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Development of a Scale to Assess Performance Following Primary Total Knee Arthroplasty

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ABSTRACT

Background: Quantitative assessment of postsurgical knee motion provides sensitive measurements, but results are technical and may not be meaningful to patients. Although several knee-specific instruments exist, no patient-reported outcome (PRO) measure correlates function with improved stability, motion, satisfaction, and confidence.

Objective: To address both the above limitations by developing a PRO measure to assess the phenomenon of a “normal” knee after primary total knee arthroplasty (TKA). **Methods:** A draft conceptual model linking the impact of clinical mechanics to hypothesized functional outcomes was generated after a literature review of available assessment tools. Participants aged 18 to 80 years having undergone TKA within the past 10 to 18 months were identified and screened by clinical sites to participate in phase 1 focus groups or phase 2 in-depth interviews. Participants were asked to describe their TKA experiences, including how their knee feels now, followed by cognitive debriefing of

Patient's Knee Implant Performance (PKIP) draft items. **Results:** Phase 1 results indicated that concepts of confidence, stability, and satisfaction in patients' replacement knee when performing certain activities were distinct and important in the patients' assessment of their TKA. Phase 2 efforts yielded a final version of the PKIP measure containing nine items assessing the broader concepts of stability, confidence, and satisfaction in association with activities. Presurgical and postsurgical versions of the measure were created. **Conclusions:** Results of this qualitative study support use of the PKIP as a complementary PRO measure to assess performance after primary TKA. Psychometric evaluation of the PKIP is planned.

Keywords: arthroplasty, knee, qualitative research, questionnaires, replacement, self-report.

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Introduction

Primary total knee arthroplasty (TKA) is one of the most commonly performed orthopaedic procedures, and it can help relieve pain and restore function in diseased knee joints. In 2004, knee and hip arthroplasties accounted for 95% of the 1.07 million arthroplasty procedures performed in the United States [1]. From 1991 to 2004, the annual number of TKAs increased almost threefold in the United States [2]. Approximately 431,485 primary TKAs were performed in the United States in 2004, a 53% increase from the year 2000 (281,534 TKAs) [2]. According to a recent study presented at the 2012 Annual Meeting of the American Academy of Orthopaedic Surgeons, more than 4.5 million Americans are living with a total knee replacement. The number of total knee replacement surgeries has more than doubled over the past decade, with the sharpest rise among younger patients [3]. Based on future projections, the demand for TKA in adults aged 45 to 54 years is anticipated to grow 17-fold by 2030 [4,5]. These younger patients will require their implants to function several decades longer and typically demand more performance from their implant than required for the average older patient [6].

The goal of TKA, like the goal of total hip arthroplasty (THA), is to reduce joint pain, increase range of motion, and improve function and quality of life [7]. Clinicians and patients generally have the misconception that THA and TKA have similar recovery patterns [8]. Evidence shows, however, that patients with TKA actually experience significantly smaller improvements in postoperative pain and function than do patients undergoing THA [8–10].

Both patients and clinicians increasingly identify that the objective of TKA is to closely approximate with a prosthesis the feel and function of a healthy knee that has never undergone surgery [11]. As such, another important aspect of the discrepancy in THA and TKA outcomes is that patients who have undergone THA can (more often) “forget” about their prosthesis after surgery, whereas patients who have undergone TKA are aware of the prosthetic [12].

Before the conduct of this study, a review of the literature in PubMed and EMBASE identified available assessment tools designed to measure functional outcomes after TKA. This literature search was intentionally broad and included outcomes tools used for unicompartmental knees and outcomes more commonly reported in the sports medicine and physical therapy literature.

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The primary objectives of the review were 1) to better understand the concepts related to patient perception of a “forgotten” or “normal” knee after TKA, and, 2) if available, to identify a suitable, existing tool(s) to meet this need. Patient-reported outcome (PRO) instruments were identified, including the Western Ontario and McMaster Universities Arthritis Index (WOMAC), Knee injury and Osteoarthritis Outcome Score (KOOS), Oxford Knee Score (OKS), Kujala Scoring Questionnaire, and the International Knee Documentation Committee Knee Form. In addition, a historically popular clinician measured outcome tool, the Knee Society Score, was reviewed. None of the currently available PRO measures evaluate patients’ perception of their biomechanics (i.e., the relationship of function with improved stability, motion, satisfaction, and confidence). For example, the KOOS assesses the degree of difficulty with functioning due to the patient’s knee (e.g., descending stairs, ascending stairs) but does not delve into whether this degree of difficulty is due to knee stability, confidence, and so on. Thus, the KOOS provides an assessment of the level of difficulty the patient experiences but provides no information regarding what aspect of knee functioning causes this level of difficulty. Similar issues are found with the WOMAC, OKS, and International Knee Documentation Committee Knee Form.

