



## Responsiveness of Patient Reported Outcome Measures in Total Joint Arthroplasty Patients



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### ABSTRACT

This study reports the responsiveness to change and minimal clinically important difference (MCID) of three patient reported outcome measures following total hip arthroplasty (THA) and total knee arthroplasty (TKA). Patient-reported outcome measures were collected preoperatively and 3 months postoperatively for 391 patients enrolled in the California Joint Replacement Registry. Effect size, standardized response means, and MCID were calculated for each measure. The WOMAC and the SF12v2 physical component summary (PCS) score were the most responsive to perioperative changes. The MCID was 4.97 for the SF12v2 PCS and 10.21 for the WOMAC. THA patients were more likely to exhibit improvements above the MCID than TKA patients. The WOMAC and SF12v2 PCS are useful to measure health status changes in TJA patients.

Level of Evidence: Prognostic Level II.

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With over one million hip and knee arthroplasties performed each year in the United States [1], there is increased interest in using patient-reported outcome measures (PROMs) to evaluate the effectiveness of total joint arthroplasty (TJA) procedures. There is a clear need for comprehensive, scientific assessment of the comparative effectiveness of devices, treatment protocols, surgical approaches, and patient factors influencing the outcomes of these surgeries. This assessment involves collecting and incorporating clinical information from providers as well as direct feedback from patients. Patient-reported outcome measures are a key component of comparative effectiveness research in that they focus on the outcomes of most interest to patients including subjective assessments of pain, function, and overall health.

Despite the importance of reporting patient-centered outcomes, it remains unclear which PRO measures should be used, and how responsive they are to change, following TJA in patients with hip

and knee arthritis. The CJRR is a collaborative effort of the California Orthopaedic Association, Pacific Business Group on Health, and California Healthcare Foundation to collect prospective outcomes data on hip and knee arthroplasty surgeries [2]. The purposes of this study are to report the responsiveness to change of three commonly used PROMs among patients who undergo total hip and knee arthroplasty; to calculate the minimal clinically important difference (MCID) for each PROM; and to determine the proportion of patients exhibiting this level of improvement after surgery.

### Patients and Methods

#### Patient Sample

PROMs were collected preoperatively and three-months postoperatively for 391 patients enrolled in the California Joint Replacement Registry (CJRR). Patients undergoing either unilateral or bilateral primary total hip arthroplasty (THA) or primary total knee arthroplasty (TKA) were included. In order to ensure the analysis was performed on a relatively homogenous patient population, the data analysis excluded patients with pathological fracture or malignant neoplasms (primary or metastatic cancer).

This study reports the initial 33 month experience of the California Joint Replacement Registry, formed as a collaboration of the California Orthopaedic Association, Pacific Business Group on Health, and the California Healthcare Foundation. CJRR enrollment and data

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**Table 1**  
Demographic Profile of Patients Who Completed All Three Surveys at Both Preop and 3-Month Follow-Up By Surgery Type.

	Overall (N = 391)	Hip (N = 162)	Knee (N = 229)	P-value
Age, mean (SD)	65.1 (9.7)	64.1 (10.0)	65.9 (9.5)	0.071
Age				0.110
≤65	196 (50.1)	89 (54.9)	107 (46.7)	
>65	195 (49.9)	73 (45.1)	122 (53.3)	
Gender				0.450
Female	226 (57.8)	90 (55.6)	136 (59.4)	
Male	165 (42.2)	72 (44.4)	93 (40.6)	
Caucasian				0.477
No	285 (72.9)	115 (71.0)	170 (74.2)	
Yes	106 (27.1)	47 (29.0)	59 (25.8)	
ASA classification				0.019
1 or 2	246 (62.9)	113 (69.8)	133 (58.1)	
3 or 4	145 (37.1)	49 (30.3)	96 (41.9)	
Bilateral vs. unilateral				0.046
No	371 (94.9)	158 (97.5)	213 (93.0)	
Yes	20 (5.1)	4 (2.5)	15 (7.0)	

Note: There was no statistically significant difference in prevalence of preop comorbidities such as diabetes, immunocompromise, obesity, hypertension, CAD, PAD, CLD and VTE between hip and knee surgery.

collection began with three hospital sites. Each site had a team including a physician champion and administrator responsible for coordinating recruitment of physicians and data collection. Data from each site were validated by the administrator prior to submission to the CJRR. Sites were eligible with at least one participating surgeon and sites were not required to enroll all their surgeons to participate. The registry recruitment was expanded on a rolling basis after the initial 12 months. At the conclusion of 33 months, a total of fifteen centers had enrolled at least one patient, with 391 eligible patients having follow-up PROM data completed.

