Efficacy of a Novel Precision Iterative Device and Material

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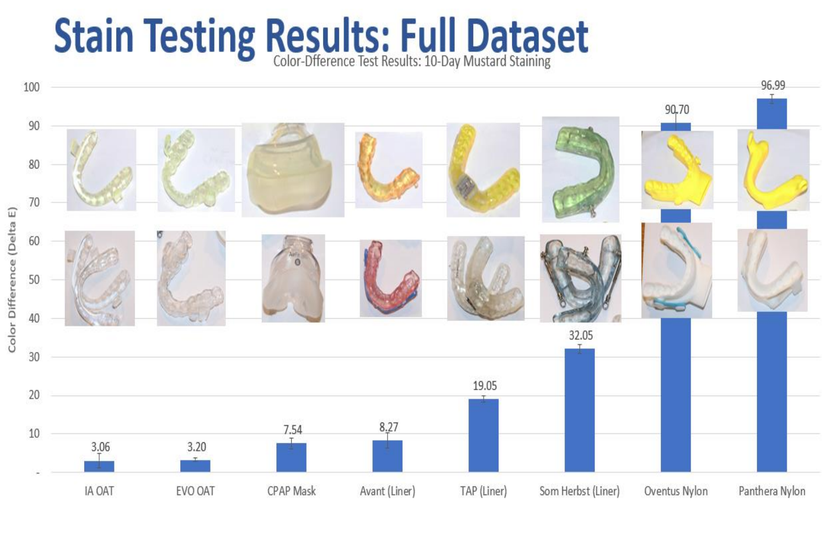
Introduction

Launching a new device design or use of a new material with optimistic expectations should always be undertaken with caution and an ounce of skepticism. When this novel device and material was first described in an IRB Abstract derivative report at the AASM, it was under the umbrella of a patient and provider preference survey. The IRB demonstrated extreme material testing of Class VI Medical Grade material and stain resilience comparable to milled acrylic. In April 2020, the broader availability post FDA clearance is providing strong early indications of excellent efficacy.

No.	Test	Standard	Report No.	Test Conclusion
1	Skin Sensitization	ISO 10993-10 ISO 7405	BIO-ATX 1856	Under the conditions of this study, the polar and non-polar extracts of the test item was found to be "non-sensitizer" to the skin of the guinea pigs under the experimental conditions employed.
2.	Acute Oral Mucosa Irritation	ISO 10993-10 ISO 7405	BIO-ATX 1857	Under the conditions of this study, evaluation of biological response to application of polar and non-polar extract of the test item to the cheek pouch in Golden Syrian Hamsters was considered as a non-irritant.
3.	Acute Systemic Toxicity	ISO 10993-11 ISO 7405	BIO-ATX 1858	Under the conditions of this study, the polar and non-polar extracts of the test item when administered to Swiss Albino Mice through intravenous and intraperitoneal routes respectively at a dose volume of 50 mL/kg body weight did not reveal any systemic toxicity under the experimental conditions employed.
4.	In Vitro Cytotoxicity by Agar Diffusion Method	ISO 10993-5 ISO 7405	BIO-GNT 831	Under the conditions of this study, the test item was found to be "non-cytotoxic" to the subconfluent monolayer of L-929 mouse fibroblast cells tested under laboratory conditions.
5.	In Vitro Cytotoxicity by Filter Diffusion Method	ISO 10993-5 ISO 7405	BIO-GNT 832	Based on the results obtained, the test item, ProSomnus® EVO Sleep and Snore Device was found to be "non-cytotoxic" to the subconfluent monolayer of L-929 mouse fibroblast cells tested under laboratory conditions.
6.	In Vitro Cytotoxicity by Elution Method	ISO 10993-5 ISO 7405	BIO-GNT 833	Under the conditions of this study, the test item was found to be "non-cytotoxic" to the subconfluent monolayer of L-929 mouse fibroblast cells tested under laboratory conditions.



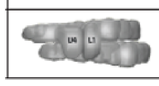
Objectives

- Measure the efficacy of a novel precision milled iterative advancement device manufactured out of a new material (the company previously offered a very efficacious device design that was similar and made from polymethylmethacrylate)
- Compare and combine results from four clinics sites provided by different dentists of a consecutive series of patients.

