RESPONSIVENESS, RELIABILITY AND VALIDITY OF THE ARABIC VERSION OF OXFORD KNEE SCORE IN PATIENTS UNDERGOING TOTAL KNEE ARTHROPLASTY

ABSTRACT

Introduction. The Oxford Knee Score (OKS) is a reliable, valid and sensitive assessment tool for individuals having a total knee arthroplasty (TKA). The published psychometric assessment of the Arabic version of OKS (OKS-Ar) is limited to male patients and has no assessment of responsiveness following TKA.

Aim. To assess the reliability, validity and responsiveness of the OKS-Ar in inclusive patients undergoing TKA.

Methods. One hundred Arabic-speaking patients awaiting TKA were assessed with OKS-Ar, the Arabic version of the Knee Injury and Osteoarthritis Outcome Score (KOOS-Ar), and a visual analogue scale for pain (VAS-P), in order to assess the correlation between OKS-Ar and KOOS-Ar and VAS-P and determine the construct validity. Repeat assessments were completed 7–10 days later and six months post-TKA.

Results. Questionnaires were completed by 80 female and 20 male participants with a mean age of 60 years and 69 years respectively. The test and re-test median scores showed no significant difference, with a strong Spearman's correlation between the two measurements (rs=.94). Bland-Altman's limits of agreement showed no significant bias. Cronbach's α was 0.98, indicating high internal consistency. There was no floor or ceiling effect pre-TKA, and the post-TKA ceiling effect was only 2%. The OKS-Ar pain component correlated strongly with the KOOS-Ar pain subscale (rs=.73). The OKS-Ar effect size was 3.09, which is larger than all KOOS subscales at six months post -TKA.

Conclusion. This is the first study to assess OKS-Ar's reliability, validity and responsiveness post-TKA. The validity and reliability results are like those found for both the original English

OKS and in other translated languages. This is the first study to assess OKS-Ar responsiveness post-TKA and show a large effect size. We found that OKS-Ar is a feasible, valid, reliable and sensitive measurement tool to assess pain and function in individuals whose main language is Arabic and who are undergoing TKA.

KEYWORDS

Osteoarthritis Arthroplasty Oxford knee score Arabic Validity Reliability Responsiveness

INTRODUCTION

There is a trend toward greater involvement of patients in deciding their care and assessing outcomes of their treatment. Patient-reported outcome measures (PROMs) have evolved to assess the patient's perspective of the quality of care both for that routinely delivered by healthcare organisations and when conducting studies of clinical trial outcomes [1]. Specific PROMs have been designed to assess health and functional changes in relation to specific pathologies or interventions to improve their sensitivity and minimise ceiling effects [2]. The Oxford Knee Score (OKS), a 12-item questionnaire, was developed to assess patients after total-knee arthroplasty (TKA). The aim of the questionnaire is to measure the patient's perspective of outcomes after TKA in a short, reliable, and valid way with sensitivity to clinically relevant changes [3]. OKS score has been approved as a specific PROM to evaluate pain and functional performance and for audit purposes post-TKA [4]. It has been translated and validated in a variety of languages, such as German [5], French [6], Chinese [7], Thai [8], Arabic [9,10], and Turkish [11]. However, there are only two studies assessing the Arabic version of the OKS (OKS-Ar). The study by Alghadir et al. was limited to male patients only [9], although there is a greater risk in females for prevalent and incident knee osteoarthritis (KOA) than males and females tend to have more severe KOA than males [12]. The other paper by Ahmed et al. [10] was a mixture of knee pathology (30 subjects for anterior cruciate ligament reconstruction, 20 subjects for partial meniscectomy, 20 subjects for high tibial osteotomy, and only 30 subjects for TKA), so it is hard to isolate the knee arthroplasty findings as they encounter different problems. In addition, without clear justification for the sample size included for each pathology, this makes their conclusion questionable. Neither Arabic study assessed responsiveness following TKA, or ceiling and floor effects. Responsiveness is one of the critical criteria for PROMs selection as it assesses a questionnaire's ability and cultural sensitivity to accurately detect change after intervention

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[2]. The purpose of the present study was to explore the reliability, validity and responsiveness of OKS-Ar in inclusive patients undergoing TKA. Although there was no published prevalence regarding knee arthroplasty surgeries in the Arabic population, females from the Middle East and North Africa had a greater rate of knee arthroplasty than people from Australia, east Asia, the Americas and Sub-Saharan Africa [13,14], which emphasises the need for a valid, reliable and sensitive tool to assess Arabic-speaking patients post-TKA.

