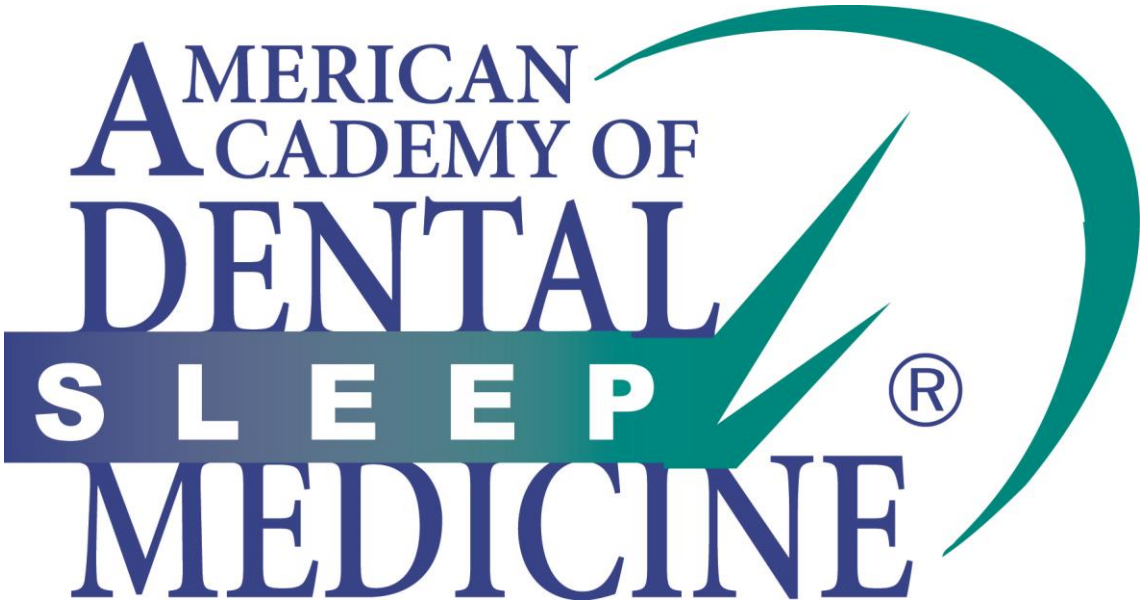

RESEARCH PACKET

DENTAL SLEEP MEDICINE

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Research: Phenotyping and Oral Appliance Therapy

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Title: Health Outcomes of Continuous Positive Airway Pressure Versus Mandibular Advancement Device for the Treatment of Severe Obstructive Sleep Apnea: An Individual Participant Data Meta-Analysis

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

Citation: Trzepizur W et al., Health Outcomes of Continuous Positive Airway Pressure Versus Mandibular Advancement Device for the Treatment of Severe Obstructive Sleep Apnea: An Individual Participant Data Meta-Analysis, *SleepJ* 2021

Web URL Link: https://academic.oup.com/sleep/advance-article-abstract/doi/10.1093/sleep/zsab015/6119670

Summary: "Mandibular advancement device therapy (MAD) is the main alternative therapy for OSA. Numerous trials and meta-analyses have compared CPAP and MAD on various OSA outcomes. However, none of the previously published studies have compared CPAP and MAD exclusively in patients with severe OSA. In the present work, individual data of severe OSA patients were extracted from previously published RCTs comparing CPAP and MAD. Titratable MAD and CPAP had a similar impact on major patient-centered outcomes (sleepiness and quality of life) and sleep structure while CPAP was more effective in reducing AHI and ODI. However, treatment adherence and preference were largely in favor of MAD treatment. This meta-analysis suggests that MAD represents an effective alternative treatment option in all OSA patients, including those with severe OSA."

Key Research Highlights:

- At the time of publication, this was the first meta-analysis to directly compare the impact of OAT and 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.

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.

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.

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.

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

Importance: As many studies only measure the efficacy of CPAP vs. OAT (how well they work in laboratory settings), 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: Sutherland K, Phillips CL, Cistulli PA. Efficacy versus effectiveness in the treatment of obstructive sleep apnea: CPAP and oral appliances. *Journal of Dental Sleep Medicine* 2015;2(4):175–181.

Web URL Link: https://aadsm.org/docs/JDSM.2.4.175.pdf

Summary: "Obstructive sleep apnea (OSA) is a chronic disorder and effective long-term treatment is necessary to prevent associated health risks. Standard treatment remains continuous positive airway pressure which is highly efficacious but has well-recognized limitations, with suboptimal patient acceptance and adherence rates, which in turn obviates the desired health benefits. The leading alternative device treatment is oral appliances. Patients often report preferring oral appliances to CPAP treatment, with better usage rates. However, unlike CPAP, inter-individual variability in the efficacy of oral appliance therapy means that patients are often left with some residual OSA. Despite discrepancies in efficacy (apnea-hypopnea index [AHI] reduction) between CPAP and oral appliances, randomized trials show similar improvements in health outcomes between treatments, including sleepiness, quality of life, driving performance, and blood pressure. Similar results in terms of health outcomes suggests that although the two treatments have different efficacy and treatment usage profiles, these result in similar overall effectiveness. In this narrative review, we discuss efficacy versus effectiveness in relation to CPAP and oral appliance treatment of OSA."

