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Title:

Preliminary results on the impact of simultaneous palatal expansion and mandibular advancement on the respiratory status recorded during sleep in OSAS children

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ABSTRACT:

Introduction: The study aimed to evaluate the evolution of the respiratory status during sleep of OSAS children treated with a custom-made device combining maxillary expansion and mandibular advancement.

Material and methods: Sleep studies were performed before and after the treatment for 103 children presenting an initial OSAS and Class II malocclusion. Sleep questionnaires were also addressed to parents several years after the end of the treatment to evaluate its long-term effects.

Results: After nine months of treatment, the sleep breathing quality significantly improved: the Apnea/Hypopnea Index systematically decreased ≤ 5 . According to the sleep questionnaires results, 84% of the patients did not show any loud or troubled breathing several years after the end of the treatment.

Discussion: Simultaneous maxillary expansion and mandibular advancement induced an increase of the oral space in the three spatial dimensions, helping in the significant improvement of the OSAS symptoms, with long-terms effects on the sleep breathing quality.

Keywords: Maxillary expansion; Mandibular advancement; Custom-made oral appliance; Child; Obstructive Sleep Apnea; Sleep study

1. Introduction

Obstructive Sleep Apnea Syndrome (OSAS) is a respiratory disorder characterized by a partial or complete obstruction of the upper airways during sleep (respectively apnea or hypopnea). Its prevalence within the pediatric population ranges between 1% and 5% [1]. Because of this abnormal ventilation, this disorder leads to an oxygen desaturation and a sleep fragmentation and is associated with various signs and symptoms as snoring, excessive daytime sleepiness, reduced concentration, hypertension or even cardiac arrhythmia [1]. Its early management and resolution are therefore important for the healthy development of the child.

Several factors should be considered to choose the more efficient therapeutic strategy: the etiology of the obstruction, its degree of severity and the patient's compliance to undergo continuous treatment. Among the therapies available, the adenotonsillectomy presents good short-term results but several cases of recurrence were reported, especially in children with an underdeveloped maxilla or a retrusive mandible [2]. Even though less invasive, the Continuous Positive Air Pressure (CPAP) technique outcomes depend on the obstruction severity and the child's compliance [3].

Constricted maxillary dental arch and a retrusive position of the mandible are considered as common characteristics in the pediatric OSAS [4]. Besides, according to the systematic review of Caron et al., OSAS is associated to a craniofacial anatomy anomaly in 7% to 67% of the pediatric population [5]. Indeed, considering their anatomical connections, a posterior displacement of the mandible results in a fall of the tongue in the pharynx and an antero-posterior narrowing of the upper airways [6]. Likewise, a narrow palate is associated with an insufficient development of the nasal cavities, so an oral breathing pattern is commonly observed in these patients [7].

Considering these anatomic abnormalities, dentists are in favorable position to identify and help in the management of pediatric OSAS [8]. Besides, oral appliances have been widely used in adults, with great amount of success [9]. Among the various designs of oral appliances, rapid maxillary expanders and mandibular advancement devices improve the upper airways patency and relieve their obstruction: by widening the palatal vault and the nasal cavities, by moving the tongue outside the pharynx, by changing hyoid bone position or by modifying airways dimensions. Even though the effects of these techniques on the oral space have already been observed [10,11], very few studies applied them simultaneously [12,13].

In the present study, the effects of an innovative custom-made oral device combining these two technics were reported in children with OSAS and Class II malocclusion: this study aimed to demonstrate that simultaneous palatal expansion and mandibular advancement modifies sufficiently the craniofacial anatomy to improve the respiratory status during sleep.

2. Materials and Methods

2.1. The study sample

The study sample was selected from the patients of a French private orthodontic practice who consulted for a Class II malocclusion. Only children who were identified as OSAS during a diagnostic polysomnography prescribed by the orthodontist were selected. OSAS was diagnosed with an Apnea/Hypopnea Index (AHI) ≥ 1 event per hour of sleep. These children were systematically treated with the personalized innovative oral appliance described below.

