

# Test-retest reliability of the Arabic translation of the Lower Extremity Functional Status of the Orthotics and Prosthetics Users' Survey

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## Abstract

**Background:** The number of amputations secondary to diverse factors in Arabic countries is expected to rise in the coming years. Therefore, there is a need for high-quality service that can be monitored by the use of standardized patient-reported outcome measures of amputee patients' functional status. This study aimed to translate the Lower Extremity Functional status Orthotics and Prosthetics Users' Survey (OPUS-LEFS) to Arabic and test its reliability in a sample of Arabic-speaking people with amputation.

**Methods:** Standard forward and backward translation, followed by an examination by a team of experts, and then preliminary testing were conducted on the final translation. The OPUS-LEFS was cross-culturally validated, and its test-retest reliability was examined in patients with lower extremity amputations (N = 67).

**Results:** No issues were observed concerning the patients' understanding or the meaning of the items on the Arabic translation of the OPUS-LEFS. The intraclass correlation coefficient was 0.99 (95% confidence interval [CI]: 0.985 to 0.995), and the mean difference was -0.278 (95% CI: -5.83 to 5.28), indicating excellent test-retest reliability.

**Conclusions:** The study's results suggest that the Arabic translation of the OPUS-LEFS is a reliable tool that can be recommended for future use as an outcome measure for patients from Arabic-speaking nations with little knowledge of the English language.

## Keywords

patient-reported outcome, amputation, lower extremities, functional scale

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## Background

Amputation prevalence has sharply increased in the past 2 decades,<sup>1</sup> and the increase has mostly been attributed to peripheral artery disease and diabetes. Multiple Arabic countries are experiencing epidemic rates of diabetes.<sup>2,3</sup> In addition, in the Gulf countries, road traffic accidents are another significant risk factor for increased amputations.<sup>3,4</sup> Furthermore, Middle Eastern countries have been unstable war zones for more than 10 years, and casualties have increased. These factors predict a rise in amputations among Arabic-speaking populations in the future and highlight the need for a greater emphasis on the quality of care for patients with amputations and the satisfaction of prosthesis users.

Health outcomes are changes in patients' health, behavior, and satisfaction that can be attributed to the treatment they have

received. The measurement of the change in health outcome is fundamental to evaluate and monitor the treatment provided. Therefore, there is an urgent need to use standardized patient-reported outcome measures to assess amputee patients' functioning status and satisfaction.<sup>5</sup> The availability of such outcome measures is central for documenting successful treatment outcomes and providing value-based care. Several patient-reported outcome measures could be used in the patient's rehabilitation after amputation and prosthesis fitting.<sup>6</sup> One of the established measures in the orthotics field is the Orthotics and Prosthetics Users' Survey (OPUS), which assesses functional outcomes and satisfaction of both orthotics and prosthetics users.<sup>6,7</sup> The OPUS, which consists of five scales, each of which can be completed separately, is used to assess patients' upper extremity functional status, lower extremity functional status, health-related quality of life, and satisfaction with devices and services.<sup>7</sup> The survey have been translated and psychometrically tested in different languages.<sup>8-12</sup>

Test-retest reliability is concerned about the stability of test scores, and better reliability indicates more precision in individual measures and, as a result, a greater ability to recognize changes in test results.<sup>13</sup> Despite the increasing number of amputees in Arabic countries, the number of Arabic outcome measures with evidence of reliability is still limited,<sup>8,14</sup> and one study<sup>9</sup> was conducted using a sample with less than ten participants. A study by Bakhsh et al<sup>8</sup> examined the satisfaction component of the OPUS with only orthotic participants. Hence, there is a need for a reliable outcome measure in Arabic to assess and improve the care of the growing population of prosthetics users. Besides, in view of the data, a higher prevalence of lower extremity amputations is likely due to

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the risk factors mentioned earlier. Therefore, this study aimed to translate the Lower Extremity Functioning Scale of the OPUS (OPUS-LEFS) to Arabic and test its reliability in a sample of Arabic-speaking people with amputation. We expected the OPUS-LEFS to be culturally appropriate and to have good to excellent reliability (intraclass correlation coefficient [ICC] > 0.75) based on Jarl et al.<sup>15</sup>

## Methods

### Participants

All patients with lower limb amputations, regardless of the level, number, or etiology of the amputation, who presented to the amputation clinic of the outpatient department of the institution in which the study was conducted were invited to participate in the study after giving their written consent. All patients who did not speak and read Arabic or were unable to complete the questionnaire twice were excluded from the study. Ethical approval for the study was obtained from the institution in which the study was conducted (IRB: XXXX).