METHODS

Participants and study design

Ethical approval was obtained from the Salford University Ethical Panel and King Khalid University Hospital before patients were recruited. The study methodology is registered at ClinicalTrials.gov (NCT02998125). A translated Arabic version of OKS was obtained and used with permission from the OKS copyright holder (Oxford University Innovation, licence number, OXF508807). All Arabic speaking patients who were scheduled for elective primary unilateral TKA, for knee osteoarthritis, were identified during preadmission orthopedic-clinic visits between March and May 2017.

As one of the main study objectives was to assess OKS score responsiveness following primary unilateral TKA without the effect of other uncontrolled pathologies, further exclusions were applied to minimise confounding factors that might affect pain and functional changes post-TKA. Potential research participants were excluded from the study if they had been diagnosed with other comorbidities, including: unstable diabetes mellitus, uncontrolled hypertension, unstable ischemic heart disease, a significantly debilitating neurological disorder; if they were morbidly obese with a body mass index (BMI) > 40. A total of 132 patients were identified during the recruitment period; four patients were excluded as they did not meet the study inclusion criteria (two patients BMI > 40, one patient with unstable ischemic heart disease, one patient with a history of post-stroke hemiplegia). An information sheet outlining the objectives

of the study was given to all 128 patients who matched the inclusion criteria. Patients agreeing to participate signed a consent form following detailed explanation of the study and were given the opportunity to ask questions by the researcher [15]. All patients underwent a midline incision with a medial parapatellar approach to surgery by one of five consultant surgeons.

Sample-size estimation

The required sample-size estimation was made according to Walter et al.'s (1998) recommendations for reliability. Based on two observations with a significance level of α =0.05, a power of (1- β) 0.90 and acceptable reliability of po=0.75, this indicated a minimum of 100 patients was required [16]. A total of 128 patients were invited to participate in the study, of whom 100 agreed to participate. The remaining 28 patients declined. The 100 patients who participated were not significantly different from those who declined in terms of their age, gender or BMI (P>.05).

After demographic data were collected, the participants were requested to complete a study questionnaire package which included: OKS-Ar, visual analogue scale for current pain (VAS-P) and the Arabic version of Knee Osteoarthritis Outcome Score (KOOS-Ar). Patients were asked to complete the same questionnaire package again after 7–10 days and six months following TKA. The interviewer was present at all three time points to provide help with any questions or difficulties that might arise.

Data processing

Scoring of the OKS data entry was performed according to the 2015 revised scoring version of the OKS guidelines, in which overall scores range from 0 (worst) to 48 (best). A maximum of two unanswered questions per questionnaire is acceptable. In the case of one or two missing scores, the mean value representing all other responses fills this gap. [11]. All KOOS subscales were scored according to the KOOS guidelines [17]. For pain score, the assessor used a ruler

to measure the distance in mm from the origin (0) to the patient's mark on a VAS-P 100mm line, where (0) points represents no pain and 100 points is intolerable pain [18].

Statistical analysis

Analysis was performed using the Statistical Package for the Social Sciences (SPSS) for Windows, version 24 (IBM Inc., Chicago, Illinois, USA). The assumption of a normal distribution of the OKS-Ar differences before and six months after TKA was violated as assessed by a Kolmogorov-Smirnov test (p < 0.05). Therefore, non-parametric analysis was used. Feasibility was assessed by measuring the percentage of the questionnaire filled in, the percentage of empty responses or the percentage of patients facing difficulties and asking for help with any questions [5]. Reliability of the two measurements before arthroplasty was assessed using: Spearman's correlation between two measurements, test and re-test median difference using a Wilcoxon signed rank test, and a Bland-Altman plot [19]. Internal consistency was assessed based on Cronbach's alpha values [20]. The ceiling effect determined the percentage of responses between the maximum score and the maximum score reduced by one standard deviation, while the floor effect determined the percentage of responses between the minimum score and the minimum score increased by one standard deviation [6]. Responsiveness was assessed by the questionnaire's ability to detect change before and after the TKA using a Wilcoxon signed-rank test. The effect size was calculated based on the ratio of the mean change in pre and post-operative scores, divided by the pre-operative standard deviation. The effect size was considered to be large, moderate, or small based on the values of 0.8, 0.5, or 0.2 respectively [3, 20]. Construct validity of the OKS-Ar was assessed by correlation with the KOOS-Ar and VAS-P using Spearman correlation [20].

