2017

Upper Airways and Sleep-Breathing Changes in Skeletal Class II Children Post-Functional Appliance Therapy

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This thesis was submitted to Hiroshima University, Faculty of Dentistry, Japan, in partial fulfillment of the degree of Doctor in Philosophy in Dentistry (Orthodontics) in 2017

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Dedication

This work is dedicated to my family, whose understanding, support and encouragement throughout the years made this achievement possible.

Acknowledgements

This study was carried out in the Orthodontics Department of Hiroshima University Faculty of Dentistry, during 2013-2017.

I would like to extend sincere appreciation and gratitude to Dr. Kotaro Tanimoto, Professor and Chairman Department of Orthodontics, Applied Life Sciences, Hiroshima University, Institute of Biomedical & Health Sciences, for his support, valuable suggestions, and well-timed supervision throughout the evolution of this Ph.D. research.

My most sincere appreciation and gratitude are also extended tenfold to Dr. Hiroshi Ueda, your concern, care and support towards my stay in Japan, as well as your wise advice, invaluable guidance, encouragement and teachings are one of the main reasons this study was completed.

Special thanks are due to Professor Masaru Sugiyama, from the Department of Oral Health, Professor Makoto Sugita from the Physiology and Oral Physiology Department and finally, Professor Kazuhiro Tsuga from the Department of Advanced Prosthodontics, for their much-appreciated insights and comments on this study.

Thank you to all the colleagues in the Department of Orthodontics for their kind cooperation and positive attitude at different moments of this research work. Also, warm feelings of appreciation go to Professor Emeritus Kazuo Tanne, who kindly accepted me into the program of Orthodontics.

Last but not least, thank you to my beloved family for their continuous support for the last four years.

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1 Introduction

Sleep, along with shelter and proper feeding is among the most important human needs, this is an imperative biological process that helps restore and maintain proper health. Nonetheless, the basic function of sleep remains a mystery, despite that it has been proven that proper sleep contributes to a person having an optimal cognitive and physiological state.

Proper sleep is highly related to proper breathing patterns, if these patterns go awry many developmental complications may derive, becoming a catalyst for serious decrease of cognitive ability.

This is rather relevant when we want to consider sleep–breathing in children; lack of proper sleep and/or the presence of sleep breathing problems may cause a decline in the development of the child's intellectual and social abilities (Mindell and Owens, 2010).

Developmental issues that dentists can diagnose and treat during childhood include mandibular deficiencies, (it has been generally observed that several conditions, including obesity, abnormal craniofacial characteristics, amongst other factors may increase the risk of Obstructive Sleep Apnea (OSA). One of the most frequent craniofacial deformities most associated with OSA is maxillomandibular anteroposterior and vertical disproportion which is a result of poor mandibular growth (Subramani *et al.,*2016)), 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. Recently, it has been suggested that this kind of therapy could not

only correct the skeletal abnormalities, but also could potentially treat OSA and have a long–term effect that could prevent obstructive events in adulthood (Amaral *et al.,* 2014). Therefore, we assessed the effects of one such appliances (Andresen Activator, also called FKO) 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 airways to widen thus favoring a better sleep–breathing pattern for children undergoing this therapy. These are similar mechanics by which both the FKO Activator and the Oral Appliance (OA) for Obstructive Sleep Apnea Syndrome treatment in adults advance the mandible forward.

1.1 Review of literature

Humans are born conditioned to eat by the mouth and breathe through the nostrils. The imbalance or breaking of this physiological pattern affects growth and development, not only on facial harmony but in general health terms also.

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 (Gottlieb *et al.,* 2004; Stone *et al.,* 2009). Many authors (Dayyat *et al.,* 2009; Zhong *et al.*, 2010) agree that obesity is a major risk factor for disordered sleep breathing which includes 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 (Endo *et al.,*2003).

Previous studies agree that an abnormal maxilla–mandible relationship correlates better than obesity as an OSA predictor, especially in oriental populations. According to Subramani *et al.,* 2016, some characteristics that are predominantly associated with OSAS 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. Separate studies done by Brouillette, 1982, Teculescu, 1992, and Suen, 1995, concur that the occlusion of the airways was highly associated to the anatomical structure of the upper airways and the mandible (e.g. hyperplasia of the pharyngeal and palatine tonsils) as one of the major causes of OSA or sleep disordered breathing in children.

Functional appliances that stimulate the harmonious growth of the mandible by positioning it forward during development of growing children have been in use since 1908 when Vigo Andresen first used a “Biofunctional Retainer” with his daughter, which he later renamed as “Activator”, taking advantage of the musculature forces and the corresponding soft tissue, guiding them to a better arrangement for a more balanced relation (Pancherz, 1976). Many modifications have been done to the original design, despite this, the principle of action remains the same, to redirect the mandible growth in a more horizontal direction, so that an improved postured and balanced soft tissue facial profile are developed in children who have a retropositioned lower jaw (Singh *et al.,* 2006).

This mechanical action is similar if not identical to the OA that is used in adults as a treatment tool for patients that suffer from primary snoring and mild to moderate OSA (Almeida *et al.,* 2006). This appliance repositions the lower jaw in a more forward position with the purpose of enlarging the upper airways. But as mentioned in a previous study (Horihata *et al.,*2013), an OA is not a permanent solution for OSA, furthermore, for adults this kind of therapy does not produce permanent dentofacial structural changes that may maintain the widened upper airways even when the OA is not inserted (Ueda *et al.,*2008). Contrasting this, functional appliances such as the FKO activator could promote a soft tissue reorganization and a sagittal malocclusion improvement which may lead to an increase in the oropharyngeal space hence facilitating normal air flow (Pancherz, 1997). Hence, maxillo–mandibular correction represents an important and effective treatment to snoring and a preventive measure for OSA during childhood, as previously demonstrated in children

with 4 to 10 years treated with removable oral appliances for 6 months (Villa *et al.,* 2002; Barros Schüts *et al.,*2011).

2 Aim

Restrepo *et al.,* said in 2011 that “a small airway during the growth peak leads to problems such as mouth breathing, bruxism and skeletal Class II owing to retrognathism. To advance the mandible [using functional appliances] before the growth peak could avoid this kind of problems. “

For better understanding if there is an actual improvement to the children’s sleep breathing patterns, an at–home sleep monitoring of several conditions including when the activator inserted or not and a follow–up monitoring must be considered if the assessment of a betterment of sleep breathing patterns induced by the activator is to be true. Therefore, the aim of this study is to confirm if besides the intended inducement of development of the mandible the FKO Activator may also help improving healthy sleep breathing patterns in children.

3 Materials and methods

3.1 Subjects

Subjects in this study consisted of 39 children (Table 1), 20 for activator group (mean age 10.9 ± 0.9; BMI 16.2 ± 1.4), 19 for control group (mean age 9.8 ± 1.4; BMI 17.6 ± 2.1).

Table 1. Summary of subjects in this study.

	SUBJECTS (N)	AGE (yrs.)	BMI (Weight in Kgs / (Height in Meters X Height in Meters))
Control group total	**19**	**10.8 ± 1.0**	**17.1 ± 2.2**
(Boys)	*13*	*10.4 ± 1.4*	*16.7 ± 2.5*
(Girls)	*6*	*9.1 ± 2*	*16.1 ± 2.3*
Activator group total	**20**	**10.7 ± 1.8**	**16.6 ± 2.2**
(Boys)	*10*	*10.9 ± 2.5*	17.5 ± *2.3*
(Girls)	*10*	*10.6 ± 1.6*	*16.6 ± 1.8*

The anatomical references that divide the skeletal pattern into Class I and II are ∠SNA, ∠SNB and ∠ANB, from the average assessed values all our participants were divided accordingly with characteristics that the literature consensus agreed are skeletal Class I and Class II respectively (Table 2).

Table 2. Summary of the skeletal relationship of the subjects in this study.

	∠SNA° (antero–posterior position of the maxilla)	**∠SNB° (antero–posterior position of the mandible)**	**∠ANB° (relationship between the maxilla and the mandible)**
Control group	81.3 ± 0.3	76.4 ± 2.3	4.8 ± 1.2
Activator group	80.7 ± 2.5	74.6 ± 0.9	6.8 ± 1.7

For the Activator group, the requirements are patients currently undergoing Activator (FKO) therapy and have no previous history of sleep–related child breathing disorder have successfully cleared all screening tests which include:

- Completion of two questionnaires; The Epworth Daytime Sleepiness Scale (ESS) modified for children, and the Sleep Related Breathing Disorder sub–scale(SRBD).
- Three successful monitoring of sleep breathing with a portable sleep monitor, once wearing the appliance and twice without.
- Same requirements go for two lateral cephalometric radiographs.
- One extra lateral cephalometric radiograph to assess and compare growth and changes naturally brought upon by the activator, this one to be taken 1 year after activator therapy.

For the Control group, 19 children that fulfill the following criteria:

- Completion of the ESS and SRBD questionnaires
- One successful monitoring of sleep breathing
- One cephalometric radiograph

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.

Data was collected in three stages, specifically for the Activator group, T0, first time without insertion of the Activator; T1 the first time with the Activator inserted, and T2 the final

collection with no appliance inserted, with a mean average time of 8.7 ± 2.3 months elapsed in between stage.

3.2 Dental Appliance

All patients were treated using the acrylic–splint Andresen Activator henceforth called FKO appliance to the point of mandibular advancement (Figure 1). It consisted of two anterior labial bows, one for the superior dentition and another for the inferior 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 the case.

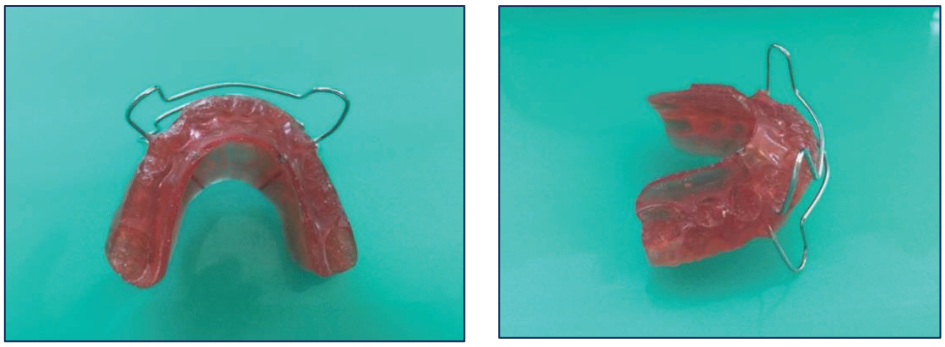

Figure 1. The Andresen (FKO) Activator.

