Effects On Palatal Surface Area In Mixed Dentition Patients Treated With Leaf Expander And Rapid Palatal Expander, Compared To Untreated Subjects: A Randomised Clinical Trial

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Abstract

Aim To evaluate palatal surface effects induced by LE and RPE, alongside spontaneous changes in an untreated group, and to compare differences in canine and molar inclination among the three groups.

Materials and Methods This randomised clinical trial aimed to compare digital models pre- and post-treatment over 12 months in patients receiving tooth-borne Leaf Expander® (LE) and tooth-borne Hyrax-type maxillary expander (RPE) treatments, alongside untreated patients. Analysis included 24 LE patients (13 males, 11 females, mean age 8.5±1.5), 22 RPE patients (10 males, 12 females, mean age 7.9±1.6), and 17 untreated subjects (7 males, 10 females, mean age 8.1±1.2). Inclusion criteria comprised indications for maxillary expansion treatment, mixed dentition, CVMS ≤ 3, erupted first molars, and good oral hygiene. Digital models were obtained using an intraoral scanner pre- and post-treatment. Palatal surface, segmented into anterior, median, and posterior zones, and canine/molar inclination were measured at T0-T1 using VAM software as the primary and secondary endpoint. Statistical analyses involved paired-sample T-tests for intra-group comparisons and ANOVA tests with Bonferroni correction for inter-group comparisons.

Results Total surface increment for LE was 155.4 mm² (±49.92 mm²); for RPE, it was 187.7 mm² (±58.06 mm²); and for the control group, it was 55.35 mm² (±18.69mm²), significant in all three groups. Statistically significant differences were observed in the anterior, median, and posterior zones, as well as in the total surface increment, between the LE and control groups, and between the RPE and control groups. No significant difference was found between the LE and RPE groups in surface increments. The RPE group exhibited a significant increase in vestibular inclination for molars and canines post-therapy.

Conclusions No significant difference in palatal surface increment was found between the two experimental groups (LE and RPE); both demonstrated a significant increase in palatal surface. The greatest increment occurred in the median palate zone for both experimental groups. The increment in the untreated control group was not significant. Furthermore, the RPE group showed a greater inclination of permanent molars compared to those treated with LE, indicating that expansion with lighter and continuous forces may lead to fewer dental side effects.

KEYWORDS Headache, Maxillary expansion, Nasal Septum, Orofacial Pain, Primary Headache.

Introduction

Although the transverse maxillary deficiency is a thoroughly debated topic in the literature, its study remains a pivotal concern in orthodontics due to the multiplicity of etiological factors and available treatment modalities [Bucci et al., 2016]. Transverse maxillary deficit, often associated with unilateral or bilateral posterior crossbite, is a malocclusion that frequently occurs during deciduous and mixed dentition. Early diagnosis and treatment through palatal expansion are important to prevent potential complications, such as mandibular displacement, asymmetrical jaw growth, severe crowding of the permanent dentition, or compromised airway patency [Baccetti et al., 2005]. Over the years, various tooth- and bone-borne appliances have been tested for orthopedic maxillary expansion with different treatment protocols [Bucci et al., 2016]. Among the tooth-borne expanders, Rapid Maxillary Expansion (RME) and Slow Maxillary Expansion (SME) have been utilised for maxillary expansion. The effects of such devices have been extensively investigated in the literature, with both approaches demonstrating the ability to induce transverse changes in the maxilla [Bucci et al., 2016]. RME produces immediate mid-palatal suture separation using heavy and intermittent forces for a short duration, while SME employs intermittent and lower forces over an extended period [Ugolini et al., 2021]. In recent years, the Leaf Expander® (Leone, Sesto Fiorentino, Italy) has garnered attention for its ability to provide light, predetermined, and constant forces for gradual expansion [Lanteri et al., 2018; Ugolini et al., 2020; Nieri et al., 2021; Rutili et al., 2021; Cossellu et al., 2020]. Unlike conventional screw-based expanders, the Leaf Expander incorporates a nickel–titanium (Ni–Ti) leaf spring that regains its shape after compression due to activations, thereby delivering steady and calibrated forces for palatal expansion [Ugolini et al., 2020]. Compared to conventional RME, the Leaf Expander offers

