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# Efficacy of the rapid maxillary expansion with a modified acrylic splint palatal expander: A randomized clinical trial

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## Highlights

- The modified acrylic splint palatal expander (MASPE) does not increase the amount of skeletal effects.
- The MASPE does not increase palatal area compared to the tooth-borne bonded palatal expander.
- Even with the extended acrylic covering the palatal vault, the intergroup comparison showed a similar expansion for both appliances.

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## Abstract

**Aim:** This prospective randomized clinical trial aimed at analyzing the skeletal effects of this modified acrylic splint palatal expander (MASPE) used for maxillary transversal deficiency treatment in mixed dentition. **Methods:** Eligibility criteria included maxillary transverse deficiencies in children between 7 and 10 years of age. Eighteen individuals who met the inclusion criteria and reached the end of treatment were evaluated (mean age of 8.66 years old) and randomly assigned to be submitted to rapid maxillary expansion with either the MASPE experimental device or a well-known tooth-borne expander (control group). CBCT scans taken before expansion and at the end of the retention period were evaluated. The palatal area was calculated, and the length of expansion was measured. Treatment changes were analyzed using paired t-tests, whereas independent t-tests were used to compare the two groups. **Results:** There were statistically significant ($p<0.05$) increases in maxillary width at the suture level in both groups, with a substantial increase in the palatal area. The group differences were not significant. **Conclusions:** MASPE showed good efficiency and skeletal effects but no superiority over the control group.

**Keywords:** Maxillary expansion; Mixed Dentition; Orthodontics; Orthopedics

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## INTRODUCTION

The prevalence of posterior crossbite ranges from 8 to 22% in children with deciduous/mixed dentition[1-2] and represents one of the most common skeletal deformities of the craniofacial region.[3] The main treatment protocol relies on using rapid maxillary expansion (RME), an orthodontic procedure designed to increase the hard palate's transverse diameter by opening the maxilla's mid-palatal suture. The maxillary expansion has been performed for over a century to correct transverse deficiencies, expand the arch perimeter, and alter the nasal volume.[4-6] Treatments can generally be categorized as slow maxillary expansion (SME) or rapid maxillary expansion (RME).

The rapid maxillary expansion has become more popular in recent years because of advancement in Obstructive sleep apnea syndrome (OSAS) studies during childhood that leads to significant physical and neuro-psychomotor impairment. Adenotonsillectomy and, in selected cases, continuous positive airway pressure (CPAP) has been the preferred treatment for OSAS in children, although they are ineffective at fully alleviating the disease. RME, a much less invasive treatment, is an alternative treatment for this syndrome.[21]

The adequate appliance to expand the maxilla orthopedically is a fixed structure with a screw positioned in the sagittal palatine suture that can be banded or bonded, tooth-borne, or tooth-tissue-borne. Those made of acrylic splints bonded to teeth have received special attention regarding some benefits other than merely palatal expansion, such as closing open bites by posterior intrusive effect,[7-8] spontaneous correction of Class II and III malocclusions during mixed dentition,[9-10] occlusal interference removal,[10-11] decreasing resistance to expansion,[12] posterior vertical restriction during expansion procedure,[13] more bodily movement of the two halves of the maxilla,[3,12,14] reduction of unwanted rotation and inclination,[12] and less posterior inferior rotation of the mandible compared to other banded expanders.[15]

The bonded expander also seems to be more suitable for younger patients.[16] Moreover, banding the first molars is sometimes challenging during mixed dentition due to distal gingiva or because these teeth are partially erupted. Thus, acrylic splint expanders simplify the expansion procedure and maintain the appliance's stability.

Recently, a tooth tissue-borne acrylic splint appliance was developed[18] with an acrylic screw placed in the palate, forming a unique structure with a larger contact area, aiming to reinforce the anchorage, reduce the dental effects, and increase the orthopedic effects. The modified acrylic splint palatal expander (MASPE) is a tooth-tissue-borne type that improves the contact area, which might be more comfortable for the patient.[17-18] The effects of maxillary expansion are not limited to the hard palate as they may also influence the anatomy and physiology of the nasal cavity.[19-20]

To date, no work in the literature has studied whether the splint with acrylic covering the palate and dental area increases the effectiveness of expansion more than with acrylic covering only the teeth. Also, most studies compare banded expanders in patients with older mean age and have traditionally evaluated orthopedic expansion of the maxilla with two-dimensional (2-D) radiography, as the posteroanterior x-ray, losing accuracy of detail, by overlapping images. Cone beam computed tomography (CBCT) has been used progressively because it provides a volumetric dataset and is more reliable.[22] Since this imaging technique has numerous advantages over conventional radiography, the purpose of this study was to compare a modified expander, a tooth-tissue-borne acrylic splint appliance

(MASPE), with a traditional tooth-borne expander that served as a control group, regarding their effects on the maxillary vault and suture by using CBCT scans.

