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# How Do Patients Above Patient Acceptable Symptom State Pre-Operatively Recover Following Total Knee Arthroplasty?

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**Abstract:** Background/Objectives: Patient acceptable symptom state (PASS) thresholds have been used as a marker of good functional outcome following total knee arthroplasty (TKA) but have not been applied to pre-operative subjective function. This study aimed to compare the outcomes of patients above and below PASS thresholds prior to TKA. Methods: A secondary analysis of a multicenter prospective observational study was used, including 1182 patients prescribed a smartphone-based care management platform following TKA with pre-operative and 1-year KOOS JR scores available. Patient demographics, pain, satisfaction, and KOOS JR were compared between those above and below PASS pre-operatively by student *t*-test. Logistic regression was used to quantify the odds of decline or no improvement at 1 year. Results: In this cohort, 191 (16.2%) KOOS JR scores were above PASS thresholds prior to TKA. Those above PASS reported lower pain pre-operatively ($3.7 \pm 1.9$ vs. $6.0 \pm 1.9$, $p < 0.0001$) and less pain reduction at 90 days ($-1.4 \pm 2.5$ vs. $-3.2 \pm 2.6$, $p < 0.0001$). Patients above PASS also demonstrated higher KSS satisfaction scores pre-operatively ($20.7 \pm 7.9$ vs. $12.1 \pm 6.7$, $p < 0.0001$) with less improvement ($9.9 \pm 10.6$ vs. $16.5 \pm 11.2$, $p < 0.0001$) at 90 days. In logistic regression, those above PASS pre-operatively were 5.1 times more likely to report a decline or no improvement in KOOS JR at 1 year (5.10 95% CI 2.73–9.53, $p < 0.0001$). Conclusions: Patients above previously defined PASS thresholds who presented for TKA appreciated less improvement in pain and satisfaction and were more likely to experience functional decline or no improvement in KOOS JR post-operatively. The application of PASS thresholds pre-operatively may be useful for patient selection or guidance of patient expectations.

**Keywords:** patient acceptable symptom state; patient-reported outcomes; total knee arthroplasty; functional decline



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## 1. Introduction

Despite advancements in total knee arthroplasty (TKA) techniques and implant designs, approximately 20% of patients remain dissatisfied following surgical intervention [1–3]. Authors have suggested this may be related to patient selection, with as many as 30% of surgeries being potentially inappropriate [4,5]. Research has demonstrated that patients whose interventions were considered inappropriate reported less functional improvement and lower satisfaction following TKA [6].

Methods for measuring improvement and assigning success of procedures have focused on both the "journey" (feeling better) [7] and the "destination" (feeling well) [8]. The use of minimal clinically important difference (MCID) and substantial clinical benefit (SCB) are often applied to quantify improvement [9], while patient acceptable symptom state (PASS) thresholds have been determined for several outcome measures to categorize success [10–13]. An increased likelihood of achieving MCID has been observed in patients with lower baseline function pre-operatively [14,15]. However, those with higher function

prior to TKA appear more likely to reach PASS post-operatively, highlighting the difficulty of balancing the importance of the journey and the destination as markers of success [4,16].

Given the increased potential for improvement in those with lower pre-operative function, some commercial insurers in the United States and national programs outside the U.S. have proposed maximum thresholds for access to TKA, measured via patient-reported outcome measures (PROMs) [17,18]. Critics applying arbitrary cutoffs for pre-operative PROMs suggest a significant proportion of patients who would be denied intervention would benefit from the procedure and achieve a satisfactory result. While complication and readmission rates were similar in these denied groups [18], we are unaware of any studies that have investigated the proportion of patients likely to experience a decline in function following TKA.

As PASS thresholds are considered the highest level of symptom in which a person considers themselves to be well and potentially the functional goal post-operatively, this may be a reasonable theoretical threshold to apply as a proxy for surgical appropriateness. This study aims to determine the proportion of patients with pre-operative PROMs above the PASS threshold who undergo TKA and investigate the odds of functional decline or lack of improvement as evidenced by post-operative PROMs. We hypothesize that patients who reported pre-operative function at or above PASS values would demonstrate less average improvement in PROMs, pain, and satisfaction.

## 2. Methods

This was a secondary analysis of a multicenter prospective longitudinal study of patients prescribed a smartphone-based care management platform for self-directed rehabilitation following primary total knee arthroplasty (NCT#03737149). Patients were required to be over 18 years of age, suitable for home rehabilitation at the surgeon's discretion, own an iPhone® (Apple Inc., Cupertino, CA, USA) capable of pairing with the Apple Watch®, and be ambulatory with the use of a single cane or crutch pre-operatively. Patients who were participating in pain management or other physical therapy trials, were current drug or alcohol abusers, or planned simultaneous bilateral arthroplasty or staged $\leq$90 days apart were not eligible for enrollment. All patients were provided a smartwatch for continuous passive collection of objective mobility data and were required to download the application at least 14 days prior to surgery to complete pre-operative education, exercises, and completion of PROMs. Knee Injury and Osteoarthritis Outcome Score—Joint Replacement (KOOS JR) surveys were delivered via the mobile application with push notification reminders or could be completed via paper during in-clinic evaluations. Additional surveys were completed via an electronic data collection platform (iMednet, Minnetonka, MN, USA). All patients were treated according to each institution's standard of care, including peri- and post-operative analgesics.

