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RESEARCH ARTICLE

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Dentoskeletal changes because of rapid maxillary expansion in growing patients with tooth-borne and tooth-bone-borne expanders: A randomized clinical trial

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Abstract

Objectives: To compare, using cone-beam computed tomography, the dentoskeletal changes in rapid maxillary expansion with tooth-bone-borne (Hybrid Hyrax) and tooth-borne (Hyrax) appliances.

Setting and sample population: Forty-two patients who met the eligibility criteria (aged 11-14 years; transverse maxillary deficiency, posterior crossbite, and presence of upper first premolars and molars) were screened and allocated into two groups: HHG (treatment with Hybrid Hyrax) and HG (treatment with Hyrax).

Main outcome measures: The primary outcomes included nasomaxillary dimensional changes. CBCT was performed before and 3 months after the activation phase. Measurements were performed using Dolphin®. Baseline data were compared using one-way ANOVA. For intergroup comparison, ANCOVA was used to analyze the initial age, appliance activations (mm), and mid-palatal suture maturation data as covariates. Statistical significance was set at 5%.

Results: The premolar region in HHG showed increased skeletal changes than in HG, with the difference being 1.5 mm (0.5; 2.6) in the nasal cavity ($P = .004$), 1.4 mm (0.3; 2.5) in the nasal floor ($P = .019$), and 1.1 mm (0.2; 2.1) in the maxilla ($P = .022$). The molar region in HHG showed increased skeletal changes with the difference being 0.9 mm (0.2; 1.5) in the nasal cavity ($P = .005$), and 0.9 mm (0; 1.8) in the maxilla ($P = .042$) than in HG. Premolar inclination was higher in HG.

Conclusion: Hybrid Hyrax showed more skeletal changes and fewer dental side effects, especially in the first premolar region. The amount of activation influenced the higher nasal skeletal changes in the Hybrid hyrax group.

KEYWORDS
cone-beam computed tomography, maxillary expansion, orthodontic anchorage technique

1 | INTRODUCTION

Posterior crossbite associated with maxillary transverse deficiency is among the most discussed topics in orthodontics, with the prevalence being 13.3% in patients with mixed dentition.[1] Such discrepancies, if left untreated, may cause deviations in facial growth, compromising esthetics and resulting in a functional deviation of the mandible.[2] Therefore, early correction is important, and the treatment of choice is rapid maxillary expansion (RME). In the 1960s, successful outcomes were achieved by Haas,[3] and variations in the original design of the appliances were introduced to treat maxillary transverse deficiency. RME is considered safe and effective.[4]

However, RME can cause some side effects, such as buccal inclination of the posterior teeth, root resorption, and buccal bone thickness reduction.[5-8] To minimize these side effects and increase the skeletal changes of RME in growing patients, the Hybrid Hyrax expander was introduced.[9] The appliance shares the load of expansion between two mini-implants in the anterior palate and two posterior teeth (bands). The device is well accepted by patients; the risk of infection is low and the insertion of mini-implants is minimally invasive.[10] In addition, the device can be used with digital technology for better accuracy in appliance manufacturing.[11,12]

Despite its safety and efficacy,[13,14] there is a lack of evidence on the effects of Hybrid Hyrax on RME in growing patients. Initial discussions and analyses showed optimal results related to the effect of the appliance as a skeletal anchorage during maxillary protraction.[15-17] With respect to dentoskeletal changes during RME, the experimental data from a few published studies are rather controversial.[18-22] Therefore, there is a need to identify the orthopedic benefits of Hybrid Hyrax as it is more invasive than tooth-borne appliances.

This study was designed to evaluate and compare the dentoskeletal changes after RME using the Hybrid Hyrax expander and a tooth-borne expander (Hyrax) in growing patients.

2 | MATERIALS AND METHODS

2.1 | Trial design

The study was a two-arm parallel-group randomized controlled trial (RCT) performed at a single center. This study was approved by the Ethics Committee on Human Research of University of São Paulo – School of Dentistry, under the protocol number: 3.311.813. This study was also registered in the REBEC clinical trials (RBR-48g9q6).

