Function Plateaus by One Year in Patients With Surgically Treated Displaced Midshaft Clavicle Fractures

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Abstract

Background Based on short-term (1 year or less) followup, primary fixation of displaced midshaft clavicle fractures reportedly results in better function compared with that reported for nonoperative methods. Whether better function persists beyond 1 year is unclear.

Questions/purposes For displaced midshaft clavicle fractures, do the better mean Disabilities of the Arm, Shoulder and Hand (DASH) and Constant-Murley Shoulder (CSS) scores for operative versus nonoperative treatment at 1 year change between 1- and 2-year followup?

Patients and Methods We previously reported 132 patients in a randomized prospective trial at 1 year, and here we report a further followup of 95 of the 132 patients (72%) at 2 years after injury. We evaluated all patients with the DASH and CSS scores.

Results The mean DASH and CSS scores were similar at 2 years compared with 1 year postinjury for both the

nonoperated and operated patients. The mean scores for the operated patients remained higher than those in the nonoperative group (DASH operative 4.1 ± 7.0 versus DASH nonoperative 11.4 ± 19.7 , CSS operative 97.1 ± 4.5 versus CSS nonoperative 91.6 ± 14.1) at 2 years postinjury.

Conclusions The improvement in DASH and CSS scores seen with primary fixation of displaced clavicle fractures persists at 2 years but does not differ from values seen after 1 year of followup, suggesting a clinical steady state has been reached whereby outcome is unlikely to change with time.

Level of Evidence Level I, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Clavicle fractures represent 2.6% of all fractures and 44% of those involving the shoulder girdle [18]. Midshaft fractures are the most common and account for 81% of these injuries with 48% being displaced [20]. Clavicle fractures are traditionally treated nonoperatively with immobilization in a sling or a figure-of-eight bandage [21]. This has been the standard of care as a result of the greater than 99% union rates reported in several influential studies with large numbers of patients [14, 21]. However, the inclusion of pediatric fractures and lack of modern functional assessments in these studies may have resulted in unrealistically good results [20]. Conversely, some investigators present a 15% nonunion rate and a 30% dissatisfied rate in active patients with displaced midshaft clavicle fractures after closed treatment [7] with other studies showing similar trends [2, 12, 13, 15].

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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The Canadian Orthopaedic Trauma Society (COTS) subsequently conducted a multicenter randomized trial comparing operative versus nonoperative care of these injuries [1]. At 1-year followup, higher mean Disability of the Arm, Shoulder and Hand (DASH) and Constant-Murley Shoulder (CSS) scores were achieved in the operated patients [1]. However, that study and others [9] described short followup times of only 6 to 12 months. These time periods are often considered insufficient in the trauma literature for patients to have reached the point of maximal medical recovery after fracture. Two-year followup is generally required to determine whether function is maintained and to detect late complications such as infection, requirement for hardware removal, refracture, deterioration or improvement of outcome, or other unforeseen complications. Marsh and coworkers, for instance, noted deterioration in Ankle Osteoarthritis pain and disability scales for tibial plafond fractures between 6 months and 1 year followed by trends toward improvement between 1- and 2-year followup times [11]. Given the potential changes in pain and function 1 year after injury, a 2-year clinical update of our original 1-year COTS data is of clinical interest.

We therefore asked whether the mean DASH and CSS scores from the original cohort of the aforementioned COTS investigation would be the same at 1 and 2 years postinjury.

Patients and Methods

Our original COTS research trial was a multicenter, prospective, randomized clinical trial [1]. Between April 2001 and December 2004, 132 patients were randomized to operative (ie, plate fixation, $n = 67$ patients) or nonoperative (ie, sling, $n = 65$ patients) care for completely displaced midshaft clavicle fractures. Outcome measures were the DASH and CSS scores determined at 0, 6, 12, 24, and 52 weeks. Among the original operated patients, there were 60 males and six females with a combined average age of 33.5 ± 12.1 years. Among the original nonoperative patients, there were 49 males and 17 females with a combined average age of 33.5 ± 12.7 years. Ninety-five of these original 132 patients (52, operative; 43, nonoperative) completed the 2-year (ie, 104 weeks) assessment for this current study. This was a young, predominantly male trauma population with a high migration rate and, thus, we were unable to locate the other 37 patients. Among the operated patients who completed the 2-year followup, there were 46 males, five females, and one patient with missing gender information, having a combined average age of 34.9 ± 12.6 years. Among the nonoperative patients who completed the 2-year followup, there were 31 males and 12 females with a combined average age of 33.9 ± 12.8 years.

