



RESEARCH PACKET

DENTAL SLEEP MEDICINE

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Research: Oral Appliance Therapy vs. Continuous Positive Airway Pressure

Title: Efficacy of Positive Airway Pressure and Oral Appliance in Mild to Moderate Obstructive Sleep Apnea

Importance: Due to the significantly higher patient compliance rate with oral appliance therapy, this clinical trial shows that an oral appliance is an effective alternative treatment option to continuous positive airway pressure therapy.

Citation: Barnes MR, et al., Efficacy of Positive Airway Pressure and Oral Appliance in Mild to Moderate Obstructive Sleep Apnea, *AJRCCM* 2004; 170: 656-664.

Web URL Link: <http://www.atsjournals.org/doi/pdf/10.1164/rccm.200311-1571OC>

Summary: The efficacy of currently recommended treatments is uncertain in patients with mild to moderate obstructive sleep apnea, defined by an apnea-hypopnea index (AHI) of 5-30. A group of 114 sleep clinic patients with an AHI of 5-30 participated in a randomized controlled crossover trial of three months with each of the following treatments: nasal continuous positive airway pressure (CPAP), a mandibular advancement splint and a placebo tablet. Outcome measurements were sleep fragmentation and hypoxemia, daytime sleepiness, quality of life, neurobehavioral function and blood pressure. This study demonstrated that although both CPAP and mandibular advancement splint [oral appliance therapy] effectively treated sleep-disordered breathing and sleepiness, the expected response in neurobehavioral function was incomplete.

Key Research Highlights:

- Both CPAP and oral appliance therapy treat OSA, reducing the AHI and frequency of arousals and improving nocturnal oxygen saturation, although CPAP has a greater effect.
- Adherence to oral appliance therapy is significantly greater than CPAP.
 - Past research shows that effective treatment of OSA with CPAP requires use for at least 70 percent of nights for a minimum of four hours each night. Based on this criterion, 43 percent of subjects received adequate treatment with CPAP and 76 percent of subjects received adequate treatment with an oral appliance.
- CPAP treatment resulted in no greater improvement than oral appliance therapy in measures of daytime function, including sleepiness, executive function and quality of life – which may correlate with treatment adherence.
- Oral appliance therapy showed a significant improvement in nighttime diastolic blood pressure. This effect was not found with CPAP treatment.
- Overall, nearly two-thirds of the subjects had the best overall response to CPAP treatment, while one-fourth of subjects responded best to oral appliance therapy – demonstrating that oral appliance therapy can be an effective alternative treatment option for OSA patients.

Research: Oral Appliance Therapy vs. Continuous Positive Airway Pressure

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

Importance: This study demonstrates that oral appliance therapy is an effective treatment option for patients with mild to moderate obstructive sleep apnea.

Citation: Vanderveken OM, et al., Oral Appliance Therapy versus Nasal Continuous Positive Airway Pressure in Obstructive Sleep Apnea: A Randomized, Placebo-Controlled Trial, *Respiration* 2011; 81: 411-419.

Web URL Link: <https://www.ncbi.nlm.nih.gov/pubmed/20962502>

Summary: The aim of the present study was to compare the treatment effects of a titrated mandibular advancement device (MAD) with those of nasal continuous positive airway pressure (nCPAP) and an intra-oral placebo device. In contrast to previous studies, both MAD and nCPAP were titrated objectively. Sixty-four mild to moderate patients with obstructive sleep apnea (OSA; 52.0 ± 9.6 years) were randomly assigned to three parallel groups: MAD, nCPAP and placebo device. From all patients, two polysomnographic recordings were obtained at the hospital: one before treatment and one after approximately six months of treatment. Between the baseline and therapy evaluation, no differences were found in the apnea-hypopnea index (AHI) between the MAD and nCPAP therapy, whereas the changes in AHI in these groups were significantly larger than those in the placebo group. This study concludes that there is no clinically relevant difference between MAD and nCPAP in the treatment of mild to moderate OSA when both treatment modalities are titrated objectively.

