UNIVERSIDADE DE SÃO PAULO
HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

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Slow and rapid maxillary expansion in patients with bilateral complete cleft lip and palate: a cephalometric evaluation

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

Área de Concentração: Fissuras Orofaciais e Anomalias Relacionadas

Orientadora: Profa. Dra. Daniela Gamba Garib

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"Tu te tornas eternamente responsável por aquilo que cativas."

Antoine de Saint-Exupéry

ABSTRACT

Slow and rapid maxillary expansion in patients with bilateral complete cleft lip and palate: a cephalometric evaluation

Introduction: The objective of this study was to compare the dentoskeletal effects of the slow (SME) and rapid maxillary expansion (RME) in patients with bilateral complete cleft lip and palate (BCLP). **Methods: The** sample comprised 46 patients with BCLP (34 male and 12 female) with a mean age of 9,2 years. They were randomly assigned into two groups: Group RME comprised 23 patients with posterior crossbites treated with Hyrax or Haas appliances. Group SME comprised 23 patients with posterior crossbites treated with quad-helix appliance. Both expansion modalities were performed prior to secondary alveolar bone graft procedure. Cone-beam computed tomography (CBCT) was performed before expansion (T1) and after appliance removal at the end of a 6-month retention period (T2). Sagittal and vertical changes were evaluated using the cephalometric reformatted images that were obtained from the CBCT. Cephalometric analysis was performed using Dolphin Imaging Software (Chatsworth, CA, USA). Intraclass correlation coefficient (ICC) was used to calculate intraexaminer agreement. Intragroup changes were evaluated using paired “t” test. Intergroup comparisons were performed using “t” test ($p<0.05$). **Results**: The intraexaminer agreement was excellent (ICC varied from 0.88 to 0.96). RME group showed a significant increase of lower anterior facial height ($p=0.042$), mandibular length ($p= 0.003$) and maxillomandibular difference ($p=0.006$). SLM group demonstrated an increase of mandibular length ($p<0.001$) and maxillomandibular difference ($p<0.001$) and a decrease of the ANB angle ($p=0.034$). No significant differences between RME and SME were found. **Conclusions:** Rapid and slow maxillary expansion produced similar sagittal and vertical changes in patients with BCLP.

Key words: Palatal expansion technique. Cephalometry. Cleft lip and palate.

RESUMO

Expansão lenta e rápida da maxila em pacientes com fissura labiopalatina completa e bilateral: avaliação cefalométrica.

Introdução: O objetivo desse estudo foi comparar os efeitos dentoesqueléticos da expansão lenta (ELM) e expansão rápida (ERM) da maxila em pacientes com fissuras labiopalatinas completa e bilateral (FLPCB). **Métodos:** A amostra compreendeu 46 pacientes com FLPCB (34 do sexo masculino e 12 do feminino) com idade média de 9,2 anos. Eles foram aleatoriamente alocados em dois grupos: Grupo ERM compreendeu 23 pacientes com mordida cruzada posterior (MCP) tratados com aparelho Hyrax ou Haas. Grupo ELM compreendeu 23 pacientes com MCP e tratados com aparelho quadrihélice. Ambas as modadlidades de expansão foram realizadas previamente ao enxerto ósseo alveolar secundário. Tomografia computadorizada de feixe cônico (TCFC) foi realizada antes da expansão (T1) e após a remoção do aparelho, no fim do período de contenção de 6 meses (T2). Alterações anteroposteriores e verticais foram mensuradas em imagens cefalométricas reformatadas a partir da TCFC. A análise cefalométricas foi realizada usando o Software Dolphin Imaging® (Chatsworth, CA, EUA). O coeficiente de correlação intraclasse (CCI) foi usado para calcular o erro do método. Alterações intragrupo foram calculadas usando teste “t” pareado. Alterações intergrupo foram calculadas usando teste “t” ($p<0,05$). **Resultados:** A confiabilidade foi considerada excelente (CCI variou entre 0,88 a 0,96). O grupo ERM demonstrou aumento significativo na altura facial anterior inferior ($p=0,042$), no comprimento mandibular ($p<0,003$) e na diferença maxilo-mandibular ($p=0,006$). O grupo ELM mostrou aumento no comprimento mandibular ($p<0,001$) na diferença maxilomandibular ($p<0,001$) e uma redução do ângulo ANB ($p=0,034$). Não foram encontradas diferenças entre ERM e ELM. **Conclusões:** Expansão rápida e lenta da maxila produziram alterações cefalométricas sagitais e verticais semelhantes em pacientes com FLPCB.

Palavras-chave: Técnica da expansão palatina. Cefalometria. Fissura de lábio e palato.

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LIST OF ABBREVIATIONS AND ACRONYMS

BCLP	Bilateral Cleft Lip and Palate
RME	Rapid Maxillary Expansion
SME	Slow Maxillary Expansion
CBCT	Cone-Beam Computed Tomography
ICC	Intraclass Correlation Coefficient
Alt-RAMEC	Alternative Rapid Maxillary Expansions and Constrictions
T1	Timing 1
T2	Timing 2
SD	Standard Deviation

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1 INTRODUCTION

1 INTRODUCTION

After primary lip and palate repair, soft tissue traction and scar fibrosis produces a significant reduction of the overjet due to a retrusion of the premaxilla, anteriorly advanced at birth (Hotz et al., 1987). At the same time, they result in a medial displacement of the palatal segments frequently causing a maxillary transversal constriction and posterior crossbites (Silva Filho et al., 1992; Larson et al., 1983; Bishara et al, 1985; Heidbuchel and Kuijpers-Jagtman, 1997).

