UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

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3D longitudinal evaluation of dental arch in children with unilateral cleft lip and palate

Avaliação longitudinal 3D dos arcos dentários de pacientes com fissura labiopalatina unilateral

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

Orientadora: Prof.ª Dr.ª Thais Marchini Oliveira Valarelli

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DEDICATÓRIA

Dedico este trabalho às minhas avós e madrinhas Maria Ondina (*in memorian*) e Therezinha (*in memorian*), que sonharam junto comigo, torceram e rezaram sempre para que meus objetivos fossem alcançados, por terem sido minha estrutura familiar por muitos anos. Pessoas com coração bondoso que dedicaram toda sua vida à família, pelo amor que ambas me envolveram, vocês moram nas minhas lembranças e no meu coração, meu eterno amor e saudade.

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A **Deus**,
pelos momentos bons e ruins, pois Ele sabe que eu poderia ultrapassá-los e adquirir sabedoria.

Aos **meus pais e a minha irmã,**
pelos momentos em que chorei vocês vieram com palavras doces que acalmaram meu coração e me fizeram sorrir. Pelos momentos de alegria que fiz questão de compartilhar entre sorrisos e abraços.

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"Temos que devolver o poder à infância, especialmente à criança adormecida dentro de nós. Vamos deixar de lado as ideias prontas, concebidas para todos e boas para ninguém. Vamos reaprender a silenciar nossos pensamentos, a ouvir o sussurro de nossa consciência, a escutar nosso coração. Vamos descobrir nossa sabedoria profunda."

Dominique Glocheux

RESUMO

Avaliação longitudinal 3D dos arcos dentários de pacientes com fissura labiopalatina unilateral

O propósito deste estudo foi realizar uma análise das alterações dimensionais dos arcos dentários superiores de crianças com fissura labiopalatina, antes e após as cirurgias plásticas primárias. A amostra foi composta por 150 modelos dentários digitalizados de crianças entre 3 e 36 meses de vida, divididos em 2 grupos: fissura completa de lábio unilateral (FLU) e fissura de lábio e palato unilateral (FLPU). Os arcos dentários foram avaliados nas seguintes fases: pré-queiloplastia (F1), pré-palatoplastia (F2) e 1 ano pós-palatoplastia (F3). Os modelos dentários foram mensurados por meio de um software do sistema de estereofotogrametria. Analisou-se distâncias intercanino e intertuberosidade, comprimentos anterior e total do arco dentário, além da área dos arcos dentários. A análise da reprodutibilidade intraexaminador demonstrou que todas as mensurações foram suficientemente reprodutíveis ($p>0.05$). Foram aplicados os Testes t independente e Mann-Whitney para verificar as alterações ocorridas entre os diferentes grupos. Para avaliação intragrupos, a Análise de Variância de medidas repetidas (ANOVA de medidas repetidas) foi utilizada para analisar as fases do protocolo reabilitador no grupo FLPU, seguido do Teste de Tukey. Os Testes t pareado e Wilcoxon foram aplicados na comparação às fases do tratamento da FLU. Em F1, as distâncias intercanino e intertuberosidade apresentaram valores significativamente maiores no grupo FLPU em relação ao grupo FLU. Os comprimentos, anterior e total, do arco dentário, e a área foram significativamente menores no grupo FLPU. Na pré-palatoplastia, todas as variáveis analisadas, exceto a distância intertuberosidade, apresentaram valores estatisticamente maiores no grupo FLU. A distância intercanino e o comprimento anterior apresentaram uma redução significativa, no entanto a intertuberosidade e o comprimento total do arco dentário demonstraram um crescimento significativo entre F1 e F3 (grupo FLPU). De acordo com os resultados obtidos, a cirurgia plástica primária influenciou no crescimento e desenvolvimento dos segmentos ósseos dos arcos dentários das crianças com FLU e FLPU. A queiloplastia afetou negativamente o desenvolvimento da região anterior do palato, de forma mais notória no grupo FLPU. A palatoplastia não afetou o crescimento da região posterior do palato.

Palavras-chave: Fenda labial. Fissura palatina. Modelos Dentários.

ABSTRACT

3D longitudinal evaluation of dental arch in children with unilateral cleft lip and palate

This study aimed to analyse the alterations of the maxillary dental arches of children with cleft lip and palate before and after the primary plastic surgeries. The sample comprises 150 digitized dental casts from children, age between 3 and 36 months, divided in: unilateral complete cleft lip (UCL) and unilateral complete cleft lip and palate (UCLP). The dental arches were evaluated in the following phases: before cheiloplasty (T1), before palatoplasty (T2), and one year after palatoplasty (T3). The digitized dental casts were measured three-dimensionally through the software of the stereophotogrammetry systems. The following distances were analysed: intercanine and intertuberosity distances; anterior and total dental arch length; dental arch area. The intraexaminer agreement analysis demonstrated that all measurements were reproductible ($p>0.05$). 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 UCLP. Paired t test and Wilcoxon test compared the different phases of the group UCL. At T1, intercanine and intertuberosity distances had statistically higher values in group UCLP than in group UCL. The dental arch lengths and the area were significantly smaller in group UCLP. Before palatoplasty, maxillary dimensions significantly increased, except for intertuberosity distance in UCL. The intercanine distance and the anterior length had a significant decreased, but the intertuberosity measurement and the total dental arch length showed significant increase between T1 and T3 (group UCLP). Based on these results, the primary plastic surgery negatively influences the bone segments growth and development of the maxillary dental archs of children with UCL and UCLP. The cheiloplasty negatively affected the development of the anterior palate, more evidently for the group UCLP. The palatoplasty did not affect the growth of the posterior palate.

Key words: Cleft Lip. Cleft Palate. Dental Models.

SUMMARY

1 Introduction

1 INTRODUCTION

Cleft lip and palate (CLP) is a huge public health problem, because CLP is the most prevalent craniofacial anomaly in humans (YAKOB et al., 2017), caused by lack of fusion of one or more embryonic facial processes resulting in discontinued areas in lip and/or palate (DIXON et al., 2011). Oral clefts take place between the 4th and 12th weeks of intrauterine life (FREITAS et al., 2012) and have multifactorial etiology determined by genetic and environmental factors (SHAH et al., 2016).

A diagnosis hypothesis can be performed at pregnancy, but the definitive proof occurs only after birth (JAMES; SCHLIDER, 2016; SHIBUI et al., 2016). The multidisciplinary rehabilitation requires a specific approach according to the size of the anatomic defect within the different CLP types (FREITAS et al., 2012; LAMBERT et al., 2016). The goal is not only to repair the anatomic defect, but also to assure favourable conditions to swallow, breath, speak, and hear, achieving esthetics and consequently to reach the adaptation and acceptance of the child in social life (FREITAS et al., 2012; RUSKOVÁ et al., 2014).

Among the numerous surgical interventions to rehabilitate the individual with cleft lip and palate, the cheiloplasty and palatoplasty are performed months after the child's birth (FREITAS et al., 2012b; CHEPLA; GOSAIN, 2013), the so-called primary plastic surgeries. Although these procedures promote the anatomic-functional reconstruction, studies suggest that these surgeries may restrict the growth and development of the dental arches (REISER et al., 2013; ZHU et al., 2016). However, the literature lacks consensus on which surgery would cause the most significant negative effects and which period would be the most suitable to perform those surgeries (FUCHIGAMI et al., 2011; VALENTOVÁ-STRENÁČIKOVÁ; MALINA, 2016).

