UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

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Three-dimensional morphometric analysis of dental arches of children with cleft lip and palate: longitudinal study

Análise morfométrica tridimensional dos arcos dentários de crianças com fissura labiopalatina: estudo longitudinal

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Tese apresentada a Faculdade de Odontologia de Bauru da Universidade de São Paulo para obtenção do título de Doutora em Ciências no Programa de Ciências Odontológicas Aplicadas, na área de concentração de Odontopediatria.

Orientadora: Profa. Dra. Thais Marchini de Oliveira Valarelli

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Dedico minha tese de doutorado e tudo que conquisto à minha família:

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"A família é o amor de Deus nos oferecendo
um pouquinho do céu aqui na Terra".

Autor desconhecido

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temos certeza que estão sempre lá"

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ABSTRACT

Three-dimensional morphometric analysis of dental arches of children with cleft lip and palate: longitudinal study

This study aimed to present two papers that show the alterations in the dental arch dimensions of children with cleft lip and palate before and after the primary surgeries. The first study aimed to evaluate the dimensional alterations of the dental arches of neonates with unilateral complete cleft lip and palate before and after two different primary plastic surgeries. The sample was composed of 114 dental casts of 57 children, divided into two groups: Group 1 – 26 neonates whose lip closure was accomplished at 3 months of life by Millard´s technique and the anterior and posterior palate closure by von Langenback's technique (VL); Group 2 – 31 neonates whose lip closure, nose's ala correction, and anterior palate closure were accomplished of life by Millard´s technique, Mcomb's or Skoog's technique, and vomer's flap, respectively at 3 months of life; posterior palate closure was accomplished by VL at 12 months of life. The dental casts were analyzed at two phases: (T1) pre-cheiloplasty and (T2) one year after palatoplasty. The second study aimed to evaluate morphometrically and longitudinally the alterations of the dental arch dimensions of children with cleft lip and palate. The sample was composed by digital dental casts of children with complete cleft lip (Group 1), complete cleft lip and palate (Group 2), and complete cleft palate (Group 3), obtained at pre-cheiloplasty (T1), pre-palatoplasty (T2), and one year after palatoplasty (T3). The measurements of the dental arch dimensions of both studies were performed directly on the digitized models and analyzed by Appliance Designer software. The following dimensions were obtained: intercanine distance, inter-tuberosity distance, anterior arch length, and total arch length. A previously trained and calibrated examiner performed the assessments of both studies. To verify the alterations among groups, t test and ANOVA followed by Tukey was applied. In the first study, no statistically significant differences occurred at pre-cheiloplasty. At one year after palatoplasty, Group 1 had statistically significant greater anterior-posterior arch length (P=0.002) than Group 2. This suggested that the outcomes of the different surgical techniques may cause alterations in the dental arch growth and development of neonates with cleft lip and palate. In the second study, in Group 1, the distances C-C', T-T', and I-TT' were statistically greater at T2 than at T1. In Group 2, the distances C-C' and I-CC' were smaller at T3. T-T' distance decreased and I-TT' distance increased at all phases. In Group 3, the C-C', T-T', and I-TT' distances were statistically greater at T3. The intergroup comparisons showed that C-C' and T-T' distances were statistically greater in Group 1; C-C' and I-CC' distances were statistically smaller in Group 2; and I-TT' distance was statistically greater in Group 3. The longitudinal evaluation of the changes occurred in the dental arches of children with different oral cleft types showed that cheiloplasty and palatoplasty caused the most alterations in the growth and development of the maxillary dimensions of children with complete cleft lip and palate.

Keywords: Cleft palate. Dental models. Imaging, three-dimensional. Cleft lip.

RESUMO

O propósito deste estudo foi apresentar dois artigos que mostram as alterações das dimensões dos arcos dentários de crianças com fissura labiopalatina antes e depois das cirurgias primárias. O primeiro estudo foi proposto para avaliar as alterações dimensionais dos arcos dentários de neonatos com fissura labiopalatina antes e após a realização de duas técnicas distintas de cirurgias plásticas primárias. A amostra foi composta de 114 modelos dentários em gesso de 57 crianças, divididos em dois grupos: Grupo I – 26 neonatos, fechamento do lábio realizado aos 3 meses de vida pela técnica de Millard e palato total aos 12 meses, pela técnica de von Langenback (VL); Grupo II – 31 neonatos, fechamento do lábio pela técnica de Millard aos 3 meses de vida, correção de asa nasal (técnicas de Mcomb ou Skoog) e palatoplastia anterior com retalho de vômer aos 3 meses. A palatoplastia posterior foi realizada aos 12 meses pela técnica VL. Os modelos foram analisados em 2 fases: (F1) pré-queiloplastia e (F2) 1 ano pós-palatoplastia. No segundo estudo o objetivo foi realizar uma avaliação longitudinal das alterações das dimensões dos arcos dentários de crianças com fissura labiopalatina. A amostra foi composta de modelos digitais de crianças com fissura completa de lábio (Grupo 1), completa de lábio e palato (Grupo 2), e completa de palato (Grupo 3), obtidos nas fases de pré-queiloplastia (Fase 1), pré-palatoplastia (Fase 2), 1 ano póspalatoplastia (Fase 3). As medidas das dimensões dos arcos dentários nos dois estudos foram realizadas nos modelos digitalizados e analisados utilizando software Appliance Designer. As seguintes dimensões foram obtidas: distância intercaninos, distância intertuberosidade, comprimento anterior do arco dentário e comprimento total do arco. Um avaliador previamente calibrado e treinado realizou as avaliações para os dois estudos. Foi aplicado o Teste t e a Análise de Variância, seguida do Teste de Tukey. Para o primeiro estudo não houve diferença estatisticamente significante na fase pré-queiloplastia entre os grupos. Na fase 1 ano pós-palatoplastia houve diferença para o comprimento anteroposterior do arco dentário (p=0,002), entre os grupos, com valores maiores para o grupo I. Para o segundo estudo, no Grupo 1, as distâncias C-C', T-T' e I-TT' apresentaram diferença estatisticamente significante entre a F1 e F2, com aumento na F2. Para o Grupo 2, houve diferença estatisticamente significante em todas as fases avaliadas. As distâncias C-C' e I-CC' apresentaram menor valor na F3, T-T' diminuiu em todas as fases, e I-TT' aumentou em todas as fases. No Grupo 3, as distâncias C-C', T-T' e I-TT' mostraram diferença estatisticamente significante com aumento na F3. Quando avaliadas as medidas entre os grupos e fases, C-C' e T-T' mostraram um valor maior para o Grupo 1. A comparação entre F2 e F3 mostraram para as distâncias C-C' e I-CC' valor menor para o Grupo 2, e I-TT' foi maior para o Grupo 3. As avaliações longitudinais nos arcos dentários mostraram que a queiloplastia e palatoplastia causam maiores alterações de crescimento e desenvolvimento maxilares de pacientes com fissura completa de lábio e palato.

