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RESEARCH

Upper arch expansion and spontaneous upper first molar distorotation with Ni–Ti leaf springs and rapid maxillary expander compared to clear aligners

A randomized controlled trial

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Abstract

Purpose This study aimed to compare the distorotation of the upper first molars (U6) and the expansion of the upper dental arch achieved using clear aligners (CA), Leaf Expander® (LE; Leone, Sesto Fiorentino, Italy), and rapid maxillary expander (RME), all anchored to the second primary molars.

Materials and methods The research was structured as a superiority randomized controlled trial conducted in two academic medical centers in Italy. Participants included children in growth phase presenting transverse maxillary deficiency with intermolar width less than 30 mm, early mixed dentition with fully erupted upper first molars, and a cervical vertebral maturation stage (CVMS) 1 or 2, without systemic diseases or syndromes. Subjects were randomly assigned to one of the three treatment groups: CA, LE, or RME. The main variable measured was the distorotation of U6, with secondary variables including the width between canines, first molars, and second primary molars.

Results In all, 60 subjects were randomized equally into the three groups. Average treatment time was 8 ± 3 months for the LE group and 9 ± 1 months for the RME group ($p = 0.089$). Mean treatment time for the CA group was 15 months with a standard deviation of 2 months. A significant difference was observed in the number of clinical visits: 6 ± 2 for LE and 8 ± 1 for RME ($p < 0.001$). The RME group completed the active treatment phase in 10 ± 2 days, which was notably shorter than the 3.5 ± 0.71 months required for the LE group ($p < 0.001$). Analysis of variance (ANOVA) revealed statistically significant differences among the groups in terms of U6 distorotation ($p < 0.05$), whereas no significant differences were found for the expansion of the upper arch. Overall molar distorotation was highest in the LE group (11.73°), surpassing the RME group (6.22°), and was similar to the result observed in the CA group (11.89°).

Conclusion Both CA and maxillary expanders fixed to upper primary molars produced comparable levels of dentoalveolar expansion. The spontaneous distorotation of the U6 obtained with LE was similar to the planned distorotation achieved with CA and significantly higher than that observed with RME.

Keywords Transverse maxillary deficiency · Leaf expander · Rapid maxillary expansion · Clear aligners · Molar rotation

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Oberkiefererweiterung und spontane Distorotation des ersten Oberkiefermolaren mit Ni-Ti-Blattfedern und Rapid Maxillary Expander im Vergleich zu transparenten Alignern

Eine randomisierte kontrollierte Studie

Zusammenfassung

Zielsetzung Ziel dieser Studie war es, die Distorotation der oberen ersten Molaren (U6) und die Erweiterung des oberen Zahnbogens zu vergleichen, die mit an den zweiten Milchmolaren verankerten transparenten Alignern (CA), Leaf Expander® (LE; Leone, Sesto Fiorentino, Italien) und Rapid Maxillary Expander (RME) erreicht wurden.

Materialien und Methoden Die Studie wurde als randomisierte kontrollierte Überlegenheitsstudie konzipiert und in 2 akademischen medizinischen Zentren in Italien durchgeführt. Zu den Teilnehmern gehörten Kinder in der Wachstumsphase mit transversaler Oberkieferdefizienz mit einer Intermolarbreite von weniger als 30 mm, frühem Wechselgebiss mit vollständig durchgebrochenen oberen ersten Molaren und einem zervikalen Wirbelsäulenreifungsstadium (CVMS) 1 oder 2, ohne systemische Erkrankungen oder Syndrome. Die Probanden wurden randomisiert einer der 3 Behandlungsgruppen zugewiesen: CA, LE bzw. RME. Die wichtigste gemessene Variable war die Distorotation von U6, sekundäre Variablen waren die Breite zwischen den Eckzähnen, den ersten Molaren und den zweiten primären Molaren.

Ergebnisse Insgesamt wurden 60 Probanden gleichmäßig auf die 3 Gruppen verteilt. Die durchschnittliche Behandlungsdauer betrug 8 ± 3 Monate für die LE- und 9 ± 1 Monate für die RME-Gruppe ($p = 0{,}089$). Die durchschnittliche Behandlungsdauer für die CA-Gruppe betrug 15 Monate mit einer Standardabweichung von 2 Monaten. Ein signifikanter Unterschied wurde bei der Anzahl der klinischen Besuche beobachtet: 6 ± 2 für LE und 8 ± 1 für RME ($p < 0{,}001$). Die RME-Gruppe schloss die aktive Behandlungsphase in 10 ± 2 Tagen ab, was deutlich kürzer war als die $3{,}5 \pm 0{,}71$ Monate, die für die LE-Gruppe erforderlich waren ($p < 0{,}001$). Die Varianzanalyse (ANOVA) ergab statistisch signifikante Unterschiede zwischen den Gruppen hinsichtlich der U6-Distorotation ($p < 0{,}05$), während für die Erweiterung des Oberkieferbogens keine signifikanten Unterschiede festgestellt wurden. Die Gesamtdistorotation der Molaren war in der LE-Gruppe am höchsten (11,73°), übertraf die RME-Gruppe (6,22°) und war ähnlich wie in der CA-Gruppe (11,89°).

Schlussfolgerung Sowohl CA als auch maxilläre Expander, die an den oberen Milchmolaren befestigt wurden, erzielten vergleichbare Ergebnisse hinsichtlich der dentoalveolären Expansion. Die mit LE erzielte spontane Distorotation des U6 war ähnlich wie die mit CA erzielte geplante Distorotation und signifikant höher als die mit RME beobachtete.

