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# Intraoral Appliance Therapy - A Better Alternative for Apnea than CPAP?

Bryan Teigman

Bryan Teigman will graduate in June 2023 with a Bachelor of Science degree in Biology.

## Abstract

Obstructive sleep apnea (OSA) is a condition where there is a physiologic hindrance of airflow to the lungs, triggering the brain to interfere with the sleep cycle and awaken an individual to provide sufficient oxygen flow. For years, the continuous positive airway pressure (CPAP) machine has been the gold standard of care for patients suffering from OSA. Nonetheless, the machine has its flaws of being bulky, noisy, and other side effects, causing a low adherence rate and thus a lower relief rate of OSA symptoms. Accordingly, there have been many researchers seeking a more effective way to treat OSA, such as intraoral devices that manipulate the jaw and tongue placement to prevent pharyngeal airway collapse. The purpose of this paper is to compare the efficacy of continuous positive airway pressure (CPAP) and intraoral devices in the treatment of obstructive sleep apnea (OSA) based on the available evidence from original studies. To diagnose OSA, the studies used the Epworth sleepiness scale (ESS), the apnea hypopnea index (AHI), polysomnography (PSG), and the respiratory disturbance index (RDI). All studies found that, when adhered to properly, CPAP is more efficient in reducing OSA symptoms such as excessive daytime sleepiness, nighttime arousals, and hypertension, especially in more severe cases. Nonetheless, these studies also found CPAP to have lower adherence rates when compared to intraoral devices, influencing the effectiveness of the treatment. Furthermore, it was found that the margin for treatment relief between CPAP and intraoral devices decreased with a decline in OSA severity. This can be explained due to the fact that less severe cases do not require as rigorous treatment to control by symptoms. Accordingly, treatment planning needs to be individualized according to severity and expected adherence of each patient. In patients with mild-to-moderate OSA, intraoral devices seem to provide adequate relief of symptoms, while boasting a much higher adherence rate. Furthermore, in patients with severe sleep apnea, CPAP treatment continues to prove superior results. However, in patients who do not use the machine properly, intraoral devices may be considered.

## Introduction

Almost nothing is as precious as a good night's sleep. It is essential in promoting optimal health and well-being. For adults aged 18–60 years, at least seven hours of sleep each night is recommended. However, in 2014, the CDC declared a sleep disorder epidemic within the United States based on a study that found that more than a third of American adults are not getting enough sleep on a regular basis, oftentimes due to sleeping disorders (Liu, et. al., 2014). These include insomnia, parasomnias like sleep walking, sleep related bruxism, snoring, obstructive sleep apnea (OSA), central sleep apnea, and several others. This is concerning, as aside from the immense economic impact, which is estimated at a loss of 411 billion dollars or 2.28% U.S. GDP, sleeping less than seven hours per night is associated with increased risk for diabetes, stroke, obesity, hypertension, coronary heart disease, and frequent mental distress (Hafner, et. al., 2017). In addition, insufficient sleep has been proven to impair cognitive performance, which can increase the likelihood of motor vehicle accidents, industrial accidents, medical errors, and loss of work productivity (Basner, et. al., 2017). Thankfully, there are several effective treatments, specifically for obstructive sleep apnea and snoring, that offer promising solutions to the sleep epidemic. They include behavioral modification (e.g., weight loss and alteration in sleep posture) or interventions such as maxillomandibular osteotomy, continuous positive airway pressure therapy (CPAP), intraoral appliances (IOA) like maxillary oral appliances, and mandibular advancement splints (MAS), also called mandibular advancement devices (MAD). This paper will specifically focus on CPAP and intraoral device treatments with the purpose of determining

if intraoral device therapies provide superior alternative treatments when compared to CPAP machines in the treatment of OSA?

## Methods

This document was written by researching peer reviewed scholarly articles and medical journals to assess the efficacies of CPAP and intraoral appliances. Online scholarly databases were searched for relevant articles, including Google Scholar and PubMed. While most of the material found is available to the public, many of the articles required special access, which was provided by Touro College.

