

ASX Release

Oventus presents abstract at World Sleep Congress in Prague on study of its O₂Vent technology

Key points:

- Oventus' O₂Vent oral appliance device with built in proprietary airway technology shown to significantly reduce Obstructive Sleep Apnoea events (Apnoea-Hypopnoea Index (AHI) reduced median number of events per hour from 34.4 to 7.0 events/hour sleep, p=0.03 – a reduction of 80%)
- O₂Vent shown to be as effective for patients with and without high nasal resistance
- Increased nasal resistance may be a reason for non-response when using other oral appliances
- Further evidence of the benefit of O₂Vent technology bypassing multiple levels of obstruction
- Study conducted by NeuRA, a world renowned research institute based in Sydney, Australia
- Abstract to be presented by leading NeuRA sleep and respiratory physiologist and Principal Investigator, Associate Professor Danny Eckert
- The NeuRA study is funded by the Australian Federal government's \$2.95 million CRC-P grant

Brisbane, Australia 10th October 2017: Oventus Medical Ltd (ASX: OVN) is pleased to announce that the interim results of a clinical study being conducted in collaboration with NeuRA (Neuroscience Research Australia) on patients with Obstructive Sleep Apnoea (OSA) using Oventus' O₂Vent oral appliance will be presented at the 7th World Sleep Congress in Prague, Czech Republic from 7-11 October, 2017.

The biennial World Sleep Congress is jointly run by the World Association of Sleep Medicine (WASM) and World Sleep Federation (WSF). The congress presents recent advances in sleep medicine and is visited by leading sleep specialists around the world.

Presentation details

Abstract: Oventus' abstract is entitled '*The effects of posture and mandibular advancement on nasal resistance and obstructive sleep apnea treatment outcome with a novel oral appliance therapy device*'. The abstract is appended to this announcement.

Presenter: The abstract will be presented by Principal Investigator, Associate Professor Danny Eckert of Neuroscience Research Australia (NeuRA). Associate Prof. Eckert is a leading sleep and respiratory physiologist and Principal Investigator overseeing the collaborative study between Oventus and NeuRA.

Date/time: Associate Prof Eckert presented from 2pm on 9th October 2017 (Prague time).

Location: The presentation was at the Panorama Hall on the first floor of the Prague Congress Centre.

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About the study and interim results

The 'NeuRA' study is assessing the efficacy of Oventus' O₂Vent oral appliance used by patients with OSA. It is being conducted over three years and is currently in its first year which will see 40 patients recruited, followed by a further 40 patients in year two and 100 patients in year three, totalling 180 patients. The abstract presents data on seven patients aged between 35-78 years with OSA.

Interim study results indicated:

- Oventus' O₂Vent oral appliance with its proprietary airway technology significantly improved OSA by reducing the median number of sleep events experienced by patients on the trial.

Apnoea-Hypopnoea Index (AHI) reduced from 34.4 to 7.0 events/hour sleep, $p=0.03$ – a reduction of 80%.

Sleep events occur where the breathing airway collapses temporarily, leading to disruptions in breathing and sleep.

- The O₂Vent airway technology was as effective in people with and without high nasal resistance.

Increased nasal resistance may be a reason for treatment failure when using a device that only provides mandibular advancement (Zeng et al SLEEP 2008). Mandibular advancement devices manage tongue base obstructions. O₂Vent oral appliances manage tongue base obstructions and also bypass nasal obstruction, soft palate collapse and reduce airway collapsibility.

- This is further evidence of the benefit of O₂Vent managing multiple levels of obstruction.

The tongue base may only be involved in as little as 40% of obstructions (Genta et al CHEST 2017). Oventus' O₂Vent technology is the only oral appliance that manages other levels of obstruction such as the nose and soft palate.

Under current treatments, patients in the study would typically be using a CPAP device with facial mask. Reducing their AHI to a level of 7.0 events/hour sleep using Oventus' O₂Vent mean they no longer require a CPAP device.

The 'NeuRA' study is funded by the Australian Federal government's \$2.95 million CRC-P grant. Oventus is the lead participant alongside Medical Monitoring Solutions Pty Ltd, Western Sydney University and CSIRO.