The null hypothesis is that there is no enhancement in palatal expansion or palatal area with the modified acrylic splint palatal expander (MASPE) compared to traditional bonded expanders.

## METHODS

This is a randomized clinical trial conducted at a post-graduation orthodontic center. The sample was selected from public school students and patients seeking treatment in the department. Informed consent was obtained from all parents or caretakers of the children, and the study was approved by the local research ethics committee according to protocol number 3.734.184.

The sample size was calculated based on an alpha level of significance of 0.05 and beta of 0.2 to obtain 80% power to detect a true difference of 0.4 mm and a standard deviation of 0.3mm midpalatal suture opening. Thus, the sample size calculation showed that ten patients per group would be needed for the present study.

### Trial design

This study is a single-center randomized clinical trial designed as a prospective two-arm parallel group with a 1:1 allocation ratio. The Consolidated Standards of Reporting Trials (CONSORT) checklist was used as a guideline for conducting and reporting this trial. Changes in participant numbers were performed after trial commencement and were described in the flow chart (Figure 1).

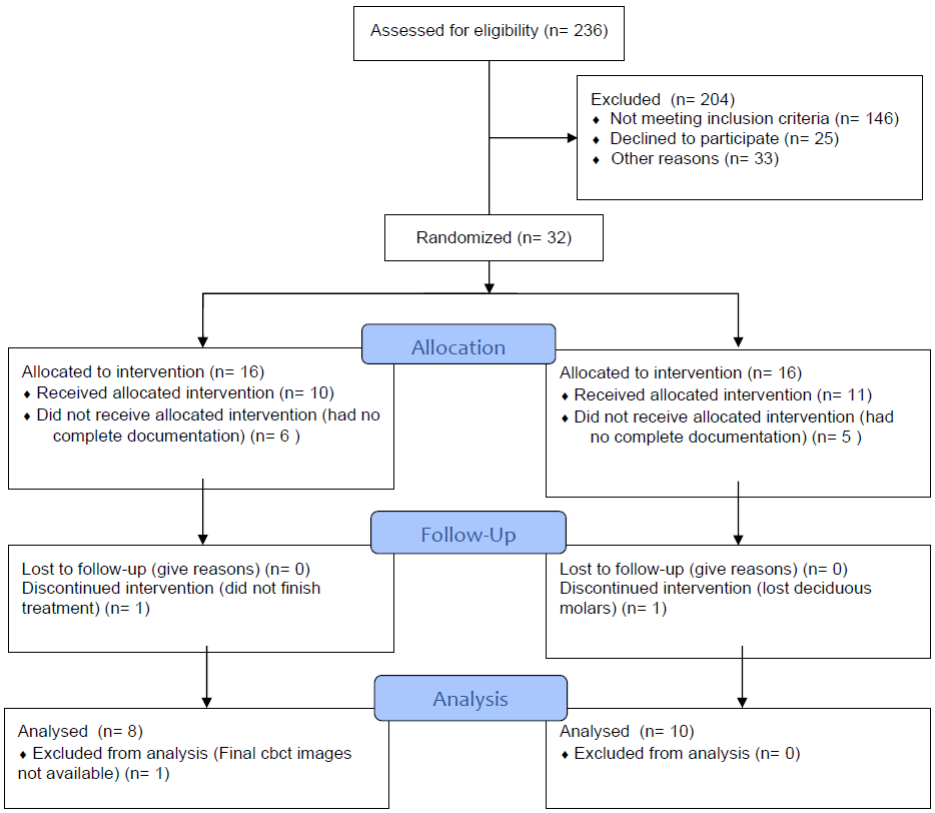


Figure 1. Reporting trial eligibility

### Participants, eligibility criteria, and settings

The patients were recruited from an epidemiological study performed in public schools surrounding the post-graduation orthodontic center in children from preschool and elementary school (6 to 11 years of age).[23] The sample comprised 18 patients with posterior crossbite aged 7 to 10 years. The eligibility criteria included: (1) mixed dentition; (2) both sexes; (3) posterior crossbite, either uni or bilateral; (4) no anterior crossbite. Exclusion criteria included patients with a history of previous orthodontic treatment, nonerupted maxillary permanent molars, syndromic patients, presence of caries, or premature loss of maxillary deciduous molars or canine.