Palavras-chave: Fissura palatina. Modelos dentários. Imagem tridimensional. Fenda labial.

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1 INTRODUCTION

1 INTRODUCTION

Cleft lip and palate (CLP) are one of the most prevalent craniofacial malformations of the humans, considered a burden of care by the World Health Organization (2002). Individuals with CLP are affected by functional and anatomical alterations compromising the esthetics and speech, and associated with serious orthodontic problems (HOFFMANNOVA et al., 2016; VALENTOVÁ-STRENÁČIKOVÁ; MALINA, 2016). CLP early diagnosis can be performed at pregnancy through of ultrasonography (BUNDUKI et al., 2001), but the rehabilitative treatment onset is after the child's birth and continues up to the adulthood. The rehabilitative team needs to focus on the strict correlation between the morphological and functional aspects of CLP treatment to avoid long-term unfavorable prognosis. The rehabilitation should not be restricted to the anatomic repair of the cleft. Depending on the cleft type, many other aspects (occlusion, hearing, and speech) are affected, demanding a multidisciplinary team (VARGERVIK; OBEROI; HOFFMAN, 2009; WANG et al., 2009; FREITAS et al., 2012; ROCHA et al., 2012) to achieve the anatomical and functional rehabilitation of the individual until the skeletal maturity (ROCHA et al., 2012).

The literature lacks consensus on CLP rehabilitative protocol (BEARN et al., 2001; HSIEH; LIAO; SHETTY, 2012). Many different options are available regarding the moment to accomplish the primary plastic surgeries of the lip (HARRIS et al., 2010; VALENTOVÁ-STRENÁČIKOVÁ; MALINA, 2016), for example, currently it is possible to close the lip at the first weeks of life (CALTEUX et al., 2013). The most used protocol performed the cheiloplasty and palatoplasty during the first months of life (3 months of age) (HARRIS et al., 2010; FREITAS et al., 2012; FALZONI et al., 2016).

Greater caution is need regarding the deleterious effects of the primary plastic surgeries (JONES et al., 2016). Both the cheiloplasty and palatoplasty performed just after the birth may disturb the craniofacial growth by restricting the maxillary growth of the newborn while they correct the esthetics and function, mainly in children with complete cleft lip and palate (SEMB et al., 2005; GNOINSKI; RUTZ, 2009, KREY; BÖRNGEN; DANNHAUER, 2009; JONES et al., 2016). Some studies affirm that the lack of three-dimensional maxillary growth is directly influenced by the effects caused by the cheiloplasty (CAPELOZZA FILHO; NORMANDO; DA SILVA FILHO, 1996; LI et

al., 2006), while other authors believe that the palatoplasty causes more damages (HAN; SUZUKI; TASHIRO, 1995; LIAO; MARS, 2005).

The sequelae are variable and extremely influenced by the following sum of factors: cleft amplitude, frequency of plastic surgeries, surgeon's ability, tissue trauma caused by the surgeries, presence or absence of Simonart's band, and the genetically determined facial growth pattern of the individual determined (TRINDADE; SILVA FILHO, 2007). Notwithstanding, it is believed that the surgical intervention causing the healing tissue contraction on the segmented maxilla is the main factor that alters the growth pattern (LILJA et al., 2006). Commonly, the outcome of CLP rehabilitative treatment is evaluated by the balance among face appearance, speech, and face growth (FREITAS et al., 2012).

Thus, taking into consideration the complexity of the craniofacial structures, in particular of the cleft lip and palate, broader measurements should be accomplished to understand better the dimensional alterations in the dental arches of individuals with CLP because these alterations influence on the rehabilitative process outcomes (FREITAS et al., 2012; FERNANDES et al., 2015; CERÓN-ZAPATA et al., 2016). This rehabilitative process is challenging and demands a systematic dental documentation since the birth of a neonate with CLP (FREITAS et al., 2012). The dental documentation aims to provide a correct planning by tailoring the procedures required at the many phases of the treatment and to enable the longitudinal assessment of the rehabilitative treatment (MELLO et al., 2013; FERNANDES et al., 2015; CERÓN-ZAPATA et al., 2016). The obtainment of the dental documentation at first childhood enable the evaluation of the dental arches affected by the cleft even before the primary surgeries (JORGE et al., 2016).

The literature reports longitudinal studies on individuals with CLP in which dimensional anatomical measurements are performed on study casts (SABARINATH et al., 2010; ROUSSEAU et al., 2013) and imaging examinations (photographs and radiographs) (KIM et al., 2012.; OTERO et al., 2012; YANG et al., 2012). These methods may result in errors not only during the individual's positioning, but also during the analysis of data. Moreover, studies that compare measurements obtained through study casts are associated with the inconvenience of the documentation travelling (ROSATI et al., 2012). All these aforementioned reasons lead to the development of

alternative methods for assessing morphologically the anatomical structures of the dental arches.

