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Comparative Functional and Radiological Outcomes of Locking Plate Fixation Versus Proximal Humeral Nailing for Displaced Two- and Three-Part Proximal Humerus Fractures: A 12-Month Comparative Study

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Abstract

Background: Proximal humerus fractures are common injuries, and both locking plate fixation and intramedullary nailing are established surgical treatment options. However, the relative advantages of these techniques remain debated, particularly regarding perioperative efficiency, functional recovery, range of motion, fracture union, and implant-related complications.

Methods: This prospective, non-randomised comparative study included 60 patients with displaced two-part or three-part proximal humerus fractures according to the Neer classification; 30 underwent proximal humerus internal locking system (PHILOS) plating, and 30 underwent proximal humeral nailing (PHN). Treatment selection was based on fracture characteristics and the operating surgeon's clinical decision; random sequence generation and allocation concealment were not used. All patients completed 12 months of follow-up. Constant-Murley scores were assessed at 6 weeks, 12 weeks, 6 months, and 12 months. Repeated scores were analysed using a linear mixed-effects model with treatment group, categorical follow-up time, their interaction, and a patient-specific random intercept. Other continuous outcomes were compared using Welch independent-samples t-tests and categorical outcomes using chi-square or Fisher's exact tests, as appropriate.

Results: Mean operative time was shorter with PHN than PHILOS (75.43 ± 8.92 vs 111.93 ± 10.64 minutes; $p < 0.001$), and mean estimated blood loss was lower (132.33 ± 33.37 vs 201.67 ± 39.90 mL; $p < 0.001$). Mean Constant-Murley scores increased in both groups over follow-up. The linear mixed-effects model showed no statistically significant group-by-time interaction (Wald $\chi^2(3) = 6.72$; $p = 0.0814$). At 12 months, the estimated PHN-minus-PHILOS difference was 2.60 points (95% CI: 0.97-4.23; $p = 0.0018$). Mean time to union was similar (15.23 ± 2.10 vs 15.53 ± 2.80 weeks; $p = 0.640$). Two complications occurred in each group (2/30, 6.7% per group; 4/60, 6.7% overall).

Conclusions: PHILOS plating and PHN produced clinically similar shoulder function at 12 months in this cohort, despite a small statistically significant difference in Constant-Murley scores. PHN was associated with shorter operative time and lower estimated blood loss. The similar observed union and complication frequencies should not be interpreted as proof of equivalent safety, given the modest sample size and 12-month follow-up.

Categories: Trauma, Pain Management, Orthopedics
Keywords: constant-murley score, neer's classification, philos, proximal humeral nail, proximal humerus fracture

Introduction

Proximal humerus fractures account for approximately 5%-6% of adult fractures and are particularly common in older individuals, in whom low-energy falls are a frequent mechanism of injury [1]. Their management is influenced by patient age, functional demand, bone quality, fracture morphology, displacement, and associated soft-tissue injury. Although many minimally displaced fractures can be managed nonoperatively, displaced and unstable fracture patterns may require surgical fixation to restore anatomy and shoulder function.

Classification of proximal humerus fractures is important for describing fracture morphology and guiding treatment planning. The Neer classification remains one of the most widely used systems and categorizes fractures according to the number and displacement of the major proximal humeral segments [2]. Increasing fracture complexity may make stable fixation more challenging, particularly in patients with reduced bone quality, making fracture pattern an important consideration when operative techniques are compared.

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Several surgical options have been described for displaced proximal humerus fractures, with locking plate fixation and intramedullary nailing being commonly used methods of internal fixation. The proximal humerus internal locking system (PHILOS) plate permits direct visualization of the fracture, anatomical reduction, and multidirectional locking-screw fixation. These characteristics can be useful for stabilizing complex fracture configurations and maintaining fixation in the proximal humeral head [3].

Despite these advantages, locking plate fixation is associated with recognized implant- and fracture-related complications. Screw penetration, varus collapse, loss of reduction, avascular necrosis, and subsequent reoperation have been reported after locking plate fixation of proximal humerus fractures [4]. The extent of surgical exposure and soft-tissue dissection required for plate fixation may also influence perioperative morbidity and recovery.

Proximal humeral intramedullary nailing (PHN) provides an alternative load-sharing fixation construct with relatively limited surgical exposure. A meta-analysis involving 1,384 patients reported shorter operative time and lower perioperative blood loss with intramedullary nails compared with locking plates [5]. However, nailing also has potential disadvantages, including rotator-cuff morbidity and screw-related complications, and appropriate entry-point placement and fracture reduction remain important technical considerations.

