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ORIGINAL RESEARCH



Dentoskeletal and Soft Tissue Effects in the Treatment of Class II Malocclusion with Klammt's Elastic Open Activator

¹Sheila Marques Inamassu-Lemes, ²Acácio Fuziy, ³André Luiz Ferreira Costa, ⁴Paulo Eduardo Guedes Carvalho ⁵Ana Carla Raphaelli Nahás-Scocate

ABSTRACT

Aim: The purpose of this study was to evaluate the dentoskeletal and soft tissue effects resulting from treatment with Klammt's elastic open activator (EOA) functional orthopedic appliance in patients with Class II malocclusion characterized by mandibular deficiency.

Materials and methods: Teleradiographs were evaluated in the lateral aspect of the initial (T1) and final (T2) orthopedic phases for 16 patients with Class II, Division 1 malocclusion. The age range was from 9 to 11.2 years, with a mean age of 9.9 years. The cephalometric points were demarcated, and cephalometric measurements were obtained by the same investigator to avoid interobserver variability.

Results: The EOA promoted increased lower anterior facial height (LAFH), increased effective mandibular length, clockwise rotation of the mandible, retrusion and verticalization of the upper incisors, proclination and protrusion of the lower incisors, extrusion of the upper molars, mesial movement of the lower molars and anterior projection of the lower lip.

Conclusion: Skeletal changes characterized by an increase in mandibular length and dentoalveolar changes with an emphasis on the verticalization and retrusion of the upper incisors, proclination of the lower incisors and mesial positioning of the lower molars were key to improving the occlusal relationship and esthetic facial factors.

Clinical significance: The EOA is well indicated in patients with Class II malocclusion due to mandibular deficiency with increased overbite, proclined upper incisors and verticalized lower incisors.

Keywords: Activator, Cephalogram, Class II malocclusion, Orthopedic appliance.

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¹⁻⁵Department of Orthodontics, University of São Paulo City São Paulo, Brazil

Corresponding Author: Acácio Fuziy, Professor, Department of Orthodontics, University of São Paulo City, São Paulo Brazil 03071000, Phone: +551121781310, e-mail: acaciofuziy@ hotmail.com with Klammt's Elastic Open Activator. J Contemp Dent Pract 2016;17(1):63-69.

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INTRODUCTION

Class II malocclusion has a high prevalence in the population¹⁻⁴ and is the result of a combination of skeletal and dental factors.^{5,6} Mandibular skeletal retrusion is the factor that contributes most to the determination of this sagittal problem.^{6,7} In this context, several mandibular propulsion appliances have been used to correct Class II malocclusions.⁸⁻¹² The effectiveness of this therapy depends on a correct diagnosis, age,¹² the patient's morphogenetic pattern and tolerance level, the cooperation level of the individual and family^{11,12} and the treatment time.¹¹

The ideal time to apply dentofacial orthopedics is directly related to the period of acceleration and intense growth, and functional appliances aim to promote maxillomandibular and dentoalveolar changes that can contribute to the correction of the occlusal relationship and the establishment of adequate muscle function in the growth phase.^{4,13} Early treatment promotes an improvement in facial esthetics, reintegration of the child into his or her social life,¹³ a reduction in the number of extractions, simplification of orthodontic movements and less need for orthognathic surgery.^{14,15}

There are several devices that are characterized by a mandibular propulsion action mechanism to correct Class II malocclusion, including the functional orthopedic appliance developed by Klammt in 1953. This device is called the elastic open activator (EOA) and is considered to be an activator that induces anterior mandibular positioning and stimulates facial muscle activity. It is elastic in that it consists of two segments of acrylic held together by a steel wire in the form of a palatal arch, which facilitates dental arch expansion, improving arch shape, aligning the teeth and modifying the functional occlusal plane, and it is also called open due to the reduction or absence of acrylic in the anterior region of the palate, which makes contact between the tongue and the palatal mucosa possible.^{16,17} The EOA acts freely in the oral cavity, stabilized by the mechanical action of the tongue and muscle tissue, allowing force to act intermittently on the jaw bones and teeth, inducing changes in growth and establishing new morphological relationships.¹⁸

Due to its simplicity, mode of action and reduced size, this orthopedic device has become widely accepted in orthodontics, and this study therefore aimed to analyze the dentoskeletal and soft tissue effects resulting from the use of the EOA in the treatment of Class II, Division 1 malocclusion.

