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Snoring and Obstructive Sleep Apnea: Objective Efficacy and Impact of a Chairside Fabricated Mandibular Advancement Device

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Abstract

Purpose: Obstructive sleep apnea (OSA) has been described as a common sleep respiratory disorder. Its prevalence in the adult population has been reported to be high, varying from 3% to 28%. Dental practitioners play a key role in the treatment of this disease, using tailor-made mandibular advancement devices (MADs). This pilot study assessed the efficacy and compliance of a custom-fitted thermoplastic MAD for the treatment of moderate to severe OSA syndrome.
Materials and Methods: In this open study without a control group, OSA syndrome sufferers were enrolled by four centers. One specific MAD was custom fitted to the patients. Polysomnography, Epworth, and snoring scales were administered from inclusion to 45 days postinclusion.
Results: The study population consisted of 33 men and 8 women; 35 patients completed the study. Patient response was high with 69% of them considered as responders, and 60% showing a complete response. Also, 77.3% of patients with moderate OSA syndrome presented a complete response. An improvement was observed in the apnea hypopnea index, which decreased from 34.1 $\pm$ 18.9 to 12.8 $\pm$ 14.1. The Epworth Sleepiness Scale score, snoring, and quality of sleep scores decreased with the device ($p < 0.0001$). Compliance rates were high, with patients wearing the device 6.5 nights a week. Side effects and patient complaints were minor and transient.
Conclusion: This custom-fitted MAD improved respiratory and somnolence parameters, with response rates similar to those published in the literature with other devices.

Obstructive sleep apnea syndrome (OSAS) is one of the most common sleep respiratory disorders.[1] It is caused by repetitive complete or partial dynamic obstruction of the oropharyngeal airway during sleep.[2] Its prevalence in the adult population varies from 3% to 28%, depending on the study.[3]

Continuous positive airway pressure (CPAP) is considered to be the gold standard treatment for severe OSAS but compliance with treatment measures can be poor.[4,5] A recent study concerning the efficacy of mandibular advancement devices (MADs) versus CPAP found that CPAP was more effective than MADs but had poorer compliance rates. This has led to a reassessment of the therapeutic benefits of each of the two treatments in clinical practice.[6]

There are broad differences in the various types of MADs available, including manufacturing methods used, design (mono- or duo-block), and freedom of jaw movements. In addition, certain device-specific factors also influence treatment outcome. Most of the literature concerning the efficacy of MADs as a treatment for OSAS has focused on custom-made MADs. The primary disadvantages of these devices are their cost, the time required to manufacture them, and the prolonged adjustment period they require.[7] Immediately fitted devices could therefore represent an alternative to custom-made MADs, reducing the cost and time required for their manufacture.[8] However, few studies have been conducted on immediately fitted devices; most of the results available focusedd on mono-block MADs,

which had lower success rates than custom-built devices.[9-14] Some authors have suggested that the lower efficacy of monoblock MADs could be related to two parameters: first, the stability in the mouth, and second, the degree of control of mandibular advancement, which were both better with custom-made MADs, due to the tailored production and use of different length connectors.[9,12,14] Several studies have shown that there is a relationship between OSAS treatment efficacy and degree of control over mandibular advancement.[8,15-17] Also, freedom of movement at night could contribute to increased patient acceptability.[18]

Some dual-block thermoplastic MADs with individualized setting of mandibular advancement have been already described and studied,[13,19] with results comparable to custom-made devices.[20-22] The aim of this pilot study was to test the efficacy of a chairside MAD (Oniris; Laboratoire Oniris, Chaville, France).

Materials and Methods

A total of 41 patients were identified and enrolled from four study centers in France. In accordance with previous studies, 32 patients were required to determine that 75% experienced a 50% reduction in the apnea/hypopnea index (AHI) per hour of sleep by the end of the study, and the extra nine patients allowed for compensating for possible incomplete data sets.[13,14] All the participants attended a preselection visit to assess their eligibility (inclusion/exclusion criteria). The enrolled patients were 18 to 80 years old and presented with moderate ($10 < AHI < 30$) or severe OSAS ($AHI > 30$, or $10 < AHI < 30$ combined with excessive sleepiness) after rejection of CPAP. The exclusion criteria were as follows: fewer than eight teeth per dental arch, dental infection, periodontal diseases, muscular or articular pathology on the temporomandibular joint assessed by a dental specialist, as well as neurological or psychiatric disorders, obesity, clinical nasal obstruction, bone disease (e.g., osteoporosis), and patients with cardiac pacemakers.