Studienregistrierung Die Studie wurde unter ClinicalTrials.gov ID: [NCT05135962] registriert.

Schlüsselwörter Transversale Oberkieferdefizienz · Blattfeder · Schnelle Gaumennahterweiterung · Transparente Aligner · Molarenrotation

Introduction

Orthodontic interventions targeting transverse expansion of the maxillary arch and distorotation of the upper molars are essential objectives, particularly in mixed dentition cases [1, 39]. The orthodontic treatment of maxillary contraction and the distorotation of the upper molars are primary objectives, particularly in mixed dentition cases [11].

Transverse maxillary deficiencies often require expansion techniques, with a selection of appliances generally informed by both scientific literature and clinicians' individual experiences and preferences [2, 3, 39].

Recent evidence supports the efficacy of clear aligners (CA) in promoting transverse development of the upper arch, not only in adults [4, 15, 18, 21, 33, 42] but also in pediatric populations. In adults, aligners predominantly induce buccal tipping of the crowns rather than bodily movement, achieving an average predictability rate close to 70% [12, 15, 18, 30, 33, 38, 42]. Moreover, these systems have demonstrated notable efficiency in derotating the permanent upper first molars [13, 22, 23]. Such derotation can contribute to the increase of the upper arch perimeter and aid in correcting molar class II discrepancies [5].

Although aligners offer a controlled means of achieving both expansion and molar distorotation, the extent to which conventional devices such as the rapid maxillary expander (RME) and Leaf Expander® (LE) contribute to molar distorotation remains underexplored. Both devices are traditionally employed to correct transverse discrepancies. Some studies have suggested that when the RME is supported by the second primary molars, an increased distorotation effect on the first molars may occur [10, 14, 36]. Furthermore, current research indicates that maxillary expansion obtained using LE or RME with anchorage on the second deciduous molars can lead to spontaneous derotation of the upper first molars. Anchoring to primary teeth may also limit buccal tipping and enhance the distorotational movement of the first upper molars.

Such spontaneous molar distorotation is especially beneficial in crowded arches, potentially enlarging the perimeter and improving molar relationships [10, 36]. Moreover, deciduous molars are often preferable for anchorage as their use may preserve buccal bone thickness [14].

To date, only one randomized controlled trial (RCT) [1] has investigated the extent of spontaneous distorotation of the permanent first molars following maxillary expansion using appliances anchored to the second primary molars. The mentioned study compared the effects of the LE and the RME in growing patients. The findings revealed that both devices produced a significant increase in the transverse dimensions of the maxillary arch, with no statistically significant differences between them. Notably, both expansion methods induced spontaneous distorotation of the upper first molars, and this effect was more pronounced in the LE group, especially in patients presenting with posterior crossbite.

Thus, given the increasing use of clear aligners in the pediatric population, the aim of this study was to compare the effects of CA, LE, and RME anchored on maxillary second primary molars on upper first molar distorotation (U6) and transverse arch development. The null hypothesis (H0) proposed that no significant differences would be found in U6 distorotation or arch width changes among the three intervention groups.

Materials and methods

Study design and registration

This randomized clinical trial was officially recorded on the ClinicalTrials.gov platform under the identifier (NCT05135962). All information related to the study, including updates, was submitted using the Protocol Registration and Results System (PRS). The research adhered to the recommendations outlined in the CONSORT (CONsolidated Standards of Reporting Trials) 2010 guidelines for randomized studies [34].

Prior to initiation, ethical approval was obtained from the Institutional Ethics Committee of Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico in Milan, Italy (reference number 51/2021, issued on 18 May 2021). All clinical procedures conducted throughout the RCT complied with the ethical principles articulated in the 1964 Declaration of Helsinki and its subsequent revisions, as well as with applicable institutional and international regulations.

Before starting treatment, informed written consent was required from each participant's parent or legal guardian, ensuring their understanding and voluntary agreement to participate in the study.

Participants and study setting

The trial was carried out across two academic institutions in Italy: the Department of Surgical and Dental Sciences at the IRCCS Ca' Granda Foundation, University of Milan (center 1), and the Department of Orthodontics at the University of Genoa (center 2). Participant recruitment was conducted from November 2021 until November 2023.

Eligibility criteria for inclusion in the study were defined as follows: (a) presence of transverse maxillary deficiency with intermolar width less than 30 mm; (b) early mixed dentition with a cervical vertebral maturation stage (CVMS) < 3 [2]; (c) complete eruption of the upper and lower first permanent molars; (d) upper second premolars exhibiting cusp tips positioned apically to the half-pulp chamber (HPC) level of the ipsilateral maxillary first permanent molars on pretreatment panoramic radiographs—indicating adequate root support of the second deciduous molars for anchorage for at least 12 months [31]; and (e) overall systemic health based on clinical and medical assessment.

Exclusion criteria included subjects with craniofacial anomalies such as cleft lip and/or palate, prior orthodontic therapy, history of orofacial trauma, presence of oral pathologies, and those currently undergoing any form of orthodontic treatment.

Intervention

Participants assigned to the RME group underwent rapid palatal expansion using a hyrax-style tooth-borne expander (Fig. 1a). This device was cemented on the maxillary second deciduous molars through orthodontic bands and incorporated a self-locking midline expansion screw (12 mm; Forestadent, Pforzheim, Germany) with 0.9 mm pitch per full turn. The activation protocol consisted of one quarter-turn administered twice daily, resulting in a daily expansion of 0.45 mm. Activation continued until overcorrection was achieved, defined by contact between the palatal cusps of the upper molars and the buccal cusps of the lower molars. Following the active phase, the appliance remained in place passively for at least 6 months to allow for retention.

