ORAL APPLIANCE THERAPY

EVIDENCE BRIEF

FOR OSA, CONSIDER OAT

DENTAL SLEEP MEDICINE RESEARCH PACKET
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Loud snoring may be the most obvious consequence of sleep apnea, but the condition, if left untreated, can lead to a broad range of complications, including high blood pressure, heart disease, liver dysfunction and Type 2 diabetes.

- NICHOLAS BAKALAR
as quoted in NYT article, "For Sleep Apnea, a Mouth Guard May be a Good Alternative to CPAP" published 5/31/21
The Efficacy of Oral Appliance Therapy

TITLE
Cardiovascular Effects of Oral Appliance Therapy in Obstructive Sleep Apnea: A Systematic Review and Meta-Analysis

IMPORTANCE
While more research is needed, initial evidence shows that oral appliance therapy (OAT) can help reduce the risk of serious cardiovascular outcomes and cardiovascular-related death.

CITATION

SUMMARY
This systematic review and meta-analysis of 16 studies examined the impact of OAT on cardiovascular outcomes. OAT has small but positive impact on daytime systolic and diastolic blood pressure. The authors write that “[i]n some patients, OAT and continuous positive airway pressure (CPAP) can be equally effective in reducing blood pressure." Furthermore, OAT improves mean daytime heart rate, when compared to a sham device. One study examined showed that OAT and CPAP were equally effective in reducing the risk of cardiovascular mortality. The authors conclude that while more rigorous research is necessary, OAT can reduce cardiovascular morbidity and mortality.

WEB URL LINK
The authors of this study conducted a meta-analysis of 7 studies, which enrolled a total of 399 patients with mild-to-moderate OSA. The main objective of the study was to understand the effect of OAT on blood pressure. The meta-analysis shows that OAT improves blood pressure control for patients with mild to moderate sleep apnea. Reductions in both systolic blood pressure (SBP) and diastolic blood pressure (DBP), as well as in nocturnal SBP, were seen with OAT. “Although the reductions in BP with OAs were modest, these effects were comparable to those reported with continuous positive airway pressure (CPAP) treatment.” Across the board, effective oral appliance therapy, as evidenced by a decreased apnea-hypopnea index (AHI), leads to a decrease in SBP, DBP and mean arterial blood pressure (MAP). “Previous studies have shown that even a modest reduction in BP may reduce the risk of coronary artery disease and stroke.” Thus, both CPAP and OAT can lead to a similar modest reduction in blood pressure.

Effect of Oral Appliances on Blood Pressure in Obstructive Sleep Apnea: A Systematic Review and Meta-analysis


https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3544387/
THE EFFICACY OF ORAL APPLIANCE THERAPY

TITLE
Cardiovascular Mortality in Obstructive Sleep Apnea Treated with Continuous Positive Airway Pressure or Oral Appliance: An Observational Study

IMPORTANCE
This study shows that oral appliance therapy (OAT) can reduce the risk of heart-related death for patients with severe obstructive sleep apnea (OSA).

CITATION

SUMMARY
This non-concurrent cohort study of 570 patients with severe OSA was conducted to understand the long-term outcomes for cardiovascular mortality. Patients began their therapy with continuous positive airway pressure (CPAP). OAT was offered to patients who were not compliant with CPAP therapy. Patients were more compliant with OAT than with CPAP, overall. While AHI was lower in patients using CPAP, there was no significant difference between the two therapies in terms of cardiovascular death rate. Thus, both CPAP and MAD “may be equally effective in reducing the risk of fatal cardiovascular events in patients with severe OSA."

WEB URL LINK
The Efficacy of Oral Appliance Therapy

**Title**
Oral Appliance Therapy Reduces Blood Pressure in Obstructive Sleep Apnea: A Randomized, Controlled Trial

**Importance**
Oral appliance therapy (OAT) may be an effective alternative to continuous positive airway pressure (CPAP) when it comes to reduction of blood pressure.

**Citation**

**Summary**
This study was a randomized, controlled, crossover trial with obstructive sleep apnea (OSA) patients. These patients wore an OA and a placebo device for 4 weeks each. Compared to the placebo device, patients experienced a 50% reduction in AHI. 34% of patients were considered a complete treatment success while another 30% were considered partial responders. When patients used the OA, they experienced a significant decrease in 24-hour diastolic blood pressure (compared to the control device). “Awake blood-pressure variables were reduced with the MAS by an estimated mean (± SEM) of 3.3±1.1 mmHg for systolic blood pressure (P = .003) and 3.4 ± 0.9 mmHg for diastolic blood pressure (P < .0001).” The study did not find any significant differences when measuring blood pressure variables during sleep. The authors argued that OAT can successfully reduce blood pressure in a manner similar to CPAP.

