ORIGINAL ARTICLE

Short-term and long-term treatment outcomes with the FR-3 appliance of Fränkel

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Introduction: The aim of this retrospective controlled investigation was to analyze the short-term and long-term skeletal and dentoalveolar treatment outcomes of Function Regulator 3 (FR-3) therapy. **Methods:** A group of 32 subjects with Class III malocclusion treated with the FR-3 appliance of Fränkel was compared with untreated Class III controls. The first observation was prepubertal, and the long-term observation was postpubertal for all subjects. Treatment consisted of full-time wear of the appliance for about 2.5 years, followed by a retention phase with the same appliance for at least 3 years. The overall observation period was 9 years 2 months. All patients showed a good level of compliance. Active treatment and posttreatment cephalometric changes were evaluated statistically with Mann-Whitney U tests. **Results:** The FR-3 sample showed significant improvements in both maxillary size and position. No significant reduction in the increase of total mandibular length was recorded, but significant closures of both the gonial angle and the mandibular plane angle were found. Intermaxillary and interdental changes produced in the craniofacial skeleton were maintained successfully through the pubertal growth spurt. **Conclusions:** Long-term results of FR-3 therapy in patients with good compliance consisted of significant maxillary modifications and induced changes in mandibular morphology. Long-term appliance wear (more than 5 years) should be emphasized when considering treatment outcomes. (Am J Orthod Dentofacial Orthop 2008;134:513-24)

One of the most perplexing conditions in orthodontics to diagnose and treat is a Class III malocclusion. Paradoxically, the occlusal problem is identified readily, and a negative horizontal overlap of the incisors often prompts parents to seek orthodontic treatment for their child at an early age. The morphologic basis of the malocclusion, however, is the result of a combination of various skeletal and dental abnormalities.

Several treatment strategies for young patients with Class III malocclusion have been aimed at growth modification. These approaches include treatment with the Function Regulator 3 (FR-3) of Fränkel. The effects of the FR-3 have been investigated infrequently, although the introduction of the appliance in clinical orthodontics dates back to 1970 with the classic article by Rolf Fränkel.[1] It was not until the late 1980s that studies on the dentofacial modifications produced by the FR-3 incorporated untreated control groups for statistical comparisons. Kerr and TenHave[2] examined hard-tissue changes in FR-3 patients using tensor analysis. They found no significant increase in maxillary dimensions as a result of treatment nor a significant restraint in mandibular growth, with the effects of the appliance confined to alterations of incisor inclinations. These results are directly in line with changes observed in the case series of Robertson.[3] Only the investigation by Falck[4] in the German literature substantiated Fränkel's claim of a substantial effect on maxillary basal bone.

The first clinical study to use untreated Class III subjects as controls was that of Biren and Erverdi in 1993.[5] The study was prospective, and the subjects were observed for 1 year. Again, the FR-3 appeared to be ineffective for altering Point A anteriorly. Redirection of mandibular growth in the vertical direction caused an increase in total face height and a reduction in overbite, with no effect on the total size of the mandibular corpus. Changes in mandibular incisor inclination contributed to the favorable change in overjet. Ülgen and Fíratlí[6] used a control group of 20 subjects with functional Class III malocclusions (patients who could move the mandible backward and bite with their incisors edge-to-edge). Overjet in the FR-3

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group improved by almost 4 mm during treatment. The main contributions to overjet correction were identified as downward and backward rotation of the mandible and retroclination of the mandibular incisors, the former accompanied by significant decreases in SNB angle and increases in ANB angle. Findings of a similar magnitude and direction were reported by Baik et al[7] in their Korean sample of mild or pseudo-Class III patients treated with the FR-3 appliance. It appears that, in the short-term, the FR-3 appliance produces significant and favorable changes in overjet through adjustment of maxillary and mandibular incisor inclinations along with backward rotation or repositioning of the mandible, usually manifested as an increase in lower facial height. Forward displacement of the maxillary complex has not been demonstrated with any consistency. Changes in the soft-tissue profile are favorable and generally reflect the observed hard-tissue changes.[2,6,8,9]

Only the study of Lestrel and Kerr[10] reported data on the long-term stability of craniofacial changes with FR-3 appliance therapy. Their sample consisted of 14 patients with lateral cephalograms available at an average follow-up period of 2.5 years. The data were analyzed with elliptical Fourier functions and showed little relapse tendency. The conclusions of this morphometric study, however, were based solely on regional maxillary and mandibular superimpositions, and no untreated control group was used for comparison.

Our aim in this investigation was to evaluate the treatment and posttreatment skeletal and dentoalveolar modifications of FR-3 therapy in growing white subjects with Class III malocclusions. More specifically, treatment changes were compared with the growth observed in matched untreated Class III control subjects.

MATERIAL AND METHODS

The original sample consisted of the lateral cephalometric records for 54 patients treated consecutively with the FR-3 appliance[1,8] by Rolf Fränkel at the former Heinrich Braun Regional Hospital in Zwickau, Germany. All subjects had cephalograms available for analysis at 3 observation times: pretreatment (T1), immediately after active appliance therapy (T2), and in the long term (T3). The primary inclusionary criterion was a Class III malocclusion at T1, characterized by an anterior crossbite or an edge-to-edge incisor relationship, with a Wits appraisal of –2 mm or more. Selected subjects were identified as having satisfactory cooperation during treatment and having achieved adequate anterior oral seal at T3.

The exclusionary criteria were as follows.

1. Subjects who were not at stage CS 4 or more mature at T3 (CS 4-CS 6, postpubertal), as assessed with the cervical vertebral maturation method.[11]
2. Cephalograms of inadequate quality for hard-tissue analysis.
3. Auxiliary appliances used either before, during, or after FR-3 therapy, including palatal expanders, removable plates, and fixed mechanotherapy.
4. Congenitally missing permanent teeth or permanent teeth extracted before or during the active treatment interval (T1-T2).

After application of the inclusionary and exclusionary criteria, 32 patients (15 boys, 17 girls) comprised the FR-3 group.

