



A Comparative Study On Outcome Of Fixation Versus Conservative Management Using A Novel Shoulder Brace In Proximal Humeral Fractures In Elderly

¹Sayak Setua, ²Kaushik Banerjee, ³Siddhartha Mahapatra, ⁴Mainak Chandra*,
⁵Sanjay Kumar, ⁶Sandip Ghosh, ⁷Arup Kundu
^{1,7}Junior Resident, ²Professor, ³Senior Resident, ⁴Assistant Professor, ⁵Professor, ⁶Professor,
Department of Orthopaedics, R.G. Kar Medical College & Hospital, Kolkata, India

***Corresponding Author:**
Mainak Chandra

Assistant Professor, Department of Orthopaedics, R.G. Kar Medical College & Hospital, Kolkata

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Abstract

Background: Proximal humerus fractures account for 5% to 6% of adult fractures. Surgical treatment is being increasingly used although there is insufficient evidence to conclude whether it produces consistently better outcomes than nonsurgical treatment. Conventionally in conservative management sling is used; the greater tuberosity is displaced posteriorly and superiorly which leads to poor healing when the arm is maintained in this internally rotated and adducted position. We have designed a low cost indigenous brace which can maintain the arm in a neutrally rotated abducted position. We shall compare its radiological and functional outcomes with operative treatment in elderly patients.

Aims and objective: To compare outcomes of operative fixation of proximal humerus NEER 3 and 4 part fractures and conservative management with a novel shoulder brace in elderly.

Materials and methods: In this two arm prospective observational study 30 patients were selected by simple random sampling each for conservative and operative management. They were followed up with functional parameters Oxford Shoulder Score and Quick DASH Score and radiology at 1,3 and 6 months.

Result: We found that functional scores were better in operated group at 1 month but were comparable at 3 and 6 month followup. Complication rates were also comparable in both groups though malunion rate was much higher in conservative group.

Conclusion: We conclude that this novel shoulder abduction brace can provide significantly good functional outcome in proximal humerus fractures of elderly as evidenced by the improving function scores without predisposing them to the possible complications of operative techniques.

Keywords: Oxford Shoulder Score, Proximal humerus fractures, Quick DASH Score , Shoulder brace

Introduction

Proximal humeral fractures account for 5% to 6% of all adult fractures; an estimated 706 000 occurred worldwide in 2000 1 . Approximately half (51%) of these fractures are displaced, the majority of which involve the surgical neck (77%). Patient comorbidity and poor bone quality seem to influence the overall outcome, as well as degenerative changes in the rotator cuff.

Surgical treatment (mainly internal fixation or humeral head replacement) is being increasingly used although a Cochrane review found insufficient evidence from randomized clinical trials to conclude whether surgical intervention produces consistently better outcomes than nonsurgical treatment 2,3,4 .

Currently there is much variation in the use of surgery and a lack of good quality evidence to inform this decision 5 . Many previous studies have been done comparing outcomes of open reduction internal

fixation to conservative management for proximal humerus fractures 6,7.

But the included patient cohorts are often heterogeneous and the results are therefore difficult to transfer into clinical practice.

Conventionally in conservative management sling and bust band(shoulder immobilizer) are used; fracture fragments are sometimes displaced when the arm is maintained this position. During shoulder immobilization, the arm is often internally rotated and adducted. Several reports have described complications associated with maintenance of the arm in internal rotation.⁸ Conversely, Boileau *et al.*¹⁰ reported good results with maintenance of the arm in the neutral position. From these results we speculated that an alternative immobilization position could be used and that anatomically neutral rotation of the arm is a better position for avoiding displacement. Moreover, an external rotation shoulder brace can maintain the arm in such a neutrally rotated position^{15,16,17}. But such commercially available braces are relatively high cost. For the economically unprivileged patients we have designed a low cost indigenous brace in addition to conventional arm pouch sling which maintains abduction and external rotation of the shoulder. We shall compare the radiological and functional outcomes versus operative treatment in elderly patients.

Aims And Objectives:

1. To assess functional and radiological outcome of open reduction and internal fixation of proximal humerus NEER 3 and 4 part fractures compared to conservative management with a novel shoulder abduction and external rotation brace.
2. To assess complications of the two methods

Materials And Methods :

Study Design: Institution based two-arm observational study

Place Of Study: Patients attending Outpatient/Inpatient department and Trauma care of orthopaedics, RG Kar, Kolkata.

