



# Translation, Adaptation and Validation of the Middle East Lower Limb Score (MELLS) into Arabic

Sager Samir Hanna<sup>1</sup>, Fahad AlKhalaf<sup>2</sup>, Awdhah AlSamhan<sup>3</sup>, Hend Abdulrahman AlHamdan<sup>4</sup>,  
Bader Mohammad AlAdwani<sup>5</sup>, Aliaa Khaja<sup>6</sup>

<sup>1</sup>Department of Orthopaedics, AlRazi Orthopaedic Hospital, Kuwait; [Sager2012@gmail.com](mailto:Sager2012@gmail.com)

<sup>2</sup>Department of Sports medicine, AlRazi Orthopaedic Hospital, Kuwait; [dr.alkhalaf@gmail.com](mailto:dr.alkhalaf@gmail.com)

<sup>3</sup>Department of Orthopaedics, AlRazi Orthopaedic Hospital, Kuwait; [a.alsamhan099@hotmail.com](mailto:a.alsamhan099@hotmail.com)

<sup>4</sup>Department of Orthopaedics, King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia;  
[H.alhamdan@live.com](mailto:H.alhamdan@live.com)

<sup>5</sup>Department of Orthopaedics, Division of Arthroplasty, AlRazi Orthopedic Hospital, Kuwait; [Bader\\_131@hotmail.com](mailto:Bader_131@hotmail.com)

<sup>6</sup>Department of Orthopaedics, AlRazi Orthopaedic Hospital, Kuwait; [Aliaa.khaja@gmail.com](mailto:Aliaa.khaja@gmail.com)

\*Corresponding author: Aliaa Khaja; [Aliaa.khaja@gmail.com](mailto:Aliaa.khaja@gmail.com)

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## Abstract

**Background:** The Middle East Lower Limb Score (MELLS) is an adaptation of the WOMAC questionnaire, specifically adjusted according to the cultural issues of the middle eastern patients with Knee or hip disabilities. **Objectives:** The primary objective of this study was to verify if the translation and adaptation of the MELLS into Arabic could be used with ease and consistency by Arab-speaking patients suffering lower limb disabilities. **Material & Methods:** 110 participants were involved in this study. We performed the internal consistency tests with Cronbach's alpha. We also calculated floor effects, ceiling effects, as well as test-retest reliability (intra-correlation coefficient). To estimate the validity of MELLS, we used two validated questionnaires – WOMAC and OHS. We confirmed the validity of MELLS questionnaire using Spearman's correlation. **Results:** MELLS had a Cronbach's alpha of 0.88 in the first assessment and 0.92 in the second assessment, which was very high and reliable. Both subscales of MELLS had an internal consistency higher than 0.85. No relevant ceiling and floor effect were observed among the responses. Furthermore, strong significant correlation with WOMAC subscales and OHS was observed, which suggested good construct validity. Responsiveness of MELLS, however, proved to be lower (but not considerably) than other two questionnaires. **Conclusion:** The Arabic Middle East Lower Limb Score (MELLS) is a useful and reliable diagnostic tool for Middle eastern patients with knee and hip problems.

**Keywords:** Joint pain, patient reported outcomes, knee, hip, surgery

## Introduction

The Middle East Lower Limb Score (MELLS) is an adaptation of the WOMAC questionnaire, specifically adjusted according to the cultural issues of the middle eastern patients with Knee or hip disabilities. The Middle East Lower Limb Score is designed to test pain and functional outcomes for patients with cultural influences such as praying five times daily (kneeling and bending), squatting when toileting, sitting on the floor, and sitting cross-legged.

We made up the Middle East Lower Limb Score to determine which surgeries work and how to avoid giving patients unnecessary anterior knee pain or positional hip pain.

MELLS is derived from the WOMAC questionnaire. WOMAC is an acronym for the Western Ontario and McMaster Universities Osteoarthritis Index. It is a measure of physical disability and symptoms developed originally for osteoarthritis

patients [1,2]. WOMAC was developed to evaluate clinically relevant changes in patient's health status due to treatment intervention [3]. More than a decade ago, Bellamy and colleagues provided proof of the reliability, responsiveness, and validity of the WOMAC in osteoarthritis patients undergoing hip or total knee arthroplasty, and in osteoarthritis patients treated with nonsteroidal anti-inflammatory drugs [1,2]. But then, creating the measurement properties of any instrument within any group of patients is a continuous process [3]. Several studies reporting the responsiveness, validity, and reliability of the WOMAC have been carried out since these initial studies [4]. Also, the WOMAC has served as an outcome measure for the evaluation of the efficacy of other therapeutic interventions (such as acupuncture), and in groups of patients other than osteoarthritis of the knee and hip [5-7].