Due to the well-known limited availability of longitudinal records for white subjects with untreated Class III malocclusion, 3 longitudinal control groups (CG) were used, one for each observation interval under investigation: CG T1-T2 (n = 32), CG T2-T3 (n = 32), and CG T1-T3 (n = 26). The subjects for these groups were derived from records at the University of Florence and the University of Michigan. Untreated Class III subjects matched the treated group for Class III malocclusion (as indicated in the inclusionary criteria of the treated group), stages of skeletal maturity at T1 and T3, quality of cephalograms, and absence of congenitally missing teeth (as indicated in the exclusionary criteria of the treated group).

Descriptive statistics of their ages at the time points and duration of observation intervals in the treated group and the control groups are given in Table I.

After an initial break-in period of 5 weeks, during which the appliance was worn on an increasing basis (although it was not worn during the night until the third month), the FR-3 (Fig 1) was worn full-time for an average of 2 to 3 years. This protracted rate of wear follows directly from the primary role of the FR-3 as an orthopedic exercise device. The patients were instructed to perform lip seal exercises to improve the low postural position of the tongue.[12]

Correction of the overjet and overbite relationships and achievement of competent lip seal without muscular strain were the decisive criteria for moving a patient into the retention phase of appliance therapy (T2). The T2-T3 interval included a retention phase of about 3 years, when the appliance was worn afternoons and nights, or nights only.

Lateral cephalograms were hand-traced during one sitting by one investigator (A.S.L.) and then verified for anatomic contour, landmark identification, and tracing superimpositions by a second investigator (J.A.M.). The

Table I. Descriptive statistics for ages and observation intervals in the FR-3 treated group and untreated Class III control groups

Time point or observation interval	*Male*	*Female*	*Sample mean*	*SD*
FR-3 group (n = 32)				
T1	15	17	7 y 0 mo	1 y 4 mo
T2	15	17	9 y 5 mo	1 y 6 mo
T3	15	17	16 y 2 mo	2 y 2 mo
T1-T2	15	17	2 y 5 mo	11 mo
T2-T3	15	17	6 y 9 mo	2 y 1 mo
T1-T3	15	17	9 y 2 mo	2 y 2 mo
CG T1-T2 (n = 32)				
T1	15	17	6 y 10 mo	1 y 0 mo
T2	15	17	9 y 3 mo	1 y 3 mo
T1-T2	15	17	2 y 5 mo	10 mo
CG T2-T3 (n = 32)				
T2	15	17	9 y 9 mo	1 y 7 mo
T3	15	17	16 y 3 mo	1 y 9 mo
T2-T3	15	17	6 y 7 mo	1 y 11 mo
CG T1-T3 (n = 26)				
T1	13	13	7 y 4 mo	1 y 3 mo
T3	13	13	16 y 2 mo	1 y 8 mo
T1-T3	13	13	8 y 11 mo	2 y 3 mo

functional occlusal plane was included on each acetate drawing.

Regional superimpositions in a series were done by hand, as described by Ricketts[13] and McNamara.[14] Maxillary and mandibular fiducial markers were placed on the T2 tracing and then carried through to the T1 and T3 tracings in a series with maxillary and mandibular regional superimpositions, respectively.

Maxillary regional superimpositions characterized movements of the maxillary dentition relative to maxillary basal bone. Maxillae were superimposed along the palatal plane, registering on the bony internal details of the maxilla superior to the incisors and the superior and inferior surfaces of the hard palate. Fiducial markers were placed in the posterior and anterior parts of the maxilla, along the palatal plane.

Mandibular regional superimpositions characterized movements of the mandibular dentition relative to mandibular basal bone. Mandibular superimpositions occurred posteriorly on the outline of the inferior alveolar nerve canal and any tooth germs (before initial root formation) and were registered anteriorly on the anterior contour of the bony chin and the internal structures of the mandibular symphysis. One fiducial marker was placed in the body of the mandible near the gonial angle and another near the center of the symphysis.

A customized cephalometric analysis containing measures chosen from the analyses of Steiner,[15] Jacobson,[16] Ricketts,[17] and McNamara[14] was developed for this study. Thirty-nine variables (25 linear, 14 angular) were generated for each tracing. The data in each cephalogram were entered into a specialized software program (version 2.5, Dentofacial Planner Plus, Toronto, Ontario, Canada). After digitization, all cephalograms were standardized to an enlargement of 8%.

In a preliminary comparison, the FR-3 group was contrasted to both control groups at T1 (CG T1-T2 and CG T1-T3) to evaluate craniofacial starting forms. Then the FR-3 subjects were contrasted with the untreated Class III control groups in the following manner, each comparison attempting to evaluate the following information: (1) FR-3 T1-T2 vs CG T1-T2, the effects of active treatment with the FR-3 (appliance worn full time); (2) FR-3 T2-T3 vs CG T2-T3, posttreatment effects of FR-3 therapy (including a retention phase with part-time wear of the appliance followed by a period with no appliance); and (3) FR-3 T1-T3 vs CG T1-T3, the overall long-term effectiveness of FR-3 therapy.

Statistical analysis

All data generated were analyzed by using both descriptive and inferential statistics. Computations were performed with 1 of 2 Windows-based statistical software packages (Statistical Package for the Social Sciences, SPSS, version 12.0, Chicago, Ill, or SigmaStat, version 3.11, Systat Software, Richmond, Calif). Sample means and standard deviations were calculated for each cephalometric variable in every group for each time point and observation interval. The demographic homogeneity between the treated and untreated groups allowed for direct between-groups comparisons without the need for annualization (Table I).

