Immediate Mobilization Compared with Conventional Immobilization for the Impacted Nonoperatively Treated Proximal Humeral Fracture

A Randomized Controlled Trial

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Background: There have been few randomized controlled trials evaluating nonoperative treatment of proximal humeral fractures. To investigate shortening the period of dependence, we assessed the feasibility and efficacy of early mobilization of the shoulder (within three days after the fracture) in comparison with those of conventional three-week immobilization followed by physiotherapy.

Methods: We randomly assigned seventy-four patients with an impacted proximal humeral fracture to receive early passive mobilization or conventional treatment. The primary outcome was the overall shoulder functional status (as measured with the Constant score) at three months. The secondary outcomes were the Constant score at six weeks and at six months, the change in pain (on a visual analog scale), and the active and passive range of motion.

Results: At three months and at six weeks, the early mobilization group had a significantly better Constant score than did the conventional-treatment group (between-group difference, 9.9 [95% confidence interval, 1.9 to 17.8] [p = 0.02] and 10.1 [95% confidence interval, 2.0 to 18.1] [p = 0.02], respectively) and better active mobility in forward elevation (between-group difference, 12.0 [95% confidence interval, 1.7 to 22.4] [p = 0.02] and 28.1 [95% confidence interval, 7.1 to 49.1] [p = 0.01], respectively). At three months, the early mobilization group had significantly reduced pain compared with the conventional-treatment group (between-group difference, 15.7 [95% confidence interval, 0.52 to 30.8] [p = 0.04]). No complications in displacement or nonhealing were noted.

Conclusions: Early mobilization for impacted nonoperatively treated proximal humeral fractures is safe and is more effective for quickly restoring the physical capability and performance of the injured arm than is conventional immobilization followed by physiotherapy.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

Osteoporosis-related proximal humeral fractures are common (representing 4% to 5% of all fractures), and the rate increased by 13% a year, on the average, between 1970 and 2002 to reach an annual age-adjusted population incidence of 129 per 100,000 in women and 48 per 100,000 in men[1-5]. Approximately 50% to 80% of proximal humeral fractures can be treated nonoperatively[4-9]. In those cases, the ideal duration of immobilization in a sling before physiotherapy begins has not been clearly defined[10-13]. A recent survey in the United Kingdom showed a large varia-

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tion in treatment in terms of the duration of immobilization and the timing of the first physiotherapy session[13]. The duration of arm immobilization for these fractures varies from two to six weeks[8,14]. There have been few randomized controlled trials evaluating the treatment of these common fractures.

A proximal humeral fracture can result in severe and prolonged disability in a previously independent patient. Most studies have shown that a year is necessary for good or very good recovery, with better results for nondisplaced than displaced fractures[7,11,15-18]. Indeed, one study showed that before the fracture, 86.5% of patients lived at home and only 21% required help with their routine daily activities[6]. In the first few weeks, people with these fractures may be unable to dress, bathe, or even feed themselves and may be housebound. Restoring the overall functional status of the injured arm to reduce the dependence period is the goal of physiotherapy.

Immediate mobilization of the shoulder was first proposed by Brostrom to limit the capsular retraction and to quickly restore mobility and function of the injured arm[18]. Three other trials subsequently demonstrated favorable outcomes after early mobilization[12,17,19]. In the two controlled studies, shoulder mobilization was proposed within one week, and the inclusion criteria were limited to patients with minimally displaced two-part fractures[12,17]. Most metaphyseal impacted fractures without marked displacement, such as three-part impacted fractures, can be treated nonoperatively[5,6,8,15].

The purpose of the present study was to test the efficacy of immediate shoulder mobilization (begun within seventy-two hours after the fracture) in comparison with that of conventional treatment (three weeks of immobilization followed by physiotherapy) for patients with nonoperatively treated impacted proximal humeral fractures in a controlled clinical trial.

