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Oral appliances in the treatment of obstructive sleep apnea in adults

Author	Section Editor	Deputy Editor
Peter A Cistulli, MBBS, PhD, FRACP	Nancy Collop, MD	Geraldine Finlay, MD

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INTRODUCTION – Obstructive sleep apnea (OSA) is a disorder that is characterized by obstructive apneas and hypopneas due to repetitive collapse of the upper airway during sleep. The concept of using an oral appliance to relieve upper airway obstruction was first reported in the 1930s and applied to OSA approximately 30 years ago. There has been increasing interest in oral appliances in recent years because of the high prevalence of OSA and recognition of the limitations of positive airway pressure therapy (eg, frequent non-adherence) and surgical therapy.

The management of patients with OSA using an oral appliance is reviewed here. Relevant definitions and the treatment of OSA using other modalities (eg, continuous positive airway pressure) are discussed in detail elsewhere.

GENERAL APPROACH – A multidisciplinary approach is required to manage a patient who has OSA with an oral appliance. This begins with medical assessment and sleep study to confirm the diagnosis of OSA. Dental evaluation by a qualified dentist or oral surgeon follows, which includes assessment of suitability for oral appliance therapy, device selection, and fitting.

Once oral appliance therapy is initiated, the effectiveness should generally be evaluated by objective testing, since subjective assessment alone is often unreliable. Long-term follow-up should be performed by both a medical and a dental clinician. This approach is described in this section.

Diagnosis – The diagnosis of OSA should be confirmed and its severity determined prior to the initiation of therapy with and oral appliance [1,2]. Disease severity guides the selection of patients for treatment by identifying those who are at greatest risk for developing complication of OSA. It also provides a baseline from which to measure the effectiveness of therapy. The diagnostic approach to OSA in adults is described in detail separately.

Patient selection – Once it has been confirmed that a patient has OSA and the severity of the OSA measured, it must be determined whether treatment is indicated and, if so, whether an oral appliance is an appropriate modality. Indications for the treatment of OSA and selection of an appropriate modality are discussed in detail separately [2,3].

C.L. Morreale D.M.D., M.A.G.D.
Boston Center For Oral Health
400 Commonweath Avenue, Boston, MA 02215
(617) 536-4620
www.bcoh.com
Email: bcoh@bcoh.com

Oral appliances are appropriate for patients with any of the following characteristics [1,2]:

- Mild to moderate OSA, defined as an apnea hypopnea index (AHI, the number of apneas and hypopneas per hour of sleep) of 5 to 30 events per hour.
- Treatment beyond behavior modification is indicated. Behavior modification refers to weight loss, abstinence from alcohol, etc.
- Preference for an oral appliance, rather than positive airway pressure therapy.
- Non-adherence with positive airway pressure therapy, non-responsiveness to such therapy, or refusal of such therapy.

Oral appliances are most appropriate for patients with mild or moderate OSA because they may be less effective in patients with severe OSA (ie, AHI >30 events/hour). Patients with severe OSA usually receive positive airway pressure as first-line therapy, although severe OSA is not an absolute contraindication to oral appliances (successful treatment has been reported) [4,5]. For patients with severe OSA who begin positive airway pressure therapy and either do not adhere to it or want to change to an oral appliance, efforts should be directed toward improving adherence with positive airway pressure therapy before switching to an oral appliance.

Upper airway surgery may be preferable to oral appliances in patients who have an anatomic upper airway narrowing that is causing or exacerbating the OSA and can be ameliorated surgically (eg, adenotonsillar hypertrophy or retrognathia) [1,2].

Advantages – Patients may prefer oral appliances over positive airway pressure because they are easier to use, more easily portable, quiet, and do not require a power source [3]. Oral appliances may also be a useful substitute for positive airway pressure during travel.

Contraindications – There are several clinical situations in which oral appliances should not be used:

- Patients in whom rapid initiation of treatment is desirable (eg, patients with severe symptomatic OSA, sleepiness while driving, or active cardiovascular comorbidities) should be treated with positive airway pressure instead of an oral appliance. The former may be more effective and can be initiated quickly, while the latter requires incremental advancement of the mandible over weeks to months.
- Severe oxyhemoglobin desaturation (large magnitude or prolonged) should prompt initiation of an alternative therapy (usually positive airway pressure) because oral appliance therapy may not provide optima improvement [3].

