BETTER SLEEP, BETTER HEALTH and a BETTER LIFE

ASX Release

Oventus to present interim data from study on its O_2Vent technology at Sleep DownUnder conference in Auckland

Key points:

- Interim data from Oventus' study in collaboration with the University of Western Australia to be presented at Sleep DownUnder conference in Auckland this week
- Oventus' Airway Technology reduced residual 'sleep events' compared to traditional mandibular advancement a further 30%, indicating that the O_2Vent T with Airway Technology may be more effective than just moving the jaw forward (ie. using standard mandibular advancement therapy)
- Findings support the position that Oventus' Airway Technology is able to assist patients with multiple levels of obstruction and therefore deliver improved outcomes for these patients
- Data from this study (n=10) builds the dataset across multiple clinical studies to 50 patients with consistent results

Brisbane, Australia 26th October 2017: Oventus Medical Ltd (ASX: OVN) is pleased to announce that the preliminary results of a clinical study being conducted in collaboration with the University of Western Australia will be presented at the Sleep DownUnder conference in Auckland this week. The study examined patients with Obstructive Sleep Apnoea (OSA) using Oventus' O_2Vent oral appliance, and has further demonstrated Oventus' O_2Vent oral appliance technology's ability to bypass multiple levels of airway obstruction during sleep, and provide a 30% improvement over standard of care oral appliances offering mandibular advancement alone.

Presentation details

Abstract: The poster presentation is entitled '*The effect of a novel oral appliance therapy on obstructive sleep apnea: preliminary results*'. A copy of the poster is appended to this announcement.

Presenter: The poster will be presented by Principal Investigator, Dr Jennifer Walsh, who is overseeing the collaborative study between Oventus and the Centre for Sleep Science, University of Western Australia.

Date/time: The poster presentation will occur at 12pm on Friday 27th October 2017 (Auckland time).

Location: SkyCity Convention Centre.

About the study and interim results

Oventus in collaboration with the University of Western Australia is assessing the efficacy of Oventus' O_2Vent T oral appliance used by patients with OSA, in what is called "the Perth study".

First patient recruitment was announced in January 2017 and the full trial will see 30 patients recruited, with data collection to be completed by the end of December 2017. Final results are expected to be released in the first quarter of calendar 2018.

Preliminary study results indicated:

- Oventus' O_2Vent T oral appliance device with built in proprietary airway technology showed a significant (72% reduction) in the number of OSA events experienced by patients (n=10) on the Perth study.

  The key sleep measurement index for OSA, the Apnoea-Hypopnoea Index (AHI) was used to measure sleep events. Sleep events occur where the breathing airway collapses temporarily, leading to disruptions in breathing and sleep.

- AHI reporting showed that the O_2Vent oral appliance reduced the average number of events per hour of sleep from 69.6±32.0 to 27.3±17.2 events per hour of sleep with mandibular advancement (moving the jaw forward), with the O_2Vent Airway closed. This setup emulated what a patient might experience with standard mandibular advancement devices, which bring the lower jaw forward to reduce tongue based throat obstruction.

- A further 30% reduction in AHI was achieved (AHI reduced from 27.3±17.2 events per hour of sleep to 19.4±16.8 per hour of sleep) when Oventus' O_2Vent Airway was open, indicating improved outcomes when Oventus' airway technology is incorporated into mandibular advancement devices.

- Additionally the analysis of nasal resistance in these patients supports the clinical rationale for using Oventus' Airway technology to improve treatment outcomes for patients with multiple levels of obstruction.

While the preliminary evidence in the Perth study reported above relates to 10 patients, it is consistent with the growing body of data being accumulated across Oventus' four parallel clinical studies. When reviewed in aggregate, data shows that 50 patients have had improved outcomes across four separate studies when Oventus Airway Technology is incorporated into both oral appliances and CPAP interfaces. The aggregate results indicate that >50% patients receive significant benefit from Oventus Airway Technology, in a market valued in excess of $4 Billion per year[1].

Oventus' Clinical Director, Dr Chris Hart commented, "We are delighted with the excellent results we've seen come through the Perth study to date. Our growing body of clinical evidence, together with deep IP protection and a low cost, scalable manufacturing process position Oventus well to

[1] Sleep Apnoea Diagnostic & Therapeutic Devices Market, Markets and Markets, Table 98. China data – Anti-snoring Devices and Snoring Surgery Market: 2016-2024 p101 (excludes cost of CPAP machine)

capture a share of a large and growing market as we focus on driving sales in CY18 with the support of our Modern Dental distribution agreement."

