UNIVERSIDADE DE SÃO PAULO

HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

PATRICIA MARTINS BUENO

Impact of orthognathic surgery on bite force of individuals with repaired cleft lip and palate

Impacto da cirurgia ortognática sobre a força de mordida de indivíduos com fissura labiopalatina reparada

BAURU

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

Orientadora: Profa. Dra. Ivy Kiemle Trindade Suedam

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FOLHA DE APROVAÇÃO

DEDICATÓRIA

Dedico este trabalho a meus pais,

Rosemeire Martins Bueno e João Bueno Sobrinho,

Que tanto amo, por estarem presentes e sempre me incentivarem na busca dos meus sonhos, sem nunca desistir.

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Profa. Dra. Ivy Kiemle Trindade Suedam

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A ciência nunca resolve um problema

sem criar pelo menos outros dez.

George Bernard Shaw

RESUMO

Bueno PM. Impacto da cirurgia ortognática sobre a força de mordida de indivíduos com fissura labiopalatina reparada. [dissertação]. Bauru (SP): Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo; 2020.

Introdução: As fissuras labiopalatinas causam uma alteração morfofuncional significativa no sistema estomatognático, principalmente pela deficiência maxilar induzida pelas cirurgias plásticas reconstrutivas primárias, muitas vezes sendo necessária a cirurgia ortognática na fase adulta. **Objetivo:** Avaliar o impacto da cirurgia ortognática sobre o sistema estomatognático de indivíduos com fissura labiopalatina reparada, por meio da avaliação da força de mordida. **Material e Métodos:** foram selecionados para essa pesquisa prospectiva, 40 indivíduos, divididos em 2 grupos: 1) CON: 20 indivíduos sem fissura labiopalatina, com classe I de Angle (10 homens, 10 mulheres, 20 anos ± 7,4), e, 2) FLP: 20 indivíduos com fissura labiopalatina (unilateral=10; bilateral=10; 10 homens, 10 mulheres, 23,5 anos ± 5,9) e com indicação para cirurgia ortognática. Para tanto, avaliou-se a força de mordida (FM) em três regiões da arcada dentária em três momentos distintos, no período pré-operatório imediato (PRÉ), período pós-operatório de 3 meses (PO3M) e no período pós-operatório de 6 meses (PO6M), com o uso de um gnatodinamômetro (IDDK Kratos, Cotia-SP, Brazil). **Resultados:** A FM do grupo FLP em todas as regiões e períodos avaliadas foi significativamente menor que do grupo CON. A FM de indivíduos com FLP no PO3M, foi significativamente menor quando comparada ao PRÉ e ao PO6M. No PO6M, a FM estava aumentada em relação ao PRÉ, porém sem significância estatística. Na comparação entre PO3M e PO6M houve um aumento significante da FM. Já, na comparação dos indivíduos com FLP unilateral versus bilateral, observou-se FM estatisticamente similares. Indivíduos do gênero masculino apresentaram FM quase duas vezes maior que o gênero feminino. **Conclusão:** A fissura labiopalatina impacta negativamente a função do sistema estomatognático, interferindo em seu principal parâmetro, a força de mordida. Apesar de ter se observado aumento dos valores de FM no período pós-operatório tardio de 6 meses, em relação à FM prévia à cirurgia ortognática, ainda assim, ela estava significativamente reduzida em relação à indivíduos sem fissura labiopalatina, não atingindo os parâmetros de normalidade.

Palavras-chave: cirurgia ortognática, fissura palatina, força de mordida, sistema estomatognático.

ABSTRACT

Bueno PM. Impact of orthognathic surgery on bite force of individuals with repaired cleft lip and palate. [dissertation]. Bauru (SP): Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo; 2020.

Introduction: Cleft lip and palate (CLP) frequently leads to a maxillary deficiency, induced by primary reconstructive plastic surgery, often requiring orthognathic surgery (OS) in adulthood. **Objective:** To evaluate the impact of orthognathic surgery on the stomatognathic system of individuals with repaired CLP by assessing bite force (BF). **Material and Methods**: Forty individuals were prospectively divided into 2 groups: 1) CON: 20 individuals without CLP (10 male, 10 female, 20y±7.4), 2) CLP: 20 individuals with CLP and with indication for OS (11 male, 9 female, 23.5y±5.9; 10 unilateral; 10 bilateral), BF was evaluated in the immediate preoperative period (PRE), 3 months postoperatively (POST3M) and 6 months postoperatively (POST6M), by means of a gnathodynamometer (IDDK Kratos, Cotia-SP, Brazil). **Results:** BF of the CLP was significantly lower than that of the CON in all evaluated periods. BF of individuals with CLP was significantly lower in POST3M when compared to PRE and POST6M. Although not significant, BF was increased in POST6M when compared to PRE. A significant increase in BF was observed between POST3M and POST6M. The BF of unilateral and bilateral CLP individuals were statistically similar. Males presented a BF almost twice as high as females. **Conclusion:** Cleft lip and palate negatively impacts BF. Although BF values increased 6 months after orthognathic surgery, it was still significantly reduced when compared to control individuals, not reaching normative values.

Keywords: orthognathic surgery, cleft lip, cleft palate, bite force, stomatognathic system.

LIST OF ABBREVIATIONS AND ACRONYMS

ABG	Alveolar bone graft
BF	Bite force
CLP	Cleft lip and palate
CON	Control group
FOB/USP	Bauru Dental School
HRAC/USP	Hospital for Rehabilitation of Craniofacial Anomalies
I	Incisor
LM	Left molar
MA	Maxillary advancement
MAMS	Maxillary advancement + Mandibular setback
N	Newton
PAKT	Paulo Alceu Kiemle Trindade
PMB	Patricia Martins Bueno
POST3M	3-month postoperative cleft lip and palate group
POST6M	6-month postoperative cleft lip and palate group
PRE	Preoperative cleft lip and palate group
RM	Right molar
SD	Standard deviation

SUMMARY

1 General Introduction

1 GENERAL INTRODUCTION

1.1 CLEFT LIP AND PALATE CONSIDERATIONS

Congenital defects identified as cleft lip and palate (CLP) are the most common anomalies that affect the human face and occur with an average prevalence of one individual per 1000 births (Fernandez, Escobar & Zarante, 2016). These craniofacial anomalies are established early in intrauterine life, more precisely in the embryonic period and early fetal period, which means until the 12th gestational week (Freitas et al., 2012). The etiology of CLP is complex and multifactorial, requiring a long lasting and complex treatment for a complete rehabilitation (Sipert, Sampaio, Trindade & Trindade- Junior, 2009).

The classification system adopted at the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo (HRAC / USP) is based on two principles: the morphology and embryological origin of the cleft (Trindade et al., 2007, Silva Filho et al., 1992), using the incisive foramen as an anatomical reference, to classify the clefts into three main groups: 1) cleft lip - clefts affecting the structures anterior to the incisive foramen, 2) clefts lip and palate – those affecting the structures located anteriorly and posteriorly to the incisive foramen, 3) cleft palate – clefts affecting hard palate, posteriorly to the incisive foramen. The first two groups can present unilateral, bilateral or median clefts, being complete or incomplete whilst, the third group can present complete or incomplete clefts only. A fourth group represents the rare facial clefts, i. e., those affecting facial structures, besides the lip and the palate. (Table 1). Such classification was described by Spina et al. (1972) and modified by Silva Filho et al. (1992) (Figure 1).

Due to this complexity, the rehabilitation of individuals with CLP starts early in life. Surgical procedures for rehabilitation include primary repair of the lip (cheiloplasty) and palate (palatoplasty) at 3 and 12 months respectively. These surgical procedures provide clear benefits for facial aesthetics and function. However, it is known that primary plastic surgery can lead to a restrictive maxillary growth in patients with complete CLP (Freitas et al., 2011).

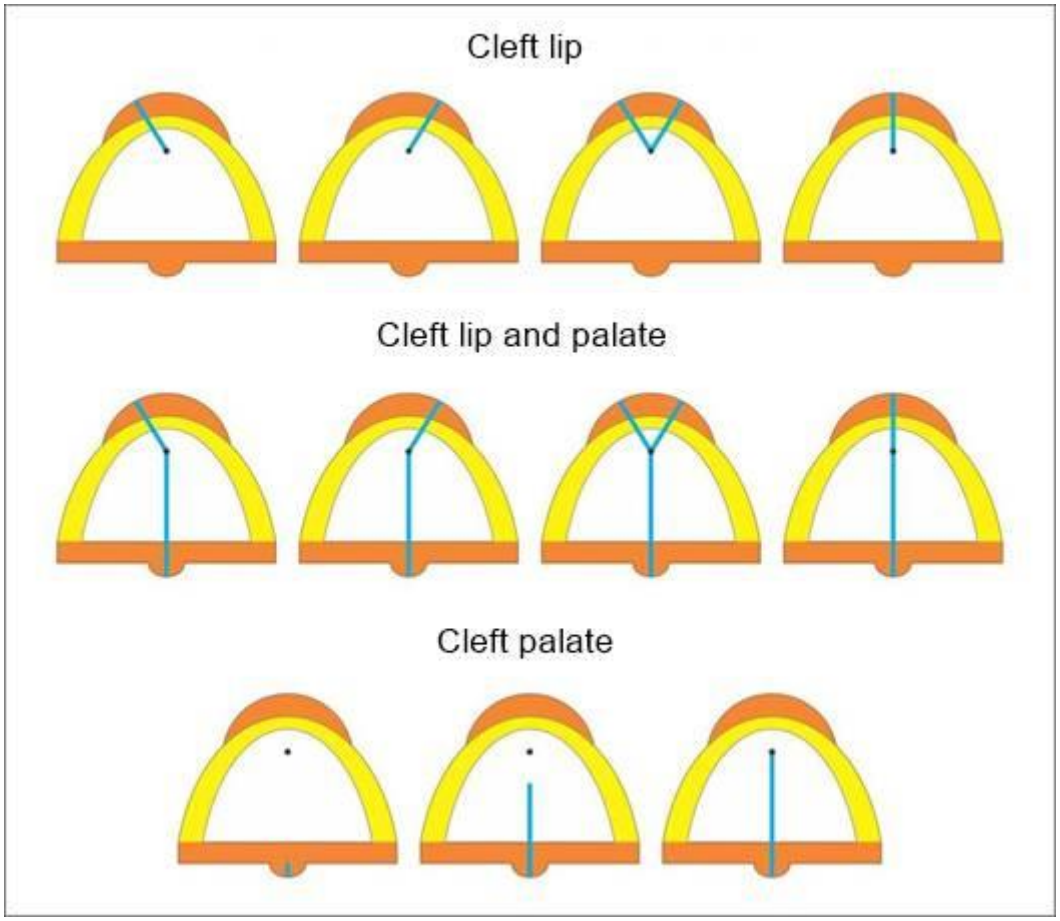
CLP can affect the stomatognathic system in three consequent ways: 1) the anatomical rupture itself affecting the alveolar ridge, 2) the dental problems caused by

