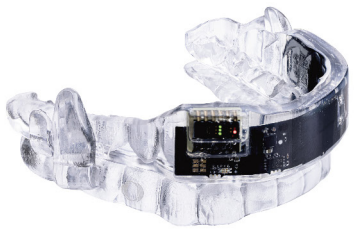
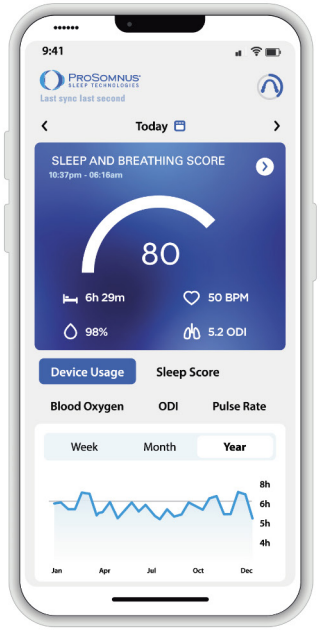
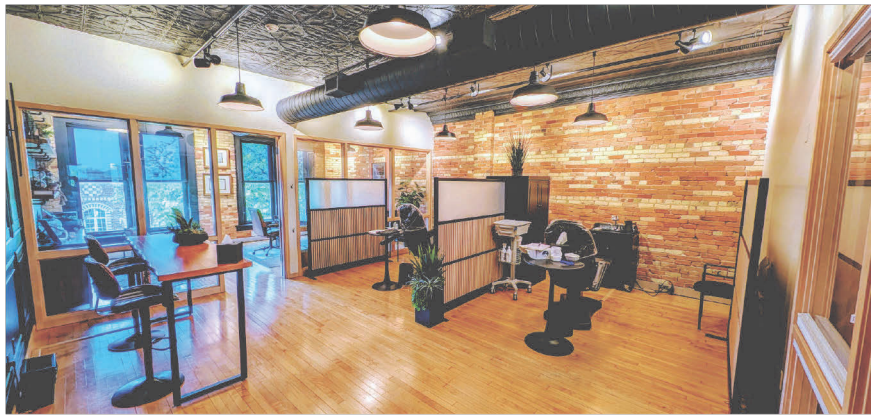
Fax referrals to
616-772-9380 My
direct email:
DrV@wmCPAPalternatives.com
www.wmCPAPalternatives.com
Downtown Holland 31
E 8th St. Suite 330
Main practice number:
616-741-9035





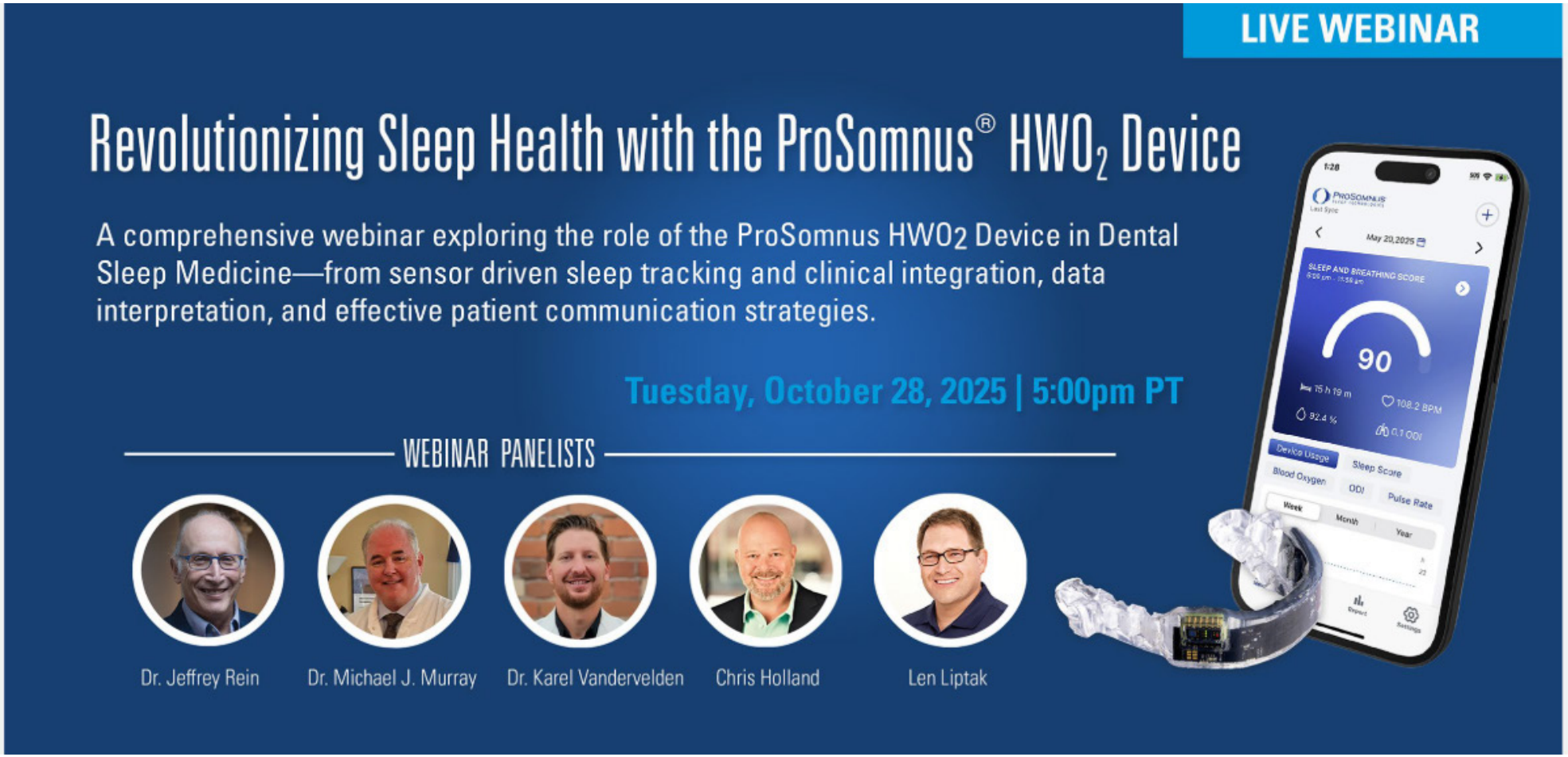
I'm located downtown Holland. The newest precision post mandibular advancement devices shown above are proven to work significantly better than oral appliances of the past provided by most dentists today. These devices are FDA approved to treat obstructive sleep apnea and as a remote monitoring device. The upper piece has an embedded oximeter that is more accurate than peripheral oximeters mainly due to fact that it is in the mouth (temperature, melanocyte concentration, and distance are advantages). I've included the most up to date studies using these precision post appliances. The latest studies suggest that these new precision post mandibular advancement devices 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 fully custom precision post mandibular advancement devices and instead often use less effective semi-custom devices due to costs and insurance rules. Also, most other dentists 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



WEST MICHIGAN CPAP Alternatives
Customized Sleep Apnea Solutions
Dr. Vandervelden

Now referred to as RPM02 OSA Device System (FDA Approved Recently)- Formerly referred to as "HWO2"



Link to recorded webinar: https://prosomnussleeptechnologies.showpad.com/share/qxZjdE2zS4Bs2tF2v6Eqn

WEST MICHIGAN CPAP Alternatives
Customized Sleep Apnea Solutions
Dr. Vandervelden

Appliance With Chip: Dr. V's Choice

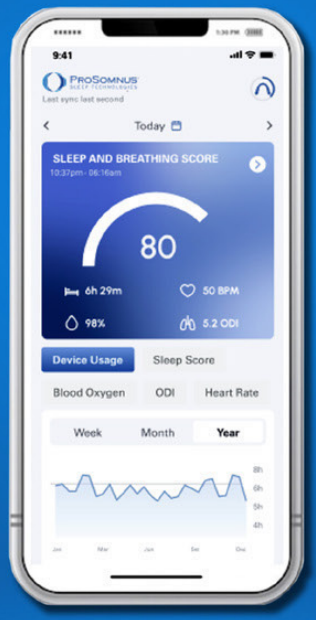
Highest Efficacy

Most Accurate

Best Results

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.

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Androids: version 14 or higher
Apple: iOS 13 or higher

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Why not medical grade mandibular advancement devices first over CPAP and surgery?

Scan to see "chip device" in action

A BUCCAL MUCOSAL OXIMETER ACCURATELY MEASURES ARTERIAL OXYHEMOGLOBIN SATURATION AND PULSE RATE

G. Vogel, MS[1]; E.V. Mosca, PhD[1]; C. Snow, BSc[2]; M. Pun, MBBS, PhD[2]; S. Magnison-Benoit, BSc[2]; T.R. Tripp, PhD[2]; A. Clarke, BSc[2]; B. Hansen, BA[2]; L. Transfiguracion, RT, AA[3]; G. Di Simone, BSCE, MBA[1]; M. Lai, PhD[1]; J.M. Rawling, PhD, MD[2]; S. Roy, MD[2]; S. Adatia, DMD[4]; J.E. Remmers, MD[1]; M.J. Poulin, PhD, DPhil[2]
[1]ProSomnus Sleep Technologies, Pleasanton, CA
[2]University of Calgary, Calgary, Alberta, Canada
[3]Alberta Health Services, Calgary, Alberta, Canada
[4]Symmetry Dental, Calgary, Alberta, Canada

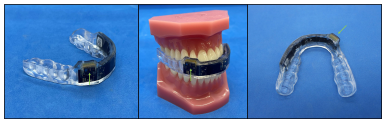
Introduction

Pulse oximeter (SpO_2) devices suitable for multi-night monitoring of arterial oxyhemoglobin saturation (SaO_2) are not readily available despite a need to monitor SaO_2 decreases in patients with sleep apnea and pulmonary diseases during sleep. The objective of the current study was to assess the SpO_2 and pulse rate accuracy of a buccal mucosal oximeter embedded into a custom-fitted overlay of the upper teeth by comparison to a gold standard (CO-oximeter SaO_2 and ECG heart rate).

Methods

Accuracy of the buccal mucosal oximeter was assessed in healthy participants (n = 12) under non-motion conditions. Participants were made progressively hypoxic by decreasing the fraction of inspired oxygen in a stepwise manner to achieve a range of SaO_2 from approximately 97-70% using a dynamic end-tidal forcing system. SpO_2 and pulse rate values from the buccal mucosal oximeter were compared with CO-oximeter values of SaO_2 and ECG heart rate, respectively.

