Headgear versus function regulator in the early treatment of Class II, Division 1 malocclusion: A randomized clinical trial

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A prospective randomized clinical trial was conducted to evaluate the early treatment of Class II, Division 1 malocclusion in prepubertal children. Facial and occlusal changes after treatment with either a headgear or a Fränkel function regulator are reported. Molar and canine relationships, overjet, intermolar and intercanine distances were measured from casts taken every 2 months, and mounted on a SAM II articulator. Cephalometric radiographs were taken annually. The results indicate that both the headgear and function regulator were effective in correcting the malocclusion. A common mode of action of these appliances is the possibility to generate differential growth between the jaws. The extent and nature of this effect, as well as other skeletal and occlusal responses differ. Treatment in late childhood was as effective as that in midchildhood. This finding suggests that timing of treatment in developing malocclusions may be optimal in the late mixed dentition, thus avoiding a retention phase before a later stage of orthodontic treatment with fixed appliances. However, a number of conditions may dictate an earlier intervention in the individual patient. (Am J Orthod Dentofacial Orthop 1998;113:51-61.)

Controversies about early orthodontic treatment, particularly Class II, Division 1 malocclusion, revolve about modalities and timing of treatment. The most critical issue regarding methods of treatment has been the capability to affect facial growth. The claim that functional appliances may stimulate mandibular growth has shaped the nature of the debate on the interaction between treatment and growth. The argument on timing of early treatment involves intervention in the primary dentition, the early mixed dentition (permanent first molars and incisors present), midmixed dentition (intertransitional period, before the emergence of first premolars and permanent mandibular canines), or late mixed dentition (before the emergence of second premolars and permanent maxillary canines).

These issues have defined the scope of considerable clinical research for at least the last two decades, culminating in the commitment of significant resources by the National Institute of Dental Research to study alternative approaches to early treatment of Class II, Division 1 malocclusion. The University of Pennsylvania was a recipient of one of these awards. Two principal specific aims were to compare extraoral traction and functional appliance therapy in the early correction of distoclusion and to establish whether treatment in early to midchildhood is necessary if intervention in late childhood is timely enough to correct the malocclusion.

In this progress report of the ongoing prospective clinical trial, data on differences between the headgear and the Fränkel function regulator (FR) are presented with a specific focus on selected occlusal and cephalometric changes.

MATERIAL AND METHODS

The material consisted of data from 63 children of an initial total sample of 84 patients who met strict criteria for enrollment in the study. These criteria included: Class II, Division 1 malocclusion associated with bilateral distoclusion (unilateral Class I excluded) and a minimum ANB angle of 4.5°; between 7 and 12.5/13 years of age; no prior orthodontic treatment; and expected residential stability of 3 years. Children with systemic, mental, behavioral, bleeding, and craniofacial disorders were excluded. If siblings presented with the same malocclusion, only one of them was recruited because they share in both the genetic background and environment.

The children's chronologic ages ranged from 7 years 2 months to 13 years 4 months, and their skeletal ages,

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determined on the basis of comparing hand wrist radiographs to the Greulich and Pyle[1] standards, ranged from 5 years 9 months to 13 years 9 months. Skeletal age was the basis of classification between two age groups: early to midchildhood (< 10 years in girls, < 10.5 years in boys) and late childhood (≥ 10 years in girls, ≥ 10.5 years in boys). The level of severity of the malocclusion was defined by the discrepancy in the cephalometric ANB measurement as low (ANB, 4.5 to 6.5°) or high (≥ 6.6°). Within each severity group, the children were assigned at random to treatment with either a headgear (n = 41) or a Fränkel FR (n = 43).

Headgear

A straight-pull headgear was inserted in the buccal tubes of bands cemented on the permanent maxillary first molars and adjusted to direct the forces through the approximate center of resistance of the molars and parallel to the occlusal plane. The straight-pull headgear was used to minimize the extrusive effect usually obtained with a cervical (low-pull) headgear, and yet maintain the potential for more distal movement than with a high-pull headgear. Baumrind et al.[2] reported that each of five types of extraoral appliances they studied, including high-pull, straight-pull, and cervical headgears, produced a change in mandibular plane orientation "too small to be of itself a major factor in the choice of extraoral appliances in individual cases."

The inner bow was adjusted at every visit to avoid any constriction or major expansion of the intermolar distance. When the bow was inserted in the molar tube on one side, the other arm of the bow laid passively against and parallel to the outer surface of the tube attached to the opposite molar. This adjustment represented a total expansion of the inner bow of about 1.5 to 2 mm. An average distalizing force of 14 to 16 ounces per side was used; it provided an optimal amount of force necessary to move maxillary molars distally or at least stabilize them and was tolerated by the patient. Clinical experience and research suggested that a force of 12 to 16 ounces per side transmitted to maxillary molars by means of a face bow moved the teeth distally or stabilized them.[3,4] At each monthly visit (every 4 weeks), the force level was measured with a Dentronix gauge to ascertain maintenance of force level. The measurement was performed with the patient standing or sitting up in the chair to ensure an accurate reading of the force level. The intraoral load at the maxillary molar teeth was expected to be generally the same as or greater than the measured extraoral force.[5]

Patients and their parents were instructed with respect to the patient wearing the headgear 14 hours a day, starting with an average of 10 hours during the first week to allow the patient to adjust to the new appliance. A regimen of 12 to 14 hours has been shown to produce satisfactory tooth movement with all types of headgear.[3] After achievement of neutroclusion, patients were asked to keep wearing the headgear (at least to bed, usually 10 hours in our population) until they were ready for Phase 2 of their orthodontic treatment (fixed appliances).

