UNIVERSIDADE DE SÃO PAULO

HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

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Morphology and dimensions of maxillary dental arch in individuals with bilateral cleft lip and palate: evaluation of the influence of primary plastic surgeries

Morfologia e dimensões do arco dentário superior em indivíduos com fissura transforame incisivo bilateral: avaliação da influência das cirurgias plásticas primárias

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

Orientador: Drª. Gisele da Silva Dalben.

BAURU

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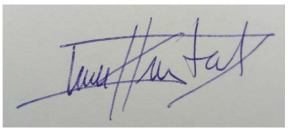

Huayta-Aguirre, Ingrid Ivanna

Morphology and dimensions of maxillary dental arch in individuals with bilateral cleft lip and palate: evaluation of the influence of primary plastic surgeries / Ingrid Ivanna Huayta Aguirre – Bauru, 2019.
117p. : il. ; 30 cm.

Dissertação (Mestrado - Área de concentração Fissuras Orofaciais e Anomalias Relacionadas) – Hospital de Reabilitação de Anomalias Craniofaciais.

Orientadora: Drª. Gisele da Siva Dalben.

Comitê de Ética HRAC-USP
Protocolo n”: 93459618.4.0000.5441
Data: 02 de agosto de 2018

FOLHA DE APROVAÇÃO

Ingrid Ivanna Huayta Aguirre

Dissertação apresentada ao Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo para a obtenção do título de Mestre.
Área de Concentração: Fissuras Orofaciais e Anomalias Relacionadas

Aprovado em:

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____

Prof.(a) Dr.(a)

Instituição (Orientador)

____

Prof.(a) Dr.(a)

Presidente da Comissão de Pós-Graduação do HRAC-USP

Data de depósito da dissertação junto à SPG: ___/___/ ____

DEDICATÓRIA

A mi familia…ciertamente nunca me alejé de su seno.

AGRADECIMENTOS

A mi familia: mis padres, Fernando, Cristian y Andrés, por todo el cariño y el apoyo otorgado desde siempre. Creyeron en mi incluso cuando yo no lo hacía, mi deuda con ustedes es inmensa, así como el cariño que les tengo a cada uno.

A la Dra. Gisele da Silva Dalben, quien es sin duda una de las personas que más he admirado, le agradezco inmensamente que me haya acogido bajo su ala y guiado en esta experiencia única de la investigación científica. Usted es un ejemplo a seguir del tipo de mujer que quiero convertirme.

A la Dra. Daniela Gamba Garib y Dra. Terumi Okada Ozawa, por todo el apoyo, paciencia y abrazo reconfortante. Mujeres inalcanzables, pero al mismo tiempo capaces de compartir una sonrisa y hacerte sentir la calidez de una amiga.

Al Dr. Adriano Porto Peixoto, por haberme guiado en cada paso rumbo a la maestría y haber respondido hasta a la más tonta de mis preguntas. El apoyo que me mostró desde el comienzo me dio el valor necesario para esta nueva aventura.

A mi querida colega y amiga Leticia de Almedia Prestes, no sabría como agradecerte por cada cosa que hiciste por mí y todo lo que me enseñaste. Me abriste tu casa y me permitiste sentirme parte de tu familia cuando yo sentía la falta de la mía, no imaginas la magnitud de la marca que dejaste en mi vida. Siempre estaré en deuda, sin ti talvez no lo habría logrado.

A Erika, Renata, Mariana y Carolina, mis compañeras de curso y colegas con quienes me formé como ortodoncista primero y con quienes pude disfrutar otros dos años de aprendizaje y amistad que sé que perdurarán para siempre.

A todos los orientadores, profesionales y auxiliares del sector de Ortodoncia del HRAC-USP por haber hecho de mis primeros años en el hospital tan reconfortantes que hicieron que me quede más tiempo del planeado. Aprendí tanto de cada uno, que es difícil verme como ortodoncista sin sentir tenerlos en mi pensamiento.

A los residentes de Ortodoncia y Odontopediatria por haberme ayudado a desarrollar esta investigación y por cada muestra de empatía y amistad.

A las profesionales del sector de Odontopediatría, por toda la paciencia y estar dispuestas a ayudar en cada etapa de este proyecto.

A los funcionarios del laboratorio de Ortodoncia, por todas lo que me enseñaron y por cada risa emotiva compartida, realmente son insuperables.

A mis compatriotas estudiando en la misma casa de estudio, en especial a Eymi, quienes me hicieron sentir de nuevo en mi tierra en los momentos compartidos.

A los funcionarios de la Sección de Posgraduación, por siempre estar dispuestas a ayudar y todo el cariño mostrado.

Al HRAC-USP y los pacientes de esta institución, por haberme otorgado la oportunidad de realizar este proyecto.

A este hermoso país Brasil, que voy queriendo cada día más y al cual siempre volveré, porque me dio grandes amigos, experiencias y oportunidades.

Finalmente, a todos quienes de forma directa o indirecta contribuiron para la realización de este trabajo.

RESUMO

RESUMO

Huayta-Aguirre II. Morfologia e dimensões do arco dentário superior em indivíduos com fissura transforame incisivo bilateral: avaliação da influência das cirurgias plásticas primárias (dissertação). Bauru: Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo; 2019.

A fissura transforame incisivo bilateral (FTIB) pode ser considerada a mais severa das fissuras labiopalatinas devido às implicações estéticas e funcionais que acarreta. O processo reabilitador é árduo desde o início, pois a pré-maxilla muito projetada é uma caraterística importante neste tipo de fissura e dificulta o desenvolvimento das primeiras intervenções cirúrgicas, as mesmas que podem influenciar negativamente o desenvolvimento maxilar. O objetivo deste estudo foi avaliar a influência das cirurgias plásticas (queiloplastia e palatoplastia) no desenvolvimento dos segmentos maxilares em crianças com fissura transforme incisivo bilateral. Este estudo retrospectivo longitudinal observacional foi conduzido no Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo, Bauru, Brasil. Foram utilizados modelos dentários digitalizados em dois tempos, o primeiro antes das cirurgias primárias (T0) e o segundo a partir dos 5 anos (T1). Os modelos dentários digitalizados foram analisados em um software para obtenção de medidas angulares e lineares. Foram aplicados na análise estatística o teste t, teste de Mann-Whitney e teste de correlação de Spearman. Houve mudanças significativas nos modelos dentários no T1 que evidenciam a influência das cirurgias primárias no desenvolvimento maxilar. A estrutura mais afeitada foi a prémaxila, e o seu retroposicionamento agravou o colapso dentário anterior. O desenvolvimento maxilar e da pré-maxila são altamente suscetíveis às cirurgias primárias realizadas no indivíduo com FTIB.

Descritores: fissura labial, fissura palatina, modelo dentário.

ABSTRACT

ABSTRACT

Huayta-Aguirre II. Morphology and dimensions of maxillary dental arch in individuals with bilateral cleft lip and palate: evaluation of the influence of primary plastic surgeries (dissertação). Bauru: Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo; 2019.

Bilateral cleft lip and palate (BCLP) can be considered the most severe of cleft lip and palate (CLP) anomalies, due to its esthetic and functional implications. The rehabilitation process is arduous from the beginning because of the marked forward premaxilla projection, which is an important characteristic in this type of CLP and increases the difficulty of initial surgical procedures. These plastic surgeries can negatively influence the maxillary development. The objective of this study was to evaluate the influence of plastic surgeries (lip and palate repair) on the development of maxillary segments in children with BCLP. This longitudinal observational retrospective study was conducted at the Hospital for Rehabilitation of Craniofacial Anomalies of University of Sao Paulo, Bauru, Brazil. Dental casts were obtained in two times, the first before primary plastic surgeries (T0) and the second after 5 years of age (T1) in the same individual. The scanned dental models were analyzed on a software to obtain angular and linear measurements. The t-test, Mann-Whitney test and Spearman´s correlation test were applied for statistical analysis. There were significant changes in dental casts in T1 that evidenced the influence of primary plastic surgeries on maxillary development. The most affected structure was the premaxilla, and its retropositioning worsened the anterior dental arch collapse. The maxillary and premaxillary development are highly susceptible to primary surgeries performed on the individual with BCLP.

Key words: cleft lip, cleft palate, dental cast.

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1 INTRODUCTION

1 INTRODUCTION

Cleft lip and palate represent one of the most frequent craniofacial anomalies that affect the human being, and complete bilateral clefts have been considered the most complex and difficult to treat (FREITAS, J.A et al., 2012). Due to involvement of the middle facial third, functional alterations also occur, and esthetics is highly impaired, especially by the extreme projection of the premaxilla, anterior lip and nasal columella deficiency (BERTIER, 2007). There are several treatment protocols for patients with bilateral cleft lip and palate (BCLP), beginning with primary plastic surgeries. From an early age, the rehabilitation team faces the challenge of premaxilla projection. Because of this, many centers have begun to use three types of alternative therapies prior to primary surgeries to reduce the premaxillary projection. Among these, preoperative premaxilla and presurgical orthopedic repositioning and repositioning of the premaxilla are the most reported in the literature (BERTIER, 2007), but with unpredictable and even damaging results for craniofacial development (BITTERMANN et al. al., 2016).

The Hospital for Rehabilitation of Craniofacial Anomalies of University of São Paulo (HRAC-USP) adopts a conservative protocol that avoids the use of other alternative therapies to reduce the anterior premaxilla projection, since the literature shows that primary surgeries *per se* restrict maxillary growth in their transverse and sagittal dimensions when compared to the normal pattern (DA SILVA FILHO et al., 2003). In addition, the premaxilla projection gradually decreases after lip repair, thus early alternative therapies for its repositioning may not be necessary (SILVA FILHO O.G. 2007). The Spina technique is usually employed at HRAC/USP, in which bilateral lip repair for bilateral cleft can be performed on both sides in a surgical time; or in two periods, closing one side at a time (BERTIER, 2007). Despite the existence of numerous surgical techniques, no consensus regarding the best technique or timing has been reached. However, one-stage lip repair is more adopted for providing more symmetric results (CHUNG, 2018).

The follow-up of postoperative results after primary surgeries and their correlation with the condition prior to primary surgery are relevant to evaluate the rehabilitation protocol for cases with specific clinical conditions (arch size, premaxilla projection, cleft, etc.). In addition, analysis of the transverse and sagittal dimensions of the alveolar arch with their variations and also deviation and projection of the premaxilla could help objectively in the choice of surgical technique and as a predictor of prognosis. For this purpose, digital casts are widely used for maxillary evaluation in cleft and non-cleft individuals since early childhood. The absence of teeth in dental casts at this age can raise doubts about the accuracy of positioning of reference points; however, the reproducibility of these points has been studied (SECKEL et al., 1995; WUTZL et al., 2009) with positive results in children with cleft lip and palate.

The prevalence of Simonart's band in BCLP seems to be higher than observed in individuals with unilateral cleft lip and palate (UCLP) (Silva Filho et al., 2006). However, only studies on UCLP have been conducted showing the mild positive influence of this soft tissue bridge on the facial pattern in adulthood (Semb et al., 1991). Silva Filho (1992) evaluated unoperated CLP individuals and observed that this band provided a more favorable anterior maxillary morphology, reducing the anterior projection of the noncleft segment. The presence of a more favorable maxillary morphology with reduced segmental displacement allows a less traumatic lip repair and the need of secondary surgeries (Semb et al., 1991). However, no studies have evaluated this influence in individuals with BCLP, as well as maxillary development after primary surgery and without preoperative functional orthopedics and with longitudinal or short-term postoperative follow-up.

The aim of this retrospective study was to evaluate the characteristics of maxillary development in individuals with BCLP, considering the influence of lip and palate repair. The study also analyzed the correlation between dental cast digital measurements for individuals in T1 and the age at which surgeries were performed, as well as the influence of Simonart's band on maxillary growth and the accomplishment of a third surgery.

2 Objectives

2 OBJECTIVES

To evaluate the influence of lip and palate surgery on maxillary growth of individuals with bilateral cleft lip and palate on digitized dental casts, obtained from the archives of HRAC/USP, before any surgery and after five or nine years of development.

Overall objective

To evaluate the influence of reconstructive surgeries (lip and palate repair) on the development of maxillary segments in children with bilateral cleft lip and palate, by analysis of digital dental casts obtained before primary surgeries (T0) and between 5 and 9 years of age (T1), before orthodontic treatment.

Specific objectives

1- To measure and compare the maxillary transverse, sagittal and vertical dimensions in T0, T1 and the T0/T1 difference.
2- To correlate dental cast digital measurements for individuals in T1 and the age at which surgeries were performed, as well as the age at which the T1 dental cast was obtained.
3- To evaluate the Simonart's band influence on maxillary dimension in T0, T1 and the T0/T1 difference.
4- To evaluate the influence of a third surgery on the maxillary dimensions in T1 and the T0/T1 difference

Hypothesis (H0):

1. Primary surgeries in individuals with bilateral cleft lip and palate do not redirect the maxillary and premaxillary growth.

