

Changes in airway patency and sleep-breathing in healthy skeletal Class II children undergoing functional Activator therapy

Purpose

Several studies agree that an abnormal maxilla-mandible relationship correlates better as an Obstructive Sleep Apnea (OSA) predictor, rather than obesity. One of the orthodontic therapies recommended for this kind of craniofacial deformity is to advance the mandible forward with an orthodontic activator, therefore, the aim of this study is to determine if healthy children that use this appliance experience a widening of the upper airway as well as an improvement in their sleep-breathing patterns.

Materials and Methods

39 healthy children, 20 for activator group (10 boys and 10 girls, 4 mean age 10.9 + 0.9; BMI 16.2 + 1.4), 19 for control group (13 boys and 6 girls, mean age 5 9.8 + 1.4; BMI 17.6 + 2.1) participated in this study. They were required to submit 2 lateral cephalometric radiographs both at initial and final stages of evaluation, and finally three at-home sleep-breathing monitoring results for the activator group and one for the control group.

Results

After radiographic evaluation, it was found that children in the activator group experienced an increase in all measured variables. After evaluation with the sleep monitor, an improvement of sleep-breathing was found in children from the activator group ($p < 0.05$).






Conclusion

The activator not only provides a harmonious occlusion and proper development of the mandible, but it also helps improve the quality of sleep-breathing through widening of the upper airway and reducing the number of disordered breathing events in children that undergo this therapy.

Keywords: Orthodontic activator, sleep-breathing, upper airway, retrognathic mandible, at-home sleep monitoring

Introduction

Humans are born conditioned to eat by the mouth and breathe through the nostrils, an imbalance of this physiological pattern affects growth and development, not only on facial harmony but also in general health terms; when the child's breathing patterns are abnormal, they are then considered a multifaceted clinical entity, which produces alterations than can affect their physical and mental development (1,2). Many authors agree that obesity is a major risk factor for disordered sleep breathing which includes Obstructive Sleep Apnea (OSA) in children and adults, however, obesity levels are comparatively low in Japanese society, meaning that obesity may not be a leading cause of OSA in Japanese children and adult patients (3-7). Previous studies agree that an abnormal maxilla-mandible relationship correlates better than obesity as an OSA predictor, especially in oriental populations (8,9). According to a study in 2017, some

Cynthia Concepción Medina¹ ,
Hiroshi Ueda¹ ,
Koji Iwai¹ ,
Ryo Kunimatsu¹ ,
Kotaro Tanimoto¹ 

ORCID IDs of the authors: C.C.M. 0000-0001-7649-6688;
H.U. 0000-0002-7705-3616; K.I. 0000-0002-9925-6465;
R.K. 0000-0002-5016-4957; K.T. 0000-0003-4439-1579

¹Department of Orthodontics and Craniofacial Developmental Biology, Graduate School of Biomedical and Health Sciences, Hiroshima University, Japan

Corresponding Author: Cynthia Concepción Medina

E-mail: cynthiac@hiroshima-u.ac.jp;
milm@hiroshima-u.ac.jp

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characteristics that are predominantly associated with OSA include retropositioning of the mandible, a smaller cranial base, an increase in the cranio-cervical angle as well as abnormal upper airway soft tissue morphology (10). Separate studies concur that the occlusion of the airway was highly associated to the anatomical structure of the upper airway and the mandible (e.g. hypertrophy of the pharyngeal and palatine tonsils) as one of the major causes of OSA or sleep disordered breathing in children (11-13).

One of the craniofacial deformities most frequently associated with OSA is maxillomandibular anteroposterior and vertical disproportion which is a result of poor mandibular growth, that can be ameliorated with simple orthopedic appliances during a relatively brief time; in children one of the treatment options include advancing the mandible forward by fixed or removable orthodontic functional appliances (10).

Hence, maxillomandibular correction represents an important and effective treatment to snoring and a preventive measure for OSA during childhood, as previously demonstrated in children of 4 to 10 years of age treated with removable oral appliances for 6 months (14,15). Therefore, we assessed the effects of one of those previously mentioned appliances, the functional activator, on healthy children, to determine if there actually is an improvement in said breathing patterns. By advancing the mandible forward during orthopedic therapy with the activator there is the possibility for the upper airway to widen, thus favoring a better sleep-breathing pattern for children undergoing this therapy (16,17). Therefore, the aim of this study is to confirm the hypothesis that besides the intended inducement of development of the mandible the activator may also help improving healthy sleep breathing patterns in skeletal Class II children even when there is an absence of sleep disordered breathing by increasing their upper airway dimensions. To test this hypothesis, several evaluations, including radiographical assessment of the upper airway, sleep-breathing monitoring and questionnaires aimed both to the evaluated children and their parents were implemented.

