[Print Version]
[PubMed Citation] [Related Articles in PubMed]

TABLE OF CONTENTS

[INTRODUCTION] [MATERIALS AND...] [RESULTS] [DISCUSSION] [CONCLUSIONS] [REFERENCES] [TABLES] [FIGURES]

The Angle Orthodontist: Vol. 72, No. 5, pp. 418-425.

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

Marcio Rodrigues de Almeida, DDS, MSc, PhD; José Fernando Castanha Henriques, DDS, MSc, PhD; Renato Rodrigues de Almeida, DDS, MSc, PhD; Weber Ursi, DDS, MSc, PhD

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.

KEY WORDS: Functional Regulator appliance, Class II, division 1 malocclusion, Functional orthopedics.

Accepted: February 2002. Submitted: October 2001

INTRODUCTION Return to TOC

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. Fixed appliances usually require intermaxillary Class II elastics, extraoral traction, or both, to generate a force for correction of the Class II malocclusion. McNamara 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. The FR-2 features projecting vestibular shields that expand the orofacial capsule and cause an anterior functional shift of the mandible. According to Fränkel, 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. Fränkel 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, Ghafari et al noted that the function regulator restrains the growth of the maxilla.

Histologic studies reported by Stöckli and Willert, ²² Petrovic et al, ²³ and McNamara ²⁴ 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 ¹⁴ and Perillo et al ²⁰ found that mandibular growth can be increased during Fränkel therapy, but others ^{7,25–28} have been unable to detect such an increase. On the other hand, McNamara et al ²⁷ 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 dentoalveolar components of patients presenting with Class II, division 1 malocclusion, using untreated patients with similar malocclusions as a control sample.

MATERIALS AND METHODS Return to TOC

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 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 O=). 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. 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. 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 STATTM, Statistical Software for Windows, Version 1.0, SPSS Inc, Chicago, III). The main purpose of this study was to conduct between-group comparisons of the various skeletal and dentoalveolar changes occurring during treatment. Because the length of treatment varied 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 (<u>Table 2</u> •). Likewise the changes over the treatment/observation period were compared between the two groups using the same analysis (<u>Table 3</u> •).

RESULTS Return to TOC

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 —T₁ (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 <u>Table 3</u> \bigcirc =.

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 maxillomandibular 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 Return to TOC

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. \(\frac{1.14.15.17-20.27.32}{1.14.15.17-20.27.32} \) Falck and Fränkel \(\frac{30}{20} \) 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 13,25,33-35 noted some restrictive effect, particularly when the SNA angle was used. However, as McNamara et al 27 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-tognathion and condylion-to-gnathion length measures increased 3.1 mm and 3.9 mm, respectively, during a standardized 13-month period. Other authors 14,17-20,25,27 have reported an effective increase in total mandibular length during FR-2 treatment of 1.8 mm, 18 3.3 mm, 20 3.6 mm, 19/3.8 mm, 25/4.0 mm, 27/4.4 mm, 14/4 and 4.6 mm 17/2 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).20 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, 14,17,19,20,26,27 although others 15,25 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.²⁷ 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. 20,26,36 However, it does not agree with McNamara et al,27,28 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.

15,18,25,33,37,38

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 ArGoMe, between Fränkel and the control groups, according to the results of the current study. Schulhof and Engel²⁶ also 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 (<u>Table 3</u>), with a statistically significant difference. Improvement in basal bone relations resulted from small changes in maxillary anterior 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 authors 36.39-47 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 authors 11,14,27,28,43,44 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 in agreement with the results published by Righellis 14 and Nelson et al, 49 who found no evidence of increased facial height during FR-2 treatment. This finding, however, is not supported by Toth and McNamara, 17 who found a lower anterior facial height increase of 1.0 mm more in FR-2

patients than in untreated subjects. Posterior facial height (S-Go) increased similarly in both groups, showing no statistical significant difference.

