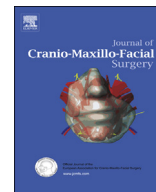




Contents lists available at ScienceDirect

## Journal of Cranio-Maxillo-Facial Surgery

journal homepage: [www.jcmfs.com](http://www.jcmfs.com)

## Cross-cultural adaptation and validation of the Spanish version of the Orthognathic Quality of Life Questionnaire for patients with dentofacial deformities



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### ARTICLE INFO

#### Article history:

Paper received 7 June 2020

Accepted 25 October 2020

Available online 31 October 2020

#### Keywords:

Oral health-related quality of life

Orthognathic surgery

Patient-reported outcome measures

### ABSTRACT

**Objective:** The aim of this study was to develop a Spanish version of the Orthognathic Quality of Life Questionnaire (OQLQ) that is conceptually equivalent to the original questionnaire, as well as acceptable, reliable, valid, and responsive for use in Chilean patients with dentofacial deformities.

**Material and methods:** The recommended standard methodology, with direct and back-translation, was used. A prospective longitudinal multicenter study of adult patients diagnosed with dentofacial deformity was carried out, self-administrating OQLQ, OHIP-14 (Oral Health Impact Profile), and SF-36 (Short Form 36 Health Survey) during the presurgery visit in order to examine construct validity. To evaluate reproducibility, questionnaires were re-administered 4 weeks later to subjects with a stable dental condition. Responsiveness was assessed among subjects followed up until 3 months after surgery.

**Results:** Of the 230 patients under presurgical orthodontic treatment included in the study, 216 completed the questionnaire, 142 formed the reliability sub-sample, and 30 were evaluated 3 months after surgery. Cronbach's alpha ranged from 0.78 to 0.94 and test-retest intraclass correlation coefficients ranged from 0.84 to 0.91 ( $p = 0.001$ ) by dimension. The correlation matrix between OQLQ dimensions and SF-36 and OHIP-14 confirmed most of the associations previously hypothesized as moderate ( $r_s > 0.4$ ). Confirmatory factor analysis supported the same structure as the original instrument, considering four dimensions. Responsiveness was demonstrated by the large improvement observed in the global score 3 months after surgery: mean change  $\pm$ SD =  $-15.1 \pm 18.05$  and standard response mean =  $-0.84$  ( $p < 0.001$ ).

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**Conclusions:** The Spanish version of OQLQ has demonstrated good levels of reliability, validity, and responsiveness – similar to those of the original questionnaire.

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## 1. Introduction

Dentofacial deformities have been defined as conditions in which the facial skeleton diverges from normality, there is malocclusion (dentomaxillary anomalies), and facial appearance is affected (Posnick, 2014). It is estimated that approximately 5% of the US or UK population have dentofacial deformities that are treated with a combination of orthodontic and surgical treatment (Harrington et al., 2015).

Dentomaxillary anomalies are among the oral health problems that are most perceived by the population, because they affect the aesthetics and functionality of the stomatognathic system, the quality of social relations, and self-esteem (Echeverría et al., 2019). The need to treat dentofacial deformities is mainly based on functional and psychosocial factors, with quality of life improvement as the ultimate goal for these patients.

The Orthognathic Quality of Life Questionnaire (OQLQ) was developed in the UK (Cunningham et al., 2000) with the aim of evaluating the benefits of orthognathic surgery in terms of its effect on Oral Health-Related Quality of Life (OHRQoL). In 2002, the validity and sensitivity to change of the questionnaire was reported (Cunningham et al., 2002). The OQLQ is the only instrument specifically designed to assess OHRQoL in patients with dentofacial deformities. Other questionnaires, such as the Malocclusion Impact Questionnaire, have been developed to evaluate young people with dentomaxillary anomalies, but not patients with dentofacial deformities (Benson et al., 2016).

Prior to development of the OQLQ, studies in patients with this condition frequently used generic questionnaires, such as the Short Form 36 Health Survey (SF-36) and the Oral Health Impact Profile (OHIP-14) (Soh and Narayanan, 2013). The OQLQ has been adapted for other languages: German (Bock et al., 2009), Arabic (Abdullah, 2015), and Portuguese (Bortoluzzi et al., 2011; De Araújo et al., 2013).