Clinic staff recorded patient age, body mass index (BMI), race, and comorbid conditions upon enrollment. Race was recategorized as white vs. non-white. Presence of congestive heart failure; coronary artery or valve disease; diabetes; chronic pulmonary disease including asthma, chronic bronchitis, COPD or emphysema; dementia or Alzheimer's disease; previous stroke or transient ischemic attack; muscular dystrophy; previous cervical spinal surgery; previous lumbar spinal surgery; history of cancer; chronic kidney disease; liver disease; rheumatoid arthritis; or paralysis were aggregated to create a continuous variable for comparison and inclusion in multivariate models. The average daily step count was collected via smartwatch and averaged over seven days prior to TKA. Patients reported pain on the 0–10-point numeric rating scale (NRS), anxiety via the General Anxiety Disorder-7 (GAD-7) questionnaire, and knee function satisfaction (KSS satisfaction subscale) pre-operatively and at 30 and 90 days post-operatively. KOOS JR and EQ-5D-5L were delivered pre-operatively and at 1, 3, 6, and 12 months post-operatively. Clinic staff reported adverse events post-operatively; TKA-related complications (manipulation under anesthesia, wound healing complications, revision) were compared between groups to further investigate whether functional declines were related to post-operative events.

A total of 1182 patients from 27 individual sites in the United States and Australia who underwent TKA between November 2018 and November 2022 completed both the pre- and post-operative KOOS JR and were included in this analysis (Figure 1). Patients were not included if no objective mobility data was transmitted to ensure that only patients who logged in and utilized the application were analyzed. In addition, bilateral arthroplasty cases during the study period were excluded as it is unknown how subsequent surgery may impact recovery of the initial procedure. Patients who were above the PASS threshold pre-operatively were older (66.5 ± 8.0 vs. 63.9 ± 8.7, $p = 0.0002$), with lower BMI (29.9 ± 6.0 vs. 31.9 ± 6.3, $p < 0.0001$), and more frequently male (56.0% vs. 44.0%, $p < 0.0001$). Similar proportions of patients above and below PASS pre-operatively reported white race (90.6% vs. 96.2%, $p = 0.10$).

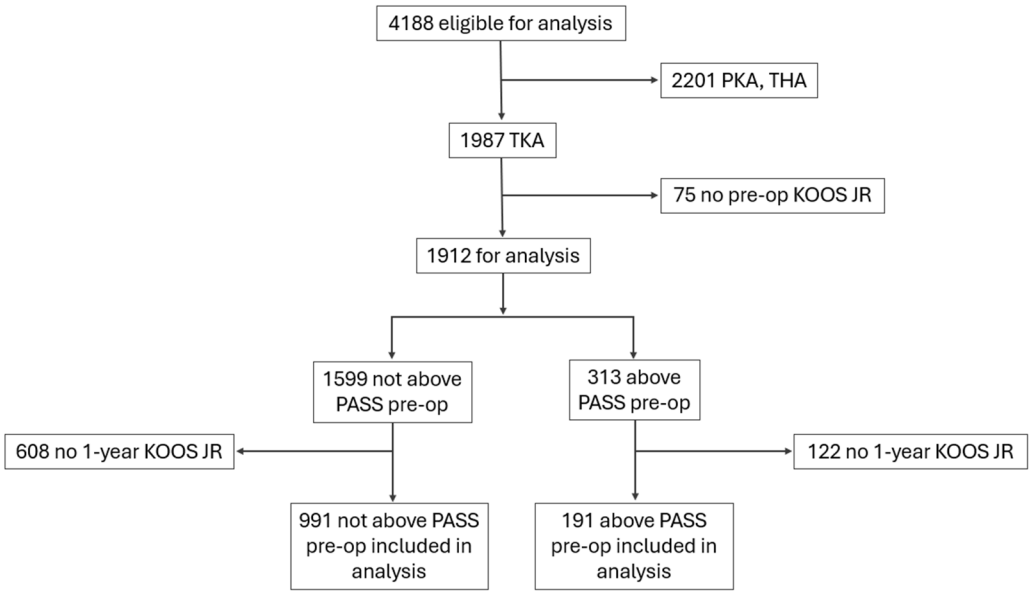



**Figure 1.** Patient flowchart.

*Statistical Analysis*

Pre-operative KOOS JR scores were categorized as above or below PASS (63.7 points) to create two groups for comparison and a categorical predictor of functional decline [10]. Change from baseline to 1-year function was categorized as either improvement or decline/no improvement (net negative or zero change on KOOS JR from pre-operative). KSS satisfaction scores were converted to a dichotomous variable, where ≥30 points were categorized as satisfied [19,20]. Continuous variables are reported as mean ± SD and were compared by student *t*-tests. Categorical variables are presented as frequency and percent and were compared by chi-square test or Fisher's Exact test, where appropriate. Logistic regression models were created, including baseline patient characteristics, to investigate the impact of pre-operative PASS status on odds of satisfaction at 90 days and functional decline at 1 year. All analyses were performed with SAS version 9.4 (2013, SAS Institute, Inc., Cary, NC, USA); a $p$-value < 0.05 was considered statistically significant.