As a result of the observed interplay of both the anterior and the posterior facial heights, the mandibular plane was not significantly affected. The equal increases in both anterior and posterior vertical facial dimensions resulted in maintenance of the mandibular plane angle (SNGoMe). Similar conclusions were reached by Toth and McNamara. This observation is probably related to the posterior bite-opening that occurred when the mandible was brought forward in the experimental group and the molars were encouraged to erupt. There was a greater tendency for a clockwise rotation of the palatal plane angle (SNPP) during Fränkel therapy compared to the control group, which experienced a counter-clockwise rotation.

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°, <u>Table 3</u>). 40.45-47.50-58 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 appliance 13,15,18,19,25–28 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 Moshiri, 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 contributes 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.

CONCLUSIONS Return to TOC

The pretreatment and postreatment 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:

- 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.

ACKNOWLEDGMENTS

This work was supported by CNPQ (Brazilian National Research Foundation).

REFERENCES Return to TOC

- 1. Remmer KR, Mamandras AH, Hunter WS, Way DC. Cephalometric changes associated with treatment using the Activator, the Fränkel appliance, and the fixed appliance. *Am J Orthod.* 1985; 88:363–372. [PubMed Citation]
- 2. McNamara JA Jr. Components of Class II malocclusion in children 8–10 years of age. *Angle Orthod.* 1981; 51:177–202. [PubMed Citation]
- 3. Fränkel R. The theoretical concept underlying the treatment with functional correctors. Trans Eur Orthod Soc. 1966; 42:233–254.
- 4. Fränkel R. The treatment of Class II, Division 1 malocclusion with functional correctors. *Am J Orthod.* 1969; 55:265–275. [PubMed Citation]
- 5. Fränkel R. A functional approach to orofacial orthopedics. *Br J Orthod.* 1980; 7:41–51. [PubMed Citation]
- 6. Fränkel R. Biomechanical aspects of the form/function relationship in craniofacial morphogenesis: a clinician's approach. In McNamara JA Jr, Ribbens KA, Howe RP, eds. Clinical Alteration of the Growing Face, Monograph 14, Craniofacial Growth Series. Ann Arbor, Mich: Center for Human Growth and Development, The University of Michigan; 1983.
- 7. Harvold EP, Vargervik K. Morphogenetic response to Activator treatment. Am J Orthod. 1971; 60:478–490. [PubMed Citation]
- 8. Moss JP. Cephalometric changes during functional appliance therapy. Trans Eur Orthod. Soc. 1962; 38:327–341.
- 9. Evald H, Harvold EP. The effect of activators on maxillary-mandibular growth and relationships. Am J Orthod. 1966; 52:857
- 10. Meach CL. A cephalometric comparison of bony profile changes in Class II, Division 1 patients treated with extraoral force and functional jaw orthopedics. *Am J Orthod.* 1966; 52:353–370. [PubMed Citation]
- 11. Freunthaller P. Cephalometric observations in Class II, Division 1 malocclusions treated with the activator. *Angle Orthod.* 1967; 37:18–25. [PubMed Citation]
- 12. Hotz R. Application and appliance manipulation of functional forces. Am J Orthod. 1970; 58:459–478. [PubMed Citation]
- 13. Ghafari J, Shofer FS, Jacobsson-Hunt U, Markowitz DL, Laster LL. Headgear versus function regulator in the early treatment of Class II, division 1 malocclusion: a randomized clinical trial. *Am J Orthod Dentofacial Orthop.* 1998; 113:51–61. [PubMed Citation]
- 14. Righellis EG. Treatment effects of Fränkel, Activator and extraoral traction appliances. *Angle Orthod.* 1983; 53:107–121. [PubMed Citation]
- 15. Robertson NRE. An examination of treatment changes in children treated with the function regulator of Fränkel. *Am J Orthod.* 1983; 83:299–310. [PubMed Citation]
- 16. Bookstein FL. Measuring treatment effects on craniofacial growth. In McNamara JA Jr, Ribbens KA, Howe RP, eds. Clinical Alteration of the Growing Face, Monograph 14, Craniofacial Growth Series. Ann Arbor, Mich: Center for Human Growth and Development, The University of Michigan; 1983.
- 17. Toth LR, McNamara JA Jr. Treatment effects produced by the Twin-block appliance and the FR-2 appliance of Fränkel compared with an untreated Class II sample. *Am J Orthod Dentofacial Orthop.* 1999; 116:597–609. [PubMed Citation]
- 18. Hamilton SD, Sinclair PM, Hamilton RH. A cephalometric, tomographic, and dental cast evaluation of Fränkel therapy. *Am J Orthod Dentofacial Orthop.* 1987; 92:427–434. [PubMed Citation]
- 19. Kerr WJS, Tenhave TR, McNamara JA Jr. A comparison of skeletal and dental changes produced by function regulators (FR-2 and FR-3). *Eur J Orthod.* 1989; 11:235–242. [PubMed Citation]
- 20. Perillo L, Johnston LE Jr,, Ferro A. Permanence of skeletal changes after function regulator (FR-2) treatment of patients with retrusive Class II malocclusions. *Am J Orthod Dentofacial Orthop.* 1996; 109:132–139. [PubMed Citation]
- 21. Bass NM. Orthopedic coordination of dentofacial development in skeletal Class II malocclusion in conjuction with edgewise therapy.

