UNIVERSIDADE DE SÃO PAULO
HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

MARIANA CHAVES PETRI FEITOSA

The impact of orthognathic surgery on quality of life in oral clefts

**O impacto da cirurgia ortognática na qualidade de vida de
pacientes com fissura labiopalatina**

BAURU

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Dissertação constituída por artigo apresentada ao Hospital de Reabilitação em Anomalias Craniofaciais da Universidade de São Paulo para obtenção do título de Mestre em Ciências da Reabilitação, na área de concentração Fissuras Orofaciais e Anomalias Relacionadas.

Orientador: Dr^a. Daniela Gamba Garib Carreira

BAURU

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Descritores: Fissura labial. Fissura palatina. Qualidade de vida. Cirurgia ortognática.

FOLHA DE APROVAÇÃO

Mariana Chaves Petri Feitosa

Dissertação apresentada ao Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo para a obtenção do título de Mestre.

Área de Concentração: Fissuras Orofaciais e Anomalias Relacionadas

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*“Sempre que puder, fale de amor e com amor para alguém. Faz bem aos
ouvidos de quem ouve e à alma de quem fala.”*

Santa Dulce dos pobres

RESUMO

Feitosa, MCP. O impacto da cirurgia ortognática na qualidade de vida de pacientes com fissura labiopalatina [dissertação]. Bauru: Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo; 2019.

O objetivo deste estudo foi avaliar as relações entre fatores individuais, ambientais, biológicos e qualidade de vida relacionada à saúde bucal (QVRSB) em pacientes com fissura labiopalatina (FLP) antes da cirurgia ortognática e 6 meses após a cirurgia. O estudo foi realizado com 69 adultos com FLP unilateral e bilateral em tratamento ortodôntico. Entrevistas e exames intraorais foram realizados antes da cirurgia ortognática (T0) e 6 meses após a cirurgia ortognática (T1) para coletar dados demográficos (idade e sexo), bem-estar psicológico, medidas clínicas dentárias (cárie dentária, má oclusão), apoio social, redes sociais e status socioeconômico (renda e educação familiar) e QVRSB (OHIP-14). O modelo de equações estruturais foi utilizada para estimar associações diretas e indiretas entre as variáveis. A redução da má oclusão entre a linha de base e o acompanhamento previu diretamente uma pior QVRSB no acompanhamento ($\beta = 0,02$), enquanto o aumento no bem-estar psicológico entre a linha de base e o acompanhamento foi associado a uma melhor QVRSB no acompanhamento ($\beta = -0,07$). Uma pior OHRQoL no início do estudo previu uma pior QVRSB no acompanhamento ($\beta = 0,28$). A má oclusão na linha de base foi indiretamente ligada a uma pior QVRSB no acompanhamento via QVRSB na linha de base e pela redução da má oclusão ($\beta = 0,02$). A idade e a QVRSB na linha de base mediarão a ligação entre a cárie dentária e QVRSB no T1. O curto período de acompanhamento de 6 meses após a cirurgia ortognática e o uso de um questionário inespecífico para avaliar a QVRSB em pacientes com FLP devem ser reconhecidos como possíveis limitações do presente estudo. A cirurgia ortognática impactou positivamente a qualidade de vida. Melhores resultados psicológicos previram uma melhor QVRSB após cirurgia ortognática nesta população. Por outro lado, uma maior redução na severidade da má oclusão pode induzir a uma pior qualidade de vida nos primeiros seis meses pós-cirúrgicos.

Descritores: Fissura labial. Fissura palatina. Cirurgia ortognática. Qualidade de vida.

ABSTRACT

Feitosa, MCP. The impact of orthognathic surgery on quality of life in oral clefts. [dissertação]. Bauru: Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo; 2019.

The aim of this study was to evaluate the relationships between individual, environmental, biological factors, and oral health-related quality of life (OHRQoL) in patients with cleft lip and palate (CLP) before orthognathic surgery and 6 months after surgery. The study was conducted involving 69 adults with unilateral and bilateral CLP under orthodontic treatment. Interviews and oral examinations were carried out before orthognathic surgery (baseline) and 6 months after orthognathic surgery to collect demographics (age and sex), psychological well-being, dental clinical measures (dental caries, malocclusion), social support, social networks, and socioeconomic status (family income and education) and OHRQoL (OHIP-14). Structural equation modelling was used to estimate direct and indirect associations between the variables. Reduction of malocclusion between baseline and follow-up directly predicted poor OHRQoL at follow-up ($\beta = 0.02$) whereas increase in psychological well-being between baseline and follow-up was associated with better OHRQoL at follow-up ($\beta = -0.07$). Poor OHRQoL at baseline predicted worse OHRQoL at follow-up ($\beta = 0.28$). Malocclusion at baseline was indirectly linked to poor OHRQoL at follow-up via OHRQoL at baseline, and via reduction of malocclusion ($\beta = 0.02$). Age and OHRQoL at baseline mediated the link between dental caries OHRQoL at T1. The short follow-up period of 6 months after orthognathic surgery, the use of a non-specific questionnaire to assess OHRQoL in patients with CLP and the sample size should be acknowledged as possible limitations of the present study. Orthognathic surgery positively impacted the quality of life. Better psychological outcomes predicted a better OHRQoL after orthognathic surgery in this population. On the other hand, a greater decrease in the severity of malocclusion can induce a worse quality of life in the first post-surgical six months.

