Effect of palatal expansion and Up-Locker Activator on sleep behavior and architecture and pharynx dimensions in children with Sleep Disordered Breathing

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INTRODUCTION

Sleep quality and duration are critical determinants of health, contributing to optimal cognitive function, memory consolidation, and overall neurodevelopment children[1]. Adequate respiratory function plays a pivotal role in maintaining healthy sleep patterns, and quality and, consequently, children's quality of life[2].

There is growing evidence that Obstructive Sleep Apnea (OSA)[3] and, even sleep disorder breathing (SDB) are associated with a wide variety of adverse outcomes in children, both systemic and neurocognitive[4]. Even though there are controversies in the literature, about the affection of sleep stage architecture in the presence of SDB and/or OSA[5], arousal is an important defensive mechanism against sleep disordered breathing, leading to sleep fragmentation[6]. The most frequently used overnight polysomnographic metric for evaluating the severity of SDB is the apnea-hypopnea index (AHI). This index serves as a composite score that combines the total number of obstructive and central apneic events along with the total number of hypopneas experienced per hour of sleep[7].

Orthodontic interventions aimed at modifying hard palate morphology, such as the Hyrax appliance, have demonstrated efficacy in expanding the transverse dimensions of the hard palate and enhancing the dimensions of the upper airway up to 30%[8,9], and thus, improve sleep quality. Previous studies evaluated the effect of semi-rapid maxillary expander (SRME) on sleep architecture[6]. SRME treatment almost normalized sleep architecture and improved sleep respiratory disturbances; however, sleep structure and respiratory parameters did not completely recover[6]. These results may stem from the fact that isolated palatal expansion might not fully address functional factors like tongue posture and orofacial stability. Poor tongue posture—characterized by a downward position during both rest and activity—hinders the development of sufficient suction and the preservation of Donders' space. This can lead to increased inflammation in the upper airway[10,11].

The proposed therapeutic approach using the Hyrax appliance in combination with the Up-Locker vacuum activator offers the potential not only to expand the palatal and dental arches but also improve the resting posture of the tongue[11]. By restoring negative pressure in the upper airway through vacuum activation, this combined intervention may enhance orofacial function[12], optimize airway dimensions[13], reduce SDB[14], improve sleep physiology, and stabilize treatment outcomes with maxillary expansion[11], by establishing adequate tongue posture at rest and function[15].

The hypotheses of this investigation are that intervention with Hyrax + Up-Locker vacuum activator has better effect on improving airway dimensions, and sleep behavior (reduction of snoring, scores of SDB, night wakings and daytime

sleepiness) and sleep architecture (reducing sleep latency more than 12 minutes, and AHI to less than 5. Additionally, it is expected to increase the percentage of Rapid Eye Movement (REM) sleep more than 3%, no-REM (nREM) sleep stage 3 more than 5%, and total sleep time more than 30 minutes) compared with treatment with the treatment with Hyrax alone. Thus, the aim of the present investigation is to evaluate the effectiveness of the combined intervention of Hyrax + Up-Locker vacuum activator in reducing snoring and enhancing nasopharynx and nasal airway dimensions, improve sleep behavior and sleep architecture, specifically by measuring improvements in daytime sleepiness, SDB, night wakings, sleep latency, apnea-hypopnea index, percentages of REM and non-REM sleep stage 3, and total sleep time, in comparison to treatment with Hyrax alone.

METHODOLOGY

A prospective, single-blind, randomized controlled clinical trial will be conducted. Children aged 6 to 8 years will be recruited from the clinics of the postgraduate program of Pediatric Dentistry and the private practice of one of the investigators (CR).

The sample size will be calculated based on the differences reported by Sökücü et al.[16], assuming a 95% confidence level, 80% power, and a 20% treatment difference. According to the analysis, 17 participants per group (total n = 34) will be required.

Inclusion Criteria

Presence of sleep-disordered breathing symptoms, with a minimum score of 6 on the Children's Sleep Habits Questionnaire (CSHQ)[17]—which will be described below in the outcome measures—documented snoring recorded by SnoreLab™ for at least five consecutive days, and transverse maxillary deficiency of at least 5 mm, with a normal superior intermolar distance defined as a minimum of 40 mm (measured between the mesiopalatine cusps of teeth 16 and 26).

