Effects of activator and high-pull headgear combination therapy: skeletal, dentoalveolar, and soft tissue profile changes

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SUMMARY The aim of this study was to evaluate skeletal, dentoalveolar, and soft tissue profile changes with activator and high-pull headgear combination therapy in patients with Class II malocclusions caused by maxillary prognathism and mandibular retrognathism. The subjects, all in the mixed dentition, were selected from a single centre and were divided into two groups: 28 patients were treated with an incisor double capping activator and a high-pull headgear combination appliance (13 girls, 15 boys mean chronological age 11.7 \pm 1.2 years, skeletal age 12.1 \pm 1.4 years) and an untreated group of 28 subjects (14 girls, 14 boys mean chronological mean age 11.9 \pm 1.1 years, skeletal age 12.3 \pm 1.3 years). The skeletal, dentoalveolar, and soft tissue profile changes that occurred were compared on lateral cephalograms taken before treatment (T0) and after 1.1 \pm 0.3 years when the combination appliance was removed (T1). In the control group, the radiographs were obtained at the start (T0) and after an observation period 1.2 \pm 0.4 years (T1). Statistical analysis was undertaken with Wilcoxon's ranked-sum test for intra-group comparisons and differences between groups with *t*-test and Bonferroni's test at a level of significance of *P* < 0.05.

Activator and high-pull headgear combination treatment in these growing patients resulted in a correction of the skeletal Class II relationship (ANB –3.4 degrees), a restriction of maxillary growth (SNA –2.0 degrees, OLp–A –2.3 mm), an advancement of the manibular structures (SNB +2.6 degrees, FH–NPg +2.3 degrees, OLp–B +2.7 mm, OLp–Pg +2.2 mm), an increase in lower face height (ANS–Me +3.9 mm), a correction of the overjet (–5.4 mm), an improvement in overbite (–2.2 mm), uprighting of the maxillary incisors (U1–FH –5.3 degrees, OLp–U1 –2.5 mm), protrusion of the mandibular incisors (IMPA +2.0 degrees, OLp–L1 +2.7 mm), and a correction of the dental Class II malocclusion (OLp–L6 +3.5 mm). The soft tissue profile changes were a correction of facial convexity (G⁻Sn–Pg⁻ angle 2.3 degrees, MIf–Li-*x*-axis angle 9.1 degrees), and an increase in lower antero-posterior (MIf–*y*-axis 5.6 mm, Pg⁻*y*-axis 5.3 mm), and lower vertical (SIs–x-axis 3.8 mm, Pg⁻*x*-axis 3.8 mm, Me⁻*x*-axis 5.1 mm) soft tissue dimensions. The mentolabial fold depth (MIf–E line) also significantly decreased, –0.8 mm in the treated group.

The activator and high-pull headgear combination appliance was effective in treating growing patients with maxillary prognathism, mandibular deficiency, and facial convexity by a combination of skeletal and dentoalveolar changes and improvement in the soft tissue facial profile.

Introduction

The nature of a Class II malocclusion is related to many factors, such as facial structure, maxillary and mandibular growth patterns, and dentoalveolar development (McNamara, 1981). Individual variations of these factors have to be considered in relation to treatment procedures to correct malocclusions.

The effects of treatment combining extraoral force and functional appliances have been reported in several studies, illustrating the variability of responses in the importance of controlling the posterior vertical dimension (Meach, 1966; Bass, 1982; Williams and Melsen, 1982; Altuğ *et al.*, 1989; Jacobsson and Paulin, 1990; Dermaut *et al.*, 1992; Öztürk and Tankuter, 1994; Cura *et al.*, 1996; Başçiftçi *et al.*, 2003; Janson *et al.*, 2004).

In general, Class II division 1 malocclusion correction using high-pull headgear-activator combination therapy produces restriction of forward maxillary growth, inhibition of the mesial and vertical displacement of the maxillary teeth, improvement of the mandibular posterior teeth, condylar and glenoid fossa remodelling, and an improvement in muscle pattern (Wieslander and Lagerström 1979; Vargervik and Harvold, 1985; Janson *et al.*, 2004).

Angle Class II malocclusions have been studied extensively regarding their skeletal and dental characteristics, timing, and method of treatment. In subjects with maxillary excess, orthopaedic forces are directed on the maxilla to inhibit further maxillary growth. Functional appliances may be combined with extraoral force applied to either the maxilla or the mandible (Pfeiffer and Grobéty, 1982; Ülgen et al., 1984; Van Beek, 1984; Graber and Swain, 1985; Teuscher, 1986; Kigele, 1987; Altuğ et al., 1989; Bishara and Ziaja, 1989; Gögen and Parlar, 1989; Lehman and Hulsnik, 1989; Lagerström et al., 1990; Deguchi, 1991; Dermaut et al., 1992; Öztürk and Tankuter, 1994; Cura et al., 1996; Weiland et al., 1997; Yüksel et al., 1997). The