## Discussion

### Diagnosing Sleep Disorders

There are several different tests that are employed in diagnosing sleep disorders. The present reference or “gold” standard is the polysomnogram (PSG). PSG is defined as the continuous monitoring and simultaneous recording of physiologic activities like eye movements during sleep, using a combination of continuous electroencephalogram (EEG) and electrocardiography. EEG records electrical cortical activity and calculates relative differences in electrical fields across brain regions to analyze sleep states, specifically rapid eye movement (REM) sleep, using body position sensors (Markun, et. al., 2020). The data collected and integrated in this method is termed the “sleep study.”

Regarding sleep apnea specifically, the apnea-hypopnea index (AHI) is the primary measurement for diagnosis (Thornton, et. al., 2012). This is an average that reflects the total number of apneas and hypopneas that occur during

a single hour of sleep. The respiratory disturbance index (RDI) is a numeric index which helps to define the degree of apnea (Abeyratne, et. al., 2010). RDI is calculated as the number of apnea, hypopnea, and respiratory-effort related arousals per hour of sleep. A respiratory-effort related arousal is defined as a breathing abnormality detected by the EEG during a sleep study that does not fit the requirements for apnea or hypopnea and is instead considered an “arousal” event that is connected to a respiratory effort (Kushida, et. al., 2005). The diagnosis severity of an apnea patient for both the AHI and RDI is as follows:

- Normal Sleep: AHI/RDI < 5 events/hour
- Mild apnea: AHI/RDI between 5-15 events/hour
- Moderate apnea: AHI/RDI between 15-30 events/hour
- Severe apnea: AHI/RDI > 30 events/hour

Other common diagnostic tools used in detecting symptoms of OSA are the Epworth Sleepiness Scale (ESS) and Multiple Sleep Latency Test (MSLT), the former being the most common measure of subjective daytime sleepiness and the latter in detecting objective daytime sleepiness. The ESS is a validated eight-question survey asking patients to rate the perceived likelihood of falling asleep in various situations. The test is scaled from a score of 0 to 24, with 0 indicating no daytime sleepiness, 24 indicating the most severe sleepiness, and a score of 11 or greater the standard for determining significant sleepiness. For the MSLT, patients are instructed to try to fall asleep in a dark quiet room four or five times at two-hour intervals. The MSLT score is the average number of minutes required to fall asleep, which is measured by electroencephalography. Normal adults score between 10 and 20 minutes with anything below indicating sleepiness and below five indicating pathologic drowsiness.

### Sleep Apnea

Two distinct respiratory conditions comprise sleep apnea-hypopnea syndrome: central (originating in the central nervous system) and obstructive apnea (involving collapse of the anatomical structures of the upper airway). In some instances, however, the conditions can be mixed (co-existing central and obstructive clinical symptoms). This paper will solely focus on the obstructive component of sleep apnea.

Obstructive sleep apnea (OSA) is a common disorder in the general middle-aged population, affecting approximately 2% of women and 4% of men (Young, et. al., 1993). Although nonobese individuals may suffer from OSA, obesity is a primary epidemiologic risk factor. In fact, increases in body mass index, neck circumference, and central accumulation of adipose tissue are effective

predictors of disease (Young, et. al., 2004). According to American Academy of Sleep Medicine, OSA is defined as a respiratory condition that, despite continued breathing efforts, sees a reduction or cessation of airflow. When this happens during sleep, muscles around the pharynx such as the platoglossus and palatopharyngeus muscles relax, causing soft tissue in the back of the throat to collapse and obstruct the upper airway (Remmers, et. al., 1978). The human pharynx is uniquely susceptible to collapse due to the presence of a floating hyoid bone, a longer airway, and a less direct route for inspired air to travel. All these factors increase the pharynx’s sensitivity to alterations in anatomically imposed mechanical loads (Patil, et. al., 2007).

As a result of an obstruction, there may be partial decreases (hypopneas) and/or total pauses (apneas) in breathing. Hypopnea is usually defined as a 25% to 50% reduction in oronasal airflow combined either with a reduction in oxyhemoglobin saturation or an arousal from sleep. Snoring, heart rate abnormalities, and paradoxical breathing are specific diagnostic criteria for this population group. Apneas, on the other hand, are defined as cessations in breathing lasting at least 10 seconds while asleep (Shiroh, et. al., 2009). Most apnea gaps last between 10 and 30 seconds but in severe cases can last for a minute or longer. This may lead to a sudden decline in blood oxygen saturation, with oxygen levels dropping by as much as 40% or more in extreme circumstances. The body will then alert the brain of the oxygen shortage, resulting in a short awakening from sleep before briefly restoring breathing. In a single night, this sequence can repeat itself hundreds of times, resulting in a disturbed sleep pattern that frequently causes excessive daytime sleepiness and hypoxemia. Most OSA sufferers snore loudly and regularly, stopping only when their airway is restricted or closed.

