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EFFECT OF OSTEOTOMY OF THE PTERYGOID PROCESS ON MAXILLARY DISJUNCTION: A DOUBLE-BLIND, RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Surgical maxillary expansion is indicated for the treatment of transverse facial deformities of the upper arch. The aim of this study was to evaluate the effect of osteotomy of pterygoid processes on the posterior gain of atrophic maxilla of individuals with bilateral transverse deficiency, from adouble-blind parallel-arm randomized controlled trial, of a convenience sample. Distances between the two medial and lateralpterygoid plates, and the inclinations of the lateral pterygoid plates, were analyzed using computed tomography in the preoperative period and at 30 days post-expander device (maximum maxillary expansion). The increases in the distance between the two medial pterygoid plates linear measurements were significantly greater in Group 2 than in Group 1, as well as those of distance between the two lateral pterygoid plates. The posterior gain in both groups confirmed the efficiency of maxillary expansion surgery without or with osteotomy of the pterygoid processes. The mean posterior amplitude was approximately twice that observed in Group 2, compared to Group 1. The osteotomy of the pterygoid process resulted in greater posterior gain in maxillary expansion surgeries.

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INTRODUCTION

Maxillary atresia is a dentofacial deformity characterized by a discrepancy in the width of the maxilla in relation to the mandible. This condition results in bilateral or unilateral posterior crossbite, narrowing of the upper arch, ogival palate and/or narrowing of the pyriform aperture potentially associated with difficulty in nasal breathing (Alves, 2020 and Bays, 1992). During the growth phase, discrete transversal deficiencies can be treated with functional orthopedics of the jaws, without adjuvant surgical treatment. However, in cases of transverse deficiencies greater than five millimeters or after joining the intermaxillary suture, surgical intervention is indicated to release maxillary bone interferences (Bays, 1992 Bell, 1976 and Betts, 1995).

The posterior maxilla has a complex anatomy due to the relationship with the internal maxillary artery, the pterygopalatine ganglion and the sphenoid bone through the pterygoid plates in the pterygomaxillary region. Therefore, osteotomy of the posterior region should be performed with caution following the principles of the operative technique, since it is not possible to directly view the osteotomized area (Betts, 1995; Byloff, 2004 and Capelozza Filho, 1997). There is no consensus on which surgical technique is most effective for maxillary disjunction. In this sense, the need or not to perform osteotomy of the pterygoid processes is an important point to be investigated. Therefore, the aim of this study was to evaluate the effect of osteotomy of the pterygoid processes

on surgical maxillary expansion, based on the final bone position assessed by means of computed tomography.

MATERIALS AND METHODS

This is a double-blind, parallel-arm randomizedcontrolledtrial of a convenience sample. The research was approved by the ethics committee of the University of Pernambuco – UPE: CAAE protocol0118.0.097.000-10. The ethical precepts described in Resolution 466/2012 of the National Health Council and complementary legislation of the National Research Ethics Committee were followed _ all research participants agreed to participate in the study and signed the Free and Informed Consent Form. The research instituted in temporal conditions, was carried out in the metropolitan region of the city of Recife-PE, obtained from the spontaneous or referenced demand of the Service of Buccomaxillofacial Surgery of the Faculty of Dentistry of Pernambuco (FOP/UPE), of Hospital da Face attached to Hospital Geral de Areias, and Hospital Getúlio Vargas _ units of the Sistema Único de Saúde (SUS). This paper is in accordance with the Consolidated Standards of Reporting Trials (Moher et al., 2012).

Research participants: Twenty patients undergoing surgical maxillary expansion were randomly allocated to two study groups: Group 1, 10 patients operated without osteotomy of the pterygoid processes (control group), and; Group 2, 10 patients operated with osteotomy of the pterygoid processes. The random allocation of research subjects to study groups was due to block randomization. There were included patients with absolute transverse bilateral maxilla deficiency > 7 mm, young adults who completed skeletal growth, patients without systemic changes that contraindicate the surgical procedure and patients who did not have malformations in the middle third of the face.Patients who had unilateral transverse maxillary deficiency, had already undergone previous maxillary surgery, or had any intraoperative complications that would compromise the condition of the allocated study group, were excluded.