Thus, the study sample was composed of 103 children aged between 3 and 12 years (mean \pm standard deviation = 7.0 ± 1.8 years old).

According to the French law n°2012-300 of March 5th, 2012 on researches involving human beings, because this study was retrospective and non-interventional, and because data were anonymized, no signed consent was required. This study was reviewed and approved by the Institutional Review Board of Aix-Marseille University (no. 2019-14-03-001).

2.2. The custom-made oral appliance

All children were treated with a personalized innovative oral appliance composed of two thermoformed intra-buccal pieces (Fig. 1) and described as follows:

- The maxilla expander is a hyrax-type screw 13 mm (RMO®, Denver, Colorado) fixed with an imbedded 0.045-inch wire framework on an acrylic maxillary plate (Duran®, Scheu Dental, Iserlohn, Germany) glued to the buccal, lingual and occlusal surfaces of the canine and first and second deciduous molars (with the glue Fuji ORTHO™ LC, GC America, Alsip, Illinois). Activation of the expander screw corresponded to a maxillary arch expansion of about 0.25 mm.
- The mandibular advancement device is a removable acrylic plate (Durasoft®, Scheu Dental, Iserlohn, Germany) which covers all the lower teeth. The device was designed to create an initial maximal jumping, to achieve a normal dental occlusion (Class I occlusion). For two months, this protrusion could be readjusted by the physician according to the achieved outcomes and the child's comfort, with an advancement of 1-2 mm.
- The upper and lower plates could be connected by sliding an embedded 0.045-inch wire framework on the mandibular plate in the embedded acrylic tubes located on the labial side of the maxillary plate.

The child's parents were instructed to advance the maxillary expander screw once a night for 20 days and then twice a night for 10 days. During a consultation at the end of these 30 days,

the extension rate should have been > 10 mm. If not, new activations were planned; otherwise the patient was instructed to stop activations and to wear the mandibular advancement device, only during night. At this time, the maxillary expander screw remained in the child's mouth for another two months to ensure the calcification of the palatine suture. After these three months (30 days of activations + two months of calcification), the expander screw was deposited whereas the acrylic maxillary plate remained glued to the superior deciduous teeth during the whole treatment period to fix the mandibular advancement device. At this time, a lingual rehabilitation with a speech therapist was also initiated. After approximately nine months of treatment, a functional Class I bite was achieved. At that time, the device (both the lower and upper parts) was removed. This treatment protocol is summarized in Fig. 2 where T0 referred to the initiation of the treatment.

2.3 Sleep studies

The respiratory status during sleep was assessed with sleep studies performed with SOMNOlab[®] (Weinmann, Hamburg, Germany) at patient's home, at the beginning and at the end of the treatment.

An Apnea/Hypopnea Index (AHI) was defined as the number of apneas and hypopneas events per hours of recorded sleep. In accordance with the reviewed literature, this index was used to assess the severity of the child's OSAS as: mild ($1 \leq \text{AHI} < 5$), moderate ($5 \leq \text{AHI} < 10$) or severe (≥ 10) [14].

An Oxygen Desaturation Rate (ODR) was defined as the amount of time the blood oxygen saturation was $\leq 96\%$ over the recorded sleep period. A pediatric OSAS was considered when this rate was $> 1.4\%$ [14].

An Arousal Index (AI) was computed as the number of arousals per hour of total sleep time. An AI ≥ 11 was considered pathological [15,16]. This index was classified as respiratory-

related (AI_{SRRD}) if the arousal occurred immediately after an apnea or hypopnea. If so, a Sleep Respiratory-Related Disorder (SRRD) was identified when the AI_{SRRD} was >1 [16,17]. Likewise, when the arousal occurred together with a series of consecutive leg movements, it was classified as related to a Periodic Limb Movement syndrome (PLM) [18]. When this kind of arousals (reported as AI_{PLM}) occurred ≥ 5 times per hours of recorded sleep, it was considered pathologic [19].

