

1 **A systematic review on cross-cultural validations and psychometric solidity of the**
2 **orthotics and prosthetics user survey (OPUS)**

3

4 **Abstract**

5 Research to contemplate and reflect patients' satisfaction with their devices in the field of
6 Prosthetics and Orthotics (P&O), record their performance and know the related quality
7 of life, of prosthetized or orthotized users, with health is fundamental. It requires
8 questionnaires with consistent psychometric properties and questions adapted to the
9 culture and language of each country, region, or area. The study identifies the cross-
10 cultural validations in different languages, depending on the country, of the Orthotics and
11 Prosthetics User Survey (OPUS) and the robustness of its psychometric properties. Study
12 design: Systematic review. A specific systematic bibliographic search was carried out in
13 the specialized search engines: Alcorze (University of Zaragoza), MEDLINE (Pubmed)
14 and EMBASE of original articles published since 2000. A total of 11 items belonging to
15 the Orthotics and Prosthetics User Survey (OPUS) were obtained, according to the
16 language of the country in which they were validated and confirmed to have good and
17 promising psychometric properties (sample size, reliability, and consistency). The study
18 was concluded by stating that the Orthotics and Prosthetics User Survey (OPUS) has been
19 validated in different languages, reporting good psychometric robustness according to its
20 parts, cultural and grammatical characteristics. Further deployment, refinement, and
21 validation of this survey by country is warranted in view of its promising uses in
22 rehabilitation and prosthetics.

23 MESH terms: Quality of life, Psychometrics, patient satisfaction, cross-cultural
24 comparison, surveys, and questionnaires.

25 **Background**

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3 26 As of 2017, the World Health Organization (WHO) reported that 0.5% of the world's
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5 27 population needs prostheses, orthoses, and rehabilitation¹, affecting between 35 and 40
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7 28 million people. It warns that only 1 in 10 people who need prostheses and/or orthoses
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9 29 have access to them due to high prices, lack of knowledge, lack of qualified personnel,
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11 30 specific assessments, lack of policies and financing¹⁻⁴. It establishes, together with
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13 31 subsequent studies, that in the coming decades the population with orthoprosthetic needs
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15 32 will grow significantly, estimating its population affection at 1% of the world total^{1,3-10}.

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21 33 The people with orthoprosthetic needs refer to motor, articular, muscular, sensory,
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23 34 proprioceptive and exteroceptive alterations, among others¹¹. In specific cases of absence
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25 35 or body fraction, such as limbs, it generates functional impairment and decrease,
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27 36 reflecting in many cases negative socio-labor, family, and personal performance.
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29 37 Reporting the tremendous psychological impact essentially in cases in which optimal
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31 38 interdisciplinary rehabilitative treatments were not implemented^{1-4, 6, 7, 11, 12}.

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36 39 Today, expectations for quality orthoprosthetic treatments have increased significantly
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38 40 due to research, assessment, qualification, and technological advances. On the other hand,
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40 41 need is a key factor, since many users wear their orthoprosthetic devices for long
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42 42 chronological periods or even throughout their lives^{1,8,10-17}.

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44 43 Consequently, the information reported by users will be of vital importance, both to
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46 44 improve their quality of life and to improve patient care. This translates into the need to
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48 45 promote the use, creation and dissemination of truly useful assessment instruments with
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50 46 reliable and acceptable psychometric properties^{11-15,17,18-25}.

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57 47 In more recent years, there has been an increasing need to evaluate orthoprosthetic
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59 48 practice, with instruments that users can answer honestly, but which are also reliable and
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49 valid, so that centers and professionals can improve care practice and the quality of life
50 of those affected^{11-13,15-25}.

51 Once a questionnaire that compiles, specifies, and evaluates several of the affected areas
52 such as: functional status, quality of life, satisfaction with the devices and services¹² has
53 been obtained, its psychometric properties must be correctly assessed so that it is useful<sup>11-
54 13,17-19,21-25</sup>.

55 After establishing the correctness of the questionnaire, it would be advisable to use it in
56 a generalized and routine manner, favoring the extrapolation of interprofessional data
57 globally. This would require cross-cultural validation in each of the countries, to adapt its
58 use to the culture and language, as well as the corresponding investigation of its statistical
59 foundations, to verify its viability^{11-13,18-26}.

60 The Orthotics and Prosthetics User Survey (OPUS) was developed to compute patients'
61 satisfaction with their devices in the field of Orthotics and Prosthetics, to compute their
62 performance and to know the health-related quality of life of prosthetized (or orthotized)
63 users^{12,22}. In current studies it is reflected as "the only measure designed with the explicit
64 purpose of assessing patient satisfaction in the field of orthotics and prosthetics"¹¹.

65 The survey, which is self-administered, consists of five distinct tools that include
66 functionality of the lower extremity, upper extremity, client satisfaction with the device
67 worn, satisfaction with clinical/care services, and health-related quality of life^{11-13,18-26}.

68 In view of the good results originally obtained, the study carried out here aims to contrast
69 and demonstrate its usefulness in different countries according to cultural identity, as well
70 as to show its reliability and validity in each one of them, knowing the increase in
71 confidence in its use for different populations and cultures^{11-13,18-26}.

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73 **Methods**

74 A specific and wide bibliographic search (according to PRISMA methodology) of studies
75 published since the year 2000 (chronologically between February 2022 and April 2022)
76 was carried out.

77 The search engines Alcorze (University of Zaragoza), MEDLINE (Pubmed) and
78 EMBASE of original indexed articles published from 2000 to the present (April 2022)
79 were used.

80 The terms used were Orthotics and Prosthetics User Survey validation; Orthotics and
81 Prosthetics User Survey translation; Orthotics and Prosthetics User Survey translation;
82 Orthotics and Prosthetics User Survey; Orthotics and Prosthetics User Survey validation;
83 Orthotics and Prosthetics User Survey cross cultural adaptation. "AND" was used as
84 Boolean operator.

85 In accordance with the established search plan, cross-cultural validation articles were
86 selected, indicated according to the target country, published in any language, although
87 all those that met the requirements were published in English. Review articles, repeated
88 articles and articles that did not deal with cross-cultural validations of the Orthotics and
89 Prosthetics Users Survey (OPUS) and did not contain psychometric data: sample size,
90 reliability, and consistency were eliminated (Figure 1).

91 Finally, the bibliographies of the selected articles were examined for other relevant
92 articles with the same characteristics. The titles, abstracts and full text of the articles
93 identified by the search and to bring psychometric soundness to the study, a systematic
94 study of the statistical properties of the survey, on the satisfaction module (most studied
95 module), was analyzed out of review²¹.

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96 Reading by two independent reviewers was suggested to identify those that met the
97 selection criteria and extract the data, as well as the expert directors of the study.

98 **Orthotics and Prosthetics Wearer Survey (OPUS), Modules and Measurement**

99 The Orthotics and Prosthetics User Survey (OPUS) was originally developed for self-
100 reporting. It presents five evaluative modules, which can be recorded individually or
101 completely, consisting of: functionality of the lower extremity, upper extremity, client
102 satisfaction with the device worn, satisfaction with clinical/care services and health-
103 related quality of life^{11-13,18-26}.

104 It was developed with the aim of being a comprehensive tool for assessing orthoprosthesis
105 services, to be clinically useful, with good measurement properties and not to be
106 burdensome for patients and clients. The survey contains enough items, demonstrating
107 good internal consistency¹¹⁻¹³. This study compares the results in the countries of record
108 in terms of n (sample size), reliability and internal consistency^{11-13,18-26}.

109 **Translation and cultural adaptation or cross-cultural validation process**

110 Generally, cross-cultural validations have a specific protocol common to all cases, with
111 minimal possible differences. In any case, permission is requested from the author/s; the
112 translation is made (by independent specialists); it is reviewed by a committee of experts
113 in the subject/s of the same, who share their assessment (which is treated and modified if
114 necessary); it is consolidated, so that it is adapted to the country's own culture; it is
115 completed by those affected; and finally, statistical robustness is extracted in that
116 population^{11-13,18-26}.

117 **Results**

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118 The systematic and bibliographic research resulted in 399 studies, 10 of which met the
119 inclusion criteria, with the addition of an article reviewing their psychometric
120 characteristics. From the extracted works, the country; language; sample (n); reliability
121 and consistency (Cronbach's α) were analyzed. (Table 1).

122 In the study of the data obtained, the first and most outstanding feature is the scarcity of
123 studies of the complete survey (only in the cases of 1, 6 and 10), that is, of the five
124 modules of which it is composed, only two other languages (Swedish/Spanish-Latin) have
125 been fully validated, given that there were only two studies: the original and original one,
126 and the one carried out internally with the participation of the original author (A.
127 Heinemann). This represents 30% of the total number of works analyzed. (Table 2).

