Mini-Review

Oral appliances for the treatment of obstructive sleep apnea

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Background: Obstructive sleep apnea (OSA) is a disabling condition which reduces the sufferer's ability to work effectively due to somnolence during the day. It can be life threatening, resulting in nocturnal anoxia and cardiac arrythmias. OSA is due to intermittent cessation of airflow at the upper airway level of at least 10 seconds duration. Severe cases may stop breathing for 2-3 minutes. It is a rare condition with a prevalence of up to 4 percent in middle aged adults. OSA can be due to central apnea where the neural drive is transiently abolished. In obstructive apnea, the neural drive remains but there is occlusion of the oropharyngieal airway. Therapeutic approaches range from weight reduction, improving nasal patency, avoidance of alcohol and sleeping in the supine position and may include surgical procedures to increase the airway space. Continuous positive airway pressure (CPAP) at night is a common therapeutic modality but not always tolerated by the patient. *Objective:* This essay reviews current practices using airway dilators.

Keywords: Oral airway, sleep apnea, snoring, treatment by oral appliance.

Case Study. A 37-year old father of three had tried unsuccessfully to use continuous positive airway pressure (CPAP) for more than three years, followed by palate surgery (uvulopalatopharyngoplasty) which had produced little improvement. He had severe daytime symptoms that caused him to fear for his job, and his obstructive sleep apnea (OSA) disqualified him for life insurance. The patient received a custom oral airway dilator with 1 mm adjustability. He was fitted with a titanium connector, which allows adjustments at 1 mm increments in both the anterior and vertical planes. The patient's apnea-hypopnea index (AHI) was reduced from 48 to 14, as confirmed by overnight polysomnography. Additional fine tuning, amounting to a 1 mm change in the vertical position, was guided by overnight home pulse oximetry. It further reduced the AHI to 2.0. When he provided the polysomnographic confirmation of his 2.0 AHI to his insurance company, his life insurance acceptability status was restored.

Nasal continuous positive airway pressure (nCPAP), surgery and oral appliances have been the three most common treatments for OSA, with CPAP remaining the gold standard. The oral device has recently gained more universal acceptance in the wake of broader clinical experience and evidence based studies of effectiveness. These devices are referred to variously as mandibular advancement devices (MADs), mandibular repositioning devices (MRDs), anterior mandibular positioners (AMPs) and oral airway dilators (OADs). Whatever the name, they all increase the patient's upper airway crosssectional area by supporting the mandible in a slightly forward and open position during sleep. Oral Appliances to Treat Sleep Apnea made their appearance about 20 years ago; generally as modified night guards or orthodontic appliances. They were mostly fitted only on the upper teeth in a single, non-adjustable position. Most of them were bulky and often required severe mandibular positioning, tending to compromise comfort and earning them a poor reputation. Little information was available on the anatomical and physiological factors associated with the use of oral devices in managing OSA. Dental school curricula largely ignored this field and an information chasm existed between published dental and medical research on this topic.

Although science and materials were evolving in each profession, it has only been recent that dental and medical researchers and clinicians have begun collaborative efforts. Physicians and Dentists knowledge about treating OSA still spans a broad spectrum and needs improvement.

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Modes of action of oral airway dilators

Oral airway dilators preserve the airway during sleep in a passive manner by reconfiguring the architecture in the oropharyngeal area at the base of tongue. This is in contrast to the constant air pressure supplied by CPAP. The retropalatal and retroglossal areas of the upper airway are the primary sites of obstruction in OSA. When an OAD supports the jaw in an anterior (protruded) and more open position, the tongue is shifted forward and the muscle tone of associated small muscles increases. These changes are preserved during sleep, maintaining an adequate airway for normal breathing [1-3]. Effective anterior positioning usually varies between 3-8 mm and the vertical opening range is 6-15 mm. The entire device fits in the mouth, so it does not influence sleeping positions. It also allows breathing through the nose, mouth or a combination. Oral devices are effective for mild to moderate OSA, and in some cases of severe OSA [3-5]. Effectiveness is significantly influenced by airway architecture and is very difficult to predict. All effective OADs consist of upper and lower units that grip the teeth and are connected together in a way that allows some level of adjustment for optimum airway opening while allowing the mandible some freedom in order to minimize the influence of grinding of teeth during sleep (bruxing). The rule of thumb is that a minimum of eight teeth per dental arch are required; however, individual anatomical variables may sometimes allow successful use in patients with edentulous maxillas.

Two categories of oral airway dilator

Premanufactured devices usually involve a single clinical appointment to fit and adapt the device to the patient's mouth. Short-term devices are more completely premanufactured and require a single clinical fitting and modifying. They usually have an outer rigid shell with a thermal material inside the shell that adapts to the teeth after heating. A two-part putty can also be mixed and placed in the outer shell just before fitting over the teeth. These devices are economical but bulky, less durable and frequently cover the gums adjacent to the teeth which are not desirable. Their effectiveness is often restricted by their limited adjustability. They generally last for about a year. Custom-fabricated devices require impressions of the teeth and usually a bite registration of the jaw-to-jaw relationship. They are sent to an outside laboratory where a trained technician hand-carves the device in a special wax to fit the teeth more accurately and in contour to the dental arches before they are processed at high temperature in a dense acrylic. The connectors, usually premanufactured medical-grade titanium or stainless steel, are embedded in the acrylic during the processing period. Custom devices provide more subtle and flexible adjustment increments. They are less bulky, more comfortable, more durable and more effective. They seldom cover any of the adjacent gum tissue. In addition to the laboratory costs, three to seven appointments may be required. Five years' durability is common, and some show no signs of deterioration at 10 years. The patient's care of the device and the passive/active nature of facial muscles (e.g., bruxism) during sleep affect any oral device's longevity.