Finally, the Chervin's French translated pediatric sleep questionnaires were sent to the treated children's parents, 2 to 6 years after the end of the treatment [20,21]. This questionnaire is composed of 22 items which can be answered by Yes / No / Do not know. Parents were asked if they noticed moments of apnea, snoring, mouth breathing, daytime sleepiness or behavioral issues after their child's treatment. According to Chervin et al., a score superior to 8 (i.e. 8 positive answers) demonstrated a reoccurrence of the OSAS symptoms, with a sensibility and a specificity of 85% and 86% respectively [20,21].

Any remarks reported by the parents on their child's sleep quality and feelings during the consultations were also collected.

2.4 The statistical analyses

Statistical analyses were performed with RStudio [22] (version 3.3.2) with a significance threshold fixed at 5%.

Data are expressed as means \pm standard deviation. The significance of the evolution of the polysomnographic parameters collected pretreatment versus posttreatment was evaluated with Student's T-Tests for paired groups.

3. Results

The evolution of the polysomnographic data is summarized in Table 1, associated to the Student's T-Tests results assessing the significance of the observed pre- and post-treatment differences.

All children presented a pathological AHI (≥ 1). For 31% of the sample, the OSAS was moderate ($5 \leq \text{AHI} < 10$) and for 7 children, it was severe ($\text{AHI} \geq 10$). After the treatment, the AHI systematically decreased < 5 , except for 2 children, even though it remains close to it (from 7 to 5.7 and from 8.3 to 5.1 respectively). This index was even < 1 for 41% of the sample. Beside this significant decrease of the AHI values, their post-treatment spread was also reduced, assessing a normalization of this parameter.

The desaturation rate also decreased, even though not significantly. However, for majority of the patients, this index did not become inferior to the pathological threshold ($\text{ODR} < 1.4/\text{h}$) at the end of the treatment: an improvement was observed for 48% of the sample.

Sleep became less fragmented following the treatment: for 76% of the sample, the AI decreased < 11 . This improvement of the sleep quality was more particularly characterized by the significant diminution and normalization of the SRRD ($\text{AI}_{\text{SRRD}} < 1$). However, the PLM syndrome did not evolve for 82% of the sample. The AI_{PLM} even increased ≥ 5 for 22% of the sample.

Finally, 75 of the 103 treated children answered to the questionnaires (i.e. 73% of the total study sample). These results are summarized in Table 2. The mean score of the questionnaire was 4.16.

Among these 75 children, only 12 (16%) had a final score superior to 8, marking a reoccurrence of the OSAS symptoms. In more than half of the cases (68%), parents answer

YES to the question n°10, reporting behavior problems with easy distraction and a child generally excited. For almost 50% of the cases, parents also reported that, despite of the treatment, their child trend to have an oral breathing (question n°3).

The biggest number of “Do Not Know” answers (around 20%) has been counted for the questions referring to the apneic event observed during sleep (question n°2) and to the oral or nasal breathing mode of the child (question n°3).

4. Discussion

The present study demonstrated that the simultaneous rapid maxilla expansion and nocturne mandibular advancement effectively modified the oral space in the three spatial dimensions (Fig. 3) associated with a significant improvement of the sleep breathing quality. A significant increase in the oropharyngeal space was also observed after the treatment. As cephalometric changes induced by such treatment strategy has already been described in the literature, they will not be discussed here [12,13].

Indeed, all the collected polysomnographic parameters, which assess the severity of the OSAS symptoms, decreased following the orthopedic treatment. This decrease was even significant for the main pathologic criteria: the AHI which decreased ≤ 5 for 98% of the sample. Moreover, there was a complete recovery (AHI < 1, ODR <1.4/h and AI_{SRRD} < 1) for 14% of the sample.