- Part I. Am J Orthod. 1983; 84:361–383. [PubMed Citation]
- 22. Stöckli PW, Willert HG. Tissue reactions in the temporomandibular joint resulting from anterior displacement of the mandible in the monkey. *Am J Orthod.* 1971; 60:142–155. [PubMed Citation]
- 23. Petrovic A, Stutzman J, Oudet C. Control processes in the postnatal growth of the condylar cartilage of the mandible. In McNamara JA Jr, ed. Determinants of Mandibular Form and Growth, Monograph No 4, Craniofacial Growth Series. Ann Arbor, Mich: Center for Human Growth and Development, University of Michigan; 1975:101–153.
- 24. McNamara JA Jr. Neuromuscular and skeletal adaptations to altered function in the orofacial region. *Am J Orthod.* 1973; 64:578–606. [PubMed Citation]
- 25. Creekmore TD, Radney LJ. Fränkel appliance therapy: orthopedic or orthodontic?. Am J Orthod. 1983; 83:89–108. [PubMed Citation]
- 26. Schulhof RJ, Engel GA. Results of Class II functional appliance treatment. J Clin Orthod. 1982; 16:587–99. [PubMed Citation]
- 27. McNamara JA Jr., Bookstein FL, Shaughnessy TG. Skeletal and dental changes following functional regulator therapy on Class II patients. *Am J Orthod.* 1985; 88:91–110. [PubMed Citation]
- 28. McNamara JA Jr,, Howe RP, Dischinger TG. A comparison of the Herbst and the Fränkel appliances in the treatment of Class II malocclusion. *Am J Orthod Dentofacial Orthop.* 1990; 98:134–144. [PubMed Citation]
- 29. McNamara JA Jr., Huge SA. The Fränkel appliance (FR-2): model preparation and appliance construction. *Am J Orthod.* 1981; 80:478–497. [PubMed Citation]
- 30. Falck F, Fränkel R. Clinical relevance of step-by-step mandibular advancement in the treatment of mandibular retrusion using the Fränkel appliance. *Am J Orthod Dentofacial Orthop.* 1989; 96:333–341. [PubMed Citation]
- 31. Houston WJB. The analysis of errors in orthodontic measurements. Am J Orthod Dentofacial Orthop. 1983; 83:382–390.
- 32. Almeida MR, Henriques JFC, Almeida RR, Janson GRP. Cephalometric evaluation of Fränkel Appliance effects in the treatment of Class II, division 1 malocclusion patients. *Rev Dental Press Ortod Ortop Fac.* 1998; 3:53–70.
- 33. Gianelly AA, Arena AS, Bernstein L. A comparison of Class II treatment changes noted with the light wire, edgewise, and Fränkel appliances. *Am J Orthod.* 1984; 86:269–76. [PubMed Citation]
- 34. Nielsen IL. Facial growth during treatment with the function regulator appliance. Am J Orthod. 1984; 85:401–410. [PubMed Citation]
- 35. Owen AH. Maxillary incisolabial responses in Class II, division 1 treatment with Fränkel and edgewise. *Angle Orthod.* 1986; 56:67–87. [PubMed Citation]
- 36. Derringer K. A cephalometric study to compare the effects of cervical traction and Andresen therapy in the treatment of Class II division 1 malocclusion. Part 1-Skeletal changes. *Brit J Orthod.* 1990; 17:33–46. [PubMed Citation]
- 37. Adenwalla ST, Kronman JH. Class II, division 1 treatment with Fränkel and edgewise appliances. A comparative study of mandibular growth and facial esthetics. *Angle Orthod.* 1985; 55:281–298. [PubMed Citation]
- 38. Haynes S. Profile changes in modified functional regulator therapy. Angle Orthod. 1986; 56:309–314. [PubMed Citation]
- 39. Wieslander L, Lagerström L. The effect of Activator treatment on Class II malocclusions. *Am J Orthod.* 1979; 75:20–26. [PubMed Citation]
- 40. Mills JRE. The effect of functional appliances on the skeletal pattern. *Brit J Orthod.* 1991; 18:267–275. [PubMed Citation]
- 41. Tulloch JFC, Phillips C, Proffit WR. Benefit of early Class II treatment: progress report of a two-phase randomized clinical trial. *Am J Orthod Dentofacial Orthop.* 1998; 113:62–72. [PubMed Citation]
- 42. Tulloch JFC, Phillips C, Koch G, Proffit WR. The effect of early intervention on skeletal pattern in Class II malocclusion: a randomized clinical trial. *Am J Orthod Dentofacial Orthop.* 1997; 111:391–399. [PubMed Citation]
- 43. Jakobsson SO, Paulin G. The influence of Activator treatment on skeletal growth in Angle Class II: 1 cases. A roentgenocephalometric study. *Eur J Orthod.* 1990; 12:174–184. [PubMed Citation]
- 44. Lange DW, Kalra V, Broadbent BH Jr,, Powers M, Nelson S. Changes in soft tissue profile following treatment with the Bionator. *Angle Orthod.* 1995; 65:423–430. [PubMed Citation]

