

Definition of an Effective Oral Appliance for the Treatment of Obstructive Sleep Apnea and Snoring: An Update for 2019.

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1.0 INTRODUCTION

Oral appliance therapy (OAT) is effective for treating patients with snoring and obstructive sleep apnea (OSA).¹ OAT can be an effective treatment for patients who prefer oral appliances over continuous positive airway pressure or who are unable to tolerate continuous positive airway pressure.²⁻⁷ The American Academy of Dental Sleep Medicine (AADSM) originally created a definition for an effective oral appliance in 2013. Since then, a large amount of scientific literature has been published focusing on oral appliances. Thus, the original definition was revisited to determine whether it was consistent with current scientific evidence and clinical practice. This article presents the updated definition of an effective oral appliance.

2.0 BACKGROUND

In February 2013, the AADSM convened a consensus conference to determine the definition of an effective oral appliance.⁸ This definition was formed in response to The Centers for Medicare and Medicaid Services publication of a Local Coverage Determination L33611, which defined an oral appliance quite narrowly. Prior to the consensus conference, a literature search was conducted which resulted in 113 articles to support the definition of an effective oral appliance. In March 2013, the AADSM Board of Directors approved this definition.⁸

In November 2018, the AADSM convened a task force meeting to determine whether the original definition should be updated.

3.0 METHODS

In November 2018, the task force was asked to review the original consensus conference paper detailing the definition of an oral appliance, The Centers for Medicare and Medicaid Services definition of an effective oral appliance, and relevant recent scientific literature regarding oral appliances. Literature was gathered from PubMed, using the search terms from the

2013 consensus paper.⁸ Included articles were published from March 13, 2013 – October 24, 2018. Review articles were screened for full-text availability, relevance to OAT, and detailed discussion of OAT. Clinical trials were screened for full-text availability, relevance to OAT, and detailed definition of oral appliance(s) used. A total of 45 review articles and clinical trials were reviewed by the task force. After review of this literature, the task force recommended that the definition be updated.

A second literature search was conducted, using both the original search terms as well as keywords and MeSH terms associated with each change proposed. Articles were screened for relevance to the changes proposed by the task force. A total of 58 articles were included in the final review (articles were included if published between March 9, 2000 – January 10, 2019). After being asked to review these articles, the task force met to discuss the finalization of changes in February 2019.

4.0 UPDATED DEFINITION

The task force presented their updated definition to the AADSM Board of Directors in March 2019. The final approved definition is as follows:

The purpose of an oral appliance is to treat obstructive sleep apnea (OSA), primary snoring, and associated symptoms. Effective oral appliance therapy is best achieved when it is provided by qualified dentists. A properly fitted oral appliance worn nightly will 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 positive airway pressure (PAP) therapies. Although oral appliances are typically used as a stand-alone therapy, with some patients they may be prescribed as an adjunct to PAP therapy and/or other treatment modalities for the management of OSA.

Oral appliances refer to mandibular advancement devices because they are the most effective and widely used in clinical practice. The function of an oral appliance is to protrude (advance) 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 and physical needs. A custom-fabricated oral appliance may include a prefabricated component; however, it is not a primarily prefabricated item that is subsequently 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 advances the mandible in increments of 1 mm or less with a protrusive adjustment range of at least 5 mm. This mechanism may or may not include fixed mechanical hinges or metallic materials. 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, prevents dislodging, and retains the prescribed setting during use.

5.0 DISCUSSION OF MAJOR CHANGES TO THE DEFINITION

Five major changes were made to the original definition that relate to oral appliance effectiveness. These changes focused on the physical features and functions of an oral appliance.

An Oral Appliance Must be Made of Materials That Meet Patients' Physical Needs

An oral appliance must be made of biocompatible materials for it to be considered safe for patient use.⁸ Furthermore, materials must be suitable for an individual patient's oral structure and physical needs. For example, such physical needs may include the need for nonmetallic materials for those with metal hypersensitivities.

