# Oral Appliances in Obstructive Sleep Apnea

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## **KEYWORDS**

- Obstructive sleep apnea Snoring Oral appliance therapy
- Mandibular advancement device Temporomandibular joint Home sleep testing
- Bruxism Dental sleep medicine

## **KEY POINTS**

- Oral appliance therapy (OAT) should be considered for appropriate patients who request treatment of primary snoring or obstructive sleep apnea and express a preference for OAT rather than alternative treatment.
- Patients who are considered appropriate for OAT should ideally have a minimum of 10 healthy, well-supported and distributed teeth of sufficient size and contour in each arch; and have a stable temporomandibular joint system without pain or restriction during lateral or protrusive excursions.
- Dentists who treat patients with sleep disorders require advanced training in dental sleep medicine, which is not commonly provided in dental school or residency programs.
- There are many types of oral appliances available, and these should be selected from patient anatomy, physiology, sleep behavior, and preferences.
- Patients who have been treated with OAT should maintain long-term follow-up care with both dentists and physicians beyond the initial adjustment period.

## BACKGROUND

Oral appliances for the treatment of airway obstruction were first addressed in 1923 in the literature by French pediatrician, Pierre Robin,<sup>1</sup> who described the fall of the base of the tongue as the cause of nasopharyngeal impairment and proposed a prosthetic device to correct "the dysmorphic atresia of the mandible." However, these appliances were not commonly used for the treatment of sleep disordered breathing until the early 1980s, when a tongue-retaining device for the treatment of snoring and sleep

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apnea was described by Cartwright and Samelson.<sup>2</sup> This device was followed by renewed interest in mandibular advancement devices (MADs) that reposition the mandible in a protrusive position in order to help maintain the patency of the upper airway during sleep.

The ensuing popular demand for these appliances led to a plethora of appliance designs being targeted to both the dental professional and directly to the general population seeking relief from snoring. The US Food and Drug Administration (FDA) has classified over-the-counter antisnoring mouth guards as class II medical devices, which places restrictions on their sale without prescription by a physician. Although this classification was challenged and upheld in *United States v Snoring Relief Labs Of America* (manufacturer of SnorBan an OTC mouthpiece), these devices continue to be readily available over the Internet, taking advantage of the FDA exemptions from adequate directions for use, which require consumers to appropriately answer a questionnaire before fulfilling an order. The variety of available devices also led to much confusion among practitioners and third-party payers as to which features of appliances were fundamental to treatment success.<sup>3</sup>

In 2014, the American Academy of Dental Sleep Medicine (AADSM) released a position paper designed to address these issues and define the characteristics of an effective MAD.<sup>4</sup>

## Mechanism of Oral Appliance Therapy Action

A mandibular advancement device functions by protruding and stabilizing the mandible in order to maintain a patent upper airway during sleep.<sup>4</sup> The precise physiologic and anatomic changes that result from mandibular advancement remain elusive.

Tsuiki and colleagues<sup>5</sup> reported that the protruded mandible results in changes in the anteroposterior width of the upper airway, and positions of the hyoid bone and the third cervical vertebra. However, Ryan and colleagues<sup>6</sup> reported that MAD use resulted in an increase in the lateral dimension of the velopharynx greater than the increase in the anteroposterior dimension (Fig. 1).

Various clinical attributes have been associated with successful treatment outcome. These attributes include younger age, female sex, less severe obstructive sleep apnea (OSA), supine-dependent OSA, lower body mass index, and smaller neck circumference.<sup>7,8</sup>

Analysis of lateral cephalometric images have shown an association between certain characteristics, such as retrognathic mandible, lower hyoid position, and greater angle between the cranial base and mandibular plane, with favorable MAD outcomes. However, none of the cephalometric associations are considered strong enough to have any clinically significant predictive value.<sup>9</sup>