128 On the other hand, the Orthotics and Prosthetics User Survey (OPUS) presents five
129 modules, in self-report mode, which can be completed individually. These modules are:

130 OPUS: Measurement of functional status of the lower extremities.

131 OPUS: Satisfaction with the device (CSD)

132 OPUS: Satisfaction with services

133 OPUS: Health Quality of Life Index (HQOL)

134 OPUS: Functional status of upper extremity

135 The work carried out reflects that four of the articles analyzed reflect the cross-cultural
136 validation of the satisfaction module (in the cases of 2, 3, 5 and 7), translating into the
137 following languages: Slovenian, Italian, Arabic and Persian, involving 40% of the works
138 reviewed. (Table 3).

139 Two cases were validated in Japanese and Swedish, in addition to confirming the
140 psychometric properties in American (items 8 and 4) for the module of mobility or

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141 functional status of the lower extremities (20% of the total). And in another case, in
142 Slovenian (item 9), the module of functional status of the upper extremity. This accounted
143 for 10% of the papers (Tables 4 and 5).

144 **Outcome measures. Psychometric characteristics of the studies.**

145 Sample size. After analyzing the articles, the sample size varies between 10 and 321
146 subjects for cross-cultural validation in the different languages (taking into account the
147 work in process of implementation). The largest number of subjects was used in the joint
148 work Sweden-United States (USA) for the validation of the lower extremity's
149 functionality module. The smallest size, under study, corresponds to the validation in
150 Japanese language, analyzing the same module. In this regard, it should be noted that the
151 author, in his original work, indicates that the number of participants would be sufficient
152 with 100 subjects¹².

153 If reliability is considered as the relationship between the actual dispersion of measures
154 and their measurement error, evaluated in terms of "separation", the item separation
155 indices provide a value of dispersion or "separation" of items along the measured
156 construct¹⁹. The value of dispersion of individuals will estimate the dispersion or
157 separation of individuals along the measure. This index allows to calculate the number of
158 statistically perceptible measures (resulting in a separation of 2.0 good as it allows to
159 differentiate three layers)¹⁹⁻²².

160 Separation reliability will be a related index, providing the degree of confidence of the
161 consistency of the approximations, resulting in range from 0 to 1; coefficients greater than
162 (>) 0.80 good, and greater than (>) 0.90 excellent¹⁹⁻²².

163 In the work carried out, the reliability (between-item-between-person) is reflected in
164 different ways in the studies. Finding values such as >2 resulting in a good value (item

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165 1). In other works, it is expressed with the values of reliability of separation of items and
166 of persons, with values (respectively) as: 0.62 and 0.83 (item 2), between 0.69-0.79 and
167 0.70 (item 3), 0.95 (item 4), 0.79 (item 5), 0.76 and 0.90 (item 7) and 0.91 (item 9). In
168 two cases it is concluded with the good quality of such value, but without expressing it
169 numerically and in the last case it is in the process of elaboration (Table 1).

170 One way of checking internal consistency is through Cronbach's alpha (α). In this case,
171 the closer it is to the value 1, the greater the internal consistency of the items measured.
172 It is desirable that it takes values between 0.85 and 0.90 (although values above 0.79 are
173 recommended)¹⁹⁻²².

174 The internal consistency reflected in the study, through Cronbach's α , concludes in values
175 ranging from 0.71 to 0.95. This last value results in three of the works (items 1, 4 and 9),
176 showing a good psychometric correction. In two cases it takes values between 0.80 and
177 0.90 (items 5-0.83 / 7-0.89). Two results reflect 0.76 (item 2) and 0.73 (item 3), while one
178 paper with no conclusion for this section reflects good psychometric characteristics⁸ and
179 the remaining two (3 and 10) are in process and do not refer to specific data.

180 As should be emphasized in this work, all the studies, from the first one, seek to provide
181 professionals and clinical services with a useful routine instrument validated in the
182 language of each country, so that results can be contrasted at an international level. For
183 this purpose, the measurement properties of the analyzed modules of the Orthotics and
184 Prosthetics User Survey (OPUS) were evaluated by means of methodological
185 investigations (factor analysis and Rasch or rating scale model) on the results of self-
186 administered interviews¹².

187 This is reflected in the original studies, which show good psychometric properties with
188 good internal consistency, being able to detect (the OPUS survey) extensive functions,

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189 quality of life and satisfaction¹². It is established as an excellent measure for the
190 evaluation of orthoprosthetic treatments and care improvement, the better the measure is
191 established at a global level, allowing the exchange of results between professionals,
192 improving clinical quality and the patient's experience¹².

193 The results show a high confidence of consistency, both in the ability of the person and
194 in the difficulty of the items. The item separation reliability is high, being possible its
195 replication with different groups. It is an adequate and accurate scale for measuring
196 functional ability and resolves the confidence in personal ability estimates. It shows that
197 it is a promising instrument for measuring the degree of manual functioning after
198 amputation^{12,13}.

199 The Slovenian and Italian validation studies confirmed the unidimensionality of the scale
200 and the effective psychometric conditions, as well as the correct internal validity^{11,19}. The
201 Italian validation study corroborated a person separation reliability of 0.70 and a
202 Cronbach's alpha (α) of 0.73, constituting correct metric values. This demonstrates the
203 internal construct validity of the cross-cultural translation/adaptation into Italian¹¹ (Table
204 1).

205 The Swedish American study indicates good internal consistency, supported by the
206 comparative validity of OPUS (Orthotics and Prosthetics User Survey) measures between
207 people from both countries and reveals its ability to discern between patient groups.
208 Minor linguistic adaptations (mere semantic issues) had to be made for its adaptation and
209 validation in the Swedish language²².

210 The transcription into Arabic language also corroborated the unidimensionality of the
211 survey, reflecting values, identified as good, of 0.75 for person separation reliability and

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212 a Cronbach's alpha (α) of 0.83. Confirming the internal validity in patients with various
213 types of orthoses, resulting in a promising tool applicable in rehabilitation²³ (Table 1).

214 As for the results in the Persian language yielded Cronbach's alphas (α), of the modules
215 analyzed, of 0.71 and 0.89 (satisfaction with the device and service, respectively). While
216 the intraclass correlation coefficients were 0.76 and 0.90 (respectively). Concluding with
217 the reaffirmation of scalar unidimensionality, being the validation to the Persian language
218 a reliable and validated measure²⁴ (Table 1).

219 The Japanese version concluded, after specific revisions, with the non-alteration of items,
220 determining its clarity, good comprehension, and cultural applicability, for clinical care
221 use, to improve user care. It also emphasizes its high utility worldwide²⁵ (Table 1).

222 **Discussion**

223 The work carried out corroborates the need to provide useful and validated global
224 instruments to clinical services and units. It defends the growing interest of specialists
225 and researchers in the global evaluation and contrast of data to assess orthoprosthetic use
226 as a relevant clinical finding, both for functionality and performance, as well as for client
227 satisfaction^{11-13,18-26}.

228 The results of the validation in Italian identify OPUS as a great working tool, identifying
229 as weaknesses of the study, in terms of reliability, the scarcity of items related to
230 difficulties with the sample (relatively limited) and its dimensionality¹¹.

231 The Swedish American study showed the hierarchical differences between countries (due
232 to demographic differences) of the items. It demonstrated the correct possibility of
233 comparing the measures between Swedish and American patients, which is fundamental
234 and useful in the realization of international works, people of different sexes, ages, and
235 amputation. He concludes with the need for further studies²².

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236 The Arabic language validation work emphasizes the need for the use of robust outcome
237 measures to improve health services, prescribing, policy making and spending in the field
238 of orthotics and prosthetics. It demonstrates the internal construct validity of the Saudi
239 Arabian version. However, it reveals as a point to be developed, the reliability resolving
240 the great need for further studies to confirm the psychometric properties, it alludes to the
241 sample size since its realization occurred in only one of the 22 Arabic-speaking
242 countries²³.

243 Including the original study, all the papers report that the psychometric properties have
244 not been developed or investigated in sufficient quantity. In fact, the Orthotics and
245 Prosthetics User Survey (OPUS), of all its modules, has not been fully studied, being
246 reflected in three of the papers. It would be relevant to perform a joint dimensionality
247 analysis and to avoid the use of single questions, to provide more information.

248 On the other hand, validations have been adequately performed by analyzing
249 psychometric characteristics and with Rasch analysis, improving the outcome measures.
250 However, the development and validation of the measures still needs to be improved, for
251 example, in terms of sample sizes.