Materials and Methods

Patients and Procedures

Patients with a nonoperatively treated proximal humeral fracture who had been referred to the emergency department of a tertiary care hospital were recruited between October 2002 and March 2005. Within seventy-two hours after the fracture, an experienced orthopaedic trauma surgeon (A.B.) confirmed, on the basis of radiographs, that the fracture was impacted and that surgery was not needed. An impacted fracture was defined according to the AO classification system as a stable fracture of the metaphysis or epiphysis in which the fragments are driven into each other[20,21].

Patients who were more than twenty years old were eligible. Patients were excluded if they had (1) a preexisting pathologic condition involving the shoulder, (2) a neurological disorder of the upper limb, (3) an indication for operative treatment of the shoulder, (4) multiple injuries, (5) high-energy trauma, or (6) difficulties with language or comprehension to understand a rehabilitation program and other treatment information.

Patients provided written informed consent. The rationale of the study and the potential for side effects were explained to the patients. Ethics approval was obtained from the institutional review board. An independent examiner (M.M.L.-C.) recorded baseline data and performed the randomization, with supervision by the trial statistician (J.F.). Block randomization involved choosing randomly from among blocks of lengths 4 and 2 to prevent the risk of predictability. After completion of the trial entry details, an independent researcher responsible for treatment allocation was contacted by telephone.

Interventions

Early Mobilization Group

Rehabilitation began within seventy-two hours after the fracture and consisted of two-hour sessions that were supervised by a physiotherapist, five times a week, with the patient using oral analgesics. Treatment began with physical techniques to manage pain (icing, massage of the cervical area). Passive motion in abduction with pendulum suspension of the arm and forearm and with the patient lying in a supine position was then performed by the physiotherapist. Mobilization was stopped when the maximum bearable range of motion was reached. At the second session, the same procedure was performed with passive range of motion in forward elevation, with the patient in a lateral supine position. External rotation was added at the eighth session, with the patient in a seated position. After three weeks, sessions occurred twice a week without arm suspension. Patients wore a sling between sessions for four to six weeks, depending on the level of pain. After six weeks, active range of motion was begun during weekly sessions. Strengthening began at three months in twice-monthly sessions. After four to six weeks, patients were advised to perform daily exercises at home. Patients underwent a total of thirty-two therapy sessions.

Conventional Treatment Group

After three weeks of immobilization of the arm in a sling, patients underwent two-hour sessions supervised by a physiotherapist four times a week for four weeks. Passive mobilization in all planes without arm suspension was performed by the physiotherapist, with the patient using oral analgesia during and after therapy sessions to manage pain. The patient kept the arm in a sling between sessions for one to three additional weeks, depending on the level of pain. Then sessions were scheduled twice weekly for five weeks. Active range-of-motion exercises began after six weeks. After nine weeks of rehabilitation, sessions occurred twice monthly until six months. Four to six weeks after the fracture, patients were advised to perform daily exercises at home. Each patient underwent a total of thirty-three sessions.

Patients were discharged from the study at six months.

Outcome Measures

The primary study outcome was clinical assessment of the overall shoulder functional status as measured with the Constant score at three months[22]. This score could not be assessed at baseline because of the fracture. The Constant score is a

numerical scale that is widely used to assess shoulder pain, function, and physical performance; the scale ranges from 0 to 100, with higher scores indicating better overall shoulder functional status[9,15,16,23-26]. The Constant score can be divided in two subscores: a subjective subscore measuring pain and the ability to perform activities of daily living (range, 0 to 35) and an objective subscore measuring physical performance (active range of motion and strength) (range, 0 to 65). The secondary outcomes were the Constant score and subscores at six weeks and at six months.

The baseline assessment included determination of the patient's age, gender, dominant side, social status, and level of sports participation; the cause of the injury; and the level of pain as recorded on a 100-mm visual analog scale[27].

