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Original Research

Preoperative Function Affects Ability to Achieve One-Year Minimum Clinically Important Difference for Patients Undergoing Total Knee Arthroplasty

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ABSTRACT

Background: Minimum clinically important difference (MCID) values are commonly used to measure treatment success for total knee arthroplasty (TKA). MCID values vary according to calculation methodology, and prior studies have shown that patient factors are associated with failure to achieve MCID thresholds. The purpose of this study was to determine if anchor-based 1-year Knee Injury and Osteoarthritis Outcome Score Joint Replacement (KOOS-JR) MCID values varied among patients undergoing TKA based on patient-specific factors.

Methods: This was a retrospective review of patients undergoing TKA from 2017-2018. Patients without baseline or 1-year KOOS-JR or Patient-Reported Outcome Measurement Information System Global Health data or that underwent procedures other than primary TKA were excluded. MCIDs were calculated and compared between patient groups according to preoperative characteristics.

Results: Among the included 976 patients, 1-year KOOS-JR MCIDs were 26.6 for men, 28.2 for women, 30.7 for patients with a diagnosis of anxiety and/or depression, and 26.7 for patients without a diagnosis. One-year MCID values did not differ significantly according to gender ($P = .379$) or mental health diagnosis ($P = .066$), nor did they correlate with body mass index ($\beta = -0.034$, $P = .822$). Preoperative KOOS-JR decile demonstrated an inverse relationship with 1-year MCID values and attainment of MCID.

Conclusions: The proportion of patients attaining KOOS-JR MCID values demonstrated an inverse relationship with preoperative baseline function. Future investigation may identify patient factors that allow surgeons to better capture patient satisfaction with their procedure despite failure to attain a 1-year MCID.

Introduction

Total knee arthroplasty (TKA) is the gold standard of treatment for end-stage knee osteoarthritis [1-3], with patient satisfaction rates reported ranging from 75%-92% [4]. Patient-reported outcome measures (PROMs) are increasingly being used to evaluate TKA outcomes and determine patient satisfaction and treatment success. To do so, these PROMs must demonstrate reliability, validity, and responsiveness [5-8]. For TKA patients, the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement 7-item form (KOOS-JR) demonstrates high responsiveness, validity, and reliability [9]. Additionally, PROMs that describe general health or quality of life have been validated for TKA outcomes. For example, the Patient-Reported Outcomes Measurement Information System Global Health 10-item form (PROMIS10) and some of its specific subscales, such as the physical health item (PROMIS10–Global

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Physical Health [GPH]), have been shown to be responsive for patients undergoing TKA [10,11]. With the increasing use of PROMs, it is important to use appropriate measurement instruments to determine treatment success for patients.

Despite the ubiquity of validated PROMs in evaluation of TKA outcomes, PROM scores may not necessarily indicate a patient-perceived clinical benefit. Parameters such as the minimum clinically important difference (MCID) attempt to address this issue [12]. MCID is a statistical measure that helps determine treatment success by describing the minimum PROM change perceived to be clinically meaningful to the patient [12]. However, MCID does have technical limitations. MCID values vary by population size, calculation methodology [13-16], and postoperative time period [15,16]. Recent studies have also shown that other baseline patient characteristics, such as body mass index (BMI) or preoperative PROM scores, may affect the attainment of MCID thresholds [17-21]. Two of the most common mental health diagnoses are depression and anxiety, with lifetime prevalences ranging from 6.8%-21.3% for depression and 5.4%-17.2% for anxiety [22]. Studies have shown that mental health status can affect postoperative PROM scores in total joint arthroplasty (TJA) [23-25].

