

**UNIVERSIDADE DE SÃO PAULO
HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS**

VICTOR PRADO CURVÊLLO

**Comparative analysis of dental arches stability in patients with cleft
lip and palate after rehabilitation treatment**

**Análise comparativa da estabilidade dos arcos dentários em
pacientes com fissura labiopalatina após tratamento reabilitador**

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Tese apresentada ao Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo, para obtenção do título de Doutor em Ciências da Reabilitação.

Área de Concentração: Fissuras Orofaciais e Anomalias Relacionadas.

Orientadora: Profa. Dra. Simone Soares

Coorientadora: Profa. Dra. Thais Marchini de Oliveira Valarelli

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**UNIVERSIDADE DE SÃO PAULO
HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS**

Rua Sílvio Marchione, 3-20

Caixa Postal: 1501

17012-900 – Bauru – SP – Brasil

Telefone: (14) 3235-8000

Prof. Dr. Vahan Agopyan – Reitor da USP

Prof. Dr. José Sebastião dos Santos – Superintendente “pro tempore” do Hospital de Reabilitação de Anomalias Craniofaciais - Universidade de São Paulo

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Aprovada em: ____/____/____

Banca Examinadora

Prof(a). Dr(a). _____

Instituição: _____

Prof(a). Dr(a). _____

Instituição: _____

Prof(a). Dr(a). _____

Instituição: _____

Prof(a). Dr(a). _____

Instituição: _____

Profa. Dra. Ana Paula Fukushiro

Presidente da Comissão de Pós-Graduação HRAC-USP

Data de depósito da tese junto à SPG: ____/____/____

DEDICATÓRIA

Dedico esta tese aos meus queridos e amados filhos **Matheus** e **Henrique**; motivo pelo qual sigo a vida adiante, e me esforço todos os dias para ser uma pessoa melhor.

Ao meu amado pai **Valter**, e as mulheres da minha vida: Minha amada mãe **Purita** e minha amada irmã e amiga **Patricia**.

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"Por muito má a sua vida possa parecer, sempre há alguma coisa que você pode fazer e ter sucesso. Enquanto há vida, há esperança."

Stephen Hawking

ABSTRACT

Curvêllo VP. Comparative analysis of dental arches stability in patients with cleft lip and palate after rehabilitation treatment [thesis]. Bauru: Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo; 2018.

While the maxillary growth and development in patients with cleft lip and palate (PLC) is very studied at early age, the literature lacks studies at adulthood. The study of dental arches after oral rehabilitation with dental prostheses is necessary in this group of patients to verify the stability of the interdisciplinary treatment performed. This study aimed to evaluate the stability of dental arches in adults with cleft lip and palate who received orthodontic treatment and were rehabilitated with dental prostheses compared with adults who received implant-supported prosthesis and conventional fixed partial dentures, both in the area of cleft lip and palate. The group rehabilitated with implants was composed of 20 patients (7 males, 13 females; mean age of 25 years) and the group rehabilitated with a conventional fixed partial denture consisted of 15 patients (8 females and 7 males; mean age of 25 years). The dental casts were scanned with a laser scanner in the two proposed treatment phases: T1- immediately after completion of orthodontic treatment and T2- at least 1 year after oral rehabilitation with dental prostheses. The stability evaluation comprised the subtraction of T2 from T1 measurements ($\Delta = T2-T1$). All linear, inter-canine, inter-molar and total arch length measurements were performed digitally. The independent t-test compared the groups between the times ($p \leq 0.05$). Among groups, the stability comparison showed statistically differences in inter-canine measurements, but non-significant differences in inter-molar distance and total arch length. Adults with cleft lip and palate rehabilitated with fixed partial and implant-supported dentures had a difference in dental arch stability. Fixed partial prosthesis provided a greater linear dimensional stability of dental arches in this group of individuals.

Keywords: Cleft lip. Mouth rehabilitation. Dental implants. Denture, partial, fixed.

RESUMO

Curvêllo VP. Análise comparativa da estabilidade dos arcos dentários em pacientes com fissura labiopalatina após tratamento reabilitador [tese]. Bauru: Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo; 2018.

O crescimento e desenvolvimento da maxila em pacientes com fissura labiopalatina (FLP) tem sido muito estudado na idade precoce, porém em idade adulta há uma escassez de trabalhos. O estudo dos arcos dentários após a reabilitação oral com próteses dentárias se faz necessário nesse grupo de pacientes, com o intuito de verificar a estabilidade do tratamento interdisciplinar realizado. O objetivo do estudo foi avaliar a estabilidade dos arcos dentários em pacientes com fissura labiopalatina que receberam tratamento ortodôntico e foram reabilitados com prótese dentárias, comparando os pacientes que receberam uma prótese sobre implante com indivíduos que receberam uma prótese parcial fixa convencional, ambas na área da fissura labiopalatina. O grupo reabilitado com implantes foi composto por 20 pacientes (7 do sexo masculino, 13 do sexo feminino e idade média de 25 anos) e o grupo reabilitado com uma prótese parcial fixa convencional foi composto por 15 pacientes (8 do sexo feminino e 7 do sexo masculino e idade média de 25 anos). Os modelos de gesso foram digitalizados com um scanner a laser nas duas fases de tratamento propostas: T1- imediatamente após a conclusão do tratamento ortodôntico e T2- pelo menos 1 ano após a reabilitação oral com próteses dentárias. A subtração das medidas no tempo 2 pelo tempo 1 caracterizou a equação delta ($\Delta = T2 - T1$), para a avaliação da estabilidade. Todas as lineares, inter-canino, inter-molar e comprimento total do arco foram realizadas digitalmente. O teste t independente foi utilizado para a comparação dos grupos e entre os tempos ($p \leq 0,05$). Houve diferença estatística na comparação da estabilidade entre os grupos para medições inter-canino, mas não houve diferença na distância inter-molares e no comprimento total do arco. Há diferença na estabilidade dos arcos dentários de pacientes com fissura labiopalatina em idade adulta, reabilitados com prótese parcial fixa e prótese sobre implante, sendo que a prótese parcial fixa consiste em um tratamento que conferiu maior estabilidade dimensional linear dos arcos dentários nesse grupo de pacientes.

Palavras-chave: Fenda labial. Reabilitação bucal. Implantes dentários. Prótese parcial fixa.

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1 INTRODUCTION

1 INTRODUCTION

The craniofacial anomalies are a diversified group of congenital defects. Among them, cleft lip and palate (CLP) are the most prevalent ones, affecting 1 at every 500 – 700 births, and considered a public health burden of care according to the World Health Organization (2002, 2015). CLP is caused by the lack of fusion of one or more facial embryological processes resulting in a discontinuity in lip and/or palate (DIXON et al., 2011), occurring also in animals, but more prevalent in humans (YAKOB et al., 2018). Problems in the craniofacial complex growth are often observed in individuals with CLP, generally expressed in the transversal, anterior-posterior, and vertical dental relations (SAKODA et al., 2017).

Oral clefts may involve the lip, alveolus, and palate and may occur up to the 12th week of intra-uterine life (FREITAS et al., 2012b). CLP has a multifactorial etiology determined mainly by genetic and environmental factors (WATKINS et al., 2014). Currently, the interaction of these factors increased the risk for non-syndromic CLP (PANAMONTA et al., 2015). The early diagnosis is accomplished at the gestational period by means of the ultrasound examination (TONNI; GRISOLIA; SEPULVEDA, 2013), but the rehabilitative treatment takes place immediately after birth with the primary surgeries.

Cheiloplasty and palatoplasty are the primary surgeries usually performed up to 12 months of age; however, the rehabilitative treatment is not restricted to the anatomic repair of the cleft (FREITAS et al., 2012b). This requires an interdisciplinary team (VARGERVIK; OBEROI; HOFFMAN, 2009; WANG et al., 2009; FREITAS et al., 2012b; ROCHA et al., 2012) to provide the anatomic and functional rehabilitation of the individual until the skeletal maturity (ALJOHAR; RAVICHANDRAN; SUBHANI, 2008; ROCHA et al., 2012). The interdisciplinary team comprises Plastic Surgeons, Dentists, and Speech and Hearing Therapists, who play an essential role in rehabilitation (NOORDHOFF, 2009; REDDY, S.; REDDY, L.; REDDY, R., 2009; VARGERVIK; OBEROI; HOFFMAN, 2009; WANG et al., 2009).