Comparative evidence has not demonstrated a uniform long-term superiority of either fixation method. A recent systematic review and meta-analysis found that longer-term functional outcomes and overall complication rates were broadly comparable between intramedullary nails and locking plates, despite differences in some perioperative and early outcomes [6]. A recent comparative clinical study also reported shorter operative time and higher 12-month Constant-Murley scores in patients treated with PHN [7]. Earlier meta-analyses comparing locking plates with intramedullary nails also reported perioperative advantages for nailing, particularly shorter operative time and lower blood loss, while finding no consistent difference in Constant-Murley scores [8,9]. A prospective randomized trial of two-part surgical-neck fractures also compared locking plates with intramedullary nails [10].

Because both PHILOS plating and PHN have distinct biomechanical characteristics, technical considerations, and complication profiles, the choice of fixation remains clinically relevant. Further comparative evaluation can help clarify differences in functional recovery, fracture union, range of motion, perioperative parameters, and implant-related complications. The present study therefore aimed to compare the functional, radiological, perioperative, and complication outcomes of PHILOS plating and PHN over a 12-month follow-up period.

Materials And Methods

Study design and setting

This prospective, non-randomised comparative study was conducted in the Department of Orthopaedics, Government Medical College and Rajindra Hospital, Patiala, Punjab, India. Operative dates in the study dataset ranged from February 9, 2025, to September 23, 2025. The study protocol was approved by the Institutional Ethics and Research Committee, Government Medical College, Patiala (approval no. Trg.8(109) 2025/44231-276). Informed consent for participation and publication was obtained from all participants. All 60 enrolled patients had 12-month follow-up data recorded.

Participants

The study included 60 patients with proximal humerus fractures who underwent operative fixation, with 30 treated using PHILOS plating and 30 using PHN. Inclusion criteria were (1) age 18-75 years, (2) displaced two-part or three-part proximal humerus fracture according to the Neer classification, (3) closed fracture, and (4) provision of informed consent. Exclusion criteria were (1) open fracture, (2) refusal to provide informed consent, (3) medical unfitness for surgery, and (4) pathological fracture.

Sample size calculation

The sample size was calculated a priori for the primary outcome, the between-group difference in Constant-Murley score at 12 months. For a two-group comparison of means, the sample size per group was determined using the standard two-group comparison-of-means approach described by Charan et al. [11], using the following formula:

$$n = 2 \times (Z\alpha/2 + Z1 - \beta)^2 \times \sigma^2/d^2.$$

Here, n is the number of patients required in each group, Zα/2 is the standard normal deviate for a two-sided type I error, Z1−β is the standard normal deviate corresponding to the desired power, σ is the expected standard deviation of the outcome, and d is the difference to be detected. A two-sided alpha of 0.05 (Zα/2 = 1.96) and 80% power (Z1−β = 0.84) were specified. The expected standard deviation was set at 12 Constant-Murley points and the target difference at 10 points. The 10-point target was informed by a published 10.4-point minimal clinically important difference estimate for patients undergoing rotator-cuff surgery [12]; this

estimate is not specific to proximal humerus fractures and is used here as a planning assumption rather than a validated fracture-specific threshold. Substitution yielded

$$n = 2 \times (1.96 + 0.84)^2 \times 12^2/10^2 = 22.6,$$

rounded up to 23 patients per group. Allowing for approximately 20% loss to follow-up (23 / 0.80 = 28.8) gave a target of 30 patients per group, or 60 patients in total. The arithmetic is shown in Appendix 1. No interim analysis was planned.

Fracture assessment and treatment

Fractures were categorized using the Neer classification [2]. This was a non-randomised comparison: treatment selection was based on fracture characteristics and the operating surgeon's clinical decision. No random sequence generation or allocation concealment was used. The available masterchart distinguishes two-part from three-part fractures but does not separately record the specific two-part fracture subtype. PHILOS plate fixation was performed through a standard deltopectoral approach, as described for open reduction and locking-plate fixation of the proximal humerus [11,12]. PHN was performed through a limited anterolateral (deltoid-splitting) approach, with the nail entry point at the apex of the humeral head in line with the medullary canal and with protection of the rotator cuff and axillary nerve, following the described intramedullary nailing technique [13,14]. PHN was performed through a limited anterolateral (deltoid-splitting) approach, with the nail entry point at the apex of the humeral head in line with the medullary canal and with protection of the rotator cuff and axillary nerve, following the described intramedullary nailing technique [15]. Genius implants were used in both treatment groups (Genius Ortho Industries, Ghaziabad, Uttar Pradesh, India): a proximal humerus locking plate of PHILOS type for the plate group and a proximal humeral interlocking nail for the nail group. Implant length and screw configuration were selected intraoperatively according to fracture pattern and bone size; a single catalog number was not prespecified. Fracture reduction and implant placement were performed under fluoroscopic guidance with a mobile C-arm image intensifier. Tuberosity fragments, when present, were secured as required. Postoperative rehabilitation progressed from protected/assisted motion to active range-of-motion and strengthening according to fracture stability and clinical recovery; however, the available study records do not provide a sufficiently detailed, fixed rehabilitation schedule or adherence data to establish that the protocol was fully standardised across participants.

