

Stability of Class II treatment with the Bionator followed by fixed appliances

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ABSTRACT

Objective: This prospective study assessed the stability of Class II treatment with the Bionator, followed by fixed appliances, 10 years after treatment. Material and methods: The experimental group comprised 23 patients of both sexes (10 boys, 13 girls) at a mean initial age of 11.74 years (late mixed or early permanent dentitions), treated for a mean period of 3.55 years who were evaluated at three stages: initial (T1), final (T2) and long-term posttreatment (T3). A total of 69 lateral cephalograms were evaluated and 69 dental casts were measured using the PAR index. The difference between initial and final PAR indexes, the percentage of occlusal improvement obtained with therapy and the percentage of relapse were calculated, using the PAR index. The variables were compared by repeated measures analysis of variance (ANOVA) followed by Tukey tests. Results: The significant improvement in apical base relationship, the palatal inclination of the maxillary incisors and the labial inclination of the mandibular incisors, and the significant improvement in molar relationship and reduction of overjet and overbite, obtained with treatment, remained stable in the long-term posttreatment period. There was also significant improvement in the occlusal relationships which remained stable in the long-term posttreatment period. The percentage of occlusal improvement obtained was of 81.78% and the percentage of relapse was of 4.90%. Conclusions: Treatment of Class II division 1 malocclusions with the Bionator associated with fixed appliances showed to be stable in the long-term posttreatment period.

Key words: Orthodontics. Recurrence. Malocclusion. Angle Class II. Functional orthodontic appliances.

INTRODUCTION

The combined use of functional and fixed appliances for treatment of certain malocclusions, in determined periods of the growth, can generate greater outcomes than that achieved by the use of functional or fixed appliances separately. Orthodontists should, therefore, consider this possibility when dealing with multiple factors that determine a malocclusion¹⁹.

After its introduction in 1964, the Bionator has been the object of several investigations aimed to identify both the dentoalveolar and skeletal effects of this appliance. Most studies dealt with short-term outcomes of Bionator therapy by using various types of control groups (untreated Class I or Class II subjects)^{1,3,14}.

In general, correction of Class II, division 1 by combined orthopedic-orthodontic therapy is related to skeletal and dental factors. Retraction and uprighting of the maxillary incisors, associated with proclination of the mandibular incisors; increase in mandibular molar eruption; no skeletal modification of the maxilla and favorable increase in total mandibular length have been consistently described in cases treated with the Bionator¹⁶. However, these changes can be considered satisfactory only if they remain stable. Longitudinal studies show that changes achieved with active treatment tend to undergo relapse toward the original malocclusion in the years following the end of orthodontic treatment²⁷. The relationship between teeth and bone bases does not necessarily remain constant over the years, but can often be changed during

growth. It is possible that many orthodontic relapse cases represent only the results of an unfavorable posttreatment growth²⁷. In addition, bucofacial muscles exert a great influence on the development of the face and teeth. After the correction of Class II malocclusion, the final disposition of the teeth is a reflection of the result of the interaction of hard and soft tissues². Many orthodontists believe that it is possible to prevent relapse by positioning teeth in harmony with the lips, cheeks and tongue; eliminating harmful habits, using appropriate retention and establishing a favorable occlusion¹¹.

Therefore, because stability is known to be the fundamental key to the successful outcome of orthodontic treatment, this prospective study investigated stability of the occlusal and dentoskeletal changes 10 years after treatment with the Bionator, followed by fixed appliances.

MATERIAL AND METHODS

This study was approved by the Ethics in Research Committee of Bauru School of Dentistry, and all subjects signed informed consent.

The sample size was calculated based on an alpha significance level of 0.05 and a beta of 0.2 to achieve 80% of power to detect a mean difference of 0.5° with a standard deviation of 0.5° in ANB angle change between the posttreatment and

long-term posttreatment stages¹⁰. The sample size calculation showed that 9 patients were needed, and to increase the power even more it was decided to select 23 patients for the experimental group.

