Predictors of Improved Early Clinical Outcomes After Elective Implant Removal

Laurence B Kempton, Greg E Gaski, Krista Brown, Todd O McKinley, Walter W Virkus

Abstract

Objectives: The purpose of this study was to determine preoperative factors predictive of improvement in pain and function following elective implant removal. We hypothesized that patients undergoing orthopaedic implant removal to relieve pain would have significant improvements in both pain and function.

Design: Prospective Cohort Study

Setting: Level I Trauma Center

Patients/Participants: 189 patients were enrolled after consenting for orthopaedic implant removal to address residual pain. 163 were available for 3-month follow-up.

Main Outcome Measurement: Preoperative and postoperative outcome measures including Patient Reported Outcomes Measurement Information System (PROMIS) scores were compared. Preoperative scores, surgeon prediction of pain improvement, and palpable implants were analyzed as predictors of outcomes.

Results: Median PROMIS physical function and pain interference (PI) scores and VAS significantly improved by 6, 8, and 2 points, respectively ($p<0.001$ for all). Worse preinjury scores predicted improvement in respective postoperative outcomes ($p<0.001$ for all). Surgeon prediction of improvement was associated with improved PROMIS PI ($p=0.005$), patient subjective assessment of pain improvement ($p=0.03$), and subjective percent of pain remaining at 3 months ($p=0.02$). Implant superficial palpability was not predictive for any postoperative outcomes.

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Conclusions: Although the primary indication for implant removal in this population was pain relief, many patients also had a clinically relevant improvement in physical function. Additionally, 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.

Level of Evidence: Level II therapeutic

Introduction

Implant-related pain is a common outcome following otherwise routine healing of surgically treated fractures. Multiple studies have investigated improvements in pain and function as well as complications following elective implant removal. Outcomes vary greatly depending on the reason for implant removal, patient factors, and implant location, but most patients who start with pain and dysfunction experience measurable improvements in standardized scoring systems such as visual analogue scale (VAS) pain scale, short musculoskeletal functional assessment (SMFA), and SF-36.[1-10]

Data reported in prior studies were limited to the assessment tools available at those times such as subjective pain scores and patient satisfaction. These metrics are commonly used to report patient outcomes but have substantial weaknesses. More recently, the Patient Reported Outcome Measurement Information System (PROMIS) Physical Function (PF) and Pain Interference (PI) computer adaptive tests have been developed and have been commonly used to report outcomes in orthopaedic patients. The PROMIS PI domain can provide more useful information than subjective pain scores because it relates pain to the ability to accomplish daily

activities and has established societal mean and standard deviation values that improve score interpretation.[11]

Prior studies also have left unanswered questions that surgeons may have regarding how to counsel patients with respect to postoperative expectations. For example, outcomes after elective implant removal have not been reported in terms of the minimal clinically important difference (MCID). Without this information, it is more difficult to know the likelihood that a patient will experience a change that is noticeable or meaningful rather than a change in score that they may not perceive.

The purpose of this study was to examine preoperative factors that may predict patient reported outcomes after elective implant removal. Our hypotheses were that removal of implants in appropriately selected patients with residual pain will improve both subjective and objective short-term outcomes and that quantifiable improvements in function and pain would exceed minimal clinically important differences.

Materials and Methods

This was a prospective cohort study of patients who elected to undergo implant removal. Our institutional review board approved the study. Inclusion criteria were: (1) age ≥18 years, (2) pain being the primary reason for implant removal, (3) established clinical and radiographic healing of all fractures or reconstructive procedures related to the removed implants, and (4) failure of improvement in pain despite attempts at nonsurgical treatment (e.g. symptomatic treatment, anti-inflammatories, physical therapy). This means that asymptomatic patients who requested implant removal for reasons other than pain and patients with planned

staged implant removal were not included. Exclusion criteria were ongoing pain at locations unrelated to the implant site, history of implant-related infection, and current nonunion.

