

Assessment of Residual Pain and Dissatisfaction in Total Knee Arthroplasty

Methods Matter

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Background: Residual pain after total knee arthroplasty (TKA) refers to knee pain after 3 to 6 months postoperatively. The estimates of the proportion of patients who experience residual pain after TKA vary widely. We hypothesized that the variation may stem from the range of methods used to assess residual pain. We analyzed data from 2 prospective studies to assess the proportion of subjects with residual pain as defined by several commonly used metrics and to examine the association of residual pain defined by each metric with participant dissatisfaction.

Methods: We combined participant data from 2 prospective studies of TKA outcomes from subjects recruited between 2011 and 2014. Residual pain was defined using a range of metrics based on the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) pain score (0 to 100, in which 100 indicates worst), including the minimal clinically important difference (MCID) and patient acceptable symptom state (PASS). We also examined combinations of MCID and PASS cutoffs. Subjects self-reported dissatisfaction following TKA, and we defined dissatisfied as somewhat or very dissatisfied at 12 months. We calculated the proportion of participants with residual pain, as defined by each metric, who reported dissatisfaction. We examined the association of each metric with dissatisfaction by calculating the sensitivity, specificity, positive predictive value, and Youden index.

Results: We analyzed data from 417 subjects with a mean age (and standard deviation) of 66.3 ± 8.3 years. Twenty-six participants (6.2%) were dissatisfied. The proportion of participants defined as having residual pain according to the various metrics ranged from 5.5% to >50%. The composite metric Improvement in WOMAC pain score ≥20 points or final WOMAC pain score ≤25 had the highest positive predictive value for identifying dissatisfied subjects (0.54 [95% confidence interval, 0.35 to 0.71]). No metric had a Youden index of ≥50%.

Conclusions: Different metrics provided a wide range of estimates of residual pain following TKA. No estimate was both sensitive and specific for dissatisfaction in patients who underwent TKA, underscoring that measures of residual pain should be defined explicitly in reports of TKA outcomes.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

P rimary total knee arthroplasty (TKA) is a common procedure typically performed for severe knee osteoarthritis. In 2018, 715,200 TKAs were recorded in the National Inpatient Sample in the United States¹. In 2019, 109,540 TKAs were performed in England, Wales, and Northern Ireland². Pain and pain-related functional limitations are the main clinical indications for undergoing TKA, widely considered an efficacious treatment for those with painful knee osteoarthritis who have undergone failed conservative therapy^{3,4}.

Although TKA is generally regarded as a successful intervention, some patients report that they are dissatisfied, do not have improvement in quality of life, or continue to experience pain⁵⁻⁷. Postoperative pain is expected following TKA, but pain persisting beyond 3 to 6 months postoperatively is referred to as residual pain⁸. Systematic reviews and registry data have suggested that the proportion of patients with residual pain several months after TKA varies widely across studies^{8.9}. For example, in a systematic review of 11 prospective studies,

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Beswick et al. found that estimates of unfavorable pain outcomes after TKA ranged from 8% to 27%⁹, and more recent cohort studies have reported that 16% to 33% of patients experience residual pain after TKA^{10,11}. In a cross-sectional study of 250 patients undergoing TKA, 19% reported "severe" to "unbearable" pain at 3 years after primary TKA¹⁰. In a prospective study from an Ontario registry, 28% reported dissatisfaction with relief of pain when climbing stairs and 15% reported dissatisfaction with relief of pain when walking on flat ground 1 year after TKA¹².

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The wide range of pain estimates following TKA may relate to the way in which each study defined residual pain⁸⁹. Patientreported outcome measures such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) are typically used to assess TKA outcomes and have been demonstrated to be valid, reliable, and responsive to change³. Reported estimates of residual pain are typically based on achieving either an absolute score threshold at the follow-up assessment or a specified improvement in score between baseline and follow-up, such as the minimal clinically important difference (MCID)^{13,14}. In the systematic review by Beswick et al.⁹, each estimate of residual pain was based on failing to meet a threshold of improvement on the WOMAC, Knee Osteoarthritis Outcome Score, Oxford Knee Score, or a visual analog scale (VAS) for pain over a 3-month to 5year postoperative period.

We hypothesized that estimates of residual pain vary widely depending on the method used to define the threshold for residual pain. We reasoned that the most meaningful definitions of residual pain should be associated with dissatisfaction with the results of TKA. To that end, we examined the association between the various estimates of residual pain, using commonly used metrics such as the MCID, and patientreported dissatisfaction.

Materials and Methods

Study Participants

We used the data from 2 prospective studies. The AViKA (Adding Value in Knee Arthroplasty) Navigator study was a randomized controlled trial of subjects undergoing TKA for knee osteoarthritis by 5 orthopaedic surgeons at a tertiary medical center (Brigham and Women's Hospital)¹⁵. Between August 2011 and November 2013, we screened 1,234 participants scheduled to undergo TKA at that center¹⁵. The study compared 2 management strategies over the first 6 months postoperatively: enhanced postoperative care with frequent follow-up by a care navigator, and usual postoperative care¹⁶. Subjects were followed for up to 60 months. The results of the trial have been reported previously¹⁷.

