No Clinically Significant Difference Between Adult and Pediatric IKDC Subjective Knee Evaluation Scores in Adults

Nicole Stegmeier, BS, Sameer R. Oak, MD, Colin O'Rourke, MS, Greg Strnad, MS, and Kurt P. Spindler, MD*

Background: Two versions of the International Knee Documentation Committee (IKDC) Subjective Knee Evaluation form currently exist: the original version (1999) and a recently modified pediatric-specific version (2011). Comparison of the pediatric IKDC with the adult version in the adult population may reveal that either version could be used longitudinally.

Hypothesis: We hypothesize that the scores for the adult IKDC and pediatric IKDC will not be clinically different among adult patients aged 18 to 50 years.

Study Design: Randomized crossover study design.

Level of Evidence: Level 2.

Methods: The study consisted of 100 participants, aged 18 to 50 years, who presented to orthopaedic outpatient clinics with knee problems. All participants completed both adult and pediatric versions of the IKDC in random order with a 10-minute break in between. We used a paired t test to test for a difference between the scores and a Welch's 2-sample t test to test for equivalence. A least-squares regression model was used to model adult scores as a function of pediatric scores, and vice versa.

Results: A paired t test revealed a statistically significant 1.6-point difference between the mean adult and pediatric scores. However, the 95% confidence interval (0.54-2.66) for this difference did not exceed our a priori threshold of 5 points, indicating that this difference was not clinically important. Equivalence testing with an equivalence region of 5 points further supported this finding. The adult and pediatric scores had a linear relationship and were highly correlated with an R^2 of 92.6%.

Conclusion: There is no clinically relevant difference between the scores of the adult and pediatric IKDC forms in adults, aged 18 to 50 years, with knee conditions.

Clinical Relevance: Either form, adult or pediatric, of the IKDC can be used in this population for longitudinal studies. If the pediatric version is administered in adolescence, it can be used for follow-up into adulthood.

Keywords: knee; general sports trauma; patient-reported outcome

The International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, designed in 1999, is a knee-specific patient-reported outcome (PRO) that measures symptoms, function, and sports activity.[11] It is reliable and valid for a variety of knee problems, such as ligament and meniscal injuries, articular cartilage lesions, and patellofemoral

pain.[4,7,11,16] The original form of the IKDC (adult IKDC) was developed and validated in adult subjects and has been shown to be valid in pediatric subjects.[11,14] However, a study that utilized cognitive interviews in children and teenagers, 10 to 18 years old, reported that most of these subjects found the original adult IKDC difficult to understand and answer.[12] More specifically, all subjects had problems interpreting directions: half found the time frame references to be unclear, and half did not understand that all the questions pertained to their injured knee.[12] Subjects in this age group did not understand the concepts of pivoting, locking, giving way, and catching in questions.[12] These issues with the original adult IKDC revealed the need for a form designed specifically for the pediatric population. Therefore, the pediatric IKDC was developed, which involved splitting of complicated questions and language modification to create a more understandable form for patients 10 to 18 years old. With the clarification of language and questions, the newer pediatric IKDC could be easier to understand for adults as well.[5]

The selection of an appropriate PRO is especially important given that physicians now have multiple potential outcome assessments available for patients with knee injuries.[17] This makes PRO selection and testing even more important for specific populations.[6]

Accurate longitudinal studies require the use of the same PRO throughout follow-up. If the pediatric IKDC is used in adolescent subjects, follow-up of these same patients into adulthood may lead to confusion regarding whether the adult or pediatric form should be used. Therefore, it would be best for either one form or the other to be selected for use in adolescents and continued into adulthood. If the pediatric version is more easily understood without any clinically significant difference compared with the adult version, then it could be used in adults as well. In a comparison of the pediatric and adult versions of the IKDC in an adolescent population (aged 13-17 years), there was no clinically significant difference (unpublished data, 2015). The current study aims to (1) compare the scores of the adult and pediatric versions of the IKDC Subjective Knee Evaluation Form in adults with knee conditions and (2) determine whether the scores are highly correlated and can be converted between each other. We hypothesize that there will be no clinically significant difference in the adult and pediatric IKDC form scores in adults, aged 18 to 50 years, presenting to orthopaedic outpatient clinics with knee conditions.