2.2 | Participants, eligibility criteria, and settings

Patients aged 11 to 14 years were assessed for eligibility in the trial between January and July 2018. All participants included in the study met the following inclusion criteria: transverse maxillary deficiency, unilateral or bilateral posterior crossbite, age between 11 and 14 years, and presence of maxillary first premolars (right and left) and maxillary first permanent molars (right and left). Patients with a history of previous orthodontic treatment, presence of cleft lip or palate, systemic diseases, congenital deformity, loss of permanent teeth, or agenesis were excluded from the study. The study and the treatment involved were explained to all participants and their guardians. Signed informed consent was obtained from all participants.

2.3 | Interventions

The Hybrid Hyrax device used in this study (Hybrid Hyrax group - HHG; Figure 1A) was based on the device by Wilmes and Drescher.[9] Following the administration of local anesthesia, mini-implants (1.5 mm in diameter and 8 mm in length, Dental Morelli LTDA - Sorocaba/SP, Brazil) were inserted in the anterior region of the palate, posterior to the third palatal rugae line, and paramedian by 2 to 3 mm from the mid-palatal raphe.[13,23,24] The first maxillary permanent molars were selected as the posterior anchorage (bands) sites.

A standard triangle language (STL) file of the maxillary arch was created using an intraoral scanner (Trios Pod Version, 3Shape, Copenhagen, Denmark). The model was printed using a Form 2 printer (Form labs - Somerville, Massachusetts, United States), and the appliance was manufactured. Laser welding was used to join the bands to the expander screw (Hyrax type, 11 mm expander, Peclab, Belo Horizonte, Brazil) (Figure 1A). A similar digital workflow and an identical expander screw were used to manufacture the Hyrax appliance (Hyrax group - HG, Figure 1B).

All patients received treatment from the same orthodontist. In both groups, the first activation was a complete turn of the expander screw (0.8 mm), and thereafter, the activation was continued with two-quarter turns per day until the correction of the posterior crossbite was achieved with overcorrection (occlusion of the palatal cusp

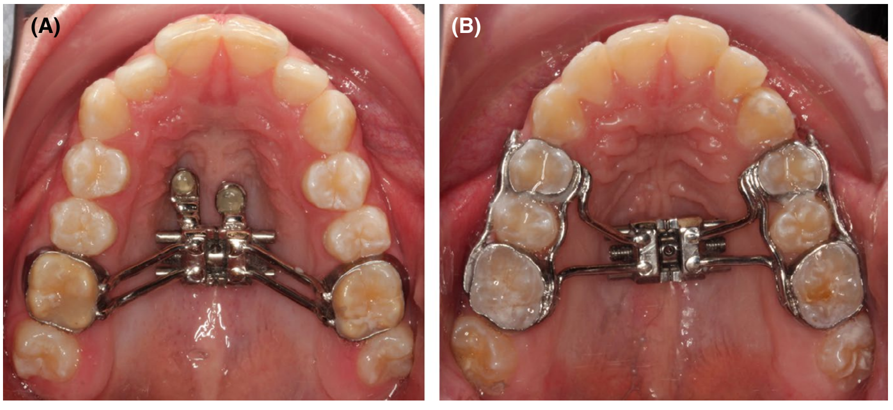

FIGURE 1 (A) Hybrid hyrax (HHG); (B) Hyrax (HG)

