Journal of Oral Biology and Craniofacial Research 15 (2025) 33–40

Contents lists available at ScienceDirect

Journal of Oral Biology and Craniofacial Research

journal homepage: www.elsevier.com/locate/jobcr

Long-term effects of orthognathic surgery on masticatory function in individuals with cleft lip and palate: A prospective study

Patricia Martins Bueno [a], Paulo Alceu Kiemle Trindade [b], Laís Hollara Medeiros [a], Leide Vilma Fidélis da Silva [a], Ivy Kiemle Trindade-Suedam [c,*]

[a] Postgraduate Program in Rehabilitation Sciences, Laboratory of Physiology, Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo, Bauru, SP, Brazil

[b] Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo, Bauru, SP, Brazil

[c] Department of Biological Sciences, Bauru School of Dentistry and Laboratory of Physiology, Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo, Bauru, SP, Brazil

ARTICLE INFO

Keywords:
Orthognathic surgery
Palatal cleft
Bite force
Stomatognathic system
Masticatory efficiency
Masticatory

ABSTRACT

Objective: To prospectively evaluate the long-term effects of orthognathic surgery on masticatory function in individuals with repaired complete cleft lip and palate and to compare the results with a control group.

Material and methods: A total of 40 individuals were prospectively analyzed before (PRE-ORTHOG) and approximately 12 months after orthognathic surgery (POST-ORTHOG). The participants were divided into two groups: 1) Cleft Lip and Palate Group (CLP): 20 adults with CLP undergoing orthognathic surgery (14 ♂, 6 ♀, age 24 ± 3 years), and 2) Control Group (CON): 20 paired adults with Angle Class I skeletal pattern who had never undergone orthognathic surgery (14 ♂, 6 ♀, age 25 ± 5 years). Three variables were evaluated: 1) Bite Force (BF) (measured in Newtons – N) presented as the average of the bite force from the right and left molars ($\bar{x}$ RM + LM), using a gnathodynamometer (IDDK Kratos), 2) Masticatory Efficiency (ME) (ranging from 0 to 1, with values closer to 1 indicating poorer efficiency), assessed through a dual-color masticatory gum test analyzed visually and optoelectronically (ViewGum©), and 3) Masticatory Capacity (MC): patient-reported ability to chew, rated on a two-point scale (P/R = poor to reasonable, G/O = good to optimal).

Results: In the PRE-ORTHOG phase, the BF for the CLP group ($\bar{x}$ RM + LM = 285 ± 141) was significantly lower compared to the CON group ($\bar{x}$ RM + LM = 524 ± 202). In the POST-ORTHOG phase, the CLP group ($\bar{x}$ RM + LM = 373 ± 129) showed significant improvements in BF in relation to the PRE-ORTHOG phase, with values similar to those of the CON group. Masticatory efficiency improved significantly in the POST-ORTHOG phase (0.222 ± 0.071) compared to PRE-ORTHOG (0.470 ± 0.126) in the CLP group, while PRE-ORTHOG values were worse than those of the CON group (0.148 ± 0.050). Furthermore, 45 % of CLP participants reported P/R MC before surgery, while none reported this after surgery, a statistically significant improvement. The POST-ORTHOG MC results for CLP participants were comparable to the CON group, with 100 % reporting G/O MC after surgery.

Conclusions: Overall, the group with CLP demonstrated impaired masticatory function in the preoperative phase compared to the control group across all variables analyzed. Orthognathic surgery improves masticatory function in patients with CLP, with postoperative parameters comparable to those of the control group.

1. Introduction

Cleft lip and palate (CLP) are among the most prevalent congenital malformations in humans, occurring in approximately one individual per 1000 births.[1] They can involve, individually or concurrently, the upper lip, the alveolar ridge, and the palate. These malformations manifest early, as the face completes its formation by the eighth week of intrauterine life and the palate by the twelfth week.[2,3]

Individuals with CLP face a complex interplay of functional, aesthetic, and psychological challenges from childhood into adulthood that significantly affect their quality of life. Functionally, they may experience difficulties with speech, feeding, and masticatory function due to structural abnormalities. Aesthetically, visible facial deformities can lead to self-consciousness and social stigma. Psychologically, the

* Corresponding author.
E-mail address: ivytrin@usp.br (I.K. Trindade-Suedam).

https://doi.org/10.1016/j.jobcr.2024.11.002
Received 2 October 2024; Received in revised form 29 October 2024; Accepted 8 November 2024
Available online 2 December 2024

emotional burden of living with CLP often results in anxiety and depression, particularly during critical developmental periods. It is crucial to address these interconnected dimensions for effective rehabilitation, as this ensures a holistic approach that fosters both physical health and overall well-being.[2–4]

The rehabilitation of individuals with CLP begins early, with primary surgeries to repair the lip and palate typically occurring around three months of age. However, these procedures can restrict maxillary growth, leading to maxillomandibular discrepancies in adulthood, which affect the performance of the stomatognathic system.[5,6] Understanding the impact of CLP on masticatory function and the long-term effects of procedures such as orthognathic surgery, performed to correct skeletal discrepancies in adulthood, is crucial, and this unique study aims to evaluate them as key elements in the rehabilitation process for CLP patients.[7–9]

