SPECIAL ARTICLE

http://dx.doi.org/10.15331/jdsm.7370

Adequate Oral Appliance Therapy Trial Prior to Surgical Treatment

Michelle Cantwell, DMD, D. ABDSM[1]; Becky Fox, DMD, D. ABDSM[2]; Paul Jacobs, DDS, D. ABDSM[3]; Kevin Postol, DDS, D. ABDSM[4]; Rosemarie Rohatgi, DMD, D. ABDSM[5]

[1]Wellspan Health, Pulmonary and Sleep Medicine, York, PA; [2]Pennsylvania Dental Sleep Medicine Network, Harrisburg, PA; [3] Upper Peninsula Sleep Dentistry, Escanaba, MI; [4] Gateway Center for Sleep Apnea and TMJ Therapy, Twin Oaks MO; [5]San Diego, CA

It is the position of the American Academy of Dental Sleep Medicine (AADSM) that patients with obstructive sleep apnea (OSA) should be referred to a qualified dentist for an oral appliance (OA) trial prior to surgical treatment. Oral appliance therapy (OAT) is a proven, effective treatment for OSA that reduces the apnea-hypopnea index and respiratory disturbance index in patients. While some clinical protocols recommend a positive airway pressure (PAP) trial before proceeding with a surgical procedure, it should be noted that studies have demonstrated that OAT and PAP therapy are similarly effective. Trials of less-invasive therapies are important because surgical treatments for OSA carry risks associated with any invasive procedure and are significantly more expensive than OAT. We firmly believe that due to its efficacy, lower associated risks and lower cost, patients should have an opportunity to try OAT prior to any surgical treatment for OSA. This paper provides guidance on what constitutes an adequate OA trial prior to surgical treatment.

An adequate OAT trial prior to surgical treatment should be conducted using a custom-fabricated oral appliance - not a prefabricated appliance. The trial should be overseen by a qualified dentist who determines whether OAT is contraindicated for a patient, delivers the appliance, manages care during the trial, and evaluates the patient's response to treatment. An adequate OAT trial should, ideally, be a minimum of 90 days, unless the qualified dentist, in consultation with the patient, determines it is in the patient's best interest to end the trial sooner.

Patients cannot provide informed consent for invasive procedures unless they have been given the opportunity to explore OAT provided by a qualified dentist. Informed consent involves a provider communicating with a patient on "burdens, risks and expected benefits" of a therapy, including providing information on treatment alternatives.[1] OAT is a reversible, noninvasive and removable alternative to continuous positive airway pressure (CPAP) and surgical interventions. The patient's future medical decisions, including the potential for invasive surgery, hinge on the OA treatment outcomes.

KEY TAKEAWAYS:

- Using a custom-fabricated OA is critical to an adequate OA trial prior to surgical treatment; prefabricated appliances are not appropriate for an adequate oral appliance trial prior to surgical treatment.
- Qualified dentists have the education and experience to oversee an adequate OA trial prior to surgical treatment.
- An adequate OA trial prior to surgical treatment should, ideally, be conducted for a minimum of 90 days, unless the qualified dentist determines that the trial should be ended early due to adverse effects or because the patient is intolerant of OAT or is not responding to treatment.

Custom-Fabricated Oral Appliances

Using a custom-fabricated OA is critical to the success of an adequate OA trial prior to surgical treatment; prefabricated appliances are not appropriate for an adequate OAT prior to surgical treatment. A custom-fabricated OA stabilizes the mandible to maintain a patent upper airway during sleep. According to the AADSM's definition, custom-fabricated oral appliances:[2]

- Are FDA-cleared to treat OSA.
- Are made of biocompatible FDA-cleared materials appropriate for long-term, intraoral use without corrosion of components.
- Engage both maxillary and mandibular arches.
- Include a mechanism that advances the mandible in increments of 1 mm or less and has a protrusive range of at least 5 mm. The advancement should be reversible.
- Maintain a verifiable protrusive setting.
- Allow for the repeatable path of insertion by the patient or caregiver.
- Are dimensionally stable to maintain retention over time without risk of unintentional dislodgement during use.

There is insufficient scientific evidence of efficacy

to support the use of prefabricated or over-the-counter (OTC) appliances as medically necessary to treat OSA.[3] According to one study, approximately one-third of patients treated with prefabricated devices did not adhere to therapy, typically due to insufficient retention of the appliance during use. Most patients with prefabricated devices (69%) failed therapy. The majority of patients who failed therapy with a prefabricated device succeeded when switched to a custom-fabricated OA.[4] Studies also indicated that custom-made appliances have greater effectiveness, adherence, and patient tolerance and preference due to a better fit, compared to ready-made devices.[5,6] Without the expert guidance of a qualified dentist, prefabricated and OTC devices place the burden of device selection, fit, modification, and management solely on the patient.

