Title: The impact of orthognathic surgery on quality of life in individuals with oral clefts

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ABSTRACT

Background/Objectives: To evaluate the relationships between individual, environmental, clinical factors and oral health-related quality of life (OHRQoL) in patients with cleft lip and palate (CLP) following orthognathic surgery.

Materials/method: A follow-up study was conducted involving 69 adults with unilateral and bilateral CLP under orthodontic treatment. Interviews and oral examinations were conducted prior to orthognathic surgery (T_0) to evaluate age, sex, psychological well-being, dental caries, malocclusion, social support, social networks, family income and education and OHRQoL. All participants were reviewed after six months (T_1) to re-assess psychological well-being, malocclusion and OHRQoL. Structural equation modelling estimated the associations between the variables.

Results: OHRQoL total scores reduced following orthognathic surgery, from 11.7 to 6.9 ($P < 0.01$). Occlusal characteristics psychological well-being improved between T_0 and T_1. In the SEM, reduction of malocclusion ($\beta = 0.02$) between T_0 and T_1 directly predicted poor OHRQoL at T_1. Improvement of psychological well-being between T_0 and T_1 was associated with better OHRQoL at T_1 ($\beta = -0.07$). Dental caries and malocclusion at T_0 were indirectly linked to poor OHRQoL at T_1 ($\beta = 0.02$).

Limitations: The short follow-up period of 6 months after orthognathic surgery.

Conclusions/implications: This represents the first prospective study examining the interrelationships of predictors of OHRQoL in patients with CLP after orthognathic surgery. OHRQoL and psychological well-being improved after orthognathic surgery. Clinical and psychological characteristics were important determinants of OHRQoL. These findings suggest the importance of the biopsychosocial model of health and the patient-centred approach in oral health care in individuals with CLP.

Short running title: Quality of life in patients with CLP after orthognatic surgery

Introduction

Cleft lip and palate (CLP) is the most prevalent craniofacial malformation that is commonly associated with several aesthetic and functional disabilities. Patients with unilateral and complete bilateral CLP usually present severe dentofacial deformities and speech impairments (1). The functional rehabilitation and management of those patients involves lengthy and complex treatments aiming to enhance social inclusion and quality of life (2).

Previous studies evaluating treatment outcomes of surgical and non-surgical procedures of individuals with orofacial clefts predominantly focused on normative clinical measures. According to this approach, oral health outcomes are objectively determined by health professionals through clinical measures, radiographs, photographs and dental casts (3, 4). However, this method has been criticized because patients' perceptions are not considered in the assessment of treatment outcomes. The assessment of quality of life using self-reported measures has become more frequent in health research since quality of life measures are multidimensional scales measuring different aspects of health, such as functional limitation, psychological impairments, and social and emotional wellbeing. Patients with CLP frequently experience poor health-related quality of life (HRQoL) (5, 6).

Noticeable clinical characteristics of malocclusion and dentofacial appearance complaints are meaningful factors that are frequently associated with seeking for orthodontic treatment. The functional and/or aesthetic impairments associated with tooth misalignment, crowding and spacing may also negatively impact on individual's psychological well-being and oral health-related quality of life (OHRQoL) (7). The complex interrelationships between malocclusion, psychological factors and perception of oral health in patients with CLP reinforces the importance of using subjective self-reported measures in dental research (4).

Previous studies investigating OHRQoL in patients with CLP and skeletal jaw abnormalities requiring orthognathic surgery were exploratory. The possible mechanisms that correlate craniofacial malformations with poor quality of life are also poorly understood (8, 9). In addition, previous studies did not evaluate the impact of orthognathic surgery on OHRQoL in patients with CLP. The above-mentioned gaps generated two important research questions. What is the impact of orthognathic surgery on OHRQoL among patients with CLP? What are the potential pathways by which orthognathic surgery influences quality of life in patients with CLP?

The aim of the present study was to assess whether orthognathic surgery improved OHRQoL in adult patients with oral clefts 6 months after treatment. In addition, the study examined the relationships between dental clinical measures, individual characteristics, environmental factors and OHRQoL before orthognathic surgery and 6 months after treatment in the same patients according to the Wilson and Cleary conceptual model (10, 11).

Sample and Methods

Study Design and Sample

A prospective 6-month follow-up study was conducted using a consecutive sample of adult patients with complete unilateral or bilateral CLP who completed orthodontic treatment at a public referral centre for patients with craniofacial anomalies from 2017 to 2019. The inclusion criteria were age 18 years and older, interarch relationship index 3, 4 or 5 (Goslon yardstick/Bilateral index) (3, 12), and referral for treatment planning of Le Fort I osteotomy for maxillary advancement. Patients with syndromes, communication impairments, mental disabilities and learning disorders were excluded.

