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# Routine Early Radiographic Follow-up After Conservatively Treated Proximal Humeral Fractures Does Not Change Outcomes: A Multicenter Randomized Clinical Trial

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# Abstract

**Purpose:**

As the population ages, the incidence of proximal humeral fractures (PHF) is rising, placing a significant burden on healthcare systems. While evidence increasingly supports conservative management over surgery, follow-up protocols remain unstandardized. This study evaluates whether routine one-week radiographic follow-up affects clinical outcomes or management decisions of patients who sustained a PHF conservatively treated.

**Methods**:

This multicenter randomized clinical trial included patients with conservatively treated PHF across four centers. Participants were randomized into Group I (routine one-week X-ray) or Group II (no one-week X-ray). The primary outcomes were the Constant Score and Simple Shoulder Test (SST) at 12 months. Secondary outcomes included pain (VAS) and the rate of secondary surgical interventions.

**Results:**

No significant differences were observed between groups in functional outcomes (Constant Score and SST) at 6 or 12 months. Pain levels remained comparable at all follow-up intervals. Routine X-rays in Group I rarely led to management changes, and omitting the early radiograph in Group II did not result in delayed complications or worse functional recovery.

**Conclusion:** Routine one-week radiographic evaluation after PHF provides no clinical benefit in terms of functional recovery or treatment optimization. In the context of Value Based Healthcare (VBHC), eliminating this practice reduces unnecessary healthcare costs, radiation exposure, and the logistical burden on elderly patients. These findings help identifying the routine X-ray follow-up as a possible low-value intervention that could be safely omitted.

Trial Registration: ClinicalTrials.gov Identifier: NCT04651543. 2022/04/08


# KEY POINTS

**Question:** Does routine one-week radiographic follow-up improve functional outcomes or clinical management in patients with conservatively treated proximal humeral fractures?

**Findings**: In this multicenter randomized clinical trial of 143 patients, there were no significant differences in 12-month functional outcomes between the group receiving a routine one-week radiograph (mean Constant Score 70.7) and the group without routine early imaging (mean Constant Score 70.8). Routine imaging rarely led to changes in management, and omitting the early radiograph did not result in delayed complications.

**Meaning:** Routine one-week radiographic evaluation after proximal humeral fractures provides no clinical benefit and can be safely omitted to reduce healthcare costs, radiation exposure, and logistical burdens for patients.

# INTRODUCTION

Proximal humeral fractures (PHF) represent a significant public health challenge due to their high prevalence, particularly among the elderly population [1–4]. As the global population ages, the incidence of these fractures is projected to rise, placing an increasing burden on healthcare systems. Despite their frequency, the optimal management of PHF remains a subject of ongoing debate. While surgical interventions are common, high-level evidence has demonstrated that nonoperative treatment yields functional outcomes equivalent to surgery for the majority of displaced and non-displaced fractures with a lower rate of complications. Furthermore, economic analyses have suggested that surgical intervention is frequently not cost-effective compared to non-operative care [5–11].

Given the shifting consensus towards non-operative management, the focus must turn to optimizing conservative treatment protocols. Currently, there is substantial variability in clinical follow-up strategies[12, 13], including the duration of immobilization and the scheduling of outpatient visits. Specifically, the timing and frequency of radiographic monitoring are often dictated by tradition rather than evidence. Standard practice frequently includes routine radiographic controls—such as at one week post-injury—based on the theoretical concern that early detection of secondary fracture displacement is necessary to indicate a switch to surgical management [14]. However, the clinical utility of these routine serial images is increasingly questioned. Previous research on minimally displaced (one-part) fractures indicates that routine radiographic follow-up rarely alters management, as secondary displacement does not consistently correlate with poorer functional outcomes [15]. Apparent changes in fracture alignment on serial radiographs frequently reflect variations in beam projection rather than true displacement. Accordingly, in the absence of clinical indications, routine follow-up imaging may constitute a low-value intervention, increasing healthcare costs and radiation exposure without demonstrable benefit to patient quality of life. [15, 16]

In an era of increasing emphasis on value-Based healthcare, identifying and minimizing interventions that do not meaningfully improve patient outcomes is a priority [17]. Systematic reviews of orthopedic trauma care have identified routine imaging in asymptomatic patients as a practice that consumes resources without enhancing care [18]. It remains unclear, however, whether this principle applies to the broader spectrum of nonoperatively treated proximal humeral fractures, including displaced patterns, in which concern for secondary displacement has historically been greater. The objective of this study was to evaluate the need for a routine one-week X-ray assessment in patients with a proximal humeral fracture who were initially considered for nonoperative treatment.

