Original Article

Long-Term Dentoskeletal Effects and Facial Profile Changes Induced by Bionator Therapy

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ABSTRACT

Objective: To evaluate the long-term skeletal and soft tissue changes induced by the bionator in Class II subjects.

Materials and Methods: The treatment sample consisted of 20 Class II patients (6 males and 14 females) treated consecutively with the bionator. The sample was evaluated at T1, start of treatment; T2, end of bionator therapy; and T3, long-term observation (including fixed appliances). Mean age at the start of treatment was 10 years 2 months (T1); at posttreatment, 12 years 4 months (T2); and at long-term follow-up, 18 years 11 months (CS 6). The control group consisted of 20 subjects (8 males and 12 females) with untreated Class II malocclusions. Lateral cephalograms were analyzed at the three time points for all groups. Student's *t*-tests were used for comparisons of starting forms, and of the T1–T2 and T1–T3 changes between groups.

Results: The bionator group showed significant, favorable T1–T2 changes both at the skeletal and dentoalveolar levels. The vertical dimension was increased. Significant modifications were assessed for the soft tissues as well. The treated group showed a final improvement in soft tissue pogonion of about 2.5 mm. Significant mandibular changes were noted in the treated group, with a net average 3.3 mm long-term increase in mandibular length compared with untreated Class II controls.

Conclusions: This study suggests that bionator treatment of Class II malocclusion maintains favorable results over the long-term with a combination of skeletal, dentoalveolar, and soft tissue changes. (*Angle Orthod* 2010;80:10–17.)

KEY WORDS: Bionator; Class II malocclusion; Functional jaw orthopedics; Cephalometrics; Soft tissues

INTRODUCTION

When Class II division 1 malocclusion is associated with a retrognathic mandible, a viable treatment option is the alteration of the amount and direction of mandibular growth by using functional appliances.[1] Among these, the bionator is a tooth-borne appliance that has been reported to produce significant changes in the dental and skeletal facial structures through a repositioning of the mandible in a more protrusive position, control of the overbite, modification of dental eruption, and improvement of the profile.[2–5] The literature contains a large number of studies (including randomized clinical trials on one-phase vs two-phase treatment) that have investigated the mechanisms of action and the effects of bionator appliance in Class II division 1 malocclusion.[3–8]

In a recent systematic review of the literature,[9,10] the bionator has shown moderate effectiveness and efficiency in inducing supplementary growth of the

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mandible in treated subjects vs untreated Class II controls, with approximately 30% of the preadolescent bionator patients showing correction of Class II molar and skeletal relationships when reevaluated after phase-2 treatment. Only a few of the clinical trials on bionator treatment recorded the dentoskeletal changes in the long term.[11,12] Faltin et al[12] reported the significant impact of treatment timing on the changes induced by the bionator appliance, since treatment at puberty was found to produce significantly greater increases in mandibular total and ramus lengths when compared with controls long-term.

A systematic review of bionator effects on the soft tissue facial profile revealed that the studies were short-term in nature, and they failed to provide enough evidence on the amount or stability of the changes following bionator therapy.[2] This information is needed, as recent data from a clinical trial have identified patients with retruded chins as ideal candidates for functional jaw orthopedics with respect to orthopedic forces directed to the maxilla (headgear treatment).[13]

The aim of this study was to analyze the dentoskeletal effects and facial profile changes induced by bionator appliance therapy. The investigation featured final observations in the long term (at the completion of active craniofacial growth) and the use of untreated Class II controls.

MATERIALS AND METHODS

Cephalometric records of 20 white patients (6 females and 14 males) with Class II division 1 malocclusion consecutively treated with the bionator were collected from a single orthodontic practice (K.F.). Patients included in the present study consisted of a different sample than did a previous investigation on the effect of treatment timing on the outcomes of bionator therapy.[12] The treatment protocol consisted of a bionator, constructed without coverage of the lower incisors, to be worn 16 hours a day and followed by approximately 1 year of fixed appliance therapy. Those patients still in the mixed dentition phase by the end of bionator treatment were instructed to wear the appliance only at night until complete eruption of the premolars and permanent canines. After the comprehensive phase of treatment, each patient was given a lower incisor fixed retainer. Lateral cephalograms were obtained at three time periods: T1, at the start of treatment; T2, at the end of bionator therapy; and T3, at long-term observation after completion of growth,[14] including the phase with fixed appliances. At T3 an evaluation of successful or unsuccessful long-term outcomes of treatment was performed.