## 3. Results

A total of 191 (16.2%) patients who were eligible for analysis were above the PASS threshold prior to TKA and demonstrated higher KOOS JR (68.5 ± 5.0 vs. 48.7 ± 10.0, $p < 0.0001$), KSS satisfaction (20.7 ± 7.9 vs. 12.1 ± 6.7), EQ-5D-5L index scores, and step counts pre-operatively (Table 1). Those below PASS prior to intervention reported higher pain (6.0 ± 1.9 vs. 3.7 ± 2.0, $p < 0.0001$) and anxiety scores; average comorbidities were similar between groups.

**Table 1.** Patient demographics by pre-operative PASS threshold status.

| | Not Above PASS Pre-Operatively | Above PASS Pre-Operatively | *p*-Value |
|---|---|---|---|
| Sex | | | |
| Female<br>Male | 652 (65.79)<br>339 (34.21) | 84 (43.98)<br>107 (56.02) | <0.0001 |
| Race—white | 854 (86.18) | 173 (90.58) | 0.10 |
| Age | 63.90 ± 8.66 (991, 21.73–87.18) | 66.45 ± 7.96 (191, 43.05–85.57) | 0.0002 |
| BMI | 31.87 ± 6.32 (991, 15.06–57.15) | 29.85 ± 5.97 (191, 8.56–57.98) | <0.0001 |
| Comorbidity score | 1.00 ± 1.30 (991, 0–9.00) | 0.99 ± 1.36 (191, 0–8.00) | 0.93 |
| Average steps pre-op | 5251 ± 2872 (976, 270–20,182) | 6244.8 ± 3562.5 (188, 666–30,705) | 0.0004 |

At 30 and 90 days post-operatively, patients who were below the PASS threshold pre-operatively continued to report higher pain and lower KSS satisfaction (Figures 2 and 3). However, this group demonstrated greater reductions in pain than those who were above PASS prior to TKA, as well as greater improvements in satisfaction. Similarly, patients above PASS pre-operatively reported higher KOOS JR (Figure 4) and EQ-5D-5L (Figure 5) scores throughout the entire study period but demonstrated less improvement in each measure at each interval.

At 1 year post-operatively, 56 patients within the entire cohort (4.7%) reported no net improvement or functional decline on KOOS JR. The proportion of patients who were above the PASS threshold pre-operatively and did not appreciate improvement was significantly greater than those who were below the PASS threshold before TKA (13.1% vs. 3.1%, $p < 0.0001$). At 1 year post-operatively, 15 (7.9%) patients whose KOOS JR were above symptom thresholds before surgery reported no or negative score change compared to 21 (2.1%) of those who were below PASS before TKA ($p = 0.0002$). Of those who were above PASS pre-operatively, only 57.1% met MCID (14 points) at one year, compared to 86% of patients who were below PASS before surgery ($p < 0.001$). However, those above PASS before TKA were more likely to fall into this category at one year after surgery (96.9% vs. 89.1%, $p < 0.001$).

On logistic regression considering baseline characteristics (Figure 6), only pre-operative PASS status was significantly associated with odds of no improvement or decline on KOOS JR at 1 year (OR 5.10 95% CI 2.73–9.53, $p < 0.0001$). BMI, age, and pre-operative patient-reported anxiety were not independent predictors of lack of improvement, though comorbidities and race trended toward significance (both, $p = 0.06$). Considering only those who reported no improvement or a decline in function, fewer of those who were above the PASS threshold pre-operatively experienced a knee-related event with the potential to impact the report of function (14.3% vs. 34.3%, $p = 0.009$).

While those below PASS prior to TKA reported greater improvements in KSS satisfaction subscale scores at 90 days post-operatively (16.5 ± 11.2 vs. 9.9 ± 10.6, $p < 0.0001$), those whose KOOS JR scores were above PASS prior to intervention continued to report higher satisfaction scores post-operatively, and a larger proportion were considered satisfied (65.2% vs. 56.7%, $p = 0.02$). However, in the logistic regression, only sex was significantly associated with odds of satisfaction; males were more likely to report satisfaction at 90 days post-operatively (Figure 7).