The Sud-Méditerranée IV Ethics Committee and the French Health Products Safety Agency (ANSM) approved this study, and it is registered in the ANSM database, according to the current regulatory framework. All patients provided written informed consent.

Baseline data were collected at inclusion (day 0): AHI, apnea index (AI), hypopnea index (HI), oxygen desaturation index (ODI), and results of earlier polysomnography tests (less than 6 months prior to day 0). Each patient underwent an examination of the mouth, jaws, and teeth; one specialist practitioner in each center made dental impressions and measurements of maximum mandibular protrusion. The patients also completed the Epworth Sleepiness Scale (ESS), visual analogue scale (VAS: 1 to 10), snoring, and tiredness on waking scales and a quality of sleep questionnaire to establish the Pittsburg Sleep Quality index (PSQI).

The MAD used in this study was the Oniris, a thermoplastic MAD applied in a chairside method (Fig 1) and comprising two half-arches heat-molded to fit the patient's dental arches. Two connectors with different length available allowed individual adjustments of mandibular advancements, millimeter by millimeter (Fig 2).

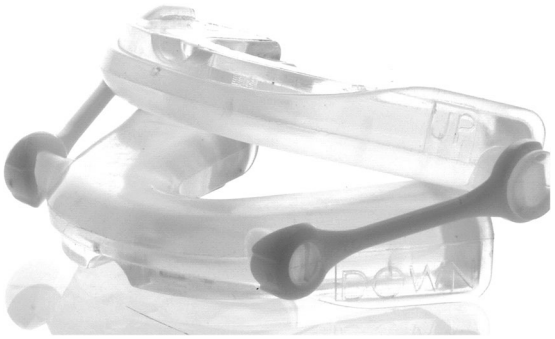

Figure 1 Oniris mandibular advancement device.

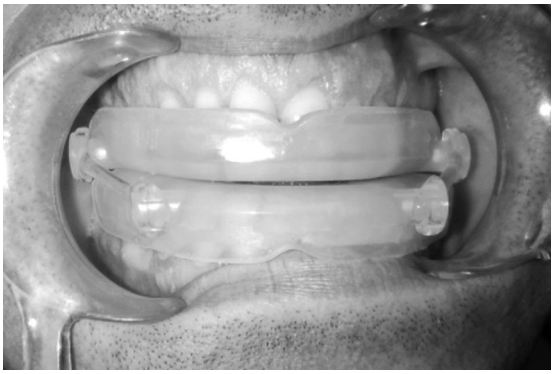

Figure 2 MAD in a patient's mouth (front view).

The MADs were adjusted to fit each patient's dentition, and the initial mandibular advancement was fixed at 60% to 80% of the maximum protrusive movement as measured diagnostically. The advancement was subsequently adjusted on the basis of patient-reported snoring and/or daytime fatigue at the outpatient clinic. The positions were controlled and the ESS and VAS scales were administered during the three follow-up visits 15, 30, and 45 days after inclusion. The PSQI was only established at day 45 after inclusion. An intermediate polysomnography with the MAD in place was done 30 to 45 days after inclusion; if the results of this test did not indicate that the treatment was effective (AHI index decrease $< 50\%$), the device was readjusted. A final polysomnography was done between 50 and 60 days after inclusion. Patients were classified as "responders" when the decrease in the AHI was more than 50% with $AHI \geq 10$ at the end of the study; they were classified as "full responders" when the AHI was < 10 at the end of the study.

All data were analyzed by an independent organization: the Contract Research Organization (CRO) BIOSTATEM (Castries, France). The results for quantitative variables were expressed as the mean $\pm$ standard deviation (SD), and the results for qualitative variables were described as absolute and relative frequencies (%).

