

# The effect of a novel oral appliance therapy on obstructive sleep apnea: **preliminary results**



## INTRODUCTION:

Oral appliance (OA) therapy is ineffective in some individuals with obstructive sleep apnea (OSA). The reasons for this remain unclear, but may relate to disproportionate collapsibility of the velopharyngeal airway or high nasal resistance. This study sought to assess the effect on OSA severity of a new OA that addresses such possibilities by providing an alternative (oral) route of breathing to conventional OA devices (Oventus, O<sub>2</sub>Vent T).

## METHODS:

Participants were recruited from those already using an OA for treatment of OSA. Each underwent 3 separate PSG studies. PSG #1 was undertaken to determine baseline OSA severity (AHI, apnea hypopnea index) without the OA device. The new OA device with oral route OPEN was titrated during PSG #2 to determine optimal device advancement. This degree of advancement was used in PSG #3 to determine the effect on AHI when with oral route OPEN vs CLOSED (half night under each condition, order randomised).

## RESULTS:

Preliminary data have been obtained in 3 male participants aged 61.3±5.7 yrs with BMI 27.0±1.0 kg.m<sup>-2</sup> (see Table). OSA severity was decreased in all individuals with the OA device and oral route CLOSED. Further marked decreases in OSA severity were seen in two of the three individuals when the oral route was OPEN.

Gender	Age	BMI	AHI		
			PSG #1 (no OA)	PSG #3	
				Oral Route CLOSED	Oral Route OPEN
	yrs	kg.m <sup>-2</sup>	events.hr <sup>-1</sup>	events.hr <sup>-1</sup>	events.hr <sup>-1</sup>
M	66	26.1	92.2	46	5.3
M	63	28.0	74.2	33.8	38.4
M	65	26.8	43.9	23.5	7.9

## CONCLUSIONS:

The provision of an alternative (oral) route of breathing in an OA device further reduces OSA severity in some individuals using OA therapy, suggesting bypass of nasal or nasopharyngeal obstruction. These mechanisms and the characteristics of individuals who may benefit from such a device require further elucidation. Studies are ongoing.

## SUPPORT:

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See poster for final clinical data presented

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# The Effect of a Novel Oral Appliance Therapy on Obstructive Sleep Apnoea: Preliminary Results

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## Background

- An oral appliance (OA) can provide effective treatment of obstructive sleep apnoea (OSA) in some individuals
- Traditional OAs may not be efficacious in some patients with OSA, possibly due to high nasal resistance
- The Oventus O<sub>2</sub>Vent T is a novel OA device which permits oral breathing may be efficacious in people with high nasal resistance

## Aims

- Examine the efficacy of the O<sub>2</sub>Vent T with oral breathing route CLOSED and OPEN for the treatment of OSA
- Identify responders and non-responders to the O<sub>2</sub>Vent T
- Assess the relationship between nasal resistance and effect of the O<sub>2</sub>Vent T (oral route CLOSED and OPEN) on OSA severity

## Methods

### Participants

- Participants were recruited from those already using an OA for treatment of OSA

### Protocol

- Participants underwent three polysomnography (PSG) studies:
  - PSG #1 established BASELINE OSA severity (total AHI, apnoea hypopnea index) without an OA
  - PSG #2 established the optimal level of advancement of the O<sub>2</sub>Vent T with the oral route OPEN
  - PSG #3 established OSA severity with the oral route CLOSED vs OPEN (half night under each condition, order randomised) at the optimal level of advancement (or as close to it as tolerated)

### Instrumentation/Analysis

- For all PSG studies participants wore a full face mask which was partitioned into nasal and oral sections and each connected to pneumotachographs to measure nasal and oral flow
- For PSG #1 & #3, a catheter was inserted via the nares to measure pressure at the retro-palatal, retro-glossal, hypo-pharyngeal and oesophageal regions
- Nasal resistance at a flow of 0.1 l.sec<sup>-1</sup> was determined (from the relationship between UA pressures & nasal flow) during wakeful supine nasal breathing in the evening prior to PSG #1 & #3
- PSGs were scored according to AASM 2012 criteria with oral flow used to differentiate apnoeas and hypopnoeas
- Responders to the O<sub>2</sub>Vent T were those with AHI (CLOSED) and/or AHI (OPEN) <50% AHI (BASELINE)

