Translation and testing of measurement properties of the Swedish version of the IKDC subjective knee form

Hanna Tigerstrand Grevnerts, K. Gravare Silbernagel, Sofi Sonesson, Clare Ardern, Annika Österberg, Håkan Gauffin and Joanna Kvist

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Running title: The Swedish IKDC subjective knee form

Authors:

Authors:

1. First name: Hanna

Last name: Tigerstrand Grevnerts

Degree: PT, MSc

Affiliation: Rorelse och Hals, Primary Healthcare rehabilitation, Region Ostergotland;

Division of Physiotherapy,

Department of Medical and Health Sciences, Linkoping University

2. First name: Karin

Last name: Grävare Silbernagel

Degree: PT, PhD, ATC

Affiliation: Department of Physical Therapy, University of Delaware,

3. First name: Sofi

Last name: Sonesson

Degree: PT, PhD

Affiliation: Division of Physiotherapy,

Department of Medical and Health Sciences, Linköping University

4. First name: Clare

Last name: Ardern

Degree: PT, PhD

Aspetar Orthopaedic & Sports Medicine Hospital, Doha, Qatar; Division of Physiotherapy,

Department of Medical and Health Sciences, Linköping University, Linköping, Sweden,

5. First name: Annika

Last name: Österberg

Degree: PT, MSc

Affiliation: Centre for Clinical Research Sormland, Uppsala University, Eskilstuna, Sweden; Division of Physiotherapy, Department of Medical and Health Sciences, Linköping University

6. First name: Håkan

Last name: Gauffin

Degree: Orthopedic Surgeon, PhD

Affiliation: Orthopaedic Department, Linköping University; Department of Clinical and Experimental Medicine, Linköping University

7. First name: Joanna

Last name: Kvist

Degree: PT, Professor

Affiliation: Division of Physiotherapy, Department of Medical and Health Sciences, Linköping University

Corresponding Author:

Joanna Kvist: Joanna.kvist@liu.se

Phone: 0046 13 284664

Fax: 0046 13 149403

Address: Joanna Kvist, Linköping University, Div of Physiotherapy, Department of Medical and Health Sciences, 581 83 Linköping

Abstract

Purpose: To translate to Swedish language and cross-culturally adapt the IKDC-SKF, and test the measurement properties of the Swedish version of IKDC-SKF in ACL-injured patients undergoing reconstruction surgery.

Methods: The translation and cross-cultural adaption was performed according to guidelines. 76 patients with an ACL injury filled out the IKDC-SKF and other questionnaires before ACL reconstruction and at 4, 6 and 12 months after surgery. 203 patients from the Swedish ACL-Registry, participated at 8 months post-operative. Measurement properties were tested according to the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines.

Results: The Swedish IKDC-SKF had high internal consistency (Cronbach's $\alpha = 0.90$) and test retest reliability ($ICC_{2,1} = 0.92$, CI 95%: 0.81- 0.97, $P < .001$). A single factor solution accounted for 46.1% of the variance in IKDC-SKF scores. Criterion validity was moderate to high. All ten predefined hypotheses for hypothesis testing were confirmed. The six hypotheses for responsiveness testing were confirmed. The effect size was 1.8 and the standardized response mean was 1.9, the Minimal Clinically Important Difference was 13.9 points.

Conclusion: The Swedish version of the IKDC-SKF had good measurement properties and can be recommended for use in a population of ACL deficient patients undergoing ACL reconstruction.

Keywords: Patient reported outcome, knee surgery, ACL injury, ACL reconstruction

Introduction

Evaluation of symptoms, function and sports participation during the rehabilitation phase after ACL injury is of importance to monitor treatment and progression, and to evaluate the outcome. The most frequently used patient-reported outcome in ACL reconstruction populations worldwide is the International Knee Documentation Committee Subjective Knee Form (IKDC-SKF) (Wera et al., 2014). The IKDC-SKF is a 19-item, knee-specific, patient-reported outcome, that measures symptoms, function and physical activity. Answers are provided in a five-point Likert scale (item 1, 4, 5, 7 - 17), 0-10 rating scale (item 2, 3, 18, 19) and dichotomous (item 6). The possible score ranging from 0-100 (calculated on 18 items since item 19 refers to knee function before injury), with a higher score indicating less symptoms, better function and a higher level of sports activity (Irrgang et al., 2001).