Other secondary outcomes that were recorded at six weeks and at three and six months included the decrease in the intensity of shoulder pain (maximal pain) from baseline as assessed on a visual analog scale[27], the difference (Δ) in global active range of motion between the two shoulders of each patient as measured with a universal goniometer in three planes (abduction, anterior elevation, and lateral rotation), and the difference (Δ) in passive range of motion between the two shoulders as measured with a universal goniometer in three planes (abduction, anterior elevation, and lateral rotation) with the scapula manually stabilized.

At each follow-up visit, the patient's global satisfaction with the efficacy of treatment was recorded on a 5-point scale as very satisfied (5 points), satisfied (4 points), neither satisfied nor dissatisfied (3 points), dissatisfied (2 points), or very dissatisfied (1 point).

Outcome measures were recorded by two physicians, including one of the authors (F.F.), who were blinded to the treatment assignments.

Analysis of Radiographic Images

The type of fracture according to the Neer[28] and AO[20] classification systems was assessed by a single experienced orthopaedic trauma surgeon (A.B.), who affirmed the status of impaction (yes/no) and the need for surgery (yes/no).

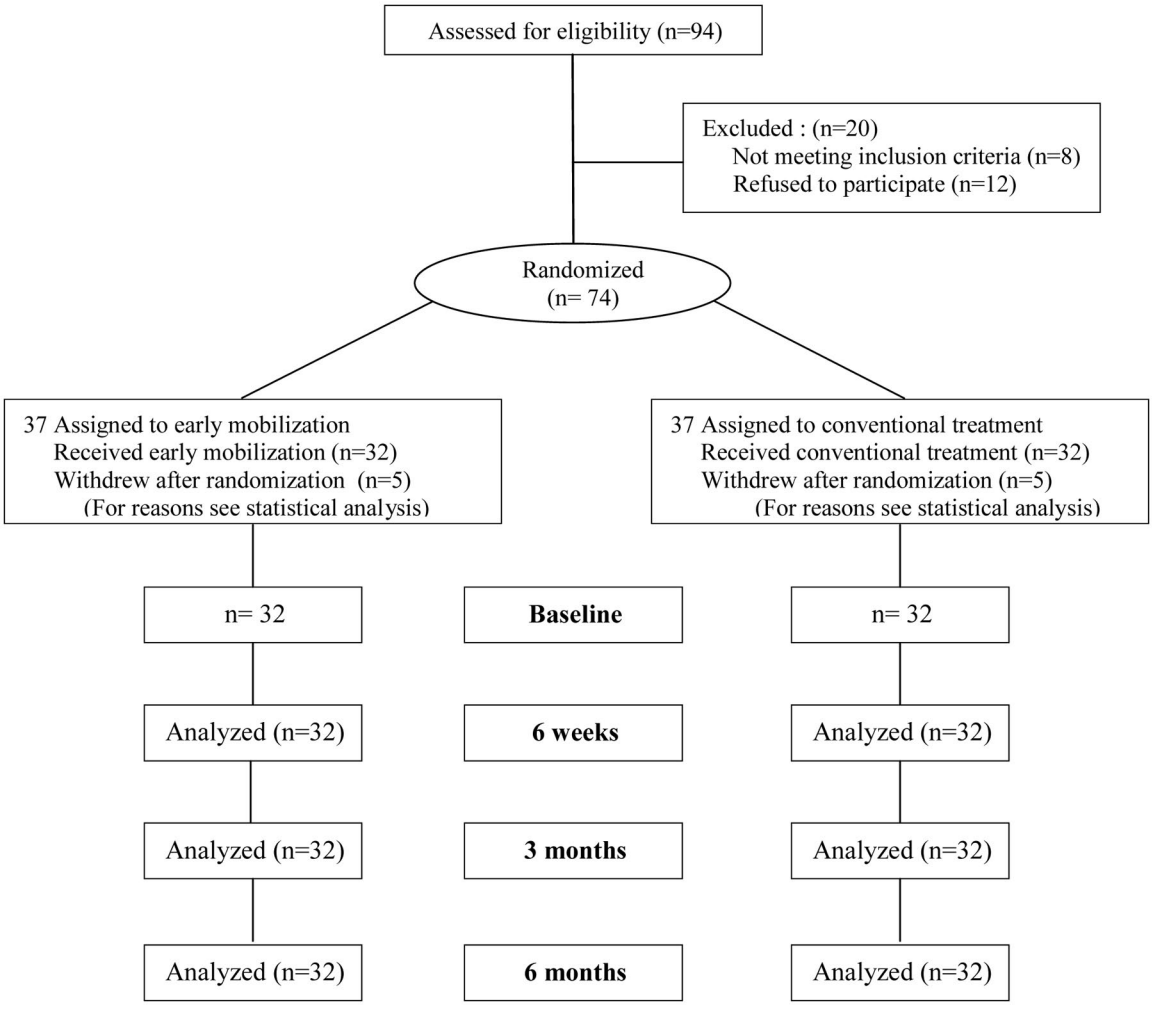

Fig. 1

Diagram illustrating the flow of participants through the study.

TABLE I Patient Characteristics at Baseline

Characteristics	Early Mobilization Group (N = 37)	Conventional Treatment Group (N = 37)
Age* *(yr)*	63.2 ± 18.4	63.4 ± 17.5
Female gender *(no. of patients)*	24 (65%)	30 (81%)
Affected side, left *(no. of patients)*	22 (59%)	21 (57%)
Fracture on dominant side *(no. of patients)*	14 (38%)	17 (46%)
Employed *(no. of patients)*	18 (49%)	13 (35%)
No physical exercise *(no. of patients)*	23 (62%)	27 (73%)
Living alone *(no. of patients)*	22 (59%)	21 (57%)
No domestic help *(no. of patients)*	27 (73%)	24 (65%)
Fracture due to fall *(no. of patients)*	31 (84%)	34 (92%)
Shoulder pain on VAS*†	57.3 ± 20.0	55.1 ± 26.9

*The values are given as the mean and the standard deviation. †VAS = visual analog scale (range, 0 to 100 mm).