Key words: Cleft lip. Cleft palate. Orthognathic surgery. Quality of life

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1 INTRODUCTION

1 INTRODUCTION

Cleft lip and palate are the most common congenital malformations and affect 1 in 600 live births (SHAW, 1996; WHO, 2002). These can affect the lip, alveolar ridge and palate unilaterally or bilaterally, cause aesthetic, functional and psychosocial impairments (FREITAS et al. 2012). The functional rehabilitation and management of those patients involves lengthy and complex treatments aiming to enhance social inclusion and quality of life (ANTONARAKIS, PATEL, TOMPSON, 2013).

The cleft lip and palate appear in different ways. Those that affect the lip, alveolar ridge and palate are classified as complete clefts and cause major changes related to dental and facial growth and development (FREITAS et al. 2012). Most patients with this type of cleft present skeletal discrepancies with a facial profile and deficient maxillary growth in the anteroposterior, transverse and vertical directions (TRINDADE & SILVA FILHO, 2007). Malocclusion is a relatively common condition that can negatively affect functional status and psychological well-being. Previous studies have demonstrated that individuals with malocclusion (e.g. Angle Class III) and presenting concave facial profiles have poor oral health-related quality of life (OHRQoL) than those with normal occlusion and facial appearance (NICODEMO, PEREIRA & FERREIRA, 2008; PALOMARES, CELESTE & MIGUEL, 2016)

The World Health Organization (WHO) defines Quality of life (QL) as “a perception of the well-being of an individual with his life in the cultural context and value system in which he lives, in relation to his goals, expectations, standards and concepts” (WHO, 1993). Therefore, it is a broad concept, used to assess the general well-being of an individual's life and includes emotional, social and physical aspects (ANTONARAKIS; PATEL; TOMPSON, 2013). The term health quality of life (HRQoL) was used to evaluate how a disease, as well as treatment may affect the patient (WARD et. Al., 2013). More specifically, the concept of oral health-related quality of life (OHRQoL) was used to describe the impact of problems affecting oral health (SHEIHAM & TSAKOS, 2007).

Most studies on the evaluation of treatment outcomes of individuals with cleft lip and palate involve objective measures, such as anatomic and radiographic characteristics, as well as the evaluation of clinical photographs and study models

(MØLSTED et al. 2005; SILVA FILHO, OZAWA & BORGES, 2007; PAPAMANOU et al. 2012). Although important, professional judgment in evaluating treatment outcomes alone seems no longer sufficient. As cleft lip and palate affect facial appearance and speech, a considerable impact on self-perceived QL is expected in patients with cleft lip and palate. Thus, studies evaluating patient perception of treatment outcomes have become frequent because they consider that self-reported information that includes aesthetic components, functional, self-image, social inclusion and QL provides a more comprehensive assessment of treatment outcomes (OOSTERKAMP et al. , 2007; QUEIROZ HERKRATH, 2015).

The results of the few studies that evaluated the impact of OHRQoL of patients with cleft lip and palate are not in agreement. Some report that young adult patients have a positive or similar OHRQoL to other groups without cleft, while others demonstrate that the type of cleft may influence OHRQoL assessment (JOKOVIC et al, 2004; MUNZ, EDWARDS & INGLEHART, 2011; BOS & PRAHL , 2011). In addition, studies shows that severe Class III skeletal malocclusion impacts the OHRQoL of individuals (NICODEMO, PEREIRA & FERREIRA, 2008; PALOMARES, CELESTE & MIGUEL, 2016). Thus, the fact that many patients with complete cleft lip and palate may present this type of malocclusion indicates the need to evaluate the relationship between these oral conditions and their impact on OHRQoL.

2 OBJECTIVES

2 OBJECTIVES

The aim of the present study was to examine the influence of demographics (age and gender), psychological well-being, socioeconomic status (family income and education), social support, social networks from relatives and friends, dental caries and malocclusion characteristics on OHRQoL in adult patients with oral clefts before orthognathic surgery and 6 months after the surgical procedure, using the Wilson and Cleary conceptual model.

3 ARTICLE

3 ARTICLE

The article presented in this Dissertation was written according to The European Journal of Orthodontics instructions and guidelines for article submission.

THE IMPACT OF ORTHOGNATHIC SURGERY ON QUALITY OF LIFE IN ORAL CLEFTS

ABSTRACT

Background/Objectives: To evaluate the relationships between individual, environmental, biological factors, and oral health-related quality of life (OHRQoL) in patients with cleft lip and palate (CLP) before orthognathic surgery and 6 months after surgery.

Materials/Methods: A six-months follow-up study was conducted involving 69 adults with unilateral and bilateral CLP under orthodontic treatment. Interviews and oral examinations were carried out before orthognathic surgery (baseline) and 6 months after orthognathic surgery to collect demographics (age and sex), psychological well-being, dental clinical measures (dental caries, malocclusion), social support, social networks, and socioeconomic status (family income and education) and OHRQoL (OHIP-14). Structural equation modelling was used to estimate direct and indirect associations between the variables.

Results: Reduction of malocclusion between baseline and follow-up directly predicted poor OHRQoL at follow-up ($\beta = 0.02$) whereas increase in psychological well-being between baseline and follow-up was associated with better OHRQoL at follow-up ($\beta = -0.07$). Poor OHRQoL at baseline predicted worse OHRQoL at follow-up ($\beta = 0.28$). Malocclusion at baseline was indirectly linked to poor OHRQoL at follow-up via OHRQoL at baseline, and via reduction of malocclusion ($\beta = 0.02$). Age and OHRQoL at baseline mediated the link between dental caries OHRQoL at T1.

Limitations: The short follow-up period of 6 months after orthognathic surgery, the use of a non-specific questionnaire to assess OHRQoL in patients with CLP and the sample size should be acknowledged as possible limitations of the present study.