3.3 Statistical analysis

All statistical analyses were performed using MedCalc Statistical Software version 17.8.6 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2017) and/or Microsoft Excel–based software unless otherwise stated. Data are presented as mean ± standard deviation (SD); Odds ratio with a 95% confidence interval analysis were used for assessment of the oropharyngeal crowding values; reliability of the SRBD subscale questionnaire was determined with the calculation of Cronbach's alpha for its internal consistency; finally ANOVA tests were used to compare the differences between the baseline and follow–up cephalometric and Poisson inference/zero–inflated negative binomial tests were used for the at home sleep monitoring values for each variable. Paired t–test was used to determine significance of the changes in the skeletal pattern of the children. The patients were divided into Activator group, which in turn is subdivided into T0, T1 an T2 subgroups, depending on the timing of the activator therapy, and Control group. A P value of < 0.05 was considered to indicate statistical significance.

3.4 Screening

3.4.1 The Epworth Sleepiness Scale (ESS)

As a method for screening if the child or the parents have noticed any abnormal sleep–related behavior 2 different questionnaires were given to the patients and to the parents.

First, an Epworth Sleepiness Scale (ESS) questionnaire (Johns 1991) is distributed among the children. This is a self–administered questionnaire that provides a scaled measure of a person's, in this case children, general level of daytime sleepiness; it has become an

extensively used survey for making this assessment. This questionnaire asks children, to rate from 0 to 3 their usual chances of dozing off or falling asleep in 8 different situations or activities that they are likely to engage in their everyday life. Because we are dealing with underage subjects, questions related to the consumption of alcohol included in the original questionnaire have been modified.

The total ESS score is the sum of the 8 answers, and can range from the lowest which is 0 to the highest score of 24 points. This total provides an estimate of a general characteristic of each child's self–reported average level of daytime sleepiness in daily life. This can be influenced by a range of factors, as for example the children being in exams in school, that can produce various levels of sleepiness and the ESS does not distinguish which of these factors have caused a level of daytime sleepiness. This survey is not a diagnostic tool in itself, but is a useful device for measuring one important aspect of a child's sleep–wake health status.

3.4.2 The SRBD sub–scale.

This tool was developed tested and validated by Dr. Ronald Chervin at the University of Michigan, it has also been tested and validated in several countries and languages proving an asset for screening sleep related breathing disorder tools. In this case, this questionnaire is answered by the parents with information concerning what they have witnessed of their child's usual sleep behavior. It consists of 22 questions, which are divided into different sections concerning several aspects of sleep and sleep–breathing behavior, that are answered by the parents by choosing the options *"yes, no, I don't know"*, with a score of 1

point for “yes” and 0 points for “no”, “I don’t know” answered items are not counted in for scoring. The results are then divided by the total of yes/no questions and the result is a number, a proportion that ranges from 0.0 to 1.0%. Scores over 0.33% are considered positive and suggestive of elevated risk for pediatric sleep–related breathing disorder. This threshold is based on a validity study that suggested optimal sensitivity and specificity at 0.33 cut–off. (Chervin, *et al.,*1999).

Even though this questionnaire includes questions for hyperactivity and attention deficit and hyperactivity disorder (ADHD) as they are closely related to poor sleep breathing in children (Melendres *et al.,*2004) it was decided to change the last five questions for Upper Airway Resistance Syndrome (UARS) which were initially considered when developing this survey. (Chervin *et al.,*1999). (*visual guide used for this procedure can be seen in the complimentary materials section*)

4 Procedure I, Oropharyngeal crowding

The tendency for upper airway collapse is increased when patients with OSA have an anatomic imbalance of the upper airway in which the amount of soft tissue inside the craniofacial bony enclosure (e.g., tongue) is excessive relative to the size of the craniofacial bony enclosure (e.g., maxilla, mandible). But since these are growing children oropharyngeal collapsibility is inferred to be less than those of OSA patients. Nonetheless, it is our hypothesis that the oropharyngeal crowding levels of skeletal Class II children could be slightly larger than that of the skeletal Class I children.

The Mallampati score (MS) enables us to instantaneously evaluate the state of crowding in the oropharyngeal region caused by a large tongue and/or a small craniofacial bony enclosure. In this part of the research procedure, the MS and tonsillar grade score were used to evaluate the oropharyngeal crowding of the tested subjects.

Due to its simplicity, noninvasiveness and low cost, the Mallampati score is a technique that involves visualization of the oropharynx, it is easy to learn, not requiring any special setting or equipment. Its use dates back from three decades to evaluate the ease of anesthesiology intubation (Mallampati 1983; Mallampati *et al.,*1985)

The patient's head was supported by the dental chair to avoid neck extension in the supine position. The head position was fixed parallel to the Frankfort horizontal plane. The score was assessed by asking the patient to open the mouth maximally without emitting sounds, while protruding the tongue as far as possible. A standard 1 to 4 grading system was used to assign scores: class 1: soft palate and entire uvula visible; class 2: soft palate and portion of the uvula visible; class 3: soft palate visible (may include the base of the uvula); class 4: soft palate not visible.

To assess tonsillar grade, the Brodsky scale was used (Brodsky, 1989), this grading system has been deemed as having a high intra–observer reliability (Kumar *et* al., 2014); the same instructions for Mallampati scoring were given to the patients, but this time a dental mirror was inserted to the back of the mouth as comfortably as possible and the subject was told to emit an “Ah” sound, scoring was 0 for surgically removed tonsils, 1 for small pillars, 2 for medium sized pillars, 3 for pillars that cover 1/3 of the oropharynx. (*visual guide used for this procedure can be seen in the complimentary materials section*).

5 Procedure II, Cephalometric analysis

To confirm in a physical tangible way that the changes we are looking for are indeed happening, three lateral cephalometric radiographs were required from the patients.

Lateral cephalometric radiographs were taken in the upright natural head position both with the activator in and activator out, tracing was constructed on each lateral cephalography and they were supervised and checked by a veteran doctor before doing the analysis. And traced again after a month to check for inconsistencies. All cephalography were taken by an experienced technician in a standard natural head position and manually traced by CCM with a 0.3 mechanical pencil in matte acetate paper (Ortho/Trace, 8”x 10” .003, RMO Rocky Mountain Orthodontics, Denver, CO, USA) with the following anatomical landmarks.

5.1 Reference lines and points

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.

H: Most anterior–superior point on the body of the hyoid bone.

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.

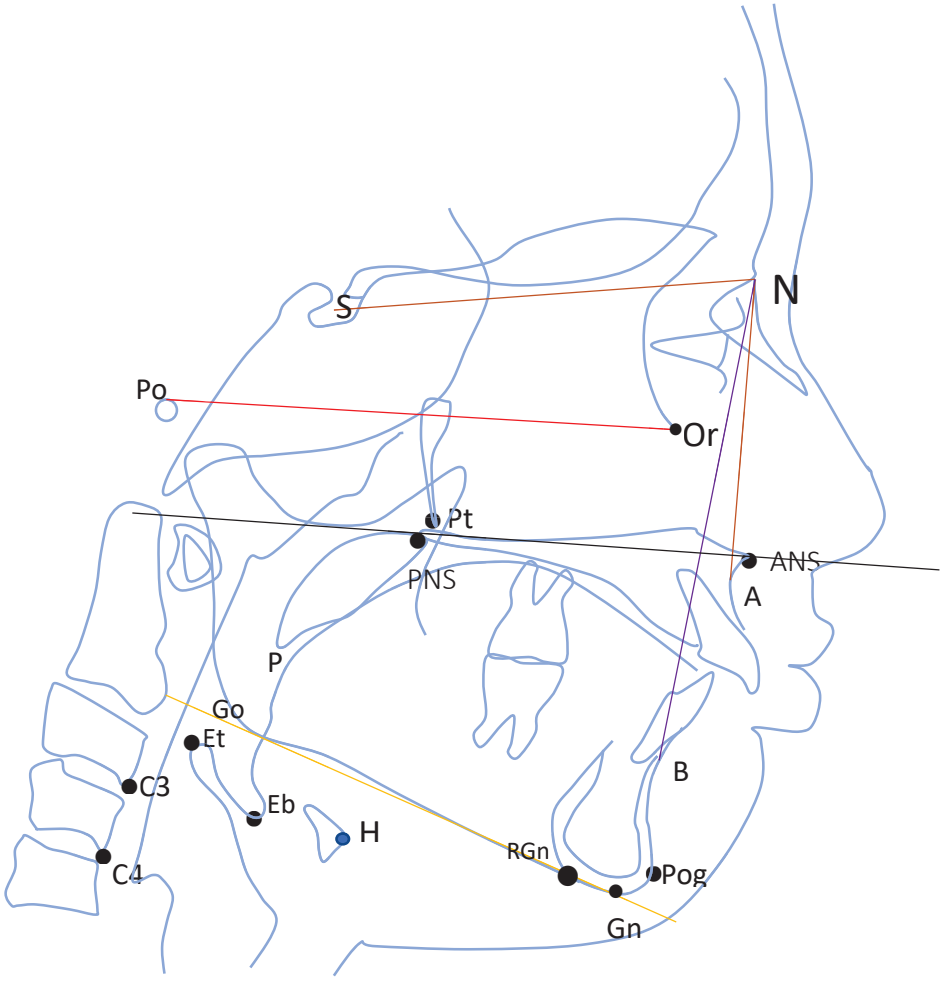

Figure 2. Landmarks and anatomical points of reference.

5.2 Cephalometric analysis of the Adenoids

The size of the soft tissues of the upper airways (tonsils, adenoids, fat pads and musculature) are determined by genetics. Besides this, these tissues could have their size affected by infection, inflammation and infiltration by various metabolic or storage of several components (Arens and Marcus 2004).

Soft tissues, particularly the tonsils and adenoids, can potentially narrow the upper airways (Arens and Marcus 2004), in case of the adenoids the nasopharynx (the upper part of the pharynx, connecting with the nasal cavity above the soft palate) is the affected section. These tissues experience progressive growth during childhood (Fujioka *et al.,*1979; Jeans *et al.,*1981; Vogler *et al.,*2000) and their maximal is present in the prepubescent years (Vogler *et al.,*2000) coinciding with the peak incidence of childhood OSA (Marcus Cl 2001). In normal childhood, the size of the airways grows proportionately with the surrounding soft tissues (Arens *et al.,*2002). To asses this affirmation it was decided on several anatomical points of refence to properly evaluate the size of the adenoids in three–time points (T0, T1, and T2).

5.2.1 Measurements

Ba (Basion) = the most postero–inferior point on the clivus of occipitale.

Ptm (Pterygomaxillary) = the intersection between the nasal floor and the posterior contour of the maxilla.

S (Sella) = the center of the Sella turcica.

So = the midpoint on the line joining Sella and basion.

Ad1 = the intersection of the posterior nasopharyngeal wall and the line Ptm–So.

Ad2 = the intersection of the line Ptm–Ba and the posterior nasopharyngeal wall.

