Digital analysis of the occlusal changes and palatal morphology using elastodontic devices. A prospective clinical study including Class II subjects in mixed dentition



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Abstract

Aim The aim of the present prospective study was to evaluate the effectiveness of elastodontic appliance (EAs) in the treatment of subjects presenting Class II sagittal discrepancy in mixed dentition, and to evaluate palatal morphological development during treatment.

Materials and methods The study group, composed of 19 subjects, received treatment with EA for 1 year. The control group consisted of 17 untreated subjects. Inclusion criteria: age between 6 and 11 years, mixed deciduous dentition and skeletal and/or dental Class II malocclusion. Exclusion criteria: previous orthodontic therapy, systemic diseases and signs of temporal dysfunction. Skeletal and dentoalveolar parameters were compared between T0 and T1. A 3D imaging technology was used to compare palatal morphology obtained from intra-oral digital scans between T0 (pre-treatment) and T1 (post-treatment).

Results A significant reduction of the overjet and improvement of the overbite were registered in the study group ($p < 0.05$); instead, a slight increment of the overjet and overbite was detected at T1 in the control group, however without statistical significance ($p > 0.05$). The number of subjects presenting anterior crowding decreased at T1 in both arches ($p < 0.05$), while in the control group there was a small increase of subjects presenting anterior crowding in both arches ($p > 0.05$). In the study group, no significant differences were found between the SNA$\hat{}$ values detected at T0 and T1 ($p > 0.05$); instead, a significant increment was found for SNB$\hat{}$, ANB$\hat{}$, and IIA$\hat{}$ values ($p < 0.05$). The 3D deviation analysis showed in both group a pre-treatment palatal asymmetry which partially recovered at T1 in the study group, compared to controls.

Conclusion EAs can successfully mitigate early signs of malocclusion in Class II subjects as well as contribute to the harmonious development of the palate.

KEYWORDS Elastodontic appliances; dental Class II malocclusion; Digital workflow; Surface-to-surface superimposition; 3-D technology.

Introduction

Orthodontic treatment at paediatric age consists of a preventive approach for the correction of those malocclusions that do not self-correct with age [Tausche et al., 2004; Keski-Nisula et al., 2003; Ingelsson-Dahlström and Hagberg, 1994]. However, a general consensus for interceptive treatment has not been reached since there is evidence that early stage treatment could lead to a stable occlusion [Ackerman and Proffit, 1980; Pavlow et al., 2008], while other studies suggest that children would not benefit from early intervention, except for a temporary increase in self-esteem [Harrison et al., 2007; Seehra et al., 2011]. In particular, interceptive treatment could be indicated when it is necessary to eliminate factors interfering with the harmonious development of maxillary and mandibular arches, often resulting in compensatory skeletal and dento-alveolar responses to maintain a stable function and occlusion.

Elastodontics is an interceptive therapy using removable appliances made of silicone elastomer, which allows the development of light, biological elastic forces. These forces would allow the correction of malocclusions at developmental age, correcting the position of teeth and potentially affecting growth [Corbett, 1992; Methenitou et al., 1990]. The elastomeric material promote the orthodontic movement in synergy with the neuromyofascial system, while the vestibular flanges prevent the perioral muscles from influencing the movement of the teeth [Bergersen, 1995]. In this regard, elastodontic appliances (EAs) originate from its precursor Occlus-O-Guide®, or Eruption Guidance Appliance (EGA), designed to generate minor positional correction or to guide dental eruption. In addition, preformed EAs can feature an anterior slope for mandibular advancement in Class II patients, similar to the concept of removable functional appliance. Previous evidences [Keski-Nisula et al., 2003; Janson et al., 2007; Fichera et al., 2021; Inchingolo et al., 2022; Quinzi et al., 2022] would suggest that EAs could be effective in promoting significant clinical improvement of early signs

