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REVIEW ARTICLE

# Oral Appliance Therapy for the Management of Sleep Disordered Breathing: An Overview

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***ABSTRACT*** *A burgeoning new arena in healthcare has opened to dental professionals with the potential to relieve the suffering of millions of people worldwide. Qualified dentists are increasingly being called upon to interface with the medical profession in an effort to manage the unstable upper airway during sleep. What has come to be called "oral appliance therapy" (OAT) involves the coordinated efforts of sleep physicians and the newly recognized sleep disorders dentist.*

**KEYWORDS:** oral appliances, dental appliances, snoring, sleep apnea

## A HISTORIC PERSPECTIVE

The concept underlying OAT is not new, as the relationship of the tongue and mandible to airway patency has been well known for many years. In the early 1900s surgeons occasionally saved the lives of micrognathic infants by suturing the tongue in a forward position to the lower lip in an effort to open and stabilize the upper airway during sleep. By 1930, helmets and chinstraps were utilized by physicians for mandibular repositioning in an effort to accomplish the same goal. The first use of intraoral devices in this regard is generally attributed to the French pediatrician Pierre Robin in 1934. More recently, surgical advancement of the maxilla and mandible has been reported and in 1982, Charles Samelson, a psychiatrist, designed a tongue retaining device that has been shown to be effective.[1]

Since then, substantial progress has been documented in the growing literature. In 1995, a milestone review of the topic appeared in the literature that effectively summarized the efficacy of this new therapy and for the first time, suggested practice parameters.[2,3] For purposes of the review, 21 publications were considered and data from 320 patients were examined. As such, it was clear that in most, but not all cases, therapy with oral appliances (OA) improved OSA, appeared to be safe, and was accepted for long-term use. The practice parameters indicated that OAs would be suitable for initial treatment of simple snoring and mild OSA, and be appropriate alternative therapy in more severe cases when positive pressure was not tolerated and surgery was not indicated.

In the years following publication of the 1995 Review and Practice Parameters, research has steadily continued to support the efficacy and scientific basis for therapy with oral appliances. Once past these basic queries of effectiveness and preliminary protocol, investigators began addressing more specific areas to more fully support the use of oral appliances in the battle against sleep disordered breathing. Loube has shown the reversal of upper airway resistance syndrome with OAT,[4] and Menn has objectively documented its beneficial effect on sleepiness.[5] In addition, Millman has demonstrated that UPPP treatment failures responded favorably in a significant number of cases.[6]

When it became apparent that OAT was a legitimate and desirable part of the treatment mix, questions naturally arose regarding its comparative effectiveness with positive airway pressure modalities. Recently, four studies have focused on OAT going head to head with nasal CPAP.[7–10] Three of them used a cross-over design and the fourth a parallel group design. All of the investigations were randomized, controlled treatment trials. Each of the studies focused on effectiveness as a product of treatment efficacy in combination with acceptance and adherence to treatment. Treatment efficacy was similar in all the trials and did not deviate significantly from past investigations. It was shown that OAT often, but not always, decreased the apnea-hypopnea index, whereas CPAP nearly always resolved sleep disordered breathing entirely. Acceptance and adherence to treatment with CPAP was limited while that of OAT was less so, resulting in the proportion of successfully

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treated patients being about the same in each study. In all three cross-over trials where patients were asked to choose a preferred treatment, the majority chose OAT.

## Why Are Oral Appliances Effective?

Oral appliances (OAs) placed in the mouth and utilized during sleep serve to prevent the collapse of the upper airway, thus maintaining patency to allow adequate ventilation and normal sleep. It is believed that the appliances function in several different ways.