Materials and Methods

Ethical statement

This research has been approved by the Ethics Review Committee of Hiroshima University (No. E – 56). Both groups needed to have provided informed consent from the parent or guardian prior all evaluations. This study has followed the guidelines stated in the Helsinki Declaration for clinical investigations.

Study sample

Subjects in this study consisted of 39 children, 20 for activator group (10 boys and 10 girls, mean age 10.9 ± 0.9 ; BMI 16.2 ± 1.4), 19 for control group (13 boys and 6 girls, mean age 9.8 ± 1.4 ; BMI 17.6 ± 2.1). This sample size was decided from the subjects that were indicated to wear an activator to treat a Class II skeletal discrepancy.

Anatomical features

The anatomical references that divide the skeletal pattern into Class I and II are SNA angle (anteroposterior position

of the maxilla), SNB angle (anteroposterior position of the mandible) and ANB angle (relationship between the maxilla and the mandible). The skeletal pattern of the subjects in the control group at the beginning of the evaluation period was, SNA 81.3 ± 0.3 , SNB 76.4 ± 2.3 and ANB 4.8 ± 1.2 , and for the subjects of the activator group were SNA 80.7 ± 2.5 , SNB 74.6 ± 0.9 and ANB 6.8 ± 1.7 , from the average assessed values all our participants were divided accordingly with characteristics that the literature consensus agreed are skeletal Class I for the control group and Class II for the activator group respectively.

Inclusion and exclusion criteria

For the activator group, the specific inclusion/exclusion requirements included being skeletal Class II patients currently undergoing Andresen orthodontic activator and to have successfully cleared all screening tests. For the control group the specific inclusion/exclusion requirements, irrespectively of the orthodontic appliance used, that fulfill the following criteria: healthy skeletal Class I children who have successfully cleared all screening tests. Inclusion criteria for both groups included no previous history of sleep-related child breathing disorders, general good health, and agreement to be evaluated for the duration of this study, exclusion criteria included previous adenoidectomy, allergic rhinitis, muscular disorders, maxillofacial clefts or any systemic diseases.

Dental appliance

All patients in the activator group were treated using the acrylic-splint Andresen functional activator appliance to the point of mandibular advancement. It consisted of two anterior labial bows, one for the upper dentition and another for the lower dentition, both being straight 0.9 mm wires that embrace the labial surface of the anterior dentition from each left and right lateral tooth with two loops that go upwards to the buccal corridor from half point the labial surface of both left and right canines and end in the palatal surface immediately behind the canines. The average treatment time was 18.3 ± 3.2 months. The mandible was initially advanced 6.0 ± 1.7 mm on average and was opened by $4.0 + 1.0$ mm vertically. Subsequent stepwise anterior activations were needed depending on the case.

For the control group, the orthodontic appliance used for their respective cases was irrelevant for this study, unless it impeded the use of a portable sleep monitor to evaluate their sleep-breathing patterns.

Questionnaires

As a method for screening if the child or the parents have noticed any abnormal sleep-related behavior, two different questionnaires were given to the patients and to the parents, respectively. First, an Epworth Daytime Sleepiness Scale (ESS) questionnaire was distributed among the children (Figure 1). This is a self-administered questionnaire that provides a scaled measure of a person's, in this case children, general level of daytime sleepiness. Because we are dealing with under-age subjects, questions related to the consumption of alcohol included in the original questionnaire have been modified

(18). The second questionnaire used was the Sleep Related Breathing Disorder Subscale (SRBD) (Figure 1). In this case, this questionnaire is answered by the parents with information concerning what they have witnessed of their child's usual sleep behavior (19). Both surveys were given to the subjects and their parents or guardians at the initial stage and towards the end of active treatment to both study groups.

Cephalometric analysis

To confirm in a physical tangible way that the changes measured in this study were indeed happening, three lateral cephalometric radiographs were required from the patients. Lateral cephalometric radiographs were taken in the upright standard natural head position at two time points (T0, initial record, and T1' towards the end of active orthodontic treatment) for both groups; tracing was constructed on each lateral cephalography before performing the analysis. All radiographs were traced again after a month to check for inconsistencies. All cephalography radiographs were taken by an experienced technician in and manually traced by the first author, with the anatomical landmarks presented in Figure 2.

