

ORIGINAL ARTICLE

Treatment effects produced by the Twin-block appliance and the FR-2 appliance of Fränkel compared with an untreated Class II sample

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This retrospective cephalometric study compares the treatment effects produced in 40 patients treated with the Twin-block appliance to those seen in a matched sample of 40 children treated with the FR-2 appliance of Fränkel and to changes undergone in 40 untreated Class II controls from *The University of Michigan Elementary and Secondary School Growth Study*. The average starting ages for the Twin-block, Fränkel, and control groups were 10 years 5 months, 10 years 2 months, and 9 years 11 months, respectively. The T_2 to T_1 observation period was adjusted to an average of 16 months for all groups. Significant decreases in overbite and overjet were observed at the end of treatment in the Twin-block and Fränkel groups. Compared with the untreated subjects, statistically significant increases in mandibular length were observed in both treated groups. The Twin-block patients achieved an additional 3.0 mm of mandibular length, whereas the Fränkel group increased 1.9 mm more than did the controls. No significant restriction of midfacial growth was observed in either functional appliance group relative to controls. A significant increase in lower anterior facial height was evident in both treatment groups. Vertical increase in the Twin-block patients was significantly greater than in the FR-2 group. In general, more extensive dentoalveolar adaptation was observed with the tooth-borne Twin-block appliance than with the more tissue-borne FR-2 of Fränkel. The Twin-block and FR-2 samples both showed significant retroclination and extrusion (eruption) of the maxillary incisors. The Twin-block patients also exhibited distal movement of the upper molars; however, there was no extrusion. Slight lower incisor proclination was noted in both treatment groups, and lower molar extrusion was found to be significantly greater in the Twin-block group compared with the other 2 samples. No horizontal differences were detected in the lower molars among groups. The present study suggests, therefore, that Class II correction with the Twin-block appliance is achieved through normal growth in addition to mandibular skeletal and dentoalveolar changes. Class II correction with the FR-2 is more skeletal in nature, with less dentoalveolar changes noted. (*Am J Orthod Dentofacial Orthop* 1999;116:597-609)

Functional appliance therapy has become an increasingly popular method of correcting Class II malocclusion, with appliances such as the bionator,¹³ the FR-2 of Fränkel,^{4,7} the fixed and removable types of Herbst appliances,⁸⁻¹² and the Jasper Jumper¹³ waxing and waning in popularity during the last 25 years. Another functional appliance system that has shown increased use during the last decade is the Twin-block

appliance. The Twin-block was developed by William J. Clark of Fife, Scotland, for use in the correction of Class II malocclusions characterized in part by mandibular skeletal retrusion.¹⁴⁻¹⁹

Only 2 clinical investigations of the treatment effects of the Twin-block appliance have been published in refereed journals. In contrast to most previous studies of functional appliance therapy, both investigations compared the Twin-block patients to untreated Class II samples. Lund and Sandler²⁰ conducted a prospective clinical trial in which they compared 36 patients treated with the Twin-block with a control sample of 27 Class II patients who were on a waiting list to receive orthodontic treatment. In comparison to the controls, the treated group demonstrated an increase in mandibular length. A difference in maxillary skeletal growth, however, could not be detected between the 2 groups. Lund and Sandler also noted distal movement of the upper molars and lower molar

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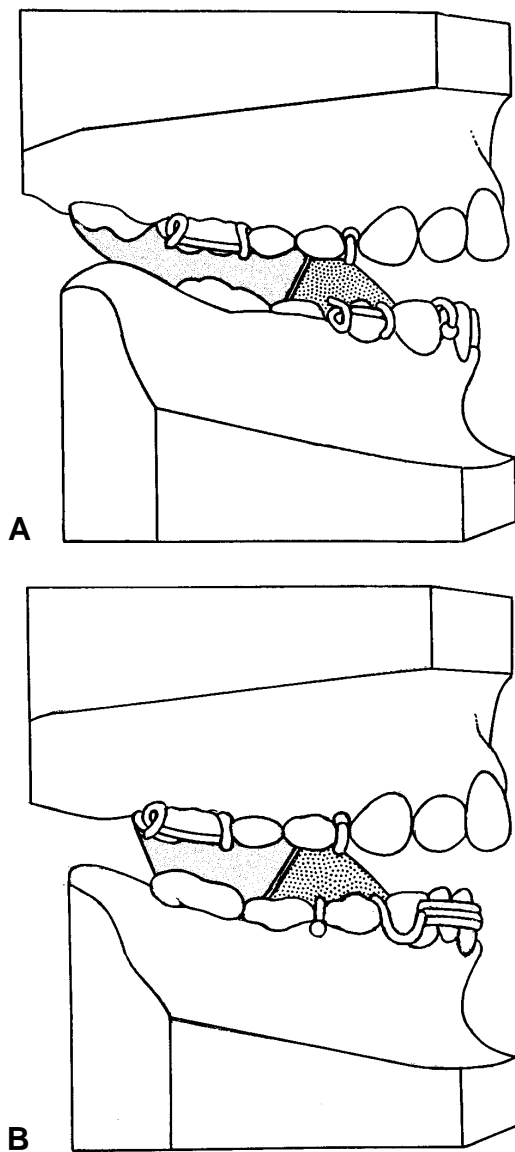


Fig 1. Sagittal view of Twin-block appliance. **A**, Traditional design according to Clark. Note that ball clasps are used to provide anterior retention in both arches. **B**, Modified Twin-block design. Anterior ball clasps are replaced by a labial bow to which clear acrylic has been added, which increases anterior retention of the lower appliance, especially during the period of the transitional dentition.

eruption in an anterior and superior direction in the Twin-block group. In addition, there was a significant amount of tipping of the anterior teeth in both arches in the treated group.

Mills and McCulloch²¹ evaluated 28 consecutively treated patients from a private practice and compared them with a control group of 28 untreated Class II sub-

jects from the *Burlington Growth Study*.²² They noted an increase in mandibular length in the Twin-block group as well as significant increases in both anterior and posterior facial height and a slight inhibition of forward maxillary growth. The upper molars were distalized in the Twin-block group; some proclination of the lower incisors and lingual tipping of the upper incisors were noted as well.

Neither study provides a direct comparison between the Twin-block, primarily a tooth-borne appliance, and one that is primarily tissue-borne. Accordingly, the purpose of the present study is to compare the skeletal and dentoalveolar effects produced by the Twin-block to an appliance that is primarily tissue-borne, the function regulator (FR-2) appliance of Fränkel. The results of both treatments are compared with the normal growth of a matched sample of untreated Class II subjects monitored during a similar time period in order to determine the relative skeletal and dentoalveolar effects produced by these presumably different types of functional appliances.

