UNIVERSIDADE DE SÃO PAULO
HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

Fernando Dos Santos Pugliese

Dental arch size and shape after maxillary expansion in bilateral complete cleft lip and palate (BCLP): Comparison between Hyrax, Quad-helix and Expander with differential opening

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

Coorientador: Prof. Dr. José Roberto Pereira Lauris

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RESUMO

O objetivo desse estudo foi comparar os efeitos no tamanho e forma do arco dentário superior após a expansão maxilar com o Hyrax, Quad-helix e Expansor com abertura diferencial em pacientes com fissura lábio palatina completa e bilateral (BCLP). Setenta e cinco pacientes foram randomizados em três grupos: Hyrax (H), Quad-helix (QH) e Expansor com abertura diferencial (EDO). Modelos digitais foram obtidos de pacientes BCLP antes (T1) e seis meses depois (T2) da expansão maxilar. Doze pontos homólogos foram marcados, por um investigador, nos modelos digitais de T1 e T2 de cada grupo e as coordenadas x e y de cada ponto foram coletadas. Para a análise do tamanho do arco dentário, o tamanho do centroide de cada arco dentário em T1 e T2 foi calculado a partir das coordenadas originais e foi utilizado como a medida de tamanho. Para a análise de da forma do arco dentário, foi realizada a Análise de Procrustes. Análises de variância (ANOVA) foram utilizadas para comparar os grupos quanto ao tamanho e a forma do arco dentário ($p < 0,05$). Não houve diferença de tamanho de arco dentário entre os grupos, em T1 nem em T2. Diferenças na forma do arco foram encontradas entre todos os grupos em T2. A forma do arco apresentou uma variação significativa para os grupos QH e EDO enquanto manteve-se estável no grupo H. Quando alterações na forma do arco dentário forem desejadas, com maior expansão intercanina do que intermolar, tanto o Qhad-helix quanto o Expansor com abertura diferencial devem ser utilizados, enquanto o expansor Hyrax deve ser utilizado quando alterações na forma do arco não forem desejadas.

Descritores: Técnica de Expansão Palatina, Fissura Palatina, Fenda Labial, Ortodontia

ABSTRACT

Pugliese F. Dental arch size and shape after maxillary expansion in bilateral complete cleft lip and palate (BCLP): Comparison between Hyrax, Quad-helix and Expander with differential opening [dissertação]. Bauru: Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo; 2014

The objective of this study was to compare the effects in upper dental arch size and shape after maxillary expansion with Hyrax, Quad-helix and a differential opening expander in bilateral cleft lip and palate (BCLP) patients. Seventy-five patients were divided into three groups: Hyrax (H), Quad-helix (QH) and Expander with differential opening (EDO). Digital models were obtained from BCLP patients before (T1) and after 6 months (T2) of the maxillary expansion. Twelve landmarks were placed, by one investigator, on T1 and T2 dental models of each group and x,y coordinates for each landmark were collected. For dental arch size analysis, centroid size of each dental arch at T1 and T2 was calculated from the raw coordinates and was used as the measure of size. Procrustes Analysis was performed for dental arch shape analysis. Analysis of variance (ANOVA) was used to compare the groups for size and shape differences ($p < 0,05$). There were no significant dental arch size differences among expanders, either at T1 or T2. Differences in arch shape were found between all groups at T2. Intragroup arch shape showed a significant variation for QH and EDO groups while remained stable in H group. When dental arch shape changes are desired, with greater intercanine than intermolar increase, either the Quad-helix or the Expander with differential opening should be used, while the Hyrax expander should be used when no arch shape changes are desired.

Keywords: Palatal Expansion Technique, Cleft Palate, Cleft Lip, Orthodontics

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1 INTRODUCTION

1 INTRODUCTION

Bilateral complete cleft lip and palate (BCLP) is the most severe cleft lip and palate type, maintaining the embryological maxillary division and challenging the multidisciplinary treatment team (Semb 1991). In untreated patients, premaxilla maintains its anterior projection, and the posterior segments tend to approximate, resulting in a narrow dental arch (Silva Filho et al. 1998). Lip and palate repair surgeries often have a negative influence on the maxillary growth and development, resulting in maxillary dental arch constriction and maxillary sagittal deficiency (Naqvi et al. 2015). Transverse maxillary constriction in BCLP results in a triangular-shaped dental arch. Inter canine distance decreases more markedly during growth than the intertuberosity distance (Heidbuchel, Kuijpers-Jagtman 1997).

