Dental and Maxillofacial Devices: A Review of OSA Treatments

OSA Treatments: Review of Dental Devices

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Abstract

Introduction: Obstructive Sleep Apnea (OSA) is characterized by recurrent upper airway blockages during sleep, impacting oxygen levels, sleep patterns, and increasing the risk of cardiovascular and metabolic disorders. Continuous Positive Airway Pressure (CPAP) therapy, the traditional treatment for OSA, often suffers from low patient compliance. Oral appliances (OAs) have emerged as a viable alternative, especially for mild to moderate OSA cases.

Methods: Our literature review focused on PubMed-sourced peer-reviewed articles, clinical trials, and comparative studies, emphasizing OAs' effectiveness, patient compliance, and long-term outcomes. The review included various types of OAs, namely Mandibular Advancement Devices (MAD), Tongue-Retaining Devices (TRD), and Soft Palate Lifters (SPL), and excluded unrelated or non-English publications.

Results: MADs have demonstrated significant effectiveness in reducing the Apnea-Hypopnea Index (AHI) and are well-tolerated compared to CPAP, with better compliance rates reported. However, long-term effectiveness remains a concern, with issues like dental alterations affecting efficacy. TRDs and SPLs, while effective in some aspects, show lower tolerance and effectiveness compared to MADs. Issues such as discomfort with SPLs and adverse effects like drooling with TRDs limit their clinical preference.

Conclusion: OAs, particularly MADs, are effective in managing OSA symptoms with better patient compliance than CPAP. However, their long-term efficacy is challenged by factors like dental changes and aging. The need for personalized OA selection and continuous treatment re-evaluation is highlighted. Further research is required to understand long-term outcomes and the impact of OAs on oral health, which will inform future OA designs and improve patient outcomes in OSA management.

Keywords: Obstructive Sleep Apnea (OSA); Oral Appliances (OA); Mandibular Advancement Devices (MAD); Tongue-Retaining Devices (TRD); Soft Palate Lifters (SPL); Apnea-Hypopnea Index (AHI); Continuous Positive Airway Pressure (CPAP); Patient Compliance.

Introduction

Obstructive sleep apnea (OSA) is a persistent medical condition marked by recurrent episodes of total or partial blockage of the upper airway[1]. Polysomnography, which evaluates neurologic and cardio-respiratory functions during sleep, is considered the definitive diagnostic tool for OSA[2]. This test quantifies the frequency of obstructive events and expresses it as the apnea-hypopnea index (AHI). The American Academy of Sleep Medicine categorizes OSA severity based on AHI thresholds: mild OSA is defined as ≥ 5 and < 15 events per hour; moderate OSA as ≥ 15 and < 30 events per hour; and severe OSA as ≥ 30 events per hour[3]. This condition is often linked with reduced oxygen levels, disruptions in sleep patterns, daytime drowsiness, and an increased risk of heart-related and metabolic disorders[4]. Traditionally, the primary approach for treating patients with OSA has involved encouraging weight loss and the utilization of nasal continuous positive airway pressure (CPAP). In more severe instances, upper airway reconstructive surgery may be necessary. However, there is a notably low compliance rate with CPAP therapy, with long-term adherence dropping to about 50%[5]. Moreover, research on PAP indicates that acceptance rates among patients range from 58% to 80%, with only 49% maintaining compliance during the initial month of therapy[6]. Given this, there is a significant demand for alternatives to CPAP and surgical options. Oral appliances (OAs) represent a viable option, particularly for individuals with mild to moderate OSA[7] with clinically significant results for even moderate to severe OSA[8].

In the management of OSA, OAs are typically divided into three main types: Soft Palate Lifters (SPL), Mandibular Advancement Devices (MAD), and Tongue-Retaining Devices (TRD)[9]. Alongside these, the market offers a variety of commercially designed OAs, such as the 'Boil and Bite' models[10] (Fig. 1)[11]. Nevertheless, custom-made OAs have demonstrated superior effectiveness[12]. Among these options, MAD has emerged as a particularly effective treatment. MAD operates on the principle of repositioning the mandible downwards and forwards, which helps in reducing the collapse of the upper airway[13]. However, this widening of the bite has been linked to various dental issues, such as the following: atypical occlusion, muscle soreness, stiffness in the jaw, temporomandibular disorders, backward leaning of the upper incisors, forward leaning of the lower incisors, reduction in overjet and overbite, teeth tipping, diminished esthetics, and more[14].

