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Validation of the Knee Injury and Osteoarthritis Outcome Score (KOOS) for the treatment of focal cartilage lesions

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Summary

Objective: To validate the Knee Injury and Osteoarthritis Outcome Score (KOOS) for the treatment of focal cartilage lesions.

Methods: A total of 40 patients (mean age 35 ± 12 years,) treated for a focal cartilage lesion in the knee were included in this study. Test–retest data were collected with an intermediate period of 2 days. Patients were asked to complete the Dutch KOOS and complementary questionnaires [short form-36 (SF-36), Lysholm, EuroQol-5D (EQ-5D)] to evaluate the clinimetric properties of the KOOS in terms of internal consistency (Cronbach's alpha), reliability [intra-class-correlation (ICC) and Bland and Altman plots], construct validity (Spearman's rank correlation), floor and ceiling effects and responsiveness.

Results: The Cronbach's alpha of the KOOS subdomains and total score ranged from 0.74 to 0.96. The overall ICC of the KOOS was 0.97 while the subscales ranged from 0.87 to 0.95. The Bland and Altman plots showed a small individual variance between the two assessments in time. Spearman's rank correlations between the subscales of the KOOS and representative subscales of the SF-36, Lysholm and EQ-5D were high to moderate ranging from 0.43 to 0.70. We observed no floor effect while the largest observed ceiling effect was 10.3%. The responsiveness was moderate to large with the effect size ranging from 0.70 to 1.32 and the standardized response mean 0.61 to 0.87.

Conclusion: This study illustrates the validity and reliability of the KOOS in measuring the clinical condition of patients after treatment of focal cartilage lesions. This study provides a basis for the use of the KOOS for future clinical research in cartilage repair.

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Key words: Cartilage, Regeneration, KOOS, Reliability, Validity.

Introduction

The growing activity in the field of regenerative cartilage therapy creates a need for validated outcome tools. Several instruments have been developed to measure the outcome of such treatment in both research and clinical setting. For example, the International Cartilage Repair Society (ICRS) Score and the Oswestry Arthroscopy Score (OAS) have shown to be useful tools for the macroscopic evaluation of cartilage repair¹. However, patient-reported, self-administered questionnaires are preferred as instruments for the assessment of clinical outcome to prevent from observer administered bias². The Western Ontario and McMaster Universities Index (WOMAC) is a frequently used disease-specific questionnaire to measure the treatment effect in patients with osteoarthritis (OA)³. However, the population presenting with focal cartilage lesions is generally younger and more active as compared to patients with OA. Therefore, the Knee Injury and Osteoarthritis Outcome Score (KOOS) would fit this population better. The KOOS was developed as an extension of the WOMAC and designed to assess short-term and long-term symptoms and function in younger and/or more active patients with knee injuries, cartilage damage or different stages of OA⁴. Validated

language versions are available for use in Sweden, Germany, the United States, France, Singapore, Iran and the Netherlands^{2,5–8}. The KOOS has been validated for several stages of OA^{6–8} and for orthopaedic interventions such as anterior cruciate ligament reconstruction⁴, meniscectomy² and total knee replacement⁹. Recently, short forms of the WOMAC and KOOS have also been validated for patients with different stages of OA^{10,11}.

Although already accepted and applied in several clinical trials to measure the outcome after treatment of focal cartilage lesions, the KOOS has not yet been validated for this patient population^{12–14}. The aim of the present study was to evaluate the clinimetric properties of the KOOS for patients with focal cartilage defects, eligible for cartilage repair.

Methods

PATIENTS

Between February and April 2008 a total of 60 patients were invited by phone to participate in this study. All patients had been treated for a symptomatic focal cartilage lesion by either autologous chondrocyte implantation or microfracturing between February 2002 and July 2006 at the University Medical Center Utrecht, the Netherlands. The study was approved by and conducted according to the guidelines of the ethics committee at the University Medical Center of Utrecht.

