0363-5465/101/2929-0600$02.00/0
THE AMERICAN JOURNAL OF SPORTS MEDICINE, Vol. 29, No. 5

Development and Validation of the International Knee Documentation Committee Subjective Knee Form*

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ABSTRACT

A committee of international knee experts created the International Knee Documentation Committee Subjective Knee Form, which is a knee-specific, rather than a disease-specific, measure of symptoms, function, and sports activity. The purpose of this study was to evaluate the reliability and validity of the new International Knee Documentation Committee Subjective Knee Form. To provide evidence for reliability and validity, we administered the final version of the form, along with the Short Form-36, to 533 patients with a variety of knee problems. Analyses were performed to determine reliability, validity, and differential item function related to age, sex, and diagnosis. Factor analysis revealed a single dominant component, making it reasonable to combine all questions into a single score. Internal consistency and test-retest reliability were 0.92 and 0.95, respectively. Based on test-retest reliability, the value for a true change in the score was 9.0 points. The International Knee Documentation Committee Subjective Knee Form score was related to concurrent measures of physical function (r = 0.47 to 0.66) but not to emotional function (r = 0.16 to 0.26). Analysis of differential item function indicated that the questions functioned similarly for men versus women, young versus old, and for those with different diagnoses. In conclusion, the International Knee Documentation Committee Subjective Knee Form is a reliable and valid knee-specific measure of symptoms, function, and sports activity that is appropriate for patients with a wide variety of knee problems. Use of this instrument will permit comparisons of outcome across groups with different knee problems.

The evolution of knee surgery has been predicated on the development, evaluation, and refinement of new surgical techniques. Historically, empiric assessment was used to document the relative efficacy of treatment. This unscientific approach often resulted in erroneous conclusions by researchers and it prompted O'Donoghue to state, "results from various methods have been unsatisfactory despite the rather glowing reports by the promulgator of each."[26] The problem lies not in veracity but in human nature, subjective interpretation of variables, and difficulty in evaluating results. Even the most conscientious researcher, especially the surgeon, is subject to bias, and patients may present an optimistic assessment to please the surgeon.

In 1955, O'Donoghue[26] tried to standardize assessment by devising a rating system to evaluate results. This and other rudimentary scales were used as a foundation for several comprehensive systems of evaluation.[8,10,13,32]

*Presented at the 27th annual meeting of the AOSSM, Keystone, Colorado, June 2001; at the 68th annual meeting of the American Academy of Orthopaedic Surgeons, San Francisco, California, March 2001; and at the International Society of Arthroscopy, Knee Surgery, and Orthopaedic Sports Medicine Congress, Montreux, Switzerland, May 2001.

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No author or related institution has received any financial benefit from research in this study.

Feagin and Blake[9] were the first to recognize that comparing results of different methods of treatment was impossible without a standard method of evaluation. This problem was exacerbated in the 1980s when new operative procedures, designed to correct ACL insufficiency, were evaluated with numerous rating systems.[2] Researchers have subsequently demonstrated that differences in existing scales were sufficiently great to preclude predicting results from one scale based on another.[1,5,9,18,28,33] The consensus of opinion was that discrepancies among existing scales have been an impediment to the evolution of knee surgery, and a standard method of evaluation was vital to the evaluation of treatment. Consequently, the International Knee Documentation Committee (IKDC) was formed in 1987 to develop a standardized international documentation system.

The initial objectives of the IKDC were to develop a one-page form, including only the essential reproducible criteria necessary to evaluate results, and to keep the form simple enough to be used by any clinician, including both those with and without research assistance. It was anticipated that the standard form would serve as a framework for a more comprehensive evaluation system.

The IKDC initially agreed on standard terminology to document knee motion and function.[25] Next, clinical examination of the limits of knee motion was critiqued and a core (set) of measurements was validated.[6,23,24] Finally, methods to document activity, evaluate limb function, and assess symptoms were evaluated and a format to record these observations was adopted. The IKDC standard knee evaluation form was published by Hefti et al.[12] in 1993 and revised in 1994.[1]

In March 1997, the AOSSM board of directors moved to support revision of the knee ligament evaluation form created by the IKDC. The board's interest in revision stemmed from the success of the initial form, as demonstrated by widespread clinical use, and the opportunity to integrate advances in measurement of medical outcomes into the knee ligament form, making it more broadly applicable and credible.

In the fall of 1997, work on the revision process began. Committee members (Table 1) were assigned to one of three item-work groups related to the ACL, PCL, or patellofemoral joint. Each member was charged with reviewing background material for the purposes of identifying new measures or making revisions to existing measures that could be included in the objective portion of the revised form. Parallel to the development of new objective measurements, new demographic and subjective components were drafted to be compatible with the objective module.

TABLE 1
International Knee Documentation Committee Members

North American members	European members
Allen Anderson, Co-chairman	Hans-Uli Staubli, Co-chairman
John Bergfeld	Fritz Hefti
Art Boland	Jorgen Hoher
Scott Dye	Roland Jakob
Christopher Harner	Werner Mueller
Mininder Kocher	Phillipe Neyret
John Richmond	
Donald Shelborne	
Glenn Terry	
Pacific Rim members	**Ex-Officio**
K. M. Chan	John Feagin
Masahiro Kurosaka	John Fulkerson

The first version of the demographic component was derived primarily from the current health assessment module of the AAOS Musculoskeletal Outcomes Data Evaluation and Management Systems (MODEMS) questionnaires. The demographic component includes standard age, sex, race, and education questions, as well as a fully tested comorbidity index (Greenfield Comorbidity Index).[27] The new subjective component included a general health status questionnaire (Short Form-36, or SF-36),[19,20,34] which represents a new dimension of measurement for the knee ligament evaluation form. The demographic component and general health status questionnaire were included because patients with knee conditions may have other health-related problems that could adversely affect the outcome score. Additionally, documentation of general health status assures accurate comparison of results from one group of subjects to another.

Between October 1997 and March 1998, three revisions of the subjective component of the IKDC form were completed, including the addition, deletion, and modification of hundreds of items. By March 1998 the committee agreed that a testable form had been drafted. The purpose of this manuscript is to report the process used to develop the IKDC Subjective Knee Form as well as its reliability and validity.

METHODS

Development of the IKDC Subjective Knee Form included specification of the purpose of the instrument; defining the construct (that is, the underlying nonobservable concept; see Appendix 1) to be measured; generation, review, and preliminary tryout of questions; field testing of preliminary questions on a large representative sample; determination of statistical properties of the questions; selection of questions for the final version of the form; and administration of the final version of the IKDC Subjective Knee Form to a sample of patients to provide evidence for reliability and validity. These activities were performed under the auspices of the IKDC with the advice of a psychometric consultant.

