European Journal of Orthodontics 26 (2004) 65–72
European Journal of Orthodontics vol. 26 no. 1

Treatment effects produced by the Bionator appliance. Comparison with an untreated Class II sample

Marcio R. Almeida*, José F. C. Henriques*, Renato R. Almeida*,
Renata R. Almeida-Pedrin* and Weber Ursi**
Departments of Orthodontics, *Bauru Dental School, University of São Paulo and **São José dos Campos Dental School, UNESP, Brazil

SUMMARY The purpose of this retrospective investigation was to evaluate the dentoalveolar and skeletal cephalometric changes of the Bionator appliance on individuals with a Class II division 1 malocclusion. Lateral cephalograms of 44 patients were divided into two equal groups. The control group comprised 22 untreated Class II children (11 males, 11 females), with an initial mean age of 8 years 7 months who were followed without treatment for a period of 13 months. The Bionator group (11 males, 11 females) had an initial mean age of 10 years 8 months, and were treated for a mean period of 16 months. Lateral cephalometric headfilms were obtained of each patient and control at the beginning and end of treatment.

The results showed that there were no changes in forward growth of the maxilla in the experimental group compared with the control group. However, the Bionator treatment produced a statistically significant increase in mandibular protrusion, and in total mandibular and body lengths. There were no statistically significant differences in craniofacial growth direction between the Bionator group and the control group, although the treated patients demonstrated a greater increase in posterior face height. The Bionator appliance produced labial tipping of the lower incisors and lingual inclination of the upper incisors, as well as a significant increase ($P < 0.01$) in mandibular posterior dentoalveolar height. The major effects of the Bionator appliance were dentoalveolar, with a smaller significant skeletal effect. The results indicate that the correction of a Class II division 1 malocclusion with the Bionator appliance is achieved not only by a combination of mandibular skeletal effects, but also by significant dentoalveolar changes.

Introduction

A common strategy in the treatment of Class II division 1 malocclusions is frequently aimed at correcting or masking the skeletal discrepancy. Several types of functional appliance are currently in use for Class II treatment aimed at improving existing skeletal imbalances, arch form and orofacial function (Almeida *et al*., 2002a, b) Among contemporary 'functional appliances', one of the most popular is the Bionator (Balters, 1964). Although few clinicians deny their clinical efficacy, proof of their growth-modifying effect remains elusive. Björk (1951), Harvold and Vargervik (1971), Nelson *et al.* (1993), and Pancherz (1984) stated that there is little evidence to support the claim that functional appliances significantly affect mandibular growth. However, a number of authors have suggested that mandibular growth can be increased with functional appliance treatment (Janson, 1977; Bolmgren and Moshiri, 1986; Op Heij *et al*., 1989; Jakobsson and Paulin, 1990; DeVincenzo, 1991; Mills, 1991; Cura *et al.*, 1996; Ghafari *et al.*, 1998; Illing *et al.*, 1998). Other studies are in agreement that the most significant treatment effects are restricted to dentoalveolar changes (Tulley, 1972; Robertson, 1983; Chadwick *et al.*, 2001). The purpose of this retrospective research was to evaluate cephalometrically the possible effects of the Bionator appliance on the skeletal and dentoalveolar components in patients presenting with a Class II division 1 malocclusion, using an untreated control sample with similar malocclusions for comparison.

Materials and method

Sample selection

Control sample. The control sample was obtained from the files of the Orthodontic Department longitudinal growth study at the Bauru Dental School, University of São Paulo, Brazil and comprised 22 subjects (11 males, 11 females) with Class II division 1 malocclusions with an initial mean age of 8 years 7 months (range 8 years to 9 years 3 months) and a final mean age of 9 years 8 months (range 8 years 11 months to 10 years 6 months). This sample had no previous orthodontic treatment and was observed for a period of 13 months (range 10 months to 2 years 1 month).

Bionator sample. The 22 patients (11 males, 11 females) treated with the Bionator for a mean period of 16 months presented an initial mean age of 10 years 8 months (range 8 years 10 months to 13 years) and a final mean age of 12 years (range 10–14 years). The patients were treated at the University of São Paulo, Bauru. These 22 subjects were selected from a sample of 35 patients based on the 'best' results obtained and compliance level from among the broader sample after 10 months of treatment. The patients were instructed to wear the appliances 24 hours a day, with the exception of eating and playing certain sports. The Bionator appliances were constructed according to Ascher (1977). To avoid labial tipping of the lower incisors, Janson and Noachtar (1998) recommended that the acrylic was extended to cover the incisal edges. The acrylic in the Bionator appliance was trimmed away in the posterior inferior region providing no contact with the lower posterior teeth. This procedure allows a greater vertical increase of the lower posterior teeth, and helps correct the overbite, the Class II molar relationship and the deep curve of Spee. McNamara *et al.* (1985) described this theory as the 'differential eruption principle of Harvold'. The mandible was brought forward 5.0 mm and opened the bite 5.0 mm from the intercuspal position. When necessary, a second appliance was constructed to re-advance the mandible until the overjet was eliminated.

