Changes in pharyngeal airway space and hyoid bone position after Bionator treatment of skeletal Class II malocclusions

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Objectives: The objective of this study was to investigate the treatment effectiveness of long-term Bionator use on the craniofacial pattern, nasopharynx, oropharynx, hypopharynx, hyoid bone, and cervical vertebrae in patients presenting with a skeletal Class II malocclusion involving mandibular retrognathia.
Methods: A treatment group of 27 patients with a skeletal Class II malocclusion treated using a Bionator was compared with a control group of 27 patients presenting with a skeletal Class I malocclusion managed without Bionator treatment. The Bionator was worn in the subject group until the complete eruption of the second molars. Lateral cephalograms of the group before (T0) and after Bionator treatment (T1) were compared. A two-way analysis of variance and a paired *t*-test were applied for statistical analyses.
Results: A significant increase in the SNB angle and a decrease in the ANB angle were apparent in the Bionator treatment group. The dimensions of the oropharyngeal and hypopharyngeal airways and the hypopharyngeal area increased significantly.
Conclusion Long-term treatment using a Bionator resulted in the advancement of a retrognathic mandible. In addition, the dimensions of the oropharyngeal and hypopharyngeal airways and the hypopharyngeal area increased significantly, reaching the same level as that of skeletal Class I subjects.
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Introduction

Many studies have been conducted on functional orthodontic appliances and of the various appliances, the Bionator has been noted to deliver similar treatment efficacy compared to other functional appliances[1,2] and so remains a valid option for the treatment of a Class II malocclusion.

It has been reported that the anteroposterior relationship of the mandible, the width of the pharyngeal airway, and the position of the hyoid bone and cervical vertebrae are related.[1,3–5] It has been further stated that the position of the hyoid bone is associated with mandibular growth and changes in cervical vertebrae position[6] and that the more anteriorly positioned the mandible, the more anteriorly positioned the hyoid bone and the larger the dimension of the pharyngeal airway.[7] In addition, Ohnmeiß et al. examined the relationship between the changes in position of the cervical vertebrae and mandibular growth after treatment by multiple functional appliances, and described a relationship between anterior mandibular growth and changes in the position of the cervical vertebrae.[8] A further examination of the cervical vertebral angle after treatment using the Frankel Functional Regulator appliance by Tecco et al.[9] stated that the cervical vertebral angle may increase as a result of anterior mandibular displacement.

Many reports have stated that in childhood, a narrow pharyngeal airway is associated with a skeletal Class II malocclusion as a result of mandibular retrusion, which is an indication for treatment incorporating functional orthodontic appliances.[10,11] Furthermore, it has been suggested that paediatric skeletal Class II patients, similar to obstructive sleep apnoea syndrome (OSAS) patients, have a narrow pharyngeal airway,[12] and recent attention has focused on the possibility of increasing the pharyngeal airway via a functional orthopaedics to reduce the risk of developing OSAS. It is further suggested that the lower pharyngeal airway is established at an early age,[13] and paediatric OSAS peaks in both males and females between the ages of 2 and 8 years.[14] Treatment using functional orthodontic appliances for skeletal Class II paediatric patients with a retrognathic mandibular and the treatment of paediatric OSAS patients using oral appliances are known to produce similar responses.[15] The therapeutic effect of functional appliances on skeletal Class II patients may not only improve mandibular growth during orthodontic treatment, which, as Pamir et al. also indicated, is beneficial in both dentistry and medical science.[2]

In adulthood, 80% of adult obstructive sleep apnoea syndrome (OSAS) patients requiring surgery are reported to have a narrow hypopharyngeal airway.[16]

Furthermore, it has been suggested that the oropharyngeal airway is significantly narrower in adult patients possessing a skeletal Class II malocclusion with a retrognathic mandible than in those with normal mandibular growth and position.[17] Additionally, it has been shown that a narrow pharyngeal airway and a retrognathic mandible are characteristics of adult skeletal Class II cases.[18,19] However, while orthognathic surgery is the principal treatment option for an adult skeletal Class II patient presenting with mandibular retrognathia,[20] it is noted that a narrow pharyngeal airway will not increase unless a functional appliance is used in childhood or the mandible is surgically advanced.[21]

Previous studies have indicated that the anteroposterior position of the mandible is related to the size of the pharyngeal airway.[3,22,23] However, few studies have measured the pharyngeal airway after Bionator treatment, and distinguished between the nasopharyngeal, oropharyngeal, and hypopharyngeal airways. In addition, rare studies have examined the hyoid bone and its relationship with the cervical vertebrae and few have examined the effects of wearing the Bionator over a long period of time.[23–25]

Based on earlier reports, the present study aimed to determine the changes in the nasopharynx, oropharynx, and hypopharynx following Bionator wear over a long period of time. It was also aimed to perform an exploratory examination regarding changes in the position of the hyoid bone and cervical vertebrae.

