

# Airway open-airway closed: The effect of mandibular advancement therapy for obstructive sleep apnoea with and without a novel in-built airway.



## INTRODUCTION:

CPAP is the first-line treatment for OSA, however, it is often poorly tolerated with adherence rates of  $\leq 50\%$ . Mandibular advancement splints (MAS) are a viable alternative for mild to moderate obstructive sleep apnoea for patients who are CPAP intolerant. In addition to mandibular advancement, the O<sub>2</sub>Vent MAS incorporates a novel in-built airway. This study aimed to determine the effects of the built-in airway on treatment response measured using the Apnoea Hypopnoea Index (AHI).

## METHODS:

Single centre randomised crossover trial to examine the effect of the O<sub>2</sub>Vent MAS device with airway open (AO) and airway closed (AC) on Level 1 polysomnography (PSG) derived variables including AHI. After baseline PSG, participants were randomised to receive treatment in AO-AC or AC-AO sequence. Following the manufacture and fitting of the fully customised devices, titration and acclimatisation occurred under close dental supervision. Once subjective symptoms were eliminated, or maximal level of tolerance was achieved for at least 2 weeks, PSG was repeated with the device in situ. Crossover to the second arm occurred ensuring the alternate device was worn at the same level of advancement for at least 2 weeks before the final PSG. Treatment response was defined as  $\geq 50\%$  reduction in AHI.

## RESULTS:

32 (20 Male: 12 Female) mean $\pm$ SD age 56.1 $\pm$ 9.7 years, BMI 30.4 $\pm$ 5.0 kg/m<sup>2</sup> completed the study. Baseline AHI 23.9 $\pm$ 14.7 events/hr decreased with AC to 11.5 $\pm$ 7.2 ( $p < 0.001$ ) and AO to 10.2 $\pm$ 6.2 ( $p < 0.001$ ), despite a significant increase in supine sleep from baseline 21.1 $\pm$ 24.4% to AC 32.0 $\pm$ 23.6% and AO 34.6 $\pm$ 27.1% (both  $p < 0.01$ ). AHI with AC and AO was similar as was the response rate (AC 47%, AO 56%,  $p = ns$ ). However, in the 17 AC non-responders, AO resulted in approximately 20% reduction in mean residual AHI and a further 6 were classified as responders with AO.

## DISCUSSION:

Preliminary findings indicate that inclusion of a built-in airway into MAS devices achieves similar results to MAS without airway. However, in a subgroup of patients who are non-responders to advancement alone or traditional MAS therapy, the inclusion of the airway may provide additional benefits that may result in further improvements in treatment efficacy and response rate.

Abstract ID Number P119

Poster presentation: Sleep DownUnder, Brisbane.  
Saturday October 20, 2018 – 11.24am to 11.30am

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See poster for final clinical data presented

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# AIRWAY OPEN-AIRWAY CLOSED:

## THE EFFECT OF MANDIBULAR ADVANCEMENT THERAPY FOR OBSTRUCTIVE SLEEP APNOEA WITH AND WITHOUT A NOVEL IN-BUILT AIRWAY.



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### INTRODUCTION

**CPAP is the first-line treatment for obstructive sleep apnoea (OSA). However, it is often poorly tolerated with adherence rates of  $\leq 50\%$ . Mandibular advancement devices (MAD) are a viable alternative for mild to moderate OSA or for patients who are CPAP intolerant.**

**In addition to mandibular advancement, the O<sub>2</sub>Vent MAD incorporates a novel in-built airway to circumvent nasopharyngeal obstruction.**

### AIMS

To determine the effects of the built-in airway on treatment response and to identify responders.

### METHODS

Level 1 attended PSG was performed to determine baseline OSA severity.

Two devices were manufactured for each participant, one with airway open (AO) and one with airway closed (AC).

Following randomisation to either AO-AC or AC-AO sequence, MAD fitting, titration and acclimatisation occurred under dental supervision.