This study aims to prove the reliability and validity of the MELLS, as a PRO score to be used by clinicians in for evaluating

Arabic speaking patients. The WOMAC and OHS were used for comparison in this study, as they have been translated into Arabic and cross-culturally adapted in the literature.

## Methods and Materials

### Participants

A pilot study was conducted on 10 patients initially (5 with hip problem and 5 with knee problems), in clinic chosen at random to fill out the questionnaire. Then the patients were asked about their interpretation of each item, language ease and understanding of the concepts and assessed for need of assistance when filling out the questionnaire before launching the full-scale study.

The data was gathered randomly from 110 patients who had undergone a surgical intervention for their knee or hip. The subjects completed the MELLs questionnaire. They gave their written consent to use the information they had provided for the purpose of this study. The average age of the participants was 48.1 years, with standard deviation of 15.07 years; implying that the majority of the sample was between 33 and 63 years of age. The youngest participant was 18, and the oldest was 78 years of age. The female to male ratio 1:1. The patients were given 3 patient related outcome questionnaires adapted for Arabic speakers, including MELLs, WOMAC and OHS.

## Questionnaires

### The Middle East Lower Limb Score (MELLs)

This questionnaire consists of 43 questions, all of which are focused on the problems patients are experiencing with their lower limbs (knee and hip). This questionnaire is primarily an adaptation of WOMAC questionnaire, which is adjusted to specifically address the cultural issues of the middle eastern patients. MELLs uses five point Likert-type scale, where 0 indicates that the respondent is not experiencing any difficulties/pain, and 5 indicates that the patient experiences the highest level of difficulty/pain. Unlike WOMAC, this questionnaire consists of two domains, Pain (25 Items) and Daily activity (18 Items). One score is calculated for each patient by summing the responses to all of the 43 items. Therefore, a score of 172 means that the patient is experiencing severe hip/knee difficulty/pain. In order to standardize the scores with 0-100 metric system, the following formula is used:

$$\frac{100}{\text{Maximum Possible Domain Score}} \times \text{Actual Score}$$

All 110 patients have completed MELLs-questionnaire in at least two different occasions after the surgical intervention (T1 and T2). There was a 2 week interval between the first two times they had filled the questionnaires<sup>[4-5]</sup>.

### Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Arabic version of WOMAC has been already validated in the study conducted by Guermazi M. et al., thus, it was used in this study to investigate the validity of MELLs<sup>[8]</sup>. There were 24 Likert-type questions here and each patient had scores from three different subscales. First subscale – pain – had 5 questions (score range 5-20), 2 questions addressed stiffness (score range 2-8), and physical function had 17 questions (range 17-68). A minimum score on each of the subscales means that patient essentially did not feel any discomfort in his/her hip (if any), and a higher score suggests greater disability. At the end, the WOMAC scores were rescaled

according to 0-100 system. The survey was taken in two different occasions, with a time period of 2 weeks between them.

### Oxford - 12 Item Hip Score

Another questionnaire which was used in this study to investigate the validity of MELLs was Oxford Hip Score (OHS). Arabic version of OHS has already been validated by Khaja A. et al. and could be used to examine the validity of MELLs<sup>[9]</sup>. This questionnaire consists of 12 questions, all of which are focused on the patients' hip problems. To answer these questions, respondents use five point Likert-type scale, where 1 indicates that the respondent is not experiencing any difficulties, while 5 indicates that the patient experiences the highest level of difficulty. One score is calculated for each patient by summing the responses to all of the 12 items. Therefore, a score of 60 means that the patient is experiencing severe hip pain.

### Patient Burden and feasibility

We recorded the average time it took each participant to fill out the questionnaire as well as if they required any assistance during the process as part of the patient-burden investigation. The feasibility was determined. It took an average of 6 minutes to complete the questionnaire. There were no difficulties understanding the language of the survey.

