

UNIVERSIDADE DE SÃO PAULO  
HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

**LEONARDO BEZERRA FEITOSA**

**Aesthetic outcome of the face after 2-stage palate repair for complete unilateral cleft lip and palate**

**Resultado estético da face no reparo de fissura labiopalatina completa unilateral com fechamento de palato em dois tempos**

**BAURU**

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Orientador: Prof.Dr.Cristiano Tonello

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Assinatura



Leonardo Bezerra Feitosa

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FOLHA DE APROVAÇÃO

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## **DEDICATÓRIA**

Àqueles que são muito mais que uma estatística de um para cada setecentos nascidos, eles trazem uma história de vida única e suas cirurgias certamente representam a menor de suas lutas. Dedico essa tese aos portadores de anomalias craniofaciais e seus familiares, que depositam sua confiança em nossas mãos e nos trazem a responsabilidade e desejo de querer ser cada vez melhor, como profissional e ser humano.



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Diferente da visão estatística, a significância das pessoas não pode ser confirmada com um simples valor de “p”. Então, é impossível resumir e agradecer nesse pequeno espaço a todos que passaram em minha vida e contribuíram de forma direta ou indireta para a realização desse sonho.

*“Ó Mestre, fazei que eu procure mais:  
consolar, que ser consolado;  
compreender, que ser compreendido;  
amar, que ser amado.  
Pois é dando que se recebe.  
É perdoando que se é perdoado.  
E é morrendo que se vive para a vida eterna.”*

**ORAÇÃO DE SÃO FRANCISCO**



## ABSTRACT

**Feitosa, Leonardo Bezerra.** Aesthetic outcome of the face after 2-stage palate repair for complete unilateral cleft lip and palate. Bauru: Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo; 2022.

**Introduction:** Cleft lip and palate repair aims to rebuild the function of orofacial structures, decreasing the impact on language development, masticatory function and airways, as well as creating a harmonic, symmetrical nasolabial appearance with minimal scarring. There is no consensus on the best surgical technique to be adopted, but unsatisfactory results can lead to an unaesthetic appearance and have negative consequences on the individual's self-esteem. **Objective:** To evaluate the aesthetics of the nasolabial appearance and the facial profile of children with complete unilateral cleft lip and palate and the fistula index based on the 2-stage palatoplasty technique with vomer flap. **Method:** This is a retrospective study, evaluating the nasolabial appearance during the mixed dentition age using the Asher-McDade index by three craniofacial surgeons and analyzing the fistula rate in 139 patients with complete unilateral cleft lip and palate submitted to the same surgical protocol and performed in a single center, Hospital for Rehabilitation of Craniofacial Anomalies (HRAC-USP). Kappa tests were used to assess inter- and intra-rater reproducibility. **Results:** 139 children were evaluated (90 boys and 49 girls). The mean age of the population during mixed dentition photography was 6.29 years. Mean Asher-McDade Index scores ranged between 2.25 and 2.4 for all parameters. Reproducibility values ranged from moderate to substantial agreement. The incidence of palatal fistula was 21.74% and the most frequent location was in the hard palate (Pittsburgh type IV), in 36.67%. Palate function was considered adequate in 79% (n=109/138) of individuals and 21% had speech impairment. **Conclusion:** The results of the 2-stage palatoplasty protocol seem to be favorable in the long-term follow-up, proving to be a reliable option for the treatment of patients with unilateral cleft lip and palate.

**keywords:** Cleft lip; Cleft Palate; Treatment Results; Palatal fistula;



## RESUMO

**Feitosa, Leonardo Bezerra.** Resultado estético da face no reparo de fissura labiopalatina completa unilateral com fechamento de palato em dois tempos. Bauru: Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo; 2022

**Introdução:** O reparo da fenda labiopalatina visa reconstruir a função das estruturas orofaciais, diminuindo o impacto no desenvolvimento da linguagem, mastigação e vias aéreas, assim como criar uma aparência nasolabial harmônica, simétrica e com cicatrizes mínimas. Não há um consenso sobre a melhor técnica cirúrgica a ser adotada, porém resultados insatisfatórios podem levar a uma aparência inestética e gerar consequências negativas na autoestima do indivíduo. **Objetivo:** Avaliar a estética da aparência nasolabial e do perfil facial de crianças com fissura labiopalatina unilateral completa e o índice de fístulas com base na técnica de fechamento de palato em dois tempos. **Método:** Trata-se de um estudo retrospectivo, sendo avaliada a aparência nasolabial pelo método de escore Asher-McDade por três cirurgiões craniofaciais e analisado o índice de fístulas em 139 pacientes portadores de fissura labiopalatina unilateral completa submetidos a um mesmo protocolo cirúrgico e realizado em um único centro, Hospital de Reabilitação de Anomalias Craniofaciais (HRAC-USP). Testes de Kappa foram utilizados para avaliar a reprodutibilidade inter e intra-avaliadores. **Resultados:** 139 crianças foram avaliadas (90 meninos e 49 meninas). A média de idade da população durante a fotografia de dentição mista foi de 6,29 anos. As pontuações médias do Índice Asher-McDade variaram entre 2,25 e 2,4 para todos os parâmetros. Os valores de reprodutibilidade variaram de concordância moderada a substancial. A incidência de fístula palatina foi de 21,74% e a localização mais frequente foi no palato duro (Pittsburgh tipo IV), em 36,67%. A função do palato foi considerada adequada em 79% (n=109/138) dos indivíduos e 21% apresentavam comprometimento da fala. **Conclusão:** Os resultados do protocolo de fechamento de palato em 2 tempos parecem ser favoráveis no seguimento a longo prazo, demonstrando ser uma opção confiável para o tratamento de pacientes com fissura labiopalatina unilateral.

**Descritores:** Fenda labial. Fissura palatina. Resultado do tratamento. Fístula.



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## **LIST OF ABBREVIATIONS**

CLP - Cleft lip and palate

HRAC - Hospital de Reabilitação de Anomalias Craniofaciais

UCLP - Unilateral Cleft lip and palate

VAS- Visual Analog Scale

VPI - Velopharyngeal Insufficiency

## **SUMMARY**

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# 1

## Introduction



## 1. INTRODUCTION AND LITERATURE REVIEW

Cleft lip, with or without involvement of the palate, is characterized by a partial or complete defect in the closure of the upper lip during the first weeks of the embryological period, which may be unilateral or bilateral, in addition to affecting the alveolar crest and hard palate. According to the World Health Organization (2006), they stand out as the congenital malformations with the highest incidence among craniofacial anomalies, with a worldwide prevalence of approximately one for every 700 live births, with variations occurring between different ethnicities and gender.

Although the etiology is still uncertain, about 70% of individuals with orofacial cleft present the cleft as an isolated finding, without other structural or cognitive abnormalities, being classified as non-syndromic (DIXON, 2011). A history of increased incidence in the family after an individual already affected with this pathology has been described in the literature. Little and Bryan (1986) reported a concordance rate of 40 to 60% in monozygotic twins, higher than the rate of 3 to 5% in dizygotic twins, which also suggests a strong, but not exclusive, genetic etiology. Recent studies demonstrate a multifactorial relationship, genetics and environmental factors, including maternal diet, smoking, alcohol consumption and anticonvulsants during pregnancy (SCAPOLI et al., 2008).