Outcome assessment

The primary functional outcome was the Constant-Murley shoulder score, a 100-point composite measure of shoulder pain, activities of daily living, range of motion, and strength [16]. It was documented at 6 weeks, 12 weeks, 6 months, and 12 months; no preoperative Constant-Murley score was available. The same examiner assessed the functional outcomes at each follow-up, but the examiner was not blinded to the fixation method. Shoulder range of motion included forward flexion, extension, abduction, adduction, external rotation, and internal rotation and was measured with a standard universal goniometer; the goniometer brand and model were not recorded. The specific positioning and technique used to quantify internal rotation were not sufficiently detailed in the available records. Standard shoulder radiographs were recorded at 6 weeks, 12 weeks, 6 months, and 12 months. The master chart recorded radiographic status as early callus or united and documented implant position and avascular necrosis. However, an explicit prespecified radiographic definition of union and the identity/blinding status of the radiograph assessor were not documented in the available study records. Perioperative outcomes included operative time, recorded from skin incision to skin closure, and estimated blood loss, recorded from the operative and anesthesia notes. Time to union, overall complications, reoperation, and reason for reoperation were also recorded.

Statistical analysis

Continuous variables are presented as mean ± standard deviation and categorical variables as counts and percentages. Continuous between-group comparisons for perioperative outcomes, range-of-motion measures, and time to union were performed using Welch independent-samples t-tests. Categorical outcomes were assessed using Pearson chi-square tests when expected cell counts permitted and Fisher's exact tests for sparse tables. The four repeated Constant-Murley measurements per patient were analysed in long format using a linear mixed-effects model fitted by maximum likelihood, with treatment group, categorical follow-up time, and the group-by-time interaction as fixed effects and a patient-specific random intercept to account for within-patient correlation. The group-by-time interaction was evaluated using a Wald chi-square test; the estimated PHN-minus-PHILOS difference at 12 months was reported with a 95% confidence interval. The analysis included 240 repeated observations from 60 participants. A two-sided p-value <0.05 was considered statistically significant. No formal multiplicity adjustment was applied to secondary outcomes; these comparisons were considered exploratory. All analyses were recalculated from the individual patient-level entries in the updated 60-patient master chart rather than from group summary means and standard deviations alone. Analyses were performed in Python (Python Software Foundation, Wilmington, DE) using SciPy and Statsmodels.

Results

Patient characteristics

Sixty patients were included, with 30 patients in each treatment group; all 60 had recorded 12-month follow-up data. The sex distribution was identical (12 males and 18 females per group). Mean age was 51.00 ± 7.89 years in the PHILOS group and 54.23 ± 5.79 years in the PHN group (p = 0.076). Side and mechanism of injury were similar. All patients had either two-part or three-part fractures. The PHILOS group included 13 two-part (43.3%) and 17 three-part (56.7%) fractures, while the PHN group included 10 two-part (33.3%) and 20 three-part (66.7%) fractures. Neer fracture-pattern distribution was not statistically different between groups ($\chi^2 = 0.64$, df = 1, p = 0.426) (Table *1*). Treatment allocation was non-randomised and reflected fracture characteristics and the operating surgeon's clinical decision. Figure *1* presents the patient selection and non-randomised treatment allocation flow diagram.