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ACTIVATOR AND HIGH-PULL HEADGEAR COMBINATION

majority of studies on the effects of functional appliances have tended to focus on hard tissue changes as opposed to the soft tissue profile despite the fact that the soft tissue profile is the ultimate determinant of treatment success (Vargervik and Harvold, 1985; Malmgren et al., 1987; Başçiftçi et al., 2003). The main reason for this is the difficulty in reliably investigating the soft tissues. Forsberg and Odenrick (1981) reported that lip retrusion and forward movement of soft tissue pogonion were significantly increased in subjects treated with the activator and McDonagh et al. (2001) a significant forward positioning of soft tissue pogonion after treatment with the Bass appliance. Ülgen et al. (1984) found that an insignificant retrusion of the upper lip occurred with an activator-headgear combination, whereas Gögen and Parlar (1989) reported a significant retrusion of the upper lip with these appliances. Hansson et al. (1997, 2000), Singh and Thind (2003), and Mergen et al. (2004) reported that a flattened soft tissue profile was produced with functional and headgear combination appliances.

The purpose of this investigation was to evaluate quantitatively, on lateral cephalograms, the skeletal, dentoalveolar, and soft tissue facial parameters before (T0) and after 1.1 ± 0.3 years (T1) of activator and high-pull headgear appliance treatment. In order to compare the effects of growth versus activator and high-pull headgear treatment, cephalogram data taken at the start (T0) and after a period of 1.2 ± 0.4 years (T1) from a matched group of untreated Class II subjects were analyzed.

Subjects and methods

The subjects for both the study and control groups were Caucasian and selected from a single centre (Department of Orthodontics, Faculty of Dentistry, Istanbul University). The following selection criteria were used: 11–12.5 years of age; overjet greater than 5 mm; Class II molar relationship, with at least half a cusp width distal molar relationship; and no history of previous orthodontic therapy.

Patients satisfying these criteria were divided into two groups: a control group, 28 subjects (14 girls, 14 boys), and a treatment group, 28 subjects (13 girls, 15 boys), who undervent activator and high-pull headgear therapy. The control and treated groups were matched with respect to initial age, malocclusion, and observation period. The control group was selected from subjects who declined activator-headgear therapy.

The appliance used was an acrylic monobloc attached to the upper arch by a high-pull occipital headgear placed into the tubes attached to the acrylic in the premolar area on each side. A central screw was placed and activated only to follow maxillary transversal growth. The incisal edges of the maxillary and mandibular incisors were capped to prevent tipping. A labial wire, placed in front of the upper incisors, was used for the retention of the appliance.

The activator was produced from a construction bite that positioned the mandible anteriorly in an edge-to-edge incisor relationship (Moore et al., 1989). The lower jaw was postured forward in to a Class I molar relationship to stimulate mandibular growth. As a general rule, the bite registration was obtained 3 mm short of maximum protrusion, with care being taken to ensure that lateral displacement did not occur. The height of the bite exceeded the freeway space by 2-3 mm. During treatment, contact was maintained between the appliance and the maxillary posterior teeth; the mandibular posterior teeth were encouraged to erupt by trimming the acrylic on the occlusal and lingual aspect. The high-pull headgear placed the force through the presumed centre of resistance of the maxilla. Treatment commenced with 400-500 g of force per side. The patients were instructed to wear the appliance for a minimum of 14 hours a day.

The skeletal, dentoalveolar, and soft tissue profile changes that occurred were assessed from two lateral cephalograms. In the treatment group, the first lateral cephalogram was taken before treatment (T0) and after 1.1 ± 0.3 years, when the appliance was removed (T1). In the control group, the cephalograms were obtained at the start (T0) and after 1.2 ± 0.4 years (T1). All cephalograms were taken with the teeth in occlusion and the lips in a relaxed position.

The initial cephalometric patterns of the control and treated subjects, as well as the alterations due to growth or treatment, were assessed using the following angles and distances (Figure 1)—sagittal analysis: SNA (degrees), SNB (degrees), ANB (degrees), Ao–Bo (mm), N perp–A (mm), N perp–Pg (mm), NSCo (degrees), Co–A (mm), Co–Gn (mm), Go–Me (mm), FH–NA (degrees), FH–NPg (degrees), vertical analysis: FMA (degrees), FH–OL (degrees), SN–PP (degrees), PP–Go–Me (degrees), N–ANS (mm), ANS–Me (mm); and dental analysis: U1–FH (degrees), IMPA (degrees), interincisal angle (degrees), overjet (mm), overbite (mm), L1–OL (mm).

Other points and reference lines used were those defined by Pancherz (1984). These linear measurements for the assessment of sagittal relationships were performed using the occlusal line (OL) and the occlusal line perpendicular (OLp) drawn through sella. The reference grid, taken from the first head film (T0), was transferred to the T1 tracing using the sella–nasion (SN) line, with sella as the registration point (Figure 2).