METHODS

Participants

This study was approved by the Cleveland Clinic Institutional Review Board and all participants gave informed consent prior to enrollment in the study. Participants were recruited, using a convenience sample, from orthopaedic outpatient clinics. Inclusion criteria for participants were patients aged 18 to 50 years presenting with preoperative, postoperative, or
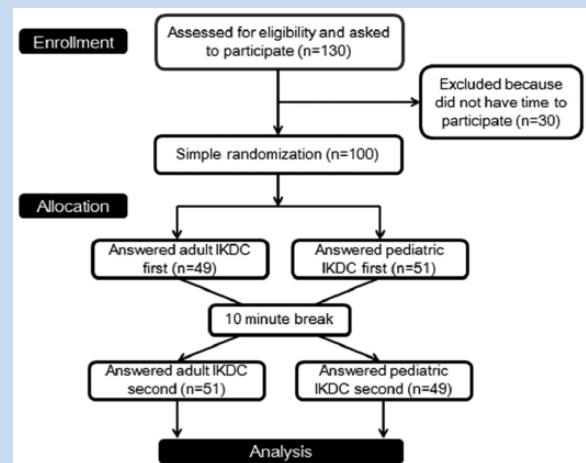

Figure 1. Flow diagram of study design. Number of participants asked to participate, randomization, and crossover is shown. IKDC, International Knee Documentation Committee.

nonoperative knee complaints. Exclusion criteria were patients outside of this age range or patients who presented for an issue unrelated to the knee. A total of 130 patients were asked to participate, and 100 were enrolled (Figure 1).

Study Design

This study utilized a randomized crossover design. All participants completed both the pediatric and adult versions of the IKDC. However, the order in which a participant completed these forms (ie, pediatric version first or second) was randomized using REDCap (Research Electronic Data Capture). Simple randomization was used. The participants were blinded to the form version. All participants were given a 10-minute break between finishing the first form and beginning the second form; this study design was similar to that used by Gudbergsen et al[9] and Bischoff-Ferrari et al[1] in their comparison of PROs (Figure 1). After completion of the second survey, all participants were asked which version (first or second) they preferred. The IKDC forms and the postsurvey preference question were completed on computers in the clinical setting. All participants were compensated for their time with a $10 gift card. The study data were collected and managed using REDCap electronic data capture tools.[10] REDCap is a secure, web-based application designed to support data capture for research studies, providing: (1) an intuitive interface for validated data entry, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for importing data from external sources.

Study Instruments

The IKDC Subjective Knee Form was designed for the purpose of detecting a change, either improvement or deterioration, in

Table 1. Participant demographic characteristics

	Adult IKDC First (n = 49)	Pediatric IKDC First (n = 51)	All Participants (N = 100)
Age, y, mean (SD)	30.9 (9.6)	32.7 (9.4)	31.8 (9.5)
Female, n (%)	21 (42.9)	21 (41.2)	42 (42.0)
Education completed, n (%)			
Less than high school	0 (0.0)	1 (2.0)	1 (1.0)
High school	24 (49.0)	21 (41.2)	45 (45.0)
Associate degree	3 (6.1)	0 (0.0)	3 (3.0)
Bachelor degree	16 (32.7)	24 (47.1)	40 (40.0)
Postgraduate degree	6 (12.2)	5 (9.8)	11 (11.0)

IKDC, International Knee Documentation Committee.

symptoms, function, and sports activity in patients with a variety of knee conditions.[11] The IKDC is knee-specific and can be used for ligament and meniscal injuries, articular cartilage lesions, patellofemoral pain, and other conditions.[11] It was developed to reflect symptoms and limitations in function and sports activity due to a knee condition, and it was designed to maximize reliability, responsiveness, and validity.[11] The IKDC Subjective Knee Evaluation Form is scored by summing the scores for the individual items, and this is then transformed to a scale that ranges from 0 to 100 (http://www.sportsmed.org/research/IKDC_forms/). The score is interpreted as a measure of function, with higher scores representing higher levels of function and lower levels of symptoms. Thus, a score of 100 would indicate no limitation in daily or sports activities and no symptoms. The pediatric and adult versions are scored in the same way, but the pediatric version has 21 items, rather than 18, because of the splitting of some questions for clarity. The pediatric version also includes some modifications in language. Previously, the pediatric IKDC has been shown to be reliable, valid, and responsive in the pediatric population.[13]