Despite prior literature demonstrating that a variety of patient factors may affect attainment of MCID values in TJA patients, few, if any, studies have calculated MCID values specific to baseline patient characteristics. Patient-specific factor MCID values (eg, gender, BMI, mental health diagnoses) may help establish a more patient-specific outcome goal for treatment. Additionally, the calculation of more personalized MCID values will only increase in relevance with the integration of patient-reported outcomes into reimbursement policies in North America. The purpose of this study was to determine 1-year MCID values for KOOS-JR and evaluate for differences in patients undergoing TKA based on preoperative factors including gender, BMI, mental health diagnosis (anxiety and/or depression), and preoperative KOOS-JR, a proxy for functional status. It was hypothesized that differences in MCID values exist between patient factor cohorts.

Material and methods

Study design and setting

This was a retrospective review of prospectively collected data conducted in a multi-hospital healthcare system in a metropolitan area. An institutional review board determined that this study is exempt. The institutional PROM database was queried for all patients that underwent TKA from 2017-2018. Inclusion criteria consisted of patients undergoing primary TKA with completed baseline and 1-year PROM data. Patients undergoing procedures other than primary TKA and patients without baseline or 1-year KOOS-JR or PROMIS10 data were excluded. Any patients with an American Society of Anesthesiologists score $\geq$4 were also excluded to reduce the amount of possible confounding comorbidities.

Variables and outcome measures

The primary outcomes of this study were: (1) anchor-based MCID values, and (2) the proportion of patients attaining KOOS-JR MCID thresholds. Preoperative and 1-year KOOS-JR and PROMIS10 data were extracted from the PROM database. PROMs were distributed to patients electronically at regular intervals throughout the patient's 1-year episode of care. KOOS-JR MCID values were calculated according to the distribution method [26,27] and the anchor method [14] using one question from the PROMIS10-GPH portion as described in prior work [16]. The distribution method is calculated by halving the standard deviation of the change in KOOS-JR score from preoperative baseline to follow-up. There are a variety of ways to calculate MCID within the anchor method. Specifically, the average change approach was utilized to calculate the anchor-based MCID in this study. This method determines the MCID to be the average change in KOOS-JR scores in patients who report an increase in a particular question from the PROMIS10-GPH. The PROMIS10-GPH was chosen as the anchor PROM as it reliably measures patient-reported physical health outcomes [28-31], correlates well with the KOOS-JR [10], and exhibits high responsiveness for TKA patients [10,11]. One question was taken from the PROMIS10-GPH portion, which prompts, "In general, how would you rate your physical health?". This prompt is rated on a 5-point Likert scale with the answers "poor," "fair," "good," "very good," or "excellent." The MCID using the anchor-based approach was calculated for patients reporting a one- or 2-point increase in this specific question from the PROMIS10-GPH [32,33]. Additional variables of interest included (1) gender, (2) BMI, and (3) the presence of a mental health diagnosis (anxiety and/or depression).

Statistical analysis

Statistical analysis was conducted using STATA (SE version 17.0; StataCorp College Station, TX). A power analysis was conducted to determine the minimum sample size required to detect a difference between patients who met MCID and those who did not. This was found to be 125 patients per group (80% power, $\alpha = 0.05$). The aforementioned anchor-based MCID methodology [16] was employed to calculate MCID values for each group. Additionally, an average MCID consisting of the distribution and anchor-based methods was calculated. Summary statistics are reported as averages and standard deviations for continuous variables and counts and percentages for categorical variables. Patients were stratified into groups and compared according to gender (men vs women) and presence of a diagnosis of anxiety and/or depression (yes vs no). Student 2-sample *t*-tests and Pearson's Chi-square were conducted for continuous and categorical/binary variables, respectively, to identify significant between group differences. Simple linear regression evaluated the association between BMI and MCID value. Patients were separated into preoperative KOOS-JR score deciles, with the 10th percentile being the lowest and the 90th being the highest. This was a purposeful statistical treatment by the author group to allow for subgroup analysis of the ability to achieve a 1-year MCID based on preoperative KOOS-JR score. Significance was set at $P = .05$ (2 tails).

