

## In-Home Evaluation of Efficacy and Titration of a Mandibular-Advancing Device for Obstructive Sleep Apnea

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### Introduction:

Obstructive Sleep Apnea (OSA), a highly prevalent, under diagnosed disorder, causes daytime drowsiness, neurocognitive impairment and increased risk of hypertension, cardiovascular disease, diabetes and stroke.

Mandibular-Advancing Devices (MADs) are generally recommended for patients with mild to moderate disease severity or those who fail CPAP treatment. In this study, the Apnea Risk Evaluation System (ARES), a single-site portable recorder was used pre- and post-treatment to assess treatment efficacy and provide guidance for further titration of the MAD.



### Methods:

Nine females and 17 males (mean age=50±11, BMI=29±3.7, neck circumference =16.0±1.5 inches) were scheduled for a two-night in-home study prior to treatment with a TAP II Mandibular Advancing Device (MAD). The in-home study was repeated approximately 3-weeks post-insertion, when the dentist concluded that the patient had reached his/her titration end point (i.e., self-reported snoring cessation or symptoms resolved). The mean ± S.D and minimum pre- and post-treatment valid recording times were 9.6 ± 3.6 and 3.5 hours; and 10.3 ± 2.4 and 4.6 hours, respectively. Two criteria were used to measure OSA severity: 1) AHI by Medicare Criteria (AHI-4%), and 2) AHI using a 50% change in flow, 1% SpO2 desaturation/resaturation and at least one arousal indicator (snoring, pulse rate or head movement)(AHI-1%). Self-reported sleepiness, anxiety, depression, quality-of-life and the ARES Screener Questionnaire were used as additional measures of treatment efficacy. Of the 26 participants, 22 had failed a CPAP trial; ten had a pre-test AHI-4% > 30.

ARES AHI Criteria								
Group Apnea	Desat	AirFlow	Arousal	Present Events for editing	4%	3%	1%	0%
ApA	N/A	Apnea	Yes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Ap	N/A	Apnea	No	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
H4A	>3.5%	Hypop	Yes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
H4	>3.5%	Hypop	No	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
H3A	~3%	Hypop	Yes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
H3	~3%	Hypop	No	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
H1A	~1%	Hypop	Yes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
H0A	0%	Hypop	Yes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

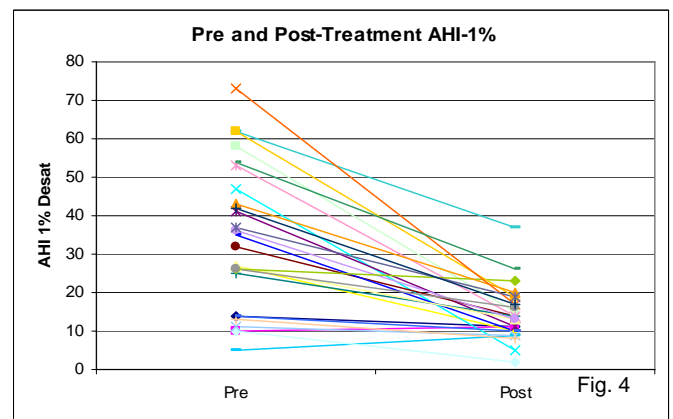
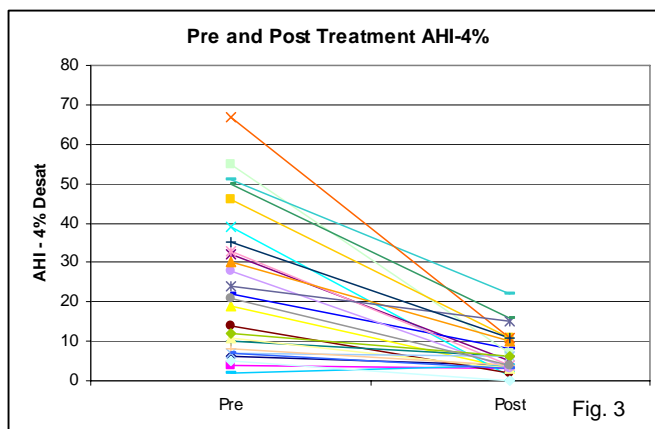
AHI criteria presented on front page of ARES Report

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In order to identify factors that may have affected treatment outcomes, patients were stratified into one of two groups using a clinical cutoff of a post-treatment AHI-4% ≤ 10 plus an AHI-1% ≤ 15.

