



Proximal humeral fractures in patients over 60 years old: a randomized study of nonoperative versus operative treatment with locking plate

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Background: Proximal humerus fractures (PHFs) are common in the elderly, with a rising incidence. Despite advances in surgical techniques, the optimal treatment for displaced PHFs remains controversial, as high-quality studies show no significant differences in functional outcomes between surgical and nonsurgical treatments. This study aims to compare nonoperative with surgical treatment using a locking plate (LP) for displaced PHFs in patients over 60 year old.

Methods: This prospective, randomized clinical trial compared nonoperative and operative treatments using LPs for displaced PHFs in patients over 60 year old. Patients were randomized 1:1 into 2 groups using a block randomization stratified by tuberosity involvement. The primary outcome was the Constant-Murley score at 24 months. Secondary outcomes included the Individual Relative Constant Score, American Shoulder and Elbow Surgeons (ASES) score, and Single Assessment Numeric Evaluation (SANE) score at 3, 6, 12, and 24 months. The incidence of complications and the need for reoperations were evaluated.

Results: Eighty patients were randomized, with 71 completing 24 months of follow-up: 40 in the non-operative group and 31 in the operative group. At 24 months, the mean Constant-Murley scores were 68.7 ± 16.1 for the non-operative group and 66.5 ± 15.8 for the operative group ($P = .433$). The ASES score at 24 months was 77.0 ± 23.1 for the nonoperative group and 79.1 ± 20.0 for the operative group ($P = .871$). The SANE scores at 24 months were 83.8 ± 19.3 for the nonoperative group and 88.5 ± 17.2 for the operative group ($P = .236$). The Individual Relative Constant Score at 24 months was $79.5 \pm 25.2\%$ for the nonoperative group and $73.0 \pm 29.2\%$ for the operative group ($P = .244$). Seventeen patients experienced complications, with 6 (15.0%) in the nonoperative group and 11 (35.5%) in the operative group ($P = .070$). The rate of a new surgical indication was 12.5% in the nonoperative group and 22.6% in the operative group ($P = .421$). Rotator cuff tears were 20.0% in the nonoperative group vs. 25.8% in the operative group ($P = .768$).

Conclusion: The operative treatment of displaced proximal humeral fractures with LP osteosynthesis in patients over 60 year old shows no evidence of differences in clinical outcomes compared to nonoperative treatment, as measured by the Constant-Murley Score, Individual Relative Constant Score, ASES, SANE, and complication rates.

The Comissão de Ética para Análise de Projetos de Pesquisa do HCFMUSP approved this study (CAAE. 49255615.0.0000.0068).

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Proximal humerus fractures (PHFs) account for about 4%-5% of all fractures and are the third most common in the elderly population.³¹ The incidence of these fractures has risen significantly, with studies indicating a threefold increase over the past 33 years,³¹ reaching 175 per 100,000 inhabitants.³⁸ These fractures significantly impact the quality of life, with over 25% of patients experiencing poor outcomes, even after 24 months.³⁰ Mortality rates are also substantial, ranging from 10% to 25%, with the risk of death during hospitalization being 1.8 and 2.8 times higher for surgically treated patients.^{1,6,8,37}

Nonsurgical treatment is often preferred for minimally displaced fractures, showing satisfactory outcomes.^{16,28} However, the treatment of displaced fractures remains controversial. High-quality studies, such as the PROFHER trial, have demonstrated no significant differences in functional outcomes between surgical and nonsurgical treatments for displaced PHFs.³² Studies by Launonen et al.^{24,25} and Fjalestad et al.¹¹ support these findings, indicating similar outcomes regarding pain relief and functional recovery. Studies have included mostly fractures with mild and moderate displacement, and less frequently severe three- and four-part fractures, which could minimize the differences between treatments and result in a smaller effect size for surgical treatment.^{18,24,36}

Despite biomechanical advancements with locking plates (LPs), clinical outcomes do not consistently surpass those of nonoperative treatments, and complication rates remain high.⁵ The high complication rates associated with LPs may be due to problems with fracture reduction and plate positioning.^{4,18} Despite the high quality of Rangan et al.'s³² pragmatic study, it was conducted in various centers with different levels of surgical expertise and it used multiple surgical techniques (plates, percutaneous wires, and arthroplasty), which may introduce biases related to surgical technique or the quality of fracture reduction.

Our study aims to address these gaps by focusing on a specific population treated by experienced shoulder surgeons using standardized techniques for LP fixation and postoperative rehabilitation. We hypothesize that this study, comparing nonoperative and operative treatments using LPs, will address limitations in prior research caused by broader variability in treatment protocols, providing more robust evidence regarding outcomes.

The primary objective is to compare nonoperative vs. operative treatment using a LP for displaced PHFs in patients over 60 year old, measured by the Constant and

Murley score at 24 months. Secondary objectives include comparing clinical outcomes using the Individual Relative Constant Score (IRCS), the American Shoulder and Elbow Surgeons (ASES) score, and the Single Assessment Numeric Evaluation (SANE) score at 3, 6, 12, and 24 months. Additionally, the incidence of complications and the need for reoperations were evaluated.

Materials and methods

Study design

A prospective, randomized (1:1), parallel-group clinical trial in a single tertiary academic medical center specializing in orthopedic care and complex fracture management was conducted. Patients diagnosed with PHF who met the selection criteria were randomized into one of 2 groups: nonoperative or operative with LP fixation. An independent evaluator was blinded to the group allocation. All selected patients had the details of the research explained to them by a research assistant not involved in the treatment and were offered the option to participate or not. All participants or their legal guardians signed the informed consent form, ensuring the option to withdraw from participation without prejudice to medical care.

