

## What's New in Oral Appliances for Snoring and Sleep Apnea

### Introduction

Recently, going through airport security, the TSA inspector was calling out in a loud voice, "Computers and CPAPs must be removed from their cases and placed on the belt in a separate bin for screening." My wife confirmed with him that we heard correctly. He did say, "CPAPs". This served to emphasize to me how endemic *obstructive sleep apnea* (OSA) is today, and puts in perspective the magnitude of the market for oral appliances as a viable alternative to CPAP.

The insidious nature of the sequelae associated with OSA have brought a new imperative to successful treatment modalities. OSA has been linked to such problems as excessive daytime sleepiness, neurocognitive impairment, mood disturbances, hypertension, myocardial infarction, stroke, diabetes, obesity, hormonal imbalances, increased risk of motor vehicle accidents, and workplace injuries.

### History

Oral appliances for treating OSA have been around since the early 1980s. Samelson introduced the tongue retaining device (TRD), that was essentially a rubber bulb that surrounded the tongue and protruded it beyond the lips. Intraorally created negative pressure pulled the tongue into the bulb and the suction kept the tongue extended outside the lips. TRDs provided active tongue protrusion and passive mandibular protrusion. They were only indicated in competent nasal breathers because the lips were sealed on the bulb. Later, straw-like devices were added laterally to allow oral breathing. TRDs were rarely well tolerated by patients, usually because of jaw and tongue discomfort, and they soon fell into disuse by dentists.

The advent of mandibular advancement devices (MADs) came shortly after the introduction of TRDs. The purpose of a MAD is to anteriorly reposition the mandible to prevent the airflow being blocked by hypotonic collapse of the tongue onto the airway, or to prevent the tongue from being so close to the posterior pharyngeal wall as to get sucked closed by negative airway pressure. MADs cause active mandibular protrusion, and the tongue, by virtue of its attachment to the genial tubercle of the mandible, passively follows. MADs are made in a great variety of configurations and attachment systems but basically in two styles, 1) adjustable or nonadjustable, and 2) open-anterior which facilitates anterior tongue movement, or closed anterior which restricts anterior movement of the tongue. Some adjustable appliances have the adjustment device positioned in the anterior which limits protrusive tongue advancement. Other adjustable MADs have the adjustment device in the buccal area so they allow or even facilitate tongue protrusion. MADs are adjustable either sagittally, vertically or in both directions.

Typically, a MAD is custom laboratory constructed device, based on the prescription of a dentist. There are also a variety

of one-size-fits-all, prefabricated MADs commonly referred to as *boil and bites*. Boil and bites have all been FDA approved for safety and efficacy. Their cost is considerably less than laboratory fabricated custom devices. The efficacy compared to custom made appliances has not been reported. Boil and bites are bulkier, and in situations where comfort and tongue space are major issues, they do not favorably compare to custom made appliances. The analogy is a hearing challenged person holding a megaphone to their ear as an alternative to getting fitted for a digital hearing aid.

The salient point is that a diagnosed apneic should not sleep without an airway device. Either a CPAP or an oral appliance is indicated for OSA patients. The most appropriate indications for boil and bite MADs are as a temporary device, should laboratory repair of the permanent appliance be necessary, or as an immediate device in severe cases of OSA while the permanent device is being fabricated in the dental laboratory.

### Situation Analysis

According to recently published guidelines of the American Academy of Sleep Medicine, oral appliances are appropriate for primary treatment of mild to moderate OSA, and for those patients who fail other treatments such as CPAP and/or surgery.

MADs, according to literature studies have 80% compliance<sup>1</sup> compared to a reported 46% patient compliance for CPAP.<sup>2</sup> This 46% figure is really interesting because compliance for CPAP is defined as, "at least 4 hours per night of use and CPAP being used on more than 70% of all nights". The basis for the criteria for CPAP compliance is based on hours of usage and not related to successful physiological results. Further, it is a rather low standard for compliance. Usage 70% of all nights amounts to approximately 5 nights per week. Four hours per night combined with usage 5 nights a week calculates to 20 hours usage per week to meet compliance standards. Seven hours of sleep per night is recommended by the American Academy of Sleep Medicine. Therefore to be a "compliant user" of CPAP one must use it roughly 40% of the time. A study by Kribbs Pack et al.<sup>3</sup> demonstrated that sleeping without CPAP for one night reversed virtually all of the sleep and daytime alertness gains derived from sleeping with CPAP. Studies involving CPAP disclose more failure from non-compliance than from treatment failures.

