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Original article

Cross-cultural adaptation and Rasch validation of the Slovene version of the Orthotics and Prosthetics Users' Survey (OPUS) Client Satisfaction with Device (CSD) in upper-limb prosthesis users

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ABSTRACT

Objective: To validate the Slovene version of the Orthotics and Prosthetics Users' Survey (OPUS) 8-item Client Satisfaction with Device (CSD) questionnaire in upper-limb prosthesis users and to further verify measurement properties of this tool with Rasch analysis.
Design: Participants consisted of a convenience sample of 76 adults (54 men) using a prosthesis after unilateral upper-limb amputation who consecutively attended a follow-up visit at our centre.
Methods: After translation and cross-cultural adaptation of the CSD into the Slovene language, we evaluated functioning of the rating scale categories, item fit (internal construct validity), reliability indices and dimensionality, as well as convergent and discriminant construct validity of the questionnaire.
Results: Rasch analysis indicated that: (1) functioning of the 4 response options was acceptable; (2) all items fitted the measured construct [information-weighted (infit) and outlier-sensitive (outfit) mean-square statistics 0.60 to 1.40]; (3) person separation reliability was 0.62 (and Cronbach $\alpha = 0.76$), item separation reliability was 0.83; (4) on principal component analysis (PCA) on the standardised residuals, the CSD showed borderline but acceptable unidimensionality and no local item dependency. Moreover, as expected, the CSD score showed good correlation with the QUEST 2.0 score ($r_s = 0.57$) and little to fair correlation with the OPUS Upper Extremity Functional Status score ($r_s = 0.21$).
Conclusion: The metric properties of the Slovene version of CSD agree with previous studies. The present study confirms the validity of CSD for measuring patient satisfaction with an upper-limb device, enhances the confidence in this tool for assessing upper-limb prosthesis users, and contributes to further refining the technical quality of this measure.

1. Introduction

NiMhurchadha et al. [1] defined a successful rehabilitation outcome in people with upper-limb loss as being one in which the person uses their prosthesis as often as they wish and as it is intended to be used. Deciding not to wear a prosthesis or wearing a passive prosthesis only are not considered a successful outcome of rehabilitation. Different studies have reported different proportions of people who rejected or did not wear their upper-limb prosthesis. In a review of the literature, Biddis at al. reported rates of rejection in adult populations as 26% for body-powered prostheses and 23% for electric prosthesis; the average incidence of non-wear was 20% [2]. Among important factors for prosthesis abandonment is also the user's satisfaction with all aspects of the prosthesis design, including appearance, comfort, function, ease of control, reliability and cost [3].

To our knowledge, the only outcome measure specifically developed to measure user satisfaction with a prosthesis or orthosis is the Client Satisfaction with Device (CSD) module [4,5],

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part of a set of clinical outcome measures known as the Orthotics and Prosthetics Users' Survey (OPUS), which was developed in 2003 to assess relevant aspects of users' perspectives on function, quality of life and satisfaction in terms of their orthosis or prosthesis. OPUS consists of 5 independent patient-reported modules: in addition to the CSD, the other 4 modules assess upper-extremity functional status (UEFS), lower-extremity functional status, client satisfaction with services, and health-related quality of life.

The original 5 questionnaires have undergone refinement [6]. From a psychometric viewpoint, the best modified version of CSD is considered the one with a 4-point rating scale and 8 items [6–8]. Over the years, 3 original items have been deleted: in 2012, one item "My clothes are free of wear and tear from my device" was considered to be misfitting [6], and in 2015, the other 2 items, related to economic issues with the prosthesis/orthosis, were considered to belong to another dimension [9]. When the 11-item version of the CSD is administered, the scores of these 3 misfitting items should not be combined with the score of the 8-item scale to obtain a total measure but should be used independently, as relevant for assessing client compliance and health care policy issues.

The OPUS has been translated into several different languages; so far, the CSD module has been validated in the United States [4,6,9,10], Sweden [6,9,11,12], Italy [7] and Saudi Arabia [8].

