UNIVERSIDADE DE SÃO PAULO
HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

PRISCILA VAZ AYUB

**Analysis of the maxillary dental arch after rapid maxillary expansion
in patients with unilateral complete cleft lip and palate**

BAURU
2014

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in patients with unilateral complete cleft lip and palate**

Dissertação apresentada ao Hospital de Reabilitação de
Anomalias Craniofaciais da Universidade de São para
obtenção do título de Mestre em Ciências

Área de Concentração: Fissuras Orofaciais e Anomalias
Relacionadas

Orientadora: Profa. Dra. Daniela Gamba Garib

BAURU
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UNIVERSIDADE DE SÃO PAULO
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Rua Silvio Marchione, 3-20.
Caixa Postal: 1501
17012-900 Bauru/SP - Brasil
(14) 3235-8000

Prof. Dr. Marco Antônio Zago - Reitor da USP
Dr.^a Regina Célia Bortoleto Amantini - Superintendente HRAC/USP

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Ayub, Priscila Vaz

A989a Analysis of the maxillary dental arch after rapid maxillary expansion in patients with unilateral complete cleft lip and palate / Priscila Vaz Ayub. Bauru, 2014.
80p.: il.; 30 cm

Dissertação (Mestrado – Área de Concentração: Fissuras Orofaciais e Anomalias Relacionadas) – Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo

Orientadora: Prof.^a Dr.^a Daniela Gamba Garib

Descriptors: 1. Maxillary expansion. 2. Cleft lip and palate. 3. Digital models

FOLHA DE APROVAÇÃO

Dissertação apresentada e defendida por Priscila Vaz Ayub e aprovada pela Comissão Julgadora em ____/____/____.

Prof.(a) Dr.(a)
Instituição

Prof.(a) Dr.(a)
Instituição

Profa. Dra. Daniela Gamba Garib Carreira - Orientadora
Hospital de Reabilitação e Anomalias Craniofaciais - USP

Prof. Dr. José Roberto Pereira Lauris
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*Um feito se faz
Nunca às custas de um só
Mas de um coletivo.
Da vontade de crescer,
Lapidar, desvendar,
Do afã em ajudar,
Esclarecer, multiplicar,
Do querer um bem maior.*

*Reabilitar é somar,
Orquestrar especialidades,
Aprender com a Natureza.*

*E diante da segmentação dos arcos,
A Ortodontia se faz plena.
Previne, intercepta, corrige.
Esculpe sorrisos,
Devolve a forma.
O perfeito casamento da ciência com beleza,
Do amor e do servir.*

*Dedico essa dissertação a todos os que tem a curiosidade do aprender e
paixão ao ensinar*

AGRADECIMENTO ESPECIAL

À Profa. Dra. Daniela Garib

minha querida orientadora,

Obrigada pela confiança em dividir projetos tão especiais, pelos
ensinamentos, pelo equilíbrio e garra.

Conviver com você é sempre inspirador!

AGRADECIMENTO ESPECIAL

Ao meu maior mestre, **Prof. Omar Gabriel da Silva Filho**, quem me ensinou a amar
a Ortodontia e enxergar toda sua beleza.

Gênio ao extremo e humilde na mesma medida, a convivência com o senhor foi
capaz de influenciar minha vida.

Obrigada por cada minuto!

AGRADECIMENTO

A Deus, pela sua sabedoria infinita, bondade e presença em minha vida

Aos meus amados pais Eduardo e Dulcinéa, meus maiores exemplos e
eterno porto seguro

A minha irmã Karen, por me completar e dar sentido a minha vida.

Ao meu marido Glauco, meu companheiro, meu amor!

Vocês são minha força motriz!

Amo vocês!

AGRADECIMENTOS

A toda minha família, pela alegre convivência e eterno incentivo.

A toda família Batista Almeida, também minha, pelo amoroso acolhimento.

Ao meu tio Omar Ayub, meu parceiro! Obrigada pelo constante carinho, pela sempre pronta ajuda e motivação.

Ao meu tio Carlos e Tia Lynne, por driblarem a distância e serem sempre tão carinhosamente presentes.

Aos avaliadores dessa dissertação na qualificação e banca, suas considerações são muito importantes e sinto-me honrada em recebê-las

Aos meus mestres de Bauru, Leopoldino Capelloza Filho, Mauricio Cardoso, José Antonio Capelloza, Terumi Okada Ozawa, Arlete Cavassan, Araci Malagodi, Tulio Silva Lara, Celeste Okada, Rita Lauris, Flávio Ferrari, Carlos Alberto Aiello por cada conhecimento e pela amizade valiosa.

Aos colegas, funcionários e residentes do setor de Ortodontia do Centrinho, pelas clínicas e aprendizado no desafio da reabilitação. Foi muito bom conviver com cada um de vocês!.

Aos professores, funcionários e colegas do departamento de Ortodontia da Faculdade de Odontologia de Bauru, obrigada pela ajuda, disponibilidade dos equipamentos e pelos ensinamentos. Obrigada especial ao **Daniel Bonné** pelo precioso auxílio ao longo deste trabalho.

Aos alunos do curso de Ortodontia Preventiva e Interceptiva “Dr Omar Gabriel da Silva Filho”, da Profis, pela oportunidade de aprender muito mais do que ensinar. **Aos funcionários**, pela amizade e simpatia ao longo desses anos.

A equipe da UEP, da Pós Graduação, do Arquivo e todos os setores do Hospital, meu muito obrigada pela simpatia, boa-vontade e cordialidade com que sempre me receberam.

Ao Hospital de Reabilitação de Anomalias Craniofaciais, obrigada pelo acolhimento, incentivo e ensino nestes anos! Serei sempre grata!

Aos meus amigos de Bauru, que tanto foram significantes nessa caminhada, meu muito obrigada por cada minuto, por cada momento. Agradeço especialmente a **Louise Resti**, pela amizade, ajuda e companheirismo. Sem você esse trabalho não seria o mesmo! Agradeço a querida **Carolina Maia**, por me emprestar sua casa em BH e me acolher tão calorosamente. A sua amizade é muito importante! E ao **Arthur Cesar**, pela sempre pronta ajuda e alegria.

Ao Bruno Gribel e toda família Compass pelo auxílio nas metodologias, pela paciência, pela sempre carinhosa recepção e cordialidade com que fui recebida em Belo Horizonte! Obrigada e muito sucesso!

Aos amigos e colegas da Pós Graduação, foi maravilhoso conviver com vocês. Obrigada por cada trabalho, cada seminário e por crescermos juntos. Obrigada especial a minha irmã bauruense, **Amanda Ohashi**, pela tão sincera e querida amizade ao longo desses anos.

Aos Professores Stephen Yen, José Polido e Wanda Blasca por me ensinarem que existem muitas formas de aprender e de ensinar. Parabéns pela competência e por incansavelmente buscarem por novas formas de disseminar o conhecimento.

Aos pais e pacientes pela confiança depositada! Vocês são a razão de nossos estudos!

A toda equipe do **Instituto Eduardo Ayub**, vocês são nossa família! Obrigada pelo constante apoio e presença em minha vida.

A todos que colaboraram indiretamente para a conclusão desse trabalho e que por ventura não foram relacionados.

Muito obrigada!!!

