AJO-DO

# Maxillary expander with differential opening vs Hyrax expander: A randomized clinical trial

**Arthur César de Medeiros Alves,[a] Guilherme Janson,[a] James A. Mcnamara Jr.,[b,c] José Roberto Pereira Lauris,[d] and Daniela Gamba Garib[e]**

*Bauru, São Paulo, Brazil, and Ann Arbor, Mich*

**Introduction:** The aim of this 2-arm parallel trial was to compare the dentoskeletal effects of the expander with differential opening (EDO) and the Hyrax expander in the mixed dentition. **Methods:** Patients aged 7-11 years with maxillary dental arch constriction and Class I or Class II sagittal relationships were randomly allocated into 2 study groups. The experimental group comprised 22 patients (10 males, 12 females) with a mean age of 8.46 years treated with the EDO. The comparison group was composed of 24 patients (6 males, 18 females), mean age of 8.92 years treated with the conventional Hyrax expander. One complete turn per day for 6 days was performed for the posterior screw of the EDO and for the Hyrax expander. The anterior screw of the EDO was activated 1 complete turn per day for 10 days. The primary outcomes were the anterior opening of the midpalatal suture, changes on the interincisal diastema width, maxillary dental arch widths, arch perimeter, arch length, palatal depth, inclination of maxillary posterior teeth and on dental arch shape, and the amount of differential expansion in the anterior region compared with the posterior region of the maxillary dental arch. Computer-generated randomization was used. Allocation was concealed with sequentially, numbered, sealed, and opaque envelopes. Blinding was applicable for outcome assessment only. Occlusal radiographs of the maxilla were obtained at the end of the active expansion phase (T2). Intraoral photographs were obtained immediately pre-expansion (T1) and at T2. Digital dental models were obtained at T1 and 6 months after the active expansion period (T3). Intergroup comparisons of T1-T2 changes were performed using multiple linear regression analysis ($P < 0.05$). The independent variables were both treatment and the starting forms. Bonferroni correction for multiple tests was applied. **Results:** The experimental group showed a significantly greater opening of the anterior region of the midpalatal suture, a greater increase of the interincisal diastema width, and greater increases of the intercanine distance and inter–first deciduous molar distance than the Hyrax expander. The experimental group showed a significant differential expansion between the anterior and posterior regions, whereas the Hyrax group produced a similar expansion in the canine and molar regions. Serious harm was not observed. **Conclusions:** The EDO was capable of promoting greater orthopedic and dental changes in the anterior region of the maxilla than the conventional Hyrax expander. Similarity between the 2 expanders was observed for changes in the posterior region width, arch perimeter, arch length, palatal depth, and posterior teeth inclination. (Am J Orthod Dentofacial Orthop 2020;157:7-18)

Rapid maxillary expansion (RME) is the most common orthopedic procedure used to treat maxillary constriction and posterior crossbites.[1] The dentoskeletal effects of RME are well documented in the orthodontic literature.[2-5] Conventional RME expanders open the midpalatal suture and increase

[a]Department of Orthodontics, Bauru Dental School, University of São Paulo, Bauru, São Paulo, Brazil.

[b]Department of Orthodontics and Pediatric Dentistry, School of Dentistry, School of Medicine, and Center for Human Growth and Development, University of Michigan, Ann Arbor, Mich.

[c]Private practice, Ann Arbor, Mich.

[d]Department of Public Health, Bauru Dental School, University of São Paulo, Bauru, São Paulo, Brazil.

[e]Department of Orthodontics, Bauru Dental School and Hospital for Rehabilitation of Craniofacial Anomalies, University of São Paulo, Bauru, São Paulo, Brazil.

All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and none were reported.

Registration: The trial was registered in ClinicalTrials.gov under the identifier NCT02810353.

Protocol: The protocol was published on the ClinicalTrials.gov database before-trial commencement.

Funding: This research was supported by the Coordination for the Improvement of Higher Education Personnel.

Address correspondence to: Arthur César de Medeiros Alves, Department of Orthodontics, University of São Paulo, Bauru Dental School, Al. Octávio Pinheiro Brisolla, 9-75, Vila Santa Tereza, Bauru, São Paulo 17012 191 Brazil; e-mail, arthurcesar_88@hotmail.com.

Submitted, April 2018; revised and accepted, July 2019.

0889-5406/$36.00



https://doi.org/10.1016/j.ajodo.2019.07.010

maxillary widths and the arch perimeter with a parallel-opening screw, centrally positioned in the palate.[6-9] Alternatively, the fan-type expander concentrates changes in the anterior region of the dental arch with negligible changes in the molar region.[10,11]

Approximately one third of patients with maxillary constriction have a greater transversal deficiency in the intercanine width than the intermolar width.[12] In these cases, conventional RME expanders would overexpand the molar region to correct the intercanine width because the screws have a parallel opening. This undesirable effect could cause a significant decrease of the buccal alveolar bone plate thickness with an increased risk of bone dehiscences and gingival recessions.[13,14] Additionally, previous studies on the long-term stability of conventional RME showed greater relapse of the intercanine distance than the interpremolar and intermolar distances.[15,16]

Recently, a novel orthopedic maxillary expander was proposed aiming to promote greater expansion on the anterior than on the posterior region.[17] The expander with differential opening (EDO) has 2 parallel-opening screws, 1 anteriorly and the other posteriorly positioned in the palate.[17] Different amounts of activation in the anterior and posterior expansion screws determine a trapezoid-shaped opening of the appliance diverging toward anterior.[17] A recent study analyzed the dentoskeletal effects of the EDO in patients with complete bilateral cleft lip and palate (BCLP).[18] Patients with BCLP do not have midpalatal suture, and therefore the effects of EDO might be different in noncleft individuals. No previous studies evaluated the dentoskeletal outcomes of EDO in noncleft patients.

### Specific objectives and hypotheses

The aim of this study was to compare the dentoskeletal outcomes of the EDO and the conventional Hyrax expander during the mixed dentition in noncleft individuals. The null hypothesis was that there is no difference for the dentoskeletal effects between the EDO and the Hyrax expander.

## MATERIAL AND METHODS

### Trial design and any changes after trial commencement

This single-center study was a randomized clinical trial with 2-parallel arms. This randomized clinical trial followed the Consolidated Standards of Reporting Trials' statement and guidelines,[19] and no changes in methods after trial commencement were required.

### Participants, eligibility criteria, and settings

This study was ethically analyzed before trial commencement by the Research Institutional Board of the Bauru Dental School, University of São Paulo, and was approved under protocol number 1.292.365. Additionally, the protocol of this study was registered in the ClinicalTrials.gov with the identifier NCT02810353.

