

McKee RC, Whelan DB, et al. Operative Versus Nonoperative Care of Displaced Midshaft Clavicular Fractures: A Meta-Analysis of Randomized Clinical Trials. JBJS Am 2012;94A:675-684.

Design: Meta-analysis of randomized clinical trials

PICOS:

- Patient population: patients with acute, completely displaced midshaft fractures of the clavicle
- Intervention: Operative treatment of the fracture
- Comparison: Nonoperative treatment of the fracture
- Outcomes: Primary outcomes were scales such as the Constant Shoulder Score, Disabilities of Arm, Shoulder, and Hand (DASH), an Italian shoulder rating questionnaire, and the Single Assessment Numeric Evaluation
 - o A set of “complications” were also combined into a single outcome: nonunion at 52 weeks, delayed union at 24 weeks, symptomatic malunion, infection, hardware removal, neurologic symptoms, and refracture
 - Radiographic malunion was not counted as a complication
- Study types: only randomized trials; quasi-randomized trials were excluded
 - o Studies of delayed union, of pathological fractures, and of fractures in children were excluded

Study selection:

- MEDLINE was the only online database searched, but proceedings of annual meetings of several orthopedic societies from 1990 through 2010 were manually reviewed by one of the authors, who also consulted experts for information about unpublished trials and trials in progress
- Two authors independently assessed the methodological quality of the studies, using a scale (Detsky et al 1992) which rated studies on randomization (including concealment of allocation), blinded assessment of outcome, inclusion/exclusion criteria (including how many patients did not participate in the trial), full description of each intervention, and appropriate statistical analysis

Results:

- 12 RCTs were found through the literature search, of which 4 met inclusion criteria; in addition, 2 studies were found through the search of annual society meetings, yielding a total of 6 RCTs for analysis
 - o These 6 studies had 412 patients (212 treated operatively , 200 nonoperatively) , all enrolling patients with completely displaced midshaft clavicular fractures
 - o The studies enrolled predominantly young men age 25 to 41; one was done at West Point with military cadets; one enrolled athletes only
 - o 3 studies used plate fixation as the operative treatment, and 3 used intramedullary pin fixation
 - o All 6 studies used a standard sling for nonoperative treatment
 - o 5 studies were in English; one was in German
- 3 studies of 222 patients used Constant shoulder scores; at 1 year, the mean scores for the operative group (94.3) were similar to those for the nonoperative group (90.2)
 - o 3 studies also reported DASH scores for 162 patients, but only 2 reported them numerically; the weighted average DASH at 1 year favored the operative groups (4.9) versus the nonoperative groups (10.7)
- “Complications” in the aggregate definition were less frequent for operative treatment (29%) than for nonoperative treatment (43%)
 - o However, in Figure 2, the meta-analysis which pooled data from all the included studies did not find a statistically significant difference between operative and non-operative treatments for overall complication rates
 - o This discrepancy was accounted for by one study which used an intramedullary pin, which frequently led to irritation and pin protrusion, necessitating its removal
- When other outcomes were analyzed, as in Figure 3, the occurrence of nonunion + symptomatic malunion was markedly less with operative than nonoperative treatment (risk for the operative group was 11% of that of the nonoperative group)
 - o Similarly, the risk of nonunion by itself for the operated fractures, in Figure 4, was 18% of the risk in the nonoperated group
- Data on early return to function were not uniformly reported, but superior function did appear to occur earlier for the operated than for the nonoperated groups
 - o Data on functional outcome at one year was not very different between treatment groups; the advantage in scores such as the Constant and the DASH were about 5 points better for the operated group, below the threshold of 10 to 15 points considered as the minimal clinically important difference

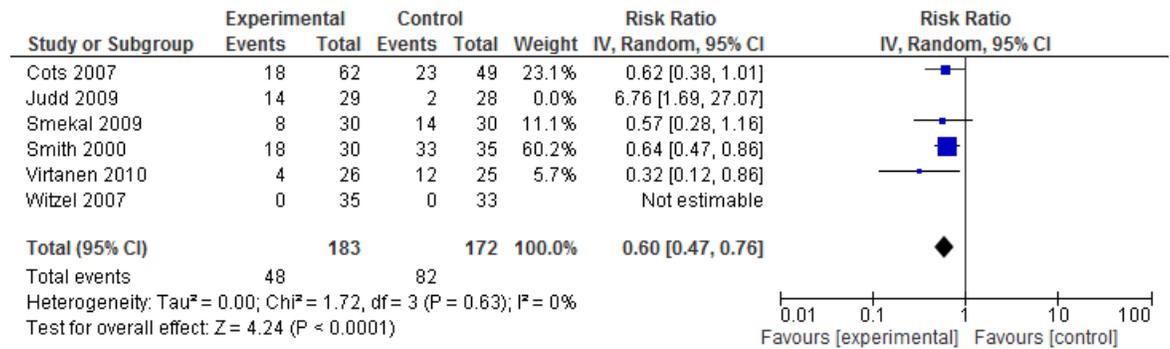
Authors’ conclusions:

- Although most nonoperated fractures did well, surgical repair of the fractures had lower rates of nonunion and symptomatic malunion during the first year after the injury
- The operative intervention for nonunion tends to be greater in magnitude than that needed for repair of the primary fracture
- There is no basis for justifying an indiscriminate surgical approach to all displaced clavicular fractures; patients may be counseled that they will have a higher risk of nonunion, but there is little evidence that their long term function will suffer if they do not receive an operation
- There was one study which had an unusually high rate of complication in the operated group, and this was likely to be due to the pin which was used in that group; this may warrant the use of less prominent implants or improved insertion techniques

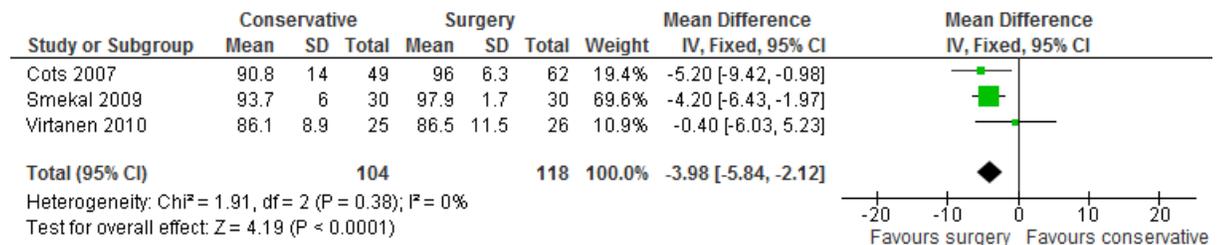
Comments:

- The authors used only a single electronic database (MEDLINE), but it is not likely that any high-quality studies of the treatment of clavicular fractures were missed due to this strategy
- The authors report numbers needed to treat (NNT) to prevent the occurrence of nonunions and symptomatic malunions with operative treatment, but these should be interpreted with caution
 - o The reason for caution is that NNT is sensitive to the frequency of events in the control group, which should be about equal between studies, and this varied considerably in the included studies
 - For example, in Figure 3, the largest study (Cots 2007, with 49% of the weight) had an event rate in the control group of 16/49 patients; the study with the second weight (Judd 2009) had an event rate of only 1/28 patients
 - It appears that Judd 2009 enrolled a number of minimally displaced fractures with minimal comminution, which may account for the low rate of nonunion in the nonoperated group; the event rates were nearly equal in the two groups, meaning that the NNT would be extremely large for the population in the Judd study
- Figure 2, the pooled data for “complication” rates, is (as the authors note), heterogeneous due to one study (Judd 2009), which affects the statistical significance of the relative risk (0.70, with 95% confidence intervals from 0.42 to 1.18)
- If Judd 2009 is removed from the analysis in Figure 2, the heterogeneity disappears, and the relative risk is statistically significant; RR is 0.60 with 95% confidence

intervals from 0.47 to 0.76:



- The intramedullary pin used in Judd 2009 may be associated with frequent need for hardware removal (Strauss 2007, Mudd 2011), and its use appears to be under discussion at this time, with the optimal approach being determined by the individual circumstances of the fracture (van der Meijden 2012)
- Functional differences in terms of Constant scores were reported by only three studies, and the differences between groups were small, only about 4 points on a 100 point scale:



- A separate meta-analysis (Xu et al 2013) reviews the same body of evidence and arrives at similar conclusions regarding lower rates of nonunion and symptomatic malunion with operative treatment of midclavicular fractures

Assessment: high quality meta-analysis supporting good evidence that operative treatment of displaced midshaft clavicular fractures lead to lower rates of nonunion and symptomatic malunion compared to treatment with a sling, but patients with preferences for nonoperative treatment may be counseled that they will probably do well, even though their fractures may not heal as well. Inadequate for evidence that patient-reported functional outcomes are significantly better for surgery than for conservative treatment at one year.

References:

Judd DB, Pallis MP et al. Acute Operative Stabilization Versus Nonoperative Management of Clavicle Fractures. Am J Orthop 2009;38:341-345.

Mudd CD, Quigley KJ, Gross LB. Excessive Complications of Open Intramedullary Nailing of Midshaft Clavicle Fractures With the Rockwood Clavicle Pin. *Clin Orthop Relat Res* 2011; 469:3364–3370.

Strauss EJ, Egol KA, et al Complications of intramedullary Hagie pin fixation for acute midshaft clavicle fractures. *J Shoulder Elbow Surg* 2007;16:280-284.

van der Meijden OA, Gaskill TR, Millet PJ. Treatment of clavicle fractures: current concepts review. *J Shoulder Elbow Surg* 2012; 21,;423-429.

Xu J, Xu L et al. Operative versus nonoperative treatment in the management of midshaft clavicular fractures: a meta-analysis of randomized controlled trials. *J Shoulder Elbow Surg* 2014; 23: 173-181.