Characteristic	PHILOS (n=30)	PHN (n=30)	Test statistic	p-value
Age, years	51.00 ± 7.89	54.23 ± 5.79	t = −1.81	0.076
Male/female	12/18	12/18	$\chi^2 = 0.00$	1.000
Right/left	16/14	15/15	$\chi^2 = 0.07$	0.796
Fall/road traffic accident	21/9	18/12	$\chi^2 = 0.66$	0.417
Neer two-part	13 (43.3%)	10 (33.3%)	$\chi^2 = 0.64$	0.426
Neer three-part	17 (56.7%)	20 (66.7%)	$\chi^2 = 0.64$	0.426

TABLE 1: Baseline demographic and injury characteristics

PHILOS: proximal humerus internal locking osteosynthesis system; PHN: proximal humerus nail

Data are presented as mean ± standard deviation for age and as n or n (%) for categorical variables. Age was compared with a Welch independent-samples t-test (t statistic; approximate df = 53.2). Sex, side, mechanism of injury, and Neer pattern were compared with Pearson chi-square tests without continuity correction (df = 1). A two-sided p-value <0.05 was considered statistically significant. No baseline comparison met this threshold.

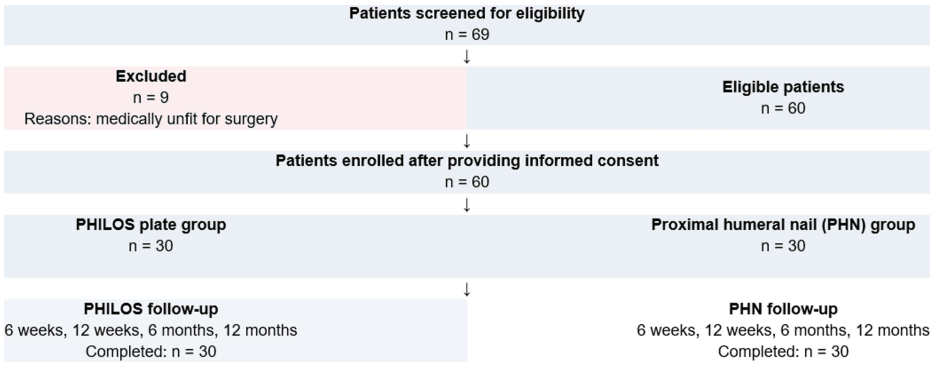


FIGURE 1: Patient selection and non-randomised treatment allocation flow diagram

PHILOS: proximal humerus internal locking system

Perioperative outcomes

The PHN group had a significantly shorter mean operative time and lower estimated blood loss than the PHILOS group. Mean operative time was 75.43 ± 8.92 minutes for PHN versus 111.93 ± 10.64 minutes for PHILOS (t = 14.40, df = 56.3, p < 0.001). Mean estimated blood loss was 132.33 ± 33.37 mL versus 201.67 ± 39.90 mL, respectively (t = 7.30, df = 56.2, p < 0.001) (Table *2*; Appendix 2). No intraoperative complications were recorded in either group.

Characteristic	PHILOS (n=30)	PHN (n=30)	Test statistic	p-value
Operative time, min	111.93 ± 10.64	75.43 ± 8.92	t = 14.40	<0.001
Estimated blood loss, mL	201.67 ± 39.90	132.33 ± 33.37	t = 7.30	<0.001
Recorded intraoperative complications	0	0	-	-

TABLE 2: Comparison of perioperative outcomes

PHILOS: proximal humerus internal locking osteosynthesis system; PHN: proximal humerus nail

Operative time and estimated blood loss are presented as mean ± standard deviation and were compared with Welch independent-samples t-tests (approximate df = 56.3 for operative time and 56.2 for blood loss). Intraoperative complications are presented as counts; no test statistic was calculated because no events were recorded. A two-sided p-value <0.05 was considered statistically significant; both timed and blood-loss comparisons met p < 0.001.

Functional outcome

Constant-Murley scores improved progressively in both groups. The descriptive mean scores were 37.47 ± 3.23 versus 39.87 ± 2.73 at six weeks, 48.83 ± 3.16 versus 53.43 ± 3.09 at 12 weeks, 62.13 ± 4.36 versus 64.53 ± 2.86 at six months, and 73.37 ± 3.31 versus 75.97 ± 3.19 at 12 months for PHILOS and PHN, respectively (Table 3). The linear mixed-effects model showed no statistically significant group-by-time interaction (Wald $\chi^2(3) = 6.72$, $p = 0.0814$). The estimated 12-month difference (PHN minus PHILOS) was 2.60 points (95% CI: 0.97-4.23; $z = 3.13$; $p = 0.0018$). The point estimate was statistically different from zero, but its magnitude was small and below the 10-point difference used for sample-size planning; its clinical importance is therefore uncertain.