The local institutional review board approved the study, and it was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (registration number: NCT02913378). The study was conducted as part of the routine clinical care provided at our hospital, and all costs were covered by the public health care system. No external funding or sponsorship was involved in the execution of this study.

Study population

Patients presenting with proximal humeral fractures confirmed by standardized radiographs were included in the study. All cases were evaluated for surgical indication criteria by the main author. Surgeries were performed by 2 shoulder and trauma surgeons at the same institution with 14 years of experience.

Selection criteria

Patients were included in the study if they met all the following criteria: age ≥ 60 years, proximal humeral fracture involving the surgical neck with at least one of the following parameters: head-shaft angle deviation between 100° and 120° or above 175°, head-shaft translation greater than 1 cm, associated fracture of the greater and/or lesser tubercle with deviation >0.5 cm, head-shaft angle in the sagittal or axial plane $>45^\circ$, fracture

occurring within the last 30 days, and consent to participate in the study.

Patients were not included in the study if they met any of the following criteria: proximal humeral fracture with one of the following parameters: no contact between the head and humeral shaft, varus deviation with head-shaft angle $<100^\circ$, articular fracture of the humeral head with deviation >2 mm, head depression $>40\%$, fracture-dislocation, open humeral fracture, bilateral humeral fracture, associated fracture of the ipsilateral or contralateral upper limb, pathological humeral fracture, full-thickness tear of one of the rotator cuff tendons previously diagnosed, active or previous infection in the affected shoulder, neurological injury in the affected limb, previous surgery on the affected shoulder, and need for arthroplasty due to osteosynthesis invariability.

Interventions

Nonoperative group

The nonoperative treatment consisted of using a Velpeau sling associated with early rehabilitation. Analgesics and opioids were administered for a minimum of seven days and then as needed for pain. The sling was recommended for 30 days. Cervical, scapular, elbow, wrist, and hand exercises were advised from the first day of inclusion in the study. Patients were instructed to start physical therapy within 5 to seven days of inclusion. Pendulum exercises started on the seventh day. By the 15th day, passive shoulder exercises for elevation, abduction, and rotations were initiated. By the 30th day, active-resisted elbow exercises, active-assisted and active-free shoulder exercises, and isometric exercises for the rotator cuff, deltoid, and scapular belt were initiated, as tolerated. Active-resisted exercises for the rotator cuff, deltoid, and scapular belt began on the 45th day.

Operative group

Surgery was done under balanced general anesthesia and interscalene brachial plexus block and routine antibiotic prophylaxis. A traditional LP fixation technique was performed.¹⁵ Patients were positioned supine with a 30° elevation, and the shoulder and arm were positioned laterally for fluoroscopy. A 10 cm deltopectoral approach was used, retracting the cephalic vein and deltoid muscle laterally. The subacromial bursa, biceps tendon, and rotator cuff tendons were identified. The supraspinatus and infraspinatus tendons were repaired with nonabsorbable sutures. The humeral head was reduced and temporarily fixed with Kirschner wires. For tubercle fractures, transosseous sutures were placed before the plate. A Philos plate (DePuy Synthes, Solothurn, Switzerland) was positioned 8-10 mm below the greater tubercle and 10 mm lateral to the biceps tendon. At least 5 proximal locking screws and 3 distal screws were then inserted.

Postoperative follow-up

After surgery, patients were immobilized with a sling. Analgesics and opioids were administered for a minimum of 7 days and then as needed for pain. Patients were hospitalized for at least 24 hours. After this period, discharge depended on the patient's clinical condition. Patients were advised to wear the sling for 2 weeks but were encouraged to remove it during the day for personal hygiene and light household activities without exerting the operated upper limb. The physical therapy protocol was the same for all operated

patients, regardless of preoperative variables or fracture pattern. Immediately after surgery, patients were advised to perform active movements of the hand, wrist, and elbow. Passive shoulder mobilization was done on the first postoperative day, before discharge. Passive shoulder exercises were guided by a physical therapist during hospitalization, and the patient received a document with instructions for immediate home exercises, personal hygiene, and sling use. Patients began physical therapy after the seventh day of surgery. Fifteen days postsurgery, active-assisted and active-free shoulder exercises, and isometric exercises for the rotator cuff, deltoid, and scapular belt were initiated. Active-resisted exercises for the rotator cuff, deltoid, and scapular belt began on the 30th day, and functional exercises on the 45th day, as tolerated.

Outcomes and evaluation periods

Outcomes included functional assessment at 3, 6, 12, and 24 months according to the Constant-Murley score, the IRCS, ASES and SANE score, as well as the complication rates. Constant-Murley score at 24 months was adopted as the primary outcome of the study.

The Constant-Murley score was applied to the contralateral side at 3 months. The absolute value of the Constant-Murley scale in the affected limb is divided by the absolute value of the contralateral limb, yielding a percentage value, described by Fialka et al.¹⁰ as IRCS.

Clinical evaluation included general characteristics such as gender, age, dominance, and the affected side, as well as habits like smoking and comorbidities.

Image evaluation

Radiographs

The preoperative evaluation was performed with radiographs in 4 views: true AP, true lateral, axillary lateral, and Velpeau views. Initial radiographs, before group allocation, assessed the following classifications: Neer, AO, binary described by Hertel et al,^{19,27} and modifications described by Resch et al.³⁴ Radiographic parameters evaluated included head-shaft angle, length of the humeral head metaphyseal fragment, displacement of the greater tuberosity and the shaft relative to the humeral head, and presence of medial metaphyseal comminution.¹⁴ Postoperative radiographs were taken immediately, and at 3, 6, 12, and 24 months for both groups. Radiographs were evaluated using the institution's image storage system (iSite enterprise 4.1, Phillips).