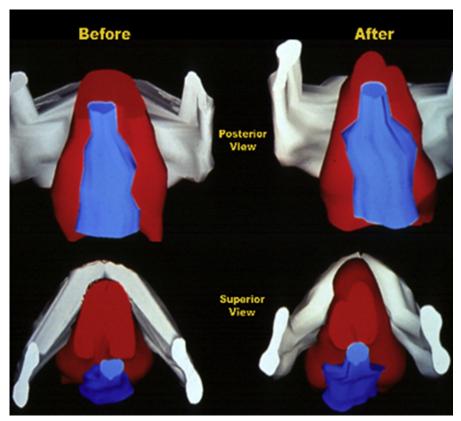
In short, there is currently no reliable way to predict who will respond positively to MAD based on observable clinical features. In some patients, mandibular advancement results in improvement in the airway obstruction, whereas in others it results in increased obstruction.<sup>10</sup> However, Remmers and colleagues<sup>11</sup> reported predicting MAD therapeutic success using a remotely controlled mandibular positioning device during polysomnography.

## Definition of an Effective Oral Appliance

The abundance of trademarked custom MAD appliances available on the market all share the common characteristic of protrusively repositioning the mandible. Differences in materials, weight, size, range, placement of protrusive element, and a host

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**Fig. 1.** Three-dimensional reconstruction of the velopharynx before and after MAD use. Red: tongue; white: mandible; blue: airway. (*Courtesy of* Alan A. Lowe, DMD, PhD, FRCD, Vancouver, British Columbia.)

of other factors provide dentists with a wide variety of appliance choices to accommodate patients' physiologies and preferences (**Table 1**). Studies support that custommade, adjustable MADs are superior in efficacy to prefabricated and nonadjustable alternatives.<sup>12,13</sup> The tongue-retaining device has similar efficacy but lower compliance than the MAD, but remains an option for significantly or partially edentulous patients.<sup>14</sup>

In 2014, the AADSM published a position report defining what constituted an effective oral appliance for the treatment of OSA in an effort set the standard of care and provide scientific rationale for the inclusion or exclusion of various device parameters.<sup>4</sup>

This article defined an effective oral appliance as one that:

- Has a dual arch design
- Is adjustable in a way that permits gradual protrusive advancement over a range of at least 5 mm
- Has an expected lifespan of at least 3 years
- Has a mechanism of protrusion that is verifiable and reversible
- · Is custom fabricated for optimum fit and comfort

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Table 1	
The variations of some	commonly used MAD designs

Materials	Laser-sintered polyamide 12 body, polyamide 11 removable bars	Acrylic resin, stainless steel screw mechanism and bar	Acrylic resin, stainless steel screw mechanism	Control cured Poly (methyl methacrylate)
Protrusive mechanism	Replaceable bars of marked length	Telescopic fixed bar, adjustment screw on upper element with millimeter ruler	Fixed dorsal fin, adjustment screw on lower element	Fixed dorsal fin, no moving parts
Protrusive range	15 mm in 0.5-mm increments	8 mm, continuously variable	5 mm, continuously variable	2 upper and 2 lower interchangeable elements for a maximum of 3 different positions

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## Efficacy

Several studies provide evidence for the efficacy of MADs in reducing the overall apnea-hypopnea index [AHI], but with lower effectiveness compared with continuous positive airway pressure (CPAP). Treatment success across all levels of OSA severity using MADs is around 50%, with an overall average reduction in baseline AHI of 55%. MADs were also shown to have a positive effect on snoring and daytime symptoms, decreasing excessive daytime sleepiness and improving quality of life compared with placebo.<sup>8,12,13,15</sup> These results were more evident when the MADs were custom made compared with prefabricated ones.<sup>16</sup>

In a recent meta-analysis, Sutherland and colleagues<sup>17</sup> showed that 37% of patients using MADs achieved an AHI less than 5/h, 52% achieved AHI less than 10/h, and 64% reduced AHI by greater than or equal to 50%. Response rates were lower in patients with severe OSA; however, 70% of those showed a reduction in AHI greater than or equal to 50%, and 23% had complete resolution of OSA.

