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# Cross-cultural adaptation and validation of the French version of the Knee injury and Osteoarthritis Outcome Score (KOOS) in knee osteoarthritis patients[1]

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## Summary

*Objective*: To adapt the Knee injury and Osteoarthritis Outcome Score (KOOS) into French and to evaluate the psychometric properties of this new version.

*Methods*: The French version of the KOOS was developed according to cross-cultural guidelines by using the "translation-back translation" method to ensure content validity. KOOS data were then obtained in patients with symptomatic knee osteoarthritis (OA). The translated questionnaire was evaluated in two knee OA population groups, one with no indication for joint replacement (medicine), and the other waiting for joint replacement (surgery). The psychometric properties evaluated were feasibility: percentage of responses, floor and ceiling effects; construct validity: internal consistency using Cronbach's alpha, correlations with osteoarthritis knee and hip quality of life domains using Spearman's rank test, and known group comparison between medicine and surgery groups; reliability: intra-class correlation coefficient (ICC), Bland and Altman representation; responsiveness using data obtained prior to and 3 months after surgery: standardized response mean (SRM), and effect size.

*Results*: Thirty-seven patients were included in the medicine group (68% women, mean age = 70 ± 10 years) and 30 in the surgery group (73% women, mean age = 71 ± 10 years). The percentage of responses was excellent. Neither a floor nor a ceiling effect was observed, except for the sport and recreation subscale (20.6% of patients with the worst possible score in the medicine group, 40 and 0% in the surgery group prior to and after surgery, respectively). Results for internal consistency (Cronbach's alpha ranging from 0.76 to 0.93), and convergent and divergent construct validity were satisfactory. The patients waiting for knee surgery presented with significantly lower scores in all KOOS domains. The reproducibility of measurements of all KOOS subscales was good to excellent, with ICC ranging from 0.755 to 0.914. The responsiveness was high, with SRM ranging from 0.89 to 1.93, and effect size from 1.31 to 2.8.

*Conclusion*: The French version of KOOS is a valid, reliable, and responsive instrument to capture specific aspects of functional disability affecting quality of life of knee OA patients.
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*Key words*: Knee osteoarthritis, KOOS, Cross-cultural validation.

Osteoarthritis (OA) is a common, degenerative joint disease characterized by progressive destruction of cartilage, affecting to large extent weight-bearing joints, such as the knee.

The pain and disability associated with knee OA have a significant impact on the patients' health-related quality of life (QOL)[1,2]. Various instruments are available to assess knee in OA patients[1,3–5]. In particular, the Western Ontario and McMaster Universities Index (WOMAC) is a validated and widely used disease-specific instrument, which assesses OA-induced pain, stiffness, and functional limitation[6]. The Knee injury and Osteoarthritis Outcome Score (KOOS) was developed as an extension of the WOMAC for young and/or active patients with knee OA or knee injury[7,8]. The main difference between the WOMAC and the KOOS is the inclusion of the sport and recreation function and QOL domains. The

KOOS has been shown to be more sensitive and responsive than WOMAC in younger or more active patient[8–10]. Several studies suggest that the current aging population, which includes those with knee OA awaiting joint replacement, is physically more active when compared to a similar population decades ago. In Germany, 42% of knee OA patients maintained involvement in sports at the time of joint replacement, and 34% continued 5 years after surgery[11]. In addition, it has been observed that some patients started participating post-operatively in sports which they were not able to do prior surgery. For example, only a few patients were able to go hiking prior to knee joint replacement, compared to nearly 30% 5 years post-surgery[11]. In another study performed in patients with knee OA awaiting joint replacement (mean age = 71 years), 51 and 91% of the patients considered that the KOOS sport/recreation and QOL subscales, respectively, were extremely very important[9]. Thus, the KOOS sport/recreation and QOL subscales may capture additional important information in elderly patients with knee OA. Consequently, the KOOS was evaluated in knee OA patients, including those with advanced disease progression. The KOOS was found to be valid, reliable, and responsive in OA patients before and after total joint replacement[9,10].

Due to the increase in large multicenter international studies and the requirement for globally meaningful epidemiologic and/or therapeutic study results, there is a need for cross-cultural adaptation and validation of health status measures. The cross-cultural adaptation of the KOOS may require not only translation but also adjustment of cultural words, idioms, and colloquialism. This process may involve substantial transformation of some items to fully capture the essence of the original concepts. Validated versions of KOOS have been currently published for use in English, Swedish[7], Danish, German[12], Singapore English and Chinese[13], and in numerous other languages[14].

The aim of this study was to cross-culturally adapt the KOOS in French and to evaluate the psychometric properties of this adaptation, as expressed by its feasibility, construct validity, reliability, and responsiveness.