In the LE group, subjects were treated with the Leaf Expander® (LE; Leone, Sesto Fiorentino, Italy), a fixed appliance banded to the upper second deciduous molars (Fig. 1b). The device featured a central screw mechanism composed of chrome–cobalt steel, which, when turned, compressed a set of nickel–titanium leaf springs, typically two or more, providing continuous low-force activation of 900 g.

The prescribed activation protocol was tailored to the individual's transverse deficiency. A total force of 900 g was delivered during expansion. Each activation of the central screw corresponded to 0.1 mm of arch widening, mean-

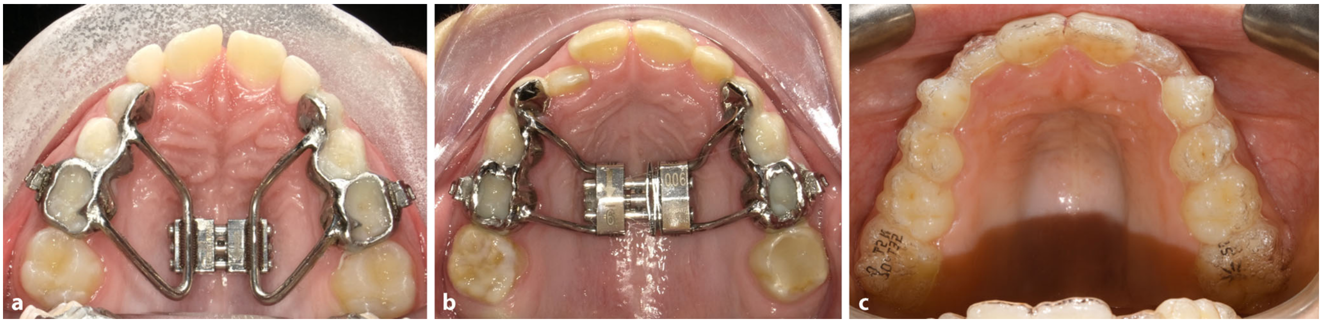

Fig. 1 **a** Hyrax expander bonded to the second primary molars, **b** leaf expander (900 g) bonded to the second primary molars, **c** clear aligner on the upper arch

Abb. 1 **a** Hyrax-Expander, angebracht an den zweiten Milchmolaren, **b** Blattexpander (900 g), angebracht an den zweiten Milchmolaren, **c** transparente Aligner auf dem Oberkiefer

ing 10 activations produced 1 mm of expansion. For the 6 mm model, a maximum of 30 activations was recommended, while the 9 mm version allowed up to 45 activations, usually divided into three clinical sessions.

For patients assigned to the CA, group, orthodontic treatment was conducted using the Invisalign® system (Align Technology, Inc., Santa Clara, CA, USA; Fig. 1c). Patients were instructed to wear the aligners between 22 and 24 h per day throughout treatment. Treatment plans were developed using the ClinCheck® software (Align Technology, Inc.), based on digital models oriented to the patient's natural occlusal plane. The mean treatment time for the CA groups was 15 months with a standard deviation of 2 months.

Customized attachments were designed to improve aligner retention and to control tipping forces, ensuring torque compensation and avoiding an increased curve of Wilson [39, 41].

Expansion protocols involved 0.15 mm of extrusion combined with an additional 2°of buccal root torque per stage; treatment was carried out until the palatal cusps of the maxillary posterior teeth were aligned with the buccal cusps of the mandibular posterior teeth. Regarding the amount of distorotation, it was individually planned so that the line connecting the distobuccal and mesiopalatal cusps was aligned with the deciduous canine of the contralateral hemiarch.

Randomization and blinding

Participants who met the inclusion criteria were enrolled and randomly assigned to one of the three intervention arms using a randomization list generated in Microsoft Excel (Microsoft, Redmond, WA, USA). A combination of block randomization and stratification ensured an even distribution of patients across the three treatment groups within both study centers. Although orthodontists involved in treatment delivery were unaware of the randomization sequence, blinding was not feasible due to the visibly distinct designs of the appliances. As a result, clinicians administering the treatments remained unblinded throughout the study.

Measurements taken from the digital models were independently conducted by two calibrated operators (A.A. and A.B.), both of whom were blinded to the type of appliance used in each case. This was done to eliminate potential bias in outcome assessment.

Outcomes

For all enrolled patients, complete digital intraoral scans were obtained using the 3Shape Trios 3 scanner (3Shape, Copenhagen, Denmark) at baseline (T0), prior to appliance placement, and after the active phase or retention period (T1), upon removal of the device.

The resulting stereolithographic (.STL) files were imported into Mimics Materialize¬Æ 26.0 (Materialise, Leuven, Belgium), a reverse modeling software used for three-dimensional analysis. Measurements were conducted independently by two operators (A.A. and A.B.), following protocols previously validated in the scientific literature for landmarks identification and metric evaluation [10, 19].

On the upper digital dental model, the following anatomical landmarks were identified (Fig. 2a):

- R1 and R2: two reference points along the median palatal raphe. R1 was placed near the second palatal rugae, while R2 was located 10 mm posterior to R1,
- 53 and 63: cusp tips of the upper right and left deciduous canines, respectively, and
- 55 and 65: mesiobuccal cusps of the upper right and left second deciduous molars.