The craniofacial growth of an individual with cleft lip and palate is restricted by the primary surgeries performed at early childhood, which despite of the rehabilitation of the esthetics and function, cause a deleterious effect on the maxillary growth, mainly

in individuals with clefts involving the lip, alveolus, and palate. Some studies affirmed that the lack of three-dimensional maxillary growth is directly influenced by the effects caused by the cheiloplasty (LI et al., 2006; BICHARA et al., 2015), while other authors state that the palatoplasty is more harmful (LIAO; MARS, 2005; FARRONATO et al., 2014).

The sequelae is variable and extremely influenced by the sum of factors consisting of the cleft amplitude, frequency of plastic surgeries, surgeons' ability, tissue trauma caused by the surgeries, presence or absence of Simonart's band, and the facial growth pattern determined by genetics of the individual (FREITAS et al., 2012b). Notwithstanding, the literature reports that the tissue scarring with shrinkage effect on the segmented maxilla is the main factor leading to the alteration in the growth factor (LILJA et al., 2006). Commonly, the result of the rehabilitative treatment is evaluated by the balance among facial appearance, speech, and facial growth (FREITAS et al., 2012b).

The rehabilitation of individuals with cleft lip and palate challenges the dentist because the anatomic and functional alterations are directly related to the malformation type and age of the treatment onset. Thus, prostheses rehabilitate many cases. These fixed/removable, tooth/implant-supported prostheses aim at reestablishing the esthetics, phonetics, and function and depend on the bone, dental, and periodontal condition and on the maxillo-mandibular relation (FREITAS et al., 2013). To reach the rehabilitative treatment success, firstly, one must obtain dental casts capable of providing previous reliable information to enable the study of the case and to be part of the individual's file.

A systematic dental documentation since the birth of a child with CLP provides the accurate and prospective planning by individualizing the procedures required at every treatment stage (WUTZL et al., 2009), and the longitudinal evaluation of the rehabilitative process (MELLO et al., 2013). Through study casts, the changes on craniofacial growth are diagnosed by analyzing the transversal, vertical, and anterior-posterior relations (LILJA et al., 2006; SINKO et al., 2008).

The literature reports longitudinal studies on individuals with CLP through dimensional anatomic measurements on study casts (SABARINATH et al., 2010; ROUSSEAU et al., 2013), and image tests, such as photographs and radiographs (OTERO et al., 2012; YANG et al., 2012). These methods may lead to errors not only

during the individuals' positioning, but also during the information analysis. Moreover, studies on the comparison of measurements on study casts have the inconvenience of transportation of the files (ROSATI et al., 2012). These challenges lead to the development of alternative methods for the morphological assessment of these anatomic structures. The three-dimensional analysis of the dental arches is a notable change in data collection (LATIEF et al., 2012; SFORZA et al., 2012; HUANCA GHISLANZONI et al., 2013; MELLO et al., 2013; SFORZA; MENEZES; FERRARIO, 2013; KUIJPERS et al., 2014; UGOLINI et al., 2015; DE MENEZES et al., 2016).

The 3D digital images have many advantages as rotation and handling similar to those of the study casts (GOONEWARDENE et al., 2008; LEIFERT et al., 2009; BOOTVONG et al., 2010); more accurate measurements, handling, and storage; and on-line share of the information which enable the collaboration among rehabilitative centers to perform the assessment, planning, and execution of every rehabilitative treatment phase (KUIJPERS et al., 2014; UGOLINI et al., 2015; DE MENEZES et al., 2016). Studies comparing the measurement on digital images and study casts concluded that 3D images are clinically acceptable and reproducible (GOONEWARDENE et al., 2008; LEIFERT et al., 2009; BOOTVONG et al., 2010).

It is important that the dentist is aware of the 3D changes in the dental arches of individuals with CLP because these alterations influenced on the outcomes of the rehabilitative process (FREITAS et al., 2012b), which aims at not only achieving the anatomic-functional rehabilitation, but also providing the insertion of the individual in the society (REDDY, S.; REDDY, L.; REDDY, R., 2009).

Due to the lack of studies on the assessment of the dental arch dimensions of individuals with CLP immediately after the orthodontic finalization and on the stability obtained with dental prosthesis, this study aimed to analyze the measurement of the dental arches of adults with CLP immediately after the orthodontic finalization and one year after prosthetic rehabilitation to provide information on the stability of the dental arches in this specific population. Thus, the information provided by study will help in a better understanding of the factors that interfere in the dental arch relation of adults with CLP after the prosthetic rehabilitative treatment and in establishing parameters for protocols and further researches.

This study aimed to perform a longitudinal linear evaluation of the dimensional alterations of dental arches in individuals with CLP, before and after oral rehabilitation,

by comparing: 1 - the maxillary dimensions of adults with unilateral complete cleft lip and palate, immediately after the finalization of the orthodontic treatment and one year after the prosthetic rehabilitative treatment with implant-supported prosthesis; 2 - the maxillary dimensions of adults with unilateral complete cleft lip and palate, immediately after the finalization of the orthodontic treatment and one year after the prosthetic rehabilitative treatment with fixed tooth-supported prosthesis; 3 - the dimensional alterations between individuals rehabilitated by either tooth or implant-supported prosthesis.

2 OBJECTIVES

2 OBJECTIVES

2.1 GENERAL OBJECTIVE

This study aimed to perform a longitudinal linear evaluation of the dimensional alterations of dental arches in individuals with CLP, after the orthodontic treatment and at least one year after the oral rehabilitation with dental prostheses, by comparing individuals who received implant-supported prostheses with those who received conventional fixed partial denture, to evaluate the stability of the interdisciplinary treatment of these individuals.

2.2 SPECIFIC OBJECTIVES

- To evaluate the maxillary dimensions of adults with unilateral complete cleft lip and palate, immediately after the finalization of the orthodontic treatment and one year after the oral rehabilitation by implant-supported prosthesis.
- To evaluate the maxillary dimensions of adults with unilateral complete cleft lip and palate, immediately after the finalization of the orthodontic treatment and one year after the oral rehabilitation by conventional fixed partial denture.
- To evaluate and compare the dimensional alterations between individuals rehabilitated by either tooth or implant-supported prosthesis.

3 ARTICLES

3 ARTICLES

The articles presented in this thesis were written according to the instructions and guidelines for article submission of the corresponding journals.

- ARTICLE 1 – Comparative analysis of dental arches stability in patients with cleft lip and palate after rehabilitation treatment. *International Journal of Oral and Maxillofacial Surgery*. (Submitted)
- ARTICLE 2 – Impact of orofacial dysfunction on the quality of life of adult patients with cleft lip and palate. *Cleft Palate Craniofac J*. (In press)

3.1 ARTICLE 1 – Comparative analysis of dental arches stability in patients with cleft lip and palate after rehabilitation treatment*

ABSTRACT

While the maxillary growth and development in patients with cleft lip and palate (PLC) is very studied at early age, the literature lacks studies at adulthood. The study of dental arches after oral rehabilitation with dental prostheses is necessary in this group of patients to verify the stability of the interdisciplinary treatment performed. This study aimed to evaluate the stability of dental arches in adults with cleft lip and palate who received orthodontic treatment and were rehabilitated with dental prostheses compared with adults who received implant-supported prosthesis and conventional fixed partial dentures, both in the area of cleft lip and palate. The group rehabilitated with implants was composed of 20 patients (7 males, 13 females; mean age of 25 years) and the group rehabilitated with a conventional fixed partial denture consisted of 15 patients (8 females and 7 males; mean age of 25 years). The dental casts were scanned with a laser scanner in the two proposed treatment phases: T1- immediately after completion of orthodontic treatment and T2- at least 1 year after oral rehabilitation with dental prostheses. The stability evaluation comprised the subtraction of T2 from T1 measurements ($\Delta = T2-T1$). All linear, inter-canine, inter-molar and total arch length measurements were performed digitally. The independent t-test compared the groups between the times ($p \leq 0.05$). Among groups, the stability comparison showed statistically differences in inter-canine measurements, but non-significant differences in inter-molar distance and total arch length. Adults with cleft lip and palate rehabilitated with fixed partial and implant-supported dentures had a difference in dental arch stability. Fixed partial prosthesis provided a greater linear dimensional stability of dental arches in this group of individuals.

Key words: cleft lip; mouth rehabilitation; dental implants; denture, partial, fixed.

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INTRODUCTION

The craniofacial anomalies are a diversified group of congenital defects. Among them, cleft lip and palate (CLP) are the most prevalent one, considered a public health burden of care according to the World Health Organization^{1,2}. The lack of fusion of one or more facial embryological processes causes CLP, resulting in a discontinuity in lip and/or palate³. CLP has a multifactorial etiology determined mainly by genetic and environmental factors⁴.