SUBJECTS AND METHODS

Sample Selection

Twin-block sample. The cephalometric records of 79 patients treated with the Twin-block appliance (Fig 1) were collected from 7 private orthodontic practices as well as from the Graduate Orthodontic Clinic at the University of Michigan. Practitioners were asked to send pretreatment (T_1) and posttreatment (T_2) records of all patients treated with the Twin-block appliance, regardless of treatment results or patient compliance. Orthodontists with patients currently undergoing Twin-block therapy were asked to take posttreatment cephalograms at the completion of Twin-block treatment and forward the records for analysis.

Fifty-three patients from the original 79 were selected for inclusion in the study based primarily on the dates of the radiographs relative to the start and end of treatment (Table I). All patients had a Class II molar relationship at the beginning of the study; their cephalometric records had been obtained within the specified intervals. Thirteen additional patients were eliminated for other reasons: 5 were excluded because of poor film quality, and 8 were eliminated because they had received additional orthodontic treatment or extractions of permanent teeth during the period of Twin-block therapy. The remaining 40 sets of cephalograms were analyzed in the present study. Although successful treatment outcome was not a criterion for inclusion in the study, all patients had a Class I or super-Class I molar relationship at the end of the Twin-block phase of treatment. Hand-wrist radiographs and height/weight data were unavailable on the 2 treated samples.

Table I. Twin-block sample selection

	N
Inclusionary criteria	
Parent sample	79
Pretreatment cephalogram revealing a Class II malocclusion (end to end or worse)	77
Pretreatment cephalogram taken no more than 3 months before the initiation of treatment	64
Posttreatment cephalogram taken within 1 month of the end of treatment	53
Exclusionary criteria	
Poor film quality/unidentifiable landmarks	48
Other orthodontic treatment during Twin-block therapy	43
Extraction of permanent teeth during Twin-block therapy	40
Final sample size	40

Function regulator of Fränkel (FR-2) sample. In order to compare Twin-block therapy with treatment of a primarily tissue-borne functional appliance, the records of 40 patients treated with the function regulator of Fränkel (FR-2) were identified from a larger sample studied previously by McNamara et al,⁷ with additional landmarks added for the present analysis. The inclusionary criteria differed from those described earlier for the Twin-block sample in 2 ways. First, participating clinicians were asked to exclude any patients who were judged to have demonstrated very poor cooperation. Second, a few patients with severe retroclination of the upper incisors were eliminated. As with the control sample, the records of 40 FR-2 patients who fell into the age range of the Twin-block sample were selected for the present analysis.

Control sample. Changes during treatment were compared with the cephalometric records of 40 untreated children from *The University of Michigan Elementary and Secondary School Growth Study (UMGS)*.^{23,24} The *UMGS* archives include annual growth and development data of children (ages 3-18) who were enrolled in the University School, a laboratory school located on the Ann Arbor campus from the mid-1930s through the late 1960s. Forty untreated Class II subjects were selected for the current study based on similarity of ages with the Twin-block sample.

Descriptive statistics for ages and treatment time are presented for the 3 groups in Tables II and III. The Twin-block group consisted of 18 males and 22 females, and the FR-2 sample included 21 males and 19 females. Males and females were equal in number in the untreated Class II sample.

Treatment Protocols

Twin-block. Most of the Twin-block appliances used in this study were of the design originally developed by Clark. This version of the appliance is composed of maxillary and mandibular appliances that fit

Table II. Descriptive statistics: Average starting ages

	N	T_1	T_2
Twin-block	40	10y 5m	11y 9m
FR-2	40	10y 2m	12y 2m
Control	40	9y 11m	11y 10m

Table III. Descriptive statistics: Average treatment/observation time

	N	T_1-T_2 (months)
Twin-block	40	16
FR-2	40	24
Control	40	23

tightly against the teeth, alveolus, and adjacent supporting structures (Figs 2 and 3). Delta clasps¹⁸ were used bilaterally to anchor the maxillary appliance to the first permanent molars; 0.030 inch ball clasps (or arrow clasps) typically were placed in the interproximal areas anteriorly. The precise clasp configuration depended on the type (deciduous or permanent) and number of teeth present at the time of appliance construction. In the lower arch, Clark¹⁸ has recommended the use of a series of ball clasps that lie in the interproximal areas between the canines and lower incisors (Fig 3A). For a few of the appliances used in the study, the design was modified by placing a labial bow anterior to the lower incisors with labial acrylic similar to that of a lower spring retainer as designed by Barrer²⁵ (Fig 3B). In contrast to the fabrication of a spring retainer, however, the positions of the lower incisors were not altered in the work model before appliance construction.

For those patients undergoing Twin-block treatment with mild-to-moderate overjets at the beginning of treatment, the appliances were constructed from bite registrations taken with the incisors in an end-to-end

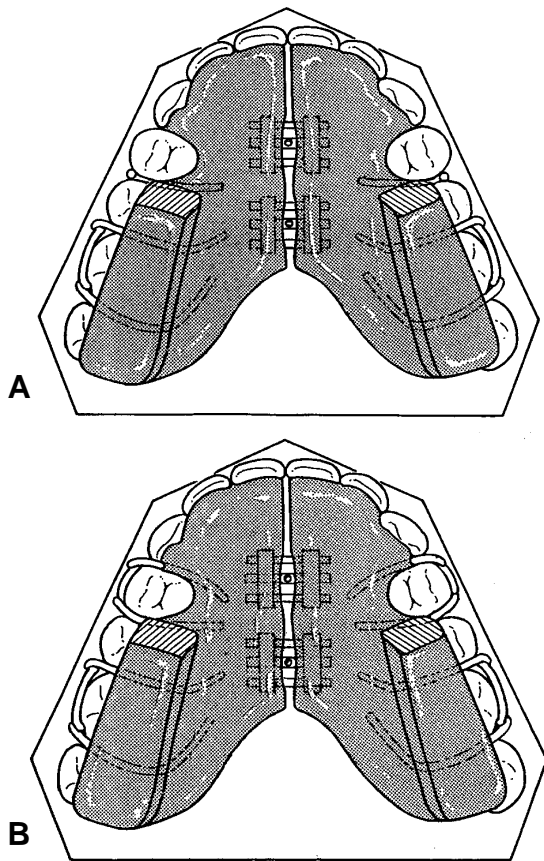


Fig 2. Maxillary occlusal view of Twin-block appliance. Two expansion screws are placed in the midline. Delta clasps are used to secure the appliance to the molars posteriorly, whereas ball clasps (**A**) or occasionally delta clasps (**B**) are used to anchor the plate in the premolar/deciduous molar region.

position. In instances in which the pretreatment overjet exceeded 6 to 7 mm, the bite registration protocol varied. In about half of the large-overjet patients, the bite registration was obtained with the mandible initially postured forward 4 to 6 mm, with the appliance reactivated after a few months so that the incisors ultimately were in an end-to-end position. In the remaining patients with large overjets, the Twin-block appliance was constructed with the incisors in an end-to-end position initially.