Key Research Highlights:

- The patients who were treated with a MAD had the highest compliance rate, using their appliances 90.6% of the nights throughout the six month period. The patients who used nCPAP adhered to the treatment 82.9% of the nights.
- Eighty-five percent of the patients in the MAD group were treated successfully, demonstrating that oral appliance therapy is an effective, alternative treatment option for patients with mild to moderate OSA.
- The overall results of the study show that both MAD and nCPAP are most effective at treating OSA when patients sleep in the supine position.
- Most of the side effects reported by the MAD patients were mild and did not differ from those reported in previous studies. In the nCPAP group, however, three patients dropped out of the study because they experienced more side effects than benefits from the treatment – suggesting that nCPAP patients may show more problems in accepting their treatment modality compared to MAD patients.
- Overall, this study concludes that there is no clinically relevant difference between MAD and nCPAP in the treatment of mild to moderate OSA.

Research: Oral Appliance Therapy vs. Continuous Positive Airway Pressure

Title: Health Outcomes of Continuous Positive Airway Pressure versus Oral Appliance Treatment for Obstructive Sleep Apnea

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

Citation: Phillips CL, et al., Health Outcomes of Continuous Positive Airway Pressure versus Oral Appliance Treatment for Obstructive Sleep Apnea, *AJRCCM* 2013; 187 (8): 879-887.

Web URL Link: <http://www.atsjournals.org/doi/full/10.1164/rccm.201212-2223OC>

Summary: The objective of this study was to compare health effects after one month of optimal treatment using continuous positive airway pressure (CPAP) and mandibular advancement devices (MAD) to treat obstructive sleep apnea. Measured outcomes were focused on cardiovascular (blood pressure and arterial stiffness), neurobehavioral (subjective sleepiness, driving simulator performance, etc.) and quality of life (Functional Outcomes of Sleep Questionnaire; Short Form-36). A total of 108 patients completed the study with both devices, with the majority (86%) having moderate to severe OSA, defined by an apnea-hypopnea index (AHI) of 32-42. Important health outcomes were similar with MAD and CPAP treatment. The results may be explained by greater efficacy of CPAP being offset by inferior compliance relative to MAD, resulting in similar effectiveness.

Key Research Highlights:

- Health outcomes in patients with moderate to severe OSA were similar after treatment with CPAP and MAD.
 - These findings strongly challenge current practice parameters recommending MAD treatment be considered only for patients with mild to moderate OSA or for those who have failed or refuse CPAP treatment.
- MAD had a significantly greater compliance rate among participating patients.
- Treatment preference results showed that more than half (51%) of patients preferred MAD, while less than a quarter (21.3%) preferred CPAP.
- The data suggests that both CPAP and MAD may reduce the risk of motor vehicle accidents among OSA patients who suffer from sleepiness.
- Overall, this study found that improvements with MAD in sleepiness, quality of life measurements and driving simulator performance were as good as or better than CPAP.

Research: Oral Appliance Therapy vs. Continuous Positive Airway Pressure

Title: Titrated Mandibular Advancement versus Positive Airway Pressure for Sleep Apnea

Importance: The results of this study support a successfully titrated mandibular advancement device as an effective treatment for significantly reducing the sleep apnea-hypopnea index in patients with mild to severe obstructive sleep apnea.

Citation: Gagnadoux F., et al., Titrated Mandibular Advancement versus Positive Airway Pressure for Sleep Apnea, *European Respiratory Journal* 2009; 34(4): 914-20.

Web URL Link: <http://erj.ersjournals.com/content/34/4/914.long>

Summary: The aim of this multi-site, randomized crossover study was to compare eight weeks of mandibular advancement device (MAD) therapy and eight weeks of continuous positive airway pressure (CPAP) therapy in a mixed-severity group of patients with obstructive sleep apnea (OSA) in terms of efficacy, reported side-effects, compliance and preference after one-night polysomnographic (PSG) titration of both treatments. Fifty-nine patients with mild to severe OSA participated in the trial after effective titration. Outcome measurements included home sleep study, sleepiness, health-related quality of life (HRQoL), cognitive tests, side effects, compliance and preference. Both treatments significantly improved subjective and objective sleepiness, cognitive tests and HRQoL. Although less effective than CPAP, the study successfully demonstrated that titrated MAD was very effective at reducing the apnea-hypopnea index (AHI) and was associated with a higher reported compliance.