Follow-up	PHILOS	PHN	Mean difference (PHN−PHILOS)	Separate time-point test	p-value
6 weeks	37.47 ± 3.23	39.87 ± 2.73	2.40	Not performed	-
12 weeks	48.83 ± 3.16	53.43 ± 3.09	4.60	Not performed	-
6 months	62.13 ± 4.36	64.53 ± 2.86	2.40	Not performed	-
12 months	73.37 ± 3.31	75.97 ± 3.19	2.60	Not performed	-

TABLE 3: Functional outcomes using Constant-Murley scores during follow-up

PHILOS: proximal humerus internal locking system; PHN: proximal humeral nail

Constant-Murley shoulder scores at four follow-up intervals. Values are mean ± standard deviation (n = 30 per group at each time point); the mean difference is PHN minus PHILOS. Individual time-point p-values are not reported because repeated measurements were analysed jointly using a linear mixed-effects model. The group-by-time interaction and the 12-month between-group contrast are reported in the Results and Appendix 2.

Range of motion

At 12 months, mean forward flexion and internal rotation were greater in the PHN group, whereas abduction and external rotation did not differ significantly (Table 4). Mean forward flexion was 132.90° ± 6.29° with PHN and 121.00° ± 8.37° with PHILOS (mean difference: 11.90°; $p < 0.001$). Mean internal rotation was 65.00° ± 4.86° versus 61.00° ± 6.34° ($p = 0.008$). Abduction was 120.00° ± 5.90° versus 123.00° ± 7.53° ($p = 0.092$), and external rotation was 48.17° ± 4.68° versus 47.00° ± 5.94° ($p = 0.401$). These secondary range-of-motion comparisons were not adjusted for multiple testing and should be interpreted as exploratory.

Characteristic	PHILOS (n=30)	PHN (n=30)	Test statistic	p-value
Forward flexion, degrees	121.00 ± 8.37	132.90 ± 6.29	t = −6.23	<0.001
Abduction, degrees	123.00 ± 7.53	120.00 ± 5.90	t = 1.72	0.092
External rotation, degrees	47.00 ± 5.94	48.17 ± 4.68	t = −0.85	0.401
Internal rotation, degrees	61.00 ± 6.34	65.00 ± 4.86	t = −2.74	0.008
Time to union, weeks	15.53 ± 2.80	15.23 ± 2.10	t = 0.47	0.640
United by 6 months	30 (100%)	30 (100%)	-	-
Any complication	2 (6.7%)	2 (6.7%)	Fisher's exact	1.000
Reoperation	1 (3.3%)	0	Fisher's exact	1.000
Avascular necrosis at 12 months	0	0	-	-

TABLE 4: Twelve-month radiological, functional, and complication outcomes

PHILOS: proximal humerus internal locking system; PHN: proximal humeral nail

Twelve-month range-of-motion, union, and complication outcomes. Continuous variables are presented as mean ± standard deviation and were compared using Welch independent-samples t-tests calculated from individual patient-level observations. Categorical variables are presented as n (%). Complications and reoperation were compared using two-sided Fisher exact tests because of sparse cells; the odds ratio for reoperation was not estimable because one cell was zero. Union at six months and avascular necrosis had no discordant events, so no comparative p-value is presented. No multiplicity adjustment was applied to secondary outcomes; these findings are exploratory.

Radiological outcome and complications

All 60 fractures demonstrated early callus at six weeks. At 12 weeks, five PHILOS fractures and four PHN fractures were recorded as united; the remainder showed early callus. By six months and at 12 months, every fracture was recorded as united. Mean time to union was 15.53 ± 2.80 weeks in the PHILOS group and 15.23 ± 2.10 weeks in the PHN group (p = 0.640). Two complications occurred in each group (2/30, 6.7% per group; 4/60, 6.7% overall): one intra-articular screw and one plate cut-through in the PHILOS group, and two screw back-outs in the PHN group. One patient initially treated with PHILOS (GMCP9 in the de-identified master chart) underwent reoperation with conversion to PHN because of plate cut-through; this patient was retained in the PHILOS group according to the initial fixation method for the comparative summaries, and the event was counted as a PHILOS complication and reoperation. No PHN patient underwent reoperation. No avascular necrosis was recorded in either group through 12 months. The small number of events does not permit a reliable comparison of uncommon complications (Table *4*). Figure *2* presents the proximal humerus fracture treated with PHILOS plating, and Figure *3* presents the proximal humerus fracture treated with proximal humeral nailing.