Resnik and Borgia validated the original version of CSD in lower-limb amputees [10], and Jarl et al. [6] refined the CSD in a mixed population of 197 persons with prostheses, orthoses, shoe insoles and orthopaedic shoes (60 were users of an upper-limb prosthesis), and later Bravini et al. [7] and Bakhsh et al. [8] examined the modified 8-item version in orthosis users only. Finally, a cross-cultural validation study involved Swedish and United States users of a lower-limb prosthesis [9].

Most of these validation procedures involved using modern psychometric models such as Rasch analysis (RA), a sophisticated statistical technique able to test to what degree the scale complies with a wide range of psychometric requirements of measurement (in terms of response format, item content, appropriate targeting, etc.) that cannot be analysed by classical test theory (CTT) alone [13,14]. In Slovenia, no validated version of any measure assessing user satisfaction with a prosthesis is currently available. Furthermore, a detailed psychometric analysis of the actual performance of the modified OPUS CSD [6] in people with upper-limb prosthesis is lacking.

Thus, considering the importance of collecting patient-reported outcomes in the prosthetics/orthotics field with validated measurement tools, we aimed to validate, using Rasch analysis, the Slovene version of the modified 8-item OPUS CSD [6] in upper-limb prosthesis users and further verify the measurement properties of the scale, to ensure a more confident use of the scale in clinical practice and research.

2. Methods

2.1. Participants

This monocentric prospective study involved a convenience sample of adults who in 2014 consecutively attended a follow-up visit at our outpatient clinic for rehabilitation after unilateral upper-limb amputation and prosthetics follow-up. We included all individuals who were $>$ 18 years old and able to fluently read and write Slovene, had unilateral upper-limb amputation at the wrist or above, and had been using a prosthesis for at least 1 year. An exclusion criterion was the inability to fully understand and appropriately complete the questionnaire (e.g., cognitive/language impairment; or non-native Slovene-speakers); assistance with questionnaire completion from a relative or friend was allowed.

Our local ethics committee approved the study. All patients provided their written consent prior to enrolment.

2.2. Procedure

2.2.1. Translation and cross-cultural adaptation of CSD into the Slovene language

Translation and adaptation consisted of several steps, in accordance with international guidelines [15]. First, the original version was translated into Slovene by the first author (HB), a native Slovene-speaking and fluent in English. Then, a group of 4 local professionals working in the rehabilitation field (including MM and DB), fluent in English and expert in the methodological and/or clinical areas, revised the text. Following this, a native English-speaker without a medical background and without prior knowledge of the objectives or specific context of the study independently translated the consensus version back into English, so that we could check potential inconsistencies with the original English version. On the basis of these versions, an expert committee consisting of all persons involved in the translation procedure reviewed and consolidated a prefinal version of the CSD, discussing phrasing and contents and striving to select terms that captured the connotative meanings of the source text and also reflected everyday spoken ("layman's") language. This version was then tested with 9 subjects (of different age, sex, and socioeconomic and clinical background), who were asked by an experienced interviewer (cognitive debriefing) about the intelligibility, appropriateness, cultural relevance and potential ambiguity of the questionnaire. Finally, because no particular concerns emerged from the prefinal version testing, this version was accepted as the definitive version of the CSD in Slovene language. A copy of the questionnaire was sent to the original author of the OPUS for approval and is available in the Appendix and on request from the corresponding author.

2.2.2. Outcome measures

For the psychometric validation of the CSD according to classical test theory methods, participants were asked to complete the following on the same day:

- the modified OPUS CSD questionnaire [6]. The questionnaire has 8 questions. Responses were rated on a 4-level Likert scale: 1, strongly disagree; 2, disagree; 3, agree; 4, strongly agree. Thus, higher scores indicated higher agreement/satisfaction;
- the OPUS UEFS [4], which asks patients to evaluate the ease of performing 23 self-care and instrumental activities of daily living. The framing question was "Please indicate how easily you perform the following activities". Subjects responded on a 5-point scale, from 0, cannot perform activity to 4, very easy;
- the 8-item subscale of the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0_Device) [16], a generic outcome measure designed to evaluate patients' satisfaction with their assistive technology device.