# MATERIAL AND METHODS

# Study Design

A prospective randomized multicenter study was designed to evaluate whether an X-ray assessment after one week of the fracture was needed for the conservatively treated PFH. This study involved 4 different centers. Enrollment began in February 2021 and ended in November 2021. The reporting of this study adheres to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

## Inclusion and exclusion criteria

The inclusion criteria were patients over 18 and below 85 years old, acute PHF, conservative treatment agreement, and the absence of a previous pathology of the affected shoulder.

The exclusion criteria were cognitive deterioration and medical injuries that made it impossible to carry out a proper rehabilitation program as well as patient unwillingness to participate in the study.

The decision to perform a surgical or conservative treatment was made after considering age, functional demand, and the fracture pattern. It was determined in accordance with the criteria of each shoulder surgeon from the different participating institutions. The fracture pattern was assessed by means of the initial X-ray study (including the anteroposterior and outlet view) and after the analysis of a computed tomography (CT) scan obtained on the same day as the initial X-ray.

## Randomization

After opening a sealed opaque envelope containing the group number obtained from a computer-generated randomization list, the patients were allocated to either group I (with one-week X-Ray assessment) or group II (without X-ray assessment). The type of randomization was simple randomization. All included patients were followed for 1 year. Participants were enrolled during the first check-up, at 1 week after the fracture, after assessment of the inclusion and exclusion criteria.

## Treatment Regimen

All the patients from both groups were immobilized for three weeks with a sling bandage with restriction of arm rotation. Regardless of the group to which the patients were assigned, they were instructed to do passive elbow movements 5 times a day from the first day after the fracture. After the immobilization period of three weeks, all the patients followed the same progressive rehabilitation program, which included both self-assisted exercises at home and supervised exercises in a rehabilitation center.

## Outcomes

The functional outcome was evaluated at 6- and 12-months follow-up using the Constant score expressed in absolute values [19, 20]. To assess the functional disability of the shoulder, a self-reported shoulder-specific questionnaire, the Simple Shoulder Test (SST), was also used at the 6- and 12-month follow-up.

The pain was assessed using a Visual analogue scale (VAS) that was administered at 1 week after the fracture, at 3 weeks, and then at the 3, 6 and 12-month follow-up.

Radiographs (anteroposterior and outlet views) were obtained at the 1-week follow-up for the patients in Group 1. After the one-week visit, radiographs were obtained for both groups at the 3-, 6- and 12-month follow-up.

All the PHFs included were classified following the Neer classification system [21]. Given the known low reproducibility and concordance of the Neer classification system, fractures were classified based on a consensus reached among the shoulder surgeons in each center after reviewing the radiographs and the CT scans[22–25].

Complications including stiffness, non-union, osteonecrosis and the need for a subsequent surgery were also recorded for both groups. Those complications were also recorded for patients in group II that, for whatever reason, required a one-week X-ray exam.

All the clinical assessments were done by an independent observer blinded to the group in which the patient was allocated. All the included patients signed informed consent forms to participate in this study. This study was approved by the Hospital Ethical Committee (2021/9694/I) and registered at Clinicaltrials.gov (NCT04651543).

# Statistical analysis

With a sample size calculation accepting an alpha risk of 0.05 and a beta risk of 0.2 in a bilateral contrast, 45 subjects in the first group and 45 in the second group were required to detect a difference equal to or greater than 10 units on Constant's Functional scale. The common standard deviation was assumed to be approximately 15 units. A loss to follow-up rate of 20% was estimated.

Previously to the statistical analysis, changes were calculated for each variable (12 months – 6 months). Continuous variables, including the calculated differences, were described as mean and standard deviations. Qualitative variables were described with frequency tables (number and percentage). Between group differences were assessed with the Student t-test for continuous variables and the Chi-square or Fisher exact test, as appropriate, for categorical variables. Statistical analyses were performed using STATA 15.1. The results were considered statistically significant at p-value < 0.05.

