

# West Virginia Sleep and TMJ Treatment Center

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## Measuring Compliance & Determining Overall Efficacy of Oral Appliances

In the past, compliance data for oral appliance therapy has been largely anecdotal. While modern CPAP devices are increasingly able to self-report on compliance, compiling similar objective data for oral appliances has been limited to clinical environments, which may not reflect real-world use patterns.

A study at the University of Antwerp, Belgium, sought to provide more objective data through the use of micro-sensor thermometers embedded into oral appliances. The devices were embedded in the upper right side of the oral appliances, with compliance data based on the assumption that the device was in use when the recorded temperature was greater than 35°C.

During a three-month clinical trial, a group of 51 patient participated in the study. None were aware of the monitoring device when they were initially provided with the oral appliance, and they were given no special instructions regarding compliance expectations. The study group had an established diagnosis of sleep breathing disorder and a mean AHI of 18 (+/-11.9), a median age of 47 (=-/10), a BMI of 26.6 (+/-4).

Post-study interviews and examinations determined that there were no adverse effects from use of the embedded monitoring devices, and the study groups overall mean rate of oral appliance use was shown to be 6.6 hours per day (=-/1.3 h). These numbers were used to calculate compliance by dividing time of appliance use by total sleep time.

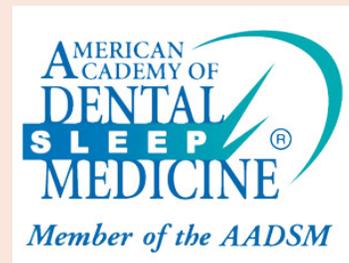
Treatment efficacy was calculated based on reductions of the apnea/hypopnea index (AHI). Prior to beginning oral appliance therapy, and again at the end of the three-month study, all participants underwent a level 1 overnight polysomnography. Success was defined as a 50 percent or greater reduction in AHI and an AHI of less than 5 per hour of sleep. The study's overall reported success rate was 62 percent.

Using a combination of the objective compliance data obtained from the study, and AHI reduction success rates, the overall mean disease alleviation with oral appliance therapy was determined to be 51 percent. This was calculated based on a formula that took into account overall efficacy and compliance rates. In comparison, a generally-accepted MDA score for CPAP therapy is 50 percent.

Sources: Objective Measurement of Compliance During Oral Appliance Therapy for Sleep-Disorder Breathing; Anwerp University Hospital, Vanderverken. European Respiratory Journal, 2000/16



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## Australian Study Indicates That MADs Compare Favorably with CPAP

During treatment, reductions in arterial stiffness of between 1 and 2 percent was recorded, based on the aortic augmentation index, and these results were similar for both therapies.

Neither MAD or CPAP therapy provided a significant reduction in baseline blood pressure measurements for the overall study group, but within the subset of patients who were initially hypertensive, both therapies provided a roughly equivalent reduction in BP of between 2 and 4 mm Hg.

More significant changes were recorded from the neuro-behavioral metrics. According to the authors: "Overall, this study found that improvements with MAD in sleepiness, quality of life and driving simulator performance were as good or better than CPAP.

Previous studies that have compared subjective sleepiness and quality of life after treatment with CPAP and oral appliances have either favored CPAP or have shown similar effectiveness between treatments.

However, in the studies that favored CPAP, non-adjustable oral appliances were used and these may have been inferior to full adjustable models, as used in our study."

In their summary conclusion, the authors noted that; "This short-term study has demonstrated that the health outcomes in patients with moderate to severe OSA were similar after treatment with CPAP and MAD. The results are likely explained by the greater efficacy of CPAP being offset by inferior compliance relative to MAD, resulting in a similar 'treatment' AHI with each device.

These findings strongly challenge current practice parameters that recommend that MAD treatment should only be considered in patients with mild to moderate OSA or in those who have failed or refuse CPAP treatments.

Our findings provide a strong rationale for a long term comparative effectiveness study of those two treatment modalities.

It is hoped that such studies will allow a rigorous evidence-based approach to challenging current treatment recommendations.