ABSTRACT

Objective: The aim of this study was to evaluate the dentoalveolar effects of rapid maxillary expansion in children with unilateral complete cleft lip and palate in comparison with non-cleft patients. **Methods:** The experimental group (EG) was composed of 25 patients with unilateral and complete cleft lip and palate (9 males and 15 females) with a mean age of 10.6 years. The control group (CG) comprised of 27 patients without cleft lip and palate (14 males and 13 females) with a mean age of 9.1 years. Dental models of the maxillary dental arch were obtained immediately pre-expansion (T1) and 6 months post-expansion (T2) at the time of appliance removal. Digital dental models were obtained using the 3Shape R700 3D laser scanner (3Shape A/S, Copenhagen, Denmark). Transversal widths, arch perimeter, arch length, palatal depth, palatal volume, canine and posterior tooth inclination were digitally measured. Paired t-test was used to perform interphase comparisons and independent t-test to perform intergroup comparisons ($p < 0.05$). **Results:** In the experimental group, the expansion produced a significant increase of all maxillary transverse measurements, palatal volume, arch perimeter and palatal depth while decreased the arch length. RME caused a buccal tip of posterior teeth in patients with UCLP. No differences were observed between experimental and control groups for all the measurements performed except for the intermolar distance (6-6), which showed a greater increase in patients with cleft. **Conclusion:** Rapid maxillary expansion showed similar dentoalveolar effects in children with UCLP and without oral clefts.

Key words: Maxillary expansion. Cleft lip and palate. Digital models.

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LISTA DE ABREVIATURA E SIGLAS

WHO	World Health Organization
UCLP	Unilateral Cleft Lip and Palate
BCLP	Bilateral Cleft Lip and Palate
RME	Rapid Maxillary Expansion
RPE	Rapid Palatal Expansion
CG	Control Group
EG	Experimental Group
AL	Arch Length
AP	Arch Perimeter
PD	Palatal Depth
USA	United States of America

LISTA DE SÍMBOLOS

mm	milímetros
mm ³	milímetros cúbicos
%	porcentagem
3-3	distância intercaninos a nível oclusal
3-3'	distância intercaninos a nível cervical
4-4	distância inter primeiros pré molares ou inter primeiros molares decíduos a nível oclusal
4-4'	distância inter primeiros pré molares ou inter primeiros molares decíduos a nível cervical
5-5	distância inter segundos pré molares ou inter segundos molares decíduos a nível oclusal
5-5'	distância inter segundos pré molares ou inter segundos molares decíduos a nível cervical
6-6	distância inter molares a nível oclusal
6-6'	distância inter molares a nível cervical

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1 INTRODUCTION

1 INTRODUCTION

Cleft lip and palate are the most common congenital malformation in men and represents one of the most relevant problems of public health (WHO 2002). It is estimated that a child is born with an oral cleft every 150 seconds in the World (WHO 2002). The prevalence of oral clefts varies considerably in different geographical areas and/or ethnic groups (WHO 2002). In Brazil, it is estimated a prevalence of 1 in 719 (13.9:10000) births, with 51 births a year (WHO, 200). Oral clefts have a multifactorial etiology including genetic and environmental factors (Freitas et al, 2012).

Non-syndromic complete unilateral cleft lip and palate (UCLP) are the most frequent type of oral clefts with a prevalence of 30% (da Silva Filho et al, 1992; WHO 2002). In UCLP patients, the left side is affected twice as much when compared to the right side (Derijcke, et al 1996). The rehabilitation process of these patients is challenging and chronologically extensive. Lip and palate repair are performed at 3 and 12 months respectively (Freitas et al, 2012). The operated lip and palate influence maxillary growth frequently causing anteroposterior, vertical and transversal maxillary deficiency. (Semb, 1991; Freitas et al, 2012). The maxillary transverse deficiency specifically can be assigned to both the absence of the midpalatal suture and the restrictive effect of early lip and palate repair (da Silva Filho et al. 1992). The lip repair probably has a greater influence of maxillary constriction than the palate repair (Enemark et al 1990; Seo et al 2011).

In UCLP newborns, the maxilla shows an increase of all transversal dimensions, as well as a protrusion of premaxilla that is usually deviated to the non-cleft side (Robertson and Fish, 1975; Robertson, 1974; Reisner et al 2013). During growth, arch form is interfered and the maxillary segments tend to move toward medial mainly the smaller one, without any control (Isaacson and Murphy, 1964; Møsted and Dahl, 1990; da Silva Filho et al.1992). In operated patients, the maxillary arch constriction increases, cleft width decreases and no increase on arch widths can be found (Robertson and Fish, 1974; Møsted and Dahl, 1990; Reiser et al 2013), mainly next to the scar tissues (Ishikawa, 1998; Al-Gunaid et al., 2008). As a

consequence, the dental arch usually shows a constriction with an increasing magnitude from the molar to the canine region, so patients reach the mixed dentition period with an anterior rather than posterior severe constriction of the maxilla (Pruzansky, Aduss 1964; Wada, Miyazaki 1975; Wada, Miyazaki 1976; Mazaheri et al. 1993; Spauwen 1993; Diah 2007; Lewis et al 2008). Athanasiou et al (1986) stated that the frequency of crossbite in children with complete UCLP in deciduous, mixed and permanent dentition varied from 45.8 to 61.1%. Semb (1991) found approximately 25% of crossbite while evaluating Oslo CLP Growth Archive. Pruzansky and Aduss (1964) when evaluating 33 children with UCPL during deciduous dentition noted only 30% of crossbite related to collapse of the arch. A recent study showed that children with UCLP in the mixed dentition tend to show a more severe maxillary transversal constriction as the maxilla is more retrognathic (Garib et al. 2013).

In the rehabilitation protocol of patients with UCLP, maxillary expansion is frequently necessary before the secondary alveolar bone graft procedure (Freitas et al. 2012). Rapid maxillary expansion (RME) is commonly used for correcting the maxillary constriction (Isaacson and Murphy, 1964; Matthews, 1975; Athanasiou, 1986 and 1988; Pan, 2007; Holberg, 2007; Wang, 2009; Gautan, 2011; Yang, 2012; Façanha et al., 2014). RME increases the maxillary dental arch, aligns the maxillary segments and provides room in the alveolar cleft for bone graft (Semb, 1991; Yang, 2012; Façanha et al., 2014). The skeletal and dental effects of rapid maxillary expansion in a patient with UCLP were assessed previously in clinical experiments (Isaacson and Murphy 1964; Matthews, 1975; Tindlund et al, 1993; Lewis et al, 2008; Façanha et al. 2014) and finite element studies (Pan, 2007; Holberg, 2007; Wang, 2009; Gautan, 2011). An asymmetric expansion was found by many authors (Isaacson and Murphy, 1964; Matthews, 1975; Wang 2009; Pan, 2007). Isaacson and Murphy (1964) reported no correlation between the cleft location and the relative amount of lateral movement of each maxillary segment, emphasizing that RME laterally repositioned the maxillary segments in an unpredictable manner. Holberg (2007), Pan (2007) and Gautan (2011) considered that the amount of displacement at the cleft side was larger than that at the non-cleft side and the amount posterior expansion was greater than the anterior expansion. Evaluating dental models, Isaacson and Murphy (1964) showed that the anterior and posterior teeth in each

