Feasibility Pilot Evaluating the Use of Pre-Fabricated Titratable Mandibular Advancement Device for Management of Obstructive Sleep Apnea

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BACKGROUND

Mandibular advancement device therapy (MAD) for obstructive sleep apnea is an effective alternative to CPAP, but response to MAD is incomplete.

Customized MAD devices made by dentists carry a high up-front cost, but ability to predict response beforehand is limited.

We evaluate the use of a simple-to-fit pre-fabricated titrable MAD device (ApneaRX; Apnea Sciences©). It is a 1-step boil-and-bite device where the lower tray can be advanced relative to the upper tray in 1mm increments (up to 10mm) similar to custom MAD **(See Figure Below)**

This pilot study was performed to determine feasibility of using it in an anticipated custom MAD predictor-of-response research study.

Study goals are to assess:
1. Initial fitting technique
2. Home titration process (patient self-titrate)
3. Efficacy
4. Acceptance of MAD therapy

AHI event is defined by apnea or hypopnea with flow decrease ≥30% and ≥4% oxygen desaturation

METHODS

Kaiser Permanente Fontana Sleep Center MAD Therapy Workflow:

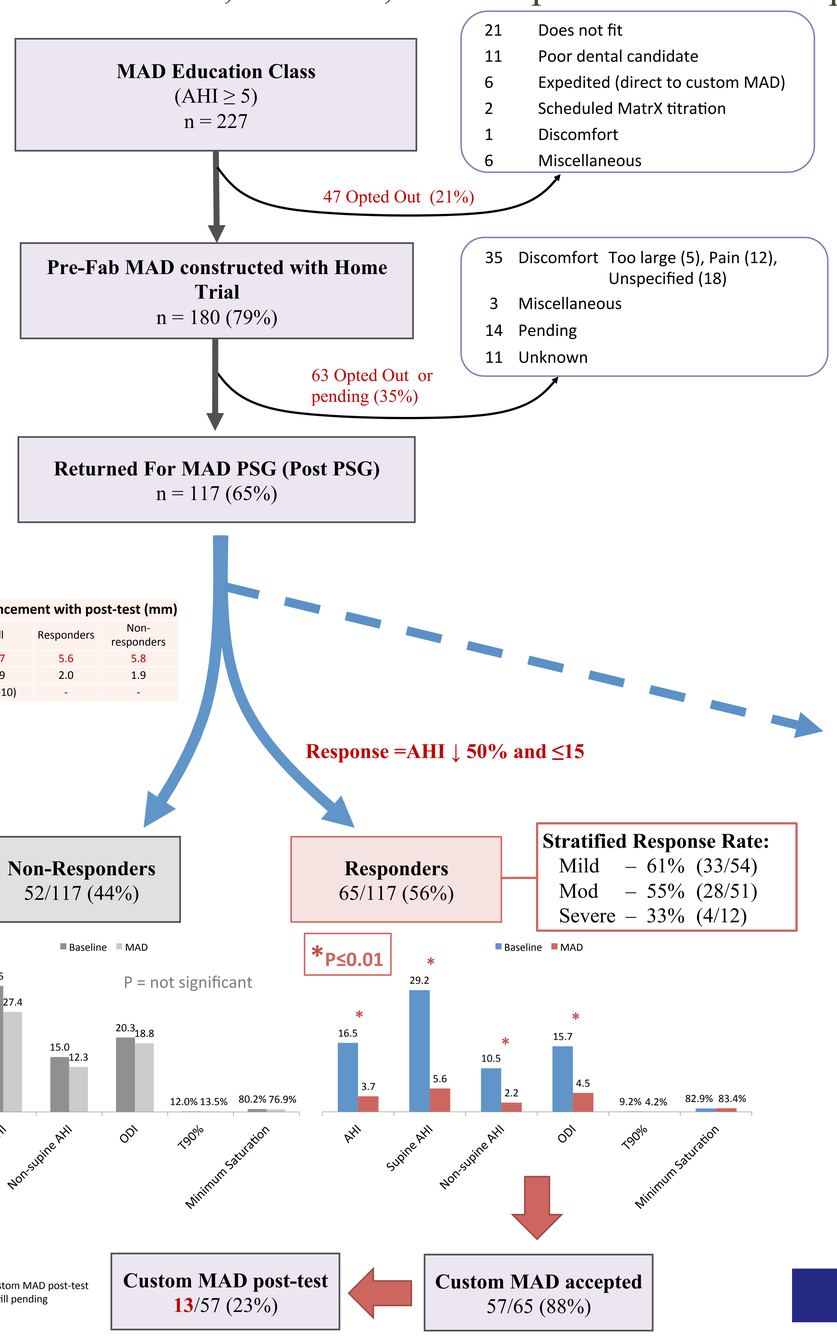
OSA patients interested in MAD are enrolled into *MAD Education Class*
- Up to 4 per class
- Educated on MAD and potential side effects
- Those interested are fit for a Pre-Fab MAD
  - 1-3 mm advancement is standard setting at fitting
  - 1-Step Boil-and-Bite (3-5 minutes to fit)

Home Titration: patients asked to advance 1mm every 1 to 2 nights with target 7+ mm advancement and resolution of snoring.

