http://dx.doi.org/10.2106/JBJS.15.01291

Appendix

Questionnaire Development Phase

The development of our comprehension questionnaire followed a detailed validation process prior to beginning the randomized controlled trial. We enrolled an expert panel of orthopaedic surgeons, researchers, and a questionnaire methodologist (psychometrician) to design a comprehension questionnaire and patient satisfaction survey. Participants of the test and pilot study groups gave consent prior to enrollment in the questionnaire development phase of our study.

Test and Pilot Groups

Our first group contained 38 participants who were categorized as the test group. The test group was used to test the rough draft of our comprehension questionnaire, satisfaction survey, and informed consent discussion script. The content of the discussion script included knee anatomy, knee osteoarthritis description, symptoms, common physical examination and imaging findings, treatment options and uncertainties (emphasis on the advantages and disadvantages of corticosteroid injections), the patient decision-making role, and a notation that each participant must finalize a treatment preference. The discussion script was based on information from the OrthoInfo patient education web site.

Our expert panel categorized the questions into three levels of importance: high, moderate, and low. Therefore, a patient failing to correctly answer one question about the name of a bone in the knee joint may not be interpreted as having an equally critical deficiency as not knowing the complications of the procedure. Furthermore, although our questionnaire assesses overall patient comprehension of the discussion, it can also be used to identify specific knowledge deficiencies to be addressed by the orthopaedic team in future discussions.

The expert panel incorporated feedback from the test group to design the final comprehension questionnaire. Our second group contained 12 participants who were categorized as the pilot group. This group completed the final version of our comprehension questionnaire and satisfaction survey to determine areas of improvement prior to beginning the trial.

Our comprehension questionnaire validation process incorporated clinical sensibility testing of acceptability, feasibility, item retention, and item deletion. We also established content validity and discriminant validity.

Acceptability and Feasibility

Acceptability was established by the expert panel examining the length of time that participants needed to complete the comprehension questionnaire. Our questionnaire was delivered in an interview format and was written at an eighth-grade reading level assessed by the Flesch-Kincaid Grade. The interviewer recorded the questionnaire completion time. The mean completion time for the questionnaire was 14 minutes.

Feasibility was established by examining the rates of missing responses after the participants completed the questionnaire. There were no missing responses in our testing group.

Item Retention and Item Deletion

We evaluated which items to retain and which to delete in the development of the final questionnaire. The expert panel examined each question for difficulty, redundancy, and problematic format.

Content Validity

Content validity was established through expert evaluation of our questionnaire. We examined the proportion of orthopaedic surgeons on our expert panel who considered our questionnaire topics to be important (and found 100% acceptance).

Discriminate Validity

Discriminate validity was established through an expert panel evaluating whether our questionnaire distinguished between people of different levels of knowledge. We evaluated whether orthopaedic surgeons had a higher mean knowledge score compared with our knee osteoarthritis participants (and found a mean comprehension score of 100% for orthopaedic surgeons and 48% for the pilot group).

Finalized Comprehension Questionnaire: The Nkem Test

Our validated comprehension questionnaire was our primary outcome measure, which contained 14 multiple-choice questions addressing the topics of the informed consent discussion script. All answer choices were confirmed twice by the interviewer before documentation.

Finalized Satisfaction Survey

The final satisfaction survey had five questions. The first three were exploratory multiple-choice questions assessing patient satisfaction with the discussion content, time limit, and delivery method. The last two questions on the satisfaction survey were in the pre-post design using a Likert-scale format. The assessment occurred immediately after the participant completed the comprehension questionnaire.