

# Cephalometric effects of the elastodontic appliance in managing skeletal Class II division 1 cases

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**Aim:** The aim of the study was to evaluate the cephalometric effects of the elastodontic appliance (EA) in the management of patients presenting with a skeletal Class II/1 malocclusion.

**Methods:** Twenty Class II patients treated using the EA (Group EA) were compared with 20 Class II untreated children (Group C). Cephalograms were compared at the start (T0) and after 24 months (T1) after which time, skeletal, dental, and aesthetic variables were evaluated. A statistical evaluation was conducted by applying an unpaired *t*-test for normally distributed variables.

**Results:** From T0 to T1, the EA group showed a significant increase in lower facial height (LFH), in mandibular length (Co-Gn), in the upper incisor and cranial plane angle (I + SN) and in the distance between a true vertical line (TVL)-soft tissue B (B') and TVL-soft tissue Pogonion (Pog') points. From T0 to T1, group C showed a significant decrease in SN-occlusal plane (PO) ( $p < 0.01$ ), of SN-mandibular plane (Go-Me) ( $p < 0.01$ ) and of total gonal (N-Go-Me) angles ( $p < 0.05$ ); a significant reduction of the distance between TVL-upper incisor (I+), TVL-lower lip (Li), and TVL-Pog' was shown. No statistical differences were observed between the groups in dental and aesthetic outcomes, except for a skeletal increase in LFH ( $p < 0.05$ ) and in Co-Gn length ( $p < 0.05$ ), which was statistically significant in the EA group.

**Conclusion:** In Class II growing patients, the EA induces minor skeletal effects, compared to untreated control patients.  
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## Introduction

A Class II malocclusion is the most common skeletal sagittal relationship found in Caucasian populations.<sup>1</sup> Although various crano-facial components are involved, skeletal mandibular retrusion is the most frequent characteristic of Class II patients.<sup>2</sup>

Orthodontists have numerous treatment approaches available for Class II correction, which include extra-oral traction, arch expansion mechanics, extraction procedures, and functional jaw orthopaedic appliances.<sup>2</sup> Several functional orthopaedic appliances have been reported to influence mandibular growth as a result of

the skeletal and neuromuscular adaptations that occur as a response to therapy.<sup>3-9</sup>

Recent studies have indicated that the elastodontic appliance (EA) is effective in Class II treatment,<sup>10-12</sup> because of its ability to affect mandibular growth and position, and therefore contribute to the correction of a Class II sagittal discrepancy.<sup>3,10-12</sup>

The EA is a removable appliance,<sup>3</sup> made of a silicone elastomer.<sup>13</sup> It is considered a combination of a functional appliance and a tooth positioner<sup>14</sup> as it advances the mandible to improve a Class II relationship and, further, acts as a tooth positioner

as tooth movements are generated by the elastomeric material.<sup>15</sup>

The EA is indicated for Class II cases presenting during the mixed or early permanent dentition<sup>3</sup> to advance the mandible and guide the eruption of the posterior teeth into a Class I relationship whilst improving the overbite.<sup>10–12,14,16,17</sup> The myofunctional effects induced by the appliance reduce the overjet and manage the sagittal correction, and so increase neuromuscular balance.<sup>18</sup>

Although the effects of the appliance are largely reported to be dentoalveolar,<sup>19</sup> significant skeletal changes have been described.<sup>10,11,14</sup>

Therefore, the aim of the present study was to evaluate the cephalometric effects of EA treatment of Class II/1 growing patients, compared to an untreated Class II/1 sample.

## Materials and methods

Two sample groups of Class II patients from records obtained from the Orthodontic Department, University of Foggia were retrospectively identified. The first group had been treated using an EA (group EA) and the second group received no treatment and served as a control group (group C). Informed consent was provided by the parents of the participating patients. The conducted procedures were in accordance with the Helsinki Declaration of 1975, as revised in 2008.

The inclusion criteria determined patients who had a skeletal Class II ( $\text{ANB} > 4^\circ$ ); an overjet  $\geq 5 \text{ mm}$ ; a molar Class II relationship; in the late mixed dentition and had adequate growth potential remaining. Growth potential was evaluated using the cervical-vertebral maturation method (CVM) and all patients presented at a stage of CS2 or CS3.