## Compliance

MADs have higher compliance rates than CPAP with a median use of 77% of nights during the first year.<sup>15,18</sup> A short-term study by Philips and colleagues<sup>18</sup> showed that subjective reports of nightly compliance were less for CPAP compared with MAD.

## Side Effects of Mandibular Advancement Devices

MAD use is usually associated with mild and transient side effects that tend to resolve within several days or weeks, given that the device has a good fit and is used by the patient regularly.<sup>19</sup>

Commonly reported side effects include:

- Temporomandibular joint (TMJ) discomfort or pain
- Myofascial pain
- Tooth tenderness
- Excessive salivation
- Gum irritation and bleeding
- Dry mouth

Occasionally, side effects negatively affect treatment compliance, but significant and persistent side effects are rare.<sup>13,15</sup>

Long-term MAD use may lead to dental and skeletal side effects that include:

- Decrease in overjet and overbite
- Retroclination of the maxillary incisors
- Proclination of the mandibular incisors
- Increases in the mandibular plane angle
- Increases in the anterior facial height
- · Decrease in the number of occlusal contact points
- Anteroposterior change in occlusion<sup>20,21</sup>

Morning jaw exercises following MAD use have been shown to:

- Improve compliance
- Reduce side effects
- Improve quality of life
- Reduce sleep symptoms
- Alleviate muscle stiffness
- Aid in the mandible returning to its normal position<sup>22,23</sup>

## Hybrid Therapy

The use of a hybrid therapy combining nasal CPAP with MAD therapy for patients with OSA has been reported in the literature. Thornton<sup>24</sup> reported the first case in 2002 of combined MAD and CPAP therapy in a patient with severe OSA who initially could not tolerate treatment with CPAP because of increased pressures and leakage, and later failed treatment with MAD because of TMJ symptoms at maximum protrusion. The combination therapy was better tolerated by the patient with fewer side effects, because the combination therapy allowed for the use of a lower CPAP pressure and less advancement of the MAD.

This treatment strategy leads to reduced CPAP pressure, better fit, less leakage, and greater compliance.  $^{\rm 24}$ 

Another case report was published by Denbar<sup>25</sup>; both reports agree that MADs increase the upper airway size, decreasing the need for high CPAP pressures to maintain airway patency with combination therapy, and leading to better tolerance than with CPAP or MAD alone.

A study by El-Solh and colleagues<sup>26</sup> in 2010 included 10 patients who were using MAD therapy for OSA after they could not tolerate CPAP and still had incomplete response to treatment. This study showed that combination therapy was well tolerated by all patients and resulted in a reduction of CPAP pressure and AHI by 29% and 86% respectively from baseline.<sup>26</sup>

This finding suggests that combination therapy may be effective in patients who cannot tolerate treatment with either CPAP or MAD alone.

#### Patient Selection

#### Clinical examination of oral appliance candidates

An oral examination preceding a referral to a dentist for oral appliance therapy (OAT) should include evaluation of the overall condition of the existing dentition, their supporting structures, the TMJ, and health of the soft tissue (**Box 1**).

#### Dental Caries and Oral Appliance Therapy

The teeth that support an MAD should be free from active dental caries, periodontally healthy, and structurally sound in order to withstand the forces resisting the displacement of the arch over the long term.<sup>27–29</sup>

Evaluation of potential MAD candidates should include a complete intraoral examination that includes visual inspection of the teeth for caries, structural compromise, and their supporting tissues. Advanced dental decay can result in the devitalization of the pulp chamber, which can in turn lead to pain that is exacerbated by tapping

#### Box 1

#### Characteristics of an ideal oral appliance candidate

- No active dental decay or periodontitis.
- A stable dentition with at least 10 well-supported teeth well distributed in each arch.
- A healthy TMJ complex with pain-free and unrestricted protrusive, lateral, and vertical excursive movements.
- Has been diagnosed with OSA and expresses a desire for a nonsurgical alternative to positive airway pressure treatment.
- Expresses a desire for a nonsurgical treatment of primary snoring.