The professionals must have knowledge about the factors causing dimensional alterations on dental arches. The studies indicate that the cleft width, the type of surgical technique, the number of plastic surgeries, the surgeon’s ability, the tissue trauma caused by the surgeries, the amount of scar tissue, and the individual’s genetic pattern of growth (REISER et al., 2013; FUCHIGAMI et al., 2011; RUSSEL et al., 2015; JONES et al., 2016) may cause alterations that influence on the outcome of the rehabilitation protocol.

Plaster dental casts are an indispensable dental examination that must be performed from birth to skeletal maturity (FREITAS et al., 2012b), once they enable the view of maxillary and mandibular dental arch morphology, contributing for diagnosis, pre- and post-surgical planning, and following-up of the rehabilitation protocol (ZHU et al., 2016). Although dental casts are the gold standard for diagnosis and treatment, their disadvantages comprise large rooms for storage, material's fragility, and likelihood to loss the casts (CHAWLA et al., 2013; LIPPOLD et al., 2015).

The most suitable method to replace study casts is either laser or stereophotogrammetry scanning (SFORZA et al., 2013; KUIJPERS et al., 2014; LAMBERT et al., 2016; ZHU et al., 2016; CERÓN-ZAPATA et al., 2016; DE MENEZES et al., 2016), because both are non-invasive methods and make easy the longitudinal analysis of the outcomes for the rehabilitation process (CODARI et al., 2016).

The advantages of scanning relate to less space for storing information, easy access and transfer of data, and information durability (SFORZA et al., 2012; CHAWLA et al., 2013; LIPPOLD et al., 2015). Also, the digital file can be attached to the person's file, which aids in the interchange of information among researchers, professionals, and institutions.

The early evaluation of dental arches enables improving the technique and quality of the surgical interventions and excludes some steps of the rehabilitation process resulting in unsatisfactory outcomes (REISER et al., 2013; LAMBERT et al., 2016). This analysis is an important marker of the quality of the therapeutic approach in individuals with cleft lip and palate (CERÓN-ZAPATA et al., 2016; DE MENEZES et al., 2016).

2 Article

2 ARTICLE

This paper will be submitted to the Journal of Dental Research.

Introduction

Cleft lip and palate (CLP) is a huge public health problem, because CLP is the most prevalent craniofacial anomaly in humans (YAKOB et al., 2017), caused by lack of fusion of one or more embryonic facial processes resulting in discontinued areas in lip and/or palate (DIXON et al., 2011). Oral clefts take place between the 4th and 12th weeks of intrauterine life (FREITAS et al., 2012) and have multifactorial etiology determined by genetic and environmental factors (SHAH et al., 2016).

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Plaster dental casts are an indispensable dental examination that must be performed from birth to skeletal maturity (FREITAS et al., 2012b), because they enable the tridimensional (3D) view of maxillary and mandibular dental arch morphology, contributing for diagnosis, pre- and post-surgical planning, and following-up of the rehabilitation protocol (ZHU et al., 2016). Although dental casts are the gold standard for diagnosis and treatment, their disadvantages comprise large rooms for storage, material's fragility, and likelihood to loss the casts (CHAWLA et al., 2013; LIPPOLD et al., 2015).

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The early evaluation of dental arches enables improving the technique and quality of the surgical interventions and excludes some steps of the rehabilitation process resulting in unsatisfactory outcomes (REISER et al., 2013; LAMBERT et al., 2016). This analysis is an important marker of the quality of the therapeutic approach in individuals with cleft lip and palate (CERÓN-ZAPATA et al., 2016; DE MENEZES et al., 2016). Thus, this study analysed the 3D alterations of the maxillary dental arches with unilateral complete cleft lip (UCL) and unilateral complete cleft lip and palate (UCLP) before and after the primary plastic surgeries.

Material and methods

Experimental design

This study was submitted and approved by the Institutional Review Board regarding the ethical aspects under protocol nº CAAE 48123315.4.0000.5441 (Annex A).

The sample size was calculated so that the number of individuals met that required to enable the study. For that purpose, we used the study of Lo et al. (2003). With level of significance of 5%, power test of 80%, and the minimum difference to be clinically detected of 100 mm², the minimum sample size calculated was of 29 children per group.

One hundred and fifty dental casts were obtained from 60 children with UCL (n=30) and UCLP (n=30), with or without Simonart's band, both genders, age between 3 and 36 months, without syndromes or malformations. The dental casts were performed in the Hospital for the Rehabilitation of Craniofacial Anomalies, University of São Paulo, Brazil (HRAC/USP). The children were regularly enrolled at the institution and should have the dental casts at the following rehabilitation periods: pre-cheiloplasty (T1), pre-palatoplasty (T2), and 1 year after palatoplasty (T3) - only for UCLP children.

Obtaining of the digital casts and the measurements

The dental casts were scanned through a commercially available laser scanner (3Shape´s R700™ Scanner) at HRAC/USP. The files of the 3D images were stored in STL format.

The measurements were executed through the appropriate tool of the stereophotogrammetry system software (Mirror imaging software, Canfield Scientific Inc., Fairfield, NJ, USA) at the University of Milan (UniMi), Italy (SFORZA et al., 2012, 2013; PUCIARELLI et al., 2015; CERÓN-ZAPATA et al., 2016; CODARI et al., 2016; DE MENEZES et al., 2016).

Linear measurements

The anatomic landmarks (Table 1, Figure 1) were marked on the maxillary dental arches to perform the linear measurements. All measurements were performed at each point through the software measurement tool that acquired the image according to the Cartesian planes, linked them all, and processed the image.

The following linear measurements were obtained (Table 2, Figure 1): intercanine and intertuberosity distances (SFORZA et al., 2012; REISER et al., 2013; CARRARA et al., 2016; FALZONI et al., 2016; JORGE et al., 2016), anterior (REISER et al., 2013) and total length of dental arch (REISER et al., 2013; CARRARA et al., 2016; HOFFMANNOVA et al., 2016; JORGE et al., 2016).

Table 1 – Anatomic reference points

Anatomic points	Abbreviation	Definition
Interincisor	I	Point on the mesial incisal areas between the maxillary central incisors.
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).

Table 2 – Linear measurements

Measurements	Definition
C - C’	Intercanine distance – transversal line on the dental arch between points C and C’.
T - T’	Intertuberosity distance – posterior transversal line on the dental arch between points T and T’.
I-CC’	Anterior length of dental arch – sagittal line from point I perpendicular to distance C - C’.
I-TT’	Total length of dental arch – sagittal line from point I perpendicular to distance T - T’.

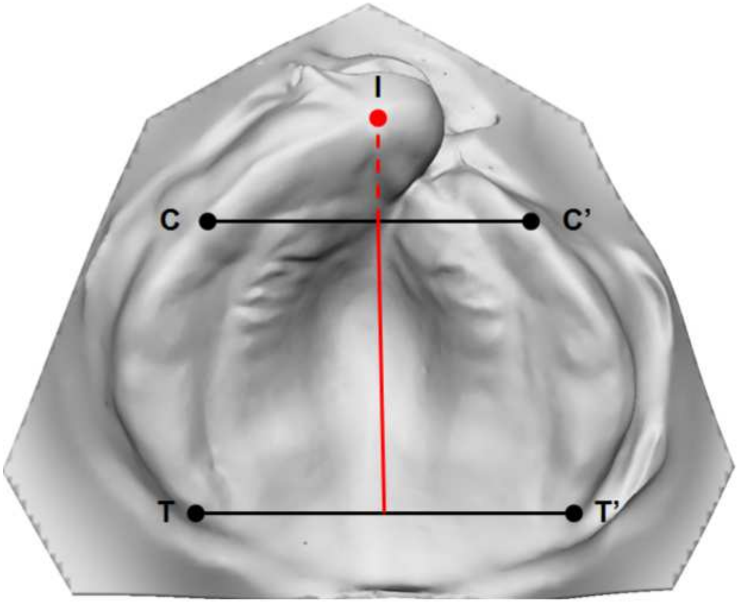

Figure 1: Anatomic landmarks and linear measurements.