Material and method

The Research Ethics Committee of the Nippon Dental University Hospital approved the research protocol (ECNG-R-433). Informed consent was obtained using the "opt-out" approach.

The sample size was calculated based on an a priori power analysis using G* power version 3 (Heinrich Heine Universität, Dusseldorf, Germany) for a two-way analysis of variance (ANOVA) at an effect size of 0.25 (Cohen's medium effect size), an alpha error probability of 0.05, a power of 0.90, and the number of groups equal to 2. The analysis showed that a total of 46 subjects were required.

The patient records from the orthodontic clinic of the Nippon Dental University Hospital (Niigata, Japan) from 2012 to 2019 were searched. Identified were the data of 32 patients who had a skeletal Class II and bilateral Angle Class II molar relationship and were treated using a Bionator, plus the data of 35 patients who had a bilateral Angle Class I molar and a skeletal Class I relationship who were not treated. These were back-traced and randomly selected. In addition, the following conditions were applied.

The inclusion criteria were: (1) fully erupted maxillary and mandibular incisors at T0; (2) fully erupted

Table I. Mean ages at T0 and T1 and mean treatment/observation time

	Treatment group						Control group					
	Male		Female		Both sexes		Male		Female		Both sexes	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Age at T0	10y3m	1y5m	10y0m	2y1m	10y1m	1y9m	9y9m	1y5m	9y8m	1y6m	9y8m	1y5m
Age at T1	13y10m	1y7m	13y10m	1y5m	13y10m	1y5m	13y5m	1y3m	13y5m	1y3m	13y5m	1y6m
Treatment/observation time	3y7m	0y11m	3y10m	1y4m	3y8m	1y2m	3y8m	1y5m	3y9m	1y5m	3y9m	1y4m

SD, standard division; T0, before treatment; T1, after treatment.

Table II. Definitions of the reference points and lines used

	Definition
	Reference point
S	Sella turcica
N	Nasion
A	Subspinale
B	Supramentale
PNS	Posterior nasal spine
P	Tip of the soft plate
R	Midpoint of the distance between S and PNS
Cv3	Anteroinferior point of the third cervical vertebra
PPW1	Intersection of the posterior pharyngeal wall and the line parallel to HR through PNS
PPW2	Intersection of the posterior pharyngeal wall and the line parallel to HR through P
PPW3	Intersection of the posterior pharyngeal wall and the line parallel to HR through Cv3
APW3	Intersection of the anterior pharyngeal wall and the line parallel to HR through Cv3
Hi	Anterior point of the hyoid bone
	Reference lines
SN	S-N plane, line thorough S and N
HR	Horizontal reference plane, line 7° to S-N plane
VR	Vertical reference plane, line perpendicular to HR through S
CVT	Cervical vertebrae tangent, tangential line along the cervical vertebrae
OPT	Odontoid process tangent, tangential line along the cervical vertebrae

maxillary and mandibular second molars at T1; (3) two consecutive good quality panoramic radiographs and lateral cephalograms; and (4) acceptable co-operation. The exclusion criteria were: (1) congenital deformities; (2) the extraction of permanent teeth during treatment/observation; and (3) previous orthodontic treatment.

Of the 32 patients treated using the Bionator appliance, two patients had unclear lateral cephalometric images and three patients had no lateral cephalometric images at T0, and therefore they were excluded. Of the 35 patients who did not receive Bionator treatment, three had unclear lateral cephalometric images and five had no lateral cephalometric images at T0, therefore they were also excluded. As a result, 27 patients were retrospectively selected for the treatment and control groups.

The patients were included regardless of treatment outcomes. The two groups were well matched with respect to mean age at T0 and T1 (Table I).

