# Changes in soft tissue profile following treatment with the bionator

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In its early days, orthodontics was primarily concerned with skeletal and dental tissues because the objective of orthodontic treatment was the attainment of normal occlusion. Soft tissue measurements were introduced into cephalometrics in the 1950s and were quickly recognized as an important factor in treatment planning. This was the result of clinical observations that a single skeletal and dental pattern could be associated with a wide variety of integumental profiles. A number of articles have been published containing soft tissue cephalometric analyses. 8

Class II, Division 1, malocclusion is fairly common and the bionator has been widely used for its correction. The effects of treatment with the

bionator on hard tissue have been well documented, although the conclusions have been mixed. Some studies<sup>9,10</sup> have reported orthopedic effects as part of the correction, while others<sup>11</sup> have found that the effects of the bionator are mostly dentoalveolar in nature. While the bionator affects the hard tissue, it also impacts the soft tissue profile. Proponents of the bionator claim that it improves soft tissue facial balance. However, the effects of bionator therapy on the integument and, consequently, esthetics, have not been quantified. The objective of this study was, therefore, to determine the treatment effects of the bionator appliance on facial soft tissues and, secondarily, on the skeletal and dental tissues

#### **Abstract**

The purpose of this study was to determine the changes in the soft tissue profile in patients treated in the mixed dentition with a bionator. Two groups of 30 individuals, between 9 and 12 years old and with Class II, Division 1, malocclusion were matched for age, sex, observation time, and dentofacial characteristics. Patients in the first group were treated with a bionator for an average of 18.7 months, resulting in a Class I molar relationship and reduction of overjet. The second group acted as a control and individuals did not receive any form of orthodontic treatment. Pretreatment and posttreatment cephalograms were analyzed and paired t—tests were used to compare the significance of changes between the two groups. Compared with the control group, the treated group demonstrated 1.97° decrease in ANB, a 3.35 mm increase in anterior facial height, 2.22° decrease in soft tissue profile convexity, and 17.4° increase in mentolabial angle.

# **Key Words**

Bionator • Class II • Soft tissue profile • Esthetics

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Table 1 Sample size, age, and treatment or observation time								
Group	Number	Mean age Start	SD	Mean treatment or observation time	SD			
Bionator	30	10 y 6 m	1 y 2 m	18.7 m	4.8 m			
Control	30	10 y 6 m	1 y 1 m	18.3 m	4.9 m			

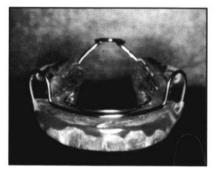




Figure 1A

Figure 1 Frontal and lateral views of the bionator appliance used in this study.

Figure 1B

# Materials and methods Sample

The sample for this study consisted of pretreatment and posttreatment cephalograms of 60 individuals with Class II, Division 1, malocclusion. Thirty individuals were treated with a bionator appliance and 30 individuals did not receive any form of orthodontic treatment. The age at the start of treatment ranged from 9 years to 12 years 5 months (Table 1). In order to be included in the study, the subjects had to be in the mixed dentition and possess the following characteristics: ANB of 5° or more, FMA 20° to 29°, overjet 6 mm to 10 mm, positive overbite, have complete records available, including lateral cephalograms taken with lips in repose, and have noncontributory medical and dental histories.

The 30 patients had been treated successfully with a bionator in a private practice for an average treatment time of 18.7 months. Successful treatment was defined as achievement of a Class I molar relationship at the end of treatment. Once the treated group had been chosen, each subject was closely matched for age, sex, treatment time, and dentofacial characteristics with one of the untreated individuals from the Bolton-Brush Growth Study Center in Cleveland, Ohio.

#### **Appliance**

The bionator used in this study was a variation of the appliance designed by Balters in the 1950s (Figure 1). Because the patients included in this study demonstrated excessive overbite, the bionator allowed for eruption of both maxillary

and mandibular posterior teeth, while the mandibular incisors were capped with acrylic. The construction bite was taken with the incisors in an edge-to-edge relationship and an opening of approximately 4 mm to 5 mm in the molar region.

