

UNIVERSIDADE DE SÃO PAULO
HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAS

BRUNO MARIANO RIBEIRO BRAGA

**Canine eruption pathway after alveolar grafting with
different materials in patients with complete unilateral cleft
lip and palate**

**Trajeto de irrupção dos caninos após enxertia alveolar com
diferentes materiais em pacientes com fissura labiopalatina
unilateral completa**

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Orientadora: Prof.^a. Dr.^a. Terumi Okada Ozawa

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DEDICATÓRIA

Ao Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo, carinhosamente chamado de Centrinho, e a todos os seus mais de 130 mil pacientes e/ou responsáveis atendidos durante seus 55 anos de história. Uma verdadeira escola ao ensinar das mais belas formas a humanização em seus atendimentos e equidade para com cada família acolhida.

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*“A mente que se abre a uma nova ideia
jamais voltará ao seu tamanho original”.*

Albert Einstein

ABSTRACT

The aim of this study was to evaluate the outcome of cleft-permanent canine (CPC) in individuals with complete unilateral cleft lip and palate (CUCLP) submitted to secondary alveolar grafting (SAG) with different materials. **Study Design:** Retrospective longitudinal study analyzed 120 individuals undergoing alveolar grafting with iliac crest, rhBMP-2 and mandibular symphysis. The individuals were selected at a single center and divided equally into three groups. Panoramic radiographs were analyzed by Dolphin Imaging 11.95 to measure CPC angulation and distance from occlusal plane of the CPC at two different timepoints. Interphases and intergroup comparisons were performed using analysis of variance ($p < 0,05$). **Results:** No statistical significance was found between grafting materials ($P = 0.416$). At T1, the distance from occlusal plane was greater for rhBMP-2 and mandibular symphysis. Lateral incisor was not related to success or not eruption of CPC ($P = 0.870$). **Conclusion:** CPC eruption was similar for materials studied. The lateral incisor on the cleft side did not influence the spontaneous eruption of CPCs.

Keywords: cleft lip; cleft palate; bone transplantation.

RESUMO

Trajeto de irrupção dos caninos após enxertia alveolar com diferentes materiais em pacientes com fissura labiopalatina unilateral completa

O objetivo deste estudo foi avaliar o comportamento do canino permanente (CP) em indivíduos com fissura labiopalatina unilateral completa (FLPC) submetidos a enxerto alveolar secundário (EOAS) com diferentes materiais. **Desenho do Estudo:** Estudo longitudinal retrospectivo analisou 120 indivíduos submetidos a enxerto alveolar com crista ilíaca, rhBMP-2 e sínfise mandibular. Os indivíduos foram selecionados em um único centro e divididos igualmente em três grupos. Radiografias panorâmicas foram analisadas pelo Software Dolphin Imaging (11.95) para medir a angulação do CP e sua distância em relação ao plano oclusal em dois momentos diferentes. As comparações interfases e intergrupos foram realizadas por meio de análise de variância ($P < 0,05$). **Resultados:** Não foi encontrada significância estatística entre os materiais de enxertia ($P = 0,416$). Em T1, a distância do CP em relação ao plano oclusal foi maior para rhBMP-2 e sínfise mandibular. O incisivo lateral não foi determinante para a irrupção do CP ($P = 0,870$). **Conclusão:** A irrupção do CP foi semelhante para os materiais estudados. O incisivo lateral do lado fissurado não influenciou a irrupção espontânea dos CPs.

Palavras-chave: fenda labial; fenda palatina; transplante ósseo.

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LIST OF ABBREVIATIONS AND ACRONYMS

%	Porcentagem
*	Statistical significance
<	Menor que
>	Maior que
±	Mais ou menos
ABG	Enxerto ósseo alveolar
AG	Enxerto ósseo
BMPG	Grupo rhBMP-2
CLP	Fissura de lábio e palato
CP	Canino permanente
CPC	Canino permanente adjacente à fissura
CUCLP	Fissura de lábio e palato unilateral completa
DDS	Cirurgião-Dentista
EA	Enxerto alveolar
EAS	Enxerto alveolar secundário
et al.	Colaboradores
FLPC	Fissura labiopatina unilateral completa
G	Grupo
h	Altura
HRAC	Hospital de Reabilitação de Anomalias Craniofaciais
HRAC-USP	Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo
IBM	International Business Machines Corporation®
IC	Crista ilíaca
ICC	Índice de correlação intraclasse
ICG	Grupo crista ilíaca
Inc	Incorporated
LI	Incisivo lateral
mm	Milímetro
MS	Sínfise mandibular
MSc	Mestre em Ciências
MSG	Grupo sínfise mandibular
º	Grau

p	Significância estatística
p	Significância estatística
PC	Canino permanente
PhD	Doutor em Ciências
PMC	Canino permanente maxilar
rhBMP-2	Proteína morfogenética óssea humana recombinante
RME	Expansão rápida da maxila
S	Cirurgião
SABG	Enxerto ósseo alveolar secundário
SAG	Enxerto alveolar secundário
SD	Desvio padrão
SPSS	Statistical Package for the Social Sciences®
t Test	Teste estatístico
T1	Tempo um
T2	Tempo dois
UCLP	Fissura de lábio e palato unilateral
USA	Estados Unidos da América
α	Alfa