In patients with BCLP, the correction of maxillary constriction is usually performed before the secondary alveolar bone graft procedure (Freitas et al., 2012). Expansion improves the maxillary arch morphology and segmental alignment creating appropriate conditions for bone graft surgery (Freitas et al., 2012; Cavassan et al., 2004). Maxillary expansion also correct posterior crossbites (Freitas et al., 2012; Capelozza Filho et al., 1994; Isaacson and Murphy, 1964; Aizenbud et al., 2012; Huang et al., 2012). In general, two therapeutic options are available for maxillary expansion in patients with complete cleft lip and palate, rapid maxillary expansion (RME) with Hyrax or Haas-type appliances[1, 5, 13] and slow maxillary expansion (SME) with quad-helix appliance (Aizenbud et al., 2012; Huang et al., 2012; Ainzenbud et al., 2013; Dholakia et al., 2012).

Brunetto et al., 2013 compared the results of RME and SME in noncleft patients. They used Haas appliance for both modalities of expansion to isolate the bias of the different source of the force (coin or screw), but changing the expansion protocol of activation. They concluded that RME resulted in more buccal tipping of the anchorage teeth. On the other hand, SME resulted in a tooth buccal body movement, with minor buccal tipping. Buccal alveolar bone showed significant losses at the region of the anchorage molar in the SME Group (Brunetto et al., 2013).

Almeida et al, 2016 compared the transversal skeletal effects of slow and rapid maxillary expansion in BCLP using pre-expansion and post-retention CBCT. Quad-helix and Hyrax/Haas-type appliances produced similar orthopedic effect with decreasing transversal gains from the alveolar crest level to the nasal cavity. The authors also reported similar buccal bone inclination of anchorage teeth for both appliances (Almeida et al, 2016). Recently, Medeiros Alves et al. performed a randomized clinical trial for comparing slow and rapid maxillary expansion in patients with BCLP by means of digital dental models. Arch widths and perimeter were significantly increased with both expanders. No differences were observed for RME and SME except the capability of quad-helix in promoting differential expansions in the anterior and posterior regions. A shorter therapy time was observed for RME (Medeiros Alves et al., 2015).

The different dentoskeletal changes promoted by RME and SME in noncleft patients are well known. The different transversal changes in the maxilla, as well the occlusal changes observed in dental models, in patients with BCLP after RME or SME, were recently reported. However, anteroposterior and vertical dentoskeletal changes are not described in the literature. Considering BCLP show a predominant hyperdivergent facial pattern (Semb et al., 1991), the investigation of the vertical effects of maxillary expansion procedures becomes relevant.

2 PURPOSE

2 PURPOSE

The purpose of this study was to compare the dentoskeletal sagittal and vertical effects of the rapid and slow maxillary expansion in patients with complete bilateral cleft lip and palate. The null hypothesis was that there are no differences for sagittal and vertical dentoskeletal effects between quad-helix and Hyrax or Haas-type expanders.

3 ARTICLE

3 ARTICLE

INTRODUCTION AND LITERATURE REVIEW

The rehabilitation of individuals with complete cleft lip and palate starts right after birth[1]. Lip and palate repair are performed in the first months and years of life, respectively[1, 2, 3]. At the same time the primary surgeries repair lip and palate morphology, a side effect of maxillary growth restriction is frequently observed[2, 3, 4, 5, 6, 7]. Individuals with complete bilateral cleft lip and palate (BCLP) shows, at birth, enlarged anteroposterior and transversal maxillary dimensions[4, 7]. After primary lip and palate repair, soft tissue traction and scar fibrosis produces a medial displacement of the palatal segments frequently causing a maxillary transversal constriction and posterior crossbites[4, 8, 9, 10]. At the same time, a significant reduction of the overjet occurs, due to a retrusion of the premaxilla, anteriorly advanced at birth[11].

In patients with BCLP, the correction of maxillary constriction is usually performed before the secondary alveolar bone graft procedure[1]. Expansion improves the maxillary arch morphology and segmental alignment creating appropriate conditions for bone graft surgery[1,12] Maxillary expansion also correct posterior crossbites[1,5,13,14,15]. In general, two therapeutic options are available for maxillary expansion in patients with complete cleft lip and palate, rapid maxillary expansion (RME) with Hyrax or Haas-type appliances[1, 5, 13] and slow maxillary expansion (SME) with quad-helix appliance [14, 15,16, 17].

Brunetto et al.[18] compared the results of RME and SME in noncleft patients. They used Haas appliance for both modalities of expansion to isolate the bias of the different source of the force (coin or screw), but changing the expansion protocol of activation. They concluded that RME resulted in more buccal tipping of the anchorage teeth. On the other hand, SME resulted in a tooth buccal body movement, with minor buccal tipping. Buccal alveolar bone showed significant losses at the region of the anchorage molar in the SME Group[18].

Almeida et al[19] compared the skeletal effects of slow and rapid maxillary expansion in BCLP using pre-expansion and post-retention CBCT. Quad-helix and Hyrax/Haas-type appliances produced similar orthopedic effect with decreasing transversal gains from the alveolar crest level to the nasal cavity. The authors also reported similar buccal bone inclination of anchorage teeth for both appliances. Recently, Medeiros Alves et al.[20] performed a randomized clinical trial for comparing slow and rapid maxillary expansion in patients with BCLP by means of digital dental models. Arch widths and perimeter were significantly increased with both expanders. No differences were observed for RME and SME except the capability of quad-helix in promoting differential expansions in the anterior and posterior regions. A shorter therapy time was observed for RME.

No previous studies, however, reported the anteroposterior and vertical effects of RME and SME in complete cleft lip and palate. Considering BCLP show a predominant hyperdivergent facial pattern[2], the investigation of the vertical effects of maxillary expansion procedures become relevant.

PURPOSE

Therefore, the purpose of this study was to compare the dentoskeletal sagittal and vertical effects of the rapid and slow maxillary expansion in patients with complete bilateral cleft lip and palate. The null hypothesis was that there are no differences for sagittal and vertical dentoskeletal effects between quad-helix and Hyrax or Haas-type expanders.

