Treatment Effects Produced by Fränkel Appliance in Patients with Class II, Division 1 Malocclusion*

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Abstract: The purpose of this investigation was to evaluate the dentoalveolar and skeletal cephalometric changes produced by the Fränkel appliance in individuals with a Class II, division 1 malocclusion. Lateral cephalograms of 44 patients of both sexes were divided in two groups of 22 each. The control group was comprised of untreated Class II children with an initial mean age of eight years and seven months who were followed without treatment for a period of 13 months. The Fränkel group had an initial mean age of nine years and was treated for a mean period of 17 months. Lateral cephalometric headfilms of each patient were obtained at the beginning and end of treatment. The Fränkel appliance produced no significant changes in maxillary growth during the evaluation period, while a statistically significant increase in mandibular length was observed. The maxillomandibular relationship improved mostly because of an increase in mandibular length. In addition, there were no statistically significant differences in the craniofacial growth direction between the Fränkel and the control group, both showing a slight downward rotation of the palatal plane. The Fränkel appliance produced a labial tipping of the lower incisors and a lingual inclination of the upper incisors as well as a significant increase in mandibular posterior dentoalveolar height. It was concluded that the main effects of the Fränkel appliance during this time period were mostly dentoalveolar with a smaller but significant skeletal mandibular effect. (Angle Orthod 2002;72:418–425.)

Key Words: Functional Regulator appliance; Class II, division 1 malocclusion; Functional orthopedics

INTRODUCTION

The Class II, division 1 malocclusion has been called the most frequent treatment problem in the orthodontic practice. The solution can involve the use of functional or fixed orthodontic appliances, or both.1 Fixed appliances usually require intermaxillary Class II elastics, extraoral traction, or both, to generate a force for correction of the Class II malocclusion. McNamara2 claimed that the most frequent skeletal problem in Class II patients is mandibular retrognathia. This suggests that an appliance with a demonstrated ability to stimulate clinically significant mandibular growth would be an important part of the clinician’s armamentarium. Moreover, functional appliances alter a Class II relationship through the transmission of muscular forces to the dentition and alveolus by positioning the mandible anterior to its usual position.

Among contemporary functional appliances, one of the most popular is the function regulator (FR-2) of Fränkel.3–6 The FR-2 features projecting vestibular shields that expand the orofacial capsule and cause an anterior functional shift of the mandible. According to Fränkel,3,5 this bodily translation takes place through a modification of the immature postural pattern of the muscles of mastication. Thus, the functional approach to orofacial orthopedics is concerned not only with skeletal disorders, but also with aberrant muscular function. Fränkel3 has argued that the function regulator is an exercise device and that its mode of action is based on medical orthopedic principles that consider exercise and muscle training as important factors in the normal development of skeletal tissues.

Activator/Bionator therapy has been shown to restrict
maxillary development. Controversy exists concerning the effect of the functional regulator upon the maxilla. Most studies of FR-2 therapy indicate that there is no appreciable effect on the position of the maxilla; however, Ghaafari et al noted that the function regulator restrains the growth of the maxilla.

Histologic studies reported by Stöckli and Willert, Petrovic et al, and McNamara on laboratory animals have consistently shown a significant increase in cellular activity when the mandible is hyperpropulsed. Until recently, few human studies have examined whether the FR-2 can cause an increase in mandibular growth that would not have occurred without treatment. Righellis and Perillo et al found that mandibular growth can be increased during Fränkel therapy, but others have been unable to detect such an increase. On the other hand, McNamara et al found a greater increase in mandibular length in patients in the circumpubertal growth period as opposed to younger individuals. The purpose of this research was to cephalometrically evaluate the possible effects of Fränkel’s Functional Regulator (FR-2) appliance on the skeletal and dental components of patients presenting with Class II, division 1 malocclusion, using untreated patients with similar malocclusions as a control sample.

MATERIALS AND METHODS

Sample Selection

Control sample. The control sample was obtained from the files of the Orthodontic Department Longitudinal growth study at the Bauru Dental School of the University of São Paulo, and was comprised of 22 subjects (11 boys and 11 girls) with Class II, division 1 malocclusions and an initial mean age of eight years and seven months. This sample had no previous orthodontic treatment and was observed for a period of 13 months.

