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### EDITORIAL

## From Dumb and Dumber to Case Reports to Decision-Making in the DSM Practice

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I really enjoyed the AADSM annual meeting in Dallas, TX this year. However, after the meeting, a friend of mine complained to me that one of the speakers made a presentation on a topic, introduced a technique with little-to-no evidence of success, and then presented a case report to justify the approach (please note: my friend's opinion is entirely his own). This situation happens at a lot of different meetings and across a wide variety of presentation topics.

This particular complaint reminded me of a scene in the iconic (to me at least) movie *Dumb and Dumber* made in 1994<sup>1</sup>. In that scene, Jim Carrey's character declares his love to Lauren Holly's character. The dialogue goes somewhat like this:

"Jim: What are the chances that you and I end up together?

Lauren: Not good...

Jim: Like, one out of one hundred?

Lauren: More like one out of a million...

Jim (ecstatic): So you are telling me there is a chance! Yeah!"

What is the relationship between this silly conversation and decision-making in DSM? This is the exact thought process that we dentists often go through when something works on a single patient or is described in a single case report! We often don't recognize that it is as likely to work again as it is to not work. And thus, we fall in the same trap as Jim Carrey's character.

Experienced speakers use case reports to illustrate complex situations which would be boring to the audience if presented otherwise. They tell a true story that we can all relate to and understand. However, a case report only proves that we were able to do a case one time. Maybe it is once out of one hundred. It could be once out of a million. We just don't know if the concept can be generally applied to other patients as well.

So, we also need good studies to prove it can be done over and over again and to warn us when to expect failure. Without these studies, we sometimes are like Jim Carrey's character; we want it so much to work that we are willing to hang on to one chance, one case.

To speakers, I say this: a good study can be presented on one slide in the slideshow, in two minutes

or less. By not presenting evidence, you are doing a disservice to your colleagues who believe in you. The audience may make wrong decisions without having a good understanding of the current state of the evidence. They may try something and take a long time before they figure out that when and how it may work. Sometimes they can get discouraged because they think they are failing when in fact they are using a procedure that has only worked once in a hundred trials. By presenting generalizable evidence, you give your topic depth and perspective. The speaker becomes the expert, not a clinical instructor giving tricks to the dental student.

What if there are no studies to support case reports? Is this a bad thing? Of course not. Cutting edge techniques often start just with ideas, and it may take a while before we get validation. We love to hear about novel procedures and consider if they are something that can be implemented in our DSM practices. In these instances, the case report is meant to be a source of inspiration rather than a way to convey data to the audience. I believe it is the duty of the speaker to explicitly mention when there are not that many studies about the subject. Yes, it may diminish the hype, but it gives the audience the appropriate perspective to make up its mind.

As I am reading back over my editorial, it looks as if I am putting responsibility solely on speakers. Am I? Yes and no. Yes, some speakers can be clearer and more direct regarding the current level of evidence on what they are presenting. On the other hand, we as dentists have come to expect recipes. This is how we were mostly trained. Operative dentistry is often just a series of recipes: etch for 20 seconds, rinse 15 seconds, then apply bonding and so on. Case reports are recipes as well. We dentists just love this format and often ask for it. So, it is no wonder that some of our colleagues present that way. But to truly advance DSM and provide optimal patient care, we must recognize that DSM is not operative dentistry. We must demand that speakers review the current evidence. We must go and review the evidence on our own. We must recognize each patient is different and that "one in a million" never deserves a "yeah."

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### Comparison of Three Mandibular Advancement Device Designs in the Management of Obstructive Sleep Apnea: A Retrospective Study

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**Study Objectives:** To evaluate the efficacy of three mandibular advancement device (MAD) designs in terms of apnea-hypopnea index (AHI), minimum blood oxygen saturation (min SpO<sub>2</sub>), and Epworth Sleepiness Scale (ESS) between pretreatment and posttreatment sleep studies for the management of obstructive sleep apnea (OSA). The protrusive range at the time of the second sleep study was correlated with the effectiveness of MAD designs.

**Methods:** Retrospective data from 49 patients with OSA referred to the Orofacial Pain Clinic at University of Kentucky (March 2016-March 2021) treated with MAD, with a post-treatment sleep study, were included. Treatment success was defined as 50% improvement in AHI, or as 50% improvement with residual AHI < 10/h.

**Results:** Posttreatment AHI improved with Herbst and SomnoDent-Classic (P = .003 and P = .000, respectively). Posttreatment ESS score improved with Herbst, SomnoDent-Classic, and D-SAD designs (P = .004, P = .000, and P = .018, respectively). No differences were found between the three MADs in terms of change in AHI, min SpO<sub>2</sub>, and ESS (all P > .050). Treatment success was achieved in 59.18% and 48.97%, according to the criteria, with no difference between the appliances and no correlation with the range of protrusion.

**Conclusion:** The three MADs were efficacious in improving AHI and ESS, but not min SpO2, in patients with OSA, with no differences between MAD designs. Because some patients showed a worsening in AHI, a posttreatment sleep study is of great importance.

Clinical Implications: MAD should be selected on an individual basis, according to patient preference and trained dentist recommendation, as the design did not affect the effectiveness in terms of AHI improvement.

Keywords: obstructive sleep apnea, mandibular advancement device, effectiveness, design.

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#### INTRODUCTION

Obstructive sleep apnea (OSA) is the most common sleep-related breathing disorder, with a prevalence varying from 10% to 17% in male and from 3% to 9% in female adults.1 Treatment options for OSA include behavioral modification such as weight loss and alcohol avoidance, positional therapy,<sup>2</sup> surgical intervention, hypoglossal nerve stimulation,<sup>3</sup> pharmacologic regimen,<sup>4</sup> continuous positive airway pressure (CPAP), and oral appliances (OAs). CPAP therapy is considered the gold standard for the management of OSA, particularly in severe OSA disease.<sup>5,6</sup> Routine CPAP use remains problematic for some patients, due to mask discomfort, claustrophobia, pressure intolerance, noise, nasal congestion, rhinorrhea, eye irritation, sense of suffocation, and lifestyle or social considerations.<sup>7</sup> Unfortunately, its effectiveness is highly dependent on patient adherence, which accounts for 4 hours/night on average.8

OAs are recognized as an effective alternative treatment in the management of mild to moderate OSA, primary snoring, or in case of lack of tolerance to the CPAP machine.<sup>9</sup> OAs intend to protrude and stabilize the mandible to maintain a patent airway during sleep.<sup>9</sup>

Among OAs, mandibular advancement devices

(MADs) are the most commonly prescribed in the management of OSA. Several studies have shown that despite the inferior efficacy of MAD compared to CPAP in reduction of apnea-hypopnea index (AHI), both treatments are similar in terms of effectiveness, because the suboptimal efficacy of MAD therapy is counterbalanced by the higher compliance of the patients.<sup>10</sup> Likewise, MADs are more effective than other types of OAs in managing OSA.<sup>11</sup> A systematic review by Ahrens et al. found that all MADs improved polysomnographic indices when compared with inactive appliances,<sup>12</sup> and custom-made monobloc MADs were found to be more effective than thermoplastic monobloc MADs.<sup>13</sup> This suggests that the characteristics of MAD design can affect effectiveness.

To the best of the authors' knowledge, only a few studies in the literature assessed the difference in effectiveness between the MAD designs, with conflicting outcomes: Verburg et al. found no significant difference between Somnodent-Flex and Herbst designs<sup>14</sup> and two studies found no difference between Herbst and Twin Block designs.<sup>15,16</sup> Interestingly, Gauthier et al. found that the Silencer design was more effective than the Klearway design,<sup>17</sup> and Rose et al. found that the Karwetzky activator Figure 1. Different designs of MAD. A, SomnoDent-Classic. B, Herbst. C, D-SAD.



produced a higher reduction in respiratory disturbance index compared to the Silencor design.<sup>18</sup>

The aim of the study was to evaluate the efficacy of three different MAD designs, by comparing pretreatment and posttreatment sleep study, in terms of AHI, minimum blood oxygen saturation (min SpO<sub>2</sub>), and Epworth Sleepiness Scale (ESS) score. It was hypothesized that the MAD design would not have a significant effect on the efficacy of OSA management. A secondary aim was to evaluate whether the protrusive range at which MAD was set at the time of the second sleep study was correlated with the efficacy of the different MAD designs.

### MATERIALS AND METHODS

### **Subjects**

In this retrospective study, data were analyzed for all consecutive patients between March 2016 and March 2021, referred to the Orofacial Pain Clinic at the University of Kentucky by a sleep physician for the management of OSA with a MAD. The included patients presented with a diagnosis of OSA confirmed by a sleep study (polysomnography [PSG] or home sleep apnea test [HSAT] (mild  $5/h \le AHI < 15/h$ , moderate  $15/h \le AHI < 30/h$ , severe  $AHI \ge 30/h$ ), and had undergone a second posttreatment sleep study (PSG or HSAT prescribed,

interpreted, and approved by a certified sleep physician) performed with MAD in situ, after obtaining a maximum subjective improvement or the maximum range of protrusion.

### **Data Collection**

Patients' demographic data, medical records, and sleep parameters were collected.

### Primary outcome measures:

- *Efficacy of MADs*, assessed by comparing AHI and min SpO<sub>2</sub> values at pretreatment and at posttreatment study with MAD.

- *ESS*, recorded at baseline before MAD delivery and on the follow-up visit before the posttreatment study with MAD. Total score ranges from 0 to 24, with higher value indicating greater daytime sleepiness.

### Secondary outcome measures:

- Treatment success, established using two different criteria: first criterion was established as 50% reduction in AHI, with residual AHI < 10/h; second criterion was established as 50% reduction in AHI.

**Table 1**. Demographic data and clinical features of patients treated with mandibular advancement devices (Herbst, SomnoDent-Classic, and D-SAD)<sup>a</sup>

	Baseline	MAD Herbst	MAD SomnoDent	MAD D-SAD	Р
			-Classic		
Total (%)	49 (100)	13 (26.53)	30 (61.22)	6 (12.24)	
Male (%)	23 (46.93)	7 (53.84)	14 (46.66)	2 (33.33)	.720
Age (mean $\pm$ SD)	$61.16 \pm 9.60$	$69.54 \pm 6.07$	$58.27 \pm 9.43$	$57.50 \pm 5.64$	.001
BMI (mean $\pm$ SD)	$31.75\pm7.60$	$32.38 \pm 7.60$	$30.65\pm5.57$	$34.38 \pm 4.63$	.033
Neck circumference	$15.38 \pm 1.54$	$15.31 \pm 1.93$	$15.30 \pm 1.42$	$15.87 \pm 1.66$	.758
$(\text{mean} \pm \text{SD})$					
Previous CPAP (%)	36 (73.46)	13 (100)	19 (63.33)	4 (66.66)	.040
Severity of OSA (%)					.568
Mild	15 (22.44)	4 (30.76)	10 (33.33)	1 (16.67)	
Moderate	23 (46.93)	7 (53.84)	12 (40.00)	4 (66.66)	
Severe	11 (22.44)	2 (15.38)	8 (26.67)	1 (16.67)	

<sup>a</sup> One-way analysis of variance was used to compare the three groups. BMI = body mass index, CPAP = continuous positive airway pressure, MAD = mandibular advancement device, OSA = obstructive sleep apnea, SD = standard deviation

- *Treatment failure*, defined as an increase of AHI after MAD therapy.

- *Range of protrusion*, percentage of appliance advancement after reaching the maximum subjective improvement, or the maximum range of protrusion.

- Subjective improvement, measured via questionnaire with visual analog scale and expressed as a percentage ranging from "no improvement at all" (0%) to "maximum possible improvement" (100%); it was recorded during the follow-up appointment prior to the posttreatment study.

### Appliances

Three US Food and Drug Administration-approved commercially produced MADs were used: Herbst (Great Lakes, Tonawanda, NY, USA), SomnoDent-Classic (SomnoMed, Sydney, Australia) and D-SAD (Panthera Dental, Quebec, QC Canada) appliances (Figure 1). All three designs are duo bloc, customized, titratable OAs that fulfill the criteria of adjustability of mandibular protrusion, and limited lateral and vertical mandibular movement during sleep.<sup>19</sup> Each design presents a different attachment and propulsion mechanism. Herbst is characterized by an attached bilateral compression (bilateral push), SomnoDent-Classic by an unattached bilateral interlocking, and D-SAD by an attached bilateral traction (bilateral pull). Appliance selection was determined based on the preference of the clinician and the patient. The initial protrusion was established between 60% and 70% of the maximum protrusion, and subsequent advancements were performed progressively every 2 weeks based on the patient's tolerance. Once the maximum anatomic protrusion or the maximum therapeutic benefit at 100% subjective improvement were attained, the patient was referred to the sleep physician for reevaluation of the MAD effectiveness.

### **Statistical Analysis**

Normality of distribution was tested with the Shapiro-Wilk test. Assumption of homogeneity of variances was verified with the Levene test. Normally distributed continuous variables are presented as mean  $\pm$  standard deviation.

Herbst, SomnoDent-Classic, and D-SAD appliances were categorized as independent variables; AHI, min SpO<sub>2</sub>, and ESS values were dependent variables. Paired samples *t*-test was used to compare pretreatment ( $T_0$ ) and posttreatment ( $T_1$ ) dependent variables for each appliance.

Pearson correlation was used to examine the correlation between reported subjective improvement and range of titration, reported subjective improvement and posttreatment AHI, posttreatment ESS and posttreatment AHI, and treatment success and severity of pretreatment AHI.