These alternative methods take place with the current advancements of the computer science, raising interest in the use of three-dimensional (3D) images in Dentistry (ROSATI et al., 2014; ZHOU et al., 2016; ALAZZAWI et al., 2017). The use of 3D digital models has many advantages: easy and effective storage, easy access, durability, portability, versality in the diagnosis (WESTERLUND et al., 2015) due to easy rotation and handling of the images, similar to those of the plaster casts. Studies comparing 3D models and plaster casts concluded that the first had an accurate reproduction (GOONEWARDENE et al., 2008; LEIFERT et al., 2009; BOOTVONG et al., 2010). Other studies report more important advancements in Dentistry, showing that other methods of facial evaluation as stereophotogrammetry (DE MENEZES et al., 2016; ALAZZAWI et al., 2017) are not significantly different from cone-beam computed tomography (CODARI et al., 2016). This technology of 3D evaluation enables accurate measurements, more adequate handling, time-saving on-line information research, which provide the information exchange among different educational centers, aiming to plan, and evaluate rehabilitative treatments (BOOTVONG et al., 2010, MELLO et al., 2013; KUIJPERS et al., 2014; UGOLINI et al., 2015; DE MENEZES et al., 2016). 3D analysis of the dental arches is a notable change in data collection and reconstruction (SFORZA et al., 2012; HUANCA GHISLANZONI et al., 2013; MELLO et al., 2013; SFORZA; DE MENEZES; FERRARIO, 2013; KUIJPERS et al., 2014; UGOLINI et al., 2015; DE MENEZES et al., 2016).

By using 3D models, it is possible to obtain morphometrically records of individuals with CLP aiming at a better diagnosis, growth following-up, and definition of the real effect of the rehabilitation (DE MENEZES et al., 2016; SHETTY; AGRAWAL; SAILER, 2017). Furthermore, these method enables to conduct studies comparing the surgical outcomes of individuals with CLP submitted to different treatment protocols to define which protocol causes the least side effect regarding craniofacial growth and development (CARRARA et al., 2016). Thus, 3D technology is increasingly used in Dentistry in the diagnosis, planning, and treatment of many conditions (ZHOU et al., 2016). The treatment and case study of individuals underwent orthodontics,

orthognathic surgery, face plastic surgery has a great link to 3D technology (DE MENEZES et al., 2009; GENERALI et al., 2017).

The studies here presented were developed aiming to evaluate the dental arch dimensions and would aid in understanding better the factors interfering in the craniofacial growth and development of individuals with CLP to establish parameters for further researches.

2 ARTICLES

2 ARTICLES

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

- ARTICLE 1 – Three-dimensional evaluation of surgical techniques in neonates with orofacial cleft. Annals of Maxillofacial Surgery.
- ARTICLE 2 – 3D longitudinal analysis of dental arch in children with cleft lip and palate. International Journal of Oral and Maxillofacial Surgery. (Submitted)

2.1 ARTICLE 1 – Three-dimensional evaluation of surgical techniques in neonates with orofacial cleft*

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Link Manuscript: http://www.amsjournal.com/temp/AnnMaxillofacSurg62246-694565_183545.pdf

* Carrara CFC, Ambrosio ECP, Mello BZF, Jorge PK, Soares S, Machado MAAM, Oliveira TM. Three-dimensional evaluation of surgical techniques in neonates with orofacial cleft. Ann Maxillofac Surg. 2016;6(2):246-50.

2.2 ARTICLE 2 – 3D longitudinal analysis of dental arch in children with cleft lip and palate*

ABSTRACT

This study aimed to evaluate longitudinally the alteration of the dental arch dimensions of children with complete cleft lip and palate, before and after the primary surgeries. The sample was composed by digitized models of children with complete cleft lip (Group 1), complete cleft lip and palate (Group 2), and complete cleft palate (Group 3), obtained at pre-cheiloplasty (T1), pre-palatoplasty (T2), and one year after palatoplasty (T3). The measurements of the dental arch dimensions were performed directly on the digitized models and analyzed using Appliance Designer software. The following measurements were obtained: intercanine distance (C-C'), intertuberosity distance (T-T'), anterior arch length (I-CC') and total arch length (I-TT'). To verify the alterations occurred among groups, t test and ANOVA followed by Tukey test were used. In Group 1, the distances C-C', T-T', and I-TT' were statistically greater at T2 than at T1. In Group 2, the distances C-C' and I-CC' were smaller at T3. T-T' distance decreased and I-TT' distance increased at all phases. In Group 3, the C-C', T-T', and I-TT' distances were statistically greater at T3. The intergroup comparisons showed that C-C' and T-T' distances were statistically greater in Group 1; C-C' and I-CC' distances were statistically smaller in Group 2; and I-TT' distance was statistically greater in Group 3. The longitudinal evaluation of the changes occurred in the dental arches of children with different oral cleft types showed that cheiloplasty and palatoplasty caused the most alterations in the growth and development of the maxillary dimensions of children with complete cleft lip and palate.

Keywords: Cleft palate. Dental models. Imaging, three-dimensional. Cleft lip.

* 3D longitudinal analysis of dental arch in children with cleft lip and palate. Int J Oral Maxillofac Surg. (Submitted)

INTRODUCTION

The individual with cleft lip and palate (CLP) undergo a long rehabilitative treatment to correct the anatomical alterations caused by the cleft itself just at the first months of life, that requires a multidisciplinary team [1]. On one hand, the plastic surgeries performed at the beginning of life are indispensable to correct the defect and return the function and the esthetics generating favorable conditions to improve the quality of life of these children [1,2]. On the other hand, CLP surgical repair results in deleterious effects on the maxillary growth, thus caution is necessary regarding the growth and development of the child [2]. Both the cheiloplasty and palatoplasty performed just after the birth may disturb the craniofacial growth by restricting the maxillary growth of the newborn while they correct the esthetics and function, in children with complete cleft lip and palate [2-5].