## Methods

### CROSS-CULTURAL ADAPTATION PROCESS

The cross-cultural adaptation was performed according to published recommendations[15,16]. Three people (two rheumatologists and an English teacher) native in the target language independently translated the English version of the KOOS into French. A final version was written based on the consensus of the three translators. Backward translation was performed by a bilingual native English speaker (PB), blinded to the original English version. A multidisciplinary consensus committee was formed to ensure that the translation was comprehensive and verify cross-cultural equivalence of the source and final versions. The committee consisted of three rheumatologists (PO, LG, and JFM), an orthopedic surgeon (YJ), a rheumatologist and epidemiologist specialized in cross-cultural adaptation (FG), a retired rheumatologist suffering from knee OA (JS), and a native French English teacher (PG). The final version was pre-tested on 15 French patients suffering from knee OA. The patients were asked whether they fully understood all items and whether they had problems with the formulation.

### EVALUATION OF THE PSYCHOMETRIC PROPERTIES OF THE FRENCH VERSION OF KOOS

#### Study design

Bicentric prospective study.

#### Patients

Two patient populations were evaluated. The medicine group was formed by all consecutive outpatients consulting for knee OA in the Rheumatology

Department of the Dijon University Hospital (France). The surgery group was recruited in the Orthopedic Surgery Department of the Marseille University Hospital (France). It was constituted by all consecutive knee OA patients waiting for total knee replacement (TKR).

The inclusion criteria were patient age of at least 40 years, and primary knee OA according to the American college of rheumatology (ACR) criteria[17]. Additionally, the patients in the medicine group must not have been considered as candidate for knee joint replacement while patients in the surgery group must have been presented with an indication for knee replacement. Patients had to be able to understand and complete the self-report questionnaires.

The non-inclusion criteria were the presence of other significant rheumatic disease, such as low back pain and other inferior limb joints OA, severe inflammatory arthritis as confirmed by physical examination, intra-articular use of corticosteroids within the previous 3 months and, in the medicine group, expected changes in knee OA treatment during the following 2 weeks.

#### Questionnaires

During the initial assessment, patients in the medicine group were asked to fill in the French version of the KOOS questionnaire and the osteoarthritis knee and hip quality of life (OAKHQOL) questionnaire. The OAKHQOL was recently validated as a specific hip and knee OA QOL instrument[18]. The KOOS includes five domains and 42 items. The main difference between the WOMAC and the KOOS is the inclusion of two additional domains, a five-item sport and recreation function domain, and a four-item QOL domain. In addition, four items were added to the WOMAC pain domain, and the two-item WOMAC stiffness domain was changed to a seven-item symptom domain. For each domain, scores are normalized on a 0−100 scale, 100 being the best result. The OAKHQOL contains 43 items spread over five domains (pain, physical activities, mental health, social support, and social functioning) and three independent items (sexual activity, relationships, and professional life). Scores again ranged from 0 (worst) to 100 (best).

The patients in the medicine group were given a second KOOS questionnaire which they were asked to complete 2 weeks later and to mail back, using a pre-stamped envelope.

The patients in the surgery group were asked to fill in the KOOS questionnaire pre-operatively, and during a follow-up visit, 3 months after surgery.

Missing values were handled according to KOOS and OAKHQOL guidelines. For the KOOS, when more than two of the items of a domain were missing, the score was not calculated. For OAKHQOL, when at least half of the items of a dimension were missing, the score was not calculated. In other situations, missing values were replaced by the average of values observed in the same domain for the individual.

#### Statistical analysis

*Feasibility.* Feasibility was assessed using the percentages of responses and using the floor and ceiling effects in the medicine and surgery samples. The surgery group was assessed prior to and 3 months after surgery. Floor and ceiling effects were considered to be present if more than 15% of the respondents achieved the highest or the lowest possible scores.

*Construct validity.* Internal consistency was assessed using Cronbach's alpha coefficient. A Cronbach's alpha equal or superior to 0.7 is generally considered as satisfactory.

Convergent and divergent construct validity was determined by comparing the results of the KOOS and OAKHQOL questionnaires. The Spearman's rank correlation was used to assess the association between domains. Coefficient correlations >0.5, 0.5−0.35, and <0.35 were considered as strong, moderate, and weak, respectively[13]. *A priori* hypotheses were generated for convergent (moderate to strong correlation expected) and divergent (weak correlation expected) construct validity, according to the theoretical measurement of similar or divergent construct and results of the validation studies of the KOOS questionnaires in other languages[7,9,13]. It was hypothesized that: (1) the KOOS symptom, pain, and activity of daily life (ADL) domains would correlate strongly or moderately with the OAKHQOL pain and physical activities domains, and would correlate weakly with the other OAKHQOL domains, (2) the KOOS sports and recreation domain would correlate weakly with all OAKHQOL domains, since this domain has previously been reported as weakly correlated with all 36-item short form health survey (SF36) domains[9] and (3) the KOOS QOL domain would correlate strongly or moderately with all OAKHQOL domains.

In addition, the baseline scores obtained in the surgery sample (prior to knee joint replacement) and the medicine sample (no indication for total joint replacement) were compared using an ANOVA (analysis of variance) (after variance homogeneity was checked). It was hypothesized that scores in the surgery sample would be statistically lower than in the medicine sample.

*Reliability.* The reliability of the KOOS subscales was assessed using the two questionnaires completed at a 2-week interval by the medicine sample patients. It was assumed that, using such an interval, the probability of