CONTINUING EDUCATION

Anteroposterior skeletal and dental changes after early Class II treatment with bionators and headgear

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In this study we examined anteroposterior cephalometric changes in children enrolled in a randomized controlled trial of early treatment for Class II malocclusion. Children, aged 9.6 ± 0.8 years at the start of study, were randomly assigned to control (n = 81), bionator (n = 78), and headgear/biteplane (n = 90) treatments. Cephalograms were obtained initially, after Class I molars were obtained or 2 years had elapsed, after an additional 6 months during which treated subjects were randomized to retention or no retention and after a final 6 months without appliances. Calibrated examiners, blinded to group, used Johnston's analysis to measure anteroposterior cephalometric changes. Statistical analysis was used to determine annual skeletal and dental changes during treatment, retention, and follow-up, and overall. Our data reveal that both bionator and head-gear treatments corrected Class II molar relationships, reduced overjets and apical base discrepancies, and caused posterior maxillary tooth movement. The skeletal changes, largely attributable to enhanced mandibular growth in both headgear and bionator subjects, were stable a year after the end of treatment, but dental movements relapsed. (Am J Orthod Dentofacial Orthop 1998;113:40-50.)

We have previously reviewed many of the important issues concerning the two timing strategies for the treatment of Class II malocclusion.[1] Although it is apparent that growth modification for Class II correction is quite effective in certain individuals, much remains unknown about the mechanisms involved in the success or failure of these treatment approaches. For this reason, the optimal timing of Class II correction and its related effect on the various risks and benefits of treatment is of considerable clinical significance.

What do we know or believe as a specialty about the skeletal and dental effects of early headgear and bionator (activator) therapy, and how firmly grounded are these perceptions? English-language articles published over the past 30 years whose authors have described the effect of headgears and bionators are listed and characterized in Tables I through III. To be included, each article had to fulfill the following requirements: (1) treatment effects determined in relation to an untreated control, (2) cephalometric data presented on anteroposterior changes that could be independently interpreted by the reader, and (3) treatment effects not confounded by additional, concomitant treatments. Well-known articles that do not permit reader interpretation of the data[2] or lack control data[3-6] were not included.

There is good agreement that these appliances do effect favorable anteroposterior apical base, molar-relation, and overjet changes. However, disagreement exists over the mechanism of anteroposterior changes with these appliances. The clearest consensus concerns the inhibitory effect of headgear therapy on maxillary anterior displacement. Most have concluded that activator therapy also inhibits maxillary anteroposterior displacement but that the headgear is more effective. The effect of these appliances on mandibular anteroposterior displacement is less clear, with most authors suggesting no effect. A few studies (4 of 14) suggest activator therapy effects favorable anteroposterior mandibu-

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Table I. Characteristics of previous activator studies in preadolescent children and their outcomes with regard to anteroposterior orthopedic/orthodontic changes. Only studies involving comparison with a control group are included.

Author	*Design*	*No. treated/no. controls*	*Control type**	*Matched*	*Age of treated patients/ controls*	*Activator type*	*Study limitations*	*Maxillary*	*Mandibular*	*ABCH*	*U6*	*L6*	*U1*	*L1*	*U6/L6*	*U1/L1*
Meach, 1966	Retro	30/34	Historical	No	10-13/8-11	Andresen	Scant data, limited analysis, controls Class I	NA	0	NA	NA	NA	NA	NA	NA	NA
Jakobsson, 1967	RCT	19/19	Random	Yes†	8.5/8.5	Andresen		+	0	NA	NA	NA	NA	NA	NA	+
Trayfoot and Richardson, 1968	Retro	17/17	Selected	a, s, t	8-13/NA			+	0	+	NA	NA	+	0	NA	NA
Harvold and Vargervik, 1971	Pro	20/20	Selected	a, s, m, t	9.7/8.4			+	0	NA	0	0	NA	NA	+	+
Wieslander and Lagerstrom, 1979	Retro	30/30	Historical	a, s, o, t	8-11/NA			0	0	+	0	0	+	0	+	NA
Forsberg and Odenrick, 1981	Retro	47/31	Selected	a, s, m, t	10.8/10.4	Andresen		+	0	+	NA	NA	NA	NA	NA	+
Luder, 1981	Retro	25/39	Selected	No	8.6/9.2	Holz		+	+	NA	+	0	+	+	NA	NA
Calvert, 1982	Retro	29/19	Selected	No	11.9/11.7	Andresen		+	+	NA	+	0	+	+	NA	NA
Baumrind et al, 1983; Ben-Bassat et al, 1986	Retro	61/50	Selected	No‡	10.0/8.4	Modified		0	+	NA	+	0	NA	NA	NA	NA
Johnston, 1985	Retro	47/44	Historical	Growth§	10.8/11			+	+	+	+	0	NA	NA	+	NA
Vargervik and Harvold, 1985	Pro	52/variable	Self	No	10-5/NA			+		+	0	0	NA	NA	NA	+
Looi and Mills, 1986	Retro	30/22	Historical	No	11.5/11.7	Andresen		0	0	+	NA	NA	+	0	NA	+
Jakobsson and Paulin, 1990	Retro	53/60	Selected	Growth‖	10.9/10.4 11.6/ 10.5	Andresen	Girls matched on a, t, but not g and m; boys matched on g, not on a, t, m	+	+	+	NA	NA	NA	NA	NA	NA
Nelson et al, 1993; Courtney et al, 1996	RCT	17/12	Random	a, s, m	11.7/11.5	Harvold	Treated subjects removed for not following instructions	0	0 (5)	NA	0	NA	+	+	NA	+
Tulloch et al, 1996	RCT	53/61	Random	s, o, g	9.4/9.4	Bionator		0	+	+	NA	NA	NA	NA	NA	+

Retro, retrospective; *pro,* prospective; *NA,* not measured; +, Class II correction; *0,* no change; —, more Class II; *a,* age; *s,* sex; *t,* treatment/observation time; *o,* malocclusion; *m,* skeletal morphology; *g,* growth.