The aim of this study was to develop a Spanish version of OQLQ that is conceptually equivalent to the original questionnaire, as well as acceptable, reliable, and valid for use in the Chilean patients with dentofacial deformities.

## 2. Material and methods

### 2.1. Description of the Orthognathic Quality of Life Questionnaire

The OQLQ is a self-administered instrument with 22 items (Cunningham et al., 2000, 2002) covering four domains: facial aesthetic (five items, score range 0–20), oral function (five items, score range 0–20), awareness of dentofacial deformity (four items, score range 0–16), and social aspects of dentofacial deformity (eight items, score range 0–32). Each question is rated on a five-point Likert scale ranging from 'does not bother me at all' (score 0) to 'bothers me a lot' (score 4). The total score range is from 0 to 88. A lower score indicates a better OHRQoL (Cunningham et al., 2002).

### 2.2. Translation and cross-cultural adaptation

The objective of the process of cross-cultural adaptation is to achieve an equivalence of meanings between the culture in which the questionnaire was developed and that in which it is intended to

be applied. The process was carried out according to the methodology recommended for these purposes (Guillemin et al., 1993; Hunt et al., 1991), following four steps: 1) direct translation; 2) translation synthesis; 3) back-translation; and 4) cognitive debriefing.

- Step 1 – direct translation: A conceptual translation of the instrument was carried out by two independent bilingual translators whose mother language was the target language (Spanish). Directions were provided to translators, emphasizing semantic/conceptual equivalence and trying to make sense of the items in Spanish, but without changing the meaning or intention of the original version.
- Step 2 – translation synthesis: The translations were analyzed by a multidisciplinary committee of experts, who identified the discrepancies between both translations until consensus was reached and a single synthesis version was obtained.
- Step 3 – back-translation (reverse translation): The synthesis version was translated into the original English language by two bilingual translators whose native/mother language was British English, as in the original instrument, and who were blind to the original questionnaire. The back-translation report was sent to the developer for identification of significant semantic or conceptual differences with respect to the original questionnaire.
- Step 4 – cognitive debriefing: A total of 20 patients with dentofacial deformities were asked to respond to the consolidated Spanish version, and to comment on any aspect that was difficult to understand. All the patients said that the questionnaire was easy to understand, easy to answer, and closely related to their problems. The response to the questionnaire required approximately 10–15 min, with no suggestions for modification. The version obtained at the end of the process of direct translation and back translation was approved by the author of the original questionnaire, Dr S. Cunningham.

### 2.3. Study of metric properties of the OQLQ Spanish version

This was a prospective longitudinal multicenter study of patients with dentofacial deformities, recruited from public and private clinics specialized in the treatment of dentofacial deformities with orthognathic surgery. Inclusion criteria were: over 18 years of age, diagnosis of dentofacial deformity confirmed, and informed consent to participate before surgical treatment. Exclusion criteria were: dentomaxillary anomalies and/or dentofacial deformities in the context of syndromes (e.g. Pierre Robin sequence or cleft lip and palate), or sequelae due to maxillofacial trauma.

The sample size was calculated as 110 patients, according to the recommended 5:1 proportion of subjects with respect to the number of variables (items) (Anthoine et al., 2014).

### 2.4. Instruments of measurement

Once written consent was obtained from the patients, socio-demographic data were recorded and the OQLQ, OHIP-14, and SF-36 were self-administered during the clinical visit.

The OHIP-14 (Locker, 1988; Slade and Spencer, 1994; Rodakowska et al., 2014) assesses seven OHRQoL dimensions:

functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap (Montero-Martín et al., 2009). Each dimension comprises two different questions from a total of fourteen, referring to a period of 1 year. Response options are on five-point Likert scales, and the scores are computed by adding responses. The total score ranges between 0 and 56, with higher scores indicating worse OHRQoL.

The SF-36 version 2 (SF-36v2) is a generic health-related, quality-of-life questionnaire (Alonso et al., 1998; Vilagut et al., 2005), which consists of 36 questions that measure eight domains. Scores are constructed for domains and for two component summaries – physical and mental (Németh, 2005; Farivar et al., 2007). Unlike the OQLQ and OHIP-14, higher SF-36 scores imply better HRQoL (Vera-Villarroel et al., 2014).