At eight days, three weeks, and each follow-up visit, radiographs were made in two planes (anteroposterior and lateral). The orthopaedic trauma surgeon, who was blinded to treatment, assessed healing and displacement as seen on the radiographs. Fracture displacement was assessed in comparison with the initial fracture alignment. Fracture union was defined as complete when trabeculation appeared across the fracture or, in the case of a displaced fracture, when the lateral bone bridge was complete.

Adverse Effects Monitoring

Adverse effects and tolerance were systematically and actively monitored during physiotherapy sessions and medical visits.

Compliance

Patient compliance with the rehabilitation protocol was considered to be satisfactory if the subject attended at least 70% of the supervised sessions.

Statistical Methods

On the basis of a pilot study of twenty-two patients with a three-month follow-up and the analysis of the literature, we determined that a difference of 12 points between the mean Constant scores for the two groups would be clinically relevant[17,25]. We calculated that sixty-six patients would be needed to obtain a power of 0.90 and a significance level of 0.05. With allowance for a 10% rate of loss to follow-up, the required number of patients was seventy-four.

Analysis was carried out with an intention-to-treat approach. After patient randomization and before treatment, five patients in the early mobilization group and five in the conventional group withdrew from the study (Fig. 1). One person performed a careful semidirective telephone interview of these patients to identify the reasons for withdrawal. In all cases, the withdrawal was attributed to difficulties in reaching the hospital for scheduled sessions because of the time required for travel. No patient withdrew because of treatment allocation. In each group, patients who withdrew did not differ significantly from those who were studied in terms of age, gender, pain score, sports activities, social status, cause of injury, or type of fracture.

Considering that withdrawals from the study were not influenced by treatment allocation, we excluded these ten patients from the analysis, without introducing bias in the statistical results[29,30]. The use of this "full analysis set" of sixty-four patients provided a conservative strategy and preserved the intention-to-treat principle[29].