Conclusions/Implications: Orthognathic surgery positively impacted the quality of life. Better psychological outcomes predicted a better OHRQoL after orthognathic surgery in this population. On the other hand, a greater decrease in the severity of malocclusion can induce a worse quality of life in the first post-surgical six months.

Introduction

Cleft lip and palate (CLP) is considered the most prevalent craniofacial malformation that is commonly associated to 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 surgical and non-surgical treatment outcomes of individuals with orofacial clefts predominantly focused on normative measures. According to this approach, oral health outcomes are objectively determined by health professionals using anatomic and radiographic measurements, clinical photographs and dental casts evaluation (3, 4). The use of professional judgment to evaluate treatment outcomes have been criticized as they are considered limited to provide a comprehensive assessment of the health status. The use of questionnaires to assess self-reported quality of life in health research has become more frequent since these measures involve different dimensions of health, including aesthetics, functional limitation, psychological and emotional wellbeing, and social aspects. Patients with CLP frequently experience a poor quality of life and more impacts on health-related quality of life (HRQoL) (5, 6).

The extension and severity of maxillary deficiencies vary among patients with different types of CLP. The management of unilateral and bilateral complete CLP frequently requires maxillary advancement surgical procedures (3, 7). Malocclusion is a relatively common condition that can negatively affect functional status and psychological well-being (8). Previous studies have demonstrated that individuals with malocclusion (e.g. Angle Class III) and presenting concave facial profiles have poor oral health-related quality of life (OHRQoL) than those with normal occlusion and facial appearance (9, 10). Individuals with malocclusion and/or facial abnormalities usually seek for orthodontic treatment due to either functional and/or aesthetic reasons that are oftenly related to underlying psychological issues (9). The importance of psychological factors on self-perceived dental treatment needs in patients with CLP resulted in a paradigm shift towards the use of self-reported assessment measures and the adoption of a patient-centred care approach (4).

Most of previous studies on OHRQoL in patients with CLP and skeletal jaw abnormalities requiring orthognathic surgery was exploratory and did not assess the potential confounders and other factors that may influence the link between craniofacial malformations and quality of life (11, 12). In addition, previous studies on this subject did not evaluate the

impact of the procedure on quality of life of these patients. The aforementioned gaps in the literature generated two important questions. What is the impact of orthognathic surgery on quality of life among patients with CLP? What is the role of demographics, socioeconomic status, psychological factors, and social support on the influence of orthognathic surgery on quality of life in patients with CLP?

Health-related quality of life (HRQoL) and oral health related quality of life (OHRQoL) are subjective and multidimensional construct, that includes physical, emotional, social, and psychological, dimensions (13), 14). The Wilson and Cleary conceptual model addresses the complex relationships between biological variables, symptom status, functioning, general health perceptions, and overall quality of life that are influenced by individual and environmental factors. Structural equation modelling (SEM) is considered the adequate statistical approach to explore the relationships between variables within a complex theoretical model, and to identify the direct and indirect effects between variables (15, 16).

The aim of the present study was to examine the influence of demographics (age and gender), psychological well-being, socioeconomic status (family income and education), social support, social networks from relatives and friends, dental caries and malocclusion characteristics on OHRQoL in adult patients with oral clefts before orthognathic surgery and 6 months after the surgical procedure, using the Wilson and Cleary conceptual model. It was hypothesized that individual characteristics, socioeconomic status, and dental clinical measures would predict poor OHRQoL before orthognathic surgery. In addition, we also conjectured that demographics, social support, social networks from relatives and friends, change in psychological well-being, dental caries and improvements on occlusal characteristics would predict OHRQoL 6 months after orthognathic surgery.

Population and Methods

Study Design and population

A prospective 6-month follow-up study was conducted using a convenience sample of adult patients with complete unilateral or bilateral cleft lip and palate who underwent orthodontic treatment from 2017 to 2019 at a single center. The study included patients aged 18 years or older; presenting interarch relationship index 3, 4 or 5 (Goslon yardstick/Bilateral index) (3, 17); and those referred to treatment planning of Le Fort I osteotomy for maxillary advancement. Patients with syndromes; those with hearing loss; speaking and reading inability; mental disabilities and history of learning disorders were excluded.

During the recruitment period, 69 patients were invited and agreed to participate. All participants met the inclusion criteria. Thus, the final sample consisted of 69 patients. Of them, 51 (73.9%) had unilateral (UCLP) and 18 (26.1%) had bilateral complete cleft lip and palate (BCLP). All patients underwent dental alignment and leveling orthodontic treatment for orthognathic surgery with multibracket fixed appliances in both arches that was started one to two years before the baseline. At T1 no patients had the fixed appliance removed.

Participants were interviewed and examined one week before orthognathic surgery (Baseline) and 6 months after the orthognathic surgery (T1). A trained and calibrated orthodontist conducted individual interviews using standardized questionnaires and carried out clinical oral examinations in the dental office.

Measures

Individual characteristics

Demographic and psychological well-being were the individual characteristics. The former included age and sex. Psychological well-being was assessed using General Health Questionnaire (GHQ-12) validated for Brazilian adults (18, 19). The GHQ has 12 items followed by a four-point scale aiming to detect current mental disturbances and mental disorders. The answers of the items related to a worst psychological well-being are reversed and then all items are summed up to obtain the final score. The higher the GHQ-12 scores the better the psychological well-being. The change on psychological well-being from the period before the orthognathic surgery and 6 months after the surgery was calculated by difference between T1 and baseline GHQ-12 scores. Thus, a positive variation of GHQ-12 scores means improvement on psychological well-being.