Fränkel FR

The function regulator type II (FR-II) was constructed according to the general guidelines published by McNamara and Huge.[6] All appliances were fabricated at the Great Lakes Orthodontics Laboratory (Tonawanda, N.Y.). The amount of initial mandibular forward positioning with the appliance was planned to be less than 5 mm and usually did not exceed 4 mm. When needed, particularly in severe malocclusion, one additional activation was included in the same appliance, and further activation incorporated in a new appliance. This guideline seemed appropriate in view of the publications of Fränkel et al.,[7-9] who advocate gradual mandibular advancement by the appliance, although several authors[10,11] suggested that gradual forward positioning by a functional appliance may not be critical to the desired correction.

Patients were instructed to wear the appliance at least 16 hours a day by the end of the first 4-week period (1-hour increase in duration every 1 or 2 days) and to return for evaluation if discomfort developed at any time after insertion of the appliance. In a study of patient cooperation with wearing a functional appliance system, Malmgren et al.[12] reported that patients who wore the appliance only at night, but regularly, achieved similar results as patients who wore the appliance both day and night. They stated, however, that better cooperation was achieved by requiring patients to wear the appliance almost full time. The labial bow was adjusted at every visit to barely touch the maxillary incisors, most commonly to stand 1 mm labial of these teeth. The reason for this adjustment was to prevent the maxillary incisors from being an obstacle to the expression of any distal force transferred against the maxillary first molars. After achievement of neutroclusion, patients were asked to wear the appliance as stipulated above for the headgear.

Compliance

At each visit, compliance with instructions on appliance maintenance and wear was reviewed with the child and parent(s), separately, then together. Presentation of report cards completed by patient and parent(s) was requested. Incentive programs contributed positively to compliance with the majority of the patients. In addition to a financial incentive for participation in the study, patients who wore their appliance in addition to the minimum time requested earned points toward a specified award. This practice is followed by orthodontists[13] and in other medical fields where compliance is essential for the success of treatment.[14,15] The incentive program was implemented, not to create a maximum treatment effect by getting noncompliant or minimally compliant patients to wear the appliance, but mainly to retain recruited patients who represent a valuable resource in a prospective longitudinal study. We have noted from prior experience that parental as well as patient involvement and follow-through is critical to facilitate patient compliance, regardless of the patient's initial disposition toward the acceptance of the recommended appliance. Consequently, the parent(s) were included both as observer(s) and as change agent(s). Because the parents were involved in reporting and checking on the time their child wears the appliance, they were inclined to encourage, and at times require, the child to wear the appliance, thus helping to change the behavior of an initially noncompliant or lazy child. The reported data include records from patients who met or exceeded the minimum requirements (16 hours for Fränkel, 14 hours for headgear wear), but also all the patients who wore the appliance regularly, albeit only to bed (usually 10 hours).

Measurements of the dentition

In order to record significant changes of the dentition, impressions were taken every 2 months, along with a facebow transfer, and two sets of centric occlusion (CO) and centric relation (CR) wax bites. The dental casts were mounted on a SAM II articulator with the CR bite registration. Anteroposterior molar and canine relationships, overjet, maxillary and mandibular intermolar and intercanine distances were measured from the bimonthly casts, with the use of digital calipers accurate to 0.01 mm. The molar relationship was measured between the axes of the mesiobuccal cusps of the permanent maxillary first molars, and the canine occlusion between the cuspal buccal planes of the canines. Intermolar distances were measured between the mesiobuccal cusps, and the palatal and lingual mesial cusps of the permanent first molars. Because of the possible development of wear facets, the mesiobuccal cusp tips (and the corresponding vertical midcuspal axes) of the permanent mandibular first molars were marked at the intersection of the occlusal contour of the cusp and the vertical axis drawn at a distance of 2 mm from, and parallel to the buccal groove of the tooth. Intercanine distances were measured between the cusp tips of primary canines, and later permanent canines. The cusp tips were consistently marked at the same point: the intersection of the cusp occlusal contour with the cusp vertical (occlusogingival) axis. All measurements were repeated three times by the same investigator (D.L.M.); the averages of these measurements were used for statistical analysis. At several timepoints, the sample size was smaller for anteroposterior canine relationship and intercanine width because of the transition from primary to permanent canines.