Once subjective symptoms were managed or maximal level of titration was achieved for at least 2 weeks, PSG was repeated with the device in situ. Crossover to the second arm occurred ensuring the alternate device was worn at the same level of advancement for at least 2 weeks before the final PSG assessment. Nasal resistance was assessed using anterior rhinomanometry prior to each PSG.

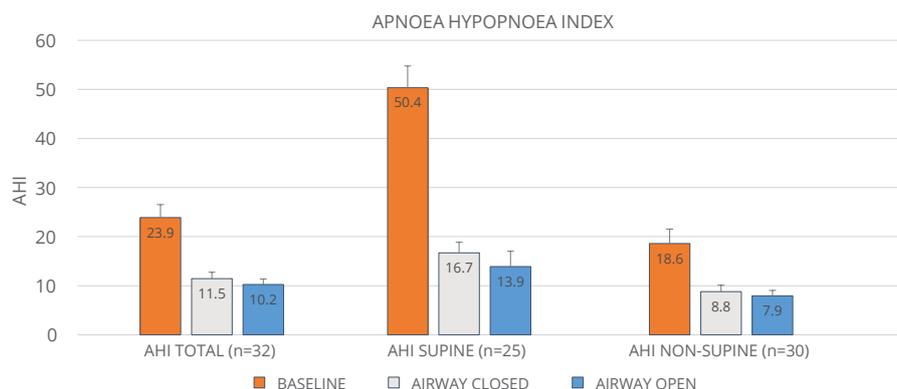
Treatment response was assessed as AHI < 10 as well as  $\geq 50\%$  reduction in AHI from baseline.

### RESULTS

32 participants (20 Male) mean $\pm$ SD age 56.1 $\pm$ 9.7 years, BMI 30.4 $\pm$ 5.0 kg/m<sup>2</sup> completed the study. Mean level of advancement was 10.9 $\pm$ 2.2 mm.

Baseline AHI 23.9 $\pm$ 15.0 events/hr decreased with AC to 11.5 $\pm$ 7.3 ( $p < 0.001$ ) and AO to 10.2 $\pm$ 6.3 ( $p < 0.001$ ), despite a significant increase in supine sleep from baseline 21.1 $\pm$ 24.1% to AC 32.0 $\pm$ 23.6% and AO 34.6 $\pm$ 27.1% (both  $p < 0.01$ ). From baseline, the average reduction in AHI Total was 52% with AC and 57% with AO. Larger reductions in AHI were observed during supine sleep, with average reductions in AHI Supine of 56% with AC and 68% with AO for participants who had supine ( $n = 25$ ) and non-supine sleep ( $n = 30$ ) in all 3 conditions (Figure 1).

**FIGURE 1: TOTAL, SUPINE AND NON-SUPINE AHI AT BASELINE, AIRWAY CLOSED AND AIRWAY OPEN**



The overall response rate as defined by AHI < 10 was 56% for AC and 62% for AO; response rate as defined by  $\geq 50\%$  reduction from baseline was 47% for AC and 56% for AO; response rate meeting both criteria was 41% for both AC and AO (Table 1 Overall response rate).

**TABLE 1: OVERALL RESPONSE RATE**

	AHI Total (n=32)		
	$\leq 10$ N (%)	$\geq 50\%$ reduction N (%)	Both Criteria Met N (%)
Closed	18 (56%)	15 (47%)	13 (41%)
Open	20 (62%)	18 (56%)	13 (41%)

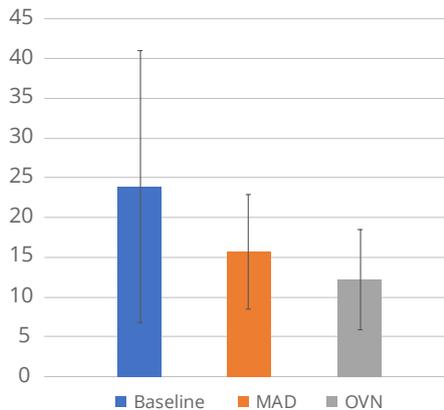
Of the 17 non-responders to AC, using a  $\geq 50\%$  reduction in AHI from baseline, AO resulted in approximately 20% reduction in mean residual AHI ( $p < 0.04$ ) (Figure 2) and a further 6/17 (35%) were classified as responders.