On the first upper permanent molars:

- DV16 and DV26: distobuccal cusps of the upper right and left first molars,

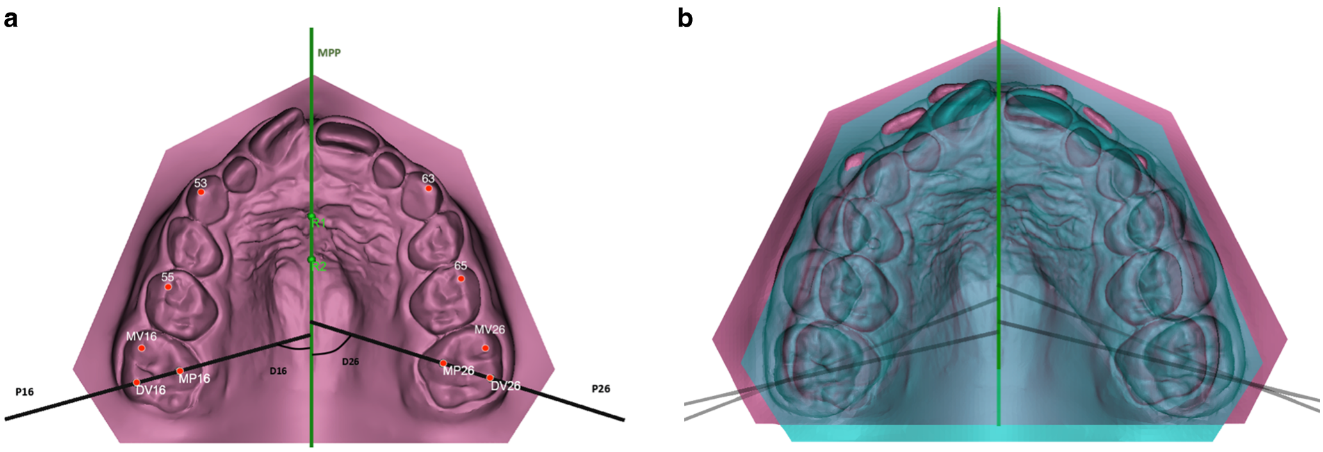

Fig. 2 **a** Representation of the midpalatal plane (MPP), delineated by connecting two defined landmarks along the palatal raphe: R1, located adjacent to the second palatal ruga, and R2, situated 10 mm posterior to R1. The P16 plane was constructed through the distobuccal (DV16) and mesiopalatal (MP16) cusps of the right first molar; similarly, the P26 plane was created through the DV26 and MP26 cusps of the left first molar. **b** Three-dimensional depiction of planes MPP, P16, and P26 used to assess the rotational changes of the upper first molars

Abb. 2 **a** Darstellung der mittleren Gaumenebene (MPP), die durch die Verbindung zweier definierter Orientierungspunkte entlang der Gaumennaht abgegrenzt wird: R1, neben der zweiten Gaumenfalte gelegen, und R2, 10 mm hinter R1. Die P16-Ebene wurde durch die distobukkalen (DV16) und mesiopalatinalen (MP16) Höcker des rechten ersten Molaren konstruiert; analog dazu wurde die P26-Ebene durch die DV26- und MP26-Höcker des linken ersten Molaren erstellt. **b** Dreidimensionale Darstellung der Ebenen MPP, P16 und P26, die zur Beurteilung der Rotationsveränderungen der oberen ersten Molaren verwendet wurden

- MV16 and MV26: mesiobuccal cusps of the right and left first molars, and
- MP16 and MP26: mesiopalatal cusps of the right and left first molars.

The primary outcome was the distorotation of the upper first molar (U6), defined by the angular measurement between a reference line connecting the distobuccal and mesiopalatal cusps and the mid-palatal plane (MPP).

For angular assessment (Fig. 2b), the following planes were defined:

- MPP (midpalatal plane): a plane intersecting R1 and R2 and perpendicular to the model's base,
- P16: a plane passing through DV16 and MP16, and
- P26: a plane passing through DV26 and MP26.

Angular values were calculated as D16 and D26, corresponding to the angles formed by the intersection of the MPP with planes P16 and P26, respectively.

Secondary outcomes involved linear dental measurements, including the following:

- Intercanine width (53–63): the distance between the cusp tips of the upper deciduous canines,
- Intermolar width (MV16–MV26): the distance between the mesiobuccal cusp tips of the upper first molars, and
- Interdeciduous second molar width (55–65): the distance between the cusp tips of the upper second deciduous molars.

Sample size and statistical analysis

The sample size calculation was conducted using G*Power software (version 3.1.9.4; Franz Faul, University of Kiel, Germany). The primary outcome variable used for the power analysis was the distorotation angle of the upper first molars. As no prior published data were available, the calculation was based on pilot data from an internal sample of 15 patients, which reported the following mean values and standard deviations: RME group (mean = 7.56°, standard deviation [SD] = 2.84), LE group (mean = 11.06°, SD = 2.27), and clear aligner group (mean = 15.33°, SD = 3.24).

Using a two-tailed test with a 5% significance level, 80% statistical power, and a 20% beta error, the analysis determined that a minimum of 12 patients per group would be necessary to detect significant differences. Statistical analysis was performed using SPSS software for Windows (version 23.0; IBM, Armonk, NY, USA).