Qualitative variables were recorded as percentages, and comparisons between treatments involved the use of a chi square or Fisher exact test as appropriate. Quantitative variables were described as the mean and the standard deviation; means were compared with use of the two-independent sample Student t test, and mean differences were calculated with 95% confidence intervals. The Mann-Whitney test was also used to compare the outcome measures between the two groups. We used a two-sided level of 0.05 for significance for all tests. This study was registered with ClinicalTrials.gov as NCT 00326794.

Results

Figure 1 shows the number of patients who were screened and included in the trial. Thirty-seven patients were assigned to the early mobilization group, and thirty-seven were assigned to the conventional rehabilitation group. The characteristics of the study population at the time of enrollment are shown in Table I. The two groups did not differ significantly in terms of these characteristics ($p > 0.05$). Most participants had been previously independent, with no domestic help, and about half had been living alone. The fracture types according to the Neer[28] and AO[20] classification systems are shown in Table II. The proportions of the fracture types for the two groups did not differ ($p > 0.05$). In the Neer classification

TABLE II Type of Proximal Humeral Fracture According to the Neer and AO Classification Systems

Fracture Classification System	Early Mobilization Group (N = 37) *(no. of patients)*	Conventional Treatment Group (N = 37) *(no. of patients)*
Neer system		
One part*	18 (49%)	16 (43%)
Two-part displaced and impacted†		
Anatomic neck	0	0
Surgical neck	7 (19%)	8 (22%)
Greater tuberosity	0	1 (3%)
Lesser tuberosity	0	0
Three-part displaced and impacted†		
Surgical neck and greater tuberosity	12 (32%)	12 (32%)
Surgical neck and lesser tuberosity	0	0
AO system		
A1. Extra-articular unifocal fracture of tuberosity		
1. Greater tuberosity, not displaced	1 (1%)	1 (3%)
2. Greater tuberosity, displaced	0	1 (3%)
A2. Extra-articular unifocal fracture, impacted metaphyseal		
1. Without frontal malalignment	4 (11%)	7 (19%)
2. With varus malalignment	2 (5%)	1 (3%)
3. With valgus malalignment	3 (8%)	5 (14%)
B1. Extra-articular bifocal fracture, impacted metaphyseal		
1. Lateral + greater tuberosity	27 (73%)	22 (59%)
2. Medial + lesser tuberosity	0	0
3. Posterior + greater tuberosity	0	0

*No bone segment should be displaced >1.0 cm or angled >45°. †Impacted fracture was defined as a stable fracture of the metaphysis or epiphysis in which the fragments are driven into each other.

system, displaced-impacted fractures and displaced nonimpacted fractures are not distinguished[28]. In Table II, all fractures classified as two and three-part fractures according to the Neer classification system were displaced but impacted.

Main Outcome Measure

The results according to the Constant global score and subscores are shown in Table III. At three months, the mean Constant score was significantly higher for the early mobilization group than for the conventional treatment group (71.0 compared with 61.1; between-group difference, 9.9 [95% confidence interval, 1.9 to 17.8]) ($p = 0.02$ and $p = 0.02$ for the t test and Mann-Whitney test, respectively).

The objective Constant subscores, used to evaluate physical performance, were also significantly higher for the early mobilization group than for the conventional treatment group at three months (Table III).

Secondary Outcome Measures

At six weeks, the mean Constant score was significantly higher for the early mobilization group than for the conventional treatment group (44.0 compared with 33.9; between-group difference, 10.1 [95% confidence interval, 2.0 to 18.1]) ($p = 0.02$ and $p = 0.01$ for the t test and Mann-Whitney test, respectively). At six weeks, the objective and subjective Constant subscores were significantly higher for the early mobilization group than for the conventional treatment group (Table III). The mean Constant scores and subscores were not significantly different between the groups at six months.

