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The American Academy of Dental Sleep Medicine Begins Offering Qualified Dentist Designation

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The American Academy of Dental Sleep Medicine (AADSM) has now begun offering the Qualified Dentist designation, which was announced in 2016, to help dentists promote their knowledge of dental sleep medicine. This new entry-level designation will help demonstrate the beginning of clinical competency to the payers, sleep physicians and patients who are increasingly looking for evidence of expertise.

The AADSM Qualified Dentist designation is an attainable form of recognition that will help dentists who provide oral appliance therapy grow and thrive early in their dental sleep medicine careers. These dentists will hold the designation while they are on the path to American Board of Dental Sleep Medicine (ABDSM) board certification or AADSM Dental Sleep Medicine Facility Accreditation, both of which continue to stand apart as the highest recognitions in our field.

An Evolving Landscape

The increasingly competitive and frequently changing health care landscape has created the need to define basic competency in oral appliance therapy. Sleep physicians are asking for criteria that proves an individual dentist is skilled in practicing dental sleep medicine. Additionally, patients want coverage for oral appliances from their medical insurance, and insurance companies are looking for appropriate criteria to include in their coverage policies.

Insurance companies often lack the time, expertise and resources to determine competency and, therefore, rely on industry protocols and credentials to set reimbursement policies. ABDSM Diplomate status and AADSM Facility Accreditation are two great options for showcasing proficiency in oral appliance therapy, but both take time and resources to complete. The growing demand for oral appliance therapy in the marketplace means that we need to offer the Qualified Dentist designation in order to provide a baseline qualification for our field.

Defining the Qualified Dentist Designation

The best practices that define the Qualified Dentist designation are supported by the joint American Academy of Sleep Medicine (AASM) and AADSM Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy.[1] This guideline refers to a "qualified dentist" as the dental provider of choice to provide oral appliance therapy, and makes the case for needing the definition:

> The need to append the word "qualified" stems from two things: (1) all of the studies conducted to evaluate the efficacy and risks of oral appliances were conducted by dentists with considerable experience in dental sleep medicine, and (2) the unfortunate fact that training in dental sleep medicine is uncommon. Therefore, not all dentists have the training or experience required to deliver knowledgeable care, and application of the literature to practice dental sleep medicine.

Educational training in dental sleep medicine during dental school is rare, and not all dentists can claim de facto competence in oral appliance therapy. The successful delivery of oral appliances requires technical skill, acquired knowledge and judgment regarding outcomes and risks of the therapy that can only be acquired through adequate continuing education. The Qualified Dentist designation is attainable and positions both the individual dentist and the entire field of dental sleep medicine for growth. It must be stated very clearly that the difference between the Qualified Dentist designation and ABDSM Diplomate certification is significant. The Qualified Dentist designation refers to the very beginning of competency while Diplomate status demonstrates a high level of competency through more education and experience.

How to Earn the Qualified Dentist Designation

The AADSM Qualified Dentist designation is intended only for those who need proof of basic competency to show to patients, sleep physicians and payers, and it is meant to be a stepping stone that provides interim recognition for those who are in the process of accumulating the experience, education and cases needed to earn board certification in dental sleep medicine. Therefore, the designation can be held for two years from the date the application is approved by the AADSM, without the option to reapply. If, however, a dentist submits an application to either sit for the ABDSM certification exam or accredit their dental sleep medicine facility through the AADSM, they will be given an opportunity to reapply for the Qualified Dentist designation for an additional two-year period.

To earn the Qualified Dentist designation, a dentist needs:
- A valid state dental license;
- Proof of liability coverage; and
- At least 25 hours of recognized continuing education in dental sleep medicine (e.g., American Dental Association Continuing Education Recognition Program [ADA CERP] or Academy of General Dentistry Program Approval for Continuing Education [AGD PACE]) provided by a dental sleep medicine focused non-profit organization or accredited dental school in the last two years from the date of the application.

AADSM educational offerings—including courses, webinars, online learning modules and more—make it easy for dentists to attain Qualified Dentist status. The AADSM Annual Meeting, which will be held June 2–4, 2017, in Boston, also offers dentists the premier opportunity to acquire CE hours in dental sleep medicine. Upon completion of CE hours, dentists can use the step-by-step instructions on the AADSM website to submit proof of credits, dental license and liability coverage. For AADSM members, the Qualified Dentist application is a free member benefit.

Benefits for Qualified Dentists

The AADSM Qualified Dentist designation is a proactive solution developed to help dentists entering the field provide proof of skill and continue getting referrals and insurance payments even as the landscape continues to change.

To help patients find the most qualified sleep dentists, the "Find a Dentist" locator on the AADSM website will transition in 2018 to display only those members who have earned one of the three AADSM-recognized credentials—the Qualified Dentist designation, ABDSM Diplomate certification and/or AADSM Dental Sleep Medicine Facility Accreditation. These prioritized listings will help the AADSM demonstrate our support of the expertise that dental sleep medicine designations bring to the table.

With significant growth in dental sleep medicine comes increased scrutiny and competition—and it is our role, as the leading association in the field, to protect the reputation of oral appliance therapy that we have worked so hard to create—that of a proven, effective treatment solution for sleep-disordered breathing. It is in all of our best interest to support dentists who demonstrate a high level of competency through education, experience and the successful completion of a rigorous board certification exam and to nurture a dental sleep medicine profession that values best practices and successful patient outcomes above all else.

CITATION

Smith HA. The American Academy of Dental Sleep Medicine begins offering qualified dentist designation. *Journal of Dental Sleep Medicine*. 2017;4(2):25–26.

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SUBMISSION & CORRESPONDENCE INFORMATION

DISCLOSURE STATEMENT

Dr. Smith has indicated no financial conflicts of interest.

What Does the ADA Proposed Policy on Sleep-Related Breathing Disorders Mean for Dentists and Patients?

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It is a start and it is long overdue. That is what I can say about the American Dental Association (ADA) Proposed Policy Statement on the Role of Dentistry in the Treatment of Sleep-Related Breathing Disorders.[1] In 2016 the ADA undertook the task of creating a policy statement on how member dentists should be involved in the treatment of sleep-related breathing disorders such as snoring and obstructive sleep apnea. I was asked to be part of a team of ADA dentists that were charged with evaluating literature in hopes that we could shape decisions and commentary pertaining to such a policy statement. This group partook in discussions with other members of the ADA and their scientific affairs chairman to help guide the policy that the ADA will adopt in the future. We have come to a milestone in the treatment of snoring and sleep apnea. For the first time since the inception of the American Academy of Dental Sleep Medicine (AADSM) the ADA has taken an active role in the policy fabrication for dentists who are members of the ADA. The proposed policy begins to challenge the status quo with regards to treatment of these medical disorders by dentists. It also endorses member dentists treating patients ubiquitously, but in my opinion the policy falls short in a few ways.

I would have liked the policy to take a stronger stance on the need for continuing education in dental sleep medicine. The fact that dentists coming out of school and even those who have been practicing general dentistry for years are bundled together with those of us who have studied extensively and committed to passing the Diplomate examination of the American Board of Dental Sleep Medicine (ABDSM) is myopic. The proposed policy says that "Dentists should continually update their knowledge and training of dental sleep medicine with related continuing education" which naively assumes that they have any knowledge or education of sleep-related breathing disorders to begin with. Dental schools and even weekend courses cannot adequately begin to shed the needed light on the vast amount of material that one needs to properly treat our sleep patients. It is my opinion that to condone the practice of dental sleep medicine without adequate training is setting up these doctors for potential liability as well as the patients for failure. Continued education in dental sleep medicine is an absolute mandate and just joining an organization is not enough. Dentists must commit to attending meetings, shadowing sleep physicians and even shadowing dentists already skilled in dental sleep medicine to augment their knowledge.

The ultimate goal should be credentialing by the ABDSM. Until dental school education incorporates comprehensive dental sleep medicine curricula, neophytes matriculating from our dental institutions should be cautioned about the intricacies of dental sleep medicine and the relationships that are required to adequately prepare for this expertise.

As dentists we are able to treat myriad maladies of the teeth, head and related oral structures. We routinely screen our patients for hypertension we look for signs and symptoms of diabetes, oral cancer, thyroid cancer, viral and bacterial infections, anemia, and other medical conditions. When we are placed in a position to diagnose obstructive sleep apnea we are told to put the brakes on as it might be out of our scope of practice. The ADA has the opportunity to put forth a major campaign to treat a very large public health problem and at this juncture we don't have the authority to do so. I would like the ADA to be bold enough to confront this issue in the future policy statement regarding sleep-related breathing disorders. We should be permitted to screen our patients and refer them for appropriate treatment just as we would if we screened a patient for cancer and found a lump. We would be co-diagnosing and treating patients, based on the appropriateness of the therapy we could provide. I would no sooner remove a lump in a patient's neck than I would provide a CPAP or an oral appliance without the proper communication, co-diagnosis and recommendations from my medical colleagues. The mutual respect of our medical colleagues will be earned and we will no longer be simply technicians.

We are asked to act like physicians while treating these patients with an oral appliance; we bill medical insurance and Medicare; and keep records that are like our medical colleagues; however, we are told to refrain from anything that might resemble a diagnosis because that is out of our dental scope of practice and jurisdiction. But is it really out of our scope and jurisdiction? That discussion is far too complicated to entertain in this short editorial.

I commend the ADA on beginning the long and arduous task of creating a policy on the treatment of obstructive sleep apnea and sleep-related breathing disorders. I will continue to offer my recommendations in any way I can.

The number of undiagnosed patients with OSA is far too large of a public heath concern to not have dentists included in the overall health screening and treatment of these patients. I believe that we have made great strides in treating these patients diagnosed with sleep-related breathing disorders. With more comprehensive dialogue with the ADA we have the ability to play a major role in managing this health concern.

I am confident that the future of our role in this will benefit patients overall care, hone the relationship with our medical colleagues, and provide another area of expertise within the scope of dentistry. I believe that the education provided by the dental schools with the guidance of the AADSM and the ADA

will be comprehensive and universally disseminated which will continue to foster ideal overall therapy as dentists.

CITATION

Schwartz DB. What does the ADA proposed policy on sleep-related breathing disorders mean for dentists and patients? *Journal of Dental Sleep Medicine.* 2017;4(2):27–28.

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1. Proposed Policy Statement on the Role of Dentistry in the Treatment of Sleep-Related Breathing Disorders. American Dental Association website. http://www.ada.org/en/member-center/leadership-governance/councils-commissions-and-committees/dentistry-role-in-sleep-related-breathing-disorders. Accessed March 1, 2017.

SUBMISSION & CORRESPONDENCE INFORMATION

DISCLOSURE STATEMENT

Dr. Schwartz serves on the American Academy of Dental Sleep Medicine's Board of Directors; however, the opinions stated in this editorial are his and do not necessarily represent the views of the American Academy of Dental Sleep Medicine.

A Descriptive Report of Combination Therapy (Custom Face Mask for CPAP Integrated With a Mandibular Advancement Splint) for Long-Term Treatment of OSA With Literature Review

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STUDY OBJECTIVES: This is a descriptive retrospective study about the efficacy of combination therapy using the TAP-PAP custom face mask (CFM) interface, with a literature review of combination therapy. The purpose of this study is to determine which group of failed obstructive sleep apnea (OSA) therapies would benefit from combination therapy with the CFM. The three failed therapies are mandibular advancement splint (MAS) monotherapy, continuous positive airway pressure (CPAP) monotherapy, and TAP-PAP CS (nasal pillows) combination therapy. Clinically, this will assist the clinician to understand the benefit of the CFM when the patient's current therapy fails.

METHODS: There was a retrospective chart review of patients on combination therapy from 2006–2012. The 75 patients who underwent combination therapy with the CFM were categorized into the three failed groups. OSA severity was compared between groups. CPAP and compliance were compared before and after CFM use. A 6-year follow-up was conducted.