Patients were identified in the orthopaedic clinic and enrolled in the study during the appointment at which informed consent was obtained for implant removal. Preoperative data collected included PROMIS PF and PI scores, VAS pain scores, the presence of local physical exam findings (tenderness, prominence, crepitus), and the surgeon's opinion of whether the patient would have pain improvement postoperatively.

Data collected 3 months postoperatively included PROMIS PF and PI scores, VAS pain scores, and complications. Patients completed a questionnaire asking about subjective assessment of pain (improved, unchanged, or worse) and percent of pain remaining.

Data analysis

Patients with 3-month follow-up data were included in the analysis. Preoperative to postoperative changes in PROMIS and VAS pain scores were calculated, and differences were compared using the Wilcoxon signed-rank test after testing for normality of data distribution. The minimal clinically important difference (MCID) for PROMIS scores was considered 5 based on half the established standard deviation.[12]

Preoperative PROMIS scores, VAS pain scores, surgeon prediction of whether pain would improve, and presence of local physical exam findings were analyzed as predictors of 3-month outcomes, including change in PROMIS scores and VAS pain scale, patient subjective improvement (as a categorical variable), and subjective percent of pain remaining. Contingency tables were generated and analyzed with Fishers exact test for categorical variables. Predictive value of categorical variables for continuous outcomes was analyzed with the independent

student's t-test or Mann-Whitney U test after determining normality of data distribution. Linear regression was used to analyze the relationship between continuous preoperative variables and outcomes. Statistical significance was set at $p<0.05$.

Results

189 patients met inclusion criteria and were enrolled in the study. 26 patients were excluded from the analysis due to insufficient follow-up, leaving 163 patients available for data analysis. Mean age was 43 years (range 18-79). There were 74 males and 89 females. All implants removed were plates, screws, or intramedullary nails that were placed for fracture fixation or reconstructive osteotomies. 149 involved the lower extremities, and 14 involved the upper extremities. Table 1 describes locations of implants removed. Table 2 describes the types of implants removed. 30 patients (18%) had complete resolution of pain at the 3-month f/u. 68 patients (42%) estimated at least 90% pain resolution.

Tables 3 and 4 summarize the analysis of preoperative versus postoperative PROMIS scores and VAS pain scale. Note that increasing PROMIS PF and decreasing PROMIS PI represent patient improvement. Most patients demonstrated improvement in outcome measures, but approximately one-fifth of patients worsened for each outcome measure. Linear regression analyses shown in Figures 1-3 demonstrate that worse preoperative PROMIS PF, PROMIS PI, and VAS pain scores were significant positive predictors for improvement in each of the respective scores at 3-month follow-up (PF: $R^2 = 0.33$, $p<0.001$; PI: $R^2 = 0.25$, $p<0.001$; and VAS: $R^2 = 0.32$, $p<0.001$).

Surgeon prediction of whether pain would improve was correct 82% of the time overall, 84% of the time when predicting improvement (130 of 155 patients), and 50% of the time when

predicting no improvement (4 of 8). Preoperative prediction of improvement was significantly associated with improvements in PROMIS PI (p=0.005), patient subjective assessment of whether pain improved(p=0.03), and patient percent estimate of pain remaining at 3 months (p=0.02). However, it was not predictive for improvement in VAS pain score (p=0.08). Table 5 summarizes these results.

There were 114 patients (70%) with palpable implants associated with tenderness and/or crepitus. This factor was not predictive for changes in PROMIS PF (p=0.66), PROMIS PI (p=0.91), VAS pain (p=0.85), patient assessment of whether pain improved (p=0.51), or percent of pain remaining at 3 months (p=0.73). Table 6 summarizes these results.

Two patients (1.2%) had complications associated with the implant removal procedure including 1 patient with a postoperative infection treated with surgical debridement and 1 patient with postoperative neuropathic pain that persisted at the 3-month follow-up.