All sagittal registrations were performed to the same reference line (OLp) and parallel to OL: OLp–Co, OLp–A, OLp–B, OLp–Pg, OLp–U1, OLp–L1, OLp–U6, OLp–L6 (Figure 2).

For soft tissue variables, an x-y cranial base co-ordinate system was constructed on the cephalograms through sella, with the x-axis drawn 7 degrees to the SN line and the vertical axis passing through sella perpendicular to the xaxis. The aesthetic line (E line, Ricketts, 1972), constructed between Pronasale and Pg', was used as the soft tissue





Figure 2 Skeletal and dentoalveolar linear measurements: (1) N perb-A, (2) Ao-Bo, (3) N perp-Pg, (4) Co-A, (5) Co-Gn, (6) Go-Me, (7) N-ANS, (8) ANS-Me, (9) LI-OL, (10) overjet, (11) overbite, (12) OLp-Co, (13) OLp-A, (14) OLp-B, (15) OLp-Pg, (16) OLp-U1, (17) OLP-L1, (18) OLp-U6, (19) OLp-L6.

 $\label{eq:Figure 1} Skeletal reference points—S: sella; N: nasion; A: A point; B: B point; Pg: pogonion; Po: porion; Co: condylion; Or: orbitale; Ar: articulare; Go: gonion; ANS: anterior nasal spine; PNS: posterior nasal spine; Me: menton; U1: upper incisor; L1: lower incisor; U6: upper first molar; L6: lower first molar. Soft tissue reference points—G': soft tissue glabella; Pn: pronasale; Cm: columella; Sn: subnasale; Sls: superior labial sulcus; Ls: labrale superior; Stm:: stomion superior; Stm:: stomion inferior; L1: labrale inferior; Mlf: mentolabial fold; Pg': soft tissue pogonion; Me': soft tissue menton.$

aesthetic line. The initial soft tissue analysis of the control and treated subjects, as well as the alterations, due to growth or treatment, were assessed using the following distance to the *y*- or *x*-axis.

Horizontal—y-axis: Pn, Cm, Sn, Sls, Ls, Stms, Stmi, Li, Mlf, Pg', Me', mentolabial fold depth (Mlf–E line). Vertical—x-axis: Pn, Cm, Sn, Sls, Ls, Stms, Stmi, Li, Mlf, Pg' Me'. Angular: upper lip inclination (Ls–Sn–x-axis angle), lower lip inclination (Mlf–Li–x-axis angle), nasolabial angle (Cm–Sn–Ls angle), facial convexity angle (G'–Sn–Pg').

Each cephalogram was traced and measured manually. All measurements were repeated after a period of 7 days and the mean value of the two measurements was used. All measurement error coefficients were found to be close to 1.00 and within acceptable limits using Dahlberg's (1940) formula.

Statistical analysis

Descriptive statistics included the mean and standard deviation (SD). The collected data were subjected to statistical analysis using the Statistical Package for Social Sciences (SPSS for Windows, Release 7.5.1, Chicago, Illinois, USA). Wilcoxon's ranked-sum test was used for intra-group comparisons. Differences between groups were evaluated by *t*-test and Bonferroni's test. The level of significance was P < 0.05.

Results

Sagittal analysis

In the treatment group, SNA angle dccreased on average -2.0 degrees (SD 1.5, P < 0.05) and OLp–A distance -2.3 mm during therapy (SD 3.0, P < 0.05; Tables 1 and 2 and supplementary data). Co–A distance significantly increased 3.1 mm (SD 4.4, P < 0.01) while FH–NA dccreased -2.0 degrees (SD 4.0, P < 0.05). ANB angle diminished during therapy on average 3.4 degrees (SD 2.7, P < 0.001). The relative sagittal position of the jaws, when measured along the OL (Ao–Bo), showed an average reduction of 1.2 mm (SD 1.8, P < 0.01). In the treated group, the increase in SNB was on average 2.6 degrees (SD 1.6, P < 0.001).

There was a significant increase in the horizontal measurements at pogonion after treatment. The variables N perp-Pg and FH-NPg increased on average 3.1 mm (SD 2.5, P < 0.001) and 2.3 degrees (SD 2.7, P < 0.05). Co-Gn distance increased significantly in both groups after therapy (treatment group 6.1 mm, SD 5.3, P < 0.001; control group 2.3 mm, SD 2.4, P < 0.001).

Table 1 Comparison of the differences between pre- and post-treatment, pre- and post-observation periods using Wilcoxon's ranked-sum test, and treatment changes with a *t*-test.