buccal segment expanded laterally approximately the same amount that the expansion screw was opened. The amount at the gingival level, however, was often not as great suggesting lateral tipping of the teeth, without differences for the cleft or non-cleft segments. Tindlund et al (1993), Pan (2007) and Gautan (2011) concluded that a marked amount of displacement and deformation occurred in the dental region on both cleft and non-cleft sides. According to these authors, the most significant transverse displacement was found at the crown of the maxillary permanent first molar with a decreasing effect toward the anterior region of the dental arch. Wang (2009) observed that the reaction force at the molar on the non-cleft side was higher than at the cleft side because expansion met more resistance on the non-cleft. Façanha et al (2014) found similar changes in dental models when compared Haas-type and Hyrax expanders in UCLP patients. These authors have found that RME in complete UCLP produced produced significant increase of maxillary transversal widths without difference between the appliances. Maxillary expansion occurred in a pyramidal shape with the base located at the oral side increasing the cleft area according to clinical (Isaacson and Murphy 1964; Tindlund et al,1993) and finite element models studies (Pan, 2007; Holberg 2007; Wang, 2009; Gautan, 2011).

No previous studies on RME in patients with cleft analyzed the arch volume and tooth inclination. Additionally, no previous studies compared the RME effects in cleft and non-cleft patients. Therefore, the aim of this study was to evaluate the dentoalveolar effects of rapid maxillary expansion in children with complete UCLP in comparison with non-cleft patients. The null hypothesis was that RME produces similar effects in patients with and without oral clefts.

2 LITERATURE REVIEW

2 LITERATURE REVIEW

Cleft lip and palate is considered a serious birth defect which affect approximately 1 in every 600 newborn babies worldwide. It has a multifactorial etiology, joining genetic and environmental factors, being the second one important for prevention (WHO, 2002).

Derijcke et al (1996) reviewed epidemiological studies on the incidence of oral clefts. The authors called the attention about the higher incidence of cleft lip and/or palate compared with cleft palate and stated that there was a predominance of girls in the cleft palate group, while the cleft lip and/or palate group comprised mainly boys. The left side was affected twice as often as the right side.

Freitas et al (2012) described the treatment protocol of Hospital for Rehabilitation of Craniofacial Anomalies. For all cleft types, the surgery protocol starts at three months with the lip repair surgery (cheiloplasty), followed by the palatoplasty, the surgical reconstruction of the palate, at the age of 12 months.

On a subsequent study, Freitas et al (2012) described the importance of pediatric and orthodontic care on cleft patients. The authors suggested that pediatric dentistry follows patients from growth to adolescence, motivating breastfeeding, maintaining a high level of oral hygiene and refereeing for orthodontic treatment in adequate timing. The protocol of orthodontic interventions should be simplified, prioritizing the approaches that have significant impact on the final outcome.

2.1 Maxillary dental arch

In 1964, Pruzansky and Aduss studied 33 cases of complete UCLP to evaluate arch form and deciduous occlusion. Prior to lip repair, the casts revealed great separation between the segments. On the other hand, after lip repair there was a coaptation of the palatal segments with narrowing of the palatal cleft on anteroposterior length. One third of the total sample presented no crossbite and only 30% of crossbite related to collapse of the arch was found, mainly canine crossbite.

Cephalometric studies using metal implants demonstrate that the suture growth in patients without cleft have an important role to the maxillary transverse development (Björk and Skieller 1974).

Robertson and Fish (1975) studied serial records of fifty patients with complete unilateral cleft lip and palate from birth to 3 years of age. At birth, an increase of all transversal dimensions was found. During the evaluated time, a reduction in the arch width in the intercanine area occurred while molar arch width slightly decreased when compared to non-cleft patients. Despite of that, in the 3-year-olds maxillary arch widths was greater in non-cleft children, with individual variations.

Matthew (1975), described that the secret of success in moving bony segments rather than teeth contained in them lies in the rapidity of the expansion that should be performed in 3 weeks, turning the screw 3 times a day and preferably only on permanent teeth.

Wada et al (1975) compared growth changes of the maxillary arch of 62 normals and 87 complete unilateral cleft lip and cleft palate subjects. The authors showed that by the age of 4 the depths and heights of alveolar points in the cleft group were found to be smaller than those of the normal group.

With the same sample, in 1976, Wada et al extended the evaluation. The children ranged in age from six months to four years and were evaluated at four developmental stages. In order to clarify the character of the maxillary arch deformity, measurements of depth, width, height, and length were made and analyzed statistically. Prior to lip repair, cleft and non-cleft subjects showed similar patterns of maxillary growth, which decreased with age and after surgery. Anterior-posterior growth inhibition of the maxilla appeared to occur after lip repair and to remain a problem by age four.

Dahl (1979) using metallic implant method studied radiographically the transverse maxillary growth in 5 boys with combined cleft lip and palate – 3 with bilateral and 2 with unilateral cleft lip and palate. He concluded that the growth curves for maxillary with differed definitely from normal and the spontaneous

transverse palatal growth was inhibited in this group. The increase in maxillary width was mainly produced by orthodontic widening.

Rune et al (1980) also using metal implants in 1 unilateral and 4 bilateral complete cleft lip and palate patients evaluated the movement of maxillary segments after expansion and secondary bone grafting and concluded that there was great increase of dental arch that could be attributed to factors such as bone bending, movement of the teeth and rotation of the segments. Besides complicated movements of the segments, a stable relationship between them was not achieved by means of secondary bone grafting.

Athanasίου et al (1986) analyzed the dental arch relationship during deciduous, mixed and permanent dentition of 72 children with UCLP to estimate the frequency of crossbite in surgically treated cleft lip and palate patients and revealed that the incidence of crossbite from deciduous to permanent dentition ranged from 45.8 to 61%.

Athanasίου et al (1988) assessed arch dimensions of the same sample from the previous study comparing to a non-cleft sample with the same age. The dental casts evidenced that maxillary interdental widths and lengths were significantly smaller than the control group at all ages, except for intermolar width at age 12 years.

Enemark et al (1990) evaluated 57 complete UCLP followed longitudinally from birth to 21 years of age. They found that Fifty-one patients had acceptable occlusion following orthodontic treatment, despite the majority had deficiency in growth probably attributed to the early plastic surgeries. Nevertheless, normal and acceptable profiles were obtained in 50/57 of the patients.

Mølsted and Dahl (1990) searched for asymmetry of the maxilla in children with complete UCLP and compared to a group of 24 children with incomplete clefts of the lip using cephalometric films. They found that there was a positional deviation and a change of arch shape of the maxillary segment on the cleft side. The basal maxillary width was similar in the two groups and at the dentoalveolar level a decrease in width was localized to the cleft side in the UCLP group.

The analysis of 257 lateral and frontal cephalometric of complete UCLP patients from Oslo Growth Archive were evaluated by Semb in 1991. 25% of posterior crossbite was found as well as a short, retrusive maxilla with vertical elongation of the anterior face, even though upper face height was shorter. A retrusive mandible was also found. Between 5 to 18 years of age there was almost no increase in length of the maxilla measured.

