Review

Most Custom Oral Appliances for Obstructive Sleep Apnea Do Not Meet the Definition of Custom

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Most Custom Oral Appliances for Obstructive Sleep Apnea Do Not Meet the Definition of Custom

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Abstract: Obstructive Sleep Apnea is a highly prevalent respiratory disease linked with increased morbidity and mortality, reduced quality of life and increased economic costs if not treated. Oral Appliances are an emerging treatment option for Obstructive Sleep Apnea. This review concludes that many oral appliances marketed as "custom" include modifications and prefabricated items, and therefore do not meet the definition of "custom" oral appliances. This misclassification could hinder accurate characterization and appropriate prescription of oral appliances. To better inform clinical utilization of custom oral appliances and to more closely align sleep medicine with the benefits of personalized medicine, we propose further refining the custom oral appliance classification into semi-custom and precision-custom.

Keywords: personalized medicine; obstructive sleep apnea; oral appliance therapy; sleep apnea; respiratory medicine; sleep disordered breathing; dental sleep medicine

Introduction

Obstructive Sleep Apnea ("OSA") is a highly prevalent chronic respiratory disease affecting an estimated 1 billion people globally and 74 million in the United States [1,2]. Unmanaged OSA is linked to increased morbidity and mortality, reduced quality of life, and significant economic costs[3].

Oral appliances (OA), also known as mandibular advancement devices ("MAD"), mandibular repositioning devices ("MRD"), or mandibular advancement splints ("MAS"), are an emerging treatment option for OSA, largely driven by the low compliance rates associated with continuous positive airway pressure ("CPAP") therapy[4,5]. Clinical practice guidelines ("CPGs") recommend custom, titratable OAs for patients who refuse or discontinue CPAP therapy or prefer an alternative[6]. Recently, another CPG recommended custom, titratable OAs as frontline therapy for mild and moderate OSA and for severe OSA patients who fail or refuse CPAP trials[7].

This review and follow on analysis evaluates if the definition of 'custom' from the AASM CPG effectively describes, classifies, and differentiates OAs for the treatment of patients with OSA. A more exact classification could facilitate a better understanding of the merits and limitations of this therapy to better inform clinical utilization. The AASM CPG for Oral Appliance Therapy ("OAT") defines custom OAs as devices, "fabricated using digital or physical impressions and models of an individual patient's oral structures," and, "Not primarily prefabricated items that are trimmed, bent, relined, or otherwise modified." Prefabricated items are those manufactured without a specific patient in mind. "Records" refer to digital or physical dental casts that are used to create a custom OA[5].

Background

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OAs have three components. The first is an overlay of the maxillary dental arch. The second is an overlay of the mandibular dental arch. The third is the titration mechanism.

Dental arch overlays are fabricated from the records of each individual patient's oral structures. Records can be either digital scans or physical molds that are used to create dental casts. Proper fit between the overlays and the dental arches is crucial for mitigating the risk of dental side effects. Repositioning the mandible introduces orthodontic forces that can cause side effects. Overlay fit is essential for absorbing, distributing and mitigating the potentially injurious orthodontic forces. Prior research identifies a dose dependent relationship between the degree of mandibular protrusion and the prevalence of dental side effects[8]. Overlays that poorly fit the dentition, use soft liner materials, or use prefabricated items such as ball clasps to enhance retention may also compromise fit and increase risks of dental side effects.

The third component of an OA is the titration mechanism component. The titration mechanism component articulates and stabilizes the mandibular overlay relative to the maxillary overlay to beneficially reposition the mandible. Prior research reports a dose dependent association between stepwise mandibular repositioning and reductions in airway collapse events[9]. The target therapeutic mandibular location is determined by the healthcare provider. A bite registration is made at the target therapeutic mandibular location and is included in record of oral structures provided to the OA maker.

Overlays can be prefabricated or custom-made. Prefabricated overlays, often called "Boil and Bite" or "Do-it-Yourself" OA's, are non-custom. Similarly, titration mechanisms can be prefabricated or custom. We identified three categories of titration mechanisms: prefabricated displacement screws, prefabricated interchangeable connectors, and custom interlocking overlays.

There are three categories of titration mechanism components: 1. prefabricated displacement screws, 2. prefabricated interchangeable connectors, and 3. custom, interlocking overlays.

Prefabricated Displacement Screws

These mechanisms are prefabricated items. Displacement screws require overlay modifications to embed the prefabricated fixtures that anchor the displacement screws to the overlays. Examples include anterior pull-OAs and interlocking dorsal-OAs with prefabricated screws, which can be seen in Figures 1 and 2.