2.3. Statistical analysis

Internal consistency of the Slovene CSD was determined by calculating the following [17,18]:

- the Cronbach α; the closer to 1, the higher the internal consistency of the items in the scale. Cronbach α values $>$ 0.70 are recommended for group-level comparisons,

and a minimum of 0.85 to 0.90 is desirable for individual judgments;
- item-rest correlation (i.e. to what degree each item is correlated with the total score, omitting that item from the total) by Spearman's rank correlation: values > 0.30 are considered satisfactory;
- inter-item correlations: values < 0.15 to 0.20 indicate that the items are not measuring the same construct very well (if at all) and correlations > 0.70 indicate that the 2 items are so similar that they are redundant.

Both convergent and discriminant construct validity were examined by assessing the extent to which Spearman correlations (r_s) between the CSD score and validating variables were consistent with expectations. Because of no "gold standard" in this area, we hypothesized that we would find a moderate to good correlation (r_s = 0.50 to 0.75) with the QUEST 2.0_Device score (convergent validity) and only little to fair correlation (r_s < 0.30) with the OPUS UEFS score (discriminant validity).

Raw data underwent Rasch analysis (Winsteps software v3.68.3) with the rating scale model (due to the items' Likert response structure). We began by investigating the rating scale properties of the CSD. We evaluated the response categories using criteria suggested by Linacre [19]. Next, we examined the internal construct validity by evaluating the fit of individual items to the latent trait. Information-weighted (infit) and outlier-sensitive (outfit) mean-square statistics (MnSq) for each item were calculated (similar to a chi-square analysis) to test whether items fit the model expectations. In accordance with the literature [19], we defined an acceptable fit as mean-square values from 0.6 to 1.4. Items with larger values were considered misfitting, and items with smaller values were considered overfitting [20].

Reliability was evaluated in terms of "separation" (G), defined as the ratio of the true spread of the measures to their measurement error [19,20]. The item separation index gives an estimate (in standard error units) of the spread or "separation" of the items along the measurement construct; the person separation index gives an estimate of the spread or separation of persons along the measurement construct. This index allows for calculating the number of "strata" of measures that are statistically discernible (e.g., a separation of 2.0 is considered good because it allows for distinguishing 3 strata). A related index is the reliability of these separation indices, providing the degree of confidence one has in the consistency of the estimates (range 0 to 1; coefficients > 0.80 are considered good, > 0.90 excellent) [20].

Finally, principal component analysis (PCA) of the standardized residuals was performed to verify that the standardized residuals are uncorrelated. This analysis provides a further confirmation of the unidimensionality of the scale. Correlation of standardized residuals was used to test the local independence of each item pair (a high correlation of residuals for 2 items indicates that they may not be locally independent, because they duplicate some feature of each other or because they both incorporate some other shared dimension) [19].

3. Results

A flowchart of the enrolment of participants is in Fig. 1. The main clinical and demographic characteristics of our sample (n = 76) are in the Table 1.

The median raw score for the Slovene CSD was 12 (Q1–Q3: 10–16). Four missing responses (different items in 4 different strings) were replaced with the median score of the items completed.

The Cronbach α was 0.76, which indicates acceptable internal consistency. The analysis of the Cronbach α with omitted items suggested that the removal of any item would result in a significantly lower Cronbach α. The item-rest correlation values (r_s) ranged from 0.32 (item 5 "looks good") to 0.66 (item 3 "comfortable throughout the day"). The inter-item correlations ranged from 0.20 to 0.60, except for those of item 5 that were in 2 cases 0.10 to 0.15.

Consistent with expectations, correlations of the CSD score with the QUEST 2.0_Device and OPUS UEFS scores were r_s = 0.57 and r_s = 0.21.