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. The cephalograms were digitized (DT-11 digitizer, Houston Instruments, Austin, TX, USA) and the points/measurements are shown in Figures 1–4. The data were stored on a 586 Pentium IBM computer and analysed with the Dentofacial Planner 7.0 (Dentofacial Planner Software Inc., Toronto, Canada), which corrected the 6 per cent image magnification factor of the control and initial experimental group radiographs. The magnification of the experimental group radiographs was 9.2 per cent, as they were taken on different X-ray machines, and it was also corrected for enlargement.

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 Science, Chicago, IL, USA). The main purpose of this study was to conduct between-group comparisons of the various skeletal and dentoalveolar changes occurring during treatment. As 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 in the Bionator group were adjusted to the time interval of the control sample, namely 13 months, according to the protocols of Toth and McNamara (1999).

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 after approximately 1 month by the same examiner (MRA). The casual errors were assessed using Dahlberg's (1940) formula and systematic errors were ascertained using paired *t*-tests similar to the recommendations of Houston (1983). The casual error of the method (Dahlberg formula) did not exceed 0.77 degrees or 0.56 mm. Paired *t*-tests demonstrated statistically significant systematic error differences in only five measurements (SNB, SN.GoMe, IMPA, B–FHp and S–Go).

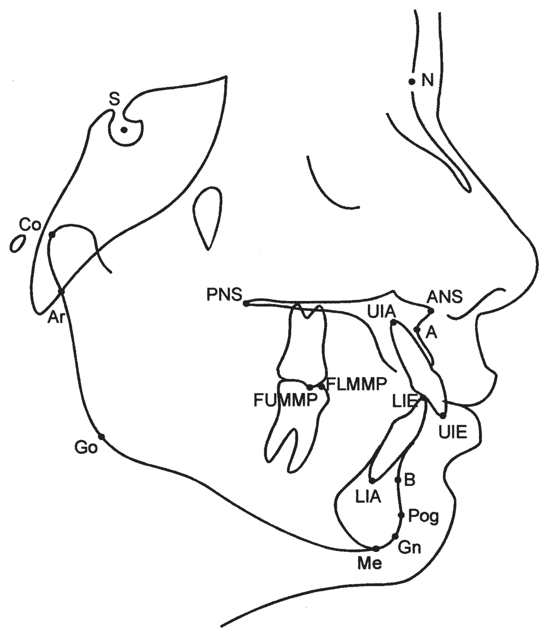

Figure 1 Cephalometric landmarks. Sella (S), midpoint of sella turcica; nasion (N), most anterior point of the frontonasal suture; subspinal (A), deepest concavity of the anterior maxilla; supramental (B), deepest concavity of the anterior mandibular symphysis; ANS, anterior nasal spine; PNS, posterior nasal spine; menton (Me), most inferior point on the mandibular symphysis; gonion (Go), most posterior inferior point of the angle of the mandible; gnathion (Gn), most anterior inferior point on the mandibular symphysis; pogonion (Pog), most anterior point of the bony chin; articulare (Ar), point at the junction of the posterior border of the ramus and the inferior border of the posterior cranial base; condylion (Co), most posterior superior point of the condyle; UIE, upper incisor edge; LIE, lower incisor edge; UIA, upper incisor apex; LIA, lower incisor apex; FUMMP, first upper molar mesial point; FLMMP, first lower molar mesial point.

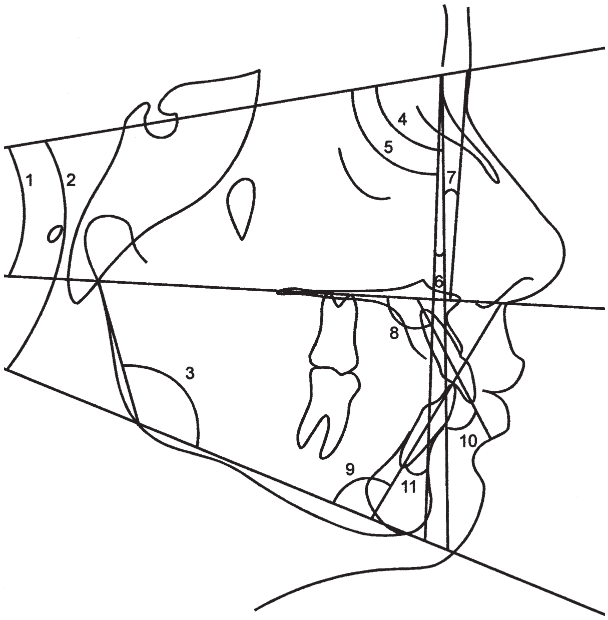

Figure 2 Angular measurements. 1, SN.PP (palatal plane–SN line); 2, SN.GoMe (mandibular plane–SN line); 3, Ar.GoMe (mandibular plane–ArGo line); 4, SNA (sella–nasion–A); 5, SNB (sella–nasion–B); 6, ANB (maxillary–mandibular relationship); 7, NAP (angle of convexity-intersection of line N–point A to point A–pogonion); 8, 1.PP (upper incisor long axis–palatal plane angle); 9, IMPA (lower incisor long axis–mandibular plane angle); 10, 1.NA (angle between upper incisor long axis–NA line); 11, $\bar{1}$.NB (angle between lower incisor long axis–NB line).