The exclusion criteria included patients with a Class III malocclusion, who had a crossbite, other oral or systemic

diseases, missing teeth, congenital malformations, advanced CS5 development or previous orthodontic treatment.

Pre-treatment (T0) and post-treatment (T1) records included study models, photographs, panoramic radiographs, and lateral head films.

The patients were divided into two groups.

### **Group EA**

Group EA consisted of 20 patients (11 females and 9 males) with an initial mean age of 9.46 years ( $\pm 0.3$ ) who were treated using an EA (Figure 1). The mean treatment time was 24 months (range 18–32) and, at the end of treatment, the mean patient age was 11.5 years ( $\pm 0.9$ ) (Figure 2A, B).

The EA used (AMCOP SC series, Micerium, Genova, Italy) was a pre-formed appliance made of silicone elastomer. To select the correct size, patient impressions were taken and the distance between the buccal cusps of upper first molars was measured and compared to a size selection chart provided by the manufacturer. Each patient was instructed to wear the appliance while sleeping and for four hours during the day. No myofunctional exercises were recommended. The occlusion changes were monitored monthly.

### **Group C**

Control Group C consisted of 20 patients (13 females and 7 males) who had an initial mean age of 9.7 years ( $\pm 0.4$ ) and a final mean age of 11.4 years ( $\pm 0.5$ ). These patients received no treatment.

### **Cephalometric analysis**

Lateral head films (Gendex GXDP-700) were taken with the patient fixed in a cephalostat, in centric



Figure 1. Elastodontic appliance.



Figure 2. (A) Pre-treatment intra-oral photographs; (B) post-treatment intra-oral photographs.

occlusion, with adequate visualisation of reference structures, and without appreciable head rotation. All of the lateral radiographs were taken by the same technician and on the same machine in the same radiology department.

A cephalometric analysis was performed before (T0) and at the end of the treatment (T1). The landmarks and reference lines used in the cephalometric analysis are presented in Figure 3 and described in Figure 4.

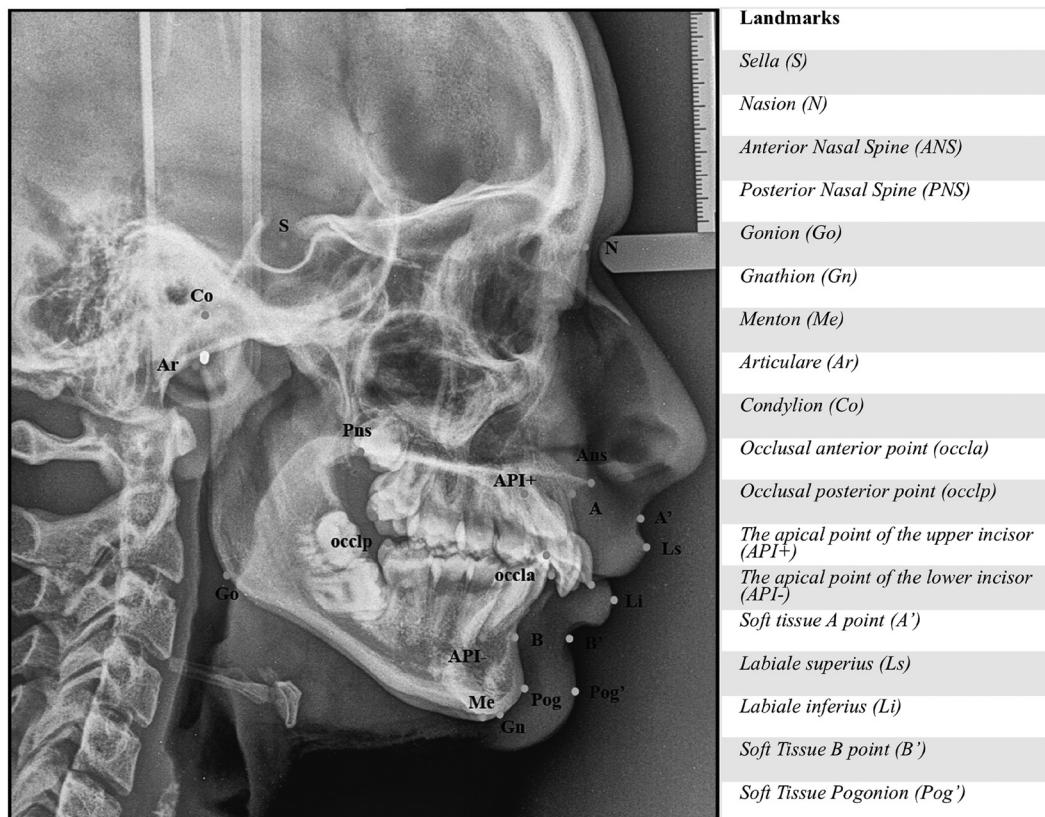


Figure 3. Landmarks.