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Fig. 1 Custom-fabricated oral airways dilator made of acrylic titanium connectors.

The effectiveness of oral airway dilators (OAD) can compare with CPAP

With appropriate patient selection, as in the case described above, opening the airway with an OAD can accomplish a similar goal as CPAP, and the physiological outcomes may also be similar. Research has demonstrated that an effective OAD can reduce blood pressure, prevent blood oxygen desaturation and eliminate the more typical sleep disorder symptoms of morning grogginess and daytime somnolence [1-8]. Cardiologists have reported reductions in heart arrhythmias, and patients have noted a reduction or elimination of nocturia.

Oral devices are not for every patient. An adequate evaluation should include a full medical examination and polysomnography to document sleep apnea severity and screening for predisposing factors associated with neck and shoulder muscles, including mandibular range of motion, occlusion, dentition and the intra-oral anatomy, tongue size and architecture of the oropharyngeal junction. A device may then be selected to best meet the patient's unique needs. Acoustic reflection pharyngometry can be a valuable tool for measuring upper airway baseline dimension and determining whether and how much mandibular repositioning will enlarge the airway [9]. Each person seems to have an anterior/vertical position that produces his or her unique optimum airway.

Prescribing the oral airway dilators

Obstructive sleep apnea is a serious condition and should be diagnosed by an overnight monitored sleep study. Oral airway dilator evaluation and treatment is by referral from a physician [10]. OADs are a prescription device when indicated. Efficacy must be confirmed by an overnight polysomnogram after final

adjustments to the OAD are completed. Subjective reports of improved daytime alertness are not reliable evidence of treatment efficacy [10]. Side effects occur in 1-3 percent of patients, and tend to be a function of patient tolerance, age, oral habits (bruxing, tongue thrusting), device design, initial jaw position and diligence in following daily preventive procedures and follow-up evaluations. Contraindications for OADs include insufficient teeth to support the OAD, periodontal problems, active temporomandibular joint disorders and maximum protrusive distance less than 6 mm [11]. In a study of 100 unselected polysomnography subjects examined by maxillofacial surgeons, 31 percent had an insufficient number of teeth; 16 percent had periodontal abnormalities that would require treatment prior to OAD use; and 2 percent had significant temporomandibular joint disorders [11]. Potential problems with OADs may include the development of occlusal or skeletal changes. Orthodontists, in a study of 34 OAD users, reported occlusal changes after a mean treatment duration of 29 months. These patients, using the devices six to eight hours per night for at least five days per week, experienced changes in the anteroposterior position of the molars and in the inclination of the upper and lower incisors [12]. Complications generally are reversible when identified in the early stages.

Long-term efficacy of OADs requires careful follow-up care

Few data have been published regarding the longterm efficacy of treatment with OADs. A two-year and a four-year follow-up study both emphasize that the efficacy of OADs as well as that compliance may decrease over time. They recommend careful

- M 16	OSA	CPAP
Target population	Mild to moderate OSA	All cases of OSA
	A few severe cases	
Patient preference	More acceptable, convenience,	High acceptance if severe OSA
	Lack of noise	
Short term	Complete elimination OSA 10 %	Elimination almost 100 %
effectiveness	Partial response 50-60 %	
Long-term	Declines with time, needs regular	Excellent if tolerated
effectiveness	follow-up and motivation %	
Side effects	Potetial exacerbation of TM joint	Skin irritation
	dysfunction, skeletal changes	

Table 1. Comparison of OSA with CPAP.

follow-up examinations for adjustments and repair and regular polysomnographic follow-up to ensure longterm efficacy [13-15]. Repeat polysomnography is advised if the patient gains weight or exhibits a return of excessive daytime sleepiness. In the last 10 years, advances in devices and positive airway pressure machines have greatly improved and given many a despondent patient hope. Insurance coverage for OADs has progressed from denials due to it being "experimental," to routine processing of claims. The patient profile has also changed. Three years ago there were few patients under 50 years of age, and 80 percent were male. They were referred primarily due to CPAP intolerance. Today the male-female ratio is almost equal and it is common to see patients between 35-40 years with mild to moderate OSA who are otherwise healthy. OADs are very user-friendly, socially acceptable and portable. Public awareness is much higher and patients appear to be more motivated to address their OSA early with a focus on prevention.

Conclusions

Oral appliances (OADs) are indicated for selected patients with mild to moderate OSA who prefer them to continuous positive pressure (CPAP), or who do not respond to, are not appropriate candidates for CPAP or had failed treatment attempts with CPAP. Until there is higher qualified evidence to suggest efficacy, CPAP is indicated whenever possible for patients with severe OSA but OADs are another option [17].

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