Further poster presentation

Oventus recently presented an abstract on a further ongoing study of its O_2Vent oral appliance at the World Sleep Congress in Prague, Czech Republic. The interim results are of a clinical study being conducted in collaboration with NeuRA in Sydney, announced on 10th October 2017. The same abstract will also be presented as a poster at Sleep DownUnder by Benjamin Tong on Saturday 28th October at 11.30 am, Auckland time.

To view a copy of the abstract, please follow this link: http://www.asx.com.au/asxpdf/20171010/pdf/43n36rqrw1rzpj.pdf

A copy of the poster which accompanies the abstract is also appended with this announcement.

About the Oventus O_2Vent airway technology

The Oventus O_2Vent is an oral appliance device which brings the lower jaw forward (a process commonly referred to as mandibular advancement) and incorporates an opening to the oral cavity to allow breathing through the device airway, minimising pressure swings during sleep.

Further information can be found on our website: http://oventus.com.au/how-it-works/.

—ENDS—

For more information, please contact:

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About Oventus

Oventus is a Brisbane based medical device company that is commercialising a suite of oral appliances for the treatment of sleep apnoea and snoring. Unlike other oral appliances, the Oventus devices have a unique and patented airway within the device that delivers air to the back of the mouth bypassing multiple obstructions from the nose, soft palate and tongue. They are particularly designed for the many people that have nasal obstructions and consequently tend to mainly breathe through their mouth. While it may seem counterintuitive, the device actually prevents oral breathing. The O_2Vent is designed to allow nasal breathing when the nose is unobstructed, but when obstruction is present, breathing is supplemented via the airways in the appliance.

A clinical study completed earlier this year showed the company's first generation product, the O_2Vent Mono™, is successful in treating Obstructive Sleep Apnoea (OSA) and that snoring was either

eliminated or significantly reduced to 100 per cent of patients. The positive results included those people who had nasal obstructions and mainly breathed through their mouths, including when they were asleep. It also improves oxygen levels for patients.

According to a report published by the Sleep Health Foundation Australia, an estimated 1.5 million Australians suffer with sleep disorders and more than half of these suffer with obstructive sleep apnoea.[1]

Continuous positive airway pressure (CPAP) is the most definitive medical therapy for obstructive sleep apnoea, however many patients have difficulty tolerating CPAP[2]. Oral appliances have emerged as an alternative to CPAP for obstructive sleep apnoea treatment.[3]

[1] *Deloitte Access Economics. Reawakening Australia: the economic cost of sleep disorders in Australia, 2010. Canberra, Australia.*

[2] *Beecroft, et al. Oral continuous positive airway pressure for sleep apnea; effectiveness, patient preference, and adherence. Chest 124:2200–2208, 2003*

[3] *Sutherland et al. Oral appliance treatment for obstructive sleep apnea: An updated Journal of Clinical Sleep Medicine. February 2014.*

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

Jen Walsh,[1,2] Christopher Pantin, [1,3] Alan Lim, [4] Kathleen Maddison,[1,2] Vanessa Baker, [1,2] Irene Szollosi, [5] Nigel McArdle,[1,2] David Hillman,[1,2] & Peter Eastwood,[1,2]

1 Centre for Sleep Science, School of Human Sciences, The University of Western Australia; 2 West Australian Sleep Disorders Research Institute, Sir Charles Gairdner Hospital; 3 Absolute Dental, West Perth; 4 QV1 Dental, Perth; 5 Oventus Medical Ltd.

