Oral appliance therapy (OAT) for the management of obstructive sleep apnea (OSA) and snoring has become widely accepted.1,2 Many different mandibular advancement oral appliances have been approved by the Food and Drug Administration (FDA) of the United States of America to be marketed and used in the management of snoring and OSA.3 Most insurance companies and government payors in the United States provide benefits for OAT based on similar criteria to their coverage for Continuous Positive Airway Pressure therapy.4 OAT for the management of snoring and OSA is gaining acceptance in large part due to the significant increase in scientific evidence being published regarding OAT over the past 20 years and the positive clinical experience of healthcare providers and their patients.1,2 The study was conducted as a randomized, controlled, crossover trial at a multidisciplinary sleep disorders clinic in a university teaching hospital. Patients received either a MAD or a Control Oral Appliance for four weeks each. Polysomnography and 24-hour Ambulatory Blood Pressure Monitoring were carried out at baseline and following each four-week intervention period.

The purpose of this paper is to state the position of the American Academy of Craniofacial Pain Task Force on Mandibular Advancement Oral Appliance Therapy for Snoring and Obstructive Sleep Apnea and make recommendations related to the education and experience of dentists engaged in, or who wish to engage in, the assessment and management of patients with snoring and OSA using mandibular advancement oral appliances.

It is well recognized that temporomandibular disorders (TMDs) (including disorders directly related to the temporomandibular joints, muscles of mastication and associated structures) and the broader term of craniofacial pain (including various intraoral and extraoral pains, related neuralgias, certain headache disorders, etc.) are common in the general population, and appear to be even more common in patients with OSA.5-9 Current research and observations in clinical practice indicate that there is significant co-morbidity of OSA and TMDs/craniofacial pain.10

The marketing of oral appliances used for the management of snoring and OSA is regulated by the Dental Division of the FDA under special controls. Currently, there are no appliances approved by the FDA for snoring and sleep apnea that are for “over the counter” distribution, as all approved appliances are prescription only. The FDA requires that manufacturers of oral appliances marketed for the management of snoring and OSA provide product labeling warning patients that OAT may result in “pain or soreness to the temporomandibular joint,” as well as precautions stating that OAT should not be utilized by patients with “active TMJ disorder.”3

Oral Appliance Therapy Shown to Reduce Blood Pressure in OSA Patients

A recent study at the University of New South Wales in Sydney, Australia, indicates that Mandibular Advancement Device (MAD) Therapy can provide similar reductions in blood pressure as CPAP therapy. The study looked at the short-term effect of Oral Appliance Therapy for obstructive sleep apnea on blood pressure. The four-week study involved a total of 61 patients diagnosed with Obstructive Sleep Apnea. Every patient in the study had an Apnea Hypopnea Index (AHI) of 10 events/hour or greater and showed at least two symptoms that include daytime sleepiness, snoring, witnessed apneas and fragmented sleep. All the patients were over the age of 20 and maintained a minimum Mandibular Protrusion of 3mm.

The study was conducted as a randomized, controlled, crossover trial at a multidisciplinary sleep disorders clinic in a university teaching hospital. Patients received either a MAD or a Control Oral Appliance for four weeks each. Polysomnography and 24-hour Ambulatory Blood Pressure Monitoring were carried out at baseline and following each four-week intervention period.

The study data showed that patients experienced a 50 percent reduction in mean AHI with MAD therapy compared with the control, along with a significant improvement in both minimum oxygen saturation and arousal index. There was also a significant reduction in mean 24-hour diastolic blood pressure with MAS therapy, (1.8 ± 0.5 mmHg) compared with the control, but not in 24-hour systolic blood pressure. Awake blood-pressure variables were reduced with the MAD by an estimated mean of 3.3±1.1 mmHg for systolic blood pressure (P = .003) and 3.4 ± 0.9 mmHg for diastolic blood pressure. There was no significant difference in blood pressure measured during sleep.