3 Article

3.1 ARTICLE 1

Article 1 presented in this Dissertation was written according to The Journal of Craniofacial Surgery instructions and guidelines for article submission.

Manuscript title: Morphology and dimensions of maxillary dental arch in individuals with bilateral cleft lip and palate: influence of primary plastic surgeries

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Abstract:

Introduction: The purpose of this study was to evaluate the characteristics of maxillary development in individuals with bilateral cleft lip and palate considering the influence of lip and palate repair, as well as the correlation between the age at which surgeries were performed and the final dental cast measurements.

Methods: A total of 41 individuals with bilateral cleft lip and palate treated at the same institution were evaluated in two times: prior to surgical intervention and in the mixed dentition using 3-dimensional digital dental casts. The angular and linear digital measurements were analyzed and compared using T tests and Spearman Correlation test for relation analysis.

Results: Statistical differences between T0 and T1 were found in 13 of 14 measurements analyzed ($p<0.05$), all demonstrating pronounced differences ($p<0.01$). Maxillary posterior transverse development was positive, as opposed to the anterior transverse and sagittal development that was highly reduced after surgeries, due to the premaxillary retropositioning that also affected the vertical plane. The premaxilla was centralized, and no direct growth influence was detected in its area evaluation. Low positive and moderate negative correlation with statistical relevance ($p<0.05$) was found in 11 from 112 correlation coefficients.

Conclusions: The restorative surgeries (cheiloplasty and palatoplasty) had a great influence on maxillary development, especially in the anterior region due to premaxilla retropositioning. There was correlation between the age at first surgery and some maxillary characteristics after surgical intervention.

Key words: cleft lip, cleft palate, reconstructive surgical procedures, maxilla.

Introduction:

Among the different types of cleft lip and palate (CLP), the bilateral presentation is considered the most complex and difficult to treat[1] and results in significant esthetic and functional problems. The maxilla is segmented into three parts, independent of each other, usually with projection of the premaxilla[2,3], which constitutes a challenge for the rehabilitation team. This maxillary presentation at birth increases the need for surgical and non-surgical interventions throughout the rehabilitation process[4]. In this process, the first surgical interventions performed on the individual with bilateral cleft lip and palate (BCLP) may cause alterations in facial growth[5,6], mainly in the middle facial third[7]. These primary surgeries approximate the three bone segments, leading to premaxillary retropositioning, reduction in the upper dental arch length, and worsening the approximation of palatal processes[7,8,9].The maxillary growth restriction and its consequences should be managed by a team of specialists in the field[1] for a long period of time, which makes the rehabilitation more expensive and increases the burden of care[10].

In order to avoid the maxillary growth restriction and allow handling of the premaxilla, many surgical techniques have been developed as well as other non-surgical interventions like pre-surgical infant orthopedics (PSIO). Concerning plastic reconstruction, the BCLP repair is considered by Zhang et al[3] as "half as common and twice as difficult as unilateral cleft lip repair", not only by the variable presentations of the anomaly (size, shape and position of the maxilla segments), but also due to tissue deficiency and intrinsic growth potential[5]. Despite the existence of numerous surgical techniques, no consensus regarding the best technique or timing has been reached. However, one-stage lip repair is more adopted for providing better results with regard to achieving a more symmetric result[11]. PSIO and its long-term effects on maxillary development are still controversial[12,13] and is not part of all rehabilitation protocols around the world. like the HRAC-USP protocol[1].

Digital dental casts are widely used to evaluate the maxillary development in cleft and non-cleft individuals. For this purpose, several measurements are used to identify and compare changes in the three planes of space of dental casts obtained since the early childhood. The absence of teeth in dental casts at this age raise doubt about the accuracy of reference points positioning; however, the reproducibility of these points has been studied[14,15] with positive results in CLP children.

The literature addressing the maxillary morphology in BCLP shows significantly narrowed anterior arch width, anterior shorter arch depth and wider posterior arch width in 4 years old[8]. Honda et al[5] suggested that the prominent premaxilla in BCLP can be set back by pressure from the reconstructed lip. However, this evaluation on individuals with BCLP has been studied on the use of PSIO devices before primary surgeries, and no interrelation between time of surgery and maxillary development was studied. The aim of this retrospective study was to evaluate the characteristics of maxillary development in individuals with BCLP considering the influence of lip and palate repair. The study also analyzed the existence of correlation between the dental cast digital measurements for individuals in T1 and the age at which the surgeries were performed. For this purpose, digital dental casts of children with BCLP were evaluated before any surgical intervention and after 5 years of age, before any orthodontic-orthopedic treatment.

Materials e methods:

This retrospective study was conducted at the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo (HRAC-USP), Bauru, Brazil. The study was approved by the Institutional Review Board, according to the Brazilian Health Ministry no. 196/96 resolution.

The sample was selected from the files of HRAC-USP, encompassing records of individuals with BCLP of both genders, for whom initial digital dental casts (prior to primary surgeries) and after 5 years old (according to the institutional protocol) were available.

Individuals with clinical diagnosis of BCLP with available dental casts prior to surgeries (T0) were first identified by a search on the Pediatric Dentistry database, to retrieve the number of individuals with available records.

The inclusion criteria were: individuals born between 2010 e 2013, both genders, regularly registered and undergoing surgical rehabilitation treatment performed entirely at HRAC-USP, individuals with dental casts obtained between 5 and 9 years old (T1), casts scanned using the 3D scanner (3Shape's R700TM Scanner, 3Shape, Copenhagen, Denmark) and 3D digital models available in the digital files of the institution. Individuals submitted to any orthodontic or orthopedic therapy between the two dental casts or with associated syndromes were excluded from the study.

The reconstructed images were analyzed using OrthoAnalyzer Softtware 3D Software (Copenhagen, Denmark) and the maxillary measurements were performed on sagittal, vertical and horizontal planes directly on the scanned images according to Seckel et al[14] and Durwald et al[16] (Figure 1, 2 and 3). A total of 28 measurements per individual were identified and compared between T0 and T1 for identification of maxillary growth development, considering the influence of lip and palate repair. The study also analyzed the correlation between dental casts digital measurements for individuals in T1 and the age at which the surgeries were performed.

Pilot Study and Error Analysis

All evaluation and measurements were performed by a single investigator. For sample calculation, a pilot study was performed on 10 individuals randomly selected from a previous data collection composed of 17 individuals who met the inclusion criteria. For error analysis, the evaluations of individuals in the pilot study were performed in T0 and T1 twice at 15-day intervals to determine the reliability of the method. The random error was calculated by intraclass correlation coefficient.

Statistical Analysis

The t test was applied for variables that passed the normality test and the Mann-Whitney test for those that did not. Statistical evaluation of digital dental casts values between T0 and T1 was performed using parametric and non-parametric tests. The results were compared by the t test, Mann-Whitney test and Spearman correlation. Statistica software (Statistica for Windows – version 7.0 – Statsoft) was used for statistical analysis. Statistical significance was set at $P < 0.05$.

Results:

The study included 41 individuals (10 female, 31 male) with mean age 4 months at T0 and 6 years and 6 months at T1 (Table 1) with digital casts available from the files of HRAC-USP (Figure 4). All 41 individuals underwent bilateral lip repair (one-stage), especially by the Spina technique, and labial adhesion at mean age 4 months (according to HRAC-USP protocol, the first dental cast is obtained two days before surgery). The second surgery was a total palate repair in 28 individuals and anterior palate repair in 13, the main techniques used were Hans Pichler and Von Langenbeck, at a mean age of 1 year and 5 months. The third surgery, at mean age of 3 years, was performed only in 26 individuals, including 4 secondary lip repair, 13 posterior palate repair and 9 tertiary palate repair to treat palatal fistula. The surgeries were performed by 7 experienced surgeons of HRAC-USP. From the study sample, 13 had Simonart's band, being 5 bilateral, 6 on the left side and 2 on the right side.

The angular and linear dental cast digital measurements for individuals in T0/T1 and the statistical difference between them are shown in Table 2. The intraclass correlation coefficient was evaluated in T0 and T1 measurements, with a 0.98 correlation in both times. Statistical differences between T0 and T1 were found in 13 of 14 measurements analyzed ($p<0.05$), all demonstrating pronounced differences ($p<0.01$). Maxillary posterior transverse measurement (TT´) was longer in T1 than observed in T0, contrary to the anterior transverse measurement (CC´). Sagittal measurements (I-CC´/I-TT´/APm-TT´) showed smaller maxillary length in T1. Cleft alveolar (PL/P'L') and cleft palatal amplitude were also significantly smaller in T1. Concerning the premaxillary deviation, one angular and two linear measurements were made; linear measurements showed a slight tendency to premaxillary left deviation in T0 opposite to T1 results, nevertheless both linear means were shorter in T1 than those observed in T0. Angular premaxillary deviation also showed premaxillary left deviation in T0 and right deviation in T1, yet without statistical difference. The premaxilla extrusion was also measured, in relation to a modified occlusal plane, evidencing intrusion in T0 and extrusion in T1. Finally, the premaxillary area was compared in T0 and T1, showing an increase in measurements in T1.

The correlation between angular and linear dental casts digital measurements for individuals in T1 group and the age at which surgeries were performed was performed by the Spearman Correlation test. Besides T1, measurement of the difference between T0 and T1 was also analyzed. From a total of 112 measurements, only 11 presented statistical relevance ($p<0.05$); with low positive correlation coefficient in 3 measurements and moderate negative correlation in the other 8 (Table 3). No relevant correlation was found for the second and third surgery, thereby they were not considered further. According to these results, the older the age at first surgery, the greater the posterior transverse, left alveolar cleft width and premaxilla left deviation in T1. Maxillary length decreased as age progressed in T1 and in T0/T1 difference measurements. The premaxilla area was negatively influenced by the age at first surgery, and decreased as the age at surgery increased. Another moderate negative correlation showed that the premaxilla was more extruded when the first surgery was performed earlier and more deviated to the left.

Data from this paper indicate that significant differences in maxillary development are present in individuals with BCLP submitted to lip and palate repair (Figure 5).

Discussion:

Dimensional changes in the maxillary arch in individuals with BCLP were evaluated from infancy up to 5 to 8 years of age and related only to the primary surgical interventions. The maxillary posterior transverse development was positive, contrary to anterior transverse and sagittal development, which was markedly reduced after the surgical interventions. All sagittal measurements showed smaller maxillary length at 5 to 8 years old due to premaxilla retropositioning, which was also evident in the vertical plane, in which it was extruded. The premaxilla had a slight tendency to left deviation at onset, and right deviation was found after the primary surgeries. Additionally, the premaxillary area was increased and all cleft widths (two alveolar and two palatal) decreased up to the final evaluation. The age at first surgery can also influence some dimensional changes; some initial characteristics (posterior transverse and left alveolar cleft width/premaxilla intrusion and left deviation) can be maintained after the primary surgeries if they are performed in an older individual. Also, as years go by, the maxillary sagittal development decreases in individuals with BCLP after lip and palate repair. Finally, the premaxilla area decreases as the age at the first surgery increases.

Considering that BCLP accounts for 13% to 20% of all individuals with non-syndromic CLP[17,18], it is understandable that there is low number of studies with a significant sample of more than 30 individuals in growth studies compared to UCLP. Moreover, longitudinal dental cast studies with follow-up of at least 4 years evaluating the same individual in more than two moments are even scarcer[8]. Our study included 41 subjects being 31 males and 10 females, agreeing with the high CLP male prevalence in the literature[1,17,18]. To evaluate the maxillary growth, dental casts were obtained at mean ages of 4 months and 6.6 years. The infancy and early childhood are considered to have the greatest postnatal growth change[4]; maxillary growth changes occurring between 0.5 and 5 years of age were greater than those occurring between 5 and 16 years according to Laowansiri et al [19]. This age is also favorable for maxillary growth evaluation considering the influence of primary surgeries, because orthodontic/orthopedic active treatment usually begins later[20] and might alter the actual maxillary development in BCLP. PSIO is not part of HRAC-USP protocol due to the absence of significant effects on facial esthetics, maxillary dentoalveolar variables and dental arch relationships[13,21] as shown so far. Therefore, no individuals in this study underwent any type of PSIO therapy before or between surgical procedures.