Functional Regulator of Fränkel (FR-2) sample. This group was comprised of 22 school children (11 boys and 11 girls) with Class II, division 1 malocclusions.
11 girls) with an initial mean age of nine years and was treated at the orthodontic graduate program at Bauru Dental School, University of São Paulo. All patients presented with Class II, division 1 malocclusion with at least an end-to-end Class II molar relationship, minimal or no crowding and were treated for a mean period of 17 months (Table 1). Patients were instructed to wear the appliances four hours a day in the first week, eight hours a day in the second week, 12 hours a day in the third week, and 24 hours a day thereafter (with the exception of eating and playing certain sports) until the end of treatment. These 22 cases were a subsample of a larger parent sample of 50 cases. They represented the best results obtained in terms of occlusal relationship and compliance in wearing the appliance. The FR-2 appliances worn by patients were fabricated according to the principles of McNamara and Huge.29 On average, the FR-2 advanced the mandible forward 5 mm and opened the bite 5 mm from the intercuspal position. When the overjet was larger than 7 mm, the mandible was advanced gradually in 2–3 mm increments following Falck and Fränkel.30 Lateral cephalometric radiographs in habitual occlusion were taken initially and after 17 months of treatment. During this period no appliance was used other than the FR-2.

Cephalometric analysis

The 88 lateral cephalograms were traced on acetate paper by one investigator (MRA) and verified by a second author (JFCH). Any disparities in landmark position were resolved by mutual agreement. All cephalograms were digitized (Houston Instruments DT-11 digitizer, Austin, Texas). The data were stored on a computer and analyzed with the Dentofacial Planner 7.0 (Dentofacial Planner Software Inc, Toronto, Canada), which corrected the 6% image magnification factor of the radiographs present in the control group and the initial experimental group. The radiographs of the experimental group after 17 months were exposed on a different X-ray machine having a magnification of 9.2%, which was also corrected.

Statistical analysis

All statistical analyses were performed with the aid of a commercial statistical package (SIGMA STAT™, Statistical Software for Windows, Version 1.0, SPSS Inc, Chicago, Ill). The main purpose of this study was to conduct between-group comparisons of the various skeletal and dental changes occurring during treatment. Because the length of treatment varied between groups, a direct comparison of the cephalometric changes would be difficult to interpret. Thus, a patient treated for 18 months, for example, would be expected to grow more than a patient treated for 12 months, even if treated identically. Therefore, in order to conduct direct and meaningful comparisons, all cephalometric increments of the FR-2 group were adjusted to the time interval of the control sample, namely 13 months, according to the protocols of Toth and McNamara.17

Error of the Method

In order to assess the error of localizing the reference points and the digitizing procedure, 20 randomly selected tracings were retraced and remeasured by the same examiner (MRA) about one month after the initial data was recorded. The casual errors were assessed using Dahlberg’s formula and systematic errors were ascertained using paired t-tests similar to the recommendations of Houston.31 The casual error of the method (Dahlberg formula) did not exceed 0.77° or 0.56 mm. Paired t-tests demonstrated statistically significant differences only in five measurements (SNB, SN-GoMe, IMPA, B-FHp, and S-Go) for systematic errors.

Descriptive Statistics

Means and standard deviations for the two groups isolated according to gender and then grouped together, were calculated for all cephalometric variables at T1 and T2. In addition, mean differences and standard deviations were determined, as well as mean differences and standard deviations calculated for the adjusted 13-month interval for both groups, as mentioned previously.

Inferential Statistics

Sexual dimorphism in the two groups was evaluated using paired t-tests. The starting forms of the two groups (T1) were compared using a Student t-test (Table 2). Likewise the changes over the treatment/observation period were compared between the two groups using the same analysis (Table 3).