Assessment of gain in posterior maxilla: The maxillary bone dimensions were assessed by means of computed tomography in the periods: T_0, preoperative evaluation; and, T_1, 30 days of treatment with an expander device (maximum maxillary expansion); the exams, data collection and analysis were performed by a single professional, specialist in oral radiology, who was not informed about the surgical technique employed. Axial sections were collected in order to visualize the posterior region of the maxilla and the pterygoid processes. Tomographic analysis also established the transversal width at the level of the pterygoid process: DTSB, distance in millimeters (mm) between the two side plates (right and left),and DTMB, distance in millimeters (mm) between the two medial plates (right and left) of the pterygoid processes.The inclinations of the lateral plates (ILB) were evaluated from the angle formed between the right and left lateral plates. The differences between the linear distances between the lateral plates on each side and the medial plates on each side measured at times T_0 and T_1 were performed using ruler tools from the InVersalius® 3.0 program (Figure 1), also used to highlight and analyze the angles formed by the inclinations of the lateral plates of the pterygoid processes (right and left) at times T_0 and T_1.

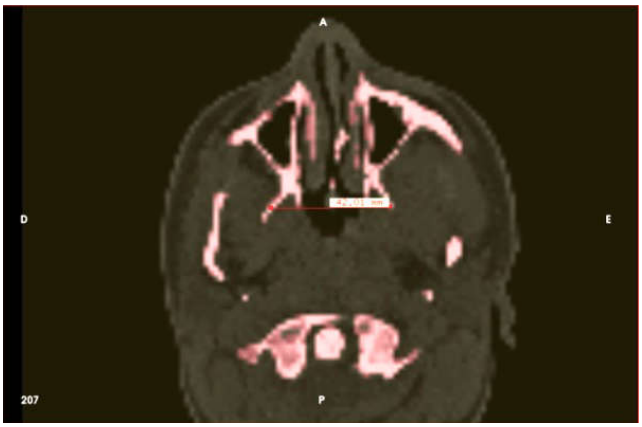


Figure 1. Measurement of the linear distance between the pterygoid plates on the right and left sides (axial computed tomography section)

Surgical technique: All participants were submitted to the same surgical protocol, attended by the same team in a hospital environment. The surgical technique employed was devised by Bays and Grego (1992).[2] General anesthesia, nasotracheal intubation and complementary anesthesia using the infiltrative technique with 2 % lidocaine with vasoconstrictor in the buccal region of the upper teeth were performed. Surgical access was conducted from an electric scalpel incision in the region of the maxillary vestibule, approximately 3 to 5 mm from the mucogingival junction, extending from the distal region of the canines to the mesial of the first molars, bilaterally. Mucoperiosteal detachment allowed access to the entire length of the maxillary anterior and lateral walls, from the pyriform aperture to the zygomatic-maxillary pillar. Osteotomy was performed with a surgical burr 702 (Komet® USA, Rock Hill-SC, USA) from the pyriform aperture to the region of the zygomatic-maxillary pillar.

A second surgical approach was performed through a vertical incision around the insertion of the upper labial frenulum for exposing the anterior region of the medial palatal suture and the anterior nasal spine. Initially, a surgical burr 701 (Komet® USA, Rock Hill-SC, USA) was used in the intermaxillary suture region, followed by straight chisels (Quinelato®, SchobellInsdustrial Ltda., Rio Claro-SP, Brazil) in the anterior region posterior and up-down direction to finish the osteotomy.The osteotomy of the pterygoid processes was performed with appropriate curved chisels, separating the pterygoid plates from the sphenoid bone of the posterior region of the maxilla, in Group 2.After osteotomies, the Hyrax expander was activated until clinical signs such as a diastema between the incisors and ischemia of the incisive papillae were visible, indicating the expansion limit. Before activating the device (closed until 1 mm of activation remains), the osteotomy was checked to confirm the bilateral maxilla expansion, and the soft tissues were sutured with Caprofyl® 4-0 (Ethicon©, Inc., Johnson & Johnson©, New Jersey, USA).The surgical cavity was abundantly irrigated with 0.9 % saline (Eurofarma, São Paulo-SP, Brazil). After the surgical procedure, the patient remained at rest in the ward receiving post-operative drugs and local cryotherapy; The postoperative drug prescription consisted of amoxicillin 500 mg(Amoxil®, GlaxoSmithKline Brazil Ltda., Rio de Janeiro-RJ, Brazil) t.i.d., P.O., for five days, nimesulide 100 mg (Eurofarma, São Paulo-SP, Brazil)b.i.d., P.O., for three days,andparacetamol 750mg (Tylenol®, Johnson & Johnson© do BrasilIndústria e

Comércio de Produtos para Saúde Ltda., São Paulo-SP, Brazil) q.i.d., P.O., for two days or in case of pain or fever above 37º C. On the seventh postoperative day, patients were reevaluated and activation of the expander started, maintained with two daily activations (one in the morning and one at night). Reaching the desired expansion, the Hyrax expander was locked by the orthodontist and kept in restraint for about 6 months.