Eighteen of the 27 patients in the treatment group had sectional brackets applied to correct crowding of the maxillary incisors and produce an overjet equal to, or greater than, the molar discrepancy. After preparatory treatment, Hawley type retainers were inserted and worn during the day except when wearing the Bionator, eating, or tooth brushing. The Bionator was worn for at least 14 hr a day, including during sleep, until complete eruption of the second molars. Panoramic radiographs and lateral cephalograms were obtained before (T0) and after (T1) the Bionator treatment. The changes that occurred during the T0–T1 time period were compared to those that occurred during the corresponding time period in a control group of 27 patients (10 male and 17 female) with a skeletal and dental Class I malocclusion.

Twenty-two of the 27 control group were treated for maxillary incisor crowding using sectional bracket appliances following which, Hawley-type retainers were inserted and subsequently monitored. The additional untreated control group was monitored and examined once during the T0–T1 time period.

Cephalometric analysis

All lateral cephalograms were obtained using the same cephalostat (CX-150SK, Asahi Roentgen, Kyoto, Japan) in a standardised setting and routine. Each cephalogram was coded by a person who was not directly involved in the study and subsequently traced and measured by one investigator (M.T.).

Jiang et al. provided the primary reference for establishing the measurement landmarks.[18] Thirteen reference points and five lines were selected (Table II, Figures 1 and 2), and six linear, five angular, and three area measurements were taken to investigate craniofacial and pharyngeal morphology (Table III, Figures 1 and 2). Angular and linear measurements were made using the WinCeph analysis software (Rise Corp, Miyagi, Japan), and area measurements were obtained using Image J (version 1.53a, National Institutes of Health, Bethesda, MD, USA).

Statistical analysis

Statistical analyses were conducted using SPSS for Mac (version 27, IBM, Tokyo, Japan). Two-way repeated-measures ANOVA was performed to test the main effects of group (between-subject factor) and time (within-subject factor) on craniofacial and pharyngeal morphology, after testing the normality of the distribution and the homogeneity of the variance. If two-way repeated-measures ANOVA showed a significant interaction between two factors, simple main effects and Bonferroni tests were applied to compare the measurement between the groups and between the times. Unpaired *t*-tests were used to determine significant differences in the treatment / observation changes (T1–T0) between the treatment and control groups.

To assess measurement errors, 40 coded cephalograms were randomly selected and re-examined by the same investigator (M.T.) three months following the first assessment. Random errors, calculated according to the Dahlberg formula,[26] were found to be less than 0.43° for the angular measurements, less than 0.45 mm for the linear measurements, and 9.93 mm^2 for the area measurements, which were unlikely to affect the significance of the present results.

Results

The two-way analysis of variance conducted in the present study revealed significant differences between T0 and T1 in multiple measurements. Specifically, the following variables showed statistical significance: SNA angle (the sella–nasion–subspinale angle, $P<0.05$), Hi-HR (vertical position of the hyoid bone, $P < 0.05$), PNS-R (upper nasopharyngeal airway dimension, $P < 0.05$), PNS-PPW1 (lower nasopharyngeal airway dimension, $P < 0.05$), P-PPW2 (lower oropharyngeal airway dimension, $P < 0.05$), nasopharyngeal area (nasopharyngeal airway area, $P < 0.05$), and oropharyngeal area (oropharyngeal airway area, $P < 0.05$). However, when comparing the treatment and control groups, no significant differences were observed for these measures. Additionally, no significant interactions were found between the group and time factors. These findings are presented in Tables IV and V.