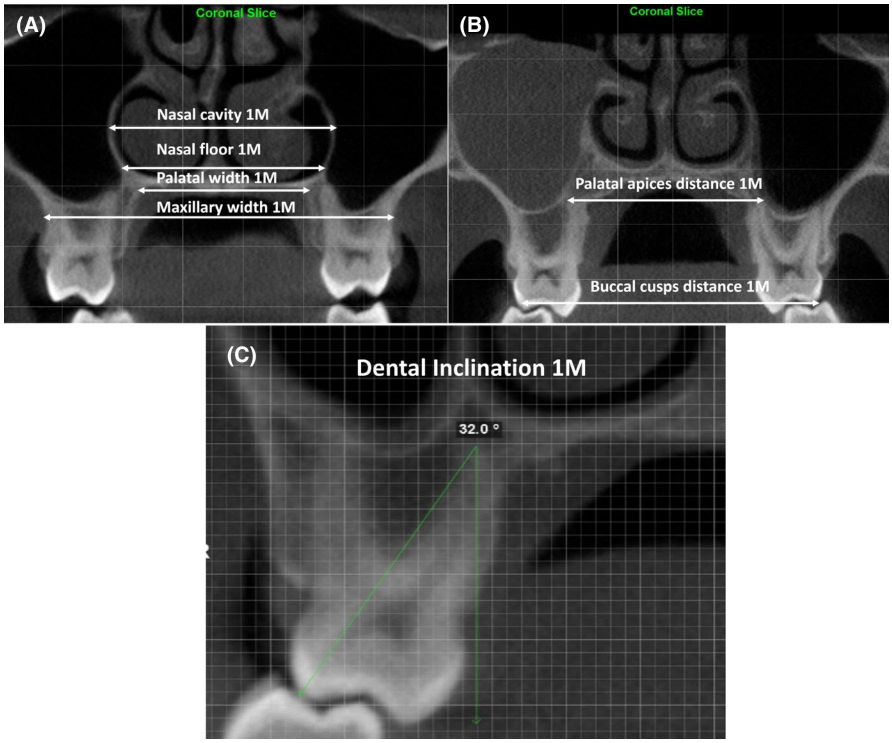

FIGURE 2 Coronal section of computed tomography. (A) nasomaxillary skeletal dimensions. (B) Dental inclination. (C) Dental dimensions. All measurements were assessed in the first premolar and first molar regions

of the maxillary first molars with the corresponding buccal cusp of the mandibular first molars). The activation data were counted such that each activation quarter was equivalent to 0.2 mm (according to the screw manufacturer).

Cone-beam computed tomography (CBCT) was performed to assess the dentoskeletal changes. CBCT was performed using iCAT (Imaging Sciences International, Hatfield, Pennsylvania) with the following settings: 120 kVp, 18 mA; exposure time, 8.9 s; voxel size, 0.2 mm^2[25]; and a field of view (FOV) of 160 × 60 mm. To minimize radiation exposure, CBCT scans were obtained only in the maxillary area. The participants were oriented with the Frankfurt horizontal plane parallel to the floor and the midsagittal plane perpendicular to the Frankfurt plane to standardize the head position during CBCT acquisition. Scans were obtained before treatment (T0) and 3 months after the activation phase (T1), based on a previously defined methodology.[5,7,18,26,27] The appliances and mini-implants were removed before CBCT acquisition in T1.

Data were exported to Dolphin software (Dolphin 3D version 11 premium, Dolphin Imaging and Management Solutions, Chatsworth, CA, USA) for analysis.

2.4 | Measurements and outcomes

The head position in the CBCT images (T0 and T1) was standardized by aligning the palatal plane (plane formed by the union of the points of the anterior nasal spine and posterior nasal spine) parallel to the floor in the sagittal section, and by positioning the vertical plane simultaneously in the anterior and posterior nasal spine in the axial section.[22] For the coronal section, the orientation was adjusted such that the nasal floor plane was parallel to the floor in the first molar region as the tomography scan was performed only in the maxillary region (Appendix S1). In T1, as the tomography was performed three months after the activation phase, it was possible to visualize the beginning of bone neoformation, and therefore, possible to locate the median point of the anterior and posterior nasal spine and perform the positioning of the tomography without difficulty in both sagittal and axial sections (Appendix S1). A previous study[22] used the orbital plane as a reference; however, for ethical reasons, as the tomography used in the present study was only for the maxillary region, the orbital plane was not considered.

All measurements, both primary and secondary outcomes were assessed at T0 and T1. The primary outcome was the magnitude of skeletal expansion (in millimeters) in the region encompassing the nasal cavity, nasal floor, palate, and maxilla based on the assessment of the coronal section of CBCT of all individuals at the level of the maxillary premolar and the first permanent molar regions (Figure 2A, Table 1). The measurements and their respective landmarks are presented in Table 1. As secondary outcomes, the dental changes were assessed by measuring the distances between the crowns at the buccal cusp tips and the apexes of the palatal roots (Figure 2B, Table 1). The axial inclinations (degrees) of the maxillary first premolars and first permanent molars were assessed (Figure 2C, Table 1).