One-way analysis of variance (normally distributed variables) was performed to compare the appliance designs in terms of change in min SpO2, treatment success, and treatment worsening. The Kruskal-Wallis test (skewed variables) was used to assess the difference between appliance design and efficacy, and change in posttreatment ESS. Significance level was set at  $\alpha = 0.05$ . Data were analyzed with SPSS software (IBM SPSS Statistics for Macintosh, Version 27.000, IBM Corp, Armonk, NY).

**Table 2.** Intragroup and intergroup difference between pretreatment and posttreatment dependent variables in total patient population treated with mandibular advancement devices<sup>a</sup>

MAD therapy	T <sub>0</sub>	T <sub>1</sub>	$\Delta T_0$ - $T_1$	Р	95% CI	Р
(Herbst +	mean (SD)	mean (SD)	mean (SD)	(paired <i>t</i> -test)		(Kruskal-Wallis test)
SomnoDent-						between three MADs
Classic + D-						
SAD)						
AHI (/hour)	23.44 (17.47)	10.20 (9.02)	13.24 (17.36)	.000 <sup>b</sup>	8.25 - 18.22	.753
Min SpO <sub>2</sub> (%)	84.02 (5.94)	84.98 (4.83)	0.96 (6.65)	.316	-2.87 - 0.94	.219
ESS	10.09 (5.81)	5.72 (4.48)	4.36 (4.30)	.000 <sup>b</sup>	3.11 - 5.61	.185
BMI	31.75 (7.60)	31.44 (7.06)	-0.30 (6.11)	.727	-1.45 - 2.06	.416

<sup>a</sup>Intragroup differences were analyzed with paired sample *t*-test; inter-group differences were assessed with Kruskal-Wallis test. Dependent variables: AHI, min SpO<sub>2</sub>, ESS.

<sup>b</sup> p < .05.

AHI = apnea-hypopnea index, BMI = body mass index; 95% CI = confidence interval of the difference, ESS = Epworth Sleepiness Scale, MAD = mandibular advancement device,  $T_0$  = pretreatment;  $T_1$  = posttreatment;  $\Delta T_0$ -T<sub>1</sub>: pretreatment and posttreatment difference, SD = standard deviation, min SpO<sub>2</sub> = minimum oxygen saturation.

**Table 3.** Paired sample *t*-test to compare dependent variables (apnea-hypopnea index, minimum oxygen saturation, Epworth Sleepiness Scale) for Herbst, SomnoDent-Classic, D-SAD at pretreatment, posttreatment, and pretreatment and posttreatment difference

MAD design	N	Dependent variables	T <sub>0</sub> mean (SD)	T <sub>1</sub> mean (SD)	$\Delta T_0 - T_1$ mean (SD)	P	95% CI
MAD Herbst	13	AHI (/hour)	18.97 (8.40)	8.92 (7.87)	10.04 (9.71)	.003 a	4.17 - 15.91
		Min SpO <sub>2</sub> (%)	87.46 (5.60)	85.51 (6.53)	1.94 (7.61)	.375	-2.65 - 6.55
		ESS	11.11 (6.44)	7.84 (4.98)	3.26 (3.29)	.004 <sup>a</sup>	1.27 - 5.26
MAD SomnoDent- Classic	30	AHI (/hour)	24.96 (20.04)	9.98 (9.21)	14.98 (20.40)	.000 ª	7.36 - 22.59
		Min SpO <sub>2</sub> (%)	83.07 (5.61)	85.21 (3.93)	-2.14 (6.16)	.067	-4.44 - 0.16
		ESS	9.03 (5.55)	5.00 (4.26)	4.03 (4.01)	.000 a	2.50 - 5.56
MAD D-SAD	6	AHI (/hour)	25.59 (18.95)	14.11 (14.30)	11.47 (14.30)	.106	-3.53 - 26.48
		Min SpO <sub>2</sub> (%)	81.33 (4.45)	82.71 (5.02)	-1.38 (5.95)	.594	-7.63 - 4.86
		ESS	13.00 (5.17)	4.6 (3.38)	8.33 (5.88)	.018 <sup>a</sup>	2.15 - 14.51

 $^{a}p < .05.$ 

AHI = apnea-hypopnea index, BMI = body mass index; 95% CI = confidence interval of the difference, ESS = Epworth Sleepiness Scale, MAD = mandibular advancement device, N = number of patients,  $T_0$  = pretreatment;  $T_1$  = posttreatment;  $\Delta T_0$ - $T_1$ : pretreatment and posttreatment difference, SD = standard deviation, min SpO<sub>2</sub> = minimum oxygen saturation.

**Table 4.** Treatment success, treatment failure and number of patients with residual AHI > 30 events per hour at posttreatment for each appliance<sup>a</sup>

	N	Success (1 <sup>st</sup> criterion)	Success (2 <sup>nd</sup> criterion)	Failure	AHI > 30
MAD Herbst (%)	13	7 (29.17)	8 (27.59)	1 (7.69)	0 (0.00)
MAD SomnoDent- Classic (%)	30	15 (62.50)	18 (62.07)	4 (13.33)	1 (3.33)
MAD D-SAD (%)	6	2 (8.33)	3 (10.34)	1 (16.67)	1 (2.04)
Total (%)	49	24 (48.97)	29 (59.18)	6 (12.24)	2 (4.08)
Р		.710	.890	.831	

<sup>a</sup>Intergroup differences were assessed with one-way analysis of variance. AHI = apnea-hypopnea index, MAD = mandibular advancement device, N = number of patients.

### RESULTS

Forty-nine patients met the inclusion criteria and were included in the study. Demographic data and clinical features are presented in Table 1. Thirteen patients (26.53%) received Herbst, 30 (61.22%) SomnoDent-Classic, and 6 (12.25%) the D-SAD appliance. Patients treated with the Herbst appliance were older compared to the other two groups, and none of them could tolerate a previous CPAP therapy (P < 0.05) (Table 1).

Patients' body mass index decreased by  $0.30 \text{ kg/m}^2 \pm 6.11$  during the observation period, although it was not statistically significant (P = .727, 95% CI -1.45 - 2.06) (Table 2).

### **Treatment Efficacy**

Mean baseline AHI was  $23.44 \pm 17.47$  (range, 6 to 88 events/h) (Table 2). An overall decrease in AHI by  $13.24 \pm 17.36$  was noted, with a residual AHI with MAD of  $10.20 \pm 9.02$  (95% CI 8.25 - 18.22). The difference between AHI at baseline and residual AHI with MAD was statistically significant (P = .000). The Kruskal-Wallis test revealed no statistically significant difference between the three appliance designs (P = .753) (Table 2). AHI improvement was statistically significant for Herbst and SomnoDent-Classic (P = .003, P = .000, respectively), and not statistically significant for D-SAD (P = .106) (Table 3).

Treatment success, defined as 50% improvement with residual AHI < 10, was achieved in 24 patients (48.97%): 7 with Herbst (29.17%), 15 with SomnoDent-Classic (62.50%), and 2 with D-SAD (8.33%). Treatment success, defined as 50% improvement in AHI, was achieved in 29 patients (59.18%): 8 with Herbst (27.59%), 18 with SomnoDent (62.07%), and 3 with D-SAD (10.34%). No statistically significant difference was found between the

three appliance designs, according to both criteria (F(2,46), = .117, P = .890 and F(2,46), = .345, P = .710, respectively). Treatment success was not correlated with baseline severity of OSA (r(48) = -.128, p = .427).

The mean percentage of protrusion obtained at the end of titration was 91.77% of the maximum anatomic protrusion: 91.65% with Herbst, 90.74% with SomnoDent-Classic, and 93.87% with D-SAD. There was no statistically significant correlation between range of protrusion and treatment success (r(45) = -.049, P = .747), and posttreatment ESS (r(45) = .175, P = .250).

Treatment worsening was noted in 6 patients (12.24%), with no statistically significant difference between the appliances (F(2,46) = .186, P = .831), and no correlation with body mass index change (r(49) = -.009, P = .952) (Table 4).

### Minimum Oxygen Saturation

Change in mean min SpO<sub>2</sub> was not statistically significant, from a baseline of  $84.02 \pm 5.94$  to a posttreatment value of  $84.98 \pm 4.83$  (P = .316) (Table 2). No significant difference in change of min SpO<sub>2</sub> at T<sub>1</sub> was found between the three appliances (F(2, 64) = .808, P = .219). Min SpO<sub>2</sub> changed by 2.14 ± 6.21 (P = .067) with SomnoDent-Classic, by 1.38 ± 5.95 (P = .594) with D-SAD, and by -1.94 ± 7.61 with Herbst (P = .375) (Table 3).

### **Epworth Sleepiness Scale**

Overall, ESS statistically reduced in all three groups by an average of  $4.36 \pm 4.48$ , to a mean value of  $5.72 \pm 4.48$  secondary to MAD therapy (p = .000). No significant difference was found between the different designs (p = .185) (Table 2 and 3). Posttreatment ESS was not statistically significantly correlated with residual AHI (r(48) = -.146, P = .322), nor with subjective improvement (r(45) = -.183, P = .228).

### **Subjective Improvement**

Subjective improvement (81.25% with Herbst, 83.08% with SomnoDent-Classic, and 90.00% with D-SAD) was not statistically significantly correlated with range of protrusion (r(42) = .092, P = .564), nor with residual AHI (r(45) = .083, P = .590).

### DISCUSSION

The results of this study revealed no difference between the three MAD designs in terms of AHI, min SpO<sub>2</sub>, and ESS values. All of them were efficacious in improving AHI and ESS posttreatment, whereas the change in min SpO<sub>2</sub> was negligible and not statistically significant.

### **Treatment Efficacy**

This study analyzed three custom titratable OAs, reported in the literature to obtain better outcomes in AHI compared to noncustom OAs,<sup>20</sup> with a mean reduction of 13.89 events/h compared to a mean reduction of 6.28 events/h.<sup>21</sup>

In accordance with the findings of 34 randomized controlled trials,<sup>10</sup> the current study revealed a statistically significant difference between pretreatment and posttreatment AHI, with a mean AHI reduction by  $13.24 \pm 17.36$  events/h, comparable with studies in the literature (mean reduction by 13.60 events/h).<sup>19</sup>

Interestingly, the decrease in posttreatment AHI was significant for patients treated with SomnoDent-Classic and Herbst appliances but not with D-SAD. This lack of significant difference can be attributed to the small number of patients treated with D-SAD.

No significant difference was found between the three appliances with respect to improvement in AHI. This result is in accordance with a wide body of the literature, which supported the findings that MAD effectiveness is generally independent of design features.<sup>11</sup> Verburg et al. found no difference between 67 patients treated with Somnodent-Flex and 70 patients treated with Herbst (P = .608).<sup>14</sup> Similarly, Bloch et al. compared Monobloc, Herbst, and a control appliance, revealing that treatment with MAD was significantly more effective than a control appliance, and that Monobloc was more effective than Herbst, although the difference was not significant.<sup>15</sup> Likewise, Lawton et al. found no significant difference between Herbst and Twin Block (p = .071), with both improving AHI.<sup>16</sup> Conversely, a study by Rose et al. reported a higher effectiveness of the Karwetzky activator compared with Silencor (P < .010), although the two appliances differed not only on design but also on vertical and sagittal dimension.<sup>18</sup> This confirmation has a direct influence on patient management in an everyday clinical setting. Indeed, if a precise MAD design was found to be more effective than another, the clinical decision would have been driven by this evidence. Instead, the results of the study suggest that the treatment should be tailored based on individual needs and personal preference, also considering the crucial role of the compliance of the patient in the success rate. The adoption of a precise design can take into consideration other clinical conditions, such as the presence of parafunctional activities (grinding), absent or tilted posterior teeth, and crowded anterior teeth.<sup>22</sup>

### **Minimum Oxygen Saturation**

The literature reported a modest improvement in min SpO<sub>2</sub> in patients with OSA treated with OAs, with a mean value of 3.09% in a weighted analysis of 22 randomized controlled trials.<sup>19</sup> The values vary across the studies, with the greatest improvement reported by Hoekema et al., with min SpO<sub>2</sub> increasing by 13%.<sup>11</sup>

On the contrary, in accordance with some other reports,<sup>7,8</sup> the current study did not show a statistically significant change in min SpO<sub>2</sub> with MAD. Interestingly, the Herbst population revealed a decrease in min SpO<sub>2</sub> by  $1.94 \pm 7.61$  posttreatment, although this difference was not significant. Similarly, the change achieved with SomnoDent-Classic and D-SAD ( $2.14 \pm 6.16$  and  $1.38 \pm 5.95$ , respectively) did not reach the significance level. Concordant with the literature,<sup>17,23</sup> no significant difference was found by comparing appliance design and min SpO<sub>2</sub>. The explanation of Lawton et al. suggests that the arterial blood SpO<sub>2</sub> level may be influenced by other factors, including supine sleeping position, individual low hematocrit, and heart failure.<sup>23</sup>

### **Epworth Sleepiness Scale**

The ESS, an 8-item questionnaire assessing daytime sleepiness,<sup>24</sup> has been shown to be positively correlated with OSA severity.<sup>24</sup> The current study found a statistically significant improvement in daytime sleepiness between pretreatment and posttreatment values, with the greatest change in the group treated with D-SAD. The reduction in ESS by 4.36 was slightly higher than what was reported by a meta-analysis, where the mean reduction was 3.81.<sup>19</sup> However, the effect on daytime sleepiness is uncertain, particularly in patients within the mildest spectrum of disease severity and in snorers, as some studies did not observe any significant improvements in daytime sleepiness when compared to placebo.<sup>25</sup>

The current study corroborates the findings of other reports<sup>17,23</sup> in that the improvement in ESS is not influenced by MAD design. This suggests that the crucial factor may

be the mandible protrusion rather than the distinctive propulsion mechanism of the different designs.