RESULTS: A total of 220 charts of patients undergoing combination therapy were reviewed; 75 patients were in combination therapy with a CFM. The populations of the three groups were as follows: MAS monotherapy failed in 11 (11%), TAP-PAP CS failed in 21 (27%), and CPAP failed in 43 (57%) before the CFM was used. These patients had severe OSA with mean CPAP 14 cm H_2O. At 6-year follow-up, a 78% compliance rate and average CPAP of 13 cm H_2O were reported.

CONCLUSIONS: This study suggests that patients in whom CPAP monotherapy failed would benefit the most from the CFM. The application of the CFM is for patients with more severe OSA and is well tolerated with improved compliance. The CFM should be considered when other therapeutic methods of treating OSA have failed or when CPAP or the CPAP mask are intolerable to the patient.

KEYWORDS: combination therapy, CPAP, custom face mask, MAS, TAP-PAP

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INTRODUCTION

Obstructive sleep apnea (OSA) is a common sleep disorder manifested by repetitive closure or partial closure of the upper airway causing hypoxemia, hypercapnia, and increased sympathetic activity resulting in sleep fragmentation. The natural history of untreated OSA has been well described, including but not limited to daytime sleepiness, hypertension, cognitive impairment, metabolic syndrome, and obesity. In patients who are symptomatic (presence of excessive daytime sleepiness, cognitive dysfunction, mood disorders, insomnia, hypertension, ischemic heart disease, or cerebrovascular accident) the diagnosis is established if there are five or more sleep-disordered respiratory events/h of sleep (apneas, hypopneas, or respiratory effort related arousals). If the patient does not exhibit the previously noted symptoms, the presence of 15 or more events/h is sufficient to make the diagnosis.[1] The severity of OSA varies from mild to severe based on a combination of clinical and polysomnographic determinants.

Oral appliance therapy, specifically mandibular advancement splint (MAS) monotherapy and continuous positive airway pressure (CPAP), are indicated for the treatment of mild to moderate OSA.[2] Oral appliance therapy and CPAP are equally effective for mild to moderate OSA,[3] however for patients with severe OSA, the use of MAS monotherapy is generally not recommended; instead, CPAP is typically the preferred method of treatment because of its effectiveness for treating severe OSA.[4] It is generally thought that as the number of apneas/hypopneas increase, the pressure required to maintain upper airway patency also typically increases. As the pressure increases, so do the challenges of CPAP acceptance and/or compliance. With increased pressure, there is increased mask leakage, air leakage out of the mouth, and patient discomfort.[5] Standard off-the-shelf noncustom masks often are not effective in these severe cases.

Combining CPAP therapy and oral appliance therapy with MAS monotherapy has been shown to be a tolerable and effective therapeutic option. With combination therapy, many of the challenges of CPAP intolerance can be overcome, resulting in improved therapeutic outcomes. Combination therapy utilizes a standard CPAP machine to deliver positive air pressure through a standard nasal and/or oronasal interface in conjunction with MAS monotherapy.[6,7]

Combination therapy is categorized into two types. Type 1 is CPAP therapy used with MAS monotherapy. There is no integration of the two therapies other than both are applied to the

Figure 1—Custom face mask with completed fabrication and ready for insertion.

Figure 2—TAP-PAP CS on face features nasal pillows attached to mandibular advancement splint.

This photograph is used with the consent of the patient pictured.

patient at the same time. Type 2 involves connecting the CPAP device directly to the MAS. The TAP-PAP CS (nasal pillows) is one application of type 2 combination therapy (**Figure 1**); and the TAP-PAP CM (custom face mask, CFM) is another application of type 2 combination therapy (**Figure 2**).

The CFM for combination therapy was developed by W. Keith Thornton, DDS in 1993.[8] Since then, there have been limited reports (case reports and small proof-of-concept studies) that have utilized combination therapy for the treatment of OSA.

As an interesting historical side note, the CFM for combination therapy was developed by a dentist in response to a critical need of postpolio patients. In 1993, Sue Sorter, a respiratory therapist, under the direction of Dr. Joseph Viraslav of the Dallas Rehabilitation Institute, was using a modification of a mask developed in Lyon, France called the "Lyon mask" on postpolio patients with severe OSA. She constructed an oral appliance along with an acrylic mask for her patient. She then used an acrylic post to attach the separate components together (personal communication, Dr. Keith Thornton, January 14, 2011). Dr. Thornton perfected this idea with a custom oral device from dental impressions, and a CFM from an impression of the face, connected by a stainless steel post.

In 2002 Dr. Thornton reported the successful use of combination therapy in a patient who was intolerant of auto-set positive airway pressure (APAP).[9]

In 2015, Upadhyay et al.[10] reported on the use of a custom-made mandibular advancement device with concomitant use of APAP (the devices were separate without structural integration) in a patient who could not tolerate CPAP at 12.7 cm H_2O and was deemed to be "unfit" for palatal surgery. The initial use of MAS monotherapy elicited complaints of excessive salivation and jaw pain, which were temporary. The APAP was applied and on day 1 of combined treatment the pressure was reduced to 8.5 cm H_2O and at day 90 it was 6.5 cm H_2O.[10]

In 2011 El-Solh et al.[7] performed a multipatient study that assessed the efficacy and tolerability of using a custom-made

MAS in combination with a standard positive airway pressure (APAP) system compared to CPAP alone. Of note was that the MAS lacked mechanical integration of the intraoral device with the nasal mask. The MAS device was fabricated using the Herbst attachment to bring the mandible to at least 65% of the patient's maximal protrusion in combination with a standard nasal CPAP mask. After 3 days of treatment the combination approach allowed for a significant reduction in the pressure necessary to maintain upper airway patency as well as reduction of residual apnea-hypopnea index (AHI). CPAP pressures were reduced from 9.4 ± 2.3 cm H_2O to 7.3 ± 1.4 cm H_2O, and residual AHI was reduced from 11.2 ± 3.9 to 3.4 ± 1.5 respiratory events/h of sleep.[7]

In another study that assessed patient comfort, compliance, and preference between standard CPAP and "hybrid therapy," de Vries et al.[11] chose seven patients with moderate to severe OSA who tolerated their "high" CPAP pressures (> 10 cm H_2O) who were then fitted with the TAP 3 type MAS with an integrated set of nasal pillows. The mandible was set at 70% of the patient's maximum protrusion and CPAP was set at 6 cm H_2O. If OSA symptoms persisted or worsened the pressure was increased. Patients filled out questionnaires at baseline (CPAP treatment alone) assessing comfort, compliance, and satisfaction with treatment and again after 3 months of treatment with the hybrid system. After 3 months a polysomnographic study was performed. Four of seven patients reported hybrid therapy to be more comfortable and effective and preferred it over conventional CPAP. There were no differences between baseline (conventional CPAP) and follow-up (hybrid therapy) scores in compliance, satisfaction, daytime sleepiness, and quality of life. Effectiveness of hybrid therapy was good as AHI significantly decreased from median AHI at diagnosis (64.6 events/h; range, 31.0–81.0) to median AHI with hybrid therapy (1.5 events/h). There was no statistical difference in effectiveness between conventional CPAP and hybrid therapy (median AHI with conventional CPAP was 2.4 events/h. It was concluded that although pressure could be lowered, hybrid therapy was perceived as a comfortable alternative to conventional CPAP.

Figure 3—TAP-PAP CM on face features custom face mask attached to mandibular advancement splint.

This photograph is used with the consent of the patient pictured.

Table 1—Diagnostic nocturnal polysomnography results of patients with a custom face mask.

PSG Results	
Diagnostic AHI, events/h	39 ± 27
Diagnostic RDI, events/h	45 ± 26
Diagnostic PSO$_2$, %	82 ± 9
CPAP pressure, cm H$_2$O	14 ± 4
Diagnostic PES (9 patients), cm H$_2$O	−35 ± 19*

Values presented as mean ± standard deviation. *normal is −5 cm H$_2$O. AHI = apnea-hypopnea index, CPAP = continuous positive airway pressure, PES = lowest esophageal pressure, PSG = polysomnography, PSO$_2$ = lowest blood oxygen desaturation during period tested, RDI = respiratory disturbance index.

There were no differences between both therapies regarding compliance, satisfaction, and effectiveness.[11]

The purpose of this study was to review and summarize the characteristics of patients who had undergone combination therapy with a MAS secured to a CFM. Failure of three common therapeutic options, MAS monotherapy, CPAP monotherapy, and TAP-PAP CS (nasal pillows) combination therapy, were considered for this study. The application of the results of this study in a clinical setting would help the clinician to understand the benefit of the CFM when the patient's current therapy fails. The decision to move into type 2 combination therapy with the CFM will depend on which current therapy is failing. This study will help clarify that decision process for the clinician. This study will also determine the efficacy and tolerability of type 2 combination therapy with the CFM as a therapeutic option in patients with all degrees of OSA who presented to a dental sleep center.

METHODS

A retrospective chart review (evaluation of quality of care) of all the combination therapy patients was conducted to determine who had underwent CFM treatment and what therapies had been attempted prior to the CFM. All patients who had been provided combination therapy from 2008 to 2012 at the Center for Facial Pain and Dental Sleep Medicine in The Woodlands, Texas were included in the review.

The CFM (**Figure 1**) fabrication process has been well described.[12] It should be noted that every patient fitted with a CFM underwent an in-laboratory titration to determine the therapeutic pressure for the CPAP aspect of the therapy.

Patient Selection

CPAP monotherapy and MAS monotherapy typically failed in patients in this study before they were considered for combination therapy. All patients underwent a diagnostic nocturnal polysomnogram and all underwent a CPAP titration study prior to institution of combination therapy. The dental sleep center used two types of combination therapy; both utilize the basic TAP3 MAS (Airway Management, Inc., Dallas, Texas). The first type 2 device is the TAP-PAP CS (chair side TAP3 with post and nasal pillows) (**Figure 2**). The second type 2 device is the TAP-PAP CM (TAP3 with post and CFM) (**Figure 3**).

Two hundred twenty consecutive charts of patients who underwent type 2 combination therapy were analyzed for this study. Of these 220 patients, 145 were excluded because they had a successful outcome utilizing the TAP-PAP CS (nasal pillows) device. This left 75 patients who were prescribed the TAP-PAP CM (CFM).

Patients who were included in this study were those for whom a sequence of previous treatments failed. There were three groups comprising failed therapy. Group 1 included those for whom MAS monotherapy failed; group 2 included those for whom combination therapy with the MAS attached to nasal pillows (TAP-PAP CS) failed; and group 3 included those for whom CPAP monotherapy failed. Charts were reviewed and patients were placed into one of these three groups based on the type of failed therapy used before the CFM was used. Original diagnostic nocturnal polysomnography and CPAP titration results were recorded. Many patients had undergone esophageal pressure monitoring (PES studies) as part of their nocturnal polysomnography; as a result, those pressures were recorded as well.

RESULTS

The charts of the 75 patients who were prescribed the TAP-PAP CM (CFM) were surveyed and the type of previously failed therapies were determined. The nocturnal polysomnography results of the 75 CFM patients were determined along with the results of the previous CPAP titration studies that were accomplished with a stock non-custom CPAP mask (**Table 1**).

The level of severity of this group (**Table 1**) reflects the type of patient who would benefit from combination therapy with the CFM. These patients represent individuals on the moderate to severe end of the spectrum of OSA.

These patients were then grouped into three categories: the first group involved failed MAS monotherapy; the second, failed combination therapy with the TAP-PAP CS (nasal pillows), and the third, failed CPAP monotherapy (**Table 2**).

Table 2—Number of patients for whom therapy failed before starting custom mask.

