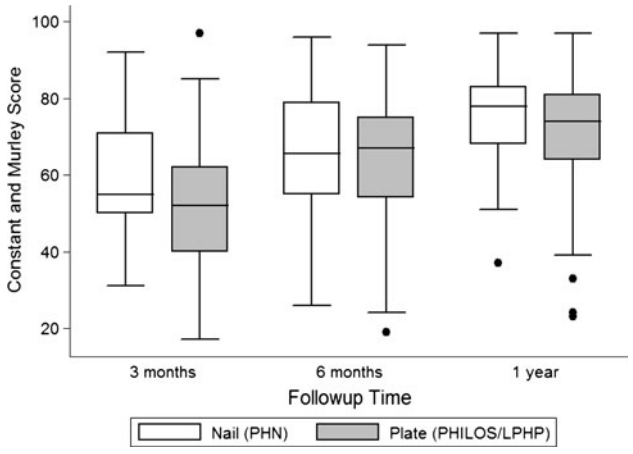

Fig. 1 The box plot shows the absolute Constant and Murley scores for the plate and nail osteosynthesis treatment groups at the 3-, 6-, and 12-month followups.

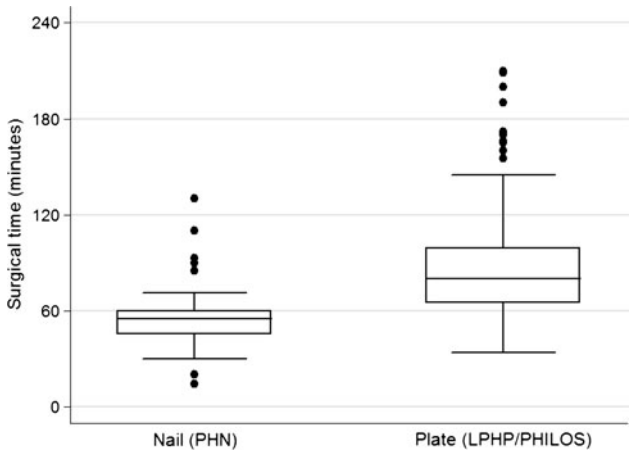

Fig. 2 The box plot shows the surgical time taken for plate and nail osteosynthesis of three-part proximal humerus fractures. The ends of each rectangle correspond to the upper and lower quartiles of the data values. The line drawn through the rectangle corresponds to the median value. The whiskers, starting at the ends of the rectangle (or points representing extreme values), indicate minimum and maximum values.

Table 2. Pain at the fracture site

Followups	Pain	PHN		Plate		p Value[§]
		Number*	%	Number*	%	
3 months	Yes	21	41%	95	68%	0.003
	No	30		45		
6 months	Yes	9	18%	69	53%	0.001
	No	42		60		
1 year	Yes	9	19%	54	42%	0.015
	No	38		75		

PHN = proximal humeral nail; Plate = proximal humeral interlocking system (PHILOS) and locking proximal humerus plate (LPHP); * actual number of patients with followup data at the specific time; [§]Wald test of binomial regressions.

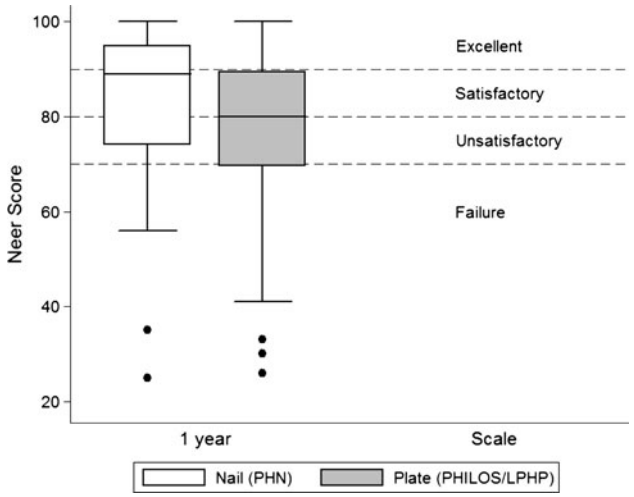

Fig. 3 The box plot shows the categorized Neer scores for the plate and nail osteosynthesis treatment groups at 1 year.

