

Success Rates of Nasal Expiratory Positive Airway Pressure (nEPAP) Via Expiratory Resistive Load for the Treatment of Obstructive Sleep Apnea

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Introduction:

Prior investigations have shown that nEPAP is efficacious at reducing AHI^{1,2}. To increase the power of calculations and to present data from these investigations against established therapeutic success criteria, data from these two prior nEPAP studies were pooled.

Methods:

In both prior investigations, subjects underwent monitored polysomnography with and without nEPAP (PROVENT® Sleep Apnea Therapy, Ventus Medical, Inc., Belmont, CA) on separate nights, in random order. All sleep data were scored by a blinded reader.

In the literature, several different success thresholds have been reported for OSA therapies. Most thresholds focus on changes in AHI, in either absolute or percent reduction terms, e.g. treatment AHI<5, AHI<10, AHI improved by >50% or combinations thereof.

Demographics	
Age	
Mean SD	50.4 9.4
Range	27 to 67
Gender	
Male	46 (79%)
Female	12 (21%)
Race	
Caucasian	40 (69%)
Black	6 (10%)
Asian or Pacific Islander	7 (12%)
Hispanic	2 (3%)
Other	2 (3%)
Unknown	1 (2%)
Weight (lbs)	
Mean SD	199 47.2
Range	103 to 314
Height (in)	
Mean SD	68.9 4.0
Range	59 to 77
BMI (kg/m²)	
Mean SD	29.3 5.4
Range	18 to 45

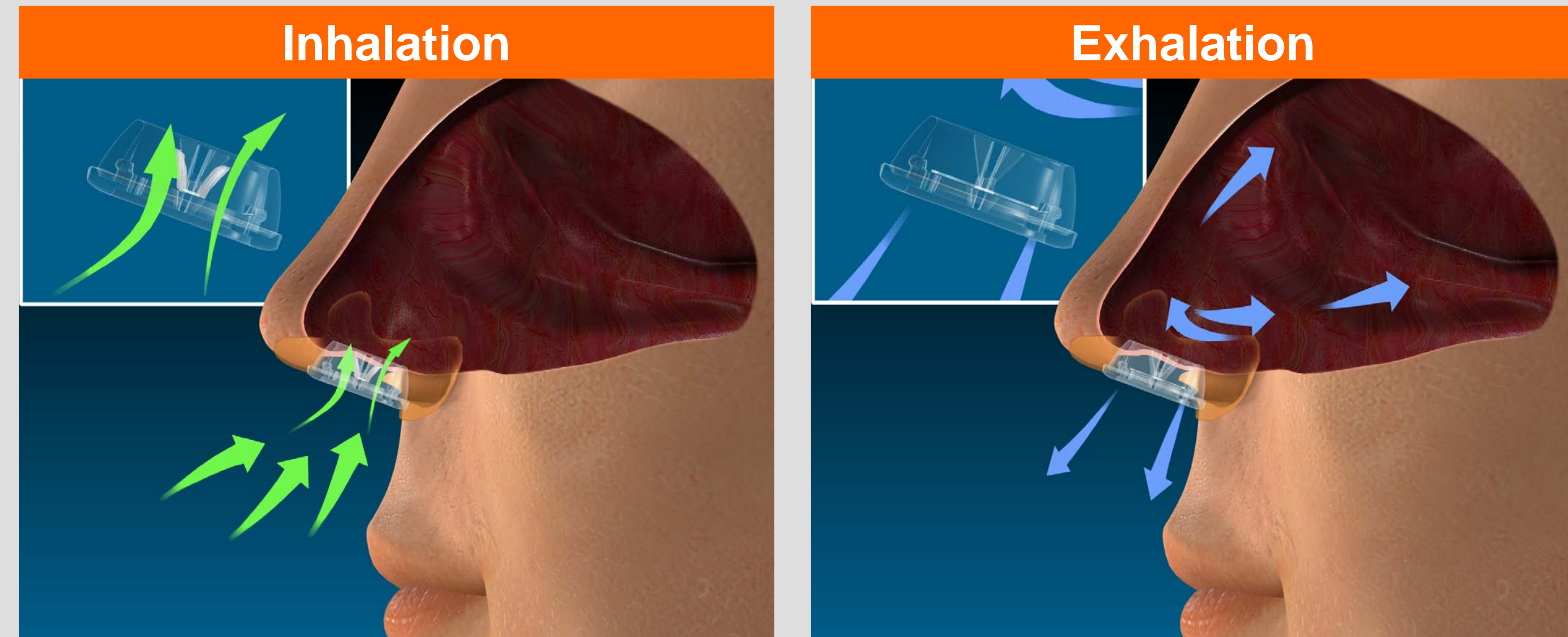
Results				
	N	Mean	STD	P-value
Apnea-Hypopnea Index				
Control	58	26.6	24.9	<.001
Treatment	58	13.7	20.1	
Apnea Index				
Control	58	16.9	21.8	<.001
Treatment	58	7.8	18.0	
Apnea Duration (sec)				
Control	53	21.0	5.8	0.303
Treatment	53	20.3	6.1	
3% Oxygen Desaturation Index				
Control	58	13.1	17.4	0.001
Treatment	58	9.2	14.7	
Total Sleep Time (min.)				
Control	58	345	69	0.998
Treatment	58	345	72	
Sleep Efficiency				
Control	58	79	13	0.910
Treatment	58	79	13	

