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## Skeletal and dental changes induced by bionator in early treatment of class II

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**ABSTRACT.** The purpose was to investigate the amount of skeletal and dentoalveolar changes after early treatment of Class II, Division 1 malocclusion with bionator appliance in prepubertal growing patients. Forty Class II patients were divided in two groups. Treated group consisted of 20 subjects treated consecutively with bionator. Mean age at the start of treatment (T0) was 9.1 years, while it was 10.6 years at the end of treatment (T1). Mean treatment time was 17.7 months. Pretreatment and post-treatment cephalometric records of treated group were evaluated and compared with a control group consisted of 20 patients with untreated Class II malocclusion. Intergroup comparisons were performed using Student's t-tests and chi-square test with Yates' correction at a significance level of 5 per cent. Bionator appliance was effective in generating differential growth between the jaws. Cephalometric skeletal measurements ANB, WITS, Lfah, Co-A and dental L6-Mp, U1.Pp, IslI, OB, OJ showed statistically significantly different from the control. Bionator induced more dentoalveolar changes than skeletal during treatment in prepubertal stage.

**Keywords:** activator appliances, malocclusion, cephalometry.

## Alterações esqueléticas e dentárias induzidas pelo bionator no tratamento precoce da classe II

**RESUMO.** Este estudo quantificou as alterações esqueléticas e dentoalveolares no período pré-puberal de crescimento após o tratamento da má oclusão de classe II, divisão 1 com bionator. Quarenta pacientes classe II foram divididos em dois grupos. Um grupo com 20 pacientes tratados consecutivamente com bionator. A média de idade no início do tratamento (T0) foi de 9,1 anos, enquanto ao final (T1) foi de 10,6 anos. O tempo médio de tratamento foi de 17,7 meses. Os dados cefalométricos antes e após o tratamento foram avaliados e comparados com um grupo controle de 20 pacientes com má oclusão de classe II, divisão 1 não tratada. A comparação intergrupo foi realizada pelo teste t de Student e teste qui-quadrado com correção de Yates para um nível de significância de 5 por cento. O aparelho foi efetivo em gerar diferencial de crescimento entre os arcos dentários. As medidas cefalométricas esqueléticas ANB, WITS, Lfah, Co-A e as dentárias L6-Mp, U1.Pp, IslI, OB, OJ demonstraram diferença estatística significativa entre os grupos. O bionator induziu maiores alterações dentoalveolares que esqueléticas no tratamento da classe II, divisão 1 durante o período pré-puberal.

**Palavras-chave:** aparelhos ativadores, má oclusão, circunferência craniana.

### Introduction

The Balters Bionator is a functional appliance designed and introduced by Wilhelm Balters in 1960 and is still one of many functional removable appliances used for correction of Class II division 1 malocclusions (Illing, Morris, & Lee, 1998; Rudzki-Janson & Noachtar, 1998; Ahn, Kim, & Nahm, 2001). There are various reasons for bionator use, but the main reason is its low cost and simplicity of its construction. In developing countries, these reasons have a positive social influence and this

benefit from bionator treatment can have a wide societal scope.

Bionator is a tooth-borne appliance that moves mandible anteriorly and a new postural position of mandibular arch is achieved, improving the maxillomandibular relationship (Faltin et al., 2003; Marsico, Gatto, Burrascano, Matarese, & Cordasco, 2011). Moreover, it has been reported that it produces significant changes in dental and skeletal facial structures through a repositioning of mandible in a more protrusive position, control of overbite,

modification of dental eruption and improvement of profile (Flores-Mir & Major, 2006).

All aspects of genetically determined individual growth patterns are important in functional orthopedics, most especially time, potential, and direction of growth (Bishara, Peterson, & Bishara, 1984; Kreig, 1987; Cozza, Baccetti, Franchi, Toffol, & McNamara, 2006). While there is minimal skeletal growth during prepubertal period, significant growth occurs during puberty, but with great individual variation (Silveira, Fishman, Subtelny, & Kassebaum, 1992; Moore, 1997). Early functional orthopedic intervention in prepubertal period is used to prevent damage to erupting teeth and to normalize jaw development (Omblus, Malmgren, & Hagg, 1997; Martins, Martins, & Buschang, 2008).