Failed Therapy Group	n (%)
MAS monotherapy	11 (15)
TAP-PAP CS (type 2 combination therapy)	21 (28)
CPAP monotherapy	43 (57)

CPAP = continuous positive airway pressure, MAS = mandibular advancement splint.

Table 4—Follow-up 2008–2015 (n = 44).

Years with CFM	n (%)
10	1 (2)
9	3 (7)
8	6 (14)
7	12 (27)
6	5 (11)
5	8 (18)
4	9 (21)

CFM = custom face mask.

Table 3—Subgroup failed continuous positive airway pressure (monotherapy) nocturnal polysomnography results showing severity of obstructive sleep apnea.

PSG Results	Subgroup CPAP Failure	Total CFM Patients
AHI, events/h	41 ± 25	39 ± 27
RDI, events/h	50 ± 25	45 ± 26
PSO_2, %	80 ± 10	82 ± 9
Average PES level, cm H_2O	−41 ± 19	−35 ± 19
Average CPAP pressure, cm H_2O	15 ± 4	14 ± 4

Values presented as mean ± standard deviation. AHI = apnea-hypopnea index, CFM = custom face mask, CPAP = continuous positive airway pressure, PES = lowest esophageal pressure, PSG = polysomnography, PSO_2 = lowest blood oxygen desaturation during period tested, RDI = respiratory disturbance index.

Table 5—Follow-up after 3 to 6 years (n = 56).

Current Status (2014)	n (% contacted patients)
Still wearing custom mask	44 (78)
Went back to stock CPAP	5 (10)
Lost weight/OSA resolved	3 (4)
Surgery/OSA resolved	2 (4)
Bad CPAP side effect	1 (2)
Deceased	1 (2)

CPAP = continuous positive airway pressure, OSA = obstructive sleep apnea.

Previous MAS Monotherapy Failures

In 15% of patients using a CFM, MAS monotherapy failed (**Table 2**). The most frequent reason for MAS monotherapy failure was the inability to tolerate advancement of the mandible. These patients all had a history of recent temporomandibular joint (TMJ) therapy and the forward movement of the mandible resulted in pain. The most cited reason for the desire to discontinue MAS monotherapy in this group was continued daytime fatigue. Because CPAP in many of these patients had previously failed, they were willing to abandon all types of therapy at this point. However, when presented with the description of combination therapy, they were willing to try the CFM. The acceptance rate of this group of patients for combination therapy was 98%. There was one patient who could not tolerate the CPAP even with the CFM.

Previous TAP-PAP CS (Nasal Pillow) Failures

In 28% of patients, type 2 combination therapy using the TAP-PAP CS failed (**Table 2**). The TAP-PAP CS device utilizes the MAS as its foundation with a blue swivel nut secured to the post to allow direct integration of the nasal pillows into the MAS (**Figure 1**). The main reason given for failure of this therapy was discomfort due to the flow of air directly into the nares; this in turn led to mouth leakage and fluttering of the cheeks. The net result, as in the MAS monotherapy failure group, was persistent daytime fatigue. There were also some mouth breathers in this group. These patients required a CFM in order to seal the mouth.

Previous CPAP Monotherapy Failures

In 57% of patients undergoing combination therapy with the CFM, CPAP monotherapy failed (**Table 2**). The reason for failure of CPAP was mask and/or headgear discomfort. Leakage around the mask was also cited as an unacceptable side effect. These patients were willing to abandon therapy

despite the severity of their OSA. Although the nocturnal polysomnography results for all groups have been outlined (**Table 1**), a subgroup analysis was determined to understand the severity of this CPAP monotherapy failure group, when compared to the entire CFM group (**Table 3**). The largest group of CFM patients experienced CPAP monotherapy failure (57%, 95% confidence interval: 46% to 69%).

The severity of OSA in the subgroup of CPAP monotherapy failure reflects a group of patients on the more severe end of the spectrum of OSA (**Table 3**). For each indicator of severity, the patients for whom CPAP monotherapy failed had more severe OSA than the average of the entire group.

Follow-Up Survey

All patients included in this follow-up survey (seen in the Dental Sleep Clinic from 2006–2012) were followed up with a phone call in June 2015 to determine if they were still wearing the CFM (**Table 4**). Of the original 75 patients, only 56 were able to be contacted. Of those 56 patients, 44 were still wearing the CFM.

Table 4 demonstrates the longevity of the CFM. Approximately 61% of patients who received the CFM had it for more than 6 years.

Included in the telephone survey was a question concerning patients' current status with the CFM regarding combination therapy for OSA (**Table 5**).

Table 5 demonstrates that 78% of the patients contacted were still wearing the CFM in 2015. After attempts were made to contact all patients in the study, 19 patients were unable to be contacted, which left 56 participating in the telephone survey.

Table 6—Comparison of continuous positive airway pressures before and after custom face mask use.

Average CPAP Pressures for CFM Patients (n = 35)	
Before CFM	**With CFM in situ**
14 ± 4 cm H_2O	13 ± 3 cm H_2O

Values presented as mean ± standard deviation. CFM = custom face mask, CPAP = continuous positive airway pressure.

Table 7—Compliance of the noncustom mask compared with the custom face mask.

Hours Worn	Noncustom Mask	Custom Face Mask
< 1	3	1
1–2	1	0
2–4	3	3
4–6	4	5
7–8	9	11
Total patients	**20**	**20**

As a part of this follow-up, records were reviewed to determine the CPAP pressures before and after CFM fabrication (**Table 6**).

Table 6 revealed that the average CPAP pressures were reduced after the fabrication of the CFM. Post-CFM fabrication CPAP titrations of 35 patients were obtained. Most patients (n = 23) in this follow-up survey who had any post-CFM insertion reduction of CPAP pressures had significant reduction of pressures. Twelve patients had increased CPAP after the fabrication of the CFM. These pressures were mostly raised by just a few points. These patients had an increased body mass index.

A subgroup analysis (**Table 7**) by separate telephone survey of the CPAP monotherapy failure group was performed (n = 20) to determine compliance and satisfaction with the CFM. These patients presented to the dental sleep center and were ready to abandon CPAP monotherapy.

Table 7 demonstrates that this population represented those on the severe end of the CPAP failure subgroup. The average respiratory disturbance index of 48, AHI of 42, PSO_2 of 77% and average CPAP pressures was 15 cm H_2O (compare **Table 3**). The top two noncustom stock mask complaints were leakage (80%) and strap discomfort (40%). With the CFM there was 100% compliance. The top features of the CFM revealed by the patients were comfort (40%) and absence of straps (20%).

These results demonstrate the significant increase in compliance to the CPAP interface with the CFM. The number of patients wearing the stock mask 4 hours or more was 13 (65%); whereas the number of patients wearing the CFM 4 hours or more was 16 (80%).

DISCUSSION

The MAS is clinically accepted as a safe and effective treatment for mild to moderate OSA. From a historical clinical standpoint, they have been used primarily as second-line treatment for patients who are CPAP intolerant for many reasons (mask discomfort, leakage, claustrophobia, skin irritation) in patients with mild to moderate OSA. This retrospective review of patients seen in a single dental sleep clinic is important in demonstrating that combination therapy can be used successfully in patients who have failed the more traditional forms of therapy (MAS or CPAP as monotherapy) in all ranges of OSA severity.

In patients for whom CPAP monotherapy has failed and who subsequently used MAS monotherapy, combination therapy provides a therapeutic option for those who cannot tolerate MAS monotherapy. The most common reason for failure of MAS monotherapy for patients in this study were TMJ symptoms. The next most common side effect of MAS monotherapy for patients in this study was a change in the alignment of the teeth. Both of these side effects increase in frequency, as the mandible is advanced to stabilize the airway.[13,14] In utilizing combination therapy, the oral aspect of the device can be set to minimize the advancement of the mandible, thereby reducing these side effects. The chief clinical advantage of combination therapy is its ability to reduce the pressure from the CPAP machine necessary to maintain upper airway patency (particularly in those patients with moderate to severe OSA) as well as the reduction in the degree of advancement of the mandible to lessen the TMJ discomfort and tooth movement that typically accompanies the use of MAS monotherapy. Some of the failures involved the inability of MAS monotherapy to resolve daytime sleepiness. Even if the patients in the MAS monotherapy group showed resolution of OSA on a polysomnogram, respiratory effort related arousals may still be present, resulting in fragmented sleep and continued daytime sleepiness.[15]

Along with the development of the TAP-PAP CM (CFM) (**Figure 3**), the TAP-PAP CS with nasal pillows (**Figure 2**) was available. However, many patients who elected to use CFM either knew they did not want the nasal pillows, or were at the "end of their rope" and just wanted to try one more therapy. In the patients for whom TAP-PAP CS failed, the most common residual sleep symptom was fatigue. The failures of the TAP-PAP CS (nasal pillows) were most often due to intolerance of the high pressures applied through the nasal pillows. The clinical experience of the authors and others who provide this combination therapy with the TAP-PAP CS have observed that the combination system is effective with CPAP less than 15 cm H_2O.[16] Leakage from or around the mouth was the most common side effect. Even though the intraoral component of the device was the same as the CFM, the leakage occurred between the MAS and the cheeks, resulting in a fluttering or leakage out the mouth that resulted in a loss of effectiveness. In our series, two patients reported discomfort that they attributed to the nasal pillows. The most common negative issue reported was fatigue. Fragmented sleep may have resulted from persistence of the OSA, discomfort of the nasal pillows, the noise of leakage or other factors including residual excessive daytime sleepiness in patients in whom OSA is adequately treated. CFM appears to have resolved many of these issues for those who could not tolerate TAP-PAP CS (nasal pillows).

The noncompliance rate with the CPAP machine (35% to 85%) as defined by nightly use of fewer than 4 h/night and less than 70% of all nights is well documented in the literature.[17–20] In our study, the most common reasons for patients to seek alternative treatment options for CPAP machine usage were mask leakage and discomfort related to the elastic

Figure 4—Impression of the face in preparation of the fabrication of the custom face mask.
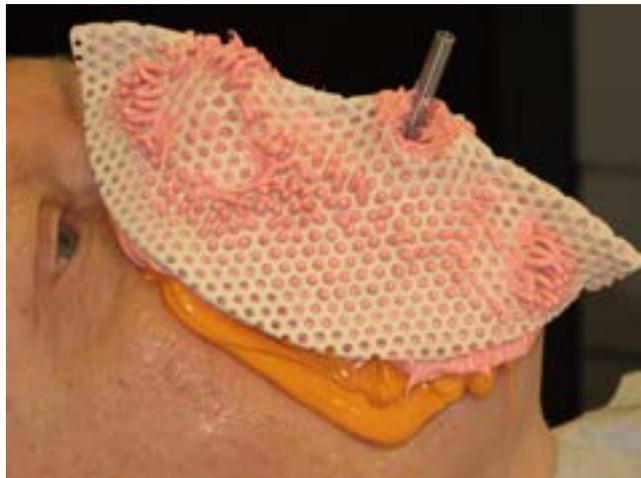
This photograph is used with the consent of the patient pictured.

headgear (mask straps) (**Table 7**). The patients electing to use a CFM generally had more severe OSA. The patients in this group required pressure from the CPAP mask (on average) of 15 cm H_2O (**Table 3**), and exhibited greater breathing effort as demonstrated by esophageal pressures of less than −35 cm H_2O (**Table 1**). One of the significant problems with stock noncustom CPAP masks is their inability to work well under high pressures with high amounts of leakage. This has led to the empirical use of full-face masks. However, there is literature to suggest that full-face masks have a higher noncompliance rate compared with nasal masks and can increase the AHI just by the use of an oronasal interface.[21,22] If air leakage occurs, then a chin strap is commonly prescribed with or without tightening the headgear/mask straps. Unfortunately, addition of a chin strap tends to have significant negative effects on the size of the oropharyngeal airway because of the vector force placed on the mandible causing distalization (posterior movement of the mandible back toward the airway), which results in a greater degree of airway obstruction.[23] Combination therapy addresses these issues by increasing the retrolingual space by moving the mandible (and the tongue base) anteriorly while stabilizing the mandible. It eliminates the straps by connecting the CPAP airflow interface directly to the oral device and it decreases leakage by means of a customized fit of the facial/nasal interface.