MATERIAL AND METHODS

The study was approved by the ethical committee at the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo (protocol number **990,232/2015**). Considering a significance level of 5%, an 80% test power, a standard deviation of 1.7^{o} for the SN.GoGn[21], and a power to detect a minimal difference of 2^{o} between the groups, a sample of 22 patients was required.

One hundred patients with BCLP with 8 to 10 years of age were recruited from September/2011 to September 2013 for a previous study[20]. Sixty patients attended the appointment and were examined. The eligibility criteria were: 1 – Middle or late mixed dentition; 2 - Both genders; 3 - Lip repair performed between 3 and 6 months of age and palate repair performed between 12 and 24 months of age; 4 – Presence of maxillary constriction and need of maxillary expansion previously to the secondary bone graft; 5 – Permanent first molars without extensive restorations; 6 - Good periodontal health; 7 – No previous orthodontic treatment; and 8 – Absence of syndromes or other craniofacial anomalies. Forty six patients (34 males and 12 females) were selected according to the inclusion criteria (Figure 1).

Computed-generated randomization based in random permute blocks of 20 patients was accomplished using Stata® Software (StataCorp, College Station, Tex) to ensure equal distributions of participants in the groups. Allocation concealment was achieved with sequentially, numbered sealed, opaque envelopes containing the expansion modality allocation cards, which were prepared before trial. One operator was responsible for opening the next envelope in sequence and implementing the randomization process[20]. Patients were assigned into two groups:

Group RME comprised 23 patients (16 males and 7 females) with a mean age of 9.25 years (SD=1.35), who received maxillary expansion with Haas-type or Hyrax appliance (Figure 3A). Bands were adapted on either second deciduous molars or first permanent molars and C-shape clasps were bonded on the deciduous canines. The 11-mm screw (Dentaurum, Ispringen, Germany) was activated two turns twice a day (0.8mm/day) until overcorrection. The expansion active phase ranged from 7 to 14 days. The appliance was maintained as a retainer during 4 to 6 months. The mean amount of expansion was 5.11mm (SD=2.74) for intercanines (3-3) and 6.58mm (SD=3.58) for intermolars (6-6) region.

Group SME comprised 23 patients (18 males and 5 females) with a mean age of 9.15 years (SD=0.99) who received Quad-helix appliance (Figure 3B). Bands were adapted either on second deciduous molars or on first permanent molars. The appliance was performed using 0.9mm-round stainless steel wires. The first activation was performed at the installation and at every 60 days until overcorrection. The amount of activation for each appointment was 4mm. The expansion therapy mean time was 11 months. The appliance remained in the mouth as retainer during 4 to 6 months. The mean amount of expansion was 3.53mm (SD=2.73) for intercanines (3-3) and 3.98mm (SD=2.41) for intermolars (6-6) region.

For both groups, the overcorrection criterion was the occlusion between the palatal cusps of maxillary teeth and the buccal cusps of the mandibular teeth. After appliance removal, T2 CBCT was performed. Fixed retainers were placed and patients were referred to the secondary alveolar bone graft surgery.

Cone Beam Computed Tomography was performed using i-CAT® (Imaging Sciences, Hartfield PA, USA) immediately before the expansion (T1) and after the retention period when the expander was removed (T2). All CBCT scans were taken with the following conditions: sitting position, natural head position, tongue in a relaxed position, and natural breath, as suggested in previous sutudies[22]. The protocol adopted was 120kVp, 8mA, 26.9s time exposition, FOV of 13cm and a 0.25mm voxel size.

Lateral cephalometric images were reformatted using Dolphin software (Chatsworth, CA, USA). The head position was standardized with the Frankfurt plane was parallel and the sagittal median plane was perpendicular to the floor, passing through the Galli crest at ethmoid. The third plane passed through both acoustic meatus and was perpendicular to the floor and the other two planes. In order to improve soft and hard tissues visualization, Filter 1 was used. Cephalometric measurements are shown in Figure 2. During analysis, the examiner was blinded.

The same examiner repeated the measures in half of the sample. The reliability was calculated using Intraclass Correlation Coefficient (ICC). Intragroup changes were calculated using *paired t* test. Intergroup comparison was performed using "*t*" test. The level of significance regarded was 5%.

RESULTS

Intraexaminer agreement was considered excellent (ICC>0.75), varying from 0.88 to 1.00 (Table I).

Table II shows the intergroup comparison before treatment (T1). There was no difference between the cephalometric measurements in the starting forms.

Interphase changes for RME Group are showed in Table III. Mandibular length (Co-Gn) significantly increased. Maxillomandibular difference and LAFH showed a significant increase after RME.

Interphase changes for SME Group are shown in Table IV. Mandibular length and maxillomandibular difference increased significantly. The ANB angle was reduced after expansion.

The intergroup differences for expansion changes were not significant (Table V).

Figure 4 illustrates superimposition of the intragroup average cephalometric tracing superimposition, before (T1) and after (T2) expansion for RME (Figure 4A) and SME (Figure 4B) groups.

DISCUSSION

The method using cephalometric reconstruction from CBCT images showed excellent reproducibility. Figueiredo et al.[23] also used the cephalometric reconstruction from CBCT scans obtaining adequate reproducibility of the method[23,24]. The position of the head image should be standardized before reconstructing the cephalometric reformatted image, otherwise possible turns of the head images, in all the three planes, may jeopardize the measurements. The head positioning must be observed in the three planes of the space. At the axial plane, Frankfurt plane is usually adopted[23,24,25]. Patients with cleft generally show much asymmetry of the vertical structures of the face that could be reference for the sagittal plane positioning, as midline of the upper incisors, or middle structures of the nose cavity like vomer. For these patients, midsagittal plane should coincide with the line connecting crista galli and basion[23]. Coronal plane might be used as the transporionic or right and left frontozygomatic sutures, perpendicular to the other two planes aforementioned[23,25].