When considering masticatory function, it is known that it can be assessed objectively through clinical tests, such as bite force—considered the gold standard—and masticatory efficiency. Subjectively, it can be evaluated through questionnaires that assess masticatory capacity.[10] *Bite force* quantifies the maximum force exerted during dental clenching, reflecting the strength and coordination of the masticatory muscles, which is crucial for effective food processing. *Masticatory efficiency* assesses how well food is processed during chewing, often measured by particle size distribution, which indicates the functional performance of the stomatognathic system in terms of food preparation for swallowing and digestion. *Masticatory capacity*, often evaluated through subjective questionnaires, gauges the individual's perception of their chewing ability and satisfaction with their masticatory function. Together, these variables not only highlight different aspects of masticatory performance but also have significant clinical implications. Understanding these factors can inform treatment planning, rehabilitation strategies, and ultimately improve the quality of life for individuals with CLP, particularly after orthognathic surgery.[11–17]

Therefore, the main objective of this study was to prospectively evaluate the long-term effects of orthognathic surgery on masticatory function in individuals with repaired complete CLP and to compare the results with those from a control group with Angle Class I skeletal patterns. This study specifically focuses on the long-term assessment of masticatory function both before and after orthognathic surgery in individuals with CLP. By connecting the study's findings to potential clinical outcomes, it emphasizes the significance of understanding long-term masticatory function after surgery for effective patient care and treatment strategies.

2. Material and methods

2.1. Participants and sample selection

This prospective study was approved by the Institutional Review Board of the Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo (HRAC/USP), (CAAE: 47813221.3.0000.5441) and was conducted at the HRAC/USP Physiology Laboratory and the HRAC/USP Division of Orthognathic Surgery. All participants were properly informed about the procedures and signed an informed consent form before examinations.

Considering an alpha error of 5 %, a beta error of 20 %, and adopting a mean deviation of 160N and 0.075 VOH (Circular Variance of the Hue), with a significant difference in the pre- and postoperative period of at least 150N and 0.070 VOH,[9,18] referring to bite force and masticatory efficiency respectively, the formal sample calculation estimated a sample size of 20 individuals per period.

Inclusion criteria for the CLP group were: adults over 18 years old with unilateral or bilateral complete cleft lip and palate, indicated for orthognathic surgery, established molar occlusion, and without tooth loss, periodontal disease, or cavities that could negatively affect the examination. Exclusion criteria were: cleft posterior to the incisive foramen, individuals with craniofacial anomalies without cleft lip and palate, presence of pain or discomfort during the examination, and postoperative complications. For the CON, inclusion criteria were: adults over 18 years old, without CLP or any craniofacial anomalies, with normal occlusion and facial pattern type I. Exclusion criteria were: altered occlusion or facial pattern type II or III, and presence of pain or discomfort during the examination. Participants in the CLP group were selected at the HRAC/USP, while those in the CON group were selected from the USP/Bauru campus community, including undergraduate students from the Dentistry and Speech-Language Pathology programs.

The data collection period lasted two years and four months, from August 2021 to December 2023. Out of 41 individuals with complete CLP operated by the same surgeon, who met the inclusion and exclusion criteria, 30 agreed to participate in the study. However, 10 did not return for the POST-ORTHOG evaluation, resulting in a final sample of 20 participants. Regarding the control group, from a total of 360 potential candidates, 30 met the inclusion criteria and agreed to participate in the study. Of these, 20 were selected through matching by sex and age (Fig. 1). The final sample of 40 individuals was divided into two groups as follows: 1) Cleft Lip and Palate Group (CLP): 20 adults with CLP undergoing orthognathic surgery (14 ♂, 6 ♀, age 24 ± 3 years), and 2) Control Group (CON): 20 paired adults with Angle Class I skeletal pattern who had never undergone orthognathic surgery (14 ♂, 6 ♀, age 25 ± 5 years). The participants were analyzed two days prior to orthognathic surgery (PRE-ORTHOG) and approximately 12 months post-surgery (POST-ORTHOG).

Orthognathic surgery was performed by a single surgeon (PAKT), with the same surgical technique. Le Fort I osteotomy was used for maxillary advancement using 2.0 miniplates fixation system on canine and zygomatic buttresses areas, while mandibular setback was performed by bilateral sagittal split osteotomy stabilized with hybrid fixation technique using 2.0 miniplates fixation system. The data collection for bite force (BF), masticatory efficiency (ME), and masticatory capacity (MC) was carried out by the same operator (PMB), a trained dentist responsible for data collection. Prior to data collection, patients were instructed on how to perform the exams and trained before the actual measurements were taken. For the first six months after surgery, patients returned monthly for postoperative follow-up. After six months, follow-up visits were scheduled every two months until one year post-surgery, allowing for close monitoring and ensuring compliance with postoperative care recommendations.

2.2. Bite force assessment

The individuals underwent BF testing using a gnathodynamometer (digital dynamometer model IDDK, Kratos, Cotia, SP, Brazil), with a capacity of approximately 980 N, which is part of the equipment at the Physiology Laboratory of the HRAC/USP. This device consists of a stainless-steel cylinder (10 × 10 mm) containing a load cell that, when deformed, measures the force exerted during dental clenching (Fig. 2). The device, which displays force in Newtons (N), has a "set-zero" button for precise control of obtained values and a "peak" function that facilitates reading the maximum force during measurement.

To measure the maximum molar bite force, the gnathodynamometer was positioned on the first molar regions on the right and left sides of the dental arch, alternately (Fig. 2A and C). For measuring the maximum incisor BF, the device was positioned at the central incisor region (Fig. 2B). Three measurements were taken, and the highest value was used for analysis.[9] The gnathodynamometer is a closed system and can only be calibrated by the manufacturing company, with this process conducted semi-annually. In any case, the operator ensured that the display showed the value 'zero' before each measurement.

