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The Recovery Curve for the Patient-Reported Outcomes Measurement Information System Patient-Reported Physical Function and Pain Interference Computerized Adaptive Tests After Primary Total Knee Arthroplasty

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ABSTRACT

Background: We sought to characterize the typical recovery in physical function (PF) and pain interference (PI) after TKA using Patient-Reported Outcomes Measurement Information System (PROMIS) patient-reported outcome (PRO) measures.
Methods: Ninety-one patients were enrolled into an institutional review board -approved prospective observational study. PROs were obtained preoperatively and postoperatively at 6 weeks, 3 months, 6 months, and 1 year. PROs included the PROMIS PF computerized adaptive test (CAT) and the PROMIS PI CAT. Generalized estimating equations were used to evaluate outcomes over time.
Results: There was no difference in the preoperative and 6-week postoperative T-scores for the PF CAT ($P = .410$). However, all subsequent postoperative T-scores were greater than the preoperative T-score (all, $P < 0.05$). There was a significant reduction in PI CAT T-scores between the preoperative and all subsequent postoperative T-scores (all, $P < .05$). A clinically important difference in PF CAT T-scores ($\beta = 5.44$, 95% confidence interval 4.10-6.80; $P < .001$) and PI CAT T-scores ($\beta = -7.46$, 95% confidence interval −9.52 to −5.40; $P < 0.001$) was seen between the preoperative and 3-month postoperative visits. Sixty-three percent of the improvement in PF occurred by 3 months, and 89% had occurred by 6 months. The majority of reduction in PI (68%) occurred by 3 months and 90% had occurred by 6 months.
Conclusion: The greatest magnitude of improvement in both PF and PI occurred within the first 3 months. After 6 months, patients might expect modest improvements in PF and mild reductions of PI. Patients and surgeons should use this information for setting expectations, planning for recovery, and improving care.

Total knee arthroplasty (TKA) is a reliable surgical procedure to improve function and alleviate pain associated with end-stage osteoarthritis [1]. Thus, it is not uncommon for patients preparing for TKA to question their surgeon on the expected postoperative recovery of these items. Although many providers have a general sense of what their patients can typically expect after TKA surgery, there may be a role for an improved chronologic description of an average expected postoperative recovery. With this information, both the patient and surgical team alike may have a better understanding of the level of recovery to be expected at various postoperative time intervals, which in turn may improve their own expectations and preparedness.

A patient's recovery of physical function (PF) and pain after TKA has been measured in a variety of ways including physical examination findings such as scar healing, range of motion, and lower limb strength. In addition, performance-based metrics based on timed walking, stair climbing, and chair-rising tasks have also been

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studied [2]. More recently, the focus has been on patient-reported outcomes (PROs). PROs offer the advantages of direct input from the patient's perspective on how influential the degree of pain and functional ability have been affected after surgery. Unfortunately, historical PROs (legacy scales) suffer from disadvantages of floor and ceiling effects, low collection rates, high patient and provider burden, clinical naivety in applying results, and the lack of patient involvement in the creation of such instruments [3–6]. Given the weaknesses associated with legacy scales, the National Institutes of Health developed the Patient-Reported Outcomes Measurement Information System (PROMIS) initiative to improve health status measurements [6–10]. Instead of disease-specific measures, the PROMIS developed measures to test domains of health, such as physical, mental, and social health.

The PROMIS was rigorously developed with item banks that yielded conceptually clear and well-calibrated measurement instruments and can use Item Response Theory (IRT) and computerized adaptive testing (CAT) [5,7]. The IRT and CAT techniques can increase reliability and statistical power [8]. The CAT-based PF (PF CAT) has demonstrated superior performance over static forms of equal length with high levels of accuracy and decreased patient and administrative burden [10–12]. Although one of the driving factors for the PROMIS initiative was to establish standardized metrics for clinical research across National Institutes of Health–funded research, some studies suggest that these instruments could assist in clinical decision making and the modification of treatment plans based on patient response [3,7]. Given the functionally restorative benefits of TKA, the PROMIS PF CAT is particularly relevant to accurately assess the severity of functional limitation in this population. Although the PROMIS PF CAT may be gaining traction in the TKA arena, there appears to be little, if any, research on the use of the PROMIS pain interference (PI) CAT in this population [3,13]. Pain is often measured as a level of intensity; however, this may not demonstrate the impact (interference) pain has on the individual's level of function. As such PI is gaining in popularity when measuring the patients experience with care [14,15]. In a recent publication by Kendall et al [16], the relationship of the PROMIS PF CAT with the PROMIS PI CAT is evaluated in a spine population. They demonstrated a strong association between the two suggesting that PI, as measured by the PI CAT, may be a good indicator of how a patient's subjective experience of pain interferes with their level of function.