Upper airway linear width

The anteroposterior size of the upper airway has always been a topic of scrutiny when speaking about the effects of certain oral appliances, in this case we divided our analysis into linear and volumetric area of the upper airway. The anteroposterior lines of reference used to evaluate the width of the upper airway were (20): SPAS: The thickness of the airway behind the soft palate along a line parallel to Go-B. MAS: The thickness of the airway along a line parallel to Go-B through P. IAS: The thickness of the airway along a line extended through Go-B. (Figure 3t0') To measure the total volume or area of the remaining sections of the upper airway, the oropharynx (the part of the pharynx that lies between the soft palate and the hyoid bone) and the hypopharynx (part

of the pharynx extending from the hyoid bone to the lower margin of the cricoid cartilage) (Figure 3)(20).

At-home monitoring of sleep-breathing

As a method of assessing the changes of breathing patterns during functional orthopedic therapy, the patients were asked to use a type 3 portable sleep monitor (BRIZZY Nomics, Liege, Belgium) (Figure 4) three times, once without using the activator to check normal breathing parameters (T0); a second time with the child wearing the activator to confirm whether sleep-breathing improves (T1), data collection for this stage with the activator inserted was done once use of the oral appliance had been stable and continuous. A third time was asked for the subject patients in the activator group when activator therapy was finished or almost finished (T2). For control group, only one time was required to compare. This portable monitor (PM) works with midsagittal sensors which are positioned one in the chin and the other on the forehead, these must be positioned on the same axis and parallel to each other; these sensors measure the jaw movement by electromagnetism which is released in very low energy magnetic pulses and in short duration. By measuring the movements and behavior of the lower jaw during sleep, this monitor can determine which kind of respiratory event the patient is having.

From using this device many indicators of sleep disturbance can be measured, such as, Respiratory Disturbance Index (RDI), or apnea hypopnea index, is the number of obstructive, central, and mixed events per hour of sleep, Arousal Index, (ARL) or number of arousals or discontinuity per hour of sleep. This monitor also provides valuable information about a patient's obstructive, central and mixed respiratory events.

Statistical analysis

All statistical analyses were performed using MedCalc Statistical Software version 17.8.6 (MedCalc Software bvba,

Epworth Sleepiness Scale—Children

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, think about how they would have affected you. Use the following scale to choose the most appropriate number for each situation.

- 0=would never doze or sleep
1=slight chance of dozing or sleeping
2=moderate chance of dozing or sleeping
3=high chance of dozing or sleeping.

Circle the most appropriate number for each situation:

1. Sitting and reading	0	1	2	3
2. Watching television	0	1	2	3
3. Sitting inactive in a public place (for example, a movie theater or classroom)	0	1	2	3
4. As a passenger in a car for an hour without a break	0	1	2	3
5. Lying down to rest in the afternoon when circumstances Permit	0	1	2	3
6. Sitting and talking to someone	0	1	2	3
7. Sitting quietly after lunch	0	1	2	3
8. Doing homework or taking a test	0	1	2	3

4. The SRBD questionnaire.

Child's Name: _____ Study ID #: _____
Person completing form: _____ Date: _____

Please answer these questions regarding the behavior of your child during sleep and wakefulness. The questions apply to how your child acts in general during the past month, not necessarily during the past few days since these may not have been typical if your child has not been well. You should circle the correct response or print your answer neatly in the space provided. A "Y" means "yes," "N" means "no," and "DK" means "don't know."

1. WHILE SLEEPING, DOES YOUR CHILD:				
Snores more than half the time?	Y	N	DK	A2
Always snores?	Y	N	DK	A3
Snores loudly?	Y	N	DK	A4
Have "heavy" or loud breathing?	Y	N	DK	A5
Have trouble breathing, or struggle to breathe?	Y	N	DK	A6
2. HAVE YOU EVER SEEN YOUR CHILD STOP BREATHING DURING THE NIGHT?	Y	N	DK	A7
3. DOES YOUR CHILD:				
Tend to breathe through the mouth during the day?	Y	N	DK	A24
Have a dry mouth on waking up in the morning?	Y	N	DK	A23
Occasionally wet the bed?	Y	N	DK	A32
4. DOES YOUR CHILD:				
Wake up feeling unrefreshed in the morning?	Y	N	DK	B1
Have a problem with sleepiness during the day?	Y	N	DK	B2
5. HAS A TEACHER OR OTHER SUPERVISOR COMMENTED THAT YOUR CHILD APPEARS SLEEPY DURING THE DAY?	Y	N	DK	B4
6. IS IT HARD TO WAKE YOUR CHILD UP IN THE MORNING?	Y	N	DK	B6
7. DOES YOUR CHILD WAKE UP WITH HEADACHES IN THE MORNING?	Y	N	DK	B7
8. DID YOUR CHILD STOP GROWING AT A NORMAL RATE AT ANY TIME SINCE BIRTH?	Y	N	DK	B9
9. IS YOUR CHILD OVERWEIGHT?	Y	N	DK	B22
10. THIS CHILD OFTEN:				
Does not seem to listen when spoken to directly.	Y	N	DK	C1
Has difficulty organizing tasks and activities.	Y	N	DK	C1
Is easily distracted by extraneous stimuli.	Y	N	DK	C1
Fidgets with hands or feet or squirms in seat.	Y	N	DK	C18
Is "on the go" or often acts as if "driven by a motor".	Y	N	DK	C14
Interrupts or intrudes on others (eg., butts into conversations or games).	Y	N	DK	C18

Thank you!