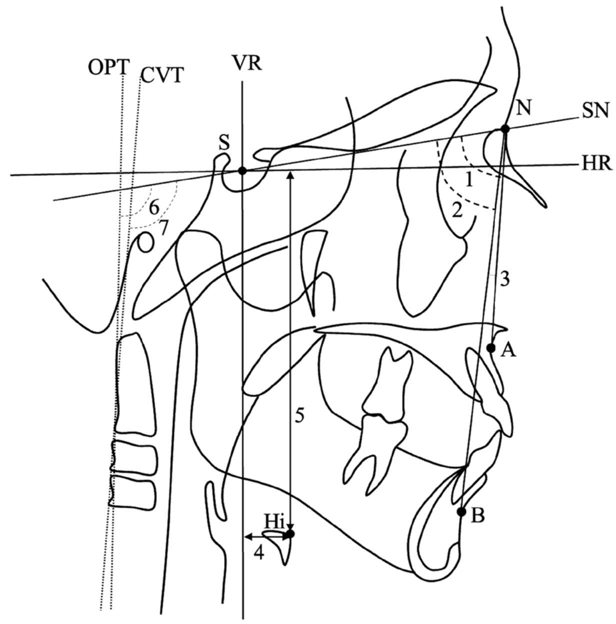

Figure 1. Linear and angular measurements. 1. SNA; 2. SNB; 3. ANB; 4. Hi-VR; 5. Hi-HR; 6. SN-OPT; 7. SN-CVT.

In addition, no significant differences in the Hi-VR dimension (horizontal position of the hyoid bone), the SN-OPT angle (odontoid process angulation), and the SN-CVT angle (cervical vertebral angulation)

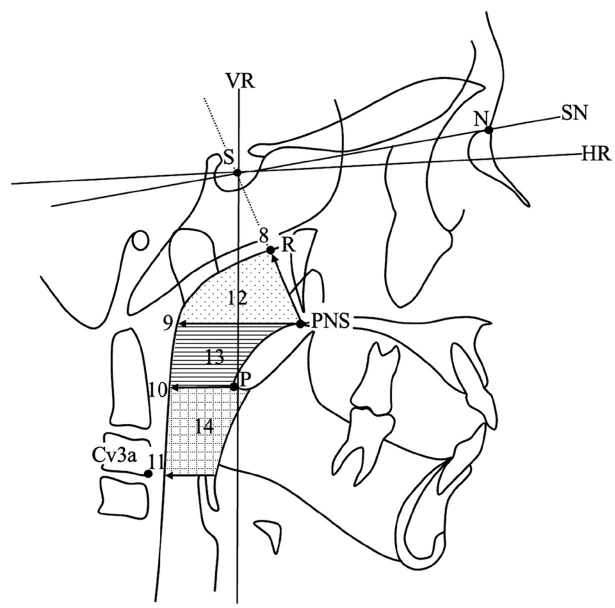

Figure 2. Linear and area measurements. 8. PNS-R; 9. PNS-PPW1; 10. P-PPW2; 11. APW3-PPW3; 12. Nasopharyngeal; 13. Oropharyngeal; 14. Hypopharyngeal.

Table III. Definitions of measurements

Measurement	Figure 1	Definition
SNA (°)	1	Prognathism of the maxillary alveolar bone, angle formed by S, N, and A
SNB (°)	2	Prognathism of the mandibular alveolar bone, angle formed by S, N, and B
ANB (°)	3	Sagittal jaw relationship angle, angle formed by A, N, and B
Hi-VR (mm)	4	Horizontal position of the hyoid bone, distance from Hi to VR
Hi-HR (mm)	5	Vertical position of the hyoid bone, distance from Hi to HR
SN-OPT (°)	6	Odontoid process angulation, angle formed by SN and OPT
SN-CVT (°)	7	Cervical vertebrae angulation, angle formed by SN and CVT
	Figure 2	
PNS-R (mm)	8	Length of upper nasopharyngeal airway, distance from PNS to R
PNS-PPW1 (mm)	9	Length of lower nasopharyngeal airway, distance from PNS to PPW1
P-PPW2 (mm)	10	Length of lower oropharyngeal airway, distance from P to PPW2
APW3-PPW3 (mm)	11	Length of lower hypopharyngeal airway, distance from P to PPW3
Nasopharyngeal (mm^2)	12	Area of nasopharyngeal airway, airway area PNS-R and PNS-PPW1 line
Oropharyngeal (mm^2)	13	Area of oropharyngeal airway, airway area PNS-PPW1 and P-PPW2 line
Hypopharyngeal (mm^2)	14	Area of nasopharyngeal airway, airway area P-PPW2 and Cv3-PPW3 line

were observed between the groups between T0 and T1, and without significant interactions between the two factors (Tables IV, V).