To evaluate the influence of tooth emergence on occlusal changes, the children were grouped on the basis of emergence or nonemergence of the permanent canines, premolars, and second molars. Specifically, emergence of the second premolars and permanent second molars, the most adjacent teeth to the first molars, was evaluated as it interacted with the development of the sagittal occlusion.

Cephalometric measurements

Lateral cephalographs were taken with a Quint Linear Sectograph (Quint Sectograph Corp., Los Angeles, Calif.), and the midsagittal plane-film distance was standardized at 13 cm. All cephalographs obtained subsequent to the pretreatment film were taken immediately after retrieving leaf gauges used between the anterior teeth to force the mandible posteriorly (see rationale and method in the following section). Cephalometric data from only 26 patients (14 FR, 12 headgear) are presented in this progress report. All the lateral films were traced by two orthodontist co-investigators (excluding the principal investigator). Reliability studies, processing, and analysis of cephalometric data were done according to the guidelines recommended by Baumrind and Curry[16] and built into the CRIL computer software. Several specific cephalometric landmarks, planes, and axes were defined; only selected sagittal and vertical angular and linear measurements are presented in this article that depict maxillary and mandibular skeletal and dentoalveolar relations.

A critical aspect in the enlargement of the face is mandibular growth. The distance between condylion, the most superior-posterior point on the condylar head, and pogonion, the most anterior point on the chin, was obtained as an overall measurement reflecting the length of the mandible. The image of condylion is often blurred on cephalographs because of superimposed structures. For this reason, cephalometric films were evaluated immediately after exposure by the principal investigator and a radiologist. If the condyle was not clearly delineated, another lateral head film was taken with the mouth open to identify condylar anatomy and trace its contour. The accuracy of identifying condylion was analyzed previously,[17] and the resulting guidelines for accurate reporting and research involving measurement of mandibular growth were followed. In this article, two sets of data are presented from two cohorts of patients. In a first set ($n = 26$), the distance condylion was identified on the closed mouth radiograph only; in the other set ($n = 27$), the tracing of condylion from the head film taken with the mouth open and closed were used according to the published guidelines.[17]

Criteria for treatment success

Ideally, the major goal of early treatment of distoclusion is the achievement of neutroclusion of the permanent first molars and canines and an optimal overjet (< 3 mm). However, these goals are not necessarily attained simultaneously. For this reason, treatment goals were separated into the correction of the molar relationship and overjet. This separation constitutes a stringent assessment of appliance performance and differential efficacy.

Achievement of goals was confirmed by two examiners

Fig. 1. Correction of distoclusion in child in early/mid-childhood group treated with headgear. **A,** Pretreatment lateral occlusion. **B,** Posttreatment occlusion. Note spacing among anterior teeth.

over a period of 2 months since first observation, using leaf gauges to minimize evaluation on the basis of mandibular position,[18,19] as the presence of a dual bite may lead to mislabeling of the occlusion. This tendency may occur particularly with functional appliances, which can stimulate the so-called "pterygoid response" wherein the mandible is rigidly held forward by splinting of the pterygoid muscle. The application of leaf gauges may not guarantee the detection of this problem but is an accepted method to minimize or perhaps negate the effect of the "pterygoid response." Thus, to confirm the achievement of neutroclusion and before taking progress cephalometric radiographs, the patients were instructed to hold leaf gauges for 5 to 7 minutes between the anterior teeth to disocclude the posterior teeth.[18,19] The gauges are plastic leaves of equal predetermined thickness. The number of leaves needed by each patient depends on the amount of incisor overbite or open bite and is recorded whenever used. Based on the leaf gauge–aided occlusal evaluation, a sagittal occlusion with a difference of more than 1 mm between CO and CR is not considered as having achieved neutroclusion.

Table I. Description of sample*

	Males		*Females*		*Total*	
Group	*N*	*%*	*N*	*%*	*N*	*%*
Headgear	16 (5)	24	19 (1)	5	35 (6)	15
Fränkel FR	15 (5)	25	13 (10)	43	28 (15)	35
Total	31 (10)	24	32 (11)	26	63 (21)	25

*Original number of patients: 84.
( )Number and percentage of patients discontinued from the study for lack of cooperation (includes two patients, one boy (HG) and one girl (FR) whose compliance was sporadic but whose records were taken over the period of 2 years of early treatment.)

Statistical analysis

Statistical significance of differences in categoric data (Table I) was evaluated by a Mantel Haenzel χ^2 test. Intraclass correlation coefficients and errors of measurement were calculated for each of the parameters to assess examiner variability of repeated measurements. Two-way analyses of variance and covariance were applied to examine the interaction between treatment and several groupings (severity, gender, and age). Separate time-specific *t* tests of average change from baseline were used. Linear correlation and regression techniques were used to evaluate relationships among and between occlusal and cephalometric measures.