### **Treatment Success**

The definition of treatment success is variable in the literature and the success rate of OSA treatment with MAD can vary remarkably according to success criteria.<sup>26</sup> Hence, two sets of criteria, normally accepted as a cutoff across studies,<sup>27</sup> were applied to effectively differentiate between success and failure.

When treatment success was defined as 50% improvement with residual AHI < 10, MAD was successful in treating 24 patients (48.97%), which is in line with the range of 30% to 94% reported by a systematic review.<sup>28</sup> When treatment success was defined as 50% reduction in AHI, it was achieved in 29 patients (59.18%), in accordance with a meta-analysis that reported greater than 50% AHI reduction in 23 of the 25 randomized controlled trials included.<sup>19</sup> However, the broad variability of effectiveness suggests the lack of good and consistent predictors of successful MAD treatments. In the literature, treatment success has been correlated with degree of protrusion,<sup>29</sup> and inversely related to disease severity.<sup>26</sup> However, the current study did not find any correlation between range of protrusion and treatment success. Interestingly, the most protruded position was achieved in the D-SAD group (i.e., protrusion of 93.87%), which actually coincided with a nonstatistical improvement in post-treatment AHI. However, a larger sample size is warranted to replicate these results.

The sample of this retrospective analysis showed a heterogeneity disease severity at baseline: most of the patients exhibited moderate OSA (46.93%), for which MAD is recognized as an effective treatment. Nevertheless, MAD therapy obtained promising results also in the group of patients with severe OSA (22.44%), considering that only 2 patients (4.08%) had residual severe AHI in the posttreatment study. Surprisingly, the most relevant improvements in AHI were found in 4 patients with severe OSA. The most impressive case was a patient with a baseline AHI of 88 events/h, which reduced to 5 events/h after treatment.

This study confirmed the unpredictability of treatment success secondary to MAD;<sup>30</sup> indeed, not appliance design, range of protrusion, or pretreatment OSA severity could predict treatment success.

Moreover, for those patients who cannot tolerate CPAP therapy (73.46% in this study), MAD may constitute a valuable and encouraging option, beside surgical and pharmacologic treatments. In addition to the objective reduction in AHI with MAD, ultimately the goal of OSA therapy is to improve daytime somnolence, sleep quality, and overall quality of life,<sup>30</sup> and at the same time to reduce health risks, including those related to cardiovascular function and neurocognitive behavior.<sup>9</sup>

### Importance of a Second Sleep Study

This study revealed some cases of AHI worsening following MAD therapy, even if the patients reported a subjective improvement. The percentage of treatment worsening AHI was 12.24%, in line with the 14% reported in the literature.<sup>30</sup> A 12.24% reported treatment worsening AHI is a noteworthy finding. However, the current analysis did not reveal any significant confounding factors, such as appliance design, body mass index, or OSA severity. Use of drug-induced sleep endoscopy before embarking on a specific OSA treatment might help identifying good responders to OA therapy.<sup>31</sup>

These results suggest that prescribing a second sleep study is therefore essential, as PSG-based definitions of success and subjective improvement reported by the patient do not always coincide. Thus, if the end of titration is exclusively driven by subjective feedback, the patient may remain sub-optimally treated.

### Strengths and Limitations of the Study

The current study is the first to compare three commercially available appliances, which differ in propulsion mechanism, design, and attachment, by comparing polysomnographic parameters at baseline and with MAD in situ.

The current study is not exempt from some limitations:

- Small and heterogeneous sample size, especially in the group treated with the D-SAD appliance due to the recent commercialization of the design.
- No power analysis nor randomization, due to the retrospective design of the study, which resulted in unequal distribution of subjects to different appliance designs.
- Heterogeneous disease severity at baseline.
- Heterogeneity in age distribution among the appliance designs due to insurance coverage. Patients older than 65 years were usually limited to the Herbst design.
- No placebo group; however, MAD effectiveness in reducing apneic events and improving subjective daytime sleepiness is well established in the literature compared to placebo.<sup>7</sup>
- Because of the retrospective nature of this study, the device used to assess sleep parameters at baseline and with the MAD in situ varied among patients. All sleep studies were prescribed and interpreted by the treating certified sleep physician, as recommended by American Academy of Sleep Medicine.<sup>32</sup> However, it should be taken into consideration that HSAT and PSG have different specificity and sensitivity.

### CONCLUSIONS

The three MAD designs demonstrated to be similarly efficacious in the improvement of AHI and ESS scores in the management of OSA, and to not differ in terms of change in min SpO<sub>2</sub>. Based on the results on this study, some patients showed a worsening in AHI with MAD; therefore, a posttreatment sleep study is of great importance to assess MAD efficacy.

### **ABBREVIATIONS**

OSA: obstructive sleep apnea

MAD: mandibular advancement device

AHI: apnea-hypopnea index

ESS: Epworth Sleepiness Scale

Min SpO<sub>2</sub>: minimum oxygen saturation

CPAP: continuous positive airway pressure

OAs: oral appliances

PSG: polysomnography

HSAT: home sleep apnea test

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### Emerging Models: 30 Years of Breaking through Dental Sleep Medicine Barriers to Help Patients

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Thirty years ago, a group of dentists had the vision and passion to create the Sleep Disorders Dental Society, which later became the American Academy of Dental Sleep Medicine (AADSM). The founding documents stated that the organization was being incorporated "to effectively impact the treatment of sleep disorders through the utilization of oral appliances as an integral part of overall therapy and to facilitate a coordinated, synergistic approach to research, education/accreditation, and treatment within the medical community that is focused on the well-being of both the patient and the health care team." As we reflect on the 30th anniversary of the AADSM, it is incumbent upon us to move forward today's mission to "advance the dentists' role in the screening, evaluation and treatment of sleep-disordered breathing and strive to reduce the number of undiagnosed and untreated people with sleep-disordered breathing ... "1

The AADSM was founded on the belief that dentists working directly with sleep physicians and accredited sleep facilities could provide an alternative or adjunct treatment for patients who were unable to tolerate continuous positive airway pressure (CPAP). This belief soon evolved into a practice model with bidirectional referrals. The dentist screened patients for obstructive sleep apnea (OSA) and those suspected of having OSA were referred to the sleep physician for further evaluation, diagnosis, and treatment. In many instances, the treatment was oral appliance therapy (OAT), but not always. Alternatively, the sleep physician referred patients who were unable to tolerate CPAP or simply preferred a different treatment to the dentist for OAT. When this practice model was developed, home sleep apnea tests (HSATs) did not exist; all testing was done at a sleep facility. OAT was also still in its infancy, and few dentists were trained to provide OAT. This model made perfect sense, and it is still currently in practice in many parts of the country. Building upon this foundation, we continue to work with the American Academy of Sleep Medicine to develop closer collaborations between qualified dentists and accredited

sleep facilities and to ensure that sleep physicians are offering OAT as a treatment option for OSA. However, this model is not available to all patients throughout the country, and the number of sleep physicians is declining.<sup>2</sup>

Fortunately, evolving technologies and advances in the field have made it possible for qualified dentists to implement alternative practice models that will allow them to build sustainable dental sleep medicine (DSM) practices, while continuing to provide optimal patient care. HSATs, for example, provide a way for patients to obtain a diagnosis of OSA without needing an overnight inlaboratory test at an accredited sleep facility. This expands access to care for populations that do not live within reasonable proximity to accredited sleep facilities or sleep physicians. Initially, OAT was only considered as an alternative treatment for those who could not tolerate CPAP. Over time, with advances in oral appliances and additional research, OAT has become a first-line treatment for patients who prefer it, especially those with mild to moderate OSA. In 2018, the AADSM created both the Dental Sleep Medicine Standards for Screening, Treating, and Managing Adults With Sleep-Related Breathing Disorders<sup>2</sup> and AADSM Mastery Program, facilitating a standardized pathway to provide OAT and for dentists to become trained. The AADSM Qualified Dentist designation and American Board of Dental Sleep Medicine Diplomate designation verify knowledge and skill in practicing DSM. Currently, almost 2,000 dentists have earned these designations. Qualified dentists can now consider alternative practice models, some of which are outlined in the next paragraphs, to play a larger role in helping the millions of Americans with undiagnosed and untreated OSA. To be clear, the AADSM is not endorsing the models outlined in this paper, but instead qualified dentists are encouraged to reflect on and discuss emerging models of care in DSM that may work in their communities.

As outlined in the AADSM's Position on the Scope of Practice for Dentists Ordering or Administering Home *Sleep Apnea Tests*<sup>3</sup>, qualified dentists can help identify patients with undiagnosed OSA by working with local licensed medical providers to develop agreed-on criteria for whether patients are candidates for HSATs. The qualified dentist can then screen patients, identify those who are suspected to have OSA, order or distribute HSATs to appropriate patients, and refer them to the licensed medical provider for diagnosis. Dentists have a front seat to patients' airways, see patients often, and have built relationships - sometimes across generations - with them. These opportunities and trusted relationships put dentists in an optimal position to identify patients with undiagnosed OSA. Recently, the American Dental Association updated its policy on the role of dentists treating sleep apnea to incorporate language that dentists can use HSATs as part of their armamentarium, as permitted by laws. There are only a few state dental boards that specifically prohibit dentists from using HSATs, and we are engaged in the modification of these policies based on the American Dental Association's recent statement.

In addition, qualified dentists may consider playing a larger role in treating patients in whom OSA has been diagnosed by a licensed medical provider, but who are not receiving any treatment. This could include patients who have abandoned CPAP or those who have denied CPAP in favor of OAT. These patients have documentation of the diagnosis of OSA, but may not have access to a prescription from a licensed medical provider for various reasons (inconvenience, access to care, expenses, etc.). As we consider prescribing trends relative to insurance requirements for OAT, it is important to consider that only qualified dentists have the appropriate training to assess whether a patient is a suitable candidate for OAT, select the appropriate appliance, deliver and calibrate the appliance, and provide long-term care.

As an example, licensed medical providers do not prescribe hypoglossal nerve stimulation surgery or gastric bypass surgery to help treat patients with OSA. Rather, they refer the patient to a surgeon to determine whether the patient is a suitable candidate for the procedure.<sup>4</sup> OAT should follow the same process; the licensed medical provider refers a patient to a qualified dentist. The qualified dentist then evaluates the appropriateness of OAT for the patient, formulates the specific design, writes the prescription to the laboratory, and is ultimately responsible for the delivery and maintenance of the oral appliance. Similarly, if a patient initiates treatment for OAT directly from a qualified dentist and has documentation of the diagnosis, it is appropriate for the dentist to respect patient preferences, evaluate whether the patient is a candidate for OAT, provide informed consent including information about other therapies for OSA, and communicate the initiation of the therapy with the patient's licensed medical providers. Dentists routinely prescribe and provide multiple medical treatments. Most state dental boards have not prohibited a qualified dentist from providing OAT

without a prescription to a patient with OSA that has been diagnosed by a licensed medical provider. We often prescribe OAT to patients in whom snoring has been diagnosed by a licensed medical provider.

Thirty years ago, our founding members had the forethought to recognize that qualified dentists and OAT could benefit patients and that a professional organization needed to be developed to focus solely on this goal. As we continue to strive to ensure that all patients have access to care for OSA, it is imperative that we consider new practice models as technology and training evolve. Over the next several issues of JDSM, we will introduce other ways we can consider evolving our practices to meet the public burden of OSA, while continuing to provide optimal patient care. We recognize that models are affected by many factors, including but not limited to state regulations, geographic location, relationships with referring licensed medical providers, reimbursement models, and dentists' capacity to provide OAT in relation to other areas of their practice, so we have started a discussion thread titled "Emerging Models" on the AADSM's online discussion forum and encourage you to submit thoughts of your own.

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Directors. Dr. Schwartz declares investments in Prosomnus Sleep.

### **JDSM**

### SPECIAL ARTICLES

## Perspectives on the 30<sup>th</sup> Anniversary of the American Academy of Dental Sleep Medicine

Disclaimer: The use, mention or depiction of any product, device, service or appliance shall not be interpreted as an endorsement, recommendation or preference by the AADSM. Any opinion expressed is solely the opinion of the individual, and not that of the AADSM.

As the American Academy of Dental Sleep Medicine (AADSM) celebrates its 30<sup>th</sup> anniversary this year, some long-time AADSM members shared some of their memories and thoughts about how far the academy has come over the past 30 years.

### AS A LONGTIME MEMBER OF THE AADSM, WHAT HAS BEING PART OF THE AADSM MEANT TO YOU?

"Being involved in dental sleep medicine practically since its inception has been an amazing and rewarding journey. Having stumbled upon oral appliance therapy in 1991 to help solve my own snoring problem, I never expected that incident to change the course of my practice and turn dentistry from a healing art into a life-saving one.

After treating myself, I realized I could also help my patients suffering with the same conditions. Once I saw the impact I could have on a person's sleep, their health, their marriage, and their entire life, I was determined to learn as much as I could and reach out to physicians to let them know this treatment existed. This is when reality checked in. Nearly every physician I visited slammed the door on me. Without sound medical data, clinical studies, or credentials on my behalf, they were not interested.

Like many of my dental sleep medicine colleagues, I started out basically treating snoring with very little knowledge of obstructive sleep apnea. They say, "timing is everything." As luck would have it, the internet was also developing as I was delving into this new field. The Internet enabled me to search out information about oral appliances (and everything else on the planet) on a level that I had not experienced in my life until then. Remarkably, I found other dentists around North America who were pioneering this field. The Internet allowed us to share ideas and learn from each other. A few were developing their own appliances and some decided to form study clubs. Eventually, members of these study clubs organized into the Sleep Disorders Dental Society, then into the Academy of Dental Sleep Medicine, and eventually into what we now know as the American-Academy of Dental Sleep Medicine.