The maxillary expansion is important to align the palatal segments preparing the upper arch to receive the secondary bone graft. Conventional RME expansion with Hyrax appliance may lead to a posterior overexpansion in order to align the maxillary segments in the cleft area. For this reason, the expander with differential opening (EDO) was presented for achieving different anterior and posterior amount of expansion in BCLP (Garib et al. 2014).

Unlike previous methodologies (Berkowitz, 1971; Harding, Mazaheri, 1972; Heidbuchel, 1997) that used linear measurements to describe the BCLP dental arch, landmark-based geometric morphometrics involves summarizing shape in terms of a landmark configuration (Bookstein 1991). This gives the intuitive visualization of the shape and the spatial localization of shape variation easily with graphical representation (Rohlf F, Marcus LF 1993).

Aiming the morphological analysis of the expansion outcomes, the purpose of this study was to compare the effects of Hyrax, Quad-helix and EDO on the maxillary dental arch size and shape in BCLP patients.

2 OBJECTIVE

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Aiming the morphological analysis of the maxillary expansion outcomes, the objective of this study was to compare the effects of Hyrax, Quad-helix and EDO on the maxillary dental arch size and shape in BCLP patients.

3 ARTICLE

3 ARTICLE

The article presented in this Dissertation was written according to the American Journal of Orthodontics and Dentofacial Orthopedics instructions and guidelines for article submission.

Dental arch size and shape after maxillary expansion in bilateral complete cleft lip and palate (BCLP): Comparison between Hyrax, Quad-helix and Expander with differential opening

ABSTRACT

Introduction: The objective of this study was to compare the effects in upper dental arch size and shape after maxillary expansion with Hyrax, Quad-helix and a differential opening expander in bilateral cleft lip and palate (BCLP) patients.

Methods: Seventy-five patients were divided into three groups: Hyrax (H), Quad-helix (QH), and Expander with differential opening (EDO). Digital models were obtained from BCLP patients before (T1) and after 6 months (T2) of the maxillary expansion. Twelve landmarks were placed, by one investigator, on T1 and T2 dental models of each group and x,y coordinates for each landmark were collected. For dental arch size analysis, centroid size of each dental arch at T1 and T2 was calculated from the raw coordinates and was used as the measure of size. Procrustes Analysis was performed for dental arch shape analysis. Analysis of variance (ANOVA) was used to compare the groups for size and shape differences ($p < 0,05$). **Results:** There were no significant dental arch size differences among expanders, either at T1 or T2. Differences in arch shape were found between all groups at T2. Intragroup arch shape showed a significant variation for QH and EDO groups while remained stable in H group. **Conclusions:** When dental arch shape changes are desired, with greater intercanine than intermolar increase, either the Quad-helix or the Expander with differential opening should be used, while the Hyrax expander should be used when no arch shape changes are desired.

Keywords: Palatal Expansion Technique, Cleft Palate, Cleft Lip, Orthodontics

INTRODUCTION

Cleft lip and palate is the craniofacial anomaly with the highest prevalence in the human population.¹ Bilateral complete cleft lip and palate (BCLP) is the most severe cleft lip and palate type, maintaining the embryological maxillary division and challenging the multidisciplinary treatment team.² At birth, the premaxilla is often deviated from the midline and extremely projected forward, causing a facial convexity.³

In untreated patients, premaxilla maintains its anterior projection, and the posterior segments tend to approximate, resulting in a narrow dental arch.⁴ Lip, and palate repair surgeries often have a negative influence on the maxillary growth and development, resulting in maxillary dental arch constriction and maxillary sagittal deficiency.⁵ As consequence, anterior and posterior crossbites arch and maxillary arch perimeter reduction are frequently observed.⁶ The maxillary transversal expansion is often required before secondary bone grafting.⁷ A vast range of appliances has been used for maxillary expansion in cleft lip and palate including the Quad-Helix appliance and Hyrax and Haas-type expanders. All appliances showed to be effective on maxillary dimension improvement, with the Quad Helix promoting a greater expansion of the intercanine width.⁸⁻¹¹

