

# Assessing Performance Following Primary Total Knee Arthroplasty: Development of the Patient's Knee Implant Performance (PKIP) Measure

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## BACKGROUND

- Total knee arthroplasty (TKA) is one of the most common orthopedic procedures performed and can help relieve pain and restore function in severely diseased knee joints. By the year 2015, the annual number of primary knee arthroplasties in the US will be greater than 1.3 million.<sup>1</sup>
- Based on future projections, the demand for TKA in adults aged 45 to 54 years is anticipated to grow 17-fold by 2030.<sup>2,3</sup> These younger patients will require their implants to function several decades longer and with increased durability than required for the average older patient.<sup>4</sup>
- Evidence shows that patients with primary TKA experience significantly smaller improvements in functional performance compared with patients undergoing total hip arthroplasty.<sup>5-8</sup>
- 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.<sup>9</sup>
- Despite significant advances in device design and performance, patient satisfaction and self-reported function after TKA have not improved.<sup>5,8,10-12</sup>
- Although several instruments have been developed to assess patient-reported outcomes (PROs), assessment is limited due to ceiling effects, because the instruments have been primarily designed to assess pain and basic activities of daily living. In addition, the existing instruments are limited due to a lack of focus on activities that are challenging from a biomechanics perspective.

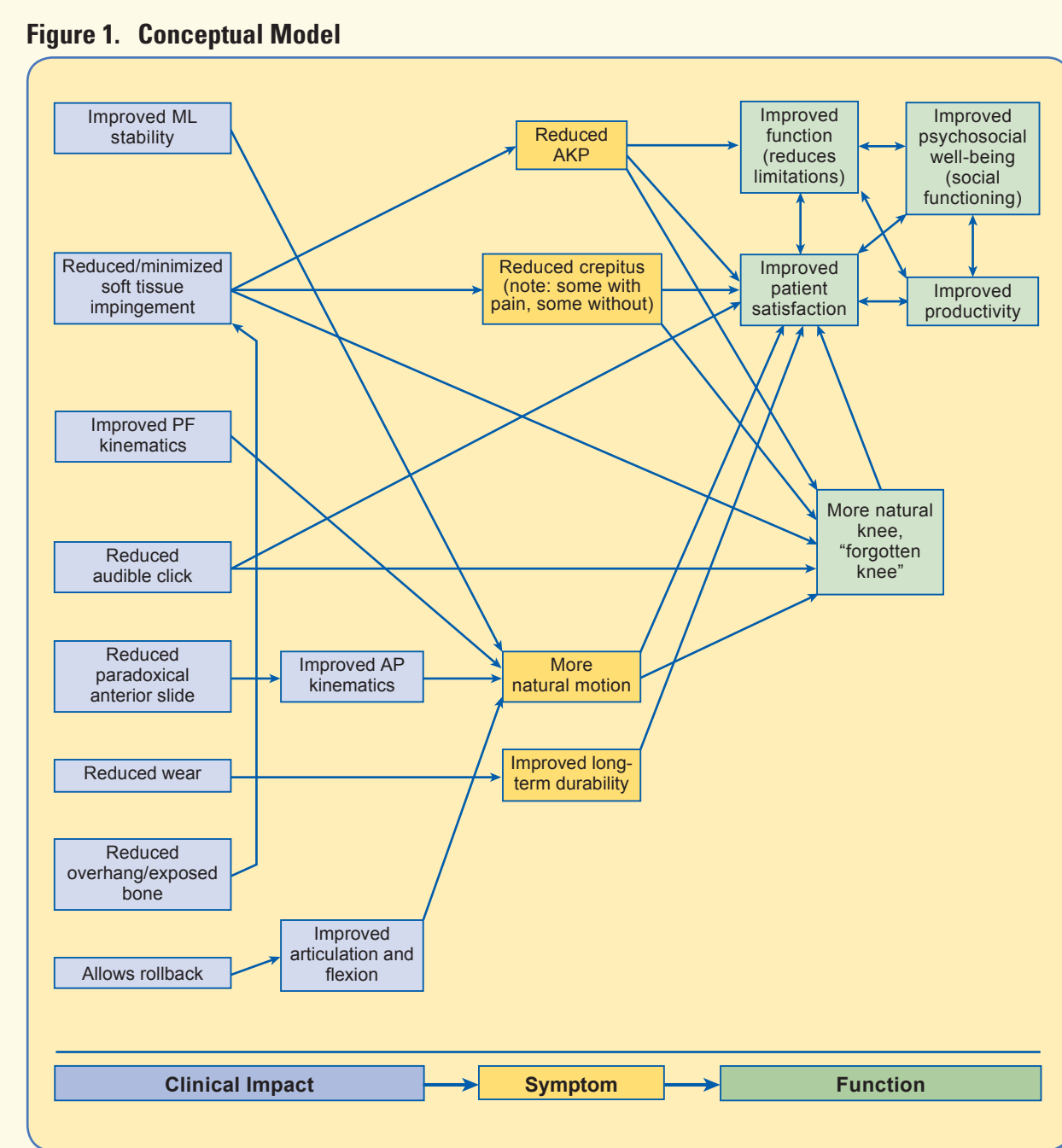
## OBJECTIVES

- The primary objectives of this study were to confirm the importance and relevance of the concept of a healthy, "normal" knee to patients after TKA and to develop a new instrument designed to measure patients' perceptions regarding the performance of the replacement knees after primary TKA.