RESULTS

No statistically significant differences existed between treatment or severity groups at baseline, indicating similarities between the randomized groups. Of the original 84 children recruited to the study, 21 (25%) were discontinued for lack of cooperation, a term we differentiate from compliance (Table I). At this point, two patients (one boy in the headgear group, one girl in the FR group) whose compliance was sporadic are included in the noncooperative group. Their records were taken over the period of 2 years of early treatment. Eventually, all patients will be included in an intent-to-treat analysis.

Compliant patients were children who wore the appliance regularly, even if less than instructed, over the period of treatment (2 years). Noncooperative children were those patients who, at some point in time, refused to receive treatment, despite all efforts to retain them. The largest percentage of these children were girls who wore the Fränkel regulator (42%); by contrast, the smallest number discontinued were girls in the headgear group (5%). The difference between these two groups of girls was statistically significant ($p < 0.05$). The percentages of boys lost to the study were similar in the headgear (24%) and FR (25%) groups.

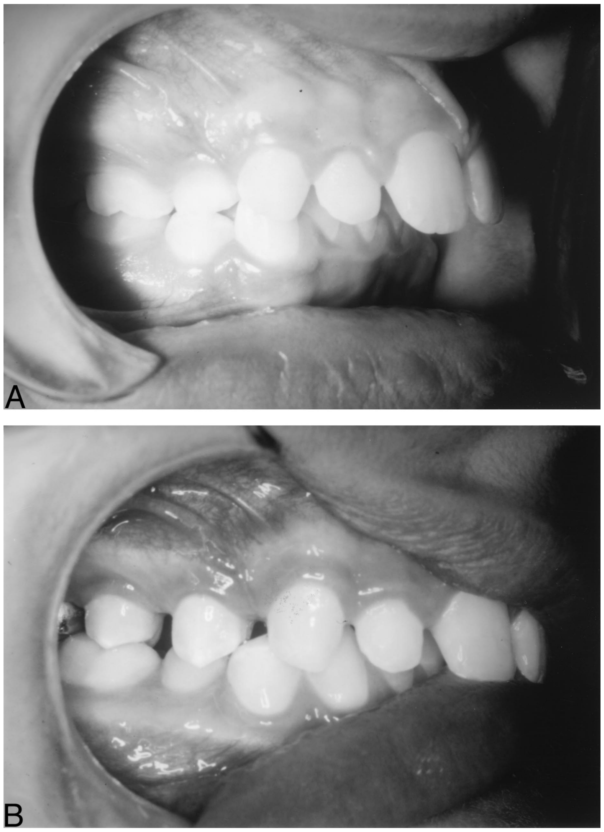

Fig. 2. Correction of distoclusion in child in late childhood group treated with headgear. **A,** Pretreatment lateral occlusion. **B,** Posttreatment occlusion. Note spacing among anterior teeth.

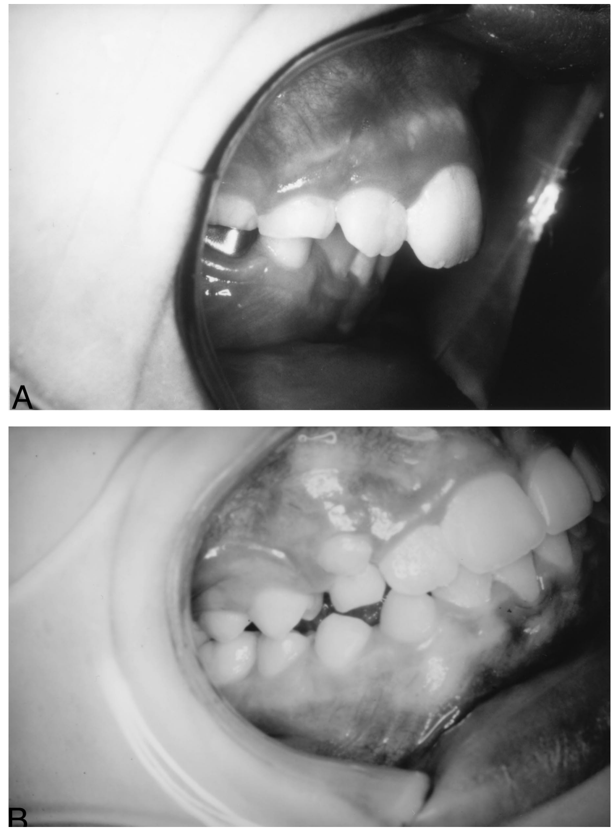

Fig. 3. Correction of distoclusion in child in early/midchildhood group treated with function regulator. **A,** Pretreatment lateral occlusion. **B,** Posttreatment occlusion.

The investigated hypotheses and corresponding findings to date relate to therapeutic differences between the headgear and functional appliance, measurements of somatic and facial growth, and associations between treatment and growth.[20-23] In this article, only selected occlusal and cephalometric measurements are presented.

Effect of treatment on the dentition

Records of patients successfully treated with the headgear and FR are shown for both age groups (Figs. 1, 2, 3, and 4). The errors of occlusal measurements ranged from 0.08 to 0.19 mm, and the intraclass correlation coefficients were very high ($0.994 < r < 0.999$).