Statistics

The sample size calculation was performed using G*Power1 (version 3.1) software and 1-sided testing with a significance level of 5%.[8] To obtain 90% power to detect a 5-unit difference between mean IKDC version scores, assuming a standard deviation of 20 and a conservative correlation of 0.75, 87 participants were required. Based on this calculation, we aimed to enroll 100 participants. Paired t tests were used to test for a difference in the adult and pediatric IKDC scores and to test for a difference in the times required to complete the adult and pediatric IKDC versions. Because the distribution of times was skewed, the times were transformed onto a log scale for comparison and then transformed back to their original units to present results. To test for equivalence between the adult and

pediatric IKDC scores, a 1-sided equivalence test was performed, assuming an equivalence region of 5 points. This equivalence region was selected because it is lower than the clinically important difference reported for the adult IKDC, which ranges from 6.3 to 20.5.[2] For this test, the null hypothesis states that the difference in the pediatric and adult IKDC scores is greater than 5, and the alternative hypothesis states that this difference is less than 5. Therefore, a significant P value (<0.05) indicates that the evidence is sufficient to show the pediatric and adult IKDC mean scores are equivalent for clinical purposes. Least-squares models were used to generate formulas that allow for the prediction of adult scores when given pediatric scores and vice versa. Performance of these models was assessed using mean squared errors and R^2 values. All calculations were done using R software (version 3.1.1). Unless otherwise stated, testing was 2-sided and assumed a 5% significance level.

RESULTS

Participants

Overall, 130 patients were asked to participate in the study from August 25, 2014, to October 16, 2014. Of these, 100 patients agreed to participate. Table 1 provides the demographic characteristics of the participants by randomization group. After randomization, 49 participants completed the adult IKDC first, and 51 participants completed the pediatric IKDC first. The mean age of all participants was 31.8 years, and 42% of all participants were women. Table 2 provides the distribution of diagnoses for the participants.

IKDC Score Comparison

The mean adult IKDC score was 44.74 with an SD of 19.62, and the mean pediatric IKDC score was 46.34 with an SD of 19.45. Based on a paired t test, this difference between the adult and

Table 2. Reasons for outpatient visit

Diagnosis	n
Undiagnosed knee injury/pain	20
ACL injury	15
Meniscal injury	10
Postop ACL reconstruction	10
Patellofemoral pain	8
Postop arthroscopy with meniscectomy	8
Osteoarthritis	5
MCL injury	3
Patellar tendinitis	3
Postop arthroscopy with lateral release	3
IT band syndrome	2
Postop arthroscopy with chondroplasty	2
Medial femur and tibia osteochondral lesions	1
Parameniscal cyst with meniscal tear	1
Patellar contusion	1
Patellar dislocation	1
Patellar subluxation	1
Patellar tendon rupture	1
PCL injury	1
Plica syndrome	1
Postop arthroscopy with meniscus repair	1
Postop arthroscopy with osteochondral autograft	1
Postop MPFL reconstruction	1
Total	100

ACL, anterior cruciate ligament; IT, iliotibial; MCL, medial collateral ligament; MPFL, medial patellofemoral ligament; PCL, posterior cruciate ligament.
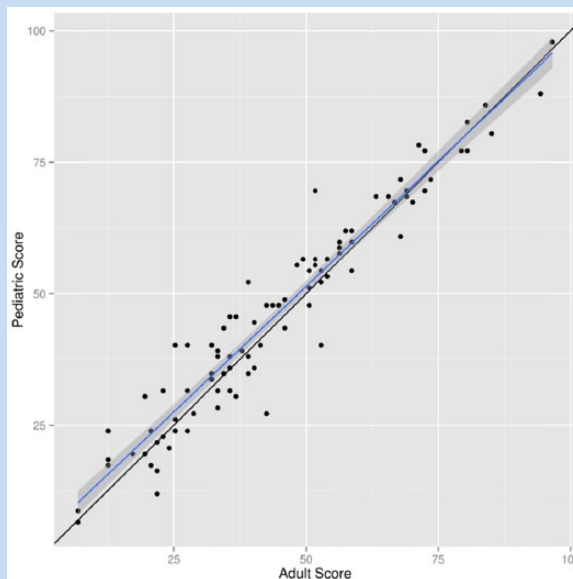

Figure 2. Scatterplot of pediatric by adult International Knee Documentation Committee scores, with superposed least squared regression line shown ($y = 0.95x + 3.64$). The 45° line also provided for reference.

pediatric scores of −1.60 is statistically significant, with a *P* value of 0.003 and 95% CI of −2.66 to −0.54. However, this confidence interval demonstrates that the difference in scores is less than the 5-point difference chosen a priori based on the minimum clinically important differences for the IKDC.

In order to evaluate the clinical relevance of this difference, a 1-sided equivalence test was also performed with a defined equivalence region of 5 units. There is significant evidence to show that the 2 measurements are equivalent for clinical purposes with a *P* value of <0.001 and 95% CI of −2.48 to −0.72. Thus, we conclude that, although the difference in the adult and pediatric IKDC scores was statistically significant, the difference in scores is within limits where it is not clinically important.