### Translation and back translation

After permission is granted from the developers to translate the OPUS-LEFS to the Arabic language. The translation process, which followed the guidelines suggested by Beaton et al<sup>15</sup> and Guillemin et al,<sup>16</sup> included six stages: the initial translation, synthesis of the translations by the independent translators, back translation, expert committee review, the test of the prefinal translation, and submission of documentation for appraisal.<sup>15</sup>

Two independent translators (one with experience in the health sciences) converted the original English instrument to Arabic. The study committee then evaluated the two translations to ensure they accounted for Arabic cultural differences and misunderstandings. The two translations of the instrument were then merged to create a new consensus translation (T1). Next, two other translators who were fluent English speakers and had not seen the original questionnaire translated the T1 translation back to English (T2). After inspecting the grammar, the study committee compared the two T2 variants with the original instrument, and a similar translation was consolidated in Arabic (T12).

### Cross-cultural validity

After consolidating the T12 translation of the OPUS-LEFS, a convenience sample of 18 patients with lower extremity amputations were invited to answer questions on the translated outcome measure and provide a qualitative assessment by suggesting modifications as needed to ensure the text was understandable. Their responses were collected, reflecting all modifications to the outcome measure, and reported to the same expert committee. Furthermore, the responses collected from participants in the cross-cultural validity step were not included in the reliability testing.

### Reliability

The test–retest reliability was assessed by administering the OPUS-LEFS twice to the patients; the first administration was during the

initial appointment after they consented to participate. Participants were provided with the outcome measure to fill-in in a paper and pencil format. On this occasion, the assessor obtained basic demographic data (age, sex, occupation, date of amputation, and diagnosis). The second measurement was taken 5 to 7 days after the initial appointment to eliminate the recall bias. The second measurement was obtained by phone by one of the research team.

### Outcome measure

The OPUS-LEFS is structured to evaluate patients' perceptions of their functioning after various lower extremity injuries. It is a patient-administered questionnaire consisting of 20 items that inquire about specific activities involving the lower extremities. Each item is scored using a 5-point ordinal scale ranging from extremely difficult or unable to perform the task to no difficulty in performing the task. All items summed to provide a total score out of a possible score of 80, with higher scores indicating higher levels of lower extremity function. This outcome measure requires less than 2 minutes to complete and less than 20 seconds to score. A study that examined the measurement properties of the original OPUS-LEFS showed a good internal consistency (Cronbach alpha = 0.88)<sup>7</sup> in a sample of patients with lower limb amputations.

### Data analysis

The ICC (two-way mixed-effects model, absolute-agreement) was used to estimate the test–retest reliability of the OPUS-LEFS. An ICC of 0.70 is considered acceptable for a group-level analysis, and an ICC of 0.90 is recommended for evaluations of individual participants.<sup>17</sup> Differences between the two measurements were plotted against the means of the two scores using Bland–Altman plots with a 95% confidence interval (CI) for the limits of agreement.<sup>17</sup> Beta coefficients of the linear regression were used to determine the difference between the two tests of the independent and dependent variables.<sup>13</sup> At least 50 participants were needed to examine the reliability according to Terwee et al.<sup>18</sup>

We also calculated the standard error of measurement and the minimal detectable change.