Patient compliance plays a pivotal role in determining the effectiveness of treatments, which is why OAs are considered a viable option given the notably inconsistent adherence rates associated with CPAP therapy. Indeed, compliance with CPAP has been reported to vary widely, with rates ranging from as low as 17% to as high as 71%, according to one study[15]. However, regarding MAD, several studies, which mainly concentrate on subjective compliance, have shown a broad variation in the rates of continued use after one year, with figures spanning from less than 10% to up to 76%[16]. For instance, a long-term study involving a follow-up questionnaire revealed that approximately 64% of patients persisted with the treatment, and the prevalent reasons for discontinuation included discomfort and perceived ineffectiveness[17]. Notably, MAD have shown marginally better subjective compliance compared to CPAP, as highlighted by the American Academy of Sleep Medicine[7]. Despite MAD's lower efficacy relative to CPAP, their better compliance rates might enhance their overall effectiveness. However, a challenge persists in measuring objective adherence due to most oral appliances lacking the necessary mechanisms for such assessment. This aspect of patient compliance and its implications for treatment efficacy forms a pivotal area of exploration in OA therapy.

The effectiveness of OA therapy in treating OSA is supported by previous data, which indicate an average reduction in OSA severity by about 55%[18]. This notable decrease in severity underscores the potential of these appliances in managing OSA symptoms effectively. Complementing this finding, a recent study utilizing an earlier version of a contemporary novel oral appliance also reported a substantial reduction in the AHI, a crucial measure of OSA severity, by approximately 60%[19]. Notably, this same study observed a high self-reported adherence rate of 88%, suggesting that when patients consistently use their oral appliances, the therapy's efficacy in mitigating OSA can be significantly amplified, leading to improved patient outcomes. The goals of this review are to analyze the effectiveness, design features, patient compliance, and long-term outcomes of OA in the treatment of OSA.

Background

The principle of advancing the tongue and jaw to improve a compromised airway has been a longstanding, effective strategy in both anesthesiology and orthodontics, and is now being successfully adapted for the treatment of OSA. Pierre Robin is widely recognized for his pioneering clinical efforts in Oral Appliance Therapy (OAT). In 1902, he initially introduced a “monoblock” device aimed at treating glossoptosis[20]. He later employed an OA specifically designed to reposition the mandible[21]. It wasn't until 50 years later that OAs began to be reported for the treatment of snoring and OSA, and these early appliances included a TRD[22] and a MAD[23]. Soon after, "boil and bite" models entered the commercial market, but they have been identified as being less effective[24] and more uncomfortable[25] compared to custom-made models.

The pathophysiology of OSA involves obstruction of the upper airway during sleep typically occurring due to negative pressure that causes collapse during inhalation. Yet, narrowing of the airway in the retro palatal area during exhalation also plays a significant role[26]. The extent of this upper airway narrowing during sleep often correlates with the body mass index, suggesting that both anatomical (micrognathia, mandibular hyperplasia, etc.) and neuromuscular factors are involved in airway obstruction[27]. Thus, the fundamental therapeutic action of oral appliances is the protrusion of the lower jaw[28], a mechanism that has been demonstrated to expand the airway space, as seen in MRI and nasopharyngoscopy studies[29] (Fig. 2). Concurrently, the tongue often shifts forward in response to the advancement of the mandible, though the degree of this shift varies among individuals[30]. Furthermore, advancing the mandible has been shown to reduce upper airway collapsibility[31], and observations of reduced spontaneous collapse during sedation[32]. This stabilization of the pharyngeal airway is primarily attributed to the anatomical enlargement of the airway and the anterior positioning of the tongue[29].

Methods

We conducted our literature search by primarily using PubMed, focusing on publications that included terms such as "Obstructive Sleep Apnea (OSA)", "Oral Appliances (OA)", "Mandibular Advancement Devices (MAD)", "Tongue-Retaining Devices (TRD)", "Soft Palate Lifters (SPL)", and "Long-term Outcomes of OSA Treatment". The scope of our search was confined to peer-reviewed articles, clinical trial reports, and studies that offered comparative analyses with other treatment modalities for OSA.