the clefted maxilla, and 3) the induced sagittal and transverse maxillary deficiency caused by the reconstructive plastic surgery (Freitas et al., 2011).

Table 1: Spina et al., 1972 classification, modified by Silva Filho et al. and adopted at the HRAC / USP.

Group I **Cleft lip**	Unilateral (left or right)	Incomplete Complete
	Bilateral	Incomplete Complete
	Median	Incomplete Complete
Group II **Complete cleft lip and palate**	Unilateral (left or right) Bilateral Median	
Group III **Cleft palate**	Incomplete Complete	
Group IV **Rare facial clefts**	Rare facial clefts usually occurring distant from the areas of formation of the primary and secondary palate.	

Figure 1: Schematic overview of CLP classification



Source: Silva Filho OG, Freitas JAS, 2007

In: Trindade IEK, Silva Filho OG. Fissuras labiopalatinas: uma abordagem interdisciplinar.

1.2 ORTHOGNATHIC SURGERY FOR MAXILLOMANDIBULAR DISCREPANCY CORRECTION

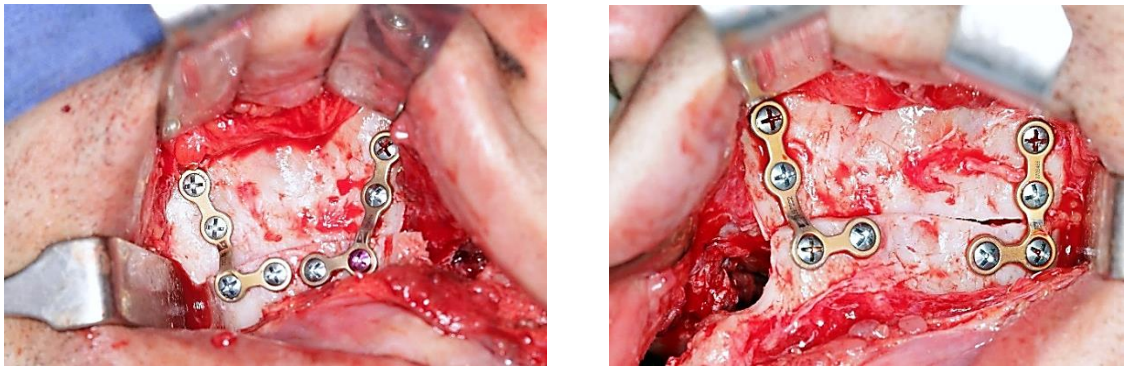
Orthognathic surgery aims to correct, in early adulthood, the skeletal facial deformities, when present (Figure 2). It is one of the last surgeries performed on the rehabilitation process of the patient with CLP. It is a complex surgery that purpose to correct maxillomandibular discrepancies that cause malocclusions, promoting significant aesthetic and functional gains (Robinson & Holm, 2010).

At the age of 8-12y, early before orthognathic surgery, patients are submitted alveolar bone graft (ABG) surgery, which aims at inducing bone formation, joining the alveolar segments divided by the cleft to allow orthodontic mechanics in the anterior region of the maxilla (Trindade et. al. 2007). Because of this procedure, the maxilla can be advanced as a single structure, during orthognathic surgery. Approximately 40% of patients with complete CLP in HRAC-USP submitted to orthognathic surgery, particularly maxillary advancement or combined maxillary advancement surgery and mandibular retro position. In these cases, the amount of maxillary advancement required is considered clinically large, usually around 15 mm (Freitas et al. 2012).

Post-orthodontic dental casts, frontal and profile facial analysis, temporomandibular and mastication muscles analysis, cephalometric tracing and dental cast surgery, comprehend the clinical step prior to orthognathic surgery. (Freitas et al. 2012). After surgical planning, a splint is obtained and will keep the maxilla and the mandible in its final position after surgery.

After surgical planning, the next step is the surgical procedure. The most commonly used osteotomies are Le Fort I for maxillary repositioning (advancement in most of the cases) (Figure 2) and mandibular bilateral sagittal splint osteotomy (Figure 3). The osteosynthesis is performed with 2.0 system plates and screws. The patient remains hospitalized for 2 to 4 days until good hygiene can be maintained and the patient can correctly change the intermaxillary orthodontic elastics. Clinical and radiographic postoperative follow-up is performed every 60 days for the first 6 months and then every 6 months for at least 2 years.

Figure 2: Le Fort I osteotomy used for maxillary advancement.



Source: Dr. Paulo Alceu Kiemle Trindade archieves – HRAC/USP

Figure 3: Mandibular bilateral sagittal splint osteotomy.

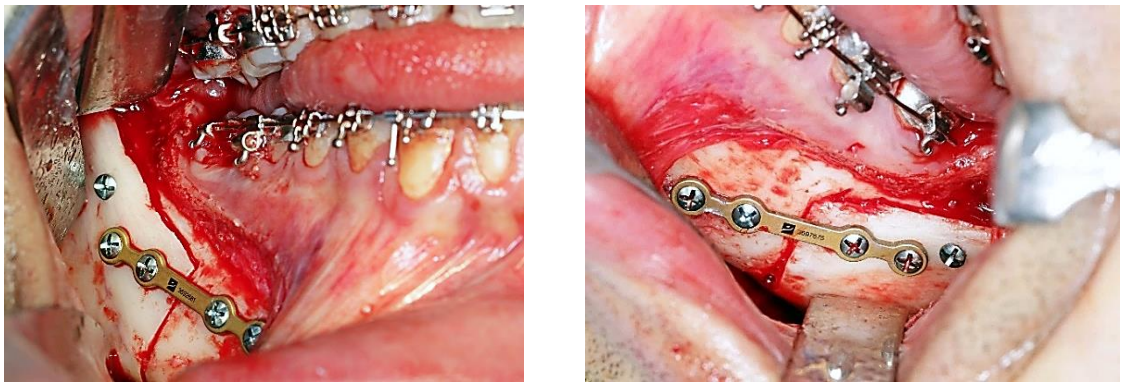


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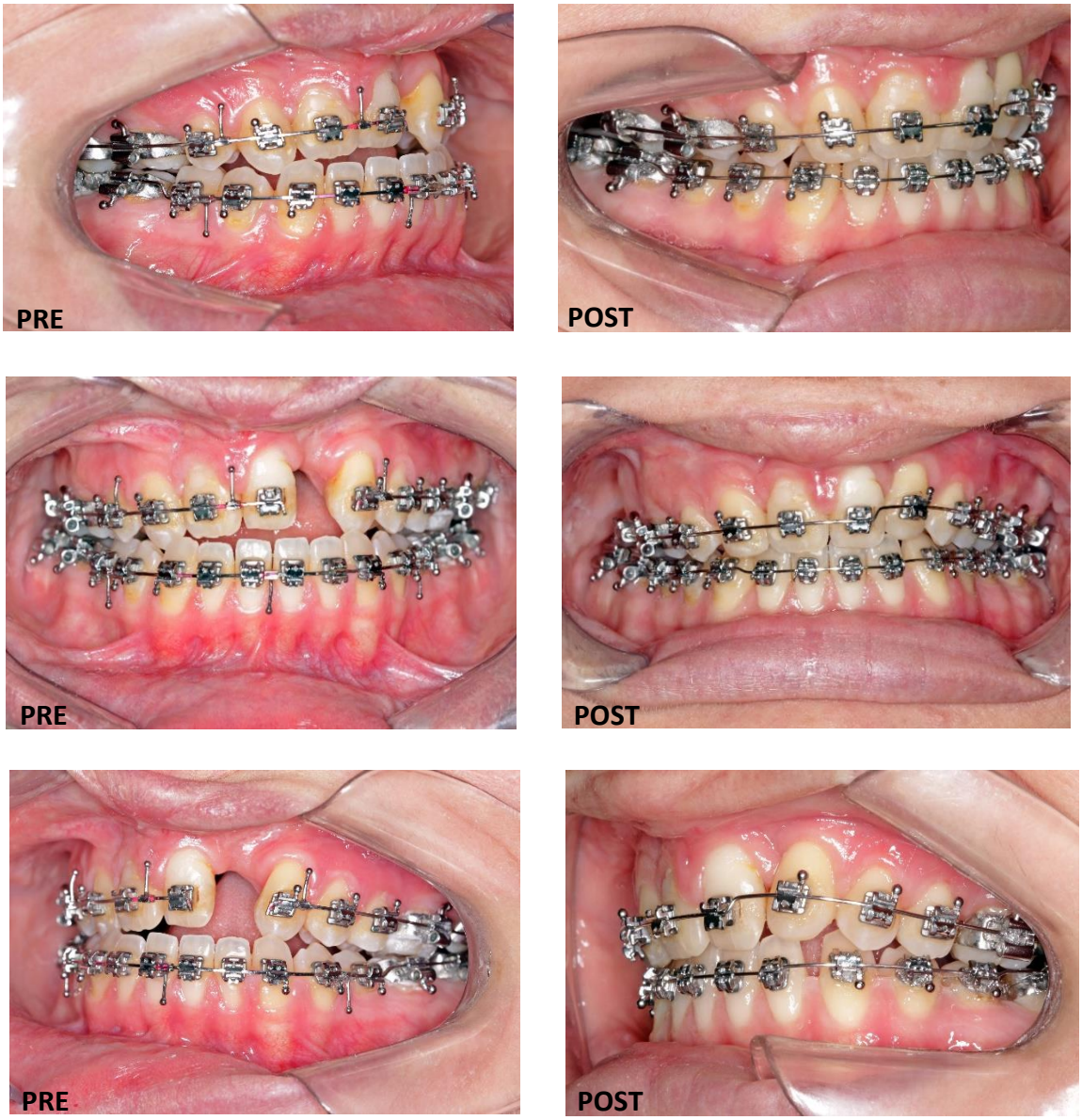
Figure 4: Pre (left side) and 6 months postoperative (right side) comparison of orthognathic surgery.