Based on the results of this study, the authors
Cardiovascular Benefits of MAD Therapy for OSA Patients

A study at the Universidade Federal de São Paulo, Brazil examined the effects of Mandibular Advancement Device (MAD) Therapy as compared to Continuous Positive Airway Pressure (CPAP) treatment for obstructive sleep apnea (OSA), in relation to cardiovascular parameters including blood pressure (BP), oxidative stress, and heart rate variability (HRV). This was a randomized, crossed-over, single-blind, and controlled trial involving a total of 29 adult OSA patients between the ages of 25 to 65, with moderate to severe symptoms (AHI > 20 and BMI < 35 kg/m²) and a minimum Mandibular Protrusion of 7mm.

Patients underwent an initial clinical evaluation which included a baseline, full-night polysomnography exam and simultaneous 24-hour ambulatory blood pressure monitoring. HRV was analyzed from electrocardiograph data obtained from polysomnography. Blood samples were collected for oxidative stress analysis for parameters that included lipid peroxidation (malondialdehyde), catalase, superoxide dismutase, vitamins C, E, B-6, B-12, folate, uric acid, homocysteine, and HRV. Patients were instructed to maintain a similar diet over the entire study period. After baselines were established, patients were divided into three groups, and over the course of the study, each group was administered a one-month treatment with CPAP, MAD and a placebo oral appliance. All monitored parameters were reassessed after the conclusion of the month’s trial, and one-week wash-out periods were included after each therapy rotation.

Results of the study showed that both active treatments—CPAP and MAD—resulted in decreases in apnea and hypopnea index and Epworth Sleepiness Scale, with CPAP showing a greater effect. Frequency of diastolic BP dipping was higher in the MAD group compared with the CPAP group. A significant drop from baseline levels for catalase activity was observed after MAD. For HRV, there was a significant decrease in total power at night with both CPAP and MAD as compared with the placebo oral appliance. There was a decrease in index of sleep autonomic variation with MAD as compared with baseline levels. Compliance rates were higher with MAD than with CPAP.

The authors of the study concluded that: “even though CPAP proved to be more effective at attenuating OSA, better compliance with MAD favored the reduction of one of the enzymes which participates in oxidative stress and better autonomic modulation during sleep.

Source: Mandibular advancement device and CPAP upon cardiovascular parameters in OSA. Cibele Dal-Fabbro and Silverio Garbbuio, Universidade Federal de São Paulo, Brazil. Sleep and Breathing, January 2014.
Dual Roles of MAD in Airway Expansion

A study at the University of New South Wales used imaging techniques to identify the ways that mandibular advancement devices work to expand the airway. The study’s specific objective was to characterize tongue and lateral upper airway movement and to image tongue deformation during mandibular advancement.

This was accomplished by means of a dynamic imaging study involving 30 subjects age 31 to 69, who displayed a wide range of apnea hypopnea index (AHI) scores (0-74 events/hour), and body mass index (BMI) scores ranging from 17-39 kg/m². All subjects were fitted with mandibular advancement devices and imaged using dynamic tagged magnetic resonance imaging with the devices in place. Tissue displacements were quantified with the harmonic phase technique.

The mean mandibular advancement for the study group was 5.6 ± 1.8 mm. This advancement produced movement through a connection from the ramus of the mandible to the pharyngeal lateral walls in all subjects. In the sagittal plane, the patterns of posterior tongue deformation were seen with mandibular advancement: en bloc anterior movement, anterior movement of the oropharyngeal region, and minimal anterior movement.

The results showed that subjects with lower AHI were more likely to have en bloc movement than minimal movement. Antero-posterior elongation of the tongue increased with AHI, and mean anterior displacements of the posterior nasopharyngeal and oropharyngeal regions of the tongue were 20% (± 13%) and 31% (± 17%) of mandibular advancement. The posterior tongue compressed an average 1.1mm (± 2.2 mm) superoinferiorly.

The results of the study allowed the authors to conclude that mandibular advancement has two mechanisms of action, which increase airway size. In subjects with low AHI, the entire tongue moves forward. Mandibular advancement also produces lateral airway expansion via a direct connection between the lateral walls and the ramus of the mandible.

Source: Tongue and lateral upper airway movement with mandibular advancement. Brown EC; Cheng S; McKenzie DK; Butler JE; Gandevia SC; Bilston LE. School of Medical Sciences, University of New South Wales, Australia. SLEEP 2013, 3.