Rasch analysis indicated that the functioning of the 4 response options in CSD was acceptable.

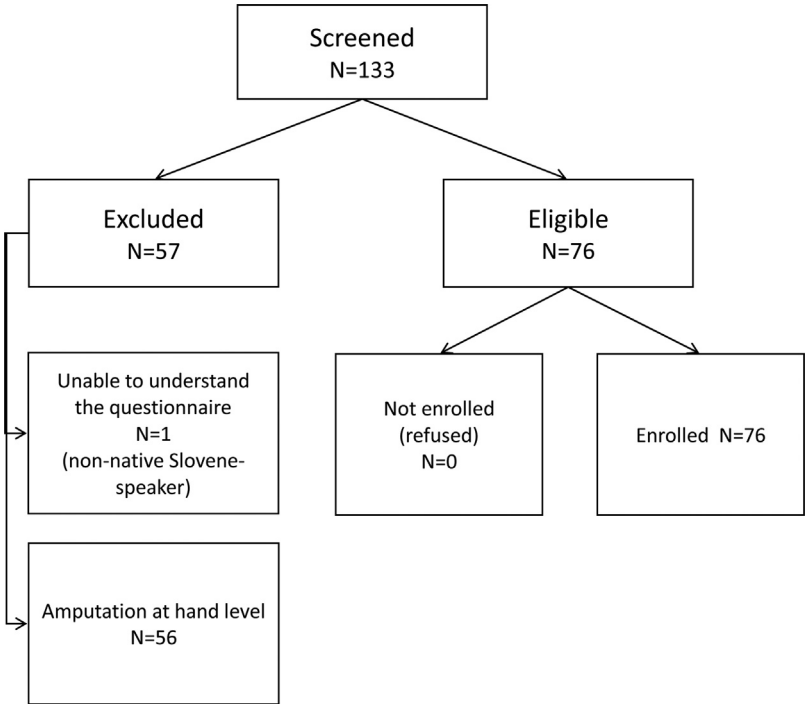

Fig. 1. Flowchart of enrolment procedure.

Table 1
Main clinical and demographic characteristics of the study participants ($n = 76$).

Age, years, mean (SD)	51 (18)
Sex (male: M), *n* (%)	54 (71)
Time since amputation, years, mean (SD)	30 (17)
Level of amputation	
Wrist disarticulation, *n* (%)	5 (7)
Trans-radial, *n* (%)	55 (72)
Elbow disarticulation, *n* (%)	2 (3)
Trans-humeral, *n* (%)	11 (14)
Shoulder disarticulation, *n* (%)	3 (4)
Cause of amputation	
Injury, *n* (%)	55 (73)
Congenital, *n* (%)	19 (25)
Tumour, *n* (%)	1 (1)
Other, *n* (%)	1 (1)
Type of prosthesis	
Passive, *n* (%)	55 (73)
Passive for work, *n* (%)	4 (5)
Body-powered, *n* (%)	10 (13)
Myoelectric, *n* (%)	7 (9)

Item fit statistics showed that all items fitted the measured construct (Infit and Outfit MnSq 0.60 to 1.40). The PCA on the standardised residuals showed (1) a borderline but acceptable unidimensionality — variance explained by the Rasch factor = 40%; Eigen value of the first contrast = 1.7 (unexplained variance 12.8%) — and (2) all between-item residual correlations lower than +0.3, thus denoting the absence of local dependency in the item set. In addition, the CSD presented a fairly poor targeting of item difficulty to patient ability (i.e., the extent to which the items were of appropriate difficulty for the mean level of satisfaction of the sample), with mean person ability = −1.39 logits (range −4.58 to 1.52). Fig. 2 shows the Wright map [i.e., the location of the "ability" (satisfaction) for each individual in our sample and the difficulty of the 8 items of the questionnaire, on the same logit scale]. The reliability indices were quite low: person separation reliability = 0.62 and item separation reliability = 0.83. Such a person separation value allowed for distinguishing 2 different ability strata.