*Data from control subjects were obtained from a historical database, from a previously unreported cohort of selected subjects, from subjects randomly assigned to control status before the start of the study, and from subjects serving as their own controls.

†Cases were randomly assigned to control, headgear, and activator groups. Author states that groups are similar, but no data are presented to demonstrate this.

‡Cases not balanced by sex, age, film interval, or morphology. Authors examined associations between positions of various original landmarks and their observed displacements and, finding none, concluded that antecedent group differences did not affect interpretation of the results.

§Cephalometric changes adjusted for expected growth units.

‖Cephalometric changes co-varied on Ba-Na changes.

Table II. Outcomes of previous headgear studies concerning anteroposterior orthopedic/orthodontic changes

Author	*Design*	*No. treated/ no. controls*	*Control type**	*Matched*	*Age of treated patients/ controls*	*Headgear type*	*Study limitations*	*Maxillary*	*Mandibular*	*ABCH*	*U6*	*L6*	*U1*	*L1*	*U6/L6*	*U1/L1*
Meach, 1966	Retro	30/46	Historical	No	9-4/8-11	Kloehn	Scant data, limited analysis, Class I controls	NA	—	NA	NA	NA	NA	NA	NA	NA
Jakobsson, 1967	RCT	19/19	Random	No data	8.5/8.5	Kloehn		+	0	NA	NA	NA	NA	NA	NA	+
Wieslander, 1974	Retro	28/28	Selected	a, s, t, o	9/9	C ± U 2 × 4 ± BP	No group equivalency data shown	+	0	+	+	NA	NA	NA	NA	NA
Mills et al, 1978	Retro	51/20 84/13	Historical	a	11.6/10.9 10.4/10.4	J hook to U 2 × 4	Malocclusion greater in treated patients than in controls at start	+	—	+	+	—	+	—	NA	+
Baumrind et al, 1983; Ben-Bassat et al, 1986	Retro	74/50	Selected	No	10.3/8.4	Cervical		+	0†	NA	NA	0	NA	NA	NA	NA
	Retro	53/50	Selected	No	10.0/8.4	High pull		+	0	NA	NA	0	NA	NA	NA	NA
Tulloch et al, 1996	RCT	52/61	Random	s, o, g	9.4/9.4	Combination		+	0	+	NA	NA	NA	NA	NA	+

Only studies involving comparison with a control group are included.
Retro, retrospective; *NA,* not measured; *+,* Class II correction; *—,* more Class II; *0,* no change; *a,* age; *s,* sex; *t,* treatment/observation time; *o,* malocclusion; *m,* skeletal morphology; *g,* growth.
*Data for control subjects were obtained from a historical database, from a previously unreported cohort of selected subjects, from subjects randomly assigned to control status before the study or from subjects serving as their own controls.
†Data in 1981 Baumrind article show greater condylion pogonion change in cervical headgear and activator groups than that in controls; however, their 1983 article shows the changes in the headgear group are not expressed in an anterior direction.

Table III. Outcomes of previous studies comparing activators and headgears concerning anteroposterior orthopedic/orthodontic changes

Author	*Maxillary*	*Mandibular*	*ABCH*	*U6*	*L6*	*U1*	*L1*	*U6/L6*	*U1/L1*
Meach, 1966	NA	A > HG	NA	NA	NA	NA	NA	NA	NA
Jakobsson, 1967	HG > A	0	NA	NA	NA	NA	NA	NA	A > HG
Baumrind et al, 1983;	HG > A	A > HG	NA	0	0	NA	NA	NA	NA
Ben-Bassat et al, 1986	HG > A	A > HG	NA	HG > A	0	NA	NA	NA	NA
Tullock et al, 1996	HG > A	A > HG	0	NA	NA	NA	NA	NA	A > HG

NA, not measured; *A,* activators; *HG,* headgear; *0,* no difference.

lar displacement. Some suggest that headgear therapy actually inhibits such displacement.

The effect on the teeth has been investigated less frequently. Activators appear to retract the upper incisors and, perhaps, the upper molars, with little effect on the mandibular teeth. Headgear seems to cause only distal maxillary molar movement.

