

AADSM Protocol for Oral Appliance Therapy for Sleep Disordered Breathing in Adults: An Update for 2013

DISCLAIMER

Conditions presented by a patient may require the dentist to deviate from this protocol while collaborating with the patient's physician to maximize treatment efficacy.

1. Medical assessment must be made by a physician before oral appliance therapy (OAT) is initiated. (1-4)

- a. In order for the dentist to practice within the limits of his or her license as designated and required by the state in which the dentist practices, and in compliance with all applicable state and federal regulations, the dentist shall refer the patient to the physician for a complete medical evaluation and diagnosis to determine the absence or presence, and severity, of sleep-disordered breathing (SDB), which may include snoring, upper airway resistance syndrome (UARS) or obstructive sleep apnea (OSA). Following diagnosis, the dentist may provide OAT as appropriate with a prescription provided by a physician that has had a face-to-face evaluation. The treatment of primary snoring does not require a physician's prescription; or
- b. The physician refers the patient directly to the dentist for OAT as appropriate.

2. The diagnostic sleep study is interpreted by a medical sleep specialist, who provides a copy of the interpretation to the dentist for review. The reviewed copy of the interpretation shall be maintained in the patient record.

3. The dentist assesses the patient through a complete clinical examination, including a determination of the current health and prognosis of oral tissues that might be affected by OAT. Evaluation of a recent radiographic survey is important to a complete examination. The dentist recommends the choice of appliance (1, 2, 5, 6, 7, 8), discloses and discusses relevant fees with the patient, and explains the rationale for OAT to the patient while recording all appropriate documentation. A dentist who owns or has any partial ownership of the device, or patent for the device, that is being recommended for treatment must disclose this information to the patient as a potential conflict of interest (COI) prior to the delivery of the device to the patient.

4. The dentist communicates the proposed plan for OAT to the patient's physician, and appropriate health care providers, and the dentist regularly provides the patient's physician and other health care providers with progress and follow-up notes, as well as other pertinent information. (1,2)

5. The dentist shall provide the patient with a copy of the consent form prior to appliance delivery. (9)

6. In accordance with protocol established between the treating dentist and referring physician, the dentist fabricates a custom-made oral appliance and meets with the patient for an initial calibration and adjustment. After this initial calibration, the dentist may obtain objective data during an initial trial period to verify that the oral appliance effectively improves upper airway patency during sleep by enlarging the upper airway and/or decreasing upper airway collapsibility. If necessary, the dentist makes further adjustments to the device during a final calibration to ensure that optimal fit and positioning have been attained. (10-13)

7. Following the final calibration, the dentist refers the patient back to the physician for a medical evaluation and assessment of OAT outcomes. To ensure satisfactory therapeutic benefit, an order may be written for the patient to undergo an overnight sleep test with the oral appliance in place. If the treatment is sub-therapeutic, the physician and dentist collaborate to discuss: the possibility of further calibration, validated alternative treatments, or combining positive airway pressure (PAP) therapy with OAT. (11-13)

8. Patients diagnosed with primary snoring may be treated without objective, follow-up data; however, the patients should be reevaluated at least annually.

9. Follow-up protocol after the final calibration should include a patient evaluation every six (6) months for the first year and at least annually thereafter. The annual recall exam should: verify appliance efficacy and occlusion stability; check the structural integrity of the device; ensure that there is a resolution of symptoms such as snoring and daytime sleepiness; inquire about patient comfort and adherence to therapy; and screen for possible side effects. If the patient's annual assessment reveals symptoms of worsening OSA or the potential need for additional adjustments to the device, then the dentist shall communicate this information to the patient's physician. (1, 2, 5, 14-16)

10. Knowledge of various appliances is strongly recommended, as no single appliance is effective for treatment of all patients. Dentists who treat SDB are encouraged and have a responsibility to routinely pursue additional education in the field and to comply with all applicable state and federal regulations. (6, 7, 8, 17, 18)

Reference List

- 1. Kushida CA, Morgenthaler TI, Littner MR, et al. American Academy of Sleep Medicine Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances: An Update for 2005. *Sleep*. 2006; 29(2):240-3.
- Epstein LJ, Kristo D, Strollo PJ Jr., et al. Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. *J Clin Sleep Med.* 2009; 5(3):263-76.