252 The results of this work coincide in adding value to the survey and to the psychometric
253 values of the research reported and provide the need to increase the sample size and the
254 number of validations in other languages to generalize it at an international level. It will
255 also be necessary to make a specific distinction between the Spanish language. This is
256 spoken in more than 20 countries (in Europe, America, and Africa) since there are
257 numerous differences between the Spanish spoken in Europe and in Latin American
258 countries, both phonetic and in expressions²⁷.

259 **Conclusions**

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260 This review reflects the interest aroused by the Orthotics and Prosthetics User Survey
261 (OPUS) which, to date, has been validated, from its American origin, in its entirety or in
262 modules in the following languages: Italian, Swedish, Slovenian, Persian, Arabic,
263 Japanese and Guatemalan (Spanish Hispanic American).

264 It reflects the interest and need on the part of specialists in the orthoprosthesis area to
265 collect relevant information from their users and to have validated instruments for their
266 care application. It also underlines the interest of specialists in knowing both physical
267 factors (functionality, utility, etc.) and psychosocial factors (satisfaction and quality) and
268 being able to count on global tools so that the data can be contrasted in any hospital,
269 clinic, or entity.

270 On the other hand, it is evident the need to continue with the development of the
271 assessment, increasing the number of participants to further demonstrate its adequate
272 psychometric properties, given its solid metric features, in different conditions and
273 environments.

274 Perceptual understanding of users, their functionality and performance is critical for better
275 clinical identification of existing devices and treatments, as well as improving quality of
276 care. The use of psychometrically sound outcome measures influences specialist
277 decisions for clinical improvement, prescribing, policy making and healthcare spending.

278 Due to all this and to the quality of the Orthotics and Prosthetics User Survey (OPUS), it
279 is justified the elaboration of works and studies on its improvement, improvement, metric
280 validation, and adaptations to other languages, resulting in a very useful instrument at
281 international level in the orthoprosthesis field.

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386 **Figure 1 legend:** Study selection process.

1 **A systematic review on cross-cultural validations and psychometric solidity of the**
2 **Orthotics and Prosthetics Users Survey (OPUS)**

3 **Abstract**

4 Research to reflect patients' satisfaction with their devices in the field of Prosthetics and
5 Orthotics (P&O), record their performance and health-related quality of life is essential.
6 This requires culturally adapted questionnaires for each country. Periodic assessment of
7 validity and test fit are essential elements for the long-term utility and effectiveness of
8 psychometric tests. This article reviews the psychometric properties of the Orthotics and
9 Prosthetics Users Survey (OPUS). The purpose, in addition to its adaptation to the
10 Spanish-speaking population, involves a review/update of content, statistical analyses and
11 validity studies, until a larger number of studies are conducted. Study design: Systematic
12 review. A systematic literature search was carried out in specialised search engines:
13 Alcorze (University of Zaragoza), MEDLINE (Pubmed) and EMBASE of original
14 articles published since 2000. Eleven items belonging to the OPUS were obtained,
15 according to the language of the country where they were validated, and promising
16 psychometric properties were confirmed (reflecting reliability values between 0.62 and
17 0.95; Crombach's α scores between 0.73 and 0.98) with sample sizes between 10 and 321.
18 The study concluded by stating that the OPUS was validated in different languages,
19 reporting good psychometric robustness so far. Further deployment, refinement, and
20 validation of this survey by country is warranted in view of its promising use.

21 MESH terms: Quality of life, Psychometrics, patient satisfaction, cross-cultural
22 comparison, surveys, and questionnaires.

23 **Background**

24 In 2017, the World Health Organization (WHO) reported that 0.5% of the world's
25 population needs prostheses and orthoses¹ (35 and 40 million people). Warning that only
26 1 in 10 people who need prostheses and/or orthoses have access to them due to: high
27 prices, lack of personnel, specific assessments, policies, and funding¹⁻⁴. It establishes,
28 along with subsequent studies, that the population with prosthetic/orthotic needs will
29 grow globally by 1%^{1,3-10}.

30 P&O users report various alterations¹¹, generating functional and psychological
31 deterioration, reflecting negative performances in cases without optimal treatments¹⁻⁴,
32 ^{6,7,11,12}. The expectations of users and professionals in P&O have increased (research,
33 evaluation, technology...) and with it, the need to promote the use and dissemination of
34 useful, psychometrically adequate evaluation instruments^{1-8,10-25}.

35 Having obtained a questionnaire that collects and assesses several affected areas such as:
36 functional status, quality of life, satisfaction with devices and services¹², its psychometric
37 properties must be properly assessed^{11-13,17-19,21-27}.

38 A questionnaire must be evaluated according to reliability and validity criteria (criterion,
39 content, and construct)²⁷. Reliability refers to the way in which a test measures a
40 dimension and is determined by its internal consistency (measured by Cronbach's alpha
41 and test-retest reliability). It is intended to measure whether a person taking the test again
42 would obtain the same or different results. When repeated, it provides similar scores, it is
43 considered reliable, but the existence of external variables such as psychological,
44 physical, or environmental factors influence the results by intervening in personal
45 performance.

46 Reliability implies internal consistency (it indicates whether the items measure the same
47 dimension). A high internal consistency coefficient indicates that the items are similar in
48 content (homogeneous). Internal consistency is measured with Cronbach's alpha (0 = low
49 / 1 = high). Test-retest reliability indicates the degree of repetition of the score over time
50 and reflects the stability of the construct²⁷.

51 Validity refers to the characteristics measured by the test and its accuracy of evaluation,
52 gives meaning to the scores, and informs about its usefulness. We must speak of criterion,
53 content, and construct validity. Criterion validity is assessed by examining the correlation
54 or other statistical relationship between the performance (test) and another external
55 criterion. If it is obtained at the same time as the performance (test), we speak of
56 concurrent validity and, if obtained later, of predictive validity.

57 Content validity is assessed by examining whether the content is representative of the
58 measurable construct. Construct validity requires demonstration (measuring the intended
59 characteristic), either by presenting it to a panel of experts and asking for an opinion
60 between items (content) and the evaluated construct (face validity), or by administering
61 it together with other tests developed with theoretically similar constructs and examining
62 their correlation. Finally, social desirability, an evaluation bias that corresponds to a
63 person's inclination to respond in a way that is seen as favorable by others, is also
64 assessed²⁷.

65 OPUS was developed to assess device satisfaction, test functionality and health-related
66 quality of life of P&O users^{12,22}. Current studies, such as the Italian validation reflect it
67 as "the only measure designed with the explicit purpose of assessing patient satisfaction
68 in the P&O field "¹¹. In view of the good psychometric results initially obtained in the
69 countries in which it has been validated, the study aims to reflect its data^{11-13,18-26}.

70 **Methods**

71 A specific and wide bibliographic search (according to PRISMA methodology) of studies
72 published since the year 2000 (chronologically between February 2022 and April 2022)
73 was carried out. The search engines Alcorze (University of Zaragoza), MEDLINE
74 (Pubmed) and EMBASE of original indexed articles published from 2001 to the present
75 (April 2022) were used (Figure 1).

76 The terms used were Orthotics and Prosthetics User Survey validation; Orthotics and
77 Prosthetics User Survey translation; Orthotics and Prosthetics User Survey; Cross cultural
78 adaptation Orthotics and Prosthetics User Survey; Translation Orthotics and Prosthetics
79 User Survey; Traducción Orthotics and Prosthetics User Survey. "AND" was used as
80 Boolean operator (Figure 1)..

81 Figure 1. Study selection process.

82 According to the established search plan, articles were selected with the following
83 inclusion criteria: Original OPUS with data (reliability and Crombach's alpha); Cross-
84 cultural validations of OPUS according to language and specific country, other than the
85 USA; Validations that share the same psychometric data (reliability and Crombach's
86 alpha); Validations where the sample size appears; JCR articles with DOI; Articles
87 published between 2001 and 2022; Full text. We eliminated those that: Were
88 repeated/duplicated; Did not address validation to another language; Addressed OPUS
89 without reflecting specific data; Articles on OPUS only in the U.S. One original study
90 (USA)¹², one paper on psychometrics from OPUS (satisfaction)²¹ and one not published
91 but registered (Guatemala)²⁶ were added.

92 The review process was carried out according to the following steps: Establishment of
93 objectives and hypotheses; inclusion/exclusion criteria; systematic text search; extraction

94 of results; discussion; reflection of the work; reading by the study directors, a professional
95 with Psychometrics studies and an expert in Psychometrics (Chair Director).

96 **Orthotics and Prosthetics Users Survey, Modules and Measurement**

97 OPUS was originally developed for self-assessment. It features five assessment modules,
98 which can be recorded individually or completely, consisting of: lower extremity
99 functionality, upper extremity, client satisfaction with the device (CSD), satisfaction with
100 clinical/care services, and health-related quality of life (HQOL)^{11-13,18-26}.