The Shapiro–Wilk test was applied to evaluate the normality of distribution for continuous variables, with a significance threshold of $P < 0.05$ indicating nonnormality. Group comparisons at baseline for the clear aligner (CA), Leaf Expander® (LE), and rapid maxillary expander (RME) groups were carried out using one-way analysis of variance (ANOVA) to assess sample homogeneity.

For outcome comparisons among the groups, ANOVA was used with post hoc Tukey correction for the risk of type I errors due to multiple comparisons. A corrected alpha

Fig. 3 Consolidated Standards of Reporting Trials (CONSORT)-compliant flow diagram outlining participant enrollment, group allocation, treatment execution, and follow-up, including reasons for patient exclusion and dropout across the three study arms

Abb. 3 CONSORT(Consolidated Standards of Reporting Trials)-konformes Ablaufdiagramm zur Darstellung von Teilnehmerrekrutierung, Gruppenzuteilung, Behandlungsdurchführung und Nachbeobachtung, einschließlich Ausschlussgründen und Ausscheiden von Patienten in den 3 Studienarmen

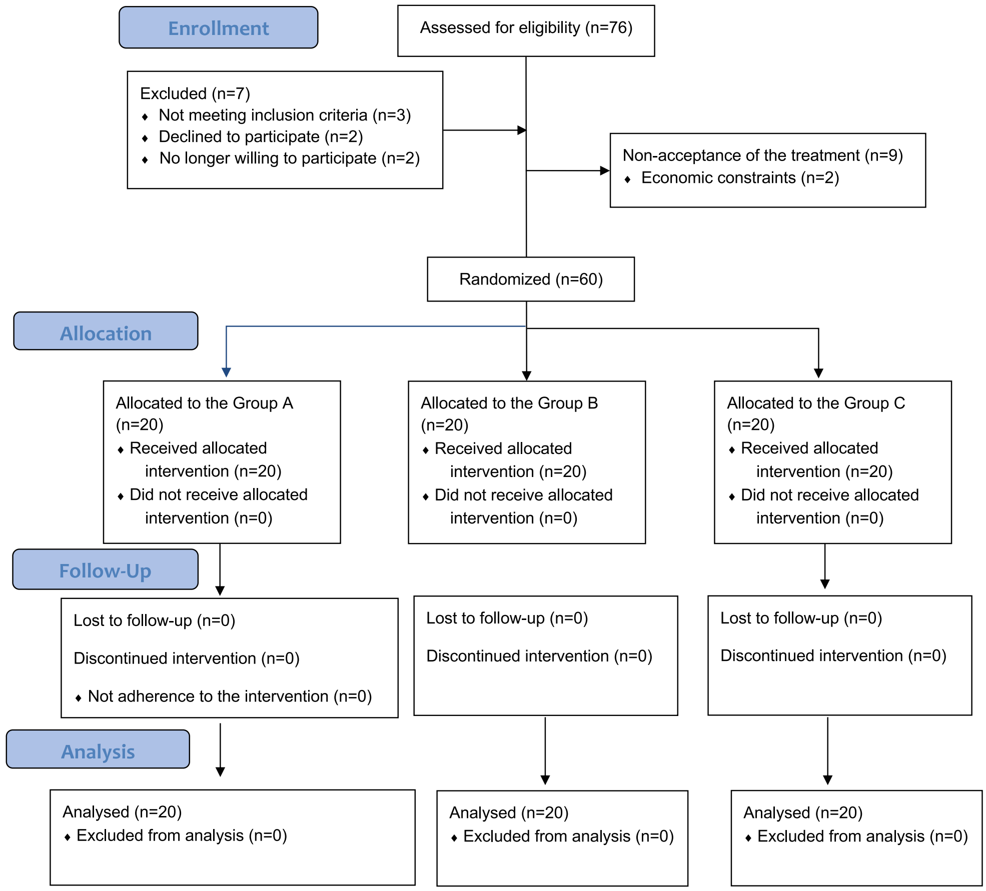

Table 1 Baseline (T0) comparison of various dental measurements (angles and widths) among clear aligner (CA), Leaf Expander® (LE), and rapid palatal expansion (RPE) groups

Tab. 1 Ausgangswert (T0) Vergleich verschiedener Zahnmessungen (Winkel und Breiten) zwischen den Gruppen Clear Aligner (CA), Leaf Expander® (LE) und schneller Gaumennahterweiterung (RPE)

Variables	CA (*N* = 20)	LE (*N* = 20)	RPE (*N* = 20)	Tukey's multiple comparison test CAT vs LE *P*-value	 CAT vs RPE *P*-value	 LE vs RPE *P*-value
DV1.6—MP 1.6 to palatine raphe (°)	76.13 ± 2.96	76.97 ± 2.32	77.89 ± 1.97	0.5316	0.0700	0.4689
DV2.6—MP 2.6 to palatine raphe (°)	76.88 ± 2.73	77.50 ± 2.67	77.43 ± 2.78	0.7568	0.8023	0.9965
Intercanine width (Cusp level) (mm)	30.62 ± 2.39	30.20 ± 2.48	29.49 ± 2.47	0.8488	0.3180	0.6343
Interprimary first molar width (Cusp level) (mm)	36.82 ± 2.44	36.95 ± 95	36.21 ± 2.18	0.9789	0.6618	0.5389
Interprimary second molar width (Cusp level) (mm)	42.51 ± 2.46	42.47 ± 2.10	41.18 ± 2.55	0.9981	0.1914	0.2124
Intermolar width (Cusp level) (mm)	48.70 ± 2.81	48.35 ± 1.86	47.16 ± 1.93	0.8809	0.0851	0.2178