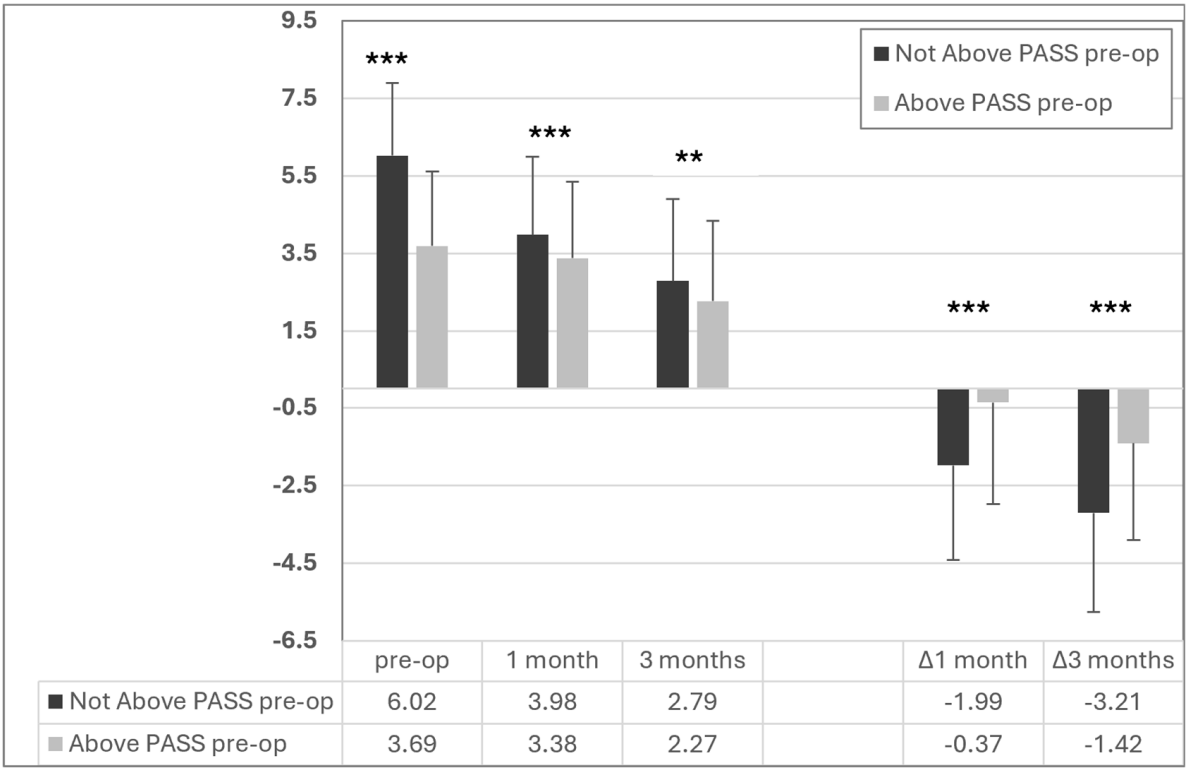



**Figure 2.** Numeric pain rating and change over time according to pre-operative PASS status. ** $p < 0.01$, *** $p < 0.001$.