The efficacy analyses were performed for all patients enrolled in this MAD study. The patients with missing data for a given criteria were not included in the corresponding analysis. The change in the efficacy parameters was assessed using paired tests: either Student's *t*-test, if normality was verified, or the Wilcoxon test if not. Changes in the parameters during the study

Table 1 Characteristics of the patients enrolled

	Total N = 41
Age (years) mean ± std (min-max)	49.6 ± 14.1 (23 to 78)
Males n (%)	33 (80.5)
Medical history n (%)	26 (63.4)
Concomitant disease n (%)	21 (51.2)
Mean AHI ± SD	34.1 ± 18.8
AI (apnea index) mean ± SD	13.8 ± 15.3
HI (hypopnea index) mean ± SD	20.3 ± 10.8
Mean ODI ± SD	26.6 ± 22.4
Dental occlusion n (%)	
Type I	36 (90.0)
Type II	3 (7.5)
Type III	1 (2.5)

(D0, D15, D30, and D45) were analyzed using ANOVA for repeated measures if normality was verified, or a Friedman test if not. The paired comparisons were done with Tukey's method. Statistical analyses were carried out using SAS v9.1 statistical software. All *p*-values were bilateral with a 5% significance threshold ($p < 0.05$).

Results

In a total population of 41 recruited participants, 23 patients had a moderate AHI ($15 < AHI < 30$), and 18 had a severe AHI (>30). Thirty-three participants (80.5%) completed the study, and eight patients dropped out (19.5%). Of these latter patients, two completed the two polysomnography tests but dropped out early for treatment failure. They considered that there was a lack of effect based on subjective criteria; however, these two subjects were nevertheless included in the analysis set. Finally, six patients were lost to follow-up in the study before the control polysomnography.

Among the 41 patients enrolled, 33 were men and 8 women. The mean age was 49.6 ± 14.1 years. The mean AHI score was 34.1 ± 18.8 events per hour, the mean ESS score was 10.7 ± 5.8, and the mean ODI score was 26.6 ± 22.4 (Table 1). Dental occlusion was type I in 36 patients, type II in three patients, and type III in one patient. The mean maximum protrusion was 9.6 ± 1.8 mm, and the mean initial protrusion was 5.7 ± 1.3 mm (59.7 ± 10.0%). Almost 80% of the patients had at least one tooth missing, and at least 48.8% had a fixed partial denture.

The results of treatment were determined for the 35 patients who had undergone the baseline and final polysomnography tests. At the end of the study, a total of 24 patients (69%) were considered to be responders, of which 21 (60%) showed a complete response, and three (9%) a partial response (Fig 3). Seventeen responders had moderate OSAS at inclusion and four had severe OSAS; three patients with severe OSAS had a partial response. Of the eleven patients (31%) classified as nonresponders, five had presented with moderate OSAS, and six with severe OSAS.

The polysomnography results presented a mean significant improvement in the AHI of 20.0 ± 18.1 events per hour (58 ± 32%), dropping from 34.1 ± 18.8 to 12.8 ± 14.1 (Fig 4). Patients with moderate OSAS presented a mean decrease in the AHI of 14.2 ± 8.9 events per hour (59 ± 32%), dropping from 21.8 ± 5.8 to 7.5 ± 3.9 ($p < 0.001$). The mean AHI in the 18 patients with severe OSAS dropped by 29.9 ± 25.1 (56 ± 31%), decreasing from 49.8 ± 17.9 to 21.7 ± 20.0 events per hour ($p < 0.001$). In the overall study population using the MAD, significant decreases were observed between the baseline and the last check-up, in the mean AI from 13.8 ± 15.3 to 2.9 ± 3.8, the mean HI from 20.3 ± 10.8 to 9.9 ± 11.9, and ODI from 26.6 ± 22.4 to 12.6 ± 15.7 ($p < 0.001$ for all parameters, Fig 4).

The patients' evaluation of treatment showed significant reductions between the baseline and D45 in snoring and fatigue scores, dropping from 7.5 ± 2.3 to 2.6 ± 2.0, and from 6.3 ± 2.5 to 2.4 ± 1.5, respectively ($p < 0.0001$ for both, Fig 5). The ESS score dropped significantly from 10.7 ± 5.8 at inclusion to 4.5 ± 2.3 at D45 ($p < 0.0001$). The change in ESS score was analyzed as a function of the ESS score at inclusion (<10 or ≥ 10). A significant difference was observed in patients with an initial ESS score <10, but it was less pronounced than for the patients whose ESS score was ≥ 10 at inclusion (Table 2). The results of the PSQI showed a significant decrease in the scores for subjective sleep quality, sleep disorders, and daytime dysfunction, and in the overall score, which decreased from 6.9 ± 3.7 to 4.3 ± 2.8 (Table 2).