The purpose of this study was to examine the anteroposterior skeletal and dental effects that occur as a result of early treatment with the headgear/biteplate and bionator, as well as those changes that occur after appliance removal before the second phase of full appliance therapy. Specifically, this study was designed to answer the following questions: (1) Can facial growth be altered by early treatment appliances, such as the headgear and bionator? (2) If so, does normal facial growth with additional time catch up to negate any apparent early advantage? (3) Does relapse occur? (4) If so, is it primarily dental or skeletal? (5) Is retention necessary between phases in the two-phase approach to counter

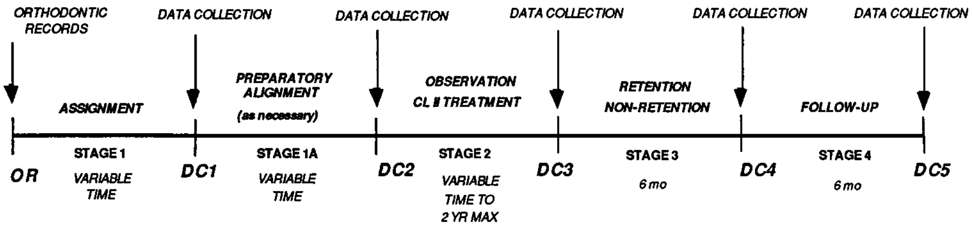

Fig. 1. Study stages and data-collection points for the RCT. *OR,* orthodontic records; *DC,* data collection.

Table IV. Inclusion and exclusion criteria for the RCT

Inclusion	*Exclusion*
Bilateral ≥ ½ cusp Class II molars, or if one side < ½ cusp Class II, the other side > ½ cusp Class II	Lacks bilateral ≥ ½ cusp Class II molars, or if one side < ½ cusp Class II, the other side > ½ cusp Class II
Fully erupted permanent first molars	Lacks full erupted permanent first molars
Emergence of not more than 3 permanent cuspids or bicuspids	Emergence of more than 3 permanent cuspids or bicuspids
Positive overbite and overjet	Lacks positive overbite and overjet
Willingness to undergo orthodontic treatment/observation for ≤ 2 years, followed by 6 months of retention/no retention and an additional 6 months of follow-up	Not willing to undergo orthodontic treatment/observation for ≤ 2 years, followed by 6 months of retention/no retention and an additional 6 months of follow-up
Willingness to be randomly assigned to an observation, bionator, or headgear group and, if assigned to a treatment group, to be randomly assigned to a retention or no-retention group after treatment	Not willing to be randomly assigned to an observation, bionator, or headgear group and, if assigned to a treatment group, to be randomly assigned to a retention or no-retention group after treatment
Good general health, free from systemic illness/dysfunction requiring continued supervision by a physician	Poor general health, presence of systemic illness/dysfunction requiring continued supervision by a physician
Absence of active dental or periodontal pathology	Presence of active dental or periodontal pathology
Signed informed consent	Failure to sign informed consent

relapse while the succedaneous dentition is being completed?

MATERIAL AND METHODS

The experimental design was a prospective, longitudinal randomized controlled trial (RCT) of the treatment of children with Class II malocclusion. The complete details of this trial have been previously reported.[7] In brief, Class II subjects were identified, notified of the study, and, through a parent, invited to participate. Inclusion and exclusion criteria are listed in Table IV.

After informed consent was obtained, standardized routine orthodontic records were taken, including a clinical examination, medical and dental histories; maxillary and mandibular impressions; centric occlusion bite registration; lateral cephalometric, panoramic, and hand-wrist radiographs; and facial and intraoral photographs.

A stratified block-randomization procedure was used to assign each subject to a treatment protocol. Each subject had an equal likelihood of assignment to an observation, retention, or no-retention group. In addition, subjects assigned to undergo retention or no retention were equally likely to be assigned to undergo treatment with headgear/maxillary retainer with bite plane or treatment with a bionator.

We used several criteria to define strata: First was severity of Class II malocclusion (mild: bilateral half-cusp; moderate: one-side three-quarter cusp; and severe: one-side full cusp). The second criterion was the need for preparatory treatment/observation ([1] maxillary incisor alignment to produce an overjet equal to or greater than the greater molar discrepancy—only subjects assigned to treatment received this, if necessary; [2] posterior crossbite correction; [3] incisor eruption; and [4] habit cessation). Third was the mandibular plane angle (MPA): low (< 30°), normal (30° to 40°), and high (>40°). The fifth criterion was race (black, nonblack), and the sixth was the patient's sex (in cases in which the mandibular plane angle was >40°).

After assignment to a treatment group and any preparatory treatment/observation, there were three stages: Class II early treatment, retention/nonretention, and follow-up. For each subject, data collection was conducted as indicated in Fig. 1.

Class II treatment/observation (stage 2) ended when two orthodontists independently agreed during a 3-month interval that at least a bilateral Class I molar relation existed or two years had elapsed from the start of treatment. Stage 3 (retention/nonretention) and stage 4 (follow-up) were fixed at 6-month intervals.

The headgear group received a cervical (MPA ≤ 40°) or high-pull (MPA > 40°) headgear and a flatplane