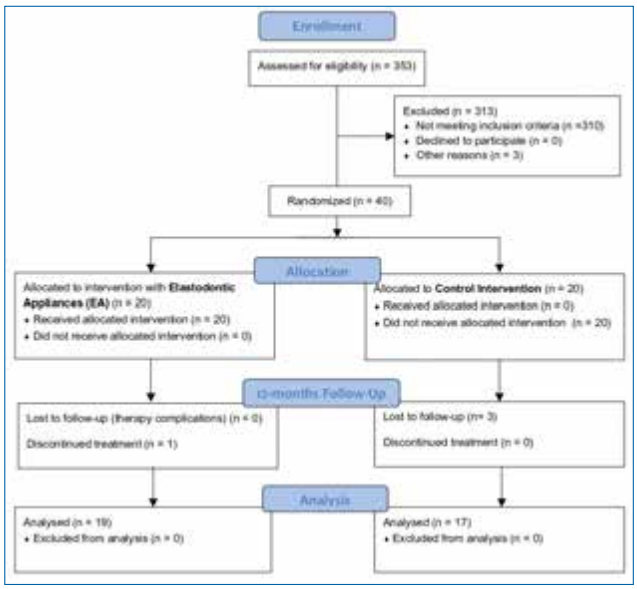


FIG. 1 The CONSORT flowchart.

of malocclusions such as crowding, overbite, overjet and sagittal molar relationships. However, these studies were designed as case reports or were limited to the retrospective observation of the data outcomes, while the only prospective study available [Ortu et al., 2021] included also subjects in permanent dentition and did not provide information about the morphological changes occurring during treatment with EAs. The aim of the present prospective clinical trial was to evaluate the effectiveness of EAs in correcting early signs of malocclusion in a cohort of subjects presenting Class II sagittal discrepancy in mixed dentition. A specific 3D imaging technology, involving superimposition of pre-treatment and post-treatment maxillary intra-oral scans was also used to evaluate the morphological changes of the palate and alveolar processes during the treatment stage.

Materials and methods

Study sample

This study was carried out in accordance with the Helsinki Declaration on medical protocols and ethics, and was approved by the Institutional Ethical Committee of the University of Catania (protocol n. 119/2019/po-Q.A.M.D.I). The study sample included subjects seeking orthodontic treatment at the Department of Orthodontics, Paediatric Unit, University of Catania (Italy), between January 2017 and December 2020. All enrolled subjects adhered to a local health protocol for orthodontic treatment in growing patients with a low or limited socio-economic background. According to specific socio-economical parameters defining the waiting list, subjects who could adhere to the local healthcare protocol were immediately included in the study group, while subjects who should wait at least 12 months served as controls. The inclusion criteria were: age between 6 and 11 years, mixed deciduous dentition, skeletal and/or dental Class II malocclusion, overjet ≥ 4 mm, overbite ≥ 2/3 of overlapping incisors or anterior crowding in association with an overjet of ≥ 4 mm. Exclusion criteria: previous orthodontic treatment, Class III malocclusion and retroclined upper incisors, temporomandibular dysfunction, index of orthodontic treatment need (IOTN) > 4, systemic disease.



FIG. 2 The II Class AMCOP SC bio-activator used for the subjects in the treatment group.

From a larger pool of subjects (353), 40 participants who satisfied the inclusion/exclusion criteria were randomly recruited. Four participants were excluded from the final study sample: one subject (study group) discontinued the therapy, while 3 subjects (control group) were lost to follow-up. As a consequence, the final sample consisted of 19 subjects in the study group (9 males, 10 females; average age = 9.1 ± 0.7 years) and 17 subjects in the control group (7 males, 10 females; average age = 8.8 ± 0.8 years). The CONSORT flowchart is reported in Figure 1.

Treatment protocol

All patients in the treatment group received a II Class AMCOP SC bio-activator (Ortho Protec, BA, Italy) (Fig. 2). This preformed appliance is based on a polymer/elastomer combination; it features a vestibular and lingual flange delimiting a free central zone where teeth are free to erupt, without constriction or generating orthodontic movements. The two flanges are connected by an anterior slope that keeps the mandible in an advanced position, favouring the correction of Class II malocclusion. The appropriate size for each individual patient was selected considering the inter-molar diameter and the inclination of the incisors. All participants in the treatment group were recommended to wear the appliance at night and one hour during the day. The patients were also instructed to bite the device during the daily wear, keeping the lips in contact.

Digital impressions and bite registration were taken (Carestream 3600, Carestream Dental LLC, Atlanta, GA, USA) before treatment (T0) and after 12 months (T1). Lateral cephalograms (ORTHOPHOS XG, Sirona Dental GmbH, Wals bei Salzburg, Austria) were also taken at T0 and T1 for the study group. Subjects in the control group were excluded from X-ray examinations to avoid unnecessary radiation exposure [Jaju and Jaju, 2015].