Compliance rates were high, with patients wearing their MAD for a mean of 6.2 hours a night, 6.5 nights a week. No serious adverse events were reported with the MADs used during this study. The patients' complaints mainly concerned excessive salivation or dry mouth, and muscle, tooth, or joint sensitivity. Compliance was considered to be excellent for the 43% of patients wore their MADs every night for more than 6 hours a night and acceptable for the 54% of patients who wore their MADs more than 4 nights a week for more than 4 hours a night. Compliance was considered to be insufficient for one patient (3%) who wore the MAD for fewer than 4 days a week.

Discussion

This study demonstrated that this specific MAD offered a satisfactory short-term treatment option to patients with moderate to severe sleep apnea syndrome since a complete response was achieved in 60% of cases. The complete response rate actually rose to 77% when only the patients with moderate to severe OSAS and an AHI < 30 were taken into consideration. These levels are comparable to those reported recently in the literature for custom-made devices.[21,22] In those studies, the complete response rates were 52% and 46%, with outcome criteria similar to those applied in the present study.

The positive impact of the MAD on snoring, morning fatigue, and sleep quality was also confirmed in this study (Fig 5). This efficacy improved during the study, possibly as a result of the increase in mandibular protrusion observed during follow-up.

The results of this study also showed an improvement in the Epworth scores, including in patients whose baseline score was nonpathological. One study has shown that fewer than 20% of symptomatic patients in the general population were referred for a diagnostic examination.[23] Furthermore, many patients do not present with excessive sleepiness of a type detectable with

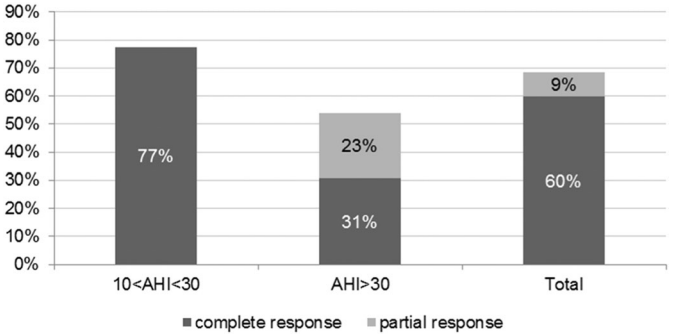

Figure 3 Response rates depending on severity of OSAS.

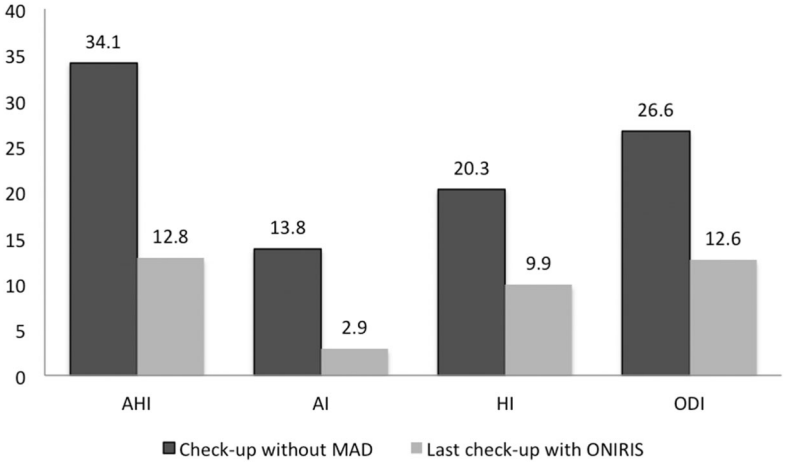

Figure 4 Respiratory events.