This significant diminution of the AHI at the end of an orthodontic treatment was already observed by Villa et al. who performed during 12 months a rapid maxillary expansion therapy on 40 patients aged between 4-10 years old and initially showing clinical signs of malocclusion and an AHI >1 [23]. In the present study, the same outcomes were obtained

with a shorter treatment period: 9 months. This short length of intervention may be explained by the early treatment intervention, when the bone is plastic, and growth is maximal. In another study on an oral jaw-positioning appliance for the management of 32 OSAS children with clinical signs of dysgnathia, Villa et al. [24] also reported a decrease of at least 50% in the AHI for 64% of the sample. According to this definition, the custom-made oral device used in the present study achieved a better success rate of 79%. This demonstrates the importance of the combination of two effective techniques (rapid maxillary expansion and nocturnal mandibular advancement) so their effects are optimized.

Few months after the end of the treatment, 59% of the treated children presented a residual OSAS with an AHI which remained >1 . Pirelli et al. [25], who also performed a 4-months rapid maxillary expansion on 31 OSAS children, got for their part a systematic decrease of the AHI <1 . However, their sample included children showing orofacial anomalies restricted to the maxilla whereas the present study analyzed children with Class II malocclusion.

Associated to this significant decrease of the AHI, a significant improvement of the sleep quality was also noticed, which was less fragmented: most particularly, there was a significant decrease of the arousals related to respiratory disorders (AI_{SRRD}). The oxygen desaturation rate (ODR) and the global arousal index (AI) also decreased below the pathological threshold (<1.4 and <11 respectively) for 48% and 76% of the sample respectively. However, arousals related to Periodic Leg Movements (AI_{PLM}) were still omnipresent following the treatment. As suggested by several authors, this emphasizes the importance to identify the cause of airways obstruction: the pathophysiology of the pediatric OSAS is complex, the respiratory disorders being induced by a combination of factors [26].

Despite this significant improvement of the respiratory status during sleep, demonstrated with the significant decrease of both the AHI and AI_{SRRD} , the sleep quality was not totally restored.

Indeed, even though the ODR and the AI did decrease after the treatment, this decrease was not significant. Nevertheless, parents reported during the consultations an immediate improvement of the sleep quality of their child. These results may highlight the importance of a long-term follow-up as an improvement of the pediatric OSAS symptoms may not appear as soon as few months after the end of the treatment: normal cephalometric growth recovery is a slow process. Besides, according to pediatric sleep questionnaires results, only 17% of the present study sample showed a reoccurrence of the OSAS symptoms several years after the end of the treatment.

Thus, these outcomes may suggest that when the orofacial anomaly affects both the maxilla and the mandible, the normal ventilation could be progressively and permanently restored. It also highlights the importance of the intervention of a multidisciplinary team in the management of pediatric OSAS. Longitudinal studies should still be performed to observe the evolution of the quantitative sleep parameters several years after the end of the treatment.

This significant improvement of OSAS symptoms through the simultaneous maxillary expansion and mandibular advancement has been already observed [12,13]. However, their samples were smaller than the sample of the present study and were mainly focused on the cephalometric effects of the orthopedic treatment.

The present study did not include a control group of untreated subjects with Class II malocclusion and OSAS: because of the ethical concern of not treating patients during their pubertal growth spurt. Indeed, not treating OSAS children may result in various problems as behavioral disorders or serious morbidities as growth failure, cor pulmonale, hypertension ... [27]. However, considering the literature, the authors may assert the real impact of this therapeutic strategy. Indeed, Pavoni et al. observed more significant changes in mandibular length, airways dimensions or hyoid and tongue position in children treated with an

orthopedic device than in untreated Class II control group [28]. Regarding spontaneous resolution of OSAS symptoms, Chervin et al. observed it for 42% of the 5 to 9 years old children included in the ChildHood Adenotonsillectomy Trial (CHAT), but without defining the cephalometric status of these children [29].

Finally, this innovative therapeutic strategy, used at an early stage of the child's growth and associated with myofunctional rehabilitation exercises, significantly increased the OSAS child's oral space in the three spatial dimensions. Moreover, the present outcomes suggest the effectiveness of the custom-made oral appliance for OSAS children management since it prevents airflow obstruction by enlarging the upper airways, and by promoting the lingual advancement during the night. These results are in accordance with previous studies investigating a similar therapeutic strategy [12,13]. Thus, simultaneously treating OSAS children with a rapid maxillary expansion and a nocturne mandibular advancement should be recommended.