Improvement in the molar and canine relationship toward neutroclusion was more significant with the headgear than the Fränkel FR (Table II). Overjet correction was larger with the FR, and the difference was not statistically significant. The maxillary intercanine distance increased significantly in the headgear group compared with the FR group. Arch length and circumference increased with the headgear, and spacing occurred among the anterior teeth (Figs. 1 and 2).

The mean palatal intermolar distance was larger in the Fränkel than the headgear group (Table II), and the difference between the groups was evident 4 months after the initiation of treatment.[20,21] The difference between the maxillary buccal intermolar distances, however, was not statistically significant between the FR and the headgear. As treatment progressed, the palatal intermolar distance in the headgear group increased, but this distance in the Fränkel group was still larger.[20,21]

Changes from baseline of the mandibular intermolar and intercanine distances were higher in the Fränkel group than the headgear group (Table II). The analysis of covariance revealed that skeletal age and treatment time did not affect the outcome in occlusal relations or arch parameters.

Changes in molar occlusion and overjet ap-

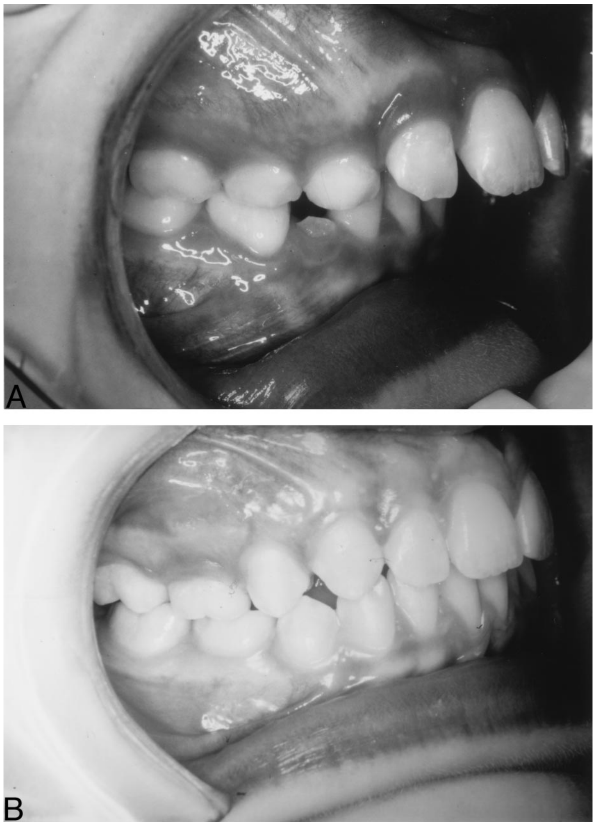

Fig. 4. Correction of distoclusion in child in late childhood group treated with function regulator. **A,** Pretreatment lateral occlusion. **B,** Posttreatment occlusion.

peared to be influenced by the emergence the second premolars (PM2) and the permanent second molars (M2), as the differences between the treatment groups were greater before the eruption of these teeth. However, within each appliance group, the emergence of PM2 and M2 did not affect the amount of progress toward Class I significantly ($p > 0.05$), indicating that change from distoclusion to neutroclusion with each appliance is not influenced by the timing of emergence of the PM2s and permanent M2.[23]

Cephalometric changes

The errors of cephalometric identification were accounted for through the CRIL method.[16] The sagittal discrepancy between the jaws was reduced with both appliances (Table III), as demonstrated by the ANB angle and the Wits analysis. However, the reduction in the ANB angle was almost twice with the headgear than after functional appliance therapy. The contribution by each of the jaws to this reduction differed between appliance groups. The headgear significantly affected the maxilla, as the SNA angle was reduced; the FR resulted in a more anterior position of the mandible as demonstrated by the increase in the SNB angle. The effect of the appliances on the position of the maxillary incisors also differed, the FR leading to the retroclination of these teeth, whereas the headgear had an opposite effect. Both methods of treatment resulted in a proclination of the mandibular incisors, but the amount of proclination of these teeth to NB or to the mandibular plane by the function regulator was more than twice that in the headgear group.

The average mandibular plane (MP) position relative to the anterior cranial base (SN) increased with the headgear, but remained basically unchanged with the FR; the difference between the two appliances was statistically significant. A similar trend existed for the angle between palatal and mandibular planes, with the exception that this angle decreased significantly with headgear treatment. The angle between occlusal and palatal planes increased significantly with the headgear. The angle between occlusal and mandibular planes was higher after functional therapy, but the differences between treatment groups were not statistically significant.

Because a change in the angles SNA and SNB may be due to the change in location of nasion, particularly when this landmark is displaced by growth in a more forward direction relative to sella, changes in sella-nasion were evaluated. They were not statistically significantly different between treatment groups.