Source: Dr. Paulo Alceu Kiemle Trindade archieves – HRAC/USP

Figure 5: Pre and postoperative 6 months comparison of orthognathic surgery.

Source: Dr. Paulo Alceu Kiemle Trindade archieves – HRAC/USP

1.3 THE STOMATOGNATHIC SYSTEM OF INDIVIDUALS WITH CLP

The stomatognathic system is an anatomofunctional group of structures consisting of several components such as mandible, maxilla, temporomandibular joint, teeth, tongue, muscles, nerves and glands. Its primary function is mastication, in addition to other functions such as swallowing, sucking, breathing and speaking. The stomatognathic system ensures organic homeostasis, thus playing a fundamental role in the maintenance of the species. Its action occurs in a balanced way with its constituents, and any alteration in this balance, such as malocclusions, can lead to malfunction of craniofacial structures (Garcia, Rios, Honório & Trindade-Suedam, 2016).

Considering, therefore, that the CLP causes a significant morpho functional change on the stomatognathic system, as describe previously, it is mandatory that masticatory performance be one of the factors to be investigated in the rehabilitation of individuals with CLP, as a success parameter. Among the ways to evaluate quantitatively the functionality of the stomatognathic system is the BF (van der Bilt, van der Glas &Abbink, 2008), that is, the maximum force performed by the individual during dental contact. Some studies reported in the literature use BF as a clinical indicator of chewing performance. As expected, some variables influence BF, such as craniofacial morphology and the degree of maxillomandibular discrepancy when present, gender, age, temporomandibular dysfunction, periodontal status, number of teeth, among others (Garcia et al., 2016; Proffit et al., 1989; Palinkas et al., 2010; Sipert et al., 2009; Sun et al., 2016; Trawitzki et al., 2011). Thus, the voluntary maximum BF is an important variable to evaluate the functional status of the masticatory system.

BF is determined with a gnathodynamometer composed of a stainless-steel cylinder (10x10 mm) which contains a load cell that measures force when deformed (Lujan-Climent et al., 2008; Garcia et al., 2016).

It has been confirmed in a previous study (Sipert et al., 2009) conducted in our laboratory that patients with CLP present a reduction in maximal isometric BF (362 Kgf) when compared to patients without cleft (735Kgf). However, important variables such as age, cleft type, alveolar bone grafting and orthognathic surgery were not controlled.

In a more recent study (Garcia et al., 2016), also performed in our laboratory, we evaluated the BF in children with unilateral and bilateral repaired CLP before bone graft surgery was evaluated. To this end, the volunteers were divided into 5 groups according to their cleft. Among the main results, it was found that, contrary to what was expected, to previous study, no significant differences between the BF of individuals with and without CLP were obtained. When comparing BF among the cleft types, it was seen that the segmentation of the maxilla in complete clefts impacts negatively the BF when compared with cleft lip individuals only. Moreover, significantly higher BF values were observed in the posterior region of the maxilla when compared to the values of the anterior region and no differences were observed between genders.

In general, these studies contribute to better understand the stomatognathic system of individuals with CLP. Thus, considering that orthognathic surgery is a fundamental part of the rehabilitation process of individuals with CLP, and that its main objective is to correct the maxillomandibular discrepancies frequently observed in this population, the evaluation of BF, as a parameter of masticatory system functionality, is necessary. In this sense, a search performed on PubMed on 23/01/2020, with the MeSH terms “bite force AND orthognathic surgery AND cleft palate” resulted in 2 articles. The first one has been previously described (Garcia et. al. 2016) and the second one, by Esen et al. (2012), did not assess BF but compared the stability of three different titanium plate-and-screw fixation systems after Le Fort I osteotomy in polyurethane models of unilateral clefts. This lack of information with respect to this specific issue reinforces the importance of this study.

However, studies assessing BF after orthognathic surgery in the general population have been found (Choi et al., 2014; Moroi et al., 2015 Ueki et al., 2014). All studies indicate a significant increase in BF, especially in the late postoperative period, around 1 year after orthognathic surgery. In face of the relation among CLP malocclusions, and the impairment of the stomatognathic system, previously demonstrated by our group, it is our hypotheses that orthognathic surgery improves BF, enhancing the mastication performance in this population.

2 Objective

2 OBJECTIVE

The primary objective of the present study was to evaluate the impact of orthognathic surgery on the stomatognathic system of individuals with repaired CLP by assessing bite force.

Secondary, the specific objectives were to compare the BF in the following situations:

1. Control group versus cleft lip and palate group
2. Immediate preoperative period versus postoperative period of 3 months versus the postoperative period of 6 months
3. Unilateral versus Bilateral clefts
4. Maxillary advancement versus Maxillary advancement + Mandibular setback

3 Manuscript

Bite force assessment before and after orthognathic surgery in individuals with repaired cleft lip and palate

Submitted to the "Archives of Oral Biology" journal

ABSTRACT

Objective: To evaluate the impact of orthognathic surgery on the stomatognathic system of individuals with repaired CLP by assessing bite force (BF). **Material and Methods**: Forty individuals were prospectively divided into 2 groups: 1) CON: 20 individuals without CLP (10 male, 10 female, 20y±7.4), 2) CLP: 20 individuals with CLP and with indication for OS (11 male, 9 female, 23.5y±5.9; 10 unilateral; 10 bilateral), BF was evaluated in the immediate preoperative period (PRE), 3 months postoperatively (POST3M) and 6 months postoperatively (POST6M), by means of a gnathodynamometer (IDDK Kratos, Cotia-SP,Brazil). **Results:** BF of the CLP was significantly lower than that of the CON in all evaluated periods. BF of individuals with CLP was significantly lower in POST3M when compared to PRE and POST6M. Although not significant, BF was increased in POST6M when compared to PRE. A significant increase in BF was observed between POST3M and POST6M. The BF of unilateral and bilateral CLP individuals were statistically similar. Males presented a BF almost twice as high as females. **Conclusion:** Cleft lip and palate negatively impacts BF. Although there was a *tendency* for BF values to increase 6 months after OS, it was still significantly reduced when compared to control individuals, not reaching normative values.

Keywords: orthognathic surgery, cleft lip, cleft palate, bite force, stomatognathic system.

1 INTRODUCTION

Congenital defects like CLP (CLP) are the most common among anomalies affecting the human face (Fernandez, Escobar & Zarante, 2016). These craniofacial anomalies are established early in intrauterine life, more precisely in the embryonic period and early fetal period, that is, until the 12th week of pregnancy (Freitas et al., 2012). It has a complex and multifactorial etiology, requiring a long lasting and complex treatment that encompasses several clinical and surgical procedures until adulthood (Sipert, Sampaio, Trindade & Trindade-Junior, 2009).

The stomatognathic system is an anatomofunctional group of structures consisting of several components such as mandible, maxilla, temporomandibular joint, teeth, tongue, muscles, nerves and glands. Its primary function is mastication, in addition to other functions such as swallowing, sucking, breathing and speaking. The stomatognathic system ensures organic homeostasis, thus playing a fundamental role in the maintenance of the species. Its action occurs in a balanced way with its constituents, and any alteration in this balance, such as malocclusions, can lead to malfunction of craniofacial structures (Garcia, Rios, Honório & Trindade-Suedam, 2016).

Due to CLP individual's treatment complexity, early rehabilitation is considered mandatory by means of primary plastic surgeries. Those surgical interventions are no doubt useful achieving facial function and aesthetics. However, those surgical procedures inhibit maxillary growth in complete CLP patients. For these reasons, CLP can affect the stomatognathic system in several ways, as following: 1) the anatomical rupture itself commonly promotes maxillary atresia and posterior crossbite, 2) dental agenesis are frequently observed, and 3) the induced sagittal deficiency leads to a Class III malocclusion (Freitas et al. 2011).