Measurements

All digital models were imported into Ortho Analyzer software (3Shape A/S, Copenhagen, Denmark) to perform occlusal and dento-alveolar evaluations. Specifically, the following parameters were recorded at T0 and T1: overjet (mm), overbite (mm) and crowding (mm). The severity of crowding was defined as follow: aligned dentition (no rotation or interproximal surface overlap), mild crowding (≤ 2 mm), moderate crowding (3–4 mm) and severe crowding (> 4 mm).

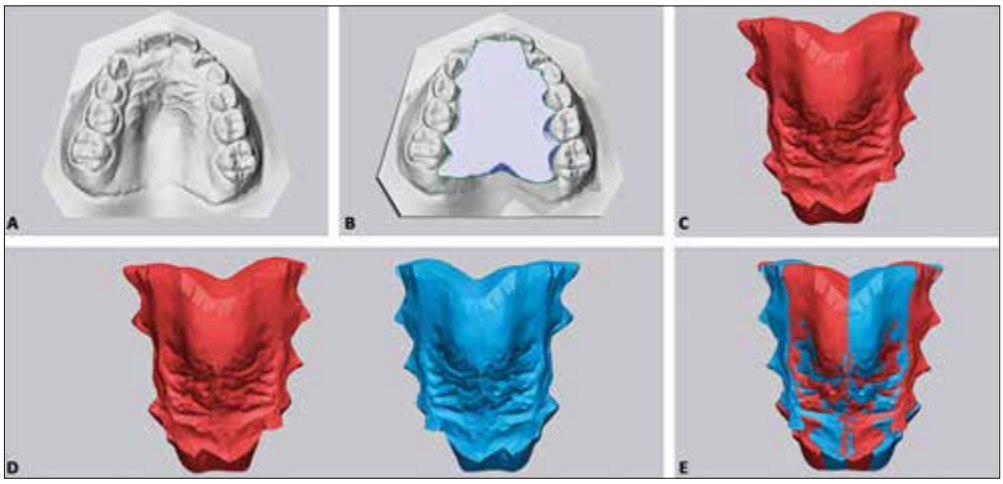


FIG. 3 3D intra-oral scans taken at T0 and T1 were used to perform surface analysis of the palate and assess morphological changes.

A simplified cephalometric analysis was performed at T0 and T1 for the treatment group, using Dolphin3D software (Dolphin Imaging, version 11.0, Chatsworth, CA, USA. The values recorded for data analysis were: SNA^, SNB^, ANB^ and inter-incisal angle.

To verify the morphological changes (symmetry/asymmetry) and perform surface analysis of the palate, a specific 3D imaging technology was carried out using intra-oral scans taken at T0 and T1, according to a consolidated methodology [Lo Giudice et al., 2020]. The procedure involved 4 steps (Fig. 3) as follows.

- Segmentation of the palate (Ortho Analyzer software, 3Shape A/S, Copenhagen, Denmark): a 3D model was defined by generating a gingival plane passing through all the most apical points of the dento-gingival junction of all teeth, from the right first molar to the left first molar.
- Mirroring (Geomagic Control™ X (version 2017.0.0, '3D Systems', Rock Hill, USA): a duplicated mirrored model of the palate was generated using the midpalatal plane (MPP) as reference, that is the line passing through a point placed at the level of the second rugae and a second point 1 cm distal, along the palatal raphe.
- Surface registration: the original and mirrored palate models were superimposed via preliminary registration using MPP as reference plane, and a final registration was executed using the "Best-fit alignment" feature in the Geomagic Control X software.
- Deviation analysis and matching percentage calculation: using the same software, the deviation analysis automatically calculated the mean and maximum values of the linear distances (Euclidean distance) between the surfaces of the two palatal models, measured across 100% of the surface points. The analysis was complemented by the visualisation of the 3D colour-coded maps, set at 0.3 mm range of tolerance (green colour), to better evaluate and locate the discrepancy between the model surfaces (Fig. 4). The percentages of all the distance values within the tolerance range were calculated. These values represented the degree of correspondence between the original and the mirrored models and, therefore, provided quantitative data of the morphological characteristics of the palate detected at T0 and T1.

