

## 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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**Abstract :** Introduction: The study's purpose was to assess the efficacy of the oral appliance device O2Vent Optima + ExVent as compared to Optima in the treatment of OSA. Methods: A prospective, open-label study conducted at 3 sites included subjects with mild to moderate OSA ( $AHI \geq 5$  and  $\leq 30$ ). Screening Phase: A diagnostic in-lab PSG study was performed to confirm a diagnosis of mild to moderate OSA. Treatment I: Subjects used O2Vent Optima for 6 weeks and underwent an in-lab PSG sleep night while using the O2Vent Optima. Treatment II: Subjects used O2Vent Optima + ExVent for 6 weeks and underwent an in-lab 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  $22.5 \pm 6.4/hr$  to  $12.6 \pm 4.5/hr$  to  $5.9 \pm 2.7$  ( $p < 0.005$  baseline vs. Optima and Optima + ExVent;  $p < 0.05$  Optima MAD vs. Optima + ExVent). The 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. An even greater benefit was observed with the addition of ExVent to the Optima in mild to moderate OSA.

**Keywords :** oral appliance, O2Vent, sleep dentistry, sleep apnea

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