The objective of surgical repair of cleft lip and palate (CLP) is based on improving the individual's quality of life, reconstructing the affected anatomical region and restoring its function. One of the main determinants of the success of this repair is the final aesthetic result. The importance of appearance in patients with orofacial clefts is extremely relevant and evaluating its result has been the subject of numerous studies due to its complexity and subjectivity. It is known that a bad result can be associated with behavioral problems during the individual's development, relating to learning, self-esteem and the establishment of interpersonal relationships (HUNT et al., 2005).

In addition to the possible psychosocial impact related to appearance after surgery, individuals with orofacial clefts may present other disorders, such as difficulties with food intake in the first days of life, growth retardation, and impairment of speech and hearing (MOSSEY et al., 2009). Thus, the importance of monitoring

these individuals with a multidisciplinary team from childhood to adulthood is emphasized.

### **1.1. CLASSIFICATION OF THE CLEFT LIP AND PALATE**

In the literature, there is a vast diversity of classifications of orofacial malformations, varying with their anatomical reference, with the incisive foramen, the limit between the primary and secondary palate, adopted in most of these. SPINA (1972) proposed an objective system, modified in 1992 by SILVA-FILHO, widely accepted until the present day. In this classification, individuals were categorized into three groups, subdivided according to laterality (left, right or bilateral), their location in relation to the incisive foramen (pre-foramen, trans-foramen and post-foramen) and in complete when they reach, in addition to the lip, the alveolar ridge or incomplete. A fourth group was represented by clefts with involvement of other regions of the face, being categorized as rare clefts.

Based on SPINA's classification (1972), unilateral trans-foramen cleft, or unilateral complete cleft lip and palate (UCLP), stands out as the one with the highest incidence. Freitas et al (2004) reported a prevalence of 37.1% of patients with trans-foramen clefts in a study with more than 800 patients, followed by isolated post-foramen clefts (31.7%) and isolated pre-foramen clefts (28, 4%). Cymrot et al (2010) observed an even more expressive frequency in a sample of 551 patients who underwent surgery at a children's hospital in northeastern Brazil. In their study, 264 patients were classified as having unilateral trans-foramen cleft, showing about 47.9% of the entire series.

### **1.2. TREATMENT PROTOCOLS**

The ideal moment for the surgical approach is variable, considering the surgeon's experience, the anesthetic risks and the psychosocial impact on the family (SHKOUKANI, 2013). There are many different surgical treatment protocols for complete CLP, with variations in the initial age of treatment and technique adopted. In a large study involving several European centers specializing in the treatment of

orofacial clefts, “The Eurocleft study”, more than 190 different protocols were identified exclusively for the treatment of UCLP (PHILLIPS et al., 2017; SHAW et al., 2001).

Treatment of transforamen clefts can occur in a single or multiple stages. It is suggested that early closure of the palate could be associated with an improvement in the developmental aspect of speech, but producing a negative impact on maxillary growth. There is no consensus in the literature on the most appropriate choice and there is disagreement between authors regarding the positive and negative consequences of each conduct (GUNDLACH et al, 2013).

When performed in a single stage, the surgery aims to correct CLP simultaneously, being defended by some authors who claim a reduction in hospital costs, less aggression to soft tissues and, consequently, better healing. However, such results are conflicting in the literature and adopted by a restricted number of institutions (FUNDALEJ et al, 2015).

Conceived by Pichler in 1926, the use of a vomer flap to correct the hard palate has gained wide acceptance by centers specialized in the treatment of orofacial clefts. It can be applied in a two-stage protocol, combining anterior palate closure and cheiloplasty in a primary surgery and, subsequently, soft palate correction. This procedure has shown excellent results, proving to be safe and associated with lower rates of postoperative complications, such as fistulas (SMARIUS, 2016).

In the “Eurocleft” study, centers that adopted the two-stage palate surgery in their protocol, associating the vomer flap in the first stage, showed excellent rates, standing out in the long term as the best results related to maxillary growth, as well as favorable esthetic results (SHAW et al., 2001; OZAWA et al., 2018).

### **1.3. AESTHETIC EVALUATION**

After cheiloplasty and surgical correction of the nose, patients with CLP tend to exhibit better facial symmetry, but the interventions are not without sequelae during growth and the healing process. Although surgical intervention is performed in early childhood and followed by adequate multidisciplinary rehabilitation, a remaining

asymmetry in the nose and upper lip region can be seen in the vast majority of patients (MEYER-MARCOTTY et al., 2011).

Assessing facial aesthetics in individuals with CLP is a subjective topic and still a major challenge for the surgeon. Although there is still no gold standard model adopted with a high rate of reliability, several classifications were used in multiple studies for qualitative analysis and showed good statistical reliability results, such as the "Visual Analog Scale" (VAS), the " Q-sort" and the Asher-McDade method (STOUTLAND, 2017).

As the method of choice in large multicenter studies, such as Americleft (MERCADO et al., 2011), the Asher-McDade assessment system has gained notoriety. It is based on the use of standardized photos, evaluating the characteristics of 4 components: nasal shape, nasal symmetry, profile view and vermilion border. Points are assigned from 1 to 5, with 1 referring to the best result and 5 to the worst result. It stands out for being a fast, reliable and low-cost method (MULDER et al., 2018).

Comparing aesthetic results by different individuals through photographs consists of a qualitative analysis, which may be biased for each evaluator. In order to reduce the bias of this analysis, the Kuijpers-Jagtman system was developed, adopting the average scores of all observers regarding nasolabial appearance and evaluating their correlation coefficient. In addition, a standard of photographs was assigned for reference in the score of each evaluated component, similar to the Goslon occlusal index, facilitating its replicability by different centers (KUIJPERS-JAGTMAN, 2009).

#### **1.4. COMPLICATIONS**

Complications associated with complete CLP repair include suture dehiscence, vermilion misalignment, asymmetries in nasolabial appearance, velopharyngeal insufficiency, and fistulas. Among these, the importance of the aesthetic result is emphasized once again, since the surgeries for refinement or correction of asymmetries in the lip and nose region represent the main reason for seeking additional treatment by patients and their families (SEMB et al., 2005).

The occurrence of oronasal fistulas is also an important factor in evaluating the results of surgery. They present wide divergence in their incidence, with variations from 0 to 77.8%, being associated with factors related to the patient, such as the age of the surgery and the width of the cleft, as well as the technique adopted, if there was tension in the repair, bleeding, infection and the surgeon's experience. More often, they affect the junction of the hard and soft palate, and may be asymptomatic or result in speech and food intake consequences (CROKETT, 2014; HARDWICKE; LANDINI; RICHARD, 2014).

Based on these literature data, we sought to better understand the long-term surgical outcomes at our institution. Seeking to identify in a homogeneous sample the impact of a specific surgical protocol in relation to the aesthetic result and one of its main complications, the incidence of fistulas.