## Results

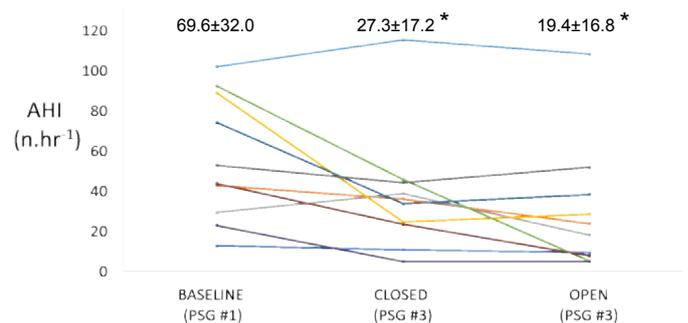
- Preliminary data have been obtained in 10 participants (8 male) aged 54.4±8.1 yrs and BMI 28.8±3.2 kg.m<sup>-2</sup>

Disclosure: This study was sponsored by Oventus Medical Ltd.



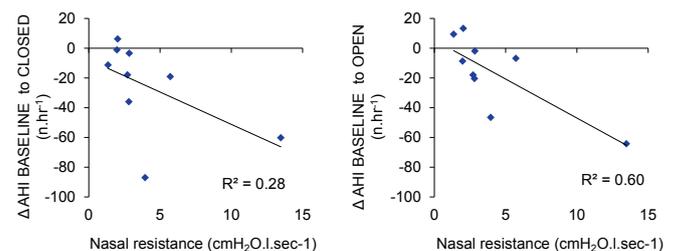
## Results

- Relative to BASELINE OSA, severity was decreased in 8/10 individuals with the O<sub>2</sub>Vent T oral route CLOSED. Relative to CLOSED, with the O<sub>2</sub>Vent T oral route OPEN, OSA severity was further decreased in 6/8 participants (Fig 1)



**Figure 1.** AHI in BASELINE, CLOSED and OPEN conditions in all participants (n=10). Mean ± SD shown above each condition. \* p<0.05 vs BASELINE

- Five participants were responders to the O<sub>2</sub>Vent T. Nasal resistance of responders was approximately double that of the non-responders, although the difference did not reach statistical significance (5.7±5.2 vs 2.8±1.7 cmH<sub>2</sub>O.l.sec<sup>-1</sup>, respectively; p=0.27)
- Nasal resistance was not related to OSA severity at BASELINE, CLOSED or OPEN (all r<sup>2</sup><0.10) but was related to mean snoring intensity (dB) during CLOSED (r<sup>2</sup>=0.50; p<0.05)
- Higher nasal resistance prior to PSG #3 was associated with a greater reduction in AHI from BASELINE during OPEN (r<sup>2</sup>=0.60, p<0.05) but not when the device airway was CLOSED (r<sup>2</sup>=0.28, p=0.14; Fig 2)



**Figure 2.** Relationship between nasal resistance (n=9) and change in AHI from BASELINE to CLOSED (left) and BASELINE to OPEN (right).

- Changes in a number of other measures of OSA severity including O<sub>2</sub> desaturation index 4%, supine AHI and arousal indices from BASELINE to CLOSED and/or OPEN were also related to nasal resistance

## Conclusion

- Provision of an oral route of breathing in an OA device further reduces OSA severity in some individuals using OA therapy, suggesting bypass of nasal/nasopharyngeal obstruction.
- Further data is required to fully elucidate mechanisms and characteristics of individuals who may benefit from an OA with an oral breathing route. However, this preliminary data suggests that the degree of efficacy of this novel OA device appears to be greater in those with higher nasal resistance