Transverse plane

Consistent with published studies[5,8,24], the present results showed narrowed anterior arch width (CC´) (mean 5.33 mm of T0-T1 difference) and wider posterior arch width (TT´) at 6.6 years old compared with measurements at 4 months of age. Although the studies of Heidbuchel[8] and Honda[5] were conducted on individuals up to 4 years and with the use of PSIO, the transverse results were similar. The first dental cast TT´ measurement prior to lip repair in the study by Honda[5] was more similar to the present than the study of Heidbuchel et al, probably because the Honda team used only extraoral strapping before lip repair, which can have a greater impact on sagittal than transverse development. The initial posterior arch width in the study of Heidbuchel was 3 mm shorter than our findings, and in comparison with a non-cleft control group displayed a greater initial maxillary width. Other studies[22,23] support the fact that the BCLP maxillary arch at birth is bigger in transverse and sagittal planes compared with non-cleft individuals, and that the influence of lip repair on anterior maxillary arch development is undeniable and can be greater than the influence of palate repair[6,7]. The larger posterior arch width and narrower anterior arch width after primary surgeries was evident in the present sample (total palate repair=28 subjects; two-stage palate repair, hard palate first=13 subjects and one-stage lip repair), in the studies of Heidbuchel[8] (twostage palate repair, soft palate first and one-stage lip repair) and Honda[5] (one-stage palate repair and lip repair) despite the surgical technique used and previous PSIO intervention. Therefore, the anterior collapse of the lateral segments in BCLP is not related to the width of the posterior dental arch, as suggested by Krey[24]. The age at surgery can also play an important role in maxillary transverse development. To date, there is still great controversy between the ideal surgical timing (especially for palate repair), maxillary growth and speech development[25,26]. The present study showed positive correlation between first surgery (lip repair) and posterior transverse width. Since no other similar correlation was found in the literature, this finding may be mainly due to the age at which all surgical procedures begin, rather than lip repair itself. No other significant correlation between the age at second and third surgeries with transverse coefficients was found.

Sagittal plane

Premaxillary projection can be considered the most significant characteristic in newborns with BCLP[3] and its severity influences the sagittal measurements of maxillary growth. Several studies[15,22,23] comparing arch depth between the different types of CLP before surgical procedures indicated that BCLP individuals have a major arch depth and can be highly influenced by surgical procedures. Our findings showed a mean of 4.93 (anterior arch depth) to 6.85 mm (total arch depth) decrease on sagittal measurements after surgical procedures. Heidbuchel et al[8] sagittal study showed an anterior arch depth decrease in BCLP group compared to a non-cleft group however, it remained larger in BCLP. Also, total arch depth was smaller than the control group and decreased slightly regarding initial measurements in Heidbuchel´s finds. Despite the use of the same reference planes[8,14], one stage cheiloplasty and the use of PSIO with extraoral strapping in Heidbuchel´s[8] sample, the initial sagittal measurements were larger than in this study, possibly believe due to the presence of Simonart’s band in 13 of 41 individuals in our sample. Clinically, individuals with this band presented minor premaxillary projection, especially in bilateral Simonart's bands, that is the case of 5 individuals in our study. The sagittal growth deficiency or premaxilla retropositioning was more severe in our study. The study of Honda[5] found a reduction in anterior arch depth measurement at 4 years old after primary surgeries, in agreement with our study and that of Heidbuchel. Oppositely, a slight increase in total arch depth was found, which can be attributed to a more posterior tuberosity landmark and reference plane. Despite this, all sagittal measurements before and after primary surgeries showed greater arch depth in BCLP compared to UCLP[5]. Besides these differences between T0 and T1, the sagittal measurements were correlated with the age at which the last dental cast was obtained, which revealed a known negative correlation. The maxillary length decreases as age progresses after 5 years old. This was previously widely studied in dental cast evaluation[27] and cephalometric measurements[28] to compare institutional protocols, and studies on non-operated BCLP adults[7] also indicated that adults submitted to lip repair had a reduction in premaxillary anterior projection compared with non-operated individuals. Therefore, this demonstrated the high influence of plastic surgeries on maxillary sagittal development in BCLP.

Premaxilla characteristics

The independent premaxilla and its variety in shape, size and position has been the reason why BCLP management is one of the most challenging. Premaxillary anterior projection and deviation encouraged the development of many surgical[11] and PSIO techniques[13,21] to achieve symmetrical results. For this purpose, initially two-stage lip repair was performed in individuals with severe premaxillary deviation[29]. Currently, one-stage lip repair is widely used, with or without PSIO devices, in all types of of BCLP due to better results[29,30]. This is evident in the preference of HRAC-USP team; in our initial sap,le, 3 of 44 subjects had undergone two-stage lip repair and were excluded from the study to standardize the first surgical technique. The premaxillary deviation was originally measured on the maxillary occlusal view taking the maxilla tuberosity as reference point. The linear measurements indicated a slight tendency of premaxilla deviation to the left side prior to any surgical intervention; however, the presence of a left Simonart's band in 6 of the 41 individuals of the sample could have influenced this result. The influence of a Simonart´s band on the maxillary dimensional changes shall be discussed in a correlated article by our group. The premaxilla fragility is evident after the surgical procedures, since an initial left deviation evolved to a slight right deviation, consequently centralizing the premaxilla as required and planned by the plastic surgeon[29,30]. An angular measurement was developed to evaluate the premaxillary tendency and showed the same findings as the linear measurements, however without statistical difference. Similar dental cast measurements were not found in the literature to compare our findings. There is positive correlation between the age at lip repair and the initial left premaxillary deviation, since its initial characteristics can remain greater if the first surgery is delayed, as described by Silva Filho et al [7].

Vertical plane

The vertical maxillary development in our study was analyzed using an occlusal modified plane described by Durwald et al[16] and Hak et al[31]. Due to the lack of dental references at 4 months of age, this plane uses anatomical references already available in this early dental cast. Since it employs an anterior alveolar point to create the plane, only premaxilla vertical changes can be studied. Our findings initially showed an intruded premaxilla that evolved to an extruded position in relation to the occlusal modified plane, similar to the study of Durwald et al[16]. This change can be more considered as a premaxilla sagittal retropositioning as a consequence of lip repair[2-8] than a real extrusion and shows the great influence of sagittal changes on the vertical plane. As pointed by Krey et al[24], the vertical maxillary development should include evaluation of the lateral segments, since the cleft edges can be more cranial than the premaxilla cleft edges. A moderate negative correlation showed that the premaxilla is more extruded when lip repair is performed earlier.

In order to evaluate the premaxilla growth, its area was measured using the OrthoAnaliser 3D Software and an occlusal modified plane[16,31]. The created plane crossed the entire premaxilla, depending mainly on the premaxilla projection/deviation and dental cast quality (especially in the impression process), and the cross-section software tool allows the premaxilla area measurement. Due to the variability in premaxilla position and to standardize the measurement, the premaxilla area was obtained 4 mm cranially from the plane intersection with the top of the alveolar crest. The same plane and references were used for final dental cast analysis (no classical occlusal plane was used), however with more difficulty in premaxilla location due to anterior arch collapse in most individuals. Our findings showed an increase in premaxilla area measurement, reflecting a positive premaxillary development independent of the surgical interventions. This can also be attributed to the dental development, since individuals at the second analysis were in the mixed dentition stage. No previous studies investigated studied the BCLP premaxillary development after primary surgeries using its area as reference. The volume was used with this purpose in the study of Mooney et al[32], in which the premaxilla length and volume were studied in UCLP and non-cleft individuals in 8 to 21 weeks fetuses, whose findings exhibited significantly reduced premaxillary volume rate changes in the UCLP subjects. CLP studies analyzing area are focused on palatal surface area measurements correlated with the dentoskeletal growth[33]. An unexpected low correlation was found in our study; the premaxilla area was negatively influenced by the first surgery age, thus it decreased as the age at the first surgery (lip repair) increased. No literature support was found to back up this finding and seems contrary to what we recently described, since no negative premaxilla growth was found. This last result should be taken with caution.

Cleft width

The literature suggests that the initial cleft width can influence the maxillary development[34,35]: a wider cleft may generate more scar tissue and affect the maxillary growth; the cleft size can also be related with the palatal area and a reduced area may negatively affect the maxillary growth as well. Our study findings show an almost similar alveolar cleft, being that the right cleft width is slightly bigger and can be related with the tendency of premaxilla left side deviation. The study of Chiu et al[34] study on UCLP, with similar anterior, middle and posterior cleft width measurements, showed that individuals with a small cleft area have a more protruded maxilla at a 9 years old cephalometric evaluation. However, the initial cleft severity cannot be correlated with the outcome in terms of dental arch relationship, as found by Russel et al[36] in a Goslon yardstick evaluation in UCLP mixed dentition subjects.

Conclusion:

The reconstructive surgeries (lip and palate repair) had a great influence on the BCLP maxillary development, especially in the anterior region. Maxillary posterior transverse development was positive, contrary to the anterior transverse relationship that was collapsed. The sagittal and vertical planes can be considered the most affected after surgeries, due to premaxilla retropositioning, worsening the anterior arch collapse. Besides the premaxilla centralization after surgeries, the premaxillary development was positive, as evidenced by its area measurement. However, the premaxilla area decreased as age at the first surgery increased.

Some initial characteristics (posterior transverse and left alveolar cleft width/premaxilla intrusion and left deviation) can be maintained and increased after the primary surgeries if they are performed in an older individual. Also, as years go by, the maxillary sagittal development decreases in BCLP individuals after lip and palate repair. This shows the importance of the age at which surgeries are performed and their influence on maxillary development.

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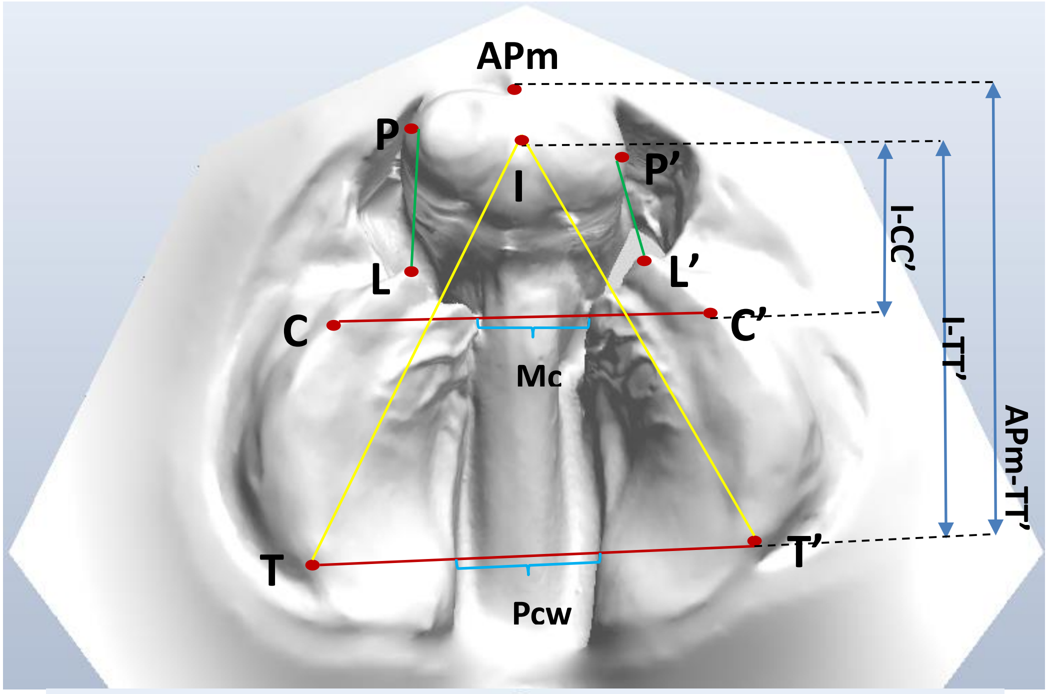
Figures:

FIGURE 1. Reference points used in cast analysis: Point I (incisal point)-point on the top of the alveolar crest where the incisive papilla and labial frenulum meet, or the tip of the interdental papilla between the central incisors. Point C (cuspid point)-where the lateral sulcus crosses the crest of the alveolar ridge, or the tip of the interdental papilla between the deciduous canine and first deciduous molar. Point T (tuberosity point)-posterior limit of the maxillary tuberosity in the sulcus where the pterygomandibular raphe adheres, or the distal point of the second deciduous molar. Point L-most anterior point of the alveolar crest of the lateral segment. Point P- most lateral point of the premaxilla. Point APm-premaxilla anterior and apical point or insertion point of the medial lip frenum. Calculated distances: CC´- intercanine width or maxillary anterior arch width. TT´- intertuberosity width or maxillary posterior arch width. PL-anterior right cleft width. P´L´-anterior left cleft width. TI-right premaxilla deviation. IT´-left premaxilla deviation. Mcw-medium cleft width measured on intercanine distance. Pcw-posterior cleft width measured on intertuberosity distance. I-CC´-anterior arch depth. I-TT´-total arch depth- APm-TT´-premaxilla arch length.