MADs are preferred by patients over CPAP primarily because they are more comfortable, more portable, more socially acceptable, make no noise and have fewer undesirable side effects. Side effects associated with CPAP are bloated feeling, nasal congestion, rhinorrhea, sneezing and mucosal dryness of the upper airway.

A study by Lowe et al. using covert monitoring, showed excellent agreement between objective and subjective estimates of compliance using MADs. MADs are not as robust as CPAP



Fig. 1. TRD.



Fig. 2. TAP™ restricts anterior tongue movement.

and successful treatment outcome is not as reliably obtained. Ferguson and Cartwright et al<sup>4</sup> report that a suboptimal treatment outcome can occur in 30–50% of patients. The success of MADs, especially in moderate to severe cases of OSA, has not been as predictable as that of CPAPs.

### Reflex Control of Tongue and Breathing

Motor neurons responsible for the reflex activity of the head and neck are located in the brainstem, the pons, medulla and midbrain. The reflexes associated with swallowing and respiration can be modified and adapted by peripheral and central input to the central pattern generator. Reflexes elicited from stimulating the oral region alter recruitment of lip, tongue and jaw muscles. Most reflexes function as supporting networks of neurons assisting in control of complex motor responses. The type of sensory stimulus determines the type of reflex elicited – from simple reflexes to complex behavior effecting oral and pharyngeal regions.

The tongue is a complex muscular organ. It consists of 1) extrinsic muscles that attach to at least one bone and alter the shape of the tongue and 2) intrinsic muscles that have both origin and insertion in muscle, and protrude, retrude and move the tongue laterally. The tongue is a mass of uncompartimentalized interdigitating muscles that rapidly and accurately change the directions of movement in response to the demands for multiple complex orofacial behavior.

The speed and precision which the tongue must flawlessly move between respiration, chewing, swallowing and speech are governed by its contractile properties, the hypoglossal motoneurons, central pattern generators located in the medulla and pons, and influenced by cortical and subcortical nuclei in the brain. The hypoglossal nerve provides all the motor innervation to the muscles of the tongue. All tongue reflexes are activated by hypoglossal motoneurons. More than 7,000 axons comprise the efferent portion of the hypoglossal nerve. This is seven times as many as devoted to groups of limb motoneurons. Fine motor control of the tongue is based on huge amounts of neurological circuitry.

The size of the upper airway depends on a balance between the collapsing forces, such as muscle flaccidity or negative intraluminal pressure, and the forces maintaining airway patency. Important airway patency factors are hyoid bone position, the pharyngeal dilator muscles, genioglossus tonus and position. Genioglossus is actually considered to be a respiratory muscle. Its electromyographic activity is in

phase with respiration both when awake and in a resting state. Altered daytime tongue posture in apnea patients is responsible for altered tonus, resulting in muscular fatigue and facilitating collapse of genioglossus during sleep. During sleep OSA patients reduce upper airway dilator activity more than normal subjects.

Increasing the dilating forces reduces the collapsibility. Certain complex reflexes controlling the oral and pharyngeal muscles do not emanate from sensory input. Changes in blood gas levels of O<sub>2</sub> and CO<sub>2</sub> can cause rhythmic recruitment of the tongue protruding muscle (genioglossus). Electrostimulation of genioglossus to protrude the tongue has been reported in numerous papers. Neural stimulation of genioglossus is also an effective way to increase the caliber of the hypopharyngeal airway.

One proposition currently being studied is whether a new device, the Moses Appliance, can stimulate reflex activity, using mechanical or proprioceptive stimulation, as an adjunct to prevent genioglossus atonia and OSA. A search of the medical literature revealed four protrusive tongue reflexes and one that inhibits retrusive tongue activity.<sup>5</sup>

1. **Jaw-Hypoglossal Reflex** The reflex activity is that opening the mandible and forward advancement of the mandible increases the electromyographic activity of genioglossus. Increased EMG activity of genioglossus causes tongue protrusion if the appliance allows it. Forward protrusion of the posterior part of the tongue helps maintain a patent airway. The Moses Appliance is wide open in the anterior area to allow tongue protrusion.
2. **Masseter-Hypoglossal Reflex** Stimulation of the masseteric nerve effects an inhibition of hypoglossal motoneurons to retrusive tongue muscles. The Moses Appliance supports a 6–8 mm jaw opening therefore stimulates the masseteric nerve and inhibits hypoglossus motoneurons to retrusive tongue muscles.
3. **Lingual-Hypoglossal Reflex** Mechanical stimulation of the tongue surface inhibits or excites different tongue muscles depending on where the input originates. This reflex can be facilitated by a prior conditioning reflex. The Moses Appliance also includes exercises to condition tongue awareness of mechanical stimulation from the edges of teeth, tongue on lips, tongue on rugae, tongue against lower incisors, and against oral appliance.
4. **Glossopharyngeal-Hypoglossal Reflex** Stimulation of the Glossopharyngeal nerve at the lateral border along