4. Discussion

This study validated the Slovene version of the 8-item OPUS CSD [6], demonstrating several positive psychometric characteristics of the instrument, including its acceptable internal construct validity.

This is the first study conducted with the CSD to assess users' satisfaction with a prosthesis in people with upper-limb prosthesis only. Previous studies using CSD have involved users of a mix of assistive devices (prosthesis, orthosis, shoe insoles or orthopaedic shoes) [6,11,12,21] in lower-limb prosthesis users [9], and orthotic-users with orthopaedic, neurological and rheumatic conditions [7,8]. This feature may explain some (minor) discrepancies in the different CSD validation studies; however, it is crucial to check that the main psychometric properties of the CSD are confirmed in each of the medical conditions it was developed to assess, this tool having been designed to be widely applicable across different contexts, pathologies and devices.

In a time of increasing use of outcome measures in clinical practice, for quality control and audit procedures, the psychometric properties of assessment measures require an extensive testing procedure. Rasch methods provide in-depth psychometric information on basic measurement properties that cannot be obtained by Classical Test Theory methods [14,17,20], such as the appropriateness of the rating scale categories, the evaluation of how well an item performs in terms of its usefulness for measuring the underlying construct, the amount of the construct targeted by each question, and the possible redundancy of an item relative to other items in the scale, etc.

In our study, Rasch analysis demonstrated correct functioning of the rating categories of the scale. All items fitted the underlying construct (satisfaction with device) that the scale intends to measure, and no item was found redundant or locally dependent, thus confirming that the set of selected items is adequate [4].

The reliability values we found for CSD compare well with those of previous studies calculated using both Classical Test Theory methods and Rasch analysis (e.g., the internal consistency of CSD, measured by the Cronbach α, was 0.76 in our sample, in line with Jarl et al. (0.75) [6], Bravini et al. (0.73) [7], and Bakhsh et al. (0.83) [8]. Overall, these values show that:

- the instrument is useful for group decisions about patient satisfaction but not for clinical application in single individuals, for whom a minimum reliability threshold of 0.90 is desirable [17];
- the 2 statistically discernible ability "strata" provide a clear distinction between satisfied and unsatisfied persons (but do not permit a more fine-grained assessment of satisfaction levels).

In addition, the somewhat weak reliability levels found in present and previous papers [6–9,12] (and their correlation with precision/accuracy in measuring change) indicate that both sensitivity to change and responsiveness of the CSD, although not yet examined, will tend to be poor [18].

Moreover, our results confirmed some points that warrant discussion.

First, the unidimensionality of the CSD agrees with previous results [6–8]: it was not high but without significant residual loadings on extraneous factors (unexplained variance < 15% with Eigen value units of the first contrast < 2) [19,20,22–24]. In comparing our results with those of Jarl et al. [6], in both studies, the contrast seems between comfort (the main factor) and look/durability (items 5 and 6, respectively). In particular, the item "My prosthesis/orthosis looks good" is the one showing the lowest inter-item and item-to-rest correlations (i.e., it is the item farthest from the common latent construct being measured). The "look" of the upper-limb prosthesis is really not related to weight, comfort, ease of donning/doffing but is mainly related to the shape of the prosthetic hand and type of glove used. Second, the targeting of item difficulty to patient ability (i.e., the extent to which the items are appropriately difficult for the sample) was quite poor (Fig. 1): as compared with the mean value of 0 logits routinely assigned for items, the average satisfaction level of this sample (−1.39 logits) was considerably higher than the difficulty levels of these items. From a clinical point of view, this poor targeting is quite reasonable: patient satisfaction for individuals who actually use prosthetic limbs can be quite high [25], even though exceptions have often been reported [2,26,27]. Nevertheless, poor targeting means a relative lack of items analysing in detail the higher levels of satisfaction with the device (e.g., questions on satisfaction about device functionality or ease of use); further studies are needed to test whether a few well-selected additional items would be able to improve coverage of the construct (internal validity) and technical quality of the tool (also in terms of reliability). In addition, mistargeting also negatively affected the person separation reliability (i.e., the ability of the questionnaire to distinguish distinct strata of person satisfaction). Hence, the questionnaire is just able to distinguish 2 levels of satisfaction with the device: low versus high [19,20]. Finally, the item hierarchy was somewhat inconsistent with that found in previous studies on different prosthetic and orthotic users, in which this lack of a stable difficulty of each item was already observed (even after correcting for the opposite direction of the rating scale). This finding could be expected: as Jarl et al. recently observed [9], scales assessing satisfaction (including CSD) are based on a