Sixty-nine patients were invited to participate during the recruitment period. A post hoc power calculation was carried out using the 0.05 level of significance ($\alpha = 0.05$) in a structural equation model with three latent variables and eight observed variables and found the power to be 0.72. All participants agreed with their participation and met the inclusion criteria. Of them, 51 (73.9%) had unilateral CLP (UCLP) and 18 (26.1%) had bilateral complete CLP (BCLP). All patients had dental alignment and leveling orthodontic treatment for orthognathic surgery with multibracket fixed appliances in both arches from one to two years before orthognathic surgery. The fixed appliances were maintained until the end of study.

Data collection

Participants were interviewed and examined by a calibrated orthodontist (M.C.P.F.) seven days prior orthognathic surgery (T_0) and 6 months after the orthognathic surgery (T_1). The examiner was not involved in the provision of any clinical treatment of the participants and was calibrated for all clinical measures and questionnaires used in this study. Clinical oral examinations were conducted through visual examination using a plain dental mirror and a WHO probe (Golgran) in the dental office at the referral centre. Personal protective

equipment was used during dental examinations.

Measures

Demographic characteristics included age and sex. The General Health Questionnaire (GHQ-12) was used to measure psychological well-being (13, 14). The GHQ-12 records current mental disturbances and mental disorders. The response format was a 4-point Likert scale. The final score was obtained by summing all scores and may range from 12 to 48. A higher GHQ-12 score indicates better psychological well-being. The difference of GHQ-12 scores between T_0 and T_1 was used to record the change of psychological well-being. Thus, positive changes of GHQ-12 scores suggested improvement in psychological well-being.

Socioeconomic status included education and family income. Education was assessed based on the number of completed years of schooling with approval. Monthly family income was recorded according to Brazilian minimum wages (BMW): ≤ 1 BMW, >1 to 2 BMWs, > 2 to 5 BMWs and > 5 BMWs. One BMW (R$954.00) corresponded to US$ 240.25 during the data collection. Social network from relatives and friends was measured using the Medical Outcomes Study (MOS) questionnaire (15, 16). Participants were asked how many family members and friends they feel comfortable with and whom they could talk to about almost everything. Social support was measured using the Social Support Survey questionnaire (16-18). The questionnaire has 19 items encompassing five domains: material support, affectionate support, emotional support, information support and positive social interaction. Patients are asked how often the different types of support are available: never, rarely, sometimes, often or always. The scores of each dimension was computed by summing the individual scores. The scores of the different dimensions were standardize, ranging from 0 to 100. The higher the score, the greater the social support. Social support was a latent variable using the scores of each dimension as indicators.

The interarch occlusal relationship of participants with UCLP and BCLP was evaluated using the Goslon yardstick index and the Goslon Bilateral/Bauru index, respectively. These measures assess the clinical characteristics of craniofacial growth according to five categories. The Goslon yardstick index varies from ‘excellent’: Good horizontal and vertical relations. One tooth in the lateral segment in cross bite is acceptable (code = 1) to ‘very poor’: Severe negative overjet with a narrow upper arch (code = 5). The Bilateral/Bauru Index ranges from ‘excellent or good’: Apical base relationship Class I or

Class II, positive overjet and overbite (codes = 1 and 2) to 'very poor': Apical base relationship Class III; corrected incisors do not touch lower incisors (code = 5). The Goslon indices discriminate the quality of dental arch relationships within and between centers (3, 12). Dental caries and malocclusion were assessed according to the number of decayed teeth, missing and filled teeth index (DMFT index) (19) and the Dental Aesthetic Index [DAI]), respectively (20). Dental casts of the participants were used to obtain Goslon Yardstick, Bilateral index and DAI measures. The higher DAI score, the worse the malocclusion. The reduction of malocclusion was assessed based on the difference of DAI scores between T_0 and T_1. Thus, positive differences of DAI scores indicate reduction of malocclusion.

Oral health-related quality of life (OHRQoL) was measured using the Oral Health Impact Profile short-form (OHIP-14) questionnaire (21). Patients are asked about their experiences regarding their teeth and mouth during the past six months. The response format is a 5-point Likert scale ranging from 'never' (score = 0) to 'very often' (score = 4). The scores of the physical, social and psychological OHIP-14 domains were used as indicators of the OHRQoL latent variable (22). OHIP-14 total scores range from 0 to 56. Higher OHIP-14 scores indicate worse OHRQoL (22). OHRQoL at T_1 was considered the main outcome of the study. The validated versions of GHQ-12, social network (MOS questionnaire), social support survey questionnaire, and OHIP-14 for Brazilian adults were used in the study.