2.3. Masticatory efficiency assessment

Masticatory efficiency was assessed using a previously validated

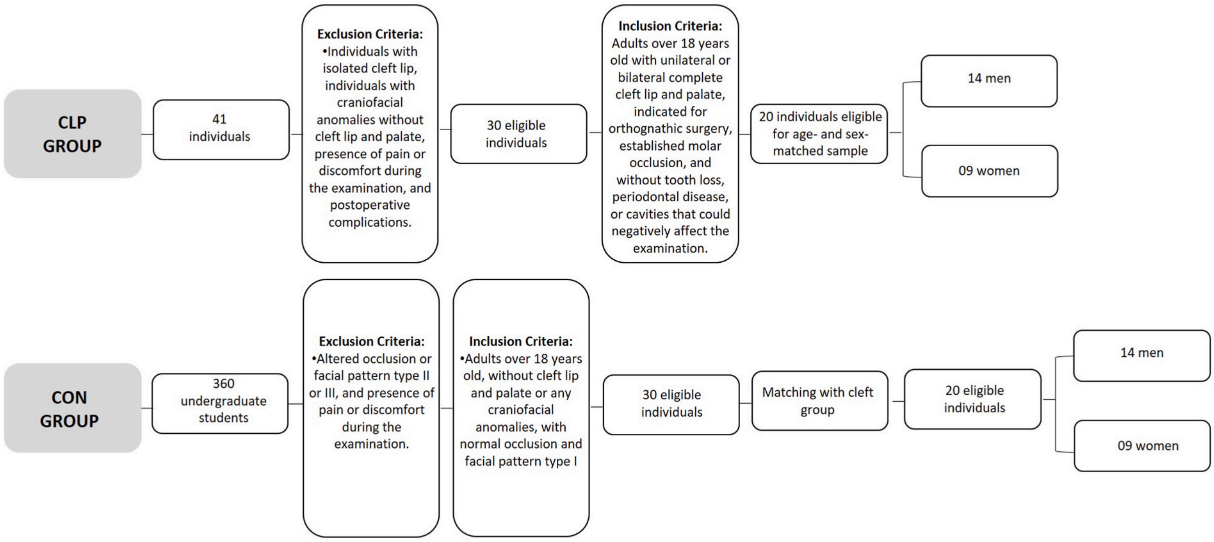

Fig. 1. Flowchart of the study sample selection.

Fig. 2. Positioning of the gnathodynamometer in the regions where bite force was measured. for the CON and CLP group. 2A: left posterior region of the maxilla; 2B: anterior region of the maxilla; 2C: right posterior region of the maxilla; 2D: gnathodynamometer used to perform the measurements (digital dynamometer, IDDK model, Kratos, Bauru, SP, Brazil).

color mixing capacity test, and the test food selected for masticatory performance testing was Vivident Fruitswing gum "Karpuz/Asai Uzumu" (Perfetti van Melle, Turkey)[10,19] This chewing gum is composed of two layers of two colors: green (watermelon flavor) and violet (grape flavor) - with dimensions 43 mm × 12 mm x 3 mm. The criteria for selecting this gum for the study included: two colors; a specimen relatively easy to chew (with an average hardness of 67.4 for the green side and 58.4 for the violet side as measured by a Shore durometer - Shore Scale, 1.11 N)[18]; and no sugar in its composition.[10,19–21]

Each participant was instructed to chew the gum as they would normally do. The operator was responsible for counting 10 masticatory cycles, and upon completion, the participant was asked to discard the gum into a labeled transparent plastic container, where digital analysis was performed. The chewed gum was then compressed into a 1 mm thick sheet using controlled pressing with two glass plates, one serving as the base and the other as the top. At the edges of the bottom plate, a 1 mm thick utility wax strip was placed to standardize the thickness of the gum sheet. Both sides of the sheet were then scanned, and each pair of images was saved as a single composite image of both sides of the gum.

The files were imported into the open-source software ViewGum© (dHAL Software, Greece, www.dhal.com), which performs automatic analysis. The unit of measurement for masticatory performance is called circular variance of hue (VOH), represented in the software as *Ch* 0 St. *Dev*., and can range from 0 to 1. A lower VOH value indicates better mixing of the colors in the gum. Thus, it can be inferred that a higher VOH value corresponds to poorer masticatory performance of the individual (Fig. 3).

2.4. Self-reported masticatory capacity assessment

The methodology used to assess masticatory capacity was based on previous studies in the literature, including Liedberg et al. (1995)[14] and Yurkstas and Manly (1950).[22] All participants agreed to complete a questionnaire as part of the research.

For the assessment of masticatory capacity, patients were interviewed by a single researcher, who explained the questions as needed without influencing the patients' responses. Masticatory capacity was self-assessed by the patients on a two-point scale (P/R = poor to reasonable, G/O = good to optimal).