Therefore, 69 lateral cephalometric headfilms and dental casts of 23 Class II division 1 malocclusion patients (10 male; 13 female) who were treated with Balters' Bionator followed by fixed appliances, were collected from the files of the Orthodontic Department at Bauru School of Dentistry, University of São Paulo.

The sample was selected according to the following inclusion criteria: in the late mixed or early permanent dentitions; at least half-cusp bilateral Class II molar relationship and 5 mm of overjet; absence of agenesis, supernumerary or lost teeth; convex profile; without history of previous orthodontic treatment³⁰. No cephalometric characteristic was considered as inclusion criteria.

The treatment protocol consisted of Class II correction with the Bionator during a mean period of 1.52 years (S.D.=0.79, range from 0.41 to 3.08 years) (Table 1) constructed with coverage of the mandibular incisors (Figure 1), followed by a mean period of 1.76 years (S.D.=0.94, range from 0.56 to 4.45 years) (Table 1) of fixed appliance therapy, after correction of the Class II anteroposterior discrepancy, for leveling and alignment of the teeth and to refine the occlusion. In all cases,

Table 1- Mean, standard deviation (SD), minimum and maximum values of the ages at T1, T2 and T3 and of the treatment with the Bionator, fixed appliance, and both (T1-T2) and long-term posttreatment (T2-T3) periods

	Mean	Minimum	Maximum	SD
T1 age	11.74	9.92	14.42	1.30
T2 age	15.38	13.00	19.50	1.69
T3 age	24.99	18.83	32.92	3.37
Bionator period	1.52	0.41	3.08	0.79
Fixed Appliance period	1.76	0.56	4.45	0.94
T1-T2 period	3.55	1.08	7.33	2.14
T2-T3 period	9.91	5.00	17.42	3.66

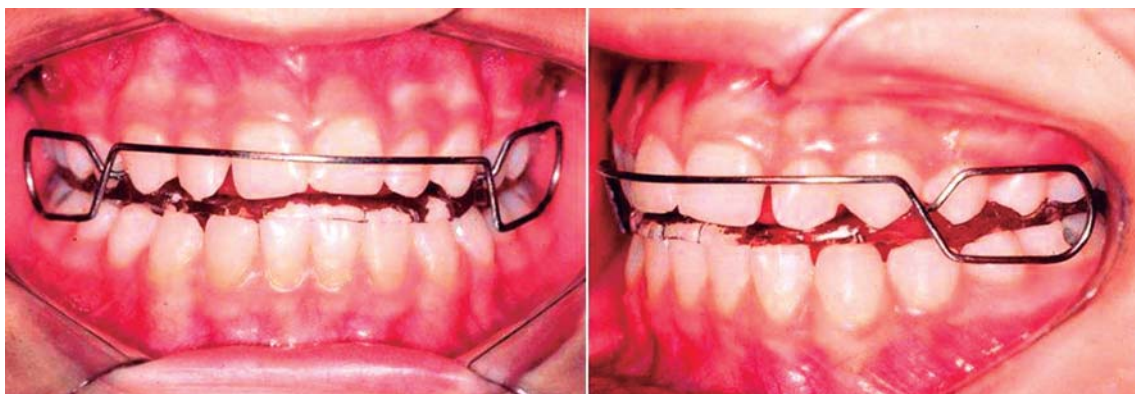


Figure 1- Balters' Bionator with coverage of the mandibular incisors

after correction with the Bionator, active retention was made with Class II intermaxillary elastics. After comprehensive treatment, each patient was given a fixed mandibular canine-to-canine retainer and a Hawley plate. Maxillary removable Hawley retainers were worn all day long for 6 months and only during sleeping for additional 6 months, and mandibular fixed canine-to-canine retainers were used for a minimum period of five years or until the end of growth.

The patients were evaluated at three stages (Table 1): initial (T1), final (T2), and long-term posttreatment (T3). The mean initial age was 11.74 years (S.D.=1.30, range 9.92 to 14.42), the mean final age was 15.38 years (S.D.=1.69, range 13.00 to 19.50 years) and the mean age at the long-term posttreatment stage was 24.99 years (S.D.=3.37, range 18.83 to 32.92 years). All patients were treated non-extraction for a mean period of 3.55 years (S.D.=2.14; range 1.08 to 7.33 years).

