

# Long-term treatment effects of the FR-2 appliance of Fränkel

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**Introduction:** The objective of this study was to evaluate the long-term effectiveness in a group treated with the FR-2 appliance of Fränkel compared with an untreated Class II control group. **Methods:** The sample consisted of 30 patients (17 boys, 13 girls) treated exclusively with the FR-2 by Rolf Fränkel. The mean age at the start of treatment was 8 years (T1), with a posttreatment cephalogram (T2) taken 10 years later. The control group included 20 subjects (11 boys, 9 girls) with untreated Class II malocclusion. Their mean ages at T1 and T2, and the mean times of observation, matched the treatment group closely. Lateral cephalograms were analyzed with a specific tracing regimen at both T1 and T2 in both groups. The Student *t* test was used to compare changes between the groups. **Results:** The FR-2 group maintained stable correction of the initial Class II malocclusion over the evaluation period. Significant mandibular and intermaxillary changes and dentoalveolar changes were noted in the treated group, with a 3-mm long-term increase in mandibular length compared with the untreated Class II controls. **Conclusions:** This study suggests that correction of a Class II malocclusion with the FR-2 appliance maintains favorable results over the long term with both skeletal and dentoalveolar changes. (Am J Orthod Dentofacial Orthop 2009;135:570.e1-570.e6)

Patients with a Class II malocclusion are common in orthodontic practice (about one-third of all patients), with various combinations of dental and skeletal factors contributing to the malocclusion.<sup>1</sup> One treatment modality available for their treatment is the function regulator (FR-2) appliance of Fränkel. Rolf Fränkel developed this appliance nearly 50 years ago as an orthopedic exercise device designed to reprogram the neuromuscular system of the orofacial complex. The FR-2 is used to eliminate functional disorders that can interfere with normal skeletal and dental development by targeting poor postural behavior of the orofacial musculature and inadequate space conditions in the oral cavity.<sup>2</sup> With the FR-2, correction of Class II

malocclusion is achieved by advancing the mandible with muscular training.<sup>2,3</sup>

Much research has been conducted to evaluate the effectiveness of the FR-2 appliance. It consistently has been shown to correct a Class II malocclusion, but the nature of its effect has been debated widely. Some controversial claims in various studies include that the FR-2 does not produce a significant skeletal change,<sup>4-9</sup> it significantly restricts maxillary growth,<sup>10-12</sup> and it primarily induces a significant increase in mandibular length.<sup>10,13-19</sup> Few investigations, however, have followed the stability of this treatment protocol over a long term.<sup>20,21</sup> Our aim in this study was to analyze the long-term effects of FR-2 appliance therapy compared with an untreated control group (Class II sample), focusing specifically on changes that might contribute positively to the correction of Class II malocclusion.

## MATERIAL AND METHODS

The treatment sample (FR-2 group) consisted of 30 patients, 29 treated by Rolf Fränkel and 1 treated by his daughter, Christine Fränkel. The occlusal features of these patients at the first observation (T1) were excessive overjet and full-cusp Class II molar relationship.

The FR-2 appliance was used according to the following protocol: full-time wear (with a gradual increase in wearing time) for 2 to 2.5 years, an initial retention phase of 1.5 to 2 years during which the FR-2 was worn in the afternoon and at night, and a second retention phase of 1.5 years with the FR-2 worn only at night.

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**Table I.** Demographics of observation times

Group	T1 age (y)		T2 age (y)		T2-T1 (y)	
	Mean	SD	Mean	SD	Mean	SD
FR-2 (17 boys, 13 girls)	8.1	1.3	18.0	3.4	9.9	3.4
Class II (11 boys, 9 girls)	8.5	1.2	18.2	3.7	9.7	3.8

All patients were treated exclusively with the FR-2 appliance; no fixed appliances were used. The final observation (T2) was at least 3 years postretention.