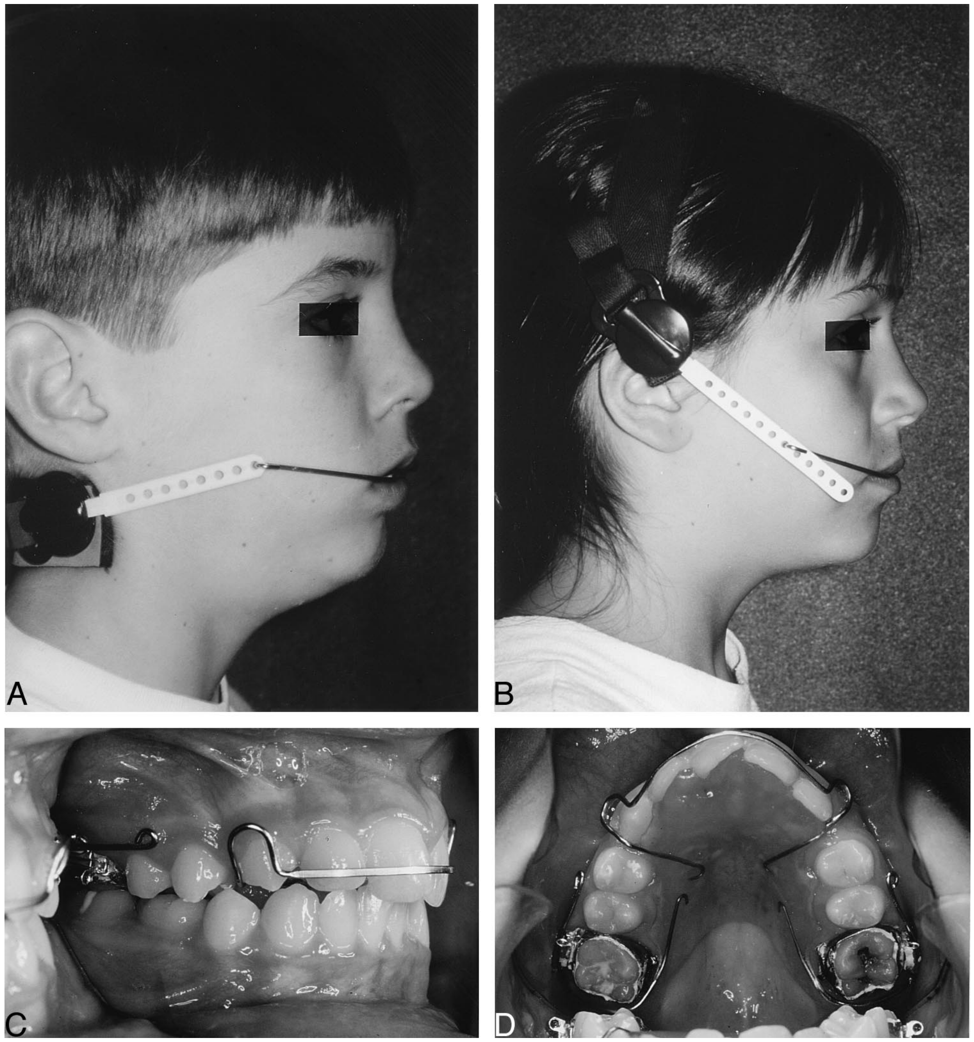

Fig. 2. A, Cervical and **B,** high-pull headgears and maxillary Hawley retainer with anterior biteplane were used **(C and D)**. Note that circumferential clasps are wrapped around the first molars and that the biteplane discludes the posterior teeth in patients with deep overbites.

maxillary acrylic anterior biteplane with labial bow and molar circumferential wires designed to disclude posterior teeth (Fig. 2). The headgear facebow did not touch the maxillary incisors. The circumferential wires of the biteplane were loosely adapted and clipped over the buccal tubes for retention purposes. Subjects were instructed to wear the acrylic retainer/biteplane full-time, removing it for eating, brushing, and contact sports; they were instructed to wear the headgear at least 14 hours each day. Headgears were adjusted at each appointment to deliver 16 ounces of force per side.

Bionator subjects received a bionator to maintain the bite, with occlusal stops for maxillary and mandibular teeth (Fig. 3). Subjects were instructed to wear their bionators 22 hours a day, with removal for eating, brushing, and contact sports.

During the retention phase, both bionator and headgear/biteplane retention subjects were instructed to wear their appliances every other night to bed, approximately 10 hours each day. Subjects in the nonretention groups had their appliances taken away.

Children in each of the treatment groups were encouraged by the attending orthodontist at each visit to wear their appliances as instructed. Subjects with poor or no cooperation in following instructions and those with poor progress were not dismissed; they were monitored and data were collected at each time point.

To control for proficiency bias, each child's clinic appointments were rotated among the four project orthodontists. Children wearing appliances were scheduled for a visit once each month; children without appliances were scheduled for a visit once every 3 months.

