

Δ General Health Outcomes Following Distal Clavicle Fractures: Results From a Previous Randomized Controlled Trial

Christine Schemitsch, BS; Michael D. McKee, MD, FRCSC; Niloofar Dehghan, FRCSC, MD, MSc; Emil H. Schemitsch, MD; Aaron Nauth, MD; Milena Vicente, RN; Jeremy Hall, MD, FRCS (ORTHO), MEd
St. Michael's Hospital, University of Toronto, Toronto, ON, Canada

Purpose: The decision whether to operate on or to treat distal clavicle fractures conservatively remains controversial. The purpose of this study was to examine general health outcomes in patients who were randomized to operative or nonoperative treatment for distal clavicle fractures.

Methods: The Short Form (SF)-36 scores from a previous randomized controlled trial were analyzed. Patients who had sustained a displaced, type II distal clavicle fracture were randomized to either conservative treatment or surgical intervention. Patients completed the SF-36 at baseline, 6 weeks, 3 months, 6 months, 12 months, and 24 months. Both the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores were calculated from the SF-36 questionnaire. A linear mixed model was used to predict the PCS and MCS scores over time and between groups. A regression analysis was conducted to determine if any baseline characteristics predict general health status at 2 years.

Results: 57 patients were randomized: 27 patients to the operative group and 30 to the nonoperative group. There were no significant differences in the baseline characteristics between the 2 groups. Analysis of the PCS scores demonstrated no difference between the operative and nonoperative groups at any time point ($P = 0.88$). The PCS scores decreased significantly between baseline and 6 weeks ($P < 0.001$); however, by 2 years the scores were not significantly different from patients' preinjury scores ($P = 0.09$). Analysis of the MCS scores demonstrated that there were no significant differences between the 2 groups at any time point ($P = 0.15$). The mean PCS score at 2 years was 55.9 and the mean MCS score was 54.7. Male sex ($P = 0.039$) and the injury occurring on the dominant side ($P = 0.044$) were both associated with higher PCS scores in the conservative group. In the operative group, only male sex was associated with higher MCS scores ($P = 0.003$). There were no significant predictors of the PCS scores in the operative group or MCS scores in the conservative group. The SF-36 scores from this study were compared to a previous trial performed by our group that randomized patients who had sustained an acromioclavicular (AC) joint dislocation to operative or conservative treatment. No difference in general health status was found between the groups at preinjury or 2 years after the injury ($P > 0.05$).

Conclusion: The results of this study demonstrated that there was no difference in general health outcomes between operatively and nonoperatively treated distal clavicle fractures at 1 and 2 years. By 2 years, general health outcome scores were similar to preinjury scores. Moreover, our findings suggest surgical intervention for both distal clavicle and AC joint injuries appears to have uncertain benefits.

Δ OTA Grant

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.