At three months, the mean change in pain intensity was significantly greater for the early mobilization group than for the conventional treatment group (34.9 compared with 19.2; between-group difference, 15.7 [95% confidence interval, 0.52 to 30.8]), with the early mobilization group showing a significant decrease in pain intensity ($p = 0.04$ and $p = 0.05$ for the t test and Mann-Whitney test, respectively). Changes in pain intensity were not significantly different between the groups at six weeks and six months.

The early mobilization group showed significantly higher active and passive mobility for abduction and anterior elevation than the conventional treatment group at six weeks. This difference was maintained at three months but not at six months (Table III).

TABLE III Outcome Measures for Early Mobilization and Conventional Treatment Groups at Six Weeks, Three Months, and Six Months After Nonoperative Treatment for Impacted Proximal Humeral Fracture

Evaluation	Early Mobilization Group* (N = 32)	Conventional Treatment Group* (N = 32)	Difference Between Groups (95% Confidence Interval)	P Value	
				Two-Sample Student t Test	Mann-Whitney Test
Constant score (range, 0 to 100)					
6 weeks	44.0 ± 16.5	33.9 ± 16.5	10.1 (2.0 to 18.1)	0.02	0.01
3 months	71.0 ± 14.6	61.1 ± 17.0	9.9 (1.9 to 17.8)	0.02	0.02
6 months	81.5 ± 11.2	75.4 ± 14.4	6.1 (0.4 to 12.5)	0.07	0.11
Constant pain and activities of daily living subscore (range, 0 to 35)					
6 weeks	20.0 ± 6.3	16.8 ± 6.3	3.2 (0.0 to 6.4)	0.05	0.04
3 months	26.4 ± 6.6	23.5 ± 6.8	2.9 (−0.5 to 6.3)	0.09	0.09
6 months	31.3 ± 4.4	29.4 ± 5.5	1.9 (−0.5 to 4.4)	0.12	0.10
Constant active range-of-motion and strength subscore (range, 0 to 65)					
6 weeks	24.5 ± 12.1	17.0 ± 13.1	7.5 (1.2 to 13.9)	0.02	0.01
3 months	44.6 ± 10.6	37.6 ± 11.6	7.0 (1.4 to 12.5)	0.02	0.02
6 months	50.2 ± 8.9	46.1 ± 10.3	4.1 (−0.7 to 8.9)	0.09	0.08
Change of pain intensity† *(mm)*					
6 weeks	22.9 ± 34.1	19.3 ± 35.9	3.6 (13.1 to 21.5)	0.68	0.60
3 months	34.9 ± 25.8	19.2 ± 35.4	15.7 (0.52 to 30.8)	0.04	0.05
6 months	38.8 ± 25.5	39.0 ± 32.0	0.2 (11.9 to 18.6)	0.97	0.78
Difference in active mobility† *(deg)*					
Abduction					
6 weeks	74.5 ± 39.6	100.5 ± 46.2	26 (4.3 to 47.6)	0.02	0.01
3 months	23.0 ± 17.5	35.0 ± 27.9	12.0 (0.4 to 23.7)	0.04	0.12
6 months	10.5 ± 12.0	17.1 ± 23.1	6.6 (2.9 to 16.1)	0.18	0.35
Anterior elevation					
6 weeks	66.5 ± 33.6	94.5 ± 48.5	28.0 (7.1 to 49.1)	0.01	0.01
3 months	20.8 ± 16.8	32.9 ± 23.9	12.1 (1.7 to 22.4)	0.02	0.04
6 months	10.6 ± 11.3	14.2 ± 14.5	3.6 (3.2 to 10.3)	0.30	0.31
Lateral rotation					
6 weeks	29.8 ± 21.1	38.1 ± 20.4	8.3 (2.2 to 18.8)	0.12	0.09
3 months	14.8 ± 13.2	21.4 ± 17.8	6.6 (1.3 to 14.4)	0.10	0.16
6 months	11.7 ± 10.6	14.2 ± 16.2	2.5 (4.8 to 9.6)	0.50	0.17
Difference in passive mobility† *(deg)*					
Abduction					
6 weeks	28.5 ± 13.9	49.6 ± 27.3	21.1 (10.0 to 32.0)	0.001	0.001
3 months	19.3 ± 14.6	30.7 ± 21.4	11.4 (2.1 to 20.6)	0.02	0.03
6 months	11.4 ± 13.1	18.9 ± 18.2	7.5 (0.45 to 15.4)	0.06	0.11
Anterior elevation					
6 weeks	26.8 ± 15.2	45.1 ± 28.6	18.3 (6.5 to 29.1)	0.003	0.002
3 months	18.5 ± 16.7	29.0 ± 21.1	10.5 (0.9 to 20.1)	0.03	0.03
6 months	10.7 ± 14.2	14.5 ± 17.2	3.8 (4.1 to 11.6)	0.35	0.37
Lateral rotation					
6 weeks	24.7 ± 19.2	32.1 ± 22.8	7.4 (3.1 to 18.0)	0.16	0.14
3 months	12.7 ± 14.2	24.3 ± 18.5	11.6 (3.2 to 19.8)	0.007	0.006
6 months	8.1 ± 9.6	11.3 ± 10.1	3.2 (1.8 to 8.1)	0.21	0.18