Typically the bite registration was taken to allow 5 to 7 mm of vertical opening in the region of the posterior bite blocks. A proposed benefit of the Twin-block appliance is the ability to control vertical development of the molars and premolars through selective removal of acrylic during treatment. In patients with a short lower anterior facial height or an accentuated curve of Spee, the acrylic on the posterior portion of the maxil-

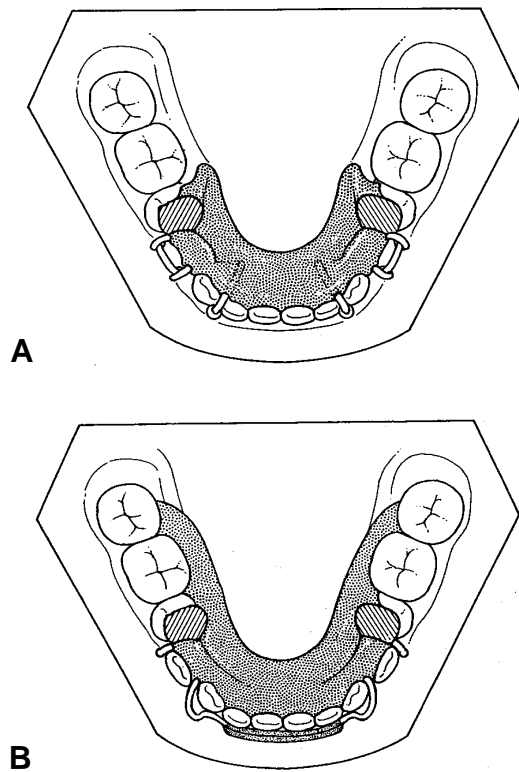


Fig 3. Mandibular occlusal view of Twin-block appliance. **A**, Original design of Clark that incorporates acrylic on the lingual surfaces of the teeth anterior to the first permanent molars. **B**, Modified design in which the lower lingual acrylic extends posteriorly into the permanent molar region. The lower labial bow with clear acrylic covering extends anteriorly to cover the labial surfaces of the lower anterior teeth. In both designs, the bite blocks terminate 2 to 3 mm in front of the lower first molar.

lary bite block was trimmed according to the recommendations of Clark¹⁸ in order to promote eruption of the posterior dentition. All patients involved in the study were asked to wear the appliance 24 hours a day (with the exception of eating and playing certain sports) until the end of treatment. The compliance to these instructions, however, varied among patients.

FR-2 of Fränkel. The FR-2 appliances worn by patients examined here were fabricated according to the principles of Fränkel^{26,27} and McNamara and Hugué.²⁸ The mandible was brought forward in a "step-by-step" manner (3 to 5 mm at each advancement), leaving sufficient vertical opening for adequate occlusal clearance of the crossover wires that extended to the lower lingual shield. Excessive bite opening was avoided. Subsequent reactivations of the appliance were accomplished by cutting the vestibular shields and advancing the lower anterior portion of

the appliance until the incisors were in an end-to-end relationship.²⁸

Cephalometric Analysis

Lateral cephalograms were traced by one investigator (L.R.T.), and then the tracings were verified by another (J.A.M.). Any disparities in landmark position were resolved by mutual agreement. Serial cephalograms were superimposed on the basion-nasion line with registration on the pterygomaxillary fissure.^{29,30} For each patient, 6 fiducial registration points also were identified and transferred from the T_1 to the T_2 radiographs. These points allowed superimposition on stable structures of the cranial base, maxilla, and mandible in order to assess skeletal and dentoalveolar change.³¹ Eighty landmarks plus the 6 fiducial markers were digitized with a customized digitization package. The error of the method has been described previously¹¹ and is within acceptable limits for this type of cephalometric study.

From the digitizations, 53 measurements were generated, including variables from the analyses of McNamara et al,^{7,11,30} Ricketts,²⁹ and Steiner,³² as well as from the Wits appraisal.^{33,34} Horizontal movement of the upper teeth was measured from pterygoid vertical (a line perpendicular to Frankfort horizontal drawn from the most posterosuperior point on the pterygomaxillary fissure), whereas vertical change was measured relative to the palatal plane. Reference lines for determining lower dental movement included the mandibular plane and pogonion perpendicular, a line tangent to pogonion and perpendicular to the mandibular plane.⁷ In addition, changes in the dentition were measured with regional superimpositions based on the fiducial registration points. Reference lines were constructed parallel and perpendicular to Frankfort horizontal at the pterygomaxillary fissure in the maxilla and to the mandibular plane at pogonion in the mandible.

In order to make comparisons, all linear cephalometric measures were converted to a standardized enlargement. For all sample sources for which the enlargement factor of the cephalograms was unknown, a radiographic test object³⁵ was sent. The object consisted of a square piece of 2 mm thick Biocryl with 4 small pieces of lead shot implanted exactly 100 mm apart at each of the 4 corners, plus a fifth shot to assist in orientation. Polyvinyl chloride piping was attached to the center of the sheet in order to allow the object to be clamped between the ear rods. Each clinician was asked to take an exposure of the test object in the same manner in which the cephalogram was taken (same subject to film distance). By measuring the distance

between each of the lead shots on the radiograph, the specific enlargement factor could be calculated. All linear cephalometric measures then were converted to a standardized enlargement of 8.0%.