RESULTS

Sexual Dimorphism

The results demonstrated that sexual dimorphism was not present at T1 for both groups evaluated. Only one statistically significant difference was observed between boys and girls for Fränkel group with a linear measurement Co-A. Once this was determined, the two sexes were grouped and evaluated together.
Comparison of Starting Forms — T, (Table 2)

The equivalence of starting form was examined by comparing pretreatment cephalometric values between the groups (Table 2). In general, there was an equivalence of the initial cephalometric measures between both groups; however, in the control group, the maxilla and the upper incisors were more retruded than in the FR-2 group. Growth direction was predominantly vertical in both groups, while the palatal plane was rotated more clockwise in the control group.

Analysis of Treatment Effects

The average interval varied between the pretreatment and post-treatment cephalograms between the groups (13 months in the control group and 17 months in the FR-2 group). Statistical comparisons of the adjusted changes for the two groups are shown in Table 3.

Maxillary Skeletal Measures. No statistically significant differences were observed between the groups in all measures evaluated. Therefore, no effect should be attributed to the FR-2 as it relates to influencing maxillary sagittal growth and position.

Mandibular Skeletal Measures. Mandibular size was influenced significantly and positively in the Fränkel group. The effective mandibular length (Co-Gn), for instance, increased 3.2 mm in the control group and 3.9 mm in the FR-2 group. These statistically significant differences between two groups are also evident in the Ar-Gn and Go-Gn measurements. No significant differences between the two groups were observed in the SNB angle that remained almost unchanged in the control and FR-2 group.

Maxillomandibular Measures. Considering the maxillo-

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**Table 2. Comparison of Starting Forms**