Transverse maxillary constriction in BCLP results in a triangular-shaped dental arch. Intercanine distance decreases more markedly during growth than the intertuberosity distance, a fact that usually requires greater expansion in the anterior region.^{4,12} For this reason, the expander with differential opening (EDO) was presented for achieving different anterior and posterior amount of expansion in BCLP.¹³ EDO promote a greater expansion in the anterior region of the maxillary dental arch, with no skeletal differences from the traditional Hyrax.¹⁴ Aiming the morphological analysis of these outcomes, the purpose of this study was to compare the effects of Hyrax, Quad-helix, and EDO on the maxillary dental arch size and shape in BCLP patients.

MATERIALS AND METHODS

This study, a secondary data analysis of prospective studies^{10,11} was approved by the ethics committee (Protocol number 1.991.298) in research committee of the Hospital for Rehabilitation of Craniofacial Anomalies at the University of São Paulo, Brazil.

Patients with BCLP were selected in a single center from 2011 to 2013. The inclusion criteria were: age between 7 and 11 years, lip and palate repair performed between 3 and 24 months of age, presence of maxillary arch constriction and need for maxillary expansion prior the secondary bone graft. Exclusion criteria were: associated syndromes, history of previous orthodontic treatment, caries lesions, loss of periodontal tissue, absence of teeth to support the expansion appliance. The final sample was composed of 75 patients with BCLP (55 males and 20 females) with a mean age of 8,7 years.

Patients were divided into three groups in sequence: Hyrax (group H, n=25), Quad-helix (group QH, n=25) and expander with differential opening (group EDO, n=25). The expanders were supported by bands adapted to the first permanent molars or the second deciduous molars. Hyrax and EDO also had C-shape clasps bonded to the deciduous canines (Figure 1). Hyrax screw was activated 1 turn per day divided into two quarters in the morning and two quarters in the evening until the posterior maxillary teeth palatal cusps align to the mandibular posterior teeth buccal cusps. After the active phase, the appliance was maintained in the dental arch as a retainer for six months. Quad-helix appliance was constructed with 0.36" stainless steel wire (Figure 1) and activated 6mm every two months until reaching over-expansion using the same reference of Hyrax group. After the expansion phase, quad-helix was maintained in the dental arch as retention for six months. Both anterior and posterior screws of the expander with differential opening were activated two quarters in the morning and two quarters in the evening until maxillary molar palatal cusps align to the mandibular molar buccal cusps. In the following days, only the anterior expander screw was activated until an approximately 2mm overcorrection was reached in the deciduous canine region. The amount of anterior region expansion depended on the severity of the maxillary constriction of each patient. The appliance was maintained in the dental arch as retention for six months. Dental models were obtained before the expansion (T1) and six months after the

active phase when the appliance was removed (T2). Two dental models of the group H were lost. Ten patients of each group were in transition dentition at T2. The absence of some teeth made the methodology impossible to be performed. Therefore, these patients were removed from the sample (Figure 2).

The dental models were scanned using the 3Shape R700 3D scanner (3Shape A/S, Copenhagen, Denmark). The digitalized casts were saved in (.STL) format through the software Scan It (3Shape A/S, Copenhagen, Denmark). After scanning, the digital models were imported to the software Stratovan Checkpoint (Stratovan Corporation, Davis, USA). Twelve homologous landmarks according to previous studies^{15,16} were placed, by one investigator, on T1 and T2 maxillary dental models of each group (Figure 3, Table I). The x,y coordinates for each landmark were collected and exported in (.TXT) format. The raw landmark coordinates were imported into the software MorphoJ (Klingenberg Lab, Manchester, UK).

For arch size analysis, centroid size of each dental arch in T1 and T2 was calculated from the raw coordinates and used as maxillary dental arch size measurement.

For arch shape analysis, Generalized Procrustes Analysis^{17,18} was performed using the software MorphoJ. With this method, non-shape variation is removed from the raw data, expressing pure shape differences between groups. A mean shape dental arch was determined for each group and time point after dental arches translation, rotation and scale (Figure 4).