Table 3. Radiologic outcomes for the proximal humerus cohorts treated with plate or nail osteosynthesis at 1 year

Deviation	PHN		Plate	
	Number*	%	Number*	%
Varus > 45°	0	0%	9	6%
Varus > 30°–45°	7	12%	19	12%
Varus > 15°–30°	11	19%	34	22%
Anatomic ±15°	40	69%	85	56%
Valgus > 15°	0	0%	6	4%

PHN = proximal humeral nail; Plate = proximal humeral interlocking system (PHILOS) and locking proximal humerus plate (LPHP); * actual number of patients with radiologically assessed deviation outcomes.

difference in varus deviations greater than 15° between the cohorts (p = 0.54).

Thirty-five intraoperative and 44 postoperative local complications occurred in 60 of 211 patients (28%) throughout the 1-year followup (Table 4). The risk of experiencing at least one local complication did not significantly differ between patients in any of the two treatment groups (p = 0.15). There were 26 primary screw perforations of the humeral head that were not identified during the surgical procedure, and in six patients, the nail or plate was positioned too far cranially which led to subacromial impingement. In three patients, a neurologic lesion was diagnosed. There were two cases each of deep and superficial wound infections in the patients treated with plate osteosynthesis. The most common local postoperative complications were secondary loss of reduction/impaction (n = 25) and secondary screw perforation (n = 16). There were no significant risk differences between the patient cohorts (p = 0.56) for local implant and bone/fracture postoperative complications.

Thirty-four (16.1%) patients (9/58 in the nail group and 25/153 in the plate group) had an unplanned secondary operation within 12 months after the initial procedure. In addition to the four infection-related revisions, there were 21 early implant removals attributable to primary or secondary implant perforation or impingement. Implantation of a shoulder prosthesis was performed in two patients as a result of head necrosis, and seven patients with loss of reduction, plate breakage, or plate pullout underwent a reosteosynthesis.

Table 4. Complications

Complication type	PHN 58* Number	Plate 153* Number
Intraoperative complications†	5	27
Primary screw perforation	3	23
Plate impingement	2	4
Nerve complication	1	2
Postoperative complications‡	12	28
Implant complications	10	19
Secondary screw perforation	3	13
Implant loosening	1	0
Screw backing out	5	2
Plate and/or screw pull-out	0	2
Implant breakage	0	3
Other implant/surgery	1	0
Bone/fracture complications	9	19
Loss of reduction	4	10
Secondary dislocation fragment	1	3
Impaction	4	7
Delayed union	0	5
Nonunion	0	0
Head necrosis	1	2
Impingement	0	1
Other bone/fracture	0	0
Soft tissue/wound complications	0	4
Superficial infection	0	2
Deep infection	0	2
Hematoma	0	0
Other soft tissue	0	0
Any local complication§	12	48
Complication risk (95% CI)‖	21% (11.2–33.4)	31% (24.1–39.4)

PHN = proximal humeral nail; Plate = proximal humeral interlocking system (PHILOS) and locking proximal humerus plate (LPHP); * total number of patients per cohort; †total number of patients with intraoperative complications takes into account patients with more than one intraoperative event; ‡total number of patients with postoperative complications takes into account patients with more than one postoperative event; §total number of patients experiencing at least one local complication takes into account patients with more than one intraoperative and/or postoperative event; ‖estimated risk of at least one local complication developing = the number of patients experiencing at least one local complication divided by the total number of patients in each treatment group.

Discussion

Proximal humeral fractures are the third most common fractures in elderly patients after hip fractures and distal radial fractures [15]. For displaced and unstable proximal humeral fractures, many surgical techniques have been described [5, 11, 12, 18, 19, 26, 27, 32], but no single approach is considered the standard of care. Most studies included a small number of patients and did not distinguish between different fracture types, eg, three- and four-part fractures. The objective of this prospective multicenter observational study was to compare plate versus nail

fixation of three-part proximal humeral fractures regarding surgical, radiologic, and functional outcomes and the complication rate.