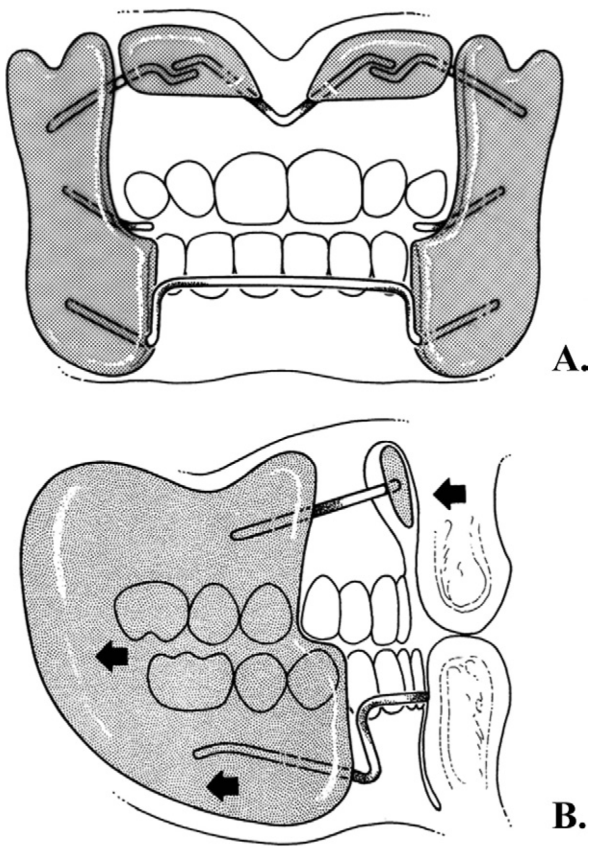

Fig 1. The FR-3 appliance of Fränkel: **A,** frontal view; **B,** lateral view with graphic representation of mode of action (from McNamara and Brudon [unpublished material]).

An exploratory Shapiro-Wilks test for lack of normality was applied to every distribution of a cephalometric variable in both groups. Approximately 10% of all tests were statistically significant ($P < 0.05$), and, therefore, nonparametric inferential statistics were used. Craniofacial starting forms were analyzed with the Kruskal-Wallis test on ranks for independent samples ($P < 0.05$) followed by post-hoc testing with Dunn's method. The Mann-Whitney U test ($P < 0.05$) was used for all treatment-effect comparisons.

Concerning the power of the study, a power of 90% required a sample size of at least 25 subjects in each group. This calculation was based on the average effect of FR-3 therapy on the sagittal intermaxillary relationship (ANB angle) as reported in previous studies with untreated controls. In these studies, average ANB changes were approximately 2° with standard deviations that did not exceed 2°. Because the power of a nonparametric test is approximately 95% that of a parametric test, the required sample size increased slightly (about 5%) to 26.

Eleven subjects from the final FR-3 sample (33 cephalograms) were selected at random. All films were retraced and redigitized, and cephalometric variables were reassessed. Intraclass correlation coefficients were calculated to compare within-subjects variability with between-subjects variability. Correlation coefficients for cephalometric measures were extremely high; with the exception of 3 variables (Pt A-Na perp, Pg-Na perp, and FH-PP), all correlation coefficients were greater than 0.952. These exceptions can be explained by slight variability in construction of the Frankfort horizontal and the identification of Point A.

RESULTS

Craniofacial starting forms were analyzed at T1, contrasting FR-3 subjects with CG T1-T2 and CG T1-T3, respectively. Overall, all groups were well matched with respect to craniofacial morphology at T1. All significant differences between the FR-3 subjects and the untreated controls at T1 were dentoalveolar (Tables II and III); the maxillary incisor was less compensated in the FR-3 subjects compared with the long-term controls, and both short-term and long-term controls had a slightly larger Class III molar discrepancy. None of the anteroposterior or vertical skeletal measures differed significantly between any of the 3 groups at the outset.

Short-term changes with FR-3 therapy (FR-3 vs CG T1-T2), including descriptive and inferential statistics, are summarized in Table IV. Effective midfacial length increased 1.3 mm over the controls ($P < 0.01$); SNA and Pt A-Na perp improved by 1.3° ($P < 0.001$) and 0.8 mm ($P < 0.01$) over the controls, respectively. In the mandible, only the change in chin projection was statistically significant ($P < 0.05$). All intermaxillary measures (ANB, Wits, Mx/Mn diff) were highly statistically significant ($P < 0.001$). In the vertical dimension, there were no significant differences between the FR-3 subjects and the untreated Class III controls.

Improvements in overjet and molar relationship between groups also were highly statistically significant. During active full-time treatment, overjet in the FR-3 subjects improved by 4.4 mm, a 3.9 mm increase over the controls ($P < 0.001$). Although, in absolute terms, the molar relationship improved only 2.1 mm, this was a 3.1 mm increase over the untreated Class III controls ($P < 0.001$). Occlusal correction at the dentoalveolar level was facilitated by significant uprighting of the mandibular dentition.

Posttreatment changes with the FR-3 (FR-3 vs CG T2-T3) are summarized in the descriptive and inferential statistics in Table V. There were continued statistically significant improvements in the ANB angle and

Table II. Comparison of starting forms for the FR-3 subjects and the untreated Class III controls (CG T1-T2) at T1

	FR-3 (n = 32)		CG T1-T2 (n = 32)		FR-3 vs CG T1-T2	
Cephalometric measures	*Mean*	*SD*	*Mean*	*SD*	*Mean difference*	P *value*[†]
Cranial base						
SN-FH (°)	9.5	2.6	9.9	3.2	−0.4	NS
S-N (mm)	66.5	3.5	66.0	3.4	0.5	NS
Ba-S-N (°)	131.4	4.7	128.8	5.4	2.6	NS
Maxillary A-P skeletal						
SNA (°)	78.9	2.6	79.3	4.6	−0.4	NS
Pt A-Na perp (mm)	−1.5	1.9	−0.8	3.2	−0.8	NS
Co-Pt A (mm)	79.5	3.7	78.5	4.4	1.0	NS
Mandibular A-P skeletal						
SNB (°)	78.5	3.4	79.3	4.2	−0.8	NS
Pg-Na perp (mm)	−3.8	4.8	−1.7	6.3	−2.1	NS
Co-Gn (mm)	103.6	5.4	103.5	5.9	0.2	NS
Intermaxillary						
ANB (°)	0.3	2.1	0.0	2.1	0.4	NS
Wits (mm)	−6.0	1.6	−6.1	2.9	0.1	NS
Mx/Mn diff (mm)	24.1	3.0	25.0	4.1	−0.9	NS
Vertical skeletal						
FH-PP (°)	−1.5	3.1	−1.0	3.0	−0.5	NS
FH-FOP (°)	11.6	3.6	10.7	3.9	1.0	NS
FMA (°)	26.2	4.4	26.5	5.6	−0.4	NS
Gonial angle (°)	130.0	4.3	130.4	5.3	−0.4	NS
UFH (mm)	46.1	3.2	46.2	3.1	−0.1	NS
LAFH (mm)	60.2	5.5	58.4	4.1	1.9	NS
UFH:LAFH	0.8	0.1	0.8	0.1	0.0	NS
PFH (mm)	49.9	3.4	48.5	3.8	1.4	NS
PFH:LAFH	0.8	0.1	0.8	0.1	0.0	NS
Maxillary dentoalveolar						
U1-SN (°)	88.9	7.7	94.7	10.2	−5.6	NS
U1-Pt A V (mm)	1.0	1.4	1.7	1.9	−0.8	NS
Mandibular dentoalveolar						
IMPA (°)	85.3	5.1	85.2	7.1	0.1	NS
L1-APg (mm)	3.5	0.9	3.6	2.0	−0.1	NS
Interdental						
Overjet (mm)	−3.0	1.5	−2.4	2.0	−0.5	NS
Overbite (mm)	1.6	2.0	0.6	2.0	1.0	NS
I/I (°)	150.1	10.0	143.7	13.3	6.4	NS
6/6 (mm)	3.3	1.8	4.5	1.9	−1.2	*