101 It was developed with the aim of being a comprehensive tool for evaluating orthopedic
102 and rehabilitation services, being clinically useful, initially (in the absence of further
103 studies) with good measurement properties, and not being burdensome for users and
104 professionals¹¹⁻¹³.

105 **Translation and cultural adaptation or cross-cultural validation process**

106 Generally, cross-cultural validations have common protocols, with as few differences as
107 possible. Permission is requested from the author(s); the translation is done (by
108 specialists); it is reviewed by a committee of experts; it is consolidated, adapting it to the
109 country's own culture; it is completed by the users; and finally, the statistical robustness
110 in that population is extracted^{11-13,18-26}. In this case, the data that could be reflected in a
111 common way according to the studies were: reliability (test/re-test) and Cronbach's
112 alpha. In addition, the languages to which the original was adapted and the sample (which
113 differed greatly among the studies) were also reflected. Not all of them reflected the same
114 modules so it was specified in the tables (tables 1 to 5).

115 Table 1. Global results obtained in the studies. Where: Complete (indicates whether or not all OPUS
116 modules were studied); Year (of the study); Language (of the article/language, country of validation); n
117 (sample size); A*- Satisfaction with the devices; B** - Services provided (test/re-test); a. Item split
118 reliability/ b. Persons, (a-b; respectively) Cronbach's α (coefficient); Correct/study in progress = Indicates

119 that the preliminary results are good, but is in the process of study and development; NEOM = Not specified
120 (no information).

121 Table 2. Items collected OPUS in complete. Where: Complete (indicates whether or not all OPUS modules
122 were studied); Year (of the study); Language (of the article/language, country of validation); n (sample
123 size); A*- Satisfaction with the devices; B** - Services provided (test/re-test); a. Item split reliability/ b.
124 Persons, (a-b; respectively) Cronbach's α (coefficient); Correct/study in progress = Indicates that the
125 preliminary results are good, but is in the process of study and development; NEOM = Not otherwise
126 specified (no information).

127 Table 3. Results of OPUS studies, only of the satisfaction module (devices/services). Where: Complete
128 (indicates whether or not all OPUS modules were studied); Year (of the study); Language (of the
129 item/language, country of validation); n (sample size); A*- Satisfaction with devices; B** - Services
130 provided (test/retest); a. Item split reliability/ b. Persons, (a-b; respectively) Cronbach's α (coefficient);
131 Correct/study in progress = Indicates that preliminary results are good, but is in the process of study and
132 development; NEOM = Not specified (no information).

133 Table 4. Results of the OPUS studies, only of the lower extremity functionality module. Where: Complete
134 (indicates whether or not all OPUS modules were studied); Year (of study); Language (of item/language,
135 country of validation); n (sample size); Cronbach's α (coefficient).

136 Table 5. Results of OPUS studies, only of the upper extremity functionality module. Where: Complete
137 (indicates whether or not all OPUS modules were studied); Year (of study); Language (of item/language,
138 country of validation); n (sample size); Cronbach's α (coefficient).

139 **Results**

140 The systematic and bibliographic research resulted in 399 studies, 8 of which met all the
141 inclusion criteria, with the addition of a review article by the author of the questionnaire
142 (to know and relate its psychometric characteristics) and a registered, unpublished
143 questionnaire, used and sent by the author (Guatemala). The study compares the results
144 in the countries of registration in terms of country, validation language, n (sample size),
145 reliability and internal consistency (Cronbach's α). All the data, from the total of the 10
146 items, were initially reflected in a general way (Table 1).

147 The methodological differences between them and the difference in the exposition of
148 measurement parameters (results) are evident. For this reason, some studies expressed
149 reliability with the results of the test/re-test, in other cases as a single measure (Tables 1,4
150 y 5) and studies in which it has not yet been studied (Tables 1 and 2).

151 The study of data obtained reflects the scarcity of works reflecting all the modules of the
152 survey (it was complete only in the cases of 1, 6 and 10), i.e., of the five modules that
153 compose it, only two other languages (Swedish/Spanish Latin) have been fully validated.
154 This represents 30% of the total number of works analyzed (Table 2).

155 The work performed reflects that five of the articles analyzed reflect the cross-cultural
156 validation of the satisfaction module (in the cases of 2, 3, 5, 7 and 8), being translated
157 into the following languages Slovenian, Italian, Arabic, Persian and Turkish, accounting
158 for 50% of the reviewed papers (Table 3).

159 Only one study (Swedish-American version) validated the reliability properties and
160 Crombach's alpha for the lower extremity mobility/functional status module (Table 4), as
161 occurred with the upper extremity functionality module (Slovenian version), obtaining
162 only one study (Table 5). Assuming in each case 10% of the total number of studies.

163 **Outcome measures. Psychometric characteristics of the studies.**

164 Sample size. This data was included given its relevance (implementation-need for further
165 work) and accurate reflection of the study. After item analysis, the sample varies between
166 29 and 321 subjects for the different cross-cultural validations. The largest number of
167 subjects appears in the joint Sweden-US work for the validation of the lower extremity
168 functionality module. The smallest size corresponds to the Swedish validation, analyzing
169 all modules. In this regard, it should be noted that the author, in his original work,
170 indicates that the number of participants would be sufficient with 100 subjects¹².

171 Identified as reliability, the results of test-retest reliability or fidelity and Crombach's
172 alpha (reflecting internal consistency) have been collected. The reliability of the studies
173 (reflected in tables 1 to 5). The disparity in the elaboration and/or transcription of results
174 in each study is reflected, given that not all of them carried out test-retest tests, and/or

175 analyzed item and person separation reliability (it is true that some works are in the
176 process of being carried out). We found values between 0.82-0.98 / 0.74-0.94 very correct
177 in the first study analyzed (study 1). Other works, expressed with reliability values of
178 item and person separation, as (respectively): 0.62 and 0.83 (study 2), between 0.69-0.79
179 and 0.70 (study 3), 0.95 (study 4), 0.79-0.75 (study 5), 0.76 and 0.90 (study 7), 0.92-0.91
180 (study 8) and 0.91 (study 9). In two cases it is concluded with the good quality of such
181 value, but without expressing it numerically (item 8) and in the last case (item 10) it is in
182 the process of elaboration (Table 1).

183 The general internal consistency reflected in the study, through Cronbach's α , concludes
184 in values ranging from 0.71 (study 7) to 0.98 (study 1). Three of the works (studies 4,8
185 and 9) reflect values of 0.95 (4 studies present values higher than 0.94), showing a good
186 psychometric correction initially. Four studies reflect initial data lower than 0.77 (studies
187 1,2,3 and 7), 3 studies reflect values between 0.83 and 0.89 (studies 5,7 and 8), while the
188 remaining two (6 and 10) are in progress and do not refer to specific data.

189 The Slovenian and Italian validation studies confirmed the unidimensionality of the scale
190 and effective initial psychometric conditions, as well as the apparent correct internal
191 validity^{11,19}. The Italian validation study corroborated a person separation reliability of
192 0.70 and a Cronbach's alpha (α) of 0.73, reflecting correct primary metric values. This
193 demonstrates a promising internal construct validity of the Italian cross-cultural
194 translation/adaptation¹¹ (Tables 1 y 3).

195 The Swedish American study indicates good internal consistency, supported by the
196 comparative validity of OPUS measures between people from both countries and reveals
197 its ability to discern between patient groups. Minor linguistic adaptations (mere semantic
198 issues) had to be made for its adaptation and validation in the Swedish language²².

199 Transcription into Arabic also corroborated the unidimensionality of the survey,
200 reflecting values, initially identified as good, of 0.75 for person separation reliability and
201 a Cronbach's alpha (α) of 0.83 (Table 1).

202 The Turkish version, whose reliability data (0.92-0.91) and Cronbach's alpha (0.95-0.84)
203 initially reflected clarity, good understanding, and cultural applicability for clinical care
204 use to improve user care, as well as an acceptable sample size (according to the author's
205 criteria)²⁵ (Tables 1 y 3).

206 As for the results in the Persian language yielded Cronbach's alphas (α), of the modules
207 analyzed, of 0.71 and 0.89 (satisfaction with the device and service, respectively). While
208 the intraclass correlation coefficients were 0.76 and 0.90 (respectively). Concluding with
209 the reaffirmation of scalar unidimensionality being a reliable and validated primary
210 validation to the Persian language²⁴ (Table 1 and 3).

211 **Discussion**

212 The work carried out corroborates the need to provide useful and validated global
213 instruments to clinical services and units. It defends the growing interest of specialists
214 and researchers in the global evaluation and contrast of data to assess orthoprosthetic use
215 as a relevant clinical finding, both for functionality and performance, as well as for client
216 satisfaction^{11-13,18-26}.