SUMMARY

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1 INTRODUCTION

Cleft lip and palate (CLP) is one of the most common congenital anomalies that compromise craniofacial development, on a scale of 1:700 births worldwide, of multifactorial etiology (CANDOTTO *et al.*, 2019), predominantly in males; most frequently affecting the left lip. It occurs between the 4th and 12th week of intrauterine life, due to the absence of elimination of the mesodermal grooves that exist between prominences and processes that will form the face, not completing the expected structure for growth within normal standards (FREITAS *et al.*, 2012). Cleft lip and/or palate treatment is long-term and requires a specialized, multidisciplinary and interdisciplinary team. The first consultations occur soon after the baby is born and, electively, there are the first plastic surgeries for the lip and/or palate in early childhood (FREITAS *et al.*, 2012).

Secondary alveolar bone graft (SABG) is performed at the mixed dentition, preferentially before the CPC eruption, because the eruption contributes to the maintenance of the grafted area and adjacent supporting periodontium (BOYNE and Sands, 1972; SILVA-FILHO *et al.*, 1995; TRINDADE-SUEDAM *et al.*, 2012). Furthermore, the SABG provides several benefits to the patient: stabilization of the upper maxillary segments, induction of spontaneous eruption of the CPC, closure of oronasal fistulas, in orthodontic treatment and installation of dental implants (NISHIHARA *et al.*, 2014).

The most used material and considered the gold standard is the autogenous medullary bone harvest from the iliac crest (IC), due to the absence of immunogenicity, its osteogenic, osteoinductive and osteoconductive capacity (SPRINGFIELD, 1992). The bone harvest from the mandibular symphysis (MS) (SINDET-PEDERSEN and ENEMARK, 1990) and the use of recombinant human bone morphogenetic protein (rhBMP-2) in resorbable collagen membrane (CARVALHO, 2011) are alternative materials to the IC. The prevalence of CPC impaction after alveolar bone grafting using IC is 20 times higher compared to a 1% to 2% risk of impaction in individuals without cleft (RUSSEL and MCLEOD 2008). In a study of 101 cleft patients comparing the IC and the mandibular symphysis, it was shown that 32% of patients in the MS group had CPC impaction (ENEMARK *et al.*, 2001). Data reporting impaction rates in BMP-2 alveolar grafting (AG) have already

been describing the prevalence of PCs impaction in cleft and non-cleft sides were 24% and 1.3%, respectively (HOLZ *et al.*, 2018).

Hurme (1949) define impaction as the infra-osseous position of the tooth after the expected time of eruption, while the anomalous infra-osseous position of the canine before the expected eruption time can be defined as a displacement. Besides that, palatal displacement of the maxillary canine results in impaction. RIZELL *et al.* (2021) inferred a more abnormal position of CPC often required surgical exposure and impaction comparing to general population are understudied.

Presurgical and postsurgical orthodontic treatments shown a superior outcome for reconstructing the residual bone defect in cleft patients as well to perform the surgery before the canine eruption (LIAO *et al.* 2015). In addition, rapid maxillary expansion (RME) to create more transverse space can promote spontaneous eruption when used in the early mixed dentition and can also be a successful attempt to increase the eruption rate of palatally displaced canines (65.7%) as inferred in the study by BACETTI *et al.* (2009).

The prevalence of maxillary canine impaction in non-cleft populations ranges from 1.7% to 3%. (ERICSON and KUROL, 1986; SHAH *et al.*, 1978). In patients with CLP, the frequency of CPC impaction is 12% to 35% after ABG (ENEMARK *et al.*, 2001; WESTERLUND *et al.*, 2014). Some authors have associated impacted canines and lack of bone in alveolar defects which can reduce the available space and result in CPC ectopic eruption (TORTORA *et al.* 2008). The time when the ABG is performed (RUSSELL and MCLEOD, 2008) to repair residual alveolar defect can also interfere with the CPC eruption. Studies have shown that increased mesiodistal tipping of CPC after autogenous bone grafting appears to be associated with canine impaction in patients with CLP (RUSSELL and MCLEOD, 2008; OBEROI *et al.*, 2010; TORTORA *et al.*, 2008; WESTERLUND *et al.*, 2014). In addition, a relationship between tooth agenesis, clefts and genetic disorders has been suggested (LIDRAL *et al.*, 2008; RUSSELL and MCLEOD, 2008).

2 OBJECTIVES

The aim of this study was to evaluate the outcome of cleft-permanent canine (CPC) in individuals with complete unilateral cleft lip and palate (CUCLP) submitted to secondary alveolar grafting (SAG) with three different materials: iliac crest, mandibular symphysis and rhBMP-2.

3. ARTICLE

The article presented in this Dissertation was written according to the Oral Surgery, Oral Medicine, Oral Pathology, and Oral Radiology instructions and guidelines for original research article submission.

Outcomes of cleft-permanent canines after secondary alveolar grafting using different materials in complete unilateral cleft lip and palate

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Abstract

Objective: The aim of this study was to evaluate the outcome of cleft-permanent canine (CPC) in individuals with complete unilateral cleft lip and palate (CUCLP) submitted to secondary alveolar grafting (SAG) with different materials.