The patients were instructed to wear the bionator 24 hours a day (except during meals) and were advised to keep the lips together to form a lip seal when the appliance was being worn. Full-time wear continued throughout the active phase of bionator therapy. However, once the objectives were attained, the bionator was worn at night only.

# Cephalometric analysis

Two lateral cephalograms were traced for each of the 60 subjects used in the study. In the bionator group, the cephalograms consisted of a pretreatment and a posttreatment radiograph. In the untreated control group, radiographs were selected to match the age and treatment time of individuals in the bionator group. Cephalometric analysis was performed to determine the effects of growth and treatment. Pretreatment and posttreatment cephalometric tracings for each subject were superimposed upon the anterior cranial base registering on the greater wings of the sphenoid.12 An x/y coordinate system was used to quantify changes between the pretreatment and posttreatment cephalograms. 13 Constructed Frankfort horizontal plane (7° less than sella nasion plane) served as the x-axis, and a vertical line perpendicular to Frankfort horizontal passing through sella point was the y-axis. Displacement of the landmarks was recorded to the nearest 0.5 mm in both the vertical and horizontal plane.

In addition, changes were analyzed by certain linear and angular measurements made on pretreatment and posttreatment cephalometric tracings (Figures 2 and 3). The analysis included skeletal, dental, and soft tissue measurements.

# Statistical analysis

The mean value and standard deviation were calculated for each measurement. Student t-tests were performed to determine the significance of difference between time 1 ( $T_1$ ) and time 2 ( $T_2$ ) cephalograms within each group. Matched pair t-tests were used to compare the differences between the treatment and control groups. P value  $\leq 0.05$  denoted a significant difference.

### Error analysis

Ten cephalograms were randomly selected in order to determine the combined degree of tracing and measurement error. The selected headfilms were retraced and measured. Statisti-

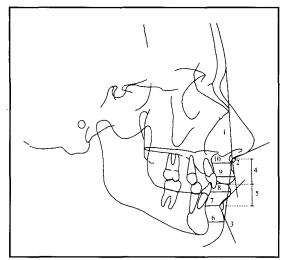


Figure 2

cal significance of the differences were ascertained using paired t-tests and correlation coefficients. Differences with a P value of  $\leq 0.05$  were considered significant. None of the measurements were found to be significantly different.

#### Results

Changes in the control group due to growth and changes in the treatment group during treatment over a period of 18.5 months are presented in Tables 2 and 3.

#### **Hard Tissue**

#### Mandible

SNB increased  $1.05^{\circ}$  more in the bionator group than in the control group (P $\leq$ 0.001). As determined by cranial base superimposition, B point moved forward 0.80 mm more. The length of the mandible as represented by Ar–Gn increased 6.45 mm in the treated group compared with 2.83 mm in the control group. The difference was statistically significant (p<0.001).

# Maxilla

SNA decreased 0.50° in the bionator group and increased 0.40° in the control group. The difference between the two groups was significant (P≤0.001). Cranial base superimposition showed that in the treated group, A point moved anteriorly 1.17 mm less than in the control sample. The length of the maxilla as represented by Co–ANS increased 2.30 mm in the treatment group and 2.77 mm in the control group. The difference, however, was not statistically significant.

# Facial convexity

Skeletal convexity was measured by the ANB angle. There was a reduction of 1.97° in the ANB angle in the bionator group compared with the control group, which was significant at the 0.001 level.

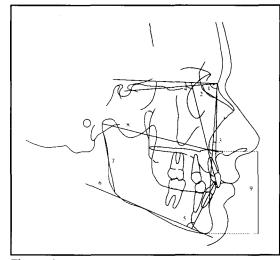


Figure 3

# Facial height

There were significant increases in anterior and posterior facial height in both the treated and control groups. However, anterior facial height, N–Me, increased 3.35 mm more in the bionator patients than in the controls (P $\leq$ 0.001). The bionator group also demonstrated 2.20 mm additional increase in posterior facial height as measured by Ar–Go, compared with the control group (P $\leq$ 0.001).