# RESULTS

In the period from February 2021 to November 2021, 145 patient-candidates were included. Two of them were excluded due to severe dementia, leaving a total of 143 patients to be included. After randomization, 73 patients were assigned to group I and got the radiological assessment at one-week. The remaining 70 were assigned to group II and did not get the radiological assessment. There were 2 patients who died during the follow-up period, and 21 patients were lost during the follow-up for unknown reasons. That left 120 patients for the final analysis (Fig. 1).

The mean age of the 143 patients included was 69.01 years (range, 19 to 94 years). There were 114 women and 29 men. The left arm was affected in 62 cases and the right arm in 81 cases. Most of the patients were right-handed, 124 vs. 19 cases. In the Neer classification system, there were 52 one-part fractures, 58 two-part fractures, 32 three-part fractures and 1 four-part fracture. The two groups were comparable in terms of age, gender, laterality, hand dominance, and fracture classification distribution, without significant differences between them (Table 1).

No significant differences between the two groups were found in terms of functional outcomes as measured with the Constant score at 6 months (63.68 group I vs 64.22 group II, P = .871), and at 12-months (70.74 group I vs 70.82 group II, P = P=.982). Moreover, there were no differences in the Constant subscale scores (pain, daily living activities, forward elevation, abduction, lateral rotation, internal rotation, and strength) between the groups (Table 2).

No statistically significant differences were noted between the two groups in terms of pain as measured with the VAS at 1 week (6.04group I vs 6.09 group II, P = .914), 3 weeks (4.49 group I vs 4.07 group II, P = .351), 3 months (2.69 group I vs 2.16 group II, P = .229), 6 months (2.11 group I vs 1.7 group II P = .353), and 12 months (1.47 group I vs 1.36 group II, P = .559) (Table 2).

No significant differences between the two groups were found in the scores on the SST questionnaire items at 6 months (P = .864) and 12 months (P = .319) (Table 2). Moreover, no significant differences were found between the two groups relative to complications (P = .945). There were 8 complications (5.6%) reported during the follow-up period. Of those, there were 4 cases of stiffness (2 in group I and 2 in group II), 2 cases of avascular necrosis and stiffness in group I, 1 avascular necrosis in group I, and 1 non-union in group II.

Two patients required surgery; both were included in the group I with the one-week X-Ray assessment. One was due to avascular necrosis that was detected at the 10-month follow-up and required a reverse shoulder arthroplasty. The other one was due to stiffness over 8-months that followed by arthroscopic releases. No other patients in either group required further surgery or a change in the treatment regimen.

In one patient assigned to group II, a one-week X-ray was considered necessary and was subsequently ordered. However, it did not lead to any change in the treatment regimen. At the follow-up, the patient was not experiencing any complication. The patient was analyzed in group II as per intention to treat.

# DISCUSSION

The results of this multicenter randomized clinical trial suggest that routine radiographic evaluation at 1-week post-injury does not alter final functional outcomes in patients with proximal humeral fractures treated nonoperatively. These findings indicate that a scheduled one-week radiograph is unlikely to provide additional information that influences management. Therefore, a more selective follow-up strategy based on clinical assessment rather than routine imaging may be appropriate in this setting.

The epidemiological impact of PHFs cannot be overstated. As one of the most common fractures in the elderly, their incidence is expected to rise sharply alongside global demographic shifts toward an older population[5, 6]. The best treatment for PHF remains undetermined, and the need for radiological assessment and its frequency when a non-operative treatment is chosen is controversial [7, 8, 14, 15, 26–37].

In orthopedics, routine imaging of asymptomatic patients has been flagged as a primary target for reduction [18, 38–41]. In the nonoperative management of proximal humeral fractures, concern for secondary displacement often underlies the use of early follow-up imaging to identify cases that may require conversion to surgical treatment. However, the need for surgery in this setting is uncommon [9, 15, 42–44]. Consistent with prior evidence indicating that minimally displaced fractures rarely require a change in management [15, 42], only 2 patients in the present cohort underwent surgery. Notably, these interventions were performed at 8 and 10 months after injury due to stiffness and avascular necrosis, rather than as a result of radiographic evidence of secondary displacement. Furthermore, even when secondary displacement occurs, it does not consistently correlate with worse functional outcomes or quality of life [9, 45]. This suggests that clinical progress and patient-reported symptoms are more reliable indicators for intervention than static radiographic images. Furthermore, as noted by Jud et al. [16], many perceived changes in fracture alignment on follow-up films are actually artifacts of different beam projections rather than true anatomical displacement. Pursuing these "radiographic ghosts" can lead to unwarranted surgical interventions, thereby decreasing the overall value of the care cycle. For both reasons, the role of early imaging in the assessment of conservatively treated fractures is questionable.