Figure 1. The buccal mucosal oximeter device. The photoplethysmography unit is indicated by the green arrows.



Results

Table 1. Participant Baseline Data

Gender (M/F; n)	
Age (years; mean ± SD; range)	30.7 ± 6.7 (22-39)
Body weight (kg; mean ± SD; range)	81.4 ± 20.4 (53.0-126.0)
Height (m; mean ± SD; range)	1.8 ± 0.1 (1.6-2.0)
Body mass index (kg/m2; mean ± SD; range)	26.0 ± 5.5 (17.5-38.0)
	White: 9; Middle Eastern: 1; Black: 2
Fitzpatrick skin type (n)	I: 2; II: 3; III: 2; IV: 2; V: 1; VI: 2

Figure 2. Arterial blood SaO_2 versus $PETO_2$ values from the dynamic end-tidal forcing system.

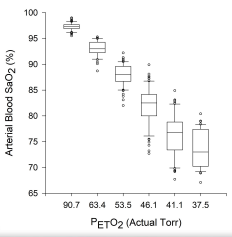


Figure 3. Data trace from one participant. Blue line/diamonds: buccal mucosal oximeter; black line/*: reference pulse oximeter; pink circles: CO-oximeter SaO_2.

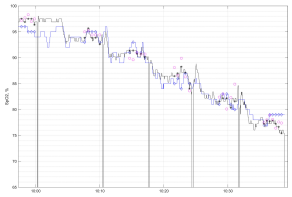


Figure 4. Linear regression and Bland-Altman for buccal mucosal oximeter SpO_2 and CO-oximeter SaO_2.

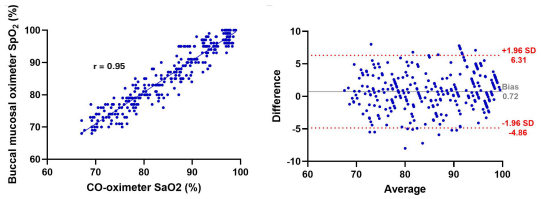


Figure 5. Linear regression and Bland-Altman for buccal mucosal oximeter pulse rate and ECG heart rate.

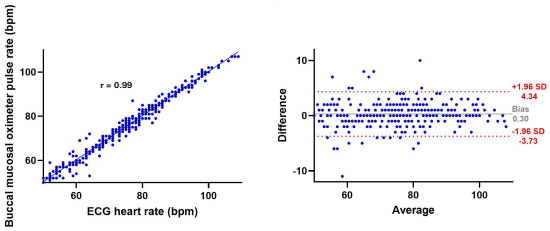


Table 2. Accuracy root-mean-square (A_{RMS}) across the full range of SaO_2 tested and by SaO_2 decade.

	70-100%	90-100%	80-<90%	70-<80%
Data pairs (n)	325	117	100	108
Bias	0.72	0.92	0.26	0.94
A_{RMS} (%)	2.94	2.63	3.31	2.88

Conclusions

The results of the study indicate that the buccal mucosal oximeter accurately measures SpO_2 and pulse rate, as shown by good agreement with a gold standard, over a wide range of arterial hypoxemia. Such clinically acceptable accuracy indicates that this novel reflectance oximeter may prove useful in management of patients with sleep-induced hypoxemia by providing multi-night monitoring of SaO_2. Additionally, the intraoral placement of the oximeter may be particularly convenient due to its temperature regulation, protection from ambient light, and relative lack of mucosal melanin.

This study was supported by ProSomnus Sleep Technologies

Take aways: Peripheral oximeters suffer from inaccuracy due to: Distance from source, temperature (cold hands), melanin concentration (dark skin).

Central oximeters like this (in the mouth) are closer to the source, provide consistent temperature and melanocyte concentrations.

In the mouth is more accurate than on the finger

Snap shot of provider Oxymetrx portal: currently tracks device usage, sp02, pulse rate, and ODI (oxygen desaturation index). Free portal access available to providers (just supply carmen or myself your email). Set up is easy and seamless.

Dr. V now remotely monitors your patients to ensure the highest sleep apnea treatment efficacy and compliance. If desired, providers can get free access to this portal for their own treatment purposes or to co-monitor with Dr. V. Remote monitoring billing codes are applicable (FDA cleared remote monitoring device)

Recent studies shows that these medical grade devices outperform CPAP and surgery in: total hours sleep, energy levels, daytime sleepiness, memory, performing tasks, mood, and long term adherence.

Want Dr. V to come into your clinic for a quick 15 minute information session to answer questions and to see the devices he offers up close? Email Carmen@wmCPAPalternatives.com.
Questions for Dr. V? Email him directly at DrV@wmCPAPalternatives.com.

What patients should providers refer:

- All patients you suspect have sleep apnea, or snore.
- All patients who do not tolerate their CPAP, don't use it enough (common), or want an alternative (most).
- All patients prior to considering surgery (Inspire, Genio, ENT procedures).

Learn more

How to refer? Fastest way: simply tell patients to call and set up free consultation with Dr. V while still in your waiting area. 616-741-9035.
To refer directly simply fax pt. demographics with note "eval pt. for OMAD (oral mandibular advancement device) " to 616-772-9380.

Agenda:

- Current state of sleep medicine and challenges.
- Newest research supports OAT as first line option (when newest precision post appliance used and oversight provided with qualified provider)
- Why dosing OAT to achieve most conservative protrusive position matters.
- Newest precision post appliances allow more conservative lower jaw positioning.
- Dentist are currently setting patients lower jaws too far forward.
- Why NON-CPAP solutions are needed
- OAT with Dr. V prior to surgery
- Continuous patient monitoring with Dr. V results in better management of severe OSA patients and improves outcomes.
- What patients to refer to Dr. V

Current State - Sleep Medicine Challenges

- **Night to night variability**
  - Single-night sleep studies misdiagnose ~20% of people (Punjabi, 2020)
  - 30% under-diagnosed and 15% over-diagnosed with single night studies (LeChat, 2022)
- **Disease progression**
  - OSA event severity and frequency may progress over time (Leppänen, 2017)
- **Current metrics poorly predict outcomes**
  - "[AHI] poorly predicts the adverse outcomes of sleep apnoea" (Azarbarzin, 2018)
  - "insufficient evidence exists to assess the validity of AHI as a surrogate or intermediate outcome for long-term clinical outcomes." – Agency for Healthcare Research and Quality (AHRQ, 2021)

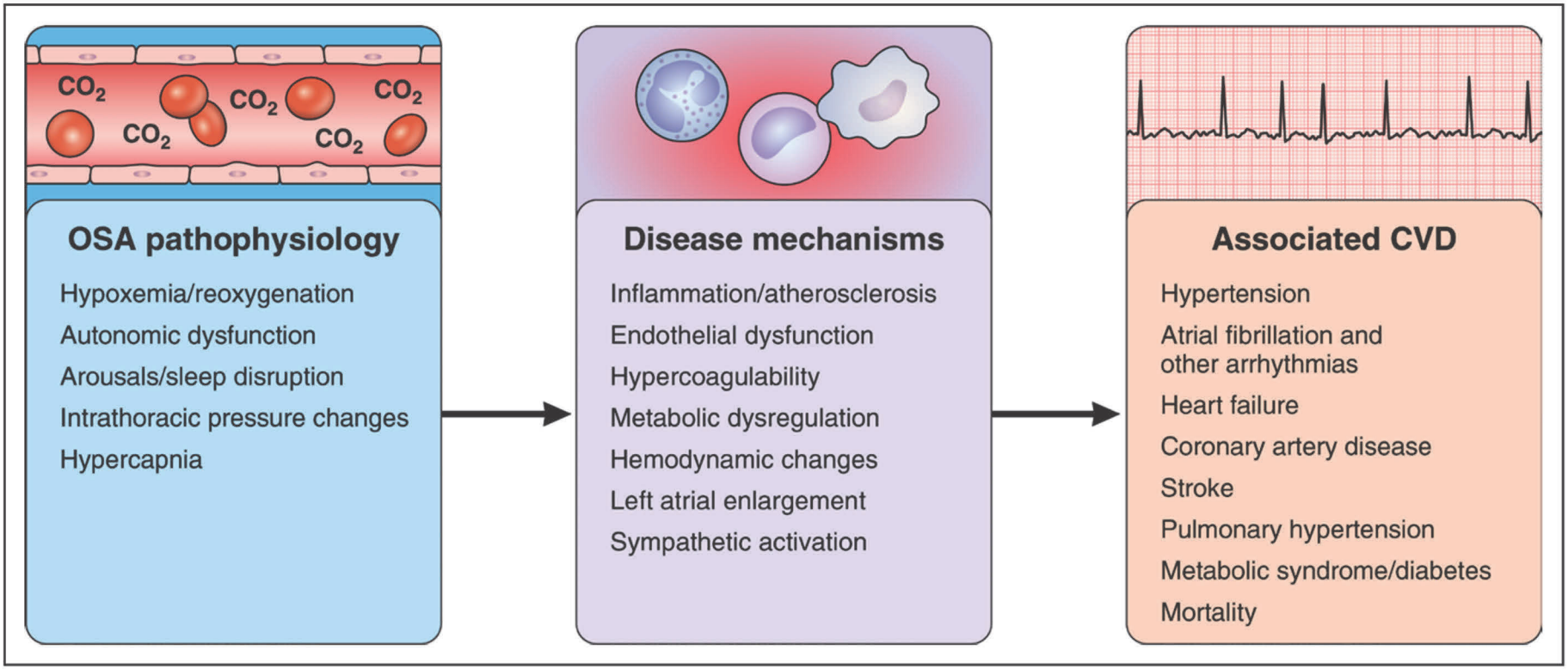
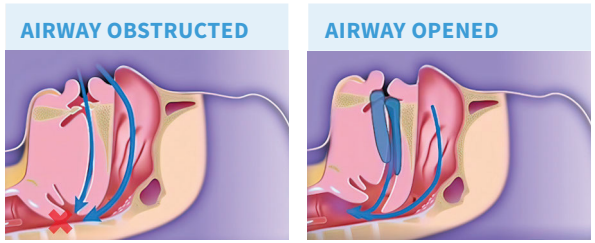


Figure 2. Cardiovascular complications of obstructive sleep apnea (OSA).
CVD indicates cardiovascular disease.

WHAT PATIENTS NEED TO KNOW

A Custom Mandibular Advancement Device 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.
- Dr. V's custom devices work better than other devices found elsewhere.
- Research show the newest custom devices outperform CPAP and Surgery in hours you sleep per night, sleep quality, energy level, mood, and memory.
- 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 device 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.