FH, Frankfort horizontal; *Pt,* point; *perp,* perpendicular; *A-P,* anteroposterior; *Mx/Mn diff,* maxillomandibular differential; *PP,* palatal plane; *FOP,* functional occlusal plane; *UFH,* upper facial height, as measured from nasion to anterior nasal spine in mm; *LAFH,* lower anterior face height; *PFH,* posterior face height; *U1,* maxillary central incisor; *V,* vertical; *L1,* mandibular central incisor; *I/I,* interincisal angle; *6/6,* molar relationship.
*P <0.05; NS, not significant.
[†]Kruskal-Wallis on ranks, post-hoc Dunn method.

the Wits appraisal. Maxillary length also continued to show significant gains over the controls during this phase (2.2 mm; P <0.05). In the vertical dimension, there were significant closures of the mandibular plane and gonial angles over the controls, 1.4° (P <0.05) and 2.3° (P <0.01), respectively, but without a significant decrease in lower anterior face height.

As for the dentoalveolar changes, U1-SN and U1-Pt A vertical increased by 3.8° and 0.7 mm less in the FR-3 subjects than in the controls (P <0.05), respectively, whereas IMPA increased 3.7° more (P <0.001). Interdental measures in the FR-3 subjects remained relatively stable, with continued worsening of overjet (1.0 mm; P <0.05) and molar relationship (2.1 mm; P <0.001) noted in the untreated controls.

Descriptive and inferential statistics for the long-term effectiveness of FR-3 therapy (FR-3 vs CG T1-T3) (approximately 9 years) are summarized in Table VI. The changes are illustrated in Figure 2.

All measures of intermaxillary change were highly statistically significant. ANB and Wits in-

Table III. Comparison of starting forms for the FR-3 subjects and the untreated Class III controls (CG T1-T3) at T1

	FR-3 (n = 32)		*CG T1-T3 (n = 26)*		*FR-3 vs CG T1-T3*	
Cephalometric measures	*Mean*	*SD*	*Mean*	*SD*	*Mean difference*	P *value*[‡]
Cranial base						
SN-FH (°)	9.5	2.6	9.9	2.8	−0.4	NS
S-N (mm)	66.5	3.5	66.2	3.4	0.2	NS
Ba-S-N (°)	131.4	4.7	128.6	4.9	2.8	NS
Maxillary A-P skeletal						
SNA (°)	78.9	2.6	78.5	3.9	0.4	NS
Pt A-Na perp (mm)	−1.5	1.9	−1.5	2.5	0.0	NS
Co-Pt A (mm)	79.5	3.7	78.6	4.8	1.0	NS
Mandibular A-P skeletal						
SNB (°)	78.5	3.4	78.4	3.7	0.1	NS
Pg-Na perp (mm)	−3.8	4.8	−3.0	6.8	−0.8	NS
Co-Gn (mm)	103.6	5.4	103.8	6.4	−0.2	NS
Intermaxillary						
ANB (°)	0.3	2.1	0.1	2.1	0.2	NS
Wits (mm)	−6.0	1.6	−6.0	2.5	0.0	NS
Mx/Mn diff (mm)	24.1	3.0	25.3	3.4	−1.2	NS
Vertical skeletal						
FH-PP (°)	−1.5	3.1	0.0	3.2	−1.5	NS
FH-FOP (°)	11.6	3.6	11.4	4.2	0.2	NS
FMA (°)	26.2	4.4	26.9	5.9	−0.7	NS
Gonial angle (°)	130.0	4.3	129.7	6.0	0.4	NS
UFH (mm)	46.1	3.2	46.8	2.4	−0.7	NS
LAFH (mm)	60.2	5.5	59.1	4.4	1.1	NS
UFH:LAFH	0.8	0.1	0.8	0.1	0.0	NS
PFH (mm)	49.9	3.4	49.0	4.9	0.9	NS
PFH:LAFH	0.9	0.1	0.9	0.1	0.0	NS
Maxillary dentoalveolar						
U1-SN (°)	88.9	7.7	97.4	9.9	−8.4	†
U1-Pt A V (mm)	1.0	1.4	2.3	2.0	−1.3	*
Mandibular dentoalveolar						
IMPA (°)	85.3	5.1	86.4	7.4	−1.2	NS
L1-APg (mm)	3.5	0.9	3.7	2.3	−0.1	NS
Interdental						
Overjet (mm)	−3.0	1.5	−1.8	1.6	−1.2	*
Overbite (mm)	1.6	2.0	−0.1	2.0	1.6	*
I/I (°)	150.1	10.0	139.4	14.7	10.7	*
6/6 (mm)	3.3	1.8	4.8	1.9	−1.5	†

FH, Frankfort horizontal; *Pt,* point; *perp,* perpendicular; *A-P,* anteroposterior; *Mx/Mn diff,* maxillomandibular differential; *PP,* palatal plane; *FOP,* functional occlusal plane; *UFH,* upper facial height, as measured from nasion to anterior nasal spine in mm; *LAFH,* lower anterior face height; *PFH,* posterior face height; *U1,* maxillary central incisor; *V,* vertical; *L1,* mandibular central incisor; *I/I,* interincisal angle; *6/6,* molar relationship.
*$P < 0.05$; †$P < 0.01$; NS, not significant.
‡Kruskal-Wallis on ranks, post-hoc Dunn method.

creased 2.8° and 4.1 mm, respectively, over the untreated Class III controls, and the maxillomandibular differential improved 4.0 mm over the controls ($P < 0.01$). The long-term improvement in maxillary size (3.6 mm; $P < 0.01$) was associated with a significant, favorable change in mandibular position (1.9°; $P < 0.01$). The gonial angle closed a total of 6.9° from T1 to T3—3.6° over the untreated controls ($P < 0.01$). Compared with the controls, there also was a significant decrease in the mandibular plane angle (2.2°; $P < 0.05$).