Statistical Analysis

The main purpose of this study was to conduct between-group comparisons of the various skeletal and dentoalveolar changes occurring during treatment. Because the length of treatment varied among groups, a direct comparison of the cephalometric changes would be difficult to interpret. A patient treated for 24 months, for example, would be expected to grow more than a patient treated for 16 months, even if treated identically. In order to conduct direct and meaningful comparisons, therefore, all cephalometric increments of the untreated controls and the Fränkel patients were adjusted to the time interval of the Twin-block sample, namely 16 months. All statistical analyses were performed with the aid of a commercial statistical package (SYSTAT for Windows, Version 5.0, SYSTAT, Inc).

Descriptive statistics. Means and standard deviations for the 3 groups (Twin-block, FR-2, and control) were calculated for all cephalometric measures at T_1 and T_2 . In addition, mean differences and standard deviations were determined as well as mean differences and standard deviations calculated for the adjusted 16-month interval for the FR-2 and untreated groups.

Inferential statistics. The starting forms of the 3 groups (T_1) were compared with an analysis of variance (ANOVA). Tukey's pairwise comparison tests were used to distinguish which groups were statistically different. Likewise, the changes over the treatment/observation period were compared among the 3 groups using ANOVA and again, differences among groups were distinguished by Tukey's method of multiple comparisons.

RESULTS

Comparison of Starting Forms (T_1)

Skeletal measures. The equivalence of starting form was examined by comparing pretreatment cephalometric values among the three groups (Table IV). In general, craniofacial measures of size, both in the maxilla and in the mandible, tended to be slightly larger in the Twin-block patients than in the FR-2 and control groups. Significant differences were found mostly between the Twin-block and control patients. For example, condylion to ANS and gonion to pogonion were 3.6 mm and 3.2 mm larger, respectively, in the Twin-block group. No significant differences were found in starting form measures of upper and lower

Table IV. Comparison of starting forms

Cephalometric measures	Twin-block (N = 40)		FR-2 (N = 40)		Control (N = 40)		Significance		
	Mean	SD	Mean	SD	Mean	SD	T-C	F-C	T-F
Maxillary skeletal									
SNA (°)	80.8	3.9	80.2	3.0	80.6	2.9	NS	NS	NS
Na perp to pt A (mm)	-1.6	3.0	-1.3	2.3	-0.9	3.1	NS	NS	NS
Co to ANS (mm)	92.4	4.7	89.6	4.9	88.8	4.1	**	NS	*
Co to pt A (mm)	89.3	4.7	87.5	4.6	86.8	3.9	*	NS	NS
Mandibular skeletal									
SNB (°)	75.6	3.4	74.4	3.3	74.8	2.5	NS	NS	NS
Na perp to pog (mm)	-10.1	5.3	-11.1	4.9	-10.8	5.2	NS	NS	NS
Articulare to Gn (mm)	101.4	5.6	98.9	5.3	98.5	4.2	*	NS	NS
Go to pog (mm)	71.7	5.2	69.5	4.5	68.5	3.7	**	NS	NS
Co to Gn (mm)	108.5	5.7	106.9	5.5	106.3	4.1	NS	NS	NS
Maxilla to mandible									
ANB (°)	5.2	1.9	5.8	1.7	5.7	1.8	NS	NS	NS
WITS (mm)	2.1	2.4	2.8	2.2	2.2	2.3	NS	NS	NS
Articulare to PTM (mm)	33.6	3.3	32.6	2.6	31.3	2.6	**	NS	NS
Facial plane angle (°)	84.4	2.9	84.0	2.6	84.1	2.8	NS	NS	NS
Max/md differential (mm)	19.2	3.4	19.4	3.1	19.5	2.5	NS	NS	NS
Vertical									
FH to occl plane (°)	11.2	4.4	11.2	3.5	11.6	3.7	NS	NS	NS
FH to pal plane (°)	-0.5	3.4	-0.2	2.7	-1.3	2.7	NS	NS	NS
FH to mand plane (°)	23.9	5.6	26.9	5.4	27.1	4.3	*	NS	*
Facial axis angle (°)	-0.7	4.2	-3.7	4.5	-2.9	3.1	*	NS	**
Na to ANS (mm)	50.7	3.6	50.8	3.1	49.5	3.4	NS	NS	NS
ANS to Me (mm)	62.4	5.2	62.9	4.9	63.1	4.0	NS	NS	NS
Condylion to Go (mm)	51.6	4.0	50.8	4.2	50.5	3.4	NS	NS	NS
Maxillary dental									
Pt A vertical (mm)	4.3	1.6	4.7	2.0	4.4	1.8	NS	NS	NS
Upper 1 to SN (°)	107.7	9.0	104.9	8.6	103.4	7.2	NS	NS	NS
Upper 6 vertical (mm)	42.0	3.2	41.9	2.9	41.1	2.7	NS	NS	NS
Upper 6 horizontal (mm)	23.9	3.5	23.2	3.1	24.0	3.0	NS	NS	NS
Upper 1 vertical (mm)	49.6	3.9	49.3	3.7	48.6	4.3	NS	NS	NS
Upper 1 horizontal (mm)	55.6	4.8	54.2	4.4	54.4	3.8	NS	NS	NS
Mandibular dental									
Lower 1 to N-B (mm)	3.6	1.2	4.5	2.0	6.1	1.9	***	***	NS
IMPA (°)	97.4	7.3	94.6	7.3	97.3	7.7	NS	NS	NS
FMA (°)	58.7	5.9	58.5	6.3	55.6	7.5	NS	NS	NS
Lower 6 vertical (mm)	32.6	3.4	30.3	2.4	30.5	2.0	**	NS	**
Lower 6 horizontal (mm)	-31.5	2.7	-33.2	2.3	-31.5	2.3	NS	NS	NS
Lower 1 vertical (mm)	42.8	4.2	40.7	4.0	40.5	2.6	NS	NS	NS
Lower 1 horizontal (mm)	-8.1	2.8	-9.2	3.2	-7.4	3.1	NS	NS	NS
Interdental									
Overbite (mm)	5.9	1.9	5.1	2.5	4.1	2.5	**	NS	NS
Overjet (mm)	6.1	2.1	8.0	2.4	5.9	2.0	NS	***	***
Interincisal (°)	123.4	10.3	125.1	10.7	123.7	11.3	NS	NS	NS

T, Twin-block; F, FR-2; C, Control; NS, not significant.

* $P < .05$; ** $P < .01$; *** $P < .001$.

facial heights. The Twin-block patients, however, had a smaller Frankfort-mandibular plane angle than the other groups (23.9° as compared with 26.9° and 27.1°; Table IV).