Loss of upper airway patency during sleep is multifactorial. Anatomic considerations, however, play an essential role, and it is presumed that a major effect of the oral devices is to physically reposition and stabilize certain tissues. In qualified, experienced hands, OAs can effect the repositioning of the tongue, mandible, soft palate, hyoid bone, and related pharyngeal muscles that by virtue of the effects of sleep or abnormal size and shape would otherwise tend toward upper airway instability. A number of imaging techniques including cephalometrics, MR, and endoscopy have demonstrated airway opening with OA use in the awake patient and the anesthetized patient.[2,8,11–15]

Increase in baseline genioglossus muscle activity has been shown to occur with placement of oral appliances in addition to a direct repositioning of the mandible and other tissues. It is speculated that this may induce a stretching of the displaced muscle and result in a reduced compliance or lesser tendency toward collapse.[16] In addition, a cephelometric study has shown a decrease in length of soft palate in responders to OAT, suggesting that the presence of the appliance may affect pharyngeal muscles other than those of the tongue.[17]

## Functional Classifications and Design Variations

The variety of OAs used to treat sleep disordered breathing can be overwhelming at first glance. However, despite the availability of several dozen devices, only a few major themes seem to be playing out. In the mid-1980s, dentists were originally focused on four functional classifications: mandibular repositioning devices (MRD), tongue retaining devices (TRD), soft palate lifters, and tongue posture trainers. Today, only the MRDs and the TRDs seem to have found a place in the clinical practice of the sleep disorders dentist.

### Mandibular Repositioning Devices

Mandibular repositioning devices are by far the most commonly utilized appliances today with over 20 different types available. They all function to reposition the mandible in a protruded position during sleep and have been the most widely studied functional classification by researchers. Within this functional classification, numerous design variations exist giving rise to the plethora of MRDs, although to date, no significant research has clearly demonstrated any great advantage of one design feature over another.

Even so, certain trends are driving the evolution of appliance design and are vital for the practitioner to recognize. Of primary import are the serial protrusive adjustability of the MRD and the notion of titrating the device to ascertain both an effective and comfortable jaw position. A decade of anecdotal experience has made it abundantly clear that the initial jaw position is quite often not the most comfortable and effective for the patient and that appliances that offer protrusive capability that is quick, easy, reproducible, and available in very small increments most often offer significant advantage.

Other important design variations include durability to resist the hostile environment of the oral cavity, improved lining materials to increase the retention to the dentition and freedom of mandibular movement to allow greater TMJ comfort. Custom-made laboratory appliances are generally felt to offer more comfort, better retention, increased durability, and more sophisticated protrusive engineering than the off-the-shelf "boil and bite" designs whose major advantage seems to be limited to immediate availability and decreased cost. Due to the present lack of objective information to aid in the selection of one appliance over the other, it is incumbent upon the sleep disorders dentist to become familiar with the design variations of numerous appliances and develop clinical preference over time. The sleep disorders physician in this regard must affiliate with dentists of appropriate education and experience.

### Tongue Retaining Devices

Tongue retaining devices do not enjoy the popularity of the MRDs but nonetheless offer the practitioner and the patient an excellent alternative to mandibular repositioning. Therapy with TRDs has been objectively studied since the mid 1980s and shown to be effective in many cases.[1,18,19]

TRDs function by directly engaging the tongue and holding it in a forward position to open the upper airway during sleep. Few variations of the TRD exist and many practitioners have little or no experience with this functional classification. The major advantage of the TRD may be its ability to promote forward tongue position without having to engage the dentition or significantly stressing the temperomandibular joint. As such, these appliances may offer significant advantage for patients with loose or no teeth or those with TMJ dysfunction.

## Orally Delivered Positive Airway Pressure

In view of the limited patient compliance with nasal CPAP and the imperfect efficacy of therapy with oral appliances, a hybrid device has been developed that seeks to maximize the benefits of each modality and overcome the shortcomings. Recently, the FDA has certified a delivery system that shows promise of being able to deliver positive airway pressure via an intraoral apparatus that simultaneously protrudes the mandible.[20] The intraoral apparatus so described is conceptually a one-piece, nonadjustable mandibular repositioning device with a dual palate to introduce a stream of forced air from the CPAP compressor to the oropharynx.

A 1997 study examined 10 non-CPAP compliant patients with mild to severe OSA who were treated with orally delivered positive airway pressure via the protrusive oral device.[21] Post-treatment AHI levels were reduced to those comparable with nasal CPAP and in most cases the pressures were less than those required by the nasal delivery. One case improved as a result of the mandibular protrusion alone in the absence of any applied pressure.