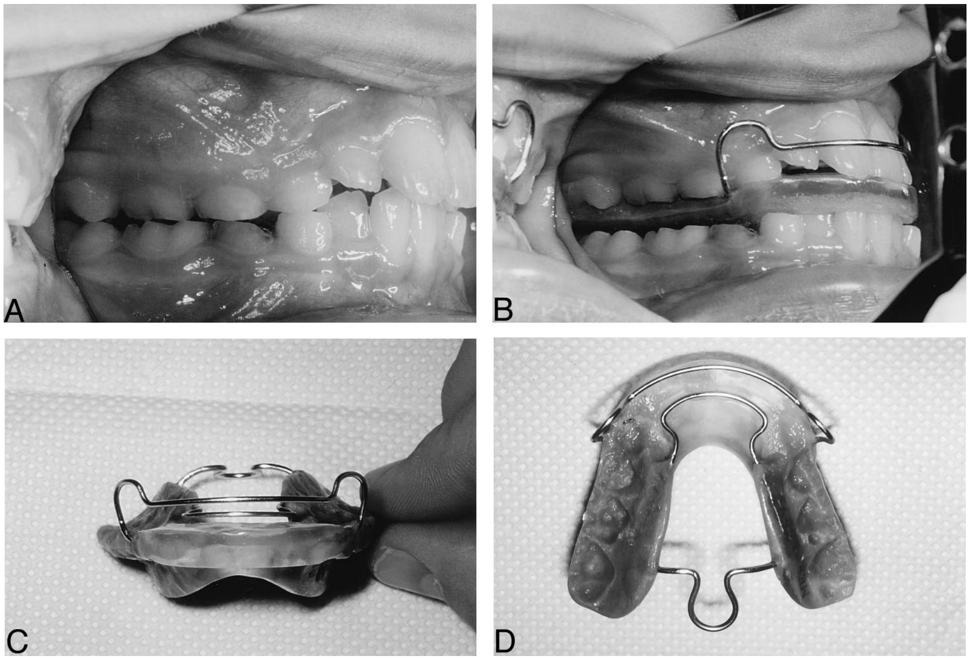

Fig. 3. Bionators to maintain the vertical dimension were used initially to advance the mandible to a Class I molar relationship **(A and B)**. Mandibular occlusal acrylic was removed during treatment to permit tooth eruption, as explained in the Methods section. **C,** Frontal and **D,** superior views of the bionator illustrate construction.

All appliances were removed by the clinic dental assistant (a dentist) at each data-collection appointment before the examiner obtained any data, including radiographs, and replaced, as necessary, afterward, so that examiners would remain blinded to treatment group and treatment stage.

Skeletal and dental changes were determined by standardized examiners using Johnston's analysis, which has been described in detail previously by Johnston[8] and assessed for reliability by our group.[9] Skeletal variables assessed were maxilla, mandible, and apical base change (sum of maxillary and mandibular values). Dental variables assessed were maxillary and mandibular molars and incisors. Molar discrepancy was defined as the sum of the apical base change and the maxillary and mandibular molar change. Change in overjet was defined as sum of the apical base change and the maxillary and mandibular incisor change. Positive numbers reflected Class II correction.

We examined baseline (DC1) differences in age and each stratification variable (sex, race, mandibular plane angle, molar class severity, need for pretreatment) among the groups (bionator, control, and headgear) to determine the initial homogeneity of the groups. These differences were also examined between those included in this analysis and those subjects, assigned to a group, whose data were not included (dropouts, those with incomplete data sets). Stratification and screening data were available on all subjects.

We generated χ^2 tables to explore univariate relationships among categorical variables and the groups.[10] ANOVA and the Kruskal-Wallis test were used to explore univariate relationships among continuous variables and the groups.[11]

The general linear-models program (PROC GLM) was used to examine the annualized skeletal and dental changes during treatment (DC1 to DC3), retention (DC3 to DC4), follow-up (DC4 to DC5), and overall (DC1 to DC5). We also examined the effect of retention status during the retention and follow-up periods. Stratification variable of sex, initial molar class severity, initial mandibular plane angle, pretreatment status, and race, along with initial age, were included in all models. Treatment group or treatment and retention group significance was assessed; Fisher's least significant difference test was used to determine which groups differed.

RESULTS

A total of 360 subjects who had previously been screened by one of the project orthodontists in their schools gave informed consent for the study and had orthodontic records taken. Twenty-nine of these patients were judged by the project orthodontists to represent screening failures because they did not meet inclusion criteria. Six more withdrew before data collection at DC1. These 35 subjects were never assigned to a treatment/observation group.

Table V. Equivalency of baseline variables of treatment and control subjects with baseline (DC1) and end of the phase 1 protocol (DC5) data

Variable	*Bionator*	*Headgear*	*Control*	*p*	*Significance*
Sex					
Female	24	35	28	0.524*	None
Male	46	46	46		
Race					
Nonwhite	9	6	4	0.252*	None
White	61	75	70		
Pretreatment					
No	34	41	66	0.001*	Control vs. Bionator & headgear
Yes	36	40	8		
Class II severity					
Severe	35	33	33	0.841*	None
Moderate	14	20	18		
Mild	21	28	23		
Mean Md plane	32.7	33.8	33.6	0.466†	None
Mean age (yr)	9.7	9.7	9.5	0.370†	None

*χ^2 Test.
†ANOVA.

Table VI. Equivalency of individuals who withdrew from the study with those who participated in the study, including those who completed the study

Variable	*Included*	*Not included*	*p*
Sex			
Female	87	45	0.283*
Male	138	55	
Race			
Nonwhite	19	19	0.006*
White	206	81	
Pretreatment			
No	141	52	0.071*
Yes	84	48	
Class II severity			
Severe	101	52	0.185*
Moderate	52	26	
Mild	72	22	
Mean Md Plane	33.4	32.8	0.338†
Mean age (yr)	9.6	9.6	0.692†
Treatment			
Bionator	70	39	0.380*
Headgear/BP	81	32	
Control	74	29	

*χ^2 Test.
†ANOVA.

Thus 325 subjects were stratified to a group, entered the RCT, and underwent data collection at DC1. Forty-nine of these subjects dropped out before reaching the end of the treatment period at DC3. This report includes data on 249 subjects (bionator 79, control 78, and headgear 92) with data from DC1 to DC3, 235 subjects (bionator 75, control 75, and headgear 85) with data from DC3 to DC4, 217 subjects (bionator 69, control 70, and headgear 78) with data from DC4 to DC5, and 225 subjects (bionator 70, control 74, headgear 81) with data from DC1 to DC5. Differences in sample sizes for the various intervals reflect missing data resulting from missed appointments.