  Dental conditions such as temporomandibular joint disease, periodontal disease, insufficient dentition to support appliance retention in the mouth, and inadequate range of motion of the jaw are relative contraindications and require expert dental assessment prior to consideration of treatment with an oral appliance [1]. Limited capacity for mandibular protrusion (<6 mm) may also be a contraindication, but the evidence for this is not strong. Individuals must also have sufficient manual dexterity to put in and pull out the device. One study found that 34 percent of patients with OSA may not be suitable candidates for treatment with an oral appliance [6].

Predictors of benefit – It is not yet possible to reliably identify which patients will benefit from therapy with an oral appliance. The following factors are potential predictors of a better outcome, but none have been prospectively validated:

- Mild to moderate OSA [7]. Although it seems reasonable to expect increasing severity of OSA to predict treatment failure, this is an imperfect predictor because complete responses have been reported among patients with severe OSA [4,5].
- Younger age and lower body mass index, among others [8]. Supine OSA, defined when at least twice as many events occur in the supine position compared with a nonsupine position, has been associated with treatment response in some studies [9, 10], but not others [11, 12].
- Certain cephalometric variables (eg, shorter soft palate, decreased distance between mandibular plane and hyoid bone), alone or in combination with other anthropomorphic and polysomnographic variables [4,5].
- A higher ratio of the expiratory to inspiratory flow rate at 50 percent of vital capacity (MEF50: MIF50), as determined from flow-volume curves during pulmonary function testing [13].
- Lower nasal resistance, as measured by posterior rhinomanometry [14].

Until the value of the last three predictors are confirmed by prospective investigation, we do NOT recommend routine cephalometry, pulmonary function testing, or rhinomanometry for deciding upon the appropriateness of oral appliance therapy in patients with OSA.

High therapeutic continuous positive airway pressure (CPAP) pressure has been identified as a predictor of poor responses to an oral appliance [15, 16]. The cutoff value for defining high therapeutic pressure may vary by ethnicity, however. In a Japanese study, pressures >10.5 cm H_2O were associated with poor response to subsequent oral appliance therapy [16], whereas pressures >13 cm H_2O were predictive in a primarily Caucasian population [15]. CPAP therapeutic pressure should therefore be considered in combination with other clinical factors, such as age, BMI, and OSA severity, rather than in isolation.

Single-night titration is a novel approach for predicting treatment outcome, involving incremental advancement of the mandible under technician supervision while the patient sleeps [17, 18]. One study has prospectively validated the utility of this method for predicting treatment outcome and the protrusive target across all OSA severity categories [19]. (See 'Device titration' below.)

Device Selection – The two major types of oral appliances are mandibular advancement splints and tongue retaining devices:

Mandibular advancement splints – Mandibular advancement splints (MAS, also called mandibular repositioning appliances) are the most commonly used oral appliances. They are anchored to the dental arches and induce mandibular advancement (ie, protrusion), resulting in several beneficial anatomical changes. These changes can include anteroposterior and lateral retrolingual and velopharyngeal enlargement, resulting in increased cross-sectional areas and upper airway volume.

MAS differ in configuration (ie, one or two pieces), size, material, degree of customization to a patient's dentition, coupling mechanism (ie, the method by which two pieces connect), occlusal coverage (ie,

coverage of the surfaces of the teeth that contact each other when the mouth is closed), ability to titrate the mandibular advancement (only two-piece devices can be titrated), amount of mandibular mobility permitted, and amount of oral respiration permitted:

- Two-piece MAS allow more mandibular movement and have a greater range of settings that one-piece MAS. As a result, they tend to be most comfortable.
- MAS that maintain mandibular advancement while permitting lateral jaw movement, jaw opening, or jaw closing may reduce the risk of complications and achieve better patient acceptance, although some clinicians believe the amount of vertical opening should be minimized.
- Custom-fitted MAS are preferable to self-administered over-the-counter (ie, boil and bite) varieties because they appear to be more effective, comfortable, and are more likely to be retained by both the upper and lower teeth, insuring that the lower jaw does not fall out of the appliance during sleep [20,21].
- Full occlusal coverage may be desirable to distribute the dental forces associated with mandibular advancement.

