Fax referrals to
616-772-9380
My direct email:
DrV@wmCPAPalternatives.com
www.wmCPAPalternatives.com

WEST MICHIGAN
CPAP Alternatives
Customized Sleep Apnea Solutions
Dr. Vandervelden

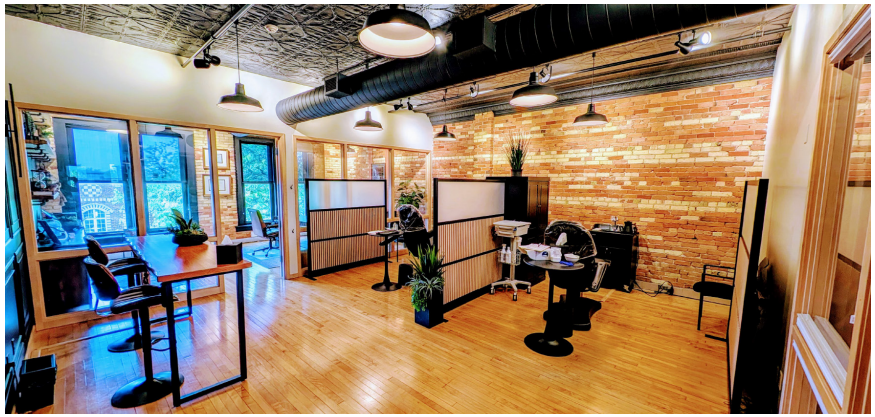
WATCH MY VIDEO FOR MORE INFO

Now available for your patients. This precision post appliance with built in buccal mucosal oximeter is pending FDA review. It will predict AHI and SASHB (Sleep-Apnea-Specific-Hypoxic-Burden). It syncs to an app on the patients phone and once FDA approved it will also sync to a provider portal to allow professional monitoring by sleep physicians and sleep dentists. FDA approval expected in Q4 2025. Currently it shows ODI, heart rate, sPO2, and calculates a "breathing/sleep score". All other features will be turned on for patients once FDA cleared. Few dentists in the country have access to this right now.

95 degree reverse "hook" post

I'm located downtown Holland. The newest precision post appliances I now provide are proven to work significantly better than oral appliances of the past provided by most dentists today. I've included the most up to date studies using these precision post appliances. The latest studies suggest that the new precision post oral appliances outperform CPAP in sleep quality, energy levels, daytime sleepiness, alertness, and cognition. They are also over 90% effective at reducing sleep-apnea-specific-hypoxic-burden (SASHB) from an unsafe level to a safe level, and internationally they are increasingly being utilized as a first-line option to treat all severity levels of OSA. Given the efficacy of these newer appliances, they should be considered first before surgery. Most other dentists do not provide precision post appliances due to costs and insurance rules, and do not use extensive multi-night sleep testing to dose therapy more accurately and safely, or provide long term monitoring of their OSA like I do. My patients are more effectively treated, have less side effects, and are more likely to stick to therapy long term. Results matter.

Dr. Vandervelden's sleep practice in downtown Holland →



Summary of presentation:

- Precision post appliances are significantly more effective than oral appliances of the past. Few dentists provide precision post appliances, especially the newest ones, mainly due to cost, or they simply don't know, or because insurance hasn't caught up yet and doesn't pay enough for providers to offer them (Insurance should reimburse based on the mechanism (see slide 8) and type (precision vs. non-precision) of appliance used in my opinion). The newest studies using precision post appliances suggest they are at least non-inferior to CPAP and outperform CPAP in various wellness metrics.
- Precision post appliances using my methodical calibration process gets better results compared to others, and is a highly effective first line option to treat all levels of OSA.
- What truly sets me apart is that I dose this therapy more accurately than others. This is very important for long term success. I have patients undergo up to 15 nights of sleep testing at multiple lower jaw positions to set the lower jaw in the most effective yet furthest back position. I don't set the jaw any further than necessary. This leaves room for further adjustment in the future if sleep apnea gets worse (as it does in most cases). I provide long term follow up with my patients, and have them undergo OAT efficacy assessments every 2 years with home sleep testing. Other dentists don't do this.
- Compared to other dentists, my patients are more effectively treated, and have better follow up and compliance.
- Maximizing effectiveness and achieving long term results for patients has always been my main focus and drives me to continually improve.

I have no conflicts of interest. I receive nothing from the companies that make the products I use. I use them because they work the best for my over all goal, and that is to treat my patients as effectively as possible and to keep them successfully treated long term.

Dr. Vandervelden

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The newest precision post appliance; 95 degree "hook" post provides better lower jaw stabilization- more tongue space- less protrusion necessary- can close your mouth more

These are the patients you should refer to me:

- All patients diagnosed with sleep apnea who would prefer an alternative to CPAP
- All CPAP non-compliant patients
- Patients that would benefit from combining a precision post appliance with AutoPAP (they require much less forward jaw positioning and patients can close their mouths more making it easier to get a good mask seal)
- All patients prior to Hypoglossal Nerve Stimulation or other surgeries

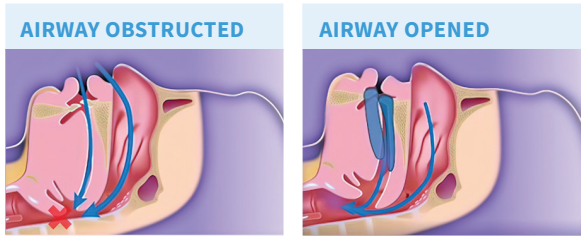
I partner with Dr. Singh from iSleep group to expedite OSA care and get patients into therapy fast. I provide follow up OAT efficacy assessments every 2 years, and provide around 15 nights of sleep testing in order to dose this therapy more accurately. My process would take too long partnering with local sleep centers, which is why I facilitate my own sleep testing (most testing centers do not offer the extensive amount of sleep testing my process requires- and even if they did it would likely be very expensive). I take care of everything from start to finish for OSA treatment (Dr. Singh can also prescribe and manage AutoPAP for patients expeditiously if OAT alone is not adequate and patients wants to pursue combining OAT with AutoPAP). If patients are being managed for other sleep disorders you should still manage that aspect of care for patients. My practice specializes in treating and managing OSA, but not other sleep disorders. Simply give your patients my information, or fax over a referral. I will get my notes to you and keep you informed on the patients progress. Expect OAT results 15-20 weeks from time of referral assuming patient moves forward right away.

Highlights

I partner with board-certified sleep physicians, and airway-centric ENT's to provide patients the option of combining oral appliance therapy with other therapies if what I do is not enough to manage their OSA. Starting with an oral appliance at my practice first makes sense. My patients have the least side effects, the average yearly costs for therapy at my practice is less than CPAP and Inspire, and my patients adhere to therapy long term. My therapy can be combined with all other therapies for better results than any one therapy alone. I can help make CPAP better (by lowering pressure requirements), Improve Inspire efficacy and adherence (by lowering voltage requirements), or can improve the outcomes of ENT procedures like septoplasty's, UPPP, RFA, turbinate reductions, Inspire, and other ENT services. This means that even if the oral appliance isn't enough by itself, it will not be a waste of time or money for the patient. My therapy improves all other therapies when combined. In my hands, oral appliances are a first line option. What I do is very different compared to other dentist that provide oral appliances on the side. Since going full time practicing dental sleep medicine, my process has changed significantly and I am getting better results than before. Fewer than 100 dentists in the country do what I do. If you still prefer all your patients to try CPAP first, refer me your CPAP-non compliant patients or those that refuse CPAP. Feel free to tell them my costs ahead of time. I understand not all patients are willing to pay for the level of care that I offer, and for some patients an in-network dentist who provides cheaper, less effective appliances with minimal oversight may be their preference. For your most health conscientious patients and those who want the best results, refer to my practice.

WHAT PATIENTS NEED TO KNOW

A Custom Oral Appliance is like a retainer you wear in your mouth while you sleep. It works by positioning the lower jaw forward which opens the airway.



- Treats sleep apnea. No CPAP or surgery needed.
- Eliminates snoring.
- Comfortable.
- Sleep better.
- Have more energy.
- Improves overall health.
- Can sleep in any position.
- Easy to clean and easy to travel with.
- First consultation is free. No referral required.

"My oral appliance is working out great! I'm not snoring and I am sleeping much better. I've also seen a significant improvement with my sleep apnea. My wife loves it!"

— LONNIE H.

ANY PROVIDER? RESULTS MATTER

Most providers are not Diplomates of the American Board of Dental Sleep Medicine like Dr. Vandervelden and do not have specialist level knowledge or training in treating obstructive sleep apnea. Even if you put knowledge and experience aside, most other providers do not do multiple nights of home sleep testing at multiple different jaw positions. They instead rely heavily on "subjective feedback" when setting the lower jaw. In many cases, this results in the provider setting the lower jaw too far forward. Dr. Vandervelden relies on up to 20 nights of objective sleep data to find the optimal lower jaw position to maximize effectiveness while also maximizing compliance. Results matter.

I'm **Dr. Vandervelden** and I have sleep apnea myself. I struggled with CPAP, then switched to a Custom Oral Appliance and loved it. I'm passionate about Custom Oral Appliance Therapy.

SERIOUSLY, WATCH OUR VIDEO TO LEARN MORE

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SLEEP APNEA?

SEE **DR. VANDERVELDEN** FOR CUSTOM ORAL APPLIANCE THERAPY

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WHAT PROVIDERS NEED TO KNOW

- Dr. Vandervelden specializes in Custom Oral Appliance Therapy, it's all he does.
- Easy for referring providers. West Michigan CPAP Alternatives takes care of EVERYTHING from start to finish, including coordinating initial and follow up home sleep testing and consulting with board certified sleep physicians. We keep referring provider updated with progress notes.
- **New studies using precision post appliances suggest higher clinical effectiveness compared to CPAP and these appliances outperformed CPAP on various wellness metrics.**
- Approved by American Academy of Sleep Medicine as first line option for mild and moderate obstructive sleep apnea.
- Approved by American Academy of Sleep Medicine for severe obstructive sleep apnea if noncompliant with CPAP or refuse CPAP.
- Sleep Doctors can't provide Custom Oral Appliances. Must be a Dentist.
- Patients DO NOT need to try CPAP first.
- Studies show Oral Appliance Therapy is over all just as effective as CPAP for all sleep apnea severity levels. (Studies using older appliances)
- Comfortable. Patients strongly prefer Custom Oral Appliance Therapy over CPAP.
- Refer patients for Custom Oral Appliance Therapy prior to surgical options like Inspire.

WATCH OUR VIDEO TO LEARN MORE

Precision post appliances under Dr. V's supervision are a first line option to treat all levels of OSA.

WHAT'S THE PROCESS?

- Refer any patient with or without existing diagnosis of Obstructive Sleep Apnea to Dr. Vandervelden for a free consultation to determine if the patient is suitable for Custom Oral Appliance Therapy. No need to see a sleep doctor first.
- Every patient receives comfortable, cutting edge, multi-night home sleep testing at multiple different jaw positions to find the most conservative yet effective position. Dr. Vandervelden collaborates closely with board-certified sleep physicians throughout his process to get the best results. Each patient undergoes an average of 20 nights of home sleep testing. The etire process start to finish takes approximately 20 weeks.
- West Michigan CPAP Alternatives is fast. Most patients have their oral appliance within 6 weeks of their doctor making a referral. Sleep centers take months to get their patients in a CPAP.

SIDE EFFECTS?

- Side effeSide effects are mostly caused by the lower jaw being set too far forward. Luckily, due to Dr. Vandervelden's process, his patients' lower jaws are set in the least forward position shown to be effective, avoiding many of the common side effects reported in literature. The reported side effects include jaw muscle pain, teeth loosening, bite changes, dry mouth, TMJ. Luckily, side effects experienced by the vast majority of Dr. Vandervelden's patients are minor and temporary and rarely lead to patients quitting therapy.

COST?

- The average yearly cost for treating your sleep apnea with Dr. Vandervelden is significantly cheaper than CPAP or Inspire.

COMFORTABLE?

- Most Patient Strongly prefer a Custom Oral Appliance over a CPAP. It is far more comfortable.
- While wearing the appliance patients can still open their mouth, talk, and drink.
- Over 95% of Dr. Vandervelden's patients are still wearing their appliance a°er 1 year. Studies show only 26% of mild OSA patients are still using CPAP after 1 year, and less than 40% of moderate/severe OSA patients stick with CPAP after 1 year. Patients love their oral appliance!

WHY NOT BUY AN ORAL APPLIANCE ONLINE?

- Online appliances tend to take up more space in your mouth, requiring a more aggressive forward jaw position to open the airway which increases side effects. Dr. Vandervelden provides top-of-the-line appliances that are smaller, fit better, and are more durable than online appliances.
- The appliance is important, but what really sets Dr. Vandervelden apart from others is his process that results in the lower jaw being set in just the right spot; Not too far forward, but forward enough to open the airway. There really is no comparison to what Dr. Vandervelden does and online appliance services. Results matter.

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RESULTS MATTER

	Dr. Vandervelden	Other doctors
Precision post appliance recent studies show are non-inferior to CPAP and surpass CPAP on wellness variables.	✓	✗
Everything is included for 4 years	✓	✗
Lower jaw is set forward enough to open airway, but not so far forward to cause side effects that result in patients quitting therapy	✓	✗
Doctor completed specialist-level training and practices at highest level	✓	✗
Doctor collaborates closely with Board Certified Sleep Physician	✓	✗
Fast, hassle free home sleep testing	✓	✗
Most tongue space, superior jaw stability, furthest back jaw position	✓	✗
Lowest risk of side effects	✓	✗

The newest precision post appliances work significantly better than legacy appliances . The following explains why: They stabilize the lower jaw better, take up less tongue space, allow the lower jaw to be set further back, and have less clearance requirements allowing patients to close their mouths more.

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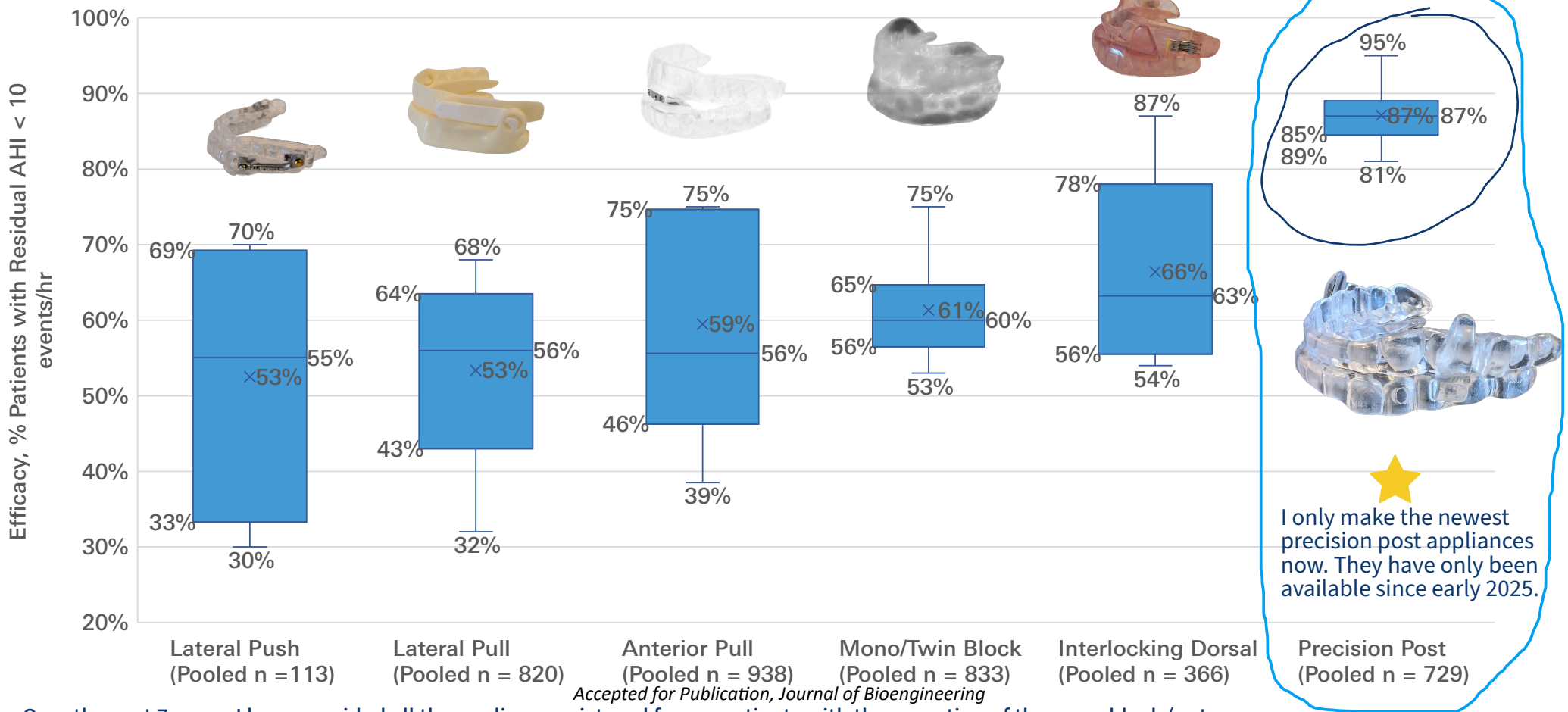
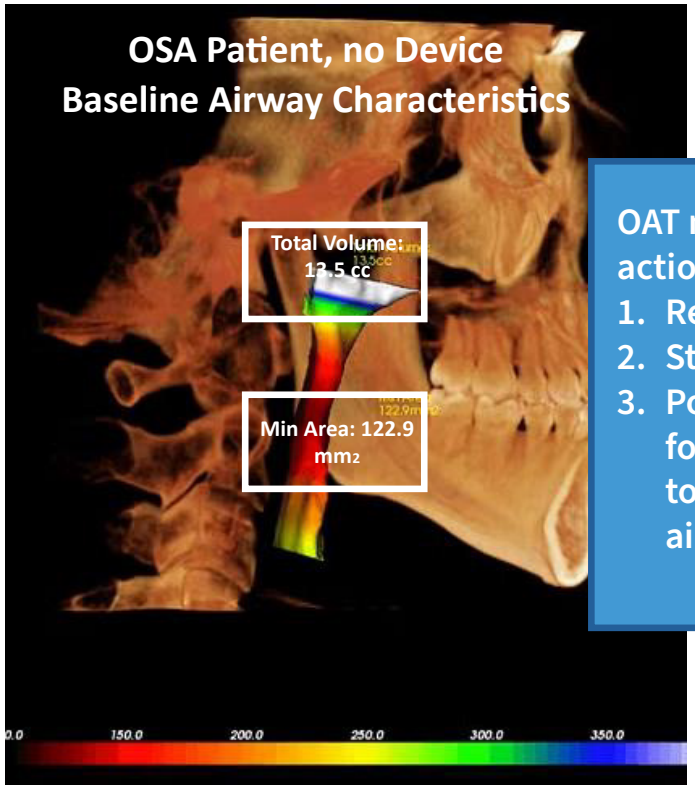
Efficacy (%AHI < 10) by Oral Appliance Design Type



Accepted for Publication, Journal of Bioengineering

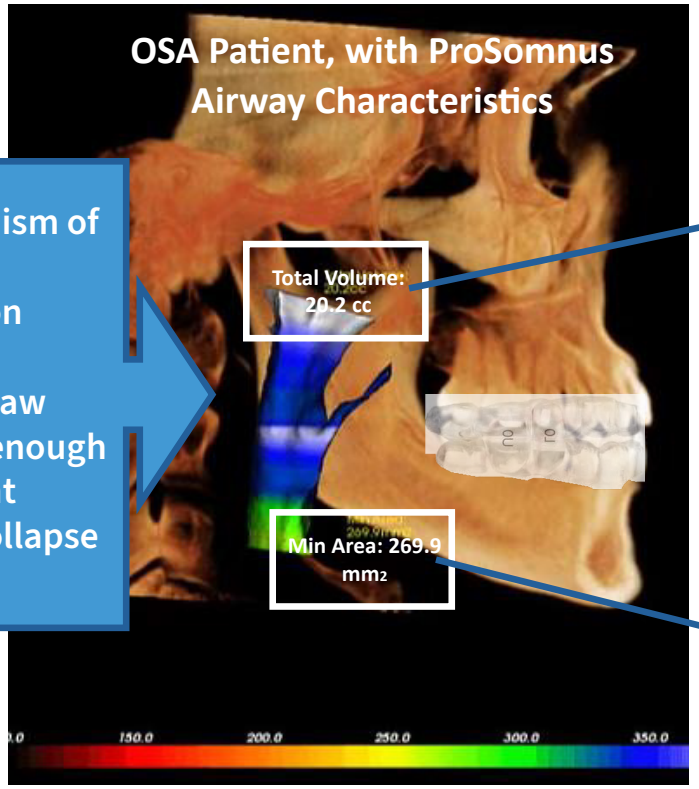
Over the past 7 years, I have provided all the appliances pictured for my patients with the exception of the monoblock (not up to my standards). Precision post oral appliances like the one pictured offer superior jaw stabilization, which is the main mechanism of action of OAT's. These appliances take up the least amount of space where it counts (where the tongue lives), providing more tongue space and allowing for less protrusion overall. These appliances start working at 30 percent protrusion (lower jaw set further back), where appliances of the past typically required 50 to 60 percent protrusion to start working.