AIMS AND OBJECTIVES

The present study aimed to analyze the dentoskeletal and soft tissue effects arising from the use of Klammt's EOA in treating individuals with Class II, Division 1 malocclusion characterized by mandibular deficiency.

MATERIALS AND METHODS

The study group consisted of 16 Brazilian Caucasian patients (11 females and 5 males) with initial ages ranging from 9 to 11.2 years and a mean age of 9.9 years. The basic criteria for inclusion in the sample were as follows: angle Class II, Division 1 dental relationship, sagittal mandibular deficiency facial feature, mixed dentition, absence of premature tooth loss and no prior orthodontic treatment. All of the selected children were in the circumpubertal growth phase¹³ (C2 and C3) and were treated with an EOA for an average of 381 days (Fig. 1).

Teleradiographs were obtained in the lateral aspect of the initial (T1) and final (T2) orthopedic phases. Cephalograms, cephalometric points and angular and



Fig. 1: Klammt's elastic open activator (EAO)

linear measurements were determined manually by the researcher (SMI-L) (Fig. 2, Tables 1 and 2).

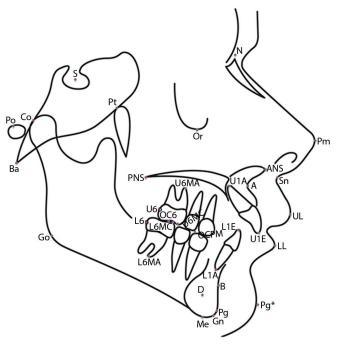


Fig. 2: Cephalometric landmarks

Table 1: Cephalometric landmarks, lines and planes

Table I	. Cephalometric landmarks, lines and planes
S	Sella turcica
Ва	Basion
Ν	Nasion
A	Subspinale
В	Supramentale
Pg	Pogonion
Gn	Gnathion
Me	Menton
Go	Gonion
Со	Condylion
ANS	Anterior nasal spine
PNS	Posterior nasal spine
U1E	Upper central incisor edge
U1A	Upper central incisor apex
L1E	Lower central incisor edge
L1A	Lower central incisor apex
U6MC	Upper first molar mesial cusp
U6MA	Upper first molar mesial apex
U6D	Upper first molar distal
L6MC	Lower first molar mesial cusp
L6MA	Lower first molar mesial apex
L6D	Lower first molar distal
OC6	Occlusal contact of the first molars
OCPM	Occlusal contact of the premolars
Po	Porion
Or	Orbitale
Pr	Pronasale (most anterior point on the nose)
Sn	Subnasale
UL	Upper lip (most anterior point of the upper lip)
LL	Lower lip (most anterior point of the lower lip)
Pg'	Soft-tissue pogonion



Class II Malocclusion and Treatment

Table 2: Skeletal cephalometric variables

Maxillary skeletal

- 1. SNA: SN to NA angle
- A-NPerp: linear distance from the A-point to the nasionperpendicular (a line perpendicular to the Frankfort plane through the nasion)
- 3. A-Vert: linear distance from the A-point to a vertical line (a line perpendicular to the horizontal line through to S).
- 4. ANS-Vert: linear distance from the ANS point to a vertical line
- 5. PNS-Vert: linear distance from the PNS point to a vertical line

Mandibular skeletal

- 6. SNB: SN to NB angle
- 7. SND: SN to ND angle
- 8. Pg-NPerp: linear distance from the pogonion to the nasionperpendicular
- 9. B-Vert: linear distance from the B-point to a vertical line
- 10. Pg-Vert: linear distance from the Pg-point to a vertical line
- 11. Go-Vert: linear distance from the Go-point to a vertical line

Maxillomandibular

- 12. N-Vert: linear distance from the N-point to a vertical line
- 13. ANB: NA to NB angle
- 14. Wits: linear distance from the projection of the A-point on the functional occlusal plane to the projection of the B-point on the functional occlusal plane
- 15. Co-A: linear distance from the Co-point to the A-point
- 16. Co-Gn: linear distance from the Co-point to the Gn-point

Vertical skeletal

- 17. SN.GoGn: SN to GoGn angle
- 18. NSGn: Angle between the points N, S and Gn
- LAFH (lower anterior face height): distance from the anterior nasal spine to the Me-point