SnoreLab™[18] will be used as a validated mobile application created to monitor and analyze snoring behavior, providing insights into sleep patterns and potential underlying sleep disorders. Employing advanced sound detection technology, the app will record snoring episodes during the night, offering detailed feedback on the frequency and intensity of snoring. Users will be required to demonstrate valid recordings for at least 50% of each night, with data collection continuing until five nights of recordings are achieved. To qualify for inclusion in the study, participants will need to exhibit snoring—whether light, loud, or epic—across these five nights.

Exclusion Criteria

History of previous treatment for OSA (including tonsillectomy and adenoidectomy), overweight or obesity (Body Mass Index (BMI) at or above the 85th percentile for their age and sex), chronic systemic diseases unrelated to upper airway respiratory alterations (e.g., chronic cardiopulmonary or neuromuscular diseases), facial malformations (e.g., syndromes with facial or cleft lip/palate anomalies, or clinically evident palatal malformations), presence of dental caries, prior treatment with maxillary orthopedics or orthodontics, and failure to comply with scheduled control visits.

Weight will be measured at the Universidad CES dental clinic or the private practice of one of the investigators (CR) using a standard physician's scale, ensuring that the children are dressed in light clothing and not wearing shoes, with the scale providing a precision of 0.1 kg. Height will be assessed using a wall-mounted height board, adhering to specific criteria: children will stand barefoot, with their heels together, and their heels, buttocks, shoulders, and head in contact with the wall while maintaining a neutral gaze. Measurements will be recorded to the nearest 0.1 cm. BMI will then be calculated using the formula kg/m^2.

Participants will be randomly assigned using a random number generator in REDCap™ to one of two groups: Group 1 (Control group: Treatment with the Hyrax expansion appliance alone) or Group 2 (Intervention group: Treatment with the Hyrax appliance in combination with the Up-Locker vacuum activator).

Intervention

For both groups, the semi-rapid maxillary expansion (SRME) will be performed using a Hyrax device with a Leone™ standard expansion screw for all children. Bands will be placed on the maxillary first permanent molars, and a frame containing the maxillary canines and primary first molars will support the expander. All expanders will be constructed by the same expert technician. In both groups, the expander screw will be activated a quarter turn twice a day for the first 7 days, followed by once a day until the palatal cusp of the upper molar comes into contact with the buccal cusp of the lower molar. After the active phase, the expanders will remain in the oral cavity for 4 months for retention.

Patients in Group 2 will receive a standardized training device (Up-Locker Vacuum Activator from Forwardontics™, approved by the FDA) immediately after completing the retention period and removing the expansion Hyrax device. Patients will be instructed to gather saliva while positioning the Up-Locker vacuum activator between

their front teeth and lips, using a mirror to monitor the placement of the membrane within the funnel. During the swallowing of saliva, negative pressure formation will be observed with the Up-Locker vacuum activator by the inversion of the membrane into the funnel. They will be informed that the objective of the treatment will be to establish a nasal breathing pattern and a tongue resting posture against the palate to help stabilize both the tongue and the soft palate. Patients will be advised to refrain from creating excessive negative pressure during the exercises to prevent potential adverse effects related to pressure on the gums. After instruction, the patients will undergo 30 minutes of daily home training during the first week, 60 minutes daily during the second and third weeks, followed by 120 minutes daily until completion of a 90-day program. The recommended timeframe for usage will be during the afternoon while watching TV or reading, or in the evening before rest. The investigator (CR) will perform revisions of adequate usage of the device every 4 weeks.

Outcome Measures

Sleep Behavior

Sleep behavior will be evaluated using the validated CSHQ[17], which consists of a 35-item questionnaire administered to parents, asking them to report their child's sleep behaviors and patterns over the last typical week. The instrument is designed to address significant clinical sleep complaints commonly observed in this age group and will provide data on the following subscales (with score ranges in parentheses): Bedtime Resistance (6–36), Sleep Onset Delay (1–3), Sleep Duration (3–9), Sleep Anxiety (4–12), Night Awakenings (3–9), Parasomnias (7–21), Sleep Disordered Breathing (3–9), Daytime Sleepiness (8–24). Each item on the questionnaire will be rated on a three-point scale: "usually" (5–7 times a week) = 3, "sometimes" (2–4 times a week) = 2, and "rarely" (0–1 time a week) = 1. A composite score will be computed as the sum of scores on the 33 items across all subscales. A total score of 41 will be considered the clinical cut-off, indicating a potential risk of sleep problems.