Materials and Methods

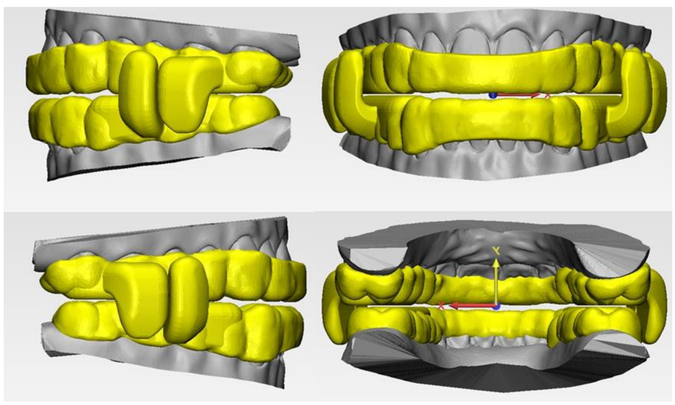
An analysis of data from four treatment centers using this novel device and material was undertaken. Patients were to be included if they had a diagnosis of mild, moderate, or severe OSA confirmed by a physician, and an AHI score >5 and a follow up study resulting in treatment success or failure. Results would be grouped as Complete Success = AHI <5, Clinical Success = 50% reduction and <10. All patients were to be treated with the Novel ProSomnus EVO Iterative Advancement device.

Advancement Guide

5 DEVICES U0, U2,U4, L0, L1	COMBINATION	ADVANCEMENTS
	Upper 0 + Lower 0	0mm
	Upper 0 + Lower 1	1.0mm
	Upper 2 + Lower 0	2.0mm
	Upper 2 + Lower 1	3.0mm
	Upper 4 + Lower 0	4.0mm
	Upper 4 + Lower 1	5.0mm

When ordering additional advancement arches, please use the following guide for the next recommended arch sequence:

U6 + L0 = 6.0mm
U6 + L1 = 7.0mm
U8 + L0 = 8.0mm
U8 + L1 = 9.0mm



Results

55 total consecutive patients were treated at four centers for dental sleep medicine. 37 male and 18 female patients with an average age of 53.3 ranging from 30 to 78 with pre and post data were included and treated with a ProSomnus EVO. The initial AHIs ranged from 6.0 to 116.0 with an average of AHI pretreatment of 26.4 (15 mild, 23 moderate and 17 severe). Follow up testing for this group demonstrated an average overall reduction in AHI of 75%, from 26.4 to 6.6. Overall, 62% resolved to below an AHI of 5 (75% of mild, 68% of moderate and 33% of severe patients). Similarly, 85% resolved to below an AHI of 10 (100% of mild, 96% of moderate and 59% of severe patients). Additionally, 65% of severe's resolved below and AHI of 15, (a common metric for severe success in other studies) and had a 75% reduction in AHI.

Table 1

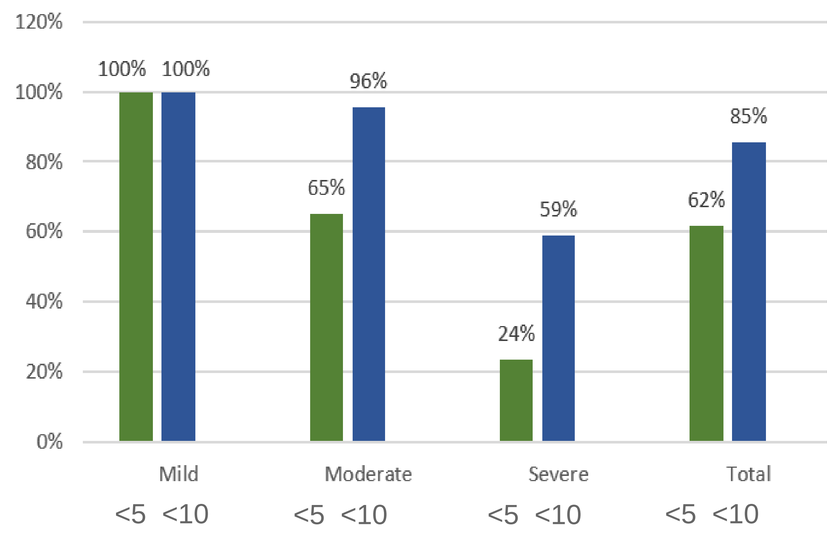
Disease Severity of 55 (37M 18F) Average Age 53

MILD	15
MODERATE	23
SEVERE	17

ProSomnus® EVO™ Iterative Advancement Device.

Table 2

% Treated to Below 5 and 10 AHI



Conclusion

This novel precision milled iterative device and material combination appear, after early analysis, to yield significantly better results that previous data has demonstrated. The literature suggests that legacy oral appliance efficacies range from 50%-62% and other AADSM poster/abstracts have reported similar precision milled, control cure PMMA appliances in the 74% - 76% range. These results suggest a need for further investigation of exceptional efficacy for this device design and material.

No support was provided for this abstract