

The Role of Temporary Appliances in Obstructive Sleep Apnea Treatment

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J. Michael Adame, DDS, D.ABDSM¹; Michelle Cantwell, DMD, D.ABDSM²; Jennifer Q. Le, DMD D.ABDSM, CPCC³; Sue Ellen Richardson, DDS, D.ABDSM⁴; Charles Schumacher, DDS, D.ABDSM⁵

¹Adame Dental Sleep Medicine, ²Wellspan Pulmonary and Sleep Medicine, ³Wake Dental Sleep Dental Solutions, ⁴Sue Ellen Richardson, DDS; ⁵Desert Hills Dental Care

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 appliance⁹⁻¹² 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.

39 **DEFINITION OF A TEMPORARY APPLIANCE**

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

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

53 Temporary appliances as defined are unlikely to meet the definition of Healthcare
54 Common Procedure Coding System code E0486 “oral device/appliance used to reduce
55 upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes
56 fitting and adjustment.²¹” As stated in Medicare’s policy article for the treatment of OSA,
57 prefabricated appliances (E0485) are produced without a specific patient in mind,
58 whereas custom-fabricated OAs are fabricated for a particular patient;²² therefore,
59 temporary appliances may fit the definition of prefabricated appliances (E0485).
60 Additionally, Medicare classifies OAs as durable medical equipment, which by definition
61 must be able to function for 3 to 5 years before needing replacement. Temporary
62 appliances also do not meet the definition of an effective OA as defined by the AADSM.
63 Custom appliances are fabricated based on impressions, models, or scans of the
64 patient’s teeth that are used to construct the appliance. If it does not go through this
65 process, it is not a custom-fabricated appliance. Custom-fabricated appliances are
66 intended for long-term use; however, a qualified dentist may determine that such a
67 device may be appropriate to use on a short-term basis by a specific patient.

68

69 **POTENTIAL USES OF TEMPORARY APPLIANCES**

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

76 Temporary appliances are typically lower in cost than custom-fabricated appliances²³
77 and may be well accepted by patients in the short term. Additionally, temporary
78 appliances may provide some improvement of symptoms during their initial use.²³

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

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

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

101

102 **IMPORTANT CONSIDERATIONS**

103 **Informed Consent**

104 The task force developed an informed consent template specifically for use of a
105 temporary appliance. Qualified dentists should obtain the patient's informed consent to
106 ensure understanding of the temporary nature of the device and its role in long-term
107 treatment. Patients should be informed that the use of temporary appliances may be
108 associated with greater incidence of adverse effects,²³ and that the materials and
109 durability of temporary appliances may result in a shorter recommended lifespan for the
110 appliance. Using a temporary appliance longer than intended may place the patient at
111 increased risk for adverse effects²⁴ and long-term compliance with temporary
112 appliances is unknown. Because temporary appliances are not indicated for long-term
113 use, the qualified dentist must ensure that patients understand their successful
114 treatment depends on returning to the dental office at the conclusion of their use of the
115 temporary appliance to proceed with the next steps in treatment.

116

117 Collaboration With Other Providers

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

121 Qualified Dentist Must Oversee Treatment

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

133

134 Most of the available studies are based on dentist-delivered temporary appliances
135 rather than on appliances sold directly to patients. Therefore, conclusions from studies
136 based on dentist-delivered temporary appliances cannot be applied to temporary
137 appliances delivered directly to the patient without the involvement of a qualified dentist.
138 Patients who purchase a temporary appliance directly from a supplier may not be aware
139 of their own oral and maxillofacial features and conditions that may contraindicate OAT
140 and may not be able to manage the therapy on their own, including mitigating any
141 adverse effects that may occur.

142 Lifespan of the Temporary Appliance

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

149 Financial Considerations

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

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

159 Using a Temporary Appliance to Predict Treatment Success

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

169

170 CALL FOR FUTURE RESEARCH

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

176 METHODOLOGY

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

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