La falta de la Escala de Impacto Familiar (FIS) en el idioma español limita su uso como indicador en países hispanohablantes, así como impide las comparaciones con diferentes grupos culturales y étnicos. Por lo tanto, el objetivo de este estudio fue adaptar transculturalmente el FIS al idioma español de Perú y evaluar su validad y confiabilidad. Para traducir y adaptar transculturalmente el FIS, 60 padres respondieron al instrumento en dos pruebas piloto. Posteriormente, el FIS fue probado en 200 padres de niños de 11 a 14 años de edad, quienes fueron clínicamente evaluados para la experiencia de caries dental y maloclusiones. La consistencia interna fue evaluada por el coeficiente alfa de Cronbach, mientras que la re-aplicación del FIS en los mismos 200 padres permitió la evaluación de la confiabilidad test-retest por medio del coeficiente de correlación intraclase (CCI). La validez de constructo y discriminante se basaron en asociaciones del FIS con las puntuaciones globales de salud bucal y grupos clínicos, respectivamente. La media (desviación estándar) de la puntuación total del FIS fue 5.20 (5.86). La consistencia interna fue confirmada por el coeficiente alfa de Cronbach de 0.84. La confiabilidad test-retest reveló una excelente reproducibilidad (CCI = 0.96). La validez de constructo fue buena, demostrando statistically significant associations entre total FIS score and global ratings of oral health (p<0.007) and overall wellbeing (p<0.002), así como for the subscale scores (p<0.05) con excepción de la sub-escala de carga financiera. El FIS fue capaz de discriminar niños con y sin caries dental y maloclusiones (p<0.05). Satisfactorio psychometric results for the Peruvian Spanish FIS confirm it as a reliable, valid instrument for assessing the impact on the family caused by children’s oral conditions.

Palabras clave: salud bucal; calidad de vida; familia.
INTRODUCTION
Oral diseases and disorders are common during childhood and have a negative impact on children’s oral health-related quality of life (OHRQoL)\(^1,2\). The American Academy of Pediatrics defines child health as "the social, physical and emotional functioning of the child and, when indicated, his or her family... therefore, measurement of health-related quality of life must be from the perspective of the child and the family"\(^3\). However, there are few instruments that evaluate the impact of a child’s oral condition on the family’s quality of life (QoL). The only instrument available for this purpose is the Family Impact Scale (FIS)\(^4\).

To date, the validity and reliability of the FIS have been demonstrated in English-speaking parents in Canada\(^5\), United Kingdom\(^6\), China\(^7\) and Brazil\(^8\). Nevertheless, although it has been validated in some languages, to the best of our knowledge, it has not been cross-culturally adapted and validated in Spanish. The lack of the FIS in Spanish language limits its use in Spanish-speaking countries, such as Peru, and precludes comparisons with data from other cultural and ethnic groups\(^9\). In addition, the FIS has a potential role considering that a parent’s reports of the child’s oral health or OHRQoL may be influenced by the degree to which the parent is physically or psychological affected by the child’s condition\(^5,10\).

Therefore, the aim of the present study was to carry out the cross-cultural adaptation of the FIS to the Peruvian Spanish language and to test its reliability and validity.

MATERIAL AND METHODS
The study was approved by the Human Research Ethics Committee of the Científica del Sur University, Peru. The participants’ legal guardians signed an informed consent form.

Description of the Family Impact Scale (FIS)
The FIS consists of 14 items divided into three subscales: parental / family activity (PA), parental emotions (PE), family conflict (FC) and financial burden (FB). The items refer only to the frequency of events in the previous 3 months. The items have five Likert response options: ‘never = 0’, ‘once or twice = 1’, ‘sometimes = 2’, ‘often = 3’, and ‘every day or almost every day = 4’. The number of ‘don’t know’ responses was counted, but excluded from the total FIS score for each patient.

Total FIS scores and scores for individual subscales are calculated as a simple sum of the response codes. Since there are 14 items, the final score can range from 0 to 56, where a higher score denotes greater impact of a child’s oral condition on family QoL. Following the validation process of the original FIS, answers were obtained to two questions asking the parents for global ratings of their children’s oral health and the extent to which their oral health affected their overall well-being\(^5\). These global ratings had a five-point response format. The responses were scored as follows: “excellent”=0, “very good”=1, “good”=2, “average”=3, “poor”=4 for oral health, and not at all=0, very little=1, somewhat=2, a lot=3 and very much=4 for general wellbeing.