The operated patients had surgery within 28 days after injury. The fracture was reduced and fixed with a small-fragment plate on the superior surface of the bone using a minimum of three screws in proximal and distal aspects of the clavicle. Comminuted fragments were secured with lag screws if possible while preserving soft tissue attachments, and a longer plate was used to maintain a minimum of three screws in principal proximal and distal fragments. If fragments were too small to accept fixation, they were secured and positioned under the plate with suture.

All seven nonoperated patients with symptomatic non-unions later underwent open reduction and internal fixation, and all nine patients with symptomatic malunions later requested osteotomy and correction of deformity. No shaving or ostectomy of the clavicle was performed for any patient.

Patients were seen at 6 weeks, 12 weeks, 24 weeks, 52 weeks, and 104 weeks. At each visit, a focused history was taken and a physical examination was performed. Standardized AP and 20° upshot view radiographs were taken. A CSS score was then calculated, and the patient filled out DASH and SF-36 questionnaires. Five investigators (EHS, MDM, and other coworkers) from the original COTS and one of us (MDM) in the current study judged radiographic union in their own patients. We defined radiographic union as complete cortical bridging of all four projected cortices between proximal and distal fragments based on AP and 20° cephalad (nonorthogonal) radiographs. Each radiograph was evaluated by only one observer (MDM); we did not determine interobserver or intraobserver variability.

A repeated-measures analysis of variance was conducted because DASH and CSS were measured repeatedly on the same patients at different times. The main effects of treatment were analyzed with a two-way analysis of variance with treatment (operative or nonoperative) and time (6, 12, 24, 52, and 104 weeks) as independent factors. Tests were two-sided. Perfect scores for DASH and CSS, respectively, are 0 and 100.

Results

There was no difference in mean DASH scores at 1 versus 2 years for the operated ($p = 0.63$) and nonoperated ($p = 0.59$) patients (Fig. 1). The mean DASH score was better ($p = 0.014$) in the operated patients at 104 weeks compared with that for the nonoperated patients: 4.1 versus 11.4, respectively. The operative group had better mean DASH scores at three of five followup time points, including at the 2-year followup.

There was no difference in mean CSS scores at 1 versus 2 years for the operated ($p = 0.34$) and nonoperated

Fig. 1 Graphic analysis comparing mean DASH scores in the operative and nonoperative groups. Values were statistically improved in the operative group at three of five followup times, namely, 6 weeks ($p = 0.000$), 52 weeks ($p = 0.005$), and 104 weeks ($p = 0.014$). Error bars indicate one standard error of the mean. DASH = Disabilities of the Arm, Shoulder and Hand.

Fig. 2 Graphic analysis comparing mean CSS scores in the operative and nonoperative groups. Values are statistically improved for the operative group at each followup time, namely, 6 weeks ($p = 0.002$), 12 weeks ($p = 0.003$), 24 weeks ($p = 0.005$), 52 weeks ($p = 0.008$), and 104 weeks ($p = 0.012$). Error bars indicate one standard error of the mean. CSS = Constant-Murley Shoulder score.

($p = 0.73$) patients (Fig. 2). The CSS score was 97.1 in the operated patients at 104 weeks compared with 91.6 in the nonoperated patients ($p = 0.012$). The operated patients had higher CSS scores at all time points in the study.

Discussion

The motivation for this study was to determine if the better mean DASH and CSS scores for operative versus nonoperative treatment at 1 year change between 1- and 2-year

followup for displaced midshaft clavicle fractures. We extended the followup time to 2 years for the patient cohort from our original COTS investigation [1] of operative versus nonoperative treatment of displaced midshaft clavicle fractures. DASH and CSS scores remained essentially unchanged at 2 years versus 1 year postinjury for both groups. Scores in the operative group remained statistically superior at all followup times for the CSS and at three of five followup times for the DASH.

