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Cross-cultural adaptation and validation of the KOOS, JR questionnaire for assessing knee osteoarthritis in Spanish-speaking patients

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Abstract

Purpose The present study aims to translate, adapt and validate a Spanish version of the Knee Injury and Osteoarthritis Outcome Score, Joint Replacement (KOOS, JR), including a reliability and validity analysis in patients with knee osteoarthritis (OA).

Methods This study conducted a prospective validation study following the six stages of the "Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures". Psychometric testing was conducted in patients with knee osteoarthritis. Subjects answered the Spanish KOOS, JR (S-KOOS, JR) and a validated Spanish Oxford Knee Score (S-OKS). Retest was conducted at 10 days. Acceptability, floor and ceiling effect, internal consistency (Cronbach's α), reproducibility (mixed-effect model coefficient [MEMC]) and construct validity (Spearman's correlation; $p = 0.05$) were assessed.

Results Forty-one patients (mean age: 65.6 ± 5.39; 48.8% female) participated in the study. All patients (100%) answered both scores during the first assessment and 38 (92.7%) during the second assessment. All patient-reported outcomes measures were answered completely (100%). The S-KOOS, JR resulted in 100% acceptability when answered. There were no ceiling or floor effects detected. The Cronbach's α for the S-KOOS, JR was 0.927 and its MEMC was 0.852 (CI 95% 0.636–1.078). The Spearman's correlation between the S-KOOS, JR and the S-OKS was 0.711 (CI 0.345–0.608; $p < 0.001$) and 0.870 (CI 0.444–0.651; $p < 0.001$) for the first and second assessments, respectively.

Conclusion The S-KOOS, JR has very high internal consistency and reproducibility, with a high correlation with the S-OKS; it is a reliable and valid instrument for characterising Spanish-speaking patients suffering from knee OA.

Level of evidence IV.

Keywords Knee osteoarthritis · Knee replacement · Patient-reported outcome measure · KOOS · KOOS, JR · Spanish · Adaptation · Validation

Abbreviations

CI	Confidence interval
ICC	Interclass correlation coefficient
KOOS	Knee Injury and Osteoarthritis Outcome Score

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KOOS, JR	Knee Injury and Osteoarthritis Outcome Score Joint Replacement
MEMC	Mixed-effect model coefficient
OA	Osteoarthritis
OKS	Oxford Knee Score
PSI	Person Separation Index
PROMs	Patient-reported outcomes measurements
S-KOOS, JR	Spanish Knee Injury and Osteoarthritis Outcome Score Joint Replacement
S-OKS	Spanish Oxford Knee Score
SD	Standard deviation
TKR	Total knee replacement
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

Introduction

Patient-reported outcomes measures (PROMs) have become the gold standard for patient-centred evaluation after surgical procedures [5, 10, 19]. They offer insights into care quality, delivery and clinical research [5, 21]. Specifically in knee replacement-related surgery, the most widely used PROMs are the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Oxford Knee Score (OKS) and the Knee Injury and Osteoarthritis Outcome Score (KOOS) [20, 21].

Unfortunately, these PROMs are lengthy, obstructing their efficient incorporation into routine clinical practise. They introduce challenges related to incomplete responses and missing data, and many patients find these instruments burdensome, mentally demanding and overwhelming [3, 20]. Furthermore, some PROMs are proprietary (WOMAC, Oxford Knee Score), making widespread administration in public spheres incompatible [20]. For these reasons, shorter adaptations of the KOOS have been created [12, 20, 26]. The KOOS Joint Replacement (KOOS, JR) survey, is a validated short form (7 questions) from the original KOOS score (42 questions), providing a single "knee health PROM" that combines pain, symptoms and functional limitations of activities of daily living in a single score [20].The KOOS, JR has demonstrated a higher response rate amongst other PROMs in patients suffering from knee osteoarthritis (OA), proved excellent correlations with its longer original form (KOOS), the WOMAC and OKS in preoperative and postoperative total knee replacement (TKR) evaluations [5, 20, 27].

As within many PROMs, the full utilisation of the KOOS, JR is hindered by language and cultural differences. To address this gap, translating and validating outcome measure instruments into languages beyond English is crucial for broad applicability. Notably, the original KOOS 42 questions-form has been translated and validated into Spanish [30], the second most widely spoken language globally [15]. However, a validated Spanish version of the KOOS, JR, to characterise patients from Spanish-speaking countries, and the more than 13% of Americans [8] and 8% of Europeans [16] native Spanish speakers, is still unavailable.