Results

A total of 3025 patients were identified, and 976 met inclusion criteria. Survey response rates for each time point were 29.0% at baseline and 26.7% at 1-year. There were 16 surgeons who were involved in this patient population. The cohort consisted of 61.8% women and had an average age of 65.9 $\pm$ 9.0 (range: 35-87). BMI was found to be 32.7 $\pm$ 6.2 (range: 18-58), and approximately 24.9% of patients had a mental health diagnosis. Average preoperative KOOS-JR was 51.8 $\pm$ 11.7, whereas the 1-year average KOOS-JR was 76.3 $\pm$ 14.5 (Table 1) (Fig. 1). The overall 1-year MCID for the anchor method was 27.6 and 8.2 for the distribution method. The average 1-year MCID for these 2 methods was 17.9 $\pm$ 9.7 (range: 8.2-27.6).

The 1-year MCID for KOOS-JR for men and women was 26.6 and 28.2, respectively (Table 2). Patients with a diagnosis of anxiety and/or depression had a 1-year MCID of 30.7, whereas patients without a mental health diagnosis had a 1-year MCID of 26.7 (Table 2). There were no significant differences in the calculated KOOS-JR 1-year MCID according to gender ($P = .379$) or mental

Table 1
Demographics of patients undergoing total knee arthroplasty.

Demographic factor	Count (N = 976)[a]
Age	65.9 (35-87)
<50	27 (2.8)
50-59	194 (19.9)
60-69	424 (43.4)
>70	331 (33.9)
Gender	
Male	373 (38.2)
Female	603 (61.8)
BMI	32.7 (18-58)
<18.5	1 (0.1)
18.5-24.9	86 (8.9)
25.0-29.9	263 (27.1)
30.0-34.9	286 (29.5)
35.0-39.9	210 (21.6)
>40	125 (12.9)
Mental health diagnosis	
None	733 (75.1)
Depression alone	126 (12.9)
Anxiety alone	46 (4.7)
Both	71 (7.3)
Preoperative KOOS-JR	51.8 ± 11.7
1-y KOOS-JR	76.3 ± 14.5
1-y MCID: Anchor method	27.6
1-y MCID: Distribution method	8.2

[a] Continuous data is reported as mean ± S.D. or mean (range). Categorical data is reported as N/n (%).

Table 2
MCID values and attainment according to patient factors in patients undergoing TKA (N = 976).

	1-y MCID	Achieved 1-y MCID	Beta coefficient	*P* value[a]
Gender			-	.379
Male	26.6	131 (35.1)		
Female	28.2	231 (38.3)		
Mental health diagnosis			-	.066
Yes	30.7	100 (41.2)		
No	26.7	262 (35.7)		
BMI	-	-	−0.034	-

Continuous data is reported as mean ± S.D. Categorical data is reported as N/n (%).
[a] Statistical analyses for gender and mental health diagnosis included the Student's T-test and Pearson's Chi-square. BMI was evaluated using simple linear regression.

health diagnosis ($P = .066$). BMI similarly did not correlate with MCID value ($\beta = -0.034$, $P = .822$) (Table 2). The proportion of patients attaining KOOS-JR MCID thresholds and the proportion of patients reporting clinically meaningful improvements per the anchor question demonstrated an inverse relationship with preoperative KOOS-JR score deciles (Figs. 2 and 3). Patients in the lower deciles of patient function achieved 1-year MCID values in proportions of 80% for the 10th percentile, 53% for the 50th percentile, and 24% for the 70th percentile. No patients with a baseline KOOS-JR greater than the 80th percentile attained a 1-year MCID threshold value. Similarly, patients in the lower deciles of patient function reported clinically meaningful improvements as measured by the PROMIS10-GPH anchor question value in proportions of 40% for the 10th percentile, 36% for the 50th percentile, and 28% for the 70th percentile. No patients in the 80th or greater percentile attained clinically meaningful improvements as measured by the anchor question. Patients reporting clinically meaningful improvements per the physical health anchor question that did not meet MCID were identified. Specifically, despite only 14% of them achieving MCID, approximately 23% of patients in the 70th decile reported clinically meaningful improvements based on their responses to the PROMIS10 anchor question (Figs. 2 and 3).