The entire workflow, including segmentation and respective generation of the mask, was carried out by the same experienced operator (A.L.G.). Measurements were performed by the same operator 4 weeks later to obtain data for intra-operator reliability. A second expert operator (V.R.) also performed the digital workflow in order to obtain data for the assessment of inter-operator reliability.

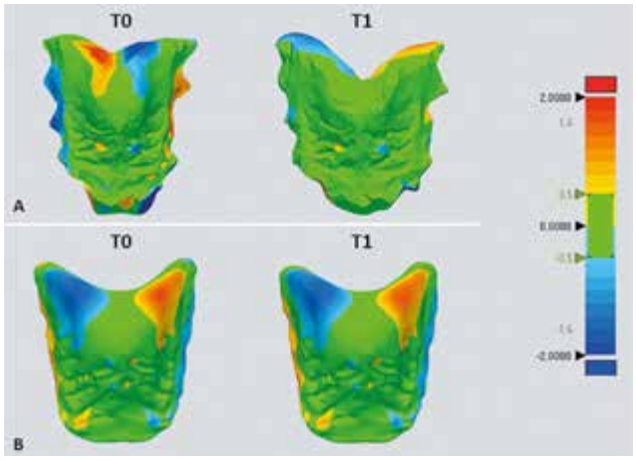


FIG. 4 Visualisation of the discrepancy between the model surfaces by means of te 3D colour-coded maps.

Statistical method

Sample size was determined after performing power analysis from previous published data [Fichera et al., 2021]. The analysis suggested that 8 patients were required for each group to reach the 80% power to detect a mean difference of 2.9 mm3 in the changes of the overjet, with a confidence level of 95% and a beta error level of 20%. However, according to the inclusion criteria, we were able to implement the study sample which increased the robustness of the data. Preliminary data analysis was performed using the Shapiro-Wilk test and Levene's test, respectively to assess data distribution and equality of variance. Since data showed normal data distribution, parametric tests were used. In particular, paired Student's t test and Chi-square test were used to compare data recorded at T0 and T1 in each group, instead unpaired Student's t test was used to evaluate data changes for inter-group assessments (only data from analysis of study models). Statistical significance was set at $p < 0.05$.

Intra-examiner reliability was assessed using intraclass correlation coefficient (ICC). Datasets were analysed using SPSS® version 24 Statistics software (IBM Corporation, Armonk, New York, USA).

	Treated Group					Control group				
	T0		T1			T0		T1		
	Mean	SD	Mean	SD	Significance*	Mean	SD	Mean	SD	Significance*
Overjet	5,6	0,7	2,8	0,63	p < 0.05	5,2	1,3	5,8	1,4	NS
Overbite	4,3	0,82	2,1	0,32	p < 0.05	4	1,1	4,5	1,2	NS

T0 = pre-treatment, T1= post-treatment, SD = standard deviation
** = p value set at p < 0,05 based on paired Student's t test for intertiming comparisons; ** = p value based on Independent Student's t test for inter-groups comparisons of changes between T0 and T1*

TABLE 1 Inferential statistics of overjet and overbite detected within treated and control group.

		T0			T1		
		TG	CG		TG	CG	
		n	n	Significance*	n	Mean	Significance*
Maxilla	Crowding	15	12	NS	10	14	NS
	Normal	4	5		9	3	
	Total	19	17		19	19	
Mandibular	Crowding	18	13	NS	10	17	NS
	Normal	1	4		9	0	
	Total	19	17		19	17	

T0 = pre-treatment, T1= post-treatment, SD = standard deviation, n = subjects' number
**= p value set at p < 0.05 and based on Chi-Square test*

TABLE 2 Inferential statistics of data distribution of crowding between treatment group (TG) and control group (CG).

	Treated Group				
	T0		T1		
	Mean	SD	Mean	SD	Significance*
SNA^	80,7	1,57	81,1	1,76	NS
SNB^	76	1,63	78,4	1,96	p < 0.05
ANB^	4,7	1,42	2,6	1,43	p < 0.05
IIA^	128,1	9,97	131,4	7,71	p < 0.05

T0 = pre-treatment, T1= post-treatment, SD = standard deviation
** = p value set at p < 0,05 based on paired Student's t test for intertiming comparisons;*
*** = p value based on Independent Student's t test for intratiming comparisons*

TABLE 3 Inferential statistics of overjet and overbite detected within treated and control group.