Translation and Adaptation of the FIS
The original FIS was translated and adapted to Spanish for Peru following standard guidelines\(^11-13\). Based on these guidelines, two initial translations into Spanish were made independently by two native Spanish translators. Both translations were reviewed in a consensus meeting in Peru. The Review Panel for this meeting consisted of four postgraduate professors, fluent in both Spanish and English, who knew the objectives of the study and had experience in OHRQoL studies\(^13\). The Review Panel evaluated the translations and determined the conceptual and item equivalence in order to retain content similarity in the different cultures. A consensus-translated version of the FIS was developed as a result of this process and then pilot-tested on a convenience sample of 40 parents of children aged 11–14 years old. Modifications were made according to parents’ suggestions, in order to clarify the content of the instrument. The panel developed a first Peruvian version of the FIS, which was translated back into English by two native English-speaking translators. The back-translated English consensus version was compared to the original English version to determine semantic equivalence.

Finally, the draft of the first version of the FIS was pilot-tested for a second time on a different convenience sample of twenty parents of 11-to-14-year-old children. There was no change in terms of new suggestions or difficulties in comprehension, and the Review Panel wrote the final Peruvian version of the FIS.
The Peruvian version of the FIS during pilot tests and assessment of psychometric properties was administered in face-to-face independent interviews. Structures, instructions, mode of administration and measurement methods of the instrument were similar to the original English version of the FIS.

Assessment of validity and reliability

Validity is usually assessed on a sample size of 50 to 200 people in a cross-sectional design, while test-retest reliability is assessed on a sub-sample (of about 10% or 30 people)\(^{10-11}\). In line with this requirement, the Peruvian version of the FIS was administered in face-to-face independent interviews with 200 parents of 11- to 14-year-olds from four schools – two public schools in a deprived area and two private schools in a wealthy area. All schools were located in the city of Lima, capital of Peru. Children were randomly selected from official school registries. All parents were invited to participate in the study according to the following inclusion criteria: parents who have children with no systemic and/or neurological diseases, with children who could be examined intra-orally and who had not received dental treatment during the study.

Interviews were carried out before the clinical oral examinations by three trained interviewers who were blind to the oral screening examination findings. The interviewers were trained in the administration and intonation of each item of the Peruvian FIS. They were also clearly instructed to avoid suggesting responses or showing the answer options while reading them.

The children’s oral examinations looked at dental caries and malocclusions and were carried out by a single specialist in pediatric dentistry who was previously trained and calibrated (Kappa intra-agreement = 0.92 and 0.89 for dental caries and malocclusions, respectively). Dental caries experience was assessed as number of decayed, missed and filled teeth (DMFT)\(^4\). Then, children were divided into two clinical groups\(^5\): those with no dental caries experience (DMFT=0) vs. those with dental caries experience in one or more teeth (DMFT \(\geq\)1). Malocclusions were classified using the Dental Aesthetic Index (DAI)\(^6\), and the children were divided into two clinical groups: children with malocclusions and without malocclusions.

Data analysis

The SPSS software program (version 17.0 SPSS Inc., Chicago, IL, USA) was used for data analysis. Descriptive analyses were performed initially to assess the prevalence of oral impacts and measures of central tendency (means and standard deviations) of total and individual domain scores of the Peruvian FIS.

Internal consistency of the FIS was assessed using Cronbach’s alpha, inter-item and item-total correlation coefficients. The test-retest reliability was assessed by calculating the Intraclass Correlation Coefficient (ICC) for the FIS score using the data from the same 200 parents who were interviewed for a second time, 7–14 days after the first interview, by the same interviewers.

To test construct validity, correlations between the scores of each subscale, total scale and global ratings were analyzed using Spearman’s correlation coefficient. Discriminant validity was tested by comparing the mean FIS scores between children with caries experience/malocclusions and those without. As the FIS scores were not normally distributed, the nonparametric Mann-Whitney test was used to evaluate the difference in mean scores between clinical groups. The level of significance was set at 0.05.

RESULTS

A total 243 parents were invited to participate in the validation study, of whom 43 were not included because they did not conform to the study criteria. All 200 eligible parents provided signed parental informed consent, resulting in a response rate of 82.3%.