Period Of Study: April 2021 to August 2022 Sample size and design: Simple random sampling

For equivalence design randomised controlled trial the formula for sample size is

$$N = 2 \times \left(\frac{z_{1-\alpha/2} + z_{1-\beta}}{\delta_0} \right)^2 \times s^2$$

From previous study1 pooled standard deviation(s)= 7.7. For 95% confidence limit, $z_{1-\alpha/2}$

$\alpha/2=1.96$. For power of study 90%, $z_{1-\beta}=1.28$. Minimal clinically important difference for Oxford Shoulder score(δ_0)=5. Adjusting for drop out, the total sample size comes to be 60. So, 30 patients will be included in each group.

Patients visiting our hospital with proximal humerus Neer 3 & 4 part fractures and fulfilling the inclusion and exclusion criteria shall be included in either group A or group B based on mode of management.

Group A: Patients who are conservatively managed using brace

Group B: Patients who are managed with open reduction internal fixation with proximal humerus locking plate

Ethical Clearance: Ethical Clearance for the study was obtained from the institutional ethical committee.

Inclusion Criteria:

Patients above 55yrs with NEER 3 and 4 part proximal humerus fractures Exclusion criteria:

Open Fractures

Associated life threatening injuries/ polytrauma patients Pathological fractures

Past history of surgery due to fractures to humerus or surrounding bones Old fractures (>1 month)

Study Variables:

Demographic: Age, sex, duration of injury , comorbidities Radiological: Time to union, position of fragments(grade)

Functional: Oxford shoulder score(subjective), Quick DASH score(subjective) Complications: Wound complications, non union, malunion, stiffness

Lab investigations in control: Routine blood investigations for PAC

Radiological Investigations: Xray humerus with shoulder and elbow- AP and Lat view , 3D NCCT scan if required

Procedure:

Group A: Novel brace & analgesics for 3 weeks. Then remove brace and start pendulum & passive flexion & abduction exercises for 2 weeks followed by a 1-month physical training. Afterwards, active movement of the shoulder was initiated.

Group B: Initially arm sling + lab investigations then operate via delto pectoral approach with proximal humerus locking plate. Passive exercise was started soon after followed by active exercise 2 weeks later.

The patients are followed for observation at 1 month, 3 month, and 6 month. Anteroposterior and lateral X-ray were taken at each follow-up to evaluate fracture healing progress and bone-implants relationship. Moderate weightlifting began at the fourth to sixth postoperative week according to the sign of bony healing. Heavy weightlifting was not allowed until the fractures healed clinically and radiographically.

Statistical Analysis Plan: Data obtained from the study will be analyzed using standard statistical

methods and SPSS version 25. All data will be compiled on Microsoft Excel. For comparing mean and standard deviation t-test will be used for continuous data(age, duration) and chi-square for categorical data(age, complication rates).

Results:

In our study group, 20(33.3%) patients were 55-65 yrs old, 25(41.7) patients were 66-75 yrs old, 15(25%) patients were >75 years old. (Table 1)

In our study total complication rate was comparable in both groups however malunion and stiffness rate was much higher in Group A. (Table 2)

In our study there was significant($p<0.05$) difference in Oxford Shoulder Score of both groups at 1month follow up which decreased at 3months and was not significant($p=0.22$) at 6months.(Table 3)

In our study there was significant($p<0.5$) difference in Quick Dash Score of both groups at 1month follow up which decreased at 3months and was not significant($p=0.39$) at 6months.(Table 4).

Table 1: Distribution of age :

Age in group	Frequency	Percent
55-65	20	33.3
66-75	25	41.7
>75	15	25

Table 2: Complications:

COMPLICATION	Group A	Group B
Mal-union and stiffness	12	6
Non union	3	2
Infection	-	5
Neuro-vascular	-	3
Total	15	16

(Non union: Fracture not united clinically and radiologically at 6 months followup) (The classification of proximal humerus malunions proposed by Beredjiklian et al. (20)

describes as Type 1 a misalignment of greater or lesser tuberosity of more than 1 cm, as Type 2 an incongruity of the articular surface and as Type 3 a malunion of the tuberosities and the humeral head relative to the shaft)

