Emerging Sleep Technologies: Novel Obstructive Sleep Apnea Treatment Alternatives

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Side-by-Side Comparison and Supplemental References

Emerging OSA Treatment Alternatives – Side-by-Side Comparison

AASM Emerging Technology Committee

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	Somnera	Bongo Rx	ULTepap	iNAP	eXciteOSA
Manufacturer	Somnera www.somnera.com	AirAvant Medical www.airavant.com	Bryggs Medical www.bryggsmedical.com	Somnics www.somnics.com	Signifier Medical Technologies www.exciteosa.com
Intended indication	OSA with PAP airflow intolerance	Mild to moderate OSA	Mild to moderate OSA	Snoring and OSA	Snoring and mild OSA
Short summary	The Somnera System (previously Fresca) is a PAP system comprising an airflow generator and a nasal interface (nasal mask or pillows) with a patented SmartValve seated in it. The system outputs pressure within a programmable range of 4 – 20 cm H20. Adherence, but not AHI, can be measured and displayed.	The Bongo Rx is a reusable nasal EPAP device based on the concept of Provent. Its silicone nasal pillows form a seal just inside the nasal openings as opposed to an adhesive seal in the Provent therapy. The Bongo Rx is available in four sizes, and the starter kit has all four sizes. Optional headgear can be worn to hold Bongo Rx in place.	The ULTepap is a reusable, nasal EPAP device comprising silicon nasal pillows. The ULTepap has a proprietary pair of "flow cartridges" (Rashidi-Sleeper valves) comprising a cylinder and a flexible, thin-walled shell, which is aligned in series with nasal pillows. There are three available sizes. ULTepap is held in place with headgear.	The iNAP system is a new battery-operated, negative intra-oral pressure device. It consists of six main components: a portable console, a saliva container, a saliva absorbent (iNAP DryPad), flexible polymer tubing, a polymer oral interface, and an app for mobile devices (iNAP LAB+) that tracks usage and seal time.	The eXciteOSA (previously Snoozeal) is an electrical stimulator device used on the tongue while awake. The device provides electrical stimulation when orally inserted and activated. It consists of a mouthpiece that delivers therapy, a control unit to power the mouthpiece, and an app that controls the therapy intensity and reports adherence. It is used for 20 minutes once a day while awake for six weeks, and twice a week thereafter.
Claimed capabilities	Somnera claims their system is effective in reducing the AHI in patients with mild, moderate, and severe OSA. The low-airflow SmartValve (1) eliminates the need for a humidifier; (2) introduces a new acclimation feature: No-flow GoToSleep comfort setting; (3) enables use of a small (9 mm), lighter Somnera hose; (4) and eliminates programmed leak in the Somnera mask.	AirAvant claims the AHI can be significantly reduced while using the Bongo Rx, and it has lower inspiratory and expiratory resistance than Provent. The Bongo Rx is easy to use, requires no power, and is handy for traveling, camping, or use any place where electricity is unavailable. Bongo Rx is small enough to fit in a shirt. It is intended to be replaced quarterly.	Bryggs claims the ULTepap airflow cartridges generate EPAP equivalent to Provent at various flow rates based on bench testing performed by Bryggs. The ULTepap does not require a power source, and it can be used as a direct substitute for CPAP, or as a complement to CPAP when there is no power source, such as when camping or traveling.	Somnics claims the iNAP system is effective in treating all severities of OSA. It requires no mask, has a more comfortable oral interface compared to the Winx, delivers an intermittent suction (as opposed to continuous suction in Winx), and is portable for travel. It can pair with FitBit and certain pulse oximeters to provide ODI through the iNAP LAB+ app.	Signifier Medical Technologies claims the device reduces snoring and lowers AHI in patients who have mild OSA and are 18 years of age or older. The eXciteOSA device is not intended for patients who are suspected of having moderate or severe OSA or have an AHI of 15 or higher. Mouthpieces need to be replaced quarterly.
Proposed mechanisms	Somnera System uses a valve and low airflow to treat OSA by delivering a therapeutic pressure. The valve controls airflow to provide PAP during exhalation (EPAP) when a patient exhales by utilizing the patient's own breathing effort along with airflow from the generator to keep the upper airway open. On inspiration, the patient draws air from the room through the valve supplemented by airflow from the flow generator.	When inhaling, small valves open to allow normal breathing. When exhaling, the valves close, which directs exhaled air through vent holes to generate EPAP and keep the upper airway open. The Bongo Rx also acts as a nasal dilator.	During inhalation, the ULTepap patented Rashidi-Sleeper valve deflates, allowing air to flow in. During exhalation, the valve inflates and causes exhalation through a fixed orifice. This creates EPAP and splints the upper airway open.	During sleep, the iNAP system creates a negative pressure of -40 mm Hg (or -53 cm H20) within the oral cavity to stabilize the tongue and open the airway. When the proper seal is established, the pump stops, and the device is idle.	The eXciteOSA stimulates the tongue using a variation of therapeutic stimulation frequencies over 20 minutes, which achieves muscle contraction to improve muscle functionality. The device delivers pulses for 60% of the therapy session while 40% of the time is spent allowing the tongue to rest.