Key Research Highlights:

- A complete response with MAD (defined as $\geq 50\%$ reduction in AHI to < 5 events h^{-1}) was achieved in 58.3% of patients with mild to moderate OSA and 31.2% of patients with severe OSA.
- MAD and CPAP similarly improved subjective and objective daytime sleepiness, cognitive function and health-related quality of life (HRQoL).
- For CPAP, a significant improvement was observed for two out of six domains of HRQoL including emotional reaction and energy. For MAD, HRQoL was significantly improved for four out of six domains including emotional reaction, pain, physical mobility and sleep.
- The mean side-effects score was similar for MAD and CPAP in the patients who completed the study.
- Reported daily compliance was significantly higher with MAD for both the number of hours of daily use and the percentage of nights on which the treatment was used.
- At the end of the study, 42 out of 55 patients (71.2%) preferred MAD, five (8.5%) preferred CPAP and eight had no treatment preference.
- The study results support successfully titrated MAD as an effective therapy for reducing AHI in patients with mild to severe of OSA.

Research: Custom-fitted Dental Oral Appliances vs. Prefabricated Oral Appliances

Title: Comparison of Adjustable and Fixed Oral Appliances for the Treatment of Obstructive Sleep Apnea

Importance: This comparative study shows that custom-fitted oral appliances are significantly more effective than prefabricated oral appliances at treating all degrees of obstructive sleep apnea.

Citation: Lettieri CJ, et al., Comparison of Adjustable and Fixed Oral Appliances for the Treatment of Obstructive Sleep Apnea, *Journal of Clinical Sleep Medicine* 2011; 7(5): 439-445.

Web URL Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3190841/>

Summary: This study compared the efficacy of adjustable versus fixed oral appliances for the treatment of patients with mild to severe OSA. Six-hundred and two patients (74.8%) were treated with either an adjustable appliance and 203 (25.2%) patients were treated with a fixed oral appliance. The fixed oral appliances were fabricated at an acceptable comfort level for the patient, typically 60-80% of the maximum possible anterior advancement of the mandible. Effective treatment was defined as an apnea-hypopnea index (AHI) < 5 events/h or < 10 events/h with resolution of sleepiness (Epworth < 10). Successful therapy was significantly more common with adjustable appliances.

Key Research Highlights:

- For all degrees of severity (from mild to severe OSA), adjustable oral appliances (OAs) produced a greater mean reduction in AHI and number of obstructive events per night, and had higher treatment success rates compared to fixed OAs.
- In comparison to the baseline polysomnography, those using adjustable OAs experienced a 74.4% reduction in AHI, compared with a 64.9% decrease with fixed devices.
- Obstructive events were reduced to < 5/h in 56.8% with adjustable OAs, compared to 47% with fixed OAs.
 - Similarly, a reduction of events to < 10 with resolution of sleepiness occurred in 66.4% with adjustable appliances versus 44.9% with fixed appliances.
- Improvements in subjective measure of sleepiness (using the Epworth Sleepiness Scale) were significantly more likely with adjustable OAs.
- Overall, successful therapy was achieved in 57.2% of patients using an adjustable appliance and only 46.9% of those using a fixed appliance.

Research: Custom-fitted Dental Oral Appliances vs. Prefabricated Oral Appliances

Title: Comparison of a Custom-made and Thermoplastic Oral Appliance for the Treatment of Mild Sleep Apnea

Importance: This study demonstrates that it is not an effective strategy to use a prefabricated oral appliance as a screening method to predict a sleep apnea patient's success with a custom-made oral appliance.

Citation: Vanderveken OM, et al., Comparison of a Custom-made and Thermoplastic Oral Appliance for the Treatment of Mild Sleep Apnea, *AJRCCM* 2008; 178: 197-202.

Web URL Link: <http://www.atsjournals.org/doi/pdf/10.1164/rccm.200701-114OC>

Summary: The study compared the efficacy of prefabricated mandibular advancement devices made of thermoplastic material (MAD_{tp}) with custom-made devices by a dentist (MAD_{cm}) for the treatment of patients with mild to moderate OSA. A total of 35 patients with a sleep apnea-hypopnea index (AHI) of 13 ±11 events completed the randomized controlled cross-over trial, comprising four months of treatment with a thermoplastic and a custom-made device. In this study, a custom-made device turned out to be more effective than a thermoplastic device in the treatment of OSA. The results suggest that the thermoplastic device cannot be recommended as a therapeutic option nor can it be used as a screening tool to find good candidates for oral appliance therapy.

