Effectiveness of Aligners Versus Rapid Palatal Expander on Palatal Volume in Mixed Dentition Patients: A Randomized Controlled Trial

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Research article

Keywords: Transverse maxillary deficiency, maxillary hypoplasia, maxillary constriction, Rapid Maxillary Expansion, Rapid Palatal Expansion, RME, RPE, Clear Aligner Treatment, CAT, Clear Aligner, Invisalign

Posted Date: October 7th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1961728/v1

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Abstract

Aim. The aim of the present study is to evaluate the effects on the palatal volume and surface area measurements, as well as on the inter-dental linear measurements, produced by CAT compared with RPE in mixed dentition patients. Methods. In this open two-arm parallel groups multi-center equal-randomized (1:1) interventional prospective trial 39 patients were assigned to one of two expansion methods (arm A: Invisalign® First clear aligners, arm B: tooth-borne Hyrax-type maxillary expander) according to a computer-generated randomization list immediately before the start of treatment. Inclusion criteria were (1) indications for maxillary expansion treatment, (2) mixed dentition, (3) cervical vertebral maturation stage (CVMS) not exceeding 4, (4) erupted first molars, (5) transverse discrepancy ≤5mm, (6) upper second premolar cusps position apical to half pulp chamber (HPC) line of the ipsilateral upper first permanent molars on pre-treatment panoramic radiographs, (7) good standards of oral hygiene. Digital models were obtained before and after treatment using intraoral scanner (iTero® Element, AlignTechnology, San Jose, CA, USA). Palatal volume and surface area were measured with Geomagic Control X (3D Systems Inc., Rock Hill, SC, USA) as the primary endpoint. Linear measures of upper arch (inter-canine width at cusp and gingival level; inter-molar width at cusp and gingival level) were measured as the secondary endpoint. Due to the nature of the intervention blinding was not possible. Potential statistical differences between the two intervention groups were evaluated. Results. A significant increment in palatal volume (p<0.05) was observed in aligner group aligners (243,95±473,24 mm$^3$ mean increase) and in RPE group (532,01±540,52 mm$^3$ mean increase). Also surface area has increased in aligner group (64,51±64,25 mm$^2$ mean increase) and RPE group (81,34±71,05 mm$^2$ mean increase). A significant increase was experienced in both groups for linear measurements too. No differences (p<0.05) were detected in terms of variation from T0 to T1 between aligners and RPE group for all the outcomes assessed, except for inter-molar width at gingival level (tab.3). Conclusions. A significant increase in palatal volume, so as in the other parameters, has been proved for both treatments.

Background

Maxillary constriction represents one of the most pervasive problems in the craniofacial region, with several clinical features occurring in all the planes of space. These features could appear independently but, in most cases, they take place together, as in what might be termed maxillary deficiency syndrome[1, 2].

The most easily recognizable clinical signs are the posterior cross-bite and the dental crowding[1, 2], but other signs could be protrusion, buccally flared maxillary posterior teeth, accentuated curve of Wilson, lingual cusps of the upper posterior teeth tipped below the occlusal plane, and dark spaces at the corner of the mouth in case of a maxillary constriction camouflaged by the dentition[3].

Maxillary transverse deficiency usually requires expansion of the palate, achievable through several treatment modalities[4] that practitioners select based on scientific evidences[5] together with their personal beliefs and experiences[6].
Palatal expansion might be performed with two different mechanisms, depending on the frequency of activation, magnitude of the force applied, patient's sutural maturation, and treatment duration\[7–10\]: rapid maxillary expansion (RME) or slow maxillary expansion (SME).

If expansion is carried out at a rate of about 0.5 mm/day, it is called \textit{rapid} palatal/maxillary expansion. In this instance, the expander jackscrew appliance, anchored to teeth or tissues (e.g. Hyrax or Haas), acts transferring mechanical load across mid-palatal suture, promoting disjunction of upper jawbones, when interdigitation and bony bridging are still incomplete, modulating bone remodeling and formation\[11\]. The exogenous forces produced by these appliances result in sutural bone strain that promote cellular growth in response to changes in their mechanical environment\[12\]. This orthopedic effect of palatal expander decreases with increasing skeletal maturation and circumaxillary sutures closure.

On the other hand, expansion of the top jaw is termed \textit{slow} when expansion takes place at a rate of 0.5mm/week\[13\], promoting a dentoalveolar expansion rather than an orthopedic disjunction obtained through lighter and continuous forces applied over a longer period of time.