advantages such as easy activation, minimal patient cooperation, and reduced levels of pain during the initial days following expander placement [Ugolini et al., 2020; Cossellu et al., 2019; Altuhafy et al., 2023; Rutili et al., 2022b; Nieri et al., 2021]. Recent studies have evaluated and compared the dentoskeletal effects between RME and the Leaf Expander, employing methods such as CBCT to demonstrate morphological changes in the maxilla aimed at verifying increases in jaw width and tooth inclinations [Abate et al., 2023; Maschio et al., 2023]. Additionally, other studies have assessed changes in maxillary morphology, including palate morphology and depth, using dental cast models. These studies have shown volumetric and superficial increases in the maxilla, which remained stable over the long term, with the palate exhibiting a wider, more harmonious, and shallower morphology. Greater transverse increases were observed in the regions of the permanent molars and primary molars [Primožič et al., 2013; Gracco et al., 2010]. To date no studies in literature have investigated the changes in the palatal surface after leaf expander and compare it with other expansion protocols. Thus, the aim of the present study was to assess the palatal surface area of growing patients who underwent different expansion protocols, specifically Rapid Maxillary Expansion (RME) and the Leaf Expander, comparing them with a control group that did not receive orthodontic treatments.

Material and methods

Study design and registration

The trial was registered at the ClinicalTrial.gov website (ClinicalTrials.gov ID: [NCT05135962]). The Protocol Registration System (PRS) was used to upload and update data about the clinical trial. The protocol followed guidance from the CONsolidated Standards of Reporting Trials (CONSORT) Guidelines [Schulz et al., 2010]. The study received approval from the Ethics Committee of the of the Fondazione IRCCS Ca'Granda, Ospedale Maggiore, Milan - Italy (No. 51/2021 dated 18.05.21). All procedures performed in this RCT involving human participants were in accordance with the ethical standards of the institutional and/or research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The parents or the legal guardians of each subject of the sample had to accept an informed written consent before the beginning of dental treatment.

Participants and study setting

The study was conducted at the Department of Surgical and Dental Sciences, IRCCS Cà Granda Foundation, University of Milan (center 1#), and at the Orthodontics Department of the University of Genoa (center 2#). and were recruited from November 2021 to November 2023. The inclusion criteria were as follows: a) patients with transverse maxillary deficiency intermolar width < 30 mm; b) mixed dentition phase with cervical vertebral maturation stage (CVMS) less than 3 [Baccetti et al., 2005]; c) fully erupted upper and lower first molars; d) upper second premolar cusps positioned apically to half pulp chamber (HPC) line of the ipsilateral upper first permanent molars on pre-treatment panoramic radiographs [Quinzi et al., 2021], indicating that the primary molars can serve as secure anchoring teeth for a minimum of 12 months; e) good general health, according to medical history and clinical judgment. Subjects with craniofacial malformations (including cleft lip or palate), a history of dental trauma, oral neoformations, and other oral cavity pathologies, or previous or concurrent orthodontic treatment were excluded from the study.