Related technologies	PAP	Provent by Provent Sleep Therapy (discontinued in June 2020); ULTepap, Optipillows	Provent by Provent Sleep Therapy (discontinued in June 2020); Bongo Rx, Optipillows	Winx by Apnicure (discontinued in 2017)	None
FDA Status	FDA-cleared class 2 device for OSA; Note that Somnera's predecessor (Fresca) was cleared through the DeNovo pathway.	FDA-cleared class 2 device for OSA	FDA-cleared class 2 device for OSA	FDA-cleared class 2 device for OSA	FDA-cleared class 2 device for OSA, DeNovo pathway
Other technical information	The Somnera System is cloud-connected and allows transfer of data from the device to the cloud via a smartphone app. Sleep data can be viewed by patients on the smartphone or accessed from the cloud by patients, DME suppliers, and health care providers.	No adherence monitoring available	No adherence monitoring available	The iNAP system is cloud-connected and allows the transfer of data from the device to the cloud via a smartphone app. Data can be viewed by providers on a secured website and by patients on their smartphones.	The eXciteOSA therapy is cloud-connected to a provider portal. The adherence, intensity, and other data are available for clinicians to review.
Availability in the US	Physician prescription required. Currently not covered by commercial insurers or CMS but fits within the existing DME HCPCS reimbursement coding for a CPAP device. No pediatric indication.	Physician prescription is required in the U.S., but it is available in Canada as a non-prescription device. No coverage by commercial insurers or CMS, but available for veterans via the VA system. No pediatric indication.	Physician prescription required. No coverage by commercial insurers or CMS. No pediatric indication.	Physician prescription required. Currently not covered by commercial insurers or CMS. The device is also available by joining the "iNAP Club." No pediatric indication.	Physician prescription required. No coverage by commercial insurers or CMS. No pediatric indication.
Available abstracts or peer-reviewed articles	Two randomized controlled trials (NCT02387476 and NCT03999944) presented in abstract form demonstrated the non-inferiority of Somnera in treating OSA compared to CPAP. No full peer-reviewed articles have been published as of July 2021.	One clinical trial (NCT02878590) presented in abstract form showed a decrease of AHI with Bongo Rx in patients with mild to moderate OSA. A 2019 meeting abstract showed lower expiratory resistance in Bongo Rx vs. Provent in bench testing. Another lab experiment published in 2021 investigated the pressure generated by Bongo Rx, Theravent, and Optipillows.	Six references quoted on the ULTepap website are publications on Provent. No peer-reviewed clinical trial articles have been published as of June 2021.	Five peer-reviewed articles and two abstracts were published as of July 2021. These industry-funded studies with small numbers of Taiwanese and Japanese patients suggest that the iNAP can lower AHI in patients of varying OSA severity. There was one multi-center, prospective, two-stage, cross-over study (NCT 02698059) done in Germany, and this work was presented in abstract form.	Three peer-reviewed articles were published as of June 2021. These early industry-funded clinical trials suggest that this device is effective in reducing snoring. It may also lower AHI, ODI, ESS score, and PSQI score in patients with mild OSA who have an AHI < 15.
Additional comments	PubMed searches (7/31/21) did not produce clinical evidence to support patient preference for this device over other PAP devices, or that heated humidification is not required. More clinical research is needed to support the claims. The mask and hose are proprietary and only work with the Somnera device, which offers only nasal mask and nasal pillow options.	In the original industry-sponsored, prospective, non-randomized, open-label, single-center clinical study, only 10 patients completed the study (abstract). Additional clinical trials with more patients and improved study design are warranted. Also evaluation of long-term efficacy, acceptance, and satisfaction is needed.	The FDA 510(K) premarket notification indicates that clinical studies were not done prior to approval. Bench testing results have not been published. Clinical trials are needed for the assessment of efficacy, tolerance, and safety.	Studies showed AHI reduction in non-obese Asian populations. An imaging study was carried out to differentiate the anatomical features of iNAP responders versus non-responders. Larger, longer-term studies are needed in varied patient populations.	The published studies included patients with snoring and mild OSA. Patients with BMI >35 (32 in one study) were excluded. All three studies reported improvement of snoring, and one study assessed and reported AHI improvement. Additional studies are warranted. This is a daytime treatment modality.

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