The control group consisted of 20 white subjects (8 females and 12 males) with untreated Class II division 1 malocclusions. Cephalograms of the untreated subjects were obtained from the University of Michigan Growth Study and the Denver Child Growth Study. Significant effort was directed toward matching the control sample to the treatment sample as closely as possible with respect to gender distribution (for the effect this variable would have on head size), age at all observation periods, duration of observation intervals (T1–T2, T2–T3, and T1–T3), and skeletal maturity at all time points. All treated and untreated patients had completed active growth (CS6) at T3. Demographic data of the samples are reported in Table 1.

Cephalometric Analysis

Lateral cephalograms of each patient and untreated subject were hand traced at a single sitting by one investigator. Landmark location and accuracy of the anatomical outlines were verified by a second. A customized digitization regimen (Dentofacial Planner version 2.5, Toronto, Canada) was created and used for cephalometric evaluation.

Lateral cephalograms for each patient at T1, T2, and T3 were digitized using a custom cephalometric analysis. Twenty-four variables were generated for each tracing. Lateral cephalograms of treated and control groups at T1, T2, and T3 were standardized as to magnification factor (8%).

For analysis of the soft tissue profile changes, the method by Arnett et al[15] was used with modifications originally proposed by Silvestri et al,[16] who substituted the true vertical line (TVL) with a reference vertical line (VL) perpendicular to the skeletal Frankfort plane, and traced through subnasale (Sn) (Figure 1). Profile points measured to VL were soft tissue A-point (A′), upper lip anterior (ULA, the most prominent point of the upper lip contour), lower lip anterior (LLA, the most prominent point of the lower lip contour), and soft tissue pogonion (Pg′).

Method Error

Eleven subjects from the final samples (33 cephalograms) were selected at random. All films were retraced and redigitized. Intraclass correlation coefficients were calculated to compare within-subjects variability to between-subjects variability. Correlation coefficients for the dentoskeletal measures were greater than 0.95, while the coefficients for soft tissue variables ranged from 0.92 to 0.96. The estimate of random errors was made with Dahlberg's formula.[17] Errors for linear measurements ranged from 0.1 mm for the Wits appraisal to 1.2 mm for condylion to A-point. Errors for angular measurements ranged from 0.4° for the ANB angle to 1.4° for the interincisal angle.

Table 1. Age and Stages in Skeletal Maturation at Different Time Points in Treated and Untreated Groups

Bionator Group (n = 20; 6 females, 14 males)	Age	
	Mean	*SD*
T1	10 y 2 mo	1 y 6 mo
CS1 = 5, CS2 = 7, CS3 = 8, CS4 = 0, CS5 = 0, CS6 = 0		
T2	12 y 4 mo	1 y 11 mo
CS1 = 3, CS2 = 1, CS3 = 4, CS4 = 8, CS5 = 4, CS6 = 0		
T3	18 y 11 mo	2 y 2 mo
CS1 = 0, CS2 = 0, CS3 = 0, CS4 = 0, CS5 = 0, CS6 = 20		

Control Group (n = 20, 8 females, 12 males)	Age	
	Mean	*SD*
T1	9 y 1 mo	1 y 5 mo
CS1 = 7, CS2 = 8, CS3 = 5, CS4 = 0, CS5 = 0, CS6 = 0		
T2	12 y 3 mo	1 y 3 mo
CS1 = 0, CS2 = 4, CS3 = 4, CS4 = 10, CS5 = 2, CS6 = 0		
T3	17 y 10 mo	2 y 6 mo
CS1 = 0, CS2 = 0, CS3 = 0, CS4 = 0, CS5 = 0, CS6 = 20		

Statistical Analysis

Descriptive statistics were calculated in both treated and untreated groups for all cephalometric measures at T1 (starting forms), and for changes between T1, T2, and T3. Comparisons between craniofacial starting forms, T1–T2 changes (to describe the effects of active therapy with the bionator), and T1–T3 changes (to describe the long-term, overall effects of both treatment and posttreatment intervals) were performed by means of parametric statistics (Student's *t*-test) with a statistical software package (Statistical Package for the Social Sciences, SPSS, Version 16.0.1 Chicago, Ill). Normal distribution of the data was determined by exploratory tests (Shapiro-Wilk). Statistical significance was tested at $P < .05$, $P < .01$, and $P < .001$. The power of the study was calculated on the basis of the difference in means and standard deviation of the changes in mandibular length (Co-Pg) in a previous long-term study,[12] as well as on sample size. The resulting power was 0.85.