2.5 | Sample size calculation

The sample size calculation was based on the skeletal changes observed in the coronal section of CBCT images, specifically in the premolar region.[18] The mean difference according to the literature was

TABLE 1 Description of landmarks for transverse maxillary assessment in the coronal section of the CBCT

Landmarks for transverse maxillary assessment	
Skeletal parameters	
Nasal cavity 1 PM	Nasal cavity width in the first upper premolar region. Width at the widest portion of nasal aperture in the first upper premolar region
Nasal floor 1 PM	Nasal floor width in the first upper premolar region. Width at the widest portion of nasal cavity floor in the first upper premolar region
Palatal width 1 PM	Palatal maxillary width in the first upper premolar region. Distance between the points located at the internal lateral boundary of the palate in the right and left sides, respectively, in the region of the first premolar
Maxillary Width 1 PM	Maxillary width in the first upper premolar region. Distance between the left and right maxillary bone convexities on the first upper premolar region
Nasal cavity 1 M	Nasal cavity width in the first upper molar region. Width at the widest portion of nasal aperture in the first upper molar region
Nasal floor 1 M	Nasal floor width in the first upper molar region. Width at the widest portion of nasal cavity floor in the first upper molar region
Maxillary width 1 M	Palatal maxillary width in the first upper molar region. Distance between the points located at the internal lateral boundary of the palate in the right and left sides, respectively, in the region of the first molar
Palatal width 1 M	Maxillary width in the first upper molar region. Distance between the left and right maxillary bone convexities on the first upper molar region
Dental parameters	
Inclination 14	First upper right premolar inclination. The angle formed between a reference line perpendicular to the ground and a line extending from the buccal tip cusp to the palatal apex of the upper right first premolar.
Inclination 24	First upper left premolar inclination. The angle formed between a reference line perpendicular to the ground and a line extending from the buccal tip cusp to the palatal apex of the upper left first premolar.
Buccal cusps distance 1 PM	Buccal cusp tips distance between upper first premolars. Distance between the buccal cusp tips of the right and left first premolars
Palatal apices distance 1 PM	Palatal Apices distance of upper first premolars. Distance between the apices of palatine root of permanent first premolars, on the right and left sides, respectively.
Inclination 16	First upper right permanent molar inclination. The angle formed between a reference line perpendicular to the ground and a line extending from the mesiobuccal tip cusp to the palatal apex of the upper right first molar.
Inclination 26	First upper left permanent molar inclination. The angle formed between a reference line perpendicular to the ground and a line extending from the buccal tip cusp to the palatal apex of the upper left first molar.
Buccal cusps distance 1 M	Buccal cusp tip distance between upper first permanent molars. Distance between the mesiobuccal cusp tips of the right and left first molars
Palatal apices distance 1 M	Palatal apices distance of upper first permanent molars. Distance between the apices of palatine root of permanent first molars, on the right and left sides, respectively.

3.33 mm,[18] with a standard deviation of 3.58 [mean of the standard deviation of two groups].[18] Considering a significance level of 0.05, and a type II error of 20%, the minimum number of individuals per group was determined to be 19, using a bicaudal test. Considering a sample loss of 10%, the final sample size was calculated to be 42, with 21 patients in each group.

2.6 | Randomization

Randomization was performed with numeric sequences generated by the Excel function "RANDOM". After the number generation, the list was rearranged in ascending order and divided into two groups, with the first part attributed to HHG and the second part attributed to HG. Prior to the randomization procedure, the individual names were converted into letters and numbers by another operator to ensure allocation concealment.

2.7 | Blinding

Before the assessment, all CBCT scans were deidentified with a coded ID number in Dolphin software® to avoid bias. Therefore, the examiner did not know which patient the images belonged to.

2.8 | Statistical analysis

Statistical analyses were performed using the Statistical Package for Social Sciences version 21 (SPSS Inc, Chicago, IL, USA). For the