### 2.5. Metric properties evaluated: Reliability, validity, and responsiveness

Reliability refers to the degree to which an instrument is free of random error (Aaronson et al., 2002). To measure this metric property, internal consistency and test–retest reproducibility were assessed. For the latter, the OQLQ was applied twice, with 4 weeks between tests, in the reproducibility subsample. The reproducibility subsample, defined by stability of the clinical condition measured, comprised patients undergoing presurgical treatment who were not subjected to any intervention (such as installation of splints or removal of third molars) during the following 4 weeks.

Validity refers to the degree to which the instrument measures what it purports to measure (Aaronson et al., 2002). Specifically, construct validity refers to evidence that supports a proposed interpretation of scores based on theoretical implications associated with the constructs being measured, through factorial analysis and examining the logical relations that should exist with other measurements (Garín et al., 2008; Comín-Colet et al., 2011). Because the OQLQ is the only existing specific condition instrument for evaluating OHRQoL in patients with dentofacial deformities, the logical relationships with SF-36 and OHIP-14 questionnaires, both previously translated and validated for use in Chile (Olivares-Tirado, 2005; León et al., 2014), were hypothesized and tested.

According to the construct validity hypothesis proposed by developers, since it primarily addresses the mental and social impacts of dentofacial deformities, there would be: moderately negative correlations between the OQLQ domains and the SF-36 mental component summary, and poor correlations with the SF-36 physical component summary – physical functioning, role-physical, and bodily pain domains. On the other hand, moderately positive correlations were expected between OQLQ and OHIP-14 domains, since both measured OHRQoL using similar domains: social aspects/social disability, oral function/functional limitations and physical disability, and awareness/psychological discomfort.

Finally, responsiveness is viewed as an important part of the longitudinal construct validation process. Responsiveness refers to an instrument's ability to detect change (Aaronson et al., 2002). To evaluate responsiveness, instruments were applied twice: 1 week before surgery (T1) and then 3 months after surgery (T2) in the first 30 completed cases.

A global change question was also administered 3 months after surgery, asking participants if their dental/facial problems were much better/better/the same/worse or much worse than before treatment.

### 2.6. Statistical analysis

Sociodemographic characteristics of the participants and questionnaire scores were described and analyzed using  $\chi^2$  for categorical variables, and parametric or non-parametric tests for continuous variables (according to their distribution). Feasibility was assessed by calculating the percentage of patients with some item not answered in each dimension.

Confirmatory factorial analysis was carried out to confirm the structure of the Chilean version of the instrument in four dimensions and a global construct proposed by developers. This was performed using the weighted least squares method, and its goodness of fit was assessed using the comparative fit index, the Tucker–Lewis index, and the root mean square error of approximation. For the comparative fit index and Tucker–Lewis index, values equal to or greater than 0.90 suggested an acceptable fit of the model; while for root mean square error of approximation, values needed to be below 0.08, or ideally below 0.05 (Hu and Bentler, 1999).

To examine the distribution of scores, statistics of central tendency and dispersion, observed range, and ceiling and floor effects (percentage of patients with maximum and minimum scores, respectively) were calculated.

To assess reliability, internal consistency was estimated using the Cronbach alpha coefficient (Cronbach, 1951), and test–retest reproducibility was estimated using the intraclass correlation coefficient (Prieto et al., 1998), which was calculated with data for the two evaluations in the reproducibility sub-sample. Reliability coefficients  $>0.70$  were considered acceptable,  $0.71–0.80$  respectable, and  $>0.80$  very good (Cortina, 1993).

