

## **Validation of a Persian-version of Knee injury and Osteoarthritis Outcome Score (KOOS) in Iranians with knee injuries**

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### **Summary**

**Objective:** To adapt culturally and validate Persian-version of the Knee injury and Osteoarthritis Outcome Score (KOOS) in a sample of Iranians with knee injuries.

**Methods:** Cultural adaptation included providing of forward and backward translations, quality rating and pilot testing. A sample of 147 patients with anterior cruciate ligament (ACL), meniscus and combined (ACL and meniscus) injuries was asked to complete two questionnaires including the KOOS and Short-Form 36 Health Survey (SF-36). The KOOS was readministered to 54 patients 6–8 days after the first visit. Test–retest reliability and internal consistency were assessed, using Intraclass Correlation Coefficient (ICC) and Cronbach's alpha, respectively. Dimensionality was assessed, using item-scale correlation after correction for overlap and construct validity, using *a priori* hypothesized correlations with the SF-36.

**Results:** All patients found the Persian-version of the KOOS to be clear and unambiguous in pilot testing. Minimum ICC level of 0.70 was exceeded by all subscales with the exception of Sport and Recreation (Sport/Rec) subscale. Minimum Cronbach's alpha level of 0.70 was exceeded by all subscales with the exception of Symptoms and Knee-related Quality of Life (QoL). Minimum Spearman correlation coefficient of 0.40 for each item-scale was exceeded by 34 items. All *a priori* hypotheses were supported by the presence of higher correlations between similar constructs than between dissimilar constructs of the KOOS and SF-36.

**Conclusion:** The Persian-version of the KOOS is a culturally-adapted, reliable and valid outcome measure to be used in Iranian patients with knee injuries, with its psychometric properties in agreement with the original versions.

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**Key words:** Knee injuries, Outcome, Validation, Iran.

### **Introduction**

It is now widely accepted that there is a need for clinical outcome research to evaluate the benefits and cost effectiveness of new diagnostic, surgical and rehabilitative approaches for the treatment of knee problems<sup>1</sup>. Clinicians and researchers wishing to select an instrument for measuring health outcome of patients with knee injuries have a choice of several patient-centered instruments.

Characteristics of patients that the instrument is developed for, instrument content and psychometric properties are criteria recommended for selection of instruments<sup>2</sup>.

The Knee injury and Osteoarthritis Outcome Score (KOOS), as an extension of the Western Ontario and McMaster Universities (WOMAC), is a relatively new, well-designed, simple self-administered instrument developed to assess short-term and long-term symptoms and function in patients with knee injuries and osteoarthritis. It has a good evidence of reliability, validity and responsiveness in different populations with varying pathologies, injury durations, ages and activity levels<sup>3</sup>. The KOOS has been validated in American-English, Swedish, German, Singapore-English and Chinese<sup>4–7</sup>.

It has been argued that cross-cultural validation of patient-centered outcome measures are needed to compare

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Received 19 August 2007; revision accepted 1 March 2008.

and contrast results, aggregate data from different countries, strengthen causal inference on effects of treatments and to investigate the natural history of health conditions<sup>8</sup>. The aims of this study were to linguistically validate of a Persian-version of KOOS and present data on its psychometric properties in patients with Anterior Cruciate Ligament (ACL), meniscus and combined (ACL and meniscus) injuries.

## Methods

### TRANSLATION PROCESS

Guidelines recommended by International Quality of Life Assessment project group were used to translate the KOOS from English to Persian, the Iranian language<sup>9</sup>. At the first step, two independent bilingual translators, native in Persian translated the original English version into Persian and then agreed on a common forward version. Two other bilinguals, who were native Persian speakers, scored the quality of the agreed-on forward version from the aspects of clarity, common language and conceptual equivalence. Quality ratings were used to modify the translation as needed to develop a preliminary common forward translation. At next step, forward version was back translated into English by another translator with further modifications, if needed. Finally, the forward version was tested as pilot among 30 Persian speaking patients with ACL, meniscus and combined injuries for taking into account any difficult or confusing item or response choice.

### PATIENTS

From March 2006 to March 2007, a convenient sample of 147 patients (age range 16–59; 131 males, 16 females) with knee injuries was recruited from the Department of Orthopedics at Moayeri Hospital and Milad Hospital, Tehran, Iran. All patients were diagnosed as ACL, meniscus and combined injuries by their orthopedic surgeon, based on clinical and Magnetic Resonance Imaging findings. All patients were Persian native speakers with an intermediate or higher educational level. Patients were excluded if they had other diagnoses than ACL, meniscus and combined injury, involvement of other joints affecting lower extremity or back, systematic inflammatory rheumatic disease (e.g., rheumatoid arthritis, ankylosing spondylitis, etc.), osteoarthritis, neurological or vascular conditions and psychiatric disorders. The patients suffered from knee injuries for at least 1.5 months prior to participation in the study. Questionnaires including the KOOS and Short-Form 36 Health Survey (SF-36) were administered to each patient by a trained clinician when visiting the surgeon. The Ethics Committee at University of Social Welfare and Rehabilitation approved the study. All patients gave their informed consent before participation in the study.