There are circumstances where the delivery of airway pressure through the nose is not effective because of nasal pathology (mouth breathers) and it is desirable to have CPAP delivered orally. Both are effective in therapeutic outcomes.[24] With this in mind, the CFM can be modified to create a communication port between the nasal vestibule and the mouth vestibule to allow airflow from the CPAP mask to enter the mouth and nose simultaneously. This was done in four patients in this study. One patient had Graves disease and had undergone an infra-orbital decompression that caused her to be intolerant of nasal pressure as it put outward stress on her eyes. The CFM was further customized by adding a communication between the nasal vestibule and the oral vestibule to resolve these issues.

The follow-up telephone survey (**Table 5**) revealed another aspect of combination therapy with the CFM that has not been considered until now. This survey suggests that the CFM has a longer clinical shelf life when compared to a stock noncustom CPAP mask, raising the possibility that this is a cost-effective therapeutic option. The longevity of this device affects its cost-effectiveness. Sixty-one percent of patients were still wearing their CFM after more than 6 years.

In the analysis of the average CPAP pressure before and after CFM use (**Table 6**), it was shown that the average pressure was reduced by 1 cm H_2O. When there was a reduction in CPAP pressure (for 23 patients) the reduction was significant. This speaks to the efficacy of the seal of the mask and the efficiency of the interface as a whole. The other 12 had an increase in CPAP pressures after the fabrication of the CFM. The reason is probably because the OSA disorder may have actually become worse (nothing to do with the CFM) and the CFM is helping to keep these patients in effective therapy with the higher pressures; or perhaps these patients were undertitrated to begin with (intolerance of high pressures) and now they are able to tolerate these higher pressures with the CFM. A unique aspect of the CFM is that leakage around the mask is significantly reduced by providing an improved seal of the mask against the face. The design of the mask by virtue of the way it is fabricated from an accurate impression of the face (**Figure 4**), specifically in line with facial and nasal contours, enables the pressure of the PAP to expand the facial skin outward towards the mask, creating a more secure seal.

A subgroup analysis of the failed CPAP monotherapy group (Group 3) regarding compliance and comfort (**Table 7**) revealed that the CFM had a higher compliance and satisfaction when compared to the stock CPAP mask. We hypothesize the reasons for increased compliance and comfort are the elimination of the headgear straps and the stability of the mask. In a study by Prehn,[25] there was an unanticipated benefit accorded to the bed partner, with greater satisfaction of the bedroom ambiance with this far quieter therapeutic option.

This is a new therapy for OSA that integrates MAS monotherapy and CPAP. The success of this therapy involves the collaboration of a qualified sleep physician and a qualified sleep dentist. As the technology of combination therapy improves, so will the need for further research. With the modifications available to this mask system, the applications will be expanded as well.

As noted previously, the ability of this combination therapy system to improve treatment effectiveness is accomplished via two mechanisms. The first is the protrusion of the mandible. This physical advancement allows the physical space of airway to increase the lateral dimension of the velopharynx region of the oropharynx.[26–28] There is also an increase in tone of the genioglossus muscle.[29,30] Both of these mechanisms provide the foundation of the mechanism of action of MAS monotherapy for the treatment of OSA.[31] In addition, the combination of effective airflow through the nasal passage[32] along with mandibular stabilization offers a potentially superior method of treating OSA.

As more qualified dentists are trained in utilizing the CFM as a therapeutic option in their practice to treat OSA, the data

for its application will also expand. It is difficult to deny that for those with severe OSA, this retrospective study of the CFM suggests there may be increased therapeutic success.

Terminology

As we carried out this study and as we prepared the manuscript for publication, we have been engaged in an ongoing discussion about the terminology used to describe the types of combination therapy that are the focus of this study. There is no consistency in the literature to date, and even in discussions with medical/dental professionals there is little clarity about the preferred nomenclature. Since this is an emerging therapeutic option, we suggest that consistent terminology be used going forward. In this study, the term "type 1 combination therapy" refers to therapy that combines MAS and CPAP. We suggest that the term "dual therapy" be used henceforth since it describes two distinct monotherapies that are applied to the patient at the same time. We suggest that the term "type 2 combination therapy," as used in this study, should instead be "integrated therapy" because it describes two therapies that are integrated into one therapy. Following this terminology, treatment using the CFM would be called integrated therapy.

CONCLUSIONS

This retrospective study suggests that patients for whom CPAP monotherapy fails comprise the group that would benefit the most from type 2 combination therapy with the CFM. Although the patients who experienced failure of the other two types of OSA therapy (MAS monotherapy and TAP-PAP CS nasal pillows combination therapy) did benefit from the CFM, the majority of patients (57%) who underwent type 2 combination therapy with the CFM were from the CPAP monotherapy group. This suggests that the CFM should be high on the therapeutic options considered by the clinician when CPAP monotherapy fails.

This study suggests that the application of the integrated TAP-PAP CM (CFM) in type 2 combination therapy for patients with more severe OSA is well tolerated with improved compliance. The CFM appears to enable patients to tolerate higher CPAP pressures. The CFM should be considered when other therapeutic methods of treating OSA have failed or when pressures or the CPAP mask are intolerable to the patient.

Because of the cost of the mask (including the hours of labor involved in fabricating and fitting), it is currently not well suited as a first-line therapeutic option. However, we think the cost should decrease over time as more cost-efficient systems to create custom hardware (for example, face scanners, three-dimensional printers) become available. Furthermore, the longevity of the CFM may prove that it is a cost-effective option in the long-term.

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SUBMISSION & CORRESPONDENCE INFORMATION

DISCLOSURE STATEMENT

Utilization of a Mandibular Advancement Device for Obstructive Sleep Apnea in the Veteran Population

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Study Objectives: Obstructive sleep apnea (OSA) is a common health problem with significant cardiovascular complications. Nonsurgical treatment options include continuous positive airway pressure as well as mandibular advancement devices (MAD). We sought to determine which factors explain the adherence rate of custom-fit MADs within the military veteran population with OSA.

Methods: All patients receiving a custom-fit MAD from the Department of Dentistry at a regional veterans health center between December 2007 and August 2013 were retrospectively reviewed. Patient demographic and clinical characteristics were collected and reviewed. Binomial univariate logistic regression models were utilized to assess for the association of these characteristics with the primary outcome: adherence at 6 months after delivery of the MAD.

Results: There were 48 patients meeting inclusion criteria, with a mean age of 60 years. The mean (standard deviation) body mass index was 30.4 (4.76), and the mean (standard deviation) apnea-hypopnea index on the preintervention polysomnogram was 32.1 (26.5). Adherence among all patients was 66.8% at 2 weeks, and 58.3% at 6 months. Among the subgroup of patients identified as having limiting social circumstances, the adherence was 100% at 2 weeks and 100% at 6 months.

Conclusions: The MAD is a valuable first-line treatment option for mild or moderate OSA, particularly in patients anticipated to have difficulty complying with continuous positive airway pressure.

Keywords: continuous positive airway pressure, mandibular advancement device, obstructive sleep apnea, sleep-disordered breathing, veterans

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INTRODUCTION

Obstructive sleep apnea (OSA) is a common health problem in the United States, with an estimated prevalence of 4% in men and 2% in women.[1,2] OSA is associated with hypertension, cardiovascular disease, insulin resistance, and asthma, as well as reduced quality of life and increased likelihood of motor vehicle accidents; its treatment is therefore of great importance.[3–5] Treatment options include weight loss in overweight patients, continuous positive airway pressure (CPAP), mandibular advancement device (MAD), and surgery focused on the appropriate level of obstruction.[6–8]

OSA may be suspected after a thorough history and physical examination, but the diagnosis requires confirmation with a polysomnogram (PSG). The initial PSG may include titration for a CPAP machine, which is the most common intervention for OSA.[9] CPAP is highly effective; however, many patients find it to be intolerable, and long-term adherence rates in some series are less than 50%.[10] Some typically cited reasons for discontinuation of CPAP are bothersome noise, discomfort from the mask, xerostomia, aesthetic appearance, and difficulty transporting the device to different sleep sites. CPAP is meant to be used throughout sleep; however, even the typical metric of 4 h/night is accomplished in only 46% to 83% of patients.[10] In the veteran population, when good adherence was defined as use of CPAP on 3 or more nights per week, only 39% to 53% of patients with mild to severe OSA maintained good adherence.[11]

Oral appliances such as the MAD are frequently recommended for patients with mild or moderate OSA because they are simple to use, noninvasive, and may be tolerated better than CPAP.[12] They may be considered first-line treatment in these patients. Randomized controlled trials have shown that they are a good alternative for snoring and OSA because of their low cost, relative comfort, and ease of use, which may result in greater patient adherence.[13]

With the increasing understanding of the need for adequate treatment of OSA, investigations into the populations most likely to benefit from particular interventions is of great importance. Patients in the veteran population have a high rate of OSA, as well as increased rates of comorbid medical and psychiatric problems.[11,14,15] As many as 34% to 47% of veterans are considered to be at high risk for OSA. In addition, there is a greater frequency of socioeconomic challenges and lack of support systems, which can make adherence with medical treatment more difficult.[16] Adherence to CPAP in the veteran population has been found to be 50% or less,[10,11] and thus an alternative treatment with high ease of use, low cost, and improved tolerability might result in improved adherence. We therefore examined patients within the military veterans population with OSA receiving treatment with a custom-made MAD to understand adherence to the device in this unique patient population.

Table 1—Demographic and clinical characteristics of patients.

Characteristic	n (%)
Mean age (SD), y	60 (15)
Male	46 (96)
African American	16 (33.3)
White	15 (31.5)
Hispanic	6 (12.5)
Asian	5 (10.4)
Average BMI (SD), kg/m^2	30.4 (4.76)
Average AHI (SD)	32.1 (26.5)
History of limiting social circumstance	7 (14.6)
History of prior OSA surgery	5 (10.4)

AHI = apnea-hypopnea index, BMI = body mass index, OSA = obstructive sleep apnea, SD = standard deviation.

Table 2—Patient adherence with mandibular advancement device therapy depending on social circumstance.

	Limiting Social Circumstance		
	Yes	No	
Adherence at 2 wk	7/7 (100%)	26/41 (63.4%)	P = .0819
Adherence at 6 mo	7/7 (100%)	21/41 (51.2%)	P = .0319

METHODS

We selected patients receiving treatment for OSA at the Greater Los Angeles Veterans Affairs Healthcare System from December 2007 to August 2013. All patients older than 18 years receiving the MAD fitted by the Department of Dentistry during the period of the study were included for analysis. Patients were eligible for use of the MAD according to Veterans Affairs criteria: mild to moderate OSA, or moderate to severe OSA after failing CPAP, or in conjunction with other modalities; with sufficient periodontally sound teeth, and without significant temporomandibular joint (TMJ) disorders. All patients underwent a detailed discussion about treatment options, including MAD as well as CPAP, prior to electing MAD therapy. The custom-fit Silencer device (Silencer Products International Ltd., Vancouver, BC, Canada)was used in all cases.[17] Institutional Review Board A granted approval for this study (# 2014-080869).