**Web URL Link**
A total of 96 patients (27 women and 58 men) were included in this double-blind, randomized controlled trial. One group was given an OAT and the other a sham appliance. Among the female participants, nighttime systolic blood pressure was 10.8 mm Hg lower and diastolic pressure was 6.6 mm Hg lower among those using the OAT, compared to the sham appliance. These results were adjusted for confounding variables. Among the male participants, neither daytime or nighttime blood pressure levels differed significantly between the OAT group and the sham group.

**WEB URL LINK**

https://www.ahajournals.org/doi/full/10.1161/JAHA.118.008642
THE EFFICACY OF ORAL APPLIANCE THERAPY

TITLE
Improved Cognitive Functions after Treatment with an Oral Appliance in Obstructive Sleep Apnea

IMPORTANCE
This study shows that, after only six months of treatment, oral appliance therapy (OAT) can significantly improve daytime sleepiness and cognitive functions, specifically alertness and focus, of patients with mild to several obstructive sleep apnea (OSA).

CITATION

SUMMARY
This prospective study of 50 male patients with OSA was conducted to better understand the impact of OAT on cognitive function. “Working memory, vigilance, executive functioning and mental pace” were assessed before and after 6 months of OAT. A total of 43 patients completed the treatment protocol. AHI, oxygen desaturation and daytime sleepiness were all significantly reduced. Furthermore, there was a reduction in the mean Epworth Sleepiness Scale. Results from patients with severe OSA were similar to that of the rest of the study participants.

WEB URL LINK
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3630975/
The authors of this study conducted a randomized controlled trial of 73 patients who had “at least 2 symptoms of obstructive sleep apnea and an AHI ≥ 10 per hour.” This study was designed to better understand the impact of OAT on mood and neuropsychological functioning. Patients were treated with both an active OA and an inactive placebo device, each for 4 weeks. OAT use was associated with “improvements on the somatic component of the Beck Depression Inventory and the Vigor-Activity and Fatigue-Inertia scales of the Profile of Mood States.” Overall, OAT use was associated with increased psychomotor speed, as well as improved self-reported sleepiness and energy levels.

Effect of Oral Appliance Therapy on Neurobehavioral Functioning in Obstructive Sleep Apnea: A Randomized Controlled Trial

Oral appliance therapy (OAT) can be an effective therapy for patients who complain that their OSA is causing them to experience neuropsychological issues.


The authors of this study conducted a randomized controlled trial of 73 patients who had “at least 2 symptoms of obstructive sleep apnea and an AHI ≥ 10 per hour.” This study was designed to better understand the impact of OAT on mood and neuropsychological functioning. Patients were treated with both an active OA and an inactive placebo device, each for 4 weeks. OAT use was associated with “improvements on the somatic component of the Beck Depression Inventory and the Vigor-Activity and Fatigue-Inertia scales of the Profile of Mood States.” Overall, OAT use was associated with increased psychomotor speed, as well as improved self-reported sleepiness and energy levels.

THE EFFICACY OF ORAL APPLIANCE THERAPY

TITLE
Oral Appliance Therapy Improves Symptoms in Obstructive Sleep Apnea: A Randomized, Controlled Trial

IMPORTANCE
Oral appliance therapy (OAT) improves daytime sleepiness and other subjective symptoms related to obstructive sleep apnea (OSA).

CITATION

SUMMARY
This randomized crossover study involved randomizing 73 patients with OSA to either a group that received OAT or a placebo device. The trial lasted 4 weeks. Although objective sleepiness did not vary between the groups, subjective sleepiness was significantly better in the OAT group. Furthermore, OAT had a greater impact on snoring, sleep quality, witnessed apneas, and treatment satisfaction.

WEB URL LINK
A total of 28 patients participated in this randomized, controlled, three-period crossover study. Two devices were used – an OA that advanced the mandible and an OA that did not advance the mandible. 26 patients completed the trial. Overall, the advanced appliance was well tolerated by 87.5% of respondents with high compliance (87.5% of participants reported using the advanced appliance nightly). Using the advanced appliance, 37.5% of patients achieved a complete response (reducing AHI to <5/h) and another 25% achieved a partial response (≥50% reduction in AHI but ≥5/h remaining) to treatment. The advanced appliance was associated with significant improvements in arousal index, MinSaO2 and AHI, compared with the non-advanced appliance. Overall, the authors concluded that OAT is effective, even with patients that have moderate-to-severe OSA.

https://www.atsjournals.org/doi/full/10.1164/ajrccm.163.6.2004213
But CPAP machines can be noisy, cumbersome and uncomfortable, and many people stop using the devices altogether, which can have dire long-term consequences.

