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The use of oral appliances in obstructive sleep apnea: a retrospective cohort study spanning 14 years of private practice experience

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Abstract

Purpose In 2005, the American Academy of Sleep Medicine stated, "Oral appliances are indicated for use in patients with mild to moderate obstructive sleep apnea (OSA) who prefer them to CPAP therapy, or who do not respond to, are not appropriate candidates for, or who fail treatment attempts with CPAP." However, this recommendation is based upon variable results from only six studies with more than 100 participants. These studies have assessed the effectiveness of mandibular advancement devices (MADs) in specific groups (military populations, academic institutions, or hospital settings) with no large study conducted in a fee-for-service private practice where the majority of patients receive MADs for OSA. The purpose of this study is to report outcomes of a board-certified dental sleep practitioner managing mild, moderate, and severe OSA using customized titratable MADs. We hypothesize that patients will demonstrate a significant reduction in apnea-hypopnea index (AHI) scores after adjusting their customized titratable MADs.

Methods This is a 14-year retrospective study design with pre- and post-treatment sleep studies. An AHI score < 10 respiratory events per hour with therapy is defined as treatment success. This study was performed by a single private practitioner.

Results Of 2419 patient records analyzed, 544 (22%) had pre- and post-treatment sleep studies (89% polysomnograms). Of 510 patients with complete data, 459 (90%) revealed a decrease in AHI score < 10 respiratory events per hour indicating treatment success.

Only 51 of these patients (10%) had a final AHI ≥ 10 and were considered treatment failures. Among the patients who lacked post overnight polysomnogram, 66/1921 (3%) discontinued the MAD due to adverse effects. Considering these patients as treatment failures as well, and therefore adding their number to the patients with complete sleep study data, the total treatment failures were 117/576 or 20%. Of the treatment successes, OSA was categorized by AHI at baseline as mild in 170 (34%), moderate in 181 (36%), and severe in 138 (28%).

Conclusions In patients with evaluable data, there was an 80% success rate for treatment of OSA using a custom-fabricated adjustable MAD including substantial numbers of patients with moderate and severe disease.

Keywords Obstructive sleep apnea (OSA) · Adjustable dental appliance · Apnea-hypopnea index (AHI) · Polysomnogram · Continuous positive airway pressure (CPAP) · Mandibular advancement devices (MAD)

Introduction

Obstructive sleep apnea (OSA) in adults is more prevalent than asthma (6%) and diabetes (8%) with at least 15% of the US adult population affected [1–3]. An estimated 12 to 18 million people with OSA are untreated [4]. Along with more immediate symptoms of poor sleep quality and daytime sleepiness and fatigue, OSA is an independent contributor to hypertension and mortality [5].

Besides weight reduction, there are three major interventions for obstructive sleep apnea: positive airway pressure (PAP) therapy, surgery, or oral appliance therapy (OAT). The majority of patients diagnosed with OSA receive PAP therapy as it is generally considered to be the "gold standard" of OSA treatment [6]. Approximately two million patients per year in the USA utilize PAP therapy compared to an estimated 138,000 patients with OSA treated with OAT [7]. The reasons

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for this relatively low use of OAT are not clear, especially in view of the fact that OAT is generally reported to be effective [8].

A type of OAT currently utilized for OSA, the mandibular advancement device (MAD), either holds the tongue forward or holds the mandible in a protruded position. Tongue retaining devices are rarely used [9]. MADs are either adjustable or nonadjustable. The mechanism of action for mandibular advancement is unclear though MADs are presumed not only to hold the tongue forward but also increase the dimension of the oropharynx [10].

MADs are considered to be a viable alternative to PAP therapy as stated in the Practice Parameters of Care of the American Academy of Sleep Medicine (AASM) in 2005 and again in 2009 [11]. These recommendations are based upon observations that MADs have a higher subjective compliance rate compared to PAP therapy [12, 13] as well as reports that patients frequently struggle with PAP therapy to a degree that will restore normal functioning [14].