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Figure 1. LEFT – The ESS questionnaire modified for children. RIGHT – The SRBD scale questionnaire.

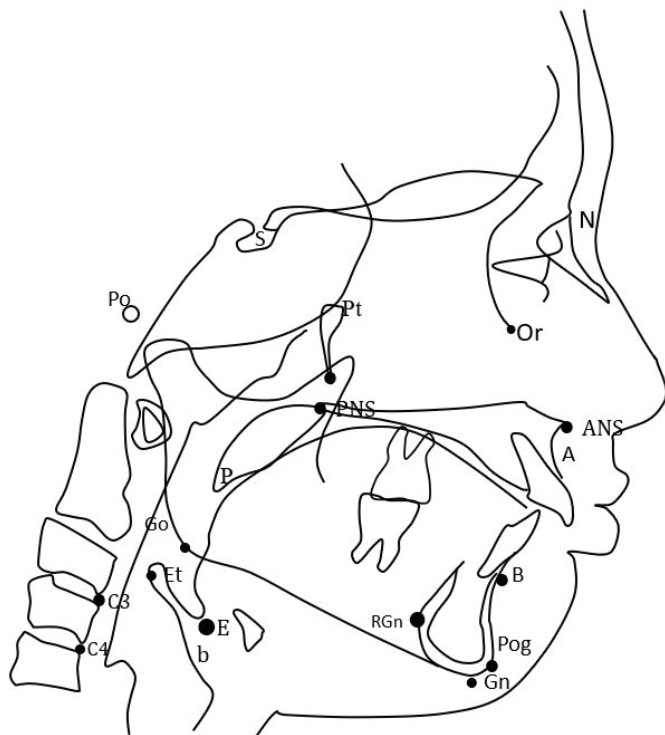


Figure 2. Anatomical points of reference used for the cephalometric analysis in this study. They include: S: Center of Sella. N: Most anterior point of the frontonasal suture. Or: Lowest point on the average left and right inferior borders of the bony orbit. Po: Highest point on the superior surface of soft tissue of the external auditory meatus. Pt: Pterygoid point. ANS: Apex of the anterior nasal spine. PNS: Intersection between the nasal floor and the posterior contour of the maxilla. A: Most posterior point on the anterior contour of the upper alveolar process. B: Most posterior point on the anterior contour of the lower alveolar process. P: Lowest point of the soft palate. Pog: Most anterior point of the contour of the chin. Gn: Point on the chin determined by bisecting the angle formed by the facial and mandibular planes. RGn: Retrognathion, the most posterior point of the mandibular symphysis along the FH plane. Go: Most posterior-inferior point on the convexity of the angle of the mandible. Eb: Most anterior-inferior point of the epiglottic fold. Et: Tip of the epiglottis, the most superior point of the epiglottis. C3: third cervical vertebra. C4: fourth cervical vertebra.

Ostend, Belgium; <http://www.medcalc.org>; 2019) and/or Microsoft Excel-based software unless otherwise stated. Data are presented as mean \pm standard deviation (SD); ANOVA tests were used to compare the differences between the baseline and follow-up cephalometric and for the at home sleep monitoring values for each variable. Unpaired t-test was used to determine significance of the changes in the skeletal pattern of the children, as well as the upper airway size for both groups. A *P* value of < 0.05 was considered to indicate statistical significance.

Results

Questionnaires

The mean score of ESS administered to both groups are as follows; for the control group an average score of 4.7 ± 1.5