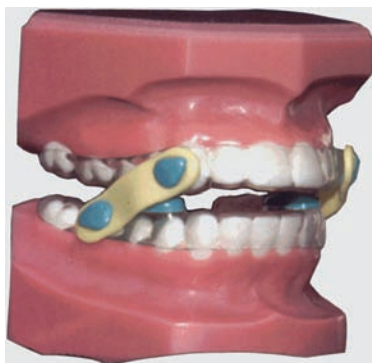


Fig. 3. EMA™, open anterior.



Fig. 4. Klearway, closed anterior.

the posterior one-third of the tongue induces protrusion. The Moses Appliance has grooves that fit and position the lateral border of the posterior one-third of the tongue.

5. Tongue-Tongue Reflex Touch or stroking on the tip of the tongue orients the tongue toward the stimulus. The more intense the stimulation, the higher the probability of tongue movement. Instructions for use of the oral appliance teach positioning of the tip of the tongue on the incisal edges of the teeth, against the lips, palatal rugae and incisive papilla.

A series of exercises to condition protrusive tongue posture during sleep is given to all Moses Appliance patients. Design factors are built into the Moses Appliance intended to cause reflex stimulation of tongue reflexes to condition specific patterns of genioglossus activity. This premise is based on an article by Arthur J. Miller<sup>5</sup> above. These prescribed sensorimotor exercises re-educate tongue muscles to maintain a protrusive posture, based on established principles of orofacial myology. Whether the tongue can be trained to stay in this forward position during sleep is equivocal. No definitive studies have been done to resolve whether the successful therapeutic activity of the Moses Appliance is based on training a more protrusive tongue posture.

Studies have been done however, establishing that people can be trained to sleep in certain prescribed positions (i.e., non-supine) and that tongue function can be retrained in both swallowing and speech. It has been shown that patients whose swallow has been retrained while awake, swallow in the corrected method when asleep. That Andrianopoulos and Hanson<sup>6</sup> found orofacial myological therapy for tongue thrust to be effective at limiting orthodontic relapse, strongly implies that the corrected tongue function did not revert at night. A controlled



Fig. 5. The Moses Appliance™ a mandibular advancement device that facilitates tongue protrusion.

study by Puhan, Suarez et al.<sup>7</sup> on didgeridoo training published in the British medical journal (2005) decreased the AHI in 25 patients from 22.3 to 11.6 on the average. They clearly demonstrated that daytime training of pharyngeal muscles decreased collapsibility of the upper airway during sleep.

### Predicting and Measuring Success of Oral Appliance Therapy

Zeng, Ng et al.<sup>8</sup> reported that collapse occurring in OSA patients in the oropharyngeal area was predictive of success by oral appliance therapy. Zeng, Ng et al.<sup>9</sup> recently reported significant differences in awake flow-volume curve parameters between patients with oropharyngeal versus velopharyngeal collapse during sleep. Using a portable spirometer (Spiropro™ by Viasys) to record expiratory flow volume rate at 50% of vital capacity (MEF<sub>50</sub>) and maximum inspiratory flow rate at 50% of vital capacity (MIF<sub>50</sub>), logistic regression analysis revealed that the MEF<sub>50</sub>:MIF<sub>50</sub> was the most important factor for predicting successful treatment outcome with MADs.

### A Portable Spirometer

An MEF<sub>50</sub>:MIF<sub>50</sub> ratio greater than 0.7 resulted in a positive predictive value of 83% using a MAD. Using a combined cut-off of MIF<sub>50</sub> less than 6.0 liters per second and an MEF<sub>50</sub>:MIF<sub>50</sub> ratio greater than 0.7 resulted in a positive predictive value of success at 89% using an MAD, and a negative predictive value of 76%. The sensitivity and specificity were dependent on the stringency of the definition of success, but when the most rigorous definition of success was utilized, the magnitude of the AHI was eliminated as a factor predictive of treatment success using oral appliances.

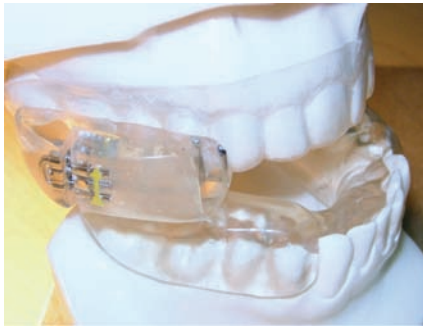
Based on this study, spirometry screening of OSA and snoring patients may be a valuable clinical aid in determining those patients most likely to get successful treatment results from MADs.