Computed tomography

A computed tomography scan was performed on all patients before inclusion in the study. The results were used to complement the definition of the radiographic variables of the fracture, such as classifications and characteristics of displacements.

Magnetic resonance and ultrasound imaging

Magnetic resonance imaging (MRI) and ultrasound imaging were performed at 6 months to evaluate the integrity of the rotator cuff. The findings related to the rotator cuff tendons were classified according to the presence or absence of full-thickness tears.

Complications

Complications were recorded according to their occurrence, and the total number was documented separately for each treatment group. The evaluated complications included osteonecrosis, nonunion, secondary displacement of the humeral head, secondary displacement of the tuberosities, infection, hardware-related issues such as screw cutout and articular protrusion. The need for a new surgical treatment was also recorded. Rotator cuff tears were not included in the total count of complications and were analyzed separately due to the variability of symptoms associated with these injuries.

Sample size calculation

The sample size calculation was based on the Constant-Murley score. An expected difference of 8.5 points between the groups was considered, based on the minimally significant clinical difference.^{26,39} The standard deviation used was 12.8.¹⁵ A two-tailed test with a 95% confidence interval and 80% power indicated the need for 36 patients in each group. Anticipating a 10% follow-up loss, a necessary sample size of 40 patients per group was estimated, totaling 80 cases.

Randomization

Randomization was based on a list generated on the site “<http://www.randomization.com>”. Block randomization, stratified by the presence of tuberosity involvement regardless of displacement, was used. Two separate randomization lists were created: one for cases with tuberosity fractures and another for cases without tuberosity fractures. Both lists utilized blocks of 2 and 4, with 60% of the blocks being size 2 and 40% being size 4. Allocation was done via a password-protected database. A nonstudy collaborator was responsible for generating the randomization lists, entering them into the database, and managing initial data entry. Following patient consent and eligibility confirmation, the patient's name was entered into the database by the collaborator, and the treatment allocation was communicated to the treating surgeon and study coordinator.

Blinding

Clinical evaluation and application of clinical scores were performed by an evaluator who was blinded to the group allocation and did not participate in either the patient's rehabilitation or surgery. As this was a single-blind study, the surgeon was aware of the treatment group, but the evaluator's blinding was maintained by conducting assessments with the patient dressed, preventing visualization of the surgical scar, and ensuring unbiased outcome measurements.

Statistical analysis

The mean values of the primary clinical outcome (Constant-Murley scale) and secondary clinical outcomes (IRCS, ASES, and SANE) for the 2 groups were compared over time at 4 evaluation

points (3, 6, 12, and 24 months). To ensure the validity of the statistical analyses, data normality was assessed using the Shapiro-Wilk test and histogram analysis prior to applying parametric tests. Parametric data were analyzed using Student's *t*-test, while nonparametric data were analyzed using the Mann-Whitney *U* test. Group homogeneity was tested using Levene's test before conducting *t*-tests for comparisons of continuous data. Differences between preoperative clinical and radiographic characteristics and outcome analysis were evaluated using Student's *t*-test (parametric continuous data), Mann-Whitney *U* test (nonparametric continuous data), or chi-square test (categorical data). Continuous data were presented as means, standard deviations, medians, and interquartile ranges, while categorical data were presented as absolute and percentage values.

The analysis compared the evolution of Constant, ASES, SANE, and CRI scores over time within the 2 treatment groups: nonoperative and operative. Repeated measures analysis of variance, with Bonferroni correction applied to adjust for multiple comparisons across time points, was used to assess differences in scores across time points, taking into account the correlation between repeated measures for the same patient. Complications were analyzed using the chi-square test with Yates' correction. A *P* value of $< .05$ was considered statistically significant.

Subgroup analyses were conducted using the Constant-Murley score at 24 months as the outcome measure. The Mann-Whitney *U* test was employed for comparisons between the nonoperative and operative groups within each subgroup. Subgroups were defined based on tuberosity involvement, Neer classification, the presence of rotator cuff tears, and complication.

The analysis was conducted using a per-protocol approach, including only patients who adhered to their assigned treatment group. Only patients who completed the 6-month clinical evaluation were included in the analysis. For patients with missing data at subsequent follow-ups, the last observation carried forward method was applied to impute the last available data point.

A *P* value of $< .05$ was considered statistically significant. Statistical analysis was performed using Google Colab (Python version 3.10; Google LLC, USA), utilizing libraries such as pandas (version 1.5.3) for data manipulation and scipy (version 1.10.1) for statistical computations and for generating graphs.

Results

Patient flow

Between January 2016 and November 2018, 177 patients were evaluated for inclusion (Fig. 1). Ninety-seven patients (54%) did not meet the inclusion criteria, with the most common reason being the presence of acceptable displacement for nonoperative treatment. Eighty patients were randomized. Seventy-one patients were analyzed: 40 in the nonoperative group and 31 in the operative group. In the operative group, 4 patients did not receive the intervention due to not having the clinical conditions for surgery after randomization.