### Treatment

All patient's dental casts were obtained by a single researcher and were randomly assigned to either tooth-borne bonded palatal expander[9] (group 1, control) or tooth-tissue-borne bonded MASPE (group 2, experimental) by a single technician who made the expanders and was blinded to the study's purpose. Then, the appliances were placed by a single professional who only became aware of the type of device on the day of placement. Both appliances were constructed with the same screw brand (Figures 2 and 3). Bonding was performed with the mixture of two types of glass ionomer cement (i.e., dual and chemical curing) to increase the retention and decrease the failure rate of appliances.

The tooth-borne RME group included eight patients (5 girls and 3 boys), with a mean age of 8.6 years old at the start of expansion (T0), whereas the MASPE group included ten patients (7 girls and 3 boys), with a mean age of 8.6 old at the start of expansion as well.

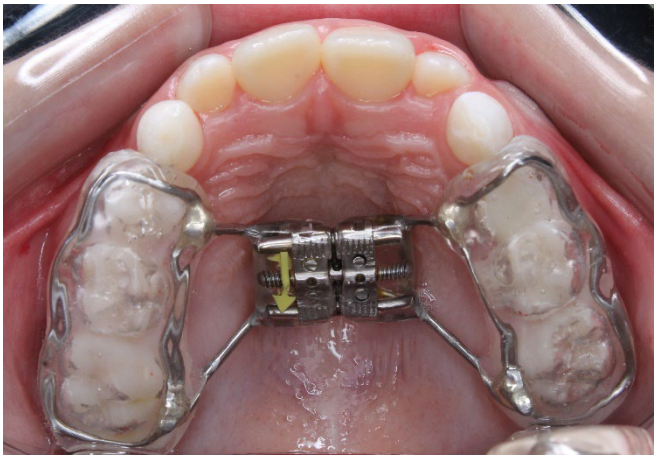

Figure 2. Tooth-borne acrylic bonded palatal expander

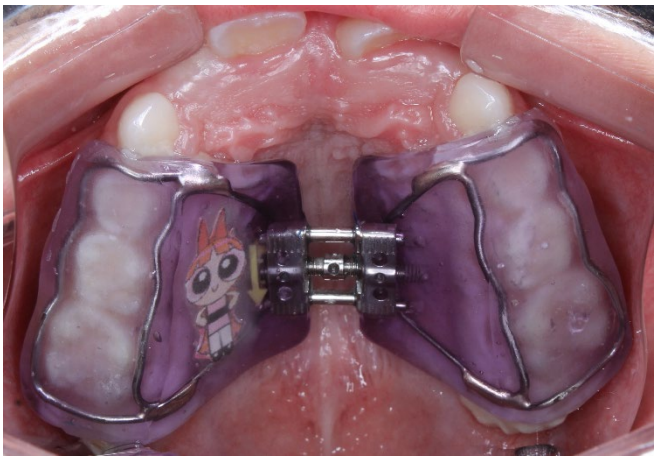

Figure 3. Tooth-tissue-borne modified acrylic splint palatal expander (MASPE)

Activation protocol involves one-half turn *per* day for fifteen days, remaining in retention for three months. CBCT scans were taken at T0 (before placement) and T1 (after retention) with an i-CAT unit (Imaging Science International, Hatfield, PA, USA) operating at 120 kV, 5 mA, field of view (FOV) of 13 x 16 cm, voxel size of 0.25 mm and scanning time of 40 seconds. After acquisition, the images were saved as DICOM files and imported to CS 3D Imaging software (Carestream Dental, Atlanta, GA, USA). The three-dimensional orientation was achieved by using the sagittal, coronal, and axial planes.

### Outcome measurements

The amount of expansion and the palatal area were calculated based on the coronal plane and obtained from the axial plane. The most apical view of the first molar palatal root canal was initially detected, and a line passing through it on both the right and left sides served as a reference for the coronal view (Figure 4).

Only one independent examiner, not related to the patient's treatment and unaware of the type of appliance and patient identification, visually evaluated all sectional images on a 24.1-inch LCD monitor with 1920 x 1200 pixels resolution in a dark room and did the measurements to minimize the risk of bias.

Two reference points at the inferior border of both orbits were detected to determine the palatal area, and a line was drawn to define the upper limit geometrically. The right and left limits were represented by the first molar palatal root axes and the lower limit by a line passing through the points where these long axes encounter the most inferior point in the occlusal fossae of each permanent molar.