Intervention

Subjects assigned to the RPE group underwent rapid maxillary expansion using a tooth-borne Hyrax-type appliance. The Hyrax-type maxillary expander was a tooth-borne expansion appliance that is fixed to the upper second deciduous molars using bands and includes a midline 12-mm self-locking screw (Forestadent, Pforzheim, Germany; 0.9 mm, complete turn). The expansion screw was connected to the conventional molar bands or printed clasps, modeled surrounding the molars, via a 0.9mm stainless steel wire framework. The framework was soldered to the bands and extended on the palatal side to the deciduous canines. A qualified laboratory technician fabricated the expander. The Hyrax-type maxillary expander was bonded to the teeth with orthodontic band composite (Transbond Plus Light Cure Band Adhesive, 3M Unitek, Monrovia, CA, USA), light-cured using a halogen lamp (Optilux, Kerr, Orange, CA, USA) for 20 seconds per tooth. The expansion protocol was one quarter-turn twice a day (0.45 mm activation per day) until overcorrection with the maxillary lingual cusps contacting the mandibular buccal cusps. The expander was left passively for retention for a minimum of 6 months. At the time of appliance delivery, written and verbal oral hygiene instructions were given, including cleaning methods. Also, written informed consent was obtained from each patient or the parents. Subjects in the Leaf Expander group (LE) underwent maxillary expansion using the Leaf Expander® (Leone, Sesto Fiorentino, Italy), a device fixed to the upper second deciduous molars using bands. This expander features a double nickel-titanium leaf spring design, activated by turning a central chrome-cobalt steel screw, compressing two or more nickel-titanium leaf springs. The activation protocol involved selecting the maximum expansion quantity (in mm) based on the patient's transverse discrepancy, utilising a force of 450 grams. Each activation of the central screw produced 0.1 mm of expansion, requiring 10 activations for 1 mm. For the 6 mm type, a maximum of 30 activations was recommended, while the 9 mm type allowed up to 45 activations, typically distributed across three sessions. In addition, the screw was connected to conventional molar bands or printed clasps, modeled around the molars, via a 0.9mm stainless steel wire framework. The framework, extending to the palatal side and deciduous canines, was soldered to the bands. Fabricated by a qualified laboratory technician, the Leaf Expander was bonded to the teeth using orthodontic band composite (Transbond Plus Light Cure Band Adhesive, 3M Unitek, Monrovia, CA, USA). The bonding was light-cured using a halogen lamp (Optilux, Kerr, Orange, CA, USA) for 20 seconds per tooth. In both intervention groups, the amount of expansion was determined individually, depending on the severity of maxillary arch constriction.

Randomisation

Patients who fulfilled the eligibility criteria were enrolled and randomly allocated into the two groups using the Microsoft Excel (Microsoft, Redmond, WA, USA) random number generator. The LE group comprised patients who underwent Leaf Expander® (Leone, Sesto Fiorentino, Italy) treatment, and the RPE group comprised patients who

underwent rapid maxillary expansion treatment with tooth-borne Hyrax-type appliance.

Control

Patients who declined any form of treatment due to economic reasons were included in the untreated control group. In the control group, no orthodontic treatments were administered throughout the entire 12-month observation period due to treatment refusal primarily attributed to economic reasons. This period of observation, spanning from the initial selection of subjects (T0) to the conclusion of the observation period (T1), involved abstaining from any orthodontic interventions.

Outcomes

For all patients, full mouth intraoral scans were obtained using an intraoral scanner (3Shape Trios 3, 3Shape, Copenhagen, Denmark) before appliance placement (T0) and at the end of the retention period/treatment (T1), when the appliances were removed. The stereolithographic (.STL) files obtained from the scanner were imported into software package VAM software (VECTRA Analysis Module, version 3.7.6, Fairfield, New Jersey) to perform all measurements by the same operator. Each study cast scan was manually pre-processed to remove unwanted data artifacts from the analysis. The primary outcome was to the variation in palatal surface area. The palatal surface was calculated within the boundaries of the palate, whose limits were defined using the gingival plane and the distal plane. The gingival plane was created by passing through all points on the dentogingival junction selected for each dental element (distal, middle, mesial points). The distal plane was created by passing through two points furthest distal from the first permanent upper molars perpendicular to the gingival plane. The palatal surface obtained through this method was subsequently divided into three segments. The anterior segment ranges from the most mesial point of the deciduous canines to the most mesial point of the central incisors. The middle segment spans from the midpoint of the deciduous second molars to the most mesial point of the deciduous canines. Lastly, the posterior segment extends from the most distal point of the right and left first molars to the midpoint of the deciduous second molars. The two observers (FP and AB) carried out all measurements two times.

