

Definition of an Effective Oral Appliance

Oral appliances are an accepted and common treatment for sleep-related breathing disorders. Until now, the field has lacked an empiric definition of an effective oral appliance. A consensus conference was held on February 15-17, 2013 in Tampa, FL attended by 15 experts in the field of dental sleep medicine and dental sleep research. The purpose of the conference was to discuss available evidence and reach a consensus on a definition using a modified RAND Appropriateness Method process. A manuscript detailing the conference proceedings and available evidence supporting the final definition will be published in the *Journal of Dental Sleep Medicine*.

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FINAL DEFINITION

The purpose of an oral appliance is to treat obstructive sleep apnea (OSA), primary snoring, and associated symptoms. Oral appliances are intended to decrease the frequency and/or duration of apneas, hypopneas, respiratory effort related arousals (RERAs) and/or snoring events. Oral appliances have been demonstrated to improve nocturnal oxygenation as well as the adverse health and social consequences of OSA and snoring. Oral appliances are indicated for patients with mild to moderate OSA and primary snoring. Oral appliances are accepted therapy for patients with severe OSA who do not respond to or are unable or unwilling to tolerate PAP therapies. Although oral appliances are typically used as a stand-alone therapy, they can serve as an adjunct to PAP therapy and/or other treatment modalities for the management of OSA.

For this definition oral appliances refer to mandibular advancement devices because they are the most effective and widely used in clinical practice. Accordingly the function of an oral appliance is to protrude and help stabilize the mandible in order to maintain a patent upper airway during sleep.

An oral appliance is custom fabricated using digital or physical impressions and models of an individual patient's oral structures. As such, it is not a primarily prefabricated item that is trimmed, bent, relined or otherwise modified. It is made of biocompatible materials and engages both the maxillary and mandibular arches. The oral appliance has a mechanism that allows the mandible to be advanced in increments of 1 mm or less with a protrusive adjustment range of at least 5 mm. In addition, reversal of the advancement must be possible. The protrusive setting must be verifiable. The appliance is suitable for placement and removal by the patient or caregiver. It maintains a stable retentive relationship to the teeth, implants or edentulous ridge and retains the prescribed setting during use. An oral appliance maintains its structural integrity over a minimum of 3 years.

This definition includes the key design features of effective oral appliances, is evidence based or, in the absence of evidence, is agreed upon using a modified RAND Appropriateness Method process. Its intent is not to replace clinical judgment but instead represents a compilation of the best currently available appliance design features.