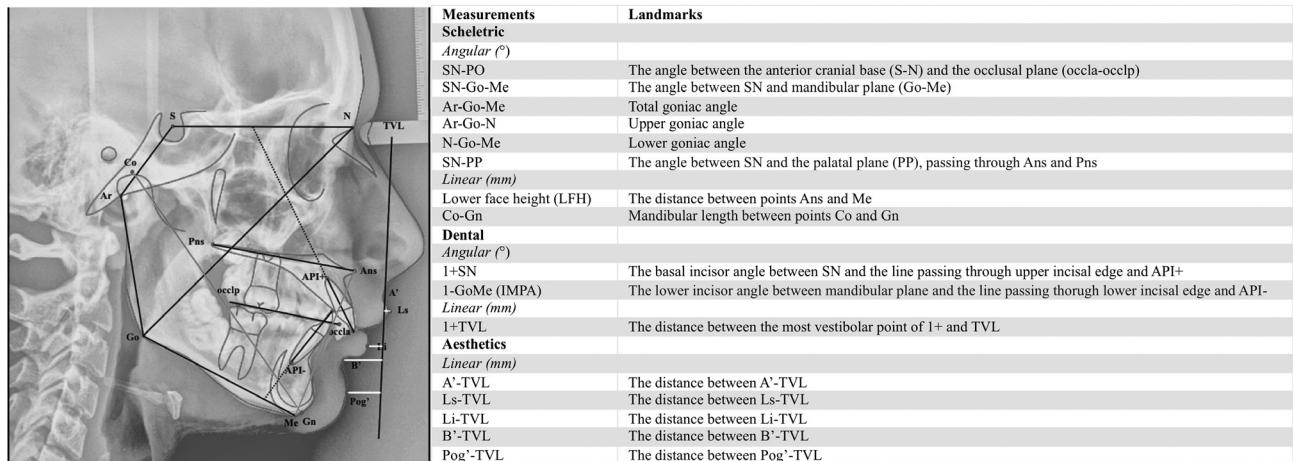


Figure 4. Reference lines for cephalometric analysis.

The following cephalometric skeletal variables were analysed: SN-PO, SN-Go-Me, and SN-PP angles; the lower facial height (LFH); Ar-Go-Me, Ar-Go-N, N-Go-Me angles; Co-Gn distance.

The dental assessment was based on the following cephalometric values: 1-SN and 1-GoMe angles and the distance between TVL and the upper incisor. The aesthetic analysis evaluated the distances between TVL and the upper imcisor, A', Ls, Li, B', and Pog' points, respectively.

### Measurements error

To reduce the error of the method, the cephalometric analyses were performed by a trained examiner and all measurements were conducted twice by the same operator at T0 and T1 for both groups.

### Statistical analysis

Graph Pad version 6 software was used for statistical analysis. Data (skeletal, dental, and aesthetic) were analysed and means and standard deviations (SD) were calculated for both groups at T0 and T1 (Tables I and II). The Shapiro-Wilk Test was used to test the normal distribution of data. When applicable, a paired sample *t*-test was performed to investigate the difference in means of both sample groups, while the Mann-Whitney test was used as a non-parametric test in case of a non-normal distribution of the data. A threshold of a *p*-value lower than 0.05 was considered as statistically significant.

## Results

### Skeletal outcomes

During treatment with the EA, no significant differences (*p* = n.s.) were observed in SN-PO, SN-Go-Me, and SN-PP angles. In addition, the noted changes of the gonial angles (Ar-Go-Me; Ar-Go-N; N-Go-Me) were not statistically significant (*p* = n.s.), while the LFH and the mandibular length (Co-Gn) increased significantly (*p* < 0.05) in the EA group (Table I).