Sleep Architecture

All children in both the control and intervention groups will undergo a one-night PSG study in a sleep laboratory in Medellín, Colombia, before treatment (T0) and at the end of treatment for the intervention group (T1, nine months after initiating treatment for both groups). The sleep study will utilize a sleep recording system and dedicated scoring software (Neuron-Spectrum-65/PSG system™, Neurosoft Ltd. Ivanova,

Russia). The measurements will be conducted between 9:00 pm and 6:00 am for all participants, with audio and video signals recorded in parallel. A nasal flow cannula and a thermistor respiratory monitor will record respiration, while a finger pulse oximeter will monitor blood oxygen saturation (SaO2). All electrodes and sensors will be installed by a trained research team.

The sleep architecture will be evaluated according to the AASM Manual for the Scoring of Sleep and Associated Events[19]. The following measures will be taken:

- **Total Sleep Duration (TSD):** Cumulative time (in hours) spent in non-REM (nREM) stages 1, 2, and 3, and Rapid Eye Movement (REM) sleep from sleep onset to lights-on time.

- **Sleep Onset Latency (SOL):** The elapsed time between lights-out and the first occurrence of any sleep stage other than a stage of awakening.

- **Time and Proportion Spent in Each Sleep Stage:** Cumulative time and proportion of sleep spent in each sleep stage (nREM stages 1, 2, and 3 [N3 and N4 will be grouped] and REM sleep) from sleep onset to lights-on time.

-**Arousals/Hour during REM and nREM sleep:** 3-5 seconds of arousal (abrupt alterations of oscillatory patterns, characterized by low-voltage fast-rhythm EEG oscillations during REM and nREM sleep).

Airway dimensions

The dimensions of the airway will be measured using lateral cephalometric radiographs. All x-rays will be taken with an Orthophos Plus Ceph™ for lateral cephalograms in children from both groups before the start of treatment (T0) and after the conclusion of the treatment period in the intervention group (T1)

The measurements will include[20]:

- **ad1-PNS:** The lower nasopharyngeal airway space will be measured in millimeters between the point ad1 (the lower adenoid point, which is the most prominent point of the pharyngeal tonsil, drawn in the PNS-Ba plane) and PNS.

- **ad2-PNS:** The upper nasopharyngeal airway space will be measured in millimeters between the point ad2 (the superior adenoid point, which is the most prominent point of the pharyngeal tonsil, drawn perpendicular to the S-Ba line extending to the PNS point) and PNS.

- **SPAS:** The superior posterior airway space, representing the width of the airway in the upper part of the pharynx, specifically behind the soft palate, will be measured as the distance between the posterior pharyngeal wall and the dorsal surface of the soft palate, parallel to the palate horizontal plane.

- **MAS:** The measurement for the space of the airway corresponding to the upper glossopharynx will be taken, which represents the width of the airway along a line parallel to the palatine plane passing through point P (the extreme point of the soft palate).

- **IAS:** The inferior airway space will be evaluated behind the tongue base in the glossopharynx, traced along a line parallel to the palatine plane through the intersection of the jaw and the airways.

Additionally, panoramic radiographs will be obtained using an Ortopantomograph™ in children from both groups before (T0) and after the end of the treatment time in the intervention group (T1) to calculate the anterior nasal two-dimensional area. The shape of the anterior nasal space (radiolucent area) will be outlined by one examiner, and the program (Image J for PC, Softonic™) will subsequently determine the area in terms of pixels.

Statistical Analysis

Data will be analyzed using IBM SPSS Statistics version 27™. Descriptive statistics will summarize demographic and clinical characteristics. T-tests and Mann-Whitney tests will be employed to compare outcome measures between groups. A significance level of $p < 0.05$ will be applied to all comparisons. The Shapiro-Wilks test will be utilized to determine the normality of the variables.

INFORMED CONSENT

Informed Consent for Participation in a Clinical Study

Study Title: Evaluation of Treatment Options for Children with Sleep-Disordered Breathing

Principal Investigator: Claudia Restrepo-Serna, Postgraduate Program in Pediatric Dentistry, Universidad CES

You are being invited to participate in a clinical research study regarding treatments for children aged 6 to 8 years with sleep-disordered breathing. This document aims to provide you with information to help you decide whether you would like your child to participate. Your participation is entirely voluntary, and you may choose to withdraw at any time without any consequences.

Purpose of the Study:

The purpose of this study is to evaluate the effectiveness of two treatment approaches for children experiencing symptoms of sleep-disordered breathing. This study aims to gather data on sleep behavior, sleep architecture, and airway dimensions before and after treatment.