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THE EFFECT OF MANDIBULAR ADVANCEMENT THERAPY FOR OBSTRUCTIVE SLEEP APNOEA WITH AND WITHOUT A NOVEL IN-BUILT AIRWAY.

**FIGURE 2**

EFFECT OF OVENTUS AIRWAY TECHNOLOGY ON MAD TREATMENT FAILURES (AHI)

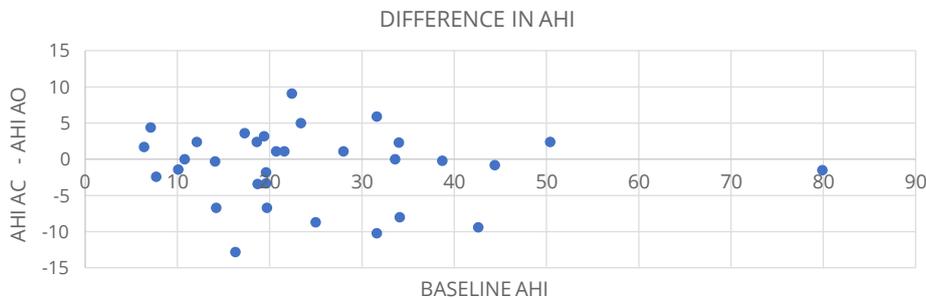


**TABLE 2: RESPONSE RATE IN SUPINE AND NON-SUPINE SLEEP**

	AHI Supine					AHI Non-Supine				
	N	≤ 10 N (%)	N	≥50% reduction N (%)	Both Criteria Met N (%)	N	≤ 10 N (%)	N	≥50% reduction N (%)	Both Criteria Met N (%)
Closed	30	11 (37%)	26	19 (73%)	10 (38%)	31	22 (71%)	31	14 (45%)	13 (42%)
Open	29	12 (41%)	25	20 (80%)	12 (48%)	31	23 (74%)	31	15 (48%)	10 (32%)

Whilst the mean reduction in AHI and response rate with AC and AO was similar, there was considerable individual variability in response to AC and AO. Approximately half of the participants had a greater reduction in AHI Total with AC and half with AO – see Figure 3. Those with a negative AHI AC – AHI AO on the graph had a greater reduction in AHI with AO. 2/32 participants had > 5 events per hour reduction in AHI with AC compared to AO, whilst 7/32 participants had > 5 events per hour reduction in AHI with AO compared to AC (Figure 3).

**FIGURE 3**



Additionally, there was a moderate negative correlation between inspiratory nasal resistance and AHI with AO ( $r=-0.48$ ,  $p=0.028$ ). Preference data was gathered on 27 patients, of which 63% participants indicated a preference for AO 15% had no preference and 22% preferred AC at the conclusion of the study.

## SUMMARY

The results suggest that, on the whole, treatment response is similar with and without a MAD airway. However, individual variability exists in treatment response. Approximately 50% of participants had a lower AHI with AO compared to AC. Whilst the other 50% had a lower AHI with AC, it appears that when a significant differential response occurred i.e. difference > 5 events per hour in AHI, it occurred more frequently favouring AO. Patients that failed to respond on MAD treatment with AC and those with higher inspiratory nasal resistance tended to respond more favourably to AO.

## CONCLUSION

Approximately 50% of patients prescribed MAD treatment may receive a greater treatment response from inclusion of a MAD airway. Further studies are required to understand the pathophysiology behind the individual variability and to determine predictors of response.

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