

Oral Appliance Therapy

An Effective CPAP Alternative to Treat Obstructive Sleep Apnea



FLORIDA DENTAL
SLEEP DISORDERS

Kenneth A. Mogell, DMD

Diplomate ABDSM, ABCDSM

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Welcome

Dear Colleagues,

Having treated patients with sleep disorders for more than a decade, I consider myself fortunate to have worked alongside many local medical professionals to treat their patients suffering from Obstructive Sleep Apnea (OSA).

At Florida Dental Sleep Disorders, our mission is to explore all options to ensure positive OSA treatment outcomes. We have a solution for your patients who have been diagnosed with sleep apnea but are unable to tolerate Continuous Positive Airway Pressure (CPAP) therapy.

Here are a few key differentiators that set us apart:

- Board-certified sleep expert
- Medical insurance accepted, including Medicare and TriCare
- Practice focused exclusively on treating sleep apnea and snoring
- Ongoing support to ensure treatment success
- Variety of appliances offered

This booklet outlines case studies and outcomes of oral appliance therapy and is meant to serve as a resource for you and your colleagues. **If you have questions or would like a few of our practice brochures, simply email me at drmogell@fldsd.com.** I welcome the opportunity to partner with you and serve your patients struggling with CPAP-intolerance.



Sincerely,

Kenneth A. Mogell

DMD Diplomate ABDSM, ABCDSM

Our Process

How to Identify Patients Who Might Benefit from Oral Appliance Therapy

When seeing patients who may be suffering from obstructive sleep apnea, there are a few key questions to ask. We've compiled a checklist here for reference:

- Have you been told that you snore?
- Do you awaken from sleep with shortness of breath?
- Has anyone said that you seem to stop breathing while sleeping?
- Have you ever been diagnosed with sleep apnea?
- Do you have a CPAP machine but are unable to tolerate it?
- Have you experienced any of the following?
 - Diabetes
 - High blood pressure
 - Shortness of breath
 - Stroke
 - Coronary artery disease
 - Congestive heart failure
 - Atrial fibrillation

Our Commitment to Transparent Communication

We have partnered with local physicians to treat sleep apnea for over a decade. The result is that we are well versed in communicating with and providing you everything you need to ensure your referred patient receives the appropriate treatment.

After the initial consultation, we will send you SOAP notes and provide you with periodic updates. When the patient has achieved maximum medical improvement, they will be referred back to your practice for your evaluation. You always know where your patient is in the treatment process. Whether the patient is fitted for an oral appliance, or declines treatment, you will be notified.

Insurance

Nearly all medical insurance plans will cover an oral appliance as a treatment for sleep apnea. Though coverage may vary by insurer and individual policy, we will help your patient understand their benefits prior to beginning treatment.

We accept Medicare, TriCare, and are able to file in-network with most insurance companies.

- AETNA
- BCBS
- CIGNA
- Health First
- Humana
- UHC
- UMR

If you have a patient ready to explore oral appliance therapy, please share our information:

Dr. Kenneth A. Mogell
Florida Dental Sleep Disorders
844-692-7632 • www.fldsd.com

Patient Outcomes

Patient 1 - Female, Age 17

Teen suffering from snoring, OSA, obesity and depression following adenotonsillectomy.

- Pre-AHI: 33.5
- Post-AHI: 2.9

Patient 2 - Male, Age 67

10-year history of sleeping problems including snoring, apneas, and gasping in sleep. He has tried CPAP on numerous occasions with no benefit.

PRE: 18 events/hour with desaturation nadir of 88%

- Pre-AHI: 59.6
- Post-AHI: 1.4

Patient 3 - Male, Age 47

- Pre-AHI: 70.2
- Post-AHI: 10.8

Patient 4 - Male, Age 39

Snoring, witnessed apnea, fatigue, excessive daytime sleepiness and hypertension.

- Pre-AHI: 31.2
- Post-AHI: 5.1



Oral Appliance Therapy Myth vs Facts

While Oral Appliance Therapy (OAT) is a proven way to treat obstructive sleep apnea, many in the medical community are still unfamiliar with it. Here are a few myths that I often hear from medical partners about both obstructive sleep apnea and oral appliance therapy.

MYTH 1:

Sleep apnea is just snoring.

