Precision Oral Appliance Therapy: The Prime - Time Treatment for OSA

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Introduction

A growing body of research has established that Oral Appliance Therapy delivers non-inferior outcomes in comparison to CPAP. CPAP was previously considered the "gold standard" due to its high efficacy in eliminating obstructive events. However, despite improvements in technology, the "effectiveness" of CPAP has been compromised by poor real- world compliance. At the same time, technological improvements have endeavored to improve the "effectiveness" of Oral Appliance Therapy. This study reports the efficacy of a novel, precision engineered Oral Appliance Therapy device for the primary treatment of all severities of OSA.

Objectives

- Report OAT outcomes across all severities for a precision oral appliance.
- Test the success rate against common literature metrics of AHI reduction of >50%, AHI <10 and AHI >50% & <10.
- Define a reproducible bite taking technique considering the design features of a precision anatomical custom oral appliance.
- Discuss the impact of a precision oral appliance on RDI (RERAs).

Materials and Methods

For this retrospective, private practice, investigation, OAT outcomes data was analyzed for consecutively treated patients (n=115) with complete pre/post sleep tests.

The sample was comprised of 48.6% females and 51.4% of males. Mean pre-treatment AHI was 24.1 +/- 19.2, RDI 30.7 +/- 17.2 and O2 Nadir 84% +/- 5.7%. OSA severity was distributed as 41.7% Mild, 33.0% Moderate and 25.2% Severe.

Patents were diagnosed by a physician boarded in sleep medicine and treated by a dentist with a diplomate in dental sleep medicine by the ABDSM. Digital Scans (TRIOS, 3 Shape) and digital bite registrations were recorded with a George Gauge utilizing a 3mm bite fork and were obtained on all patients. The patients were consecutively ordered with complete follow up data, many patients did not return for follow ups.

Bite and Titration Protocol

Patients are asked to protrude to a comfortable forward position. With comfort in mind the initial protrusion was set at approximately 40-60% and was varied according to the degree of overbite and overjet, the severity of the OSA, and the presence or absence of TMJ symptoms. All patients were fitted with a ProSomnus [IA] Sleep Devices (ProSomnus Sleep Technologies, Pleasanton CA) shown below, and titrated according to their subjective symptoms (snoring, hypersomnolence, jaw discomfort). An efficacy study was obtained with a HST after titration and compared to the initial HST or PSG.

Results

Outcome data on 115 patients was retrospectively reviewed. The pre-treatment AHI was 24.1 +/- 19.2 Post-treatment residual AHI was 6.1 +/- 6.4 with an AHI reduction of 69.2% % +/- 21.2%. 74.8% of the patients were treated successfully per >50% & <10 success metric. 56% of the patients were treated to an AHI of <5. O2 Nadir improved by 4.6 percentage points overall. 37 patients had RERA's (RDI-AHI) > 10 with an average of 17.2 +/- 7.5, of these patients 31 saw a reduction of RERA's of 55% from 17.2 to 7.8. 64% of the patients were titrated within the standard range of the appliance, 3.0 mm, 36% required additional arches to be ordered.

Table 1 Success Metrics

Severity	N	<10	>50%	>50%&<10
All	**115**	**87.0%**	**80.9%**	**74.8%**
Mild	48	100.0%	72.9%	72.9%
Moderate	38	78.9%	78.9%	76.3%
Severe	29	75.9%	96.6%	75.9%

Table 2 Residual AHI

Severity	Pre-AHI	STDEV	Residual AHI	STDEV
All	**24.1**	**+/-19.2**	**6.1**	**+/-6.4**
Mild	10.4	+/-2.6	3.9	+/-2.3
Moderate	20.7	+/-3.9	6.1	+/-4.4
Severe	51.5	+/-18.7	9.9	+/-10.5

Table 3 Change Percentages

	AHI Reduction	O2 Increase	RDI Reduction
All	69.2%	4.6%	61.0%
Mild	62.3%	3.4%	53.5%
Moderate	68.9%	5.0%	55.4%
Severe	81.1%	6.1%	71.2%

Table 4 Change in RERAs

	Initial RERAs	Final RERAs	% Change
All	8.9	6.3	29%
Mild	9.2	5.0	46%
Moderate	11.0	8.3	24%
Severe	5.4	6.5	-20%

Conclusions

The data shows that a precision oral appliance is capable of successfully treating patients with all levels of severity, with the majority of patients treated to an AHI <5. 29 severe patients with an average AHI of 51.5 were treated to a final average of 9.9. Additionally, patients successfully saw a reduction in upper airway resistance airflow as evidenced by the reduction of RERA's of 55% for 37 of the patients, showing that a precision oral appliance can have a significant impact on the upper airway.

The results of this study suggest that precision oral appliance therapy be considered as the primary form of therapy for all levels of severity of OSA depending on the preference of the patient.

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