Result

A statistically significant reduction of the overjet and improvement of the overbite were registered between T0 and T1 (p < 0.05) in the study group; conversely, a slight increment of the overjet and overbite was detected at T1 in the control group, however without statistical significance (p > 0.05) (Table 1).

In the study group, the number of subjects presenting anterior crowding decreased at T1, considering both maxillary and mandibular arches; instead, in the control group there was a small increase of subjects presenting anterior crowding in both arches. However, the changes in patients' distribution according to the presence of crowding was not statistically significant between the two groups at T0 and T1 (Table 2).

No significant differences were found between the SNA^ values detected at T0 and T1 (p > 0.05), instead both SNB^ and ANB^ showed a significant increment between pre-treatment and post-treatment recordings (p < 0.05). The IIA^ also showed a significant increment after treatment (p < 0.05), reflecting a reduction of the overjet along with the increment of SNB^ and ANB^ (Table 3).

Results of the intra-timing analysis at T0 (T0 vs. T0m) showed a limited percentage agreement, respectively of 79.58 % (± 2.54) in TG and of 82,41 (± 3.79) in the CG, suggesting a small asymmetry of the maxillary anatomy. At T1, there was a statistically significant increment of the percentage of agreement of palatal surfaces (T1 vs. T1m = 88.05% ± 3,29) in the TG (p < 0.05); instead in the CG there was a slight reduction of the palate matching percentage (T1 vs. T1m = 80.90% ± 4.74), however without statistical significance (p > 0.05) (Table 4).

Concerning deviation analysis, palatal vault showed a prevalence of green colour, which indicates that this area was coincident between the original and the mirrored models. Instead, the colour-coded map showed an intense blue colour on one side of the palatal surface of the alveolar process and an intense red colour on the other side. This data would suggest that the palatal asymmetry was mainly confined to the lower part of the palate at the alveolar processes level as shown in Figure 4.

No differences were found between intra-operator readings, with excellent correlation indexes ranging from 0.901 to 0.923 for measurements performed on digital models and ranging from 0.931 to 0.957 for cephalometric measurements.

Discussion

EAs are widely used for the preventive or interceptive orthodontic treatment in growing subjects, however the available scientific evidence concerning their effectiveness in mixed dentition is limited to case series and retrospective studies. To the best of our knowledge, this is the first study in literature designed as prospective clinical trial and evaluating the short-term effectiveness of EAs in a cohort of children showing Class II malocclusion.

We included a control group of untreated subjects to discriminate the changes related to the treatment from those occurred due to growth. The control group comprised subjects which were excluded from the local health program supporting the orthodontic treatment, according to specific socio-economic parameters used to draft the attendance list. The same children had the opportunity to receive the treatment one year later, avoiding the ethical issues related to the recruitment of growing subjects in the control group for scientific purpose [Jaju and Jaju, 2015].

	Treated Group					Control group					
	T0		T1			T0		T1			
	Mean	SD	Mean	SD	Significance*	Mean	SD	Mean	SD	Significance*	Significance**
Matching percentage	79,58	2,54	88,05	3,29	p < 0.05	82,41	3,79	80,9	4,74	NS	p < 0.05

** = p value set at p < 0,05 based on paired Student's t test for intertiming comparisons;*
*** = p value based on Independent Student's t test for inter-groups comparisons of inter-groups changes*

TABLE 4 Comparison of intra-timing matching percentage agreement between original and mirrored palate models in treated group (TG) and control group (CG).

Subjects treated with EAs showed a significant improvement (reduction) of the overjet and overbite parameters restoring a physiological inter-incisal relationship, meanwhile untreated subjects showed a slight worsening of the same parameters. These findings are in agreement with previous evidence [Myrlund et al., 2015] and could be explained considering that EAs allow a controlled eruption of the maxillary incisors and of the posterior dentition. In particular, the vestibular flange prevents incisor flaring during eruption while the different thickness of the occlusal surface of the appliance (thicker in the anterior section and thinner in the posterior unit) allows the eruption of the permanent and deciduous molars, avoiding overeruption of the upper and lower incisors [Ramirez-Yañez et al., 2007; Methenitou et al., 1990]. In this regard, it would seem appropriate to initiate the interceptive treatment at the early stage of incisors eruption since the EA acts as an erupting guide that helps the establishment of normal contact and tipping of the incisors as well as an improvement in the crowding supported by natural transversal growth of the dento-alveolar process [McNamara et al., 1990].