*The values are expressed as the mean and the standard deviation. †The values are expressed as the improvement from the baseline value for shoulder pain intensity as assessed with a 100-mm visual analog scale. ‡The values are expressed as the difference in the range of motion between the two shoulders.

At six weeks, the proportion of patients who were satisfied or very satisfied with the treatment was not significantly different between the two groups (97% for the early mobilization group and 94% for the conventional treatment group). At three and six months, all patients were satisfied or very satisfied.

The groups did not differ with regard to analgesic intake during the first three weeks or during rehabilitation (data not shown). During the first three weeks of rehabilitation, the mean maximum pain score during physiotherapy sessions was not significantly higher in the early mobilization group than in the conventional treatment group (40.1 compared with 34.1; between-group difference, 6.1 [95% confidence interval, −3.3 to 15.4], $p = 0.20$). Moreover, no patient withdrew from the study in the early mobilization group because of pain during the first three weeks.

The fracture-healing rate at three months was 100% in both groups; there were no cases of fracture displacement. No patient withdrew from the study because of adverse effects. One patient in each group received a subacromial injection of steroids to treat a subacromial impingement syndrome.

All patients in both groups attended at least 70% of the supervised physiotherapy sessions.

Discussion

Immediate passive joint mobilization after an impacted nonoperatively treated proximal humeral fracture offers a better chance for a more rapid gain in overall shoulder functional status than does classic three-week immobilization followed by physiotherapy. Early joint mobilization appears to be feasible and safe without complications such as nonunion or fracture displacement.

No consensus exists with regard to which type or types of nonoperatively treated proximal humeral fractures should be treated with strict immobilization. Therefore, we chose to extend the indications of early mobilization to all types of impacted fractures (as defined in the AO classification system), including two and three-part displaced but impacted fractures[20,28]. Our results strongly suggest that immediate passive mobilization is safe for these fractures because we did not observe nonunion or fracture displacement among the thirty-two patients who were so managed in the present study. In studies evaluating impacted proximal humeral fractures that were conventionally treated nonoperatively (including those in the conventional treatment group in the present study), four cases of nonunion or displacement were reported among a total of 373 patients (prevalence, 1.07%)[8-10]. In studies evaluating early mobilization for nonoperatively treated impacted proximal humeral fractures (including those in the present study), no case of displacement or nonunion was reported among a total of 165 patients[12,17,19]. Using the Fisher exact test, we found that these two proportions did not differ significantly ($p = 0.32$). This analysis, based on pooled data, suggests but does not demonstrate with certainty that the rate of nonunion or displacement is probably not different with the two treatment options.