Da Silva Filho et al (1992) evaluated 97 study models of untreated complete unilateral cleft lip and palate adults, with and without Simonart's band. Maxillary dimension and arch form were compared to a control group of 51 non-cleft patients. They found that the dental arch was severely affected by the presence of a cleft becoming constricted mainly at medial and anterior region. The presence of Simonart's band affects the cleft arch form, redirecting the anterior part of the major segment towards the minor one.

Spauwen et al (1993) determined the differences in maxillary and dentoalveolar relationship between untreated and treated patients with unilateral cleft. They concluded that surgical treatment seems to cause maxillary and dentoalveolar deformities once the surgeries had a molding effect on the maxilla and mandible.

Mazaheri et al (1993) evaluated upper dental arch form in complete UCLP patients from one month to four years, after lip and palate repair. The casts were available at four age increments. A moulding effect of lip repair on the alveolar segments caused the contact of the alveolar segments at the cleft site. After palatal repair, the tendency of segment contact. At age 4 was perceived a tendency that previous overlap of segments improved to a more desirable nonoverlapped relationship.

Ishikawa et al. (1998), investigated the relationship between maxillary dental arch form and distribution of postsurgical scar tissue of 21 Japanese isolated cleft patients. The scar tissue was classified into five types and clearly indicated that the relationship between maxillary dental arch constriction was closely related to the scar tissue distribution on palates.

In 2007, Diah et al. compared the growth potential of adult patients with unoperated clefts to the normal population. Measuring palatal surface area showed a significantly smaller area in patients with cleft when compared to non-cleft controls. A significantly narrow area was in the anterior part up to the first premolar region as compared to the control group, especially in the complete cleft groups (UCLP and BCLP). Dentoalveolar arch was also deeper and longer in these complete cleft groups.

In 2008, Al-Gunaid et al investigated the relapse tendency in the maxillary dental arch form of 32 UCLP patients treated by one stage surgical palatal closure using dental casts. The maxillary arch could be divided in three groups according to their symmetrical or collapsed form. The authors concluded that the arch form might influence the stability of the maxillary dental arch widths after orthodontic treatment when a severe degree of maxillary narrowness and collapse of both segments were previously existing.

Lewis et al (2008) evaluated differences in size of the maxillary permanent anterior teeth and arch dimensions using study casts of 30 subjects with repaired unilateral cleft lip and palate (UCLP) and thirty control subjects. They found a narrower maxillary intercanine width on cleft group as also smaller anterior teeth.

Seo et al (2011) studied lateral cephalograms of cleft children taken 1 month before alveolar bone grafting. They concluded that when the degree of cleft involvement increases from the primary palate to the secondary palate, the predominance of the Class III relationship and the hyperdivergent pattern increases likewise.

Reiser et al, in 2013, analyzed the study models of 79 cleft children (28 with UCLP, 39 with cleft palate and 12 with Pierre Robin sequence). Cleft size and arch dimensions was measured before lip and palate surgeries and at 2 and 5 years, respectively. They found that cleft widths decreased from infancy up to 2 years, anteroposterior cleft length was unchanged and at 5 years the children with unilateral cleft lip and palate had similar maxillary widths as the children with cleft palate and/or Pierre Robin sequence.

2.2 Maxillary Expansion on cleft patients

In 1964, Isaacson and Murphy evaluated some effects of RME in cleft lip and palate patients through lateral, anteroposterior roentgenograms and study models. Six silver implants were placed bilaterally in the maxilla of 5 males patients and evidenced that the expansion occurred in the osseous defect between the premaxilla and maxilla or the incisive suture region instead of at the midpalatal suture as occurs in non-cleft palates. Maxillae lateral movement occurred asymmetrically and indicated a lateral tipping of the teeth. The amount of lateral tipping, however, did not appear to significantly differ between cleft and non-cleft quadrants.

Tindlund et al (1993) studied the intercanine widening of maxillary expansion using a modified quad-helix in 112 cleft lip and palate patients with crossbite comparing to a control group. Bilateral cleft lip and palate patients had a greater expansion, followed by the unilateral ones with mean intercanine widening of 8.9 mm.

Holberg et al (2007) using three finite element models compared the biomechanical effect on maxillary expansion in one complete UCLP, one BCLP and one non-cleft patient of 20 years old. The bilateral cleft model showed higher expansion, followed by the unilateral one and then the model without cleft. They also concluded that there were usually slightly higher expansions on the cleft side when compared to the side that was not clefted.

Pan et al (2007) also studied the biomechanical effect of RPE using a finite element model of a 14 years old female patient with UCLP. The authors found that an asymmetric expansion was evidenced more on the cleft side than on the non-cleft side with the most significant transverse displacement was at the crown of the maxillary first molar. The same occurred with the level of stress distributed that was greater at the cleft side.

With similar findings, Wang et al (2009) with a complete UCLP finite element model of a 14 years old girl stated that an asymmetric distribution of the displacement occurred on dental and skeletal complex, differing cleft from non-cleft sides. There was a higher reaction force of the molar on the side without cleft than on

the cleft side because the same transversal expansions met a bigger resistance on the normal side than that on the cleft side.

The 16 years old male finite element model from Gautam et al (2011) showed an asymmetric response of the cleft and non-cleft segments with expansion forces. The maximum lateral displacement for maxillary teeth was observed at the second molar, followed by the first molar, second premolar, canine, and central incisor on both cleft and non-cleft sides; consequently, posterior expansion was greater compared to the anterior expansion.

Yang et al (2012) after a review of the literature suggested that the growth of the maxillary dental arch in cleft patients is inhibited owing to congenital developmental deficiency, palatal muscle strain, scar retraction, and a history of surgical treatment. Consequently, maxillary transverse deficiency, constricted upper arch, and crossbite are common manifestations in these patients. The authors made RPE using Hyrax appliance after secondary alveolar bone grafting and found opening of midpalatal suture together with significant increases in maxillary and dental arch width.

When comparing transversal changes on maxillary dental arch after RPE, Façanha et al (2014) stated that both Haas and Hyrax expanders promote great increase on unilateral cleft lip and palate arches with higher increase at inter molars width.

2.3 Maxillary expansion on non-cleft patients

Davis and Kronman (1969) analyzed 26 cephalometric x-rays and dental casts from Caucasian children who had undergone RME. The distances between the maxillary tips increased in all cases, greater at the molar region than at intercanine. The height of the palatal vault did not decrease and was found to be relatively constant, but more flattened.

In 1961, Haas brought about the potential benefits of maxillary expansion on 10 mouth breathers patients. The author observed that the gap created between the central incisor was about one half as great as the distance the screw had been opened, the central roots diverged a greater distance than the crowns and that after manipulation, the roots remain diverged while the crowns tipped toward the midline.

Few years later (1964), Haas stated that the acrylic masses of the split palatal appliance move laterally, the inclined planes of the palatal vault would operate to force the appliance occlusally.

Sixty patients treated with RPE was described by Wertz in 1970. Maxillary halves arced laterally with fulcrum located close to the maxillofrontal suture. Besides skeletal widening, apparently alveolar bending accounted.

Fried (1971) evaluated 38 patients with unfavorable physical size of the palate after maxillary expansion in search of increase palate size and alter palatal contours. He concluded that there was a significant increase in vault width after expansion and lowering of the palatine processes of the maxilla. The maxillary central incisors tended to move mesially and commonly uprighted following stabilization, helping to close the midline diastema. A time after that, the roots began move medially and in some months the teeth resumed their original long axis.