APm
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I-CC’
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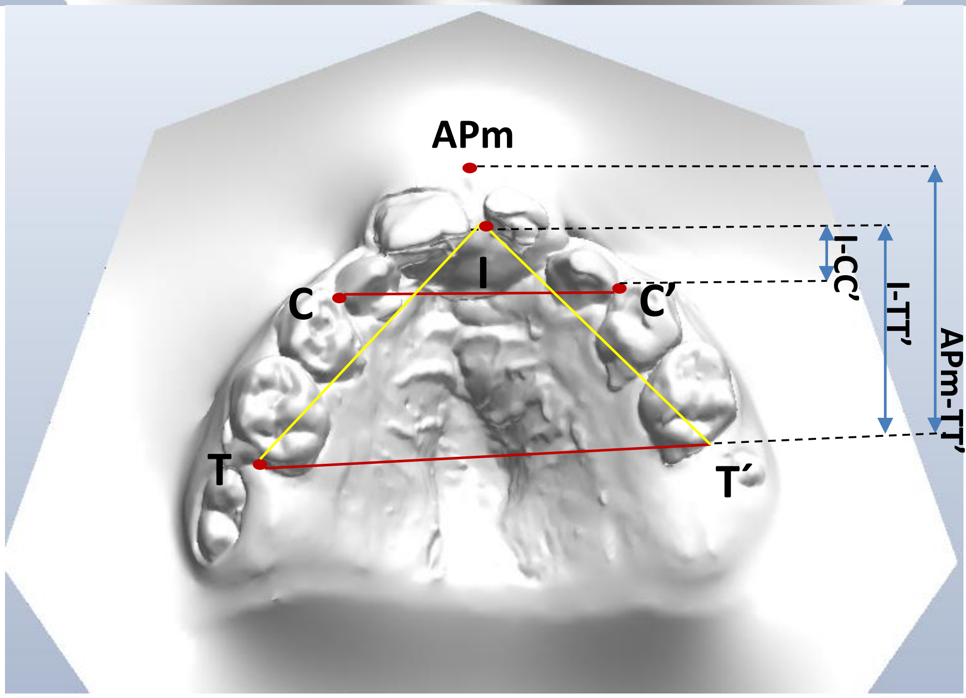
APm
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FIGURE 2. Occlusal and frontal view of the basal plane (TT´C)

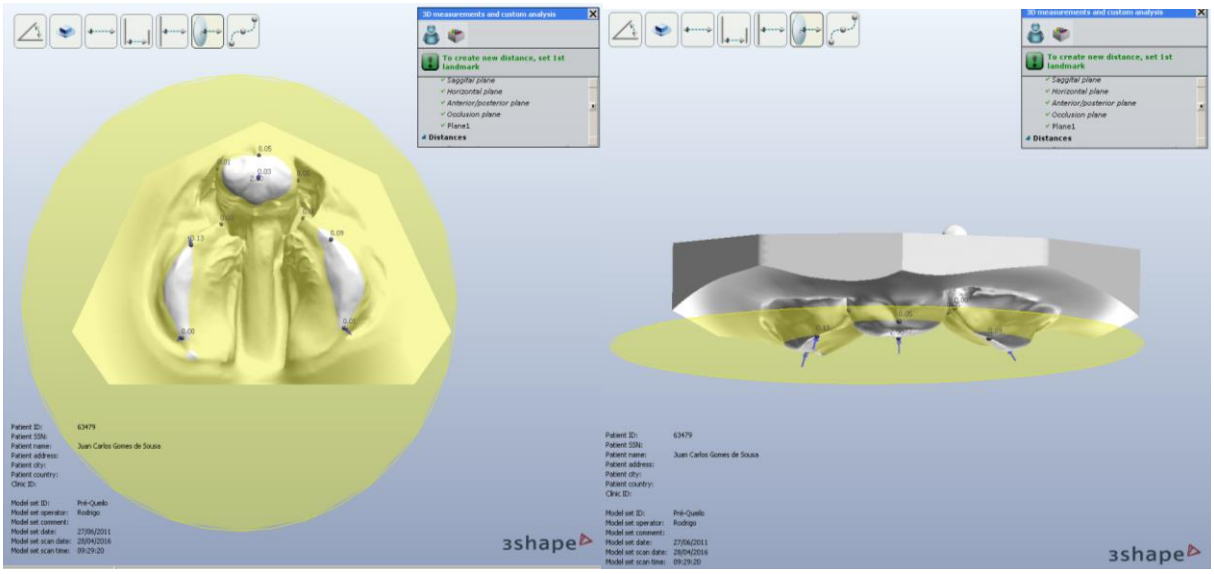


FIGURE 3. Conformation of the premaxilla angle and premaxilla area (in yellow) on the 2D Cross section tool.

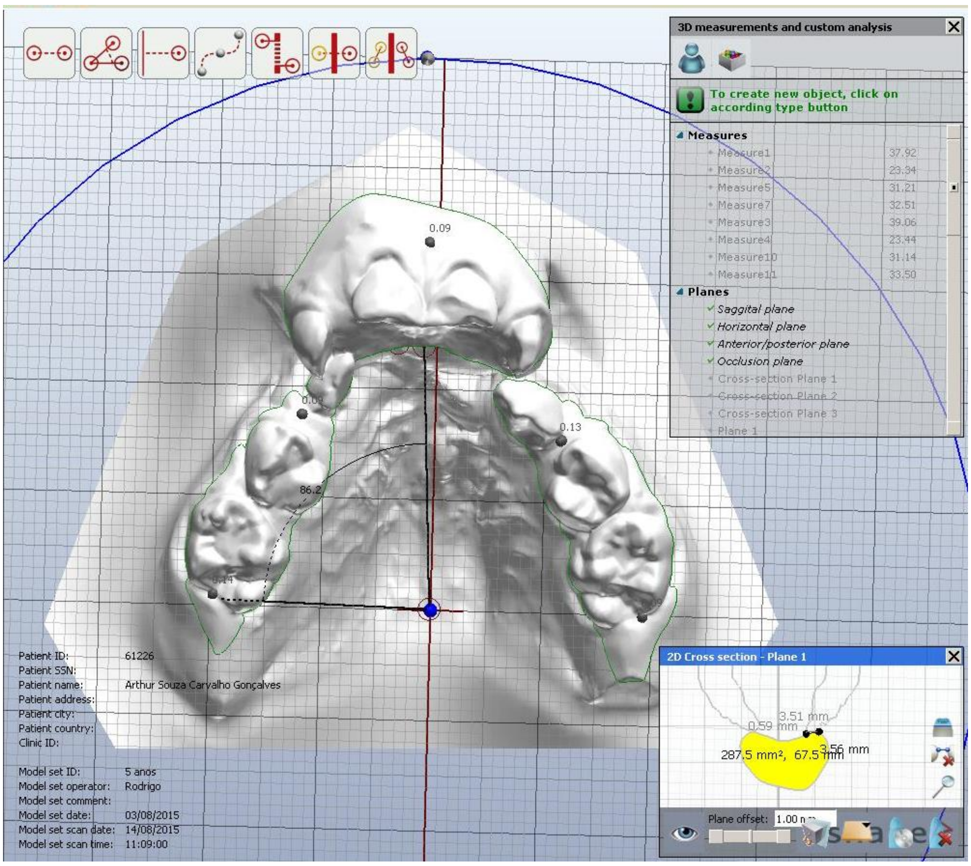


FIGURE 4. BCLP maxilla dental arch in T0 (left) and T1 (right).

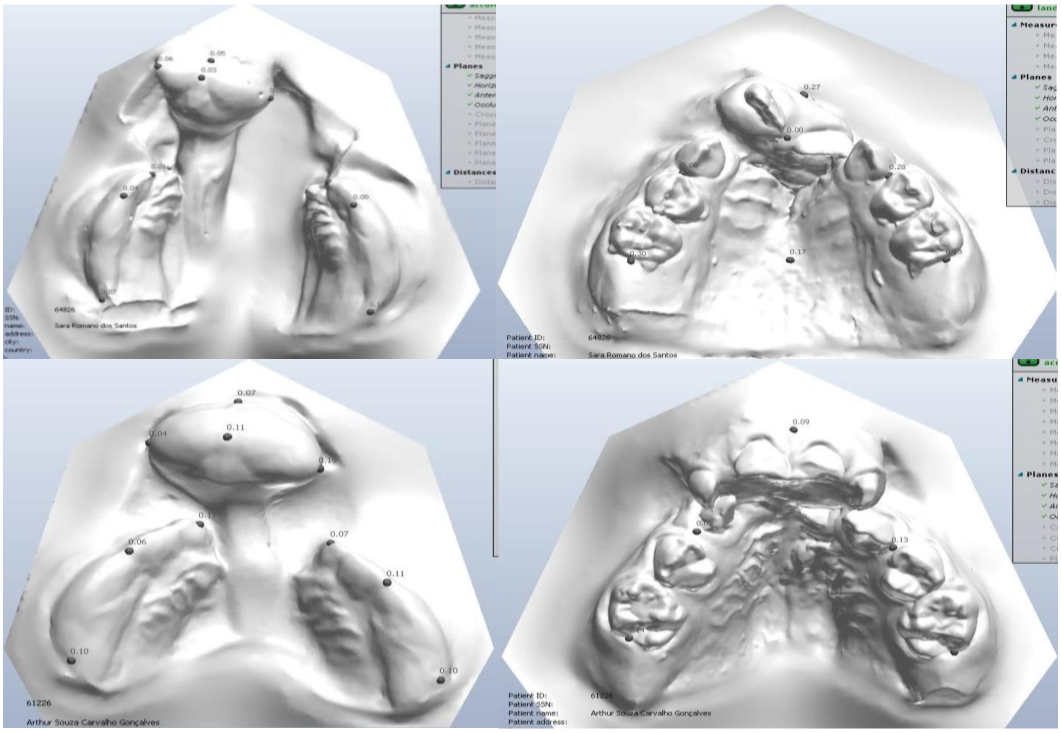
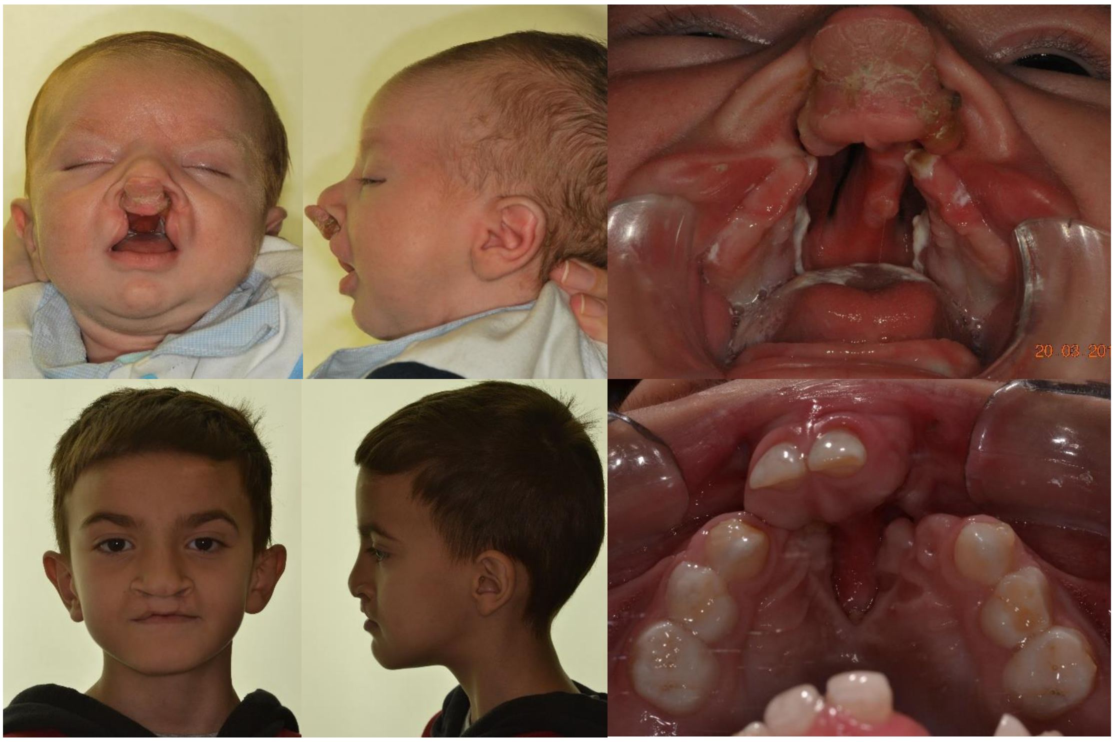


Figure 5: Extra and intraoral characteristics in a BCLP male subject



Tables:

TABLE 1. Surgery and documentation age

	n	Mean	Std Dev	C.I. of Mean	Range	Max	Min
1st surgery/ T0	41	0.45	0.23	0.07	1.08	1.25	0.17
2nd surgery	41	1.50	0.70	0.22	3.67	4.67	1.00
3rd surgery	26	3.09	1.52	0.61	5.58	6.92	1.33
T1	41	6.58	1.28	0.40	4.92	9.50	4.58