Long-term between-groups changes in position and angulation of the dentitions were not significant. Overjet and molar relationship each improved a total of 5 mm in the FR-3 subjects vs the untreated Class III controls ($P < 0.01$).

DISCUSSION

In this study, we attempted to characterize the short-term and long-term hard-tissue treatment outcomes of FR-3 therapy in growing white subjects with Class III malocclusions. Many previous FR-3 studies were limited in their conclusions due to small

Table IV. Comparison of the short-term changes (T1-T2)

	FR-3 (n = 32)		CG T1-T2 (n = 32)		FR-3 vs CG T1-T2	
Cephalometric measures	*Mean*	*SD*	*Mean*	*SD*	*Mean difference*	P *value*§
Cranial base						
Ba-S-N (°)	−0.7	1.5	0.1	1.9	−0.8	
Maxillary A-P skeletal						
SNA (°)	0.7	1.1	−0.5	1.4	1.3	‡
Pt A-Na perp (mm)	−0.1	0.8	−0.9	1.2	0.8	†
Co-Pt A (mm)	4.0	1.8	2.7	1.8	1.3	†
Mandibular A-P skeletal						
SNB (°)	−0.3	1.6	0.4	1.3	−0.8	
Pg-Na perp (mm)	−0.7	2.1	1.0	2.2	−1.6	*
Co-Gn (mm)	5.4	2.7	6.5	3.0	−1.0	
Intermaxillary						
ANB (°)	1.1	1.3	−1.0	1.3	2.1	‡
Wits (mm)	2.1	1.9	−0.6	2.2	2.7	‡
Mx/Mn diff (mm)	1.4	1.7	3.8	2.2	−2.4	‡
Vertical skeletal						
FH-PP (°)	0.5	1.3	0.6	2.0	−0.1	
FMA (°)	−0.2	1.7	0.2	1.7	−0.4	
Gonial angle (°)	−2.3	2.0	−1.2	2.6	−1.1	
LAFH (mm)	3.1	2.1	2.9	2.6	0.2	
PFH (mm)	2.4	1.7	2.8	1.5	−0.4	
Maxillary dentoalveolar						
U1-SN (°)	12.0	9.2	8.3	7.5	3.7	
U1-Pt A V (mm)	2.4	1.2	2.1	1.5	0.3	
U6-FH (°)	0.2	5.1	−0.4	3.1	0.7	
U1H (mm)	2.4	1.5	2.4	1.5	0.0	
U1V (mm)	0.7	1.4	0.9	1.4	−0.3	
U6H (mm)	1.8	1.5	1.4	1.2	0.4	
U6V (mm)	2.2	1.3	1.5	1.3	0.7	
Mandibular dentoalveolar						
IMPA (°)	−2.1	5.4	−0.7	4.2	−1.4	
L1-APg (mm)	−1.6	1.1	0.7	1.1	−2.2	‡
L6-MP (°)	−2.0	3.7	−0.2	3.5	−1.8	*
L1H (mm)	−1.1	1.0	−0.1	1.0	−1.1	‡
L1V (mm)	2.3	1.2	2.1	1.6	0.2	
L6H (mm)	0.3	1.0	0.6	0.9	−0.2	
L6V (mm)	1.6	1.4	1.6	1.8	−0.1	
Interdental						
Overjet (mm)	4.4	1.5	0.6	1.7	3.9	‡
Overbite (mm)	0.9	2.3	0.5	1.7	0.3	
I/I (°)	−9.0	12.2	−7.5	8.3	−1.5	
6/6 (mm)	−2.1	1.7	0.9	1.5	−3.1	‡

FH, Frankfort horizontal; *Pt,* point; *perp,* perpendicular; *A-P,* anteroposterior; *Mx/Mn diff,* maxillomandibular differential; *PP,* palatal plane; *LAFH,* lower anterior face height; *PFH,* posterior face height; *U1,* maxillary central incisor; *U6,* maxillary first molar; *V,* vertical; *H,* horizontal; *MP,* mandibular plane; *L1,* mandibular central incisor; *L6,* mandibular first molar; *I/I,* interincisal angle; *6/6,* molar relationship.
*$P < 0.05$; †$P < 0.01$; ‡$P < 0.001$.
§Mann-Whitney U test.

sample sizes, less than ideal control subjects, or lack of a suitable follow-up observation interval. To date, there is no controlled evaluation of the long-term cephalometric changes with FR-3 therapy in the literature. Important facets of this study are the following.

1. All FR-3 subjects were treated by Rolf Fränkel, using his specified appliance design, fabrication, and treatment protocol. As such, observed treatment outcomes in this study can be considered a gold standard with this appliance, even more so because all patients in the treated sample had high levels of compliance.
2. The patients wore the appliance for a long time during childhood and adolescence. An average period of 2.5 years of full-time wear of the appliance was followed by an additional average

Table V. Comparison of the changes after active treatment (T2-T3)