Surface measurements

The area of the dental arches of the children with CLP were analysed and measured in mm^2 (LO et al., 2003; DARVANN et al., 2007; DE MENEZES et al., 2016).

At all phases of the group UCL, the area was marked from the alveolar ridge to the intertuberosity distance - posterior limit - (LO et al., 2003) (Figures 2 and 3). At phases T1 and T2, in group UCLP, the dental arch area was marked from the alveolar ridge, outlining all palatal segment adjacent to the cleft (Figure 4), obtaining: the area of the major palatal segment (Area M) and minor palatal segment (Area m). Also, the area of the cleft (Area c) was measured at T1 and T2 (CARRARA et al., 2016). At phase T3 of group UCLP, after palatoplasty, the area was measured as described above for the group UCL. Thus, to enable a comparative inter- and intragroup analysis (UCLP), we performed the sum of the areas of the bone segments (Area).

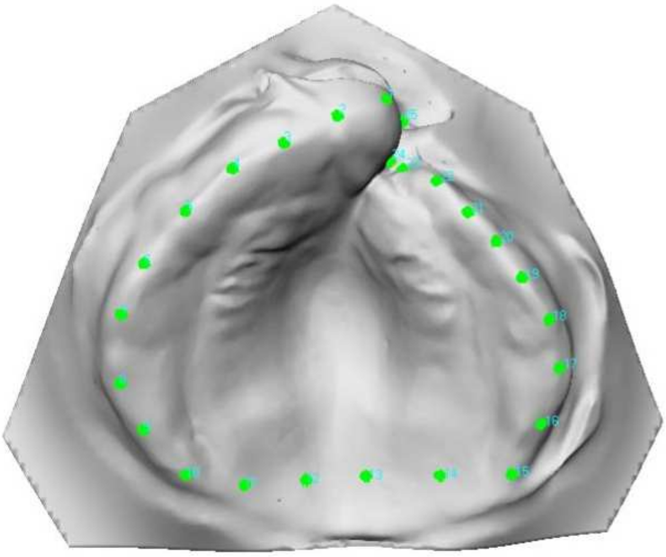

Figure 2 - Delimitation of the dental arch of group UCL.

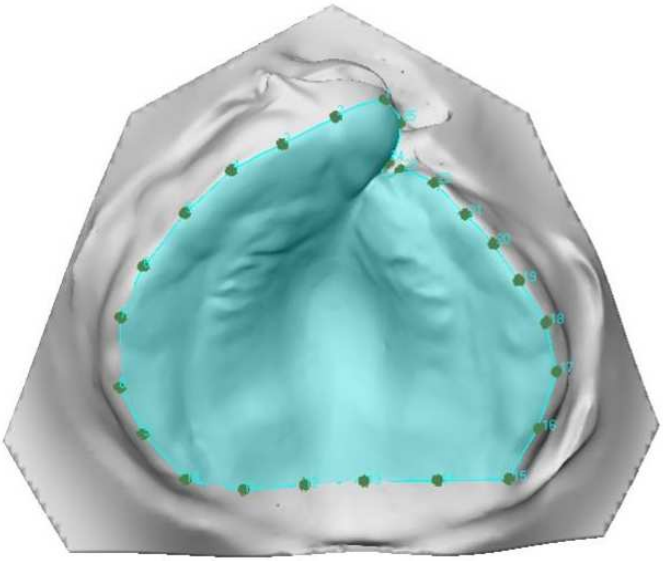

Figure 3 - Area of the dental arch of group UCL.

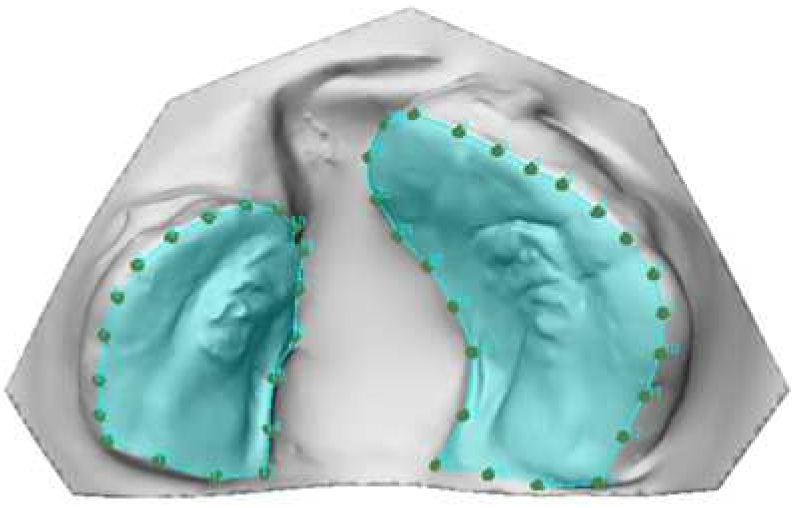

Figure 4 - Areas of the palatal bone segments of group UCLP.

Statistical analysis

All statistical analyses were executed by GraphPad Prism software (Prism 5 for Windows - Version 5.0 – GraphPad software., Inc.), adopting the level of significance of 5%. The Shapiro-Wilk normality test was applied in the quantitative measurements (Annex B).

To analyse the intraexaminer error, paired t test was applied in 1/3 of the dental casts, measured again 15 days after the first measurement. When the variable did not show normal distribution, Wilcoxon test was used. The casual error was determined by Dahlberg's formula. 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 UCLP. Paired t test and Wilcoxon test compared the different phases of the group UCL.

Results

Table 3 displays the sample characterization regarding gender and cleft side of the children participating in the study.

Table 3 – Sample characterization regarding gender and cleft side

Variables	UCL	UCLP
Gender, n(%)		
Male	12 (40%)	17 (56.7%)
Female	18 (60%)	13 (43.3%)
Cleft side, n(%)		
Right	5 (16.7%)	11 (36.7%)
Left	25 (83.3%)	19 (63.3%)

The age (in years) of the children were compared at the different treatment phases. The age median of group UCL was 0.295 (T1) and 1.749 (T2). In group UCLP, the age median was 0.291; 1.083; and 2.25 years, respectively for T1; T2; and T3. Statistically significant differences in age occurred between groups UCL and UCLP at T2 and in the difference between T2-T1 ($p < 0.001$).

Method error

The intraexaminer reproducibility was analysed and no statistically significant differences in the repeated measurements (Tables 4 and 5).

Table 4 – Analysis of the intraexaminer reproducibility for the repeated measurements in group UCL (Paired t test and Wilcoxon test, Dahlberg's Formula)

Variables	1st measurement Mean (Median)	SD (IA)	2nd measurement Mean (Median)	SD (IA)	Dahlberg's formula	*P*
T1						
C - C'	25.18	1.37	25.21	1.55	0.259	0.804
T - T'	31.47	2.07	31.45	2.11	0.265	0.919
I - CC'	8.66 [A]	3.78 [A]	8.35 [A]	3.12 [A]	0.246	0.556
I - TT'	30.79	3.08	30.75	3	0.252	0.761
Area	1049.5 [A]	88.5 [A]	1064.5 [A]	92.25 [A]	1.516	0.474
T2						
C - C'	28.97	2.09	29.02	2.21	0.206	0.572
T - T'	35.82	2.67	35.93	2.64	0.233	0.335
I - CC'	8.61	1.63	8.55	1.62	0.198	0.585
I - TT'	32.75	3.41	32.73	3.47	0.321	0.918
Area	1152.07	419.59	1245.9	158.43	2.479	0.266

[A] Median and IA (interquartile amplitude), Wilcoxon test.