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RESULTS

The properties of the OKS-Ar were assessed in 100 patients waiting for knee replacement. The 80 female and 20 male patients had a mean age of 62 (SD \pm 7.8 years). The BMI means were **34.7** (SD \pm 5.1) for females and 30.0 (SD \pm 4.6) for males. In terms of feasibility, all patients completed the questionnaire without any difficulty at all three measurements points with a 100% response rate.

1. OKS-Ar reliability testing

The score for the first and second OKS-Ar measurements was significantly correlated (rs = .94, p < 0.001). All questions showed excellent to large correlation, with rs ranging between .92 and .70 (Table 1). There were no significant differences between the first and second OKS-Ar measurements' median scores (p = 0.85; z = .18, median=15, median different=.01). In addition, the Bland-Altman plot showed almost all scores were within the limits of agreement (95% CI: -0.366 to 0.326) (Figure 1).

Internal consistency

The OKS-Ar showed high internal consistency, with all Cronbach's α at 0.84 and all the item total corrections at above 0.3. The alpha values did not improve beyond 0.84 if one question was deleted.

Ceiling and floor effect

Before operation, no ceiling effect was found (with no score above 42). Six months post-TKA, the ceiling effect was 2% (two scores were above 42). The floor effect was not shown before or post-TKA (no score below 6 was recorded).

2. OKS-Ar responsiveness to change

A Wilcoxon signed-rank test determined that there was a significant median increase in score of 20 points after TKA (p < 0.0005, z = 8.68). Both Pain and Function subscales showed a statistically median increase in score after TKA (Table 2). Six months after TKA,

the OKS-Ar effect size was large at 3.09.

All KOOS subscales showed a significant median score increase post-TKA (with high scores associated with better performance) with all Ps<.0005 and a large effect size (Table 2). There was a significant median reduction in pain score using VAS-P and a large effect size of 4.4 (Table 2).

3. OKS-Ar validity testing – correlation with other scales

The OKS-Ar Pain component revealed a positive strong correlation with the Pain subscale of KOOS-Ar, with the variables increasing concurrently as the patients got better. In contrast, the OKS-Ar Pain component demonstrated a negative weak correlation with pain score in VAS-P (Figure 2 & Table 3).

The Functional component of OKS-Ar revealed a positive strong correlation with the KOOS-Ar ADL subscale, a positive moderate correlation with the KOOS-Ar QoL subscale, a weak positive correlation with the KOOS-Ar Symptom subscale and no correlation with the Sport and Recreation subscale (all p < 0.01) (Figure 2 & Table 3).

DISCUSSION

This is the first study to assess OKS-Ar's validity, reliability and responsiveness. The study demonstrates that OKS-Ar is both feasible to use and a reliable, valid and responsive assessment tool for individuals whose main language is Arabic and who are undergoing TKA. The OKS-Ar is a useful assessment tool, not only for use among Saudi patients but also for the more than 290 million Arabic-speaking people in the world [21]. There were more female patients than male, and this relates well to KOA prevalence. The females tend to have more severe KOA than males, and this emphasised the need for sensitive assessment tools to measure their pain and function changes post-TKA [12].