Cheiloplasty and palatoplasty are the primary surgeries usually performed up to 12 months of age; however, the rehabilitative treatment is not restricted to the anatomic repair of the cleft⁵. This requires an interdisciplinary team^{5,6,7,8} to provide the anatomic and functional rehabilitation of the individual until the skeletal maturity^{8,9}. The interdisciplinary team comprises Plastic Surgeons, Dentists, and Speech and Hearing Therapists, who play an essential role in rehabilitation^{6,7,10,11}. The main consequence of primary surgeries is generally expressed in the transversal, anterior-posterior, and vertical dental relations¹².

The rehabilitation of individuals with cleft lip and palate challenges the dentist because the anatomic and functional alterations are directly related to the malformation type and age of the treatment onset. Thus, prostheses rehabilitate many cases. These fixed/removable, tooth/implant-supported prostheses aim at reestablishing the esthetics, phonetics, and function and depend on the bone, dental, and periodontal condition and on the maxillo-mandibular relation¹³. To reach the rehabilitative treatment success, one firstly must obtain dental casts capable of providing previous reliable information to enable the study of the case and to be part of the individual's file.

A systematic dental documentation since the birth of a child with CLP provides the accurate and prospective planning by individualizing the procedures required at every treatment stage¹⁴ and the longitudinal evaluation of the rehabilitative process¹⁵. Through study casts, the changes on craniofacial growth are diagnosed by analyzing the transversal, vertical, and anterior-posterior relations^{16,17}.

Due to the lack of studies on the assessment of the dental arch dimensions of individuals with CLP immediately after the orthodontic finalization and on the stability obtained with dental prosthesis, this study aimed to analyze the measurement of the

dental arches of adults with CLP immediately after the orthodontic finalization and one year after rehabilitation with fixed tooth- or implant-supported prostheses to provide information of the stability of the dental arches in this specific population. Thus, the information provided by study will help in a better understanding of the factors that interfere in the dental arch relation of adults with CPL after the prosthetic rehabilitative treatment and in setting up parameters for protocols and further researches.

This study aimed to perform a longitudinal linear evaluation of the dimensional alterations of dental arches in individuals with CLP, before and after oral rehabilitation, by comparing: 1 - the maxillary dimensions of adults with unilateral complete cleft lip and palate, immediately after the finalization of the orthodontic treatment and one year after the prosthetic rehabilitative treatment with implant-supported prosthesis; 2 - the maxillary dimensions of adults with unilateral complete cleft lip and palate, immediately after the finalization of the orthodontic treatment and one year after the prosthetic rehabilitative treatment with fixed tooth-supported prosthesis; 3 - the assessment and comparison of the dimensional alterations between individuals rehabilitated by either tooth or implant-supported prosthesis.

MATERIAL AND METHODS

Sample selection

This study was submitted and approved by the Institutional Review Board, regarding ethical aspects (protocol CAAE #50808215.2.0000.5441).

The sample comprised digitized models of adults with unilateral complete cleft lip and palate, aged from 20 to 30 years, matched by gender, regularly enrolled in the Hospital. Inclusion criteria were no associated syndrome or malformation; individuals not submitted to orthognathic surgery; individuals without overdenture prosthesis, total prosthesis, and protocol prosthesis; presence of study casts at the treatment phases evaluated by this study. The study casts were obtained from the files of the Hospital.

Sample size was calculated based on a previous pilot study to detect a minimum difference in width measurement of 0.8 mm, with standard deviation of 0.7 mm, level of significance of 5%, and study power of 80%. The minimum number of models to conduct the study was of 15.

The digitized models were divided into two groups:

- Group Implant-supported Prosthesis (G1) – 20 adults with unilateral complete cleft lip and palate, rehabilitated with implant-supported prosthesis;
- Group Fixed Prosthesis (G2) – 15 adults with unilateral complete cleft lip and palate, rehabilitated with fixed prosthesis.

The assessment was performed through 3D images of the maxillary models at the following periods:

- Time 1 (T1): after the orthodontic treatment, requiring prosthetic rehabilitation;
- Time 2 (T2): one year after the prosthetic rehabilitation.

Scanning of the models

We used a laser scanner (3Shape's R700TM Scanner, Copenhagen, Denmark) to digitize the study casts obtained from the files of the institution. The images were analyzed through Appliance Designer Software (3Shape, Copenhagen, Denmark).

Obtaining of the measurements

The maxillary dimensions were evaluated through the linear measurements: inter-canine (C-C'), inter-molars (M-M'), and total arch length (I-M), that is, the results were analyzed by the change in the measurements at the studied periods. Considering the study variables, period and groups, we verified the stability of the dental arches.

The dental arch stability was evaluated by the variation in the linear measurements during the study interval (from T1 to T2). We used the following formula $\Delta=T2-T1$, where Δ was the difference in the measurements from T2 to T1. This method was chosen to allow an objective and coherent data analysis. The results of this formula can be either positive or negative. Positive values indicated an increase in dental arch, that is, no expansion loss occurred, leading to dental arch stability. Negative values, on the other hand, indicated expansion loss after the orthodontic treatment. Moreover, the Δ values indicate the stability amplitude, that is, the measurement in millimeters (mm) of the expansion loss, when present.

Landmarks were marked on the images of the maxillary arch to obtain the linear measurements (Table 1 and Figure 1). All measurements were performed point-by-point through the measurement tool of the software.

Table 1 - Definition and description of the Linear Measurements (mm)

Linear Measurements (mm)	Abbreviation	Definition
Inter-canine	C-C'	From the right maxillary canine cusp tip to the left maxillary canine cusp tip.
Inter-molar	M-M'	From the mesial-buccal cusp tip of the right maxillary first molar to the mesial-buccal cusp tip of the left maxillary first.
Incisor-molar line	I-M	Anterior-posterior length – determined from the line perpendicular to the Incisor point (I) to the line of the inter-molar distance (MM').

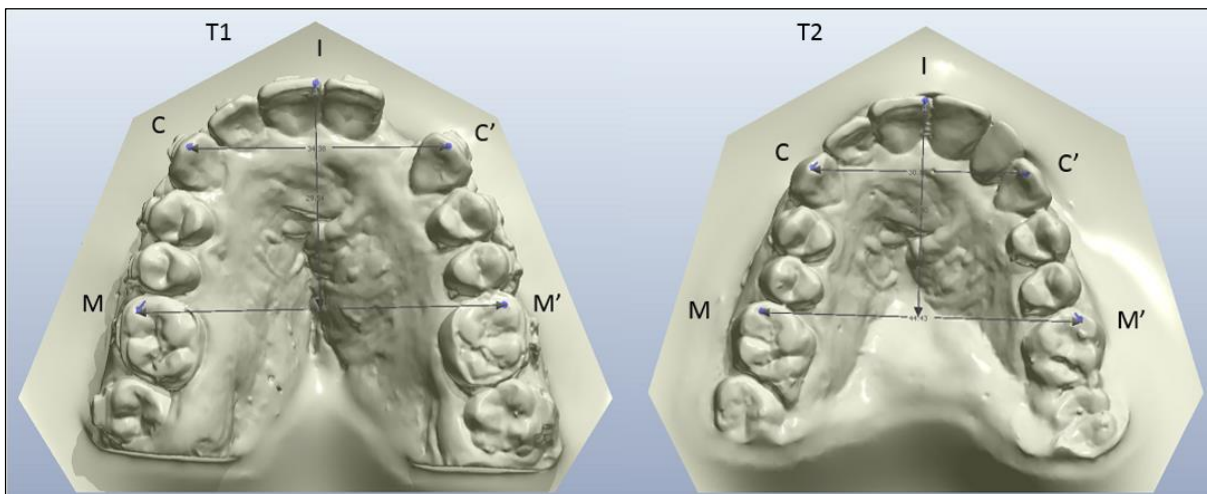


Figure 1 - Landmarks used for the analysis of the digital models

Statistical analysis

All statistical analyses were performed by Statistica software (Statistica for Windows - Version 7.0 - StatSoft). To analyze the intraexaminer error (systematic error), half of the sample was measured again 15 days after the first measurement. To calculate the systematic error, paired t test was used at level of significance of 5%. Dahlberg's formula determined the casual error. Shapiro-Wilk test was applied to verify the data homogeneity and normality. We applied t test and Mann-Whitney, at level of significance of 5%.