MY DENTIST SAYS THEY DO THIS. WHY DR. V?

- Dr. V's gets better results because his process is different from others. His objective, data-driven method for adjusting his devices in addition to using the highest quality custom devices get better results than others.
- Dr. V is has received the highest level of training in this niche field of sleep medicine.
- Dr. V's patients are more effectively treated, and have less side effects

I'm **Dr. Vandervelden** and I have sleep apnea myself. I struggled with CPAP, then switched to a custom mandibular advancement device. I'm passionate about helping people get better, healthier sleep.

SERIOUSLY, WATCH MY VIDEO TO LEARN MORE

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Customized Sleep Apnea Solutions
Dr. Vandervelden

www.wmCPAPalternatives.com

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Carmen@wmCPAPalternatives.com
DrV@wmCPAPalternatives.com

SLEEP APNEA?

SEE **DR. VANDERVELDEN** FOR CUSTOM MANDIBULAR ADVANCEMENT DEVICES

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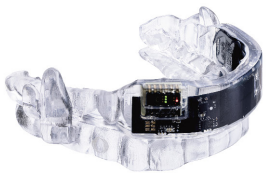
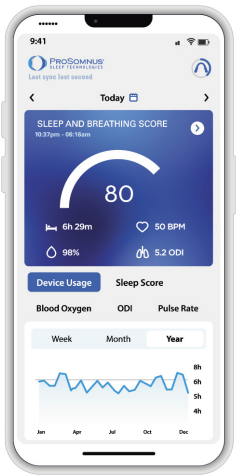
Customized Sleep Apnea Solutions
Dr. Vandervelden
Downtown Holland 616 741 9035

REMOTE MONITORING WITH "CHIP DEVICE"

- Just like CPAP machines "talk" back to sleep doctors to let them know if CPAP is working properly, the newest "chip devices" allow Dr. V to monitor your breathing while you are sleeping.
- DOT compliant. The chip device is FDA approved for remote monitoring, and provides proof of usage. Great for truck drivers and pilots.
- A medical-grade oximeter chip is embedded into the custom mandibular advancement device, and your sleep data is easily accessed from an app on your phone.
- A provider portal allows Dr. V to periodically monitor your sleep. No visits to the sleep center needed. Remote monitoring saves you time and hassle.





"CHIP DEVICE IN ACTION"

WHY TREAT THIS?

- Healthy sleep is a pillar of health, and those with untreated sleep apnea are not getting healthy sleep.
- Sleep apnea causes strokes and causes high blood pressure. Untreated sleep apnea is serious.

WHAT'S THE PROCESS?

- Call 616-741-9035 to schedule a free consultation with Dr. V. You can also request his practice to reach out to you by requesting an appointment online at www.wmCPAPalternatives.com
- Dr. V provides everything from start to finish, so you don't have to go to a sleep center first. Dr. V provides fast and comfortable home sleep testing as part of his care package.

SIDE EFFECTS?

- Side effects are rare, but may include temporary jaw discomfort, temporary sore teeth, minor insignificant bite changes, dry mouth, rarely temporary TMJ. In fact, most patients see improvement in their TMJ, and report less tension in their jaw muscles and grind their teeth less after wearing their device. Dr. Vandervelden has over 9 years of clinical experience with custom devices and knows how to limit side effects. In his hands, these devices are extremely safe.

COST?

- Studies show that overall, treating your sleep apnea is less expensive than not treating it. Dr. Vandervelden operates on a flat fee model and offers different tiers of care. All costs are discussed up front, with low cost monthly options available.

COMFORTABLE?

- Most people strongly prefer a custom mandibular advancement devices over non custom devices, and strongly prefer all devices over a CPAP. It is far more comfortable.
- With Dr. V's devices, you can still talk, open your mouth, and even have a drink while wearing your device.
- Over 98% of Dr. Vandervelden's patients are still wearing their device after one year. Studies show less than half of patients are using their CPAP after one year.

WHY NOT BUY CHEAP DEVICE ONLINE?

- Studies show these cheaper devices are significantly less effective than custom ones.
- Non custom devices have more potential serious side effects like tooth loss, damaged dental work, permanent TMJ/jaw pain, and major permanent bite changes than custom devices.
- Dr. Vandervelden uses the latest technology and customizes each device to get a precision fit to ensure a comfortable, well working device.
- Dr. Vandervelden is one of only a few providers in the country that offers truly custom devices. Many other devices that claim to be custom are actually semi-custom and come with pre-fabricated parts.
- Simply put, getting a device online or from most other providers is not the same.

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Dr. Vandervelden

Dr. V's appliances:

- **Most effective**
- **Fully customizable**
- **Precision fit**
- **Extremely comfortable**
- **Can close your mouth more**

Dr. V's unique data driven (objective) approach compared to others subjective approach results in:

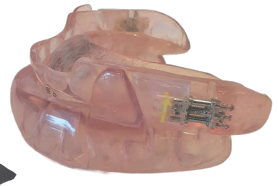
- **less forward jaw positioning**
- **fewer side effects**
- **Higher reduction in both quantity and quality of breathing events**
- **less likely to need CPAP or surgery**
- **Better health outcomes**

Fully-custom: most effective

	Dr. Vandervelden	Others
Fully custom mandibular advancement device (no pre-fabricated parts)	✓	?
Fast and hassle free	✓	✗
No need to sleep at a sleep center, home sleep testing equipment dispensed on site, is comfortable and easy	✓	✗
Specializes in treating and managing sleep apnea and snoring	✓	✗
Uses medical grade oxygen based physiologic health metrics to custom adjust appliance resulting in better long term success and better health outcomes	✓	✗
Fewest Side Effects	✓	✗
Remote monitoring	✓	✗

RESULTS MATTER

Semi-custom: Less effective



"Daybreak professionally managed" semi-custom appliance- Cost $2,495 if paying cash. Not precision fit. Less effective. More frequent replacement necessary"

Learn More

11

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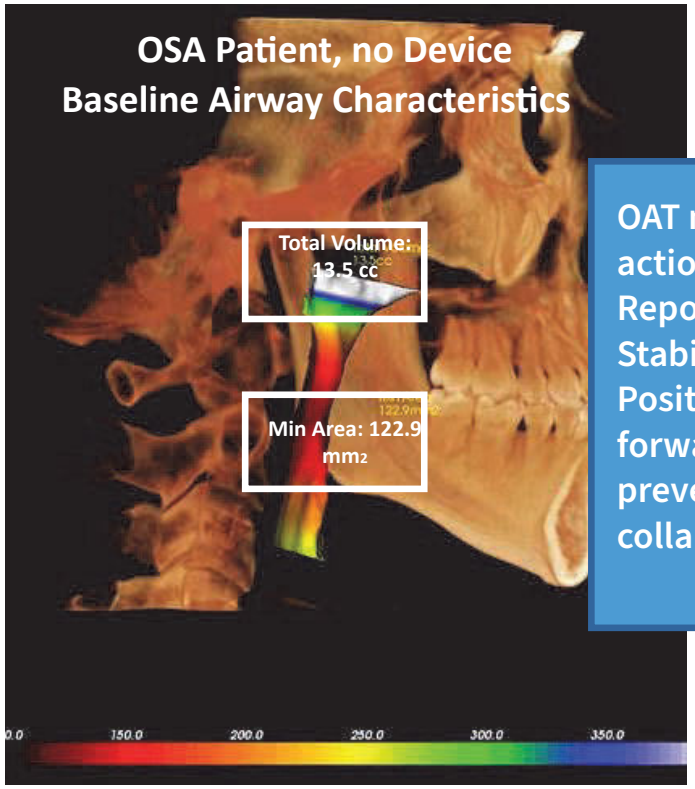
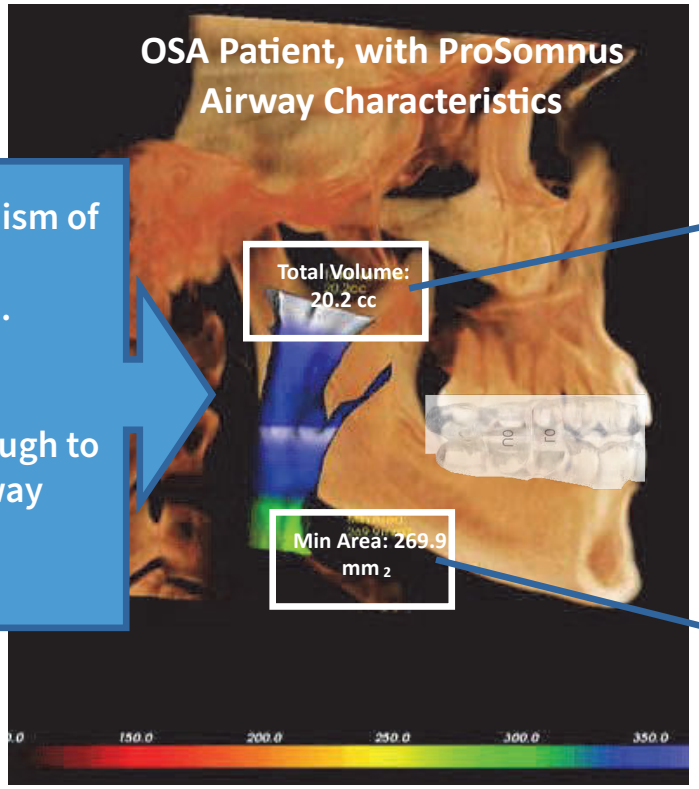
Precision Post Oral Appliances are Engineered to Perform the Mechanisms of Action for OAT: Reposition, Stabilize & Titrate the Jaw with < 1 mm of target to Prevent Airway Collapse



OAT mechanism of action: 1. Reposition 2. Stabilize 3. Position jaw forward enough to prevent airway collapse

