Efficacy of a Pre-Fabricated Myofunctional Appliance for the Treatment of Mild to Moderate Pediatric Obstructive Sleep Apnea: A Preliminary Report

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Objective: *The purpose of this study was to determine the efficacy of the Myobrace/MyOSA myofunctional appliance for the treatment of mild to moderate Obstructive Sleep Apnea (OSA) in children, by means of the Apnea/Hypopnea Index (AHI).* ***Study design:*** *Nine children with a diagnosis of mild to moderate OSA were included in the study. The subjects wore the Myobrace/MyOSA myofunctional appliance for a period of 90 days. The initial AHI, determined by means of a sleep test, was used as baseline (To), and a second AHI, computed at the end of the experimental period, was used as final data (T_1). The differences between the AHIs at To and T_1 were calculated (diff AHI) and used for statistical purposes. The level of Oxygen Saturation (SaO_2) was also recorded before and after treatment, and their differences calculated as diff SaO_2. Statistical analysis was performed with a paired-t- test and statistical significance was established at 95 per cent level of confidence.* ***Results:*** *A statistical significant reduction in the AHI of the studied subjects was computed at the end of the experimental period ($p = 0.0425$). Although there was an improvement in the SaO_2, it did not reach a statistically significant difference.* ***Conclusions:*** *The present results suggest that the Myobrace/MyOSA myofunctional appliance can be an alternative to treat mild to moderate OSA in children. However further studies are necessary to determine the stability of the results after treatment.*

Key words: *Obstructive Sleep Apnea; Hypopnea; Oxygen Saturation; Myobrace/MyOSA; Dental Appliance.*

INTRODUCTION

Obstructive Sleep Apnea (OSA) in children is a disorder of breathing during sleep, characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction that disrupts ventilation during sleep and fragments sleep patterns [1]. Its incidence is between 1.2 to 5.7 percent of the general pediatric population and, it can produce neuro-psychological and cognitive impairment in the child, as well as systemic and pulmonary hypertension and endothelial dysfunction [2-5]. OSA in children is generally accompanied by nocturnal snoring and sleep disorders, as well as by a neuropsychological deficit in the child´s cognitive potential [1,6,7].

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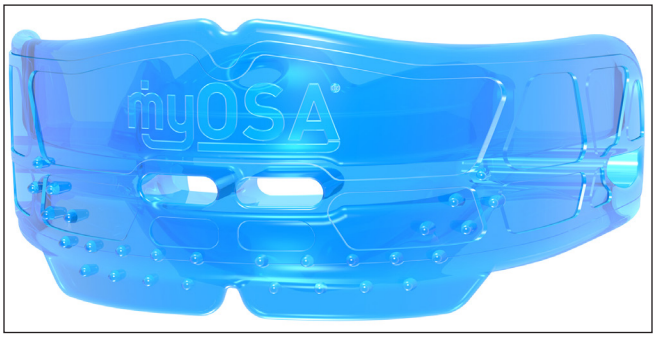
Pediatric OSA is diagnosed by means of a sleep study (Polysonography, PSG), which is generally performed at the hospital with the child staying there overnight or, performed at home with a portable device (known as Home Sleep Test, HST). Although a hospital based PSG is the optimal test to accurately diagnose pediatric OSA, the American Academy of Pediatrics have recommended that all children should be screened for OSA and, that HST could be prescribed in cases where hospital PSG is not available or not easily scheduled [1]. In that context, a sleep test (PSG or HST) is necessary to determine if a child is suffering of OSA by means of establishing the Apnea and Hypopnea Index (AHI). In children, an AHI lower than 1 is considered normal; between 1 and less than 5 is diagnosed as mild OSA; between 5 and less than 10 is considered moderate OSA; and, AHI higher than 10 is classified as severe OSA [8].

As OSA during childhood has been correlated with an overgrowth of the tonsils and adenoids, surgical removal of that lymphoid tissue has been proposed as the first line of treatment. Although the surgery has been reported to significantly reduce the signs and symptoms associated with pediatric OSA, it may not fully resolve the OSA and a significant number may require additional therapy [9,10]. Based on recent reports stating that pediatric OSA is associated with disturbances in craniofacial growth and development in non-syndromic children [11-13], oral appliances have risen as an alternative treatment to manage the breathing disorder at an early age. So, appliances designed to either stimulate maxillary transverse

development [14], or advancing the mandible [15], have been reported to significantly reduce OSA in children. Besides that, myofunctional therapy has been shown to improve breathing disorders in children, as it improves the position of the tongue and corrects mouth breathing [16].

