Early versus late mobilization after hemiarthroplasty for proximal humeral fractures

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This randomized controlled trial compares 2 mobilization regimens after shoulder hemiarthroplasty for acute 3- and 4-part fractures. The aim was to establish whether the length of immobilization plays a role in the functional outcome, tuberosity healing, and subsequent range of motion. The same prosthesis and surgical technique were used. We recruited 59 patients into the study; 31 were randomized to early (2 weeks) mobilization and 28 to late (6 weeks) mobilization. Greater tuberosity migration was assessed with a series of radiographs, and the functional outcome was assessed with the Constant Shoulder Assessment and Oxford shoulder scores. Of the patients, 49 (mean age, 70 years) met the inclusion criteria and were followed up for 12 months. Greater tuberosity migration occurred in 3 cases in the early mobilization group and once in the late mobilization group (P > .10). There was no significant difference in the Constant Shoulder Assessment and Oxford scores between the 2 groups. Although there was a decreased incidence of tuberosity migration in the group undergoing late mobilization, this was not statistically significant. (J Shoulder Elbow Surg 2007;16:33S-38S.)

Shoulder hemiarthroplasty is an established method for treating articular and 4-part fractures of the proximal humerus, particularly in elderly patients with poor bone quality. However, the results vary greatly, from disappointing to excellent,[6,13-17,20-23,27,30,32-35] despite advances in surgical technique, instrumentation, and prosthetic design.

Age, fracture pattern, bone and soft-tissue quality, timing of surgery, surgical experience, technical accuracy, rehabilitation, and compliance have all been recognized as factors affecting the outcome.[1-3,10,13-17,22,24,33] Moreover, most authors agree that adequate tuberosity reconstruction is of paramount importance.[2,3,7,13-18,24] Tuberosity malunion or nonunion has been recognized as the most common single identifiable reason for failure.[2,3,16,22,33] For a given prosthetic design, tuberosity union will depend on the prosthetic height and retroversion, the fixation technique, and the rehabilitation protocol.[5,10,18,24] Most postoperative rehabilitation protocols are based on Neer's early passive motion regimen[26] and gradually evolved into even earlier mobilization formats.[1,24] However, it was Boileau et al[3] who first recognized some discordance between the necessity to mobilize the shoulder early and high rates of tuberosity migration. In their series of 406 patients they found that patients immo-

