

Mechanism of Action of a Novel Device Using Oral Pressure Therapy (OPT) for the Treatment of OSA

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Introduction

A novel oral pressure therapy (OPT) system (Winx™, ApniCure, Inc.) has been shown to be an effective treatment for patients with obstructive sleep apnea (OSA). This new therapy provides negative pressure to the oral cavity, presumably increasing the size of the retropalatal airway by pulling the soft palate and tongue forward. Magnetic resonance imaging (MRI) was performed to investigate the mechanism of action for the device.

Hypotheses

With the application of oral pressure therapy (OPT):

- Mean, minimum and maximum airway area in the retropalatal region would increase
- Retropalatal anterior-posterior and lateral airway dimensions would increase
- 3-dimensional centroid of the soft palate and anterior segment of the tongue would move anteriorly and superiorly.

Materials and Methods

Subject Recruitment

5 adults (4 men and one woman) (mean BMI: 30.4 ± 3.1 [SD] kg/m², age: 64.6 ± 7.2 years, AHI: 38.8 ± 25.0 events/hr) with OSA were identified as responders to treatment. Of the 5 subjects, 3 had severe OSA, 1 had moderate OSA, and 1 had mild OSA.

Treatment Device

The OPT system consists of 3 components to deliver treatment: mouthpiece, tubing, and vacuum delivery console (Figure 1).

Figure 1 – Oral pressure therapy (OPT) system (Winx™)



Polysomnography

Polysomnographic data were scored by an independent, blinded scorer using AASM scoring criteria (AASM Manual for Scoring Sleep, 2007).

Magnetic Resonance Imaging (MRI)

Subjects underwent axial and sagittal upper airway imaging (during wakefulness) in the supine position with and without the device in a 1.5T MRI scanner. The head position was secured so that the Frankfurt horizontal plane oriented perpendicular to the scanner table. Images were collected at baseline with no device, with device and no suction, and with the activated device at two different physiologic levels of oral vacuum (10 and 20 inches of H₂O).

Upper Airway Analysis

The Amira 4.1.2 software suite (Visage Imaging, Inc., San Diego, CA) was used in the reconstruction and volumetric analysis of the upper airway images. Each slice was manually segmented and analyzed for the soft palate, tongue, and airway.

Results

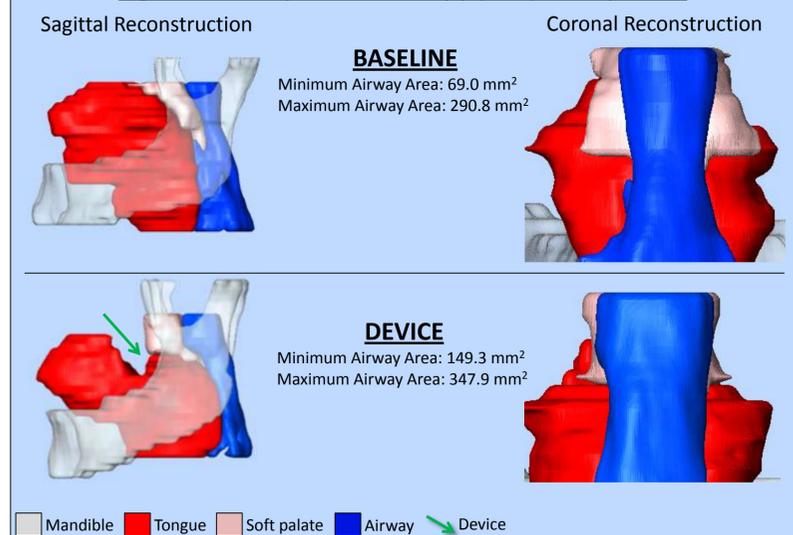
Application of the OPT system on patients with OSA led to the following airway changes in the retropalatal region (Table 1, Figure 2):

Table 1 – Oral pressure therapy (OPT) airway effect

	Mean % Change Between Device with Suction and Baseline	P-value
Average Retropalatal Airway Area per Slice (mm ²)	75.4 ± 56.4%	0.07
Retropalatal Minimum Cross-Sectional Area (mm ²)	52.8 ± 84.1%	0.27
Retropalatal Maximum Cross-Sectional Area (mm ²)	39.1 ± 30.2%	0.07
Retropalatal Minimum Area – Lateral Distance (mm)	7.4 ± 5.2%	0.07
Retropalatal Minimum Area – A-P Distance (mm)	74.0 ± 100.1%	0.47
Retropalatal Maximum Area – Lateral Distance (mm)	13.2 ± 10.2%	0.07
Retropalatal Maximum Area – A-P Distance (mm)	11.1 ± 15.2%	0.27