Tongue retaining devices -- Tongue retaining devices use a suction cavity to pull the tongue out of the mouth, thus improving retrolingual dimensions. These devices have not been well studied. One clear advantage is that they can be used in edentulous patients.

Comparative efficacy -- There is paucity of evidence comparing the two types of oral appliances. One trial randomly assigned 27 patients with OSA to receive either a MAS or a tongue retaining device for one week [22]. After a one week washout period, the patients then crossed over and used the other device for one week. The following findings were noted:

- There was no statistically significant difference in the degree to which the two devices reduced the apnea hypopnea index (AHI)
- There was a trend toward a greater frequency of complete and partial improvement in the AHI and symptoms with the MAS compared to the tongue retaining device
- Tolerance and compliance were better with the MAS

Device titration – MAS need to be titrated. The amount of advancement required for a clinical response generally ranges from 50 to 90 percent of the maximum protrusion [23]. However, this can vary substantially among individuals, with some patients failing treatment regardless of the degree of advancement. The titration process is generally based on clinical response over a period of weeks and months, followed by polysomnography or a suitable surrogate (eg out-of-center sleep testing [OCST]). Some clinicians titrate the appliance during follow-up polysomnography [24]. Patient tolerance is a major determinant of the extent and speed of advancement that is feasible. For most patients, tolerance increases with time.

Single-night titration is a promising approach whose practical application has begun to enter clinical practice. It involves incrementally advancing the mandible under technician supervision while the

patient sleeps [17, 18]. Single-night titration of an oral appliance during polysomnography was evaluated by two observational studies, which found that the approach successfully identified the target amount of mandibular advancement. In a randomized trial, single-night titration of an oral appliance followed by ongoing oral appliance therapy was compared to single-night titration of CPAP followed by ongoing CPAP therapy [25]. Both approaches improved subjective and objective outcomes over two months, including sleepiness, neurocognitive function, and quality of life. Single-night titration studies may also be useful as a method for predicting which individuals will have a successful treatment outcome with an oral appliance [19].

Adherence – Adherence to therapy is an important part of achieving maximum therapeutic effectiveness in studies of CPAP adherence, patients tend to overestimate their use of CPAP compared with objective adherence data obtained from the device, and average nightly use is often less than six hours.

Less is known about adherence with oral appliances, but limited data suggest that adherence may be better than CPAP [25, 26]. In a small prospective study of 51 consecutive patients beginning treatment with a mandibular advancement device for treatment of mild to moderate OSA (mean AHI 18 events per hour), adherence was measured both subjectively using daily diaries and objectively, using a temperature-sensitive microsensor embedded in the device [27]. After one-year follow-up, the discontinuation rate was 10 percent. Among continuing users, the objective mean daily use rate was 6.4 hours per night, and there was fairly close agreement between subjective and objective adherence measures (users overestimated their mean nightly use by about 30 minutes per night). Such thermal chips are now commercially available.

Follow-up – Once the dentist has completed the titration of MAS therapy, patients should generally be reevaluated by someone with expertise in the treatment of sleep disorders soon after, in order to assess the efficacy of treatment both clinically and diagnostically (ie, with testing). This consists of asking whether the symptoms of OSA have resolved and by performing fully polysomnography or OCST with the oral appliance in place [1,2]. Subjective measures alones are insufficient to assess efficacy because oral appliance therapy may be associated with a placebo effect [4,5].

Dental follow-up every six months for one year and annually thereafter is recommended [1,2]. The purpose of dental evaluation is to monitor for comfort, adherence, device deterioration, device maladjustment, bite changes, occlusion integrity, and symptoms or signs of recurrent OSA. Similarly, long-term follow-up by someone with expertise in the treatment of sleep disorders is recommended to monitor for recurrent symptoms of OSA or the development of complications of OSA.