The IKDC-SKF has been translated from the original English version to several languages, and the versions that meet the standards for translation process can be found at the webpage of the American Orthopaedic Society for Sports Medicine; www.sportsmed.org. The measurement properties of the original version of the IKDC-SKF have been tested extensively and showed to be good (Grevnerts et al., 2014), but measurement properties of the Swedish version of the IKDC-SKF have not been established.

The aim of this study was to perform translational and cross-cultural adaption for the Swedish version of the IKDC-SKF, and to test the validity, reliability, responsiveness and interpretability (floor and ceiling effect and Minimal Clinical Important Difference) of the IKDC-SKF in patients with an ACL injury undergoing reconstruction surgery, from before reconstruction to up to 1 year follow up.

Material and methods

Translation procedure

The translation of the IKDC was completed according to the guidelines by Guillemin et al (1993). In the assessment of the measurement properties of the Swedish version of the IKDC, we followed the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines, and the taxonomy, terminology and definitions for measurement properties developed by the COSMIN group (Mokkink et al. 2006; Mokkink et al., 2010).

The English version was first translated to Swedish by a physiotherapist and researcher experienced in ACL rehabilitation. The accordance of the translations was examined by two physiotherapist researchers and then translated back to English by a professional translator. The back-translation was compared to the original version, by the three physiotherapist researchers, to ensure consistency. An expert panel from different locations in Sweden consisting of two orthopedic surgeons who perform the majority of the ACL reconstructions in Sweden and four research physiotherapists experienced in knee injuries and experienced in writing in English, examined the Swedish version and commented on it. Comments on the translation were discussed thoroughly with other orthopedic surgeons and physiotherapists as well as with the developer of IKDC-SKF. The Swedish version of the IKDC-SKF was discussed in the expert panel before consensus was reached.

Cross-cultural adaption

Two cultural adaptations were made: (i) “basketball” was changed to “handball or floorball”, because these sports are more common in Sweden; (ii) the term “skiing” was clarified to “alpine skiing”, to distinguish it from cross-country skiing.

Face validity testing

Ten patients with an ACL injury (age ranging from 17-38 years, 5 females) tested the Swedish and English version of the IKDC-SKF. All participants were active in sports before injury and nine were active in sport or rehabilitation at the time of completing IKDC-SKF. Six patients had had an ACL reconstruction and four had not. The first five patients were interviewed after filling out the questionnaire, and their opinions led to minor changes in the form (how the term “pivoting” and “giving way” should be translated into Swedish). The remaining five patients were asked if they thought the questions in the Swedish version corresponded to the questions in the English version of the IKDC-SKF. All patients stated that the versions were similar and that the questions were relevant. The scores the patients showed on the Swedish and English forms were coherent.

The translation and cross-cultural adaptation process together with face validity testing resulted in the final Swedish version of the IKDC-SKF.

Data Collection

Patients with an ACL-injury, aged 16-45 years old, and who had been wait-listed for an ACL reconstruction, were invited to participate during January 2012 to August 2013. They were recruited from four different orthopaedic clinics in Sweden.

Questionnaires were sent to the participants approximately 4 weeks prior to their surgery, for baseline measurement. Participants could choose between answering the questionnaires

on paper and return in a prepaid envelope or log in to a web based system to complete an electronic version of the questionnaire. The questionnaire was sent again at 4, 6, and 12 months after surgery. For reliability testing, the form was sent again 5 days after the 6 months follow-up, to participants that completed the questionnaire at 6 months. Reminders were sent after 3 and 6 days to participants who had not responded.

Additionally, participants from the Swedish National ACL register who had undergone an ACL reconstruction 8 months earlier, were asked to participate by filling out the questionnaire and sending it back in a prepaid envelope.