Snoring is a common symptom of sleep apnea, but the two are actually very different. Snoring is the sound that results when air pushes past soft tissues in the throat, causing the tissues to vibrate. Sleep apnea is a medical condition that is defined by frequent pauses in breathing throughout the night.

MYTH 2:

Sleep apnea is no big deal.

This idea could not be further from the truth. The pauses in breathing that is characteristic of sleep apnea make it impossible for an individual to get an adequate amount of rest. Hence, they may suffer from headaches, daytime fatigue, decreased work productivity, and mood disorders. If sleep apnea remains untreated for long enough, it can even contribute to heart attack, stroke, and unhealthy weight gain.

MYTH 3:

A CPAP machine is the only way to treat sleep apnea.

Doctors commonly prescribe a CPAP machine to help their patients cope with sleep apnea; however, there are a number of effective alternatives. Many people find that a custom-fit oral appliance, which moves the jaw forward in

order to keep the airway open at night, is much more comfortable and convenient than a CPAP machine. Lifestyle changes and surgery are also potential solutions to address sleep apnea.

MYTH 4:

Oral appliances aren't covered by insurance or Medicare.

For patients with a prescription for an oral appliance, treatment will be covered by most medical insurance, Medicare, and TriCare.

MYTH 5:

Oral appliances aren't as effective as CPAP.

Studies show that both therapies treat sleep apnea with only minor differences in treatment outcomes. In fact, oral appliances have a higher compliance rate than CPAP, giving more weight to their long-term effectiveness.¹

MYTH 6:

Oral appliances don't work for severe cases.

Oral appliances have been proven to treat mild-to-moderate OSA and in some cases, severe OSA. In data collected, patients at all levels of OSA experienced significant AHI reduction.²

¹ Grietje E. De Vries, Aarnoud Hoekema, Peter J. Wijkstra. European Respiratory Journal 2017 50: PA4725; DOI: 10.1183/13993003.congress-2017.PA4725.

² Doff MH, Hoekema A, Wijkstra PJ, et al. Oral appliance versus continuous positive airway pressure in obstructive sleep apnea syndrome: A 2-year follow-up. SLEEP. 2013;36(9):1289-96.

Mandibular Advancement Devices Lower Apnea-Hypopnea Index at All Obstructive Sleep Apnea Severity Levels

A dental sleep medicine practitioner shares 5 years of data that show moderate and severe OSA patients can achieve successful outcomes with MADs. He calls for greater awareness of oral appliance utility. By Kenneth A. Mogell, DMD, DABDSM (Published October 2016, Sleep Review)

The question about when a Mandibular Advancement Device (MAD) should or could be used is debated. Various sleep health professionals and insurance providers have rendered opinions as to what they believe is the most effective means for managing patients with Obstructive Sleep Apnea (OSA).

The status quo option to manage OSA is CPAP [Continuous Positive Airway Pressure]. Often CPAP is the correct choice; if the patient is compliant, CPAP is indisputably the most effective means to manage OSA. But compliance with CPAP is most often fair at best.

I have often wondered: Why isn't the option of a MAD typically made available to patients from the onset of their diagnosis when compliance with a MAD has been shown to be subjectively higher than a CPAP? Clearly, the biggest barrier is that MADs are not as effective as CPAP. At first, I also suspected one of the following concerns might be a large barrier to physicians for referral of an MAD as a first-line treatment: changes in the bite; temporomandibular joint pain/jaw discomfort; insurance/Medicare coverage; or cost of a non-returnable device.

But I find that even after addressing and satisfying these concerns with physicians who are considering referring their OSA patients for MADs,

there is still hesitation. So I have come to believe that the primary barrier is related to the perception that MADs have a limited application—that is, the idea that MADs only work for patients with mild OSA. For patients with an apnea-hypopnea index (AHI) 15 or over, many sleep professionals have the mistaken belief that MADs cannot be efficacious.

In my experience, MADs should be considered for OSA patients without severity restrictions. This is consistent with the Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015, which states, "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."¹ It is also consistent with several published peer-reviewed case reports and studies.²⁻³

I have also found that many health professionals have limited experience and awareness of the objective efficacy of a properly titrated MAD. So to allay efficacy concerns, about five years ago I began to keep track of diagnostic polysomnography (PSG) AHI (pre-MAD) as well as titration MAD AHI data in my patient population.