OKS assessed the severity of pain and the ability to engage in the basic daily activities of living, such as personal hygiene, use of transportation, ability to walk pain-free, sit-to-stand

movement, limping due to knee pain, kneeling, bed mobility and pain, housework, general stability, shopping and use of stairs [3]. Most studies have assessed construct validity using the 36-Item Short Form Survey (SF-36), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), or the Knee Society Score. The current study showed a good correlation between the OKS-Ar Functional component and the KOOS-Ar ADL and QoL subscales, and this is similar to the correlation obtained by Ahmed et. al [10]. This correlation may be due to the similarity of the two questionnaires, ADL & QoL KOOS subscale and functional components of OKA-Ar assess patients' ability and possible limitations of mobility in terms of stairs, walking and position changes.

The pain component showed agreement with the KOOS-Ar pain and symptoms subscale, as both assessed the pain during different daily activities. This is in agreement with the WOMAC pain subscale correlation that was found in German [5], Arabic [9], and Turkish [11] studies, and with the SF-36 correlation in the original English version [3], the Chinese version [7], and the Thai version [8].

The weak correlation between OKS-Ar and the KOOS-Ar Sport and recreation subscale may be due to differences in their content, only one of five items – kneeling ability – is assessed in both questionnaires, which may explain the weak correlation. The remaining four items on the sport and recreation subscale – squatting, running, jumping and pivoting – are not covered by OKS, as most patients who have just had a total knee arthroplasty are not ready for running, jumping or pivoting sports.

In terms of test/re-test testing and correlation coefficients, the reproducibility of the OKS-Ar showed excellent agreement between the two measurements, with no significant differences. This is in line with the original English version [3] and other translation studies that assessed repeatability, such as for the German [5], Arabic [9], and Turkish versions [11]. The internal consistency of OKS-Ar showed good Cronbach's α value, similar to both the original English

OKS [3] and other translated versions such as the French [6], German [5], Chinese [7], and Turkish versions [11], Table 4. The absolute reliability was assessed by a Bland-Altman plot, which confirmed no significant bias. This agrees with the original English [3] and with the studies assessing the German [5] and Arabic versions [9].

The floor and ceiling effects of OKS-Ar are similar to those of the original version [3] and other official translations [5, 6, 7, 8, 11]. The absence of a floor effect confirms the ability of OKS-Ar to detect any clinical changes post-TKA. The average score pre-surgery was lower than the Turkish study [11], this may be due to the younger age range of their study participants (38–83 years old) compared to the current one. The Turkish study [11] was the only one to use the updated 2015 scoring system and consequently easiest for comparison, in which the overall score was between 0 (worst possible) and 48 (best possible). The remaining studies [3, 5, 6, 7, 8, 9] used the original scoring system; the overall score was from 12 to 60 (with 12 being the best outcome).

The current study is the only one to assess the responsiveness and sensitivity of translated OKS after TKA (Table 4). The study showed a large effect size, in agreement with the original English version [3], and more than KOOS. This confirms its sensitivity to detect changes post-TKA more than KOOS. The current study's effect size was larger than the original [3], score changes in current study were 20 points, in the original 15 points. This may be due to pre-TKA OKS scores or demographic differences between the two samples. OKS scores before surgery in the original study were higher than in the current one. The current study's OKS median score before TKA was 14 points, which may be due to high BMIs in comparison to the original study's participants (BMI=34.7 (SD \pm 5.1) for females and 30.0 (SD \pm 4.6) for males). In terms of the age factor, the original study's mean age was 73 (46–89) years, while the current study's mean age was 62 (54–70) years. This may explain the large improvement in OKS scores 6 months post-TKA as the current patients were younger.

No patients showed any difficulties in understanding or completing the OKS with an excellent response rate at all assessment time points, which indicates its excellent feasibility for use in clinical practice as it is short and simple. A future study is recommended to assess the feasibility and reliability of the electronic version as it is simple and does not require any further clarification or help from a clinician.

The current study's limitations include a lack of comparison to other Arabic versions of knee score in addition to KOOS, such as Lysholm Knee Score (LKS) and the International Knee Documentation Committee Subjective Knee Form (IKDC), which might allow us to better assess the construct validity. Although the current OKS-Ar version used classic Arabic, the level of understanding and completion of this version may not reach 100 per cent, given the widespread use of Arabic slang across the Arab world. OKS-Ar sensitivity was limited to 6 months post-TKA, as the plan is to address that in a subsequent prospective study with a 12-month follow-up.