5.2.2 Reference lines

- Palatal line (PL): Line representing palatal plane passing most superior point on Dens Axis.
- Anterior atlas line (AAL): Line perpendicular to palatal plane tangent to anterior surfaces of Dens Axis.
- Pterygomaxillary line (PML): Line perpendicular to palatal plane that intersects palatal plane at pterygomaxillary fissure.
- Sphenoid line (SpL): Line tangent to lower border of sphenoid bone registered at basion.

5.2.3 Linear measurements

- Ptm–ad1 = linear distance from the point Ptm to the point ad1, in cm.
- Ptm–ad2 = linear distance from the point Ptm to the point ad2, in cm.

5.2.4 Area measurements

- NP area (nasopharyngeal area): Corresponds to the nasopharyngeal bony area in vertical and antero–posterior dimensions, measured in cm^2.

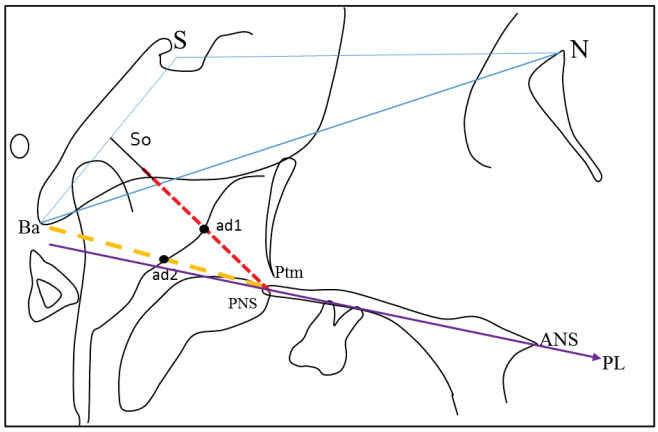

Figure 3a. Anatomical points and lines of reference.

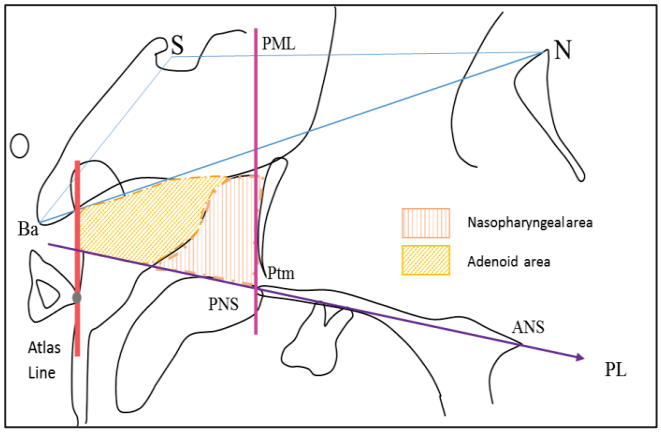

Figure 3b. Area measurements.

5.3 Upper airways linear width

The anteroposterior airways size 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 also the most lower point related to the hyoid bone. The anteroposterior lines of reference (Iwamoto *et al.,*2012) used to evaluate the width of the upper airways were:

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 4)

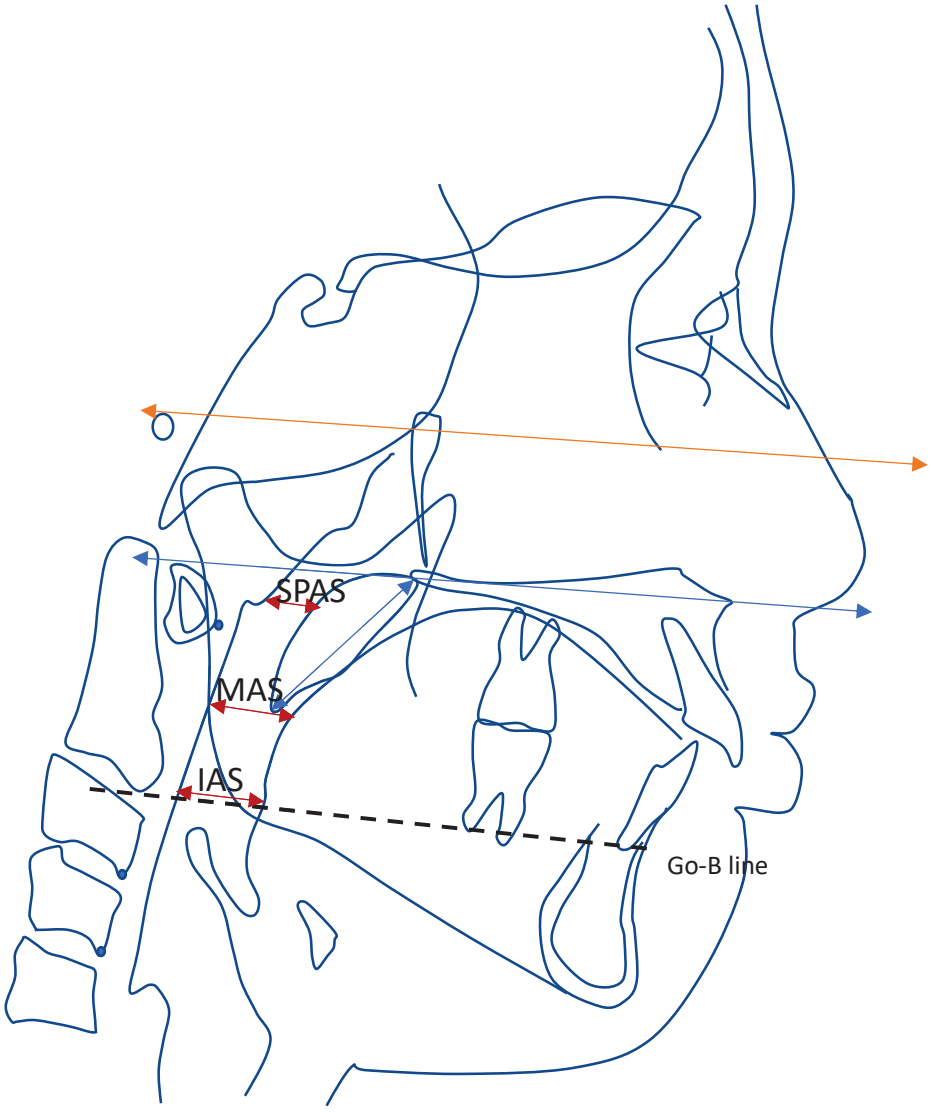

Figure 4. Linear planes used to evaluate the anteroposterior width of the upper airways.

5.4 Airways area measurement

To measure the total volume or area of the remaining sections of the upper airways, 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). The anatomical points of reference used for the cephalometric analysis are explained as follows.

5.4.1 Oropharynx

The area outlined by the inferior border of the nasopharynx, the posterior surface of the soft palate and tongue, a line parallel to the palatal plane through point Et, and the posterior pharyngeal wall in cm^2 (Iwamoto *et al.,*2012) (Figure 5).

5.4.2 Hypopharynx

The area outlined by the inferior border of the oropharynx, the posterior surface of the epiglottis, a line parallel to the palatal plane through point C4, and the posterior pharyngeal wall in cm^2 (Iwamoto *et al.,*2012) (Figure 5).

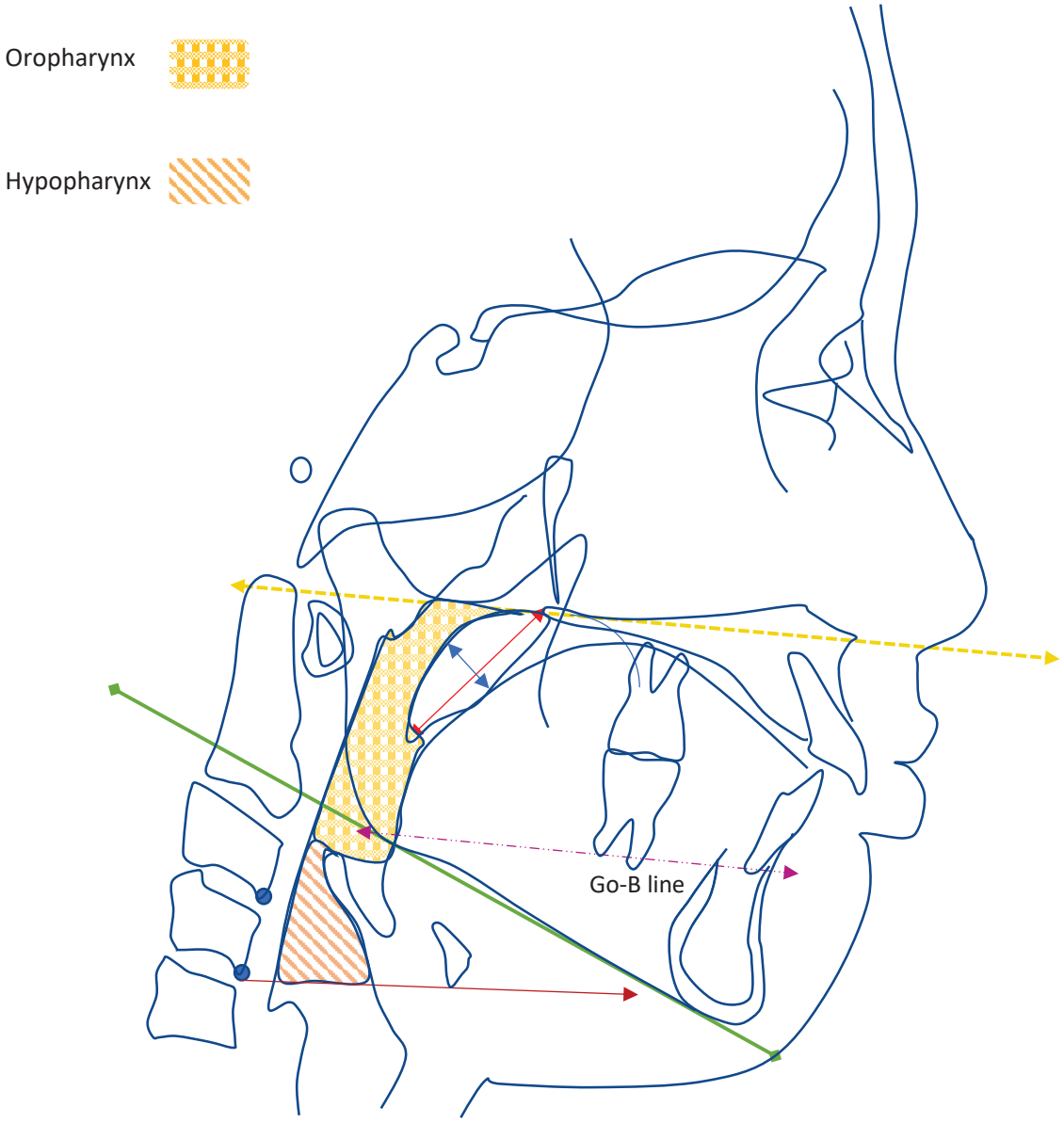

Figure 5. The areas delimitating the volume of the oropharynx and the hypopharynx.