<table>
<thead>
<tr>
<th>Cephalometric Measures</th>
<th>Control (N = 22)</th>
<th>Fränkel (N = 22)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary Skeletal</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>SNA (°)</td>
<td>80.1 ± 2.2</td>
<td>82.2 ± 2.9</td>
<td>*</td>
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<tr>
<td>CO–A (mm)</td>
<td>84.3 ± 3.8</td>
<td>68.5 ± 3.6</td>
<td>NS</td>
</tr>
<tr>
<td>A–FHp (mm)</td>
<td>65.7 ± 3.6</td>
<td>66.6 ± 3.4</td>
<td>NS</td>
</tr>
<tr>
<td>ANS–FHp (mm)</td>
<td>71.1 ± 4.0</td>
<td>71.0 ± 3.6</td>
<td>NS</td>
</tr>
<tr>
<td>Mandibular Skeletal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNB (°)</td>
<td>75.3 ± 2.8</td>
<td>76.3 ± 2.8</td>
<td>NS</td>
</tr>
<tr>
<td>Ar–Go (mm)</td>
<td>40.5 ± 3.3</td>
<td>41.5 ± 4.3</td>
<td>NS</td>
</tr>
<tr>
<td>Go–Gn (mm)</td>
<td>69.5 ± 3.2</td>
<td>69.5 ± 3.6</td>
<td>NS</td>
</tr>
<tr>
<td>Ar–Gn (mm)</td>
<td>99.3 ± 4.1</td>
<td>100.8 ± 5.2</td>
<td>NS</td>
</tr>
<tr>
<td>Co–Gn (mm)</td>
<td>103.4 ± 4.6</td>
<td>106.1 ± 6.2</td>
<td>NS</td>
</tr>
<tr>
<td>B–FHp (mm)</td>
<td>56.3 ± 5.2</td>
<td>56.8 ± 5.4</td>
<td>NS</td>
</tr>
<tr>
<td>Pog–FHp (mm)</td>
<td>56.8 ± 5.4</td>
<td>57.8 ± 6.2</td>
<td>NS</td>
</tr>
<tr>
<td>Ar–GoMe (°)</td>
<td>128.1 ± 4.8</td>
<td>129.5 ± 4.2</td>
<td>NS</td>
</tr>
<tr>
<td>Vertical Maxilla to mandible</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>ANB (°)</td>
<td>4.8 ± 1.6</td>
<td>5.8 ± 1.7</td>
<td>NS</td>
</tr>
<tr>
<td>NAP (°)</td>
<td>8.5 ± 3.6</td>
<td>10.0 ± 3.7</td>
<td>NS</td>
</tr>
<tr>
<td>SN–GoMe (°)</td>
<td>35.5 ± 3.6</td>
<td>34.8 ± 4.0</td>
<td>NS</td>
</tr>
<tr>
<td>SN–PP (°)</td>
<td>8.9 ± 2.1</td>
<td>6.5 ± 3.1</td>
<td>*</td>
</tr>
<tr>
<td>LAFH (mm)</td>
<td>61.4 ± 4.6</td>
<td>63.1 ± 4.1</td>
<td>NS</td>
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<tr>
<td>S–Go (mm)</td>
<td>66.9 ± 4.6</td>
<td>69.4 ± 6.1</td>
<td>NS</td>
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<tr>
<td>Maxillary dental</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>1. PP (°)</td>
<td>111.9 ± 6.0</td>
<td>114.3 ± 6.6</td>
<td>NS</td>
</tr>
<tr>
<td>1. NA (°)</td>
<td>22.8 ± 5.1</td>
<td>25.6 ± 5.6</td>
<td>NS</td>
</tr>
<tr>
<td>1–NA (mm)</td>
<td>4.3 ± 1.5</td>
<td>6.0 ± 1.4</td>
<td>**</td>
</tr>
<tr>
<td>1–FHp (mm)</td>
<td>69.2 ± 4.0</td>
<td>72.4 ± 5.1</td>
<td>**</td>
</tr>
<tr>
<td>6–PP (mm)</td>
<td>19.5 ± 1.8</td>
<td>19.7 ± 1.6</td>
<td>NS</td>
</tr>
<tr>
<td>Mandibular dental</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMPA (°)</td>
<td>94.5 ± 6.4</td>
<td>94.4 ± 6.5</td>
<td>NS</td>
</tr>
<tr>
<td>1 to NB (°)</td>
<td>25.4 ± 5.7</td>
<td>25.5 ± 4.8</td>
<td>NS</td>
</tr>
<tr>
<td>1 to N–B (mm)</td>
<td>4.4 ± 1.3</td>
<td>5.2 ± 1.1</td>
<td>NS</td>
</tr>
<tr>
<td>1 to FHp (mm)</td>
<td>63.1 ± 5.1</td>
<td>64.0 ± 4.8</td>
<td>NS</td>
</tr>
<tr>
<td>6 to GoMe (mm)</td>
<td>27.0 ± 1.7</td>
<td>27.5 ± 2.6</td>
<td>NS</td>
</tr>
</tbody>
</table>

*: SD indicates standard deviation; N, number of patients; and NS, not significant.

**: P ≤ .05.

**: P ≤ .01.
mandibular measures (ANB, NAP), the Fränkel group produced a reduction in the sagittal Class II discrepancy while the control group remained basically unchanged. The ANB angle was reduced by 0.8° in the FR-2 patients and remained unchanged in the control patients. The NAP angle did not show a significant difference between the two groups.

Vertical Measures. Mandibular plane orientation (SN-GoMe) was unaffected by treatment, while the palatal plane rotated significantly more clockwise in the treated group. It is interesting to note that the control group actually rotated counter-clockwise. No difference was noted in the increases in lower anterior face height (LAFH) and posterior facial height (S-Go) between the groups.

Maxillary Dentoalveolar Measures. The upper dentoalveolar component was the single component that presented more significant changes, with incisor retraction of 4.8° for 1-NA and about 1.1 mm for the 1-NA evaluation (control group moved forward 0.8 mm and the treated group moved back 1.1 mm). Vertically, the FR-2 appliance did not inhibited upper molar eruption. Therefore, upper molars extrusion to the palatal plane did not differ significantly between the two groups.

Mandibular Dentoalveolar Measures. No significant between-group differences in incisor mandibular plane angle (IMPA) were seen. However, the lower incisors proclined significantly in the treated group about 2° more than did the controls at about 0.4 mm, depending on the variable evaluated. The lower molars extruded significantly more (1.1 mm) in the treated group than did the controls (0.3 mm).

