increasing/stable trends in sleep duration are positive, the declining trends in sleep quality may place Canadians at increased risk of adverse health outcomes. The results of this study will provide evidence to inform programs and policy recommendations related to sleep health, including the identification of more negatively affected population subgroups.

Use of the ExVent Accessory with the O2Vent Optima Oral Appliance for the Treatment of Obstructive Sleep Apnea – A Clinical Trial

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ABSTRACT Obstructive sleep apnea (OSA) is a widely prevalent sleep-related breathing disorder, which leads to several life-threatening diseases. There are three main treatment modalities for OSA including Continuous Positive Airway Pressure (CPAP), mandibular advancement devices (MADs) and surgical intervention. The safety and efficacy of MADs and CPAP are well studied.

MADs work by modifying the upper airway by changing the position of the mandible and tongue. Both CPAP and MAD have variable compliance and tolerance and are associated with adverse effects. The ExVent is an optional accessory to the O2Vent Optima MAD and provides oral Expiratory Positive Airway Pressure (EPAP). Oral EPAP with the ExVent is designed to provide upper airway support via similar mechanisms of action of nasal EPAP devices in commercial distribution, e.g., passive dilatation of the airway, which reduces flow limitation. Nasal EPAP devices are in commercial distribution as stand-alone therapies for the treatment of OSA. The oral EPAP provided by the ExVent accessory is designed to augment the OSA therapy provided by the O2Vent Optima. Purpose The purpose of this study was to assess the performance of the O2Vent Optima + ExVent in the treatment of OSA. Results Patients with mild to moderate OSA were treated with Optima MAD and ExVent for 3 months at 3 different sites in North America. Preliminary data analysis demonstrated that treatment with Optima MAD and ExVent reduced AHI from 13.5±6.4/hr to 6.6±4.5/hr ($p<0.05$), average 58% reduction in AHI. The lowest oxygen during sleep increased from 84.6±2.7% to 88.6±2.9% ($p<0.05$). Overall success rate (>50% reduction in AHI) with treatment was 80%. During the trial patients on treatment with Optima MAD and ExVent demonstrated no excessive adverse events or device malfunction. Conclusion The clinical trial confirmed successful treatment with combined use of O2Vent Optima MAD and oral Expiratory Positive Airway Pressure, ExVent in patients with mild to moderate OSA. Treatment was well tolerated with no excessive adverse effects.