Precision Post Oral Appliances are Engineered to Perform the Mechanisms of Action for OAT: Reposition, Stabilize & Titrate the Jaw with < 1 mm of target to Prevent Airway Collapse



OAT mechanism of action:

1. Reposition
2. Stabilize
3. Position jaw forward enough to prevent airway collapse



Total Airway Volume
No device = 13.5 cc With ProSomnus = 20.2 cc
Improvement +50%

Minimum Cross Section No device = 122.9 mm_2 With ProSomnus = 269.9 mm_2
Improvement +120%

★ Newest precision post appliance would likely get even better improvement due to superior jaw stabilization and tongue space.

belun ring

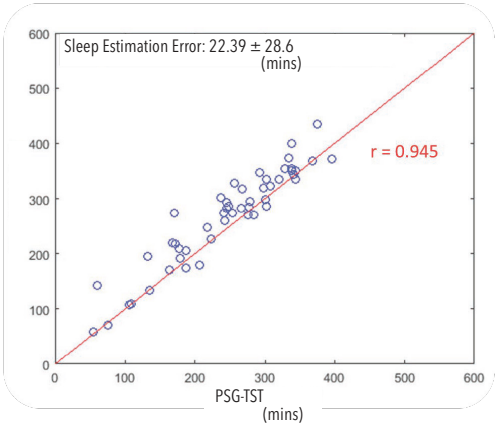
Simple and Comfortable

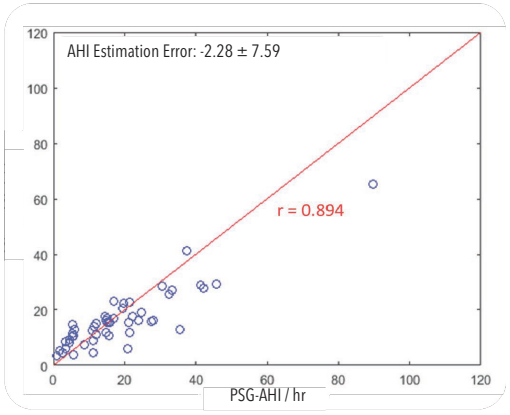
- Simple and easy to be used by users
- Small, lightweight and cableless design for non-intrusive measurement at night
- Cost effective multiple-night home sleep test

New updated reports include AHI3 and AHI4

Accurate and Reliable

- FDA 510(k) cleared and ISO 13485 certified
- Clinically validated
- High correlation with PSG in both Total Sleep Time (TST) and AHI
- High Sensitivity (0.85) and Specificity (0.87) for AHI ° 15





Gu W, et al. (2020) Belun Ring Platform: a novel home sleep apnea testing system for assessment of obstructive sleep apnea. J Clin Sleep Med. 16(9):1611–1617.

Yeh E, et al. (2021) Detection of obstructive sleep apnea using Belun Sleep Platform wearable with neural network-based algorithm and its combined use with STOP-Bang questionnaire. PLoS ONE 16(10): e0258040.

Fast and 24x7

- Cloud-based proprietary AI algorithm for sleep analysis
- Sleep report is ready within minutes for instant review
- Cloud platform let you access sleep data anywhere and anytime

Belun Sleep Analysis Report

The best research tool with piles of physiological parameters for long-term studies

Sleep Statistics

Start Time	2022-04-25 22:59	Total Recording Time (TRT)	387.5	mins
End Time	2022-04-26 05:29	Total Sleep Time (TST)	338.5	mins
Time Zone	UTC+07:48	Sleep Efficiency (TST/TRT)	87.4	%

Sleep Stage Statistics

Wake		REM		NREM	
Duration (mins)	Counts	Duration (mins)	% in TST	Duration (mins)	% in TST
49.0	14	60.5	17.9	278.0	82.1

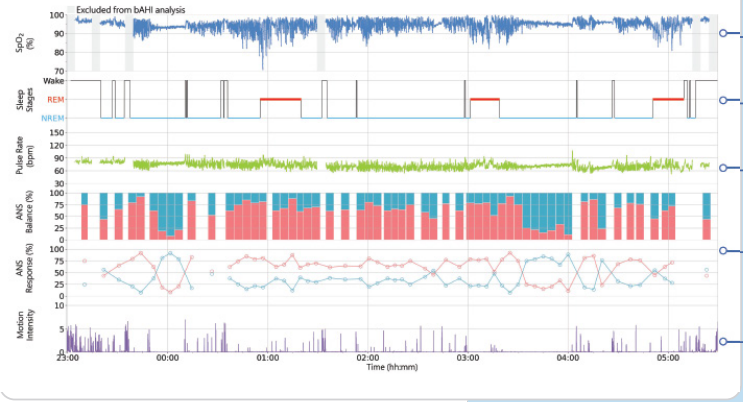
Respiratory Statistics

	TRT	TST	REM	NREM
bAHI (/hr)	-	67.0	69.4	66.5
ODI (/hr)	56.5	-	-	-

SpO_2			<90% (T90)		<80% (T80)	
Mean (%)	Max. (%)	Min. (%)	Duration (mins)	% in TRT	Duration (mins)	% in TRT
95	100	≤ 70	19.0	4.9	0.5	0.1

Pulse Rate Statistics

Mean (bpm)	72	Max. (bpm)	107	Min. (bpm)	53



Sleep Statistics

Sleep Stage Statistics

Respiratory Statistics

Pulse Rate Statistics

SpO_2

Sleep Stage

Pulse Rate

Autonomic Nervous System Balance/Response

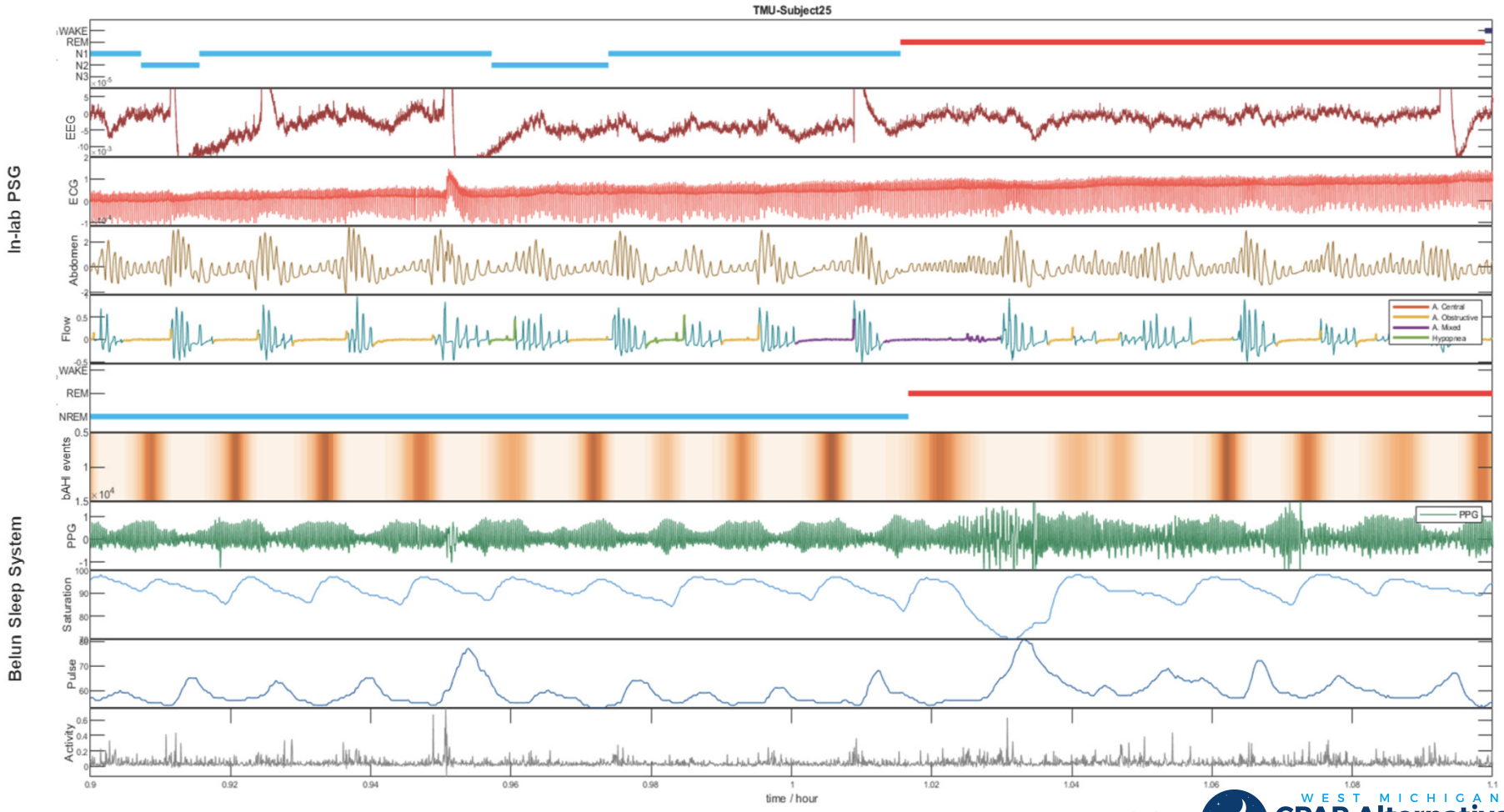
Motion Intensity

Remarks: Belun Core for breathing effort, posture and body temperature is available as an accessory for central sleep apnea.

My protocol:

- 4-6 nights for baseline
- 12-16 nights while wearing oral appliance at 3 to 4 different lower jaw positions
- 4 nights 2 years post appliance delivery
- 4 nights 4 years post appliance delivery
- At 4 years, a new baseline and new appliance are made. The process starts over again.

Belun® Ring BLR-100X, an FDA 510(k) cleared Class II reflectance pulse oximeter, acquires users' photoplethysmography (PPG). The clean PPG signals at a high sample rate (200 Hz) deliver physiological information on oxygen saturation, pulse rate, and heart rate variability (HRV). Our cutting-edge algorithms, Belun Sleep System BLS-100, capture intricate patterns of these signals and accurately estimate AHI and categorize sleep stages. Several clinical trials have validated its robust generalizability in patients even with co-morbidities..[2,3,11]



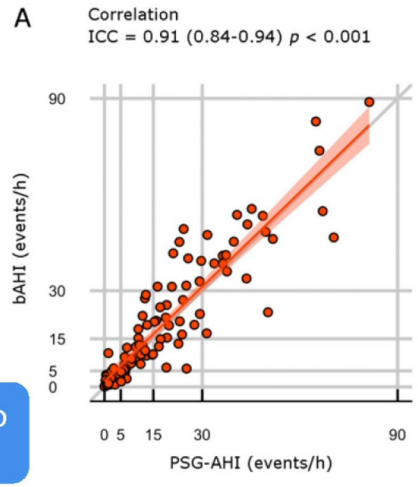
belun | High Accuracy and Precision in OSA classification (New Generation)

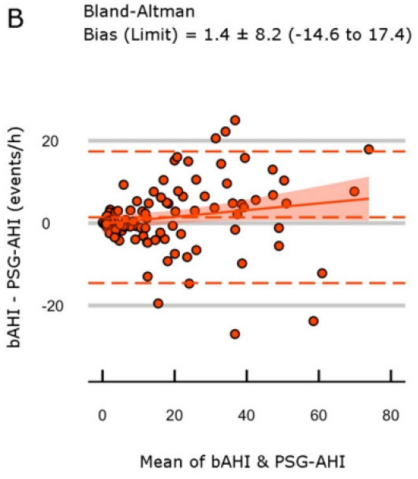
Apnea-Hyponea Index ≥ 5 : **Accuracy**: **93%**; **Sensitivity**: **94%**; **Specificity**: **93%**
Apnea-Hyponea Index ≥ 15 : **Accuracy**: **90%**; **Sensitivity**: **89%**; **Specificity**: **90%**

Cutoff	Accuracy	Sensitivity	Specificity	PPV	NPV	LR+	LR-	Cohen's Kappa
5	**0.93 (0.87-097)**	**0.94 (0.86-0.98)**	**0.93 (0.77-0.99)**	0.97 (0.91-1.00)	0.84 (0.67-0.95)	13.56 (3.56-51.71)	0.07 (0.03-0.16)	0.84 (0.72-0.95)
15	**0.90 (0.82-0.95)**	**0.89 (0.77-0.97)**	**0.90 (0.79-0.96)**	0.88 (0.75-0.95)	0.90 (0.81-0.95)	8.79 (4.10-18.88)	0.12 (0.05-0.27)	0.79 (0.67-0.91)
30	0.90 (0.82-0.95)	0.91 (0.70-0.99)	0.89 (0.81-0.95)	0.68 (0.48-0.84)	0.97 (0.91-1.00)	8.55 (4.54-16.10)	0.11 (0.03-0.40)	0.71 (0.55-0.87)

1. No. of subjects: 106
2. OSA severity distribution:
   - No OSA: 27%, BMI: 38.0 ± 10.3
   - Mild: 28%, BMI: 37.5 ± 9.5
   - Moderate: 25%, BMI: 43.4 ± 9.7
   - Severe: 20%, BMI: 39.2 ± 7.8
3. Race:
   - African American: 65%
   - Caucasian: 27%
   - Hispanic: 1%
   - Asian: 2 %
   - Others: 1%
   - Unknown: 4%

Clinically validated vs. in-lab PSG (gold standard)





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I am aware that PSG's are still the gold standard, but PPG powered by AI is getting better and better, and this comfortable ring allows patients to sleep more normally, and allows for more nights of data. Sleep varies from night to night, so having 15 nights of data with Belunring is more useful when assessing OAT efficacy vs. a single night PSG (and significantly less expensive).

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belun | High Accuracy and Precision in Sleep Stage Classification (New Generation)

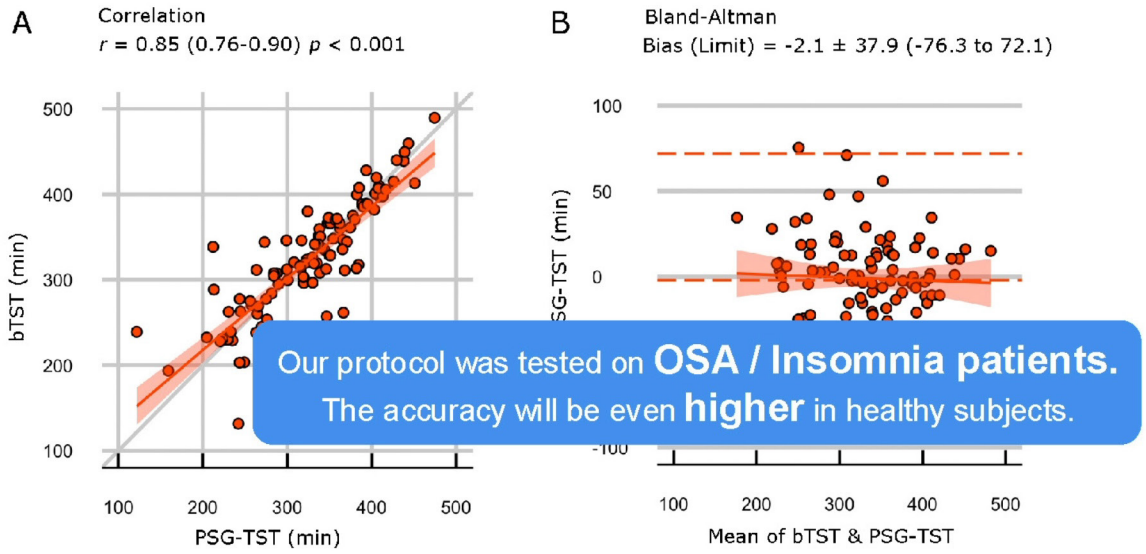
Sleep Stages Accuracy: **Wake**: **90%**; **REM**: **93%**; **NREM**: **85%**

	Number of Epochs	Accuracy	Sensitivity	Specificity	PPV	NPV	LR+	LR-	Kappa
Wake	88,229	0.90 (0.89-0.90)	0.78 (0.77-0.78)	0.93 (0.93-0.93)	0.76 (0.75-0.76)	0.94 (0.93-0.94)	11.10 (10.79-11.42)	0.24 (0.23-0.25)	0.70 (0.70-0.71)
NREM		0.85 (0.85-0.86)	0.90 (0.90-0.90)	0.78 (0.77-0.78)	0.87 (0.87-0.87)	0.82 (0.82-0.83)	4.04 (3.96-4.12)	0.13 (0.13-0.13)	0.68 (0.68-0.69)
REM		0.93 (0.90-0.90)	0.68 (0.67-0.69)	0.97 (0.97-0.97)	0.81 (0.81-0.82)	0.94 (0.94-0.95)	24.09 (23.06-25.17)	0.33 (0.32-0.34)	0.70 (0.69-0.71)

Watch-PAT[2]:

- *Wake:*
  Acc: 0.852; Se: 0.647; Sp: 0.905
- *REM (not including wake):*
  Acc: 0.873; Se: 0.681; Sp: 0.918
- *NREM (not including wake):*
  Acc: 0.873; Se: 0.924; Sp: 0.660

Besides WatchPAT, we are the **ONLY** wearable device in the market who has **FDA-cleared sleep stage classification in OSA diagnosis.**



Our protocol was tested on **OSA / Insomnia patients.** The accuracy will be even **higher** in healthy subjects.