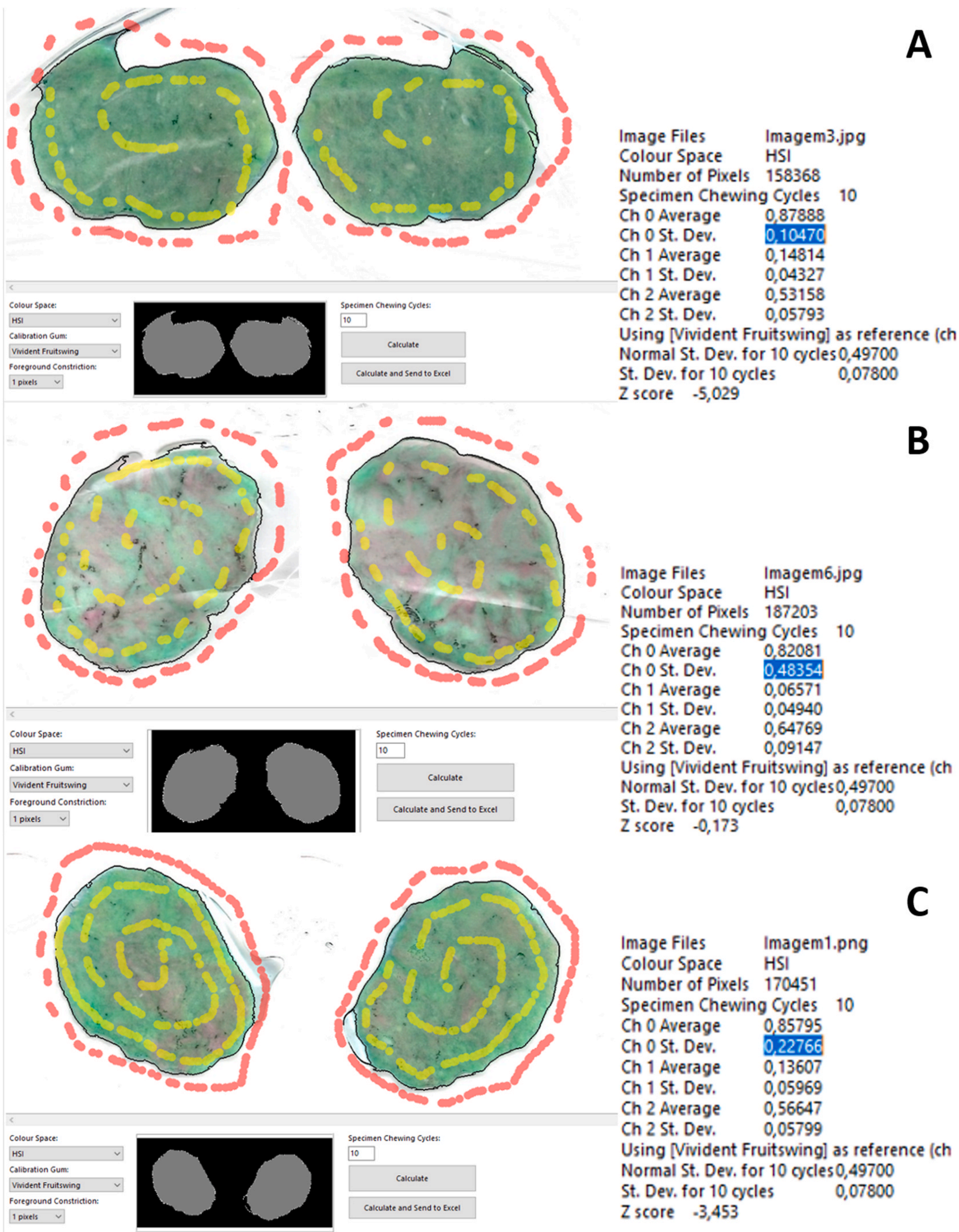

Fig. 3. Images were obtained by scanning both sides of the flattened gum (A-CON; B-PRE- ORTHOG; C-POST-ORTHOG). After drawing mouse trails on the images, where yellow dots represent the foreground and red dots represent the background, the software segmented the gum area, indicated by the black outline in the thumbnail image below the main images.

2.5. Statistical analysis

Measurements were performed by the same operator, and statistical analyses were conducted using SigmaPlot 12.0 software. Values of $p < 0.05$ were considered statistically significant. Given the normal distribution, assessed by the Shapiro-Wilk test, the results are expressed as mean ± standard deviation. The Friedman test was used to compare three or more related groups when normality assumptions were not met. Ordinal quantitative and qualitative comparisons between two independent variables were assessed using the Mann-Whitney test. Intragroup comparisons of pre- and post-treatment and control groups were performed using ANOVA for repeated measures, with subsequent differences assessed using the Tukey test for multiple comparisons.

3. Results

3.1. Demographics

The clinical and demographic data for both groups (CLP and CON) at both analysis periods (PRE-ORTHOG and POST-ORTHOG) are presented in Table 1. No significant differences were found between the groups in terms of age and sex distribution. In the CLP group, a similar distribution of unilateral and bilateral cases was observed. Regarding clinical data, maxillary advancement was performed in 35 % of the cases, while bimaxillary surgery (maxillary advancement + mandibular setback) was performed in the remaining 65 %.

3.2. Bite force

The mean values ($\overline{x}$) and standard deviations (σ) for the CLP and CON groups, for bite BF and ME evaluations during the two analysis periods of CLP (PRE-ORTHOG and POST-ORTHOG) are reported in Table 2 and Figs. 3 and 4. The results of the MC assessment are shown in Fig. 5. The BF in the PRE-ORTHOG phase of the CLP group corresponded to I = 84 ± 52, MD = 281 ± 136, ME = 290 ± 160, $\overline{x}$ MD + ME = 285 ± 141, and in the POST-ORTHOG phase of the CLP group, it corresponded to I = 127 ± 49, MD = 377 ± 134, ME = 368 ± 135, $\overline{x}$ MD + ME = 373 ± 129. In the CON group, the values corresponded to I = 168 ± 30, MD = 520 ± 210, ME = 528 ± 209, $\overline{x}$ MD + ME = 524 ± 202, respectively. Significantly higher values were observed in the POST-ORTHOG phase of the CLP group in all evaluated regions compared to the PRE-ORTHOG phase of the same group, except in the ME region. When comparing BF between the CON group and the PRE-ORTHOG CLP group, significantly lower values were observed in the CLP group. However, when comparing BF between the CON group and the POST-ORTHOG CLP group, statistically similar values were observed.