A more precise methodology to evaluate the deleterious effects of the surgical repair is the three-dimensional (3D) evaluation of the dental arches of the individuals with CLP. These alternative methods take place with the current advancements of the computer science, raising interest in the use of three-dimensional (3D) images in Dentistry [6,7]. Studies comparing 3D models and plaster casts concluded that the first had an accurate reproduction [8-10]. Other studies report more important advancements in Dentistry, showing that other methods of facial evaluation as stereophotogrammetry [11,12] and analysis of 3D models [13,14] have good quality, easy access and are non-invasive [15]. This technology of 3D evaluation enables accurate measurements, more adequate handling, time-saving on-line information research, which provide the information exchange among different educational centers, aiming to plan, and evaluate rehabilitative treatments [10,11,16-18]. 3D analysis changed notably the data collection of individuals undergone complex and extensive rehabilitative treatments both in Dentistry and Medicine [11,16-21].

This study aimed to evaluate longitudinally the alteration of the dental arch dimensions of children with complete cleft lip and palate, before and after the primary surgeries. The hypothesis tested is that the dental arch dimensions of children with complete cleft lip and/or palate do not change after primary surgeries.

MATERIAL AND METHODS

Sample selection

This study was approved by the Institutional Review Board of the Hospital for the Rehabilitation of Craniofacial Anomalies (HRAC/USP), under protocol CAAE 48136215.0.0000.5441. The sample was composed by the digital models of children with CLP aged three moths, 12 months, and 24 months, of both genders, regularly enrolled in the institution. The inclusion criteria comprised the presence or absence of Simonart's band, no associated syndrome or malformation, and dental casts at the treatment phases evaluated in the study. All dental casts were obtained in the institution's files.

The sample size was calculated so the minimum number of children allowed to conduct the study. For this purpose, the study of Lo et al [22] was used. Considering a levle of significance of 5%, power of test of 80%, and the minimum difference to be detected of 100 m^2, the minimum sample size was 29 children per group, totalizing 90 children.

The children were divided into the follwing groups: Group 1 (G1) – complete cleft lip (n=33); Group 2 (G2) – complete cleft lip and palate (n=36); Group 3 (G3) – complete cleft palate (n=30).

The assessment was performed through 3D images of the digitized models of the maxillary dental arch, obtained at the following treatament phases: T1 – pre-cheiloplasty; T2 – pre-palatoplasty; and T3 – one year after palatoplasty.

Linear measurements

The following anatomical points [19,23-25] were measured on the maxillary dental arch to perform the linear measurements (Figure 1): Canine (C and C') - Points of eruption of canine teeth on the alveolar ridge; Tuberosity (T and T') - Points on the posterior extremity (junction of the alveolar ridge crest with the tuberosity contour); Interincisor (I) - Point on the mesial incisal areas between the maxillary central incisors; Intercanine distance (C-C') - transversal line on the dental arch between points C and C'; Intertuberosity distance (T-T') - posterior transversal line on the dental arch between points T and T''; Anterior dental arch length (I-CC') – sagittal line from point I

perpendicular to distance C - C'; Total length of dental arch (I-TT') – sagittal line from point I perpendicular to distance T - T'. The digitized models were analyzed using Appliance Designer Software (3Shape Denmark).

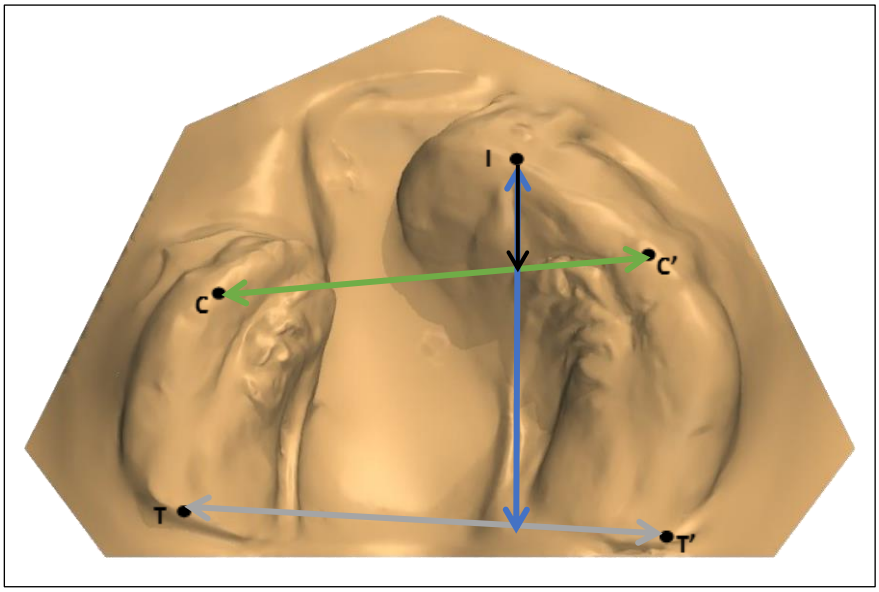

Figure 1. Anatomic landmarks and linear measurements to analyze the complete cleft lip and palate (Group 3)

All statistical tests were executed with Statistica software (Statistica for Windows - Version 7.0 - StatSoft), with level of significance of 5%. The Shapiro-Wilk normality test was applied in the quantitative measurements. To analyse the intraexaminer error, paired t test was applied in 1/3 of the dental casts, measured again 1 month after the first measurement. When the variable did not show normal distribution, Wilcoxon test was used. Independent t test and Mann-Whitney test were used to verify the changes occurred between groups. Repeated-measures ANOVA followed by Tukey test analysed the different phases of the rehabilitation protocol in the group of children with complete cleft lip.

RESULTS

Table 1 displays the sample characterization regarding gender and cleft side of the children.

Table 1. Sample characterization regarding gender and cleft side

Variable	Group 1 n (%)	Group 2 n (%)	Group 3 n (%)
Gender			
Male	16 (48.4%)	23 (63.9%)	13 (43.4%)
Female	17 (51.6%)	13 (36.1%)	17 (56.6%)
Cleft side			
Right	11 (33.3%)	15 (41.7%)	-
Left	22 (66.7%)	21 (58.3%)	-

The age (in years) of the children were compared among the different treatment phases and showed no statistically significant differences, except at T3 for G1 in comparison with G2 and G3 (P <0.001).