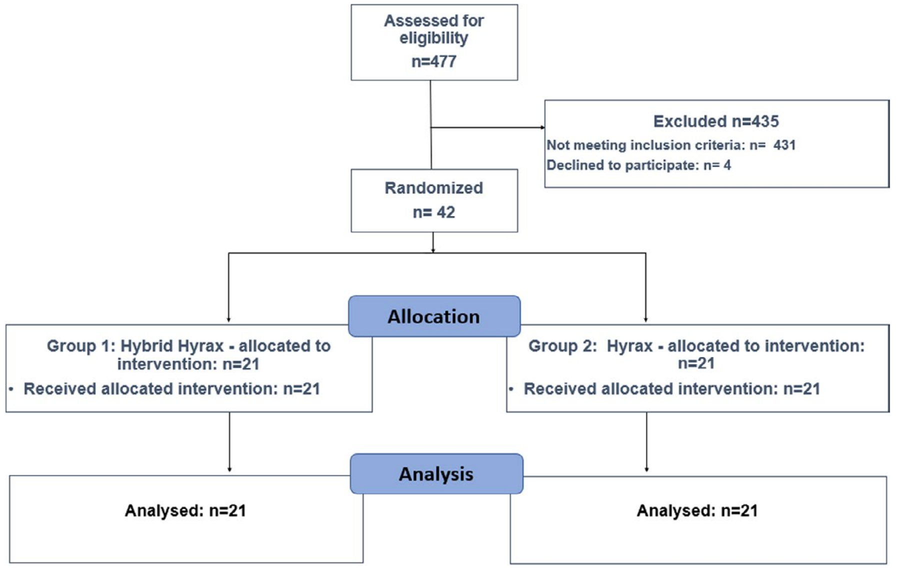

FIGURE 3 CONSORT flow diagram

intra-rater reliability analysis, 10 patients were randomly selected and reassessed after 4 weeks. The method error was calculated using the correlation coefficient of concordance. The normality assumption of the data was investigated using the Kolmogorov-Smirnov test (corrected by Lilliefors), and Levene's variance homogeneity was performed. Gender allocation was verified using Pearson's chi-squared test. We used *t*-tests for the baseline intergroup comparisons of initial age, appliance activation (mm), and mid-palatal suture maturation. The homogeneity of the clinical dentoskeletal baseline characteristics was verified using a one-way ANOVA. An analysis of covariance (ANCOVA) of the data, including initial age, appliance activation (mm), and mid-palatal suture maturation, was performed to adjust for the influence of these covariates on RME changes. A significance level of 5% was considered for all tests.

3 | RESULTS

A total of 477 patients were screened for this study, of which 431 did not meet the eligibility criteria and were excluded. Four patients opted out of the study (Figure 3). After a thorough clinical examination, 42 patients were considered eligible for the study and randomly assigned into two groups in a 1:1 ratio. There were no losses or exclusions after the allocation. RME was successfully performed in all treated patients. A stability rate of 100% was observed for the mini-implants in HHG.

3.1 | Baseline data

The baseline data are presented in Table 2. A total of 25 boys and 17 girls participated in the trial; HHG consisted of 9 boys and 12 girls, while HG consisted of 16 boys and 5 girls. The mean age of HHG and HG was 13.3 years (±1.3) and 13.2 years (± 1.4), respectively. The baseline characteristics of the dentoskeletal structure were similar, except for the variable maxillary width in the first molar region ($P = .008$; Table 2). In HHG, this value was measured to be 60.1 mm (± 4.6), and in HG, it was 56.9 mm (± 2.9).

3.2 | Numbers analyzed for each outcome, estimation, and precision

The mean concordance correlation coefficient for reliability was 0.9873 ± 0.14, which is considered an excellent correlation.[28]

ANCOVA showed a significant difference between the groups for skeletal effects, mainly in the premolar region (Table 3). HHG showed a higher increase than those in HG, with the mean difference being 1.5 mm (95% CI: 0.5; 2.6) in the nasal cavity ($P = .004$), 1.4 mm (95%CI: 0.3; 2.5) in the nasal floor ($P = .019$), and 1.1 mm (95%CI: 0.2; 2.1) in the maxilla ($P = .022$). In addition, HHG demonstrated a significantly higher increase in the molar region of nasal cavity width and maxillary width, with a mean difference of 0.9 mm (95%CI: 0.2; 1.5) ($P = .005$) and 0.9 (95%CI: 0; 1.8) ($P = .042$), respectively.

Regarding dental effects (Table 3), the inclination of the first premolars was more pronounced in HG. The difference between the groups (HHG - HG) was −3.2° (95%CI: −5.5; −0.9) ($P = .009$) on the right side and −2.5° (95%CI: −4.9; −0.1) ($P = .043$) on the left side. The increase in the distance between the premolar crowns (buccal cusp distance 1 PM) was higher in HG, with the difference being −1.8 mm (95%CI: −3.2; −0.4) ($P = .006$). There were no differences between the groups in terms of the distance between the apices of the palatal roots of the premolars. No differences were found in respect to the dental changes between the two groups in the molar region.