Approximately 10% to 15% of the population is hypersensitive to metals.⁹ Thus, alternate, biocompatible materials must be used when fabricating oral appliances for such patients. Oral appliance materials that were

previously made with metal can now be made with other materials. For instance, the connecting mechanisms in duobloc appliances can be made of elastic, plastic, or even magnets.¹⁰

A Custom-Fabricated Oral Appliance May Include a Prefabricated Component

Current evidence indicates that custom oral appliances are superior to prefabricated devices.¹¹⁻¹⁶ Custom-made devices have been associated with patient comfort and compliance with treatment.¹⁷ Overall, custom-made appliances have been associated with improved apnea-hypopnea index (AHI), reduced daytime sleepiness, improved endothelial function, and increased muscle activity.¹⁷⁻²⁶ The literature heavily supports use of custom-made oral appliances over prefabricated devices.⁸ Nevertheless, if the device itself is custom made, it may include a prefabricated component (such as the connection mechanism) as long as the device is customized to the patient and not primarily prefabricated.²⁷

An Oral Appliance Mechanism is Not Limited to Fixed Mechanical Hinges or Metallic Materials

Oral appliance designs now feature connecting mechanisms other than fixed mechanical hinges. Additionally, many newer oral appliances feature nonmetallic connectors, which are necessary for those who have OSA and suffer from metal hypersensitivity.

As technology has progressed, a number of nonhinged appliances have been proven effective in treating OSA. For example, AHI was improved using a device that advanced the mandible using elastics connected to Adams clasps.²⁸ Another study comparing oral appliances with elastic bands to the same appliance without bands found no significant difference in AHI after use.²⁹

Another nonhinged device is connected and adjusted using flexible, nonmetal rods and was associated with significant improvement in OSA symptoms. In one study, 76% of patients were effectively treated using this device (decrease in AHI $\geq 50\%$) and 64% achieved a complete treatment response.²² Another study with this oral appliance showed that 56% of patients using the device achieved treatment response.³⁰

Furthermore, an appliance that used ball clasps to protrude the mandible significantly reduced AHI in one study. This study found that 57% of patients achieved AHI < 10 per hour and 31% achieved an AHI < 5 per hour. Overall, the study concluded that the device was successful in treating OSA in 58% of patients, excessive daytime sleepiness in 56%, and snoring in 76%.²³ Thus, such studies indicate that appliances featuring

connecting mechanisms other than fixed mechanical hinges can also effectively treat OSA.

An Oral Appliance Must Prevent Dislodging

An effective oral appliance must have retention to one or both dental arches.¹⁰ Lack of proper oral appliance stability can lead to poorer health outcomes. For example, it has been suggested that monobloc could be less effective than duobloc appliances because of poor stability (among other factors).³¹ Thus, the oral appliance must have good retention to the dentition and prevent dislodging.

Lifetime of an Oral Appliance

The original definition included a clause that stated that an effective oral appliance must “maintain its structural integrity over a minimum of 3 years.”⁸ After review, it was determined that there was very little evidence outside of the AADSM definition itself that an appliance should last at least 3 years in order for it to be effective. Thus, this sentence was removed from the definition.

CONCLUSION

An oral appliance can be an effective treatment option for those with OSA and snoring. As dental sleep technology rapidly changes, new and effective appliances have emerged. To promote consistency and best treatment practices, the AADSM has updated its definition of an effective oral appliance to reflect current scholarly literature and clinical practice. As further updates in science, technology, and practice develop, future edits to this definition may be made.

CITATION

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DISCLOSURE STATEMENT

Dr. Mogell reports being on the editorial advisory board of *Sleep Review* and receiving an honorarium to present at the American Academy of Oral Medicine Meeting in 2017. Dr. Mason reports being an unpaid member of the Board of Directors for the Virginia Academy of Sleep Medicine, accepting honoraria and gifts for Prosomnus speaking engagements, and being involved in speaking engagements for “thedentalspeaker.com” and NDX Laboratory. Dr. Rohatgi reports serving as part of an advisory group for Prosomnus. Dr. Schwartz reports serving as part of an advisory group for Prosomnus and having a financial stake in Prosomnus. Dr. Shah reports giving paid lectures for Sleep Group Solutions. Dr. Blumenstock has no conflicts of interest to disclose.