

Benefit of Mandibular Repositioning Device Therapy in Patients with Moderate and Severe OSA

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Introduction: AASM practice parameters recommend mandibular repositioning devices (MRD) in patients with mild- to moderate-obstructive sleep apnea (OSA). Those with increased sleep disordered breathing, however, show the greatest benefit in Quality of Life Years resulting from therapeutic intervention. This study assesses outcomes resulting from MRD therapy in patients with moderate and severe OSA.

Methods: A retrospective study design was conducted with sixteen females and 43 males identified with moderate (AHI 15-29) or severe OSA (AHI \geq 30) based on an ARES in-home sleep study. The two groups are profiled in Table 1. Previously validated automated algorithms were used to compute an Apnea/Hypopnea Index based a 10-sec cessation in airflow or a 50% reduction in tidal volume with \geq 4% reduction in SpO₂. Sleep studies were repeated with the Unicorder at one- (38%) or two-months (62%) post-insertion, depending on when the MRD was determined to be optimally adjusted based on validated protocols. Outcomes includes changes in AHI by position, %-time SpO₂ < 90%, snoring > 30 and 40 dB, pulse rate arousal index (PRIA), changes in Epworth-Sleepiness-Scale (ESS) Beck-Depression-Index (BDI), and Comfort and Efficacy Index (CEI). T-tests and chi-squared analysis were used to identify significant differences.

Table 1. Demographic/anthropomorphic data

	Moderate n = 35	Severe n = 26
Females, # (%)	8 (22.9)	8 (30.8)
Age, years (SE)	53 \pm 10.6	53 \pm 8.6
Neck size, cm (SE)	42 \pm 3.4	42 \pm 3.4
BMI, km/m2 (SE)	29 \pm 5.5	31 \pm 5.1

Table 2. Changes in nocturnal and subjective outcome measures resulting from MRD therapy

	Moderate OSA			Severe OSA		
Nocturnal Outcome Measures						
	Pre-treat	Post-Treat	p<	Pre-treat	Post-Treat	p<
% change AHI, mean \pm SE	N/A	73 \pm 3.8	0.0001	N/A	74 \pm 2.7	0.0001
AHI reduced \geq 50%, n (%)	N/A	29 (83)	0.0001	N/A	25 (96)	0.0001
Post-treatment AHI \leq 10, n (%)	N/A	28 (80)	0.0001	N/A	14 (54)	0.0001
AHI-Overall, mean \pm SE	21 \pm 0.7	6 \pm 0.9	0.0001	44 \pm 2.0	11 \pm 1.3	0.0001
AHI-Supine, mean \pm SE	39 \pm 2.3	9 \pm 2.1	0.0001	62 \pm 3.2	17 \pm 2.1	0.0001
AHI-Non-Sup, mean \pm SE	10 \pm 1.6	7 \pm 2.9	0.0001	26 \pm 3.3	7 \pm 1.4	0.0001
Snoring>30 dB, mean \pm SE	32 \pm 2.6	24 \pm 2.6	0.05	37 \pm 2.9	31 \pm 3.1	NS
Snoring>40 dB, mean \pm SE	24 \pm 3.1	12 \pm 2.6	0.01	31 \pm 3.1	22 \pm 3.4	NS
% SpO ₂ <90%, mean \pm SE	5 \pm 1.2	2 \pm 0.6	0.05	9 \pm 1.7	4 \pm 1.7	0.05
PRIA, mean \pm SE	46 \pm 4.0	41 \pm 4.0	NS	81 \pm 5.4	54 \pm 5.4	0.001
Subjective Outcome Measures						
Epworth, mean \pm SE	10.7 \pm 0.6	6.6 \pm 0.6	0.0001	13.0 \pm 0.9	7.0 \pm 0.9	0.0001
Epworth > 10, n (%)	17 (49)	5 (14)	0.01	19 (76)	5 (20)	0.0001
Beck, mean \pm SE	8.8 \pm 1.1	5.3 \pm 1.0	0.05	7.9 \pm 1.0	4.3 \pm 0.6	0.01
Beck > 10, n (%)	13 (39)	6 (18)	0.057	10 (42)	2 (8)	0.01
CEI, mean \pm SE	4.4 \pm 0.2	5.6 \pm 0.1	0.0001	4.6 \pm 0.2	5.9 \pm 0.1	0.0001

Results: A mean reduction in AHI > 70% and an AHI-reduction >50% was observed 83% of moderate and 96% of the severe patients (Table 2). For those classified with moderate-OSA, 66% had a post-treatment AHI in the normal range (AHI \leq 5), 26% shifted to the mild range (AHI=6-15), 8% were unchanged. For patients with severe-OSA (AHI>30), 12% shift into normal range, 65% into mild and

19% into moderate, and 4% unchanged. Significant reductions in the % time SpO₂ < 90% occurred from both moderate- and severe-OSA patients. The %-time snoring > 30 and 40dB was only observed in the moderate-OSA group. Significant reductions in ESS, BDI and CEI were reported. The percentage of moderate- and severe-OSA patients with abnormal ESS was reduced from 49% to 14% and from 76% to 20%, respectively. Forty-two percent of the severe OSA patients had abnormal BDI pre-treatment, with only 8% reporting abnormal values post-treatment.