Declaration of Interest Statement

The authors report no conflict of interest.

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Ethical approval

According to the French law n°2012-300 of March 5th, 2012 on researches involving human beings, because this study was retrospective and non-interventional, and because data were anonymized, no signed consent was required. This study was reviewed and approved by the Institutional Review Board of Aix-Marseille University (no. 2019-14-03-001).

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Table 1

Mean and standard deviation of the polysomnographic parameters collected before and after the treatment, associated to the Student's T-Tests p.value assessing the significance of the differences. Shaded cases correspond to p.values < 5%

Parameter	Mean \pm standard deviation		P.value
	Pre-treatment	Post-treatment	
Apnea/Hypopnea Index (AHI)	5.3 \pm 3.9	1.4 \pm 1.2	7.72 ^{E-18}
Oxygen Desaturation Rate (ODR)	3.3 \pm 3.5	2.6 \pm 2.9	0.07
Arousal Index (AI)	7.7 \pm 5.0	6.9 \pm 4.6	0.08
Arousal Index respiratory-related (AISRRD)	0.6 \pm 0.7	0.4 \pm 1.1	7.17 ^{E-03}
Arousal Index related to Period Limb Movement Syndrome (AI _{PLM})	13.8 \pm 11.4	14.8 \pm 12.3	0.12

Table 2

Summary of the replies to the post-treatment pediatric sleep questionnaires, as perceived by the parents (for more information about the questions, please refer to the article of Chervin et al. 2000)