In such context, orthognathic surgery aims at connecting the facial skeletal deformity in early adulthood, consequently improving chewing (Robinson & Holm, 2010) as improves chewing function secondary to discrepancies correction. Considering, therefore, that the CLP causes a significant morpho functional change on the stomatognathic system, as describe previously, it is mandatory that masticatory performance be one of the factors to be

investigated in the rehabilitation of individuals with CLP, as a success parameter. Among the ways to evaluate quantitatively the functionality of the stomatognathic system is the BF (van der Bilt, van der Glas & Abbink, 2008), that is, the maximum force performed by the individual during dental contact. Some studies reported in the literature use BF as a clinical indicator of chewing performance. As expected, some variables influence BF, such as craniofacial morphology and the degree of maxillomandibular discrepancy when present, gender, age, temporomandibular dysfunction, periodontal status, number of teeth, among others (Garcia et al., 2016; Proffit, Turvey, Fields & Phillips, 1989; Palinkas et al., 2010; Sipert et al., 2009; Sun et al., 2016; Trawitzki, Silva, Regalo & Mello-Filho, 2011). Thus, the voluntary maximum BF is an important variable to evaluate the functional status of the masticatory system.

In face of the relation among CLP malocclusions, and the impairment of the stomatognathic system, previously demonstrated by our group, it is our hypotheses that orthognathic surgery improves BF, enhancing the mastication performance in this population.

In other words, the primary objective of this study was to evaluate the impact of orthognathic surgery on the stomatognathic system of individuals with repaired CLP by assessing BF. The specific objectives were to compare the BF in the following situations: 1) Control group versus cleft lip and palate group, 2) Immediate preoperative period versus postoperative period of 3 months versus the postoperative period of 6 months, 3) Unilateral versus Bilateral clefts, and, 4) Maxillary advancement (MA) versus Maxillary advancement + Mandibular setback (MAMS).

2 MATERIAL AND METHODS

This prospective study was approved by the Institutional Review Board of the HRAC/USP, (CAAE: 89376118.6.3001.5417), and was performed at the Physiology Laboratory of HRAC/USP and at the orthognathic surgery sector of HRAC/USP. All participants were informed about the procedures involved in the study and signed an informed consent form before examinations.

Considering an 5% alfa error, a 20% beta error and adopting a mean deviation of 3 Kgf and a difference in the pre- and post-operative period of at least 5 Kgf (Palinkas et al., 2010), of BF, the formal sample calculation predicted a *n* of 15 patients per group.

Inclusion criteria for the CLP group consisted of: adults (≥18 - ≤40 years of age) with complete CLP (unilateral or bilateral), with indication for orthognathic surgery, operated by a single surgeon (PAKT), an interocclusal molar established relationship, no tooth loss, no periodontal disease or caries that could negatively influence the acquisition of the exam. Exclusion criteria were: individuals under 18 years old, individuals with cleft lip, with associated craniofacial anomalies, pain or discomfort during the exam. For the control group (CON), inclusion criteria were: adult individuals (≥18 - ≤40 years of age), without CLP and without any craniofacial anomaly, with normal occlusion and type I skeletal pattern. Assumed exclusion criteria were: individuals under 18 years old, with CLP or other craniofacial anomalies, altered occlusion or type II or III skeletal pattern.

Data collection period lasted one year, between August 2018 to August 2019. On that time 40 patients were enrolled in the study and were divided in to groups: 1) CON: 20 control individuals (10 males, 10 females, 20 years ± 7.4), without CLP, 2) CLP: 20 individuals with CLP (11 males, 9 females, 23.5 years ± 5.9; 10 unilateral; 10 bilateral) and with indication for orthognathic surgery, regularly enrolled in HRAC- USP.

Patients from the CLP group were invited to participate during the pre-operative evaluation at the orthognathic surgery sector at the HRAC/USP while individuals from the CON group corresponded to dental students from Bauru School of Dentistry - University of São Paulo.

Orthognathic surgeries were performed under general anesthesia by the same surgeon (PAKT). Le Fort I osteotomy was used to reposition maxilla using miniplates 2.0 fixation system on canine and zygomatic buttresses areas whilst for mandible the bilateral sagittal split osteotomy was stabilized with hybrid fixation technique using miniplates 2.0 fixation system.

BF assessment was done using a gnathodynamometer (IDDK digital dynamometer model, Kratos, Cotia-SP, Brazil), with a capacity of ~ 100kgf (~ 980 N) (Figure 1), by a stainless-steel cylinder (10 x 10 mm) which contains a load cell that measures force when deformed.

The device has a force kilogram (Kgf) or Newton (N) scale, a “set-zero” key that allows the exact control of the obtained values and also a “peak” recording, which favors the maximum force reading while obtaining values.

Measurements were all performed by the same operator (PMB), for three consecutive times, with an interval of about 1 minute between measurements to avoid patient fatigue (Garcia et al. 2016). Highest obtained score was considered for analysis.

To measure the maximum BF, the gnathodynamometer was positioned alternately in the right (Figure 2A) and left (Figure 2C) first molar regions. For maximal incisor BF measurement (Figure 2B), the device was positioned in central incisors’ region.

The measurements were performed by the same operator and statistical analysis were performed in Sigma Plot 12.0 software. Values of $p<0,05$ were considered statistically significant. Considering the normal distribution, assessed by Shapiro-Wilk test, the results are expressed as mean ± standard deviation. Quantitative and ordinal qualitative comparisons among variables were assessed through Mann Whitney test.

3 RESULTS

Demographic and clinical data of both groups, in the three periods of analysis (PRE, POST3M and POST6M), are shown in Table 1. No significant differences were found between the groups in the distribution of gender or age. In the CLP group, a similar distribution of unilateral and bilateral cases is seen. Regarding clinical data, the majority (70%) of the CLP patients had undergone alveolar bone graft (ABG) and maxillary advancement was performed in 55% of the cases while bimaxillary surgery (maxillary advancement + mandibular setback) was performed in the other 45%.

The mean values (standard deviation) of BF, expressed as N (Newton), for the regions of the right molar, incisors and left molar during the three periods of analysis are reported in table 2. The BF of the CLP group was reduced when compared to the CON group, independently of the period (PRE, POST3M or POST6M) and region (molars or incisors) analyzed.

The BF values on POST3M (CLP group) decreased in comparison with the values prior to surgery (PRE) and the BF values on POST6M increased when compared to the POST3M values. Although not significant, the BF values of the POST6M were greater than the BF values observed on PRE. These findings refer to the BF on the right and left molar regions. No variations in BF of the CLP group were observed on the three periods analyzed.

On both groups, BF on the molar region was greater when compared to the incisor region. Finally, no BF differences were observed in the comparison unilateral versus bilateral clefts nor in the comparison maxillary advancement versus maxillary advancement + mandibular setback.

4 DISCUSSION

The present study has shown that adults with CLP have a significant lower BF when compared to control subjects with the same age. This is contrary to the findings of a previous study published by our group (Garcia et al. 2016) in which we have found that the BF of children with CLP are similar to the BF of non-cleft children. According to Garcia et al. (2016) and Palinkas et al. (2010), hormonal factors that influence force, muscle thickness and muscle activity, are not yet active in childhood and this fact might explain the divergent results. In fact, the difference in BF between CLP and CON is expected since this craniofacial anomaly segments the maxilla in 2 or three parts, frequently leading to a class III skeletal pattern.

Indeed, all patients in the present study had Class III dentofacial deformity, characterized by mandibular prognathism and / or maxillary deficiency. Trawitzki et al. (2011) conducted a study comparing BF in individuals with Class II and III dentofacial deformities and comparing them with a control group. They demonstrated that there was no difference in BF between the different patterns of dentofacial deformities (Class II and Class III), but the values for these two groups were lower than the control, indicating that deformity, affects BF.

Maxillomandibular discrepancy treatment comprehends orthognathic surgery, which main purpose is to reposition the maxilla and the mandible in relation to the cranial base, promoting a stable and functional dental occlusion (McNamara, Junior, Carlson & Yellick, 1978). In this sense, the BF, which represents the main functional parameter of the masticatory system, should increase after orthognathic surgery. The findings of the present

study show, a reduction of about half in three months after surgery when compared to the pre-operative values. The temporary muscle instability observed in the immediate postoperative period, associated with the possibility of pain occurrence during the exam and the fear of damaging the surgery are factors that justify the BF reduction observed in this period of analysis.

On the other hand, the BF values increased 6 months after surgery and, although not statistically significant, it was greater than the pre-operative values., It is our understanding that in the immediate postoperative period, the muscles are not yet adapted to the changes promoted by surgery, despite the harmonization of dental occlusion. According to our results, this adaptation occurs with time and, for this reason, the authors strongly believe that BF values will reach the control values one year after surgery. Astrand et al. (1974) and Quast, Biggerstaff & Haley (1983) have mentioned that individuals should be followed for at least 1 and a half years after orthognathic surgery for appropriate assessment of results.

It is also important to mention that two hypothesis of this study were not confirmed, as follows: 1) “the greater the surgical manipulation, the lower would be the BF” - this was not confirmed since no differences in BF were observed in those patients submitted to maxillary advancement only when compared to those submitted to maxillary advancement + mandibular setback; 2) “subjects with bilateral clefts, which have a maxilla segmented in three parts, present a lower BF when compared to unilateral clefts, whose maxilla are segmented in two parts” – once again, no differences were observed in BF of patients with unilateral and bilateral clefts.

Independently of the group evaluated, significantly higher BF values were obtained in the posterior region when compared to the anterior region, as already demonstrated by Roldán, Buschang, Saldarriaga Isaka & Throckmorton (2015). This result was already predicted, as physiologically, molars are designed to grind food and incisors to tear, as shown by Regalo et al. (2008) and by Garcia et al. (2016).