Continuous variables are expressed as means ± standard deviations. $P < 0.05$ was considered for significance

Table 2 Differences among T0–T1 variation (Δ) in primary and secondary outcome measures
Tab. 2 Unterschiede in den T0–T1-Variationen (Δ) bei primären und sekundären Endpunkten

Outcome measure	CA (*N* = 20)	LE (*N* = 20)	RPE (*N* = 20)	CAT vs LE *P*-value	CAT vs RPE *P*-value	LE vs RPE *P*-value
DV1.6—MP 1.6 to palatine raphe (°)	–8.10 ± 1.20	–5.86 ± 1.29	–3.12 ± 0.86	*< 0.0001**	*< 0.0001**	*< 0.0001**
DV2.6—MP 2.6 to palatine raphe (°)	–8.15 ± 1.45	–5.87 ± 1.60	–3.10 ± 0.73	*< 0.0001**	*< 0.0001**	*<0.0001**
Interprimary canine width (Cusp level) (mm)	+ 4.60 ± 0.68	+5.10 ± 1.00	5.30 ± 2.39	0.2719	0.0798	0.7980
Interprimary first molar width (Cusp level) (mm)	+4.99 ± 0.92	+5.38 ± 1.22	+5.68 ± 0.77	0.4249	0.0740	0.5944
Interprimary second molar width (Cusp level) (mm)	+4.94 ± 0.95	+5.22 ± 1.14	+5.67 ± 1.05	0.6719	0.0780	0.3701
Intermolar width (Cusp level) (mm)	+6.10 ± 0.49	+6.12 ± 0.36	+6.41 ± 0.44	0.9854	0.0664	0.0949

CA clear aligner, *LE* leaf Expander®, *RPE* rapid palatal expansion
Continuous variables are expressed as means ± standard deviations. $P < 0.05$ was considered for significance

level of α/3 (with α = 0.05) was applied to account for the three pairwise comparisons.

To evaluate measurement reliability, intraclass correlation coefficients (ICC) were calculated. Intrarater reliability was assessed by repeating all measurements after 4 weeks by the same examiner (A.A.), while interrater reliability was determined by having a second examiner (A.B.) replicate all measurements after a 15-day interval.

Results

A total of 60 patients were included in the study, consisting of 30 males and 30 females, with a mean age of 7.8 ± 1.2 years. Participants were evenly distributed across the three groups: 20 (12 males and 8 females) patients with a mean age of 8.1 ± 1.0 years received CA, 20 patients(10 females and 10 males) with a mean age of 7.5 ± 1.3 years were assigned to the LE group, and 20 patients (11 females and 9 males) with a mean age of 7.8 ± 1.4 years to the RME group. The flow of participants through the trial, including recruitment, allocation, and exclusions, is detailed in the Consolidated Standards of Reporting Trials (CONSORT) flowchart in Fig. 3.

No statistically significant baseline differences were identified among the three groups at T0 for any measured variable, confirming initial homogeneity of the sample (Table 1).

ANOVA revealed significant differences in U6 distorotation among the groups ($p < 0.05$). The mean distorotation angles were –8.10° ± 1.20° for the CA group, –5.86° ± 1.29° for the LE group, and –3.12° ± 0.86° for the RME group (Table 2). Post hoc Tukey tests showed that the CA group achieved significantly greater distorotation than both the LE ($p < 0.0001$) and RME ($p < 0.0001$) groups, while LE also significantly outperformed ($p < 0.0001$) RME in the distorotation of the upper first molars (Fig. 4a).

Regarding transverse changes, no significant differences were observed between the groups for upper intercanine width (53–63), interdeciduous second molar width (55–65), or intermolar width (MV16–MV26) ($p > 0.05$). All groups demonstrated comparable expansion outcomes (Table 2; Fig. 4b–e).

Specifically, the mean increase in intercanine width was 4.60 ± 0.68 mm for CA, 5.10 ± 1.00 mm for LE and 5.30 ± 2.39 mm for RME. Interdeciduous second molar width gains were 4.94 ± 0.95 mm (CA), 5.22 ± 1.14 mm (LE), and 5.67 ± 1.05 mm (RME), while intermolar width increased by 6.10 ± 0.49 mm, 6.12 ± 0.36 mm, and 6.41 ± 0.44 mm, respectively, for CA, LE, and RME.

Treatment duration averaged 8 ± 3 months in the LE group and 9 ± 1 months in the RME group, with no statistically significant difference ($p = 0.089$). However, the number of clinical visits differed significantly: 6 ± 2 appointments for LE and 8 ± 1 for RME ($p < 0.001$). Active treatment time was significantly shorter for RME (10 ± 2 days) compared to LE (3.5 ± 0.71 months, $p < 0.001$; Cohen's d = 6.31). No emergency appointments were required throughout the entire duration of the treatment.

Reliability analysis demonstrated high measurement consistency. Intrarater ICC was 0.987 ± 0.018, indicating near-perfect agreement. Interrater ICC was 0.942 ± 0.025, confirming substantial agreement between operators.