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_2Vent 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_2Vent T with oral breathing route CLOSED and OPEN for the treatment of OSA
- Identify responders and non-responders to the O_2Vent T
- Assess the relationship between nasal resistance and effect of the O_2Vent 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_2Vent 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 $l.sec^{-1}$ 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_2Vent 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 $kg.m^{-2}$

- Relative to BASELINE OSA, severity was decreased in 8/10 individuals with the O_2Vent T oral route CLOSED. Relative to CLOSED, with the O_2Vent T oral route OPEN, OSA severity was further decreased in 6/8 participants (Fig 1)

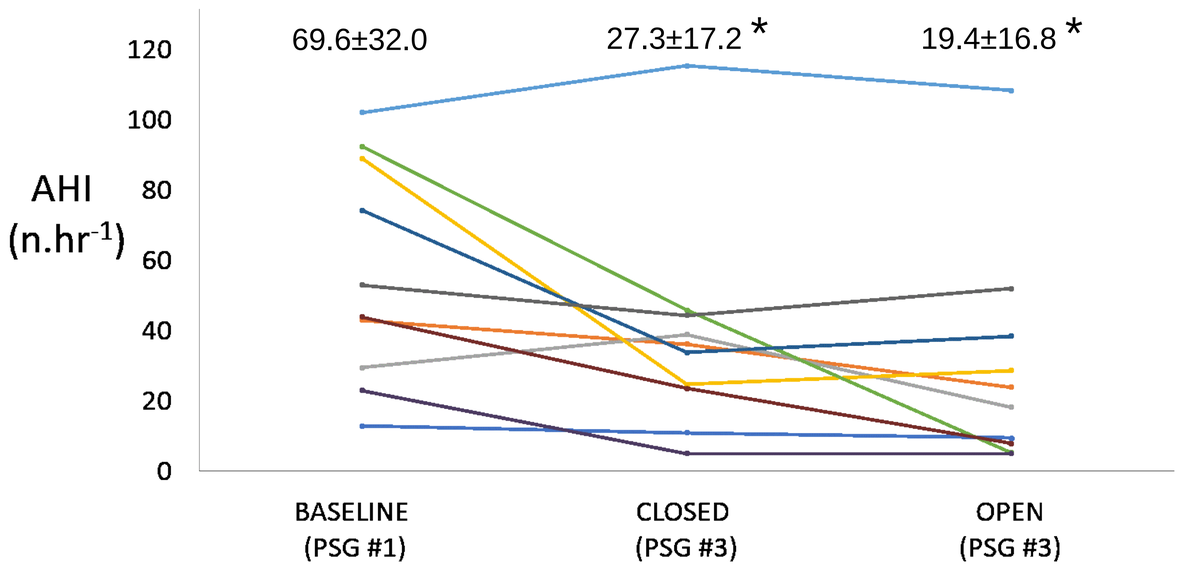

Figure 1. *AHI in BASELINE, CLOSED and OPEN conditions in all participants (n=10). Mean ± SD shown above each condition. * p<0.05 vs BASELINE*

- Five participants were responders to the O_2Vent 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 $cmH_2O.l.sec^{-1}$, respectively; *p*=0.27)
- Nasal resistance was not related to OSA severity at BASELINE, CLOSED or OPEN (all r^2<0.10) but was related to mean snoring intensity (dB) during CLOSED (r^2=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^2=0.60, p<0.05) but not when the device airway was CLOSED (r^2=0.28, *p*=0.14; Fig 2)

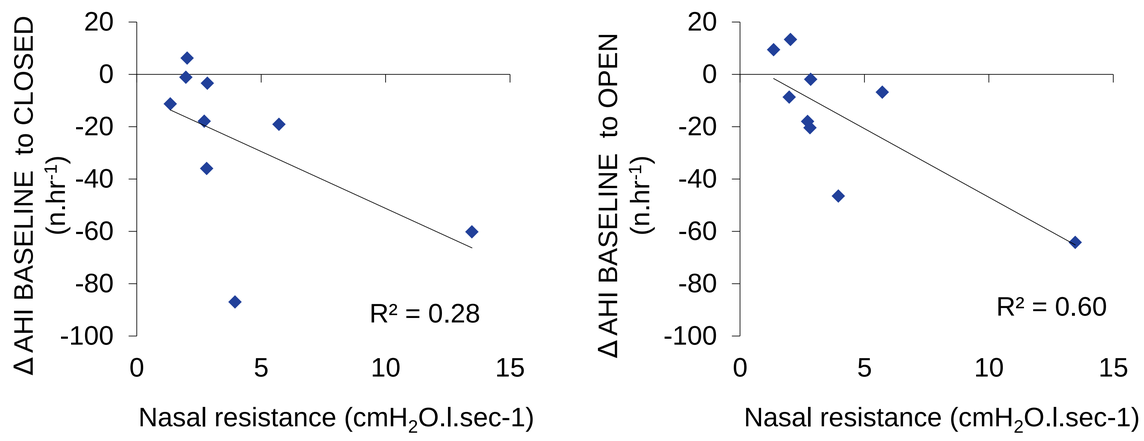

Figure 2. *Relationship between nasal resistance (n=9) and change in AHI from BASELINE to CLOSED (left) and BASELINE to OPEN (right).*

- Changes in a number of other measures of OSA severity including O_2 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

Disclosure: This study was sponsored by Oventus Medical Ltd.