Finally, it is important to highlight the strict sample selection criteria. Subjects of both groups should follow a strict age range (adults 18 to 40 years old), should be operated by a single surgeon and BF should be assessed by a single evaluator (PMB). It has been shown that

BF decreases with age (Palinkas et al., 2010) and surgeon experience plays an important role on post-operative results (Antonini et al., 2019).

Besides that, a similar distribution of gender was observed on both groups. This is particularly important since it has been shown that male gender is a significant factor associated with maximal BF (Palinkas et al., 2010) and reinforce homogeneity in sample selection.

In summary, the results of the present study show that cleft lip and palate negatively impacts bite force. However, although BF values increased 6 months after orthognathic surgery, it was still significantly reduced when compared to control individuals.

Results of this research should be complemented by future studies that address long-term postoperative results of bite force. Masticatory efficiency, using bolus granulometry, comprehends another parameter that should be assessed. Furthermore, the impact of alveolar bone grafting on BF should also be assessed.

5 CONCLUSION

Cleft lip and palate negatively impact the stomatognathic system, and its main functionality parameter, bite force. Although bite force values to increase in the late postoperative period of 6 months after orthognathic surgery, it was still significantly reduced when compared to individuals without cleft lip and palate, not reaching the parameters of normality.

6 ACKNOWLEDGEMENTS

The authors would like to thanks for the patients of Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo, HRAC/USP, Bauru, SP, Brazil.

7 CONFLIT OF INTEREST

The authors report no conflict of interest.

8 FINANCIAL SUPPORT

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9 REFERENCES

1. Antonini, F., Borba, A. M., Pagnoncelli, R. M., Han, M., Markiewicz, M. R., & Miloro, M. (2019). Does a learning curve exist for accuracy in three-dimensional planning for maxillary positioning in bimaxillary orthognathic surgery? International Journal of Oral and Maxillofacial Surgery.

2. Astrand P. (1974). Chewing efficiency before and after surgical correction of developmental deformities of the jaws. Swed Dent J. 67(3), 135-45.

3. Fernandez, N., Escobar, R. & Zarante, I. (2016). Craniofacial anomalies associated with hypospadias. Description of a hospital based population in South America. International Braz J Urol, 42, 793–797.

4. Freitas, J. A. de S., Garib, D. G., Trindade-Suedam, I. K., Carvalho, R. M., Oliveira, T. M., Lauris, R. de C. M. C., … Pinto, J. H. N. (2012). Rehabilitative treatment of cleft lip and palate: experience of the Hospital for Rehabilitation of Craniofacial Anomalies - USP (HRAC-USP) - part 3: Oral and Maxillofacial Surgery. Journal of Applied Oral Science, 20(6), 673–679

5. Freitas J. A., Neves L. T., Almeida A. L., Garib D. G., Trindade-Suedam I. K., Yaedú R. Y., et al. (2011). Rehabilitative treatment of cleft lip and palate: experience of the Hospital for Rehabilitation of Craniofacial Anomalies/USP (HRAC/USP) - Part 1: overall aspects. J Appl Oral Sci. 20(1), 9-15.

6. Garcia, M. A., Rios, D., Honório, H. M., & Trindade-Suedam, I. K. (2016). Bite force of children with repaired unilateral and bilateral cleft lip and palate. Archives of Oral Biology, 68, 83–87.

7. McNamara, J. A., Junior, D. S., Carlson, G. M. & Yellick, R. P. H. (1978). Musculoskeletal adaptation following orthognathic surgery, in McNamara, J. A., Jr.; and Carlson, D. S.: Muscle adaptation in the craniofacial region. Craniofacial growth series. Center for Human Growth and Development. The University of Michigan, Ann Arbor, Michigan.

8. Palinkas, M., Nassar, M. S., Cecílio, F. A., Siéssere, S., Semprini, M., Machado-de- Sousa, J. P., Hallak, J. E. C. & Regalo, S. C. H. (2010). Age and gender influence on maximal BF and masticatory muscles thickness. Archives of Oral Biology, 55, 797–802.

9. Proffit, W. R., Turvey, T. A., Fields, H. W., & Phillips, C. (1989). The effect of orthognathic surgery on occlusal force. Journal of Oral and Maxillofacial Surgery, 47(5), 457–463.

10. Quast, D. C., Biggerstaff, R. H., & Haley, J. V. (1983). The short-term and long-term soft-tissue profile changes accompanying mandibular advancement surgery. American Journal of Orthodontics, 84(1), 29–36.

11. Regalo, S. C. H., Santos, C. M., Vitti, M., Regalo, C. A., de Vasconcelos, P. B., Mestriner, W., Siéssere, S. (2008). Evaluation of molar and incisor bite force in indigenous compared with white population in Brazil. Archives of Oral Biology, 53(3), 282–286.

12. Robinson, R. C., & Holm, R. L. (2010). Orthognathic Surgery for Patients with Maxillofacial Deformities. AORN Journal, 92(1), 28–52.

13. Roldán, S., Buschang, P. H., Saldarriaga Isaza, J. F., & Throckmorton, G. (2009). Reliability of maximum bite force measurements in age-varying populations. Journal of Oral Rehabilitation, 36(11), 801–807.

14. Sipert, C. R., Sampaio, A. C. M., Trindade, I. E. K., & Trindade Junior, A. S. (2009). Bite force evaluation in subjects with cleft lip and palate. Journal of Applied Oral Science, 17(2), 136–139.

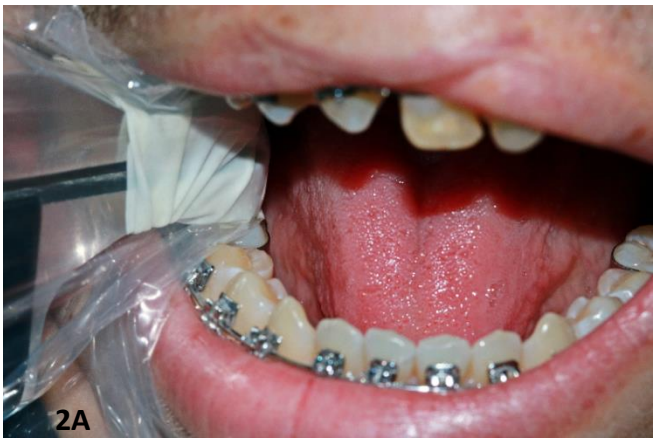
15. Sun, K.-T., Chen, S.-C., Li, Y.-F., Chiang, H.-H., Tsai, H.-H., Li, C.-Y., & Tu, M.-G. (2016). Bite-force difference among obese adolescents in central Taiwan. Journal of the Formosan Medical Association, 115(6), 404–410.

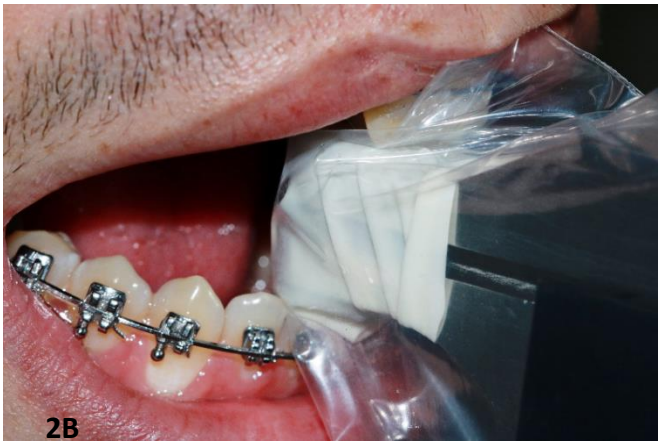
16. Trawitzki, L. V. V., Silva, J. B., Regalo, S. C. H., & Mello-Filho, F. V. (2011). Effect of class II and class III dentofacial deformities under orthodontic treatment on maximal isometric bite force. Archives of Oral Biology, 56(10), 972–976.

17. van der Bilt, A., Tekamp, A., van der Glas, H., & Abbink, J. (2008). Bite force and electromyography during maximum unilateral and bilateral clenching. European Journal of Oral Sciencies, 116, 217–222.

Figure 1: Gnathodynamometer used to perform the measurements (digital dynamometer, IDDK model, Kratos, Bauru, SP, Brazil).

Figure 2: Location of measurements for the CON and CLP group. 2A: right posterior region of the maxilla; 2B: anterior region of the maxilla; 2C: right posterior region of the maxilla.





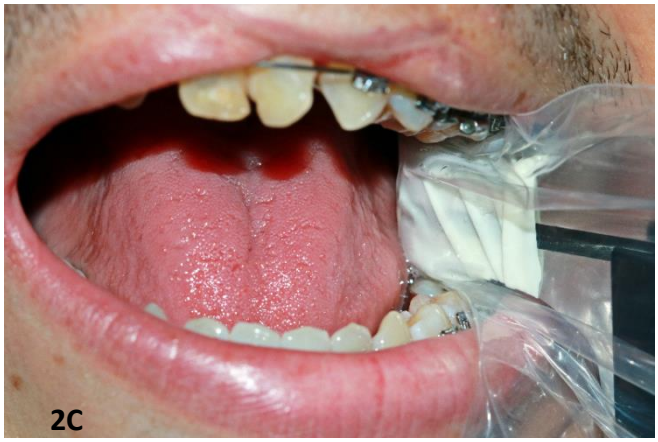


Table 1: Demographic distribution and clinical data of the study population.