Recruitment of patients occurred in the Clinic of Orthodontics, Bauru Dental School, University of São Paulo from May to November 2015. Eligibility criteria included patients of both sexes in the mixed dentition, with ages ranging from 7 to 11 years diagnosed with maxillary constriction and Class I or Class II sagittal relationships. Exclusion criteria were the presence of cleft lip and palate, craniofacial syndromes, carious lesions, and history of previous orthodontic treatment.

### Interventions

Patients who met the eligibility criteria during recruitment were invited to participate in the study. Written consent terms were obtained from the patients and legal guardians. At this time, 1 researcher opened an envelope that contained a card with the name of 1 of the 2 types of expanders. Therefore, patients were randomly allocated into 1 of the 2 study groups. The treatment of the patients from both groups was performed by the same operator (ACMA).

The experimental group comprised patients treated with the EDO (Fig 1, *A-C*). The EDO was composed of 2 11-mm prefabricated screws, 1 posteriorly positioned on the palate at the level of the first permanent molars and the other anteriorly positioned at the level of the first deciduous molars (Great Lakes Orthodontics, Tonawanda, NY). Orthodontic bands were preferentially adapted on the maxillary first permanent molars, and clasps were bonded on the maxillary deciduous canines. When the maxillary first permanent molars were partially erupted, or the distal aspect of the crown was covered by gingiva, the maxillary second deciduous molars were banded, and a wire extension was soldered on the palatal aspect of the first permanent molars. Both expander screws were concurrently activated for 6 days, with an activation protocol of half a turn in the morning and half a turn in the evening. Afterward, only the anterior screw was activated for an extra 4-day time with the same protocol. After the active expansion period, the expander was kept in the mouth as a retainer for 6 months. At the end of the retention phase, the expanders were removed, and a removable retention plate was installed.

The comparison group comprised patients who underwent RME using the conventional Hyrax expander

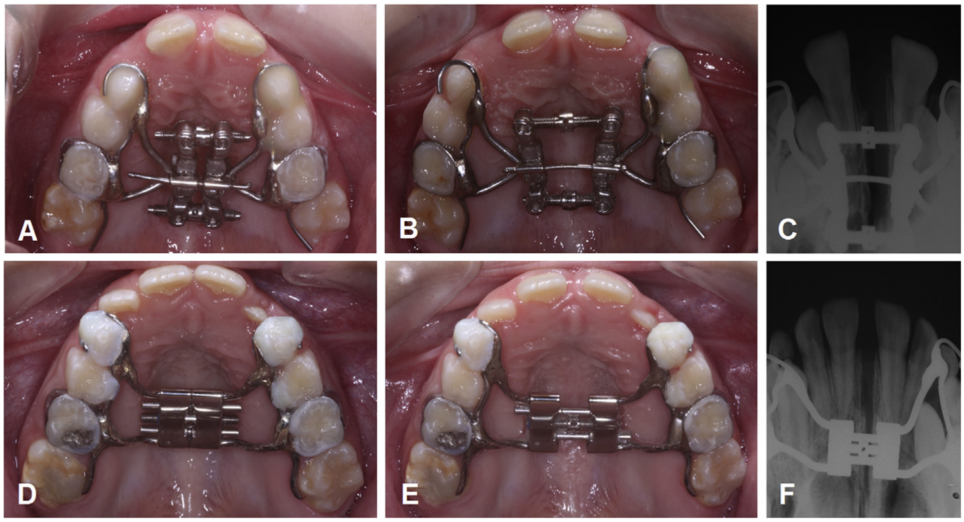


**Fig 1.** Expander with differential opening (**A-C**) and conventional Hyrax expander (**D-F**).

(Fig 1, *D-F*). The Hyrax expander was composed of a 11-mm screw centrally positioned on the palate. Similar to the experimental group, either maxillary first permanent molars or maxillary second deciduous molars were banded, and circumferential clasps were bonded on the maxillary deciduous canines. The screw was activated half a turn in the morning and half a turn in the evening for 6 days. After the active expansion period, the expander was kept in the oral cavity as a retainer for 6 months. At the end of the retention phase, the expander was removed, and a removable retention plate was installed.

Maxillary occlusal radiographs were obtained at the end of the expansion active phase (T2). The radiographic images were taken according to the biosecurity and radioprotection requirements, using the Insight occlusal radiographic film (Kodak Company, Rochester, NY) and a dental x-ray machine of 10 mA and 70 kV. The radiographic films were manually processed in a darkroom, using the temperature or time technique. Standardized frontal intraoral photographs were taken orthostatically for each patient immediately pre-expansion (T1) and at the end of the active expansion phase (T2); for example, 6 or 10 days after the appliance's installation. The photographs were taken at a distance of 30 cm from the patients using a Canon T1i digital camera (Canon EOS Digital Rebel Inc, Tokyo, Japan), 100-mm macro lens, circular flash, f 11, shutter speed 1/125, and ISO 200. Standardized conventional dental models were obtained for each patient immediately pre-expansion (T1) and 6 months after expansion (T3). The maxillary dental arch models were digitized using a 3Shape R700 3D scanner (3Shape A/S, Copenhagen, Denmark), and the obtained 3-dimensional images were saved in an .stl file format.

**Fig 2.** Dimension of midpalatal suture opening was analyzed measuring the distance between prosthion landmarks (*Pr-Pr'*) on the maxillary occlusal radiographs, obtained at the end of the expansion active phase.

### Outcomes (primary and secondary) and any changes after trial commencement

The primary outcomes of this study were the dimension of anterior midpalatal suture opening (*Pr-Pr'*); the changes in the interincisal diastema, maxillary dental arch widths (*c-c*, *d-d*, *e-e*, and *6-6*), arch perimeter and length, palatal depth and inclination of posterior teeth (*Ic*, *Ie*, and *I6*), dental arch shape, and the amount of differential expansion in the anterior region compared with the posterior region of the maxillary dental arch. No outcome changes occurred after trial commencement.