TABLE 2. T0-T1 results

	T test							Mann-Whitney test						
	T0		T1		Difference		P	T0			T1			P
Variable	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev		Median	25%	75%	Median	25%	75%	
TT´	37.77	3.76	43.10	3.63	-5.33	3.93	<0,001*							
CC´	30.54	3.88	28.87	4.52	1.68	4.08	0,012*							
Anterior arch length	15.02	3.83	10.10	2.59	4.93	3.71	<0,001*							
Total arch length	31.49	4.99	24.63	3.08	6.85	5.57	<0,001*							
Premaxila arch length	35.89	4.85	29.77	3.01	6.12	5.29	<0,001*							
Right anterior cleft width								11.33	3.76	13.97	0.00	0.00	0.00	<0,001*
Left anterior cleft width								10.93	5.48	15.07	0.00	0.00	0.00	<0,001*
Médium cleft widht	11.51	3.45	0.16	1.01	11.35	3.42	<0,001*							
Posterior cleft widht	15.26	3.32	0.00	0.00	15.26	3.32	<0,001*							
Right premaxilla deviation								37.15	34.08	39.94	32.18	30.35	34.41	<0,001*
Left premaxilla deviation								36.60	32.97	39.77	33.50	30.18	35.00	0,004*
Premaxilla deviation°	91.09	9.86	88.96	9.18	2.13	11.61	0,246							
Premaxilla extrusion								-1.94	-3.22	-0.33	1.07	-0.82	2.40	<0,001*
Premaxilla area	166.43	30.67	184.35	37.46	-19.14	35.67	0,002*							

***statistical significance**

TABLE 3. Spearman rank order correlation on T1 and T0/T1 difference

		T1_TT´	T1_Total arch lenght	T1_Premaxilla arch lenght	T1_Left anterior cleft width	T1_Left premaxilla deviation	T1_Premaxilla area	Dif_total arch lenght	Dif_premaxilla arch lenght	Dif_left premaxilla deviation	Dif_premaxilla extrusion	Dif_premaxilla area
1st surgery	Correlation Coefficient	0.35			0.37	0.31	-0.40				-0.45	-0.42
	P Value	0.027*			0.017*	0.046*	0.013*				0.004*	0.008*
	Number of individuals	41			41	41	39				41	39
T1 age	Correlation Coefficient		-0.51	-0.54				-0.49	-0.43	-0.42		
	P Value		0.001*	0.000*				0.001*	0.005*	0.006*		
	Number of individuals		41	41				41	41	41		

*statistical significance

Article 2 presented in this Dissertation was written according to The Cleft Palate-Craniofacial Journal instructions and guidelines for article submission.

Title: Evaluation of plastic surgeries and Simonart's band influence on maxillary dimensions in individuals with bilateral cleft lip and palate

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Abstract:

Objective: To evaluate the characteristics of maxillary development in individuals with bilateral cleft lip and palate (BCLP) who underwent lip and palate repair only, and the influence of Simonart´s Band (SB) on maxillary growth as well as the existence of a third surgery.
Design: Retrospective longitudinal observational study
Setting: Hospital for Rehabilitation of Craniofacial Anomalies – University of Sao Paulo, Brazil.
Participants: 41 BCLP individuals with mean age 4 months at T0 and 6.6 years at T1. From this sample, 13 individuals had SB (SB group) contrary to the remaining 28 (non-SB group).
Interventions: Initial dental cast before any surgical procedure and a second dental cast after 5 years old. No presurgical infant orthopedics was performed.
Main outcome measures: angular and linear measurements in digital maxillary dental cast 3D images for growth evaluation.
Results: Initially, the SB group presented all sagittal and cleft width measurements decreased (P <0,005) and a slight tendency of premaxilla left deviation compared to the other group. At T1, this deviation was maintained in the SB group opposite to the other group (P 0.026). Only one sagittal measurement showed statistical relevance (P 0.048), even though all of them were smaller in the SB group. The influence of third surgery was observed mainly for the maxillary transverse condition at T1 (p<0.05).
Conclusions: The SB greatly influences the initial premaxilla anterior projection and, after reconstructive surgeries, it induces a more retropositioned premaxilla maintaining its initial deviation. Only the transverse width is negatively affected by the accomplishment of a third surgery in BCLP subjects.

Key words: cleft lip, cleft palate, Simonart’s band, casts.

Introduction:

The bilateral cleft lip and palate (BCLP) is considered the most complex, difficult to treat (Freitas et al., 2012) and posing more esthetic and functional problems among all types of cleft lip and palate. The maxilla segmentation into three parts leads to a very usual projection of the premaxilla (Latham 1973; Zhang et al., 2017), which is considered an obstacle to be overcome. During the rehabilitation of individuals with BCLP, the first surgical interventions may cause alterations in facial growth (Honda et al., 1995; Huang et al., 2002) because the three bone segments are approximated, leading to premaxillary retropositioning and reduction mainly in upper dental arch length principally (Heidbuchel et al., 1998; Jiang et al., 2018; Silva Filho et al., 2003). The rehabilitation process become longer, more expensive and with increased burden of care (Alberconi et al., 2018) in order to treat the maxillary growth restriction and its consequences (Freitas et al., 2012).

During the years, many surgical techniques and non-surgical interventions like presurgical orthopedics have been developed in order to handle the premaxilla and allow a correct maxillary growth. However, no consensus regarding the best technique or timing has been reached. Currently, one-stage lip repair is more adopted and highly practiced (Chung, 2018), different than presurgical infant orthopedics, which is not part of the rehabilitation protocol of HRAC-USP as other centers around the world, because of its controversial long-term effects on maxillary development (Ross et al, 1994; Papadopoulos 2012).

The prevalence of Simonart's band (SB) in BCLP seems to be higher than observed in individuals with unilateral cleft lip and palate (UCLP) (Silva Filho et al., 2006). However, only UCLP studies have been developed showing the mild positive influence of the soft tissue bridge on the facial pattern in adulthood (Semb et al., 1991). Silva Filho (1992) evaluated unoperated CLP individuals and indicated that this band provided a more favorable anterior maxillary morphology, reducing the anterior projection of the noncleft segment. The presence of a more favorable maxillary morphology with reduced segmental displacement allows less traumatic lip repair and reduces the need of secondary surgeries (Semb et al., 1991).

The maxillary morphology in BCLP described by the literature suggested that the BCLP prominent premaxilla can be set back by pressure from the reconstructed lip (Honda et al., 1995). It also shows significantly narrowed anterior arch width, shorter anterior arch depth and wider posterior arch width at 4 years old (Heidbuchel et al, 1998) in individuals with BCLP who used presurgical orthopedics devices before primary surgeries. The difference in maxillary development in the presence of SB was described in UCLP only, despite the greater incidence in BCLP (Silva Filho et al., 2006). The aim of this retrospective study was to evaluate the characteristics of maxillary development in individuals with BCLP submitted only to lip and palate repair only (primary surgeries), and the influence of SB on maxillary growth, as well as the accomplishment of a third surgery. For this purpose, digital dental casts of children with BCLP were evaluated before any surgical intervention around 4 months of age and later, in the same individual, after 5 years of age.

Materials and methods:

This retrospective study was conducted at the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo (HRAC-USP), Bauru, Brazil. The study was approved by the Institutional Review Board, according to the Brazilian Health Ministry no. 196/96 resolution.

The sample was selected from the files of HRAC-USP, encompassing records of BCLP individuals of both genders for which initial digital casts (prior to primary surgeries) and at 5 years old (according to the institutional protocol) were available.

The inclusion criteria of the sample were: individuals born between 2010 e 2013, both genders, regularly enrolled and undergoing surgical rehabilitation treatment performed entirely at HRAC-USP, with dental casts performed between 5 and 9 years old (T1), and 3D digital models available in the digital files of the institution. Individuals submitted to any orthodontic/orthopedic therapy in the time between the two impressions or presence of associated syndromes were excluded from the study.

The digital images were analyzed using OrthoAnalyzer Softtware 3D Software (Copenhagen, Denmark) and the maxillary measurements were performed on the three planes of space directly on the scanned images according to Seckel et al, 1995 and Durwald et al, 2007 (Fig. 1, 2 and 3). Each subject had 14 measurements in both T0 and T1, adding up to 28 measurements for identification of maxillary growth development under the influence of lip and palate repair in individuals with and without Simonart's band. The influence of a third surgery on maxillary growth evaluated in T1 was also assessed on both groups.

Pilot Study and Error Analysis

All evaluations and measurements were performed by a single investigator. For sample calculation, a pilot study was performed on 10 individuals randomly selected from a previous data collection composed of 17 individuals who met the inclusion criteria. For error analysis, the evaluations of the pilot study were performed in T0 and T1 twice at intervals of 15 days to determine the method reliability. The random error was calculated by intraclass correlation coefficient.

Statistical Analysis

Statistical evaluation of digital dental casts values between T0 and T1 was performed using parametric and non-parametric tests. The results were compared by the t test and Mann-Whitney test. Statistica software (Statistica for Windows – version 7.0 – Statsoft) was used for statistical analysis. Statistical significance was set at $P < 0.05$.

Results:

From the 41 individuals included in the sample, 10 were females and 31 males, with mean age 4 months at T0 and 6 years and 6 months at T1 (Table 1). Thirteen individuals had SB, being 5 bilateral, 6 on the left side and 2 on the right side (Fig. 4). All individuals underwent one-stage lip repair (first surgery) with Spina technique and labial adhesion at mean age 4 months (according to HRAC-USP protocol, the first dental cast is obtained two days before surgery) as first surgery. The second surgery was palate repair; total in 28 individuals and anterior in 13, the main techniques were Hans Pichler and Von Langenbeck, performed at mean age of 1 year and 5 months. Only 26 individuals were submitted to a third surgery, at mean age of 3 years: 4 were secondary lip repair, 13 posterior palate repair and 9 tertiary palate repair to treat palatal fistula (Fig. 5). The surgeries were performed by 7 experienced surgeons of HRAC-USP.

The influence of SB on the digital maxillary measurements in T0, T1 and T0/T1 difference was evaluated (Tables 2, 3 and 4; Fig. 6, 7 and 8). The intraclass correlation coefficient was evaluated in T0 and T1 measurements, with a 0.98 correlation in both times. In T0, prior to any kind of surgical or non-surgical intervention, the presence of SB decreased all sagittal measurements and the alveolar cleft width (left and right), leading to smaller premaxillary projection. The left premaxillary deviation was also presented in the presence of SB, however with minor values in relation to individuals without SB. In T1, only one sagittal measurement (APm-TT´) showed statistical relevance (P 0.048), even though all of them were smaller in the SB group. Concerning the premaxillary deviation, the angular and linear measurements showed a tendency to left deviation of the premaxilla in individuals in SB group, opposite to the non-SB group. The premaxilla was less extruded and with larger area in SB group; however, these two results were not statistically significant. Finally, in T0/T1 difference measurements, the sagittal data showed smaller maxillary length in SB group corresponding to the premaxillary projection detected in T0. Because of this reason, the T0/T1 difference showed a decreased alveolar cleft width with statistical relevance. The transverse measurements (TT´, CC´) showed no statistical relevance in T0, T1 and T0/T1 difference, despite the same measurement in both groups at T0, the SB group showed wider transversal measurements than the non-SB group, especially in the anterior area.

The influence of a third surgery was evaluated in T1 and T0/T1 difference measurements (Table 5), and only 3 values had statistical relevance ($p<0.05$). The influence of third surgery was observed mainly for the maxillary transverse condition in T1, since the TT´ and CC´ distances were smaller in individuals submitted to a third surgery. This surgery also helped to diminish the right premaxillary deviation.

Data from this paper indicate that significant maxillary development differences are present in BCLP individuals submitted to lip and palate repair according to the presence or absence of SB.

Discussion:

Changes in maxillary arch dimensions in BCLP individuals with and without SB were evaluated from infancy up to 5 to 9 years of age and related to plastic surgical interventions. Premaxillary anterior projection was minimal in BCLP individuals with SB at the first stage before any surgical intervention. This was reflected by the decreased values in all sagittal, vertical and premaxillary deviation measurements, as well as anterior cleft width. Transverse measurements (TT´, CC´), including medial and posterior cleft width, were very similar in both groups, showing no influence of SB on this plane at this time. The premaxillary area remained slightly larger in the SB group at study onset and completion. At T1, the premaxilla was retropositioned and the maxillary dimensions in both groups were more similar than those initially found. However, sagittal and vertical measurements remained decreased. Transversally, the maxillary development was greater in the SB group, especially in the anterior region.

Also, the influence of a third surgery on maxillary development affected mainly the transverse plane and right premaxillary deviation.