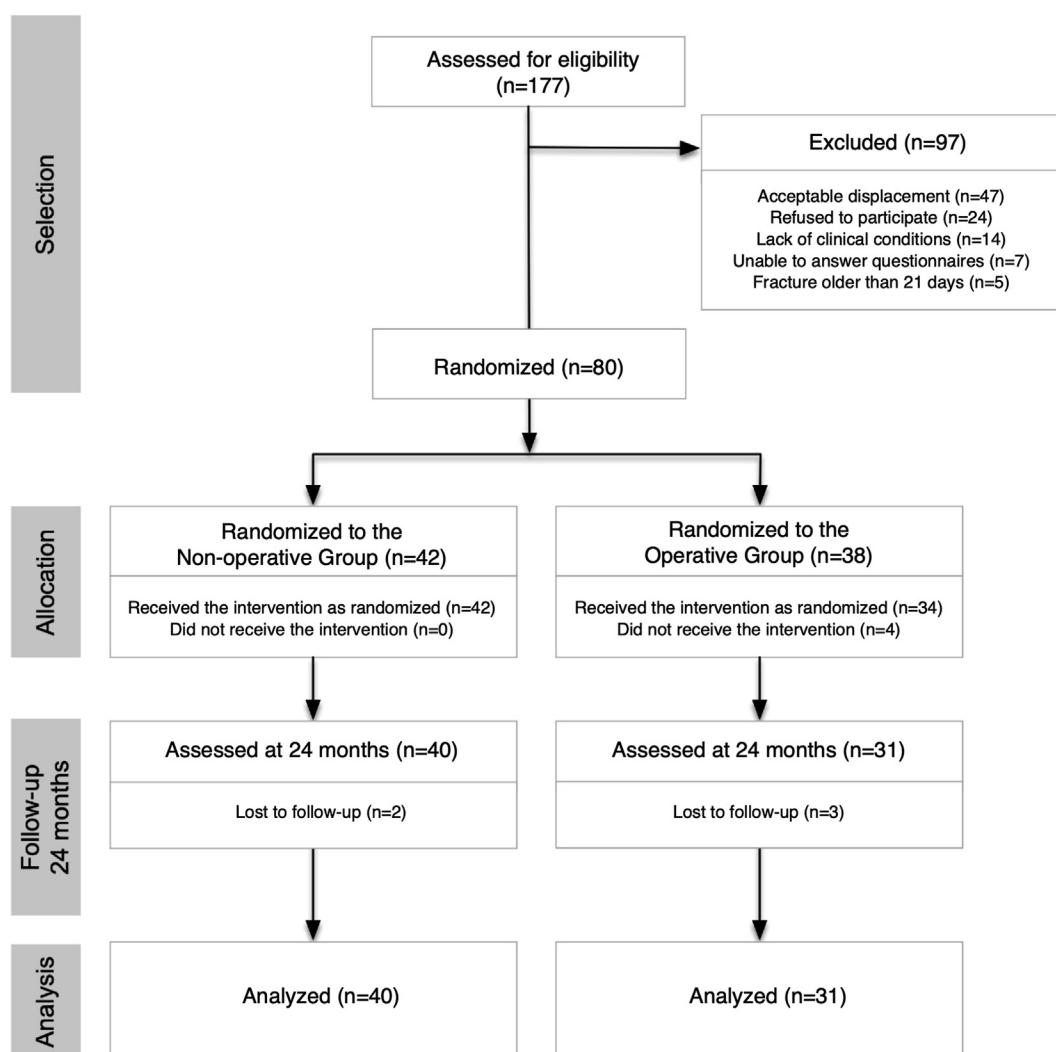


Figure 1 Patient flow diagram.

Demographic characteristics

The demographic characteristics of the randomized patients were well balanced between the groups (Table I). The majority of the sample was female, without involvement of the dominant limb, and nonsmokers. The only variable that showed a statistically significant difference between the groups was the number of days between the injury and the start of treatment (nonoperative group: 6.6 ± 4.1 days; operative group: 10.5 ± 6.8 days; $P = .004$).

Regarding the radiographic characteristics of the fractures, the groups did not show statistically significant differences (Table II). For Neer classification, the nonoperative group had 25% two-part fractures, 47.5% three-part fractures, and 27.5% four-part fractures. The operative group had 32.3% two-part fractures, 38.7% three-part fractures, and 29.0% four-part fractures ($P = .722$). The analysis revealed no statistically significant difference in tuberosity involvement between the nonoperative

(85.0%) and operative (77.4%) groups ($P = .610$). Figures 2 and 3 display pretreatment and post-treatment radiographs of nonoperative and operative management, respectively.

Clinical outcomes

There were no statistically significant differences between the 2 treatment groups at any follow-up point (Table III), regarding any of the functional scales evaluated.

The mean Constant-Murley score at three months was 56.1 ± 16.8 for the nonoperative group and 57.6 ± 14.7 for the operative group ($P = .672$). At two years, the scores were 68.7 ± 16.1 for the nonoperative group and 66.5 ± 15.8 for the operative group ($P = .433$).

The mean ASES score at 24 months was 77.0 ± 23.1 for the nonoperative group and 79.1 ± 20.0 for the operative group ($P = .871$). For the SANE score at 24 months, the

Table I Clinical demographic characteristics

	Nonoperative (N = 40)	Operative (N = 31)	P value
Age (yr)*	69.1 ± 6.0	68.4 ± 5.3	.875
Interval between injury and treatment (d)†	6.6 ± 4.1	10.5 ± 6.8	.004
Female sex	33 (82.5%)	27 (87.1%)	.841
Smoking	5 (12.5%)	6 (19.4%)	.461
Diabetes	10 (25.0%)	6 (19.4%)	.099
Hypertension	25 (62.5%)	18 (58.1%)	.726
Depression	3 (7.5%)	2 (6.5%)	.999
Right shoulder	18 (45.0%)	12 (38.7%)	.099
Involvement of the dominant arm	15 (37.5%)	17 (54.8%)	.451

Values are presented as the number with the percentage in parentheses.

* Mean and standard deviation (SD).

† Median and interquartile range (IQR).

