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Operative Versus Nonoperative Treatment of Acute Displaced Distal Clavicle Fractures: A Multicenter Randomized Controlled Trial

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Objectives: To evaluate the differences in patient outcomes after operative or nonoperative treatment of displaced, type II distal clavicle fractures.

Design: Multicenter, prospective, randomized controlled trial.

Setting: Level I trauma centers.

Patients/Participants: Patients with completely displaced type II distal clavicle fractures were included. Fifty-seven patients were randomized: 27 to the operative group and 30 to the nonoperative group.

Intervention: Patients randomized to nonoperative care received a standard shoulder sling, followed by pendulum or gentle range of motion shoulder exercises at any time as directed by the attending surgeon. Patients randomized to the operative group received plate fixation with a precontoured distal clavicular plate or a "hook" plate within 28 days from injury.

Main Outcome Measure: Disabilities of the Arm, Shoulder and Hand scores at 1 year.

Results: There were no between-group differences in Disabilities of the Arm, Shoulder and Hand or Constant scores at 1 year. More patients in the operative group went on to union (95% vs. 64%, $P = 0.02$) within 1 year. Twelve patients in the operative group underwent a second operation for implant removal (12/27, 44%). In the nonoperative group, 6 patients (6/30, 20%) subsequently underwent 8 operative procedures.

Conclusion: Although this study failed to demonstrate a difference in functional outcomes between operative and nonoperative treatment of Neer type II distal clavicle fractures, nonoperative management led to more complications including a moderate rate of nonunion, which often required secondary surgery to correct, a higher rate of early dissatisfaction with shoulder appearance, and a delayed return to activities in the first 6 months. Operative management provided a safe and reliable treatment option with few complications, but often required secondary implant removal, especially with hook plate fixation.

Key Words: type II distal clavicle fractures, operative treatment, nonoperative treatment, functional outcome

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

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INTRODUCTION

Distal clavicle fractures, or fractures of the lateral third of the clavicle, represent 10%–30% of all clavicle fractures.[1–3] Neer type II fractures (Figs. 1A–C) include those which occur medial to the coracoclavicular complex (medial to the coracoclavicular ligament or through the conoid portion of the coracoclavicular ligament), are typically displaced fractures, and are considered unstable.[4] The treatment of type II distal clavicle fractures, however, remains controversial, as both nonoperative and operative treatment have shown satisfactory outcomes.[2,5]

Good functional outcomes have been reported in patients who have been treated nonoperatively for type II distal clavicle fractures.[2] However, rates of nonunion after nonoperative treatment have been reported to be as high as 33%.[2,6,7] Many of these nonunions are clinically asymptomatic and do not have a significant effect on functional outcome.[2,8] In a study of 101 patients treated nonoperatively for a displaced distal clavicle fracture, Robinson et al[8] reported that although 21% developed nonunion, only 14% of patients required a delayed surgical procedure as a result of persistent symptoms due to a nonunion or acromioclavicular (AC) arthritis.

Alternatively, several studies support operative treatment of type II distal clavicle fractures, reporting high rates of

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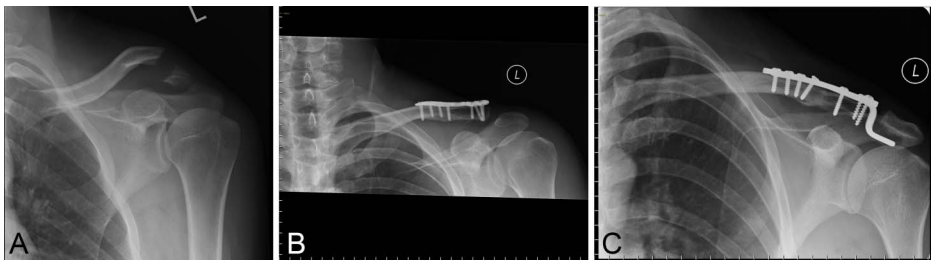

FIGURE 1. A, Neer type II distal clavicle fracture. B, Healed type II distal clavicle fracture at 12 months treated with a precontoured distal clavicular plate. C, Healed type II distal clavicle fractures at 12 months, treated with hook plate fixation. **Editor's Note**: A color image accompanies the online version of this article.