Key Research Highlights:

- AHI was only reduced with the custom-made dental device, concluding that a custom-made MAD is more efficacious than a prefabricated MAD to treat snoring and OSA.
- The custom-made dental devices (MAD_{cm}) had a 60% treatment success rate, while the prefabricated thermoplastic devices (MAD_{tp}) only achieved a 31% success rate.
- Fifteen out of 24 patients (63%) who failed treatment with the MAD_{tp} experienced treatment success with the MAD_{cm}.
- The MAD_{cm} significantly reduced snoring in 80% of patients, whereas the MAD_{tp} only reduced snoring in 51% of patients.
- Patients had a 92% compliance rate with the MAD_{cm}, compared to a 64% compliance rate with the MAD_{tp}.
- At the end of the study, 82% of OSA patients preferred the custom-made dental devices (and 9% had no preference).
- One-third of the patients demonstrated compliance failure with the MAD_{tp}, mainly because of insufficient overnight retention. No compliance failures occurred with the MAD_{cm} due to lack of retention.
- Patients had an exceptionally high total failure rate of 69% with the MAD_{tp}. The fact that a majority of these patients experienced treatment success with the MAD_{cm} despite failure with MAD_{tp} clearly demonstrated that the outcome with MAD_{tp} is not related to treatment outcome with MAD_{cm}.
 - These data provide convincing evidence to abandon using a prefabricated oral appliance as a low-cost screening strategy to predict a patient's success with a custom-made oral appliance.

Research: Health Benefits of Oral Appliance Therapy

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

Importance: This research concludes that oral appliance therapy effectively lowers blood pressure in patients with mild to moderate obstructive sleep apnea.

Citation: Iftikhar IH, et al., Effect of Oral Appliances on Blood Pressure in Obstructive Sleep Apnea: A Systematic Review and Meta-analysis, *Journal of Clinical Sleep Medicine* 2013; 9(2): 165-174.

Web URL Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3544387/>

Summary: Obstructive sleep apnea (OSA) is an independent risk factor for the development of hypertension, and the effect of continuous positive airway pressure (CPAP) on lowering systemic blood pressure (BP) in OSA patients has been conflicting. A research team of three independent reviewers conducted a meta-analysis of studies that evaluated the effect of oral appliances (OAs) on BP in patients with OSA. A total of seven studies that enrolled 399 participants with mild to moderate OSA met the inclusion criteria. Data from observational and randomized controlled trial (RCT) studies was extracted for pre- and post-treatment systolic, diastolic and mean arterial blood pressure (SBP, DBP and MAP). The pooled estimate shows a favorable effect of oral appliance therapy on SBP, MAP and DBP.

Key Research Highlights:

- The meta-analysis shows that oral appliance therapy for patients with mild to moderate sleep apnea improves blood pressure control.
- Reductions in both systolic blood pressure (SBP) and diastolic blood pressure (DBP), as well as in nocturnal SBP, were seen with oral appliance therapy. Although the reductions in BP with OAs were modest, these effects were comparable to those reported with 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.
- It can be concluded from this study that oral appliance therapy and CPAP are associated with similarly significant, albeit modest, blood pressure reduction in OSA patients.

Research: Health Benefits 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 can reduce the risk of heart-related death for patients with severe obstructive sleep apnea.

Citation: Anandam A, et al., Cardiovascular Mortality in Obstructive Sleep Apnea Treated with Continuous Positive Airway Pressure or Oral Appliance: An Observational Study, *Respirology* 2013; 18(8): 1184-90.

Web URL Link: <https://www.ncbi.nlm.nih.gov/pubmed/23731062>

Summary: The objective of this study was to evaluate the long-term cardiovascular mortality in patients with severe obstructive sleep apnea (OSA) treated with either continuous positive airway pressure (CPAP) or mandibular advancing device (MAD). All patients received CPAP initially; MAD was offered to those who were non-adherent to CPAP. Over a median of 79 months, 208 control subjects, 177 patients treated with CPAP, 72 with MAD and 212 who declined treatment were analyzed. Forty-two patients had a fatal cardiovascular event during the course of the study. The non-apneic group had the lowest cardiovascular death rate followed by the CPAP-treated and the MAD-treated OSA group, with the highest cardiovascular mortality rate observed in the untreated OSA group. Although the residual apnea-hypopnea index (AHI) for MAD-treated patients was significantly higher than CPAP-treated patients, there was no difference in cardiovascular death rate between the two groups.