The objective of this study was to evaluate the amount of skeletal and dentoalveolar modification produced by bionator appliance in a sample of subjects with Class II, Division 1 malocclusion treated before the pubertal peak of mandibular growth.

## Material and methods

This retrospective study was conducted in Orthodontics department at Araraquara Dental School, Universidade Estadual Paulista (FOAr-Unesp), after approval by the local Institutional Review Board.

Individuals were selected based on the following criteria: Class II facial pattern associated with mandibular retrusion, Class II division 1 malocclusion, mixed dentition, absence of severe crowding in mandibular arch and transverse problems.

To determine skeletal Class II division 1 malocclusion were clinically analyzed face and occlusion. Facial analysis observed the convex profile, straight nasolabial angle, short mentocervical line and occlusion analysis the molar and canines in Class II, equal to or higher than the half of a cusp, and overjet equal to or greater than 5mm. Exclusion criteria were syndrome patients, extreme vertical growth pattern and prior orthodontics treatment.

Bionator utilized in this study had the lingual portion of acrylic in mandibular arch extended apically two to three millimeters (mm) more than originally recommended to provide a better skeletal effect. Anteriorly, the acrylic touched the alveolar process and extended over the edges of the incisors, covering a small portion of the labial surface. The buccal shield served as an active element if needed. Construction bite was taken into an edge-to-edge

relationship of maxillary and mandibular incisors, regardless of the amount of overjet. Patients were instructed to use the appliance for at least 16 to 18 hours a day. Once correction was achieved and confirmed by mandibular manipulation, they used bionator only during sleep, eight to ten hours a day. Patients were seen monthly for any necessary adjustments.

Cephalometric records of 40 Class II, division 1 caucasian subjects with Class II malocclusion before pubertal peak of mandibular growth were evaluated. Skeletal maturity was evaluated by means of the cervical vertebrae maturation method (O'reilly & Yanniello, 1988).

Treated group (TG) consisted of 20 subjects (10 female and 10 male) were collected at Orthodontics department at the Araraquara Dental School, Universidade Estadual Paulista. Mean and standard deviation (SD) age of TG at the start of treatment (T0) and at end of treatment (T1) was 9.1 (SD = 0.7) and 10.6 (SD = 0.7), respectively. Mean treatment period was 17.7 (SD = 6.5) months.

Control group (CG) comprised 20 subjects (11 female and 9 male). Cephalograms of the untreated subjects were obtained from Burlington Growth and Research Centre, University of Toronto. Mean and standard deviation (SD) age of TG at T0 and T1 was 9.0 (SD = 0.1) and 11.6 (SD = 0.5), respectively. The mean observation period was 31.3 (SD = 6.2) months.

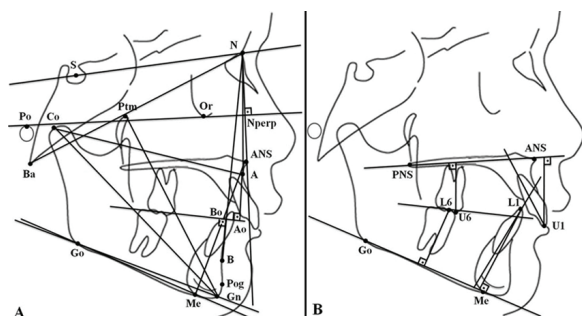
For treated group, X-rays were carried out using a machine (Rotograph Plus, model MR05, regulated to 85 Kilovoltage (Kvp) and 10 miliamperage (mA) and exposure time of 0.5 s and for control the radiographs were obtained with equipment of brand Keleket™ set to 120 Kvp, 25 mA and exposure time of 0.3 s.

Although these radiographs were obtained by different X-ray machines, the correction of image magnification was not conducted. Magnification of image, percentage of magnification on experimental sample was 10 per cent, representing a magnification of 0.1000 cm, (1.000 mm). In control group, the percentage of magnification reported was of 9.84 per cent, according to records of Burlington Growth and Research Centre. Magnification percentage difference between samples would be 0.16 per cent, what would not affect comparison of variables obtained from radiographs taken in different X-ray machines. This difference in magnification would correspond to a difference in magnification between X-rays of 0.0016 cm (0.016 mm).