RESULTS

The sample was selected according to inclusion and exclusion criteria with homogenous distribution of age and gender, without statistically significant differences (Table 2).

Table 2 - Sample distribution

Groups	N	Gender n (%)	Mean ± SD (years)	p
G1	20	Female 13 (65%) Male 7 (35%)	25.35 ± 2.88	0.79
G2	15	Female 8 (53.3%) Male 7 (46.7%)	25.06 ± 3.36	

G1= Group Implant-supported prosthesis; **G2**= Group Fixed prosthesis; **SD**= standard-deviation.

Method error

The examiner (VPC) reassessed all measurements (C-C', M-M', and IM) after 20 days to verify the intraexaminer reproducibility and the Dahlberg's formula¹⁸ and paired t test analyzed the data, without statistically significant differences ($p \geq 0.05$).

Maxillary dimensions

At T1, immediately after the orthodontic treatment finalization, the intergroup comparison showed no statistically significant differences in the maxillary dimensions (Table 3). At T2, at least one year after the prosthesis installation, the groups showed a similar behavior, without statistically significant differences in maxillary dimensions (Table 4).

Table 3 - Intergroup comparisons of maxillary dimensions (mm) immediately after the orthodontic treatment finalization (T1) (t test)

Measurements T1	G1	G2	95% CI	p ≤ 0.05
	Mean ± SD	Mean ± SD		
C-C'	34.01 ± 3.43	31.49 ± 4.07	-0.07 – 5.09	0.056
M-M'	52.74 ± 3.66	52.61 ± 3.37	-2.32 – 2.59	0.912
I-M	26.80 ± 3.73	24.35 ± 3.91	-0.20 – 5.09	0.069

G1= Group Implant-supported prosthesis; **G2**= Group Fixed prosthesis; **SD**= standard-deviation; **CI**= confidence interval.

Table 4 - Intergroup comparisons of maxillary dimensions (mm) at least one year after the prosthesis installation (T2) (t test)

Measurements T2	G1	G2	95% CI	p≤0.05
	Mean ± SD	Mean ± SD		
C-C'	34.00 ± 3.40	32.83 ± 3.50	-1.22 – 3.56	0.32
M-M'	52.08 ± 3.25	51.82 ± 2.74	-1.85 – 2.38	0.80
I-M	26.79 ± 3.29	24.69 ± 3.53	-0.26 – 4.46	0.07

G1= Group Implant-supported prosthesis; G2= Group Fixed prosthesis; SD= standard-deviation; CI= confidence interval.

Only the intercanine measurement (ΔC) showed statistically significant differences ($p=0.01$) between groups (Table 5).

Both ΔM and ΔIM showed no statistically significant differences (Table 5). The inter-molar measurement (ΔM) exhibited a similar behavior in all individuals rehabilitated either by implants or conventional fixed prosthesis with a decrease in the measurements of -0.65 mm and -0.7 mm, respectively (Table 5).

Table 5 - Intergroup comparison of the stability ($\Delta = T2-T1$) of the maxillary dimensions (mm) (t test)

Variables	G1	G2	95% CI	p≤0.05
	Mean ± SD	Mean ± SD		
ΔC	-0.005 ± 1.17	1.334 ± 1.83	-2.37 – 0,30	0.01*
ΔM	-0.659 ± 1.65	-0.788 ± 1.78	-1.06 – 1,32	0.82
ΔIM	-0.010 ± 1.27	0.338 ± 1.56	-1.32 – 0,62	0.47

G1= Group Implant-supported prosthesis; G2= Group Fixed prosthesis; SD= standard-deviation.

*Statistically significant difference $p\leq 0.05$.

DISCUSSION

The treatment of individuals with CLP is long and requires and interdisciplinary team, starting with the accomplishment of the primary surgeries (cheiloplasty and palatoplasty), usually up to 12 months of life, but not restricted only to the anatomic repair of the cleft⁵. The interdisciplinary team is necessary^{5,6,7,8} to promote the anatomic and functional rehabilitation until the individual reaches the skeletal maturity^{8,9}.

The primary surgeries lead to a deleterious effect on the maxillary growth, mainly in individuals with clefts involving the lip, alveolus, and palate. The main consequence is the restriction of the maxillary growth, caused by the tissue healing

shrinkage on the segmented maxilla, the main factor for the alteration in the growth pattern¹⁶. To correct the cleft is only the onset of the treatment and the challenge for the interdisciplinary team because the treatment outcome is evaluated by the balance between the facial appearance, speech, and face growth⁵, aiming at the social insertion of the individual.

The study casts obtained by the dentists involved in the oral rehabilitation of the individual with CLP are of easy and fast execution and effective to observe the changes in craniofacial growth that can be diagnosed by the analysis of the transversal, vertical, and anterior-posterior dental relations^{16,17}.

The 3D technology is a modern tool to improve the potential of these dental assessment because the digitized models allow the three-dimensional analysis, which is a significant change in data collection^{15,19,20,21,22,23,24,25}. The digitized models has many advantages as: rotation and handling similar to that of study casts^{26,27,28}, accurate measurements, more adequate handling and storage, on-line sharing of the information that enable multicenter studies to evaluate, plan, and execute the phases of the rehabilitative treatment^{23,24,25}. Studies on the comparison of measurements on digital and conventional models concluded that 3D images are clinically acceptable and reproducible^{26,27,28}. The easy data collection and handling through specific software were important advantages in this present study that evaluate longitudinally at two different periods: just after the orthodontic treatment finalization and at least one year after the oral rehabilitation with either tooth- or implant-supported prosthesis.

This study used strategic anatomic landmarks to evaluate and compare the dimensional alterations of the dental arches in permanent dentition: intercanine relation –measured by the cusp tips of the maxillary canines (C-C’); intermolar relation – measured by the mesial-buccal cusp tips of the maxillary first molars (M-M’), and total arch length (I-M) – measured by mesial-incisal angle of the left central incisor^{20,26,27,28,29,30,31,32,33,34}.

The oral rehabilitation of individuals with oral clefts involves all dental specialties during all the different treatment phases, but the orthodontic treatment and the planning of dental prosthesis play a decisive role in rehabilitation. The orthodontics is a complex treatment in individuals with CLP because the agenesis of the lateral incisor is very frequent and should be previously evaluated⁵. The dental prosthesis is required when the orthodontic movement is not enough to rehabilitate the esthetics

and function⁵. Among the many options of dental prostheses, the main types to rehabilitate the cleft area are the conventional tooth-supported and the implant-supported prostheses.

The stability of the dental arches of individuals with CLP is largely studied during and after the orthodontic treatment aiming at evaluating the maxillary expansion^{30,35}, which is required due to the deficient maxillary growth pattern^{5,35}. But, the maxilla segmentation due to cleft itself is a factor contributing for the stability of the rehabilitative/orthodontic treatment.

At T1, the groups were homogenous, validating the sample. At T2, after the prosthesis installation on cleft area (tooth- or implant-supported) no statistically significant differences occurred between groups. The stability achieved after the orthodontic treatment should be maintained by the prosthetic rehabilitation. In this study, the difference in ΔC revealed that the conventional fixed prosthesis stabilized the anterior area of the maxillary dental arch in individuals with CLP. Thus, although the implant-supported prosthesis appeals to the individuals, with adequate biological and mechanical conditions, not even this is the more adequate therapeutic option because the implant-supported prosthesis showed lack of stability in the inter-canine relation.

Brägger, Burger and Ingervall (1991) evaluated individuals with unilateral and bilateral CLP at the ending of the surgical and orthodontic treatment and after the installation of a short removable partial denture (for the individuals with unilateral CLP – 8 years of following-up). They observed a small decreasing in the maxillary width and in the inter-molar measurements³⁶. Similarly, in this present study, the inter-molar relation decreased for both groups in individuals with unilateral CLP. Also, Ramstad and Jendal (1997) reported a decreasing in the inter-molar distances. These authors evaluated the study casts of 22 individuals (mean age of 18.1 years) treated through orthodontic expansion and prosthesis as retainer. The prosthesis comprised a fixed partial denture, supported by the central incisor and the cleft-side canine tooth. The authors found a decrease in the inter-canine measurements and affirmed that most of the post-treatment changes occurred during the first five years. The authors did not find a total stability even after 13.5 years of following-up³⁷. This result is different from those of this present study, which found a stability in CC' measurement in-group fixed

prosthesis. The different following-up periods may account for this difference between the study findings.