Recent studies showed that clear aligners can achieve satisfactory arch expansion in growing patients\[14, 15\] apparently promoting a dentoalveolar expansion similar to what is obtainable with slow palatal expanders. The light continuous forces released by the slow palatal expanders are perceived as intermittent by the periodontium due to its viscoelastic nature\[16\], intermittent as the forces released by clear aligners.

The expansion of upper arch with aligners in growing patients mainly resulted in buccal tipping of permanent molars, while the greatest amount of expansion was revealed in the deciduous canine and first molar regions\[14, 15\]. Inter-dental linear measurements have been used in the vast majority of previous publications on CAT\[14, 15, 17–19\], for assessing upper arch changes after expansion treatments ignoring the complex three-dimensional morphological characteristics of the palate.

The primary aim of this study is to compare the expansion effectiveness, assessed on palate morphology measured on digital models, of Invisalign® First aligners and tooth-borne Hyrax-type maxillary expander following rapid expansion protocol; the secondary aim is to investigate changes in upper arch linear dimensions.

The primary endpoint of the study is to test the null hypothesis \(H_0\) that there are no significant differences in palatal volume and surface area measurements between CAT and RPE.

\section*{Methods}

\subsection*{Trial design}

This is open two-arm parallel groups multi-center equal-randomized (1:1) interventional prospective trial on the clinical effectiveness of different sets of expansion devices.
The trial was registered at the ClinicalTrial.gov website (ClinicalTrials.gov ID: [NCT04760535]). The Protocol Registration System (PRS) was used to upload and update data about the clinical trial.

The study protocol was approved by the Institutional Ethics Committee (approval number: 0006323) of the coordinating center.

**Participants and study setting**

In this multicentric clinical trial, patients were enrolled by a competitive pattern, from January 2020 to January 2021, at the Department of Orthodontics of the University of Turin, which is the coordinating center and at other private practitioners who want to contribute. Practitioners completed an enrollment questionnaire to joining the trial, which collected information on the practitioners and their practices. The inclusion criteria for practitioners were as follows: orthodontist or dentist who routinely performs orthodontic treatment; routinely takes cephalometric radiographs (cephalograms) before and after treatment; has the ability to scan plaster model or to collect intraoral scans and upload (via internet) the files obtained to a central repository; affirms that the practice can devote sufficient time in patient scheduling to allow focused recording of all data required for the study; and does not anticipate retiring, selling the practice, or moving during the study[20]. Signed, written informed consent was required before inclusion in the trial.

The inclusion criteria were as follows: a) patients with maxillary transverse deficiency; b) mixed dentition phase with cervical vertebral maturation stage (CVMS) less than 4[21]; c) fully erupted upper and lower first molars; d) a transversal discrepancy $\leq$ 5mm; e) upper second premolar cusps position apical to half pulp chamber (HPC) line of the ipsilateral upper first permanent molars on pre-treatment panoramic radiographs[22] f) good general health, according to medical history and clinical judgment. Subjects with craniofacial malformations (including cleft lip or palate), history of dental trauma, oral neoformations and other oral cavity pathologies, or previous or concomitant orthodontic treatment were excluded from the study. This study was performed according to the Declaration of Helsinki, with pertinent national and international regulatory requirements. All participants provided written informed consent and were free to withdraw from the study at any time.

**Interventions**

All patients enrolled in this trial, were randomly allocated in two arms.

In the *Arm A*, Invisalign® First Phase I treatment (Align Technology, Inc., Santa Clara, CA, USA) was performed.

The Invisalign® First aligners are fabricated in a multilayer aromatic thermoplastic polyurethane/co-polyester 0.75mm (.030")-thick with a fine 3D manufacturing process. Subjects in this arm were instructed to wear aligners 24h/day for the entire duration of the therapy. They were asked to remove their retainers only while eating, drinking (except water), or cleaning.
About staging, permanent molars moved buccally first, using the rest of the arch as anchorage. When they have reached their final position, the deciduous molars and canines moved buccally using permanent molars and incisors as anchorage unit. Because of the short clinical crowns of deciduous teeth, specific attachments shapes were designed in order to increase aligner retention and to control the tipping movement (in order to obtain torque compensation and to avoid a deepening of the Curve of Wilson). The expansion was carried out until the palatal cusp tip of the maxillary posterior teeth should contact the buccal cusp tip of the mandibular posterior teeth.

In the Arm B, patients received a tooth-borne expansion appliance.

The Hyrax-type maxillary expander is a tooth-borne expansion appliance that is fixed to the upper second deciduous molars (or to the first permanent molars) using bands and includes a midline 12-mm self-locking screw (Forestadent, Pforzheim, Germany; 0.9 mm, complete turn).