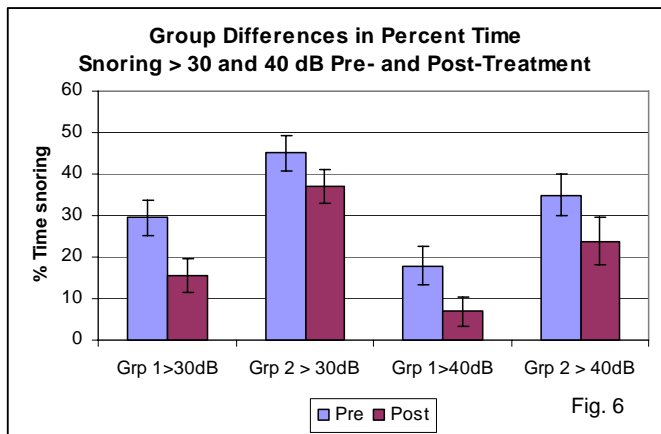
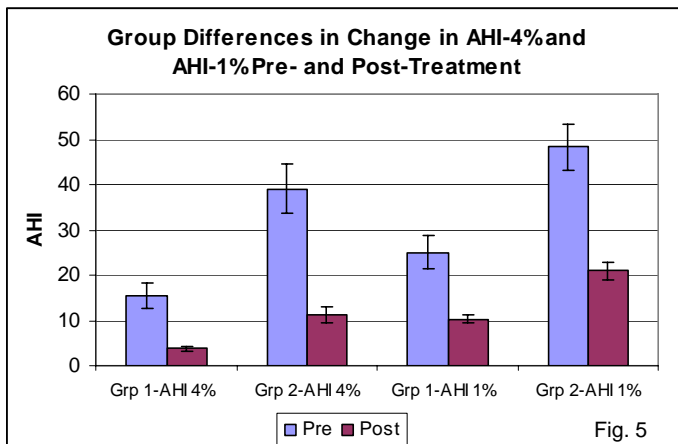
### Results:



Significant results included: reduction in pre- vs. post-treatment AHI-4% (overall:  $p < 0.001$ , mean  $\pm$  S.D.  $25 \pm 18$  and  $6 \pm 5$ ; supine:  $p < 0.001$ , means  $40 \pm 28$  and  $9 \pm 6$ ) (Figure 3) and AHI-1% (overall:  $p < 0.001$ , means  $34 \pm 19$  and  $14 \pm 7$ ; supine:  $p < 0.001$ , means  $50 \pm 27$  and  $18 \pm 11$ ) (Figure 4).

Based on conventional outcome measures, the MAD therapy was highly efficacious. Twenty of the 26 (77%) patients had a post-treatment AHI-4%  $\leq 10$  and 23 of 26 (88%) had an AHI-4%  $\leq 11$ . Ninety-six percent (25 of 26) of the patients exhibited at least a 50% decrease in AHI-4% or had a post-treatment AHI-4%  $\leq 10$ .

Using an alternative measure of AHI, developed to identify sleep disordered breathing in patients who do not desaturate as deeply, seventeen of 26 (65%) had a post-treatment AHI-1%  $\leq 15$  and 22 of 26 (85%) had an AHI-1%  $\leq 20$ . Eighty-five percent (22 of 26) of the patients exhibited at least a 50% decrease in AHI-1% or had a post-treatment AHI-1%  $\leq 15$ .



Paired t-test comparisons of the pre- and post-treatment scores revealed statistically significant differences for Beck Depression Index, ARES 4-class risk level, Epworth sleepiness score and the Flemmons QOL (all at the  $p \leq 0.001$  level) (Figure 7). All patients reported some level of subjective improvement on at least one of these subjective measures. Three of the 26 subjects (12%) reported higher Epworth scores, three reported lower QOL scores, and three reported higher Beck Depression Indexes post-treatment. Twelve of the 26 (46%) showed no change in the ARES 4-class OSA risk level.

