

## **Patient And Surgical Factors Associated With Achieving The Medicare-driven 20-point Substantial Clinical Benefit Threshold In Patient-reported Outcomes**

**Background:** The Centers for Medicare and Medicaid Services (CMS) now mandate the collection of patient-reported outcome measures (PROMs) for total knee arthroplasty (TKA), with a 20-point increase in KOOS JR scores required to achieve substantial clinical benefit (SCB). Hospitals that fail to meet compliance standards may face reimbursement penalties. However, the factors influencing patients' likelihood of achieving SCB remain unclear. This study aimed to identify patient demographics, surgical characteristics, and medical risk factors associated with failure to achieve a 20-point improvement in KOOS JR scores after TKA.

**Methods:** This retrospective cohort study analyzed 1,935 primary TKA patients treated at a single academic medical center between January 2016 and May 2023. Patients were categorized into two groups: those who achieved a  $\geq 20$ -point improvement in KOOS JR scores (improvement group) and those who did not (non-improvement group). Demographic and surgical data were collected using the FORCE Registry. Statistical analyses included t-tests, Chi-square or Fisher's exact tests, multivariable logistic regression, and ROC curve analyses. The study was powered at 80% to detect effect sizes, and statistical significance was set at  $p < 0.05$ .

**Results:** Among the 1,935 patients, 78.7% achieved SCB, while 21.3% did not. The median age was 69, and 65% of patients were female. Compared to the non-improvement group, patients in the improvement group were older (median 69 vs. 68 years,  $p = 0.015$ ), more likely to be female (66.6% vs. 59.0%,  $p = 0.004$ ), and less likely to have visited the emergency department (ED) in the past three years (32.5% vs. 38.4%,  $p = 0.023$ ). No significant differences were observed in BMI, smoking status, ASA score, or Charlson Comorbidity Index. Surgical characteristics, including operative time, anesthesia time/type, implant type, and fixation method, were not associated with SCB. Preoperative KOOS JR scores were lower among those who improved, including lower scores in pain, ADLs, and QoL domains. These patients also demonstrated significantly greater improvements postoperatively in each domain. Postoperative ADL, QoL, and pain scores were all significantly better in the improvement group (all  $p < 0.001$ ). Similarly, improvements were seen in functional status and mental health, as measured by PCS and MCS scores, respectively. Patients in the improvement group had lower preoperative PCS scores (32.6 vs. 37.1,  $p < 0.001$ ) but higher postoperative PCS scores (47.7 vs. 36.8,  $p < 0.001$ ). MCS scores were also higher in the improvement group both preoperatively (59.8 vs. 59.0,  $p = 0.02$ ) and postoperatively (59.3 vs. 55.9,  $p < 0.001$ ). Logistic regression showed that increasing age decreased the odds of non-improvement (AOR 0.98 per year,  $p = 0.025$ ), while male sex (AOR 1.33,  $p = 0.014$ ) and ED visits in the prior three years (AOR 1.33,  $p = 0.014$ ) were associated with higher odds of failure to improve. ROC analysis demonstrated that age and BMI were not predictive (AUCs 0.539 and 0.511, respectively), while preoperative PROMs had moderate predictive value. Preoperative ADL (AUC 0.670), QoL (AUC 0.667), and pain scores (AUC 0.661) were the strongest predictors of achieving SCB.

**Discussion:** This is the largest known analysis identifying factors that predict failure to achieve SCB following TKA. Patients who are younger, male, have recent ED visits, and lower preoperative mental health scores are at increased risk of poor PROM improvement. In contrast, surgical characteristics such as anesthesia type or fixation method do not appear to influence outcomes.

**Significance/Clinical Relevance:** As CMS ties reimbursement to PROM performance, accurate risk assessment and patient selection are increasingly critical. Surgeons should pay close attention to psychosocial factors and recent healthcare utilization when counseling patients and developing quality improvement initiatives in arthroplasty care.