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P H Y S I C I A N S<sup>®</sup>



## Dental Appliance Treatment for Obstructive Sleep Apnea\*

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Oral appliances for the treatment of obstructive sleep apnea (OSA) are worn during sleep to maintain the patency of the upper airway by increasing its dimensions and reducing its collapsibility. Oral appliances are a simpler alternative to continuous positive airway pressure (CPAP). Over the last decade, there has been a significant expansion of the evidence base to support the use of oral appliances, with robust studies demonstrating their efficacy. This work has been underpinned by the recognition of the importance of upper airway anatomy in the pathophysiology of OSA. The updated practice parameters of the American Academy of Sleep Medicine now recommend their use for mild-to-moderate OSA, or for patients with severe OSA who are unable to tolerate CPAP or refuse treatment with CPAP. Oral appliances have been shown to have a beneficial impact on a number of important clinical end points, including the polysomnographic indexes of OSA, subjective and objective measures of sleepiness, BP, aspects of neuropsychological functioning, and quality of life. Elucidation of the mechanism of action of oral appliances has provided insight into the factors that predict treatment response and may improve the selection of patients for this treatment modality. Longitudinal studies to characterize the long-term adverse effects of oral appliance use are now beginning to emerge. Although less efficacious than CPAP for improving the polysomnographic indexes of OSA, oral appliances are generally preferred by patients. This has the potential to translate to better patient adherence and may provide an equivalent health outcome. (CHEST 2007; 132:693–699)

**Key words:** mandibular advancement splints; obstructive sleep apnea; oral appliances; sleep apnea syndrome

**Abbreviations:** AHI = apnea-hypopnea index; CPAP = continuous positive airway pressure; OSA = obstructive sleep apnea; TRD = tongue-retaining device

The obstructive sleep apnea (OSA) syndrome is a common condition that is associated with serious adverse health consequences.<sup>1</sup> Since the first description of this disorder in the medical literature in 1965,<sup>2</sup> effective treatments that modify these health risks have emerged.<sup>3</sup> Although continuous positive airway pressure (CPAP) is the most efficacious treatment,<sup>4</sup> it requires the use of a mask interface, sealed tubing, and a device connected to a power source.

This complexity limits its acceptance by patients and leads to suboptimal treatment adherence.<sup>5–7</sup>

Oral appliances are a simpler alternative to CPAP for the treatment of OSA.<sup>8</sup> They are often considered by patients to be a more acceptable treatment modality compared to CPAP,<sup>9</sup> as they are quiet, portable, and do not require a power source. While the role of oral appliances for the treatment of OSA was unclear in the past, this has changed substantially in the last decade. There is now an increasing evidence base to support the use of oral appliances in

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*Clinical Effectiveness of Oral Appliances*

clinical practice.<sup>10</sup> The purpose of this article is to provide an overview of the role of dental appliances for the treatment of OSA, focusing on the developments that have occurred in three areas of particular clinical relevance: (1) the clinical effectiveness of oral appliances for the treatment of OSA; (2) the prediction of oral appliance treatment outcome; and (3) the adverse effects of oral appliances.

TYPES OF ORAL APPLIANCES AND MECHANISM  
OF ACTION

In broad terms, oral appliances can be regarded as being either mandibular advancement splints or tongue-retaining devices (TRDs). Mandibular advancement splints generally attach to the dental arches and mechanically protrude the mandible. They are also known as mandibular advancement devices or mandibular repositioning appliances. TRDs use suction pressure to maintain the tongue in a protruded position during sleep. Mandibular advancement splints therefore require the patient to have sufficient teeth; whereas TRDs can be used by edentulous patients. Most research studies have used mandibular advancement splints, as they represent the most common type of oral appliance.

Within these categories, there are further variations in oral appliance design. Some of these differences relate to the type of construction material, configuration, type and location of the coupling mechanism, degree of customization, and the amount of vertical opening and lateral jaw movement permitted. As these factors have the potential to influence the clinical outcome, the design features of the oral appliance need to be considered when applying research evidence to clinical practice. Oral appliances that allow lateral jaw movement and vertical opening may reduce the risk of adverse effects and improve patient adherence. It is also important to take patient factors into account, such as dentition and the hard-tissue and soft-tissue anatomy. The selection of an appropriate design will vary on a case-by-case basis. Few studies have assessed the effect of these variations on clinical outcome.