the affected tooth with a mirror handle or similar instrument. These necrotic chambers often drain to the buccal and lingual surfaces, resulting in a draining fistula adjacent to the affected root (Fig. 2).<sup>30</sup>

The use of a removable oral appliance can lead to increased tooth decay by acting as a new retentive surface for the colonization of *Streptococcus mutans* and other cariogenic bacteria.<sup>31</sup> In addition, any appliance that covers the surface of the teeth has the potential to compromise the caries-protective cleansing effect of saliva, which can lead to an increased rate of dental caries.<sup>32</sup> Likewise, xerostomia (dry mouth), immune suppression, or any other condition that reduces the ability to resist dental decay or periodontal inflammation should be addressed before referral for an oral appliance.<sup>33,34</sup>

#### Can the Existing Teeth Support a Dental Appliance?

MADs reposition the mandibular arch to a protrusive position, and place a protrusive force on the lower teeth and an equal and opposite retrusive force on the upper teeth. In addition, oral appliances that have the upper element connected to the lower element by a hinge, bar, or elastic can act to dislodge the appliance when the mouth is opened. Accordingly, the teeth retaining the appliance should be large enough, adequately secured in bone, and possess the physical undercuts necessary to resist the various forces placed on the appliance.

Although a minimum of 10 healthy teeth per arch is traditionally considered the general requirement to retain most types of tooth-borne MADs, it must be considered that not all teeth provide equal resistance to unwanted tooth movement, also known as anchorage.<sup>35</sup> This anchorage is generally related to the size and root area of the teeth that are secured to bone, with the canines and molars providing significantly greater anchorage than the smaller rooted incisors and bicuspids.<sup>36</sup>

In situations in which natural undercuts are inadequate to retain an MAD, dentists can alter the contour of the teeth either by enameloplasty or the addition of composite resin (Fig. 3), creating undercuts that enable satisfactory retention of the appliance. In addition, if teeth are not well distributed throughout the arch, the resulting forces will be disproportionality distributed as well.

Anchorage can be compromised by periodontitis or occlusal trauma, which can lead to the loss of the tooth's bony support (Fig. 4). The root of a tooth is anchored to the supporting bone by a periodontal ligament, which is attached to both the tooth



Fig. 2. Dental caries with fistula.



Fig. 3. Short teeth and bonded undercuts; enameloplasty shown in pink and addition of composite resin in blue.

and supporting bone. In many cases, a tooth becomes visibly mobile because of secondary occlusal forces overcoming the ability of the tooth to resist those forces.<sup>37</sup> Exceptions to the paradigm that only teeth can retain an MAD are discussed in reports of MAD designs that secure their retention by means of dental implants, extraoral soft tissue, and the edentulous arch.<sup>38–40</sup>

Periodontitis can often appear as red, swollen gingiva adjacent to the teeth, and readily bleeds on probing. In other cases, the disease exists without signs of obvious surface inflammation, with the inflammatory process existing beneath the surface of the gingiva in the space adjacent to the tooth, known as the periodontal pocket (Fig. 5). Tooth mobility can easily be observed by applying gentle pressure with a mirror handle. Active periodontitis and/or mobility in 1 or more of the teeth can be

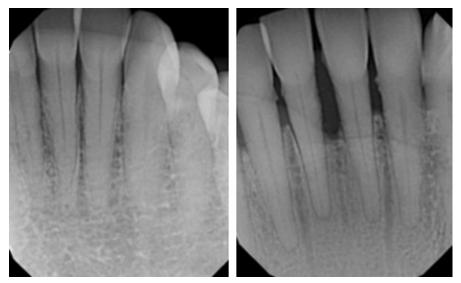


Fig. 4. Normal bone level without periodontitis (*left*). Reduced bone level and anchorage secondary to periodontitis (*right*).



Fig. 5. Periodontal probe revealing loss of bone mesial of tooth 9. Note draining fistula buccal to base of the periodontal pocket.

exacerbated by the use of an oral appliance and must be addressed before fabrication of the device is considered. Clearly, patients presenting with a high caries rate and/or active periodontal disease, coupled with a history of only emergencyrelated dental visits, are better served by alternative therapies for their sleep disordered breathing.