### Dentition

The overjet in the treated group decreased 4.75 mm as compared with the control group ( $P \le 0.001$ ). Furthermore, the treated group showed 3.15 mm reduction in overbite ( $P \le 0.001$ ). Maxillary incisor angulation, as represented by U1–FH, decreased 3.93° ( $P \le 0.001$ ), but mandibular incisor angulation did not change.

#### Soft tissue

#### Facial form

G–Sn–Pg′, which is a measure of soft tissue facial convexity (Figure 4), decreased 2.22° in the treated group, representing a significant reduction in the convexity of the profile ( $P \le 0.001$ ). As determined by cranial base superimposition, subjects in the treated group demonstrated 3.73 mm anterior movement of Pg′, whereas the control group showed 2.80 mm forward movement of Pg′. The 0.93 mm additional anterior movement of Pg′ in the treated group was significant ( $P \le 0.001$ ).

# Upper lip

Protrusion of the upper lip, as determined by the distance of the upper lip to the Sn-Pg' line, decreased 1.1 mm in the treated group as compared with the control group (P≤0.001). However, the 3° increase in the nasolabial angle in the treated group was not significant (Figure 5). As determined by cranial base superimposition, A'

#### Figure 2 Soft tissue measurements

- G-Sn-Pg'
- 2. Nasolabial angle
- 3. Mentolabial angle
- 4. Upper lip length
- 5. Lower lip length6. Pg' thickness
- 7. B' thickness
- 8. Labrale inferior thickness
- 9. Labrale superior thickness
- 10. A' thickness.

### Figure 3 Hard tissue measurements.

- 1. SNA
- 2. SNB
- 3. ANB
- 4. U1-FH
- 5. IMPA
- 6. FMA
- 7. Ar-Go 8. Co-ANS
- 9. ANS-Me

Table 2 Comparison of hard tissue changes in the treatment and control groups (T1-T2)							
Measurement	Control Group (N=30)		Treatment Group (N=30)		Mean		
	<u>M</u> ean	SD	Mean	SD	Difference	P value	
Mandible AP							
, SNB (°)	0.53	0.7	1.58	1.3	1.05	<0.001	
AR-Grı (mm)	2.83	1.7	6.45	2.0	3.62	< 0.001	
Rotation	_						
FMA (°)	-0.22	1.1	0.28	1.5	0.50	NS	
Maxilla AP							
SNA (°)	0.40	0.7	-0.50	1.0	-0.90	<0.001	
Co-ANS (mm)	2.77	1.5	2.30	2.30	0.47	NS	
<del>-</del>							
Facial convexity ANB (°)	-0.11	0.6	-2.08	1.0	1.97	-A AA1	
AND ( )	<del>-</del> U. 1 1	0.0	-2.00	1.0	1.37	<0.001	
Facial height							
Anterior							
N-Me (mm)	2.98	1.9	6.33	2.2	3.35	<0.001	
N-ANS (mm)	1.57	1.2	3.45	3.4	1.88	<0.01	
ANS-ME (mm)	1.35	1.8	2.88	3.8	1.53	< 0.05	
Posterior	. = 5	, .					
Ar-Go (mm)	1.53	1.4	3.73	1.2	2.20	<0.001	
Dentition							
Overjet (rnm)	0.12	8.0	-4.63	0.8	<i>-</i> 4.75	<0.001	
Overbite (mm)	0.70	1.1	-2.45	1.8	-3.15	< 0.001	
U1-FH (°)	-0.35	3.6	-4.28	4.4	-3.93	<0.001	
IMPA (°)	-0.23	3.2	0.22	3.8	0.43	NS	
Cranial base superimposition Horizontal (mm)							
A	+1.98	1.1	+0.82	1.3	-1.17	<0.001	
Upper incisal tip	+2.17	1.6	-0.30	1.9	-2.47	< 0.001	
Lower incisal tip	+2.17	1.4	+3.43	1.7	+1.27	<0.01	
В	+2.00	1.2	+2.80	1.8	+0.80	< 0.05	
Pg	+2.2-	1.1	+3.13	1.7	+0.93	<0.01	
Vertical (mm)							
A	+1.47	1.3	+3.53	1.3	+2.07	<0.001	
Upper incisal tip	+1.85	1.3	+3.23	1.9	+1.38	<0.001	
Lower incisal tip	+1.47	1.4	+5.60	1.6	+4.13	<0.001	
В	+2.43	1.8	+6.13	1.7	+3.70	< 0.001	
Pg	+2.68	1.6	+5.97	2.0	+3.28	< 0.001	