	CON	CLP		
	n=20	PRE n=20	POST3M n=14	POST6M n=9
AGE	20 ± 7.4		23.5 ± 5.9	
GENDER n(%)				
Female	10 (50)	9 (45)	6 (42)	3 (33)
Male	10 (50)	11 (55)	8 (57)	6 (66)
CLEFT TYPE n(%)				
UCLP	-	10 (50)	6 (42)	4 (44)
BCLP		10 (50)	8 (57)	5 (55)
BONE GRAFT n(%)				
With ABG	-	14 (70)	9 (64)	6 (66)
Without ABG		6 (30)	5 (35)	3 (33)
SURGERY n(%)				
MA	-	11 (55)	10 (71)	6 (66)
MAMS		9 (45)	4 (28)	3 (33)

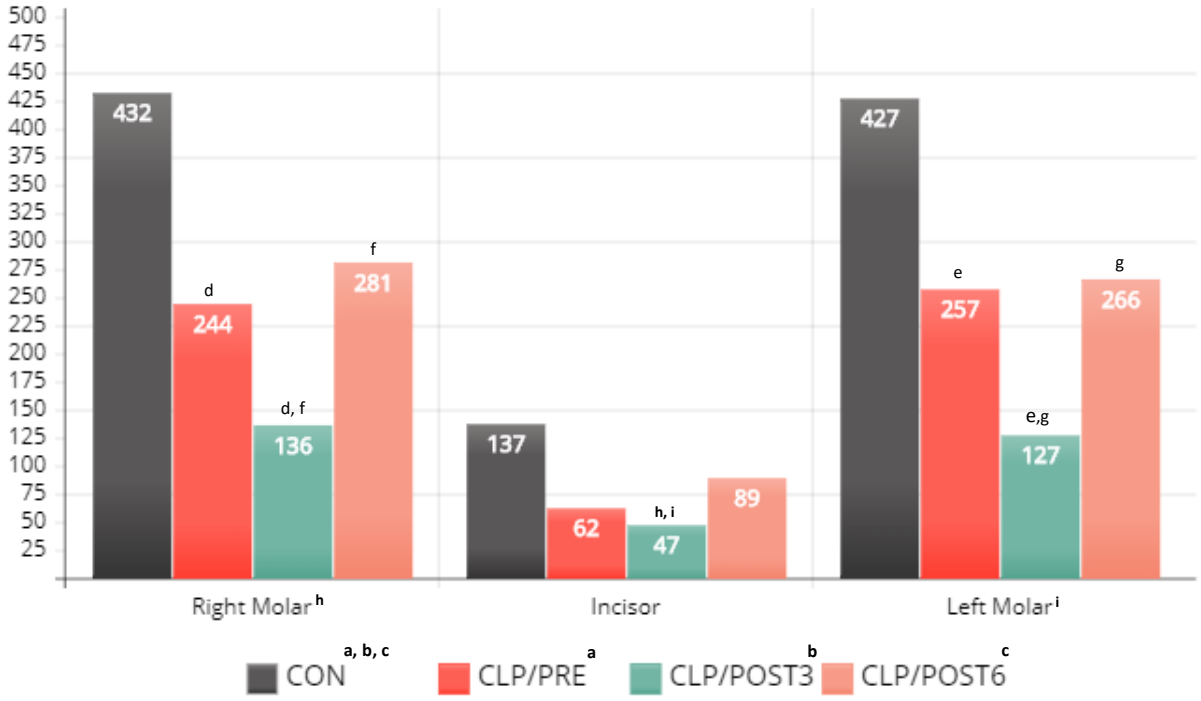
CON: control group; PRE: cleft lip and palate preoperative group; POST3M: CLP postoperative 3 months' group; POST6M: CLP postoperative 6 months' group.

Table 2: Mean values (standard deviation) of bite force, expressed in N, from the control group (CON), CLP preoperative group (PRE); CLP postoperative 3 months' group (POST3M) and CLP postoperative 6 months group (POST6M), on the anterior and posterior regions of the maxilla.

			BITE FORCE		
GROUP	**PERIOD**	**n**	**MEAN (SD) RIGHT MOLAR [h]**	**MEAN (SD) INCISOR [h, i]**	**MEAN (SD) LEFT MOLAR [i]**
CON [a, b, c]		20	432.93 (134.28)	137.44 (53.05)	427.33 (147.17)
CLP	**PRE [a]**	20	244.37 (146.55) [d]	62.57 (33.95)	257.33 (152.54) [e]
	POST3M [b]	14	136.09 (106.65) [d, f]	47.67 (35.36)	127.35 (107.83) [e,g]
	POST6M [c]	9	281.80 (169.03) [f]	89.61 (50.96)	266.46 (140.55) [g]

[a ,b, c] means statistical difference of Bite force between groups on the different regions ($p<0,05$)
[d, e, f, g] means difference in each region between periods ($p<0,05$)
[h,i] means difference between the BF of anterior and posterior regions, on both groups ($p<0,05$)

Figure 3: Mean values of bite force, expressed in N, from the control group (CON), CLP preoperative group (PRE); CLP postoperative 3 months group (POST3M) and CLP postoperative 6 months group (POST6M), on the anterior and posterior regions of the maxilla.



[a ,b, c] means statistical difference of Bite force between groups on the different regions ($p<0,05$)
[d, e, f, g] means difference in each region between periods ($p<0,05$)
[h,i] means difference between the BF of anterior and posterior regions, on both groups ($p<0,05$)

4 General Conclusions

4 GENERAL CONCLUSIONS

Cleft lip and palate negatively impact the stomatognathic system, and its main functionality parameter, bite force. Although bite force values to increase in the late postoperative period of 6 months after orthognathic surgery, it was still significantly reduced when compared to individuals without cleft lip and palate, not reaching the parameters of normality.

5 References

5 REFERENCES

1. Antonini, F., Borba, A. M., Pagnoncelli, R. M., Han, M., Markiewicz, M. R., & Miloro, M. (2019). Does a learning curve exist for accuracy in three-dimensional planning for maxillary positioning in bimaxillary orthognathic surgery? International Journal of Oral and Maxillofacial Surgery.

2. Astrand P. (1974). Chewing efficiency before and after surgical correction of developmental deformities of the jaws. Swed Dent J. 67(3), 135-45.

3. Choi, Y. J. et al. Two-year follow-up of changes in bite force and occlusal contact area after intraoral vertical ramus osteotomy with and without le Fort i osteotomy. International Journal of Oral and Maxillofacial Surgery, v. 43, n. 6, p. 742–747, 2014.

4. Esen, A., Isik, K., Saglam, H., Ozdemir, Y. B., & Dolanmaz, D. (2016). Biomechanical eva uation of different fixation systems after Le Fort I osteotomy in polyurethane models of unilateral clefts. British Journal of Oral and Maxillofacial Surgery, 54(7), 757–761.

5. Fernandez, N., Escobar, R. & Zarante, I. (2016). Craniofacial anomalies associated with hypospadias. Description of a hospital based population in South America. International Braz J Urol, 42, 793–797.

6. Freitas, J. A. de S., Garib, D. G., Trindade-Suedam, I. K., Carvalho, R. M., Oliveira, T. M., Lauris, R. de C. M. C., … Pinto, J. H. N. (2012). Rehabilitative treatment of cleft lip and palate: experience of the Hospital for Rehabilitation of Craniofacial Anomalies - USP (HRAC-USP) - part 3: Oral and Maxillofacial Surgery. Journal of Applied Oral Science, 20(6), 673–679

7. Freitas J. A., Neves L. T., Almeida A. L., Garib D. G., Trindade-Suedam I. K., Yaedú R. Y., et al. (2011). Rehabilitative treatment of cleft lip and palate: experience of the Hospital for Rehabilitation of Craniofacial Anomalies/USP (HRAC/USP) - Part 1: overall aspects. J Appl Oral Sci. 20(1), 9-15.

8. Garcia, M. A., Rios, D., Honório, H. M., & Trindade-Suedam, I. K. (2016). Bite force of children with repaired unilateral and bilateral cleft lip and palate. Archives of Oral Biology, 68, 83–87.

9. Lujan-Climent, M. et al. (2008). Influence of static and dynamic occlusal characteristics and muscle force on masticatory performance in dentate adults. European Journal of Oral Sciences, 116, 229–236.

10. McNamara, J. A., Junior, D. S., Carlson, G. M. & Yellick, R. P. H. (1978). Musculoskeletal adaptation following orthognathic surgery, in McNamara, J. A., Jr.; and Carlson, D. S.:

Muscle adaptation in the craniofacial region. Craniofacial growth series. Center for Human Growth and Development. The University of Michigan, Ann Arbor, Michigan.

11. Moroi, A. et al. Changes in occlusal function after orthognathic surgery in mandibular pr gnathism with and without asymmetry. International Journal of Oral and Maxillofacial Surgery, v. 44, n. 8, p. 971–976, 2015.

12. Palinkas, M., Nassar, M. S., Cecílio, F. A., Siéssere, S., Semprini, M., Machado-de- Sousa, J. P., Hallak, J. E. C. & Regalo, S. C. H. (2010). Age and gender influence on maximal BF and masticatory muscles thickness. Archives of Oral Biology, 55, 797–802.

13. Proffit, W. R., Turvey, T. A., Fields, H. W., & Phillips, C. (1989). The effect of orthognathic surgery on occlusal force. Journal of Oral and Maxillofacial Surgery, 47(5), 457–463.

14. Quast, D. C., Biggerstaff, R. H., & Haley, J. V. (1983). The short-term and long-term soft-tissue profile changes accompanying mandibular advancement surgery. American Journal of Orthodontics, 84(1), 29–36.

