Reliability, Validity, and Responsiveness of a Modified International Knee Documentation Committee Subjective Knee Form (Pedi-IKDC) in Children With Knee Disorders

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Reliability, Validity, and Responsiveness of a Modified International Knee Documentation Committee Subjective Knee Form (Pedi-IKDC) in Children With Knee Disorders

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Background: The International Knee Documentation Committee (IKDC) Subjective Knee Form is a knee-specific measure of symptoms, function, and sports activity. A modified IKDC Subjective Knee Form (pedi-IKDC) has been developed for use in children and adolescents. The purpose of this study was to determine the psychometric characteristics of the pedi-IKDC in children and adolescents with knee disorders.

Hypothesis: The pedi-IKDC is a reliable, valid, and responsive patient-administered outcome instrument in the pediatric population with knee disorders.

Study Design: Cohort study (diagnosis); Level of evidence, 2.

Methods: Test-retest reliability, content validity, criterion validity, construct validity, and responsiveness to change were determined for the pedi-IKDC in patients aged 10 to 18 years with a variety of knee disorders. Test-retest reliability was measured in a group of 72 patients with a stable knee disorder. Validity was measured in a group of 589 patients with the Child Health Questionnaire to determine criterion validity. Responsiveness was measured in a group of 98 patients undergoing a variety of knee surgical procedures.

Results: The overall pedi-IKDC had acceptable test-retest reliability (intraclass correlation coefficient, .91) and excellent internal consistency (Cronbach alpha, .91). The form also demonstrated acceptable floor (0%) and ceiling (6%) effects. There was acceptable criterion validity with significant ($P < .01$) correlation between the overall pedi-IKDC and 9 relevant domains of the Child Health Questionnaire. Construct validity was acceptable, with all 11 hypotheses demonstrating significance ($P < .0001$). Responsiveness to change was acceptable (effect size, 1.39; standardized response mean, 1.35).

Conclusion: The pedi-IKDC demonstrated overall acceptable psychometric performance for outcome assessment of children and adolescents with various disorders of the knee.

Keywords: validations; International Knee Documentation Committee Subjective Knee Form; outcome; children

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The modern outcomes assessment movement has seen a shift toward patient-derived outcomes assessment.[3,4,6,7,9,17,20] As a result, numerous outcome instruments have been developed, including both generic and condition-specific measures.[14] These instruments have clinical and economic significance with broad applications, including the assessment of general health status, the development of health care models, and the improvement of health care delivery.[3,4,6,7,9,17,20]

It is essential to use outcome instruments with vigorously tested psychometric properties. The important psychometric properties of an outcome instrument are reliability, validity, and responsiveness.[14,15] Reliability refers to the reproducibility of an outcome measure between tests (test-retest reliability) or between observers (interobserver reliability). Validity—which consists of content validity, criterion validity, and construct validity—determines whether an instrument measures what it intends to

measure. Content validity assesses whether an instrument represents the characteristic being measured according to expert consensus opinion or measurement of floor effects (the proportion of patients who obtain the lowest possible score) and ceiling effects (the proportion of patients who obtain the highest possible score). Criterion validity assesses an instrument's relationship to an accepted gold standard. Construct validity assesses whether an instrument follows accepted hypotheses and produces results consistent with theoretical expectations. Responsiveness assesses the ability of an instrument to detect change in a patient's status over time or treatment.

Thorough evaluation of the psychometric properties of outcome instruments in target populations is also essential. Much of the research within the orthopaedic literature has focused on adults.[8] Unfortunately, adult outcome measures are not necessarily appropriate or transferable to the pediatric population.[8] Self-reported medical outcomes inherently rely on literacy and comprehension, and children may misunderstand items.[13] There exists a clear need for valid and appropriate outcome instruments that specifically assess health status in children and adolescents.

The International Knee Documentation Committee (IKDC) Subjective Knee Form[11] was developed as a knee-specific, rather than disease-specific, outcome instrument. This instrument intends to be an evaluative measure that can detect improvement or deterioration in symptoms, function, and sports activity as experienced by patients with a variety of knee conditions.[11] Whereas the IKDC Subjective Knee Form has been subjected to psychometric evaluations in a broad adult orthopaedic population,[5,10-12] it has not been validated in children and adolescents.