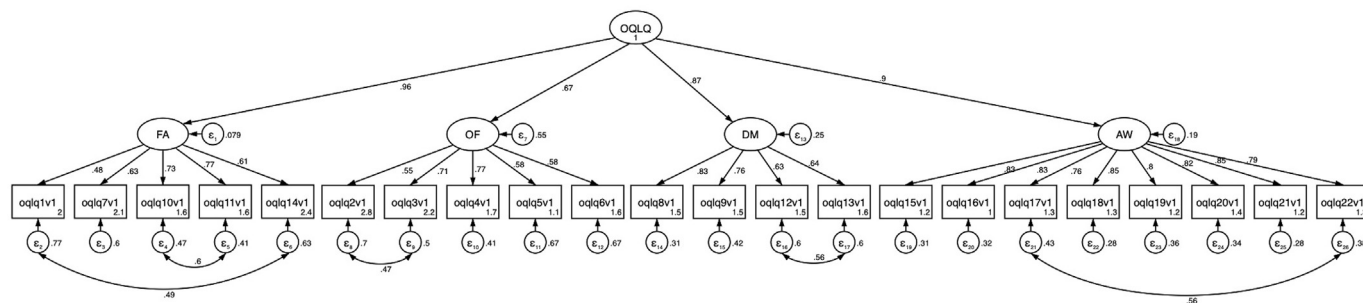
Construct validity was evaluated by analyzing the hypothesized relationships between scores. This was achieved by calculating the Spearman correlation coefficients ( $r_s$ ), which were interpreted as follows: negligible relationship when  $r_s < 0.20$ ; weak when  $0.20–0.40$ ; moderate when  $0.40–0.60$ ; strong–moderate when  $0.60–0.80$ ; and strong when  $> 0.80$  (Franzblau, 1958).

To evaluate responsiveness, a paired *t*-test was used to assess the score changes in patients undergoing orthognathic surgery. The magnitude of the change was evaluated by calculating the standardized response mean as the mean change divided by the standard deviation of the change, which allowed interpretation of the magnitude and meaningful comparisons between different instruments (Garratt et al., 1994). Standardized response means of 0.2, 0.5, and 0.8 represented small, moderate, and large clinical changes (Liang et al., 1990; Garratt et al., 1994). Statistical analysis was performed using Stata 15 [Stata Corp, College Station, TX, USA].

## 3. Results

In total, 230 patients under presurgical orthodontic treatment were included in the study: 88 of them with a scheduled date for the surgical procedure and 142 in process (the latter formed the reliability sub-sample, with an 84.5% response rate). After excluding 14 patients who did not respond, 216 participants were entered in the analysis. Mean age was 23.7 (SD 6.2), with a high percentage being female (63.9%). Their main motivation for treatment was aesthetic and functional (72.2%), followed by only functional motivation (25%).

Fig. 1 shows the structure of the OQLQ model tested through confirmatory factor analysis, in which the 22 items are distributed into four latent factors and a general factor. Since values of indices related to goodness of fit (comparative fit index = 0.818, Tucker–Lewis index = 0.794, and root mean square error of approximation = 0.116), a Lagrange multiplier test was applied and covariances were incorporated between the following pairs of



**Fig. 1.** Confirmatory factor analysis for the 22-item Orthognathic Quality of Life Questionnaire. FA: facial aesthetics domain; OF: oral function domain; AW: awareness of dentofacial deformity domain; SA: social aspects domain.

items: item 1 (teeth appearance) and 14 (facial appearance); item 10 (dislike of being photographed) and 11 (dislike of being seen on video); item 2 (biting) and 3 (chewing); item 12 (staring at people's teeth) and 13 (staring at people's faces); and item 17 (worrying about comments on my appearance) and 22 (upset about comments on my appearance). This final model showed acceptable goodness of fit (comparative fit index = 0.902, Tucker–Lewis index = 0.887, and root mean square error of approximation = 0.086).

Table 1 shows the reliability results. Only a low item–total correlation was observed in question 2 of the third component (function), with a value below 0.5; all other items gave values between 0.51 and 0.80. The alpha coefficients for the four components were high, between 0.77 and 0.94. The intraclass correlation coefficient for test–retest analysis was >0.7 in the four dimensions.

The proportion of patients with some item without a response was low for OQLQ and OHIP-14 (5% and 3%, respectively), and practically null for SF-36 (Table 2). Floor and ceiling effects for OQLQ global score were 0% and less than 15% in all dimensions,

respectively. The mean and median global scores were 47.66 and 47.5, respectively.

Table 3 shows the correlation matrix between the OQLQ components, SF-36, and OHIP-14. In general, the OQLQ scores presented weak or even negligible correlations with SF-36. Otherwise, most correlations between OQLQ and OHIP-14 were at least moderate.

All the correlations that had previously been hypothesized as moderate (cells marked “a”) were  $r_s > 0.36$ , except the correlation between vitality and the social aspects of dentofacial deformity dimension ( $r_s = -0.27$ ), and between general health and the dentofacial aesthetic dimension ( $r_s = -0.13$ ). On the other hand, the hypothesis of poor correlation between the SF-36 bodily pain component and the oral function domain, and between SF-36 mental health and the awareness of dentofacial deformity domain ( $r_s = -0.37$  for both) was rejected.