Key Research Highlights:

- Both CPAP and MAD are equally effective in reducing the risk of fatal cardiovascular events in patients with severe OSA.
- As expected, the group without sleep apnea had the lowest cardiovascular death rate, while untreated sleep apnea sufferers had the highest death rate. The two groups of treated patients had adjusted cardiovascular mortality rates that were similar to that of the control group.
- There was a higher adherence rate with the use of MAD compared with CPAP.
- Even though oral appliance therapy achieved less satisfactory results in normalizing polysomnographic indices compared with CPAP, the risk of cardiovascular mortality in both treatment groups was comparable.

Research: Health Benefits 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 can significantly improve daytime sleepiness and cognitive functions, specifically alertness and focus, of patients with mild to several obstructive sleep apnea.

Citation: Tegelberg A, et al., Improved Cognitive Functions after Treatment with an Oral Appliance in Obstructive Sleep Apnea, *Nature and Science of Sleep* 2012; 4: 89-96.

Web URL Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3630975/>

Summary: The objective of this study was to evaluate the effect of oral appliance therapy on cognitive functions in patients with obstructive sleep apnea (OSA). In a prospective study, 50 male patients with verified moderate to severe OSA received an oral appliance (OA) with mandibular advancement. The cognitive functions assessed included working memory, vigilance, executive functioning and mental pace, measured before as well as after six months of treatment. Somnography was used to measure physiological treatment effects. Forty-three patients completed the six-month follow-up study. The apnea-hypopnea index (AHI) and oxygen desaturation indices decreased significantly after treatment – and all measured domains of cognitive functioning improved after six months of treatment with an OA. Oral appliance therapy with mandibular advancement is a treatment modality for the physiological symptoms of OSA, and may have a positive impact on cognitive functions, after only six months of treatment.

Key Research Highlights:

- Treatment with oral appliance therapy has a positive impact on certain cognitive functions in patients with OSA, specifically improved vigilance, sustained attention, motor and mental speed.
- A substantial decrease in daytime sleepiness was reported by 44% of the patients.
- At baseline, the mean Epworth Sleepiness Scale (ESS) was 11.2 and, after treatment, the ESS was reduced to 6.8.
- Notably, the results of the subgroup of patients with severe OSA (AHI > 30) were generally similar to the total group of patients.
- The results of this study demonstrate that oral appliance therapy is important in the treatment of OSA and the diminished cognitive functions associated with the sleep disorder that have an impact on the performance of everyday and occupational tasks and quality of life.

Research: Dental Sleep Medicine Practice Parameters

Title: Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015

Importance: This research establishes oral appliance therapy as an effective alternative treatment option for patients with obstructive sleep apnea (OSA) and dentist-physician collaboration as necessary to achieve successful OSA treatment with oral appliance therapy.

Citation: Ramar K, et al., Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015, *Journal of Dental Sleep Medicine* 2015; 2(3): 71-125.

Web URL Link: <http://www.idsm.org/ViewArticle.aspx?pid=30106>

Summary: Since the most recent practice parameters on the treatment of snoring and OSA with oral appliances (OAs) was published by the American Academy of Sleep Medicine (AASM) in 2006, the scientific literature has grown considerably, particularly related to clinical outcomes after use of OAs. The purpose of this joint AASM and AADSM guideline is to replace the recommendations in the 2006 guideline for the use of OAs in the treatment of OSA and snoring.

Key Research Highlights:

- The new guideline supports increased teamwork between physicians and dentists to achieve optimal treatment of patients with OSA.
- Data show that oral appliance therapy can significantly reduce sleep-disordered breathing, and patient adherence to the treatment is higher than for CPAP therapy.
- The guideline recommends oral appliance therapy as an effective treatment for OSA and primary snoring in adults.
- The clinical practice guideline comprises the following recommendations:
 1. We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea). (STANDARD)
 2. When oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea, we suggest that a qualified dentist use a custom, titratable appliance over non-custom oral devices. (GUIDELINE)
 3. We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy. (STANDARD)
 4. We suggest that qualified dentists provide oversight – rather than no follow-up – of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence. (GUIDELINE)
 5. We suggest that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances. (GUIDELINE)
 6. We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits – as opposed to no follow-up – with a qualified dentist and a sleep physician. (GUIDELINE)