A Novel EPAP Device for the Treatment of Mild-to-Moderate Obstructive Sleep Apnea

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INTRODUCTION

PAP therapy has long been first-line treatment for obstructive sleep apnea (OSA). However, long-term compliance continues to range from 30 to 70%, diminishing response to therapy. Options for OSA treatment include oral appliances, surgery and nasal expiratory positive airway pressure (EPAP).

The Bongo Rx was recently cleared by the FDA for the treatment of mild-to-moderate OSA using EPAP. This novel device consists of a conjoined set of soft nasal EPAP valves inserted in the nares, also providing a mild degree of dilation. (Figure 1) The aim of this study was to determine the efficacy of this novel EPAP device and what that might mean for patient comfort and ease of use.

Figure 1 – Novel EPAP device

Table 1 **Summary of Baseline Demographics**

Number of Subjects (N)		**10**
Age (years)	Mean (Std Dev)	52.7 (12.9)
	Median (min. 31 and max 70)	53
BMI (kg/m^2)	Mean (Std Dev)	31.6 (5.5)
	Median (min. 20.7 and max 39.8)	32.1
Gender	Male	6 (60.0%)
	Female	4 (40.0%)
Race	American Indian	0 (0%)
	Asian	1 (10.0%)
	Black or African American	2 (20.0%)
	Native Hawaiian or other Pacific Islander	1 (10.0%)
	White	4 (40.0%)
	Other	2 (20.0%)

METHODS

This was a prospective, non-randomized, open label study. Subjects had a diagnosis of mild-to-moderate OSA (AHI ≥5 and ≤30) determined by a diagnostic PSG within 12 months of screening. Subjects were currently using CPAP successfully or were non-compliant with their prescribed therapy. Full face mask users, mouth breathers and subjects with nasal congestion were excluded. Qualifiers were fitted with the correct size novel EPAP device to maximize comfort, seal and to allow for a brief acclimation period. The novel EPAP device is available in four sizes labeled SM, MD, L and XL, to accommodate variability in subjects nares. Subjects were evaluated with PSG while wearing the device, wore the device at home for two weeks and returned for a follow-up PSG.

STUDY PROCEDURES

Potential subjects were scheduled for a screening visit. Screening visits included:

- Informed consent
- Physical exam
- Review of medical history
- CPAP data download (if available)

During the screening visits, subjects also selected a novel EPAP device size of their preference according to the instructions for use and wore the device for at least ten minutes to ensure they could tolerate the device. There were no subjects who refused the novel EPAP device when they initially wore it during the screening visit.

Subjects who met the inclusion and exclusion criteria had the following study schedule:

1. In-lab PSG 1 with the novel EPAP device
2. Nightly at home use of the novel EPAP device for 2 weeks
3. In-lab PSG 2 with the novel EPAP device
4. Study termination visit

Prior to PSG, subjects were screened for recent alcohol use with a breathalyzer and assessed for nasal infection, nasal congestion, or nasal allergies that might impair the ability of the subject to breathe through the nose. Subjects showing evidence of recent alcohol use, nasal infection, nasal congestion, or nasal allergies were sent home and re-scheduled once symptoms were resolved.

PSGs were conducted consistent with American Academy of Sleep Medicine (AASM) guidelines, including subject preparation procedures and the standard PSG recording montage. To record airflow data during PSG1 with the novel EPAP device, sampling tubes were connected between the nasal inserts (via a sampling port on each nasal insert) to the pressure transducer of the recording equipment (Figure 2).

Subjects that qualified for the at home study period continued using the novel EPAP device nightly for two weeks and then returned for PSG 2. Subjects kept a nightly log of hours of use at home.

During PSG 2, subjects used the same novel EPAP device that they had been using at home. Subjects were allowed to sleep in any position.

Adverse events were monitored and collected throughout subject participation.