Our research included studies that directly related to the use of OAs in the treatment of OSA, focusing on patient compliance, long-term outcomes, and comparisons with other treatments like CPAP. We excluded studies that did not directly address the effectiveness or long-term use of OAs in OSA, publications focusing solely on unrelated medical specialties, and non-English language articles.

Our primary outcomes included the effectiveness of different types of OAs (MAD, TRD, SPL) in treating OSA, patient compliance rates with these treatments, and the long-term outcomes of OA therapy. We also aimed to identify factors influencing the efficacy of these devices, such as patient-specific characteristics and the nature of oral appliance adjustments over time. Moreover, our review method was systematic, ensuring a thorough and unbiased examination of the available literature. We critically appraised the methodology and findings of each study, considering the diversity of OAs and patient demographics in our analysis to provide a comprehensive overview of OA therapy in the context of OSA management.

Types of Oral Appliances:

In 1923, the first known usage of an intra-oral device for repositioning the mandible is widely attributed to Pierre Robin, a French pediatrician[20]. MADs function by moving the mandible, and consequently the tongue, forward. This action distances the upper airway from critical narrowing points, likely due to an increase in pharyngeal dimensions and a reduction in airway collapsibility, though the precise mechanisms are not fully understood and may differ among individuals[33]. Usage of a MAD has been demonstrated to enlarge the total area of the pharynx, especially around the soft palate. This enlargement is linked with a decrease in the pressure drop across the upper airway during inhalation, which aids in preventing apneas[34]. Additionally, there is some evidence indicating that the reduction in pharyngeal collapsibility achieved through MAD therapy may be dose-dependent, meaning it becomes more effective with greater mandibular protrusion[31].

TRDs were first designed by Charles Samelson in 1982, and were introduced as a treatment option for patients with OSA[22]. In the late 1990s, Christopher Robertson introduced a non-customized, preformed version of the TRD, known as the tongue-stabilizing device (TSD)[35] (Fig. 3). In cases where there are no teeth, a TRDs may be indicated. Unlike devices that rely on dentition to move tissues forward, TRDs employ a suction bulb to keep the soft tissue of the tongue in a forward position[20]. While the effectiveness of TRD in reducing snoring, sleep apnea, and daytime sleepiness has been demonstrated in smaller study groups[22], its acceptability appears to be lower compared to MADs in certain studies[36]. This lesser tolerance could explain why TRDs are infrequently prescribed.

SPLs aim to minimize vibrations by raising the soft palate and uvula and were first patented in 1964 by Corniello[37]. However, the evidence to confirm their effectiveness is limited[38]. Moreover, they are seldom utilized due to issues with gag reflex, discomfort, and the comparative success of laser and radiofrequency procedures targeting the soft palate[39]. In theory, SPLs should enhance the dimensions of the upper airway passage, contributing to the cessation of snoring and the alleviation of airway blockages[40].

Over the years, a substantial number of "boil and bite" appliances have been developed. These appliances are notably easy to fit and adjust directly on the patient and are generally well-tolerated. However, they may encounter retention issues over extended periods of use. Thermoplastic appliances, which include "boil and bite" models, tend to have higher failure rates compared to custom-made appliances, and due to their lower success rates, there are recommendations against using them as preliminary screening tools for custom-made appliances[24]. Additionally, these appliances do not allow for controlled or reproducible amounts of mandibular protrusion, especially in the absence of study models and accurate bite registration.

Effectiveness of the Devices

In recent years, numerous review studies have assessed the effectiveness of MADs in treating OSA. Consistently, these studies have affirmed that MADs effectively reduce the AHI, though they are not as effective as CPAP therapy[41]. Consequently, MADs are recognized as a viable alternative for patients with mild to moderate OSA, as well as for those with severe OSA who cannot tolerate CPAP therapy[42]. Moreover, in one study of 318 patients treated with MAD for OSA, 65.5% reported successful outcomes, with a significant decrease in AHI. Over half experienced side effects, primarily temporomandibular dysfunction, leading 23.3% to discontinue treatment due to side effects or therapy failure. This suggests MAD's effectiveness for OSA, but with a considerable rate of side effects[43].