Two-way ANOVA and simple main effect tests demonstrated that the SNB angle (the sella–nasion–supramentale point angle, $P < 0.05$) showed a significant difference between the treatment and control groups at T0 and between T0 and T1 in both groups. The ANB angle (the subspinale point–nasion–supramentale point angle, $P < 0.05$) showed significant differences between the groups at T0 and T1 and between T0 and T1 in the treatment group. The P-PPW2 dimensions (lower oropharyngeal airway dimensions, $P < 0.05$), the APW3-PPW3 dimensions (lower hypopharyngeal airway dimensions, $P < 0.05$), and hypopharyngeal area (hypopharyngeal airway area, $P < 0.05$) showed significant differences between groups at T0 and between T0 and T1 in the treatment group (Tables IV, V).

The unpaired *t*-test showed significant differences in the changes in the SNB and ANB angles, P-PPW2 and APW3-PPW3 dimensions, and hypopharyngeal area between the treatment and control groups (Tables VI, VII).

Discussion

The present study determined that, after Bionator treatment, the mandibular retrognathia of skeletal Class II malocclusion patients exhibited anterior growth, and the narrow pharynx increased in dimension and area. Many studies have detailed the changes related to the pharynx due to functional appliance treatment[3,27,28] but most measurements did not include the hypopharynx. Several previous studies treated both the oropharynx and hypopharynx (as defined in the present study) as solely the oropharynx.[3,10] However, when separate measurements of the nasopharynx, oropharynx, and hypopharynx were conducted, it was theorised that only the oropharynx grew larger,[29–31] while others found that only the hypopharynx grew.[32,33] However, some concluded that the oropharynx and the hypopharynx enlarged.[34] A previous study examined Bionator treatment and reported that the hypopharynx grew, but without comparison with a control group.[33] The present study focused on a comparison of Bionator treatment against a control group, which provided a high level of objectivity to the results. Whereas a study by Ulusoy measured the oropharynx and hypopharynx (as defined in the present study) as the oropharynx and found enlargement after activator treatment,[10] the current study conducted a more precise evaluation of the changes in the pharyngeal airway, through separate measurements of the nasopharynx, oropharynx, and hypopharynx, and revealed an increase in the dimensions of the oropharynx and hypopharynx as well as the area of the hypopharyngeal airway.

The present study indicated that the dimensions and area of the hypopharyngeal airway increased significantly following Bionator treatment and related to a change in the horizontal position of the hyoid bone. A movement of 5% has been considered insignificant ($P = 0.050$) but 10% considered significant, and therefore a tendency towards anterior movement of the hyoid bone was measured. It was found that enlargement of the hypopharynx resulted from forward movement of the hyoid bone.[11] By moving the mandible forward, the Bionator is reported to normalise muscle interplay and prevent inferior growth of the surrounding dentition and jawbone.[35] The findings of previous studies and of the present study show that Bionator treatment may affect the muscles attached to the hyoid bone. Moreover, the wear of the appliance for longer than a year in the present study, which is longer than in previous studies using other functional appliances, may have encouraged the normalisation of muscle interplay,[35] and led to the increases seen in the oropharyngeal and hypopharyngeal airways.

Noted in the present study, the oropharynx and hypopharynx were narrower in the treatment group than in the control group. It has been found that the use of a functional appliance in childhood may enhance biological performance during growth and development, compared to class II patients without treatment.[22] In the present study, the significant increase in the dimensions of the oropharynx and hypopharynx of the treatment group suggests that the pharyngeal airway changes surpassed normal growth and reached healthy pharyngeal airway dimensions following Bionator treatment. This further suggests that it is possible to reduce the risk of developing future OSAS and therefore avoid highly invasive surgery as a treatment option.

Many studies have indicated that treatment using functional appliances for skeletal Class II patients with mandibular recessiveness in childhood is associated with a reduced risk of developing OSAS. Activator treatment, which encourages an increase in the pharyngeal airway and normalises nocturnal