A decision to continue or discontinue oral appliance therapy may need to be made if adverse dental effects are detected. The decision should balance the magnitude of the adverse effect, the severity of OSA, the response to therapy, and the desirability of treatment alternatives.

OUTCOME – Most trials that evaluated oral appliance therapy used mandibular advancement splints (MAS), rather than tongue retaining devices. The effects of MAS on both short-term and long-term outcome measures are reviewed in this section. In addition, clinical outcomes due to MAS are compared to those due to positive airway pressure or surgery.

Short-Term – MAS reduce the frequency of arousals and respiratory events (eg, apneas and hypopneas) during sleep, while also improving oxyhemoglobin saturation and snoring [4,5,7,28]. These effects were illustrated by a cross-over trial that performed polysomnography on 28 patients with OSA who had been randomly assigned to receive either a MAS or a control device [4]. Compared to the group that received a control device, the group that received a MAS had a better apnea hypoapnea index (14 versus 30 events per hour), minimal oxygen saturation (91 versus 87 percent), and arousal index (27 versus 41 events per hour) after one week of treatment.

Some studies suggest that complete resolution of OSA, defined as an apnea hypoapnea index (AHI) <5 events per hour during treatment, is more likely in patients with mild to moderate OSA (AHI 5 to 30 events per hour) than in patients with severe OSA (AHI >30 events per hour) [2,7]. However, this finding has not been universal [4,5]. Until more definitive data are available, clinicians should preferentially use positive airway pressure as primary therapy in patients with severe OSA because positive airway pressure has consistently demonstrated benefit across multiple trials [1].

MAS have also been shown to decrease subjective day time sleepiness [3,7,28]. However, the clinical significance of this finding is uncertain because a placebo-effect has been identified among patients who use oral appliances and the effect on objective daytime sleepiness has not been well studied. One cross-over trial randomly assigned 68 patients with OSA (respiratory disturbance index ≥ 10 events per hour plus at least two symptoms or signs of OSA) to receive a MAS or a control device [5]. The MAS induced small but statistically significant improvements in mean sleep latency (10.3 versus 9.1 minutes) and subjective sleepiness (seven versus nine), which were assessed by the Multiple Sleep Latency Test (MSLT) and Epworth Sleepiness Scale, respectively. This trial was supported by a randomized trial that compared oral appliance therapy to continuous positive airway pressure (CPAP) and found that both therapies reduced daytime sleepiness compared to baseline, as assessed by both the Epworth Sleepiness Score and the OSLER test [25].

The impact of MAS on a range of other outcome measures has been evaluated and is the subject of ongoing studies. Studies have reported a small but significant improvement of blood pressure, neurocognitive function, depressive symptoms, and quality of life [3, 29-33]. The impact of MAS on blood pressure was illustrated by a cross-over trial that randomly assigned 61 patients with OSA (AHI ≥10 events per hour of sleep) to receive a MAS or a control device for four weeks [29]. MAS treatment significantly reduced the awake mean systolic and diastolic blood pressures, with the peak effect (approximately 3 mmHg) noted during the late sleeping period and early morning. Oral appliances have also been reported to improve driving simulator performance, with a magnitude of effect similar to that seen with CPAP [34].

Long-term – The beneficial effects of MAS persist long-term in many patients [7,9,35,36]:

- An observational study followed 619 consecutive patients with OSA (mean AHI 16 events per hour of sleep) who were treated with MAS for one year [9]. Treatment was successful (defined as an AHI <10 events/hr) at one year in 54 percent of patients. However, 24 percent of patients discontinued their device, primarily due to discomfort.

- An observational study followed 33 consecutive patients with OSA (mean AHI 22 events per hour of sleep) who were treated with MAS [36]. Among the 19 patients who returned for

follow-up at five years, treatment was successful (defined as an AHI <10 events/hr) in 84 percent.

The main reasons for long-term relapse of OSA appear to be appliance failure due to wear and tear, as well as weight gain [9,36].