A recent study investigated the need for secondary surgery to detect secondary displacement in 100 one-part PHF as well as the functional result [32]. One group underwent routine radiological assessment while the other did so only if persistent pain was present. They concluded from their results that serial radiological evaluation of patients with a one-part PHF was only needed in those cases with comminution as serial radiological evaluation did not identify more displacement and thereby change the indication of conservative management. Only 4 out of the 100 patients included needed operative treatment because of secondary displacement [15]. These results are consistent with those obtained in the present study where only 2 out of 119 patients required surgical treatment. In the present study, not only one-part fractures were analyzed but also 2-, 3- and 4-part fractures. This is validation that even displaced fractures can be followed without the need for serial imaging exam. By demonstrating that omitting this early X-ray does not compromise patient safety or the Constant score at 12 months, we provide a clear pathway for reducing unnecessary interventions.

In recent years, healthcare systems have increasingly focused on Value-Based Healthcare (VBHC), a framework that prioritizes achieving the best possible patient outcomes relative to the cost and resources utilized [46–50]. Central to this transition is the identification of "low-value care"—interventions that are performed by habit or tradition but provide little to no clinical benefit [18]. Our study identifies the one-week X-ray as a possible example of such care. While global initiatives like "Choosing Wisely" have advocated for the reduction of unnecessary imaging in asymptomatic patients [51], our data provides the specific clinical validation needed for PHF management. We found that the routine one week X-ray rarely led to a change in treatment, suggesting that the "value" of this test—in terms of clinical impact—is low.

This study has several limitations. Although the multicenter design enhances generalizability, the findings are most applicable to the older population in whom proximal humeral fractures are most prevalent. Loss to follow-up occurred in 19.5% of participants; however, the sample size calculation accounted for a 25% attrition rate, and study power was therefore likely preserved. Secondary fracture displacement was not systematically assessed, as the study was designed to detect differences in clinical outcomes and complications; in the absence of such differences, the clinical relevance of unmeasured displacement is likely limited. Finally, the analysis focused on the one-week time point, and further research is needed to determine whether other routine imaging intervals (eg, at 3 or 6 weeks) can also be safely omitted in the absence of clinical indications.

In conclusion, routine early radiographic follow-up for proximal humeral fractures appears to provide limited clinical value and does not influence management decisions or functional recovery. In this multicenter randomized clinical trial, omitting a scheduled one-week radiograph in the absence of clinical indications did not adversely affect outcomes, supporting a more selective, clinically driven approach to follow-up imaging.

# Declarations

### Ethics approval and consent to participate

All the included patients signed informed consent forms to participate in this study. This study was approved by Comité de Ética de la Investigación con medicamentos (CEIM) del Parc de Salut Mar (2021/9694/I) and registered at Clinicaltrials.gov

Clinical trial number: NCT04651543 ; registration date 2022/04/08.

### Standards of reporting

The study reporting adheres to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. A completed CONSORT checklist is provided as an additional submission file.

### Consent for publication

Not applicable

## Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## Competing interests

The authors declare that they have no competing interests


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## Authors' contributions

IP: formal analysis, writing-original draft, writing-review and editing;

JM: writing original draft, writing-review and editing, formal analysis.

EC: writing-review and editing, visualization;

RM: writing-review and editing, visualization;

FS: writing- review and editing, visualization;

MS: writing- review and editing, visualization;

LV: writing- review and editing, visualization;

CT: conceptualization, formal analysis, writing-original draft, writing-review and editing;


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## Conflict of interests

The authors declare that they have no relevant conflicts of interest.

The authors declare that they have no other financial activities that would otherwise influence their contributions to this manuscript.