- NICHOLAS BAKALAR

as quoted in NYT article, “For Sleep Apnea, a Mouth Guard May be a Good Alternative to CPAP” published 5/31/21
Often, OAT studies only report subjective compliance with therapy. This 3-month prospective clinical trial examined objectively measured compliance with OAT. 51 patients were given an OA with a microsensor compliance monitor. Overall, the objective mean use of the appliance was .6 ± 1.3 h per day. 93% of patients used the appliance for more than 4 hours per night. Subjective compliance was also measured and did not significantly differ from the objective measurement. Finally, 51.1% of cases were considered treatment successes.


Objective Measurement of Compliance During Oral Appliance Therapy for Sleep-Disordered Breathing

Compliance with oral appliance therapy (OAT) is high, even when it is measured objectively.

**CITATION**


**SUMMARY**

Often, OAT studies only report subjective compliance with therapy. This 3-month prospective clinical trial examined objectively measured compliance with OAT. 51 patients were given an OA with a microsensor compliance monitor. Overall, the objective mean use of the appliance was .6 ± 1.3 h per day. 93% of patients used the appliance for more than 4 hours per night. Subjective compliance was also measured and did not significantly differ from the objective measurement. Finally, 51.1% of cases were considered treatment successes.

**WEB URL LINK**

This study examined the long-term adherence and clinical outcomes among patients using OAT. A total of 99 women and 204 men responded to this survey. Mean follow-up time was 3.3 years. Over this time, 86% of patients remained adherent to therapy. 97% of patients used the device for at least 4 hours a day and the mean daily use was 7.2 ± 1.1 hr. AHI significantly decreased and both respiratory and asthma symptoms improved with OA use. 83% of patients reported an improved quality of life with OA treatment. OAT was also associated with a reduction in nocturia and use of nasal decongestants. Finally, OAT was associated with improvements in mood, headache and working ability.
COMPLIANCE WITH ORAL APPLIANCE THERAPY

TITLE
Adherence and Side Effects Among Patients Treated with Oral Appliance Therapy for Obstructive Sleep Apnea

IMPORTANCE
Most patients continue to be adherent to OAT despite side effects. Education on the importance of treatment for OSA and mitigation of side effects could possibly reduce discontinuation of therapy. Qualified dentists are well prepared to mitigate side effects of OAT.

CITATION

SUMMARY
The authors of this study conducted a survey of 136 patients who were either adherent to OAT, discontinued to use CPAP or who had discontinued all therapy and were no longer being treated. The majority of those surveyed continued to be adherent to OAT (76.1%). Of those in the no treatment group, 61.1% discontinued due to jaw pain and 22.2% due to occlusion changes. Of those in the CPAP group, 42.6% discontinued due to change in occlusion. While those in the adherent group reported some side effects, the authors hypothesize that the benefits of treatment outweighed the side effects. Furthermore, the respondents who continued OAT therapy had a greater concern about the negative effects of OSA, compared to the no treatment group. Partner satisfaction was significantly higher for participants still using OAT, compared to those using CPAP or no therapy.

WEB URL LINK
https://www.aadsm.org/docs/jdsm.1.10.20.o1.pdf
ORAL APPLIANCE THERAPY VS. CONTINUOUS POSITIVE AIRWAY PRESSURE

“[OAT] is easy to tolerate, effective and it costs a lot less than CPAP. Thirty to 40 percent of our patients can’t use CPAP, and these patients almost always find the dental appliance helpful. I would recommend it as a first-line treatment.”

- DR. GUILLAUME BUIRET
  Head of Otolaryngology at Valence Hospital
  as quoted in NYT article, “For Sleep Apnea, a Mouth Guard May be a Good Alternative to CPAP” published 5/31/21
At the time of publication, this was the first meta-analysis to directly compare the impact of OAT and continuous positive airway pressure (CPAP) for patients with severe sleep apnea. The authors of this study included four randomized controlled trials in the final analysis. Although CPAP was more effective in reducing AHI and ODI, most patients preferred OAT. Furthermore, patients were far more compliant with OAT. There was no statistically significant difference between OAT and CPAP in terms of sleep architecture. Both therapies had a similar effect on sleep structure by increasing N3 and REM sleep. OAT was similar to CPAP in terms of impact on sleepiness and quality of life. The authors concluded that OAT is an effective alternative to CPAP, even among patients with severe OSA.