Of the 200 parents interviewed, 85.0% were mothers and 15.0% fathers. The mean (standard deviation) age of children was 12.5 (1.12), of whom 95 (47.5%) attended public schools and 105 (52.5%) attended private schools. Of these, 54.0% were girls and 46.0% boys, and a total 108 (54.0%) and 148 (74.0%) had dental caries experience and presence of malocclusions, respectively. All questionnaires were completed. The scores for the total scale in the study population ranged from 0 to 28, with a mean (standard deviation) of 5.20 (5.86). Overall, 64.5% of parents reported oral impact (total FIS scores >0). Of these, 121 parents (60.5%) reported experiencing impact on parental/family activity; 110 (55.0%) reported impact on
parental emotions; 98 (49.0%) reported impact on family conflict and 46 (23.0%) reported financial burden impacts.

Reliability
Cronbach’s alpha coefficient was 0.84 for the total scale and ranged from 0.23 for financial burden subscale to 0.77 for parental/family activity subscale (Table 1). Test-retest reliability was assessed using the ICC, which was 0.96 for the total scale ranging from 0.78 for financial burden subscale to 0.97 for parental/family activity subscale (Table 1).

Construct validity
The correlations between global ratings (oral health and overall well-being) and the full scale (r= 0.190 and r= 0.214), parental/family activity subscale (r= 0.195 and r= 0.241) and family conflict subscale (r= 0.158 and r= 0.140) were not strong but statistically significant (Table 2). The financial burden subscale was not significantly associated to global ratings.

Discriminant validity
There was a significant difference in total scale and subscales scores of the FIS between children without dental caries experience and those with dental caries experience in one or more teeth (Table 3). This result was similar for malocclusion groups (Table 4).

DISCUSSION
This study adapted and validated the FIS cross-culturally for use among Peruvian parents. To the best of our knowledge, this is the first study that has adapted and evaluated the psychometric properties of this measure in a Latin American language such as Spanish after its original validation in English.

Table 1: Reliability statistics for total FIS scale and subscales (n = 200).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number of items</th>
<th>Cronbach’s alpha</th>
<th>Intraclass correlation coefficient (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total scale</td>
<td>14</td>
<td>0.84</td>
<td>0.96 (0.90-0.98)</td>
</tr>
<tr>
<td>Subscales</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parental/family activity</td>
<td>5</td>
<td>0.77</td>
<td>0.97 (0.94-0.94)</td>
</tr>
<tr>
<td>Parental emotions</td>
<td>4</td>
<td>0.70</td>
<td>0.96 (0.93-0.98)</td>
</tr>
<tr>
<td>Family conflict</td>
<td>4</td>
<td>0.68</td>
<td>0.96 (0.91-0.98)</td>
</tr>
<tr>
<td>Financial burden</td>
<td>1</td>
<td>0.23</td>
<td>0.78 (0.67-0.85)</td>
</tr>
</tbody>
</table>

*Two-way random effects model: p < 0.001 for all values

Table 2: Construct validity: rank correlations between total FIS scale and subscale scores, and global rating of oral health and overall wellbeing (n = 200).

<table>
<thead>
<tr>
<th></th>
<th>Global ratings</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Oral health</td>
<td>Overall wellbeing</td>
</tr>
<tr>
<td></td>
<td>r*</td>
<td>p-value</td>
<td>r*</td>
</tr>
<tr>
<td>Total scale</td>
<td>0.190</td>
<td>0.007</td>
<td>0.214</td>
</tr>
<tr>
<td>Subscales</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parental/family activity</td>
<td>0.185</td>
<td>0.006</td>
<td>0.241</td>
</tr>
<tr>
<td>Parental emotions</td>
<td>0.181</td>
<td>0.007</td>
<td>0.221</td>
</tr>
<tr>
<td>Family conflict</td>
<td>0.158</td>
<td>0.025</td>
<td>0.140</td>
</tr>
<tr>
<td>Financial burden</td>
<td>-0.064</td>
<td>0.369</td>
<td>0.047</td>
</tr>
</tbody>
</table>

*Spearman’s rank correlation coefficient
When a QoL instrument is translated for use in a context and country different from those it was created in, the cross-cultural adaptation should be evaluated, considering that it will be influenced by the wider social context including family environment, friends, schools and cultural customs in different countries. By adapting the QoL instrument, its validity and reliability will be similar to those in the original version. Our study meticulously applies standard guidelines for the translation and cross-cultural adaptation of QoL measures and conducts pilot tests to identify any potential problems in its content, such as misunderstandings of the intended meaning of the items, clarity and cultural relevance. The results showed semantic equivalence between the English and Peruvian Spanish language versions of the FIS. The Peruvian version of the FIS for the Spanish language also exhibited good psychometric properties and provided acceptable support for its validity and reliability. Test-retest reliability was confirmed by the ICC, which showed excellent correlations between the first and second total FIS scale and subscales scores. Cronbach’s alpha coefficient for the full scale and subscales indicates good internal consistency, as values of 0.5 or above are considered acceptable. Similar results were obtained in the Canadian, Chinese and Brazilian validation studies.