An initial investigation was performed with a series of cognitive interviews to determine how well children understand the individual components of the IKDC Subjective Knee Form. This investigation revealed that children had difficulty comprehending and answering certain questions within the form.[13] Based on areas of misunderstanding, a modified IKDC Subjective Knee Form (pedi-IKDC) was developed and used for this psychometric evaluation (Appendix 1, available in the online version of this article at http://ajs.sagepub.com/supplemental/).[13] The purpose of this study was to evaluate the psychometric properties—including reliability, validity, and responsiveness—of the pedi-IKDC in children and adolescents with a variety of knee conditions.

MATERIALS AND METHODS

Institutional review board approval and informed patient consent were obtained for this study. The design is a prospective cohort study. Patients aged 10 to 18 years who were evaluated and treated for a knee disorder at a single large tertiary care children's hospital were eligible to participate. When necessary, parents or caregivers could help children complete the forms.

TABLE 1
Diagnosis at Time of Inclusion in the Study

Diagnosis	n (%)[a]
Ligament injury	
Anterior cruciate ligament	129 (22)
Posterior cruciate ligament	4 (1)
Medial collateral ligament	13 (2)
Lateral collateral ligament	2 (1)
Meniscal injury	
Medial meniscus	47 (8)
Lateral meniscus	47 (8)
Discoid lateral meniscus	23 (4)
Patellofemoral injury	
Patellofemoral syndrome	116 (20)
Lateral patellar subluxation	94 (16)
Patellar dislocation	7 (1)
Osteochondritis dissecans	70 (12)
Fracture	
Proximal tibia	12 (2)
Inferior pole patella	3 (1)
Distal femur	2 (1)
Plica syndrome	67 (11)
Osgood-Schlatter	29 (5)
Arthrofibrosis	13 (2)
Acute chondral injury	11 (2)
Contusion	9 (2)
Tendinosis/tendinitis	13 (2)
Knee pain with unknown origin	21 (4)
Other[b]	23 (4)

[a]N, 589. Some patients had more than 1 diagnosis.
[b]Other diagnoses included chronic regional pain syndrome, osteochondroma, psoriatic arthritis, pain from a bioabsorbable screw, genu valgum, exertional compartment syndrome, meniscal cyst, septic knee, giant cell tumor, pigmented villonodular synovitis, multiple epiphyseal dysplasia, neuroma, and tibial periostitis.

A total of 589 patients participated in this study, consisting of 288 males (48.9%) and 301 females (51.1%). The average age (and standard deviation) of the cohort was 14.6 ± 2.5 years (range, 10.0 to 18.9 years). Patients participating in the study had a variety of knee disorders (Table 1). Patients were assigned to groups based on data collected (Figure 1). There were no significant differences between groups in age (P = .46, t test) or sex (P = .56, chi-square test).

Study Groups

Three study groups were used. Group A consisted of all 589 patients included in the study cohort. These patients completed both the pedi-IKDC (Appendix 1) and the Child Health Questionnaire CF-87 (CHQ), a generic outcome instrument designed to assess the health-related quality of life in children and adolescents.[16] The CHQ has been validated for a range of pediatric conditions.[1,2,18,19,21] Ninety-three patients (15.8%) in group A reported a previous knee disorder that predated the chief complaint at the time of completion of the outcome instruments. The

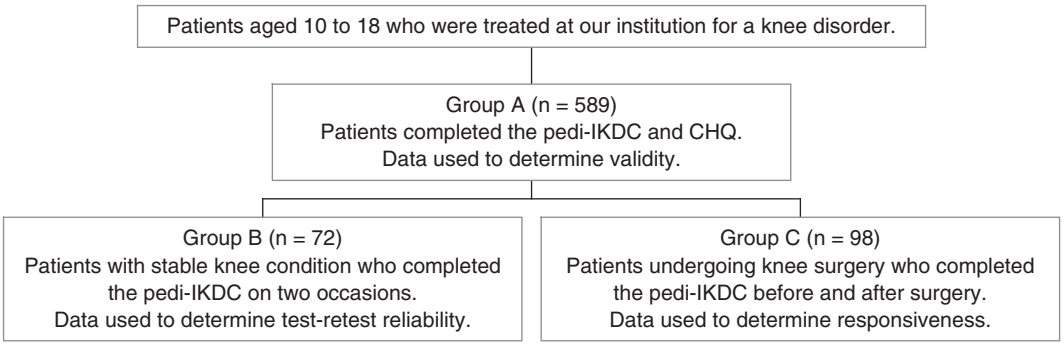

Figure 1. The groups of patients included in the study. IKDC, International Knee Documentation Committee; CHQ, Child Health Questionnaire.

remaining 496 patients (84.2%) had no previous knee problem. Treatment consisted of surgical intervention in 341 patients (57.9%) and nonsurgical intervention in 248 patients (42.1%).