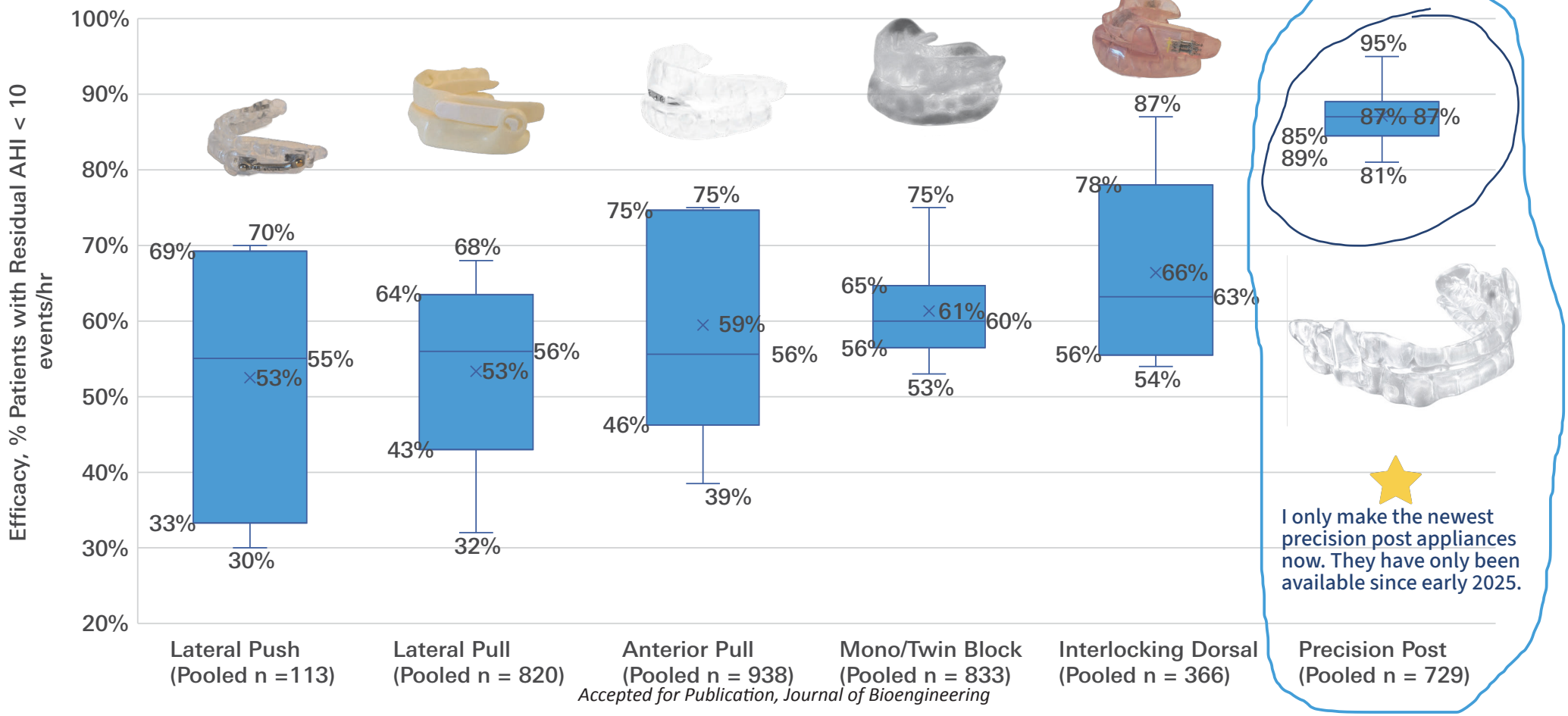


Total Airway Volume
No device = 13.5 cc With ProSomnus = 20.2 cc
Improvement +50%

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.

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



Accepted for Publication, Journal of Bioengineering

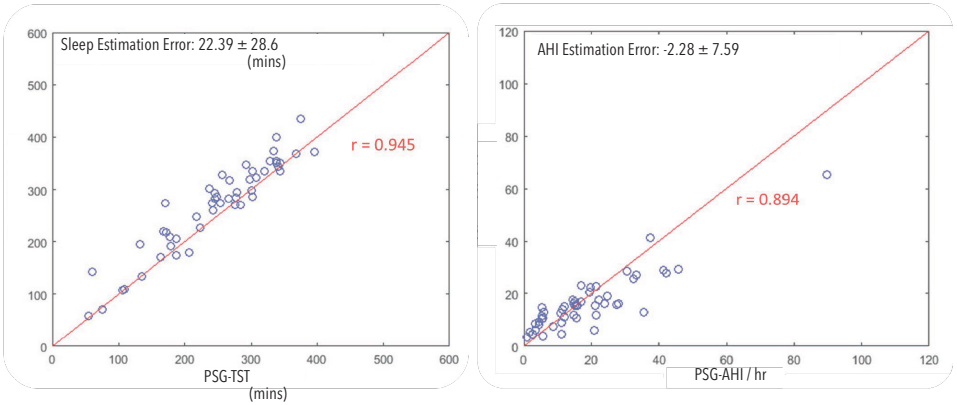
Over the past 7 years, I have provided all the appliances pictured for my patients with the exception of the monoblock (not up to my standards). Precision post oral appliances like the one pictured offer superior jaw stabilization, which is the main mechanism of action of OAT's. These appliances take 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.

belun ring

Belun ring is a FDA validated home sleep study that is highly accurate, and is very comfortable to sleep with (unlike most sleep studies). Below is a sample report. Belun ring tracks more useful sleep and cardiovascular health metrics than most other home sleep studies.

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 (0.89) and Specificity (0.90) for AHI ° 15



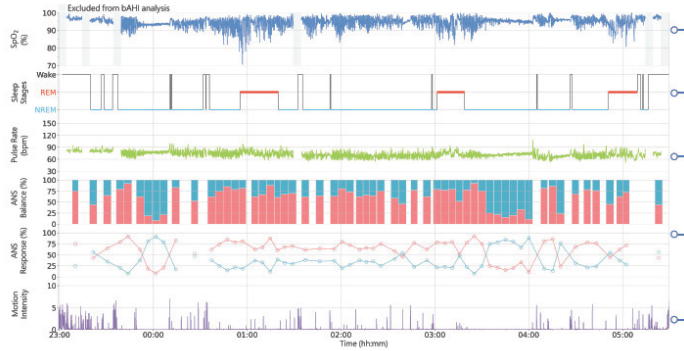
Sleep Statistics				
Start Time	2022-04-25 22:59	Total Recording Time (TRT)	387.5	mins
End Time	2022-04-26 05:29	Total Sleep Time (TST)	338.5	mins
Time Zone	UTC+07:48	Sleep Efficiency (TST/TRT)	87.4	%

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.

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.

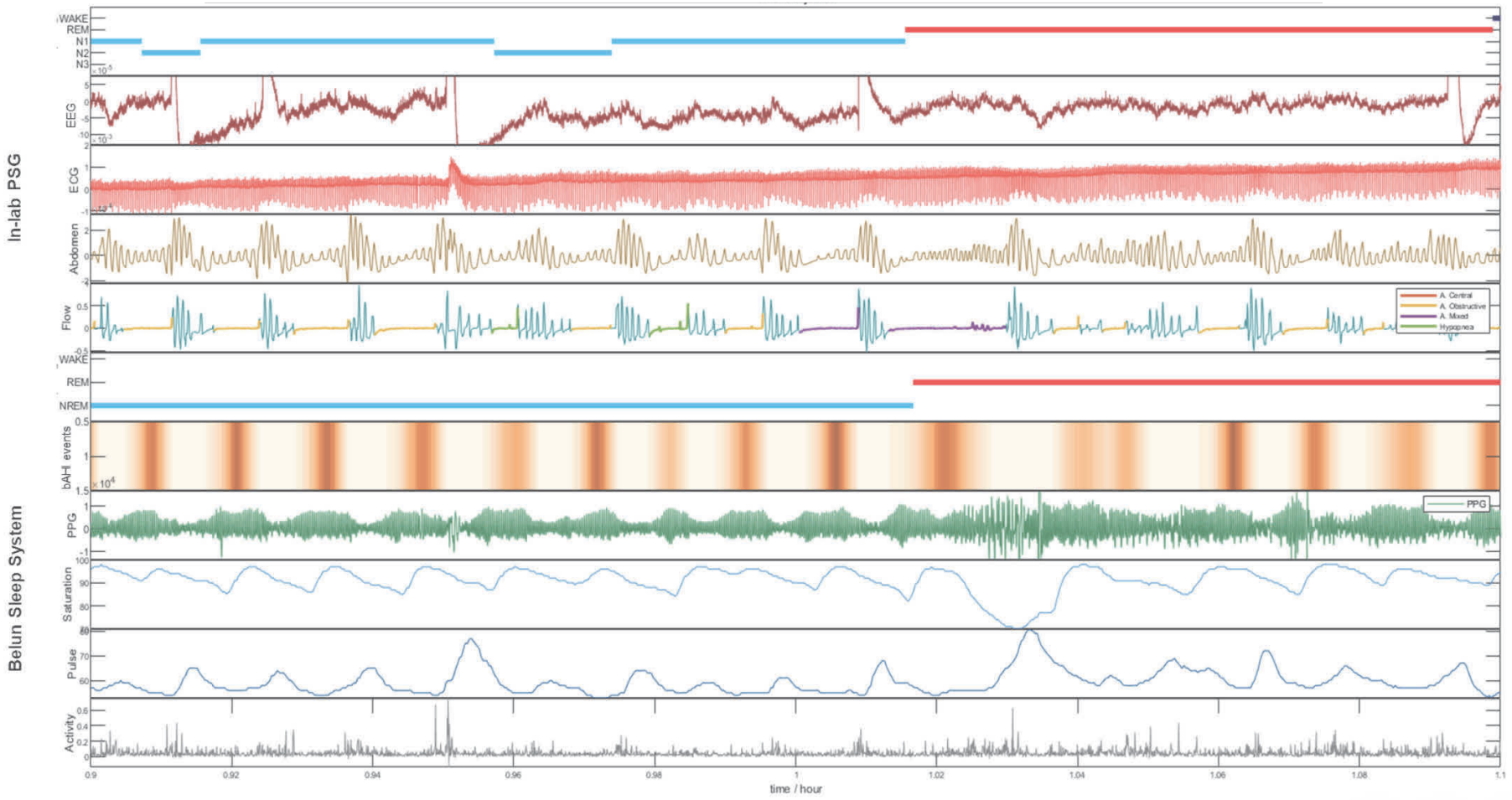
Yeh E, et al. (2021) Detection of obstructive sleep apnea using Belun Sleep Platform wearable with neural network-based algorithm and its combined use with STOP-Bang questionnaire. PLoS ONE 16(10): e0258040.

Dr. V's Data-driven approach gets better results:

- 4 nights for baseline
- 8 nights while wearing oral appliance at 2 different lower jaw positions
- 8 More nights at 2 further lower jaw positions if necessary
- 4 nights 2 years post appliance delivery
- At 4 years, a new baseline and new appliance are made. The process starts over again.