The mean age at T1 of the FR-2 group was 8.1 years, with the T2 cephalogram taken on average 9.9 years later (Table I). The untreated group included 20 subjects with Class II malocclusion. These subjects had excessive overjet and full-cusp Class II molar relationship (matching the initial characteristics of the FR-2 group). The cephalograms of the untreated patients were obtained from the University of Michigan Elementary and Secondary School Growth Study and the Denver Growth Study. The mean start of observation for the untreated Class II group was 8.5 years, and the mean time of observation was 9.7 years (Table I). Significant effort went into matching the control sample to the treatment sample as closely as possible with respect to sex distribution (for the impact that this variable might have on head size), age at T1, duration of observation, and skeletal maturity (measured with the cervical vertebral maturation method<sup>22</sup>) at both times. The subjects in both groups had a prepubertal stage of skeletal development at T1 (CS1 or CS2) and a postpubertal stage of skeletal development at T2 (CS5 or CS6).

Both lateral cephalograms of each patient or untreated subject were hand traced at 1 sitting in the same way. The cephalograms were traced by 1 investigator (D.C.F.); landmark location and the accuracy of the anatomic outlines were verified by a second (J.A.M.). The functional occlusal plane was included on each tracing. A customized digitization regimen (version 2.5, Dentofacial Planner, Toronto, Ontario, Canada) that included 78 landmarks and 4 fiducial markers was created and used for the cephalometric evaluation. This program allowed analysis of cephalometric data and superimpositions between serial cephalograms to meet the needs of this study.

Regional superimpositions were done by hand, as described by Ricketts<sup>23</sup> and McNamara.<sup>24</sup> Cranial base superimpositions showed changes in maxillary and mandibular skeletal positions. Films were oriented along the basion-nasion line and registered at the most posterosuperior aspect of the pterygomaxillary fissure, with the contour of the skull immediately posterior to

the foramen magnum used to verify the accuracy of the superimposition.

Maxillary regional superimpositions identified movements of the maxillary dentition relative to the maxillary basal bone. The maxilla was superimposed along the palatal plane by registering on bony internal details of the maxilla superior to the incisors and the superior and inferior surfaces of the hard palate. Mandibular regional superimpositions characterized movements of the mandibular dentition relative to the mandibular basal bone. Mandibular superimpositions were made posteriorly on the outline of the inferior alveolar nerve canal and any tooth germs (before root formation), and anteriorly on the anterior contour of the bony chin and the internal structures of the mandibular symphysis.

Lateral cephalograms for each patient at T1 and T2 were digitized, and a custom cephalometric analysis derived from the analyses of Steiner,<sup>25</sup> Jacobson,<sup>26</sup> Ricketts,<sup>23</sup> and McNamara was used.<sup>24</sup> Thirty-three variables were generated for each tracing. After digitization, all linear measurements were standardized to an enlargement of 8%.

### Statistical analysis

Means and standard deviations were calculated for age, duration of treatment, and changes between T1 and T2 of all cephalometric measures for the 2 groups. The Student *t* test was used for significant differences between the means of the cephalometric measures of the starting forms of the 2 groups. An equivalent test was run to compare average changes from T1 to T2 to analyze differences between the 2 groups. The data were analyzed with a statistical software package (version 12.0, SPSS, Chicago, Ill). Statistical significance was tested at  $P < 0.05$ ,  $P < 0.01$ , and  $P < 0.001$ .

Due to sample size and standard deviation of examined cephalometric variables, the power of the study exceeded 0.85. Method error for the cephalometric data derived from the analysis described above was reported in a previous study.<sup>16</sup>

### RESULTS

Descriptive data and statistical comparisons for starting forms and cephalometric changes in the 2 groups from T1 to T2 are given in Tables II and III, respectively. All patients in the FR-2 group finished with Class I occlusion and reasonable facial balance.