5.5 Hyoid bone position

The position of the hyoid bone has received considerable attention when it concerns to the relation of its placement and the collapsibility of the upper airways. Studies have shown that in various samples of several population groups that the changes in the hyoid bone position seem to be related to the changes in the mandibular position and other facial structures in general (Amayeri *et al.,*2014).

Bibby and Preston, (1981), Trenouth, (1999) and Ferraz *et al.,* (2006) mentioned the importance of the fact that the high relevance of the hyoid bone lied in its unique anatomic relationship. They also remarked on the fact that there is a great variability on its position depending on even the slightest movement of the head. Therefore, they recommended to determine its position by using the cervical vertebra and the mandible as reference points.

The hyoid bone position had been examined in response to mandibular advancement in subjects with mild and moderate OSA. A study conducted by (Battagel *et al.,* 1999) showed that in the protruded mandible the hyoid bone became closer to the mandibular plane in the same time it got a more upward position. In this case, we examined skeletal Class II children and compared the results to those of skeletal Class I children to determine the differences in position of this structure in different craniofacial patterns. The analysis that were included in this study incorporated the following measurements (Bibby and Preston, 1981; Deljo *et al.,* 2012; Jose *et al.,*2014):

5.5.1 Linear measurements of the hyoid bone position

- SN–H perpendicular: linear distance along a perpendicular from H to the S–N plane.
- FH–H perpendicular: linear distance along a perpendicular from H to FH plane.
- H–MP: linear distance between H and MP.
- H–PP: linear distance between H and palatal plane.
- H–TT: linear distance between H and the tip of the tongue.
- H–Eb: linear distance between H and Eb (epiglottis).

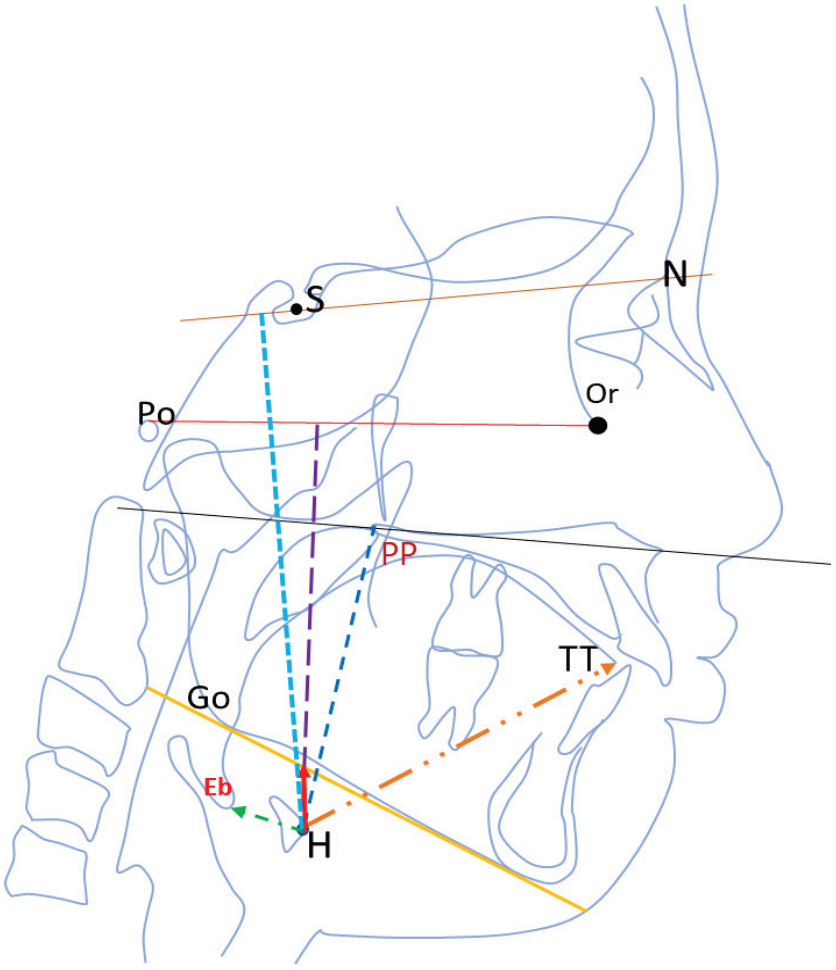

Figure 6. Linear measurements of the hyoid bone.

5.5.2 The hyoid triangle

The hyoid triangle allows determination of hyoid bone position in three directions and, since it is not dependent on a cranial reference plane, incorrectness that may stem from changes in head posture is minimized (Bibby and Preston 1981). Thus, the possible functional importance of changes in hyoid position can be assessed using the following reference points:

- C3–RGn: linear distance between C3 and RGn
- C3–H: linear distance between H and C3.
- H–RGn: linear distance between H and RGn.
- H–H': linear distance between H and a perpendicular to the C3– RGn line.

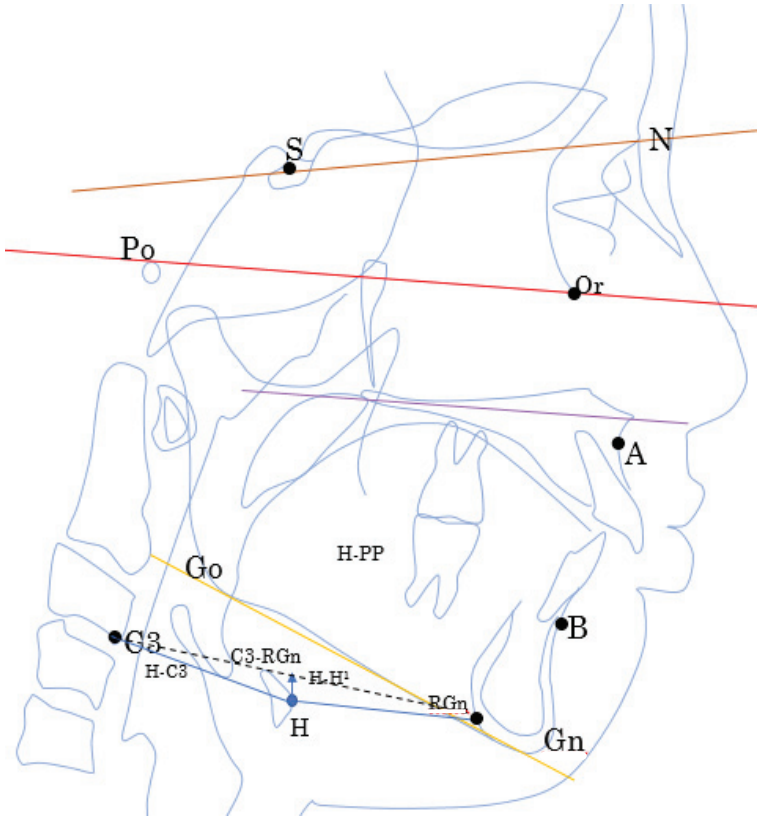

Figure 7. The hyoid triangle.

5.5.3 Lower airway space

Based on the hypothesis that the more anteriorly positioned the hyoid bone is, the wider the lower section of the upper airways become, thus the following antero–posterior measurements were proposed and analyzed:

- MspwEp: middle airway space assessed from the posterior border of the tongue body to the pharyngeal wall, touching the most superior point of the epiglottis in a line parallel to FH plane.

- LspwEb: lower airway space, evaluated from the base of the epiglottis to the pharyngeal wall in a line parallel to FH plane.

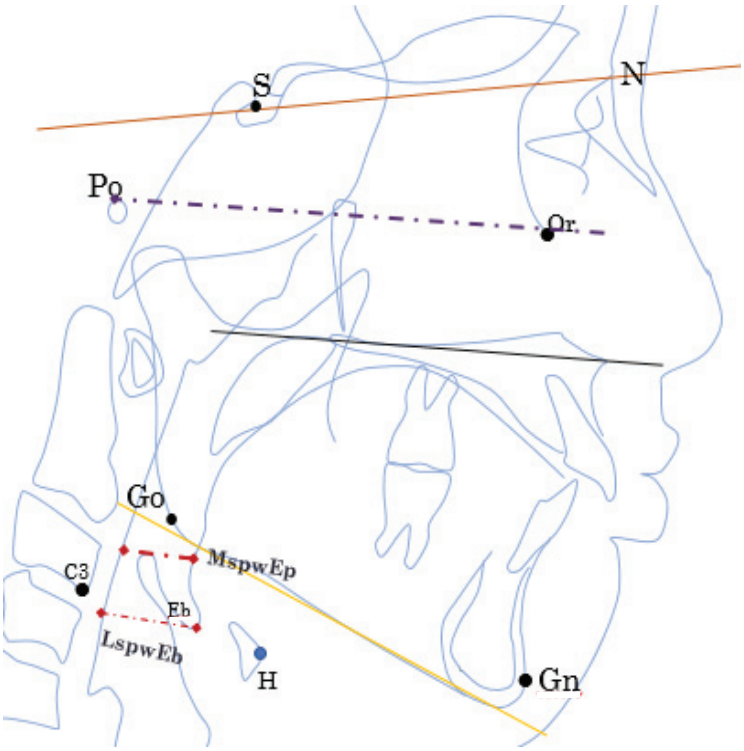

Figure 8. The lowest section of the upper airways assessed with the hyoid bone.

6 Procedure III, At–home sleep monitoring

6.1 The portable sleep monitor

In–laboratory polysomnography (PSG) has long been considered the gold standard for OSA diagnosis, however this procedure is considered expensive and requiring highly specialized resources (Flemon *et al.,*2004; Pack Al 2004). Different ambulatory options have come forth for the management, diagnosis and treatment of OSA that have also been employed to meet the ever–rising clinical demand (Ballester *et al.,*2000; Douglas *et al.,*1992; Calleja *et al.,*2002; Epstein *et al.,*2009; Trikalinos *et al.,*2007). The American Academy of Sleep Medicine (AASM) recommends unattended home sleep testing (HST) using portable monitors (PM) for OSA diagnosis along with an exhaustive clinical evaluation as an alternative to PSG for patients with a relative high pretest probability of OSA (Love and Kuna 2015).