Despite these differences, the aim of all of these devices is to improve the patency of the upper airway during sleep by increasing its dimensions<sup>11</sup> and reducing its collapsibility.<sup>12</sup> This is mediated by the anatomic changes that occur as a result of the mechanical advancement of the mandible or tongue; however, the activation of upper airway neuromuscular reflexes may also be relevant. That these anatomic changes are not uniformly seen in all patients may explain differences in the treatment response.

Randomized-controlled trials<sup>13,14</sup> using a cross-over design and an inactive acrylic dental plate as a placebo have confirmed that oral appliances are effective for the treatment of OSA, across all grades of severity. Applying rigorous outcome criteria, a complete response (reduction of the apnea-hypopnea index [AHI] to  $< 5$  events per hour) can be expected in approximately 35 to 40% of patients and a partial response ( $\geq 50\%$  reduction in AHI compared to baseline, but residual AHI remaining  $> 5$  events per hour) in 25% of patients. Treatment failure occurs in approximately 35 to 40% of patients.<sup>13,14</sup> Thus, approximately two thirds of patients can expect a clinically important response to oral appliance treatment.

Compared to CPAP, oral appliances are less efficacious for improving the polysomnographic indexes of OSA. In all seven cross-over trials<sup>15-21</sup> comparing oral appliance treatment with CPAP, CPAP achieved a greater degree of improvement of AHI and oxygen saturation. Despite this, there were similar improvements in subjective and objective measures of daytime sleepiness. These comparison studies also indicate that, in general, patients find oral appliances to be a more acceptable treatment compared to CPAP. The extent to which a treatment alleviates the health risk associated with a disease in clinical practice is a function of its efficacy and the treatment adherence. The greater acceptance by patients of oral appliances could result in better treatment adherence and provide equivalent clinical effectiveness, despite the lower efficacy of oral appliances for improving the polysomnographic indexes of OSA.

When results from oral appliance treatment trials were pooled, an adherence rate of 77% at 1 year was found.<sup>10</sup> Objective adherence data for oral appliances are limited. A study<sup>22</sup> using a novel intraoral monitoring device to assess objective adherence found that the average use of the oral appliance was 6.8 h per night, which is similar to the self-reported adherence in other studies.<sup>13,20</sup> In contrast, 46% of patients used CPAP for at least 4 h per night for  $> 70\%$  of nights.<sup>7</sup>

The modification of the health risk associated with OSA is a key goal of treatment. To this end, the evaluation of the effect of oral appliances on these clinical end points has been an important new research focus.

Cardiovascular outcomes represent an important measure of the clinical impact of treatment for OSA. Two randomized, placebo-controlled trials<sup>13,15</sup> using intention-to-treat analyses have assessed the effect of

oral appliance treatment on BP. Both studies showed a modest reduction in the 24-h BP (2 to 4 mm Hg) over a period of 1 month<sup>13</sup> and 3 months.<sup>15</sup> Whether certain subpopulations are more likely to achieve a reduction in BP with oral appliance treatment (such as those patients with excessive daytime sleepiness) and the impact on metabolic function and other cardiovascular end points (including endothelial function and cardiovascular events and mortality) are issues that remain unresolved. Early indications are that oral appliance treatment may have a positive impact.<sup>23</sup>

The effect of oral appliance treatment on neuropsychological functioning has been examined in studies using inactive oral devices,<sup>24</sup> placebo tablets, and CPAP as comparisons.<sup>15</sup> A small-to-moderate improvement in psychomotor speed was found after treatment for 1 month with an oral appliance, but there were no changes in other aspects of neuropsychological functioning.<sup>24</sup> Comparisons of the effect of oral appliances and CPAP on neuropsychological functioning are conflicting. Although no differences were reported in one study,<sup>17</sup> another study<sup>15</sup> found that oral appliances and CPAP have differing effects on a range of neuropsychological parameters. The overall quality of evidence in this area is weak. There are only a small number of studies using different neuropsychological parameters as outcome measures. Work is needed to better define the impact of oral appliance treatment on neuropsychological functioning. Improvements in objective measures of sleepiness using the maintenance of wakefulness test<sup>25</sup> and the multiple sleep latency test<sup>13</sup> have been demonstrated, but there have been no published studies of the effect of oral appliance treatment on motor vehicle accident risk or workplace safety.