Data analysis

The descriptive results were presented in textual form, in tables and figures; descriptive statistics: mean (standard deviation). Intergroup comparisons (Group 1 vs Group 2) were evaluated using the Mann-Whitney statistical test, and the intra-group paired analyzes were performed using the Wilcoxon test (non-parametric tests). The level of statistical significance was established in a type I error of 5 % ($p< 0,05$).

Of the 20 survey participants, 12 (60%) were men and 8 (40%) women. All operated patients were adolescents and young adults, mean age 26.7 years old (range, 16 to 44 years). Regarding the facial pattern, seven patients had a dolichofacial profile with a tendency to vertical growth, 10 had a mesocephalic pattern and three were bradycardic.Nine patients had Angle's class II malocclusion and 11 patients had Angle's class III malocclusion. Bilateral crossbite was observed in all participants and the ogival palate was present in nine of them. Both changes are the most common intraoral clinical findings of maxillary atresia. During surgical approaches and osteotomies, there were no complications or unwanted events. Osteotomies favored maxillary expansion with posterior gain and in the anterior region of the maxilla, clinically confirmed by the presence of diastemas between the upper central incisors (Figure 3).The surgical technique employed allows the maximum preservation of the vascular supply of the maxillary bones, periodontal and dental structures.

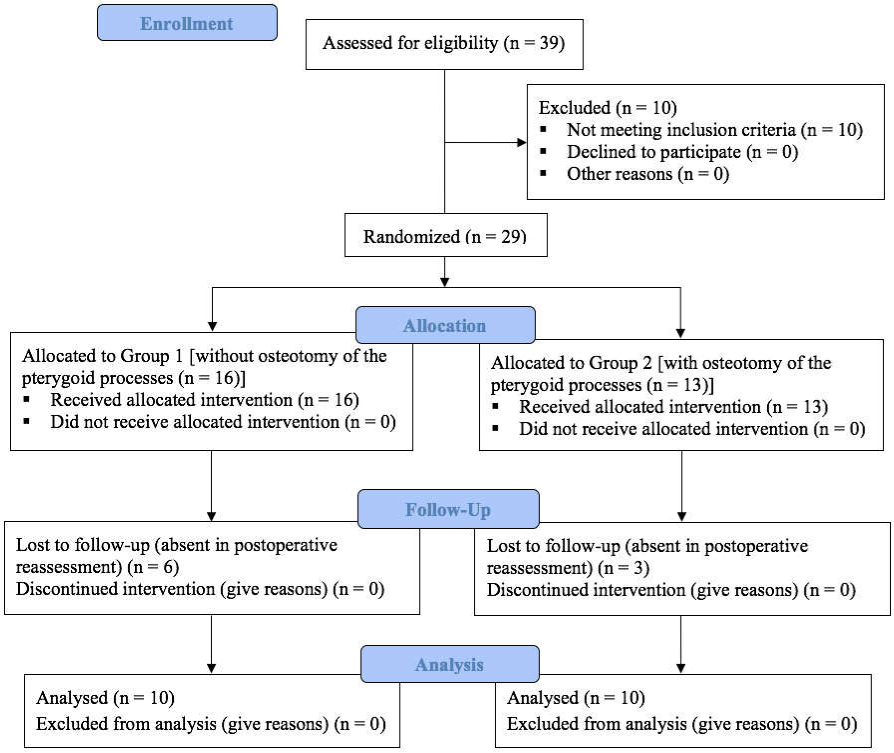
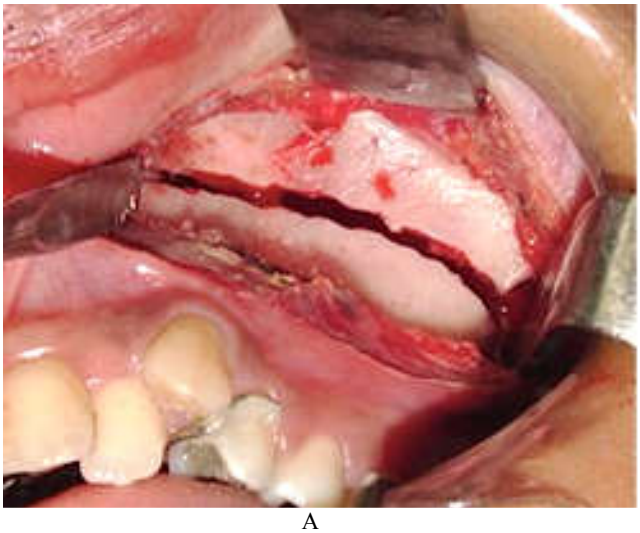