A calibration study was conducted prior to the main study in the same public referral centre and involved 20 patients with CLP who did not participate in the main study. They were interviewed and examined twice at a 8-hour interval to assess questionnaires and intraexaminer calibration for DMFT, Goslon/Bauru Index and DAI clinical measures. The 8-hour interval between examinations and completion of questionnaires was chosen because most patients come from other regions of the country and stay only one day in the city.

The Kappa coefficients for the three clinical measures were 1.00. Intraclass correlation coefficient (ICC) for social support scale, GHQ-12 and OHIP-14 were 0.987, 0.799 and 0.945. Internal consistency of the instruments in the main study was assessed using Cronbach's α. The Cronbach's α coefficients for social support scale, GHQ-12 at T_0 and OHIP-14 at T_0 were 0.956, 0.815 and 0.861, respectively. The Cronbach's α coefficients at T_1 were: GHQ-12=0.845 and OHIP-14=0.790.

Statistical analysis

Descriptive analysis reported the distribution of demographic characteristics, socioeconomic status, psychosocial well-being, social support, dental clinical measures and OHRQoL using mean and standard deviations (continuous variables) and frequencies (categorical variables). Psychological well-being, OHRQoL, malocclusion and dental caries were compared between baseline and 6 months follow-up through Wilcoxon paired test (continuous variables) and McNemar test (categorical variables). The effect size (Cohen's *d*) for changes in psychological well-being (total GHQ-12 scores), OHRQoL (total OHIP-14 scores and OHIP-14 dimensions), malocclusion (DAI scores) and interarch occlusal relationship (Goslon index scores) were calculated dividing the mean difference by the standard deviation at T_0. Effect sizes were classified as small (0.20), medium (0.50) and large (0.80) (23). The measurement model was tested through confirmatory factor analysis (CFA) to evaluate the latent variables (social support, OHRQoL at T_0 and OHRQoL at T_1. Structural equation modeling (SEM) tested multiple hypotheses and examined the direct and indirect relationships among the observed variables (age, sex, psychosocial well-being at T_0, change of psychological well-being, dental caries, occlusal characteristics at T_0, changes in occlusal characteristics, social networks, monthly family income and education) and latent variables (social support, OHRQoL at T_0 and OHRQoL at T_1) according to the Wilson and Cleary conceptual model (Figure 1) (11).

The direct, indirect and total effects were estimated using STATA 14.0 software. Indirect effects between variables represent the sum of one or more direct paths. Standardized estimates (betas) and standard errors were obtained using Maximum likelihood estimation method. First, the hypothesized theoretical model (full model) was tested. Then non-significant links between variables were removed and the model was re-estimated to generate a statistically parsimonious model. The full model and parsimonious model were compared with Chi-square test. The adequacy of the parsimonious and the full model fit was assessed using the following fit indices and thresholds: root mean square error of approximation (RMSEA) < 0.06, comparative fit index (CFI) ≥ 0.90, and Tucker-Lewis index (TLI) ≥ 0.90. The significance level established for all analyses was 5% ($P < 0.05$).

Ethical aspects

This study was approved by the Committee of Ethics and Research of the Hospital of Rehabilitation of Craniofacial Anomalies, University of São Paulo, Brazil (protocol CAAE no

62551316.6.0000.5441). All participants signed an informed consent form before data collection. They were informed they could withdraw from the study any time.

Results

The final sample consisted of 69 patients. The participants were younger adults whose age ranged from 18 to 30 years old. Male and female participants show similar sociodemographic characteristics regarding education and family income. In both gender groups, the mean of years of schooling was around 12 years and most of them were from families with monthly income between 2 and 5 Brazilian Minimum Wages (Table 1).

Table 1. Demographic and socioeconomic characteristics, social support and social networks of the sample at baseline.