Li and Lin (2007) by evaluating the post-orthodontic retainers in individuals with CLP verified that the distances increased after the orthodontic treatment and decreased after the retainer installation³⁰. This result is partially different from that of this present study evidencing the stability of the inter-canine relation in the group fixed prosthesis, probably a response to the retention provided by the fixed prosthesis.

Fixed partial denture is characterized by the tooth preparation and splinting of the teeth aiming at replacing the missed tooth. In individuals with CLP, the metal superstructure strategically retains the cleft area. On the other hand, the rehabilitation with implant-supported prosthesis comprised a single prosthesis on the area of the secondary bone graft. Our results showed that this latter approach led to expansion loss of 0.005 mm, while the fixed prosthesis reached stability with the increase of 1.33 mm in the inter-canine distance (Table 5).

The inter-molar measurement decreased in both groups, with loss of expansion of -0.65 mm and -0.7 mm for group implant and fixed prosthesis, respectively (Table 5). We hypothesize that in the posterior area of the arch, without prosthesis in both groups, the behavior of the palate segmentation caused by the cleft led to the lack of dental arch stability.

This is the first study analyzing the stability of dental arches in individuals with CLP and further studies on different prosthesis types and on different rehabilitation protocols provided by other centers are necessary to establish protocols for adults with CLP.

CONCLUSION

In adults with CLP rehabilitated by either conventional fixed or implant-supported prosthesis, the dental arch stability was different. The conventional fixed prosthesis resulted in greater stability of linear dimensions of the maxillary dental arch.

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3.2 ARTICLE 2 – Impact of orofacial dysfunction on the quality of life of adult patients with cleft lip and palate*



Original Article



Impact of Orofacial Dysfunction on the Quality of Life of Adult Patients With Cleft Lip and Palate

Natalia Cristina Reinaldo Mariano, DDS, MSc¹,
 Mariana Naomi Sano, DDS², Victor Prado Curvêllo, DDS, MSc¹,
 Ana Lúcia Pompéia Fraga de Almeida, DDS, MSc, PhD³,
 Karin Hermana Neppelenbroek, DDS, MSc, PhD⁴,
 Thais Marchini Oliveira, DDS, MSc, PhD⁵,
 and Simone Soares, DDS, MSc, PhD³

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Abstract

Objective: This study assessed the prevalence of orofacial dysfunctions (ODs) and quality of life (QoL) in adults with and without a cleft lip and palate.

Design: Cross sectional.

Setting: Craniofacial Center, Hospital for Rehabilitation of Craniofacial Anomalies, Bauru, São Paulo, Brazil.

Methods: The study was composed of a sample of 120 patients: 60 adults in the cleft lip and palate group (CLPG) and 60 adults in the control group with no craniofacial anomalies. Each patient underwent an interview and clinical examination, using the Nordic Orofacial Test-Screening (NOT-S) and the 36-Item Short Form Survey. Data were analyzed using Mann-Whitney *U* test, χ^2 , and the Spearman correlation coefficients.

Results: There was a higher prevalence of OD in CLPG ($P < .001$) on the NOT-S. The adults in the CLPG had higher QoL in the areas of general health ($P = .003$), physical function ($P = .014$), social function ($P < .001$), and vitality ($P = .006$). The CLPG had significant associations between higher OD and lower QoL for general health ($P = .004$), emotional role function ($P = .028$), and vitality ($P = .05$).

Conclusion: Orofacial dysfunctions were more prevalent in adults with a cleft, negatively impacting their QoL in general health, emotional role function, and vitality. However, adults with a cleft also had significantly higher QoL, reflecting possible resiliency when compared to adults without a cleft.

Keywords

quality of life, muscle function, epidemiology

Introduction

Orofacial function is the interaction of complex coordinated activities of the central nervous and the neuromuscular systems (Bakke et al., 2007), which includes several vital actions such as breathing, chewing, swallowing, and speaking. The orofacial function acts as a basis for social interaction in terms of verbal and emotional communication, facial expression, and appearance. When compromised, these physiological processes can cause or worsen tooth malocclusion. Malocclusion may result from either hereditary prenatal factors (hypoplasia) or intrinsic

¹ Hospital of Rehabilitation of Craniofacial Anomalies, University of São Paulo, Bauru, Brazil

² Bauru School of Dentistry, University of São Paulo, Bauru, Brazil

³ Department of Prosthodontics, Bauru School of Dentistry, Hospital of Rehabilitation of Craniofacial Anomalies, University of São Paulo, Bauru, Brazil

⁴ Department of Prosthodontics, Bauru School of Dentistry, University of São Paulo, Bauru, Brazil

⁵ Department of Pediatric Dentistry, Orthodontics and Public Health, Bauru School of Dentistry, University of São Paulo, USP, Hospital for Rehabilitation of Craniofacial Anomalies, Bauru, Brazil

Corresponding Author:

Simone Soares, DDS, MSc, PhD, Department of Prosthodontics, Bauru School of Dentistry, University of São Paulo, Alameda Dr. Octávio Pinheiro Brisolla, 9-75, 17012-901, Bauru, SP, Brazil.

Email: sisoares@usp.br

* Mariano NCR, Sano MN, Curvêllo VP, Almeida ALPF, Neppelenbroek KH, Oliveira TM, Soares S. Impact of orofacial dysfunction on the quality of life of adult patients with cleft lip and palate. *Cleft Palate Craniofac J*. In press 2018.

postnatal factors (early tooth loss). Malocclusion can also be due to extrinsic postnatal factors, which refer to harmful habits, such as sucking with no nutritional purpose, respiratory disorders, tongue interposition, changes in swallowing and chewing, and speech articulation (Moreno Uribe and Miller, 2015). Disorders or congenital anomalies, such as cleft lip and palate (CLP; Mossey et al., 2009), can substantially compromise aesthetic, morphological, and functional aspects of orofacial function (Freitas et al., 2012a, 2012c).

Patients with CLP generally have maxillary hypoplasia (Lee et al., 2014) and mouth breathing; consequently, they exhibit reduced salivation and self-cleaning, greater periodontal problems (Bolor and Thomas, 2010; Perdikogianni et al., 2009), and more dental and orofacial impairment (Dadáková et al., 2016). These factors can impact the quality of life (Foo et al., 2012). According to the World Health Organization, quality of life (QoL) is "an individual's perception of their position in life and in the context of culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns" (WHOQOL, 1993). The degree of satisfaction or dissatisfaction of an individual may affect his or her values and compromise his or her overall QoL (Leme et al., 2012). Quality of life evaluations are important to seek results capable of setting up standards for further clinical research and improvements for the treatment protocol of individuals with CLP (Mani et al., 2010). There is a vast literature on health-related quality of life (HRQoL) and oral health-related quality of life (OHRQoL) in adult patients with CLP (Marcusson et al., 2001; Sinko et al., 2005; Mani et al., 2010; Munz et al., 2011; Foo et al., 2012; Reddy et al., 2012). The recent systematic review and meta-analysis by Queiroz Herkrath et al. (2015) compared HRQoL and OHRQoL of nonsyndromic individuals with and without CLP and aimed to identify the dimensions most affected in individuals with CLP. These authors concluded that the cleft and palate itself negatively affects HRQoL, mainly in the psychosocial dimensions.

Orofacial dysfunctions, such as dentofacial deformities and speech intelligibility, may have an impact on health status and QoL, regardless of their etiology. This has been the subject of research in clinical and longitudinal studies with people without CLP (Frejman et al., 2013; Knipfer et al., 2014), with some studies of individuals with CLP (Montes et al., 2017). This study aimed to evaluate the prevalence of orofacial dysfunctions in adults with CLP in comparison with a control group (CG) without CLP and correlate these dysfunctions with QoL. There are several cleft-related risk factors impacting orofacial functioning. The hypotheses tested were that orofacial dysfunction would not equally affect adults with and without CLP and that orofacial dysfunction is related to QoL.

Material and Methods

Sample Selection

Inclusion criteria for adults with CLP included those who had a diagnosis of isolated CLP were older than age 30, and had

completed CLP treatment including pharyngoplasty and speech and hearing therapy. All individuals with CLP were recruited from December 2015 to April 2016 in a Craniofacial Center for the treatment of CLP, and individuals without CLP were recruited in the clinics of a Dental School by a trained and calibrated examiner (master's degree student). The Dental School and Craniofacial Center serve the same geographic area and the patients had similar free access to the treatment and the same care.