A limitation of our study may be the fact that the quality of the radiographs varied from hospital to hospital, as the fracture classification and the occurrence of complications were dependent on the quality of radiographic analysis. All radiographs were reviewed by each treating surgeon and the primary author (GK) and senior author (NS) regarding fracture classification, fracture healing, and the possible occurrence of complications to standardize the measurements. The variability in surgical technique and postoperative management between different surgeons or different hospitals is another limitation. However, the multicenter design might represent an average of the hospitals treating proximal humeral fractures, and all surgeons involved in the study are trained in trauma management and had experience using either locking plates or nails. Another limitation of the study is the lack of randomization associated with a higher level of evidence, as we cannot exclude that compared groups differed according to factors other than the investigated treatment. Restriction to three-part fractures and statistical adjustment for factors showing differences among the groups were used to minimize potential treatment allocation bias. Finally, the 1-year results might not be sufficient to draw final conclusions regarding functional outcome after these challenging fractures, especially when the occurrence of complications prolonged the functional recovery. Furthermore, the results may deteriorate in the nail group over a longer followup secondary to the higher incidence of rotator cuff tearing in the nail group versus the plate group.

Nailing of three-part proximal humeral fractures was significantly faster than locking plate fixation. This may be attributable to the less invasive approach used for intramedullary nailing. The average operation time in our study is comparable to the values from other studies investigating only one treatment option. Lin [20] reported 65 minutes for locked nailing of displaced three-part proximal humeral fractures, whereas in another study, the mean operative time was 55 minutes [16]. Stabilizing a proximal humeral fracture using the PHN required longer radiographic screening time than using an angular stable plate. We could not find any previously published data concerning xray time for comparison with our results.

Three months, 6 months, and 12 months after open reduction and internal fixation, the PHN group showed advantages regarding pain level compared with the angular stable plate group. This may be explained by the minimal invasive approach of the nail implant.

We observed no significant difference between the nail and the plate groups concerning the Constant and Murley score at any followup, although there was a trend toward lower scores for the locking plate cohort. However, the mean Constant and Murley and Neer scores of the injured side were not significantly different suggesting that all three techniques may be useful for internal fixation of three-part proximal humeral fractures.

For our comparative series, the Constant and Murley score was greater than 85% of the mean for the contralateral side. Similar results were reported in a prospective study with 28 patients [10]. One year postoperatively, the mean Constant and Murley score of the injured side for our patients was 72 points corresponding to 87% of the score on the contralateral side. In some other studies, the mean Constant and Murley scores after angular stable plate or angular stable nail fixation of proximal humeral fractures ranged between 72 and 89 points [12, 17, 21, 28, 30], which also are comparable to our results. Nevertheless, most of these published studies do not distinguish between different fracture types. Our intention of limiting this study to a single fracture type allows the observed outcomes to be targeted and limits the possibility of generalizing the results.

There are a limited number of studies investigating antegrade angular stable nailing of proximal humeral fractures [12, 20, 21]. In a multicenter study, Gradl et al. [12] prospectively followed 152 patients with proximal humeral fractures treated with either an antegrade angular stable nail or an angular stable plate; relative 1-year postoperative Constant and Murley scores were 81% and 77%, respectively. No differences were observed between the two groups at 3, 6, and 12 months after surgery.

Sixty-four percent of all fractures showed an anatomic reduction at the 1-year followup. There was no difference between the treatment groups. However, auxiliary exploratory analysis revealed a significant correlation between deviation and the functional result according to the Constant and Murley score: patients with varus deviations greater than 30° to 45° and greater than 45° had, on average, nine ($p = 0.008$) and 14 ($p = 0.027$) percentage points less on the relative Constant and Murley score at 1 year, respectively. This finding is consistent with previously reported results from other studies [1, 23, 28].

In previous studies focused on LPHP and PHILOS fixation of complex fractures, reported complications included avascular necrosis, loss of reduction, plate breakage, and pseudarthrosis/nonunion [6, 10, 17]. We observed 79 local complications in 60 of 211 patients during the 1-year followup; 35 intraoperative complications were directly related to the initial surgical procedure. Most common intraoperative complications were primary screw perforations of the humeral head which were unrecognized during surgery and subacromial impingement because the nail or the plate was positioned too far cranially. Adequate surgical skills and experiences with the

surgical technique are necessary to achieve correct implant fixation and avoid these intraoperative errors.

The similar outcomes for nail versus plate fixation of three-part proximal humeral fractures after 1 year for our patients suggest that all three techniques may be useful for internal fixation of three-part proximal humeral fractures. Many complications were related to incorrect surgical technique and therefore can be avoided. Advanced surgical skills and experience are considered to be more critical for successful operative treatment of three-part proximal humeral fractures than the selection of the implant.

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