Measurements of mandibular length (condylion-pogonion, Co-Po) were not statistically significantly different between the headgear (4.56 ± 2.81 mm) and the Fränkel FR (5.02 ± 2.01 mm). The average difference between these changes over the 2-year period of early treatment was 0.46 mm. A similar finding was observed in a previous evaluation of mandibular length from cephalographs taken with closed and open mouth in a cohort of 27 patients. However, the means were slightly larger, and the standard deviations smaller in both the headgear (5.69 ± 1.78 mm) and the Fränkel (6.18 ± 1.60 mm) groups. Interestingly, the difference between the mean changes of the treatment groups was almost the same (0.49 mm).

Correlations among and between all the different angular and linear measurements were conducted. Statistically significant correlation coeffi-

Table II. Effect of treatment on dentition*

	Headgear			Fränkel FR			
	Mean	*SE*	*n*	*Mean*	*SE*	*n*	*p*
Molar occlusion							
Right	−6.47	0.43	35	−3.01	0.48	28	0.0001
Left	−5.86	0.43	35	−3.08	0.49	28	0.0004
Canine occlusion							
Right	−3.18	0.39	33	−2.12	0.44	27	0.082
Left	−3.14	0.34	32	−1.82	0.36	28	0.0099
Overjet	−2.66	0.38	35	−4.19	0.42	28	0.0093
Intercanine distance							
Maxillary	3.90	0.37	32	1.73	0.40	28	0.0003
Mandibular	0.02	0.30	33	0.44	0.35	25	NS
Maxillary intermolar distance							
Palatal	1.31	0.35	35	2.90	0.39	28	0.034
Buccal	2.40	0.30	35	2.80	0.30	28	NS
Mandibular intermolar distance							
Lingual	0.40	0.18	35	1.04	0.20	28	0.02
Buccal	1.18	0.21	35	1.80	0.23	28	0.05

*Over a period of treatment (2 years).

cients were observed between ANB and SNB in the headgear group (r = 0.63, p = 0.03), and between Co-Po and Ar-Po both in the headgear (r = 0.73, p = 0.02) and the FR (r = 0.56, p = 0.04) groups.

Relationship between occlusal and cephalometric changes

The cephalometric findings were consistent with the occlusal data. The proclination of the maxillary incisors after treatment with headgear was compatible with the increased spacing among the maxillary anterior teeth, whereas the retroclination of these incisors and the proclination of the mandibular incisors with the FR would correspond to the larger overjet reduction observed with this appliance. When the associations between occlusal parameters and cephalometric changes were investigated, the only significant correlations were between overjet and incisor inclination in the FR group (1/NA: r = 0.58, p = 0.04; 1/NB: r = 0.57, p = 0.05).

DISCUSSION

Treatment modalities

Both the headgear and FR were effective in the treatment of Class II, Division 1 malocclusion, but the findings indicate differences of response at the level of the dentition and facial measurements. The initial data suggest that both appliances affect the position of the jaws in a differential manner. However, the headgear, on average, has a distal effect on the maxilla and first molars, but not the maxillary incisors, whereas the FR restrains the growth of the maxilla and results in a retroclination of the maxillary incisors, a more forward position of the mandible and a proclination of the mandibular incisors. In this context, the headgear, used without any other orthodontic movement, targets primarily the maxilla exclusive of the maxillary incisors, whereas the FR affects the jaws and both maxillary and mandibular incisors differentially. The effect of both appliances on mandibular length seems to be, on average, similar.

Occlusal changes. The greater improvement in the molar and canine relationships toward neutroclusion with the headgear suggests that restraining and distalizing forces on maxillary molars appear more effective with the headgear than the Fränkel FR.[21] This conclusion, however, must be corroborated with the later analysis of superposed serial cephalographs.

The larger correction of the overjet with the FR is at least partially due to the distal force exerted on the maxillary incisors with the labial bow. The retroclination of these teeth relative to NA supports this hypothesis. The proclination of the mandibular incisors, as well as the increase in the position of the mandible as suggested by the SNB angle, presumably contributed to this decrease. Conceivably, the headgear would provide similar results if combined with a distal force against the maxillary incisors. The overjet reduction observed with the headgear may be attributed to the differential growth between maxilla and mandible, whereby a distalizing effect on the entire maxilla appears to be significant enough to account for a reduction in the ANB angle. In contrast, the average position of the mandible is relatively unchanged.