	FR-3 (n = 32)		*CG T2-T3 (n = 32)*		*FR-3 vs CG T2-T3*	
Cephalometric measures	*Mean*	*SD*	*Mean*	*SD*	*Mean difference*	P *value*[§]
Cranial base						
Ba-S-N (°)	−0.2	1.8	−0.5	2.7	0.4	
Maxillary A-P skeletal						
SNA (°)	1.6	1.8	1.7	2.1	−0.1	
Pt A-Na perp (mm)	0.9	1.8	0.8	1.9	0.1	
Co-Pt A (mm)	8.9	3.4	6.7	3.9	2.2	*
Mandibular A-P skeletal						
SNB (°)	2.1	1.8	3.2	2.4	−1.1	
Pg-Na perp (mm)	4.5	3.3	5.7	4.1	−1.1	
Co-Gn (mm)	16.4	5.6	15.8	5.8	0.6	
Intermaxillary						
ANB (°)	−0.5	1.4	−1.4	1.4	0.9	*
Wits (mm)	0.5	2.9	−1.8	2.5	2.2	†
Mx/Mn diff (mm)	7.6	3.2	9.1	3.0	−1.5	
Vertical skeletal						
FH-PP (°)	1.3	1.9	0.6	1.7	0.7	
FMA (°)	−2.9	2.5	−1.6	2.9	−1.4	*
Gonial angle (°)	−4.6	3.1	−2.3	3.4	−2.3	†
LAFH (mm)	6.7	3.0	7.8	3.6	−1.1	
PFH (mm)	10.6	4.0	9.5	3.5	1.1	
Maxillary dentoalveolar						
U1-SN (°)	1.5	5.7	5.3	5.7	−3.8	*
U1-Pt A V (mm)	1.3	1.7	2.0	1.7	−0.7	*
U6-FH (°)	3.9	3.4	4.6	4.3	−0.7	
U1H (mm)	2.0	1.9	2.6	1.8	−0.6	
U1V (mm)	2.1	1.8	2.1	1.6	0.0	
U6H (mm)	3.6	2.3	3.4	1.9	0.1	
U6V (mm)	4.6	1.6	4.1	1.4	0.5	
Mandibular dentoalveolar						
IMPA (°)	2.5	3.9	−1.2	4.9	3.7	†
L1-APg (mm)	−0.1	1.4	0.9	1.3	−1.0	†
L6-MP (°)	0.5	4.1	−1.7	4.0	2.2	
L1H (mm)	−0.3	1.4	−0.5	1.6	0.2	
L1V (mm)	4.3	2.1	4.4	2.4	−0.2	
L6H (mm)	1.7	2.7	2.1	1.7	−0.3	
L6V (mm)	4.2	1.9	4.4	2.7	−0.2	
Interdental						
Overjet (mm)	0.1	1.2	−0.9	2.2	1.0	*
Overbite (mm)	−0.1	1.5	−0.4	2.0	0.3	
I/I (°)	−0.5	7.6	−1.8	8.9	1.3	
6/6 (mm)	0.6	1.7	2.7	2.2	−2.1	‡

FH, Frankfort horizontal; *Pt,* point; *perp,* perpendicular; *A-P,* anteroposterior; *Mx/Mn diff,* maxillomandibular differential; *PP,* palatal plane; *LAFH,* lower anterior face height; *PFH,* posterior face height; *U1,* maxillary central incisor; *U6,* maxillary first molar; *V,* vertical; *H,* horizontal; *MP,* mandibular plane; *L1,* mandibular central incisor; *L6*, mandibular first molar; *I/I,* interincisal angle; *6/6,* molar relationship.
*$P < 0.05$; †$P < 0.01$; ‡$P < 0.001$.
§Mann-Whitney U test.

of 3 years of part-time wear. The FR-3 subjects in this study were followed for a total average of 6 years 5 months after full-time appliance wear, for an overall observation period of 9 years 2 months.

3. The FR-3 subjects were compared with matched untreated controls with Class III malocclusions.
4. The treated and control groups had no statistically significant differences for race, sex distribution, mean ages at observation times, average lengths of observation intervals, and skeletal morphology. This between-groups similarity allowed for a direct comparison of treatment changes without annualization.

Table VI. Comparison of the long-term changes (T1-T3)

Cephalometric measures	FR-3 (n = 32) Mean	FR-3 (n = 32) SD	CG T1-T3 (n = 26) Mean	CG T1-T3 (n = 26) SD	FR-3 vs CG T1-T3 Mean difference	P value§
Cranial base						
Ba-S-N (°)	−0.9	2.3	−1.4	2.5	0.5	
Maxillary A-P skeletal						
SNA (°)	2.3	2.1	1.5	2.6	0.9	
Pt A-Na perp (mm)	0.8	2.0	−0.1	2.9	1.0	
Co-Pt A (mm)	12.9	3.4	9.3	4.9	3.6	†
Mandibular A-P skeletal						
SNB (°)	1.8	2.7	3.7	2.7	−1.9	†
Pg-Na perp (mm)	3.9	3.8	6.0	5.6	−2.1	
Co-Gn (mm)	21.9	5.5	22.3	7.7	−0.4	
Intermaxillary						
ANB (°)	0.6	2.0	−2.2	2.2	2.8	‡
Wits (mm)	2.5	2.9	−2.5	4.1	5.0	‡
Mx/Mn diff (mm)	9.0	3.5	13.0	5.0	−4.0	†
Vertical skeletal						
FH-PP (°)	1.9	2.3	1.2	2.9	0.7	
FMA (°)	−3.2	3.4	−0.9	4.0	2.2	*
Gonial angle (°)	−6.9	3.9	−3.3	4.0	−3.6	†
LAFH (mm)	9.8	3.5	11.4	4.4	−1.6	
PFH (mm)	13.0	4.3	12.3	5.3	0.7	
Maxillary dentoalveolar						
U1-SN (°)	13.5	8.7	10.5	9.4	3.0	
U1-Pt A V (mm)	3.6	1.9	3.6	2.1	0.1	
U6-FH (°)	4.2	5.7	4.2	4.0	0.0	
U1H (mm)	4.4	2.0	4.5	2.0	−0.1	
U1V (mm)	2.7	1.5	3.5	1.8	−0.8	
U6H (mm)	5.4	2.4	4.9	2.2	0.5	
U6V (mm)	6.8	1.8	5.7	1.6	1.0	
Mandibular dentoalveolar						
IMPA (°)	0.4	6.3	−3.0	5.2	3.4	
L1-APg (mm)	−1.7	1.6	1.4	1.4	−3.1	†
L6-MP (°)	−1.5	4.8	−2.3	4.9	0.9	
L1H (mm)	−1.5	1.8	−0.7	1.6	−0.8	
L1V (mm)	6.6	2.3	7.0	3.4	−0.4	
L6H (mm)	2.1	3.0	2.7	1.7	−0.6	
L6V (mm)	5.7	1.9	6.1	2.7	−0.4	
Interdental						
Overjet (mm)	4.5	1.5	−0.5	2.5	5.0	‡
Overbite (mm)	0.8	2.5	0.5	1.8	0.3	
I/I (°)	−9.5	11.2	−5.3	10.9	−4.2	
6/6 (mm)	−1.6	1.8	3.4	2.7	−5.0	‡