Discussion

TKA clinical outcomes are increasingly being evaluated in the context of PROMs and their respective MCIDs to determine treatment success. MCID values are thought to be inherent to the measuring instrument and broadly applicable to patients. A growing body of literature demonstrates that MCID values vary by calculation methodology, cohort size, and follow-up time [13,14,16,34]. Studies have found that patient characteristics are associated with failure to achieve an MCID threshold [17-20,25,35-37]. One-year MCID for KOOS-JR was calculated and compared between different patient cohorts. There were no significant differences in MCID values based on gender, mental health diagnosis,

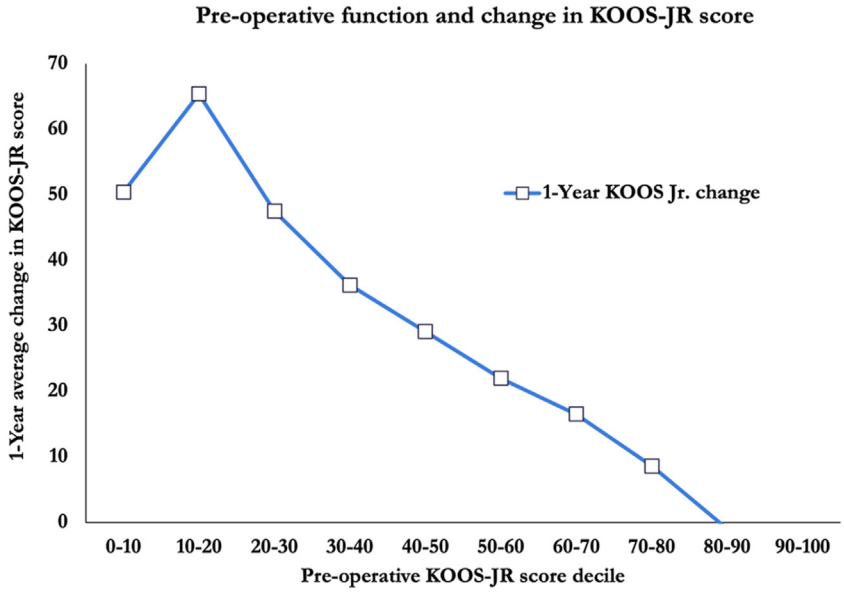

Figure 1. This line graph represents the average 1-year change in KOOS-JR score (light blue) across the spectrum of preoperative KOOS-JR scores.