Being part of the AADSM and having this Journal of Dental Sleep Medicine organization behind me, as well as becoming a Diplomate of the ABDSM has changed the playing field. Returning to my medical colleagues, it was as though I had transformed, in their eyes, into one of them. Doors were opening! The AADSM, along with the Diplomate status, legitimized not only me but oral appliance therapy. They were now ready to listen and refer patients."

> - Neal Seltzer, DMD, FAGD, D. ABDSM, D. ACSDD, D.ASBA (Member since 1993)

"My introduction to dental sleep medicine was a lecture given by Dr. Dennis Bailey at the University of Medicine and Dentistry of New Jersey (now Rutgers) during my post-grad work in orofacial pain in 1992. He talked about devices like palatal lifters and tongue retaining devices and a group called the AADSM as a source for more information. I did not attend my first national meeting until 1994, but I had already tried to use a TRD with some success on a patient. In those days, the TRD was customized with a bite registration and was the device of choice. I subsequently shifted to a number of other MADs. At that first meeting, there were maybe 200 dentists, with the focus being more commercially oriented. ("My piece of plastic is better than yours.") That focus continued for a number of years. It has been great seeing the transformation as it has become more oriented towards a medical/scientific-based organization. After state boards, pediatric boards and orofacial pain boards, I vowed not to take another exam. I relented, however, and received my ABDSM diplomate status in 1996. I am grateful for the organization and many mentors for guiding me through this journey. Since retiring, I continue to teach this subject to physicians and dentists at various institutions and meetings. Since I was a pediatric dentist initially, I concentrate on children, adolescents and teens. My pilot study at Children's Hospital focuses on this age group. Best wishes ASDSM for continued success."

Sylvan Mintz, DDS, MSD, ABDSM, ABOP (Member since 1994) "I joined the Sleep Disorders Dental Society in 1993. This was a mom-and-pop organization of dentists interested in oral appliance therapy. I met dentists and dental specialists with enthusiasm and an eye on the future possibilities. Our organization grew slowly and became the American Academy of Dental Sleep Medicine (AADSM) and I became a Diplomate of the American Board of Dental Sleep Medicine (ABDSM) and the president of the ABDSM. I served as president of the AADSM twice: 2002 to 2004 and 2016 to 2018.

This journey of leading and working with dentists, inspired by a goal of learning and educating other dentists to successfully treat patients suffering with obstructive sleep apnea, gave me a vast knowledge and understanding of dental sleep medicine (DSM). I became educated about the landscape of DSM locally, regionally, nationally and internationally.

I have practiced dental sleep medicine/oral appliance therapy (DSM/OAT) for 29 years while treating over 10,000 sleep apnea patients. All my patients are referred to me by physicians, and I work as a valued member of the medical team.

None of my success would have been as satisfying and stimulating without the constant connection to our AADSM and the comradery of the many wonderful dentists and staff. We are the true voice and educational arm of DSM throughout our country and the world. The AADSM has always been the catalyst for my experience, expertise, knowledge and love of DSM/OAT."

- Harold Smith, DDS, D.ABDSM (Member since 1993)

### WHAT IS YOUR FAVORITE MEMORY OF YOUR TIME AS AN AADSM MEMBER?

"At the end of a long day, I was writing up a chart of a patient that I had just seen (a 50-year-old woman - let's call her Sally) who was referred by a pulmonary sleep specialist. She was well-dressed, had an engaging personality and was concerned that her loud snoring would not allow her to date anyone. After a complete clinical exam and review of her medical records, I realized that her case was extremely complex...and I could handle it well. I chatted easily with her about the management of her case with an oral device. I answered her questions, and we commenced the treatment. Just. Like. That.

I then leaned back in my chair and smiled to myself, remembering my first sleep apnea patient. Twenty years prior, I was approached by a local physician who asked me if I did oral appliances. I brazenly assured him I did, as I had just attended my first course in oral appliance therapy. He then referred a CPAP-intolerant male patient to me. I realized how uncertain I was about managing this patient. I immediately reached out to the speaker who introduced me to what was once called the SDDS and my journey in dental sleep medicine began. That patient did fine, and I survived too!

The heartwarming memory I had of the moment I realized how far I had come, has stayed with me. It was a point in my career when I felt my competence, confidence and experience were in harmony. I shortly delivered the oral appliance to Sally and a month later she bought me homemade cookies. They were delicious, but not sweeter than the feelings of competence and accomplishment that I gained from my journey with the AADSM"

Leila Chahine, DMD, D.ABDSM (Member since 2000)

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### **JDSM**

### LETTER TO THE EDITOR

### Be Cautious in the Interpretation of the Findings of The Laryngoscope 2022 Paper Associating Cancer to CPAP Polyurethane Foam: It is One piece of Evidence, Not the End of the Story!

Gilles Lavigne, DMD, PhD<sup>1,2,3</sup>; Cibele Dal Fabbro, DDS, PhD<sup>1,2,3</sup>; Thays Crosara Abrahão Cunha, DDS, PhD<sup>4</sup>; Thulio Marquez Cunha, MD, PhD<sup>5</sup>

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As always with new findings, and more importantly when these findings can create a high level of anxiety in our patients, professionals in dental sleep medicine must be cautious in their interpretations.

### The Story

Most of you know that a safety issue was officially announced by the Food and Drug Administration (FDA) related to the degradation of the continuous positive airway pressure (CPAP) device polyurethane sound abatement foam. The July 2021 recall notice followed a CPAP company's declaration that the foam carried a potential carcinogenicity risk.<sup>1</sup> An FDA notice is not a ban; rather, it is part of a surveillance process. The mitigation for this issue is still ongoing and the risks remain to be proven.

In the meantime, this recall has generated major concerns and some anxiety in CPAP users and prescribers. We must recognize that a declaration of possible risk is not ultimate proof of a risk. Assessing the causes and effects of a risk is a long process toward a final demonstration of evidence over any reasonable doubt. Until this is confirmed or rejected, physicians and dentists working in sleep medicine must reassure their patients and guide them to the best alternatives for therapy.

### The Paper Associating CPAP Foam with Cancer Risk

A 2022 paper from Brauer PR et al., published in *The Laryngoscope*, reported an association of cancer to CPAP foam degradation.<sup>2</sup> According to the analysis of the databank managed by the FDA, the *Manufacturer and User Facility Device Experience* (MAUDE) database,<sup>3</sup> a sudden rise of CPAP polyurethane foam material degradation was associated with cancer during 2021!

The rise was very sudden; from 9 cases between 2014-

2020 to more than 200 cases for the first 9 months of 2021. Among the 2571 CPAP reported 'injuries' (the word used in the MAUDE database), cancer was ranked second (4.6%). More specifically, of the 1902 events reported in relation to CPAP material degradation, 174 (9.15%) have been associated with a cancer 'verdict.' In the order of reported CPAP injuries, reports of headache were first in frequency and, surprisingly, fire with CPAP use in high oxygen environments, the third.

### The Cautions in Interpreting the Paper

The Food and Drug Administration (FDA) recommend the following regarding use of *medical device report* (MDR) data file information:<sup>3</sup>

- "MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices."
- "Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated."
- "MAUDE data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions."<sup>3</sup>

### **Other Considerations:**

- 1. Since it is mandatory for manufacturers to report device 'injuries' or other complaints and since these data are based on patient self reports, it may be possible they may be imprecise regarding the cancer status: suspected or confirmed by a medical diagnosis.
- 2. The MAUDE database does not have information on the type of cancer, its duration, severity (staging) and association with other health comorbidities. This is essential in assessing risk specificity.
- 3. Since the physician declarations are voluntary, accuracy of reported complaints frequency may be questionable. The physician may have judged the complaints or worries related to CPAP device as less critical than other life-threatening patient's health issues. In a busy practice, some of these complaints may not have been reported on the MAUDE WEB site at all.<sup>3</sup> Moreover, patient concerns about foam and cancer risk may not have reached the physician at all, since follow-ups to verify comfort with CPAP are frequently done by independent health care providers.
- 4. The data presented in the Brauer et al. paper are descriptive.<sup>2</sup> As listed below, it is obvious that future studies will need to address the power of statistical analysis, assess the probability of risk and strength of the association, identify bias, etc.
- 5. Finally, can it be possible that the sudden rise in the incidence of cancer reported in CPAP users jumped to such a high level because of global awareness brought on by the FDA safety recall notice?<sup>1</sup> Large public diffusion of that type of health information may have influenced the magnitude of the rise.

### **Other Studies**

A recent retrospective analysis, over a period of 7.5 years, was conducted in a cohort of CPAP-treated patients in four Ontario (Canada) hospital. The study revealed no difference in hazard ratio in incidence of lung cancer when comparing different CPAP devices.<sup>4</sup> This analysis, with a large sample size, has many merits but it is based on a posthoc analysis from a governmental registry, merging cancer and CPAP database.

Another governmental registry database comparison, this time from Sweden, analyzed data over an 8-year period. A first statistical comparison revealed significantly higher incidence of all-cause cancer and, more specifically, lung cancer. However, the observed difference disappeared when smoking was included in the model.<sup>5</sup>

More publications will emerge and no single study will provide a clear and final conclusion. There is a need for well-controlled analyses, considering contributing cancer risk and other confounding factors such as age, smoking, gender, time of CPAP use, other comorbidities, etc. For obvious reasons, prospective and randomized controlled studies will not be ethically acceptable; we need to accept such limitations.

### Conclusion

The potential risks of cancer due to CPAP foam is an important health concern. We have to remind ourselves that a cancer diagnosis is among the most stressful events a patient can face. Other issues should be further analyzed to confirm such risk and its impact on patient health. These analyses will likely be done in the long-term as cancer may take time to be expressed. Furthermore, cancer occurrence can result from a combination of environmental and genetic factors. Other health conditions may also be associated with such foam particles and volatile product release. Do we need to reiterate that association does not equal causality?

No health device is without discomfort, problem or risk. Managing sleep apnea, a putative life-threatening condition, whether with a CPAP or an oral device, is part of health prevention and maintenance. To better guide our patients, we must stay informed with solid scientific evidences.

### CITATION

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### **DISCLOSURE STATEMENT**

The authors have no relevant conflicts of interest to disclose.

### ABSTRACTS

### 2022 AADSM Annual Meeting Abstracts

Disclaimer: The following are the abstracts and case reports accepted for the 2022 Annual Meeting.

Abstracts and case reports do not follow the same peer-review process followed for the submission of original research articles for the Journal of Dental Sleep Medicine. Rather, all submissions were blind peer-reviewed for acceptance by members of the AADSM Scientific Committee. The committee uses criteria to score research abstracts which include (but are not limited to) applicability to dental sleep medicine, novelty, clarity, proper research methodology and data analysis, well-founded conclusions and creativity. Criteria to score case reports include (but are not limited to) applicability, well-founded discussion and creativity.

It is important to keep in mind that abstracts and case reports presented at the Annual Meeting are intended to spur education and discussion for both attendees and authors.

Brand names are not permitted to be used in titles and are limited to two references within the submission body. Furthermore, the abstracts include author disclosures of any conflicts of interest or affiliation with a company. If a company or governmental body provided any financial support for the research, this is also disclosed. The AADSM does not endorse or recommend any products or services presented in these abstracts.

### CASE REPORT #001

### EFFECTIVENESS OF MANDIBULAR ADVANCEMENT DEVICE IN THE MANAGEMENT OF MODERATE OBSTRUCTIVE SLEEP APNEA WITH CONCOMITANT TEMPOROMANDIBULAR DISORDER: A CASE REPORT

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**Introduction:** The comorbidity between obstructive sleep apnea (OSA) and temporomandibular disorder (TMD) is high. Approximately one in four patients with clinically diagnosed TMD has polysomnographic-diagnosed OSA. This comorbidity poses difficulty for management because neither appliance is considered effective in treating both conditions. Mixed results have been reported with some studies claiming mandibular advancement device (MAD) worsened TMD. In contrast, other studies found symptoms to be alleviated. In addition, MAD therapy is not efficacious for all, with approximately one-third of patients experiencing no therapeutic benefit. However, there is strong evidence demonstrating MAD improve OSA in the majority of patients.

**Report of Case:** 55-year-old female, diagnosed with moderate OSA (AHI=16.3 and 84% O2) with chronic history of TMD symptoms. A through clinical history and examination completed, BMI 31.6, neck circumference 12.5", and cephalometric analysis depicted a low mandibular angle and reduced hyoid bone-to-mandible distance. Intolerant to CPAP due to air leakage and facial pain aggravated by the mask. MAD as

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an alternative therapy was suggested to the patient by the sleep physician. TMD symptoms included bilateral masticatory myofascial pain, TMJ sounds, and headaches. A bilateral traction oral appliance design was selected with 50% of mandibular protrusion, and 5 mm of vertical dimension of occlusion (VDO). The sleep oral device and morning repositioning aligner were fabricated, delivered, and fitted. A lower stabilization orthotic appliance for daytime use was fabricated to address TMD symptoms. The patient returned for a follow-up with and reported increased dreaming, decrease in snoring, headaches, bite changes, facial and jaw pain from moderate to mild based on a subjective report by the patient confirmed by visual analog scale (VAS). Additional titration and occlusal adjustments of the oral sleep device and daytime orthotic device were made to achieve further therapeutic jaw protrusion and management of TMD symptoms. After completing the MAD titration protocol, she was referred to the sleep physician for a follow-up sleep study to objectively assess the efficacy of the appliance, which revealed an AHI of 3.5 and 89% 02 (baseline AHI 16.3 and 84% 02). Long-term follow-up was implemented as standard of dental sleep medicine clinical care at six months for the first year and yearly after.