## Decision-making Pathways and Protocol

As previously noted, the 1995 Practice Parameters developed by the American Sleep Disorders Association[3] stated that therapy with OAs is indicated as a first-line approach for simple snoring and mild OSA and as an alternative in more severe cases when CPAP was not tolerated and surgery not indicated. Two recent studies have suggested that OSA severity can serve as a general predictor to treatment success. Marklund[22] and Lowe[10] have both shown increased appliance success with cases where AHI was less than 30. Similarly, Pancer[23] has identified the difference between responders and non-responders at a mean AHI level of 39.

Although guidelines are useful, the notion of successful treatment is more complex than application of generalities. While the overall predictability may decline at an AHI level of between 30 and 40, appliances have often been shown to be significantly effective in more severe cases. In the same study, where success was determined to be an AHI of less than 10, Pancer documents some "non-responding" patients with pretreatment AHI's of 92, 98, 76, 112, 70, 115, 86, and 93, falling a mean 80% to post-treatment levels of 25, 29, 10, 26, 27, 30, 16, and 11 respectively. As such, the committed clinician is often challenged to weigh the benefits and risks to the patient of varying degrees of residual sleep disordered breathing.

When to refer a patient to a sleep disorders dentist for OAT is a question that many physicians grapple with. Ultimately, proficiency will increase as they become familiar with the research available and as they build strong relationships with qualified dentists. Based on a decade of experience and research, Schmidt-Nowara, widely considered a pioneer in this area, offers the following model:[24] CPAP is recommended to patients with AHI greater than 30, especially if they are significantly sleepy. Less severely affected patients, however, are offered OAT as the initial treatment choice. Patients who do not succeed with the initial choices are crossed over to the other treatment.

OAT demands that the dental and medical professions function as an integrated team. There are good reasons for this. At the present time, dentists are not medically qualified or legally capable of making the diagnosis of OSA and upper airway resistance syndrome and differentiating between primary snoring and these conditions. Similarly, physicians are neither medically nor legally capable of properly managing appliance construction, fitting and titrating, or the inherent concerns of tooth movement, TMJ dysfunction, and occlusal discrepancies.

Currently there are numerous approaches to the utilization of oral appliances that reflect the varying degrees of experience, understanding and philosophy among practitioners. Many successful teams consist of a physician who thoroughly understands the concept of OAT and a dentist with adequate knowledge of sleep disorders who is educated and trained in handling OAs. Communication channels play an important role as the physician refers the patient to the sleep disorders dentist along with the data from an objective evaluation that may include an overnight polysomnogram, MSLT, Epworth Sleepiness Scale, or other indices deemed appropriate. It is incumbent on the dentist to be familiar with the functional classifications and design variations of the myriad appliances available and choose one appropriate for the patient. Following construction and fitting of the appliance, the dentist may take from several weeks to several months for titration procedures using subjective feedback from the patient and bedpartner and possibly pulse oximetry to arrive at a subjectively effective and comfortable jaw position. Finally, a referral back to the physician for objective follow-up evaluation completes the cycle. If the dentist and physician deem the therapy effective, the patient will then benefit from regular periodic monitoring by the dentist to ensure the integrity of the oral structures.

## Side Effects and Complications

Many studies make mention of side effects and complications but fail to describe their method of determination making true assessment difficult. Excessive salivation is often reported during the initial accommodation period but tends to diminish over a short period

of time in most cases. Similarly, transient discomfort of teeth and the temperomandibular joint during the night and upon awakening is often described with the use of mandibular repositioning devices. With regular use and adjustment of fit, these symptoms subside or become so minor as to be easily disregarded. The mandibular repositioners almost universally cause a minor, temporary change in the occlusive relationship of the teeth the morning after use. In most cases, the mandible will return to its normal posture within an hour or two allowing a return to normal dental occlusion.

Occasionally, occlusive changes may persist, resulting in permanent changes in the patient's "bite". Preliminary work by Lowe suggests that minor tooth movement can result from the nightly forces placed on the teeth by jaw repositioning appliances in approximately 20% of the cases. A published study by Bondemark[25] involving 30 patients showed that after two years' use of a jaw repositioning device, an overall change of 0.4 mm in mandibular position was seen. The mandibular posture changed between 0.5 mm to 2.0 mm in 17 of the 30 patients and did not change at all in the remaining patients. Interestingly, no significant tooth movement was documented, and no patients reported an altered sense of occlusion.