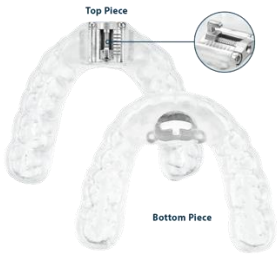

Figure 1. Anterior Pull-OA with Prefabricated Displacement Screws.

Figure 2. Interlocking Dorsal-OA with Prefabricated Screws.

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Prefabricated Interchangeable Connectors

Connector mechanisms are prefabricated items of various materials and sizes. The maxillary and mandibular overlays must be modified to embed the prefabricated fixtures that anchor the connector items to the overlays. Examples include push-OAs and pull-OAs with prefabricated connectors or Herbst arms. Figures 3–5 provide examples of OA's with prefabricated interchangeable connector and prefabricated fixture items.

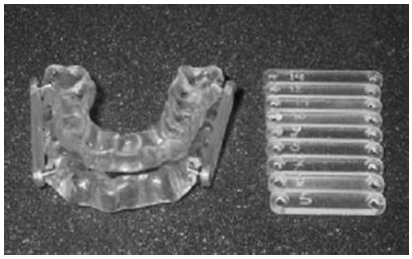

Figure 3. Push-OA with Prefabricated Connectors of Different Lengths.

Figure 4. Pull-OA with Prefabricated Connectors of Different Lengths.

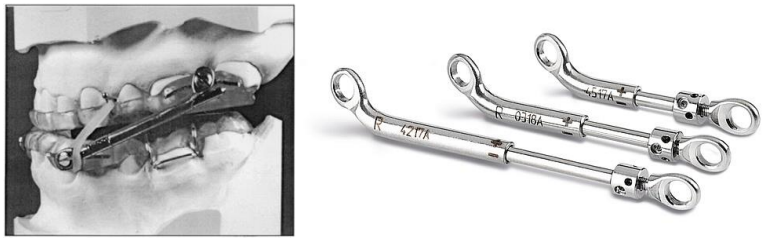

Figure 5. Push-OA with Prefabricated Herbst Arms of Different Lengths.

Custom Interlocking Overlays

Each overlay has a monolithically embedded interlocking titration post that is directly designed based on the oral structures for each individual patient using computer aided design and forward engineering technologies. There are no prefabricated items. No modifications are required. Each interlocking overlay is purely custom and has a specific mandibular advancement setting defined by the healthcare provider. The combination of different maxillary and mandibular overlays included within a treatment kit enables a range of specific protrusive or retrusive mandibular positions. Figure 5 provides an example of a Dual Post OA with custom interchangeable overlays.

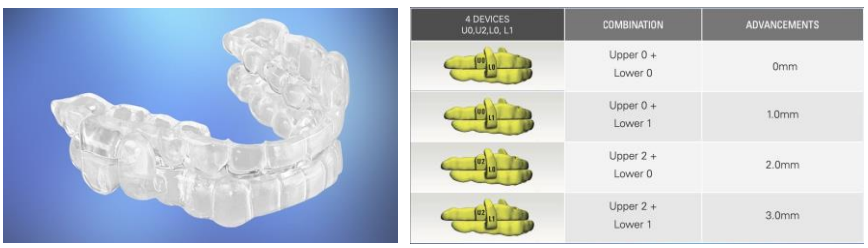

Figure 5. Dual Post-OA with Interchangeable Overlay Components.

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We hypothesize that most OAs labeled as custom do not meet the definition of custom. Most OA's use prefabricated items and are modified to embed fixtures.

We propose two classifications: Semi-custom and Precision-Custom OAs.

Semi-Custom Oral Appliances

Semi-custom OA's are made from the records of oral structures for each individual patient. Semi-custom OA's are either modified, or include prefabricated items, or both.

Precision-Custom Oral Appliances

Precision-custom OA's are directly and fully designed and manufactured based on the records of an individual patient's oral records. They are not modified. They do not use prefabricated items. See Table 1 for a summary of our proposed OA classifications.

Table 1. Proposed OA classifications.

	Custom OA Definition Criteria (Summarized)		
Proposed Classifications	**Made from Oral Records of an Individual Patient?**	**Modified (Trimmed, Bent, Relined)?**	**Includes Prefabricated Items?**
Semi-Custom	Yes	Yes	
Precision-Custom	Yes	No	

Further we postulate that semi-custom OA's, with prefabricated items and modifications, are inherently more complex, which may describe reports of inconsistent performance.