Study of Total Knee Arthroplasty Responses (STARs) was a prospective cohort study of patients who underwent TKA that recruited subjects at 1 academic center (NYU Langone Medical Center) and 2 community orthopaedic centers (Orthopaedic & Spine Center of the Rockies and University of Maryland St. Joseph Medical Center). Participants were screened and enrolled between September 2012 and April 2014. All participants completed a baseline questionnaire within 6 weeks prior to the surgical procedure and were followed postoperatively for up to 60 months¹⁸.

Both AViKA and STARs study participants were followed for at least 12 months after the TKA, the follow-up interval used in this analysis. The AViKA and STARs protocols were approved by the Partners Healthcare (now Mass General Brigham) institutional review board (protocol 2010P002597). Data were collected and managed using Research Electronic Data Capture (REDCap)¹⁹.

Inclusion and Exclusion Criteria

AViKA and STARs participants were adults who were \geq 40 years of age and underwent TKA for knee osteoarthritis. In the AViKA and STARs cohorts, participants were excluded if they had dementia, had psychological issues that precluded participation, lived in a nursing home, or had plans for bilateral TKA. To investigate the association between residual pain and dissatisfaction in this study, we further excluded participants with missing 12-month WOMAC pain scores or satisfaction scores.

Baseline Data

We assessed baseline (preoperative) demographic and clinical characteristics. We dichotomized several continuous measures to make them more interpretable. For example, we dichotomized body mass index (BMI) at \geq 30 kg/m². We used the 5-item Mental Health Inventory (MHI-5) as a measure of anxiety and depressive feelings²⁰. The scale ranges from 1 to 100 (best); we dichotomized it at 68²¹, as an MHI-5 score of <68 has been validated to indicate worse mental health²². We dichotomized the 5-question subscale of the Pain Catastrophizing Scale, which measures catastrophic thinking related to pain on a scale measuring from 0 to 52, with higher scores corresponding to higher levels of pain catastrophizing²³. We used a cutoff of \geq 30 to represent a high degree of pain catastrophizing²⁴.

Dissatisfaction

We defined dissatisfaction following TKA at 12 months using 2 questions from the validated Self-Administered Patient Satisfaction (SAPS) questionnaire²⁵. Participants were deemed dissatisfied if they answered "very dissatisfied" or "somewhat dissatisfied" to the questions of "How satisfied are you with the results of your knee replacement in relieving your pain?" or "Overall, how satisfied are you with the results of your knee replacement?" (possible responses: very dissatisfied, somewhat dissatisfied, somewhat satisfied, very satisfied). We chose these 2 satisfaction items because they represent the individual participant's overall assessment of the outcome following TKA and of pain relief, often the primary indication for TKA^{26,27}.

Residual Pain

We defined residual pain by a range of thresholds involving baseline and follow-up WOMAC pain scores. The WOMAC pain scores are a validated 5-item pain questionnaire where subjects respond to each item by checking 1 of 5 ordinal Likert responses²⁸. The WOMAC pain scores are responsive to change following surgical intervention for knee osteoarthritis, with minimal floor effects²⁹. The score was converted to a 0-to-100 scale, with 100

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being the worst pain. Definitions of residual pain, chosen from the published literature, have been derived in samples of patients with knee osteoarthritis undergoing several different therapies including TKA, high tibial osteotomy, and drug therapies (Table I)³⁰⁻³³.

We first calculated the proportion of subjects with residual pain as defined by various commonly used metrics (algorithms involving a threshold value) using the WOMAC pain scores. We present and define these metrics in Table I, along with the nomenclature that we use in this study for each metric. Kim et al. reported WOMAC pain on a 0-to-20 scale; hence, we multiplied their reported MCID by 5, as we used a WOMAC pain score of 0 to 100³⁴. Escobar et al. used an anchor-based method to determine a patient acceptable symptom state (PASS) value of 75 that was based on reverse WOMAC pain scores; hence, we used a value of 25 on WO-MAC pain scores as the PASS threshold³⁵. In addition, we created 2 composite outcomes combining literature-based estimates of the PASS and MCID. Second, we calculated the proportion of subjects with residual pain using a series of thresholds for improvement (e.g., 5 points, 10 points, 15 points) in WOMAC pain scores.