Variable	Study sample Mean (±) / N (%)	Female participants Mean (±) / N (%)	Males participants Mean (±) / N (%)
Age	24.8 ± 6.0	24.6 ± 6.0	25.0 ± 6.2
Years of schooling	12.0 ± 2.4	11.9 ± 2.8	12.1 ± 2.3
Monthly family income			
Up to 1 BMW	5 (7.2)	2 (7.7)	3 (7.0)
> 1 to 2 BMW	18 (26.1)	9 (34.6)	9 (20.9)
> 2 to 5 BMW	39 (56.5)	13 (50.0)	26 (60.5)
> 5 MW	7 (10.1)	2 (7.7)	5 (11.6)
Social support total score	77.1 ± 15.5	73.3 ± 16.9	79.4 ± 14.2
Material	16.8 ± 3.5	16.1 ± 3.8	17.2 ± 3.2
Affective	12.9 ± 2.6	12.4 ± 2.6	13.2 ± 2.6
Emotional	15.6 ± 4.2	14.6 ± 4.6	16.1 ± 3.8
Information	15.5 ± 3.9	14.4 ± 4.4	16.2 ± 3.4
Positive social interaction	16.3 ± 3.3	15.8 ± 3.5	16.6 ± 3.1
Number of social networks from relatives	3.7 ± 2.9	3.0 ± 2.0	4.1 ± 3.2
Number of social networks from friends	3.0 ± 2.1	2.7 ± 1.6	3.2 ± 2.3

BMW: Brazilian Minimum wage. One BMW (R$954.00) corresponded to US$ 240.25

Comparisons of psychological well-being, OHRQoL, and malocclusion between baseline and 6 months after orthognathic surgery show important changes (Table 2). The changes in psychological well-being and OHRQoL between the above-mentioned study periods were small and moderate, respectively. There was marked reduction on the frequency of participants presenting very severe or handicapping malocclusion. DAI scores as a measure

of malocclusion declined by less than a half 6 months after orthognathic surgery. Malocclusion and interarch occlusal relationship changes showed large effect sizes.

Table 2. Psychological well-being, oral health-related quality of life and dental clinical measures at baseline and 6 months after orthognathic surgery.

Variable	Baseline Mean (±)/N (%)	6 months follow-up Mean (±)/N (%)	Effect size	*P*
Psychological well-being	38.5 ± 5.8	39.6 ± 6.0	0.19	0.011†
OHRQoL				
Total score	11.7 ± 8.4	6.9 ± 6.1	0.57	< 0.001†
Functional limitation	2.0 ± 1.7	1.7 ± 1.5	0.18	0.397†
Physical pain	1.7 ± 1.6	1.1 ± 1.3	0.38	0.002†
Psychological discomfort	2.8 ± 2.3	1.4 ± 1.8	0.61	< 0.001†
Physical disability	0.9 ± 1.4	0.5 ± 1.0	0.29	0.018†
Psychological disability	2.4 ± 1.7	1.2 ± 1.6	0.71	< 0.001†
Social disability	1.1 ± 1.4	0.8 ± 1.4	0.21	0.074†
Handicap	0.8 ± 0.3	0.3 ± 0.6	0.36	0.001†
Malocclusion (DAI score)	41.9 ± 15.8	19.1 ± 4.1	1.44	< 0.001†
Malocclusion (DAI categories)				< 0.001‡
None, or only slight	8 (11.6)	63 (91.3)		
Definitive	5 (7.2)	4 (5.8)		
Severe	12 (17.4)	2 (2.9)		
Very severe or handicapping	44 (63.8)	0 (0.0)		
Interarch occlusal relationship (Goslon index)	4.6 ± 0.6	1.2 ± 0.5	5.67	< 0.001†

OHRQoL: oral health-related quality of life
DAI: Dental Aesthetic Index
† *P* value refers to Wilcoxon test between baseline and 6 months follow-up
‡ *P* value refers to McNemar test between baseline and 6 months follow-up

The mean DMFT at T_0 was 6.0 ± 5.0. The mean of the number of decayed, missing and filled teeth at T_0 was 0.3 ± 0.2, 0.2 ± 0.9, and 5.8 ± 4.7, respectively.

The measurement model comprised social support, OHRQoL at T_0 and OHRQoL at T_1 latent variables (Supplementary file 1). CFA supported the measurement model according to the following fit indices: RMSEA = 0.055, CFI = 0.983, TLI = 0.975. The items confirming the latent variable social support were the social support scale dimensions: material (β =0.669), affective (β =0.816), emotional (β = 0.941), information (β = 0.901) and positive interaction (β = 0.881). Items confirming the latent variable OHRQoL at T_0 were OHIP dimensions at T_0 biological (β = 0.557), psychological (β = 0.850) and social (β =0.812).

Items confirming OHRQoL at T_1 were OHIP dimensions at T_1 biological (β = 0.493), psychological (β = 0.917) and social (β =0.660).