The dimension of the anterior midpalatal suture opening was digitally measured on the maxillary occlusal

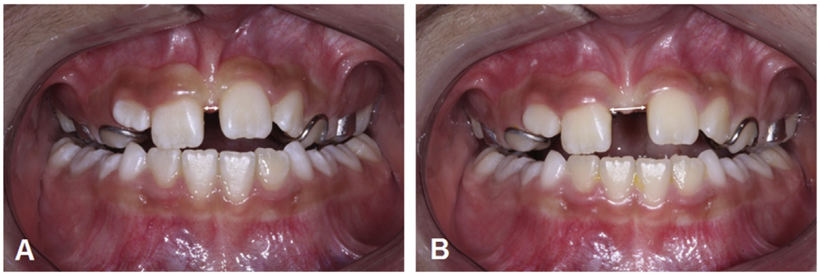


**Fig 3.** The interincisal diastema width was analyzed measuring the distance between the points located at the confluence of the mesial aspect of the maxillary central incisors with the gingival papilla on the intraoral frontal photographs obtained before (**A**) and after (**B**) the active phase of rapid maxillary expansion. Interincisal diastema change was considered the difference between the values obtained at T2 and T1.

radiographs using Dolphin Imaging software, version 11.0 (Dolphin Imaging and Management Solutions, Chatsworth, Calif), as shown in Figure 2.

The width of the interincisal diastema was measured using a modification of a method proposed in a previous study.[20] Initially, the mesiodistal width of the clinical crown of the maxillary right central incisor of each patient was manually measured on the pre-expansion conventional dental models using a caliper. Using a digital millimetric ruler, the photograph was resized in Microsoft PowerPoint 2013 (Microsoft Corporation, Redmond, Wash) according to the actual size of the measured tooth. The interincisal diastema was measured using Dolphin Imaging software, as shown in Figure 3.

The measurements of maxillary dental arch widths, arch perimeter and length, palatal depth, and inclination of posterior teeth were performed on the pre- and post-expansion digital dental models using the OrthoAnalyzer 3D software (3Shape A/S), as shown in Figures 4-6.

The dental arch shape was evaluated using the Geomagic Wrap 2015 software (Raindrop Geomagic Inc, Morrisville, NC) and the Microsoft Excel 2013 (Microsoft Corporation). In the Geomagic Wrap 2015 software, Andrews' facial axis points[21] were set on the maxillary teeth. These points were decomposed in 3 cardinal directions generating values on the x-, y-, and z-axis. Considering the y-axis values referred to the depth dimension (cervico-oclusal plane), only the x-axis values (transversal plane) and the z-axis values (sagittal plane) were tabulated. Microsoft Excel 2013 was used to graphically determine the mean maxillary dental arch shape for both study groups at T1 and T2, using the interpolar function.

### Sample size calculation

A minimum difference of 2 mm in the intercanine distance, a standard deviation of 1.65, an alpha error of 5%, and a test power of 80% were considered for sample size calculation.[11] Twenty participants were required in each group.

### Interim analyses and stopping guidelines

Not applicable.

### Randomization (random number generation, allocation concealment, implementation)

A simple electronically generated randomization was performed before trial commencement using the Random Allocation Software program.[22] Randomization ensured patients' allocation in both groups with a 1:1 ratio. Allocation concealment involved numbered, sealed, and opaque envelopes prepared before trial commencement. One envelope was sequentially opened for each participant during recruitment. Each envelope contained a card with the name of 1 expander. The initials of the name of the participant, the type of expander, and the date of allocation were identified in the external surface of the envelope. One operator was responsible for the randomization process, allocation concealment, and implementation.

### Blinding

Double-blinding was not possible because the operator and patients were aware of the type of expander that was being installed. However, blinding was accomplished during outcome assessment once the maxillary occlusal radiographs, the photographs, and the digital dental models were unidentified during analysis.

### Error study

One operator (ACMA) performed all the measurements and repeated them in 30% of the sample at least 1 month later. The intraexaminer error was assessed using the intraclass correlation coefficient.[23]

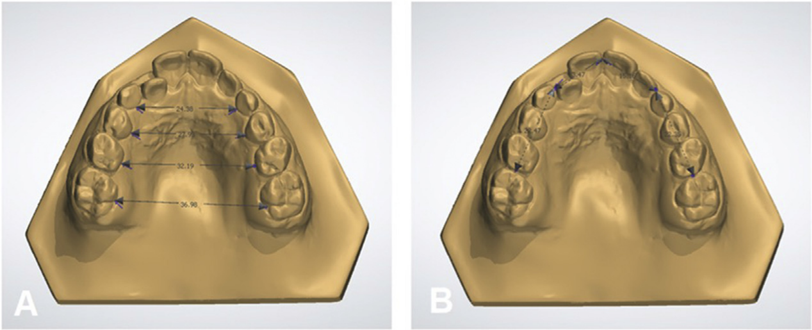


**Fig 4.** Maxillary arch widths (**A**) comprised the distances *c-c* (deciduous intercanine distance at the level of the palatal gingival margin midpoint), *d-d* (inter–first deciduous molars distance at the level of the palatal gingival margin midpoint), *e-e* (inter–second deciduous molars distance at the level of the palatal gingival margin midpoint), and 6-6 (inter–first permanent molar distance at the level of the palatal gingival margin midpoint). Arch perimeter (**B**) was the sum of *P6-c* (linear distance between the mesial aspect of the right first permanent molar to the mesial aspect of the right deciduous canine), *Pc-1* (linear distance between the mesial aspect of the right deciduous canine to the most prominent point of the mesial aspect of the left permanent central incisor), *P1-c*' (linear distance between the most prominent point of the mesial aspect of the left permanent central incisor to the mesial aspect of the left deciduous canine), and *Pc*'*-6*' (linear distance between the mesial aspect of the left deciduous canine to the mesial aspect of the left first permanent molar).

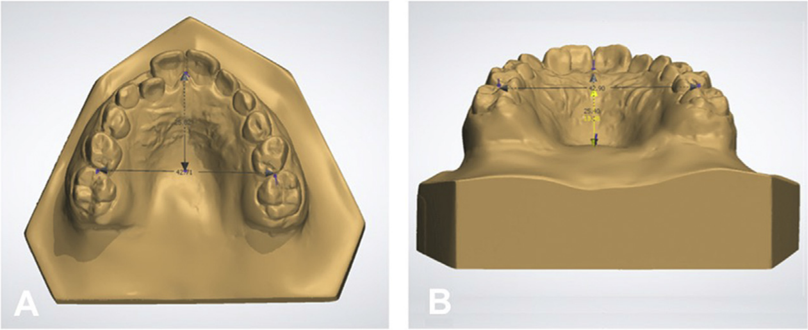


**Fig 5.** Arch length (**A**) was measured perpendicularly in the horizontal plane from a line connecting the mesial aspects of the first permanent molars to the point between the maxillary central incisors at the level of the gingival papilla. Palatal depth (**B**) was measured from a line passing through the mesial gingival papilla of the first permanent molars to the deepest point on the palate surface, perpendicularly to the arch length.