union and good functional results.[9–16] Numerous treatments with varying degree of success have been described, including fixation with plate and screws, hook plate fixation, transacromial screws, Kirshner wires, tension band sutures, Knowles pins, and distal radius locking T-plates. Operative treatment, however, is associated with a high rate of secondary surgeries, primarily due to the need for implant removal.[2,10,17]

To our knowledge, there are no randomized controlled studies comparing operative versus nonoperative treatment of displaced, type II distal clavicle fractures. Most studies available in the literature comprised retrospective studies, with small numbers of patients and no control group. As such, there is no Level I evidence comparing operative and nonoperative treatment of these injuries. However, there is evidence that surgical fixation is beneficial with some clavicular injuries. A 2007 randomized controlled trial[18] has shown that surgical fixation may be indicated for midshaft fractures of the clavicle in young, active individuals. The purpose of this study was to conduct a randomized controlled trial to evaluate the differences in patient outcomes after operative versus nonoperative treatment of displaced, type II distal clavicle fractures.

METHODS

This was a multicenter randomized controlled trial conducted by the Canadian Orthopaedic Trauma Society at 7 centers, including St. Michaels Hospital in Toronto, ON; Foothills Medical Centre in Calgary, AB; Royal Columbian Hospital and Vancouver General Hospital in British Columbia; The Ottawa Hospital in Ottawa, ON; McGill Hospital in Montreal, QC; and Queen Elizabeth II Hospital in Halifax, NS. This study was approved by the research ethics committee of each institution.

Potential patient candidates were identified on presentation to the emergency department or fracture clinic. Inclusion criteria were patients 16–60 years of age, who had sustained a completely displaced, closed, Neer type II distal third clavicle fracture. Patients were required to be medically optimized to undergo general anesthesia and able to provide informed consent. Patients were excluded from the study if they presented more than 28 days after injury, had sustained a pathologic fracture, presented with a neurologic or vascular injury, or were unable to comply with follow-up and/or form completion. Included patients were randomized to operative or nonoperative treatment through the use of an internet-based randomization system.

Treatment

Nonoperative Care

Patients randomized to nonoperative care received a standard shoulder sling for comfort, followed by pendulum or gentle range of motion shoulder exercises at any time as directed by the attending surgeon, approximately 2 weeks after injury. Strengthening exercises were implemented at the discretion of the attending surgeon, approximately 6 weeks after injury.

Operative Care

Patients randomized to plate fixation had surgery within 28 days after injury. Prophylactic antibiotics were administered. A general or regional anesthetic was administered. The patient was placed in either the beach chair or the semi-sitting position and the involved shoulder was prepared and draped. An oblique incision was made centered over the fracture, extending to the AC joint. A skin/subcutaneous layer was developed, the delto-trapezial muscle/fascia split longitudinally over the distal clavicle, and the fracture site identified. After this, the fracture site was cleared of debris and hematoma, and the fracture reduced anatomically. The provisional reduction was held with a K-wire or reduction clamp and definitive fixation was applied. A precontoured titanium, distal clavicular plate was used for fixation with a minimum of 3 screws in the distal fragment. If this was not possible (due to a very small distal fragment), or distal fixation was considered inadequate, then fixation across the AC joint with the use of a stainless steel "hook" plate was allowed at the surgeon's discretion. The posterior aspect of the AC joint was opened, and deep dissection was made to allow insertion of the hook into the posterior subacromial space. The purchase of the hook was used to maintain reduction of the fracture and prevent superior migration of the proximal (shaft) fragment. Care was taken to avoid overreduction of the fracture with the hook plate. With either construct, no supplemental fixation to the coracoid was performed (either with screw, suture, or flexible button). After fixation, a 2-layer closure was performed including delto-trapezial fascia and skin/subcutaneous layers. A standard dressing and sling were applied.

Postoperatively, the patient was immobilized in a sling until follow-up at approximately 2 weeks. At that time, range of motion exercises were reviewed and initiated by a physiotherapist. Strengthening exercises were implemented at approximately 6 weeks after surgery.