Key Research Highlights:

- Efficacy and effectiveness are two different constructs – efficacy refers to how well an intervention works under perfect circumstances while effectiveness refers to how a treatment works under real-world circumstances.
- While the efficacy of CPAP is high, the actual benefits of using the device over time are compromised by lack of adherence to treatment.
- The commonly used efficacy measure (AHI) may not be sufficient to capture real-world treatment effectiveness. Assessment of effectiveness should account for hours ON and OFF treatment (e.g. SARAH Index).

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.

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 $\pm$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.

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.

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.

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.

Title: Identifying the Appropriate Therapeutic Position of an Oral Appliance

Importance: This research establishes protocols for the qualified dentist to use in order to advance an oral appliance.

Citation: Sheats R, Essick G, Grosdidier J, Katz S, Kim C, Levine M, Patel I. Identifying the appropriate therapeutic position of an oral appliance. J Dent Sleep Med. 2020;7(4).

Web URL Link: https://www.aadsm.org/docs/jdsm.10.10.2020.sa2.pdf

Summary: Since the appropriate therapeutic position varies from patient to patient, the American Academy of Dental Sleep Medicine (AADSM) put together a task force to evaluate a variety of methods that are commonly used to position an oral appliance. This paper provides protocols for several positioning methods that are both appropriate and supported by literature.

Key Research Highlights:

- The task force defines the appropriate therapeutic position of an oral appliance as: "*A position of the mandible that achieves improvement of signs, symptoms, or objective indices of sleep-related breathing disorders. The determination of improvement is agreed upon by the patient, dentist, and medical provider using clinical experience and, when available, evidence-based approaches. At this position, the appliance can be used comfortably, on a nightly basis."*
- The following methods are supported by evidence:
    - The **initial mandibular position** is defined as: "*the starting position of the mandible when an oral appliance is delivered at initiation of therapy*" and may be recorded as a millimeter measurement or as a percentage of maximum mandibular excursion from the posterior reference point to maximal protrusion. This initial position differs based on the oral appliance. A protocol is provided to determine the initial mandibular position.
    - **"Signs and symptoms** reported by the patient or the bed partner is a clinically useful method for determining the appropriate therapeutic position of an oral appliance." A protocol is provided to position based on signs and symptoms.
    - The task force determined that **[pulse oximetry]**, including high-resolution pulse oximetry (HRPO), administered by dentists is a supported strategy for identifying the appropriate therapeutic position.
    - "**[Home sleep apnea tests]** are a supported method for identifying the appropriate therapeutic position. HSATs are unattended sleep studies that measure a variety of sleep parameters."
    - "**[Polysomnography]** is a supported method for identifying the appropriate therapeutic position of an appliance. Adjustment of the oral appliance to achieve the best improvement of signs and symptoms usu-ally precedes the PSG.
- Pulse oximetry and HSATs may be administer by a qualified dentist, unless prohibited by the qualified dentist's state dental board. Protocols are provided for when pulse oximetry and HSATs are administered by a dentist. A separate set of protocols are provided for when HSAT or PSG is ordered by a physician.

Research: Dental Sleep Medicine Practice Parameters

Title: Dental Sleep Medicine Standards for Screening, Treating, and Managing Adults with Sleep-Related Breathing Disorders

Importance: This document helps guide the dentist through the key steps of providing oral appliance therapy to patients with OSA.

Citation: Levine M, Bennett K, Cantwell M, Postol K, Schwartz D. Dental sleep medicine standards for screening, treating, and managing adults with sleep-related breathing disorders. *J. Dent Sleep Med.* 2018;5(3):61-68.

Web URL Link: https://aadsm.org/docs/JDSM.2.4.175.pdf

Summary: "Oral appliance therapy (OAT) has been used to manage sleep-related breathing disorders (SRBDs), such as obstructive sleep apnea (OSA) and snoring, for more than 20 years. However, dental sleep medicine standards of clinical practice have not been clearly defined. SRBD prevalence rates have grown to double digits, presenting an increased need for dentists proficient in dental sleep medicine. A standardized approach to patient management, which underscores the collaborative nature necessary between dentists and physicians, is needed. These standards provide guidance for patient examination, patient screening, education, and treatment management including follow-up care. Although this paper introduces best practices for the practice of dental sleep medicine as it currently exists, the reader should recognize the fluid and dynamic nature of dental sleep medicine and understand that periodic updates to these standards will be required."