### Statistical analysis (primary and secondary outcomes, subgroup analyses)

Kolmogorov-Smirnov tests were used to verify normal distribution of variables. Considering that the variables showed normal distribution, parametric tests were used. Intergroup comparisons for initial age were performed with *t* tests. A chi-square test was used for intergroup comparison regarding sex ratio. Intergroup comparisons of T1-T2 changes were performed using multiple linear regression analysis. The independent variables were both treatment and the starting forms to adjust the comparisons to possible differences at T1. Results were regarded significant at $P < 0.05$. Bonferroni correction for multiple tests (tests performed on a set of 12 measurements) was applied. Differential expansion assessment was performed, comparing the difference between *c-c* and *6-6* width change in both groups using *t* tests. Associated 95% confidence intervals were calculated. All statistical tests were conducted with SPSS Statistics for Windows, version 25.0 (IBM, Armonk, NY).

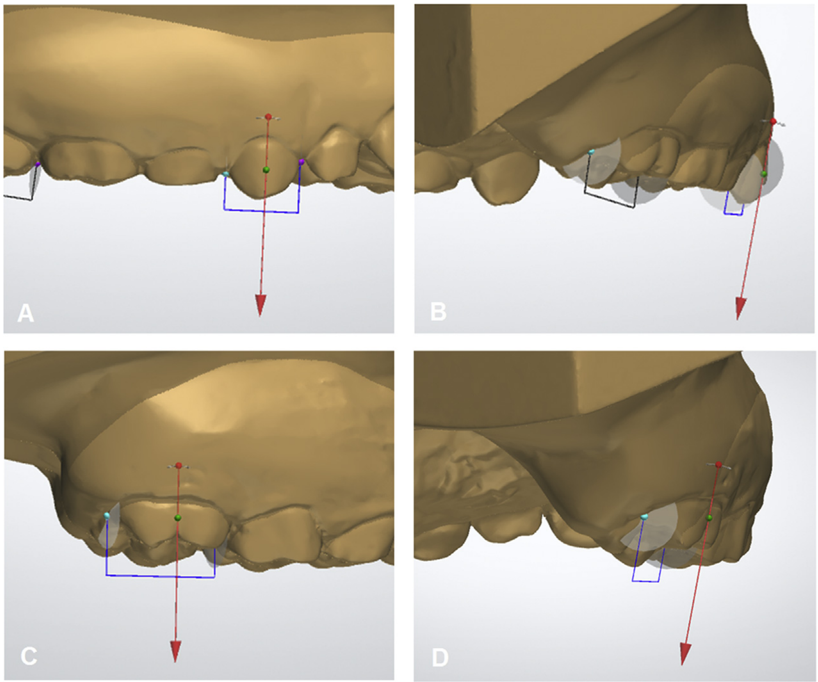


**Fig 6.** Tooth inclination was measured using as reference the occlusal plane passing through the mesiobuccal cusp tips of the maxillary first permanent molars, bilaterally, and through a mesioincisal point on the left central incisor. The tooth long axis was represented as an arrow in the virtual setup of the OrthoAnalyzer software. On the buccal view of each tooth (**A** and **C**), this arrow was mesiodistally manipulated to represent tooth angulation according to Andrews' facial axis point.[21] On the distal view of each tooth (**B** and **D**), the arrow was buccolingually manipulated to represent the crown tip, according to Andrews. The angle between the arrow and the occlusal plane was automatically calculated by the software. After expansion, increasing values of the angle meant tooth buccal inclinations of the teeth, and decreasing values meant lingual tooth inclination.

## RESULTS

One hundred sixty-one participants were recruited from May to November 2015; 105 patients (65.21%) were excluded because they did not meet the eligibility criteria. Fifty-six patients were randomized in a 1:1 ratio to the study groups (experimental group, 28; comparison group, 28). The trial ended when the sample size allowed a dropout rate of approximately 30%. Figure 7 shows the participants' flow chart with reasons of losses and exclusions before and after randomization.

### Baseline data

Baseline characteristics were similar in both groups (Tables I and II).

### Numbers analyzed for each outcome, estimation, and precision, subgroup analyses

Five of 28 (17.86%) and 2 of 28 (7.14%) patients, respectively, from the experimental and comparison groups were lost during the enrollment. Expanders were installed in 23 patients of the experimental group and 26 participants of the comparison group. One patient from the experimental group was excluded from the sample because both EDO screws spontaneously closed after the active phase because of unknown reasons. Two participants from the comparison group were excluded because of recurrent appliance breaks and residence move. Considering the primary analysis was carried out on a per-protocol basis, 22 patients of the experimental group and 24 participants of the comparison group were properly analyzed in their original assigned groups. All patients from both groups demonstrated a midpalatal suture split.

Intraexaminer reliability was considered very good because the intraclass correlation coefficient ranged from 0.894 to 0.999.[23]

The EDO promoted significantly greater opening of the anterior region of the midpalatal suture, greater increase of the interincisal diastema width, and greater