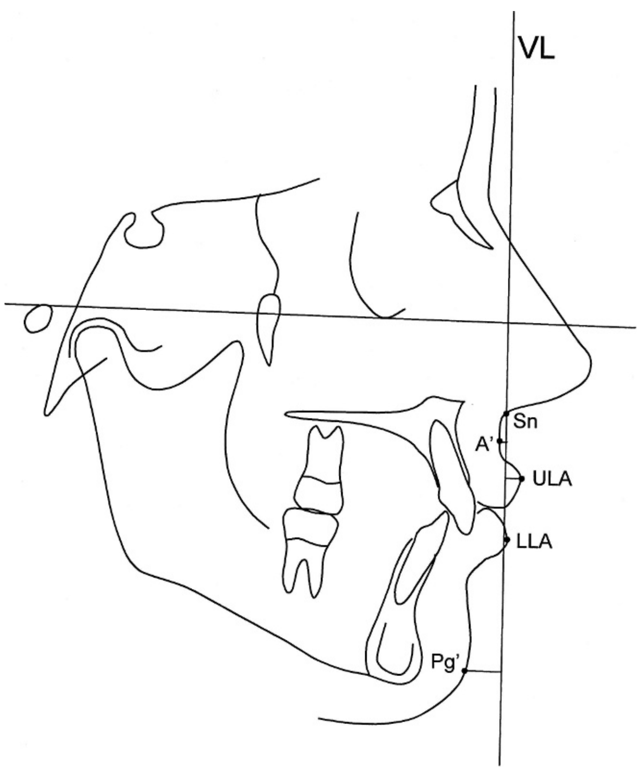

Figure 1. Soft tissue cephalometric analysis.

RESULTS

Descriptive data and statistical comparisons between treated and control groups for starting forms and cephalometric changes from T1 to T2 and from T1 to T3 are given in Tables 2, 3, and 4, respectively.

There were only a few significant differences in the starting forms of the two groups. There were no differences between the groups when comparing maxillary and mandibular sagittal measures. Among the vertical measures, the treated group presented with greater values for FH-PP and FMA measures. The treated group also had greater values for overbite and interincisal angulation. The bionator group presented a slightly more protracted lower lip when compared with the control group (Table 2). The

Table 2. Comparison of Starting Norms

Cephalometric Measures	Bionator Group n = 20 Mean	Bionator Group n = 20 SD	Control Group n = 20 Mean	Control Group n = 20 SD	Difference	Significance
Cranial Base						
Ba-S-N (°)	130.0	4.9	132.9	4.3	−2.9	NS
Maxillary A-P Skeletal						
SNA (°)	82.0	3.1	80.4	3.6	1.6	NS
Co-Pt A (mm)	84.1	3.5	84.7	4.1	−0.6	NS
Mandibular A-P Skeletal						
SNB (°)	75.7	2.8	75.6	3.4	0.1	NS
Co-Gn (mm)	103.1	4.5	102.6	4.7	0.5	NS
Intermaxillary						
ANB (°)	6.3	2.0	5.2	1.9	1.1	NS
Wits (mm)	3.7	2.2	5.2	2.0	−1.5	NS
Mx/Mn diff (mm)	19.0	3.2	18.1	2.6	0.9	NS
Vertical Skeletal						
FH-PP (°)	0.5	3.2	−2.2	3.9	2.7	*
FMA (°)	27.6	5.5	23.9	4.4	3.7	*
LAFH (mm)	62.0	4.3	60.1	4.8	1.9	NS
Gonial angle (°)	124.9	6.8	125.6	6.6	−0.7	NS
Co-Go-Me (°)	125.8	5.0	123.4	4.5	2.4	NS
Interdental						
OJ (mm)	7.4	2.4	5.6	2.5	1.8	NS
OB (mm)	4.9	1.3	3.1	3.5	1.8	*
I/I (°)	118.6	5.4	127.2	9.6	−8.6	**
6/6 (mm)	−0.9	1.3	−1.6	1.8	0.7	NS
Maxillary Dentoalveolar						
U1-Pt A vert (mm)	4.6	1.2	3.6	1.6	1.0	NS
Mandibular Dentoalveolar						
IMPA (°)	99.8	6.1	96.7	4.0	3.1	NS
Soft Tissue						
U Lip protraction (mm)	4.7	1.5	3.4	1.3	1.3	NS
L Lip protraction (mm)	4.0	1.7	2.1	1.8	1.9	*
A′ to N perp (mm)	1.2	2.5	1.2	2.7	0.0	NS
Pg′ to N perp (mm)	−0.2	4.2	1.4	4.5	−1.6	NS

* $P < .05$; ** $P < .01$.

prevalence rate for unsuccessful cases in the treated group as assessed by the Wits appraisal and molar relationship was 10% (2 out of 20 treated cases).