# 2

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## Objective

## **2. OBJECTIVE**

### **Main objective**

To evaluate the aesthetic results and the fistula rates of a specific surgical protocol in a reference institution in the treatment of CLP.

### **Specific objectives**

- To analyze the results of nasolabial appearance and facial profile of the same surgical protocol in a reference institution in the treatment of CLP.
- Identify the fistula rates and their place of occurrence of the same surgical protocol in a reference institution in the treatment of CLP.

# 3

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## STUDY #1

### **3 STUDY # 1**

The article was written according to the Journal of Cranio-Maxillofacial Surgery instructions and guidelines for article submission.

## **FISTULA RATES AFTER 2-STAGE PALATE REPAIR FOR UNILATERAL CLEFT LIP AND PALATE: AN AUDIT OF 139 CHILDREN**

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## Abstract

**Background and aim:** This study presents a preliminary report of the institutional experience after adopting the vomer flap for early closure of hard palate associated with lip and nose repair, as the first stage of primary surgeries for unilateral cleft lip and palate. This paper focuses on analyzing the postoperative rates of fistula development after 2-stage palate repair.

**Methods:** A retrospective chart review identified one hundred and thirty-nine non-syndromic patients with unilateral cleft lip and palate who received a vomer flap for the closure of the hard palate during cleft-lip repair in a Brazilian cleft center. The occurrence of primary palatal fistula was assessed during the postoperative multidisciplinary follow-up and registered by the team in the medical chart and photographic records.

**Results:** The mean age at the primary lip repair and simultaneous vomer flap was  $4.3 \pm 1,7$  months and  $18 \pm 10,52$  months for posterior palatal closure. The incidence of palatal fistula was 21,74% and the most frequent location was the hard palate (Pittsburgh type IV), in 36,67%. Adequate palatal function was present in 79% (n=109/138) and 21% had speech impairment.

**Conclusions:** The authors' data show that post-operative fistula formation rates were relatively high, but functional impairment was quite reliable. Thus, 2-stage palatoplasty could be an optional surgical protocol for patients with unilateral cleft lip and palate.

**Keywords:** Cleft lip and Palate; surgical protocol; palatal fistula; treatment results

## INTRODUCTION

Cleft lip and palate surgical treatment aims to improve the individual's quality of life, reconstructing the affected anatomical region and restoring its appearance and function. Palatal fistula is the most frequent complication following palatoplasty and can result in undesirable oronasal communication.

The occurrence of oronasal fistulas is an important factor when assessing surgical outcomes. Previous studies present a wide range of fistula incidence, with variations from 0 to 77.8%. Patient-related factors, such as age, extent of the cleft and postoperative care can be involved in its etiology; as well as the surgical technique, surgeon's experience and perioperative factors, such as repair under tension, bleeding

and infection. More often, fistulas affect the junction of the hard and soft palates, and may be asymptomatic or result in speech and food intake problems. (Crockett and Goudy, 2014; Hardwicke et al., 2014)

This study presents a report of one specialized center experience after adopting the vomer flap for early closure of hard palate, associated with lip and nasal ala repair, as the first stage of primary surgeries for unilateral cleft lip and palate (UCLP), followed by soft palate repair as second stage, and the occurrence of palatal fistula associated with this protocol.

## **METHODS**

This retrospective analysis included 139 non-syndromic patients with unilateral cleft lip and palate who underwent primary surgical repair in a Brazilian cleft center by one of nine experienced plastic surgeons. All the children were examined and followed up under standardized protocols developed by the multidisciplinary cleft team composed mainly by plastic surgeons, orthodontists, speech therapists, and otolaryngologists. This study was approved and reviewed by the institution's Human Research Ethics Committee.

### **Study Eligibility Criteria**

Inclusion criteria included (1) individuals with UCLP; (2) absence of syndromes and other associated malformations; (3) use of vomer flap for the closure of the hard palate during cleft-lip repair (4) no history of previous orthodontic treatment; (5) no secondary lip and nasal repair; and (5) availability of facial photographs in mixed dentition age. Exclusion criteria included (1): inadequate photographic documentation.

### **Analysis**

The occurrence of primary palatal fistula was assessed during the postoperative multidisciplinary follow-up and registered by the team in the medical chart and photographic records until the end of data collection, and the oldest patient in the sample was ten years old at the time. Subsequently, they were categorized in terms of estimated size (in millimeters), their location according to the Pittsburgh Fistula Classification System (Figure 1) and presence of symptoms related to speech

and feeding. Fistulas located anteriorly to the incisive foramen (types VI and VII) were excluded from our analysis.

## RESULTS

### Demographics

One hundred and thirty-nine children, 89 male and 49 female, with unilateral cleft lip and palate, were included in the study. The mean age at the primary lip repair and simultaneous vomer flap was  $4.3 \pm 1,7$  months (range, 2-12 months) and  $18 \pm 10,52$  months for the second stage, posterior palatal closure. A team of nine experienced plastic surgeons performed the surgical procedures as well as the and follow-up.

### Incidence of fistula

The overall fistula incidence at any time point after the 2-stage palate repair was 21,01% (n=29), excluding those anterior to the incisive foramen. The location of the fistulas, using the Pittsburgh Fistula Classification System, was: type IV (37,93%), type III (34,48%) and type II (6,9% and type I(20,69%). (Fig 2)

Female (n=11/49) and male (n=18/89) patients had similar rates. Seventeen fistulas (58.6%) were described as having minimal size (less than 1mm). Only two patients presented large fistulas, with an extension greater than 5 mm.

### Function

Speech was classified according to its intelligibility as normal (n=54) or abnormal in three different degrees: mild (n=55), moderate (n=24) and severe (n=4). Adequate palatal function was present in 79% (n=109/138) and 21% had speech impairment reported during speech and language face-to-face assessment (Fig 3). One individual was excluded from this sample due to difficulties in cooperation during the clinical examination.

## DISCUSSION

After a multidisciplinary team discussion regarding the need for an audit report on institutional protocols as a necessary step for outcomes measure, this study was planned as part of a global team effort.

Cleft surgeons from different centers have developed many techniques to create the ideal protocol and achieve the best results, minimizing the impact of surgical procedures on facial growth, promoting normal speech and avoiding complications, such as fistulas and dehiscence. Conceived by Pichler in 1926, the use of a vomer flap has been gaining wide acceptance by specialized centers in the treatment of orofacial clefts. It can be applied in a two-stage protocol, associating closure of the anterior palate and cheiloplasty in a primary surgery and, later, correction of the soft palate. This procedure showed excellent results in previous studies and has been adopted as part of our surgical routine for over twelve years. (Smarius and Breugem , 2016)

The analysis of previous studies reporting the incidence and characterization of fistulas in cleft patients may demonstrate an important bias, justifying their significant divergence in the literature. Although there are numerous classifications, based on embryological and morphological criteria, and even including the presence of symptoms, the application of the Pittsburgh classification was fundamental to categorize and facilitate our analysis, once it is simple and widely accepted. Consistent with other studies, all perialveolar fistulas were considered as an intentional residual alveolar cleft, planned to be corrected at bone grafting age, thus excluded from our main results. (Brosco et al., 2021; Hardwicke et al., 2014; Cohen et al; 1991)