	Skeletal and dentoalveolar	Pre-treatn (T0)	tent	Post-treatr (T1)	nent				Pre-observ (T0)	ation	Post-obser (T1)	vation				
	measurements	Mean	SD	Mean	SD	D	SD	Ρ	Mean	SD	Mean	SD	D	SD	Ρ	t-test, P
	SNA (°)	83.2	3.8	81.2	3.4	-2.0	1.5	*	81.8	3.6	82.2	3.2	0.4	1.3	ns	*
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	SNB (°)	74.3	3.9	76.9	3.4	2.6	1.6	***	74.7	3.0	75.1	3.0	0.4	1.6	ns	***
	ANB (°)	6.8	1.9	3.3	2.7	-3.4	2.7	***	6.9	1.8	7.0	2.1	0.1	1.2	ns	***
	Ao-Bo (mm)	1.6	1.6	0.4	1.4	-1.2	1.8	**	0.9	1.7	1.1	1.8	0.1	1.4	ns	
	N perp-A (mm)	-0.6	3.6	-2.0	2.7	-1.4	2.9	*	-1.5	3.3	-0.5	3.4	1.0	2.2	*	*
	N perp-Pg (mm)	-9.2	6.8	-6.1	6.3	3.1	2.5	***	-11.2	3.9	-10.3	4.4	0.8	3.2	ns	*
	NSCo (°)	144.2	5.8	142.9	6.5	-1.3	6.4	*	138.0	7.6	137.5	7.1	-0.4	5.6	ns	**
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	Co-A (mm)	88.8	5.9	92.0	6.0	3.1	4.4	**	86.2	4.7	87.7	5.2	1.5	1.9	*	**
	Co-Gn (mm)	111.8	7.1	117.9	7.2	6.1	5.3	***	106.7	5.1	109.0	5.4	2.3	2.4	***	**
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	Go-Me (mm)	61.8	3.9	66.5	5.1	4.6	3.5	***	60.6	3.7	62.7	3.8	2.1	1.5	**	**
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	FH-NA (°)	88.8	4.1	86.8	3.9	-2.0	4.0	*	88.2	3.4	89.3	2.8	1.0	2.6	ns	*
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	FH-NPg (°)	83.0	2.7	85.3	2.6	2.3	2.7	*	84.6	3.5	84.7	3.2	0.1	2.1	ns	*
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	FMA (°)	29.6	4.4	30.0	4.0	0.4	2.5	ns	28.8	4.1	27.7	3.9	-1.1	2.3	ns	ns
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	FH-OL (°)	16.8	4.3	18.4	4.6	1.6	4.6	ns	16.8	4.4	18.1	4.0	1.3	4.0	ns	ns
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	SN-PP (°)	8.9	4.3	9.8	3.9	0.8	2.9	ns	7.9	4.8	7.1	4.3	-0.7	2.9	ns	ns
	PP-Go-Me (°)	28.3	3.9	27.6	4.8	-0.7	2.9	ns	27.3	5.1	26.5	4.4	-0.8	3.2	ns	ns
	N-ANS (mm)	52.2	3.5	54.2	3.5	1.9	2.4	***	50.6	3.7	51.8	3.6	1.2	2.0	**	ns
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	ANS-Me (mm)	60.5	3.8	64.4	4.8	3.9	3.3	***	56.5	3.9	57.9	4.2	1.3	1.9	**	**
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	UI-FH (°)	116.0	6.0	110.6	8.6	-5.3	6.0	**	112.5	L.L	113.1	7.5	0.6	3.6	ns	*
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	IMPA (°)	95.0	5.4	97.0	7.2	2.0	4.8	*	6.79	6.6	7.76	7.8	-0.1	3.2	ns	*
	Interincisal angle	119.2	6.9	122.7	8.9	3.5	4.6	*	117.4	6.3	119.0	7.2	1.5	4.7	ns	*
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	Overjet (mm)	8.9	2.2	3.5	1.4	-5.4	2.4	***	8.8	2.1	8.6	2.2	-0.1	1.3	ns	***
$ \begin{array}{llllllllllllllllllllllllllllllllllll$	Overbite (mm)	5.1	1.3	2.8	0.9	-2.2	1.0	***	4.8	1.2	5.0	1.7	0.1	0.7	ns	***
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	L1-OL (mm)	-1.9	1.9	-0.8	1.7	1.1	1.9	**	-2.2	2.1	-2.1	1.8	0.1	2.0	ns	ns
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	Olp-Co (mm)	-11.0	4.0	-13.0	3.5	-2.0	2.7	***	0.6-	5.3	-9.8	5.6	-0.8	1.9	ns	*
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	Olp-A	L'LL	4.0	75.4	4.3	-2.3	3.0	*	71.1	9.8	71.5	9.2	0.3	2.2	ns	*
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	Olp-B (mm)	77.2	4.2	9.9L	4.1	2.7	2.5	***	76.2	6.5	76.0	5.9	-0.2	4.0	ns	*
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	Olp-Go (mm)	11.9	2.2	14.1	3.7	2.2	2.4	*	10.8	4.2	9.4	3.5	-1.3	2.8	ns	*
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	Olp-Pg (mm)	82.3	5.9	84.6	6.2	2.2	4.4	*	80.3	6.5	80.2	6.0	-0.1	4.2	ns	*
Olp-L1 (mm) 79.1 4.6 81.8 5.1 2.7 3.4 *** 77.8 5.0 78.1 5.0 0.3 3.3 11s * 0.10-U6 (mm) 4.30 4.3 4.7 -0.6 3.9 ns 41.5 4.0 0.3 3.3 ns ns ns 41.5 4.0 0.1 3.2 ns ns ns 41.5 4.0 0.1 3.2 ns <td>Olp-UI (mm)</td> <td>89.1</td> <td>4.5</td> <td>86.6</td> <td>5.4</td> <td>-2.5</td> <td>3.6</td> <td>**</td> <td>87.2</td> <td>5.6</td> <td>87.8</td> <td>5.3</td> <td>0.5</td> <td>3.2</td> <td>ns</td> <td>*</td>	Olp-UI (mm)	89.1	4.5	86.6	5.4	-2.5	3.6	**	87.2	5.6	87.8	5.3	0.5	3.2	ns	*
Olp-U6 (mm) 43.0 4.3 4.2 4.7 -0.6 3.9 ns 41.5 4.9 41.6 4.4 0.1 3.2 ns ns 0lp-L6 (mm) 42.5 4.6 4.60 4.9 3.5 3.5 *** 40.8 5.2 41.0 4.5 0.2 3.7 ns *	Olp-L1 (mm)	79.1	4.6	81.8	5.1	2.7	3.4	***	77.8	5.0	78.1	5.0	0.3	3.3	ns	*
Olp-L6 (mm) 42.5 4.6 46.0 4.9 3.5 3.5 *** 40.8 5.2 41.0 4.5 0.2 3.7 ns *	Olp-U6 (mm)	43.0	4.3	42.3	4.7	-0.6	3.9	ns	41.5	4.9	41.6	4.4	0.1	3.2	ns	ns
	Olp-L6 (mm)	42.5	4.6	46.0	4.9	3.5	3.5	***	40.8	5.2	41.0	4.5	0.2	3.7	ns	*