The authors hold no relevant patents or copyrights relevant to this work.

The authors declare that they have no other outside relationship.

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# Tables

Tables 1 and 2 are available in the Supplementary Files section.

# Figures

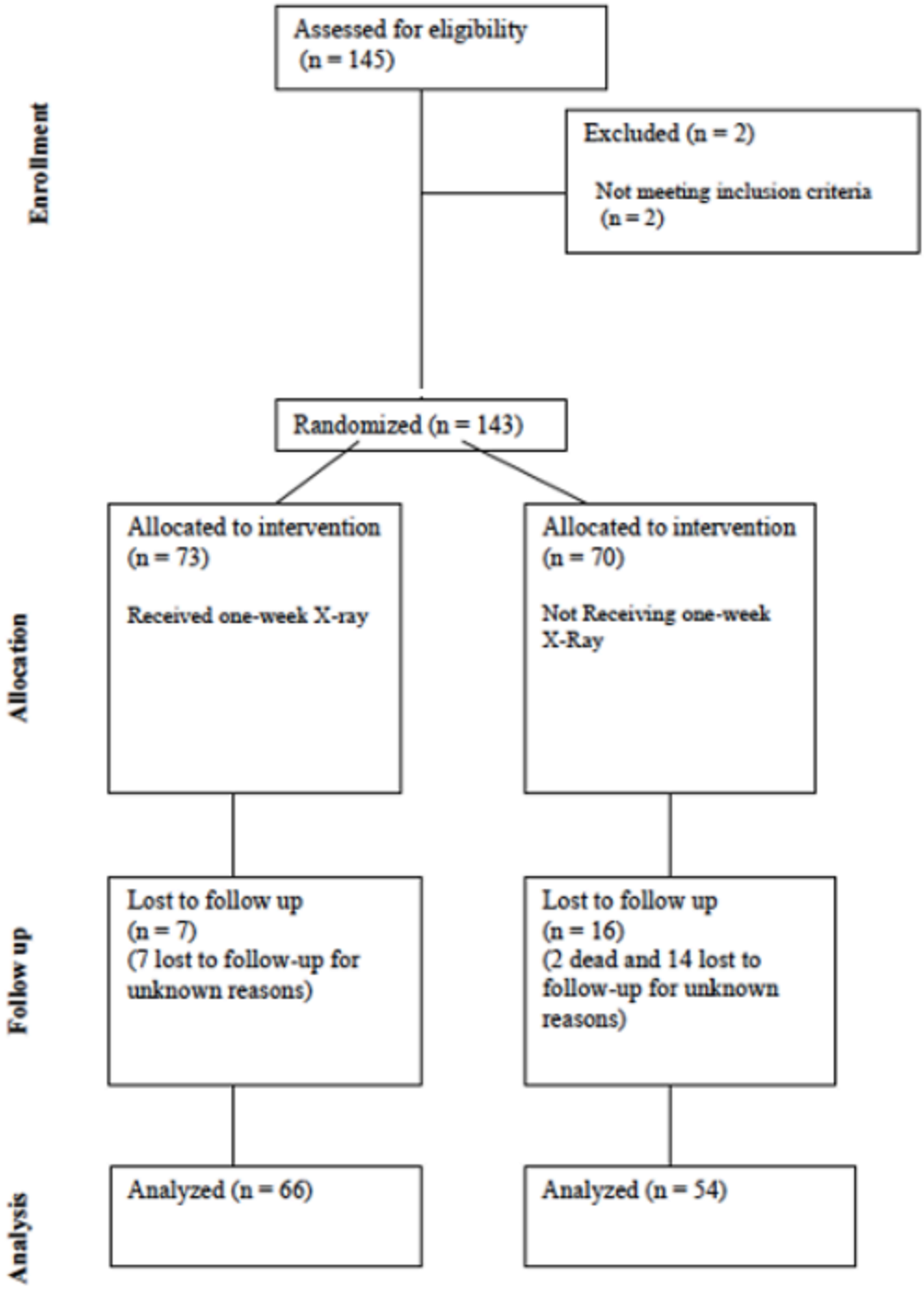



**Figure 1**

Consolidated Standards of Reporting Trials (CONSORT) flow diagram outlining patient recruitment, allocation, and follow-up.

# Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Tables.docx