Review

To test our hypotheses and challenge our proposed OA classifications, we evaluated OAT devices from two recent review articles[10,11], including 49 source articles referencing 74 OAT devices. Of these, 51 were described as titratable and custom, with 41 providing enough detail for our evaluation. We assessed each of these devices based on the AASM CPG definition criteria: made from individual patient records and not modified or primarily prefabricated. Figure 6 describes our review approach.

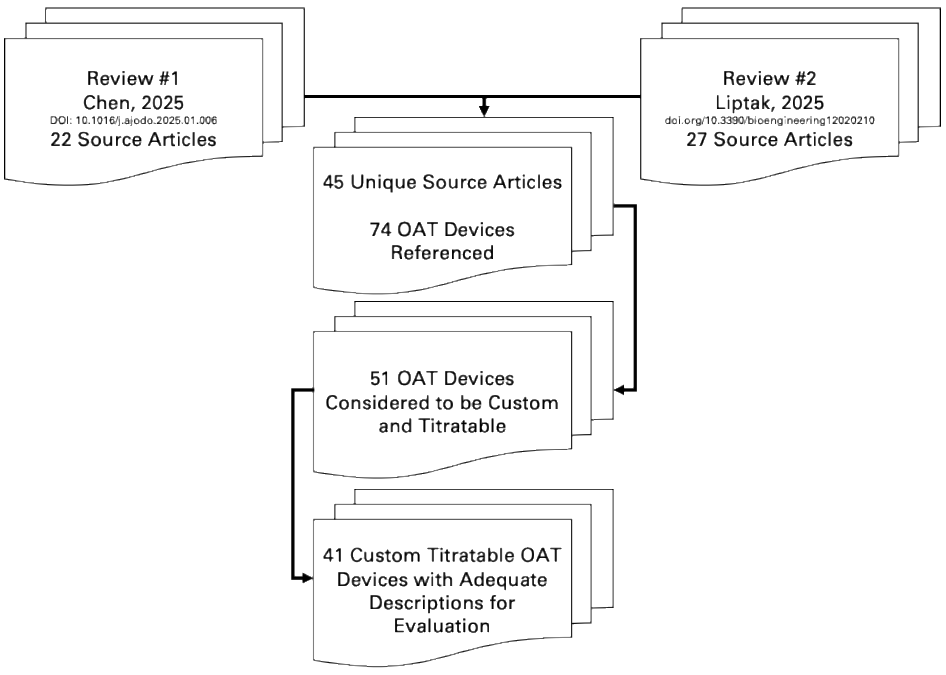

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Figure 6. Review Approach.

The 2015 AASM CPG's definition for custom OAT can be distilled into two criteria. These two criteria are as follows:

1. Is the OA made from records of an individual patient's oral structures?
2. Is the OA modified (trimmed, bent, relined) or primarily a prefabricated item?

The forty-one OAT devices from our review strategy were evaluated according to these two criteria.

Results

Criterion 1: Made from records of an individual patient's oral structures?

All 41 OA's included in our analysis were made from individual patient records, based on descriptions contained in the source articles for each OA.

Criterion 2: Is the OA modified or primarily a prefabricated item?

However 32 of the 41, 78% of the OA's included in our analysis used prefabricated items. The prefabricated items used were titration mechanisms, anchor fixtures for titration mechanism, or prefabricate retention items like ball clasps. Each included overlay modifications to embed prefabricated fixtures that anchor prefabricated titration mechanisms.

Only nine of forty-one OA's fully met the two criteria of the AASM CPG definition of a custom OA. These nine did not use prefabricated items. They were not modified.

See Table 2 for an evaluation of each OA according to the definitional criteria.

Table 2. Evaluation of OA's.

Review Article	Author	Reference	Basic Description	1. Made from Records of Oral Structures?	2. Is the Device Modified or Primarily Prefabricated?
Chen 2025	Bloch 2000	[12]	Push	Yes	Yes
Chen 2025	Pepin 2019	[13]	Push	Yes	Yes
Chen 2025	Pepin 2019	[13]	Push	Yes	Yes
Liptak 2025	Randerath, 2022	[14]	Push	Yes	Yes
Liptak 2025	Ghazal, 2008	[15]	Push	Yes	Yes
Liptak 2025	Gagnadoux, 2009	[16]	Push	Yes	Yes
Chen 2025	Yanamoto 2021	[17]	Pull	Yes	Yes
Chen 2025	Zhou 2012	[18]	Pull	Yes	Yes
Chen 2025	Isacsson 2017	[19]	Pull	Yes	Yes
Liptak 2025	Vecchierini, 2016	[20]	Pull	Yes	Yes
Liptak 2025	Vecchierini, 2016	[14]	Pull	Yes	Yes
Liptak 2025	Tegelberg, 2020	[21]	Pull	Yes	Yes
Liptak 2025	Kuna, 2005	[22]	Pull	Yes	Yes
Liptak 2025	Henke, 1999	[23]	Pull	Yes	Yes
Liptak 2025	Vanderveken, 2024	[24]	Pull	Yes	Yes
Liptak 2025	Schneiderman, 2020	[25]	Pull	Yes	Yes
Liptak 2025	Pancer, 1999	[26]	Pull	Yes	Yes