Participants recruited from orthopaedic clinics

A total of 179 patients who were on the waiting list for ACL reconstruction were asked to participate. Seventy-six patients (42%) accepted (table 1). The mean age of participants was 25 years (SD 8, range 16-45 years) and there was equal numbers of men and women (37 of 76 were female, 49%). Six patients (6 of 76, 8%) had a revision of ACL reconstruction. One participant was excluded from baseline evaluation, two were excluded from 4-month evaluation group, and one was excluded from 12-month evaluation group due to the omission of three or more items of the IKDC. The majority of patients (72 of 76, 95%) reported that they were physically active before their ACL injury.

Participants recruited from the Swedish National ACL registry

All patients from the Swedish National ACL Registry who were asked to participate had undergone primary ACL reconstruction at a mean of 8 months earlier. Of 514 eligible patients, 203 (39%) agreed to participate. There were 102 men (50%), with a mean age of 24 years (SD 9 years, range 15-45 years). Four participants (2% of 203) were excluded due to omission of three or more items of the IKDC-SKF. Twenty-one participants (10% of 203) had

had a previous contralateral ACL reconstruction. The majority reported that they were physically active before injury (195 of 203, 96%) and at the time of completing the IKDC-SKF (189 of 203, 93%).

Questionnaire package

The questionnaire package contained the IKDC-SKF, the Knee Injury and Osteoarthritis Outcome Score (KOOS) (Roos, Toksvig-Larsen, 2003), the Short-Form 36 health survey questionnaire (SF-36) (Mohtadi, 1998; Sullivan et al., 1995; Persson et al., 1998; Sullivan and Karlsson, 1998), the ACL Return to Sport after Injury scale (ACL-RSI) (Kvist et al., 2012) (Table 2) and a Global Rating of Change (GRC) question (Kamper et al., 2009) with response options “fully recovered”, “great improvement but not fully recovered”, “some improvement but not fully recovered”, “unchanged”, “some deterioration”, “great deterioration”. Some study specific questions were used to evaluate satisfaction with knee function (“If you were to spend the rest of your life with knee function just the way it has been the last week, would you feel...”; response options: happy, satisfied, mostly satisfied, mixed feelings, mostly dissatisfied, dissatisfied and unhappy) and knee stability (“how stable do you consider your knee in activities of daily living” and “how stable do you consider your knee in exercise and sports” response options in a 10-point scale).

Data from Swedish National ACL Registry population, and patients from the clinics at 6 months after reconstruction were merged in the analysis of internal consistency, structural validity and criterion validity. Data from patients recruited from clinics were used for the reliability testing, using measurements taken at 6 months follow-up and again 5 to 21 days later. For responsiveness hypothesis testing the change score from baseline and 4 months and from baseline and 12 months was used. Minimal Clinically Important Difference (MCID)

was assessed with the baseline and 4 month follow-up data. Floor and ceiling effects were evaluated at all measurement occasions.

All participant got written and verbal information of the study and gave their written consent to participate before study initiation. The study was approved by the Ethical Review Board in Linköping, Dnr: 2011 450-31.

Measurement properties that were evaluated: Reliability

Internal consistency

Internal consistency is the extent to which items in a questionnaire are correlated, thus measuring the same concept (Mokkink et al., 2010). A Cronbach's alpha value between 0.7 and 0.95 is considered to show good internal consistency (Terwee et al., 2007).

Test-retest reliability

Test-retest reliability is the extent to which scores are the same across repeated measurements in patients whose health status has not changed (Mokkink et al., 2010). The time from test to re-test (5-21 days) was chosen to minimize the risk for patients to have a change in symptoms between measures, but were still long enough for them not to recall their previous answers. Forty-one patients filled out the form for test–retest analysis; responses from 13 patients were excluded because there was more than 21 days between measurement occasions, to avoid changes in their physical knee condition. Therefore, data from 28 patients were included in the analysis and they scored an IKDC-SKF mean of 60 (SD 17.6, 95% Confidence Interval 53.1-66.7) at the first measurement and 63 (SD 17.8, 95%

Confidence Interval 56.1- 69.9) at the re-test measure. None of the included patients reported new injury that affected their knee during the time between tests.