References:

1. *Strumphf et al. "Belun Ring: A Deep learning-facilitated Wearable Enables OSA Detection, Apnea Severity Categorization, and Sleep Stage Classification in Patients Suspected of OSA, Sleep Health (Accepted in Sleep Health, March 2023)*
2. *Hedner et. al, Sleep Staging Based on Autonomic Signals: A Multi-Center Validation Study. J Clin Sleep Med, 2011*

Integrating Body Sensor into a Wearable Platform to Enhance the Identification of Central and Mixed Apneas

GU, Wenbo[1,2]; WU, Peter[2]; LIU, Arthur[2]; LIU, Wen-Te[3]; KUAN, Yi-Chun[3]; LEE, Hsin-Chien[4]; LEUNG, Lydia[2]; WU,I-Chen[1]; CHIANG, Ambrose[5]

INTRODUCTION

Accurate identification of apnea types is crucial for effective diagnosis and management of sleep-disordered breathing. The Belun Sleep System (BLS-100, a.k.a., Belun Ring (Figure 1a) is an FDA-cleared home sleep apnea testing system (K222579) comprising an adjustable ring-shaped wearable, a cradle, and deep learning-powered algorithms. The Belun Cor (Figure1b and 1c), a novel BLS-100 subxiphoid sensor equipped with accelerometry, can detect respiratory effort, respiratory rate, and body position, and facilitates the detection of central events. This preliminary analysis aims to assess the performance of the integrated BLS-100 in detecting apnea events containing central components.

METHODS

This interim analysis evaluated the performance of BLS-100 in a clinical cohort of hospitalized patients admitted for acute ischemic stroke. Eligible patients underwent in-lab polysomnography (PSG) alongside concurrent BLS-100 testing. PSG scoring adhered to the latest AASM scoring manual, with scoring technicians blinded to the BLS-100 results. The BLS-100 derived total sleep time (bTST), sleep stages (bSTAGE), apnea-hypopnea index (bAHI), and combined central and mixed apnea index (bCMAI).

RESULTS

As of 12/17/2023, 25 consecutive Taiwanese patients were enrolled. Four patients were excluded due to short bTST (<120 mins). The analysis was conducted on 21 patients (Table1). M:F 19:2; age 59.7; PSG TST 270 ± 61.9mins; PSG AHI 27.0 (1.4-81.9) with 3 normal, 3 mild, 7 moderate, and 8 severe OSA cases. The mean PSG central apnea index (PSG-CAI) was 4.8 (0.0-34.0), with 5 patients having PSG-CAI ≥5. The mean PSG central and mixed apnea index (PSG-CMAI) was 8.4 (0.0-47.3). Pearson correlation coefficients between PSG-CAI and bCMAI, as well as PSG-CMAI and bCMAI, were 0.939 (P<0.001) and 0.982 (P<0.001), respectively (Table 2). Using bCMAI ≥5 to predict PSG-CAI ≥5, the accuracy, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and Cohen's Kappa were 0.81, 1.00, 0.75, 0.56, 1.00, and 0.59, respectively(Table 3). Similarly, using bCMAI ≥5 to predict PSG-CMAI ≥5, the corresponding values were 0.86, 0.88, 0.85, 0.78, 0.92, and 0.70, respectively (Table 3).

CONCLUSION

Early findings indicate that the BLS-100 with Belun Cor shows promising performance in identifying apnea events that include central components. An elevated bCMAI serves as a valuable indicator for clinicians, signaling the presence of central or mixed apneas.

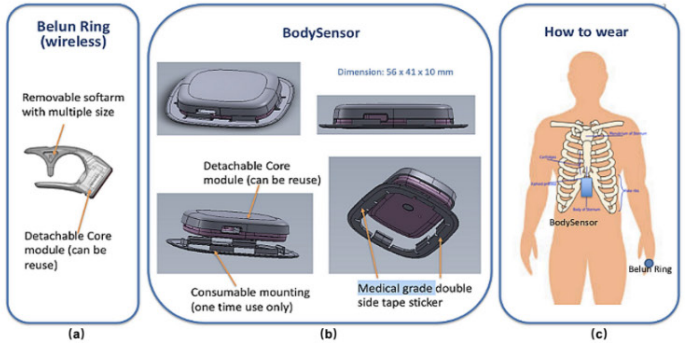


Figure1. Belun Sleep System (Belun Ring & Belun Cor)

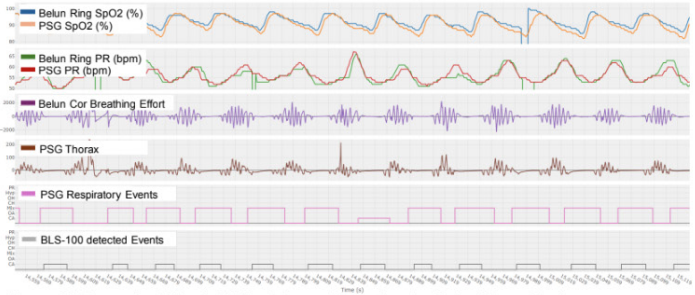


Figure 2. Example of Central/Mixed Apnea Detection by Belun Sleep System

Table 1. Patient Demography

Variables	Mean ± SD	Range
No. of subjects	21	-
Age	59.7 ± 10.0	40 ~ 75
Sex, M/F	-	M:19, F:2
BMI (kg/m²)	26.6 ± 3.1	20.2 ~ 32.2
AHI4 (events/hr)	27.1 ± 22.9	1.4 ~ 81.9
CAI (events/hr)	4.8 ± 8.2	0 ~ 34.0
CMAI (events/hr)	8.4 ± 15.1	0 ~ 47.3

Table 2. Estimation Error of bCMAI vs. PSG CAI/CMAI

Ring vs. PSG	Correlation	Mean Absolute Error	Error Mean ±SD
bCMAI vs. PSG CAI	0.939	6.09	5.73 ±11.22
bCMAI vs. PSG CMAI	0.982	2.66	2.18 ± 4.65

Table 3. Performance endpoints of bCMAI

Cut-off	Accuracy	Sensitivity	Specificity	PPV	NPV	LR+	LR-	Kappa
CAI ≥ 5	81.0%	100.0%	75.0%	55.6%	100.0%	inf	0.44	0.59
CMAI ≥ 5	85.7%	87.5%	84.6%	77.8%	91.7%	9.33	0.20	0.70

Table 4. Confusion Matrix (bCMAI vs. PSG CAI)

	PSG-CAI			
	< 5	5~10	10~15	≥15
bCMAI <5	12	0	0	0
bCMAI 5~10	4	1	0	0
bCMAI 10~15	0	1	0	0
bCMAI >15	0	1	0	2

Table 5. Confusion Matrix (bCMAI vs. PSG CMAI)

	PSG-CMAI			
	< 5	5~10	10~15	≥15
bCMAI <5	11	1	0	0
bCMAI 5~10	2	3	0	0
bCMAI 10~15	0	0	1	0
bCMAI >15	0	0	0	3

1. Department of Computer Science, National Yang Ming Chiao Tung University; 2. Belun Technology Company Limited, Hong Kong; 3. Sleep Center, Shuang Ho Hospital, Taipei Medical University; 4. Department of Psychiatry, Taipei Medical University Hospital; 5. Division of Pulmonary, Critical Care, and Sleep Medicine, Case Western Reserve University;

Market launch expected 2026 (I already have early access to this tech)

Key advances:

- Central/mixed apnea detection
- **Next generation BelunRing sleep reports will show hypoxic burden.**

Snoring: 91% Response to Precision Post Appliances in RCT

⭐New precision post appliance will likely get even better results

JAMA Otolaryngology–Head & Neck Surgery

RCT: Mandibular Advancement vs Combined Airway and Positional Therapy for Snoring

POPULATION

16 Men, 26 Women

Adults without sleep apnea who snore and their sleeping partners

Mean age of snorers, 48 y

SETTINGS / LOCATIONS

One academic medical center in St Louis, MO

INTERVENTION

42 Snorer-sleeping partner dyads analyzed

23 Mandibular advancement device (MAD) Fitted by a maxillofacial prosthodontist and self-titrated to maximum tolerable advancement

19 Combined airway and positional therapy (CAPT) External nasal dilator, nasal saline lavage with mometasone, mouth taping, and lateral positional therapy

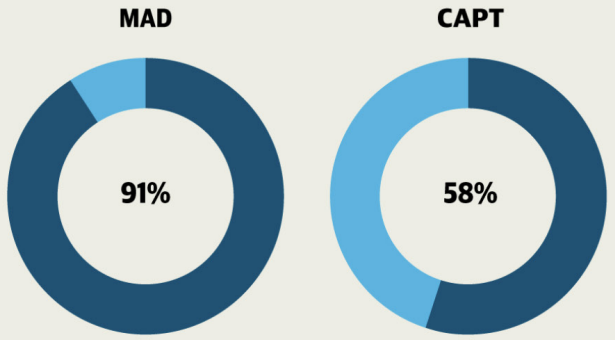
PRIMARY OUTCOME

Response to treatment, defined by the sleeping partner rating their partner's snoring as "very much improved" or "much improved" on the Clinical Global Impression of Improvement Scale for snoring

FINDINGS

Compared with the CAPT group, a significantly greater percentage of snorers in the MAD group had a response to treatment as rated by their sleeping partners

Snorers with response to treatment, as rated by sleeping partners



Rate difference, 33 percentage points (95% CI, 8-58 percentage points). Number needed to treat, 3 snorers

45

Ioerger P, Afshari A, Hentati F, et al. Mandibular advancement vs combined airway and positional therapy for snoring: a randomized clinical trial. *JAMA Otolaryngol Head N*
Published online May 23, 2024. doi:10.1001/jamaoto.2024.1035

Respiratory Medicine 234 (2024) 107826

Contents lists available at ScienceDirect

Respiratory Medicine

journal homepage: www.elsevier.com/locate/rmed

Hypoglossal nerve stimulation for obstructive sleep apnea in adults: An updated systematic review and meta-analysis

Warda A. Alrubasy [a,1], Mohammad T. Abuawwad [a,1], Mohammad J.J. Taha [a], Mohammed Khurais [a], Muhammad Sabrah Sayed [a], Amneh M. Dahik [a], Noha Keshk [b,c], Sameh Abdelhadi [a], Hashem Abu Serhan [d,*]

[a] Department of Clinical Medicine, Kasr Alainy Faculty of Medicine, Cairo University, Egypt
[b] University and Department of Pharmacy Practice, Purdue University, USA
[c] Department of Clinical Pharmacy, Mansoura University, Egypt
[d] Depa

4.9.3. Success rate

In the included studies the success rate among patients undergoing HNS therapy was defined according to the Sher criteria, which required a 50 % reduction in AHI and an overall AHI <20. Patients meeting these criteria were considered responders to therapy. In the included studies, the rates of responders among patients who received the Inspire device were as follows: 69.4 % at 6 months, 93.5 % at 12 months, 64 % at 18 months, 77 % at 2 years, 70 % at 3 years and 75 % at 5 years. For the Apnex device, the rates were 67 % at 6 months and 55 % at 12 months. And for ImThera device the rate of responders was 76.9 % at 6 months and 35 % at 12 months.

4.9.2. Adherence:

The included studies reported high adherence among patients to nightly HNS device use. On average, patients used the device for approximately 5.7 h per night, with a median of 5.8 h [IQR 6.1–5.4] hours. Notably, the STAR trial, reported patient self-reported rates of nightly device use as follows: 86 % at 1 year, 81 % at 3 years, 81 % at 4 years, and 80 % at 5 years.

Inspire

Meta Analysis-Updated 2024-High Quality Study Design:

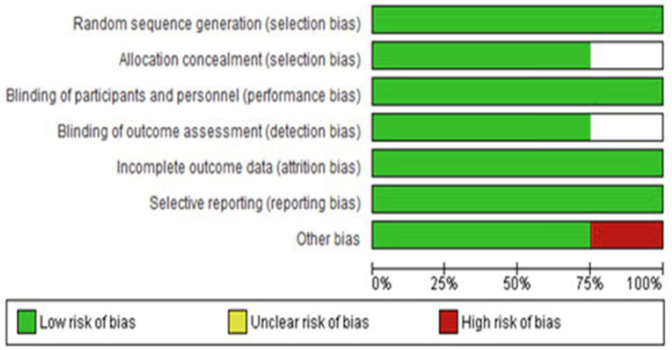


Fig. 3. Risk of bias summary for RCTs using Cochrane Risk of Bias Tool.

Table 3
Summarization of the reported adverse events.

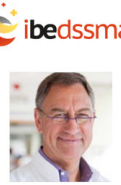
Nature of the adverse events	Type of the adverse event	Percentage
Commonly reported adverse events	Perception of the stimulation sensation	33 %
	intermittent tongue sores and abrasions	27 %
	pain at the incision site	24 %
	numbness and paresthesia at the incision sites	13.2 %
	temporary tongue weakness	12.5 %
	bleeding	7 %
	postoperative infection	6 %
	device malfunction and cuff dislodgement	5 %
	postoperative hematoma	4 %
	anesthesia complications	1 %
Serious adverse events[a]	device malfunction	7.8 %
	painful stimulation	0.7 %
	pain	2.8 %
	infection	3 %
	hematoma and bleeding	2 %
	device migration	1.6 %
Less commonly reported non serious adverse events	dysarthria, local edema, painful swallowing, tongue fasciculation, the twiddler phenomenon, and fever	

[a] These adverse events were described as serious in their corresponding studies.

Belgium Study: 91% Success Reducing "Moderate or Severe" to "no or Mild" OSA

Oral Appliance Treatment in general hospital setting: effects on obstructive apnea-hypopnea index (oAHI) measured with polygraphy, at multiple general hospitals.

Marc BRAEM[1,2], DDS, PhD
(1) Translational Neurosciences, Faculty of Medicine and Health Sciences, University of Antwerp, Wilrijk, Belgium;
(2) Department of ENT, Head and Neck Surgery, Antwerp University Hospital, Edegem, Belgium Oral Appliance Clinic (Edegem, BE)

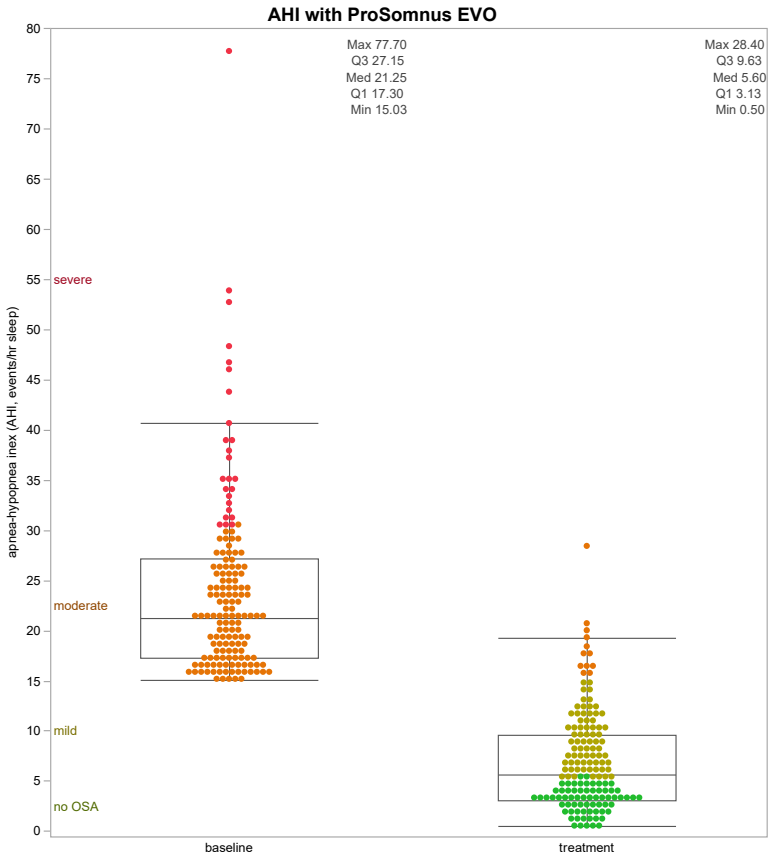


Aims: To evaluate the effectiveness of a specific OA in patients diagnosed with OSA, fitted and followed-up at multiple (six) general hospitals, in terms of improvement in obstructive apnea-hypopnea index (oAHI), scored on polygraphy (type 3) at each sleep centre.

findings (n=152)

- Significant reduction in median AHI from **21.2** to ***5.6 events/hr sleep*** [IQR = 6.5] with $p < 0.0001$ in the study population
- Reducing OSA severity to:
  - "**no OSA**" in n = **68**/152 (45%)
  - "**mild** OSA" in n = **71**/152 (47%)
  - ***"no OSA" + "mild OSA" = 139/152 (91%)***
  - "**moderate** OSA" in n = **12**/152 (8%)
  - "**severe OSA**" in n = **0**/152 (0%)

success definition	overall n=152	moderate n=127	severe n=25
Δ AHI < 0 and AHI_MAD < 5	45%	46%	40%
Δ AHI < 0 and AHI_MAD < 10	79%	80%	72%
Δ AHI < 0 and AHI_MAD < 15	92%	94%	76%



These are impressive results and suggest precision post appliances are not inferior to Inspire, and should be considered first. The newest precision post appliances would likely get even better results.

success definition	overall n=152	moderate n=127	severe n=25
Δ AHI < 0 and AHI_MAD < 5	45%	46%	40%
Δ AHI < 0 and AHI_MAD < 10	79%	80%	72%
Δ AHI < 0 and AHI_MAD < 15	92%	94%	76%

If using Sher criteria (used for Inspire success rates) which defines success as AHI improvement of 50% and AHI below 20, we would see a higher than %76 success rate for treating severe OSA with precision post oral appliances.