The starting forms of the 2 groups were similar (Table II). The Wits analysis value was significantly larger in the Class II group compared with the FR-2 group, and

**Table II.** Comparison of starting forms

Cephalometric measurement	FR-2 n = 30		Class II n = 20		Significance FR-2–Class II
	Mean	SD	Mean	SD	
Cranial base					
Ba-S-N (°)	134.0	3.8	132.9	4.3	NS
Maxillary A-P skeletal					
SNA (°)	80.1	2.7	80.4	3.6	NS
Pt A-Na perp (mm)	-0.3	2.3	0.3	2.6	NS
Co-Pt A (mm)	84.8	3.7	84.7	4.1	NS
Mandibular A-P skeletal					
SNB (°)	73.9	2.3	75.6	3.4	NS
Pg-Na perp (mm)	-9.4	3.7	-7.2	4.4	NS
Co-Gn (mm)	100.9	4.0	102.6	4.7	NS
Intermaxillary					
ANB (°)	6.2	1.9	5.2	1.9	NS
Wits (mm)	3.5	2.3	5.2	2.0	*
Mx/mn diff (mm)	16.1	2.9	18.1	2.6	NS
Vertical skeletal					
FH-PP (°)	-2.4	2.6	-2.2	3.9	NS
FMA (°)	24.2	4.0	23.9	4.4	NS
Gonial angle (°)	128.0	5.0	125.6	6.6	NS
LAFH (mm)	60.1	4.5	60.1	4.8	NS
PFH (mm)	49.8	3.0	50.4	4.2	NS
Interdental					
Overjet (mm)	7.1	3.9	5.6	2.5	NS
Overbite (mm)	3.9	2.8	3.1	3.5	NS
I/I (°)	129.0	7.4	127.2	9.6	NS
6/6 (mm)	-2.4	1.1	-1.6	1.8	NS
Maxillary					
dentoalveolar					
U1-SN (°)	103.7	8.5	103.2	8.4	NS
U1-Pt A vert (mm)	3.9	1.9	3.6	1.6	NS
Mandibular					
dentoalveolar					
IMPA (°)	93.8	4.7	96.7	6.6	NS
L1-APg (mm)	-0.8	0.9	0.7	1.6	*

A-P, Anteroposterior; perp, perpendicular; Mx/mn diff, maxillomandibular differential; vert, vertical, I/I, interincisal angle.

\*P < 0.01; NS, not significant.

L1-APg was significantly smaller in the FR-2 group compared with the untreated Class II group.

From T1 to T2 (Figs 1 and 2), the FR-2 group had a significant reduction of about 1.5 mm in Point A, as measured from nasion perpendicular, when compared with the control group (Table III). There was a net statistically significant increase (3 mm) in mandibular length (Co-Gn) when comparing the FR-2 group to the Class II control group. SNB angle increased significantly in the FR-2 group compared with the Class II control group. The values for ANB angle and the Wits appraisal also were significantly decreased in the FR-2 group compared with both controls. A significant clockwise rota-

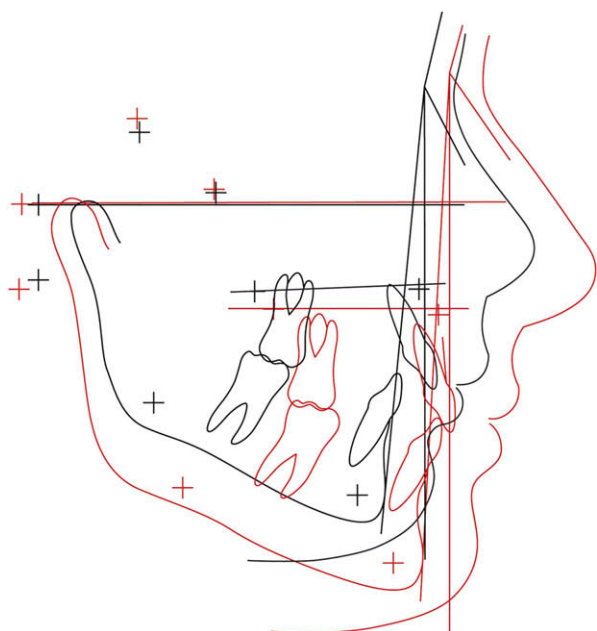
**Table III.** Comparison of changes during observation (approximately 10 years, that including active treatment, retention, and at least 3 years postretention)