Development of Initial Version of the IKDC Subjective Knee Form

The IKDC Subjective Knee Form was designed as an evaluative measure to detect improvement or deterioration in symptoms, function, and sports activity experienced by patients with a variety of knee conditions, including ligament and meniscal injuries, articular cartilage lesions, and patellofemoral pain. Important measurement characteristics of an evaluative measure of health status

include test-retest reliability, responsiveness, and validity.[17] Thus, the IKDC Subjective Knee Form was designed to represent symptoms and limitations in function and sports activity due to impairment of the knee and to maximize test-retest reliability, responsiveness, and validity.

The initial set of questions for the IKDC Subjective Knee Form was developed by members of the IKDC. The committee considered questions from the previous version of the IKDC Subjective Knee Form, the MODEMS Lower Limb Instrument, and the Activities of Daily Living and Sports Activity Scales of the Knee Outcome Survey.[14] The initial set of questions included 27 questions related to symptoms, 8 questions related to function during activities of daily living, 4 questions related to function during sports activities, 3 questions related to current function of the knee, 5 questions related to participation in sports or work activities or both, and 1 question related to mood. Symptoms represented on the initial version of the IKDC Subjective Knee Form included pain, swelling, stiffness, giving way, and locking. Questions related to function during activities of daily living included the ability to walk on level surfaces, ascend and descend stairs, stand, kneel on the front of the knee, squat, sit with the knee bent, and to rise from a chair. Questions related to function during sports activities included the ability to run straight ahead, jump and land on the involved leg, stop and start quickly, and to cut and pivot. A variety of formats were used to create responses for the questions. These included dichotomous responses (2 questions) and Likert-type responses with 3 to 6 responses per question (45 questions); an 11-point rating scale was used for one question.

Pilot Testing of the Initial Version of the IKDC Subjective Knee Form

The initial version of the IKDC Subjective Knee Form was pilot tested on a sample of 144 patients seen at the orthopaedic sports medicine practices of 3 surgeons (AFA, CDH, JCR) for evaluation of the knee. The average age of this sample was 36.1 years (standard deviation, 16.2; range, 13 to 75) and 57.8% (74 of 128) of the subjects were male; sex of the patient was not recorded in 16 cases. The majority of patients (134 of 143, or 93.7%) were white, 81.3% (117) had graduated from high school, and 39.6% (57) had graduated from college. In this sample, 78.3% (112 of 143) participated in sports activities; 15.4% (22) were competitive athletes and 63% (90) were recreational athletes. The remaining patients did not participate in sports activities. Diagnoses were not recorded for patients in this sample; however, no patients were excluded on the basis of diagnosis.

Evaluation of the data revealed that many questions were unanswered. Questions most frequently unanswered were related to pain, swelling, and the presence and frequency of giving way during very strenuous, strenuous, moderate, and light activities. The results of pilot testing were used to revise or delete existing questions and to develop new questions. The second version of the IKDC Subjective Knee Form consisted of 41 questions: 19 questions related to symptoms, 8 questions related to function during activities of daily living, 4 questions related to function during sports activities, 3 questions related to current function of the knee, 5 questions related to participation in sports or work activities, 1 question related to mood, and 1 question related to overall health compared with a subject of similar age.

Field Testing and Item Reduction to Produce the Final Version of the IKDC Subjective Knee Form

The second version of the IKDC Subjective Knee Form was administered to 222 patients seen at the orthopaedic sports medicine practices of 3 surgeons (AFA, CDH, JCR) for evaluation of the knee. The average age of this sample was 38.4 years (standard deviation, 18.6; range, 12 to 91) and 54.7% (116 of 212) were male; the patient's sex was not recorded in 10 cases. Diagnoses were provided for 217 patients by the physician based on the history, physical examination, and diagnostic studies. The most common diagnoses included ligament injury (57, or 26.2%), osteoarthritis (56, or 25.8%), meniscal injury (31, or 14.3%), and patellofemoral pain (29, or 13.4%). Other diagnoses included contusions, fractures, dislocations, tendinitis, synovitis, bursitis, loose bodies, and nonspecific joint pain.

Evaluation of the data revealed fewer questions that were unanswered; however, some questions still had more than 15% missing data. Questions most frequently unanswered were related to swelling and instability during very strenuous, strenuous, and moderate activities. Because of the relatively high number of missing answers, these questions were either reworded or deleted from the final version IKDC Subjective Knee Form.

The data were used to calculate statistics for each question and the resultant statistics were used by members of the IKDC to select questions for the final version of the IKDC Subjective Knee Form. The statistical analyses included the correlations between each individual question and the total score, coefficient alpha with each question sequentially deleted, factor loadings, and infit and outfit statistics from a Rasch analysis. Details of the statistical analyses used to select questions for the final version of the IKDC Subjective Knee Form are provided in Appendix 1.

By considering the statistical properties and content of individual questions, the committee reduced the final version of the IKDC Subjective Knee Form to 18 questions. The final version is included in Appendix 2.

Evidence for Interpretation of the Final Version of the IKDC Subjective Knee Form

The final version of the IKDC Subjective Knee Form was administered to 590 patients seen at the orthopaedic sports medicine practices of 7 surgeons (AFA, ALB, CDH, MK, PN, JCR, and KDS). Only those patients who had less than 10% missing data for the IKDC Subjective Knee Form (that is, those who answered at least 16 of the 18 items) were included in the final analysis. Thus, 533 patients were included in the final analysis. The average age of the patients was 37.5 years (standard deviation, 16.2; range, 6.2 to 86.6) and 52.6% (252 of 479) were male; the

patient's sex was not recorded in 54 cases. The majority of patients were white (492, or 92.3%), 83.2% (412 of 495 in which education was recorded) had graduated from high school, and 48.7% (241) had graduated from college. In this sample, 76.1% (379 of 498 in which activity was recorded) participated in sports activities; 19.1% (95) were competitive athletes and 57.0% (284) were recreational athletes. The remaining patients did not participate in sports. Diagnoses were established by the physician based on a history, physical examination, and diagnostic studies and are summarized in Table 2.

To provide evidence for validity, the Medical Outcomes Study SF-36 was administered concurrently with the IKDC Subjective Knee Form. The SF-36, a general measure of health status, measures eight dimensions of health, including physical function, role limitations due to physical problems, bodily pain, general health, vitality, social function, role limitations due to emotional problems, and mental health. The eight scores were combined to produce physical and mental component summary scores. The reliability and validity of the SF-36 have been investigated extensively.[19,20,34] Several studies have recently provided evidence for the usefulness of the SF-36 in patients with impairment of the knee.[7,15,29] It was hypothesized that the IKDC Subjective Knee Form would be highly related to physical and social function but not to emotional function as measured by the SF-36.