We found no differences in age, sex, race, molar class severity, mandibular plane angle, or need for pretreatment between treatment groups in those subjects with records at DC1 and DC5 (Table V). The control group did differ from the treatment group with regard to whether pretreatment was received.

There were no differences between the study subjects and those subjects who withdrew from the study with respect to age, sex, molar class severity, mandibular plane angle, or need for pretreatment. However, a larger proportion of nonwhite children did not complete the first phase of this study (Table VI).

The skeletal and dental treatment effects are shown in Fig. 4. The bionator and headgear groups showed significantly more skeletal Class II correction than did the controls with regard to mandible and apical base measures. In addition, the headgear group showed a significant dental Class II correction by the maxillary molar and maxillary incisor. We noted significant combined dental and skeletal differences, as indicated by differences between the treated and control groups in overjet and molar discrepancy.

There was significant molar relapse during the 6-month retention phase in the headgear groups. We also noted a significant difference in this measure between the nonretained bionator group and the controls (Fig. 5).

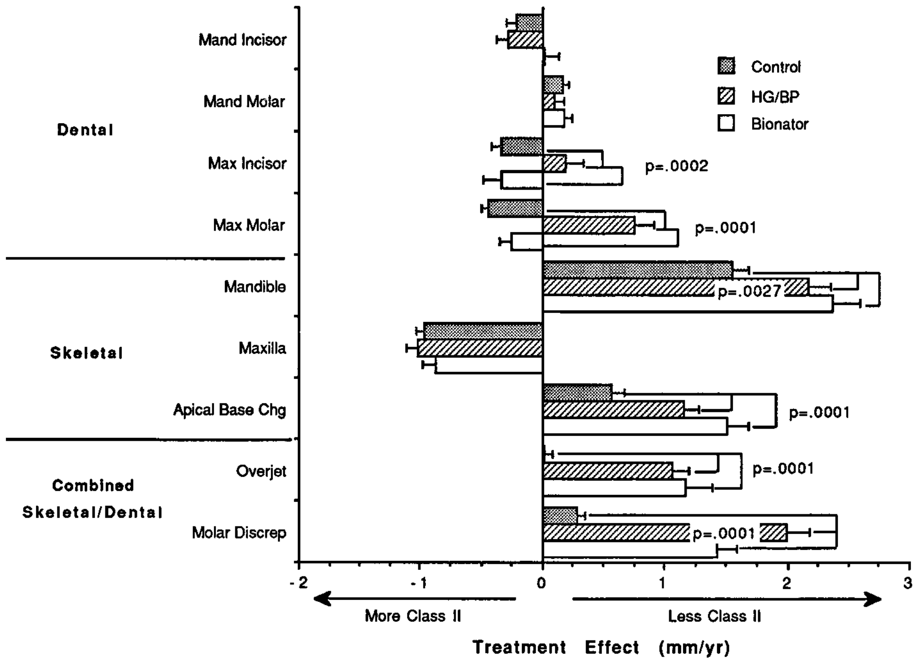

Fig. 4. Effect of treatment with bionator (n = 79) or headgear/biteplane (n = 92) and changes in control group (n = 78). Values have been annualized (millimeters/year), and direction of Class II correction is shown. Significant *p* values are shown and group differences indicated.

We noted significant maxillary molar and incisor relapse in the headgear groups compared with the bionator and control groups (Fig. 6) during the 6-month observation phase.

Overall apical base correction was found in both treated groups compared with the controls (Fig. 7). The treated groups with retention had a greater mean apical base correction than did the nonretained treated groups, although this difference was not significant. Dentally, the maxillary molars came forward about twice as much in the control and bionator groups as in the headgear-retained group.

The combined skeletal and dental measures (i.e., overjet and molar discrepancy) showed significantly greater Class II correction in both of the treated groups over the control group.

DISCUSSION

The contradictions in the literature concerning early Class II treatment from retrospectively designed studies are many. These discrepancies are summarized in Table I and need not be referenced further in this section. The authors of two previous studies[12-14] have examined Class II early treatment with the headgear and bionator with the use of the methodology of the RCT.

Jakobsson[14] randomly assigned a group of 60 Class II mixed-dentition subjects, mean age 8.5 years, to observation, Andreasen activator, and Kloehn headgear groups. He reported on treatment effects after 18 months but did not examine relapse. Jakobsson reported that both appliances reduced overjet compared with control, with greater effect in the activator group. Both appliances restricted maxillary anterior displacement and had no effect on anterior mandibular growth compared with control; the headgear was more effective in restraining maxillary advancement than the bionator. Jakobsson did not report individual tooth movements or on the effect of age, severity, or sex.