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

	CON	CLP
	n = 20	PRE/POT n = 20
AGE	23,7 ± 3,4	24,7 ± 4,4
GENDER n(%)		
Male	14 (70)	14 (70)
Female	06 (30)	06 (30)
CLEFT TYPE n(%)		
UCLP	–	12 (60)
BCLP		08 (40)
SURGERY n(%)		
MA	–	07 (35)
MAMS		13 (65)

CON: control group; PRE-ORTHOG: cleft lip and palate preoperative group; POST ORTHOG: CLP postoperative >12 months' group.

3.3. Masticatory efficiency

Statistically significant better results were observed in the POST-ORTHOG phase (0.222 ± 0.071) compared to the PRE-ORTHOG phase (0.470 ± 0.126) in the CLP group. The PRE-ORTHOG results were significantly worse than those of the CON group (0.148 ± 0.050). Although the results were clinically similar, statistical differences were detected between the POST-ORTHOG and CON data.

3.4. Masticatory capacity

Forty five percent of the participants with CLP reported P/R MC in the PRE-ORTHOG phase, and none reported P/R in the POST-ORTHOG phase, a statistically significant difference. Additionally, there was an improvement in the POST-ORTHOG phase, with 100 % reporting G/O compared to the PRE-ORTHOG phase. When comparing the CLP PRE-ORTHOG and POST-ORTHOG groups with the CON group, 55 %, 100 %, and 100 %, respectively, reported G/O, comparisons that were also considered statistically significant.

4. Discussion

The main findings of the present study indicate that the masticatory function of individuals with CLP is impaired compared to control individuals with no CLP. Additionally, the results confirm that orthognathic surgery can restore masticatory function in this population to levels seen in the CON, as all evaluated parameters showed improvements after surgery.

Although primary plastic surgeries have a significant positive impact on both aesthetics and functionality, the scar tissue resulting from these procedures can lead to anterior and posterior crossbite, preventing children with CLP from achieving fully satisfactory masticatory function.[23] On the other hand, there is a lack of information on functional status in adult patients with CLP. Studies conducted at our Lab during and after orthodontic and surgical treatment highlight the need for further research in this area.[4,8,9]

The present study demonstrates that adults with CLP exhibit significantly lower masticatory force compared to sex- and age-matched control individuals preoperatively. These results align with the findings of Bueno et al. (2021),[8] which were also conducted in our laboratory. Their study evaluated BF in individuals with CLP at preoperative, 3-month postoperative, and 6-month postoperative stages, comparing these values with a control group. The study concluded that CLP negatively impacts the stomatognathic system and one of its primary functional parameters, BF. Although BF values increased in the late postoperative period (6 months after surgery), they remained lower compared to the control group and did not reach normal levels.

However, one aspect that was still missing was the status of BF in the *long-term postoperative period*, i.e., 12 months or more, when the patient has fully recovered from the surgical procedure and is expected to clinically perform masticatory function optimally. This was the objective of the present study, to evaluate the impact of surgery in the long-term postoperative period through three parameters: bite force, masticatory efficiency, and self-perceived masticatory quality.

Indeed, the results demonstrated that after 12 months or more postoperative, the BF values were comparable to those of the CON in all assessed regions (molars and incisors). Additionally, it was shown that the BF values in the molars increased by an average of 34 % in the postoperative period compared to preoperative values. These values were statistically significant in the right molar and incisor regions. Although not statistically significant, the BF values in the postoperative period were 27 % higher than the preoperative values in the left molar region.

The increase in BF at 12 months postoperative is documented in several studies, such as Di Palma et al. (2009),[24] which demonstrated that the balance of the masticatory muscles begins to stabilize

Table 2
Mean values and standard deviation of masticatory efficiency, expressed in VOH (Variance of Hue) and bite force, expressed in N (Newton) from the CON, CLP preoperative group (PRE-ORTHOG); CLP postoperative >12 months' group (POST-ORTHOG).

		GROUPS			P VALUE		
		CONTROL	CLEFT PRE-ORTHOG	CLEFT POST-ORTHOG	CON vs CLP PRE-ORTHOG	CON vs CLP POST-ORTHOG	PRE-ORTHOG vs POST-ORTHOG
BITE FORCE (N)	RIGHT MOLAR ($\underline{x} \pm \sigma$)	520,1 ± 210,0[a]	280,5 ± 135,8[a,b]	376,9 ± 133,7[b]	p=<0,001	p = 0,415	p = 0,004
	LEFT MOLAR ($\underline{x} \pm \sigma$)	527,8 ± 208,7[c]	289,9 ± 159,9[c]	368,2 ± 135,3	p=<0,001	p = 0,191	p = 0,069
	INCISOR ($\underline{x} \pm \sigma$)	168,3 ± 30,2[d]	84,1 ± 51,6[d,e]	126,6 ± 49,2[e]	p = 0,003	p = 0,883	p = 0,012
	RIGHT + LEFT MOLAR ($\underline{x} \pm \sigma$)	523,95 ± 202,05[f]	285,23 ± 140,88[f,g]	372,56 ± 128,50[g]	p=<0,001	p = 0,271	p = 0,002
MASTICATORY EFFICIENCY (VOH)	($\underline{x} \pm \sigma$)	0,148 ± 0,050[h,i]	0,470 ± 0,126[h,i]	0,222 ± 0,071[i,h]	p=<0,001	p=<0,001	p = 0,037

[a-i] means statistical difference of bite force and masticatory efficiency groups (p<0,05).

