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Psychometric properties of the French translation of the reduced KOOS and HOOS (KOOS-PS and HOOS-PS)

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Summary

Objective: To evaluate the psychometric properties of the French KOOS physical function (KOOS-PS) and HOOS physical function (HOOS-PS), specifically its feasibility, reliability, construct validity, and responsiveness.

Methods: Consecutive outpatients consulting for primary knee or hip osteoarthritis (OA) in a rheumatology department were included. During the initial assessment, patients were asked to complete the Knee injury and Osteoarthritis Outcome Score (KOOS) or Hip disability and Osteoarthritis Outcome Score (HOOS) questionnaire and the OsteoArthritis Knee and Hip Quality Of Life questionnaire (OAKHQOL). The patients were given a second KOOS or HOOS questionnaire to complete and return by mail 2 weeks later.
Feasibility was assessed by calculating the percentage of missing items and the floor and ceiling effects. Test–retest reliability was evaluated using the intra-class correlation coefficient (ICC). Convergent and divergent construct validity was determined by comparing the results of the KOOS-PS or HOOS-PS and OAKHQOL questionnaires using Spearman's rank test. Responsiveness was evaluated using data obtained in other hip or knee OA patients prior to and 1 month after intra-articular hyaluronic acid injection, using standardized response mean (SRM) and effect-size (ES).

Results: Eighty-seven patients with knee OA and 50 hip OA patients were included. The KOOS-PS and HOOS-PS scores were obtained for all patients as there were no missing items. Neither a floor nor a ceiling effect was observed. The ICC of KOOS-PS and HOOS-PS was 0.861 (0.763–0.921) and 0.859 (0.725–0.929), respectively. A strong or moderate correlation was observed, as expected, between KOOS-PS, HOOS-PS, and the OAKHQOL physical activities, pain, and mental health domains. A weak correlation was observed, as expected, between KOOS-PS, HOOS-PS, and the other OAKHQOL domains, except for a moderate correlation between the KOOS-PS and social functioning. The responsiveness was demonstrated with SRM and ES of 0.80 and 0.51 (KOOS-PS), 1.10 and 0.62 (HOOS-PS), respectively.

Conclusion: The French versions of KOOS-PS and HOOS-PS are reliable, valid, and responsive questionnaires for capturing functional disability in people with knee and hip OA.

Key words: Knee osteoarthritis, Hip osteoarthritis, Functional evaluation, KOOS-PS, HOOS-PS, OMERACT, OARSI, Cross-cultural adaptation, Validity, Reliability, Responsiveness.

Osteoarthritis (OA) is the most common joint disease characterized by progressive destruction of cartilage, affecting to large extent weight-bearing joints, such as the knee and hip, as well as the hand joints. The pain and disability associated with knee and hip OA have a significant impact on the patients' health-related quality of life[1,2]. As the frequency of knee and hip OA increases as a result of life-style changes associated with higher body mass index (BMI) and less physical activity and the aging of the population, this disorder increasingly will become a major health problem. Thus, it is important to evaluate interventions that might decrease patients' disability and/or prevent or delay the progression of the disease.

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Various instruments are available to assess physical function in knee and hip 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 limitations[6]. Since there were concerns that the WOMAC physical function subscale did not include items of sufficient difficulty, the Knee injury and Osteoarthritis Outcome Score (KOOS) and Hip disability and Osteoarthritis Outcome Score (HOOS) were developed as an extension of the WOMAC[7–12]. Recently, a working group created under the auspices of OARSI (Osteoarthritis Research Society International) and OMERACT (Outcome Measures in Rheumatology Clinical Trials) considered what would be an optimal tool to evaluate physical function states that represent the progression of physical disability from early to late disease for individuals with OA of the hip and knee)[13,14]. Of primary consideration were items that represented the spectrum of disability in a short measure with appropriate measurement properties. Using the Rasch analysis and data from samples representing a spectrum of OA severity, the group developed short measures of physical function in knee and hip OA that represent the progression of physical disability, the KOOS physical function (KOOS-PS) and HOOS physical function (HOOS-PS)[13,14]. These short measures are derived from the KOOS and HOOS and are reduced to seven (KOOS-PS) and five (HOOS-PS) items, achieving feasible, short scales with interval measurement properties that can be used as a function component of a knee and hip OA severity scoring system, covering a range of difficulty.