STUDY DESIGN AND QUESTIONNAIRES

Patients received two sets of questionnaires (marked as Day 1 and Day 3) by mail, each containing the Dutch KOOS and complementary questionnaires [short form-36 (SF-36), Lysholm, EuroQol-5D (EQ-5D)] which

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previously proved to measure similar constructs^{15–17}. Each patient was instructed to fill out the first set of questionnaires and immediately return them to the University Medical Center Utrecht using a pre-stamped envelope. Patients were asked to repeat the assessments with a 2 days interval¹⁸. Each patient was instructed by the investigator to open the second set of questionnaires 2 days after the first assessment. Scores which were not completed conform the set time-interval for the test–retest (both returned on the same day or with a >4-day interval) or those with two or more missing items in any of the questionnaires were excluded from further analysis.

The KOOS is a patient-based, site-specific, questionnaire that was developed to be used for short- and long-term follow-up of knee injury and knee OA. The KOOS comprises five separately scored subdomains, based on 42 individual items. The subdomains are symptoms (seven items), pain (nine items), activities of daily living (ADL) (17 items), function in sport and recreation (five items) and knee-related quality-of-life (QoL) (four items). Each item is scored from 0 (least severe) to 4 (most severe). For each subdomain as well as the total KOOS the score was normalized to a 0–100 scale with 100 being the best possible outcome, as previously described¹⁹.

The SF-36 is a widely used patient-based generic QoL questionnaire containing 36 items measuring health in eight domains. These include physical functioning, role limitations due to physical health problems, role limitations due to emotional problems, social functioning, vitality, mental health, bodily pain and general health perceptions. The Dutch version has been validated by Aaronson *et al.*¹⁵.

The EQ-5D is a questionnaire to measure health-related QoL on the day of the assessment and contains five domains, namely, mobility, self-care, usual activities, pain/discomfort and anxiety/depression and a visual analogue scale (VAS) for overall health. The EQ-VAS is a vertical scale on which the subject rates their overall health from 0 to 100 (worst to best imaginable, respectively)¹⁶.

The Lysholm knee scoring scale is an eight-item questionnaire designed for the assessment of symptoms and functional disabilities resulting from a ligamentous injury. The items include pain, instability, locking, swelling, limping, walking stairs, squatting and keeping support. Scores are calculated into one score from 0 to 100 (100 indicating normal knee function). Recently, the Lysholm knee scoring scale has been validated as an outcome measure for knee chondral damage¹⁷.

EVALUATION OF THE CLINIMETRIC PROPERTIES

Test–retest reliability of the KOOS subdomains and total score was determined with an interval of 2 days¹⁸, assuming the probability of a significant change in symptoms would be absent and the intermediate time too long for the patient to remember the exact previous answers. The test–retest reliability was measured with the intra-class-correlation (ICC) coefficient with 95% confidence interval, along with the smallest detectable difference (SDD). An ICC equal or superior to 0.70 is considered acceptable for test–retest reliability while an ICC of more than 0.80 represents excellent reliability^{6,8}. The SDD indicates the smallest change that can be distinguished from the measurement error [mean change \pm 1.96 standard deviation (SD) change]⁶. In addition, the internal consistency was assessed and Bland and Altman plots were obtained. The internal consistency was measured by the Cronbach's alpha. A Cronbach's alpha coefficient equal or superior to 0.7 is generally considered to be acceptable²⁰. For the Bland and Altman plots the differences between the first and second assessments were plotted against the mean of the two assessments, describing the distribution of patients along the scoring scale within the 95% limits of agreement²¹.

Construct validity was measured by comparing the subdomains of the KOOS with *a priori* hypothesized corresponding domains of the complementary questionnaires (SF-36, Lysholm, EQ-5D). For all *a priori* hypotheses the Spearman's rank correlation coefficients were obtained. Correlations of <0.35, 0.35–0.5 and >0.5 were considered as weak, moderate and strong, respectively. *A priori* moderate–strong hypothesis of domains measuring similar constructs was generated according to theoretical hypothesis and the related literature^{2,9,17}: (1) KOOS symptoms with SF-36 physical functioning; (2) KOOS pain with SF-36 bodily pain and EQ-VAS; (3) KOOS ADL with the complete SF-36 questionnaire; (4) KOOS sport and recreation with the Lysholm knee scoring scale; (5) KOOS QoL with EQ-5D.