Environmental characteristics

Socioeconomic status, social networks and social support were considered the environmental characteristics. 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 and categorized ≤ 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 according to the Medical Outcomes Study (MOS) questionnaire (20, 21). The participants were required to inform how many family members and friends they feel comfortable with and who they could talk to about almost everything.

Social support was measured using the Medical Outcome Study (MOS) Social Support Survey questionnaire validated for Brazilian adults (21-23). The questionnaire consisted of 19

items, comprising five dimensions of social support: material support; affectionate support; emotional support; information support; and positive social interaction. For each item, patients were asked to indicate how often each type of support was available when needed using the following response choices: (1) never, (2) rarely, (3) sometimes, (4) often, and (5) always. The scores of each dimension were obtained by adding the points of each dimension and dividing by the maximum score of the dimension. This value was multiplied by 100 in order to standardize the scores across the different dimensions. The higher the score, the greater the social support. Social support was a latent variable using the scores of each dimension as indicators.

Biological factors

Dental clinical measures were the biological factors. A trained and calibrated orthodontist conducted the oral examinations. The interarch occlusal relationship of patients with UCLP and BCLP was evaluated using the Goslon yardstick and the Bilateral index, respectively (3, 17). Dental caries and malocclusion were assessed through visual examination using a plane dental mirror and a WHO probe (Golgran) according to the number of decayed teeth, number of missing teeth index (DMFT index) (24) and the Dental Aesthetic Index [DAI], respectively (25). The difference between DAI scores before and 6 months after orthognathic surgery was used to evaluate the change in malocclusion between the two periods.

Oral health-related quality of life

The Oral Health Impact Profile short-form (OHIP-14) questionnaire validated for the Brazilian population was used to assess oral health-related quality of life (OHRQoL) (26). All patients were instructed to answer the OHIP-14 questions based on their experiences regarding their teeth and mouth in the last six months using a five-point scale ranging from 1 ('never') to 5 ('very often'). Three subscales representing the indicators of the OHRQoL latent variable were computed according to the three OHIP-14 domains: physical, social and psychological (27). OHIP-14 total scores range from 0 to 56. Higher OHIP-14 scores indicate worse OHRQoL (27).

Reliability study

Twenty non-syndromic patients with CLP not included in the main study were selected from a single center and were examined with over 8-hour intervals between examinations to assess intraexaminer reliability for dental clinical measures for one examiner (M.C.P.F.). Kappa statistics were used to test the reliability between measures. Kappa coefficients were 1.0 for DMFT and 1.0 for Goslon/Bauru Index. Questionnaires reliability was evaluated using the intraclass correlation coefficient (ICC). ICC were 0.987 for social support scale, 0.799 for the

GHQ-12 questionnaire, and 0.945 for OHIP-14. The internal consistency of the instruments was assessed using Cronbach's α coefficient of reliability in the main study. Cronbach's α for social support scale, GHQ-12 and OHIP-14 at baseline were 0.956, 0.815 and 0.861, respectively. Cronbach's α for social support scale, GHQ-12 and OHIP-14 at 6 months follow up were 0.965, 0.845 and 0.790, respectively.

Statistical analysis

Descriptive analysis reported the distribution of demographics, socioeconomic status, psychosocial well-being, social support, dental clinical measures and OHRQoL using mean and standard deviations and frequencies. Dental clinical measures, psychological well-being, social support, social network and OHRQoL scores were compared between baseline and at 6 months follow-up through Wilcoxon paired test (continuous variables) and McNemar test (categorical variables). The measurement model was tested through confirmatory factor analysis (CFA) to evaluate the latent variables (social support, OHRQoL at baseline and OHRQoL at 6 months follow-up). Structural equation modeling (SEM) examined the direct and indirect relationships between the observed variables (age, gender, social support, psychosocial well-being at baseline, social networks at baseline, dental caries, occlusal characteristics at baseline and changes in occlusal characteristics, years of schooling, family income) and latent variables (social support, OHRQoL at baseline and OHRQoL at 6 months follow up) according to the Wilson and Cleary conceptual model (Figure 1) (16).

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: 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% ($P \leq 0.05$).

Ethical aspects

This study was approved by the Committee of Ethics and Research of the Hospital of Rehabilitation of Craniofacial Anomalies of the University of São Paulo HRAC-USP (protocol CAAE no 62551316.6.0000.5441). Patients that met the inclusion criteria were invited to

participate and signed an informed consent form. They were informed they could withdraw from the study any time.

Results

The final sample consisted of 69 patients (62.3 % men) with a mean age of 24.8 ± 6.0 years. The mean of years of schooling was 12 years ($SD = 2.4$). The majority of patients (56.5%) had family monthly income from > 2 to 5 BMW. (Table 1). Occlusal characteristics (DAI scores) and interarch occlusal relationship (Goslon Index) improved significantly between baseline and 6 months follow up after orthognathic surgery ($P < 0.001$) The frequency of participants presenting very severe or handicapping malocclusion decreased from 63.8% to 0% between baseline and follow up. DMFT and number of filled teeth increased between baseline and follow up (Table 2). Psychological well-being (GHQ-12 scores) ($P = 0.011$) and oral-health related quality of life (OHIP-14 total score) ($P < 0.001$) improved between baseline and 6-month follow up (Table 3).