Recent global studies show that TRDs effectively lower the AHI by 53%, raise the lowest oxygen saturation by 4.1 points, reduce the oxygen desaturation index by 56%, and decrease

Epworth sleepiness scale scores by 2.8 points. These findings establish TRDs as a statistically significant alternative treatment for OSA[44]. Additionally, a crossover study comparing TRDs and CPAP included a final analysis of 27 patients. It found that the mean AHI decreased from 38.7 ± 24.0 to 2.5 ± 0.5 events/h with CPAP and to 12.7 ± 2.6 events/h with TRD. Adverse effects of TRD included drooling, tongue numbness, and pain, while CPAP users reported nasal blockage, mask compression, and challenges in portability. In conclusion, CPAP outperformed TRD in improving polysomnography parameters, but both treatments similarly enhanced quality of life and reduced daytime sleepiness. The study concluded that TRD may be considered as a short-term alternative treatment option for OSA[45].

Literature involving the usage of SPL is limited but what is available has not been promising. In a study with 8 participants, only two could complete the night wearing a SPL device. The majority discontinued use due to significant discomfort, primarily gagging. The baseline AHI was 47.3±8.0, increasing to 57.4±31.0 when using the device. Consequently, the SPL showed ineffectiveness, with an AHI of 52.4±8.0 at baseline and 47.3±31.0 while using the device, and was poorly tolerated[46]. Additionally, another study found that four out of five patients, SPLs showed minimal impact on snoring[38].

Long-term Outcomes:

Majority of studies assessing long-term outcomes of OAs primarily focus exclusively on MAD with the literature lacking on studies done for TRD and SPL. The stability of MAD in treating OSA appears consistent for up to a decade, as indicated by various small-scale longitudinal studies[47]. However, beyond this period, limited data from a single study suggests an increase in AHI both with and without the OA[48]. This increase occurred without any notable weight gain or increased sleepiness in patients. To counteract the forward movement of the lower teeth, a common side-effect, all OAs were adjusted for greater advancement, impacting their efficacy. Aging, which often correlates with higher AHI[49], might also explain the worsened disease severity. Continuous changes in the patients' ability to maintain open airways, coupled with bite alterations, can affect the lower jaw's advancement and, consequently, the OA's effectiveness. The relationship between the OA mechanism and the pathophysiology of OSA, along with the actual jaw advancement, is crucial. There's a notable gap in research regarding long-term OA effectiveness in a larger patient population, and which patients might benefit from long-term use versus those requiring more intensive monitoring.

Over time, the efficacy of OAs may decline as some patients stop treatment due to adverse effects or subjective dissatisfaction, and others might experience diminished objective treatment outcomes[50]. The patient profile changes over years due to age and dental adjustments, affecting the OA's action mechanism, which is more susceptible to these changes compared to CPAP therapy. This necessitates ongoing treatment assessment. More comprehensive research is needed to understand OA therapy's long-term effects, particularly its impact on oral health, to determine whether it improves or worsens with treatment, and to identify which patient groups are most affected.

Conclusion:

The exploration of OAs as a treatment option for OSA highlights their potential efficacy and practicality, especially in comparison to CPAP therapy. This review indicates that while MADs, TRDs, and SPLs each present unique advantages and challenges, MADs have emerged as a particularly effective intervention for OSA. They demonstrate a notable reduction in the AHI and have a relatively better compliance rate, making them a viable alternative for patients who struggle with CPAP therapy.

However, the long-term effectiveness and patient adherence to MADs and other OAs remain areas of concern. Studies suggest that the efficacy of MADs is generally stable up to a decade, but beyond this period, challenges such as dental alterations and aging-related increases in AHI may reduce their effectiveness. The need for continuous adjustment of these appliances due to dental changes further complicates their long-term use. Additionally, the lack of mechanisms to objectively measure adherence in most OAs poses a challenge in evaluating their true efficacy over time.