Statistical Analysis

We determined the relationship of each estimate of residual pain with dissatisfaction using the 12-month follow-up data. We created a contingency table to determine the association between the presence of residual pain and dissatisfaction using each metric defined in Table I. We calculated the sensitivity, specificity, and positive predictive value of each measure of residual pain in relation to dissatisfaction with the results of the TKA, along with their 95% confidence intervals (CIs). For each residual pain definition, we plotted the sensitivity against 1 – specificity for dissatisfaction. We then calculated the Youden index (the percentage of sensitivity plus the percentage of specificity – 100) for each metric. The Youden index permits the selection of an optimal threshold value or cutoff between sensitivity and specificity³⁶. A Youden index of \geq 50% has been considered appropriate for a diagnostic test³⁷. All analyses were conducted using R statistical software (version 12.0; The R Foundation).

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Results

Cohort Characteristics

There were 575 participants enrolled in the AViKA and STARs cohorts. Of these, 158 subjects (27.5%) had missing satisfaction or WOMAC pain scores at 12 months and were excluded from this study. The included and excluded participants had similar baseline demographic characteristics, although

Metric	Definition	Cutoff	Treatment	Nomenclature in This Manuscript	Interpretation	Study
Minimal clinically important difference (MCID)	The smallest difference that individuals consider important ⁴¹	11	ТКА	MCID11	WOMAC pain score change ≥ 11	Clement ³⁰
		25	High tibial osteotomy	MCID25	WOMAC pain score change ≥ 25	Kim ³⁴
Minimally mportant change [MIC)	The change in the WOMAC score, relative to the baseline score, for individuals who report a little improvement in their quality of life ³⁰	21	ТКА	MIC21	WOMAC pain score change ≥ 21	Clement ³⁰
Ainimal clinically mportant change MCIC)	The smallest difference in score, in the domain of interest, that individuals perceive as beneficial ⁴²	31.25	ТКА	MCIC31.25	WOMAC pain score change ≥ 31.25	Maratt ⁴²
Minimally mportant difference (MID)	ortant outcome that individuals identify		ТКА	MID7.5	WOMAC pain score change ≥ 7.5	Holtz ³¹
Meaningful vithin-person :hange (MWPC)	The smallest change at which individuals experience a meaningful clinical benefit ³³	30% improvement	Oral medical therapy	MWPC30%	WOMAC pain score change ≥ 30% of baseline	Conaghan
PASS	The highest level of symptoms at which individuals consider themselves well ⁴⁴	25	ТКА	PASS25	Final WOMAC pain scale score ≤ 25	Escobar ³⁵

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Metric	Proportion Not Meeting Threshold*	WOMAC Pain Improvement	Dissatisfied†		Confusion Matrix Derivations				
							Positive	Youden	
			Yes	No	Sensitivity†	Specificity*	Predictive Value [†]	Index (%)	
MCID11 5	56 (13.4%)	<11	12	44	0.46 (0.27 to 0.67)	0.89 (0.85 to 0.92)	0.21 (0.14 to 0.3)	35	
		≥11	14	347	_	_	_	_	
MIC21	128 (31%)	<21	19	109	0.73 (0.52 to 0.88)	0.72 (0.67 to 0.76)	0.14 (0.11 to 0.18)	45	
		≥21	7	282	_	_	_	_	
MWPC30% 38 (9	38 (9.1%)	<30%	11	27	0.42 (0.23 to 0.63)	0.93 (0.9 to 0.95)	0.28 (0.18 to 0.41)	35	
		≥30%	15	364	_	_	_	_	
MCIC31.25 217 (217 (52%)	<31.25	23	194	0.88 (0.7 to 0.98)	0.5 (0.45 to 0.55)	0.1 (0.09 to 0.11)	38	
		≥31.25	3	197	_	_		_	
MID7.5 40	40 (9.6%)	<7.5	9	31	0.35 (0.17 to 0.56)	0.92 (0.89 to 0.95)	0.22 (0.13 to 0.34)	27	
		≥7.5	17	360	_	_	_	—	
MCID25	129 (31%)	<25	19	110	0.73 (0.52 to 0.88)	0.72 (0.67 to 0.76)	0.14 (0.11 to 0.18)	45	
		≥25	7	281	_	_	_	—	
PASS25	29 (7%)	Follow-up score ≤25	12	17	0.46 (0.27 to 0.66)	0.96 (0.93 to 0.97)	0.4 (0.27 to 0.56)	42	
		Follow-up score >25	14	374	_	_	_	_	

*The values are given as the number of patients, with the percentage of the 417 patients in parentheses. †The values are given as the number of patients. †The values are given as the estimate, with the 95% CI in parentheses.

those excluded were slightly more likely to be female (68% compared with 60%) and baseline WOMAC pain scores were also slightly worse in those excluded (48 compared with 40).