Changes in the anteroposterior position of the maxilla may occur after the expansion in noncleft patients[24]. In this study, no changes were observed for the sagittal position of the maxilla in relation to the skull base in both groups (Tables III and IV). Positive findings, confirming anterior maxillary displacement in patients without clefts, are commonly described in the literature[23, 24, 27]. Figueiredo et al.,[23] found a significant anterior displacement of the maxilla after RME with the *inverted mini Hyrax* in patients with clefts, even though, the expansion with *Hyrax* and *Fan-type* devices have not produced sagittal changes in the maxilla[23]. One possible reason for this difference might be that our study comprised patients with BCLP, while Figueiredo et al. studied expansion in UCLP. Probably the disconnected premaxilla in patients with BCLP might be less affected by the expanders, supported in the other two maxillary segments, than patients with UCLP. In a previous study, patients with BCLP showed a shorter arch length after expansion, caused by the retrusion of the premaxilla, which seems to be tendency in patients with BCLP[20]. In a previous study, authors compared the standard RME to a rapid expansion and contraction protocol, prior to maxillary protraction, and concluded that A point has shifted significantly in the latter [27]. The sample comprised patients with UCLP whom received 1 week of RME of traditional protocol expansion. The results were compared with the other group that, with the same expander type, received a 9 weeks of alternate expansion and constriction that lasted 7 days each Alt-RAMEC. Both expansion modalities resulted in some anterior displacement of the maxilla, but the alternative protocol showed almost twice success. The authors' hypothesis for the increased results of the Alt-RAMEC is that the alternative protocol might disarticulate the circumaxillary sutures better than a single course of the RME. Therefore, the stress caused in the sutures of the maxilla with other face bones might foment growth, with anterior displacement results. And for the authors, the more stress caused, the more growth might be observed [27].

In both groups, mandibular length (Co-Gn) increased during T1-T2 interval even though SNB changes were not significant. ANB angle and maxillo-mandibular difference changes were similar in both groups (Table V). Previous studies in noncleft patients evaluated the spatial changes of the jaw after the rapid maxillary expansion and noted that there was a mandibular posterior displacement immediately after expansion. They observed though, that after the retention period, the mandible tends to return forward[21,28].

A previous recent study compared the facial changes of the RME, with Hyrax bonded appliance, and SME with quad helix appliance in noncleft patients[29]. The authors observed that quad helix showed no differences at lower facial height, total facial height, facial axis, and Frankfort Mandibular Plane Angle (FMA) and facial convexity compared to the control group, on the contrary of the RME group results[29]. They concluded that the quad-helix expander had more control over skeletal vertical measurements than the bonded rapid maxillary expander [29]. Quad-helix promotes more extrusion of the banded teeth in relation to the palatal plane, which might explain some results of increase of facial height and mandible clockwise rotation in other studies [28,29].

None of the expansion modalities produced changes in the mandibular plane angle. (Tables III, IV and V). On the other hand, LAFH increased significantly after rapid maxillary expansion (Table III), corroborating previous findings in noncleft patients[21,24,28]. When both SME and RME groups were compared, however, no difference was observed for vertical changes. A previous study found a significant increase of lower facial height, total facial height, facial axis, and Frankfort Mandibular Plane Angle (FMA) and facial convexity in patients that received RME therapy, compared to SME therapy[29]. The lower anterior facial height increase was also observed in this study after expansion with Hyrax appliance. The stress at circumaxillary sutures might promote vertical displacement of the maxilla[27]. This and other factors, as extrusion of anchorage teeth, added to the overcorrection of 2 to 3 mm during activation of the screw gives rise to occlusal interferences when the lingual cusps of maxillary teeth occlude against the buccal cusps of mandibular teeth, contributing to vertical increases[21]. A previous report showed no vertical changes after ERM with three different expander appliances in patients with cleft[23]. The difference might be that their sample comprised patients with UCLP[23]. The LAFH increase after RME in patients with cleft might be a concern considering a hyperdivergent growth pattern is frequent in BCLP[2, 21]. However, the vertical changes after RME are not significant in the long term[21].

The maxillary incisors (U1.PP) and mandibular incisors (IMPA) showed no changes after expansion for both groups (Table III, IV and V). Some previous studies found a significant retroinclination of maxillary incisors[20,24,30], which resulted in a distal movement of these teeth in relation to the cranial base, maxilla and palatal plane[24]. One possible reason for this finding might be the loss of the posterior contact of the premaxilla with the two other palatal segments after expansion in patients with BCLP. The absent of the posterior contact enable a posterior movement caused by the pressure of the upper lip.

The soft tissue profile (NA.APog) and the nasolabial angle were not affected by both the slow and rapid maxillary expansion. A previous study evaluated soft-tissue profile changes in patients with UCLP and BCLP who received expansion with a modified quad-helix appliance before facemask therapy and no changes of the upper lip was found[31]. However authors observed a significant projection of the lower lip (N.PG-LL and E.line-LL) after expansion in patients with BCLP, but a retrusion tendency of lower lip in patients with UCLP[31]**.** The authors described that this may be attributable to greater expansion and greater increase of the lower facial height[31]. They also observed a significant increase of the soft-tissue face height (N-GN)[31].

The greater therapy length with quad-helix appliance compared to Haas-type/Hyrax appliance is a limitation of the study concerning growth comparison. This study was based upon secondary data from previous randomized clinical trial, with 3-D images that led to the reconstruction of 2-D images. Further studies with longer follow-up to evaluate stability and relapse tendency of the cephalometric results after rapid and slow maxillary expansion are necessary. Therefore, more studies with greater follow-up period are suggested to contribute to the complete understanding and knowledge of the maxillo-mandibular changes after maxillary expansion procedures and their relapse tendency in patients with complete bilateral cleft lip and palate.

Quad-helix appliance has similar cephalometric changes comparable to RME, however the former has the inconvenience of a greater expansion therapy time[20] and a less practical clinical procedure to orthodontist once it is necessary to take the appliance out for activations. These findings are very relevant to the clinical practice.