As this research aimed to investigate treatment stability, the selected subjects had to have been out of treatment for five years, at least. The mean long-term posttreatment period was 9.91 years (S.D.=3.66, range 5.00 to 17.42 years).

The anatomic tracing and location of dentoskeletal landmarks were manually carried out by a single investigator (M.F.F.) and digitized (Numonics AccuGrid XNT, model A30TL.F - Numonics Corporation, Montgomeryville, Penn, USA). These data were then stored in a computer and analyzed with Dentofacial Planner 7.2 (Dentofacial Planner Software Inc., Toronto, Ontario, Canada). This software also corrected the magnification factor (6% and 9.8%) of the radiographic images and calculated the angular and linear cephalometric variables employed in this study. The unusual cephalometric variables are illustrated in Figures 2 and 3.

The peer assessment rating (PAR) index²³ was

LAFH (mm)- Linear distance between ANS and Me points (ANS anterior nasal spine, Me menton point).
S-Go (mm)- Linear distance between S and Go points (S sella point, Go gonion point).
1-NA (mm)- Linear distance between the most anterior point of maxillary central incisor and the NA line.
1.NA (°)- Angle formed by the maxillary incisor long axis and the NA line.
1-NB (mm)- Linear distance between the most anterior point of mandibular central incisor and the NB line.
1.NB (°)- Angle formed by the mandibular incisor long axis and the NB line.
Nasolabial angle (°)- Angle formed by the Prn'-Sn line and UL-Sn' line (Prn' pronasal point, Sn subnasal point, UL upper lip).

Figure 2- Definitions of abbreviations of unusual cephalometric variables used^{12,18,24,28}

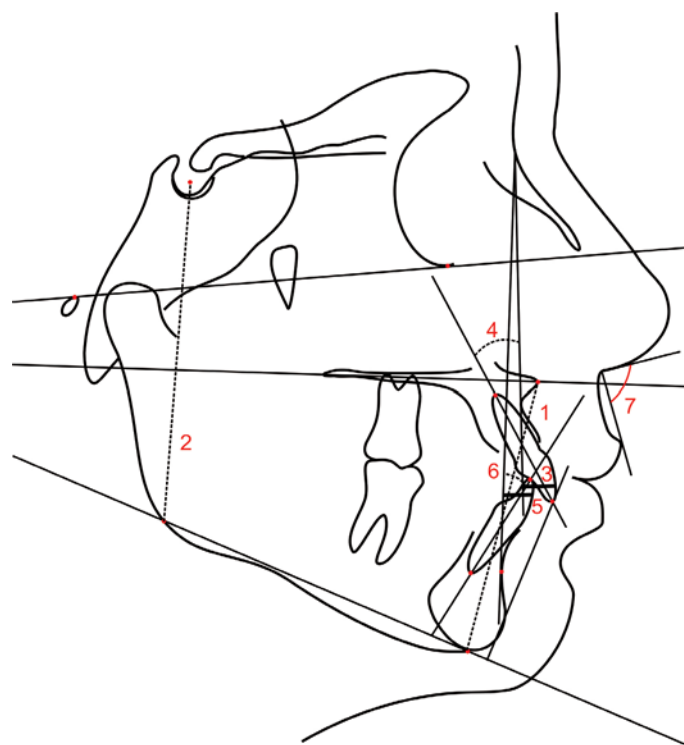


Figure 3- Cephalometric variables: 1) LAFH; 2) S-Go; 3) 1-NA; 4) 1.NA; 5) 1-NB; 6) 1.NB; 7) Nasolabial angle

calculated on the dental casts of each patient according to the American weightings suggested by De Guzman, et al.⁶ (1995). The index was ranked by scores for molar and premolar anteroposterior (AP) relationship, overjet (OJ), overbite (OB), crowding and midline to quantify the initial malocclusion severity (PAR1), the treatment occlusal results (PAR2), the occlusal status at the long-term posttreatment stage (PAR3), the amount of treatment (PAR1-PAR2) and long-term posttreatment changes (PAR3-PAR2) and the percentage of PAR treatment and long-term posttreatment changes^{6,23}, which are better estimates of the occlusal changes¹⁰.