The present study aims to translate, adapt and validate a Spanish version of the KOOS, JR (S-KOOS, JR), including a reliability and validity analysis in patients with knee OA. The hypothesis is that the S-KOOS, JR is a reliable and valid instrument for characterising Spanish-speaking patients suffering from knee OA.

Methods

A prospective validation study was conducted on a consecutive sample of patients diagnosed with moderate and severe knee OA awaiting TKR in a Chilean Public Hospital from May until June 2020. Knee OA was diagnosed by knee orthopaedic surgeons according to the American Rheumatism Association's criterion [1] considering weight bearing X-ray films and classified according to the Kellgren–Lawrence classification [17]. Patients with inflammatory arthritis, previous knee replacement or the inability to independently answer the PROMs were excluded. All patients provided informed consent at the time of study enrolment. This investigation was approved by an Institutional Ethics Committee for Clinical Research.

Cross-cultural translation and adaptation of the KOOS, JR to the Spanish version

The six stages of the "Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures" [4] were followed to obtain the S-KOOS, JR.

Stage I: Translation. Two native Spanish speakers independently translated the original KOOS, JR English version [20] to Spanish.

Stage II: Synthesis. These Spanish translators cooperated to harmonise their translated versions into a uniform Spanish-translated version. During this process, linguistic and legibility tests were performed to resolve any discovered issues (e.g. adequate translation/adaptation of "slowness", "first wakening", "twisting/pivoting", "experienced" and "bending to floor").

Stage III: Back translation. Two blinded native English speakers independently translated the uniform Spanish-translated version back into English versions to ensure a consistent translation and highlight imperfections [4].

Stage IV: Expert committee review of the final Spanish version. The expert committee consisting of six orthopaedic surgeons, one translator and two non-health-related worker volunteers compared the various versions developed and

worked to adapt the uniform Spanish-translated version into a pre-final version for evaluation.

Stage V: Pretesting in ten volunteers with similar demographic characteristics as the target study population. Subjects completed the questionnaire and were interviewed about their interpretation of each question and their chosen response. Both the meaning of the items and responses were explored.

Stage VI: Approval by the expert committee and the original developer.

An additional file shows the final S-KOOS, JR (see Additional file 1).

Validation of the S-KOOS, JR

A new group of participants (patients with knee OA) answered the S-KOOS, JR, and a previously validated Spanish Oxford Knee Score (S-OKS) [22]. PROMs administration were repeated after 10 days to evaluate reliability. There were no new treatments given to the participants between the PROMs administration.

Statistical analysis

The minimum number of participants was calculated considering the accepted subject–item ratio for PROMs of 5–1 (50 participants for a 10-item question) [13], which gives 35 subjects.

Scores were analysed using raw values (each question of the S-KOOS, JR from 0 to 4, and the S-OKS from 1 to 5), giving a total possible score from 0–29 to 12–60 for each test, respectively. In both tests, the lowest values represent the best possible outcome/least symptoms. Continuous variables were described by measures of central tendency and dispersion. Confidence intervals, statistical significance and ceiling or floor effects were set at 95%, $p < 0.05$ and 15%, respectively. The number of unanswered questionnaires and skipped questions was documented for acceptability assessment. There was no imputation of lost data or interim analyses in this study. Data were analysed with SPSS software version 22.0 (SPSS Inc).

Reliability of the S-KOOS, JR*:* Internal consistency, the extent to which all the items in a test measure the same concept, was attained using Cronbach's α [29]. On a scale from 0 to 1, the higher the score, the more questions in a test are correlated to each other. Reproducibility was assessed by a mixed-effects model analysis in a test–retest method. A threshold of 0.6 and 0.8 was considered for substantial and almost perfect levels of agreement, respectively [18].

External validity of the S-KOOS, JR: Spearman's correlation was used for comparing S-KOOS, JR and S-OKS scores. A threshold of 0.7 and 0.9 was considered for high and very high correlation, respectively [23].

Results

Forty-one patients (mean age: 65.6 ± 5.39; 48.8% female) agreed to participate in the study. Table 1 summarises the results from the responses given by patients to the S-KOOS, JR, and S-OKS scores.