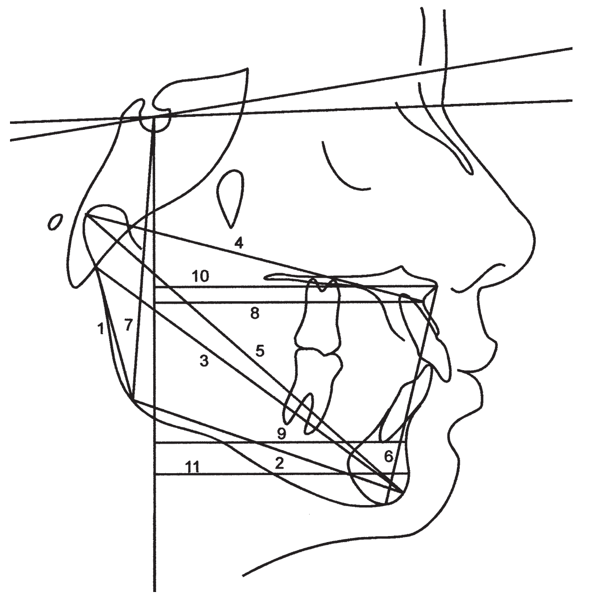

Figure 3 Skeletal linear measurements. 1, Ar–Go (distance between points Ar and Go); 2, Go–Gn (distance between points Go and Gn); 3, Ar–Gn (distance between points Ar and Gn); 4, Co–A (distance between points Co and A); 5, Co–Gn (distance between points Co and Gn); 6, LAFH (lower anterior face height); 7, S–Go (distance between points S and Go); 8, A–FHp (perpendicular distance between point A and the Frankfort perpendicular line); 9, B–FHp (perpendicular distance between point B and the Frankfort perpendicular line); 10, ANS–FHp (perpendicular distance between point ANS and the Frankfort perpendicular line); 11, Pog–FHp (perpendicular distance between point Pog and the Frankfort perpendicular line).

Descriptive statistics. Means and standard deviations (SD) for the two groups, isolated according to sex and then grouped together, were calculated for all cephalometric variables at T_1 and T_2. In addition, mean differences and SD were determined as well as mean differences and SD calculated for the adjusted 13 month interval for both groups.

Inferential statistics. The pre-treatment cephalometric measurements of the two groups (T_1) were compared using Student's *t*-test. Likewise the changes over the treatment/observation period were compared between the two groups using the same analysis.

Results

Comparison of pre-treatment cephalometric measurements (T_1)

The equivalence of the control and Bionator groups was examined by comparing pre-treatment cephalometric values (Table 1). In general, craniofacial evaluations, particularly linear measurements, tended, as expected, to favour the older group, comprising Bionator patients. Maxillary and mandibular sagittal positions compared favourably in the two groups, as well as the resulting ANB and NAP angles. The growth direction was predominantly vertical in both groups, with larger linear measurements for the Bionator group. The upper incisors were more proclined in the experimental group, while the lower incisors were not statistically significantly different for any of the measurements.

Analysis of treatment effects

The average interval between the pre- and post-treatment/observation cephalograms varied between groups (13 months in the control group and 16 months in the Bionator group). Statistical comparisons of the adjusted changes for the two groups are shown in Table 2.

Maxillary skeletal measurement. No statistically significant differences were observed between either group for any measurement. Therefore, no effect should be attributed to the Bionator appliance as it relates to its influence on maxillary sagittal growth and position.

Mandibular skeletal measurement. Mandibular size was significantly ($P < 0.05$ and $P < 0.01$) positively influenced in the Bionator group. The effective mandibular length (Co–Gn), increased 3.2 mm in the control group