Assessment

After enrolment in the study, patients were seen for clinical and radiologic assessment at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year. The primary outcome was the Disabilities of the Arm, Shoulder and Hand (DASH) score at 1 year.[19,20] The DASH is an upper limb-specific, patient-reported outcome measure, where higher scores are indicative of greater disability. Secondary outcomes included the Constant–Murley score[21] measured at 1 year, visual analogue scale (VAS) pain scores, patient satisfaction, return to work and activities, and radiographic evaluation of healing of the fracture. Radiographic union was defined as complete cortical bridging between the medial and lateral fragments on radiographs. Nonunion was defined as lack of radiographic healing with clinical evidence of pain and motion at the fracture site at 1 year. Radiographic malunion was defined as loss of the anatomic contour of the clavicle and was universal in the nonoperative group. Symptomatic malunion was defined as union of the fracture in a shortened, angulated, or displaced position with any symptoms of weakness, easy fatigability, and/or pain with activity, neurologic symptoms, and shoulder asymmetry. At each visit, any adverse events (AE) or complications were recorded. An AE or complication was defined as any event that necessitated another operative procedure or medical treatment.

Statistical Analysis

Baseline demographics were calculated as mean and SD for continuous variables or counts and percentages for categorical variables. Continuous variables were tested for normality using the Shapiro–Wilks test. Continuous variables were analyzed using an independent t test or the Mann–Whitney U test for nonparametric data. Categorical variables were analyzed using the χ^2 test or Fisher exact test. For the primary outcome, DASH scores were analyzed between the 2 groups at 1 year using an analysis of covariance, taking into account baseline scores (which were considered the patients' preinjury scores). All tests were 2-sided. The results were considered significant at $P < 0.05$. Statistical analysis was performed using R version 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria. URL: https://www.R-project.org/).

Sample Size Calculation

An a priori sample size calculation was performed based on the primary outcome of DASH shoulder function scores using data from a previously published study.[18] Using an alpha of 0.05 and 80% power, a total sample size of 74 patients (37 in each group) was required.

RESULTS

Fifty-nine patients were recruited into the trial between July 2009 and December 2015 (Fig. 2). The study was concluded before achieving our sample size due to declining recruitment and investigator fatigue. A total of 110 patients declined to participate in the study; 43 patients wanted nonoperative treatment, 42 patients wanted operative treatment, and in 25 patients, the treatment type was not listed. Twenty-nine patients were randomized to the operative group and 30 to the nonoperative group. Two patients in the operative group withdrew from the study at baseline and were not included in the analysis. One patient in the operative group declined surgery, and 2 patients in the nonoperative group insisted on surgery (one immediately after randomization and one 6 weeks after randomization due to a painful shoulder). Each was followed by the intention-to-treat principle. The baseline demographics are reported in Table 1. The 2 groups were similar to one another, except for mechanism of injury. In the operative group, 14 patients were treated with a hook plate, 11 patients were treated with a precontoured distal clavicle plate, and 1 patient was treated with 2 plates (which was a protocol deviation). In the nonoperative group, for the 2 patients who crossed over to surgical intervention, 1 was treated with a pre-contoured distal clavicle plate and 1 was treated with a hook plate.

There was a low loss to follow-up, with 87% of patients (50/57) having completed the primary outcome (DASH score) at 1 year (25 patients in the nonoperative group and 25 patients in the operative group).

DASH Scores

After adjustment for baseline DASH scores, there was no difference in the DASH scores between the operative (mean = 6.7) and nonoperative (mean = 10.8) groups at 1 year ($P = 0.3077$) (Fig. 3). There was also no difference between the 2 groups at 6 weeks, 3 months, and 6 months.

Constant Scores

There was no significant difference in the Constant–Murley scores between the operative (mean = 89.9) and nonoperative (mean = 90) groups at 1 year ($P = 0.88$) (Fig. 4). There was no evidence of a difference at any of the other follow-up time points.

Pain

There were no significant differences in the VAS scores for pain between the operative (mean VAS = 13.1) and nonoperative (mean VAS = 12.9) groups at 1 year ($P = 0.53$), and no difference at 6 weeks, 3 months, and 6 months.