## Bruxism and Oral Appliance Therapy

The presence of teeth with flattened occlusal surfaces suggests a history of or active tooth grinding or bruxism, a condition that has been associated with sleep apnea.<sup>41</sup> The precise nature of this association, or whether or not there is a causal relationship between bruxism and OSA, remains unclear.<sup>42</sup> Bruxism (Fig. 6) is commonly evaluated during polysomnography by electrodes placed on the masseter muscle, but is not typically evaluated during type 3 home sleep testing.<sup>43,44</sup> Nocturnal bruxism commonly results in breakage of acrylic oral appliances (Fig. 7) and its presence suggests that the device should be fabricated from one of the newer, more durable materials.<sup>45</sup>

## Temporomandibular Joint Considerations in Oral Appliance Therapy

A healthy TMJ complex that enables the patient to have pain-free and unrestricted protrusive, lateral, and vertical movement is a prerequisite for any OAT. It is



Fig. 6. Bruxism; note the characteristic wear pattern on the lower incisors (*left*); and loss of vertical dimension resulting from destruction of the incisal portion of the dentition (*right*).

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Fig. 7. Appliance failure secondary to nocturnal bruxism.

unreasonable to expect a patient to wear an MAD if it is uncomfortable. Therefore, careful consideration must be given before attempting fabrication of an MAD for a patient with significant pain or restrictions when entering protrusive, lateral, or vertical mandibular excursions. Clinical evaluation of the TMJ complex should include observation of anything suggestive of disorder during these excursions (clicks, pops, or pain). In addition, the muscles of mastication, including the temporalis, masseter, and internal pterygoid, should be palpated and any tenderness noted.<sup>46</sup>

## Which Patients with Sleep Disorder Should Be Referred for Oral Appliance Therapy?

The July 2015 American Academy of Sleep Medicine (AASM)/AADSM guidelines<sup>47</sup> recommend that oral appliances should be offered to adult patients:

- Who request treatment of primary snoring (without sleep apnea)
  - The guideline recommends that patients who have failed traditional conservative measures such as positional therapy, weight loss, and alcohol avoidance be offered OAT.
  - Because loud snoring is often a warning sign of underlying OSA,<sup>48</sup> the diagnosis of primary snoring should be made by a sleep physician rather than a dentist. This notion has recently been challenged by the Texas Board of Dental Examiners, which passed Rule 108.12 referring to sleep studies as a screening tool that dentists may use to differentiate OSA from primary snoring and left it to the dentists' discretion to determine which patients require physician assessment before the initiation of treatment. In response, the Texas Medical Association and the AASM are currently challenging the ruling and requested the court to void the rule. This challenge has been supported by the AADSM, which maintains that treatment by a dentist may proceed only after a diagnosis of OSA or snoring has been made by a physician.<sup>28</sup>
- Are intolerant or prefer an alternative treatment to CPAP therapy
  - This new guideline no longer differentiates between different levels of OSA (mild, moderate, and severe). This recommendation was based on a metaanalysis of past studies that showed no statistically significant difference in the mean reduction in AHI before and after treatment in patients using oral appliances versus CPAP across all levels of OSA severity. However, the probability of achieving a target AHI in patients with moderate to severe OSA is significantly greater with CPAP than OAT.<sup>47</sup>

## Treatment Protocol and the Dental Referral

OAT should be undertaken by a qualified dentist only after a referral from a qualified physician trained in sleep medicine who has performed a face-to-face evaluation of the patient.<sup>49</sup>

Dentists who treat patients with sleep disorders require advanced training in dental sleep medicine, which is not commonly provided in dental school or residency programs. The AASM/AADSM defines a qualified dentist as one who has completed 25 hours of continuing education in dental sleep medicine within the past 2 years from a nonprofit organization, been designated a dental director of an accredited dental sleep medicine facility by a nonprofit organization, or has certification in dental sleep medicine from a nonprofit organization.<sup>47</sup>

The dental evaluation for OAT should include examination of the oral cavity including the teeth and their supporting structures, soft tissue, temporomandibular complex, and review of a recent complete dental radiographic survey. A medical and sleep history should be taken and sleep studies reviewed. A thorough review of informed consent that includes the benefits, alternatives, potential side effects, and risks of the proposed therapy, along with the risks inherent in not treating the condition, should be reviewed in detail and signed by the patient in the presence of a witness.