Table II Radiographic characteristics of the fractures

	Nonoperative (N = 40)	Operative (N = 31)	P value
Tuberosity involvement			
Yes	34 (85.0%)	24 (77.4%)	.610
No	6 (15.0%)	7 (22.6%)	
Tuberosities fractured			
None	6 (15.0%)	7 (22.6%)	.052
Greater tuberosity	22 (55.0%)	8 (25.8%)	
Greater + lesser tuberosity	12 (30.0%)	14 (45.2%)	
Lesser tuberosity	0 (0.0%)	2 (6.5%)	
Neer classification			
Two-part	10 (25.0%)	10 (32.3%)	.284
Three-part	19 (47.5%)	9 (29.0%)	
Four-part	11 (27.5%)	12 (38.7%)	
Resch classification			
1	6 (15.0%)	5 (16.1%)	.330
2	4 (10.0%)	0 (0.0%)	
3	13 (32.5%)	10 (32.3%)	
4	17 (42.5%)	16 (51.6%)	
AO classification			
A	9 (22.5%)	8 (25.8%)	.293
B	20 (50.0%)	10 (32.3%)	
C	11 (27.5%)	13 (41.9%)	
Coronal impaction			
Impaction	29 (72.5%)	22 (71.0%)	.432
Distraction	3 (7.5%)	5 (16.1%)	
Neutral	8 (20.0%)	4 (12.9%)	
Preoperative coronal neck-shaft angle, degree			
2 (125-150)	13 (32.5%)	11 (35.5%)	.958
1 (110-124 or 151-165)	13 (32.5%)	10 (32.3%)	
0 (<110 or >166)	14 (35.0%)	10 (32.3%)	
Medial comminution, n (%)			
Yes	16 (40.0%)	13 (41.9%)	.999
No	24 (60.0%)	18 (58.1%)	
Medial hinge integrity, n (%)			
Yes	18 (45.0%)	10 (32.3%)	.398
No	22 (55.0%)	21 (67.7%)	

Values are presented as the number with the percentage in parentheses.

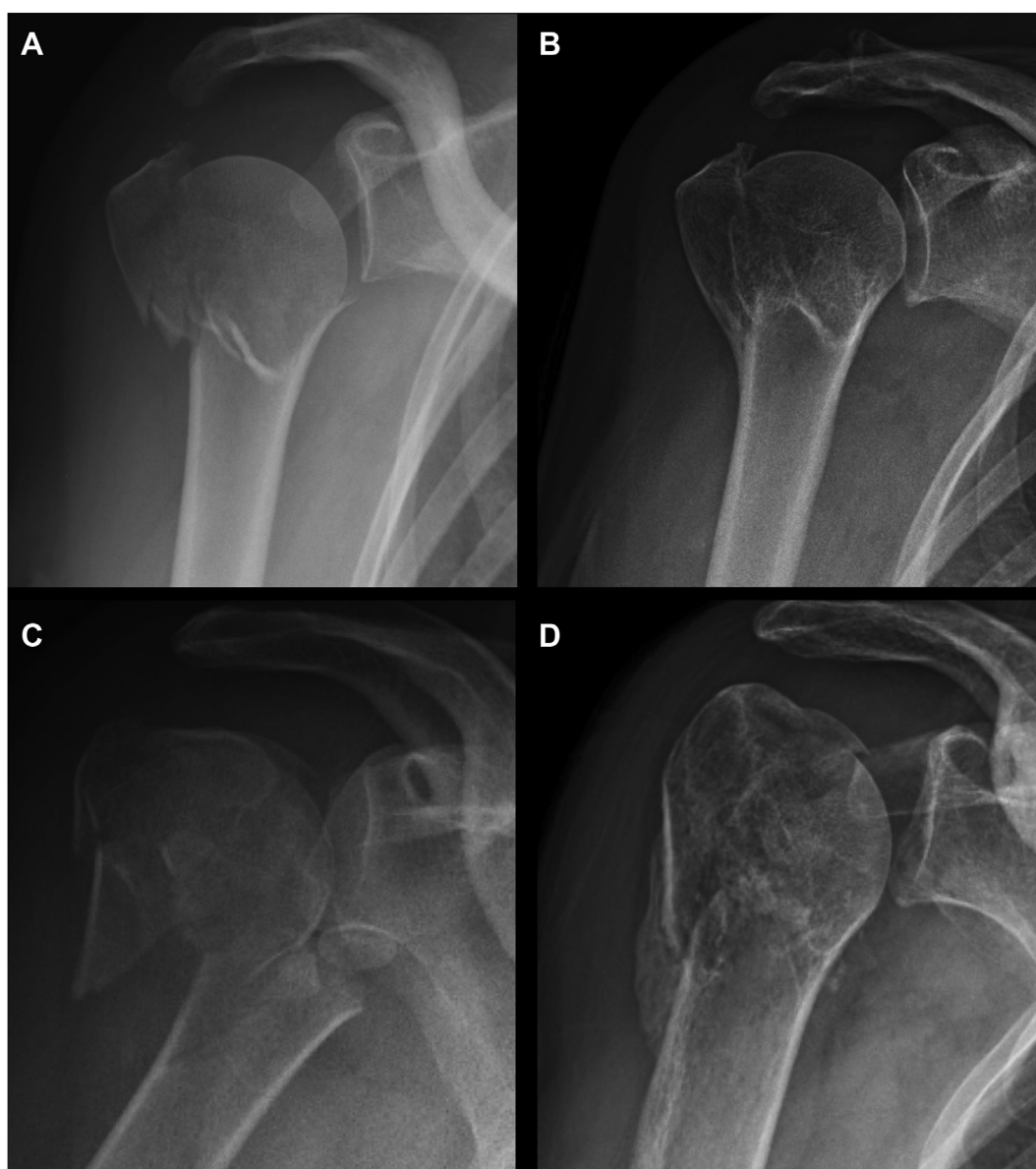


Figure 2 Radiographs of nonoperative treatment. (A) Neer 3-part fracture before treatment; (B) 12 months post-nonoperative treatment; (C) Severe displaced proximal humerus fractures before treatment; (D) 12 months postoperative treatment.

nonoperative group had a mean score of 83.8 ± 19.3 , compared to 88.5 ± 17.2 in the operative group ($P = .236$). At 24 months, the nonoperative group had a mean IRCS of $79.5 \pm 25.2\%$, while the operative group had a mean IRCS of $73.0 \pm 29.2\%$ ($P = .244$).

