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## External fixation in proximal humeral fractures: is it worth it? A retrospective analysis in a single Urban Hospital

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### Abstract

**Objective:** The purpose of this study was to assess the outcome of a series of patients with proximal humeral fractures (PHF) treated with a dedicated external fixation (ex-fix) system in a single urban hospital. **Methods:** Sixty-six patients were enrolled in the study treated between January 2015 and June 2020. Fractures classification, length of hospital stay, surgical time and the mean external fixation time and postoperative complications were collected. Clinically at a mean 44,81 months follow-up, each patient was assessed retrospectively using the Constant-Murley score (CMS), Quick-Disabilities of the Arm, Shoulder and Hand score (Quick-DASH), Numeric Rating Scale (NRS) and University of California at Los Angeles Activity Score (UCLA). **Results:** Of these patients, 57 were women and 9 men. The mean age was 71,73 years. The mean Quick-DASH score was 10.16 (SD: ±9.05), the mean NRS was 0.4 (SD: ±0.61), the mean CMS score was 73.25 (SD: ±13.21) and the mean UCLA score was 28.68 (SD: ±4.44). Post-operative complications were seen in 3 patients including 1 with fracture non-union and 2 with avascular necrosis. **Conclusion:** Our study suggests that a dedicated external fixator could be a value option for fixation of proximal humeral fractures comparable to other surgical treatments reported in literature. Randomized controlled trials with a larger number of patients and a longer follow-up are required to confirm these results.

**Keywords:** Shoulder Fractures; Humeral Fractures; External Fixation; Osteoporotic Fractures; Fracture Fixation.

### INTRODUCTION

Fractures of the proximal humerus (PHF) are a common problem in clinical practice and represent approximately 5% of all fractures seen in an orthopedic trauma unit. PHF have a higher incidence in females and in elderly patients [1]. Multiple treatment options have been described for these fractures aimed at achieving rapid limb function restoration and optimal long-term outcomes [2,3].

Recently, external fixation has been proposed as a useful technique for managing fractures of the proximal humerus [4,5]. Use of an external fixator (ex-fix) has been advocated for these fractures because of its potential advantages including soft tissue sparing and minimal blood loss. This less invasive technique is favored by some authors because it is a rapid fixation method in polytrauma and elderly patients, reproducible and has a low deep infection incidence [6].

The literature contains few studies, mainly retrospective, that have analyzed the outcomes of proximal humeral fractures treated with an ex-fix. Zhang *et al* [7]. reported a number of advantages over other methods of treatment including being minimally invasive, short duration surgery and facilitating fracture manipulation. In another retrospective review by Ebraheim *et al* [8]. using a mini-external fixation device for two- and three-part proximal humeral fractures reported excellent results in 63.4% of patients, good in 18.8%, fair in 12.7%, and poor in 5.1%. Both these studies reported only 2 major complications including a non-union and a deep infection. Gupta *et al* [9]. highlighted improved functional outcomes following use of an external fixator to manage closed PHF. They noted the ex-fix allowed early shoulder mobilization one week after surgery without adverse effect on fracture healing.

However, despite these reported advantages, in current orthopaedic surgical practice external fixation is

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not routinely considered as a viable solution in managing PHF in many guidelines [2,3,10].

Aim of the study was to determine the functional and radiological outcomes of a consecutive series of PHF treated in a single urban hospital with a specifically created external fixation system (Galaxy Fixation Shoulder, Orthofix, Bussolengo, Italy) and to compare the results in terms of complications and outcomes with other surgical procedures advocated in literature.

## MATERIALS AND METHODS

Between January 2015 and June 2020, 91 patients underwent surgical treatment with ex-fix for PHF in a single surgical center and clinical and demographic were collected from hospital database and anonymized. The exclusion criteria in our study included patients presenting with open fractures, pathologic fractures, fractures with associate dislocation of the shoulder, an associated nerve or vascular injury, absence of in database radiograph and TC series at fracture time and a follow-up shorter than 12 months from the index procedure.

