

Thank you for the opportunity to participate today. Respironics is a worldwide leader in providing solutions to the sleep and respiratory markets. Our products and programs help clinicians and patients manage sleep problems. Our focus at this meeting is to address two potential concerns regarding the Over the Counter use of occlusal splint (bruxism) therapy:

- Research validates that occlusal splints for the treatment of bruxism can aggravate Obstructive Sleep Apnea, and
- Occlusal splints have documented side effects associated with oral dryness, pain, etc.

Our purpose in attending this meeting is to educate our audience, given that given that FDA determined based on the outcomes of the Joint Meeting of the FDA Dental Products and Ear, Nose and Throat (ENT) Panels on October 2004 that FDA will not allow OTC marketing of intraoral devices for snoring/OSA based on the risks involved with the selection, fit and use of these devices.

## **Clinical Use of Mandibular Advancement Devices (MAD)**

In clinical dentistry and sleep medicine, the use of mandibular advancement devices (MAD) is a recognized management strategy for two respiratory disturbances during sleep: snoring and sleep apnea. (18, 19) In sleep medicine, snoring and sleep apnea are classified under “obstructive sleep apnea and hypopnea syndrome” (OSAHS). (21) Although snoring is found in 25% of the adult population, the prevalence of OSAHS, when estimated with sleep PSG recordings, is around 2 to 4%. Clinicians should be aware that patients who complain about snoring may suffer from undiagnosed sleep apnea (2, 3, 4), a medical condition that carries an increased risk for cardiovascular disease (including hypertension and stroke), daytime sleepiness, altered memory, enuresis, performance deficit, lost productivity, reduced quality of life and periodic limb movement during sleep (5, 7, & 22). At the other end of the SDB spectrum lies snoring which affects up to 40 million Americans. In addition to the physiological co-morbidities, snoring presents patients with significant social and quality of life impacts. (6, 8)

Sleep disordered breathing (SDB) describes a group of disorders characterized by abnormalities of the respiratory pattern (e.g., pauses in breathing) or the quality of ventilation during sleep. SDB may affect up to 50 million Americans (1, 9).

### **OTC Oral Appliances for the treatment of bruxism**

In the general population, the estimated prevalence of tooth grinding – sleep bruxism is 8%(10). The prevalence of pain caused by temporomandibular disorders (TMD) is 8% to 15% for women and 3% to 10% for man (11-13). It has been estimated that more than 3, 000,000 oral splints (also called occlusal splints) are fabricated each year in the United States to manage sleep bruxism and TMD.

Although the mechanism of action of the splint is unknown, it is possible that splints modify the space between the dental arches; the mandible is then slightly lowered and could be reduced, and the space for the tongue may also be reduced. This leads one to ponder whether using such a device might alter airway patency, especially during sleep. This conjecture is based on the observation that in the sleep of normal subjects, the tongue and hyoid bone tend to move backward and airway patency is reduced in the supine position. (15-17) Moreover, in apneic patients, the rationale behind using an MAD is that functional airway patency may be recovered by causing the mandible to

protrude. (18, 19) Taking this information into account, as well as the possibility that sleep apnea/OSAHS may be under-recognized in patients treated with an oral splint for bruxism or pain caused by TMD, one could hypothesize that the use of a single maxillary oral splint may aggravate respiratory disturbance in sleep apneic patients.

In support of this hypothesis, research (20) was performed to determine if a group of 10 patients with a history of snoring and a recording night confirming the diagnosis of sleep apnea were studied. Data collected during the study included total sleep time, sleep efficiency and number of awakenings, micro arousals, apnea-hypopnea index per hour of sleep (AHI), respiratory disturbances index per hour of sleep (RDI) and percentage of sleeping time with snoring. Results from this study determined that there was no statistically significant difference in AHI between baseline and splint nights, however four patient experiences an aggravation in apnea diagnosis category on the night they used the splint. The AHI was increased by more than 50% in 5 of the 10 patients. These RDI showed a 30% increase from baseline to splint nights. The percentage of sleeping time with snoring also increased by 40% with the splint. Based on these results one may conclude that the use of an occlusal splint is associated with a risk of aggravation of respiratory disturbances. Therefore it may

be relevant for clinician to questions patients about snoring and sleep apnea when recommending an occlusal splint.

In support of these conclusions, the outcomes from the 2004 Joint Meeting of the FDA Dental Products and Ear, Nose and Throat (ENG) Panels stated that oral appliances for the treatment of snoring and/or OSA must be classified as prescription type devices dues to the various risks associated with the use of these devices in an OTC environment.

Some of the risks discussed at the panel meeting included:

- Can the lay person accurately self-diagnose their medical condition?
- Can the lay person accurately self-diagnose their oral health status?
- And, can the lay person choose the correct oral appliance and fit it accurately such that the device is safety and effective and does not cause adverse events (i.e. applying forces on the teeth, tissue and the temporomandibular joint)

## **Conclusions**

These risks, as well as the outcomes from the research study (20), provide conclusive evidence that mouth guards, intended to provide protection against bruxism, teeth clenching and grinding, currently classified as Product Code MQC should be classified as Prescription type devices because of the potential risk associated with the fit, use, and self awareness/diagnosis of the potential for OSA of a person using these types of devices. We agree and support the agency's ruling made in the 2004 Dental Panel Meeting to regulate these devices as prescription controlled, such that that a dental or medical professional will:

- have oversight/professional intervention on the use of the device, such that the potential for diagnosis of sleep apnea is not delayed
- fit the device to ensure successful use to minimize the potential for significant adverse impact on the airway function and jaws if not properly fitted
- and to ensure safety and efficacy for patient using the occlusal splint.

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