To assess test-retest reliability, the IKDC Subjective Knee Form was administered twice to a sample of 33 subjects participating in several long-term outcome studies. The average time between repeat administrations of the IKDC Subjective Knee Form was 49.7 days (standard deviation, 24.2; range, 4 to 92). The average time from surgery to follow-up was 2.9 years (standard deviation, 1.4; range, 1.2 to 8.0). Thus, it was not likely that there would be a change in the patient's level of symptoms, function, and sports activity between repeat administrations of the instrument. The average age of this sample was 37.2 years (standard deviation, 10.5; range, 17.4 to 57.4) and 39.4% (13) were female.

TABLE 2
Frequency of Diagnoses of Patients in the Sample Used to Validate the Final Version of IKDC Subjective Knee Form

Injury	Number[a]
Ligament injury	150
Anterior cruciate ligament	129
Posterior cruciate ligament	3
Medial collateral ligament	17
Lateral collateral ligament	1
Meniscal injury	108
Medial meniscus	91
Lateral meniscus	17
Patellofemoral pain syndrome	93
Patellar dislocation	15
Osteoarthritis	92
Other conditions[b]	22
Not recorded	83

[a] Number does not total 533 because some patients had more than one diagnosis.
[b] Other conditions include contusions, fractures, and osteochondritis dissecans.

Data Management and Analysis

All data were entered into a computerized database for analysis. Unless otherwise noted, all analyses were performed with SPSS version 10.0 (SPSS Inc., Chicago, Illinois) for a personal computer.

The IKDC Subjective Knee Form was designed to measure symptoms, function, and sports activity in patients with a variety of knee conditions, including ligament and meniscal injuries, articular cartilage lesions, and patellofemoral pain. The initial step in the data analysis was to perform a factor analysis to determine the structure of the IKDC Subjective Knee Form. If symptoms, function, and sports activities represent a single construct, then a factor analysis should identify a single dominant component or factor that represents this construct. Evidence for this would be provided by a factor that has an eigenvalue (that is, the amount of variance accounted for by the factor) that is much larger than that of all the other factors. The factor analysis was performed with NOVAX Version 1.3 (Poor Professor Software, Davis, California). It was hypothesized that one dominant component or factor would be identified that would represent the construct of symptoms, function, and sports activity in subjects with impairment of the knee.

Three methods of scoring the IKDC Subjective Knee Form were assessed. These methods included adding the scores for all of the questions, adding the scores of the questions after weights were applied to the questions, and scoring the questions based on item-response theory (Appendix 1). To calculate the score based on adding the questions, the responses to the questions were assigned a rating scale such that higher numbers reflected the absence of symptoms and higher levels of function and sports activity. The score was calculated as the sum of all questions minus the lowest possible total score divided by the range of possible scores multiplied by 100 (Appendix 1). The resulting score ranged from 0 to 100, with higher scores representing lower levels of symptoms and higher levels of function and sports activity.

The factor loadings for individual questions from the factor analysis were used to create the weighted-item score. Factor loadings indicate the importance of the question to the construct as a whole.[30] The weighted sum of the questions was created by transforming the individual scores for each question to standard scores, multiplying the standard score by the factor loading, and then adding the weighted standard scores for all of the questions. The resulting score had a mean of zero and a standard deviation of one. Item-response theory was also used to create a score for the IKDC Subjective Knee Form according to the partial credit model (see Appendix 1 for details). Pearson correlation coefficients were used to compare the three methods of scoring.

Coefficient alpha was used to determine internal consistency of the IKDC Subjective Knee Form. Test-retest reliability was estimated as the degree of concordance between repeat administrations of the IKDC Subjective Knee Form with an intraclass correlation coefficient (formula 2,1).[31]

Evidence for validity was provided by calculating Pearson correlation coefficients between the IKDC Subjective Knee Form score and the eight scale and two summary component scores of the SF-36. It was hypothesized that the IKDC Subjective Knee Form would be more strongly related to concurrent measures of physical and social function (that is, the physical function, role limitations due to physical function, bodily pain, and social function scales, as well as the physical components summary score of the SF-36) than to concurrent measures of mental function (that is, the role limitations due to emotional problems and mental health scales, as well as the mental components summary score of the SF-36).

The intent of the IKDC Subjective Knee Form was to create a single instrument that would be valid for patients with a variety of knee problems including ligament and meniscal injuries, articular cartilage lesions, and patellofemoral pain. Consequently, a major concern of the committee was that the form would work equally well for patients with different knee problems. Item-response theory was used to determine if the questions on the final version of the IKDC Subjective Knee Form functioned differently for young versus old, men versus women, or for patients with different knee problems. This was accomplished by calculating the statistics for each question separately for each of the subgroups. The resulting pairs of statistics for each question were plotted. If the statistics for the questions were the same in each subpopulation, the resulting plot should approximate a line with an intercept of zero and a slope of one.

RESULTS

The factor analysis revealed a single dominant component that had an eigenvalue much greater than the others (9.03 versus 1.76 and 1.19). The first factor accounted for 50.2% of the total variance. The next largest component accounted for 9.8% of the total variance. The finding of a single dominant component implies that it was reasonable to combine all of the questions into a single total score that represents the construct of symptoms, function, and sports activity.

The factor loadings for the dominant component are presented in Table 3. Questions with factor loadings less than 0.50 imply the question may not be an important measure of the construct and may contribute to measurement error. The results indicated that all items, except items 2 (pain frequency), 6 (locking), and 9e (sitting with bent knee) had factor loadings greater than 0.50. Members of the IKDC elected to include these items to ensure adequate content coverage of the construct.

The average IKDC Subjective Knee Form score based on addition of the scores for the questions in this sample of patients was 45.1 (standard deviation, 18.9; median, 42.2; range, 8.4 to 100). The distribution of scores was positively skewed (skewness, 0.341; standard error of skewness, 0.106) and platykurtic (kurtosis, −0.595; standard error of kurtosis, 0.211). A platykurtic distribution implies the distribution is somewhat flatter than the normal distribution.[30] No patients had a score of zero (that is, there were no floor effects), and only one patient had a score of 100 (that is, 0.2% had a ceiling effect).