STATISTICAL ANALYSIS

To determine the method error involved in the method, the same investigator replaced the twelve landmarks in 100% of the sample after three weeks. The random error was calculated by intraclass correlation coefficient (ICC) for both x and y coordinates values.

Intergroup comparisons for arch size were performed using the analysis of variance (ANOVA) and Kruskal-Wallis. SPSS Statistics, version 23 (IBM, Armonk, USA) was used.

The mean shapes of maxillary dental arch were compared using analysis of variance (Procrustes ANOVA)^{17,19,20} in the software MorphoJ.

Results were considered significant at $P<0.05$.

RESULTS

ICCs showed a high degree of reliability for repeated landmark placement. 0.999 for the x coordinates and 0.987 for the y coordinates.

There were no significant dental arch size differences among expanders, either at T1 or T2 (Table II).

Before expansion, variation in arch shape was found between QH and EDO groups (Table III). After expansion, differences in arch shape were found between all groups (Table III).

Both the Quad-helix and the EDO expanders changed the maxillary arch shape between T1 and T2, while the Hyrax expander showed no change in arch shape between T1 and T2 (Table IV).

DISCUSSION

Geometric morphometrics has been used in biology and anthropology to observe species variation in evolutionary and biological processes.²¹ Landmark-based geometric morphometrics involves summarizing shape regarding a landmark configuration.²² This gives the intuitive visualization of the shape and the spatial localization of shape variation easily with graphical representation.²³ Morphometrics has been previously used as an alternative cephalometric analysis,^{24,25} overcoming limitations of the traditional method of do not separate size from shape.²⁶⁻²⁸ For this study, centroid size was used as size measurement. Centroid size is an isometric estimator of size, calculated as the square root of the sum of the squared distances between each landmark and the centroid of the form.²⁹ Generalized Procrustes Analysis was performed for shape analysis. With this method, non-shape variation is removed from the raw data by translating all dental arches to a common location (same centroid), rescaling all dental arches to unit centroid size and rotating all dental arches into an optimal least-squares alignment (Figure 4). All differences in location, size, and orientation are removed, and intergroup differences express pure shape differences.³⁰ The principal limitation of the method in this study was the necessity of the twelve homologous points be placed on digital models for running Procrustes superimposition. In case of missing tooth, correspondent point would not be placed making it impossible to use the digital model. Lele,³¹ in addition to

describing this limitation of the need for all landmarks, also assumed that the superimposition method approaches yield inconsistent estimators of mean form as well shape. However, Procrustes analysis was well used in growth and maturation studies,³²⁻³⁴ facial profile analysis,^{35,36} skeletal shape evaluation^{37,38} and even in facial attractiveness.³⁹

The lack of references using similar methodology for dental arch shape analysis made impossible to calculate sample size. And because it was a secondary analysis of a prospective study,^{10,11} the sample size was limited to the existing one. Additionally, two dental models of the group H were lost, and ten patients of each group were in transition dentition at T2. The absence of some teeth made the methodology impossible to be performed (points placement on models). Therefore, these patients were removed from the sample (Figure 2).

There was no statistically significant difference in dental arch size between all groups at T1 and T2, indicating the homogeneity of the sample due to the successful randomization. Results at T2 are in agreement with Medeiros Alves et al.¹⁰ and Almeida et al.¹¹ that there were no differences between the orthopedic changes of Hyrax and Quad-helix expansions in BCLP patients. The greater intercanine expansion in Groups QH and EDO may have been compensated by the also greater posterior movement of the incisor in these two groups, which would explain the similarity of the dental arch size with the Group H at T2. It seems that the maxillary expansion promoted by the three appliances produced effective dental arch size changes in BCLP patients.