CONCLUSIONS

The null hypothesis was accepted. No anteroposterior and vertical cephalometric differences were observed between SME and RME in patients with bilateral cleft lip and palate.

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FIGURE CAPTIONS

Figure 1 – Flowchart steps of the sample distribution

Figure 2 – Cephalometric variables measured in the study: 1 - SNA, 2 - SNB, 3 - ANB, 4 – Co - A, 5 – Co-Gn, 6 – Diff Mx-md, 7 – Nperp-A, 8 – Nperp-Pog, 9 - Wits, 10 – SN.GoGn, 11 - FMA, 12 - LAFH, 13 - IMPA, 14 – 1.PP, 15 – Nasolabial Angle, 16 – NA.APog.

Figure 3 – The appliances used in the study. A. Hyrax; B. Quad-helix

Figure 4 – Superimposition (S-N in S) of the average cephalometric tracings of each group of study in each stage of the study. A- Superimposition of T1 (black) and T2 (green) for RME group. B- Superimposition of T1 and T2 for SME group

FIGURES

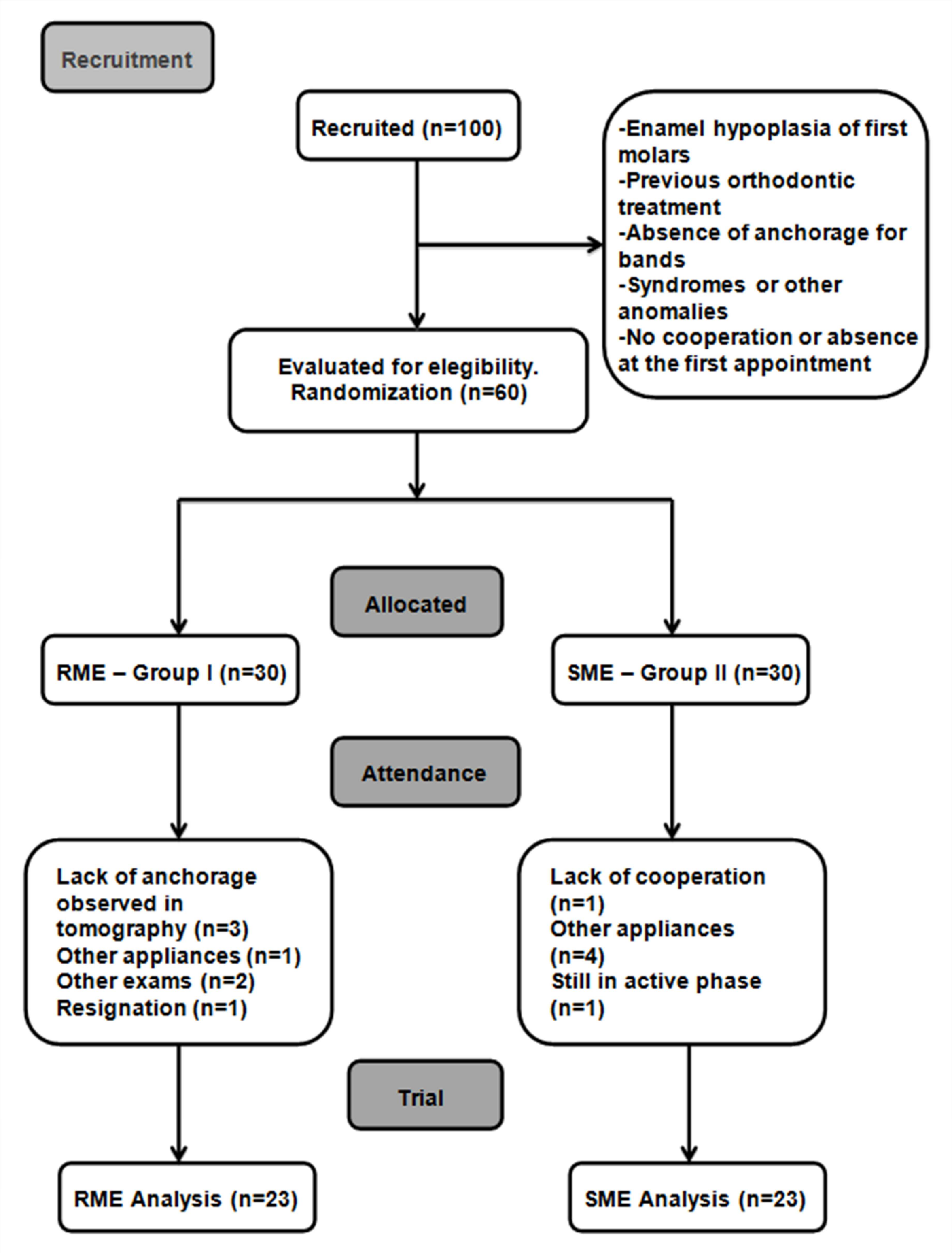

Figure 1

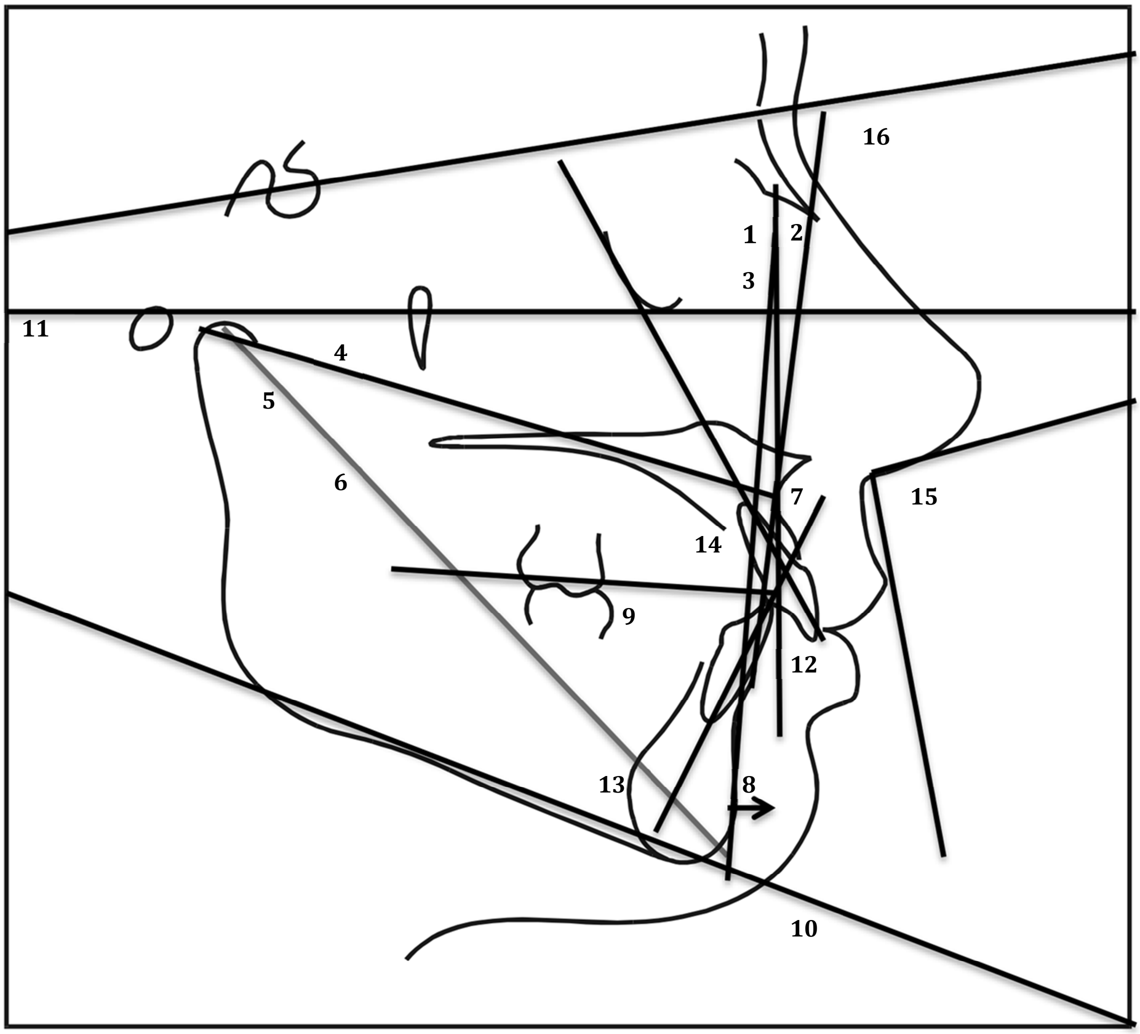

Figure 2

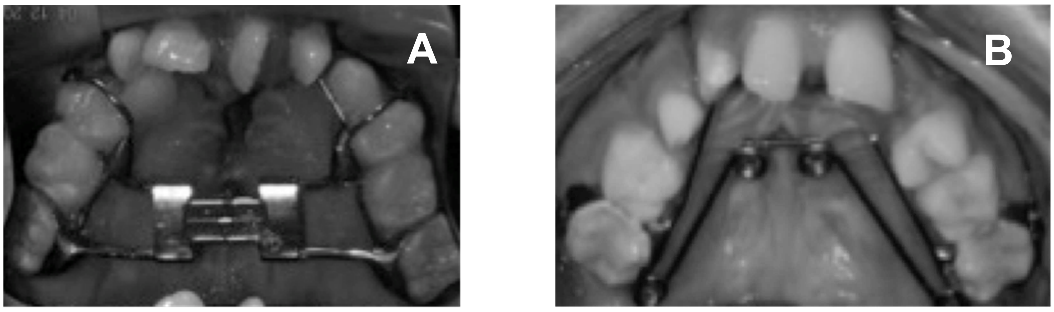

Figure 3

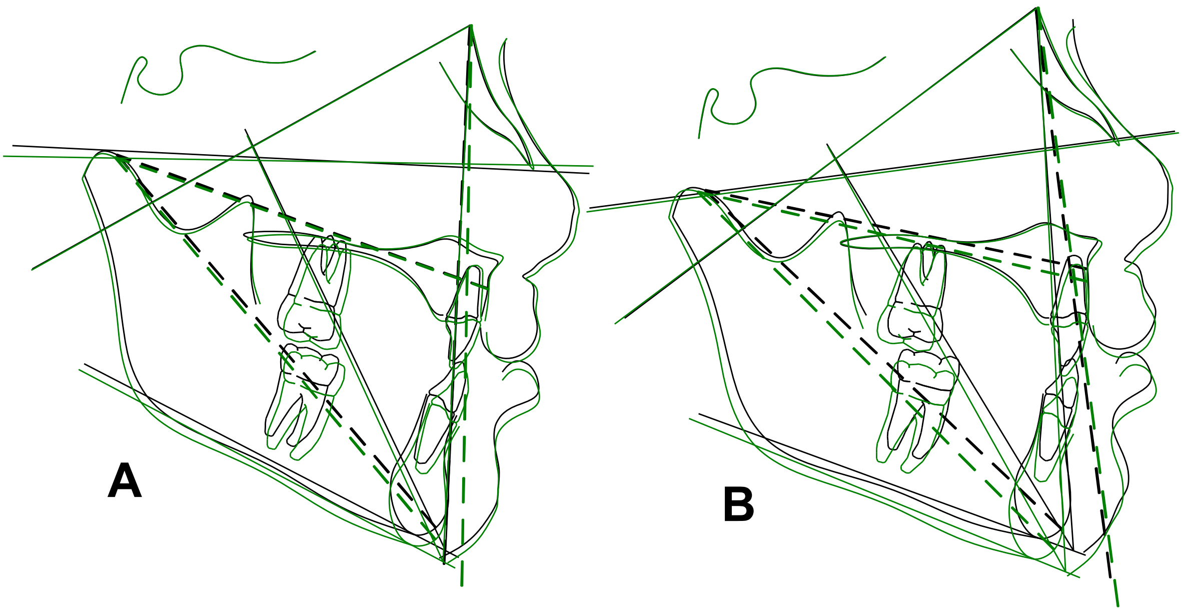

Figure 4

TABLES

Table I – Intraexaminer agreement (ICC).