A-P: Anterior-Posterior

Figure 2 – Oral pressure therapy (OPT) airway effect



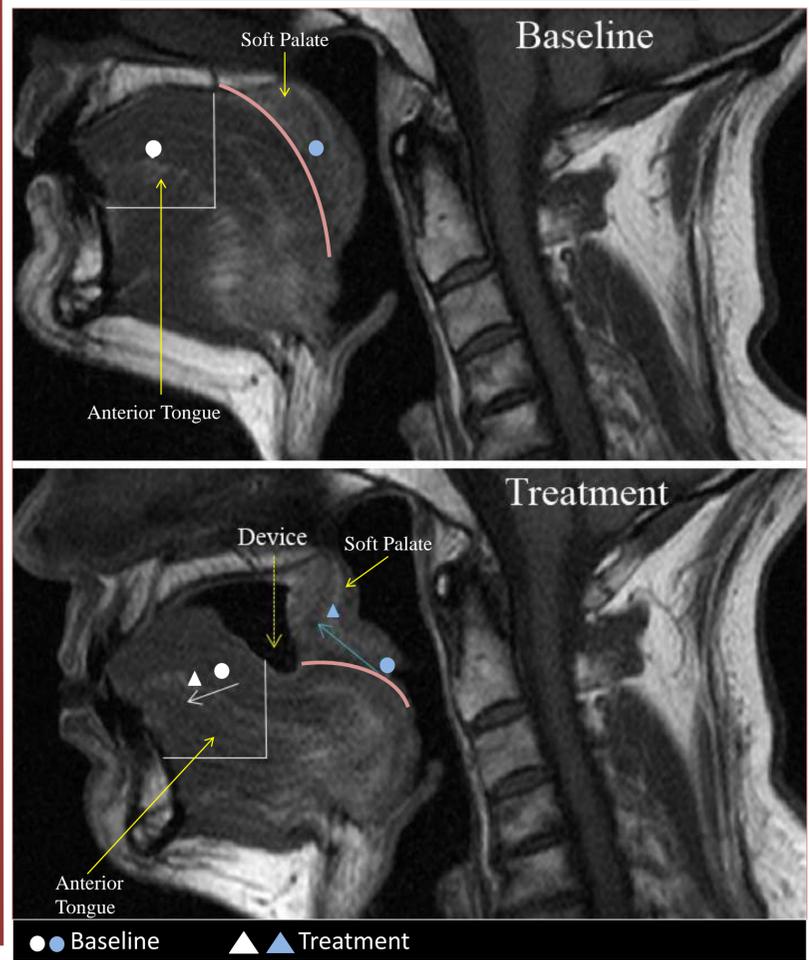
- Treatment by oral pressure therapy (OPT) resulted in an increase of all maximum and minimum retropalatal airway parameters (lateral and anterior-posterior distances and cross-sectional areas) (Table 1, Figure 2).
- Treatment by oral pressure therapy (OPT) did not result in an improvement of the retroglottal airway dimensions.

Application of the OPT system on patients with OSA led to the following soft tissue changes in the retropalatal region (Table 2):

Table 2 – Oral pressure therapy (OPT) soft tissue effect

	Mean Difference Between Device with Suction and Baseline	P-value
Soft Palate – Anterior Displacement (mm)	12.39 ± 4.60	0.04
Soft Palate – Superior Displacement (mm)	9.90 ± 4.04	0.04
Anterior Tongue Section – Anterior Displacement (mm)	7.69 ± 3.56	0.04
Anterior Tongue Section – Superior Displacement (mm)	0.09 ± 2.53	0.89

Figure 3 – Oral pressure therapy (OPT) soft tissue effect



- Oral pressure therapy (OPT) treatment moved the 3-dimensional centroid of the soft palate (blue circle and triangle) anteriorly 12.4 ± 4.6 mm and superiorly 9.9 ± 4.0 mm (see Figure 3 – circle dots represent baseline, triangles represent after treatment; pink lines define the border between the soft palate and tongue).
- Oral pressure therapy (OPT) treatment moved the centroid of the anterior segment of the tongue (white circle and triangle) forward, towards the teeth, 7.7 ± 3.6 mm (see Table 2).

Application of the OPT system on patients with OSA led to the following AHI change):

- Baseline AHI was significantly reduced to 4.9±3.0 events/hr by OPT treatment.

Key Findings

- Maximum cross-sectional area, lateral dimension, and anterior-posterior dimension of the retropalatal airway were significantly increased as a result of OPT treatment.
- Soft palate moved anteriorly and superiorly and the tongue moved in the anterior direction as a result of OPT treatment.

Conclusions

Oral pressure therapy (OPT), a novel treatment for sleep apnea, increases the size of the retropalatal airway by moving the soft palate anteriorly and superiorly and the anterior segment of the tongue forward, towards the teeth. OPT increases airway caliber in both the anterior-posterior and lateral dimensions. Our data suggest that patients manifesting an enlarged soft palate or exhibiting retropalatal airway collapse would be ideal candidates for oral pressure therapy.

Future Directions

Future MRI studies would include:

- Varying degrees of suction and new mouthpiece designs to improve all regions of the airway, especially that of the retroglottal region
- Comparisons of the OPT device to CPAP and how they effect the airway dimensions and soft tissue centroids differently
- Baseline soft tissue and airway differences between OPT treatment responders and non-responders

Acknowledgements

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