FH, Frankfort horizontal; *Pt,* point; *perp,* perpendicular; *A-P,* anteroposterior; *Mx/Mn diff,* maxillomandibular differential; *PP,* palatal plane; *LAFH,* lower anterior face height; *PFH,* posterior face height; *U1,* maxillary central incisor; *U6,* maxillary first molar; *V,* vertical; *H,* horizontal; *MP,* mandibular plane; *L1,* mandibular central incisor; *L6*, mandibular first molar; *I/I,* interincisal angle; *6/6,* molar relationship.
$*P < 0.05$; $^{\dagger}P < 0.01$; $^{\ddagger}P < 0.001$.
§Mann-Whitney U test.

5. All subjects were prepubertal at T1 and postpubertal at T3.

In the short term, the response of the craniofacial complex to treatment with the FR-3 appliance included significant favorable changes in the maxilla. The large improvements seen in maxillary size and position have not been reported by previous investigators, with the exception of Fränkel[1] and Falck.[4] Our results documented a 4.0-mm gain in effective midfacial length of the FR-3 subjects from T1 to T2, 1.3 mm more than in the untreated Class III controls (CG T1-T2). Moreover, because this improvement in midfacial length was accompanied by improvement in maxillary position, the claims by Fränkel[1] that the FR-3 stimulates not only

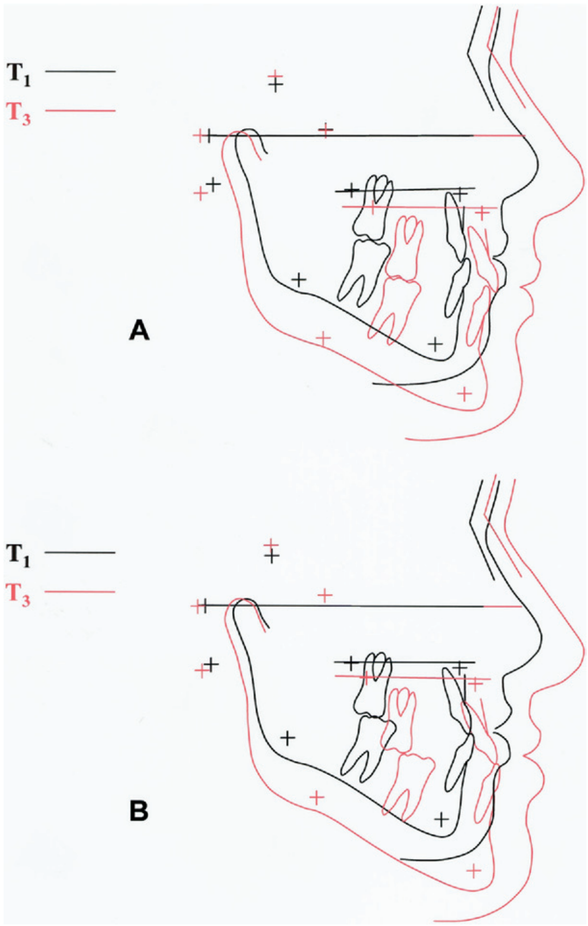

Fig 2. Average superimpositions of changes over the T1-T3 observation interval for: **A,** FR-3 subjects and **B,** untreated Class III controls (CG T1-T3).

alveolar basal development, but also the translative posteroanterior growth of the maxilla appears to be supported. As Enlow[18] pointed out, "a bone grows into the space being created as the whole bone is displaced by amounts determined by the extent of surrounding soft tissue enlargement." In Class III patients with deficient maxillary growth, the buccal shields and the lip pads of the FR-3 are intended to create space for the forward displacement of the maxilla as a prerequisite for bone deposition on the posterior border of the maxillary tuberosity.[1,18]

In general, studies that failed to detect significant maxillary changes analyzed subjects with average ages greater than 7 years at the start of FR-3 therapy. This observation reinforces the notion that an orthopedic effect on the maxilla is possible in Class III subjects, but this effect is more pronounced if treatment begins at an early developmental phase (late deciduous dentition, early mixed dentition, or CS 1 in skeletal maturation).[11,19-21] Fränkel and Fränkel[22] also stressed the favorable influence of the lip pads on the circumoral capsule at this young age because of the creation of adequate space for the sagittal and vertical eruption of the maxillary incisors.

As for the short-term changes in mandibular skeletal relationships, only the position of the mandible showed significant improvement (Pg-Na perp). The magnitude of the change in sagittal mandibular position in this study, however, was less than recorded previously.[2,7,9] Sagittal intermaxillary changes were significant in this study and ranged from an improvement of 2.1° for the ANB angle to 2.7 mm for the Wits appraisal. Baik et al[7] observed the most dramatic improvement in the ANB angle over the shortest period of time (2.3° in 1.3 years). Contrary to most other reports, there were no significant short-term findings in any measures of vertical change.[2,5-7,9]

With regard to dentoalveolar findings, Kerr and TenHave[2] reported significant protrusion of the maxillary incisors with treatment; the changes we observed were not statistically significant. Occlusal correction at the dentoalveolar level was facilitated by significant uprighting of the mandibular dentition. Retroclination of the mandibular incisors has been demonstrated consistently in previous studies.[2,5-7] In most instances, however, retroclination was greater than in this sample and, in 1 study, by as much as 3°.[7] This point stresses the importance of proper appliance fabrication techniques; the lower labial wire of the FR-3 should fit tightly across the labial surfaces of the incisors and canines at the height of the papillae. The low position of the wire is important to prevent lingual tipping of these teeth and to restrict the anterior growth of the mandible.[20]

The main criterion by which success in the treatment of Class III malocclusion is judged is the ability to correct an anterior crossbite. With the exception of Kalavritinos et al,[9] who recorded a mere 0.8 mm of absolute improvement in the overjet of their FR-3 subjects, the average potential overjet correction seems to be about 3 to 5 mm, an amount typically more than adequate to correct most mild-to-moderate Class III patients. Moreover, 11 FR-3 subjects in our study experienced overjet corrections greater than 5 mm, including the 4 who began treatment with a negative overjet larger than –5 mm. Overjet was not overcorrected in this sample; average positive overjet at T2 was 1.4 mm.