The expansion screw is connected to the conventional molar bands or printed clasps, modelled surrounding the molars, via a framework of 0.9mm stainless-steel wire. The framework is soldered to the bands and extending on the palatal side to the deciduous canines. The expander was fabricated by a qualified laboratory technician. The RPE was bonded to the teeth with orthodontic band composite (Transbond Plus Light Cure Band Adhesive, 3M Unitek, Monrovia, CA, USA), light-cured by the means of 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. When an increase of the lower anterior arch perimeter or a curve of Wilson flattening was requested a removable lower Schwarz appliance was used for mandibular “dental decompensation”[23]. The Schwarz appliance is an acrylic made horseshoe-shaped appliance that fits along the lingual border of the mandibular dentition, extending distally aspect to permanent first molars. It includes a midline 9-mm self-locking screw (Forestadent, Pforzheim, Germany; 0.9 mm, complete turn) and the connection with the lower second deciduous molars was ensured by ball clamps at their interproximal undercut. It was fabricated by a qualified laboratory technician. The expansion protocol for lower appliance was one quarter-turn a week with full-time wearing. The expander was left passively for retention for a minimum of 6 months and the Schwarz appliance continued to be worn full-time as a passive retainer until the maxillary expander was removed. At the time of appliance delivery, both written and verbal oral hygiene instructions were given, including methods for cleaning appliances themselves. Also, written informed consent were obtained for each patient or the parents.

Patients wearing Invisalign® First were also be asked to complete an aligner wear chart. The self-reported compliance levels were categorized as follows:

- compliant (reported wear of aligners as advised);
- partially compliant (aligners wear instructions not followed precisely);
- noncompliant (not wearing aligners).
In case of breaking or losing the appliances, the patients were asked to come to the Orthodontic Department as soon as possible.

In both intervention groups the amount of expansion was determined on an individual basis, depending on the severity of maxillary arch constriction, not exceeding 6mm.

For each patient full mouth intraoral scanning were performed before appliance placement (T0) and at the end of retention period/treatment (T1), when the appliances were removed.

**Outcomes**

**Primary outcome: palate morphology**

The primary outcome was to evaluate the changes in palatal morphology defined as the variation in palatal volume (Table 1). These were measured from digitized study models within the boundaries of the palate, the gingival and distal planes, defined as follow. The gingival plane was created by connecting the midpoints of the dentogingival junction of all upper erupted deciduous and permanent teeth. The distal plane was created through two points at the distal of the first upper permanent molars perpendicular to the gingival plane (Fig. 1; Fig. 2).

<table>
<thead>
<tr>
<th>MEASUREMENT</th>
<th>UNIT</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palatal volume[24]</td>
<td>mm³</td>
<td>Volume calculates within the boundaries of the palate</td>
</tr>
<tr>
<td>Palatal surface[24]</td>
<td>mm²</td>
<td>Surface calculate within the boundaries of the palate</td>
</tr>
</tbody>
</table>

Digital dental casts were obtained using a laser scanner with a reported manufacturing accuracy of 20µm, at 2 time-points during the trial (T0-T1) and was measured by the same examiner. The stereolithographic (.STL) files obtained from the scanner were imported into reverse modelling software package Geomagic Control X (3D Systems Inc., Rock Hill, SC, USA) to perform all measurements. Each scan of a study cast was further manually pre-processed to remove unwanted data artifacts from the analysis.

**Secondary outcome: upper arch linear dimensions**

Changes in upper arch dimensions were also recorded. The Table 2 and Fig. 3 provide details of these measurements.
Table 2
Linear measures of maxillary arch.

<table>
<thead>
<tr>
<th>MEASUREMENT</th>
<th>UNIT</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper inter-canine width (ICW)[24] – cusp level</td>
<td>mm</td>
<td>Distance between the cusp tips of right and left maxillary canines.</td>
</tr>
<tr>
<td>Upper inter-molar width (IMW)[24] – cusp level</td>
<td>mm</td>
<td>Distance between the mesiobuccal cusp tips of right and left maxillary first molars.</td>
</tr>
<tr>
<td>Upper inter-canine width (ICW)[24] – gingival level</td>
<td>mm</td>
<td>Distance between midpoints of the palatal dentogingival junction of right and left maxillary canines.</td>
</tr>
<tr>
<td>Upper inter-molar width (IMW)[24] – gingival level</td>
<td>mm</td>
<td>Distance between midpoints of the palatal dentogingival junction of right and left maxillary first molars.</td>
</tr>
</tbody>
</table>

Figure 3

Digital dental casts were be obtained at 2 time-points during the trial (T0-T1) and was measured by the same examiner with the equal modalities above-mentioned.

