Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances: An Update for 2005

An American Academy of Sleep Medicine Report

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Summary: These practice parameters are an update of the previously published recommendations regarding use of oral appliances in the treatment of snoring and Obstructive Sleep Apnea (OSA). Oral appliances (OAs) are indicated for use in patients with mild to moderate OSA who prefer them to continuous positive airway pressure (CPAP) therapy, or who do not respond to, are not appropriate candidates for, or who fail treatment attempts with CPAP. Until there is higher quality evidence to suggest efficacy, CPAP is indicated whenever possible for patients with severe OSA before considering OAs. Oral appliances should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion and associated oral structures. Follow-up polysomnography or an attended cardiorespiratory (Type 3) sleep study is needed to verify efficacy, and may be needed when symptoms of OSA worsen or recur. Patients with OSA who are treated with oral appliances should return for follow-up office visits with the dental specialist at regular intervals to monitor patient adherence, evaluate device deterioration or maladjustment, and to evaluate the health of the oral structures and integrity of the occlusion. Regular follow up is also needed to assess the patient for signs and symptoms of worsening OSA. Research to define patient characteristics more clearly for OA acceptance, success, and adherence is needed.

Keywords: Practice parameters; practice guidelines, standards of practice, snoring, obstructive sleep apnea syndrome, oral appliances, dental devices

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1.0 INTRODUCTION

SNORING AND OBSTRUCTIVE SLEEP APNEA (OSA) ARE CAUSED IN PART BY REPETITIVE DYNAMIC OBSTRUCTION OF THE OROPHARYNGEAL AIRWAY. There is growing epidemiological and experimental evidence that OSA, and to a lesser degree snoring, are associated with a wide variety of adverse health outcomes.[1, 2] OSA is considered one of several potentially treatable contributors to systemic hypertension, and has been associated with coronary artery disease, stroke, congestive heart failure, atrial fibrillation, increased motor vehicle accident rate, sleepiness, impaired quality of life, and increased mortality. Although several epidemiologic studies suggested a relationship between snoring and hypertension, cardiovascular disease, and cerebrovascular disease, most of these studies were not able to discern the difference between primary snoring and patients with a mild variant of OSA. Nevertheless, snoring represents an important social problem, and contributes to impaired sleep quality of the bed partners of those who snore.[3]

Oral appliances are increasingly used as a treatment modality for patients with OSA. In 1995, the American Academy of Sleep Medicine (AASM, formerly the American Sleep Disorders Association) published a position paper on the clinical use of oral appliances in the treatment of snoring and obstructive sleep apnea. The paper presented clinical guidelines developed by the Standards of Practice Committee (SPC) of the AASM, based upon Level V evidence (Table 1). Since publication of the practice guidelines, the scientific literature regarding oral appliances has matured and expanded significantly.[4] For these reasons, the following new and updated recommendations were developed regarding the use oral appliances in the treatment of snoring and OSA.

The purpose of this practice parameter paper is to reissue, modify and, if necessary, replace recommendations for the use of oral appliances in the treatment of snoring and OSA based on the scientific literature published since 1995. Recommendations are based on the accompanying review paper produced by a Task Force established by the Standards of Practice Committee.[4] Rec-

Table 1—AASM Classification of Evidence

Evidence Levels	Study Design
I	Randomized well-designed trials with low alpha and beta error*
II	Randomized trials with high alpha and beta error*
III	Nonrandomized concurrently controlled studies
IV	Nonrandomized historically controlled studies
V	Case series

Adapted from Sackett[5]

*Alpha (type I error) refers to the probability that the null hypothesis is rejected when in fact it is true (generally acceptable at 5% or less, or $p < 0.05$). Beta (Type II error) refers to the probability that the null hypothesis is mistakenly accepted when in fact it is false (generally trials accept a beta error of 0.20). The estimation of Type II error is generally the result of a power analysis. The power analysis takes into account the variability and the effect size to determine if sample size is adequate to find a difference in means when it is present (Power generally acceptable at 80-90%).

ommendations are targeted to the practice of adult sleep medicine. Although oral appliances are being used in treatment of children, the literature is not well developed. The paucity of evidence regarding pediatric usage limits the scope of these recommendations to adolescents and adults.