Note, there is consensus by researchers that AHI is not a great measurement to evaluate OSA success (it does not predict improved health outcomes, cardiovascular benefits, or all-cause mortality), as I will show in future slides. There is growing consensus that hypoxic burden is a better metric to evaluate treatment success. My clinic will soon be able to measure hypoxic burden using the latest photoplethysmogram (PPG) technology in our sleep studies and chips that are now being embedded in my oral appliances (pending FDA clearance)- Stay Tuned!

NOTUS 3 Study: 85% achieved their treatment goals

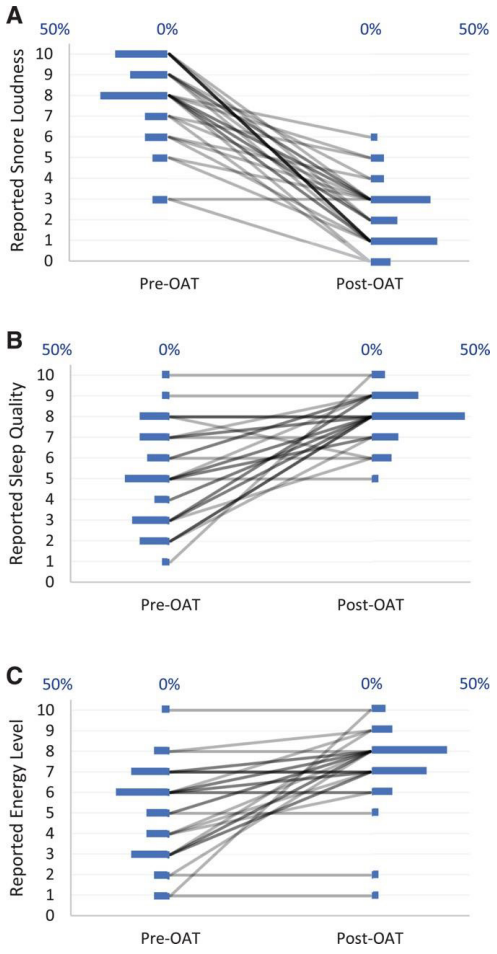
JCSM | Journal of Clinical Sleep Medicine

SCIENTIFIC INVESTIGATIONS

In-home mandibular repositioning during sleep using MATRx plus predicts outcome and efficacious positioning for oral appliance treatment of obstructive sleep apnea

Erin V. Mosca, PhD[1]; Sabina Bruehlmann, PhD[1]; Shaelynn M. Zouboules, BSc[1]; Alexandra E. Chiew, BSc[1]; Curtis Westersund, DDS[2]; Dillon A. Hambrook, PhD[1]; Seyed A. Zareian Jahromi, PhD[1,3]; Joshua Grosse, MMath[1]; Zbigniew L. Topor, PhD[1,3]; Shouresh Charkhandeh, DDS[1]; John E. Remmers, MD[1,3]

[1]Zephyr Sleep Technologies, Calgary, Canada; [2]Dentalife, Calgary, Canada; [3]University of Calgary, Calgary, Canada



- 85% achieved their stated treatment goals
- 97% reported reduction in snoring
  - Median snoring reduction of 6-points on a 10-point snoring scale
- 68% reported improved sleep quality
- 61% reported improved daytime energy levels

Oral appliances being titrated using now discontinued MATRx system (mechanically moved lower jaw forward during sleep to determine ideal jaw position)- I effectively do the same thing in my clinic by evaluating multiple different lower jaw positions with extensive multi-night sleep testing- where you set the jaw matters

Study Design

- Independent, prospective clinical study
- Sample size = 58:
  - Mild = 18, Mod = 15, Severe = 25
- Intervention:
  - Oral Appliance Therapy
  - MATRx plus and Precision intraoral devices (ProSomnus)
- Baseline
  - AHI = 31.4; ODI = 32.2; BMI = 30.7

- Adverse Events
  - Serious adverse events = 0
  - Non-serious adverse events
    - Teeth irritation = 12.1%
    - Jaw irritation = 15.2%
    - Gums irritation = 0.0%
    - Excessive salivation = 6.1%
    - Sleep disturbance = 3.0%
  - Non-serious adverse events were transient

FLOSAT: OAT Non-inferior to CPAP in Prospective H2H X-over Trial

Comparison of clinical effectiveness and patients' preference for two non-invasive treatment options for patients diagnosed with moderate to severe obstructive sleep apnea: The FLOSAT Study - UPDATE

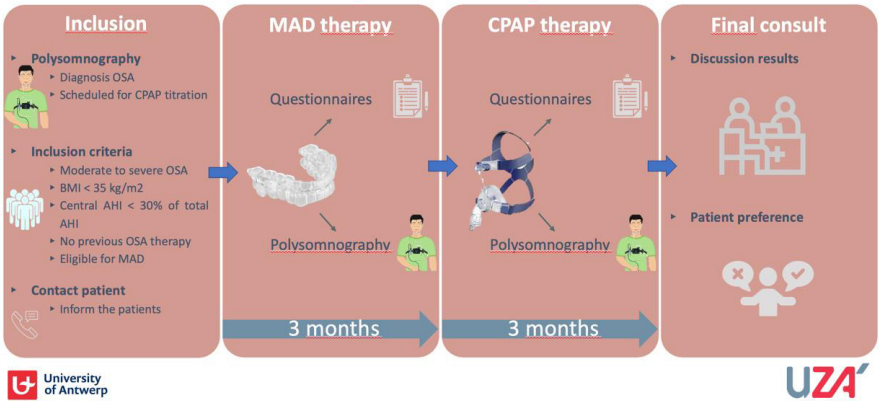
Marijke Dieltjens, Shouresh Charkhandeh, Karlien Van den Bossche, Sanne Engelen, Dorine Van Loo, Johan Verbraecken, Marc J. Braem, Olivier M. Vanderveken

*All slides are courtesy of the Sleep Research Team at the UZA lead by Prof. Dr. Vanderveken & Prof. Marijke Dieltjens
- Kindly granted permission to be presented by the presenter (Dr. Shouresh Charkhandeh)
- Ahead of Publication

University of Antwerp

ibedssma
Interdisciplinary Belgian Dental and Surgical Sleep Medicine Academy

fwo



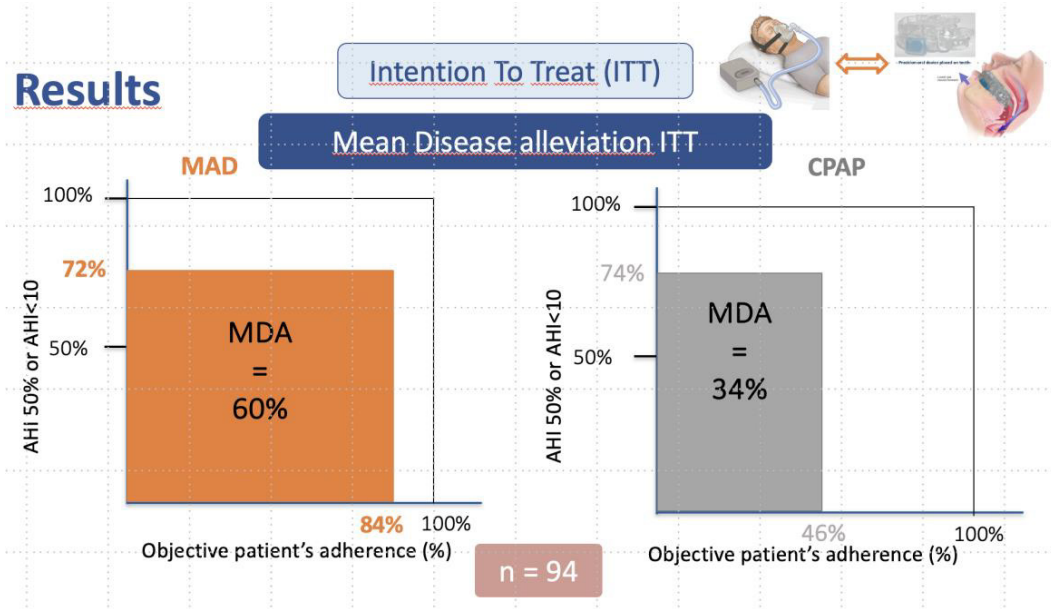
University of Antwerp

UZA

Results

Intention To Treat (ITT)

Mean Disease alleviation ITT



n = 94

Putting it into perspective

FLOSAT

- Comparable, equal and non-inferior (or even better) effectiveness of MAD relative to CPAP in this pragmatic study in the light of CPAP supply shortage
- CPAP 22% discontinuing users in first 3 months – MAD 2% discontinuing users
- Greater efficacy of CPAP being offset by inferior adherence relative to the statistically significant higher overnight usage MAD
- Confirming other published data in the literature on equal effectiveness of CPAP and MAD

Why put everyone on CPAP first if the true clinical effectiveness of this therapy is not higher than other OSA therapies such as a custom-made MAD evaluated in this trial – MAD as first line OSA therapy

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Head-to-Head X-Over Trial: Effectiveness of Precision OAT as front-line treatment for moderate and severe OSA at least non-inferior to CPAP

Comparison of clinical effectiveness and patients' preference for two non-invasive treatment options for patients diagnosed with moderate to severe obstructive sleep apnea: The FLOSAT Study - UPDATE

Marijke Dieltjens, Shouresh Charkhandeh, Karlien Van den Bossche, Sanne Engelen, Dorine Van Loo, Johan Verbraecken, Marc J. Braem, Olivier M. Vanderveken

*All slides are courtesy of the Sleep Research Team at the UZA lead by Prof. Dr. Vanderveken & Prof. Marijke Dieltjens
- Kindly granted permission to be presented by the presenter (Dr. Shouresh Charkhandeh)
- Please do not take any photos, as the data is not published yet

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Interdisciplinary Belgian Dental and Surgical Sleep Medicine Academy

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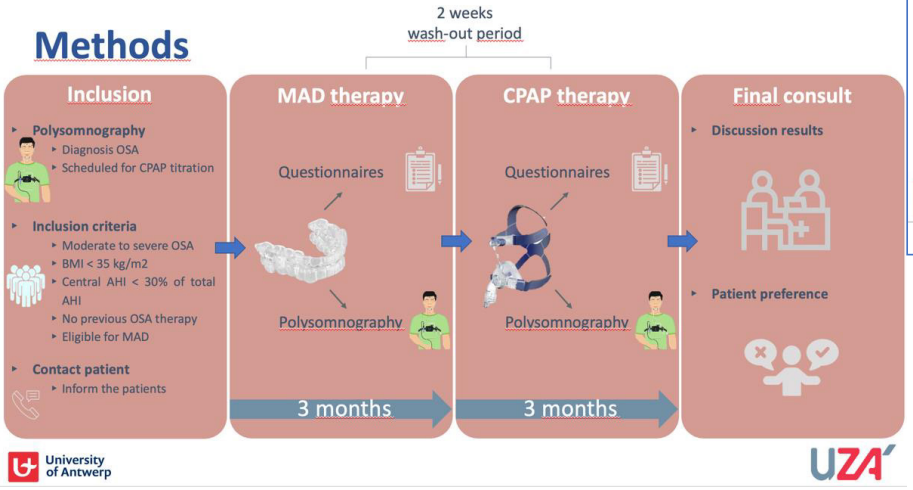
Methods



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UZA

FLOSAT

Putting it into perspective

- Comparable, equal and non-inferior (or even better) effectiveness of MAD relative to CPAP in this pragmatic study in the light of CPAP supply shortage
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Why put everyone on CPAP first if the true clinical effectiveness of this therapy is not higher than other OSA therapies such as a custom-made MAD evaluated in this trial – MAD as first line OSA therapy

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The Precision Post MAD's are a first line option to treat OSA

WEST MICHIGAN CPAP Alternatives
Customized Sleep Apnea Solutions
Dr. Vandervelden

AHRQ: Insufficient evidence AHI Predicts Health Outcomes

Technology Assessment Program

Project ID: SLPT0919

Long-Term Health Outcomes in Obstructive Sleep Apnea: A Systematic Review of Comparative Studies Evaluating Positive Airway Pressure and the Validity of Breathing Measures as Surrogate Outcomes

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract No. 290-2015-00002-I
Task Order No. 75Q80119F32017

Prepared by:
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Wangnan Cao, Ph.D.
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Shaun Forbes, Ph.D.
Shivani Mehta, M.P.H.
Orestis Panagiotou, M.D., Ph.D.
Carolyn D'Ambrosio, M.D.
Thomas A. Trikalinos, M.D., Ph.D.

Conclusions. Studies are highly inconsistent as to how they define breathing measures during sleep studies and OSA itself. Insufficient evidence exists to assess the validity of change in AHI as a surrogate or intermediate measure for long-term health outcomes. Until such validation has been conducted, it cannot be assumed that changes (e.g., improvements) in intermediate or surrogate outcomes are correlated with long-term health outcomes.

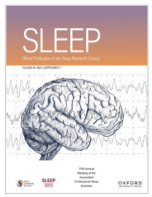
RCTs do not provide evidence that CPAP prescription affects long-term, clinically important outcomes. Specifically, with low SoE, RCTs do not demonstrate that CPAP affects all-cause mortality, various CV outcomes, clinically important changes in psychosocial measures, or other clinical events. NRCSs reported associations between CPAP use and reduced risk of all-cause death. NRCS results did not differ from RCTs for other outcomes. We have limited confidence that the summary estimates are close to any true effect.

Comparative studies did not adequately address whether the effect of CPAP varies based on disease severity (e.g., as assessed by AHI), symptoms (e.g., as assessed by sleepiness scales), other patient characteristics, different features or modes or CPAP, or different criteria or definitions of sleep measures or OSA diagnosis.

Additional well-conducted comparative studies are needed to better assess the potential effects of CPAP on long-term outcomes for patients with OSA, whether any particular group of patients may benefit to a greater or lesser degree from CPAP treatment, and whether of changes in AHI (and/or other breathing measures) are valid intermediate or surrogate measures of health outcomes. Associations identified in comparative studies could serve as the basis for more rigorous trials.

Momentum is building to use Sleep Apnea Specific Hypoxic Burden (SASHB) over AHI in the future to better determine OSA treatment success. There is growing awareness that AHI is a poor predictor of overall health outcomes, cardiovascular benefits, and all-cause mortality. SASHB shows greater promise to predict the things we care most about.

SASHB Study: 91% Success Improving SASHB to a Safe Level (SASHB<60%min/h)



Volume 46, Issue Supplement_1 May 2023

JOURNAL ARTICLE

0513 Assessing precision oral appliance efficacy using frequency- and risk-based indices FREE

Erin Mosca, Joshua Grosse, Seyed Abdolali Zareian Jahromi, John Remmers

Sleep, Volume 46, Issue Supplement_1, May 2023, Pages A226–A227,
https://doi.org/10.1093/sleep/zsad077.0513
Published: 29 May 2023

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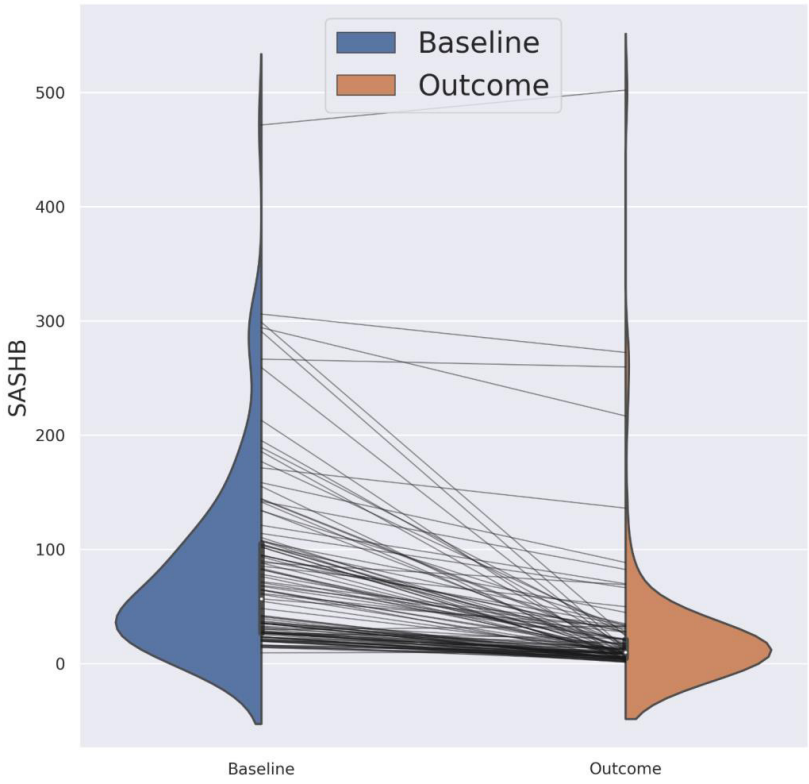
METHODS: Data previously obtained from two clinical studies that investigated the prediction of response to precision OAT in OSA were analyzed. Data from 109 participants with OSA (n = 36 mild, n = 35 moderate, and n = 38 severe) completed two-night type 3 home sleep tests before and after receiving an oral appliance (ProSomnus Sleep Technologies, Pleasanton, CA). Apnea-hypopnea index and SASHB were calculated. For SASHB, a cut-off of 53 %min/h was used based on data indicating that values above this limit are associated with OSA-related risk; for AHI, cut-offs of $< 10\ h^{-1}$ and $< 15\ h^{-1}$ were used because of their prevalence in clinical practice.

RESULTS: Of the participants with mild OSA at baseline, none had a baseline SASHB ≥ 53 %min/h, whereas 54% of participants with moderate and 97% of participants with severe OSA had a baseline SASHB ≥ 53 %min/h. Precision oral appliance therapy reduced AHI from 29.1 ± 20.3 h^{-1} to 10.5 ± 14.6 h^{-1} ($p < 0.001$) and SASHB from 81.8 ± 79.4 %min/h to 27.3 ± 63.2 %min/h ($p < 0.001$). Using an AHI-based definition of therapeutic efficacy, 85% (for AHI $< 15\ h^{-1}$) and 76% (for AHI $< 10\ h^{-1}$) of participants achieved efficacy with precision OAT. However, when the risk-based SASHB definition of therapeutic efficacy (SASHB < 53 %min/h) was used, precision OAT efficacy increased to 91%. When assessed by severity, 89% of moderate and 68% of severe participants achieved an AHI $< 15\ h^{-1}$ and 77% of moderate and 55% of severe participants achieved an AHI $< 10\ h^{-1}$. When SASHB < 53 %min/h was used to define therapeutic efficacy, efficacy increased to 94% for moderate and 79% for severe OSA.