The measurement model was composed by social support, OHRQoL at baseline and OHRQoL at 6 months follow up latent variables (Fig. 2). The confirmatory factor analysis (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 ($\beta = 0.669$), affective ($\beta = 0.816$), emotional ($\beta = 0.941$), information ($\beta = 0.901$) and positive interaction ($\beta = 0.881$). The items confirming the latent variable OHRQoL at baseline were OHIP dimensions at baseline biological ($\beta = 0.557$), psychological ($\beta = 0.850$) and social ($\beta = 0.812$). The items confirming OHRQoL at 6 months follow up were OHIP dimensions at 6 months follow up biological ($\beta = 0.493$), psychological ($\beta = 0.917$) and social ($\beta = 0.660$).

The variables sex, interarch occlusal relationship at baseline, change in interarch occlusal relationship and social network from relatives were removed from the full model because it was not associated with any other variable. The full model (Fig. 1) and the parsimonious model (Fig. 3) were acceptable fit to the data, meeting the three a priori criteria. 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 variables social network from relatives and sex and the non-significant links were not relevant to the model.

Figure 3 shows the direct and indirect effects of the parsimonious model. Direct paths showed that reduction of malocclusion between before surgery and 6 months after orthognathic

surgery was linked to poor OHRQoL 6 months after orthognathic surgery ($\beta = 0.02$). The increase in psychological well-being before surgery and 6 months after orthognathic surgery was associated with better OHRQoL 6 months after orthognathic surgery ($\beta = -0.07$). A higher OHRQoL before surgery predicted greater OHRQoL 6 months after orthognathic surgery ($\beta = 0.28$). Being older was linked to poor OHRQoL at baseline ($\beta = 0.14$). A higher psychological well-being was linked to better OHRQoL at baseline ($\beta = -0.14$). Higher number of decayed, missing and filled teeth predicted better OHRQoL at baseline ($\beta = -0.11$). Higher social support was linked to greater psychological well-being at baseline ($\beta = 0.50$). Higher years of schooling was linked to greater family income ($\beta = 0.91$).

Indirect paths showed that social support was linked to increase in psychological well-being via psychological well-being at baseline ($\beta = -0.40$). Social support predicted better OHRQoL at baseline via psychological well-being at baseline ($\beta = -0.16$). Number of decayed, missing and filled teeth was associated with OHRQoL 6 months after orthognathic surgery via OHRQoL at baseline ($\beta = -0.03$). Malocclusion predicted poor OHRQoL 6 months after orthognathic surgery via OHRQoL at baseline, and via improvement of malocclusion between before surgery and 6 months after orthognathic surgery ($\beta = 0.02$).

Discussion

This longitudinal study explored the associations between demographics, socioeconomic status, social support, social network, psychological well-being, malocclusion, dental caries and oral health-related quality of life in adults with cleft lip and palate who undergone to surgical-orthodontic treatment for correction of severe maxillary deficiency. Participants reported better oral health-related quality of life and better psychological well-being 6 months after orthognathic surgery. In addition, occlusal characteristics and interarch occlusal improved significantly after the surgery. Better OHRQoL before surgery and improvement in psychological well-being between pre and post surgical periods predicted better OHRQoL after orthognathic surgery. Conversely, greater reduction in malocclusion severity 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 reduction in malocclusion severity and OHRQoL at baseline also mediated the link between malocclusion at baseline and OHRQoL after orthognathic surgery. Demographic and socioeconomic characteristics were not associated to OHRQoL.

Previous studies corroborate these findings showing that OHRQoL improved after surgical maxillary advancement in patients with cleft lip and palate (11, 12). On the other hand, another study did not report any change of quality of life in patients with cleft after comprehensive orthodontic treatment (28). However, no information on the type of cleft and the need for orthognathic surgery was provided in this study and the patients were younger (12.7 years at the baseline) than our sample. The association between malocclusion and OHRQoL at baseline was expected, as the studies involving patients without cleft suggest (29). The inclusion of dental caries in the model intended to control the effect of the most prevalent and impacting buccal disease on OHRQoL, as a confounder in the relationship between malocclusion and quality of life. As expected, dental caries was directly linked to OHRQoL at baseline and indirectly linked to OHRQoL at follow-up (30).

The strengths of the present study include the longitudinal study design, the selection of homogeneous sample concerning the type of CLP since all participants had complete cleft lip and palate with skeletal Class III malocclusion. Another noteworthy aspect of this study was the use of the Wilson and Cleary conceptual model to investigate the complex relationships between possible predictors of oral health-related quality of life (16). As far as the authors are aware, no previous studies considered the abovementioned methodological aspects in a study involving individuals with oral clefts. A previous cross-sectional research have reported the determinants of OHRQoL in adults with cleft lip and palate, including family income, sex, social support, type of oral cleft, and dental caries (31). Other studies involving individuals without CLP have also adopted the Wilson and Cleary conceptual model and the structural equation modelling statistical approach to investigate the predictors of HRQoL and OHRQoL (32, 33).

The improvement in OHRQoL after orthognathic surgery was associated with a greater increase in psychological well-being. This result might be related to an increased on self-confidence and self-esteem of the subjects with CLP after the orthognathic surgery. Previous studies support these findings in non-cleft patients even though our study did not assess specific psychosocial factors (10, 34). Another factor that might contribute to poor oral health-related quality of life is the lack of social support and low social ties (20). In our study, high social support was linked to better psychological well-being at baseline, whereas improvement psychological well-being directly predicted better OHRQoL 6 months after orthognathic surgery. Other studies relating social support and psychological well-being corroborate this finding. A higher quality of social support improves mental health (35). Considering that

individuals with CL/P are more prone to social isolation and negative interactions during childhood and adolescence (36, 37) it is important to improve social support of this individuals.