<sup>+</sup> denotes forward or downward movment and - denotes backward or upward movement of the landmark as determined with cranial base superimposition.

moved forward 1.1 mm less in the bionator group than in the control ( $P \le 0.01$ ). Similarly, labrale superior moved forward 1.37 mm less in the treated group than in the control group.

### Lower lip

The lower lip was the region of the integumental profile that demonstrated the most significant changes (Figure 6). During treatment, the lower lip uncurled, thereby increasing the mentolabial angle by  $15.2^{\circ}$  (P $\leq$ 0.001). Concurrent

with the angular change and uprighting of the lower lip, lip length increased 2.53 mm and lip thickness decreased 2.65 mm.

#### **Discussion**

Treatment with the bionator resulted in significant changes in the dentofacial complex.

#### Hard tissue

SNA decreased 0.90° more in the treated group than in control group. Cranial base superimpo-

Comparison of soft tissue changes in the treatment and control groups							
Measurement	Control Group (N=30)		Treatment Group (N=30)		Mean		
wieasurement	Mean	SD	Mean	SD	Difference	P value	
Facial							
G-Sn-Pg'(°)	0.4	1.9	-1.82	1.5	-2.22	<0.001	
Interlabial gap (mm)	-0.42	1.2	-0.85	2.6	-0.43	NS	
Upper Lip							
Length							
Sn-Stm (mm)	0.33	1.0	0.58	1.8	0.25	NS	
Thickness							
A' (mm)	0.31	1.3	0.53	1.3	0.22	NS	
Labrale superior (mm)	0.48	1.6	0.37	1.7	-0.12	NS	
Procumbency							
Upper lip to Sn-Pg' (mm)	-0.18	1.3	-1.32	1.3	-1.13	< 0.001	
Nasolabial angle (°)	-0.12	7.2	3.10	7.8	3.22	NS	
Lower Lip							
Length							
Stm-B' (mm)	0.10	1.7	2.63	1.9	2.53	< 0.001	
Thickness							
B' (mm)	0.42	1.3	0.92	0.9	0.50	NS	
Labrale inferior (mm)	0.78	1.6	-1.87	2.4	-2.65	<0.00	
Procumbency							
Lower lip to Sn-Pg' (mm)	-0.28	1.3	-0.22	1.7	-0.07	NS	
Lower lip to E Line (mm)	-0.60	1.5	-1.07	1.7	-0.47	NS	
Mentolabial angle (°)	-2.20	2.4	15.20	5.8	17.40	< 0.001	
Chin , , .							
Thickness							
Pg' (mm) `	0.75	1.1	0.58	1.1	-0.17	NS	
Cranial Base Superimposition							
Horizontal (mm)							
Sn	+2.60	1.4	+2.10	1.4	-0.50	NS	
A'	+2.73	1.5	+1.63	1.8	-1.10	<0.0	
Labrale Superior	+2.53	1.5	+1.17	2.0	-1.37	<0.0	
Labrale Inferior	+2.82	1.4	+2.53	2.3	-0.28	NS	
B'	+2.58	1.5	+3.30	2.0	+0.72	NS	
Pg'	+2.80	1.2	+3.73	2.0	+0.93	< 0.0	
Vertical (mm)							
Sn ` ´	+1.83	1.7	+3.00	1.6	+1.17	<0.0	
Α'	+2.03	1.4	+4.10	1.8	+2.07	-<0.00	
Labrale Superior	+2.01	1.5	+3.83	1.9	+1.82	< 0.00	
Labrale Inferior	+1.58	2.0	+4.33	3.0	+2.75	< 0.00	
B'	+1.67	2.0	+5.73	2.7	+4.07	< 0.00	
Pg'	+2.47	2.1	+5.73	2.9	+3.27	<0.00	