The factors associated with this common morbidity could be related to the type and width of the palatal cleft, sex of the patient, closure under tension, hematoma and experience of the surgeon. Similarly, to other studies, our results showed that the most frequent fistula location was the hard palate (Pittsburgh IV), followed by the transition zone (type III), but no sex differences were found. (Rautio et al., 2017)

Despite the establishment of a single protocol in our institution for closing the anterior palate in primary surgery, the technique adopted in the second stage varied among surgeons, with the Sommerlad and classical Von Langenbeck techniques being the most used. Even though a previous meta-analysis has shown that fistula rates vary only slightly between the different techniques used for primary cleft palate

repair, this could be one of the factors that explains the variability of our results. (Bykowski et al., 2015)

Determining whether velopharyngeal function is adequate or not is a multi-variable step, ideally requiring the application of standardized data acquisition and analysis by more than one professional, as well as inter and intra-evaluator comparison. Our results were based on objective reports of previous consultations with experienced speech therapists, identifying patients who had speech disorders affecting intelligibility and oronasal resonance. Although the total incidence of fistulas in our sample was considered high, our speech results can be considered similar to most centers, reporting a rate of up to 30% of velopharyngeal insufficiency. Concurrent with the development of the present study, a criterious speech assessment of all individuals is being designed and performed for a more accurate and detailed analysis. (Inman et al., 2005)

Although based on a retrospective analysis, this data could be the basis for further studies due to the sample size, duration of follow-up and also for reflecting the outcomes of an international reference high-volume center for the treatment of patients with cleft lip and palate. Furthermore, proper assessment of a surgical protocol includes as minimum parameters the aesthetic, facial growth and speech results.

## **CONCLUSION**

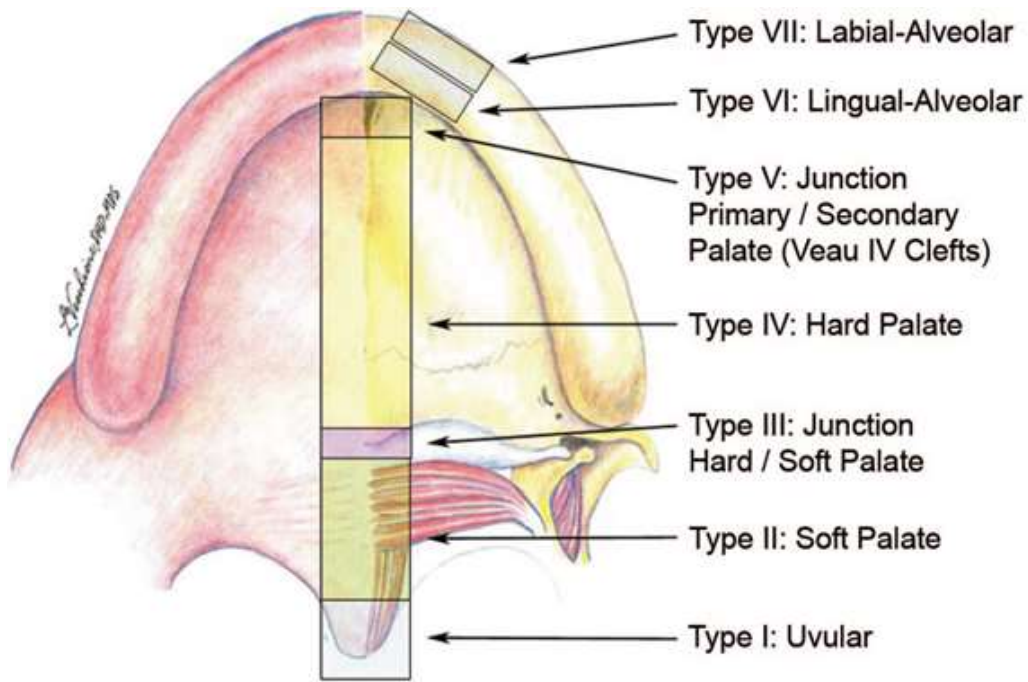
Two-stage palatoplasty could be an optional surgical protocol for patients with unilateral cleft lip and palate. Although our preliminary follow-up results show that the palatal fistulas rates were relatively high, functional impairment can be considered fairly reliable, corroborating previous studies and showing good outcomes with the vomer flap for early closure of hard palate.

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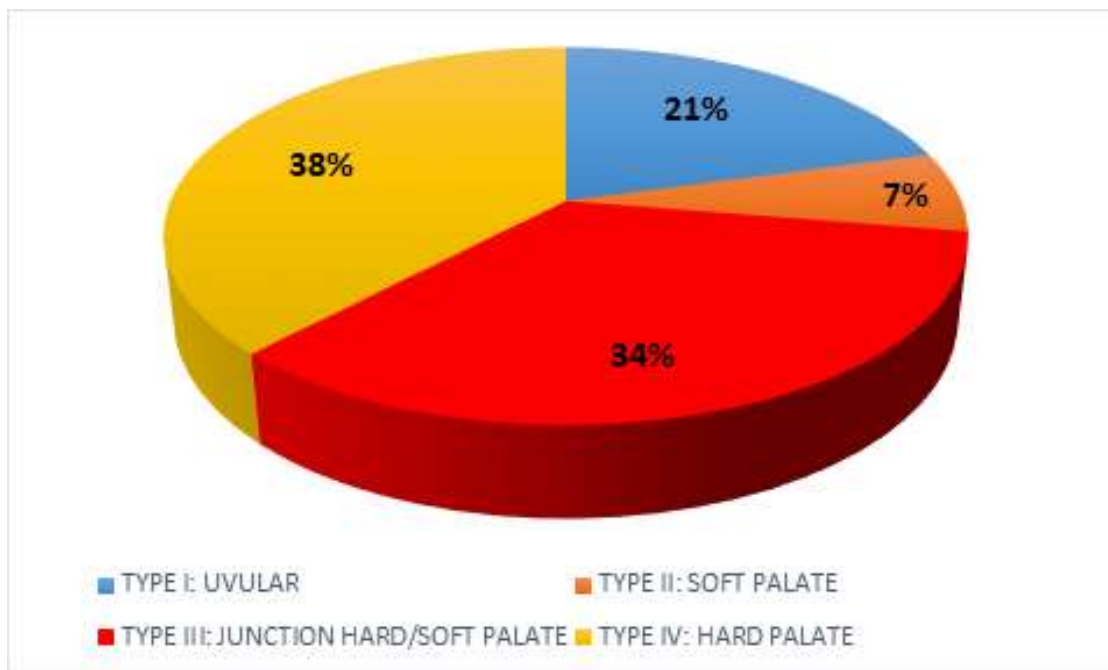
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**Fig1.** The Pittsburgh Fistula Classification System. (Figure reproduced from Losee et al., 2008)