Role of posture on nasal resistance and OSA severity with a novel mandibular advancement device

Benjamin Tong, Jason Amatoury, Jayne Carberry and Danny Eckert

Neuroscience Research Australia (NeuRA) and the University of New South Wales, Sydney, Australia

Introduction

- Oral appliance therapy is the leading alternative to CPAP to treat obstructive sleep apnoea (OSA)
- Compliance is higher but efficacy varies & is difficult to predict
- ↑ nasal resistance has been associated with treatment failure

Oventus - O_2 Vent T

- Oral appliance device that incorporates an opening to the oral cavity
- ↓ pharyngeal pressure swings during sleep which may benefit OSA patients including those with ↑ nasal resistance

Aims

1. Assess the effects of posture and mandibular advancement on nasal resistance in people with OSA
2. Determine the efficacy of the O_2Vent T device in OSA patients including those with high nasal resistance

Methods

7 people with OSA (AHI range: 5.4-63.3 events/hour) [4 males, 3 females, age: 35-78 years, BMI: 24-35kg/m^2] have been studied to date (ACTRN12617000492358)

Experimental design

Awake nasal resistance measured in 5 postures (order randomised):
- Seated upright (with and without MAS)
- Supine (with and without MAS)
- Lateral (without MAS)

↓

Standard split night in-laboratory PSG
- With & without MAS (order randomised)

Participant set up (Awake nasal resistance)
- Participants were instrumented with a choanal pressure transducer, nasal mask, pneumotachograph and pressure transducer attached (Figure 1)

Measurements (Awake nasal resistance)
- Awake nasal resistance was measured at Flow = 200mL/s
- 5 minutes of quiet nasal breathing in each of the 5 postures

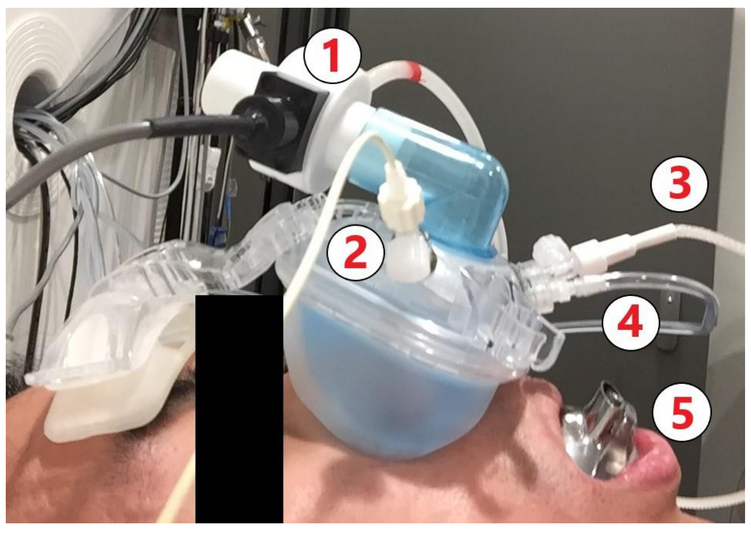

Figure 1: Awake nasal resistance set up
1: Pneumotachograph, 2: Choanal pressure, 3: End tidal CO_2 , 4: Mask pressure, 5: MAS (O_2 Vent T)