Time-dependent improvements in shoulder function were observed for the Constant, ASES, and SANE scores in both treatment groups, as confirmed by Bonferroni-corrected repeated measures analysis of variance. Significant improvements were noted for the Constant score in the nonoperative group ($P < .001$) and the operative group ($P < .001$). Similarly, the ASES score showed significant time-dependent changes in the nonoperative group ($P < .001$) and operative group ($P < .001$), as did the SANE

score (nonoperative: $P < .001$; operative: $P < .01$). In contrast, CRI scores did not demonstrate significant changes over time in either group (nonoperative: $P = .341$; operative: $P = .447$). These findings underscore that the most substantial improvements occurred in the early stages (3-12 months) and were sustained over the 24-month follow-up period, as illustrated in Figure 4.

Complications

Six patients (15.0%) in the nonoperative group presented with complications, including osteonecrosis in 4 patients and pseudoarthrosis in 2 patients, whereas 11 patients



Figure 3 Radiographs of operative treatment. (A) Neer 3-part fracture before treatment; (B) 12 months postoperative treatment; (C) severe displaced proximal humerus fractures before treatment; (D) 12 months postoperative treatment.

(35.5%) in the operative group presented with one or more type of complication (Table IV). The complication rates were not statistically different between the groups ($P = .070$).

In the operative group, the complications were more diverse. One patient had a combination of osteonecrosis, screw cutout, and secondary screw protrusion. Another patient experienced both osteonecrosis and loss of tuberosity reduction. A third patient had a combination of loss of tuberosity reduction, loss of head reduction, and infection. There was also a patient who suffered from secondary screw protrusion. Additionally, 2 other patients experienced osteonecrosis individually, while 3 patients had loss of tuberosity reduction alone, and 2 had loss of head reduction

alone. One patient died two years after surgery due to oncological complications unrelated to the orthopedic treatment.

Five patients (12.5%) in the nonoperative group and 7 patients (22.6%) in the operative group had an indication for operative treatment ($P = .421$). Of the patients in the nonoperative group, 5 (12.5%) were indicated for reverse total shoulder arthroplasty (rTSA). In the operative group, 6 patients (19.4%) were indicated for rTSA, and one patient (3.2%) required removal of the plate. None of the patients indicated for rTSA underwent the procedure during the 24-month follow-up period, as the surgical interventions followed the availability of resources within the study time-frame. As such, an “as-treated” analysis was not

Table III Clinical results for functional scales

	Nonoperative (N = 40)	Operative (N = 31)	P value
Primary outcome			
Constant-Murley (points)			
At 3 mo	56.1 ± 16.8	57.6 ± 14.7	.672
At 6 mo	64.2 ± 15.9	62.9 ± 16.5	.643
At 12 mo	68.5 ± 16.3	66.1 ± 14.9	.378
At 2 yr	68.7 ± 16.1	66.5 ± 15.8	.433
Secondary outcomes			
Individual Relative Constant Score (%)			
At 6 mo	75.3 ± 24.9	76.0 ± 18.6	.451
At 12 mo	81.0 ± 21.8	79.9 ± 16.3	.259
At 2 yr	79.5 ± 25.2	73.0 ± 29.2	.244
ASES (points)			
At 3 mo	59.4 ± 23.3	59.6 ± 20.9	.986
At 6 mo	70.7 ± 24.6	71.1 ± 20.2	.737
At 12 mo	77.6 ± 23.7	75.0 ± 19.2	.238
At 2 yr	77.0 ± 23.1	79.1 ± 20.0	.871
SANE (points)			
At 3 mo	66.9 ± 22.8	73.2 ± 24.4	.182
At 6 mo	81.6 ± 19.6	80.8 ± 23.7	.861
At 12 mo	84.5 ± 19.0	86.3 ± 17.7	.748
At 2 yr	83.8 ± 19.3	88.5 ± 17.2	.236

ASES, American Shoulder and Elbow Surgeons; SANE, Single Assessment Numeric Evaluation.
Values are presented as means and standard deviations.

performed, and the patients were analyzed in their initially allocated groups, consistent with the study design.

Rotator cuff tears, assessed by MRI and ultrasound, were observed in 8 patients (20.0%) in the nonoperative group vs. 8 patients (25.8%) in the operative group ($P = .768$).

Subgroup analysis

In the subgroup analysis, we evaluated the Constant-Murley scores at 24 months based on tuberosity involvement, Neer classification, presence of rotator cuff tears, and complications (Table V). Patients with tuberosity involvement, more complex fractures (as per Neer classification), presence of rotator cuff tears, and those with complications generally presented with worse outcomes. However, these differences were not statistically significant between the nonoperative and operative groups.

Discussion

Our findings indicated that both nonoperative treatment and surgical treatment with a LP yielded similar functional outcomes in patients with proximal humeral fractures. Secondary outcome measures such as the IRCS, ASES, and SANE scores also showed no significant differences between the groups at any follow-up points. These results

highlight that, even under optimal surgical conditions, the benefits of operative treatment with a LP for displaced proximal humeral fractures in elderly patients remain questionable.