**Discussion:** In this case report, we describe the impact of OSA on chronic pain as a vicious cycle with mutual deleterious influences causing an increase in pain and disrupted sleep. MAD is a well-established alternative to the gold standard CPAP currently recommended for mild to moderated OSA management. This case report demonstrates successful management of concomitant moderate OSA with an existing TMD condition when

evidence-based and clinical expertise help to customize a treatment plan based on the patient's unique medical history and examination.

**Support:** Authors declared no conflict of interest and no financial support provided for this case report.

### ABSTRACT #002

### SELF-REPORTED IMPROVEMENT IN OBSTRUCTIVE SLEEP APNEA SYMPTOMS COMPARED TO POST TREATMENT AHI WITH MANDIBULAR ADVANCEMENT DEVICE THERAPY: A RETROSPECTIVE STUDY

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**Introduction:** Mandibular advancement device (MAD) is recognized as a treatment option for the management of obstructive sleep apnea (OSA) in mild to moderate cases and/or patients unable to tolerate PAP therapy.

According to AADSM guidelines, it is recommended to refer the patient for a post-treatment sleep study to establish the efficacy of MAD. Patients will be referred when the maximal therapeutic benefit has been achieved based on self-reported improvement of OSA symptoms or maximum anatomical protrusion.

The aim of the study was to investigate the difference between *responders* and *non-responders* in terms of selfreported improvement of OSA symptoms.

Methods: Medical chart of patients referred to the Orofacial Pain Clinic at University of Kentucky between 2016 and 2021 for the management of OSA with MAD were retrospectively evaluated. Only participants with a post-treatment sleep study with MAD in situ and with a previous follow-up investigating subjective OSA symptoms were included. Participants were categorized as responders if MAD treatment resulted in 50% improvement in AHI. Subjective symptoms were recorded using a 100-mm Numerical Rating Scale (NRS). OSA symptoms measures were loudness of snoring (0-100 NRS, 0=not snoring at all), witnessed apneas (0-100 NSR, 0=never), sleep quality (0-100 NRS, 0=very sound restful), tiredness upon awakening (0-100 NRS, 0=completely rested), daytime fatigue (0-100 NRS, 0=not at all tired), daytime sleepiness (0-24 Epworth Sleepiness Scale, 0=not sleepy at all).

Differences in pre-, post-treatment variables within and between groups were analyzed with paired t test and independent t test, respectively. Logistic regression was used to investigate if any variable was able to predict the treatment group.

**Results:** From 79 patients, 6 were excluded due to lack of sleep study or data on subjective OSA symptoms. 73 participants (36 women and 37 men, aged  $64.32 \pm 10.77$ ), with mean pre-treatment AHI of  $20.99 \pm 15.84$ , were evaluated. Of those, 37 (50.68%) were classified as responders and 36 as non-responders (49.32%). The two groups differed in pre- and post-treatment AHI (p = .022) and .000, respectively). The responders had a mean pretreatment AHI of 25.24 ± 19.67 and a mean posttreatment AHI of  $6.99 \pm 6.06$ ; the non-responders had a mean pre-treatment AHI of  $15.77 \pm 8.73$  and a mean posttreatment AHI of  $15.99 \pm 10.39$ . Pre-treatment AHI was a weak predictor of response to treatment ( $\beta = .240$ , p =.072). Before referring the participant to the posttreatment sleep study, the responders reported a significant improvement in sleep quality compared to the non-responders  $(21.51 \pm 24.07 \text{ vs. } 34.81 \pm 29.66, p)$ =.039), and scored weakly better in tiredness upon awakening compared to the non-responders (22.76  $\pm$ 21.16 vs.  $32.53 \pm 26.02$ , p = .082). The remaining OSA symptoms measures did not differ between the two groups (all p's >0.05). None of the self-reported OSA symptoms predicted the treatment group.

**Conclusions:** Based on the results of this study, among the self-reported OSA symptoms, only sleep quality was significantly improved in *responders* compared to the *non-responders*.

Support: None

### ABSTRACT #003

THE USE OF A DIGITALLY MILLED ORAL APPLIANCE IN THE TREATMENT OF SEVERE OBSTRUCTIVE SLEEP APNEA

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**Introduction:** Oral appliances (OAs) that advance the mandible are commonly used for the treatment of mild to moderate obstructive sleep apnea (OSA) but are less accepted as a therapy for severe OSA, likely due to their supposed lower rate of therapeutic success in that population. However, the preference for OAT over CPAP and relative lack of other non-surgical treatment options highlights the need for acceptance of OAT for all severities of OSA. Data from two prospective studies that collected data on OAT efficacy were analyzed retrospectively to evaluate the success rate of OAT in severe OSA using a digitally milled OA.

**Methods:** Data from the severe OSA cohorts of two studies conducted for the validation of an in-home auto-titration test were evaluated. Study participants (n = 41

with severe OSA) received a precision iterative advancement OA (ProSomnus Sleep Technologies, Pleasanton, CA). The OAs used in the studies were CAD/CAM generated from digital intraoral scans and precision milled from control cured grade PMMA. The OAs consisted of sets of upper and lower trays that, when interfaced together, allowed for advancement of the mandible to a treated position. Oral appliances were set to the target protrusion provided by an in-home autotitration test that predicts response to OAT (MATRx plus; Zephyr Sleep Technologies, Calgary, Alberta, Canada). Participants not predicted to respond to OAT were assigned a sham mandibular protrusion.

Oral appliance therapy was initiated at the target protrusive position, sham position, or highest tolerated position for individuals who were unable to have their OA inserted at target. Once participants were habituated to OAT, a 2-night home sleep apnea test (HSAT) was conducted to assess treatment efficaciousness, and the mandible was advanced as necessary to lower the respiratory event index (REI).

**Results:** The study population included 36 male and 5 female participants with a mean age of  $50.6 \pm 8.4$  years (range: 32-74 years), mean BMI of  $32.1 \pm 5.5$  kg/m<sup>2</sup> (range: 19.8-45.4 kg/m<sup>2</sup>), mean baseline REI of  $49.5 \pm 17.1$  h<sup>-1</sup> (range: 30.3-101.8 h<sup>-1</sup>), and median Epworth Sleepiness Scale (ESS) score of 10 (range: 0-23).

Oral appliance therapy was well-tolerated in the study population. The majority of study participants achieved some level of therapeutic success, with 73.2% of participants achieving a decrease in REI from baseline of at least 50% and 68.3% achieving an REI < 15 h<sup>-1</sup>. Of the study participants who achieved an REI < 15 h<sup>-1</sup>, the average protrusive position of the OA was 86.7±15.3% (range: 54.8-100%).

**Conclusions:** The OAs used in the studies provided efficacious treatment for the majority of individuals with severe OSA, indicating that oral appliance therapy could be a suitable alternative to CPAP. The rate of therapeutic success was higher than that reported previously in the literature and might be a result of the precision of appliances generated from digital intraoral scans using a CAD/CAM approach.

**Support:** Study data were collected by and used with the permission of Zephyr Sleep Technologies. ProSomnus Sleep Technologies provided the OAs used in the studies.

### ABSTRACT #004

**RECAPTURING A POSTERIOR OPEN BITE USING A PRECISION MILLED MORNING OCCLUSAL GUIDE** Shandra Rosenfeldt DDS<sup>1</sup>, Mark T Murphy DDS D-ABDSM FAGD<sup>2</sup> <sup>1</sup> Serenity Valley Family Dental Fargo, ND; <sup>2</sup> Funktional Sleep, Rochester Hills, MI

Introduction: Posterior open bite is often mentioned in the literature as a common and unavoidable side effect of oral appliance therapy. Reducing the therapeutic dose using smaller precision devices (less advancement) and providing the patient with a morning maximum intercuspal position (MIP) re-alignment device (Morning Occlusal Guide) manufacturing of and daily wear of a precision MOG can help patients prevent development of a posterior open bite. MIP posterior contact is often evaluated and recorded using articulating paper and having the patient bite together. If the bite does change, the paper would pull out with little or no resistance. If this condition does occur upon loss of or non-use of their MOG, we can use the archival digital records to recreate the MIP position and re-make a MOG at the original bite relationship. This patient had moved from Dr. Rosenfeldt's care in Fargo, ND to the Detroit, MI area and was referred to Dr. Murphy for evaluation of a posterior open bite due to a lost MOG and 4 months' time passing.

**Methods:** The patient was examined and did demonstrate a unilateral posterior open bite. Two new MOGs were ordered from the digital case archives at ProSomnus of the original delivered EVO appliance and MOG, instructions for use were reviewed and the device was delivered to the patient. The patient was also given instructions for exercises according to the AADSM side effect of OAT document.

The patient presented 10 days after delivery and wearing the new MOG and doing the exercises. Posterior occlusion had been re-established as demonstrated with resistance of the articulation paper upon closing together in MIP. The patient reported no discomfort and was happy to have his teeth feel normal again.

**Conclusions:** Digital archives and the ability to remake a MOG in the same MIP can be an important step in recapturing bite changes in oral appliance therapy.

**Support:** No financial support was provided for the treatment of this case.

#### ABSTRACT #005

### EFFICACY OF A NOVEL 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. In April 2020, the broader availability post FDA clearance is providing strong early indications of excellent efficacy.

**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.

**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 revealed an average overall reduction in AHI of 75%, from 26.4 to 6.6. Overall, 62% resolved to below an AHI of 5 (100% of mild, 65% of moderate and 24% of severe patients). Similarly, 85% resolved to below an AHI of 10 and a 50% reduction (100% of mild, 96% of moderate and 59% of severe patients)

**Conclusions:** This novel interactive device and material combination appear, after early analysis, appear 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.

Support: No support was provided for this abstract

### ABSTRACT #006

### PREVALENCE AND RISK FACTORS OF SEVERE SLEEP BRUXISM IN ADULTS WITH NON-APNEIC SNORING: A LARGE-SCALE POLYSOMNOGRAPHIC STUDY

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Introduction Sleep bruxism (SB) is characterized by rhythmic masticatory muscle activity (RMMA) during sleep. The prevalence of severe SB (RMMA≥4 events/hour) is 3% in the general population. SB has a strong association with sleep-related breathing disorders, however, previous studies mainly focused on obstructive sleep apnea and not on non-apneic snoring (NAS). Adults with NAS may receive oral appliance therapy for their snoring problem. When they also suffer from severe SB, they may consequently break their oral appliance during sleep. It is therefore clinically relevant to determine the prevalence and risk factors of severe SB in adults with NAS. Current evidence shows that SB may be associated with age, gender, body mass index (BMI), and specific sleep-, respiratory-, and psychosocial conditions. We hypothesize that in adults with NAS: 1) severe SB is highly prevalent; 2) higher age and lower BMI decrease the odds of having severe SB; and 3) more sleep arousals increase the odds of having severe SB. Therefore, the aim of this study was to determine the prevalence and risk factors of severe SB in adults with NAS.

**Methods** This prospective polysomnographic study included 292 NAS adults (140 males, 152 females; mean  $\pm$  SD age = 42.8  $\pm$  12.2 years; mean  $\pm$  SD BMI = 26.7  $\pm$ 4.7 kg/m<sup>2</sup>) with an AHI < 5 events/hour and without any previous treatment for snoring. Adults with an RMMA index  $\geq$  4 events/hour were diagnosed with severe SB. A stepwise backward binary logistic regression was performed, with severe SB (yes or no) as the dependent variable and with age, gender, BMI, polysomnographic sleep- and respiratory-related parameters, and SB-related comorbidities (psychological conditions and other sleeprelated disorders) as the independent variables.

Results The prevalence of severe SB was 17.5% in adults

with NAS. Severe SB was associated with lower BMI (odds ratio = 0.919, P =0.034), lower percentage of sleep stage 2 (odds ratio = 0.953, P = 0.008), and higher total arousal index (odds ratio = 1.070, P = 0.004).

**Conclusions** Severe SB is highly prevalent in adults with non-apneic snoring compared to the general population. The increase of sleep arousal increases the odds of having severe SB, while higher BMI and higher percentage of sleep stage 2 decreased the odds of having severe SB.

Support Not applicable.

### ABSTRACT #007

#### AN INTERNATIONAL EXPERTS' ASSESSMENT OF DENTAL SLEEP CONDITIONS AND THE ROLE OF ORAL HEALTHCARE PROVIDERS: A SCOPING REVIEW OVER THE PAST 20 YEARS

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<sup>4</sup>Medical Library, Vrije Universiteit Amsterdam, Amsterdam, the Netherlands

**Introduction:** Dental sleep medicine (DSM) is a discipline that was first described over 20 years ago. Snoring, obstructive sleep apnea (OSA), sleep bruxism (SB), xerostomia, hypersalivation, gastroesophageal reflux disorder (GERD), and orofacial pain were identified as sleep-related dental conditions. Given the long time that has passed since this first description, we hypothesized that there will be other dental sleep conditions that have not yet been identified as such, and that oral healthcare providers will have new roles in DSM. Therefore, the aims of this scoping review were 1) to identify so far unidentified dental sleep condition(s); and 2) to identify the role of oral healthcare providers in the prevention, assessment, and management of dental sleep conditions.

**Methods:** A systematic search strategy that combined dentistry-related terms and sleep-related terms was formulated with the help of a medical librarian (RdV). The literature search was conducted in PubMed, Embase.com, Web of Science, and Cochrane from inception up to February 14, 2020. Studies were included that reported an actual or likely role of oral healthcare

providers in the prevention, assessment, and/or management of sleep-related conditions.