Due to the rigorous methodological nature of this study, it gives strong evidence for the effectiveness of oral appliance therapy (OAT) in populations with severe obstructive sleep apnea (OSA).


ORAL APPLIANCE THERAPY VS. CONTINUOUS POSITIVE AIRWAY PRESSURE

TITLE
Health Outcomes of Continuous Positive Airway Pressure versus Oral Appliance Treatment for Obstructive Sleep Apnea: A Randomized Controlled Trial

IMPORTANCE
This study found that oral appliance therapy (OAT) is as effective as or better than continuous positive airway pressure (CPAP) therapy at improving adverse health effects in patients with moderate to severe obstructive sleep apnea (OSA).

CITATION

SUMMARY
The objective of this study was to compare health effects after one month of optimal treatment using CPAP and OAT to treat obstructive sleep apnea. A total of 108 patients completed the study with both devices, with the majority (82%) having moderate to severe OSA, with an average apnea-hypopnea index (AHI) of 22 and 42, respectively. Patients were significantly more compliant with OAT. Furthermore, more than half (51%) of patients preferred OAT, while less than a quarter (21.3%) preferred CPAP. The data suggest that both CPAP and OAT may reduce the risk of motor vehicle accidents among OSA patients who suffer from sleepiness. CPAP and OAT were similar in measures of quality of life, sleepiness and driving performance. These results may be explained by the greater compliance with OAT, when compared with CPAP. “These findings strongly challenge current practice parameters recommending [OAT] treatment be considered only in patients with mild to moderate OSA.”

WEB URL LINK
TITLE
Oral Appliance Therapy versus Nasal Continuous Positive Airway Pressure in Obstructive Sleep Apnea: A Randomized, Placebo-Controlled Trial

IMPORTANCE
Continuous positive airway pressure (CPAP) and oral appliance therapy (OAT) are equally effective treatments, when the appliance is properly positioned.

CITATION

SUMMARY
Many studies comparing OAT to CPAP use OAs that are not positioned objectively while the CPAP is objectively titrated. Thus, the comparison can be somewhat biased. This randomized controlled trial compared a placebo device, an objectively titrated CPAP and an objectively positioned OA. 64 patients were randomly assigned to these groups. The researchers found no difference in change to apnea-hypopnea index (AHI) between OAT and CPAP, although both were significantly better at reducing AHI than the placebo device. They concluded that there is no clinical difference between CPAP and OAT when it comes to treating patients with mild-to-moderate sleep apnea.

WEB URL LINK
https://www.karger.com/Article/FullText/319595
ORAL APPLIANCE THERAPY VS. CONTINUOUS POSITIVE AIRWAY PRESSURE

TITLE
Efficacy versus Effectiveness in the Treatment of Obstructive Sleep Apnea: CPAP and Oral Appliances

IMPORTANCE
As many studies only measure the efficacy (how well a therapy works in perfect conditions) of continuous positive airway pressure (CPAP) vs. oral appliance therapy (OAT), it is important to also consider the comparative effectiveness of the two treatments (how well they work in the real world). When looking at effectiveness, OAT may be a far better treatment than CPAP.

CITATION

SUMMARY
While CPAP is often considered more efficacious, patients tend to prefer OAT over CPAP. Also, while the efficacy of CPAP is high, the actual benefits of using the device are compromised by lack of adherence to treatment. Thus, many studies show similar improvements in health outcomes between CPAP and OAT. The commonly used efficacy measure (apnea-hypopnea index, AHI) may not be sufficient to capture real-world treatment effectiveness. Assessment of effectiveness should account for hours ON and OFF treatment. Therefore, the authors propose a new measure of effectiveness (the SARAH Index).

WEB URL LINK
https://aadsm.org/docs/JDSM.2.4.175.pdf
This 8-week multi-site, randomized crossover study compared oral appliance therapy (OAT) to continuous positive airway pressure (CPAP) and included 59 patients with mild-to-severe OSA. 58.3% of patients with mild-to-moderate OSA achieved complete treatment response (defined as > 50% reduction in AHI to < 5 events h⁻¹), as did 31.2% of patients with severe OSA. OAT and CPAP performed similarly in relation to objective daytime sleepiness, cognitive function and health-related quality of life (HRQoL). Compliance was higher with OAT and patients preferred it to CPAP. This study shows that when effectively positioned, OAT is effective for patients with mild-to-severe OSA.


http://erj.ersjournals.com/content/34/4/914.long
ORAL APPLIANCE THERAPY VS. CONTINUOUS POSITIVE AIRWAY PRESSURE

TITLE
Mandibular Advancement Splints and Continuous Positive Airway Pressure in Patients With Obstructive Sleep Apnoea: A Randomized Cross-Over Trial

IMPORTANCE
This study shows that not only is oral appliance therapy (OAT) an effective alternative to continuous positive airway pressure (CPAP), it also shows that patients prefer OAT over CPAP.