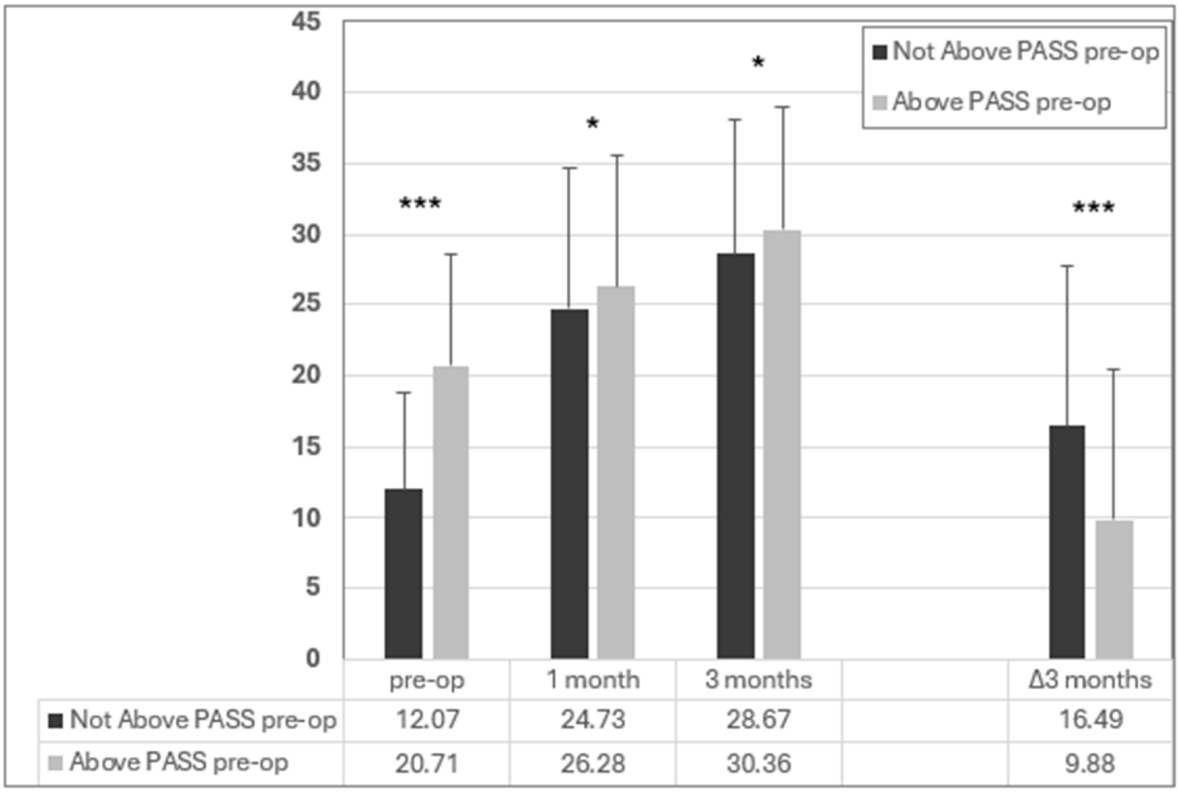
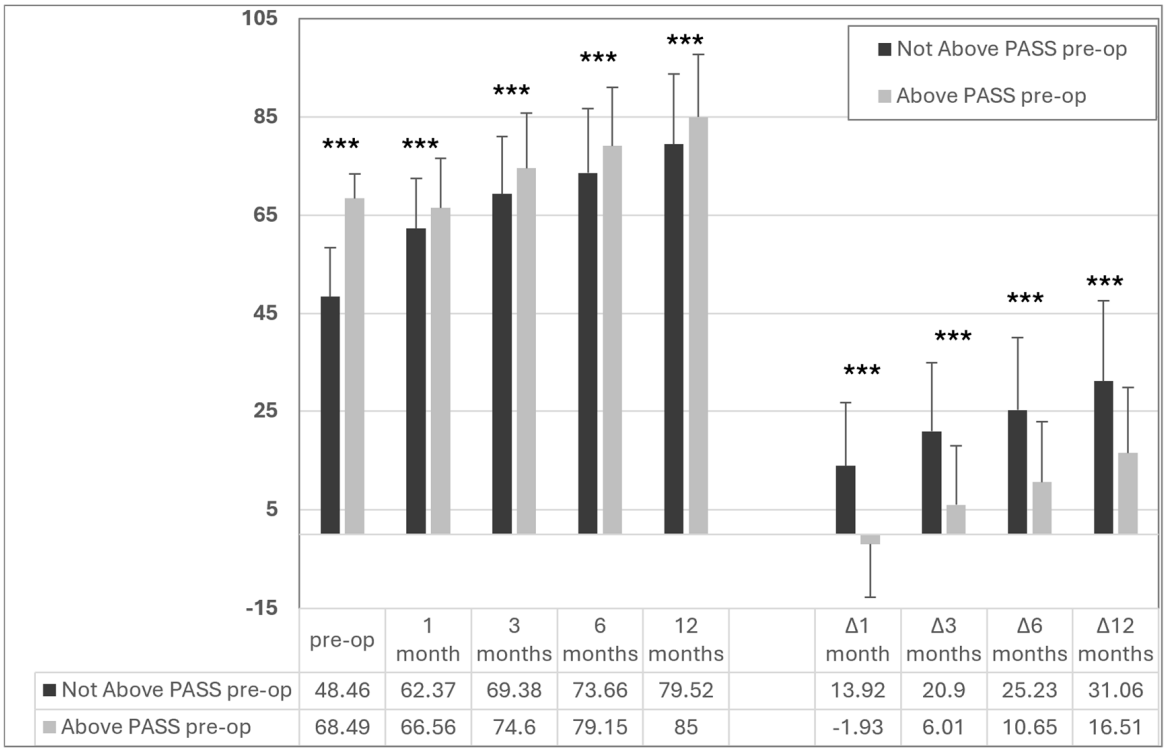
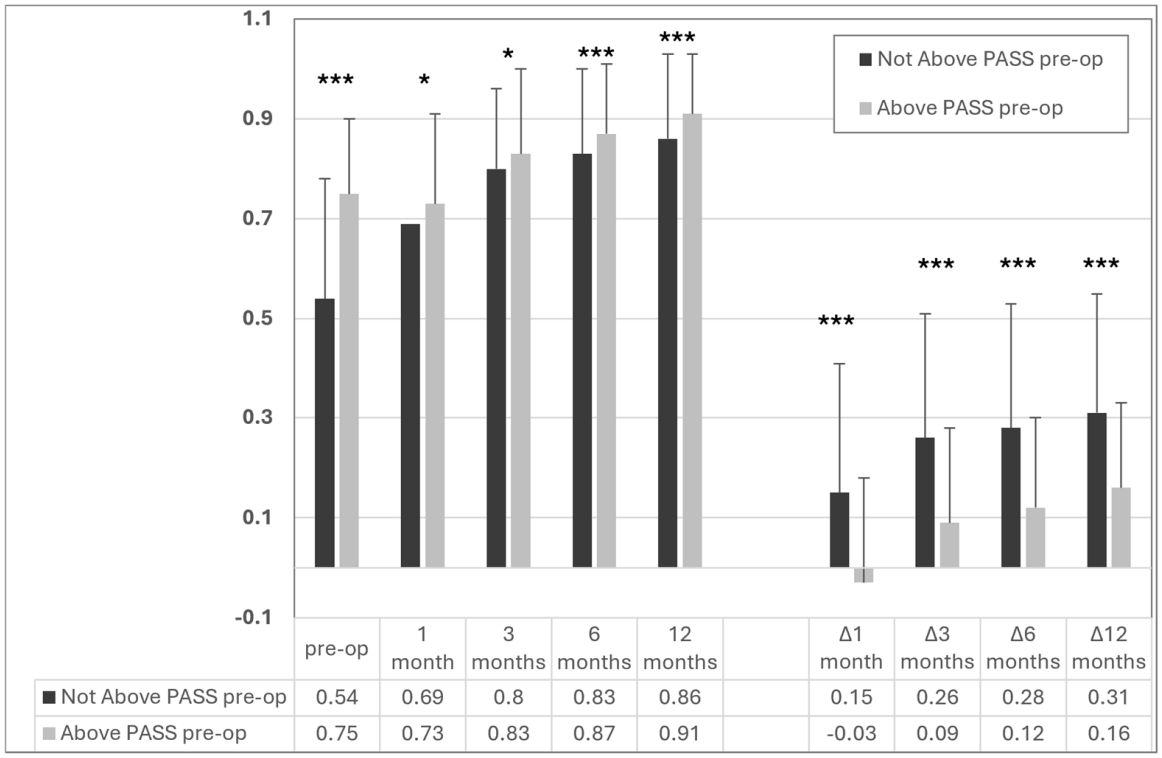