Sample size and statistical analysis

The sample size was calculated a priori for the two groups that received the expansion treatment. Based on the primary objective of comparing palatal surface area change assessed by calculating its surface area in both the treatment group and the active control group, the calculation was conducted using the software GPower 3.1 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). The sample size was determined considering a primary outcome of variations in the palatal surface of 30 mm2, derived from preliminary data from a pilot sample of 12 patients. To achieve a beta (ß) of 0.1 with alpha (α) set at 0.05 (power of 0.9), a sample size of at least 20 subjects was required for each treated group. Univariate and bivariate descriptive statistics for categorical variables were described as relative/absolute frequencies, while continuous ones as mean and standard deviation (SD). Bivariate descriptive statistics for continuous variables were estimated for the whole cohort or stratified by the Group (RPE, Leaf and Control) and the -pre vs -post measures. Shapiro Wilk test and Skewness and kurtosis test were performed to verify the distribution of continuous variables, considering $P<0.05$ for significance. Wilcoxon match-paired test assessed the intra-group differences for all parameters from T0 to T1 in both groups. Differences among the three groups were assessed using Analysis of Variance (ANOVA), with Tukey correction applied to mitigate the risk of Type I errors from multiple comparisons. Results were considered significant at a corrected significance level of α/3, where α represents the initial significance level (0.05), accounting for the three group comparisons.

All reported p-values were obtained by the two-sided exact method at the conventional 5 % significance level. The intra-class correlation coefficient (ICC) was calculated to assess the intrarater and interrater reliability. For intrarater reliability, measurements for palatal surface and dental inclination were conducted by one investigator (FP) using a specified approach detailed in the outcomes' subparagraph. The same investigator (FP) then repeated all measurements after a 4-week interval to evaluate the consistency of the assessments. For interrater reliability, a different investigator (AB) applied the same standardised procedure to palatal surface and dental inclination. The objective was to evaluate the concordance between different investigators for each parameter under examination. Data were analysed using Gaphpad Prims 10 (GraphPad Software, Inc., San Diego, CA), also used for chart making.

Results

Out of seventy-six patients screened for eligibility, three did not meet the inclusion criteria, two subjects declined to participate, and two were no longer willing to participate. Nineteen patients did not accept the treatment due to economic reasons: among these, 17 agreed to participate in the study as the untreated control group. Fifty patients were randomised into the two experimental groups. Therefore, sixty-seven patients (35 males and 32 females, with a mean age of 8.1±1.5 years) were enrolled and divided into three groups: 25 in the LE group, 25 in the RPE group, and 17 in the control group. One patient discontinued follow-up in the LE group, and three patients were lost to follow-up in the RPE group. Thus, 24 patients (13 males, 11 females, mean age of 8.5±1.5) were analysed from the LE group, 22 patients (10 males, 12 females, mean age of 7.9±1.6) from the RPE group, and 17 subjects (7 males, 10 females, mean age of 8.1±1.2) in the untreated control group. Refer to the CONSORT Flow Diagram in Figure 1 for a detailed illustration of participant flow, including the screening process, enrollment, and reasons for excluding some patients from the final analysis Eight patients reported bilateral crossbite. The mean treatment duration in the LE group was 8±3 months. in the RPE group, the mean active treatment duration was 10±2 days, and the total treatment duration was 9±1 months. The average number of appointments was 6±2 in the LE group and 8±1 in the RPE group. A Shapiro-Wilk, D'Agostino & Pearson and Kolmogorov-Smirnov tests were performed to determine the variables' distribution. They did not show evidence of non-normality for all the variables ($P>0.005$). The ICC for assessing palatal surface showed excellent reliability, with a 0.989 (95% CI, 0.985–0.993). Intrarater and interrater reliabilities were shown to be excellent with an intraclass correlation coefficient of 0.98 (95% confidence interval [CI], 0.84-0.99) and 0.93 (95% CI, 0.79-0.98) respectively for assessing palatal surface.