With respect to ANCOVA, in the isolated comparison of the covariables, there was no statistically significant difference between

TABLE 2 ANOVA's were employed for the intergroup comparison of the initial dentoskeletal measurements. T tests were used to compare age and appliance activations; and chi-square test was used to assess sex distribution. A significance level of 5% was considered

Parameter	Hybrid Hyrax – HHG Mean (SD)	Hyrax – HG Mean (SD)	Mean difference HHG - HG (CI95%. Lower bound; Upper bound)	P value
Gender				
Female (%)	12 (57.1%)	5 (23.8%)		.028*[a]
Male (%)	9 (42.1%)	16 (76.2%)		
Midpalatal suture maturation	3.2 (1.5)	3.1 (1)	0.1 (−0.6; 0.4)	.944[b]
Age (years)	13.3 (1.3)	13.2 (1.4)	−0.1 (−0.9; 0.7)	.7826[b]
Appliance activations (mm)	6.4 (1.6)	6.6 (1.2)	−0.2 (−1.1; 0.7)	.651[b]
Skeletal parameters				
Nasal cavity 1 PM (mm)	29.5 (2.9)	30.2 (3.6)	−0.8 (−2.8; 1.3)	.442
Nasal floor 1 PM (mm)	23.9 (3.4)	25.8 (4.2)	−1.9 (−4.3; 0.5)	.114
Palatal width 1 PM (mm)	15.9 (2.8)	16.8 (2.9)	−0.9 (−2.7; 0.9)	.344
Maxillary width 1 PM (mm)	40.4 (6.9)	41 (4.5)	−0.6 (−4.3; 3)	.737
Nasal cavity 1 M (mm)	32.8 (2.7)	31.8 (3.8)	1 (−1; 3.1)	.314
Nasal floor 1 M (mm)	27.9 (3.4)	27.8 (4.4)	0.1 (−2.4; 2.6)	.938
Palatal width 1 M (mm)	24.4 (3.6)	23.9 (3.9)	0.5 (−1.9; 2.8)	.672
Maxillary width 1 M (mm)	60.1 (4.6)	56.9 (2.9)	3.3 (0.9; 5.7)	.008*
Dental parameters				
Inclination 14 (°)	20.8 (9.4)	19.3 (8.4)	1.5 (−4.1; 7.1)	.590
Inclination 24 (°)	17.7 (8.3)	18.7 (6.7)	−0.9 (−5.7; 3.7)	.671
Buccal cusps distance 1 PM (mm)	42 (3.6)	41.6 (4.3)	0.5 (−2.1; 2.9)	.719
Palatal apices distance 1 PM (mm)	28.8 (3.9)	28.7 (4.3)	0 (−2.6; 2.6)	.995
Inclination 16 (°)	27.4 (5.3)	30.1 (7.4)	−2.7 (−6.7; 1.3)	.179
Inclination 26 (°)	30.9 (4.2)	29.1 (7.9)	1.9 (−2.1; 5.8)	.342
Buccal cusps distance 1 M (mm)	54.1 (3.9)	51.8 (4.4)	2.3 (−0.4; 4.9)	.088
Palatal apices distance 1 M (mm)	32.2 (3.2)	31.1 (3.5)	1.1 (−0.9; 3.2)	.293

Note: Abbreviations: CI, confidence interval; SD, standard deviation.

*$P < .05$; **$P < .01$; ***$P < .001$; ****$P < .0001$.

[a]P values for Pearson's chi-square test.

[b]P values for independent-t test.

the groups, according to the covariate age and midpalatal suture maturation (Appendix S2). The covariate appliance activation presented statistically significant differences in the variables (Appendix S2): nasal cavity 1 M ($P = .011$), nasal floor 1 M ($P = .049$), buccal cusps distance 1PM ($P = .001$), palatal apices distance 1PM ($P = .017$), and buccal cusps distance 1 M ($P = .010$).

4 | DISCUSSION

The present study evaluated dentoskeletal changes with RME using two types of appliances. CBCT was used for this assessment as it is considered to be a consolidated tool for observing the dentoskeletal changes after RME.[5-8,18,19,21,22] The FOV was limited to the maxillary region because of ethical concerns, especially in children.