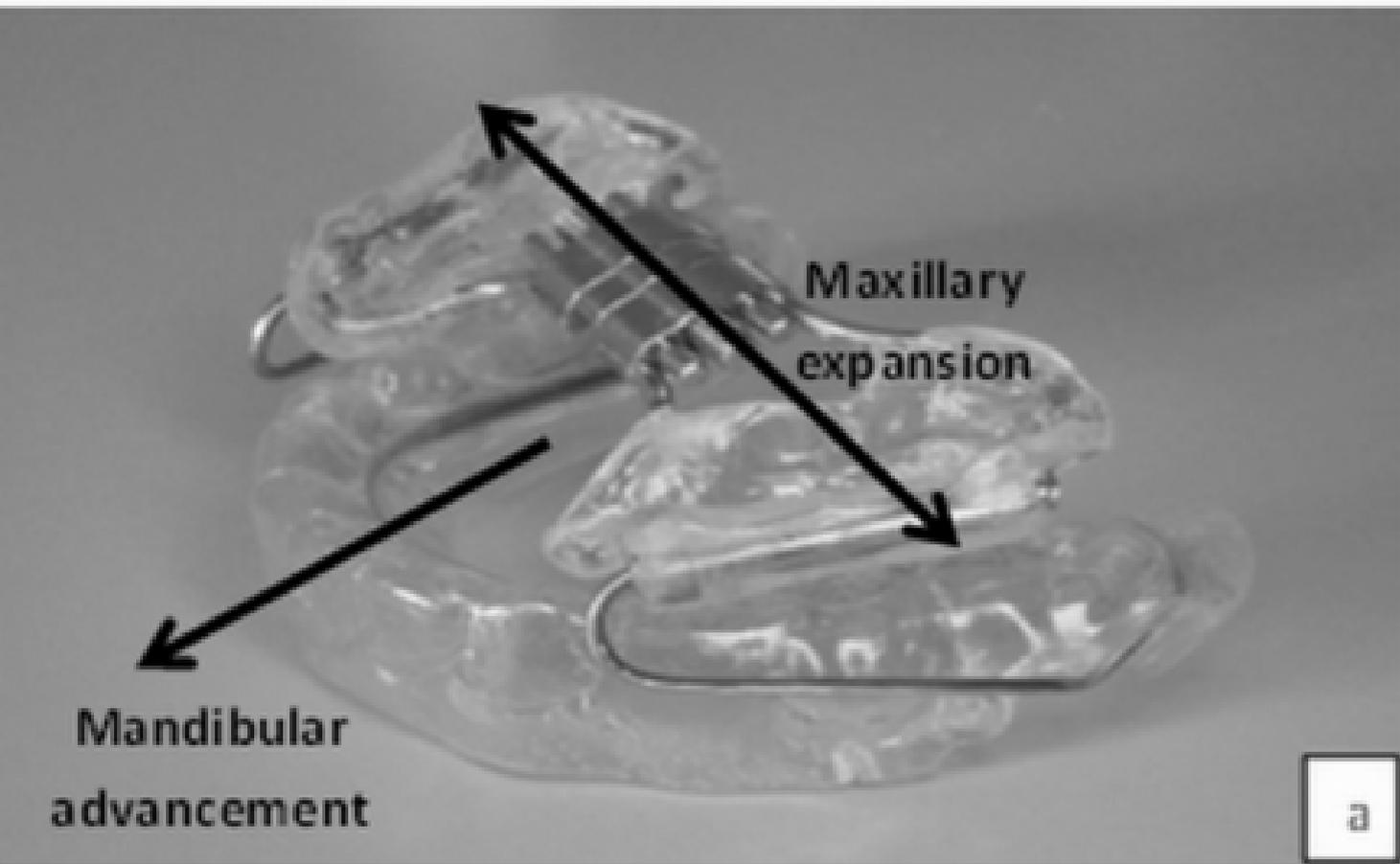
	YES	NO	DO NOT KNOW
	Count (%)	Count (%)	Count (%)
Question n°1 About snoring, loud and trouble breathing	15 (20 %)	54 (72 %)	6 (8 %)
Question n°2 About breathing interruption	7 (9 %)	54 (72 %)	14 (19 %)
Question n°3 About mouth breathing	23 (31 %)	39 (52 %)	13 (17 %)
Question n°4 About awakening and daytime sleepiness	18 (24 %)	52 (69 %)	5 (7 %)
Question n°5 About daytime sleepiness	4 (5 %)	69 (92 %)	2 (3 %)
Question n°6 About awakening difficulties	20 (27 %)	55 (73 %)	0 (0 %)
Question n°7 About headaches in the morning	3 (4 %)	70 (93 %)	2 (3 %)
Question n°8 About growth rate	5 (7 %)	66 (88 %)	4 (5 %)
Question n°9 About overweight	4 (5 %)	69 (92 %)	2 (3 %)
Question n°10 About concentration and agitation problems	51 (68 %)	19 (25 %)	5 (7 %)

Figures caption:

Fig. 1 Presentation of the custom-made oral device (a) and its isolated components: the maxillary expander (b) and the mandibular advancement splint (c)

Fig. 2 Summary of the orthopedic treatment protocol

Fig. 3 On top: lateral views of the 3D numeric printings of the maxillary and mandibular arches nested in their anatomical relationship, illustrating the correction of the malocclusion with the mandibular advancement (pre-treatment on the left / post-treatment on the right); At the bottom: inferior views of the 3D maxillary numeric model illustrating the significant increase of its transverse dimension (pre-treatment on the left / post-treatment on the right)



Maxillary expansion

- 1 activation/night during 20 days
- 2 activations/night during 10 days

T0

Consultation : extension rate > 10 mm ?

- NO → New activations planned
- YES → Stop activations

T0 +30 days

Mandibular advancement & Stabilization of the maxillary expansion

- Mandibular device worn during nights only
- Maxillary device still in mouth to ensure the calcification of the palatine suture

T0 +2 months

Consultation: follow-up

- Depose of the expander screw
- Acrylic maxillary plate still in mouth to fix the mandibular device
- Initiation of lingual rehabilitation

T0 +9 months

Consultation: Class I occlusion achieved?

- NO → Continuation of the treatment
- YES → Depose of the device (lower and upper parts)