Methods: Most of the oral appliance candidates referred to me during this time were CPAP

failures; a few were newly diagnosed patients who requested an alternate therapy. The patients who were then compliant with managing their OSA with a MAD, after achieving a subjective level of maximum medical improvement (MMI), would return to the referring physician for a titration PSG to objectify the MAD's efficacy. These titration PSGs were performed at many different sleep centers, scored by numerous registered sleep technologists, and interpreted by various board-certified sleep physicians. Because most of my patients are Medicare patients, the MADs were mostly Herbst devices (covered by Medicare) though about 10% were other styles of MADs.

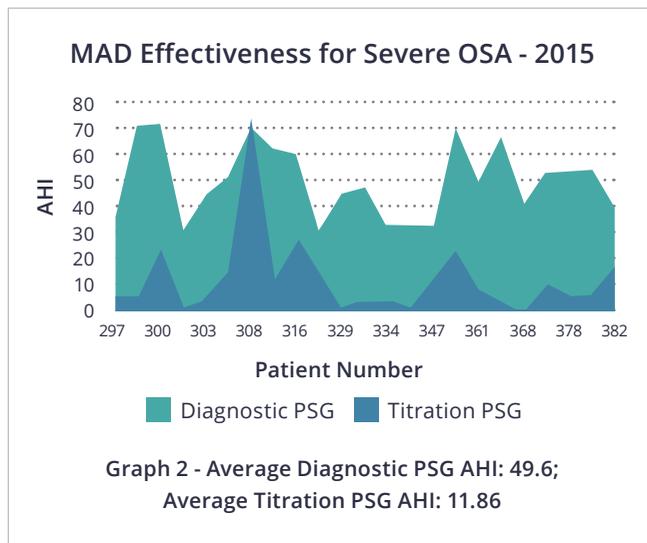
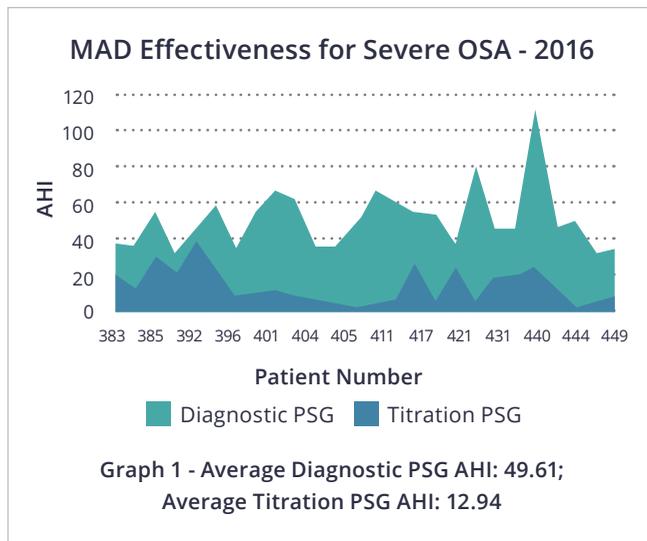
Limitations: Because this was not a double-blinded randomly controlled trial, this data may be considered less than a scientific level of research. Nevertheless, the objective overall results of the titration PSGs merit examination because it provides evidence that MADs can and do effectively manage all severity levels of OSA.

Results: There were 306 patients with an AHI of 15 or greater (that is, moderate to severe OSA) who completed the sequence of having a diagnostic PSG and a follow-up titration PSG to verify and maximize the efficacy of the MAD. The average diagnostic PSG showed an AHI of 36.3/hour. The average AHI after appropriately titrating the device during the PSG was 10.7/hour (see Table 1).

Further breakdown of the studies shows that 154 of these patients were diagnosed with severe OSA (an AHI of 30 or greater). The average AHI of those individuals was 49.0/hour prior during their diagnostic PSG. Once again after achieving a subjective level of MMI, the patient returned for a titration PSG. The average AHI with the MAD for these severe OSA patients was 14.1/hour. See Graph 1 and Graph 2, which highlight the efficacy of MADs with patients diagnosed with severe OSA in 2016 and 2015, respectively.