The variables sex, interarch occlusal relationship at T_0, change in interarch occlusal relationship, social network from relatives and social network from relatives were removed from the full model because they were not associated with any other variable. The full model (Fig. 1) and the parsimonious model (Fig. 2) showed good fit since the three criteria were met. Fit indices for the full model were: RMSEA = 0.051, CFI = 0.961, TLI = 0.945. Values obtained for the parsimonious model were: RMSEA = 0.055, CFI = 0.954, TLI = 0.944. The difference between the full and parsimonious models was not significant ($\chi 2$ = 4.096, df = 211, P = 1.00) suggesting that removal of the above-mentioned variables and the non-significant links were not relevant to the model.

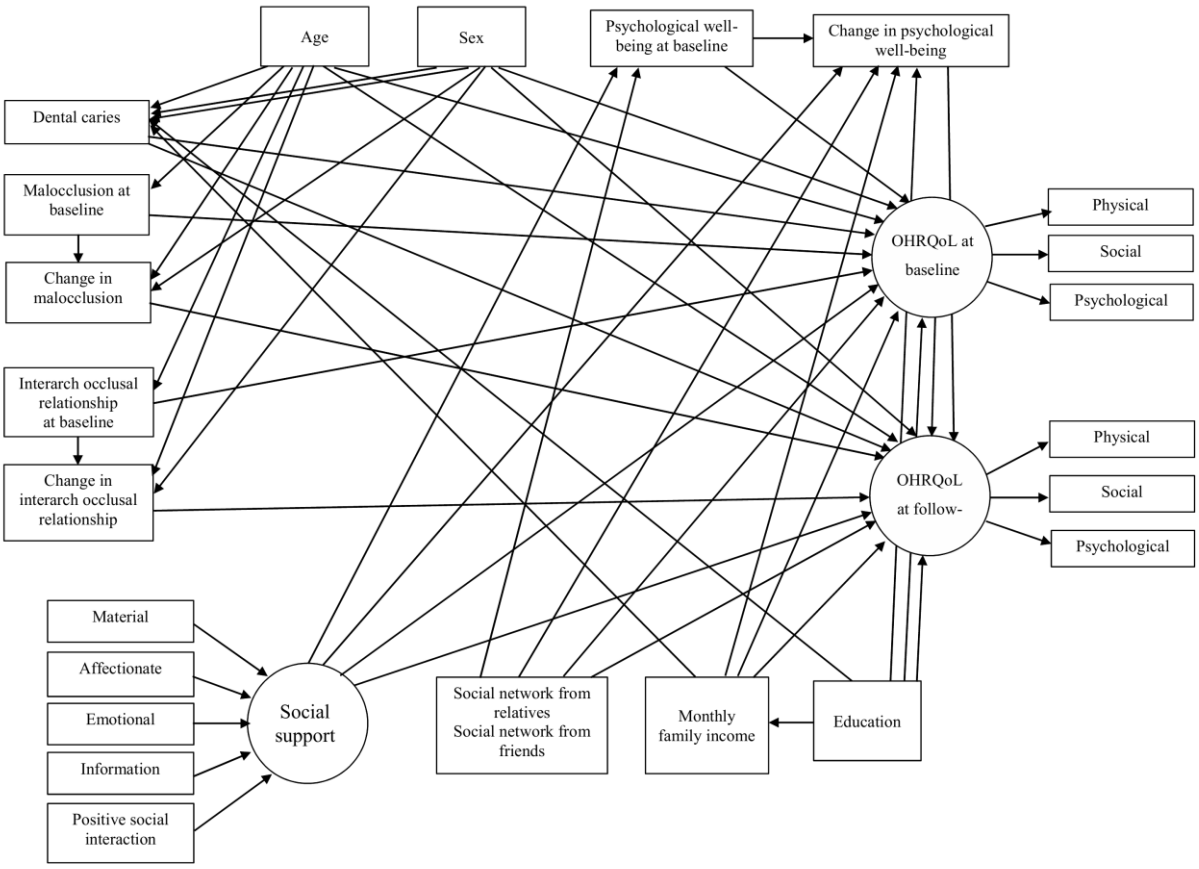

Figure 1. Full theoretical model on the relationships between demographic characteristics, psychological well-being, dental clinical measures, socio-economic status, social support, social networks and oral health-related quality of life (OHRQoL) in adults with oral clefts according to the conceptual model of Wilson and Cleary (11).
Latent variables are given in circles, indicators and observed variables are given in rectangles, and direct effects are shown with solid lines.