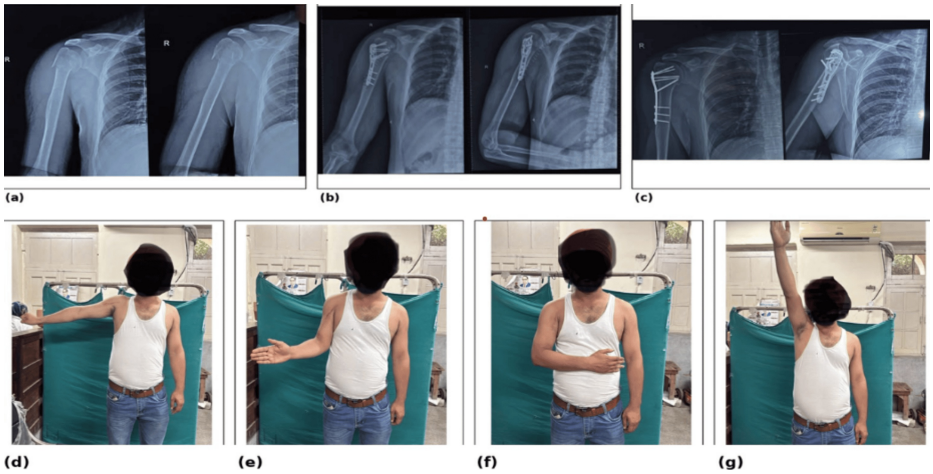


FIGURE 2: Proximal humerus fracture treated with PHILOS plating

PHILOS: proximal humerus internal locking system

Representative right shoulder case treated with a PHILOS locking plate. (a) Preoperative anteroposterior radiograph showing a displaced proximal humerus fracture. (b) Immediate postoperative radiograph after PHILOS plate fixation. (c) 12-month follow-up radiograph. (d-g) 12-month clinical photographs of forward elevation, abduction, and rotational range of motion. Identifying features should remain obscured in accordance with consent and institutional requirements.

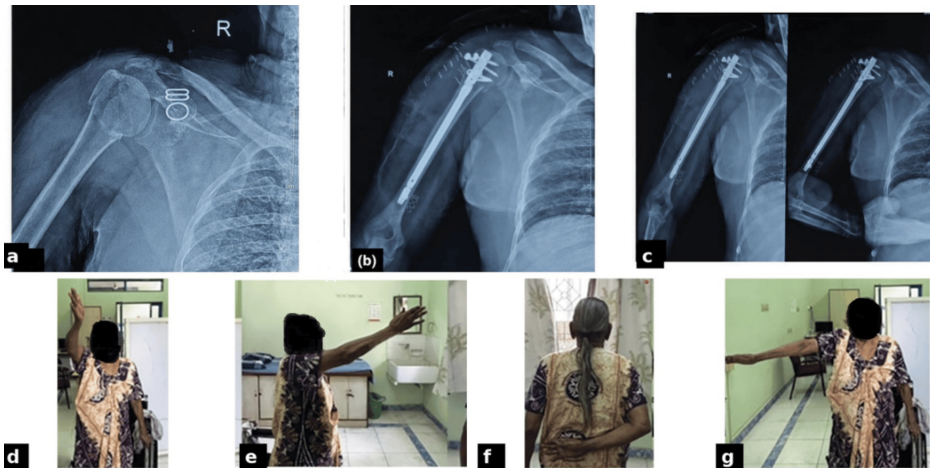


FIGURE 3: Proximal humerus fracture treated with proximal humeral nailing (PHN)

Representative right shoulder case treated with a proximal humeral nail. (a) Preoperative anteroposterior radiograph showing a displaced proximal humerus fracture. (b) Immediate postoperative radiograph after proximal humeral nailing. (c) 12-month follow-up radiograph. (d-g) 12-month clinical photographs of forward elevation, abduction, and rotational range of motion. Identifying features should remain obscured in accordance with consent and institutional requirements.

Discussion

The principal findings of this 60-patient prospective, non-randomised comparative study of displaced two- and three-part proximal humerus fractures were that PHN was associated with shorter operative time and lower estimated blood loss, while both techniques achieved union in all recorded patients by six months. The longitudinal analysis did not demonstrate a statistically significant group-by-time interaction (Wald $\chi^2(3) = 6.72$, $p = 0.0814$). Although the estimated 12-month Constant-Murley score was 2.60 points higher in the PHN group (95% CI: 0.97-4.23; $p = 0.0018$), this difference was small relative to the 10-point difference used for sample-size planning and the 10.4-point reference estimate cited from rotator-cuff surgery [12]. The latter is not a fracture-specific minimal clinically important difference. On balance, the findings support clinically similar shoulder function at 12 months rather than a clinically meaningful functional advantage of PHN. Because treatment allocation was based on fracture characteristics and surgeon decision rather than

randomisation, causal interpretation is limited.