Test-retest reliability was assessed with a two-way random intraclass correlation coefficient ($ICC_{2,1}$) for absolute agreement. An ICC value of >0.9 was considered to reflect excellent test-retest reliability (Kline, 1999).

Measurement error

Standard error of measurement with included systematic differences ($SEM_{agreement}$) was calculated using the change score from 6 months to Reliability testing measures, with the formula: $SD_{diff}/\sqrt{2}$ (Hopkins, 2000). The smallest detectable change (SDC) was calculated for both individuals ($SDC_{ind} = 1.96 \times \sqrt{2} \times SEM$) and groups ($SDC_{group} = SDC_{ind}/\sqrt{n}$) (Beaton, 2000; Terwee et al., 2007).

Measurement properties that were evaluated: Validity

Structural validity

Structural validity is the extent to which the items of a scale fit together and reflect the construct that is being measured (Terwee et al., 2007). Structural validity was assessed with an exploratory factor analysis using a principal component model and varimax rotation.

Criterion validity

Criterion validity is the extent to which the scores of the measurement instrument examined correlates to the score of a gold standard (Terwee et al., 2007). Criterion validity was tested using Short Form 36 (SF36) as a gold standard. We hypothesised that the IKDC-SKF would

correlate more strongly ($r > 0.5$) to the physical component summary (PCS) of the SF36 than to the mental component summary (MCS) ($r < 0.5$).

Hypothesis testing

Hypothesis testing is part of testing construct validity. Confirmation of 75% hypotheses is considered to reflect good hypothesis testing as a measurement property (Terwee et al., 2007).

Ten predefined hypotheses were specified by the authors, all with the predefined hypothesised magnitude of $r > 0.5$. The hypotheses were tested with a Pearson's correlation test or Spearman rho correlation test as appropriate.

Measurement properties that were evaluated: Responsiveness

Responsiveness is the ability of an outcome measure to detect change over time in the construct being measured (Mokkink et al., 2010). Responsiveness was tested with both a criterion and construct approach (de Vet et al., 2011).

Criterion approach. We used the Global Rating of Change (GRC) as a gold criterion, with the answers dichotomized to either "no change" or "improved" compared to baseline. For the "no change" group, we included patients who reported "unchanged" or "some improvement but not fully recovered" on the GRC. For the "improved group" we included patients who reported "great improvement but not fully recovered" or "fully recovered" on the GRC (de Vet et al., 2011). We used the change of IKDC-SKF and GRC score from baseline to 4 months to test responsiveness. At that time we would expect some patients to be significantly improved in condition and some not, and we considered it was sufficient time for patients to recall whether a change in function had occurred. A Receiver Operating Characteristics (ROC) curve was plotted with the sensitivity and specificity for each possible change in score, and

the Area under the Curve (AUC) was used to interpret the possibility for the IKDC-SKF to detect change in the patient-reported outcome. An AUC of > 0.70 is considered adequate (Terwee et al., 2007).

Construct approach. We tested the correlations between IKDC-SKF change score to the change score of the five subscales of KOOS and the PCS of SF36. We used the change scores from baseline to 4-months and, to evaluate responsiveness for a longer follow-up time-frame, from baseline to 12-months. The time intervals were chosen since it was considered sufficient time for patients to be changed in their condition, compared to baseline.

The Effect Size (ES) and Standardized Response Mean (SRM) were calculated for change from before reconstruction to 12 months after, using the mean change scores divided by the standard deviation of scores from before reconstruction for ES, and mean change scores divided by the standard deviation of the change of scores for SRM (de Vet et al., 2011).

Measurement properties that were evaluated: Interpretability

Interpretability is not considered a measurement property, but regarded as important for the interpretation of the score. To evaluate interpretability, we examined two aspects: (i) floor- and ceiling effect (0 and 100 points score respectively), where below 15% for either was considered acceptable (Terwee et al., 2007) and (ii) Minimal Clinically Important Difference (MCID).

MCID was determined by analyzing the ROC curve from responsiveness testing with data from 4 months. The score that was the closest to the left upper corner in the curve, was taken as the value on the IKDC-SKF that, at 4 months after ACL reconstruction, best

distinguished a patient who reported improvement from a patient who reported no change. This value corresponds to the highest sensitivity and specificity. We used the Youden index (Fluss et al., 2005; Youden, 1950) to calculate the value of MCID.