*Outcome Measures*

Preoperative and 3-month post-operative surveys were conducted for all patients and included the SF12v2, WOMAC and UCLA activity scores. Surveys were collected either through an electronic interface

or in paper format. Mean preoperative and postoperative scores and standard deviations were determined using the scoring algorithms for each of the outcomes instruments. The outcomes analyzed were the SF12v2 Physical Component Summary (PCS) and Mental Component Summary (MCS) score, the total WOMAC score, and the UCLA activity score.

*Statistical Analysis*

We first performed paired t-test to assess the significance of changes in patient reported outcomes for each survey. The responsiveness of each questionnaire was then quantified by computing the effect size and standardized response means for each survey tool (SF12v2, WOMAC and UCLA). The effect size was defined as the average change between scores for patients divided by the standard deviation of the baseline scores. The standardized response mean was defined as the average change between scores for patients divided by the standard deviation of these changes between paired measurements [3,4].

The minimal clinically important difference (MCID) was identified as change equal to or greater than one-half of a standard deviation for the mean change between paired measurements [5]. We developed regression models to determine patient attributes associated with higher probability of patients achieving MCID.

**Results**

*Patient Sample*

The patient sample consisted of 391 patients from 12 hospitals who completed all three PRO surveys both preoperatively and 3-months postoperatively. A total of 162 THA patients and 229 TKA patients were included in the analysis (Table 1). The mean age at the time of the index procedure was 65 with a standard deviation of 9.7 years. The study population consisted of 57.8% female patients and 72.9% patients of Caucasian race. The THA and TKA patients were statistically similar with the exception that TKA patients were more

**Table 2**  
Preop and 3-Month Comparisons in PRO Measures by Type of Surgery (Paired T-Test Results), CJRR Data as of 1/23/2014.

Surgery Type	PRO Measure	Interval	N	Mean	Std Dev	Mean Difference (95% CI)	Paired T-Test: P-value																																																																																																																				
Overall	SF12v2—Physical component score	Preop	391	30.84	8.57	10.11 (9.12–11.10)	<0.0001																																																																																																																				
		3-Month		40.95	9.45			Hip	SF12v2—Physical component score	Preop	162	31.00	8.29	11.58 (10.07–13.09)	<0.0001	3-Month	42.58	10.05	Knee	SF12v2—Physical component score	Preop	229	30.73	8.78	9.07 (7.77–10.36)	<0.0001	3-Month	39.80	8.84	Overall	SF12v2—Mental component score	Preop	391	51.85	11.25	1.45 (0.44–2.47)	0.005	3-Month	53.31	9.60	Hip	SF12v2—Mental component score	Preop	162	50.78	11.40	3.23 (1.63–4.84)	0.001	3-Month	54.01	9.29	Knee	SF12v2—Mental component score	Preop	229	52.61	11.12	0.19 (–1.10–1.49)	0.768	3-Month	52.81	9.80	Overall	WOMAC Total score	Preop	391	48.70	17.30	28.74 (26.71–30.77)	<0.0001	3-Month	77.44	15.60	Hip	WOMAC Total score	Preop	162	48.07	18.37	33.29 (30.02–36.56)	<0.0001	3-Month	81.36	15.70	Knee	WOMAC Total score	Preop	229	49.16	16.53	25.51 (23.00–28.03)	<0.0001	3-Month	74.67	14.94	Overall	UCLA activity score	Preop	391	4.21	1.76	0.84 (0.66–1.02)	<0.0001	3-Month	5.05	1.76	Hip	UCLA activity score	Preop	162	4.31	2.01	0.96 (0.66–1.27)	<0.0001	3-Month	5.28	1.97	Knee	UCLA activity score	Preop	229	4.14	1.56
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