Error study

Twenty four lateral cephalograms and dental casts were randomly selected, retraced, redigitized, and remeasured by the same examiner (M.F.F.) after a 30-day interval. Casual and systematic errors were calculated comparing the first and second measurements with Dahlberg's formula⁵ and dependent t-tests, respectively, at a significance

level of 5%.

Statistical analyses

Normal distribution was evaluated with Kolmogorov-Smirnov tests. Because all variables showed normal distribution, repeated measures ANOVA, followed by Tukey tests were used to compare the variables at the three stages. The statistical tests were performed with Statistica software (Statistica for Windows 6.0; Statsoft, Tulsa, Okla, USA). Results were considered significant for $P < 0.05$.

RESULTS

Only 3 (SN.GoGn, S-Go and 6-PP) of the 16 evaluated variables showed statistically significant systematic errors, and no variable showed casual errors greater than 1.0 mm or 1.5°.

There were no significant changes in the maxillary component with treatment, but there was significant increase in the effective maxillary length in the long-term posttreatment period (Table 2). Treatment

Table 2- Comparison of the cephalometric variables at the three stages (repeated measures ANOVA followed by Tukey tests)

Variable	Initial (T1) Mean (SD)	Final (T2) Mean (SD)	Long-term PT (T3) Mean (SD)	P
Maxillary Skeletal Component				
SNA (°)	82.59 (2.75) ^A	81.63 (2.74) ^A	82.10 (3.43) ^A	0.180
Co-A (mm)	81.51 (4.26) ^A	82.83 (5.40) ^A	86.05 (4.10) ^B	0.000*
Mandibular Skeletal Component				
SNB (°)	76.85 (3.24) ^A	78.63 (3.20) ^B	79.16 (3.88) ^B	0.000*
Co-Gn (mm)	99.64 (4.79) ^A	107.81 (6.75) ^B	112.07 (6.32) ^C	0.000*
Maxillomandibular Relationship				
ANB (°)	5.68 (2.72) ^A	3.01 (2.42) ^B	2.93 (2.73) ^B	0.000*
Facial Pattern				
SN.GoGn (°)	30.52 (4.89) ^A	30.47 (6.47) ^A	28.43 (6.96) ^B	0.008*
Vertical Component				
LAFH (mm)	58.32 (4.72) ^A	62.92 (5.09) ^B	64.70 (6.28) ^C	0.000*
S-Go (mm)	66.55 (4.94) ^A	73.27 (6.58) ^B	77.20 (7.77) ^C	0.000*
Maxillary Dentoalveolar Component				
1-NA (mm)	5.41 (2.76) ^A	4.96 (2.74) ^A	5.04 (2.95) ^A	0.706
1.NA (°)	31.94 (6.04) ^A	27.68 (6.56) ^B	26.84 (7.14) ^B	0.000*
Mandibular Dentoalveolar Component				
1-NB (mm)	3.37 (2.40) ^A	5.53 (2.46) ^B	5.00 (2.38) ^B	0.000*
1.NB (°)	26.40 (5.66) ^A	31.06 (5.71) ^B	29.16 (5.83) ^{AB}	0.002*
Dental Relationships				
Molar Rel. (mm)	1.17 (1.93) ^A	-3.27 (0.61) ^B	-2.95 (0.46) ^B	0.000*
Overjet (mm)	8.61 (2.34) ^A	3.22 (0.70) ^B	3.80 (1.17) ^B	0.000*
Overbite (mm)	4.17 (1.84) ^A	2.27 (0.97) ^B	2.78 (1.10) ^B	0.000*
Soft tissue Component				
Nasolabial angle (°)	109.79 (9.45) ^A	112.01 (11.92) ^A	110.06 (10.42) ^A	0.523

*Significant at $P < 0.05$; SD= Standard Deviation

Table 3- Comparison of the occlusal statuses at the three stages (repeated measures ANOVA followed by Tukey tests)