Dentoalveolar measures. Among group T₁, differences were not statistically significant for any of the maxillary dentoalveolar measures. The position of the

lower incisors, as measured relative to the nasion-point B line, was larger (ie, the lower incisors were more forward) in both functional appliance groups as compared with controls. In addition, the FR-2 patients initially had a larger overjet than the control and Twin-block patients (2.1 mm larger than the controls and 1.9 mm larger than the Twin-block group).

Table V. Differences T₁ to T₂ standardized to 16 months

Cephalometric measures	Twin-block (N = 40)		FR-2 (N = 40)		Control (N = 40)		Significance		
	Mean	SD	Mean	SD	Mean	SD	T-C	F-C	T-F
Maxillary skeletal									
SNA (°)	0.2	1.3	-0.4	0.7	0.3	1.1	NS	NS	NS
Na perp to pt A (mm)	-0.5	1.1	-0.3	0.9	0.3	0.7	**	**	NS
Co to ANS (mm)	1.4	2.1	1.5	1.3	1.4	1.1	NS	NS	NS
Co to pt A (mm)	1.4	1.9	1.4	1.1	1.6	0.8	NS	NS	NS
Mandibular skeletal									
SNB (°)	1.6	1.2	0.7	0.9	0.3	0.7	***	NS	***
Na perp to pog (mm)	1.9	2.0	1.1	1.8	0.5	1.3	**	NS	NS
Articulare to Gn (mm)	6.1	2.4	4.3	2.4	1.8	1.5	***	***	***
Go to Pog (mm)	3.1	2.0	2.3	1.4	2.1	1.0	**	NS	*
Co to Gn (mm)	5.7	2.4	4.6	2.4	2.7	1.5	***	***	**
Maxilla to mandible									
ANB (°)	-1.8	1.2	-1.1	0.9	0.0	0.7	***	***	***
WITS (mm)	-3.7	3.3	-2.2	1.5	0.3	1.2	***	***	*
Articulare to PTM (mm)	0.4	1.2	0.1	0.6	0.3	0.5	NS	NS	NS
Facial plane angle (°)	1.3	1.0	0.8	0.9	0.4	0.7	***	NS	*
Max/md differential (mm)	4.4	1.8	3.2	2.0	1.1	1.1	***	***	***
Vertical									
FH to occl plane (°)	1.9	3.1	0.9	2.1	-0.7	2.0	***	*	NS
FH to pal plane (°)	0.3	1.6	0.5	0.9	0.3	0.8	NS	NS	NS
FH to mand plane (°)	1.8	1.6	-0.2	1.3	-0.3	0.9	**	NS	NS
Facial axis angle (°)	0.6	1.1	0.3	1.0	0.1	0.6	NS	NS	NS
Na to ANS (mm)	1.7	1.9	1.9	0.8	1.5	0.8	NS	NS	NS
ANS to Me (mm)	3.0	1.6	2.1	1.5	1.1	1.1	***	**	*
Condylion to Go (mm)	3.2	2.0	2.9	2.1	1.5	1.3	***	**	NS
Maxillary dental									
Pt A vertical (mm)	0.2	1.6	-0.6	1.2	0.3	0.8	NS	**	*
Upper 1 to SN (°)	-4.3	6.2	-3.3	4.7	0.1	2.0	***	**	NS
Upper 6 vertical (mm)	1.6	1.8	1.8	1.4	2.0	0.9	NS	NS	NS
Upper 6 horizontal (mm)	-0.6	1.9	0.8	1.3	1.5	0.9	***	NS	***
Upper 1 vertical (mm)	2.4	1.8	1.9	1.1	1.4	0.9	**	NS	NS
Upper 1 horizontal (mm)	-0.0	2.7	-0.1	2.0	1.4	1.2	**	**	NS
Mandibular dental									
Lower 1 to N-B (mm)	1.1	1.0	1.0	0.9	0.3	0.5	***	***	NS
IMPA (°)	2.8	5.4	1.1	3.0	0.2	2.4	*	NS	NS
FMIA (°)	-3.0	5.3	-0.9	3.4	0.1	2.5	**	NS	NS
Lower 6 vertical (mm)	2.6	2.2	1.7	1.1	0.7	0.7	***	*	**
Lower 6 horizontal (mm)	0.5	1.1	-0.1	0.8	0.3	0.8	NS	NS	NS
Lower 1 vertical (mm)	2.3	5.4	0.7	1.2	1.1	0.8	NS	NS	NS
Lower 1 horizontal (mm)	1.0	1.8	0.2	1.4	-0.4	0.7	***	*	NS
Interdental									
Overbite (mm)	-2.5	2.0	-1.3	1.5	0.3	0.7	***	***	*
Overjet (mm)	-3.6	2.7	-3.1	1.5	0.3	0.6	***	***	NS
Interincisal (°)	1.7	7.6	2.4	6.1	-0.1	4.1	NS	NS	NS

T, Twin-block; F, FR-2; C, Control; NS, not significant.

*P < .05; **P < .01; ***P < .001.

Analysis of Treatment Effects

As mentioned previously, the average interval between pretreatment and posttreatment cephalograms varied among the 3 groups (16 months in the Twin-block group, 24 months in the FR-2 group, and 23 months in the control group). Statistical comparisons of the adjusted changes for the 3 groups are shown in Tables V and VI.

Maxillary skeletal measures. For the Twin-block and FR-2 patients, differences among maxillary skeletal measures were not significant. Compared with the untreated children, however, there were small but statistically significant decreases in the distance from nasion perpendicular to Point A in both treatment groups. No measures of midfacial length showed sig-

Table VI. Regional superimpositions: Differences T_1 to T_2 standardized to 16 months