**Fig 2.** Location of fistulas

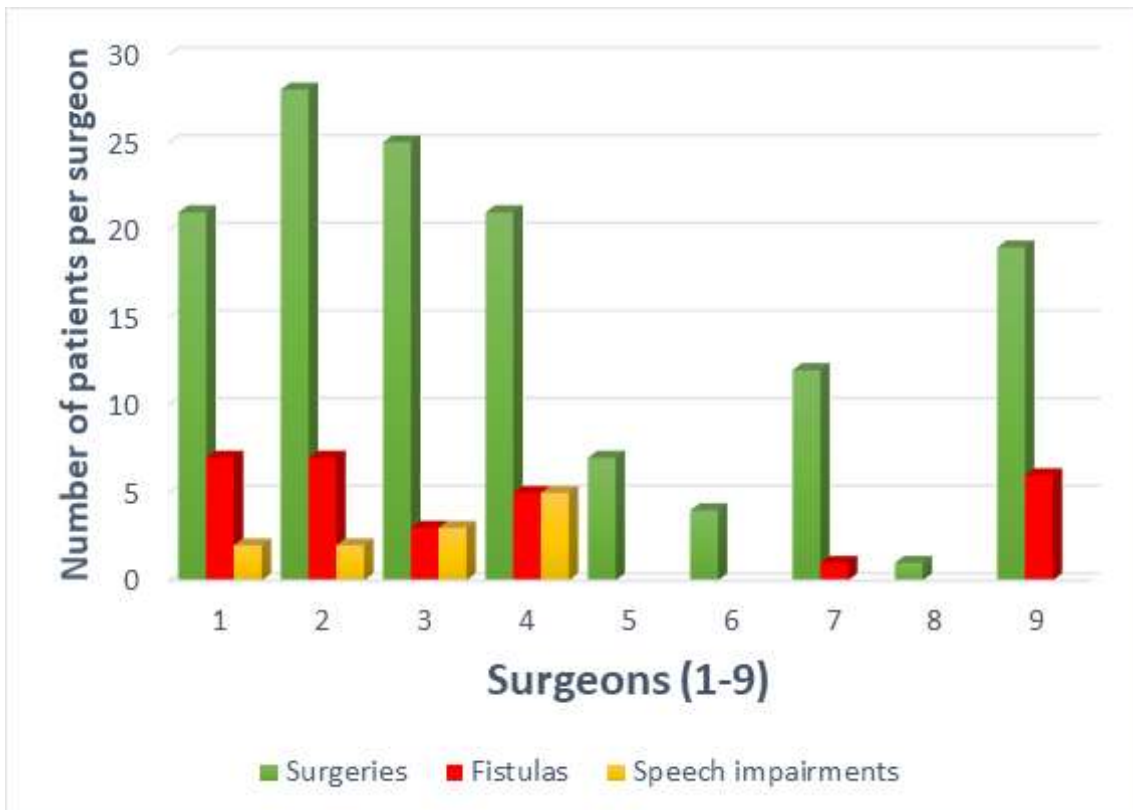


Fig 3. Surgical Outcome

# 4

## STUDY #2

#### **4 STUDY #2**

The article was written according to the Journal of Cranio-Maxillofacial Surgery instructions and guidelines for article submission.

### **NASOLABIAL APPEARANCE AFTER 2-STAGE PALATE REPAIR FOR UNILATERAL CLEFT LIP AND PALATE: AN AUDIT OF 139 CHILDREN**

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## Abstract

**Background and aim:** The aesthetic appearance of the nasolabial region is critical to assess the success of treatment in patients with cleft lip. This study aimed to audit the process and the result in terms of facial aesthetics in one hundred and thirty-nine children with non-syndromic unilateral cleft lip and palate (UCLP) treated with the same surgical protocol in a single center.

**Methods:** A five-point rating scale (Asher-Mcdade index) was used for assessment by three plastic surgeons and was repeated after 2 weeks. The photographs were taken at mixed dentition age. Kappa scores were used to assess agreements within and between rater reliability.

**Results:** 139 children were enrolled (90 boys and 49 girls). At the time of the photograph, the mean age of the study population was 6.29 years old. The average Asher-McDade Aesthetic Index scores varied between 2.25 and 2.4 for all parameters. Intra-observer values ranged from moderate to substantial agreement.

**Conclusion:** The 2-stage palate repair results seem to be favorable in the long-term follow-up regarding esthetic appearance, however, there are limitations related to the subjective methodology adopted.

**Keywords:** Cleft lip and Palate; surgical protocol; treatment results

## INTRODUCTION

There is a wide variety of surgical treatment protocols for complete unilateral cleft lip and palate (UCLP), with variations in the initial age of treatment and technique adopted. Early closure of the palate may be associated with an improvement in the developmental aspect of speech, however producing a negative impact on maxillary growth and, consequently, affecting facial aesthetics. (PHILLIPS et al., 2017; SHAW et al., 2001; GUNDLACH et al, 2013)

Nasolabial appearance after cleft surgery has a major role in determining surgical success. The assessment of facial aesthetics is subjective and still a major challenge for the surgeon. However, a poor outcome has been associated with behavior problems, social anxiety and depression. (HUNT et al., 2005).

Although there is still no standard model adopted with a high level of reliability, several classifications were applied for qualitative analysis and showed good results of statistical reliability, such as the "Visual Analog Scale" (VAS), the "Q-sort" and the Asher-McDade method. Demonstrating relevant and good reliable results, the Asher-McDade method has stood out as one of the most popular and already validated in previous studies, including Americleft and Eurocleft. (SEMB et al., 2005; MERCADO et al., 2011; STOUTLAND, 2017)

In light of this, this study is the second part of a report of the institutional experience after adopting the vomer flap for early closure of hard palate and aims to evaluate the aesthetic results of 139 children who underwent a standardized surgical protocol in our cleft center.

## **MATERIAL AND METHODS**

This retrospective analysis included 139 consecutive non-syndromic patients with complete UCLP who underwent primary surgical repair in a Brazilian cleft center by nine plastic surgeons. They underwent lip repair using the Millard technique, anterior palate repair with a vomer flap and nasal ala repositioning by the Skoog technique at 3 months of age. In a second surgery, at 18 months of age, posterior closure of the palate was performed. This study was approved and reviewed by the Research Ethics Committee of the Hospital for Rehabilitation of Craniofacial Anomalies.

### **Study Eligibility Criteria**

Inclusion criteria included (1) individuals with UCLP between 6 and 9 years of age; (2) absence of syndromes and other associated malformations; (3) no history of previous orthodontic treatment; (4) no secondary lip and nasal repair; and (5) facial photographs in mixed dentition age available. Exclusion criteria included (1): inadequate photographic documentation.

## PHOTOGRAPHS

Digital photographs of the face at a high resolution, saved as JPEG files, standardized in anterior and profile, at the age of mixed dentition, following the criteria of Asher-McDade et al. (1991) and Kuijpers-Jagtman et al. (2009) indexes. The images were cropped to display only the nasolabial area, PowerPoint slides were created and they were titled randomly from number 1 to 139. (FIG.1)

Three plastic surgeons with experience in cleft lip and palate treatment independently rated each slide presented twice at a 2-week interval on the same computer monitor. The photographic sequence was rerandomized in a different sequence for the second assessment. Scores from 1 to 5 were assigned based on the nasal shape, nose alignment, vermilion border and profile view. Score 1 represents "excellent appearance," score 2 "good appearance," score 3 "fair appearance," score 4 "poor appearance," and score 5 "very poor appearance". A fourth surgeon previously explained the entire procedure and performed the calibration session using a panel of photographs of 21 children that had not been used in our sample.