Figure 2. CONSORT flow diagram of participants through each stage (Moher *et al*., 2012)

RESULTS

In total, 39 patients were evaluated, of which 29 met the research eligibility criteria and were included. Nine follow-up losses occurred due to the absence of participants in the postoperative reassessment, being more frequent in Group 1 (control) than in Group 2 (test) (Figure 2).The random sequence generation was performed using a computer random number generator (software Random, available at https://www.random.org/). Participants and investigators enrolling participants could not foresee the intervention because sequentially numbered, opaque, sealed envelopes were used to conceal allocation. The randomization and random allocation of participants were conducted by the researcher N.S.R., and the participants and the researcher responsible for data collection and analysis (V.B.S.P.) were blinded.

The increase in linear measurements performed between the left and right lateral plate and the medial plate (left and right) was greater in Group 2, comparing T_1 with T_0 ($T_1 - T_0$), compared to Group 1 (Table 1). Regarding the DTMB, Group 1 varied from 0 to 3 mm [3.2 (0.298)], while in Group 2 the observed variation was from 1 to 7 mm [3.1 (0.290)] (p, 0.008).The linear measurements of the DTSB increased from 1 to 6 mm [0.2 (0.171)] and 2 to 10 mm [0.5 (0.274)] in groups 1 and 2, respectively (p, 0.021).There was a greater gain in the posterior region when the osteotomy of the pterygoid process was performed. The mean posterior amplitude (ILB) was approximately twice that seen in Group 2, compared to Group 1. Although this result is expressive, the difference between the groups was not statistically significant (p, 0.058). There was an increase in ILB of 4.9 (3,143) degrees and 9.4 (4,695) degrees in groups 1 and 2, respectively (Table 1).



A

B

Figure 3. Intraoperative photographs of the performed osteotomies. A, osteotomy from the pyriform aperture to the region of the zygomatic-maxillary pillar; and, B, osteotomy in the region of the intermaxillary suture

Table 1. Descriptive data and intergroup comparison based on imaging exams

	Group 1	Group 2	
Variables	Mean(SD)	Mean(DP)	*p*-valor
DTMB, T_0	3.1 (0.318)	2.7 (0.278)	0.008
DTMB, T_1	3.2 (0.298)	3.1 (0.290)	0.224
DTMB, $T_1 - T_0$	0.1 (0.100)	0.4 (0.212)	0.008
DTSB, T_0	5.1 (0.391)	4.8 (0.510)	0.206
DTSB, T_1	5.4 (0.346)	5.2 (0.524)	0.383
DTSB, $T_1 - T_0$	0.2 (0.171)	0.5 (0.274)	0.021
ILB, T_0	57.4 (9.594)	52.2 (16.137)	0.307
ILB, T_1	62.5 (9.192)	61.8 (17.184)	0.970
ILB, $T_0 - T_1$	4.9 (3.143)	9.4 (4.695)	0.058

Legend: SD, standard deviation; *p*-value, level of statistical significance. Quantitative data presented in the form of descriptive statistics [mean (standard deviation)] and intergroup comparisons using the Mann-Whitney statistical test.

The estimate of the sample size from the gain differences (DTMB, $T_1 - T_0$; DTSB, $T_1 - T_0$; and, ILB, $T_1 - T_0$) between groups 1 and 2, evaluated by the formula $n = \frac{2\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 \sigma^2}{d^2}$, suggested a number of 8, 16 and 14 patients for each of the three parameters, respectively.

Both surgical techniques demonstrated statistically significant effects of posterior gain when comparing the T_0 and T_1 measurements (Table 2).