Concerning construct validity, our findings on the associations of the full FIS scale and subscale scores with global ratings on oral health and overall well-being proved the validity of the measure, except between the financial burden (FB) subscale and global ratings. In agreement with our study, the Brazilian FIS version also found that the FB subscale did not correlate with global ratings. In contrast, in the Chinese version, the FB subscale was only associated with the overall wellbeing rating. In Canada, the FB subscale was associated

### Table 3: Discriminant validity: total FIS scale and subscales scores for children without and with caries experience.

<table>
<thead>
<tr>
<th></th>
<th>Without caries experience (n=92)</th>
<th>With caries experience (n=108)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total scale</td>
<td>Mean(SD) 1.49 (2.51) Median 0.00</td>
<td>Mean(SD) 8.36 (6.06) Median 8.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Parental/family activity</td>
<td>Mean(SD) 0.65 (1.15) Median 0.00</td>
<td>Mean(SD) 3.04 (2.39) Median 2.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Parental emotions</td>
<td>Mean(SD) 0.53 (1.03) Median 0.00</td>
<td>Mean(SD) 2.61 (1.96) Median 3.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Family conflict</td>
<td>Mean(SD) 0.23 (0.54) Median 0.00</td>
<td>Mean(SD) 2.19 (2.13) Median 2.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Financial burden</td>
<td>Mean(SD) 0.08 (0.30) Median 0.00</td>
<td>Mean(SD) 0.52 (0.77) Median 0.00</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Mann-Whitney test

### Table 4: Discriminant validity: total FIS scale and subscale scores for children without malocclusion and with malocclusion.

<table>
<thead>
<tr>
<th></th>
<th>Without malocclusion (n=52)</th>
<th>With malocclusion (n=148)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total scale</td>
<td>Mean(SD) 2.96 (4.40) Median 0.00</td>
<td>Mean(SD) 5.99 (6.11) Median 4.00</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Parental/family activity</td>
<td>Mean(SD) 1.31 (2.01) Median 0.00</td>
<td>Mean(SD) 2.16 (2.31) Median 1.50</td>
<td>0.007</td>
</tr>
<tr>
<td>Parental emotions</td>
<td>Mean(SD) 0.98 (1.54) Median 0.00</td>
<td>Mean(SD) 1.89 (1.87) Median 2.00</td>
<td>0.002</td>
</tr>
<tr>
<td>Family conflict</td>
<td>Mean(SD) 0.56 (1.06) Median 0.00</td>
<td>Mean(SD) 1.55 (2.04) Median 1.00</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Financial burden</td>
<td>Mean(SD) 0.12 (0.58) Median 0.00</td>
<td>Mean(SD) 0.39 (0.65) Median 0.00</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*Mann-Whitney test
with both global indicators. This may be because the FB subscale comprises a single item and addresses economic rather than psychosocial or behavioral impact. It has therefore been recommended that the full scale score be used as a primary outcome, as there is stronger support for its validity than for the subscales alone. The ability of the Peruvian FIS to discriminate significantly between different clinical groups according to caries experience and presence of malocclusions was also demonstrated. Similar results were found in the Chinese validation. However, the Canadian and Brazilian FIS versions did not find significant differences between clinical groups in total scores. Considering the mean values found for both clinical groups in our study, children with dental caries experience achieved higher scores on the total scale and subscales than the malocclusion group, indicating that dental caries could have higher negative impact than malocclusion at this sample age. This may be because dental caries commonly causes toothache and discomfort, demanding more parental attention and concern than malocclusions, which do not usually produce oral symptoms. Parents may thus choose to treat malocclusions or not, sometimes also resulting in higher treatment costs.

Since the FIS is a short instrument, it can be used in epidemiological surveys and also as an indicator for purposes such as political, research, public health and clinical actions.

CONCLUSION

The Peruvian Spanish version of the FIS proved to be valid and reliable for assessing the impact of a child’s oral condition on the family’s quality of life.

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