Functional Patient-Reported Outcome and Pain Interference Scores Do Not Improve After Hardware Removal Following Lower Extremity Trauma

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Purpose: Removal of hardware (ROH) is one of the most common orthopaedic procedures performed with a wide range of indications. Previous work suggests that approximately half of patients who undergo hardware removal may experience an improvement in symptoms; however, there are few studies evaluating patient-reported outcomes following these surgeries. Given the commonplace nature of these surgeries, clearly defining the risk/benefit profile is of importance. The goal of this study was to evaluate patient-reported physical function and pain in a population of orthopaedic patients undergoing elective hardware removal.

Methods: This was a retrospective review of all patients who underwent ROH following operative fixation of a lower extremity fracture at a single Level I tertiary referral center. CPT codes and chart review were used to identify patients over a 7-year study period (2014-2021). Patient-Reported Outcome Measurement Information System (PROMIS) Physical Function (PF) and Pain Interference (PI) scores at all available time points were reviewed. Demographic information including age, sex, body mass index, insurance class, American Society of Anesthesiologists class, and Charlson Comorbidity Index were evaluated. Primary outcome was defined as PROMIS PF and PI before and after ROH.

Results: 621 patients were included in this study. 53.4% had ankle fractures, 26.7% tibia fractures, 9.8% femur fractures, 5.4% hindfoot fractures, and 1.1% pelvis fractures. There were 11,344 unique PROMIS PF scores and 3123 PROMIS PI scores available. Patients demonstrated an initial improvement in PROMIS PF from 6 weeks post-fracture fixation (29.5) to 6 months post-fixation (42.2). However, the improvements following ROH were less significant at the 6-week (42.4) to the 6-month (43.8) post-hardware removal visits. There was minimal improvement between the long-term fixation score and hardware removal scores (change 1.6, P = 0.05). PROMIS PI changed from 57.9 at the 1-month period before ROH to 57.5 in the follow-up period (change -0.4, P = 0.29). Additionally, there was a 14.6% reoperation rate following ROH (5% rate of subsequent ROH).

Conclusion: Patients who undergo elective ROH have minor improvements in PROMIS PF but this difference failed to reach previously published minimally clinically important differences. Furthermore, no difference in PROMIS PI was noted following ROH. Given the significant rate of reoperation and unclear functional or symptomatic benefit, the decision to remove hardware should be approached with caution.

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