This study evaluated 41 BCLP individuals, with mean age 4 months at the first evaluation and 6.6 years on the second. This period of time is considered important for maxillary growth because of the greatest postnatal growth changes that occur, especially in the maxilla (Laowansiri et al., 2013). Also, orthodontic/orthopedic active treatment usually begins after 9 years of age (Freitas 2012b), thus the maxilla growth study according to plastic surgeries can be favorably conducted. From this sample, 13 subjects (32%) had SB. being 5 bilateral, 6 on left side and 2 on the right side (Figure 1). A prevalence study of SB (Silva Filho et al., 2006) in complete cleft lip and alveolus and complete cleft lip and palate showed a prevalence of 31.2% in these cleft types. From this study, a total of 106 BCLP individuals were evaluated with a prevalence of 28.3% with SB, which is lower than our findings. Bilateral SB was the most prevalent with 43%, almost similar percentage in our study corresponded to the left side SB, the right SB with 30% and the left side with 27%. Another SB prevalence study by Silva Filho et al. (1994) in UCLP individuals showed 19.6% of cases with the band, from which the most prevalent were on the left side, similar to our findings. In a gender comparison, this same study pointed a higher prevalence of male individuals with SB; from our sample of 13 individuals with the band, only 1 was female. This can be related to the high CLP male prevalence described in the literature (Freitas, 2012), and also corresponds with our findings, since 31 boys and 10 girls were found in our sample of 41 subjects.

Premaxilla

The premaxilla spatial position is greatly influenced by the presence of SB (Semb and Shaw, 1991; Silva Filho et al., 1992). The anterior projection can be measured in two planes of space, namely sagittal and vertical. Initially in our study, before any surgical interventions, all sagittal measurements in the SB group were nearly 4 to 5 mm smaller than those found in the group without SB. Depending on the size and unilateral or bilateral presentation of the band, the premaxilla was almost at the same level as the lateral maxillary segments. This was clinically observed in BCLP individuals with bilateral SB, in which the premaxillary projection could not be identified on the lateral view. Unilateral SB individuals presented moderate anterior projection, being asymmetry the main characteristic, since the level of projection can vary on the left or right side lateral view depending on the SB side. Classic dental cast growth evaluation studies (Heidbuchel et al., 1998; Honda et al., 1995) excluded SB individuals from their sample, and their initial dental cast evaluation was similar to our non-SB sample, especially Heidbuchel´s study. Also in this study that compare maxillary development in BCLP and non-cleft individuals, we found our SB group measurements more similar with the non-cleft group than the BCLP group, the SB group had slightly higher measurements (2.81 mm of difference in anterior arch depth and 2.03 mm in total arch depth), with a less protruded premaxilla. In the second evaluation, after surgical intervention, both groups showed a decreased and almost similar final sagittal measurements, the SB group had smaller arch depth and T0/T1 difference compared to the other group. Besides, these results were very similar to those found in the non-cleft group in the study of Heidbuchel (1998) (10.9 mm anterior arch depth). Honda et al (1995) longitudinal analyzed the maxillary arch dimension changes and showed very similar anterior arch depth in BCLP individuals (9.2 mm) to our SB group (9.75 mm) and a smaller anterior arch depth in UCLP subjects (6.5mm). Therefore, BCLP with SB anterior arch depth is smaller than non-SB BCLP but greater than UCLP subjects and very similar to non-cleft individuals.

The significant premaxillary anterior projection increased the arch depth and also appeared to be intruded if measured based on an occlusal plane. Due to the absence of teeth at this stage (4 months of age), an occlusal modified plane, also named basal plane, was used as described by Durwald and Dannhauer (2007) and Hak et al (2012). In our findings, the premaxilla was more intruded in the non-SB group, corresponding to the more anterior projection in this group. After plastic surgeries, the premaxilla suffers an important clockwise rotation and appears extruded in relation to the basal plane (no classical occlusal plane was used), being more severe in the non-SB individuals. At this point, the vertical maxillary development has to include evaluation of the lateral segments, since its cleft edges can be more cranial than the premaxilla cleft edges (Krey et al., 2009). An extruded premaxilla at this age can be the result of an initial overgrowth at the premaxillary-vomerine suture (Heidbuchel et al., 1993) resulting in protrusion and retropositioning after plastic surgeries, underdevelopment of the lateral maxillary segments (Padwa et al., 1999) and counterclockwise rotation or a combination of both. An adequate differential diagnosis must be done for premaxilla extrusion treatment.

Another great influence of the presence of SB is in the anterior cleft width and premaxilla deviation. The initial cleft width is related to the maxillary development, since a wider cleft may generate more scar tissue and negatively affect the maxillary growth (Chiu et al., 2011). In our study, there was a great difference in left and right cleft width in SB and non-SB individuals, since the non-SB group showed a centralized premaxilla because of the equal cleft width measurements, the SB group had a larger right cleft width, thus with tendency to left premaxilla deviation. To support this finding, we created three premaxilla deviation measurements, two linear (left and right premaxilla deviation) and one angular. The maxillary tuberosity point was used as fixed reference point and the measurement reached the incisal point accompanying the premaxilla deviation. According to this, the SB group showed evident left premaxilla deviation and the other group a very slight left tendency. The premaxilla deviation measurement in degrees was assessed using the basal plane on an occlusal view, used for vertical evaluation, where three points previously used were located: the right tuberosity point, incisal point and a point in the middle of the intertuberosity distance as the vertex. According to this measurement, the non-SB group showed a centralized premaxilla (89.91°) and left deviation in the other group (93.63°). Only lineal premaxilla deviation measurement had statistical significance at this evaluation time, evidencing that, before any surgical intervention, the premaxilla is centralized in the non-SB BCLP individuals, and there is a left tendency deviation for BCLP with SB. This can be related to the higher number of left SB (46%) in our sample, contrary to right SB (15%). The post-surgical evaluation evidenced the premaxilla fragility, since its initial centralized position evolved to a slight right deviation (86.81°) in non-SB group and the left deviation in the SB group (93.59°) was maintained, this time the premaxilla angle had statistical significance. This finding was unexpected, since a centralized premaxilla theoretically causes equal lip tension after lip reconstruction (Zhang and Arneja, 2017). Perhaps the surgical technique and surgeon's experience (Williams et al., 1999) can have influence on this evolution, since two lip repair techniques were performed by 7 surgeons. Clinically, this slight premaxilla deviation is not evident in BCLP individuals and most of them showed the typical more symmetrical maxilla and dentoalveolar characteristics than UCLP subjects. No other studies addressed the evolution of premaxilla deviation before in digital dental casts evaluation, despite the challenge that premaxilla management represents for the rehabilitation team.

To evaluate the premaxilla growth, its area was measured using the basal plane previously employed for vertical evaluation. The basal plane crossed the premaxilla, depending mainly on its projection/deviation and quality of the dental cast, and the cross-section software tool allows the premaxilla area measurement. The premaxilla position variability is high and, to standardize the measurement, the premaxilla area was obtained 4 mm cranially from the basal plane intersection with the top of the alveolar crest. The same plane and references were used for final dental cast analysis, however with more difficulty due to the anterior arch collapse in most individuals (Silva Filho, 2007). Initially, the premaxilla area was greater in the SB group, yet with a small difference, and a greater difference was found in the final dental cast evaluation despite the positive premaxillary development found in both groups. This can also be assigned to dental development and collapsed anterior arch that hindered the measurement.

Transverse characteristics and the influence of third surgery

The presence of SB did not affect the transverse measurements (TT´, CC´). In the initial dental cast evaluation both groups were equal, also in the initial median and posterior palate cleft width. Consistent with similar published studies (Honda et al, 1995 and Heidbuchel et al, 1998) our growth results showed a narrower anterior arch width and a wider posterior arch width at 6.6 years old. Although the studies of Heidbuchel et al (1998) and Honda et al (1995) were performed on individuals up to 4 years of age with utilization of PSIO, the transverse findings are alike. The SB group development seemed to be greater, since the both transverse width measurements were bigger than those found in our non-SB group, and it was also greater than the aforementioned studies; only the CC´ width in the SB group (30.38 mm) was equal to the non-cleft group in the study of Heidbuchel (30.6mm). Therefore, individuals without SB presented a more collapsed anterior dental arch than BCLP individuals with SB, and the collapse is not related to the posterior dental arch width, as suggested by Krey et al (2009). The influence of lip repair on anterior maxillary arch development is undeniable and can be greater than the influence of palate repair (Huang et al., 2002 and Silva Filho et al., 2003); however, the band seems to offer a better environment for anterior transverse growth due to the minor premaxilla projection.

There is great controversy regarding the best timing and surgical technique for cleft palate repair (Leow and Lo, 2008) and the effects on speech and maxillofacial growth. Besides, the number of surgeries and anesthesia events in children with clefts should be considered by the rehabilitation team, since a BCLP individual can have an average of 10 procedures of this kind from birth to adulthood (McIntyre et al., 2016). Our study also evaluated the influence of a third surgery on the maxillary development, in 63% of the sample. From all measurements, only the transverse ones and the right premaxilla deviation had statistical significance, showing a minor transverse growth in individuals who underwent a third surgery. The right premaxilla deviation value cannot be interpreted alone to determine a premaxilla deviation. Using the other premaxilla deviation indicators, yet without statistical significance, the premaxilla showed a tendency to the right side in individuals who did not undergo a third surgery; conversely, those submitted to this surgery showed left premaxilla deviation. Although there seems to be no answer to explain the premaxilla deviation in the last finding, the diminished transverse width can be expected, since 75% of all third surgeries were palate repairs. About this, 9 individuals (35%) presented a palatal fistula to treat and 13 individuals (50%) underwent posterior palatoplasty as part of a two-stage palatoplasty. In the case of palatal fistula, the existence of a fistula indicates a poor condition for proper maxillary growth. The factors that can contribute to fistula occurrence are gender, cleft width, and surgeon’s experience (Parwaz et al., 2009), however the fistula rate did not differ between one or two-stage palate repair and timing of repair (Tache and Mommaerts, 2019). The tertiary palate repair to treat the fistula causes a new surgical aggression that can negatively influence the transverse maxillary development (Silva Filho, 2007; Manna et al., 2009). Probably, the results of individuals with a treated fistula are mainly influencing the final result in transverse measurements. Until the time of this study, only 2 individuals that underwent a two-stage palate repair were submitted to tertiary palate repair (fourth surgery) for fistula treatment. It seems that one-stage palate repair has better maxillary development but with high palatal fistula presence than the two-stage palate repair. However, a specific study comparing the two techniques should be conducted to properly demonstrate this.

Conclusion:

The initial maxillary dimensions are highly influenced by the presence and presentation of SB (unilateral left or right and bilateral), except for the transverse width. The band limits the premaxillary anterior projection and, after reconstructive surgeries, it seems to provide better anterior transverse development. Although all BCLP individuals suffered premaxillary retropositioning, the greater changes occurred in individuals without SB and the final results were slightly larger than the SB group. The initial deviation in unilateral SB subjects is maintained after primary surgeries, however an initial centralized premaxilla in subjects without SB can lead to a slight right deviation yet without clinical consequences.

Respecting the influence of a third surgery on maxillary dimensions after reconstructive surgeries, the transverse width is negatively affected by exposure to this third surgery, mainly because most surgeries were performed on the palate and in 35% of cases for palatal fistula treatment.

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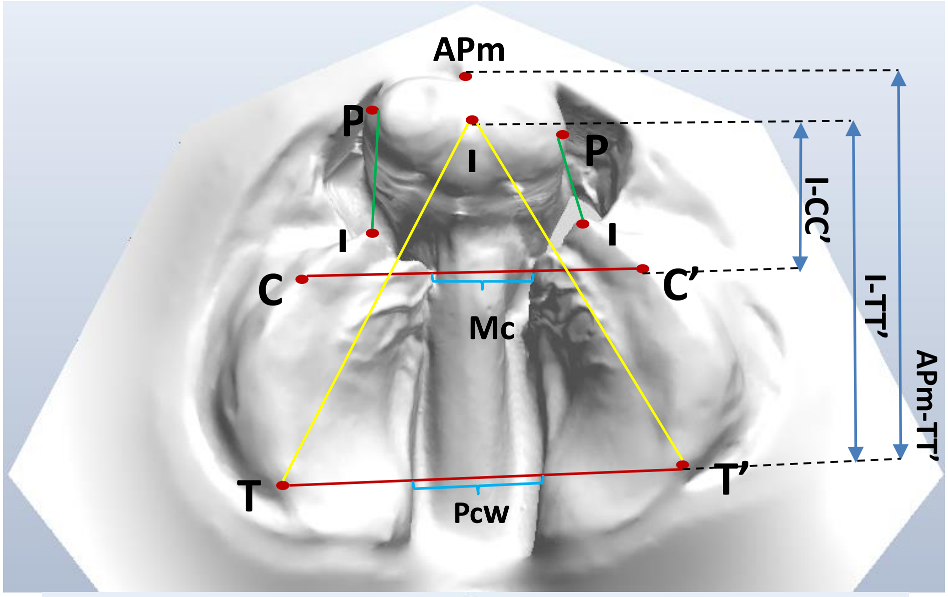
Figures:

FIGURE 1. Reference points used in cast analysis: Point I (incisal point)-point on the top of the alveolar crest where the incisive papilla and labial frenulum meet, or the tip of the interdental papilla between the central incisors. Point C (cuspid point)-where the lateral sulcus crosses the crest of the alveolar ridge, or the tip of the interdental papilla between the deciduous canine and first deciduous molar. Point T (tuberosity point)-the posterior limit of the maxillary tuberosity in the sulcus where the pterygomandibular raphe adheres, or the distal point of the second deciduous molar. Point L-most anterior point of the alveolar crest of the lateral segment. Point P- most lateral point of the premaxilla. Point APm-premaxilla anterior and apical point or insertion point of the medial lip frenum. Calculated distances: CC´- intercanine width or maxillary anterior arch width. TT´- intertuberosity width or maxillary posterior arch width. PL-anterior right cleft width. P´L´-anterior left cleft width. TI-right premaxilla deviation. IT´-left premaxilla deviation. Mcw-medium cleft width measured on intercanine distance. Pcw-posterior cleft width measured on intertuberosity distance. I-CC´-anterior arch depth. I-TT´-total arch depth- APm-TT´-premaxilla arch length.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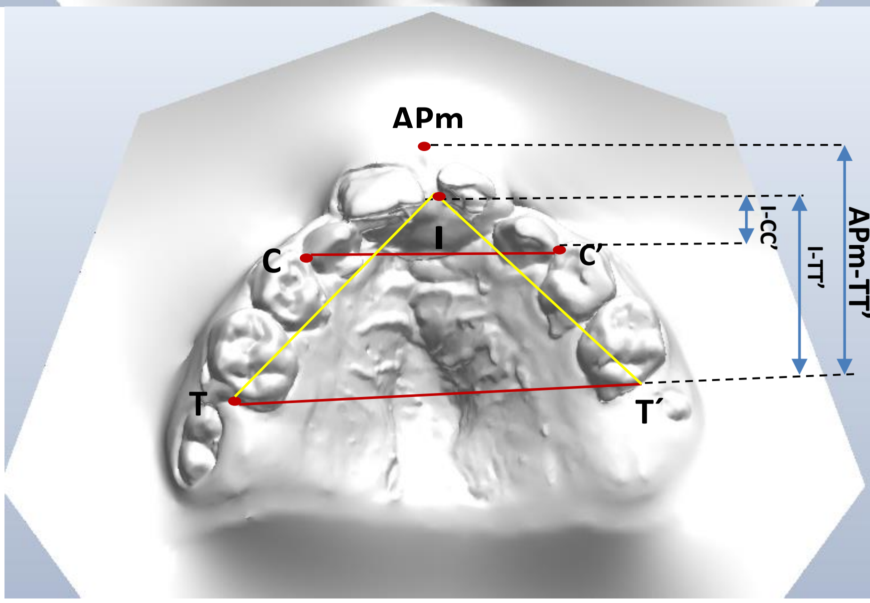
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FIGURE 2. Occlusal and frontal view of the basal plane (TT´C)

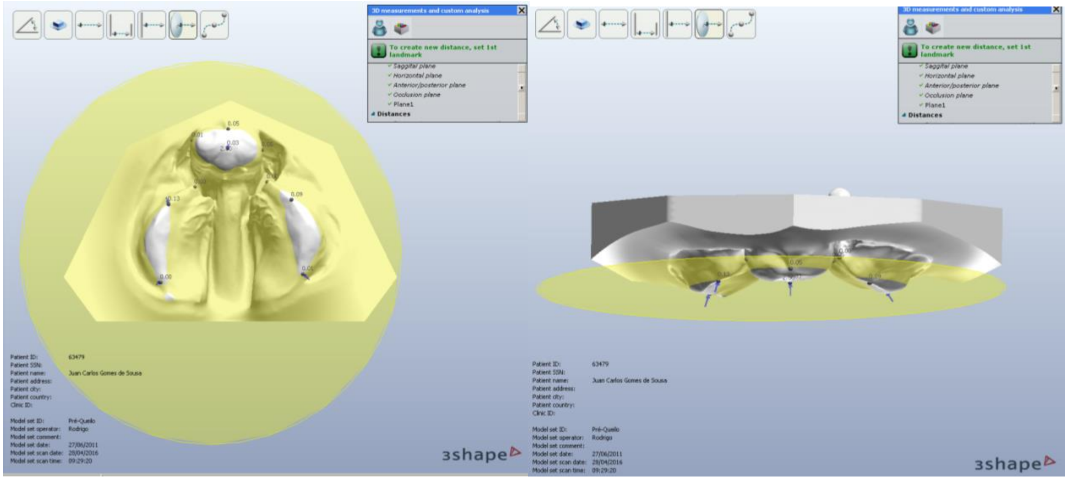

FIGURE 3. conformation of the premaxilla angle and premaxilla area (in yellow) on the 2D Cross section tool.

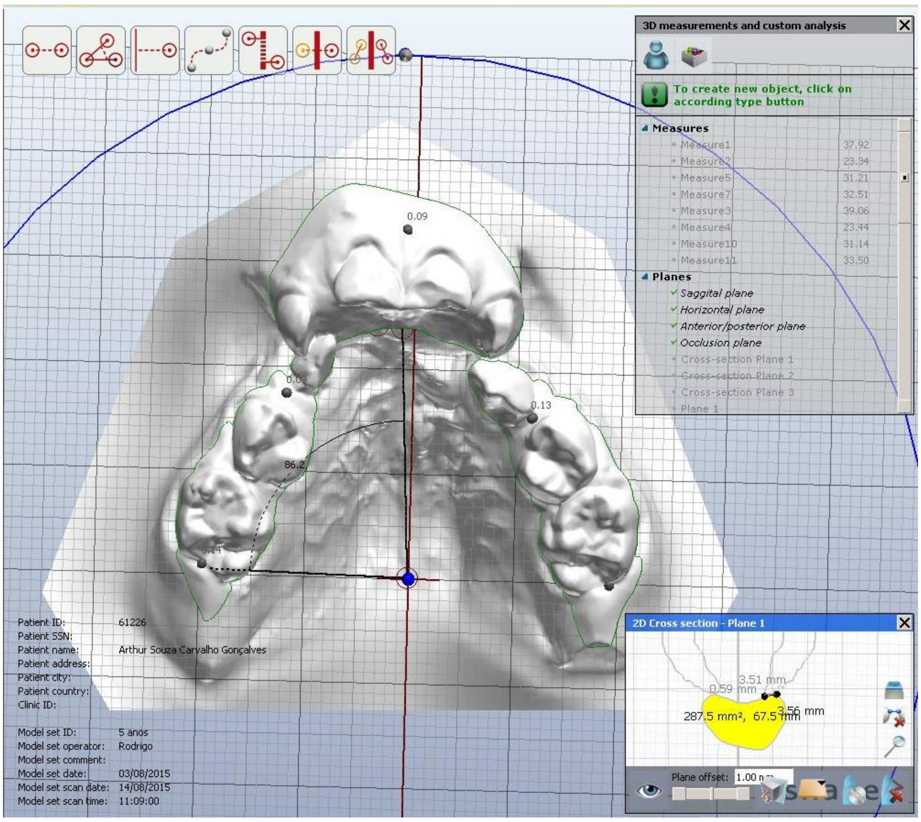

FIGURE 4. Simonart's band prevalence.

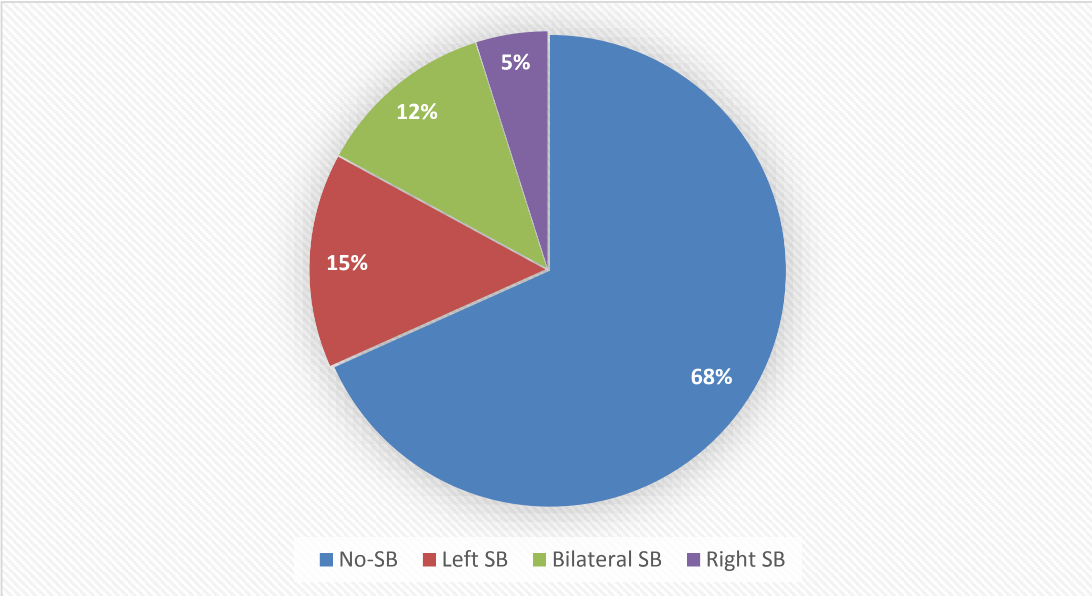

FIGURE 5. Surgical procedures in BCLP individuals (n=41)

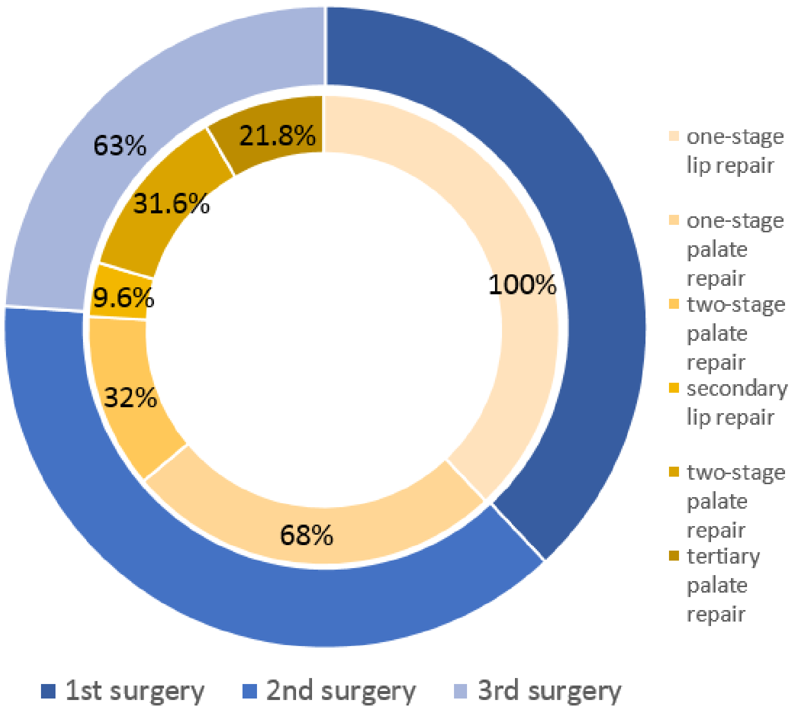

FIGURE 6. BCLP maxilla dental arch in T0 (left) and T1 (right). a: without SB, b: bilateral SB and c: unilateral SB.