217 As general weaknesses, several aspects should be pointed out, such as the absence of a
218 greater number of studies, the sample limitation of several of them (studies 2,6,9 and 10)
219 and their methodological differences both at the level of modules/items worked on and at
220 the psychometric level. In all the studies, the estimation of reliability and consistency
221 (measurement of the same dimension) has not been carried out in the same terms. The

222 measure of internal consistency through Crombach's alpha is not reflected to the same
223 extent in the studies. As for test-retest reliability, not all studies have done so.

224 If reliability is considered as the relationship between the actual dispersion of measures
225 and their measurement error, evaluated in terms of "separation", the item separation
226 indices provide a value of dispersion or "separation" of items along the measured
227 construct¹⁹. The value of dispersion of individuals will estimate the dispersion or
228 separation of individuals along the measure. This index allows to calculate the number of
229 statistically perceptible measures (resulting in a separation of 2.0 good as it allows to
230 differentiate three layers)¹⁹⁻²².

231 Separation reliability will be a related index, providing the degree of confidence of the
232 consistency of the approximations, resulting in range from 0 to 1; coefficients greater than
233 (>) 0.80 good, and greater than (>) 0.90 excellent¹⁹⁻²². Initially, we found that most of the
234 studies (studies 1,2,4,7,8 and 9) show values higher than what is considered good (6
235 studies) and 5 studies contemplate results expressed as excellent (1,4,7,8 and 9).

236 The initial results of the Italian validation (study 3) identify the OPUS as a great working
237 tool, identifying as weaknesses of the study, in terms of reliability, the scarcity of items
238 related to the difficulties of the sample (relatively limited) and its dimensionality¹¹, in
239 contrast to the good results obtained by the original version (study 1).

240 The Swedish American study (study 4) showed the hierarchical differences between
241 countries (due to demographic differences) of the items. It demonstrated the correct
242 possibility of comparing the measures between Swedish and American patients, which is
243 fundamental and useful in the realization of international works, people of different sexes,
244 ages, and amputation. He concludes with the need for further studies²².

245 The Arabic language validation work highlights the need to use robust outcome measures
246 to improve health services, prescribing, policy making and spending in orthopedics and
247 prosthetics. It initially demonstrates internal construct validity of the Saudi version.
248 However, it reveals as a point to develop, reliability resolving the great need for further
249 studies to confirm the psychometric properties, it alludes to the sample size as its conduct
250 occurred in only one of 22 Arabic-speaking countries²³.

251 Including the original study, all papers report that the psychometric properties have not
252 been developed or investigated in sufficient quantity. OPUS, in all its modules, has not
253 been studied in its entirety. It would be relevant to perform a joint dimensionality analysis
254 and avoid the use of single questions, in order to provide more information.

255 On the other hand, adequate primary validations have been (and are being) performed
256 through the analysis of psychometric characteristics, improving the outcome measures.
257 However, the development and validation of the measures still need to be improved, for
258 example, in terms of sample size and unification of methodological criteria.

259 The results of this work coincide in adding value to the survey and to the psychometric
260 values of the research reported and provide the need to increase the sample size and the
261 number of validations in other languages to generalize it at an international level. It will
262 also be necessary to make a specific distinction between the Spanish language. This is
263 spoken in more than 20 countries (in Europe, America, and Africa) since there are
264 numerous differences between the Spanish spoken in Europe and in Latin American
265 countries, both phonetic and in expressions²⁸.

266 **Conclusions**

267 The work reflects the interest in OPUS which, to date, has been validated, since its
268 EE.UU. origin, in its entirety or in modules in Italian, Swedish, Slovenian, Persian,
269 Arabic, Turkish and Guatemalan (Spanish / Hispanic American).

270 Understanding user perception, functionality and performance is critical to better clinical
271 identification of devices, treatments and improving quality of care. The use of
272 psychometrically sound outcome measures influences utilization decisions. Therefore, a
273 good psychometric test should not be biased (positively or negatively) towards a
274 particular socio-cultural group, should not favor a particular population, and should not
275 show any discrimination based on the religion, gender, ethnicity or cultural background
276 of the test taker.

277 The results obtained initially reflect that OPUS presents promising psychometric data, in
278 its different validations (according to country/culture), but the evident need for more
279 validation and evaluation studies is reflected. Given that there are currently few studies,
280 in very few countries, the samples are still insufficient, and it would be highly advisable
281 to demonstrate its adequate or inadequate psychometric properties in different conditions
282 and environments.

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Figure 1.

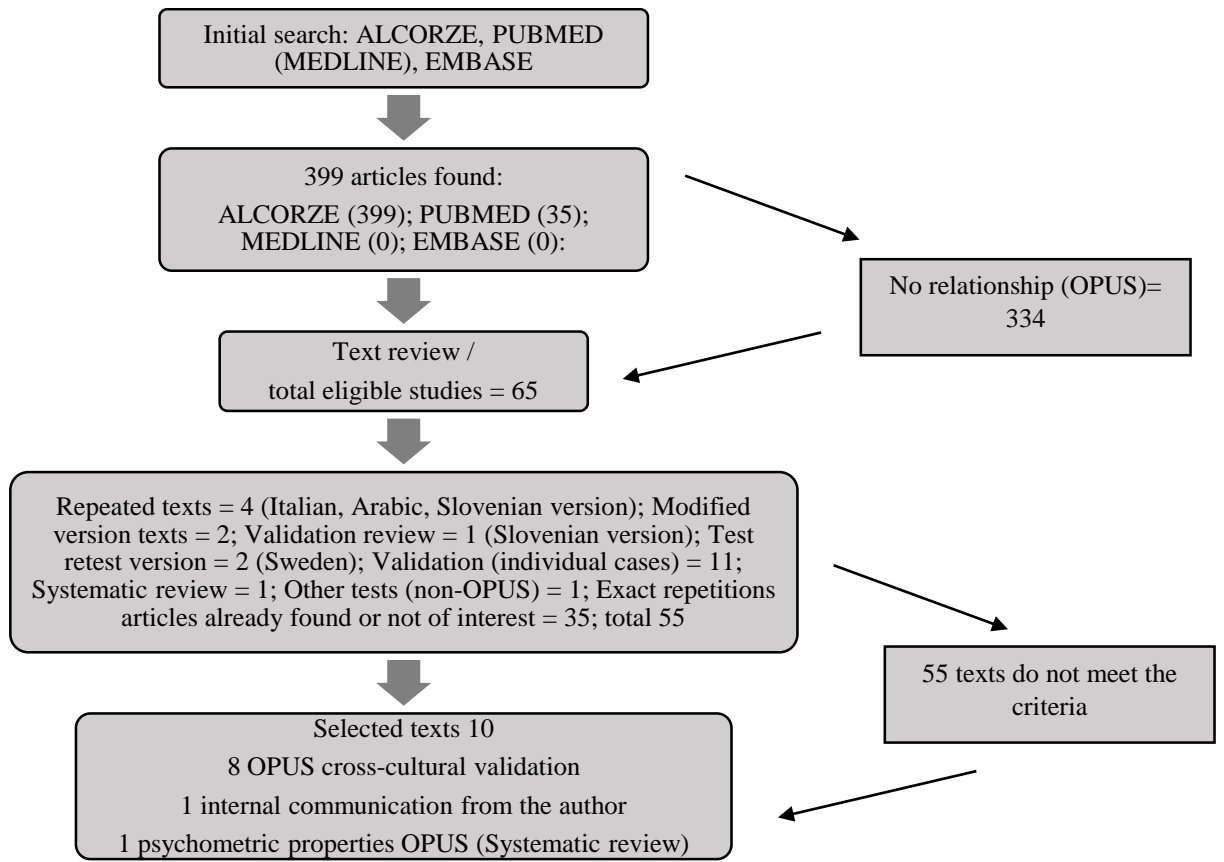


Figure 1. Study selection process.

Table 1. Global results obtained in the studies. Where: Complete (indicates whether or not all OPUS modules were studied); Year (of the study); Language (of the article/language, country of validation); n (sample size); A*- Satisfaction with the devices; B** - Services provided (test/re-test); a. Item split reliability/ b. Persons, (a-b; respectively) Cronbach's α (coefficient); Correct/study in progress = Indicates that the preliminary results are good, but is in the process of study and development; NEOM = Not specified (no information).