Group B was a subset of group A, and it consisted of 72 patients whose knee condition was determined by the treating physician to be stable. The average age of the patients in this group was 14.6 ± 2.4 years (range, 10.2 to 18.5 years). There were 29 males (40.3%) and 43 females (59.7%). Individuals in this group completed the pedi-IKDC on 2 occasions at an average of 17 days apart (range, 3 to 67 days). Patients in this group were those awaiting surgical intervention and those with a knee condition that was not anticipated to change. For those patients awaiting surgery, completion of the instrument on both occasions occurred before the scheduled surgical date. Patients who had surgery or an acute injury within the past 6 months were excluded from this group.

Group C was a subset of Group A, and it consisted of 98 patients undergoing any knee surgery (Table 2). Mean age of the patients in this group was 14.9 ± 2.3 years (range, 10.4 to 18.9 years). There were 47 males (48%) and 51 females (52%). Patients in this group completed the pedi-IKDC on 2 occasions, once before surgery and once at a postoperative clinic visit. Preoperative completion of the pedi-IKDC occurred an average of 7.5 weeks before surgery (range, 0.4 to 29.1 weeks), and postoperative completion was an average of 7.6 months after surgery (range, 3.1 to 12.1 months).

TABLE 2
Surgical Procedures Performed on Patients in Group C: The Responsiveness Analysis

Surgical Procedure	n (%)[a]
Anterior cruciate ligament reconstruction	36 (37)
Meniscal procedure	
Meniscectomy	25 (26)
Meniscal repair	16 (16)
Patellar procedure	
Lateral release	13 (13)
Lateral release with medial plication	11 (11)
Distal realignment	2 (2)
Articular cartilage procedure	
Microfracture	15 (15)
Chondroplasty	11 (11)
Osteochondral fragment fixation	3 (3)
Cartilage cell transplant	1 (1)
Plica excision	19 (19)
Synovectomy	14 (14)
Other[b]	7 (7)

[a]n = 98. Some patients had more than 1 surgical procedure.
[b]Other surgical procedures included arthroscopic lysis of adhesions, screw removal, and irrigation.

Test-Retest Reliability

Test-retest reliability was determined in group B. The intraclass correlation coefficient (ICC) was determined for the overall pedi-IKDC score. An ICC >.70 was considered acceptable.[14]

Internal Consistency

Internal consistency was determined in group B. Preoperative pedi-IKDC scores were used to establish internal consistency. Cronbach alpha >.60 was considered acceptable.[14]

Content Validity

Content validity was determined in group A. Preoperative pedi-IKDC scores were used to establish content validity. Floor and ceiling effects were determined for the overall pedi-IKDC score, for each of the 18 domains of the pedi-IKDC, and for the overall pedi-IKDC score for patients with the most common diagnoses. The 18 domains of the pedi-IKDC are as follows: activity with pain, pain in the past 4 weeks, severity of pain, swelling, activity with swelling, catching, activity with giving way, highest activity, going upstairs, going downstairs, kneeling, squatting, sitting, rising, running, jumping, stopping, and overall knee function. Floor and ceiling effects <30% were considered acceptable.[14]

Criterion Validity

Criterion validity was determined in group A. Preoperative pedi-IKDC scores were used to establish criterion validity.

Correlation of the overall pedi-IKDC score to the 11 domains of the CHQ was performed. The 11 CHQ domains are as follows: physical functioning, emotional limitations, behavioral limitations, physical limitations, bodily pain, behavior, mental health, self-esteem, general health perceptions, family activities, and family cohesion. The Pearson product-moment correlation coefficient (r) was used to measure correlation between continuous variables.

Construct Validity

Construct validity was determined in group A. Preoperative pedi-IKDC scores were used to establish construct validity. The following 11 hypotheses (constructs) were developed by consensus from questions in the CHQ and were tested using the t test.