sition analysis also showed that A point moved forward 1.17 mm less in the treated group than in the control (P≤0.001). Harvold and Vargervik<sup>14</sup> found a significant inhibition of anterior maxillary translation. In addition, Forsberg and Odendrick<sup>9</sup> reported a significant decrease in SNA with the use of the activator. Restriction of the forward movement of the maxilla is probably the result of the posteriorly directed force placed on the maxilla by the bionator when the man-

landmark as determined with cranial base superimposition.

dible is repositioned anteriorly. The difference between the two groups in changes in SNA and the position of A point, though statistically significant, is quite small. In fact, the increase in the length of the maxilla as measured by Co-ANS did not show any statistically significant difference between the two groups, but this may be because both condylion and ANS are difficult landmarks to identify. Overall, it would appear from this study that the bionator has only a slight

Figure 4
Change in angle of facial convexity (G-Sn-Pg') in the treated and control groups during treatment or observation.

Figure 5
Changes in upper lip angulation (nasolabial angle), and procumbency (upper lip to Sn-Pg') during treatment or observation.

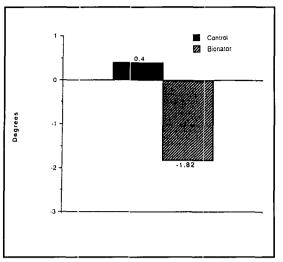


Figure 4

restrictive effect on the anteroposterior dimension of the maxilla.

#### Mandible

The length of the mandible, as represented by Ar-Gn, increased 3.6 mm more in the treated group over a period of 18 months. This resulted in 0.80 mm additional anterior movement of B point in the treated group and 1.0° increase in SNB. The increase in SNB found in this study is supported by the results of Marschner and Harris15 and Mamandras.10 The increase in mandibular length (Ar-Gn) found in this study is consistent with studies which show an increase in mandibular growth with the use of functional appliances. 15-19 However, some studies do not show an increase in mandibular length with the use of such appliances. 14,20-25 One should bear in mind that the subjects in this study were selected on the basis of successful treatment, i.e., they achieved a Class I molar relationship at the end of treatment. These patients may, therefore, have experienced growth at the higher end of the normal range of variation. The increase in length of the mandible in the treated group as compared with the control group might, therefore, be due in part to the criteria of sample selection.

# Convexity

As a result of the decreased forward movement of the maxilla and increased forward movement of the mandiple, there was a significant improvement in skeletal convexity, represented by 2.0° decrease in ANB in the treated group. There is no consensus of opinion concerning the skeletal effects of treatment with functional appliances. Previous studies both support<sup>9,10,19</sup> and refute<sup>20,21</sup> the changes in skeletal convexity presented in this study. The differences in findings might be attributed to sample size, selection criteria, appliance design, and amount of wear.

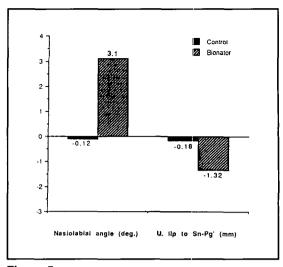


Figure 5

Face height

Because the bionator used in this study was designed to open the bite by allowing eruption of the posterior teeth, there were significant increases in anterior and posterior facial heights in the treated group. Although anterior face height increased significantly, the mandibular plane did not steepen. This can be explained by the fact that there was a concomitant increase in posterior face height. In addition, remodeling of the gonial angle<sup>15</sup> may also have helped maintain the mandibular plane angle.