Maxillary dentoalveolar

- 20. U1-NA: maxillary incisor long axis to NA angle
- 21. U1-NA: distance between the maxillary central incisor edge and the NA line
- 22. U1E-Horiz: linear distance from U1E-point to a horizontal line (7.0° in relation to the SN line)
- 23. U1A: linear distance from the U1A-point to a horizontal line
- 24. U6D-PTV: linear distance from the U6D-point to the pterygoid vertical line
- 25. U6MC-Horiz: linear distance from the U6MC-point to a horizontal line
- 26. U6MA-Horiz: linear distance from the U6MA-point to a horizontal line

Mandibular dentoalveolar

- 27. <L1-NB: mandibular incisor long axis to NB angle
- 28. L1-NB: distance between the mandibular central incisor edge and the NB line
- 29. L1E-Horiz: linear distance from the L1E-point to a horizontal line
- 30. L1A-Horiz: linear distance from the L1A-point to a horizontal line
- 31. L6D-PTV: distance from the L6D-point to a horizontal line
- 32. L6MC-Horiz: distance from the L6MC-point to a horizontal line
- 33. L6MA-Horiz: distance from the L6MA-point to a horizontal line
- 34. <U1-L1: angle between the long axis of the maxillary and mandibular incisors

Soft-tissue profile

35. LL-E plane: distance from the lower lip to the esthetic plane of Ricketts (line from Pg=to Pr)

Moldings and the obtaining of plaster models for EOA construction were carefully performed by the same operator (SMI-L) as a standardization criterion. The appliance was always constructed by the same technician. At the time of installation, the adaptation, midline coincidence and mandibular advancement to the top-to-top position were observed.

The patients were instructed to use the EOA 24 hours a day except during meals and while practicing sports for a period of 12 months, and they were monitored monthly.

STATISTICAL ANALYSIS

To determine the reliability of the method, 30 days after obtaining the first set of measurements, teleradiographs of six patients, totaling 37.5% of the sample, were randomly selected for repeat measurements. Bland and Altman's limit of agreement and Lin's concordance correlation coefficient were used. A comparison between the two replicates was performed using Student's t-test (Table 3).

Statistical analysis, adopting a significance level of 0.05 and confidence level of 95%, was performed using the R software: A language and environment for statistical computing (R Development Core Team, 2011; R Foundation for Statistical Computing, Vienna, Austria). Descriptive statistics provided a description of the sample, and the comparison of the measurements before and after EOA use was performed using Student's t-test.

RESULTS

Table 3 presents the results of Bland and Altman's limit of agreement and Lin's concordance correlation coefficient. In a total of 35 variables, no significant differences were found between the measurements taken at the two different times. Table 4 summarizes that significant differences were found in skeletal variables [Co-Gn, <SN-GoGn, <NS-Gn, lower anterior facial height (LAFH)], dental variables (<U1-NA, U1-NA, U1E-Horiz, U1A-Horiz, U6MC-Horiz, U6MA-Horiz, L1-NB, L1E-Horiz, L1A-Horiz, L6D-PTV, L6MC-Horiz) and one soft tissue variable (LL-E plane).

DISCUSSION

Maxillary Changes

The EOA is an orthopedic appliance commonly used for the correction of Class II, Division 1 malocclusion due to mandibular deficiency. Restrictive maxillary growth effects have been reported with the use of the EOA.^{11,18,19} In this study, although no significant change in the