Randomization

Immediately after signing a specific informed consent form, patients were randomly assigned into either ARM A (experimental) Invisalign® First aligners (Align Technology, Inc., Santa Clara, CA, USA) group and ARM B (active comparator) tooth-borne Hyrax-type maxillary expander group, following a 1:1 simple randomization (A vs B) procedure according to a computer-generated list. An external randomization manager prepared the randomization list. He was the only person to have possession of the list, and he had no clinical involvement in the trial.

Different staff members (blind to the randomization sequence) evaluated the inclusion criteria and obtained the patients’ informed consents. Immediately after this phase, staff members contacted the external randomization manager, who assigned the patients to one of the two groups.

Finally, independent staff members planned the two intervention pathways, namely, Invisalign® First in arm A and tooth-borne Hyrax-type maxillary expander in arm B.

Blinding

Except for the interventionists (specialist of Department of Orthodontics of the University of Turin or private practitioners), investigators and staff were kept blind to group assignment of the participants. The trial adhered to established procedures to maintain separation between staff taking outcome measurements and staff delivering the intervention. Staff members who obtained outcome measurements were not informed about the group assignment. Intervention staff who delivered the
intervention did not take outcome measurements. All investigators, staff, and participants were kept blinded to outcome measurements and trial results.

Patients and interventionist were not blinded due to the nature of the intervention.

**Sample size and statistical analysis**

The sample size was determined based on the primary objective of comparing palatal morphology change assessed calculating its volume in both treatment group and control group.

Assuming a clinically relevant difference of $490 \text{ mm}^3$ between the two randomized groups, a common standard deviation of $450 \text{ mm}^3$, a power of 80%, an effect size of 0.91 and a significance level of 5% ($\alpha = 0.05$), the study will require 17 subjects in each of the two groups.

To account for a potential dropout rate of 10%, the sample size is increased to 19 per group resulting in a total of 38 subjects.

Univariate and bivariate descriptive statistics for categorical variables were described as relative/absolute frequencies while continuous ones as mean and SD (Standard Deviation). Bivariate descriptive statistics for continuous variables were estimated either for the whole cohort or stratified by the arm (Aligner vs ERP) and by 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. To test for the existence of selection bias in the cohort at the baseline (T0), a Mann–Whitney–Wilcoxon test were performed. The inferential analyses for the independent measures of continuous variables were performed by the two-sample t-test, while for their repeated measures by the paired t-test. All reported P-values were obtained by the two-sided exact method at the conventional 5% significance level. Data were analyzed as of March 2021 by StataBE 17 (StataCorp LLC., College Station, TX, USA) that was also used for chart making.

**Results**

A total of 50 patients were screened for eligibility and 41 met eligibility criteria and were randomized between January 2020 and January 2021, as illustrated in the CONSORT[25] Flow Diagram (Fig. 4).

*Figure 4*

From the 41 randomized patients, 39 completed the trial.

19 patients (5 male and 14 females, mean age: $8.48 \pm 1.42$ years old) were randomized in the Invisalign® First group, the remaining 20 (12 male and 8 female, mean age: $7.83 \pm 1.19$) in the tooth-borne Hyrax-type maxillary expander group. The mean treatment duration in the Arm A was $8 \pm 3$ months, the mean treatment duration in the Arm B was $9 \pm 2$ months.
The (absolute) frequency and (valid) relative frequency of the categorical variables were reported in Table 3.

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aligner</td>
<td>19</td>
<td>48.72</td>
</tr>
<tr>
<td>Control</td>
<td>20</td>
<td>51.28</td>
</tr>
<tr>
<td>Total</td>
<td>39</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Full cohort parameters at baseline (T0) are shown in Table 4. Stratified cohort parameters, by testing arms at baseline (T0) are shown in Table 5.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTER-CANINE WIDTH (CUSP LEVEL)</td>
<td>29.27216</td>
<td>2.907442</td>
<td>0.0360*</td>
</tr>
<tr>
<td>INTER-CANINE WIDTH (GINGIVAL LEVEL)</td>
<td>23.35514</td>
<td>2.343154</td>
<td>0.1141</td>
</tr>
<tr>
<td>INTER-MOLAR WIDTH (CUSP LEVEL)</td>
<td>47.40769</td>
<td>2.772858</td>
<td>0.0255*</td>
</tr>
<tr>
<td>INTER-MOLAR WIDTH (GINGIVAL LEVEL)</td>
<td>32.30923</td>
<td>2.026973</td>
<td>0.3914</td>
</tr>
<tr>
<td>PALATAL SURFACE</td>
<td>1145.373</td>
<td>125.7778</td>
<td>0.5365</td>
</tr>
<tr>
<td>PALATAL VOLUME</td>
<td>4773.49</td>
<td>985.9617</td>
<td>0.4651</td>
</tr>
</tbody>
</table>
Table 5
Stratified cohort parameters, by testing arms at baseline (T0).