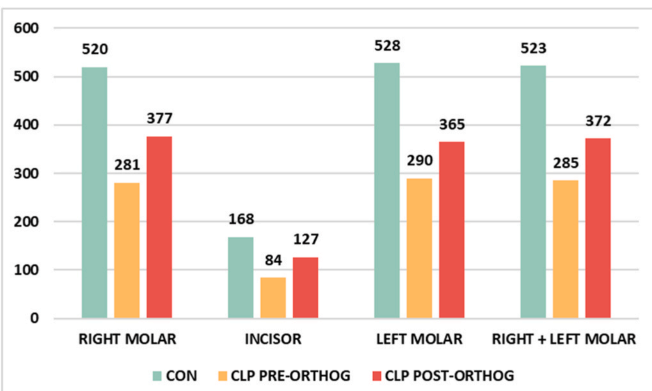

Fig. 4. Mean values of bite force, expressed in Newton, from the control group (CON), CLP preoperative group (PRE-ORTHOG) and CLP postoperative >12 months group (POST-ORTHOG).

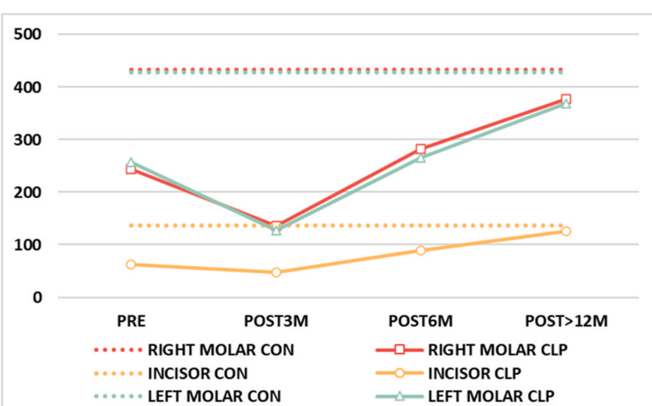

Fig. 5. Comparison of BF between the study by Bueno et al. (2021), which includes mean values from PRE, POST3M, and POST6M, and the data collected in the present sample (POST-ORTHOG). Although the samples are not the same, both studies follow the same inclusion and exclusion criteria, use the same surgical technique, are conducted by the same surgeon, and apply the same methodology, equipment, and operator.

approximately 8 months after orthognathic surgery in patients with no craniofacial anomalies. It is considered that the surgical treatment induced occlusal improvements and, consequently, enhanced neuromuscular balance. Research on short-term recovery after orthognathic surgery has revealed that discomfort, pain, or use of medications may persist in some patients for 2–3 weeks post-surgery, and impaired oral function may take 6–8 weeks to normalize.[25] In our studies (BUENO et al., 2021 and the current one),[9] it was demonstrated that this recovery period is longer, as around 6 months postoperative, the BF values still did not compare to those of the control group, which occurred only in the 12-month postoperative period.

Indeed, a difference in BF between the CLP and control groups is expected, as this anomaly segments the maxilla into 2 or 3 parts, often leading to a skeletal Class III facial pattern. All patients in this study had Class III dentofacial deformity, characterized by maxillary deficiency and/or mandibular prognathism, with the mandible positioned more anteriorly relative to the maxilla. Several studies suggest that skeletal relationship affects masticatory performance in various ways, although all these studies assessed BF in individuals with no craniofacial anomalies. In these studies, individuals with Class I malocclusion, like our control group, exhibit the best masticatory performance, followed by those with Class II and III malocclusions.[26] Trawitzki et al. (2011)[27] compared BF in individuals with Class II and III dentofacial deformities to a control group. They found that, although there was no significant difference in BF between the different deformity patterns (Class II and Class III), the BF values in both groups were lower than those of the control group. As a suggestion for improving the present study, the inclusion of a Class III control group without CLP could allow for a more effective evaluation of the specific effect of CLP on BF.

Another important parameter for evaluating masticatory function is food comminution efficiency. Masticatory efficiency, or the performance in food comminution, emerges as a crucial indicator of the integrated and harmonious functioning of the stomatognathic system. Traditionally, sieves were frequently used for granulometric analysis.[11,12] In the present study, masticatory efficiency was assessed using an innovative and previously validated color mixing test,[10,19] where two-color chewing gum was analyzed optoelectronically (ViewGum©, Dhal Software, Greece) through hue circular variance.

A relevant factor to consider is that the color mixing ability test appears to be more suitable for individuals with compromised oral function, such as those with CLP, compared to the sieve method. Certainly, it is clinically more effective and biosafe. As observed by Speksnijder et al. (2009),[28] this is due to the fact that the BF required to fragment food in the sieve method is higher than what is typically exhibited by these individuals.[29] Therefore, the color mixing ability test is more appropriate as it takes into account the functional limitations of these patients. Another relevant point is that data collection of the present study was performed in 2021, during the COVID-19 pandemic, which led us to seek a method that offered the highest possible safety for both patients and the operator. In this context, the evaluation of ME using chewing gum was chosen as the preferred method, as it minimized contact with patients' saliva, thereby reducing the risk of virus transmission. According to our current knowledge, this study represents the first instance of employing straightforward and freely accessible methods (open-access software) to evaluate masticatory efficiency in individuals with CLP, both pre- and post-orthognathic surgery.

Our study demonstrated that individuals with CLP exhibit compromised masticatory efficiency compared to individuals without craniofacial anomalies. Although there was 53 % improvement 12 months postoperatively, these values still did not reach the levels observed in the control group. In other words, although orthognathic surgery significantly improved masticatory efficiency in the CLP group, with better results in the POST-ORTHOG phase, some differences remained when compared to the control group (CON). While surgery improved function, the CLP group did not fully match the efficiency of individuals with normal skeletal patterns, likely due to residual anatomical or functional limitations. Further research is needed to address these discrepancies. Anyway, although the sample size reached the number suggested by the sample size calculation, we believe that a larger sample would likely have revealed statistically significant differences.