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	Repei	Repetition 1	Repet	Repetition 2						LA	А	
Variable	Mean	SD	Mean	SD	Bias	SE	d	CI	LA	TL	ΠL	20
<sna (degrees)<="" th=""><td>81.17</td><td>3.43</td><td>81.33</td><td>2.94</td><td>-0.17</td><td>0.48</td><td>0.741</td><td>[-1.39; 1.06]</td><td>[-2.5; 2.17]</td><td>[-4.63; -0.38]</td><td>[0.05; 4.3]</td><td>0.932</td></sna>	81.17	3.43	81.33	2.94	-0.17	0.48	0.741	[-1.39; 1.06]	[-2.5; 2.17]	[-4.63; -0.38]	[0.05; 4.3]	0.932
A-NPerp (mm)	0.50	2.42	0.67	2.73	-0.17	0.38	0.677	[-1.13; 0.8]	[-2.01; 1.68]	[-3.69; -0.33]	[0.00; 3.35]	0.934
A-Vert (mm)	59.65	6.98	59.98	7.48	-0.33	0.31	0.343	[-1.12; 0.47]	[-1.84; 1.19]	[-3.22; -0.46]	[-0.19; 2.57]	0.993
ANS-Vert (mm)	63.70	7.55	64.03	7.25	-0.32	0.53	0.564	[-1.68; 1.03]	[–2.9; 2.25]	[-5.24; -0.56]	[-0.09; 4.59]	0.984
PNS-Vert (mm)	16.06	2.70	16.83	2.53	-0.78	0.45	0.142	[-1.92; 0.37]	[-2.96; 1.41]	[-4.94; -0.97]	[-0.58; 3.39]	0.875
<snb (degree)<="" th=""><th>76.00</th><th>4.15</th><th>76.67</th><th>3.98</th><th>-0.67</th><th>0.49</th><th>0.235</th><th>[-1.94; 0.6]</th><th>[-3.09; 1.76]</th><th>[-5.29; -0.89]</th><th>[-0.45; 3.96]</th><th>0.943</th></snb>	76.00	4.15	76.67	3.98	-0.67	0.49	0.235	[-1.94; 0.6]	[-3.09; 1.76]	[-5.29; -0.89]	[-0.45; 3.96]	0.943
<snd (degree)<="" th=""><td>73.17</td><td>3.97</td><td>74.00</td><td>3.79</td><td>-0.83</td><td>0.48</td><td>0.141</td><td>[-2.06; 0.39]</td><td>[-3.17; 1.5]</td><td>[-5.3; -1.05]</td><td>[-0.62; 3.63]</td><td>0.933</td></snd>	73.17	3.97	74.00	3.79	-0.83	0.48	0.141	[-2.06; 0.39]	[-3.17; 1.5]	[-5.3; -1.05]	[-0.62; 3.63]	0.933
Pg-NPerp (mm)	0.64	9.47	1.39	10.35	-0.75	0.70	0.332	[-2.55; 1.05]	[-4.17; 2.67]	[-7.29; -1.06]	[-0.44; 5.79]	0.982
B-Vert (mm)	50.48	8.96	51.08	9.82	-0.60	06.0	0.535	[-2.91; 1.71]	[-5.01; 3.81]	[-9.02; -1]	[-0.2; 7.82]	0.971
Pg-Vert (mm)	51.87	10.12	51.08	10.86	0.78	0.44	0.134	[-0.35; 1.91]	[-1.37; 2.93]	[-3.32; 0.59]	[0.98; 4.89]	0.992
Go-Vert (mm)	8.36	5.03	8.50	5.14	-0.14	0.57	0.812	[-1.6; 1.31]	[-2.92; 2.63]	[-5.44; -0.39]	[0.11; 5.15]	0.962
N-Vert (mm)	61.66	5.27	61.37	6.25	0.29	0.52	0.598	[-1.04; 1.62]	[-2.25; 2.83]	[-4.55; 0.06]	[0.52; 5.14]	0.975