Table 4 compares mean scores at baseline (presurgery) and at the 3-month postsurgery follow-up. Standardized response means were considerably higher for the OQLQ and OHIP-14 than for the SF-36. The highest standardized response means were found for the

**Table 1**  
Reliability of the Chilean version of the OQLQ (n = 216).

OQLQ component/item	Item–total <sup>a</sup> correlation	Alpha coefficient <sup>a</sup> for each component	Intraclass <sup>b</sup> correlation coefficient (test–retest)
<b>Component 1 – social aspects of dentofacial deformity</b>			
15. Cover mouth when meeting people	0.79	0.94	0.91 (p = 0.001)
16. Worry about meeting people	0.78		
17. Worry people will make hurtful comments	0.76		
18. Lack confidence socially	0.78		
19. Do not like smiling	0.76		
20. Get depressed about appearance	0.79		
21. Sometimes think people are staring	0.80		
22. Comments about appearance upset me	0.76		
<b>Component 2 – facial aesthetics</b>			
1. Self-conscious about appearance of my teeth	0.56	0.80	0.86 (p = 0.001)
7. Don't like seeing side view of face (profile)	0.59		
10. Dislike having photograph taken	0.71		
11. Dislike being seen on video	0.75		
14. Self-conscious about appearance	0.63		
<b>Component 3 – oral function</b>			
2. Problems biting	0.46	0.78	0.88 (p = 0.001)
3. Problems chewing	0.51		
4. Avoid eating some foods	0.55		
5. Don't like eating in public	0.63		
6. Pains in face/jaw	0.49		
12. Stare at people's teeth	0.64		
<b>Component 4 – awareness of dentofacial deformity</b>			
8. Spend time studying face	0.72	0.83	0.84 (p = 0.001)
9. Spend time studying teeth	0.66		
12. Stare at people's teeth	0.64		
13. Stare at people's faces	0.68		

<sup>a</sup> Calculated using presurgery responses to the OQLQ from all the participants (n = 216).

<sup>b</sup> Calculated using presurgery responses to the OQLQ from participants in the test–retest subsample (n = 120).

**Table 2**  
Distribution of questionnaire scores (n = 216).

Instruments	% of items not answered	Theoretical range	Observed range	Floor effects	Ceiling effects	Mean (SD)	Median (IQR)
<b>OQLQ</b>	5%	0–88	4–85	0%	0%	47.66 (20.53)	47.5 (31)
Social aspects of dentofacial deformity	0%	0–32	0–32	5.09%	4.17%	14.55 (9.86)	13 (17)
Facial aesthetics	2%	0–20	1–20	0.93%	11.11%	13.12 (5.09)	14 (9)
Oral function	3%	0–20	0–20	1.39%	1.39%	11.85 (4.69)	13 (6)
Awareness of dentofacial deformity	0%	0–16	0–16	4.63%	2.31%	8.13 (4.36)	8 (7)
<b>Short-Form 36</b>							
Physical functioning	<1%	0–100	10–100	0%	52.31%	92.29 (13.06)	100 (10)
Role-physical	0%	0–100	0–100	0.46%	48.15%	87.42 (18.18)	93.75 (18.75)
Bodily pain	0%	0–100	0–100	0.46%	23.61%	73.57 (21.04)	74 (22.5)
General health	0%	0–100	20–100	0.46%	5.56%	71.74 (17.75)	72 (25)
Vitality	0%	0–100	0–100	0.46%	3.24%	61.51 (20.77)	62.5 (25)
Social functioning	0%	0–100	12.5–100	0.93%	34.72%	79.16 (20.84)	87.5 (37.5)
Role-emotional	0%	0–100	0–100	0.46%	38.43%	81.90 (19.44)	83.33 (29.16)
Mental health	0%	0–100	20–100	0.46%	4.63%	70.32 (18.15)	75 (25)
Physical health component summary	N/A	< ó > 50	24.71–67.9	0.46%	0.46%	54.74 (6.01)	55.98 (7.59)
Mental health component summary	N/A	< ó > 50	18.64–63.89	0.46%	0.46%	47.29 (9.74)	49.24 (13.36)
<b>OHIP-14</b>	3%	0–56	0–48	0.46%	0%	17.71 (9.57)	16.5 (13.5)
Functional limitation	0%	0–8	0–8	32.41%	0.46%	1.76 (1.64)	2 (3)
Physical pain	1%	0–8	0–8	5.56%	1.85%	3.66 (1.91)	4 (3)
Psychological discomfort	0%	0–8	0–8	9.26%	6.94%	3.56 (2.20)	4 (3)
Physical disability	1%	0–8	0–8	18.52%	2.78%	3.10 (2.17)	3 (3.5)
Psychological disability	<1%	0–8	0–8	15.28%	1.85%	2.75 (2.06)	3 (3)
Social disability	0%	0–8	0–7	30.09%	0.46%	1.89 (1.75)	2 (3)
Handicap	0%	0–8	0–8	61.57%	0.46%	0.96 (1.58)	0 (2)