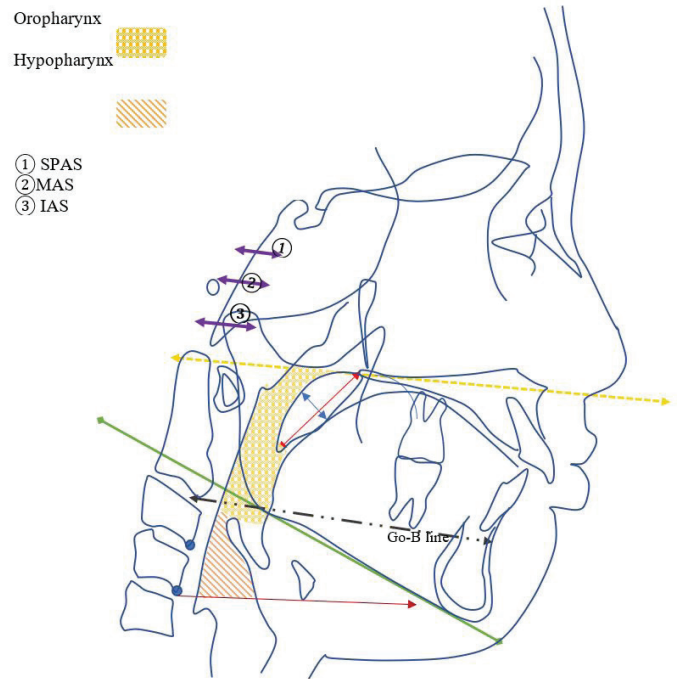


Figure 3. The areas delimitating the anteroposterior width of the upper airways and the area of the oropharynx and the hypopharynx.

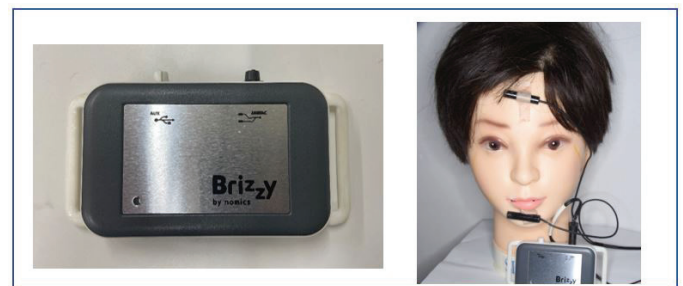


Figure 4. LEFT – The body of the PM used in this study. RIGHT – The facial sensors attached to the appliance.

was obtained, whereas for the activator group an average score of 4.8 ± 3.6 at the initial stage and of 4.5 ± 3.0 towards the end of active treatment. Because all results are below 8 marks at all assessed points, we can say that these scores are within the normal range. The results yielded from the SRBD subscale were of 0.15 ± 0.1 for the control group and of 0.22 ± 0.2 for the activator group at the initial stage of treatment and of 0.14 ± 0.1 towards the end of active treatment, revealing a slight betterment in the sleep breathing patterns of the children as perceived by their parents.

Cephalometric analysis

After tracing, digitizing, and determining the linear measurements to be assessed, it can be seen on the different tests that the airway space is generally wider in the test group than in the control group. The mean values for the measurement of the linear and volumetric size of the upper airway when comparing the activator (1.00 ± 0.30) and control group (0.87 ± 0.17) at T0, show that at baseline both groups have a very similar width and area size of the upper airway (Table 1).

The anteroposterior width of the airway is shown to have an increasing trend over time. A significant increment in the linear width of SPAS measurement can be observed at T1' of the activator group (1.13 ± 0.29). After one-year measurements potentially show that these changes are kept with continuous use of the activator. The volumetric area of the upper airway is shown to widen when the activator is in mouth, with the oropharyngeal space showing a significant increase when comparing T1' of the control group (3.65 ± 0.87) and T1' of the activator group (4.37 ± 0.97). Overall, the upper airway sees an increasing trend over time, and even more so at T1' than at the starting point in T0' (Table 1).

At-home monitoring of sleep breathing

All indicators of severity decrease significantly when the children wear the activator to sleep, which means the

sleep quality is improved when the activator is in mouth during sleep time. RDI and ARL values show a statistical difference of $P < 0.05$ when evaluating the statistical significance. All indicators of severity decrease significantly especially in T1, when the activator is inserted, RDI keeps the same decreasing trend after removal of the activator, in T2. Even though the number of arousals (ARL) is a little higher in T2 than in T1, it has the same levels as control group (Table 2). Because the subjects for this study were all generally healthy children, there is some sleep-breathing interruption to be expected. Respiratory events quantify how many times these interruptions happen and if they are less when wearing the activator as seen on Table 3, the total number of respiratory as well as obstructive events significantly decrease from T0 to T1 and T0 to T2 in the activator group.

Table 1. Mean values of the linear and volumetric area measurements of the upper airways. * $p < 0.05$.