Acceptability and floor and ceiling effects

All patients (100%) answered both scores completely (100%) during the first assessment. During the second assessment, tests were answered by 38 (92.7%) patients, and all of them answered both scores completely (100%). Therefore, the S-KOOS, JR demonstrated 100% acceptability by this criterion.

For the total S-KOOS, JR score, there was no aggregation at the lowest end of the scale, and less than 15% of the responses scored 28 out of 28 possible points in the first (4.9%) and second (13.2%) assessments, respectively. Therefore, the presence of floor or ceiling effects was ruled out.

Reliability

Regarding the S-KOOS, JR internal consistency, Cronbach's α was 0.927 for the 41 patients who answered during the first assessment. Concerning the S-KOOS, JR reproducibility, the mixed-effect model coefficient (MEMC) was 0.852 (CI 95% 0.636–1.078) between the first and second assessments

Table 1 Summary of the responses (raw score) from the S-KOOS, JR and S-OKS

	Total (*n*)	Average (SD)	Median (range)	*n* (%) in the lowest score	*n* (%) in the maximum score
S-KOOS, JR (first time)	41	20.1 (5.87)	22 (6–28)	0 (0%)	2 (4.9%)
S-KOOS, JR (second time)	38	20.6 (5.63)	21 (13–28)	0 (0%)	5 (13.2%)
S-OKS (first time)	41	44.9 (9.37)	46 (19–59)	0 (0%)	0 (0%)
S-OKS (second time)	38	44.9 (9.07)	48 (21–60)	0 (0%)	1 (2.6%)

SD Standard deviation

of the 38 patients who answered the questionnaire at both time points.

Validity

The correlation between S-KOOS, JR and S-OKS is summarised in Fig. 1. Spearman's correlation was 0.711 (CI 0.345–0.608; $p < 0.001$) and 0.870 (CI 0.444–0.651; $p < 0.001$) for the first and second assessments, respectively. When grouping the total information obtained from the 79 answers (first and second assessment grouped), the Spearman's correlation between S-KOOS, JR and S-OKS was 0.779 (CI 0.424–0.592; $p < 0.001$).

The correlations between the S-KOOS, JR and S-OKS during the first and second assessments are plotted in Fig. 1A and B, respectively. Spearman's correlation was 0.711 (CI 0.345–0.608; $p < 0.001$) and 0.870 (CI 0.444–0.651; $p < 0.001$) for the first and second assessments, respectively.

The total correlation between the 79 answers (first and second assessment grouped) is plotted in Fig. 1C. The Spearman's correlation between the total S-KOOS, JR and S-OKS responses was 0.779 (CI 0.424–0.592; $p < 0.001$).

Discussion

The most important finding of the present study is that the S-KOOS, JR has proven well-accepted, reliable and valid for assessing knee OA symptoms. The KOOS, JR has been translated, adapted and validated into a Spanish version employing a structured step-guided process [4], including the author of the original score [20].

The 41 participants included in the validation process were all patients diagnosed with knee OA awaiting TKR. It is important to consider that in an effort to avoid perception bias, the present S-KOOS, JR has been validated in patients without previous knee arthroplasty. Another critical aspect to consider is that the KOOS, JR is a self-reported scale, which was originally created as short form to avoid obstructing efficient clinic daily practise, challenges for follow-up