Year	N	Average Diagnostic AHI	Average Titration AHI	% Change
2012	71	38.6	12.7	67%
2013	59	35.8	10.3	71%
2014	81	35.6	11.5	68%
2015	48	34.6	8.7	75%
2016	47	36.3	8.8	76%

Table 1 - AHI Percent Change for Patients Who Utilized MAD During PSG.



¹ Ramar K, Dort LC, Katz SG, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. *J Clin Sleep Med.* 2015;11(7):773-827. ² Doff MH, Hoekema A, Wijkstra PJ, et al. Oral appliance versus continuous positive airway pressure in obstructive sleep apnea syndrome: A 2-year follow-up. *SLEEP.* 2013;36(9):1289-96. ³ Takaesu Y, Tsuiki S, Kobayashi M, et al. Mandibular advancement device as a comparable treatment to nasal continuous positive airway pressure for positional obstructive sleep apnea. *J Clin Sleep Med.* 2016;12(8):1113-9.

Health Outcomes of CPAP vs Oral Appliance Treatment for Obstructive Sleep Apnea

A Randomized Controlled Trial

Craig L. Phillips, Ronald R. Grunstein, M. Ali Darendeliler, Anastasia S. Mihailidou, Vasantha K. Srinivasan, Brendon J. Yee, Guy B. Marks, and Peter A. Cistulli

Rationale: Continuous positive airway pressure (CPAP) and mandibular advancement device (MAD) therapy are commonly used to treat obstructive sleep apnea (OSA). Differences in efficacy and compliance of these treatments are likely to influence improvements in health outcomes.

Objectives: To compare health effects after one month of optimal CPAP and MAD therapy in OSA.

Methods: In this randomized crossover trial, we compared the effects of one month each of CPAP and MAD treatment on cardiovascular and neurobehavioral outcomes.

Measurements and Main Results: Cardiovascular (24-h blood pressure, arterial stiffness), neurobehavioral (subjective sleepiness, driving simulator performance), and quality of life (Functional Outcomes of Sleep Questionnaire, Short Form-36) were compared between treatments. Our primary outcome was 24-hour mean arterial pressure. A total of 126 patients with moderate-severe OSA (apnea hypopnea index [AHI], 25.6 [SD 12.3]) were randomly assigned to a treatment order and 108 completed the trial with both devices. CPAP was more efficacious than MAD in reducing AHI (CPAP AHI, 4.5 6 6.6/h; MAD AHI, 11.1 6 12.1/h; P, 0.01) but reported compliance was higher on MAD (MAD, 6.50 6 1.3 h per night vs. CPAP, 5.20 6 2 h per night; P, 0.00001). The 24-hour mean arterial pressure was not inferior on treatment with MAD compared with CPAP (CPAP-MAD difference, 0.2 mm Hg [95% confidence interval, 20.7 to 1.1]); however,

overall, neither treatment improved blood pressure. In contrast, sleepiness, driving simulator performance, and disease-specific quality of life improved on both treatments by similar amounts, although MAD was superior to CPAP for improving four general quality-of-life domains.

Conclusions: Important health outcomes were similar after 1 month of optimal MAD and CPAP treatment in patients with moderate severe OSA. The results may be explained by greater efficacy of CPAP being offset by inferior compliance relative to MAD, resulting in similar effectiveness. Clinical trial registered with <https://www.anzctr.org.au> (ACTRN 12607000289415).

Keywords: obstructive sleep apnea; continuous positive airway pressure; mandibular advancement device; health outcomes; efficacy and compliance

The Costs of OSA Treatments: Is OAT More Expensive?

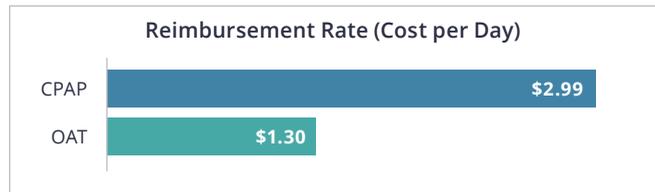
Len Liptak, MBA
ProSomnus Sleep Technologies

Introduction: Does Oral Appliance Therapy (OAT) for the treatment of Obstructive Sleep Apnea (OSA) cost more than Continuous Positive Airway Pressure (CPAP) therapy? This topic is salient. The prevalence, incidence and progression of OSA in the United States indicates a large and growing population of people with untreated OSA that is becoming more severe over time. Cost of care is one of several factors that shape policies that facilitate access to care.