When compared with the controls, the bionator group presented with a significant increase of 3.2 mm in mandibular length (Co-Gn; Table 3). There were no significant between-group differences for sagittal maxillary measures. The treated group showed a significantly greater increase in the inclination of the mandibular plane to Frankfort horizontal (FMA) than did the control group, along with a significantly smaller amount of clockwise rotation of the palatal plane to the Frankfurt plane. The gonial angle and the Co-Go-Me angle exhibited statistically significant increases in the bionator group when compared with the control group. Both overjet and overbite showed a significant decrease in the bionator group. Distal molar relationship was significantly improved in the treatment group, which also exhibited a significant retroclination of upper incisors in association with a significant proclination of the lower incisors.

Regarding soft tissue measures, the treated group demonstrated a significant restriction in the sagittal position of both the upper lip and soft tissue A-point, while showing a significantly smaller amount of retrusion of Pg′.

Results of the long-term effects of bionator therapy are in Table 4. There were no significant between-group differences for sagittal maxillary measures. The treated group had a significant increase of 3.3 mm in mandibular length (Co-Gn) when compared with controls. The treated group showed a significantly

Table 3. Comparison of Changes During Treatment with Bionator (T1–T2)

	Bionator Group		Control Group			
	n = 20		n = 20			
Cephalometric Measures	*Mean*	*SD*	*Mean*	*SD*	Difference	Significance
Cranial Base						
Ba-S-N (°)	0.0	1.1	−0.2	2.5	0.2	NS
Maxillary A-P Skeletal						
SNA (°)	−0.2	1.3	0.0	1.2	−0.2	NS
Co-Pt A (mm)	2.5	2.4	1.3	3.3	1.2	NS
Mandibular A-P Skeletal						
SNB (°)	0.6	1.9	0.5	1.3	0.1	NS
Co-Gn (mm)	6.5	4.1	3.3	4.2	3.2	*
Intermaxillary						
ANB (°)	−0.8	1.1	−0.9	0.8	0.1	NS
Wits (mm)	−1.9	1.6	−2.2	2.0	0.3	NS
Mx/Mn diff (mm)	3.9	2.2	3.8	1.9	0.1	NS
Vertical Skeletal						
FH-PP (°)	1.3	2.1	5.0	2.6	−3.7	**
FMA (°)	1.2	1.1	−1.2	3.1	2.4	**
LAFH (mm)	4.8	3.1	3.4	3.1	1.4	NS
Gonial angle (°)	0.4	2.1	−3.0	2.6	3.4	***
Co-Go-Me (°)	0.5	1.8	−2.5	2.4	2.0	***
Interdental						
OJ (mm)	−2.4	2.0	0.3	1.4	−2.7	**
OB (mm)	−2.0	1.5	0.7	1.3	−2.7	*
I/I (°)	5.2	5.6	2.0	12.1	3.2	NS
6/6 (mm)	−0.9	1.6	0.3	1.2	−1.2	*
Maxillary Dentoalveolar						
U1-Pt A vert (mm)	−1.0	1.4	1.1	1.8	−2.1	*
Mandibular Dentoalveolar						
IMPA (°)	0.2	4.7	−1.5	4.4	1.7	*
Soft Tissue						
U Lip protraction (mm)	−1.4	1.3	0.2	1.6	−1.6	**
L Lip protraction (mm)	0.1	1.5	−1.5	2.4	1.6	NS
A′ to N perp (mm)	−0.1	1.6	2.3	2.4	−2.4	**
Pg′ to N perp (mm)	−0.4	2.5	−2.4	3.3	2.0	*

* $P < .05$; ** $P < .01$; *** $P < .001$.

smaller amount of closure of FMA, a significant counterclockwise rotation of the palatal plane, and a significantly greater increase in lower anterior facial height (LAFH) with respect to the controls. Both overjet and overbite showed a significant decrease in the bionator group. The molar relationship was significantly improved in the treatment group that presented also with a significant retroclination of upper incisors. As to the soft tissue analysis, the results showed a significantly smaller protrusion of soft tissue A-point and a significantly smaller retrusion of Pg′ in the bionator group when compared with the control group.

