Does delay matter? The restoration of objectively measured shoulder strength and patient-oriented outcome after immediate fixation versus delayed reconstruction of displaced midshaft fractures of the clavicle

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Outcome after surgical treatment for nonunion and malunion of midshaft displaced clavicle fractures has generally been described as favorable and equal to results of acute repair. This assumption has been based on subjective criteria, however, and no direct comparison is available in the literature. This study used objective measurements of limb function to compare outcome in patients who underwent delayed operative intervention for nonunion and malunion with the outcome of patients who underwent immediate open reduction and internal fixation after displaced clavicle fracture. All patients had sustained completely displaced, closed, isolated midshaft clavicle fractures, of whom 15 had undergone acute open reduction and internal fixation with a compression plate at a mean of 0.6 months after injury (acute group). Another 15 patients had undergone delayed reconstruction with open reduction, bone grafting, and compression plate fixation for nonunion or malunion a mean of 63 months after injury (delayed group). The 2 groups were similar in age, gender, original fracture characteristics, and mechanism of injury. Complete assessment included standard history and physical examination, the Disabilities of the Arm, Shoulder and Hand (DASH) score and Constant Shoulder Score, subjective rating of outcome satisfaction, and objective muscle strength testing using a previously validated and published protocol on the Baltimore Therapeutic Equipment (BTE) work simulator. There were no significant differences between acute fixation and delayed reconstruction groups with regard to strength of shoulder flexion (acute, 94%; delayed, 93%; P = *.82), shoulder abduction (acute, 97%; delayed, 97%;* P = *.92), external rotation (acute, 97%; delayed, 90%;* P = *.11), or internal rotation (acute, 98%; delayed, 96%;* P = *.55). Constant scores in the acute group were superior (acute, 95; delayed, 89;* P = *.02), but differences in DASH scores were not significant (acute, 3.0; delayed, 7.2;* P = *.15). Shoulder flexion muscle endurance was significantly decreased in the delayed group (acute, 109%; delayed, 80%;* P = *.05). Differences in muscle endurance in other planes were not significantly different (abduction endurance: acute, 107%; delayed, 81%;* P = *.24). Both groups rated their satisfaction with the procedure as excellent. Late reconstruction of nonunion and malunion after displaced midshaft fractures of the clavicle is a reliable and reproducible procedure that results in restoration of objective muscle strength similar to that seen with immediate fixation; however, there are subtle decreases in endurance strength and outcome compared with acute fracture repair. This information should not be used to justify primary operative repair in isolation but is useful in decision-making when counseling patients with displaced midshaft fractures of the clavicle. (J Shoulder Elbow Surg 2007;16:514-518.)*

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Recent evidence indicates that outcome after nonoperative care of displaced midshaft fractures of the clavicle may not be as consistently positive as originally thought.[2,7,8,14,19,21] In light of this evidence, debate has arisen over the best course of treatment of displaced fractures of the midshaft of the clavicle. Some studies suggest primary open reduction and internal fixation is ideal,[2,18] but others maintain that nonoperative treatment remains the best option.[6,15] Despite variation in the reported rates of symptomatic malunion and nonunion after conservative treatment, it is clear that negative outcomes do exist.[13-17]

An important factor in considering the initial treatment of any fracture is the efficacy of reconstructive procedures in the event of primary care failure. Open reduction and plate fixation has been the standard treatment for symptomatic nonunion or malunion that occurs after nonoperative treatment of clavicle fractures. Corrective osteotomy, followed by plate fixation, has been reported to improve shoulder function significantly in cases of malunion,[1,3,4,13] whereas open reduction and plate fixation combined with autogenous bone graft has been shown to be similarly effective in treating cases of nonunion.[17] However, outcomes have been assessed relative to the preoperative condition and give no information on how results compare with alternative methods of primary treatment. Conventional wisdom dictates that outcome after delayed reconstruction is equivalent to that seen after immediate operative repair of an acute fracture; however, objective data to support this position are lacking.[6,11]

