Comparative study of the Fränkel (FR-2) and bionator appliances in the treatment of Class II malocclusion

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The purpose of this investigation was to compare the dentoalveolar and skeletal cephalometric changes produced by the Fränkel (FR-2) and bionator appliances in persons with Class II malocclusion. Lateral cephalograms were available for 66 patients of both sexes, who were divided into 3 groups of 22. The control group included untreated Class II children, with an initial mean age of 8 years 7 months; they were followed without treatment for 13 months. The FR-2 appliance group had an initial mean age of 9 years; those children were treated for a mean period of 17 months. The bionator group initially had a mean age of 10 years 8 months; on average, they were treated for 16 months. The results demonstrated no significant changes in maxillary growth during the evaluation period. Both appliances showed statistically significant increases in mandibular growth and mandibular protrusion, with greater increases in patients treated in the bionator group. Both experimental groups showed an improvement in the maxillomandibular relationship. There were no significant changes in growth direction, while the bionator group had a greater increase in posterior facial height. Both appliances produced similar labial tipping and protrusion of the lower incisors, lingual inclination, retrusion of the upper incisors, and a significant increase in mandibular posterior dentoalveolar height. The major treatment effects of bionator and FR-2 appliances were dentoalveolar, with a smaller, but significant, skeletal effect. (Am J Orthod Dentofacial Orthop 2002;121:458-66)

Many investigators have claimed that a Class II molar relationship occurs in a variety of skeletal and dental configurations. Some studies 1-7 have shown that the components of Class II malocclusion can be categorized into 4 main groups: anterior position of the maxilla, anterior position of the maxillary dentition, mandibular skeletal retrusion in absolute size or relative position, and excessive or deficient vertical development. McNamara 8 stated that most Class II patients present a deficiency in the anteroposterior position of the mandible. If the contemplated treatment option includes correcting the component most deviated from normal, then several treatment strategies should be considered. One that has gained interest and generated heated controversies over the last 2 decades is the so-called functional jaw orthopedic appliance. Several types of these functional appliances are currently in use for Class II treatment aimed to improve skeletal imbalances, arch form, and orofacial function. The expected effects of these appliances include alteration of maxillary growth, a possible change in mandibular growth and position, and an improvement in dental and muscular relationships. It has been claimed that forward growth of the maxilla may be either inhibited, 9-11 redirected downward, 12 or unaffected. 13-15 Some authors have suggested that mandibular growth can be increased with functional appliance treatment, 16-20 but others believe that mandibular length cannot be altered by such treatment. 21,22 Many studies agree that the most significant treatment effects are restricted to dentoalveolar changes. 23,24 Two of the most popular functional appliances used today are Balters’ bionator 25,26 and Fränkel’s Function Regulator (FR-2). 27,30 Few studies provide a direct comparison between the soft tissue-borne FR-2 and the primarily dentally borne bionator. The purpose of this research...
was to cephalometrically compare the possible effects of the FR-2 and the bionator appliances on the skeletal and dentoalveolar components in a sample of patients with Class II Division 1 malocclusion with an untreated control sample of persons with similar malocclusion.

**MATERIAL AND METHODS**

A control group, obtained from the files of the Longitudinal Growth Study of the University of São Paulo at Bauru, comprised 22 subjects (11 boys and 11 girls) with Class II Division 1 malocclusions with an initial mean age of 8 years 7 months (Table I). This sample had no previous orthodontic treatment and was observed for 13 months.

The FR-2 sample included 22 children (11 boys and 11 girls) with an initial mean age of 9 years treated in the orthodontic graduate program at the University of São Paulo at Bauru. They were chosen from a parent sample of 50 based on best results obtained and compliance level from among the broader sample after 10 months in treatment. Initially, all patients had a Class II Division 1 malocclusion with at least an end-to-end Class II molar relationship and minimal or no crowding; they were treated for a mean period of 17 months (Table I). The patients were instructed to wear the appliances 4 hours a day the first week, 8 hours a day the second week, 12 hours a day the third week, and 24 hours a day thereafter (except for eating and playing certain sports) until the end of treatment. The FR-2 appliances worn by patients were fabricated according to the principles of McNamara and Huge.31 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 2 to 3 mm, following Falck and Fränkel.32