Variable	Initial (T1)	Final (T2)	Long-term Posttreatment (T3)	P
	Mean (SD)	Mean (SD)	Mean (SD)	
PAR	30.13 (5.90) ^A	5.39 (3.39) ^B	5.60 (4.55) ^B	0.000*

*Significant at P<0.05; SD= Standard Deviation

Table 4- Results of the peer assessment rating (PAR) index changes during treatment and during the long-term posttreatment period

Variable	Mean	SD
IPAR – FPAR	24.73	6.64
long-term PAR – FPAR	0.21	2.62
Percentage of PAR treatment changes	81.78%	11.26
Percentage of PAR long-term posttreatment changes	4.90%	12.26

PAR=peer assessment rating; SD=Standard Deviation

produced a significant increase in mandibular protrusion and in the effective mandibular length, which also significantly increased in the long-term posttreatment period. These changes contributed to a significant improvement in apical base relationship, which remained stable. The facial pattern angle remained stable with treatment but significantly reduced in the long-term posttreatment period. There were significant increases in anterior and posterior face heights with treatment and in the long-term posttreatment period. The maxillary incisors presented a significant palatal inclination and remained stable afterwards. The mandibular incisors presented significant labial inclination and protrusion which remained stable afterwards. Treatment also produced significant improvement in molar relationship and reduction of overjet and overbite, which remained stable in the long-term posttreatment period.

There was significant reduction of the PAR index during treatment which remained stable in the long-term posttreatment period (Table 3). The percentage of occlusal improvement obtained with treatment was 81.78% and the percentage of occlusal relapse was 4.90% (Table 4).

DISCUSSION

Sample and methodology

Even though the Bionator has been part of routine functional appliance therapy for nearly four decades, surprisingly few methodologically sound clinical studies of this treatment approach, at least by today's standards, have appeared in the orthodontic literature^{3,14}. Although several cephalometric investigations on the short-term treatment effects of the Bionator appliance in growing subjects with Class II malocclusion have been published^{3,14,26}, no previous research has

dealt with the issue of long-term response to this type of therapy. Since stability is known to be the fundamental key to successful outcome of orthodontic treatment, this prospective study investigated the stability of dentoskeletal changes 9.91 years after treatment with Balters' Bionator, followed by fixed appliances. Consequently, the results are due to several effects of the Balters' Bionator associated with fixed appliances.

The absence of a control group is a shortcoming of the present study. Nevertheless, relevant information can still be obtained in the long-term posttreatment period.

Maxillary component

There were no significant changes in any of the two variables used to evaluate the maxillary component between the initial (T1) and final (T2) stages (Table 2). These results are in agreement with previous studies that also found no significant restriction of maxillary growth with Bionator treatment^{3,14}. Only changes in the effective maxillary length showed a statistically significant increase in the long-term posttreatment stage, which were possibly consequent to normal growth and development.

Mandibular component

A statistically significant increase in mandibular protrusion and length was observed during treatment, which is in agreement with the results of a number of investigations involving the Bionator/activator appliance^{1,3,8,14} (Table 2). Mandibular length continued to significantly increase in the posttreatment period probably consequent to normal growth. This can contribute to stability of Class II relationship correction, but it did not contribute to further significant increase in mandibular protrusion.

Maxillomandibular relationship

The maxillomandibular relationship showed significant improvement during treatment and remained stable in the long-term posttreatment period (Table 2). Improvement in basal bone relationship during treatment resulted from the significant mandibular growth and protrusion, as previously discussed. Similar findings were obtained with the Bionator/activator therapy^{1,29}. Most important is that the maxillomandibular relationship achieved with Bionator treatment remained stable in the long-term posttreatment period, similarly to non-extraction Class II malocclusion treatment with other appliances²².

Facial pattern

The mandibular plane angle was unaffected during treatment¹⁷, while in the long-term posttreatment period it experienced a counterclockwise rotation. Growth that usually takes place in the long-term posttreatment period is characterized by mandibular counterclockwise rotation in response to vertical redirection of condylar growth²⁰ (Table 2).