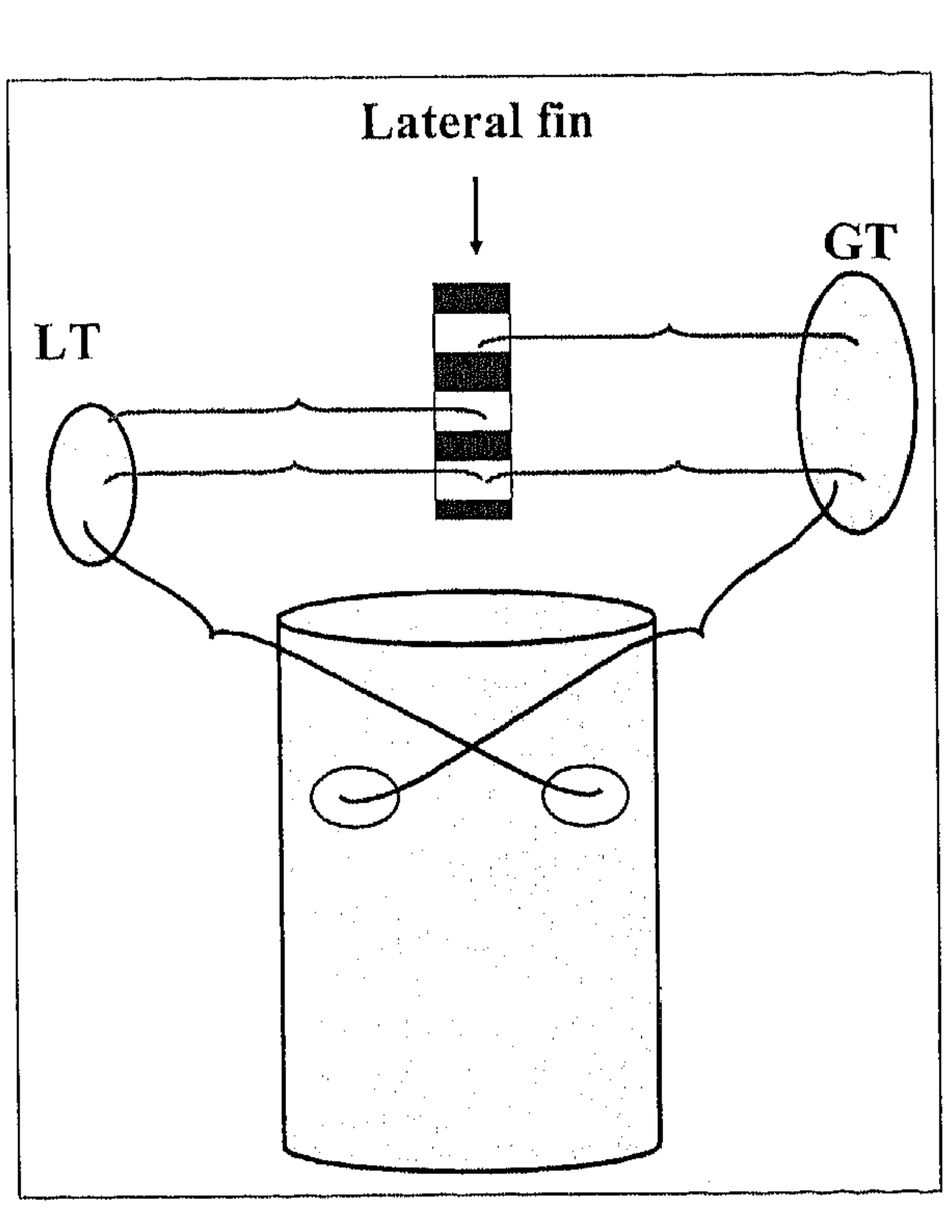

Figure 1 Diagram illustrating technique of tuberosity reattachment, following the principle to shaft, to fin, to each other. *LT*, Lesser tuberosity.

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1058-2746/2007/$32.00

doi:10.1016/j.jse.2006.07.004

Table I Baseline characteristics of patients included in trial

	Early mobilization group	Late mobilization group	*P* value of difference
No. of patients	26	23	—
Gender (female/male)	21:5	18:5	>.99*
Mean age (y) (SD, range)	72 (12, 38-84)	67 (14, 34-85)	.08†
Mean delay to surgery (d) (SD, range)	9.2 (7.3, 1-30)	11 (7, 1-28)	.83†
Ratio of 3-part fractures to 4-part fractures	4:22	5:17	.71*

*Fisher exact test.
†Mann-Whitney test.

Table II Occurrence of GT migration and superior prosthetic subluxation

	Early mobilization group	Late mobilization group	*P* value of difference
No. of patients	26	23	—
GT migration	3	1	.61*
Superior subluxation	6	4	.73*

*Fisher exact test.

bilized postoperatively were 2 times less likely to have tuberosity migration than those mobilized immediately (14% vs 27%). They recommended immobilization in neutral rotation until tuberosity healing had occurred.[4]

The decision of how soon the shoulder should be mobilized after hemiarthroplasty for fracture is often empirical, if not arbitrary. On the basis of the lack of published studies that focus on this particular subject, we undertook a randomized controlled trial that compares 2 different mobilization regimens and their effect on tuberosity healing, range of motion, and function.

MATERIALS AND METHODS

The study was approved by the local research and ethics committee. The inclusion criteria were isolated nonpathologic fractures of the proximal humerus, less than 6 weeks old, that required primary hemiarthroplasty. The indications for hemiarthroplasty were displaced 3- and 4-part fractures or articular fractures in physiologically old patients with poor bone quality. All patients fulfilling these criteria were asked to participate in the trial, and informed consent was obtained preoperatively. Fractures were classified by use of Neer's classification.[25] The endpoint of the study was set at the 12-month outpatient visit.

Between October 2002 and October 2003, we recruited 59 patients fulfilling the inclusion criteria. Randomization took place in the operating theater after the procedure, by use of sequentially numbered, sealed envelopes. Three upper limb surgeons performed all of the procedures, having previously agreed to use the same technique. This included a deltopectoral approach, tenotomy and tenodesis of the long head of the biceps, cementation, and bone grafting of the tuberosities by use of the extracted humeral head. The same unconstrained prosthesis was used in 55 cases (Nottingham Shoulder; Biomet UK, Bridgend, South Wales). The prosthetic retroversion was individualized, but the general rule was that the head should be centered in the glenoid with the arm at the side and the forearm on the abdomen.[18] During surgery, 2 longitudinal rotator cuff tears, which were approximated with sutures, and 1 massive irreparable tear were encountered.