<table>
<thead>
<tr>
<th>Arm</th>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>INTER-CANINE WIDTH</td>
<td>30.24</td>
<td>2.84</td>
</tr>
<tr>
<td></td>
<td>(CUSP LEVEL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>INTER-CANINE WIDTH</td>
<td>23.93</td>
<td>2.20</td>
</tr>
<tr>
<td></td>
<td>(GINGIVAL LEVEL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>INTER-MOLAR WIDTH</td>
<td>48.46</td>
<td>2.70</td>
</tr>
<tr>
<td></td>
<td>(CUSP LEVEL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>INTER-MOLAR WIDTH</td>
<td>32.57</td>
<td>1.82</td>
</tr>
<tr>
<td></td>
<td>(GINGIVAL LEVEL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PALATAL SURFACE</td>
<td>1160.42</td>
<td>114.20</td>
</tr>
<tr>
<td></td>
<td>PALATAL VOLUME</td>
<td>4926.94</td>
<td>995.58</td>
</tr>
<tr>
<td>B</td>
<td>INTER-CANINE WIDTH</td>
<td>28.35</td>
<td>2.73</td>
</tr>
<tr>
<td></td>
<td>(CUSP LEVEL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>INTER-CANINE WIDTH</td>
<td>22.80</td>
<td>2.40</td>
</tr>
<tr>
<td></td>
<td>(GINGIVAL LEVEL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>INTER-MOLAR WIDTH</td>
<td>46.41</td>
<td>2.52</td>
</tr>
<tr>
<td></td>
<td>(CUSP LEVEL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>INTER-MOLAR WIDTH</td>
<td>32.06</td>
<td>2.22</td>
</tr>
<tr>
<td></td>
<td>(GINGIVAL LEVEL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PALATAL SURFACE</td>
<td>1129.53</td>
<td>138.25</td>
</tr>
<tr>
<td></td>
<td>PALATAL VOLUME</td>
<td>4611.95</td>
<td>975.86</td>
</tr>
</tbody>
</table>

To test for the existence of selection bias in the cohort at the baseline (T0), a Mann–Whitney–Wilcoxon test (Table 4) were performed showing no significative difference between the two intervention groups (p > 0.05 for each pre-treatment continuous variables except for inter-canine width at cusp level and inter-molar width at cusp level).

Since we had a small sample size, determining the distribution of the all the variables was important for choosing an appropriate statistical method. A Shapiro-Wilk and a Skewness and kurtosis test were performed and did not show evidence of non-normality (p-value > 0.005 for all the variables) (Tables 6 and 7). Based on this outcome, and after visual examination of the histogram of X and the QQ plot,
parametric tests were chosen. Also, the mean with the standard deviation were used to summarize all the variables.

**Table 6**
*Shapiro-Wilk test* for distribution of all parameters. *P* < 0.05 was considered for significance.

<table>
<thead>
<tr>
<th>Variable</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTER-Canine Width</td>
<td>0.32329</td>
</tr>
<tr>
<td>(Cusp Level)</td>
<td></td>
</tr>
<tr>
<td>INTER-Canine Width</td>
<td>0.42799</td>
</tr>
<tr>
<td>(Gingival Level)</td>
<td></td>
</tr>
<tr>
<td>INTER-Molar Width</td>
<td>0.75998</td>
</tr>
<tr>
<td>(Cusp Level)</td>
<td></td>
</tr>
<tr>
<td>INTER-Molar Width</td>
<td>0.51290</td>
</tr>
<tr>
<td>(Gingival Level)</td>
<td></td>
</tr>
<tr>
<td>Palatal Surface</td>
<td>0.29784</td>
</tr>
<tr>
<td>Palatal Volume</td>
<td>0.16717</td>
</tr>
</tbody>
</table>
Mean values and standard deviations of the intercanine and intermolar widths, palatal surface areas and volumes and p-values at T0 and T1 were reported in Table 8 for Aligner group, Table 9 for RPE group. All the outcome measures significantly improved from T0 to T1 in both groups (p-value < 0.005).
Table 8
Wilcoxon match-paired test for the intra-group differences (arm A). P < 0.05 was considered for significance.