Intercanine distance and anterior spacing. A sig-

Table III. Effect of treatment on facial measurements*

	Headgear			*Fränkel FR*			
	Mean	*SE*	*n*	*Mean*	*SE*	*n*	*p*
Sagittal skeletal							
SN (mm)	1.89	0.27	12	1.35	0.20	14	NS
SNA (degrees)	−3.14	0.39	12	0.15	0.30	14	0.0001
SNB (degrees)	−0.55	0.44	12	1.44	0.31	14	0.001
Co-Po (mm)	4.56	0.85	11	5.02	0.54	14	NS
Ar-Po (mm)	3.89	0.66	12	5.56	0.43	14	0.04
Gonial angle (deg)	0.13	0.49	12	−0.68	0.34	14	NS
ANB (degrees)	−2.59	0.47	12	−1.30	0.26	14	0.02
WITS (mm)	−2.05	0.60	11	−2.40	0.40	14	NS
Sagittal dentoalveolar							
I/NA (degrees)	1.77	1.67	11	−5.22	0.87	14	0.0006
I/NA (mm)	0.88	0.65	11	−1.52	0.30	14	0.005
I/NB (degrees)	1.23	0.86	12	3.10	1.24	14	NS
I/NB (mm)	0.80	0.43	12	1.20	0.36	14	NS
I/MP (degrees)	0.74	0.93	12	2.23	1.28	14	NS
Vertical skeletal							
SN/MP (degrees)	1.04	0.53	12	−0.57	0.53	14	0.05
PP/MP (degrees)	−2.11	0.51	12	−0.55	0.52	14	0.05
OP/PP (degrees)	−2.51	0.68	11	0.62	0.60	14	0.002
OP/MP (degrees)	0.23	0.57	11	−1.17	0.23	14	NS

Co, condylion; *Po,* pogonion; *Ar,* articulare; *MP,* mandibular plane; *PP,* palatal plane; *OP,* occlusal plane.
*Over a period of treatment (2 years).

nificant finding of the study is the increased maxillary intercanine distance with the headgear, a finding first established in this study.[23,24] This finding, along with the increased spacing among the maxillary anterior teeth, suggests that the headgear has a "lip bumper" effect on the maxillary canines and incisors (and possibly the premolars). The fact that the increase in intercanine distance was larger than that observed with the Fränkel FR may be due to a distal movement (to a wider section of the arch) of the maxillary canines toward neutroclusion in the headgear group. In contrast, the mandibular intercanine distance increased with the FR more than the headgear, albeit that this increase was not statistically and possibly not clinically significant. This effect has been documented with the Fränkel FR[8,25] and "lip bumper" appliances.[26-20] The following clinical implication may be formulated: the increased maxillary intercanine distance and interdental spacing among the anterior maxillary teeth with the headgear suggest that the headgear is effective in the correction of distoclusion combined with anterior crowding. Class II, Division 2 malocclusions fall within this category.

Intermolar distance. The increased maxillary intermolar distance, particularly with the Fränkel FR, is widely reported in the literature.[25,31-34] However, the increments in this distance relate to different mechanisms with the headgear than with the FR. Whereas a passive buccal displacement of the molars presumably occurs with the FR, the headgear exerts a direct transverse force on these teeth. The increase of this distance with the headgear was smaller probably because the inner bow was not "expanded" beyond the outer surface of the molar tube on one side, while inserted in the tube attached to the opposite molar. Further expansion of the arms of the inner bow would lead to additional increases in the maxillary intermolar distance.

A larger increase occurred in the maxillary buccal distance than in the palatal intermolar distance with both appliances (Table II). The difference, however, was greater with the headgear and suggests that a mesiobuccal rotation of the molars occurred during treatment. This occurrence is consistent with the fact that a toe in bend was not incorporated in the inner bow to counteract the mesiobuccal moment generated by the extraoral forces applied at a level labial to the center of resistance of the molars.

Facial changes. Differential growth between the maxilla and the mandible is demonstrated in both appliance groups, albeit that the headgear affected mostly the position of the maxilla, and the FR the position of both jaws. This differential growth, induced by treatment, may be considered an "orthopedic" effect. More definitive conclusions should be drawn when all subjects are included in the analysis, and when coordinate changes are assessed on regional superimpositions on cranial, maxillary, and mandibular basal structures.

The effect of the FR on mandibular position suggested a possible stimulation of growth by this appliance, a tenet held by many proponents of the FR. However, the differences in mandibular length between the treatment groups do not support this hypothesis, unless both the headgear and FR stimulate mandibular growth, a possibility that can be demonstrated only in comparison with untreated controls.

The ability of the headgear, by delivering forces at the level of the first molars only, to affect significantly the forward growth of the maxilla is remarkable. Presumably, "orthopedic" forces were transferred throughout the totality of the maxilla, whereas at the same time the headgear has an "orthodontic" effect on the first molars, and a lip-bumper effect on the maxillary incisors. In this context, in the absence of any other orthodontic movement, the headgear appears to have a cumulative effect on the skeletal discrepancy (ANB) larger than that of the FR.

In the vertical plane, the headgear apparently led to an average backward rotation of the mandible, as the SN/MP angle increased by an average of 1°. This result corroborates the finding of Baumrind et al.,[2] who concluded that this average change may not be clinically significant. Interestingly, however, the angles between mandibular and palatal planes, as well as palatal and occlusal planes decreased in the headgear group, suggesting a possible backward rotation of both maxillary and mandibular planes.