Table 5 – Analysis of the intraexaminer reproducibility for the repeated measurements in group UCLP (Paired t test and Dahlberg's Formula)

Variables	1st measurement Mean	SD	2nd measurement Mean	SD	Dahlberg's formula	*P*
T1						
C - C'	28.73	2.93	28.88	2.85	0.219	0.141
T - T'	36.67	4	36.63	4.04	0.184	0.676
I - CC'	7.52	1.74	7.43	1.52	0.219	0.360
I - TT'	27.46	1.96	27.39	2.04	0.251	0.566
Area	1338	175.48	1340.9	173.72	1.204	0.812
T2						
C - C'	28.32	2.11	28.42	2.09	0.141	0.148
T - T'	37.65	2.13	37.54	1.98	0.258	0.391
I - CC'	6.75	1.03	6.76	1.15	0.212	0.891
I - TT'	29.42	2.4	29.43	2.39	0.152	0.924
Area	1350.1	158.79	1358.3	161.95	2.024	0.144
T3						
C - C'	26.89	2.8	27.03	2.94	0.180	0.083
T - T'	39.42	3.15	39.49	3.08	0.185	0.456
I - CC'	6.33	1.4	6.15	1.21	0.296	0.195
I - TT'	31.39	1.81	31.51	1.8	0.202	0.196
Area	1164	124.86	1173.2	110.72	2.144	0.336

Dimensional changes in group UCL

The maxillary dimensions of group UCL, during the evaluated phases are described in table 6.

Table 6 – Analysis of the maxillary linear (mm) and surface dimensions (mm²) in group UCL, at T1 and T2 (Paired t test and Wilcoxon test)

Variables	T1 Mean (Median)	T1 SD (IA)	T2 Mean (Median)	T2 SD (IA)	*P*
C - C’	25.86	1.63	29.25	1.75	**< 0.0001***
T - T’	31.07	2.14	37.63	3.69	**< 0.0001***
I - CC’	8.28	1.68	7.99	1.65	0.515
I - TT’	31.18	2.66	31.62	2.97	0.526
Area	1080 [A]	94.25 [A]	1264 [A]	160.5 [A]	**< 0.0001***

*Statistically significant difference.
[A] Median and IA (interquartile amplitude), Wilcoxon test.

The intercanine (C - C’) and intertuberosity distances (T - T’) showed statistically higher values at T2. The anterior length of the dental arch (I - CC’) decreased after surgery, but without statistically significant differences. The total length of the dental arch (I - TT’) increased after the surgery, again without significant differences. The area showed statistically higher values at T2 than that of T1.

Dimensional changes in group UCLP

The maxillary dimensions of group UCLP, during the evaluated phases are described in table 7.

Table 7 - Analysis of the maxillary linear (mm) and surface dimensions (mm²) in group UCLP at Phases 1; 2; and 3 (ANOVA, Tukey test)

Variables	T1 Mean	T1 SD	T2 Mean	T2 SD	T3 Mean	T3 SD	*P*
C - C’	28 [a]	3.22	27.29 [ab]	2.77	26.63 [b]	2.68	**0.001***
T - T’	35.05 [a]	4.28	36.85 [b]	3.23	38.82 [c]	3.14	**< 0.0001***
I - CC’	7.26 [a]	1.29	6.51 [b]	1.12	5.96 [b]	1.28	**< 0.0001***
I - TT’	27.44 [a]	2.48	28.62 [b]	2.65	29.96 [c]	2.67	**< 0.0001***
Area	965.58 [a]	168.58	1100.2 [b]	128.17	1082.7 [b]	147.9	**< 0.0001***

* Statistically significant difference.
Equal lowercase letters in line means no statistically significant difference.

The distance C - C' decreased after cheiloplasty, but without statistically significant difference between T1 and T2. At the last phase, this distance had statistically lower values than that at T1. The distance T - T' and the total length of the dental arch (I - TT') showed significant increase at all evaluated phases. The anterior length of the dental arch (I - CC') exhibited statistically reduction between T1 and T2 (after cheiloplasty), but without statistically difference between T2 and T3. The area had a significant increase after cheiloplasty. However, after the palatoplasty, the area did not have significant changes (Table 8).

Table 8 – Analysis of the maxillary surface dimensions (mm²) in group UCLP, at T1 and T2 (Paired t test)

Variables	T1		T2		*P*
	Mean	**SD**	**Mean**	**SD**	
Area M	567.36	97.32	647.23	81.92	**0.0011***
Area m	398.38	94.84	452.96	66.65	**0.0016***
Area c	309.4	73.74	212.66	83.39	**< 0.0001***

* Statistically significant difference.

The major (Area M) and minor (Area m) palatal segments significantly increased at the evaluated periods. However, the cleft area (Area c) significantly decreased after cheiloplasty.

Dimensional changes between groups UCL and UCLP

The comparison of the maxillary dimensions of groups UCL and UCLP, at phases T1 and T2 are described in tables 9, 10, and 11.

Table 9 – Analysis of the maxillary linear (mm) and surface dimensions (mm²) of groups UCL and UCLP, at T1 (Independent t test)

Variables	UCL		UCLP		*P*
	Mean	**SD**	**Mean**	**SD**	
C - C'	25.86	1.63	28	3.22	**0.0020***
T - T'	31.07	2.14	35.05	4.28	**< 0.0001***
I - CC'	8.28	1.68	7.26	1.29	**0.0108***
I - TT'	31.18	2.66	27.44	2.48	**< 0.0001***
Area	1098.3	82.96	965.66	168.58	**0.0003***

* Statistically significant difference.

The distances C - C’ and T - T’ had statistically higher values in group UCLP than in group UCL, before the surgery. The sagittal lengths I - CC’, I - TT’ and the area were significantly smaller in group UCLP.

Table 10 – Comparison of the maxillary linear (mm) and surface dimensions (mm²) of groups UCL and UCLP, at T2 (Independent t test and Mann Whitney test)

Variables	UCL Mean (Median)	UCL SD (IA)	UCLP Mean (Median)	UCLP SD (IA)	*P*
C - C’	29.25	1.75	27.29	2.77	**0.0018***
T - T’	37.63	3.69	36.85	3.23	0.3925
I - CC’	7.99	1.65	6.51	1.12	**< 0.0001***
I - TT’	31.62	2.97	28.62	2.65	**< 0.0001***
Area	1264 [A]	160.5 [A]	1079.5 [A]	174.75 [A]	**0.0001***

* Statistically significant difference.
[A] Median and IA (interquartile amplitude), Mann Whitney test.

After cheiloplasty, the distance C - C’, the dental arch lengths (I - CC’, I - TT’), and the area exhibited statistically lower values in group UCLP. No statistically significant change occurred in the intertuberosity distance between groups at T2.

Table 11 – Comparison of the changes in the maxillary linear (mm) and surface dimensions (mm²) between T2-T1, in groups UCL and UCLP (Independent t test)

Variables	UCL Mean	UCL SD	UCLP Mean	UCLP SD	*P*
C - C’	3.39	1.84	- 0.7	1.91	**< 0.0001***
T - T’	6.55	3.8	1.8	2.75	**< 0.0001***
I - CC’	- 0.28	2.4	- 0.74	1.2	0.3540
I - TT’	0.43	3.74	1.17	2.68	0.3827
Area	165.6	125.34	134.53	148.23	0.3844

* Statistically significant difference.