Of the 417 subjects who met the study inclusion criteria, 244 (58.5%) were enrolled in the AViKA study and 173 (41.5%) were enrolled in the STARs study. Overall, the included

	Proportion		Dissatisfied†		Confusion Matrix Derivations				
Composite Not Meet	Not Meeting Threshold*	WOMAC Pain Score	Yes	No	Sensitivity ⁺	Specificity*	Positive Predictive Value†	Youden Index (%)	
MCID25 and		Improvement ≤25 and final score ≥25	19	116	0.73 (0.52 to 0.88)	0.7 (0.65 to 0.74)	0.14 (0.11 to 0.17)	43	
PASS25	Improvement ≥25 and final score ≤25	7	275	_	_	_	—		
MCID25 or PASS25	()	Improvement ≤25 or final score ≥25	12	11	0.46 (0.27 to 0.67)	0.97 (0.95 to 0.98)	0.5 (0.3 to 0.68)	43	
		Improvement ≥25 or final score ≤25	14	380	_	_	_	—	
WOMAC=20 or PASS25		Improvement ≤20 or final score ≥25	12	10	0.46 (0.27 to 0.67)	0.97 (0.95 to 0.99)	0.54 (0.35 to 0.71)	43	
		Improvement >20 or final score ≤25	14	381	_	_	_	—	
WOMAC=20 and PASS25	103 (24.7%)	Improvement ≤20 and final score ≥25	18	85	0.69 (0.48 to 86)	0.78 (0.74 to 0.82)	0.17 (0.12 to 0.22)	47	
		Improvement ≥20 and final score ≤25	8	306	—	—	—	_	

*The values are given as the number of patients, with the percentage of the 417 patients in parentheses. †The values are given as the number of patients. †The values are given as the percentage, with the 95% CI in parentheses.

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cohort was middle-aged (mean age [and standard deviation] of 66.3 \pm 8.3 years) and predominantly female (60.0%), White (93%), and overweight (mean BMI, $30.6 \pm 6.3 \text{ kg/m}^2$), with 205 (49%) of 417 participants classified as obese (BMI \geq 30 kg/ m²). The mean WOMAC pain score was 40.0 ± 17.1 points. Nineteen participants (4.6%) answered "somewhat dissatisfied" or "very dissatisfied" to "How satisfied are you with the TKA in relieving pain?" Twenty-six participants (6.2%) were deemed dissatisfied, having answered "very dissatisfied" or "somewhat dissatisfied" to "How satisfied are you with the results of your knee replacement in relieving your pain?" or "Overall, how satisfied are you with the results of your knee replacement?" The mean baseline WOMAC pain score was 40.2 ± 15.7 points for dissatisfied participants and 39.6 ± 17.3 points for satisfied participants. The mean 12-month WO-MAC pain score was 30.4 ± 22.3 points for the 26 dissatisfied participants and 7.2 \pm 10.6 points for the satisfied participants. Five percent of the participants had baseline Pain Catastrophizing Scale scores of >30 points, and 24.7% had an MHI-5 of <68.

Relationship Between Metrics and Youden Index

Table II highlights the proportion of participants who met each criterion for residual pain and those who were dissatisfied. The estimates of residual pain varied widely from 5.5% to >50.0% according to the metric employed. The composite metric MCID25 or PASS25 was defined as having a WOMAC pain improvement of at least 25 points or meeting the PASS threshold score of 25. The composite metric MCID25 or PASS25 had the highest positive predictive value (0.54 [95% CI, 0.35 to 0.71]), meaning that 54.0% of subjects who met this definition of residual pain were dissatisfied with the results of the TKA. The MCIC31.25 (a WOMAC pain score improvement exceeding a minimal clinically important change [MCIC] of 31.25) had the highest sensitivity (0.88 [95% CI, 0.7 to 0.98]); 88% of dissatisfied participants did not improve by >31.25 points. The highest specificity was found for the composite metric MCID25 or PASS25 (0.97 [95% CI, 0.95 to 0.98]) and WOMAC=20 or PASS25 (0.97 [95% CI, 0.95 to 0.99]) (Table III). The MIC21 (a WOMAC pain score improvement exceeding a minimally important change [MIC]