Moreover, the literature on TRDs and SPLs is less extensive, with findings indicating lower effectiveness and tolerance compared to MADs. Issues such as discomfort and minimal impact on snoring with SPLs, and drooling, tongue numbness, and pain with TRDs, have been reported. These factors contribute to a lower preference for these devices in clinical practice.
Given these considerations, it becomes apparent that the choice of OA, particularly MAD, for OSA treatment must be personalized, taking into account the patient's specific needs, the severity of their condition, and their ability to tolerate and adhere to the treatment. Furthermore, continuous re-evaluation of the treatment effectiveness, considering age and dental changes, is essential for ensuring optimal patient outcomes.

This review underscores the need for more in-depth research into the long-term outcomes of OA therapy, particularly in larger patient cohorts. Understanding the impact of OAs on oral health and identifying patient groups that might benefit most from long-term use or require more intensive monitoring is crucial. Such research will not only inform clinical practice but also guide future innovations in OA design and application, ultimately enhancing the management of OSA and improving patient quality of life.

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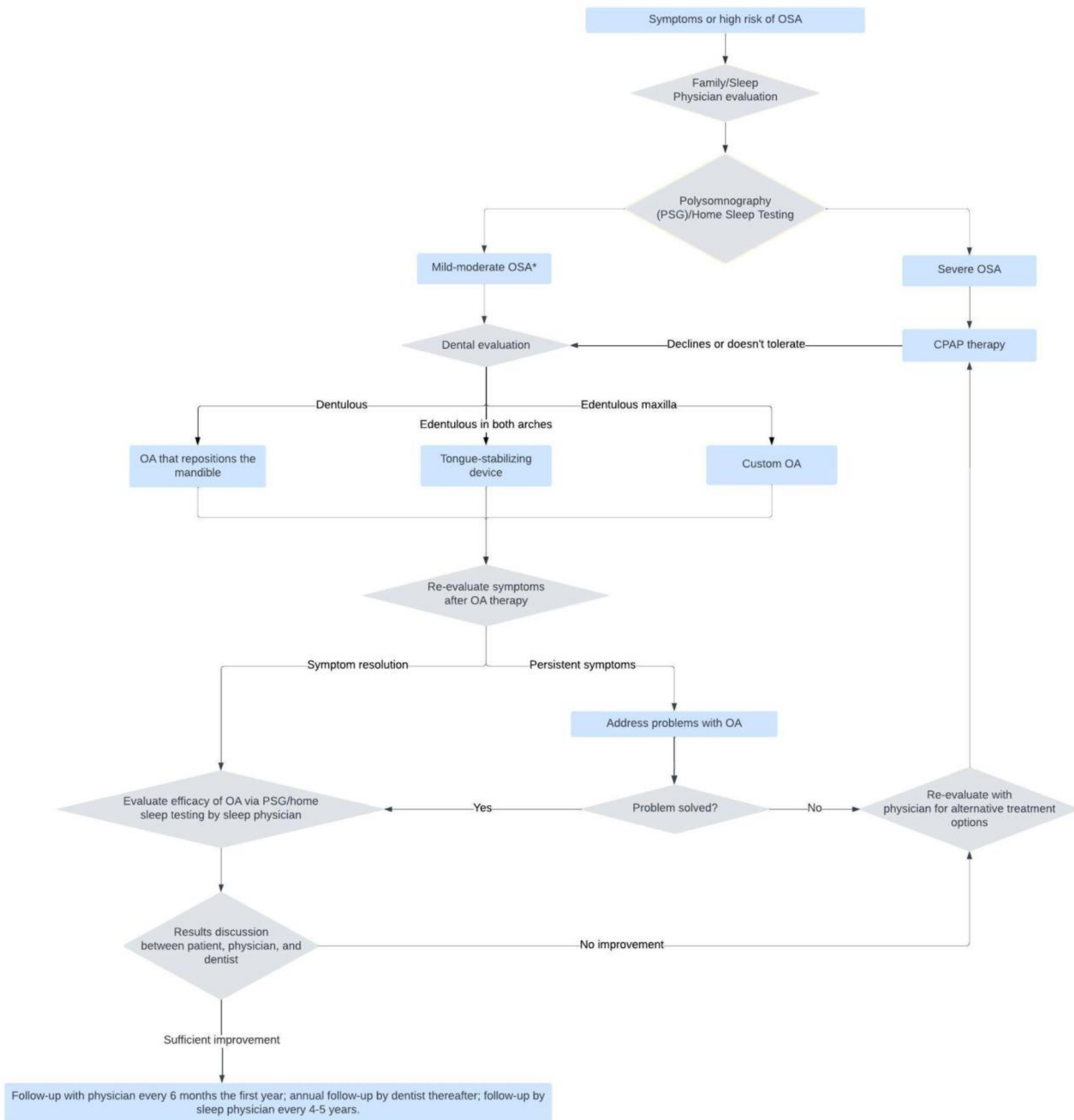

Figure 1. Recommended treatment pathway for patients with OSA.