Tulloch et al[12,13] randomly assigned 175 Class II subjects who had at least 7 mm of overjet to observation, bionator, and headgear groups and treated/observed all subjects for 15 months. These investigators reported that both appliances reduced apical base discrepancies equally compared with control; however, the mechanism of correction was different between the two treated groups. The headgear restricted maxillary anterior growth, whereas the bionator promoted increased anterior mandibular growth. These authors' study design did not include a retention or follow-up period; at 15

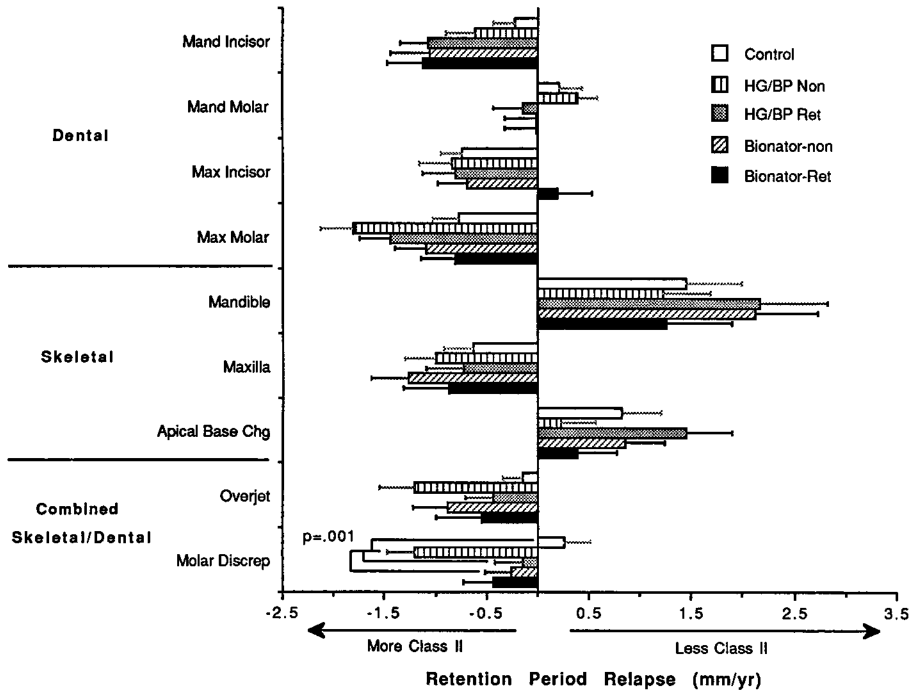

Fig. 5. Relapse after 6 months of retention with bionator or headgear/biteplane, as indicated in the Materials and Methods section. Groups shown are controls (n = 75), bionator with retention (n = 34), bionator without retention (n = 41), headgear/biteplane with retention (n = 44), and headgear/biteplane without retention (n = 41). Values have been annualized (millimeters/year), and direction of Class II correction is shown. Significant *p* values are shown and group differences indicated.

months the subjects in all groups proceeded to full appliance treatment.

Our data show that facial growth is altered during both bionator and headgear/biteplane therapies. The headgear/biteplane and bionator both enhanced mandibular growth without detectable relapse a year after the end of active treatment. Baumrind[15] reported increased mandibular growth in a cervical headgear sample, but the growth was expressed vertically and most likely did not affect Class II correction. Our data reveal growth enhancement in the anterior direction along the occlusal plane that contributed to Class II correction. We are analyzing the dental and skeletal changes in the vertical dimension. Tipping and extrusion of the molars will then be studied. Baumrind's subjects differed from ours in one important respect: Our headgear subjects also wore a maxillary retainer with biteplane. The contribution of the biteplane to enhanced growth is unclear, although it is likely a major component: Tulloch et al. reported no enhancement of mandibular growth with the headgear only. Could the biteplane alone have produced the effect? Our data do not provide the answer, but the dichotomy in the findings between our RCT and the findings of Tulloch et al forms the basis for a much-needed study. The localization of the enhanced growth of the mandible is unclear. Future assessment of condylar growth direction changes and fossa changes may allow us to understand where these appliances produce their effect.

We found that the 6-month retention period had no effect on the skeletal or dental changes achieved during the early treatment phase. There were no significant differences between the retained and nonretained treatment groups or controls except for the molar discrepancy in the nonretained headgear group. This variable is the sum of both dental and skeletal changes in both the maxilla and mandible. The difference observed in this variable may indicate that when the total skeletal/dental complex is considered, our retention protocol in the headgear group did prevent some relapse, but our methods did not reveal where it occurred. Our experimental protocol did not test whether other retention schemes (for example, every-night wear) would be effective.