Our results align with several systematic reviews and meta-analyses, which consistently show no significant difference in functional outcomes between operative and nonoperative treatments.^{5,18,23,29} Beks et al.⁵ conducted a comprehensive systematic review and meta-analysis comparing operative vs. nonoperative treatment of proximal humeral fractures. They found no significant difference in functional outcomes, as measured by the Constant-Murley score, between the 2 treatment modalities. Additionally, they noted a higher rate of major additional surgeries in the operative group. Launonen et al.²⁴ conducted an open-label randomized trial comparing nonoperative treatment with surgical treatment using either LPs or hemiarthroplasty (HA) in older patients with 3- and 4-part proximal humeral fractures. Their results indicated no significant benefit of surgical treatment over nonoperative treatment at the 2-year follow-up, with similar DASH scores across all groups. The study also highlighted high complication rates associated with surgical treatments, particularly with LPs.²⁴

Another significant study is the PROFHER trial by Rangan et al,³² which compared surgical vs. nonsurgical treatment for displaced proximal humeral fractures involving the surgical neck. This pragmatic, multicenter trial found no significant differences in patient-reported

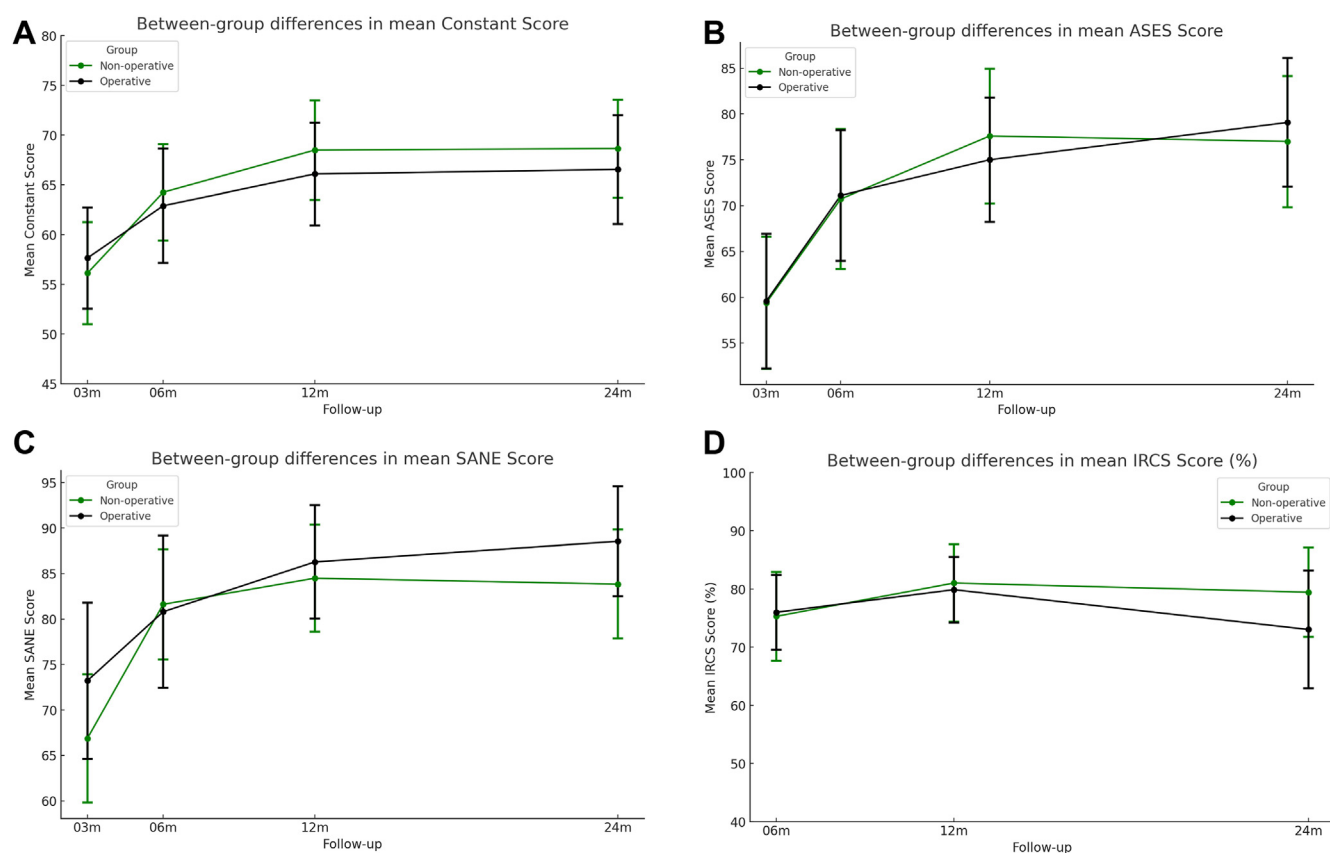


Figure 4 Between-group differences in mean clinical scores across different follow-up periods. (A) Constant-Murley score; (B) ASES score; (C) SANE score; (D) IRCS score. ASES, American Shoulder and Elbow Surgeons; IRCS, Individual Relative Constant Score; SANE, Single Assessment Numeric Evaluation; m, months; 95%CI, 95% confidence interval.

Table IV Description of complication frequencies by treatment group

Complications	Nonoperative (N = 40)	Operative (N = 31)	P value
Patients with complications			
Yes	6 (15.0%)	11 (35.5%)	.070
No	34 (85.0%)	19 (61.3%)	
New surgical indication			
Yes	5 (12.5%)	7 (22.6%)	.421
No	35 (87.5%)	24 (77.4%)	
Rotator cuff tear			
Yes	8 (20.0%)	8 (25.8%)	.768
No	32 (80.0%)	23 (74.2%)	

Values are presented as the number with the percentage in parentheses.

outcomes (Oxford Shoulder Score) or complication rates between the surgical and nonsurgical groups over a 2-year period.