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Liptak 2025	Ghazal, 2008	[12]	Pull	Yes	Yes
Chen 2025	Gagnadoux 2012	[13]	Interlocking	Yes	Yes
Liptak 2025	Vanderveken, 2024	[18]	Interlocking	Yes	Yes
Liptak 2025	Van Haesendonck, 2016	[27]	Interlocking	Yes	Yes
Liptak 2025	Schneiderman, 2020	[19]	Interlocking	Yes	Yes
Liptak 2025	Remmers, 2013	[28]	Interlocking	Yes	Yes
Liptak 2025	Mehta, 2001	[29]	Interlocking	Yes	Yes
Liptak 2025	de Ruiter, 2020	[7]	Interlocking	Yes	Yes
Chen 2025	Abd-Ellah 2022	[30]	Bi Block	Yes	Yes
Chen 2025	Isacsson 2019	[31]	Bi Block	Yes	Yes
Chen 2025	Bosschieter 2022	[32]	Anterior	Yes	Yes
Chen 2025	Johal 2015	[33]	Anterior	Yes	Yes
Chen 2025	Friedman 2012	[34]	Anterior	Yes	Yes
Chen 2025	Lettieri 2011	[35]	Anterior	Yes	Yes
Chen 2025	Sari 2011	[36]	Anterior	Yes	Yes
Liptak 2025	Stern, 2021	[37]	Dual Post	Yes	No
Liptak 2025	Silva, 2023	[38]	Dual Post	Yes	No
Liptak 2025	Sall, 2023	[39]	Dual Post	Yes	No
Liptak 2025	Sall, 2021	[40]	Dual Post	Yes	No
Liptak 2025	Remmers, 2017	[41]	Dual Post	Yes	No
Liptak 2025	Murphy, 2021	[42]	Dual Post	Yes	No
Liptak 2025	Mosca, 2022	[43]	Dual Post	Yes	No
Liptak 2025	Kang, 2024	[44]	Dual Post	Yes	No
Liptak 2025	Knowles, 2023	[45]	Dual Post	Yes	No

Discussion

Our review and follow-on analysis confirms our hypothesis that most OAs marketed as custom do not meet the AASM CPG's criteria for custom OA's. Although 100% of OA's in this analysis were made from oral records for an individual patient, 78% included at least one prefabricated component, or were modified, or both.

That 32 of the 41 OA's use prefabricated titration mechanism items is potentially significant. It reveals that for these 32 OA's, the titration mechanism, the component that most directly establishes and stabilizes the therapeutic mandibular reposition, is not made based on the oral records for each individual patient. It is prefabricated. It is generic.

Moreover, many of these prefabricated items are repurposed for the treatment of OSA. They were originally designed for other therapies. For example, displacement screws were designed for orthopedic procedures. Herbst arms were designed to correct Class II malocclusions in the field of orthodontics. These prefabricated items were not designed for the treatment of OSA, let alone customized treatment for each individual patient.

Prefabricated titration mechanisms, not made based on individual patient records, limit customization, increase complexity and decrease consistency. Complex product designs, in general, with more parts, modifications and steps, are associated with relatively lower quality and performance than less complex designs[46]. Occam's razor, the principle of parsimony, applies: all things being equal, a simple product design will be better than a relatively more complex design.

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This applies to OA's. Precision-custom OAs, with fewer parts, fewer steps, and no modifications are inherently less complex and relatively smaller tolerance stacks. Smaller tolerance stacks are associated with less variability and more consistent, predictable performance. Inconsistent performance is often cited as a key barrier to increased OA utilization[47].

Personalized medicine, also known as precision medicine, optimizes therapies by matching treatments with individual patient characteristics[48]. Precision medicine is associated with improved treatment efficacy[49], reduced adverse events[50], enhanced patient engagement[51] and cost-effectiveness[52].

Precision-custom OA's are a step closer to the promise of personalized medicine than semi-custom OA's. Unlike semi-custom OA's, precision custom OA's are exclusively made from records of each individual patient's oral records without the modifications and deviations necessary to accommodate prefabricated items. Modifications and prefabricated items make an OA more generic and less personalized.