<anb (degrees)<="" th=""><td>5.00</td><td>2.61</td><td>5.00</td><td>2.53</td><td>0.00</td><td>0.26</td><td>1.000</td><td>[-0.66; 0.66]</td><td>[-1.26; 1.26]</td><td>[-2.41; -0.12]</td><td>[0.12; 2.41]</td><td>0.970</td></anb>	5.00	2.61	5.00	2.53	0.00	0.26	1.000	[-0.66; 0.66]	[-1.26; 1.26]	[-2.41; -0.12]	[0.12; 2.41]	0.970
Wits (mm)	-2.35	1.93	-1.09	3.11	-1.26	1.16	0.329	[-4.25; 1.73]	[-6.96; 4.44]	[-12.13; -1.78]	[-0.74; 9.62]	0.352
Co-A (mm)	78.76	8.18	79.53	7.40	-0.78	0.37	0.092	[-1.73; 0.18]	[-2.6; 1.05]	[-4.25; -0.94]	[-0.61; 2.7]	0.988
Co-Gn (mm)	98.37	9.45	98.98	8.87	-0.62	0.40	0.182	[-1.64; 0.41]	[-2.57; 1.33]	[-4.34; -0.79]	[-0.44; 3.11]	0.992
<sn-gogn (degrees)<="" th=""><td>35.00</td><td>8.00</td><td>36.00</td><td>10.06</td><td>-1.00</td><td>1.41</td><td>0.511</td><td>[-4.64; 2.64]</td><td>[-7.93; 5.93]</td><td>[-14.22; -1.63]</td><td>[-0.37; 12.22]</td><td>0.922</td></sn-gogn>	35.00	8.00	36.00	10.06	-1.00	1.41	0.511	[-4.64; 2.64]	[-7.93; 5.93]	[-14.22; -1.63]	[-0.37; 12.22]	0.922
NS-Gn (degrees)	69.17	6.31	69.17	6.49	0.00	0.26	1.000	[-0.66; 0.66]	[-1.26; 1.26]	[-2.41; -0.12]	[0.12; 2.41]	0.995
LAFH (mm)	56.33	5.65	56.01	5.71	0.32	0.39	0.457	[-0.69; 1.33]	[-1.61; 2.24]	[-3.36; 0.14]	[0.49; 3.99]	0.984
<u1-na (degrees)<="" th=""><td>23.33</td><td>8.07</td><td>23.33</td><td>7.55</td><td>0.00</td><td>0.73</td><td>1.000</td><td>[-1.88; 1.88]</td><td>[-3.58; 3.58]</td><td>[-6.83; -0.33]</td><td>[0.33; 6.83]</td><td>0.974</td></u1-na>	23.33	8.07	23.33	7.55	0.00	0.73	1.000	[-1.88; 1.88]	[-3.58; 3.58]	[-6.83; -0.33]	[0.33; 6.83]	0.974
U1-NA (mm)	4.49	2.68	4.49	2.31	0.00	0.35	1.000	[-0.89; 0.89]	[-1.7; 1.7]	[-3.24; -0.15]	[0.15; 3.24]	0.942
U1E-Horiz (mm)	62.82	5.23	63.59	5.18	-0.78	0.71	0.325	[-2.6; 1.05]	[-4.26; 2.71]	[-7.42; -1.09]	[-0.46; 5.87]	0.934
U1A-Horiz (mm)	41.03	4.06	41.50	4.84	-0.48	0.48	0.363	[-1.7; 0.75]	[-2.8; 1.85]	[-4.92; -0.69]	[-0.26; 3.97]	0.961
<l1-nb (degrees)<="" th=""><td>28.67</td><td>7.89</td><td>29.67</td><td>7.26</td><td>-1.00</td><td>0.45</td><td>0.076</td><td>[-2.15; 0.15]</td><td>[–3.19; 1.19]</td><td>[-5.18; -1.2]</td><td>[-0.8; 3.18]</td><td>0.981</td></l1-nb>	28.67	7.89	29.67	7.26	-1.00	0.45	0.076	[-2.15; 0.15]	[–3.19; 1.19]	[-5.18; -1.2]	[-0.8; 3.18]	0.981