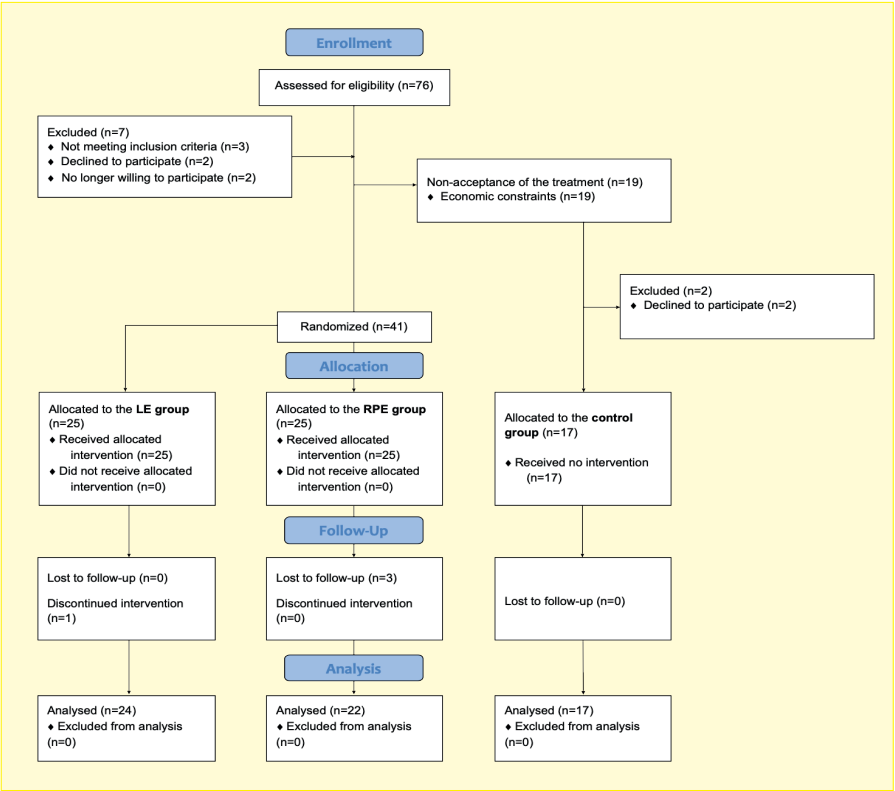

FIG. 1
Flow Chart according to the CONSORT guidelines(Schulz et al., 2010)

Regarding the Leaf group, the average surface increment in the anterior zone is 28 mm² (±11,25 mm²), in the median zone is 70 mm² (±31,66 mm²), and in the posterior zone is 57 mm² (±36,15 mm²) with a total surface increment of 155,4 mm² (±49,92 mm²). For the RPE group, the surface increment is 34,05 mm² (±12,71 mm²) in the anterior zone, 83,38 mm² (±40,51 mm²) in the median zone, 70,32 mm² (±33,22 mm²) in the posterior zone with a total surface increment of 187,7 mm² (±58,06 mm²). In the control group, the surface increment is 14,18 mm² (±3,24 mm²) in the anterior zone, 18,12 mm² (±9,3 mm²) in the median zone, 23,6 mm² (±11,34 mm²) in the posterior zone with a total surface increment of 55,35 mm² (±18,69 mm²). Paired t-test was performed for the intra-group differences for all parameters from T0 to T1 in both groups (Table 1). All the outcome measures significantly improved from T0 to T1 in both groups (P<0.005). We also investigated the differences between groups regarding variation from T0 to T1, as described in Table 2. There was not a significant difference in terms of variation from T0 to T1 between groups LE and RPE for all the outcomes (P>0.005). There was significant difference in terms of variation from T0 to T1 between LE and CNT and between RPE and CNT groups for all the outcomes (P<0.005). Statistically significant differences were observed in anterior, in the median and posterior zones between the Leaf and Control groups, as well as between the RPE and Control groups, and in the total surface increment.

Group	Outcome measure	T0	T1	P value
LE	Anterior Palatal Surface (mm2)	106.1±25.44	134.4±30.78	<0.001
	Median Palatal Surface (mm2)	697.7±144.9	767.8±149.4	<0.001
	Posterior Palatal Surface (mm2)	472.6±62.67	529.6±67.39	<0.001
	Total Palatal Surface (mm2)	1276±189.3	1432±208.8	<0.001
RPE	Anterior Palatal Surface (mm2)	104.7±22.6	138.7±21.73	<0.001
	Median Palatal Surface (mm2)	660.2±64.75	743.5±60.09	<0.001
	Posterior Palatal Surface (mm2)	499.3±36.55	569.6±37.7	<0.001
	Total Palatal Surface (mm2)	1264±95.3	1452±77.59	<0.001
CNT	Anterior Palatal Surface (mm2)	143.6±33.41	157.8±35.54	<0.001
	Median Palatal Surface (mm2)	470.2±72.5	488.4±76.92	<0.001
	Posterior Palatal Surface (mm2)	533.9±64.02	557±63.26	<0.001
	Total Palatal Surface (mm2)	1148±113.9	1203±118.5	<0.001
Continuous variables are expressed as means ± standard deviations. P<0.05 was considered for significance.				