Cephalometric measurement	FR-2 n = 30		Class II n = 20		Significance FR-2–Class II
	Mean	SD	Mean	SD	
Cranial base					
Ba-S-N (°)	-1.2	2.7	-0.3	4.4	NS
Maxillary A-P skeletal					
SNA (°)	0.0	1.7	0.7	2.1	NS
Pt A-Na perp (mm)	-1.6	1.4	0.1	1.5	†
Co-Pt A (mm)	10.2	3.4	10.4	3.7	NS
Mandibular A-P skeletal					
SNB (°)	3.5	1.7	1.8	2.1	†
Pg-Na perp (mm)	2.5	3.6	3.0	3.1	NS
Co-Gn (mm)	20.6	4.9	17.6	4.5	*
Intermaxillary					
ANB (°)	-3.5	1.2	-1.3	1.7	‡
Wits (mm)	-3.1	2.4	1.8	2.5	‡
Mx/Mn diff (mm)	10.4	2.6	7.8	2.8	NS
Vertical skeletal					
FH-PP (°)	2.6	2.2	0.7	1.6	†
FMA (°)	-2.1	2.8	-2.8	2.5	NS
Gonial angle (°)	-5.0	3.8	-5.6	3.7	NS
LAFH (mm)	8.6	3.7	7.4	3.2	NS
PFH (mm)	13.3	4.0	12.1	4.1	NS
Interdental					
Overjet (mm)	-4.1	3.8	0.5	2.1	‡
Overbite (mm)	-0.7	2.6	2.2	2.8	**
I/I (°)	5.4	8.6	5.2	9.7	NS
6/6 (mm)	4.7	1.5	0.7	1.8	‡
Maxillary					
dentoalveolar					
U1-SN (°)	-4.8	8.3	-1.7	6.9	*
U1-Pt A vert (mm)	0.0	1.9	1.5	2.1	*
U6-FH (°)	5.7	3.0	6.6	3.8	NS
U1H (mm)	0.3	2.2	0.8	3.1	NS
U1 V (mm)	4.4	2.6	4.5	2.2	NS
U6H (mm)	2.9	1.8	2.1	2.7	NS
U6 V (mm)	2.9	1.5	2.5	1.9	NS
Mandibular					
dentoalveolar					
IMPA (°)	0.8	3.9	-2.4	5.5	NS
L1-APg (mm)	2.7	1.3	0.1	1.5	‡
L6-MP (°)	-0.3	3.3	-2.8	5.3	NS
L1H (mm)	1.5	1.7	0.8	1.9	NS
L1 V (mm)	5.0	2.9	5.2	2.3	NS
L6H (mm)	4.4	1.5	3.5	2.8	NS
L6 V (mm)	6.0	2.5	4.8	2.2	NS

A-P, Anteroposterior; perp, perpendicular; Mx/mn diff, maxillomandibular differential; vert, vertical, I/I, interincisal angle; H, horizontal movement; V, vertical movement.

\*P < 0.05; †P < 0.01; ‡P < 0.001.

tion of the palatal plane was found in the FR-2 group. The mandibular plane angle decreased in both groups by about 2° to 3°, with no difference between the groups.



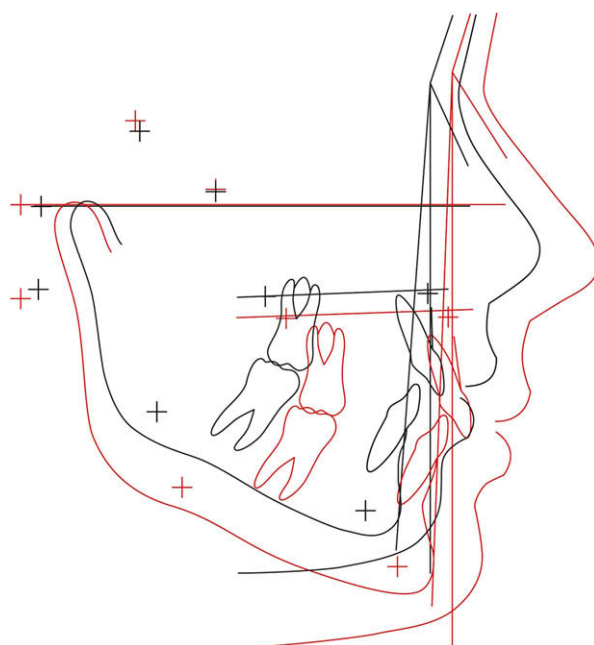
**Fig 1.** Average dentoskeletal configuration of the FR-2 group at T1 (black line) and T2 (red line).