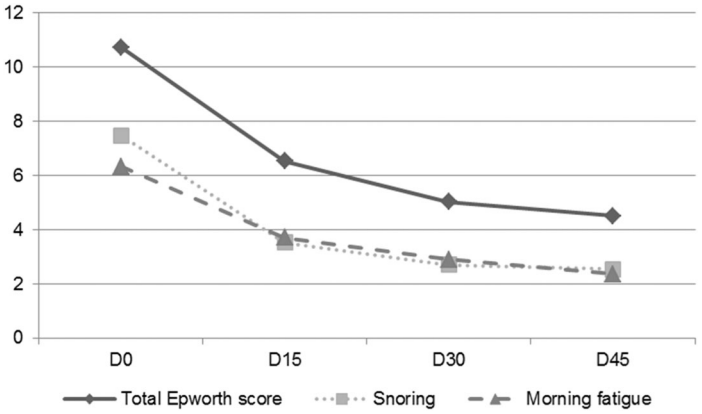

Figure 5 Snoring, morning fatigue, and Epworth score during follow-up.

the Epworth scale, as was shown by the data for the participants enrolled in this study. These asymptomatic patients are difficult to detect and diagnose. This effect could potentially be useful for the detection of OSAS in snorers in the general population. During this study, the patients stated that they wore the MAD 6.2 hours a night, 6.5 nights a week. These results are comparable to those observed for custom-made MADs.[20-22]

The aim of this study was to test the efficacy of a new MAD via a treatment protocol reflecting current acceptable clinical practices. Being a pilot study, there were several limitations to this study. First, it had an open label design, with no control group and consequently no comparison with a placebo or another treatment. Second, as the follow-up period only lasted 2 months, adverse events including changes in occlusion, which tend to emerge after a longer period of use, may not have been detected during the study.[23] Third, several studies also suggested that compliance with MAD treatment decreases over time. Therefore, other studies will be required to fully explore the long-term compliance, efficacy, and adverse events associated with this new device.

Some MADs are now considered to be an effective first-line solution for patients with moderate OSAS ($5 < AHI < 30$ with daytime sleepiness). They could be used as a second-line treatment for patients who refuse or are unable to tolerate CPAP. These MADs are custom-made, and their main disadvantages are their cost and the time required for their manufacture and titration. The MAD investigated in this study could allow immediate customized treatment, for example as temporary apnea treatment or to validate the efficiency of a MAD on a patient's symptoms. Naturally, this system also has some

Table 2 Results for the parameters studied

	Inclusion	With MAD	
AHI	34.07 ± 18.78	12.78 ± 14.11	$p < 0.001$
AI	13.77 ± 15.34	2.94 ± 3.82	$p < 0.001$
HI	20.31 ± 10.78	9.87 ± 11.92	$p < 0.001$
ODI	26.62 ± 22.37	12.61 ± 15.72	$p < 0.001$
Pittsburg Quality of Sleep	6.85 ± 3.70	4.32 ± 2.82	$p < 0.001$
Snoring (VAS: 1 to 10)	7.49 ± 2.30	2.55 ± 1.98	$p < 0.0001$
Morning fatigue (VAS: 1 to 10)	6.34 ± 2.45	2.37 ± 1.52	$p < 0.0001$
Epworth score	10.73 ± 5.81	4.51 ± 2.34	$p < 0.0001$
Epworth score (D0<10)	5.74 ± 2.42	3.83 ± 2.01	$p < 0.0001$
Epworth score (D0≥10)	15.05 ± 4.13	5.24 ± 2.51	$p < 0.0001$

disadvantages. The volume of the MAD is more important than for one that is custom-made. This may be the cause of rejection and treatment failure. A future study will investigate this possibility by comparing the efficacy of this MAD to the reference therapy. A second main disadvantage may be the durability of this MAD due to its thermoplastic material. This aspect has not been evaluated in the present study and will need observations over a longer period of time. Finally, even if the placement of the MAD is immediate, a professional follow-up could be needed, generating an increase of the time spent for treatment.

Conclusions

This study contributes to demonstrating the efficacy of an immediately fitted MAD as a treatment for snoring and OSAS. Most patients responded to treatment after an adjustment process. In view of the observed efficacy and treatment compliance, this specific MAD could be considered as a suitable treatment for patients with snoring and moderate to severe OSAS, given new perspectives on chairside sleep apnea treatment for the dental practitioner. Other control-group studies are needed to compare this MAD to other devices.

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