20221205

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]



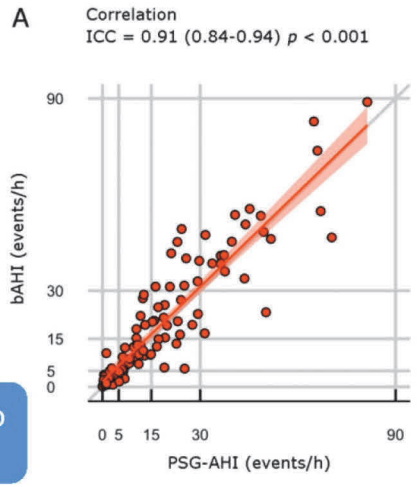
belun | High Accuracy and Precision in OSA classification (New Generation)

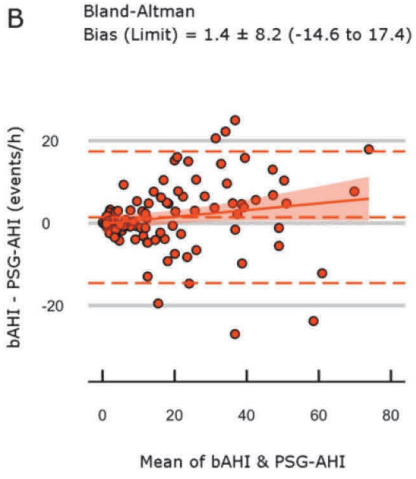
Apnea-Hyponea Index ≥ 5 : **Accuracy**: **93%**; **Sensitivity**: **94%**; **Specificity**: **93%**
Apnea-Hyponea Index ≥ 15 : **Accuracy**: **90%**; **Sensitivity**: **89%**; **Specificity**: **90%**

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)





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 multiple nights of data with Belunring is more useful when assessing OAT efficacy vs. a single night PSG (and significantly less expensive).

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

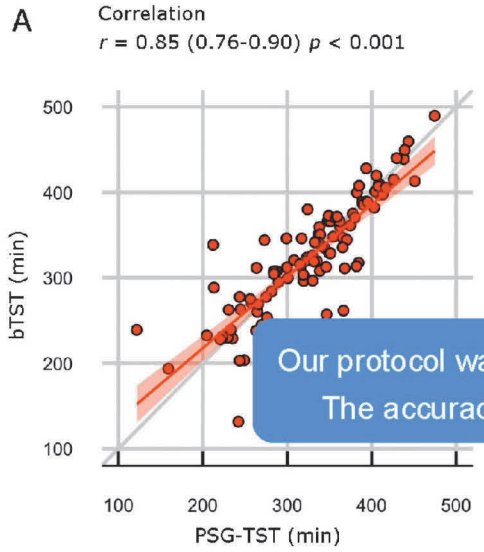
Sleep Stages Accuracy: **Wake**: **90%**; **REM**: **93%**; **NREM**: **85%**

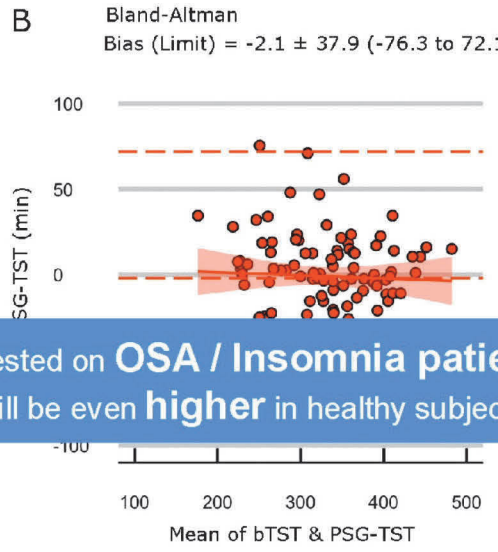
	Number of Epochs	Accuracy	Sensitivity	Specificity	PPV	NPV	LR+	LR-	Kappa
Wake	88,229	0.90 (0.89-0.90)	0.78 (0.77-0.78)	0.93 (0.93-0.93)	0.76 (0.75-0.76)	0.94 (0.93-0.94)	11.10 (10.79-11.42)	0.24 (0.23-0.25)	0.70 (0.70-0.71)
NREM		0.85 (0.85-0.86)	0.90 (0.90-0.90)	0.78 (0.77-0.78)	0.87 (0.87-0.87)	0.82 (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.

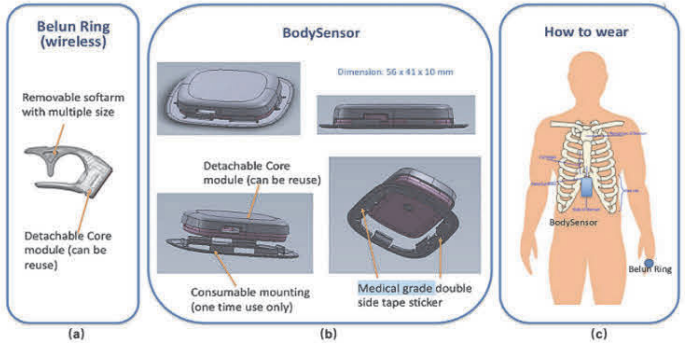


Figure1. Belun Sleep System (Belun Ring & Belun Cor)

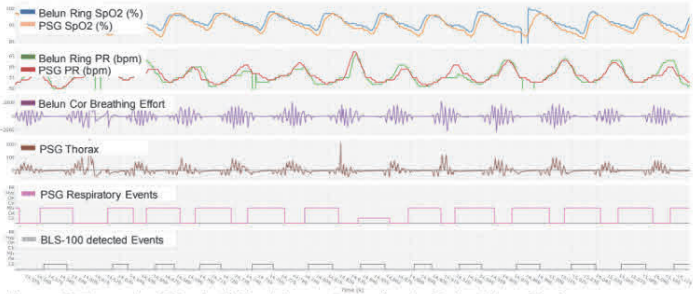


Figure 2. Example of Central/Mixed Apnea Detection by Belun Sleep System

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/m^2)	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.**

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:
Brown Evidence-based Practice Center
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Wangnan Cao, Ph.D.
Monika Reddy Bhuma, B.D.S, M.P.H.
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 growing to use Sleep Apnea Specific Hypoxic Burden (SASHB) over AHI to better determine health outcomes. 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.

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.

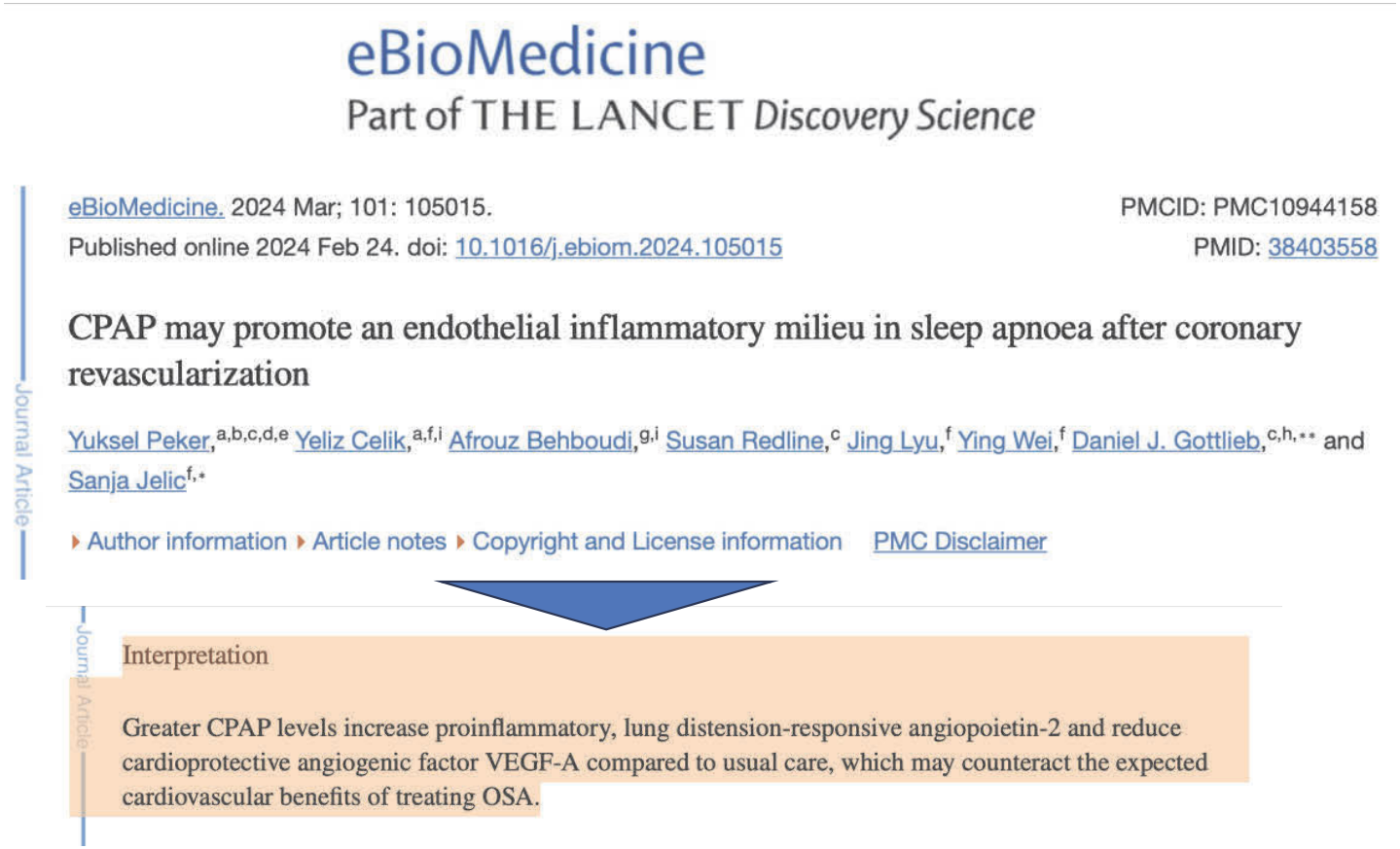
N Engl J Med 2016;375:919-31.
DOI: 10.1056/NEJMoa1606599

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 3.3 hours per night

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

CPAP May Counteract CV Benefits



eBioMedicine
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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. 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.

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

Inspire

Meta Analysis-Updated 2024-High Quality Study Design:

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.