CBCT results showed a more pronounced increase in the maxillary skeletal width in the premolar region with the Hybrid Hyrax appliance (Table 3), possibly because of skeletal anchorage.[14,22] In the molar region (Table 3), a significant difference was observed between the groups for maxillary width, with a higher increase in HHG than in HG (Table 3). Garib et al[22] found similar results and suggested that hybrid appliances had a higher orthopedic effect in this region. In our study, the maxillary width in the first molar region was already higher in HHG at T0 (baseline data, Table 2). In addition, the P-value of ANCOVA for intergroup comparisons in this region was close to 0.05 (Table 3), thus suggesting that skeletal effects were similar to those in the Hyrax-treated group, corroborating the results described by Gunyuz.[18]

The changes caused by Hybrid Hyrax in the nasal cavity were more significant (Table 3), and there were no differences according to appliance activations, baseline characteristics, and skeletal maturation between the groups. Conversely, Gunyuz et al[18] did not observe significant differences in the nasal skeletal dimensions between the Hybrid Hyrax and Hyrax groups. However, the main

TABLE 3 Intergroup comparison of dentoskeletal RME changes in HHG (T1-T0) and HG (T1-T0). ANCOVA result (5% significance), N = 42

Parameter	Hybrid Hyrax – G Mean (SD)	Hyrax – HG Mean (SD)	Mean difference HHG – HG (CI 95%. Lower bound; Upper bound)	*P* value between groups
Skeletal parameters				
Nasal cavity 1 PM (mm)	3 (0.4)	1.5 (0.4)	1.5 (0.5; 2.6)	.004**
Nasal floor 1 PM (mm)	2.9 (0.4)	1.6 (0.4)	1.4 (0.3; 2.5)	.019*
Palatal width 1 PM (mm)	3.7 (0.4)	2.5 (0.4)	1.2 (−0.1; 2.4)	.076
Maxillary width 1PM (mm)	3.1(0.3)	1.9 (0.3)	1.1 (0.2; 2.1)	.022*
Nasal cavity 1 M (mm)	2.4 (0.2)	1.5 (0,2)	0.9 (0.2; 1.5)	.005**
Nasal floor 1 M (mm)	2.1 (0.3)	1.5 (0.2)	0.6 (−0.2; 1.3)	.108
Palatal width 1 M (mm)	2.7 (0.5)	2.6 (0.5)	0.2 (−1.2; 1.5)	.769
Maxillary width 1 M (mm)	2.6 (0.3)	1.8 (0.3)	0.9 (0; 1.8)	.042*
Dental parameters				
Inclination 14 (°)	−0.6 (0.8)	2.7 (0.8)	−3.2 (−5.5; −0.9)	.009**
Inclination 24 (°)	0.3 (0.9)	2.8 (0.8)	−2.5 (−4.9; −0.1)	.043*
Buccal cusps distance 1 PM (mm)	3.9 (0.5)	5.7 (0.5)	−1.8 (−3.2; −0.4)	.006**
Palatal apices distance 1 PM (mm)	4.1 (0.5)	3.9 (0.5)	0.2 (0.5; 2.9)	.779
Inclination 16 (°)	3.9 (0.8)	3.2 (0.7)	0.8 (−2.9; 1.3)	.442
Inclination 26 (°)	3.1 (0.9)	2 (0.9)	1,1 (−3.8; 1.6)	.406
Buccal cusps distance 1 M (mm)	6.1 (0.4)	5.7 (0.4)	0.3 (−0.8; 1.2)	.533
Palatal apices distance 1 M (mm)	3.7 (0.3)	3.9 (0.3)	−0.2 (−1.5; 0.8)	.637

Note: Abbreviations: CI, confidence interval; SD, standard deviation; SE, standard error.
**P* < .05; ***P* < .01; ****P* < .001; *****P* < .0001.

limitation of this study was the small sample size, which may explain the differences in the results.

It is evident that the skeletal changes are more pronounced when activation is higher. In our study, the average appliance activation was approximately 6.5 mm. Garib et al[22] observed similar skeletal changes in the nasal cavity with Hybrid Hyrax, even with smaller activation (5.6 mm). These results enhance our understanding that skeletal changes are more pronounced in the nasal region with Hybrid Hyrax. Previous studies have shown a positive correlation between maxillary expansion and reduction in nasal airway resistance,[29] which is likely because of the increase in nasal cavity width. A randomized clinical trial showed a significantly greater reduction in nasal airway resistance with Hybrid Hyrax.[30] Motro et al[31] found a positive increase in air volume in individuals treated with Hybrid Hyrax at a more advanced age (17 years). Cheung et al[21] also reported positive results for Hybrid Hyrax with respect to upper airway enlargement. Although nasal airway resistance was not assessed in the present study, the observed skeletal nasal changes suggest a possible indication to consider hybrid anchorage in cases with upper airway obstruction. A recent clinical trial[32] presented better results with Hybrid Hyrax in terms of obstruction resolution after RME, when compared to tooth-borne appliances. More clinical studies are necessary to explain these possible benefits.[33]