The severity of malocclusion at baseline indirectly predicted a worse OHRQoL after orthognathic surgery. The more severe the initial malocclusion, the less the orthognathic surgery can contribute to an increase in patient's quality of life. Considering the potential impact of primary surgical protocols on dentofacial growth and development, this finding indicates the need to establish protocols that minimize severe malocclusion in patients with cleft lip and palate. The number of surgeons in a same center, experience and skill of the surgeons, use or nonuse of a standardized protocol, and the surgical timing and sequence of procedures can all be suggested as factors that influence the severity of malocclusion (3, 7). Other factors that can not be controlled, such as initial extent of cleft and ethnic and genetic background, also play a role in the severity of malocclusion in patients with cleft lip and palate (38, 39).

In addition, a greater decrease in the severity of malocclusion from baseline to follow up was associated with poor OHRQoL after orthognathic surgery. The meaningful change on occlusion after surgery morphology might have led to greater difficulties to dealing with the radical change of facial image and functional aspects of oral health. Additionally, we may assume that patients with more severe malocclusions initially had higher expectations on the benefits of the surgical procedure as a solution for functional, social and psychological problems. After orthognathic surgery, adults with CLP with severe malocclusion and those who experienced greater improvement on occlusal conditions perceived worse OHRQoL, which might suggest disappointment and frustration. Another possible explanation for these results is the aspects related to speech problems after orthognathic surgery. Maxillary advancement may contribute to the impairment of a previously existing hypernasality in subjects with cleft or lead to the development of this symptom (40). According to Maegawa et al (1998), maxillary advancement is effectively harmful in terms of speech intelligibility when it exceeds 10 mm (41). On the other hand, a recent study presented no statistical correlation between the extent of maxillary advancement and the presence of hypernasality after surgery (42). Intelligibility speech also have a negative influence the quality of life in individuals with CL/P (6, 43, 44).

Some limitations of this study must be acknowledged. First, the follow-up period of 6 months after orthognathic surgery may be considered a short interval to detect some of the hypothesized associations. Similarly, the small sample size might have influenced on the study's power. In addition, a general questionnaire to assess OHRQoL (OHIP-14) was used, which does not consider specific aspects of oral clefts that may impact on the individual's

quality of life related to oral health. Future studies should consider these limitations when investigating the predictors of OHRQoL in patients with CLP submitted to orthognathic surgery.

In general, individuals with complete CLP unilateral or bilateral, and severe Class III malocclusion, experienced an increase in quality of life after the orthognathic surgery. Better psychological outcomes (change in psychological well-being) predicted a better OHRQoL after orthognathic surgery in this population. A greater decrease in the severity of malocclusion can induce a worse quality of life in the first post-surgical six months. These findings are relevant as it is growing the emphasis on patient-centered care. This is especially true for individuals with CLP, whose treatment is recognized as multidisciplinary, complex and long-lasting. The protocols of rehabilitation process already state that a team of specialists must be involved in the management and treatment of these individual. Using quality of life measures helps improving the multidisciplinary clinical practice, health care quality and services organization, assessing the effectiveness and impacts of different intervention.

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LEGENDS TO FIGURES

Figure 1. Full theoretical model on the relationships between demographics, 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 (16).

Latent variables are given in circles, indicators and observed variables are given in rectangles, and direct effects are shown with solid lines.

Figure 2. Confirmatory factor analysis of the three-factor and eleven-item measurement model.

*****P < 0.01***

Figure 3. 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***

FIGURE 1

FIGURE 2

FIGURE 3

Table 1. Demographics, socioeconomic characteristics, social support and social networks of the sample.

Variable	Mean ($\pm$) / N (%)
Age	24.8 $\pm$ 6.0
Sex	
Male	43 (62.3)
Female	26 (37.7)
Years of schooling	12 $\pm$ 2.4
Monthly family income	
Up to 1 MW	5 (7.2)
> 1 to 2 MW	18 (26.1)
> 2 to 5 MW	39 (56.5)
> 5 MW	7 (10.1)
Social support total score	77.1 $\pm$ 15.5
Material	16.8 $\pm$ 3.5
Affective	12.9 $\pm$ 2.6
Emotional	15.6 $\pm$ 4.2
Information	15.5 $\pm$ 3.9
Positive social interaction	16.3 $\pm$ 3.3
Number of social networks from relatives	3.7 $\pm$ 2.9
Number of social networks from friends	3.0 $\pm$ 2.1

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

Table 2. Dental clinical measures at baseline and 6 months after orthognathic surgery.

Variable	Baseline Mean ($\pm$)/N (%)	6 months follow-up Mean ($\pm$)/N (%)	<i>P</i>
Malocclusion (DAI score)	41.9 $\pm$ 15.8	19.1 $\pm$ 4.1	< 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 $\pm$ 0.6	1.2 $\pm$ 0.5	< 0.001 [†]
DMFT	6.0 $\pm$ 5.0	6.2 $\pm$ 5.0	0.032 [†]
Number of decayed teeth	0.3 $\pm$ 0.2	0.3 $\pm$ 0.2	1.000 [†]
Number of missing teeth	0.2 $\pm$ 0.9	0.2 $\pm$ 0.9	1.000 [†]
Number of filled teeth	5.8 $\pm$ 4.7	5.9 $\pm$ 4.7	0.008 [†]

[†] *P* value refers to Wilcoxon test

[‡] *P* value refers to McNemar test

Table 3. Psychological well-being and oral health-related quality of life at baseline and 6 months after orthognathic surgery.

