

# Assessing Changes in the Apnea/Hypopnea Index Resulting from Increased Vertical Dimension of Occlusion of Mandibular Repositioning Devices

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**Introduction:** Mandibular repositioning devices (MRD) are frequently used in the treatment of mild and moderate obstructive sleep apnea (OSA) but guidelines for determining the optimal vertical dimension of occlusion (VDO) are lacking. The goal of this investigation is to assess the impact of VDO on the improvements in apnea/hypopnea index (AHI) of OSA patients treated with MRD.

**Methods:** Twenty-six subjects with clinically significant sleep disordered breathing (baseline AHI=36.0 ± 22.3, range: 7-74) participated in this study. Prior to consenting, all subjects had previously undergone a two-night in-home sleep study with the ARES Unicorder (Advanced Brain Monitoring, Carlsbad, CA). Previously validated auto-scoring algorithms were used to calculate the AHI and RDI; both measured apneas based on a 10-sec cessation in airflow and hypopneas based on a 50% change in tidal volume. The AHI required a 4% reduction in SpO<sub>2</sub>, the RDI required a SpO<sub>2</sub> desaturation/resaturation > 1% and at least one behavioral arousal indicator (based on changes in snoring, pulse rate and/or head movement). Subjects were fitted with a TAP III MRD (Airway Management, Dallas, TX) and after at least one month of use underwent a three-night titration sleep study to establish the optimal advancement setting. A second lower tray was then fabricated so the VDO could be increased from 7mm to 10mm while using the same advancement/protrusion setting. Finally, subjects completed a four-night study with the VDO-7mm tray on Nights-1 and -2 and the VDO-10mm tray on Nights-3 and -4. Patients were categorized with positional OSA based on their pre-treatment baseline data having a minimum of 15-minutes recording time in each position and a supine to non-supine AHI ratio ≥ 2.0. One male was dropped from the analysis because the time supine was insufficient. The rationale for evaluating the impact of VDO only in the supine position is based on increasing evidence that MRD therapy is most efficacious in the supine position. Thus optimization of this condition would have the greatest impact on outcomes.

**Results:** Both VDO settings led to significant decreases in AHI as compared to the baseline in both supine (VDO-7mm: AHI=30.0 ± 16.2; VDO-10mm: AHI=27.2 ± 14.0, p<0.001) and non-supine position (VDO-7mm: AHI=17.1 ± 9.8; VDO-10mm: AHI=13.8 ± 6.1, p<0.001). Percentage of time spent snoring significantly decreased with either 7 or 10 mm at both 30dB (baseline: 34.2±15.7; 7mm: 20.6±13.4; 10mm: 20.4±14.6, p<0.0001) and 40dB (baseline: 27.2±18.4; 7mm: 10.2±9.3; 10mm: 10.7±10.8, p<0.0001). However, the differences between the AHI and snoring levels with the different VDO settings were not significant. The patients spent significantly more time supine with the VDO-10mm than with the VDO-7mm (50±19% vs. 40±21%, p=0.043).

When the data were stratified by gender, conflicting patterns emerged. The 17 males showed significant reductions in the AHI and RDI with either VDO, while the eight females did not show significant therapeutic reductions (possibly a result of the smaller sample size)(Figure 1). Figures 2.a. and 2.c. display a strong positive trend toward increased percent change (reduced AHI and RDI) in males. Figures 2.b. and 2.c. suggest the trend is either negative or at best neutral for females.

Table 1. Distribution of subjects with changes greater than clinically relevant AHI/RDI thresholds.

% of subjects	Males		Females	
	AHI ≥ 3	RDI ≥ 4	AHI ≥ 3	RDI ≥ 4
7mm < 10mm	5.9%	17.6%	50.0%	50.0%
7mm = 10mm	23.5%	17.6%	50.0%	50.0%
7mm > 10mm	70.6%	64.7%	0.0%	0.0%

To assess the potential clinical impact of switching from VDO-7mm to VDO-10mm, we calculated the distribution of males and females that showed a change in the AHI ≥ 3 and RDI with ≥ 4 events/hr (Table 1). Of interest, males showed either a clinically relevant

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reduction or no change when VDO was increased by 3 mm in 94% of cases based on the AHI and 84% of the cases based on changes in the RDI values. The opposite trend occurred in females, with 100% showing an increase or no change in the AHI and RDI values when the VDO was increased. Female gender ( $F=6.55$ ,  $p<0.01$ ) and non-positional OSA in either gender ( $F=7.29$ ,  $p<0.01$ ) were predictive of an increase in RDI with increased VDO. Neither BMI nor neck size alone correlated with the effect of increased VDO on RDI.

**Conclusions:** These preliminary results suggest that a VDO-10mm contributes to improved AHI and RDI values in men, whereas the same VDO setting causes increased or unchanged AHI and RDI in females. The female data should be interpreted with caution because there was no group treatment effect from baseline with either VDO setting. No other demographic, anthropomorphic or clinical variable was associated with the effect of VDO on outcome.

