



Data Published by Cureus Journal of Medical Science Shows Successful Treatment of Obstructive Sleep Apnea with ProSomnus Precision Oral Appliance Devices

December 19, 2023

Additional clinical research indicates patients using ProSomnus devices have decreased apnea-hypopnea index events per hour, with strong treatment adherence

PLEASANTON, Calif., Dec. 19, 2023 (GLOBE NEWSWIRE) -- ProSomnus, Inc. (NASDAQ: [OSA](#)) (the "Company"), the leading non-CPAP Obstructive Sleep Apnea (OSA) therapy™, today announced the publication of a study by the *Cureus Journal of Medical Science*, in which the Company's precision oral appliance therapy (OAT) devices successfully treated patients' OSA.

"The study underscored what we see daily in our practice at Star Sleep & Wellness. Our team continues to favor the ProSomnus® EVO® Sleep and Snore Device, as it not only garners the fewest number of patient complaints regarding fit and comfort, but also shows to be superior in resolving chief complaints such as partner discontent, fatigue and daytime sleepiness," said Dr. Kent Smith, D-ABDSM, ASBA, a co-author of the study.

Key findings from the study, titled "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," include:

- 89% of all patients and 98.5% of mild to moderate OSA patients were treated to an apnea-hypopnea index (AHI) of fewer than 10 events per hour.
- 80% of severe OSA patients were treated to an AHI of fewer than 20 events per hour with a 50% improvement.
- After a minimum one-year follow-up period, 96% of patients continued using their precision OAT devices.

"Oral appliance success is traditionally evaluated with the AHI metrics. My experience with the ProSomnus® EVO® precision oral appliance is that it exceeds the American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine (AADSM) standards for efficacy. This study shows that residual AHI using an EVO device is superior to other oral appliances, and superior to hypoglossal nerve stimulation in reducing the AHI. Clinically speaking, I have delivered over 300 EVO devices. I find EVO to have great patient compliance, minimal delivery adjustments, and overall better patient comfort than other traditional oral appliances for sleep apnea," said John A. Carollo, DMD, D-ABDSM, D-ASBA, a co-author of the study.

"My experience with ProSomnus began in 2019 and since that time, I have come to appreciate the benefit to my patients in delivering precision oral appliances such as these. The study irrefutably demonstrates this," said Dr. Aditi Desai, BDS, MSc, FCGDent, a co-author of the study. "The ethos of the company has certainly helped drive the field of oral appliance therapy as a most credible alternative to CPAP."

ProSomnus also announced additional clinical research highlighting the efficacy, decreased AHI incidents, and strong therapy adherence associated with the Company's precision OAT devices:

- In a six-center study assessing the efficacy, repeatability and predictability of treating 58 moderate to severe OSA patients with ProSomnus® EVO® and a standard treatment protocol, participants' median obstructive AHI decreased from 20.54 to 3.9 events per hour, while 90% of patients experienced fewer than 15 events per hour. The data were presented at the 2023 Interdisciplinary Belgian Dental and Surgical Sleep Medicine Academy meeting by Prof. Dr. Marc Braem, DDS, PhD., in an abstract titled "Oral Appliance Treatment in General Hospital Setting: Effects on Obstructive Apnea-hypopnea Index (oAHI) Measured with Polygraphy, at Multiple General Hospitals."
- In a study of 22 mild to moderate OSA patients, the ProSomnus® EVO® was associated with a decreased AHI and strong compliance. After being treated with the EVO, patients' median AHI decreased from 21 to 4 events per hour, while 95% of patients experienced fewer than 10 events per hour. Patients' compliance with the EVO, reported in the first three months of therapy, was 100%. These findings were presented at the 2023 World Sleep Congress by Dr. Raquel Silva, in an abstract titled "New Generation Oral Appliances for Treatment of Obstructive Sleep Apnea."

"In an effort to offer patients an effective titration schedule, the bite registration is generally made at the so called maximal comfortable protrusion, minus 2.0 mm after DISE investigation. In a retrospective analysis of this procedure at 6 general hospitals, the reduction in Obstructive Apnea-Hypopnea index, as measured with type 3 polygraphy, was highly significant lowered to 3.9 events/hr sleep, irrespective of the sleep center methodology used," said Prof. Dr. Marc Braem, DDS, PhD.

"These studies demonstrate that precision oral devices offer consistent efficacy across multiple clinical and hospital settings, and are associated with reliable adherence. Traditional oral devices are typically associated with inconsistent efficacy due to imprecise repositioning and stabilization of the jaw and unreliable durability due to side effects and mechanical issues," said Len Liptak, ProSomnus Chief Executive Officer. "This new data adds to a body of evidence underscoring that ProSomnus devices are a safe and efficacious option for millions of OSA patients who have terminated or refused CPAP, or been impacted by the CPAP recall."

About ProSomnus

ProSomnus (NASDAQ: [OSA](#)) is the leading non-CPAP therapy for the treatment of Obstructive Sleep Apnea, a serious medical disease affecting over 1 billion people worldwide, that is associated with comorbidities including heart failure, stroke, hypertension, morbid obesity, and type 2 diabetes. ProSomnus intraoral medical devices are engineered to precisely track the treatment plan and anatomy for each patient. Non-invasive, patient

preferred and easy to use, ProSomnus devices have demonstrated excellent efficacy, safety, adherence, and overall outcomes in a growing body of clinical investigations. ProSomnus precision intraoral devices are FDA-cleared, patented, and covered by commercial medical insurance, Medicare, TRICARE and many Government sponsored healthcare plans around the world, representing over 200 million covered lives. To learn more, visit www.ProSomnus.com.

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