When using Sleep Apnea Specific Hypoxic Burden (SASHB), OAT is over 94% effective for moderate OSA and 79% effective in Severe OSA cases according to this study. Previous studies on OAT effectiveness for severe OSA suggest success rates of only 30%, but when you take a deeper look they are using AHI below 5 as "success", using legacy appliances that do not work as well, provide limited lower jaw adjustments, and rely on single night sleep studies. You will see similar flaws in other research that shows limited benefit for OAT. Sadly, I see sleep doctors still referencing these flawed studies.

WEST MICHIGAN CPAP Alternatives
Customized Sleep Apnea Solutions
Dr. Vandervelden

Integrating Body Sensor into a Wearable Platform to Enhance the Identification of Central and Mixed Apneas

GU, Wenbo[1,2]; WU, Peter[2]; LIU, Arthur[2]; LIU, Wen-Te[3]; KUAN, Yi-Chun[3]; LEE, Hsin-Chien[4]; LEUNG, Lydia[2]; WU,I-Chen[1]; CHIANG, Ambrose[5]

INTRODUCTION

Accurate identification of apnea types is crucial for effective diagnosis and management of sleep-disordered breathing. The Belun Sleep System (BLS-100, a.k.a., Belun Ring (Figure 1a) is an FDA-cleared home sleep apnea testing system (K222579) comprising an adjustable ring-shaped wearable, a cradle, and deep learning-powered algorithms. The Belun Cor (Figure1b and 1c), a novel BLS-100 subxiphoid sensor equipped with accelerometry, can detect respiratory effort, respiratory rate, and body position, and facilitates the detection of central events. This preliminary analysis aims to assess the performance of the integrated BLS-100 in detecting apnea events containing central components.

METHODS

This interim analysis evaluated the performance of BLS-100 in a clinical cohort of hospitalized patients admitted for acute ischemic stroke. Eligible patients underwent in-lab polysomnography (PSG) alongside concurrent BLS-100 testing. PSG scoring adhered to the latest AASM scoring manual, with scoring technicians blinded to the BLS-100 results. The BLS-100 derived total sleep time (bTST), sleep stages (bSTAGE), apnea-hypopnea index (bAHI), and combined central and mixed apnea index (bCMAI).

RESULTS

As of 12/17/2023, 25 consecutive Taiwanese patients were enrolled. Four patients were excluded due to short bTST (<120 mins). The analysis was conducted on 21 patients (Table1). M:F 19:2; age 59.7; PSG TST 270 ± 61.9mins; PSG AHI 27.0 (1.4-81.9) with 3 normal, 3 mild, 7 moderate, and 8 severe OSA cases. The mean PSG central apnea index (PSG-CAI) was 4.8 (0.0-34.0), with 5 patients having PSG-CAI ≥5. The mean PSG central and mixed apnea index (PSG-CMAI) was 8.4 (0.0-47.3). Pearson correlation coefficients between PSG-CAI and bCMAI, as well as PSG-CMAI and bCMAI, were 0.939 (P<0.001) and 0.982 (P<0.001), respectively (Table 2). Using bCMAI ≥5 to predict PSG-CAI ≥5, the accuracy, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and Cohen's Kappa were 0.81, 1.00, 0.75, 0.56, 1.00, and 0.59, respectively(Table 3). Similarly, using bCMAI ≥5 to predict PSG-CMAI ≥5, the corresponding values were 0.86, 0.88, 0.85, 0.78, 0.92, and 0.70, respectively (Table 3).

CONCLUSION

Early findings indicate that the BLS-100 with Belun Cor shows promising performance in identifying apnea events that include central components. An elevated bCMAI serves as a valuable indicator for clinicians, signaling the presence of central or mixed apneas.

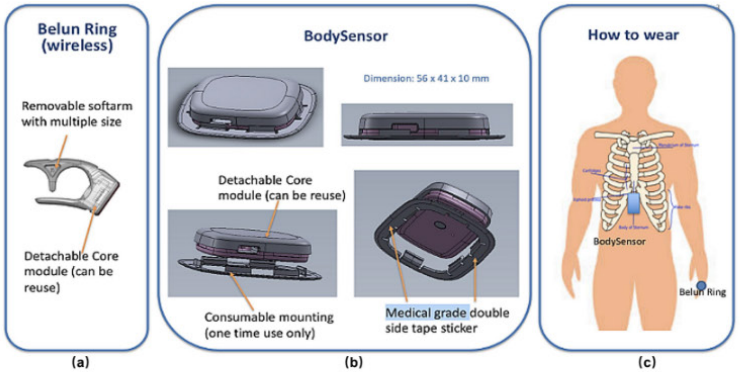


Figure1. Belun Sleep System (Belun Ring & Belun Cor)

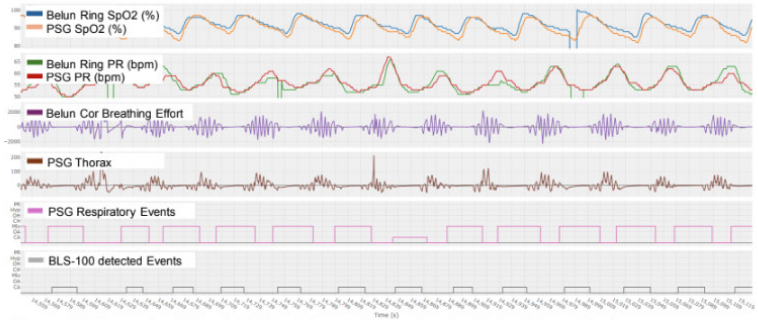


Figure 2. Example of Central/Mixed Apnea Detection by Belun Sleep System

Table 1. Patient Demography

Variables	Mean ± SD	Range
No. of subjects	21	-
Age	59.7 ± 10.0	40 ~ 75
Sex, M/F	-	M:19, F:2
BMI (kg/m²)	26.6 ± 3.1	20.2 ~ 32.2
AHI4 (events/hr)	27.1 ± 22.9	1.4 ~ 81.9
CAI (events/hr)	4.8 ± 8.2	0 ~ 34.0
CMAI (events/hr)	8.4 ± 15.1	0 ~ 47.3

Table 2. Estimation Error of bCMAI vs. PSG CAI/CMAI

Ring vs. PSG	Correlation	Mean Absolute Error	Error Mean ±SD
bCMAI vs. PSG CAI	0.939	6.09	5.73 ±11.22
bCMAI vs. PSG CMAI	0.982	2.66	2.18 ± 4.65

Table 3. Performance endpoints of bCMAI

Cut-off	Accuracy	Sensitivity	Specificity	PPV	NPV	LR+	LR-	Kappa
CAI ≥ 5	81.0%	100.0%	75.0%	55.6%	100.0%	inf	0.44	0.59
CMAI ≥ 5	85.7%	87.5%	84.6%	77.8%	91.7%	9.33	0.20	0.70

Table 4. Confusion Matrix (bCMAI vs. PSG CAI)

	PSG-CAI			
	< 5	5~10	10~15	≥15
bCMAI <5	12	0	0	0
bCMAI 5~10	4	1	0	0
bCMAI 10~15	0	1	0	0
bCMAI >15	0	1	0	2

Table 5. Confusion Matrix (bCMAI vs. PSG CMAI)

	PSG-CMAI			
	< 5	5~10	10~15	≥15
bCMAI <5	11	1	0	0
bCMAI 5~10	2	3	0	0
bCMAI 10~15	0	0	1	0
bCMAI >15	0	0	0	3

1. Department of Computer Science, National Yang Ming Chiao Tung University; 2. Belun Technology Company Limited, Hong Kong; 3. Sleep Center, Shuang Ho Hospital, Taipei Medical University; 4. Department of Psychiatry, Taipei Medical University Hospital; 5. Division of Pulmonary, Critical Care, and Sleep Medicine, Case Western Reserve University;

Market launch expected 2026 (I already have early access to this tech)

Key advances:

- Central/mixed apnea detection
- **Next generation BelunRing sleep reports will show Hypoxic Burden.**

Multi-Center Study: 89% Success AHI < 10 (All Severities)

Cureus
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PMID: 38077673

December 07, 2023 Original Article

Evaluating the Clinical Performance of a Novel, Precision Oral Appliance Therapy Medical Device Made Wholly From a Medical Grade Class VI Material for the Treatment of Obstructive Sleep Apnea

Edward Sall, Kent Smith, Aditi Desai, John A. Carollo, Mark T. Murphy, Sung Kim, Leonard A. Liptak

PUBLIC HEALTH INTERNAL MEDICINE OTOLARYNGOLOGY

Objective

The objective of this study is to evaluate the clinical performance of a novel, precision, oral appliance therapy (OAT) medical device made entirely from a US Pharmacopeia (USP) medical grade class VI qualified material for the treatment of obstructive sleep apnea (OSA).

Results

Go to:

The study population consisted of 91 patients diagnosed with OSA. The mean age was 53.3 +/- 11.4 years. Sixty-seven percent of patients were male; 33% were female. The mean, baseline AHI was 23.9 +/- 16.7 events per hour. The maximum, baseline patient AHI was 116 events per hour. The minimum, baseline patient AHI was 6 events per hour. Thirty (33%), 36 (40%), and 25 (27%) patients were classified with mild, moderate, and severe OSA, respectively.

Outcome #1: The mean improvement in AHI events per hour relative to baseline was 76.7% with the novel OAT intervention.

Outcome #2: Eighty-nine percent of the patients enrolled in this study were efficaciously, successfully, treated, achieving the AHI < 10 performance goal.

Outcome #3: Ninety-eight and one-half percent of the sixty-six patients diagnosed with mild to moderate OSA were successfully treated to the performance goal of AHI < 10. Of the twenty-five patients classified with severe OSA, 80% successfully demonstrated efficacy with the novel OAT device according to the Sher's criteria performance goal of AHI <20 and 50%.

Keep in mind, these studies do not use the newest and most effective oral appliances. Expect success rates to be even higher.

	Sample Size	Baseline AHI	Residual AHI	Significance Level
Total Sample	91	23.9 +/- 16.7	5.6 +/- 5.3	P < 0.0001
Mild and Moderate OSA	66	16.2 +/- 6.1	3.8 +/-2.4	P < 0.0001
Severe OSA	25	44.4 +/-18.7	10.2 +/-7.8	P < 0.0001

WEST MICHIGAN CPAP Alternatives
Customized Sleep Apnea Solutions
Dr. Vandervelden

Carlton Study: 75% Success AHI < 10

DENTAL SLEEP PRACTICE

Is Selecting the Appropriate Sleep Device for You and Your Patient Important?

by Dr. David "Trey" Carlton III

Study Design

- Retrospective, comparative, independent study
- Sample size = 37
- Interventions
  - Group 1: n = 20 received traditional OAT devices (others)
  - Group 2: n = 17 received Precision Intraoral Device (ProSomnus)
- Testing
  - Baseline: polysomnography
  - Follow up: home sleep testing

Key Finding: Favorable Residual AHI for Patients Treated with Precision OAT Devices

Table 2: Comparison of average PSG outcomes for Populations 1 and 2

Population	AVG Initial PSG	AVG Final HST	AVG Delta AHI
1	33.5 +/- 22.7	11.9 +/- 8.9	24.9 +/- 16.3
ProSomnus	35.6 +/- 23.1	9.0 +/- 8.6	27.8 +/- 21.1

Additional Findings

- Fewer appointments and reduced mean time to treatment for patients treated with precision OAT devices

Table 4: Comparison of Appointment Efficiency for Populations 1 and 2

Population	Treatment Appointments	Treatment Duration Months
1	7.8 +/- 3.6	10.3 +/- 7.0
ProSomnus	6.0 +/- 3.0	3.8 +/- 2.9

Detroit Study: 84% Success to AHI <10

JDSM

ABSTRACTS

http://dx.doi.org/10.15331/jdsm.7208

2021 AADSM Virtual Annual Meeting Abstracts

ABSTRACT #004

DOSE MANAGEMENT IN DSM; ANALYSIS OF EFFICACY, STARTING POSITION, ADVANCEMENT AND SIDE EFFECTS IN A CONSECUTIVE PATIENT SERIES TREATED WITH PRECISION PLATFORM Mark Murphy DDS D ABDSM, Kimberly Munro Facility Director[2]

1 Funktional Sleep; 2 Funktional Sleep

Study Design

- Retrospective, company supported study
- Sample size = 50 consecutive patients
  - Mild = 19, Moderate = 19, Severe = 12
- Intervention
  - Precision oral appliance therapy (ProSomnus EVO)
  - Starting position: 50% range of motion (ROM)

Key Findings

- 92% of mild and moderate OSA patients successfully treated to an AHI < 10
- 84% of mild, moderate and severe successfully treated to an AHI < 10

Additional Findings

- 76% overall reduction in AHI
- Mean starting position was 50.3% of range
  - Mean titration of 1.29 mm [range 0.0 – 5.0 mm]
  - 80% treated within 2 mm of starting position
  - 36% required no titration from starting position

Military 1 Study: 86% Success AHI < 10 (All Severities)

MILITARY MEDICINE, 00, 0/0:1, 2021

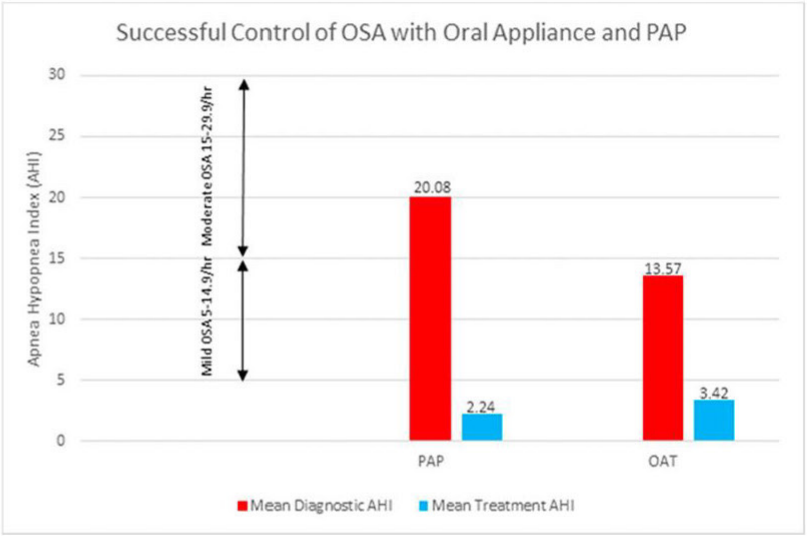
Oral Appliances for OSA Treatment: Meeting the Quadruple Aim

S. Knowles, MD, MSBA, FAASM; Matthew Dekow, DMD, MS, ABGD, FAGD, D-ABDSM; Michele L. Williamson, RRT

Study Design

- Independent, retrospective study, n = 288
- Comparison: pre/post; sleep clinic PAP data
- 50% mild, 31% moderate, 19% severe
- Intervention:
  - Oral Appliance Therapy
  - Precision Intraoral Devices (ProSomnus)

Key Finding: 85.5% Successfully Treated with Precision OAT



Additional Findings

- Estimated cost savings of $500k/year versus treating same patients with CPAP
- 72.9% treated to AHI < 5

NOTUS 3 Trial: 81% Success Improving All Severities of OSA to ODI < 10

JCSM | Journal of Clinical Sleep Medicine

SCIENTIFIC INVESTIGATIONS

In-home mandibular repositioning during sleep using MATRx plus predicts outcome and efficacious positioning for oral appliance treatment of obstructive sleep apnea

Erin V. Mosca, PhD[1]; Sabina Bruehlmann, PhD[1]; Shaelynn M. Zouboules, BSc[1]; Alexandra E. Chiew, BSc[1]; Curtis Westersund, DDS[2]; Dillon A. Hambrook, PhD[1]; Seyed A. Zareian Jahromi, PhD[1,3]; Joshua Grosse, MMath[1]; Zbigniew L. Topor, PhD[1,3]; Shouresh Charkhandeh, DDS[1]; John E. Remmers, MD[1,3]

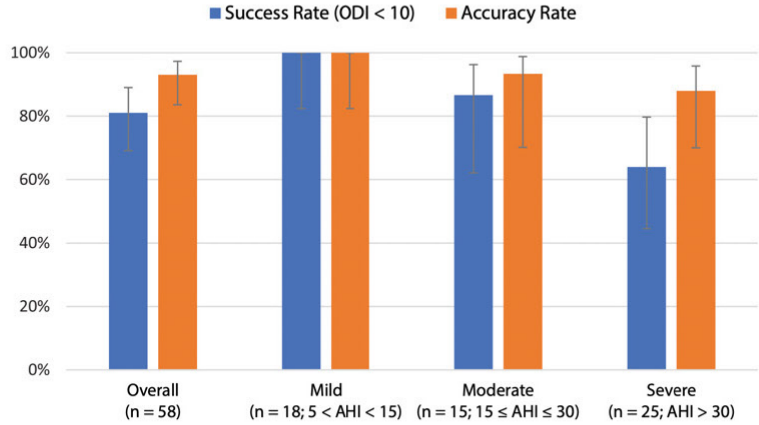
[1]Zephyr Sleep Technologies, Calgary, Canada; [2]Dentalife, Calgary, Canada; [3]University of Calgary, Calgary, Canada

Study Design

- Independent, prospective clinical study
- Sample size = 58: Mild=18, Mod = 15, Severe =25
- Intervention:
  - Oral Appliance Therapy
  - MATRx plus and Precision intraoral devices (ProSomnus)
- Baseline
  - AHI = 31.4; ODI = 32.2; BMI = 30.7

Key Finding: 94% success ODI < 10 treating mild/mod OSA with ProSomnus precision intraoral devices

Figure 2—Therapeutic success rate and AI prediction accuracy across OSA severity levels.



Additional Findings

- 81% success (ODI < 10) for entire study population
- 84.8% of patients reported achieving their treatment goals
- 96.7% reported a reduction in snoring
  - Median reduction of 6 points on 10-point scale

Portugal Study: 95% Success Improving to AHI < 10

Age [IQR]	55.50 [47.00, 64.00]
Gender F(%)/M(%)	6 (27.3)/16 (72.7)
BMI (median [IQR])	29 [28.00, 32.00]
AHI before [IQR])	21 [10.00, 24.75]
ODI before [IQR])	19 [10.50, 21.00]
AHI after [IQR])	4 [2.00, 6.00]
ODI after [IQR])	4 [2.00, 5.00]

Table 1 The demographic data of the 22 eligible subjects

Material & Methods

Twenty-two patients, six females and sixteen males with the median age of 55.5 years, median BMI of 29.5 with a base-line AHI of 21 (min 6; max 29) and an ODI of 19 (min 6 max 27) were included in this study. The demographic data are summarized in Table 1. Seven of the patients had another treatment modality for OSA with unsatisfactory compliance/efficacy (four subjects were under treatment with OA and three with CPAP). A level III sleep study was performed (Philips Alice) without treatment and after 4 weeks of adaptation to OA.