### Measuring Treatment Outcome with MADs

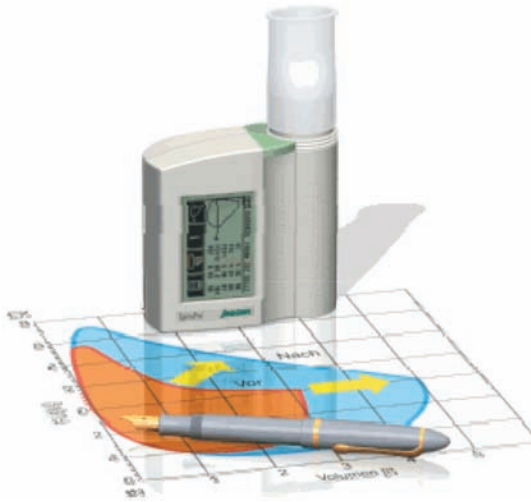
Successful treatment of OSA has been defined approximately five different ways in scientific studies evaluating MADs.

1. 50% reduction in AHI
2. 50% reduction in AHI or residual AHI <5
3. AHI <15
4. AHI <10
5. 50% reduction in AHI and a residual AHI <10

The least stringent criteria is #1 and the most stringent is #5.



**Fig. 6.** Moses Appliance demonstrating antero-posterior adjustability.



**Fig. 7.** The Viasys Spiropro™.

In measuring success of oral appliance therapy other factors must also be considered. Structural rearrangement of anatomic components of the mouth and oropharynx require an adjustment period. Allowing post-insertion time for adaptation is a factor that must be considered. MADs are usually not tested immediately after fitting and insertion.

Often a series of adjustments are necessary. It is common that these adjustments be gradual. Extreme changes that may appear indicated in a one night titration study of a MAD in a sleep lab may not be tolerated. Typically a series of small progressive changes are tolerated the best and achieve the most successful treatment results.

The importance in oral appliance therapy of reliable ambulatory testing devices for evaluating treatment outcome is strongly emphasized. Ideally an ambulatory PSG device would measure obstructive apneas, central apneas, mixed apneas, hypopneas, AHI, desaturations, body position, nasal/oral airflow resistance, pulse rate and snoring. One such device is the Braebon Medibyte. The patient connects an abdominal belt, a chest belt which holds the recorder, a nasal/oral cannula, the pulse oximeter, and a tiny snore microphone. They sleep in the comfort of their own bed at home. The software allows the doctor to evaluate the entire study, rescore any events or accept the computer interpretation. It records snores in decibels and allows the user to click and listen



**Fig. 8.** Braebon Medibyte, a miniature 10-channel PSG diagnostic screener.

to any snore or series of snores chosen. The cost of the Medibyte is very reasonable, the cost per study for expendibles is cheap, the reliability is excellent. The data is presented in a language that facilitates excellent communication and reports to referring doctors. It allows a clinician to practice at the state of the science and test as frequently as needed to get it right.

Oral appliance titration is not reimbursed at the present time by medical insurance. This is to reinforce the importance of low cost testing. The expense of repeated PSG studies at a sleep center after each adjustment could be prohibitive and unnecessary. Final PSG testing after maximum medical improvement by oral appliance therapy is appropriate.

