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ORIGINAL RESEARCH

Cross-Cultural Validity and Differential Item Functioning of the Orthotics and Prosthetics Users' Survey With Swedish and United States Users of Lower-Limb Prosthesis

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Abstract

Objectives: To investigate the cross-cultural validity of the Orthotics and Prosthetics Users' Survey (OPUS), to evaluate differential item functioning (DIF) related to country, sex, age, amputation level, and amputated side (unilateral, bilateral), and to determine known-group validity of the OPUS.

Design: Survey.

Setting: Outpatient clinics.

Participants: The sample (N = 321) consisted of Swedish (n = 195) and U.S. (n = 126) adults using lower-limb prostheses.

Interventions: Not applicable.

Main Outcome Measures: Four OPUS modules were used: lower extremity functional status, client satisfaction with device (CSD), client satisfaction with services (CSS), and health-related quality of life. Rasch analysis was used to calculate measures for persons and items.

Results: The cross-cultural validity was satisfactory. Many items demonstrated DIF related to country and demographic characteristics, but the impact on mean person measures was negligible. The rating scales of CSD and CSS needed adjustments, and the unidimensionality of CSD and CSS was weak. The differences between the mean measures of known patient groups were statistically significant for 2 out of 6 comparisons.

Conclusions: This study supports the validity of OPUS measure comparisons between Sweden and the United States and between subgroups with different demographic characteristics. Some of the country-related DIF may reflect the different health care financing systems. The findings demonstrate that the OPUS can discriminate between certain patient groups. The results also challenge some of our preconceptions about persons with bilateral amputation, indicating that we might know these persons less well than we think.

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Lower-limb amputation can result in significant physical, mental, and social consequences.[1,2] Rehabilitation of patients with lower-limb amputations should consider not only physical functioning and prosthetic fitting but also factors such as quality of life and prosthesis satisfaction. High-quality instruments that cover these areas are needed to evaluate rehabilitation outcomes, and this means that the instruments need to be validated for the patient population and need to function invariantly for different patient groups to allow for valid comparisons.[3] The Orthotics and Prosthetics Users' Survey (OPUS) was developed in the United States to assess rehabilitation outcomes of prosthetic and orthotic interventions,[4] and it has been translated and validated in Slovenia,[5] Italy,[6] and Sweden.[7,8] However, no study has investigated the cross-cultural validity of the OPUS (ie, if person measures from different countries are comparable). Cross-cultural equivalence is important when conducting international studies and when comparing clinical results between countries.

Previous studies of the OPUS have investigated unidimensionality, rating scale functioning, and reliability.[4,5,7,9,10] However, the rating

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scales have not been evaluated with U.S. subjects, the dimensionality needs further evaluation, and the issue of measurement invariance across groups has been given only limited attention.[7] Measurement invariance requires that the item measures are stable across different groups; invariance can be investigated by analysis of differential item functioning (DIF). In the presence of DIF, some factor confounds the person-item interaction such that the probability of a particular response depends on factors such as country, sex, age, or type of amputation in addition to the underlying trait. We can almost always find some magnitude of DIF if the sample is large enough; therefore, the question is not if DIF exists but if it is large enough to matter.[11] The impact of DIF can be investigated by differential test functioning (DTF), which is the extent to which different groups get different measures based on the instrument as a whole as a consequence of item DIF. Some OPUS items demonstrated DIF in a previous study, but no substantial DTF was found.[7] Still, the sample used in that study was heterogeneous and smaller than recommended for DIF analysis,[12] and only DIF related to sex and age was investigated. There is also a need to investigate DIF and DTF related to amputation level and amputated side because the presence of DIF and DTF could confound measurements of satisfaction, function, and quality of life.

In addition, an instrument should discriminate between groups known to be different, so-called known-group validity.[13] For the OPUS, this has only been investigated for upper-limb prosthesis users,[5] and there is a need for studies of lower-limb prosthesis users. The aim of this study was to investigate the cross-cultural validity of the OPUS; the DIF and DTF related to country, sex, age, amputation level, and amputated side (unilateral, bilateral); and the validity evidence based on differences between known groups.

Methods

Study design

This study had a cross-sectional survey design where each participant completed the OPUS on a single occasion.

Participants

In total, 321 subjects (195 from Sweden, 126 from the United States) participated in the study (table 1). In both samples the average age was high and most of the participants were men. Most subjects had a unilateral, distal amputation.

Procedures

During January and February 2013, study information, consent form, and the OPUS modules were sent to the residence of lower-limb prosthesis users who were patients at 2 outpatient prosthetics and orthotics clinics in Sweden. A reminder was sent if no response was received within 4 weeks. In the United States, participants were recruited from 7 outpatient prosthetics and orthotics clinics as part of a quality improvement research project between September 2009 and August 2013. Patients completed the OPUS modules 2 months after delivery of a new prosthesis or a new socket, either during an appointment at the clinic or at home. The patients mailed the modules to the clinic or returned the modules at subsequent appointments. Subjects were included if they were ≥18 years old. Exclusion criteria were osseointegrated prosthesis (in Sweden only) and the inability to answer the questionnaires because of insufficient language skills, dementia, or blindness.

The Regional Ethics Committee Review Board of Uppsala approved the data collection in Sweden, and the subjects gave their informed consent to participate. The Institutional Review Board of Northwestern University in Chicago approved the data collection in the United States and a waiver of consent for patients because completing the OPUS was deemed to pose no greater than minimal risk and because the data were deidentified and contained no confidential health information.

Outcome measures

The OPUS consists of 5 patient-reported modules, and 4 were used in this study, including lower extremity functional status (20 items), client satisfaction with device (CSD) (11 items), client satisfaction with services (CSS) (10 items), and health-related quality of life (HRQOL) (23 items) (see appendices 1–5 for details).[4] The HRQOL module comprises 2 parts, where the first part (12 items) measures the experience of being restricted and the second part (11 items) measures emotional status. The lower extremity functional status and HRQOL items are answered on 5-point rating scales. In the Swedish CSD and CSS modules, the original 4-point rating scales were used.[4] In this study, a fifth response category (neither agree nor disagree) was added to the U.S. CSD and CSS modules. Not applicable has

Table 1 Characteristics of the participants in the study

Characteristic	Swedish Sample (n=195)	U.S. Sample (n=126)	P*
Sex			
Male	135 (69.2)	68 (54.0)	.188
Female	60 (30.8)	42 (33.3)	
Missing	0 (0.0)	16 (12.7)	
Age			
<65y	82 (42.1)	79 (62.7)	<.001†
≥65y	113 (57.9)	43 (34.1)	
Missing	0 (0.0)	4 (3.2)	
Mean ± SD	65.7±15.8	58.3±16.2	.001†
Amputation level			
Knee disarticulation and proximal	71 (36.4)	37 (29.4)	.202
Transtibial and distal	119 (61.0)	85 (67.5)	
Missing/not classifiable	5 (2.6)	4 (3.2)	
Amputation side			
Unilateral	165 (84.6)	102 (81.0)	.573
Bilateral	27 (13.8)	20 (15.9)	
Missing	3 (1.5)	4 (3.2)	

NOTE. Values are n (%) or as otherwise indicated. Missing data were not included in the statistical tests.

* Two-sided chi-square tests were used to compare proportions, and a 2-sided *t* test was used to compare mean ages.

† $P<.05$.

List of abbreviations:

CSD client satisfaction with device
CSS client satisfaction with services
DIF differential item functioning
DTF differential test functioning
HRQOL health-related quality of life
MnSq mean square
OPUS Orthotics and Prosthetics Users' Survey
PCA principal component analysis