## METHODS

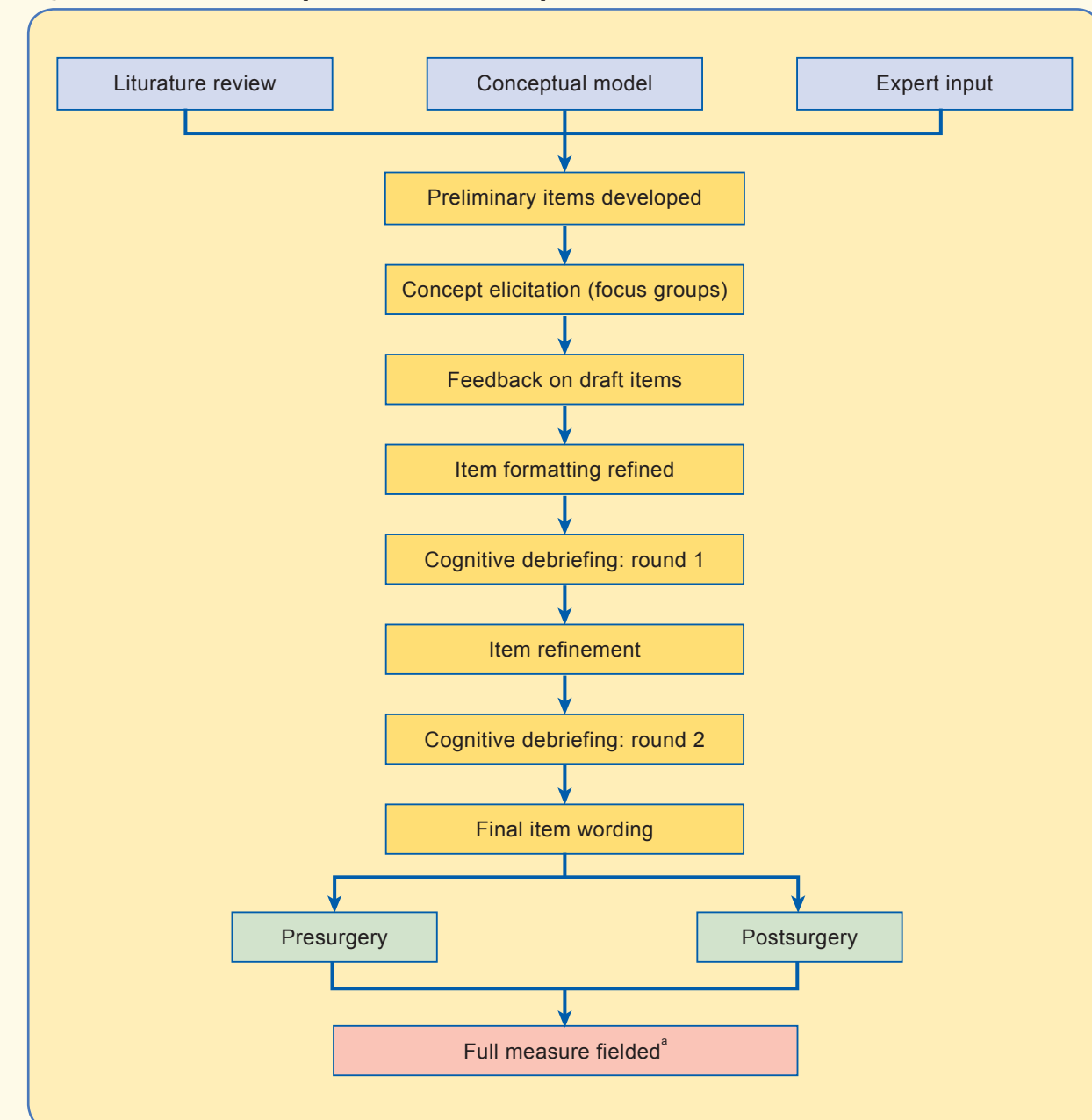
- A conceptual model was created linking clinical impacts of a TKA with measurable outcomes to support evaluation of benefit (Figure 1).
  - Clinical impact was mapped to a specific symptom experienced by the patient.
  - Reduction in these symptoms was hypothesized to improve function (i.e., reduce limitations), patient satisfaction, psychosocial well-being, and productivity.
- Draft items were developed using the working definition of "natural motion" (i.e., improved stability, motion, satisfaction, and confidence with how the knee is able to help patients perform functional activities), which was derived from a review of the published literature and clinical expertise in the design and function of replacement knee products.
- Two focus groups were conducted with patients in the United States diagnosed with noninflammatory degenerative joint disease to confirm the relevant constructs for the TKA conceptual model and gather patient feedback on a set of novel draft PRO items designed to assess patients' stability and awareness of, confidence in, and satisfaction with their replacement knee. IRB approval was obtained.
- Two rounds of cognitive debriefing interviews were conducted with participants at a total of four investigative sites in the United States, Northern Ireland, and Australia with patients diagnosed with noninflammatory degenerative joint disease. The objectives of the interviews were to provide confirmatory evidence of the content validity of the Patient's Knee Implant Performance (PKIP) items, support identification of any additional constructs that should be included in this measure, and determine the most appropriate wording and response scales for the items. IRB/Ethics Committee approval was obtained.