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. Moreover to assess a potential outcome measure, it is necessary to assess its psychometric properties, as defined by the OMERACT filter. The OMERACT filter[15] checks that a potential outcome measure is truthful, i.e., reflects what it is supposed to reflect, and is discriminant, which includes reproducibility, and sensitivity to change, over time, and between different severity stages. The last element in the OMERACT filter refers to feasibility, which relates to time, cost, availability and is not assessed through statistics.

The aim of the present study was to evaluate the psychometric properties of the French KOOS-PS and HOOS-PS, as expressed by its feasibility, reliability, construct validity, and responsiveness.

Methods

STUDY DESIGN, PROSPECTIVE STUDY

Patients

Consecutive outpatients consulting for knee or hip OA in the rheumatology department of the Dijon University Hospital (France) were included. The inclusion criteria were patient age of at least 40 years, and primary knee or hip OA according to the American College of Rheumatology criteria[16]. Patients had to be able to understand and complete the self-report questionnaires. In patients evaluated for responsiveness, an additional inclusion criterion was indication for intra-articular hyaluronate injection, according to the rheumatologist's usual criterion.

The exclusion criteria were the presence of other significant rheumatic disease, such as low back pain and other lower limb joint OA, severe inflammatory arthritis as confirmed by physical examination, and intra-articular use of corticosteroids within the previous 3 months. In patients evaluated for reliability, an additional exclusion criterion was expected changes in knee or hip OA treatment during the following 2 weeks. In patients evaluated for responsiveness, an additional exclusion criterion was expected changes in knee or hip OA treatment during the following month, except for hyaluronate injection.

Questionnaires

During the initial assessment, patients were asked to complete the French versions of KOOS or HOOS questionnaires. The translation and cross-cultural adaptation process of KOOS and HOOS into French have been conducted according to recommendations and have been described elsewhere[17,18]. Briefly, three persons (two rheumatologists and one teacher of English) native in the target language translated independently the English versions into French. A final single version was obtained after a consensus meeting. Backward translation was then performed by a bilingual native English speaker, blinded to the English original version. In the next step, a multidisciplinary consensus committee had a meeting in order to ensure that the translation was fully comprehensive and to verify cross-cultural equivalence of the source and final versions. In the last step, the final version was pre-tested among 15 French patients suffering from knee and 15 from hip OA. The KOOS-PS and HOOS-PS include seven (rising from bed, putting on socks/stockings, rising from sitting, bending to the floor, twisting/pivoting on your injured knee, kneeling, squatting) and five (descending stairs, getting in/out of bath, sitting, running, twisting/pivoting on your loaded leg) items, respectively, which were extracted in order to calculate the KOOS-PS and HOOS-PS scores. The scores were obtained as described: scored on 0–28 and 0–20 scales, respectively, then normalized on a 0–100 scale, 0 being the best[13,14]. Patients evaluated for validity also completed the OsteoArthritis Knee and Hip Quality Of Life questionnaire (OAKHQOL) during the initial assessment. The OAKHQOL was recently validated as a specific hip and knee OA quality of life instrument[19]. 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 range from 0 (worst) to 100 (best).

Patients evaluated for reliability were given a second KOOS or HOOS questionnaire that was completed and returned by mail 2 weeks later, using a pre-stamped envelope. This length of time was chosen since it was assumed that it was sufficiently important to consider that patients would not remember what they responded to the first questionnaire, and sufficiently brief to consider that no significant change in knee or hip OA disability would occur.

Patients evaluated for responsiveness were treated with intra-articular injection of hyaluronic acid. Patients with hip OA were given one ultrasound-guided intra-articular hyaluronic acid injection. The indication for injection was based on the usual criteria of the treating rheumatologist, but the procedure was performed by the same physician (PO). The hyaluronic acid varied in nature and molecular weight since patients presented with a specific prescription from their treating rheumatologist. Patients with knee OA were given three injections at 1-week intervals. The procedure was not ultrasound-guided, and was performed by the treating rheumatologist. Again, the hyaluronic acid varied in nature and molecular weight. The patients were given a second KOOS or HOOS questionnaire which they were asked to complete 1 month after the last injection, and mail back, using a pre-stamped envelope.

For the KOOS-PS and HOOS-PS, when at least one item was 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. When fewer items were omitted, 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 missing items and using the floor and ceiling effects. Floor and ceiling effects were considered present if more than 15% of the respondents achieved the highest or lowest possible scores.