### Data analysis and psychometric scale properties

All the analyses were conducted using IBM SPSS Statistics v.26 and GraphPad Prism v.8 for the visualization of the results. The test-retest reliability of the questionnaire was examined by using Cronbach's alpha, and interclass correlation coefficient. The patients completed the questionnaire on two different occasions, so Cronbach's alpha was calculated for all two situations to determine internal validity.

Convergent and divergent construct validity were tested by using the spearman's correlation coefficients for the 12-items of the oxford hip score and the WOMAC.

Content validity was tested by examining the floor and ceiling effects. Floor effect represents the percentage of patients who had the lowest score (0), and ceiling effect is the percentage of those with the highest (100).

Correlation with WOMAC and OHS subscales were estimated to evaluate convergent validity of the MELLs questionnaire. If it was a valid instrument to measure hip/knee pain, its scores should have positive correlation with all the subscales from the questionnaire.

## Results

All randomly selected patients filled out the questionnaires and the data collected were used in this study. None of the patients had any problem filling any part of the questionnaire. Hence, data of all 110 patients were used in this study.

### WOMAC & OHS Questionnaires

Before investigating the psychometric properties of MELLs, it is important to examine the instruments that are already being used in Arabic speaking countries for hip/knee pain assessment<sup>[10]</sup>.

Reliability in the first assessment, which was calculated using Cronbach's alpha - was 0.95 for the pain subscale, 0.93 for the stiffness, and 0.98 for the physical function subscale. For the second testing, reliability was 0.96, 0.95, and 0.99 (pain, stiffness, and physical function, respectively).

In order to check content validity, floor and ceiling effects were examined. Five percent of the patients have recorded floor

effect on pain subscale, 3% on stiffness subscale, and 3% on the physical function. On the other hand, 2% have recorded ceiling effect on pain subscale, 4% on stiffness subscale, and 0% on the physical function.

**Middle East Lower Limb Score (MELLS) Questionnaire**

**Table 1: Descriptive statistics of MELLS questionnaire**

Assessment		N <sup>1</sup>	Min <sup>2</sup>	Max <sup>3</sup>	Mean	SD <sup>4</sup>	Floor effect	Ceiling effect
MELLS	First	110	0	100	55.52	12.01	0%	1%
	Second	110	0	100	57.11	12.68	2%	5%

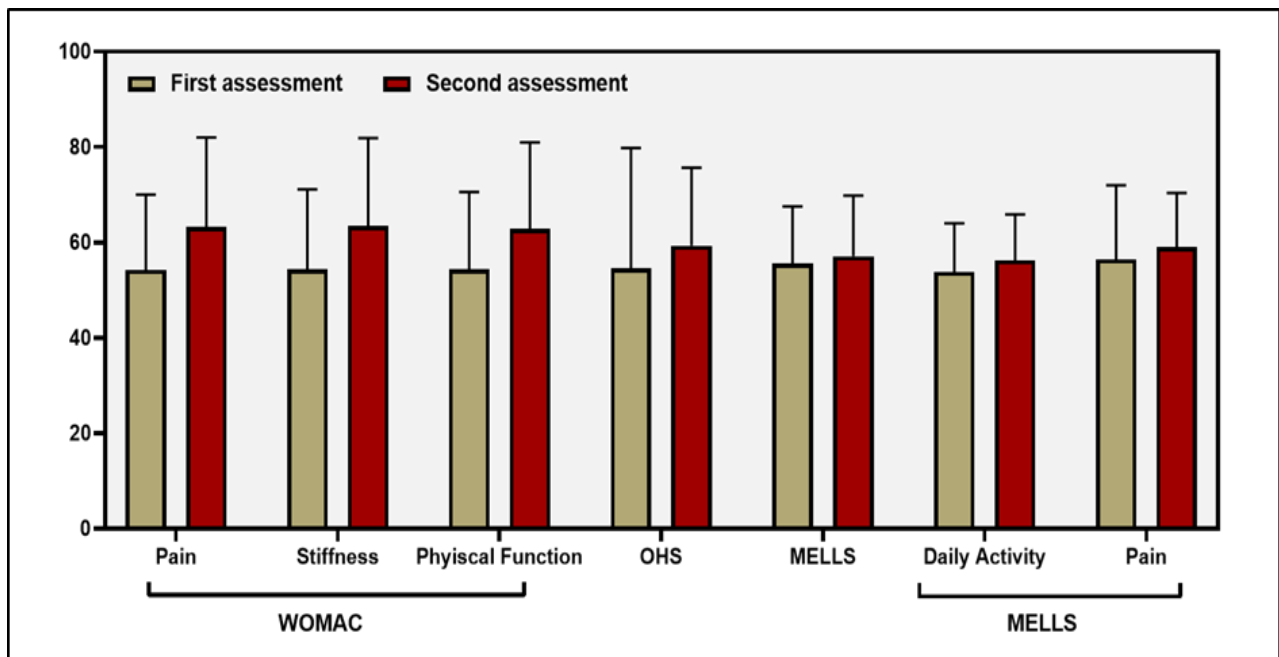
Note: <sup>1</sup>Sample size; <sup>2</sup>Minimum; <sup>3</sup>Maximum; <sup>4</sup>Standard deviation;