This is important information for a patient and surgeon who are deciding on the initial treatment. If, for example, late reconstruction is equivalent to acute fixation, then nonoperative treatment could be recommended initially, confident that reconstruction (if required) was equivalent. Alternatively, if delayed reconstruction is inferior to acute repair, this represents a relative indication to proceed with early intervention, especially in a patient with negative prognostic features (ie, shortening >2 cm).[13,14,19]

To the best of our knowledge, no study has objectively compared the outcomes of patients initially treated operatively with those who underwent delayed reconstruction for symptomatic malunion or nonunion. The purpose of this study was to determine if delayed reconstruction of clavicle nonunion or malunion was as effective in restoring objective and subjective outcome as early operative intervention.

MATERIALS AND METHODS

This study was performed at a university-affiliated level 1 trauma center and was approved by the institution's Research Ethics Board. From our fracture database, we identified 73 patients between the ages of 18 and 65 who had undergone open reduction and plate fixation acutely (≤1 month) or for malunion or nonunion after isolated, closed, completely displaced fracture of the midshaft of the clavicle between 1998 and 2004. No proximal or distal one-third fractures were included. Five of the patients in the acute group were part of a previously published randomized trial of clavicle fracture treatment.[2] Sixty patients met the inclusion criteria: 18 declined participation, 12 were lost to follow-up, and 30 were included. Inclusion in the study required that subjects were a minimum of 1 year from surgery, had achieved union according to clinical and radiographic evaluation, and had no comorbidities or injuries that would compromise upper limb strength. The delayed fixation group included patients who underwent surgical intervention 6 or more months after the original fracture date for nonunion or symptomatic malunion (delayed group). All testing was conduced by an independent examiner not involved in the clinical care of the patients.

Table I Group demographics

Variable	Delayed fixation	Early fixation	*P*
Gender			
Males	11	14	
Females	4	1	.14
Smoking status			
Smokers	3	5	
Nonsmokers	12	10	.41
Fracture side			
Dominant	7	5	
Nondominant	8	10	.41
Mechanism			
Sport	7	6	
Bicycle fall	4	5	
High-velocity fall	2	1	
Motorcycle fall	1	1	
Car accident	0	2	
Other	1	0	.62
Age	42	33	.08
Time (months)			
Fracture to surgery	63	0.6	.04
Surgery to testing	33	25	.14

The acute group consisted of 15 patients (1 woman, 14 men) who underwent operative intervention within 1 month of the original fracture (mean, 0.6 months; range, 0.1-1.0 months) postinjury. The mean duration from operation to testing was 25 months (range, 14 to 47 months). The mean age was 33 years (range, 18-58 years). Five of the affected shoulders were to the dominant side, and 10 were to the nondominant side.

The delayed group consisted of 15 patients (4 women, 11 men) with a mean age of 42 years (range, 21-65 years). The mean time from fracture to operative intervention was 63 months (range, 6-67 months), and 33 months (range, 12-72 months) from operative intervention to testing. Five patients had symptomatic malunion, and 10 had nonunion. The dominant limb was affected in 7 subjects and the nondominant in 8. Statistical analysis showed no significant differences between the 2 populations with regard to age at the time of surgery, the frequency of injuries to the dominant side, gender, or interval duration from operative fixation to testing (Table I).

Outcome assessment and patient satisfaction

All patients returned for a complete assessment, including history and physical examination, subjective rating of outcome satisfaction, completion of the disabilities of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire[9] and the Constant Shoulder Score (CSS),[5,20] and objective strength and endurance testing. The DASH questionnaire is a disability score (100 = *completely disabled extremity*, 0 = *perfect extremity*). The CSS is a surgeon-

based scoring system, with a maximum score of 100 indicating ideal shoulder function.

Patients were asked to rate their satisfaction with the surgical procedure on a 10-point scale (0 = *extremely dissatisfied*, 10 = *extremely satisfied*).