Variables	Baseline Mean ($\pm$) / N (%)	6 months follow-up Mean ($\pm$) / N (%)	<i>P</i>
Psychological well-being	38.5 $\pm$ 5.8	39.6 $\pm$ 6.0	0.011
OHRQoL			
Total score	11.7 $\pm$ 8.4	6.9 $\pm$ 6.1	< 0.001
Functional limitation	2.0 $\pm$ 1.7	1.7 $\pm$ 1.5	0.397
Physical pain	1.7 $\pm$ 1.6	1.1 $\pm$ 1.3	0.002
Psychological discomfort	2.8 $\pm$ 2.3	1.4 $\pm$ 1.8	< 0.001
Physical disability	0.9 $\pm$ 1.4	0.5 $\pm$ 1.0	0.018
Psychological disability	2.4 $\pm$ 1.7	1.2 $\pm$ 1.6	< 0.001
Social disability	1.1 $\pm$ 1.4	0.8 $\pm$ 1.4	0.074
Handicap	0.8 $\pm$ 0.3	0.3 $\pm$ 0.6	0.001

P value refers to Wilcoxon test

4 FINAL CONSIDERATIONS

4 FINAL CONSIDERATIONS

In individuals with complete CLP, whether unilateral or bilateral, and severe Class III malocclusion, the orthognathic surgery positively impacted the quality of life, a subjective patient reported outcome. Better psychological outcomes (change in psychological well-being) predicted a better OHRQoL after orthognathic surgery in this population. On the other hand, major surgeries can induce greater impact perceived by patients in the first post-surgical six months. These findings are relevant as it is growing the emphasis on patient-centered care. This is especially true for individuals with CLP, whose treatment is recognized as multidisciplinary, complex and long-lasting. The protocols of rehabilitation process already state that a team of specialists must be involved in the management and treatment of these individual. Using quality of life measures helps improving the multidisciplinary clinical practice, health care quality and services organization, assessing the effectiveness and impacts of different interventions.

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ANNEXES

ANNEX 1 – Questionário padronizado para pesquisa

INSTRUÇÕES PARA O PREENCHIMENTO

Para todo o questionário, preencher com 88 para questões que não se aplicam e com 99 para questões que o indivíduo “não sabe informar” ou “não se lembra”.

I. QUESTIONÁRIO SOCIODEMOGRÁFICO

“Primeiro vou fazer algumas perguntas sobre você, sua casa, sua família, estudo e trabalho.”

1. Sexo 1. Masculino 2. Feminino	☐
2. Quantos anos você tem? anos	<input type="text"/>
3. Qual a data do seu nascimento?	<input type="text"/>
4. Qual cidade / estado você nasceu?	
5. Qual a sua situação conjugal? 1.Solteiro(a) 2.Casado(a) 3.Viúvo(a) 4.Separado(a) 5.Vive com companheiro(a)	☐
6. Quantas pessoas moram na sua casa, contando com você?	<input type="text"/>
7. Você sabe ler e escrever? 0. Não 1. Sim 2. Mais ou menos	☐
8. Qual foi a última série/ano que você completou na escola ou faculdade? (se nunca estudou colocar 0 e 0) <input type="text"/> Série / anos completos de faculdade <input type="text"/> 1. Fundamental 2. Médio 3. Superior	
9. Qual a renda familiar TOTAL dos moradores do seu domicílio? 1. até R\$ 937,00 (até 1 salário-mínimo) 2. de R\$ 938,00 a R\$ 1.874,00 (mais que 1 salário-mínimo até 2 salários-mínimos) 3. de R\$ 1.875,00 a R\$ 4.685,00 (mais que 2 salários-mínimos até 5 salários-mínimos) 4. mais que R\$ 4.686,00 (mais que 5 salários-mínimos)	☐

II. QSG-12

“Agora gostaria de saber como voce tem passado, nas ultimas duas semanas, em relacao aos aspectos abaixo relacionados. Aqui, queremos saber somente sobre problemas mais recentes, e nao sobre aqueles que voce possa ter tido no passado”

1 = absolutamente não, 2 = não mais do que costume, 3 = um pouco mais do que costume, 4 = muito mais que de costume

Nas ultimas duas semanas, ...

10. Você tem se sentido capaz de tomar decisoes?	
11. Você tem sentindo que está desempenhando um papel útil na vida?	
12. Você tem sido capaz de enfrentar seus problemas adequadamente?	
13. Você tem perdido a confiança em si mesmo?	
14. Você tem pensado que é uma pessoa inútil?	
15. Você tem realizado com satisfação suas atividades normais do dia-a-dia?	
16. Você tem conseguido se concentrar bem naquilo que faz?	
17. Você tem tido a sensação de que nao pode superar suas dificuldades?	
18. Você se sente rzoalmente feliz, considerando todas as circurstancias?	
19. Você tem perdido o sono frequentemente por causa das suas preocupações?	
20. Você tem se sentido constantemente esgotado e sob pressão?	
21. Você tem se sentido infeliz e deprimido?	

III. REDE SOCIAL

“Agora vou fazer algumas perguntas sobre o seu dia-a-dia e convívio com amigos e familiares.”