<i>Author(s)</i>	<i>Complete</i>	<i>Year</i>	<i>Language</i> <i>Country</i>	<i>n (sampling size)</i>	<i>Reliability</i>	<i>Cronbach α</i>
1 <i>Heinemann A.W.; Bode R.K.; O'Reilly C (12)</i>	YES	2003	English / EEUU	164	A* = 0,82 - 0,98 B** = 0,74 -0,94	a = 0,74 b = 0,98
2 <i>Burger, H.; Giordano, A.; Mlakar, M.; Albensi, C.; Brezovar, D.; Franchignoni, F (19)</i>	NO	2019	English / Slovenian	76	A* = 0,62 B** = 0,83	0,76
3 <i>Bravini, E.; Franchignoni, F.; Ferriero, G.; Giordano, A.; Bakhsh, H.; Sartorio, F.; Vercelli, S (11)</i>	NO	2014	English / Italian	178	A* = 0,79 - 0,69 B** = 0.70	0,73
4 <i>Jarl G.; Heinemann A.W.; Lindner H.Y.; Norling Hermansson LM (18)</i>	NO	2015	English / EEUU and Swedish	321 (195 = Swedish 126 =EE. UU)	0,95	0,95
5 <i>Bakhsh H.; Franchignoni F.; Bravini E.; Ferriero G.; Giordano A.; Foti C (23)</i>	NO	2014	English / Arabic version	100	A* = 0,79 B* = 0,75	0,83
6 <i>Jarl, G.M.; Hermansson, L.M.N (22)</i>	YES	2009	English / Swedish	29	Correct. Study: in process	Correct. Study: in process
7 <i>Hadadi, M.; Ghoseiri, K.; Fardipour, S.; Kashani, R. V.; Asadi, F.; Asghari, A (24)</i>	NO	2016	English / Persian version	116	A* = 0,76 B** = 0,90	a = 0,71 b = 0,89
8 <i>Demirdel S, Ulaş K, Erol Çelik S, Karahan S, Topuz S. (25)</i>	NO	2022	English / Turkish	157	A* = 0,92 B* = 0,91	a = 0,95 b = 0,84
9 <i>Burger, H.; Franchignoni, F.; Heinemann A.W.; Kotnik S.; Giordano A (13)</i>	NO	2008	English / EE.UU. Slovenian	37	0.91	0,95
10 <i>Internal document. Copyright © 2001 Rehabilitation Institute Research Corporation and Northwestern University. All rights reserved (26)</i>	YES	2001	Spanish / Guatemala	NEOM	NEOM	NEOM

Table 2. Items collected OPUS in complete. Where: Complete (indicates whether or not all OPUS modules were studied); Year (of the study); Language (of the article/language, country of validation); n (sample size); A*- Satisfaction with the devices; B** - Services provided (test/re-test); a. Item split reliability/ b. Persons, (a-b; respectively) Cronbach's α (coefficient); Correct/study in progress = Indicates that the preliminary results are good, but is in the process of study and development; NEOM = Not otherwise specified (no information).

<i>Author(s)</i>	<i>Complete</i>	<i>Year</i>	<i>Language</i> <i>Country</i>	<i>n (sampling</i> <i>size)</i>	<i>Reliability</i>	<i>Cronbach</i> <i>α</i>
<i>1 Heinemann A.W.; Bode R.K.; O'Reilly C (12)</i>	YES	2003	English / EEUU	164	A* = 0,82 - 0,98 B** = 0,74 -0,94	a =0,74 b = 0,98
<i>6 Jarl, G.M.; Hermansson, L.M.N (22)</i>	YES	2009	English / Swedish	29	Correct. Study: in process	Correct. Study: in process
<i>10 Documento interno. Copyright © 2001 Rehabilitation Institute Research Corporation and Northwestern University. All rights reserved (26)</i>	YES	2001	Spanish / Guatemala	NEOM	NEOM	NEOM

Table 3. Results of OPUS studies, only of the satisfaction module (devices/services). Where: Complete (indicates whether or not all OPUS modules were studied); Year (of the study); Language (of the item/language, country of validation); n (sample size); A*- Satisfaction with devices; B** - Services provided (test/retest); a. Item split reliability/ b. Persons, (a-b; respectively) Cronbach's α (coefficient); Correct/study in progress = Indicates that preliminary results are good, but is in the process of study and development; NEOM = Not specified (no information).

<i>Author(s)</i>	<i>Satisfaction module</i>	<i>Year</i>	<i>Language Country</i>	<i>n (sampling size)</i>	<i>Reliability</i>	<i>Cronbach α</i>
2 <i>Burger, H.; Giordano, A.; Mlakar, M.; Albensi, C.; Brezovar, D.; Franchignoni, F (19)</i>	YES	2019	English / Slovenian	76	A* = 0,62 B** = 0,83	0,76
3 <i>Bravini, E.; Franchignoni, F.; Ferriero, G.; Giordano, A.; Bakhsh, H.; Sartorio, F.; Vercelli, S (11)</i>	YES	2014	English / Italian	178	A* = 0,79 - 0,69 B** = 0,70	0,73
5 <i>Bakhsh H.; Franchignoni F.; Bravini E.; Ferriero G.; Giordano A.; Foti C (23)</i>	YES	2014	English / Arabic version	100	A* = 0,79 B** = 0,75	0,83
7 <i>Hadadi, M.; Ghoseiri, K.; Fardipour, S.; Kashani, R. V.; Asadi, F.; Asghari, A (24)</i>	YES	2016	English / Persian version	116	A* = 0,76 B** = 0,90	a = 0,71 b = 0,89
8. <i>Demirdel S, Ulaş K, Erol Çelik S, Karahan S, Topuz S. (25)</i>	YES	2022	English / Turkish	157	A* = 0,92 B* = 0,91	a = 0,84 b = 0,95

Table 4. Results of the OPUS studies, only of the lower extremity functionality module. Where: Complete (indicates whether or not all OPUS modules were studied); Year (of study); Language (of item/language, country of validation); n (sample size); Cronbach's α (coefficient).

<i>Author(s)</i>	<i>Functionality lower extremities</i>	<i>Year</i>	<i>Language Country</i>	<i>n (sampling size)</i>	<i>Reliability</i>	<i>Cronbach α</i>
<i>4 Jarl G.; Heinemann A.W.; Lindner H.Y.; Norling Hermansson LM (18)</i>	YES	2015	English / EEUU and Swedish	321 (195 = Swedish 126=EE. UU)	0,95	0,95

Table 5. Results of OPUS studies, only of the upper extremity functionality module. Where: Complete (indicates whether or not all OPUS modules were studied); Year (of study); Language (of item/language, country of validation); n (sample size); Cronbach's α (coefficient).

<i>Author(s)</i>	<i>Functionality upper extremities</i>	<i>Year</i>	<i>Language Country</i>	<i>n (sampling size)</i>	<i>Fiabilidad</i>	<i>Cronbach α</i>
9 <i>Burger, H.; Franchignoni, F.; Heinemann A.W.; Kotnik S.; Giordano A (13)</i>	YES	2008	English / Slovenian	37	0.91	0,95

POI 2022 REVIEWERS' CORRECTION REPORT

1
2 With gratitude for the work done by the reviewers of the journal, we proceed to list, argue,
3 make the changes and explanations suggested by them. We begin by analyzing and
4 modifying, point by point, the aspects specifically pointed out by the reviewers. At the
5 end, we proceed to establish generalities about the modifications and additional
6 specifications requested by the reviewers.
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11 The modifications have been delayed due to the delay in receiving the report from the
12 Psychometrics expert, given his multiple occupations.
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16 Title

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18 As suggested by reviewer number 2, the term "user" has been changed to "users".
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21 As suggested by reviewer 3, the initials of the tool have been capitalized, as in the original
22 by Allen Heinemann.
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26 Abstract

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28 In response to suggestions from **reviewers (1, 2 and 3)** to "highlight" more the lack of
29 articles/studies on the properties of OPUS, we have included terms and clarifications that
30 argue the statements so that they are not generalistic given the limited evidence base
31 (reviewer 1). Less generalist expressions have been included such as "until the necessary
32 achievement of a greater number of studies" and "until the present time" (reviewer 2).
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38 As suggested by **reviewer 2**, specific data on the results have been included in the
39 summary and, once the correspondence between the acronym of the questionnaire and its
40 content has been reflected, the subsequent "open versions" have been eliminated.
41
42
43

44 The objective is included in the abstract.
45
46

47 Background

48
49 I have proceeded according to the linear numerical order indicated by the reviewers:
50
51

52 **Line 26 (reviewer 2)** = Fully agree (has been modified) the WHO report refers, reading
53 the whole of it to prosthetic and orthotic users, however, in this point, they refer and word
54 it thus, including rehabilitation (but referring to such users).
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58 **Line 32 (reviewer 3)** = LINE 31; Fully in agreement with the possibility of reader
59 confusion, the term "orthoprosthesis" has been changed to "prosthesis/orthosis".
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Line 33 (reviewer 2) = In view of possible doubts of understanding for the reader, the term "orthoprosthesis" has been changed to "prosthesis or orthosis".