Statistical analyses

All analyses were performed using SPSS version 22. The IKDC-SKF data from each measurement occasion were handled in accordance to recommendations for scores, where up to two items missing is acceptable. Total scores for the IKDC-SKF were calculated using the equation (sum of the completed items)/ (maximum possible sum of the completed items) * 100, which gives a score from 0-100.

Results

Reliability

Internal consistency was good; 0.9, as measured with Cronbach's alpha. The test-retest reliability was excellent, with an ICC_{2,1} of 0.92 (Confidence Interval 95%: 0.81- 0.97, $P < .001$). The SEM was 5.7 points, SDC_{group} was 2.4 points and SDC_{ind} was 15.8 points.

Validity

Structural validity

A single factor solution accounted for 46.1% of the variance. Factor loadings were >0.4 for 17 out of 18 items. The factor loading for item 6 ("during the past 4 weeks, or since your injury, did your knee lock or catch?") was 0.349.

Criterion validity

There was a positive correlation between IKDC-SKF and the SF36. The correlation between the IKDC-SKF and the PCS was high, $r = 0.73$ ($p < 0.001$). There was a weak correlation between the IKDC-SKF and the MCS $r = 0.32$ ($p < 0.001$), confirming the hypothesis for criterion validity.

Hypothesis testing

All hypotheses were confirmed (Table 3).

Responsiveness

The IKDC-SKF change score from baseline to 4 months was positively correlated with the global rating of change (GRC) question ($r = 0.62$, $p < 0.01$). Twenty-three participants were dichotomized to the “improved” group and 24 to the “not improved” group (Table 4).

There were no patients reporting “fully recovered” or “unchanged”. The ROC analysis showed an AUC of 0.79 (Figure. 1). Patients who reported “great improvement but not fully recovered” on the GRC had a mean change in IKDC-SKF from baseline to 4 months of 16.2 points of the IKDC-SKF (Table 4).

Correlations between change in score from baseline to 4 months and baseline to 12 months, showed a correlation greater than 0.5 for all hypotheses, thus confirming them all (Table 5). The effect size of the change from baseline to 12 months was 1.8 and standardized response mean was 1.9.

Interpretability

There was 1% ceiling effect at 6- and 8-months and 2% ceiling effect at 12-months. The other measurement occasions showed no floor or ceiling effect.

The MCID calculated with score from 4 months was 13.9 points; with a sensitivity of 65.2% and a specificity of 95.5% (Figure. 1).

Discussion

The Swedish version of the IKDC-SKF was shown to be reliable, valid and responsive to change in patients with an ACL injury undergoing ACL reconstruction. We followed the COSMIN guidelines (Mokkink et al., 2006; Mokkink et al 2010), and the questionnaire was translated and adapted to Swedish in several steps including forward and backwards translation, expert committee review, and pre-testing as recommended (Guillemin et al., 1993). The cross-cultural changes made (“basketball” was changed to “handball or floorball”, “skiing” was clarified to “alpine skiing”) were similar to cultural adaptations made in the Brazilian translation processes, where “skiing” was replaced with “surfing” (Metsavaht et al., 2010). Patients who completed both the Swedish and English version of the IKDC-SKF found both versions equivalent, which was supported by the equality of scores for both questionnaires.

The IKDC-SKF has a relatively low number of items compared to other similar forms (e.g. KOOS which has 42 items) and high internal consistency (Cronbach’s alpha 0.90), suggesting that there is limited redundancy in the scale. The high test re-test reliability ($ICC_{2,1} = 0.92$), is in accordance with previous studies on the English version (Irrgang et al., 2001; Kocher et al., 2011; Schmitt et al., 2010).