## STATISTICAL ANALYSIS

Intra- and inter-observer correlation was estimated by kappa index. Cohen kappa ( $\kappa$ ) statistical analysis was used to determine the intra-observer agreement and Fleiss' kappa was used to determine the inter-observer agreement. According to Landis and Koch (1977), values of  $\kappa$  greater than 0.8 represent almost perfect agreement, values between 0.61 and 0.80 represent substantial agreement, values between 0.41 and 0.60 moderate agreement, values between 0.21 and 0.40 fair agreement, and values below 0.20 represent slight agreement beyond chance. The mean score for each category assessed was also calculated. Data were analyzed using IBM SPSS (Statistical Package for Social Sciences) 25.0 software.

## RESULTS

### Demographics

A team of nine cleft surgeons participated in the performance and follow-up of all procedures. One hundred and thirty-nine children were enrolled in this research, 90 male and 49 female. At the time of the photograph, the mean age of the study population was 6.29 years old (0.61 standard deviation).

### Scoring agreement

Intra-observer agreement between the 3 graders during 2 sessions and  $\kappa$  statistics are displayed in **Table 1**. A mean intra-observer score of 0.62 (0.49–0.77) was found between the first and second rounds of interpretation. Overall, values ranged from moderate to substantial agreement. The average Fleiss' kappa values were in fair range of agreement (0.23-0.44), the mean inter-observer score was 0.33.

### Aesthetic outcomes

**Table 2** shows the results of the assessor evaluations according to the AsherMcDade Aesthetic Index. The mean score of the nasal form was 2.39, nasal alignment was 2.25, vermilion border was 2.31 and profile was 2.4. Overall, all four parameters were considered “fair” to ‘good’ appearance with a total mean score of 2.34 (2.25 -2.4). Only one surgeon had the result with an average score greater than “3”, being classified as “fair” for the profile aspect.

## DISCUSSION

Several authors have reported that patients undergoing 2-stage palatal repair with vomer flap have good results related to growth and facial appearance. Thus, this technique has been used concomitantly with primary lip repair as the first surgical step for more than ten years at our cleft center (Mølsted et al., 2017; Ozawa et al., 2018).

The quality of surgery results in patients with cleft lip and palate is expressed in the combination of some parameters: speech, hearing, appearance and dentoskeletal relationships (Ganesh et al., 2015). In this second part of an institutional audit, the evaluation of treatment outcome was restricted to judging facial aesthetics through a subjective assessment, the Asher-McDade index. The next evaluations of this sample will focus on hearing and speech alterations and on the dental occlusion relationship.

The Asher-McDade index is a reliable procedure to assess and differentiate aesthetic outcomes and allows surgeons to reassess a patient's aesthetics by standardized photographs. It has been used many times in the literature as well as in other cleft lip repair audits. Cropping the images in a standardized way, leaving only the nasolabial region exposed, preserves the patient's identity and makes the judges' assessment more valid (Asher-McDade et al., 1992; Kuijpers-Jagtman et al. 2009; Thomson et al., 2020).

Similar to the Americleft study (Mercado et al., 2011), which compared four centers with a sample of 124 children, the scores obtained in our study also ranged from "fair" to "good". Based on the 5-point assessment, the mean score for our results ranged from 2.25 to 2.40, with nasal alignment being the best result. Although it presented the worst score (2.4), the profile view was still considered "good", suggesting that the vomer flap did not have a negative impact on the development of the maxilla and that the vast majority of patients had an adequate growth of the face, similar to other studies (Gundlach et al., 2013; Liao et al., 2014; Fudalej et al., 2015).

Overall, the average Cohen kappa values calculated for each observer between the first and second sessions was 0.62 indicating a substantial value of intra-observer agreement using Landis and Koch's criterion (Landis and Koch, 1977). Possibly, the tutorial prior to the beginning of the analysis of the images and training with photos that were not part of the study were important to achieve good intra-observer reliability. Some studies have related the influence of the surgeon's accumulative experience with outcomes, rather than the frequency of performance of the operation (Semb and Shawn, 2013; Wes et al, 2018). In our analysis, something intriguing was evidenced demonstrating the opposite of those studies. Comparing the mean scores of individual esthetic results per surgeon, all produced "fair" to "good" nasolabial appearance (2.12-2.49). Of the nine surgeons, five performed twenty or more primary surgeries in the evaluated period. When analyzing this group, most of them have more than twenty

years of experience in treating cleft patients, but surgeon #9 showed to have the best average score (2.12), even though he was not considered a senior surgeon, having performed the procedures with less than 5 years of experience, still at the beginning of his career.

There are some limitations to consider in our paper. The Asher-McDade index did not provide details related to the appearance of the scar and, secondly, because it omitted a basal view, we could not analyze in more detail the columella and nasal symmetry. Although we have individualized a specific group, children with UCLP, the width of the cleft may be a bias, as we do not use pre-surgical nasolabial molding in our routine and a very heterogeneous group was analyzed in terms of cleft size. Thus, it is suggested that wide clefts may have a worse outcome and perhaps this subdivision should be encouraged for use in further studies.

Despite of the fact that our overall aesthetic results were not considered inappropriate (mean total = 2.34) and appear slightly better than those reported by Americleft (approx. 2.9) and Eurocleft (approx. 3.0), we must look for ways to improve our outcomes in order to achieve results that are ideally excellent (Mercardo et al.,2011; Semb et al, 2005). Thus emphasizing the importance of carrying out institutional audits to identify possible weaknesses and seek ways to correct them.

## **CONCLUSION**

Although this is a retrospective study, our evaluation using a subjective method of differentiating the esthetic result suggests a favorable outcome for 2-stage palate repair using the vomer flap. In addition, this audit is extremely relevant in the analysis of the quality of care in our institution, which has more than fifty years of experience in the treatment of cleft patients.

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Fig 1 . Example of cropped images

**Tab 1 . Intra-observer agreement between the first and second rounds. (Cohen kappa)**

Observer (1-3)	Nasal shape	Nose Alignment	Vermilion Border	Profile View
1	0.77	0.69	0.75	0.68
2	0.53	0.53	0.73	0.59
3	0.57	0.55	0.57	0.49

Tab 1. Intra-observer agreement.