The exclusion criteria were degenerative joint disease (osteoarthritis and osteoarthritis); systemic diseases, such as rheumatoid arthritis; severe psychiatric, neurological, and motor disorders; history of hormonal problems; head and neck cancer; smokers; patients who were receiving or had received radiotherapy; patients who had influenza, a cold, or allergic rhinitis; patients taking medications that could affect the activity of facial muscles directly or indirectly, such as antihistamines, sedatives, syrups, homeopathy, or drugs that depress the central nervous system, such as antidepressants and anticonvulsants; patients with disorders of systemic origin affecting the masticatory function, such as cerebral palsy and other neurological disorders; and users of narcotic drugs.

The sample size was calculated so that the number of selected individuals met the representative estimate to carry out the research (Asten et al., 2014). With a significance level of 5%, power test of 80%, p1 estimate of 77% and p2 estimate of 98%, the minimum sample size was 38 individuals per group.

The study included 120 individuals divided into 2 groups. Initially, 85 individuals were evaluated in the CLP group, but 20 were excluded based on the inclusion and exclusion criteria and 5 did not agree to participate. The CLP group ($n = 60$) included individuals with complete unilateral CLP ($n = 30$) and complete bilateral CLP ($n = 30$), equally matched by gender. The CG had 60 individuals, randomly selected, equally split by gender, who all agreed to participate in the study. The sample consisted of adults aged between 31 and 65 years, with and without CLP (41.25 ± 6.72 and 49.48 ± 8.47 , respectively). The CG was significantly older than group CLP, $P < .001$.

Orofacial Function Evaluation

The Nordic Orofacial Test–Screening (NOT-S) was used to evaluate orofacial dysfunction. This instrument consists of a structured interview and a clinical examination. The interview was held by reading the questions from the manual for each domain. Each domain contains from 1 to 5 items, which reflect the complexity of the function in question. The NOT-S instrument is validated and translated into many languages, including Brazilian Portuguese (Leme et al., 2011). The Brazilian version was culturally adapted, and NOT-S psychometric properties indicate the orofacial function areas required for accurate diagnosis and treatment planning.

The examiner was calibrated and trained using the NOT-S handbook. To evaluate the reliability, 10% of the patients were

reassessed after 15 days, and the intraexaminer agreement index was acceptable ($K = 0.75$).

The dichotomized answer for the interview items was either yes or no, and an illustrated handbook (www.mun-h-centre.se) was used as a basis for the clinical examination. When the answer to any of the questions in a domain, or the performance of any of the tasks, meets the criteria for impaired function, the item is marked yes, and a score of 1 is given to indicate a dysfunction in the respective domain. When no marking is made for any item, the patient had no problem and a score of 0 is attributed to the domain. This is the procedure for both the interview and the clinical examination. The total NOT-S scores range from 0 to a maximum of 12. The greater the NOT-S score, the greater the orofacial dysfunction prevalence.

Assessment of the Overall Quality of Life

The Medical Outcomes Study 36-Item Short Form Survey (SF-36) was applied to analyze the QoL (Ware and Sherbourne, 1992; Ware et al., 1993; Ciconelli et al., 1999). The SF-36 questionnaire is well designed and its measurement capabilities, such as reproducibility, validity, and susceptibility, have been demonstrated in previous studies (Apolone and Mosconi, 1998; Leplège et al., 1998; Sanson-Fisher and Perkins, 1998). The SF-36 was translated and culturally adapted to Brazilian Portuguese, and the psychometric measurements of validity and reliability were evaluated (Ciconelli et al., 1999). This assessment tool is easy to administer and understand. It consists of a multidimensional questionnaire composed of 36 questions divided into 8 scales or domains: physical function (10 items); physical role functioning (4 items), that is, limitation during routine and occupational activities; bodily pain (2 items); general health (5 items); vitality, that is, assessment of energy level and fatigue and of different subjective well-being levels (4 items); social function, that is, the impact of the psychological problems in the social activities (2 items); emotional role functioning (3 items); and mental health (5 items), that is, depression, anxiety, loss of emotional control and behavior, and psychological well-being. After weighing responses and converting raw scores, the mean values of each SF-36 domain were used for analysis. There is also 1 item that evaluates whether the individuals have improved their life compared to the previous year. The score ranges from 0 to 100 and higher scores indicate a higher QoL.

Statistical Analysis

The intraexaminer agreement was evaluated by reassessing 10% of the sample after 15 days, using the κ test. The descriptive analysis was performed with mean and standard deviation values. The Mann-Whitney statistical test was used to evaluate groups and genders regarding NOT-S and SF-36 performance, and the χ^2 test was used to associate NOT-S performance between the genders and groups. The authors used the Spearman correlation coefficient to correlate the instruments. A 5% significance level was adopted for all statistical tests.

Table 1. Group Differences in NOT-S Total Score and Presence of Dysfunction by Domain.

Domain	CG	CLPG	
NOT-S total	Mean (SD)	Mean (SD)	P value ^{a,b}
Total score	0.6 (0.96)	5.0 (2.23)	<.001 ^a
NOT-S interview	n (%)	n (%)	P
I Sensory function	8 (13.3)	17 (28.3)	.072
II Breathing	14 (23.3)	27 (45.0)	.021 ^b
III Habits	13 (21.7)	22 (36.7)	.108
IV Chewing/Swallowing	5 (8.3)	36 (60.0)	<.001 ^b
V Drooling	0 (0.0)	2 (3.3)	.476
VI Dryness of mouth	2 (3.3)	15 (25.0)	.002 ^b
NOT-S examination			
1 Face at rest	0 (0)	40 (66.7)	<.001 ^b
2 Nose breathing	0 (0)	19 (31.7)	<.001 ^b
3 Facial expression	0 (0)	45 (75.0)	<.001 ^b
4 Masticatory muscle/Jaw function	0 (0)	25 (41.7)	<.001 ^b
5 Oral motor function	0 (0)	21 (35.0)	<.001 ^b
6 Speech	0 (0)	30 (50.0)	<.001 ^b

^aMann-Whitney test, P values <.05 denote significant differences for total score.
^b χ^2 test, P values <.05 denote significant differences for domain distribution.

Results

In the CLP group, there was no statistically significant difference between individuals with complete unilateral and bilateral CLP for age, NOT-S, or QoL; therefore, they were evaluated as a single group for all analyses.

When evaluating the NOT-S values, there was a statistically significant difference between the CG and CLP group showing that the prevalence of orofacial dysfunction was higher in the latter for the total score and for the interview domains of breathing, chewing/swallowing, and dryness of the mouth (Table 1). It should be noted that none individual of CG displayed any area of oral dysfunction on the NOT-S examination. In the speech domain, 50% of the individuals of group CLP complained about hypernasality and anatomical impairment of the structures of the velopharynx.

The QoL, as measured by the SF-36 survey, showed higher average values for group CLP than those of CG in all domains (Table 2). There was a statistically significant difference between the groups for general health, physical role functioning, social function, and vitality.

The correlations between the QoL domains in SF-36 and the total orofacial dysfunction score from the NOT-S are shown in Table 3. In the CG, there was an unexpected and weak significant correlation reflecting higher orofacial dysfunction associated with better general health. In the CLP group, the domains of general health, emotional role functioning, and vitality had a significant negative correlation, that is, the orofacial dysfunction negatively impacts the QoL of individuals with CLP in these domains.

Discussion

In the present study, 120 patients with and without CLP reported on their orofacial dysfunction based on an interview

Table 2. Evaluation of the SF-36 Domains According to Group.

Domain	CG		Pvalue ^a
	Mean (SD)	Mean (SD)	
General health	64.2 (19.1)	74.6 (16.5)	.003^a
Physical function	86.8 (17.7)	88.4 (21.5)	.085
Physical role function	77.5 (29.5)	87.0 (27.8)	.014^a
Emotional role function	73.4 (37.2)	78.4 (34.5)	.480
Social function	78.2 (22.0)	89.1 (17.7)	<.001^a
Bodily pain	75.3 (26.5)	75.6 (25.6)	.865
Vitality	68.5 (19.6)	77.1 (19.8)	.006^a
Mental health	69.7 (19.0)	75.7 (18.6)	.056

Abbreviations: CG, control group; CLPG, cleft lip and palate group; SD, standard deviation.