All of 110 patients that filled out the questionnaire in the first assessment, responded also to the second assessment after the initial evaluation.

**Table 2: Mean, standard Deviation, Change, ICC between different assessments of each subscale**

Questionnaires	Scores				Change	ICC (95% CI)
	First assessment		Second assessment			
	Mean	SD	Mean	SD		
<b>WOMAC</b>						
Pain	54.22	15.80	63.27	18.75	9.05	0.581 (0.234 - 0.760)
Stiffness	54.38	16.74	63.44	18.40	9.06	0.593 (0.230 - 0.772)
Physical Function	54.31	16.25	62.85	18.10	8.54	0.623 (0.262 - 0.793)
<b>Oxford Hip Score</b>	54.54	25.26	59.32	16.34	4.78	0.583 (0.357 - 0.730)
<b>Total MELLS</b>	55.52	12.01	57.11	12.68	1.58	0.866 (0.780 - 0.919)
Daily Activity	53.78	10.23	56.22	9.65	2.44	0.870 (0.790 - 0.950)
Pain	56.44	15.54	59.01	11.34	2.57	0.821 (0.701 - 0.941)

Test-retest reliability was performed using Intra-class Correlation (ICC). The results (Table 2) indicated that OHS has a moderate intra-class correlation with 0.583 (95% CI 0.357, 0.730). WOMAC subscales also showed moderate intra-class correlations from 0.581 to 0.623.



**Figure 1: Mean score along with their standard deviations during 2 different assessments for MELLS, OHS and for WOMAC questionnaires.**

As shown in Figure 1, all three questionnaires have resulted in similar patterns. However, WOMAC and OHS are visually proved to be more responsive to the changes of patient's conditions between each assessment.

**Validity of MELLS**

The results of Spearman's correlation in Table 3 indicate that MELLS subscales show moderate to high correlation with

To test the reliability of the instrument, Cronbach's alpha was obtained. For both assessments, an acceptable level of internal consistency was observed –  $\alpha_1 = 0.88$ ,  $\alpha_2 = 0.92$ .

One percent of patients showed a ceiling effect in the first assessment with no floor effect. In the second assessment, 2% of them showed floor effect, and there was a recorded floor effect of 5%.

subscale of WOMAC. In the first assessment, daily activity of MELLS has the highest correlation with WOMAC Physical function ( $r = 0.73$ ;  $p < 0.01$ ). Pain subscale of MELLS is also highly correlated with Pain of WOMAC ( $r = 0.72$ ;  $p < 0.01$ ). these correlations have slightly decreased during the second assessment but remained fairly high and significant. In the second assessment, however, the correlation between MELLS subscales and OHS slightly increased.

**Table 3: Construct validity of MELLs by calculating the Spearman’s Correlation between MELLs, WOMAC and OHS**

		WOMAC			OHS
		Pain	Stiffness	Physical function	
<b>MELLs</b>	<b>First Assessment</b>				
	Daily Activity	0.67**	0.70**	0.73**	0.61**
	Pain	0.72**	0.69**	0.65**	0.65**
	<b>Second Assessment</b>				
	Daily Activity	0.65**	0.65**	0.70**	0.62**
	Pain	0.70**	0.64**	0.60**	0.66**