Vertical component

Lower anterior face height and posterior face height significantly increased during treatment and in the posttreatment period (Table 2). Usually, during treatment with a functional appliance they significantly increase more than a control group and this is regarded as an effect of these appliances^{3,13}. However, the significant increase in the posttreatment period can only be regarded as consequent to normal growth and development⁷.

Maxillary dentoalveolar component

The maxillary incisors were palatally tipped during treatment and remained stable in the long-term posttreatment period (Table 2). Palatal movement of the maxillary incisors with the use of the Bionator associated to fixed appliances has already been described in several studies which showed that almost all functional appliances produce palatal tipping of the maxillary incisors^{3,9,14,22}.

There was stability of the sagittal position of the maxillary incisors as observed in the long-term posttreatment stage, which is similar to non-extraction treatment with other appliances^{9,13,22}.

Mandibular dentoalveolar component

Proclination of the mandibular incisors was produced by the Bionator associated to fixed appliances treatment and remained stable at the long-term posttreatment stage (Table 2). The proclination effect is probably consequent to the resultant mesial force on the mandibular incisors induced by mandibular protrusion. This finding corroborates the results of previous reports¹⁴. It is

interesting to notice that even if some proclination of the mandibular incisor occurs in non-extraction Class II malocclusion treatment, it is able to remain stable, as also observed with other treatment modalities^{9,13,22}.

Dental relationships

There was significant molar relationship correction with treatment, which remained stable at the long-term posttreatment stage²¹ (Table 2). Many studies showed the same treatment effects and stability with other orthopedic appliances¹⁵.

There was decrease in the overjet during treatment and no significant relapse was observed during the long-term posttreatment stage (Table 2). Probably, stability of the sagittal changes of the maxillary and mandibular incisors contributed to stability of the overjet correction. Reduction of the overjet was reported in several studies considering appliances with similar mode of action^{3,9,15,22}. Overjet correction was obtained mainly by palatal movement of the maxillary incisors, proclination of mandibular incisors and mandibular normal growth⁹.

The overbite significantly decreased during treatment and remained stable at the long-term posttreatment stage²¹ (Table 2). Similar findings were obtained with other functional appliance therapies¹⁵.

Soft tissue component

Despite the significant dentoskeletal changes to correct Class II malocclusion with the Bionator, there was no significant change in the nasolabial angle¹⁷. This has also been observed with other functional appliances¹⁵. Consequently, there was also stability of the nasolabial angle in the posttreatment period, as observed with other functional appliances^{15,22} as well as with other non-extraction treatment modalities⁸.

Occlusal results

The analysis of the dental casts showed that the values of the PAR index presented a statistically significant reduction with an excellent outcome⁴, and remained stable at the long-term posttreatment stage (Table 3). There are few studies in the literature evaluating the long-term posttreatment period through the PAR index³¹.

According to final PAR categories suggested by Richmond, et al.²³ (1992), when the value obtained at the end of treatment is equal to or less than 5, the occlusion can be considered to be almost perfect. Patients finished the orthodontic treatment with an average PAR of 5.39, and remained stable (average PAR of 5.60) in the long-term posttreatment period (Table 3). This shows that their occlusions were close to ideal in most patients even 10 years after

the end of treatment.

The percentage of occlusal improvement obtained with this therapy was of 81.78%, which is above the value suggested by Richmond, et al.²³ (1992) and De Guzman, et al.⁶ (1995), of 70% and 65%, respectively (Table 4). In agreement with these results, Rodriguez, Hirschheimer and Vigorito²⁵ (2001) found 55.4% of improvement using only the Bionator in Class II division 1 malocclusion treatment, showing its efficacy in growing patients.

The percentage of relapse obtained with this therapy was of 4.90% implying that stability can be achieved with this type of orthopedic-orthodontic treatment, as with other functional appliances^{3,9,15,22} (Table 4).

CONCLUSIONS

Treatment of Class II division 1 malocclusions with the Bionator associated to fixed appliances showed to be stable in the long-term posttreatment period.

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