Study Design: Retrospective longitudinal study analyzed 120 individuals undergoing SAG with iliac crest, rhBMP-2 and mandibular symphysis. The individuals were selected at a single center and divided equally into three groups. Panoramic radiographs were analyzed by Dolphin Imaging 11.95 Software to measure CPC angulation and CPC height from the occlusal plane at two different timepoints.

Results: No statistical significance was found between grafting materials ($P=0.416$). At T1, the CPC height from occlusal plane was greater for rhBMP2 and mandibular

symphysis compared to iliac crest. Lateral incisor was not related to success or not eruption of CPC ($P=0.870$). **Conclusion:** CPC impaction was similar for materials studied. The lateral incisor on the cleft side did not influence the spontaneous eruption of CPCs.

Introduction

Prevalence of maxillary canine impaction in non-cleft populations ranges from 1.7% to 3%.^{1,2} Maxillary canines usually develop above other permanent teeth in the alveolar process. During spontaneous eruption, the canine moves toward the occlusal plane and gradually becomes vertical.^{3,4} In patients with cleft lip and palate (CLP), the frequency of cleft-permanent canine (CPC) impaction is from 12% to 35% after alveolar bone graft (ABG).^{5,6} CPC erupts more slowly, with delayed root development compared to the contralateral side. This longer and longer-lasting eruption makes it more susceptible to ectopic eruption and increases the risk of its impaction.^{3,4} In addition, a relationship between tooth agenesis, clefts and genetic disorders has been suggested.^{7,3} Studies have shown that increased mesiodistal angulation of CPC after autogenous bone grafting seems to be associated with its impaction.^{3,6,8,9} Some authors have associated impacted canines with the lack of bone in alveolar defects, which reduces the space available for eruption.⁹ In addition, timing of ABG surgery can also interfere with CPC eruption.^{3,10}

Secondary alveolar bone grafting (SABG) is performed at mixed dentition, preferentially before CPC eruption because its eruption contributes to the maintenance of the grafted area and the adjacent supporting periodontium.¹¹⁻¹³ In addition to favoring spontaneous CPC eruption, the main advantage of SABG is to allow orthodontic treatment into the grafted alveolar cleft without harming the periodontal tissues. Other benefits of SABG are stabilization of maxillary segments

and closure of oronasal fistulas.¹⁴ Autogenous medullary bone from the iliac crest (IC) is the most used material and considered the gold standard for SABG, due to its non-immunogenicity and its osteogenic, osteoinductive, and osteoconductive capacity.¹⁵ However, harvesting bone from the IC results in some morbidity and unsightly scarring. Furthermore, operating exclusively intraorally was experienced as a less extensive surgery by patients and their parents as compared to using the IC as a donor site.¹⁶ Therefore, studies aimed at alternative materials to IC were performed. SABGs performed from mandibular symphysis (MS)¹⁶ or from recombinant human bone morphogenetic protein (rhBMP-2) in resorbable collagen membrane¹⁷ have shown similar outcomes when compared to those from IC. Prevalence of canine impaction in patients with CLP after ABG using IC was 20 times higher compared to canine impaction in noncleft individuals.³ A study with patients with CLP and SM showed similar CPC impaction rate between groups.⁵ Prevalence of CPC impaction after alveolar grafts from rhBMP-2 was 24% and 1.3%, on the cleft and non-cleft sides, respectively.¹⁸

Prevalence of canine impaction on the cleft side and its possible risk factors have been widely in the literature. Although this higher prevalence has not been completely clarified, it is probably related to both local tooth and cleft site factors. Therefore, the objective of this study was to evaluate canines outcomes on the cleft side grafted with IC, MS or rhBMP-2. The hypothesis is that canine impaction is similar between these different types of materials.

Materials and Methods

This longitudinal retrospective study was approved by the Institutional Ethics Committee of the Hospital for Rehabilitation of Craniofacial Anomalies of the

University of São Paulo (HRAC-USP) (CAAE: 51860021.2.0000.544; protocol n. 5.072.476) and was conducted in accordance with the Declaration of Helsinki. All included patients received and signed an informed consent. The sample size calculation considered a statistical power of 80% with an alpha error of 5%; a standard deviation of 14.1⁰⁶ and a minimal intergroup difference of 10°. A minimum sample size of 37 patients was required for each group.

One hundred and twenty individuals were selected at a single center from 2006 to 2020. Patients were consecutively selected according to AG material and divided equally into three groups. Inclusion criteria were complete unilateral cleft lip and palate and successful SAG surgery performed before CPC eruption based on the modified Bergland scale modified by Williams et al. 2003.¹⁹ All surgeries were performed by the maxillofacial team of HRAC-USP using iliac crest, rhBMP-2 or mandibular symphysis. This information was collected from medical records. Exclusion criteria were associated craniofacial syndromes, comorbidities, SAG failure, and absence of preoperative or postoperative SAG radiographs. Mean age of groups was: 11 years 4 months (SD \pm 11 months) for iliac crest group (ICG), 10 years 4 months (SD \pm 12 months) for rhBMP-2 group (BMPG) and 10 years 10 months (SD \pm 13 months) for mandibular symphysis group (MSG).