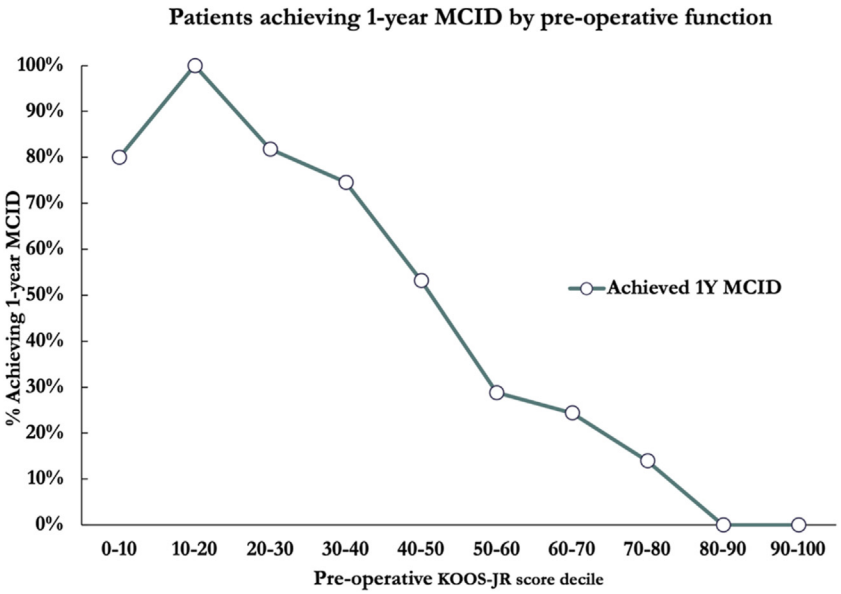

Figure 2. This line graph represents the proportion of patients reporting 1-year KOOS-JR changes above the MCID threshold (green) across the spectrum of preoperative KOOS-JR scores. 1Y, one-year.

or BMI. With increasing preoperative KOOS-JR scores, a proxy for functional status, MCID values, and the likelihood of attaining these decreases. There were patients among the 70th percentile for baseline KOOS-JR that endorsed clinically meaningful improvements but did not meet MCID.

Although direct comparison is somewhat challenging due to variation in the evaluated anchor questions and follow-up time, prior works have used other physical health and quality-of-life forms to calculate anchor-based MCIDs [11,14,34,38]. Lyman et al. used the Hospital for Special Surgery Satisfaction Survey as an anchor and reported a KOOS-JR MCID value of 14.0 [14]. Lyman et al. also showed a large range of calculated anchor-based and distribution-based MCID values (7-36 and 6-9, respectively). Deckey et al. conducted a systematic review of MCIDs in TKA and found that anchor-based MCIDs were typically higher than distribution-based MCIDs as was found in this study [39]. They also found the interquartile ranges for the anchor-based KOOS-JR were larger than distribution-based MCID [39]. Kuo et al. used the Self-Administered Patient Satisfaction Scale as an anchor for KOOS-JR and reported MCID values from 17.5 to 20.8 [34]. Goodman et al. estimated the MCID for the pain and function scales of KOOS at greater than 23.0 and 18.0, respectively, using the Short Form 12 [11]. Using the anchor methodology that was employed for this study, Only et al. calculated a 1-year MCID value of 27.9 and 8.2 with the distribution method for KOOS-JR [16]. It is evident that KOOS-JR MCID values vary depending on the anchoring question chosen and the calculation method. Validation of any one of these methodologies would be useful to surgeons hoping to include MCIDs in their clinical practice.

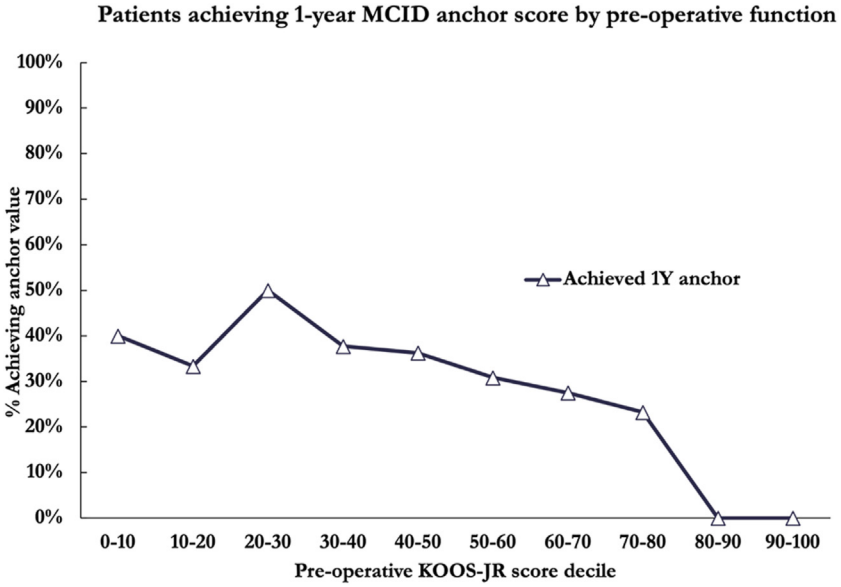

Figure 3. This line graph represents the proportion of patients reporting 1- or 2-point improvements in physical health (dark blue) per the PROMIS10 anchor question across the spectrum of preoperative KOOS-JR scores. 1Y, one-year.