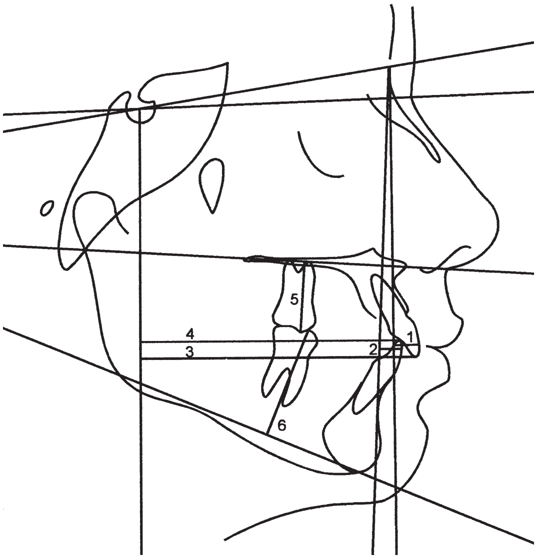

Figure 4 Dental linear measurements. 1, $\underline{1}$-NA (distance between the most anterior point of the upper central incisor and the NA line; a positive value was assigned when the structure was posterior to the line); 2, $\overline{1}$-NB (distance between the most anterior point of the lower central incisor and the NB line; a positive value was assigned when the structure was posterior to the line); 3, $\underline{1}$-FHp (perpendicular distance between the upper incisor edge and the Frankfort perpendicular line); 4, $\overline{1}$-FHp (perpendicular distance between the lower incisor edge and the Frankfort perpendicular line); 5, $\underline{6}$-PP (the perpendicular distance from the first upper molar mesial point to the palatal plane); 6, $\overline{6}$-GoMe (the perpendicular distance from the first lower molar mesial point to the palatal plane).

Table 1 Comparison of pre-treatment cephalometric measurements.

Cephalometric measures	Control (n = 22)		Bionator (n = 22)		Significance
	Mean	SD	Mean	SD	
Maxillary skeletal					
SNA (°)	80.1	2.2	81.7	2.8	NS
Co–A (mm)	84.3	3.8	90.0	3.8	**
A–FHp (mm)	65.7	3.6	68.5	3.4	*
ANS–FHp (mm)	71.1	4.0	74.1	3.7	*
Mandibular skeletal					
SNB (°)	75.3	2.8	75.9	2.5	NS
Ar–Go (mm)	40.5	3.3	42.5	3.3	NS
Go–Gn (mm)	69.5	3.2	72.8	5.2	*
Ar–Gn (mm)	99.3	4.1	104.4	5.3	**
Co–Gn (mm)	103.4	4.6	110.8	4.9	**
B–FHp (mm)	56.3	5.2	58.1	4.7	NS
Pog–FHp (mm)	56.8	5.4	58.7	5.7	NS
Ar.GoMe (°)	128.1	4.8	129.2	5.9	NS
Maxilla to mandible					
ANB (°)	4.8	1.6	5.7	1.9	NS
NAP (°)	8.5	3.6	10.0	5.1	NS
Vertical					
SN.GoMe (°)	35.5	3.6	35.6	4.7	NS
SN.PP (°)	8.9	2.1	7.8	2.5	NS
LAFH (mm)	61.4	4.6	65.4	4.2	*
S–Go (mm)	66.9	4.6	72.0	4.6	**
Maxillary dental					
$\underline{1}$.PP (°)	111.9	6.0	117.5	5.2	**
$\underline{1}$.NA (°)	22.8	5.1	27.9	5.6	*
$\underline{1}$-NA (mm)	4.3	1.5	6.7	1.9	**
$\underline{1}$-FHp (mm)	69.2	4.0	74.8	4.5	**
$\underline{6}$-PP (mm)	19.5	1.8	21.7	2.3	**
Mandibular dental					
IMPA (°)	94.5	6.4	94.0	6.3	NS
$\overline{1}$ to NB (°)	25.4	5.7	25.5	6.6	NS
$\overline{1}$ to N-B (mm)	4.4	1.3	5.6	2.2	NS
$\overline{1}$ to FHp (mm)	63.1	5.1	66.0	3.7	NS
$\overline{6}$ to GoMe (mm)	27.0	1.7	28.2	1.4	NS

SD, standard deviation.
NS, not significant; $*P \le 0.05$; $**P \le 0.01$.

and 4.9 mm in the Bionator group. These statistically significant differences between the two groups were also evident in the Ar–Gn, Go–Gn, B–FHP and Pog–FHP measurements. There was a significant difference between the groups in SNB angle, which was increased in the Bionator group.

Maxillomandibular measurements. Considering the maxillomandibular measurements (ANB, NAP), in the experimental group there was a reduction in the sagittal Class II discrepancy, while the control group remained basically unchanged. ANB angle was reduced by 1.4 degrees in the Bionator patients and remained unchanged in the control subjects. NAP angle showed a significant difference ($P < 0.01$) between groups, with a greater reduction in the Bionator group (2.8 degrees).

Vertical measurements. The mandibular plane orientation (SN.GoMe) was unaffected by treatment, while the palatal plane rotated significantly ($P < 0.05$) more clockwise in the treated group. It is interesting to note that the control group actually rotated counter-clockwise. No difference in the increase in lower anterior face height (LAFH) was noted between the groups. However, posterior face height (S–Go) increased significantly ($P < 0.01$) more in the Bionator group (3.7 mm) than in the controls (2.3 mm).