	Pre-obser (T0)	vation	Post-obse (T1)	rvation	D			Pre-treatme (T0)	snt	Post-treatr (T1)	nent	D			
	Mean	SD	Mean	SD	Mean	SD	Ρ	Mean	SD	Mean	SD	Mean	SD	Ρ	t-test, P
soft tissue linear mean	urements							Land.							
Pn-v-axis (mm)	92.6	4.0	95.0	4.0	2.3	1.9	ns	93.6	5.2	98.2	6.9	4.6	3.5	ns	ns
Cm-v-axis (mm)	85.9	4.5	87.5	4.3	1.5	2.2	ns	85.1	5.8	88.6	6.5	3.4	3.7	ns	ns
Sn-v-axis (mm)	78.5	5.2	80.0	4.7	1.5	2.1	ns	78.5	5.6	81.8	6.6	3.2	3.4	ns	ns
Sls-v-axis (mm)	77.5	5.3	79.2	4.9	1.6	2.0	ns	77.5	5.8	6.67	7.0	2.4	3.7	ns	ns
Ls-v-axis (mm)	80.1	5.9	82.1	5.6	2.0	2.1	ns	80.3	6.3	82.0	7.6	1.6	3.9	ns	ns
Stms-v-axis (mm)	75.0	5.8	76.3	5.5	1.3	2.6	ns	75.4	6.4	75.8	7.3	0.3	6.0	ns	ns
Stmi-v-axis (mm)	69.4	6.0	71.4	6.2	2.0	5.0	ns	68.2	7.4	72.7	7.1	4.5	5.2	ns	ns
Li-v-axis (mm)	74.1	6.2	76.1	6.3	1.9	4.4	ns	73.1	7.6	T.TT	7.3	4.6	4.9	ns	ns
Mlf-v-axis (mm)	63.8	6.3	65.4	5.9	1.6	4.2	ns	62.3	7.1	68.0	7.5	5.6	4.0	ns	**
Pg'-v-axis (mm)	65.3	6.9	6.99	6.6	1.6	4.1	ns	63.0	7.6	68.4	8.0	5.3	4.1	ns	**
Me'-v-axis (mm)	44.2	6.7	45.6	6.2	1.4	3.9	ns	41.3	7.5	45.4	9.0	4.1	4.3	ns	ns
Pn-x-axis (mm)	35.9	4.1	37.7	4.8	1.8	3.0	ns	37.7	4.7	38.4	3.9	0.7	4.6	ns	ns
Cm-x-axis (mm)	44.9	4.0	46.4	4.1	1.4	2.9	ns	46.4	4.5	48.6	4.5	2.1	4.9	ns	ns
Sn-x-axis (mm)	48.6	4.3	49.7	3.9	1.1	3.3	ns	49.9	4.3	51.7	4.3	1.7	4.2	ns	ns
Sls-x-axis (mm)	52.6	5.3	54.7	5.0	2.0	4.2	ns	55.0	5.3	58.8	6.3	3.8	4.9	*	*
Ls-x-axis (mm)	62.0	4.2	63.5	4.0	1.4	3.0	ns	62.9	5.1	65.2	5.6	2.3	4.5	ns	ns
Stms-x-axis (mm)	66.7	3.7	68.5	3.6	1.7	2.8	ns	68.2	4.8	70.6	5.0	2.3	4.3	ns	ns
Stmi-x-axis (mm)	69.1	4.2	6.69	3.9	0.8	3.1	ns	71.0	4.5	72.0	4.7	0.0	3.9	ns	ns
Li-x-axis (mm)	74.8	4.2	75.6	4.2	0.7	3.6	ns	76.9	4.2	78.1	4.6	1.2	4.1	ns	ns
Mif-x-axis (mm)	82.6	5.0	82.7	4.5	0.0	4.3	ns	85.6	5.0	88.6	6.9	2.9	5.3	**	us
Pg'-x-axis (mm)	92.4	5.8	92.1	6.2	-0.3	6.0	ns	94.7	5.6	98.5	6.8	3.8	5.4	**	ns
Me'-x-axis (mm)	106.5	5.6	104.9	19.3	-1.5	8.8	ns	110.6	5.4	115.7	6.6	5.1	4.7	**	*
MIf-E line (mm)	6.5	1.4	6.8	1.2	0.3	1.2	***	6.0	1.7	5.2	13	-0.8	1.8	IIS	*
Soft tissue angular var.	iables														
Ls-Sn-x-axis (°)	8.66	10.1	101.6	9.3	1.7	11.3	***	94.0	19.0	90.3	17.1	-3.7	23.8	ns	ns
MIf-Li-x-axis (°)	19.4	11.9	15.8	15.8	-3.6	12.6	ns	25.8	10.5	35.0	11.4	9.1	13.8	***	**
Cm-Sn-Ls (°)	103.6	16.2	105.4	8.2	1.7	15.2	ns	104.3	22.8	111.4	8.6	1.1	21.2	*	us
G'-Sn-Pg' (facial	160.6	4.7	159.3	5.8	-1.2	3.8	ns	158.7	4.1	161.0	4.7	2.3	3.8	**	**
convexity angle)															