Cephalometric variable	Control group (T0')	Control Group (T1')	Activator group (T0')	Activator group (T1')
SPAS (cm)	0.87 ± 0.17	1.08 ± 0.20	$1.00 \pm 0.30^*$	1.13 ± 0.29
MAS (cm)	1.20 ± 0.29	1.22 ± 0.18	1.18 ± 0.36	1.26 ± 0.29
IAS (cm)	1.00 ± 0.33	1.02 ± 0.35	0.92 ± 0.31	1.01 ± 0.22
Oropharynx (cm ²)	3.61 ± 0.82	3.65 ± 0.87	3.89 ± 1.05	4.37 ± 0.97
Hypopharynx (cm ²)	1.52 ± 0.81	1.66 ± 0.89	$1.32 \pm 0.75^*$	1.65 ± 0.72

Table 2. Changes in the values of the indicators of sleep breathing severity depending of the treatment stage for the Activator group comparing them to the values from the Control group. * $p < 0.05$, ** $p < 0.01$

	Control	Activator group (T0)	Activator group (T1)	Activator group (T2)
RDI (n/h)	1.03 ± 1.37	2.25 ± 3.6	0.84 ± 1.1	1.93 ± 2.3
ARL (n/h)	9.33 ± 1.96	11.15 ± 3.4	7.94 ± 2.5	9.56 ± 3.5
Total Respiratory events (n/h)	6.5 ± 8.3	20.45 ± 12.8	4.65 ± 7.8	13 ± 9.4
Obstructive events (n/h)	6.5 ± 8.3	20.35 ± 12.8	4.55 ± 7.8	13 ± 9.4
Central events (n/h)	0	0.05 ± 0.22	0.05 ± 0.22	0
Mixed events (n/h)	0	0.05 ± 0.22	0.05 ± 0.22	0

Table 3. Summary of the initial skeletal relationship of the subjects in this study. * $P < 0.05$

	SNA angle		SNB angle		ANB angle	
	Initial (T0')	Final (T1')	Initial (T0')	Final (T1')	Initial (T0')	Final (T1')
Control Group	81.3 ± 0.3	81.1 ± 2.7	76.4 ± 2.3	76.3 ± 2.2	4.8 ± 1.2	4.3 ± 1.5
Activator Group	80.7 ± 2.5	81.4 ± 2.8	74.6 ± 0.9	77.2 ± 1.6	6.8 ± 1.7	4.2 ± 2.2

Final skeletal pattern relationship

After a year on average of continuous functional therapy with the activator, the skeletal relationship of the activator group changed positively to a more harmonious craniofacial relationship (Table 3).

Discussion

The aim of this study was to determine if wearing a functional orthodontic activator, intended for improving a retrognathic mandible, would also help improve the child's sleep-breathing by widening of the patient's upper airway. The findings in this study demonstrate that after continuous functional therapy with the activator, not only does the upper airway widens, the changes are kept even at the end of active treatment (T2 results in the sleep monitor, T1' of the cephalometric results). This is evident when assessing the radiographic findings which are in turn corroborated by the results obtained from the PM.

The results obtained from the questionnaires used showed that according to the ESS questionnaire, the children do not self-report levels of daytime sleepiness outside what would be considered normal for school age children. The average score obtained on both stages for the evaluated skeletal Class II children demonstrate that daytime sleepiness is not a concerning issue for the children evaluated in this study.

The final results obtained from the PSQ in both stages respectively for the activator group, shows that the parents' perceived sleep-breathing patterns of the children, improve over time and by the end of active treatment, the overall score improves after wearing the activator.

The consensus around the dental community is that skeletal Class II is a complex condition that may be corrected using different alternatives of treatment such as fixed, Andresen, Twin Block, Herbst, Bio bloc or headgear appliances (21-23). Concerning the present study, it was decided to evaluate the influence that the Andresen activator has not only physically on the upper airway, but also how these changes relate to sleep-breathing patterns as assessed with a PM.

The present study reveals that the anteroposterior width of the upper airway increases in size steadily over the course of the evaluation time, especially the superior airway space or SPAS. This may be due to the fact that the children assessed did not suffer from any condition that would constrict the upper airway and the linear size of the upper airway from the activator group was comparable to that of the control group.

In a study using the Faramand appliance, it was found that mandibular advancement has the potential to increase the dimensions of the upper airway during treatment and this increase in dimension remains stable over a long period (4 years + 2-8 years), which strongly agree with the results from this study, when analyzing the anteroposterior size of the upper airway it was found that not only are the changes kept in T1', but there is also an increase in size of the evaluated measurements (24).

Regarding the dimension of the upper airway, especially on the areas delimited by the oropharynx and hypopharynx, there was a slight increase in the volume of both sites, especially the oropharynx experiences a larger increase than the hypopharynx which remains stable after a year of func-

tional therapy at T1'. This may be explained by the fact that the activator when inserted the base of the tongue which is located in front of the anterior wall of the soft palate experiences an anterior displacement of the tongue induced by the activator which in turn reduces the tongue's gravitational effect on the soft palate, thus enlarging the oropharynx's measurements (25).