Maxillary dentoalveolar measurements. The upper dentoalveolar component was the single component that presented more significant changes, with incisor retraction of 5.5 degrees for $\underline{1}$.NA and approximately 1.4 mm for $\underline{1}$-NA (the control group moved forward 0.8 mm and the treated group back 1.4 mm). Vertically, the Bionator appliance did not inhibit upper molar eruption. Therefore, the upper molars did not differ significantly when extrusion to the palatal plane was evaluated.

Mandibular dentoalveolar measurements. No significant between-group differences in incisor mandibular plane angle (IMPA) were seen. However, the lower incisors

Table 2 Difference in mean changes (T_1 to T_2) standardized to 13 months.

Cephalometric measures	Control (n = 22)		Bionator (n = 22)		Significance
	Mean	SD	Mean	SD	
Maxillary skeletal					
SNA (°)	–0.1	1.5	0.0	1.2	NS
Co–A (mm)	1.9	2.9	1.5	2.0	NS
A–FHp (mm)	0.4	1.2	1.1	1.3	NS
ANS–FHp (mm)	0.4	1.4	1.1	1.6	NS
Mandibular skeletal					
SNB (°)	0.0	1.3	1.4	1.3	**
Ar–Go (mm)	1.7	3.1	3.1	2.7	NS
Go–Gn (mm)	0.7	1.6	2.0	1.9	*
Ar–Gn (mm)	2.0	1.6	4.9	2.4	**
Co–Gn (mm)	3.2	2.6	4.9	2.4	**
B–FHp (mm)	0.4	2.1	3.1	2.3	**
Pog–FHp (mm)	0.5	2.2	3.2	2.5	**
Ar.GoMe (°)	0.2	2.2	0.6	2.1	NS
Maxilla to mandible					
ANB (°)	–0.1	0.8	–1.4	0.9	**
NAP (°)	–0.6	2.0	–2.8	2.1	**
Vertical					
SN.GoMe (°)	0.2	1.2	–0.3	1.8	NS
SN.PP (°)	–0.7	2.0	0.2	1.3	*
LAFH (mm)	1.7	1.6	2.1	2.1	NS
S–Go (mm)	2.3	2.0	3.7	2.6	**
Maxillary dental					
$\underline{1}$.PP (°)	0.0	4.4	–5.2	4.3	**
$\underline{1}$.NA (°)	0.9	4.3	–5.5	4.3	**
$\underline{1}$-NA (mm)	0.8	1.0	–1.4	1.1	**
$\underline{1}$-FHp (mm)	1.2	1.6	–0.2	2.0	*
$\underline{6}$-PP (mm)	0.3	1.1	1.0	1.2	NS
Mandibular dental					
IMPA (°)	0.2	4.3	2.6	3.6	NS
$\overline{1}$ to NB (°)	0.5	3.5	3.7	3.9	**
$\overline{1}$ to N-B (mm)	0.4	1.0	1.3	1.0	**
$\overline{1}$ to FHp (mm)	0.9	1.8	4.0	2.3	**
$\overline{6}$ to GoMe (mm)	0.3	1.2	1.4	1.0	*

SD, standard deviation.
NS, not significant; *$P \leq 0.05$; **$P \leq 0.01$.

proclined significantly in the treated group, about 3 degrees more than in the controls or approximately 1.0 mm, depending on the variable evaluated. The lower molars extruded significantly more (1.4 mm) in the treatment group than in the controls (0.3 mm).

Discussion

Study design

To assess the effects of factors that influence craniofacial growth other than appliance therapy, it is necessary to have a control group. However, there does not appear to be an ideal control group for orthodontic appliance therapy. Various authors have either used patients treated with an alternative technique (Creekmore and Radney, 1983; Owen, 1986) or untreated Class II division 1 patients (Wieslander and Lagerström, 1979; Derringer, 1990; Chadwick *et al.*, 2001) and Class I patients who did not need treatment (Luder, 1981; Trenouth, 2000). Any retrospective study is likely to introduce bias by producing an inflated view of treatment outcome. It is difficult to select truly equivalent groups without random allocation of patients to control and treatment groups so that there are favourable odds that all groups are as alike as possible. This is not possible in a retrospective study and may raise ethical problems in a prospective study (Trenouth, 2000). While a prospective randomized clinical trial is the ideal approach for research into functional appliance effectiveness, this method still presents difficulties (Chadwick *et al.*, 2001). Bias can occur in prospective trials as a result of the loss to follow-up after randomization has taken place (Tulloch *et al.*, 1997) and there are also ethical problems in selecting control groups. Whatever control group is used, it must be remembered that facial growth varies at different ages, and between the sexes. In addition, differing amounts of natural growth would result from observation times of varying lengths. Matching the control group based on the composition of the treatment group seems to be the most satisfactory alternative to randomization. Only successfully treated cases were included in the investigation because, as with most retrospective studies, the patients who failed to complete treatment did not have a final cephalometric radiograph. This is believed to exaggerate the magnitude of treatment response because it cannot be assumed that patients who defaulted would have responded to treatment in the same way as successfully treated cases. The differences in outcome between the treated patients and the control group were attributed to the effects of treatment rather than to pre-existing differences because almost all cephalometric variables, sex, number of patients and observation period were matched. Because the length of treatment varied between the groups, a direct comparison of the cephalometric changes would be difficult to interpret. Thus, in order to conduct direct and meaningful comparisons, all cephalometric increments in the Bionator group were adjusted to the time interval of the control sample, namely 13 months, according to the protocols of Toth and McNamara (1999).

