SPECIAL ARTICLE

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The Role of Temporary Appliances in Obstructive Sleep Apnea Treatment

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INTRODUCTION

A properly fitted, custom-fabricated oral appliance (OA) is an effective treatment for patients with snoring or obstructive sleep apnea (OSA).[1] In addition to custom-fabricated appliances intended for long-term use, several temporary appliances are available.[2] These appliances can be referred to in a variety of ways - as temporary, noncustom, interim, provisional, trial, and so forth. In this article, the term "temporary appliances" is used. This article provides guidance to qualified dentists for determining when a temporary appliance may be appropriate to use for a particular patient.

The literature addressing temporary appliances is limited. Some studies have compared the efficacy of temporary appliances with custom OAs with varying results and have explored whether temporary appliances can predict whether a patient will tolerate oral appliance therapy (OAT). Other trials have indicated that temporary appliances may lead to increased adverse effects and have lower compliance rates than custom-fabricated appliances.[3 -5] One meta-analysis found that custom OAs are superior to temporary appliances in several ways, such as better efficacy in reducing apnea-hypopnea index, reduced daytime sleepiness, increased functionality, increased levels of adherence, and higher patient preference over temporary appliances.[6] Other trials have indicated that temporary appliances are equivalent in efficacy to custom appliances.[7,8] These studies have limitations, such as high dropout rates, but they indicate that temporary appliances over the short term (8 to 12 weeks) can elicit responses similar to those of custom appliances.

Additional research has focused on whether temporary appliances can play a role in helping to determine the therapeutic position of an appliance[9-12] and predicting which patients are likely to respond or not respond to OAT.[13-18]

Dentists considering the use of a temporary appliance for a patient should be aware that these studies have limitations. None are long-term studies, and the literature yields few data about the use of temporary appliances selected and fit by patients themselves without the supervision of a qualified dentist per the American Academy of Dental Sleep Medicine (AADSM);[19] therefore, the conclusions that can be drawn from the evidence to date are also limited. In addition, it is noted that much of the available literature is industry-supported.

DEFINITION OF A TEMPORARY APPLIANCE

According to evidence and clinical expertise, the task force defined a temporary appliance as follows:

A temporary appliance is prescribed by a qualified dentist to treat OSA or snoring,[20] is generally prefabricated or has a prefabricated shell that can be customized to fit an individual patient and is able to be calibrated. Temporary appliances are indicated for short-term use as a transition to a properly fitted, custom-fabricated OA. Temporary appliances are not indicated to be used as a long-term substitute for a properly fitted, custom-fabricated OA. As indicated by manufacturer warranty and FDA material safety data, temporary appliances are suitable for 3 to 6 months of continued use on average or up to 12 months in situations that require interim use for restorative care (or needs), assessing tolerance, or financial reasons. Over-the-counter appliances do not meet this definition.

Temporary appliances as defined are unlikely to meet the definition of Healthcare Common Procedure Coding System code E0486 "oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment.[21]" As stated in Medicare's policy article for the treatment of OSA, prefabricated appliances (E0485) are produced without a specific patient in mind, whereas custom-fabricated OAs are fabricated for a particular patient;[22] therefore, temporary appliances may fit the definition of prefabricated appliances (E0485). Additionally, Medicare classifies OAs as durable medical equipment, which by definition must be able to function for 3 to 5 years before needing replacement. Temporary appliances also do not meet the definition of an effective OA as defined by the AADSM. Custom appliances are fabricated based on impressions, models,

or scans of the patient's teeth that are used to construct the appliance. If it does not go through this process, it is not a custom-fabricated appliance. Custom-fabricated appliances are intended for long-term use; however, a qualified dentist may determine that such a device may be appropriate to use on a short-term basis by a specific patient.

POTENTIAL USES OF TEMPORARY APPLIANCES

The literature supporting the use of temporary appliances is limited; therefore, qualified dentists should understand that the evidence base for the use of temporary appliances is not strong; however, temporary appliances may be appropriate to use for a short period of time in some circumstances based on the clinical judgment of the qualified dentist.

Temporary appliances are typically lower in cost than custom-fabricated appliances[23] and may be well accepted by patients in the short term. Additionally, temporary appliances may provide some improvement of symptoms during their initial use.[23]

Qualified dentists may want to consider a temporary appliance for use by patients who may not otherwise be able to immediately begin treatment with a custom device, such as first needing restorative dental work that would significantly change the fit of a custom appliance, other medical treatment, etc. If there is uncertainty about the patient's likely response to or compliance with treatment, a temporary appliance may help the qualified dentist determine if treatment with a custom-fabricated appliance is feasible.