Figure 2 shows the direct effects of the parsimonious model. Change in malocclusion between T_0 and T_1 was linked to poor OHRQoL at T_1 (β = 0.02). Change in psychological well-being between T_0 and T_1 was associated with better OHRQoL at T_1 (β = -0.07). Higher OHRQoL scores at T_0 predicted poor OHRQoL at T_1 (β = 0.28). Being older was linked to poor OHRQoL at T_0 (β = 0.14) and more dental caries (β = 0.39). A higher psychological well-being at T_0 was linked to better OHRQoL at T_0 (β = -0.14) and higher change psychological well-being (β = -0.40). Dental caries predicted better OHRQoL at T_0 (β = -0.11). Malocclusion at T_0 predicted higher change in malocclusion (β = 0.96) and poor OHRQoL at T_0 (β = 0.22). Higher social support was linked to greater psychological well-being at T_0 (β = 0.50). Greater education was linked to higher monthly family income (β = 0.91) and less dental caries (β = -0.24).

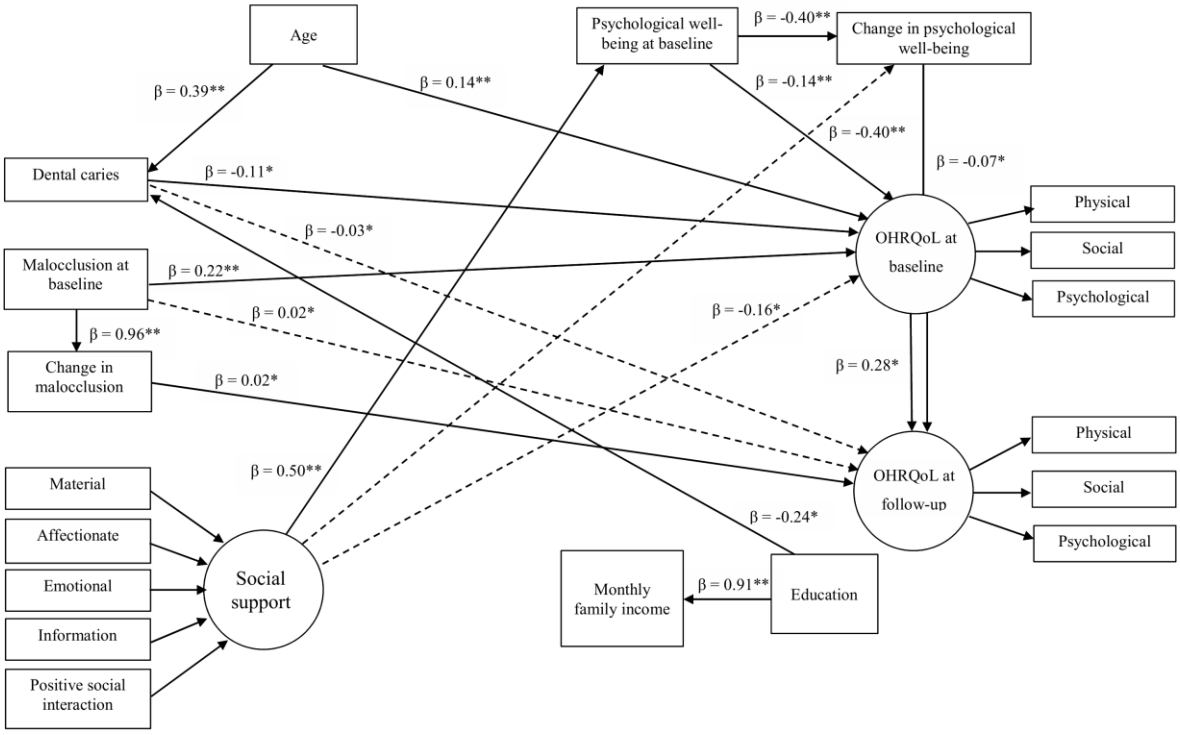

Figure 2. Standardized estimates of the direct (solid lines) and indirect effects (dotted lines)) for the final statistically parsimonious model.
Latent variables are given in circles, and indicators and observed variables are given in rectangles.
OHRQoL, oral health-related quality of life.
*$P < 0.05$, **$P < 0.01$

Indirect paths showed that social support was linked to increase in psychological well-being via psychological well-being at T_0 (β = -0.40). Social support predicted better OHRQoL at T_0 via psychological well-being at T_0 (β = -0.16). Dental caries was associated with OHRQoL at T_1 via OHRQoL at T_0 (β = -0.03). Malocclusion at T_0 predicted poor OHRQoL at T_1 via OHRQoL at T_0, and via improvement of malocclusion between T_0 and T_1 (β = 0.02) (Supplementary file 2).