The 22 patients (11 boys and 11 girls) in the bionator sample were treated with that appliance for a mean period of 16 months; they had an initial mean age of 10 years 8 months (Table I). They were treated in the same clinic as the FR-2 patients and chosen by the same inclusionary criteria as used in an original parent sample of 35 patients. They were instructed to wear the appliances 24 hours a day, except for eating and playing certain sports. The bionator appliances were constructed according to Ascher.26 The acrylic was extended to cover the incisal edges, to avoid labial tipping of the lower incisors.33 Similar to the FR-2 sample, the mandible was brought forward 5.0 mm, and the bite was opened 5.0 mm from the intercuspal position. When necessary, a second appliance was constructed to readvance the mandible until the overjet was eliminated.

**Methods**

The 132 lateral cephalograms were traced on acetate paper by 1 investigator (M.R.A.) and verified by a second (J.F.C.H.). The cephalometric measures are shown in Figures 1 through 3. Any disparities in landmark position were resolved by mutual agreement. The cephalograms were digitized (DT-11 digitizer, Houston Instruments, Austin, Tex). The data were then stored on a computer and analyzed with the Dentofacial Planner 7.0 (Dentofacial Planner Software Inc, Toronto, Ontario, Canada), which corrected the 6% image magnification factor of the control group and the 9.2% magnification of the experimental groups.
Statistical analysis

All statistical analyses were performed with a commercial statistical package (SIGMA STAT, Statistical Software for Windows, Version 1.0; SPSS Science, Chicago, Ill).

About 4 weeks later, 20 randomly selected tracings were retraced and remeasured by the same examiner (M.R.A.) to assess the error of localizing the reference points and the digitizing procedure. Casual errors were assessed with Dahlberg’s formula, and systematic errors were ascertained with paired t tests similar to the recommendations of Houston. The casual error of the method (Dahlberg formula) did not exceed 0.77° or 0.56 mm. Paired t tests showed statistically significant differences only in 5 measurements (SNB, SN.GoMe, IMPA, B-FHp, and S-Go) for systematic errors.

Means and standard deviations for the 3 groups, isolated according to sex and then grouped together, were calculated for all cephalometric variables.

Sexual dimorphism in the 3 groups was evaluated with paired t tests. The starting forms of the 3 groups (T1) were compared by using an analysis of variance (ANOVA). When differences occurred, Scheffé multiple comparison tests were used to determine which groups were statistically different. Because the length of treatment varied among groups, they were adjusted to the time interval of the control sample—13 months.

RESULTS

The results showed no sexual dimorphism at T1 for the 3 groups. There was only 1 statistically significant difference between boys and girls for the FR-2 group—a linear measurement, Co-A. Once this was determined, the sexes were grouped and evaluated together.

The equivalence of the starting form was determined by comparing pretreatment cephalometric values among the 3 groups (Table II). In general, craniofacial evaluations, particularly linear measurements, tended to favor, as expected, the older group—the bionator patients. Maxillary and mandibular sagittal positions compared favorably in the 3 groups, as well as the resulting ANB and NAP angles. Growth direction was predominantly vertical in the 3 groups, with larger linear measurements for the bionator group. The upper incisors were more proclined in the experimental groups, but the lower incisors were not statistically significantly different for any of the measurements used.