Due to better patient adherence to therapy with MADs, the effectiveness of the dental device is the same if not better for certain parameters. In 2013, a study comparing CPAP to an adjustable MAD found that mandibular advancement was superior in improving four general quality of life domains [15]. This finding was reinforced in a meta-analysis comparing CPAP and MAD therapy in patients with OSA demonstrating equivalent effectiveness in ESS, quality of life, blood pressure, and cognitive performance [16].

To date, there is a paucity of studies with large sample sizes showing the effectiveness of MAD therapy for obstructive sleep apnea in adults. There have been six studies with sample sizes larger than 100 participants using MADs. These studies report variable results. Yoshida et al. (2000) achieved a 41% reduction in apnea-hypopnea index (AHI) in patients with severe apnea using a nonadjustable customized dental device [17]. Another author found a 72% success rate (defined as treatment AHI < 10) in 219 patients with a customized nonadjustable mandibular repositioning device [18]. In a military population using a customized titratable dental device, Holley et al. achieved a 74% success rate, again using an AHI score < 10 for significant improvement [19]. For mild to moderate OSA, there was no statistical difference between a MAD and crossover CPAP therapy [19]. Lam et al. compared PAP to a nonadjustable device in 101 hospitalized subjects and found the MAD to be slightly less effective than PAP therapy. However, the authors admitted that use of an adjustable device might have added to the success of mandibular advancement therapy [20]. Comparing an adjustable customized MAD to an adjustable noncustomized MAD, Friedman achieved treatment success rates of 91% (defined as a 50% reduction in AHI) and 49% (defined as AHI < 5) for the customized device [21].

The studies by Friedman and Lam highlight other important issues that may affect the likelihood of successful treatment of OSA with a MAD. These issues involve the use of customized vs. "off the shelf" devices and adjustable compared to nonadjustable devices. In the largest study to date, Lettieri et al. (2011) addressed this discrepancy in a military population [22]. His group found that the success rate increased by 12% using an adjustable vs. nonadjustable device. Freidman, in the previously mentioned study comparing customized adjustable devices to noncustomized adjustable devices, achieved a 14% increase in success using the customized version. The advantage of a customized titratable dental device over ones that are either nonadjustable and/or noncustomized has been replicated in other studies as well [23, 24].

While previous large studies have assessed the effectiveness of MADs in specific groups (military populations, academic institutions, or hospital settings), no large study has been conducted to date in a "real-world" community setting such as a fee-for-service private dental practice. Private dental practice in the USA is the setting in which the vast majority of patients receive oral appliances for OSA. The purpose of this study is to show the effect of a board-certified dental sleep practitioner on managing mild, moderate, and severe obstructive sleep apnea using customized adjustable MADs. We hypothesize that patients will demonstrate a significant reduction in AHI scores after successfully adjusting to their customized titratable device.

Methods

Study sample

The current study uses a 14-year retrospective design with pre- and post-treatment AHI from sleep studies as the main outcome variables. With inclusive dates of January 2, 2002 and December 31, 2016, data were collected on patients with sleep apnea referred by their primary care physicians, otolaryngologists, or sleep physicians. In contrast to other reported studies, the only patients not eligible for treatment with a MAD were those with acute temporomandibular joint (TMJ) disorders and completely edentulous patients in whom a tooth-borne customized adjustable oral appliance could not be used. Some of the patients who were included in this study had an edentulous maxilla, history of TMJ dysfunction, bruxism, moderate to severe gagging, or dental issues such as gingivitis or significant alveolar bone loss.

Mandibular advancement therapy

The treatment protocol for all patients receiving a custom-fitted, laboratory-constructed, adjustable MAD was the same.