22. Com quantos parentes você se sente à vontade e pode falar sobre quase tudo? (Se for o caso, inclua esposo(a), companheiro(a) ou filhos nesta resposta) _____ parentes ☐ nenhum	
23. Com quantos amigos você se sente à vontade e pode falar sobre quase tudo? (Não inclua esposo(a), companheiro(a) ou filhos nesta resposta) _____ amigos ☐ nenhum	

Para as três perguntas seguintes (24 a 26), se sua resposta for SIM, responda com que frequência.	
1. Mais de uma vez por semana 2. Uma vez por semana 3. Duas a três vezes por mês 4. Algumas vezes no ano 5. Uma vez no ano	
24. Nos últimos 12 meses, você participou de atividades esportivas em grupo (futebol, vôlei, basquete, outros) ou atividades artísticas em grupo (grupo musical, coral, artes plásticas, outras)? ☐ sim Frequência: _____; ☐ não	
25. Nos últimos 12 meses, você participou de reuniões de associações de moradores ou funcionários, sindicatos ou partidos? ☐ sim Frequência: _____; ☐ não	
26. Nos últimos 12 meses, você participou de trabalho voluntário não remunerado, em organizações não governamentais (ONGs), de caridade, ou outras? ☐ sim Frequência: _____; ☐ não	

IV. APOIO SOCIAL

“Agora vou fazer mais algumas perguntas relacionadas a frequência que você se sente apoiado pelas pessoas que você convive”

1. nunca 2. raramente 3. às vezes 4. quase sempre 5. Sempre

27. Se você precisar, com que frequência conta com alguém que o ajude, se ficar de cama?	
28. Se você precisar, com que frequência conta com alguém para lhe ouvir, quando você precisa falar?	
29. Se você precisar, com que frequência conta com alguém para lhe dar bons conselhos em uma situação de crise?	
30. Se você precisar, com que frequência conta com alguém para levá-lo ao médico?	
31. Se você precisar, com que frequência conta com alguém que demonstre amor e afeto por você?	
32. Se você precisar, com que frequência conta com alguém para se divertir junto?	
33. Se você precisar, com que frequência conta com alguém para lhe dar informação que o(a) ajude a compreender uma determinada situação?	
34. Se você precisar, com que frequência conta com alguém em quem confiar ou para falar de você ou sobre seus problemas?	
35. Se você precisar, com que frequência conta com alguém que lhe dê um abraço?	
36. Se você precisar, com que frequência conta com alguém com quem relaxar?	
37. Se você precisar, com que frequência conta com alguém para preparar suas refeições, se você não puder prepará-las?	
38. Se você precisar, com que frequência conta com alguém de quem você realmente quer conselhos?	

39. Se você precisar, com que frequência conta com alguém com quem distrair a cabeça?	
40. Se você precisar, com que frequência conta com alguém para ajudá-lo nas tarefas diárias, se você ficar doente?	
41. Se você precisar, com que frequência conta com alguém para compartilhar suas preocupações e medos mais íntimos?	
42. Se você precisar, com que frequência conta com alguém para dar sugestões sobre como lidar com um problema pessoal?	
43. Se você precisar, com que frequência conta com alguém com quem fazer coisas agradáveis?	
44. Se você precisar, com que frequência conta com alguém que compreenda seus problemas?	
45. Se você precisar, com que frequência conta com alguém que você ame que faça se sentir querido?	

V. OHIP-14

“Agora vou fazer algumas perguntas sobre se sua saúde bucal interfere no seu dia-a-dia.”

Resposta:

0 = nunca; 1 = raramente;

2 = às vezes; 3 = repetidamente; 4 = sempre.

Pergunta:	
... por causa de problemas com seus dentes, sua boca ou sua dentadura?	
46. Você teve problemas para falar alguma palavra...	
47. Você sentiu que o sabor dos alimentos tem piorado ...	
48. Você sentiu dores fortes em sua boca?	
49. Você tem se sentido incomodado ao comer algum alimento ...	
50. Você tem ficado pouco à vontade ...	
51. Você se sentiu estressado ...	
52. Sua alimentação tem sido prejudicada ...	
53. Você teve que parar suas refeições ...	
54. Você tem encontrado dificuldade em relaxar ...	
55. Você já se sentiu um pouco envergonhado ...	
56. Você tem estado irritado com outras pessoas ...	
57. Você teve dificuldade em realizar suas atividades diárias ...	
58. Você já sentiu que a vida em geral ficou pior ...	
59. Você tem estado sem poder fazer suas atividades diárias ...	

VI. AVALIAÇÃO CLÍNICA

“Agora iremos avaliar a sua boca e os seus dentes.”

60. Tipo de fissura (Bilateral ou unilateral. Se unilateral, registrar o lado acometido)	
61. CPOD - Número de dentes cariados	
62. CPOD - Número de dentes perdidos (incluindo os com exodontia indicada)	
63. CPOD - Número de dentes obturados	
64. CPOD Total	
65. ISG- Número total de faces sangrantes (utilizar ficha clínica em anexo)	

VII. AVALIAÇÃO OCLUSAL

(Para essa avaliação, utilizaremos modelos de estudo e ficha clínica com legendas.)

DAI	
66. Dentes ausentes (pré-molar a pré-molar, 0 a 10 por arcada)	
67. Apinhamento anterior	
68. Espaçamento anterior	
69. Diastema mediano superior	
70. Desalinhamento maxilar anterior	
71. Desalinhamento mandibular anterior	
72. Trespasse horizontal	
73. Mordida cruzada anterior	
74. Mordida aberta anterior	
75. Relação ântero-posterior de molares	
76. DAI total	

Crescimento Craniofacial	
77. Índice de Goslon (FTU) ou Índice Bauru (FTB)	

ANNEX 2 - Declaração de uso exclusivo de artigo a ser publicado em periódico de língua inglesa

**DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN
DISSERTATION/THESIS**

We hereby declare that we are aware of the article “The impact of orthognathic surgery on quality of life in oral clefts” will be included in Dissertation of the student Mariana Chaves Petri Feitosa was not used and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, de 2019.

Mariana Chaves Petri Feitosa
Author

Signature

Daniela Gamba Garib Carreira
Author

Signature

Rita de Cássia Moura Carvalho Lauris
Author

Signature