- Figure 2 depicts the study flow.



AKP = anterior knee pain; AP = anteroposterior; ML = mediolateral; PF = patellofemoral.

Figure 2. Qualitative Aspects of PKIP Development



\*Additional psychometrics will be performed on full measure.

## RESULTS

- A total of 14 individuals who had undergone primary TKA in the past 10 to 18 months participated in the focus group discussions (Table 1).
- A total of 28 individuals who had undergone primary TKA in the past 10 to 18 months participated in two iterative rounds of cognitive interviews (Table 1).
- The initial descriptive responses from the focus groups fell loosely into the functional outcomes included in the TKA model, including natural motion (as demonstrated by stability, confidence, and satisfaction in the replacement knee) (Table 2).
- Results from the focus groups indicated that 9 of 10 of the draft items included were relevant and important questions to ask patients after knee replacement surgery.
- Patients believed that concepts of **confidence, stability, and satisfaction** in their replacement knee when performing activities requiring certain motions, such as walking up and down stairs and getting up from a seated position, were both distinct from each other and important to assess.
- Based on participant feedback, the draft items were modified after Round 1 of interviews. Participants described limitations following TKA and the need for subsequent modification of activities. Therefore, an item was added to ask about how often participants modified or changed the way they do certain activities.
- Results from the cognitive debriefing (Table 3) further confirmed the content validity of the measure.
- Based on two rounds of cognitive testing, the PKIP was refined to include a total of nine item stems assessing knee implant performance (presurgical and postsurgical versions were created).

Table 1. Participant Characteristics: Concept Elicitation Discussion and Cognitive Debriefing Interviews

Characteristic	Concept Elicitation Focus Groups	Cognitive Debriefing Interviews
<b>Age in years, median (range)</b>	64 (53-74)	68.5 (50-80) <sup>a</sup>
<b>Sex</b>		
Female	7 (50%)	18 (64.3%)
Male	7 (50%)	10 (35.7%)
<b>Education</b>		
Less than high school	0 (0%)	1 (3.6%)
High school or equivalent (e.g., GED)	5 (36%)	18 (64.3%)
Some college/university	4 (28.5%)	4 (14.3%)
College/university degree	4 (28.5%)	3 (10.7%)
Professional or advanced degree	1 (7%)	2 (7.1%)
<b>Race/ethnicity</b>		
Black	2 (14%)	3 (10.7%)
White	12 (86%)	25 (89.3%)
<b>Device type</b>		
Rotating platform	9 (64%)	14 (50%)
Fixed bearing	5 (36%)	14 (50%)
<b>Design type</b>		
Cruciate-retaining	2 (14%)	9 (32.1%)
Posterior-stabilized	12 (86%)	19 (67.9%)

<sup>a</sup> Median age represents data from three sites, because one site provided data in aggregate form only, as requested.