The feasibility was assessed by the floor and ceiling effects. Floor and ceiling effects were considered to be present if 15% of patients scored the highest or lowest possible scores⁶.

The responsiveness was evaluated in another cohort of 36 patients of a recently published randomized trial comparing characterized chondrocyte implantation to microfracturing¹⁴. The included patients completed the KOOS and the Marx activity rating scale (ARS)²² at baseline and 36 months follow-up. The standardized response mean (SRM) and effect size (ES) were calculated as a measure of responsiveness. ES <0.50, <0.80 and >0.80 were, respectively, considered small, moderate and large.

Table I
Mean KOOS and reliability of Dutch KOOS subdomains and total score. The ICC represents the intra-class-correlation whereas the SDD is the smallest detectable difference

KOOS subdomain	Mean KOOS (SD)		ICC (95% CI)	SDD
	First assessment	Second assessment		
Symptoms	74 (17)	75 (17)	0.95 (0.90–0.97)	5
Pain	77 (15)	77 (15)	0.92 (0.86–0.96)	6
Function ADL	84 (14)	86 (12)	0.87 (0.77–0.93)	7
Sport/recreation	55 (26)	58 (25)	0.89 (0.81–0.93)	12
QoL	49 (23)	53 (22)	0.95 (0.91–0.97)	7
Total score	74 (15)	76 (14)	0.97 (0.93–0.98)	4

The clinimetric properties were analyzed with SPSS statistical software version 15.0 (SPSS Inc. Chicago, IL). A *P*-value of *P* < 0.05 was considered to represent a statistically significant difference.

Results

PATIENTS

Out of the initial 60 contacted patients a total of 46 (response 77%) were willing to participate. An additional six patients were excluded because of missing individual questionnaire items (*n* = 4) and an insufficient response (*n* = 2) conforms the test–retest response characteristics. From the resulting 40 patients (mean age 35 \pm 12 years, range 18–55; 70% men), 20 had been treated with autologous chondrocyte implantation while the other 20 had received microfracturing. The average postoperative time was 32 months and 87% of the patients had been treated between January 2005 and July 2006.

RELIABILITY

Test–retest reliability for the KOOS as determined by the ICC was 0.97 for the total score whereas the ICCs for the subdomains ranged from 0.87 to 0.95 (Table I). The SDD for the subdomains ranged from 4 to 12 points (Table I). The KOOS internal consistency, as determined by the Cronbach's alpha, was good for the individual subdomains with Cronbach's alpha ranging from 0.74 to 0.96 (Table II). The Bland and Altman representations showed a small individual variance between the two assessments for each subdomain of the KOOS (Fig. 1).

VALIDITY

Construct validity was moderate to high with Spearman's rank correlations between the subdomains of the KOOS and representative subdomains of the SF-36, Lysholm and EQ-5D ranging from 0.43 to 0.70 (Fig. 2). Moderate

Table II
Internal consistency of the Dutch KOOS subdomains and total score

KOOS subdomains	Cronbach's alpha coefficient
Symptoms	0.74
Pain	0.88
Function ADL	0.95
Sport/recreation	0.89
QoL	0.90
Total score	0.96