The SEM value (5.7 points) is comparable to previous studies (Irrgang et al., 2001; Greco et al., 2010; van Meer et al., 2013), and the SDC_{ind} of 15.8 points indicates that a change in score in an individual patient should be above 15.8 points to be sure of a true change in condition. The result of SDC_{ind} is similar to the MCID (13.9 points) and although the values are taken from different times after ACL reconstruction (the SDC is from the reliability testing six months after reconstruction and MCID is the change value from baseline to four

months after reconstruction), it might indicate an approximate magnitude of change of score needed to consider the change both “real” (not due to measurement error) and meaningful. The SDC_{group} for a group of patients is much lower than the SDC_{ind} , i.e. 2.4 points, and is often the value used in research, where individual comparisons are less common. The discrepancy between the SDC_{group} and MCID may suggest that even though a change has occurred in a group, it might not be enough to reflect change in condition for the individual patient.

The value of MCID is debated, and should be interpreted carefully since it is not a fixed attribute; it may change depending on what is important for the patient (Wang et al., 2011). The MCID could also be a reflection of the patient’s satisfaction with his or her current knee function rather than the change from baseline, since it can be difficult for patients to recall change over time (Wright et al., 2012). The time frame is important when determining MCID, since it should be long enough for a clinically important change to have occurred, but short enough for patients to remember if there has been a change or not.

The single factor solution from the analysis for structural validity indicates that the form is one dimensional and supports previous suggestions that the IKDC-SKF should be reported as one overall score (Irrgang et al., 2001; Schmitt et al., 2010; van de Graaf et al., 2014). In our study all questions had factor loadings of > 0.4 , except item #6 (“for the past four weeks has your knee locked or caught?”). Previous studies (Irrgang et al., 2001; Schmitt et al., 2010; Higgins et al., 2007) which also have reported a lower loading for item #6, performed their factor analysis in a population with “various knee disorders”. The population in our study includes patients at six to eight months after ACL reconstruction, where “locking” or “catching” is not typically a problem (in contrast with meniscal injuries). The lower loading

value of item #6 might suggest that this item may be less relevant for an ACL reconstruction population, something that is supported by the fact that item #6 was rated as not relevant by experts in the field and patients with an acute ACL injury (van Meer et al., 2013). In addition, since previous studies of the measurement properties of the IKDC-SKF generally show a low loading value for item #6, it might suggest that the question does not entirely reflect the same construct as the remaining 17 questions.

The highest correlation at hypothesis testing was between the IKDC-SKF and the KOOS subscale “function, sports and recreational activities”. This fits with the fact that the IKDC-SKF is designed to evaluate patient-reported symptoms during physical activity. Overall, the correlation to KOOS subscales was high, compared to the correlation to ACL-RSI or the question of satisfaction with knee function. Taken together, these findings might suggest that the IKDC-SKF and KOOS measure similar constructs. When comparing the two questionnaires, the IKDC-SKF has less respondent burden than the KOOS and has a simple method for calculation of the total score. Previous studies indicate that IKDC-SKF may have superior validity, reliability and responsiveness than KOOS early after ACL injury, after ACL reconstruction, and before or after meniscal surgery (van de Graaf et al., 2014; van Meer et al., 2013).

The IKDC-SKF is responsive when measuring patient-reported changes over time in the rehabilitation process after an ACL reconstruction. This is evident in the value of AUC, the confirmed hypothesis for construct testing, the high effect size and high standardized response means. The result of our responsiveness testing supports previous reports of good responsiveness (Greco et al., 2010; van Meer et al., 2013).

The floor and ceiling effect was below 15%, which is in line with previous studies (Irrgang et al., 2001; Bjorklund et al., 2009; Crawford et al., 2007; Haverkamp et al., 2006; Kocher et al., 2011; Metsavaht et al., 2010; Padua et al., 2004).

Limitations

One limitation could be the use of the SF36 as a gold standard to IKDC-SKF, since the SF36 is not a knee injury-specific questionnaire. However it may be difficult to find an optimal gold standard for patient-reported outcomes. Often the gold standard used is one that has been accepted as a gold standard by experts in the field (de Vet et al., 2011). Our decision to use the SF36 as gold standard for construct validity was based on the fact that the SF36 was used as the criterion in the original version of the IKDC-SKF (Irrgang et al., 2007).