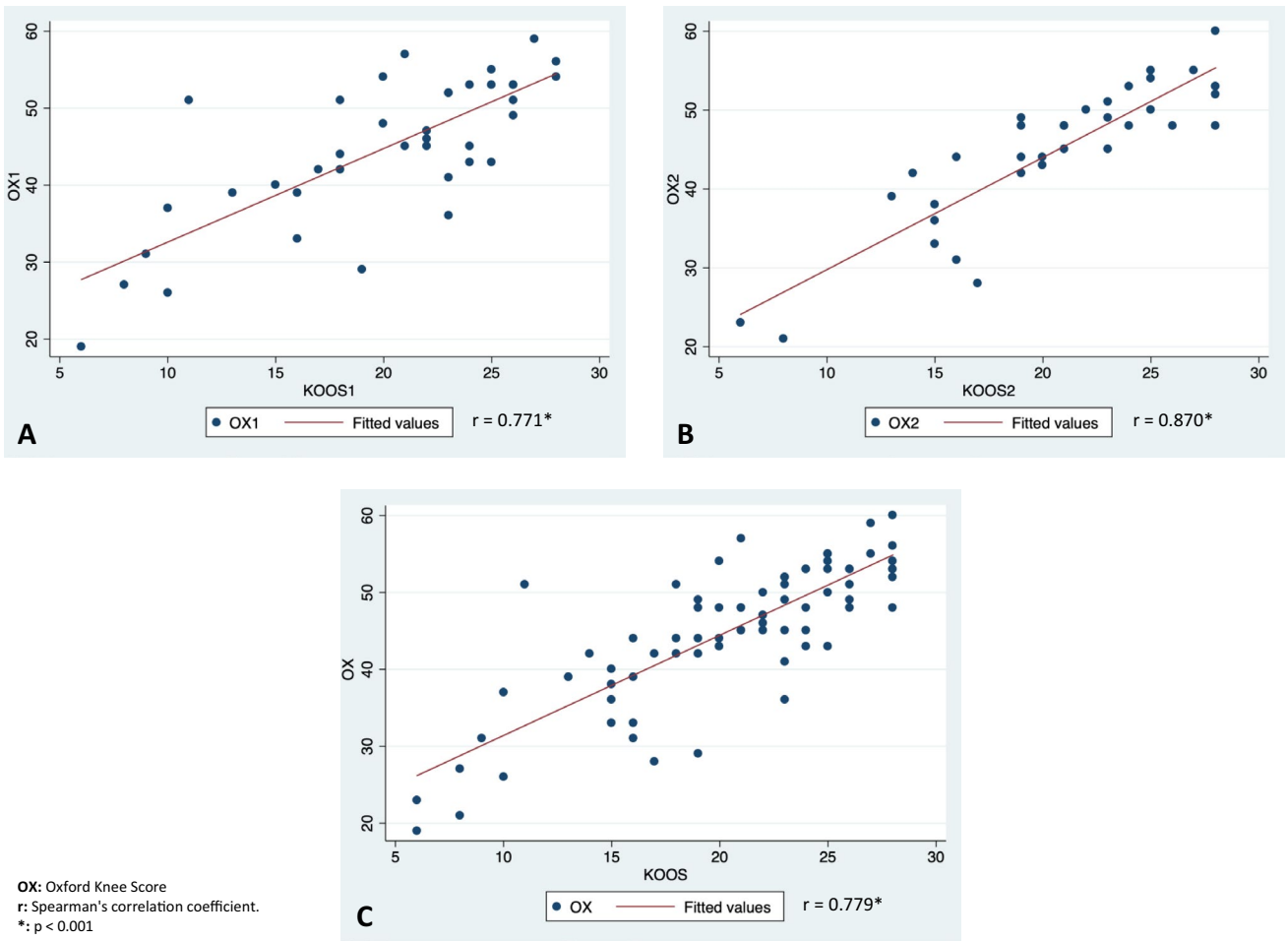

Fig. 1 Correlations between S-KOOS, JR and S-OKS

and the high non-response and missing responses in most of the common use PROMs [3, 20], which makes their widespread administration during clinical care impractical. The present S-KOOS, JR included only patients within a public institution of a low-resource and income district from Chile and had a 100% of acceptability when answered, without floor effect and low ceiling effect (< 15%), demonstrating it is a valid tool for public health practise.

The proven internal validity for the S-KOOS, JR was excellent, even higher than the original questionnaire (Cronbach's $\alpha = 0.927$ versus Person Separation Index (PSI) = 0.840) [20] and other KOOS, JR cross-cultural adaptation and validation (Romanian) (Cronbach's $\alpha = 0.816$ of the first test) [11]. It must be highlighted that the original investigation used the PSI for assessing internal validity, which, even though it is similar to Cronbach's α, might be a reason for the differences encountered. There are different reports about the acceptable values of α, ranging from 0.70 to 0.95. However, if the test length is too short, as in the KOOS-JR, the α value may be reduced [29]. According to Cortina, considering the KOOS, JR is a three-dimension tool of seven questions, the optimal Cronbach's α value should be > 0.49 [7]. The reproducibility of the S-KOOS, JR was also very high and considered almost perfect according to Landis et al. [18]. It was higher than the single and average interclass correlation coefficient (ICC) found in the Romanian version of the KOOS, JR (MEMC = 0.852 versus ICC 0.387 for single and 0.816 for average measures, respectively) [11]. Even though the ICC is an adequate tool for analysing a test's reproducibility, it is typically used when multiple raters assess the same target or when a single rater is assessing multiple targets. It must be considered that as the KOOS, JR is a PROM, each person rates themselves and there are no other raters (raters and targets are the same person); there are no "between-rater" or "between-target" differences to model. Therefore, ICC is not best suited in this context, and the mixed-effects model analysis used in the present study is a more adequate test.