The intraexaminer reproducibility was analyzed and showed no statistically significant different for the repeated measurements.

Dimensional alterations in Group 1

Table 2 displays the maxillary dimensions, at all evaluated phases. The intercanine distance (C-C') and the intertuberosity distance (T-T') showed statistically greater values at T2 than at T1. The anterior arch length (I-CC') decreased after the surgery, but no statistically differences occurred from T1 to T2. The total arch length (I-TT') statistically increased from T1 to T2.

Table 2. Analysis of the linear maxillary dimensions (mm) of Group 1, at T1 and T2 (paired t test and Wilcoxon's test)

Variables	T1		T2		*P*
	Mean	SD	Mean	SD	
C – C'	27.10	2.12	29.69	1.83	**<0.001***
T – T'	31.97	2.22	37.60	2.13	**<0.001***
I – CC'	8.94	1.70	8.18	1.66	0.052
I – TT'	28.99	2.31	31.63	2.66	**<0.001***

*Statistically significant differences.

Dimensional alterations in Group 2

Table 3 displays the maxillary dimensions, at all evaluated phases. The intercanine distance (C-C') statistically decreased from T1 to T3. The intertuberosity distance (T-T') statistically increased from T1 to T3. The anterior arch length (I – CC') reduced with statistically significant differences between T1 and T3, T2 and T3. The

total arch length increased with statistically significant differences between T1 and T3, T2 and T3.

Table 3. Analysis of the linear maxillary dimensions (mm) of Group 2, at T1, T2, and T3 (ANOVA, Teste de Tukey)

Variables	T1		T2		T3		*P*
	Mean	SD	Mean	SD	Mean	SD	
C – C'	30.37[a]	3.68	28.83[a]	2.85	26.42[b]	2.24	**<0.001***
T – T'	36.16[a]	3.03	38.56[b]	2.14	41.20[c]	2.22	**<0.001***
I – CC'	8.09[a]	1.50	7.02[a]	1.19	5.79[b]	1.37	**<0.001***
I – TT'	26.05[a]	2.41	27.13[a]	2.52	28.87[b]	2.28	**<0.001***

*Statistically significant differences.
Groups with equal lowercase letters in line showed no statistically significant differences.

Dimensional alterations in Group 3

Table 4 displays the maxillary dimensions, at all evaluated phases. The distances C-C' e T-T' statistically increased from T2 to T3. The distance I-TT' statistically increased after palatoplasty (from T2 to T3), while the distance I– CC' did not show statistically significant differences from T2 to T3.

Table 4. Analysis of the linear maxillary dimensions (mm) of Group 3, at T2 and T3 (paired t test and Wilcoxon's test)

Variables	T2		T3		*P*
	Mean	SD	Mean	SD	
C – C'	26.88	2.32	28.11	2.71	**<0.003***
T – T'	36.68	2.82	40.22	3.60	**<0.001***
I – CC'	6.23	1.06	6.64	1.46	0.113
I – TT'	28.01	2.55	31.49	2.31	**<0.001***

*Statistically significant differences.

Dimensional alterations among Groups 1, 2, and 3

Tables 5 and 6 shows the comparison of the maxillary dimensions among Groups: G1 (T1 and T2), G2 (T1, T2, and T3), and G3 (T1, T2, and T3). The comparison of the T2-T1 difference between Groups 1 and 2 revealed that Group 1 had statistically greater values of C-C' and T-T' distances (Table 5). The comparison

of the T2-T1 difference between Groups 1 and 2 showed no statistically significant differences for I-CC' and I-TT' distances (Table 5).

The comparison of the T3-T2 difference between Groups 2 and 3 exhibited that Group 2 had statistically smaller values of C-C', I-CC', and I-TT' distances (Table 6). The comparison of the T3-T2 difference between Groups 2 and 3 exhibited no statistically significant differences for T-T' distance (Table 6).

Table 5. Analysis of the difference between the maxillary linear dimensions (mm) (T2-T1) of Groups 1 and 2 (Mann-Whitney test)

Variables	Group 1		Group 2		*P*
	Mean	SD	Mean	SD	
C - C'	2.58	2.42	-1.56	3.93	**<0.001***
T - T'	5.62	2.39	2.39	2.53	**<0.001***
I – CC'	-0.77	2.19	-1.06	1.82	0.545
I – TT'	2.63	3.19	1.08	2.71	0.033

*Statistically significant differences.

Table 6. Analysis of the difference between the maxillary linear dimensions (mm) (mm) (T3-T2) of Groups 2 and 3 (Mann-Whitney test)

Variables	Group 2		Group 3		*P*
	Mean	SD	Mean	SD	
C – C'	-2.38	3.18	1.22	2.06	**<0.001***
T – T'	2.64	2.31	3.53	2.29	0.119
I – CC'	-1.19	1.19	0.40	1.36	**<0.001***
I – TT'	1.73	2.30	3.47	2.29	**<0.001***

*Statistically significant differences.

DISCUSSION

In this present study, the methodology of 3D digital models [25-27] was used to evaluate the growth of children with different cleft types, consequently at different study times (before and after cheiloplasty and palatoplasty). Thus, this study outcomes showed the specific growth features for each cleft type, different from other studies on evaluating the growth of one cleft type [24,28,29].

In Group 1 (complete cleft lip), the intercanine distance (C-C'), intertuberosity distance (T-T'), and the total arch length (I-TT') significantly increased after cheiloplasty. The anterior arch length (I-CC') decreased after cheiloplasty without

statically significant differences. This is the first study comparing these distances at these phases. The literature reports only the transversal measurements before cheiloplasty [22,30] and after cheiloplasty [31]. Lo et al [22] respectively found the following measurements for the intercanine and intertuberosity distance: 27.34 mm and 29.3 mm, which differ from the measurements of this present study. The intercanine distance of this present study was 0.04 mm smaller and the intertuberosity was 4.10 mm smaller. It is impossible to compare the results of this present study with those of Fernandes et al [30] probably because no sagittal dimension was obtained due to the cleft type (bilateral complete cleft lip and palate) and the projection of the anterior portion of the maxilla. Honda et al [31] found an increase of the transversal measurements (C-C' and T-T') and a decrease of the anterior arch length after cheiloplasty in children at four years of age, an age range different from that of this present study.