Table 2 The differences between the pre- and post-observation, pre- and post-treatment variables evaluated with Wilcoxon's ranked-sum test, and treatment effects with a *t*-test.

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*P < 0.05, **P < 0.01; not significant; D: difference.

The angle NSCo, an expression of the position of the articular complex and the condyle, decreased in the control group (-0.4 degree; SD 5.6; ns), while in the treatment group it decreased significantly (-1.3 degree, SD 6.4, P < 0.05).

The linear measurements performed to OLp and parallel to OL showed horizontal changes in the position of the mandible. Condylion (OLp–Co) moved forward significantly in the treated group (-2.0 mm, SD 2.7, P < 0.001).

There was a significant advancement of the mandibular structures in the treated group (Go–Me: 4.6 mm, SD 3.5, P < 0.001; OLp–B: 2.7 mm, SD 2.5, P < 0.001; OLp–Go:2.2 mm, SD 2.4, P < 0.05, OLp–Pg: 2.2 mm, SD 4.4, P < 0.05).

Vertical analysis

Lower anterior face height (ANS–Me) significantly increased 3.9 mm (SD 3.3, P < 0.001) and 1.3 mm (SD 1.9, P < 0.01) in the treated and control groups, respectively. The difference between the groups was significant (P < 0.01, Table 1).

Dental analysis

Activator and high-pull headgear combination therapy moved the maxillary incisors palatally (U1–FH: -5.3degrees, SD 6.0, P < 0.01) and the significant correction in overjet, which averaged -5.4 mm (SD 2.4, P < 0.001) was due to this palatal movement. The mandibular incisors moved labially, with IMPA angle significantly increased 2.0 degrees (SD 4.8, P < 0.05).

Dental measurements performed to the reference line (OLp) showed a forward movement of the lower incisors in the treated group (OLp-L1: 2.7 mm, SD 3.4, P < 0.001) while the upper incisors showed a backward movement (OLp-U1: -2.5 mm, SD 3.6, P < 0.01). The variables interincisal angle and overbite also improved (interincisal angle: 3.5 degrees, SD 4.6, P < 0.05; overbite: -2.2 mm, SD 1.0, P < 0.001).

The mandibular molars (OLp–L6) significantly moved forward in the treated group (3.5 mm, SD 3.5, P < 0.001). While maxillary molars (OLp–U6) showed distal movement (-0.6, SD 3.9, ns).