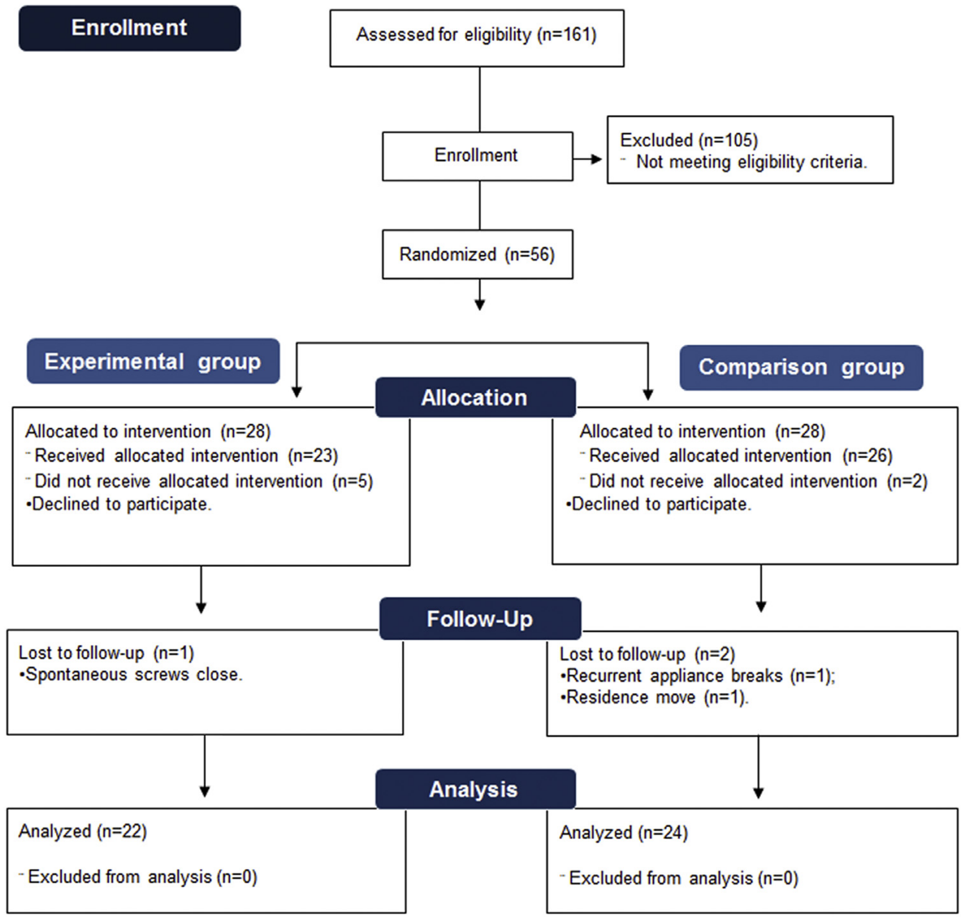


**Fig 7.** Consolidated Standards of Reporting Trials diagram showing patient flow during the trial.

**Table I.** Intergroup comparisons for age and sex ratio (*t* and chi-square tests)

| | Experimental group (n = 22) | | | Comparison group (n = 24) | | | |
|---|---|---|---|---|---|---|---|
| *Variable* | *Mean* | *SD* | *CI 95%* | *Mean* | *SD* | *CI 95%* | P |
| Initial age (y) | 8.46 | 1.40 | 1.08-2.00 | 8.92 | 1.21 | 0.94-1.70 | 0.238* |
| Sex | | | | | | | |
| Male | 10 | | | 6 | | | 0.458† |
| Female | 12 | | | 18 | | | |

*CI*, confidence interval.
**t* tests; †Chi-square test.

increases of the intercanine and inter–first deciduous molar distances than the Hyrax expander (Table III). Furthermore, regression analysis showed that the intergroup differences of variables at T1 were not relevant on the RME outcomes (Table III).

The experimental group showed significant differential expansion of the maxillary dental arch as shown in arch shape changes (Table IV; Fig 8).

### Harms

No important harm was caused to the participants of this study, such as moderate or severe pain, white spot lesions, gingival recessions, bone dehiscences, or allergic reactions. The benefits and collateral effects of differential and conventional RME were already known from previous literature.[24-26] Two of 22 patients in the EDO group and 1 of 24 patients in the Hyrax group still showed some interarch transversal discrepancy and were assigned for a second expansion procedure after the end of the evaluation period.

## DISCUSSION

### Main findings in the context of the existing evidence and interpretation

A previous study found that approximately one third of patients with maxillary arch constriction showed a 2.8 mm greater transversal deficiency in the anterior region than the posterior region.[12] In this perspective,

**Table II.** T1 and T2 variables in the sample groups

| | Experimental group (n = 22) | | | | | | Comparison group (n = 24) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | T1 | | | T2 | | | T1 | | | T2 | | |
| Variable | Mean | SD | CI 95% | Mean | SD | CI 95% | Mean | SD | CI 95% | Mean | SD | CI 95% |
| Interincisal diastema (mm) | 0.75 | 0.94 | 0.72-1.35 | 4.86 | 2.27 | 1.74-3.24 | 0.69 | 0.78 | 0.60-1.10 | 3.23 | 0.93 | 0.72-1.32 |
| c-c (mm) | 24.45 | 1.90 | 1.43-2.81 | 30.75 | 2.24 | 1.64-3.09 | 25.50 | 2.44 | 1.82-3.72 | 29.03 | 2.50 | 1.86-3.80 |
| d-d (mm) | 26.40 | 1.89 | 1.45-2.70 | 32.48 | 2.38 | 1.83-3.40 | 27.34 | 2.37 | 1.83-3.40 | 31.11 | 2.49 | 1.92-3.57 |
| e-e (mm) | 29.96 | 2.23 | 1.71-3.19 | 35.06 | 2.36 | 1.82-3.38 | 31.81 | 2.30 | 1.78-3.26 | 35.17 | 2.22 | 1.72-3.15 |
| 6-6 (mm) | 34.60 | 3.10 | 2.39-4.44 | 38.22 | 3.07 | 2.36-4.39 | 36.01 | 2.19 | 1.70-3.07 | 39.75 | 1.94 | 1.51-2.72 |
| Arch perimeter (mm) | 77.21 | 4.25 | 3.27-6.07 | 81.68 | 4.06 | 3.12-5.80 | 77.73 | 5.05 | 3.92-7.09 | 80.20 | 6.81 | 5.29-9.56 |
| Arch length (mm) | 28.40 | 2.12 | 1.63-3.03 | 27.58 | 2.28 | 1.76-3.27 | 28.50 | 2.12 | 1.65-2.98 | 27.71 | 2.06 | 1.60-2.89 |
| Palatal depth (mm) | 13.80 | 2.53 | 1.95-3.62 | 12.69 | 2.60 | 2.00-3.72 | 14.67 | 1.71 | 1.33-2.40 | 14.09 | 2.15 | 1.67-3.01 |
| Ic (o) | 74.99 | 7.34 | 5.94-9.62 | 77.47 | 6.70 | 5.41-8.59 | 77.25 | 8.85 | 5.09-7.89 | 79.32 | 5.29 | 7.20-11.50 |
| Ie (o) | 75.39 | 4.55 | 4.56-7.15 | 79.79 | 5.16 | 4.13-6.86 | 76.50 | 6.04 | 5.31-8.43 | 80.25 | 5.02 | 4.01-6.71 |
| I6 (o) | 77.03 | 6.52 | 5.51-8.46 | 81.59 | 5.26 | 4.33-6.68 | 79.37 | 5.78 | 4.81-7.24 | 82.22 | 5.08 | 4.23-6.37 |

*CI*, confidence interval; *SD*, standard deviation.

some patients may need an individualized expansion with different amounts of screw activations in the canine and molar regions.[12] The EDO is a 2-screw expander that aims to promote a distinct amount of expansion in the anterior and posterior regions of the maxillary dental arch.[15] However, no previous clinical study had analyzed the dentoskeletal effects of the EDO in noncleft individuals.