All of the surgeons agreed to use the same method for tuberosity fixation from the beginning of the study. The tuberosities were reattached in the same manner, applying the principle of to fin, to bone, to each other (Figure 1), by use of FiberWire sutures (Arthrex, Naples, FL). Six sutures were used for every case, as is shown in Figure 1. Placement of the greater tuberosity (GT) was aimed at 10 mm below the superior margin of the prosthetic head.[22]

Patients were randomly allocated to the early or late mobilization group. In the early mobilization group, the arm was kept in a sling in neutral rotation for the first 2 weeks, while only pendulum and elbow exercises were allowed. Between the third and sixth weeks, the patients progressed to active-assisted exercises and, from the seventh week, to active exercises. This represented the normal regimen in our institution. In the late mobilization group, the arm was kept in a sling in neutral rotation for 6 weeks, with only elbow exercises being allowed. From the seventh to the twelfth week, the patients progressed from pendulum to active-assisted exercises and, from the thirteenth week, to active exercises. Both mobilization protocols were supervised by a team of specialist shoulder physiotherapists.

Plain radiographs in 2 planes were obtained on the first postoperative day and subsequently at 2 and 6 weeks and at 3, 6, and 12 months, coinciding with outpatient visits. Initial GT malpositioning and subsequent migration, as well as superior subluxation of the prosthesis, were assessed radiologically. GT malpositioning was defined as a head-to-tuberosity distance of less than 3 mm or greater than 20 mm on the anteroposterior (AP) radiograph or posterior displacement on the lateral view.[19,22,29] GT migration was assessed by comparison of subsequent AP and lateral views. Superior prosthetic subluxation was defined as an acromiohumeral distance of less than 7 mm on the AP radiograph.[19]

At the 6- and 12-month visits, an independent blinded observer completed the Constant Shoulder Assessment (CSA)[8] and Oxford scores[9] for each patient. The CSA score has a maximum score of 100 points, with subjective and objective components included at a ratio of 35:65. Range