L1-NB (mm)	5.60	2.91	5.60	3.15	00.0	0.25	1.000	[-0.63; 0.63]	[-1.2; 1.2]	[-2.29; -0.11]	[0.11; 2.29]	0.980
L1E-Horiz (mm)	59.70	6.60	59.71	6.79	-0.01	0.34	0.982	[-0.89; 0.87]	[-1.69; 1.67]	[-3.21; -0.16]	[0.14; 3.19]	0.992
L1A-Horiz (mm)	76.80	4.63	76.79	4.59	0.01	0.24	0.974	[-0.61; 0.62]	[-1.16; 1.18]	[-2.23; -0.1]	[0.12; 2.24]	0.992
U6D-PTV (mm)	10.76	3.37	10.91	3.41	-0.15	0.29	0.624	[-0.89; 0.59]	[-1.56; 1.26]	[-2.84; -0.28]	[-0.02; 2.54]	0.977
U6MC-Horiz (mm)	55.82	3.06	56.13	3.24	-0.32	0.20	0.175	[-0.83; 0.2]	[-1.3; 0.66]	[-2.19; -0.41]	[-0.23; 1.56]	0.983
UGMA-Horiz (mm)	38.85	3.59	38.70	2.85	0.15	0.44	0.745	[-0.97; 1.27]	[-1.99; 2.29]	[-3.93; -0.05]	[0.35; 4.23]	0.945
L6D-PTV (mm)	9.81	3.47	9.34	3.27	0.47	0.40	0.301	[-0.57; 1.51]	[-1.52; 2.45]	[-3.32; 0.29]	[0.65; 4.25]	0.948
L6MC-Horiz (mm)	56.28	3.23	56.75	3.37	-0.47	0.21	0.076	[-1; 0.07]	[-1.49; 0.56]	[-2.42; -0.56]	[-0.37; 1.49]	0.978
L6MA-Horiz (mm)	72.78	3.28	72.93	2.84	-0.15	0.29	0.624	[-0.89; 0.59]	[-1.56; 1.26]	[-2.84; -0.28]	[-0.02; 2.54]	0.973
U1-L1 (degrees)	122.83	5.23	122.17	3.60	0.67	0.84	0.465	[-1.5; 2.83]	[-3.46; 4.8]	[-7.22; 0.29]	[1.04; 8.55]	0.884
LinhaE-Li (mm)	1.11	1.11	1.11	1.11	0.00	0.00	#DIV/0i	[o; 0]	[o; 0]	[0; 0]	[o; 0]	1.000
p-value is p-value of comparison between the two replicates; values less than 0.05 indicate significant differences; CC: Lin's concordance correlation coefficient; CI: 95% confidence interval for bias; LA: Bland and Altman limits of agreement; LL: 95% confidence interval for the lower limit of LA; SD: standard deviation; SE: standard error of the bias; UL: 95% confidence interval	oarison betwe tman limits of	en the two agreement	replicates; v ; LL: 95% c	'alues less t onfidence ir	han 0.05 ind Iterval for th	dicate signi e lower lim	ficant different different of LA; SD	ences; CC: Lin's o standard deviati	concordance corre on; SE: standard	than 0.05 indicate significant differences; CC: Lin's concordance correlation coefficient; CI: 95% confidence interval interval for the lower limit of LA; SD: standard deviation; SE: standard error of the bias; UL: 95% confidence interval	l: 95% confidence .: 95% confidence	e interval interval
tor the upper limit of LA												