Each patient was well educated as to the benefits and potential consequences of MAD therapy. Each patient received a written and verbal explanation of possible deleterious effects of the therapy, and each patient signed a consent form for therapy. The devices were initially advanced utilizing a George Gauge [25] to a position of comfortable protrusion but no more than 50% of their maximal protrusion. Once patients received the MAD, they were instructed to begin with 30 to 45 min of daytime wear for the first day. The daytime usage was increased each subsequent day until the patient had no difficulty wearing the device for 2 h. Once 2-h daytime wear was achieved, gradual night time wear was begun. Full nighttime sleeping with the device was usually achieved in 7 to 10 nights from initial office appointment delivery. All patients also received instructions on morning daily exercises to prevent muscle discomfort and/or malocclusion. Once tolerance to the device was achieved, the next goal was cessation of one or more symptoms including snoring, nocturia, and/or decrease in daytime sleepiness as self-reported by the participant or bed partner. If presenting symptoms persisted, the participant was instructed to adjust the TAP 3TL (Fig. 1) 0.25 mm every third night and 0.30 mm for both the Herbst device (Fig. 2) and Somnodent device (Fig. 3) every third night. This adjustment was repeated until symptoms resolved. During this time, regular follow-up visits were conducted to check for any dental problems, device wear and tear, and to make appropriate adjustments to optimize the desired clinical effect. Generally, this goal was realized over the next 2 to 4 weeks of nightly use of the MAD. Once these goals were reached, patients were considered to have achieved clinical success.

Adherence was determined by patient or bed partner verbal report. Patients were encouraged to return to their referring physician for an attended overnight polysomnogram to determine the resultant improvement in AHI. The sleep testing center was notified of each patient's clinical results and instructed to conduct the following protocol:

During the initial part of the sleep test, the patient should be allowed to achieve all three stages of sleep while wearing the MAD. If there is continued sleep-disordered breathing, the technician will wake the patient to advance the MAD 0.5 mm for an AHI > 5 or 1 mm for AHI > 10 events per hour. This may be repeated, if needed, as many as four times during the polysomnogram.

Fig. 1 TAP 3 LTM™

Fig. 2 HERBST

OSA severity was determined by AHI score as reported by patient's polysomnogram:

- AHI = 5–14/h—mild OSA
- AHI = 15–29/h—moderate OSA
- AHI ≥ 30/h—severe OSA

Consistent with previous studies, treatment success was defined as patients achieving an AHI < 10 on their post-treatment polysomnogram [16, 18, 21].

Statistical analysis

Statistical Package for Social Sciences (SPSS) 16.0 was used to analyze descriptive statistics between groups. Independent and paired sample *t* tests were used in order to determine differences between and within groups with an alpha level of 0.05 to establish statistical significance.

Results

The patient flow diagram for inclusion and exclusion of patients is shown in Fig. 4. In total, there were 2419 patient records that fit the fixed inclusion period set for the study. Of those, 544 patients (22%) completed pre- and post-treatment sleep studies. Most of the sleep studies performed (89%) were in-lab polysomnograms, while 11% were home sleep studies. The majority of patients 1875 (78%) lacked overnight sleep studies after receiving the MAD. Another 34 patients lacked complete clinical data. Patients lacking post-MAD sleep studies or who lacked complete clinical data were not included in the final analysis.

Fig. 3 SOMNODENT™

Of the 510 patients with complete data, 459 (90%) revealed a decrease in AHI score < 10 respiratory events per hour on post-sleep study indicating treatment success. Demographic data and severity of OSA for these 459 patients are summarized in Table 1. Of the 51 patients (10%) who were counted as treatment failures, 5 did have successful post-treatment results by sleep study, but due side effects discontinued wear soon after that study. There were 66 patients of 2419 (3%) who discontinued the MAD before accomplishing a post-MAD sleep study because of adverse effects such as gagging, tooth pain, pain in the TMJ, or masticatory muscles (as indicated in Table 2). These patients were considered to be treatment failures as well and were added to the "patients with complete data" group, raising the number of failures to 117/576 (20%).

The youngest patient was 18 years of age; the oldest was 88 years of age. There was a statistically significant difference in mean age between treatment success group (57.2 ± 12.9 years) and treatment failure group (61.4 ± 12.4 years), $t(496) = 2.2$, $p = 0.03$, though this difference may not be of clinical significance. There was no significant difference when analyzing baseline mean AHI between men (26.6 ± 18.9) and women (24.9 ± 18.02), $t(496) = -0.99$, $p = 0.32$. Even though 50 patients (10%) did not meet the definition of treatment success, there was still a significant difference in AHI scores from pre- and post-polysomnogram test for this group as shown in Table 3.