There are currently 4 types of PMs, each with distinctive characteristics and measuring different values. Broadly speaking type 1 PMs is the full PSG device(s) used in clinical evaluation of OSA; type 2 PMs collect the same signals as a traditional PSG record, however, they are designed to be used outside the sleep laboratory. These are transported to the patient's home and must be set up by the technologist prior and after the night evaluation is done; these kinds of PMs are considered highly cost effective and not very practical. (Fry *et al*., 1998; Campbell *et al.,*2011). Type 3 PMs are designed to be unattended and are the most commonly used ambulatory sleep monitors. The signals recorded range typically between 4–7 signals, which include oxygen saturation, 1 or 2 channels for respiratory

movement, airflow, and heart rate. Most of this kind of monitor also record body position, useful to detect positional sleep apneas. Patients are instructed on how to apply the sensors and self–administration is considered generally easy. Finally, type 4 PMs typically record 1–2 signals, usually airflow and oximetry. Even though this kind of monitors do not measure a vast array of channels they are the most used ones by dental practices that perform HST to confirm OAs effectiveness (Levendowski *et al.,*2007). As a method of assessing the changes of breathing patterns during functional orthopedic therapy, the patients were asked to use a portable sleep monitor (BRIZZY Nomics®, Liege, Belgium) (Figure 9) twice, once without using the activator to check normal breathing parameters and the second time with the child wearing the activator to confirm whether sleep–breathing improves. A third time was asked for the subject patients in the Activator group when activator therapy was finished or almost finished. For control group, only one time was required to compare.

Figure 9. LEFT – The body of the PM used in this study. RIGHT – The facial sensors (1–2) attached to the appliance (3). *(Brizzy and sensor picture provided by Nomics, Belgium Liege, used with permission).

This is a type 3 PM which uses the following technology according to the official site: ”The facial sensor is composed of two coils forming two circuits with matching resonant frequencies. Pulses of excitation energy are delivered to the transmitter coil, inducing a magnetic wave that travels and excites the receiver coil. The magnitude of the signal generated at the receiver coil depends, all other conditions being equal, on the distance between the coils. Therefore, that distance can be calculated from the properties of the received signal, using a patented signal processing technique.”

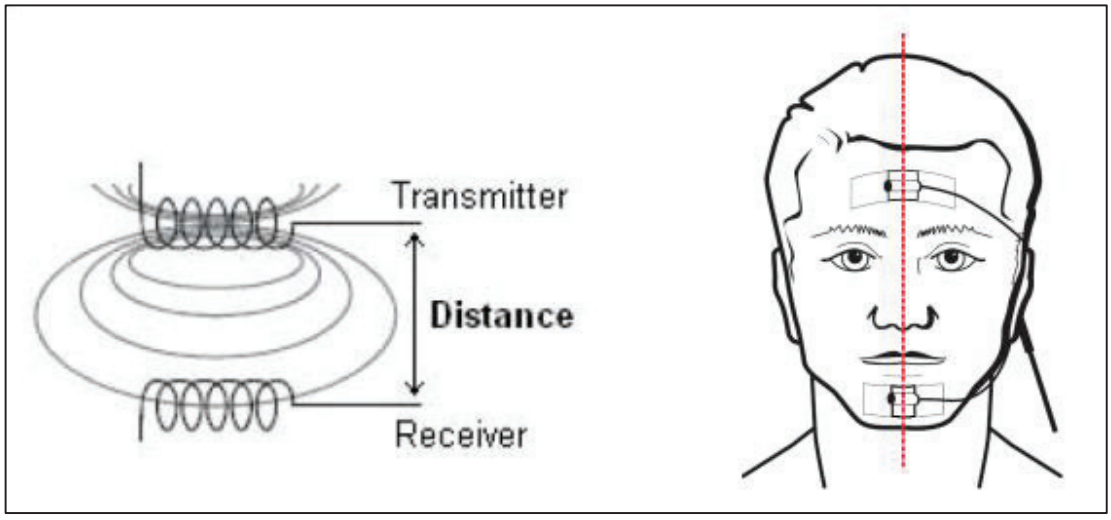

Figure 10. LEFT – Principle of the magnetic distance sensor. RIGHT – Attachment of the sensor to measure jaw movements. *(Technology and sensor picture provided by Nomics, Belgium Liege, used with permission).

This portable sleep monitor 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 (Figure 10, right); 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.

6.2 Signals

From using this appliance 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/hour of sleep.
- Sleep Fragmentation Index, ARL or number of arousal or discontinuity per hr. of sleep.
- Cumulative Time in Respiratory Effort. All period of abnormal respiratory effort expressed as a percentage of the total sleep time.

This monitor also provides valuable information about a patient's obstructive, central and mixed events, which can help determine if the patient in this case children suffer from sleep related breathing disorders (OSAS, UARS, primary snoring, etc.).

The data from the following respiratory events are also collected:

- Obstructive events: $\geq$ 10 seconds, mouth opening–closing/progressive mouth opening sequence.
- Central events: $\geq$ 10 seconds, no mandibular movements; a discontinuity.

- Mixed events ≥ 10 seconds, a period of no mandibular movements followed by movements similar to those of an obstructive event.

This monitor also yields information about the patients' Oxygen Desaturation Index, (ODI), defined as the number of times per hour of sleep that the blood's oxygen level drops by a certain degree from baseline. When breathing becomes disrupted during sleep, the oxygen levels of the blood may repeatedly fall leading to an unrefreshed sleep.

7 Results

7.1 Screening questionnaires

The mean score of ESS administered to both groups can be seen in the table below. Because all results are below 8 marks we can say that these scores are within the normal range.

Using Cronbach's alpha which is used for validating psychometric questionnaires we obtained an alpha of 0.70 at T0 and of 0.79 at T2 for the activator group and 0.63 for control group. Because the alpha we got is 0.7, ($\alpha \geq 0.6$) our results are acceptable.

Table 3. Score of both the ESS and SRBD questionnaires.

	Control group	Activator group	
		T0	T2
ESS	4.7 $\pm$ 1.5	4.8 $\pm$ 3.6	4.5 $\pm$ 3.0
SRBD (%)	0.15 $\pm$ 0.1	0.22 $\pm$ 0.2	0.14 $\pm$ 0.1
SRBD's Cronbach Alpha (α)	0.63	0.70	0.79

7.2 Oropharyngeal crowding

Both Mallampati scale and tonsillar grade scores are very similar. Despite this, the test group's scores a somewhat higher than those of the control group, meaning that oropharyngeal crowding is a slightly bigger issue on skeletal Class II children (Table 4a and 4b).

Table 4a. Results for the assessment of the oropharyngeal crowding using the Mallampati scale.

Mallampati scale	**Control group (n)**	Activator group **(n)**
Class I	5	4
Class II	**11**	**13**
Class III	2	2
Class IV	1	1

Table 4b. Results for the assessment of the oropharyngeal crowding using the Tonsillar grading.

Tonsillar Grading	**Control group (n)**	**Activator group (n)**
Grade 0	1	2
Grade 1	**12**	**11**
Grade 2	4	6
Grade 3	2	1

The odds ratio with confidence interval was used to evaluate statistical significance (Table 5).

Table 5. Statistical results for the evaluation of the oropharyngeal crowding. No statistical significance(P<0.05) could be found.

Variable	**Point Estimate** ***(Odds Ratio)***	**95% Confidence Interval**
Mallampati scale	0.3509	0.0335 to 3.6744 *P =0.38 n.s*
Tonsillar grading	1.0526	0.2299 to 4.8203 *P=0.94 n.s*

7.3 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. All radiographs were digitized using the free software ImageJ, U. S. National Institutes of Health, Bethesda, Maryland, USA, https://imagej.nih.gov/ij/, 1997–2016.

7.3.1 Adenoids linear measurements

Even though no statistical significance could be found (Table 6), from the chart, the adenoidal tissue visible from lateral cephalography is slightly larger in the Control group than on the Activator group.

Table 6. values obtained from analyzing the linear measurements of the adenoidal tissue. No statistical difference (P<0.05) was found.

Cephalometric Variable	**Control Group**	**Activator Group (T0)**	**Activator Group (T2)**
ad1 (cm)	1.82 ± 0.4	2.01 ± 0.6	2.05 ± 0.3
ad 2(cm)	1.41 ± 0.3	1.43 ± 0.4	1.53 ± 0.3

7.3.2 Adenoids and nasopharyngeal area.

The total area of adenoidal tissue and nasopharyngeal area that could be assessed from the radiographs show that even though the difference is not much, the nasopharyngeal area is bigger on the activator group with an increasing trend over time, in contrast, the adenoidal area is larger in the control group, which means that the total space that can allow for air in the upper airways is better in the activator group than on control group, however, if this increasing trend is due to growth needs to be further evaluated. A statistical significance of P> 0.01 was found (Table 7).

Table 7. Values obtained from analyzing the total measurements of the adenoidal tissue and nasopharynx.

Cephalometric Variable	**Control Group**	**Activator Group (T0)**	**Activator Group (T2)**
Nasopharynx (cm^2)	0.60 ± 0.21	0.77 ± 0.40	0.80 ± 0.29
		*	
Adenoidal Area (cm^2)	3.40 ± 0.38	3.62 ± 0.72	2.74 ± 0.45
	**		**
		**	

*P<0.05 ** P<0.01

7.3.3 Anteroposterior width of the airways.

The airways are shown to have an increasing trend over time, overall all groups seem to have the same antero–posterior dimensions of the upper airways, no statistical significance

was found. After one–year measurements (T2), potentially show that these changes are kept with continuous use of the activator (Table 8).

Table 8. Mean measurements of the linear assessment of the upper airways. No statistical significance (P<0.05) was found.

Cephalometric variable	**Control group**	**Activator group (T0)**	**Activator group (T1)**	**Activator group (T2)**
SPAS (cm)	0.87 ± 0.17	1.00 ± 0.30	1.10 ± 0.24	1.13 ± 0.29
MAS (cm)	1.20 ± 0.29	1.18 ± 0.36	1.24 ± 0.35	1.26 ± 0.29
IAS (cm)	1.00 ± 0.33	0.92 ± 0.31	0.98 ± 0.27	1.01± 0.22

7.3.4 Airways total area.

The upper airways are shown to widen when the activator is in mouth. Even though no statistical difference was found, the upper airways see an increasing trend over time, and even more so at T2 than at the starting point in T0 (Table 9).

Table 9. Mean values of the area measurements of the upper airways. No statistical difference (P<0.05) was found.

Cephalometric Variable	**Control group**	**Activator group (T0)**	**Activator group (T1)**	**Activator group (T2)**
Oropharynx (cm^2)	3.61 ± 0.82	3.89 ± 1.05	4.21± 1.05	4.37 ± 0.97
Hypopharynx (cm^2)	1.52 ± 0.81	1.32 ± 0.75	1.51 ± 0.65	1.65 ± 0.72

7.3.5 Hyoid bone position.

Statistical difference of P<0.01 was present in H–PP, H–FH and H–MP perpendicular measurements. In the sagittal plane, there is an increased distance of the hyoid bone from the anterior cranial base (H–SN perpendicular). Also in relation to the mandible, it is shown that the hyoid bone takes a more inferior and anterior position when the FKO is inserted, and this change is kept post–treatment (Table 10).

When assessing the hyoid triangle, a larger distance was noticed between the mandible (from Rgn) and the third cervical vertebra (C3) (Table 11).

The lower airway space, especially measured from the base of the epiglottis to the pharyngeal wall (LspwEb) shows a significantly (P<0.01) increased sized when compared to initial data (Table 12).