Demographic data were collected, including age, sex, and race, as well as clinical data including smoking status, and body mass index (BMI). Reports of overnight PSG performed prior to the delivery of the MAD were reviewed to determine the baseline apnea-hypopnea index (AHI). Patient records were reviewed to search for surgical interventions to treat OSA occurring either before or after delivery of the MAD. Patient-reported adherence was assessed at 2 weeks following delivery of the MAD, when patients had scheduled follow-up with the Department of Dentistry to check the appropriate fit of the device, and also at 6 months, when patients had appointments with the sleep medicine clinic or their primary care physicians. Evaluation of dental disease, occlusion, and TMJ issues were recorded at the initial visit and during subsequent visits. Adverse effects of the device were routinely assessed at these intervals, and patients verbally responded to questions on consistent device use in a dichotomous manner. Patient records were reviewed to identify those patients with limiting social circumstances, such as absent or unstable housing, or those with a need for frequent travel. Patient documentation was systematically entered into a single centralized electronic medical record encompassing the primary hospital-based clinic site as well as affiliate hospitals and outpatient clinics.

Patients with and without limiting social circumstances were analyzed using a χ^2 test for categorical variables. Binomial univariate logistic regression models were utilized to assess the association between the demographic and clinical variables and the primary outcome, adherence at 6 months after delivery of the MAD. For all statistical testing, we used a two-sided significance level of .05. Statistical analyses were performed using SPSS software, version 22.

RESULTS

There were 48 patients meeting study inclusion criteria, of whom 96% were male (**Table 1**). The mean age was 60 years (range, 30–85). The racial distribution was diverse, with 33.3% African American, 31.6% white, 12.5% Hispanic, and 10.4% Asian. Among all patients the mean (standard deviation [SD]) BMI prior to the use of the MAD was 30.4 (4.76). The mean (SD) AHI on the preintervention PSG was 32.1 (26.5), indicating that this cohort consisted of patients with both moderate and severe OSA. There were four patients with unstable living situations, and three patients with very frequent travel, and they were considered to have limiting social circumstances.

Overall adherence with the MAD device at 2 weeks after device delivery was 66.8% (n = 33), and overall adherence at 6 months was 58.3% (n = 28). Adherence was defined as patient report of continued use of the device, as we could not reliably measure hours per night or similar definite indicators of use. Among the patients with limiting social circumstances, adherence at 2 weeks was 100% (n = 7) and adherence at 6 months was also 100% (n = 7). Limiting social circumstances was the only factor that was positively associated with MAD adherence at 6 months (**Table 2**, P = .0319), and among other patients without limiting social circumstances the adherence at the 6-month time point was only 51.2% (n = 21). This indicates that no patients withdrew from treatment in the group with limiting social circumstances, whereas in the group without limiting social circumstances there were 20 patients who withdrew from treatment. Other factors, including age, BMI, AHI, sex, and smoking status, were not statistically significantly associated with adherence at either 2 weeks or 6 months.

Patients reported that reasons for discontinuing use of MAD included xerostomia, drooling, broken device, and dental or mandibular discomfort. Only three patients described intermittent tooth pain, although the relation between pain and use of the MAD or coexistent dental caries was uncertain. There were no cases of incident TMJ pain. No occlusal changes were

evident at 6-month follow-up. Notably, five patients had undergone uvulopalatopharyngoplasty prior to attempting use of MAD, and two others proceeded to surgery following unsuccessful trial of MAD. Uvulopalatopharyngoplasty was the only surgical intervention performed in this cohort, although mandibular advancement surgery was recommended but not undertaken for one patient.

DISCUSSION

In this cohort of veterans with OSA, we found that the MAD was a useful nonsurgical treatment option for OSA. Adherence was comparable to that observed in the general population for oral appliances or CPAP, with 58.3% utilizing the MAD at 6 months following device fabrication and delivery. The adherence was higher than that demonstrated in a recent cohort of 207 veteran patients, where only 29.5% were adherent to recommended CPAP therapy.[18] Importantly, we identified a subgroup of patients with limiting social circumstances, such as homelessness and frequent travel, and found that among these patients the adherence with MAD was 100%. It is likely that these patients would have great difficulty utilizing a CPAP device, which is frequently bulky, heavy, and requires routine access to electricity. We also did not find significant adverse effects on occlusion or TMJ function.

The discontinuation rate among this group of veterans was greater than that observed in a cohort of 619 patients treated with a custom fabricated MAD, wherein 24% discontinued treatment.[19] However, the percentage of women was greater in that group, and because female sex predicted treatment success this may account for the difference in adherence rates. One reason for discontinuation may be the development of dental side effects during treatment, which are known to occur with MAD use.[20] However, dental side effects may also be seen with CPAP.[21] The patients in our study did not experience significant dental or TMJ side effects. Thus, patients may have discontinued MAD use for other reasons such as perceived efficacy, comfort, or other factors.

Studies comparing MAD to CPAP have shown discordant results in assessing adherence. Doff et al. treated 103 patients with the Thornton Adjustable Positioner (Airway Management, Inc., Dallas, Texas, United States) or CPAP, and found that more patients were noncompliant with oral appliance therapy (47%) than with CPAP (33%), although this finding was not statistically significant.[22] However, Phillips et al., utilizing the Somnodent device (SomnoMed Ltd., Sydney, Australia), found that adherence was higher with the MAD than with CPAP (6.5 h/night versus 5.2 h/night, $P < .00001$).[23] Although these compliance rates are discordant, our series demonstrates that compliance with MAD at 6 months was greater than 50%, which is as good or better than reported compliance rates of veterans using CPAP, ranging from 39% to 53%.[11] Our data confirm the hypothesis that compliance with MAD would be higher than with CPAP in the veteran population, because of its ease of use, low cost, and improved tolerability, especially for veterans with limiting social circumstances.

There were certain limitations in our study. Postintervention PSGs were not available for all patients, limiting our ability to assess the effectiveness of the treatment. Patient follow-up was inconsistent, with some patients seeking continued care in the sleep medicine clinic, dental clinic, or only with the primary care doctor. This sample was also 96% male, which may limit generalizability to the young veteran population, which includes a higher percentage of females.

In veterans with sleep-disordered breathing, a PSG should be obtained to confirm OSA and assess the severity of disease. These patients should then be counseled on their treatment options, with a discussion of both CPAP and MAD, as well as surgery in selected patients. Holley et al. utilized the Thornton Adjustable Positioner in a military population, and results of their analysis of 497 patients suggested that the appliance was comparable to CPAP for mild OSA, whereas CPAP was clearly better in moderate or severe disease.[24] We therefore suggest that the device should be considered as an option for first-line therapy in patients with mild or moderate OSA, and should be preferentially selected for patients with limiting social circumstances or anticipation for extensive travel, where the use of CPAP may not be practical.

CONCLUSIONS

OSA is a chronic disease requiring long-term treatment with potentially uncomfortable devices such as CPAP or MAD. The veteran population has unique challenges, including limiting social circumstances and difficulty with long-term follow up; therefore, adherence to first-line therapy is of great importance. Patients with limiting social circumstances, including homelessness, lack of access to electricity, and frequent travel, demonstrate excellent adherence to MAD treatment.

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SUBMISSION & CORRESPONDENCE INFORMATION

DISCLOSURE STATEMENT

Prevalence of Malocclusion in Children With Sleep-Disordered Breathing

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STUDY OBJECTIVES: Correction of retrognathia or maxillary constriction has previously been shown to ameliorate sleep-disordered breathing symptoms in some children. The purpose of this study was to examine the prevalence of dental features that indicate a need for early orthodontic treatment in a cohort of children referred to a tertiary care center for the management of sleep-disordered breathing.

METHODS: A prospective observational cross-sectional study of 90 consecutive children aged 5 to 10 years, assessed at the otolaryngology clinic of a tertiary care hospital over a 14-month period, was performed. All subjects underwent a full clinical assessment by the attending otolaryngologist and orthodontist. Indications of orthodontic intervention and airway features were recorded.

RESULTS: The average patient age was 6.8 years. In terms of maxillary constriction, 15.5% of patients had a posterior crossbite, whereas 5.5% of patients had an anterior crossbite. Significant retrognathia (overjet > 7 mm) was reported in 4.8% of patients, and 8.5% of patients presented with an excessive deepbite (overbite > 90%).

CONCLUSIONS: The prevalence of malocclusion in this cohort of children with suspected sleep-disordered breathing was not greater than what has been reported for the general population. Maxillary expansion and mandibular advancement were indicated in 15.5% and 4.8% of the sample, respectively.

KEYWORDS: children, obstructive sleep apnea, orthodontics, sleep apnea complications

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INTRODUCTION

Sleep-disordered breathing (SDB) is characterized by an abnormal respiratory pattern during sleep, and encompasses a spectrum of disorders that increase in severity from snoring to obstructive sleep apnea (OSA). OSA is the most significant presentation of SDB and is now recognized as a serious medical condition that affects an estimated 1.2% to 5.7% of children.[1,2] Morbidity associated with OSA in children includes failure to thrive, attention deficit and hyperactivity disorder, excessive daytime sleepiness, and poor learning. There is also significant concern about long-term cardiopulmonary risks in these patients.[3] The inadequate function and collapse of the upper airway during sleep is a dynamic and complex process. As such, OSA in children can result from a combination of factors including inflammation and altered neuromuscular tone of the upper airway, obesity, and hypertrophic adenoids and tonsils. As the pathophysiology of SDB in children has become better defined and understood, altered craniofacial morphology has been shown as a contributing risk factor for the disease in some children.[4] The most commonly reported dentofacial characteristics in children with OSA are those associated with a long narrow face, including mandibular retrognathia, maxillary constriction, increased lower face height, and a convex profile.[5–7]

The correction of two specific dentofacial anomalies, maxillary constriction and mandibular retrognathia, have been previously shown to significantly improve or eliminate both objective and subjective measures of OSA in children.[8–13] Villa et al.[8] first described the use of a functional appliance, a monoblock-type intraoral device that positions the mandible forward, for the treatment of retrognathia associated with OSA in children. In children with transverse constriction of the maxilla, rapid maxillary expansion is indicated. This involves distraction of the midpalatal suture over a period of several weeks using an intraoral expansion appliance bonded to the upper molar teeth. Several studies have demonstrated the effectiveness of maxillary expansion in treating OSA in children both with[12] and without[11] tonsillar hypertrophy, and that results are persistent after a period of 24 months.[13]

Although orthodontics as an adjunctive form of treatment for OSA shows promise in carefully selected children with specific dentofacial abnormalities, it has not been widely adapted and the extent to which it may be applicable in everyday clinical settings has been questioned.[14] A better understanding of the prevalence and severity of altered craniofacial morphology and malocclusion in this patient population will facilitate the design and implementation of interdisciplinary treatment of pediatric OSA. The aim of this study was to report on the prevalence of malocclusion and indication for specific forms of orthodontic treatment in a cohort of children referred to a tertiary care pediatric center for the management of SDB.

METHODS

Eligible subjects were 5 to 10 years of age, and referred to the otolaryngology clinic at British Columbia Children's Hospital over a 14-month period for evaluation of SDB following an initial clinical assessment by their primary care physicians. Under an integrated multidisciplinary approach to SDB assessment in this department, referrals with a primary concern of SDB are consolidated to clinics attended by both an otolaryngologist and orthodontist. As such, during their initial visit all patients underwent a baseline interview and comprehensive clinical examination by both specialists during the same initial visit. Otolaryngologic and orthodontic clinical data were collected prospectively. The orthodontic assessment included a standardized extraoral and intraoral examination evaluating facial balance, tooth eruption, jaw morphology, and occlusion. Characteristics related to specific indications for early orthodontic intervention were recorded, including anterior crossbite (of at least one tooth), posterior crossbite (of at least one tooth), severe excess overjet (horizontal overlap of the anterior teeth > 7 mm), and severe excess overbite (vertical overlap of the anterior teeth ≥ 90%). The otolaryngology evaluation included assessment of tonsil[15] and adenoid[16] size as part of an assessment of nasal, nasopharyngeal, and oropharyngeal anatomy and function. For this study patients with cleft lip and/or palate, craniofacial syndromes, significant medical comorbidities, or those outside the age range of 5 to 10 years were excluded on the basis of potentially being unsuitable for any proposed orthodontic treatment.