Figure 2 – The novel EPAP device with sampling tubes to record pressure

RESULTS

Ten subjects completed the two-week trial. Two additional subjects qualified but subsequently withdrew, for an initial acceptance rate of 83%. The baseline diagnostic PSG apnea-hypopnea index (AHI) was compared to the AHI after two weeks of home use. Three subjects had unusable data at the two-week PSG, so their initial treatment PSG was used for analysis. Results show the mean baseline AHI (15.7 ± 6.4) was reduced to a mean AHI (7.1 ± 4.2) at the treatment PSG with the EPAP device (p=0.0093), a reduction of 45%. (Table 2) There were two mild adverse events possibly related to the device and no serious adverse events during the study.

Table 2

AHI Analysis

	AHI at Diagnostic PSG	AHI at Treatment PSG 2	AHI Difference	% of AHI Difference
N	10	10	10	10
Mean	15.7	7.1	-8.7	-44.5
Std Dev	6.4	4.2	8.3	40.1
Median	15.4	7.0	-7.2	-51.3
Min	6.1	0.4	-21.7	-98.2
Max	28.6	12.3	1.4	13.0
p value			0.0093	0.0066

CONCLUSION

The results show that this EPAP device has considerable promise for the treatment of mild-to-moderate OSA. The device was efficacious, safe and well-tolerated although the small N limits generalization to larger populations. Additional study is needed to evaluate longer term patient acceptance and satisfaction. **This EPAP device presents a potential viable alternative to PAP therapy for mild-to-moderate OSA.**

DISCUSSION

While **PAP therapy continues to be a viable first line therapy** for the treatment of obstructive sleep apnea, **compliance remains an ongoing problem**. Alternative therapies have been developed in response to this issue, facilitated by increased understanding of the multi-factorial nature of the disease and opening up newer pathways for treatment. These newer therapies include upper airway surgery, implantable stimulation devices and mandibular advancement oral appliances, all of which have demonstrated varying degrees of efficacy and patient acceptance. They also present their own associated potential problems including surgical pain, cost and, in the case of oral appliances, jaw pain and excessive salivation.

The advent of Expiratory Positive Airway Pressure as a treatment pathway has added another viable approach to the treatment of OSA. T**he EPAP device studied here has the potential to be first line therapy for patients with mild-to-moderate OSA as well as for those patients who have been unsuccessful adapting to CPAP** or who have stopped using it for a variety of reasons. In addition, this EPAP device is also an alternative to CPAP for patients traveling who may not wish to carry their unit or who are in an area with electric power unavailable. **This EPAP device is a low risk, convenient and effective approach to the treatment of mild-to-moderate OSA.**

STUDY PROCEDURES

INCLUSION CRITERIA

- Capacity and willingness to sign informed consent
- ≥ 21 years of age
- Diagnosis of mild to moderate OSA (AHI ≥ 5 and AHI ≤ 30) within the prior 12 months
- Able to tolerate using the device during a day time trial/acclimation
- Are currently using CPAP, or have been prescribed CPAP and are considered CPAP non-adherent (as per their CPAP data card and/or verbal confirmation of a unwillingness to use CPAP)

EXCLUSION CRITERIA

- Nasal deformities
- Severe nasal allergies
- Rhinitis or moderate nasal congestion, acute upper respiratory (including nasal, sinus or middle ear) inflammation or infection, or perforation of the ear drum
- Co-morbid sleep disorders
- Currently on a hypnotic for insomnia (subjects who have had insomnia for more than a month and take a hypnotic on a daily basis, and or subjects with transient insomnia being treated)
- Uncontrolled or serious illness, including but not limited to: severe breathing disorders including hypercapnic respiratory failure, respiratory muscle weakness, bullous lung disease (as seen in some types of emphysema), bypassed upper airway, pneumothorax, pneumomediastinum, etc.; severe heart disease (including heart failure); or pathologically low blood pressure.
- Full Face Mask user
- Mouth breather
- Pregnant

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