The evaluate phases of Group 2 (complete cleft lip and palate) revealed that the C-C' distance statistically decreased after cheiloplasty, without significant differences, agreeing with the study of Hoffmannova et al [28], who compared individuals with complete CLP with those without clefts and found no statistically significant differences after the cheiloplasty. One year after palatoplasty, the C-C' distance significantly decreased, corroborating the results of Falzoni et al [24]. The intertuberosity distance (T-T') and the total arch length (I-TT') significantly increased at all phases. After cheiloplasty, the total arch length increased without statistically significant differences. However, the anterior arch length (I-CC') decreased with statistically significant differences from pre-cheiloplasty (T1), pre-palatoplasty (T2) and one year after palatoplasty (T3). The distances T-T' and I-TT' significantly increased after palatoplasty, while the distances I-CC' and C-C' significantly decreased. These findings corroborate those of the study of Lambert et al [32].

In the group of children with complete cleft palate (Group 3), the distances C-C', T-T', and I-TT' statistically increased after palatoplasty probably because the cleft palate did not affect the anterior-posterior and transversal growth of the maxilla. No statistically significant differences occurred before and after palatoplasty for the distance I-CC'. The literature lacks studies on these measurements for this cleft type before and after palatoplasty.

The dimensional changes between pre-cheiloplasty (T1) and post-cheiloplasty (T2) showed that Group 1 had an increase of the mean values of the distances C-C' and T-T', while Group 2 had a decrease of these values, with statistically significant differences between groups. For both groups, the mean values of distance I-CC' decrease, while the mean values of distance I-TT' increased. This difference in growth probably occurred due to the cleft presence itself. The children with cleft lip showed no decreasing of the mean values of the palate width because the cheiloplasty does not reach the palatal tissue, while in children with complete cleft lip and palate the cleft itself affects the palate, and the cheiloplasty impairs the arch width and growth.

The dimensional alterations between pre-palatoplasty (T2) and one year after palatoplasty (T3) showed that the mean values of the distances C-C' an I-CC' decreased in Group 2 and increased in Group 3, with statistically significance. The mean values of distances T-T' and I-TT' increased for both groups, without statistically significance for the intertuberosity distance (T-T'). In Group 3, the total arch length (I-TT') was statistically greater than Group 2. These values were expected because Group 2 had more lip and palate tissue loss than Group 3. On the other hand, the increase of the mean value of the intertuberosity distance was not expected in Group 3, because the cleft affects the posterior area of the palate and we supposed that the palatoplasty would impair the growth in this area.

The literature lacks studies on the comparison of the growth of the different cleft types. Moreover, this present study used the mean values of the growth difference at each study time. This methodology is more accurate than that using the absolute values of the growth because each individual has a growth potential due to the genetics. The use of absolute values instead of mean values leads to bias and a more subjective assessment of growth [33].

Alazzawi et al [12] employed different anatomic points to evaluate the growth of individuals with cleft lip and palate through the 3D analysis of the nasolabial asymmetry by stereophotogrammetry. These authors marked the points on the individuals' face instead of on the dental arch. This methodology would allow the more accurate observation of the individual's growth but it does not eliminate the variability of the growth among individuals. The results of the study of Alazzawi et al [12] showed that the upper lip asymmetry improved after cheiloplasty, without statistically significant difference in the cleft side expansion over the non-cleft side. This information differs

from the results of this present study, in which all measurements of the cleft side exhibited a greater deleterious effect. Thus, further studies are necessary to evaluate the face changes of individuals with clefts.

According to this present study, it is worth emphasizing that further longitudinal clinical studies are necessary to evaluate, through 3D digital models, the treatment protocols used to the rehabilitation of individuals with clefts.

CONCLUSION

The longitudinal evaluation of the changes occurred in the dental arches of children with different oral cleft types showed that cheiloplasty and palatoplasty caused the most alterations in the growth and development of the maxillary dimensions of children with complete cleft lip and palate.

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3 DISCUSSION

3 DISCUSSION

Aiming at correctly exposing the data obtained with the studies, we divided the discussion into important items, as follows: sample selection, methodology, results compared to the literature, and clinical relevance.

3.1 SAMPLE SELECTION

In this study, we show two papers related to the evaluation of the craniofacial growth and development of children with cleft lip and palate. The first paper reported the effects found after two different surgical techniques comprising the rehabilitation protocol of HRAC. Thus, the sample of the first paper was composed by 57 children divided into two groups: Group 1 – 26 neonates whose lip closure was accomplished at 3 months of life by Millard´s technique and the anterior and posterior palate closure by von Langenback's technique (VL); Group 2 – 31 neonates whose lip closure, nose's ala correction, and anterior palate closure were accomplished of life by Millard´s technique, Mcomb's or Skoog's technique, and vomer's flap, respectively at three months of life; posterior palate closure was accomplished by VL at 12 months of life. The second paper reported the longitudinal changes in the craniofacial growth and development of children with CLP after the accomplishment of the primary surgeries. The sample comprised 99 3D models of children with CLP aged three months, 12 months, and 24 months, of both genders, regularly enrolled in HRAC.

The sample size of both studies was close because both studies depended on the HRAC's routine for sample selection, similarly to the other studies conducted in the same rehabilitation center (MELLO et al., 2013; FERNANDES et al., 2015; FALZONI et al., 2016; JORGE et al., 2016). The age range of both studies are the same because this is the age in which the primary surgeries are accomplished, enabling to evaluat the growth and development of the dental arch at the initial phases of the child's life (CERÓN-ZAPATA et al., 2016; DE MENEZES et al., 2016; HOFFMANNOVA et al., 2016).

This shows the proximity of the sample of both papers, because the general aim of this study was to evaluate the craniofacial growth and development of children with cleft lip and palate after the primary surgeries regarding both to the treatment protocol and to the deleterious effects.