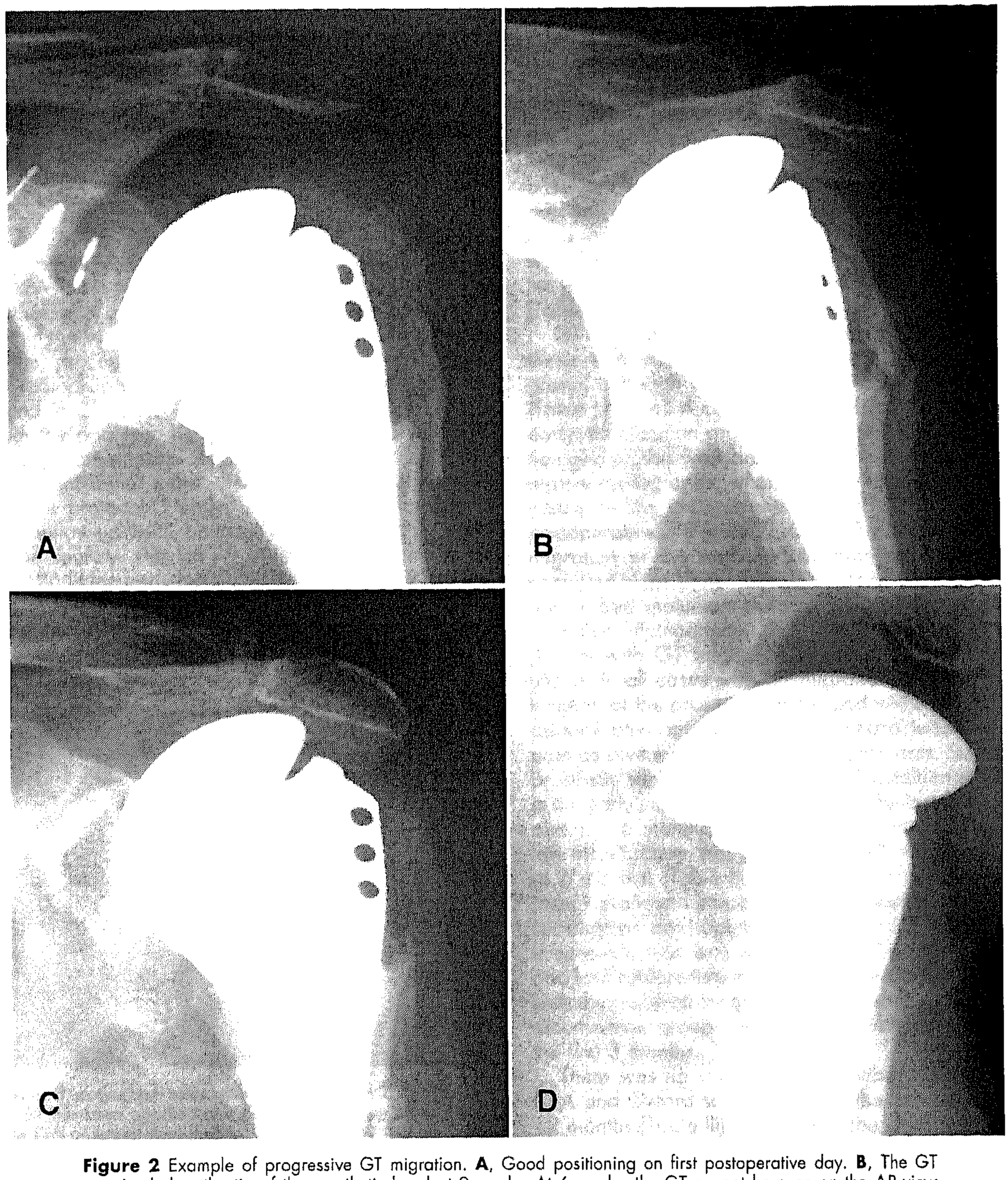

Figure 2 Example of progressive GT migration. **A**, Good positioning on first postoperative day. **B**, The GT remains below the tip of the prosthetic head at 2 weeks. At 6 weeks, the GT cannot be seen on the AP view (**C**) whereas the lateral view reveals that it has migrated posteriorly (**D**).

of motion was measured with a goniometer and power with a commercial digital spring balance. The Oxford score is purely subjective, with a maximum of 60 attributed to the worst outcome and a minimum of 12 attributed to the best outcome. In this article, the Oxford scores were converted onto a scale ranging from 0 to 100 (worst to best) to facilitate comparison with the CSA and other more conventional worse-is-lower methods.[11] The mathematic formula used for the conversion was $(60 - x) \times 100/48$, where x represents the absolute Oxford score value. However, for statistical comparisons, only the absolute Oxford score values were used.

The null hypothesis tested was that there is no difference in GT migration and functional outcome between the 2 groups. The Fisher exact test was used for categoric variables. The Wilcoxon test was used for CSA and Oxford score comparisons within each group and the Mann-Whitney test for comparisons between groups. The level of significance was set at $P < .05$.

RESULTS

A total of 10 patients were excluded from the analysis. In 4 of them, a different uncemented prosthesis was used; in 1, the fracture proved to be pathologic; and in 1, a deep infection developed within the second postoperative week and required a further procedure. Initial GT malpositioning, as seen on radiographs from the first postoperative day, was found in 2 cases. These cases were also excluded from the analysis, because malpositioning reflected intraoperative technical difficulties or prosthetic malalignment rather than being influenced by the mobilization protocol. Finally, 2 patients did not attend their follow-up visits, because they lived in other parts of the country. This left 49 patients for the final analysis, 26 in the early mobilization group and 23 in the late mobilization group, all of whom were seen at the 12-month visit.

The mean age of the sample was 70 years (range, 34-85 years), and there were 39 women and 10 men. There were 9 three-part and 39 four-part fractures. There was 1 fracture-dislocation in the early mobilization group, 2 fracture-dislocations in the late mobilization group, and 1 head-splitting fracture in the late mobilization group. The mean delay from injury to surgery was 10 days (range, 1-30 days). The baseline characteristics for each group (gender, age, surgical delay, and 3- to 4-part fracture ratio) are listed in Table I. No statistically significant difference was found for any these characteristics between the groups, which indicates successful randomization (Table I).