2.0 METHODS

The Standards of Practice Committee of the AASM, in conjunction with specialists and other interested parties, developed these practice parameters based on the accompanying review paper. A Task Force of content experts was appointed by the AASM to review and grade evidence in the scientific literature regarding the clinical use of oral appliances in the treatment of snoring and OSA. In most cases, recommendations are based on evidence from studies published in the peer-reviewed literature.

The Board of Directors of the AASM approved these recommendations. All members of the AASM Standards of Practice Committee and Board of Directors completed detailed conflict-of-interest statements and were found to have no conflicts of interest with regard to this subject.

These practice parameters define principles of practice that should meet the needs of most patients in most situations. These guidelines should not, however, be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding propriety of any specific care must be made by the physician, in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources.

The AASM expects these guidelines to have an impact on professional behavior, patient outcomes, and, possibly, health care costs. These practice parameters reflect the state of knowledge at the time of publication and will be reviewed, updated, and revised as new information becomes available. This parameter paper is referenced, where appropriate, using square-bracketed numbers to the relevant sections and tables in the accompanying review paper, or with additional references at the end of this paper. The Standards of Practice Committee's classification of evidence for evidentiary articles is listed in Table 1. Definitions of levels of recommendations used by the AASM appear in Table 2.

The AASM appointed a Task Force in 2002 to perform a comprehensive review of the medical literature regarding the use of oral appliances in the treatment of snoring and OSA, and to grade the strength of evidence for each citation. The initial literature search was performed in 2002 using Medline. An updated search was performed using the same search strategy to include all articles indexed in Medline prior to January 2004, and this was again repeated in July 2004. Details regarding search terms, exclusions, and methods for screening by Task Force members are provided in the review paper.[4] Two members of the Standards of Practice Committee (DIL and TIM) served as liaisons between the Standards of Practice Committee and the Task Force.

Table 2—AASM Levels of Recommendations

Term	Definition
Standard	This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or over whelming Level II Evidence.
Guideline	This is a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.
Option	This is a patient-care strategy, which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

Adapted from Eddy[6]

3.0 RECOMMENDATIONS

The following are recommendations of the Standards of Practice Committee and the Board of Directors of the American Academy of Sleep Medicine. The classification of evidence was adapted from the suggestions of Sackett (Table 1).[5] Recommendations are given as standards, guidelines, and options, as defined in Table 2.

3.1 Diagnosis

3.1.1 The presence or absence of OSA must be determined before initiating treatment with oral appliances to identify those patients at risk due to complications of sleep apnea and to provide a baseline to establish the effectiveness of subsequent treatment. Detailed diagnostic criteria for OSA are available and include clinical signs, symptoms and the findings identified by polysomnography.[7] The severity of sleep related respiratory problems must be established in order to make an appropriate treatment decision. (Standard)

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper. However, there is a higher level of evidence that severity of OSA is predictive of response to OAs [3.2.4.1].

3.2 Appliance Fitting

3.2.1 Oral appliances should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion and associated oral structures. Dental management of patients with OAs should be overseen by practitioners who have undertaken serious training in sleep medicine and/or sleep related breathing disorders with focused emphasis on the proper protocol for diagnosis, treatment, and follow up. (Option)

This recommendation is a modification of the recommendation of the previous practice parameter paper to specify the training of the personnel responsible for fitting the oral appliances. It is based on committee consensus [3.7].

3.2.2 Although cephalometric evaluation is not always required for patients who will use an oral appliance, appropriately trained professionals should perform these examinations when they are deemed necessary (Option).

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

3.3 Treatment

3.3.1 Treatment Objectives

3.3.1.1 For patients with primary snoring without features of OSA or upper-airway resistance syndrome, the treatment objective is to reduce the snoring to a subjectively acceptable level (Standard).

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

3.3.1.2 For patients with OSA, the desired outcome of treatment includes the resolution of the clinical signs and symptoms of OSA and the normalization of the apnea-hypopnea index and oxyhemoglobin saturation (Standard).