3.2 METHODOLOGY

In this study, both papers aimed to evaluate the children with CLP at the initial phase of the rehabilitative treatment, from 3 months to 2 years of life. In the first paper, the neonates with complete CLP underwent cheiloplasty from three months of age, following the technique chose by the plastic surgeon; palatoplasty was accomplished at 12 months of life at one or two stages. The one-stage protocol, so-called, total palatoplasty at 12 months of life; the two-stage protocol comprised the anterior palatoplasty through vomer flap together with cheiloplasty and at 12 months of life posterior palatoplasty is accomplished (FREITAS et al., 2012). In the second paper, the surgical technique was not verified, but we assessed how far these surgeries impaired the growth and development by evaluating the children with complete cleft lip, complete CLP, and cleft palate, at three months of life (before cheiloplasty), 12 months of life (before one-stage palatoplasty), and one-year after palatoplasty.

The 3D technology has been very used to evaluate the dimensional alterations of dental arches in individuals with CLP. 3D digital models enable to mark the anatomical points that will be used to analyze the growth of individuals with CLP (HUANG et al., 2002; SFORZA et al., 2012; FERNANDES et al., 2015; FALZONI et al., 2016; JORGE et al., 2016). Both studies used 3D models and the same software for image scanning. The software offered high-quality images and allowed the magnification and rotation of the images, which made easier the establishment of the anatomical points (SECKEL et al., 1995; HARILA et al., 2013), consequently making the measurements more accurate, in both studies.

Both studies evaluated the growth change before and after the primary surgeries. The studies differ about the evaluated phases and cleft types. Both studies corroborate with the methodology used in other studies in the literature (REISER; SKOOG; ANDLIN-SOBOCKI, 2013; CÉRON-ZAPATA et al., 2016; JORGE et al., 2016).

3.3 RESULTS

One difficult in this present study was that the literature lacks studies in the same cleft types and plastic surgery techniques. In the first study, the literature reports that each rehabilitation center uses different surgical techniques from that used in the first paper, e.g., Vomerplasty, Two-flap, and VL (LIAO et al., 2014; DESHPANDE et al., 2015), two-stage palatoplasty with the first stage not together with the cheiloplasty (SCHWECKENDIEK; DOZ, 1978), or two-stage palatoplasty with first stage together with the cheiloplasty, followed by the soft palate closure (Oslo Protocol) (SEMB, 1991). This enables to evaluate the risks of side-effects of each technique and the cost-benefit ratio of each technique. Even if some authors insist that the most important fact is the moment in which the hard palate closure is accomplished rather than the sequence of soft and hard palate closure (LIAO et al., 2010; YAMANISHI et al., 2011; XU et al., 2015).

In the second study, the comparison of the results with the literature was more difficult because of the absence of studies evaluating the three cleft types (cleft lip, cleft lip and palate, and cleft palate). Furthermore, many studies perform only intragroup comparisons or comparisons with individuals with and without clefts. Another difficulty was that most studies evaluated growth through absolute values. This present study used the mean values to obtain the growth difference at each phase because each individual has a growth potential linked to the genetics (MOYERS; BOOKSTEIN; GUIRE, 1979). We believe that the use of mean values instead of absolute values is more accurate and avoid bias.

Unanimously, the comparison between the outcomes of different rehabilitative centers is complex because the studied parameters, therapeutic approaches, and time periods should always be taking into consideration to define the best treatment for the individuals (BRAUMANN et al., 2003).

3.4 CLINICAL RELEVANCE

By evaluating the growth and development of the individuals is possible to obtain valuable information on the treatment outcomes, as well as the changes are

precisely observed and assessed, turning the rehabilitation process shorter, which is mandatory for the individual with CLP.

Based on the results of both studies is possible to affirm that the longitudinal assessment of craniofacial growth and development of individuals with CLP, through 3D digital models and face's images, is indispensable to evaluate the treatment protocols more accurately, improving the clinical practices and the parameters used in the present and future rehabilitation process of these individuals.

4 FINAL CONSIDERATIONS

4 FINAL CONSIDERATIONS

Conclusion Article #1: This study suggests that the results of the different surgical techniques may alter the growth and development of the dental arches of neonates with cleft lip and palate.

Conclusion Article #2: The longitudinal evaluation of the changes occurred in the dental arches of children with different oral cleft types showed that cheiloplasty and palatoplasty caused the most alterations in the growth and development of the maxillary dimensions of children with complete cleft lip and palate.

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APPENDIX

APPENDIX A

DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN THESIS

We hereby declare that we are aware of the article **Three-dimensional evaluation of surgical techniques in neonates with orofacial cleft** will be included in the Thesis of the student Bianca Zeponi Fernandes de Mello and 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, December 01, 2017.

Cleide Felício Carvalho Carrara

Eloá Cristina Passucci Ambrosio

Bianca Zeponi Fernandes de Mello

Paula Karine Jorge

Simone Soares

Maria Aparecida de Andrade Moreira Machado

Thais Marchini Oliveira

ANNEX

ANNEX A

HOSPITAL DE REABILITAÇÃO
DE ANOMALIAS
CRANIOFACIAIS DA USP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Análise 3D dos arcos dentários em crianças com fissura labiopalatina aos cinco anos de idade

Pesquisador: Bianca Zeponi Fernandes de Mello

Área Temática:

Versão: 2

CAAE: 48136215.0.0000.5441

Instituição Proponente: Hospital de Reabilitação de Anomalias Craniofaciais da USP

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.303.912

Apresentação do Projeto:

Projeto de pesquisa para tese de doutorado em Odontopediatria. O presente estudo será observacional quantitativo, segundo o desenho descrito pelas pesquisadores. A amostra será composta de 120 modelos digitais de crianças com fissura labiopalatina pré-forame (Grupo 1), transforame (Grupo 2), pós-forame (Grupo 3), e pacientes sem fissura (Grupo 4). As medidas das dimensões dos arcos dentários serão realizadas diretamente nas imagens escaneadas, por meio do Scanner 3Shape's R700TM e medidas pelo 3D Software Appliance Designer. Serão obtidas as seguintes dimensões: distância intercaninos, distância intermolar, comprimento ântero-posterior do arco dentário e área dos arcos dentários. Será utilizado o índice aos 5 anos para avaliação do padrão oclusal. Dois avaliadores
previamente calibrados e treinados realizarão as avaliações. Será aplicado o Teste t e ANOVA, seguida do Teste de Tukey, para verificar as alterações ocorridas entre os grupos. Caso necessário, outros testes poderão ser aplicados. Será adotado nível de significância de 5% para que as diferenças sejam consideradas estatisticamente significativas.