The orthopedic community was surprised by the results of the PROFHER study, sparking extensive discussions.^{2,9,13,17,20,33,36} Some criticisms were related to its pragmatic, multicenter design involving numerous health care facilities with varying levels of expertise.

Critics have argued that such a diverse setup might not accurately reflect the outcomes achievable by shoulder specialists or trauma centers with a high level of experience.¹³ Another significant critique of the PROFHER study is its inclusion criteria, which some argue did not adequately represent severe fracture cases.¹³ In their subgroup analysis, the authors reported that 119 out of 250 cases (47.6%) were two-part fractures, while only 11 out of

Table V Subgroup analysis of Constant-Murley scores at 24 months by tuberosity involvement, Neer classification, rotator cuff tear presence, and complications

Constant-Murley (points)	Nonoperative (N = 40)	Operative (N = 31)	P value
Tuberosity involvement			
Yes	73.0 ± 22.3	72.0 ± 23.3	.491
No	81.0 ± 15.3	73.0 ± 16.5	.567
Neer classification			
2	80.0 ± 7.5	72.5 ± 16.8	.384
3	74.0 ± 16.0	74.0 ± 5.0	.980
4	59.0 ± 32.0	54.0 ± 27.8	.878
Rotator cuff tear			
Yes	65.5 ± 25.8	53.0 ± 27.5	.279
No	75.5 ± 15.8	74.0 ± 16.0	.905
Patient with complications			
Yes	48.5 ± 28.5	49.0 ± 30.5	.574
No	76.5 ± 15.3	74.0 ± 11.5	.985

Values are presented as the number with the percentage in parentheses.

250 cases (4.4%) were four-part fractures. This distribution has led to concerns that the study did not sufficiently address the outcomes for more complex and severe fracture patterns.

Our study aligns with the PROFHER trial's findings, showing similar outcomes and limited benefits from surgical treatment with LPs, even in more severe cases in the elderly, despite being managed by experienced shoulder surgeons and following standardized postoperative protocols. This consistency suggests that the conclusions drawn from the PROFHER trial are robust and applicable across different patient populations and clinical settings.

Studies comparing rTSA, nonoperative treatment, and LPs have shown better outcomes with rTSA.^{5,35} For instance, Klug et al.^{21,22} found that while both angular-stable plating and rTSA could achieve favorable results, rTSA was associated with significantly fewer complications and revisions. Other studies have supported these findings. Yahuaca et al.⁴⁰ compared outcomes of open reduction internal fixation, HA, and rTSA, showing that rTSA had significantly fewer reoperations compared to open reduction internal fixation and HA.

Our findings showed poorer outcomes with increasing fracture severity. For patients with fractures classified as Neer 4, the average scores in both groups were lower than those for Neer 3-part and Neer 2-part fractures. The Neer 4-part fracture scores were approximately 30% lower than those of Neer 2-part fractures, emphasizing the challenges in managing more severe fractures. However, in none of the Neer classifications did surgical treatment with a LP prove superior to nonoperative treatment.

Our study showed complication rates of 35.5% in the operative group, higher than the 15.0% in the nonoperative group, but without a statistically significant difference. The relative risk of complications is approximately 2.4 times higher in the operative group compared to the nonoperative

group. These findings are consistent with those of Launonen et al.,²⁴ who reported a complication rate of 45% in the LP group and 10% in the HA group. In contrast, the PROFHER trial reported only 4 patients with complications in the surgical group and none in the nonoperative group, which is significantly lower than what is typically observed.³² Beks et al.⁵ systematic review also found a higher frequency of major reinterventions in the operative group, with a relative risk of 2.72 for major reinterventions compared to the nonoperative group.

Despite the higher rate of rotator cuff tears observed in the nonoperative treatment group after treatment, no significant difference was found between the groups, although our subgroup analyses did not have sufficient statistical power to draw definitive conclusions. The importance of assessing the rotator cuff in proximal humeral fractures is underscored by studies such as those by Choo et al.,⁷ which reported a concomitant rotator cuff tear in 8.6% of patients undergoing surgery for PHFs, with older age and fracture-dislocation being significant factors. Fjalestad et al.¹² found that rotator cuff tears, whether partial or full thickness, significantly impact functional outcomes in nonoperatively treated fractures. Additionally, Bahrs et al.³ highlighted that worse medium- to long-term outcomes after angular stable plate fixation are associated with secondary fracture displacement, screw perforation, residual bone deformities, and rotator cuff defects at follow-up.

Our study had some limitations. The sample size was limited compared to multicenter studies but was similar to other single-center studies.^{5,24,32} Another critique of the study is the smaller number of cases in the surgical group. This occurred because 4 patients randomized to surgical treatment were considered high clinical risk during the preoperative anesthetic evaluation and were excluded from the study. Additionally, there was a higher loss to follow-up in the surgical group. Another limitation of our study is the

exclusion of fractures where there is no contact between the humeral head and diaphysis or between the tuberosities and the humeral head or diaphysis, as well as cases with severe varus deformity. This means that our findings may not be generalizable to all types of proximal humeral fractures.

The strengths of our study include its high internal validity, achieved by involving only 2 experienced surgeons, a blinded evaluator, and stratified randomization based on tuberosity involvement, which ensured homogeneous groups. Additionally, we performed thorough preoperative radiographic evaluations and assessed the rotator cuff using both MRI and ultrasound postoperatively.

Conclusions

The operative treatment of displaced proximal humeral fractures with LP osteosynthesis in patients over 60 year old shows no evidence of differences in clinical outcomes compared to nonoperative treatment, as measured by the Constant-Murley score, IRCS, ASES, SANE, and complication rates.

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Supplementary Data

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