Oral appliances improve the quality of life of patients with OSA. When measured using validated questionnaires (Functional Outcomes of Sleep Questionnaire or the Short Form 36), quality of life is improved by oral appliance treatment compared to a placebo tablet.<sup>15</sup> Although the magnitude of this effect was comparable to that of treatment with CPAP, another study<sup>17</sup> found that treatment with CPAP was superior. Further placebo-controlled trials are needed to investigate this aspect of oral appliance treatment. The clinical benefits of oral appliance treatment are compared to those of CPAP in Table 1.

#### *Prediction of Oral Appliance Treatment Outcome*

It is clear that not all patients are able to achieve a successful treatment outcome with oral appliances.<sup>10</sup> A barrier to their use in clinical practice is the inability to reliably predict which patients will

**Table 1—Clinical End Points of Treatment of OSA With Oral Appliances and CPAP\***

End Points	Oral Appliances	CPAP
Improvement of snoring	++	+++
Improvement in AHI	++	+++
Improvement in oxygen saturation	++	+++
Reduction in sleep fragmentation	++	+++
Improvement in sleep architecture	+	++
Improvement in subjective and objective measures of daytime sleepiness	++	++
Reduction in BP	++	++
Improvement in neuropsychological function	+	+
Improvement in quality of life	+	+
Reduction in motor vehicle accident risk	?	+

\*An indication of the relative efficacy of oral appliances and CPAP is denoted by + (small benefit), ++ (moderate benefit), or +++ (large benefit). ? denotes an unresolved end point.

achieve a favorable treatment outcome. This can result in treatment delays and wastage of health resources. As such, the development of a method for prospectively predicting the outcome of oral appliance treatment would be of considerable clinical importance.

Many studies<sup>14,26–28</sup> have identified anthropomorphic and physiologic predictors of successful oral appliance treatment outcome. These include female gender, lower age, lower body mass index, smaller neck circumference, lower baseline AHI, supine-dependent OSA, and primary oropharyngeal collapse of the upper airway during sleep. Various cephalometric predictors of successful oral appliance treatment outcome (such as shorter soft palate, larger retropalatal airway space, decreased distance between the hyoid and mandibular plane, narrower angle from the sella to the nasion to the supramentale point, and wider angle from the sella to the nasion to the subspinale point) have also been demonstrated.<sup>14,29,30</sup> There are currently no prospective studies demonstrating the ability to predict the outcome of oral appliance treatment using these parameters, either singly or in combination.

Coinciding with an increasing recognition of the importance of the upper airway anatomy in the pathophysiology of OSA,<sup>31</sup> studies<sup>32,33</sup> have focused on other modalities for assessing the upper airway. Upper airway imaging during dynamic maneuvers has provided insight into the relationship between the functional properties of the upper airway and the treatment response. In a study by Sanner et al,<sup>32</sup> MRI of the upper airway was performed during the Müller maneuver. The patency of the upper airway with mandibular advancement was associated with a successful treatment outcome with an oral appliance,

whereas the persistence of upper airway obstruction following mandibular advancement was associated with treatment failure. Although this study<sup>32</sup> confirms that there are anatomic and functional differences between those who respond to oral appliance treatment and those who do not, MRI is not a clinically useful test for selecting patients for oral appliance treatment due to its high cost and limited availability.<sup>34</sup>

Nasopharyngoscopy is a modality for imaging the upper airway that, unlike MRI, is widely available in clinical practice and relatively inexpensive.<sup>34</sup> A study by Johal et al<sup>33</sup> based selection for oral appliance treatment on an improvement in airway patency with mandibular advancement during drug-induced “sleep” nasopharyngoscopy. Their results suggested that sleep nasopharyngoscopy may be useful for improving the outcome of oral appliance treatment, with 74% in their series of 19 patients achieving an AHI of < 10 events per hour. Acoustic pharyngometry appears to be increasingly used by dental practitioners to predict the outcome of oral appliance treatment; however, there has been no published research study that has confirmed its utility for this role.

