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

Dennis Hwang [1, 2], Anthony L. Daclan[1], Ernestine Wigler[1], Nehemiah S. Chang[1], Frances N. Garcia[1], Dara T. Vega[1], Kimberly French[1], Andrea M. Taylor[1], Rosa Woodrum[1], Kendra Becker[1]

[1.] Sleep Medicine, Kaiser Permanente/SCPMG, Fontana, CA, United States.

[2.] Pulmonary, Critical Care, and Sleep Medicine, NYU School of Medicine, New York, NY, United States.

BACKGROUND

Oral appliance therapy (OA) for obstructive sleep apnea is an effective alternative to CPAP, but response to OA is incomplete.

Customized OA 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 OA 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 10m in) similar to custom OA **(See Figure Below)**

This pilot study was performed to determine feasibility of using it in an anticipated custom OA 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 device (at each step of workflow)

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

METHODS

Kaiser Permanente Fontana Sleep Center non-PAP Therapy Workflow:

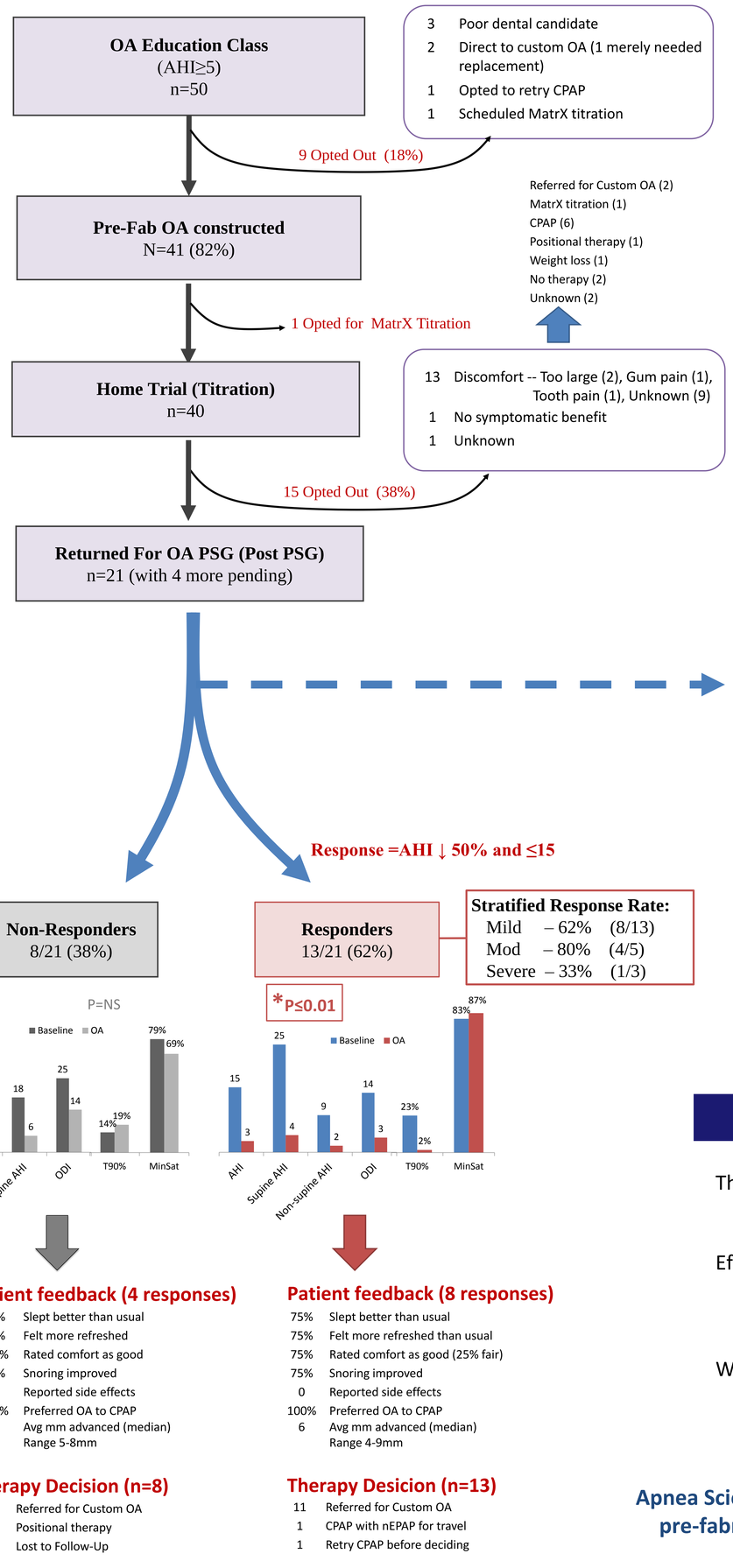
OSA patients interested in OA are enrolled into *OA Education Class*
- Up to 4 per class
- Educated on OA and potential side effects
- Those interested are fit for a Pre-Fab OA
  - 3 mm advancement is standard setting at fitting
  - 1-Step Boil-and-Bite (3-5 minutes to fit)