TABLE 3
Factor Loadings of Individual Items on First Component of Principal Components Analysis

Item number	Item content	Factor loading
1	Highest activity without pain	0.78
2	Pain frequency	0.49
3	Pain severity	0.52
4	Swelling	0.55
5	Highest activity without swelling	0.78
6	Locking	0.39
7	Highest activity without instability	0.81
8	Highest level of activity	0.67
9a	Ascending stairs	0.81
9b	Descending stairs	0.82
9c	Kneeling	0.73
9d	Squatting	0.78
9e	Sitting with bent knee	0.48
9f	Rising from chair	0.72
9g	Running straight ahead	0.86
9h	Jumping and landing	0.84
9i	Stopping and starting	0.74
10	Current function of knee	0.74

The correlations between the score based on addition of the questions with the score based on addition of the questions after weights were applied to each question and the score based on item-response theory were 0.98 and 0.99, respectively. The unweighted and partial credit model method of scoring the IKDC Subjective Knee Form identified the same five highest and lowest scoring subjects. The weighted-sum method of scoring identified four of the five highest scoring subjects and three of the five lowest scoring subjects according to the unweighted-sum method of scoring. Given these results and the simplicity of scoring, adding the scores of the questions is the recommended method to score the IKDC Subjective Knee Form.

Because questions 2, 3, and 10 had 11-point response scales, the standard deviations of these questions were greater than the standard deviations of the remaining questions. To eliminate the effects of unequal standard deviations on coefficient alpha, coefficient alpha was calculated after standardizing each question to have a mean of zero and standard deviation of one. After doing this, coefficient alpha was 0.92. Sequential deletion of each question did not appreciably influence coefficient alpha, indicating all questions contributed to the consistency of measurement of the IKDC Subjective Knee Form. The standard error of measurement using coefficient alpha was 5.4, resulting in a 95% confidence interval for the IKDC Subjective Knee Form true score of 10.5.

Analysis of the test-retest data revealed the mean IKDC Subjective Knee Form scores for the first and second administrations were 71.3 and 71.7, respectively. The test-retest reliability coefficient (intraclass correlation coefficient formula 2,1) was 0.94, and the 95% confidence for the test-retest reliability coefficient was from 0.88 to 0.97. The standard error of measurement calculated with the test-retest reliability coefficient was 4.6, resulting in a 95%

TABLE 4
Pearson Correlation Coefficient Between IKDC Subjective Knee Form and Individual Scale and Summary Component Scores of SF-36

Concurrent measure	Pearson correlation coefficient with IKDC Subjective Knee Form
Physical function	0.63
Role limitations due to physical problems	0.47
Bodily pain	0.64
General health	0.30
Vitality	0.39
Social function	0.47
Role limitations due to mental problems	0.26
Mental health	0.25
Physical components summary score	0.66
Mental components summary score	0.16

confidence interval for a true change in the IKDC Subjective Knee Form score of ±9.0. Thus, changes in the IKDC Subjective Knee Form score greater than nine points represent true changes, and score change less than nine points represent sampling error due to the occasion of testing.

The correlations between the IKDC Subjective Knee Form and the SF-36 are displayed in Table 4. As expected, the IKDC Subjective Knee Form was more strongly related to concurrent measures of physical and social function (that is, the physical function, role limitations due to physical problems, bodily pain, social function, and physical components summary scores) than to concurrent measures of mental function (that is, role limitations due to emotional problems, mental health, and mental components summary scores). These findings lend evidence for validity of the IKDC Subjective Knee Form score as a measure of symptoms and limitations in function and sports activity.

To determine if the IKDC Subjective Knee Form worked equally well for different patients, the difficulty statistics for the questions were calculated separately for the sample split by age (young versus old), sex (male versus female), and diagnosis (ligament versus no ligament injury, meniscal injury versus no meniscal injury, patellofemoral problems versus no patellofemoral problems, and osteoarthritis versus no osteoarthritis). The resulting plots are presented in Figures 1 through 6. Pearson correlation coefficients between the pairs of difficulty statistics for the questions were also calculated.

The plots for the sample split by age and sex reveal that the questions are close to a line with a slope of one and an intercept of zero (Figs. 1 and 2). The correlations between the pairs of difficulty statistics for the questions were 0.95 and 0.97 when the sample was split by age and sex, respectively. Thus, it appears that the questions function similarly for young versus old and men versus women.

The plot of difficulty statistics for the questions for those with a ligament injury versus those without a ligament injury is presented in Figure 3. Except for questions 2 (frequency of pain), 9a (ascending stairs), and 9b (descending stairs), all of the questions are close to the line with a slope of one and an intercept of zero. Thus, most of the questions function similarly for those with and without a ligament injury. Questions 2, 9a, and 9b were relatively more difficult for those with a ligament injury. The correlation between the pairs of difficulty statistics for the questions was 0.94 when the sample was split by the presence or absence of a ligament injury.

The plots of difficulty statistics for the questions for those with and without patellofemoral problems, those with and without meniscal injury, and those with and without arthritis are presented in Figures 4, 5, and 6, respectively. In all of the plots all of the items are close to the line with a slope of one and intercept of zero. The correlations between difficulty statistics for the questions were 0.95, 0.99, and 0.95 for patellofemoral problems, meniscal injuries, and osteoarthritis, respectively. These

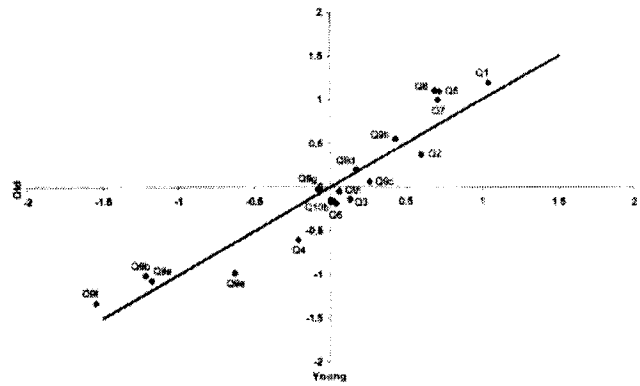

Figure 1. Plot of difficulty statistics for questions for young versus old. The median age was used to divide the sample into young and old patients. Difficulty statistics for each question were calculated separately for each subsample. Individual data points represent the pairs of difficulty statistics for each question. Letters and numbers (for example, Q1) refer to question number represented by adjacent data point. The solid line represents a line with a slope of one and an intercept of zero. If the items functioned the same in each subsample, the data points should lie close to the solid line.