Five patients were excluded because an associate dislocation of the shoulder, 1 patient because an associated nerve injury (axillary nerve), 1 patient because an associated forearm vascular injury, 12 patients because missing a radiological follow-up, and 6 patient were excluded for a missed follow-up control.

On the emergency department arrival all the patients comorbidities were assessed using the Charlson Comorbidity Index (CCI) and all fractures were investigated using the same standardized radiological trauma protocol with a shoulder radiograph series and a computer tomography scan [11]. Fractures were classified using both the Neer and AO classifications [12]. The neck-shaft angle of the proximal humerus was measured preoperatively and at follow-up routinely performed at 12 months postoperatively, on a real anterior-posterior radiograph [13]. The interval between sustaining the fracture and surgery, surgical time, length of hospital stay and duration the ex-fix was applied were recorded. Intra-operative and post-operative complications were documented.

All patients were treated using the same shoulder external fixator (Galaxy Fixation Shoulder, Orthofix, Bussolengo, Italy). The surgery was performed with the patient in a beach chair position and using a sterile surgical setting. Every patients have been treated with closed reduction, using appropriate maneuvers performed under image intensification. Hardware placement was performed using the recommended surgical technique and appropriate proximal humeral external fixation principles [14]. The first two 2.5 mm threaded wires were inserted into the humeral diaphysis from anterior to posterior and distal to proximal, using the dedicated wire guide. These wires were directed into the humeral head to stabilize the medial hinge. The third and fourth wires were inserted directly into the humeral head about 1 to 2 cm distal to the acromial border in a proximal to distal direction to stabilize the greater tuberosity. The last two wires were inserted in the humeral diaphysis proximal to the oblique wires but entering perpendicular to the diaphysis distal to them (Figure 1). During the procedure, reduction of the fracture was continuously monitored using image intensification. Finally, the Locking Clamp was applied between each pair of wires 3 cm away from the skin and connected to 6 mm diameter rods to form a Y shaped external fixator frame configuration (Figure 2). Both final reduction and construct stability was then checked using image intensification.

On discharge the same post-operative protocol was used for all the patients. Both patients and relatives were educated about the risk of superficial pin tract infection and instructed on how to perform daily pin site dressing. The fracture was immobilized in a sling for no more than 10 days postoperatively. During this period shoulder Codman pendulum exercises, elbow and wrist active movements were performed daily. At

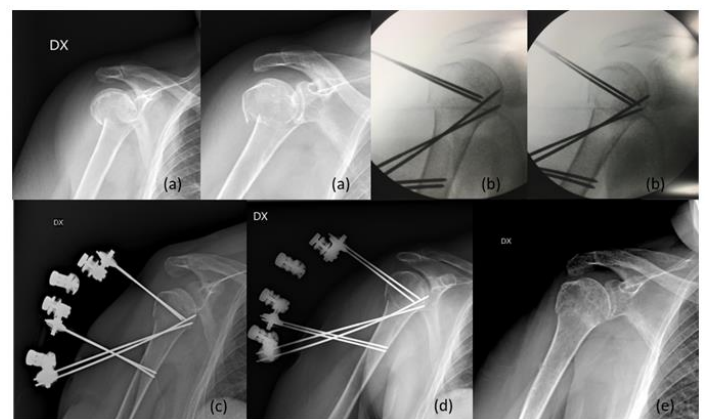
two weeks after surgery passive shoulder movements were encouraged as pain permitted.

Radiological healing of the fractures was determined as at least 3 bone bridged cortexes on 2 different radiological projections and Ex-fix removal performed in an outpatient setting. Physiotherapy was encouraged following removal to recover motion and functionality.

