

**Do Patient-Reported Outcomes Improve Following Elective Implant Removal?***Laurence Kempton, MD; Walter W. Virkus, MD; Krista M. Brown, MS;**Todd Owen McKinley, MD; Greg E. Gaski, MD**Indiana University School of Medicine, Indianapolis, IN, United States*

**Purpose:** Patients with residual pain following healed fractures may benefit from implant removal. Few studies have quantified changes in patient-reported outcomes (PROs) following elective implant removal. We hypothesized that patients undergoing hardware removal (HWR) primarily to relieve pain would also have significant improvements in PROs pertaining to both pain and function.

**Methods:** This prospective observational study enrolled 188 patients who elected to undergo removal of implants primarily to reduce pain following successful fracture fixation. Patients were excluded if they had significant pain at other locations unrelated to the HWR site. PROs were obtained preoperatively and 3 months postoperatively utilizing the Patient-Reported Outcomes Measurement Information System (PROMIS) physical function (PF) and pain interference (PI) domains. Demographic data, injury characteristics, and intraoperative and postoperative complications were also recorded. Descriptive analyses were conducted. Linear regression analyses examined whether preinjury PROs predicted 3-month postoperative PROs. Minimal clinically important difference (MCID) in PROMIS scores was  $\geq 5$  points based on 0.5 times the standard deviation (SD) of preoperative scores.

**Results:** 153 patients were available for 3-month follow-up. The mean improvement in PF was 5.7 (SD 9.9) and mean reduction in PI was 6.7 (SD 11.3). 117 patients (76%) experienced improvement in PF, 4 (3%) had no change, and 32 (21%) reported a decline. Considering MCID, 87 patients (57%) reported clinically significant improvement ( $>5$ ) in PF and 15 patients (9.8%) had a significant decline ( $>5$ ) in PF. 114 patients (75%) experienced an improvement in PI, of whom 91 (59%) improved  $>5$ . 27 patients (18%) reported a worse PI, of whom 16 (10%) had a decline in PI  $>5$ . 12 patients (8%) had no change in PI. Worse preinjury PROMIS PF and PI scores were significant positive predictors for improvement in postoperative PF and PI ( $R^2 = 0.32$ ,  $P < 0.001$  and  $R^2 = 0.23$ ,  $P < 0.001$ , respectively). The only postoperative complication and apparent direct cause of worse postoperative PROs was 1 infection treated with surgical debridement.

**Conclusion:** Although the primary indication for implant removal in this population was pain relief, 57% of patients also had a clinically relevant improvement in patient-reported physical function. Three-fourths of patients reported some degree of pain relief 3 months postoperatively. In addition, patients who start with worse global indices of pain and function are more likely to improve after HWR. This suggests that implant-related pain directly contributes to global dysfunction.