From T0 to T1 in control group C, no significant changes were observed in the SN-PP angle, of LFH and in Co-Gn distances. Untreated patients showed a significant reduction of SN-PO (*p* < 0.01), of SN-GoMe (*p* < 0.01), and of the N-Go-Me angles (*p* < 0.05), while the variations of the Ar-Go-N and Ar-Go-Me angles were not significant (*p* = n.s.) (Table I).

### Dental outcomes

The EA Group showed an increase in the 1-SN angle (*p* < 0.01). No differences in 1-GoMe (*p* = n.s.) and 1-TVL (*p* = n.s.) position were observed (Table II).

The control Group C showed no significant variations in 1-SN (*p* = n.s.) and 1-GoMe (*p* = n.s.) angles, while the reduction of 1-TVL distance was statistically significant (*p* < 0.05) (Table II).

### Aesthetic outcomes

The EA Group showed a significant reduction of B'-TVL (*p* < 0.01) and Pog'-TVL (*p* < 0.01) distances.

**Table I.** Skeletal differences.

Patients	Group EA		Group C	
	T0	T1	T0	T1
SN-PO				
Mean	15.09	15.27	15.89	12.07
StD	5.000	7.057	3.271	4.055
P	n.s. ( <i>t</i> -test)		P** (Mann–Whitney)	
SN-Go-Me				
Mean	32.58	31.58	34.61	33.76
StD	4.080	4.859	3.796	3.993
P	n.s. (Mann–Whitney)		P** ( <i>t</i> -test)	
LFH				
Mean	60.94	64.86	69.11	68.00
StD	9.043	10.71	9.328	8.882
P	P* ( <i>t</i> -test)		n.s. (Mann–Whitney)	
Ar-Go-Me				
Mean	127.3	126.1	134.7	132.6
StD	8.351	7.074	6.117	5.604
P	n.s. ( <i>t</i> -test)		n.s. (Mann–Whitney)	
Ar-Go-N				
Mean	53.44	52.37	58.88	57.89
StD	4.644	4.280	2.856	4.002
P	n.s. ( <i>t</i> -test)		n.s. (Mann–Whitney)	
N-Go-Me				
Mean	73.82	73.68	75.81	74.75
StD	4.826	4.147	4.648	3.892
P	n.s. (Mann–Whitney)		P* ( <i>t</i> -test)	
Co-Gn				
Mean	103.3	112.6	118.9	118.4
StD	15.74	17.03	12.73	14.05
P	P* (Mann–Whitney)		n.s. (Mann–Whitney)	
SN-PP				
Mean	7.929	7.924	7.046	6.267
StD	4.230	4.623	4.059	5.188
P	n.s. (Mann–Whitney)		n.s. ( <i>t</i> -test)	

\*P ≤ 0.05; \*\*P ≤ 0.01; n.s. P ≥ 0.05.

**Table II.** Dental and aesthetic differences.

Patients	Group EA		Group C	
	T0	T1	T0	T1
1+SN				
Mean	96.85	100.9	107	105.9
StD	10.84	7.775	4.827	5.809
P	P** (Mann–Whitney)		n.s. ( <i>t</i> -test)	
1-GoMe				
Mean	95.98	97.2	90.85	91.18
StD	3.092	6.347	6.486	7.244
P	n.s. ( <i>t</i> -test)		n.s. (Mann–Whitney)	
1+TVL				
Mean	-9.661	-8.838	-11.98	-10.57
StD	2.464	2.242	2.820	2.549
P	n.s. ( <i>t</i> -test)		P* (Mann–Whitney)	
A'-TVL				
Mean	0.368	0.042	-0.2400	0.0480
StD	1.749	0.9312	0.6867	2.006
P	n.s. (Mann–Whitney)		n.s. ( <i>t</i> -test)	
Ls-TVL				
Mean	2.095	2.043	1.493	0.7110
StD	2.135	2.264	1.921	3.263
P	n.s. (Mann–Whitney)		n.s. ( <i>t</i> -test)	
Li-TVL				
Mean	-2.333	-1.429	-5.448	-3.779
StD	2.964	3.358	4.004	3.480
P	n.s. ( <i>t</i> -test)		P** ( <i>t</i> -test)	
B'-TVL				
Mean	-12.19	-10.4	-15.81	-13.86
StD	2.967	3.950	5.120	3.748
P	P** ( <i>t</i> -test)		n.s. ( <i>t</i> -test)	
Pog'-TVL				
Mean	-12.85	-10.01	-17.73	-14.43
StD	3.423	3.512	5.428	5.496
P	P** (Mann–Whitney)		P* ( <i>t</i> -test)	

\*P ≤ 0.05; \*\*P ≤ 0.01; n.s. P ≥ 0.05.