Compared with positive airway pressure – Most clinical trials that compared oral appliances to positive airway pressure (usually CPAP) found that positive airway pressure is superior at improving the AHI and oxyhemoglobin saturation, but not symptoms (eg, daytime sleepiness), the arousal index, or sleep architecture [2,25,37-14]. Patients generally prefer and adhere better to the oral appliance. In this way, the greater efficacy of CPAP in terms of normalization of respiratory parameters might be offset by inferior adherence with CPAP relative to an oral appliance.

In a 2006 meta-analysis of nine randomized trials (440 patients) that compared the effects of CPAP to oral appliances, CPAP reduced the AHI, improved sleep efficiency, and attenuated oxyhemoglobin desaturation to a greater degree than oral appliances [42]. However, there was little difference in subjective outcomes, such as sleepiness. Among patients who responded to both therapies, there was a strong preference for oral appliances.

Comparative efficacy data with long-term follow-up across a wider range of outcomes, including cardiovascular endpoints, are still lacking. In at least one randomized study published subsequent to meta-analysis, mean arterial blood pressure was not inferior in patients with moderate to severe OSA treated with an oral appliance compared with CPAP after one month, despite CPAP being more effective in reducing the AHI [41]. Neither treatment improved blood pressure from baseline, although less than half of patients were hypertensive at the time of enrollment. Among hypertensive patients, both treatments produced a reduction in blood pressure by an equivalent magnitude. As with previous studies, sleepiness and quality of life improved in both groups (with some measures favoring the oral device), and subjective adherence was better with oral appliance.

Compared with surgery – Studies comparing oral appliances with surgical interventions are scant. In one trial, patients with OSA (AHI 5 to 25 events per hour) were randomly assigned to receive uvulopalatopharyngoplasty (UPPP) or an oral appliance that protruded the mandible to 50 percent of the maximum [43]. At one and four years, oral appliance therapy was more likely to normalize the AHI, normalize the apnea index, and achieve a 50 percent reduction in the apnea index.

ADVERSE EFFECTS – Most patients experiences early side effects, particularly dental discomfort (usually of the upper and lower incisors). Other early side effects include temporomandibular joint pain, dry mouth or excessive salivation, gum, irritation, and bruxism [7]. These side effects are generally mild to moderate in severity and usually last a few weeks or less. It is uncommon for these early side effects to preclude continued use of oral appliances

Occlusal changes are the major long-term adverse effect of oral appliances. Tooth loosening can also occur. Occlusal changes are characterized by backward movement of the upper front teeth and forward movement of the lower front teeth and mandible, ranging from 0.4 to 3 mm [44,45]. The changes appear to be progressive over time, without a discernible endpoint [46]. In one observational study of 70 patients with an average follow-up of 7.4 years, occlusal change was identified in 86 percent [47]. In a

cohort of 77 patients with at least eight years of oral appliance use for either snoring or mild to moderate OSA, dental cast measurements demonstrated a significant reduction in overbite (2.3 mm), overjet (1.9 mm), and mandibular crowding (1.3 mm) over an average follow-up of 11.1 years [46]. An anterior crossbite of at least one tooth developed in 62 percent, and a posterior openbite (loss of occlusal contact on at least two posterior teeth) developed in 51 percent.

Occlusal changes are usually minor and do not warrant cessation of treatment. Infrequently some patients experience larger occlusal changes, necessitating a review of treatment alternatives. It is generally thought that bite changes revert after cessation of the oral appliance. Rarely, permanent abnormalities requiring orthodontic treatment occur. Thus, it is important that patients are fully informed about these risks before commencing treatment. Further research is required to define the factors influencing dentofacial sequelae of long-term treatment.