Study Procedures:

If you agree for your child to participate, the following will take place:

1. Recruitment: Your child will be recruited from our clinics based on specific inclusion criteria, including the presence of sleep-disordered breathing symptoms, documented snoring, and transverse maxillary deficiency.

2. Screening: Your child will undergo screening to determine eligibility. This includes completing the Children's Sleep Habits Questionnaire (CSHQ) and monitoring snoring episodes using the SnoreLab mobile application for five consecutive nights.

3. Random Assignment: Eligible participants will be randomly assigned to one of two groups:

- Control Group: Treatment with the Hyrax expansion appliance alone.
- Intervention Group: Treatment with the Hyrax appliance and an Up-Locker vacuum activator.

4. Treatment: All children in both groups will have a Hyrax device fitted. This appliance will be activated for a specified period, followed by a retention phase. The intervention group will additionally receive training on using the Up-Locker vacuum activator, aimed at promoting nasal breathing and stabilizing the tongue posture.

5. Data Collection: Throughout the study, your child will undergo various assessments, including:
- Questionnaire about sleep behavior.

- One-night polysomnography (PSG) study before (baseline) and after (end of treatment, approximately nine months later) treatment.
- Lateral cephalometric radiographs to measure airway dimensions before and after treatment.
- Panoramic radiographs to measure the anterior nasal area.

Confidentiality:

Your child's participation in this study and all collected data will be kept confidential. All data will be de-identified to ensure privacy. The study findings may be published in scientific journals or presented at conferences, but individual identities will not be disclosed.

Potential Risks:

Participation in this study may involve some risks, including:

- Discomfort associated with wearing the dental appliances.
- Possible slight discomfort during the PSG study and imaging procedures.
- The risk of feelings of anxiety or distress while engaging in assessments or treatments.
- Radiation from dental x-rays. Strict control of the radiation generated by the equipment will be implemented, and the X-rays will be taken with all necessary protective measures.

Potential Benefits:

While there may be no direct benefits to your child from participating in the study, the information gained may improve understanding and treatment options for children with sleep-disordered breathing.

Voluntary Participation:

Your consent for your child to participate in this study is entirely voluntary. You have the right to withdraw your child from the study at any time without any effect on your child's future treatment. There will be no penalties or loss of benefits if you or your child chooses to withdraw.

Contacts for Questions:

If you have any questions regarding this study or your child's participation, please contact:

- Principal Investigator:
Claudia Restrepo-Serna
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Consent Statement:

By signing below, you acknowledge that you have read and understood the information provided above, and you agree for your child to participate in this study.

Parent/Guardian Name: _____

Child's Name: _____

Signature: _____

Date: _____

Thank you for considering participation in this important study.

ASSENT FORM FOR CHILDREN PARTICIPATING IN A SLEEP STUDY

Hello!

We are doing a study to learn more about how to help kids sleep better. This is important because good sleep helps you think, remember things, and feel good overall.

What is this study about?

In this study, we want to find out if using two special dental devices will make your sleep quality better than using just one device. We will help kids who have breathing problems when they sleep, which can cause snoring or waking up a lot at night.

What will happen if you join this study?

- If you agree to join, you will be asked to fill out a form about your sleep habits with the help of your parents.

- You will have a fun night in a sleep clinic where we will check how well you sleep. This may include being connected to some machines to monitor your breathing and sleep.

- X-rays (pictures of your bones from the inside) will be taken to measure your airways.

- You will be randomly placed in one of two groups:

  - In the first group, you will wear the Hyrax device, which helps your teeth and mouth.

  - In the second group, you will wear the Hyrax device and another device that helps your tongue.

- After a while, we will check how well you sleep again to see if there are any improvements.

Are there any risks?

This study is safe. However, like with any dental treatment, there could be some discomfort. If you ever feel uncomfortable or have any questions, you should tell your parent or the researchers.

Do you have to be in this study?

No, you do not have to join this study if you do not want to. It is totally your choice. If you decide to join, you can change your mind later and leave the study at any time.

What will you get?

By joining this study, you will help us learn how to make sleep better for kids like you.

If you have any questions or if you want to talk more about this study with your parents or the researchers, feel free to ask!

Do you agree to be part of this study?

Your Name: _____

Your Signature: _____

Date: _____

Thank you! Your contribution is very valuable!

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