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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SUMMARY

Objective: The aim of this study was to develop a Spanish version of the Orthognathic Quality of Life Questionnaire (OQLQ) conceptually equivalent to the original questionnaire and 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 Short-Form 36 during the pre-surgery visit 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 until 3 months after surgery.

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

Conclusions: The Spanish version of OQLQ has demonstrated good reliability, validity and

responsiveness, similar to those of the original instrument.

Key words: Oral health-related quality of life, Orthognathic surgery, patient-reported outcome measures.

INTRODUCTION

Dentofacial deformities have been defined as conditions in which the facial skeleton diverges from normality, there is malocclusion (dentomaxillary anomalies), and the 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 one of 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 aspects related to 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 United Kingdom (Cunningham et al., 2000), with the aim of evaluating the benefit of orthognathic surgery in terms of its effect on the 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 the OHRQoL in patients with dentofacial deformities. Other questionnaires, such as the Malocclusion Impact Questionnaire, were 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 measuring such as the Health Survey Short Form-36 (SF-36) and the Oral Health Impact Profile (OHIP-14) (Soh and Narayanan, 2013). The OQLQ has been adapted to other languages: German (Bock et al., 2009), Arabic (Abdullah, 2015) and

Portuguese (Bortoluzzi et al., 2011; Araújo et al., 2013).

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

METHODS

Description of the Orthognathic Quality of Life Questionnaire.

The OQLQ is a self-administered instrument with 22 items (Cunningham et al., 2000; Cunningham et al., 2002) covering 4 domains: facial aesthetic (5 items, score range 0 to 20), oral function (5 items, range 0 to 20), awareness of dentofacial deformity (4 items, score range 0 to 16), and social aspects of dentofacial deformity (8 items, score range 0 to 32). Each question is rated on a 5-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).

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 based on the methodology recommended for these purposes (Guillermin et al., 1993; Hunt et al., 1991), following four steps: 1) direct translations; 2) translation synthesis; 3) back-translation; and 4) cognitive debriefing.

- Step 1- Direct translations: A conceptual translation of the instrument was carried out by

two independent bilingual translators whose mother language is the target language (Spanish). Directions were provided to translators, emphasizing the 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 reaching consensus and obtaining a single synthesis version.

- Step 3- Back-translation (reverse translation): The synthesis version was translated into the original English language by two bilingual translators whose native/mother language is British English, as in the original instrument, 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 really related with their problems. The response to the questionnaire required approximately 10 to 15 minutes, with no suggestions for modification. The version obtained at the end of the process of direct translation and backtranslation was approved by the author of the original questionnaire, Dr. S. Cunningham.

Study of metric properties of the OQLQ Spanish version

This is 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: over 18 years of age, diagnosis of dentofacial deformity confirmed, and participation informed consent 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 sequels 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).

Instruments of Measurement

Once written consent was obtained from the patients, sociodemographic data was 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 consists of two different questions, which refer to the period of one year, from a total of fourteen. Response options are 5-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 were constructed for domains and for two component summaries, physical and mental (Németh, 2005; Farivar et al., 2007). Unlike in OQLQ and OHIP-14, higher SF-36 scores imply better HRQoL (Vera-Villarroel et al., 2014).

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 four weeks between tests, in the reproducibility sub-sample. The reproducibility sub-sample, defined by stability of the clinical condition measured, was constituted by patients undergoing pre-surgical treatment who were not subjected to any intervention (such as installation of splints or removal of third molars) during the following four 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 (Garin et al., 2008; Comín-Colet et al., 2011). Because the OQLQ is the only existing specific condition instrument to evaluate the OHRQoL in patients with dentofacial deformities, the logical relationships with SF-36 and OHIP-14 questionnaires, both previously translated and validated to use in Chile (Olivares-Tirado, 2005; León et al., 2014), were hypothesized and tested.

According to the construct validity hypothesis made by developers, since it primarily addresses mental and social impact 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, we expected moderately positive correlations between OQLQ and OHIP-14 domains, since both measured

OHRQoL with similar domains: social aspects/social disability, oral function/functional limitations and physical disability, 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: first one week before surgery (T1), and then three months after surgery (T2) in the first 30 completed cases.

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

Statistical analysis

Sociodemographic characteristics of the participants and questionnaire scores are described and analyzed by $\chi 2$ for categorical variables, and by parametric or non-parametric test 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. The confirmatory factorial analysis 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 or greater than 0.90 suggest an acceptable fit of the model; while for root mean square error of approximation values should 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, the internal consistency was estimated by the Cronbach alpha coefficient (Cronbach, 1951), and the test-retest reproducibility was estimated by the intraclass correlation coefficient (Prieto et al., 1998), which was calculated with data of the two evaluations in the reproducibility sub-sample. Reliability coefficients > 0.70 was considered acceptable, 0.71–0.80 respectable and > 0.80 very good (Cortina, 1993).

Construct validity was evaluated analyzing the hypothesized relationships between scores by calculating the Spearman correlation coefficients (r_s), which were interpreted as follows: negligible relationship when r_s is < 0.20; weak when 0.20–0.40; moderate when 0.40–0.60; strong-moderate when 0.60–0.80; and strong relationship 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 calculating the standardized response mean as the mean change divided by the standard deviation of the change, which allows to interpret the magnitude and meaningful comparisons between different instruments (Garratt et al., 1994). Standardized response means of 0.2, 0.5 and 0.8 represent small, moderate and large clinical changes (Liang et al., 1990; Garratt et al., 1994).

The statistical analysis was performed using Stata 15 [Stata Corp, College Station, TX, USA].

The study was approved by the ethics committee of the Valparaiso - San Antonio Health Service.