Objetivo da Pesquisa:

O objetivo deste trabalho será realizar uma avaliação das alterações das dimensões dos arcos

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Continuação do Parecer: 1.303.912

dentários de crianças com fissura labiopalatina aos cinco anos de idade.

Avaliação dos Riscos e Benefícios:

Riscos: Devido a moldagem que há necessidade de ser realizada para obtenção de modelos pode acontecer eventuais situações como ânsia de vômito e choro, situações totalmente controláveis durante o atendimento. Obedecendo as normas de biossegurança e guardando sigilo ético pode-se afirmar que os riscos são próximos de zero.

Benefícios: Os benefícios esperados com o desenvolvimento do presente estudo constituem uma importante contribuição ao conhecimento do desenvolvimento do crescimento craniofacial em crianças com fissura labiopalatina no que diz respeito às intervenções das cirurgias primárias realizadas em idade precoce. Melhorando a possibilidade de tratamentos para cada tipo de fissura.

Comentários e Considerações sobre a Pesquisa:

Segunda apresentação do projeto. Originalmente as pendências levantadas pelo CEP HRAC-USP foram:

Lista de inadequações:

-Esclarecer na metodologia se a pesquisa será apenas com modelos de gesso de arquivo como está escrito na seleção da amostra ou se também haverá moldagens, como indica o capitulo de riscos e benefícios, o TCLE e o termo de assentimento. Os autores deixaram claro que as moldagens serão realizadas apenas nos grupo controle, pois os grupos de estudo já possuem modelos rotineiramente realizados no HRAC-USP aos 5 anos de idade.

- TCLE com palavras de difícil entendimento para a população alvo.Deverá ser refeito inteiramente. O TCLE foi totalmente reformulado e encontra-se agora adequado.

- Acrescentar os riscos e benefícios da pesquisa no TCLE. Foram adicionados.

- Ressaltar no TCLE que não haverá ressarcimento com despesas de transporte e alimentação do participantes da pesquisa, já que eles estarão nas instituições pelo agendamento de atendimento ambulatorial de rotina. Os autores ressaltaram o não ressarcimento de despesa com alimentação e transporte devido à vinda ambulatorial.

- Acrescentar a carta de aquiescência do responsável pela clínica de odontopediatria da FOB-USP, onde serão colhidos os modelos das crianças sem fissuras labiopalatinas da FOB. Essa carta foi adicionada.

- Pesquisa com co-participação? HRAC-USP/FOB-USP? A pesquisa foi agora cadastrada como co-participação HRAC-USP/FOB-USP.

- Todas as alterações deverão ser realizadas no projeto em WORD e na plataforma Brasil.

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Continuação do Parecer: 1.303.912

Solicitação Atendida.

- Alterar o cronograma no projeto de pesquisa e na Plataforma Brasil.Solicitação Atendida.

Considerações sobre os Termos de apresentação obrigatória:

Não se aplica.

Recomendações:

Não se aplica.

Conclusões ou Pendências e Lista de Inadequações:

Como as inadequações foram corrigidas sugiro a 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, assim como os relatórios semestrais, os Termos de Consentimento Livre e Esclarecidos e/ou outros Termos obrigatórios, 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_BÁSICAS_DO_PROJETO_569414.pdf	27/09/2015 15:17:30		Aceito
Outros	Resposta_ao_CEP.pdf	27/09/2015 15:17:07	Bianca Zeponi Fernandes de Mello	Aceito
Projeto Detalhado / Brochura Investigador	Projeto.docx	27/09/2015 11:46:49	Bianca Zeponi Fernandes de Mello	Aceito
Outros	Termo.pdf	24/09/2015 09:09:00	Bianca Zeponi Fernandes de Mello	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	24/09/2015 08:25:58	Bianca Zeponi Fernandes de Mello	Aceito
Outros	Lista de checagem Plataforma Brasil - Bianca - Protocolo 86-2015.pdf	12/08/2015 10:45:29		Aceito
TCLE / Termos de Assentimento /	Termo de Consentimento Livre e Esclarecido - CEP.doc	11/08/2015 19:33:38		Aceito

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DE ANOMALIAS
CRANIOFACIAIS DA USP

Continuação do Parecer: 1.303.912

Justificativa de Ausência	Termo de Consentimento Livre e Esclarecido - CEP.doc	11/08/2015 19:33:38		Aceito
Projeto Detalhado / Brochura Investigador	Projeto Modelos - 5 anos (29_06_2015).docx	11/08/2015 16:56:49		Aceito
Outros	Termo de Assentimento(1).docx	11/08/2015 16:54:55		Aceito
Outros	Bianca_Carta de encaminhamento.pdf	11/08/2015 16:54:19		Aceito
Outros	Bianca_Termo de compromisso do pesquisador.pdf	11/08/2015 16:53:55		Aceito
Outros	Bianca_Termo de compromisso de tornar publico.pdf	11/08/2015 16:53:26		Aceito
Outros	Bianca_Termo de compromisso de manuseio de informacoes.pdf	11/08/2015 16:53:01		Aceito
Outros	Bianca_Formulario HRAC.pdf	11/08/2015 16:52:36		Aceito
Folha de Rosto	Bianca_Folha de Rosto.pdf	11/08/2015 16:50:35		Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 30 de Outubro de 2015

Assinado por:
Silvia Maria Graziadei
(Coordenador)

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