A statistical difference was found in the comparison between QH T1 and EDO T1 dental arch shapes. However, as can be seen in Figure 3, this finding is more related to the pre-maxilla deviation to the left or right side, a striking feature of BCLP patients.³ There was statistical dental arch shape difference between all groups at T2 (Figure 5). However, the intragroup comparability showed no dental arch shape difference between Hyrax T1 and Hyrax T2, indicating that only Quad-helix and EDO promoted shape changes in the dental arch after maxillary expansion (Figure 6). Even with the lack of studies analyzing the alteration of the dental arch shape in BCLP patients due to maxillary expansion, the greater expansion in the anterior region of the maxillary dental arch described by Tindlund, Rygh and Olav⁴⁰ using Quad-helix and Garib et al.¹⁴ using EDO in BCLP patients, seems to be responsible for these shape differences. These changes in dental arch shape are positive for

BCLP patients once a triangular morphology with the worse constriction in the anterior region of the dental arch was described previously.⁶

Another change observed for Quad-helix and EDO in shape superimpositions (Figure 5) was the posterior movement of the central incisor or the premaxilla as a whole, indicating that this posterior movement is enhanced by the greater intercanine expansion and by the tension of the operated soft tissue. This result was previously reported in cleft⁴¹ and noncleft^{42,43} patients. At the same time, a more parabolic dental arch shape is achieved with a greater intercanine expansion using Quad-helix and EDO, a Class III interarch relationship can be impaired by the posterior movement of the premaxilla. The sagittal hypoplasia of the midface is expected in BCLP patients as side effects of the lip and palate repair.⁴⁴

Maxillary expansion in BCLP patients affects the maxillary segments. The orthopedic effect is expressed by a lateral displacement of the posterior segments leading to an alignment of these segments with the premaxilla. The maxillary expansion is important to prepare the maxilla to receive the secondary bone graft. The alignment of the maxillary segments better achieved in the Quad-helix and EDO groups (Figures 5 and 6) provides lateral walls for performing the alveolar bone graft.⁷ Conventional rapid maxillary expansion with Hyrax appliance may lead to a posterior overexpansion to align the maxillary segments in the cleft area.¹³

Other interesting differences between groups was the first molar rotation after the expansion with Quad-helix not seen in the Hyrax and EDO groups (figure 6). This can be explained as an effect of the activation of the differential expansion at the maxillary anterior region. Quad-helix anterior extensions are pulled against the premolars and canines palatal surface, distally rotating the banded molars. The ability of rotate molars with Quad-helix during maxillary expansion was previously reported by Vasant, Menon, and Kannan.⁴⁵

Future studies with larger samples should be performed to confirm these tendencies.

CONCLUSIONS

Hyrax, Quad-helix, and Expander with differential opening promoted similar changes in maxillary dental arch size in bilateral cleft lip and palate patients. However, only Hyrax did not significantly change maxillary dental arch shape. When

dental arch shape changes are desired, with greater intercanine than intermolar increase, either the Quad-helix or the Expander with differential opening should be used, while the Hyrax expander should be used when no arch shape changes are desired.

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FIGURES CAPTIONS

Figure 1. A – Hyrax expander patient before expansion. B - Hyrax expander patient with retention 6 months after expansion. C - Quad-helix expander patient before expansion. D - Quad-helix expander patient with retention 6 months after expansion. - E - Expander with differential opening patient before expansion. - F - Expander with differential opening patient after expansion.

Figure 2. CONSORT diagram showing patient flow during the study.

Figure 3. Twelve selected points on digital models.

Figure 4. Generalized Procrustes Analysis example. A - Two configurations. B - Translation to the same centroid. C - Rotation around the corresponding centroid until the sum of the squared distances between the homologous landmarks is minimized. D - Scaling the configurations to the same centroid size. E - Mean shape in red.

Figure 5. Superimposition of Hyrax, Quad-helix, and EDO T2 Procrustes mean shapes.

Figure 6. T1 and T2 Procrustes mean shapes superimpositions. A - Hyrax. B – Quad-helix. C - Expander with differential opening.

FIGURES

Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

Figure 6

TABLES

Table I. Landmarks used for defining maxillary dental arch shape.