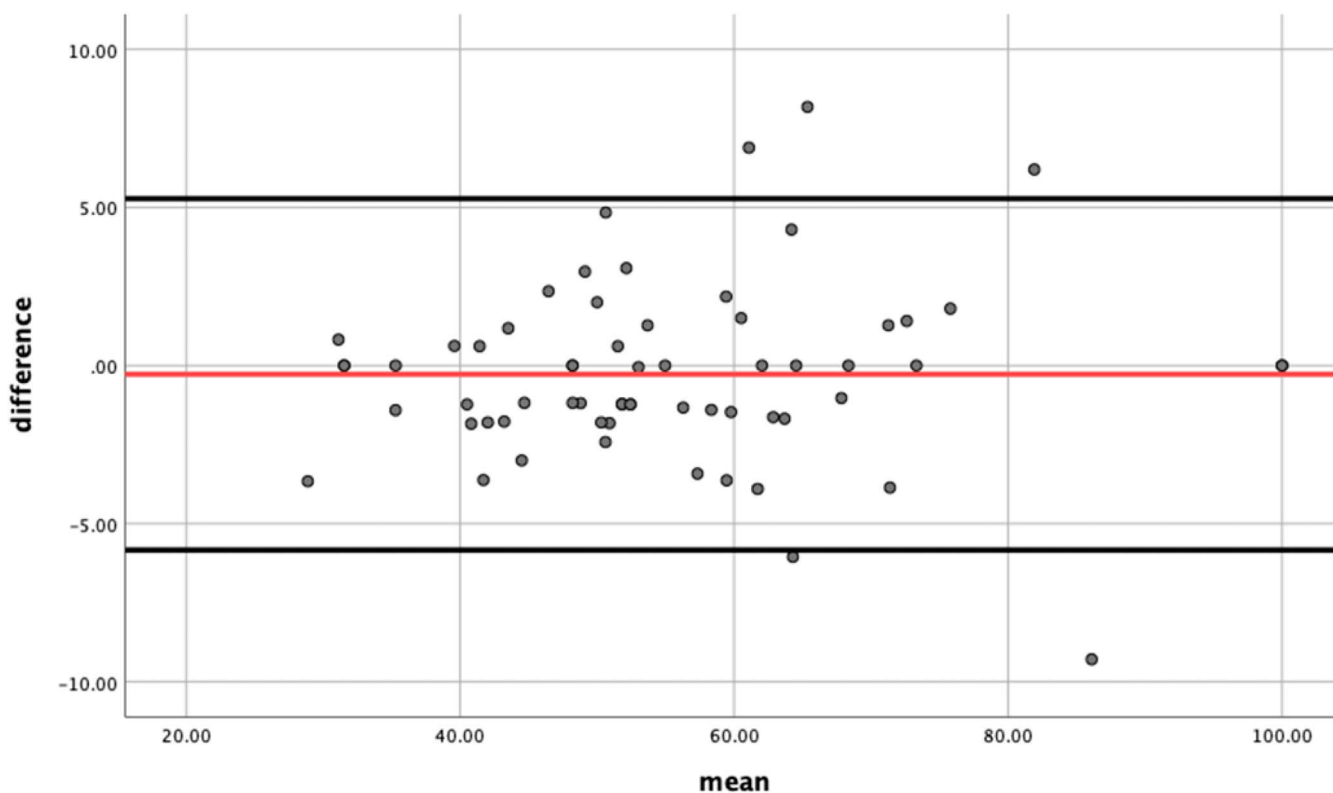
## Results

### Cross-cultural adaptation

The final Arabic translation of the OPUS-LEFS was distributed to 18 lower limb amputee patients (12 males and six females; mean age = 43 years). Among this sample, 10 patients with below-knee amputation, seven with above-knee amputation, and one with partial foot amputation. The selected sample represents more than 25% of the whole participants. All participants were able to answer the outcome measures items; no difficulties understanding the meaning of any of the items were reported.

### Reliability

A total of 63 patients (8% females) completed the OPUS-LEFS at baseline and a second time within 5 to 7 days. The sample included 33 patients (52.4%) with below-the-knee amputations, 23 patients (36.5%) with above-the-knee amputations, and seven patients



**Figure 1.** Bland–Altman plot for the Lower Extremity Functional Scale, with the 95% limits of agreement (the x-axis = the mean of the first and second scores; the y-axis = the difference between the two scores; the horizontal lines indicate the higher and lower 95% agreement limits).

(11.1%) with other kinds of amputations. The average age was 43.7 (SD = 21.4) years.