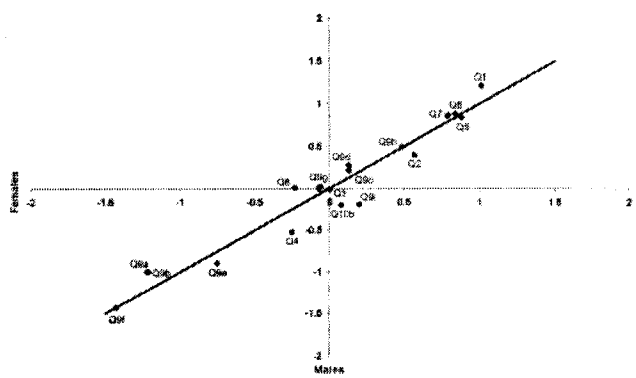

Figure 2. Plot of difficulty statistics for questions for men versus women. See legend at Figure 1 for explanation of the method.

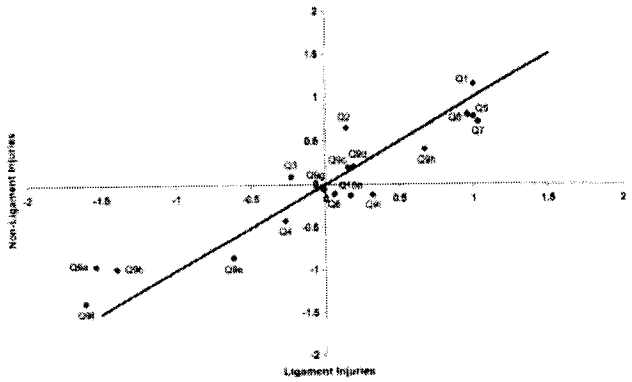

Figure 3. Plot of difficulty statistics for questions for those with a ligament injury versus those without a ligament injury. See legend at Figure 1 for explanation of the method.

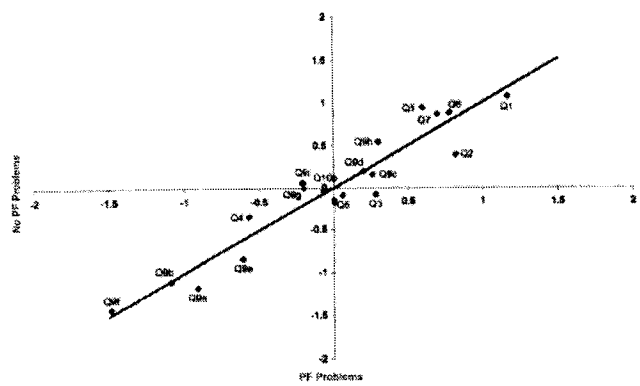

Figure 4. Plot of difficulty statistics for questions for those with patellofemoral (PF) problems versus those without patellofemoral problems. See legend at Figure 1 for explanation of the method.

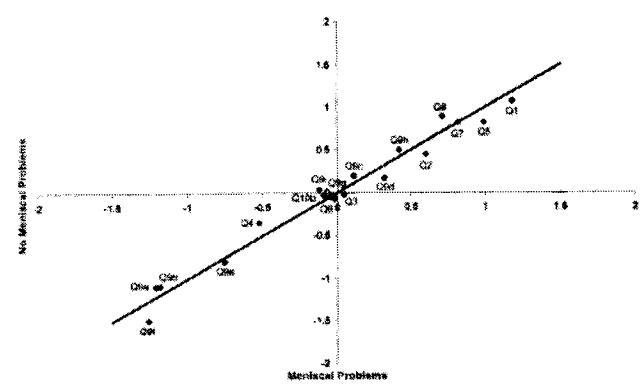

Figure 5. Plot of difficulty statistics for questions for those with a meniscal injury versus those without a meniscal injury. See legend at Figure 1 for explanation of the method.

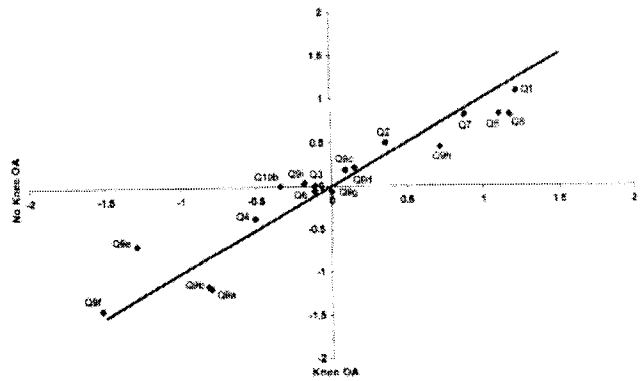

Figure 6. Plot of difficulty statistics for questions for those with osteoarthritis (OA) versus those without arthritis. See legend at Figure 1 for explanation of the method.

data indicate that the questions did not function differently for those with or without patellofemoral problems, meniscal injury, or osteoarthritis.

DISCUSSION

The results of this study indicate that the IKDC Subjective Knee Form is a reliable and valid measure of symptoms, function, and sports activity in patients with a variety of knee conditions, including ligament and meniscal injuries, articular cartilage lesions, osteoarthritis, and patellofemoral pain.

Statistical factors and content were considered when selecting questions for the final version of the IKDC Subjective Knee Form. As evidenced by the factor loadings from the factor analysis, all of the questions except 2 (pain frequency), 6 (locking), and 9e (sitting with the knee bent) were important measures. Inclusion of these questions may contribute to measurement error because they appear to be measuring something other than the construct of interest. However, deletion of these questions did not appreciably influence internal consistency. After consideration, the IKDC elected to retain these questions on the final version of the IKDC Subjective Knee Form to ensure adequate content coverage for a variety of knee conditions. Both frequency and severity are important characteristics of pain. Locking is often associated with internal derangement of the knee and may occur with meniscal injuries or loose bodies. Sitting with the knee bent may be difficult for those with patellofemoral pain or arthritis.

The factor analysis demonstrated that it is reasonable to combine all of the questions in the IKDC Subjective Knee Score into a single score. Other measures of symptoms and function have applied differential scoring based on the author's perception of what is important and how it should be scored rather than on statistical evidence. For example, the Lysholm Knee Scale[33] assigns greater weight to pain and instability than to the other items included on the scale, and the Cincinnati Knee Scale[3] assigns greater weight to overall activity level and pain than to other items. In this study, we investigated three

different methods of scoring. These included adding unweighted scores for the questions, a weighted sum of the questions that used the factor loadings from the factor analysis, and a method based on item-response theory. The correlations among the three methods of scoring were all high. Additionally, the method adding unweighted scores and the method based on item-response theory identified the same five highest and lowest scoring subjects. Given these results and the simplicity of adding the questions to create the IKDC Subjective Knee Score, adding the unweighted scores is recommended over the other two methods of scoring.