Comparison of treatment changes

Changes in maxillary skeletal component. There were no significant changes in any of the four variables used to evaluate maxillary growth in the Bionator group. This result is in agreement with Janson (1977), Janson and Hasund (1981), Bolmgren and Moshiri (1986) and Courtney *et al.* (1996), who also found no significant restriction of maxillary growth. In contrast, Pfeiffer and Grobéty (1975), Righellis (1983), Tsamtsouris and Vedrenne (1983), Derringer (1990) and Jakobsson and

Paulin (1990) noted some restrictive effect, particularly when SNA angle was investigated. However, Illing *et al.* (1998) stated that point A is a deep alveolar point rather than a true skeletal landmark. Mills (1991) pointed out that this effect could be related to lingual inclination of the upper incisors and the accompanying posterior remodelling of point A. It was concluded that the Bionator appliance did not produce any significant restriction of maxillary anterior growth.

Changes in the mandibular skeletal component. The findings suggest that functional appliance therapy results in an anterior relocation of the mandible. A statistically significant increase in mandibular protrusion and length was observed in patients treated with the Bionator. Measurements of mandibular length (Go–Gn, Ar–Gn, and Co–Gn) (Table 2) increased significantly more in the Bionator group. These differences were not only statistically, but also clinically, significant. In the experimental group, articulare to gnathion and condylion to gnathion lengths increased 4.9 mm during a standardized 13 month period. This finding of increased mandibular growth after functional appliance treatment is in agreement with the results of a number of investigations involving the Bionator/activator appliance (Janson, 1977; Bolmgren and Moshiri, 1986; Op Heij *et al.*, 1989; Jakobsson and Paulin, 1990; DeVincenzo, 1991; Mills, 1991; Cura *et al.*, 1996; Ghafari *et al.*, 1998), although others (Harvold and Vargervik, 1971; Pancherz, 1984; Nelson *et al.,* 1993) did not find such an increase. The control group, conversely, showed no such increase in SNB angle, in agreement with the results of Illing *et al.* (1998).

The more significant increase in mandibular length in the Bionator group may be attributed to the older average age of this sample compared with the controls. The initial mean age was 10 years 8 months and the final mean age was 12 years. The control group had an initial mean age of 8 years 7 months and a final mean age of 9 years 8 months. The more chronologically and probably skeletally mature Bionator sample could have been closer to the pubertal growth spurt compared with the control group. The individual variation in growth should also be considered.

There was no evidence of a morphological change in the mandible, as measured by the gonial angle (ArGoMe) between the Bionator group and the control group, in agreement with Schulhof and Engel (1982).

Changes in maxillomandibular skeletal relationship. The maxillomandibular relationship showed marked improvement in the experimental group compared with the controls (Table 2). Improvement in the basal bone relationship resulted from small changes in maxillary anterior growth and by an increase in anterior growth of the mandible in the Bionator group. Similar findings were found with Bionator/activator therapy by Hashim (1991), Courtney *et al.* (1996), and Tulloch *et al.* (1997, 1998). Changes in ANB angle in the treated group were a result of several small but cumulative effects upon the dentofacial structures associated with normal craniofacial growth, which were not sufficient to correct or improve the skeletal Class II relationship in the untreated group.

Vertical component. Righellis (1983), Jakobsson and Paulin (1990) and McNamara *et al.* (1990) reported that functional appliances do not change the craniofacial growth pattern, although face height has been noted to increase (Wieslander and Lagerström, 1979; Derringer, 1990). Although an increase in LAFH was observed in both groups, it must be stressed that there were no statistically significant differences between the control and experimental groups. Posterior face height (S–Go) showed a statistically significant difference between the groups, with a greater increase (3.7 mm) in the Bionator group compared with the controls (2.3 mm). This result is probably related to the posterior bite opening effect when the mandible was brought forward in the experimental group and the molars encouraged to erupt, a result also found by Lange *et al.* (1995).

As a result of the observed interplay of both anterior and posterior face heights, the mandibular plane (SN.GoMe) was not significantly affected. There was a greater tendency for a clockwise rotation of the maxillary plane (SNPP) during Bionator therapy compared with the control group, which did not adversely affect LAFH.