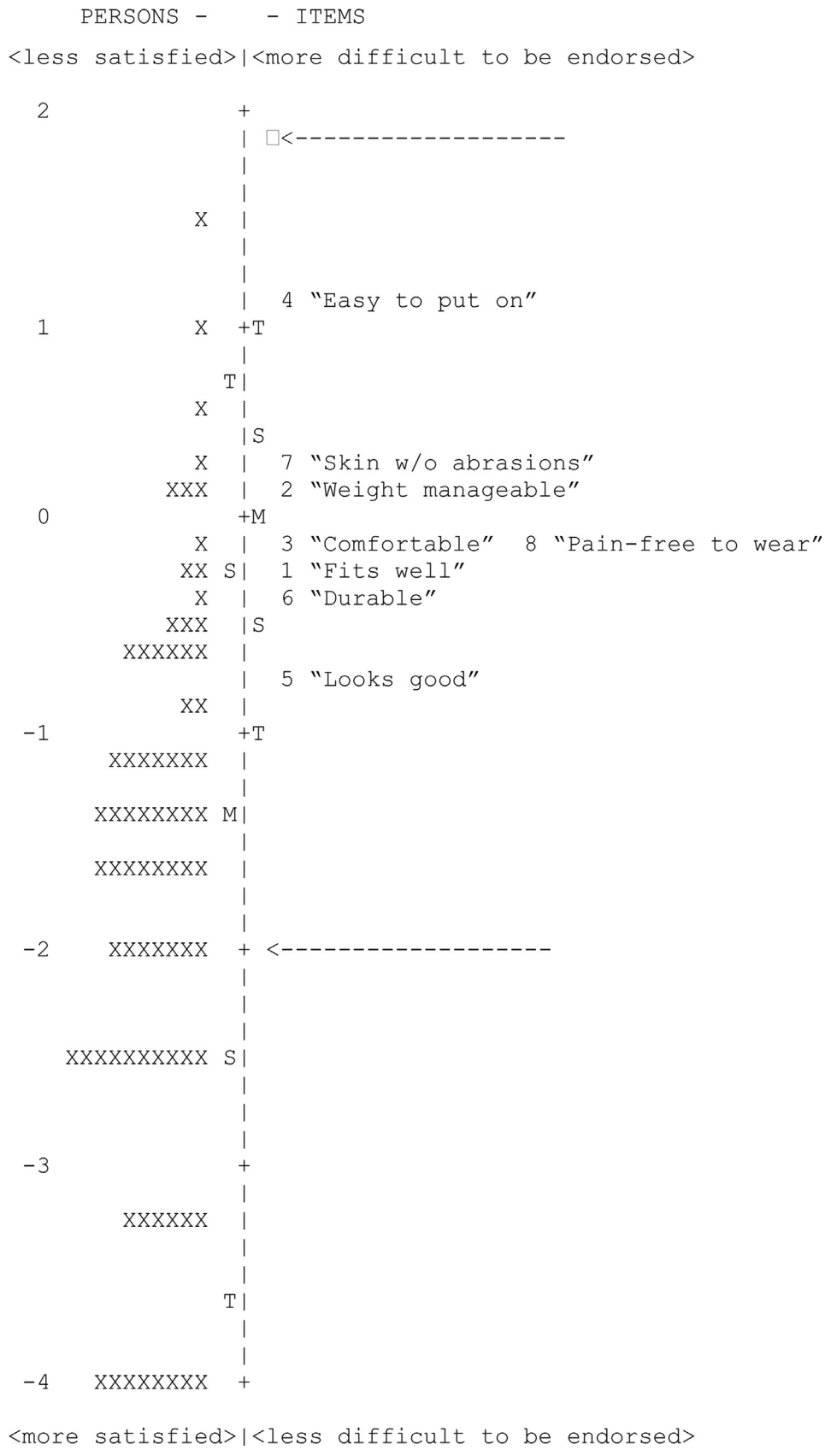

Fig. 2. Subject-ability and item-difficulty maps of the Slovene version of the Client Satisfaction with Device module. The vertical line represents the measure of the variable, in linear logit units. The left-hand column locates the participant "ability" measures (here, satisfaction with the device) along the variable: each "X" denotes one participant. Top to bottom measures indicate participants' higher to lower satisfaction with the device. The right-hand column locates the item difficulty measures along the variable (for each item, the difficulty estimate represents the mean calibration of the threshold parameters according to the rating scale model): the higher the item estimate, the more difficult the item was for the group to endorse (i.e., showing lower scores and indicating less satisfaction with this item). By convention, the average difficulty of items in the test was set to 0 logits (and indicated with M'); accordingly, an individual with average "ability" is indicated with M. Arrows indicate the highest and the lowest item response category step calibrations.

formative model (i.e., the latent construct, here "satisfaction with the device") is determined as a combination of arbitrarily selected indicators (items that create a composite index summarizing satisfaction with different aspects). Thus, such items do not necessarily correlate or orient in a consistent hierarchy, and adding or dropping an item may change the conceptual domain of the construct "satisfaction" [28,29]. Moreover, psychometric studies of CSD include individuals wearing different devices, from different cultures, and from countries with different availability of prosthesis/orthosis materials and components. Given these variable conditions, individuals are unlikely to assign the same hierarchy of importance and difficulty to some CSD items. As an example, most of our participants had a passive/cosmetic prosthesis: different factors influence the satisfaction with a device mainly worn for cosmetic reasons from that with a device that is crucial for improving function (e.g., gait performance or hand function).