Our decision to include patients who were “somewhat improved but not fully recovered” in “no change” group for responsiveness analysis (ROC curve) was based on the fact that patients might overestimate their progress to “please” the caregivers (de Vet et al., 2011). It was corroborated by the fact that those who reported “somewhat improved but not fully recovered” had a lower mean change score of the IKDC-SKF from baseline to 4 months than the SDC_{group} value or the MCID, suggesting that there was no clinically significant improvement in state.

Perspective

The IKDC-SKF is the most commonly used patient-reported outcome after ACL injury (Wera et al., 2014). Our study adds knowledge about the measurement properties of the IKDC-SKF: we found that the Swedish version of the IKDC-SKF is valid, reliable and responsive. We also provide important information about the interpretability of the scale; the MCID and floor and ceiling effect both before ACL reconstruction and at several clinically-relevant time

points during ACL reconstruction rehabilitation. The use of a well-designed patient reported outcome measurement instrument leads to extended possibilities to compare scientific data worldwide, and is important for quality clinical practice.

Conclusion

The Swedish version of the IKDC-SKF had good measurement properties in a population of ACL deficient patients undergoing ACL reconstruction.

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Table 1. The IKDC results and timing of each measurement.

Measurement occasion	n	Timing of measurement* mean(range) days	IKDC score mean(SD)	IKDC score min-max	95% Confidence Interval for mean
Baseline	76	11(0-65)	51.1 (16.2)	12.6–80.5	47.4–54.8
4 m	55	115 (87-167)	57.6 (15.3)	14.9–82.8	49.7–59.3
6-8 m**	249	201 (153-333)	70.2 (17.2)	9.2–100	67.9–72.3
12 m	50	384 (353-743)	78.1 (16.6)	31.0-98.9	70.2-82.2

* Number of days prior to ACL reconstruction for the Baseline evaluation, and number of days after the ACL reconstruction for all the other measurement occasions.

** Participants recruited from orthopaedic clinics (n=46) and the Swedish National Registry (n= 203)

Table 2. Patient Reported Outcome Measures (PROMs) scores at baseline (before ACL reconstruction) and at each measurement occasion after ACL reconstruction, used in the validation process of the Swedish IKDC subjective knee Form.

Patient reported outcome	Baseline Mean (SD) 95% CI	4 months Mean (SD) 95% CI	6-8 months Mean (SD) 95% CI	12 months Mean (SD) 95% CI
KOOS "symptoms"	69.1 (19.8) 60.9-74.0	68.4 (18.8) 64.5-75.7	76.1 (18.6) 73.2-78	80.5 (17) 77.7-86.4
KOOS "pain"	72.5 (18.8) 64.6-77.2	77.8 (16.8) 71-82	84.2 (14.9) 82-85.8	87.5 (13.7) 83.1-92
KOOS "function and daily living"	83 (17.4) 75.3-87.8	89.3 (14.3) 84.5-48.3	93.1 (10.7) 91.7-94.4	94.2 (10.1) 92-98.1
KOOS "function, sports and recreational activities"	41.5 (28.9) 28.4-48.1	42.3 (26.8) 32.2-48.3	64.5 (25.8) 60.6-67.2	70.5 (25.7) 59.9-76.9
KOOS "quality of life"	29.5 (17) 21.1-31.8	42.3 (20.1) 35.5-48.6	55.5 (21.2) 52.5-58	63.8 (22.5) 54.6-68.8
ACL-RSI	Not tested	Not tested	Not tested	6 (2.3) 5.1-6.6
SF36; PCS	41.7 (8.6) 38.1-43.3	44 (9.3) 40.9-46.3	48 (7.9) 47-49	49.8 (9) 47.8-53.2
SF36; MCS	45.2 (12.3) 41.7-49.1	45.8 (11.8) 41.4-49.3	48 (9.4) 46.8-49.3	49.2 (10.1) 45.2-51.7

SD= Standard Deviation, CI= Confidence Interval, KOOS= Knee injury and osteoarthritis outcome score, ACL-RSI= ACL- return to sport after injury scale, SF36= Short Form 36, PCS= Physical Component Summary, MCS= Mental Component Summary.