### Treatments

Considering the detriment OSA poses on health and daily function, it is essential to seek out remedies. There are several ways to treat mild to severe OSA, but this review will primarily focus on CPAP and intraoral appliance therapies in terms of their effectiveness in treating OSA.

#### Continuous Positive Airway Pressure

Continuous Positive Airway Pressure (CPAP) machine is a medical device used to treat sleep apnea. The CPAP machine delivers a constant flow of air pressure through a mask that is worn over the nose or mouth, which helps to keep the airway open and prevent pauses in breathing. The CPAP machine consists of three main parts: a motor,

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a mask, and a hose. The motor generates the airflow and is usually located in a small unit that can fit on a bedside table. The hose connects the motor to the mask. The mask can be either a full-face mask that covers both the nose and mouth or a nasal mask that covers only the nose. The pressure of the airflow delivered by the CPAP machine can be adjusted to suit the patient's needs. The doctor or sleep specialist will typically prescribe a specific pressure level based on the severity of the patient's sleep apnea (Chen, et. al., 2012). The most common side effects experienced when using CPAP include discomfort, dry mouth or nose, skin irritation, claustrophobia, gastrointestinal problems, mask leaks, and conjunctivitis.

CPAP has been proven by countless studies to drastically improve the symptoms of OSA such as snoring, daytime sleepiness, decreased blood oxygen saturation, AHI and hypertension. Accordingly, CPAP has been considered the "gold standard" of treatment for all severities of OSA. For instance, Patel and colleagues performed a meta-analysis on a diverse population, including twelve trials totaling 706 patients, and concluded that CPAP reduced the ESS score by an average of 2.9 points more than the placebo in patients with OSA. The treatment proved more effective for moderate to severe cases than those with mild OSA. This suggests that although the ESS score only slightly decreased, it is significant since the sample size was very large. Supporting these findings, another study on the long-term effects of CPAP on blood pressure in OSA patients concluded that CPAP does improve daytime sleepiness as well as significantly controls hypertension in patients with OSA. The 36 patients who received CPAP treatment scored on average over three points lower on ESS (a six-point decrease from baseline) than the control group. Also, hypertension control was improved in 69.4% of CPAP users compared to only 43.2% of control subjects over a 36-month range (Huang, et. al., 2015). While hypertension was controlled significantly, the patients in this study had much lower BMI's than most other studies. Obesity is an independent risk factor which may contribute to worsening of blood pressure control and is not affected by CPAP.

While it does seem that CPAP is very effective in improving daytime sleepiness, another analysis suggests otherwise. A study conducted on the effect of CPAP in normalizing daytime sleepiness and quality of life in patients with moderate to severe OSA, found that CPAP did not normalize daytime sleepiness responses despite seemingly adequate use for a substantial proportion of the 174 patients. In total, 40% of patients in the three-month-long trial had an abnormal ESS score at its conclusion. Of the patients who used CPAP for more than seven hours per night, 80.6% had

a normal ESS score after treatment (Antic, et. al., 2011). This study reported a generally low overall nightly CPAP usage in 45% of patients, which can explain the failure of CPAP treatment to normalize ESS. However, this may not be the explanation, since even the 19% of patients with abnormal ESS pretreatment values in the subgroup that used CPAP for more than seven hours per night failed to have normal ESS scores after treatment.

This issue of non-adherence to CPAP continues to plague the treatment. A study conducted on CPAP adherence of patients with OSA found that of 903 subjects referred for a sleep study and CPAP treatment, only 248 continued to follow up for treatment after one month. They claimed to be adherent (using the Kribbs et al definition of adherence as  $\geq 4$  hours per night for at least 70% of the days which has been used in many studies). Within this population, their subjective adherence was 85.1%, and their objective adherence was 64.5%. While both groups reported many side effects, the objectively non-adherent group complained of adverse effects more frequently. There was around a 10% difference between the groups for patients bothered by machine noise, air leakage, dry mouth and nose, morning headache and sleep discomfort (Selepci, et. al., 2013). It seems that even within the seemingly most "compliant" group, as displayed by the fact they attended follow ups, 45% still did not adhere with their device use. This can most probably be explained by the higher percentage of side effects reported by the later sub-group. Nevertheless, another justification for the low ratio of patient follow-up may be due to the low social and economic status of the patients, making extended treatment unaffordable.