- 45. Pancherz H. A cephalometric analysis of skeletal and dental changes contributing to Class II correction in Activator treatment. *Am J Orthod Dentofacial Orthop.* 1984; 85:125–134.
- 46. Thüer U, Ingervall B, Bürgin W. Does the mandible alter its functional position during Activator treatment?. *Am J Orthod Dentofacial Orthop.* 1989; 96:477–484. [PubMed Citation]
- 47. Cura N, Saraç M, Öztürk Y, Sürmeli N. Orthodontic and orthopedic effects of Activator, Activator-HG combination, and Bass appliances: a comparative study. *Am J Orthod Dentofacial Orthop.* 1996; 110:36–45. [PubMed Citation]
- 48. Webster T, Harkness M, Herbison P. Associations between changes in selected facial dimensions and the outcome of orthodontic treatment. *Am J Orthod Dentofacial Orthop.* 1996; 110:46–53. [PubMed Citation]
- 49. Nelson C, Harkness M, Herbison P. Mandibular changes during functional appliance treatment. *Am J Orthod Dentofacial Orthop.* 1993; 104:153–161. [PubMed Citation]
- 50. Bolmgren GA, Moshiri F. Bionator treatment in Class II, division 1. Angle Orthod. 1986; 56:255–262. [PubMed Citation]
- 51. Courtney M, Harkness M, Herbison P. Maxillary and cranial base changes during treatment with functional appliances. *Am J Orthod Dentofacial Orthop.* 1996; 109:616–624. [PubMed Citation]
- 52. Janson I. Skeletal and dentoalveolar changes in patients treated with a Bionator during prepubertal and pubertal growth. In: McNamara JA Jr, Ribbens KA, Howe RP, eds. Clinical Alteration of the Growing Face. Monograph 14, Craniofacial Growth Series. Ann Arbor, Mich: Center for Human Growth and Development, University of Michigan; 1983.
- 53. Vargervik K, Harvold EP. Response to Activator treatment in Class II malocclusions. *Am J Orthod.* 1985; 88:242–251. [PubMed Citation]
- 54. Janson IA. A cephalometric study of the efficiency of the Bionator. Trans Eur Orthod Soc. 1977; 28:283–298.
- 55. Janson M, Hasund A. Functional problems in orthodontic patients out of retention. Eur J Orthod. 1983; 3:173–179.
- 56. Tsamtsouris A, Vedrenne D. The use of the Bionator appliance in the treatment of Class II, division 1 malocclusion in the late mixed dentition. *J Pedod.* 1983; 8:78–104. [PubMed Citation]
- 57. Bishara SE, Ziaja RR. Functional appliances: A review. Am J Orthod Dentofacial Orthop. 1989; 95:250–258. [PubMed Citation]
- 58. Bass NM. Orthopedic coordination of dentofacial development in skeletal Class II malocclusion in conjunction with edgewise therapy. Part I. *Am J Orthod.* 1983; 84:361–383. [PubMed Citation]