Table 1 Selected data for successful patients ($n = 459$)

Age (years)	59.5 ± 13.5
Sex (male)	279 (61%)
Baseline AHI	25.1 ± 17.8
Mild OSA (AHI 5–14)	169 (37%)
Moderate OSA (AHI 15–29)	164 (36%)
Severe OSA (AHI > 30)	126 (27%)

Notable cases included two successful outcomes for patients with pretreatment AHI > 100 events per hour. For one of these patients, the result was a reduction from an AHI of 133 to 7.6 using a MAD.

Due to the large variability and skewness in pre-AHI variable, logarithmic transformation was used before running

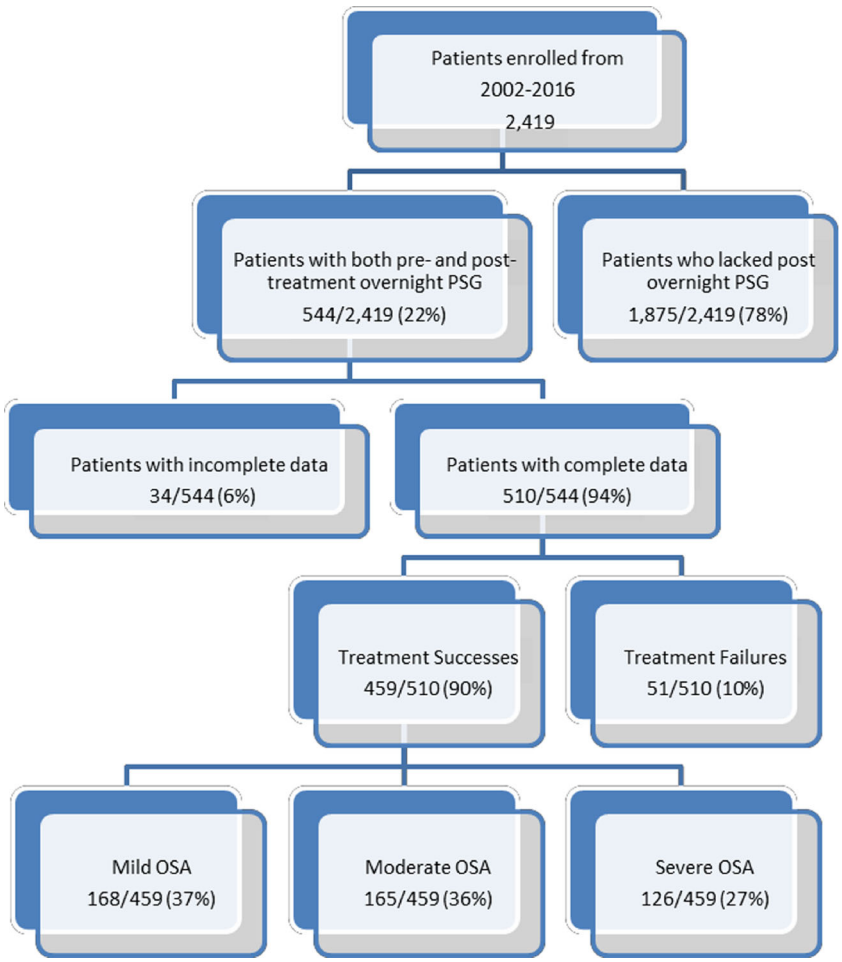

Fig. 4 Flow of participants included and excluded in data analysis. Among the patients who lacked post overnight PSG (66/2419 or 3%) discontinued the MAD due to adverse effects. Considering these patients as treatment failures as well, and therefore adding their number to the group called "patients with complete data," the total treatment failures would be 117/576 or 20%

Table 2 Side effects of MAD intolerance ($n = 66$)

TMJ or masticatory muscle pain	26 (39%)
Could not tolerate	19 (29%)
Bite change	8 (12%)
Teeth loose or tooth pain	4 (6%)
Gagging	4 (6%)
Still tired	4 (6%)
Lack of retention	1 (2%)

parametric statistical analyses. Raw data are reported in the tables. However, all statistical analyses were carried out on transformed data.