1. Patients with greater difficulty walking several blocks or climbing several flights of stairs would have lower pedi-IKDC scores.
2. Patients with greater difficulty getting around their school, neighborhood, or playground would have lower pedi-IKDC scores.
3. Patients with greater difficulty walking 1 block or climbing 1 flight of stairs would have lower pedi-IKDC scores.
4. Patients with greater difficulty doing their tasks around the house would have lower pedi-IKDC scores.
5. Patients with greater difficulty bending, lifting, or stooping would have lower pedi-IKDC scores.
6. Patients with greater difficulty doing certain kinds of schoolwork or activities with friends would have lower pedi-IKDC scores.
7. Patients with more severe bodily pain or discomfort during the past 4 weeks would have lower pedi-IKDC scores.
8. Patients with more frequent bodily pain or discomfort would have lower pedi-IKDC scores.
9. Patients who felt worse about their ability to play sports would have lower pedi-IKDC scores.
10. Patients who felt worse about the things they can do would have lower pedi-IKDC scores.
11. Patients whose health or behavior has more regularly limited the types of activities that they could do as a family during the past 4 weeks would have lower pedi-IKDC scores.

Responsiveness

Responsiveness to change was determined in group C. The effect size was calculated with the following formula: (mean postoperative score – mean preoperative score) / standard deviation of preoperative score. The standardized response mean was calculated with the following formula: (mean postoperative score – mean preoperative score) / standard deviation of the change in score. Small effects were considered >0.20; moderate effects were considered >0.50; and large effects were considered >0.80.[14]

RESULTS

Test-Retest Reliability

There was acceptable test-retest reliability for the overall pedi-IKDC score (ICC = 0.91, 95% confidence interval = .86 to .95).

Internal Consistency

There was acceptable internal consistency for the overall pedi-IKDC score (Cronbach alpha = .91, $P < .00001$).

Content Validity

The overall mean pedi-IKDC score (and standard deviation) was 59 ± 22 (range, 4 to 100) with acceptable (<30%) floor and ceiling effects (Appendix 2). There were acceptable floor effects (<30%) for each of the 18 domains of the pedi-IKDC. There were acceptable ceiling effects (<30%) for the domains of activity with pain, pain in the past 4 weeks, severity of pain, swelling, activity with swelling, activity with giving way, highest activity, kneeling, squatting, running, jumping, stopping, and overall knee function. The domains of catching, going upstairs, going downstairs, sitting, and rising had a high ceiling effect (>30%). The most common diagnostic subgroups—anterior cruciate ligament injury, meniscus injury, patellofemoral syndrome, lateral patellar subluxation, osteochondritis dissecans, and plica syndrome—all had acceptable floor and ceiling effects that did not differ from those of the overall pedi-IKDC score.

Criterion Validity

Significant ($P < .01$) correlation was found between the overall pedi-IKDC score and the CHQ domains of physical functioning ($r = .65$), emotional limitations ($r = .35$), behavioral limitations ($r = .20$), physical limitations ($r = .45$), bodily pain ($r = .61$), mental health ($r = .30$), self-esteem ($r = .32$), general health perceptions ($r = .20$), and family activities ($r = .37$). The correlations between the pedi-IKDC score and the CHQ physical domains of physical functioning, physical limitations, and bodily pain were most highly correlated ($P < .001$) (Figure 2). The overall pedi-IKDC score was not significantly correlated with the CHQ domains of behavior ($r = .15$) or family cohesion ($r = .05$).

Construct Validity

All 11 hypotheses (constructs) were found to be highly significant ($P < .0001$) (Appendix 3).