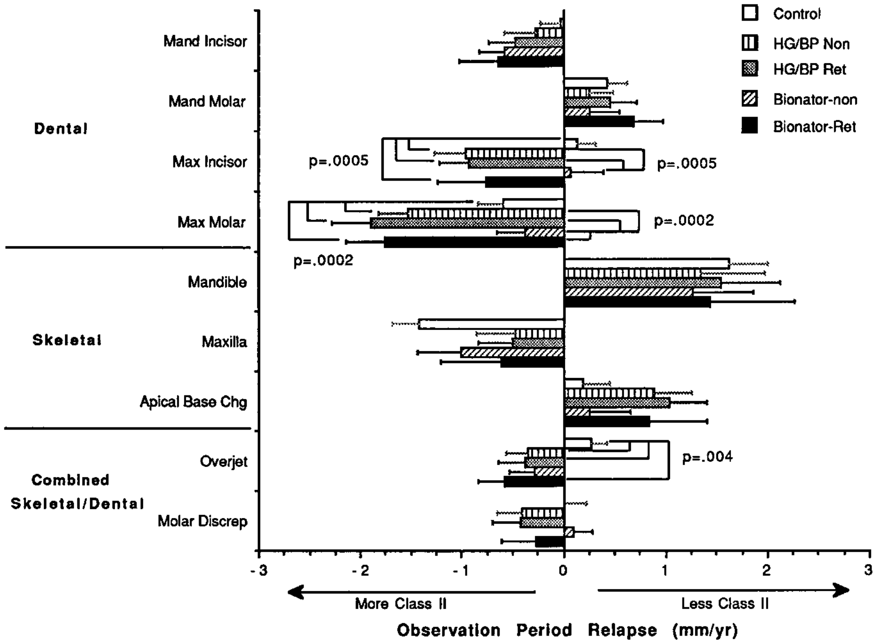

Fig. 6. Relapse after 6 additional months of observation. All appliances were discontinued during this period. Groups shown are controls (n = 70), bionator with retention (n = 31), bionator without retention (n = 38), headgear/biteplane with retention (n = 39), and headgear/biteplane without retention (n = 39). Values have been annualized (millimters/year), and direction of Class II correction is shown. Significant *p* values are shown and group differences indicated.

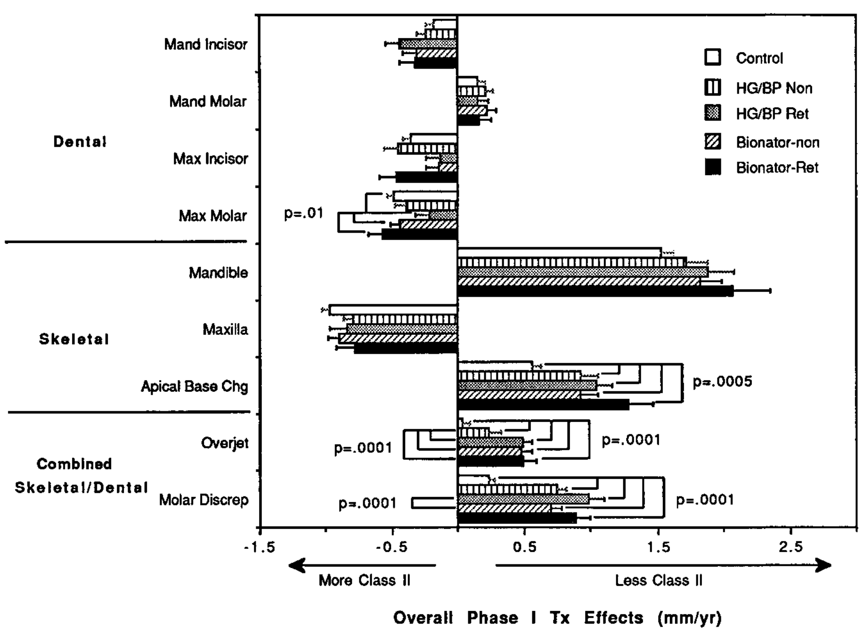

Fig. 7. Overall treatment effect of phase I orthodontic protocol. Data shown are the sum of the treatment effect, the 6-month retention period, and the 6-month observation period. Groups shown are controls (n = 74), bionator with retention (n = 32), bionator without retention (n = 38), headgear/biteplane with retention (n = 39), and headgear/biteplane without retention (n = 42). Values have been annualized (millimters/year), and direction of Class II correction is shown. Significant *p* values are shown and group differences indicated.

Our data indicate that any relapse observed during the 6 month follow-up period without appliances is clearly dental and not skeletal. It is interesting to note that the dental relapse of the maxillary molars and incisors occured in all the treatment groups except the nonretained bionator group during this observation period. It is possible that, in the nonretained bionator group, the dental units relapsed during the previous 6 months or "retention period" but it could not be detected.

All changes seen during the 6-month retention and 6-month follow-up periods were most likely due to group differences in tooth movement, not skeletal structures. Therefore retention, as provided in this RCT (every-other-night wear) was not effective in preventing dental relapse. It is possible that other retention schemes, aimed at preventing the achieved dental corrections, would have prevented this relapse. Also, longer retention with the appliances or until the beginning of phase II treatment might have prevented the relapse of the dental units. All this is speculation and must be examined further. It is important for the practicing clinician to note that retention is certainly not required to prevent skeletal relapse, but retention is necessary to prevent dental relapse.

In this RCT, all subjects were followed, regardless of level of cooperation, favorable growth, or favorable outcome, and compared with identical Class II untreated controls living in the same community at the same time; this method provided the most rigorous test to date of the hypothesis that early treatment with these appliances affects growth. The randomization and stratification procedures resulted in similar comparable groups. The roles of covariates such as initial age or molar class severity must be examined further. We will also examine the role of compliance and the relationship between "successful treatment" and cephalometric changes.

CONCLUSION

Our data counter current opinion: (1) the headgear/bite plane and bionator do not affect maxillary growth during treatment in these 9- to 10-year-old children, and (2) both appliances enhance mandibular anterior growth. Although our data do not answer all the questions dealing with retaining Class II corrections, they clearly show that skeletal changes can be achieved in this age group and that they are stable. We are continuing this RCT to examine the treatment outcomes in these patients after the second phase of orthodontic treatment.

We make a special heartfelt acknowledgment of Dr. Stephen Keeling, who died in January 1997. This study, his study, is a tribute to his dedication to the advancement of clinical knowledge in orthodontics. Although Dr. Keeling is missed, his work will live on through the publication of the outcomes of this study.

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