^aMann-Whitney test, *P* values <.05 denote significant differences.

and examination with the NOT-S and on their overall QoL using SF-36. The prevalence of orofacial dysfunction was negatively related to the QoL of individuals with CLP in specific domains. Thus, the studied hypotheses that the orofacial dysfunction not equally affects individuals with and without CLP and that orofacial dysfunction is related to QoL were accepted because the domains of general health, emotional role functioning, and vitality showed significant correlation with the total orofacial dysfunction scores.

This study confirms previous NOT-S results (Bakke et al., 2007; Bergendal et al., 2009; Bakke et al., 2011; Strini et al., 2011; McAllister and Lundeborg, 2013; Bergendal et al., 2014), namely that NOT-S can be used in establishing differences between patients with orofacial dysfunction and healthy CGs. The NOT-S interview and examination could also be used as a standard instrument for evaluating the individuals with CLP before and after rehabilitation, thus providing the potential to improve the relationship between practice and clinical research. The comparison made between the CG and CLP groups in NOT-S domains revealed statistically significant differences in the interview domains of breathing, chewing and swallowing, and dry mouth and in all domains of the NOT-S examination.

In the present study, the average values for the NOT-S were 5.0 ± 2.2 for the CLP group, corroborating the Bakke et al. (2007) study for a group of patients with congenital malformation, deformation, and chromosomal abnormalities (4.1 ± 2.6). In addition, by comparing this study's results of noncleft individuals, similar means and standard deviation values (0.6 ± 1.0) were found in previous studies on individuals without clefts: 0.4 ± 0.6 (Bakke et al., 2007), 0.7 ± 0.0 (Bakke et al., 2011), 0.3 ± 0.5 (Saeves et al., 2011), 1.8 ± 1.4 (Strini et al., 2011).

The domains of chewing/swallowing and breathing were the most prevalent difficulties in the CLP group that corresponds with communication between the oral and nasal cavity in patients with CLP, compromising the occlusal relationship and maxillo-mandibular growth, consequently affecting breathing (Freitas et al., 2012a, 2012b; Freitas et al., 2013a, 2013b). The

related palate involvement leads to functional impairment caused by the reduced size of the nasal airway and consequent mouth breathing (Warren et al., 1990). The NOT-S results for the CLP group reflected that the passage of air through the pharynx and the involvement of soft tissue affect breathing and phonation, jeopardizing the orofacial function (Aras and Dogan, 2017).

Dysfunctions relating to chewing and swallowing must be evaluated carefully. In this study on individuals treated at adulthood, the occlusal relationship, the remaining teeth of the patient, and the types of prostheses installed were not examined, and no data were gathered. It is known that prostheses substantially affect masticatory efficiency, as demonstrated by Bajoria et al. (2012), as well as Bessadet et al. (2013). For those individuals who seek treatment in a Craniofacial Center at adulthood rather than earlier at childhood, treatment options are limited to rehabilitation with prostheses (Freitas et al., 2013a). The use of prostheses is less prevalent for individuals who complete all treatment during childhood, with comprehensive orthodontic care and surgery from adolescence to early adulthood.

Analyzing the NOT-S examination in the CLP group, the prevalent domains that showed dysfunction were facial expression (75.0%), face at rest (66.7%), speech (50.0%), and masticatory muscles and jaw function (41.7%). When the facial expression of patients with CLP was assessed, the great challenge was to whistle or blow, which produced visible signs of asymmetry. Such findings are important because they revealed that, even after the plastic surgeries, asymmetry remained and may psychologically influence the individuals (Kuijpers et al., 2015).

In relation to the face at rest domain, the expected deviations were seen in this study, such as asymmetry, and these changes may affect well-being and social inclusion (da Silva Filho et al., 2003).

The speech domain of individuals with CLP was compromised for half of the sample, which was expected, because speech is characterized by hypernasality caused by the anatomical impairment of the structures of the velopharynx that acts as a sphincter responsible for separating the nasal and oral cavities during the speech and swallowing (Bessel et al., 2013). This impaired closure (velopharyngeal dysfunction) is caused by the lack of either tissue (velopharyngeal insufficiency) or palate mobility (velopharyngeal incompetence; Freitas et al., 2013b).

Contrary to what was expected, adults with CLP had higher scores across domains, which were significantly higher for general health, physical role function, social function, and vitality. Based on Sinko et al., (2005), Antonarakis et al., (2013), and Kortelainen et al., (2016), it would be more likely to see patients with CLP to show lower QoL.

The QoL of individuals with CLP may be influenced by the attention received from their family and by access to quality interdisciplinary health-care services. The current results indicate that most of these individuals are adjusted and capable of

Table 3. Spearman's Correlation Between SF-36 and NOT-S in the CG and the CLP Groups.

	SF-36	General Health	Physical Function	Physical Role Function	Role Emotional Function	Social Function	Bodily Pain	Vitality	Mental Health
NOT-S	CLPG	−0.37	−0.16	−0.08	−0.28	−0.10	−0.00	−0.36	−0.05
	P value	.004 ^a	.212	.537	.028 ^a	.436	.981	.005 ^a	.70
	CG	0.26	0.18	0.10	0.10	0.10	0.00	0.01	0.08
	P value	.047 ^a	.177	.427	.445	.448	.984	.937	.844

Abbreviations: CG, control group; CLPG, cleft lip and palate group; SF-36, 36-Item Short Form Survey; NOT-S, Nordic Orofacial Test–Screening.
^aSpearman correlation, P values <.05 denote significant differences.

dealing with adversities related to CLP (Locker et al., 2005; Kramer et al., 2009).

Foo et al. (2012) evaluated HRQoL and OHRQoL of individuals with and without CLP and found a lower value for vitality and mental health domains in individuals with CLP. In the present study, there was no significant difference for mental health values, but vitality values were significantly higher than those of the CG. Foo et al. (2012) also reported areas of higher QoL in their sample: physical function and physical role function. In this present study, the area of physical role function similarly had a statistically higher value.

Additionally, higher QoL was also seen in general health and social function domains. Given the findings that school-age individuals with CLP are often stigmatized by differences (Lorot-Marchand et al., 2015), the higher values in social functioning domain in this sample of adults may reflect that stronger adaptive coping and social skills develop in adulthood.

When examining the relationship between orofacial dysfunction and QoL in the CLP group, statistically significant negative correlations were seen in the domains of general health, emotional role function, and vitality indicating lower QoL with greater orofacial dysfunction. An unexpected finding in the CG was seen for the domain general health, which exhibited a weak but significant correlation reflecting better general health with more orofacial dysfunction.

One key limitation of this study was the fact that the individuals' demographics, socioeconomic status, education level, and civil status were not evaluated, which can all impact QoL. For example, lower socioeconomic status has been related to worse oral health-related QoL in community populations (Lawrence et al., 2008), but this variable was not accounted for in the present study. Age and gender have also been associated with QoL in individuals with CLP and have been extensively studied (Aalto et al., 2006; Piovesan et al., 2010; Trentini et al., 2011).

Conclusion

Based on the results, orofacial dysfunction was more prevalent in patients with CLP; however, this group presented better QoL. When the QoL was correlated with orofacial dysfunction, a negative impact was seen for the domains general health, emotional role functioning, and vitality for individuals with CLP.

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ORCID iD

Simone Soares, DDS, MSc, PhD  <http://orcid.org/0000-0003-0811-7302>

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4 GENERAL CONCLUSIONS

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Individuals with CLP, invariably had compromised orofacial dysfunction compared with those without clefts. Esthetics, phonetics, and stomatognathic function influences on the Quality of Life. These factors directly relate with the oral rehabilitation with tooth- or implant-supported prosthesis. When assessed alone, the Quality of Life values of individuals with CLP were higher, showing that the rehabilitative treatment of the Hospital for Rehabilitation of Craniofacial Anomalies is reaching the proposed goal. On the other hand, the correlation between the Quality of Life (SF-36) and orofacial dysfunction (NOT-S), independent of oral rehabilitation, the domains: vitality, general health, and emotional aspects negatively impact on the quality of life of individuals with CLP.

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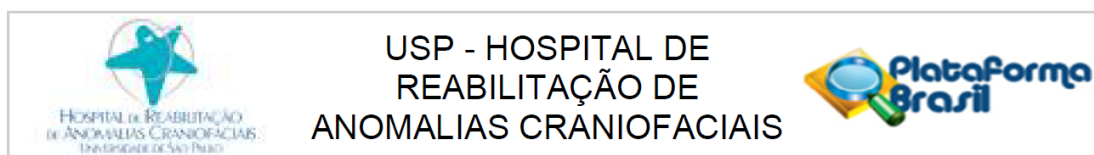
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ANNEX

ANNEX A



PARECER CONSUBSTANCIADO DO CEP

DADOS DA EMENDA

Título da Pesquisa: Avaliação longitudinal 3D da estabilidade dos arcos dentários de pacientes com e sem fissura labiopalatina após finalização ortodôntica e reabilitação protética.