Point	Description
1	Distobuccal cusp of the right first molar
2	Mesiobuccal cusp of the right first molar
3	Buccal cusp of the right second premolar*
4	Buccal cusp of the right first premolar*
5	Cusp of the right canine
6	Midpoint of the incisal edge of the right central incisor
7	Midpoint of the incisal edge of the left central incisor
8	Cusp of the left canine
9	Buccal cusp of the left first premolar*
10	Buccal cusp of the left second premolar*
11	Mesiobuccal cusp of the left first molar
12	Distobuccal cusp of the left first molar
*	Or midpoint of the buccal ridge of deciduous molars

Table II. Intergroup comparability of dental arch size at T1 and T2 (ANOVA)

	Hyrax n=13	Quad Helix n=15	EDO n=15	
Variable	Mean(SD)	Mean(SD)	Mean(SD)	P
T1 arch size	77.96(6.90)	78.12(7.05)	75.02(5.08)	0.141
T2 arch size	81.52(7.96)	85.86(5.85)	84.54(5.19)	0.200

Table III. Intergroup comparisons for arch shape in T1 and T2 shape (ANOVA)

Groups	Residual	F-value	P
Hyrax T1 vs. Quad Helix T1	0.0006578976	0.48	0.9747
Hyrax T2 vs. Quad Helix T2	0.0005744039	1.68	0.0331*
Hyrax T1 vs. EDO T1	0.0008460767	1.37	0.1286
Hyrax T2 vs. EDO T2	0.0005874717	1.94	0.0086*
Quad Helix T1 vs. EDO T1	0.0007489566	2.23	0.0017*
Quad Helix T2 vs. EDO T2	0.0005273134	2.75	<0.0001*

*Statistically significant at $P < 0.05$

Table IV. Intragroup variation for arch shape (ANOVA)

Groups	Residual	F-value	P
Hyrax	0.0006992502	0.60	0.9170
Quad Helix	0.0005446685	3.22	<0.0001*
EDO	0.0007288090	3.14	<0.0001*

*Statistically significant at $P < 0.05$

4 GENERAL CONCLUSIONS

4 GENERAL CONCLUSIONS

The maxillary expansion is a very important procedure in the treatment of BCLP patients. The maxillary segments alignment prior to the second bone graft is one of the expansion goals, and the shape of the upper arch is directly related to this alignment. So, clinically, the dental arch shape changes should be analysed. In this study, the results showed that when it is desirable dental arch shape changes, a greater increase in the intercanine distance compared to the intermolar expansion is necessary.

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REFERENCES

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ANNEXES

ANNEXES

Ethics Committee approval, protocol number 1.991.298.

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Forma de arco dentário superior após expansão maxilar em pacientes com fissura completa e bilateral: comparação dos aparelhos Quadrihélice, Hyrax e Diferencial por meio de modelos digitais

Pesquisador: FERNANDO DOS SANTOS PUGLIESE

Área Temática:

Versão: 1

CAAE: 65557417.4.0000.5441

Instituição Proponente: Hospital de Reabilitação de Anomalias Craniofaciais da USP

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.991.298

Apresentação do Projeto:

Trata-se de um projeto de dissertação de mestrado de autoria de Fernando dos Santos Pugliese, sob a orientação da Prof. Dra. Daniela Gamba Garib Carreira e Co-Orientação do Prof. Dr. José Roberto P. Lauris. Esse estudo retrospectivo pretende analisar os dados secundários de uma amostra de modelos digitais do arco dentário superior, coletados em estudos prévios (de MEDEIROS ALVES 2015; CALIL 2015) aprovados pelo CEP-HRAC (protocolos 407.763 e 885.845). A amostra será composta por modelos dentários digitais de 75 pacientes de 7 a 11 anos, com fissura labiopalatina completa e bilateral tratados com expansão maxilar entre 2011 a 2014 no Hospital de Reabilitação de Anomalias Craniofaciais. A amostra será dividida em 3 grupos de 25 modelos cada, de pacientes tratados com os 3 tipos de expansores (Quadrihélice, Hyrax e Diferencial). Os modelos digitais foram obtidos antes da expansão (T1) e 6 meses após a expansão (T2) para pesquisas anteriores e serão fonte de análises secundárias. Pontos de referência em modelos digitais serão utilizados para obtenção da forma do arco maxilar antes e após a expansão. Serão calculadas as formas médias iniciais e finais dos arcos dentários em cada grupo de estudo. Por meio da sobreposição do contorno inicial e final do arco dentário superior, serão mensuradas as áreas anterior e posterior entre as formas de arco em milímetros quadrados.