15. Regalo, S. C. H., Santos, C. M., Vitti, M., Regalo, C. A., de Vasconcelos, P. B., Mestriner, W., Siéssere, S. (2008). Evaluation of molar and incisor bite force in indigenous compared with white population in Brazil. Archives of Oral Biology, 53(3), 282–286.

16. Robinson, R. C., & Holm, R. L. (2010). Orthognathic Surgery for Patients with Maxillofacial Deformities. AORN Journal, 92(1), 28–52.

17. Roldán, S., Buschang, P. H., Saldarriaga Isaza, J. F., & Throckmorton, G. (2009). Reliability of maximum bite force measurements in age-varying populations. Journal of Oral Rehabilitation, 36(11), 801–807.

18. Silva, O. G. F.; Ferrari F. M. J.; Rocha, D. L.; Freitas, J. A. S. (1992). Classificação das fissuras lábio-palatais: breve histórico, considerações clínicas e sugestão de modificação. Rev. Bras. Cir. 82 (2): 5-65.

19. Sipert, C. R., Sampaio, A. C. M., Trindade, I. E. K., & Trindade Junior, A. S. (2009). Bite force evaluation in subjects with cleft lip and palate. Journal of Applied Oral Science, 17(2), 136–139.

20. Sun, K.-T., Chen, S.-C., Li, Y.-F., Chiang, H.-H., Tsai, H.-H., Li, C.-Y., & Tu, M.-G. (2016). Bite-force difference among obese adolescents in central Taiwan. Journal of the Formosan Medical Association, 115(6), 404–410.

21. Trawitzki, L. V. V., Silva, J. B., Regalo, S. C. H., & Mello-Filho, F. V. (2011). Effect of class II and class III dentofacial deformities under orthodontic treatment on maximal isometric bite force. Archives of Oral Biology, 56(10), 972–976.

22. Trindade, I. E. K.; Silva O. G. F. (2007). Fissuras labiopalatinas: uma abordagem interdisciplinar. São Paulo, Ed Santos.

23. Ueki, K. et al. Evaluation of recovery in lip closing pressure and occlusal force and contact are after orthognathic surgery. Journal of Cranio-Maxillofacial Surgery, v. 42, n. 7, p. 1148–1153, 2014.

24. van der Bilt, A., Tekamp, A., van der Glas, H., & Abbink, J. (2008). Bite for electromyography during maximum unilateral and bilateral clenching. European of Oral Sciencies, 116, 217–222.

6 Appendix

APPENDIX A

DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN DISSERTATION/THESIS

We hereby declare that we are aware of the article BITE FORCE ASSESSMENT BEFORE AND AFTER ORTHOGNATHIC SURGERY IN INDIVIDUALS WITH REPAIRED CLEFT LIP AND PALATE will be included in Dissertation of the student Patricia Martins Bueno 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, de 2020.

_____	_____
Author	Signature
_____	_____
Author	Signature
_____	_____
Author	Signature
_____	_____
Author	Signature

APPENDIX B

DECLARAÇÃO DE USO EXCLUSIVO DE ARTIGO EM DISSERTAÇÃO/TESE

Declaramos estarmos cientes de que o trabalho BITE FORCE ASSESSMENT BEFORE AND AFTER ORTHOGNATHIC SURGERY IN INDIVIDUALS WITH REPAIRED CLEFT LIP AND PALATE será apresentado na Dissertação da aluna Patricia Martins Bueno e que não foi e nem será utilizado em outra dissertação do Programas de Pós-Graduação da FOB-USP.

Bauru, de 2020.

_____	_____
Nome do autor	Assinatura
_____	_____
Nome do autor	Assinatura
_____	_____
Nome do autor	Assinatura
_____	_____
Nome do autor	Assinatura

APPENDIX C

Laboratório de Fisiologia

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Prezado (a) _____,
venho respeitosamente, convidá-lo (a) a participar, como voluntário (a), da pesquisa intitulada: "Impacto da cirurgia ortognática no sistema estomatognático de indivíduos com fissura labiopalatina reparada", realizada por Patricia Martins Bueno (CRO-SP 120.343), sob orientação da Profa. Dra. Ivy Kiemle Trindade Suedam (CRO-SP 66508).

Essa pesquisa tem como objetivo verificar a força máxima que você consegue fazer com os seus dentes e averiguar o inchaço após a cirurgia ortognática. O estudo será realizado no Laboratório de Fisiologia em parceria com o setor de Cirurgia Ortognática do HRAC-USP, nos intervalos de sua rotina de atendimento regular no Hospital, onde avaliaremos como está o seu caso, ou seja, qual o tipo da sua fissura, se você respira e mastiga bem, como foram suas cirurgias anteriores, como é a sua mordida, se seus dentes se encaixam bem. Também vamos utilizar um equipamento chamado gnatodinamômetro que vai medir a força máxima que você consegue fazer na mordida. Esta medida será feita, por 3 vezes seguidas, nas cadeiras odontológicas do setor de cirurgia ortognática. Essas medidas serão realizadas antes da cirurgia e nos retornos de 3 e 6 meses após a cirurgia. Isso significa que você não precisará retornar ao HRAC-USP só para fazer essas medidas. Nessa mesma hora, faremos medidas no seu rosto com fita métrica simples, para verificar se há inchaço, antes da cirurgia, 48 horas após e nos retornos de 3 e 6 meses ao hospital. Os dois procedimentos são indolores, não machucam você e assim, você não corre o risco de estragar sua cirurgia e duram aproximadamente 30 minutos.

Não existe desvantagem na participação deste estudo, que sejam do nosso conhecimento. Caso, contudo, você sinta qualquer desconforto, em qualquer um dos exames, você pode solicitar não mais participar da pesquisa, sem qualquer prejuízo ao seu tratamento regular no HRAC/USP. É importante dizer que, se for observada alguma alteração importante em você ou na sua cirurgia, que possa atrapalhar o resultado final, você será encaminhado para o setor específico dependendo da queixa que você apresentar, seja ela do setor de Cirurgia Ortognática e/ou Laboratório de Fisiologia, ou de outro setor do HRAC/USP.

Você não terá gastos com a participação neste estudo, pois esses procedimentos serão realizados durante o seu atendimento de rotina no Hospital. Sendo assim, não estão previstos pagamentos de transporte, alimentação, estadia ou qualquer outro tipo de remuneração ou ajuda financeira. Pórem nos comprometemos a indenizar você caso, numa eventualidade, sofra algum dano que seja causado pelos procedimentos que vamos realizar.

Rubricas:
Participante da pesquisa e/ou responsável legal: _____
Pesquisador Responsável: _____

HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS
UNIVERSIDADE DE SÃO PAULO

Laboratório de Fisiologia

Uma via deste Termo de Consentimento Livre e Esclarecido será arquivada no Laboratório de Fisiologia do HRAC/USP e outra via será entregue a você. Na divulgação dos resultados da pesquisa, a sua identidade será mantida em sigilo. Qualquer duvida referente ao estudo poderá ser esclarecida pela equipe do Laboratório de Fisiologia, pessoalmente, por telefone (14) 3235-8137 ou você poderá entrar em contato com a pesquisadora principal Patricia Martins Bueno por meio de contato telefônico: (14) 98133-1785 endereço de e-mail: pmartinsbueno@usp.br.

Caso você queira apresentar denúncias e/ou reclamações em relação a sua participação na pesquisa, você poderá entrar em contato com Comitê de Ética em Pesquisa-HRAC-USP, à Rua Silvio Marchione, 3-20 - Vila Universitária - CEP 17012-900 - Bauru/SP, de segunda à sexta-feira das 8 às 18 h, ou pelo telefone (14) 3235-8421, e-mail: cephrac@usp.br.

Eu_____,
portador da cédula de identidade _____, após leitura das informações neste TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO, concordo em participar da pesquisa e assino este documento em duas vias, sendo que uma via ficará comigo e outra com o pesquisador.

Bauru/SP, _____de_____de_____.

_____ _____
Assinatura participante da pesquisa Assinatura Pesquisador

APPENDIX D

HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS
UNIVERSIDADE DE SÃO PAULO

LABORATÓRIO DE FISIOLOGIA

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO
(GRUPO CONTROLE)

Prezado (a) _____,
venho, respeitosamente, convidá-lo (a) a participar, como voluntário (a), da pesquisa intitulada: "Impacto da cirurgia ortognática no sistema estomatognático de indivíduos com fissura labiopalatina reparada", realizada por Patricia Martins Bueno, CROSP: 120.343, sob orientação da Profa. Dra. Ivy Kiemle Trindade Suedam, CROSP 66508. Essa pesquisa tem objetivo de verificar a força máxima que você consegue fazer com os seus dentes.

O estudo será realizado no Departamento de Ciências Biológicas no Laboratório de Fisiologia Humana da Disciplina de Fisiologia, FOB-USP, Bauru, nos intervalos das aulas. Para avaliação da força de mordida, vamos utilizar um equipamento chamado gnatodinamômetro que vai medir a força máxima que você consegue fazer com seus dentes. Esta medida será feita, por 3 vezes seguidas, no setor de Fisiologia da FOB-USP.

Rubricas:
Participante da pesquisa e/ou responsável legal: _____
Pesquisador Responsável: _____

Garantimos que na divulgação dos resultados da pesquisa seus dados pessoais não serão divulgados publicamente. Não existe desvantagem na participação neste estudo, que sejam do nosso conhecimento. Caso, contudo, você sinta qualquer desconforto, em qualquer dos exames, você pode solicitar não mais participar da pesquisa, sem qualquer prejuízo ao seu desempenho na disciplina de Fisiologia. Se forem observadas alterações importantes nos resultados dos exames, você será orientado no próprio Laboratório de Fisiologia Humana da FOB-USP, por dentista da equipe ou, se preferir, buscar um serviço especializado em âmbito particular, de acordo com o problema encontrado. Com esse estudo esperamos que os resultados ajudem a nortear os protocolos clínicos no tratamento e controle pós-operatório de cirurgia ortognática em pacientes com discrepância maxilomandibular.