Improvement in WOMAC Pain Score	Proportion Not Meeting Threshold*	Improvement	<u>.</u>		Confusion Matrix Derivations				
			Yes	isfied† No	Sensitivity#	Specificity*	Positive Predictive Value‡	Youden Index (%	
5	29 (7%)	<5	8	21	0.31 (0.14 to 0.52)	0.95 (0.92 to 0.97)	0.27 (0.15 to 0.43)	26	
		≥5	18	370	_	_	_	_	
10	40 (9.6%)	<10	9	31	0.35 (0.17 to 0.56)	0.92 (0.89 to 0.95)	0.22 (0.13 to 0.34)	27	
		≥10	17	360	_	_	_		
15	57 (13.7%)	<15	12	45	0.46 (0.29 to 0.67)	0.88 (0.85 to 0.91)	0.2 (0.13 to 0.3)	34	
		≥15	14	346	_	_	_	_	
20	96 (23%)	<20	18	78	0.69 (0.48 to 0.86)	0.8 (0.76 to 0.84)	0.18 (0.14 to 0.23)	49	
		≥20	8	313	_	_	_	—	
25	129 (31%)	<25	19	110	0.73 (0.55 to 0.88)	0.72 (0.67 to 0.76)	0.14 (0.1 to 0.18)	45	
		≥25	7	281	_	_	_	_	
30	181 (43%)	<30	21	160	0.81 (0.6 to 0.93)	0.59 (0.54 to 0.64)	0.11 (0.1 to 0.14)	40	
		≥30	5	231		_	_	_	
35	219 (53%)	<35	24	195	0.92 (0.75 to 0.99)	0.5 (0.45 to 0.55)	0.11 (0.1 to 0.12)	42	
		≥35	2	196		_	_	_	
40	254 (61%)	<40	24	230	0.92 (0.75 to 0.99)	0.4 (0.36 to 0.46)	0.09 (0.08 to 0.1)	32	
		≥40	2	161	_	_	_	_	
45	298 (71%)	<45	25	273	0.96 (0.83 to 1)	0.3 (0.25 to 0.35)	0.08 (0.07 to 0.09)	26	
		≥45	1	118	_	_	_	_	
50	333 (80%)	<50	26	307	1 (0.87 to 1)	0.2 (0.18 to 0.26)	0.07 (0.06 to 0.08)	20	
		≥50	0	84	_	_	_	_	
60	394 (94%)	<60	26	368	1 (0.86 to 1)	0.06 (0.04 to 0.09)	0.06 (0.05 to 0.07)	6	
		≥60	0	23		_	_	_	

*The values are given as the number of patients, with the percentage of the 417 patients in parentheses. †The values are given as the number of patients. †The values are given as the percentage, with the 95% CI in parentheses.

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of 21.0) and MCID25 (a WOMAC pain score improvement exceeding an MCID of 25.0) both had a Youden index of 45%. The composite metric WOMAC Pain >20 and PASS25 had a Youden index of 47% (Table III).

Relationship Between Metrics and the WOMAC Pain Score The various thresholds for the improvement in the WOMAC pain score yielded a wide range of estimates of residual pain (7.0% to >50.0% of participants) (Table IV). Generally, the sensitivity of the residual pain cutoff for dissatisfaction increased as the required improvement in the WOMAC pain score increased (Table IV). An improvement in the WO-MAC pain score of <5 had the lowest sensitivity (0.31 [95% CI, 0.14 to 0.52]) for detecting dissatisfied subjects. A WOMAC pain score improvement of 20 had the highest Youden index of 49%. The composite outcome change in WOMAC=20.0 or PASS25 had the highest specificity (0.97 [95% CI, 0.95 to 0.99]) for detecting dissatisfaction as well as the highest positive predictive value (0.54 [95% CI, 0.35 to 0.71]) (Table III).

Figure 1 plots sensitivity versus 1 -specificity for the ability of incremental WOMAC pain improvement cutoffs and the metric cutoffs for residual pain to predict participants who

were dissatisfied. The thresholds with a Youden index close to 50% were the MIC21 (WOMAC pain improvement of >21.0) and MCID25 (WOMAC pain improvement of >25.0). Other metrics with a Youden index approaching the acceptable level were WOMAC pain score improvements of 20.0, which had a Youden index of 49%, and 25.0, which had a Youden index of 45%. The composite measurement combining WOMAC pain change of 20.0 and PASS25 score (where participants had to improve in the WOMAC pain score by 20.0 and have a score of at least the PASS value of 25.0) had a Youden index of 47% (Table III). The Youden index was 35% for the MCID11, 35% for a 30% percentage improvement in the WOMAC pain score of exceeding a meaningful within-person change (MWPC30%), and 38% for the MCIC31.25. The MID7.5 (an improvement exceeding a minimally important difference [MID] of 7.5) had a low Youden index of 27%. The Youden index for the incremental WOMAC pain score improvements ranged from 6% to 49% (Table IV).

Discussion

In this study, we determined the proportion of participants with residual pain at 1 year following TKA using various definitions of residual pain based on commonly used metrics.

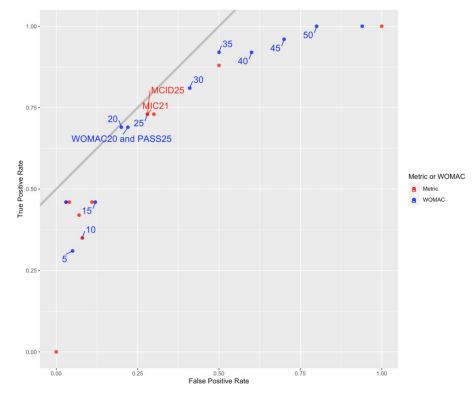


Fig. 1

Scatterplot showing the true-positive rate (sensitivity) and false-positive rate (1 -specificity) for various definitions of residual pain and dissatisfaction with TKA. The false-positive rate is plotted against the true-positive rate for each metric and each WOMAC pain improvement cutoff. The gray line represents a threshold with a Youden index of 50%. The points labeled MIC21, MCID25, and WOMAC 20 and PASS25 and WOMAC pain improvements of 20 and 25 have a Youden index close to 50%. WOMAC pain improvements of ≥ 5 are also labeled to show that increasing changes in the WOMAC pain score have increasing sensitivity and decreasing specificity for dissatisfaction. The red dots represent the metrics and metric composite thresholds as outlined in Tables II and III. The blue dots represent the incremental WOMAC pain score improvements and WOMAC composite thresholds as outlined in Tables III and IV.