The cephalometric differences observed between the treatment groups must be considered preliminary at this point. Furthermore, the long-term clinical significance of the observed differences between two nonextraction treatment modalities is not yet established, and may be a factor of when treatment is instituted.

Timing of treatment

The nature of the controversy about the timing of early treatment was enunciated in the introduction. Our findings indicate that treatment in late childhood may be as effective as that in midchildhood. To test this hypothesis, the children were grouped on the basis of emergence or nonemergence of the permanent canines, premolars, and second molars. The change from distoclusion to neutroclusion with each appliance was not influenced by the timing of emergence of the second premolars and permanent second molars. Thus, the optimal timing of early treatment of the Class II relationship may be considered in the late childhood period. This period would correspond to the time just before the loss of the primary maxillary second molar, because avoiding the loss of the leeway space by mesial movement of the permanent first molars favors the correction of the distoclusion.

Timing of space management is the other critical issue. The effect on the maxillary arch of either appliance was maintenance or increase of arch length because the maxillary molars were kept from moving mesially into the leeway space or even moved distally. The research protocol did not include any intervention in the mandibular arch where the prevalent factor in space management is the maintenance of the leeway space, more specifically, the space of the primary second molar that contributes the most to the leeway space.[23] The loss of the second primary molars, particularly in the mandibular arch, affects spacing within the dental arch and could potentially determine the timing of early treatment, thus favoring intervention in late childhood. Gianelly[35,36] reported that in 77% of children, maintenance of the primary second molar space is sufficient to align all permanent teeth within the arch. Thus, timing of space management in developing malocclusions may be most critical just before the loss of the primary mandibular second molar, also in late childhood.

The results of our research and that by other investigators[37-39] tend to concur about the value of early treatment in late childhood as the first phase of a one-stage treatment. Treatment in late childhood may be more practical and cost effective, because it reduces the total length of time a child has to be seen by an orthodontist. However, a number of conditions would require or at least favor intervention in early or midchildhood. They include malocclusions with a functional posterior crossbite,[40,41] susceptibility to trauma of the maxillary incisors, and risk of compromising the integrity of the dental arch when the primary molars, particularly second molars, are lost prematurely,[42] or when periodontal health is implicated by severe malalignment of teeth. The impact of early treatment on psychosocial development, including self-perception and self-worth does not appear to warrant early intervention, on the average.[37,38] However, such a relationship must be monitored in the individual child. Susceptibility to trauma of the maxillary incisors and potential psychological distress are both likely related to the severity of the overjet.

Intervention before late childhood may also be indicated when dental development dictates a timing of treatment independent of the requirements of craniofacial growth. A major component of our research project is the interaction of somatic growth with treatment. Detailed discussion of this interaction is not within the scope of this article. However, individual variation may be significant enough that the primary second molars are lost 2 to 3 years before the occurrence of peak height velocity, a developmental event that, in a treatment that presumes to affect growth, could define the success of the correction. Particularly in the case of a severe distoclusion, if treatment is started in midchildhood, a complete dentoalveolar correction, which would include maximal tipping of maxillary and mandibular incisors to an optimal overjet, may not be warranted. The later growth spurt would presumably enhance the differential growth of the basal bones, thus avoiding an undue dentoalveolar (incisal) overcompensation, and the associated profile changes.

The most obvious and potent conclusion from this and other prospective studies is the definition of individual characteristics that may affect both the timing of and response to treatment. The important task of researchers is "discovering and characterizing individual differences."[43]

CONCLUSION

The current analysis of data suggests the following conclusions:

1. Both the headgear and function regulator are effective in correcting the Class II, Division 1 malocclusion of prepubertal children. The common mode of action of these appliances is the possibility to generate differential growth between the jaws. The extent and nature of this effect, as well as other skeletal and occlusal responses differ.
2. On average, the headgear, has a distal effect on the maxilla and first molars, but not the maxillary incisors; the function regulator restrains the growth of the maxilla and results in a retroclination of the maxillary incisors, a more forward position of the mandible and a proclination of the mandibular incisors. The effect of both appliances on mandibular length seems to be, on average, similar.
3. A significant and new finding of the study is the increased maxillary intercanine distance and spacing among the maxillary anterior teeth with headgear treatment. An increased maxillary intermolar distance relates to different mechanisms with the headgear (active force) than with the Fränkel FR (removal of cheek pressure). The larger correction of the overjet with the Fränkel FR occurred probably, and at least partially, because this appliance can exert a distal force on the maxillary incisors. Conceivably, the headgear would provide similar results if combined with a similar force.
4. Treatment in late childhood can be as effective as that in midchildhood and thus more practical, because it reduces early treatment to the first phase of a one stage treatment. Timing of treatment in developing malocclusions may be most critical just before the loss of the primary second molars (considering both treatment of the occlusion and space management). However, a number of conditions would dictate an earlier intervention, and the imperatives of dental development may require a timing of treatment independent of the requirements of craniofacial growth. This potential discrepancy in the individual patient must be incorporated in the analysis of timing and efficacy of early treatment.

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