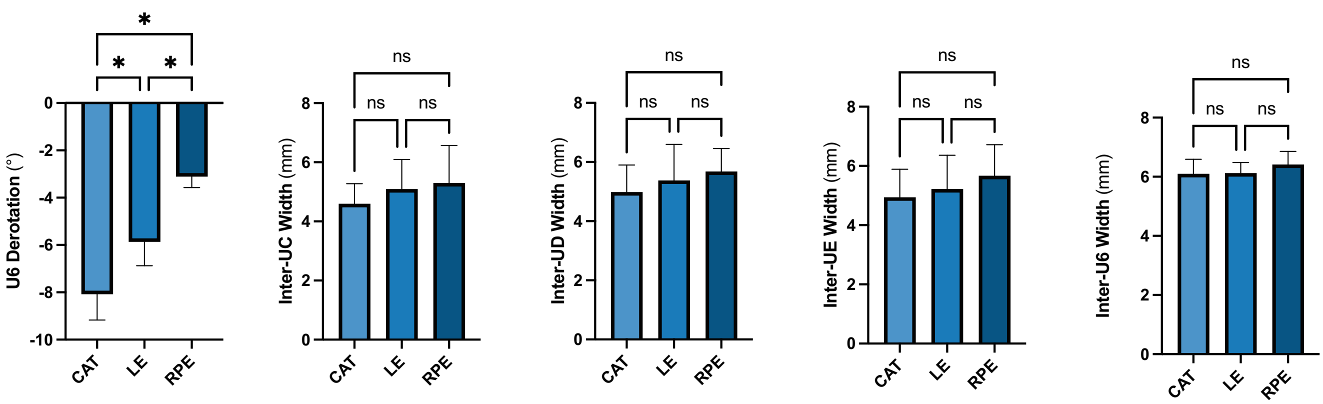

Fig. 4 Bar charts with standard deviation error bars illustrating intergroup differences in treatment-induced changes (Δ from T0 to T1) across all measured outcomes: **a** upper first molar distorotation (U6); **b** intercanine width (UC); **c** interdeciduous first molar width (UD); **d** interdeciduous second molar width (UE); **e** intermolar width. *statistically significant result. NS Not significant, CAT clear aligner therapy, RPE rapid palatal expansion

Abb. 4 Balkendiagramme mit Standardabweichungsbalken zur Darstellung der Unterschiede zwischen den Gruppen hinsichtlich der durch die Behandlung bewirkten Veränderungen (Δ von T0 zu T1) bei allen gemessenen Ergebnissen: **a** Distorotation des oberen ersten Molaren (U6); **b** Interkaninbreite (UC); **c** Breite des ersten Milchmolaren (UD); **d** Breite des zweiten Milchmolaren (UE); **e** Intermolarbreite. *Statistisch signifikantes Ergebnis. NS nicht signifikant, CAT Clear-Aligner-Therapie, RPE schnelle Gaumennahterweiterung

Discussion

Maxillary arch expansion and upper molar distorotation are pivotal treatment goals in orthodontics for growing patients. This two-center randomized controlled trial investigated the effects of CA, LE, and RME on upper first molar distorotation, alongside their impact on interdental linear measurements at the cuspidal level on upper first molar distorotation and changes in transverse dental arch dimensions at the level of deciduous and permanent molars and canines.

The study demonstrated significant spontaneous distorotation of the first permanent molars following expansion with anchorage on the second deciduous molars in both the LE and RPE groups. This aligns with previous research evaluating the effects of RME on upper first molar distorotation [10, 36]. However, the magnitude of distorotation varied significantly among the devices.

CA demonstrated superior control over the planned first molar distorotation compared to both LE and RME. Despite a statistically significant difference in all comparisons, CA achieved the highest degree of distorotation. The digital workflow associated with CA enables precise planning and execution of *synergistic movements* that mutually benefit each other, such as simultaneous expansion and molar distorotation [28]. This control is achieved through the strategic use of attachments, optimized staging of movements, and the ability to visualize the treatment plan through digital simulations. These features allow clinicians to adjust the treatment protocol to address individual patient needs effectively.

Additionally, by integrating expansion and distorotation movements, aligners more effectively distribute forces across the dental arch, minimizing unwanted side effects and improving treatment stability [28]. The predictability of distorotation varies depending on different factors such as the initial degree of rotation, attachment design, and patient adherence to the wearing protocol [9].

In a prospective study by D'Antò et al. [13], an average predictability rate of 77.5% was observed in adult patients. Similarly, Lione et al. documented an 82% rate in a retrospective study [22] and a 60% rate in growing patients [23].

Based on previous studies, orthodontic distorotation of molars, typically ranging in the amount of approximately 6°, resulted in a mean gain of arch space of about 1 mm [5]. In our study, this predictability translated to a mean arch space gain of approximately 1.35 mm in the CA group, 0.98 mm in the LE group, and 0.52 mm in the RPE group. These findings underscore the efficacy of CA in achieving distorotation while preserving arch integrity, offering a viable alternative to traditional expansion methods.

The LE demonstrated a greater degree of spontaneous distorotation compared to RME. This effect, which has already been demonstrated in the literature for this device [1], may be attributed to the device's activation protocol, which employs light, continuous forces over an extended period. The gradual, continuous forces applied by the LE likely facilitate better adaptation of periodontal and transseptal fibers, promoting rotational changes [32]. The extended activation time allows for further spontaneous adjustments without the need to directly engage the first molars. The movement of the second deciduous molars is transmitted to the upper first molars, thanks to the transseptal fibers, promoting both transverse expansion and spontaneous mesiodistal rotation [32].

Tenshin et al. [37] analyzed the dynamics of transseptal fiber remodeling during tooth movement and retention periods, highlighting that these mechanisms depend on the magnitude of force applied to the teeth. Compared to LE, RME demonstrated a lower degree of spontaneous distotation due to the differences in force application and activation protocols.