Results

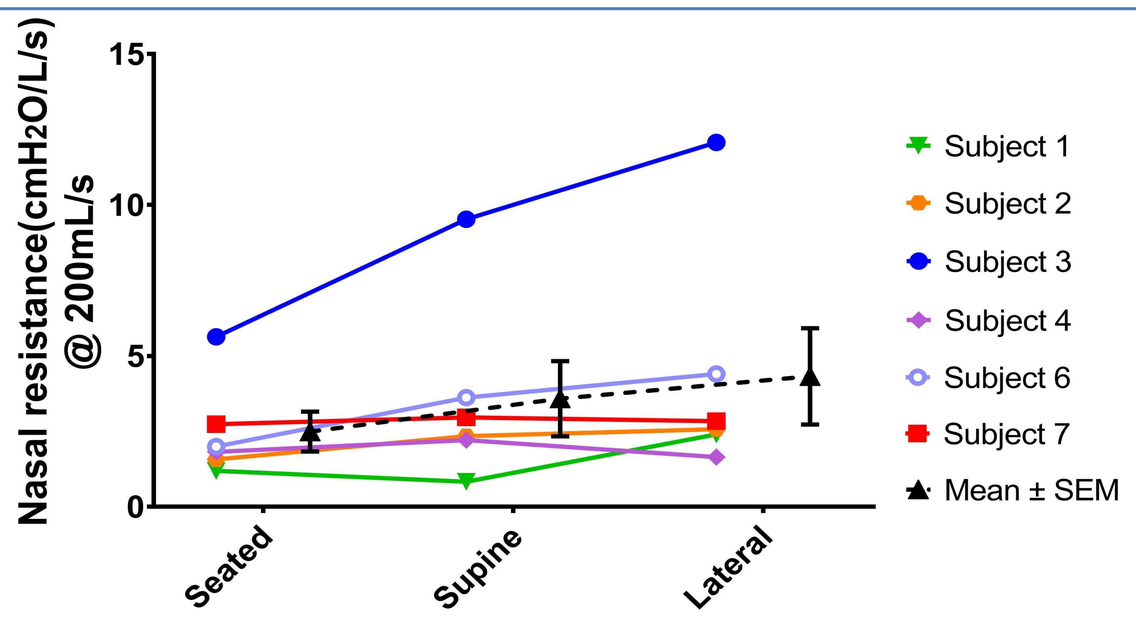

Figure 2: Changes in awake nasal resistance with posture
Awake nasal resistance tends to increase from seated to supine to lateral posture (data obtained in n=6)