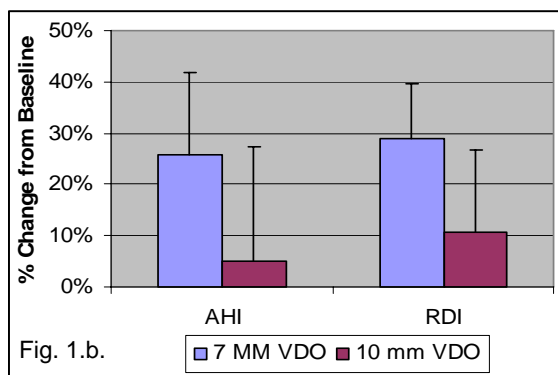
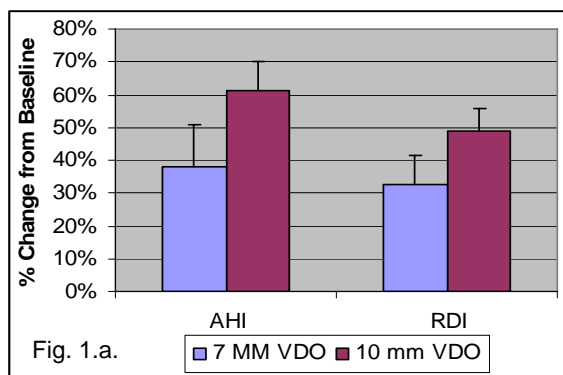


Figure 1. Percent change in the AHI and RDI from baseline for 7 and 10 mm VDO for a) males and b) females.

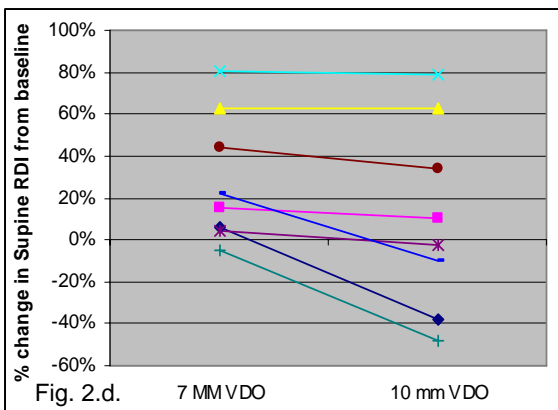
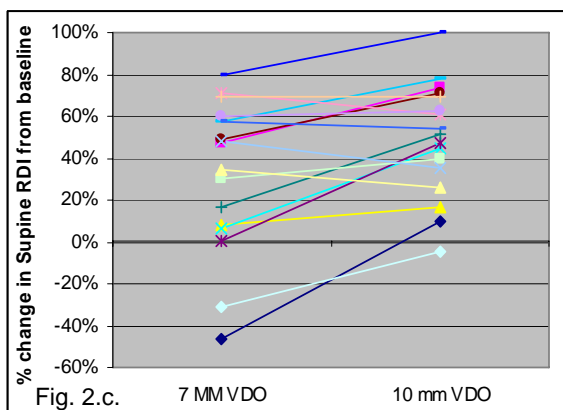
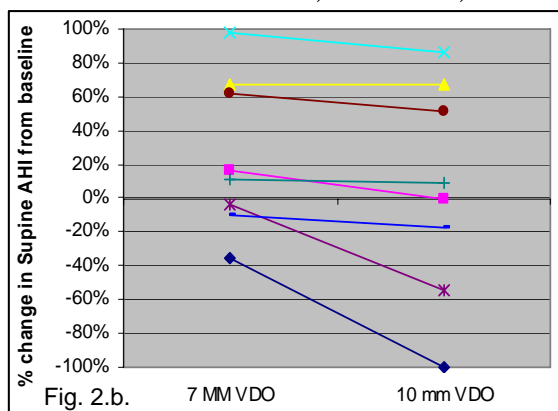
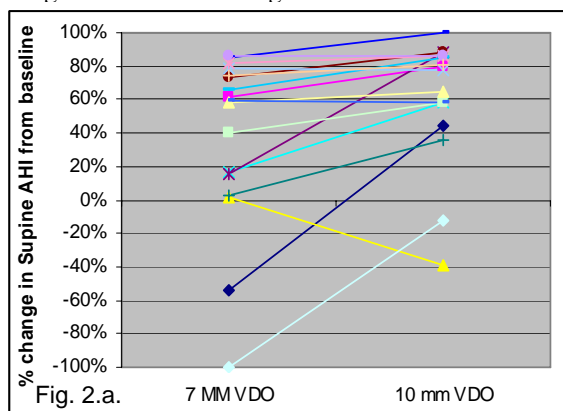


Figure 2. Presentation of individual percent changes from baseline for 7 and 10 mm VDO for AHI in a) males and b) females, and RDI in males c) and females d).