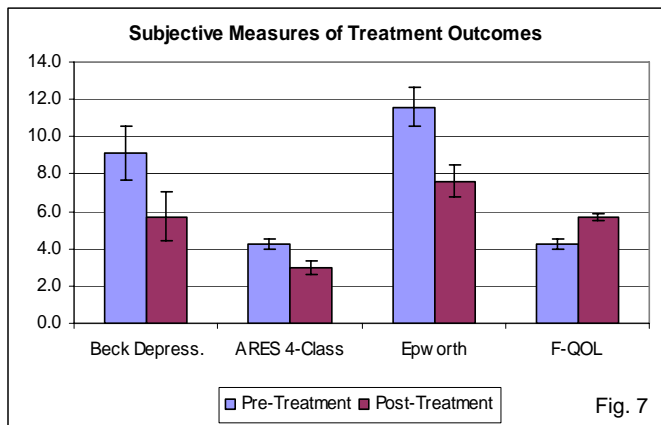
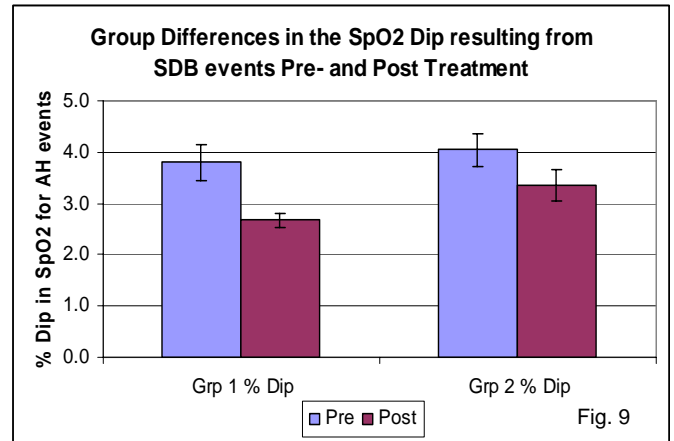
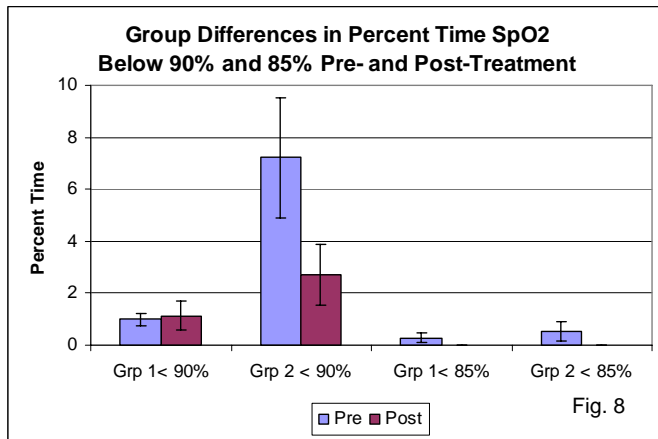


Figure 8 illustrates that the ten patients in Group 2 had significantly greater pre-treatment AHI-4% and AHI-1%, as compared to the 16 patients in group 1. Group 2 also exhibited significantly greater percentage of time snoring > 30 dB and 40 dB as compared to Group 1 (Figure 9). Both groups showed significant reductions in AHI and snoring post-treatment.

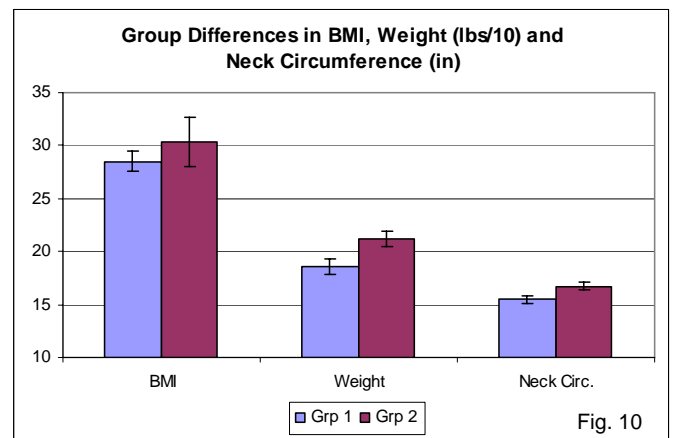
Repeated measures analysis of variance, 2 (Group) X 2 (Time pre-/post-treatment) was applied to the dependent measures: AHI-4%, AHI-1%, percent time  $SpO_2 < 90\%$  and  $SpO_2 < 85\%$ , drop in  $SpO_2$  during apneas/hypopneas (dips), and percent time snoring > 30 dB and > 40 dB. Significant main effects for group (all  $p < 0.05$ ) were obtained for all measures except the  $SpO_2 < 85\%$ . Significant main effects for time were obtained for all measures at the

p<0.01 level. Significant Group X Time interactions were obtained for AHI-4%, AHI-1%, percent time SpO2<90% and SpO2<85% but not for dips or either of the snoring measures.



Differences in hypoxemia measures between groups and pre- and post-treatment are presented in Figures 8 and 9. Group 2 had significantly greater percentage of time with SpO2 < 90% as compared to Group 1. Group 2 showed a substantially greater change in % time with SpO2 < 90% post-treatment. Both Groups 1 and 2 exhibited a significant decrease in the depth of desaturation for the apneas and hypopneas post-treatment.

T-tests were used to compare differences between Group 1 and 2 for the subjective and anthropomorphic measures. Group 2 had larger circumference necks (p=0.02), weighed more (p=0.07), and were more depressed (p=0.07)(Figure 10).



**Conclusions:**

The ARES provided multiple measures of OSA severity that demonstrated that all of the patients benefited from MAD therapy. Using a combined requirement for both a minimum or percentage reduction in AHI plus changes in subjective measures, the treatment efficacy rate for the MAD was 96%. Weight and neck circumference appear to be predictive for successful outcomes. In this study, even patients with severe sleep apnea obtained significant benefits from MAD treatment.

**Support:**

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