Single-night titration studies incorporating polysomnography and incremental mandibular advancement, analogous to CPAP titration, have the potential to be a clinically useful way to predict treatment efficacy with oral appliances.<sup>35,36</sup> At a simpler level, there are preliminary data to suggest that flow-volume curves during wakefulness may differ depending on the treatment response to oral appliances.<sup>37</sup> The predictors of a favorable response to oral appliance treatment are summarized in Table 2.

### *Adverse Effects of Oral Appliances*

The advancement of the mandible or tongue, being the principal mechanism of action of oral appliances, has the potential to cause adverse effects (Table 3). Mandibular advancement splints generate reciprocal forces on the teeth and jaw that can result in acute symptoms, as well as long-term dental and skeletal changes. While mandibular advancement splints are primarily attached to the dental arches, most extend beyond these and thus apply pressure to the gums and oral mucosa. The incidence of reported side effects and complications vary significantly between studies. This is probably due to differences in the type of oral appliance used, the design of the oral appliance, the degree of mandibular advancement, as well as the frequency and duration of follow-up.

During the acclimatization period, it is common for adverse effects to develop, which are usually

**Table 2—Predictors of a Favorable Response to Oral Appliance Treatment**

Anthropomorphic and physiologic predictors
Female gender
Lower age
Lower body mass index
Smaller neck circumference
Lower baseline AHI
Supine-dependent OSA
Primary oropharyngeal collapse during sleep
Cephalometric predictors
Shorter soft palate
Larger retropalatal airway space
Decreased distance between hyoid and mandibular plane
Narrower angle from the sella to the nasion to the supramentale point
Wider angle from the sella to the nasion to the subspinale point
Upper airway anatomic predictors
Airway patency on MRI during Müller maneuver following mandibular advancement
Improvement in airway patency with mandibular advancement during drug-induced “sleep” nasopharyngoscopy
Single-night titration of mandibular advancement
Successful single-night mandibular advancement titration study

minor and self-limiting. These include excessive salivation, mouth dryness, tooth pain, gum irritation, headaches, and temporomandibular joint discomfort. The frequencies of these adverse effects vary widely, ranging from 6 to 86% of patients.<sup>10</sup> Early recognition and attention to these symptoms are important, as they have the potential to influence the patient’s acceptance of treatment.

The long-term adverse effects of oral appliance treatment have been described in a number of longitudinal studies. Earlier studies<sup>38–40</sup> observed patients for a median of approximately 2.5 years. In these studies,<sup>38–40</sup> 14% of patients using a mandibular advancement splint had occlusal changes when assessed by a cephalometric radiography. There was a reduction in overjet by 1 to 3 mm over a 5-year

**Table 3—Summary of the Key Adverse Effects of Oral Appliance Treatment**

Short-term adverse effects
Excessive salivation
Mouth dryness
Tooth pain
Gum irritation
Headaches
Temporomandibular joint discomfort
Long-term adverse effects
Reduction in overjet
Increase in facial height
Increase in degree of mouth opening
Changes in inclination of incisors
Increase in mandibular plane angle

period; however, more than half of these patients were not aware of these changes. It was noted that these occlusal changes tended to stabilize after the first 2 years of treatment.<sup>38</sup> An increase in the facial height, an increase in the degree of mouth opening, and changes in the inclination of the incisors have also been reported.<sup>38-40</sup>

More recent studies<sup>41,42</sup> have obtained longitudinal data extending up to 7 years. An increase in the lower facial height, an increase in the mandibular plane angle, and changes in the occlusion and dental arch were found. Contrary to earlier studies, the duration of oral appliance use correlated with the extent of changes in the bite relationship and mandibular posture, suggesting that these changes continue to progress with time. Another study,<sup>43</sup> observing patients for a mean of 5.4 years, suggested that the likelihood of long-term occlusal changes could be predicted by the pretreatment dental characteristics. Specifically, a smaller change in overjet (< 1 mm) at follow-up was more common in those who had a baseline overbite of > 3 mm, an overjet of < 3 mm, or in those who had used a soft elastomeric device rather than a hard acrylic device.