(Shoulder Stiffness: Healthy individuals require 118° of forward shoulder flexion, 112° of shoulder abduction and 68° of extension are needed to perform ADL tasks, although high variability is observed. 19)

(Neuro-vascular: In 2 cases cephalic vein was injured. 1 case had axillary nerve palsy in immediate post-op period which gradually recovered)

Table 3 : Oxford Shoulder Score (scale 0-48, with a higher score indicating a better outcome): Before treatment: <15

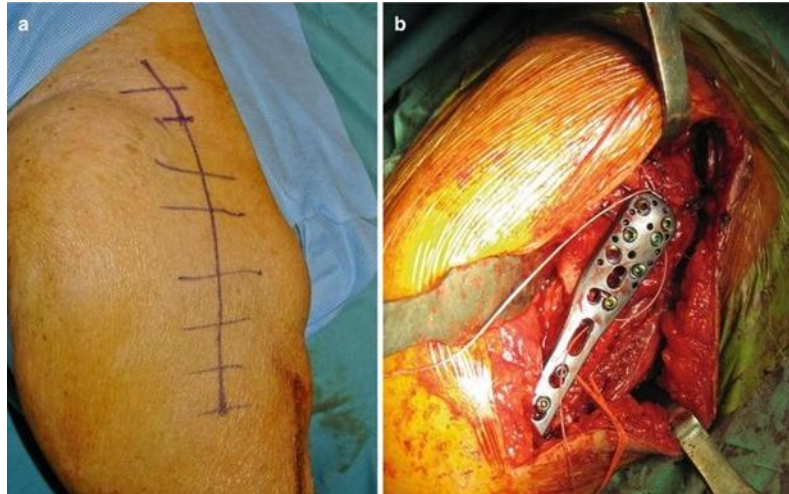
Follow up at	Group A	Group B
1 month	21.2 +- 2.9	28.8 +- 7.7
3 month	33.4 +-3.9	36.4 +- 7.2
6 month	40.2 +- 3.2	41.6 +- 5.2

Table 4: Quick Dash Score (scale 0-100, with a higher score indicating a worse outcome):

Follow up at	Group A	Group B
1 month	68.2 +- 6.1	59.8 +- 9.0
3 month	52.3 +- 4.9	45.3+- 12.5
6 month	35 +- 6.7	31.8 +- 12.8

Figure 1: Group a (Managed conservatively): Abduction bracing technique



Figure 2: Group b (Managed Surgically):Incision and dissection via deltopectoral approach

Tuberosities and hence rotator cuff muscles were fixed by ethibond suture bites through the plate.

Discussion:

Proximal humeral fractures account for 5% to 6% of all adult fractures. Similar to other primarily osteoporotic fractures, the age-specific incidence of these fractures is increasing with a 2.5-fold increase in women and a 3.4-fold increase in men older than 60 years.^{1,5} Patient comorbidity and poor bone quality seem to influence the overall outcome, as well as degenerative changes in the rotator cuff. The humeral bone itself almost always heals and the risk of continued pain is low.

Conventionally in conservative management sling and bust band (shoulder immobilizer) are used; fracture fragments are sometimes displaced when the arm is maintained this position. During shoulder immobilization, the arm is often internally rotated and adducted. Several reports have described complications associated with maintenance of the arm in internal rotation.⁸ Conversely, Boileau *et al.*¹⁰ reported good results with maintenance of the arm in the neutral position. Moreover, an external rotation shoulder brace can maintain the arm in such a neutrally rotated position^{15,16}. Functional improvement of these patients depends more on the tuberosities healing in proper place and position and the abduction external rotation position allows the posteriorly and superiorly displaced greater tuberosity to unite in better position compared to when the arm is in an internally rotated position. Since the greater tuberosity is displaced posteriorly and superiorly, the externally rotated position allows better union of the greater tuberosity fragments. And

since the arm is in a slightly abducted position in the brace, achieving abduction later on during rehabilitation becomes easier. But such commercially available braces are relatively high cost. For the economically unprivileged patients we have designed a low cost indigenous brace in addition to conventional arm pouch sling which maintains abduction and external rotation of the shoulder.