Cleft-permanent canine position was analyzed using panoramic radiographs. Panoramic radiographs were taken before (T1) and 15 months (SD \pm 8 months) after SAG surgery (T2). Mesiodistal angulation of CPC was evaluated by the angle between the long axis of CPC and the drawn bicondylar line.^{18,20,21} CPC height was measured from its cusp tip to the occlusal plane, perpendicularly (Fig.1)^{20,21} using Dolphin Imaging (11.95) Software (Patterson Dental Supply, Inc, Chatsworth, California, USA).¹⁸ In addition, agenesis of the cleft lateral incisor was considered

and development of CPC at T1 was classified according to Nolla's stage of root calcification.²²

Statistics analysis

Panoramic radiographs were analyzed by two blinded and independent examiners. Measurements were repeated with an interval of 7 days for the intra-examiner reliability. Method error was determined using Intraclass Correlation Coefficient (ICC). Systematic and random errors were evaluated using t-test and Dahlberg's formula, respectively. Interphase and intergroup comparisons were performed using analysis of variance and chi-square ($p < 0.05$). Software used for statistical analysis was SPSS Statistical (IBM Corporation, New York, USA).

Results

Intra-examiner reliability for CPC angulation and CPC height measurements was excellent with ICCs= 0.996 and 0.994, respectively. ICCs for inter-examiner reliability were also excellent (0.963 and 0.992) as shown in Table I. Intra-examiner and inter-examiner random error for CPC angulation varied from 1.17° to 3.55°, respectively. For CPC height, intra-examiner and inter-examiner random error ranged from 0.63mm to 0.74mm, respectively. Only CPC angulation showed a significant inter-examiner systematic error ($P=0.007$) (Table I).

Before SAG, differences among groups were found for CPC height (Fig. 2), root formation stage (Fig. 3) and mean age ($P < 0.001$). Patients in the ICG were on average 1year 1month older than patients in the BMPG. There was no statistical significance in CPC outcomes among materials used for reconstruction of residual alveolar defect ($P= 0.416$, Table II). Eighty-seven (72.5%) CPCs erupted

spontaneously (Table II). Intervention of time 3 was found for CPC angulation ($P < 0.001$, Fig. 4), CPC height ($P < 0.001$, Fig. 2) and root formation stage ($P < 0.001$, Fig. 3). CPC height showed a group and time interaction ($P = 0.002$, Fig. 2) and a group effect ($P < 0.001$, Fig. 2). There was a significance difference between ICG vs BMPG ($P < 0.001$) and ICG vs MSG ($P < 0.001$) at T1 - CPCs were higher by 4.61mm and 4.29mm in BMPG and MSG, respectively. Individuals in the MSG presented stage 9 of root formation more frequently compared to those in the BMPG ($P < 0.040$) and ICG ($P = 0.511$) who presented more stage 8.

Intragroup comparison was significant for CPC angulation, CPC height and root formation stage between T1 and T2 ($P < 0.001$, Fig. 2, 3 and 4). The cleft lateral incisor was not statistically related to the success or failure of CPC eruption ($P = 0.870$, Table III).

Discussion

The use of panoramic radiograph is usual to determine the angulation and height of canines.^{4,18,20,21,23} Previous studies have reported that upper condyles are easily found on panoramic radiographs allowing bicondylar tracing to define the internal angle formed between this bicondylar line and the long axis of the canine, showing the reproducibility and reliability of the technique.^{20,23} In some studies, the midline has been used to infer canine angulations, but in patients with CLP, the midline is markedly deviated. In addition, positional adaptation on the cleft maxillary incisors caused by the bone alveolar defect also makes it difficult to identify the midline difficult. Canine height in relation to the occlusal plane has been used to predict tooth impaction in previous studies with non-cleft patients.^{24,25} The occlusal plane may be traced from the cusp tip of the central incisor to the first molar of the

same side²⁵ or using the mesiobuccal cusps of the maxillary first molars.^{18,20,21} Due to the cleft central incisor malposition, the second option was chosen in this study. Intra-examiner and inter-examiner reliabilities for angulation and height ranged from ICC 0.96 to 0.99. Intra- and inter-examiner random error for CPC angulation was less than 4°. Intra- examiner and inter-examiner random error for CPC height was less than 1.00mm (Table I). Although, CPC angulation showed a significant systematic error (P=0.007, Table I), the quality of some older panoramic radiographs made it difficult to identify the condyles. A previous study also reported difficulty in identifying the condyle landmark on certain panoramic radiographs,²⁶ which encourages the use of better-quality radiographs and does not make the method unfeasible.

Despite the attempt to pair groups in starting forms in order to eliminate biases, differences among groups were found for CPC height, root formation stage, and mean age at T1. Although, patients in the ICG were chronologically older than those in the BMPG and there was no statistically significant difference between the chronological ages of ICG and MSG, tooth development was more delayed in both ICG and BMPG compared to that in MSG (Fig. 3) Probably because bone harvesting from the mandibular symphysis is safer when mandibular permanent canines have more developed roots.^{16, 27-29}

The null hypothesis of this study that SAG material does not influence CPC outcome was confirmed (P=0.416, Table II), and is in agreement with previous studies that showed similar rates of canine eruption into grafted site by iliac crest, rhBMP-2 or mandibular symphysis.^{5,17}

In agreement with previous studies that showed that the late alveolar bone graft may be associated with an increased canine angulation and a higher canine position in the horizontal and vertical sectors,^{3,10} an interaction of time was found in

the intergroup and intragroup comparisons for CPC angulation, CPC height and root formation stage in this study.