Descriptive statistics summarized baseline characteristics, as well as orthodontic and otolaryngologic examination findings. Variables were presented as percentages and analyzed using the Pearson chi-square test or the Fisher exact test for categorical data and the Mann–Whitney U test for continuous variables. Statistical significance was assessed at $P < .05$. Data were analyzed with SPSS software (version 15; SPSS, Chicago, Illinois, United States). The Clinical Research Ethics Board of the University of British Columbia approved this project (#H14-01596).

RESULTS

During the study period data were obtained on 90 consecutive subjects meeting the inclusion criteria. Initial patient characteristics and examination findings are shown in **Table 1**. The parents of 46.7% of the patients reported both a history of mouth breathing and witnessed apneas during sleep, whereas 59.1% of the patients presented with either grade 3/4 or 4/4 tonsillar hypertrophy on the Brodsky grading scale.

Overall in terms of maxillary constriction, 15.5% of patients had a posterior crossbite, whereas 5.5% of patients had anterior crossbite. An increased overjet > 7 mm was reported in 4.8% of patients, and 8.5% of patients presented with an overbite of at least 90%. No statistically significant differences were observed between male and female patients for any of the variables reported, except for Brodsky grade of tonsillar hypertrophy (more boys had grade 1/4 tonsillar hypertrophy than girls [33.3% versus 5.3%], and more girls had grade 4/4 tonsillar hypertrophy than boys [34.2% versus 9.1%])

The outcome of the clinical consultation in terms of patient treatment was varied and based on severity of sleep-related symptoms, clinical findings, and parental concerns. A polysomnography study was scheduled for 7.3% of the patients and 25.5% of patients were scheduled for adenotonsillectomy. A course of intranasal steroid therapy was prescribed for 32.7% of patients, and 34.3% of the patients were asked to follow up with their family physicians, having no specific indication for medical treatment at the time of assessment mainly due to symptoms improving since the time of initial referral. Patients presenting with a malocclusion requiring early orthodontic intervention were referred for treatment to a hospital or community-based orthodontist.

DISCUSSION

The current study reports the prevalence of malocclusion in a cohort of children referred to a tertiary care center for evaluation of suspected SDB. Altered craniofacial morphology is now established as an etiological factor in pediatric OSA, and the need to investigate this population and the efficacy of orthodontic treatment has been recently emphasized.[17] Although adenotonsillectomy has and will likely remain the gold-standard treatment for pediatric OSA, as a recent large multicenter study has shown,[18] a significant subset of children will not be adequately treated by surgery alone, making it desirable to find appropriate adjunctive or alternative treatments.

The correction of two specific dentofacial malocclusions, retrognathia and maxillary constriction, has been described to improve measures of OSA in children. In order to facilitate the design and implementation of future studies on orthodontic treatment of pediatric OSA, with the current study we report how often this treatment may be applicable to patients who are also most likely to benefit. No differences were found between the sexes with respect to the prevalence of any dentofacial characteristics, consistent with previous reports. The excess horizontal overlap, or overjet of the anterior teeth, results from a sagittal deficiency of the mandible and is an indication for orthodontic mandibular functional advancement. We defined the need to advance the mandible by the presence of an overjet of at least 7 mm, and 4.8% of our population fit this rigid criterion. In the general population in a similar age group, the prevalence of this excess of overjet ranges from 3.7% to 13.2%.[19–21]

A transverse deficiency of the maxilla often manifests as a crossbite of the posterior dentition, and can include primary or permanent molars, as well as canines and premolars if severe. The posterior crossbite can present either unilaterally or bilaterally and is an indication for orthodontic maxillary expansion. In the current study a posterior crossbite was found in 15.5% of patients, with no differences in prevalence between the sexes. Within the general population of a similar age group, this type of malocclusion has a reported prevalence ranging from 7.7% to 23.3%.[19–22] The prevalence of other specific forms of malocclusion that indicate a need for early orthodontic treatment included anterior crossbite (5.5%) and severe anterior deepbite (8.5%). These orthodontic findings have been reported to occur in 9.5% to 22.8%[20–22] and 5.2% to 18.1%[20,22] of the general pediatric population, respectively.

Table 1—Patient population characteristics and relevant examination findings.

	Total Sample (n = 90) n (%)	Males (n = 44) n (%)	Females (n = 46) n (%)	*P* value
Age in y, mean (SD)	6.8 (1.29)	6.7 (1.0)	6.9 (1.5)	.49
Female	46 (51.1)			
Parental report of:				
Witnessed apneas	42 (46.7)	20 (45.4)	22 (47.8)	.73
Mouth breathing	42 (46.7)	18 (40.9)	24 (52.2)	.28
Bruxism	22 (23.6)	15 (34.1)	7 (15.2)	.10
Tonsillar Hypertrophy	71*	33	38	
Grade I	13 (18.3)	11 (33.3)	2 (5.3)	.05
Grade II	16 (22.5)	8 (24.2)	8 (21.1)	-
Grade III	26 (36.6)	11 (33.3)	15 (39.5)	-
Grade IV	16 (22.5)	3 (9.1)	13 (34.2)	.05
Adenoid Obstruction	27*	9	18	.67
Grade I	4 (14.8)	2 (20.0)	2 (10.0)	-
Grade II	5 (18.5)	1 (10.0)	4 (20.0)	-
Grade III	14 (51.8)	4 (40.0)	10 (60.0)	-
Grade IV	4 (14.8)	2 (20.0)	2 (10.0)	-
Class I Canine Occlusion	43 (68.3)	22 (64.7)	21 (72.4)	-
Class II Canine Occlusion	20 (31.7)	12 (35.3)	8 (27.6)	.51
Anterior Crossbite	5 (5.5)	3 (6.8)	2 (4.3)	.67
Posterior Crossbite	14 (15.5)	4 (9.1)	10 (21.7)	.11
Maxillary Dentition	40*	18	22	
Crowding > 4 mm	12 (30.0)	5 (27.8)	7 (31.8)	1.00
Mandibular Dentition	40*	18	22	
Crowding > 4 mm	11 (27.5)	5 (27.8)	6 (27.3)	.70
Overjet 1–7 mm	60 (95.2)	29 (96.7)	31 (93.9)	-
Overjet > 7 mm	3 (4.8)	1 (3.3)	2 (6.1)	1.00
Overbite 10–40%	34 (57.6)	13 (43.3)	21 (72.4)	-
Overbite 50–80%	20 (33.9)	14 (46.7)	6 (20.7)	-
Overbite > 90%	5 (8.5)	3 (10.0)	2 (6.9)	.07

* = number of patients with available data for indicated variable.

It should be clear from the data presented that the majority of children presenting for management of suspected obstructive sleep issues will not have any obvious signs of altered craniofacial morphology, at least not in terms of readily identifiable indications for early orthodontic treatment. Although statistically significant differences in cephalometric variables have been reported among children with and without OSA,[23,24] these differences are not large (often < 2°) and may therefore be of limited clinical significance. Similarly, any subtle differences in dentofacial morphology and occlusion due to differences in SDB severity may have been missed by the rigid criteria (> 7 mm overjet, posterior crossbite) orthodontists use as an indication for early treatment. The challenges of clearly identifying children with OSA based on clinical assessments alone have also been reported in the medical literature.[25] Recently, data from a large multicenter trial also demonstrated that evaluation of clinical parameters such as tonsillar size and palate position by physical examination provides very limited information on OSA severity in prepubertal children.[26] Therefore, it would be prudent for clinicians to screen for symptoms of the disease in all patients and not just those who present with the classic associated features of adenoid facies. Should positive responses to a medical history form, interview, or questionnaire[27] lead to suspicion of an obstructive sleep disorder, the patient can then be referred the appropriate pediatric sleep specialist for diagnosis and management.

The data presented in this study have some limitations, most notably that the patient population was suspected of SDB following clinical evaluation by a primary care physician and history described by a parent or caregiver. It is possible that the referring primary care physicians have varying experiences and sensitivities to SDB problems in children, thus adding to the variability of the sample. This is in contrast to an objective diagnosis of OSA that requires polysomnography and would clearly strengthen the current findings. Because more than one-third of patients were referred back to their family physicians because of no specific treatment being required or inconclusive clinical history, it is clear that this population represents a very wide range of SDB symptoms. However, we think this population is reflective of a typical clinical setting for a regional sleep center, and should orthodontic treatment be applied to pediatric patients with OSA it would be best discussed in conjunction with the other planned interventions. Patient ethnicity is not routinely recorded at our institution and is missing from the current data. Because the incidence of some forms of malocclusion is known to vary among ethnicities, our results

may differ from those of other centers. Observationally we can report that this sample largely reflects the greater Vancouver population as a whole, which is very ethnically diverse, with large percentages of Asian and Southeast Asian in addition to Caucasian patients. An additional limitation of the data is the lack of information on patient weight or body mass index. Obesity is a known confounder in OSA in both children and adults; therefore, the potential influence of body weight or obesity on the current findings is unclear.

CONCLUSIONS

A significant prevalence of skeletal malocclusion was not found in this pediatric population with sleep-disordered breathing.

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SUBMISSION & CORRESPONDENCE INFORMATION

DISCLOSURE STATEMENT

Obstructive Sleep Apnea and Tooth Wear: Association and Confounding Factors

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Study Objectives: Obstructive sleep apnea (OSA) is a common health problem that is not adequately managed because of the low percentage of patients that receive the appropriate diagnosis. The multidisciplinary nature of sleep disorders mean that those other than physicians (including dentists) could aid in the identification of patients at risk for OSA. This study aimed at investigating the frequency and the association of tooth wear in patients with OSA.

Methods: Patients were selected if they had undergone a sleep study for suspected OSA. Tooth wear was assessed in these patients and was classified as mild, moderate, or severe. Anthropometric data were also obtained. Descriptive statistics and correlation analysis were performed to assess the association between tooth wear and OSA. Multiple regression analysis was also performed.

Results: Ninety-nine patients met the inclusion criteria. Using the apnea-hypopnea index to classify OSA, 31 patients had no OSA (control group). Thirty-four patients had mild OSA, 21 had moderate OSA, and 13 had severe OSA. The frequency of severe tooth wear increased as the severity of OSA increased. The frequency was zero, 5.9%, 28.6%, and 61.5% for patients without OSA, and those with mild, moderate, and severe OSA, respectively. Spearman correlation indicated the presence of a statistically significant association between the severity of tooth wear and the severity of OSA. Multiple regression analysis indicated that the severity of OSA and age affected significantly the severity of tooth wear.

Conclusions: More studies are needed on the association of tooth wear and OSA.

Keywords: age, apnea-hypopnea index, obstructive sleep apnea, OSA, tooth wear

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INTRODUCTION

Obstructive sleep apnea (OSA) is characterized by episodes of complete and/or partial collapse of the upper airway accompanied by a decrease in oxygen saturation. These events provoke temporal arousal and sleep fragmentation that lead to nonreparative sleep.[1,2] The repeated oxygen desaturation and saturation provokes endocrine and metabolic disturbances that increase the risk of systemic complications.[3,4] Many studies have established OSA as a risk factor for arterial hypertension and cardiovascular and cerebrovascular complications.[3,5–8] OSA has also been related to traffic accidents, and a higher mortality has been reported among patients with OSA.[9,10]

Despite these consequences, OSA is still not adequately managed. It has been estimated that only 10% of the population with OSA receive a diagnosis and undergo treatment.[11] Furthermore, it is estimated that more than 20% of patients have an apnea-hypopnea index (AHI) higher than 5, and 2% to 8% have severe OSA.[2,5] The prevalence of OSA has been reported to be 3.1% to 7.5% in men and 1.2% to 3.2% in women.[12] These statistics make the establishment of clinical markers to detect OSA, and the need to perform a sleep study on those found likely to be diagnosed with OSA necessary.