From pre-cheiloplasty to pre-palatoplasty periods, the intercanine and intertuberosity distances significantly increased in group UCL. The sagittal variables and the area did not show statistically significant differences between groups.

Discussion

The use of the anatomic landmarks is a common parameter used for the anthropometric analysis of children with cleft lip and palate (HONDA et al., 1995; HUANG et al., 2002; LO et al., 2003; SFORZA et al., 2012; HARILA et al., 2013; REISER et al., 2013; ROUSSEAU et al., 2013; FUCHIGAMI et al., 2011;

FERNANDES et al., 2015; CARRARA et al., 2016; FALZONI et al., 2016; HOFFMANNOVA et al., 2016; JORGE et al., 2016). The literature lacks consensus on a gold-standard procedure to mark these landmarks, which may difficult the analysis. However, the definition of these landmarks is simplified in high-quality dental casts by the 3D image magnification and rotation and by the expertise of the examiner in performing the anthropometry of the children dental arches (SECKEL et al., 1995; HARILA et al., 2013).

The linear anthropometry is used to analyse the therapeutic approach of a given institution (FUCHIGAMI et al., 2011; CARRARA et al., 2016; FALZONI et al., 2016; JORGE et al., 2016). Some studies assess the dental arch area of children with CLP (LO et al., 2003; DARVANN et al., 2007; CARRARA et al., 2016; DE MENEZES et al., 2016). In this study, the delimitation of the dental arches at the pre-surgical phases in group UCLP was based on the study of Carrara et al. (2016), who analysed the bone segments of the dental arch and the cleft. Generally, the studies analyse the palatal bone segments of children with UCLP, but not the cleft, at pre- and post-surgical phases (LO et al., 2003; DARVANN et al., 2007; DE MENEZES et al., 2016). The study of Lo et al. (2003) assessed the area of children with CLP, but not longitudinally. Thus, the measurements of the dental arches of children with oral clefts enable a careful and progressive evaluation of the rehabilitation protocol since the first months of life (FERNANDES et al., 2015).

The intercanine and intertuberosity distances of group UCL showed a significant growth after the cheiloplasty, while the sagittal distances (I - CC’ and I - TT’) did not grow expressively. To the best of our knowledge, the literature lacks studies that analyse these measurements at the pre- and post-surgical phases in children. The small anatomic-functional impairment, the small incidence, and the favourable prognosis of this cleft type account for the few studies on children with UCL.

In 2003, Lo et al. evaluated 3-month-old children prior to surgery and found the following means: 27.34 mm, 29.3 mm, and 863.15 mm² for the intercanine and intertuberosity distances, and dental arch area, respectively. The distances of this present study differed from those of the study of Lo et al. (2003) by 1.65 mm; however, the area difference between the two studies was extremely significant, higher than 215 mm². The study of Fernandes et al. (2015) also evaluated children with UCL, but together with children with bilateral cleft lip (BCL) and did not measure the sagittal dimensions of the dental arches probably because this measurement would be different in the children with BCL regarding the great projection of the anterior portion of the maxilla.

Honda et al. (1995) evaluated the post-surgical period of cheiloplasty at 4 years of age and found a growth in the transversal distances (C - C' and T - T') and a decrease in the anterior arch length, similar to the findings of this present study.

At the evaluated phase of group UCLP, the dimensions of the anterior portion of the palate (C – C` and I - CC') reduced after the primary surgeries, but the total arch length and the intertuberosity distance significantly increased. These results agree with other studies on the pre- and post-surgical digital anthropometry of the dental arches, such as Carrara et al. (2016) that verified the same surgical technique at two phases: pre-cheiloplasty and one year after palatoplasty.

In the study of Jorge et al. (2016), the analysis consisted of assessing the anthropometry of children with UCLP submitted to different rehabilitation protocols: cheiloplasty with and without pre-surgical orthopaedic treatment. In both groups, regardless of the protocol, the distance C – C` reduced and the distance T – T` increased. Nevertheless, McCance et al. (1990) affirmed that adults with UCLP that never underwent the plastic surgeries have a progressive transversal reduction compared with adults without oral clefts. The rationale behind this fact is that the palatal segments intrinsically displaced towards the midline, causing the approximation of the palatal shelves, justifying the smaller linear measurements of adults with UCLP compared with individuals without oral clefts (MCCANCE et al., 1990).

Generally, the rehabilitation protocol states that the primary plastic surgeries are conducted at the first months of life. Thus, since then, the primary surgeries influence on the position of the bone segments. In this present study, from T1 to T2, the group UCLP showed a significant surface increase of the palatal segments and reduction of the cleft area from 309.4 to 212.66 mm², together with a decrease of the linear measurements on the anterior portion of the palate.

Thus, we hypothesize that the remodelling of the fibres of the orbicularis oris muscle during the cheiloplasty causes the repositioning of the alveolar bone edge that before the surgery had an increased overjet. This pressure of the fibre direction change would justify the results of this study, in which the anterior length discreetly reduced after cheiloplasty.

In the analysis of the dimensional changes before cheiloplasty, the group UCLP exhibited an increase in distances C - C’ and T - T’ and a decrease in the sagittal and area measurements compared with group UCL. Other authors also demonstrated the smaller transversal distances and higher palatal surface in children with UCL (LO et al., 2003). For example, the study of Fernandes et al. (2015) found 26.49 mm and 28.31 mm (C – C´); 32.98 mm and 35 mm (T – T´) respectively for the groups UCL and UCLP. These data confirm that the cleft amplitude and the intrinsic lack of tissue affects the dimensions of the individuals with UCLP.

In this present study, after the cheiloplasty, the values of the distances C – C´, I – CC`, I - TT’ and the area of group UCLP were still lower than those of the group UCL. The post-cheiloplasty transversal narrowing of children with UCLP (compared with children with UCL) was observed by Honda et al. (1995) at complete deciduous dentition. The authors found a significant reduction of the measurements of the anterior portion of the palate compared with children with UCL, although the total length was higher in group UCLP, even when the children with UCLP underwent one-stage Wardill-Kilner push-back palatoplasty at 2 years of age.

It is difficult to compare the results of different studies because of different study methodologies, treatment protocols, and follow-up. These factors should be carefully analysed (BRAUMANN et al., 2003). The literature fails to point out which primary surgical technique and surgical period would cause more restrictive effects on the development of the maxillary arch. In fact, there are few studies that only measure the effects of operative procedures, considering the diversity of techniques and surgical times (HUANG et al., 2002; XU et al., 2015; CARRARA et al., 2016; TOME et al., 2016).

The face analysis of the cleft types reveals that all types are influenced by the cheiloplasty, but UCLP exhibits the most evident morphological problem (DADÁKOVÁ et al., 2016). The longitudinal study of Huang et al. (2002) clearly pointed out the growth inhibition of the anterior portion of the palate after cheiloplasty, proved by linear and angular measurements. The continuous pressure exerted by the tissue reconstruction over the dental arch explains this result (HUANG et al., 2002). Capelozza Filho et al. (1996) and Li et al. (2006) suggested that the cheiloplasty is the main responsible factor for inhibiting the maxillary growth in individuals with cleft lip and palate based on the cephalometric results.