Maxillomandibular dentoalveolar components. The differences between the groups were most pronounced for the dentoalveolar variables. Bolmgren and Moshiri (1986) and Courtney *et al.* (1996) showed that almost all functional appliances produced lingual tipping of the maxillary incisors. In the control group, the upper incisors remained stable (0.0 degrees) relative to the palatal plane, whereas in the Bionator group the upper incisors demonstrated a greater retraction (–5.2 degrees) (Table 2). This effect was expected as the labial bow may come into contact with the incisors during appliance wear, particularly during sleep. Illing *et al.* (1998) previously reported that this is an expected treatment outcome of functional appliances due to their Class II ‘traction effect’.

In the control group, the lower incisors remained stable (0.5 degrees) relative to the nasion–B line. However, some proclination of the lower incisors was found to be produced by Bionator treatment (3.7 degrees) relative to the same line. This effect is probably consequent to the resultant mesial force on the lower incisors induced by protrusion of the mandible. This finding corroborates the results of Janson (1977) and Op Heij *et al.* (1989). However, Wieslander and Lagerström (1979) and Bolmgren and Moshiri (1986) reported that treatment with an activator/Bionator appliance does not produce an alteration in the position of the lower incisors. According to the results of the present study, care should be taken when the Bionator is used in patients with proclined mandibular incisors.

In the untreated group, the upper first molars extruded 0.3 mm, which was not statistically different from the Bionator (1.0 mm) group. However, vertical eruption of the lower first molars ($\overline{6}$-GoMe) was greater in the functional appliance group (Bionator, 1.4 mm) in comparison with the controls (0.3 mm). This effect has also been reported by Tsamtsouris and Vedrenne (1983).

It can be concluded that the contribution of dental and skeletal changes was 65 per cent to the overall changes in the experimental group. The major effects of the Bionator appliance were dentoalveolar, with a smaller significant skeletal effect. The results indicate that the correction of a Class II division 1 malocclusion with the Bionator appliance is achieved not only by a combination of mandibular skeletal effects, but also by significant dentoalveolar changes.

Conclusions

It was concluded that the skeletal and dental effects produced by the Bionator appliance were as follows:

1. There were no changes in forward growth of the maxilla in the experimental group compared with the control group.
2. Compared with the Class II controls, statistically significant increases in mandibular length were observed in the Bionator group (patients achieved an additional 1.7 mm of mandibular length).
3. There was a significant improvement in the antero-posterior relationship between the maxilla and the mandible in the Bionator group.
4. There were no statistically significant differences in craniofacial growth pattern or LAFH between the groups.
5. The Bionator appliance produced labial tipping and linear protrusion of the lower incisors as well as a lingual inclination and retrusion 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 Bionator group.

Address for correspondence

Marcio Rodrigues de Almeida
Department of Orthodontics
Bauru Dental School
University of São Paulo
Alameda Octávio Pinheiro Brisolla
9–75 Bauru—São Paulo
Brazil

References

Almeida M R, Henriques J F C Ursi W 2002a Comparative study of Fränkel (FR-2) and bionator appliances in the treatment of Class II malocclusion. American Journal of Orthodontics and Dentofacial Orthopedics 121: 458–466

Almeida M R, Henriques J F C, Almeida R R, Ursi W 2002b Treatment effects produced by Fränkel appliance in patients with Class II, division 1 malocclusion. Angle Orthodontist 72: 418–425

Ascher F 1977 The Bionator. In: Graber T M, Neumman B (eds) Removable orthodontic appliances. W.B. Saunders, Philadelphia, pp. 229–246

Balters W 1964 Die Technik und Übung der allgemeinen und speziellen Bionator-Therapie. Quintessenz 15: 77–85

Björk A 1951 The principle of the Andresen method of orthodontic treatment, a discussion based on cephalometric X-ray analysis of treated cases. American Journal of Orthodontics 37: 437–458

Bolmgren G A, Moshiri F 1986 Bionator treatment in Class II, division 1. Angle Orthodontist 56: 255–262

Chadwick S M, Aird J C, Taylor P J S, Bearn D R 2001 Functional regulator treatment of Class II division 1 malocclusions. European Journal of Orthodontics 23: 495–505

Courtney M, Harkness M, Herbison P 1996 Maxillary and cranial base changes during treatment with functional appliances. American Journal of Orthodontics and Dentofacial Orthopedics 109: 616–624

Creekmore T D, Radney L J 1983 Fränkel appliance therapy: orthopedic or orthodontic? American Journal of Orthodontics 83: 89–108

Cura N, Saraç M, Öztürk Y, Sürmeli N 1996 Orthodontic and orthopedic effects of Activador, Activator-HG combination, and Bass appliances: a comparative study. American Journal of Orthodontics and Dentofacial Orthopedics 110: 36–45

Dahlberg G 1940 Statistical methods for medical and biological students. George Allen and Unwin, London, pp. 122–132

Derringer K A 1990 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. British Journal of Orthodontics 17: 33–46

DeVincenzo J P 1991 Changes in mandibular length before, during, and after successful orthopedic correction of Class II malocclusions, using a functional appliance. American Journal of Orthodontics and Dentofacial Orthopedics 99: 241–257