A trapezoidal geometric form was obtained with two different heights, so it was divided into two triangles to allow the application of the area formula, and the trapezium area was obtained by summing the areas of the two triangles (Figure 5).

The expansion extension was determined by measuring the distance between the two margins of the palatal suture, that is, at the most inferior and medial border at each side in the coronal plane (Figure 4d).

### Randomization, allocation concealment, and blinding

Patients were recruited from the mailing list of a previous epidemiological study of the same post-graduation orthodontic center. From a total of 236 individuals, 32 met the inclusion criteria (19 girls and 17 boys), with a mean age of 8.6 years old, and were randomly assigned to receive treatment to either tooth-borne bonded palatal expander[9] (group 1, control) or tooth-tissue-borne modified acrylic splint palatal expander (MASPE) (group 2, experimental). For group 1, 8 losses decreased the number of participants to 8. Six declined treatments before they started, one discontinued during therapy, and one has no final CBCT image available. For group 2, the number of losses was 6. Five declined treatments, and one was excluded because the first premolar erupted.

### Statistical Analysis

Statistical calculations were performed using the SIGMA PLOT software (version 12.0, São Paulo, Brazil). To evaluate the reliability of the measurements, the CBCT images of all patients were reoriented and measured a second time after a minimum interval of 30 days. No statistically significant differences were found between the replicates. Treatment changes were analyzed using paired t-tests, whereas independent t-tests were used to compare the two groups. A probability level of 0.05 was used to determine statistical significance.

## RESULTS

Student's t-test and Dahlberg's formula were used to analyze casual and systematic errors. All measurements made within 4-week intervals were repeated, and no statistically significant error was observed for suture opening measurement or palatal area.

A paired t-test was performed separately for each group to compare the expansion achieved between T0 and T1 (Tables 1 and 2).

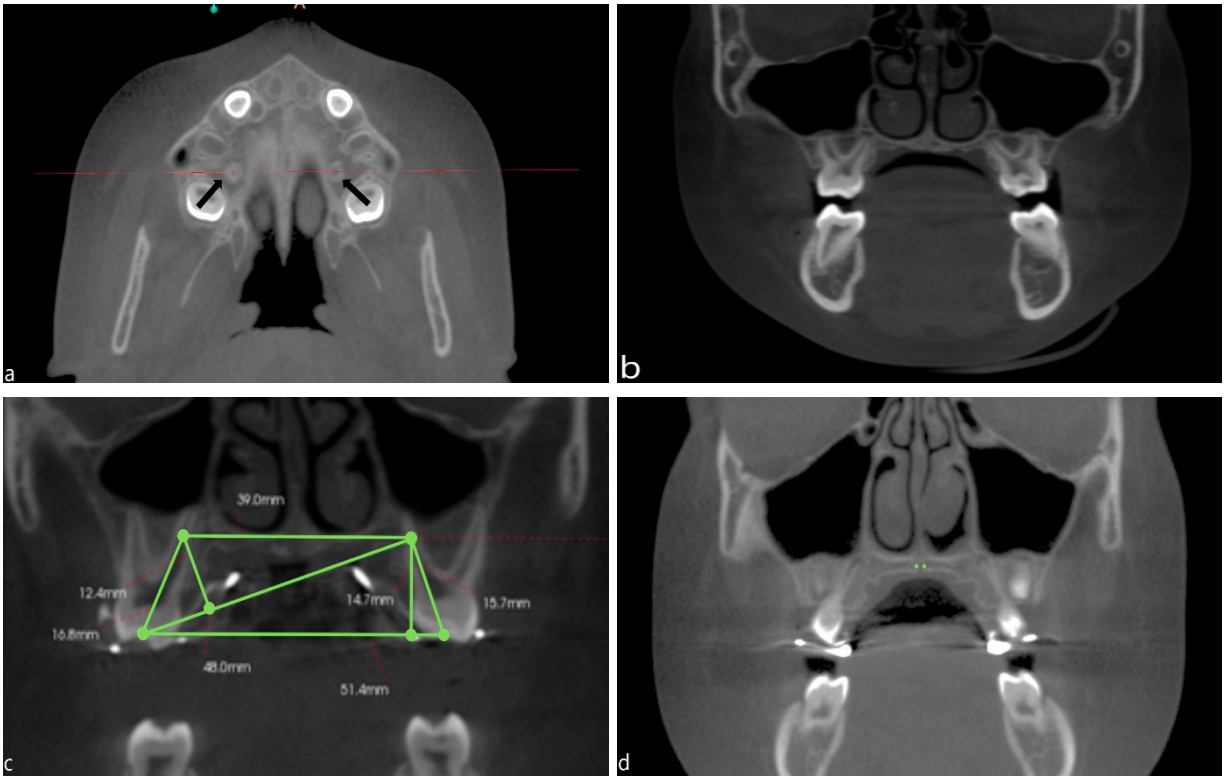


Figure 4. (a): Most apical view of the first molar palatal root canal; (b): coronal view; (c);determination of the palatal area (d): measurement of suture expansion