The external validity of the S-KOOS, JR was assessed by comparing its correlation to a validated transcultural adaptation Spanish version of the OKS [22], which has already proven to have a strong positive correlation in their original language forms [27]. Raw scores and the OKS punctuation from 12 to 60 were used, considering that in this method, the lowest values represent the best possible outcome/least symptoms in both scores. As in their original language, the present study showed a high positive [23] significant correlation between the Spanish versions of both tests in each assessment.

It is crucial to emphasise that the KOOS, JR is intended for patients with knee OA and should not be applied to other types of knee conditions without prior validation, due to the lack of content validity [14]. Alternative abbreviated versions of the original KOOS score have been validated within patients with knee OA, specifically the KOOS-12, which similarly to the original KOOS, JR and the present S-KOOS, JR, exhibited a low ceiling effect, commendable responsiveness and strong construct validity when compared with the OKS[9]. Nevertheless, whilst the KOOS-12 emerges as a valid option for outcomes assessment in the context of knee OA, the authors contend that the KOOS, JR holds the distinct advantage of even greater brevity (over 40% shorter than the KOOS-12), making it particularly well suited for evaluations within constrained timeframes, as frequently encountered in public healthcare institutions.

The study has some limitations that are important to acknowledge. First, a sample size of 41 patients may be considered "very poor" [6] for scale validations. Nevertheless, given the variation in the types of questionnaires being used, there are no absolute rules for the sample size needed to validate a questionnaire [24]. In the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) report on using and modifying existing PROMs, Rothman et al. reported that a sample size of 20–30 interviews is commonly used for practical purposes [28]. It has been proposed that 2–20 subjects per item are accepted ratios [2]. Based on this guideline, and that the present study is the first to translate, adapt and validate a Spanish version of the KOOS, JR, Gorsuch's subject–item ratio of 5–1 (50 participants for a 10-item question) [13] was contemplated, which gave a minimum of 35 subjects. Considering a possible missing answer from 6 patients is that 41 patients were included. Second, the studied subjects may not represent all Spanish-speaking countries as it was conducted within the Chilean population. As has been done with previous validations of the full KOOS, other Spanish-speaking countries may want to validate the S-KOOS, JR in their own population before its formal implementation. However, the authors made an effort to avoid the use of local Spanish dialect terms, which may increase the possibility of its global application. Third, the precise degree of OA was not considered in the demographic analysis. It is possible to encounter differences regarding pain and function (two aspects assessed with the KOOS, JR) according to the severity of knee OA; as the patient's radiographic findings worsened, the pain level increased and functionality decreased [25]. Nonetheless, all included subjects corresponded to patients with Kellgren–Lawrence grades 3 and 4 knee OA waiting for TKR.

The successful translation, adaptation and validation of the KOOS, JR into a Spanish version address the critical language barrier existing when assessing PROMs. The S-KOOS, JR offers Spanish-speaking patients a reliable tool to evaluate their knee health, enhancing patient care and facilitating informed medical decisions.

Conclusion

The S-KOOS, JR has very high internal consistency and reproducibility, with a high correlation with the S-OKS; it is a reliable and valid instrument for characterising Spanish-speaking patients suffering from knee OA.

Appendix

Additional file 1: Spanish KOOS, JR (S-KOOS, JR) questionnaire. The file shows the validated Spanish KOOS, JR questionnaire which may be printed and used for assessing knee osteoarthritis in Spanish-speaking patients.

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Author contributions Conceived and designed the experiments: RG, MI, TP. Performed the experiments: RG, MI, TP, NO, EE, SL. Analysed the data: RG. Wrote the paper: RG. Revised and approved the article: RG, MI, TP, NO, FF, EC, EE, SL, MS. All authors read and approved the final manuscript.

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Availability of data and materials The datasets used or analysed during the current study are available from the corresponding author upon reasonable request.

Declarations

Conflict of interest The authors declare that they have no competing interests.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Ethics Committees for Clinical Research: Comité Ético Científico Servicio de Salud Metropolitano Sur Oriente, Santiago, Chile.

Consent to participate All patients gave written consent for participation and publication.

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