In regard to tongue retaining devices, subjective reporting includes excessive salivation and soreness of the tongue during the night and upon awakening.Overall, the published reports and anecdotal evidence tend to support the contention that common side effects are not limiting factors and true complications are infrequent.

### Compliance

The reporting on long-term compliance is very limited at this time and is an endeavor that requires more poignant attention. In general, however, it has been shown that patient preference and adherence to treatment surpasses that of CPAP.[7–10] Bondemark[25] reports 100% compliance after two years use of a mandibular repositioning appliance while other reports range from 100% to 52% compliance after seven months to three years. Reasons given for noncompliance include objection to side effects, complications, and lack of efficacy.

## THE SLEEP DISORDERS DENTIST—QUALIFICATIONS AND COMPETENCY

The relationship between sleep disordered breathing and upper airway anatomy has recently expanded the scope of clinical dental practice. The dental profession is participating in the management of this sleep disorder by providing skill and experience that are unique to its domain, and many sleep disorder centers are including a qualified dentist on the team to provide a highly specialized service that is not available anywhere else.

Presently, it is recommended that the sleep disorders dentist become involved in the care of the SDB patient upon referral from a physician after the extent of the sleep disorder has been determined.[3,26] In addition, however, the astute dentist can serve an important role in the screening process so as to identify and refer patients to the proper sleep facility when a high degree of suspicion alerts the dentist to possible SDB in patients of his or her dental practice.

Scientific evidence is more than adequate to support the use of OAs in the management of SDB, and many physicians are seeking to partner with a qualified sleep disorders dentist. Unfortunately, the number of competent dentists looking to serve in this capacity is limited, and it occasionally becomes perplexing to locate a dentist the physician feels comfortable referring to and working with. It is possible, though, for a committed dentist to acquire the necessary background and skills.

There are many sources the prospective sleep disorders dentist may take advantage of in order to gain the background and experience necessary to provide appropriate therapy. A number of OA manufacturing companies offer courses, seminars, and workshops that enable an interested dentist to become familiar with SDB and OAT and to get started in the field. Scientific journals and texts as well as information from local sleep centers can offer valuable information. The serious dentist will apply for membership in several of the various sleep societies and associations, perhaps most importantly, the Academy of Dental Sleep Medicine.

The Academy of Dental Sleep Medicine (ADSM) is a nonprofit, international network of clinicians and researchers providing education and training to dentists and physicians through numerous venues. Recently, the ADSM began offering credentialed status to those dental practitioners who have formally demonstrated certain proficient levels of knowledge and clinical competence. The Certifying Board of the ADSM grants credentials so that patients and professional colleagues can recognize these individuals as possessing the appropriate background and skills in sleep medicine and OAT to effectively interface with the medical team. The granting of such does not imply specialty status in any way.

## CONTEMPORARY ISSUES

Several obstacles impede the accelerated utilization of OAs in the management of sleep disordered breathing. Of primary concern is the lack of universal third-party payment for this service that prevents some den-

tists and physicians from wholeheartedly supporting their use. Without proper insurance coverage, many patients opt for alternative treatment modalities. On another front, sleep physicians may be uninformed, mired in traditional protocols, or unable to identify a qualified dentist to partner with again preventing patients from smoothly transitioning into therapy with OAs. Development and research must focus on long-term compliance and complications as well as the design and manufacture of more effective appliances.

Appropriate algorithms and care maps must evolve and keep pace with this developing therapy while physicians and dentists communicate and work together to assure the most effective outcomes for their patients. As dentists become more experienced and accepted in this realm, their role in diagnosis and treatment will expand. The dentist will play a fundamental role in the early prevention of OSA by monitoring and intervening in areas of physical childhood development. Understanding the implications of bottle-feeding versus breast-feeding on the formation of the dental arches and hard palate may prove significant in the prevention of unstable airways during sleep later in life. Likewise, orthodontic treatment may intercept harmful growth patterns and obviate the need for invasive therapy later on.

## SUMMARY

Therapy with OAs is no longer new and experimental. It is well supported in the scientific literature and accepted by both patients and physicians. We are charged now with refining this therapy to maximize effectiveness through communication and teamwork.

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