Considering the individualized ANCOVA results for the covariate appliance activations (Appendix S2), it is understood that it influenced the RME skeletal results in the nasal cavity region, which was more pronounced in HHG. Motro et al,[31] one of the few studies that considered the number of activations as a factor that can influence the results of RME, observed a linear increase in nasal cavity airway volume as the number of activations increased. In the study by Cheung et al,[21] an increased orthopedic effect was observed in the nasal cavity with the use of Hybrid Hyrax, and this effect was probably associated with the increased amount of activation (9.1 mm). Based on the results of the present study, we suggest using Hybrid Hyrax with the highest possible number of activations for patients with increased nasal cavity obstruction.

It was observed that the number of activations also influenced dental side effects in the first premolar region in HG (greater distance between crowns), which can be explained by the anchorage being only tooth-borne. Although the results showed a greater distance between the palatal root in HHG in the first premolar region and in HG in the first molar region, these results were not clinically significant and the mean differences between the groups were exceedingly small. The number of activations is an important factor for understanding the effects of rapid maxillary expansion, which has rarely been explored in the literature.

Minimal changes in upper first premolar angulation were observed in the Hybrid Hyrax group (Table 3), which may be attributed to the mini-implant support that provides a better tension distribution and displacement of RME forces, reducing the dental side effects.[34] These findings corroborate previous studies.[8,18,19] In HG, a higher inclination was noted in the first premolars. Further evidence of this dental tipping was demonstrated by the increase in the distance between the premolar buccal cusps in the Hyrax group[18] (Table 3). Both groups presented increased buccal tipping of the first molars (Table 3), without significant differences, as observed previously.[18,22] This was expected, since with both the appliances, the first molars served as support teeth.[18,20]

In the present study, Hybrid Hyrax devices were well accepted by the patients,[10] showing more pronounced skeletal effects and reduced tooth inclination. The region for placement of the mini-implants was considered safe by several studies,[13,22,35,36] and provided a 100% stability rate. However, the most significant skeletal changes occurred only in the first premolar region, as well as the minor dental side effects, probably because of the mini-implants, which allowed the direct transmission of force at the center of resistance of the maxilla.[19,35] Since mini-implants aid in skeletal anchorage, the addition of more mini-implants seems to be beneficial to the treatment for patients aged 11 to 14 years. The study by Celenk-Coka[37] evaluated and compared the effects of RME using Hyrax devices and the MARPE technique (four mini-implants) in patients with a mean age of 13 years (similar to that in the present study). The authors observed better skeletal results with MARPE and fewer dental side effects, even in the molar region. However, the patient's pain and quality of life was not discussed in the study, which is necessary since MARPE is a more invasive procedure.

Therefore, this research raises many questions that should be answered by further randomized clinical investigations. More broadly, research will discern the effects of tooth-bone-borne devices and whether they should consist of two or four mini-implants in younger patients.

4.1 | Limitations and generalizability

The generalizability of these results might be limited to children aged 11 to 14 years and the types of devices used. These results should be considered cautiously in patients beyond this age range.

5 | CONCLUSIONS

- Tooth-bone-borne expander (Hybrid Hyrax) resulted in increased skeletal changes in the nasomaxillary structures in the first premolar region compared with a tooth-borne expander (Hyrax).
- Hybrid Hyrax showed higher increase in dimensions of the nasal cavity in the first premolar and first molar regions.
- Only minor tooth inclination changes were observed in the first premolars following RME with Hybrid Hyrax.
- No differences were observed between the groups in terms of dental changes after RME in the first molar region.
- The amount of activation influenced the more pronounced nasal skeletal changes on Hybrid Hyrax.

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CONFLICT OF INTEREST

The authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS

Pasqua BPM was responsible for the conceptualization, methodology, investigation, all clinical treatments, data collection and analysis, and writing the original draft. André CB made the formal analysis and methodology. Paiva CB helped in the methodology. Tarraf NE was responsible for English review and text editing. Wilmes B was responsible for methodology review and text editing. Rino-Neto J was the supervisor during all single steps of this research, since the design of the study till this paper elaboration. All the authors wrote and approved the paper for submission to the Orthodontics and Craniofacial Research.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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