TABLES Return to TOC

TABLE 1. Descriptive Statistics: Sample Description*

Groups	Ň	Male	Female	Т,	T ₂	Average Treatment/ Observation
Controls	22	11	11	8y, 7m	9y, 8m	13m
FR-2	22	11	11:	9y	10y, 5m	17m

^{*} N indicates number of patients; T₁, starting forms; T₂, ending forms; y, years; m, months, and FR-2, function regulator of Fränkel.

TABLE 2. Comparison of Starting Forms^a

	Control (N = 22)		Fränkel (N = 22)			
Cephalometric . Measures	Mean	SD	Mean	SD	Signifi- cance	
Maxillary Skeletal SNA (°)	80.1	2.2	82.2	2.9		
CO-A (mm)	84.3	3.8	68.5	3.6	NS	
A–FHp (mm)	65.7	3.6	66.6	3.4	NS	
ANS-FHp (mm)	71.1	4.0	71.0	3.6	NS	
Mandibular Skeletal	/1.1	4.0	71.0	3.0	143	
SNB (°)	75.3	2.8	76.3	2.8	NS	
Ar–Go (mm)	40.5	3.3	41.5	4.3	NS	
Go-Gn (mm)	69.5	3.2	69.5	3.6	NS	
Ar-Gn (mm)	99.3	4.1	100.8	5.2	NS	
Co-Gn (mm)	103.4	4.6	106.1	6.2	NS	
B-FHp (mm)	56.3	5.2	56.8	5.4	NS	
Pog-FHp (mm)	56.8	5.4	57.8	6.2	NS	
Ar.GoMe (°)	128.1	4.8	129.5	4.2	NS	
Maxilla to mandible	120.1	4.0	123.0	7.4		
ANB (°)	4.8	1.6	5.8	1.7	NS	
NAP (°)	8.5	3.6	10.0	3.7	NS	
Vertical	0.0	0.0	10.0	0.7	110	
SN.GoMe (°)	35.5	3.6	34.8	4.0	NS	
SN.PP (°)	8.9	2.1	6.5	3.1	*	
LAFH (mm)	61.4	4.6	63.1	4.1	NS	
S-Go (mm)	66.9	4.6	69.4	6.1	NS	
Maxillary dental	00.0			• • •		
1.PP (°)	111.9	6.0	114.3	6.6	NS	
1.NA (°)	22.8	5.1	25.6	5.6	NS	
1-NA (mm)	4.3	1.5	6.0	1.4	**	
1-FHp (mm)	69.2	4.0	72.4	5.1	**	
6-PP (mm)	19.5	1.8	19.7	1.6	NS	
Mandibular dental						
IMPA (°)	94.5	6.4	94.4	6.5	NS	
1 to NB (°)	25.4	5.7	25.5	4.8	NS	
1 to N-B (mm)	4.4	1.3	5.2	1.1	NS	
1 to FHp (mm)	63.1	5.1	64.0	4.8	NS	
6 to GoMe (mm)	27.0	1.7	27.5	2.6	NS	
# SD indicator standard deviation: N. number of nationts; and NS						