An improperly fitted device may result in adverse effects, like jaw pain or occlusal changes. Therefore, impressions and bite registrations should be done in person, overseen by a qualified dentist. Improper fit and retention of the appliance may also lead to a higher degree of inaccurate determinations that a patient is an unsuitable candidate for OAT. Consequently, prefabricated and OTC devices are also not effective for conducting an adequate OA trial prior to surgical treatment.

Qualified Dentists

Qualified dentists have the education and experience to oversee an adequate OA trial prior to surgical treatment. A dentist is the only health care provider with the appropriate training to evaluate a patient's dentition as well as intraoral hard and soft tissues. Recognizing this, in the United States, Medicare requires OAT to be provided by a qualified dentist.[7]

A qualified dentist is defined as an American Board of Dental Sleep Medicine (ABDSM) diplomate, AADSM qualified dentist, or ABDSM international certificant (see Levine et al., 2022 for a full list of key competencies of the qualified dentist).[7] Qualified dentists have completed specific training to:

- Identify if an OA is contraindicated.
- Select which appliance style or type is most appropriate for each patient to provide effective treatment with reliable retention to the teeth.
- Calibrate the appliance to its appropriate therapeutic position.
- Address treatment emergent adverse effects when necessary.
- Manage care including ongoing assessment of compliance, symptom management, and integrity of the appliance.

During a comprehensive dental sleep medicine examination, qualified dentists review medical, sleep, dental, and temporomandibular joint (TMJ) history and perform a comprehensive oral examination and TMJ examination to determine if there are any contraindications for OAT.[8] If a qualified dentist determines that the use of an OAT device is contraindicated, the OA trial should be immediately discontinued, and the patient should be referred to the medical provider to discuss alternate treatment options, including surgical treatment. Temporomandibular disorders (TMD) are not typically a contraindication for OAT. In a recent systematic review based on 12 clinical trials, Langaliya and colleagues found that oral appliances do not worsen symptoms of TMD. In fact, in some of the included studies, TMD symptoms improved.[9] It is important to note that adverse events from OAs are often temporary and can be managed by a qualified dentist.[10]

OA Trial Length

An adequate OA trial prior to surgical treatment should, ideally, be a minimum of 90 days, unless the qualified dentist determines that the trial should be ended early due to adverse effects or because the patient is intolerant of OAT or is not responding to treatment. A one-night OA trial is insufficient. An adequate OA trial includes delivery of the device, assessment of subjective symptoms, calibration based on subjective or objective metrics,[11] and evaluation of compliance. Sutherland and colleagues found that consistent users, inconsistent users, and nonusers of OAT used the appliances for a similar number of hours in the first 4 days of therapy. Their study indicated that 20 days of usage data predicted usage at 60 days, but the study did not account for the management of adverse effects and symptomatic improvements that occur throughout the entire 90 days of an adequate OA trial.[12] An adequate OA trial prior to surgical treatment should be tailored to the patient with the goals of treatment being determined collaboratively by the patient, medical provider, and qualified dentist.

When a custom-fabricated OA is provided by a qualified dentist, there will be two primary outcomes for an adequate OA trial prior to surgical intervention: trial success or trial intolerance/failed trial:

- **Trial Success**: the patient comfortably wears the device without significant discomfort or pain. The patient has adapted to using the appliance nightly, indicating a good fit and minimal interference with sleep. The patient is compliant with therapy or showing improvement over time with compliance, defined as "the appliance being worn for a minimum of ≥80% per night, starting when the OA is placed in the mouth and ending

when the OA is removed from the mouth, ≥5 nights per week."[13] Furthermore, patients see relief of subjective symptoms and improvement to objective metrics, if used for calibration. These patients should be referred to the medical provider to verify treatment efficacy.

- **Trial Intolerance/Failed Trial**: the patient is trial intolerant if additional calibration or adjustment of the appliance is not possible, the patient is noncompliant with therapy, or any significant adverse effects are unable to be resolved. A patient may fail their OA trial if despite therapy being properly provided, the patient does not respond to treatment. At this time, the patient should be referred to the medical provider to discuss alternate treatment options, including surgical treatment.