Results:

nEPAP reduced AHI in the 58 subjects from 26.6±24.9 (mean±SD) to 13.7±20.1, a 49% reduction (p<0.001). During treatment with nEPAP, 36% of subjects (21/58) had an AHI<5, 59% of subjects (26/44) had an AHI <10, and 66% of subjects (38/58) had an AHI improvement >50% compared to baseline. Further, 72% of subjects (42/58) met either the treatment AHI <10 or AHI improved by >50% criteria, and 50% of subjects (22/44) met both the AHI <10 and AHI improved by >50% criteria. There was one reported adverse event (a headache) in these studies which was deemed “possibly related” to the device. (See Chart 1)

Conclusion:

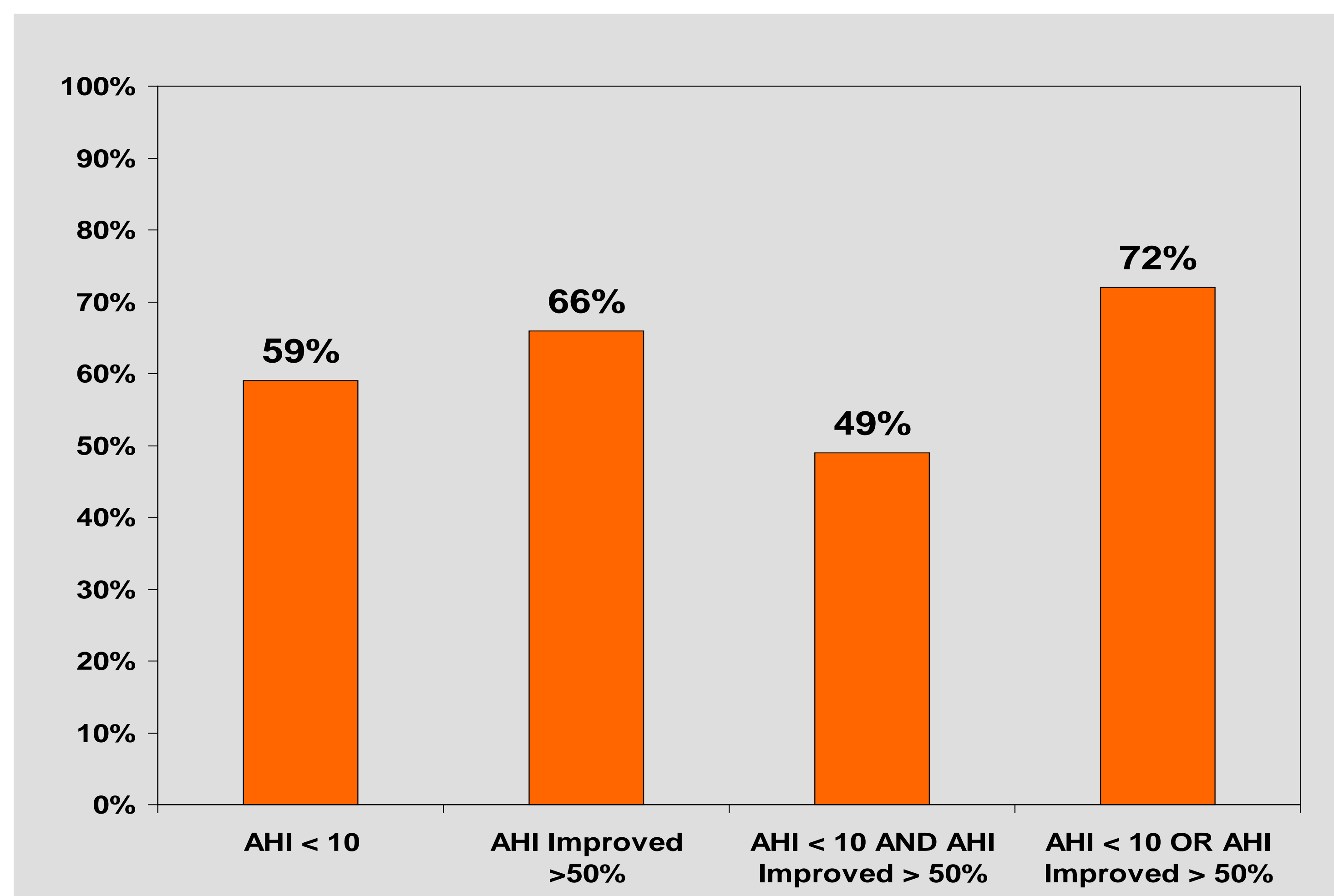
Statistically significant improvements in AHI and ability to achieve established therapeutic success criteria across this larger group of subjects demonstrate the viability of nEPAP via expiratory resistive loading in the treatment of OSA. Success rates are comparable to mandibular advancement devices and surgical approaches, both of which are associated with higher rates of adverse events. Because nEPAP has ease of trial, few adverse events, and positive efficacy, nEPAP could be an early consideration for the treatment of OSA.