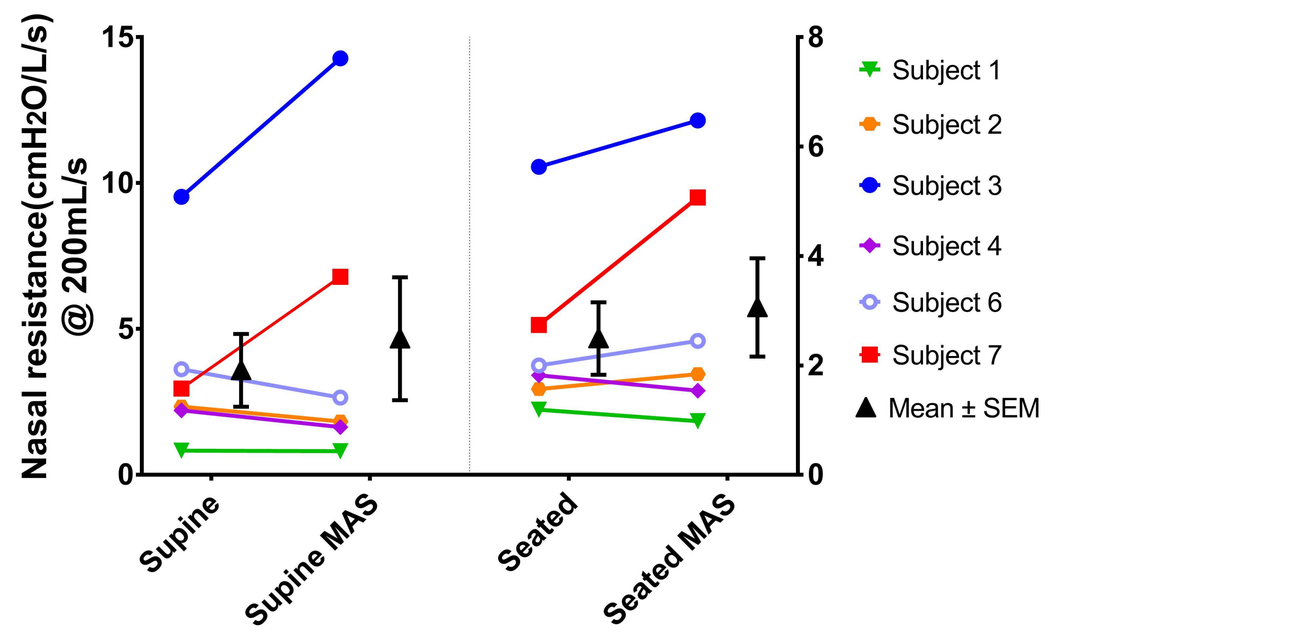

Figure 3: Changes in nasal resistance with posture and mandibular advancement (MAS)
MAS did not systematically change nasal resistance in either supine or seated postures (data obtained in n=6)

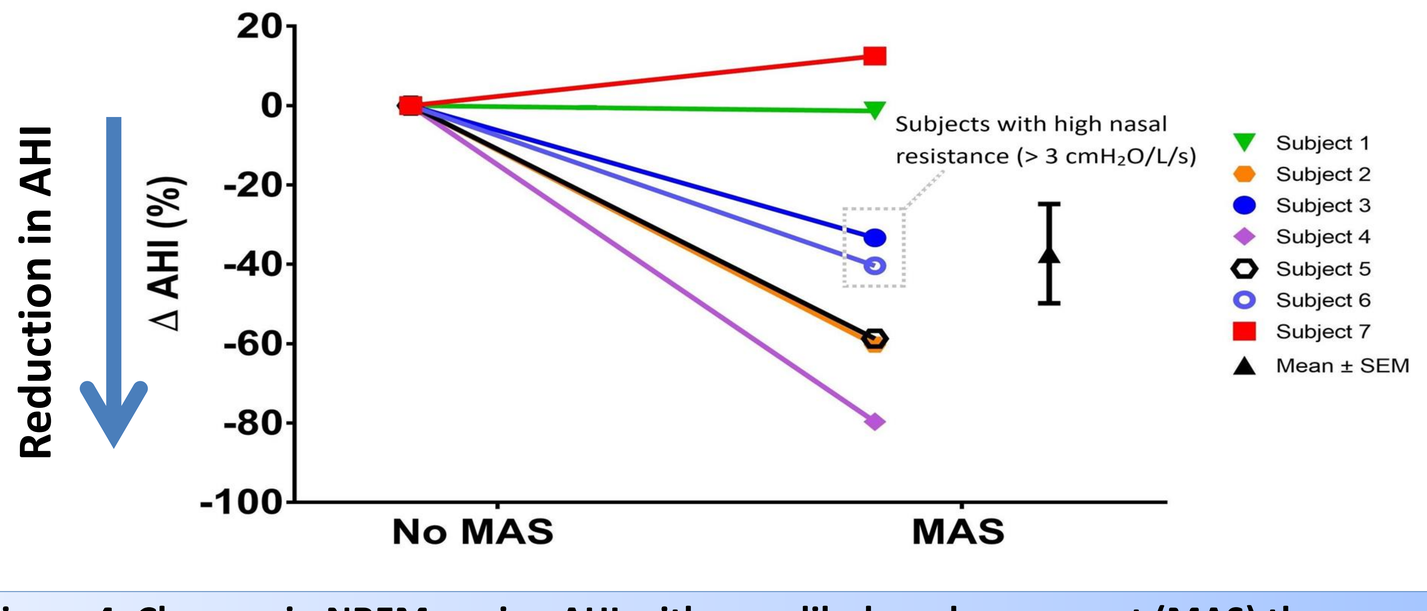

Figure 4: Changes in NREM supine AHI with mandibular advancement (MAS) therapy
Overall, there was a significant reduction in the NREM supine AHI with MAS therapy of ~40% including in participants with high nasal resistance (>3 cmH_2O/L/s) (data obtained in n=7)

Preliminary findings

- Nasal resistance appears to be posture dependent in OSA
- A novel mandibular advancement device with a built in oral airway reduced OSA severity in NREM supine sleep with comparable reductions in people with high nasal resistance

Acknowledgements

- This study was supported by a Cooperative Research Centre Project grant from the Australian Government in collaboration with academia and industry (Industry partner: Oventus Medical)
- DJE is supported by a NHMRC of Australia Senior Research Fellowship (1116942)