It is critical that an adequate OA trial be properly conducted prior to surgical treatment. When a qualified dentist provides a custom-fabricated OA, determines whether the patient is a suitable candidate for OAT and approaches the therapy in a way that is tailored to the patient, the patient has a greater chance of trial success. This could lead to a significant number of patients with OSA finding adequate relief of their disorder through a conservative, lower-risk and lower-cost therapy. Such outcomes will not only reduce economic burden to the patient, but to the overall health care system as well.

CITATION

Cantwell M, Fox B, Jacobs P, Postol K, Rohatgi R. Adequate oral appliance therapy trial prior to surgical treatment. *J Dent Sleep Med*. 2025;12(1)

REFERENCES

1. P American Medical Association. Code of medical ethics: informed consent. PolicyFinder. 2016. Updated 2017. Accessed October 16, 2024. https://policysearch.ama-assn.org/policyfinder/detail/informed%20consent%5C?uri=%2FAMADoc%2FEthics.xml-E-2.1.1.xml

2. Mogell K, Blumenstock N, Mason E, Rohatgi R, Shah S, Schwartz D. Definition of an Effective Oral Appliance for the Treatment of Obstructive Sleep Apnea and Snoring: An Update for 2019. *J Dent Sleep Med*. 2019;6(3)

3. Obstructive and central sleep apnea treatment. United Healthcare Services Inc. March 1, 2024. Accessed July 23, 2024. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/obstructive-sleep-apnea-treatment.pdf

4. Vanderveken OM, Devolder A, Marklund M, et al. Comparison of a custom-made and a thermoplastic oral appliance for the treatment of mild sleep apnea. *Am J Respir Crit Care Med*. 2008;178(2):197-202. doi: 10.1164/rccm.200701-114OC.

5. Johal A, Agha B. Ready-made versus custom-made mandibular advancement appliances in obstructive sleep apnea: A systematic review and meta-analysis. [published correction appears in *J Sleep Res*. 2024 Oct;33(5):e14130. doi: 10.1111/jsr.14130]. *J Sleep Res*. 2018;27(6):e12660. doi:10.1111/jsr.12660

6. Johal A, Hamoda MM, Almeida FR, Marklund M, Tallamraju H. The role of oral appliance therapy in obstructive sleep apnoea. *Eur Respir Rev*. 2023 Jun 21; 32: 220257. doi:10.1183/16000617.0257-2022

7. Oral appliances for obstructive sleep apnea. Centers for Medicare & Medicaid Services. April 4, 2014. Updated June 18, 2021. Accessed July 23, 2024. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33611&ContrId=389

8. Levine M, Cantwell M, Postol K, Schwartz D. Dental sleep medicine standards for screening, treating, and management of sleep-related breathing disorders in adults using oral appliance therapy. *J Dent Sleep Med*. 2022;9(4)

9. Langaliya A, Alam MK, Hegde U, Panakaje MS, Cervino G, Minervini G. Occurrence of temporomandibular disorders among patients undergoing treatment for obstructive sleep apnoea syndrome (OSAS) using mandibular advancement device (MAD): A systematic review conducted according to PRISMA guidelines and the Cochrane Handbook for Systematic Reviews of Interventions. *J Oral Rehabil*. 2023;50(12):1554-1563. doi: 10.1111/joor.13574.

10. Sheats RD. Management of side effects of oral appliance therapy for sleep-disordered breathing: summary of American Academy of Dental Sleep Medicine recommendations. *J Clin Sleep Med*. 2020;16(5):835. doi: 10.5664/jcsm.8394.

11. Sheats R, Essick G, Grosdidier J, Katz S, Kim C, Levine M, Patel I. Identifying the appropriate therapeutic position of an oral appliance. *J Dent Sleep Med*. 2020;7(4).

12. Sutherland K, Almeida FR, Kim T, et al. Treatment usage patterns of oral appliances for obstructive sleep apnea over the first 60 days: a cluster analysis. *J Clin Sleep Med*. 2021;17(9):1785-1792. doi:10.5664/jcsm.9288

13. Radmand R, Chiang H, Di Giosia M, et al. Defining and measuring compliance with oral appliance therapy. *J Dent Sleep Med*. 2021;8(3).

SUBMISSION AND CORRESPONDENCE INFORMATION

Submitted in final revised form December 10, 2024.

Address correspondence to: Kevin Postol, DDS; Email: kpostol@aadsm.org.

DISCLOSURE

Dr. Cantwell reports that she is a volunteer for the European Academy of Dental Sleep Medicine. Dr. Postol reports that he is on the advisory board of the Alliance of Sleep Apnea Partners.