No difference was observed for other aesthetic parameters (Table II).

Group C showed a significant reduction in Li-TVL ( $p < 0.01$ ) and Pog'-TVL ( $p < 0.05$ ) distances, while the other aesthetic variables were not significant (Table II).

### **Comparison of outcomes between groups**

No statistical differences were observed in the skeletal outcomes between the two groups, in respect of the following variables: SN-PO, SN-Go-Me, gonial angle (Ar-Go-Me, Ar-Go-N, and N-Go-Me) and SN-PP (Table III).

The EA Group showed a significant increase in LFH ( $p < 0.05$ ) and in Co-Gn length ( $p < 0.05$ ) compared to group C (Table III).

No statistical differences were observed in the dental and aesthetic outcomes between the two groups (Table III).

**Table III.** Comparison of skeletal, dental, and aesthetic variables between two groups.

Skeletal variables	EA/C	
	P	
SN-PO	0.1199	n.s.
SN-Go-Me	0.3378	n.s.
LFH	0.0408	P*
Ar-Go-Me	0.5780	n.s.
Ar-Go-N	0.9342	n.s.
N-Go-Me	0.9342	n.s.
Co-Gn	0.0173	P*
SN-PP	0.8513	n.s.
Dental variables		
1+SN	0.1139	n.s.
1-GOME	0.6107	n.s.
1+TVL	0.3133	n.s.
Aesthetic variables		
A'-TVL	0.3472	n.s.
Ls-TVl	0.3150	n.s.
Li-TVl	0.9453	n.s.
B'-TVL	0.6997	n.s.
Pog'-TVL	0.7158	n.s.

For all variables, a parametric test was used. \* $P \leq 0.05$ ; \*\* $P \leq 0.01$ ; n.s.  $P \geq 0.05$ .

### **Discussion**

The patients included in the present study had a skeletal Class II division 1 malocclusion. The effects of the EA were cephalometrically evaluated and skeletal, dental and aesthetic values were analysed after a treatment time of 24 months. A comparison was conducted with an untreated control sample possessing the same initial malocclusion characteristics and over a similar evaluation period of 24 months.

Several studies have previously analysed the effects of the EA and shown that the appliance was able to improve varying aspects of the Class II discrepancy.<sup>3,10,12,15</sup> The observable changes were mainly in the OJ, OB, spatial deficiencies, Class II skeletal, and molar relationship.<sup>11,12,15,20,21</sup>

Although the effects of the EA seem to be mainly dentoalveolar, significant skeletal changes have been previously reported.<sup>10,11,15</sup> In particular, EA treatment contributes to Class II correction,<sup>19</sup> by reportedly improving mandibular growth and position.<sup>11,16,19</sup>

In the present study, the focus was directed at specific aspects of the cranio-dento-facial complex. The skeletal analysis focused on changes in the vertical plane (SN-PO, LFH, Ar-Go-Me, Ar-Go-N, and N-Go-Me, SN-P) and on the sagittal increase of mandibular length (Co-Gn distance). The dental values analysed the variations in the inclination of maxillary (1-SN) and mandibular (1-GoMe) incisors. The aesthetic component focused on the changes in the soft tissues after EA treatment.

The cephalometric analysis showed a statistically significant increase in mandibular length (Co-Gn) in the EA group, which confirms the results of previous studies.<sup>11,12</sup>

During the 24-month evaluation period, mandibular length increase in the treated group showed a statistically significantly greater difference compared to the control sample.

From T0 to T1, the EA appliance enhanced condylar growth (Co-Gn distance) of +9.3 mm, and so an annual increase of approximately 4.5 mm/year was produced in the treatment group compared to the control group.

In support, Keski-Nisula et al.<sup>11</sup> reported a significant increase in mandibular length (11.1 mm), although the patients were in the early mixed dentition and the treatment time was of 3.3 years.

Janson et al.<sup>12</sup> reported a significant increase in mandibular length, in a sample of 30 patients in the early mixed dentition treated with an EA for 26 months.