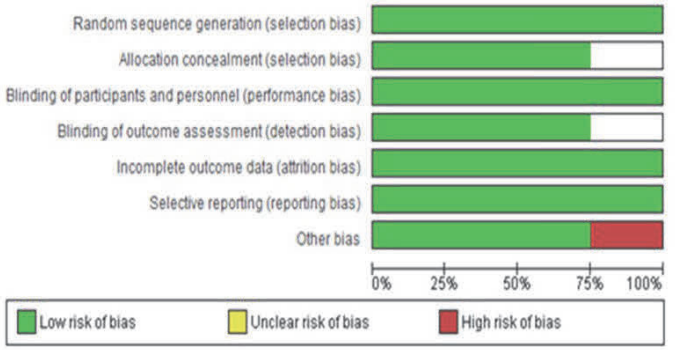

Fig. 3. Risk of bias summary for RCTs using Cochrane Risk of Bias Tool.

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.

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

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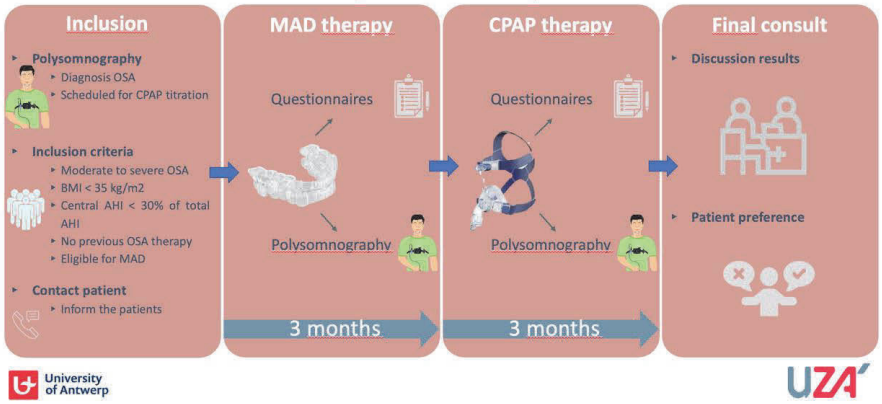
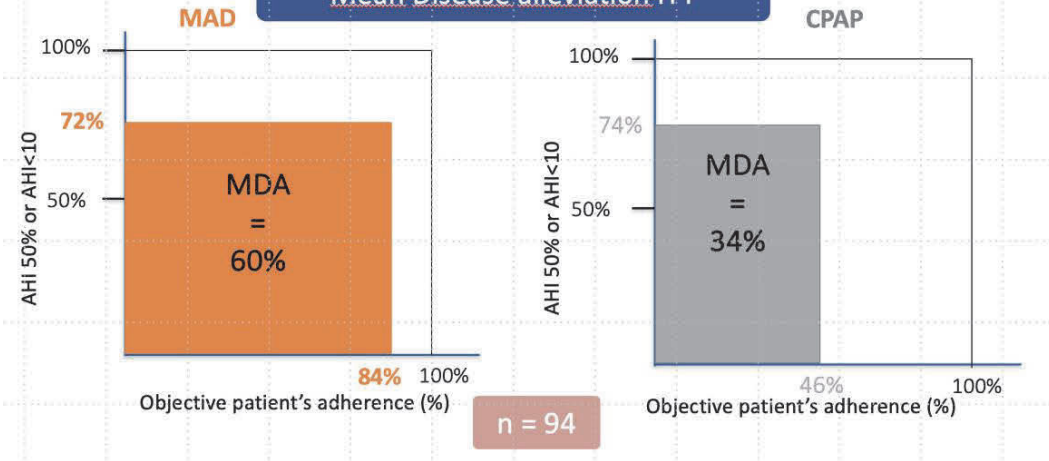


Results

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

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- 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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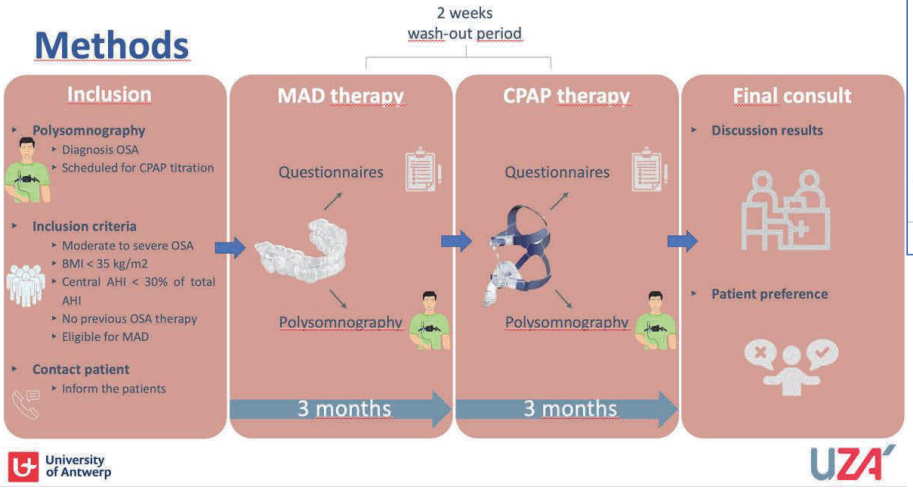
Methods



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FLOSAT

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UZA

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

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.

ibedssma

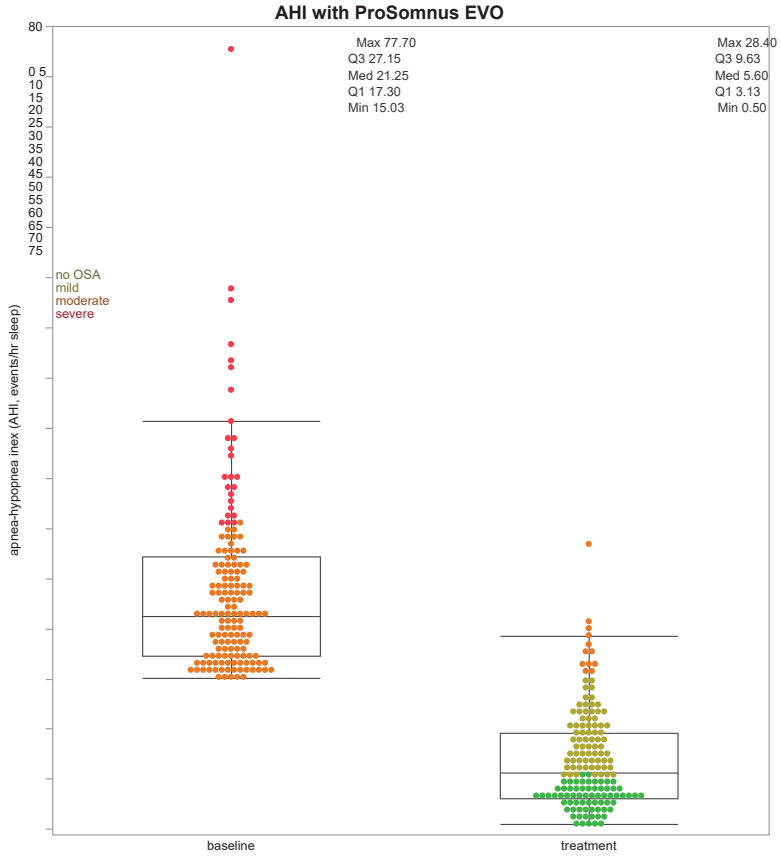
Marc BRAEM[1,2], DDS, PhD
(1) Translational Neurosciences, Faculty of Medicine and Health Sciences, University of Antwerp, Wilrijk, Belgium;
(2) Department of ENT, Head and Neck Surgery, Antwerp University Hospital, Edegem, Belgium Oral Appliance Clinic (Edegem, BE)

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%



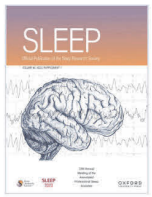
These are impressive results and suggest precision post appliances are not inferior to Inspire, and should be considered first. The newest precision post appliances would likely get even better results.

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!

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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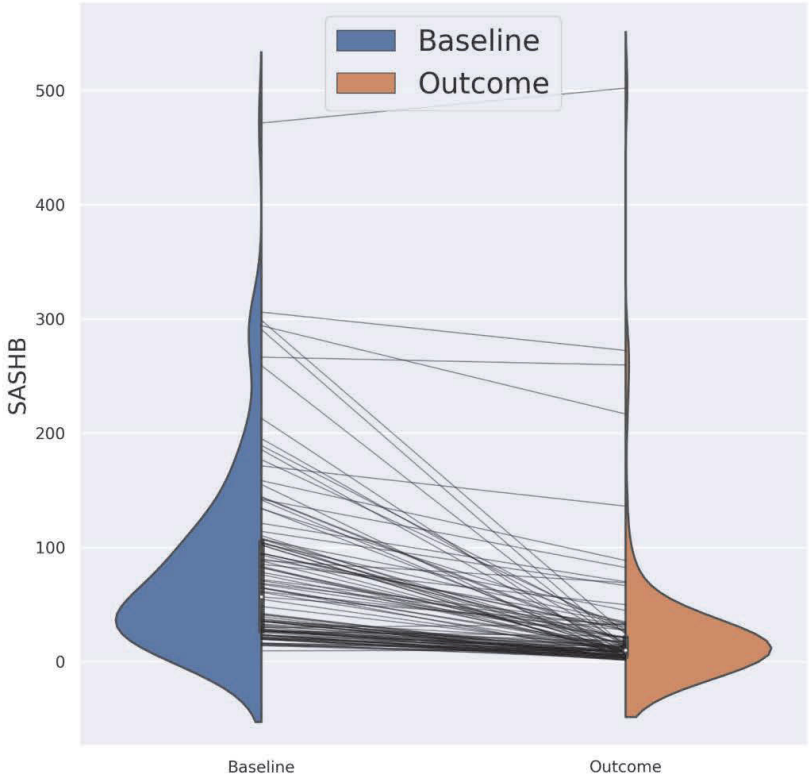
METHODS: Data previously obtained from two clinical studies that investigated the prediction of response to precision OAT in OSA were analyzed. Data from 109 participants with OSA (n = 36 mild, n = 35 moderate, and n = 38 severe) completed two-night type 3 home sleep tests before and after receiving 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.