Table 2. Statistical differences between the variables measured at T_0 and T_1

		T_0	T_1	
	Varables	Mean(SD)	Mean(SD)	*p*-valor
Group 1	DTMB	3.1(0.318)	3.2(0.298)	0.008
	DTSB	5.1(0.391)	5.4(0.346)	0.005
	ILB	57.4(9.594)	62.5(9.192)	0.005
Group 2	DTMB	3.1(0.318)	3.2(0.298)	0.008
	DTSB	5.1(0.391)	5.4(0.346)	0.005
	ILB	57.4(9.594)	62.5(9.192)	0.005

Legend: SD, standard deviation; *p*-value, level of statistical significance. Quantitative data presented in the form of descriptive statistics [mean (standard deviation)] and intra-group comparisons using the Wilcoxon statistical test.

There was no undesirable fracture of the pterygoid processes in any patient in Group 1. Tomographic exams showed only fractures of the palatine process of the maxillary bone in the region of the palatine suture and fracture of the anterior wall of the maxillary sinus, inherent to the techniques of surgical maxillary expansion.The tomographic findings showed displacement of the pterygoid plates at the end of the bone movements (T_1). The osteotomy or not of the pterygoid processes did not have a negative clinical impact. The diastema between the upper central incisors was clinically evident in all participants, in the T_1 assessment.In addition to not having intraoperative or postoperative complications, all participants reported being equally satisfied with the proposed/performed treatment.

DISCUSSION

Segmented Le Fort I osteotomies are the most studied for the treatment of transverse maxillary deficiencies.[8,9]The osteotomy of the pterygoid processes can be justified by the best expected results of expansion in the posterior region, since two processes of the sphenoid bone articulates with the maxilla and can limit this desired movement.[10]For some authors, osteotomy of pterygoid processes can be dispensed with in maxillary expansion surgeries.[11,12] Although there is no consensus on which technique presents better results, the present study points out the benefit of osteotomy of the pterygoid processes in the posterior gain in maxillary expansion surgeries.The lower bone movement observed in Group 1 may represent a greater risk of recurrence of the deformity, compared to the Group 2.[13-15] Finite element studies have shown a reduction in the degree of stress in the maxillary bones when the sutures are osteotomized, especially in the pterygomaxillary region.The statistically significant gains in both groups and the greater maxillary expansion after 30 days of treatment with the Hyrax expander (maximum maxilla expansion) in Group 2 suggest that both surgical techniques were effective. The best results obtained with osteotomy of the pterygid processes may be associated with a higher speed of bone movement due to a lower degree of stress in the maxillary bones.[14,16-19] Although osteotomy of the pterygoid process offers an additional risk of accidents or complications in maxillary expansion surgery,[20] its performance can result in greater maxillary expansion, reduced instability or bone interference during the desired movements and improve the treatment prognosis.

Fractures of the pterygoid plates or related bone structures may occur due to excessive local stress during osteotomies or incorrect use of the osteotome.The curved chisel must be used in the inferior and medial directions, in the posterior region of the maxilla. Thus, an undesirable fracture would occur in the lower portion of the pterygoid process, preserving the body of the sphenoid bone.[10]No participant in this research had an undesirable fracture of the posterior region of the maxilla or base of the skull after surgical disjunctions. This result corroborates the safety of surgical techniques established in the literature, when strictly performed.[21-27] The statistical significance of the intergroup comparisons reported in Table 1, may have been underestimated for the DTSB and DTMB, as it is a convenience sample composed of the surgical demand of the service during the research period. The sample size and the amplitude of the variables evaluated could influence the *p*-value of the statistical analysis, although the effect size of the mean differences between the groups was significant for all the measured parameters. The results of this study are considered relevant to the methodological care involved. The randomization and random allocation of the participants in the comparison groups (blinding), the standardization of the surgical procedures performed by the same maxillofacial surgeon and the blind analysis of the image exams positively influence the level of scientific evidence of this research. We also recognize as the main limitation of the study the importance of a larger sample size and the possibility of expanding the number of variables analyzed in new studies. Despite this, this clinical trial appears to be the first study to evaluate and confirm the benefit of osteotomy of pterygoid processes in surgical treatment of the transverse maxillary deficiency. Based on the results of this research, we suggest that osteotomy of the pterygoid processes is indicated in cases of significant transverse maxillary deficiency, mainly in the molar teeth region, or in cases where uniform/total maxillary alveolar arch correction is necessary.

Conclusion

Despite adding a greater risk of accident or surgical complication, osteotomy of pterygoid processes can be considered safe if performed with caution, according to the established surgical technique. The benefits of this procedure were observed for maxillary expansion, with a significant increase in the distances between the pterygoid processes and their angulation.

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