Table IV. Results of craniofacial morphological measurements in groups T and C

		Treatment group (T)		Control group (C)		Two-way ANOVA		
Measurement	Time	Mean	SD	Mean	SD	GroupxTime	Group	Time
SNA (°)	T0	81.6	4.3	81.0	3.7	NS	NS	<0.05
	T1	82.2	3.5	81.6	3.0			
SNB (°)	T0	75.4	3.0	77.7	3.1	<0.05	T0: <0.05	T: <0.01
	T1	77.7	3.0	78.8	3.1		T1: NS	C:<0.01
ANB (°)	T0	6.2	2.3	3.3	1.6	<0.05	T0: <0.01	T: <0.01
	T1	4.5	1.9	2.8	1.6		T1: <0.05	C: NS
Hi-VR (mm)	T0	9.1	5.8	8.8	5.4	NS	NS	NS
	T1	10.5	6.5	10.1	6.3			
Hi-HR (mm)	T0	87.4	6.9	88.9	8.4	NS	NS	<0.05
	T1	97.9	7.2	97.1	7.8			
SN-OPT (°)	T0	100.2	8.7	102.2	7.1	NS	NS	NS
	T1	101.0	8.0	101.3	8.1			
SN-CVT (°)	T0	106.5	8.4	107.0	6.3	NS	NS	NS
	T1	108.7	7.3	108.1	6.6			

NS, not significant; SD, standard division; T0, before treatment; T1, after treatment.

respiration, may also enhance growth hormone secretion.[21] A significant improvement in nocturnal breathing has been found after oral appliance treatment of adult OSAS patients.[36] In addition, after Herbst appliance treatment of skeletal Class II patients with habitual snoring at the peak of adolescent growth, the oropharynx is reported to be enlarged and sleep-disordered breathing improved.[37] Moreover, IGF-1 and IGFBP-3 secretion and body weight are found to increase after adenoidectomy in infant OSAS patients.[38] These findings indicate that the increase in dimensions and area of the pharyngeal airway resulting from adenoidectomy increases growth hormone secretion and thus plays an important role in promoting growth of an inadequate mandible. The Bionator treatment conducted in the present study, increased the dimensions of the oropharynx and hypopharynx and the area of the hypopharynx, and may have also enhanced growth hormone secretion, which may play an important role in promoting enlargement of a retrognathic mandible.

The hyoid bone of both the treatment and control groups in the present study was displaced significantly downward. With regard to the horizontal positional change, the hyoid bone in both groups tended to move forward. This result is consistent with several previous studies, which revealed that there was forward horizontal movement of the hyoid bone after treatment using functional appliances.[3,10,11,33,34]

As reported by previous studies, the vertical position of the hyoid bone experienced a downward movement,[3,10,39] while contrary studies have reported an upward movement.[11] In addition, there have been several studies which have investigated the positional change of the hyoid bone after mandibular advancement in adult skeletal Class II patients, and most found that the hyoid bone moved upward.[18,40,41] As noted by Tsuiki,[42] the varied results of different studies is likely because there are multiple muscles attached to the hyoid bone, and the complex functional movements result in a number of spatial changes.

There was no significant change in cervical vertebral angle after treatment for both SN-OPT and SN-CVT in the Bionator and control groups. Liu et al. examined the Class I, II, and III cervical spine positions and angles of children aged 11–14 years without orthodontic treatment using functional appliances and the NSL-OPT and NSL-CVT, in

Table V. Results of pharyngeal airway measurements in groups T and C

		Treatment		Control		Two-way ANOVA		
Measurement	Time	Mean	SD	Mean	SD	Group×Time	Group	Time
PNS-R (mm)	T0	42.7	2.9	42.8	2.9	NS	NS	<0.05
	T1	46.5	3.6	45.5	3.2			
PNS-PPW1 (mm)	T0	22.4	3.9	22.2	2.9	NS	NS	<0.05
	T1	24.3	4.6	23.8	2.7			
P-PPW2 (mm)	T0	10.4	2.4	12.5	3.3	<0.05	T0: <0.05	T: <0.01
	T1	12.5	3.3	12.6	2.7		T1: NS	C: NS
APW3-PPW3 (mm)	T0	9.4	2.5	11.0	2.3	<0.05	T0: <0.05	T: <0.01
	T1	11.9	2.8	11.6	3.4		T1: NS	C: NS
Nasopharyngeal area (mm^2)	T0	167.9	79.2	185.7	56.1	NS	NS	<0.05
	T1	238.3	92.3	235.2	79.2			
Oropharyngeal area (mm^2)	T0	165.2	39.1	184.4	49.3	NS	NS	<0.05
	T1	225.4	63.7	231.8	47.3			
Hypopharyngeal area (mm^2)	T0	248.9	104.6	337.4	90.6	<0.05	T0: <0.05	T: <0.01
	T1	355.2	105.4	370.5	113.4		T1: NS	C: NS

NS, not significant; SD, standard division; T0, before treatment; T1, after treatment.