There was a significant increase in the palate area for Groups 1 and 2, with a 99% confidence interval significance level. This shows a range of high statistical importance, even with a reduction in the number of individuals evaluated, and the same behavior was observed for the measurement of suture distance. There was a linear increase between the points demarcated in the suture height, reaching a statistical significance close to and above a confidence interval of 99%.

Tables 1 and 2 show no statistical difference in the expansion behavior in any of the measurements evaluated between the groups. In other words, both groups showed significant expansion with an increase in the palate area and suture distance, a similar behavior between the groups.

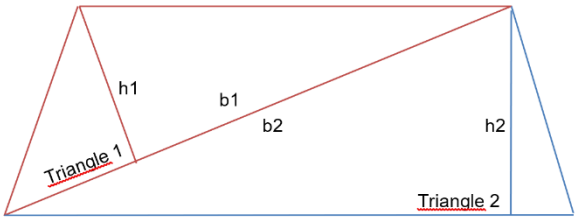


Figure 5. Trapezium area = (b1.h1)/2 + (b2.h2)/2

## DISCUSSION

Posterior crossbite malocclusion can involve posterior dentoalveolar changes only, with great lingual inclination of posterior teeth, or can result from real maxillary transverse deficiency, with a straight ogival palate.[24] Prevalence is controversial in the literature, with studies showing a range from 7.2% to 22%, but consistent with no self-correction capacity.[1-2,25]

Table 1. Area ($mm^2$) measurements before and after expansion and analysis intra and intergroups (paired t-test)

| | Palatal Area | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Variable | T0 | | T1 | | Alteration | | t | *P* |
| | Mean | SD | Mean | SD | Mean | SD | | |
| Group 1 | 561.012 | 92.387 | 634.688 | 123.078 | 73.676a | 64.119 | 3.250 | 0.014* |
| Group 2 | 539.632 | 91.692 | 610.605 | 98.388 | 70.972a | 34.165 | 6.569 | 0.001* |

*Statistically significant for P < 0.05

Table 2. Sutural distance (mm) measurements before and after expansion and analysis intra and intergroups (paired t-test)

| Sutural Distance | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Variable | T0 | | T1 | | Alteration | | t | *P* |
| | Mean | S.D. | Mean | S.D. | Mean | S.D. | | |
| Group 1 | 1.738 | 0.389 | 2.462 | 0.697 | 0.725a | 0.580 | 3.535 | 0.010* |
| Group 2 | 1.740 | 0.417 | 3.150 | 0.749 | 1.410a | 0.762 | 5.850 | 0.001* |

*Statistically significant for P < 0.05

Malocclusions require treatment with rapid maxillary expansion, especially those with skeletal involvement, to minimize dental effects.[23,26-27] It has been reported that maxillary disjunction exceeds the bounds of the median palatal suture. They also affect nasal physiology and anatomy[19-20] by broadening the nasal width and separating the palatal bones in a pyramidal form, with maximum expansion of the anterior area and the center of rotation localized at the frontonasal suture,[28] which increases the nasal cavity volume.[4] This increment can reach 45%,[10] benefiting respiratory function.[29-31] These results make RME the subject of study as an alternative treatment for early sleep apnea.[3,19,28,31]

Treatment progress outcomes have traditionally been evaluated with two-dimensional (2-D) radiography. CBCT is a rapid image acquisition technology in which 2D images are shifted into 3D ones, thus providing an anatomically accurate, volumetric dataset and widening the role of imaging in orthodontic diagnosis. In very young patients like our sample, exposure to ionizing radiation from CBCT is of particular concern because more youthful individuals are predominantly subjected to it. Children may be two to ten times more sensitive to radiation carcinogenesis than mature adults.[32]

Therefore, any radiographic technique demands using the ALARA principle (as low as reasonably achievable), supported by professional organizations.[33]