Changes of the dimension of the hypopharynx shown in the present study reveal a minor increase of this area of the upper airway that is kept stable after a year of continuous activator therapy at T1'; in spite of this no statistical significance could be found. The fact that following treatment with the activator, anterior displacement of the base of the tongue, by means of anterior repositioning of the mandible, can explain the increase in the hypopharyngeal dimension and its stability at T1'. This is in accordance with a study by Isono et al (26), which stated that there is an increase in the dimensions of the airway which result from mandibular anterior displacement even in obese individuals without failure.

Another study performed by Horihata et al, reported an increase in the anteroposterior width and total dimension of the upper airway after activator therapy when comparing to initial data, which is in accordance to the results from this study (27).

In the studies by Tsuiki et al, and Poon et al, when an oral appliance treatment was used in adult patients to treat mild OSA, they found an increase in the area behind the soft palate on the oropharynx, this conclusion agrees with this study which sees a similar result when assessing the same area (28,29).

There is a large amount of studies done to assess the changes of the upper airway post-functional therapy, despite this, the results are conflicting in that many of these studies research said changes evaluating the effects of a variety of functional appliances, and depending on the appliance being studied and the methodology the results also vary (27).

Shepard and Thawley proposed that most problems associated with respiration are present in the oropharynx, improvement of the size of this section with the use of the activator increases the importance of this functional appliance (30). However, studies done evaluating the upper airway changes following functional appliances agree that if the main mechanic is to move the lower jaw forward to achieve facial balance and correct occlusal posture, there is an added benefit when continuous use of the appliance is achieved, which is an increased size of the upper airway.

Overall, the activator produced positive changes in the skeletal pattern of children demonstrated a significant decrease in the difference of the various craniofacial angles evaluated in skeletal Class II children.

The SNA angle increased an average of ± 1.2 degrees from T0 to T1 in the activator group, this result contrast with the ones by Mills, where he found a reduction of said angle (31). The SNB and ANB angles changed significantly, with an increase of the former and a decrease of the latter. Normal craniofacial growth and development, greatly assisted by the effects of the activator, propels the changes earlier demonstrated by the widening the upper airway. This shows that with proper compliance in the use of functional appliances, the changes from skeletal Class II to Class I are achieved, this is in accordance to the study by Santamaría-Villegas et al, but contrasting to the study by Koretsi et al, which affirms

that functional appliance mainly influence dento–alveolar changes rather than skeletal ones (32,33).

Concerning the sleep test done for this study, it must be noted that type 1 polysomnography (PSG) tests remain the gold standard for the diagnosis in patients suspected of having comorbid sleep disorders, unstable medical conditions, or complex sleep–disordered breathing. Type 3 PMs used in sleep studies are safe and convenient for diagnosing OSA in patients with a high pretest probability of moderate to severe forms of the condition without substantial comorbidities (34).

The results that the PM used in this study yielded, reveal that almost all indicators of respiratory severity decrease significantly when the activator is inserted, and the decrease is significantly stable at T2 after functional therapy. The indicator for RDI shows a positive decrease from T0 at the beginning of treatment with activator and a significant improvement at T1 when the appliance is inserted during sleep time. Even though no significance was found for the results obtained for T2, there is a positive trend of a decreased RDI when the activator is removed.

The number of arousals as determined by the ARL variable also show a significant reduction from T0 to T1 in the activator group. This is explained with the fact that as the activator is inserted throughout the night, the physical changes brought upon with the increased size of the upper airway, the children experience a more refreshed and sounder sleep.

A study done with the Herbst appliance and maxillary expansion by Schüts et al, showed that when the nasopharyngeal complex is enhanced by functional therapy, PSG results show an improvement in the sleep breathing patterns of the involved subjects (15). This agrees with the present research that a wider upper airway relates to better sleeping patterns. Even though the most observed respiratory event was the obstructive one, the number of obstructive events perceived by the PM was shown to experience a significant lowering from T0 to T1 when the activator is inserted to sleep, and even though there is a slightly higher number of obstructive events from T1 to T2, the number is significantly ($P<0.01$) lower than at T0, which is considered as a positive improvement in the sleep patterns of skeletal Class II children; due to the fact that the data collected from both T0 and T2 points are with no appliances inserted to sleep, the conditions are considered similar.