Reliability

The test–retest reliability of the KOOS-PS and HOOS-PS was assessed using the two questionnaires completed at a 2-week interval. Evaluation of the reliability used the intra-class correlation coefficient (ICC) (two way model, single measure), with 95% CI (confidence interval). An ICC of more than 0.8 is usually considered to be indicative of excellent reproducibility. In addition, the Bland and Altman representation, in which the difference between the first and the second assessment is plotted against the mean of the two assessments, was obtained. Such a representation allows describing the percentage of the subjects and their distribution within the 95% limits of agreements along the range of the score scale.

Construct validity

Convergent and divergent construct validity was determined by comparing the results of the KOOS-PS or HOOS-PS and OAKHQOL questionnaires. The Spearman 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[20]. *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 constructs and to data of the literature. It was hypothesized that the KOOS-PS and HOOS-PS would correlate strongly or moderately with the OAKHQOL pain and physical activities domains, as well as with the mental health domain, since this particular domain has been shown to be strongly related to the WOMAC function subscale[19]. On the other hand, it was hypothesized that the KOOS-PS and the HOOS-PS would be weakly related with the other OAKHQOL domains.

Responsiveness

The responsiveness was evaluated by comparing the pre- and 1-month post-hyaluronic acid injection results. The standardized response mean (SRM), i.e., the mean change between baseline and 1 month after injection divided by the standard deviation (SD) of the mean change; and the effect-size (ES), i.e., the mean score change between baseline and 1 month after injection divided by the SD of the pre-injection values, were calculated.

The Statistical Package for the Social Sciences (SPSS) version 14.0 was used for data management and statistical analyses. Statistical significance was defined as $P < 0.05$.

Results

A total of 49 patients with knee OA (mean age $= 72 \pm 9$ years, 71% women) were included in the reliability assessment, of which 36 were also included in the construct validity assessment. Among these 49 patients, 46 returned their 2-week questionnaires. Responsiveness was evaluated in 38 other patients, who all mailed back their 1-month post-injections questionnaires.

A total of 30 patients with hip OA (mean age $= 65 \pm 10$ years, 74% women) were included in the reliability and construct validity assessment. All returned their 2-week questionnaires. Responsiveness was evaluated in 20 other patients, who all mailed back their 1-month post-injections questionnaires.

As no individual item was missing, the KOOS-PS and HOOS-PS scores were calculated in all patients for all assessments. Except for three independent items not used to calculate the different subscales (ability to work whereas most patients were retired, and sexual activity), the OAKHQOL questionnaires were filled in correctly, allowing calculation of the different subscales in all patients.

Neither a ceiling nor floor effect was observed as no patient had a maximal or minimal KOOS-PS or HOOS-PS score at either time of questionnaire completion.

The reproducibility of KOOS-PS and HOOS-PS was excellent (Table I). The Bland and Altman graphic representations are shown in Fig. 1. The difference between repeated measurements was included in the limits of agreements in most of cases, and was not related to the mean of the two measurements.

The results of convergent and divergent validity are shown in Table II. Eight out of 10 *a priori* hypotheses were confirmed. A strong or moderate correlation was observed, as expected, between KOOS-PS, HOOS-PS, and the OAKHQOL physical activities, pain, and mental health domains. A weak correlation was observed, as expected, between KOOS-PS, HOOS-PS, and the other OAKHQOL domains, except for a moderate correlation between the KOOS-PS and social functioning.

The responsiveness of KOOS-PS and HOOS-PS demonstrated large effects. Following the intra-articular injection, the KOOS-PS and HOOS-PS were improved after in comparison to before intra-articular injection in a great majority of patients (33 out of 38 and 17 out of 20, respectively). The SRM and ES were 0.80 and 0.51 (KOOS-PS) and 1.1 and 0.62 (HOOS-PS), respectively (Table III).

Table I
Mean KOOS-PS and HOOS-PS scores and reliability of KOOS-PS and HOOS-PS. Two assessments, separated by a 2-week interval, were made

	First assessment: mean (SD)	Second assessment: mean (SD)	ICC (95% CI)
KOOS-PS	48.3 (12.8)	49.1 (12.2)	0.861 (0.763−0.921)
HOOS-PS	51.1 (7.7)	52.1 (18)	0.859 (0.725−0.929)

Discussion

In the present work, the psychometric properties of the KOOS-PS and HOOS-PS were evaluated and found to be satisfactory. However, the findings will have to be confirmed by further studies evaluating other OA subpopulations before more extensive generalizability of the measures can be demonstrated. The data used in the present study were extracted from KOOS and HOOS questionnaires. Thus, the results will need confirmation with patients completing specifically the KOOS-PS and HOOS-PS questionnaires.