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Table 3: Results of repeatability evaluation

 Table 4: Descriptive statistics of evaluations before and after using the treatment and the results of comparisons between times (p value)

			Before					After			
Variable	Mean	SD	Min	Med	Max	Mean	SD	Min	Med	Max	p
<sna (degrees)<="" td=""><td>82.13</td><td>2.68</td><td>78.00</td><td>82.00</td><td>86.00</td><td>81.81</td><td>2.26</td><td>77.00</td><td>82.00</td><td>85.00</td><td>0.464</td></sna>	82.13	2.68	78.00	82.00	86.00	81.81	2.26	77.00	82.00	85.00	0.464
A-NPerp (mm)	0.26	3.27	-4.20	0.00	8.55	0.44	2.83	-4.50	0.00	5.70	0.730
A-Vert (mm)	61.29	5.49	53.10	60.40	70.30	60.93	4.66	51.30	61.65	67.50	0.681
ANS-Vert (mm)	65.51	5.57	55.80	64.80	75.05	64.82	5.07	54.90	64.80	72.20	0.509
PNS-Vert (mm)	16.15	2.52	12.35	16.20	19.95	17.20	2.39	13.50	18.03	20.70	0.067
<snb (degrees)<="" td=""><td>77.13</td><td>2.96</td><td>72.00</td><td>77.00</td><td>81.00</td><td>76.94</td><td>2.77</td><td>72.00</td><td>77.50</td><td>81.00</td><td>0.734</td></snb>	77.13	2.96	72.00	77.00	81.00	76.94	2.77	72.00	77.50	81.00	0.734
<snd (degrees)<="" td=""><td>73.94</td><td>2.95</td><td>69.00</td><td>74.00</td><td>79.00</td><td>73.88</td><td>2.96</td><td>67.00</td><td>74.50</td><td>78.00</td><td>0.903</td></snd>	73.94	2.95	69.00	74.00	79.00	73.88	2.96	67.00	74.50	78.00	0.903
Pg-NPerp (mm)	0.63	8.94	-13.65	-0.90	16.80	1.38	9.86	-18.00	1.35	17.10	0.434
B-Vert (mm)	52.59	6.51	43.70	52.18	65.55	53.75	4.93	40.50	54.90	59.40	0.330
Pg-Vert (mm)	53.93	7.29	43.05	54.30	68.40	53.34	5.53	39.60	54.00	60.35	0.621
Go-Vert (mm)	8.38	4.44	0.00	7.85	19.80	9.03	4.63	1.70	8.78	18.90	0.285
N-Vert (mm)	62.30	4.50	54.90	62.55	68.40	61.61	4.70	50.35	62.10	67.50	0.476
<anb (degrees)<="" td=""><td>4.94</td><td>1.61</td><td>1.00</td><td>5.00</td><td>7.00</td><td>4.81</td><td>1.91</td><td>0.00</td><td>5.00</td><td>7.00</td><td>0.728</td></anb>	4.94	1.61	1.00	5.00	7.00	4.81	1.91	0.00	5.00	7.00	0.728
Wits (mm)	-1.39	2.64	-5.40	-1.83	4.50	-0.85	3.94	-6.30	-0.93	9.90	0.587
Co-A (mm)	80.50	7.07	69.30	79.53	91.20	81.88	5.16	72.90	80.43	89.30	0.152
Co-Gn (mm)	97.14	5.60	88.35	96.15	109.00	101.53	6.36	93.60	99.00	113.05	0.015
<sn-gogn (degrees)<="" td=""><td>32.88</td><td>5.19</td><td>23.00</td><td>31.50</td><td>41.00</td><td>34.81</td><td>6.48</td><td>25.00</td><td>34.00</td><td>50.00</td><td>0.033</td></sn-gogn>	32.88	5.19	23.00	31.50	41.00	34.81	6.48	25.00	34.00	50.00	0.033
<ns-gn (degrees)<="" td=""><td>68.63</td><td>4.22</td><td>59.00</td><td>68.00</td><td>76.00</td><td>69.81</td><td>3.66</td><td>62.00</td><td>69.00</td><td>77.00</td><td>0.039</td></ns-gn>	68.63	4.22	59.00	68.00	76.00	69.81	3.66	62.00	69.00	77.00	0.039
LAFH (mm)	57.05	4.66	48.60	55.38	63.80	59.10	5.10	52.20	58.50	68.40	0.008
<u1-na (degrees)<="" td=""><td>25.63</td><td>5.63</td><td>16.00</td><td>25.00</td><td>39.00</td><td>19.69</td><td>4.98</td><td>13.00</td><td>18.50</td><td>30.00</td><td><0.001</td></u1-na>	25.63	5.63	16.00	25.00	39.00	19.69	4.98	13.00	18.50	30.00	<0.001
U1-NA (mm)	5.18	1.86	2.85	5.00	9.50	3.88	1.66	1.90	3.60	7.60	0.007
U1E -Horiz (mm)	63.73	4.87	55.80	63.38	72.62	66.22	5.31	56.70	66.55	74.70	0.001
U1A-Horiz (mm)	40.15	3.60	34.65	39.90	45.60	42.38	4.19	35.70	42.28	51.30	0.006
U6D-PTV (mm)	11.34	2.85	7.60	10.95	17.10	11.49	2.81	5.95	12.15	17.10	0.785
U6MC-Horiz (mm)	56.18	3.68	49.50	55.85	63.65	58.05	3.70	52.20	57.60	65.70	0.003
U6MA-Horiz (mm)	37.58	3.09	33.25	37.20	42.90	39.90	4.16	32.30	39.28	48.60	0.003
<l1-nb (degree)<="" td=""><td>27.81</td><td>6.06</td><td>18.00</td><td>29.00</td><td>38.00</td><td>30.50</td><td>4.27</td><td>25.00</td><td>29.50</td><td>39.00</td><td>0.067</td></l1-nb>	27.81	6.06	18.00	29.00	38.00	30.50	4.27	25.00	29.50	39.00	0.067
L1-NB (mm)	4.79	1.60	1.80	5.00	7.35	5.89	1.75	3.40	5.55	9.00	0.005
L1E-Horiz (mm)	58.68	5.06	47.70	58.70	66.00	62.80	4.94	55.25	61.93	72.90	<0.001
L1A-Horiz (mm)	77.64	4.97	69.30	76.85	85.80	80.41	4.97	72.00	79.65	90.90	0.007
L6-PTV (mm)	9.50	3.02	5.70	8.25	17.10	11.09	2.64	5.10	11.25	16.15	0.006
L6MC-Horiz (mm)	56.30	3.29	50.40	55.85	62.70	58.68	4.19	52.20	58.50	68.40	0.006
L6MA-Horiz (mm)	73.94	4.53	66.60	73.50	82.50	76.06	5.34	64.80	74.88	87.30	0.070
U1-L1 (degrees)	122.94	8.04	110.00	121.00	138.00	125.06	6.32	117.00	123.00	136.00	0.288
LL-E plane (mm)	1.54	1.46	0.00	1.43	3.80	0.92	1.50	-1.80	0.93	3.80	0.047