**Tab 2. Mean scores per surgeon grouped for each category**

Surgeons (1-9)	n (%)	Nasal shape (SD)	Nose Alignment (SD)	Vermilion Border (SD)	Profile View (SD)	Overall Score (mean)
1	28 (20%)	2,51 (0.89)	2,23 (0.65)	2,44 (1.03)	2,64 (0.95)	2,45
2	21 (15%)	2,59 (1.14)	2,19 (0.68)	2,59 (1.13)	2,59 (1.14)	2,49
3	4 (3%)	2,25 (1.25)	2,25 (0.50)	2,25 (1.89)	2,12 (0.85)	2,22
4	7 (5%)	2,07 (1.01)	2,14 (1.07)	2,7 (1.70)	3 (0.86)	2,48
5	20(14%)	2,6 (0.75)	2,45 (0.58)	2,27 (0.78)	2,47 (0.88)	2,45
6	12 (9%)	2,62 (0.88)	2,29 (0.54)	2,12 (0.74)	2,29 (0.83)	2,33
7	1(1%)	2,00	2,00	2,00	2,50	2,13
8	25 (18%)	2,5 (0.70)	2,36 (0.55)	2,46 (1.10)	2,14 (0.830)	2,36
9	21 (15%)	2,33 (0.78)	2,33 (0.68)	1,95 (0.68)	1,88 (0.8)	2,12
<b>OVERALL</b>	<b>139 (100%)</b>	<b>2,39</b>	<b>2,25</b>	<b>2,31</b>	<b>2,40</b>	<b>2,34</b>

Tab 2. Mean scores per surgeon grouped for each category.

# 5

## **GENERAL CONCLUSIONS**

## **5. GENERAL CONCLUSIONS**

Our overall nasolabial aesthetic results were considered adequate. Fistula formation rates were relatively high, but functional impairment was quite reliable. Thus, demonstrating that 2-stage palatoplasty could be an optional surgical protocol and highlighting the importance of periodically carrying out institutional audits to identify possible weaknesses in adopted protocols and seek ways to correct them and provide the best result to our patients.

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# APPENDIX

## APPENDIX

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

We hereby declare that we are aware of the article **FISTULA RATES AFTER 2-STAGE PALATE REPAIR FOR UNILATERAL CLEFT LIP AND PALATE: AN AUDIT OF 139 CHILDREN** will be included in Thesis of the student Leonardo Bezerra Feitosa was not used and may not be used in other works of Graduate Programs at the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo.

Bauru, 03/08/2022

Leonardo Bezerra Feitosa

Author



Signature

Melissa Zattoni Antoneli

Author



Signature

Terumi Okada Ozawa

Author



Signature

Nivaldo Alonso

Author



Signature

Cristiano Tonello

Author



Signature

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

We hereby declare that we are aware of the article **NASOLABIAL APPEARANCE AFTER 2-STAGE PALATE REPAIR FOR UNILATERAL CLEFT LIP AND PALATE: AN AUDIT OF 139 CHILDREN** will be included in Thesis of the student Leonardo Bezerra Feitosa was not used and may not be used in other works of Graduate Programs at the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo.

Bauru, 03/08/2022

Leonardo Bezerra Feitosa

Author



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Terumi Okada Ozawa

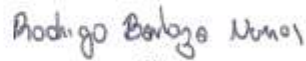
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Rodrigo Barboza Nunes

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Nivaldo Alonso

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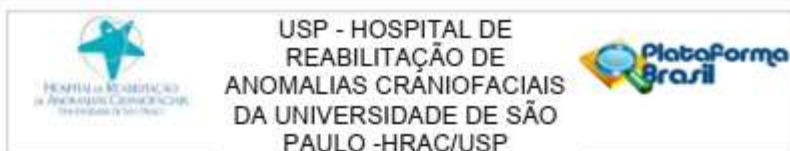
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### PARECER CONSUBSTANCIADO DO CEP

#### DADOS DO PROJETO DE PESQUISA

**Título da Pesquisa:** RESULTADO DE CIRURGIA PRIMÁRIA DE LÁBIO E PALATO EM INDIVÍDUOS COM FISSURA LABIOPALATINA COMPLETA UNILATERAL SUBMETIDOS A DOIS PROTOCOLOS DE TRATAMENTO ; ESTUDO COMPARATIVO

**Pesquisador:** LEONARDO BEZERRA FEITOSA

**Área Temática:**

**Versão:** 2

**CAAE:** 36296620.3.0000.5441

**Instituição Proponente:** Hospital de Reabilitação de Anomalias Craniofaciais da USP

**Patrocinador Principal:** Financiamento Próprio

#### DADOS DO PARECER

**Número do Parecer:** 4.315.890

#### Apresentação do Projeto:

Segunda apresentação de Projeto de Pesquisa para Dissertação. Trata-se de um estudo observacional transversal e retrospectivo, que analisará a aparência nasolabial e o índice de fístulas entre 169 pacientes com fissuras labiopalatinas unilaterais submetidos a dois protocolos cirúrgicos diferentes em um único centro, Hospital de Reabilitação de Anomalias Craniofaciais (HRAC-USP). No "grupo 1", em um único tempo cirúrgico, foi realizado o reparo do lábio pela técnica de Millard, reposicionamento da asa nasal (Skoog) e palatoplastia completa pela técnica de Von Langenbeck entre os 3 a 6 meses de idade. O "grupo 2" foi submetido a correção de lábio pela técnica de Millard, reposicionamento da asa nasal (Skoog) e reparo do palato anterior através de um retalho de vômer (Hans Pichler) entre os 3 a 6 meses, após os 12 meses de idade, correção do palato posterior pela técnica de Von Langenbeck.

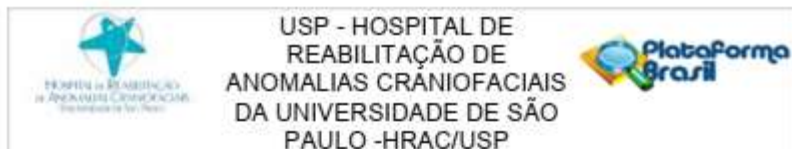
#### Objetivo da Pesquisa:

Segundo os autores:

\*Objetivo geral: Avaliar os resultados da aparência nasolabial e índice de fístula de dois protocolos de tratamento de uma instituição referência no tratamento de FLP.

Objetivos específicos

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Continuação do Parecer: 4.315.890

- Comparar os resultados de aparência nasolabial e perfil facial entre dois protocolos de tratamento de uma Instituição referência no tratamento de FLP.

- Identificar os índices de fistula e seu local de ocorrência entre dois protocolos de tratamento de uma Instituição referência no tratamento de FLP.\*

**Avaliação dos Riscos e Benefícios:**

Segundo os autores:

**\*Riscos:**

A coleta de dados envolve consulta a dados secundários, envolvendo assim, riscos mínimos para o participante. Na coleta, o acesso aos prontuários será limitado a quantidade e qualidade das informações específicas para a pesquisa e a equipe se compromete com a não violação e a manutenção da integridade dos documentos (danos físicos, cópias, rasuras).

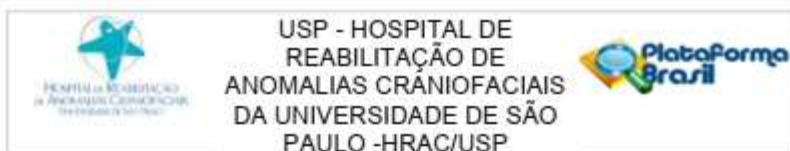
**Benefícios:**

A interpretação dos dados obtidos nos prontuários e a análise do resultado cirúrgico através de fotos do pós-operatório são importantes para o desfecho da pesquisa. A equipe de saúde responsável pelo tratamento será beneficiada ao obter informações que poderão servir de base para criação de novos protocolos institucionais, podendo melhorar a qualidade de vida dos futuros pacientes a partir do resultado da pesquisa.