The Myobrace/MyOSA pre-orthodontic appliance (Figure 1) have been reported to significantly modify the shape of both maxillaries, as well to advance the mandible when a mandibular retrusion has been diagnosed [17,18]. It has been also reported that the activity of the masticatory and facial muscles significantly improves after the treatment with the Myobrace/MyOSA pre-orthodontic appliance [19-21]. Based on those results, the following hypothesis was proposed: The Myobrace/MyOSA produces a significant positive effect in children with mild to moderate OSA, by reducing the frequency of apneas and hypopneas per hour. Thus, a preliminary study was designed to evaluate the efficiency of that oral appliance in reducing the AHI in children diagnosed with mild to moderate OSA.

Figure 1. Photograph of the pre-fabricated myofunctional appliance (Myobrace/MyOSA) used for the treatment of patients included in this study.



MATERIALS AND METHOD

Twenty non-syndromic patients whom the parents reported nocturnal snoring where initially selected for the study. Their age was between 4 and 8 years old. All children had a complete medical examination and those reporting, severe asthma, taking medications or obese were excluded from the study. Nine children were diagnosed with a mild to moderate OSA and was the final sample for the study. Those subjects selected to participate had a HST before starting using the proposed oral appliance, the Myobrace/MyOSA.

The present study was approved by the ethical board of the University of Insubria, Italy. Written informed consent was obtained from the parents, as well as verbal consent from all the children finally involved in the study. The initial AHI measured by means of a HST (NOX T3, NOX Medical, USA) was considered the baseline measurement for the OSA severity prior to treatment (To). The patients were then instructed to wear the Myobrace/MyOSA appliance for 1 to 2 hours during the daytime and when sleeping for a period of 90 consecutive days. At that time, a new HST was performed (T_1) and the differences between the AHIs at To and T_1 were calculated (*diff* AHI). Additionally, the level of Oxygen Saturation (SaO_2) reported on the HST was also recorded before and after treatment, and their differences were reported as *diff* SaO_2.

Statistical analysis was performed by means of a paired t-test, the Wilcoxon test, using the SPSS software package ((SPSS, Inc. Chicago, IL, USA). The level of significance was set at 95 per cent.

RESULTS

The AHI values and the percentages of SaO_2 were recorded and their differences statistically analyzed at To, before treatment, and at T_1 after 90 days of using the Myobrace/MyOSA appliance. The results are presented in Table 1.

The difference between AHIs computed a statistically significant decrease ($p = 0.0425$) in the occurrence of apneas and hypopneas in the studied subjects. (Figure 2) The differences between SaO_2 before and after treatment reported an improvement in the percentages of oxygen saturation, but it did not reach a statistically significant difference.

The HST results after treatment also reported that snoring was still present at the end of the 90 days period of the study. It did not significantly vary with the recordings before treatment.

Figure 2. Diagram showing the significant reduction in the Apnoea/hypopnea Index (Y-axis) of the nine patients involved in the study before (To) and after 90 days of treatment (T1) with the Myobrace/MyOSA™ myofnctional appliance ($p = 0.0425$).

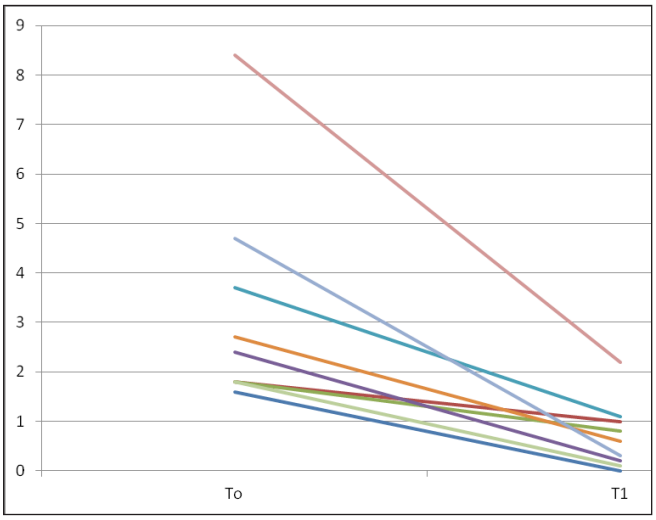


Table 1. Results recorded for the nine patients included in the study. (AHI) Apnoea/Hypopnea Index; SaO_2 Oxygen Saturation.