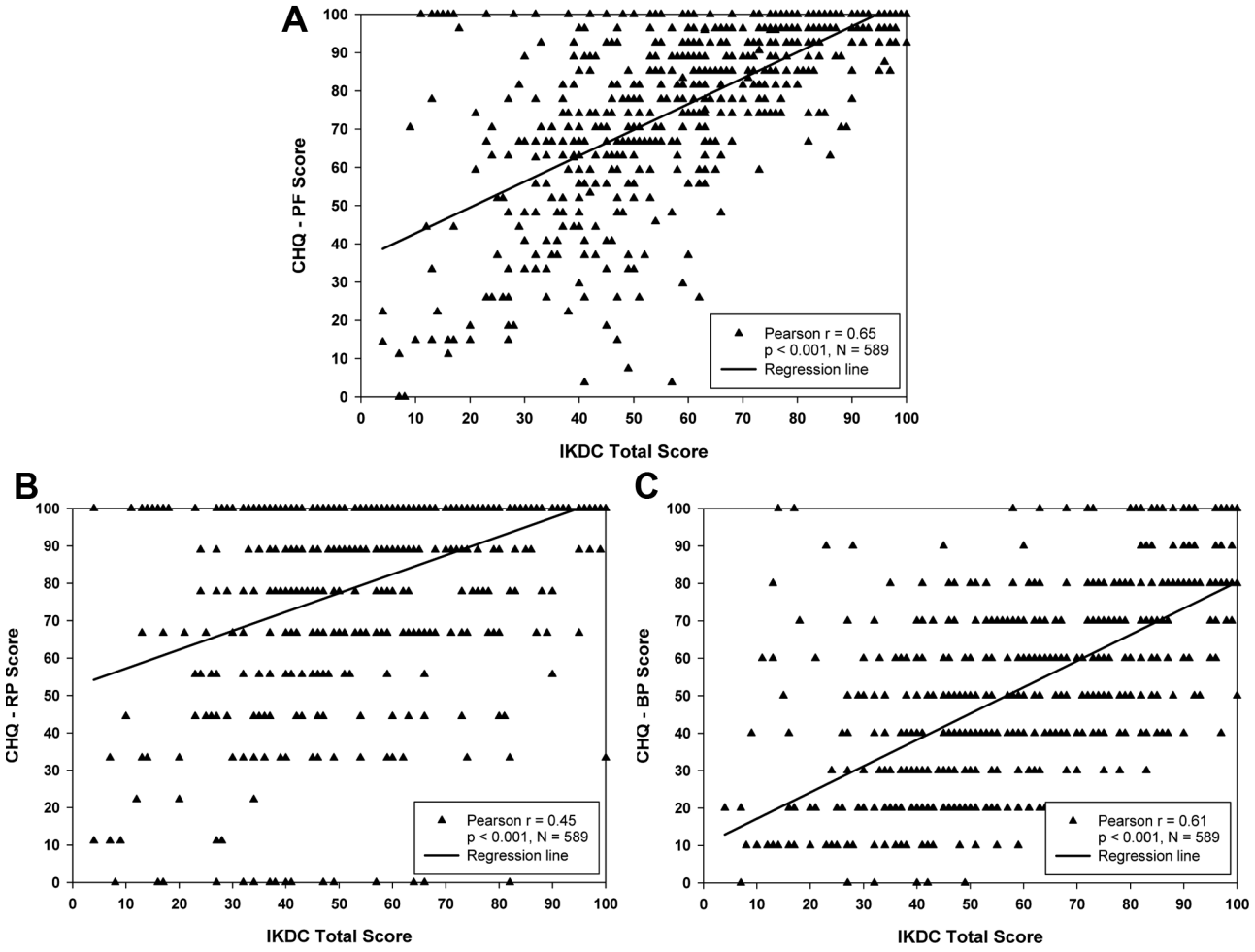

Figure 2. Correlation between the score on the pedi-IKDC (ie, the modified International Knee Documentation Committee Subjective Knee Form) and the Child Health Questionnaire (CHQ) physical domains of (A) physical functioning (PF), (B) role physical (RP), and (C) bodily pain (BP; $P < .001$).

Responsiveness

The overall pedi-IKDC score demonstrated a large effect size (>0.80; [81.8 − 52.7] / 20.9 = 1.39) and a large overall standardized response mean (>.80; [81.8 − 52.7] / 21.5 = 1.35). Overall scores improved an average of 29.1 ± 21.5 points after knee surgery ($P < .0001$, paired t test). Similar improvement was seen for the subgroups of male patients, female patients, patients aged 10 to 14 years, and patients aged 15 to 18 years (Figure 3).

DISCUSSION

This study demonstrated that the patient-administered pedi-IKDC has acceptable psychometric parameters (test-retest reliability, internal consistency, floor and ceiling effects, criterion validity, construct validity, and responsiveness) when tested in children and adolescents. The pedi-IKDC instrument is a valid outcome measure for the pediatric population with knee disorders.

An initial investigation using cognitive interviews in children suggested that the IKDC Subjective Knee Form, as utilized in adult populations,[11] presents problems in children and adolescents with respect to comprehension and response mapping (matching of an individual answer to potential options).[13] Based on these findings, the IKDC Subjective Knee Form was modified in the areas of general instruction, language (grammar and terminology), question (item) content/format, and mapping to produce the pedi-IKDC used in this study (Appendix 1).[13] In this study, parents and caregivers were permitted to assist children with completion of outcome instruments. Although this does create a potential bias related to outcome assessment by proxy, this is a fairly typical approach in pediatric outcome assessment.

An outcome instrument's reliability refers to the reproducibility of the score between tests (test-retest reliability) or between observers (interobserver reliability). In this analysis, we found acceptable test-retest reliability for the overall pedi-IKDC score. We also demonstrated acceptable internal consistency.