Few studies have compared masticatory efficiency among different types of dentoskeletal deformities, and we did not find research that analyzes this in individuals with CLP both pre- and post-orthognathic surgery. Articles from the 1970s and 1990s[30,31] reported improvements in masticatory efficiency and BF in patients with dentofacial deformities treated with orthognathic surgery. In contrast, Braber et al. (2002)[32] observed that orthognathic surgery had no significant impact on masticatory efficiency or maximum bite force. In a more recent study conducted in the Brazilian population,[33] researchers used a colorimetric method with spheres to assess masticatory efficiency in individuals with dentofacial deformities who were candidates for orthognathic surgery. The results were compared to a control group composed of individuals without alterations in facial morphology, dental occlusion, or signs of temporomandibular dysfunction. The study concluded that the presence of dentofacial deformities, whether Class II or Class III, compromises masticatory efficiency compared to the control group, highlighting that masticatory efficiency is impaired regardless of the type of deformity.

Finally, almost half of the patients with CLP had masticatory complaints before orthognathic surgery, whereas, after one year of orthognathic surgery, these complaints were no longer present. Complaints were also not observed in the non-cleft population. The main complaints were related to the use of orthodontic appliances, which made it difficult to chew certain foods, and to the negative horizontal overlap (Angle Class III patients), which also impeded proper food biting.

The main key strength of our study is the long-term outcomes (12 months post-surgery), as many studies focus only on short-term effects. The rigorous sample selection criteria, the matched sample, the restricting the age range to adults between 19 and 35 years helps control variables related to developmental and aging factors, ensuring participants are at a similar stage of dentofacial development also constitute strengths of this study. Additionally, having all surgeries performed by a single surgeon, using the same surgical technique and all evaluations conducted by a single operator minimizes variability in procedures and measurements.

Points for improvement in the study include the relatively small sample size, which, although within the range suggested by the sample size calculation, poses certain limitations on the findings. The pandemic hindered participant recruitment and consistent follow-up with surgical patients, potentially affecting the generalizability of the results. Future research should aim to enhance participant enrollment and follow-up protocols to provide a more comprehensive understanding of the effects studied.

The study highlights those individuals with CLP experience significant masticatory impairments before undergoing orthognathic surgery, compared to those without craniofacial anomalies. This disparity underscores the extent to which craniofacial conditions can affect masticatory function. Following orthognathic surgery, there were notable improvements in masticatory function for the CLP group, CLPbringing their postoperative performance similar or closer to that of the control group. While the surgery significantly enhances masticatory efficiency, it may not entirely equalize function with individuals who have no craniofacial conditions, indicating that some differences persist.

Overall, the improvement in masticatory parameters, particularly bite force, is crucial for enhancing the quality of life in individuals with CLP. Improved bite force not only signifies better masticatory function, facilitating effective chewing and better nutrition, but it also positively impacts oral motor skills. In the long term, these enhancements improve oral and general health, thereby minimizing the need for further dental and medical interventions.

5. Conclusion

This study confirms significant functional differences in mastication between individuals with CLP and those without craniofacial anomalies who have undergone orthognathic surgery. The results suggest that the surgical procedure can enhance masticatory efficiency in adult patients with CLP by restoring occlusion, temporomandibular joint function, and the associated muscles. However, despite these improvements, significant differences remain compared to the control group, particularly regarding masticatory efficiency.

Sources of funding

This study was funded by the CAPES (Coordination for the Improvement of Higher Education), Brasil (Protocol number 47813221.3.0000.5441). This is a federal funding agency for scientific research purposes and it does not imply any conflicts of interest.

Financial support

Fundação CAPES (Coordination for the improvement of Higher Education Personnel).

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

This study was funded by the CAPES (Coordination for the Improvement of Higher Education), Brasil (Protocol number 47813221.3.0000.5441). This is a federal funding agency for scientific research purposes and it does not imply any conflicts of interest.

References

1. Fernandez N, Escobar R, Zarante I. Craniofacial anomalies associated with hypospadias. Description of a hospital based population in South America. *Int Braz J Urol.* 2016;42(4):793–797.
2. Trindade I. *Tratado de Fissuras Labiopalatinas - Avanços no Diagnóstico e Tratamento Interdisciplinar*. 1. ed. São Paulo: Revinter; 2024:550.
3. Freitas JA, Garib DG, Trindade-Suedam IK, et al. 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. *J Appl Oral Sci.* 2012;20(6):673–679.
4. Sipert CR, Sampaio AC, Trindade IE, Trindade Jr AS. Bite force evaluation in subjects with cleft lip and palate. *J Appl Oral Sci.* 2009;17(2):136–139.
5. Ross RB. Treatment variables affecting facial growth in complete unilateral cleft lip and palate. *Cleft Palate J.* 1987;24(1):5–77.
6. Tate GS, Throckmorton GS, Ellis E 3rd, Sinn DP, Blackwood DJ. Estimated masticatory forces in patients before orthognathic surgery. *J Oral Maxillofac Surg.* 1994;52(2):130–137.
7. Throckmorton GS, Buschang PH, Ellis E 3rd. Improvement of maximum occlusal forces after orthognathic surgery. *J Oral Maxillofac Surg.* 1996;54(9):1080–1086.
8. Garcia MA, Rios D, Honório HM, Trindade-Suedam IK. Bite force of children with repaired unilateral and bilateral cleft lip and palate. *Arch Oral Biol.* 2016;68:83–87.