The results of the correlations support a convergent and divergent validity of KOOS-PS and HOOS-PS. As expected, higher correlations occurred when comparing KOOS-PS and HOOS-PS with the OAKHQOL subscale measuring the same domain (physical activity). The relationship with the OAKHQOL pain domain is in accordance with previous studies which demonstrated that functional activity and pain are related in OA patients[9,21]. The moderate correlation between KOOS-PS and HOOS-PS and the OAKHQOL mental health domain were expected since this particular subscale has been shown to correlate with WOMAC pain, and in particular, function domains[19]. The relationship with OAKHQOL mental health domain was statistically significant for HOOS-PS but was not for KOOS-PS. However, the latter was close to significance ($P = 0.06$), and somewhat close coefficients of correlations were obtained, which suggest that both are correlated and that the discrepancy was due to variability in sample constitution.

A moderate correlation was observed between the KOOS-PS and the OAKHQOL social functioning domain. This might be due to the inclusion in this particular OAKHQOL domain of two questions (going out whenever one would like and have friends in whenever one would like) which might also be related to function. On the contrary, no relationship was observed between OAKHQOL social functioning domain and the HOOS-PS. Further studies are needed to assess whether this discrepancy is due to variability in sample constitution or is real.

The reliability of the reduced questionnaires was excellent especially considering the time interval between the two questionnaires. According to the Bland and Altman representations, the difference between repeated measurements was not related to the mean of the measurements. The responsiveness was good or excellent, and might even be considered as surprisingly high, given the intervention. The evaluation of responsiveness 1 month after hyaluronic acid injection might be questionable, particularly for the hip, since some studies failed to demonstrate any superiority of hyaluronic acid compared to placebo in hip OA[22,23]. Thus, the improvement observed in the present study was probably related to a placebo effect, which has been shown to be prominent in OA, particularly from injections[24].

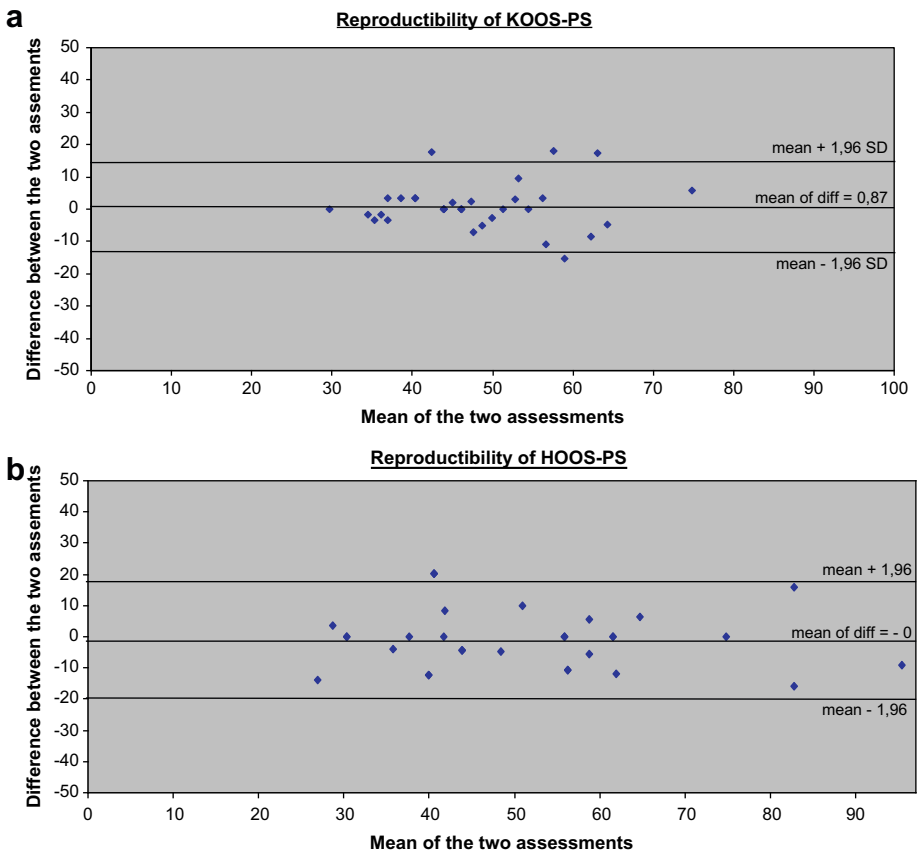

Fig. 1. Reproducibility of the French KOOS-PS and HOOS-PS: Bland and Altman representations. Two assessments, separated by a 2-week interval, were made. 95% Limits of agreement correspond to the mean difference between two measurements ±1.96 SD. (a) KOOS-PS and (b) HOOS-PS.