TABLE 1 Within-group differences for all outcome measures from T0 to T1 in both groups.

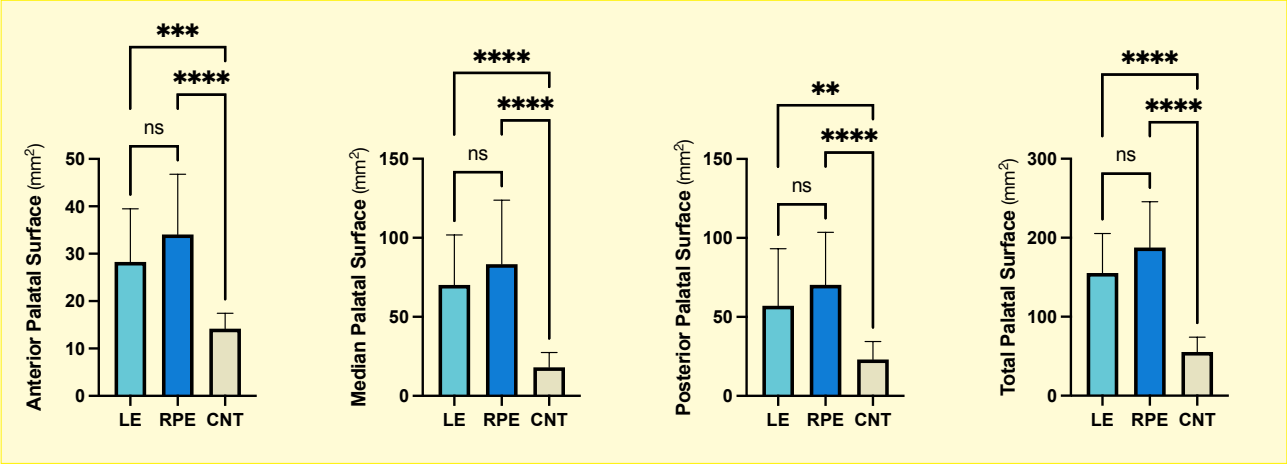

FIG. 2 Bar chart with error bars for standard deviation illustrating between-groups differences in terms of variation (Δ) from T0 to T1 for all outcome measures: A) anterior palatal surface, B) median palatal surface, C) posterior palatal surface, and D) total palatal surface.

No significant difference was found between the Leaf and RPE groups in surface increments (Figure 2).

Discussions

Palatal expansion is the treatment of choice for addressing the transverse deficiency of the upper jaw. In addition to correcting unilateral and bilateral crossbites, its use results in an increase in arch length, thereby providing more space for dental alignment. However, palatal expansion is often necessary even in the absence of crossbite and crowding, as a skeletal transverse deficiency can be masked by the dentition [McNamaraa, 2000]. Our study investigated the effect of using the Leaf Expander (LE) and Rapid Palatal Expander (RPE) on palatal surface area. It shows that similar changes in the palatal surface occur in growing patients treated with either RPE or Leaf expander devices when their initial transversal inter-molar width is ≤31mm. Interdental linear measurements [Paoloni et al., 2022] and distances between skeletal landmarks [Lanteri et al., 2018] have been used in the vast majority of previous publications comparing Leaf expander and RPE, for assessing upper arch and skeletal changes after expansion. However, they have the limitation of not capturing essential information concerning the palate, such as palatal surface area, which has been considered a reliable indicator of palatal and maxillary arch expansion [PrimožiČ et al., 2013, Bukhari et al., 2018]. Another limitation of these measurements is that they could be biased due to the axial inclination of the anchoring teeth and the alveolar bridge [PrimožiČ et al., 2013]. The present study is the first attempt to assess the effects of Leaf expander and RPE on surface area, divided into three portions to understand differences in the effects of the two treatments on the total surface and individual portions of the palate. Additionally, we included an untreated control group in the comparison to evaluate the spontaneous changes in the palatal surface following normal growth processes.