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

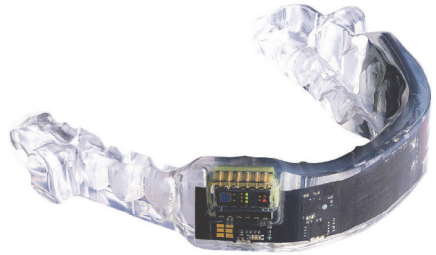
Additional Findings

- 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**

DISPOSABLE SUPPLIES

Used Over 5 Years of Treatment*

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



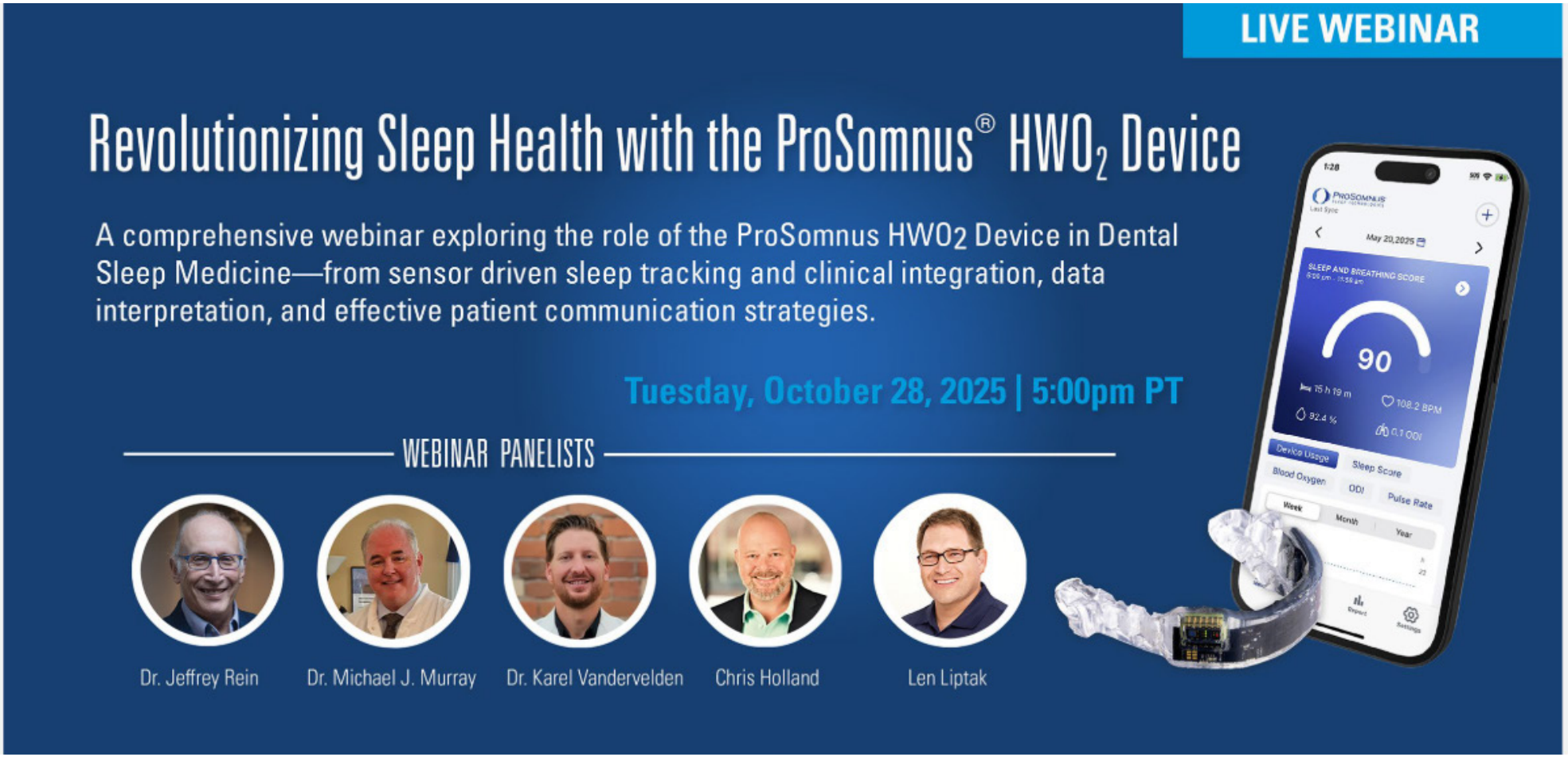
CPAP Machine

- 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/



Link to recorded webinar: https://prosomnussleeptechnologies.showpad.com/share/qxZjdE2zS4Bs2tF2v6Eqn

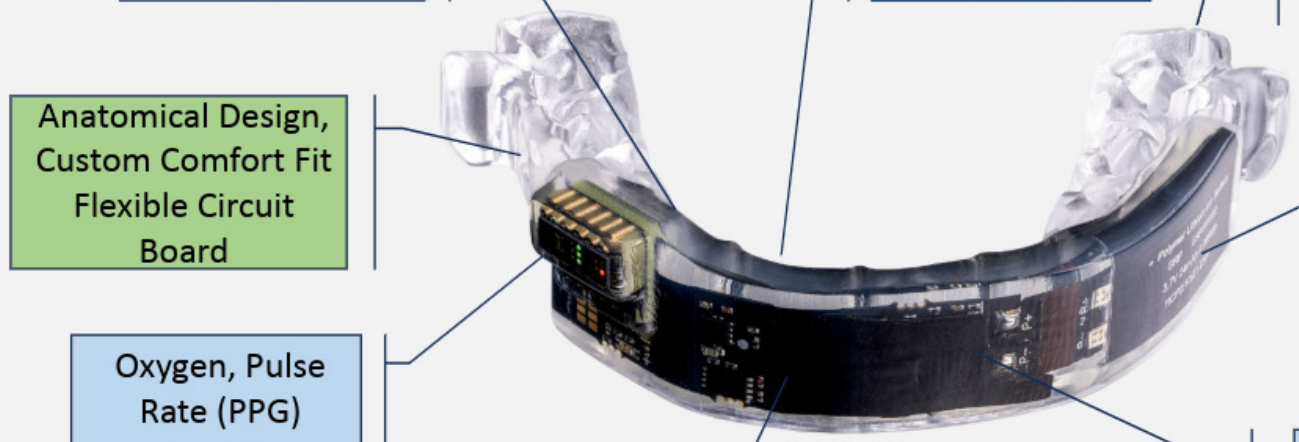
Current State - Sleep Medicine Challenges

- **Night to night variability**
  - Single-night sleep studies misdiagnose ~20% of people (Punjabi, 2020)
  - 30% under-diagnosed and 15% over-diagnosed with single night studies (LeChat, 2022)
- **Disease progression**
  - OSA event severity and frequency may progress over time (Leppänen, 2017)
- **Current metrics poorly predict outcomes**
  - "[AHI] poorly predicts the adverse outcomes of sleep apnoea" (Azarbarzin, 2018)
  - "insufficient evidence exists to assess the validity of AHI as a surrogate or intermediate outcome for long-term clinical outcomes." – Agency for Healthcare Research and Quality (AHRQ, 2021)

Medical Societies & Innovation Endorsing Remote Monitoring

- **American Medical Association** (AMA) - "Digital Health is the Future - Innovations are Fundamentally Changing the Way People Interact with Healthcare"
- **American Heart Association** (AHA) Connected Care™,
  - Remote care delivery system that will provide heart and cardiometabolic care to patients at home
- **American Association of Sleep Medicine** (AASM) – "… the AASM recommends the implementation of remote physiologic monitoring and remote therapeutic monitoring codes (as appropriate)…"

HWO_2 Device = Buccal Mucosal Oximeter



Bluetooth Communication Chip

Data Storage, Up to 3 days of Sleep Data

Proprietary, Medical-Grade Material
- Highest level of biocompatibility
- Indestructible and stain resistant

Anatomical Design, Custom Comfort Fit Flexible Circuit Board

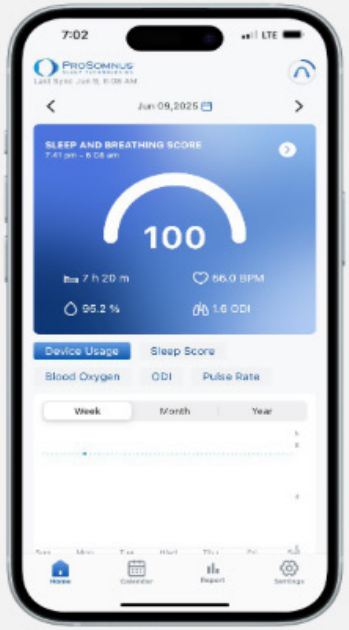
Rechargeable battery

Oxygen, Pulse Rate (PPG) Sensor

Wireless Charging

Motion (Accelerometer), Proximity & Temperature Sensors

Oxymetrx™ App – Each Night Tells A Sleep Story



HWO2 helps users understand the key variables in sleep, enabling them to tune into and take control of their sleep

- Sleep Score
- Usage time
- Pulse rate (heart rate)
- SpO_2 (blood oxygen)
- ODI (oxygen desaturation index)

Sleep and breathing score = Wearing time score + ODI score + T90 score.
Wear time and ODI make up the majority of the score

Oxymetrx™ Smartphone App

Download on the App Store

GET IT ON Google Play

Daily Monitoring

ProSomnus Sleep Technologies

Monthly Oxymetrx™ Report

Date Range: September 1, 2025 - September 30, 2025

Print Time: October 31, 2025 13:47

User Information

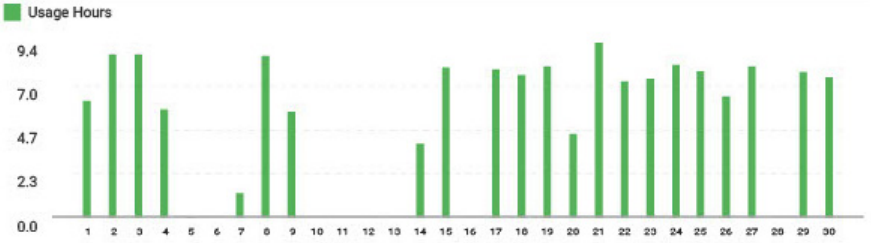
User ID: 1344898
Name: Karel Vandervelden
Email: drv@wmcpapalternatives.com
Date of Birth: 1988-04-06
Reporting Period: September 1, 2025 - September 30, 2025

Report Information

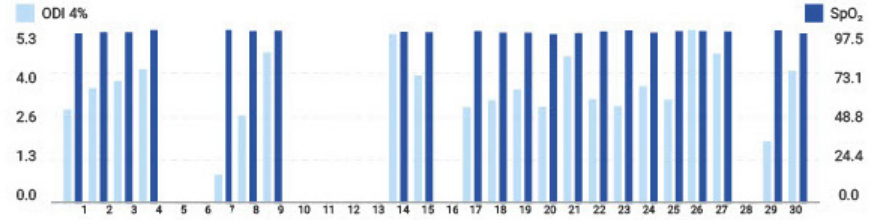
Usage Days: 23/30 76.7%
Total Usage Hours: 155 hr 7 min
Average Nightly Usage: 6 hr 45 min

