Defining and Achieving Substantial Clinical Benefit in Total Knee Arthroplasty: An Analysis of the KOOS and Patient Factors

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INTRODUCTION: With the increasing emphasis on value-based care and the mandatory collection of patient-reported outcome measures (PROMs) following Total knee arthroplasty (TKA) by the Centers for Medicare & Medicaid Services (CMS), defining clinically meaningful improvement thresholds has become crucial. Substantial clinical benefit (SCB) represents a higher level of patient-perceived improvement compared to minimal clinically important difference (MCID) and is now being used by CMS to calculate clinical significance. This study aimed to 1) establish SCB thresholds for the Knee Disability and Osteoarthritis Outcome Score (KOOS) pain, physical function short form (PS), and joint replacement (JR) after TKA and determine the proportion of patients achieving these thresholds, and 2) identify patient factors associated with failure to achieve SCB after TKA.

METHODS: A prospective cohort of 10,988 patients who underwent primary TKA between January 2016 and December 2022 was analyzed. Patient demographics, comorbidities, baseline and one-year KOOS pain, PS, and JR scores were recorded. (Table 1) Patients were categorized into 8 distinct phenotypes based on their preoperative pain, physical function, and mental health scores. The anchor question used to determine SCB was: "Since your surgery, how would you rate your overall physical activity?" Patients answering "much better" were classified as the substantially improved group, while those answering "slightly better" were classified as the improved group. Patients answering "about the same," "slightly worse," or "much worse" were classified as the unimproved group. The SCB threshold was determined using receiver operating characteristic curve analysis, selecting the cut-off that maximized the Youden J statistic to differentiate between the unimproved and substantially improved groups.

RESULTS: The SCB thresholds were 33.3 points for KOOS Pain (sensitivity 80.7%, specificity 53.0%, Area Under the Curve (AUC): 0.72), 16.4 points for KOOS PS (sensitivity 82.4%, specificity 47.9%, AUC:0.69), and 22.8 points for KOOS JR (sensitivity 82.4%, specificity 51.4%, AUC:0.72). The proportion of patients achieving SCB at one year was 59.1% for all three KOOS scores. Non-white race, current/previous smoking status, higher Charlson Comorbidity Index, Medicare/Medicaid insurance, and phenotypes with worse baseline pain, physical function, and mental health scores were significantly associated with failure to achieve SCB for all three KOOS scores. (Table 2)

DISCUSSION AND CONCLUSION: SCB thresholds for KOOS Pain, PS, and JR were defined, and patient factors linked to failure in achieving SCB after TKA were identified.These findings underscore the importance of considering patient characteristics when predicting outcomes and managing expectations. With CMS moving towards mandatory PROM collection and reporting, these SCB thresholds serve as meaningful benchmarks for assessing clinically significant improvement after TKA. Integrating SCB thresholds into clinical practice can enhance shared decision-making, guide postoperative care, and ultimately improve patient outcomes and satisfaction.

Table 1. Patient Characteristics

Variable	Level	All (n=10988)	N
Age		67.6 [61.0,73.0]	10988
Sex	F	6615 (60.2%)	10988
	M	4373 (39.8%)	
BMI		31.8 [27.3,35.5]	10987
Education		14.0 [12.0,16.0]	10988
ADI		94.0 [88.0,94.0]	10306
Race	White	9245 (86.1%)	10737
	Non-white	1492 (13.9%)	
Smoking	Never	6281 (57.2%)	10988
	Quit 4mo+	3767 (34.3%)	
	Quit <4mo	329 (2.99%)	
	Current	611 (5.56%)	
CCI		1.00 [0.00,2.00]	10862
Categorical CCI	0	5397 (49.7%)	10862
	1	2333 (21.5%)	
	2	1514 (13.9%)	
	3+	1619 (14.9%)	
Literacy	Not at all	451 (5.23%)	8618
	A little bit	322 (3.74%)	
	Somewhat	579 (6.2%)	
	Quite a bit	1864 (21.6%)	
	Extremely	5182 (58.2%)	
Use of Chronic Narcotics	< 3mon	162 (18.8%)	864
	>= 3mon	702 (81.2%)	
Phenotype	P-PS-MCS-	2620 (23.9%)	10982