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We found that the resulting prevalence of residual pain after TKA varied from 5.5% to >50.0%, depending on the definition. The dissatisfaction rate of 6.2% was lower than the 20.0% value that has been reported in the literature^{12,38}. No measure of residual pain that we considered was both highly sensitive and highly specific for dissatisfaction, suggesting that residual pain and dissatisfaction are related but distinct domains of the patient experience after TKA. A WOMAC pain score improvement of <20.0 appeared to provide the best balance between sensitivity and specificity with respect to predicting participant dissatisfaction, with a Youden index of 49%.

Our study complements findings by Beswick et al.9, who found a wide range (8% to 27%) of residual pain reporting in subjects assessed with various metrics in 11 distinct study populations across many countries. In a study of 53 participants undergoing viscosupplementation for knee osteoarthritis, Conrozier et al. reported that 90% of participants were satisfied if they met the PASS criterion of <40 for the WOMAC pain rating scale³⁹. They concluded that the PASS value more closely aligns with patient satisfaction than an absolute change in the WOMAC pain score³⁹. We found that 40% of participants who did not meet the PASS25 threshold were dissatisfied (positive predictive value, 0.4 [95% CI, 0.27 to 0.56]). Our study corroborates the findings by Beswick et al.9 that there is a wide variation in residual pain estimates and also suggests that the variation in residual pain estimates is due not solely to heterogenous cohorts but also to the variation in the methods employed.

By using incremental cutoffs for WOMAC pain, we showed that a reasonable compromise between sensitivity and specificity of residual pain metrics in estimating dissatisfaction appears to be an improvement in the WOMAC pain score in the range of 15 to 25 points (Table IV). For all commonly used metrics (e.g., the MCID), incremental improvements in WOMAC pain scores, and composite outcomes, the sensitivity was low, with wide 95% CIs (Tables II, III, and IV).

A limitation of the analysis was the loss to follow-up of 27% of the participants, as those who did not respond at 1 year did have a slightly worse baseline WOMAC pain score (48 compared with 40). We also determined satisfaction using only 2 satisfaction questions, and we acknowledge that a number of participants may be satisfied in other respects. We acknowledge that there may be a proportion of patients who are dissatisfied because of mechanical or biological implantation problems. Furthermore, our study only examined participants with residual pain. Residual pain can be used as a proxy for failure, but an individual's definition of dissatisfaction may be based on other variables, such as insufficient improvement in range of move-

ment or stiffness. A strength of our study, compared with others assessing residual pain, was that we assessed residual pain using a range of metrics in the same study sample, enabling us to disentangle heterogeneity due to the outcome metrics from that due to differences in the study samples^{9,40}.

In conclusion, the prevalence of residual pain is sensitive to the definition of residual pain. The heterogeneity of reported residual pain rates and in the outcome metrics on which they are based suggests a need for a more standardized method for using patient-reported outcome measures as measures of residual pain following TKA. In addition, a more robust measure of residual pain that better reflects patient satisfaction following TKA may be beneficial. Given that pain relief is the primary goal of participants who undergo TKA, an ideal residual pain metric would minimize the number of subjects with residual pain who report that they are satisfied and minimize the number of subjects without residual pain who are dissatisfied. Our data also support complementing residual pain metrics with other dimensions of well-being, such as satisfaction, in overall assessments of TKA

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References

5. Phillips JR, Hopwood B, Stroud R, Dieppe PA, Toms AD. The characterisation of unexplained pain after knee replacement. Br J Pain. 2017 Nov;11(4):203-9.

^{1.} Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample. 2018. Accessed 2023 Mar 3. https://hcup-us.ahrq.gov/nisoverview.jsp.

^{2.} National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. 16th Annual Report 2019. 2020. Accessed 2023 Mar 5. https://www.hqip.org.uk/wp-content/uploads/2020/10/njr-16th-annual-report-2019.pdf.

Ng CY, Ballantyne JA, Brenkel IJ. Quality of life and functional outcome after primary total hip replacement. A five-year follow-up. J Bone Joint Surg Br. 2007 Jul;89(7):868-73.
 Carr AJ, Robertsson O, Graves S, Price AJ, Arden NK, Judge A, et al. Knee replacement. Lancet. 2012 Apr 7;379(9823):1331-40.

openaccess.jbjs.org

6. Gunaratne R, Pratt DN, Banda J, Fick DP, Khan RJK, Robertson BW. Patient dissatisfaction following total knee arthroplasty: a systematic review of the literature. J Arthroplasty. 2017 Dec;32(12):3854-60.