Patient Satisfaction

At each assessment, patients were asked "Are you satisfied with the appearance of your shoulder?." At the 6-week and 3-month assessments, there was a higher proportion of patients in the nonoperative group that were dissatisfied with the appearance of their shoulder compared with patients in the operative group [33% in the nonoperative group vs. 4% in the operative group at 6 weeks ($P = 0.006$), and 24% versus 0% at 3 months ($P = 0.01$)]. There were no differences between the groups at 6 months and 1 year [7% in the nonoperative group vs. 9% in the operative group at 6 months ($P = 1$), and 28% vs. 20% at 1 year ($P = 0.73$)].

Return to Work and Sports Activities

At the time of the injury 79% of the patients (45/57) were employed. There were no significant between-group differences in return to pre-injury level of employment. More

TABLE 1. Baseline Characteristics

	All Patients (N = 57)		Nonoperative (n = 30)		Operative (n = 27)		
	n/Mean	%/SD	n/Mean	%/SD	n/Mean	%/SD	*P*
Age, y	41.8	SD = 11	42	SD = 12	42	SD = 10	0.86
Body mass index	23.8	SD = 3.5	23.9	SD = 2.6	23.6	SD = 4.3	0.76
Sex							0.46
Women	8	14	3	10	5	19	
Men	49	86	27	90	22	81	
Mechanism of injury							0.03
Cycling	22	39	11	37	11	41	
Fall	11	19	5	17	6	22	
Motor vehicle collision	7	12	3	10	4	15	
Sports	13	23	11	37	2	7	
Other	4	7	0	0	4	15	
Dominant extremity affected	21	37	10	33	11	41	0.56
Side of injury							
Left	33	56	15	50	18	67	0.20
Right	24	44	15	50	9	33	
Smoking							0.8
Nonsmoker	37	65	19	63	18	67	
Smoker	20	35	11	37	9	33	

patients in the surgical group reported having returned to their full sports and recreational activities by 6 months (78% vs. 44% $P = 0.015$). These differences did not persist at 1 year (90 vs. 76%, $P = 0.27$).

Fracture Healing

In the nonoperative group, fracture healing data were available for 27 patients. Ten patients developed radiographic nonunions, with a mean age of 43.4 years. Six of these patients were asymptomatic and did not require any further surgical intervention. The remaining 4 patients had a symptomatic nonunion requiring surgery (mean 6.5 months after injury), 2 of which had symptomatic implants requiring subsequent implant removal (which occurred at 22 and 23 months postinjury). Seventeen patients in the nonoperative group went on to union, who had a mean age of 43.1 years. All these patients had fracture healing with radiographic malunion. One patient had a delayed union at 6 months which resolved and was healed at the 12-month follow-up. In the operative group, there was 1 patient with a nonunion at 1 year.

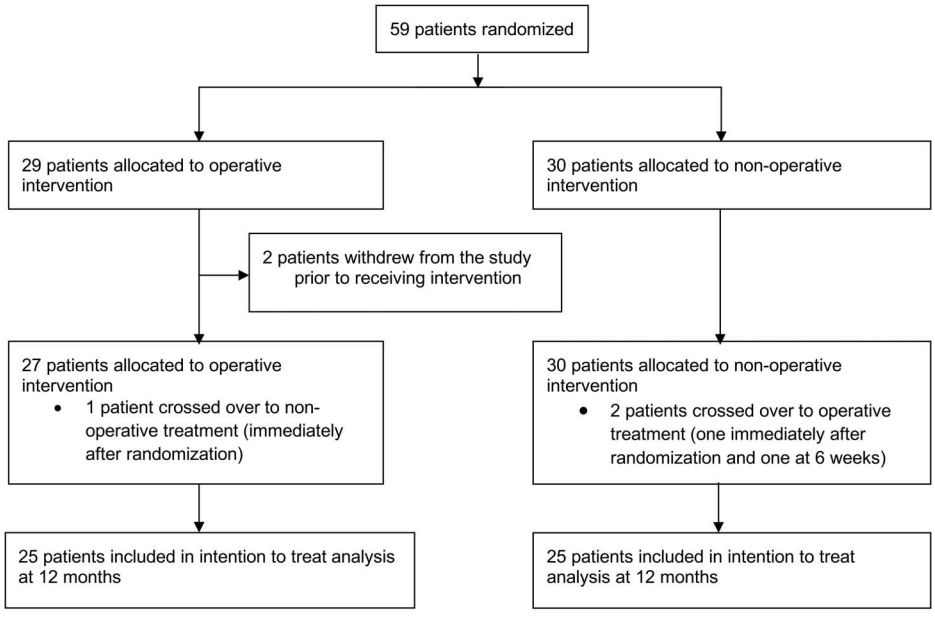

FIGURE 2. Patient enrollment and randomization.