- 3. Comparative Effectiveness of Diagnosis and Treatment of Obstructive Sleep Apnea in Adults Tufts Evidence-based Practice Ctr., July 2011. AHRQ publication No. 11-EHCO52 80-99 and 2-5.
- 4. Chan ASL, Lee RWW, Cistulli P. Dental Appliance Treatment for Obstructive Sleep Apnea. *Chest.* 2007; 132:693-699.
- 5. Marklund M, Stenhuld H, Franklin KA. Mandibular Advancement Device is in 630 Men and Women with Obstructive Sleep Apnea and Snoring. Tolerability and Predictors of Treatment Success. *Chest.* 2004; 125:1270-1278.
- 6. Lawton HM, Battagel JM, Kotecha B. A Comparison of the Twin Block and Herbst Mandibular Advancement Splints in the Treatment of Patients with Obstructive Sleep Apnea: A Prospective Study. *Eur J Orthod*. 2005; 27:82-97.
- 7. Gagnadoux F, Fleury B, Vielle B et al. Titrated Mandibular Advancement Versus Positive Airway Pressure for Sleep Apnoea. *Eur Respir J*. 2009; 34:914-920.
- 8. Lam B, Sam K, Mok W et al. Randomized Study of Three Non-surgical Treatments in Mild to Moderate Obstructive Sleep Apnea. *Thorax*. 2007; 62:354-359.
- 9. AMA Physician Resources: http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-hysicianrelationship-topics/informed-consent.page
- 10. Collop NA, Anderson WM, Boehlecke B et al. Portable Monitoring Task Force of the American Academy of Sleep Medicine. Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients. Portable Monitoring Task Force of the AASM. J Clin Sleep Med. 2007; 3(7):737-747.
- 11. Campbell AJ, Reynolds G, Tengrove H, et al. Mandibular Advancement Splint Titration in Obstructive Sleep Apnea. *Sleep Breath*. 2009: 13:157-162.
- Almeida FR, Parker JA, Hodges JS et al. Effect of a Titration Polysomnogram on Treatment Success with a Mandibular Repositioning Appliance. *J Clin Sleep Med.* 2009; 5(3):198-204.
- 13. Holley AB, Letteri CJ, Shah A. Efficacy of an Adjustable Oral Appliance and Comparison to Continuous Positive Airway Pressure for the Treatment of Obstructive Sleep Apnea Syndrome. *Chest* (online). 2011; 140(6):1511-6.
- Almeida FR, Lowe A, Sung J et al. Long-term Sequellae I of Oral Appliance Therapy in Obstructive Sleep Apnea Patients: Part 1. Cephalometric Analysis. *AJODA*. 2006; 195-204.
- 15. Almeida FR, Lowe A,Otsuka R et al. Long-term Sequellae I of Oral Appliance Therapy in Obstructive Sleep Apnea Patients: Part 2. Study-model Analysis. *AJODO*. 2006; 205-213.

Copyright $\ensuremath{\mathbb{C}}$ 2013 by the American Academy of Dental Sleep Medicine

- 16. Ghazal A, Sorichter S, Jonas I et al. A Randomized Prospective Long-term Study of Two Oral Appliances for Sleep Apnoea Treatment. *J Sleep Res.* 2009; 18:321-328.
- 17. Petri N, Svanholt P, Solow B et al. Mandibular Advancement Appliance for Obstructive Sleep Apnea: Results of a Randomized Placebo-controlled Trial Using Parallel Group Design. *J Sleep Res.* 2008; 17:211-229.
- 18. Vandervecken OM, Devolder A, Marklund M et al. Comparison of a Custom-made and a Thermoplastic Oral Appliance for the Treatment of Mild Obstructive Sleep Apnea. *Am J Respir Crit Care Med.* 2008; 178:187-202.