GT migration and superior subluxation of the prosthesis were more frequent in the early mobilization group, although this was not statistically significant (Table II). In all 4 cases with GT migration (3 in the early mobilization group and 1 in the late mobilization group), this was identified on the 6-week postoperative radiographs, whereas there was no such evidence on the previous views (1 day and 2 weeks postoperatively) (Figure 2). Of the 3 patients with GT migration in the early mobilization group, 2 had nonunion with bone resorption develop (Figure 3) and 1 had malunion develop with the GT causing posterior impingement. Malunion developed in the patient with GT migration in the late mobilization group. In all cases with GT migration, superior subluxation of the prosthesis developed within the first 3 postoperative months, and they characterized their pain as severe at the 6- and 12-month visits. Superior prosthetic subluxation occurred in 3 additional cases in the early mobilization group (2 in the first 3 months and 1 at 6 months) and in 3 additional cases in the late mobilization group (1 in the first 3 months and 2 at 6 months) (Table II). In all 3 cases in which cuff tears were found intraoperatively, superior prosthetic subluxation developed: the case with the massive irreparable tear was in the late mobilization group and had subluxation in the first 3 months; the 2 cases with the repaired longitudinal tears were in the early mobilization group and also had subluxation within the first 3 months.

There was no statistically significant difference in CSA and Oxford scores between the groups at 6 or 12 months (Table III). Analysis of the change in CSA

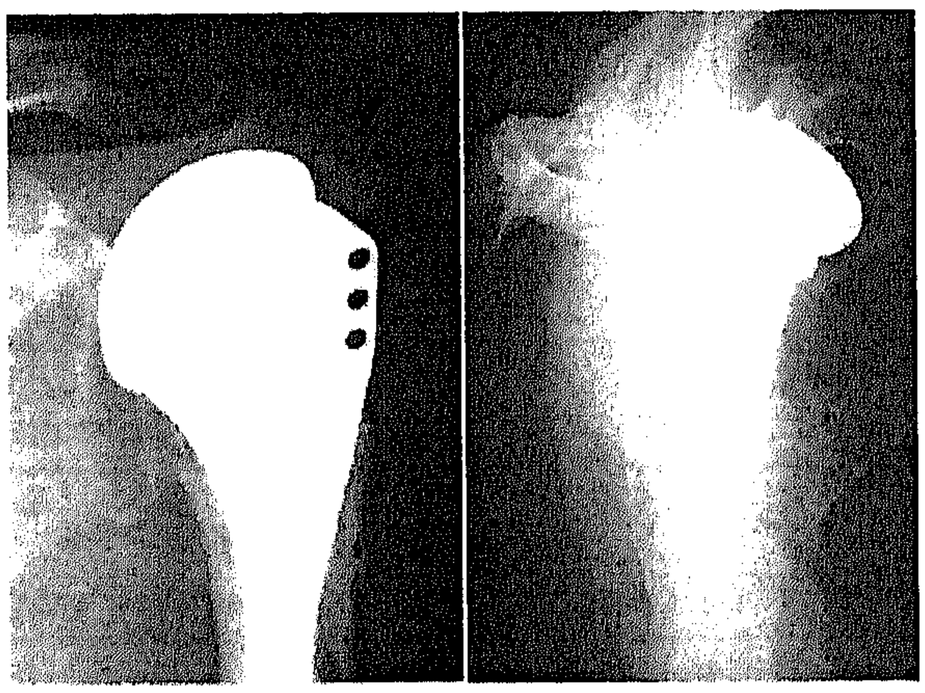

Figure 3 Images from same case shown in Figure 2. At 6 months, the GT has been resorbed and cannot be seen on either the AP view (*left*) or lateral view (*right*).

Table III CSA and Oxford score comparison between the 2 groups at 6 and 12 months

	Early mobilization group (n = 26)		Late mobilization group (n = 23)		*P* value between groups	
	6 mo	12 mo	6 mo	12 mo	6 mo	12 mo
CSA score (SD, range)	46 (17, 16-85)	47 (19, 4-88)	47 (12, 26-68)	50 (11, 33-73)	.74*	.57*
Oxford score (SD, range)	59 (23, 17-100)	65 (23, 17-100)	63 (18, 17-92)	71 (14, 31-96)	.45*	.39*

*Mann-Whitney test.

and Oxford scores within each group from 6 to 12 months demonstrates a significant improvement in Oxford scores for both groups (Table IV). The improvement was more evident in the late mobilization group with regard to both scores. Analysis of the range of motion and of the separate CSA components—mobility, strength, pain, and activities of daily living—did not reveal any statistically significant differences between the groups (Table V).