Conclusions: Significant improvement in sleep-disordered-breathing, hypoxemia, snoring, daytime somnolence and depression were achieved in patients with moderate- and severe-OSA with MRD therapy. All patients who fail CPAP should be considered for MRD therapy.

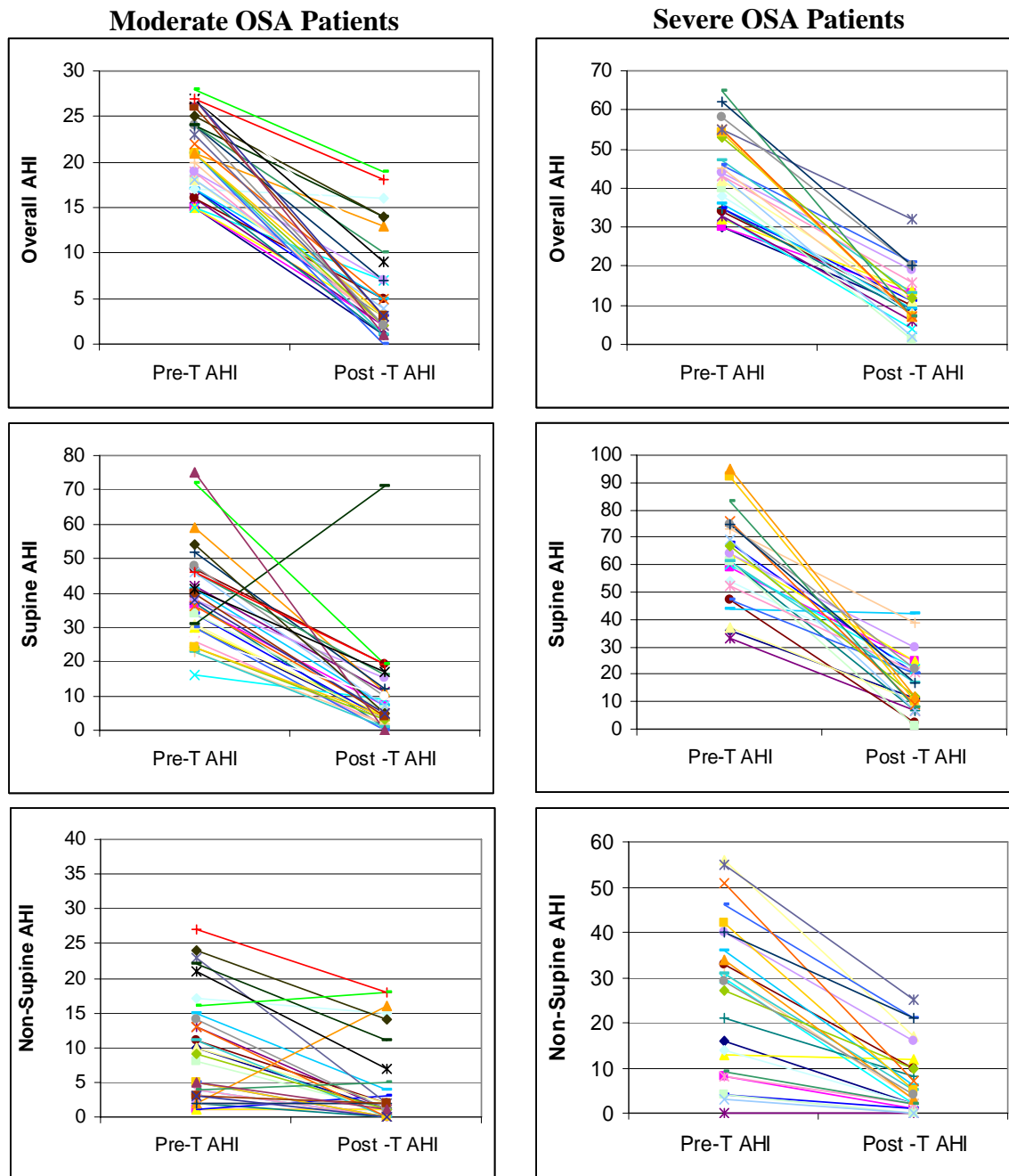


Figure 1. Changes in AHI as a result of MRD therapy for patients with a) Moderate and b) Severe OSA. Inverse values resulted from substantial differences in the percentage of time supine or non-supine.