Various options in appliances should be discussed, as should the dentist's recommendation of the appliance that would be ideally suited for that patient based on the clinical examination and the patient's preferences. It is highly advantageous for the patient to have the opportunity to physically hold and examine demonstration models of the appliances. Although CPAP has been consistently proved to be more predictably effective in treating moderate to severe OSA than OAT,<sup>50</sup> it must be remembered that the primary reason most patients seek out OAT is because they expect to be able to tolerate it better than they would a CPAP device. It is intuitively obvious that patients are even more likely to be compliant with a device that they have had a part in choosing.

The postinsertion adjustment period typically involves at least several visits over approximately 3 months before referral back to the sleep physician to confirm efficacy. During this time, the protrusive settings are gradually increased to what the dentist determines (by both subjective and sometimes objective means) to be the ideal therapeutic position.

The current clinical guidelines stress open communication between dentist and physician, OAT efficacy confirmation by physician-ordered sleep testing, and short-term and long-term medical and dental follow-up once efficacy has been established. Once the physician has verified that the OAT is effectively treating the patient's condition, the AADSM recommends that patients be seen a minimum of once every 6 months for the first 2 years and then on a once-a-year basis.<sup>51</sup> During these visits, the dentist can:

- · Monitor the physical integrity of the appliance
- Reassess the patient's subjective symptoms, such as snoring and sleepiness as measured by the Epworth Sleepiness Scale
- Evaluate potential side effects of the device, such as bite changes (by comparing with preliminary models, radiographs and photographs), caries, and temporomandibular dysfunction
- Refer the patient back to the sleep physician if there are reasons to think that the current treatment is no longer effective

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## Home Sleep Testing in the Dental Setting

The AADSM Protocol for Oral Appliance Therapy for Sleep Disordered Breathing in Adults: An Update for 2012,<sup>52</sup> states that, "After this initial fitting, the dentist may obtain objective data during an initial trial period using a portable monitor to verify that the oral appliance effectively improves upper airway patency during sleep by enlarging the upper airway and/or decreasing upper airway collapsibility. If necessary, the dentist makes further adjustments to the device during a final fitting to ensure that optimal fit and positioning have been attained."

Type 3 or type 4 home sleep tests (HSTs) are commonly given to patients by qualified dentists seeking to adjust the appliances to achieve the optimal desired effect of upper airway patency. Various protrusive and vertical positions can be assessed in order to adjust the appliance to result in optimal sleep scores. This objective information becomes particularly useful in cases in which the patient does not experience subjective symptoms such as snoring or daytime sleepiness. These tests are commonly scored by computer algorithm, and although not diagnostic, can provide valuable comparative information with respect to appliance settings.

It must be stressed to the patient that dentist-administered HSTs are performed solely to aid the dentist in the adjustment of the appliance and are not diagnostic, because the diagnosis of medical conditions is not within the ethical or legal scope of the practice of dentistry. It is the opinion of this author that, before a dentist gives an HST to a patient, the patient must agree in writing that the patient understands that the results of the test will not be shared directly with the patient, but may be shared with the patient's sleep physician.

#### SUMMARY

OAT use has become an increasingly popular option in the treatment of primary snoring and OSA in recent years. Although less consistently effective than CPAP, it remains an attractive nonsurgical treatment option because of its high levels of compliance, convenience, and stealth. A focused oral examination can help determine whether or not a patient is a candidate for an MAD. Recent studies have suggested that CPAP and OAT used together can provide a higher level of success than either used alone.

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