Pesquisador: Victor Prado Curvello

Área Temática:

Versão: 5

CAAE: 50808215.2.0000.5441

Instituição Proponente: Hospital de Reabilitação de Anomalias Craniofaciais da USP

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.189.712

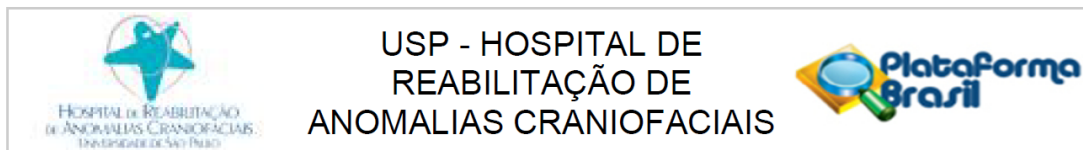
Apresentação do Projeto:

Trata-se de uma emenda do projeto de Dissertação, de autoria de Victor Prado Curvello sob orientação de Simone Soares e co-orientação de Thais Marchini de Oliveira. O propósito deste trabalho será uma avaliação longitudinal das alterações dimensionais dos arcos dentários, com fissura labiopalatina, antes e após reabilitação oral. A amostra será composta de modelos digitais de pacientes com fissura completa de lábio e palato unilateral, com idade entre 20 e 30 anos, obtidos nas fases pós tratamento ortodôntico (Fase 1) e 1 ano pós reabilitação protética (Fase 2). Serão avaliados 90 pacientes divididos em 3 grupos: 30 pacientes com prótese parcial fixa (GF), 30 pacientes com prótese sobre implante (GI) e 30 pacientes controle (GC). As medidas das dimensões dos arcos dentários serão realizadas diretamente nas imagens escaneadas, por meio do Scanner 3Shape's R700TM e medidas pelo Software Appliance Designer. Serão obtidas as seguintes dimensões: distância intercaninos, distância intermolares, área dos arcos dentários e comprimento ântero-posterior do arco dentário. Um avaliador previamente calibrado e treinado realizará as avaliações.

Objetivo da Pesquisa:

Avaliar longitudinalmente as alterações das dimensões dos arcos dentários de pacientes com fissura labiopalatina unilateral completa de lábio e palato antes e após reabilitação oral.

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Bairro: Vila Nova Cidade Universitária **CEP:** 17.012-900
UF: SP **Município:** BAURU
Telefone: (14)3235-8421 **Fax:** (14)3234-7818 **E-mail:** cephrac@usp.br



Continuação do Parecer: 2.189.712

Avaliação dos Riscos e Benefícios:

Riscos: Não se aplica

Benefícios:

Os benefícios esperados com o desenvolvimento do presente estudo constituem uma importante contribuição ao conhecimento do desenvolvimento do crescimento craniofacial em pacientes com fissura labiopalatina antes e após o tratamento reabilitador.

Comentários e Considerações sobre a Pesquisa:

Os autores enviaram emenda comunicando alteração na amostra do estudo e na equipe de pesquisa:

Os pacientes serão divididos em 3 grupos:

- Grupo Prótese Fixa (GF) – 30 pacientes com fissura completa de lábio e palato unilateral, reabilitados com prótese fixa;
- Grupo Prótese sobre Implante (GI) – 30 pacientes com fissura completa de lábio e palato unilateral, reabilitados com prótese sobre implante.
- Grupo Controle (GC) - 30 pacientes controle sem fissura.

E incluíram novos pesquisadores no projeto.

-inclusão dos seguintes autores na equipe de pesquisa: Maria Giulia Rezende Pucciarelli (aluna de mestrado HRAC/USP); Victor Fabrizio Cabrera Pazmino (aluno de doutorado HRAC/USP); Raquel DallAra de Moraes; Aliny Bisaia; Jorge Tomasio Caballero.

Considerações sobre os Termos de apresentação obrigatória:

Todos os seguintes termos foram apresentados anteriormente e estão adequados:

Os seguintes termos foram apresentados adequadamente:

Carta de encaminhamento dos pesquisadores aos CEP;

Formulário HRAC;

Folha de Rosto Plataforma Brasil;

Termo de Compromisso de Manuseio de Informações;

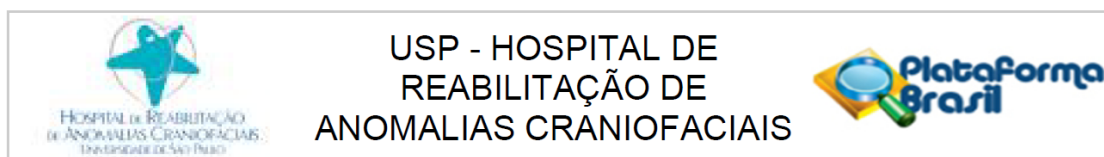
Formulário de Permissão para uso de Registros para Fins Científicos;

Termo de Compromisso de Tornar Públicos os Resultados da Pesquisa e Destinação de Materiais ou Dados Coletados;

Termo de Compromisso do Pesquisador Responsável

Recomendações:

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	E-mail: cephrac@usp.br



Continuação do Parecer: 2.189.712

Não se aplica.

Conclusões ou Pendências e Lista de Inadequações:

As alterações efetuadas não trazem implicações éticas, assim, sugiro aprovação do projeto.

Considerações Finais a critério do CEP:

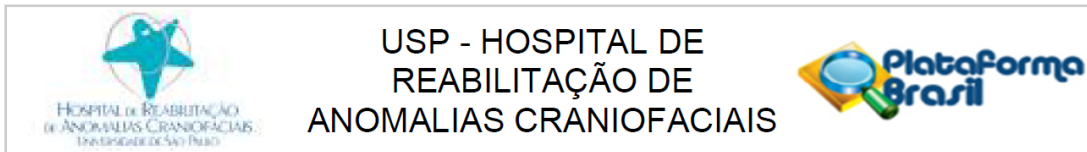
O pesquisador deve atentar que o projeto de pesquisa aprovado por este CEP refere-se ao protocolo submetido para avaliação. Portanto, conforme a Resolução CNS 466/12, o pesquisador é responsável por "desenvolver o projeto conforme delineado", se caso houver alterações nesse projeto, este CEP deverá ser comunicado em emenda via Plataforma Brasil, para nova avaliação.

Cabe ao pesquisador notificar via Plataforma Brasil o relatório final para avaliação. Os Termos de Consentimento Livre e Esclarecidos e/ou outros Termos obrigatórios assinados pelos participantes da pesquisa deverão ser entregues ao CEP. Os relatórios semestrais devem ser notificados quando solicitados no parecer.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BASICAS_913717E2.pdf	29/06/2017 12:51:26		Aceito
Outros	Of_emenda.pdf	29/06/2017 12:50:49	Victor Prado Curvello	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_final_pdf.pdf	08/05/2017 15:53:17	Victor Prado Curvello	Aceito
Folha de Rosto	Folha_Rosto.pdf	08/05/2017 15:44:15	Victor Prado Curvello	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	documento_digitalizado.pdf	07/04/2016 18:52:12	Victor Prado Curvello	Aceito
Outros	Lista_checagem_Plataforma_Brasil_124_2015.pdf	10/11/2015 09:01:15	Rafael Mattos de Deus	Aceito
Outros	Victor_Termo_Tornar_Publico.pdf	09/11/2015 14:09:26	Victor Prado Curvello	Aceito
Outros	Victor_Termo_Manuseio_Informacoes.pdf	09/11/2015 14:09:00	Victor Prado Curvello	Aceito
Outros	Victor_Termo_Compromisso_Pesquisador.pdf	09/11/2015 14:08:10	Victor Prado Curvello	Aceito
Outros	Victor_Formulario_HRAC.pdf	09/11/2015 14:07:06	Victor Prado Curvello	Aceito

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Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

BAURU, 27 de Julho de 2017

Assinado por:
Silvia Maria Graziadei
(Coordenador)

Endereço: Rua Silvío Marchione, 3-20
Bairro: Vila Nova Cidade Universitária **CEP:** 17.012-900
UF: SP **Município:** BAURU
Telefone: (14)3235-8421 **Fax:** (14)3234-7818 **E-mail:** cephrac@usp.br