Soft tissue analysis

The positive effects of treatment on the facial profile were accompanied by an increase in the facial convexity angle (G'–Sn–Pg'; 2.3, SD 3.8 degrees, P < 0.01).

The Mlf-y-axis and Pg'-y-axis vertical distances increased significantly when compared with the control group (5.6, SD 4.0 mm, P < 0.01, and 5.3, SD 4.1 mm, P < 0.01, respectively). This means that the depth of the labiomental fold decreased and pogonion moved anteriorly in the treatment group. The superior labial sulcus (Sls) to *x*-axis distance significantly increased in the treated group (3.8, SD 4.9 mm, P < 0.05).

Horizontal growth of soft tissue menton (Me') according to the Me'-x-axis parameter increased significantly in the treatment group (5.1, SD 4.7 mm, P < 0.01). The horizontal growth of the labiomental fold, according to the MIf-E line (MIf depth), significantly decreased in the treatment group.

Discussion

The aim of the present investigation was to evaluate the skeletal, dentoalveolar, and soft tissue changes occurring in subjects treated with an activator-high-pull headgear combination appliance. In an attempt to determine if there are significant growth changes over those expected, a non-randomized control group was examined. This appears to be the best method to differentiate growth changes from treatment changes.

Maxillary effects

The results show that an orthopaedic retraction of the maxillary complex seemed to be consistent. Point A moved backward by -1.4 mm when measured vertical to N perpendicular and by -2.3 mm when measured vertical to OLp in the treatment group. This finding is in agreement with Pfeiffer and Grobéty (1982), Pancherz (1984), Van Beek (1984), Lagerström *et al.* (1990), Öztürk and Tankuter (1994), and Cura *et al.* (1996).

The difference between the two groups was significant (P < 0.05). During treatment with activator and high-pull headgear appliances, it has been claimed that forward growth of the maxilla may be inhibited (Pfeiffer and Grobéty, 1982; Van Beek, 1984; Kigele, 1987; Lehman and Hulsnik, 1989; Lagerström *et al.*, 1990; Dermaut *et al.*, 1992; Öztürk and Tankuter, 1994; Cura *et al.*, 1996; You and Chen, 2002; Janson *et al.*, 2004). In the present analysis, SNA decreased in the treatement group, while in the controls it increased.

Mandibular effects

It has been reported that an increase in mandibular growth is the distinguishing aspect of functional therapy with respect to the other treatment modalities (Demisch, 1972; Owen, 1981; Luder, 1982; Toth and McNamara, 1999) while others believe that mandibular length is unaltered by functional appliance therapy (Harvold and Vargervik, 1971; Weislander and Lagerström, 1979; Vargervik and Harvold, 1985; Jacobsson and Paulin, 1990) and that the treatment changes appear to be similar to those resulting from growth (Forsberg and Odenrick, 1981).

In the present study there was an advancement of the mandibular structures in the treated group, when the cephalometric values related to the lower jaw were compared with the controls. Activator and high-pull headgear treatment resulted in approximately 3 mm of anterior mandibular displacement.

The increase in SNB of 2.6 degrees in the treated group, compared with the slight increase of 0.4 degrees in the controls, was statistically significant. Mandibular length, expressed as Go–Me increased in both groups, but significantly more in the treated group.

The results of the present study may be related to changes in the condyler glenoid fossa complex: remodelling and anterior relocation of the glenoid fossa may have contributed to the correction of the skeletal Class II malocclusion, as evidenced by NSCo angle, which decreased significantly, and by linear measurement OLp–Co which moved forward (Woodside *et al.*, 1987; Ruf *et al.*, 2001). This assumes the condyle was fully seated in the fossa.

Effects on dentition

Başçifiçi et al. (2003), Sarı et al. (2003), and Janson et al. (2004) observed significant dentoalveolar changes during activator and headgear combination treatment. In the present study, correction of upper incisor prominence appeared significant in the treated group. The overjet correction was due to a combined maxillary and mandibular orthopaedic effect, in addition to lingual movement of the upper dentition, in spite of the teeth being capped in the acrylic.

Activator and headgear combination therapy retroclined the maxillary incisors by 5.3 degrees and reduced the overjet by 5.4 mm, while the control group showed no significant differences during the observation period.

The upper dental component of overjet correction was similar to the data in the literature (Öztürk and Tankuter, 1994; Cura *et al.*, 1996; Başçiftçi *et al.*, 2003; Türkkahraman and Sayın, 2006). Pancherz (1984) found that more than 50 per cent of overjet correction was produced by upper incisor tipping. The initial angulation of the upper incisors is of importance in influencing treatment outcome (Barton and Cook, 1997). OLp–U1, used for assessing the position of the upper incisors, demonstrated a forward movement in the control group, but this was not significant.

The mandibular incisors proclined slightly in the treated group and IMPA significantly increased by 2.0 degrees. Other studies have reported that the mandibular incisors procline or advance significantly during functional appliance treatment in spite of capping (Ahlgren and Laurin, 1976; Pancherz, 1984; Nelson *et al.*, 1993).