The IKDC Subjective Knee Form has acceptable levels of internal consistency. A high value of coefficient alpha (0.92) indicates that the questions consistently measure the underlying construct of symptoms, function, and sports activity in patients with a variety of knee problems. The underlying concept for internal consistency is that the consistency with which a patient responds from one question to the next can be used to provide an estimate of reliability for the total test score.[22]

Internal consistency can affect the precision of measurement at a single point in time. The influence of internal consistency is evident when the standard error of measurement is calculated using coefficient alpha as the estimate for reliability. Using coefficient alpha, the standard error of measurement for the IKDC Subjective Knee Form was 5.4, resulting in a 95% confidence interval of ± 10.5. Thus, the 95% confidence interval for the true score of a patient with an observed score of 50 is from 39.5 to 60.5.

Test-retest reliability and responsiveness are important characteristics of a rating scale designed to measure change over time.[17] Test-retest reliability reflects measurement error associated with repeated measurement when the patient's status remains the same. Thus, high levels of test-retest reliability imply that repeated measurements yield consistent scores when a patient's symptoms, function, and sports activity have remained constant. The IKDC Subjective Knee Form had high (0.94) levels of test-retest reliability. Using the test-retest reliability coefficient, the standard error of measurement for the IKDC Subjective Knee Form was 4.6, and the resulting 95% confidence interval was ± 9 points. When a patient is measured two or more times with the IKDC Subjective Knee Form, a change of less than nine points from one time to the next should be considered to reflect measurement error rather than a true change in the patient's condition.

Responsiveness is the ability of a form to detect minimal clinically important differences when the patient's status has changed.[11] Demonstration of responsiveness requires administration of the instrument on two or more occasions to patients who are expected to undergo change. In this study the IKDC Subjective Knee Form was administered once to subjects and therefore we are not able to provide evidence for responsiveness of the IKDC Subjective Knee Form at this time. To provide evidence for responsiveness, the IKDC Subjective Knee Form is being administered longitudinally to subjects who participated in this study. The results will be presented in the near future.

Evidence for validity of the IKDC Subjective Knee Form as a measure of symptoms, function, and sports activity was provided by simultaneously administering the SF-36. As hypothesized, the IKDC Subjective Knee Form was more strongly related to concurrent measures of pain and physical and social function than it was to measures of emotional function. These results provide preliminary evidence that the IKDC Subjective Knee Form is a valid measure of symptoms, function, and sports activity. Additional evidence for validity of the IKDC Subjective Knee Form should include demonstration of hypothesized relationships with other current measures of knee function including the Lysholm Knee Scale,[33] Cincinnati Knee Score,[3] the Quality of Life Assessment for Anterior Cruciate Ligament Deficiency,[21] and the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index.[4] The ability of the IKDC Subjective Knee Form to distinguish between groups that are either known to have or expected to have different levels of function would also provide evidence for validity.

A major objective in the development of the IKDC Subjective Knee Form was to create a form that would be appropriate for patients with a variety of knee impairments, including ligament and meniscal injuries, articular cartilage lesions, and patellofemoral conditions. Development of a single form that is valid for patients with a variety of conditions affecting the knee could simplify data collection because the same form could be used for all patients with impairment of the knee. Additionally, use of a single form for all knee problems provides the opportunity to compare the effect of different knee conditions on a patient's level of symptoms, function, and sports activity. This objective influenced all phases of development of IKDC Subjective Knee Form. Emphasis was placed on the development and inclusion of questions that reflected the full spectrum of symptoms and functional limitations during activities of daily living and sports. Examples of this were the inclusion of questions related to sitting with the knee bent and rising from a chair to capture limitations commonly experienced by patients with patellofemoral conditions and osteoarthritis.

Item-response theory was used to determine if the IKDC Subjective Knee Form would perform the same for young versus old, men versus women, or for patients with different knee problems. An important feature of item-response theory is that statistics for individual questions are invariant; consequently, they are independent of the sample of patients that are used to calculate the statistics. Differential functioning of the questions was assessed for age, sex, and diagnosis (that is, ligament and meniscal injury, patellofemoral problems, and osteoarthritis). The results indicated that, with few exceptions, the questions and therefore the entire form functioned similarly regardless of age, sex, or diagnosis.

In addition to assessing responsiveness, future research will include the establishment of age- and sex-specific normative data. Because the IKDC Subjective Knee Form assesses a wide spectrum of symptoms, function, and sports activities, it is not reasonable to expect all patients to achieve the maximum score (that is, a perfect score of 100). Older subjects may not be able to participate in

strenuous activities for reasons other than their knee, and, thus, they could not receive a maximum score even though they may not have any limitations imposed by their knee. Normative data will allow for comparison of results with age- and sex-matched data. For example, the average score for men aged 45 to 55 might be found to be 70 with a standard deviation of 10. A man, age 50, undergoing a high tibial osteotomy may have an IKDC Subjective Knee Score of 80 at 1 year after surgery. While this score of 80 is not the maximum score for the IKDC Subjective Knee Form, it still represents a good outcome because it is a full standard deviation above the patient's age- and sex-specific normative data. Establishing age- and sex-specific normative data for the IKDC Subjective Knee Form will allow for more meaningful interpretation of the IKDC Subjective Knee Form score.

SUMMARY

The IKDC Subjective Knee Form is a reliable and valid measure of symptoms, function, and sports activities for patients with a variety of knee problems. Evidence based on item-response theory indicates that, with few exceptions, the items and, thus, the entire instrument function the same for patients with a variety of knee problems, including ligament and meniscal injuries, articular cartilage lesions, arthritis, and patellofemoral problems. This finding indicates that the IKDC Subjective Knee Form can be used to reliably and validly measure outcome for patients with a variety of knee problems. Data collection may be simplified because the same form can be used for all patients with impairment of the knee, regardless of the diagnosis. Additionally, this will allow for comparison of the effect of different knee problems on a patient's symptoms, function, and sports activity. Future research to establish the usefulness of the IKDC Subjective Knee Form will include assessment of responsiveness as well as establishment of normative data based on age and sex.

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APPENDIX 1

Definition of Construct

A construct represents a nonobservable behavior or event. A construct is an invented name for variables that cannot be seen and measured directly, but are inferred by measuring relevant or correlated behavior that are observable.For example, a patient's symptoms cannot be directly observed and measured. Thus, we rely on a set of questions to indirectly measure a patient's symptoms. These may include questions related to the intensity and frequency of pain; the degree of swelling; and how pain, swelling, and giving way influence a patient's ability to participate in activities. Collectively, these questions define the construct of symptoms.