Section view of nEPAP device showing flap valves which open and close in response to air flow. Green arrows (left figure) show air flow on inhalation and blue arrows (right figure) show air flow during exhalation. During inhalation, the low resistance valves open allowing air to flow freely. During exhalation, the valves close and air moves through small holes which act as resistors. Elastic recoil of the lungs is thought to generate pressure in the airway during exhalation which is maintained until the next inspiration.

Analysis of Apnea-Hypopnea Index by OSA Severity					
	N	Mean	Median	Min to Max	STD
Mild OSA (control night 5<AHI≤15)					
Control	23	9.4	9.0	5 to 15	3.79
Treatment	23	5.8	4.2	0 to 22	5.18
Treatment-Control	23	-3.6	-4.1	-12 to 16	6.41
Moderate OSA (control night 15<AHI≤30)					
Control	20	19.6	17.7	15 to 30	4.12
Treatment	20	7.7	6.3	2 to 24	5.63
Treatment-Control	20	-11.9	-13.5	-27 to 7	7.72
Severe OSA (control night AHI>30)					
Control	15	62.4	56.6	31 to 105	23.28
Treatment	15	33.8	20.9	2 to 101	31.22
Treatment-Control	15	-28.5	-26.2	-71 to 6	21.11

Chart 1: Results by Various AHI Criteria



References:

- Colrain IM; Brooks S; Black J. A pilot evaluation of a nasal expiratory resistance device for the treatment of obstructive sleep apnea. J Clin Sleep Med 2008;4(5):426-433
- Rosenthal L; Dolan DC; Massie CA; Kram J. A novel expiratory pressure device to treat mild-moderate OSA, SLEEP 2008;31(abstract supplement):A208

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Inclusion Summary

To be included in either study, subjects had a history of snoring on most nights or witnessed apnea or prior diagnosis of OSA; >18 years of age

Exclusion Summary

Subjects were excluded from the study if they were actively using CPAP or BiPAP (n=26) or had ever used CPAP or BiPAP in the home environment (n=32); flu like or upper respiratory illness symptoms at the time of assessment; history of frequent and/or poorly treated severe nasal allergies or sinusitis; persistent blockage of one or both nostrils; previously diagnosed insomnia, narcolepsy, or PLMS; history of any other unstable and/or untreated serious medical conditions (including angina/myocardial infarction, hypertension, cancer, stroke, dementia, heart failure or other heart condition, mental illness, diabetes); previously undergone surgical treatments such as somnoplasty, UPPP, LAUP, mandibular advancement, or Pillar procedure; currently taking SSRIs, benzodiazepines or other drugs known to affect sleep quantity or architecture; females who were pregnant or intending on becoming pregnant were also excluded.