Table 2. Concept Linking Table: Focus Groups

Concept	Focus Group Feedback
Forgotten knee	<ul style="list-style-type: none"> <li>Motions/activities, such as walking up or down steps, going down escalators, or walking outside in the yard, cause individuals to notice or pay more attention to their replacement knee</li> <li>Lingering numbness felt in the replacement knee seems "unnatural"</li> <li>Touching [the knee or scar], bending down, or kneeling "feels weird"; individuals "expect to feel something and don't"</li> <li>"I notice it off and on where I'm just more cautious now"</li> <li>"Twinges" in bad weather</li> <li>Can do things without thinking about knee</li> </ul>
Confidence	<ul style="list-style-type: none"> <li>"I think there's a sense, a little bit of <b>insecurity</b> with respect to balance [when walking down steps]"</li> <li>More "cautious" when walking around the backyard due to the "divots" in the yard that make the ground uneven, which have caused incidents of stumbling</li> <li>Confidence was described as somewhat "<b>more mental</b>" than physical                             <ul style="list-style-type: none"> <li>"I know that the knee works, but I'm looking down just to make sure"</li> <li>"It's being more observant"</li> <li>"...trust still has to be built up again" in the replacement knee</li> <li>"...confidence is a little shaky"</li> </ul> </li> </ul>
Stability	<ul style="list-style-type: none"> <li>"<b>Stability</b>" has improved since surgery</li> <li>"<b>Balance</b>" was somewhat of a problem still</li> <li>"Working hard to step the same" way on stairs as before experiencing knee problems</li> </ul>
Motion	<ul style="list-style-type: none"> <li>The "flex" still is not there in the replacement knee</li> <li>The knee replacement "doesn't have the same strength that the other knee has"</li> </ul>
Satisfaction	<ul style="list-style-type: none"> <li>"Disappointed with the lack of bend" in the replacement knee</li> <li>Desire to flex the replacement knee to a greater degree</li> <li>Better balance/stability</li> <li>Improved quality of life/feeling better</li> <li><b>Trust in knee</b> (that it will stay in place)</li> <li>No pain or much less pain</li> <li>Knee does not "lock up"</li> <li>No need to rely on others</li> </ul>
Function	<ul style="list-style-type: none"> <li>Ability to return to normal activities, including walking, playing golf, and cooking</li> <li>"...hold onto the handrail because it will absorb some of the shock. Naturally, you're putting more weight onto your hand to absorb the extra weight on the knee"</li> <li>"When I'm walking down steps, I'll tend to look at the steps rather than just walk. And I catch myself doing that every once in a while"</li> <li>Would feel less <b>confident</b> to attempt steps without some type of aid (cane or another person to lean on)</li> <li>Will go down the steps backward, one step at a time (bringing feet together on each individual step)</li> <li>Lingering problems going downhill due to balance difficulties</li> <li>Ability to get up from a chair or get up from lying down</li> </ul>

