Obstructive sleep apnea is a very common disorder often resulting in adverse cardiovascular consequences, daytime sleepiness, and disturbed nocturnal sleep of the patient and bed partner. Although effective and safe treatment options including continuous positive airway pressure (CPAP), oral appliances, and upper airway surgery exist, none are ideal. Given the high prevalence of OSA, new effective treatment options would be welcomed.

A novel expiratory positive airway pressure (EPAP) nasal device has been developed to provide a new therapeutic option for OSA (Provent Therapy, Ventus Medical Inc., Belmont, CA). A single use EPAP device containing a mechanical valve with very low inspiratory resistance but high expiratory resistance is applied to each nostril with adhesive to provide a seal. The high expiratory resistance results in positive pressure throughout exhalation, which splints open the upper airway, making it more resistant to collapse on subsequent inspiration.

A small pilot study and a subsequent larger prospective multicenter trial found the nasal EPAP device to significantly reduce the AHI in groups of patients with varying severity of sleep apnea. The goal of the current study was to determine the effectiveness of the EPAP device and adherence to treatment compared to a sham device over a 3-month period in a larger group of patients with OSA.

After randomization to either the nasal EPAP or sham device study arm, patients were trained on the use of the assigned device and began using the device nightly for the 3-month study duration.

A total of 195 patients (100 EPAP, 95 sham) completed the 3-month study. The percentage of dropouts in the EPAP and sham groups did not differ. A total of 144 patients in the mITT group completed the 3-month study (77 EPAP, 67 sham).

The major finding of the study was that the EPAP device significantly decreased the AHI compared to device-off nights on the week 1 sleep study, and that the difference was significantly greater than with the sham device (52.7% versus 7.3%, ITT analysis). At repeat testing at month 3, 51% of the EPAP device users had a 50% or greater reduction in the AHI (or reduction to < 10/h) on device-on compared to device-off nights. The week 1 PSG also found that the EPAP device improved oxygenation as exhibited by a small but significant decrease in the ODI and %TST with SpO2 less than 90%. Subjective sleepiness (ESS) also improved after 3 months of nasal EPAP use. The side effects of EPAP treatment were mild, and a significant proportion of patients completed the 3-month study. Median device use (adherence), as reported by patient diary, was excellent, with the nasal EPAP device worn all night for approximately 88% of nights.

The effectiveness of nasal EPAP in this study compares favorably to other treatment modalities. Although CPAP often reduces the AHI to less than 5/h, inadequate adherence to treatment often reduces effectiveness For example, if CPAP reduces the AHI from 40 to 10/h but is only used for one-half of the total sleep time, the effective AHI is 25/h. In one crossover study comparing oral appliances and CPAP, the mean AHI dropped from baseline of 21.3/h to 4.8/h with CPAP and to 14.0/h with an oral appliance. In a meta-analysis of the effectiveness of surgery for OSA, procedures less complex than maxillary-mandibular advancement (usually reserved for severe OSA) reduced the AHI to less than 10/h in 31% of patients. At month 3, the nasal EPAP device achieved a 51% treatment success rate, defined as a 50% or greater reduction in the AHI or a reduction to less than 10/h. This result compares favorably with treatment with oral appliances, upper airway surgery, and even with CPAP when one computes an "effective AHI."

In summary, a randomized, double-blind, sham-controlled study documented that the nasal EPAP device effectively reduced the AHI and improved oxygenation at both week 1 and month 3 in a substantial percentage of patients with mild to severe OSA with minimal side effects. There was significant improvement in subjective sleepiness compared to the sham device group, and self-reported adherence was > 88% with device treatment. The results of the study suggest that nasal EPAP is an effective treatment alternative for a substantial percentage of OSA patients.