An intergroup compatibility for initial age and sex distribution was found (Table I). Despite the insignificant difference between groups regarding initial age, the experimental group was slightly younger compared with the comparison group (Table I). However, this slight difference is not likely to have any clinical relevance.[27] These results confirm the sample homogeneity, ensure the effectiveness of randomization and allocation of the patients, and decrease the risk of bias for the intergroup comparisons.[28] The 6-mm intermolar amount of expansion was standardized in both groups to allow intergroup comparison.

The EDO promoted a significant increase of the anterior region of the midpalatal suture and the interincisal diastema width of 5.38 mm and 4.11 mm, respectively (Table III). These findings confirm the potential for an orthopedic effect of the EDO. The intergroup comparison showed that the EDO promoted a greater orthopedic effect in the anterior region of the maxilla than the conventional Hyrax expander (Table III). These findings are probably associated with the greater amount of activation of the anterior screw in the EDO group. The greater the intercanine distance increase, the greater will be the anterior palatal suture split. The anterior screw of the EDO was opened approximately 9 mm, causing a 60% orthopedic effect on the anterior region of the midpalatal suture (5.38 mm). The pattern of midpalatal suture opening observed for the EDO was similar to those described in previous studies with conventional RME expanders,[9,29] showing a triangular shape, as shown in Figure 1. Additionally, bone-tooth–borne expanders seem to produce a similar orthopedic effect compared with conventional Hyrax expanders.[30]

The experimental group showed significant increases of the intermolar and intercanine arch widths of 3.61 mm and 6.30 mm, respectively, causing a mean increase of 4.47 mm in arch perimeter (Table III). The intercanine distance changes were significantly greater than the intermolar distance changes owing to the anteriorly divergent opening of the EDO (Table III). A recent study analyzed the dentoskeletal effects of the EDO in patients with complete bilateral cleft lip and palate and found significant increases of the intermolar and intercanine arch widths of 5.57 mm and 7.68 mm, respectively, causing a mean increase of 7.66 mm in arch perimeter.[18] These increased values of the maxillary dental arch width and perimeter changes compared with our study may be associated with a greater amount of expansion in a more severely constricted maxilla and with the smaller resistance to expansion observed in patients with BCLP because of the absence of the midpalatal suture.[31,32] The Hyrax group showed significant increases of intercanine and intermolar arch widths of 3.42 mm and 3.74 mm, respectively, causing a mean increase of 2.46 mm in arch perimeter (Table III). In this group, the intercanine distance change was similar to the intermolar distance change (Table IV). Similar results were observed in a previous study.[11] This similarity between the amount of expansion in the anterior and posterior regions might be explained by the parallel-opening pattern of the conventional Hyrax screw.[11,33] The intergroup comparison showed that the EDO promoted a greater amount of expansion in the canine region

**Table III.** Intergroup comparisons of interphase changes (linear regression analysis)

| | *Experimental group* | | *Comparison group* | | *Estimate difference* | | |
|---|---|---|---|---|---|---|---|
| *Variable* | *Mean* | *SD* | *Mean* | *SD* | *Mean* | *95% CI* | P |
| Midpalatal suture opening (mm) | 5.49 | 2.06 | 3.18 | 1.03 | 2.31 | 1.28 to 3.34 | <0.001* |
| Interincisal diastema (mm) | 4.12 | 2.11 | 2.53 | 0.79 | 1.59 | 0.64 to 2.55 | 0.002* |
| c-c (mm) | 6.30 | 2.18 | 3.43 | 1.17 | 2.60 | 1.38 to 3.81 | <0.001* |
| d-d (mm) | 6.08 | 2.48 | 3.77 | 1.14 | 2.06 | 0.90 to 3.23 | 0.001* |
| e-e (mm) | 5.09 | 1.79 | 3.37 | 1.45 | 1.28 | 0.27 to 2.28 | 0.014 |
| 6-6 (mm) | 3.62 | 1.59 | 3.75 | 1.13 | −0.38 | −1.18 to 0.43 | 0.348 |
| Arch perimeter (mm) | 4.47 | 3.63 | 2.47 | 3.49 | 1.97 | −0.17 to 4.11 | 0.070 |
| Arch length (mm) | −0.82 | 1.38 | −0.78 | 0.89 | −0.05 | −0.72 to 0.63 | 0.889 |
| Palatal depth (mm) | −1.12 | 1.18 | −0.58 | 1.28 | −0.58 | −1.33 to 0.18 | 0.131 |
| Ic (o) | 1.87 | 6.84 | 2.18 | 8.13 | −1.33 | −5.11 to 2.45 | 0.479 |
| Ie (o) | 1.75 | 5.83 | 4.32 | 6.05 | −2.51 | −6.87 to 1.84 | 0.247 |
| I6 (o) | 3.01 | 5.39 | 2.28 | 3.98 | 1.47 | −0.66 to 3.60 | 0.170 |

*CI*, confidence interval; *SD*, standard deviation.
*Statistically significant at $P < 0.004$ with Bonferroni correction.

than the Hyrax expander (Table IV). In contrast, the amount of expansion in the molar region was similar in both groups (Table III). These findings confirm the capability of the EDO in promoting a true differential expansion when additional activations are performed in the anterior screw. One potential advantage of this differential effect may be the long-term stability. Previous longitudinal RME studies showed that the relapse of intercanine expansion is greater than intermolar expansion.[15,16] Therefore, a greater overcorrection in intercanine distance would be advisable to longitudinally improve the intercanine expansion net gain.

No differences were observed between the EDO and the Hyrax expander for arch length and palatal depth changes. The arch length slightly decreased (−0.78 mm) in the Hyrax group (Table III). This finding is in accordance with previous studies[6,34,35] that found decreases in the arch length of 0.40-1.03 mm after conventional RME. Decrease in the arch length may be associated with the slight palatal inclination of the maxillary central incisors during the interincisal diastema closure at the postexpansion period.[36] The palatal depth slightly decreased 0.81 mm after RME with the EDO (Table III). This finding is in accordance to the findings of previous studies[1,37] and is associated with the lowering of the maxillary palatine process consequent to the outward tilting of the maxillary halves.[36] The EDO and the conventional Hyrax expander promoted significant and similar increases in buccal inclination of the posterior teeth (Table III). Similar findings were observed in previous studies in patients with[18] and without[8,38] oral clefts. Buccal inclination of the anchorage teeth is expected because they received the released force of the expanders.[39]

No important difficulties were reported by the parents in performing the activations of the expander screws. This may be associated with the fact that parents and patients of both groups had watched videos, developed by the authors, demonstrating how to correctly activate the expander screws. The videos can be electronically accessed in the YouTube platform using the following links: https://www.youtube.com/watch?v=cTK_bR9FQmY and https://www.youtube.com/watch?v=chEDnQOJ7KU for the EDO and the conventional Hyrax expanders, respectively. However, patient- and parent-centered outcomes should be further investigated considering the EDO has 2 screws to be activated.