Standardized lateral cephalograms of each individual were hand traced at a single sitting by one

investigator. All cephalometric measurements were generated through the use of a customized digitization package (Dentofacial Planner version 2.5, Toronto, Canada) and used for cephalometric evaluation. Lateral cephalograms for each patient at T0 and T1 were digitized using a custom cephalometric analysis. Twenty-two variables were generated for each tracing.

Measurements for skeletal and dental, anteroposterior and vertical relationship were obtained on all cephalograms (Figure 1). Linear and angular measurements used in study are in Table 1. Cephalometric measurements in TG were compared with those in CG. The T0 to T1 changes for all cephalometric variables in both TG and CG were annualized to adjust for different treatment periods.



**Figure 1.** Skeletal (A) and dental (B) cephalometric landmarks and lines.

Systematic intra-examiner error was assessed by calculating the intraclass correlation coefficient (ICC). Shapiro-Wilk Test was used to assess normal distribution. Differences for mean age at the start of

study and the changes in TG were compared to CG using the Student's t-tests. Chi-square test with Yates' correction was used to comparisons between genders and skeletal maturity. Statistical analysis was performed using SPSS® (SPSS Inc, Chicago, Ill). Results were considered at a significance level of 5 per cent.

## Results

ICC measurement was higher than 0.90, indicated excellent reliability.

Annualized difference in skeletal cephalometric measurements ANB, WITS, Lafh and Co-Gn showed statistically significant difference. The Lafh and Co-Gn increased 0.96 and 1.15 mm in TG compared to CG, respectively. The ANB and WITS reduced 0.89° and 2.06 mm in TG in comparison to CG, respectively (Table 2).

**Table 2.** Mean ( $\bar{x}$ ), standard deviation (SD) and significance level (p) of annualized difference in skeletal cephalometric measurements between CG and TG (Student's t-tests).

Measurement	T1-T0 CG		T1-T0 TG		p Value
	$\bar{x}$	SD	$\bar{x}$	SD	
SNA	0.37	0.82	-0.31	1.39	0.068
SNB	0.42	0.58	0.61	1.11	0.508
ANB	-0.04	0.61	-0.93	1.01	0.002**
A-Nperp	0.32	0.79	-0.36	1.31	0.055
Pog-Nperp	0.56	1.06	-0.11	2.22	0.237
Co-Gn	1.75	1.05	2.90	1.85	0.020*
Co-A	0.95	1.00	1.38	1.83	0.373
MxMdDiff	0.80	0.72	1.51	2.25	0.192
Lafh	0.88	0.71	1.84	1.15	0.003**
FAxis	-0.01	0.67	-0.11	2.93	0.881
FMA	-0.54	0.82	-0.02	1.90	0.270
SN.Gn	-0.22	0.80	0.54	1.77	0.088
WITS	-0.02	0.79	-2.08	1.27	0.000***

\*p < 0.05, \*\*p < 0.01, \*\*\*p < 0.001.

**Table 1.** Cephalometric parameters used in present study.

Measurements	Definitions
SNA (°)	Maxilla position in relation to cranial base
SNB (°)	Mandible position in relation to cranial base
ANB (°)	Anterior-posterior relation of the maxilla and the mandible
A-Nperp (mm)	Maxilla position in relation to cranial base
Pog-Nperp (mm)	Mandible position in relation to cranial base
Co-Gn (mm)	Mandible length
Co-A (mm)	Maxillary length
MxMdDiff (mm)	Difference between mandible and maxillary length
Lafh (mm)	Anterior lower facial height (ANS-Me)
Faxis (°)	Facial axis (BaN.PtGn)
FMA (°)	Angle between Frankfort horizontal plane and mandibular plane
SN.GN (°)	Mandibular plane in relation to the cranial base
WITS (mm)	Wits appraisal (Ao to Bo)
U1.Pp (°)	Angle between upper incisor and palatal plane
U1-Pp (mm)	Upper incisor height
U6-Pp (mm)	Upper first molar height
L1-Mp (mm)	Vertical distance between lower incisor and mandibular plane
L6-Mp (mm)	Vertical distance between upper first molar tip and mandibular plane
IMPA (°)	Angle between lower incisor and mandibular plane
Isli (°)	Angle between upper and lower incisors
OB (mm)	Horizontal distance between upper incisor and lower incisor
OJ (mm)	Vertical distance between upper and lower incisors