Discussion

The chief finding of this study is a very high success rate of MAD for the treatment of OSA in patients who are willing to complete therapy and obtain a follow-up sleep study. The high degree of success does not appear to be related to the baseline degree of severity of OSA diagnosed. This is the first such report in a large group of patients in a real-world setting of a dental sleep medicine practitioner.

Although other studies have shown that MAD therapy for OSA is comparable to CPAP therapy for mild to moderate apnea as well as those with severe symptoms who fail CPAP therapy, this form of treatment continues to be underutilized in the USA. Underutilization may be due to the lack of education of practitioners of sleep medicine regarding the effectiveness of dental devices, effective marketing of CPAP compared to dental devices, or a mistaken belief that dental devices are not a covered entity by most health insurance companies. In that regard, Medicare allows coverage for OAT and for a trial of CPAP when treating moderate and severe sleep apnea with no comorbidities. Medicare does require comorbidities to allow coverage for OAT for mild sleep apnea just as in coverage requirements for CPAP [26].

Another possible reason for reluctance on the part of sleep practitioners to offer mandibular advancement therapy is uncertainty about the education and experience level of dentists regarding this form of treatment. The American Academy of Dental Sleep Medicine posts on the Academy website a list of members who have board certification or qualification in this field denoting a level of education and proficiency in MAD therapy for OSA.

Calibration of MADs for effectiveness over days to weeks before instituting treatment has been a disadvantage for MAD therapy compared to CPAP titration. To address this issue, a remote-controlled temporary dental device has been marketed for use in the sleep lab to mimic the titration function used with CPAP [27].

A final issue regarding underutilization of MAD therapy is that of verifying adherence to therapy, especially with managing OSA in the commercial transportation industry. Just as PAP devices come with computer chips to monitor usage, there are now three commercially available implantable devices for verification of use in MADs [28].

Although CPAP therapy has been demonstrated to be more effective than MAD in lowering AHI in the sleep laboratory, MADs are equally effective for outcomes of sleepiness, health-related quality of life, cognitive performance, or blood pressure reduction [16, 29].

Table 3 Paired sample *t* tests

Events (h)	Mean	SD	SEM	*t* statistic	*P* value
Treatment successes ($n = 459$)					
Pre-AHI	25.1	17.9	0.85	26.39	< 0.001
Post-AHI	3.4	2.9	0.14		
Treatment failures ($n = 50$)					
Pre-AHI	36.1	23.1	3.5	4.71	< 0.001
Post-AHI	20.4	8.7	1.3		

Limitation and strengths

A retrospective study has limitations such as the high likelihood of selection bias. As this is a study of patients treated by a single practitioner, the design may also be vulnerable to confirmation bias. However, the success criteria for inclusion in this study were both pre-intervention and post-intervention sleep studies. Out of 2419 treated patients over 14 years, 510 had post-treatment polysomnograms. Case attrition and reporting bias likely affect the results. Clinical failures may be under-reported. But in a private fee-for-service practice, as this was, unsuccessful patients who experience pain, tooth movement, or lack of reduction of symptoms may be reported with greater frequency than are successful patients because unimproved private practice patients are more likely to return to the office for complaints than those who feel that they are improved. The experience of the author is that many patients experiencing clinical success are reluctant to undergo a follow-up sleep study because their symptoms were resolved.

The present study has a significant strength in the numbers of patients treated and completing sleep studies before and after treatment. Another strength is that patients were fitted with adjustable, customized devices unlike similar studies in the past that utilized nonadjustable or noncustomized devices. Prior research has shown improved success rates of MAD therapy with the ability to calibrate device advancement and with the comfort derived from customization of the device. Other published studies reported results from clinicians with different levels of skill and knowledge, while the current study reports data from a single board-certified, experienced dental sleep medicine practitioner.

Conclusions

This retrospective clinical study with 510 evaluable subjects demonstrated an 80% success rate using custom-fabricated adjustable devices with the ability to calibrate settings during an overnight sleep study guided by a board-certified dentist. In view of the sample size and durability of results over time for this sleep dentist, practitioners of sleep medicine should consider MAD therapy as a first-line option for treatment of OSA regardless of the degree of disease severity.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. For this type of study, formal consent is not required.

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