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EFFICACY OF THE EXVENT ACCESSORY WITH THE O2VENT OPTIMA ORAL APPLIANCE IN THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA – A CLINICAL TRIAL

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Introduction: The study assessed the efficacy of oral appliance device O2Vent Optima and ExVent, an oral Expiratory Positive Airway Pressure (EPAP) accessory in the treatment of OSA.

Methods: A prospective, open-label study conducted at 3 sites in mild to moderate OSA (AHI ≥ 5 and ≤ 30).

Screening Phase

A diagnostic in-lab PSG study confirmed a diagnosis of mild to moderate OSA.

Treatment I

Subjects used O2Vent Optima for 6 weeks and underwent a PSG sleep night while using the O2Vent Optima.

Treatment II

Subjects used O2Vent Optima + ExVent for 6 weeks and underwent a PSG sleep night while using the O2Vent Optima + ExVent
Primary Effectiveness Measure: Change in AHI between baseline vs. O2Vent Optima MAD vs. O2Vent Optima + ExVent

Results: Treatment with Optima, Optima + ExVent reduced AHI from $22.5 \pm 6.4/\text{hr}$ to $12.6 \pm 4.5/\text{hr}$ to 5.9 ± 2.7 ($p < 0.005$ baseline vs. Optima and Optima + ExVent; $p < 0.05$ Optima MAD vs. Optima + ExVent). Average reduction in AHI with Optima was 43% and with Optima + ExVent was 72%. The lowest oxygen during sleep increased from $84.6 \pm 2.7\%$ to $88.6 \pm 2.9\%$ to $91.6 \pm 3.2\%$ ($p < 0.005$ baseline vs. Optima and Optima + ExVent; $p < 0.05$ Optima vs. Optima + ExVent). During the trial patients on treatment with Optima and Optima + ExVent demonstrated no excessive adverse events or device malfunction.

Conclusion: Treatment with O2Vent Optima and O2Vent Optima + ExVent significantly improved OSA compared to the baseline. Even greater benefit was observed with addition of ExVent to the Optima in mild to moderate OSA.