Strength testing

Strength and endurance testing was done using the Baltimore Therapeutic Equipment (BTE) work simulator (Model WS-20, Hanover, MD). Isometric shoulder strength was tested in abduction, flexion, outward rotation, and inward rotation according to a previously published protocol.[17] The unaffected upper extremity was used as a control for each patient and was tested first. Patients were allowed to practice on the machine and then rest before testing.

Isometric strength of shoulder flexion and abduction was measured with the arm at 10° and no flexion of the elbow. Isometric strength of external and internal rotation was measured with the arm abducted at 45° and the elbow in 90° flexion. The strength measurement reported is the mean of 3 trials with a coefficient of variation of less than 10%. Values were expressed in inch-pounds and as a percentage of the contralateral (normal) arm.

Endurance testing

Shoulder endurance was tested in a subset of patients (10 from the acute group, 9 from the delayed group) with no significant difference in gender ($P = .21$), injury to the dominant side ($P = .76$), duration to testing ($P = .46$), or age ($P = .15$). Endurance of shoulder flexion and abduction were tested in elbow extension with the arm beginning in neutral position beside the body and moving through a full range of motion. Resistance was set at 50% of maximum isometric strength. The test was terminated when the subject could not move through a full range of motion. Endurance was recorded as a function of total work done to fatigue.[17]

Statistical analysis

Data were analyzed using an independent-samples *t* test of means for numeric data, and χ^2 tests for nonparametric data. Statistics testing was done with SPSS 13.0 statistical software (SPSS Inc, Chicago, IL). A value of $P < .05$ was considered statistically significant.

RESULTS

Outcome assessment and patient satisfaction

The CSSs were significantly higher in the acute group (mean CSS, 95) then in the delayed group (mean CSS, 89; $P = .02$). Mean DASH scores were also different (acute group, 7.2; delayed group, 3.0), but this was not statistically significant ($P = .15$; Table II).

When asked to rate their satisfaction with the surgical procedure on a 10-point scale, both groups indicated an extremely high level of satisfaction. The mean satisfaction score was 9.8 (range, 8-10) for the acute group, and 9.6 (range, 7-10) for the delayed group ($P > .05$).

Table II Outcome scores

	Delayed fixation	Early fixation	*P*
DASH	7.2	3.0	.15
CSS	89	95	.04

DASH, Disabilities of the Arm, Shoulder and Hand; *CSS,* Constant Shoulder Score.

Table III Shoulder strength and endurance: percentage recovered versus unaffected (contralateral) limb

Variable	Delayed fixation (%)	Early fixation (%)	*P*
Strength			
Flexion	93	94	.82
Abduction	97	97	.92
External rotation	90	97	.11
Internal rotation	96	97	.55
Endurance			
Flexion	80	109	.05
Abduction	81	107	.24

Strength testing

Mean isometric strength values as a percentage of the unaffected limb are summarized in Table III. Strength was well restored in both groups, with values in each group approaching 100% of the unaffected limb in each category. The mean percentage of strength in the affected limb relative to the unaffected limb was 94% in the acute group versus 93% in the delayed group for shoulder flexion ($P = .82$), 97% and 97% for shoulder abduction ($P = .92$), 97% versus 90% for external rotation of the shoulder ($P = .11$), and 98% versus 96% ($P = .55$) for internal rotation of the shoulder.

Endurance testing

Endurance was considered as a function of total work done with the affected limb relative to the unaffected limb before fatigue. A significant difference was observed between the acute and delayed fixation group in forward shoulder flexion. Mean flexion endurance was 109% in the acute group versus 80% in the delayed group ($P = .05$). Although the average abduction endurance recovery of the acute group was 107% versus 81% in the delayed group, this was not significant ($P = .24$; Table III).

DISCUSSION

It is generally assumed that outcome after delayed reconstruction of failure of nonoperative treatment of displaced clavicular fractures is equiv-

alent to that obtained after immediate fixation.[6,11,16] This argument is frequently used to support initial nonoperative care of these injuries, with the assumption that equally effective salvage procedure is available. To date, however, no direct comparative evidence supports or refutes this supposition. Our study indicates that although delayed reconstruction is a highly effective procedure, subtle deficits persist relative to immediate fixation. Strength is well restored, but flexion endurance, which could be postulated to be a more sensitive measure of weakness, is decreased in the delayed group. Although the difference was small (6 points on a 100-point scale), surgeon-based outcome scores are decreased to some degree as well. Differences in patient-based scores were not statistically different.