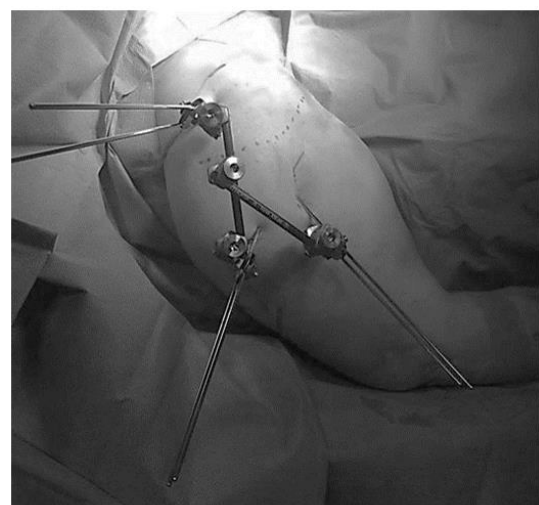
Finally each patients were assessed both clinically and radiographically at least 12 months after surgery using the Quick-Disabilities of the Arm, Shoulder and Hand score (Quick-DASH), Constant-Murley score (CMS) (comparing the operative and contralateral shoulders) and University of California at Los Angeles Activity Score (UCLA) [14]. Furthermore according the difference between injured limb and contralateral Constant score we define the results as: Poor (>30), Fair (21-30), Good (11-20) and Excellent (<11).

Residual pain was assessed using a self-administered Numeric Rating Scale (NRS) ranging from 0 to 10 points. All radiological and clinical assessments were performed by two orthopedic specialists who had not been involved in the surgical procedures.

All the data was statistically analyzed for distribution and standard deviation calculations using MedCalc for Windows, version 15.0 (MedCalc Software, Ostend, Belgium).



**Figure 1:** pre-operative X-rays (a); final intraoperative c-arm check (b); immediate post-operative x-ray (c); 30-day x-rays follow-up without any significant fracture dislocation or pin migration (d); 12 months x-ray follow-up (e)



**Figure 2:** External fixator rods connected in Y-form. This construct permits the optimal distribution of forces on fracture site.

## RESULTS

The final sample size included 66, 57 (86%) were female and 9 (14%) were male (Table 1). The mean age of the patients was 71.73 years (range:28-93; SD:  $\pm 12.89$ ) and only 9 patients (13.6%) were under 60 years of age.

According to Neer classification there were 13 (20%) patients with 2-part fractures (10 displaced and 3 undisplaced), 42 (64%) with 3-part fractures (32 displaced and 10 undisplaced), and 11 (17%) with 4-part fractures (10 displaced and 1 undisplaced). Using the AO classification, 13 patients had a type A fracture (20%), 42 had a type B fracture (64%) and 11 (17%) had a type C fracture. Displacement was determined using Neer criteria (more 45 degrees of angulation or displacement of parts more than 1 cm).

The mechanism of injury was a fall in 64 patients and car accident in 2. Eight patients had an additional fracture including 4 in the distal radius, 3 in the proximal femur, 1 in the proximal radius and 1 a rib fracture.

The mean pre-operative Charlson Comorbidity Index was 5.64 (range: 0-13; SD:  $\pm 3$ ). Surgery data and hospital staying were collected in Table 2.

In the early postoperative period we did not registered any significant migration of the threaded pins was seen at the 30-day post-operative radiograph compared with the initial post-operative imaging.

At a mean follow up of 44,81 months (range: 12-62; SD:  $\pm 22,7$ ) from the index procedure, the mean NRS score was 0.4 (range:0-2; SD  $\pm 0.61$ ) and the mean Quick-DASH score was 10.16 (range:0-25; SD:  $\pm 9.05$ ) with 4 patients (6%) reporting a Quick-DASH score over 20. The mean UCLA score at 12 months follow up was 28.68 (range: 12-34; SD:  $\pm 4.44$ ), with very good results in 4 patients (5.88%), good in 33 patients (50%), fair in 27 (41.18%) and poor in 2 patients (2.94%). The mean Constant score was 73.25 (range:55-96; SD:  $\pm 13.21$ ) for the injured limb and 79.41 (range:68-100; SD: $\pm 11.21$ ) for the contralateral unaffected limb.