CITATION

SUMMARY
This study was a prospective, randomized, cross-over trial of 24 patients. All had mild-to-moderate obstructive sleep apnea (OSA). Patients were randomly assigned to OAT and CPAP and used each for 2 months, with a 2-week washout in between. Average apnea-hypopnea index (AHI) at the beginning was 22.2 – average AHI decreased to 3.1 with CPAP and 8.0 with OAT. The authors found no statistical difference between these two treatments. Furthermore, 17 out of the 21 subjects who completed both treatments preferred OAT over CPAP.

WEB URL LINK
ORAL APPLIANCE THERAPY VS. CONTINUOUS POSITIVE AIRWAY PRESSURE

TITLe
Oral Appliance Versus Continuous Positive Airway Pressure in Obstructive Sleep Apnea Syndrome: A 2-Year Follow-up

IMPORTANCE
Oral appliance therapy (OAT) is a viable first-line alternative to continuous positive airway pressure (CPAP) for those with mild-to-moderate obstructive sleep apnea (OSA).

CITATION

SUMMARY
The authors conducted “a cohort study of a previously conducted randomized clinical trial” with 103 patients who had OSA. After 2 years, the researchers found that the percentage of mild-to-severe patients effectively treated did not differ between OAT and CPAP. While CPAP was more effective at reducing the AHI and improving oxyhemoglobin saturation levels, there was no significant difference between the two treatments when it came to health perceptions, sleepiness and functional outcomes. The authors concluded that OAT is a viable alternative for those with mild-to-moderate OSA and in severe patients if CPAP therapy fails.

WEB URL LINK
https://academic.oup.com/sleep/article/36/9/1289/2453867?login=true
The problem develops when the soft tissue at the back of the throat collapses during sleep, blocking the airway. This leads to breathing cessation for brief periods, gasping for air, difficulty staying asleep, and all the problems of daytime sleepiness, from poor job performance to fatal accidents.

- NICHOLAS BAKALAR
  as quoted in NYT article, "For Sleep Apnea, a Mouth Guard May be a Good Alternative to CPAP" published 5/31/21
This study examined the use of combination therapy in patients with severe apnea, who were resistant to both CPAP and OAT. Patients who were intolerant to CPAP were switched to OAT for 12 weeks. If residual AHI remained, the patient was then switched to combination therapy for 12 weeks. In the end, a total of 14 patients were included in this retrospective study. The researchers found that residual AHI was lower on combination therapy than on CPAP or OAT. Furthermore, patients used combination therapy for 6.4±1.5 hr/night median at the follow-up (36.5 months). Overall, combining OAT and CPAP was effective for these patients.
This study looked at patients who had failed either CPAP monotherapy, oral appliance therapy (OAT) monotherapy, or combination therapy with nasal pillows. This retrospective chart review study included 75 patients. All of these patients had either failed CPAP monotherapy, OAT monotherapy or combination therapy using a TAP-PAP appliance. Of these, the custom face mask benefited those who had failed with CPAP monotherapy the most.

A Descriptive Report of Combination Therapy (Custom Face Mask for CPAP Integrated With a Mandibular Advancement Splint) for Long-Term Treatment of OSA With Literature Review

This study sheds light on who might benefit most from combination therapy, specifically with a custom face mask. Continuous positive airway pressure (CPAP) monotherapy failures tend to have the greatest success with combination therapy using a custom face mask.


This study looked at patients who had failed either CPAP monotherapy, oral appliance therapy (OAT) monotherapy, or combination therapy with nasal pillows. This retrospective chart review study included 75 patients. All of these patients had either failed CPAP monotherapy, OAT monotherapy or combination therapy using a TAP-PAP appliance. Of these, the custom face mask benefited those who had failed with CPAP monotherapy the most.

https://aadsm.org/docs/JDSM.04.02.29.pdf
Do you have patients who struggle with OSA?

We recommend a custom device made by a dentist.

- DR. SARA E. BENJAMIN
  Neurologist and Sleep Specialist at Johns Hopkins
  as quoted in NYT article, “For Sleep Apnea, a Mouth Guard May be a Good Alternative to CPAP” published 5/31/21

Find a qualified dentist near you:
www.aadsm.org/oat_for_osas