Bearing in mind that this research study was done using data from healthy children, there is a concern if the results presented thus far could also be applied to cases of childhood OSA, regarding this there is a clinical case of one subject who was supposed to be part of the activator cohort for this study, however, due to severe signs of childhood OSA exhibited by said case, it was deemed inappropriate to include in the present study. However, after continuous activator therapy with periodical checkups and follow–up appointments, the PM showed a considerable decrease in all indicators of severity, as well as less respiratory events, especially when the activator is inserted (35, 36). All of this can be translated into saying that functional appliances do in fact offer a positive impact in skeletal Class II children, that besides providing an improved facial pattern, they also benefit from a better sleep thanks to the physical changes brought upon by functional appliance treatment. Thus, the hypothesis for this study has been accepted.

Future studies validating the results from this kind of PM should be done with a larger and more varied cohort of subjects that may include children and adults, with sleep–breathing conditions ranging from healthy to OSA.

A limitation of this study as mentioned previously include the relatively small number of participants. In the future, a bigger cohort of subjects for both Control and activator group could be evaluated, including a longer evaluation period which might include the same number of data collection points for both groups, as well as an evaluation of the stability of changes brought upon by the activator in a more extended period.

Conclusion

It can be concluded that the activator not only provides a harmonious occlusion and proper development of the mandible, but it also helps improve the quality of sleep–breathing through widening of the upper airway and reducing the number of disordered breathing events in children that undergo this kind of orthopedic therapy. It could be said that the activator might be useful for preventing and/or diminishing the future risk of OSA of the children that receive orthodontic functional treatment with this appliance, so that when they become adults, they continue to experience improved sleep–breathing thanks to this activator, however, this is subject for a future study where this assertion could be confirmed or not.

Türkçe Özet: Aktivatör tedavisi gören sağlıklı iskeletsel sınıf II çocuklarda hava yolu açıklığı ve uyku süresince solunumda oluşan değişiklikler. Amaç: Bazı çalışmalar, Obstrüktif Uyku Apnesi'nin (OSA) öngörülmesinde maksillo-mandibüler ilişkinin obesiteden daha yüksek korelasyon gösterdiği konusunda hemfikirlerdir. Bu tip bir kraniyo-fasiyal deformitenin tedavisinde önerilen ortodontik tedavilerden biri aktivatör ile alt çenenin öne alınması olduğundan; bu çalışmanın amacı bu apareyi kullanan sağlıklı çocuklarda üst havayolunda genişleme ile birlikte uyku sırasındaki solunum şeklinde bir iyileşmenin gerçekleşip gerçekleşmediğinin incelenmesidir. Gereç ve Yöntem: 30 sağlıklı çocuk, 20 çocuk aktivatör grubu (10 erkek ve 10 kız; ortalama yaş 10.9 ± 0.9 yıl; BMI: 16.2 ± 1.4); 19 çocuk kontrol grubu (13 erkek and 6 kız, ortalama yaş 9.8 ± 1.4 yıl; BMI 17.6 ± 2.1) olarak çalışmada yer almıştır. Aktivatör grubunda araştırmanın başında ve sonunda, kontrol grubunda ise bir kez alınan lateral sefalometrik filmler ve uyku sırasındaki solunum ölçümleri araştırma materyalini oluşturmuştur. Bulgular: Radyolojik inceleme sonrasında, aktivatör grubundaki çocuklarda incelenen tüm parametrelerde artış olduğu bulunmuştur. Uyku izleme sonrasında aktivatör grubundaki çocuklarda uyku sırasında solunum patternlerinde iyileşme olduğu bulunmuştur ($p<0.05$). Sonuç: Aktivatör apareyi ile tedavi gören çocuklarda tedavi sadece uyumlu bir oklüzyon ve alt çenenin uygun gelişimini sağlamakla kalmayıp, üst havayolunun genişlemesini sağlayarak uykudaki solunum kalitesinin artışı ve bazı solunum düzensizliklerinin azalmasını sağlamıştır. Anahtar Kelimeler: aktivatör, uykudaki solunum, üst havayolu, retrognatik alt çene, evde uyku izleme

Ethics Committee Approval: This research has been approved by the Ethics Review Committee of Hiroshima University (No. E – 56).

Informed Consent: All subjects needed to have provided informed consent from the parent or guardian prior all evaluations. This study has followed the guidelines stated in the Helsinki Declaration for clinical investigations.

Peer-review: Externally peer-reviewed.

Author contributions: CCM, HU participated in designing the study. CCM participated in generating the data for the study. CCM, KI, RK participated in gathering the data for the study. CCM and KT participated in the analysis of the data. CCM wrote the majority of the original draft of the paper. CCM participated in writing the paper. CCM have had access to all of the raw data of the study. CCM have reviewed the pertinent raw data on which the results and conclusions of this study are based. CCM, HU, KI, RK, KT have approved the final version of this paper. HU guarantees that all individuals who meet the Journal's authorship criteria are included as authors of this paper.

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