Variables	1st Measurement	2nd Measurement	ICC
SNA	83.27	83.25	0.89
SNB	77.47	77.23	0.93
ANB	5.81	6.02	0.89
Co-A	84.74	84.72	0.89
Co-Gn	107.94	108.3	0.96
Max/Mand Diff.	23.18	23.57	0.93
Nperp-A	4.01	4.55	0.89
Nperp-Pog	-2.68	-2.1	0.94
Wits	1.4	1.69	0.93
SN.GoGn	35.13	35.48	0.92
FMA	27.17	26.7	0.96
LAFH	64.9	65.22	0.87
IMPA	87.87	88.29	0.88
U1.PP	86.41	86.2	0.9
Nasolabial Angle	118.2	118.61	0.99
Na.APog	12.17	12.11	1.0

Table II – Intergroup comparison at T1 (t tests).

Variables	RME Group		SME Group		p
	Mean	SD	Mean	SD	*
SNA	81.68	3.89	81.81	3.80	0.913
SNB	74.79	4.42	74.77	4.23	0.990
ANB	6.89	2.72	7.04	2.81	0.860
Co-A	84.21	5.08	84.52	3.73	0.816
Co-Gn	105.68	5.43	105.73	6.01	0.977
Max/Mand Diff.	21.17	4.76	21.01	4.42	0.907
Nperp-A	4.11	4.01	2.83	4.47	0.322
Nperp-Pog	-4.04	7.07	-7.54	8.58	0.150
Wits	3.73	4.41	1.04	4.46	0.051
SN.GoGn	36.84	5.35	38.2	5.29	0.403
FMA	27.22	5.28	29.96	4.88	0.081
LAFH	64.11	5.38	67.06	6.28	0.104
IMPA	86.91	8.21	85.54	7.07	0.557
U1.PP	79.90	19.26	82.81	10.29	0.530
Nasolabial Angle	117.39	13.00	120.12	12.88	0.492
NA.APog	14.73	6.07	14.16	6.79	0.774

Table III – Dentoskeletal changes in RME Group (paired t test).

Variables	T1		T2		T2-T1 Differences		p
	Mean	SD	Mean	SD	Mean	SD	
SNA	81.68	3.89	81.60	4.56	-0.09	1.76	0.825
SNB	74.79	4.42	74.71	4.66	-0.07	1.84	0.861
ANB	6.89	2.72	6.87	3.46	-0.02	2.11	0.967
Co-A	84.21	5.08	84.39	5.62	0.19	2.90	0.772
Co-Gn	105.68	5.43	107.58	5.51	1.91	2.55	**0.003***
Max/Mand Diff.	21.17	4.76	22.94	4.87	1.77	2.66	**0.006***
Nperp-A	4.11	4.01	3.73	4.42	-0.19	2.95	0.776
Nperp-Pog	-4.04	7.07	-5.03	6.60	-1.00	5.51	0.418
Wits	3.73	4.41	2.87	4.83	-0.87	2.56	0.136
SN.GoGn	36.84	5.35	37.58	5.54	0.74	3.49	0.340
FMA	27.22	5.28	28.31	4.39	1.09	4.12	0.239
LAFH	64.11	5.38	66.89	6.14	2.77	5.83	**0.042***
IMPA	86.91	8.21	86.81	7.55	-0.09	4.01	0.919
U1.PP	79.90	19.26	79.01	18.51	-0.89	6.66	0.549
Nasolabial Angle	117.39	13.00	118.81	10.28	1,42	4.33	0.393
NA.APog	14.73	6.07	13.89	7.96	-0.84	2.70	0.383

*** Statistically significant**

Table IV – Dentoskeletal changes in SME Group (paired t test).

Variables	**T1**		**T2**		**T2-T1 Differences**		**p**
	Mean	SD	Mean	SD	Mean	SD	*
SNA	81.81	3.80	81.07	4.29	-0.74	1.88	0.071
SNB	74.77	4.23	74.68	4.21	-0.09	2.10	0.836
ANB	7.04	2.81	6.40	2.86	-0.64	1.36	**0.034***
Co-A	84.52	3.73	84.62	3.19	0.10	3.48	0.892
Co-Gn	105.73	6.01	108.55	4.44	2.82	2.74	**<0.001***
Max/Mand Diff.	21.01	4.42	23.02	4.59	2.91	3.03	**<0.001***
Nperp-A	2.83	4.47	2.15	4.62	-0.67	1.93	0.109
Nperp-Pog	-7.54	8.58	8.12	8.71	-0.58	4.34	0.526
Wits	1.04	4.46	0.87	4.26	-0.17	2.24	0.719
SN.GoGn	38.20	5.29	39.23	5.74	1.03	2.84	0.096
FMA	29.96	4.88	30.67	6.14	0.72	3.34	0.314
LAFH	67.06	6.28	68.62	6.76	1.56	5.75	0.202
IMPA	85.54	7.07	85.33	5.29	-0.21	4.57	0.829
U1.PP	82.81	10.29	84.53	11.63	1.71	5.95	0.181
Nasolabial angle	120.12	12.88	120.92	11.53	0.8	8.11	0.650
NA.APog	14.16	6.79	13.83	6.67	-0.33	3.72	0.680

***Statistically significant**

Table V – Intergroup comparisons for expansion changes ("t" test).