Discussion

In this study, adults with oral clefts reported better OHRQoL and better psychological well-being 6 months after orthognathic surgery. Furthermore, occlusal characteristics and interarch occlusal relationship improved significantly after orthognathic surgery. Better OHRQoL before surgery and improvement in psychological well-being predicted better OHRQoL after orthognathic surgery. Conversely, greater reduction in malocclusion after surgery was associated with worse OHRQoL after orthognathic surgery. In addition, a worse malocclusion at baseline and dental caries indirectly predicted poor OHRQoL after orthognathic surgery via OHRQoL at baseline. The link between malocclusion at baseline and OHRQoL after orthognathic surgery was mediated by reduction of malocclusion. Demographic and socioeconomic characteristics were not associated with OHRQoL after surgery.

Previous findings showed that OHRQoL improved after surgical maxillary advancement in patients with CLP (8, 9). However, another study did not report substantial changes in quality of life among adolescent patients with CLP after comprehensive orthodontic treatment (23). The association between malocclusion and poor OHRQoL may be considered a confirmatory finding since this relationship was reported in patients without CLP (24). Dental caries was included in the theoretical model because decayed teeth is the most prevalent dental disease and has been associated with poor OHRQoL. However, dental caries directly predicted better OHRQoL before orthognathic surgery and it was indirectly linked to OHRQoL after surgery. The number of filled teeth represented 97% of DMFT index, which may explain the unexpected association between dental caries and OHRQoL.

The severity of malocclusion at baseline indirectly predicted worse OHRQoL after orthognathic surgery. The greater the severity of malocclusion before the orthognathic

surgery, the greater the immediate negative impact of the surgery on patients with CLP quality of life. Considering the potential impact of primary surgical protocols on dentofacial development, this finding indicates the need to establish protocols to reduce malocclusion in patients with CLP before orthognathic surgery. The experience and skills of the surgeons, adoption of standardized protocols, and the appropriate surgical timing and procedures might influence the severity of malocclusion (3, 25). Other factors, such as the initial extent of the cleft, ethnicity and genetic factors may also play a role in the severity of malocclusion in patients with CLP (26, 27).

A greater decrease in malocclusion from baseline to follow-up seems to negatively impact on quality of life 6 months after orthognathic surgery. The significant modifications of occlusion after surgery might have led to greater difficulties in adapting with the changes of facial image and functional aspects of oral health in the short term. Additionally, patients with severe malocclusions before surgery might have had greater expectations on the benefits of the surgical procedure to improve their functional, social and psychological problems. However, the difficulties to adapt with their oral health status after the surgery might suggest disappointment and frustration. Another possible explanation for this finding refers to speaking problems after orthognathic surgery. Maxillary advancement may contribute to impairments of pre-existing hypernasality in subjects with CLP or lead to the development of this symptom (28). According to Maegawa et al (1998), maxillary advancement is effectively harmful in terms of speech intelligibility when it exceeds 10 mm (29). Yet, a recent study did not find a substantial correlation between the extent of maxillary advancement and hypernasality after surgery (30). Intelligibility speech can negatively influence the quality of life in individuals with CLP (6, 31, 32).

The strengths of the present study include the longitudinal study design and the homogeneous sample concerning the type of CLP since all participants had complete CLP with skeletal Class III malocclusion. Previous research has reported the associations between sex, type of oral cleft, dental caries, social support, family income and OHRQoL in adults with CLP (33). Other studies involving individuals without CLP have also adopted the Wilson and Cleary conceptual model and structural equation modelling to investigate the predictors of HRQoL and OHRQoL (34, 35). However, as far as the authors are aware, no previous study investigated the predictors of OHRQoL after orthognathic surgery in adults with CLP using a longitudinal design.

Some limitations of this study must be acknowledged. First, the follow-up period of 6 months after orthognathic surgery may be considered a short time interval to test some of the hypothesized associations. Similarly, the small sample size might have influenced the power of the study. Our findings should not be generalised to other age groups and patients with different types of CLP. In addition, since OHIP-14 is a general OHRQoL measure, specific problems and impairments related to oral clefts that may impact on OHRQoL were not assessed. Future studies using longer follow-up periods where patients with oral clefts have completed orthodontic and rehabilitation treatments should consider speech function and expectation concerning facial changes as treatment outcomes. In addition, future research should analyse the impact of orthognatic surgery on OHRQoL in patients with oral clefts according to the type of oral cleft.

In conclusion, adults with complete CLP unilateral or bilateral and severe Class III malocclusion experienced improvement in OHRQoL six months after orthognathic surgery. Improvement of psychological well-being predicted better OHRQoL after orthognathic surgery. A greater decrease in malocclusion after orthognathic surgery was associated with worse OHRQoL in the first six months after surgery. These findings suggest the importance of the biopsychosocial model of health and the patient-centered approach in oral health care in individuals with CLP. Our findings must be interpreted with caution due to the short-term follow-up.