Calculation of Statistics for Individual Questions Used in the Selection of Items for the Final Version of the IKDC Subjective Knee Form

The correlations between each individual question and the total score were calculated with SPSS version 10.0. When calculating, the individual item in question was deleted from the total score. Questions that had correlations with the total score that were less than 0.50 were considered for deletion by the committee.

Coefficient alpha is an estimate of the instrument's internal consistency. Internal consistency is the degree to which the questions on an instrument consistently measure the construct of interest and is a measure of the degree of error associated with the sampling of questions that are included on the instrument.[1] Internal consistency is high when all items consistently measure the construct of interest. If internal consistency is improved by deletion of a question, then the question does not contribute to consistent measurement of the construct. Thus, questions that resulted in improved values of coefficient alpha when deleted were considered by the committee for elimination from the final version of the instrument.

A factor analysis using polychoric correlations was performed using NOVAX version 1.3 to determine the factorial structure underlying the responses to the questions. A polychoric correlation is appropriate when two variables are ordinal in nature (that is, when the responses are classified into two or more ordered categories).[4] It was hypothesized that the factorial structure underlying the responses to questions included on the IKDC Subjective Knee Form would be unidimensional in nature, as evidenced by a single dominant factor. Evidence for a single dominant factor underlying the responses to the questions implies that the questions are measuring a single construct that is defined by the content of the questions and justifies combination of the questions into a single score.

Factor loadings are the correlations between the question and the underlying latent factor and indicate the importance

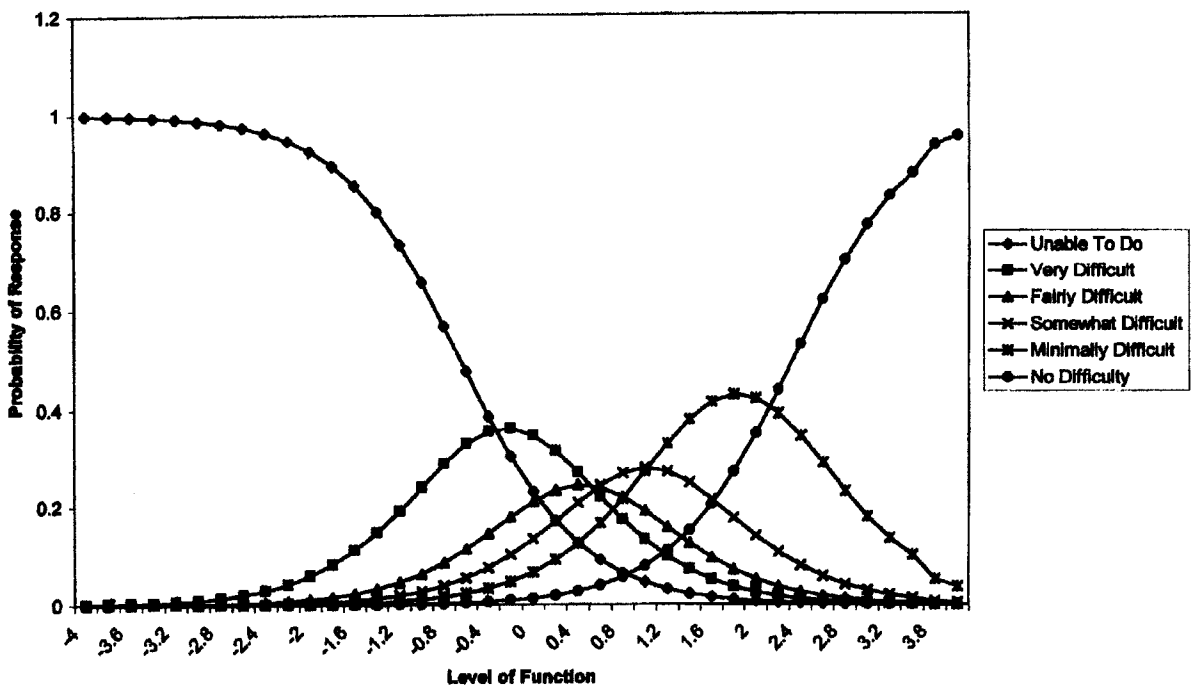

Figure A1. The horizontal axis represents the level of function, ranging from low levels of function on the left-hand side of the scale to high levels of function on the right-hand side of the scale. The vertical axis represents the probability of choosing a response in a particular category. The curves show the probability of selecting each response category as a function of the patient's level of ability. Patients with the lowest level of function have the highest probability of choosing the lowest response category. As function increases, patients have a higher probability of choosing higher response categories.

of the question to the construct measured by the instrument.[6] Low factor loadings imply the question is not an important indicator of the construct and, thus, the question may contribute to measurement error. Questions with factor loadings less than 0.50 were considered for deletion from the IKDC Subjective Knee Form.

Item-response theory is a modern method of measurement in which the characteristics of the questions (that is, the level of function at which a subject tends to choose one response category over another category) are measured on the same scale that is used to measure function of the subject.[3] As such, item-response theory links item responses to a subject's level of ability, and item statistics are reported on the same scale as ability. Item-response theory offers advantages over classical test theory in terms of test construction, providing more precise estimates of a subject's ability across the spectrum of function, and investigating item bias.

Item-response theory was used to identify questions for elimination from the final version of the IKDC Subjective Knee Form. This was accomplished using BIGSTEPS (MESA Press, Chicago, Illinois) to calibrate the questions according to the partial credit model. In the partial credit model the probability of choosing a particular response category is dependent on the subject's level of function as well as on the difficulty level associated with the transition from one response category to the next. The partial credit model assumes that all questions are equally effective in discriminating among examinees with varying levels of ability.[2] The relationship between level of function and the probability of choosing a response to an individual question is illustrated in Figure A1.

Infit and outfit statistics calculated by BIGSTEPS were used to evaluate overall fit of the partial credit model to the data as well as fit of individual questions. Infit is a statistic that is sensitive to unexpected behavior affecting responses to questions near the person's ability level and outfit is an outlier-sensitive statistic that is sensitive to unexpected behavior by persons on questions that are far from the person's ability.[5] The expectation for infit and outfit statistics is one. Values less than one indicate dependency in the data. Infit statistics greater than one indicate error, and outfit statistics greater than one indicate unexpected outliers.[5] Questions that had infit or outfit statistics less than 0.6 or greater than 1.4 were considered for elimination from the final version of the IKDC Subjective Knee Form.