Variables	**Hyrax (T2-T1)**		**Quad-helix (T2-T1)**			
	Mean	SD	Mean	SD	Mean	*
SNA	-0.09	1.76	-0.74	1.88	0.66	0.238
SNB	-0.07	1.84	-0.09	2.10	0.02	0.974
ANB	-0.02	2.11	-0.64	1.36	0.62	0.245
Co-A	0.19	2.90	0.10	3.48	0.09	0.930
Co-Gn	1.91	2.55	2.82	2.74	0.92	0.258
Max/Mand Diff.	1.77	2.66	2.91	3.03	1.15	0.191
Nperp-A	-0.19	2.95	-0.67	1.93	0.49	0.516
Nperp-Pog	-1.00	5.51	-0.58	4.34	0.41	0.783
Wits	-0.87	2.56	-0.17	2.24	0.70	0.340
SN.GoGn	0.74	3.49	1.03	2.84	0.29	0.765
FMA	1.09	4.12	0.72	3.34	0.37	0.742
LAFH	2.77	5.83	1.56	5.75	1.21	0.492
IMPA	-0.09	4.01	-0.21	4.57	0.12	0.928
U1.PP	-0.89	6.66	1.71	5.75	2.60	0.179
Nasolabial Angle	1,42	7,48	0.8	8.11	0.63	0.793
NA.APog	-0.84	4.33	-0.33	3.72	0.51	0.680

***Statistically significant**

4 FINAL CONSIDERATIONS

4 FINAL CONSIDERATIONS

The anteroposterior and vertical dentoskeletal changes promoted by RME and SME were similar. Both expansion modalities were capable of correcting the posterior crossbites in patients with complete bilateral cleft lip and palate. Some clinical important differences, however, were observed in this study and reported in the literature (Medeiros Alves et al., 2015), as the inconvenience of a greater expansion therapy time and a less practical clinical procedure to orthodontist once it is necessary to take the appliance out for activations with quad-helix appliance. On the other hand, slow maxillary expansion permits to achieve differential expansion with a greater increase of the inter canines distance (3-3) than the increase of intermolars distance (6-6).

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ANNEX

ANNEX

HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS DA USP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação cefalométrica da expansão rápida e lenta da maxila na fissura labiopalatina completa e bilateral.

Pesquisador: Leonardo Vieira Lima Gregorio

Área Temática:

Versão: 3

CAAE: 41327415.2.0000.5441

Instituição Proponente: Hospital de Reabilitação de Anomalias Craniofaciais da USP

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 990.232

Data da Relatoria: 31/03/2015

Apresentação do Projeto:

Trata-se da terceira apresentação de um projeto de Dissertação, de autoria de Leonardo Vieira Lima Gregorio sob orientação de Daniela Gamba Garib e co-orientação de Araci Malagodi de Almeida com o objetivo de comparar os efeitos cefalométricos da expansão rápida e lenta da maxila em pacientes com fissura completa e bilateral. A amostra do estudo será composta por 46 pacientes com fissura completa e bilateral (34 do sexo masculino e 12 do sexo feminino) e idade variando de 8 a 10 anos. O Grupo I composto por 23 pacientes que receberam expansão rápida da maxila (aparelho Hyrax). O grupo II compreende 23 pacientes tratados ortodonticamente com expansão lenta da maxila (aparelho quadri-hélice). O exame de tomografia computadorizada cone-beam (TCCB) foram tomadas em dois tempos distintos, imediatamente antes da instalação dos expansores (T1) e ao final do período de contenção (T2). Nesse estudo, serão analisados os dados secundários da tomografia computadorizada. Imagens de telerradiografia em norma lateral serão reconstruídas a partir dos exames de TCCB. No software Dolphin (Chatsworth, CA, EUA), de modo cego,um único examinador demarcará os pontos cefalométricos, gerando a mensuração de grandezas cefalométricas angulares e lineares em T1 e T2.

Objetivo da Pesquisa:

Avaliar e comparar as alterações cefalométricas anteroposteriores e verticais em pacientes com

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HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS DA USP

Continuação do Parecer: 990.232

fissura labiopalatina completa e bilateral, submetidos à expansão rápida (aparelho de Haas ou Hyrax) e lenta da maxila (quadrihélice).

Avaliação dos Riscos e Benefícios:

Segundo os autores:

Não existe nenhum risco, por se tratar de análise de dados secundária, com amostra já toda coletada. Não haverá portanto, contato com o paciente.

Benefícios: Reposicionamento dos semgentos maxilares para que seja viabilizada a reabilitação completa dos pacientes com fissuras labiopalatinas

Comentários e Considerações sobre a Pesquisa:

Pesquisa com boa fundamentação teórica/científica

Considerações sobre os Termos de apresentação obrigatória:

Os seguintes termos foram apresentados adequadamente:

Carta de encaminhamento dos pesquisadores aos CEP;

Formulário HRAC;

Folha de Rosto Plataforma Brasil;

Termo de Compromisso de Manuseio de Informações;

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

Critérios para Suspender ou Encerrar as Pesquisas;

Termo de Compromisso do Pesquisador Responsável.

Recomendações:

Nao há.

Conclusões ou Pendências e Lista de Inadequações:

Os autores efetuaram as alterações sugeridas.

Sugiro aprovação do projeto

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

Aprovado Ad Referendum pela Coordenadora do CEP.

O pesquisador deve atentar que o projeto de pesquisa aprovado por este CEP refere-se ao

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HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS DA USP

Continuação do Parecer: 990.232

protocolo submetido para avaliação. Portanto, conforme a Resolução CNS 466/12, o pesquisador é responsável por "desenvolver o projeto conforme delineado", se caso houver alterações nesse projeto, este CEP deverá ser comunicado em emenda via Plataforma Brasil, para nova avaliação.

Cabe ao pesquisador notificar via Plataforma Brasil o relatório final para avaliação, assim como os relatórios semestrais, os Termos de Consentimento Livre e Esclarecidos e/ou outros Termos obrigatórios, quando solicitados no parecer.

BAURU, 18 de Março de 2015

Assinado por:
Silvia Maria Graziadei
(Coordenador)

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