Results: Of the 9,151 references generated in the literature search, 195 studies were included in this review. For the first aim, 184 studies reported the known dental sleep conditions; the other eleven studies reported the role of oral healthcare providers in the assessment and management of burning mouth syndrome (BMS). The association between BMS and sleep disturbance was also reported. BMS was therefore identified as the only so far unidentified dental sleep condition and was categorized into an existing category of DSM, namely "orofacial pain". For the second aim, it was found that the oral healthcare provider can play a significant role in the prevention, assessment, and management of OSA and SB; in the assessment and management of snoring, orofacial pain, and oral dryness; and in the assessment of GERD.

**Conclusion:** Based on the available evidence, burning mouth syndrome was found to be the only so far unidentified dental sleep condition. The oral healthcare provider was found to play a significant role in the assessment of all dental sleep conditions, in the management of most conditions, and in the prevention of OSA and SB.

**Support:** Not applicable.

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### ABSTRACT #008

### ASSOCIATION BETWEEN THE SEVERITY OF OBSTRUCTIVE SLEEP APNEA (OSA) AND THE SOCIALLY DETRIMENTAL DEGREE OF SNORING IN PATIENTS WITH MILD TO MODERATE OSA

Zhengfei Huang<sup>1,2</sup>, Ghizlane Aarab<sup>1</sup>, Nico de Vries<sup>1,3,4</sup>, Antonius A.J. Hilgevoord<sup>2</sup>, Frank Lobbezoo<sup>1</sup>

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Introduction: Snoring is one of the most commonly reported symptoms of obstructive sleep apnea (OSA). Mandibular advancement devices (MADs) are commonly used to treat patients with mild to moderate OSA, i.e., with an apnea-hypopnea index (AHI) of 5-30 events/h, and concomitant snoring. Clinicians often focus on OSA itself but tend to overlook the fact that snoring can be characterized by a high snoring index (i.e., a large number of snoring events per hour of sleep) and high intensity (A-weighted decibel; dBA), and that snoring could therefore be considered socially detrimental. According to Guidelines for Community Noise by the World Health Organization (WHO), the sound level of continuous background noise during sleep should not exceed 30 dBA and noise events exceeding 45 dBA should be avoided. To the best of the authors' knowledge, no previous study has investigated whether the socially detrimental degree of snoring, as determined by its index and intensity, is correlated to the severity of OSA in patients with mild to moderate OSA. Therefore, the aim of the present study was to investigate whether the socially detrimental degree of snoring is correlated to the severity of OSA in patients with mild to moderate OSA by assessing the correlation between AHI and the index and intensity of snoring. We hypothesized that there are positive correlations between AHI and the index and intensity of snoring, i.e., the higher the AHI value, the more frequent snoring will occur and the higher intensity the snoring events will have.

**Methods:** Patients who underwent an overnight polysomnography (PSG) and simultaneous recording of snoring sounds for potential OSA were included in this prospective study at the department of clinical neurophysiology of OLVG-West (Amsterdam, The Netherlands) between July 2020 and November 2021. The PSGs and the snoring sound recordings were synchronized, and all snoring events in the sound recordings were extracted using custom software codes written by the authors. In addition, the peak intensity was calculated for each snoring event and the mean of the peak intensities was calculated for each patient. Spearman's correlation was used to investigate the correlation between AHI and the index and intensity of snoring.

**Results:** Twenty-nine patients (male: n=21 [72.4%]; age: 44.6±9.9 yrs; body mass index: 26.9±5.0 kg/m<sup>2</sup>; AHI: 12.7±7.3 events/h) with mild to moderate OSA were included. In this population, the mean snoring index was 243.6±169.5 events/h and the mean peak intensity of snoring events was 47.1±7.1 dBA. No significant correlation was found between AHI and the snoring

index (r=0.3; P=0.1). However, a moderately positive correlation between AHI and the mean peak intensity of snoring events was found (r=0.4; P=0.02).

**Conclusion:** In patients with mild to moderate OSA, the snoring index is not correlated to AHI, but the mean peak intensity of snoring events is positively correlated to AHI and exceeds the maximally acceptable nighttime noise level suggested by the WHO. These findings suggest that the socially detrimental degree of snoring is positively correlated to the severity of OSA in patients with mild to moderate OSA.

Support: Not applicable.

### ABSTRACT #009

### COMPARISON OF THE EFFECTS OF MAXILLOMANDIBULAR ADVANCEMENT ON RESPIRATORY FUNCTION AND FACIAL ESTHETICS BETWEEN OBSTRUCTIVE SLEEP APNEA PATIENTS WITH AND WITHOUT MAXILLOMANDBILAR DEFICIENCY

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Introduction: The indications for maxillomandibular advancement (MMA) in obstructive sleep apnea (OSA) have not been standardized so far. Although MMA has primarily been employed as the first-line treatment in OSA patients with maxillary and/or mandibular deficiency, MMA is currently also employed in OSA patients without this skeletal deficiency. The aims of this study were: 1) to compare the effects of MMA on respiratory function between OSA patients with and without maxillomandibular deficiency based on polysomnographic (PSG) variables and patient satisfaction in breathing; and 2) to compare the changes in facial esthetics after MMA between the two groups based on cephalometric analysis and patient satisfaction in facial esthetics. We hypothesized that: 1) the effects of MMA on respiratory function were better in OSA patients with deficiency than in those without deficiency; and 2) the changes in facial esthetics followed by MMA were more acceptable in OSA patients with deficiency than in those without deficiency.

Methods: Sixty-one MMA-treated OSA patients with both baseline and at least three-month follow-up PSG data and lateral cephalograms were enrolled in this retrospective study. Group A consisted of 21 patients without deficiency (90.5% male; age  $50.4 \pm 9.3$  y; body mass index [BMI]  $29.4 \pm 5.1$  kg/m2; baseline apnea hypopnea index [AHI]  $43.3 \pm 22.1$  /h). Group B consisted of 40 patients with deficiency (72.5% male; age 50.4  $\pm$ 10.3 y; BMI 29.1  $\pm$  3.9 kg/m2; baseline AHI 52.1  $\pm$  24.0 /h). The collected data included pre- and post-operative PSG data, pre- and post-operative cephalometric measurements, and patient satisfaction with postoperative breathing and facial esthetics assessed by a 10point visual analogue scale (VAS) (0 = not satisfied at all,10 = completely satisfied). The primary outcomes were the changes in AHI and soft tissue cephalometric parameters. Independent-samples t-tests or Mann-Whitney U tests were used to compared values between groups. Paired-samples t-tests or Wilcoxon signed-rank tests were used to compare the pre- and post-operative values

Results: At baseline, no significant differences between both groups were found in sex, age, BMI, AHI, nasal prominence, and nasolabial angle, while significantly more protrusive position of the upper lip (UL), lower lip (LL) and soft tissue pogonion (Pog') relative to the true vertical line (TVL), and smaller facial convexity were observed in group A. Postoperatively, the AHI reduction was comparable between the two groups ( $26.3 \pm 21.0$  /h vs  $37.1 \pm 24.8$  /h; P = 0.490). Significant increases in UL-TVL, LL-TVL, and Pog'-TVL were observed in both groups, with significant decreases in nasal prominence and nasolabial angle. The changes in soft tissue measurements were comparable between the two groups. The satisfaction degrees in breathing (7.0 vs 6.5, P =(0.713) and facial esthetics (6.5 vs 7.0; P = 0.983) did not differ significantly between both groups.

**Conclusions:** Within the limitations of the retrospective study, it can be concluded that there is no significant difference in the effects of MMA on respiratory function and facial esthetics between OSA patients with and without maxillomandibular deficiency.

Support: Not applicable.

### ABSTRACT #010

### AIRWAY SIZE IS NOT A SIGNIFICANT FACTOR IN THE LOW AROUSAL THRESHOLD PHENOTYPE IN OBSTRUCTIVE SLEEP APNEA

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**Introduction:** Currently, treatments for obstructive sleep apnea (OSA) are not prescribed with consideration of pathophysiologic phenotypes. One such phenotype is low respiratory arousal threshold (ArTH) —defined as the occurrence of arousal from sleep with a small rise in ventilatory drive. A non-invasive way of deriving ArTH from polysomnography (PSG) variables has recently been described. We wanted to examine the impact of airway size on the presence of low ArTH phenotype OSA.

**Methods:** This was a retrospective review of patient charts. We included patients who underwent full night diagnostic PSG. OSA was defined as an apnea hypopnea index (AHI) of >5. Epworth score, BMI, neck circumference, and upper airway size using Modified Friedman (MF) were recorded. Low ArTH was calculated using AHI, fraction of hypopneas and O2 nadir.

**Results:** 653 patients were included - 421(65%) M & 230 (35%) F. 36% of patients had a low ArTH phenotype. In the low ArTH group average MF scores were 2.6 +/- 1.0 vs 2.8 +/- 1.0 in those with normal ArTH (p=0.03). In looking at each of the 4 airway size groups, the proportion of low ArTh phenotype was 14%, 34%, 27%, and 25% respectively for MF Grade 1,2,3,4. Correlation between MF and ArTh score was -0.106 (p<0.01).

There was no significant association of low ArTH and MF score even after adjusting for age, gender, BMI, ESS, and neck circumference.

**Conclusion:** Airway size does not seem to be a major factor in impacting the low ArTh phenotype. As we move towards precision based therapy in OSA, use of oral appliance may be relevant in all grades of airway size/morphology for low ArTH phenotype OSA and could be combined with pharmacotherapy approaches in these patients. Future studies should examine the impact of use of oral appliance for OSA on ArTH in different airway size.

### Support: None

### ABSTRACT #011

### COMPARISON OF UPPER AIRWAY MORPHOLOGY BETWEEN POSITIONAL AND NON-POSITIONAL OBSTRUCTIVE SLEEP APNEA

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Introduction: Existing evidence suggests that the difference in the pathogenesis between positional obstructive sleep apnea (POSA) and non-POSA (NPOSA) may be related to differences in upper airway morphology. However, the difference in upper airway morphology between both groups is not clear. The worsening of sleep-related obstructive respiratory events in supine position may be related to gravity, which works against the anterior wall of the upper airway and may induce collapse of the upper airway in anteroposterior dimension. Therefore, we hypothesized that: (1) individuals with POSA will have a higher anatomical imbalance (i.e., an excessive tongue size relative to maxillomandibular enclosure size) compared to individuals with NPOSA; and (2) individuals with POSA will have a more elliptically shaped upper airway with the long axis oriented in the lateral direction compared to individuals with NPOSA. Therefore, the primary aim of this study was to compare anatomical balance and shape of the upper airway between individuals with POSA and individuals with NPOSA based on cone beam computed tomography (CBCT) images in supine position.

Methods: This study was a secondary analysis of data from a prospective study, in which 60 individuals with OSA (apnea-hypopnea index (AHI) > 10 events/h) were recruited for building a prediction model on oral appliance treatment outcome. Individuals were classified as POSA if the AHI in supine position was greater than twice the AHI in non-supine positions; otherwise, individuals were classified as NPOSA. Anatomical balance was calculated as the ratio of the tongue area and the maxillomandibular enclosure area as derived from CBCT scan. Upper airway shape was calculated as the ratio of the anteroposterior dimension and lateral dimension of the minimal cross-sectional area of the upper airway (CSAmin-shape). The mean differences in anatomical balance and shape of the upper airway between POSA and NPOSA groups were compared by analysis of covariance (ANCOVA).

**Results:** Thirteen participants with an incomplete dataset were excluded from the analysis. Therefore, 47 participants (28 men and 19 women) with a median (interquartile range) age of 56.0 (46.0-63.0) years, a

median AHI of 27.8 (15.0-33.8) events/h, a mean ( $\pm$ SD) body mass index (BMI) of 29.4 ( $\pm$ 5.4) kg/m<sup>2</sup>, and a mean (±SD) neck circumference of 40.1 (±3.3) cm were included in the analysis. There were no significant differences between the POSA group (n=34) and NPOSA group (n=13) in age, gender distribution, BMI, and neck circumference (P=0.07-0.88). The AHI and AHI-supine were not significantly different between the POSA and NPOSA groups (P=0.07 and 0.39, respectively). However, the median (interquartile range) AHI-nonsupine was significantly lower in the POSA group (6.0 (3.0-13.5) events/h) compared to the NPOSA group (30.7 (23.3-34.4) events/h) (P<0.01). There was no significant difference between the POSA and NPOSA groups in anatomical balance and CSAmin-shape (P=0.18 and 0.73, respectively).

**Conclusions:** Within the limitations of this study, we concluded that there is no significant difference in the anatomical balance and shape of the upper airway in supine position between individuals with POSA and individuals with NPOSA.

**Support:** This work was supported by the National Health and Medical Research Council (NHMRC) of Australia (Project grant GNT1024351).

### ABSTRACT #012

### FACTORS ASSOCIATED WITH TREATMENT ADHERENCE TO MANDIBULAR ADVANCEMENT DEVICES: A SCOPING REVIEW

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**Introduction:** Obstructive Sleep Apnea (OSA) is frequently treated with Continuous Positive Airway Pressure (CPAP) or Mandibular Advancement Devices (MADs). For various reasons, both treatment options are often affected by low adherence. While factors associated with low CPAP adherence are described in the literature extensively, less is known about adherence to MAD therapy. It is important to recognize factors associated with MAD adherence in the treatment of OSA patients, because such knowledge will contribute to more personalized medicine approaches. This scoping review aimed to synthesize the body of literature on the factors associated with adherence to MAD treatment.