81% decrease in AHI

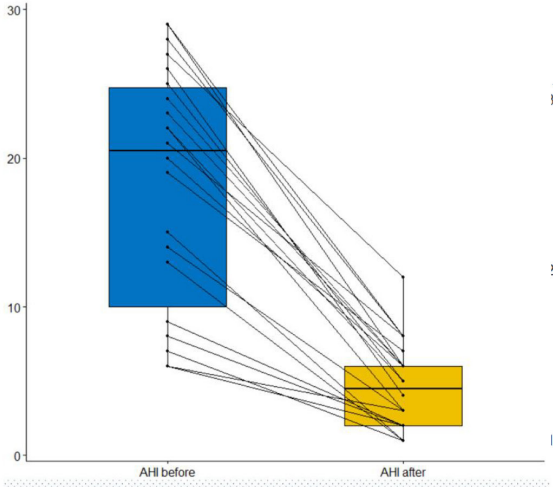


Fig. 2 Individual AHI before and after treatment with OA

79% decrease in ODI

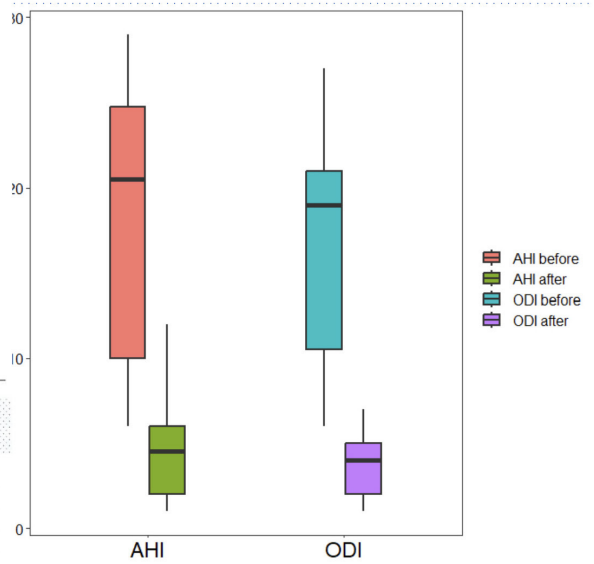


Fig. 1 The median AHI and ODI before and after treatment with OA

San Diego Study: 85% Success AHI < 15

JDSM

ABSTRACTS

http://dx.doi.org/10.15331/jdsm.7146

AADSM Accepted Late-Breaking Abstracts (2020)

IS THE RELATIONSHIP BETWEEN OAT OUTCOMES, DOSAGE AND OAT DEVICE TYPE AS EXPECTED? A PRIVATE PRACTICE, RETROSPECTIVE COHORT STUDY.

Rohatgi R[1]

[1]*San Diego Sleep Therapy, San Diego, CA*

Study Design

- Retrospective, independent study
- 306 consecutively treated patients
  - Baseline: AHI = 22.2, ESS = 12.3, BMI = 28.8
- Intervention
  - Oral Appliance Therapy
  - Precision intraoral devices (ProSomnus)
  - Traditional oral devices (Others)

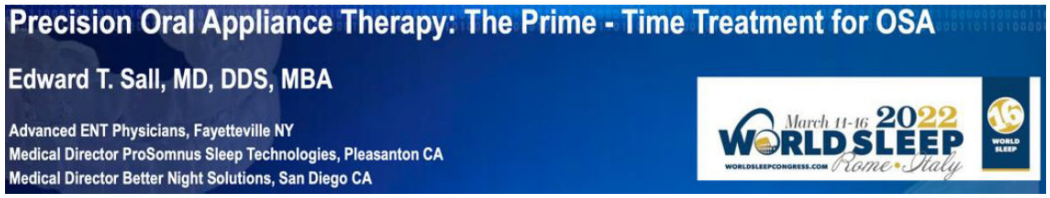
Key Finding

- 85% of patients achieved an AHI < 15 using a precision oral device at 30% protrusion

Additional Findings

- Precision intraoral device at 30% protrusion demonstrated better/non-inferior outcomes than non-precision oral devices at 60% and 90% protrusions
- At 30% protrusion with a precision intraoral device:
  - 73% achieved AHI < 10
  - ESS improved 79%

Syracuse Study: 87% Success AHI < 10



Study Design

- Retrospective, private practice, independent study
- Sample characteristics:
  - 115 consecutive patients with complete pre/post test data
  - Baseline AHI 24.1 events/hr
  - Mild 41.7%, Moderate 33.0%, Severe 25.2%
- Intervention
  - Oral Appliance Therapy
  - Precision intraoral therapy devices (ProSomnus EVO)
- COI: Dr. Sall is Medical Director for ProSomnus

Key Finding: 90.7% success (AHI < 10) for mild and moderate OSA patients

Table 1 Success Metrics

Severity	N	<10	>50%	>50%&<10
All	115	87.0%	80.9%	74.8%
Mild	48	100.0%	72.9%	72.9%
Moderate	38	78.9%	78.9%	76.3%
Severe	29	75.9%	96.6%	75.9%

Table 2 Residual AHI

Severity	Pre-AHI	STDEV	Residual AHI	STDEV
All	24.1	+/-19.2	6.1	+/-6.4
Mild	10.4	+/-2.6	3.9	+/-2.3
Moderate	20.7	+/-3.9	6.1	+/-4.4
Severe	51.5	+/-18.7	9.9	+/-10.5

Table 3 Change Percentages

	AHI Reduction	O2 Increase	RDI Reduction
All	69.2%	4.6%	61.0%
Mild	62.3%	3.4%	53.5%
Moderate	68.9%	5.0%	55.4%
Severe	81.1%	6.1%	71.2%

Army Study: OAT Outperformed CPAP on Wellness Variables

APHC
U.S. ARMY PUBLIC HEALTH CENTER
8252 Blackhawk Road, Aberdeen Proving Ground, Maryland 21010-5403

Technical Report No. S.0079064.3-21, May 2022
Clinical Public Health and Epidemiology Directorate

Obstructive Sleep Apnea Surveillance and Oral Appliance Therapy Evaluation, Active Duty U.S. Army, 2014–2019

Study Design and Sample Characteristics

- Independent, retrospective survey design
- Sample size = 8,740 surveys completed
- Interventions:
  - CPAP 93% (n= 8,128)
  - Oral Appliance Therapy 9% (n = 360)
    - Majority received precision intraoral devices (ProSomnus)
    - Remainder received non-precision intraoral devices
  - Note: Some patients received both OAT and CPAP

Key Findings: Statistically Significant Improvement

Table 16. Comparison of Pre- to Post-Treatment Wellness Ratings, Men Treated with Oral Appliance Exclusively

		Before	After	Wilcoxon Signed-Rank	Change in mean (%)
Wellness Variable	N	Median; Mean±SD	Median; Mean±SD	p-value[a]	
Sleep quality[b]	272	2; 2.10±0.91	4; 3.45±0.93	<0.001	+64
Hours of sleep/night	257	5; 5.35±1.15	6; 6.23±1.06	<0.001	+18
Performance[c]	272	3; 3.13±0.97	4; 3.85±0.91	<0.001	+23
Cognition[d]	272	3; 3.16±1.04	4; 3.84±0.95	<0.001	+22
Alertness[e]	272	3; 3.10±0.97	4; 3.83±0.91	<0.001	+24
Physical activity[f]	272	3; 3.36±1.09	4; 3.89±0.99	<0.001	+16
Fatigue[g]	272	2; 1.99±0.95	3; 3.04±1.03	<0.001	+53
Excessive daytime sleepiness[g]	269	2; 2.24±1.06	3; 3.22±1.09	<0.001	+44
Feeling rested[h]	272	2; 2.24±0.82	3; 3.22±0.93	<0.001	+44

Additional Findings

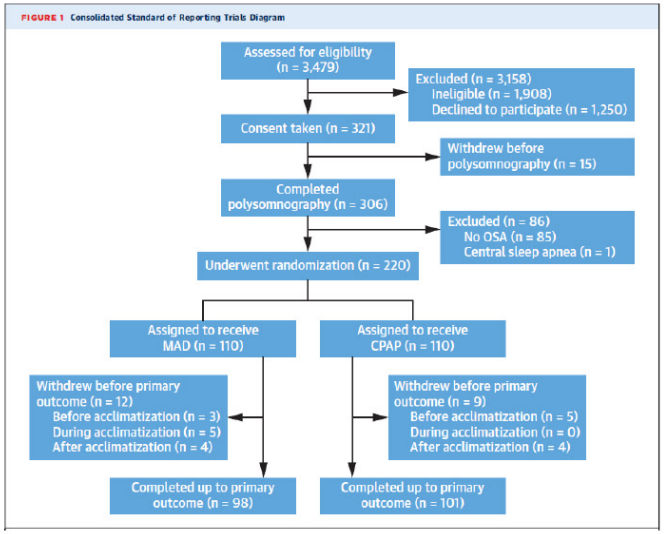
- Soldiers treated with OAT outperformed those treated with "other" methods (CPAP) on all measures
  - Sleep quality, hours of sleep per night, performing tasks, cognition, alertness, fatigue, daytime sleepiness, and feeling rested
- 88% nightly adherence, 28 months of mean use

Oral Devices Non-Inferior to CPAP for Reducing Mean Arterial Blood Pressure

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 83, NO. 18, 2024

Mandibular Advancement vs CPAP for Blood Pressure Reduction in Patients With Obstructive Sleep Apnea

Yi-Hui Ou, BSc (Pharm),[a] Juliana Tereza Colpani, DDS, MS,[b] Crystal S. Cheong, MBBS,[c] Weiqiang Loke, BDS,[b] As tar Thant, RPSGT,[a] E' Ching Shih, MBBS,[c] Frank Lee, BDS,[b] Siew-Pang Chan, PhD,[a,d,e] Ching-Hui Sia, MBBS,[e] Chieh-Yang Koo, MBBS,[e] Serene Wong, MBBS,[f] Aiping Chua, MBBS,[g] Chin-Meng Khoo, MBBS,[a] William Kong, MBBS, PhD,[a,e] Calvin W. Chin, MD, PhD,[h,i] Pipin Kojodjojo, MBBS, PhD,[e] Philip E. Wong, MBBS,[j] Mark Y. Chan, MBBS, PhD,[a,d,e] A. Mark Richards, MD, PhD,[a,d,e,k] Peter A. Cistulli, MBBS, PhD,[l,m] Chi-Hang Lee, MBBS, MD[a,d,e]



RESULTS Compared with baseline, the 24-hour mean arterial BP decreased by 2.5 mm Hg ($P = 0.003$) at 6 months in the MAD group, whereas no change was observed in the CPAP group ($P = 0.374$). The between-group difference was −1.6 mm Hg (95% CI: −3.51 to 0.24, noninferiority $P < 0.001$). The MAD group demonstrated a larger between-group reduction in all secondary ambulatory BP parameters compared with the CPAP group, with the most pronounced effects observed in the asleep BP parameters. Both the MAD and CPAP improved daytime sleepiness, with the between-group difference similar ($P = 0.384$). There were no between-group differences in cardiovascular biomarkers.

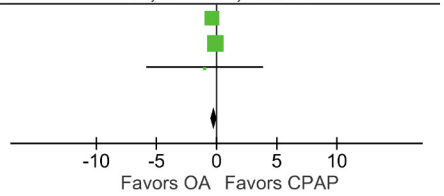
CONCLUSIONS MAD is noninferior to CPAP for reducing 24-hour mean arterial BP in participants with hypertension and increased cardiovascular risk. (Cardiosleep Research Program on Obstructive Sleep Apnea, Blood Pressure Control and Maladaptive Myocardial Remodeling—Non-inferiority Trial [CRESCENT]; NCT04119999)
(J Am Coll Cardiol 2024;83:1760–1772)

Diastolic BP RCTs Modestly Favor Oral Devices vs. CPAP; Quality of Evidence Considered Low

Figure 70—OAs vs. CPAP for OSA (Diastolic blood pressure).

	OA			CPAP				Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Barnes 2004	76.3	0.7	80	76.7	0.8	80	46.2%	-0.40 [-0.63, -0.17]	
Phillips 2013	77.1	0.7	108	77.2	0.7	108	53.5%	-0.10 [-0.29, 0.09]	
Trzepizur 2009	63	5.2	12	64	7.4	14	0.3%	-1.00 [-5.87, 3.87]	
Total (95% CI)			**200**			**202**	**100.0%**	**-0.24 [-0.50, 0.02]**	

Heterogeneity: Tau² = 0.02; Chi² = 3.98, df = 2 (P = 0.14); I² = 50%
Test for overall effect: Z = 1.84 (P = 0.07)

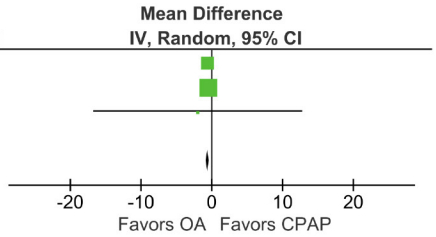


Systolic BP RCTs Modestly Favor Oral Devices vs. CPAP; Quality of Evidence Considered Low

Figure 69—OAs vs. CPAP for OSA (Systolic blood pressure).

	OA			CPAP				Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Barnes 2004	126.7	1	80	127.3	1.2	80	40.1%	-0.60 [-0.94, -0.26]	
Phillips 2013	123.9	1.1	108	124.4	1	108	59.8%	-0.50 [-0.78, -0.22]	
Trzepizur 2009	140	22.2	12	142	14.8	14	0.0%	-2.00 [-16.76, 12.76]	
Total (95% CI)			**200**			**202**	**100.0%**	**-0.54 [-0.76, -0.32]**	

Heterogeneity: Tau² = 0.00; Chi² = 0.23, df = 2 (P = 0.89); I² = 0%
Test for overall effect: Z = 4.88 (P < 0.00001)



Why put everyone on CPAP first if the true clinical effectiveness of this therapy is not higher than other OSA therapies such as a custom-made MAD evaluated in this trial –

MAD as first line OSA therapy

University of Antwerp

UZA

Successful OAT Correlates with Hypertrophic Remodeling of the IVS after 6 Months

JCSM | Journal of Clinical Sleep Medicine

SCIENTIFIC INVESTIGATIONS

Mandibular advancement device treatment and reverse left ventricular hypertrophic remodeling in patients with obstructive sleep apnea

Marijke Dieltjens, PhD[1,2]; Olivier M. Vanderveken, MD, PhD[1,2]; Bharati Shivalkar, MD, PhD[1,3,4]; Gilles Van Haesendonck, MD[1,2]; Chloé Kastoer, PhD[1,2]; Hein Heidbuchel, MD, PhD[1,5]; Marc J. Braem, DDS, PhD[1,2]; Caroline M. Van De Heyning, MD, PhD[1,5]

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Study Objectives: Obstructive sleep apnea (OSA) is associated with cardiovascular comorbidities such as left ventricular (LV) hypertrophy. Whether OSA is an independent etiological factor for this hypertrophic remodeling is yet unknown. Continuous positive airway pressure partially reverses this hypertrophy, but data regarding the effect of mandibular advancement devices on LV remodeling are scarce. The aim of this prospective trial is to evaluate the effect of mandibular advancement device therapy on LV geometry and function in patients with OSA.

Methods: At baseline and 6-month follow-up, participants underwent a home sleep apnea test, 24-hour ambulatory blood pressure monitoring and a 2-dimensional Doppler and tissue Doppler echocardiography.

Results: Sixty-three patients (age: 49 ± 11 years; body mass index: 27.0 ± 3.4 kg/m^2; baseline apnea-hypopnea index home sleep apnea test: 11.7 [8.2; 24.9] events/h) completed the 6-month follow-up visit. Overall, blood pressure values and parameters of LV function were within normal ranges at baseline and did not change under mandibular advancement device therapy. In contrast, the interventricular septum thickness was at the upper limits of normal at baseline and showed a significant decrease at 6-month follow-up (11.1 ± 2.1 mm vs 10.6 ± 2.0 mm, $P = .03$). This significant improvement is only found in responders but not in nonresponders. There was no correlation between the decrease of interventricular septum thickness and the change in blood pressure.

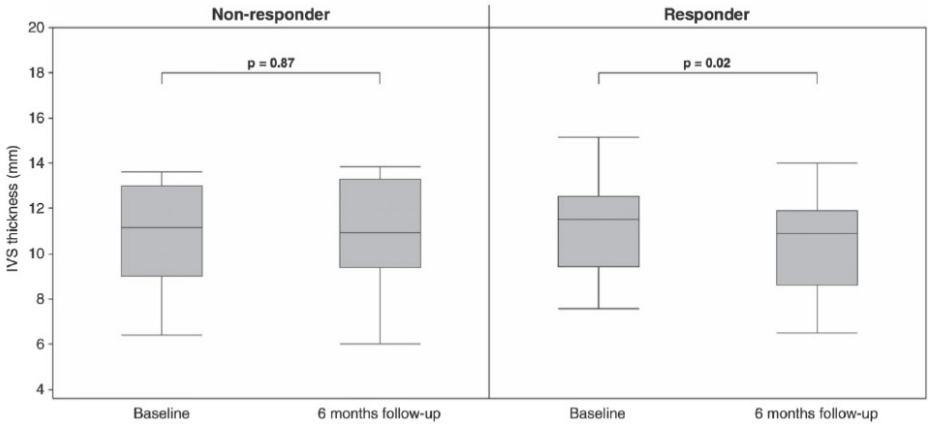
Conclusions: In mildly obese, normotensive patients with OSA we observed significant reverse hypertrophic remodeling after 6 months of successful mandibular advancement device therapy, with maintained normotensive systemic blood pressure. This suggests that OSA is an independent factor in the pathophysiology of LV hypertrophy in these patients.

Clinical Trial Registration: Registry: ClinicalTrials.gov; Name: Evaluation of the Cardiovascular Effects of the MAS in the Treatment of Obstructive Sleep Apnea; URL: https://clinicaltrials.gov/ct2/show/NCT02320877; Identifier: NCT02320877.

Keywords: hypertrophic remodeling, cardiovascular aspects, mandibular advancement treatment

Citation: Dieltjens M, Vanderveken OM, Shivalkar B, et al. Mandibular advancement device treatment and reverse left ventricular hypertrophic remodeling in patients with obstructive sleep apnea. *J Clin Sleep Med.* 2022;18(3):903–909.

Figure 2—Evolution of the interventricular septum thickness after 6 months of MAD therapy in responders vs nonresponders.