The RPE, as has been already and thoroughly mentioned, is one of the widely and long been used appliance for a wide variety of clinical conditions routinely faced by the orthodontist [McNamaraa, 2000]. The main clinical purpose of the RPE is the upper arch widening acting on both dentoalveolar and skeletal level. The biological response behind skeletal expansion occurs when the force applied to the teeth and the maxillary alveolar processes exceeds the limits needed for orthodontic tooth movement, causing the separation of the two maxillary bone halves. The Leaf expander is a device equipped with a screw whose activation generates the compression of two or more nickel-titanium leaf springs, which recover their original shape during deactivation [Lanteri et al., 2016]. It is considered a SME (slow maxillary expander),

				Tukey's multiple comparisons test		
Outcome measure	LE (N=24)	RPE (N=22)	CNT (N=17)	LE vs RPE p-value	LE vs CNT P value	RPE vs CNT P value
Anterior Palatal Surface (mm2)	28.25±11.25	34.05±12.71	14.18±3.24	0,1502	0,0002*	<0,0001*
Median Palatal Surface (mm2)	70.17±31.76	83.32±40.51	18.12±9.3	0,3361	<0,0001*	<0,0001*
Posterior Palatal Surface (mm2)	57±36.15	70.32±33.22	23.06±11.34	0,3047	0,0023*	<0,0001*
Total Palatal Surface (mm2)	155.4±49.92	187.7±58.06	55.35±18.69	0,0612	<0,0001*	<0,0001*
Continuous variables are expressed as means ± standard deviations. P<0.05 was considered for significance.						

TABLE 2 Between-groups differences in terms of variation (Δ) from T0 to T1 for all outcome measures.

generating continuous low-force systems applied over a long period of time [Rutili et al., 2021]. The sample considered includes growing patients, in mixed dentition with fully erupted first molars. According to the literature, this sample should ensure optimal expansion with good stability and few side effects [Serafin et al., 2023]. The treatment of transverse maxillary deficiency aims primarily for a skeletal effect, with disjunction of the median palatal suture overcoming the resistance offered by soft tissues and hard tissues at the level of the circum-maxillary sutures [Ghoneima et al., 2011]. In growing patients, the median palatal suture has not yet completed synostosis, allowing for the separation of the two hemimaxillae when subjected to high forces. Therefore, early treatment becomes essential [Baccetti et al., 2001]. Indeed, during growth, there is an increasing interdigitation at the level of the palatal sutures, median and circum-maxillary, which translates into increased resistance to expansion devices. Also, the stretched cheeks have been demonstrated to contribute to resistance to maxillary expansion [Küçükkeleş and Ceylanoğlu, 2003]. In our study, we selected a sample with cervical vertebral maturation stage (CVMS) less than 3. Research utilising the CVM method examined the effects of treatment timing on correcting transverse maxillary deficiency. It demonstrated that patients treated before reaching peak skeletal growth exhibited greater increases in craniofacial width compared to those treated during or after the peak. Specifically, early treatment induced more pronounced skeletal changes with greater long-term stability, while later treatment led to more dentoalveolar changes [Baccetti et al., 2001]. This highlights the significance of timing relative to skeletal maturation for achieving optimal outcomes in maxillary expansion [Baccetti et al., 2005].In this study, only patients with the second deciduous molars still present in the upper arch were included, as the expansion was carried out using these teeth as anchorage units. Numerous studies have demonstrated comparable skeletal effects when using devices anchored on deciduous teeth or permanent teeth(Ugolini et al., 2016). Furthermore, it is highlighted that the use of a maxillary expander anchored on the second deciduous molars reduces the likelihood of damage to the definitive elements, such as fenestrations, dehiscences, reduction in pulp chamber dimension, and temporary interruption of root development in elements with immature apices [Serafin et al., 2023; de Andrade Vieira et al., 2022; Maschio et al., 2023]. To ensure that the second deciduous molars could provide reliable anchorage throughout the course of treatment and during the retention phase, we evaluated the HPC line (Half Pulp Chamber Line), described as an imaginary line that crosses the pulp chamber of the first upper permanent molar. The more apical position of the cusp of the second premolar relative to the HPC line is considered a favorable prognostic factor for the stability of the anchorage for at least 12 months [Quinzi et al., 2021]. This method has demonstrated higher diagnostic accuracy than crown-to-root length ratio methods.