Patients were submitted to AG before CPC eruption; however, they were not standardized regarding root development. Root development may have influenced CPC outcomes. It is suggested future studies comparing CPC outcomes after AG performed in the same root formation stage and surgeon influence. Panoramic radiographs analyzed varied in timing and was non standardized, which can be explained by institution is a teaching hospital. In addition, institutional imaging protocol established for AG surgery is sometimes not followed because patient's socioeconomic conditions and difficulties to coming back to the hospital.

In conclusion, CPC impaction was similar between the iliac crest, rhBMP-2 and mandibular symphysis as grafting materials. The lateral incisor on the cleft side did not influence the spontaneous eruption of CPCs.

Table I. Intra and Inter examiner reliability for angulation and height of CPC (ICC, Dahlberg Formula and t Test)

	Angulation			Height		
	ICC, Dahlberg Formula and t Test			ICC, Dahlberg Formula and t Test		
Intra examiner reliability	0.996	1,17°	P=0.488	0.994	0.63mm	P=0.466
Inter examiner reliability	0.963	3,55°	P=0.007*	0.992	0.74mm	P=0.060

*statistical significance.

ICC, intraclass correlation coefficient; CPC, cleft-permanent canine.

Table II. Spontaneous and non-eruption of CPCs between groups

	ICG		BMPG		MSG		P
	n	%	n	%	n	%	
Spontaneous	28	70.0	32	80.0	27	67.5	0.416
Non-eruption	12	30.0	8	20.0	13	32.5	

CPCs, cleft-permanent canines; ICG, iliac crest group; BMPG, rhBMP-2 group; MSG, mandibular symphysis group.

Table III. Spontaneous and non-eruption CPCs according to cleft lateral incisor

	Absence of LI		Presence of LI		P
	n	%	n	%	
Spontaneous	81	72.3	6	75.0	0.870
Non-eruption	33	27.7	2	25.0	

CPCs, cleft-permanent canines; LI, lateral incisor.

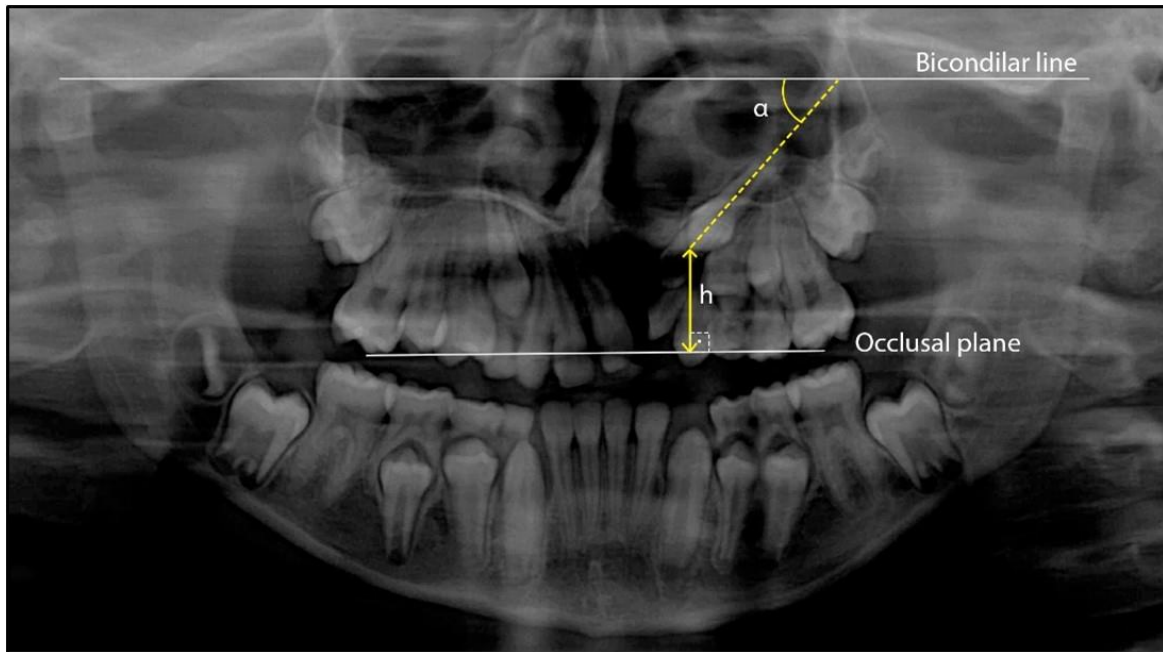


Fig. 1 A bicondylar line superior to the condyles was drawn and used as a reference to measure the mesiodistal angulation of the cleft-permanent canine (α).¹⁹⁻²¹ As alpha decreased, canine mesiodistal angulation increased. The height of the cleft-permanent canines was measured in relation to the occlusal plane by the line drawn from the tip of the mesiobuccal cusp of the maxillary first permanent molars (h).¹⁹⁻²¹