Calculation of IKDC Subjective Knee Score According to Item-Response Theory

Item-response theory was used to score the IKDC Subjective Knee Form according to the partial credit model. The partial credit model assumes that all questions are equally effective in discriminating among examinees with varying levels of ability.[2] The score according to the partial credit model score was calculated by BIGSTEPS using a maximum likelihood estimation procedure. This method of scoring considers the difficulty of the questions and the subject's particular response pattern to estimate the most likely level of ability given the combination of responses to the questions. The resulting partial credit model score was expressed in logits and had a mean of zero and standard deviation of one.

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APPENDIX 2

2000 IKDC SUBJECTIVE KNEE EVALUATION FORM

Your Full Name_____

Today's Date: _____/_____/_____ Date of Injury: _____/_____/_____
Day Month Year Day Month Year

SYMPTOMS*:
*Grade symptoms at the highest activity level at which you think you could function without significant symptoms, even if you are not actually performing activities at this level.

1. What is the highest level of activity that you can perform without significant knee pain?

❑Very strenuous activities like jumping or pivoting as in basketball or soccer
❑Strenuous activities like heavy physical work, skiing or tennis
❑Moderate activities like moderate physical work, running or jogging
❑Light activities like walking, housework or yard work
❑Unable to perform any of the above activities due to knee pain

2. During the past 4 weeks, or since your injury, how often have you had pain?

	0	1	2	3	4	5	6	7	8	9	10	
Never	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	Constant

3. If you have pain, how severe is it?

	0	1	2	3	4	5	6	7	8	9	10	
No pain	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	Worst pain imaginable

4. During the past 4 weeks, or since your injury, how stiff or swollen was your knee?

❑Not at all
❑Mildly
❑Moderately
❑Very
❑Extremely

5. What is the highest level of activity you can perform without significant swelling in your knee?

❑Very strenuous activities like jumping or pivoting as in basketball or soccer
❑Strenuous activities like heavy physical work, skiing or tennis
❑Moderate activities like moderate physical work, running or jogging
❑Light activities like walking, housework, or yard work
❑Unable to perform any of the above activities due to knee swelling

6. During the past 4 weeks, or since your injury, did your knee lock or catch?

❑Yes ❑No

7. What is the highest level of activity you can perform without significant giving way in your knee?
❑Very strenuous activities like jumping or pivoting as in basketball or soccer
❑Strenuous activities like heavy physical work, skiing or tennis
❑Moderate activities like moderate physical work, running or jogging
❑Light activities like walking, housework or yard work
❑Unable to perform any of the above activities due to giving way of the knee

Page 2 – 2000 IKDC SUBJECTIVE KNEE EVALUATION FORM

SPORTS ACTIVITIES:

8. What is the highest level of activity you can participate in on a regular basis?

❑Very strenuous activities like jumping or pivoting as in basketball or soccer
❑Strenuous activities like heavy physical work, skiing or tennis
❑Moderate activities like moderate physical work, running or jogging
❑Light activities like walking, housework or yard work
❑Unable to perform any of the above activities due to knee

9. How does your knee affect your ability to:

		Not difficult at all	Minimally difficult	Moderately Difficult	Extremely difficult	Unable to do
a.	Go up stairs	❑	❑	❑	❑	❑
b.	Go down stairs	❑	❑	❑	❑	❑
c.	Kneel on the front of your knee	❑	❑	❑	❑	❑
d.	Squat	❑	❑	❑	❑	❑
e.	Sit with your knee bent	❑	❑	❑	❑	❑
f.	Rise from a chair	❑	❑	❑	❑	❑
g.	Run straight ahead	❑	❑	❑	❑	❑
h.	Jump and land on your involved leg	❑	❑	❑	❑	❑
i.	Stop and start quickly	❑	❑	❑	❑	❑

FUNCTION:

10. How would you rate the function of your knee on a scale of 0 to 10 with 10 being normal, excellent function and 0 being the inability to perform any of your usual daily activities which may include sports?

FUNCTION PRIOR TO YOUR KNEE INJURY:

Cannot perform daily activities	0	1	2	3	4	5	6	7	8	9	10	No limitation in daily activities
	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	

CURRENT FUNCTION OF YOUR KNEE:

Cannot perform daily activities	0	1	2	3	4	5	6	7	8	9	10	No limitation in daily activities
	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	

Scoring Instructions for the 2000 IKDC Subjective Knee Evaluation Form

Several methods of scoring the IKDC Subjective Knee Evaluation Form were investigated. The results indicated that summing the scores for each item performed as well as more sophisticated scoring methods.

The responses to each item are scored using an ordinal method such that a score of 1 is given to responses that represent the lowest level of function or highest level of symptoms. For example, item 1, which is related to the highest level of activity without significant pain is scored by assigning a score of 1 to the response "Unable to Perform Any of the Above Activities Due to Knee" and a score of 5 to the response "Very strenuous activities like jumping or pivoting as in basketball or soccer". For item 2, which is related to the frequency of pain over the past 4 weeks, the response "Constant" is assigned a score of 1 and "Never" is assigned a score of 11.

The IKDC Subjective Knee Evaluation Form is scored by summing the scores for the individual items and then transforming the score to a scale that ranges from 0 to 100. **Note**: The response to item 10 "Function Prior to Knee Injury" is not included in the overall score. The steps to score the IKDC Subjective Knee Evaluation Form are as follows:

1. Assign a score to the individual's response for each item, such that lowest score represents the lowest level of function or highest level of symptoms.
2. Calculate the raw score by summing the responses to all items with the exception of the response to item 10 "Function Prior to Your Knee Injury"
3. Transform the raw score to a 0 to 100 scale as follows:

$$\text{IKDC Score} = \left[\frac{\text{Raw Score - Lowest Possible Score}}{\text{Range of Scores}}\right] \text{x} 100$$

Where the lowest possible score is 18 and the range of possible scores is 87. Thus, if the sum of scores for the 18 items is 60, the IKDC Score would be calculated as follows:

$$\text{IKDC Score} = \left[\frac{60 - 18}{87}\right] \text{x} 100$$

$$\text{IKDC Score} = 48.3$$

The transformed score is interpreted as a measure of function such that higher scores represent higher levels of function and lower levels of symptoms. A score of 100 is interpreted to mean no limitation with activities of daily living or sports activities and the absence of symptoms.

The IKDC Subjective Knee Score can still be calculated if there are missing data, as long as there are responses to at least 90% of the items (i.e. responses have been provided for at least 16 items). To calculate the raw IKDC score when there are missing data, substitute the average score of the items that have been answered for the missing item score(s). Once the raw IKDC score has been calculated, it is transformed to the IKDC Subjective Knee Score as described above.