In conclusion, this study is the first to demonstrate comprehensively that the OKS-Ar is a valid, reliable and responsive tool for use in Arabic speaking patients undergoing TKA. Therefore, clinicians are recommended to use OKS-Ar in place of other PROM Arabic translations for Arabic speaking patients undergoing TKA, given its psychometric properties' superiority.

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Figure 1. Bland-Altman plot showing reliability of the Arabic version of Oxford Knee Score (OKS).

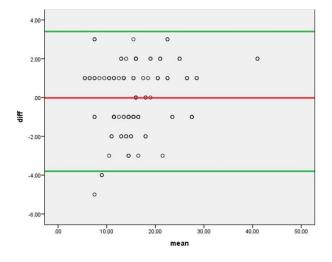
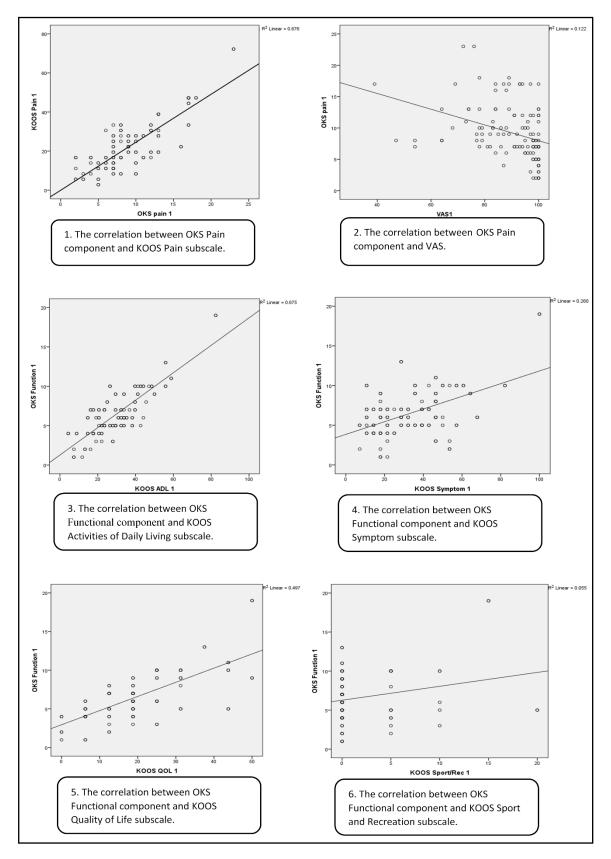


Figure 2. Scatter diagram showing the correlation between Oxford Knee Score (OKS) with visual analogue scale (VAS-P) and Knee Injury and Osteoarthritis Outcome Score (KOOS) components.



		95% Con Inter	
Correlation Coefficient	Sig. (2- tailed)	Lower Bound	Upper Bound
.731	.001	.630	.821
.890	.001	.825	.944
.806	.001	.691	.897
.758	.001	.649	.844
.760	.001	.651	.854
.814	.001	.691	.894
.887	.001	.826	.931
.914	.001	.865	.948
.803	.001	.708	.890
.921	.001	.880	.951
.705	.001	.557	.819
.760	.001	.606	.888
.945	.001	.903	.966
	.731 .890 .806 .758 .760 .814 .887 .914 .803 .921 .705 .760	Coefficienttailed).731.001.890.001.806.001.758.001.760.001.814.001.887.001.914.001.803.001.921.001.705.001.760.001	Correlation Coefficient Sig. (2- tailed) Lower Bound .731 .001 .630 .890 .001 .825 .806 .001 .691 .758 .001 .649 .760 .001 .651 .814 .001 .691 .887 .001 .826 .914 .001 .865 .803 .001 .708 .921 .001 .880 .705 .001 .557 .760 .001 .606

Table 1. Spearman's rho correlations between two Oxford Knee Score (OKS) measurements before arthroplasty (time 1 and time 2).