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Continuação do Parecer: 1.991.298

Objetivo da Pesquisa:

Avaliar e comparar as alterações na forma de arco dentário superior decorrentes da expansão maxilar em pacientes com fissura labiopalatina completa e bilateral realizada com os aparelhos expansores Quadrihélice, Hyrax e Diferencial por meio de modelos digitais. A hipótese nula é de que não há diferença nas alterações da forma do arco dentário produzidas pelos 3 tipos de aparelhos.

Avaliação dos Riscos e Benefícios:

Segundo os pesquisadores, quanto aos riscos, por se tratar do uso de dados secundários de pesquisas previamente aprovadas pelo comitê de ética e por apenas os pesquisadores terem acesso aos dados, esse estudo não apresenta riscos para os pacientes.

Em relação aos benefícios, citam que os pacientes envolvidos na pesquisa que originaram os dados secundários a serem estudados se beneficiaram anteriormente com protocolos de tratamento baseados em evidências científicas. Além de que os resultados obtidos por esse estudo poderão influenciar escolhas de protocolos de tratamento.

Comentários e Considerações sobre a Pesquisa:

Projeto de uma pesquisa com mérito científico que certamente contribuirá para ajudar a definir futuros protocolos de expansão maxilar para pacientes com fissura bilateral.

Considerações sobre os Termos de apresentação obrigatória:

Os seguintes termos foram apresentados e estão de acordo:

- Carta de encaminhamento;
- Formulário HRAC;
- Folha de Rosto da Plataforma Brasil;
- Termo de Compromisso de Manuseio de Informações;
- Termo de Permissão para uso de Registros para Fins Científicos;
- Termo de Compromisso de Tornar Públicos os Resultados da Pesquisa e Destinação de Materiais ou Dados Coletados;
- Termo de Compromisso do Pesquisador Responsável.

Por tratar-se pesquisa com fonte de dados secundários, dispensou-se o Termo de Consentimento Livre e Esclarecido; A Dra Rita Lauris como Responsável Técnica da Divisão Odontológica do HRAC-USP deu autorização de acesso aos arquivos.

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Continuação do Parecer: 1.991.298

Recomendações:

Nenhuma.

Conclusões ou Pendências e Lista de Inadequações:

O projeto não apresenta nenhum comprometimento ético, por isso sugerimos ao comitê sua aprovação.

Considerações Finais a critério do CEP:

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

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

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Outros	Checklist_Prot_Pesq_16_2017.pdf	10/03/2017 10:24:52	Rafael Mattos de Deus	Aceito
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_866941.pdf	10/03/2017 09:39:11		Aceito
Outros	Fernando_Term_Comp_Manuseio_Inform.pdf	09/03/2017 19:08:58	FERNANDO DOS SANTOS PUGLIESE	Aceito
Projeto Detalhado / Brochura Investigador	PROJETO.pdf	09/03/2017 18:55:26	FERNANDO DOS SANTOS PUGLIESE	Aceito
Outros	Fernando_Term_Comp_Tornar_Publico_Dest_Mat.pdf	09/03/2017 17:03:09	FERNANDO DOS SANTOS PUGLIESE	Aceito
Outros	Fernando_Term_Comp_Pesq_Resp.pdf	09/03/2017 17:00:17	FERNANDO DOS SANTOS PUGLIESE	Aceito
Declaração de Instituição e Infraestrutura	Fernando_Form_Cadastro_HRAC.pdf	09/03/2017 16:48:29	FERNANDO DOS SANTOS PUGLIESE	Aceito
Outros	Fernando_Carta_Encaminham.pdf	09/03/2017 16:47:45	FERNANDO DOS SANTOS PUGLIESE	Aceito
Folha de Rosto	Fernando_Folha_Rosto.pdf	09/03/2017 16:39:48	FERNANDO DOS SANTOS PUGLIESE	Aceito

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Continuação do Parecer: 1.991.298

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

BAURU, 30 de Março de 2017

Assinado por:

Renata Paciello Yamashita
(Coordenador)

Endereço: Rua Silvio Marchione, 3-20

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