Hamoda MM, Kohzuka Y, Almeida FR. Oral Appliances for the Management of OSA. Chest 2018;153(2):544–53.

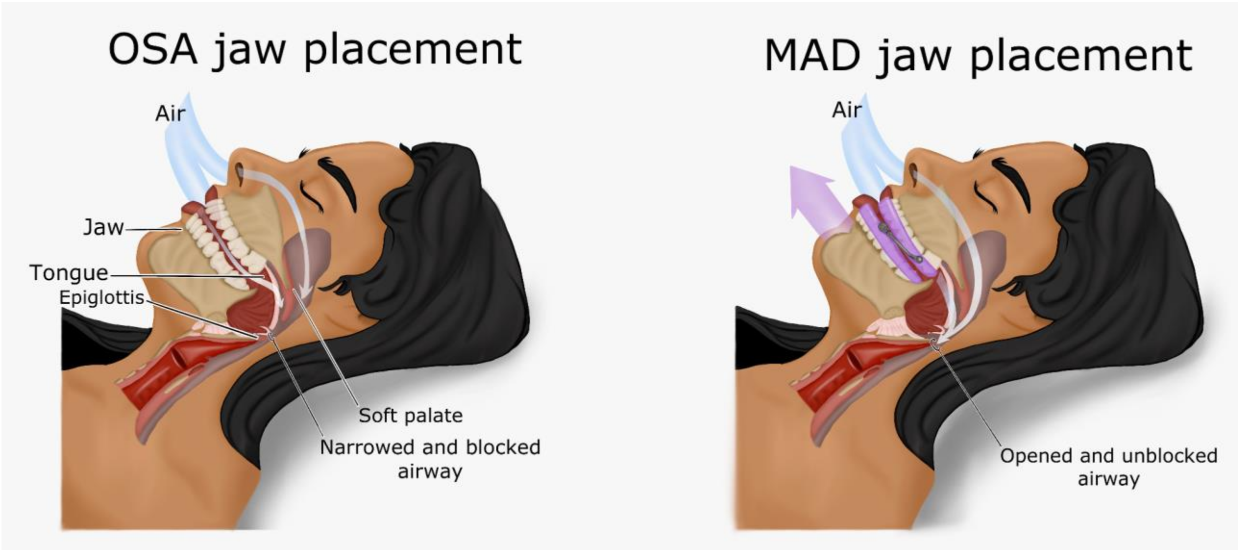

Figure 2. Mandibular advancement device allows the mandible to maintain a forward position compared to the maxilla, thereby expanding and stabilizing the pharyngeal airway to avert collapse and ensure unobstructed breathing.

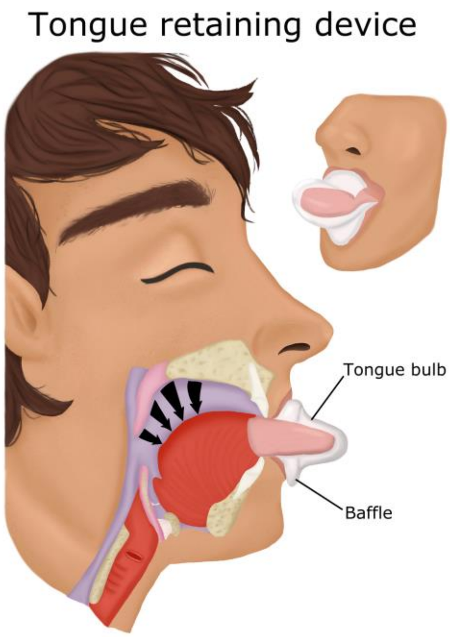

Figure 3. Tongue retaining device uses a suction bulb to maintain the tongue's soft tissue in an advanced position.