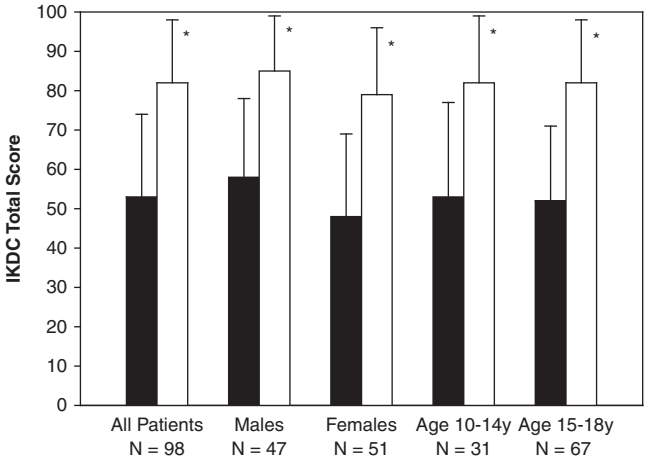

Figure 3. Total score on the pedi-IKDC (ie, the modified International Knee Documentation Committee Subjective Knee Form) preoperatively (black bars) and postoperatively (white bars). Scores were evaluated by paired *t* tests (all asterisks denote $P < .0001$).

An instrument's content validity assesses its ability to cover all dimensions of the variable. This can be determined by expert consensus opinion or, as done in this study, by measurement of floor and ceiling effects. We found the pedi-IKDC to have high ceiling effects for the domains of catching, going upstairs, going downstairs, sitting, and rising. These data imply that these domains lack the discriminatory ability to differentiate the functional status of different patients. Yet, whereas certain domains were not adequately discriminating and should not be used alone, the pedi-IKDC is intended for use as a complete instrument with an aggregate score. The floor and ceiling effects of the overall score were acceptable, as were those for the most common diagnoses of patients included in this study. It is certainly possible that another outcome instrument may be more discriminating for the domains of catching, ascending or descending stairs, sitting, and rising in children.

Criterion validity assesses an instrument's relationship to an accepted outcome instrument—ideally, a gold standard, if one exists. The CHQ is a well-established outcome instrument, and it has been used to validate other outcome tools in the pediatric literature.[1,2,18,19,21] We found the pedi-IKDC to be significantly correlated with 9 of the 11 domains of the CHQ. The physical domains of the CHQ—physical functioning, physical limitations, bodily pain—were most highly correlated, whereas the CHQ domains of behavior and family cohesion were not significantly correlated. Similarly, domains of mental health, self-esteem, emotional limitations, family activities, general health perceptions, and behavioral limitations were only moderately correlated. These findings are not surprising, given that the pedi-IKDC was designed to assess knee-specific symptoms, function, and sports activity. This instrument was not designed to assess the effect of knee disorders on emotional or social health. The finding that all 11 constructs were significant indicates that the pedi-IKDC follows accepted hypotheses and produces results consistent with theoretical expectations in children. The analysis of responsiveness, as generated by completion of the pedi-IKDC before and after a variety of surgical procedures of the knee, showed a high effect size and a high standardized response mean, indicating that this instrument is responsive.

Psychometric properties of the IKDC Subjective Knee Form have been examined in several other studies.[5,10-12] Our observed data for the pedi-IKDC in children are comparable with those found by Irrgang et al[11,12] when they performed the initial psychometric testing for the IKDC Subjective Knee Form. Our observed Cronbach alpha of .91 for internal consistency was similar to their .92; our ICC of .91 for test-retest reliability was similar to their .95.[11] Their analysis of criterion validity demonstrated correlations between the IKDC Subjective Knee Form and the Short Form-36 for physical functioning (.47 to .66) and emotional functioning (.16 to .26).[11] This is similar to our correlations to the CHQ for the physical domains (.45 to .65) and the nonphysical domains (.05 to .37). For responsiveness, we observed an effect size of 1.39 and a standardized response mean of 1.35, comparing favorably with the effect size of 1.13 and standardized response mean of 0.94.[12]

Whereas the IKDC Subjective Knee Form has acceptable psychometric properties in adult orthopaedic populations, it has diminished comprehensibility and utility in children and adolescents. The pedi-IKDC was developed to allow for greater utility in children and adolescents. This study demonstrates that the pedi-IKDC is a reliable, valid, and responsive tool to assess outcome in children and adolescents with a broad range of knee disorders. Thus, it should be used in knee outcomes assessment in patients aged 10 to 18 years.

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