9. Bueno PM, Kiemle Trindade PA, Medeiros LH, et al. Bite force assessment before and after orthognathic surgery in individuals with repaired cleft lip and palate. *J Oral Biol Craniofac Res*. 2021;11(2):138–142.
10. Schimmel M, Christou P, Herrmann F, Müller F. A two-colour chewing gum test for masticatory efficiency: development of different assessment methods. *J Oral Rehabil*. 2007;34(9):671–678.
11. Bates JF, Stafford GD, Harrison A. Masticatory function - a review of the literature. III. Masticatory performance and efficiency. *J Oral Rehabil*. 1976;3(1):57–67.
12. Olthoff LW, van der Bilt A, Bosman F, Kleizen HH. Distribution of particle sizes in food comminuted by human mastication. *Arch Oral Biol*. 1984;29(11):899–903.
13. Liedberg B, Owall B. Oral bolus kneading and shaping measured with chewing gum. *Dysphagia*. 1995;10(2):101–106.
14. Liedberg B, Ekberg O, Owall B. Chewing and the dimension of the pharyngoesophageal segment. *Dysphagia*. 1991;6(4):214–218.
15. Asakawa A, Fueki K, Ohyama T. Detection of improvement in the masticatory function from old to new removable partial dentures using mixing ability test. *J Oral Rehabil*. 2005;32(9):629–634.
16. Sato S, Fueki K, Sato H, et al. Validity and reliability of a newly developed method for evaluating masticatory function using discriminant analysis. *J Oral Rehabil*. 2003;30(2):146–151.
17. Hayakawa I, Watanabe I, Hirano S, Nagao M, Seki T. A simple method for evaluating masticatory performance using a color-changeable chewing gum. *Int J Prosthodont (IJP)*. 1998;11(2):173–176.
18. Silva LC, Nogueira TE, Rios LF, Schimmel M, Leles CR. Reliability of a two-colour chewing gum test to assess masticatory performance in complete denture wearers. *J Oral Rehabil*. 2018;45(4):301–307.
19. Schimmel M, Christou P, Miyazaki H, Halazonetis D, Herrmann FR, Müller F. A novel colourimetric technique to assess chewing function using two-coloured specimens: validation and application. *J Dent*. 2015;43(8):955–964.
20. Halazonetis DJ, Schimmel M, Antonarakis GS, Christou P. Novel software for quantitative evaluation and graphical representation of masticatory efficiency. *J Oral Rehabil*. 2013;40(5):329–335.
21. Molenaar WN, Gezelle Meerburg PJ, Luraschi J, et al. The effect of food bolus location on jaw movement smoothness and masticatory efficiency. *J Oral Rehabil*. 2012;39(9):639–647.
22. Yurkstas A, Manly RS. Value of different test foods in estimating masticatory ability. *J Appl Physiol*. 1950;3(1):45–53.
23. Montes ABM, de Oliveira TM, Gavião MBD, de Souza Barbosa T. Occlusal, chewing, and tasting characteristics associated with orofacial dysfunctions in children with unilateral cleft lip and palate: a case-control study. *Clin Oral Invest*. 2018;22(2): 941–950.
24. Di Palma E, Gasparini G, Pelo S, Tartaglia GM, Chimenti C. Activities of masticatory muscles in patients after orthognathic surgery. *J Cranio-Maxillo-Fac Surg*. 2009;37 (7):417–420.
25. Phillips C, Blakey G 3rd, Jaskolka M. Recovery after orthognathic surgery: short-term health-related quality of life outcomes. *J Oral Maxillofac Surg*. 2008;66(10): 2110–2115.
26. Abu Alhaija ES, Al Zo'ubi IA, Al Rousan ME, Hammad MM. Maximum occlusal bite forces in Jordanian individuals with different dentofacial vertical skeletal patterns. *Eur J Orthod*. 2010;32(1):71–77.
27. Trawitzki LV, Silva JB, Regalo SC, Mello-Filho FV. Effect of class II and class III dentofacial deformities under orthodontic treatment on maximal isometric bite force. *Arch Oral Biol*. 2011;56(10):972–976.
28. Speksnijder CM, Abbink JH, van der Glas HW, Janssen NG, van der Bilt A. Mixing ability test compared with a comminution test in persons with normal and compromised masticatory performance. *Eur J Oral Sci*. 2009;117(5):580–586.
29. van Kampen FM, van der Bilt A, Cune MS, Fontijn-Tekamp FA, Bosman F. Masticatory function with implant-supported overdentures. *J Dent Res*. 2004;83(9): 708–711.
30. Astrand P. Chewing efficiency before and after surgical correction of developmental deformities of the jaws. *Svensk Tandlakare Tidskrift*. 1974;67(3):135–145.
31. Shiratsuchi Y, Kouno K, Tashiro H. Evaluation of masticatory function following orthognathic surgical correction of mandibular prognathism. *J Cranio-Maxillo-Fac Surg*. 1991;19(7):299–303.
32. van den Braber W, van der Glas HW, van der Bilt A, Bosman F. The influence of orthodontics on selection and breakage underlying food comminution in pre-orthognathic surgery patients. *Int J Oral Maxillofac Surg*. 2002;31(6):592–597.
33. Picinato-Pirola MN, Mestriner Jr W, Freitas O, Mello-Filho FV, Trawitzki LV. Masticatory efficiency in class II and class III dentofacial deformities. *Int J Oral Maxillofac Surg*. 2012;41(7):830–834.