No statistically significant effect was observed for maxillary skeletal measures (Table III). The minimal effect should then be attributed to the 2 functional appliances as it relates to their influence on maxillary sagittal growth and position. Mandibular protrusion,
evaluated by SNB angle and B-FHp and Pog-FHp, however, increased significantly in the bionator patients. Mandibular size was significantly positively influenced in both the FR-2 and the bionator groups, particularly in patients treated with the latter. The effective mandibular length increased 3.0 mm in the control group, 3.9 mm in the FR-2 group, and 4.9 mm in the bionator group. Overall, bionator therapy produced a larger and more significant effect on growth and position of the mandible than did FR-2 treatment. Considering the maxillomandibular measures (ANB, NAP), both therapies produced similar reductions in the sagittal Class II discrepancy, while the control group remained basically unchanged. Mandibular plane orientation was unaffected by treatment, while the palatal plane rotated significantly more clockwise in the treated groups. The control group actually rotated counterclockwise. No difference in increase in lower anterior face height was noted between the 3 groups, while bionator therapy induced significant increases in the total posterior facial height (S-Go), about twice as much as the control group. Only the upper dentoalveolar component presented more significant changes, with incisor retractions from 4.8° to 5.5° and linear retractions of about 2.3 mm (the control group moved forward 0.9 mm and the treated groups moved back 1.4 mm) for the maxillary incisor-NA evaluation. The upper molars did not differ significantly when extrusion to the palatal plane was evaluated. The lower incisors proclined significantly in the treated groups about 3° more than did the controls, or about 0.7 mm, depending on the variable evaluated. The lower molars extruded

<table>
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<th>Control (n = 22)</th>
<th>FR-2 (n = 22)</th>
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<tr>
<td></td>
<td>Mean SD</td>
<td>Mean SD</td>
<td>Mean SD</td>
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<tr>
<td>SNA (°)</td>
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<tr>
<td>SNB (°)</td>
<td>75.3 2.8</td>
<td>76.3 2.8</td>
<td>75.9 2.5</td>
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<td>72.8 5.2</td>
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<td>Ar-Gn (mm)</td>
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<td>100.8 5.2</td>
<td>104.4 5.3</td>
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<td>106.1 6.2</td>
<td>110.8 4.9</td>
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<td>ANB (°)</td>
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<td>S-Go (mm)</td>
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<td>Maxillary dental</td>
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<td>max central incisor-PP (°)</td>
<td>111.9 6.0</td>
<td>114.3 6.6</td>
<td>117.5 5.2</td>
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<td>72.4 5.1</td>
<td>74.8 4.5</td>
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<td>max first molar-PP (mm)</td>
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<td>19.7 1.6</td>
<td>21.7 2.3</td>
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<td>IMPA (°)</td>
<td>94.5 6.4</td>
<td>94.4 6.5</td>
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<td>25.5 6.6</td>
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<td>mand central incisor-N-B (mm)</td>
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<td>5.2 1.1</td>
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<td>64.0 4.8</td>
<td>66.0 3.7</td>
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<td>mand first molar-GoMe (mm)</td>
<td>27.0 1.7</td>
<td>27.5 2.6</td>
<td>28.2 1.4</td>
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</tbody>
</table>

*P ≤ .05; **P ≤ .01.
C, Control; F, FR-2; B, bionator, NS, not significant.
significantly more (0.4-0.7 mm) in the treated groups than in the controls.

DISCUSSION

Changes in maxillary skeletal component

The results of this study showed that there were no significant changes in any of the 4 variables used to evaluate maxillary growth in the experimental groups; this result agrees with other studies\textsuperscript{35-43} of activator and bionator appliances that also showed no significant restriction of maxillary growth. In contrast, other investigators\textsuperscript{44-51} noted some restrictive effect, particularly when the SNA angle was used. However, as Mills\textsuperscript{41} pointed out, this effect could be related to the lingual inclination of the upper incisors and the accompanying posterior remodeling of Point A. The lack of maxillary skeletal effects in the FR-2 sample in the present study agrees with most other evaluations of FR-2 treatment\textsuperscript{52-56}.

Changes in the mandibular skeletal component

A statistically significant increase in mandibular protrusion and length was observed in both experimental groups, particularly patients treated with the biona-
with no statistically significant difference between the treated groups. Improvement in basal bone relationships resulted from small changes in maxillary anterior growth and by the anterior positioning of the mandible in the experimental groups. Similar findings were found with bionator or activator therapy by some authors and also for the FR-2. Changes of ANB angle in the treated groups were a result of several small but cumulative effects on dentofacial structures associated with normal craniofacial growth that were not sufficient to correct or improve the skeletal Class II relationship in the untreated group.