**Figure 3.** Knee Satisfaction score and change over time according to pre-operative PASS status. * $p < 0.05$, *** $p < 0.001$.



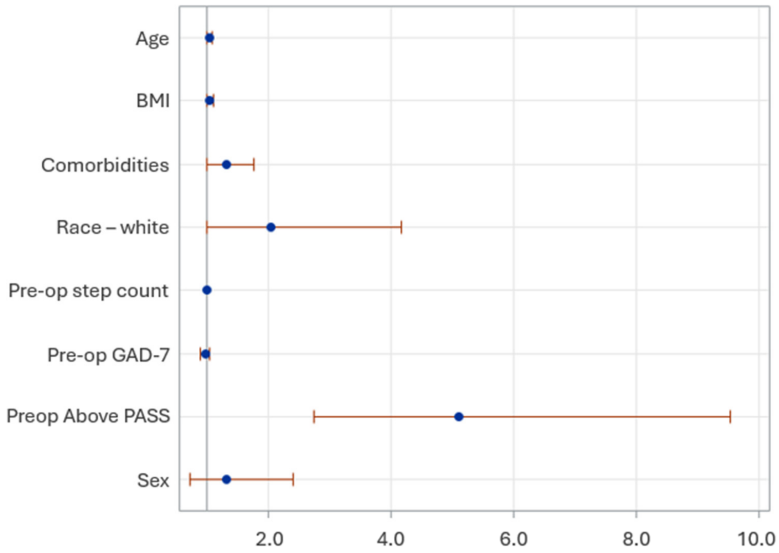

| | pre-op | 1 month | 3 months | 6 months | 12 months | | Δ1 month | Δ3 months | Δ6 months | Δ12 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Not Above PASS pre-op | 48.46 | 62.37 | 69.38 | 73.66 | 79.52 | | 13.92 | 20.9 | 25.23 | 31.06 |
| Above PASS pre-op | 68.49 | 66.56 | 74.6 | 79.15 | 85 | | -1.93 | 6.01 | 10.65 | 16.51 |

**Figure 4.** KOOS JR scores and changes over time according to pre-operative PASS status. *** $p < 0.001$.



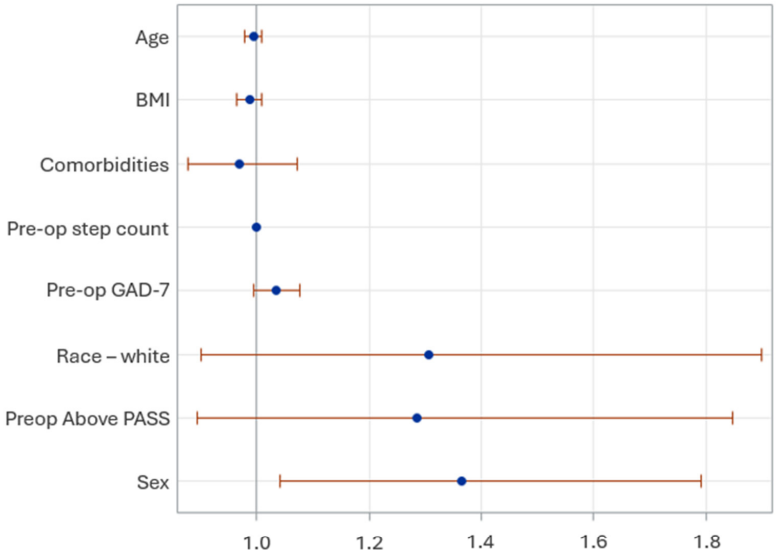

| | pre-op | 1 month | 3 months | 6 months | 12 months | | Δ1 month | Δ3 months | Δ6 months | Δ12 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Not Above PASS pre-op | 0.54 | 0.69 | 0.8 | 0.83 | 0.86 | | 0.15 | 0.26 | 0.28 | 0.31 |
| Above PASS pre-op | 0.75 | 0.73 | 0.83 | 0.87 | 0.91 | | -0.03 | 0.09 | 0.12 | 0.16 |

**Figure 5.** EQ-5D-5L scores and changes over time according to pre-operative PASS status. * $p < 0.05$, *** $p < 0.001$.