However, the aim of the study was not to evaluate the efficacy of hyaluronic acid injection, but to evaluate the responsiveness of the questionnaires. Moreover, while the KOOS-PS and HOOS-PS have been shown to capture improvement induced by total joint replacement[25], it is of satisfaction that the questionnaire demonstrated ability to capture changes induced by a less valuable intervention. Finally, it must be pointed out that the 1-month interval was not too brief, since improvements have been described as soon as 2 weeks after injection[26].

Apart from reliability, validity and responsiveness, a crucial property of an instrument aimed at being used in trials is feasibility. No floor or ceiling effects were observed with the reduced questionnaires. A potential limitation of the KOOS-PS and HOOS-PS is that, in contrary to the original KOOS and HOOS in which two missing items per domain are allowed[27], the reduced questionnaires require that each question is answered. Thus, another satisfying result was the absence of missing items.

A factorial analysis was not performed since the KOOS-PS and HOOS-PS were developed to ensure factorial unidimensionality[13,14]. An additional factor analysis would not have provided further proof of this. One could object that the present data were obtained from a new sample. However, in order to ensure generalizability, the initial development of the short measures included large samples across the spectrum of disease including population-based and clinically derived samples from multiple countries.

The KOOS-PS and HOOS-PS questionnaires were developed by a task force working under the umbrella of the OARSI and OMERACT societies aiming to establish virtual criteria for total joint replacement to be used as a hard outcome in therapeutic trials[28]. To achieve such an objective, it is critical to use instruments that represent the progression

Table II
Construct validity: correlations (Spearman's r) between KOOS-PS/HOOS-PS and OAKHQOL subscales

OAKHQOL	KOOS-PS	HOOS-PS
Physical activities	−0.44 ($P = 0.009$)	−0.665 ($P < 0.001$)
Pain	−0.366 ($P = 0.033$)	−0.385 ($P = 0.036$)
Mental health	−0.328 ($P = 0.06$)	−0.473 ($P < 0.001$)
Social support	−0.03 ($P = 0.87$)	0.022 ($P = 0.91$)
Social functioning	−0.34 ($P = 0.05$)	−0.125 ($P = 0.5$)

Table III
Responsiveness of French KOOS-PS and HOOS-PS. Patients were evaluated prior to and 1 month after three intra-articular hyaluronic acid injections (KOOS-PS) or 1 month after one intra-articular hyaluronic acid injection (HOOS-PS)

	Pre-hyaluronic acid injection: mean (SD)	Post-hyaluronic acid injection: mean (SD)	SRM	ES
KOOS-PS	48.2 (15.6)	40.3 (13.9)	0.80	0.51
HOOS-PS	51.3 (16.2)	41.3 (17.4)	1.10	0.62

of physical disability from early to late disease. The theoretical advantages of KOOS-PS and HOOS-PS are to avoid redundant items and that the Rasch model creates interval-scaled measures that provides item difficulty parameters and person functional ability parameters that are not dependant on each other. An issue might be that since the reduced questionnaires have been developed from the KOOS and HOOS, two questionnaires with numerous common items, they might not discriminate knee from hip OA. Actually, the five items of HOOS-PS are included in the KOOS questionnaire, and six out of the seven KOOS-PS items are included in the HOOS questionnaire. However, the HOOS-PS and KOOS-PS were not developed for the discrimination of the two diseases. In addition, there is only one question common to the HOOS-PS and KOOS-PS (with actually not exactly the same formulation), which means that other items of the KOOS-PS did not fit the Rash model applied to hip OA patients and other items of the HOOS-PS did not fit the Rash model applied to knee OA patients. This suggests that the reduced questionnaires discriminate the two affections.

A previous study of the HOOS-PS and KOOS-PS in people with total hip or knee replacement provided evidence of construct validity and responsiveness of the measures as compared to the longer WOMAC Likert 3.0 physical function subscale[25] but, to our knowledge, the reliability of the instruments, as well as the construct validity in patients with less advanced OA and the responsiveness following a less efficient procedure than total joint replacement, have not be assessed. Thus, apart from a validation of the French versions of the outcomes, the present work, which demonstrates a satisfying feasibility, convergent and divergent construct validity, reliability, and responsiveness can be considered as a further validation study of the new developed knee and hip OA reduced instruments aimed at assessing functional severity.

Conflict of interest

The authors have no conflict of interest.

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