**Table 3**  
Construct validity: Spearman correlations<sup>a</sup> (p-values) for OQLQ with SF-36 and OHIP-14 scores at presurgery evaluation (n = 216).

	OQLQ COMPONENTS			
	Domain 1 Social aspects of dentofacial deformity	Domain 2 Facial aesthetics	Domain 3 Oral function	Domain 4 Awareness of dentofacial deformity
<b>SF-36 COMPONENTS</b>				
Physical functioning	–0.12 (0.089)	–0.16 (0.021)	–0.15 (0.025)	–0.06 (0.376)
Role-physical	–0.12 (0.074)	–0.07 (0.300)	–0.19 (0.004)	–0.03 (0.644)
Bodily pain	–0.22 (<0.001)	–0.24 (<0.001)	–0.37 (<0.001)	–0.24 (<0.001)
General health	–0.17 (0.014)	–0.14 (0.045) <sup>a</sup>	–0.18 (0.009)	–0.13 (0.053)
Vitality	–0.27 (<0.001) <sup>a</sup>	–0.32 (<0.001)	–0.23 (<0.001)	–0.28 (<0.001)
Social functioning	–0.37 (<0.001) <sup>a</sup>	–0.36 (<0.001) <sup>a</sup>	–0.34 (<0.001)	–0.33 (<0.001)
Role-emotional	–0.23 (<0.001)	–0.28 (<0.001)	–0.26 (<0.001)	–0.21 (0.002)
Mental health	–0.41 (<0.001) <sup>a</sup>	–0.40 (<0.001) <sup>a</sup>	–0.30 (<0.001)	–0.37 (<0.001)
SF-36 physical health component summary	–0.05 (0.492)	–0.04 (0.566)	–0.20 (0.003)	–0.02 (0.723)
SF-36 mental health component summary	–0.37 (<0.001) <sup>a</sup>	–0.39 (<0.001) <sup>a</sup>	–0.29 (<0.001)	–0.36 (<0.001) <sup>a</sup>
<b>OHIP-14 COMPONENTS</b>				
Functional limitation	0.37 (<0.001)	0.35 (<0.001)	0.45 (<0.001) <sup>a</sup>	0.36 (<0.001)
Physical pain	0.32 (<0.001)	0.38 (<0.001)	0.50 (<0.001)	0.29 (<0.001)
Psychological discomfort	0.64 (<0.001)	0.58 (<0.001)	0.49 (<0.001)	0.47 (<0.001) <sup>a</sup>
Physical disability	0.36 (<0.001)	0.29 (<0.001)	0.41 (<0.001) <sup>a</sup>	0.24 (<0.001)
Psychological disability	0.42 (<0.001)	0.38 (<0.001)	0.45 (<0.001)	0.34 (<0.001)
Social disability	0.50 (<0.001) <sup>a</sup>	0.40 (<0.001)	0.54 (<0.001)	0.34 (<0.001)
Handicap	0.30 (<0.001)	0.19 (0.005)	0.36 (<0.001)	0.16 (0.018)

SF-36 0–100%, with 0 being the worst possible and 100 being the best possible quality of life.

OHIP-14 is scored such that higher scores represent lower quality of life, and vice versa (0–56; each component 0–8).

OQLQ is scored such that higher scores represent lower quality of life, and vice versa (social aspects of dentofacial deformity domain 0–32, facial aesthetics domain 0–20, oral function domain 0–20, awareness of dentofacial deformity domain 0–16).