Cephalometric measures	Twin-block (N = 40)		FR-2 (N = 40)		Control (N = 40)		Significance		
	Mean	SD	Mean	SD	Mean	SD	T-C	F-C	T-F
Maxilla to cranial base									
Ant maxilla horz (mm)	1.0	1.5	0.8	0.9	1.1	0.8	NS	NS	NS
Ant maxilla vert (mm)	1.2	1.2	1.3	0.7	0.9	0.9	NS	NS	NS
Post maxilla horz (mm)	1.0	1.5	0.9	0.7	1.1	0.8	NS	NS	NS
Post maxilla vert (mm)	1.0	1.1	0.7	0.8	0.8	0.8	NS	NS	NS
Mandible to cranial base									
Ant mandible horz (mm)	3.1	2.0	2.1	1.7	1.2	1.2	***	*	*
Ant mandible vert (mm)	4.9	2.2	3.8	1.9	2.1	1.1	***	***	**
Post mandible horz (mm)	-2.6	1.7	-1.7	1.3	-0.7	0.9	***	**	**
Post mandible vert (mm)	5.5	2.1	4.3	3.0	3.1	1.5	***	*	**
Maxillary dental									
Upper 1 horz (mm)	-0.8	1.6	0.0	1.3	0.2	0.8	*	NS	*
Upper 1 vert (mm)	1.3	1.0	0.5	0.9	0.7	0.7	*	NS	***
Upper 6 horz (mm)	-1.5	1.9	-0.1	1.2	0.3	0.9	***	NS	***
Upper 6 Vert (mm)	0.6	1.4	0.9	1.1	1.2	0.8	NS	NS	NS
Mandibular dental									
Lower 1 horz (mm)	0.7	1.3	0.3	1.1	-0.2	0.7	**	**	NS
Lower 1 vert (mm)	0.5	1.1	0.9	0.9	0.8	0.6	NS	NS	NS
Lower 6 horz (mm)	0.6	1.1	0.3	0.9	0.5	0.8	NS	NS	NS
Lower 6 Vert (mm)	2.9	1.2	2.1	2.2	1.4	1.1	***	NS	**

T, Twin-block; F, FR-2; C, Control; NS, not significant.

* $P < .05$; ** $P < .01$; *** $P < .001$.

nificant changes, although condylion to point A was slightly smaller in both treatment groups in comparison to controls. In addition, superimposition on the cranial base did not reveal significant differences among groups in maxillary skeletal change. Overall, the maxillary skeletal effects of both functional appliance treatments were minimal.

Mandibular skeletal measures. Mean mandibular length as measured from condylion to gnathion increased 2.7 mm in the control group, 4.6 mm in the FR-2 group, and 5.7 mm in the Twin-block group (Table V). These statistically significant differences among groups also are evident in the articulare-gnathion measurement. The SNB angle increased significantly in the Twin-block patients (1.6°) compared both with the control subjects (0.3°) and FR-2 patients (0.7°). There was a significant difference in all 6 measures of mandibular skeletal change between the Twin-block and control samples, whereas FR-2 treatment produced significant differences in 3 of the 6 mandibular skeletal measures as compared with the controls. Overall, Twin-block therapy produced a larger effect on the growth and position of the mandible than did FR-2 treatment.

Maxillomandibular measures. In all 4 measures of maxillomandibular relationships considered, Twin-block treatment produced the largest change; a lack of treatment resulted in the smallest. The ANB angle was

reduced by 1.8° in the Twin-block patients, 1.1° in the FR-2 patients, and remained unchanged in the control patients. Similarly, the Wits appraisal decreased by 3.7 mm in the Twin-block sample and 2.2 mm in the FR-2 sample, whereas there was only a minor change (+0.3 mm) in the untreated sample. These differences were statistically significant (Table V).

Vertical measures. Relative to controls, both functional appliance treatments tended to produce increases in vertical facial measures. These increases were most pronounced in the Twin-block patients. The occlusal plane angle was increased significantly in both the Twin-block patients and FR-2 patients. The change in the mandibular plane angle in the Twin-block patients was significantly greater than in the other groups. Lower anterior facial height increased in all groups, but the change was greatest in the Twin-block sample and least in the control group. No significant differences among groups were observed in upper anterior facial height, facial axis angle, or palatal plane angle.

Maxillary dentoalveolar measures. Relative to the maxilla, the upper incisor moved anteriorly 0.2 mm in the control sample, whereas the Twin-block treatment resulted in a posterior tipping of the upper incisors (-0.8 mm). The relative sagittal position of the upper incisor remained unchanged in the Fränkel group (Table VI).

The upper molars moved anteriorly 0.3 mm in the

control subjects, whereas they moved slightly posteriorly (-0.1 mm) in the FR-2 patients and more posteriorly (-1.5 mm) in the Twin-block patients. Although forward molar movement was restricted in both treatment groups, only that seen in the Twin-block patients was statistically significant from control values. Vertically, neither appliance inhibited upper molar eruption. The upper incisors, on the other hand, were extruded in the Twin-block patients an average of 0.8 mm more than in the FR-2 patients, and 0.6 mm more than in the controls (Table VI).

Mandibular dentoalveolar measures. From the standpoint of a superimposition on the internal structures of the mandible (Table VI), the lower incisor moved forward 0.7 mm during Twin-block treatment and 0.3 mm during FR-2 treatment, whereas the lower incisors uprighted slightly without treatment. Relative to controls, there also was a statistically significant flaring of the lower incisors only in the Twin-block group; the IMPA angle increased by 2.8° in the Twin-block sample, 1.1° in the FR-2 sample, and 0.2° in the controls (Table V).

No significant among-group differences in antero-posterior mandibular molar change were seen. The lower molars, however, erupted 2.9 mm in the Twin-block sample, 2.1 mm in the FR-2 sample, and 1.4 mm in the untreated controls (Table VI). The amount of lower molar extrusion in the Twin-block group was significant in comparison with the FR-2 group and to the untreated Class II controls.

Whereas the change in interincisal angle did not differ significantly among the 3 samples, overbite and overjet decreased significantly in the treatment groups when compared with the control group (Table V). The overbite and overjet were reduced in the Twin-block patients 2.5 mm and 3.6 mm, in the FR-2 patients 1.3 and 3.1 mm, and increased 0.3 mm and 0.3 mm in the controls, respectively.

DISCUSSION

Comparison of Treatment Changes

Maxillary skeletal effects. The results of this study reveal a minimal effect on maxillary skeletal structures in the functional appliance groups. Changes in midfacial length, as measured from condylion to anterior nasal spine and condylion to point A, did not differ among the FR-2, Twin-block, and untreated samples. Although Twin-block and FR-2 treatments did produce small but significant decreases in the nasion perpendicular to point A measurement, the overall interpretation is that neither the Twin-block nor the function regulator produced clinically significant restriction of maxillary growth. This conclusion is in agreement with stud-

ies of other functional appliances^{7,12,36-39} and contradicts the conclusions of other investigators.^{3,8-10,40-50} It should be noted that in the majority of those investigations finding no maxillary skeletal effects, the Fränkel appliance was the appliance evaluated. Furthermore, most of studies reporting a significant restriction of maxillary growth were investigations of the Herbst and activator appliances. Therefore, the lack of maxillary skeletal effects found in the Fränkel sample in the present study is in agreement with most other evaluations of FR-2 treatment. It appears that the Twin-block appliance similarly fails to produce maxillary skeletal restriction.