### Snoring and MADS

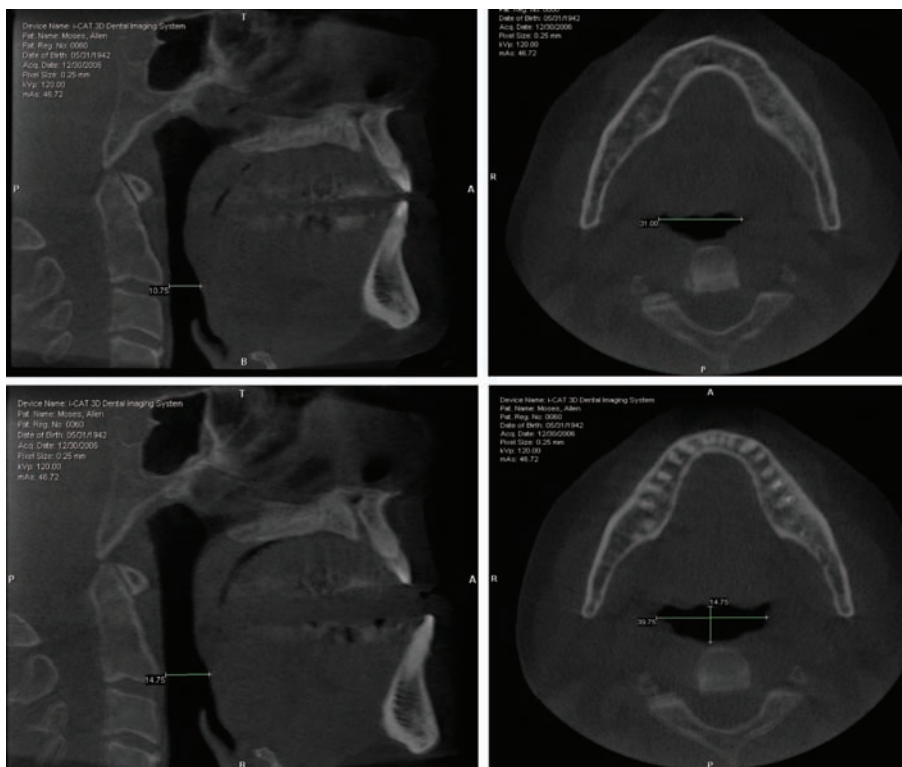
It has been reported that 91% of all apnea patients snore, but not all snorers have apnea. Therapy using MADs generally results in improvement or control of snoring in a majority of patients.

Snoring is caused by the diffuse vibrations or fluttering of pharyngeal tissues during sleep. The pathogenesis of snoring is vibrating tissue. The occurrence of snoring implies increased airway resistance during sleep. Any membranous part of the upper airway from the nose to the vocal cords that lacks cartilaginous or bony support may vibrate such as tongue, soft palate, uvula, faucial pillars, pharyngeal walls, tonsils, adenoids, or swollen nasal membranes.

Snoring may be generated at multiple sites in the flexible and compliant human airway. Snoring may occur on inhalation or exhalation. Snoring on inhalation could contribute to UARS, hypopnea and apnea. The health consequences of snoring may range from benign clinical sign to etiology of morbid pathological consequences.

The market for oral appliances that control snoring is even larger for dentists than for treatment of OSA. Successful treatment of snoring is needed not just to prevent sleep disruptions of the partners of snorers, but to prevent and more successfully direct treatment at UARS, hypopnea and apnea and their morbid consequences. Because snoring is very frequently an associated symptom of UARS, hypopnea or apnea, the occurrence of snoring warrants clinical investigation to rule them out.

It is inherent that treatment of snoring be by prescription of a sleep physician or properly documented as non-apneic benign snoring. Devices such as the Braebon Medibyte make



**Fig. 9.** Cone beam CT scans. First two radiographs across show the patient at rest position, tongue in roof of mouth and no appliance. The second two across are taken with a Moses Appliance in place, tongue in roof of mouth, lips sealed. Marked improvement is demonstrated in airway dimensions with appliance in place.

documentation of baseline condition and evaluation of treatment outcome for snoring easy. The Braebon Pursuit Advanced Software objectively records all snores, measures them in decibels and offers the healthcare provider the ability to listen to any or all of them. Having the patient listen to their baseline snoring sound compared to that after successful control using a MAD is a powerful tool for generating patient referrals.

### Imaging

Cone beam CT scanners allow clinicians to noninvasively view discrete anatomical structures such as a narrowed oropharynx which could contribute to the etiology of OSA and snoring. CT can identify the specific area in the oropharynx that is involved in causing the airway blockage, such as soft palate, tonsils, base of tongue, uvula or epiglottis.

Cone Beam CT scanners are based on volumetric tomography, using a 2D extended digital array combined with a 3D x-ray beam. The cone-beam technique involves a single 360° scan in which the x-ray source and a reciprocating area detector synchronously move around the patient's head, which is stabilized with a head holder. At certain degree intervals, single projection images, known as "basis" images, are acquired. These are similar to lateral cephalometric radiographic images, each slightly offset from one another. This series of basis projection images is referred to as the projection data. Software programs incorporating sophisticated algorithms including back-filtered projection are applied to these image data to generate a 3D volumetric data set, which can be used to provide primary reconstruction images in 3 orthogonal planes (axial, sagittal and coronal).

### Conclusion

MADs have many characteristics to recommend them as an excellent alternative to CPAP and surgery. Dentists knowledgeable in sleep dentistry have a lot of new technology to complement medical specialists who treat OSA patients. In addition to their conventional domain of constructing MADs by prescription, dentists can now consult on the prognosis of success of a MAD, training the patient in reconditioning of tongue reflexes in conjunction with MAD use and scientific evaluation of treatment outcome of OSA and snoring.

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