Device Design's Impact on Dose in Oral Appliance Therapy

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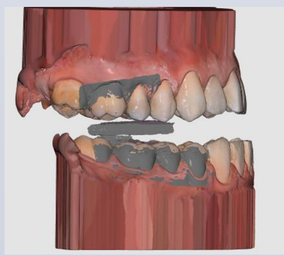
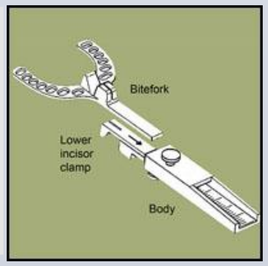
Introduction

The third recommendation of the AASM/AADSM guideline recommends physicians prescribe OAT for patients who prefer it. Thus, it is essential for providers to select a device that important clinical performance factors such as precision, strength, size, ease of delivery and cleanability. Poor device design, tooth movement, bite changes, TMD discomfort, and other reported side effects significantly impact adherence, effectiveness and physicians trust in OAT. Increased dose has long been associated with an increased risk of side effects. The utilization of a CAD CAM precision oral appliance platform that is smaller, has more tongue space, is very comfortable to wear and exhibits precision, should allow for a more conservative starting position and fewer millimeters of advancement (dose) to achieve therapeutic results and subjective symptom improvement. Similarly, this minimal dose therapeutic regimen would also result in fewer side effects that could lead to discontinuation of use.

Objectives

- Report the efficacy of patients using a precision oral appliance across three endpoints.
- Test the hypothesis that a precision oral appliance with optimized space for the tongue and 90 degree posts that maintain protrusion, requires minimal dose.
- Report the impact on side effects on patients' continuation of treatment.





Materials and Methods

49 consecutive OSA patients (19 mild, 19 moderate and 11 severe) were treated with ProSomnus platform devices (IA, PH or CA LP) over two years. Pre and post AHI/ODI values, starting position as a percentage of the protrusive ROM, total advancement and common side effects were recorded. Starting positions were determined using 50% of the protrusive-retrusive ROM +/- 1-2mm depending on comfort and a negative snore sound test.

Devices Tested: [IA], [CA] LP & [PH]

Results

Analysis of the endpoints of >50% AHI reduction, AHI <10 and the combination of the two are shown below with the 95% Confidence Intervals

Table 1 Endpoints with CI

Endpoint	% Success	95% CI
AHI Reduction >50%	89.80%	77.8-96.6%
Final AHI <10	83.70%	70.3-92.7%
AHI <10 & 50%	77.60%	63.4-88.2%

Table 2 Endpoints Vs Severity

Severity	N	<5	<10	>50%	<10 &>50%
All	49	63.3%	83.7%	89.8%	77.6%
Mild	19	84.2%	100.0%	89.5%	89.5%
Moderate	19	63.2%	84.2%	84.2%	78.9%
Severe	11	27.3%	54.5%	100.0%	54.5%

Results (continued)

Results: Efficacy

Overall; 74.5% reduction in AHI/ODI scores
Mild; 72% reduction in AHI/ODI, 84.2% under 5.0, 100% under 10.0 and 89.5% achieved a 50% reduction
Moderate; 74% reduction in AHI/ODI, 63.2% under 5.0, 84.2% under 10.0 and 84.2% achieved a 50% reduction
Severe; 79.6% reduction in AHI/ODI, 27.3% under 5.0, 54.5% under 10.0 and 100% achieved a 50% reduction

Table 3 AHI Reduction

Severity	N	AHI	STDEV
All	49	74.5%	17.3%
Mild	19	72.0%	16.1%
Moderate	19	74.0%	20.6%
Severe	11	79.6%	12.6%

Results: Starting Position

The average initial starting position was 50.3% of the max protrusive max retrusive patient range.
Select few were greater than 50% if a negative snore test was not achieved and they still felt comfortable advancing 1-2mm. A select few were less than 50% if they were not comfortable at that position.

Results: Therapeutic Advancement

The total group of 49 patents averaged 1.29 mm advancement from the starting position, with a range of 0.0 – 5.0 mm. 80% of the patients (40) were in their therapeutic position within 2mm of the staring position. 36% (18) resolved at the starting position. (4@ +3mm, 5@ +4mm and 1@ +5 mm)

Table 4 Device Adv. Vs Severity

Severity	Advancement (mm)	STDEV
Mild	0.96	0.31
Moderate	0.73	0.29
Severe	2.41	0.41

Results (continued)

Results: Side Effects

None of the patients reported discontinuation of therapy with their OA from side effects. Select patients were referred for PAP evaluation from the severe subgroup due to high residual AHI/ODI scores. 6% of patients reported transient TMD/Muscle soreness, 2% had a temporary occlusal/bite change, 6% experienced breakage to their device and 4% had a restoration removed inside the appliance that required minimal intervention. No soft tissue irritation or tooth movement was observed or reported.

Conclusions

Choosing the appropriate starting position with regards, patient comfort, protrusive range, advancement to therapeutic position and device selection are critical and effect side effects and ultimately outcomes. Smaller precision CAD CAM device platforms like the ProSomnus [IA], [IA] Select, [CA] LP, and [PH] with more tongue space can initiate therapy at more conservative positions than the literature suggest. They are also likely to experience fewer side effects that could result in discontinuation of treatment.

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