# Soft tissue

# Facial convexity

There was a significant change in the profile of patients treated with the bionator. Soft tissue facial convexity, as determined by G-Sn-Pg', decreased 2.22° more in the bionator group than in the control group. Decrease in facial convexity was, to a greater extent, the result of soft tissue pogonion coming forward and, to a lesser extent, due to subnasale being restricted in its forward movement. As determined by cranial base superimposition, the soft tissue chin advanced about 1.0 mm, while subnasale came forward 0.5 mm less in the treated group than in the control group. These finding correlate well with Forsberg and Odenrick,9 who reported a significant increase in the advancement of soft tissue pogonion, and with Korkhaus,26 who made the clinical observation that activator therapy decreases the convexity of the soft tissue profile. The inhibition of forward movement of subnasale and increased anterior movement of soft tissue pogonion are reflective of the amount of movement of the underlying skeletal structures.

The nasolabial angle did not show any significant reduction in the treated group. The upper

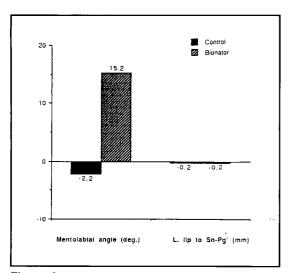


Figure 6

lip did retract about 1.0 mm more in the treated group than in the control group, relative to the Sn-Pg' line. However, this was in part due to the fact that Pg' came forward more in the treated group, thereby moving the Sn-Pg' line forward. Overall, treatment with the bionator had minimal effect on the upper lip.

The lower lip, however, showed some dramatic changes. In patients with Class II, Division 1, malocclusion, the lower lip is often distorted either behind or under the upper incisors. This results in a deep labiomental sulcus and a decreased labiomental angle. One of the major effects of treatment with the bionator was the uncurling of the lower lip, resulting in a decrease of 15.2° in the mentolabial angle (P≤0.001). The uncurling of the lower lip may be attributed to a couple of factors. The reduction of overjet removes the physical obstruction of the maxillary incisors that was causing the lower lip to deflect. In addition, during treatment with the bionator, the patient was asked to maintain a lip seal over the appliance. It is possible that the increased, sustained activity of the perioral muscles changed their tonicity and posture. As Frankel stated, the effect of the additional lip strain "requires the muscles to adopt a new permanent target of operation and causes a reeducation of the muscles."27 Uncurling of the lower lip also led to an increase of 2.5 mm in the length of the lower lip (Stm-B').

Based on the results of this study, actively growing patients with Class II, Division 1, malocclusion, decreased lower face height, and mild to moderately increased skeletal convexity would benefit most from treatment with a bionator. In terms of the soft tissue profile, the patient to benefit most from a bionator would be

one who has only a slightly protrusive upper lip, slightly to moderately increased soft tissue facial convexity, and a decreased mentolabial angle.

#### Conclusions

The purpose of this study was to determine the effects of bionator treatment on dentofacial morphology, especially the soft tissue profile. The sample consisted of 30 Caucasian children between the ages of 9 and 12 years who were successfully treated with a bionator for 18 months. Based on the sample of this study, one can conclude that treatment with a bionator results in:

- 1. Decreased skeletal convexity;
- 2. Increased anterior and posterior face heights;
- 3. Reduced overjet and overbite;
- 4. Decreased facial convexity;
- 5. Uncurling and increase in length of the lower lip;
- 6. Minimal effect on the upper lip.

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# Figure 6 Changes in lower lip

angulation (mentolabial angle) and procumbency (lower lip to Sn-Pg') during treatment or observation.

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