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

3.3.2 Oral appliances are appropriate for use in patients with primary snoring who do not respond to or are not appropriate candidates for treatment with behavioral measures such as weight loss or sleep-position change. (Guideline)

This recommendation is a modification of the recommendation of the previous practice parameter paper to exclude mild OSA patients; these latter patients are discussed in practice parameter 3.3.3. This recommendation is based on 1 level I study and 2 level V studies [3.2.3].

3.3.3 Although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA who prefer OAs to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change. (Guideline)

This is a new recommendation. It is based on 11 level I, 3 level II, and 16 level III-V studies that used stringent criteria for defining success [3.2]. In the reviewed studies, CPAP when used is routinely more efficacious than OAs in reducing measures of respiratory disturbance (AHI, oxygenation), but may be equipotent with OAs in improving subjective and objective measures of sleepiness. Stratification of the severity of OSA was not performed in most studies, but in patients with a mean AHI greater than 10 and less than 30, success (internally defined within each study, but considering only those with a reduction of AHI to less than or equal to 10) occurred in 52.6 ± 2.5% (mean ± SEM, range 19.0% - 81.0%). The quality of studies did not systematically affect the measured success rate (average success rate for studies of level I = 55.4%, level II = 47.7%, and level III-V = 52.3%). One level I study that categorized patients into mild, moderate, and severe OSA by initial AHI found better success rates in mild OSA (81%) than in moderate (60%) or severe (25%) OSA. Limited adherence to OA may result in less than perfect effectiveness, i.e., a patient using therapy with a successful result. OAs were found to be more effective than UPPP in 1 level I study. OAs are particularly more likely to succeed when OSA is positional and with lower BMI. Because of the inability to predict success reliably, when OAs are selected, follow up testing should be obtained to ensure treatment effectiveness.

3.3.4 Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations and tracheostomy) may also supersede use of oral appliances in patients for whom these operations are predicted to be highly effective in treating sleep apnea. (Guideline)

This recommendation is a modification of the recommendation of the previous practice parameter paper to clarify treatment of patients with severe OSA. It is based on 1 level II study and 2 lower level studies [3.2]. Reviewed studies of patients with severe OSA demonstrated treatment success (variably defined) with OAs in an average of 34.3% ± 13.5% (mean ± SEM, range 17.0% - 61.0%). In 1 study that used an AHI < 20 as the "success" criteria, 5/9 patients were successfully treated with OAs, but this study was small. Until there is higher quality evidence to suggest efficacy, CPAP is indicated whenever possible for patients with severe OSA before considering OAs.

3.4 Follow-up

3.4.1 Follow-up sleep testing is not indicated for patients with primary snoring.[7] (Guideline)

This recommendation is the same recommendation as the recommendation of the previous practice parameter paper.

3.4.2 To ensure satisfactory therapeutic benefit from OAs, patients with OSA should undergo polysomnography or an attended cardiorespiratory (Type 3) sleep study with the oral appliance in place after final adjustments of fit have been performed. (Guideline)

This recommendation is a modification of the recommendation of the previous practice parameter paper to generalize therapeutic evaluation to all patients with OSA, not only patients with moderate to severe OSA. The previous parameter recommended sleep testing only for those with moderate to severe OSA, and not for those with mild OSA. Subsequent data has shown that even relatively low AHI are associated with adverse health outcomes, and especially in patients with comorbid disease or risk factors, may be important.[8] Since the rate of treatment success is not predictably high with OAs, treatment should be assessed for efficacy with objective testing. Additionally, some patients experience an increase in AHI with OA treatment. This recommendation is based on 2 level I and 5 level V studies. [3.2, 3.7.6] The reader is also referred to the recent practice parameter paper regarding indications for polysomnography.[7]