Lawrence Andrews (1972) described the six keys to normal occlusion evaluating 120 models of not orthodontic treated patients. Crown inclination was determined by the resulting angle between a 90 degrees line to the occlusal plane and a tangent line to the middle of the labial or buccal clinical crown.

Wertz and Dreskin (1977) studied the average response to midpalatal suture opening and concluded that in older patients maxillary expansion was not equally effective and most difficult relapse was seen younger patients. They also found that the palate descended an average of 1 mm and the mandible permanently rotates open less than 1 degree.

Adkins et al (1990) evaluated arch perimeter changes on rapid palatal expansion using Hyrax appliance on 21 patients. The dental casts and photographs were obtained before treatment and 3 months after stabilization. RPE increased maxillary arch perimeter mainly at the first molars (6.5mm) than at the canines (2.9mm). Buccal tipping of the posterior anchor teeth were also observed as well as arch perimeter decreased associated to slight palatal movement of the maxillary incisors.

Haas-type appliance was used on that study due to its tissue-borne anchorage represented by the acrylic on palate. The design followed the one suggested by da Silva Filho (1995) with banded first permanent or second deciduous molars represented the dental anchor associated with C-shaped extension of the internal connection bar up to the buccal surface of the canine.

Garib et al (2005) evaluated rapid maxillary expansion dentoskeletal effects through computed tomography (CT), comparing tooth tissue-borne (Haas-type) and tooth-borne expanders (Hyrax). The authors stated that RME produced a significant increase in all transverse linear dimensions, decreasing in magnitude from dental arch to basal bone, with buccal movement of the maxillary posterior teeth, by tipping and bodily translation. Tooth-borne and tooth tissue-borne expanders tended to produce similar orthopedic effects.

Garib et al (2013) compared 144 pairs of dental casts of patients with UCLP with 40 pairs of dental casts of noncleft Class I patients aiming to compare the maxillary arch widths of patients with UCLP and different interarch relationships. They concluded that maxillary arch widths were significantly smaller on UCLP group, tending to show more severe transverse maxillary arch deficiencies and more severe sagittal discrepancies when compared to non-cleft patients.

3 PURPOSE

3 PURPOSE

The aim of this study was to compare the effects of rapid maxillary expansion in children with complete UCLP and non-cleft individuals, focusing on the following features:

- Arch widths, length and perimeter
 - Palatal depth and volume
 - Posterior teeth inclination
-

4 METHODS

4 METHODS

This clinical prospective study was approved by the Ethical Committee (164.747) at the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo (HRCA-USP). All patients signed the informed consents.

The experimental group (EG) was composed of 25 patients with complete unilateral cleft lip and palate (9 males and 15 females) with a mean age of 10.6 years. This group was consecutively selected from February of 2010 to March of 2011 at the Orthodontics Clinic of the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo (HRCA-USP), Bauru, São Paulo, Brazil. The inclusion criteria were: 1. Both sexes; 2. Mixed dentition or early permanent dentition; 3. History of lip and palatal repair in early childhood; 4. Presence of maxillary constriction and need for maxillary expansion prior to secondary alveolar bone graft; 5. Initial palatal depth enough to receive the Haas-type expander. Patients with shallow palate were expanded with Hyrax appliances and were not selected for this study.

The control group (CG) comprised 27 children without cleft lip and palate (14 males and 13 females) with a mean age of 9.1 years, treated at the Orthodontic program of PROFIS, Bauru, São Paulo, Brazil. This group was consecutively selected from February of 2012 to February of 2014. The inclusion criteria were: 1. Both sexes; 2. Mixed dentition or early permanent dentition; 3. Presence of maxillary constriction and need for maxillary expansion; 4. Maxillary expansion performed with Haas-type appliance.

The exclusion criteria for both groups were: 1. Need of maxillary protraction; 2. Associated syndromes; and 3. History of previous orthodontic intervention.

Rapid maxillary expansion (RME) was carried out with Haas-type expanders in all patients of EG and CG. All patients underwent the same activation protocol of one complete turn a day (2/4 twice a day) during 7 days. When necessary, more activation was performed until reaching a slight overcorrection. After

the expansion active phase, the appliance was maintained as retention for a 6-month period.

Dental models were obtained before expansion (T1) and 6 months post-expansion, at the time of appliance removal (T2). The dental models with standard trimming were scanned with a 3Shape R700 3D laser scanner (3Shape A/S, Copenhagen, Denmark). The image was saved in STL format, compatible with Windows and others specific software of tridimensional images.

Using the software OrthoAnalyzer™ 3D (3Shape A/S, Copenhagen, Denmark), arch widths, length and perimeter were measured as illustrated in Figures 1 to 4. Palatal depth (Figure 5) and molar and canine inclination (Figure 6) were also measured using the same software. Posterior tooth inclination was measured using as a reference an occlusal plane passing through the mesial buccal tip of maxillary first molars bilaterally and through a mesial-incisal point at the left central incisor (Figure 6A). Tooth long axis was represented as an arrow at the virtual setup applicative of OrthoAnalyzer software (Figure 6B and D). On a buccal view of each posterior tooth, this arrow was mesial-distally manipulated to represent tooth angulation according to Andrews's EV point (Andrews, 1972). On the distal view of each tooth, the arrow was manipulated buccal-lingually representing crown torque (Figure 6C and E) according to Andrews (1972). The angle between the arrow and the occlusal plane was automatically calculated by the software. After expansion, increasing values of the angle meant buccal inclination of the teeth and decreasing values meant lingual inclination of the teeth.

Figure 1 – Transversal dimensions of maxillary dental arch at occlusal level. From anterior to posterior the picture shows 3-3 (inter canine distance), 4-4 (inter first pre molars or inter deciduous first molars distance), 5-5 (inter second pre molars or inter deciduous second molars distance) and 6-6 (inter molar distance).

Figure 2 – Transversal dimensions of maxillary dental arch at cervical level. From anterior to posterior the picture shows 3-3' (inter canine distance), 4-4' (inter first pre molars or inter deciduous first molars distance), 5-5' (inter second pre molars or inter deciduous second molars distance) and 6-6' (inter molar distance).

Figure 3 – Arch length (AL). Arch length was measured in the horizontal plane from the mesial gingival papilla of permanent first molars to the point between the maxillary central incisors at interincisive papilla (11.21 point).

Figure 4 – Arch perimeter (AP). Arch length was measured in the horizontal plane from the mesial aspect of permanent first molars to the point between the maxillary central incisors.

Figure 5 – Palatal Depth (PD). The palatal depth was measured from a line passing through the mesial gingival papilla of permanent first molars to the deepest point on the palate, perpendicular to the arch length.

Figure 6A to E– Occlusal Plane passing through the mesial buccal tip of maxillary first molars bilaterally and through a mesial-incisal point at the left central incisor (A). Posterior teeth inclination measured in the maxillary permanent first molars or deciduous second molars (B and C) and deciduous canines (D and E). The tipping of the buccal aspect of posterior teeth and canines were measured using the occlusal plane as reference. The variable was expressed as the external angle. Increasing values mean buccal tipping of the evaluated teeth.