| Characteristic | Odds ratio (95% CI) | p-value |
|---|---|---|
| Age | 1.03 (0.99 – 1.07) | 0.10 |
| BMI | 1.04 (0.99 – 1.10) | 0.14 |
| Comorbidities | 1.32 (0.99 – 1.76) | 0.06 |
| Race - white | 2.02 (0.98 – 4.16) | 0.06 |
| Pre-operative step count | 1.00 (1.00 – 1.00) | 0.13 |
| Pre-operative GAD-7 | 0.96 (0.88 – 1.04) | 0.33 |
| Pre-op Above PASS | 5.10 (2.73 – 9.53) | <0.0001 |
| Sex | 1.30 (0.71 – 2.40) | 0.40 |

**Figure 6.** Logistic regression investigating characteristics associated with decline in function or zero net improvement in KOOS JR at 1 year post-operatively.




| Characteristic | Odds ratio (95% CI) | p-value |
|---|---|---|
| Age | 0.99 (0.98 – 1.01) | 0.39 |
| BMI | 0.99 (0.97 – 1.01) | 0.21 |
| Comorbidities | 0.97 (0.88 – 1.07) | 0.54 |
| Pre-operative step count | 1.00 (1.00 – 1.00) | 0.53 |
| Pre-operative GAD-7 | 1.03 (0.99 – 1.08) | 0.10 |
| Race – white | 1.31 (0.90 – 1.90) | 0.16 |
| Pre-op Above PASS | 1.29 (0.89 – 1.85) | 0.18 |
| Sex | 1.37 (1.04 – 1.79) | 0.02 |

**Figure 7.** Logistic regression investigating characteristics associated with satisfaction (≥30 KSS satisfaction subscale) at 1 year post-operatively.

## 4. Discussion

In this cohort, 16.2% of patients undergoing TKA presented with KOOS JR scores above the PASS threshold pre-operatively. These patients reported lower pain, better health-related quality of life and better knee satisfaction and function pre-operatively and throughout the study period. However, our hypothesis was confirmed with regard to change from baseline, as these patients also demonstrated less improvement in each of these outcome measures compared to those with lower scores before surgery. Importantly, patients with high baseline function were over 5 times more likely to experience a decline or no improvement in function at 1 year, which persisted after controlling for patient characteristics previously associated with improvement following TKA. While a greater proportion of high baseline function patients appeared to be satisfied at 90 days post-operatively, after controlling for demographics, being above PASS pre-operatively was no longer associated with odds of satisfaction.

Most studies have focused on odds of improvement following TKA, reporting the proportion of patients who achieve MCID on joint-specific PROMs post-operatively as a marker for meaningful change in function. Considering the anchor-based MCID for the KOOS JR, studies report approximately 70% [15,21] of patients reach this goal. Researchers have begun to investigate patient characteristics associated with significant improvement, finding higher BMI class, female sex, and lower baseline function are predictive of achieving MCID [14,21]. Given the relationship between pre-operative PROM scores and MCID, cutoffs for pre-operative function have been calculated to optimize the attainment of clinically meaningful improvement [15,22]. While several authors report the frequency with which patients do not meet MCID (anchor- or distribution-based definitions), we are not aware of any reports characterizing those who appreciate zero net benefit or decline in function, nor predictors of these outcomes. Moreover, studies in which theoretical cutoffs for pre-operative PROMs describe the number of patients who would be denied access to surgery and would have derived benefits have not reported the frequency with which those patients have experienced detrimental effects on function [17,18].

The PASS threshold has been considered a goal for post-operative function, signifying that a patient is "feeling well", and has been described as a more stringent criterion for success than MCID or SCB [21]. Given that this can be considered the goal of surgical intervention, it seems an appropriate cutoff for investigating appropriateness and the odds of procedural benefit or harm. However, it is possible that the application of a single value to a varying population of this sort may be problematic [23]. The PASS value for KOOS JR used within was calculated based on health-related quality of life questions rather than a single anchor question as PASS thresholds have been determined for other PROMs [3]. In addition, Kunze et al. reported in their original calculation differing PASS values across demographics, with higher values for patients who were men, had higher BMI, and higher baseline mental and physical component scores on the Short Form-36 [10]. Post-operative PASS thresholds have also been found to vary by baseline PROM scores [8,13]. Despite this, it is interesting to note in our cohort that when including a simple categorical variable for PASS status pre-operatively, no other baseline characteristic was predictive of no benefit following TKA. It is also important to note that the incidence of knee-related complications that would be expected to potentially contribute to worsening of function was lower in the group of patients with no benefit who were above PASS pre-operatively.

There are a few other interesting observations within our data that are similar to previous literature. In this cohort, a significantly lower proportion of women were above PASS prior to intervention. Fraenkel et al. noted that orthopedic surgeons were less likely to offer TKA to women than men of equal radiographic severity [24]. It is unclear from our findings whether women allowed greater deterioration prior to seeking TKA or whether clinicians require lower PROM scores in women prior to referral for surgery. It is also interesting to note that after including PASS status, age, BMI, and pre-operative anxiety were not related to lack of improvement, though these have been noted to be predictive of outcomes in other studies [3,14,21,25]. However, it should be noted that previous models

have included mental component summary scores that may be more indicative of overall mental health, including depression, rather than anxiety alone. While not the aim of this study, we also observed that those of higher baseline function were more likely to report PROM scores above PASS at one year; 96.9% of patients who were above PASS pre-operatively reported scores above this threshold compared to 89.1% in the cohort of patients who were below PASS before surgery. We also observed a larger proportion of patients with lower baseline function reached MCID (86.0% vs. 57.1%) at one year.