Overjet and overbite were reduced significantly in the FR-2 group when compared with the controls. The molar relationship change in the FR-2 group was significantly different than in the control group, with a significant improvement of molar relationship in the treated group. The variables U1 to SN and Point A vertical decreased significantly in the FR-2 group compared with untreated controls, indicating significant palatal inclination of the maxillary incisors in the treated group. L1-A-Pg increased significantly in the FR-2 group compared with the controls, signifying proclination of the mandibular incisors in the treated group.

## DISCUSSION

We compared the long-term treatment effects in a group treated with the FR-2 appliance with a group with untreated Class II malocclusion. The important features of this study were the following.

1. All FR-2 subjects were treated by Rolf and Christine Fränkel, using Rolf Fränkel's specified appliance design and treatment protocol; thus, the observed treatment outcomes can be considered the gold standard with this appliance.
2. The FR-2 treated subjects were followed for an average of 6 years 9 months beyond the active phase of appliance therapy and for at least 3 years after the end of the retention periods, for an average overall observation of 9 years 11 months.



**Fig 2.** Average dentoskeletal configuration of the untreated Class II group at T1 (black line) and T2 (red line).

3. The 2 groups had no statistically significant differences as to race, sex distribution, mean ages at observation times, and average lengths of observation times.
4. All subjects were prepubertal (CS1 or CS2) at T1 and postpubertal (CS5 or CS6) at T2.<sup>22</sup>

The forward growth of the maxilla in the FR-2 group was less than that of the untreated Class II group. The decrease in Point A to nasion perpendicular was statistically significant, whereas the changes in SNA and Co-Point A were not. Creekmore and Radney,<sup>10</sup> Nielsen,<sup>11</sup> and Rushforth et al<sup>12</sup> found that the FR-2 had a significant restraining effect on the maxilla. Many other studies found that the FR-2 had only a minimal effect on the maxilla.<sup>7,14,15,17,19,21</sup>

The effects of the FR-2 on mandibular length have been examined in many previous studies. Many investigators reported minimal changes in mandibular length,<sup>4,5,9</sup> whereas others reported significant increases.<sup>10,13,15,17-21</sup> This study showed a significant increase in the SNB angle of 1.7° in the treated group compared with the Class II group. The results also showed a statistically significant change in mandibular length in the FR-2 group that was 3 mm greater than in the Class II untreated group. These findings confirmed the previous FR-2 data of Perillo et al.<sup>21</sup>

Faltin et al<sup>27</sup> found a 5.1-mm increase in mandibular length in patients treated at puberty with the bionator

who were examined 8 years 4 months after functional jaw orthopedics and compared with untreated Class II controls. On the other hand, in the same study, the amount of long-term increase in mandibular length over the controls in patients treated at a prepubertal stage with the bionator was less than 2 mm. Because some FR-2 patients in our study might have received active treatment with the functional appliance before puberty and some at puberty, the average amount of supplementary growth of the mandible in this study was similar to the value derived by averaging both prepubertal and pubertal groups in the study by Faltin et al.<sup>27</sup> The role of timing of treatment on the mandibular effects of FR-2 therapy has been shown clearly in previous studies, with therapy at puberty exhibiting significantly greater results than prepubertal use of the FR-2 appliance.<sup>14,18</sup>

The greatest skeletal effects of the FR-2 appliance seem to emerge when the overall sagittal relationship of the maxilla to the mandible was compared. The mean ANB angle and Wits appraisal values were decreased significantly in the FR-2 group compared with the untreated Class II group. The ANB angle decreased by more than 2°, and the Wits value decreased by nearly 5 mm; both differences were statistically significant (Table III).