Patient	AHI_0	AHI_1	*diff* AHI To	% SaO_2 To	% SaO_2 T_1	*Diff* % SaO^2
1	1,6	0	+ 1,6	96,8	96	+ 0,8
2	1,8	1	+ 0,8	95	97,7	- 2,7
3	1,8	0,8	+ 1	93,6	95	- 1,4
4	2,4	0,2	+ 2,2	97	96,6	+ 0,4
5	3,7	1,1	+ 2,6	91	96,3	- 5,3
6	2,7	0,6	+ 2,1	93	94,6	- 1,6
7	4,7	0,3	+ 4,4	95	96	- 1
8	8,4	2,2	+ 6,2	94	93,7	+ 0,3
9	1,8	0,1	+ 1,7	93,4	95,2	- 1,8

DISCUSSION

Obstructive sleep apnea has been associated with deviations in the craniofacial growth and development in non-syndromic children. In that context, several oral appliances have been proposed to reduce the severity of OSA in children [14,15,22,23]. The current report presents preliminary results from nine young patients treated with the Myobrace/MyOSA, a pre-fabricated myofunctional appliance designed to positively affect the craniofacial growth and development in children by changing the posture of the mandible and balancing the muscular activity of the masticatory and facial muscles [17-20], while improving the oral functions, which were deteriorated by bad habits (eg. tongue thrust and mouth breathing).

The subjects participating in this study showed a statistically significant reduction in the AHI, which means that the numbers of apneas and hypopneas occurring during their sleep significantly reduced on average per hour. Therefore, all the subjects reported here, who were initially diagnosed with a mild to severe OSA reported an AHI which can be considered between normal values [8], after 90 days of using the Myobrace/MyOSA 1-2 hours at day time and when sleeping.

The results presented above were associated with an improvement in the SaO_2. However, the later results did not reach a statistical significance. It may be due to the short period that the study was run for. Therefore, other studies with a more extended experimental period are required to fully evaluate the effect of the Myobrace/MyOSA appliance on the SaO_2 in children with mild to moderate OSA.

The significant results on the AHI presented here are produced after 90 days of using the prescribed appliance. A longer follow up of the subjects is required to determine if the results become stable and the significant decrease in the AHI is going to stabilize and be maintained in the future. Other limitations of this study are the number of subjects included in the study, as well as the HST instead of a hospital based PSG. Regarding the first one, the small sample in the study, these results should be considered as preliminary data and further studies with a bigger sample should be designed to determine the consistency of the effects of the Myobrace/MyOSA to treat mild to moderate OSA in children.

On the other hand, the studied subjects were tested with a HST. The results produced with HST are not considered accurate as those from PSG. However in this study the severity of the OSA was determined in all the subjects with the same equipment before and after treatment. In that context, it can be argued that the results are valid as any inaccuracy in the results produced by the HST were affecting both, the before and after treatment results.

Although the limitations of this study, these preliminary data suggest that the Myobrace/MyOSA may be a positive addition to that armamentarium of oral appliances that dentists may use to treat OSA in children. One of the advantages of the Myobrace/MyOSA for this treatment is that this myofunctional appliance improves the craniofacial growth and development in children by directly improving the muscular activity of the masticatory and facial muscles [19-21], and at the same time correct bad habits, such as tongue thrust and mouth breathing.

CONCLUSION

The present results suggest that the Myobrace/MyOSA can be used to treat mild to moderate OSA in children, as it significantly reduces the AHI after 90 days of using the myofunctional appliance while sleeping. These results should be considered as preliminary data and, further research is required to fully establish the effects of this myofunctional appliance when treating OSA in children, as well as to evaluate the permanence of the positive results after treatment.

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