Table 3. Hypotheses and the results from the statistical testing

Hypothesis including the a priori estimated magnitude of correlation	Measurement occasion	r	P
1. Patients who were satisfied with their current knee function scores higher on the IKDC-SKF than those who were not ($r > 0.5$).	6 and 8 months	0.79	<0.001
2. Patients who reported they would be highly satisfied with living with their current knee function, for the rest of their lives scores higher on the IKDC-SKF than those who reported they would not ($r > 0.5$).	6 and 8 months	0.66	<0.001
3. Patients who scored high on the KOOS subscale "symptoms" would score high on the IKDC-SKF ($r > 0.5$).	6 and 8 months	0.74	<0.001
4. Patients who scored high on the KOOS subscale "pain" would score high on the IKDC-SKF ($r > 0.5$).	6 and 8 months	0.82	<0.001
5. Patients who scored high on the KOOS subscale "function, daily living" would score high on the IKDC-SKF ($r > 0.5$).	6 and 8 months	0.74	<0.001
6. Patients who scored high on the KOOS subscale "function, sports and recreational activities" would score high on the IKDC-SKF ($r > 0.5$).	6 and 8 months	0.87	<0.001
7. Patients who scored high on the KOOS subscale "quality of life" would score high on the IKDC-SKF ($r > 0.5$).	6 and 8 months	0.83	<0.001
8. Patients who scored high on the ACL-RSI would scores high on the IKDC-SKF ($r > 0.5$).	12 months	0.69	<0.001
9. Patients who estimated their knee stability as high in activities of daily living would score high on the IKDC-SKF ($r > 0.5$).	6 and 8 months	0.69	<0.001
10. Patients who estimated their knee stability as high in exercise and sports would score high on the IKDC-SKF ($r > 0.5$).	6 and 8 months	0.71	<0.001

IKDC-SKF = International Knee Documentation Committee Subjective Knee Score, KOOS= Knee injury and osteoarthritis outcome score, ACL-RSI= ACL- return to sport after injury scale.

Table 4. The answering rates for the different categories of the GRC and the change score of the IKDC-SKF from baseline to 4 months.

Answer GRC	n	Change score of the IKDC-SKF mean(SD)
"Fully recovered"	0	16.2 (14.8)
"Great improvement but not fully recovered"	23	
"Somewhat improved but not fully" recovered	24	0.3 (12.4)
"Unchanged"	0	

GRC=Global rating of change, IKDC-SKF=International Knee Documentation Committee Subjective Knee Form, SD=standard deviation

Table 5. Hypotheses and the result from statistical testing for responsiveness testing

Hypothesis for responsiveness of change including the á priori estimated magnitude of correlation	Correlation in change between Baseline and 4 months (n=55) (p)	Correlation in change between Baseline and 12 months (n= 50) (p)
1.The change in KOOS subscale “symptoms” would correlate to the change in IKDC-SKF (r>0.5)	0.54 (<0.01)	0.57 (<0.01)
2.The change in KOOS subscale “pain” would correlate to the change in IKDC-SKF (r>0.5)	0.74 (<0.01)	0.72 (<0.01)
3. The change in KOOS subscale “function, daily living” would correlate to the change in IKDC-SKF (r>0.5)	0.59 (<0.01)	0.57(<0.01)
4.The change in KOOS subscale “function, sports and recreational activities” would correlate to the change in IKDC-SKF (r>0.5)	0.77 (<0.01)	0.68 (<0.01)
5.The change in KOOS subscale “quality of life” would correlate to the change in IKDC-SKF (r>0.5)	0.71(<0.01)	0.66 (<0.01)
6.The change in SF-36 PCS would correlate to the change in IKDC-SKF (r>0.5)	0.58 (<0.01)	0.52 (<0.01)

KOOS= Knee injury and osteoarthritis outcome score, IKDC-SKF= International Knee Documentation Committee Subjective Knee Form, SF36 = Short-Form 36 health survey questionnaire, PCS= physical component summary.

Fig 1. The ROC analysis of patient data from baseline to 4 months, showing an AUC of 0.79 and the point with the highest sensitivity and specificity marked by a ring.