Objectives: The purpose of this investigation is to quantify and compare the costs associated with two popular OSA treatment modalities: CPAP and OAT.

Method and Sample: Reimbursement schedules were procured from the Centers for Medicare Services for CPAP and Oral Appliance Therapy treatment modalities. Reimbursement amounts and replacement intervals were identified for each treatment modality. Mean values were used to account for regional, and other, differences in reimbursement amounts. A daily reimbursement rate was calculated to standardize the comparison amongst the various components of CPAP and OAT. This rate was calculated as the quotient of the reimbursement fee for a given component divided by the reimbursement interval in days. Publicly available device warranty durations were also used to quantify gaps, if any, between reimbursement intervals and the device warranty periods – the assumption being that gaps between the reimbursement interval and the device warranty might result in additional costs.

Results: The average reimbursement cost for CPAP was \$2.99 per day. The average reimbursement cost for OAT was \$1.30 per day.

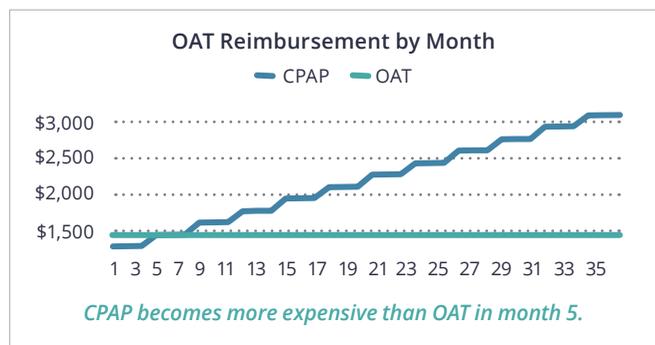


CPAP Reimbursement Rate per Day Schedule			
Items	Replacement Schedule (Days)	Average Reimbursement	Amount Per Day
Mask	90	\$89.67	\$1.00
Cushion	30	\$34.48	\$1.15
Nasal Pillows	30	\$15.15	\$0.51
Tubing	90	\$11.99	\$0.13
Headgear	180	\$18.18	\$0.10
Filters	30	\$2.11	\$0.07
CPAP Machine	1,095	\$42.46	\$0.04
Total CPAP			\$2.99

Excludes additional covered items such as chinstraps, humidifiers, water chambers and other upgrades such as tubing with heating element.

OAT Reimbursement Rate per Day			
Item	Replacement Schedule (Days)	Average Reimbursement	Amount Per Day
Total CPAP	1,825	1,429	\$0.78

Average reimbursement based on the ranges for jurisdictions A-D.



Conclusions: This analysis concludes that CPAP costs 2.3x more per day than OAT. Given the replacement intervals of CPAP components, it is useful to evaluate the accumulated costs of the two therapies over time. CPAP costs less than OAT in months 1-3. Costs are similar in month 4. CPAP costs more beginning in month 5. CPAP costs 2.3x more than OAT by month 36.

Oral Appliance Options



Prosomnus [CA] LP



SomnoMed Herbst Advance



Prosomnus EVO



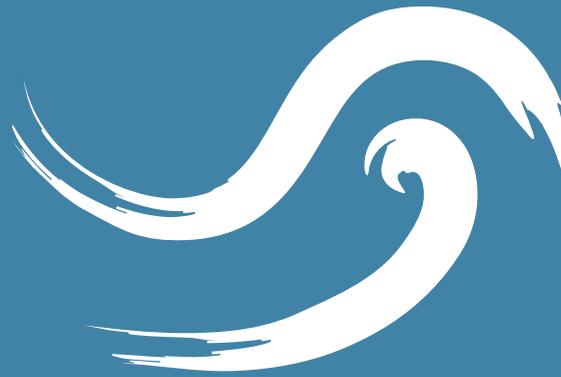
SomnoMed Air



Prosomnus [PH]



Serena Sleep



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Boca Raton

2900 N Military Trl. #212
Boca Raton, FL 33431

Vero Beach

787 37th St., Ste. 180
Vero Beach, FL 32960

Melbourne

1400 Pine St.
Melbourne, FL 32901