The previous Pilot Study (n=4) conducted by NeuRA investigating the efficacy of oral appliance therapy with and without Oventus Airway technology and investigating its use as a CPAP interface showed that Oventus' O₂Vent technology:

- Improved outcomes when incorporated into oral appliance therapy.
- Eliminated the need for a traditional mask to deliver CPAP if it was required.
- Reduced pressure requirements by 66%.

- Allowed physiologic breathing while simultaneously delivering CPAP.

This may be particularly useful for patients that are using full face mask CPAP or more importantly are not in care due to the inability to tolerate CPAP.

It is estimated that only 20% of patients with OSA are in care due to reduced diagnostic penetration and CPAP intolerance as a result of high pressure, mask related issues and nasal obstruction.

The body of evidence is growing to support the use of Oventus' O₂Vent technology in the treatment of OSA and address the massive unmet clinical need of the millions of patients that are not in care due to objections to or a lack of success with existing technologies.

Final results from the study's first cohort are expected to be released in the first half of calendar 2018.

Oventus' Clinical Director, Dr Chris Hart commented, "These results continue to build the clinical evidence that validates that the Oventus Airway Technology as a viable alternative to CPAP therapy and, in the future will allow the many OSA patients currently out of treatment, to come into care.

Our recently signed distributor – Modern Dental Group, will play a key role in accelerating this key objective, selling our O₂Vent range through their extensive global network of dentist customers."

About the Oventus O₂Vent airway technology

The Oventus O₂Vent 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.

Once fully developed and approved for marketing, Oventus' CPAP connector will allow the already in market O₂Vent oral appliance to be used in conjunction with a CPAP machine, in many cases providing a viable alternative to a full face mask. This technology has been shown in clinical trials to significantly improve patient comfort.

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

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ABSTRACT

The effects of posture and mandibular advancement on nasal resistance and obstructive sleep apnea treatment outcome with a novel oral appliance therapy device

Benjamin Tong, Jason Amatory, 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 continuous positive airway pressure in the treatment of obstructive sleep apnea (OSA). However, treatment efficacy is often poor in people with high nasal resistance. The physiological effects of changes in body position and mandibular advancement on nasal resistance in people with OSA remain unclear. We have recently shown that a new oral appliance therapy device that incorporates an opening to the oral cavity (Oventus, O₂Vent T) to allow breathing through the device airway minimizes pharyngeal pressure swings during sleep. This may be therapeutically beneficial including for patients with high nasal resistance. Accordingly, this study aimed to: 1) assess the effects of body position and mandibular advancement on nasal resistance in OSA and 2) the efficacy of the O₂Vent T device in OSA patients including in those with high nasal resistance.

Materials and Methods: To date, seven individuals with OSA (AHI range 5.4-63.3 events/h) have been studied in our sleep physiology laboratory (4 males, aged 35-78 years, BMI: 24-35 kg/m²). To quantify nasal resistance using gold standard methodology, participants were instrumented with a choanal pressure transducer (Pcho), nasal mask and pneumotachograph. Awake nasal resistance (Pcho/flow@200ml/s) was quantified during 5 minutes of quiet nasal breathing in the following 5 positions (order randomized): seated and supine (with and without mandibular advancement) and lateral (without mandibular advancement). Standard split night in-laboratory polysomnography was also performed with and without oral appliance therapy (order randomized).

Results: Awake nasal resistance tended to increase from seated, to supine, to lateral body positions (2.5±0.7, 3.6±1.2, 4.3±1.6 cmH₂O/ml/s, respectively). Mandibular advancement did not systematically alter nasal resistance in either the seated (3.1±0.9 cmH₂O/ml/s) or supine positions (4.7±2.1 cmH₂O/ml/s). Oral appliance therapy reduced the median supine non-REM AHI from 34.4 [5.1, 55.0] to 7.0 [3.1, 22.7] events/h sleep, p=0.03). Two patients had high nasal resistance (>3 cmH₂O/ml/s). The non-REM supine AHI reduced by 33% in one of these patients and by 40% in the other.

Conclusions: Preliminary findings indicate that nasal resistance is posture dependent in OSA. Increases in nasal resistance of 33±17% from seated to supine in OSA patients are greater than those reported in healthy non-OSA individuals (<10%). The novel oral appliance device with built-in oral airway significantly reduced OSA severity including comparable reductions in people with high nasal resistance.

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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 O₂Vent 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 O₂Vent 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 CPAP². 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.*

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