Ghafari J, King G J, Tulloch J F C 1998 Early treatment of Class II, division 1 malocclusion—comparison of alternative treatment modalities. Clinical Orthodontics and Research 1: 107–117

Harvold E P, Vargervik K 1971 Morphogenetic response to Activator treatment. American Journal of Orthodontics 60: 478–490

Hashim H A 1991 Analysis of Activator treatment changes. Australian Orthodontic Journal 12: 100–104

Houston W J B 1983 The analysis of errors in orthodontic measurements. American Journal of Orthodontics 83: 382–390

Illing H M, Morris D O, Lee R T 1998 A prospective evaluation of Bass, Bionator and Twin Block appliances. Part I—the hard tissues. European Journal of Orthodontics 20: 501–516

Jakobsson S O, Paulin G 1990 The influence of activator treatment on skeletal growth in Angle Class II:1 cases. A roentgeno-cephalometric study. European Journal of Orthodontics 12: 174–184

Janson I 1977 A cephalometric study of the efficiency of the Bionator. Transactions of the European Orthodontic Society, pp. 283–298

Janson I, Noachtar R 1998 Functional appliance therapy with the Bionator. Seminars in Orthodontics 4: 33–45

Janson M, Hasund A 1981 Functional problems in orthodontic patients out of retention. European Journal of Orthodontics 3: 173–179

Lange D W, Kalra V, Broadbent Jr B H, Powers M, Nelson S 1995 Changes in soft tissue profile following treatment with the Bionator. Angle Orthodontist 65: 423–430

Luder H U 1981 Effects of activator treatment: evidence for the occurrence of two different types of reaction. European Journal of Orthodontics 3: 205–222

McNamara J A Jr, Bookstein F L, Shaughnessy T G 1985 Skeletal and dental changes following functional regulator therapy on Class II patients. American Journal of Orthodontics 88: 91–110

McNamara J A Jr, Howe R P, Dischinger T G 1990 A comparison of the Herbst and Fränkel appliances in the treatment of Class II malocclusion. American Journal of Orthodontics and Dentofacial Orthopedics 98: 134–144

Mills J R E 1991 The effect of functional appliances on the skeletal pattern. British Journal of Orthodontics 18: 267–275

Nelson C, Harkness M, Herbison P 1993 Mandibular changes during functional appliance treatment. American Journal of Orthodontics and Dentofacial Orthopedics 104: 153–161

Op Heij D G, Callaert H, Opdebeeck H M 1989 The effect of the amount of protrusion built into the Bionator on condylar growth and displacement: a clinical study. American Journal of Orthodontics and Dentofacial Orthopedics 95: 401–409

Owen A H 1986 Maxillary incisolabial responses in Class II, division 1 treatment with Fränkel and Edgewise appliances. Angle Orthodontist 56: 67–87

Pancherz H 1984 A cephalometric analysis of skeletal and dental changes contributing to Class II correction in Activator treatment. American Journal of Orthodontics 85: 125–134

Pfeiffer J P, Grobéty D 1975 The Class II malocclusion: differential diagnosis and clinical application of Activators, extraoral traction, and fixed appliances. American Journal of Orthodontics 68: 499–544

Righellis E G 1983 Treatment effects of Fränkel, Activator and extraoral traction appliances. Angle Orthodontist 53: 107–121

Robertson N R E 1983 An examination of treatment changes in children treated with the function regulator of Fränkel. American Journal of Orthodontics 83: 299–310

Schulhof R J, Engel G A 1982 Results of Class II functional appliance treatment. Journal of Clinical Orthodontics 16: 587–599

Toth L R, McNamara J A Jr 1999 Treatment effects produced by the Twin-block appliance and the FR-2 appliance of Fränkel compared with an untreated Class II sample. American Journal of Orthodontics and Dentofacial Orthopedics 116: 597–609

Trenouth M J 2000 Cephalometric evaluation of the Twin-block appliance in the treatment of Class II division 1 malocclusion with matched normative growth data. American Journal of Orthodontics and Dentofacial Orthopedics 117: 54–59

Tsamtsouris A, Vedrenne D 1983 The use of the Bionator appliance in the treatment of Class II, division 1 malocclusion in the late mixed dentition. Journal of Pedodontics 8: 78–100

Tulley W J 1972 The scope and limitations of treatment with the Activator. American Journal of Orthodontics 61: 562–577

Tulloch J F C, Phillips C, Koch G, Proffit W R 1997 The effect of early intervention on skeletal pattern in Class II malocclusion: a randomized clinical trial. American Journal of Orthodontics and Dentofacial Orthopedics 111: 391–400

Tulloch J F C, Phillips C, Proffit W R 1998 Benefit of early Class II treatment: progress report of a two-phase randomized clinical trial. American Journal of Orthodontics and Dentofacial Orthopedics 113: 62–72

Wieslander L, Lagerström L 1979 The effect of Activator treatment on Class II malocclusions. American Journal of Orthodontics 75: 20–26