DISCUSSION

Successful tuberosity osteosynthesis is a prerequisite for a favorable outcome after hemiarthroplasty for proximal humeral fractures. This is a challenging task even for the experienced shoulder surgeon, who has to deal with the loss of anatomic landmarks, which is very common in cases of fracture. Tuberosity malpositioning substantially increases the torque requirements for abduction and restricts glenohumeral motion.[12,28] Excessive prosthetic height and retroversion will substantially increase the forces generated even in well-fixed tuberosities and may lead either to tuberosity displacement or to rotator cuff attenuation and failure.[5] It is also noted that, in some cases, tuberosity displacement occurs despite apparent anatomic fixation.[5]

In this study, the surgical technique was standardized to a certain extent. A limitation of this study is the lack of data regarding prosthetic version and height and their potential influence on tuberosity displacement. Collection of such data would have required computed tomography scanning of every case, as well as plain radiographs of the opposite humerus, with a substantial increase in radiation exposure and an unacceptable increase in costs for the hospital.

Cerclage wiring of the tuberosities seems to be biomechanically superior.[12,31] However, this technique was avoided because it was not routinely practiced by all surgeons.

All GT displacements in this study occurred between the second and sixth postoperative weeks in both groups. It seems that this interval was the period at risk for tuberosity displacement to occur. One could logically think of slowing down mobilization of the shoulder or even immobilizing it completely during this period, with the aim of lowering the frequency and the intensity of the forces applied to the (frequently osteopenic) tuberosities. This theory is in contradiction with modern rehabilitation protocols, which suggest that intensive rehabilitation is associated with better results.[1] As such, it is commonly proposed that mobilization should start as quickly as possible with active-assisted exercises from the first postoperative day.[24] However, in this study, the delay in mobilization did not seem to affect shoulder function or range of movement in the late mobilization group. In fact, CSA and Oxford scores were marginally better for the late mobilization group at 6 and 12 months, although this was not significant (Table III). Regarding the separate parameters of the CSA, the only areas where the late mobilization group scored less favorably were mobility at 6 months and strength throughout the follow-up period (Table V). It is also interesting that the late mobilization group reported less pain and performed better with activities of daily living throughout the study (Table V). Despite the fact that none of the previously mentioned differences between the groups was significant, at least

Table IV *P* values for CSA and Oxford score change within each group from 6 to 12 months

	Early mobilization group (n = 26)	Late mobilization group (n = 23)
CSA score	.24*	.08*
Oxford score	.02*	.004*

*Wilcoxon test.

Table V Comparison between the 2 groups at 6 and 12 months with regard to range of motion and separate parameters of CSA

	Early mobilization group (n = 26)		Late mobilization group (n = 23)		*P* value* between groups	
	6 mo	12 mo	6 mo	12 mo	6 mo	12 mo
Elevation (°) (SD, range)	73 (18, 45-100)	80 (17, 50-110)	68 (16, 40-95)	78 (13, 55-100)	.26	.6
External rotation (°) (SD, range)	15 (5, 5-32)	14 (7, 8-35)	15 (6, 5-30)	18 (10, 10-32)	.72	.19
Internal rotation (range)	L4 (thigh-L1)	L4 (S1-T10)	L5 (thigh-L1)	L4 (S1-T10)	.66	.8
CSA parameter						
Mobility (SD, range)	18 (8, 8-32)	18 (5, 12-28)	16 (5, 8-24)	18 (5, 10-24)	.43	.82
Strength (SD, range)	6 (3, 0-12)	6 (3, 0-14)	5 (3, 0-12)	5 (2, 0-12)	.44	.39
Pain (SD, range)	10 (5, 0-15)	10 (5, 0-15)	11 (4, 0-15)	11 (4, 0-15)	.53	.66
ADL (SD, range)	12 (5, 4-20)	13 (4, 4-20)	15 (5, 4-20)	16 (3, 10-20)	.79	.09

ADL, Activities of daily living.
*Mann-Whitney test.

there was no evidence that the late mobilization group sustained any of the detrimental effects of scarring that one might expect from the prolonged immobilization.[18]

Our study suggests that late mobilization is equally as safe as early mobilization. It also indicates a trend toward less tuberosity displacement and better function. We believe that this trend needs to be investigated with further studies. Finally, it must be stressed that prolonged immobilization is no substitute for secure tuberosity fixation, meticulous surgical technique, and correct placement of the prosthesis. Surgeons should adhere to the previously mentioned principles rather than relying on prolonged immobilization.

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