The IVS thickness improved significantly after 6 months of MAD therapy in the responders (n = 40) (11.1 ± 2.0 mm vs 10.5 ± 1.8 mm, $P = .022$) but not in the nonresponders (n = 19) (10.8 ± 2.2 mm vs 10.8 ± 2.3 mm, $P = .872$). IVS = interventricular septum, MAD = mandibular advancement device.

CONCLUSIONS

Overall, the results of this clinical trial showed that successful MAD therapy is able to reverse hypertrophic remodeling of the IVS at 6-month follow-up, regardless of systemic BP, suggesting that OSA is an independent factor in the pathophysiology of LVH in these patients.

★ "we observed significant hypertrophic remodeling after 6 months of successful mandibular advancement device therapy"

Successful OAT Treatment Correlated with Improved Cardiac Autonomic Adaptability

SLEEP BREATHING PHYSIOLOGY AND DISORDERS • ORIGINAL ARTICLE

Effect of mandibular advancement splint therapy on cardiac autonomic function in obstructive sleep apnoea

Seren Ucak[1] · Hasthi U. Dissanayake[1,2] · Kate Sutherland[1,2] · Yu Sun Bin[1,2] · Philip de Chazal[1,3] · Peter A. Cistulli[1,2]

Received: 31 May 2023 / Revised: 11 August 2023 / Accepted: 13 September 2023 / Published online: 28 September 2023

Abstract

Purpose This study aimed to evaluate the effect of mandibular advancement splint (MAS) therapy on cardiac autonomic function in patients with obstructive sleep apnoea (OSA) using heart rate variability (HRV) analysis.

Methods Electrocardiograms (ECG) derived from polysomnograms (PSG) of three prospective studies were used to study HRV of patients with OSA before and after MAS treatment. HRV parameters were averaged across the entire ECG signal during N2 sleep using 2-min epochs shifted by 30 s. Paired *t*-tests were used to compare PSG and HRV measures before and after treatment, and the percent change in HRV measures was regressed on the percent change in apnoea-hypopnea index (AHI).

Results In 101 patients with OSA, 72% were Caucasian, 54% men, the mean age was 56 ± 11 years, BMI 29.8 ± 5.3 kg/m^2, and treatment duration was 4.0 ± 3.2 months. After MAS therapy, there was a significant reduction in OSA severity (AHI, − 18 ± 16 events per hour, $p < 0.001$) and trends towards increased low-frequency to high-frequency ratio, low-frequency power, and reduced high-frequency power (LF:HF, − 0.4 ± 1.5, $p = 0.01$; LF, − 3 ± 16 nu, $p = 0.02$, HF, 3.5 ± 13.7 nu, $p = 0.01$). Change in NN intervals correlated with the change in AHI (β(SE) = − 2.21 (0.01), $t = -2.85$, $p = 0.005$). No significant changes were observed in the time-domain HRV markers with MAS treatment.

Conclusion The study findings suggest that successful MAS treatment correlates with changes in HRV, specifically the lengthening of NN intervals, a marker for improved cardiac autonomic adaptability.

Table 1 Description of time and frequency domain HRV measures. Adapted from Malik et al. 1996 [10]

	Description	Physiological interpretation
Time domain measures		
Average NN interval, ms	Average time between consecutive R-peaks	Primarily parasympathetic cardiac modulation
SDNN, ms	Standard deviation of normal to normal intervals	Global HRV measure
RMSSD, ms	Root mean square of successive RR interval differences	Primarily parasympathetic cardiac modulation
pNN50, %	Percentage of successive RR interval that differ by more than 50 ms	Primarily parasympathetic cardiac modulation
Frequency domain measures		
TP, ms2	The absolute power of the frequency spectrum, excluding the very low frequency band (> 0.004 Hz)	Global HRV measure
LF, ms2	Absolute power of the low-frequency band (0.04–0.15 Hz)	Sympathetic with a parasympathetic component
HF, ms2	Absolute power of the high-frequency band (0.15–0.4 Hz)	Primarily parasympathetic cardiac modulation
LF:HF, nu	Ratio of LF-to-HF power	Sympathovagal balance
LF, nu	Relative power of the low-frequency band (0.04–0.15 Hz) in normal units	Primarily sympathetic cardiac modulation
HF, nu	Relative power of the high-frequency band (0.15–0.4 Hz) in normal units	Primarily parasympathetic cardiac modulation

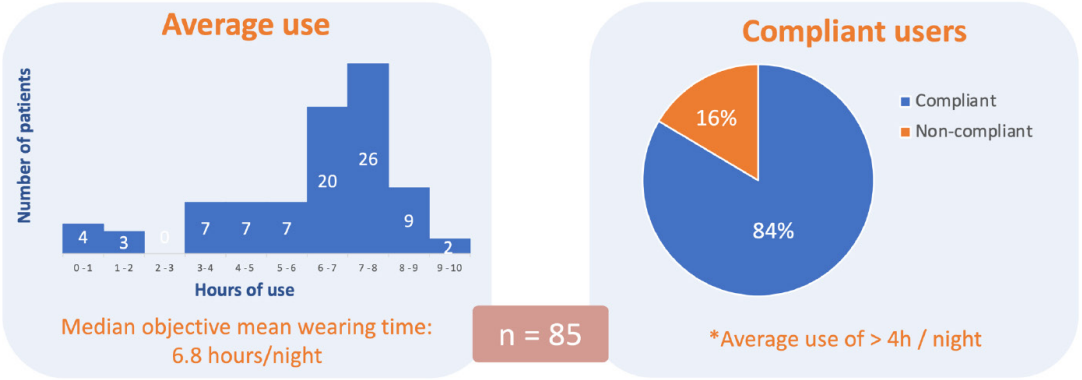
Change in HRV markers	Model 1[a]			Model 2[b]		
	β (SE)	*t*	*p*	*β* (SE)	*t*	*p*
ΔavgNN, ms	− 0.07 (4.84)	− 2.84	0.989	− 2.21 (0.78)	− 2.85	0.005
ΔSDNN, ms	− 0.01 (0.28)	− 0.32	0.752	− 0.02 (0.03)	− 0.66	0.510
ΔRMSSD, ms	0.21 (3.56)	0.06	0.955	− 0.42 (0.57)	− 0.72	0.471
ΔpNN50, %	0.21 (0.58)	0.35	0.720	− 0.17 (0.09)	− 1.87	0.065
ΔTP, ms^2	− 226.96 (928.02)	− 0.24	0.807	− 0.01 (0.01)	− 0.42	0.671
ΔLF, ms^2	− 85.73 (243.14)	− 0.04	0.725	− 0.06 (0.01)	− 0.59	0.550
ΔHF, ms^2	− 122.29 (558.97)	− 0.21	0.827	− 0.05 (0.01)	− 0.45	0.648
ΔLF:HF	0.09 (0.07)	1.43	0.156	− 0.22 (1.01)	− 0.22	0.822
ΔLF_{nu}	0.62 (0.68)	− 0.63	0.525	− 0.03 (0.10)	− 0.36	0.719
ΔHF_{nu}	− 0.33 (0.60)	− 0.55	0.580	− 0.09 (0.11)	− 0.84	0.401

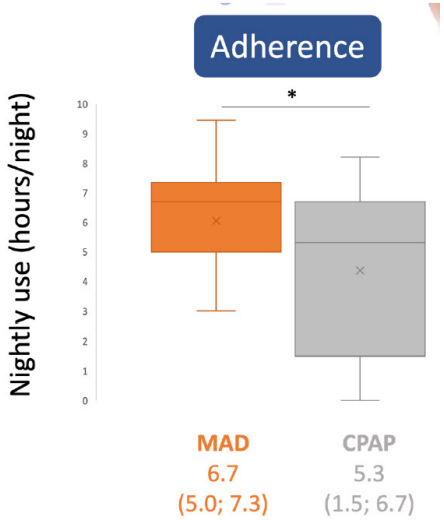
[a]Model 1. Change in HRV marker as the outcome variable and treatment duration as a predictor

[b]Model 2. Change in HRV marker as the outcome variable and treatment duration and change in AHI as a predictor

"MAS (oral appliance) treatment correlates with changes in HRV (heart rate variability)..lengthening NN intervals, a marker for improved cardiac autonomic adaptability"

FLOSAT Study: 6.8 Hours Mean Nightly Usage with ProSomnus vs. 5.3 Hours for CPAP





Alaska Study: 7.4 Hours Mean Nightly Usage

JDSM

ORIGINAL ARTICLES

http://dx.doi.org/10.15331/jdsm.7024

Evaluation of a New Oral Appliance With Objective Compliance Recording Capability: A Feasibility Study

Jerry Hu, DDS[1]; Len Liptak, MBA[2]

[1]Jerry Hu Family Dentistry, Soldotna, Alaska; [2]ProSomnus Sleep Technologies, Pleasanton, California

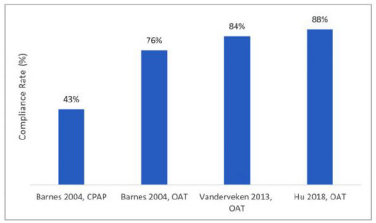
Study Design

- Prospective, company supported, pilot study
- Sample size = 8
- Interventions:
  - Precision oral appliance therapy (ProSomnus)
  - Thermosensor (Braebon)

Figure 2—Oral appliance with compliance recording chip.

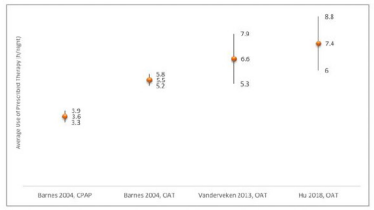
Key Finding: 88% Compliance

Figure 3—Compliance rate comparison.



Additional Finding: 7.4 hours mean nightly use

Figure 4—Nightly use comparison.



Inspire Adherence: 5.7 hours Mean Nightly Usage

4.9.2. Adherence:

The included studies reported high adherence among patients to nightly HNS device use. On average, patients used the device for approximately 5.7 h per night, with a median of 5.8 h [IQR 6.1–5.4] hours. Notably, the STAR trial, reported patient self-reported rates of nightly device use as follows: 86 % at 1 year, 81 % at 3 years, 81 % at 4 years, and 80 % at 5 years.

WEST MICHIGAN CPAP Alternatives
Customized Sleep Apnea Solutions
Dr. Vandervelden

The Mandate for Non-CPAP OSA Therapy Options

J Clin Med. 2021 Mar 1;10(5):936. doi: 10.3390/jcm10050936.

CPAP Therapy Termination Rates by OSA Phenotype: A French Nationwide Database Analysis

Jean-Louis Pépin [1], Sébastien Bailly [1], Pierre Rinder [2], Dan Adler [3], Daniel Szeftel [2], Atul Malhotra [4], Peter A Cistulli [5], Adam Benjafield [6], Florent Lavergne [7], Anne Josseran [7], Renaud Tamisier [1], Pierre Hornus [2], On Behalf Of The medXcloud Group

Affiliations + expand

PMID: 33804319 PMCID: PMC7957656 DOI: 10.3390/jcm10050936

Abstract

The nationwide claims data lake for sleep apnoea (ALASKA)-real-life data for understanding and increasing obstructive sleep apnea (OSA) quality of care study-investigated long-term continuous positive airway pressure (CPAP) termination rates, focusing on the contribution of comorbidities. The French national health insurance reimbursement system data for new CPAP users aged ≥18 years were analyzed. Innovative algorithms were used to determine the presence of specific comorbidities (hypertension, diabetes and chronic obstructive pulmonary disease (COPD)). Therapy termination was defined as cessation of CPAP reimbursements. A total of 480,000 patients were included (mean age 59.3 ± 13.6 years, 65.4% male). An amount of 50.7, 24.4 and 4.3% of patients, respectively, had hypertension, diabetes and COPD. Overall CPAP termination rates after 1, 2 and 3 years were 23.1, 37.1 and 47.7%, respectively. On multivariable analysis, age categories, female sex (1.09 (1.08-1.10) and COPD (1.12 (1.10-1.13)) and diabetes (1.18 (1.16-1.19)) were significantly associated with higher CPAP termination risk; patients with hypertension were more likely to continue using CPAP (hazard ratio 0.96 (95% confidence interval 0.95-0.97)). Therapy termination rates were highest in younger or older patients with ≥1 comorbidity. Comorbidities have an important influence on long-term CPAP continuation in patients with OSA.

- High rate of co-morbidities
  - 50.7% of OSA patients have hypertension
- 47.7% terminate CPAP after three years
- Termination rates do not include:
  - Those who refused CPAP at onset
  - Non-compliant users; have not terminated CPAP but do not wear it often enough

In conclusion, this analysis of a dataset covering almost the entire French population showed that the presence of comorbidities was an important contributor to termination or continuation of CPAP therapy in patients with OSA. Given the diversity of OSA patient phenotypes, it is highly unlikely that a "one size fits all" approach is suitable. We suggest that patient phenotyping and personalized care approaches that determine the most appropriate therapy and therapy support options should be important features of an integrated sleep-disordered breathing management strategy. Individualizing care and providing the treatment most likely to be acceptable and effective for each patient should optimize therapy and improve patient outcomes.

Studies have shown that long term adherence to CPAP is only 25.7% after 1 year for mild OSA.

Qiao et al. BMC Pulmonary Medicine (2023) 23:320 https://doi.org/10.1186/s12890-023-02612-3

CPAP for Prevention of Cardiovascular Events in Obstructive Sleep Apnea

R. Doug McEvoy, M.D., Nick A. Antic, M.D., Ph.D., Emma Heeley, Ph.D., Yuanming Luo, M.D., Qiong Ou, M.D., Xilong Zhang, M.D., Olga Mediano, M.D., Rui Chen, M.D., Luciano F. Drager, M.D., Ph.D., Zhihong Liu, M.D., Ph.D., Guofang Chen, M.D., Baoliang Du, M.D., Nigel McArdle, M.D., Sutapa Mukherjee, M.D., Ph.D., Manjari Tripathi, M.D., Laurent Billot, M.Sc., Qiang Li, M.Biostat., Geraldo Lorenzi-Filho, M.D., Ferran Barbe, M.D., Susan Redline, M.D., M.P.H., Jiguang Wang, M.D., Ph.D., Hisatomi Arima, M.D., Ph.D., Bruce Neal, M.D., Ph.D., David P. White, M.D., Ron R. Grunstein, M.D., Ph.D., Nanshan Zhong, M.D., and Craig S. Anderson, M.D., Ph.D., for the SAVE Investigators and Coordinators*

ABSTRACT

BACKGROUND

Obstructive sleep apnea is associated with an increased risk of cardiovascular events; whether treatment with continuous positive airway pressure (CPAP) prevents major cardiovascular events is uncertain.

METHODS

After a 1-week run-in period during which the participants used sham CPAP, we randomly assigned 2717 eligible adults between 45 and 75 years of age who had moderate-to-severe obstructive sleep apnea and coronary or cerebrovascular disease to receive CPAP treatment plus usual care (CPAP group) or usual care alone (usual-care group). The primary composite end point was death from cardiovascular causes, myocardial infarction, stroke, or hospitalization for unstable angina, heart failure, or transient ischemic attack. Secondary end points included other cardiovascular outcomes, health-related quality of life, snoring symptoms, daytime sleepiness, and mood.

RESULTS

Most of the participants were men who had moderate-to-severe obstructive sleep apnea and minimal sleepiness. In the CPAP group, the mean duration of adherence to CPAP therapy was 3.3 hours per night, and the mean apnea–hypopnea index (the number of apnea or hypopnea events per hour of recording) decreased from 29.0 events per hour at baseline to 3.7 events per hour during follow-up. After a mean follow-up of 3.7 years, a primary end-point event had occurred in 229 participants in the CPAP group (17.0%) and in 207 participants in the usual-care group (15.4%) (hazard ratio with CPAP, 1.10; 95% confidence interval, 0.91 to 1.32; P=0.34). No significant effect on any individual or other composite cardiovascular end point was observed. CPAP significantly reduced snoring and daytime sleepiness and improved health-related quality of life and mood.

CONCLUSIONS

Therapy with CPAP plus usual care, as compared with usual care alone, did not prevent cardiovascular events in patients with moderate-to-severe obstructive sleep apnea and established cardiovascular disease. (Funded by the National Health and Medical Research Council of Australia and others; SAVE ClinicalTrials.gov number, NCT00738179; Australian New Zealand Clinical Trials Registry number, ACTRN12608000409370.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. McEvoy at the Adelaide Institute for Sleep Health, Flinders University and Respiratory and Sleep Services, Southern Adelaide Local Health Network, Repatriation General Hospital, Daw Park, Adelaide SA 5041, Australia, or at doug.mcevoy@flinders.edu.au; or to Dr. Luo at the First Affiliated Hospital of Guangzhou Medical University, State Key Laboratory of Respiratory Disease, Guangzhou, China, or at yuanmingluo9431@yahoo.co.uk.

*A complete list of sites and trial investigators and coordinators in the Sleep Apnea Cardiovascular Endpoints (SAVE) study is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on August 28, 2016, at NEJM.org.

N Engl J Med 2016;375:919-31.
DOI: 10.1056/NEJMoa1606599

Highlights:

- 2,717 patients
- RCT trial- High Quality-Global study
- 3.7 year duration
- No reduced Cardiovascular Incidents were observed between CPAP group and usual care alone.
- CPAP usage averaged only 3.3 hours per night

"CPAP plus usual care as compared with usual care alone, did not prevent cardiovascular events....."

To be fair, 3.3 hours of usage is low. That being said, we know many patients do struggle to use CPAP enough for it to benefit them. These are the patients you should refer for OAT.

CPAP May Counteract CV Benefits

eBioMedicine
Part of THE LANCET *Discovery Science*

eBioMedicine. 2024 Mar; 101: 105015.
Published online 2024 Feb 24. doi: 10.1016/j.ebiom.2024.105015
PMCID: PMC10944158
PMID: 38403558

Journal Article

CPAP may promote an endothelial inflammatory milieu in sleep apnoea after coronary revascularization

Yuksel Peker,[a,b,c,d,e] Yeliz Celik,[a,f,i] Afrouz Behboudi,[g,i] Susan Redline,[c] Jing Lyu,[f] Ying Wei,[f] Daniel J. Gottlieb,[c,h,**] and Sanja Jelic[f,*]

Journal Article

Interpretation

Greater CPAP levels increase proinflammatory, lung distension-responsive angiopoietin-2 and reduce cardioprotective angiogenic factor VEGF-A compared to usual care, which may counteract the expected cardiovascular benefits of treating OSA.

Previous studies suggest CPAP improves inflammation, but this studies suggests greater CPAP pressures may exacerbate inflammation.

There are no randomized control trials as of yet that show CPAP improves all-cause mortality or improves cardiovascular outcomes, and the RCT's that have been performed show CPAP doesn't help improve cardiovascular outcomes or improve mortality rates. But, to be fair, patient selection and adherence to CPAP seems to be a common struggle for researchers. I am not saying CPAP doesn't have a place, but adherence matters. When patients use CPAP for more than 5.3 hours a night and adhere to this long term, CPAP is likely best (based on FLOTUS study). For those who are not using CPAP enough, these are patients you should consider referring to my sleep practice.