3.4.3 Patients with OSA who are treated with oral appliances should return for follow-up office visits with the dental specialist. Once optimal fit is obtained and efficacy shown, dental specialist follow-up at every 6 months is recommended for the first year, and at least annually thereafter. The purpose of follow up is to monitor patient adherence, evaluate device deterioration or maladjustment, evaluate the health of the oral structures and integrity of the occlusion, and assess the patient for signs and symptoms of worsening OSA. Intolerance and improper use of the device are potential problems for patients using oral appliances, which require patient effort to use properly. Oral appliances may aggravate temporomandibular joint disease and may cause dental misalignment and discomfort that are unique to each device. In addition, oral appliances can be rendered ineffective by patient alteration of the device. (Option)

This recommendation is a modification of the recommendation of the previous practice parameter paper to generalize follow-up to all patients with OSA, to specify frequency of follow-up vis-

its, and to expand upon the reasons for the follow-up visit. It is based upon committee consensus on factors described in the accompanying review paper. First, adherence to OAs declines over time, and much of the drop-out has been attributed to appliance intolerance and temporomandibular joint (TMJ) problems, issues which lie clearly in the realm of the dental specialist. Based upon the available data, the largest drop-out from OA therapy appears to occur during the first year when the median adherence averages 77%; intervention during this interval would seem likely to have the greatest impact. Secondly, changes in occlusion begin as early as 6 months. Qualified dental specialists should survey skeletal and bite changes as well as other aspects of dental health since OA appliance use is likely to be life-long. [3.5, 3.7]

3.4.4 Patients with OSA who are treated with oral appliances should return for periodic follow-up office visits with the referring clinician. The purpose of follow up is to assess the patient for signs and symptoms of worsening OSA. Close communication with the dental specialist is most conducive to good patient care. An objective reevaluation of respiration during sleep is indicated if signs or symptoms of OSA worsen or reoccur (Option)

This recommendation is a modification of the recommendation of the previous practice parameter paper to consolidate the reasons for follow-up with the referring clinician into a single practice parameter [3.7].

4.0 AREAS FOR FUTURE RESEARCH

a) Future studies should determine and emphasize use of accepted endpoints for OA therapy of OSA.

b) Adherence data for OAs mostly relies on subjective reports. In contrast, CPAP adherence can now be routinely monitored in an objective fashion. Development of similar capabilities for OA therapy should be pursued for both research and clinical purposes.

c) Research to define more clearly patient characteristics for OA acceptance, success, and adherence is needed.

d) Economic assessment, focusing on both short- and long-range costs (inclusive of needed follow-up and indirect costs of OA therapy) is needed so that OA therapy can be compared with alternate therapies through cost and effectiveness analyses.

e) Research is needed to clarify design characteristics most beneficial in given patient groups, so that device selection is driven by data that are more precise.

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REFERENCES

1. Shamsuzzaman AS, Gersh BJ, Somers VK. Obstructive sleep apnea: implications for cardiac and vascular disease.[see comment]. JAMA. 2003;290(14):1906-14.
2. Hu FB, Willett WC, Manson JE, et al. Snoring and risk of cardiovascular disease in women. Journal of the American College of Cardiology. 2000;35(2):308-13.
3. Beninati W, Harris CD, Herold DL, Shepard JW, Jr. The effect of snoring and obstructive sleep apnea on the sleep quality of bed partners.[see comment]. Mayo Clinic Proceedings. 1999;74(10):955-8.
4. Cartwright R, Ferguson K, Rogers R, Schmidt-Nowara W. Oral appliances for snoring and obstructive sleep apnea: a review. Sleep. 2005.
5. Sackett DL. Rules of evidence and clinical recommendations for the management of patients.[see comment]. Canadian Journal of Cardiology. 1993;9(6):487-9.
6. Eddy DM, ed. A manual for assessing health practices and designing practice policies: the explicit approach. Philadelphia, PA: American College of Physicians; 1992.
7. Kushida CA, Littner MR, Morgenthaler TI, et al. Practice parameters for the indications of polysomnography and related procedures: An update for 2004. Sleep. In press.
8. Shahar E, Whitney CW, Redline S, et al. Sleep-disordered breathing and cardiovascular disease: cross-sectional results of the Sleep Heart Health Study.[see comment]. American Journal of Respiratory & Critical Care Medicine. 2001;163(1):19-25.