Line 39 (reviser 2) = The paragraph has been modified to make it easier to understand: what? and who?

Lines 43 to 46 and 47 to 50 (reviewer 2) = In view of the criterion of excessive length and given the suggestion that both paragraphs are very similar, both have been condensed into one. Thus the conceptualization is not repeated and the background is reduced.

Line 60 (reviewer 2) = After reflecting the correspondence between the acronym of the questionnaire and its content, the later "open versions" (OPUS and P&O) have been eliminated.

Reviewers 1, 2 and 3 = Terms unclear to the potential reader have been modified, unifying prosthesis and orthosis users. It should be clarified that the terminology is totally different in each country as regards the nomination of the prosthesis and/or orthosis specialist.

Following the suggestion, the term "calculate" has been changed to "evaluate" as indicated by the reviewer.

Line 63 (reviewer 2) = The Italian version, as in other countries (e.g. Spain) there is no registered questionnaire with these characteristics. It has been specified "the Italian validation reflects as...".

Line 68 (reviser 2) = The paragraph has been modified to correct the grammatical error.

Observations:

As suggested by **reviewers 1 and 2**, a more "neutral" voice has been used and with less generalist terms.

In response to the suggestion of clarification for possible readers of the objective, it is considered that by separating psychometric concepts in the inclusion of specific data in the summary (reliability and Crombach's α) which are those collected fundamentally by all the studies reflected and separating them from the sample size (not being a psychometric property) is clarified, in addition it is specified throughout the text, given that the measures investigated are those reflected in the identified texts. In case it does not seem so, we will be happy to modify it again.

1 Regarding the use of references, we have used references supporting the background that
2 are not included (due to inclusion criteria) in the OPUS systematic review of cross-
3 cultural validations. To reinforce the objective and accurately reflect our work, we have
4 included (when warranted) studies included in the review, arguing further the study.
5 However, if it does not seem appropriate, we will be happy to modify what we believe to
6 be substantial.
7
8
9

10 **Methods**

11
12 **Line 75 (reviewers 1, 2 and 3)** = As we wanted to be as specific as possible with the
13 methodology, taking care of the references used and strictly complying with the PRISMA
14 methodology and OSF registry, we must clarify that, as specified in the text, a cross-
15 cultural validation was carried out in 2001 in Spanish (Hispanic American) in Guatemala.
16 This validation was copyrighted but not published and was sent by the original author
17 (Dr. Allen Heinemann) to whom we are very grateful for his collaboration. Therefore,
18 this is the reason for the time interval. The year 2000 was established as the bibliographic
19 search term. It is modified according to his suggestion to 2001 to 2022.
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29 **Line 77 (reviewer 2)** = Pubmed and Embase are two fabulous databases of great scientific
30 rigor. In this case, the search engine Alcorze was included since, it was used and as the
31 methodological guidelines recommend specifying, it is a great search engine (where you
32 can select the publications of the best journals, classification, etc.), which does not have
33 the relevance (precisely because it is not named) and of enormous value and scientific
34 rigor. We would like to reflect this fact and to give value to the great work of the
35 University of Zaragoza to which all the contributors to this work belong. If you do not
36 find it appropriate, we can modify this aspect. In addition, through this one, due to the
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 - 57 2. Did not address validation in another language.
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2. Cross-cultural validations of OPUS in another language, for each specific country, other than the USA.
3. Validations in which at least the same psychometric data (reliability and Crombach's alpha) have been studied.
4. Validations where the sample size appears.
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6. Articles published between 2001 and 2022.
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Line 107 (reviewers 1, 2 and 3) = Reflected as an objective in the text and removed from the methodology.

Line 110 (reviewers 1, 2 and 3) = The wording of the paragraph has been changed for better understanding of the text in general. As part of methodology, as it summarizes the explanation of why they have been stipulated as such, since each study has performed and presented the data differently. So that similar data can be seen/appreciated in the article in a quick, summarized, and agile way.

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*The tables have been specified as follows:

1. Composition and general reflection of all common data (test-retest reliability; Crombach's alpha; sample size; language and country; authors/article).
2. Data have been extracted (specifically) for each module (tables 2,3,4 and 5).

*The parameters reflected in the tables are all those reflecting common data. The fundamental difference is the realization of test/re-test, work not carried out in all cases (so that in some cases they are reflected only as test). Depending on the study, they have been reflected and carried out with different methodologies, depending on the country.

*As specified by the expert in Psychometrics in his report and assessments (see background and text), the values and differences according to the classical theory of tests are now clear. Thank you for your suggestion, as it adds solidity to the article.

*You are right. With the expert's report and subsequent modifications we think it is more understandable. The main difference is whether or not to test/re-test.

Reference 25 (reviewers 1, 2 and 3)

Here we must apologize for the tremendous mistake made. We must admit that we are ashamed.

For reasons that we cannot explain (probably lack of rigor in the subsequent revision of the article), we came across this reference. It does not belong to this article. In fact, it explains the lack of the article corresponding to April 2022 referred to by reviewer 3. It was misplaced since the correct reference corresponds to that date and is the following:

1 Demirdel S, Ulaş K, Erol Çelik S, Karahan S, Topuz S. Reliability and validity of the
2 Turkish version of the satisfaction module of the Orthotics and Prosthetics Users' Survey.
3 Prosthet Orthot Int. 2022;46(2):170-174. DOI: [10.1097/PXR.0000000000000067](https://doi.org/10.1097/PXR.0000000000000067)
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6 We thank you very much for bringing this fact to our attention, which we understand as
7 a lack of quality in the article if it had been maintained. We apologize and ask for your
8 understanding.
9

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27 **Lines 153 to 162 (reviewer 2)** = has been removed from results.
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45 (writing) and the explanatory notes (tables) have been clarified accordingly. We expect
46 and consider (consensual with the experts) a greater correctness of understanding and
47 relationship. **Line 201** = The relationship and significance of Crombach's alpha is
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Line 212 (reviewer 2) = Has been moved to discussion.

Discussion

Discussion (reviewers 1, 2, and 3) = It has been rewritten to reflect the weaknesses of the study. Favorable points have been stated and the work has been discussed.

Reviewers (1, 2 and 3) = The conclusions, despite the inclusion of the psychometric expert's specifications, have been largely summarized. They are not excessively long. We consider that it responds to the objective of the text or we believe that the current wording complies with it.

General (reviewers 1, 2 and 3):

- Flowcharts from other reviews have been reviewed, PRISMA protocol, OSF suggestions have been followed, and it has been specifically referenced in the text. We hope that it will be understandable to the reader. In addition, the articles included in the method have been specified in an easily reproducible manner.
- Tables 1-5;
 - All table headings have been indicated more specifically. So that there is no doubt about the heading.
 - Residual Spanish words have been corrected and the data have been corrected (in reference case 25).
- As suggested in addition to the editors of the paper, the English edition has been revised by experts in Psychometrics given their high level in that language.
- The complete OPUS terms have been eliminated for their acronym throughout the text.
- Generalized qualification words have been eliminated, modifying it with more tentative terms.
- We consider that currently the objectives coincide with the discussion and conclusions.
- The overall length of the text has been reduced from 3756 words to 2784 words (text after the modifications suggested by the reviewers). Since content has been added, according to the recommendations and the Psychometrics expert's report.

- Related to the previous point, a bibliographic reference has been added, justifying the contents according to the classical Psychometric Theory (according to an expert).
- The article has been made with a more critical view of the study.
- The directors of the project are: Dr. César Hidalgo García (University of Zaragoza) and Dr. Pedro José Satústegui Dordá (University of Zaragoza).
- Reviewers/readers: Dr. Ana Alejandra Laborda Soriano (University of Zaragoza) and Vanessa Sanz López (Psychologist and Psychometrician).
- Psychometry expert: Dr. Carlos Salavera Bordás (Director of the Chair of TEA editors/University of Zaragoza).

In any case, we thank you very much for your contribution, as we consider it a remarkable improvement of the article and understanding for the readers. We look forward to hearing from you. Should you consider any additional changes, we will be pleased to make them.

Best regards

POI 2022 REVIEWERS' CORRECTION REPORT

With gratitude for the work done by the reviewers of the journal, we proceed to list, argue, make the changes and explanations suggested by them. We begin by analyzing and modifying, point by point, the aspects specifically pointed out by the reviewers. At the end, we proceed to establish generalities about the modifications and additional specifications requested by the reviewers.

The modifications have been delayed due to the delay in receiving the report from the Psychometrics expert, given his multiple occupations.

Title

As suggested by reviewer number 2, the term "user" has been changed to "users".

As suggested by reviewer 3, the initials of the tool have been capitalized, as in the original by Allen Heinemann.