<table>
<thead>
<tr>
<th>Variable</th>
<th>T0</th>
<th>T1</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTER-CANINE WIDTH</td>
<td>30.24 ± 2.84</td>
<td>33.89 ± 1.81</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>(CUSP LEVEL)</td>
<td>(mm)</td>
<td>(mm)</td>
<td></td>
</tr>
<tr>
<td>INTER-CANINE WIDTH</td>
<td>23.93 ± 2.2</td>
<td>27.02 ± 1.43</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>(GINGIVAL LEVEL)</td>
<td>(mm)</td>
<td>(mm)</td>
<td></td>
</tr>
<tr>
<td>INTER-MOLAR WIDTH</td>
<td>48.46 ± 2.69</td>
<td>51.67 ± 2.20</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>(CUSP LEVEL)</td>
<td>(mm)</td>
<td>(mm)</td>
<td></td>
</tr>
<tr>
<td>INTER-MOLAR WIDTH</td>
<td>32.57 ± 1.82</td>
<td>34.15 ± 1.57</td>
<td>0.0003*</td>
</tr>
<tr>
<td>(GINGIVAL LEVEL)</td>
<td>(mm)</td>
<td>(mm)</td>
<td></td>
</tr>
<tr>
<td>PALATAL SURFACE</td>
<td>1160.42 ± 114.21</td>
<td>1224.93 ± 114.56</td>
<td>0.0003*</td>
</tr>
<tr>
<td>(mm2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PALATAL VOLUME</td>
<td>4926.94 ± 995.58</td>
<td>5170.89 ± 1088.56</td>
<td>0.0326*</td>
</tr>
<tr>
<td>(mm3)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Table 9
Wilcoxon match-paired test for the intra-group differences (arm B). P < 0.05 was considered for significance.

<table>
<thead>
<tr>
<th>Variable</th>
<th>T0</th>
<th>T1</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTER-CANINE WIDTH (CUSP LEVEL)</td>
<td>28.36 ± 2.73</td>
<td>32.57 ± 1.97</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>(mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTER-CANINE WIDTH (GINGIVAL LEVEL)</td>
<td>22.81 ± 2.40</td>
<td>26.55 ± 2.03</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>(mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTER-MOLAR WIDTH (CUSP LEVEL)</td>
<td>46.41 ± 2.52</td>
<td>50.51 ± 3.05</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>(mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTER-MOLAR WIDTH (GINGIVAL LEVEL)</td>
<td>32.06 ± 2.22</td>
<td>35.94 ± 2.45</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>(mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PALATAL SURFACE (mm2)</td>
<td>1129.53 ± 138.15</td>
<td>1210.87 ± 143.68</td>
<td>&lt; 0.0001*</td>
</tr>
<tr>
<td>PALATAL VOLUME (mm3)</td>
<td>4611.96 ± 957.86</td>
<td>5143.97 ± 1036.26</td>
<td>0.0004*</td>
</tr>
</tbody>
</table>

We also investigated the differences between groups, in terms of variation from T0 to T1, as described by Table 10. There was not a significant difference in terms of variation from T0 to T1 between Aligner and RPE group for all the outcomes (p-value > 0.005), except for the inter-molar width at gingival level (p-value < 0.005). The null hypothesis H₀ was retained, concluding that there is no significant difference among groups.
Table 10
Differences among T0-T1 variation (Δ).

<table>
<thead>
<tr>
<th>Variable</th>
<th>ARM A</th>
<th>ARM B</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTER-CANINE WIDTH (Cusp level)</td>
<td>3.52 ± 2.17</td>
<td>4.22 ± 1.50</td>
<td>0.2754</td>
</tr>
<tr>
<td>(mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTER-CANINE WIDTH (Gingival level)</td>
<td>3.00 ± 1.81</td>
<td>3.74 ± 1.45</td>
<td>0.2754</td>
</tr>
<tr>
<td>(mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTER-MOLAR WIDTH (Cusp level)</td>
<td>3.22 ± 2.43</td>
<td>4.10 ± 1.70</td>
<td>0.3543</td>
</tr>
<tr>
<td>(mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTER-MOLAR WIDTH (Gingival level)</td>
<td>1.58 ± 1.53</td>
<td>3.87 ± 1.67</td>
<td>0.0001*</td>
</tr>
<tr>
<td>(mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PALATAL SURFACE (mm²)</td>
<td>64.51 ± 64.25</td>
<td>81.34 ± 71.05</td>
<td>0.5668</td>
</tr>
<tr>
<td>PALATAL VOLUME (mm³)</td>
<td>243.95 ± 473.24</td>
<td>532.01 ± 540.52</td>
<td>0.3097</td>
</tr>
</tbody>
</table>