Several studies have investigated the association between sleep bruxism and OSA[13–16]; however, conclusive evidence is still lacking.[17,18] The definitive diagnosis of bruxism is made by polysomnography.[19] Polysomnography is expensive, time consuming, and has been associated with the risk of the misdiagnosis of the absence of bruxism.[18] Moreover, patients who are suspected of having OSA may have had previous episodes of bruxism that they would not demonstrate in one night of polysomnography testing. In practice, the presence of clinical signs of occlusal wear patterns on natural teeth or restorative materials is frequently used by dentists to diagnose bruxism. All of these issues would justify the assessment of the association between tooth wear and OSA. The diagnosis of tooth wear is immediate, less expensive than polysomnography, and is made by the inspection of the tooth surface.[20] Moreover, a significant correlation between the clench index and AHI has been established.[21]

Recently, an association between tooth wear and OSA has been reported.[20] However, this study was limited by a small sample size and lack of a control group to evaluate the confounding factors that could affect the association between tooth wear and OSA. The main objectives of the current study were (1) investigate the frequency of tooth wear in patients with OSA, (2) test the association between them, and (3) identify possible confounding factors. Patients who had undergone a sleep study were recruited and their grade of tooth wear was assessed. The null hypothesis was that there is no association between tooth wear and OSA.

METHODS

This article was written following the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) guidelines. The study was performed in accordance with the Declaration of Helsinki. Patient records were retrospectively reviewed to select those who were treated in the sleep disorders unit at the dental center. Patients of both sexes were eligible to participate in this study and were selected according to the following inclusion criteria:

- Older than 18 years
- Had undergone a sleep study

The exclusion criteria were:

- Complete edentulism
- Crossbite and/or tooth wear localized in one or two teeth
- Absence of posterior teeth contact in centric occlusion
- Presence of less than 8 teeth per arch
- Partial edentulism with free distal end
- Teeth with wear having as antagonists a rehabilitated tooth

To achieve a blinded evaluation, the dentist responsible for tooth wear assessment was a prosthodontist and had no opportunity to see the results of the sleep study. The sleep technician was not aware of the presence/absence of tooth wear when analyzing the sleep recordings.

Tooth Wear Assessment

The dentist evaluated the patient's dentition for type and severity of tooth wear. Intraoral radiographs, clinical photographs, and cast models were examined. The severity of the tooth wear was then classified as[22]:

- Mild: the loss of tooth substance was limited to the enamel
- Moderate: the loss of tooth substance extended to the dentin and was not limited to the occlusal/incisal surface but limited to less than one-third of the tooth (shortening of the tooth height)
- Severe: extensive wear of the dentin was observed and it affected more than one-third of the tooth

Tooth wear was also classified into abrasion, attrition, and erosion. Abrasion means that the cause of tooth wear was exogenous objects and substances.[23] Attrition occurs when the cause was tooth-tooth contact.[23] Erosion occurs when the cause was chemical action not involving bacteria.[24]

Sleep Study

The weight and height of each patient were obtained. The body mass index (BMI) was calculated by dividing the body weight in kilograms by the body height in meters squared.

A validated respiratory polygraphy (BTI APNiA, BTI Biotechnology Institute, Vitoria, Spain) was employed to perform the sleep study at the patient's home.[25] This respiratory polygraphy is a type III home sleep monitoring device. The device measured the nasal air flow with a probe connected to a transducer and the oxygen saturation with cutaneous pulse oximetry via a finger probe (model 7000A and Modl XPOD 3012LP; Nonin Medical; Plymouth, Minnesota, United States). All sleep studies were analyzed automatically by BTI-APNiA according to the criteria of the American Academy of Sleep Medicine.[26,27] The sleep analysis was controlled by a sleep technician and was supervised by a sleep medicine specialist. The minimum time of recording was 6 hours and the minimum time of sleep was 180 minutes. The following definition of the respiratory variables were used:

- Apnea: a drop in the respiratory signal of more than 90% during a minimum of 10 seconds
- Hypopnea: a drop in the respiratory signal between 30% and 90%, accompanied by a drop in oxygen saturation ≥ 3% and/or arousal

Statistical Analysis

Quantitative data were described by the calculation of the mean and standard deviation. Continuous variables were expressed by mean ± typical deviation and were compared with analysis of variance or Kruskal-Wallis test according to the results of the normality test (Shapiro-Wilk). The patients with AHI < 5 served as a control group. Qualitative variables were expressed in number of events and were compared with the χ^2 test. The frequency of qualitative variables was also calculated. The association between severity of OSA, tooth wear, and confounders (age, sex, BMI) was evaluated using Spearman correlation test. Only factors with significant association with tooth wear and OSA were then introduced in a linear regression analysis to evaluate the collinearity of variables. Then a multiple regression analysis was performed to test the effect of OSA severity, sex, age, and BMI on the severity of tooth wear. Statistical analysis was performed using SPSS 15.0 (SPSS Inc.; IBM). Statistical significance was set at $P < .05$.

RESULTS

One hundred seventy-one records were retrospectively reviewed. A total of 99 patients were included in the analysis; 72 patients did not meet the inclusion criteria or had at least one of the exclusion criteria. Tooth wear could not be evaluated in 15 patients, teeth were restored in 23, partial edentulism with free distal end and absence of posterior tooth contact were observed in 7, presence of fewer than 8 teeth per arch in 10, complete edentulism was observed in 1, crossbite/deep overbite was observed in 4 patients, no tooth contact in 1 patient, and teeth with wear having as antagonists a rehabilitated tooth was observed in 11.

The baseline demographic characteristics of the patients are shown in **Table 1**. There were 46.5% of the patients who were males, and the mean ± standard deviation age was 54 ± 11 years. The mean BMI indicated the presence of overweight subjects among the study group. Using AHI to classify OSA indicated that 31 patients had no OSA (AHI < 5) (control group), 34 had mild OSA (5 ≤ AHI < 15), 21 had moderate OSA (15 ≤ AHI < 30), and 13 had severe OSA (AHI ≥ 30). The parameters that described oxygen saturation worsened as the severity of OSA

Table 1—Baseline demographic data and results of sleep study.

Variables	All Patients	Obstructive Sleep Apnea				P	
		Group 1 Control (n = 31)	Group 2 Mild (n = 34)	Group 3 Moderate (n = 21)	Group 4 Severe (n = 13)		
Males (females)	46 (53)	6 (25)	15 (19)	14 (7)	11 (2)	.000 [a]	Comparison of group 1 with group 3 and group 4; and between group 2 and group 4 had $P < .05$
Age (y), mean ± SD	54 ± 11	50 ± 12	53 ± 11	59 ± 9	60 ± 9	.005 [b]	Group 1 versus group 3 and group 1 versus group 4 had $P < .05$
Body mass index (kg/m^2), mean ± SD	26.2 ± 5.3	24.2 ± 5.1	25.1 ± 5.2	27.9 ± 4.1	28.3 ± 6.3	.208 [b]	
Apnea-hypopnea index (events/h), mean ± SD	13.5 ± 12.3	2.6 ± 1.4	8.8 ± 2.8	22.7 ± 4.5	36.9 ± 8.4	.000 [b]	All pairwise comparisons had $P < .05$
Minimum SaO$_2$, mean ± SD	82.8 ± 12.8	84.8 ± 14.0	85.6 ± 4.4	78.9 ± 14.1	75.9 ± 19.7	.001 [c]	Only pairwise comparisons with group 1 or group 2 had $P < .05$
Mean SaO$_2$, mean ± SD	92.3 ± 7.8	94.2 ± 2.3	93.3 ± 2.5	90.3 ± 9.8	87.3 ± 18.7	.048 [c]	Only comparison between group 1 and group 3 had $P < .05$
CT90, mean ± SD	8.3 ± 17.9	3.3 ± 7.5	4.7 ± 6.3	15.6 ± 24.9	14.3 ± 29.7	.000 [c]	Only pairwise comparisons of group 3 with group 1 or group 2 had $P > .05$
Oxygen desaturation index (events/h), mean ± SD	13.6 ± 15.7	3.6 ± 3.4	13.4 ± 20.5	25.1 ± 10.9	24.5 ± 9.5	.000 [b]	Only pairwise comparisons with group 1 or group 2 had $P < .05$
Patients with arterial hypertension	29.3%	16%	29%	38%	46%	.160 [a]	Only comparison between group 1 and group 4 had $P < .05$

[a] = χ^2 test. [b] = analysis of variance. [c] = Kruskal-Wallis test. CT90 = percentage of sleep time with oxyhemoglobin saturation below 90%, SaO$_2$ = oxygen saturation, SD = standard deviation.

Figure 1—Visual representation of the classification of tooth wear.

In the currently study, tooth wear was classified as mild **(A)**, moderate **(B)**, and severe **(C)**.

increased. The fraction of patients with arterial hypertension was significantly higher in patients with severe OSA than in the control group.

Figure 1 shows mild, moderate, and severe tooth wear. The tabulation of the data according to the severity of tooth wear is shown in **Table 2**. There was a proportional relationship between the severity of tooth wear and the value of the AHI. The AHI was 29.6 ± 13.0 for patients with severe tooth wear in comparison with 4.7 ± 3.0 for those with mild tooth wear. The analysis of variance indicated that these differences were statistically significant ($P = .000$). Patients were older as tooth wear increased. The percentage of males in the group was greater as tooth wear increased.

Tooth attrition was the main cause of tooth wear in most of the patients. Three patients with moderate tooth wear had tooth abrasion, in another two both attrition and abrasion coexisted, and in one patient both attrition and erosion were identified. Tooth attrition was observed in all patients with severe tooth wear and tooth erosion was additionally observed in two patients.

The tabulation of patients according to the severity of tooth wear and the severity of OSA is shown in **Table 3**. Of the control group, 74.2% had moderate tooth wear, but no individuals in the control group had severe tooth wear. As the severity of OSA increased the number of patients with severe tooth wear increased. More than 28% and 61% of patients with moderate and severe OSA, respectively, had severe tooth wear. Spearman correlation indicated the presence of a statistically significant association between the two variables (coefficient = .532; $P = .000$) (**Figure 2**). To test the influence of age, sex, and BMI in this association a linear regression analysis was first performed to evaluate the collinearity between variables. The values of variance inflation factor were all less than 3 and a multiple regression analysis was performed. The results indicated that only age ($P = .007$) and severity of OSA ($P = .021$) had a significant effect on the severity of tooth wear (Cox and Snell pseudo $R^2 = .513$).

Table 2—Baseline demographic data according to the severity of tooth wear.

Variables	Tooth Wear			P	
	Group 1 Mild (n = 13)	Group 2 Moderate (n = 70)	Group 3 Severe (n = 16)		
Males (females)	4 (9)	28 (42)	14 (2)	.002 [a]	Only pairwise comparisons between group 1 and group 2 had P > .05
Age (y), mean ± SD	44 ± 11	54 ± 10	63 ± 9	.000 [b]	All pairwise comparisons had P < .05
Body mass index (kg/m²), mean ± SD	26.7 ± 4.8	25.1 ± 5.0	29.1 ± 5.8	.129 [b]	
Apnea-hypopnea index (events/h), mean ± SD	4.7 ± 3.0	11.4 ± 10.0	29.6 ± 13.0	.000 [b]	Only pairwise comparisons between group 1 and group 2 had P > .05
CT90, mean ± SD	4.0 ± 9.2	6.0 ± 11	19.8 ± 33.5	.017 [c]	Only pairwise comparisons between group 1 and group 2 had P > .05

[a] = χ^2 test. [b] = analysis of variance. [c] = Kruskal-Wallis test. CT90 = percentage of sleep time with oxyhemoglobin saturation below 90%, SD = standard deviation.