Postsurgical knee motion is typically assessed via gait analysis [13] and/or kinematic studies [14–17]. Key learnings from biomechanical analyses highlight that the knee motion of the three main implant components (femoral component, tibial component, and patellar component) does not routinely follow movement patterns similar to normal knees and also exhibits increased variability [14,17,18]. The altered biomechanics after TKA, particularly with higher knee flexion activities such as deep knee bends and stair ascent/descent, is thought to contribute to why patients with knee replacement are not as satisfied with their joints compared with patients with hip replacement and also compared with their non-implanted knee. Furthermore, the observed suboptimal biomechanics pose greater challenges as patients with knee replacement have their surgery at younger ages [3] and have high functional expectations. Although these biomechanical analyses are sensitive and provide quantitative measurement, they are typically done on small sample sizes and the actual results are very technical, may not be representative of broader patient populations, and may not resonate with all stakeholders, particularly the patient. Coupling the gap in existing PRO measures with the limitations associated with biomechanical analyses, a key problem is that currently, no patient-reported measure is available to assess patients’ perception of their biomechanics.

Although this concept is not presently defined in the literature, for the purposes of this study, the concept of a “natural knee” or “natural” motion or movement after TKA is defined as stability, motion, stability with motion, satisfaction, and confidence with how an individual’s replacement knee facilitates his or her functioning. Furthermore, it is important to assess these themes within the context of activities that are important to the increasingly younger TKA population. While various knee-specific instruments currently exist (e.g., WOMAC, OKS, and KOOS), the objective of the current study was to address the identified gap in patient-reported measures assessing this phenomenon of a “natural knee” and create a complementary measure that could be used with existing knee-specific instruments to provide a more robust assessment of the patient experience after knee replacement.

Conceptual Model Development

A conceptual model has been defined as “a taxonomy of patient outcomes according to the underlying health concepts they represent and proposes specific causal relationships between different health concepts” [19]. Rothman et al. [20] further refined this definition to indicate that the conceptual model “provides the rationale for and specification of the PRO measures of interest in the population of interest that will result in a specific treatment decision.” A PRO measure will lend support to the evaluation of TKA benefit by allowing the specific assessment of patients’ perceptions of their experience. Therefore, a draft conceptual model was created linking clinical impact with measurable outcomes to support evaluation of benefit. Hypothesized measurable outcomes were determined on the basis of previous research, including PRO measures [21], fluoroscopically measured biomechanics [17], engineering expertise, and clinical expertise of key opinion leaders. Experts participated in a workshop to link factors that could contribute to patient outcomes, with a specific emphasis on outcomes associated with improved functional performance. Clinical impact was mapped to a specific symptom experience by the patient (e.g., natural motion). Finally, continuing the progression outward in the model, reduction in these symptoms was hypothesized to improve function (i.e., reduce limitations), patient satisfaction, psychosocial well-being, and productivity. Figure 1 contains a depiction of the resulting model.

Within the context of this model, this article describes efforts designed to better understand and assess patients’ perceptions regarding the performance of their replacement knee. We detail

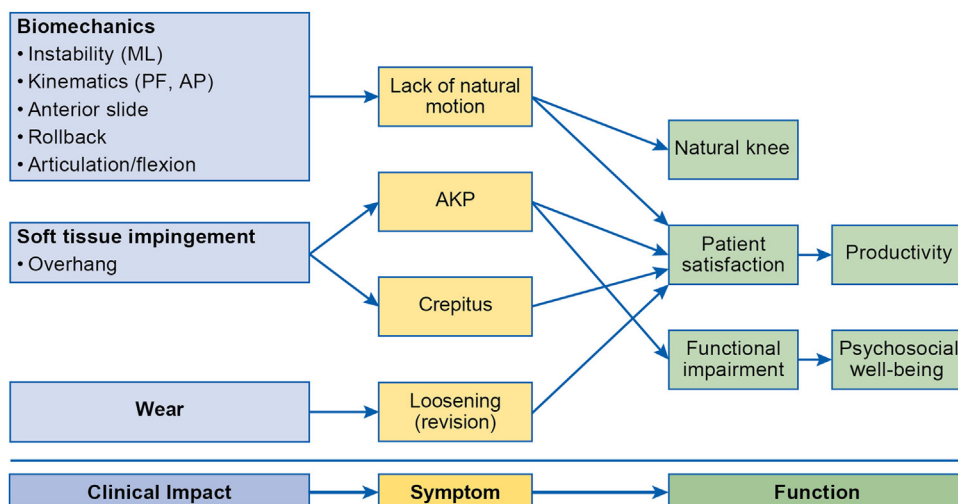


Fig. 1 – Conceptual model. AKP, anterior knee pain; AP, anteroposterior; ML, mediolateral; PF, patellofemoral.

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