The perioperative findings are consistent with prior pooled evidence. Li et al. reported shorter incision length, lower perioperative blood loss, and shorter operative time with intramedullary nails in a meta-analysis of 1,384 patients [5]. Shi et al. similarly reported perioperative advantages for intramedullary fixation [8]. A 2024 systematic review and meta-analysis concluded that longer-term functional scores and overall complication rates were broadly comparable despite some early differences between techniques [6].

The functional pattern in the present study should be interpreted cautiously. Although the PHN group had a statistically higher estimated Constant-Murley score at 12 months, the 2.60-point difference is only about one-quarter of the 10.4-point reference estimate used in the sample-size rationale. A statistically significant difference does not necessarily represent a perceptible or clinically important benefit. The non-randomised allocation, absence of preoperative Constant-Murley scores, and lack of blinded outcome assessment may have influenced the observed comparison. The non-significant group-by-time interaction also indicates that the overall pattern of score change did not differ significantly between groups. These results are consistent with describing 12-month shoulder function as clinically similar between the two fixation groups.

The overall complication frequency in the present study was 6.7% (4/60 patients), which is lower than the 33%-49% overall complication estimates reported in a systematic review of locking-plate fixation, depending on whether varus malunion was included; that review also reported a reoperation rate of approximately 14% [4]. A later systematic review reported intra-articular screw penetration in 9.5%, varus collapse in 6.8%, avascular necrosis in 4.6%, and reoperation in 13.8% of locking-plate cases [17]. These figures are not directly comparable with the present cohort because fracture mix, definitions, follow-up duration, and event ascertainment differ across studies. The present study included a relatively young cohort (combined mean age approximately 53 years), excluded four-part fractures, comprised only 60 patients, and followed patients for 12 months. These features may partly explain the lower observed frequency, but the result should not be presented as evidence of superior implant safety. The absence of avascular necrosis at 12 months does not exclude later osteonecrosis or other uncommon implant-related events.

The range-of-motion findings were mixed. Forward flexion and internal rotation were greater in the PHN group at 12 months, whereas abduction and external rotation did not differ significantly. The approximately 12° forward-flexion difference is noteworthy despite the small overall Constant-Murley difference. Potential explanations in the PHILOS group include soft-tissue scarring related to the deltopectoral exposure, plate prominence or subacromial impingement, and altered greater-tuberosity position affecting rotator-cuff mechanics. These mechanisms were not specifically measured in this study and should be regarded as plausible explanations rather than demonstrated causes. Neuralgic amyotrophy (Parsonage-Turner syndrome) can cause shoulder pain and weakness and may mimic postoperative nerve injury or poor functional recovery; persistent weakness or limited elevation should prompt appropriate clinical assessment rather than automatic attribution to the implant or approach [18]. Structured, symptom-directed rehabilitation may be useful once this diagnosis is recognised, although the cited evidence includes case-level data [18]. Persistent pain, weakness, or restricted elevation may also arise from conditions unrelated to the implant, including cervical radiculopathy, cervical spondylosis, and altered thoracic posture/kyphosis; shoulder and cervical pathology may overlap clinically [19,20]. Individual motion parameters should therefore be interpreted alongside fracture pattern, reduction quality, tuberosity position, rotator-cuff status, cervical and neurological findings, and rehabilitation adherence.

Limitations

This study has several limitations. The prospective design was non-randomised, with treatment selection based on fracture characteristics and the operating surgeon's clinical decision; therefore, selection bias and residual confounding cannot be excluded. No random sequence generation or allocation concealment was used, and outcome assessment was not blinded. The same examiner assessed the functional outcomes, but knowledge of the fixation method could have influenced subjective or effort-dependent measurements. Preoperative Constant-Murley scores were unavailable, preventing adjustment for baseline shoulder function. The 12-month Constant-Murley standard deviations were relatively narrow (3.31 points in the PHILOS group and 3.19 points in the PHN group) compared with the 12-point standard deviation assumed for sample-size planning. The study was not powered to detect differences in rare complications such as avascular necrosis or screw-related failure, and 12 months may be insufficient to capture late complications. The 10.4-point minimal clinically important difference cited in the sample-size rationale was derived from a rotator-cuff surgery population and may not be directly transferable to proximal humerus fractures [15]. No formal multiplicity adjustment was made for secondary outcomes. Pre-existing cervical spine disease, including cervical spondylosis or radiculopathy, was not recorded and may have contributed to referred shoulder pain or weakness, potentially affecting the pain and strength components of the Constant-Murley score [19,20]. Bone density, comorbidity burden, rotator-cuff status, reduction quality, neck-shaft angle, and additional patient-reported outcome measures were not available. For this, we may require a large sample size and a longer study duration. Therefore, we recommend that the results of our study be confirmed with multicentric, large-sample studies.