A faster return to prefracture physical performance and functional status is the goal of most rehabilitation programs. Most of our patients were independent and relatively fit before the fracture. As a consequence of humeral fracture, a number of previously independent patients are not able to return to independent activity for many months; these patients also have an increased risk of femoral neck fracture[31].

Until now, the recommended nonoperative treatment of proximal humeral fractures has been initial immobilization before rehabilitation to obtain better relief of pain and to prevent fracture displacement. The usual side effects of immobilization are joint stiffness and muscle atrophy, which may lead to an increased duration of disability. Specific passive mobilization of the glenohumeral joint before fracture-healing has been reported in a few studies, but most of those studies contained methodological concerns and pitfalls in evaluation[12,14,18]. Surprisingly, questions regarding the duration of immobilization or the timing of when rehabilitation should start have received little attention. Our results are in accordance with those of Hodgson et al., who showed that patients who were managed with immobilization for three weeks after the fracture and before the start of physical therapy had more pain and reported slower recovery of the overall shoulder functional status at sixteen weeks as compared with patients who underwent passive mobilization treatment within one week[17]. In the current study, the intervention group showed a significantly better Constant score than the conventional treatment group did at six weeks, and this difference was maintained at three months.

As others have found, we did not observe significant differences in primary or secondary outcomes at six months. However, in our study, the mean Constant scores in both groups suggested almost complete recovery by six months. Others have reported that patients with proximal humeral fracture recovered functional ability after one year[9,32]. Court-Brown et al., in an analysis of 125 patients with AO type-B1.1 impacted fractures that were treated nonoperatively, found a gradual improvement in the mean Constant score between six weeks and one year, with a mean score of only 72 at one year[9]. We observed better results at six months, with mean Constant scores of 75 and 82 in the conventional treatment and early mobilization groups, respectively. One possible explanation for this discrepancy could be that our rehabilitation programs were standardized, intensive, mostly center-based, and delivered by physiotherapists who were experienced in the field. Moreover, to avoid the possibility of bias related to the amount of physiotherapy received, we assigned our control group to receive the same number of supervised sessions as the early treatment group. This led to patients in the control group receiving more physiotherapy than in "real-life conditions." More pragmatic studies are now needed to define the type, number, and intensity of physiotherapy sessions according to the type of fracture, the patient, and the community setting to quickly restore mobility and performance and to maximize the ultimate function of the shoulder.

Our study had limitations. We chose the Constant score as our primary outcome measure, but although the score is a widely used international shoulder function assessment tool used for the evaluation of patients who have traumatic injuries or shoulder diseases, the minimum clinically important improvement score has not been established[9,15,16,23-26]. We considered the 10-point difference in the Constant score to be a clinically important difference in accordance with the findings of two previous clinical studies[17,25]. Moreover, we did not record generic health-related quality-of-life measures and associated morbidity during the follow-up period.

Another limitation was that we conducted our research in a tertiary referral setting with supervised physical therapy for both treatment groups, and the financial considerations of such a course need to be considered. However, we are not aware of any report on the effectiveness and feasibility of early unsupervised standard physiotherapy for two and three-part impacted fractures that have been treated nonoperatively. Two studies of minimally displaced fractures demonstrated no significant difference between unsupervised physiotherapy (receiving instruction for exercises at home and follow-up control of results) and conventional physiotherapy[33,34]. However, the studies included a limited number of patients and contained methodological flaws. A patient who has a two or three-part impacted fracture probably cannot perform early passive mobilization (e.g., elevation with a stick), and the procedure must be performed with use of a specific technique by the therapist to avoid the risk of secondary displacement or pain. Therefore, we believe that supervised sessions are needed when this type of fracture is treated with early mobilization. Finally, we did not record patients' treatment preference.

In conclusion, our results indicate that early supervised mobilization after an impacted nonoperatively treated proximal humeral fracture is feasible and safe and leads to a faster return to physical capability and performance. This rehabilitation program may offer an alternative treatment to immobilization for three weeks or longer. ■

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