There are several limitations to our study. First, a substantial number of patients was lost to followup. This was a young, predominantly male trauma population with a high degree of migration and, consequently, we were unable to locate the remaining 37 patients. However, this is a common feature of orthopaedic studies [5, 25], and we believe our conclusions are still valid given the congruence of current 2-year cohort demographic data with the 1-year cohort from our prior COTS study [1]. Second, 2 years of followup is still considered short-term for most orthopaedic studies. However, given the nature of the injury and clinical result (healed diaphyseal fracture with no articular involvement), we suspect patient deterioration or improvement is unlikely. Third, DASH and CSS scores do not consider individual patient differences resulting from age, general health, or personal problems. Even so, DASH and CSS have been used widely as standard measures of function [3, 4, 6, 8, 10, 12, 16, 19, 23, 24]. Fourth, there was substantial preoperative delay in some cases, so some fractures may have partially healed by 28 days. Although we do not believe this influenced outcome or risk to surgery, no data were analyzed in this regard. Finally, radiographic determination of union was made by multiple investigators. Interobserver and intraobserver variation was not quantified, although orthopaedic traumatologists may be more consistent in assessing the degree of long bone fracture healing from radiographs than community orthopaedic surgeons or orthopaedic residents [26].

Our results can be compared with other recent studies (Table 1) [3, 4, 6, 8, 10, 12, 16, 19, 23, 24]. Our investigation is the only one that compared nonoperative versus plating treatment using both DASH and CSS scores. For plating groups, our DASH score was superior to other studies with one exception, whereas our CSS was only slightly better than others. This may be the result of some patient deterioration during the longer followup times from most of the other studies. For nonoperative groups, our DASH and CSS results were within the range given by others.

We believe our data have clinical benefits. Patients can be initially counseled that improvements seen with primary fixation appear to last for 2 years, although we cannot state whether these findings will persist. Moreover, if patients treated nonoperatively are unsatisfied at 12 months

Table 1. Comparison of present results with prior studies that assessed operative (ie, plate) or nonoperative (ie, sling or bandage) treatment for displaced midshaft clavicle fractures

Study	Operative treatment with plating				Nonoperative treatment with sling or bandage			
	DASH	CSS	Average followup (weeks)	Number of fractures	DASH	CSS	Average followup (weeks)	Number of fractures
Present	4.1	97.1	104	52/48*	11.4	91.6	104	43/41*
Chen et al. [3]	10.3	–	182	110	–	–	–	–
Cho et al. [4]	33.9	–	57	19	–	–	–	–
Cho et al. [4]	34.8	–	52	22	–	–	–	–
Faldini et al. [6]	–	–	–	–	24	–	156	100
Jubel et al. [8]	–	–	–	–	7.6	91.3	26	27
Khan et al. [10]	24	–	145.6	11	–	–	–	–
McKee et al. [12]	–	–	–	–	24.6	71	238	30
O'Connor et al. [16]	55	–	182	24	–	–	–	–
Potter et al. [19]	3	95	108	15	–	–	–	–
Potter et al. [19]	7.2	89	143	15	–	–	–	–
Smekal et al. [23]	–	–	–	–	3.6	93.7	25/104*	30
Stufkens and Kloen [24]	23.6	–	130	21	–	–	–	–

* Number or followup used to compute average DASH and CSS scores were different; DASH = average Disabilities of the Arm, Shoulder and Hand score; CSS = average Constant-Murley Shoulder score.

postinjury, they can be counseled that they are unlikely to improve and may have reached maximal recovery. Additionally, as a result of the often young and mobile patient population having these injuries, long-term followup is more difficult. Thus, it is useful to know that the clinical results in this specific clinical situation may have reached a steady state at 1 year of followup. This would prevent the need for longer (and necessarily more expensive) assessment.

The economics of new products or techniques is increasingly scrutinized in the healthcare system [22]. Pearson et al. [17] examined the cost-effectiveness of primary fixation of displaced midshaft clavicle fractures using the quality-adjusted life-years (QALY) method. Interventions that cost less than \$50,000 per QALY were believed cost-effective and reasonable. They concluded that the cost-effectiveness of fixation depended on the durability of the functional improvement compared with nonoperative treatment. When functional benefits persisted for more than 9 years, fixation had a favorable value (cost per QALY less than \$50,000) compared with many accepted interventions. Our data suggest this difference is relatively static after 1 year and is unlikely to change. It is unlikely that another prospective, randomized clavicle fracture study will soon have a 2-year length of followup for both operative and nonoperative groups; thus, our data can be used as the best available evidence for economic calculations. With the data from our study, it also appears that on a QALY level, primary fixation for displaced clavicle fractures is likely to be cost-effective.

Midshaft clavicle fractures are common, and controversy exists regarding their management. Despite the current extension of the results by only 1 year beyond our original published study, this clinical update shows clearly that the improvement in outcome seen with primary fixation persists at 2 years and does not differ compared with 1-year data. This implies that a clinical steady state has been reached whereby function is unlikely to change later.

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