7. da Silva RR, Santos AA, de Sampaio Carvalho Júnior J, Matos MA. Quality of life after total knee arthroplasty: systematic review. Rev Bras Ortop. 2014 Sep 19;49(5): 520-7.

8. Wylde V, Beswick A, Bruce J, Blom A, Howells N, Gooberman-Hill R. Chronic pain after total knee arthroplasty. EFORT Open Rev. 2018 Aug 16;3(8):461-70.

9. Beswick AD, Wylde V, Gooberman-Hill R, Blom A, Dieppe P. What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients. BMJ Open. 2012 Feb 22;2(1):e000435.

10. Petersen KK, Simonsen O, Laursen MB, Nielsen TA, Rasmussen S, Arendt-Nielsen L. Chronic postoperative pain after primary and revision total knee arthroplasty. Clin J Pain. 2015 Jan;31(1):1-6.

11. van der Wees PJ, Wammes JJ, Akkermans RP, Koetsenruijter J, Westert GP, van Kampen A, Hannink G, de Waal-Malefijt M, Schreurs BW. Patient-reported health outcomes after total hip and knee surgery in a Dutch University Hospital setting: results of twenty years clinical registry. BMC Musculoskelet Disord. 2017 Mar 3; 18(1):97.

12. Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KD. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? Clin Orthop Relat Res. 2010 Jan;468(1):57-63.

13. Maredupaka S, Meshram P, Chatte M, Kim WH, Kim TK. Minimal clinically important difference of commonly used patient-reported outcome measures in total knee arthroplasty: review of terminologies, methods and proposed values. Knee Surg Relat Res. 2020 Apr 9;32(1):19.

14. Lo LWT, Suh J, Chen JY, Liow MHL, Allen JC, Lo NN, Yeo SJ, Howe TS, Koh JSB. Early postoperative pain after total knee arthroplasty is associated with subsequent poorer functional outcomes and lower satisfaction. J Arthroplasty. 2021 Jul;36(7):2466-72.

15. Yang HY, Losina E, Lange JK, Katz JN, Collins JE. Longitudinal trajectories of pain and function improvement following total knee replacement. ACR Open Rheumatol. 2019 Jun 24;1(5):308-17.

16. Losina E, Collins JE, Daigle ME, Donnell-Fink LA, Prokopetz JJ, Strnad D, Lerner V, Rome BN, Ghazinouri R, Skoniecki DJ, Katz JN, Wright J. The AViKA (Adding Value in Knee Arthroplasty) postoperative care navigation trial: rationale and design features. BMC Musculoskelet Disord. 2013 Oct 12;14:290.

17. Losina E, Collins JE, Wright J, Daigle ME, Donnell-Fink LA, Strnad D, Usiskin IM, Yang HY, Lerner V, Katz JN. Postoperative care navigation for total knee arthroplasty patients: a randomized controlled trial. Arthritis Care Res (Hoboken). 2016 Sep; 68(9):1252-9.

18. Dave AJ, Selzer F, Losina E, Klara KM, Collins JE, Usiskin I, Band P, Dalury DF, lorio R, Kindsfater K, Katz JN. Is there an association between whole-body pain with osteoarthritis-related knee pain, pain catastrophizing, and mental health? Clin Orthop Relat Res. 2015 Dec;473(12):3894-902.

19. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009 Apr;42(2):377-81.

20. Berwick DM, Murphy JM, Goldman PA, Ware JE Jr, Barsky AJ, Weinstein MC. Performance of a five-item mental health screening test. Med Care. 1991 Feb;29(2): 169-76.

21. Kelly MJ, Dunstan FD, Lloyd K, Fone DL. Evaluating cutpoints for the MHI-5 and MCS using the GHQ-12: a comparison of five different methods. BMC Psychiatry. 2008 Feb 19;8(1):10.

22. Rumpf HJ, Meyer C, Hapke U, John U. Screening for mental health: validity of the MHI-5 using DSM-IV Axis I psychiatric disorders as gold standard. Psychiatry Res. 2001 Dec 31;105(3):243-53.

23. Sullivan MJ, Bishop SR, Pivik J. The Pain Catastrophizing Scale: development and validation. Psychol Assess. 1995;7(4):524.