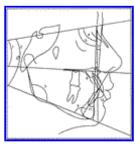
^a SD indicates standard deviation; N, number of patients; and NS, not significant. * $P \le .05$. ** $P \le .01$.

TABLE 3. Mean Changes (T_1 to T_2) Standardized to 13 Months^a

Cephalometric Measures Mean SD Mean SD Significance Maxillary Skeletal SNA (°) −0.1 1.5 −0.3 0.7 NS Co–A (mm) 1.9 2.9 1.3 1.3 NS A-FHp (mm) 0.4 1.2 0.5 0.9 NS ANS–FHp (mm) 0.4 1.4 0.8 0.9 NS Mandibular Skeletal SNB (°) 0.0 1.3 0.4 0.7 NS SNB (°) 0.0 1.3 0.4 0.7 NS Ar-Go (mm) 1.7 3.1 1.6 1.8 NS Go-Gn (mm) 0.7 1.6 1.7 1.2 * Ar-Go (mm) 2.0 1.6 3.1 1.4 ** Co-Gn (mm) 3.2 2.6 3.9 1.4 ** B-FHp (mm) 0.4 2.1 1.3 1.2 NS NarGoMe (°) 0.2 2.2 0.2 1.5 NS Maxi		Control (N = 22)		Fränkel (N = 22)		
SNA (°)		· · · · · · · · · · · · · · · · · · ·		*		Significance
SNA (°)	Maxillary Skeletal					
Co–A (mm)		-0.1	1.5	-0.3	0.7	NS
A-FHp (mm)						
ANS-FHp (mm)						
Mandibular Skeletal SNB (°)						
SNB (°)		0.4		0.0	0.0	
Ar-Go (mm)		0.0	1.3	0.4	0.7	NS
Go-Gn (mm)						
Ar-Gn (mm) 2.0 1.6 3.1 1.4 ** Co-Gn (mm) 3.2 2.6 3.9 1.4 * B-FHp (mm) 0.4 2.1 1.3 1.2 NS Pog-FHp (mm) 0.5 2.2 1.3 1.2 NS Ar.GoMe (°) 0.2 2.2 0.2 1.5 NS Maxilla to mandible ANB (°) -0.1 0.8 -0.8 1.1 * NAP (°) -0.6 2.0 -1.4 2.2 NS Vertical SN.GoMe (°) 0.2 1.2 0.2 1.3 NS SN.PP (°) -0.7 2.0 0.3 1.1 * LAFH (mm) 1.7 1.6 1.5 1.1 NS S-Go (mm) 2.3 2.0 2.2 1.2 NS Maxillary dental 1.PP (°) 0.0 4.4 -4.9 3.5 ** 1.NA (°) 0.9 4.3 -4.8 3.3 ** 1-NA (mm) 0.8 1.0 -1.1 1.1 ** 1-FHp (mm) 0.3 1.1 0.4 1.0 NS Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *						
Co-Gn (mm) 3.2 2.6 3.9 1.4 * B-FHp (mm) 0.4 2.1 1.3 1.2 NS Pog-FHp (mm) 0.5 2.2 1.3 1.2 NS Ar.GoMe (°) 0.2 2.2 0.2 1.5 NS Maxilla to mandible ANB (°) -0.1 0.8 -0.8 1.1 * NAP (°) -0.6 2.0 -1.4 2.2 NS Vertical SN.GoMe (°) 0.2 1.2 0.2 1.3 NS SN.PP (°) -0.7 2.0 0.3 1.1 * LAFH (mm) 1.7 1.6 1.5 1.1 NS S-Go (mm) 2.3 2.0 2.2 1.2 NS Maxillary dental 1.PP (°) 0.0 4.4 -4.9 3.5 ** 1.NA (°) 0.9 4.3 -4.8 3.3 ** 1-NA (mm) 0.8 1.0 -1.1 1.1 ** 1-FHp (mm) 0.3 1.1 0.4 1.0 NS Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS I to NB (°) 0.5 3.5 2.7 2.8 * I to N-B (mm) 0.4 1.0 0.8 0.7 * I to FHp (mm) 0.9 1.8 2.1 1.3 *						**
B-FHp (mm)						*
Pog-FHp (mm)						NS
Ar.GoMe (°)	,					
Maxilla to mandible ANB (°)					1.5	NS
ANB (°) -0.1 0.8 -0.8 1.1 * NAP (°) -0.6 2.0 -1.4 2.2 NS Vertical SN.GoMe (°) 0.2 1.2 0.2 1.3 NS SN.PP (°) -0.7 2.0 0.3 1.1 * LAFH (mm) 1.7 1.6 1.5 1.1 NS S-Go (mm) 2.3 2.0 2.2 1.2 NS Maxillary dental 1.PP (°) 0.0 4.4 -4.9 3.5 ** 1.NA (°) 0.9 4.3 -4.8 3.3 ** 1-NA (mm) 0.8 1.0 -1.1 1.1 ** 1-FHp (mm) 0.3 1.1 0.4 1.0 NS Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *						