Conclusions

Both PHILOS plating and PHN achieved fracture union and improvement in shoulder function in patients with displaced two-part and three-part proximal humerus fractures during 12 months of follow-up. At 12 months, shoulder function was clinically similar between groups, despite a small statistically significant difference in Constant-Murley scores. PHN was associated with shorter operative time and lower estimated blood loss. The observed union and complication frequencies were similar, but the small sample size and follow-up duration do not establish equivalent safety or exclude uncommon and late complications.

These findings should be interpreted in view of the modest sample size, single-centre design, non-randomised treatment allocation, absence of baseline functional scores and blinded assessment, restriction to two-part and three-part fractures, and the limited 12-month follow-up. Larger multicentre prospective studies with transparent allocation procedures, standardised surgical and rehabilitation protocols, blinded outcome assessment, prespecified radiographic criteria, and adequate follow-up are needed to confirm the comparative outcomes of PHILOS plating and PHN.

Appendices

Appendix 1: Sample-size calculation

This appendix is cited in the Materials and Methods (Sample size calculation) and in the Discussion. The primary endpoint was the Constant-Murley score at 12 months. The two-sample formula for a difference in means was used [8]:

$$n = 2 \times (Z\alpha/2 + Z1 - \beta)^2 \times \sigma^2/d^2$$

Inputs: two-sided α = 0.05, so Zα/2 = 1.96; power = 80%, so Z1−β = 0.84; σ = 12 Constant-Murley points; d = 10 points. The 10-point target was informed by the 10.4-point estimate reported in patients undergoing rotator-cuff surgery [15], which is not a validated proximal-humerus-fracture-specific MCID and should be regarded as a planning assumption.

Step 1: $Z\alpha/2 + Z1 - \beta = 1.96 + 0.84 = 2.80$.

Step 2: $(2.80)^2 = 7.84$.

Step 3: $\sigma^2 = 144; d^2 = 100; \sigma^2/d^2 = 1.44$.

Step 4: $n = 2 \times 7.84 \times 1.44 = 22.58$, rounded up to 23 patients per group before allowance for attrition.

Step 5. With an anticipated 20% loss to follow-up, the inflated sample size was 23 / 0.80 = 28.75, rounded up to 30 patients per group (60 patients total). All 60 enrolled patients completed 12-month follow-up, so the analyzed sample matched the target.

Appendix 2: Test statistics for tabulated comparisons

This appendix summarises analyses recalculated from the individual patient-level entries in the updated master chart (60 participants; 30 per group). The four repeated Constant-Murley scores per participant (240 observations) were analysed using a maximum-likelihood linear mixed-effects model with a patient-specific random intercept. Other continuous comparisons used Welch independent-samples t-tests; categorical comparisons used Pearson chi-square or Fisher's exact tests, as appropriate. Separate between-group tests were not performed at each Constant-Murley time point.

Comparison	Test	Statistic	df	p-value
Age	Welch t	−1.81	53.2	0.076
Sex	Pearson χ^2	0.00	1	1.000
Side	Pearson χ^2	0.07	1	0.796
Mechanism	Pearson χ^2	0.66	1	0.417
Neer pattern	Pearson χ^2	0.64	1	0.426
Operative time	Welch t	14.40	56.3	<0.001
Estimated blood loss	Welch t	7.30	56.2	<0.001
Constant-Murley group-by-time interaction	Wald χ^2	6.72	3	0.0814
Constant-Murley 12 month PHN-PHILOS difference	Mixed-model contrast: 2.60 (95% CI 0.97-4.23); z = 3.13	2.60	-	0.0018
Forward flexion	Welch t	−6.23	53.8	<0.001
Abduction	Welch t	1.72	54.9	0.092
External rotation	Welch t	−0.85	55.0	0.401
Internal rotation	Welch t	−2.74	54.3	0.008
Time to union	Welch t	0.47	53.8	0.640
Any complication	Fisher's exact	OR = 1.00	-	1.000
Reoperation	Fisher's exact	OR not estimable	-	1.000

TABLE 5: Test statistics for tabulated comparisons

The mixed-effects model used 240 repeated scores from 60 participants. Other comparisons used individual patient-level observations. No multiplicity adjustment was applied to secondary outcomes.

Additional Information

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All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

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Disclosures

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