During the posttreatment interval, statistically significant differences between treated and control subjects were due primarily to continued worsening of the apical base relationship and progressive dentoalveolar compensations in the untreated Class III controls. Thus, in contrast to many studies of protraction facemask therapy that include a posttreatment period, the return to an inherent Class III skeletal growth pattern after full-time appliance wear was not a striking feature of this FR-3 sample.[23-26] The mandible in the FR-3 subjects continued to outgrow the maxilla in the sagittal plane by a ratio of 1.8:1, or 7.6 mm. These growth increments are much less than the 2.4:1 ratio in the Class III controls (CG T2-T3) over the same interval but are slightly more than the typical 1.5:1 ratio reported for normal subjects with well-balanced faces.[27] Effective midfacial length also continued to show significant gains during this period.

During the retention phase of appliance therapy, closure of the mandibular plane and gonial angles became statistically significant. This strong tendency to maintain vertical facial proportions through remodeling has not been documented previously in the FR-3 literature; in fact, it contradicts the findings of most investigators, who reported trends of increased vertical measures during active treatment.[6-8]

Continued favorable changes are not entirely unexpected, considering Fränkel's retention protocol. The FR-3 is worn afternoons and evenings during the retention phase, which covered about the first half of the posttreatment period in this study (approximately 3 years).

Over the long term, all measures of intermaxillary change remained highly significant statistically. For each jaw independently, it appears that a long-term improvement in effective midfacial length was associated with a favorable change in mandibular position. These data do not support the possibility that the FR-3 can induce long-term inhibition of mandibular growth.

Another significant long-term finding was a mandibular shape change in the form of closure at the gonial angle, a modification that was noted by Fränkel and Fränkel.[22] According to Lavergne and Gasson,[28] anterior morphogenetic rotation of the mandible is a biologic process that attempts to dissipate excessive mandibular growth relative to the maxilla. Significant closure of the gonial angle also was observed in the untreated Class III controls (2.3° from T2 to T3, and 3.2° from T1 to T3). However, closure of the gonial angle in the FR-3 subjects was about twice as much as in the untreated controls over each observation interval, for a total reduction of 6.9° from T1 to T3. This morphologic change was effective in reducing the mandibular plane angle, but it was not effective in inducing a significant reduction in the increases of total mandibular length (Co-Gn).

The occlusal correction achieved during the T1-T2 interval withstood growth increments through the pubertal peak in mandibular growth. Overjet and molar relationship each improved by 5 mm in the FR-3 subjects vs the untreated Class III controls. The final average overjet in the FR-3 subjects was 1.5 mm, compared with –2.2 mm in the controls; overjet in the controls did not worsen as much as expected because of continued dentoalveolar compensations in this group. Furthermore, whereas the molar relationship in the untreated controls went from bad to worse by an average of 3.4 mm, turning these subjects into full-cusp Class III patients, the Class I molar relationship established in the FR-3 subjects during the active phase of appliance therapy was maintained.

These long-term findings deserve to be compared with the outcomes of the most common treatment alternative for Class III subjects showing a component of maxillary retrusion—the facemask (FM). Data on the long-term effects of the FM combined with rapid maxillary expansion (RME) became available recently.[26] The comparison is allowed because both our FR-3 sample and the RME/FM sample of Westwood et al[26] used untreated Class III controls and analyzed a posttreatment observation interval beyond puberty. In spite of similar improvements in maxillary sagittal position, overjet, and molar relationship, the FR-3 appliance produced a greater favorable change in mean maxillary dimension (Co-A improved 3.6 mm over the controls in the FR-3 sample, and 1.6 mm over the controls in the RME/FM sample). Both RME/FM therapy followed by fixed appliances and FR-3 therapy induced significant, favorable mandibular positional changes. On the other hand, FR-3 therapy did not induce the significant reduction in mandibular length of RME/FM therapy. These outcomes should be interpreted also in light of 2 additional aspects. First, the RME/FM study by Westwood et al[26] described the average effectiveness of the examined protocol regardless of patients' compliance, whereas we reported the effects of the FR-3 appliance in good cooperators. Second, the average duration of wear of the orthopedic appliance was only 10 months for the RME/FM sample, and it was more than 5 years for our FR-3 sample (about 2.5 years of active full-time appliance wear followed by at least 3 years of part-time wear). Long treatment durations for FR-3 therapy must be weighed against the high demand for efficiency expressed by contemporary orthodontics, particularly because of the exacting technical requirements of the FR-3 in terms of impression taking, appliance fabrication, and clinical management.

CONCLUSIONS

The purpose of this retrospective controlled investigation was to characterize the short-term and long-term skeletal and dentoalveolar treatment outcomes of

FR-3 therapy in a group of white subjects with Class III malocclusion. All were treated by the same clinician (Rolf Fränkel). Treatment consisted of full-time wear of the appliance for just under 2.5 years, followed by a retention phase with the same appliance for at least 3 years. All patients had a high level of compliance. These subjects were matched with untreated Class III controls.

The following craniofacial modifications were seen over the 9-year, 2-month observation interval.

1. Full-time wear of the FR-3 appliance induced significant improvements in both maxillary size and position. Increases in effective midfacial length continued into the posttreatment phase and led to an overall increase in midfacial length over the untreated controls of about 3.5 mm.
2. No significant long-term inhibition of mandibular growth was recorded. However, a significant mandibular shape change was observed in the form of closure at the gonial angle and associated closure of the mandibular plane angle.
3. Intermaxillary and interdental changes in the craniofacial skeleton were maintained successfully through the pubertal growth spurt.

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