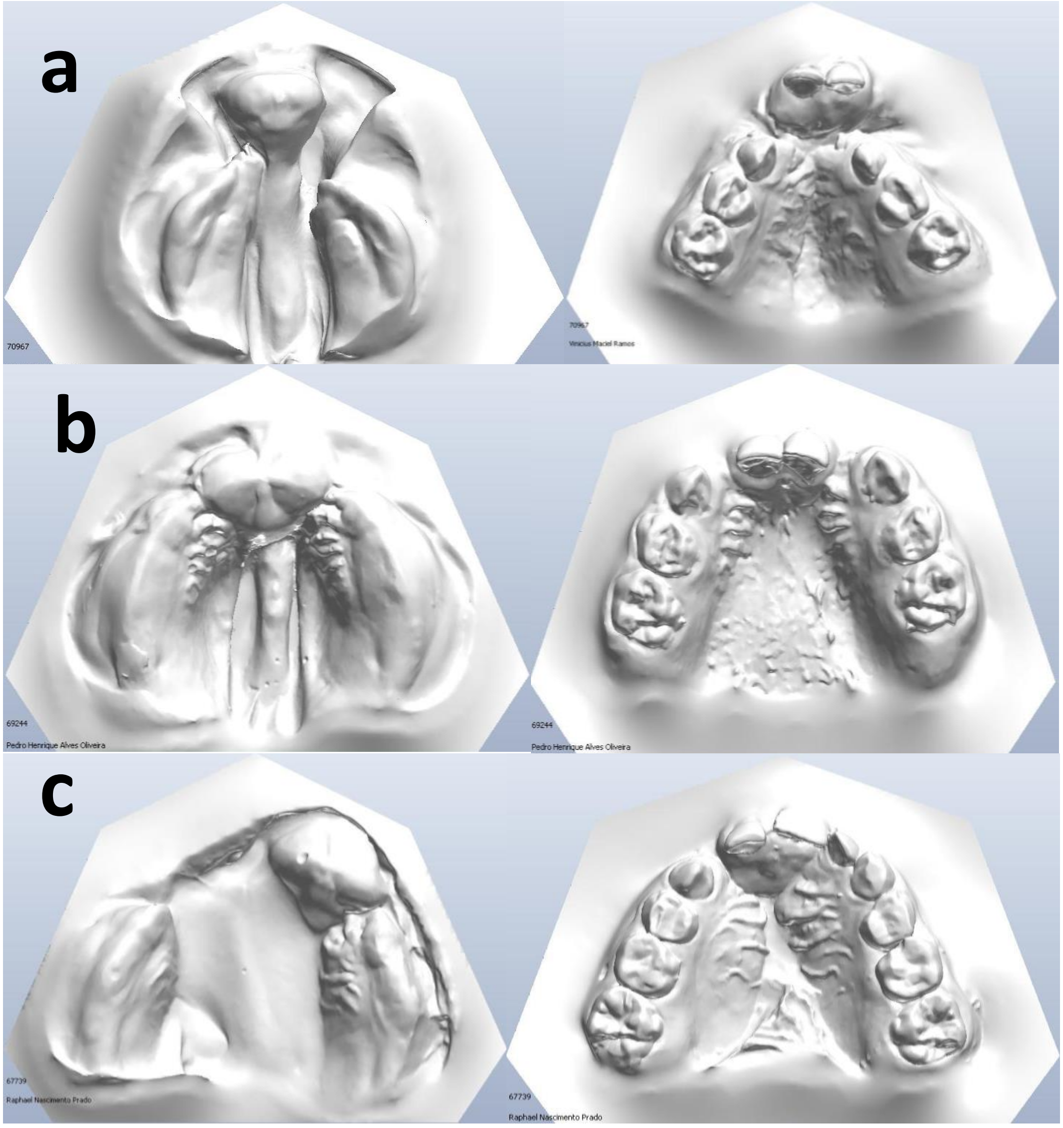

FIGURE 7. Extra and intraoral characteristics in a BCLP male subject without SB

FIGURE 8. Extra and intraoral characteristics in a BCLP male subject with bilateral SB.

Tables:

TABLE 1 Surgery and documentation age

	n	*Mean*	*Std Dev*	*C.I. of Mean*	*Range*	*Max*	*Min*
1st surgery/ T0	41	0.45	0.23	0.07	1.08	1.25	0.17
2nd surgery	41	1.50	0.70	0.22	3.67	4.67	1.00
3rd surgery	26	3.09	1.52	0.61	5.58	6.92	1.33
T1	41	6.58	1.28	0.40	4.92	9.50	4.58

TABLE 2 T0 measurements in groups with and without SB

	T test					*Mann-Whitney Test*						
	no-SB n=28		*SB n=13*			*no-SB n=28*			*SBa n=13*			
Variable	*Mean*	*Std Dev*	*Mean*	*Std Dev*	*P*	*Median*	*25%*	*75%*	*Median*	*25%*	*75%*	*P*
TT´	37.76	3.98	37.78	3.37	0,991							
CC´	30.54	4.44	30.55	2.40	0,992							
Anterior arch length	16.51	3.04	11.81	3.42	<0,001*							
Total arch lenght	33.26	4.61	27.67	3.44	<0,001*							
Premaxilla arch length	37.40	4.59	32.65	3.81	0,002*							
Right anterior cleft width						12.66	10.64	14.55	3.77	1.20	10.50	0,010*
Left anterior cleft width						12.52	8.96	15.66	0.41	0	7.055	<0,001*
Medium cleft width	11.55	3.55	11.43	3.35	0,923							
Posterior cleft width	15.44	3.22	14.87	3.64	0,615							
Rigth premaxilla deviation						38.90	34.48	40.60	36.11	31.77	37.01	0,022*
Left premaxilla deviation						37.78	35.30	41.43	32.59	30.87	34.58	0,001*
Premaxilla angle	89.91	10.47	93.63	8.21	0,267							
Premaxilla extrusion	-1.75	2.62	-1.59	1.46	0,847							
Premaxilla area	165.49	32.46	168.63	27.23	0,771							

* Statistical significance

TABLE 3 T1 measurements in non-SB and SB groups

	T test					*Mann-Whitney Test*						
	no-SB n=28		*SB n=13*			*no-SB n=28*			*SBa n=13*			
Variable	*Mean*	*Std Dev*	*Mean*	*Std Dev*	*P*	*Median*	*25%*	*75%*	*Median*	*25%*	*75%*	*P*
TT´	42.73	3.97	43.88	2.76	0,356							
CC´	28.17	4.97	30.38	3.01	0,147							
Anterior arch length	10.26	2.68	9.75	2.47	0,562							
Total arch lenght						25.05	22.40	26.70	23.28	22.30	23.95	0,127
Premaxilla arch length						30.40	28.13	32.04	28.55	27.18	29.36	0,048*
Right anterior cleft width						0	0	0	0	0	0	0,574
Left anterior cleft width						0	0	0	0	0	0	0,506
Medium cleft width						0	0	0	0	0	0	0,529
Posterior cleft width						0	0	0	0	0	0	1,000
Rigth premaxilla deviation	32.29	3.71	33.36	2.53	0,349							
Left premaxilla deviation						33.86	31.35	35.98	32.14	29.68	33.99	0,045*
Premaxilla angle	86.81	9.41	93.59	6.88	0,026*							
Premaxilla extrusion						1.29	-0.76	2.57	0.98	-0.96	2.39	0,726
Premaxilla area						177.30	160.18	197.83	189.40	149.35	207.40	0,981

* Statistical significance

TABLE 4 T0/T1 difference measurements in groups with and without SB

Variable	*T test*					*Mann-Whitney Test*						
	no-SB n=28		*SB n=13*			*no-SB n=28*			*SBa n=13*			
	Mean	*Std Dev*	*Mean*	*Std Dev*	*P*	*Median*	*25%*	*75%*	*Median*	*25%*	*75%*	*P*
TT´	4.97	3.94	6.10	3.96	0,400							
CC´	-2.37	4.23	-0.18	3.40	0,109							
Anterior arch length						-5.65	-8.43	-3.56	-1.76	-2.86	-0.33	<0,001*
Total arch lenght	-8.19	5.97	-3.98	3.17	0,022*							
Premaxilla arch length	-7.10	5.69	-4.02	3.69	0,084							
Right anterior cleft width						-12.43	-14.05	-9.47	-3.69	-9.36	0.00	0,006*
Left anterior cleft width						-11.78	-15.14	-7.88	-0.41	-7.06	0.00	<0,001*
Medium cleft width	-11.32	3.52	-11.43	3.35	0,920							
Posterior cleft width	-15.44	3.22	-14.87	3.64	0,615							
Rigth premaxilla deviation						-5.95	-9.92	-2.15	-0.65	-5.02	1.88	0,005*
Left premaxilla deviation						-6.08	-8.65	0.58	-1.88	-4.06	1.21	0,085
Premaxilla angle	-3.11	11.68	-0.04	11.64	0,438							
Premaxilla extrusion						3.04	-0.72	5.36	1.66	0.24	4.26	0,664
Premaxilla area	19.73	36.70	17.80	34.79	0,878							

* Statistical significance

TABLE 5 Influence of a third surgery on T1 measurements

	T test					*Mann-Whitney Test*						
	No 3rd S n=15		*3rd surgery n=26*			*No 3rd Surgery n=15*			*3rd surgery n=26*			
Variable	*Mean*	*Std Dev*	*Mean*	*Std Dev*	*P*	*Median*	*25%*	*75%*	*Median*	*25%*	*75%*	*P*
TT´	45.25	3.77	41.86	2.96	0,003*							
CC´	31.05	5.22	27.61	3.60	0,017*							
Anterior arch length	10.48	2.66	9.87	2.58	0,476							
Total arch length						24.83	23.38	26.55	23.83	21.91	25.85	0,180
Premaxilla arch length	30.28	3.38	30.28	3.38	0,418							
Right anterior cleft width						0	0	0	0	0	0	0,744
Left anterior cleft width						0	0	0	0	0	0	0,461
Medium cleft width						0	0	0	0	0	0	0,206
Posterior cleft width						0	0	0	0	0	0	1,000
Rigth premaxilla deviation	34.51	3.48	31.54	2.86	0,005*							
Left premaxilla deviation						33.94	30.17	36.17	33.42	30.25	34.32	0,394
Premaxilla angle	91.10	10.65	87.72	8.18	0,262							
Premaxilla extrusion						0.60	0.00	1.92	1.65	-0.93	3.20	0,372
Premaxilla area						170.80	153.50	205.10	179.00	158.43	201.80	0,598

* Statistical significance

4 Final Considerations

4 FINAL CONSIDERATIONS

The maxillary and premaxillary development are greatly influenced by the primary plastic surgeries, being sagittal and vertical planes the most affected, reflecting in a collapsed anterior dental arch in individuals with bilateral cleft and palate aged 5 to 9 years old. The initial hypothesis (HO) was rejected.

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REFERENCES

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ANNEXES

USP - HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Morfologia e dimensões do arco dentário superior em pacientes com fissura transforame incisivo bilateral: avaliação da influência das cirurgias plásticas primárias

Pesquisador: INGRID IVANNA HUAYTA
Área Temática:
Versão: 1
CAAE: 93459618.4.0000.5441
Instituição Proponente: Hospital de Reabilitação de Anomalias Craniofaciais da USP
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.797.617

Apresentação do Projeto:
Trata-se de um estudo longitudinal retrospectivo onde os dados serão coletados por medições realizadas em modelos digitais do mesmo paciente em duas etapas: pré e pós cirúrgica das dimensões dos arcos dentários de crianças com fissuras transforame incisivo bilateral.

Objetivo da Pesquisa:
Analisar a influência das cirurgias reparadoras (queiloplastia e palatoplastia) ao longo do crescimento sobre o posicionamento da pré-maxila e desenvolvimento maxilar em crianças com fissura transforme bilateral, por análise de modelos digitais obtidos antes das cirurgias primárias entre 0 a 5 meses de idade (T0) e entre os 5 a 8 anos de idade (T1) antes do início do tratamento ortodôntico.

Avaliação dos Riscos e Benefícios:
Segundo as autoras: A pesquisa envolve seres humanos INDIRETAMENTE, mediante o uso de fontes secundárias de dados, assim não existem riscos. Os benefícios são indiretos para os pacientes selecionados na amostra pelo objetivo de melhorar o protocolo de tratamento na instituição.

Comentários e Considerações sobre a Pesquisa:
A pesquisa encontra-se bem elaborada com os pontos e medidas bem descritos, bem como os testes estatísticos descriminados.

Endereço: Rua Silvio Marchione, 3-20
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USP - HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

Continuação do Parecer: 2.797.617

Considerações sobre os Termos de apresentação obrigatória:
Apresentam os seguintes documentos devidamente preenchidos: Justificativa de dispensa de TCLE, Termo de compromisso, confidencialidade e autorização de utilização de dados em projetos de pesquisa, Termo de compromisso do pesquisador responsável, Termo de compromisso de tornar públicos os resultados da pesquisa e destinação de materiais ou dados coletados, Carta de encaminhamento e Folha de rosto.

Recomendações:
Não há.

Conclusões ou Pendências e Lista de Inadequações:
Não há.

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

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

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Outros	Checklist_Prot_Pesq_48_2018.pdf	11/07/2018 10:50:52	Rafael Mattos de Deus	Aceito
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1167822.pdf	10/07/2018 12:04:32		Aceito
Outros	Term_Comp_Tornar_Publico_Dest_Mat.pdf	05/07/2018 22:53:38	INGRID IVANNA HUAYTA	Aceito
Outros	Term_Comp_Pesq_Resp.pdf	05/07/2018 22:52:38	INGRID IVANNA HUAYTA	Aceito
Outros	Term_Comp_Conf_Aut_Dados.pdf	05/07/2018 22:51:10	INGRID IVANNA HUAYTA	Aceito
Projeto Detalhado / Brochura Investigador	PROJETO_Ivanna.docx	05/07/2018 22:48:24	INGRID IVANNA HUAYTA	Aceito

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USP - HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

Continuação do Parecer: 2.797.617

Declaração de Instituição e Infraestrutura	Form_Cadastro_HRAC.pdf	05/07/2018 22:41:24	INGRID IVANNA HUAYTA	Aceito
Outros	Carta_Encaminham.pdf	05/07/2018 22:40:41	INGRID IVANNA HUAYTA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Justif_Dispensa_TCLE.pdf	05/07/2018 22:38:14	INGRID IVANNA HUAYTA	Aceito
Folha de Rosto	Folha_Rosto.pdf	05/07/2018 22:36:45	INGRID IVANNA HUAYTA	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 02 de Agosto de 2018

Assinado por:
Renata Paciello Yamashita
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