NAP (°)	ANB (°)	-0.1	0.8	-0.8	1.1	*
Vertical SN.GoMe (°)						NS
SN.PP (°)						
LAFH (mm) 1.7 1.6 1.5 1.1 NS S-Go (mm) 2.3 2.0 2.2 1.2 NS Maxillary dental 1.PP (°) 0.0 4.4 -4.9 3.5 ** 1.NA (°) 0.9 4.3 -4.8 3.3 ** 1-NA (mm) 0.8 1.0 -1.1 1.1 ** 1-FHp (mm) 1.2 1.6 -0.6 1.2 ** 6-PP (mm) 0.3 1.1 0.4 1.0 NS Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *	SN.GoMe (°)	0.2	1.2	0.2	1.3	NS
S-Go (mm) 2.3 2.0 2.2 1.2 NS Maxillary dental 1.PP (°) 0.0 4.4 -4.9 3.5 ** 1.NA (°) 0.9 4.3 -4.8 3.3 ** 1-NA (mm) 0.8 1.0 -1.1 1.1 ** 1-FHp (mm) 1.2 1.6 -0.6 1.2 ** 6-PP (mm) 0.3 1.1 0.4 1.0 NS Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *	SN.PP (°)	-0.7	2.0	0.3	1.1	*
Maxillary dental 1.PP (°) 0.0 4.4 -4.9 3.5 ** 1.NA (°) 0.9 4.3 -4.8 3.3 ** 1-NA (mm) 0.8 1.0 -1.1 1.1 ** 1-FHp (mm) 1.2 1.6 -0.6 1.2 ** 6-PP (mm) 0.3 1.1 0.4 1.0 NS Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3		1.7	1.6	1.5	1.1	NS
1.PP (°) 0.0 4.4 -4.9 3.5 ** 1.NA (°) 0.9 4.3 -4.8 3.3 ** 1-NA (mm) 0.8 1.0 -1.1 1.1 ** 1-FHp (mm) 1.2 1.6 -0.6 1.2 ** 6-PP (mm) 0.3 1.1 0.4 1.0 NS Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *	S-Go (mm)	2.3	2.0	2.2	1.2	NS
1.NA (°) 0.9 4.3 -4.8 3.3 ** 1-NA (mm) 0.8 1.0 -1.1 1.1 ** 1-FHp (mm) 1.2 1.6 -0.6 1.2 ** 6-PP (mm) 0.3 1.1 0.4 1.0 NS Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *	Maxillary dental					
1-NA () 0.9 4.3 -4.6 3.3 1-NA () 0.8 1.0 -1.1 1.1 ** 1-FHp (mm) 1.2 1.6 -0.6 1.2 ** 6-PP (mm) 0.3 1.1 0.4 1.0 NS Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *	1.PP (°)	0.0	4.4	-4.9	3.5	**
7-NA (IIIII)	1.NA (°)	0.9	4.3	-4.8	3.3	**
6-PP (mm) 0.3 1.1 0.4 1.0 NS Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *	1-NA (mm)	0.8	1.0	-1.1	1.1	**
Mandibular dental IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *	1-FHp (mm)	1.2	1.6	-0.6	1.2	**
IMPA (°) 0.2 4.3 2.0 2.8 NS 1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *	6-PP (mm)	0.3	1.1	0.4	1.0	NS
1 to NB (°) 0.5 3.5 2.7 2.8 * 1 to N-B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *	Mandibular dental					
1 to N–B (mm) 0.4 1.0 0.8 0.7 * 1 to FHp (mm) 0.9 1.8 2.1 1.3 *	IMPA (°)	0.2	4.3	2.0	2.8	NS
1 to FHp (mm) 0.9 1.8 2.1 1.3 *	1 to NB (°)	0.5	3.5	2.7	2.8	*
1 to FHP (MM) 0.9 1.8 2.1 1.3	1 to N-B (mm)	0.4	1.0	0.8	0.7	
6 to GoMe (mm) 0.3 1.2 1.1 0.4 *						
	6 to GoMe (mm)	0.3	1.2	1.1	0.4	*