Conflict of interest statement

The authors declare that they have no conflict of interest.

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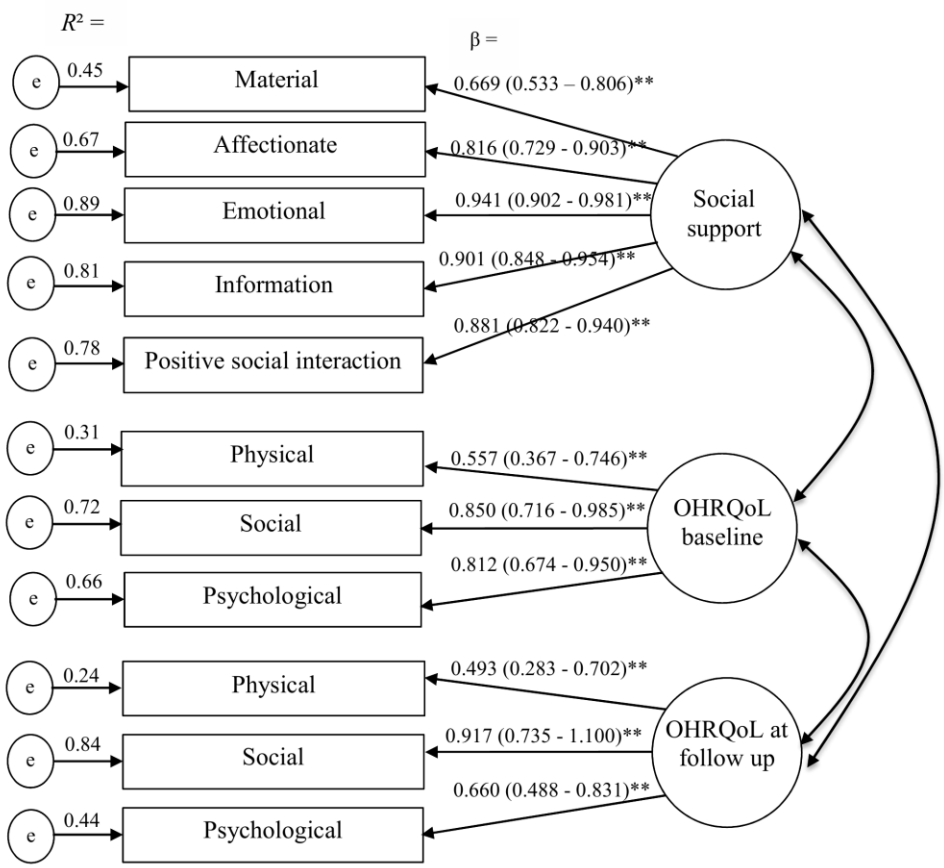
Supplementary file 1. Confirmatory factor analysis of the three-factor and eleven-item measurement model.
**$P < 0.01$



Supplementary file 2. Direct and indirect effects of the parsimonious model obtained through structural equation model.

Pathways	β	Standard Error	*P*
Direct Effects			
Age → OHRQoL at T_0	0.14	0.539	0.044
Age → Dental caries	0.39	0.084	< 0.001
Psychological well-being at T_0 → Change in Psychological well-being	-0.40	0.099	< 0.001
Psychological well-being at T_0 → OHRQoL at T_0	-0.14	0.048	0.003
Change in Psychological well-being → OHRQoL at T_1	-0.07	0.029	0.026
Dental caries → OHRQoL at T_0	-0.11	0.053	0.044
Malocclusion at T_0 → Change in malocclusion	0.96	0.007	< 0.001
Malocclusion at T_0 → OHRQoL at T_0	0.22	0.104	0.035
Social Support → Psychological well-being at T_0	0.50	0.934	< 0.001
Change in malocclusion → OHRQoL at T_1	0.02	0.087	0.047
OHRQoL at T_0 → OHRQoL at T_1	0.28	0.119	0.020
Education → Monthly family income	0.91	0.035	0.011
Education → Dental caries	-0.24	0.098	0.014
Indirect effects			
Social Support → Change in Psychological well-being via Psychological well-being at T_0	- 0.40	0.145	0.006
Social Support → OHRQoL at T_0 via Psychological well-being at T_0, and Psychological well-being at T_0 and OHRQoL at T_0	- 0.16	0.067	0.017
Dental caries → OHRQoL at T_1 via OHRQoL at T_0	- 0.03	0.015	0.044
Malocclusion at T_0 → OHRQoL at T_1 via OHRQoL at T_0 and Change in malocclusion	0.02	0.009	0.016