Discussion

Our series demonstrates that elective implant removal in appropriately selected patients with residual pain can lead to significant improvement in function and pain with low likelihood of complication. PROMIS PF, PROMIS PI, and VAS pain scores all significantly improved on average from preop to 3-month follow-up. For both PROMIS PF and PI, approximately 75% of patients reported improvement, but approximately 20% of patients worsened. Differences in median scores were greater than the MCID for both PROMIS PF and PI. Most importantly when considering clinical relevance for individual patients, more than half of patients improved scores greater than the MCID, approximately one-third of patients' scores remained within the MCID, and approximately one-tenth of patients worsened by more than

the MCID (not necessarily as a direct result of implant removal). All these results can be considered when counseling patients preoperatively regarding expected outcomes for implant removal. The incidence of patients who worsened from preoperative to 3 months postoperative is worth noting when discussing of risks of implant removal in the informed consent process.

Regarding influence of preoperative scores on postoperative improvement, one might expect that worse preoperative function would lead to less improvement after implant removal because PROMIS PF and PI scores are global metrics of function and pain and not specific to the problematic implant. However, we found the opposite for both function and pain. Lower preoperative scores were significantly associated with more improvement in 3-month follow-up scores. This suggests that painful implants can be major contributors to indices of global function and pain.

Surgeons should be confident in general with their predictions of whether a patient's pain will improve with implant removal as our series demonstrated that surgeons were correct 82% of the time when predicting an improvement in pain. We also found significantly more improvement in PROMIS PI and patient subjective reports of pain improvement when surgeons predicted pain improvement. Interestingly, surgeons were only correct 50% of the time when they guessed that pain would not improve. This suggests that in a shared decision-making model when the patient understands that surgery for implant removal is a last resort to improve pain and that there is a relatively high likelihood for treatment "failure" (no improvement), it may be reasonable to proceed with surgery even if the surgeon suspects that it will not help. However, a limitation of this conclusion is that our series only had 8 patients for

whom the surgeon guessed that there would be no improvement; therefore, it is difficult to draw definitive conclusions on a larger scale when surgeons predict no improvement.

Relatively superficial implants that are palpable with local tenderness are often thought to be a direct cause of pain. In our series, this factor was not predictive of improvement in any outcomes. This suggests that in appropriately selected patients, implant removal can lead to similar improvements regardless of implant location, depth, or physical exam findings.

Prior studies have shown results of implant removal similar to ours including significant improvements in VAS pain ratings, pain intensity, SMFA scores, SF-36, and constant scores (for upper extremity implant removal) as well as correlations between pain and dysfunction and generally low complication rates.[3,6,7,9,13] None of these studies reported information regarding minimal clinically important differences. Our study's prospective design as well as the similarity of our results to those of other studies suggest that our data are reasonable to consider when tailoring patient expectations from implant removal procedures.

A limitation of this study is its relatively short-term follow-up at only 3 months. It is possible that longer follow-up would lead to relapse of symptoms, differences in subjective patient outcomes or potentially improved pain and function in the 20% of patients that reported worsening of symptoms. We chose this follow-up duration because we felt that would give the patients enough time to recover from the surgical procedure and allow for quantifying changes that are directly related to the implant removal. A more prolonged time to final follow-up might introduce more factors that would confound results.

Another limitation is the heterogeneous group of patients. There were no exclusion criteria based on demographic or medical factors, and implant removals from all locations were

included. Therefore, it is difficult to use our data to counsel subsets of patients based on characteristics pertaining to individual situations.

A final limitation of this study is that all conclusions must take into consideration our inclusion criteria. Our data cannot be extrapolated to patients undergoing implant removal for reasons other than pain alone, such as planned staged removal or infection. Also, patients were not enrolled until after informed consent was obtained for implant removal, and there were likely many patients seen in the orthopaedic clinic with residual pain and retained implants that were not offered surgery or did not consent to surgery. This study does not include information about those patients; therefore, we cannot conclude exactly what factors differentiate patients who have their implants removed from those who do not. The logical conclusion is that our data should not be used by surgeons to decide whether a patient should be offered implant removal. Rather it should be used to counsel patients whom the surgeon already believes are candidates for implant removal.