Table 10**.** Comparison between all groups for the linear position of the hyoid bone.

Linear measurement (cm)	**Control group**	**Activator group (T0)**	**Activator group (T1)**	**Activator group (T2)**
H–SN perpendicular	8.99 ± 0.5	8.86 ± 0.9**	9.16 ± 0.7	9.59 ± 1.0**
H–FH perpendicular	7.03 ± 0.6	6.78 ± 1.0**	7.34 ±0.6	7.67 ± 0.9**
H–MP perpendicular	0.81 ± 0.4	0.78 ± 0.6	0.48 ± 0.3**	1.00 ± 0.7**
H–PP	4.91 ± 0.5	4.94 ± 0.7**	5.10 ± 06	5.36 ± 0.6**
H–TT	4.77 ± 0.4	4.98 ± 0.5	4.98 ± 0.3	5.17 ± 0.7
H–Eb	1.45 ± 0.3	1.46 ± 1.1	1.23 ± 0.2	1.35 ± 0.3

**P<0.01

Table 11. Comparison of the hyoid triangle among all groups.

Cephalometric Variables	Control group	Activator group (T0)	Activator group (T1)	Activator group (T2)
C3–RGN (cm)	5.17 ± 0.7	5.38 ± 0.5	5.61 ± 0.6	5.70 ± 0.7
C3–H (cm)	2.95 ± 0.2	2.98 ± 0.4	3.10 ± 0.2	3.19 ±0.3
H–RGN (cm)	2.66 ± 0.9	2.61 ± 0.4	2.63 ± 0.5	2.80 ± 0.5
H–H' (cm)	0.54 ± 0.3	0.56 ± 0.5	0.46 ± 0.3	0.68 ± 0.6

*P< 0.05 **P<0.01

Table 12. The lower section of the airways is wider when the hyoid position is influenced by the changes brought upon by the FKO.

Cephalometric Variables	Control group	Activator group (T0)	Activator group (T1)	Activator group (T2)
MspwEp (cm)	1.12 ± 0.23	0.93 ± 0.34	1.01 ± 0.27	1.00 ± 0.26
LspwEb (cm)	1.52 ± 0.20	1.32 ± 0.22	1.45 ± 0.24	1.45 ± 0.29

*P< 0.05 **P<0.01

7.4 At–home monitoring of sleep breathing.

7.4.1 Indicators of severity.

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. ARL and CT% values show a statistical difference of $P<0.05$ when using Poisson inference to evaluate the significance. All indicators of severity decrease significantly especially in T1, when the FKO is inserted, Respiratory Disturbance Index (RDI) keeps the same decreased trend after removal of the FKO, 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 (Figure 11).

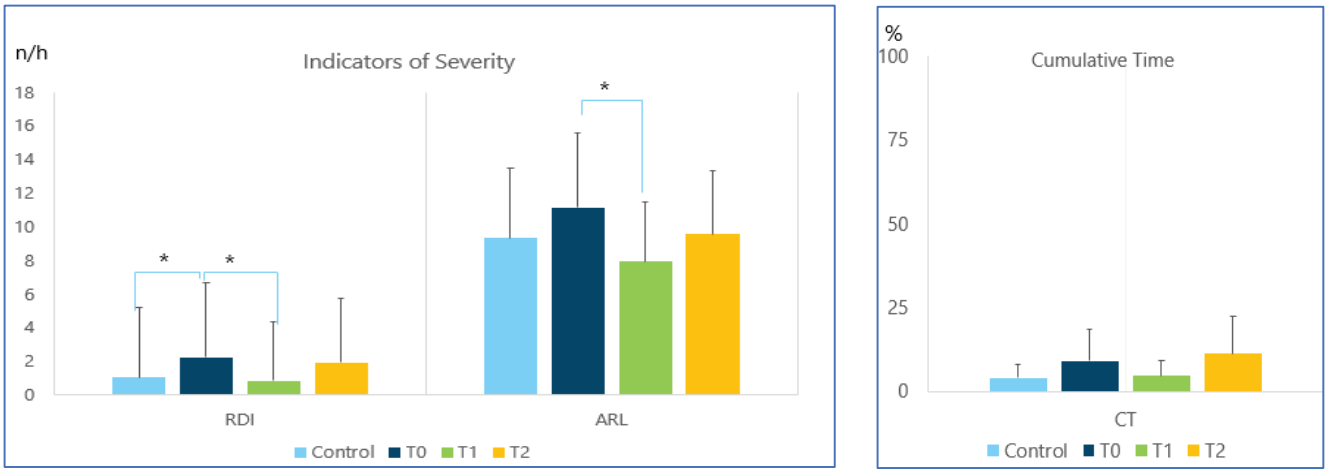

Figure 11. LEFT – Chart showing the changes in the values of the indicators of severity depending of the treatment stage for the Activator group comparing them to the values from the Control group. RIGHT – The cumulative time in respiratory disturbances did not show any statistical value.

7.4.2 Respiratory events

Even though these are 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 (Table 13; Figure 12).

Table 13. All events and especially obstructive events, which were the ones that were most observed in this study, decrease considerably when wearing the activator. ANOVA tests reveal a statically significance of $p<0.05$ in the total events category and the obstructive events category.

Respiratory Events	Control group	Activator group (T0)	Activator group (T1)	Activator group (T2)
TOTAL n/h	6.5 ± 8.3	20.45 ± 12.8	4.65 ± 7.8	13 ± 9.4
OBSTRUCTIVE n/h	6.5 ± 8.3	20.35 ± 12.8	4.55 ± 7.8	13 ± 9.4
CENTRAL n/h	0	0.05 ± 0.22	0.05 ± 0.22	0
MIXED n/h	0	0.05 ± 0.22	0.05 ± 0.22	0

*P<0.05 ** P<0.01

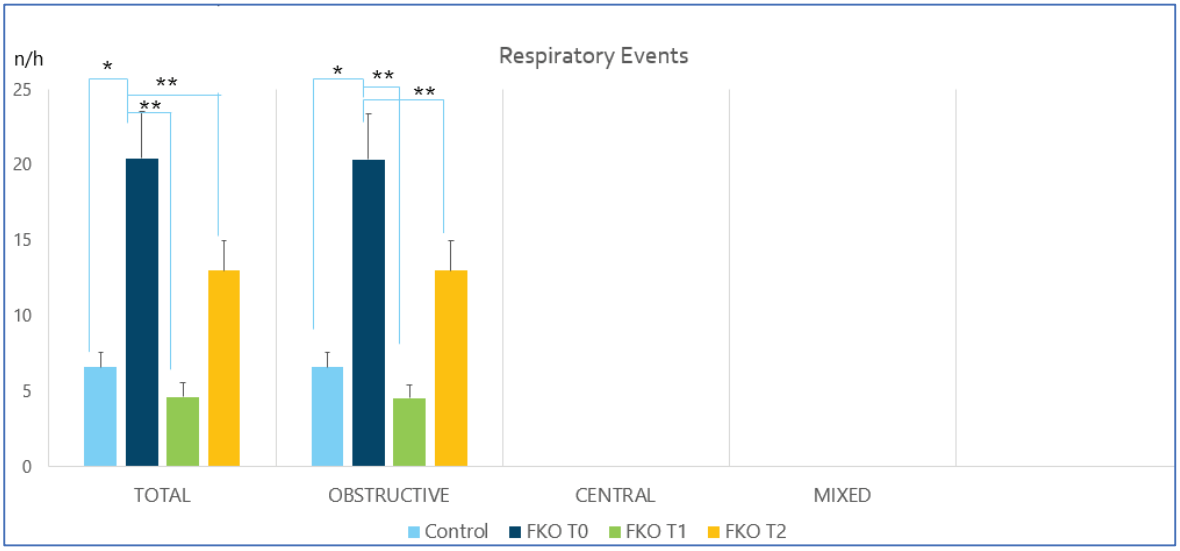

Figure 12. Differences in the number of respiratory events measured from T0 to T2 in the Activator groups, compared to Control group.

7.4.3 Oxygen desaturation index

The general level of desaturation of oxygen that is recorded when the children wear the activator to sleep can be seen to be less than that when the activator is out, and even when comparing to control group the general level of oxygen quality seems to be better than when the activator is out. However, no statistical significance could be found (Figure 13a, 13b, 13c).

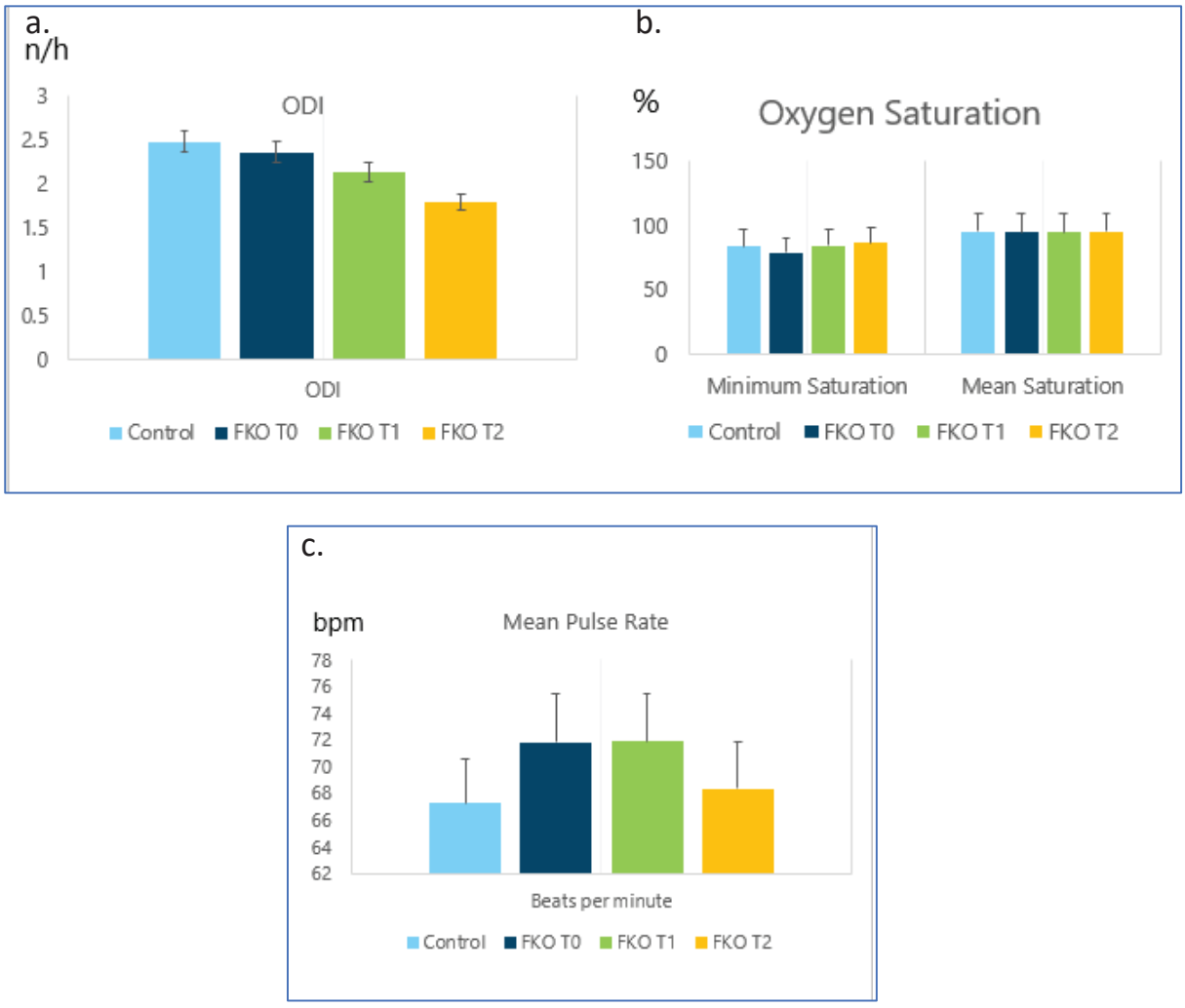

Figure 13. Differences in: a. Oxygen Desaturation Index, b. minimum/mean saturation and c. beats per minute.