Various patient characteristics have been associated with a decreased likelihood of attaining PROM score improvements above the MCID threshold for TKA patients [17-20,25,35-37]. In contrast to the results of this study, increased BMI, particularly a BMI ≥40, has been associated with failure to achieve KOOS MCID [18,19]. These differences in results are possibly explained by differing MCID calculation methodologies employed by these studies. Katakam et al. used a distribution-based methodology for the KOOS Physical Function Short Form in one study [18], while the other [19] used an anchor-based MCID value anchored to PROMIS Physical Function calculated by Hung et al. [13]. Gender has also been found to affect MCID achievement [35,37]. This study found that there were no significant differences in MCID values or MCID achievement between genders. However, Carender et al. [37] used both a distribution-based MCID and the anchor-based MCID proposed by Lyman et al. [14]. Katakam et al. similarly used a distribution-based method [35]. Although Berliner et al. found that MCID threshold varied according to Short Form 12 mental component summary [25], this study found that there was no difference in MCID value between patients with and without a mental health diagnosis, specifically anxiety and/or depression. However, Berliner et al. evaluated mental health using a distribution-based approach [25]. The conflicting results between this study and the literature and even among the literature indicate the need for standardizing calculation methods when evaluating patient characteristics and their effect on MCID.

Regarding preoperative PROM scores, several studies associate lower KOOS and PROMIS scores with a higher likelihood of MCID achievement [17,20,35,36]. Although this study did not conduct comparative statistical analysis regarding preoperative function, it similarly found that patients with lower preoperative scores appeared to have more frequently achieved 1-year MCID values. Based on this study's calculated MCID of 27.6 for the overall sample, patients with preoperative function greater than the 70th decile would not be expected to achieve a 1-year MCID. However, 23% of patients within the 70th decile in this study reported clinically meaningful improvements based on their responses to the PROMIS10 physical health anchor question, despite not all achieving KOOS-JR values above the MCID threshold. This may suggest that meaningful clinical improvements in this study could not be captured by an overall cohort MCID value. KOOS-JR has been found to exhibit sizable ceiling effects as early as 1 year after TKA [40]. Lyman et al. found a ceiling effect of 20% and suggested that the KOOS-JR is likely an inadequate measure for high-functioning, younger patients [9]. This inability to distinguish patient improvement in a higher-functioning patient population emphasizes the necessity of generating more patient-specific MCID values. This study did not determine the patient factors contributing to baseline functional status as measured by KOOS-JR. However, numerous patient, environmental, and social factors contribute to baseline patient functional status and ultimately may help determine patient-specific MCID values. PROMs and MCIDs are increasingly being used to determine successful orthopedic outcomes, insurance prior authorization, and surgeon and hospital reimbursement policies. [34,41,42] Understanding PROMs and MCIDs will therefore continue to increase in importance, especially concerning TJA, as the Centers for Medicare and Medicaid Services further incorporate them into reimbursement. It is imperative that the surgical community determine, in collaboration with patients, the definition of a successful surgical outcome rather than having this dictated by administrators and/or insurance companies. Defining patient-specific MCIDs may be a preliminary step in achieving this imperative.