The main limitation of our study is that the participants were from a single facility. However, our institute is the only facility in the country rehabilitating individuals after upper-limb amputation and fitting them with an upper-limb prosthesis. Thus, our participants seem representative of adults after upper-limb amputation in Slovenia, and their demographic characteristics are close to those in our previous studies on the same kind of people [30–32]. Of note, in Slovenia, upper-limb prostheses are reimbursed by the national health system: children and young adults (until age 26) can obtain all types of prostheses including myoelectric prostheses free of charge, whereas adults can obtain only passive (cosmetic) or body-powered prostheses free of charge. This is the main reason for the small number of participants with an active prosthesis in our sample. A second study limitation is that we did not examine the possible presence of Differential Item Functioning in the questionnaire because our relatively limited sample size did not allow for acceptable statistical power. In agreement with Jarl et al. [9], we think that "future studies should collect data from larger samples and use analytic methods that allow for the simultaneous investigation of different sources of DIF and confounding."

In conclusion, the metric properties of the Slovene version of CSD (examined with Rasch methods in patients using an upper-limb prosthesis) agree with previous studies of this tool. Thus, the present study extends the evidence for CSD as a valid measure of patient satisfaction with a device and enhances the confidence in use of this instrument for assessing a large range of users of orthotics and prosthetics. The use of such a patient-reported measure could be of great benefit in improving the quality of services provided by rehabilitation departments, particularly for group decisions (more than for everyday clinical application in single patients). Our results also provide insights for some further refinements of the technical quality of this measure.

Disclosure of interest

The authors declare that they have no competing interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.plantsci.2004.08.011.

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