Abstract

In response to suggestions from **reviewers (1, 2 and 3)** to "highlight" more the lack of articles/studies on the properties of OPUS, we have included terms and clarifications that argue the statements so that they are not generalistic given the limited evidence base (reviewer 1). Less generalist expressions have been included such as "until the necessary achievement of a greater number of studies" and "until the present time" (reviewer 2).

As suggested by **reviewer 2**, specific data on the results have been included in the summary and, once the correspondence between the acronym of the questionnaire and its content has been reflected, the subsequent "open versions" have been eliminated.

The objective is included in the abstract.

Background

I have proceeded according to the linear numerical order indicated by the reviewers:

Line 26 (reviewer 2) = Fully agree (has been modified) the WHO report refers, reading the whole of it to prosthetic and orthotic users, however, in this point, they refer and word it thus, including rehabilitation (but referring to such users).

Line 32 (reviewer 3) = LINE 31; Fully in agreement with the possibility of reader confusion, the term "orthoprosthesis" has been changed to "prosthesis/orthosis".

Line 33 (reviewer 2) = In view of possible doubts of understanding for the reader, the term "orthoprosthesis" has been changed to "prosthesis or orthosis".

Line 39 (reviser 2) = The paragraph has been modified to make it easier to understand: what? and who?

Lines 43 to 46 and 47 to 50 (reviewer 2) = In view of the criterion of excessive length and given the suggestion that both paragraphs are very similar, both have been condensed into one. Thus the conceptualization is not repeated and the background is reduced.

Line 60 (reviewer 2) = After reflecting the correspondence between the acronym of the questionnaire and its content, the later "open versions" (OPUS and P&O) have been eliminated.

Reviewers 1, 2 and 3 = Terms unclear to the potential reader have been modified, unifying prosthesis and orthosis users. It should be clarified that the terminology is totally different in each country as regards the nomination of the prosthesis and/or orthosis specialist.

Following the suggestion, the term "calculate" has been changed to "evaluate" as indicated by the reviewer.

Line 63 (reviewer 2) = The Italian version, as in other countries (e.g. Spain) there is no registered questionnaire with these characteristics. It has been specified "the Italian validation reflects as...".

Line 68 (reviser 2) = The paragraph has been modified to correct the grammatical error.

Observations:

As suggested by **reviewers 1 and 2**, a more "neutral" voice has been used and with less generalist terms.

In response to the suggestion of clarification for possible readers of the objective, it is considered that by separating psychometric concepts in the inclusion of specific data in the summary (reliability and Cronbach's α) which are those collected fundamentally by all the studies reflected and separating them from the sample size (not being a psychometric property) is clarified, in addition it is specified throughout the text, given that the measures investigated are those reflected in the identified texts. In case it does not seem so, we will be happy to modify it again.

Regarding the use of references, we have used references supporting the background that are not included (due to inclusion criteria) in the OPUS systematic review of cross-cultural validations. To reinforce the objective and accurately reflect our work, we have included (when warranted) studies included in the review, arguing further the study. However, if it does not seem appropriate, we will be happy to modify what we believe to be substantial.

Methods

Line 75 (reviewers 1, 2 and 3) = As we wanted to be as specific as possible with the methodology, taking care of the references used and strictly complying with the PRISMA methodology and OSF registry, we must clarify that, as specified in the text, a cross-cultural validation was carried out in 2001 in Spanish (Hispanic American) in Guatemala. This validation was copyrighted but not published and was sent by the original author (Dr. Allen Heinemann) to whom we are very grateful for his collaboration. Therefore, this is the reason for the time interval. The year 2000 was established as the bibliographic search term. It is modified according to his suggestion to 2001 to 2022.

Line 77 (reviewer 2) = Pubmed and Embase are two fabulous databases of great scientific rigor. In this case, the search engine Alcorze was included since, it was used and as the methodological guidelines recommend specifying, it is a great search engine (where you can select the publications of the best journals, classification, etc.), which does not have the relevance (precisely because it is not named) and of enormous value and scientific rigor. We would like to reflect this fact and to give value to the great work of the University of Zaragoza to which all the contributors to this work belong. If you do not find it appropriate, we can modify this aspect. In addition, through this one, due to the agreements with this university, it is possible to have access to paid articles.

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The text has been modified with the exact reflection of the search terms and criteria (inclusion/exclusion) for better reading comprehension. It was not reflected previously because we tried to summarize as much as possible (by number of words).

We thank you for your suggestions, since your external view enriches the reading and understanding of the text.

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In any case, we thank you very much for your contribution, as we consider it a remarkable improvement of the article and understanding for the readers. We look forward to hearing from you. Should you consider any additional changes, we will be pleased to make them.

Best regards

**Validation into Spanish (Castilian) Orthotics and Prosthetics User Survey OPUS
(Orthotics and Prosthetics User Survey)**

Julián Manuel Valero González



**Escuela de Doctorado
Universidad Zaragoza**



**Facultad de
Ciencias de la Salud
Universidad Zaragoza**

Consent to use, collaboration, and participation (creator and author of the Orthotics and Prosthetics User Questionnaire, OPUS).

Information

The Orthotics and Prosthetics User Survey OPUS has been validated in several languages and is being implemented in several countries as a tool for practitioners and users.

The several studies on the evaluation of individual items, underlying constructs and on the clinical sensitivity of each group of items, the correlations and the performance of OPUS, reflect that it can be a useful clinical management tool for use with orthotic and prosthetic clients, both for assessing quality improvement, changes in functionality, quality of life in users and satisfaction with orthotic and prosthetic devices.

The Orthotics and Prosthetics User Survey OPUS has been chosen by the Doctoral Program of Health and Sports Sciences of the University of Zaragoza for its complete integration of data, needs and performance. It reflects by modules the assessments of the quality-of-life index, the functionality of the upper and/or lower limb, the user's satisfaction with the prosthesis, the quality and evaluation of the health services of the prosthetic amputee. Likewise, the OPUS questionnaire (studied in hospitals in the United States and Canada) has high psychometric properties and internal consistency, although it has a low correlation value.

For all the above reasons, the objectives of this thesis in its first phase of study have been aimed at validating a questionnaire that can be implemented in clinical practice in a standardized manner in a cross-cultural manner in Spanish. Useful and necessary to collect the needs and efficacy of users with prosthetic limbs, for professionals in the field, thus being able to define the needs of those affected, favouring a totally individualized and cost-effective application of health resources.

**Validation into Spanish (Castilian) Orthotics and Prosthetics User Survey OPUS
(Orthotics and Prosthetics User Survey)**

Julián Manuel Valero González

To carry out and develop the work, it will be imperative to reflect the validity and specificity of the questionnaire used, placed in the context of the Spanish language, to expose and reflect other existing assessment systems, their application, specificity, and population adaptation.

This implies knowing the existing assessments/questionnaires, the opinion of experts, professionals, and associations of affected people on their ease of interpretation and use.

Given the need for multiple permissions and documentation from the University and official bodies to accredit the possibility of using the resulting questionnaire and validate it in Spanish (Castilian), I would be grateful if you would sign the following consent form. Thank you very much.

Please read and complete according to your interests.

The author of the Orthotics and Prosthetics User Questionnaire: **Allen Heinemann, PhD** (Director, Center for Rehabilitation Outcomes Research @ Shirley Ryan AbilityLab. Professor, Physical Medicine and Rehabilitation, Feinberg School of Medicine @ Northwestern University) below the undersigned person (please fill in the appropriate box(es) with an X);

Accepts the validation in Spanish (Castilian) of his/her work, on all the modules of the OPUS questionnaire).

You do not accept that your work is validated in Spanish (Castilian), on all or some of the modules of the OPUS questionnaire.

About your name:

You agree to have your name included in publications, acknowledgements and

works for academic, clinical and research purposes.

You do not agree to have your name included in publications, acknowledgements and works for academic, clinical and research purposes.

Validation into Spanish (Castilian) Orthotics and Prosthetics User Survey OPUS
(Orthotics and Prosthetics User Survey)
Julián Manuel Valero González

About the processing of your personal data:

You accept that your data and opinions will be treated with the appropriate confidentiality under the protection and according to:

- Organic Law 15/1999, the purpose of which guarantees and protects, with regard to the processing of personal data, public freedoms and also the fundamental rights of natural persons, and especially their honor, intimacy, personal and family privacy.
- Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the guarantee of digital rights.

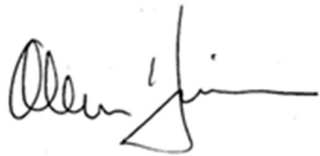
And under its protection may refuse to participate in this research, validation work at any time, in whole or in part.

I declare that I have read, understood, and accepted the consent.

For the record and for all necessary purposes.

Name: Allen Heinemann

Signed:



In Chicago USA on 4 October 2022.