p is the p-value of comparison before and after use of the appliance; SD: standard deviation

sagittal position of the maxilla was observed according to <SNA and the linear measures A-NPerp, A-Vert and ANS-Vert, it could be observed that the means of these variables had slightly reduced values (Table 4). This result is in agreement with the literature, which also includes reports of nonsignificant results with respect to orthopedic changes in the maxilla promoted by the Andresen activator^{20,21} and Fränkel appliance.⁹

Mandibular Changes

The SNB and SND angle variables showed no significant changes with the use of the EOA, nor did the Pg positioning point evaluated by the PG-NPerp and Pg-Vert measurements. The effective mandibular length (Co-Gn) showed a statistically significant increase, changing from 97.14 \pm 5.60 to 101.53 \pm 6.36 mm. A significant further lengthening in the effective length of the mandible has been reported with the use of functional appliances to correct Class II, Division 1 malocclusion,⁴ and this finding seems to be unanimous in other studies.^{8-12,17,18}

Vertical Changes

The LAFH showed a statistically significant increase from $57.05 \pm 4.66 \text{ mm}$ to $59.10 \pm 5.10 \text{ mm}$. The <NS.Gn and <SN. GoGn showed significant increases from $32.88 \pm 5.19^{\circ}$ to $34.81 \pm 6.48^{\circ}$ and $68.63 \pm 4.22^{\circ}$ to $69.81 \pm 3.66^{\circ}$ respectively. These increases justify the occurrence of clockwise rotation of the mandible. Similar results have been found with

the use of this EOA¹⁹ and other functional appliances.^{4,20} It is noteworthy that Class II correction involves not only anterior mandibular advancement but also vertical growth.¹² For each millimeter increase in anteroinferior facial height, a 1-mm increase in the mandibular length is camouflaged, so pogonion advancement does not appear to occur if the vertical dimension is increased along with the mandibular length.⁴

Dental Changes

The use of the EOA promoted significant dental abnormalities, with the upper incisors becoming verticalized as confirmed by the variable <U1-NA, which decreased from $25.63 \pm 5.63^{\circ}$ to $19.69 \pm 4.98^{\circ}$, and by the reduction in U1-NA from 5.18 ± 1.86 to 3.88 ± 1.66 mm. The mandibular incisors showed an increase in proclination and protrusion, confirmed by increases in the variables L1E-Horiz from 58.68 ± 5.06 to 62.80 ± 4.94 mm, L1A-Horiz from 77.64 ± 4.97 to 80.41 ± 4.97 mm and L1-NB from 4.79 ± 1.60 to 5.89 ± 1.75 mm. Similar results have also been observed in other studies.^{9,19-21}

Significant extrusion of the first upper molars was observed by an average increase of 1.87 ± 2.07 mm in U6E-Horiz and 2.32 ± 2.66 mm in U6A-Horiz, demonstrating an increase in the eruption of the upper molars with the use of the EOA.¹⁸

The lower molars moved mesially as confirmed by an increase in the PTV-L6D of 1.59 ± 2.0 mm, which indicated a positive effect for the Class II molar relationship correction.

Soft-tissue Changes

The lower lip showed a significant anterior shift as demonstrated by the reduction in the LL-E plane measurement from 1.54 ± 1.46 to 0.92 ± 1.50 mm. With regard to soft tissue effects, the position of the lips is influenced not only by skeletal changes but also by changes in the slope and position of the anterior teeth,^{8,12} which was confirmed by the anterior displacement of the lower lip with the use of the activator appliance.^{4,21} Significant changes in the labial mental groove have been found using the bionator and activator.²²

CONCLUSION

Skeletal changes characterized by an increase in mandibular length and dentoalveolar changes with an emphasis on the verticalization and retrusion of the upper incisors, proclination of the lower incisors and mesial positioning of the lower molars were the determining factors in an improvement in occlusal relationships and facial esthetics *via* anterior movement of the lower lip.

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Class II Malocclusion and Treatment

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