The design and wear of the appliance also may be a significant factor in the presence of a "headgear effect" in functional appliance therapy. Some of the evidence supporting maxillary growth inhibition includes studies of functional appliances in combination with extraoral force.^{46,48,51} Falck and Fränkel⁵² concluded that maxillary restriction was produced in patients treated with the FR-2 only when the bite advancement was accomplished in one large step. In instances in which the bite was advanced sequentially with a "step-by-step" protocol as used in this study, the so-called "headgear effect" was not observed. Similarly, a significant restriction of midfacial development was not observed in the 2 previous investigations of the Twin-block appliance.^{20,21}

Mandibular skeletal effects. A statistically significant increase in mandibular length compared with the control group was observed both in the Twin-block and Fränkel groups. The additional increase in condylion to gnathion length of 3.0 mm and 1.9 mm, respectively, during a standardized 16-month period can be interpreted as at least a short-term stimulation of mandibular growth. It should be noted, however, that there was a larger standard deviation in the 2 treatment groups than in the untreated sample, indicating that not all patients responded to functional appliance treatment as favorably as the average values indicate. Lund and Sandler²⁰ reported an average increase in the distance from articulare to gnathion of 2.4 mm during a 12-month period of Twin-block treatment. Mills and McCulloch²¹ found a slightly greater difference between treated and untreated Class II groups (4.2 mm). It is interesting to note that the average annualized increase in mandibular length of the control samples used in all 3 studies of the Twin-block appliance were similar (2.0 to 2.7 mm).

This observation of increased mandibular growth after functional appliance treatment is in agreement with the results of a number of investigations involving other functional appliances.^{8,10,44,46,50,52-58} Fränkel

therapy, however, did not produce significant increases in the SNB angle or nasion perpendicular to pogonion measure. The increase in mandibular length, therefore, was not translated in an advancement of the chin point in the FR-2 group. Similar observations were reported in activator and bionator patients by Livieratos and Johnston⁵⁸ and by McNamara et al⁷ in patients treated with the Fränkel appliance. The lack of change in the SNB angle in the FR-2 patients monitored during the current study probably is related to the concomitant increase in lower anterior facial height during treatment. McNamara³⁰ has shown that every millimeter of increased lower anterior facial height camouflages a millimeter of mandibular length increase by causing the chin point to rotate downward and backward.

As mentioned previously, all subjects included in the FR-2 group were studied originally because they followed instructions reasonably well, given that patients judged to have shown poor cooperation (eg, they did not seem to be wearing the appliance) were eliminated from consideration. Patient cooperation was not a criterion for selection in the Twin-block sample. It would appear, therefore, that the Fränkel sample may have been biased, and thus, a comparison of Twin-block and FR-2 treatment might well show greater change in the FR-2 group. The opposite result was observed. For all cephalometric measures of mandibular growth, Twin-block means were greater. With regard to patient compliance, although compliance has not been studied formally with either appliance, it has been suggested by a number of clinicians, including those participating in the present study, that patients may find it easier to wear the Twin-block appliance than other functional appliances. Objective evidence for this claim is not available, however.

Vertical changes. Control of the vertical dimension is one of the proposed benefits of the Twin-block appliance.¹⁸ It is believed that the acrylic bite blocks either can inhibit molar eruption in patients for whom an increase in facial height is undesirable or can be modified to allow posterior dental eruption in situations when increasing facial height is a primary goal of treatment. Indeed, Clark¹⁵ has stressed selective removal of acrylic to allow an increase in the vertical dimension as an important component of Twin-block therapy.

As mentioned previously, some of the participating clinicians chose Class II patients with short anterior facial heights specifically for Twin-block therapy and reported that they trimmed down the posterior acrylic bite blocks during treatment in an attempt to increase the vertical dimension. The significant increases in lower anterior facial height and in the mandibular plane angle observed in the Twin-block sample probably

resulted in part because of this type of acrylic contouring during treatment. It was not possible to distinguish which patients in the present study were treated with attempts to increase the vertical dimension. As the Twin-block appliance, if left unaltered, may produce a "posterior bite-block effect," the average increase in facial height observed in the study could have been a combination of inhibited vertical development in some subjects and enhancement of molar eruption in others. In any event, further investigation comparing these 2 methods of Twin-block therapy is required to make a more definitive conclusion regarding vertical effects of the appliance.

Lower anterior facial height (ANS to menton) and posterior facial height (Co-Go) increased by 1.1 mm and 1.5 mm, respectively, in the control group, and as expected the mandibular plane angle in this group decreased slightly (0.3°) during the study period. These values are consistent with rates of vertical facial growth of untreated individuals reported in other studies.^{23,30} Significant increases were observed in lower anterior and posterior facial heights in the Twin-block group (3.0 mm and 3.2 mm, respectively) and the FR-2 group (2.1 mm and 2.9 mm, respectively). The mandibular plane angle remained relatively unchanged in the Fränkel group, but increased by 1.8° in the Twin-block group, a difference that was statistically significant. These findings are consistent with those of Lund and Sandler²⁰ who reported a 2.6 mm increase in total facial height in the Twin-block patients in comparison with controls. Mills and McCulloch²¹ noted significant increases relative to controls in anterior facial height (3.8 mm) and posterior facial height (2.9 mm) in a Twin-block group. In spite of these increases, the mandibular plane angle closed slightly in the study of Mills and McCulloch.

In several studies, an increase in facial height has been attributed to treatment with the function regulator.^{7,47,59} These findings are supported further by the present data, which showed that lower anterior facial height (ANS to menton) increased 1.0 mm more in the FR-2 patients than in the untreated subjects. This observation, however, contradicts the results published by Righellis³⁶ and Nelson et al,⁵⁹ who found no evidence of increased facial height during treatment with the FR-2 appliance.