Methods: A systematic literature search was conducted by two reviewers independently. The bibliographic databases PubMed, Embase.com, Web of Science, and the Cochrane Library (Wiley) were used to identify relevant English-language publications, using the (MeSH) terms "Mandibular Advancement" and "Treatment Adherence and Compliance." After screening all titles and abstracts, the selected full-text articles were checked for eligibility based on a priori formulated inclusion and exclusion criteria. Studies were included if they described factors associated with adherence to MADs in adults in the treatment of OSA or snoring. They were excluded if they did not describe such factors, and if patients were younger than 18 years.

Results: The literature search yielded a total of 587 references. After duplicates had been removed, 584 references remained. Thirty-one studies were found eligible for inclusion in this study. The main reasons for exclusion were: no use of MAD, article not found, no association with adherence, and article not in English. Included studies were mainly randomized controlled trials, reviews, and retrospective studies. The literature showed that several factors have an association with adherence to MAD treatment. Main factors with a negative influence on the adherence to MAD treatment are: failing effectiveness of MAD; occurrence of side effects during MAD therapy, such as patient discomfort or tooth pain; usage of a thermoplastic MAD instead of a custom-made one; personality aspects like a type D personality; less severe OSA or less OSA symptoms at the start of MAD treatment; and a poor first experience with the MAD or failing guidance by the dental practitioner in the first month after the start of the MAD therapy. Factors that can have both a negative and a positive impact include: previous treatments before starting MAD therapy, patient phenotype, and dental treatments during MAD therapy.

**Conclusions:** This scoping review has described several factors that have an association with adherence to MAD therapy. The knowledge of these factors can be used to predict which patient is likely to cooperate well during MAD treatment and who is not. Matching patients to treatments in a personalized manner will contribute to the efficacy of OSA management by means of MADs.

Support: N/A

### CASE REPORT #013

### AN INNOVATIVE APPROACH TO REDUCING SEVERITY OF OSA UTILIZING DENTAL EXPANSION METHODS

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**Introduction:** This case report is to share the changes that are possible when dentists are trained in maxillary and mandibular expansion. Utilizing the mRNA (mandibular repositioning nighttime appliance) therapy, which is a class 2 FDA cleared medical device, dentists can make permanent changes to the severity of a patients obstructive sleep apnea (OSA).

**Report of Case:** Patient received expansion treatment utilizing mRNA appliance from 2020-2021. His pretreatment AHI was 47 and post-treatment AHI, without oral appliance, was 9. Patient reported much improved nasal breathing and drastically improved quality of sleep.

**Discussion and Report:** In March 2019, a 61 year old patient presented to my dental clinic for his periodic recall examination. I noticed oral signs of sleep disordered breathing and he subsequently was referred for a Type 3 HSAT (home sleep apnea test). Patient was diagnosed with severe obstructive sleep apnea (AHI 47) and referred to sleep MD for CPAP therapy. In November 2019, patient presented for routine dental examination with chief complaint of bloating when using CPAP.

In December 2019, patient began expansion therapy, in <u>conjunction</u> with current CPAP treatment. In May 2020, patient reported he stopped the CPAP on his own and was immediately referred for type 3 HSAT with oral appliance, to verify his AHI was within normal. HSAT revealed AHI 4 using oral appliance only.

After 13 months of growth & development utilizing expansive techniques, patient was referred again for type 3 HSAT with no oral appliance in place, which revealed a permanent drop in AHI from 47 to 9. Patient received formal diagnosis from board certified sleep physician that his sleep apnea severity was now mild.

It is vital that airway centric dentists are aware of this treatment modality when considering oral appliance therapy for our OSA patients.

Support: None

#### ABSTRACT #014

### SELECTION OF CUSTOM ORAL APPLIANCE FABRICATION SETTINGS IMPACT TREATMENT EFFICACY

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**Introduction:** In a previously published Study-1, custom oral appliances (Custom-OA) fabricated using a conventional dental protocol provided inferior apneahypopnea index (AHI) reductions compared to the Apnea Guard® trial appliance (AG). In this comparison, Study-2 Custom-OAs were fabricated using the AG bite registration applied to one of two randomly assigned design types, with controlled vertical mouth opening (VMO).

**Methods:** CPAP-intolerant patients completed a twonight home-sleep-apnea study; Night-1 at baseline, Night-2 with the AG. The AG VDO selection was based on tongue-scallop (women=5.5/6.5 mm, men= 6.5/8.0 mm), and "AG target protrusion" set to 70% of the neutral-maximum range, while in situ.

The Custom-OAs for Study-1 were fabricated with vertical dimension of occlusion (VDO) dependent on sex (women=2.5 mm; men=5 mm), with protrusion set using a George-Gauge measured 70% from maximum retrusion-protrusion, and dentist-directed advancement. In Study-2, the Custom-OAs were fabricated to the AG VDO and target protrusion. In Study-1, 50% of the Custom-OAs were fitted with a Herbst (CA-Herbst) and 14% with a Prosomnus® [IA], vs. randomly assigned Study-2 distributions of 51% vs. 49%, respectively. Efficacy studies were conducted after completion of the Custom-OA titration in Study-1 and at the AG target protrusion in Study-2. With the CA-Herbst, vertical elastics were optional in Study-1 and mandatory in Study-2. In Study-2, five patients at-risk for temporomandibular joint complications were excluded, i.e., <7% of patients fitted with a Custom-OA, to avoid delivery at the AG target protrusion. Statistics included Mann-Whitney, Chi-squared, Bland-Altman, and multiple logistic regression analyses.

**Results:** The Study-1 (n=84) and Study-2 (n=51) patients who completed efficacy studies had similar distributions of logistic regression variables, including scalloped tongues (64% vs. 67%), sex (women 45% vs. 43%), age (53.8 $\pm$ 11.9 vs. 54.9 $\pm$ 15.2 years), body mass index (29.4 $\pm$ 5.7 vs. 27.8 $\pm$ 4.2 km/m<sup>2</sup>), and pre-treatment AHI severities (24.6 $\pm$ 14.4 vs. 27.7 $\pm$ 17.4 events/hour).

Bland-Altman plots highlighted significant differences between the AG and the Custom-OA overall AHI values in Study-1 vs. Study-2 ( $4.2\pm7.8$  vs.  $1.2\pm6.7$ ; P=0.023). The significant differences between the Custom-OA vs. AG AHI values in Study-1 (Overall:  $12.3\pm9.2$  vs.  $8.2\pm5.9$ ; P<0.002; Supine:  $17.0\pm13.6$  vs.  $10.8\pm7.8$ ; P<0.005) were no longer apparent in Study-2 (Overall:  $11.1\pm7.7$  vs.  $9.9\pm6.8$ ; P=0.582; Supine:  $16.0\pm13.0$  vs.  $12.4\pm8.6$ ; P=0.368). The CA-Herbst was inferior to the AG by  $\geq$ 5 events/h in 40% (17/42) of the Study-1 cases vs. 15% (4/26) in Study-2 (P=0.034).

The Study-1 vs. Study-2 protocol (Odds ratio=3.34; 95%CI: 1.19-9.36; P=0.022), pre-treatment AHI (Odds ratio=0.95; 95%CI: 0.91-1.00; P<0.036), and AG AHI (Odds ratio=0.73; 95%CI: 0.62-0.85; P<0.0001) were predictive of those who achieved a Custom-OA AHI<10. The AG AHI also predicted those with a Custom-OA AHI reduction >50% (Odds ratio=0.91; 95%CI: 0.83-1.00; P<0.05), and both an AHI reduction >50% and an AHI<10 (Odds ratio=0.77; 95%CI: 0.67-0.88; P=0.0002).

With Study-2 temporomandibular joint screening, no side effects were reported in the patients delivered Custom-OAs at 70% AG target protrusion (n=69).

**Conclusions:** These findings confirm Custom-OA fabrication settings impact treatment efficacy. Custom-OA outcomes were equivalent to the AG when fabricated with the AG bite-registration, i.e., VDO and protrusion, and VMO was controlled.

Support: None

### ABSTRACT #015

### QUANTITATIVE EFFECT OF MANDIBULAR ADVANCEMENT DEVICES ON UPPER AIRWAY DIMENSIONS DURING DRUG-INDUCED SLEEP ENDOSCOPY IN OBSTRUCTIVE SLEEP APNEA

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**Introduction:** Mandibular advancement devices (MAD) are an increasingly recommended treatment modality in selected patients with obstructive sleep apnea (OSA). The predominant mode of action of MAD is to protrude the mandible, resulting in opening of the upper airway and increasing its volume. Previous studies mainly

showed a mechanical effect at the velopharynx, however, the influence on structures at a lower level is less clear. The aim of this study is to visually investigate the effect of MAD therapy on upper airway dimensions during drug-induced sleep endoscopy (DISE).

Methods: Data of 56 OSA patients, treated with MAD fixed at 75% maximal protrusion and with polysomnography baseline apnea-hypopnea index (AHI)  $\geq$  10 /h sleep, were included. All patients underwent a DISE with and without MAD during their treatment time and completed 3-month follow-up frame polysomnography with MAD. Three snapshots were selected at the beginning of inspiration from the DISE video-footage at the level of the tongue-base both at baseline and with MAD in situ for each patient by one researcher. Cross-sectional areas were digitally measured on retroglossal and retro-epiglottic level before and after mandibular advancement using the polygon selection tool in ImageJ. The airway lumen was followed transversally with consideration of light-dark interfaces to ensure a constant anatomical level. To correct for possible differences in scope-positioning, calibration according to the lateral epiglottis-length was performed.

Intraclass correlation coefficients (IC) were calculated in 60 images (n=10 patients) for the retroglossal and retroepiglottic area to assess agreement with an independent second observer, including images with and without the MAD present.

Linear mixed effects models were built to define the effect of MAD on upper airway dimensions. The presence or absence of MAD was included as fixed effect. Correlation between repeated measures in the same individual patient was accounted for through random effects.

Moreover, expansion ratios were calculated by dividing cross-sectional areas during mandibular advancement by areas at baseline. Treatment response was defined as reduction in AHI  $\geq$ 50%. To determine the association between MAD treatment response and expansion ratios, independent samples t-tests were used.

**Results:** A total of 336 images (168/168, baseline/MAD) in 56 OSA patients was scored (82.1% male; age:  $48.6\pm7.9$  years; BMI  $25.9\pm7.9$  kg/m<sup>2</sup>; baseline AHI 19.0 (12.9-25.7) events/h sleep).

Interobserver reliability measuring retroglossal and retroepiglottic areas was excellent (IC=0.97).

A significant difference was seen between retroglossal cross-sectional areas at baseline (47,823.36±2,357.58 pixels) and with MAD in situ (55,818.52±2,357.58

pixels) ( $p \le 0.0001$ ); no significant difference was found at the retro-epiglottic area (p=0.1074). Interestingly, greater expansion ratios for retroglossal area were seen in responders ( $1.31\pm0.49$ ) compared to non-responders ( $1.12\pm0.31$ ), although non-significant (p=0.0876). No significant association was found between treatment response and retro-epiglottic area.

**Conclusions:** These findings demonstrate an increase in upper airway dimensions at a retroglossal level during drug-induced sleep with MAD in situ. Furthermore, a more pronounced increase in retroglossal expansion ratios is observed in responders for MAD treatment compared to non-responders. However, larger sample sizes are needed to confirm these results. Finally, the utility of DISE in evaluating MAD treatment outcome is emphasized.

**Support:** This study was funded by a 3-year grant of the Flemish government agency for Innovation by Science and Technology (IWT-090864).

### CASE REPORT #016

#### EFFECTIVENESS OF MANDIBULAR ADVANCEMENT DEVICE IN COMPLEX SLEEP APNEA: A CASE REPORT

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**Introduction:** Complex sleep apnea syndrome (CompSAS) is a type of central sleep apnea (CSA) that develops in obstructive sleep apnea (OSA) patients during initial treatment with continuous positive airway pressure (CPAP) device. The mechanisms underlying CompSAS are not well understood.

**Report of Case:** 64-year-old male diagnosed with severe OSA (AHI = 52.3, 84.2% O2, and Central apnea index = 22) while subjectively reporting 14/24 on the Epworth Sleepiness Scale (ESS). Initially, he was prescribed and attempted PAP therapy as the first line of treatment for this level of severity. However, he was intolerant to the PAP machine and was consequently referred to Tufts Dental Sleep Clinic for assessment and therapy with a mandibular advancement device (MAD). Upon clinical history and physical examination, the patient had a BMI of 31.4 and a neck circumference measured 17", and cephalometric analysis depicted a low mandibular angle and reduced hyoid bone to mandible distance. Dental impressions and bite registration were completed, and a bilateral interlocking design MAD was fabricated with 80% of mandibular advancement as a starting point. The MAD sleep device and morning repositioning aligner were then delivered to the patient and properly fitted. The patient returned for follow up appointments to assess changes in symptoms; no additional titration of the oral device was needed based on subjective assessment, and patient reported no side effects from the use of MAD. After completion of the MAD clinical protocol, he was referred to his sleep physician for a follow up sleep study which objectively revealed a significant reduction of respiratory events (AHI = 8.8, 90% O2, and Central apnea index = 6) while subjectively reporting 5/24 on the Epworth Sleepiness Scale (ESS)

**Discussion:** Patients with CompSAS have a poor initial experience with CPAP and may be non-adherent to continued therapy. MAD are indicated for mild to moderate OSA and in selected patients with severe OSA who are non-adherent to PAP therapy. This case report showed successful management of CompSAS with MAD. Assessment of patient characteristics, predictors of MAD success, and therapeutic mandibular position must be assessed by the sleep dentist to optimize patient selection and improve treatment outcomes.