<sup>a</sup> Indicate hypothesis of moderate relationships.

oral function (–0.91), facial aesthetics (–0.68), and social aspects of dentofacial deformity (–0.62) domains, followed by OHIP-14 psychological discomfort. The value for the fourth domain (awareness of dentofacial deformity) was much smaller (–0.35). For the health transition question, most patients reported positive outcomes: 25 stated that they felt their dental/facial problems were better than prior to treatment, and only five said that they felt no change.

**4. Discussion**

The version of the OQLQ obtained has demonstrated adequate metric properties, similar to those of the original version, including

excellent reliability, validity, and responsiveness. These findings support its use in Chile, while guaranteeing international comparison.

The Chilean version has shown excellent reliability, both with regard to its internal consistency and its reproducibility, since reliability coefficients were higher than the minimum recommended in all the questionnaire scores (Cronbach, 1951; Prieto et al., 1998). Cronbach's alpha for the global score exceeded 0.9, while the intraclass correlation coefficient was >0.8 for all scores. Our internal consistency by dimensions (Cronbach's alpha coefficient between 0.76 and 0.94) was similar to the value reported by the original questionnaire, being slightly lower only for the oral function dimension (0.76 vs 0.83).

**Table 4**  
Responsiveness testing: mean change between T2 and T1 (n = 30).

Instrument	Mean score (SD) at baseline	Mean score (SD) at follow-up	Mean change (SD)	SRM	p-value
<b>OQLQ</b>	40.16 (19.52)	25.06 (15.46)	-15.1 (18.05)	-0.84	<0.001
Social aspects of dentofacial deformity	11.66 (8.60)	7.03 (6.79)	-4.63 (7.43)	-0.62	0.002
Facial aesthetics	11.03 (5.84)	7.36 (4.94)	-3.66 (5.38)	-0.68	<0.001
Oral function	11.13 (4.61)	5.53 (3.83)	-5.6 (6.15)	-0.91	<0.001
Awareness of dentofacial deformity	6.33 (3.69)	5.13 (3.75)	-1.2 (3.42)	-0.35	0.065
<b>Short-Form 36</b>					
Physical functioning	95.16 (7.70)	93.99 (17.43)	-1.16 (17.79)	-0.07	0.722
Role-physical	90.83 (12.68)	88.75 (15.43)	-2.08 (16.10)	-0.13	0.484
Bodily pain	74.96 (24.32)	73.7 (19.51)	-1.26 (29.40)	-0.04	0.815
General health	81.1 (16.22)	82.9 (16.30)	1.8 (12.81)	0.14	0.448
Vitality	68.54 (18.45)	68.95 (12.97)	0.41 (18.78)	0.02	0.904
Social functioning	83.33 (14.8)	85.41 (18)	2.08 (23.69)	0.09	0.633
Role-emotional	87.22 (17.05)	89.44 (14.34)	2.22 (20.40)	0.11	0.555
Mental health	77.5 (15.29)	79.33 (14.36)	1.83 (17.24)	0.11	0.564
Physical health component summary	55.76 (5.34)	54.97 (6.04)	-0.79 (6.83)	-0.12	0.530
Mental health component summary	50.79 (7.96)	52.16 (7.77)	1.37 (9.82)	0.14	0.450
<b>OHIP-14</b>	15.26 (9.45)	9.8 (6.18)	-5.46 (9.96)	-0.55	0.005
Functional limitation	1.3 (1.48)	1.16 (1.53)	-0.13 (1.61)	-0.08	0.654
Physical pain	3.16 (1.62)	2.86 (1.54)	-0.3 (1.6)	-0.19	0.313
Psychological discomfort	3.1 (2.20)	1.66 (2.01)	-1.23 (2.51)	-0.49	0.011
Physical disability	2.5 (2.34)	1.53 (1.50)	-0.96 (2.25)	-0.43	0.025
Psychological disability	2.56 (1.88)	1.86 (2.01)	-0.7 (2.32)	-0.30	<0.001
Social disability	1.73 (1.81)	0.93 (1.31)	-0.8 (1.95)	-0.41	0.032
Handicap	0.9 (1.47)	0.4 (1.65)	-0.5 (1.65)	-0.30	0.108

T1 = prior to surgery; T2 = after surgery, at 3-month follow-up.