RESULTS

In total, 230 patients in pre-surgical 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 entered in the analysis. Age mean was 23.7 (SD 6.2), a high percentage was female (63.9%), and their main motivation for treatment was aesthetic and functional (72.2%), followed by only functional motivation (25%).

Figure 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. As values of indices indicated poor 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 items: item 1 (teeth appearance) and 14 (facial appearance); item 10 (dislike with photographing) and 11 (dislike with being see on video); item 2 (biting) and 3 (chewing); item 12 (stare at people's teeth) and 13 (stare at people's faces); and item 17 (worry about comments of my appearance) and 22 (upset about comments of 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 results of reliability. 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 Intra-class correlation coefficient of test-retest analysis was >0.7 in the four dimensions.

The proportion of patients with some item without response was low for OQLQ and OHIP-14 (5% and 3% respectively), and practically null for SF-36 (Table 2). Floor and Ceiling effects in OQLQ global score were 0% and lower than 15% in all dimensions. The mean and the median of the global score were 47.66 and 47.5, respectively.

Table 3 shows the correlation matrix between the instrument dimensions and 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) is rejected.

Table 4 compares mean scores at baseline (pre-surgery) and at the 3 months post-surgery 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 oral function (-0.91), facial aesthetics (-0.68), and the 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). In 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 they felt no change.

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 the 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 scores of the questionnaire (Cronbach, 1951; Prieto, 1998). Cronbach's alpha of the global score exceeded 0.9, while the intraclass correlation coefficient was > 0.8 in 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).

To the best of our knowledge, there is 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 the global OHRQoL. While the initial model showed discrepancies between observed values and the values expected under the hypothetical model (original version), it was remedied by adding covariances between errors that reflect 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, though 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, -0.27 and -0.14).

Responsiveness was assessed by testing 30 subjects at the pre-surgery and three months post-surgery 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 are similar to the original article by Cunningham, who reported the same significant domains but at the end of treatment. The study by Eslamipour (2017) evaluating change at three months after surgery (with the orthodontic appliances no removed yet) 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 being low, as they tend to compare themselves with others.

The main limitations of this study are related to the assessment of responsiveness. A smaller 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-large changes in the OQLQ scores. Moreover, the magnitude of the changes observed were clearly larger than those measured by OHIP-14 and SF-36. Pre-surgical evaluation was performed just before

surgery, instead of before any pre-surgical intervention (i.e. after installation of orthodontic appliances), and post-surgical evaluation only 3 months after surgery. A greater change of health-related the quality of life is observed once the post-surgical orthodontic treatment is completed (Choi et al., 2010; Feu et al., 2017).

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

CONCLUSIONS

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 to potentially make a better treatment decision.

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Conflict of Interest:

The authors declare Community that they have no conflict of interests

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Authors contributions

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.

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Tables

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

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

* Calculated with pre-surgery responses to the OQLQ from all the participants (n=216).

** Calculated with pre-surgery responses to the OQLQ from participants in the test-retest subsample (n=120).

Table 2. Distribution of questionnaires scores (n=216)

Instruments	% of items not answered	Theoretical range	Observed range	floor effects	ceiling effects	Mean (SD)	Median (IQR)
OQLQ	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)
Short - Form 36							
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)
OHIP-14	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[a] (p values) for OQLQL with SF-36 and OHIP-14 scores at the pre-surgery 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
SF-36 COMPONENTS				
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)[a]	−0.18 (0.009)	−0.13 (0.053)
Vitality	−0.27 (<0.001)[a]	−0.32 (<0.001)	−0.23 (<0.001)	−0.28 (<0.001)
Social Functioning	−0.37 (<0.001)[a]	−0.36 (<0.001)[a]	−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)[a]	−0.40 (<0.001)[a]	−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)[a]	−0.39 (<0.001)[a]	−0.29 (<0.001)	−0.36 (<0.001)[a]
OHIP-14 COMPONENTS				
Functional limitation	0.37 (<0.001)	0.35 (<0.001)	0.45 (<0.001)[a]	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)[a]
Physical disability	0.36 (<0.001)	0.29 (<0.001)	0.41 (<0.001)[a]	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)[a]	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)

[a] indicate hypothesis of moderate relationships

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.

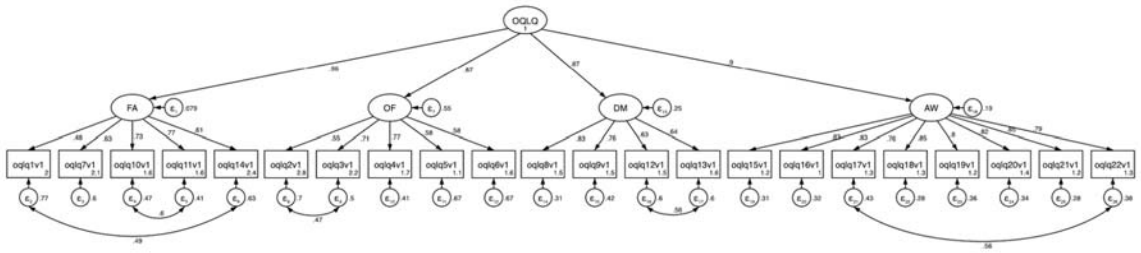
Table 4. Responsiveness testing: mean change between T2–T1 (n=30)

Instrument	Mean score (SD) at baseline	Mean score (SD) at follow-up	Mean change (SD)	SRM	p value
OQLQ	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
Short - Form 36					
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
OHIP-14	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, 3 months follow-up

Figures

Figure 1: Confirmatory factor analysis on the 22-item of the orthognathic quality of life questionnaire



FA: Facial Aesthetics domain; OF: Oral Function domain; AW: Awareness of dentofacial deformity domain; SA: Social aspects domain