Army Study: 88% Mean Nightly Usage at 28 months

APHC
U.S. ARMY PUBLIC HEALTH CENTER
8252 Blackhawk Road, Aberdeen Proving Ground, Maryland 21010-5403

Technical Report No. S.0079064.3-21, May 2022
Clinical Public Health and Epidemiology Directorate

Obstructive Sleep Apnea Surveillance and Oral Appliance Therapy Evaluation, Active Duty U.S. Army, 2014–2019

Key Findings: Statistically Significant Improvement

Table 16. Comparison of Pre- to Post-Treatment Wellness Ratings, Men Treated with Oral Appliance Exclusively

		Before	After	Wilcoxon Signed-Rank	Change in mean (%)
Wellness Variable	N	Median; Mean±SD	Median; Mean±SD	p-value[a]	
Sleep quality[b]	272	2; 2.10±0.91	4; 3.45±0.93	<0.001	+64
Hours of sleep/night	257	5; 5.35±1.15	6; 6.23±1.06	<0.001	+18
Performance[c]	272	3; 3.13±0.97	4; 3.85±0.91	<0.001	+23
Cognition[d]	272	3; 3.16±1.04	4; 3.84±0.95	<0.001	+22
Alertness[e]	272	3; 3.10±0.97	4; 3.83±0.91	<0.001	+24
Physical activity[f]	272	3; 3.36±1.09	4; 3.89±0.99	<0.001	+16
Fatigue[g]	272	2; 1.99±0.95	3; 3.04±1.03	<0.001	+53
Excessive daytime sleepiness[g]	269	2; 2.24±1.06	3; 3.22±1.09	<0.001	+44
Feeling rested[h]	272	2; 2.24±0.82	3; 3.22±0.93	<0.001	+44

Study Design and Sample Characteristics

- Independent, retrospective survey design
- Sample size = 8,740 surveys completed
- Interventions:
  - CPAP 93% (n = 8,128)
  - Oral Appliance Therapy 9% (n = 360)
    - Majority received precision intraoral devices (ProSomnus)
    - Remainder received non-precision intraoral devices
  - Note: Some patients received both OAT and CPAP

- Patient adhere to OAT long term.
- OAT improves overall health outcomes
- OAT adherence rates would be even higher if they only used the newest precision appliances in this study.

Additional Findings

- Soldiers treated with OAT outperformed those treated with "other" methods (CPAP) on all measures
  - Sleep quality, hours of sleep per night, performing tasks, cognition, alertness, fatigue, daytime sleepiness, and feeling rested
- **88% nightly adherence, 28 months of mean use**

US Military H2H Survey: Patients Prefer ProSomnus

PATIENT-PERCEIVED SUCCESS OF THREE COMMON ORAL APPLIANCES IN ORAL APPLIANCE THERAPY OF OBSTRUCTIVE SLEEP APNEA

A manuscript

Presented to the Faculty of the Advanced Education in General Dentistry, Two-Year Program,

United States Army Dental Health Activity, Schofield Barracks, HI

And the Uniformed Services University of the Health Sciences – Post Graduate Dental College

In Partial Fulfillment of the Requirements for the Degree of

Master of Science in Oral Biology

By

Gamal A. Baker, MAJ, DC, USA

April 2020

DENTAL

Uniformed Services University

DISCLAIMER

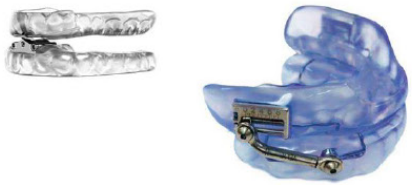
The views expressed in this manuscript are those of the author(s) and do not reflect the official policy or position of the Department of the Army, Uniform Services University of the Health Sciences, Department of Defense, or the US Government

Conclusion: In this study, the far more preferred appliance is the Prosomnus appliance.

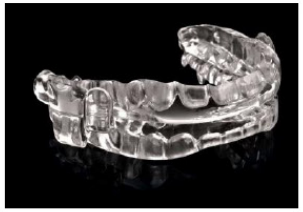
Study Devices

* denotes statistical significance

Anterior pull



Lateral Push



Precision Post (older generation)

Subjects "n"	12	13	30
Wearing my OAT is comfortable*	17%	8%	87%
Has reduced how loudly I snore	33%	8%	83%
Has reduced how often I snore	25%	0%	70%
Stopped wearing for any reason*	42%	54%	15%
Stopped wearing because uncomfortable*	33%	71%	7%
In the past week I wore my appliance 4+ nights*	50%	8%	87%

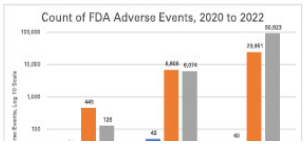
The newest precision post oral appliances are even more comfortable and require less forward lower jaw positioning.

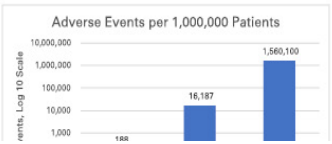
FDA MAUDE Database Study: Oral Devices Substantially Fewer Adverse Event Reports than CPAP or HNS

Introduction: This investigation analyzes adverse event reports (AERs) from the FDA MAUDE database for Continuous Positive Airway Pressure (CPAP), Hypoglossal Nerve Stimulation (HNS) and Oral Appliance Therapy (OAT) devices. Adverse events are defined by the FDA as undesirable experiences associated with medical devices that should be reported when the outcome is death, life threatening, hospitalization, disability, required intervention, or serious medical events.

Methods: The FDA MAUDE database is publicly available. For this investigation, the database was accessed on April 20, 2023. Publicly available industry reports were utilized to estimate prevalence (per 1,000,000) of AERs by device category.

Results, Overview:
AERs for CPAP were 126, 6,074 and 90,923 for the full years 2020, 2021 and 2022 respectively. AERs for HNS were 445, 6,806 and 23,951 for the same years. AERs for OAT were 24, 49 and 40 for the same years.





Results, Total AER "Device" Problems from 2020 to 2022:

Top 5 CPAP AER "Device Problems"		Top 5 HNS AER "Device Problems"		Top 5 OAT AER "Device Problems"	
Problem	Count	Problem	Count	Problem	Count
Degraded	101,141	Adverse Event Without Identified Problem	26,978	Adverse Event Without Identified Device or I	56
Contamination	806	Device Sensing Problem	2,500	Insufficient Information	33
Nonstandard Device	714	Migration or Expulsion of Device	1,012	Patient Device Interaction Problem	16
Patient-Device Incompatibility	346	Malposition of Device	270	Biocompatibility	14
Adverse Event Without Identified Problem	203	Detachment of Device	11	Break	10

Results, Total AER "Patient" Problems from 2020 to 2022:

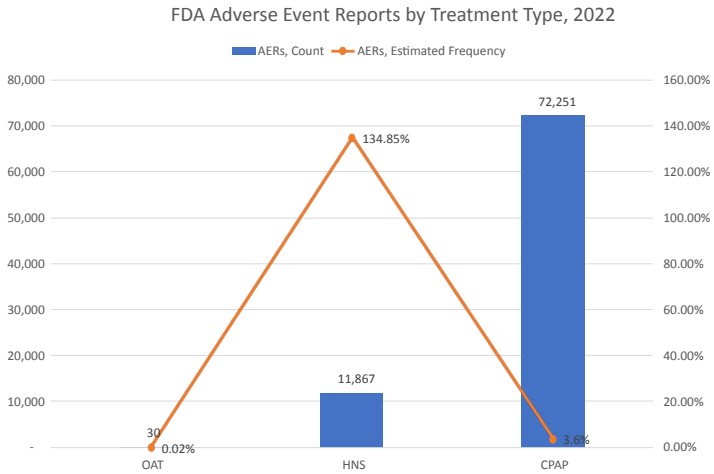
Top 5 CPAP AER "Patient Problems"		Top 5 HNS AER "Patient Problems"		Top 5 OAT AER "Patient Problems"	
Problem	Count	Problem	Count	Problem	Count
No Clinical Signs, Symptoms or Conditions	71,043	Unspecified Infection	7,207	Hypersensitivity/Allergic reaction	83
Dyspnea	9,221	Pain	5,966	Pain	9
Headache	8,444	Perforation of Vessels	3,250	Insufficient Information	6
Sore Throat	6,748	Erosion	3,610	Reaction	5
Respiratory Tract Infection	6,635	Hematoma	2,624	Ulcer	4

Conclusions: Healthcare providers may wish to consider the frequencies and severities of adverse events when selecting treatment for patients with OSA. OAT devices exhibited a rate of 188 AE's per million patients treated, 16,187 per million for CPAP and 1,560,100 per million for HNS.

Healthcare providers may place more weight on device materials, given that material may be associated with the most frequent and severe "device" and "patient" AERs.

Healthcare providers may place less weight on concerns for dental side effects from OATs. This data suggests that Dental Side effects are very low frequency and very low severity in terms of medically significant side effects.

- Key Conclusions
  - OAs have significantly fewer and lower frequency of FDA Adverse Event Reports than CPAP and HNS



- HNS and CPAP seem to have more severe AER patient problems than OAs
- Majority of adverse events reported for oral devices are tissue reactions due to the material, and not dental related

"Majority of adverse events reported for MAD's are material related." The newest appliances are allergy free, BPA free...

UoP Study: No Statistically Significant Dental Changes at 2-year Follow Up

JDSM

ORIGINAL ARTICLE

http://dx.doi.org/10.15331/jdsm.7070

Assessment of Potential Tooth Movement and Bite Changes With a Hard-Acrylic Sleep Appliance: A 2-Year Clinical Study

Nikola Vranjes, DDS[1], Gene Santucci, DDS, MA[2], Karen A. Schulze, PhD, DDS[2], David Kuhns, PhD[3], Allen Khai[2]

[1]The Snore Centre, Calgary, Alberta, Canada; [2] University of Pacific, San Francisco, California; [3]ProSomnus Sleep Technologies, Pleasanton, California

Study Design

- Prospective, independent, clinical study
- Sample size = 18
  - Follow ups at 1- and 2-year intervals
  - Mean follow up period of 2.3 years
- Interventions
  - Precision oral appliance therapy (ProSomnus)

Key Finding

- No statistically or clinically significant dental changes at 1- or 2-years (below):
  - Irregularity: Lower arch 0.007 mm or upper -0.002 mm
  - Overjet -0.008 mm or overbite 0.0007 mm
  - Intercanine distance: upper 0.01 mm or lower 0.004 mm

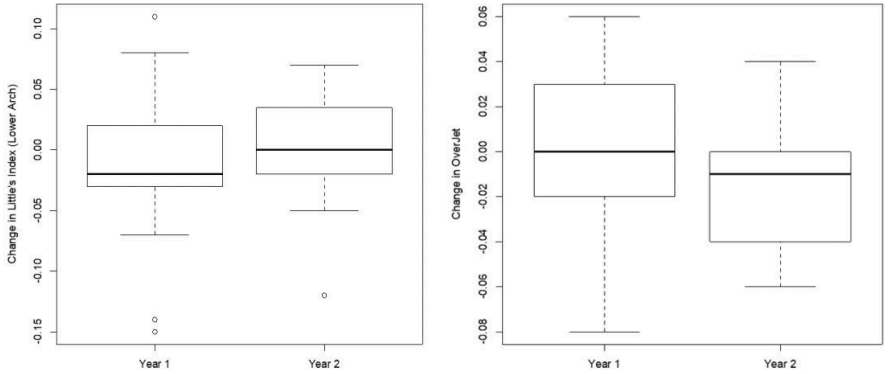


Figure 5. Lower arch and overjet analysis boxplots illustrating data symmetry.

I have been active in this field for over 7 years and provide close follow up. This is what I am seeing in my clinic:

- Minor insignificant bite changes
- TMJ improvement more likely than worsening . TMJ worsening is extremely rare (relatively easy to deal with- either home care and/or physical therapy)
- Temporary discomfort that goes away
- The appliance type, fit, regular follow up, and most importantly a furthest back lower jaw position is key to prevent side effects.

DISPOSABLE SUPPLIES

Used Over 5 Years of Treatment*

I only provide precision post appliances. I provide them with or without a chip

CPAP Machine

- 60 Mask cushions and/or nasal pillows
- 60 CPAP machine filters
- 20 Mask frames
- 20 CPAP tubes
- 10 Mask headgears
- 10 Chin straps (if applicable)
- 10 Humidifier water tubs

Oral Appliance

- The precision post appliances I provide last 4 years. To put this in perspective, cheaper MAD's found online may only last 30-60 days (and do not work nearly as well)
- At 4 years, I make a replacement appliance for my patients following a new baseline sleep study.
- For non-responders to solo therapy, I give patients the option of combining their appliance with AutoPAP, ENT services, Weightloss, or a combination of therapies. Their oral appliance still remains the cornerstone of their sleep apnea treatment.

*Based on guidelines from ResMed - https://www.resmed.com/en-us/sleep-apnea/sleep-blog/when-to-replace-cpap-supplies/

Available for your patients right now. Other dentists in the area do not have access to this yet, and if they are in-network with insurances it is unlikely they can offer it due to costs.

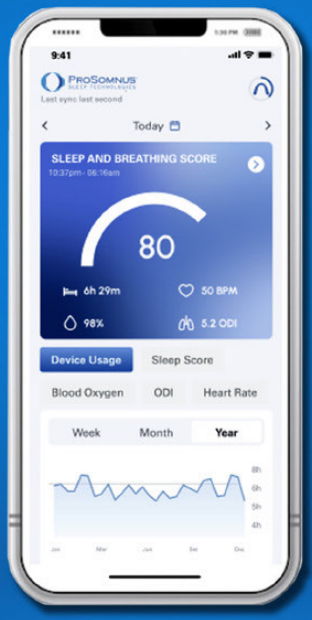
Introducing the ProSomnus Buccal Mucosal Oximeter

The Future of Sleep Medicine

Only Pulse rate, ODI, Sleep time and "Overall Sleep Score" is currently turned on. Once FDA cleared (expected in Q4 2025-fingers crossed), the embedded oximeter powered by PPG technology will accurately predict AHI and SASHB.

WEAR

MONITOR



OPTIMIZE

Regression and Bland-Altman agreement versus arterial line and ECG (Snow et al, 2025)
r = .95, SpO_2% (Device) vs SaO_2% (Co-oximeter); Bias = 0.72; n = 325
r = .99, pulse rate vs ECG heart rate (bpm); Bias = 0.30; n = 346

Disclaimer: This product is not a medical device and is not intended to diagnose, treat, cure, or prevent any disease or medical condition. For medical concerns, please consult a licensed healthcare professional.

Comparison of Costs

Untreated Sleep Apnea: **$2,000 - $3,000** per year in increased medical costs alone for lifetime (AASM Study)

- Takes an average of 10 years off your life according to study by the American Academy of Sleep Medicine
- People who suffer from obstructive sleep apnea have unprotected airways that constantly collapse during sleep, resulting in less air being delivered to the body and requiring more effort to breath, making it impossible to get deep restorative healthy sleep. This increased breathing effort and lack of air causes costly damage to the entire body.

Inspire: **$3,000 - $4,000** per year: for the first 10 years (price varies after that). Does not include diagnostic costs, provider costs.

- Inspire: hypoglossal nerve stimulator surgery may be $30,000 to $40,000 (with the implanted device itself costing about $20,000 of this total)

CPAP: **$1,900-$2,700** per year for lifetime. Does not include diagnostic costs, provider costs.

- Cost of CPAP machine: costs vary from $250 to over $4,000 depending on type of machine. This machine needs to be replaced every 5 years.
- Yearly CPAP supply costs average around $1,835

4 years of Comprehensive OSA care with Dr. Vandervelden: $3,900-$5,900:

$975-$1225 per year for lifetime depending on appliance type (No chip vs. Chip). This includes all diagnostics costs and provider costs. This breaks down to only $2.67-$3.35 per day (less than a cup of coffee) . Overall care with me is still cheaper than CPAP or Surgery.

Unlimited home sleep testing interpreted by board certified sleep physicians (baseline and efficacy studies), telehealth visits, and in person visits are included for 4 years. All costs are discussed up front with patients, and the consultation with me is free. I am out-of-network with all insurances because insurance does not cover my costs and restricts the type of appliances I am able to provide. In-network dentists typically can not afford to provide the newest precision oral appliances and medicare currently prohibits them (they have a rule that appliances must be attached- precision appliances are two separate pieces). I provide the best care because I want the best long term results for patients.

Summary of presentation:

- Precision post appliances are significantly more effective than oral appliances of the past. Few dentists provide precision post appliances, especially the newest ones, mainly due to cost, or they simply don't know, or because insurance hasn't caught up yet and doesn't pay enough for providers to offer them (Insurance should reimburse based on the mechanism (see slide 8) and type (precision vs. non-precision) of appliance used in my opinion). The newest studies using precision post appliances suggest they are at least non-inferior to CPAP and outperform CPAP in various wellness metrics.
- Precision post appliances using my methodical calibration process gets better results compared to others, and is a highly effective first line option to treat all levels of OSA.
- What truly sets me apart is that I dose this therapy more accurately than others. This is very important for long term success. I have patients undergo up to 15 nights of sleep testing at multiple lower jaw positions to set the lower jaw in the most effective yet furthest back position. I don't set the jaw any further than necessary. This leaves room for further adjustment in the future if sleep apnea gets worse (as it does in most cases). I provide long term follow up with my patients, and have them undergo OAT efficacy assessments every 2 years with home sleep testing. Other dentists don't do this.
- Compared to other dentists, my patients are more effectively treated, and have better follow up and compliance.
- Maximizing effectiveness and achieving long term results for patients has always been my main focus and drives me to continually improve.

I have no conflicts of interest. I receive nothing from the companies that make the products I use. I use them because they work the best for my over all goal, and that is to treat my patients as effectively as possible and to keep them successfully treated long term.

Dr. Vandervelden

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WEST MICHIGAN
CPAP Alternatives
Customized Sleep Apnea Solutions
Dr. Vandervelden

WATCH MY VIDEO FOR MORE INFO

The newest precision post appliance; better lower jaw stabilization- more tongue space- less protrusion necessary- can close your mouth more

These are the patients you should refer to me:

- All patients diagnosed with sleep apnea who would prefer an alternative to CPAP
- All CPAP non-compliant patients
- Patients that would benefit from combining a precision post appliance with AutoPAP (they require much less forward jaw positioning and patients can close their mouths more making it easier to get a good mask seal)
- All patients prior to Hypoglossal Nerve Stimulation or other surgeries

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Customized Sleep Apnea Solutions
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