Correlation and Linear Regression

Given a score from 1 version of the IKDC, the score from the other version can be predicted using the following linear regression models. The model for predicting the adult IKDC score when given the pediatric IKDC score yields a mean squared error of 28.9 and R^2 of 92.6%. The linear regression line for this model is $y = 0.97x - 0.027$, where y is the predicted adult score and x is the known pediatric score. The model for predicting the pediatric IKDC score when given the adult IKDC score yields a mean squared error of 28.4 and R^2 of 92.6%. This linear regression model gives the equation $y = 0.95x + 3.64$, where y is the predicted pediatric score and x is the known adult score (Figure 2).

Comparison of Completion Times

The median time required to complete the adult IKDC was 2.96 minutes, with an interquartile range of 2.38 to 3.65. For the pediatric IKDC, the median time required was 3.27 minutes, with an interquartile range of 2.79 to 4.08. A paired *t* test was used to compare these durations, and a transformation to the log scale was performed prior to the test because of the skewed distribution of the IKDC times. The mean amount of time

required to complete the pediatric version was found to be approximately 1.11 times greater than the time required to complete the adult version, with a *P* value of less than 0.001 and a 95% CI of 1.06 to 1.16. However, from a practical perspective, this difference is <30 seconds on average.

Participant Preference

Thirty-three percent of participants preferred the adult version of the IKDC, and 38% of participants preferred the pediatric version of the IKDC. The remaining 29% had no preference.

DISCUSSION

This study revealed a statistically significant 1.6-point difference between the adult and pediatric IKDC scores with a 95% CI of 0.54 to 2.66. Clinical importance was not demonstrated as this difference was less than the a priori 5-point threshold set for clinical significance. This conclusion is further supported by equivalence testing, which revealed that the adult and pediatric IKDC scores were equivalent within an equivalence region of 5 points. This evidence demonstrates that there is no difference clinically between the adult and pediatric IKDC forms when administered to adults aged 18 to 50 years. The scores were highly correlated, with a linear relationship having an R^2 of 92.6%. This relationship can be used to predict 1 score when given the other. Both forms took approximately 3 minutes to complete. The difference in times to completion was statistically significant, although the magnitude of this difference was <30 seconds.

Longitudinal cohort studies have revealed the need for the current study.[3,15] Confusion arises when participants are evaluated longitudinally and their age crosses the 18-year-old mark. In longitudinal studies using the IKDC forms, the pediatric IKDC is validated for use at baseline (at an age <18 years) and was created specifically for use in the pediatric population. However, the pediatric IKDC has not been validated for use in adults, so it cannot be used at follow-up if the patient has passed the age of 18 years. Ideally, the same form should be used at baseline and follow-up, whether it is the adult or pediatric IKDC. The adult IKDC could be used in the adolescent population at baseline and follow-up, as it has demonstrated validity in the 13- to 17-year-old age group and has been shown to have no clinically significant difference in adolescents (SR Oak, unpublished data, 2015).[14] However, cognitive interviewing has shown that children aged 10 to 18 years have difficulty comprehending the IKDC questions from the adult version.[12] In addition to language modification, the pediatric version has also been improved by splitting questions to eliminate double-barrel questions. Since the pediatric version has been developed to be more clearly worded, it is well suited for use in the adult population as well.

There are several limitations to this study. First, the sample was limited to patients presenting in outpatient orthopaedic clinics at 1 institution. Furthermore, convenience sampling may have introduced selection bias into the study. However, the

sample included a wide range of knee-specific diagnoses, ages, and education levels and a fairly even sex distribution, which indicates that, hopefully, this bias was minimal. Additionally, the scores and correlation of the pediatric IKDC in adults were evaluated, as compared with the adult IKDC. We did not evaluate validity or responsiveness, and we did not compare individual components of each form. Although validity, reliability, and responsiveness have already been evaluated in the adult population for the adult IKDC Subjective Knee Form, these have not all been evaluated for the pediatric IKDC in the adult population.[11] The 2 versions appear to be clinically equivalent; the psychometric properties of the pediatric IKDC in the adult population should also be equivalent.

In conclusion, there was no clinically significant difference between the pediatric and adult IKDC scores in adults, aged 18 to 50 years, who were being seen in orthopaedic outpatient clinics for knee problems. This result indicates that follow-up using whichever form was originally used in a longitudinal study is possible. Furthermore, the scores were highly correlated and can be converted between each other with reliability.