Table 2. Responsiveness of Oxford Knee Score (OKS), Knee Osteoarthritis Outcome Score (KOOS), and a visual analogue scale for pain (VAS-

	Median	IQR* before	Median post-	IQR post-	Median difference	IQR difference	Asymptot ic sig. (2- sided	Effect	95% Confidence Interval for effect size	
	before							size		
	TKA	TKA	TKA	TKA			test)		Lower	Upper
									Bound	Bound
OKS total score	14	6	34	5	20	7	.001	3.09	2.90	3.43
OKS pain subscale	9	5	21	4	12	6	.001	2.71	2.54	2.98
OKS function subscale	5	1	12	3	7	4	.001	2.48	2.34	2.71
KOOS pain	19	16	65	10	44	18	.001	2.83	2.59	3.21
KOOS symptoms	32	28	79	11	43	29	.001	1.99	1.92	2.11
KOOS ADL	29	17	78	8	47	19	.001	2.92	2.56	3.46
KOOS sport	0	0	5	5	5	5	.001	0.96	0.91	1
KOOS QoL	19	12	69	6	50	19	.001	3.09	2.91	3.42
Visual Analogue Scale for pain	93	17	18	12	73	21	.001	4.40	3.95	5.07

P) before and after total knee arthroplasty.

*IQR= interquartile range.

Table 3. Oxford Knee Score Spearman correlations.

	Oxford K	Knee Score Pain cor	nponent	Oxford Knee Score Functional component			
	Correlation	95% Confidence interval		Correlation	95% Confid	ïdence interval	
	Coefficient	Lower	Upper	Coefficient	Lower	Upper	
VAS-P	48	62	33	29	47	12	
KOOS pain	.73	.59	.82	.46	.28	.62	
KOOS symptoms	.63	.49	.74	.33	.14	.50	
KOOS Activities of Daily Living	.59	.43	.71	.68	.54	.79	
KOOS Sport & Recreation	.09	12	.30	05	27	.18	
KOOS Quality of Life	.68	.55	.79	.62	.46	.75	

Correlation significant at the 0.01 level (2-tailed)., VAS-P= Visual Analogue Scale for pain, KOOS= Knee Injury and Osteoarthritis Outcome Score.

Table 4 – Comparison of the OKS-Ar with the OKS orig	ginal study and subsequent translation studies.
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	Current	English [3]	German [5]	French [6]	Chinese [7]	Thai [8]	Arabic [9]	Arabic [10]	Turkish [11
emale	80	66	61	64	116	86	0	45	62
Male	20	51	39	36	15	14	97	55	29
Age	54-70	46-89	46-88	48-86	60-74	34-85	40-80	18-70	38-83
Scoring system	Updated version 2015	Original	Original	Original	Original	Original	Original	Original	Updated version 2015
Median value bre-surgery	14	45	32	43	38	23	28		21
Range pre- surgery	8-38	25-57	38-25	21-56	30-45	12-47	12-58		8-34
Feasibility	100%	92%	91.8%	100%			100%	95%	100%
The internal consistency (Cronbach's α)	0.84	0.87	0.83	0.88	0.81	0.91	0.98	0.90	0.90
Test re-test	0.0431 ± 1.8	0.4 ± .9	0.3±1.1				0.2 ±.3		20 (4403)
Correlation (ICC/Spearman) between the two measurement	R= .94	R=.92	ICC=.91				ICC=.97	ICC=.85	R=.98
Absolute reliability by Bland-Altman blot	Almost all scores within limit of agreements (95% Cl: - 0.366326)	89% between 0 ± 4 points	No significant bias				Most of score within limit of agreement		
The absolute measurement error; the standard error of measurement (SEM)	±1.18		± 6.2				2.2		
Correlation coefficient with another valid tool	Significant correlation with VAS & KOOS pain R= .74	Significant correlation with SF36& HAQ	Significant correlation with VAS (R.84) & WOMAC (R.89)	Significant correlation with WOMAC R.76	correlation with IKS R.47	correlation with SF-36 pain component (R.72) & EQ-5D (R.49)	correlation with SF-36 pain (R.71) & functional component (R.72)	Significant correlation with KOOS R.91	Significan correlation with WOMAC & SF-36
Floor effect	NO		2.1%	NO	7 scores	NO			NO
Ceiling effect	2%		1%	NO	NO	NO			4 scores
Sensitivity post total knee arthroplasty (Effect size)	3.09	2.19							