*Note: \*\* Correlation is significant at the 0.01 level (2-tailed).*

**Responsiveness**

Effects are often used to give meaning to change over time in terms of ‘trivial’ (ES < 0.20), ‘small’ (ES ≥ 0.20 < 0.50), ‘moderate’ (ES ≥ 0.50 < 0.80) or ‘large’ (ES ≥ 0.80) change. Cohen introduced this ‘matched pairs’ effect size, which was later renamed the standardised response mean (SRM) by Liang et al [11]. According to responsiveness test, MELLs in general show lower responsiveness

than OHS and WOMAC. Pain subscale in WOMAC has a SRM of 0.482 (0.382, 0.582), while SRM of Pain in MELLs is 0.397 (0.297, 0.497). Both Stiffness and Physical function in WOMAC showed higher responsiveness than MELLs (Table4). In comparison to MELLs, OHS also showed better responsiveness with SRM = 0.423 (0.361, 0.485). This is important to note, however, that responsive change of all three questionnaires are very similar and the differences are not considerable.

**Table 5: Standardized Response Mean (SRM) for the WOMAC subscales and OHS and MELLs.**

Questionnaire	Subscales	SRM	95% CI*	
<b>WOMAC</b>	Pain	0.482	0.382	0.582
	Stiffness	0.465	0.415	0.515
	Physical Function	0.473	0.439	0.507
<b>OHS</b>		0.423	0.361	0.485
<b>MELLs</b>	Daily Activity	0.384	0.374	0.394
	Pain	0.397	0.297	0.497

\* Bootstrap confidence interval (1000 iterations; random number seed: 978).

**Discussion**

Patient reported outcome (PRO) scores are helpful tools in clinical practice. They provide valuable input from the patients’ perspective, helping the treating physician to assess the results of his or her treatment [12]. PRO scores are available in categories of upper or lower limb, or joint specific. The MELLs is a modification of the WOMAC Score and OHS, both of which are joint specific PRO’s [12-13]. The authors found it necessary to assess the impact the cultural activities that might inversely affect current gold standard treatment guidelines. This will enable clinicians to justify certain treatments that divert from the recommended norms.

After careful modification of a current PRO’s, the authors produced the MELLs to serve their population [14]. To further prove reliability and validity of the MELLs score, the psychometric properties were investigated and compared to other Lower Limb PRO’s that are available in the current literature like the original WOMAC and OHS, and their Arabic counterparts. As seen from the results of this study, the MELLs compares well compared to the Arabic versions of WOMAC and OHS in terms of construct and conduct validity and internal consistency [15-17]. The numbers are closely relatable. The ICC of the MELLs and 0.866 compared to the Arabic WOMAC subscales (0.581- 0.623) and OHS (0.583). The test-retest reliability of the MELLs was 0.88 and 0.92 respectively. This compares to WOMAC which were (0.96,0.95, 0.95) [8,18].

Similar results were seen in the Moroccan version of the WOMAC score with a Cronbach’s alpha for pain, stiffness, and physical function at 0.76, 0.76 and 0.9 respectively. The ICC for all

three subscales were 0.77-0.89 [12]. More recently in 2019, a Nepali version of the WOMAC was published with an ICC score > 0.75 in all domains. Cronbach’s alpha in this study was 0.852, 0.704, 0.95 for pain stiffness and physical function [13].

In brief, the MELLs serves as a utility in regions where the ADL’s require frequent squatting, kneeling, bending and sitting cross-legged on the floor.

**Limitations**

The MELLs is a newly modified PRO score with this being the first study using the MELLs. However, a pilot study was conducted to address any outlaying burden or feasibility issues faced by the patient in completing this questionnaire. In addition, although it was tested for patients with knee and hip complaints, the authors did not include patients with ankle/foot complaints.

**Conclusion**

The need for region-specific PRO scores is on the rise, as surgeons around the globe face similar diseases but in patients from different backgrounds and cultures. This has led to discrepancies in outcomes according to different regions. The MELLs is valid and reliable tool that can help clinicians in the region tailor their treatments more closely to suit patient’s needs.

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### **Conflict of Interest:**

None

### **Financial Decelerations**

None

### **Author Contribution**

Sager Hanna: Concept, study design, data analysis, initial draft write up.

Fahad AlKhalaf: Concept, study design, data analysis, final draft editing.

Awdhah AlSamhan: Data collection and literature review.

Hend AlHamdan: Data collection and analytics. 1<sup>st</sup> draft editing.

Bader AlAdwani: Data collection and analytics. 1<sup>st</sup> draft editing.

Aliaa Khaja: Study design, data analysis, final manuscript editing.

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