AUTHORS

Nicole Stegmeier, BS (Cleveland Clinic Lerner College of Medicine; Cleveland Clinic Sports Health Orthopaedics); Sameer R. Oak, MD (Cleveland Clinic Sports Health Orthopaedics, Cleveland, Ohio); Colin O'Rourke, MS (Cleveland Clinic, Cleveland, Ohio); Greg Strnad, MS (Cleveland Clinic, Cleveland, Ohio); Kurt P. Spindler, MD (Cleveland Clinic Sports Health Orthopaedics, Cleveland, Ohio); Morgan Jones, MD, MPH (Cleveland Clinic Sports Health Orthopaedics, Cleveland, Ohio); Lutul D. Farrow, MD (Cleveland Clinic Sports Health Orthopaedics, Cleveland, Ohio); Jack Andrish, MD (Cleveland Clinic Sports Health Orthopaedics, Cleveland, Ohio); and Paul Saluan, MD (Cleveland Clinic Sports Health Orthopaedics, Cleveland, Ohio).

ACKNOWLEDGMENT

REFERENCES

1. Bischoff-Ferrari HA, Vondechend M, Bellamy N, Theiler R. Validation and patient acceptance of a computer touch screen version of the WOMAC 3.1 osteoarthritis index. *Ann Rheum Dis*. 2005;64:80-84.
2. Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM. Measures of knee function: International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS). *Arthritis Care Res*. 2011;63(suppl 11):S208-S228.

3. Cox CL, Huston LJ, Dunn WR, et al. Are articular cartilage lesions and meniscus tears predictive of IKDC, KOOS, and Marx activity level outcomes after anterior cruciate ligament reconstruction? A 6-year multicenter cohort study. *Am J Sports Med*. 2014;42:1058-1067.

4. Crawford K, Briggs KK, Rodkey WG, Steadman JR. Reliability, validity, and responsiveness of the IKDC score for meniscus injuries of the knee. *Arthroscopy*. 2007;23:839-844.

5. Cutilli CC, Bennett IM. Understanding the health literacy of America: results of the National Assessment of Adult Literacy. *Orthop Nurs*. 2009;28:27-32.

6. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient reported outcome measures in healthcare settings. *BMJ*. 2010;340:c186.

7. Esculier J-F, Roy J-S, Bouyer LJ. Psychometric evidence of self-reported questionnaires for patellofemoral pain syndrome: a systematic review. *Disabil Rehabil*. 2013;35:2181-2190.

8. Faul F, Erdfelder E, Lang A-G, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods*. 2007;39:175-191.

9. Gudbergsen H, Bartels EM, Krusager P, et al. Test-retest of computerized health status questionnaires frequently used in the monitoring of knee osteoarthritis: a randomized crossover trial. *BMC Musculoskelet Disord*. 2011;12:190.

10. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research Electronic Data Capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42:377-381.

11. Irrgang JJ, Anderson AF, Boland AL, et al. Development and validation of the International Knee Documentation Committee Subjective Knee Form. *Am J Sports Med*. 2001;29:600-613.

12. Iversen MD, Lee B, Connell P, Andersen J, Anderson AF, Kocher MS. Validity and comprehensibility of the International Knee Documentation Committee Subjective Knee Evaluation form in children. *Scand J Med Sci Sports*. 2010;20: e87-e95.

13. Kocher MS, Smith JT, Iversen MD, et al. Reliability, validity, and responsiveness of a modified International Knee Documentation Committee Subjective Knee Form (Pedi-IKDC) in children with knee disorders. *Am J Sports Med*. 2011;39: 933-939.

14. Schmitt LC, Paterno MV, Huang S. Validity and internal consistency of the International Knee Documentation Committee Subjective Knee Evaluation Form in children and adolescents. *Am J Sports Med*. 2010;38:2443-2447.

15. Spindler KP, Huston LJ, Wright RW, et al. The prognosis and predictors of sports function and activity at minimum 6 years after anterior cruciate ligament reconstruction: a population cohort study. *Am J Sports Med*. 2011;39: 348-359.

16. van Meer BL, Meuffels DE, Vissers MM, et al. Knee injury and osteoarthritis outcome score or International Knee Documentation Committee Subjective Knee Form: which questionnaire is most useful to monitor patients with an anterior cruciate ligament rupture in the short term? *Arthroscopy*. 2013;29:701-715.

17. Wang D, Jones MH, Khair MM, Miniaci A. Patient-reported outcome measures for the knee. *J Knee Surg*. 2010;23:137-151.