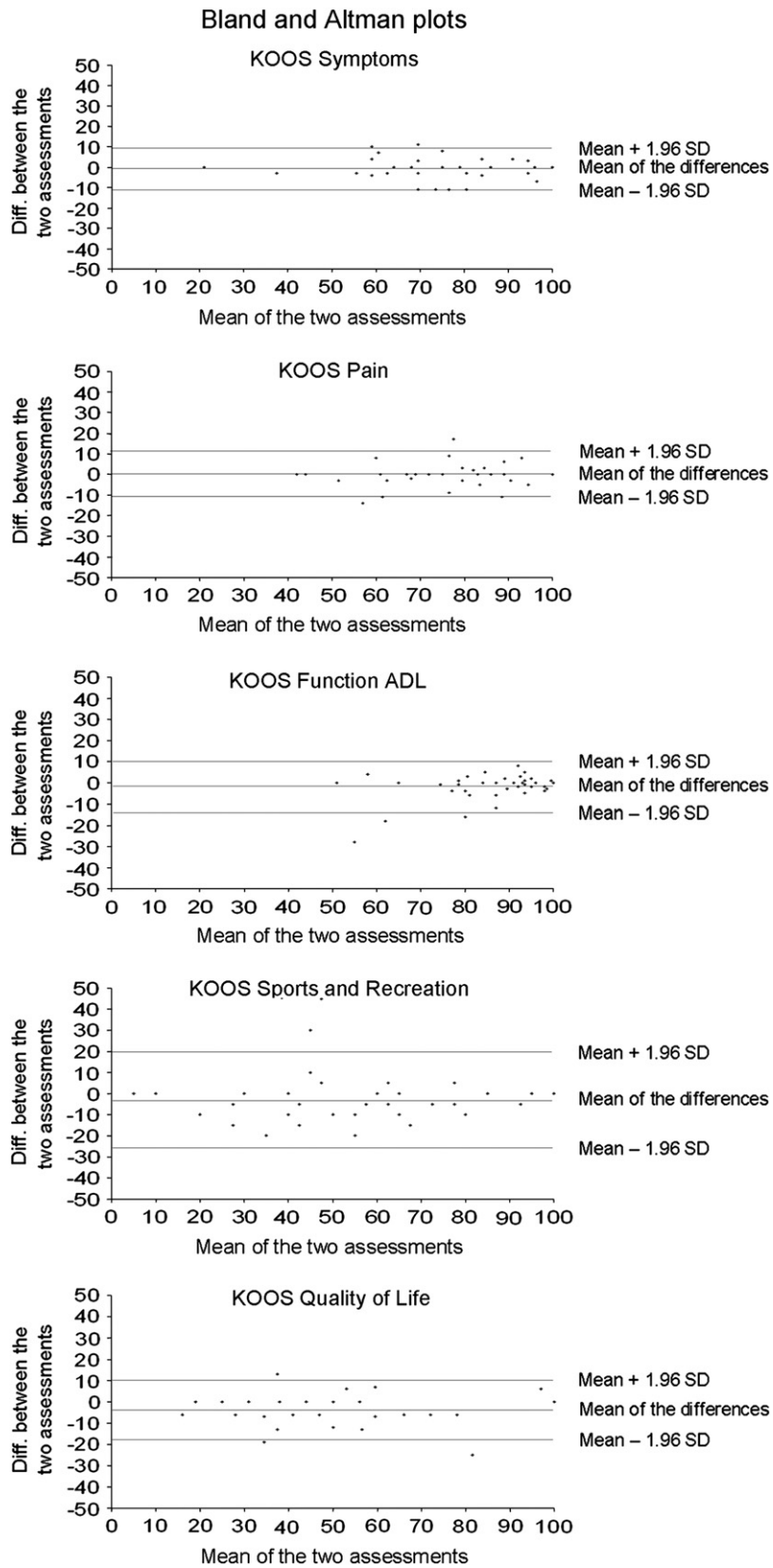


Fig. 1. Bland and Altman plots for the KOOS subdomains show a small individual variance between the two assessments.