Several studies showed increases in lower anterior facial height immediately after FR-2 treatment.<sup>10,14,28</sup> In our study, there were no statistically differences among the 2 groups in mandibular plane angle, gonial angle, lower anterior facial height, and posterior facial height. The only difference in vertical change was a slight clockwise rotation of the palatal plane in the FR-2 group compared with the Class II untreated group (2.6° vs 0.7°).

As for the dentoalveolar results, the axial inclination of the maxillary incisors was changed significantly in the FR-2 group compared with the untreated Class II group. The angle U1-SN showed greater palatal inclination of nearly 3° in the FR-2 group compared with the untreated Class II group. There was no change in the distance from U1 to Point A vertical in the FR-2 group over the evaluation period, whereas the Class II control increased by 1.4 mm. These findings agree with what predominantly is reported in the literature.<sup>4,10,14,16,28</sup> Fränkel and Fränkel<sup>2</sup> contended that the effects of the maxillary labial wire of the FR-2 do not tip the maxillary incisors beyond the normal values for axial inclination. However, our results demonstrate that the axial inclination of the maxillary incisors is affected, and that they can tip lingually beyond the normal values with FR-2 treatment.

Rolf Fränkel maintained that the FR-2 could not actively procline the mandibular incisors because the

lingual pad of the FR-2 does not actually contact the incisors.<sup>29</sup> Many reports have disagreed with this claim and have shown significant proclination of the mandibular incisors after treatment with the FR-2.<sup>6,9,10,14,28</sup> Our findings are not conclusive in this regard. L1-APg increased significantly in the FR-2 group (2.7 mm) compared with the untreated Class II (0 mm) group. The mean IMPA in the treated group increased 0.8 mm, compared with a decrease of 2.5 mm in the untreated Class II group (although this comparison was nonsignificant). In a Class II Division 1 malocclusion, the lower lip often is trapped below the maxillary incisors and can cause retroclination of the mandibular incisors. The lower labial pads of the FR-2 rest in the mentolabial sulcus, which elevates the lower lip and allows for normal contact with the upper lip. Fränkel<sup>3</sup> indicated that the lower labial pads, along with appropriate lip-seal exercises, can act as a reprogramming device for the mentalis and circumoral musculature and allow for the establishment of a proper oral seal. These changes in muscle pattern and lip posture might account for the slight proclination of the mandibular incisors.

Both overjet and overbite decreased significantly in the FR-2 group. Overjet decreased by an average of 4.6 mm and overbite by 2.9 mm, when compared with untreated Class II group. There also was a significant difference in the relationship of the maxillary and mandibular first molars. In the treated group, the improvement in molar relationship was 4.7 mm compared with 0.7 mm for the untreated Class II group.

This study illustrates that both skeletal and dentoalveolar treatment effects of the FR-2 are important for stable correction of a Class II malocclusion. The FR-2 can maintain significant improvements in intermaxillary position long after active treatment and at least 3 years postretention. These results, along with those of Falck<sup>20</sup> and Perillo et al,<sup>21</sup> show that skeletal changes from the FR-2 appliance remain in the long term. The average correction in overjet is about 4.5 mm, and the average correction in molar relationship is about 4 mm. These occlusal modifications, sustained mainly by a long-term increase in mandibular length, allow for stable correction of Class II malocclusion with the FR-2 appliance in the hands of an expert clinician, when properly fabricated and managed clinically.

## CONCLUSIONS

This study showed the following.

1. These results refer to successfully treated patients; therefore, they represent a gold standard for the FR-2 appliance.

2. The FR-2 appliance, over a long period, has a minor restraining effect on the position of the maxilla and a significant enhancing effect on mandibular length and sagittal position.
3. The FR-2 has its greatest long-term effects on anteroposterior intermaxillary measurements, as shown by the ANB angle and the Wits appraisal, as well as by significant improvements in overjet (4.5 mm) and molar relationship (4 mm).
4. Treatment with the FR-2 has no discernible effects on the skeletal vertical dimension.
5. FR-2 treatment results in significant lingual tipping of the maxillary incisors and, to a lesser degree, proclination of the mandibular incisors.

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