DISCUSSION

This study found no significant changes in any of the four variables used to evaluate maxillary growth in the Fränkel group, in agreement with most other evaluations of FR-2 treatment. Falck and Fränkel concluded that one of the groups treated with the FR-2 in their study did not show any maxillary restriction because the mandible was advanced in small increments. In instances when the mandible was brought forward in a one large step protocol, the so-called headgear effect was observed. The average mandibular advancement of the FR-2 group (5.0 mm) might have been too small to result in a maxillary skeletal inhibition and the headgear effect did not occur.

In contrast, other investigators noted some restrictive effect, particularly when the SNA angle was used. However, as McNamara et al pointed out, this effect could be related to the lingual inclination of the upper incisors and the accompanying posterior remodeling of Point A. It was concluded that the Fränkel appliance did not produced any significant restriction of maxillary anterior growth.

Changes in the Mandibular Skeletal Component

Although the present samples are relatively small (N = 22), the efforts to minimize technical error conferred an ability to detect differences in the 1- to 2-mm range. As shown in Table 3, the linear measurements Go-Gn, Ar-Gn, and Co-Gn increased significantly more in the FR-2 group. These differences are significant both statistically and clinically. In the experimental group the Articulare-to-gnathion and condylion-to-gnathion length measures increased 3.1 mm and 3.9 mm, respectively, during a standardized 13-month period. Other authors have reported an effective increase in total mandibular length during FR-2 treatment of 1.8 mm, 1.8 mm, 3.3 mm, 1.8 mm, 3.6 mm, 1.9 mm, 3.8 mm, 2.0 mm, 4.0 mm, 4.4 mm, and 4.6 mm per year. The variation among studies is probably related to differences in sampling criteria, methods used to measure mandibular growth, and differences in protocols (appliance design, starting age, and construction bite). The finding of an increase in mandibular length after functional appliance treatment is in agreement with the results of a number of investigations involving the FR-2 appliance. Falck and Fränkel did not report such increase. The finding of a small increase in the length from condylion to gnathion in the treated sample of Fränkel patients compared to the controls (only 0.7 mm) was somewhat surprising, but it is in agreement with McNamara et al, who found that there was less difference between treated and control individuals who underwent FR therapy at a younger age than those treated in the circumpubertal growth period. This increase in effective mandibular length should discriminate between ramus height and corpus length. No statistical difference was observed in the ramus height (Ar-Go) between the FR-2 and control groups. Mandibular body length (Go-Gn), however, seemed to contribute more to the effective mandibular length, consistent with other investigators. However, it does not agree with McNamara et al, who found no evidence of statistically significant increase in mandibular body length in patients treated with an FR-2.

Fränkel therapy did not produce statistically significant increases in the SNB angle compared to the control group. Others reported similar observations in patients treated with the same appliance. It should be noted, however, that the SNB angle might increase or decrease depending on incisor position changes. Indeed, the proclination of the lower incisors observed in FR-2 treatment could be a factor that contributed to a negative interpretation of mandibular protrusion.

There was no evidence of a morphologic change in the mandible, as measured by the angle Articulare-to-gnathion between Fränkel and the control groups, according to the results of the current study. Schulhof and Engel demonstrated that this mandibular morphology did not change.
Changes in Maxillomandibular Skeletal Relationship

The maxillomandibular relationship showed marked improvement in the experimental group compared to the control group (Table 3), with a statistically significant difference. Improvement in basal bone relations resulted from small changes in maxillary anterior and growth and by the increase in anterior growth of the mandible in the Fränkel group. Similar findings were found with Bionator/Activator therapy by several authors36,39±47 and also for the FR-2.17,19,20,25,27,28,48 Changes of the ANB angle in the treated group were a result of several small, but cumulative effects upon dentofacial structures associated with the normal craniofacial growth. These changes were not sufficient to correct or to improve the skeletal Class II relationship in the untreated group.