7.4.4 Final skeletal pattern relationship

After a year on average (16.5 ± 2.7 months) of continuous functional therapy with the FKO, the skeletal relationship of the Activator group changed positively to a more harmonious cranio–facial relationship (Table 14).

Table 14. Changes in the skeletal pattern of the participants (*P<0.05).

	SNA°		**SNB°**		**ANB°**	
	Initial(T0)	**Final(T2)**	Initial(T0)	**Final(T2)**	Initial(T0)	**Final(T2)**
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** *

8 Discussion

The findings in this study demonstrate that after continuous functional therapy with the FKO, not only do the upper airways get wider, the changes are kept for a considerable period. This is evident when assessing the radiographic findings which are in turn corroborated by the results obtained from the PM.

8.1 Screening questionnaires

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 of 4.7 for skeletal Class I children and 4.8 in To and 4.5 in T2 evaluated skeletal Class II children demonstrate that daytime sleepiness is not a concerning issue for the children evaluated in this study.

The final Cronbach's alpha of 0.70 and 0.79 in T0 and T2 respectively for the Activator group, shows that the internal consistency of this questionnaire can be considered as acceptable, an alpha of 0.60 for the Control group, while not as good results as the alpha from the test group still might be recognized as near acceptable levels, one of the reasons this results are like this for the control group might be that the participants reported less positive answers for certain items, also, some parents answered with the "I don't know" option more often than the parents from the Activator group, which in turn lowers the total score for this survey.

8.2 Oropharyngeal crowding

The American Academy of Pediatrics (APP) clinical practice guidelines issued in 2002 and 2012 have considered PSG evaluation as the gold standard for determining the severity and presence of OSA in children, this is due to the difficulty in successfully determining primary snoring from pediatric OSA by means of history and physical examination alone (Farber 2002; Marcus *et al.,*2012), however obtaining a PSG from every patient especially children may not be feasible because this kind of tests in children are not yet universally available, due to the scarcity of sleep centers dedicated to pediatric sleep. Besides this, pediatric PSGs are expensive and not required all the time, thus the need for a method to evaluate oropharyngeal crowding that is reliable, easy to use and comfortable for the patients.

In this study, the results for the Mallampati score in children for the Control group were of 11 children possessing what is considered a class II score, which means there was partial visibility of the tonsillar pillars, uvula and soft palate.

The American Academy of Sleep Medicine and Dutch Central Accompagnement Organization (CBO) have both stated that the Mallampati score has an additional value for diagnosing OSA in adults (Epstein *et al.,*2009). There are several studies that yield mixed results concerning the utility of this score system in predicting OSA in adults (Nuckton *et al.,*2006; Ramachandran *et al.,*2010; Bins *et al.,*2011). In children, a higher score in the Mallampati scale may be a more reliable predictive tool for the presence of OSA than in adults, because in children the main cause of respiratory obstruction is pharyngeal (Kumar *et al.,*2014). From the results of this study skeletal Class II Japanese children more often

present with a class II score with 13 children out of 20 subjects, similar to the control cohort, this score is acceptable and respiratory function may not be impaired. In a study done by Kumar *et al.,* in 2014 found that on average, the probability of childhood OSA increases by more than 6–fold for every point increase in the Mallampati score. According to the same study, AHI (severity of OSA) levels also have a positive correlation with a higher Mallampati score. For the present study when comparing the results from the Mallampati score and the PM results, the conclusions somewhat agree with Kumar's study, with the caveat that the cohort for the present research consists of a smaller group both for control and test group, also the data was recovered from healthy children.

Regarding Tonsillar grading, the results obtained in the present study revealed that both skeletal Class II and skeletal Class I children reach a grade 1, meaning that tonsil size is not of concern, at least regarding the population assessed. On average, the probability of suffering from OSA is increased 2–fold or more for every point increase in tonsillar size (Kumar *et al.,*2014). Studies done previously (Rodrigues *et al.,*2010; Nolan *et al.,*2011; Certal *et al.,*2012), have shown mixed results concerning the correlation of tonsillar size on physical examination and OSA. In the present study, it can be said that due to the low grades scored by both groups in the size of the tonsils and the results from the PM, that skeletal Class II children have on average, similar oropharyngeal crowding scores in both the Mallampati score and Tonsillar grading, of class II and grade 1 respectively, by which it could be said that oropharyngeal crowding is not of concern for Japanese skeletal Class II children. A limitation for this procedure in this study specifically is that the total number of subjects

assessed was small thus a broader study would need to be done in the future to further assert this conclusion.

8.3 Cephalometric assessment

8.3.1 Adenoid tissue and nasopharynx

Numerous studies agree that hypertrophy of the adenoids is an important cause of obstruction in the nasopharynx and commonly related to mouth breathing (Dolen *et al.,*1990; Wang *et al.,* 1995; Wang *et al.,*1997), which in turn leads to a significant rearrangement of the neuromuscular and soft tissue structures, that might result into a distorted craniofacial growth pattern and orthodontics alterations (Linder–Aronson, 1979; Vargervik *et al.,*1984; Valera *et al.,*2003).

In the present study, it was revealed that, even though no statistical significance could be found, the linear assessment of the adenoidal tissue is of a comparable size in both skeletal Class I and Class II children. The volume of the adenoids is also of a similar size in both groups, for the Activator group, it was found that dimension of the adenoidal tissue significantly ($P<0.01$) reduces in size in T2 compared to initial data at T0, translating this to an unobstructed nasopharynx, which significantly ($P<0.01$) is larger than at the beginning of functional therapy at T0, which in turn translates into better sleep breathing.

Even though the functional appliance used in this study to evaluate changes in the breathing patterns of growing children does not affect the nasopharynx nor the size of the adenoidal tissue, the study done by Freitas *et al.,*(2006) says that malocclusion type does not influence the width of the upper pharyngeal space, this study agrees with these findings, with the

difference that the present research adds information in three different points (T0–T2), providing with information concerning growth of the cohort of patients whose data were recollected. In the present study, it was recognized that the adenoids reduce their size after a period thus enlarging the nasopharyngeal space for a better breathing.

8.3.2 Anteroposterior width and area size of the upper airways

Prior studies done evaluating the upper airway changes following functional appliances agree that no matter which kind of appliance is involved, 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 airways.

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 (FKO), Twin Block, Herbst, Bio bloc or headgear appliances (Trenouth MJ 1992; Pancherz H 1999; Trenouth MJ 2001). Concerning the present study, it was decided to evaluate the influence that the Andresen Activator (FKO) has not only physically on the upper airways, 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 airways increases in size steadily over the course of the evaluation time, however no statistical significance could be found. This may be due to the fact that the children assessed did not suffer from any condition that would constrict the upper airways and the linear size of the upper airways from the Activator group was comparable to that of the Control group.

In a study by Yassei *et al.,*(2012) using the Faramand appliance found that mandibular advancement has the potential to increase the dimensions of the upper airways during treatment and this increase in dimension remains stable over a long period (4 years $\pm$ 2–8 years), which strongly agree with the results from this study, when analyzing the anteroposterior size of the upper airways it was found that not only are the changes kept in T2, but there is a slight increase in size of the evaluated measurements.

Regarding the dimension of the upper airways, 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 functional therapy at T2. This may be explained by the fact that the FKO when inserted. This can be explained with a possible mechanism: the base of the tongue is located in front of the anterior wall of the soft palate and the anterior displacement of the tongue induced by the FKO reduces the tongue's gravitational effect on the soft palate (Liu *et al.,*2000).

Changes of the dimension of the hypopharynx shown in the present study reveal a minor increase of this area of the upper airways that is kept stable after a year of continuous FKO therapy at T2, in spite of this no statistical significance could be found. The fact that following treatment with the FKO, 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 T2. This is in accordance with a study by Isono

et al., in 1997 which stated that there is an increase in the dimensions of the airways which result from mandibular anterior displacement even in obese individuals without failure.

Another study performed by Horihata *et al.,* (2013), reported an increase in the anteroposterior width and total dimension of the upper airways after FKO therapy when comparing to initial data, which is in accordance to the results from this study.

In the studies by Tsuiki *et al.,* (2004) and Poon *et al.,* (2008), OA treatment was used in adult patients to treat 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.

There is a large amount of studies done to assess the changes of the upper airways 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. (Horihata *et al.,*2013).

Shepard and Thawley proposed in 1985 that most problems associated with respiration are present in the oropharynx, improvement of the size of this section with the use of the FKO increases the importance of this functional appliance.

Because the total number of subjects whose data was collected for this study was relatively small may be an explanation for the lack of statistical significance, which could be obtained in the future with a much larger population, resulting in more reliable data.

8.3.3 Changes in hyoid bone position

In the perpendicular plane, it was noted that in the present study, the treatment of skeletal Class II malocclusion by FKO activator resulted in a significant ($P<0.01$) displacement of the hyoid bone in an anterior and inferior direction.

Findings reported by Battagel *et al.,* (1999), Liu *et al.,* (2000), Almeida *et al.,* (2006), Poon *et al.,* (2008) and Doff *et al.,* (2009), showed that the hyoid bone is positioned more upwardly after functional appliance therapy. This is a disagreement with the present study, where the hyoid bone takes a more inferior position.