Some authors demonstrated that the palatoplasty caused different consequences on the three-dimensional development of the maxilla. Carrara et al. (2016) demonstrated that one-stage technique had higher values of total arch length than two-stage technique, one year after palatoplasty. Although other authors affirmed that the difference in growth does not exist (TOME et al., 2016). In 2015, Xu et al. concluded that regardless of the number of surgical phases, the palatoplasty can inhibit the sagittal growth of the maxilla. The results of this present study did not support this influence.

According to the analyses of this present study results, further anthropometric studies using digital images are necessary to evaluate the rehabilitation protocols aiming to improve the clinical practice of the interdisciplinary team, determine new parameters for the rehabilitation process of the individuals with cleft lip and palate, and confirm the results through longer following-up periods to provide favourable quality of life of these individuals.

Conclusion

Based on these results, the primary plastic surgery negatively influences the bone segments growth and development of the maxillary dental arches of children with UCL and UCLP. The cheiloplasty negatively affected the development of the anterior palate, more evidently for the group UCLP. The palatoplasty did not affect the growth of the posterior palate.

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3 Discussion

3 DISCUSSION

Aiming at explaining properly the data obtained in this study, firstly we discuss the sample and applied methodology. Then, we discuss the results by compare them with the literature, including the clinical relevance of this study.

Sample

In this study, the sample comprised 60 children of both genders, equally divided into two groups according to the type of CLP, submitted to cheiloplasty (Millard technique) as of 3 months of age and total palatoplasty (Von-Langenback technique) as of 12 months of age (only for group UCLP) by the plastic surgeons of the institution.

The sample size was very similar to other studies which employed from 7 to 30 children (HONDA et al., 1995; CARRARA et al., 2016; CÉRON-ZAPATA et al., 2016; FALZONI et al., 2016; JORGE et al., 2016). The reasons for this number are the inclusion criteria, the incidence of the craniofacial anomaly in the geographic area, and the difficulty in longitudinally following-up the rehabilitation protocol. This latter is justified by the lack of compliance of the individuals to attend periodic following-up appointments in the institution due to cultural (beliefs) and economic (government support) challenges. Also, children depend on their parents to attend the appointments in the institution, and generally, they live in other cities far from that of the institution.

The age range used in this study agrees with those of the literature on the analysis of the clinical outcomes of the dental arch growth and development of children submitted to therapeutic approaches at the first months of life (HARILA et al., 2013; REISER et al., 2013; ROUSSEAU et al., 2013; CARRARA et al., 2016; CÉRON-ZAPATA et al., 2016; DE MENEZES et al., 2016; FALZONI et al., 2016; HOFFMANNOVA et al., 2016; JORGE et al., 2016).

Previously to each surgical phase and one year after the last primary surgery, the children enrolled at the institution are strictly followed-up by a clinical documentation protocol comprising the impression of the maxillary arch and extra- and intraoral photographs. The parents and/or legal guardians are instructed about the importance to attend these procedures, the execution of the procedure, and the possible problems during the impression (crying and nausea) (FREITAS et al., 2012; FERNANDES et al., 2015).

Caution was taken to select dental casts with good quality to enable marking the anatomic landmarks of the linear measurement and the outlining for the surface area measurement (SECKEL et al., 1995). Notwithstanding, the impression procedure in infants is difficult because the child lacks enough cognitive capacity to understand the importance of the dental documentation. Accordingly, the procedure was performed by dentists with large experience in that task and with the compliance of the parents and/or legal guardians.

Usually the studies only focus on the dimensional analyses of the dental arches of children with cleft lip and palate (HUANG et al., 2002; SFORZA et al., 2012; ROUSSEAU et al., 2013; FUCHIGAMI et al., 2011; PUCCIARELLI et al., 2015; CARRARA et al., 2016; CÉRON-ZAPATA et al., 2016; DE MENEZES et al., 2016; FALZONI et al., 2016; HOFFMANNOVA et al., 2016; JORGE et al., 2016) because this is the most prevalent type (CYMROT et al., 2010; NEVES et al., 2016; PACÁKOVÁ et al., 2016). The studies comprise the assessment of different corrective surgical techniques (CARRARA et al., 2016; TOME et al., 2016), analyses of rehabilitative protocols (ROUSSEAU et al., 2013; FUCHIGAMI et al., 2011; PUCCIARELLI et al., 2015; CÉRON-ZAPATA et al., 2016; FALZONI et al., 2016; HOFFMANNOVA et al., 2016; JORGE et al., 2016), and comparison of the cleft subtypes (HONDA et al., 1995; LO et al., 2003; HARILA et al., 2013; REISER et al., 2013; FERNANDES et al., 2015). Nevertheless, the literature lacks studies on the comparison of the dental arches anthropometry of children with and without cleft (FERNANDES et al., 2015).

Methods

Both the laser scanner and the stereophotogrammetry systems are devices largely employed in the digitation of dental casts producing high-resolution three-dimensional images (SFORZA et al., 2012; FUCHIGAMI et al., 2011; FERNANDES et al., 2015; PUCCIARELLI et al., 2015; CARRARA et al., 2016; CÉRON-ZAPATA et al., 2016; DE MENEZES et al., 2016; FALZONI et al., 2016; HOFFMANNOVA et al., 2016; JORGE et al., 2016). Moreover, these systems are non-invasive tools, with fast acquisition, which do not emit radiation that may damage the health of individuals (PUCCIARELLI et al., 2015; CODARI et al., 2016). However, the high cost may limit their use in rehabilitation centres.

The advantages of the 3D images over the traditional dental casts are: non-degradation of the documentation, no need of physical storage room, storage in databank linked to an integrated system of health institutions, easy sharing either among the professionals of the same institution or among rehabilitative centres to enable the discussion on the therapeutic approaches for the quantitative and qualitative analysis of the treatment (QUIMBY et al., 2004; FLEMING et al., 2010; SFORZA et al., 2012; DE MENEZES et al., 2016; FALZONI et al., 2016).

The use of the anatomic landmarks is a common parameter used for the anthropometric analysis of children with cleft lip and palate (HONDA et al., 1995; HUANG et al., 2002; LO et al., 2003; SFORZA et al., 2012; HARILA et al., 2013; REISER et al., 2013; ROUSSEAU et al., 2013; FUCHIGAMI et al., 2011; FERNANDES et al., 2015; CARRARA et al., 2016; FALZONI et al., 2016; HOFFMANNOVA et al., 2016; JORGE et al., 2016). The literature lacks consensus on a gold-standard procedure to mark these landmarks, which may difficult the analysis. However, the definition of these landmarks is simplified in high-quality dental casts by the 3D image magnification and rotation and by the expertise of the examiner in performing the anthropometry of the children dental arches (SECKEL et al., 1995; HARILA et al., 2013).

The linear anthropometry is used to analyse the therapeutic approach of a given institution (FUCHIGAMI et al., 2011; CARRARA et al., 2016; FALZONI et al., 2016; JORGE et al., 2016). Some studies assess the dental arch area of children with CLP (LO et al., 2003; DARVANN et al., 2007; CARRARA et al., 2016; DE MENEZES et al., 2016). In this study, the delimitation of the dental arches at the pre-surgical phases in group UCLP was based on the study of Carrara et al. (2016), who analysed the bone segments of the dental arch and the cleft. Generally, the studies only analyse the palatal bone segments of children with UCLP, but not the cleft, at pre- and post-surgical phases (LO et al., 2003; DARVANN et al., 2007; DE MENEZES et al., 2016). The study of Lo et al. (2003) assessed the area of children with CLP, but not longitudinally. Thus, the measurements of the dental arches of children with oral clefts enable a careful and progressive evaluation of the rehabilitation protocol since the first months of life (FERNANDES et al., 2015).