Annualized difference in dental cephalometric measurements L6-Mp, U1.Pp, Isli, OB and OJ showed statistically significant difference. The OJ and OB decreased 3.12 and 1.22 mm in the TG in comparison to CG, respectively. The Isli and L6-Mp increased 4.33° and 0.76 mm in TG in comparison to CG, respectively. The U1.Pp decreased 4.43° in TG in comparison to CG (Table 3).

**Table 3.** Mean ( $\bar{x}$ ), standard deviation (SD) and significance level (p) of annualized difference in dental cephalometric measurements between CG and TG (Student's t-tests).

Measurement	T1-T0		T1-T0		p Value
	CG		TG		
	$\bar{x}$	SD	$\bar{x}$	SD	
U1.Pp	-0.57	1.61	-5.00	6.48	0.007**
U1-NF	0.74	0.55	1.02	1.42	0.432
U6-Pp	0.63	0.50	0.53	1.20	0.731
L1-Mp	0.70	0.35	0.67	0.95	0.895
L6-Mp	0.34	0.55	1.10	0.90	0.003**
IMPA	0.49	1.46	0.54	2.89	0.947
Isli	-0.13	2.10	4.20	5.22	0.002**
OB	0.32	0.69	-0.90	1.62	0.005**
OJ	-0.13	0.75	-3.25	2.31	0.000***

\*\*p < 0.01, \*\*\*p < 0.001.

There was statistically significant difference for vertebral stage between TG and CG. Stage 1 showed 20 for CG and 55 per cent for TG and stage 2 showed 80 and 45 per cent in CG and TG, respectively (Table 4). There was no significant difference in gender distribution between TG and CG (Table 5) and no difference was found for mean age at the start of study between groups (Table 6).

**Table 4.** Absolute frequency and percentage frequency (%) of skeletal age (chi-square test).

Vertebral Stage	CG		TG		p Value
	Absolute	Frequency	Absolute	Frequency	
	Frequency	%	Frequency	%	
Stage 1	04	20	11	55	0.022*
Stage 2	16	80	09	45	-
Total	20	50	20	50	-

\*p < 0.05.

**Table 5.** Absolute frequency and percentage frequency (%) by gender (chi-square test with Yates' correction).

Gender	CG		TG		p Value
	Absolute	Frequency	Absolute	Frequency	
	Frequency	%	Frequency	%	
Female	11	55	10	50	0.752
Male	09	45	10	50	-
Total	20	50	20	50	-

**Table 6.** Patient mean age at the start of study in TG and CG (Student's t-tests).

Group	Number	Mean initial age (months)	SD	p Value
Treatment	20	109.85	8.44	0.607
Control	20	108.85	1.42	-

## Discussion

The nature of changes that contribute to Class II correction with functional appliances is still controversial. Some authors claim that action of functional appliances is largely, if not completely, confined to the dentoalveolar structures (Devincenzo, 1991; Martins et al., 2008). Other authors believe that, in addition to inducing dentoalveolar changes, appliance may also alter maxillary and mandibular skeletal relationship during growth (Luder, 1981; Antunes et al., 2013). Tables 2 and 3 show that out of the twenty-two variables utilized in this study, five of dental and four of skeletal variables showed statistically significant difference. Results indicate that alterations induced by bionator therapy when performed in prepubertal stage were more intense in dentoalveolar than in skeletal modification.