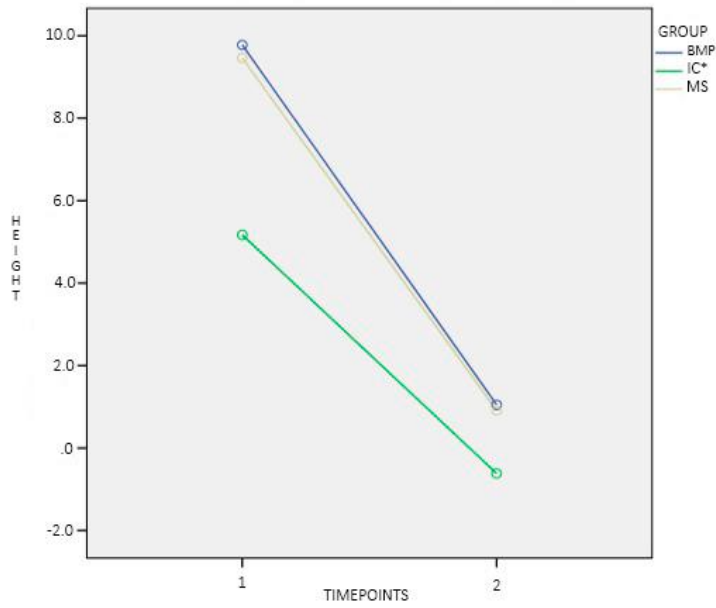


Fig. 2 Interaction of time for CPCs height(mm) from the occlusal plane.

*statistical significance.

BMP, rhBMP-2 group; IC, iliac crest group; MS, Mandibular symphysis group.

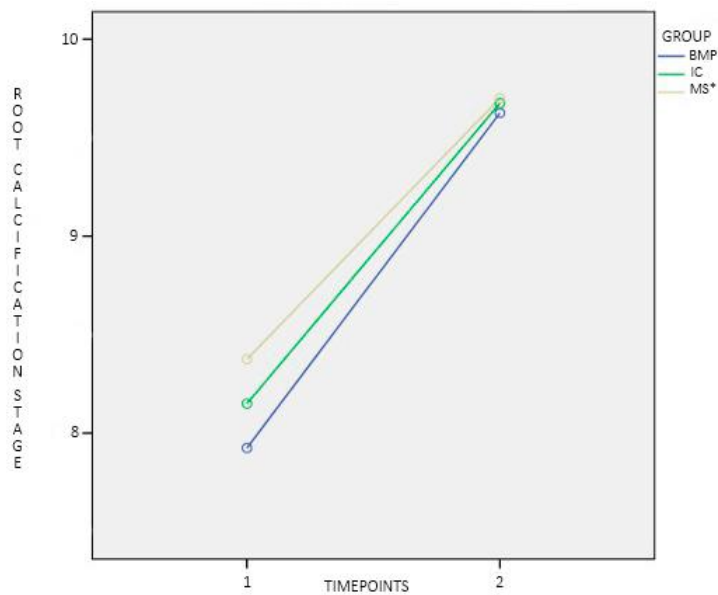


Fig. 3 Interaction of time for CPCs root calcification stage.

*statistical significance.

BMP, rhBMP-2 group; IC, iliac crest group; MS, mandibular symphysis group.

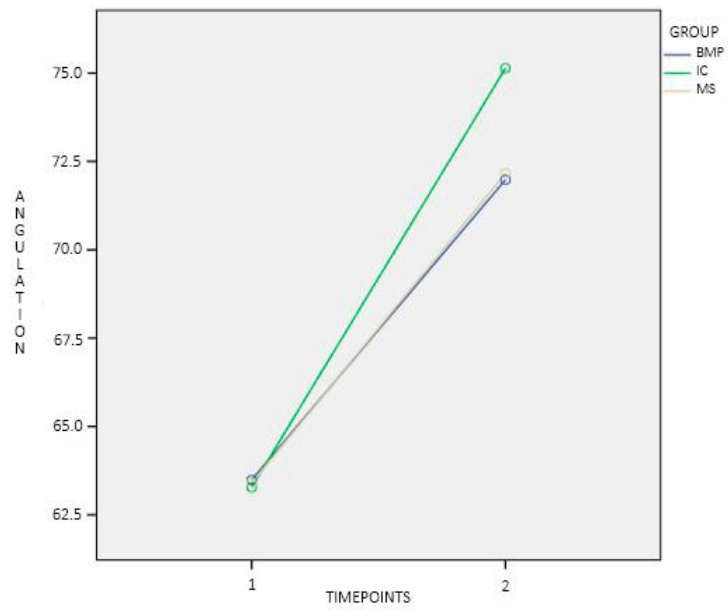


Fig. 4 Interaction of time for CPCs angulation($^{\circ}$).

BMP, rhBMP-2 group, IC, iliac crest group; MS, mandibular symphysis group.