In determining whether a temporary appliance is appropriate for a specific patient, the qualified dentist should consider the following questions:

- What are the reasons for considering a temporary appliance? For example:
    - Does the patient require major dental work immediately?
    - Could a temporary appliance aid the qualified dentist in determining compliance or effectiveness?
- Are the stability and durability of the temporary appliance suitable for the patient?
- Will using the temporary appliance discourage or encourage the patient from using an OA?
- What adverse effects might the patient experience?
- How much will the temporary appliance cost the patient?
- If considering use of a temporary appliance to predict success with an OA, will the temporary appliance use the same mechanism as the OA that is most appropriate for the patient? Can the temporary appliance predict success if it works in a different way than the OA?

IMPORTANT CONSIDERATIONS

Informed Consent

The task force developed an informed consent template specifically for use of a temporary appliance. Qualified dentists should obtain the patient's informed consent to ensure understanding of the temporary nature of the device and its role in long-term treatment. Patients should be informed that the use of temporary appliances may be associated with greater incidence of adverse effects,[23] and that the materials and durability of temporary appliances may result in a shorter recommended lifespan for the appliance. Using a temporary appliance longer than intended may place the patient at increased risk for adverse effects[24] and long-term compliance with temporary appliances is unknown. Because temporary appliances are not indicated for long-term use, the qualified dentist must ensure that patients understand their successful treatment depends on returning to the dental office at the conclusion of their use of the temporary appliance to proceed with the next steps in treatment.

Collaboration With Other Providers

A patient may have other healthcare providers involved in their care, and the qualified dentist should communicate with these providers in the event a temporary appliance is warranted.

Qualified Dentist Must Oversee Treatment

The fitting and use of temporary appliances should be overseen by a qualified dentist. A careful review of the available literature shows that the use of temporary appliances in these studies has almost exclusively been under the supervision of a dentist with training and experience in dental sleep medicine. It should not be assumed that temporary appliances will have the same efficacy if purchased directly from the manufacturer by the patient. Contraindications may exist, such as morphologic features, periodontal disease, tooth decay, temporomandibular joint disease, complete or partial edentulousness, etc. Qualified dentists are best suited to identify any contraindications, evaluate the appropriateness of a temporary appliance for a particular patient, select and fit a temporary appliance that is appropriate for the patient, and manage any adverse effects that may occur.

Most of the available studies are based on dentist-delivered temporary appliances rather than on appliances sold directly to patients. Therefore, conclusions from

studies based on dentist-delivered temporary appliances cannot be applied to temporary appliances delivered directly to the patient without the involvement of a qualified dentist. Patients who purchase a temporary appliance directly from a supplier may not be aware of their own oral and maxillofacial features and conditions that may contraindicate OAT and may not be able to manage the therapy on their own, including mitigating any adverse effects that may occur.

Lifespan of the Temporary Appliance

Temporary appliances have differing material stability and lifespans;[6] therefore, the qualified dentist should refer to FDA guidance, warranty information from the device's manufacturer, and their own expertise when selecting a temporary appliance. Most of the research cited in this article indicated a 6-month lifespan for a temporary appliance. Regardless of its ability to be customized, a temporary appliance should not be used as a long-term substitute for a properly fitted, custom-fabricated OA.

Financial Considerations

The qualified dentist should discuss the financial implications of treatment, as using a temporary appliance followed by a custom-fabricated appliance will be more costly than beginning treatment with the custom appliance. In some cases, the qualified dentist may propose using a custom-fabricated appliance on a temporary basis, followed by fabricating a second custom device, and this approach is also more costly for the patient.

The qualified dentist should provide the patient with clear information about the benefits of the proposed course of treatment but should also take the patient's preference into account.

Using a Temporary Appliance to Predict Treatment Success

In some cases, it may be appropriate to consider using a temporary appliance to help determine if OAT is a feasible treatment option for a specific patient. In considering this use of a temporary appliance, the qualified dentist should consider whether the temporary appliance works in the same way as the OA that will be most appropriate for the patient. A temporary appliance may not be able to predict treatment success and compliance if the mechanisms are dissimilar to the custom-fabricated OA that will be used. The qualified dentist should also consider whether the patient's experience with an ill-fitting or uncomfortable temporary appliance may discourage them from moving forward to a custom appliance.

CALL FOR FUTURE RESEARCH

Given the variability in current research findings related to temporary appliances, the task force encourages additional research on the role temporary appliances may play in dental sleep medicine. Research topics might include determining whether temporary appliances are suitable to predict treatment success or are appropriate for people with special conditions, such as pregnancy-related OSA.

METHODOLOGY

The AADSM commissioned a task force of four experts with extensive knowledge of dental sleep medicine. None of these task force members declared conflicts of interest related to this topic. The task force reviewed literature about temporary appliances; it was not a systematic literature review. The task force took into consideration their own clinical experience, relevant literature on the topic, clinical practicality, and patient preference when developing this article.

CITATION

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SUBMISSION AND CORRESPONDENCE INFORMATION

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DISCLOSURE

The authors report no conflicts of interest.