The palatal volume was measured before and after maxillary expansion using the software Appliance Designer (3Shape A/S, Copenhagen, Denmark) and the software VistaDent 3D software (Dentsply - Nova York, EUA). In the Appliance Designer, a plane representing the upper limit of the palate was created passing through the lower limit of interincisive papilla and through the midpoint of the lingual gingival margin of permanent maxillary first molars (Figure 7). The posterior limit for volume measurement was a plane tangent to the distal aspect of first maxillary molars (Figure 8). The midpoint of the lingual aspect of each maxillary tooth at the level of gingival margin represented the lateral border for volume measurement (Figure 8). When a tooth was totally out of the dental arch, both buccal or lingually, it was not considered for lateral demarcation of volume. A volumetric image of the palate observing the standardized borders was then created (Figure 9 A, B and C). Volume calculation in mm³ was performed using VistaDent 3D software (Dentsply - Nova York, EUA) as illustrated in Figure 10.

Figure 7 – Demarcation of the upper limit of the palatal volume was performed at the lower limit of interincisive papilla and through the midpoint of the lingual gingival margin of permanent maxillary first molars.

Figure 8 – Lateral limits of the palatal volume considered the midpoint of lingual aspects of the maxillary teeth at the level of gingival margins. The posterior limit of palatal volume was represented by a plane tangent to the distal aspect of first maxillary molars.

Figure 9A to C – Palatal Volume

Statistical Analysis

Thirty percent of the sample was measured twice, with a 1 month-interval for evaluating the study error. Casual and systematic errors were evaluated using Dahlberg Formula and paired-t tests.

The interphase changes were evaluated with paired-t tests. Intergroup comparisons were performed using independent t-test. The significance level regarded was 5%. Analyses were performed in SPSS software (20.0 version).

5 RESULTS

5 RESULTS

The casual error varied from 0.17 to 94.47 (Table I). No significant systematic error was found (Table I).

When the comparison between the initial forms of each group was performed (Table II), a statistically significant difference was found for intercanine width (3-3' and 3-3) and first premolar width (4-4' and 4-4). The experimental group had a decreased anterior arch width compared to the control group (Table II). Additionally, arch length, arch perimeter and palatal volume were significantly decreased in the patients with cleft compared to non-cleft patients (Table II). Tipping of posterior teeth were similar between the experimental and control groups (Table II).

In the experimental group, the expansion produced a significant increase of all maxillary transverse measurements, palatal volume, arch perimeter and palatal depth (Table III). On the other hand, RME in patients with UCLP produced a significant decrease of arch length (Table III). Posterior teeth were buccally tipped after expansion (Table III).

In non-cleft patients, RME caused a significantly increase of all maxillary transverse measurements, arch perimeter and palatal volume (Table IV). Arch length showed no changes while the palatal depth decreased (Table IV). Posterior teeth tipped toward buccal after expansion (Table IV).

Table V shows the comparison of RME changes between the experimental and control groups. Expansion produced a similar effect in both groups, except for the intermolar distance (6-6) that had a greater increase in the experimental group.

Table I- Method error.

Variable	1 st measurement	2 nd measurement	Difference	Casual error (Dahlberg)	Systematic error (p)
3-3'	27.08	27.22	0.14	0.89	0.16
3-3	31.4	31.03	-0.37	0.98	0.27
4-4'	27,52	27,6	0.08	0.19	0.14
4-4	38,92	38,56	-0.36	0.17	0.58
5-5'	31.11	31.23	0.12	0.19	0.77
5-5	43.99	43.61	-0.38	0.34	0.06
6-6'	36.06	36.3	0.24	1.41	0.37
6-6	46.85	46.71	-0.14	0.55	0.36
Arch Length	25.58	24.98	-0.6	0.21	0.12
Palatal Depth	14.53	14.55	0.02	0.30	0.34
Arch Perimeter	94.95	95.04	0.09	0.34	0.35
Palatal Volume	2170.59	2218.3	47.71	94.47	0.44
Tipping3	64.21	64.33	0.12	0.42	0.12
Tipping5	62.85	62.31	-0.54	1.05	0.096
Tipping6	75.66	74.77	-0.89	0.62	0.95

* Statistically significant.

Table II- Comparison of starting forms between groups CG and EG

Variables	Experimental Group		Control Group		p
	Mean	SD	Mean	SD	
	T1		T1		
3-3'	22.13	3.45	25.36	2.68	0.001*
3-3	27.50	3.51	31.44	2.62	0.000*
4-4'	24.62	2.86	26.75	1.97	0.003*
4-4	35.75	3.28	37.69	2.77	0.030*
5-5'	30.21	2.67	30.58	1.97	0.571
5-5	42.45	2.94	42.97	2.56	0.509
6-6'	36.09	3.25	35.28	1.92	0.289
6-6	45.63	2.70	45.37	2.40	0.732
Arch length	23.73	2.81	26.42	1.85	0.000*
Arch perimeter	91.59	5.79	95.98	6.75	0.016*
Palatal depth	12.81	2.68	13.49	1.77	0.296
Palatal Volume	4838.03	1415.13	5918.20	1596.81	0.017*
Tipping3	70.42	9.89	73.61	4.55	0.186
Tipping5	68.59	5.92	66.88	5.35	0.256
Tipping6	71.17	6.38	70.20	3.74	0.557

* Statistically significant.

Table III- Comparison between pre and post-expansion phases of the experimental Group (Paired t test).

Variables	Pre-expansion		Post-expansion		Change		p
	Mean	SD	Mean	SD	Mean	SD	
3-3'	22.13	3.45	25.96	3.30	4.39	2.22	0.006*
3-3	27.50	3.51	31.07	3.67	4.28	2.51	0.003*
4-4'	24.62	2.86	29.85	3.02	5.22	1.44	0.000*
4-4	35.75	3.28	40.31	7.88	5.95	1.88	0.000*
5-5'	30.21	2.67	35.45	2.47	5.25	1.72	0.000*
5-5	42.45	2.94	48.41	2.71	5.96	1.99	0.000*
6-6'	36.09	3.25	41.21	2.96	5.18	1.88	0.000*
6-6	45.63	2.70	51.12	2.76	5.50	1.66	0.000*
Arch length	23.73	2.81	22.67	3.09	-1.39	1.73	0.012*
Arch perimeter	91.59	5.79	95.24	5.04	4.46	3.00	0.000*
Palatal depth	12.81	2.68	13.27	2.65	1.18	1.18	0.000*
Palatal Volume	4838.03	1415.13	5742.82	1659.86	905.21	547.95	0.000*
Tipping3	70.42	9.89	74.00	7.88	3.58	7.29	0.027*
Tipping5	68.59	5.92	71.25	4.92	2.66	5.15	0.032*
Tipping6	71.17	6.38	73.35	7.23	2.17	5.27	0.006*

* Statistically significant.

Table IV- Comparison between pre and post-expansion phases of the Control Group (Paired t test).