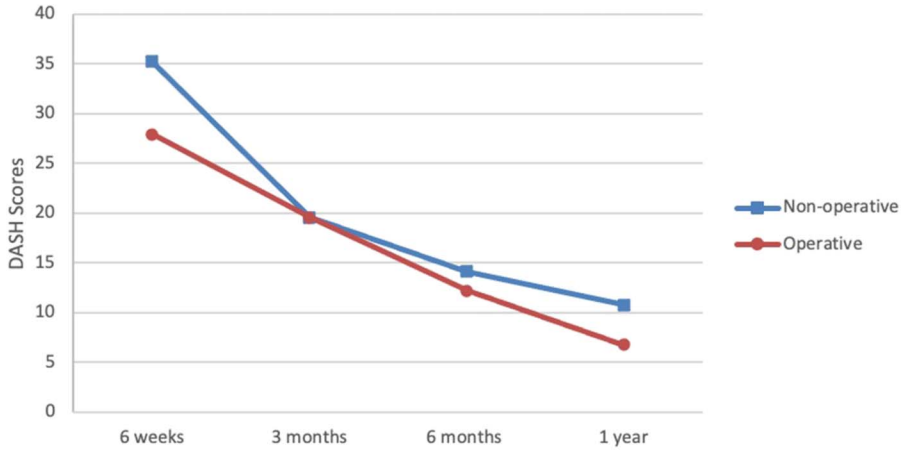

FIGURE 3. DASH scores between the operative and nonoperative groups at each follow-up visit. **Editor's Note**: A color image accompanies the online version of this article.

The rate of union was higher in the operative group compared with the nonoperative group at 3 months (56 vs. 6.7%, $P < 0.001$), 6 months (92 vs. 39.3%, $P < 0.001$), and 12 months (96 vs. 63%, $P = 0.01$).

Adverse Events

There were no immediate postoperative infections or wound complications in the operative group. There were 2 AEs in the operative group; 1 patient had a reaction to pain medication during the postoperative period which resolved, and 1 patient had a screw back out at 6 months with no further intervention required.

In the nonoperative group, there were 4 AEs; 1 patient with pain at 6 weeks crossed-over to operative intervention, 1 patient had a labral tear which was treated with a superior labrum anterior to posterior repair at 12 months, 1 patient had a frozen shoulder which was treated with physiotherapy, and 1 patient had osteolysis of the distal clavicle that was treated conservatively.

Implant Removal

In the operative group, 1 patient had a delayed union at 6 months with a symptomatic implant that resolved once the fracture was united and the implant was removed. Fourteen other patients described pain related to the implant and 11 of those underwent a second operation for implant removal. Of these 12 implant removal procedures, 2 patients had been treated with a precontoured distal clavicle plate (2/11, 18%) and 10 were treated with a hook plate (10/14, 71%). One patient in the nonoperative group who elected to undergo operative intervention immediately after randomization had symptomatic implants removed.

DISCUSSION

Distal third clavicle fractures remain a challenge for the orthopaedic surgeon. The treatment of these injuries remains controversial, as both nonoperative and operative treatment have shown satisfactory outcomes. It is well recognized that there is a high nonunion rate with nonoperative treatment but reported functional disability from nonunion or malunion has been variable.

To our knowledge, ours is the first study to prospectively compare modern operative plate fixation techniques versus nonoperative care for these injuries in a randomized fashion. Our study evaluated 57 Neer type II distal clavicle fractures randomized to either nonoperative treatment with sling and early motion or operative treatment using modern precontoured distal clavicle plating techniques with an optional hook plate "bail out" if distal fixation proved inadequate There was a low loss to follow-up at 1 year, with 87% (50/57) of patients completing the DASH score. The results of this study failed to show a difference in DASH scores and Constant scores between the 2 groups at 1 year.