DISCUSSION

No previous investigation has studied the long-term treatment effects of bionator therapy on the craniofacial hard and soft tissues in growing subjects with the use of untreated Class II controls. The present study has analyzed the skeletal, dentoalveolar, and soft tissue changes produced by the bionator in consecutively treated patients, regardless of success or lack of success of therapy, during a period of approximately 9 years of follow-up. All subjects in both treated and control groups were white. The use of well-matched historical controls, though not ideal, was due to the fact that nowadays it is unethical to leave Class II subjects without treatment in the long term, as required by the methodology of the present study. It should also be noted that, according to a recent report,[18] control groups derived from growth study data are indistinguishable from those derived prospectively from untreated Class II patients. Very similar prevalence rates were assessed for prepubertal and pubertal

Table 4. Comparison of Changes During the Long-term Overall Interval (T1–T3)

	Bionator Group n = 20		Control Group n = 20			
Cephalometric Measures	*Mean*	*SD*	*Mean*	*SD*	Difference	Significance
Cranial Base						
Ba-S-N (°)	−0.3	1.9	−1.1	3.4	0.8	NS[a]
Maxillary A-P Skeletal						
SNA (°)	−0.6	1.1	0.3	2.1	−0.9	NS
Co-Pt A (mm)	5.5	3.4	3.8	3.5	1.7	NS
Mandibular A-P Skeletal						
SNB (°)	1.5	1.2	1.5	2.1	0.0	NS
Co-Gn (mm)	14.9	5.0	11.6	5.2	3.3	*
Intermaxillary						
ANB (°)	−2.2	1.0	−1.6	1.4	−0.6	NS
Wits (mm)	−1.9	1.6	−2.4	2.5	0.5	NS
Mx/Mn diff (mm)	8.2	3.0	7.6	2.7	0.6	NS
Vertical Skeletal						
FH-PP (°)	−1.0	2.0	4.6	2.3	−5.6	**
FMA (°)	−1.0	2.1	−2.6	2.6	1.6	*
LAFH (mm)	7.7	3.1	4.2	3.1	3.5	*
Gonial angle (°)	−2.0	2.7	−2.9	3.9	0.9	NS
Co-Go-Me (°)	−1.0	3.2	−2.5	4.2	1.5	NS
Interdental						
OJ (mm)	−2.8	2.8	0.3	1.6	−3.1	**
OB (mm)	−2.0	1.2	1.0	3.9	−3.0	**
I/I (°)	3.7	7.3	3.8	9.9	−0.1	NS
6/6 (mm)	−3.0	1.3	−1.1	1.5	1.9	**
Maxillary Dentoalveolar						
U1-Pt A vert (mm)	−0.3	1.2	1.3	1.8	1.6	*
Mandibular Dentoalveolar						
IMPA (°)	−1.0	5.2	0.0	5.6	−1.0	NS
Soft Tissue						
U Lip protraction (mm)	−2.1	1.2	−0.9	1.5	−1.2	NS
L Lip protraction (mm)	0.9	1.5	−0.1	2.3	1.0	NS
A′ to N perp (mm)	1.1	2.0	2.9	1.6	−1.8	*
Pg′ to N perp (mm)	−2.4	2.9	−5.0	3.5	2.6	**

[a] NS = not significant.
* $P < .05$; ** $P < .01$.

subjects in treated and untreated groups at initial time points, whereas all examined subjects presented with CS6 at the long-term observation. Therefore, at follow-up observation all subjects had completed the circumpubertal period of active growth.

No short- or long-term sagittal maxillary effects were assessed as a consequence of bionator therapy in the Class II patients. This result confirms observations of previous authors.[3,4] The functional appliance induced a significant elongation of the mandible over controls (3.2 mm) that was maintained in the long term (3.3 mm). The supplementation in mandibular growth provided by the protocol investigated exceeded the average cumulative growth deficiency exhibited by the mandible in subjects with Class II malocclusion when compared with subjects with normal occlusion during the circumpubertal period.[19] With regard to the changes in sagittal mandibular position, no significant differences between treated and untreated samples were found for angle SNB. It should be noted, however, that the marked changes in positions of sella and nasion along with growth limit the adequacy of SNB as a cephalometric indicator of sagittal mandibular position in long-term studies.[20]

The favorable mandibular change was associated with a change in the direction of condylar growth (more posterior in the treated group) as assessed with the Co-Go-Me angle, and in the measure of the gonial angle (more open in the treated group) at the short-term evaluation. These anatomical mandibular modifications are, however, transient, treatment-induced mechanisms as they assist in the supplementary elongation of the mandible during active treatment with functional jaw orthopedics, as demonstrated in several experimental and clinical reports.[21,22] In fact, the overall long-term comparison between treated and control groups no longer revealed significant differences in mandibular angles.