Recently, a table listing indications and specific conditions for using CBCT in orthodontic patients with posterior crossbite contained the following item: "Dentofacial deformities and craniofacial anomalies, specific conditions: Skeletal discrepancies – Transverse deficiencies."[2]

Even when indicated, there are ways to reduce radiation exposure to patients by decreasing the field of view (FOV) and adjusting the exposure settings (i.e., kVp and mA). The American

Academy of Oral and Maxillofacial Radiology (AAOMR) has recently provided clinical guidelines, which were developed by a consensus panel of board-certified orthodontists and oral and maxillofacial radiologists, for the use of CBCT in orthodontics based on an analysis of the available published evidence on transverse discrepancies, indicating its use with medium FOV.[34]

Our study used an i-CAT unit at medium FOV (100 to 150 mm), medium average dose of 96μSV, 120 kV, and 5 mA. Radiation can be high compared to conventional radiography. Still, since orthodontic diagnosis usually requires three exposures (panoramic radiography, teleradiography, and post-anterior radiographs) for patients with transverse maxillary deficiencies, they were all replaced with CBCT images as radiation doses are similar.

By comparing the results, both appliances effectively promoted a huge maxillary expansion and widened the palatal area. The difference between them was not statistically different, allowing both to be used to correct the maxillary transverse deficiency. There is little data available to discuss the use of tooth-tissue expanders.

Two previous studies used CBCT to analyze rapid maxillary expansion in young individuals.[11,35] But there are some fundamental differences between those studies and ours. The authors of both studies used two samples of banded expanders, and the patient's mean age were older than ours, most of them already with complete permanent dentition, making it difficult to compare to our results. Moreover, Garib's study's purpose was not to check the accuracy of palatal suture opening and palatal area. Still, rather than the amount of skeletal versus dentoalveolar changes, our point was to verify if an extension of the acrylic plate would enhance palatal suture opening once the bonded expander is attached only to deciduous teeth and one permanent molar.

We found two studies assessing bonded expanders in a systematic review performed a couple of years ago, but the objective was to compare them to banded ones.[36] The first study used a Hyrax expander and an acrylic-bonded appliance similar to the one used in our work.[3] In contrast, the second one also used a Hyrax expander but compared it to an acrylic-bonded appliance similar to the control group, which is well-known by the orthodontic community.[17] They found a similar behavior (mean of 7.31mm of maxillary expansion for the acrylic-bonded appliance), but the measurement was made in the intermolar distance at the coronal level.

More recently, an acrylic-bonded expander was studied using CBCT. The same activation protocol and amount of expansion were also found at the suture level but in the axial view.[37] However, the patients were older, and no control group was used for comparison. They found an expansion of 4.33 mm at the first molar level, higher than ours (1.41mm). However, our result is very close to that reported by another study (1.6 mm) using the same activation protocol and measurement methodology to evaluate a tooth-borne acrylic bonded expander, like the one used in our control group.[38]

Evaluation of the palatal area in CBCT scans is scarce in the literature, as most studies have used digital models. Two studies analyzed the volume[39-40] and one the palatal area, but they studied banded expanders.[41] On the other hand, three studies evaluated bonded expanders. They reported that the palatal area increased by 38%, whereas our results showed an increase of 13% approximately.[41] The differences can be due to the methodology, appliances, and activation protocols.

This prospective, randomized clinical trial showed the effectiveness of both appliances in terms of maxillary orthopedic expansion, with no significant difference in the amount of expansion

and increase of palatal area. This benefits children at an early age with maxillary deficiency and the possible development of infant sleep apnea syndrome. Still, the greater acrylic coverage apparently does not seem to favor a greater orthopedic effect. Because studies about changes in the palatal area in children are scarce, it is interesting to have more clinical trials on acrylic-bonded expanders, including long-term evaluation of the stability of appliance configuration.

One of the limitations of this study is the small sample size. Because this was a prospective study, some patients declined treatment due to difficulties attending office hours, for presenting mobility in deciduous molars or caries lesions before starting treatment, among other reasons. Another limitation is the parents' need to activate the appliance at home, which may lead to uncontrollable misconduct. Also, the present trial had a relatively short-term follow-up (i.e., 3 months)

## CONCLUSIONS

According to the methodology employed, the modified acrylic splint palatal expander (MASPE) does not increase the amount of skeletal effects and palatal area compared to the tooth-borne bonded palatal expander. Even with the extended acrylic covering the palatal vault, the intergroup comparison showed a similar expansion for both appliances.

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## Declarations

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