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

OA PSG: Scheduled at 2 weeks after fitting

Neither acceptance of Pre-Fab OA nor clinical response were required to be referred for a Custom OA.

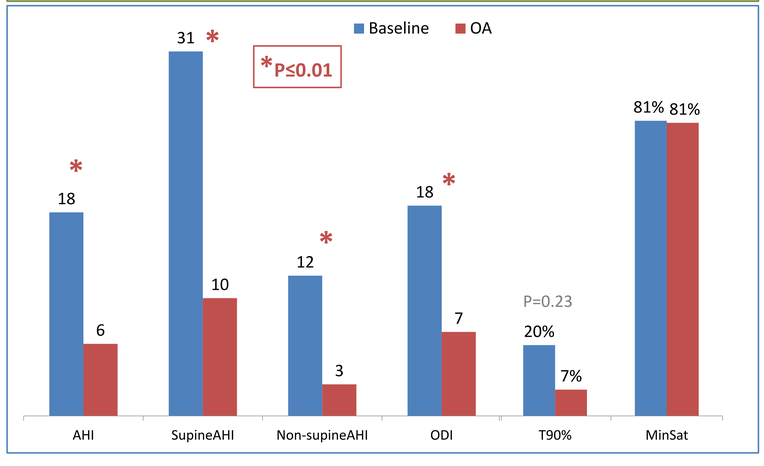
Figure



BASELINE CHARACTERISTICS

Post PSG Group (n=21)		Opted Out Prior to OA PSG or Pending (n=29)				Responders (n=13)		Non-Responders (n=8)		
Mean	SD	Mean	SD	P-Value		Mean	SD	Mean	SD	P-Value
17.5	13.2	16.7	12.7	0.83	AHI	15.1	7.8	21.5	19.1	0.39
31.4	25.4	27.9	19.7	0.65	SupineAHI	25.0	23.2	44.2	26.7	0.17
12.1	15.5	12.3	14.8	0.96	Non-supineAHI	8.6	7.4	18.4	24.2	0.37
0.4	0.3	0.3	0.2	0.24	%timeSupine	0.5	0.3	0.3	0.3	0.41
18.1	13.6	19.7	12.7	0.69	ODI	13.8	7.6	24.9	18.4	0.17
20%	31%	25%	32%	0.62	T90%	23%	38%	14%	16%	0.50
81%	7%	79%	6%	0.32	MinSat	83%	6%	79%	9%	0.28
8.7	1.7	9.8	2.7	0.21	CPAP P	8.4	1.7	9.0	1.9	0.58
12.0	5.0	11.3	5.7	0.84	Epworth	14.7	4.6	9.3	4.5	0.23
68.3	3.4	68.5	3.5	0.85	Height (in)	68.2	3.9	68.6	2.6	0.78
198.2	34.3	220.9	51.7	0.07	Weight (#)	193.4	30.0	205.9	41.3	0.47
29.8	4.5	33.0	6.4	**0.04**	BMI	29.2	3.2	30.8	6.2	0.51
51.8	10.1	55.7	7.7	0.15	Age	54.5	10.2	47.8	9.1	0.14
14	7	20	9	0.86	Gender	7	6	7	1	0.11

COMBINED EFFICACY (Responders & Non-Responders) n = 21



CONCLUSIONS

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

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

We anticipate using this device in a research protocol to assess its ability to predict clinical response and acceptance to a Custom OA.

Apnea Sciences Corporation provided support for this study by supplying the pre-fabricated oral appliance.