### INSTRUMENTS

The KOOS is a 42-item disease-specific questionnaire with five subscales: Pain, Symptoms, Activities of Daily Living (ADL), Sport and Recreation (Sport/Rec) and Knee-related Quality of Life (QoL). A five-point Likert scale ranging from 0 (no problems) to 4 (extreme problems) is used for scoring each item. Raw scores are transformed to a 0–100 scale with 0 indicating extreme problems and 100 indicating no problems, calculated for each subscale separately<sup>3</sup>.

The SF-36 is a 36-item generic self-administered instrument of health status. It consists of eight subscales: Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE) and Mental Health (MH). The eight subscales are hypothesized to form two distinct higher-ordered factors namely Physical Health and Mental Health summary measures. These eight subscales are scored from 0 to 100 with higher scores indicating better health status<sup>10</sup>. Evidence indicates that SF-36 may be a suitable outcome measure in lower limb dysfunctions<sup>11</sup>. Iranian-version of SF-36 has been validated for use in Iran<sup>12</sup>.

### ASSESSMENT OF PSYCHOMETRIC PROPERTIES

#### Reliability

The KOOS was readministered to 54 patients, including ACL ( $n=26$ ), meniscus ( $n=10$ ) and combined ( $n=18$ ) injuries, 6–8 days after the first visit to evaluate the instrument's test–retest reliability. Because the variation between trials is to a great extent related to the instrument or subject and not

rather, due to its self-administering mode, so the test–retest reliability of the KOOS was analyzed using one-way random effect model of Intraclass Correlation Coefficient (ICC) to estimate the amount of variation over time in stable patients. An ICC equal or greater than 0.70 was considered acceptable for test–retest reliability<sup>13</sup>. Also, internal consistency, an additional measure of reliability, was calculated on the first administration using Cronbach's alpha statistic to estimate the average of the correlations between items within a subscale. Cronbach's alpha equal or greater than 0.70 was considered satisfactory for internal consistency<sup>13</sup>.

#### Dimensionality

Dimensionality was assessed using the correlation between an item and the subscale score as a whole, omitting that item (item-scale correlation after correction for overlap). Spearman correlation coefficients equal or greater than 0.40 was considered acceptable<sup>13</sup>.

#### Construct validity

Evidence for construct validity can only be accumulated by *a priori* hypothesized patterns of associations with other validated instruments<sup>1</sup>. It was hypothesized *a priori* that the correlations between the KOOS Pain and SF-36 BP subscales should be high, the correlations between the KOOS ADL and Sport/Rec and SF-36 PF subscales should be high, the correlations between the KOOS subscales and the SF-36 subscales of Physical Health (PF, RP, BP) should be higher than between the KOOS subscales and the SF-36 subscales of Mental Health (GH, VT, SF, RE, MH). The Spearman's rank correlation coefficient ( $r_s$ ) was used to assess construct validity<sup>13</sup>.

## Results

### TRANSLATION PROCESS

To match with Iranian culture three items were modified. Item 13 in ADL subscale regarding degree of difficulty when “get in/out of bath”, was changed to “take a bath”, because tubs are not used frequently in Iran nowadays. The word “socks/stocking” used in items 9 and 11 of the same subscale was changed to its single Persian equivalent, because two separate words are not used for differentiating them in Persian. No difficulties encountered by the respondents were noted in pilot study.

### PATIENTS' CHARACTERISTICS

Subjects included 60 (41%), 31 (21%) and 56 (38%) patients with ACL, meniscus and combined injuries, respectively. The mean age of subjects was 31.4, mostly male (89%) and generally with High school and University educational levels (94%). Characteristics of patients in each group are shown in Table I.

### DESCRIPTIVE STATISTICS

Table II represents the mean, standard deviation (SD), median, range and proportion of patients scoring at the floor (zero) and the ceiling (100) levels on the 0–100 scale for the five KOOS and eight SF-36 subscales.

The number of patients receiving floor or ceiling effect was negligible for KOOS Pain, Symptom and ADL subscales. For the subscales Sport/Rec and QoL the worst possible score was detected in 21 and 17 subjects, respectively. For the SF-36, floor and ceiling effects were negligible for the subscales PF, BP, GH, VT and MH, among others.

Only five of 6174 items (0.08%) were missing for the KOOS data. Scoring was calculated for the five subscales in all 147 patients. However, 29 of 5292 items (0.55%) were missing for the SF-36 data. Scoring was calculated for the eight subscales in all 147 patients except RE, where scoring was done for 146 patients.

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