When the mandibular effects of bionator therapy are evaluated with respect to timing of treatment with the functional appliance, it should be emphasized that the average amount of supplementary long-term mandibular growth induced by treatment in the present study (slightly greater than 3 mm) is an intermediate value with respect to previous findings[12] in prepubertal patients (1.9 mm) and in pubertal patients (5.1 mm) derived from a different sample. These outcomes reflect the mixed distribution of prepubertal (60%) and pubertal (40%) patients in the treated sample (with a very similar distribution in the controls). Also a word of caution is mandatory when analyzing the mandibular changes induced by bionator therapy due to the rather large standard deviations associated with increases in Co-Gn in both treated and control groups, thus indicating interindividual variability in response to therapy.

Bionator therapy induced an increase in the vertical dimensions of the face, through multiple significant changes vs the untreated controls. Therapy restrained the physiological counterclockwise growth rotation of the palatal plane, and it produced a relative opening of the mandibular plane angle relative to the Frankfort plane so that at the end, the overall increase in LAFH was significantly greater in the bionator group than in the controls. The overbite was reduced by about 3 mm in the bionator group when compared with the controls long-term. A previous prospective clinical trial[8] with short-term observations reported similar findings for changes in the vertical dentofacial components induced by the bionator.

As for the dentoalveolar changes, a contribution to overjet correction in the bionator group was provided by both proclination of the lower incisors and retroclination of the upper incisors in the short term, thus confirming the findings of Illing et al.[8] However, most of these differential changes in dental inclination diminished at the long-term observation. The comparison on the overall observation period showed only a slight residual palatal inclination of the upper incisors in the treated group (about 1.5 degrees more than in untreated controls). All in all, therefore, long-term dentoalveolar changes associated with bionator therapy followed by fixed appliances can be considered very modest. It should be noted in this regard that the bionator used in the current study was constructed without coverage of the lower incisors.

Outcomes of the study indicate that bionator therapy is able to significantly alter the sagittal position of both the maxillary and mandibular soft tissue profile components. During the overall observation period, extending from an average age of 10 years to almost 19 years, functional jaw orthopedics with the bionator followed by fixed appliances produced 2 mm to 2.5 mm favorable changes in both soft tissue components, with a restraining effect on soft tissue A- point and a protrusive effective on Pg′. In this regard, the systematic review by Flores-Mir and Major[2] reported contradictory findings for the anteroposterior changes in the maxillary and mandibular soft tissue profile short-term.

The results of the present study pertaining to soft tissues should be interpreted further in the light of recent data from a clinical trial that identified in a retrusive chin one of the discriminant pretreatment features of those Class II subjects who are ideal candidates for functional jaw orthopedics.[13] In that clinical trial, the differential effect between functional appliance therapy and headgear therapy on the advancement of Pg′ was about 2.5 mm, the same amount of favorable change elicited by bionator therapy over untreated controls in the present study. The significant short- and long-term modification of the mentolabial fold and closure of the angle between the lower lip and the chin were direct consequences of the advancement of Pg′ in the treated subjects. No significant change could be assessed in the sagittal position of the lips. Nonetheless, in the bionator group the upper lip showed a tendency for a more retruded position (that reached statistical significance in the short term), while the lower lip became more protruded. It should be remembered that the position of the lips is influenced not only by the underlying skeletal changes, but also by concurrent modifications in the inclination of the teeth.

CONCLUSIONS

- The bionator appliance, over a long-term period, did not induce a restraining effect on the maxilla, while it produced a significant enhancing effect on mandibular length (3.3 mm more than untreated Class II controls).
- The bionator improved significantly the overjet and the molar relationship, with a significant reduction of the overbite associated with an increase in LAFH.
- The soft tissue profile was favorably altered by bionator therapy in the long term: the chin was advanced 2.5 mm more than that of untreated controls.

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