Box plots were used to graphically report the comparison of median intercanine distance measured at cusp level (Fig. 5), intercanine distance measured at gingival level level (Fig. 6), intermolar distance measured at cusp level (Fig. 7), intermolar distance measured at gingival level (Fig. 8), surface area (Fig. 9), palatal volume (Fig. 10) at T0 vs T0 for aligner (experimental) and RPE (active comparator) subcohorts.

Figure 5
Figure 6
Figure 7
Figure 8
Figure 9
Discussion

This in-vivo study demonstrated that maxillary expansion could be achieved with clear aligners in growing patients with a transversal interarch discrepancy $\leq$ 5mm. CAT results are comparable to those obtained with tooth-borne Hyrax-type maxillary expander in a control group with same transversal interarch discrepancy.

Inter-dental linear measurements have been used in the vast majority of previous publications CAT, for both adults[17–19] and growing patients[14, 15], for assessing upper arch changes after expansion treatments ignoring the complex three-dimensional morphological characteristics of the palate. They also could be biased due to axial inclination of the first molars and/or the alveolar bridge[26]. Palatal surface area and volume have been previously reported as reliable indicators of palatal and maxillary arch expansion[24, 27–29].

According to author knowledge, the present study is the first attempt to assess the effect of clear aligners on both palatal morphology and on maxillary inter-arch distances in mixed dentition patients.

In the present study both treatments have been demonstrated to be effective in palatal expansion, showing a significative increment in palatal volume from T0 to T1 ($p < 0.05$) with a slightly better performance by RPE ($532.01 \pm 540.52 \text{mm}^3$ average increase) over aligners ($243.95 \pm 473.24$ average increase) that does not result in statistically difference between the two groups ($p > 0.05$) considering the baseline characteristics of the sample.

Also, other parameters exhibited a significant increase ($p < 0.05$) after treatment in both groups. The RPE always shows slightly better results over CAT, but at no time statistically significant except for the inter-molar-width measured at the gingival level. The inter-arches distances increase obtained in the present study show consistency with previous articles[14, 30].

The magnitude of the forces expressed by the RPE, is significantly greater than the forces expressed by aligners[31–33], in particular in their distal portions where they are not stiff enough to exert a sufficient magnitude to support a predictable buccal movement [15]. In addition, the moderate magnitude produced by aligners probably could not be always sufficient to provide a skeletal expansion according to literature[10, 34–36]. Another factor that need to be considered is the stress relaxation of orthodontic thermoplastic appliances, due to intraoral temperature fluctuation and hygroscopic expansion[37].

A further explanation of the different way of action of the two appliances is represented by force application duration, that differs between two appliances, could impact on the clinical outcome. The aligners provide intermittent forces and their effect is strongly dependent by patient compliance. Otherwise, RPE is a bonded appliance and the intermittent forces[38] it express are strictly dependent on clinician need of activation.
In young children up to 8–9 years, opening the suture can be accomplished by using light continuous forces\[^{39}\], therefore it can be assumed that intermittent forces released by aligners can be sufficient to act on the transversal dimension of the maxilla of patients in this age group. Considering the mean age of the considered patients (8.48 ± 1.42 years old for Group A and 7.83 ± 1.19 years old for Group B), the statistically similar results in terms of expansion could be due to a certain percentage of subject with an immature midpalatal suture.

Despite the possibility of a skeletal response, the main effects of SPEs are dento-alveolar: it has been reported 2°\[^{40}\] to 24°\[^{34}\] of buccal molar tipping with the use of SPEs\[^{41}\], similar to those reported for CAT\[^{14}\]. Although the virtual treatment plan provided an overcorrection with 2 degrees of extra buccal root torque at each stage, the amount of expansion obtained by the means of aligners was presumably due to dentoalveolar displacement (buccal tipping), rather than bodily movement, as reported by other authors\[^{17}–^{19}\].

Also for RPEs, in addition to skeletal effects, several dento-alveolar effects have been reported\[^{42}\]. Indeed, most of the studies reported dentoalveolar transverse expansion larger than the skeletal expansion\[^{43}–^{45}\]. The dento-alveolar effect occur essentially as, often transient\[^{46}\], buccal tipping and extrusion of molars and alveolar bending\[^{47}\]. The dental compensation is predominant in the molar region compared to anterior region, as a consequence of the anteroposterior progressive increase in skeletal resistance\[^{46}\].