### Intraoral Appliances

A mandibular device, also known as a mandibular advancement device (MAD), is a type of oral appliance used to treat OSA. The device is custom fit to the patient's mouth by a dentist or sleep specialist. It typically consists of two separate dental trays that sit over the upper and lower teeth, connected by metal hinges. The lower tray is designed to hold the lower jaw in a slightly forward position, which helps to prevent the tongue and soft tissues at the back of the throat from collapsing and obstructing the airway during sleep. Side effects are typically mild and temporary, rarely needing intervention, and include dry mouth, hypersalivation, jaw pain, and sensitive teeth upon awakening (Fritsch, et. al, 2001).

A randomized control trial was conducted by Gotsopoulos et. al. with the aim of evaluating the effect of a MAS on both objective and subjective daytime sleepiness and a range of other symptoms in OSA. The MAS device

featured a basic design with separate upper and lower acrylic appliances anchored onto the dental arches that cover the occlusal surfaces of all teeth. A screw system enabled incremental advancement of the jaw. In contrast, the control device consisted of the upper appliance alone, which had no protrusive effect on the mandible. Patients were informed that the aim of the study was to examine the efficacy of oral appliance therapy for OSA by comparing two appliances. All patients were above the age of 20 and had evidence of OSA on polysomnography (RDI  $\geq 10$ /hour), while suffering from at least two of the following symptoms: daytime sleepiness, snoring, witnessed apneas, or fragmented sleep. The 73 patients who participated for the duration of the study period consisted of 59 men and 14 women and, as a group, were middle-aged and overweight. After undergoing a PSG, OSA severity subgroups revealed a predominance of moderate (with 41 patients (56%)) and severe (21 patients (29%)) OSA. Eleven of the original group only showed a mild OSA and were not included in the results. There were 38 patients (52%) considered subjectively sleepy, scoring greater than 8 on the Epworth Sleepiness Scale, a reliable and validated self-administered questionnaire (Rosenthal, Dolan, 2008). After randomization, group one consisted of 30 males and 6 females with an average BMI of 28.4 [Equation] 5.2 and group two consisted of 29 males and 8 females with an average BMI of 29.6 [Equation] 4.1.

At the conclusion of the study, the MAS devices proved to improve various sleep metrics. The most significant change was in the RDI which decreased by  $15 \pm 4$  from  $27 \pm 2$  disturbances per hour at baseline to just  $12 \pm 2$  disturbances per hour when using an MAS device. The control group only showed a slight reduction to  $25 \pm 2$  disturbances per hour. This amounts to a 52% reduction in mean RDI when using the MAS device. Furthermore, the MAS resulted in a substantial reduction in objective snoring frequency ( $207 \pm 20$  vs.  $366 \pm 21$ ) and in both average and maximum snoring intensity. However, there was no significant difference in mean sleep efficiency or mean total sleep time. Objective daytime sleepiness improved appreciably during active treatment. The MSLT indicated that 35 patients (48%) demonstrated a normal MSL score with active treatment, compared to only 25 patients (34%) with the control treatment (a normal MSL defined as between 10 and 20 minutes to fall asleep). There was also a small improvement in subjective daytime sleepiness with the MAS when compared to the control device ( $7 \pm 1$  versus  $9 \pm 1$  mean ESS score). Active treatment produced a normal ESS score in 60 patients (82%), compared with 45 patients (62%) on the control treatment. Interestingly, the control device still showed a significant reduction in

subjective daytime sleepiness from the baseline ( $9 \pm 1$  versus  $11 \pm 1$ ) (Gotsopoulos, et. al., 2002).