Table 1. Patient Characteristics

Variable	Level	All (n=10988)	N
	P-PS-MCS+	2690 (24.5%)	
	P-PS-MCS+	1581 (14.4%)	
	P-PS-MCS+	369 (3.36%)	
	P-PS-MCS-	384 (3.50%)	
	P-PS-MCS+	918 (8.39%)	
	P-PS-MCS+	890 (8.10%)	
	P-PS-MCS+	1330 (13.9%)	
VR12	Much Better	5093 (46.3%)	8302
	Slightly Better	1716 (26.6%)	
	About the Same	1821 (23.9%)	
	Slightly Worse	671 (8.98%)	
	Much Worse	283 (2.47%)	
Anchor	Unimproved	2697 (32.5%)	8302
	Improved	1716 (26.6%)	
	Substantially Imp	3891 (46.9%)	

Continuous variables presented as Median [IQR]. Categorical variables presented as N (column %).

Table 2. Multivariate regression for factors associated with failure to achieve SCB for KOOS pain, PS, and JR.

Predictors	Pain SCB (Failure)		PS SCB (Failure)		JR SCB (Failure)	
	Estimate [95%CI]	P-value	Estimate [95%CI]	P-value	Estimate [95%CI]	P-value
Age (QR Increase)	0.84 (0.78 – 0.92)	<0.001	0.84 (0.77 – 0.92)	<0.001	0.87 (0.80 – 0.94)	0.001
Sex (Male v Female)	1.09 (0.99 – 1.19)	0.074	1.11 (1.01 – 1.21)	0.037	1.10 (1.00 – 1.20)	0.055
BMI (QR Increase)	0.89 (0.84 – 0.95)	<0.001	0.93 (0.88 – 1.00)	0.052	0.98 (0.92 – 1.05)	0.640
Race (Non-white v White)	1.92 (1.59 – 2.06)	<0.001	1.96 (1.68 – 2.29)	<0.001	1.94 (1.65 – 2.24)	<0.001
Education (QR Increase)	0.97 (0.91 – 1.03)	0.315	0.89 (0.82 – 0.96)	0.003	0.91 (0.85 – 0.98)	0.009
Smoking (Quit v Never)	1.08 (0.98 – 1.19)	0.114	1.15 (1.03 – 1.28)	0.012	1.14 (1.03 – 1.26)	0.008
Smoking (Current v Never)	1.05 (0.85 – 1.28)	0.678	1.27 (0.98 – 1.58)	0.070	1.22 (0.98 – 1.50)	0.071
CCI (QR Increase)	1.13 (1.07 – 1.20)	<0.001	1.11 (1.04 – 1.19)	0.001	1.08 (1.01 – 1.15)	0.007
ADI (QR Increase)	1.02 (0.94 – 1.11)	0.622	1.01 (0.95 – 1.15)	0.337	1.05 (0.97 – 1.15)	0.227
Insurance (Commercial/Worker's COMP/Other v Medicare/Medicare)	0.80 (0.71 – 0.90)	<0.001	0.78 (0.68 – 0.89)	<0.001	0.80 (0.74 – 0.94)	0.003
P-PS+MCS+ v P-PS-MCS-	3.97 (3.46 – 4.55)	<0.001	3.38 (2.85 – 4.01)	<0.001	3.72 (3.21 – 4.30)	<0.001
P-PS+MCS+ v P-PS-MCS-	3.93 (3.26 – 4.43)	<0.001	2.89 (2.24 – 4.04)	<0.001	4.32 (3.47 – 7.08)	<0.001
P-PS-MCS+ v P-PS-MCS-	1.93 (1.44 – 2.58)	<0.001	1.52 (0.93 – 1.87)	0.122	1.64 (1.24 – 2.14)	0.001
P-PS-MCS+ v P-PS-MCS-	3.15 (2.47 – 4.02)	<0.001	2.46 (1.82 – 3.32)	<0.001	2.70 (2.09 – 3.39)	<0.001
P-PS-MCS+ v P-PS-MCS-	0.75 (0.62 – 0.93)	0.009	1.25 (0.98 – 1.59)	0.069	1.33 (1.09 – 1.62)	0.005
P-PS-MCS+ v P-PS-MCS-	1.32 (1.09 – 1.59)	0.004	1.88 (1.19 – 2.37)	<0.001	2.13 (1.74 – 3.49)	<0.001
P-PS-MCS+ v P-PS-MCS-	0.75 (0.64 – 0.94)	0.001	0.80 (0.63 – 1.00)	0.048	0.74 (0.61 – 0.89)	0.001
Observations	9833		9597		9697	
R²	0.144		0.096		0.123	