In the present study, the hyoid bone significantly shifts its position to a more anterior one, and the linear distance between hyoidale and the third cervical vertebra is also increased. The linear distance between the mandible from retrognathion and the third cervical vertebra is significantly ($P<0.01$) increased as well. This anterior displacement present in this study may be due to the functional therapy. Ordubazari *et al.,* (1998) disagrees with these results. Other studies agree with the present research (Battagel *et al.,*1999; Zhou *et al.,*2000; Yassei *et al.,*2012)

The present study revealed that at T2 (roughly a year after the beginning of FKO therapy) the hyoid bone continued to be anteriorly displaced. Taking into consideration that the hyoid bone displaces itself in the anterior direction during growth (Ordubazari *et al.,*1998), this anterior shift could be explained with the stability of the lower jaw and an increased ANB changes after functional therapy and stretching of the genioglossus muscle (Yassei *et al.,*2012).

The lowest section of the upper airways as affected by displacement to the anterior direction of the hyoid bone as induced by the FKO are also significantly (P<0.01) increased. Of the two newly proposed linear distances, the most inferior one (LspwEb) experiences a significant (P<0.01) increase from T0 to T1 in the Activator group, and the achieved enlargement is kept stable (P<0.05) at T2. This may be explained with the fact that as the FKO places the mandible in a more anterior position, the base of the tongue along with the hyoid bone is dragged forward by the muscles.

8.3.4 Skeletal pattern changes

Overall, the FKO produced positive changes in the skeletal pattern of children demonstrated a significant (P<0.05) decrease in the difference of the various cranio–facial angles evaluated in skeletal Class II children.

The SNA angle increased an average of $\pm$ 1.2 degrees from T0 to T2 in the Activator group, this result contrast with the ones by Mills (1990), where he found a reduction of said angle. The SNB and ANB angles changed significantly (P<0.05), with an increase of the former and a decrease of the latter. Normal craniofacial growth and development, greatly assisted by the effects of the FKO, propels the changes earlier demonstrated in both the hyoid bone position and the widening of the upper airways. This shows that with proper compliance in the use of functional appliances, in this case the FKO activator, the changes from skeletal Class I to Class II are achieved, this is in accordance to the study by Santamaría–Villegas *et al.,* (2017), but contrasting to the study by Koretsi *et al.,* (2014), which affirms that functional appliance mainly influence dento–alveolar changes rather than skeletal ones.

8.4 At home sleep monitoring

Type 1 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 (Shayeb *et al.,* 2014).

Type 3 PM have been used to assess the severity of Sleep Disordered Breathing (SDB) and the distribution of respiratory events when comparing type 2 and 3 PMs in patients admitted with acute decompensated heart failure (ADHF). The use of type 3 PMs can identify SDB in most of the patients with ADHF (Punjabi *et al 2017)*.

The results that the type 3 PM used in study yielded reveal that almost all indicators of respiratory severity decrease significantly ($P<0.05$) when the FKO is inserted and the decrease is significantly stable ($P<0.05$) at T2 after functional therapy. The indicator for RDI shows a positive decrease from T0 at the beginning of treatment with FKO and a significant ($P<0.05$) improvement at T1 when the FKO 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 FKO is removed.

The number of arousals as determined by the ARL variable also show a significant reduction ($P<0.05$) from T0 to T1 in the Activator group. This is explained with the fact that as the FKO is inserted throughout the night, the physical changes brought upon with the increased size of the upper airways, the children experience a more refreshed and sound sleep.

A study done with the Herbst appliance and maxillary expansion by Schüts *et al.,* (2011), 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. 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 ($P<0.01$) lowering from T0 to T1 when the FKO 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.

The levels of oxygen desaturation as perceived by the PM used in this study show that there is a positive trend towards less desaturations per hour of sleep in the Activator group, however, no statistical significance could be found. This may be explained with the fact that the children of this study are healthy and the desaturation levels are similar between the Activator group and the Control group.

Hosoya *et al.,* published a clinical report in 2016 detailing a case of a skeletal Class II child that underwent Twin Bloc appliance therapy, who was also given a PM to evaluate for possible childhood OSA, his findings discovered that thanks to Twin Bloc treatment the ODI levels improved greatly, albeit after a considerable time (6 months after initial recording).

This agrees with the present study, which saw an improvement in ODI values post FKO therapy.

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 FKO therapy and periodical checkups and follow–up appointments, the retesting with PM showed a considerable decrease in all indicators of severity, as well as less respiratory events, especially when the FKO is inserted (Medina *et al.,*2017). 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.

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.

9 Summary

From all the tests performed for this research, several insights into how beneficial the FKO activator is for the children that receive this kind of myo–functional therapy were observed:

1. Oropharyngeal crowding as assessed with the MS and tonsillar grade does not seem to be a big issue on these children and there seems to be no significant difference between both control and test group.

2. The hyoid bone, takes a more anterior position when the activator is inserted thus increasing the size of the lowest section of the upper airways.

3. The overall area and the anteroposterior width of the upper airways are increased when the activator is inserted, and this widening is kept even after treatment.

4. From the sleep monitor a better and more sound sleep patterns are confirmed when the activator is inserted, also this improvement is maintained after removal of the FKO.

A limitation of this study as mentioned previously include the relatively low 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 FKO in a more extended period.

10 Conclusion

The present study revealed that when the FKO is inserted, it not only activates proper mandibular growth and influences the perioral muscles, it also causes the peri–hyoideal muscles to move forward. The hyoid bone, when in an anterior position widens the lower airway space significantly, especially at the base of the tongue and base of epiglottis, thus opening the lower air space. Which relates to the results from the sleep monitor, translating this to better sleep patterns, and even after treatment these satisfactory results are kept and inferred to be carried out through growth and development.

To conclude we can say that the FKO 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 airways and reducing the number of disordered breathing events in children that undergo this kind of orthopedic therapy.

It could be said that the FKO Activator might be useful for preventing and/or diminishing the future risk of OSA of the children that receive functional treatment with this appliance, so that when they become adults, they continue to experience impaired sleep–breathing thanks to this activator, however, this is subject for a future study where this assertion can be confirmed or not.

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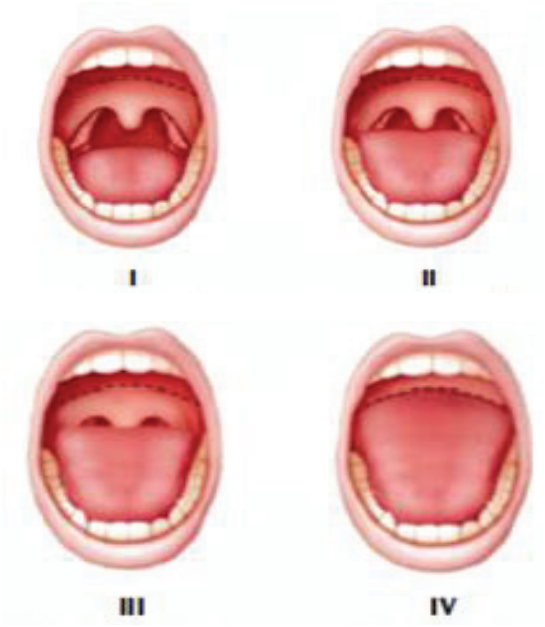
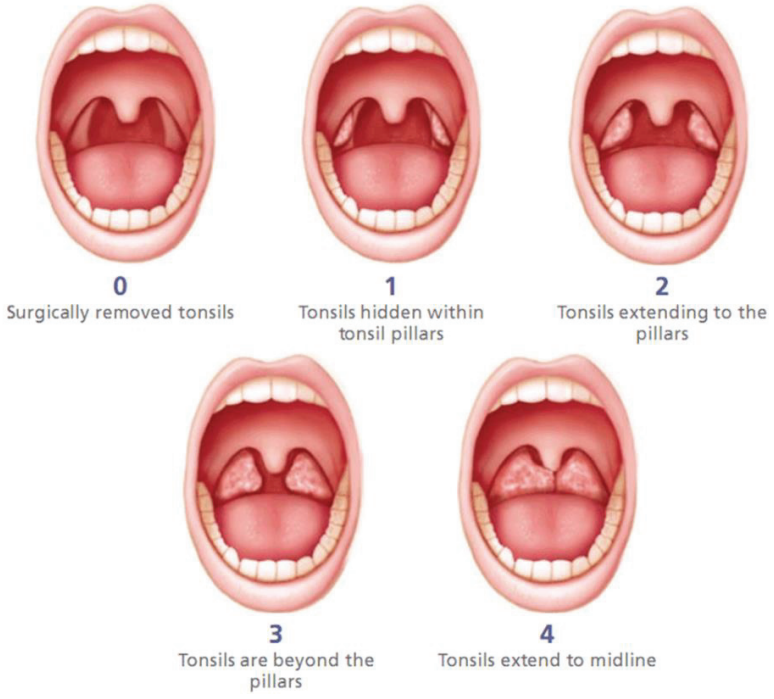
12 Complimentary materials

1. **Mallampati scoring guide used in this study.**



*Friedman *et al*., 2013

2. **Tonsillar grading guide used in this study**.



3. License agreement for the SRBD questionnaire

Nouvant License Agreement #4710–umich

INSTRUMENT: Sleep Related Breathing Disorders (SRBD) TM

University of Michigan Office of Technology Transfer File: 377

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 answers neatly in the space provided. A "Y" means "yes," "N" means "no," and "DK" means "don't know."

1. WHILE SLEEPING, DOES YOUR CHILD:				
Snore more than half the time?	Y	N	DK	A2
Always snore?	Y	N	DK	A3
Snore 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	A25
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
0. THIS CHILD **OFTEN**:				
Does not seem to listen when spoken to directly.	Y	N	DK	C3
Has difficulty organizing tasks and activities.	Y	N	DK	C5
Is easily distracted by extraneous stimuli.	Y	N	DK	C8
Fidgets with hands or feet or squirms in seat.	Y	N	DK	C10
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!

5. The ESS questionnaire modified for children.

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

6. Japanese version of the ESS modified for children

JESS™ (Japanese version of the Epworth Sleepiness Scale)

ESS **日本語版**

もし、以下の状況になったとしたら、どのくらい**うとうとする（数秒～数分眠ってしまう）**と思いますか。**最近の日常生活**を思いうかべてお答えください。

以下の状況になったことが実際になくても、その状況になればどうなるかを想像してお答え下さい。(1 ～ 8 の各項目で、○は１つだけ) すべての項目にお答えしていただくことが大切です。 **できる限りすべての項目にお答えください。**	うとうとする可能性はほとんどない	うとうとする可能性は少しある	うとうとする可能性は半々くらい	うとうとする可能性が高い
1) すわって何かを読んでいるとき（新聞、雑誌、本、書類など） →	0	1	2	3
2) すわってテレビを見ているとき →	0	1	2	3
3) 会議、映画館、劇場などで静かにすわっているとき →	0	1	2	3
4) 乗客として１時間続けて自動車に乗っているとき →	0	1	2	3
5) 午後に横になって、休息をとっているとき →	0	1	2	3
6) すわって人と話をしているとき →	0	1	2	3
7) 昼食をとった後（飲酒なし）、静かにすわっているとき →	0	1	2	3
8) すわって手紙や書類などを書いているとき →	0	1	2	3