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4. GENERAL CONCLUSIONS

It is suggested future studies comparing CPC outcomes after AG performed in the same root formation stage and surgeon influence as a risk factor for impaction. Panoramic radiographs analyzed varied in timing and was non standardized, which can be explained by institution is a teaching hospital. In addition, institutional imaging protocol established for AG surgery is sometimes not followed because patient's socioeconomic conditions and difficulties to coming back to the hospital.

In conclusion, cleft-permanent canine impaction was similar between the studied grafting materials: iliac crest, rhBMP-2 and mandibular symphysis. The lateral incisor on the cleft side did not influence the spontaneous eruption of CPCs.

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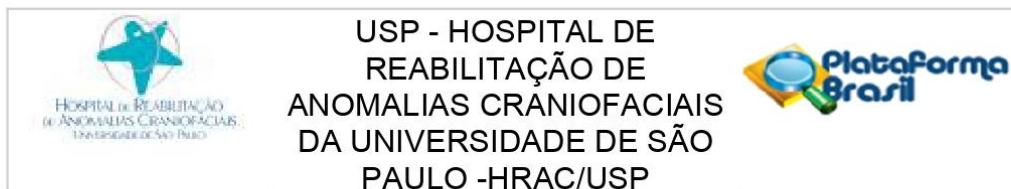
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ATTACHMENT

ATTACHMENT A



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Trajeto de nascimento dos caninos após enxerto com diferentes materiais em pacientes com fissura labiopalatina

Pesquisador: BRUNO MARIANO RIBEIRO BRAGA

Área Temática:

Versão: 2

CAAE: 51860021.2.0000.5441

Instituição Proponente: Hospital de Reabilitação de Anomalias Craniofaciais da USP

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

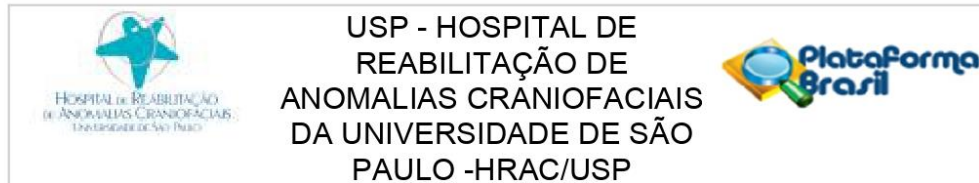
Número do Parecer: 5.072.476

Apresentação do Projeto:

Trata-se de um projeto de Dissertação, de autoria de BRUNO MARIANO RIBEIRO BRAGA sob orientação da Dra. Terumi Okada Ozawa. De acordo com o documento (PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1797941.pdf de 25/08/2021) trata-se de um estudo retrospectivo longitudinal que : Avaliar o trajeto de irrupção do canino permanente adjacente à fissura de indivíduos com fissura labiopalatina unilateral completa (FLPUC) submetidos à enxerto alveolar secundário, no tempo ideal, apontando e confrontando as ocorrências de irrupção espontânea, impacção dentária e de tracionamento ortodôntico com os três tipos de materiais preenchedores utilizados: crista ilíaca, sínfise mandibular e proteína morfogenética óssea recombinante humana do tipo 2 (rhBMP-2). Será utilizada uma amostra de radiografias panorâmicas e periapicais de 120 indivíduos com fissura de lábio e palato unilateral completa (FLPUC), submetidos à cirurgia de enxerto alveolar secundário, no tempo ideal, utilizando três tipos de materiais preenchedores: crista ilíaca anterior, sínfise mandibular e rhBMP-2. Os indivíduos serão divididos em 3 grupos com 40 indivíduos cada, de acordo com o material utilizado para a enxertia, selecionados consecutivamente. A avaliação será no trajeto de irrupção do canino permanente adjacente à fissura, observando a irrupção espontânea, impacção ou a necessidade de tracionamento ortodôntico. As concordâncias intraexaminador e interexaminador

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ATTACHMENT B



Continuação do Parecer: 5.072.476

serão calculadas usando o coeficiente de correlação intraclasse e o kappa. Também serão calculados a média e o desvio padrão dos parâmetros quantitativos. As diferenças entre as posições dos caninos superiores serão analisadas pelos testes de variância e de Tukey

Objetivo da Pesquisa:

De acordo com o documento (PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1797941.pdf de 25/08/2021) o objetivo será avaliar o trajeto de irrupção do canino permanente adjacente à fissura de indivíduos com fissura labiopalatina unilateral completa (FLPUC) submetidos à enxerto alveolar, no tempo ideal, apontando e confrontando as ocorrências de irrupção espontânea, impacção dentária e necessidade de tracionamento ortodôntico com os três tipos de materiais preenchedores utilizados: crista ilíaca, sínfise mandibular e rhBMP -2.

Avaliação dos Riscos e Benefícios:

De acordo com o documento (PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1797941.pdf de 25/08/2021) existe um risco mínimo que é a quebra de confidencialidade, por envolver indiretamente os pacientes com uso de fontes secundárias de informações, radiografias periapicais e panorâmicas.