The ICC was 0.99 (95% CI: 0.985 to 0.995), and the mean difference was  $-0.278$  (95% CI:  $-5.83$  to  $5.28$ ). The standard error of measurement of the OPUS-LEFS was 1.49, and the minimal detectable change was 4.138. Figure 1 presents a Bland–Altman plot of the differences between the two measurements. The beta coefficient of the linear regression, in which the mean of the two tests was the independent variable and the difference between the two tests was the dependent variable, was 0.01 (95% CI:  $-0.038$  to  $0.060$ ).

## Discussion

This study aimed to translate the English survey of the OPUS-LEFS to the Arabic language and examine the test–retest reliability of the translated survey. The results of this study support the reliability and cross-cultural validity of the Arabic translation of the OPUS-LEFS for clinical and research use.

The OPUS is one of the tools used in orthotics and prosthetics programs to ensure quality assessments.<sup>9,10</sup> The OPUS can also be used to assess satisfaction with prosthetic devices and evaluate patients' functional status. This study's results support the reliability of the OPUS-LEFS. The ICCs were above 0.90 (95% CI: 0.985 to 0.995), showing that the LEFS has excellent reliability.

In a similar study by Jarl et al<sup>9</sup> investigating the test–retest reliability of the translated LEFS to Swedish, 18 patients completed the OPUS-LEFS twice. The ICC was 0.96 with no systematic differences between the two measurement occasions. Although

there are multiple translations of the original OPUS, most related studies have been concerned with satisfaction scales.<sup>8,10–12</sup> For instance, a study by Hadadi et al<sup>10</sup> included only users of lower limb prostheses, which may have contributed to different day-to-day variability in the results due to phantom limb pain, skin abrasions, and various other factors. Furthermore, using a more homogenous sample in this research may have resulted in lower between-subject variance. One of the outcomes of these homogenous samples was lower ICCs because the ICC is based on the ratio of the subject variance to the total (subject + error) variance.

This study's cross-cultural validation of the Arabic translation of the OPUS-LEFS provides clinicians and researchers in Arabic-speaking countries with a reliable instrument to measure a relevant health-related domain in patients with amputations. Using the OPUS-LEFS, clinicians will be able to construct a baseline of activity limitations for their patients by comparing the degree of change in the OPUS-LEFS with the minimum observable change value to detect improved physical function as a result of the activity. In addition, researchers may use the OPUS-LEFS of the OPUS to determine activity limitations at a particular time point, monitor changes in activity limitations over time, and examine changes in activity limitations after treatments administered in clinical trials.

In this study, the OPUS-LEFS were translated into classical Arabic rather than any of the local Arabic dialects to increase the likelihood of its use by all Arabic-speaking countries, where all Arabic speakers understand classical Arabic, rather than the unfamiliar regional dialects of other Arabic countries. More than 25 nations use Arabic as their primary language. However,

different dialects exist inside these nations that are incomprehensible to most Arabic-speaking people worldwide. As a result, it should be emphasized that the translated OPUS-LEFS was recorded using a classic Arabic script, which is understandable by all Arabic speakers. Moreover, this script will promote the usage of the OPUS-LEFS in Arabic-speaking nations. Furthermore, the script language is an added benefit to get a better grasp of the meaning, given that all participants must read and comprehend the meaning before filling out the survey.

This study has limitations. First, it relied on convenience sampling of the population. Hence, the number of participants using various specific devices that were crucial for this study was small. This limitation could have significantly affected the ability to generalize the research findings. Furthermore, an additional limitation of the generalizability of the results is that the process is conducted in one country; however, the use of classical Arabic script, which is understood by most Arabic-speaking countries, is a strength point of the article. Second, although several types of devices were represented in the sample population, all of the respondents to the OPUS-LEFS were prosthetics users.

## Conclusion

This assessment of the psychometric properties of the Arabic translation of the LEFS of the OPUS revealed acceptable cross-cultural validity and test-retest reliability. This study found that the Arabic translation of the OPUS-LEFS is a reliable tool that can be recommended for future studies using patients from Arabic-speaking nations with little knowledge of the English language.

## Author contributions

All authors have contributed equally to writing the study's protocol and obtaining ethical approval. A.A. and F.A. were involved in the data collection. All authors contributed equally to the data analysis and interpretation, and all of them read and approved the final manuscript.

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## Declaration of conflicting interest

The authors disclosed no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.


## Availability of data and materials


The data sets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.


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