September 1, 2025 - September 30, 2025

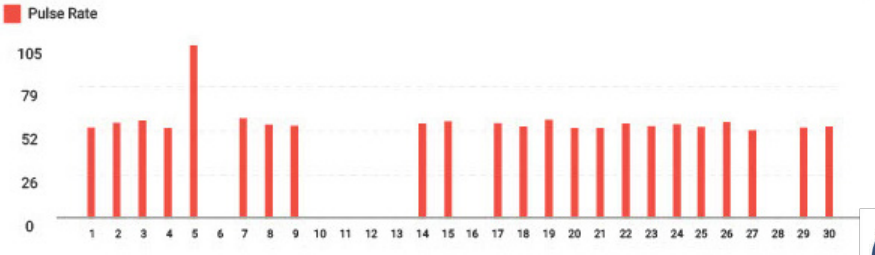
Usage Hours



ODI 4% & SpO_2



Pulse Rate



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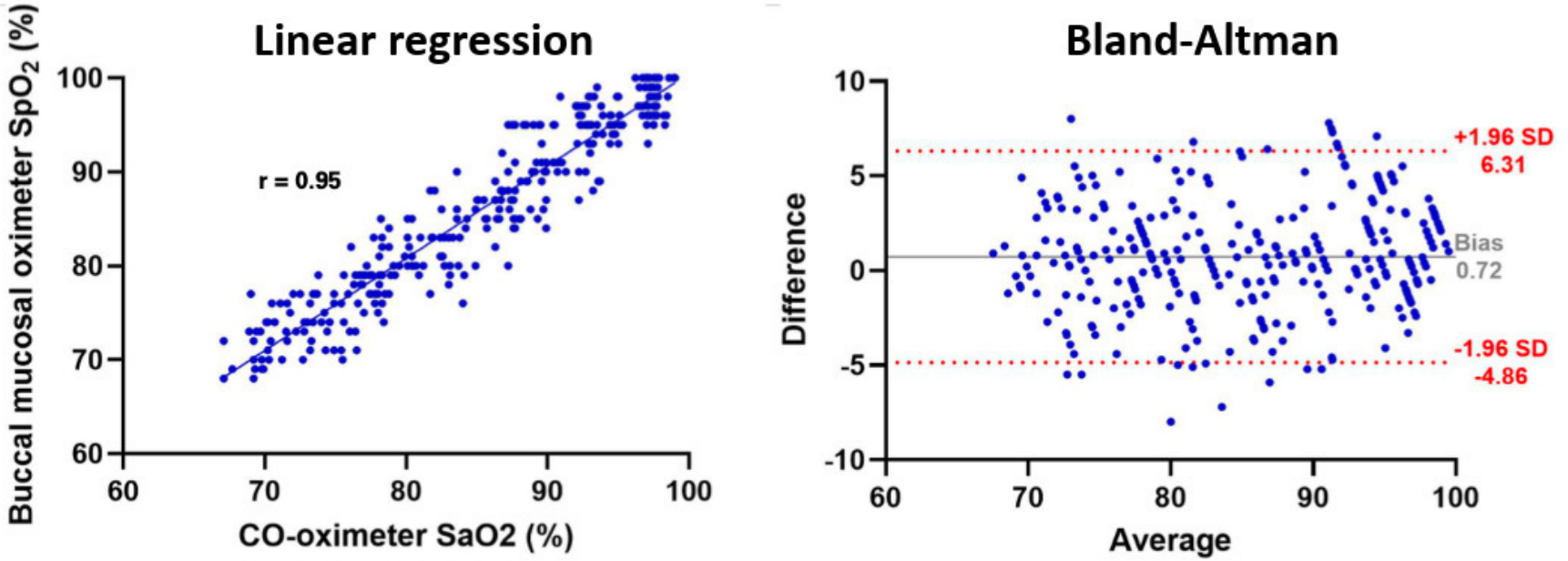
Dr. Vandervelden

HWO_2 Accurately Measures: SPO2

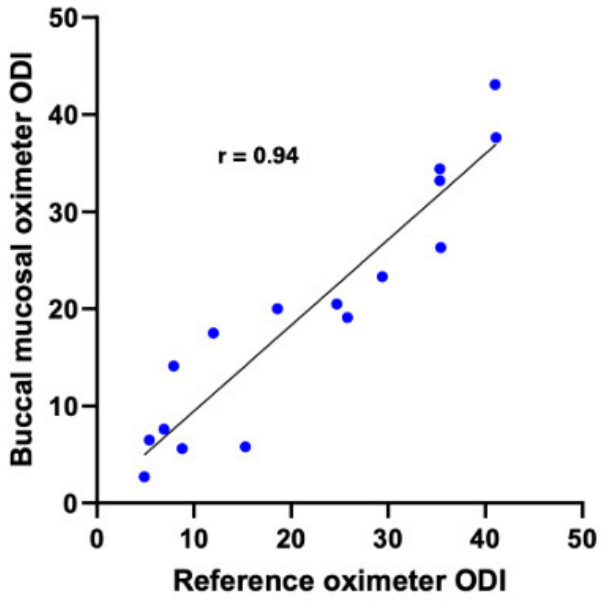
Figure 4. Linear regression and Bland-Altman for buccal mucosal oximeter SpO_2 and CO-oximeter SaO_2.



Snow C, et al. A Buccal Mucosal Oximeter Accurately Measures Arterial Oxyhemoglobin Saturation. Med Devices (Auckl). 2025 Jul 11;18:387-395. doi: 10.2147/MDER.S527510.

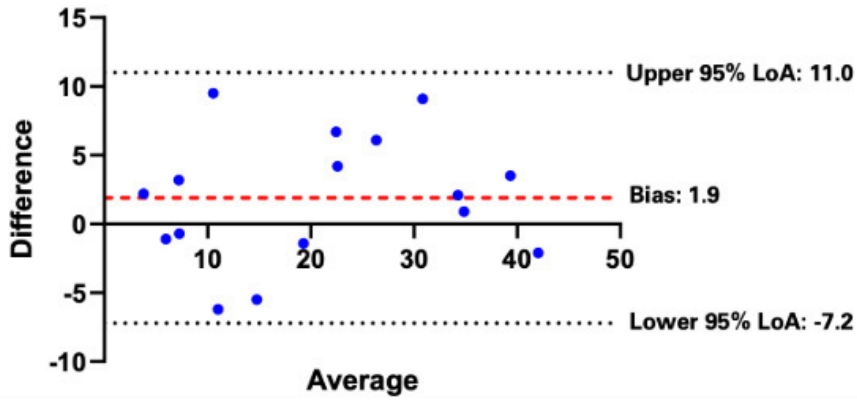
HWO_2 Accurately Reports ODI in OSA Patients

Figure 1. Linear regression for buccal mucosal oximeter oxygen desaturation index and reference oximeter oxygen desaturation index.



Mosca, et al World Sleep 2025: 2578

Figure 2. Bland-Altman for buccal mucosal oximeter oxygen desaturation index and Nonin oxygen desaturation index.



Mallampati score. JAMA 2013

Refer to Dr. Vandervelden Fax: 616-772-9830
"Evaluate pt. for OSA and treat if appropriate" or

Tell patients to call and schedule a complimentary consultation with me. 616-741-9035

Downtown Holland
www.wmCPAPalternatives.com

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Customized Sleep Apnea Solutions
Dr. Vandervelden

For most accurate mallampati reading-have patient rest tongue on lower lip and open up maximally.
Refer:

- Class 3 especially if accompanied with one of the following: *daytime sleepiness, snoring, poor sleep quality, gasping for air at night, witnessed apneas, frequent night time awakenings, morning headaches.*
- All class 4
- All patients with confirmed obstructive sleep apnea (OSA) who want an alternative to CPAP, and all OSA patients prior to surgery.
- All patients you suspect have OSA, refer to my practice first.

The latest evidence supports a causal relationship between strokes and sleep apnea, high blood pressure and sleep apnea. Cost of care related to stroke and high blood pressure:

- High blood pressure requiring brand name + combinations : $3,288 - $4,800 (per year)
- Stroke (acute care + first year): $47,800 average

cost of care related to adverse cardiac incidents where sleep apnea is a direct contributing factor:

- Worsening A-fib requiring cardiac ablation procedure: Low end~ $40,000. High end~ $80,000
- Heart attack (acute care + first year): Low end~$10,000. High end~ $50,000.

Cost of the most effective treatment options for obstructive sleep apnea:

Surgery (Inspire, Genio). All in costs: ~Equivalent to $3,000 - $7,000 per year for the first 10 years (prices vary). Most expensive and invasive

CPAP: not including diagnostic costs~Equivalent to $1,900-$2,700 per year for lifetime. Supply costs alone average around $1,835 per year. This does not include diagnostic costs associated with sleep clinic visits, sleep testing, ect....

Care with Dr. V: All in costs: Equivalent to $975 - $1,600 per year depending on appliance type desired and if remote monitoring is desired. Includes all costs for diagnostics, sleep testing, work ups by sleep medicine (Dr. V coordinates this), long term monitoring and management by Dr. V. By far the most cost effective hassle free treatment pathway. Consider referring all your sleep patients to Dr. V first.

Dr. V does not take insurance mainly due to low reimbursement rates, and a lack of appropriate CMS billing codes that accurately describe and reimburse for the care he provides. Patients should expect to pay out of pocket for his services. Low monthly options at no extra cost to the patient is available as a courtesy (Dr. V takes the hit). Research shows patients out of pocket costs of untreated sleep apnea is higher than cost of treatment. Not all patients want or can afford the level of care Dr. V provides. Mandibular advancement devices are provided by others who take insurance, but the results are not the same. For your most health conscientious patients and those who want the best results, refer to Dr. Vandervelden.

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 8-16 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.
- Remote patient monitoring is the future, and helps meet current challenges in sleep medicine, given the night to night variability of sleep and poor health outcome predictability using AHI and single night sleep studies. HWO2 is leading the way. How I utilize HWO2 will evolve as more metrics come online and monitoring capabilities improve, currently I "strongly encourage" it more for my severe OSA patients.
  - 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.

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

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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 with mallampati score 3 or higher and that
- All patients diagnosed with sleep apnea
- All patients prior to Hypoglossal Nerve Stimulation or other surgeries
- Patients who testing showed no significant sleep apnea, but who snore and are serious about finding a long term solution.
- Feel free to share my costs with all patients. I understand not all patients want the level of care I offer, and some may be okay with a cheaper less effective appliance made by an in-network dentist. For your most health conscientious patients and those who want the best results, refer to my practice.

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