Although these results do demonstrate significant objective and subjective evidence of symptom improvement in patients with mild to severe OSA with MAS therapy, patients still did not reach the threshold of a normal RDI score. In addition, 52% of patients still scored abnormally on the MSLT. Both these factors can possibly be attributed to the short treatment of 4 weeks, as longer treatment may yield better results. Also, the two-point decrease in the ESS score may not be clinically significant, since it is only a slight decrease in a small sample size and, as with any subjective report, the main limitation of the ESS is that it is open to response bias. However, given that the placebo used was very convincing in appearance to the active treatment and still there was a 20% discrepancy in normal ESS scoring between the two groups, the slight decrease in ESS score may be relevant.

In a study aimed at testing the efficacy of CPAP versus oral appliance therapy in mild to moderate OSA patients, 114 patients were included over a three-month period. The placebo group was given pills. The subjects were middle aged ( $47.0 \pm 0.9$  years), predominantly male (80%) and overweight, with mild to moderate OSA (AHI, 5–30 per hour). CPAP adherence was objectively measured by an inbuilt meter and showed CPAP pump usage to be on average  $4.2 \pm 0.3$  nights per week and for an average of  $3.6 \pm 0.3$  hours per night. The MAS adherence was measured subjectively for 49 of the 85 subjects who completed MAS treatment via subject diary and reported an average of  $5.3 \pm 0.3$  nights per week of usage for  $5.5 \pm 0.3$  hours per night over the entire treatment period. 38 of 88 (43%) subjects treated with CPAP received adequate treatment, while 37 of 49 (76%) subjects treated with MAS (for whom there was usage data) received adequate treatment. Of the patients who started treatment with mild OSA, 28% preferred CPAP and 41% preferred MAS, as they found it easier to use (Barnes, et. al., 2004). These results demonstrate that while both treatments were more effective than the placebo in improving quality of life and subjective (but not objective) sleepiness, neither treatment proved better than the other since both reported a 9.2 score on ESS (baseline was 10.7). In addition, although usage of the MAS device was reported to be significantly higher than CPAP, CPAP was superior to the MAS in treating obstructive sleep breathing events with the CPAP scoring a 4.8 AHI and MAS 14 (Baseline was 21.3). This can be easily explained by the fact that the MAS device usage was subjectively reported leading to bias. Also, although subjects reported that CPAP was the most difficult treatment to use, they felt that it was the most effective.

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A much more recent study however, found that there is no clinically relevant difference between MAD and CPAP in the treatment of mild/moderate OSA. Of the 57 patients who completed the six-month trial, only those assigned to treatments saw drastic improvements in AHI and RDI, with CPAP displaying a decrease of 19.5 and 13.5 respectively and the MAD displaying a decrease of 16.3 and 13 points respectively. In addition, snoring had decreased more frequently in the MAD group and had disappeared more frequently in the CPAP population. Regarding usage of appliances, the MAD group utilized their appliance 90.6% of the nights and the CPAP group used theirs 82.9% of nights (Arab, et. al., 2010). This indicates that patients were more likely to adhere to the MAD usage than the CPAP machine. Furthermore, although there was a small sample size in this study, the longer treatment time in this trial was a tremendous strength. In addition, the previous trials titrated (the process of determining the proper air pressure for CPAP and protrusion for MADs, by gradual manipulation) the CPAP objectively while the MADs were titrated by their dentist creating the possibility of bias in the evaluation of improvement. This trial, on the other hand, titrated both CPAP and the MAD as objectively, as PSG recordings were made for each MAD patient, thus reducing biases.

### Conclusion

These studies do suggest that although intraoral devices are effective treatments of OSA, especially for mild to moderate severities, they are slightly less effective than CPAP in decreasing AHI, RDI, MSLT and ESS scores as well as in controlling hypertension. Nonetheless, clinical outcomes for CPAP and intraoral devices are very similar for mild to moderate severities. Moreover, the major difference between devices is with adherence and side effects. Patients find it very difficult to use CPAP due to factors such as discomfort and machine noise during use. Conversely, patients find the intraoral devices more comfortable and easier to use. Side effects for the intraoral devices were usually mild and temporary, while with CPAP they persisted with use. Accordingly, treatment planning needs to be individualized according to severity and expected adherence of each patient. Since intraoral devices are easier to adhere to and are only marginally less effective than CPAP for mild-to-moderate OSA, they are a superior solution over CPAP. For severe cases of OSA, CPAP is still the preferred course of treatment since it is demonstrably more successful at reducing symptoms than intraoral devices. However, in patients who do not use the machine properly intraoral devices may be considered.

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