#### TRANSLATING RESEARCH EVIDENCE TO CLINICAL PRACTICE

The recent update of the clinical practice parameters of the American Academy of Sleep Medicine for the treatment of OSA with oral appliances recognizes the expansion of knowledge in this field. The new practice parameters state that oral appliances are indicated for the treatment of mild-to-moderate OSA in patients who prefer oral appliances to CPAP, who do not respond to CPAP, who are not suitable for treatment with CPAP, or for whom treatment attempts with CPAP are unsuccessful. As CPAP is a more efficacious treatment, it is recommended that CPAP be considered before oral appliances for patients with severe OSA.<sup>44</sup>

Overall, oral appliances provide effective treatment for approximately two thirds of patients. The remainder will not achieve a favorable treatment outcome, at least from a polysomnographic perspective.<sup>10</sup> Given that not all patients will respond to oral appliance treatment and the potential for a placebo response, there is a need for all patients to have objective evaluation of treatment outcome. An initial clinical assessment and objective overnight monitoring should be performed to confirm the presence of OSA and to determine its severity. After construction of the oral appliance and a period of acclimatization, a clinical review and another objective assessment to determine the effectiveness of treatment are strongly

recommended. Ideally, the treatment should be provided by a multidisciplinary team, comprising a sleep physician and a dental practitioner with expertise in the management of sleep disorders.<sup>44</sup> The dental practitioner has a critical role in the assessment of the suitability of patients for oral appliance treatment and the construction of customized oral appliances.

The limitations of oral appliances need to be considered when making treatment decisions. Oral appliances have no known therapeutic effect on central sleep apnea or hypoventilation. When an immediate treatment response is required (for example, when driver safety or occupational safety issues exist), an oral appliance would be inappropriate as the period of acclimatization would cause unnecessary delay.<sup>8</sup> Similarly, if marked oxygen desaturation occurs during sleep, CPAP would be more appropriate given its superiority in improving oxygen saturation.<sup>10</sup>

Although there are a range of demographic, anthropomorphic, and polysomnographic variables that have been associated with treatment outcome, it is not currently possible to identify with certainty which patients will respond to treatment in clinical practice. For example, although patients with severe OSA are less likely to respond to oral appliance treatment, there are some patients with severe OSA who will achieve a complete treatment response.<sup>10</sup> While characterization of the relationship between upper airway anatomy and treatment response may contribute to the understanding of the mechanism of action of oral appliances, this has yet to be incorporated into a clinically useful prediction model.

The potential for long-term dental and cephalometric effects highlights the need for regular review of the patient by a dental practitioner. Although cephalometric and dental changes with long-term oral appliance use have been described, their clinical significance remains uncertain. The occurrence of these changes does not always warrant cessation of therapy. The decision as to whether oral appliance treatment should be continued needs to be individualized. Follow-up with a sleep physician is also recommended to monitor the treatment response and adherence. If symptoms of OSA recur, polysomnography should be considered to re-evaluate the efficacy of treatment.<sup>44</sup>

#### CONCLUSION

Major advances in the field of oral appliances have provided a solid evidence base for the use of oral appliances in the clinical management of OSA. These developments have been reflected in the

updated practice parameters of the American Academy of Sleep Medicine, which now recommend the use of oral appliances for mild-to-moderate OSA, or for patients with severe OSA who are unable to tolerate CPAP or refuse treatment with CPAP.

This review article has focused on the developments that have occurred in three clinically relevant areas. There is robust evidence of the efficacy of oral appliances, both in regard to improving polysomnographic indexes as well as modifying the health risk associated with OSA. The identification of demographic, anthropomorphic, polysomnographic, and upper airway anatomic differences between responders and nonresponders provides insight into the mechanism of action of oral appliances and may improve the selection of patients for this treatment modality. Finally, there are now studies<sup>41,42</sup> that have assessed the long-term safety of oral appliances in patients followed up for up to 7 years.

As a simpler alternative to CPAP, oral appliances are often regarded by patients as a more acceptable treatment option for OSA. This has the potential to translate to better treatment adherence and equivalent health benefits, despite the lower efficacy of oral appliances compared to CPAP. Future research should focus on determining the influence of the design of oral appliances on clinical outcome, the development of a clinically reliable method for identifying those patients who are most likely to achieve a favorable treatment response, and the characterization of factors predisposing to long-term adverse effects of oral appliance treatment.

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