Table VI. Changes in measurements of craniofacial morphology (T1-T0) in groups T and C

	Treatment		Control		
Measurement	Mean	SD	Mean	SD	Significance
SNA (°)	0.5	1.8	0.7	1.5	NS
SNB (°)	2.3	1.9	1.2	1.6	<0.05
ANB (°)	–1.7	1.5	–0.5	1.4	<0.05
Hi-VR (mm)	1.4	5.6	1.3	4.3	NS
Hi-HR (mm)	10.5	6.7	8.2	6.9	NS
SN-OPT (°)	1.2	5.3	–0.9	5.3	NS
SN-CVT (°)	3.0	6.2	0.9	6.7	NS

NS, not significant.

harmony with SN-OPT and SN-CVT identified in the present study, indicated that there was no significant difference in Class II compared to Class I patients.[43] This supports the results of the present study, which found no significant difference in cervical vertebral angles in the Class II treatment group before Bionator treatment and the Class I control group. In addition, Kamal et al. who took lateral cephalograms under conditions similar to those of the present study, stated that there were no significant angular changes after Twin-Block treatment.[44] Similarly, Ozbek et al. reported that there were no significant changes in cervical vertebral changes after activator treatment.[22] The present study supports these findings and found no significant difference between Bionator treatment and cervical vertebral angle changes due to growth and development.

Han indicated that the growing pharyngeal airway augmented by Bionator treatment was maintained into adulthood.[23] The present study did not conduct follow-up examinations into adulthood after the use of the Bionator was discontinued. However, as previous studies have suggested, it is possible that the enlarged pharyngeal airway may be maintained in the treatment group into adulthood and beyond. However, Bionator treatment effectiveness needs to be studied further through long-term follow-up.

The main limitation of the present study was that the pharyngeal airway was measured using lateral cephalograms rather than using Cone Beam Computed Tomography (CBCT) images. Although it is not beneficial to routinely perform tests with unnecessarily high radiation exposure on patients undergoing growth and development, such as the treatment group of the present study, there is much useful information in

Table VII. Changes in measurements of pharyngeal airway (T1–T0) in Groups T and C

	Treatment		Control		
Measurement	Mean	SD	Mean	SD	Significance
PNS-R (mm)	3.8	2.2	2.7	2.0	NS
PNS-PPW1 (mm)	2.0	3.1	1.6	2.3	NS
P-PPW2 (mm)	2.1	3.0	0.1	3.5	<0.05
APW3-PPW3 (mm)	2.5	2.7	0.6	3.4	<0.05
Nasopharyngeal area (mm^2)	70.4	57.0	49.5	49.0	NS
Oropharyngeal area (mm^2)	60.3	57.6	47.4	43.7	NS
Hypopharyngeal area (mm^2)	106.3	111.6	33.1	93.2	<0.05

NS, not significant.

CBCT images that cannot be obtained from lateral cephalometric imaging. Therefore, measurements using CBCT images may provide further information regarding, not only changes in pharyngeal airway volume, hyoid bone, and cervical vertebrae position, but also of the surrounding musculature and the therapeutic effects of functional appliances. An additional limitation is that the present study used patients identified with a skeletal Class I malocclusion and normal mandibular growth as the control group, which made it difficult to exclude the influence of the treatment applied to the skeletal Class I patients. The selection of untreated skeletal Class II patients for the control group was deemed ethically problematic to withhold treatment from a skeletal Class II paediatric patient. Nevertheless, by using growing children of the same age as the treatment group, the present study was able to identify the effects of Bionator treatment, such as improvement of the mandibular retrognathia and enlargement of the narrow pharyngeal airway, based on the post-treatment results of the control group. It was considered that this was a result of major importance.

Conclusion

After Bionator treatment of patients presenting with a skeletal Class II malocclusion involving mandibular retrognathia, the mandible was shown to grow significantly more anteriorly than in the control group, and the oropharyngeal and hypopharyngeal airway dimensions and hypopharyngeal airway area were significantly increased. In addition, the hyoid bone tended to move forward, and there was no significant change in the cervical vertebral angle induced by Bionator treatment.

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Conflict of interest

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None.

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