SUMMARY AND RECOMMENDATIONS

- Oral appliance therapy should be considered only after the diagnosis of obstructive sleep apnea (OSA) and the need for treatment have been firmly established. (See 'Diagnosis' above.)
- The major types of oral appliances are mandibular advancement splints and tongue retaining devices. (See 'Device selection' above.)
- Oral appliance therapy is an alternative to positive airway pressure therapy for patients with mild or moderate OSA who have failed or declined CPAP. Potential advantages of oral appliance therapy over CPAP include portability, tolerability, and improved adherence. (See 'Patient selection' above.)
- Oral appliances are generally less effective than positive airway pressure at improving the AHI and oxyhemoglobin saturation, although there is no difference in the impact on symptoms (eg, subjective daytime sleepiness) or other health outcomes (eg, blood pressure, neurocognitive function, or quality of life). Patients often prefer oral appliances. (See 'Compared with positive airway pressure' above.)
- Oral appliance therapy should not be used for routine management of patients with severe OSA (AHI >30 events per hour), since variable efficacy of oral appliances has been reported in this patient population. Contraindications to oral appliance therapy include severe oxyhemoglobin desaturation and other dental condition (See 'Contraindications' above.)
- Most trials that evaluated oral appliance therapy used mandibular advancement splints, rather than tongue retaining devices. Mandibular advancement splints reduce subjective daytime sleepiness, the frequency of respiratory events (eg, apneas and hypopneas) during sleep, and the frequency of arousals. They also improve oxyhemoglobin saturation and snoring. The effect on objective daytime sleepiness has not been well studied, but they seem to induce a small but significant improvement in blood pressure, neurocognitive function, and quality of life (See 'Outcome' above.)

- Oral appliance therapy requires multidisciplinary care and a qualified dentist and medical practitioner for baseline evaluation, device selection and titration, and outcome monitoring. (See 'Device section' above and 'Device titration' above and 'Follow-up' above.)

- The most common adverse effect of oral appliance therapy is a dental discomfort, which typically subsides within a few weeks. The major long term adverse effects are occlusal changes, characterized by backward movement of the upper front teeth and forward movement of the lower front teeth and mandible. Tooth loosening may also occur. (See 'Adverse effects' above.)

REFERENCES

1. Epstein LJ, Kristo D, Strollo PJ Jr, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. J Clin Sleep Med 2009; 5:263.
2. Kushida CA, Morgenthaler TI, Littner MR, et al. Practice parameters for the treatment of snoring and Obstructive Sleep Apnea with oral appliances: an update for 2005. Sleep 2006; 29:240.
3. Ferguson KA, Cartwright R, Rogers R, Schmidt-Nowara W. Oral appliances for snoring and obstructive sleep apnea: a review. Sleep 2006; 29:244.
4. Mehta A, Qian J, Petocz P, et al. A randomized controlled study of a mandibular advancement splint for obstructive sleep apnea. Am J Respir Crit Care Med 2001; 163:1457.
5. Gotsopoulos H, Chen C, Qian J, Cistulli PA. Oral appliance therapy improves symptoms in obstructive sleep apnea: a randomized, controlled trial. Am J Respir Crit Care Med 2002 166:743.
6. Petit FX, Pépin JL, Bettega G, et al. Mandibular advancement devices: rate of contraindications in 100 obstructive sleep apnea patients. Am J Repir Crit Care Med 2002; 166:274.
7. Cistulli PA, Gotsopoulos H, Marklund M, Lowe AA. Treatment of snoring and obstructive sleep apnea with mandibular repositioning appliances. Sleep Med Rev 2004; 8:443.
8. Liu Y, Lowe AA, Fleetham JA, Park YC. Cephalometric and physiologic predictors of the efficacy of an adjustable oral appliance for treating obstructive sleep apnea. Am J Orthod Dentofacial Orthop 2001; 120:639.
9. Marklund M, Stenlund H, Franklin KA. Mandibular advancement devices in 630 men and women with obstructive sleep apnea and snoring: tolerability and predictors of treatment success. Chest 2004; 125:1270.
10. Chung JW, Enciso R, Levendowski DJ, et al. Treatment outcomes of mandibular advancement devices in positional and nonpositional OSA patients. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2010; 109:724.
11. Fransson AM, Tegelberg A, Leissner L, et al. Effects of a mandibular protruding devices on the sleep of patients with obstructive sleep apnea and snoring problems: a 2-year follow-up. Sleep Breath 2003; 7:131.