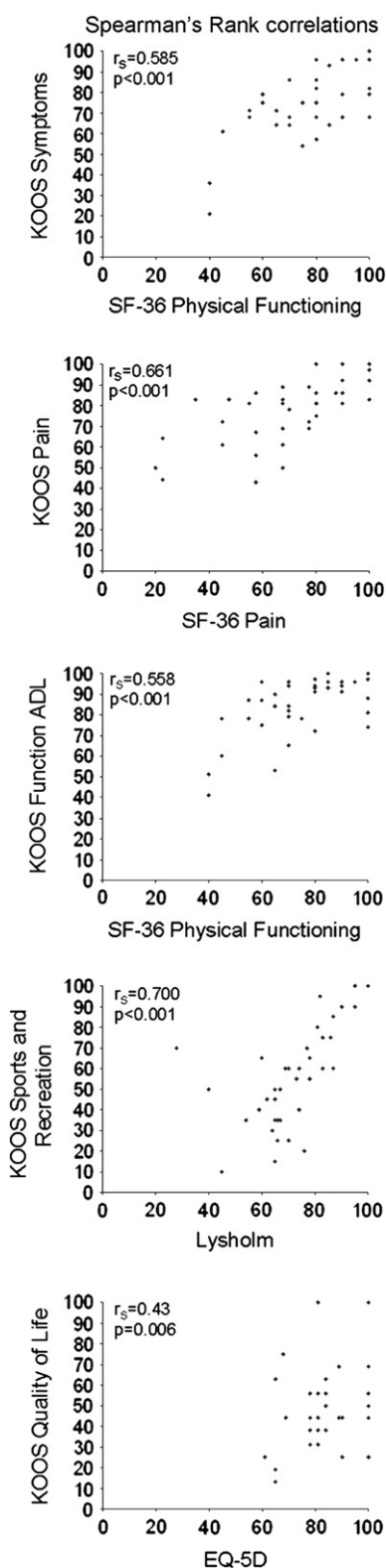


Fig. 2. Spearman's rank correlations for the KOOS subdomains show moderate to high statistically significant correlations between the subdomains of the KOOS and representative subdomains of the SF-36, Lysholm and EQ-5D.

Table III

Floor and ceiling effects of the Dutch KOOS subdomains and total score

KOOS subdomains	Floor effects	Ceiling effects
Symptoms	0%	2.6%
Pain	0%	5.1%
Function ADL	0%	7.7%
Sport/recreation	0%	7.7%
QoL	0%	10.3%
Total score	0%	2.6%

correlations were found for the QoL subdomain compared to EQ-5D and VAS scores ($r_s = 0.43$ and 0.44 , respectively). The moderate correlations were statistically significant at the $P = 0.006$ level (Fig. 2). Strong correlations were observed for the *a priori* hypotheses; KOOS symptoms and SF-36 physical functioning ($r_s = 0.585$), KOOS pain and SF-36 pain ($r_s = 0.661$), KOOS ADL and SF-36 physical functioning ($r_s = 0.558$) and KOOS sports and recreation and Lysholm ($r_s = 0.700$). All strong correlations were statistically significant with $P < 0.001$ (Fig. 2). No *a priori* unexpected weak correlations ($r_s < 0.5$) were found. Floor and ceiling effects were absent (Table III).

The KOOS evaluation showed similar outcomes for both autologous chondrocyte implantation and microfracturing patients (Table IV).

RESPONSIVENESS

The responsiveness (Table V) was moderate to large, with the ES ranging from 0.70 to 1.32 and the SRM ranging from 0.61 to 0.89, and showed a similar range as the ARS score (ES 0.76, SRM 1.10). The KOOS subdomain function ADL showed the weakest responsiveness (moderate ES 0.70) while the function in sports and recreation and QoL subdomains showed large responsiveness (ES 0.98 and 1.32, respectively).

Discussion

This study evaluated the clinimetric properties of the KOOS for a cartilage repair population to validate the KOOS as an instrument to measure the clinical outcome after the treatment of a focal, symptomatic cartilage defect in the knee. This study clearly demonstrates the validity and reliability of the (Dutch) KOOS after the treatment of focal cartilage lesions, as shown by the good internal consistency, moderate to high construct validity and excellent test-retest reliability. Given the fact that language validated KOOS versions provide similar outcome for several patient

Table IV

KOOS microfracturing vs KOOS ACI. The P-value was calculated by an independent samples' t test