In absence of posterior crossbite, the treatment of transverse maxillary deficiency must take in account the potential dentoalveolar effects on first maxillary molar (the buccal flaring could result in periodontal problems and occlusal interferences affecting both Wilson Curve and occlusal plane)\[^{48}\]; ideally an expansion limited to the anterior region of the arch, combined with a palatal movement of maxillary first molars would be desirable, and the actual space gained could result insufficient. CAT have the possibility to provide simultaneous control of all the teeth of the upper arch combining an adequate control of maxillary molar in all the planes of the space with an expansion targeted to anterior region when necessary\[^{49}\].

Taking together the results of the present study it can be concluded that CAT can be effective in controlling maxillary arch expansion when interarch discrepancy is ≤ 5mm in mixed dentition patients. A staging protocol moving permanent molars first, buccal attachments and buccal root torque compensation are required in order to obtain clinically relevant results.

### Limitations

The sample included also subjects who did not have some teeth, such as deciduous canines, elements required for both linear and volumetric measurement and therefore some measurements were missing. However, these subjects have not been excluded to avoid introducing a bias. Only those variables that were not been able to be measured were excluded from the analysis.
The real compliance of the patients allocated to arm A (clear aligners), despite the questionnaire, it has not been possible to assess, with potential difference over outcome expected.

The data for both groups was gathered considering short-term treatment effects only: the stability of results obtained through CAT could be limited, being the expansion achieved as buccal inclination of crowns. A long-term comparison should be added for strengthening the conclusions.

The intraoral scans at the end of retention period/treatment (T1), were obtained at different time point depending on patients' baseline characteristics, so the potential different length of treatment duration between groups would have had an impact on skeletal maturation and consequently on treatment outcome.

Other linear measures, such as Anterior segment length (ASL)\[24\] or Posterior segment length (PSL) \[24\], could be supplemented in future investigations as well as secondary outcomes as for example appliances survivals, patients satisfaction and periodontal health assessment.

**Conclusions**

The aim of the present in-vivo experiment is to assess the expansion efficacy of clear aligners compared to RPE, despite further studies are necessary to corroborate these findings. Taken together, the measurement obtained from the clinical trial suggest that:

- A significant increase in palatal volume, so as in the other parameters, has been proved for both treatments.
- The RPE slightly outperform clear aligners considering all the parameters tested, but this difference is not statistically significant.
- The compliance and the clinical condition could affect the potential results achievable by the clear aligners.

The Clear Aligners demonstrated a reasonable ability to achieve palatal expansion. Since the materials have improved over the last years\[50\], so as the academic efforts to better understand the potential of CAT\[51\], substantial advances can be expected in the near future.

**Abbreviations**

RPE: Rapid Palatal Expander

CAT: Clear Aligner Treatment

CVMS: cervical vertebral maturation stage

HPC: half pulp chamber
Declarations

Ethics approval and consent to participate

The study protocol was approved by the Institutional Ethics Committee (approval number: 0006323) of the Università degli Studi di Torino.

Consent to publish

Not applicable.

Availability of data and materials

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

Acknowledgements

T.C. and dr. S.P. are Invisalign speakers, therefore they have been compensated for lectures and courses organized by Align Technology. The other authors declare that they have no competing interests.

CONSORT guidelines

This article was reported according to CONSORT (Consolidated Standards of Reporting Trial) [25] guidelines, and the checklist is available as a supplementary file.

Author Credit Statement

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

References


Figures

Figure 1

_Palatal surface area on digital models._
Figure 2

*Palatal volume on digital models.*
Figure 3

_Palatal volume on digital models. Intercanine and intermolar maxillary arch widths assessed at the cusp (blue lines) and gingival (red lines) level._

Figure 4
Median intercanine distance (mm) measured at cusp level in ARM A and ARM B at T0 and T1.
Figure 6

*Median intercanine distance (mm) measured at cusp level in ARM A and ARM B at T0 and T1.*
Figure 7

Median intermolar distance (mm) measured at cusp level in ARM A and ARM B at T0 and T1.
Figure 8

Median intermolar distance (mm) measured at gingival level in ARM A and ARM B at T0 and T1.
Figure 9

Median surface area (mm$^2$) in ARM A and ARM B at T0 and T1.
Figure 10

Median volume (mm$^3$) in ARM A and ARM B at T0 and T1.

Supplementary Files

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