To the best of our knowledge, there has been no previous publication describing the factor structure of the original instrument; therefore, comparisons with other studies are not possible. Our findings confirm the four domains proposed by the developers, and that correlations between them can be explained by the second-order model representing global OHRQoL. While the initial model showed discrepancies between observed values and the values expected under the hypothetical model (original version), this was remedied by adding covariances between errors that reflected all other sources of variance in the items not explained by the construct.

Construct validity of the Chilean version of the OQLQ was assessed through exploring relationships with the OHIP-14 and the widely used SF-36 health survey questionnaire. In the study of the original questionnaire, validity was assessed with SF-36 and a 100 mm VAS, which measured respondents' own global ratings of their appearance and function. Our findings supported the majority of hypotheses previously specified. The correlations between the OHIP-14 and the four domains of the OQLQ were all significant, although the social aspects and dentofacial aesthetics domains produced the strongest relationships with the OHIP-14 psychological discomfort domain (0.64 and 0.54, respectively). Also, the hypotheses generated a priori for relationships with the SF-36 were confirmed, except for social aspects and facial aesthetics (lower than expected, at -0.27 and -0.14, respectively).

Responsiveness was assessed by testing 30 subjects presurgery and at the 3-month postsurgery follow-up. Three of the four domains showed a significant improvement (social aspects, facial aesthetics, and oral function). The magnitude of change observed in the oral function dimension of the OQLQ and in its total score (both greater than 0.8) can be considered large, following the criteria established by Cohen (Kazis et al., 1989). Our findings were similar to the original article by Cunningham, who reported the same significant domains but at the end of treatment. The study by Eslamipour et al. (2017) evaluating change at 3 months after surgery (with the orthodontic appliances not yet removed) also showed a significant change in three of these domains. The awareness of dentofacial aesthetics domain did not improve significantly in this study, nor in our findings. These findings

suggest that, to some extent, the patients' self-perception regarding their dentofacial deformity continues to be low, as they tend to compare themselves with others.

The main limitations of this study relate to the assessment of responsiveness and a small sample size (the first 30 patients who completed the follow-up 3 months after surgery). However, statistical power was enough to detect the expected moderate-to-large changes in the OQLQ scores. Moreover, the magnitude of the changes observed were clearly larger than those measured by the OHIP-14 and SF-36. Presurgical evaluation was performed just before surgery, instead of before any presurgical intervention (i.e. after installation of orthodontic appliances), and at post-surgical evaluation only 3 months after surgery. A greater change in OHRQoL is observed once postsurgical orthodontic treatment is completed (Choi et al., 2010; Feu et al., 2017).

OHRQoL should be considered in the initial clinical evaluation, including it as another factor that determines the need for surgical treatment; this would allow both assessment of the magnitude of involvement from an integral perspective and prioritization of treatments, as needed. Furthermore, longitudinal studies with pre- and postsurgical evaluations of orthognathic patients are needed to know the full treatment outcomes, and the factors related to them.

### 5. Conclusion

The Spanish version of OQLQ has demonstrated good reliability, validity, and responsiveness, similar to those of the original instrument. The use of the questionnaire in patients with dentofacial deformities treatment should be based on the notion that this instrument might be used by specialists, potentially allowing them to make better treatment decisions.

### Ethical approval

This study was approved by the ethics committee of the Valparaiso–San Antonio Health Service.

### Funding

No sources of funding.

## Declaration of Competing Interest

The authors declare that they have no conflicts of interest.

## Authors' contributions

The authors have critically reviewed the manuscript and agreed to its submission. VD, MF, CZ, and JV conceived, conceptualized, and designed the study. CV, PS, JO, MD, BM, MM, JC, and GC conducted the coordination of the study in each center and collected follow-up data. VD, CZ, and FW analyzed the data. VD, CZ, and MF drafted the manuscript, and all authors read and contributed to the final manuscript, and agreed to its publication.

## Acknowledgements

Our sincerest thanks to Susan Cunningham and colleagues at the UCL Eastman Dental Institute. For their fundamental support of this project, we thank Jaime Jamett, Evelyn Carrasco, Luz María Medina, and our beloved Tita Rodriguez. The authors would like to thank Aurea Martin for her support in English editing, proof-reading, and preparing this manuscript for submission. Thanks to participating Institutions and especially to our patients who collaborated with this project.

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