Vertical Component

Several authors11,14,27,28,43,44 have reported that functional appliances do not change the craniofacial growth pattern, although facial height has been noted to increase.* Although a small increase in lower anterior facial height (ANS to menton) was observed in both groups, it might be stressed that there were no statistically significant differences between the control and FR-2 groups. This result is supported by Toth and McNamara,17 who found that FR-2 therapy generally produced dentoalveolar changes that were not statistically different from those that occur during normal growth. Indeed, Wieslander and Lagerström,39 and Bolmgren and Mosher,50 all reported that the treatment with Activator appliance does not produce an alteration in the position on the lower incisors. Our study indicates that care should be taken when the FR-2 is used in patients with proclined mandibular incisors because this condition could become more pronounced.

In the untreated group, the upper first molars extruded 0.3 mm relative to palatal plane, which was not statistically different from the FR-2 group (0.4 mm). Toth and McNamara17 reported similar findings in which significant differences in the vertical eruption of the maxillary molars were not evident in comparison to controls or to patients treated with the FR-2 appliance of Fränkel.

The vertical eruption of the lower first molars (6-GoMe) was greater in the FR-2 group (1.1 mm) in comparison with controls (0.3 mm). This extrusive effect of the lower molars with the Fränkel appliance was usually seen by others investigators.14,25,27,28,32

In the FR-2 group, the advancement of the mandible contributed to opening the bite in the posterior region. This allows a greater vertical increase of the lower posterior teeth, and helps correct the overbite, the Class II molar relationship and a deep curve of Spee. McNamara et al27 described this theory as the differential eruption principle of Harvold.

Maxillomandibular Dentoalveolar Components

Many other investigators have shown that the Fränkel appliance, and almost all Functional appliances, produce lingual tipping of the upper incisors (−4.9°). In the control group, the upper incisors remained stable (0.0°) relative to the palatal plane. This effect was expected since the FR-2 labial bow may come in contact with the incisors during sleeping hours causing them to retract.1,13,15,17,19,25–28

In the control group, the lower incisors remained stable (0.5°) relative to the Nasion-B line. However, some proclination of the lower incisors was produced by FR-2 treatment (2.7°) relative to the same line. This effect is probably consequent to the resultant mesial force on the lower incisors induced by the protrusion of the mandible. This finding corroborates other studies for the Fränkel appliance13,15,18,19,25–28 and contradicts the result published by Toth and McNamara,17 who found that FR-2 therapy generally produced dentoalveolar changes that were not statistically different from those that occur during normal growth. Indeed, Wieslander and Lagerström,39 and Bolmgren and Mosher,50 all reported that the treatment with Activator appliance does not produce an alteration in the position on the lower incisors. Our study indicates that care should be taken when the FR-2 is used in patients with proclined mandibular incisors because this condition could become more pronounced.

CONCLUSIONS

The pretreatment and posttreatment cephalograms of 22 patients treated with the Fränkel appliance and 22 untreated children were analyzed. The mean starting age for the control group was eight years seven months and for the FR-2 group nine years. All cephalometric values were adjusted to correspond with the interval between the films of the control patients (13 months). It was concluded that the skeletal and dental effects produced by Fränkel appliance were as follows:

*References 10, 26, 30, 34, 36, 39, 49, 50, 51.
a. No significant restriction of maxillary growth was observed in functional appliance group.
b. Compared with Class II controls, statistically significant increases in mandibular length were observed in the Fränkel group (patients achieved an additional 1.1 mm of mandibular length)
c. There was a significant improvement of the anteroposterior relationship between the maxilla and the mandible in the FR-2 group.
d. There were no statistically significant differences in the craniofacial growth pattern and in the lower anterior facial height between the groups.
e. The FR-2 appliance produced labial tipping and linear protrusion of the lower incisors as well as a lingual inclination and retraction of the upper incisors in comparison with the controls. In addition, there was a significant increase in mandibular posterior dentoalveolar height and no extrusion of the upper molars in the Fränkel group.

The present study suggests that Class II corrections can be achieved with the Fränkel appliance. The FR-2 appliance appears to have mostly dentoalveolar effects with a smaller, but significant, skeletal mandibular effect.

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