Table 3. Concept Linking Table: Patient Interviews

Concept	Round 1 Interviews	Round 2 Interviews
Forgotten knee	<ul style="list-style-type: none"> <li>"Aware" of the knee when doing particular activities, including kneeling, going up and down stairs, and riding in a vehicle</li> <li>Aware due to "numbness," "pain," or "stiffness"</li> <li>"Mental" awareness                             <ul style="list-style-type: none"> <li>More cautious or careful when doing certain activities because still building confidence or afraid of reinjuring the replaced joint</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>"Aware" of the knee when doing particular activities, including kneeling, going up steps, getting in and out of a car, and walking unaided</li> <li>"Aware" due to sounds (e.g., "clicks," "crunch") or sensations (e.g., numbness, soreness, limited motion)</li> </ul>
Confidence	<ul style="list-style-type: none"> <li>Less confidence when performing activities, including walking on slippery surfaces or uneven surfaces, kneeling, getting up from a toilet</li> </ul>	<ul style="list-style-type: none"> <li>Mental association felt regarding concept of confidence</li> <li>Less confidence when performing activities, including going up stairs and walking for long periods of time</li> </ul>
Stability	<ul style="list-style-type: none"> <li>Less stable when performing activities, including walking up or going down a hill, ramp, or incline and getting out of a car after driving long distances</li> </ul>	<ul style="list-style-type: none"> <li>Less stable when performing activities, including kneeling, going down stairs, and walking downhill or on downward sloping surfaces</li> </ul>
Motion	<ul style="list-style-type: none"> <li>Difficulty with things that require bending the knee past the 90-degree point (e.g., squatting down, gardening/weeding, scrubbing the floor, twisting or pivoting)</li> <li>Additional tasks that caused difficulty (e.g., standing and working in the kitchen for any length of time, getting up out of a chair after sitting for an extended period of time, walking on slippery surfaces, kneeling)</li> </ul>	<ul style="list-style-type: none"> <li>Additional tasks that caused difficulty (e.g., using stairs or ramp, uneven surfaces, kneeling, getting in and out of a car)</li> </ul>
Satisfaction	<ul style="list-style-type: none"> <li>Absence of pain along with the ability to do desired activities</li> <li>"...confidence level is off the chart now that I'm able to get around and walk"</li> <li>"...mechanical/hinge-like feeling" was an acceptable "trade-off"</li> <li>"Occasional clicking"</li> <li>"The only thing I care about is the bending"</li> </ul>	<ul style="list-style-type: none"> <li>Largely equated to the absence of arthritic pain along with the ability to return to activities with few or no limitations or associated pain</li> <li>"...terrible" time with recovery</li> <li>Satisfaction improvements linked to activity and limitations</li> </ul>
Modification	<ul style="list-style-type: none"> <li>Less likely to use stairs or some type of compensatory approach when using steps such as using the hand rail and/or a cane for assistance and climbing or descending one step at a time</li> <li>"...kneeling" and "putting on socks" is difficult and have "to improvise"</li> </ul>	<ul style="list-style-type: none"> <li>Difficulty with tasks that require kneeling</li> <li>No longer uses a step stool or ladder</li> <li>Rails in the bathroom to help with using the toilet and shower</li> </ul>

## DISCUSSION

- Despite the increasing occurrence of TKA, a gap exists in the understanding of the patient experience regarding functional outcomes tied to stability, motion, and confidence in use of the replacement joint.
- Assessment of knee implant performance from the patient perspective can provide more robust information not only for evaluation of mechanics, but for supporting education regarding patient expectations after TKA.
- Development of the PKIP followed rigorous methodology for questionnaire development,<sup>13</sup> including the following:
  - Examination of currently available literature
  - Development of a conceptual model to guide creation of a new measure
  - Concept elicitation and cognitive debriefing to refine items and support content validity
    - Item development was supported by review of the literature and clinical evidence coupled with direct patient input
  - After a concept elicitation component to support content validity of draft items, iterative rounds of cognitive debriefing interviews were conducted with patients 10 to 18 months after TKA, during which saturation was achieved, to substantiate the optimal recall period and response options and verify that respondents were able to clearly and consistently understand both the questionnaire instructions and items
- Results from the current study suggest that the PKIP items cover concepts important to assessing performance after primary knee replacement that are not currently assessed within available measures for use in TKA studies.

## CONCLUSIONS

- This study resulted in the development of the PKIP, a self-reported measure to assess performance after primary TKA.
- The PKIP assesses relevant concepts important to measuring the ways in which a patient's knee replacement improves performance and is brief and easily administered.
- The PKIP allows for assessment of function in relation to **stability, motion, satisfaction, and confidence**, a previously unavailable measurement capability among existing knee-specific PRO measures.

## LIMITATIONS

- The representativeness of the study sample to the general TKA population is unknown, although efforts were made to recruit a diverse sample in terms of sex, age, education, race, and device design and type.
- Although the PKIP was developed in a broader English-speaking population (United States, Northern Ireland, and Australia), further assessment of translatability and adaptation into additional languages may be warranted.
- The psychometric properties of the PKIP will be evaluated in the next phase of development.

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## DISCLOSURE

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