Variables	Pre-expansion		Post-expansion		Change		p
	Mean	SD	Mean	SD	Mean	SD	
3-3'	25.36	2.68	30.22	2.86	4.86	1.77	0.000*
3-3	31.44	2.62	36.22	2.49	4.87	1.77	0.000*
4-4'	26.75	1.97	31.73	2.22	5.01	1.37	0.000*
4-4	37.69	2.77	42.89	2.67	5.25	1.36	0.000*
5-5'	30.58	1.97	35.33	2.20	4.75	1.31	0.000*
5-5	42.97	2.56	48.46	2.38	5.49	1.31	0.000*
6-6'	35.28	1.92	39.48	2.62	4.29	1.23	0.000*
6-6	45.37	2.40	49.74	2.71	4.44	1.23	0.000*
Arch length	26.42	1.85	26.46	1.85	0.73	0.72	0.856
Arch perimeter	95.98	6.75	101.77	5.18	5.79	3.27	0.000*
Palatal depth	13.49	1.77	12.64	2.04	-1.13	0.47	0.000*
Palatal Volume	5918.20	1596.81	6625.35	1736.89	747.87	540.62	0.000*
Tipping3	73.61	4.55	77.38	4.78	3.77	4.32	0.000*
Tipping5	66.88	5.35	71.78	5.07	4.89	4.96	0.000*
Tipping6	70.20	3.74	75.34	6.49	5.14	4.50	0.014*

* Statistically significant.

Table V. Comparison between experimental and control groups (independent t tests).

Variables	EG		CG		Difference	p
	Mean	SD	Mean	SD		
3-3'	4.39	2.22	4.86	1.77	-0.47	0.448
3-3	4.28	2.51	4.87	1.77	-0.59	0.377
4-4'	5.22	1.44	5.01	1.37	0.21	0.617
4-4	5.95	1.88	5.25	1.36	0.7	0.153
5-5'	5.25	1.72	4.75	1.31	0.5	0.253
5-5	5.96	1.99	5.49	1.31	0.47	0.323
6-6'	5.18	1.88	4.29	1.23	0.89	0.056
6-6	5.50	1.66	4.44	1.23	1.06	0.015*
Arch length	1.39	1.73	0.73	0.72	0.66	0.087
Arch perimeter	4.46	3.00	5.79	3.27	-1.33	0.139
Palatal depth	1.18	1.18	1.13	0.47	0.05	0.846
Palatal Volume	905.21	547.95	747.87	540.62	157.34	0.325
Tipping3	3.58	7.29	3.77	4.32	-0.19	0.983
Tipping5	2.66	5.15	4.89	4.96	-2.23	0.137
Tipping6	2.17	5.27	5.14	4.50	-2.97	0.140

* Statistically significant.

6 DISCUSSION

6 DISCUSSION

Although rapid maxillary expansion was extensively studied in non-cleft patients, scarce evidence of maxillary effects is found for patients with oral clefts. The morphology of the maxillary dental arch is distinct in patients with cleft compared to non-cleft patients (Robertson and Fish, 1975; Rune et al, 1980; da Silva Filho et al, 1992; Tindlund et al, 1993; Athanasiou, 1986; Athanasiou, 1988; Diah, 2007). In this study, the experimental group showed a more severe constriction of the dental arch in the anterior region compared to the control group (Table II). These results are in accordance with Robertson and Fish (1975), Dahl (1979), da Silva Filho (1992), Athanasiou (1988), Mølsted and Dahl (1990), Ishikawa et al. (1998), Al-Gunaid et al (2008), Lewis et al (2008) who showed that the maxillary arch of patients with complete UCLP is more constricted in the intercanine region because the shift of the anterior region of the minor segment toward medial. The anterior arch constriction in patients with complete UCLP is observed even in unoperated patients and has a greater severity in operated patients (da Silva Filho, et al. 1992; Spauwen, et al 1993; Diah et al, 2007). Previous authors assigned the arch constriction in individuals with UCLP to the absence of the midpalatal suture coupled with the transversal growth deficiency produced by early plastic surgeries including lip repair and palate repair (Subtelny and Brodie, 1954; da Silva Filho et al, 1992; Ishikawa et al., 1998; Al-Gunaid et al, 2008).

In our study, patients with UCLP showed a decreased arch perimeter compared to non-cleft patients with maxillary arch constriction (Table II). These findings agree with Athanasiou (1988) who found that the arch length in patients with UCLP is always smaller than in children without oral clefts from the deciduous to the permanent dentition. The smaller maxillary arch length can be associated to the sagittal maxillary growth deficiency caused by early plastic surgeries mainly the lip repair surgery (Semb 1991). Both transversal and anteroposterior maxillary growth deficiency had an impact on the arch perimeter and palatal volume that was decreased in the experimental group (Table II).

Surprisingly, the initial tipping of maxillary posterior teeth was similar in patients with and without cleft (Table II). This result suggests that in patients with complete UCLP, the posterior teeth do not compensate the greater maxillary constriction with inclination changes. In addition, the similar posterior tooth inclination in both groups suggests that the difference in the severity of maxillary constriction between cleft and non-cleft patients has essentially a skeletal background.

When considering the RME effects on the experimental group (Table III), a statistically significant increase of all transversal dimensions, arch perimeter, palatal depth and palatal volume was observed after expansion. The increase in arch widths varied from 4.28 to 5.96 mm (Table III). The amount of transversal gain slightly increased from the canine region toward the posterior region (Table III) in accordance with previous studies (Pan 2007, Wang 2009, Gautam, 2011; Façanha et al. 2014). A greater intercanine widening of 8.9 mm was found by Tindlund et al (1993) using a modified quad-helix on UCLP patients.

The arch perimeter showed a statistically significant increase after expansion in individuals with cleft (Table III). The mean increase corresponded to 4.5mm and may be explained by the lateral displacement of maxillary segments with enlargement of the alveolar and palate cleft widths (Subtelny and Brodie 1954, Isaacson and Murphy 1964). No previous studies reported the changes of arch perimeter in patients with UCLP after RME.

The arch length showed a mean decrease of 1.3mm (Table III). This result can be explained by the posterior movement of the premaxilla toward the expanded dental arch caused by the tension of the operated upper lip. The arch length decrease was reported previously also in non-cleft individuals (Adkins et al. 1990). Some authors reported that, in patients without cleft, there is a lingual tipping of the incisors after expansion in response to the stretched circumoral musculature (Haas 1965; Wertz 1970). The incisor lingual inclination closes the midline diastema observed after orthopedic expansion and decreases the arch length. Interesting to note that in our control group, the arch length remained stable (Table IV). These differences may be because patients of a control group were in the mixed dentition differently from patients from the study of Adkins et al. (1990) who were in the permanent dentition. In patients with cleft, lingual bars in the incisors can be added to

the Haas-type expander in order to prevent this effects who have an initial arch length deficiency. The lingual bars would be indicated specially in those patients with slight Class III skeletal pattern elected for compensatory orthodontic treatment.

Palatal depth slightly increased after expansion in the experimental group (Table III). This change can be explained by posterior teeth extrusion caused by RME (Wertz 1970) together with an absence of lower displacement of the palatal vault due to the presence of the acrylic pad of the expander. On the other hand, the palatal depth in the control group had a slight but significant decrease (Table IV). Fried (1971) and Haas (1961 and 1965) associate this finding to the fact that the palatine processes of the maxilla were lowered as a result of the outward tilting of the maxillary halves. Wertz and Dreskin, 1977 found that the palate descended an average of 1 mm. Conversely, Davis and Kronman (1969) reported that the palatal vault did not decreased and remained stable after expansion, despite more flattened.