MAD PSG: Home sleep test (Embletta, Natus Inc) scheduled at 2 weeks after fitting

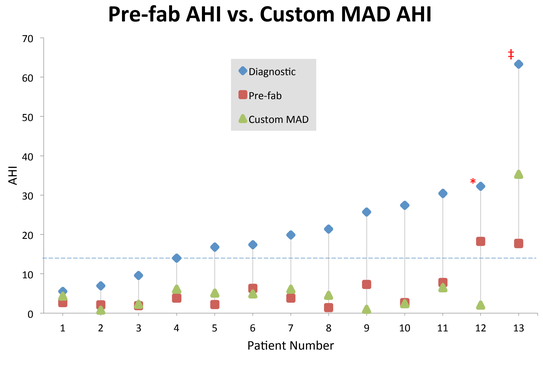
Custom MAD: Those clinically appropriate are referred to dentists for custom MAD (SomnoDent, SomnoMed Inc.)

Figure



Pre-fab MAD advancement with post-test (mm)

	All	Responders	Non-responders
Mean	5.7	5.6	5.8
SD	1.9	2.0	1.9
Median (range)	6 (1-10)	-	-



* Patient 12 had prefab AHI near 50% improvement and just over 15 with *minimal* mandibular advancement. We anticipated additional advancement would likely result in further response and thus was deemed a good candidate for a custom MAD.

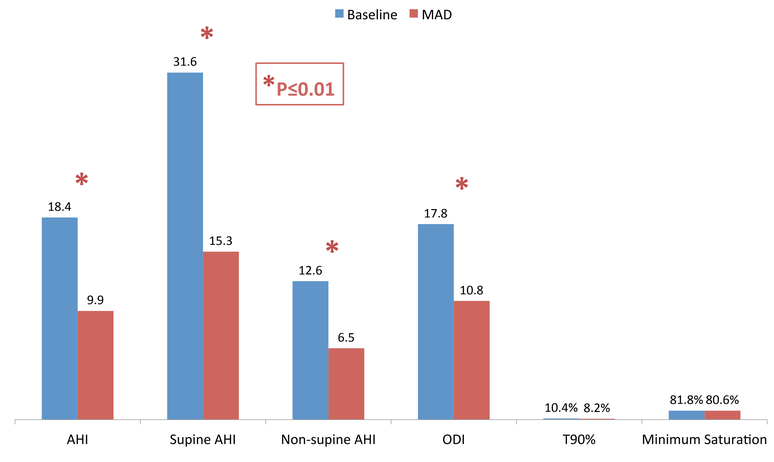
‡ Patient 13 refused CPAP and thus custom MAD ordered despite being a suboptimal candidate. Further titration of custom MAD is pending.

100% positive predictive value
12 of 12 patients deemed good candidates based on pre-fab trial had significant response to custom MAD.

BASELINE CHARACTERISTICS

Post PSG Group (n = 117)		Opted Out Prior to MAD PSG or Pending (n = 110)				Responders (n = 65)		Non-Responders (n = 52)		
Mean	SD	Mean	SD	P-Value		Mean	SD	Mean	SD	P-Value
18.4	11.8	16.5	11.5	0.25	AHI	16.5	9.9	20.7	13.6	0.07
31.6	24.1	28.1	20.1	0.72	Supine AHI	29.2	22.8	34.5	25.5	0.31
12.6	14.4	10.2	10.5	0.71	Non-supine AHI	10.5	11.6	15.0	16.8	0.16
40.4%	28.6%	39.0%	29.6%	0.83	% time supine	40.5%	26.8%	40.3%	30.8%	0.98
17.8	13.2	17.4	11.7	0.24	ODI	15.7	10.7	20.3	15.5	0.07
10.4%	17.6%	12.2%	19.4%	0.25	T90%	9.2%	17.7%	12.0%	17.6%	0.45
81.8%	6.1%	79.7%	10.0%	0.79	Min Sat	83.0%	4.72%	80.2%	7.3%	**0.03**
8.8	2.4	9.7	2.6	**0.03**	CPAP Pressure	8.5	2.2	9.2	2.6	0.24
10.4	4.9	8.8	5.9	0.16	Epworth	11.4	5.5	8.8	3.1	**0.05**
68.1	3.9	67.6	4.1	0.37	Height (in)	68.5	3.9	67.4	3.8	0.14
204.7	38.1	216.8	48.4	**0.03**	Weight (#)	202.4	38.6	207.0	37.8	0.52
31.1	5.3	33.5	7.2	**<0.01**	BMI	30.3	5.0	32.0	5.5	0.08
53.8	11.2	52.4	13.2	0.43	Age	52.7	11.1	55.1	11.3	0.26
80	37	64	46	0.11	Gender	41	24	39	13	0.17

COMBINED EFFICACY (Responders & Non-Responders) n = 117



CONCLUSIONS

This feasibility pilot demonstrated successful fitting and patient directed titration of a 1-step Boil-and-Bite pre-fabricated titratable MAD.

Efficacy of this pre-fab MAD mimics that reported in literature for custom MAD, although significant number of patients "Opted Out" prior to sleep test with MAD (mostly due to discomfort), thus selection bias could be present.

Positive predictive value for response to custom MAD based on pre-fab trial was essentially 100%.

We anticipate using this pre-fab MAD in a formal prospective study to further assess ability to predict both positive and negative responses to a Custom MAD.