## Limitations

In the present study, only 1 operator was responsible for randomization, allocation concealment, and implementation. This may be a methodological limitation because these steps of a patient's selection should be performed by independent persons, different from those involved in carrying out the study itself.[40] However, the risk of bias selection was considered low because recruitment and allocation of participants started at least 30 days after randomization. This period probably was enough to perform a blind allocation, even when it was performed by the same operator.

Another limitation of the present study was the variation in posterior anchorage teeth. In the experimental group, 91% of the patients had the bands adapted on the first permanent molars, whereas 9% of the patients had the second deciduous molars banded. In the comparison group, these frequencies were 87.50% and 13.63%, respectively. This variation was due to the fact that some patients still had the distal aspect of the first permanent molars covered by gingiva, whereas

**Table IV.** Intragroup and intergroup differential expansion comparisons (paired *t* and *t* tests)

| | c-c | | | 6-6 | | | Intragroup comparison | Dif | | Intergroup comparison |
|---|---|---|---|---|---|---|---|---|---|---|
| *Variable* | *Change* | *SD* | *CI 95%* | *Change* | *SD* | *CI 95%* | P | *Mean* | *SD* | P |
| Experimental group | 6.30 | 2.18 | 1.64-3.22 | 3.61 | 1.65 | 1.22-2.27 | <0.001* | 2.69 | 2.35 | <0.001* |
| Comparison group | 3.42 | 1.16 | 0.87-1.77 | 3.74 | 1.03 | 0.88-1.59 | 0.170 | 0.32 | 1.18 | |

*Dif*, difference; *CI*, confidence interval; *SD*, standard deviation.
*Statistically significant at $P < 0.05$.

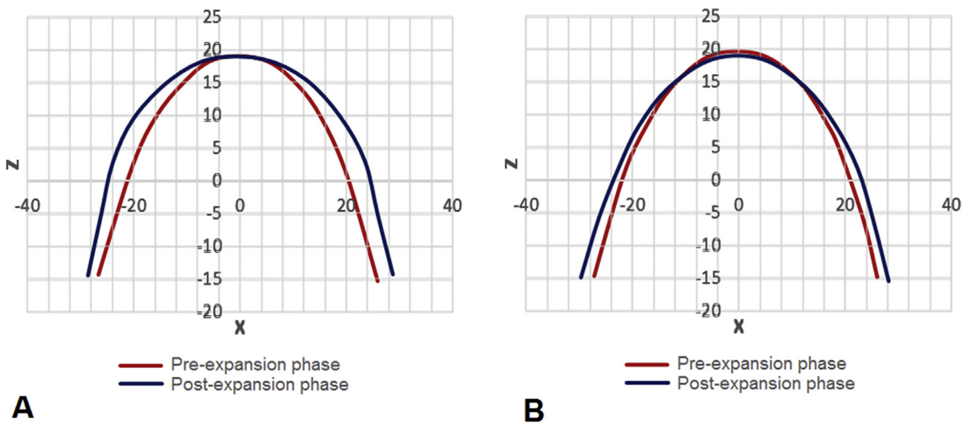


**Fig 8.** Superimposition of the mean maxillary dental arch shape before and after differential (**A**) and conventional (**B**) rapid maxillary expansions.

other patients had advanced root resorption of the second deciduous molars. This limitation should have influenced the outcomes observed for molar buccal inclination and could be avoided if fully-erupted first permanent molars had been considered as an inclusion criterion during patients' recruitment.

In the present study, the orthopedic effect of the EDO and of the conventional Hyrax expanders was assessed using maxillary occlusal radiographs obtained immediately after expansion (T2). Although these images provided information to analyze the amount of midpalatal suture opening, they did not allow the analysis of the stability of skeletal outcomes in the long term. Cone-beam computed tomography obtained before and after RME could have provided a more complete appraisal of the skeletal changes. However, cone-beam computed tomography would not provide additional clinical benefit for the patients who underwent RME alone and would expose those individuals to greater doses of ionizing radiation, with the unnecessary risks.

Another consideration is that this was a single-center study. A multicentric study would increase the sample in a shorter period and would increase validation of results because the dentoskeletal effects of EDO and Hyrax expander would be analyzed in different populations.

Future single-center and multicentric studies should compare the long-term stability of the EDO and conventional RME expanders. The dentoskeletal effects of the EDO in the permanent dentition should also be evaluated.

### Generalizability

The generalizability of these results might be limited to children in the mixed dentition without cleft lip and palate because expansion effects differ according to age and presence of oral cleft. Additionally, these results cannot be generalized to different types of expanders or to the same expanders with slow activation protocols.

## CONCLUSIONS

(1) In the mixed dentition, the EDO produced greater anterior split of the midpalatal suture and greater increase in the intercanine distance than the Hyrax expander.
(2) Similarity between the EDO and the Hyrax expander was observed for intermolar expansion, arch perimeter increases, and posterior teeth buccal inclination.

(3) The EDO may be indicated for patients with a need for greater maxillary intercanine expansion than intermolar expansion.

## ACKNOWLEDGMENTS

The authors thank Great Lakes Orthodontics for producing the expander with differential opening (EDO) for this study. The authors also thank the Coordination for the Improvement of Higher Education Personnel for the research financial support.