The current published literature with legacy PROs offer conflicting results for the expected trajectory of recovery after TKA. Lenguerrand et al [17] evaluated the trajectory of pain and function after primary TKA using the Western Ontario and McMaster Universities Osteoarthritis Index and showed that most improvement occurred within the first 3 months postoperatively without significant change thereafter. However, others report slow, but continued improvement from 3 up to 18 months after TJA [18–20]. This leaves clinicians and patients with conflicting information for their expected recoveries. To our knowledge, no study has described the trajectory of recovery after TKA for the PROMIS PF CAT or the PROMIS PI CAT in the TKA population. As such, we sought to characterize the typical recovery in PF and PI using a novel computerized adaptive PRO tool in a prospectively enrolled cohort of TKA patients.

Materials and Methods

As part of a prospective observational study on functional outcomes after TKA, the study team approached 111 patients who were scheduled to undergo primary unilateral TKA at a single academic medical center, of which written informed consent was obtained from 91 patients. Of those not consented, 11 were outside the local geographic region and did not want to participate, 3 were planning to have the contralateral knee surgery performed within the next year, 5 were not interested, and 1 patient was approached who did not meet criteria. All procedures were performed between January 2015 and November 2016. The inclusion criteria included patients who were ≥40 years of age, scheduled for primary unilateral TKA, and willing to complete the follow-up visits. Patients were excluded during the screening process if they had undergone TKA on the contralateral knee within 6 months and if they had any additional orthopedic, neurological, visual, or surgical conditions that could have affected their outcomes. This study was approved by the institutional review board (IRB# 000075446) and registered with clinicaltrials.gov (NCT02364011).

PROMIS PROs were obtained preoperatively and at the following postoperative time points: 6 weeks, 3 months, 6 months, and 1 year. The 1-year period was chosen as the last follow-up point based on recommendations within the literature for measuring outcomes after hip and knee arthroplasties [19]. The PROMIS measures collected included the PF CAT, v1.2, and the PI CAT, v1.1. The PROMIS PF CAT contains a bank of 121 individually validated items that have been calibrated using IRT. Similarly, the PI CAT contains an item bank of 40 questions. For both measures, T-scores were recorded and used for this analysis. A PROMIS T-score of 50 is the average score related to the US general population, which has a standard deviation (SD) of 10. It is important to note that a higher T-score indicates more of the item being measured. Thus, for the PF CAT, higher scores mean greater PF and for the PI CAT, higher scores indicate greater PI. For interpreting PF, an average patient in our population with a preoperative T-score between 38 and 42 often report some limitations with performing physical labor, house or yard work, and walking more than a mile. In addition, they report being greatly limited or unable to hike a couple of miles because of their health. However, a patient in our population with a PF CAT T-score of 43-47 is more likely to report little if any limitations with performing 2 hours of physical labor, house or yard work, walking a mile, or hiking a couple of miles.

Patient demographics are reported using descriptive statistics. Generalized estimating equations, with an unstructured correlation matrix, were used to evaluate PROMIS measures over time and the appropriate postestimation commands were used to compare scores between time intervals. As approximately 3% of the T-scores were missing at random for both the PF CAT and PI CAT, imputation was performed using the median T-score of the nonmissing values [21]. To determine clinical significance, the distributive method was used to evaluate the minimal clinically important difference (MCID) for both PROMIS measures, with ½ a SD being considered a clinically detectable difference [22]. As such, the MCID for the PF CAT was 3.34 T-score units and the MCID for the PI CAT was 4.43 in this patient population. Based on previous reports where the majority of change occurs within the first 3 months, we used the preoperative and 3-month postoperative visits for a power analysis [17,18,23–25]. Our sample size of n = 91 provided 80% power to detect a standardized mean difference in the repeated measures of 0.30 SD, where the 2 repeated measures (preoperative to 3 months) had a correlation of r = 0.46. Significance was assessed at the 0.05 level and the analyses were performed using commercially available statistical software (Stata v14.2, College Station, TX).

Results

The mean age of the cohort (n = 91) was 63 years (range 44-83 years). Forty-nine of the participants were male (54%) and 42 were female (46%). The mean body mass index was 29.38 kg/m^2 (range 18.4-41.5 kg/m^2).

There was no difference in the preoperative and 6-week postoperative T-scores for the PF CAT (P = .410). However, all