This study has limitations. There is no standardized best approach to calculating an anchor-based MCID, and no anchor-based methodology has been specifically validated. This study builds upon prior work [16] and deliberately uses a reliable and responsive measure for the anchor PROM (PROMIS10). MCID values vary depending on calculation methodology [13-16], and there is currently no single best practice or choice of anchor question for calculating anchor-based MCIDs. This study chose to calculate KOOS-JR MCIDs via the distribution-based method as well as an anchor-based method using a question from the PROMIS10-GPH, a metric shown to be a valid measure of physical health [28-31]. An appropriate anchor choice should at minimum correlate 0.50 with the instrument [43]. A previous study demonstrated that PROMIS10-GPH correlates greater than 0.50 at preoperative baseline and at 1-year follow-up [10]. Paulsen et al. suggested that choosing the anchor question should depend on whether the aim of the study is to analyze the effect of surgery on a specific body part or more broadly, such as the effect of the surgery on overall health [44]. This study sought to determine the effect of TKA on the patient's physical health, hence the use of a prompt from the PROMIS10-GPH.

This study also did not account for multiple important patient, surgeon, and treatment covariates that may have acted as confounders. Some examples include surgeon experience and training, rehabilitation protocol, facility level of acuity, and the presence of other mental health diagnoses. Mental health diagnoses are also multiple, frequently interrelated, and exist on a spectrum. Every effort was made to accurately record mental health diagnoses based on the available data in the electronic medical record. Although only depression and anxiety were chosen from the many mental health diagnoses that exist, these were chosen due to their relatively higher incidence compared to other diagnoses in this population. There was a large exclusion of patients; however, sufficient patients were included based on power analyses with a medium effect size. The patients in this study may not be reflective of many populations or many arthroplasty practices across the country, as the average BMI was found to be 32.7 ± 6.2. This relatively lower average BMI may limit the interpretation of the results. Another limitation of this study is a follow-up period of 1 year. As stated previously, MCID scores are affected by the follow-up period. Lyman et al. used a 2-year follow-up period, whereas this study used a 1-year follow-up period [14]. Significant MCID value and attainment differences may exist at 2 years, which was outside the scope of this study. As stated, there has been no gold standard set for how MCID is calculated, and this study can provide a picture of patient progress at the 1-year mark. Finally, the use of a single healthcare system in one metropolitan area and the exclusion of patients undergoing revision procedures with an American Society of Anesthesiologists score ≥4 impact the generalizability of the results.

Conclusions

This study evaluated 1-year MCID values for KOOS-JR in the context of patient-specific factors including gender, the presence of a mental health diagnosis, BMI, and preoperative KOOS-JR. No significant association was found between anchor-based MCID values and gender, mental health diagnosis, or BMI. Attainment of MCID values decreases with increasing preoperative KOOS-JR scores, a proxy for baseline functional status. Future investigation should focus on validating and standardizing MCID calculation methodologies for KOOS-JR, one of the most common PROM instruments for patients undergoing TKA. Furthermore, the medical community must identify which patient, environmental, and social factors may significantly contribute to baseline functional status

and MCID to determine if an individualized MCID is both technically valid and feasible.

Conflicts of interest

B. Cunningham received research support from Integra; his spouse is the founder/CEO of CODE Technology, and this has no conflict with the submitted work. P. Horst's siblings are employees of Arthrex, and there is no conflict within the submitted work. All other authors declare no potential conflicts of interest.

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CRediT authorship contribution statement

Patrick Albright: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Validation, Writing – original draft, Writing – review & editing. **Fernando A. Huyke-Hernández:** Formal analysis, Investigation, Methodology, Validation, Writing – original draft, Writing – review & editing. **Andrew Ormseth:** Conceptualization, Investigation, Methodology, Supervision, Writing – review & editing. **Stephen A. Doxey:** Methodology, Validation, Writing – original draft, Writing – review & editing. **Evan Banks:** Data curation, Investigation, Project administration, Validation, Writing – review & editing. **Arthur J. Only:** Data curation, Supervision, Writing – original draft, Writing – review & editing. **Patrick K. Horst:** Conceptualization, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Brian P. Cunningham:** Conceptualization, Investigation, Methodology, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

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