Development and Interim Validation of a Novel Post-Total Knee Arthroplasty Patient-Reported Outcome Measure

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INTRODUCTION: Up to 20% of patients report dissatisfaction following total knee arthroplasty (TKA), often citing symptoms such as instability, stiffness, or a lack of confidence in their knee. Patient-reported outcome measures (PROMs) serve as key tools in surgical outcomes evaluation by capturing a patient's perspective on symptoms, function, and quality of life. Existing PROMs for the knee, such as the Knee injury and Osteoarthritis Outcome Score (KOOS) and the Forgotten Joint Score (FJS), may not fully capture the concerns of patients living with artificial joints because they were developed in patient populations who were still living with their native knees. Patients with artificial knees often have evolving expectations and encounter new symptoms, such as mid-flexion instability or altered joint awareness. Because these concerns are not fully addressed by legacy PROMs, it is more challenging to identify dissatisfied post-TKA patients. To address this limitation of legacy PROMs, we first conducted semi-structured interviews with 30 patients dissatisfied with their primary TKA. Insights from these interviews guided the development of a novel post-TKA PROM and identified potential subscales of pain, stiffness, instability, confidence, and awareness of the artificial joint. Building directly on that foundation, the objective of this analysis is to assess construct validity and preliminary performance (via floor/ceiling effects and effect sizes) of this novel post-TKA PROM.

METHODS: 114 participants between nine and eighteen months following primary TKA (mean age 66 years, 58% female) were enrolled into this validation study. 41 participants were scheduled to undergo aseptic revision TKA. All participants completed the novel 33-item PROM, along with the KOOS, FJS, Patient Acceptable Symptom State (PASS), and Patient Global Impression of Change (PGIC). Pre-final domain scores of the novel PROM were normalized to a 100-point scale, with 100 representing a perfect score. Construct validity (i.e., whether each survey domain reflects its intended concept, such as instability questions truly capturing instability) of each domain of the novel PROM was assessed using Spearman's rank correlations (r) with legacy PROMs (PASS, PGIC, FJS, and KOOS domains). The percentage of respondents exhibiting floor or ceiling effects was calculated for the novel instrument's proposed domains and compared to legacy PROMs. The observed effect size for each novel domain was calculated between patients scheduled for revision TKA and those that were not receiving revision TKA.

RESULTS: The novel domains exhibited moderate to high correlation with each other (r = 0.57-0.85) as well as with FJS and KOOS domains (0.63-0.86). Only moderate correlations were observed between novel domains and PASS and PGIC (0.32-0.68). However, these were slightly higher than the correlations between FJS or KOOS domains and PASS and PGIC (0.29-0.62). The awareness domain was the only novel domain to exhibit a floor effect (10%) which was comparable with FJS (8%). All novel domain scores exhibited ceiling effects (4-25%), which were similar to ceiling effects for FJS and KOOS domains (4-18%). All novel domains other than awareness had effect sizes of 1.9-2.1 when comparing patients scheduled for revision TKA versus those not considering revision TKA. Only the KOOS-Quality of Life domain had an effect size >1.9 among legacy PROMs.

DISCUSSION: The novel domains performed similarly to legacy domains with regard to floor and ceiling effects while also exhibiting slightly favorable correlations with PASS and PGIC. The novel domains also had larger effect sizes than most legacy PROMs with regard to patients who were considering revision TKA. This indicates that these novel domains may be more sensitive to differences in post-TKA knee satisfaction than the legacy PROMs. Future work includes reducing the 33-item PROM into a more efficient tool for evaluation of the post-TKA knee and evaluating the responsiveness of these novel domains in patients post-revision TKA.

SIGNIFICANCE/CLINICAL RELEVANCE: By capturing dissatisfaction drivers such as instability and confidence, this PROM may offer a more sensitive method to evaluate outcomes and guide clinical decision-making after TKA. More broadly, this tool has the potential to refine revision indications and support the development of targeted interventions that better align surgical outcomes with patient expectations.