The dentoalveolar changes included a significant decrease of the overbite by 2.2 mm in the treated group. These findings are in agreement with Ahlgren and Laurin (1976), Pancherz (1984), Lagerström *et al.* (1990), and Nelson *et al.* (1993). This could be a reflection of the increase in face height. Activator and headgear combination therapy caused dentoalveolar changes in the molar area.

In the present analysis, these appliances resulted in a significant 3.5 mm of forward movement of the mandibular molars (when measured parallel to OL). This is in agreement with Vargervik and Harvold (1985), Malmgren *et al.* (1987), and Weiland *et al.* (1997) who concluded that the mandibular molars come forward with the mandibular molars due to the maximum molars was reduced by 0.6 mm in the treated group in comparison with the controls, but the difference was not significant.

Effects on vertical growth of the jaws and dentition

Activator and headgear combination therapy appears to increase vertical development of the mandible. A number of authors (Williams and Melsen, 1982; Ruf *et al.*, 2001; Cozza *et al.*, 2004a,b) have found that the majority of mandibular growth is expressed vertically with activator therapy because of backward rotation of the mandible. An increase in face height in the first molar region disturbs the balance of vertical development and thereby influences displacement of pogonion in a backward direction; variations in the vertical dimensions of the maxilla are thus related to the sagittal discrepancy.

For this reason, it appears that control of the vertical dimension is imperative for an optimal forward displacement of the correction of a skeletal Class II malocclusion. The results of the present study did not show significant modifications in vertical development of the maxillomandibular complex: the angular measurements indicated a slight increase in FH–OL and SN–PP angles in the treated subjects, while FMA angle did not change significantly; similarly, the vertical relationship appeared to be stable in the control group.

The vertical dental relationship expressed by overbite is an important feature in functional therapy associated with a good prognosis for treatment outcome (Charron, 1989). During therapy, the incisors were passively prevented from erupting by double capping as the molars erupted, which resulted in a statistically significant correction of the overbite in the treated group, while in the controls overbite remained stable.

Effects on soft tissue facial profile

The positive effects of treatment on the facial profile were accompanied by an increase in the facial convexity angle, while in the control group there was a reduction in this parameter. Singh and Thind (2003) reported a significant improvement in the soft tissue profile after treatment with the Teuscher appliance combined with headgear. McDonagh *et al.* (2001) found that greater forward positioning of soft tissue pogonion occurs after treatment with a functional appliance and headgear combination.

The upper lip-x-axis distance was increased in this study. Sarı et al. (2003) found an insignificant increase after

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treatment with activator-headgear combination appliances, whereas Ülgen *et al.* (1984) reported insignificant retrusion and Gögen and Parlar (1989) and Quintão *et al.* (2006) significant retrusion of the upper lip.

The Mlf-y-axis and Pg'-y-axis vertical distances increased significantly compared with the control group, where there were slight increases in these two parameters. This means that the depth of the labiomental fold decreased and pogonion moved anteriorly in the treatment group. Slsx-axis distance significantly increased in the treated group while a slight increase in this parameter was observed in the control group. The antero-posterior effect of the high-pull headgear may be responsible for this decrease in the depth of Sls. Hansson *et al.* (1997, 2000) reported inhibited sagittal growth of the maxilla, increased anterior face height, and a flattened soft tissue facial profile with a less pronounced labiomental sulcus after treatment with functional-headgear combination appliances.

Horizontal growth of soft tissue menton (Me') according to the Me'-x-axis parameter increased significantly in the treatment group when compared with the control group. A slight decrease was observed in the control group. This means that activator and high-pull headgear therapy may be effective on horizontal growth of soft tissue menton. Horizontal growth of the labiomental fold, according to the MIf-E line distance significantly decreased in the treatment group when compared with the control group where a slight increase was observed. Thus, activator-high-pull headgear therapy may decrease the depth of the labiomental fold. Singh and Thind (2003) and Mergen et al. (2004) reported that significant antero-posterior growth of the mental regions occurs after treatment with functional appliances combined with headgear. According to Forsberg and Odenrick (1981), Remmer et al. (1985), and Bishara and Ziaja (1989), growing Class II patients can undergo significant profile improvement with functional appliance-headgear combination treatment.

Conclusions

The results of the present investigation indicate that activator and high-pull headgear combination therapy is effective in treating Class II malocclusions and improving the soft tissue facial profile. Functional therapy is of clinical benefit in actively growing patients and should be initiated during the middle to late mixed dentition period. Dentoalveolar effects seem to play an important role in this correction, but a relative maxillo-mandibular displacement, mainly a mandibular advancement, was also apparent.

Supplementary material

Supplementary data are available at European Journal of Orthodontics online (http://www.ejo.oxfordjournals.org/).

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