 Kleiman V, Clarke H, Katz J. Sensitivity to pain traumatization: a higher-order factor underlying pain-related anxiety, pain catastrophizing and anxiety sensitivity among patients scheduled for major surgery. Pain Res Manag. 2011 May-Jun;16(3):169-77.
 Mahomed N, Gandhi R, Daltroy L, Katz JN. The self-administered patient satisfaction scale for primary hip and knee arthroplasty. Arthritis. 2011;2011:591253.
 Choi YJ, Ra HJ. Patient satisfaction after total knee arthroplasty. Knee Surg Relat Res. 2016 Mar;28(1):1-15. 27. Gademan MG, Hofstede SN, Vliet Vlieland TP, Nelissen RG, Marangvan de Mheen PJ. Indication criteria for total hip or knee arthroplasty in osteoarthritis: a state-of-the-science overview. BMC Musculoskelet Disord. 2016 Nov 9;17(1):463.
28. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. J Rheumatol. 1988 Dec;15(12):1833-40.

29. Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM. Measures of knee function: International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Score Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS). Arthritis Care Res (Hoboken). 2011 Nov;63(0 11)(Suppl 11):S208-28.

30. Clement ND, Bardgett M, Weir D, Holland J, Gerrand C, Deehan DJ. What is the minimum clinically important difference for the WOMAC Index after TKA? Clin Orthop Relat Res. 2018 Oct;476(10):2005-14.

31. Holtz N, Hamilton DF, Giesinger JM, Jost B, Giesinger K. Minimal important differences for the WOMAC osteoarthritis index and the Forgotten Joint Score-12 in total knee arthroplasty patients. BMC Musculoskelet Disord. 2020 Jun 23;21(1): 401.

32. Tubach F, Ravaud P, Baron G, Falissard B, Logeart I, Bellamy N, Bombardier C, Felson D, Hochberg M, van der Heijde D, Dougados M. Evaluation of clinically relevant states in patient reported outcomes in knee and hip osteoarthritis: the patient acceptable symptom state. Ann Rheum Dis. 2005 Jan;64(1):34-7.

33. Conaghan PG, Dworkin RH, Schnitzer TJ, Berenbaum F, Bushmakin AG, Cappelleri JC, Viktrup L, Abraham L. WOMAC meaningful within-patient change: results from 3 studies of tanezumab in patients with moderate-to-severe osteoarthritis of the hip or knee. J Rheumatol. 2022 Jun;49(6):615-21.

34. Kim MS, Koh IJ, Choi KY, Sung YG, Park DC, Lee HJ, In Y. The minimal clinically important difference (MCID) for the WOMAC and factors related to achievement of the MCID after medial opening wedge high tibial osteotomy for knee osteoarthritis. Am J Sports Med. 2021 Jul;49(9):2406-15.

35. Escobar A, Gonzalez M, Quintana JM, Vrotsou K, Bilbao A, Herrera-Espiñeira C, Garcia-Perez L, Aizpuru F, Sarasqueta C. Patient acceptable symptom state and OMERACT-OARSI set of responder criteria in joint replacement. Identification of cutoff values. Osteoarthritis Cartilage. 2012 Feb;20(2):87-92.

36. Schisterman EF, Faraggi D, Reiser B, Hu J. Youden Index and the optimal threshold for markers with mass at zero. Stat Med. 2008 Jan 30;27(2):297-315.
37. Jakubowski J, Kusy M, Migut G. Tutorial N. The Poland Medical Bundle. In:

Winters-Miner LA, Bolding PS, Hilbe JM, Goldstein M, Hill T, Nisbet R, Walton N, Miner GD, editors. Practical Predictive Analytics and Decisioning Systems for Medicine: Informatics Accuracy and Cost-Effectiveness for Healthcare Administration and Delivery Including Medical Research. New York: Academic Press; 2014. p. 697-725.

38. Nam D, Nunley RM, Barrack RL. Patient dissatisfaction following total knee replacement: a growing concern? Bone Joint J. 2014 Nov;96-B(11)(Supple A):96-100.

39. Conrozier T, Monet M, Lohse A, Raman R. Getting better or getting well? The Patient Acceptable Symptom State (PASS) better predicts patient's satisfaction than the decrease of pain, in knee osteoarthritis subjects treated with viscosupplementation. Cartilage. 2018 Oct;9(4):370-7.

40. DeFrance M, Scuderi G. Are 20% of patients actually dissatisfied following total knee arthroplasty? A systematic review of the literature. J Arthroplasty. 2023 Mar; 38(3):594-9.

41. Beaton DE, Boers M, Wells GA. Many faces of the minimal clinically important difference (MCID): a literature review and directions for future research. Curr Opin Rheumatol. 2002 Mar;14(2):109-14.

42. Maratt JD, Lee YY, Lyman S, Westrich GH. Predictors of satisfaction following total knee arthroplasty. J Arthroplasty. 2015 Jul;30(7):1142-5.

43. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. Control Clin Trials. 1989 Dec;10(4):407-15.

44. Kvien TK, Heiberg T, Hagen KB. Minimal clinically important improvement/difference (MCII/MCID) and patient acceptable symptom state (PASS): what do these concepts mean? Ann Rheum Dis. 2007 Nov;66(Suppl 3)(Suppl 3):iii40-1.