In the present study, it was observed that the palatal surfaces underwent a significant increase from T0 to T1 in all three groups examined, but the increase was greater in the treated subjects, particularly in the median palate zone. This finding aligns with existing literature, which demonstrates the significant impact of early orthodontic intervention on maxillary development compared to the absence of treatment [Ugolini et al., 2021]. The increase observed from T0 to T1 in the untreated group can be attributed to normal growth and developmental processes that occur spontaneously with advancing age, including skeletal growth, maturation, bone remodeling, and other biological factors [Cannavale et al., 2018]. These observations confirm the necessity of treatment with expanders in the presence of maxillary deficiency, as the increase in palatal surface area is significantly greater compared to that observed in untreated subjects. The absence of statistically significant differences between subjects treated with LE and those treated with RPE confirms what is reported in the literature on the use of slow expansion devices as an alternative to rapid expansion devices [Lanteri et al., 2018; Bucci et al., 2016; Lanteri et al., 2021]. Leaf Expander, allows for the expansion of the maxilla through dento-alveolar remodeling, with light and continuous forces, predetermined in intensity and direction, and which in younger subjects assumes properly orthopedic characteristics. The advantages of using slow expansion devices are mainly related to the reduction of undesirable effects compared to rapid-type devices. In particular, pain (especially in the first weeks) and bulkiness are reduced, making the LE a potentially more acceptable option for patients more sensitive to pain and anxiety, which is fundamental to ensure the long-term success of orthodontic treatments [Nieri et al., 2021; Rutili et al., 2022a; Ugolini et al., 2020; Cossellu et al., 2019]. The reduction of side effects and the overall patient experience are factors that can influence the clinical decision regardless of statistical significance. Recent studies demonstrate the importance of considering the patient's experience in the clinician's decision-making process.

Study Limitations

The sample includes patients in both the early and late phases of mixed dentition, introducing potential variations in the maturation phases of the median palatal suture, without being able to account for the wide individual variability. The sex of the included subjects may also influence the maturation of the median palatal suture as well as the resistance to expansion. Ideally, an individual assessment of suture maturation would have represented the optimal approach to standardise the sample. It is important to note that some participants were in the phase of tooth exchange, and consequently, some dental elements may have been missing, with the direct consequence of some measurements not being feasible. Furthermore, the limitation related to the small size of the sample could influence the generalisability of the results to a broader population. Studies with limited samples may not be representative of the diversity that can be found in a wider population. It should be noted that randomisation was only implemented for the two experimental groups (LE and RPE), while the untreated subjects added to the comparison were not randomised for ethical reasons. Another consideration concerns the duration of the follow-up. Shorter observation periods may not be sufficient to capture the long-term effects of the variables under examination. A prolonged follow-up would be desirable to provide a more complete view of the impacts over time.

Conclusions

No significant difference in palatal surface increment was demonstrated between the two experimental groups (Leaf Expander and RPE); both exhibited a significant increase in palatal surface. The greatest increment occurred in the median palate zone in both experimental groups. The increment in the untreated control group was not significant. The RPE

group demonstrated a greater inclination of permanent molars than those treated with the Leaf Expander, highlighting how expansion with lighter and continuous forces may result in fewer dental side effects.

Ethics approval and consent to participate

The study received approval from the Ethics Committee of the of the Fondazione IRCCS Ca'Granda, Ospedale Maggiore, Milan - Italy (No. 51/2021 dated 18.05.21). and informed consent was acquired from each subject before entering the study.

Consent to publish

Not applicable.

Availability of data and materials

The dataset supporting the conclusions of this article could be available by contacting the authors.

Competing interests

V.L declare she have competing financial and non-financial interests with Leone outside the present study. The other authors declare that they do not have any competing interests.

Fundings

This study was conducted without any external funding or support.

Authors' Contributions

Conceived and designed the study: A.B, V.Q, A.A, A.U; acquisition, analysis or interpretation: A.B, A.A, and F.P; drafting the work: A.B, V.Q, A.U and A.A; data collection: A.B, M.D and A.A; wrote the article: A.B, A.A. and M.D; critical revision of the article: A.B, V.Q, A.U, V.L and A.A; final approval of the article: A.U, V.L, A.B and A.A

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