## REFERENCES

1. Haas AJ. Rapid expansion of the maxillary dental arch and nasal cavity by opening the midpalatal suture. Angle Orthod 1961;31:73-90.
2. Bazargani F, Feldmann I, Bondemark L. Three-dimensional analysis of effects of rapid maxillary expansion on facial sutures and bones. Angle Orthod 2013;83:1074-82.
3. Lagravere MO, Major PW, Flores-Mir C. Long-term dental arch changes after rapid maxillary expansion treatment: a systematic review. Angle Orthod 2005;75:155-61.
4. Lagravere MO, Major PW, Flores-Mir C. Long-term skeletal changes with rapid maxillary expansion: a systematic review. Angle Orthod 2005;75:1046-52.
5. Liu S, Xu T, Zou W. Effects of rapid maxillary expansion on the midpalatal suture: a systematic review. Eur J Orthod 2015;37:651-5.
6. Adkins MD, Nanda RS, Currier GF. Arch perimeter changes on rapid palatal expansion. Am J Orthod Dentofacial Orthop 1990;97:194-9.
7. Cozzani M, Guiducci A, Mirenghi S, Mutinelli S, Siciliani G. Arch width changes with a rapid maxillary expansion appliance anchored to the primary teeth. Angle Orthod 2007;77:296-302.
8. Kartalian A, Gohl E, Adamian M, Enciso R. Cone-beam computerized tomography evaluation of the maxillary dentoskeletal complex after rapid palatal expansion. Am J Orthod Dentofacial Orthop 2010;138:486-92.
9. da Silva Filho OG, Lara TS, de Almeida AM, da Silav HC. Evaluation of the midpalatal suture during rapid palatal expansion in children: a CT study. J Clin Pediatr Dent 2005;29:231-8.
10. Doruk C, Bicakci AA, Basciftci FA, Agar U, Babacan H. A comparison of the effects of rapid maxillary expansion and fan-type rapid maxillary expansion on dentofacial structures. Angle Orthod 2004;74:184-94.
11. Çörekçi B, Göyenç YB. Dentofacial changes from fan-type rapid maxillary expansion vs traditional rapid maxillary expansion in early mixed dentition. Angle Orthod 2013;83:842-50.
12. Belluzzo RHL, Faltin Junior K, Lascala CE, Vianna LBR. Maxillary constriction: are there differences between anterior and posterior regions? Dental Press J Orthod 2012;17:1-6.
13. Brunetto M, Andriani Jda S, Ribeiro GL, Locks A, Correa M, Correa LR. Three-dimensional assessment of buccal alveolar bone after rapid and slow maxillary expansion: a clinical trial study. Am J Orthod Dentofacial Orthop 2013;143:633-44.
14. Garib DG, Henriques JFC, Janson G, de Freitas MR, Fernandes AY. Periodontal effects of rapid maxillary expansion with tooth-tissue-borne and tooth-borne expanders: a computed tomography evaluation. Am J Orthod Dentofacial Orthop 2006;129:749-58.
15. Gurel HG, Memili B, Erkan M, Sukurica Y. Long-term effects of rapid maxillary expansion followed by fixed appliances. Angle Orthod 2010;80:5-9.
16. Pinheiro FHSL, Garib DG, Janson G, Bombonatti R, de Freitas MR. Longitudinal stability of rapid and slow maxillary expansion. Dent Press J Orthod 2014;19:70-7.
17. Garib DG, Garcia LC, Pereira V, Lauris RC, Yen S. A rapid maxillary expander with differential opening. J Clin Orthod 2014;48:430-5.
18. Garib D, Lauris RC, Calil LR, Alves AC, Janson G, de Almeida AM, et al. Dentoskeletal outcomes of a rapid maxillary expander with differential opening in patients with bilateral cleft lip and palate: a prospective clinical trial. Am J Orthod Dentofacial Orthop 2016;150:564-74.
19. Schulz KF, Altman DG, Moher D, CONSORT. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Med 2010;8:18: updated Guidelines.
20. Normando D, da Silva PL, Mendes ÁM. A clinical photogrammetric method to measure dental arch dimensions and mesio-distal tooth size. Eur J Orthod 2011;33:721-6.
21. Andrews LF. The six keys to normal occlusion. Am J Orthod 1972;62:296-309.
22. Saghaei M. Random allocation software for parallel group randomized trials. BMC Med Res Methodol 2004;4:26.
23. Fleiss JL. Analysis of data from multiclinic trials. Control Clin Trials 1986;7:267-75.
24. De Felippe NL, Da Silveira AC, Viana G, Smith B. Influence of palatal expanders on oral comfort, speech, and mastication. Am J Orthod Dentofacial Orthop 2010;137:48-53.
25. Gecgelen M, Aksoy A, Kirdemir P, Doguc DK, Cesur G, Koskan O, et al. Evaluation of stress and pain during rapid maxillary expansion treatments. J Oral Rehabil 2012;39:767-75.
26. Needleman HL, Hoang CD, Allred E, Hertzberg J, Berde C. Reports of pain by children undergoing rapid palatal expansion. Pediatr Dent 2000;22:221-6.
27. Lu Y, Belitskaya-Levy I. The debate about p-values. Shanghai Arch Psychiatry 2015;27:381-5.
28. Berger VW, Exner DV. Detecting selection bias in randomized clinical trials. Control Clin Trials 1999;20:319-27.
29. Wertz RA. Skeletal and dental changes accompanying rapid midpalatal suture opening. Am J Orthod 1970;58:41-66.
30. Gunyuz Toklu M, Germec-Cakan D, Tozlu M. Periodontal, dentoalveolar, and skeletal effects of tooth-borne and tooth-bone-borne expansion appliances. Am J Orthod Dentofacial Orthop 2015;148:97-109.
31. de Medeiros Alves AC, Garib DG, Janson G, de Almeida AM, Calil LR. Analysis of the dentoalveolar effects of slow and rapid maxillary expansion in complete bilateral cleft lip and palate patients: a randomized clinical trial. Clin Oral Investig 2016;20:1837-47.
32. de Almeida AM, Ozawa TO, Alves ACM, Janson G, Lauris JRP, Ioshida MSY, et al. Slow versus rapid maxillary expansion in bilateral cleft lip and palate: a CBCT randomized clinical trial. Clin Oral Investig 2016;21:1789-99.
33. Weber G. The Hyrax-system according to Biederman. Quintessenz 1970;21:69-70.
34. Claro CAA, Abrão J, Reis SAB, de Fantini SM. Correlation between transverse expansion and increase in the upper arch perimeter after rapid maxillary expansion. Braz Oral Res 2006;20:76-81.
35. Mutinelli S, Cozzani M, Manfredi M, Bee M, Siciliani G. Dental arch changes following rapid maxillary expansion. Eur J Orthod 2008;30:469-76.
36. Bishara SE, Staley RN. Maxillary expansion: clinical implications. Am J Orthod Dentofacial Orthop 1987;91:3-14.

37. Fried KH. Palate-tongue relativity. Angle Orthod 1971;41:308-23.
38. Sari Z, Uysal T, Usumez S, Basciftci FA. Rapid maxillary expansion. Is it better in the mixed or in the permanent dentition? Angle Orthod 2003;73:654-61.
39. Isaacson RJ, Ingram AH. Forces produced by rapid maxillary expansion: II. Forces present during treatment. Angle Orthod 1964;34:261-70.
40. Kahan BC, Rehal S, Cro S. Risk of selection bias in randomised trials. Trials 2015;16:405.