The mean difference in the Constant score between the injured and unaffected limb was 5.62 (range:17-30; SD: $\pm 7.11$ ) achieving excellent results in 50 (76.47%) patients, good in 14 (20.59%) and fair in 2 (2.94%) (Table 3).

Post-operative complications were reported in 3 patients. In 1 patient with a 4-part fracture (AO: 11.C1) we registered a non-union with marked secondary displacement. This patient had significant pre-operative comorbidities (Charlson comorbidity index: 8) and left untreated because an unacceptable risk for any further revision surgery and managed with ex-fix removal only. Two patients developed an avascular necrosis (AVN) following fracture fixation using the ex-fix. The first of these patients had a 2-part fracture (AO 11.A2.1) and was treated non-operative because pre-existing comorbidities with an unacceptable risk for further surgery. Even the third AVN patient following a 3-part fracture (AO 11.B1.1.2) present a poor preoperative Charlson comorbidity index of 11, however in this case he was treated with a reverse total shoulder replacement. Superficial pin-tract infection occurred in 8 (12%) patients and all were successfully treated with oral antibiotics. No further intra-operative or peri-operative complications were registered as deep infections, aseptic ex-fix loosening and iatrogenic axillary nerve palsies or vascular injuries (Table 4).

**Table 1:** Patient demographic information

	Number	%
Total patients	66	100
Male	9	14
Female	57	86

**Table 2:** Inpatient data. CCI: Charlson Comorbidity Index; SD: Standard deviation

	Mean	SD	Range (Min-Max)
CCI	5.65	3	0-13
Hospital Stay (days)	7.87	7.11	02-45
Fracture-Surgery Time from fracture occurrence (days)	2.52	1.57	01-07
Surgical time (min)	57	27	20-150
External fixation time (days)	48	15	28-127

**Table 3:** Clinical outcomes at follow-up. CMS: Constant-Murley score; Quick-DASH: Quick-Disabilities of the Arm, Shoulder and Hand score; NRS: Numeric Rating Scale; UCLA: University of California at Los Angeles Activity Score

Outcome at clinical assessment	Mean	SD
NRS	0.4	0.61
QuickDASH	10.16	9.05
UCLA	28.68	4.44
COSTANT Score	73.25	13.21
Difference unaffected Constant Score	5.62	7.11

**Table 4:** Complications. CCI: Charlson Comorbidity Index

Complication	Patient (n)	%	Mean CCI (range)
Non-union	1	1.52	8
AVN	2	3.03	9 (7-11)
Total	3	4.56	8.67

## DISCUSSION

In recent trials external fixation has been proposed as a useful technique for managing PHF [4-9,16], but despite reported good results, external fixation remains an uncommon approach compared to either nonoperative treatment or other surgical options [17]. This less invasive technique is recommended in geriatric or polytrauma patients, allowing early joint mobilization and better post-operative pain management [18]. Furthermore ex-fix has been advocated in PHF because it allows simultaneous closed reduction and percutaneous fixation preserving the remaining humeral head blood supply with soft tissue and blood loss sparing [4-9,17]. In our study 58 of 66 patients (88%) were aged more than 60 years with a mean age of greater than 72 years. Fifty-seven of the fractures occurred in females (86%) with the vast majority as a result of low-energy trauma, similar to the findings reported in literature [19,20]. The preoperative mean CCI for the patients in the study was 5.66 ranging between 0 and 13 despite an high incidence of patients with multiple comorbidities (20 patients with CCI  $\geq 7$ ). Several Authors in literature suggest these high complicated patient as the ideal candidates for this technique because a less extensive surgical approach with minimal soft tissue damage and a shorter hospital staying potentially associated to a reduced risk of complications [21,22].

In our series the mean surgical time was 57 min despite simultaneous associated surgical procedures in 8 patients with additional fractures. No substantial intra-operative blood loss was registered during fracture fixation using the ex-fix confirming the findings in a retrospective study by Blonna *et al* [4], who reported mean surgical time of 66 min using a dedicated ex-fix.