Você não terá gastos com a participação neste estudo, pois esses procedimentos serão realizados durante os intervalos de sua rotina de aulas da disciplina de Fisiologia.

Sendo assim, não estão previstos pagamentos de transporte, alimentação, estadia ou qualquer outro tipo de remuneração. Pórem nos comprometemos a indenizar você caso, numa eventualidade, sofra algum dano que seja causado pelos procedimentos que vamos realizar.

Uma via deste Termo de Consentimento Livre e Esclarecido será arquivada no Laboratório de Fisiologia do HRAC/USP e outra via será entregue a você. Na divulgação dos resultados da pesquisa, a sua identidade será mantida em sigilo. Qualquer dúvida referente ao estudo poderá ser esclarecida pela equipe do Laboratório de Fisiologia, pessoalmente, por telefone (14) 3235-8137 ou você poderá entrar em contato com a pesquisadora principal Patricia Martins Bueno por meio de contato telefônico celular: (14) 98133-1785 endereço de e-mail: pmartinsbueno@usp.br.

Caso você queira apresentar reclamações em relação a sua participação na pesquisa, poderá entrar em contato com o Comitê de Ética em Pesquisa em Seres Humanos do HRAC-USP, pelo endereço rua: Silvio Marchione, 3-20 no Serviço de Apoio ao Ensino, Pesquisa e Extensão, pelo telefone: (14) 3235-8421, de 2ª a 6ª feira, no horário das 08:00 as 18:00 horas ou endereço de e-mail: cephrac@usp.br.

Eu_____,
portador da cédula de identidade _____, após leitura das informações neste TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO, concordo em participar da pesquisa e assino este documento em duas vias, sendo que uma via ficará comigo e outra com o pesquisador.

Bauru/SP, _____de_____de_____.

_____ _____

Assinatura participante da pesquisa Assinatura Pesquisador Responsável

RG:

7 Attachments

ATTACHMENT A

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

PARECER CONSUBSTANCIADO DO CEP

Elaborado pela Instituição Coparticipante

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Impacto da cirurgia ortognática no sistema estomatognático de indivíduos com fissura labiopalatina reparada

Pesquisador: PATRICIA MARTINS BUENO

Área Temática:

Versão: 1

CAAE: 89376118.6.3001.5417

Instituição Proponente: Faculdade de Odontologia de Bauru

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.397.776

Apresentação do Projeto:

O projeto de pesquisa "Impacto da cirurgia ortognática no sistema estomatognático de indivíduos com fissura labiopalatina reparada"apresenta como pesquisador responsável Patrícia Martins Bueno e como integrantes da equipe de pesquisa Profa. Dra. Ivy Kiemle Trindade Suedam e Dr. Paulo Alceu Kiemle Trindade. A FOB será coparticipante da pesquisa que foi aprovada pelo CEP do HRAC e submetida uma emenda. A pesquisa visa avaliar o impacto da cirurgia ortognática no sistema estomatognático de indivíduos com fissura labiopalatina reparada, por meio da avaliação da força de mordida e do edema facial. Serão selecionados para essa pesquisa prospectiva, 15 indivíduos com fissura labiopalatina (grupo estudo) e com indicação para cirurgia ortognática, regularmente matriculados no HRAC-USP e 2) Grupo Controle (GC): 15 indivíduos adultos sem cirurgia ortognática e com padrão esquelético do tipo classe I de Angle. Para tanto, duas variáveis principais serão avaliadas, em momentos distintos: 1) mensuração da força de mordida (PRÉ, PO3M, PO6m), com o uso de um gnatodinamômetro (modelo IDDK Kratos) 2) quantificação do edema facial, por meio de medidas faciais bilaterais entre o canto lateral do olho e o ângulo da mandíbula, entre o tragus e a comissura labial e entre o tragus e o pogônio mole (PRÉ, POi, PO3M, PO6m), das quais somente o exame de força de mordida será realizado no grupo controle.

Objetivo da Pesquisa:

Avaliar o impacto da cirurgia ortognática no sistema estomatognático de indivíduos com fissura

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Telefone: (14)3235-8356 **Fax:** (14)3235-8356 **E-mail:** cep@fob.usp.br

labiopalatina reparada, por meio da avaliação da força de mordida e do edema facial.

Avaliação dos Riscos e Benefícios:

Os riscos que esta pesquisa poderá trazer é que, no momento do exame clínico, o indivíduo pode se sentir constrangido em responder algumas das perguntas que serão realizadas. Para o teste de força de mordida, o indivíduo pode se sentir desconfortável durante o apertamento dentário. Nenhum dos exames poderá causar dor, mas o indivíduo poderá sentir um leve desconforto, porém o uso dos equipamentos se fazem necessários para a obtenção dos dados. É importante ressaltar que será avisado ao indivíduo que caso ele não se sinta à vontade para responder ou realizar os exames clínicos, ele poderá, a qualquer momento, solicitar não mais participar da pesquisa, sem prejuízo ao seu tratamento regular no HRAC/USP.

Posteriormente esta pesquisa pode vir a fomentar e desenvolver possíveis condutas, procedimentos e protocolos que possam ajudar os indivíduos aqui matriculados a minimizar alguns impactos, mesmo que temporários, do pós-operatório da cirurgia ortognática, além de compreender o conhecimento acerca das características funcionais do sistema mastigatório.

Comentários e Considerações sobre a Pesquisa:

A FOB foi indicada como coparticipante da pesquisa do HRAC.

Considerações sobre os Termos de apresentação obrigatória:

Foram apresentados os termos obrigatórios.

Recomendações:

Sugiro aprovação.

Conclusões ou Pendências e Lista de Inadequações:

Sem pendências.

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 12/06/2019, com base nas normas éticas da Resolução CNS 466/12. Ao término da pesquisa o CEP-FOB/USP exige a apresentação de relatório final. Os relatórios parciais deverão estar de acordo com o cronograma e/ou parecer emitido pelo CEP. Alterações na metodologia, título, inclusão ou exclusão de autores, cronograma e quaisquer outras mudanças que sejam significativas deverão ser previamente comunicadas a este CEP sob risco de não aprovação do relatório final. Quando da apresentação deste, deverão ser incluídos todos os TCLEs e/ou termos de doação assinados e rubricados, se pertinentes.

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Continuação do Parecer: 3.397.776

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Outros	Resposta_Pendencias.pdf	25/04/2019 12:10:56	PATRICIA MARTINS BUENO	Aceito
Brochura Pesquisa	Projeto_Patricia_CEP_Corrigido.docx	25/04/2019 12:09:55	PATRICIA MARTINS BUENO	Aceito
Outros	Termo_de_Aquiescencia.pdf	25/02/2019 19:22:06	PATRICIA MARTINS BUENO	Aceito
Outros	Ementa.pdf	25/02/2019 19:21:03	PATRICIA MARTINS BUENO	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Controle_Reformulado.pdf	25/02/2019 19:18:02	PATRICIA MARTINS BUENO	Aceito
Brochura Pesquisa	Projeto_Patricia_Novo.pdf	25/02/2019 19:17:46	PATRICIA MARTINS BUENO	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Reformulado_CEP.docx	27/06/2018 09:30:02	Silvia Maria Graziadei	Aceito
Outros	Formulario_Resposta_Pendencias.pdf	07/06/2018 10:45:19	PATRICIA MARTINS BUENO	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Reformulado.pdf	07/06/2018 10:42:19	PATRICIA MARTINS BUENO	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Reformulado_Patricia_CEP.pdf	07/06/2018 10:42:06	PATRICIA MARTINS BUENO	Aceito
Outros	Checklist_Prot_Pesq_36_2018.pdf	11/05/2018 09:25:00	Rafael Mattos de Deus	Aceito
Outros	Apendice_Tres.pdf	10/05/2018 12:18:39	PATRICIA MARTINS BUENO	Aceito
Outros	Apendice_Dois.pdf	10/05/2018 12:18:09	PATRICIA MARTINS BUENO	Aceito
Outros	Apendice_Um.pdf	10/05/2018 12:17:31	PATRICIA MARTINS BUENO	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Detalhado.pdf	10/05/2018 12:01:36	PATRICIA MARTINS BUENO	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Term_Consent.pdf	10/05/2018 12:00:30	PATRICIA MARTINS BUENO	Aceito
Outros	Term_Perm_Uso_Registro.pdf	09/05/2018 10:02:59	PATRICIA MARTINS BUENO	Aceito

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Continuação do Parecer: 3.397.776

Outros	Term_Comp_Tornar_Publico_Dest_Mat.pdf	09/05/2018 09:51:02	PATRICIA MARTINS BUENO	Aceito
Outros	Term_Comp_Pesq_Resp.pdf	09/05/2018 09:50:14	PATRICIA MARTINS BUENO	Aceito
Outros	Term_Comp_Conf_Aut_Dados.pdf	09/05/2018 09:49:34	PATRICIA MARTINS BUENO	Aceito
Outros	Carta_Encaminham.pdf	09/05/2018 09:44:36	PATRICIA MARTINS BUENO	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 17 de Junho de 2019

Assinado por:
Ana Lúcia Pompéia Fraga de Almeida
(Coordenador(a))

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