Source: Health Outcomes of Continuous Positive Airway Pressure versus Oral Appliance Treatment for Obstructive Sleep Apnea. Craig Phillips et al; American Journal of Respiratory and Critical Care Medicine, Vol 187/2013.



## Custom-Fabrication and Titration Shown to Enhance MAD Effectiveness

The effectiveness of Mandibular Advancement Devices for the treatment of OSA is well documented. A subject less often reviewed is the relative effectiveness of various designs of the MAD now on the market.

A commentary review published in the Journal of Clinical Sleep Medicine looks at a range of established studies to draw comparisons between custom-made, titratable appliances and pre-fabricated, non-adjusting appliances.

Among the conclusions drawn by the authors are that variations in the specific design of the approved MAD appliances on the market do not have a marked effect on effectiveness.

“In this review, all the studies comparing custom-made, titratable appliances have shown similar results,” the authors state, “implying that specific design does not influence appliance efficacy, and that the appliances modes of action are likely very similar.”

More noteworthy was the observation that “efficacy does depend on the method used for fabrication” (pre-fabrication or custom-made).

It is generally accepted that off-the-shelf appliances have proven to be less effective for the treatment of OSA, and are typically less accepted by patients.

The greater effectiveness of custom-fabricated appliances is linked to the capability for adjustment and titration, as the amount of anteroposterior mandibular movement can vary significantly between patients.



Studies have shown that MAD efficacy is directly related to the degree of mandibular advancement, the authors note, “and determining the optimal degree of mandibular advancement is the most important step when using MAD therapy successfully.”

These factors promoted the authors to conclude, “Despite fixed MAD being typically less expensive and requiring a shorter period of adjustment, they are significantly less effective.”

A patient-tailored treatment is synonymous with good medicine, and lifelong therapies are very dependent on the patient’s cooperation and adherence.

We believe that it is important to include patient in the decision making process regarding their treatment and also to offer more than one type of therapy.”

Source: Complexity and Efficacy of Mandibular Advancement Splints: Understanding their Mode of Action. F. Almeida, Journal of Clinical Sleep, V.7,N.5.



## MAD Therapy for Severe OSA?

Should the guidelines regarding the use of MAD therapy for severe OSA be changed? This question was raised in a commentary authored by Drs. David White and Shirin Shafazand in the Journal of Clinical Sleep Medicine. The authors note that current guidelines from the American Academy of Sleep Medicine suggest that Mandibular Advancement Devices (MAD) should be used primarily for treatment of patients who exhibit mild to moderate OSA symptoms.

The authors question these guidelines, based on their assessment of data provided by a study conducted at the Royal North Shore Hospital, St. Leonards, Australia, which involved comparative assessments of CPAP and MAD therapy.

Of the OSA patients participating in the study, 32 percent were classified as "severe" (AHI > 30). The mean AHI for this group was 42 prior to therapy, and 18-19 when using MAD therapy.

By further breaking down this data, the authors concluded that: 7 patients had a treated AHI > 30; 13 had an AHI > 20; 8 had an AHI of 10-20 and 12 had an AHI > 10.

Based on this analysis of the data, the authors concluded that while not all severe OSA patients respond well to MAD, a sizable minority does show marked improvement of symptoms. The authors also note that study patients showed a similar improvement in sleepiness based on the Epworth Sleepiness Scale with MAD as they did on CPAP.

In light of this information, the authors state that "the conclusion that MAD is not an appropriate conclusion for patients with severe OSA may be incorrect."

They go on to add that "Although MADs may not be the first-line therapy for patients with severe OSA, the take-home message here is simply that a follow-up sleep study is probably needed for severe OSA patients to assess efficacy; not that MAD is not a good choice for these patients."

Source: Mandibular Advancement Devices vs CPAP in the Treatment of Obstructive Sleep Apnea: Are They Equally Effective in Short Term Health Outcomes? David P. White M.D., F.A.A.S.M.; Shirin Shafazand M.D., M.S., F.A.A.S.M.; Journal of Clinical Sleep Medicine, V9M9, 2013.



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