Our results show that Wits and ANB decreased significantly in TG as compared with CG (Table 2). These changes suggest that bionator appliance was effective in reducing sagittal intermaxillary relationship. Bionator group demonstrated a small mean reduction in SNA and A-Nperp, in contrast to control group, which demonstrated a mean increase. This suggests that therapy restricted the forward movement of the point A in maxilla, as related in literature (Pancherz, Malmgren, Hagg, Omblus, & Hansen, 1989; Jakobsson & Paulin, 1990; Cura, Sarac, Ozturk, & Surmeli, 1996; Nucera et al., 2016). The SNB shows small mean increase in both groups and this is correlated with the minimal mandibular skeletal growth during prepubertal period (Kapila, 1992). Results suggest that bionator reduced sagittal intermaxillary relationship more by restriction of maxilla forward movement than by mandibular advance.

The Lafh increased significantly twice as much in TG as compared with CG showing effect induced by bionator appliance (Table 2). Absolute vertical growth changes are significantly greater during adolescence than prepubertal period (Buschang & Martins, 1998). Bionator restrains the physiological counterclockwise growth rotation of palatal plane, and it produced a relative opening of mandibular plane angle relative to Frankfort plane so that at the end, the overall increase in Lafh (Malta, Baccetti, Franchi, Faltin, & McNamara, 2010). Appliance restricts eruption of maxillary molars that erupted less in TG than CG (Table 3). Eruption of the mandibular first molar increased significantly in TG as compared with CG and this is correlated with increase in Lafh (Table 3). Inhibition of maxillary first molar eruption by acrylic monoblock and

trimmed of acrylic in lower posterior portion allows eruption of mandibular first molar and this is a Class II correction mechanism (Harvold, 1963).

Length of the mandible Co-Gn increased in TG as compared with CG (Table 2). Condylar changes and modelling of glenoid fossa following mandibular advancement treatment have been demonstrated that ligament stretch does not correlate to growth modifications, the reciprocal stretch of the ligament connecting the condyle to fossa may play a role in new bone formation (Voudoris et al., 2003). Antero-posterior relationship changes at different rates during development and therapy to stimulate antero-posterior mandibular growth might best be performed during puberty, when the greatest potential for modifications in antero-posterior plane exists (Kapila, 1992).

The OJ, U1.Pp decreased and Isli increased significantly in TG as compared with CG (Table 3). These changes reflect a lingual tipping of maxillary incisors and proclined prevention of mandibular incisors, because they were covered with acrylic. Some variables changed in a direction opposite to that expected during normal growth and maxillary incisors normally become slightly more procumbent with growth. The OB decreased significantly in TG as compared with CG (Table 3). Mandibular advancement with bionator increases of Lafh and L6-Mp that assists the correction of overbite.

Stages of cervical vertebra maturation are related to mandibular growth changes. There was statistically significant difference for cervical vertebra maturation stage between groups, being found stage 1 in TG and stage 2 in CG (Table 4). Despite the difference between groups, stages 1, 2 and 3 are considered before the peak of mandibular growth (O'reilly & Yanniello, 1988). There is a minimal skeletal growth during prepubertal period and significant growth occurs during puberty (Kapila, 1992). There was no difference for mean age at the start of study between groups (Table 4).

This study showed more dentoalveolar adaptations than skeletal modifications during treatment of Class II division 1 malocclusion with bionator appliance. Our results agree with literature for the early treatment of Class II malocclusion with bionator, which indicate that both dentoalveolar and skeletal changes occurred in TG and that dentoalveolar changes were more pronounced in prepubertal stage (Tulloch, Proffit, & Phillips, 1997; Rudzki-Janson & Noachtar, 1998; Tulloch, Phillips, & Proffit, 1998). Advantages of early functional orthopedic treatment for patients are less incidence of injury to maxillary incisors, prevention of psychosocial problems and improvement in

maxillomandibular relationship (Miguel, Cunha, Calheiros, & Koo, 2005).

## Conclusion

Major changes induced by bionator appliance in treatment of Class II, Division 1 malocclusion in prepubertal period were increase mandibular growth (Co-Gn), lower facial height (Lafh), vertical dental development on mandible (L6-Mp), angle between upper and lower incisors (Isli) and reduce the antero-posterior relation of maxilla and mandible (ANB and Wits), overjet (OJ), overbite (OB), angle between upper incisor and palatal plane (U1.Pp).

The early treatment of Class II, Division 1 malocclusion with Bionator appliance is effective, inducing more dentoalveolar changes than skeletal during prepubertal stage.

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