Some anthropometric analysis software licenses have considerable high costs for the rehabilitation centres. Notwithstanding, the use of the software enables not only the linear analyses, but also angular, surface, volumetric analysis, as well as superposition of pre- and post-surgical images that allow verifying the growth of the anatomic areas of interest. The software is safe analysis tools that replace the measurements directly on the dental casts, as proven by the studies evaluating these tools (LEIFERT et al., 2009; BOOTVONG et al., 2010; DOGAN et al., 2012; SFORZA et al., 2012; LIPPOLD et al., 2015).

Results

In this study, both the calibration and training of the examiner was very important for precisely identify the landmarks, particularly because of the low age of the sample. The repeatability of the measurements did not show statistically significant differences, assuring the reproducibility of the measurements. According to Seckel et al. (1995), the reproducibility of the measurements is achieved by the examiner's experience and the satisfactory quality of the dental casts.

Intragroup dimensional changes

The intercanine and intertuberosity distances of group UCL showed a significant growth after the cheiloplasty, while the sagittal distances (I - CC' and I - TT') did not grow expressively. To the best of our knowledge, the literature lacks studies that analyse these measurements at the pre- and post-surgical phases in children. The small anatomic-functional impairment, the small incidence, and the favourable prognosis of this cleft type account for the few studies on children with UCL.

In 2003, Lo et al. evaluated 3-month-old children prior to surgery and found the following means: 27.34 mm, 29.3 mm, and 863.15 mm² for the intercanine and intertuberosity distances, and dental arch area, respectively. The distances of this present study differed from those of the study of Lo et al. (2003) by 1.65 mm; however, the area difference between the two studies was extremely significant, higher than 215 mm². The study of Fernandes et al. (2015) also evaluated children with UCL, but together with children with bilateral cleft lip (BCL) and did not measure the sagittal dimensions of the dental arches probably because this measurement would be different in the children with BCL regarding the great projection of the anterior portion of the maxilla.

Honda et al. (1995) evaluated the post-surgical period of cheiloplasty at 4 years of age and found a growth in the transversal distances (C - C’ and T - T’) and total arch length and a decrease in the anterior arch length, similar to the findings of this present study.

At the evaluated phase of group UCLP, the dimensions of the anterior portion of the palate reduced (C – C` and I - CC’) after the primary surgeries, but the total arch length and the intertuberosity distance significantly increased. These results agree with other studies on the pre- and post-surgical digital anthropometry of the dental arches, such as Carrara et al. (2016) that verified the same surgical technique at two phases: pre-cheiloplasty and one year after palatoplasty.

In the study of Jorge et al. (2016), the analysis consisted of assessing the anthropometry of children with UCLP submitted to different rehabilitation protocols: cheiloplasty with and without pre-surgical orthopaedic treatment. In both groups, regardless of the protocol, the distance C – C` reduced and the distance T – T` increased. Nevertheless, McCance et al. (1990) affirmed that adults with UCLP that never underwent the plastic surgeries have a progressive transversal reduction compared with adults without oral clefts. The rationale behind this fact is that the palatal segments intrinsically displaced towards the midline, causing the approximation of the palatal shelves, justifying the smaller linear measurements of individuals with UCLP compared with individuals without oral clefts (MCCANCE et al., 1990).

Generally, the rehabilitation protocol states that the primary plastic surgeries are conducted at the first months of life. Thus, since then, the primary surgeries influence on the position of the bone segments. In this present study, from T1 to T2, the group UCLP showed a significant surface increase of the palatal segments and reduction of the cleft area from 309.4 to 212.66 mm², together with a decrease of the linear measurements on the anterior portion of the palate.

Thus, we hypothesize that the remodelling of the fibres of the orbicularis oris muscle during the cheiloplasty causes the repositioning of the alveolar bone edge that before the surgery had an increased overjet. This pressure of the fibre direction change would justify the results of this study, in which the anterior length discreetly reduced after cheiloplasty.

As far as we are concerned, the literature lacks a methodology to analyse quantitatively how much the intrinsic displacement of the bone segments, the 3D growth of the dental arch, and the plastic primary surgeries account for this reduction.

Intergroup dimensional changes

In the analysis of the dimensional changes before cheiloplasty, the group UCLP exhibited an increase in distances C - C' and T - T' and a decrease in the sagittal and area measurements compared with group UCL. Other authors also demonstrated the smaller transversal distances and higher palatal surface in children with UCL (LO et al., 2003). For example, the study of Fernandes et al. (2015) found 26.49 mm and 28.31 mm (C – C´); 32.98 mm and 35 mm (T – T´) respectively for the groups UCL and UCLP. These data confirm that the cleft amplitude and the intrinsic lack of tissue affects the dimensions of the individuals with UCLP.

In this present study, after the cheiloplasty, the values of the distances C – C´, I – CC`, I - TT' and the area of group UCLP were still lower than those of the group UCL. The post-cheiloplasty transversal narrowing of children with UCLP (compared with children with UCL) was observed by Honda et al. (1995) at complete deciduous dentition. The authors found a significant reduction of the measurements of the anterior portion of the palate compared with children with UCL, although the total length was higher in group UCLP, even when the children with CLP underwent one-stage Wardill-Kilner push-back palatoplasty at 2 years of age.

It is difficult to compare the results of different studies because of different study methodologies, treatment protocols, and follow-up. These factors should be carefully analysed (BRAUMANN et al., 2003). The literature fails to point out which primary surgical technique and surgical period would cause more restrictive effects on the development of the maxillary arch. In fact, there are few studies that only measure the effects of operative procedures, considering the diversity of techniques and surgical times (HUANG et al., 2002; XU et al., 2015; CARRARA et al., 2016; TOME et al., 2016).

The face analysis of the cleft types reveals that all types are influenced by the cheiloplasty, but exhibits the most evident morphological problem (DADÁKOVÁ et al., 2016). The longitudinal study of Huang et al. (2002) clearly pointed out the growth inhibition of the anterior portion of the palate after cheiloplasty, proved by linear and angular measurements. The continuous pressure exerted by the tissue reconstruction over the dental arch explains this result (HUANG et al., 2002). Capelozza Filho et al. (1996) and Li et al. (2006) suggested that the cheiloplasty is the main responsible factor for inhibiting the maxillary growth in individuals with cleft lip and palate based on the cephalometric results.

Some authors demonstrated that the palatoplasty caused different consequences on the three-dimensional development of the maxilla. Carrara et al. (2016) demonstrated that one-stage technique had higher values of total arch length than two-stage technique, one year after palatoplasty. Although others authors affirmed that the difference in growth does not exist (TOME et al., 2016). In 2015, Xu et al. concluded that regardless of the number of surgical phases, the palatoplasty can inhibit the sagittal growth of the maxilla. The results of this present study did not support this influence.

This present study design aimed to avoid bias by selecting only children submitted to 1) cheiloplasty by Millard's technique (both groups), as of 3 months of age; 2) one-step palatoplasty (group UCLP), as of 12 months of age, performed by experienced plastic surgeries with and following the rehabilitation protocol of the institution.

Clinical relevance

The dental documentation of children through dental casts is important for the diagnosis and evaluation of their intrinsic features without the action of saliva and soft tissues and enable to follow-up the early development and growth of the dental arches. The measurements obtained from these dental casts play a relevant role in the pre-operative planning, execution of surgeries, and following-up of the rehabilitative protocol of cleft lip and palate, both in the clinical and scientific research setting.

