Canadian Orthopaedic Trauma Society. Nonoperative Treatment Compared with Plate Fixation of Displaced Midshaft Clavicular Fractures. JBJS 2007;89-A:1-10.

Design: Randomized clinical trial

Population/sample size/setting:

- 111 patients (87 men, 24 women, mean age 33) with completely displaced midshaft clavicular fractures who completed a multicenter study in Canada after 132 were enrolled
    - Eligible if they were between 16 and 60 years old, had a completely displaced closed midshaft clavicle fracture amenable to plate fixation, no medical contraindications to general anesthesia
    - Excluded if they had fracture in proximal or distal third of clavicle, a pathological fracture, an open fracture, a fracture seen more than 28 days after injury, neurological deficits from a neurovascular injury, head injury with Glasgow Coma Scale score less than 12, upper extremity fracture distal to shoulder

Main outcome measures:

- Randomized to nonoperative care (n=67) with a sling or plate fixation (n=65)
- Nonoperative group received standard sling for 6 weeks, with variable compliance; most patients discarded sling when pain had subsided; physical therapy for strengthening was prescribed after healing
- Plate fixation was followed by sling for 7-10 days, then 6 weeks of range of motion exercises at home, taught by physical therapist, followed by strengthening exercises
- Disability of the Arm, Shoulder, and Hand (DASH) score and Constant score were completed at 6 weeks, 3 months, 6 months, and 12 months
- AP and 20° cephalad X-rays done at same intervals; union defined as complete cortical bridging on both films as determined by treating surgeon
- 5 patients in operative group and 15 patients in nonoperative group were lost to follow-up by the end of the study
- Operative group had significantly better Constant and DASH scores at time points up to 12 months
    - The DASH and Constant scores are not presented numerically but only graphically in Fig 3 and in terms of p values
    - The text states that the magnitude of the difference in the Constant scores was “approximately 10 points, which is considered a clinically measureable amount”
    - However, the appearance on the graph of Fig 3 appears to be closer to approximately 5 or 6 points; an effect size of close to 10 points cannot be ruled out if the high end of a 95% confidence interval is taken as the effect size
- Range of motion was equally well maintained in both groups
- Time to radiographic union was mean of 16.4 weeks in operative group and 28.4 weeks in nonoperative group

- Operative group was more likely to report satisfaction with shoulder; odds ratio in operative group's favor was 3.5 at 12 months
- Greater radiographic displacement of fracture site was correlated with worse DASH scores in the nonoperative group at 12 months

Authors' conclusions:

- Plate fixation of displaced midclavicular fractures produces functional outcomes and radiographic union superior to results of nonoperative treatment
- Greater dropout rate in nonoperative group does not jeopardize results
- Intramedullary fixation is also an option which would require a direct comparison in a randomized trial

Comments:

- Assertion that differences in attrition between two groups does not affect results would be more convincing if a sensitivity analysis had been done
- For example, it could be that all patients lost to follow-up had satisfactory outcomes and felt no need for re-evaluation; the differential attrition in the nonoperative group could be due to their having done well, and a full accounting of their status could decrease the apparent treatment effect
- Figures 2 and 3 would be more informative if the numbers of patients remaining in the study at the 6, 12, 24, and 52 week intervals had been given, so the times of patient attrition could be known
- Patient satisfaction differences are given in odds ratios, but numbers of patients satisfied with their shoulders would be valuable and is not reported
- The functional outcome differences are likely to fall short of a clinically meaningful differences, and the Constant and DASH scores are not reported appropriately with actual numbers

Assessment: Adequate for some evidence that in patients with displaced midshaft fractures of the clavicle, surgical treatment with plate fixation is likely to produce fewer nonunions than sling immobilization; inadequate for any evidence of an improvement in functional outcomes