Patients have been presenting with higher function prior to TKA, where surgeons are opting to refer patients for intervention prior to marked deterioration, such that significant impairment pre-operatively may be a sign of barriers to access [26]. The use of thresholds for access has been criticized due to the number of patients who would be denied intervention despite the increased likelihood of improvement. As demand for TKA has been projected to continue to increase [27], it may become necessary to institute decision-making tools that would potentially restrict access to individuals with low need based on PROMs to allow increased access to those with more severe functional impairment. Determining surgical appropriateness based on pre-operative PROM scores alone is not likely an optimal solution. However, surgeons should begin to more closely evaluate whether TKA is warranted in patients whose pre-operative scores already lie above those considered successful following treatment. Conversations with patients regarding expectations should clearly define the decreased likelihood of not only meaningful improvement but also the potentially increased odds of functional decline when baseline scores are high. Trials of conservative therapy should also be offered more frequently [5], particularly in high-function patients, as the literature suggests that nearly 30% of patients do not undergo osteoarthritis treatment prior to surgery [28].

This study is limited in that it was not designed to measure improvement or decline following TKA and was instead an observational study of patients using a mobile application for rehabilitation following arthroplasty. This may limit the generalizability as patients were required to own a smartphone and may not be fully representative of the general TKA population. The use of the application also gave patients access to education, exercises, and care team messaging that may not be reflective of the typical recovery process for those undergoing TKA. Patients who agreed to participate may have been more motivated during recovery, such that our observation of functional decline could be an underestimate of that seen in usual care. Patient selection to undergo TKA was not dictated by the study, and we did not account for surgeons or institutions that could impact results, as this was a multicenter study. Additionally, patients were treated according to each center's standard of care, so the study did not dictate potentially important factors such as post-operative analgesia. Differences in analgesia during the entire study period (pre- through to post-operatively) may have confounded patient-reported function at any time point, as we could not account for this in any of our models. Finally, it is possible that excluding patients who did not complete KOOS JR at one year may have impacted our estimates of functional decline. However, the rate of non-completion at 1 year was similar between the pre-operative PASS groups (38.0% and 39.0%). Future work to include additional patient perspectives, such as expectations or matching based on health and mental status, may help elucidate these findings.

The use of pre-operative PROM cutoffs to determine appropriateness or access to surgery is not warranted, given the proportion of patients who stand to benefit and are satisfied following intervention. However, patients who present above the established PASS thresholds pre-operatively should be counseled regarding the increased likelihood of a decline in function or no net gain within one year during the shared decision-making process.

## 5. Conclusions

These findings suggest that patients above previously defined PASS thresholds who present for TKA appreciate less improvement in pain and satisfaction and are less likely to demonstrate improvements on KOOS JR post-operatively. The application of PASS

thresholds pre-operatively may be useful for guidance of patient expectations, where those who present with KOOS JR scores above this metric may be less likely to appreciate benefit and may experience a decline in function post-operatively.

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**Informed Consent Statement:** Written informed consent was obtained from all subjects involved in the study.

**Data Availability Statement:** The data presented in this study are not publicly available due to commercial and privacy restrictions.

**Conflicts of Interest:** RER—employed by Zimmer Biomet, stock or stock options. DAC, Research support—FirstKind, Parvizi Surgical Innovation Research Institute, Prescribe Fit, Recovery Rx, SI-Bone, Smith & Nephew, SPR Therapeutics, Total Joint Orthopedics, Zimmer Biomet; paid consultant Depuy, Medacta; paid presenter or speaker, Medacta; editorial or governing board Journal or Orhtopaedic Experience and Innovation. MBA—employed by Zimmer Biomet, stock or stock options; stock OrthoGrid systems. DVA—employed by Zimmer Biomet, stock or stock options. JMC—employed by Zimmer Biomet, stock or stock options. AVL, Research support—Firstkind, Parvizi Surgical In-novation Research Institute, Prescribe Fit, Recovery Rx, SI-Bone, Smith & Nephew, SPR Therapeu-tics, Total Joint Orthopedics, Zimmer Biomet. IP royalties—Innomed, Zimmer Biomet; Paid con-sultant—Zimmer Biomet; Stock or stock options—JIS Ventures, Joint Development Corporation, Parvizi Surgical Innovation, Prescribe Fit; editorial or governing board—Clinical Orthopaedics and Related Research, Journal of Arthroplasty, Journal of Bone and Joint Surgery, Journal of Ortho-paedics and Traumatology, Journal of the American Academy of Orthopaedic Surgeons, Knee, Surgical Technology International, The Bone & Joint Journal; board or committee member—Central Ohio Orthipaedica Management Company, Current Concepts in Joint Replacement, Operation Walk USA.

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