^a SD indicates standard deviation; N, number of patients; and NS, not significant.

FIGURES Return to TOC

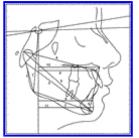


Click on thumbnail for full-sized image.

FIGURE 1. Angular measurements: (1) SN-PP; (2) SN-GoMe; (3) Ar-GoMe; (4) SNA; (5) SNB; (6) ANB; (7) NAP; (8) Upper Incisor-PP; (9) IMPA; (10) Upper Incisor-NA; (11) Lower Incisor-NB

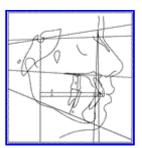
^{*} P ≤ .05.

^{**} *P* ≤ .01.



Click on thumbnail for full-sized image.

FIGURE 2. Skeletal linear measurements: (1) Ar-Go; (2) Go-Gn; (3) Ar-Gn; (4) Co-A; (5) Co-Gn; (6) LAFH; (7) S-Go; (8) A-FHp; (9)B-FHp; (10) ENA-FHp; (11) Pog-FHp



Click on thumbnail for full-sized image.

FIGURE 3. Dental linear measurements: (1) Upper Incisor-NA; (2) Lower Incisor-NB; (3) Upper Incisor-FHp; (4) Lower Incisor-FHp; (5) Upper Molar-PP; (6) Lower Molar-GoMe

^aAssociate Professor, Lins Dental School, Methodist University of Piracicaba, Lins City, São Paulo

^bFull Professor, Department of Orthodontics, Bauru Dental School, University of São Paulo, Brazil

^cAssistant Professor, Department of Orthodontics, Bauru Dental School, University of São Paulo and Full Professor at Lins Dental School, UNIMEP and at University of São Paulo City, São Paulo, Brazil

^dAssociate Professor, Department of Orthodontics, São José dos Campos Dental School, UNESP, Brazil

Corresponding author: Marcio Rodrigues de Almeida, Department of Orthodontics, Bauru Dental School, University of São Paulo, Alameda Octávio Pinheiro Brisolla, 9–75 Bauru—São Paulo, CEP: 17012-901 Brazil (E-mail: marcioralmeida@uol.com.br)

*Based on research submitted by Dr. Marcio Rodrigues de Almeida in partial fulfillment of the requirements for the PhD degree in Orthodontics, University of São Paulo, Bauru Dental School, Brazil.

*References 10, 26, 30, 34, 36, 39, 49, 50, 51.