According to the analyses of this present study results, further anthropometric studies using digital images are necessary to evaluate the rehabilitation protocols aiming to improve the clinical practice of the interdisciplinary team, determine new parameters for the rehabilitation process of the individuals with cleft lip and palate, and confirm the results through longer following-up periods to provide favourable quality of life of these children.

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Annexes

ANNEX A – The study was approved by the Institutional Review Board regarding the ethical aspects.

HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS DA USP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação longitudinal 3D dos arcos dentários de pacientes com fissura labiopalatina unilateral

Pesquisador: Eloá Cristina Passucci Ambrosio

Área Temática:

Versão: 2

CAAE: 48123315.4.0000.5441

Instituição Proponente: Hospital de Reabilitação de Anomalias Craniofaciais da USP

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.255.891

Apresentação do Projeto:

O projeto de pesquisa com o título:" Avaliação longitudinal 3D dos arcos dentários de pacientes com fissura labiopalatina unilateral",da pesquisador responsável Eloá Cristina Passucci Ambrosio,retorna a este comitê para responder as pendências recebidas quando de sua primeira apresentação.A amostra será composta por 210 modelos digitais de 60 pacientes com fissura labiopalatina divididos em 2 grupos: 30 crianças com fissura completa de lábio unilateral (Grupo 1) e 30 crianças com fissura completa de lábio e palato unilateral (Grupo 2), obtidos nas fases de pré-queiloplastia (Fase 1), pré-palatoplastia (Fase 2), 1 ano pós-palatoplastia (Fase 3) e aos 5 anos de idade (Fase 4).Serão realizadas algumas medidas nos modelos de gesso que serão escaneados,estas medidas serão analisadas por um avaliador e posteriormente receberão tratamento estatístico.

Objetivo da Pesquisa:

O propósito deste trabalho será uma avaliação longitudinal das alterações das dimensões dos arcos dentários de crianças com fissura labiopalatina completa de lábio unilateral e completa de lábio e palato unilateral, antes e após as cirurgias plásticas primárias.

Avaliação dos Riscos e Benefícios:

RISCOS:Não se aplica, pois serão utilizados dados secundários.

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Continuação do Parecer: 1.255.891

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 tenra infância. Isso contribui na melhora do tratamento para cada tipo de fissura.

Comentários e Considerações sobre a Pesquisa:

A pesquisadora respondeu as pendências conforme segue abaixo:

1.No item "Avaliação dos Riscos e Benefícios" o risco, foi modificado para "não se aplica",pois serão utilizados dados secundários.

2.Com relação ao número da amostra a pesquisadora padronizou em 210 modelos digitais de 60 pacientes anexando uma tabela com os grupos e as fases das moldagens.

3.O cronograma da pesquisa foi refeito conforme solicitado.

Considerações sobre os Termos de apresentação obrigatória:

A pesquisadora anexou os seguintes termos:

1. Carta de encaminhamento dos pesquisadores aos CEP
2. Formulário HRAC
3. Folha de rosto (CONEP)
4. Projeto de pesquisa em português
5. Orçamento detalhado
6. Termo de compromisso de manuseio de informações
7. Termo de compromisso de tornar públicos os resultados da pesquisa e destinação de materiais ou dados coletados
8. Termo de compromisso do pesquisador responsável

Recomendações:

Não se aplica.

Conclusões ou Pendências e Lista de Inadequações:

Uma vez que a pesquisadora respondeu as pendências que foram anteriormente apontadas e o projeto não apresenta envolvimento ético,com relação ao participante da pesquisa,recomendo sua aprovação por este colegiado.

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

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Continuação do Parecer: 1.255.891

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
Outros	RespostaOficioEloa.pdf	22/09/2015 15:49:13	Silvia Maria Graziadei	Aceito
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_568745.pdf	04/09/2015 22:16:32		Aceito
Outros	Oficio_de_resposta_Eloa_02_09_2015.pdf	04/09/2015 20:18:54	Eloá Cristina Passucci Ambrosio	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Modelos_corrigido_Eloa_02_09_2015.doc	02/09/2015 13:31:20	Eloá Cristina Passucci Ambrosio	Aceito
Outros	Lista de checagem Plataforma Brasil - Eloá - Protocolo 84-2015.pdf	11/08/2015 17:03:26		Aceito
Projeto Detalhado / Brochura Investigador	Projeto Modelos - Eloá 30_06_2015.doc	11/08/2015 10:11:33		Aceito
Outros	Eloa_Termo de compromisso do pesquisador.pdf	11/08/2015 10:11:02		Aceito
Outros	Eloa_Termo de compromisso de tornar publico.pdf	11/08/2015 10:10:34		Aceito
Outros	Eloa_Formulario HRAC.pdf	11/08/2015 10:10:01		Aceito
Outros	Eloa_Carta de encaminhamento.pdf	11/08/2015 10:09:27		Aceito
Folha de Rosto	Eloa_Folha de Rosto.pdf	11/08/2015 10:07:37		Aceito
Declaração de Instituição e Infraestrutura	Eloa_Termo de compromisso de manuseio de informacoes.pdf	11/08/2015 09:53:33		Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

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HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS DA USP

Continuação do Parecer: 1.255.891

BAURU, 02 de Outubro de 2015

Assinado por:
Silvia Maria Graziadei
(Coordenador)

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ANNEX B – Normality test (Shapiro Wilk)

Group UCL

Variables	T1 (P)	T2 (P)
C - C’	0.852	0.205
T - T’	0.759	0.813
I-CC	0.121	0.835
I-TT	0.199	0.139
Area	0.277	0.029*

*The variable does not present normal distribution.

Variables	T2 – T1 (P)
C - C’	0.060
T - T’	0.495
I-CC	0.408
I-TT	0.542
Area	0.945

Age	T1 (P)	T2 (P)	T2 – T1 (P)
	0*	0.046*	0.001*

* The variable does not present normal distribution.

Group UCLP

Variables	T1 (P)	T2 (P)	T3 (P)
C - C’	0.856	0.652	0.850
T - T’	0.163	0.307	0.252
I-CC	0.770	0.196	0.855
I-TT	0.123	0.250	0.554
Area m	0.681	0.737	-
Area M	0.541	0.217	-
Area c	0.344	0.334	-
Area	0.465	0.471	0.840

Variables	T2 – T1 (P)
C - C’	0.251
T - T’	0.820
I-CC	0.192
I-TT	0.657
Area	0.970

Age	T1 (P)	T2 (P)	T3 (P)	T2 – T1 (P)
	0.0001*	0*	0.0036*	0*

* The variable does not present normal distribution.

Intraexaminer error

Group UCL

Variables	1st Measurement (P)	2nd Measurement (P)
T1		
C - C’	0.117	0.394
T - T’	0.988	0.993
I-CC	0.007*	0.040*
I-TT	0.791	0.655
Area	0.034*	0.016*
T2		
C - C’	0.690	0.891
T - T’	0.301	0.084
I-CC	0.324	0.211
I-TT	0.820	0.891
Area	0.383	0.116

* The variable does not present normal distribution.

Group UCLP

Variables	1st Measurement (P)	2nd Measurement (P)
T1		
C - C’	0.735	0.691
T - T’	0.363	0.537
I-CC	0.889	0.959
I-TT	0.386	0.630
Area	0.902	0.776
T2	0.203	0.151
C - C’		
T - T’	0.950	0.665
I-CC	0.494	0.671
I-TT	0.781	0.854
Area	0.770	0.447
T3	0.346	0.339
C - C’		
T - T’	0.629	0.694
I-CC	0.705	0.310
I-TT	0.808	0.674
Area	0.506	0.884