**Comentários e Considerações sobre a Pesquisa:**

Projeto com mérito. Trata-se de um estudo retrospectivo, transversal, com abordagem descritiva e analítica, comparando aspectos da aparência nasolabial e o índice de fistulas entre dois grupos de indivíduos com fissura transforame incisivo completa submetidos a dois protocolos diferentes de tratamento. Serão avaliadas fotografias digitais da face, padronizadas em visão anterior e perfil, na idade de dentição mista, segundo os critérios de Asher-McDade et al. (1991) e índices de Kujpers-Jagtman e colaboradores (2009). Com base na forma nasal, alinhamento do nariz, borda do vermetão e visão de perfil, haverá a classificação em 5 categorias (escores de 1 a 5). Na execução da análise, 3 cirurgiões craniofaciais/plásticos experientes de um único centro serão escolhidos como examinadores para avaliar as imagens diretamente no monitor do computador. Eles serão orientados previamente com relação aos critérios e, concluído o treinamento, irão proceder com a avaliação. Serão apresentadas fotos digitais com incidência frontal e perfil, exibindo apenas a região nasolabial e cada examinador deverá atribuir uma nota de 1 a 5 para o componente analisado (forma nasal, alinhamento do nariz, borda do vermetão e

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Continuação do Projeto: 4.315.890

visão de perfil) como preconizado pelo método Asher-McCade (1991). O escore 1 representa "aparência muito boa", escore 2 "boa aparência", escore 3 "aparência justa", escore 4 "aparência ruim" e 5 "aparência muito ruim". Após duas semanas, uma nova avaliação será realizada com os mesmos avaliadores, sendo apresentadas as mesmas imagens de forma randômica.

O teste Kappa será utilizado para avaliar a reprodutibilidade Inter e Intra-avaliadores. Os resultados serão baseados nas duas avaliações, sendo calculados a mediana dos 3 avaliadores para cada paciente, escore médio de cada paciente e frequência de cada um dos 5 escores. A partir das informações registradas no prontuário e, quando disponíveis, também por fotos intraorais, será identificado a ocorrência de fistulas oronasais. Quando presentes, serão categorizada com relação ao tamanho estimado (em milímetros), a sua localização pela classificação de Pittsburgh, a presença de sintomas (relacionadas a fala e ingestão alimentar) e a conduta adotada. Após o levantamento desses dados, serão correlacionados a frequência de fistulas e suas características com cada protocolo do estudo.

O projeto havia ficado com pendência devido às inadequações abaixo:

-1- O item DESENHO na plataforma Brasil deverá ser refeito, colocar apenas: estudo retrospectivo, transversal, com abordagem descritiva e analítica. a inadequação foi corrigida. PENDÊNCIA TOTALMENTE ATENDIDA.

- 2- Atualizar na Plataforma Brasil que coleta de dados será realizada após aprovação. Os autores adequaram o cronograma. PENDÊNCIA TOTALMENTE ATENDIDA.

**Considerações sobre os Termos de apresentação obrigatória:**

Carta de encaminhamento;

Formulário HRAC;

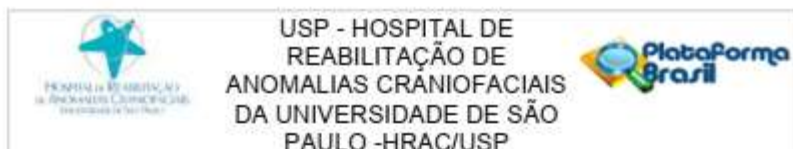
Folha de Rosto da Plataforma Brasil;

Justificativa de Dispensa de TCLE;

Termo de Compromisso, Confidencialidade e Autorização de Utilização de Dados em Projetos de Pesquisa

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

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Termo de Compromisso do Pesquisador Responsável.

**Recomendações:**

O termo de Permissão para uso de Registro para fins científicos deverá ser anexado e devidamente assinado caso os autores pretendam ilustrar o trabalho final

**Conclusões ou Pendências e Lista de Inadequações:**

Como as Inadequações foram corrigidas sugiro a aprovação do projeto.

**Considerações Finais a critério do CEP:**

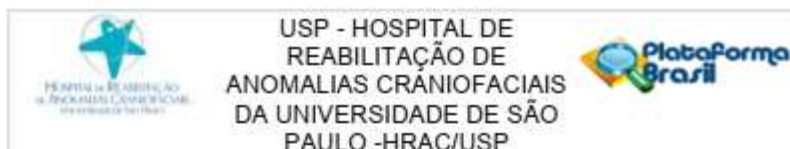
O pesquisador deve atentar que o projeto de pesquisa aprovado por este CEP refere-se ao protocolo submetido para avaliação. Portanto, conforme a Resolução CNS 466/12, o pesquisador é responsável por "desenvolver o projeto conforme delimitado", se caso houver alterações nesse projeto, este CEP deverá 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 Esclarecido(s) e/ou outros Termos obrigatórios assinados pelos participantes da pesquisa deverão ser entregues ao CEP. Os relatórios semestrais devem ser notificados quando solicitados no parecer.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1578825.pdf	18/09/2020 11:48:28		Acelto
Outros	pendencia.doc	18/09/2020 11:45:01	LEONARDO BEZERRA FEITOSA	Acelto
Outros	pendencia.docx	13/09/2020 14:58:19	LEONARDO BEZERRA FEITOSA	Acelto
Outros	DISPENSA_DO_TERMO_DE_CONSENTIMENTO.pdf	05/08/2020 20:05:15	LEONARDO BEZERRA FEITOSA	Acelto
Projeto Detalhado / Brochura Investigador	PROJETO.docx	05/08/2020 20:02:38	LEONARDO BEZERRA FEITOSA	Acelto
Outros	CADASTRO_hrac.docx	02/07/2020 12:29:05	LEONARDO BEZERRA FEITOSA	Acelto
Outros	5_termo_tomar_publico.docx	02/07/2020 12:23:27	LEONARDO BEZERRA FEITOSA	Acelto
Orçamento	ORCAMENTO.docx	02/07/2020 12:17:36	LEONARDO BEZERRA FEITOSA	Acelto

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Solicitação Assinada pelo Pesquisador Responsável	termo_pesquisador.pdf	02/07/2020 12:15:49	LEONARDO BEZERRA FEITOSA	Acelto
Declaração de Pesquisadores	3_termo_de_compromisso.docx	02/07/2020 12:09:38	LEONARDO BEZERRA FEITOSA	Acelto
Folha de Rosto	ROSTO.pdf	02/07/2020 12:06:11	LEONARDO BEZERRA FEITOSA	Acelto

**Situação do Parecer:**

Aprovado

**Necessita Apreciação da CONEP:**

Não

BAURU, 02 de Outubro de 2020

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

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