Age And Sex:

In our study group, 20(33.3%) patients were 55-65 yrs old, 25(41.7%) patients were 66-75 yrs old, 15(25%) patients were >75 years old. The mean age was 69.4 +/- 9.1. The extreme elderly patients (>=80) had to be taken up for conservative management as they were unfit for operation.

We found that, 38 (63.3%) patients were Female and 22 (36.7%) patients were Male. The result is significant at $p < .05$.

In, PROFHER Trial Collaborators *et al.* (2015)⁵ the mean age of the 250 trial participants was 66 years and 192 (77%) were female.

In Shimizu T *et al.* (2011)⁸ eleven elderly individuals ≥ 65 years who had sustained proximal humeral fractures from 2015 to 2017 and who were able to use a Shoulder Brace ER within 1 week after injury were clinically and radiographically reviewed. Among these 3 were male and, 8 were female, and their mean age was 75 years (range, 65–86 years).

So the mean age of the present study is around the 7th decade of life, which is comparable to other

similar studies. It is explained by the fact that proximal humeral fracture is a osteoporosis related fracture. It is also found that there is a female preponderance in our study which is again comparable to other similar studies. This is explained by the loss of effect of estrogen on calcium metabolism, especially in post-menopausal age.

Grade & Complications:

In our study 25(41.7%) patients were NEER 3 PART and 35(58.3%) patients were NEER 4 PART. It was also found that the total number of complication was 15(conservative group) and 16(operative). Most common complication in both groups was malunion.

PROFHER Trial Collaborators et al. (2015)⁵ identified 18 one-part fractures, 128 two-part fractures and 104 three- or four-part fractures. The choice of surgical intervention was left to the treating surgeons, who used techniques with which they were experienced. Non-surgical treatment was initial sling immobilisation followed by active rehabilitation. Surgical or shoulder fracture-related complications were 30(operative group) vs. 23(conservative group) respectively.

Shimizu T et al. (2011)⁸ had two patients with Neer Group I fractures (minimal displacement), three patients had two-part Group III fractures(surgical neck fractures), one patient had a two-part Group IV fracture (greater tubercle fracture), two patients had two-part Group VI fractures (greater tubercle fractures with dislocation),and three patients had three- part Group IV fractures (surgical neck and greater tubercle fractures).No patients exhibited displacement of fracture fragments during treatment. All patients achieved complete bone union.

Majority of patients are three or four part or tuberosity fractures. Thus conservative management is mainly reserved for the more severe comminuted fractures. Total rate of complication is mostly comparable to slightly lower in conservatively managed group.

Functional Scores:

In our study there was significant($p<0.05$) difference in Oxford Shoulder Score of both groups at 1month follow up which decreased at 3months . There was minimal mean treatment group difference in Oxford Shoulder Score at 6 months (40.2 for conservative

and 41.6 for operative group) which was not significant($p=0.22$) .

In our study there was significant($p<0.5$) difference in Quick Dash Score of both groups at 1month follow up which decreased at 3months. There was minimal mean treatment group difference in Quick Dash Score at 6 months (35 for conservative and 31.8 for operative group) which was not significant($p=0.39$).

PROFHER Trial Collaborators et al. (2015)⁵ reported OSS data for 215 participants at 2 years. There was no statistically or clinically significant differences in OSS scores between the two treatment groups over the 2-year period [difference of 0.75 points in favour of the surgery group, 95% confidence interval (CI) - 1.33 to 2.84; $p = 0.479$; data from 114 surgery and 117 non-surgery participants] or at individual time points.

There was significant difference in functional scores between conservatively and operatively managed groups at 1 and 3months. Thus operation allows early mobilisation which particularly helps to reduce chances of stiffness. But at 6 months, functional scores are comparable in both groups. Thus long term results are good enough in conservatively managed group, comparable to surgical group, while avoiding the potential complications of surgery.

Furthermore, in the PROFHER trial which used conventional arm sling in conservative group, the average Oxford shoulder score was 38.32, thus implicating the superiority of this novel brace.

Limitations Of The Study:

Only 6 month follow-up may not be enough to get accurate conclusions and long term follow up is needed

Conclusion:

The present study demonstrates that this novel shoulder abduction brace can provide significantly good functional outcome in proximal humerus fractures of elderly as evidenced by the improving function scores without predisposing them to the possible complications of operative techniques.

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