In conclusion, this study provides useful information for surgeons to use when discussing expected outcomes of elective implant removal with patients who still have residual pain. Surgeon expectation generally appears to be a reliable predictor of outcomes. Even though pain improvement is the primary reason for these patients to undergo surgery, functional improvements are often gained as well, and complication risk is minimal.

Table 1. Locations of implants removed

	Location	Number of patients
Upper extremity	Humerus	3
	Elbow	10
	forearm	1
Lower extremity	Pelvis	11
	Hip	9
	Femur	36
	Patella	8
	Tibia	27
	Ankle	44
	Foot	12
	Multiple locations	2

Table 2. Types of implants removed

Type of Implant	Number of patients
Screws/Interlocks only	**70**
Plate(s) and screws*	**72**
Intramedullary nail and interlocks*	**18**
Cable	**1**
Wire and independent screws	**3**

***One patient had both an intramedullary nail and plates and screws removed**

Table 3. Changes in patient reported outcome measures

		PROMIS PF	PROMIS PI	VAS pain
Number of patients with improvement	Any improvement	124 (76%)	117 (72%)	96 (59%)
	Improvement at least MCID*	91 (56%)	92 (56%)	n/a
Number of patients unchanged	No improvement	4 (2.5%)	13 (8.0%)	29 (18%)
	Change less than MCID*	58 (36%)	51 (31%)	n/a
Number of patients worse	Any worsening	35 (21%)	33 (20%)	38 (23%)
	Worse at least MCID*	14 (8.6%)	20 (12%)	n/a

*MCID (Minimal Clinically Important Difference) = 5 for PROMIS PF and PROMIS PI

Table 4. Analysis of preoperative versus 3-month follow-up patient reported outcomes

	preoperative	3-month follow-up	p-value*
PROMIS PF (median ± SD)	38 ± 9.6	44 ± 8.9	<0.001

PROMIS PI (median ± SD)	62 ± 8.9	54 ± 9.9	<0.001
VAS pain (median ± SD)	4 ± 2.9	2 ± 2.7	<0.001

*Wilcoxon signed-rank test

Table 5. Outcome differences based on surgeon preoperative predictions

	Surgeon predicted improvement (n=155)	Surgeon predicted no improvement (n=8)	p-value*
Change in PROMIS PI (median ± SD)	-6.4 ± 10.7	2.0 ± 5.0	0.005
Change in VAS (median ± SD)	-1.1 ± 2.9	1.2 ± 3.5	0.08
Percent pain remaining at final follow-up (median ± SD)	33.7 ± 38.4	85.0 ± 66.1	0.02

* Mann-Whitney U test

Table 6. Outcome differences based on preoperative local symptoms

	Palpable implants with local tenderness (n=114)	Implants not palpable (n=49)	p-value*
Change in PROMIS Physical Function (Mean ± SD)	5.2 ± 8.7	5.5 ± 11.7	0.66
Change in PROMIS Pain Interference (Mean ± SD)	-6.1 ± 9.9	-5.8 ± 12.3	0.91
Change in VAS pain (Mean ± SD)	-1.0 ± 2.8	-1.0 ± 3.3	0.85
Percent pain remaining at final follow-up (Mean ± SD)	35.9 ± 41.2	37.1 ± 42.3	0.73

*student's t-test

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Figure 1: Delta PROMIS physical function versus preoperative PROMIS physical function. This graph depicts the linear regression analysis revealing the statistically significant association of greater improvement in physical function with worse preoperative scores.

Figure 2. Delta PROMIS pain interference versus preoperative PROMIS pain interference. This graph depicts the linear regression analysis revealing the statistically significant association of greater improvement in pain interference with worse preoperative scores.

Figure 3. Delta VAS pain versus preoperative VAS pain. This graph depicts the linear regression analysis revealing the statistically significant association of greater improvement in VAS pain with worse preoperative scores.