A number of factors may contribute to the inability of the delayed group to attain preinjury levels of muscular endurance of the affected shoulder. Early operative intervention has the advantage of easier restoration of clavicular anatomy and requires less soft tissue and bony dissection. Chan et al[3] reported trapezius muscle atrophy in cases of clavicle malunion, although corrective osteotomy appeared to resolve this condition. In a similar study comparing late and early reconstruction of distal radius fractures, Jupiter and Ring[10] attributed poorer outcomes observed in delayed reconstruction cases to an increased difficulty in restoring bony anatomy and to soft tissue maladaptation. They stated, "Capsular, ligamentous, and tendinous structures contract to adjust to their altered orientation. It can be expected that, after skeletal alignment is restored, the contracted capsular and ligamentous structures will limit motion, and the maladapted tendons will have lost mechanical advantage, resulting in decreased grip strength." These factors could explain some of the differences seen between the groups in our study.[10]

Other potential drawbacks of delayed reconstruction that are of clinical relevance in counseling patients on the choice of initial treatment include the requirement for autogenous bone grafting for nonunion repair, the marginally higher complication rate with nonunion or malunion repair compared with acute fixation, and the often lengthy period of disability from injury to repair (63 months in this study).[6,11,17] These factors should also be considered when weighing the risks and benefits of immediate repair versus delayed reconstruction.

Our study has several weaknesses. It could be argued that the reason for the diminished endurance and lower scores in the delayed group compared with the acute group is that the groups, despite the lack of any statistical differences in demographics and fracture pattern, are not similar. It is clear that certain as yet unrecognized features of displaced fractures of the clavicle may predispose to nonunion or symptomatic malunion and that presumably the delayed group had some of these features, resulting in a group with an intrinsically worse outcome.[2,7,8,19] Unfortunately, this is not a question that is amenable to a randomized trial (to produce 2 equal groups to study).

We believe, however, that even if the acute and delayed groups are intrinsically different, it does not affect our conclusions or the way we propose to use this information. It is still valid to tell a patient that if a nonunion or symptomatic malunion develops after the failure of nonoperative care, the outcome after reconstruction, while good, is on average slightly inferior to what could have been obtained with primary fixation. Although not everyone who is treated nonoperatively will fall into this group, if they do, then our findings of our study are valid and applicable to them.

Another weakness is the potential for a type II error, a failure to detect a true clinical difference due to a small sample size.[12] Several of the variables in our study (DASH scores, abduction endurance, age) had trends toward differences that might have reached statistical significance if more patients had been included. For example, there was a trend ($P = .08$) toward an age difference between the 2 groups (delayed mean age, 42 years; acute mean age, 33 years). Although we are not aware of any difference in standard DASH or Constant scores in this age range,[5,9,20] the increased age of the delayed group might explain the decreased ability to restore strength after late reconstruction. There were more dominant limbs (7/15) in the delayed group then in the acute group (5/15); if anything, this would have a detrimental effect on the acute group.

Despite these potential drawbacks, we believe our study is the first to objectively compare the outcome of acute repair versus delayed reconstruction for displaced midshaft fractures of the clavicle in similar groups of patients. Although delayed reconstruction is a highly successful procedure, we believe that patients have marginally inferior outcomes in terms of surgeon-based outcome scores and shoulder muscle endurance compared with patients who have a primary operative repair of their fracture. We stress that these data should not be used in isolation to recommend primary operative fixation of these injuries. Whereas previously no objective information on this topic was available, now surgeons can use these data when counseling patients on the relative advantages and disadvantages of immediate operative plate repair versus potential delayed reconstruction for displaced midshaft fractures of the clavicle.[21]

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