Also, the anterior sloped plane for mandibular advancement may generate a force-system that induces a slight opening of the inter-incisal angle and a mesial advance of the molars. As consequence, the combined effects on both arches improve Class II molar relationship as well as overjet and overbite [Saccomanno et al., 2021; Gelb et al., 2021; Ravera et al., 2021; Grippaudo et al., 2020; Giuca M.R.et al. 2020].

According to cephalometric analysis, subjects treated with EAs showed a slight increase of the mandibular sagittal projection from T0 (SNB^ = 76° ± 1.63; ANB^ = 4.7° ± 1.42) to T1(SNB^ = 78.4° ± 1.96; ANB^ = 2.6° ± 1.43). The present study lacks of comparative cephalometric data from untreated subjects and it was not possible to discern the skeletal changes influenced by the treatment from those occurred due to growth. Two previous studies analysed the pre-treatment and post-treatment cephalograms of Class II subjects treated with EAs and found a significant increment of mandibular length compared to untreated individuals, with a mean difference of 3.9 mm after 3 years of treatment in the study of Keski-Nisula et al. [2003] and 2.,55 mm after 26 months of treatment in the study of Janson et al. [2007]. Instead, both studies showed no changes of the parameters related to the maxillary bone. However, the limited scientific evidence available does not justify the usage of EAs to correct skeletal Class II discrepancy, anticipating the later treatment with functional appliance (FAs). Long-term clinical trials are warmly encouraged to investigate this topic.

Despite the lack of evidence concerning the skeletal effects of Class II EAs, the findings of the present study would support the choice of treating the early signs of malocclusion in mixed dentition. In this regard, the improvements in both skeletal and dentoalveolar components of the malocclusion could be responsible for the restoration of normal muscular activities. Previous evidence from electromyography (EMG) studies suggested that one of the most frequently observed effects of wearing a myofunctional appliance was the reduction of the hypertone of the mental muscle and an increase in muscle activity of the orbicular, usually hypotonic in cases of labial incompetence [Tartaglia et al., 2009; Tallgren et al., 1998]. Furthermore, the early reduction of upper incisors inclination and the opening of the inter-incisal angle would be justified for preventing dental trauma in children [Batista et al., 2018].

The design of EAs features flanges that isolate the dento-alveolar processes and the palate from the surrounding structures, particularly perioral muscles. EAs also act as a myofunctional regulator that tends to properly rebalance muscle forces [Ortu et al., 2021]. In this regard, one assumption of the study was that EAs allow the harmonious development of the palate by contrasting the forces that may interfere during growth. We evaluated palatal morphology by surface-based superimposition of mirrored maxillary models. By using this reverse engineering, each virtual palate can be mirrored at an arbitrary point and it is possible to detect morphologic differences between the two palatal halves. Moreover, the 3D differences of the registered models are usually translated into colour codes that represent the distance between corresponding points. According to this methodology, we found that subjects in both treated and control groups presented a slight asymmetric development of the palate at T0, mostly involving the area proximal to the dento-alveolar processes. This pattern of palatal asymmetry has been documented in presence of functional cross-bite, as an adaptive response to occlusal interference leading to a functional mandibular shift toward the side of the crossbite in centric occlusion [Ferro et al., 2011; Lo Giudice et al., 2015]. None of the included subjects presented posterior crossbite, and the asymmetry found in our sample may be attributed to an adaptive response to the asymmetric function of perioral muscles [Ferro et al., 2011; Akin et al., 2015]. This assumption could be confirmed by the second data, i.e. that subjects in the treated group showed a significant improvement of the asymmetry after 1 year of therapy, compared to controls. Thus, it is possible that EAs, by rebalancing of the perioral musculatures, could somehow re-establish a normal pattern of development of the palate and alveolar processes [Giuca et al.,2021]. Further studies are encouraged to elucidate this aspect. The present findings were limited to the small sample size included and to the short-term design (1 year), and should be interpreted with caution until medium- and long-term scientific evidence will be available.

Conclusion

Subjects treated with an EAs showed a significant improvement in overjet, overbite, crowding, and the sagittal

molar relationship, compared to controls.

An asymmetric pattern of palatal growth was found in most subjects, which significantly improved in the tested group compared to controls.

EAs can be successfully mitigate early signs of malocclusion in Class II subjects as well as contribute to the harmonious development of the palate.

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