Keski-Nisula et al.<sup>19</sup> demonstrated that, in 65 Class II children treated with an EA, mandibular length increased 5 mm more from T1 (5.4 years) to T2 (8.5 years), compared to a control group of untreated Class II children. The skeletal effects of Class II treatment carried out in the early mixed dentition with the EA reportedly remain stable into the early permanent dentition.

Although the best mandibular growth rate response to functional therapy is achieved at or near the peak of the pubertal growth spurt (CS3-CS4),<sup>22,23</sup> a significant orthopaedic effect can be achieved even earlier (CS2). However, Proffit has suggested that early Class II treatment is only indicated for a select group of children.<sup>1</sup>

Several additional studies have shown that very little, if any, correction of a Class II relationship can be expected with growth,<sup>24–26</sup> in agreement with the present results in which mandibular growth did not improve the Class II relationship in the untreated group.

Keski-Nisula et al.<sup>11</sup> showed that the skeletal features of a Class II malocclusion tend to become exaggerated with age, while Heikinheimo et al.,<sup>27</sup> in a longitudinal analysis from 7 to 15 years of age, showed that the need for treatment increased rather than decreased with age.

Therefore, as other functional appliances increase mandibular growth,<sup>28</sup> the EA can also present a method of intercepting and correcting Class II development in the mid or late mixed dentition.

As demonstrated in a published clinical study,<sup>28</sup> Class II functional appliances advance the mandible along the direction of the facial axis, which increases not only mandibular length but also the vertical facial dimension.

In the present study, the LFH in the EA group increased significantly (+3.92°) compared to the control group. The results of Janson et al.<sup>12</sup> also reported an increase in lower anterior face height after EA treatment, although Keski-Nisula et al.<sup>11</sup> did not observe any significant effect. Furthermore, in contradistinction to other functional appliances, EA treatment did not significantly affect the position of other skeletal vertical components.<sup>10</sup>

The changes in the cranial-palatal plane (SN-PP) and of the cranial-occlusal plane (SN-PO) did not appear to have been significantly affected by EA therapy.

In addition, changes in the relationship between the cranial and mandibular planes observed in the two groups had similar values, suggesting that the EA appliance does not affect the crano-mandibular vertical relationship. From T0 to T1, the EA produced a decrease of SN-GoMe angle of -1°, while in the control group C, this decrease was -0.85°.

The data supports that presented by Janson et al.<sup>14</sup> and Myrlund et al.<sup>16</sup> who described a similar effect on the facial planes produced by the EA appliance. Janson et al.<sup>14</sup> observed a minor tendency for a mandibular counter-clockwise growth rotation (-1.82°) as a long-term treatment effect. Additionally, Myrlund et al.<sup>16</sup> reported a minor tendency for mandibular and maxillary counter-clockwise growth after EA therapy.

In the present study, there was no evidence of a morphological change in the mandible, as measured by the gonial angle (total, upper, and lower) between the treated and untreated groups.

From T0 to T1, the EA treatment induced a significant increase in the inclination of the maxillary incisors (1-SN) of +4.05°, while the slight increase in the protrusion of the lower incisors (1-GoMe) was not significant. Although the EA appliance produced protrusion of the upper incisors, this change was not statistically significant compared to the control group.

Several studies have suggested that a functional appliance produces lingual tipping and retrusion of the upper incisors, as well as protrusion of the lower incisors,<sup>1,29</sup> while similar tendencies have been observed using other EA appliances.<sup>12</sup> Kenski-Nisula et al.<sup>11</sup> reported no treatment effect on the inclination or protrusion of the maxillary incisors, although Janson et al.<sup>12,14,15</sup> found lingual tipping and retrusion.

From T0 to T1, EA treatment assessed B' and Pog' advancement with a significant reduction of B'-TVL (-2.5 mm) and Pog'-TVL (-2.84 mm), whereas the control group showed Li and Pog' advancement from TVL. The aesthetic mandibular improvements of the EA were not significant compared with the control group as none of the aesthetic changes were significant between the two groups.

## Conclusion

In growing patients presenting with a Class II malocclusion, EA treatment did not produce significant dental and aesthetic changes, but only minor skeletal effects. Mandibular length and lower facial height were found to slightly increase after EA treatment compared with untreated patients.

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## Conflict of Interest

The authors declare that there is no conflict of interest.

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