Key Research Highlights:

- There are two pathways for dental evaluation for SRBD:
  - Visit to a qualified dentist for screening.
  - Physician referral of patient to qualified dentist.
- A physical examination for SRBD should include:
  - BMI.
  - Blood pressure.
  - Neck circumference.
  - Descriptive assessment of the craniofacial complex.
  - Measurement of tongue size and occlusal positioning.
  - Assessment of the hard and soft tissues.
  - Examination of the TMJ.
  - Assessment of angle classification, overbite, overject, etc.
- The qualified dentist should refer the patient to a sleep physician for diagnosis of OSA.

Title: Management of Side Effects of Oral Appliance Therapy for Sleep-Disordered Breathing

Importance: Side effects can impact patient compliance with OAT. Thus, it is important for dentists to carefully manage any side effects that do occur.

Citation: Sheats RD, Schell TG, Blanton AO, Braga PM, Demko BG, Dort LC, Farquhar D, Katz SG, Masse JF, Rogers RR, Scherr SC, Schwartz DB, Spencer J. Management of side effects of oral appliance therapy for sleep-disordered breathing. *Journal of Dental Sleep Medicine*. 2017;4(4):111–125.

Web URL Link: https://aadsm.org/docs/JDSM.04.04.111.pdf

Summary: "As the field of oral appliance therapy (OAT) to manage obstructive sleep apnea has evolved over the past 30 years, side effects of therapy have become increasingly recognized. Although the most commonly observed side effect is unwanted tooth movement, a number of other side effects have been reported through anecdotes, case reports, and observational studies. Members of the American Academy of Dental Sleep Medicine developed a set of consensus recommendations to guide dentists in the management of side effects as a consequence of OAT. Thirteen expert clinicians were appointed to the panel, which used the modified RAND/UCLA Appropriateness Method to review the body of evidence on OAT side effects and to establish the recommendations. Clinicians are encouraged to use these recommendations in conjunction with their clinical expertise to minimize the side effects of OAT. The recommendations are based on knowledge to date and are expected to evolve over time. Future research should aim at timely identification of these side effects for positive treatment outcomes."

Key Research Highlights:

- Management of OAT side effects is critical to maintain compliance and treatment effectiveness.
- Side effects can be related to: TMJ, intra-oral tissue, occlusal changes, damages to teeth or restorations and appliance issues
- Common management considerations include:
    - Palliative care.
    - Watchful waiting.
    - Morning occlusal guide.
    - Daytime intraoral orthotic.
    - Verification and/or correction of the midline position.
    - Verification and/or correction of occlusion.
    - Habitual occlusion (e.g. centric relation, centric occlusion, maximum intercuspation position, bite of convenience, and intercuspation position).
    - Isometric and passive jaw exercises.
    - Conservative titration.

Research: Phenotyping and Oral Appliance Therapy

Title: Sleep Apnea Phenotyping: Implications for Dental Sleep Medicine

Importance: Phenotyping can help dentists identify which patients will be good responders to OAT and can help tailor treatment to individuals with OSA.

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Summary: "New knowledge of obstructive sleep apnea (OSA) pathophysiology has highlighted the heterogeneity of this common chronic health condition. Recent advances in OSA 'phenotyping' concepts have provided a novel framework in which to understand OSA pathophysiology on an individual patient basis. This has also provided new potential precision medicine strategies to optimize efficacy and success rates with current OSA treatments including mandibular advancement therapy. This review summarizes how different 'phenotypes' contribute to OSA pathophysiology and highlights the potential mechanisms by which mandibular advancement splints alter upper airway physiology according to an OSA phenotyping framework. In addition, it explains how understanding these phenotypes can facilitate novel and improved approaches to therapy, with a focus on phenotyping to improve mandibular advancement splint treatment prediction and efficacy. The potential to translate phenotyping concepts into the clinical setting is also discussed."

Key Research Highlights:

- The manifestations and pathogenesis of OSA are heterogenous. Since each patient is different, a phenotypic approach can help tailor their therapy.
- Four major phenotypes contribute to OSA pathogenesis: 1) a narrow, crowded or collapsible airway, 2) poor responsiveness of the upper airway dilator muscles during sleep, 3) high loop gain, and 4) low respiratory arousal threshold. Of these four, a collapsible airway is key.
- OAT helps protrude the mandible and prevent airway collapse, thus addressing the key phenotype of OSA.
    - On the other hand, there is no evidence that OAT systematically improves upper airway muscle function and little evidence about how it can impact loop gain and arousal threshold.
    - Thus, more research is needed.
- The PALM scale ("**P**crit, **A**rousal threshold, **L**oop gain and **M**uscle responsiveness") can be used to predict OAT success.
- Some phenotyping methods rely only on data that are collected during diagnosis and titration – thus, dentists may phenotype without significant additional cost.