The mean hospital stay of was 7.87 days, with 24 patients remaining in hospital less than 4 days. A possible explanation for a such relatively long

hospital staying is the presence of high comorbidities and elderly patients even with associated femoral neck fractures in some cases. Nevertheless, our length of stay was comparable to that of Dixit *et al* [23], who reported a mean of 7.86 and 7.44 days respectively for patients with PHF treated by open reduction and plating and shoulder arthroplasty.

In our study, good mean clinical outcomes were achieved (Table 3) with a mean Constant score of 73.25 confirming similar data present in literature [4,5,20]. Likewise, in a retrospective study of 188 patient, Blonna *et al* [4], reported a mean Constant score of 72.5, in another study Gumina *et al* [5], find a range of Constant score of 72.4 and 79.9.

In another non-matched comparative study Vincenti *et al* [20], reported a significantly better Constant score in a group of younger patients treated with open reduction and plating compared to a group treated with ex-fix. However, the mean Constant score in the study was 79 not too superior to our score and without any significant difference in the outcomes in patients older than 65 years.

In our study the mean head-shaft humerus angle at 12 months radiological follow-up was 136.6°. Likewise Wang *et al* [13], reported head-shaft humerus angles at 12-month follow up of 130.3° (±6.7) following open reduction and plating with a medial support achieving a stable reduction over time as well as in our case even after ex-fix removal.

The complication rate in our study was even lower (4.56%) in comparison to surgical techniques reported in the literature.<sup>24-29</sup> In 2015 a Cochrane review assessing PHF outcomes reported respectively adverse events ranging from 184 to 239 per 1000 cases and 147 to 389 per 1000 cases respectively in patients treated non-operatively and in patients treated with open reduction and plating at 2 years follow up.<sup>25</sup> A possible explanation could be the minimally invasive reduction maneuvers and percutaneous fixation, which do not further compromise humeral head perfusion [4,5]. Despite good results, external fixation remains an uncommon approach to PHF and is difficult to determine if it fares any better than nonoperative treatment or other surgical options [29].

One of the main criticisms of external fixation procedures is the additional cost and patient discomfort associated with ex-fix removal [20]. In our series ex-fix removal was performed in all cases in an outpatient setting without complications. Ex-fix removal was achieved in each case with good patient compliance and no further relevant costs.

Our study presents same bias: it is a retrospective analysis of a heterogeneous cohort of patients, radiographs were not prescribed at the clinical assessment but we use the routinely 12 month x-ray to avoid unnecessary exposure and the absence of uniform indication for ex-fix treatment in these patients.

However our study suggests that the fixation of proximal humeral fractures with a dedicated external fixator seems to be a valuable option comparable to other techniques. The good outcomes and low risk of major complications observed with this technique encourages its use in older and high comorbidities patients. Randomized controlled trials with a larger number of patients and a longer follow-up are required to confirm these results.

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ML, MG and AM participated in conceiving the study, provided clinical support, and were involved in the study design. AM was responsible for the coordination and management of the study. ML, MG and AM wrote the manuscript. ML, MG and AM reviewed the manuscript and contributed to its intellectual content. All of the authors read and approved the final manuscript.

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#### Conflict of interests

Each Author certifies that he or she has no commercial associations that might pose a conflict of interest in connection with the submitted article.

#### Ethical considerations

This study was conducted in accordance with the ethical principles laid down in the 1964 Declaration of Helsinki. The procedures carried out were approved by the local Ethics Committee (Comitato Etico Milano Area 1, No. 713, 23 June 2020).

#### Statement

This statement is to certify that all Authors have seen and approved the manuscript being submitted. We warrant that the article is the Authors' original work. We warrant that the article has not received prior publication and is not under consideration for publication elsewhere. On behalf of all Co-Authors, the corresponding Author shall bear full responsibility for the submission.

#### Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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