Table 3—Distribution of patients according to the severity of obstructive sleep apnea and the degree of tooth wear.

			Tooth Wear		
			Mild	Moderate	Severe
AHI	Control (< 5)	n = 31	8	23	0
	Mild	n = 34	5	27	2
	Moderate	n = 21	0	15	6
	Severe	n = 13	0	5	8

AHI = apnea-hypopnea index.

Figure 2—Correlation between the variables of tooth wear and obstructive sleep apnea.


DISCUSSION

The results of this study support the rejection of the null hypothesis. The severity of tooth wear is significantly correlated with the severity of OSA. This is in accordance with the previously published data by Duran-Cantolla and coworkers.[20] All patients in the control group had mild to moderate tooth wear, whereas patients with more severe OSA had more severe tooth wear. All patients with severe tooth wear had OSA.

The results of the multiple regression analysis identify age as a variable that significantly affected the association between tooth wear and OSA. This has a few possible explanations. It has been found that sleep fragmentation also results in altered sympathetic activity and psychological alterations (mood changes).[28] Altered sympathetic activity can increase the chance of masticatory muscle contraction and the risk of occlusal overloading.[28] Given that arousals precipitate sleep fragmentation, and that arousals are increasingly frequent in older people, a line could be drawn connecting sleep fragmentation and tooth wear. Tooth contact occurring in association with arousals has been more frequently observed in patients with tooth grinding than those without tooth grinding,[29] and in patients with occlusal wear, a prolongation of occlusion time has also been observed.[30]

A second explanation may be that tonic masticatory muscle activity was frequently found at the conclusion of apneic events.[31–33] Interestingly, a significant correlation between the clench index and AHI was found.[21] Phillips et al. concluded that the sleep arousal or disturbances caused by sleep apnea was related to parafunctional activities.[21]
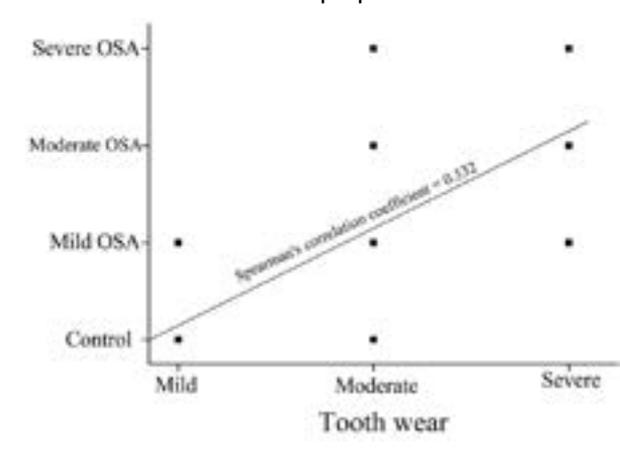
Third, it is known that the prevalence of both tooth wear and OSA increase with age.[5,34]

Pigno et al. have reported that tooth wear has been greater in patients reporting teeth grinding/clenching.[35] Several studies have investigated the association between sleep bruxism and OSA[14–16]; however, conclusive evidence is still lacking.[17,18,32] Bruxism is a factor that could be associated with tooth wear,[36] although in a 2011 study it was concluded that the overall significance of bruxism as a causative factor of tooth wear is not fully known.[37]

Tooth wear could lead to changes in the height of the lower face that could affect the patency of the upper airway. In a recent study, Sanders et al. reported that tooth loss could be an independent risk factor for OSA.[38] The loss of teeth would provoke changes that could compromise the patency of the upper airway. These changes include the horizontal and vertical atrophy of the alveolar process, the reduction in the vertical dimension of the occlusion, the upward rotation of the mandible, and the posterior positioning of the tongue at rest.[39–42]

Along with the evaluation of the degree of tooth wear, the type of tooth substance loss (attrition, abrasion, erosion, or abfraction) was also evaluated. We found only three patients with signs of tooth erosion. Tooth wear and erosion can become more severe when sleep-related gastroesophageal

reflux is comorbid with sleep bruxism.[43] This prompted the analysis of the effect of gastroesophageal reflux disease (GERD) on the association between the severity of tooth wear and the severity of OSA. GERD is considered one of the most common chronic diseases in adults and its relation to OSA has received attention.[44,45] In one cohort study, the prevalence of GERD was significantly increased in patients with primary snoring and OSA, but the severity of OSA did not influence GERD prevalence.[44] The authors concluded that OSA was not likely a causative factor for GERD. In another study, the complicating hiatal hernia was suggested to link reflux esophagitis to OSA.[46] Yang and coworkers concluded that in patients with coexisting GERD and OSA, both awakening and arousal preceded gastroesophageal reflux events, but gastroesophageal reflux does not appear to precipitate sleep-related events.[47] The role of consumption of soft drinks on tooth wear could not be assessed due to the retrospective nature of the study.

The diagnosis of tooth wear is immediate, inexpensive, and can be made based on the clinical examination of tooth surfaces. These characteristics make tooth wear a good potential identifier of patients at risk of having OSA. The involvement of more medical professionals in identifying patients who are likely to have OSA would aid in the early diagnosis of the disease and minimize the effect of its consequences. However, scientific evidence solidifying the association between tooth wear and OSA is still needed. We encourage research groups to further investigate this association and to help establish definitive conclusions.

This study is affected by the limitation of retrospective design, in which the dependency on the availability and accuracy of medical/dental records could not be excluded. It is difficult to control bias and confounders, although the dentist who evaluated tooth wear was not aware of the results of the sleep study. Another limitation is that the method of assessing tooth wear severity is subjective. However, it is a simple assessment that all dentists can adequately provide. In the current study, the combination of study models and clinical photographs permitted the evaluation of tooth wear. In future prospective studies, intraoral inspection should be included. The 32 patients with AHI < 5 served as controls to compare the results of patients with OSA. A selection bias could not be ruled out as patients were selected from those who underwent a sleep study. This means that there was a need for a sleep study from the point of view of a specialist in sleep medicine.

We think these outcomes justify the performance of prospective and controlled clinical studies to evaluate the association between tooth wear and OSA and to identify confounders that may influence this association. The results of the current study would be helpful in calculating the sample size of prospective and controlled clinical studies.

CONCLUSIONS

Tooth wear is significantly affected by the severity of OSA. Tooth wear severity may be an indicator of the presence of OSA. There is a need for more scientific evidence to further explore this relationship.

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SUBMISSION & CORRESPONDENCE INFORMATION

DISCLOSURE STATEMENT

Oral Appliance Therapy as an Alternative Therapy to Continuous Positive Airway Pressure in Severe Obstructive Sleep Apnea With Morbid Obesity: A Case Report

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Oral appliance therapy (OAT) is not recommended as a primary treatment option for severe obstructive sleep apnea (OSA). Patients with obesity are also unlikely to respond to the therapy. This report presents a case of a continuous positive airway pressure-intolerant male patient with severe OSA (apnea-hypopnea index = 55.1, lowest oxyhemoglobin saturation = 77%), and morbid obesity (body mass index = 36.26 kg/m^2), successfully treated with OAT. A custom titratable mandibular repositioning appliance was utilized for the treatment. The appliance was titrated to maximal mandibular protrusion. The follow-up sleep study shows the reduction of apnea-hypopnea index to 9.1 events/h, and the lowest oxyhemoglobin saturation level increased to 84%. This report suggests that OAT should not be ruled out in morbidly obese patients and severe OSA with continuous positive airway pressure intolerance.

KEYWORDS: custom titratable mandibular repositioning appliance, morbid obesity, oral appliance therapy, severe OSA

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INTRODUCTION

According to the most recent recommendations from the American Academy of Sleep Medicine, oral appliance therapy (OAT) can be recommended as a primary treatment option for patients with mild to moderate obstructive sleep apnea (OSA).[1] Continuous positive airway pressure (CPAP) remains a primary treatment for patients with severe OSA. However, OAT in severe OSA can be recommended when CPAP fails or by patient preference.[1] It has been reported that patients with high body mass index are not likely to respond to OAT.[2] The OAT efficacy rate also depends on amount of mandibular protrusion. The success rates were reported to be significantly higher with further advancement of the mandible.[3,4] This case report discusses a successful treatment using a titratable mandibular repositioning appliance (MRA) in a CPAP-intolerant patient with severe OSA and morbid obesity. The MRA was maximally titrated to increase the treatment efficacy. This report challenges a conventional assertion that OAT is mostly recommended in mild to moderate cases.

REPORT OF CASE

A 52-year-old male presented with a 5-year history of severe OSA. Sleep-related symptoms included loud and disruptive snoring, witnessed apnea, nocturnal awakening, and daytime sleepiness. In addition to severe OSA, a diagnosis of morbid obesity (body mass index = 36.26 kg/m^2) and hypertension was made. The patient currently takes several medications to normalize his blood pressure, and a low dose of aspirin to prevent heart attack and stroke. Although CPAP therapy provided some improvement, the patient sought alternative treatment options because of his inability to use CPAP regularly

and its cumbersomeness because of his frequent travels. His sleep physician eventually referred him for OAT with a custom titratable MRA. Baseline diagnostic polysomnography (PSG) showed an apnea-hypopnea index of 55.1, and lowest oxyhemoglobin saturation of 77%. The baseline Epworth Sleepiness Scale score was 10 on the day of diagnostic PSG.

The patient reported no history, signs, or symptoms of temporomandibular disorder syndrome. The sagittal range of mandibular excursion is determined to be 15 mm. The patient was fitted with the Fusion appliance (Somnomed, Frisco, Texas) to allow for greater mandibular advancement. The initial mandibular protrusion was set at 66% (10 mm advancement). Accommodation to the appliance was successful, with good subjective adherence without reporting any intraoral or extraoral discomfort. After the patient had 2 weeks of getting accustomed to nightly use of the MRA, the titration began and the appliance was titrated to maximal mandibular protrusion (100%, 15 mm) over a period of 2 months. Although maximal mandibular advancement is usually not a titration goal for all patients, but because of the OSA severity and obesity, it was explained to the patient that the titration goal was to advance the mandible maximally to increase the treatment efficacy. He was encouraged and motivated at every subsequent follow-up to reach the goal. After the titration was completed, the patient reported nightly use of the MRA, averaging approximately 7 h/night. He reported significant improvement in his sleep quality and reduction of daytime tiredness and sleepiness without significant side effects and discomfort. The Epworth Sleepiness Scale score was 2 after 2.5 months using the appliance. The patient was then referred for a follow-up PSG. The PSG reveals a significant apnea-hypopnea index reduction to 9.1 events/h, lowest oxyhemoglobin saturation increase to 84%, and mean oxygen saturation of 92%.

DISCUSSION

This report demonstrates that OAT with custom titratable MRA can be used successfully in a case of severe OSA with morbid obesity. The patient in this report has a larger than average range of mandibular protrusion, allowing for increased mandibular advancement. The maximal MRA advancement and tolerability could contribute to treatment success. Several authors reported dose-dependent relationship between degrees of mandibular protrusion and OAT efficacy.[3,4] In addition, Almeida et al. reported that additional titration during a follow-up PSG can increase the treatment success rate.[5] The author also believes that repeatedly encouraging the patient to reach a titration goal also contributes to the treatment success. This helped to increase the patient's motivation and appliance tolerabilty during titration. A similar approach has been shown to increase adherence among patients using CPAP.[6] This report suggests that OAT can be efficacious in morbidly obese patients with severe OSA and CPAP intolerance.

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SUBMISSION & CORRESPONDENCE INFORMATION

DISCLOSURE STATEMENT