A notable advantage of using expansion devices anchored to deciduous molars, such as LE and RME, is the reduced risk of compromising buccal bone thickness [14, 35, 36]. The use of deciduous teeth for anchorage helps avoid issues such as buccal tipping, dehiscences, and fenestrations [25, 36]. Another advantage is the preservation of the permanent dentition, reducing the risk of root resorption or damage to the permanent teeth during the expansion procedures [3]. Moreover, studies have shown that maxillary expansion may induce favorable spontaneous changes in the mandibular arch, including increased intermolar width, as documented in a recent systematic review across various expansion protocols, including the LE [39]. In contrast, CAs, in theory, achieve expansion without compromising buccal bone thickness through digital precision and controlled movement, minimizing undesirable effects. Abate et al. [1] recently conducted a two-center randomized controlled trial focusing on spontaneous upper first molar distorotation following maxillary expansion using either the LE or RME, both anchored to the second deciduous molars. Their results closely mirror those of our investigation. Specifically, they reported a mean distorotation of 12.66° for the LE and 7.83° for the RME, confirming a significantly greater rotational effect with the LE. This is consistent with our findings, where LE also outperformed RME in inducing spontaneous molar distorotation. Additionally, Abate et al. identified a positive correlation between the amount of expansion at the level of 55–65 and the degree of U6 rotation, suggesting a mechanical transduction pathway likely mediated by transseptal fibers. This correlation supports the hypothesis that continuous, low-intensity forces applied at the deciduous molars can transmit rotational movement to adjacent permanent teeth. The similarity in methodology and patient selection between our study and that of Abate et al. strengthens the validity of this clinical phenomenon and highlights the reproducibility of such effects across different clinical settings [1].

Regarding secondary outcomes, interdental linear measurements significantly increased in all groups after treatment, consistent with previous studies evaluating RME [17, 19], LE [35] and clear aligners [6, 8, 16, 20, 24, 26, 27].

However, no statistically significant differences were observed between the three expansion methods. This suggests that all devices achieved similar expansion patterns, although the mechanisms and degrees of control differed.

In summary, our findings confirm that the choice of the expansion device should be guided by the primary treatment goals, whether being achieving precise molar distorotation, maximizing skeletal expansion, or balancing both. Each appliance offers unique advantages that can be leveraged to improve patient outcomes, highlighting the need for personalized orthodontic treatment planning. For cases requiring precise molar distorotation and controlled dentoalveolar arch development, CAT would offer a comprehensive solution by integrating planned movements that minimize unwanted effects. For patients in the mixed dentition phase where skeletal transverse effects are prioritized, spontaneous distorotation could still occur as a secondary benefit. In such scenarios, the LE presents a viable alternative to achieve both expansion and rotation through continuous, light forces. Conversely, the RPE remains the most suitable choice when the primary goal is to maximize skeletal effects, albeit with less control over spontaneous rotational changes.

Limitations

One important limitation of the present study is the absence of data regarding the degree of distorotation planned in the digital setup for the CA group. Without this reference, it becomes difficult to calculate the exact predictability of the achieved molar rotation in comparison to the virtual treatment objectives.

Moreover, the short-term nature of the follow-up does not allow for conclusions on the long-term stability of the outcomes, particularly in the CA group, where arch expansion is mainly achieved through buccal inclination of posterior teeth. This type of dental movement may potentially compromise the retention of treatment results over time [6].

Additionally, relapse has been previously reported following RME therapy, which could influence the interpretation of its long-term effectiveness. The current study did not assess posttreatment relapse or the need for retention protocols beyond appliance removal.

Another potential confounding factor is the variability in malocclusion types, which was not stratified during group allocation. Different skeletal or dental patterns might influence treatment responsiveness, especially in relation to molar rotation and transverse changes [29].

Future investigations should address these limitations by incorporating long-term follow-up periods, documenting the planned versus achieved tooth movements, and including subanalysis by malocclusion type. These improvements would enhance the reliability and generalizability of the presented findings and provide deeper insight into the biomechanical behavior and clinical efficiency of the tested appliances.

Conclusion

This randomized clinical trial compared the clinical performance of three appliances clear aligners (CA), Leaf Expander® (LE), and rapid maxillary expander (RME) in producing dentoalveolar maxillary expansion and distorotation of the upper first molars in a pediatric population.

All three devices demonstrated similar results in terms of upper arch expansion. CAs provided the highest degree of controlled and predictable upper first molar distorotation. The spontaneous distorotation observed with the LE was significant and was achieved without direct force application on the molars, making it a valuable option in certain clinical scenarios. Conversely, the RPE showed the lowest degree of spontaneous distorotation, likely due to its reliance on heavier and more intermittent forces.

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

Declarations

Competing interests The authors declare no competing interests.

Ethical standards Ethical approval was obtained from the Institutional Ethics Committee of Fondazione IRCCS Ca'Granda Ospedale Maggiore Policlinico in Milan, Italy (reference number 51/2021, issued on 18 May 2021). All clinical procedures conducted throughout the RCT complied with the ethical principles articulated in the 1964 Declaration of Helsinki and its subsequent revisions, as well as with applicable institutional and international regulations. Before starting treatment, informed written consent was required from each participant's parent or legal guardian, ensuring their understanding and voluntary agreement to participate in the study. Trial registration: The trial was registered at ClinicalTrials.gov ID: [NCT05135962].

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