KOOS subdomains	Mean KOOS (SD)		P-value
	Microfracturing	ACI	
Symptoms	74 (21)	74 (12)	0.96
Pain	78 (16)	76 (15)	0.69
Function ADL	85 (16)	83 (13)	0.76
Sport/recreation	60 (27)	51 (25)	0.31
QoL	49 (23)	49 (23)	0.98
Total score	75 (17)	73 (13)	0.66

Table V

KOOS responsiveness vs ARS responsiveness. ES represents the mean change in score from baseline to 36 months follow-up divided by the SD of the preoperative score. SRM indicates the mean change in score from baseline to 36 months follow-up divided by the SD of the mean change. An effect of <0.50 , <0.80 and ≥ 0.80 was considered small, moderate and large, respectively

Responsiveness	ES	SRM
KOOS symptoms	0.72	0.61
KOOS pain	0.82	0.71
KOOS function ADL	0.70	0.75
KOOS sport/recreation	0.98	0.87
KOOS QoL	1.32	0.76
KOOS total score	0.91	0.85
ARS	0.76	1.10

populations we feel that these language versions of the KOOS are suitable instruments to measure clinical outcome after the treatment of focal cartilage lesions.

The results for the Spearman's rank correlations supported the hypothesized good construct validity. Each subdomain of the KOOS showed strong correlations with corresponding domains, except for the KOOS subdomain QoL, which only showed a moderate correlation to the EQ-5D. This is most likely due to a difference between the measured knee-related QoL (KOOS) and general health-related QoL (EQ-5D). This idea is supported by the overall higher scores obtained by the EQ-5D. Although the Lysholm knee scoring scale was originally designed to assess ligament injuries of the knee, it proved to demonstrate acceptable clinimetric performance for outcomes assessment of various chondral disorders of the knee¹⁷. This was supported by the strong correlation between the KOOS subdomain function in sports and recreation and the Lysholm scale obtained in our study. However, suboptimal performance of some subdomains of the Lysholm scale for outcome assessment of various chondral disorders of the knee has been described as well²³.

The KOOS has consistently shown acceptable responsiveness for different populations^{2,6,9}. In our study, we demonstrated relatively good responsiveness indicating the KOOS to be capable of measuring clinical improvement in patients who have been treated for a focal cartilage lesion of the knee. The moderate ES score of the KOOS subdomains is most likely a characteristic of the treatment for focal cartilage lesions instead of moderate responsiveness as the ARS score showed a similar result.

Since there has been a steady increase in clinical research activity on the repair of focal cartilage lesions in the previous years, the field needs a reliable and detailed understanding of the clinical outcome. This will play an important role in assessing the effectiveness of the therapy, and facilitate its further development. The KOOS consistently proved to be a valid instrument in different languages, including Dutch, for the quantification of OA or the success of specific orthopaedic interventions. Recently, the KOOS was compared to the International Knee Documentation Committee (IKDC) form to determine which instrument better reflected the symptoms and disabilities of the cartilage repair patient²⁴. However, they did not specify the studied cohort of articular cartilage repair patients and lacked a validation of the questionnaires used. To our knowledge this is the first study to validate the KOOS in a focal articular cartilage repair cohort. This can provide a worldwide instrument for the quantification of the clinical outcome for this patient population and increase possibilities for the comparison between (future) clinical trials.

Comparison of the KOOS in our study group to age matched population-based reference data²⁵ shows a lower score for the cartilage repair group. This indicates that the instrument is capable to discriminate between healthy subjects and patients after cartilage therapy.

Based on the clinimetric properties presented in the present study we conclude that the KOOS questionnaire is a valid instrument to measure the clinical condition of patients undergoing treatment of a focal cartilage lesion. This study provides a basis for the use of the KOOS questionnaire in future clinical trials on cartilage repair and as a valid patient-reported, site-specific instrument in daily clinical practice. A further evaluation of the clinimetric properties in subgroups, such as age and gender, would be of great value to provide self-administered questionnaires for patient specific subpopulations.

Conflict of interest

The authors declare no conflict of interest related to this manuscript.

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