Implications for Efficacy?

Studies report a dose dependent relationship between mandibular advancement and therapeutic efficacy[9]. These investigations associate 2-millimeter stepwise increases in mandibular repositioning with clinically meaningful reductions in airway collapse events. Semi-custom OAs with larger tolerance stacks may result in clinically meaningful variances in mandibular positions. Studies suggest precision-custom OAs may offer different outcomes than semi-custom oral appliances[10,37,39].

Signs of Different Outcomes Between Semi-Custom and Precision Custom OA's?

It takes time to interrogate new technologies. For example, the 53 referenced by the 2015 AASM CPG are, on average, over 18 years old[6]. However, are there any recent records, any signs, that associate precision-custom OA's with different results?

Signs of Different Efficacy

A prospective study prescribed precision-custom OA's for 288 patients with a 50%, 31% and 19% mix of mild, moderate and severe OSA. The study reported 85% success treating these patients to an AHI < 10, and 73% treating patients to an AHI < 5[45]. A second prospective study prescribed precision-custom OA's to treat 48 patients with a mix of mild, moderate and severe OSA. The study reported 88% success treating patients to an AHI < 10 and a 50% improvement over baseline[44]. Although not comparative randomized controlled studies, these results represent rates of efficacy that are directionally different than what has been previously reported for semi-custom OA's[11].

Signs of Different Patient Preferences

One randomized, controlled cross over trial compared patient preference between precision-custom OA's and semi-custom OA's[53]. Of the ten patients who completed the study, eight preferred the precision-custom OA. These patients cited comfort, ease of use, and durability as reasons for their preference. The two patients who preferred the semi-custom OA, citing ease of use in combination with their CPAP.

Signs of Different Symptom Alleviation

A prospective, comparative, randomized controlled trial reported 91% success treating snoring with a precision custom OA, in comparison with 58% for combined airway and positional therapy[54]. In a different study, a single arm investigation that included a precision-custom OA for treatment, 85% of patients stated that they achieved their treatment goals, and 97% reported a reduction in snoring[43].

Signs of Different Side Effects

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A single-arm, prospective, longitudinal study involving the treatment of OSA patients with a precision-custom OA's reported no clinically or statistically significant changes in tooth position, overbite, or overjet after a two-year follow-up period[55]. A second, single-arm, comparative, longitudinal study evaluated the side effects associated with treating OSA with precision-custom OA's. The study also reported no clinically meaningful changes in orthodontic conditions after a two-year follow-up period[56]. A third study using precision-custom OA's to treat OSA patients more broadly reported on side effects. This study reported no serious adverse events and no adverse events that resulted in the discontinuation of therapy[43]. Again, these are not randomized controlled trials, but they do indicate results that are different from what is commonly reported for OAT (cite).

There are several limitations to this study. One is that it is based on primary source records that are inconsistent in their controls, their definitions, their mix of OSA severity in their patient populations, and other variables that are relevant to our research topic. A way to remedy this would be to commission a randomized controlled trial comparing precision-custom with semi-custom style OA's.

Another limitation is dependence on concepts such as design elegance, complexity factors, and tolerance stacking to describe the reported inconsistencies in efficacy. A remedy would be a prospective investigation that directly measures and calculates these values.

Conclusions

Most OA's that are marketed as custom do not meet the definitional conditions of custom. Most OA's considered custom include primarily prefabricated items or modifications, or both.

For these OA's, the primarily prefabricated item is the titration mechanism. The titration mechanism is the critical components of the OA. The titration mechanism dictates the therapeutic relationship of the mandible relative to the maxillary arch, which is the key mechanism of action associated with preventing airway collapse.

Further, product design elegance, complexity factors and tolerance stacks describe how an OA that uses prefabricated items and requires modifications could be associated with less inconsistent performance than an OA that does not.

This analysis reveals that several OA's do satisfy the definitional conditions for a custom OA. These OA's are entirely made from records of the oral structures for an individual patient. They do not include prefabricated items. Nor are they modified. As a result, these OA's represent relatively less complex designs with considerably smaller tolerance stacks.

Several studies provide signs that there are differences in performance between semi-custom and precision-custom OA's. Although more intensive investigation is warranted, these studies offer initial signs that precision-custom devices may perform differently than semi-custom devices when it comes to efficacy, patient preference, side effects mitigation and symptom alleviation.

In closing, we propose refining the custom OA classification into semi-custom and precision-custom to better inform clinical use.

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