Vertical component

Righellis and McNamara reported that functional appliances do not change the craniofacial growth pattern, although facial height has been noted to increase, as mentioned by Nielsen. Although an increase in lower anterior facial height was observed in all 3 groups, there were no statistically significant differences between the control and the experimental groups. This result is probably related to the posterior bite opening that occurs when the mandible was brought forward in the experimental groups and the molars are encouraged to erupt. Posterior facial height (S-Go) increased in all 3 groups, showing a statistically significant difference among the groups. Despite the greater increase in the FR-2 group (2.2 mm), there was no statistical difference with the control group (2.1 mm). In contrast, the greater increase in the bionator group (3.7 mm) reached almost 2 times more than the values for the control group, a result also found by Lange et al.

As a result of the observed interplay of both the anterior and the posterior facial heights, the mandibular plane was not significantly affected. There was a greater tendency for a clockwise rotation of the maxillary plane (SN.PP) during FR-2 and bionator therapy compared with the control group; this did not adversely affect the lower anterior facial height.

Maxillomandibular dentoalveolar components

As shown by many other investigators for almost all functional appliances, both the bionator and the FR-2 produced a lingual tipping of the upper incisors. This effect was expected because both appliances have a labial wire that may come in contact with the incisors during sleeping hours, causing them to retract.

Some proclination of the lower incisors was produced by both bionator and FR-2 treatments. 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 FR-2,65,68,73 and the bionator or activator39,51,58 appliances. However, Wieslander and Lagerström14 and Bolmgren and Moshiiri35 reported that treatment with the activator appliance does not alter the position of the lower incisors. It could be inferred that care should be taken when the bionator and the FR-2 are 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, which was not statistically different from the FR-2 (0.4 mm) and the bionator (1.0 mm) groups. Toth and McNamara52 also reported similar findings, where significant differences in the vertical eruption of the maxillary molars were not evident in comparison with the controls or the patients treated with the FR-2 appliance.

The vertical eruption of the lower first molars (mandibular first molar-GoMe), however, was greater in both appliance groups (FR-2, 1.1 mm; bionator, 1.4 mm) than the controls (0.7 mm). This effect has also been reported with the FR-2 appliance16,67,69 and the bionator or activator appliance.51,58

The acrylic in the bionator group must be trimmed away in the posterior inferior region so that there is no contact with the posterior lower teeth. In the FR-2 group, the advancement of the mandible contributes to opening the bite in the posterior region. This procedure allows a greater vertical increase of the lower posterior teeth and helps to correct the overbite, the Class II molar relationship, and the deep curve of Spee. McNamara et al16 described this theory as the differential eruption principle of Harvold. It has been hypothesized by Toth and McNamara52 that tissue-borne appliances, such as the FR-2, produce less dentoalveolar change than tooth-borne appliances such as the bionator or the Twin-block. Similar to the results of Toth and McNamara52 comparing the Twin-block with the FR-2, this study reports greater dental changes in the bionator group (tooth-borne appliance) than in the FR-2 group (tissue-borne appliance). Based on these findings, it might be expected that the FR-2 appliance would have a greater skeletal effect than the bionator in Class II correction. However, this investigation did not support this consideration, because there were greater skeletal effects in the bionator group than in the FR-2 group.

Overall, it was concluded that the major effects of the bionator and the FR-2 appliances were dentoalveolar, with a smaller, but significant, skeletal effect.

CONCLUSIONS
The present study suggests that Class II correction can be achieved with either appliance system evaluated here. We concluded that the skeletal and dental effects produced by the FR-2 and the bionator appliances were as follows:

1. No significant restriction of maxillary growth was observed in either functional appliance group.
2. Both appliances provided statistically significant increases in mandibular growth and in the degree of mandibular protrusion, with greater increases in patients treated with the bionator appliance.
3. There was a similar significant improvement of the anteroposterior relationship between the maxilla and the mandible in the FR-2 and the bionator groups.
4. There were no statistically significant differences in craniofacial growth patterns among the groups. The bionator group showed a greater increase in posterior facial height.
5. Both appliances produced a similar labial tipping and linear protrusion of the lower incisors and a lingual inclination and retrusion of the upper incisors. In addition, there was a significant increase in mandibular posterior dentoalveolar height and no extrusion of the upper molars in either treatment group.

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