Although an increase in lower anterior facial height was observed in the Fränkel patients in this investigation, there was no corresponding increase in the mandibular plane angle. This finding may be interpreted as the result of equal increases in both anterior and posterior vertical facial dimensions. Similar conclusions were reached by Windmiller⁵⁰ and Mahon.⁴⁶

Dentoalveolar Effects

Relative to superimposition on stable structures within the maxilla and mandible, FR-2 therapy generally produced dentoalveolar changes that were not statistically different from those that occur during normal growth (Table VI). The only statistically significant difference was a slightly larger vertical movement of the mandibular molars in the FR-2 patients than in the controls. A lingual tipping of the upper incisors also was noted in the FR-2 group (-3.3° ; Table V). It should be noted that the FR-2 appliance has a labial bow that typically is in light contact with the upper incisors when the patient is wearing the appliance. In contrast, the Twin-block appliance does not have such a wire, and thus less lingual tipping of the upper anterior teeth was anticipated. In fact, significantly greater lingual tipping of the upper incisors (-4.3°) was observed in the Twin-block patients, presumably the result of the contact of the associated lip musculature during Twin-block treatment.

Some proclination of the lower incisors occurred as well, especially in the Twin-block group. In the control group, the lower incisor remained stable (0.2°) relative to the mandibular plane. In contrast, the Twin-block patients tipped anteriorly 2.8° (Table V) and moved forward 0.7 mm relative to superimposition of mandibular structures (Table VI). Lund and Sandler²⁰ reported an even greater proclination of the lower incisors (7.9°) relative to controls, as did Mills and McCulloch (3.8°).²¹

Both previous studies of Twin-block treatment^{20,21} indicate that there is a so-called "headgear effect" on the upper posterior teeth when the Twin-block appliance is worn. A similar observation was made here. In the untreated group, the upper first molars moved downward 1.2 mm and forward 0.3 mm when serial tracings were superimposed on stable internal structures of the maxilla (Table VI). The movement of the upper first molars in the FR-2 group was not statistically different from the controls; however, the upper molars were distalized 1.5 mm in the Twin-block group. Lund and Sandler²⁰ also noted a distal movement of the upper molars of 1.6 mm relative to control values. Further they noted an increased vertical eruption of the upper molars that they said might have been the result of a distal tipping of these teeth. In the current study, however, the vertical eruption of the upper molars was not affected significantly by Twin-block treatment. Mills and McCulloch²¹ also noted a relative distalization of the upper molars during treatment, but they reported what they termed "some significant withholding effect" on the vertical eruption of the upper molars as a result of Twin-block treatment. Interestingly, in the current study, significant differences in the

horizontal and vertical eruption of the maxillary molars (and incisors) were not evident in comparison to controls or to patients treated with the FR-2 appliance of Fränkel.

Mills and McCulloch²¹ stated that the lower molars in their Twin-block group erupted, on average, 4 times as much (2.3 mm as compared with 0.6 mm) in the Twin-block group as in the control group. They also report that the lower molars tended to erupt more mesially. Lund and Sandler²⁰ noted a mean difference of 0.9 mm in lower molar eruption in their Twin-block group, and they reported a substantial amount of forward movement of the lower first molars in the appliance patients (2.4 mm) in comparison with controls (0.1 mm). In the current study, superimposition of serial tracings on the internal structures of the mandible indicates that the forward movement of the lower molars was not different among the 3 groups; however, vertical eruption of the lower molars was greater in both functional appliance groups (Twin-block, 2.9 mm; FR-2, 2.1 mm) in comparison with controls (1.4 mm). Some of the differences in the findings relative to tooth movement may be related to differences in the method of measurement used in these 3 studies.

Skeletal and dental treatment effects often have been ascribed to the design of the specific appliance. In general, all functional appliances fit into 1 of 3 basic models: removable tissue-borne, fixed tooth-borne, and removable tooth-borne. It has been hypothesized that tissue-borne appliances, such as the FR-2, produce less dentoalveolar change than tooth-borne appliances like the bionator, Herbst, and Twin-block.⁶ Some also would state that the bionator and the Twin-block appliance have some tissue-borne components, whereas the stainless steel crown and banded versions of the Herbst appliance do not. The present study reports greater dental changes in the Twin-block group than in the FR-2 group, which were somewhat similar in nature, although less in magnitude, to those observed in studies of the fixed Herbst appliance.^{8,9,44} Based on the findings of longer term studies,^{12,43,48} however, it may be anticipated that some of the dental changes, specifically lower incisor proclination, will rebound after treatment.

Assuming that tissue-borne functional appliances produce less dental change than tooth-borne appliances, it might be expected that the Fränkel appliance therefore would have a greater mandibular skeletal effect than the Twin-block appliance in Class II correction. This investigation, however, does not support this assumption. In fact, the increase in mandibular length was shown to be slightly but significantly greater in the Twin-block sample than in the FR-2 sample.

SUMMARY AND CONCLUSIONS

The pretreatment and posttreatment cephalograms of 40 Class II patients treated with the Twin-block appliance and the records from 40 untreated children in *The University of Michigan Elementary and Secondary School Growth Study* were analyzed. In addition, the records of 40 patients treated with the function regulator of Fränkel were used for comparisons. The average starting ages for the Twin-block, Fränkel, and control groups were, respectively, 10 years 5 months, 10 years 2 months, and 9 years 11 months. All cephalometric values were adjusted to correspond with the interval between films of the Twin-block patients (16 months). The findings of this study may be listed as follows:

1. Significant decreases in overbite and overjet were observed at the end of treatment in the Twin-block and Fränkel groups compared with untreated Class II subjects.
2. Compared with the Class II controls, statistically significant increases in mandibular length were observed in both treated groups; the Twin-block patients achieved an additional 3.0 mm of mandibular length and the FR-2 group an additional 1.9 mm.
3. No significant restriction of maxillary growth was observed in either functional appliance group.
4. Compared with controls, a significant increase in lower anterior facial height was evident in both of the treatment groups. Vertical increase in the Twin-block patients was significantly greater than in the FR-2 group.
5. The FR-2 appliance produced minimal dentoalveolar changes. Lingual tipping of the upper incisors as well as a slight increase in the eruption of the mandibular molar were observed in FR-2 patients in comparison with controls. The Twin-block sample also showed significant retroclination and extrusion (eruption) of the maxillary incisors. In addition, the twin-block patients exhibited distal movement of the upper molars and proclination of the lower incisors. No extrusion of the upper molars was found in either treatment group.

The present study suggests, therefore, that Class II correction can be achieved with either appliance system evaluated here. The FR-2 appliance appears to have primarily a skeletal effect, whereas the Twin-block appliance produces both skeletal and dentoalveolar adaptations, both favorable and unfavorable, at least over the short term. It should be noted, however, that this investigation evaluated treatment effects by way of lateral cephalograms only, and thus transverse and neuromuscular effects of treatment were not evaluated.

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