This study was the first study to describe the palatal volume changes caused by RME. In the experimental group, there was a statistically significant increase of the palatal volume after expansion (Table III). The mean increase was 900mm³ considering the dental arch to the distal aspect of the first permanent molars. This increase is important for providing enough room for rest and function of the tongue (Subtelny and Brodie 1954). No previous studies were found on the palatal volume changes after expansion for comparison, probably because the digital model technology is relatively new.

Posterior teeth were buccally tipped after orthopedic expansion (Table III). The magnitude of tip change, however, was small and varied from 2.1 to 3.6 degrees (Table III). These results are in agreement with the literature on RME in non-cleft patients (Adkins et al., 1990; Garib et al., 2005) and patients with cleft (Pan, 2007; Wang, 2009). Isaacson and Murphy (1964) reported that the amount of buccal tipping did not significantly differ between cleft and non-cleft segments. Adkins et al. (1990) found a mean buccal tip of 5 degrees in the maxillary permanent first molar after RME in non-cleft individuals. On the other hand, Oliveira et al (2004) have not found tip changes of posterior teeth after orthopedic expansion in non-cleft patients. The asymmetric displacement at the cleft side when comparing to the non-cleft side found

on finite element studies could not be analyzed on digital dental models (Isaacson 1964; Pan 2007; Holberg 2007; Wang 2009; Gautan, 2011).

Table V shows the comparison of RME changes between the experimental and control groups. Considering our literature review, no previous studies have compared the effects of RME in patients with complete cleft lip and palate and a non-cleft control group. RME produced a very similar effect in both groups for all the analyzed parameters. The only difference between the experimental and control groups was the intermolar distance (6-6) which had a greater increase in patients with complete UCLP. These findings might suggest that the expansion screw was more activated in patients with cleft in comparison to the controls. The greater expansion in the molar region in patients with cleft may have two possible explanations. Considering that Haas-type expander do not permit differential expansion, the screw may be activated to compensate the greater intercanine constriction observed in the experimental group. Secondly, because of a common Class III skeletal pattern due to the maxillary sagittal deficiency, in patients with complete UCLP the maxillary arch occludes with a wider region of the mandibular arch. If the classic of expansion amount parameters are used trying to align the palatal cusp tip of maxillary posterior teeth with the buccal cusp tip of mandibular posterior teeth, intermolar width is over expanded. The limitation of our study is the different anteroposterior facial pattern of the experimental and control groups and the impossibility of standardizing the amount of screw activations. On the other hand, these differences highlighted that the amount of expansion in patients with cleft should be chosen according to inferior intermolar width. The professional must also consider if the mandibular arch is also constricted and transversally compensated. In patients with UCLP and Class III skeletal pattern, the decision of treating the case surgically or in a compensatory manner should also be considered when setting the expansion amount during the RME procedure. Surgical treatment of maxillary advancement demands lesser expansion than the camouflage option.

Further studies comparing rapid and slow expansion in complete UCLP should also be performed. Additionally, evaluating RME effects in complete bilateral cleft lip and palate would be beneficial.

7 CONCLUSION

7 CONCLUSION

In patients with complete UCLP, RME produced a significant increase of maxillary arch widths, arch perimeter and palatal volume. Posterior teeth were buccally tipped. A similar pattern of RME effects was observed for children with complete UCLP and without oral clefts.

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ANNEX

PARECER CONSUBSTANCIADO DO CEP**DADOS DO PROJETO DE PESQUISA**

Título da Pesquisa: Avaliação dos efeitos da expansão rápida da maxila em pacientes com fissura lábiopalatina transforame unilateral: estudo em modelos digitais

Pesquisador: Priscila Vaz Ayub

Área Temática:

Versão: 1

CAAE: 10138012.7.0000.5441

Instituição Proponente: Hospital de Reabilitação de Anomalias Craniofaciais da USP

DADOS DO PARECER

Número do Parecer: 164.747

Data da Relatoria: 27/11/2012

Apresentação do Projeto:

A complexidade da má oclusão e a necessidade premente de estímulo ortopédico elegeu a expansão rápida da maxila como procedimento rotineiramente empregado e requerido no processo reabilitador da maioria dos pacientes com fissuras labiopalatinas completas na fase tardia de dentadura mista objetivando normalizar as dimensões transversais do arco dentário superior usurpada pelas cirurgias da infância. A amostra desse estudo consistirá de 40 pacientes. O arco superior será moldado em três tempos: na fase de pré-tratamento (T1), imediatamente após a remoção do aparelho (T2) e um ano após a instalação da contenção (T3). Os modelos serão digitalizados com auxílio do scanner 3Shape R700 3D e as distâncias intercaninos, intermolares, o perímetro do arco dentário, a inclinação vestibulolingual dos primeiros molares permanentes, a inclinação vestibulolingual dos caninos e o volume do palato serão mensuradas pelo método digital no software OrthoAnalyserTM 3D.

Objetivo da Pesquisa:

Verificar os efeitos dentoalveolares da expansão rápida da maxila em pacientes com fissuras labiopalatinas completas e unilaterais.

Avaliação dos Riscos e Benefícios:

O estudo não apresenta riscos aos pacientes. Os benefícios esperados com o desenvolvimento do presente estudo constituem uma importante contribuição ao conhecimento da qualidade da expansão da maxila, procedimento rotineiramente empregado durante o processo reabilitador e

Endereço: SILVIO MARCHIONE 3-20
Bairro: VILA NOVA CIDADE UNIVERSITÁRIA **CEP:** 17.012-900
UF: SP **Município:** BAURU
Telefone: (14)3235-8421 **Fax:** (14)3234-7818 **E-mail:** uep_projeto@centrinho.usp.br

ainda muito controverso na literatura e sem padronização entre os diversos centros ao redor do mundo.

Comentários e Considerações sobre a Pesquisa:

Pesquisa está bem estruturada e tem mérito.

Considerações sobre os Termos de apresentação obrigatória:

Estão todos de acordo.

Recomendações:

Sugiro que o projeto seja aprovado por esse comitê

Conclusões ou Pendências e Lista de Inadequações:

Não se aplica.

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

Colegiado acatou o parecer do relator em seus aspectos éticos e metodológicos de acordo com as Diretrizes estabelecidas na Resolução 196/96 e complementares do Conselho Nacional de Saúde. Toda e qualquer alteração do projeto, assim como os eventos adversos graves, deverão ser comunicados imediatamente a este Comitê. O pesquisador fica responsável pela entrega na Seção de Apoio a Pesquisa do SVAPEPE dos relatórios semestrais e final.

Informamos que após o recebimento do trabalho concluído, este Comitê enviará o parecer final para publicação do trabalho.

BAURU, 06 de Dezembro de 2012

Assinador por:
Marcia Ribeiro Gomide
(Coordenador)

Endereço: SILVIO MARCHIONE 3-20
Bairro: VILA NOVA CIDADE UNIVERSITARIA **CEP:** 17.012-900
UF: SP **Município:** BAURU
Telefone: (14)3235-8421 **Fax:** (14)3234-7818 **E-mail:** uep_projeto@centrinho.usp.br