Benefícios: Espera-se o aprimoramento do conhecimento sobre o comportamento do canino permanente adjacente à fissura quando diferentes materiais de enxertia são utilizados no enxerto ósseo alveolar secundário

Comentários e Considerações sobre a Pesquisa:

Pesquisa retrospectiva observacional que utilizará dados dos arquivos. O estudo tem mérito científico e metodologia adequada a sua proposta

Considerações sobre os Termos de apresentação obrigatória:

Os seguintes termos foram apresentados adequadamente:

*Carta de encaminhamento (Carta_Formulario.docx de 25/08/2021)

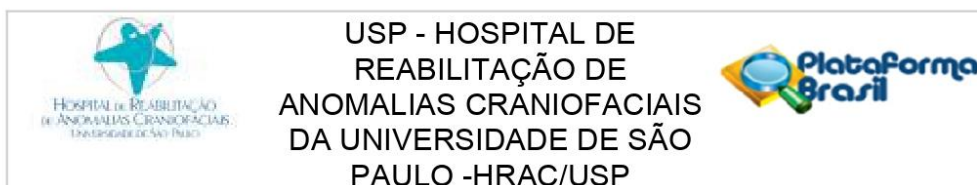
*Declaração de Concordância e Infraestrutura (Declaracao_Concordancia_Infraestrutura.pdf de 25/08/2021)

*Folha de Rosto da Plataforma Brasil (folhaDeRosto.pdf 06/08/2021)

*Termo de Compromisso de Tornar Públicos os Resultados da Pesquisa e Destinação de Materiais ou Dados Coletados (Term_Comp_Tornar_Publico.docx 25/08/2021)

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ATTACHMENT C



Continuação do Parecer: 5.072.476

*Termo de Consentimento Livre e Esclarecido (TermConsent_TCLE.docx 25/08/2021)

Termo de Assentimento (TermAssent_TALE.docx 25/08/2021)

Termo de Permissão para uso de Registros para Fins Científicos (Term_Perm_Uso_Regis.docx 25/08/2021)

Recomendações:

não há

Conclusões ou Pendências e Lista de Inadequações:

o projeto estava sob pendência pois os autores não tinham incluído um TCLE para os pais do participante.

Os autores apresentaram de acordo com a solicitação o TCLE, assim sugiro aprovação do projeto uma vez que a pendência foi totalmente atendida.

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.

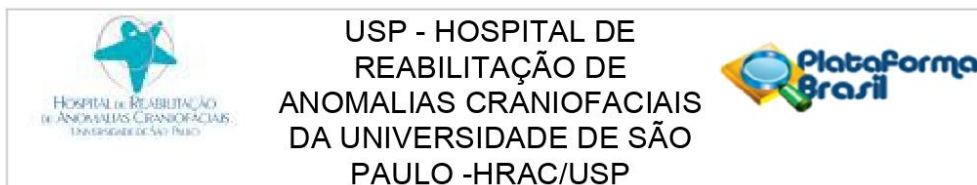
A obtenção de dados pessoais para recrutamento dos participantes da pesquisa deve ser por meio do sistema de chamados, conforme a Portaria 12/2021-SUPE.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1797941.pdf	05/10/2021 19:36:54		Aceito
Outros	Of_Pendencia.docx	05/10/2021 19:35:39	BRUNO MARIANO RIBEIRO BRAGA	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_CronogramaAtualizado.docx	05/10/2021 19:35:12	BRUNO MARIANO RIBEIRO BRAGA	Aceito

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ATTACHMENT D



Continuação do Parecer: 5.072.476

TCLE / Termos de Assentimento / Justificativa de Ausência	TermConsent_TCLE_responsaveis.docx	05/10/2021 19:34:55	BRUNO MARIANO RIBEIRO BRAGA	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_BrunoMariano.docx	25/08/2021 14:44:36	BRUNO MARIANO RIBEIRO BRAGA	Aceito
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TCLE / Termos de Assentimento / Justificativa de Ausência	TermAssent_TALE.docx	25/08/2021 14:44:08	BRUNO MARIANO RIBEIRO BRAGA	Aceito
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Outros	Term_Comp_Tornar_Publico.docx	25/08/2021 14:43:33	BRUNO MARIANO RIBEIRO BRAGA	Aceito
Declaração de Instituição e Infraestrutura	Declaracao_Concordancia_Infraestrutur a.pdf	25/08/2021 14:43:07	BRUNO MARIANO RIBEIRO BRAGA	Aceito
Outros	Carta_Formulario.docx	25/08/2021 14:42:49	BRUNO MARIANO RIBEIRO BRAGA	Aceito
Folha de Rosto	folhaDeRosto.pdf	06/08/2021 12:53:27	BRUNO MARIANO RIBEIRO BRAGA	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

BAURU, 29 de Outubro de 2021

Assinado por:
Renata Paciello Yamashita
(Coordenador(a))

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ATTACHMENT E**DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN DISSERTATION/THESIS**

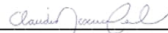
We hereby declare that we are aware of the article (Outcomes of cleft-permanent canines impaction after secondary alveolar grafting using different materials in complete unilateral cleft lip and palate) will be included in (Dissertation) of the student (Bruno Mariano Ribeiro Braga) was not used and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, 6 de JUL 2022.

Bruno Mariano Ribeiro Braga
Author


Signature

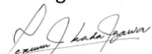
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