Radiographically, operative management of these fractures resulted in a significantly lower time to union and a lower nonunion rate. There were 8 unplanned operations in 6 patients in the nonoperative group and 12 secondary procedures in the operative group. However, the "magnitude" of the subsequent operative interventions was greater in the nonoperative group (ie, nonunion repair/reconstruction) than in the operative group (plate removal). Patients in the nonoperative group had a higher rate of dissatisfaction with the appearance of their shoulder at 6 weeks and 3 months; however, this did not persist at 6 months and 1 year. In addition, patients in this study who underwent operative intervention were more likely to return to their activities by 6 months than those treated nonoperatively, although this difference was not seen at 1 year.

There are some limitations to the current study. First, due to slow recruitment, we were unable to reach our a priori calculated sample size. As a result, we were underpowered to properly address our primary outcome (DASH). As well, we did not have information on the number of patients who were screened and excluded from the study. Second, there was heterogeneity in the surgical group as some patients had fixation with precontoured distal clavicular plates and others had hook plate fixation. At the moment, however, there is currently no consensus on the gold standard for the operative intervention for type II distal clavicle fractures.[15,22,23] Although hook plate fixation has shown similar functional

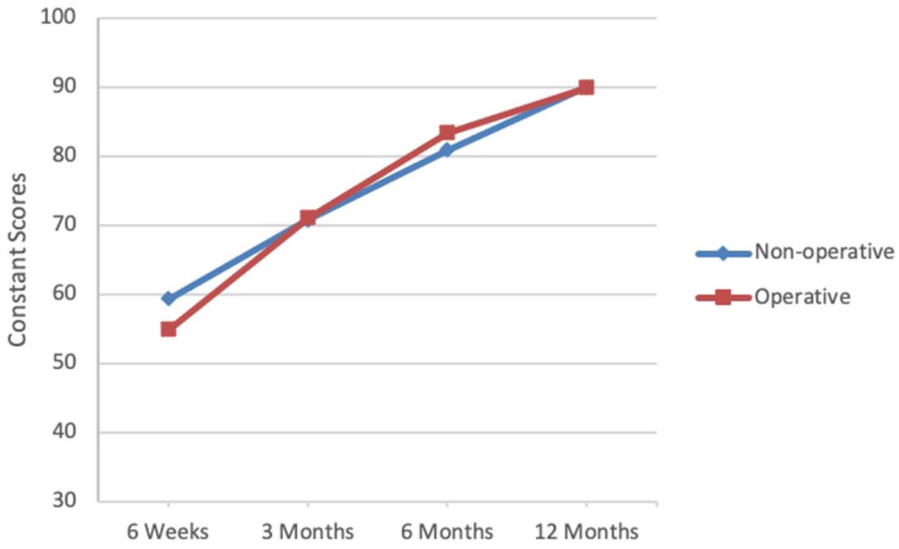

FIGURE 4. Constant scores between the operative and nonoperative groups at each follow-up visit. **Editor's Note**: A color image accompanies the online version of this article.

outcomes to distal clavicle plate fixation, there is a higher reoperation rate due to the frequent need for removal of the hook plate.[15,22,23] Both these factors should prompt some caution when interpreting the results, although this does represent the best prospective data available at the present time.

CONCLUSIONS

This study failed to demonstrate a difference in functional outcomes between operative versus nonoperative treatment of Neer type II distal clavicle fractures. Nonoperative management did lead to more complications including a moderate rate of nonunion, which often required secondary surgery to correct, whereas operative management provided a safe and reliable treatment option with few complications but often required secondary implant removal, especially with hook plate fixation. Nonoperative management led to a higher rate of dissatisfaction with shoulder appearance in the first 3 months and a delayed return to activities in the first 6 months. In conjunction with multiple other factors, including age, activity level, comorbidities, and preference for intervention, this modern, objective information may be used by the treating surgeon in shared decision making to personalize the optimal treatment of the patient with a displaced distal third clavicle fracture.

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