**Support:** Authors declared no conflict of interest and no financial support provided for this case report.

### ABSTRACT #017

### VENTILATION ANALYSIS AFTER ORTHODONTIC TREATMENT USING CFD. A SCOPING REVIEW

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**Introduction:** Computational fluid dynamics (CFD) is the numerical study and modeling of fluid flow. It can be applied to the study of the upper airway. Orthodontic, orthopedic and orthognathic surgery treatments can modify the upper airway dimension, which could influence ventilation and consequently the risk of sleepdisorders. Therefore, CFD is an interesting method to evaluate these changes in airflow characteristics after treatment. This study aims to systematically review the literature to assess the upper airway airflow response using CFD comparing the ventilation results before and after different treatments such as orthodontic, orthopedic or orthognathic surgeries.

**Methods:** Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) was used as a guideline for the methodological approach of this study. Articles that evaluated the upper airway (nasal cavity, nasopharynx, oropharynx, hypopharynx) after orthodontic/orthopedic treatment or orthognathic surgery, using CFD were included. Studies that included CFD of healthy patients or patients with sleep-breathing disorders were listed. Studies in which the patients had syndromes or craniofacial disorders were excluded. No limitations of time or language were imposed. Literature search was conducted in March 2021 in five databases: Cochrane, EMBASE, PubMed, Web of Sciences, and Scopus. Two reviewers (SGC, ACG) independently evaluated the studies by screening the titles and abstracts, using the Rayyan citation management program. The articles were screened in full text in the second phase by the same two reviewers and, in cases of disagreement, third and fourth reviewers were consulted (LT, CR). The data were extracted by the two examiners (LT, CR) and each article was recorded.

Results: Twenty-seven articles met the inclusion criteria. Different types of treatment were used to assess changes in the upper airway: Class II functional orthopedic appliance [i.e., Twin Block and Herbst]; rapid maxillary expansion (RME) [i.e., Hyrax, Hybrid-Hyrax, Keles expander, maxillary suture expansion (MSE) appliance, distraction osteogenesis maxillary expansion technique (DOME) and midpalatal corticotomy-assisted rapid maxillary expansion (MCRME) with Hyrax device]; dental extractions; surgical interventions [i.e., maxillomandibular advancement (MMA), mandibular set-back (MSS), a combination of MSS and maxillary impactation and MSS associated with maxillary advancement]; and mandibular advancement device (MAD). In general, CFD results showed that treatments that could reduce upper airway dimensions, such as premolar extraction or mandibular setback surgeries, worsened the ventilation in patients. Conversely, treatments that might increase upper airway dimension (i.e., orthopedic functional appliances, rapid maxillary expansion, mandibular advancement device and maxillomandibular advancement surgery) improved ventilation and could be associated with an improvement of obstructive sleep apnea syndrome (OSAS) signs and symptoms.

**Conclusions:** Polysomnography is the gold standard exam for OSAS diagnosis. However, due to the high cost and long waiting list related to polysomnography, CFD seems to be a good alternative method to evaluate and predict the respiratory function. CFD has the potential as an important tool to be used in conjunction with available tomography to help predict the onset or improvement of OSAS, in patients undergoing orthodontic/orthopedic treatments and orthognathic surgeries. Due to the complexity of upper airways geometry, CFD modeling may be necessary in some cases in support of treatment selection and planning.

Support: No funding was used for this project

#### MORE THAN A MOUTHPIECE...MANAGING THE POST-POLIO PATIENT Jeff Paz, DDS, D.ABDSM

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Introduction: Before the introduction of an effective vaccination paralytic poliomyelitis (polio) was a major cause of mortality (mostly respiratory failure) and morbidity in the first half of the 20th century. Approximately one third of the survivors suffer from respiratory insufficiency. 1. Hypoventilation problems are usually a result of muscular weakness complicated by deformation in the spine and thoracic cage or obstructive sleep apnea (OSA). 2 Post-polio syndrome (PPS) is defined as either a persistence of weakness from disease onset lasting for at least 15 years or post recovery onset of new weakness lasting at least a year. These new episodes of weakness may develop decades after the precipitating acute polio infection and go unrecognized due to a lack of awareness of this condition. 2 The use of non-invasive inspiratory and expiratory muscle aids can decrease the risk of acute respiratory failure, hospitalizations for respiratory complications, and need to resort to tracheal intubation.

**Report of Case:** This case describes a patient with thoracic cage deformity and chronic hypoventilation who uses an adaptive servo ventilator (ASV) 5 to assist in breathing during both awake and sleep hours. The clinical note is as follows. A pleasant 78-year-old man, accompanied by his wife and caretaker, presents to a dental sleep medicine clinic for replacement of his customized hybrid CPAP mask.

**Discussion:** Pt. presents to clinic with 11-year-old custom facemask. Pt reports, "It is not staying on my face like it use to, I think I need a new one." Fabricated new custom face mask, analog impression technique. Provided Pt. with new OA, attached to custom facemask for hybrid therapy.

### Support: None

### ABSTRACT #019

#### ADULTS WITH DOWN SYNDROME AND SLEEP APNEA CAN BE TREATED SAFELY AND EFFECTIVELY WITH MANDIBULAR ADVANCEMENT ORAL APPLIANCE (OAM) – A PILOT STUDY

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Introduction: Down syndrome (DS) is characterized by a complex set of pathologies and several clinical phenotypes, including generalized hypotonia and major craniofacial alterations (eg: narrow maxilla, hypoplasia of the middle third of the face) which directly contribute to the occurrence of obstructive sleep apnea (OSA). OSA. if left untreated, is associated to cardiorespiratory/metabolic diseases and cognitive alterations, which are already commonly present in this population. To our knowledge, no studies have accessed the effectiveness of OA<sub>m</sub> to treat OSA in adults with Down syndrome. The aim of this unique work was to evaluate the mean disease alleviation (MDA), through an embedded microsensor thermometer in an OA<sub>m</sub> for the treatment of OSA, and other sleep variables through a type II polysomnography (PSG II) in adults with DS.

Methods: Seven adults with DS were underwent to a medical anamnesis, clinical examination and dental inspection. A portable PSG II system (Embla Embletta MPR+PG ST+Proxy, Natus, California-USA) was used to perform a full-sleep study at patients' home, before and after 5 months of OAm usage. To measure the patient's compliance to OSA treatment, a thermosensitive microchip (TheraMon□) was embedded in the OAm. Patients were considered compliant when meeting a mean use rate of at least 4 h per night and 5 night per week. These measurements allowed to calculation of Mean Disease Alleviation (MDA), to quantify the therapeutic effectiveness.

**Results:** The sample presented a mean age  $21.7\pm4.3$  (females). Prevalence of OSA and SB were 93.8%. PSG data showed an improvement of AHI (apnea index), SBI (sleep bruxism index) and desaturation index (IDO) from  $16.5\pm13.8$  to  $9.6\pm8.2$ ,  $19.3\pm43.0$  to  $6.8\pm15.0$ , and  $13.9\pm11.9$  to  $9.6\pm9.6$ , respectively.

 $OA_m$  was very well tolerated by 6 patients, only one did not adhere to the treatment. The objective mean rate of  $OA_m$  use per night, for all 7 patients was  $6.7\pm4.3h/night$ , with an average use of 85% of days per week, and mean MDA=65.6%. When considering only the six compliant patients, the objective mean rate of  $OA_m$  use per night was  $7.2\pm3.1h/night$ , the average use of days per week was 94.2% and mean MDA=68.2\%. The results showed that good and clear communication, explaining the importance of the study to this group, contributed to high adherence of the  $OA_m$  usage.

**Conclusion:** The use of  $OA_m$  was effective to reduce OSA, IDO and SB. The mean MDA obtained in this

study showed that adults with DS were highly compliant to this therapy.

Oral appliance therapy may be a safe and effective option to treat OSA in this population, when CPAP is refused. Studies with more patients and for a long-term period are necessary to confirm our result.

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### ABSTRACT #020

## TREATMENT TRAJECTORY OF OSA: FROM DOCTOR RECOMMENDATION TO TREATMENT CHOICE

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**Introduction:** Obstructive sleep apnea (OSA) is a chronic condition with deleterious physical health outcomes, compromised quality of life and increased healthcare usage. OSA is under-recognized in primary care settings. After initial diagnosis, we know little about the long-term trajectory of OSA and treatment usage. The objective of the present study was to assess the 10-year prospective trajectory of OSA treatment in middle- to older-aged patients followed in a primary public healthcare setting.

Methods: Consecutive adult family medicine patients (n=176; mean age=54.5, SD=10.6), suspected of sleep disordered breathing, were approached at their doctor's office and asked to participate in a sleep study, regardless of sleep-related complaints. They all underwent inlaboratory polysomnography (PSG) and completed questionnaires in 2012-2013 (Time 1). Those receiving a diagnosis of OSA were followed for recommended treatment according to usual medical practice, primarily either positive airway pressure (PAP) or oral appliance therapy (OAT). Participants were re-contacted at three time points post-diagnosis: 3 years (Time 2), 8 years (Time 3), and 10 years (Time 4), and were administered the home sleep apnea testing and questionnaires. They were questioned regarding initiation and adherence to OSA treatment, type of treatment (e.g., positive airway pressure (PAP), oral appliance therapy (OAT), or change of treatment status (e.g., discontinuation, start of therapy). Between Time 3 and Time 4, participants with OSA were provided more information about the two main treatment options (i.e. OAT, PAP) which included more recent knowledge about long term benefits of both approaches.

**Results:** Of 176 participants who underwent PSG, 92.6% (163) received a diagnosis of OSA (Time 1). At Time 2, only 32.5% of diagnose participants initiated treatment: 46 PAP (mean AHI=36.77, SD=25.29), 5 OAT (mean AHI=21.16, SD=4.24), and 2 weight loss & gastric bypass. Of those who initiated PAP, 37% (17/46) discontinued treatment, while for OAT, 20% (1/5) discontinued treatment. At Time 3, 26% of participants who were prescribed CPAP at baseline were informed of OAT as a treatment option for OSA, as opposed to 70% at Time 4. At Times 3 and 4, rates of adherence remained stable for both PAP and OAT. Although more explanation was provided on efficacy of both treatments, no changes occurred. No additional treatment uptake was noted among the 67.5% of individuals who initially declined OSA treatment.

**Conclusions:** The high prevalence of OSA in our primary care sample reflects the importance of screening for OSA when suspected at primary care appointments. However, low rate of treatment initiation in a primary care setting should also be further investigated in terms of cost, patient lack of knowledge regarding OSA risk, low motivation, and inadequate primary caregiver communication. In addition, our data raises the question of whether treatment adherence would have improved had patients received a clear treatment choice earlier in the diagnosis-treatment sequence, with enhanced information about the OAT option.

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### ABSTRACT #021

### OROFACIAL PAIN, MASTICATORY MUSCLE HYPOTONIA AND SLEEP DISORDERS IN YOUNG AND ADULTS WITH DOWN SYNDROME

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**Introduction:** Down syndrome (DS) is a genetic disorder caused by trisomy of chromosome 21 (HSA21). This disorder is characterized by a complex set of pathologies and several clinical phenotypes, such as:

muscle hypotonia (<sub>m</sub>MH), ligament hyperlaxity, sleep disorders, and others. Temporomandibular disorders have been evidenced in this target-public; however, rare studies were found. This study aimed to investigate the presence of orofacial pain in DS and to correlate their clinical findings with the <sub>m</sub>MH and sleep disorders.

Methods: Twenty-three young and adults with DS, 10 atypical women with DS and 13 atypical men. All atypical subjects were submitted to the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD), Axis I,<sup>5</sup> to verify the presence of orofacial pain on the temporal and masseter muscles, bilaterally, and on the temporomandibular join (TMJ). The mMH was identified from electromyographic records of the temporal and masseter muscles, bilaterally, in maximum voluntary clench (MVC) condition, and in maximum bite force (MBF; kgf). The maximum mouth opening (MMO) was also calculated. The sleep disorders, including obstructive sleep apnea (OSA), sleep bruxism index (SBI; events/h), and snoring index (SI; events/h), were evaluated through the polysomnography type II home sleep test. A descriptive and comparative analysis of all clinical findings was performed, and statistical analysis was done.

Results: Non-significant differences were verified between muscle and TMJ pains according to the sexes, however, the pain in the left masseter muscle was more frequent in men (69%) and in TMJ, the pain was more frequent in men (46%). The electromyographic records of the temporal and masseter muscles and MBF intensity were well reduced in both the genders, indicating <sub>m</sub>MH. Additionally, the left masseter muscle was more affected when compared with the other studied muscles, mainly in atypical men. In MMO, 80% of atypical women and 85% of atypical men showed increased of MMO amplitude (ligament hyperlaxity). The increased values varied of 11% to 46% for atypical women and 2% to 75% for atypical men. The left masseter muscle was more affected, mainly in men. The severity of OSA, SB and SI was higher in men (38,5%, 54%, 27,65 events/h respectively).

**Conclusions:** The mMH was confirmed in all subjects with DS, leading to a high amplitude of mouth opening due to ligament hyperlaxity of TMJ, mainly in atypical men. The pain, found in the masseter and temporal muscles and in the TMJ, may have interfered in the manifestation of the MMH, decreasing the muscle force mainly in some men. No correlation was found between the orofacial pain and sleep disorders.

### Support: FAPESP 2017/06835-8

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### LATE-BREAKING ABSTRACTS

### ABSTRACT #22

EVOLUTION OF COMPLIANCE AND SELF-REPORTED SYMPTOMS OVER 36 MONTHS IN MANDIBULAR ADVANCEMENT DEVICE THERAPY FOR OBSTRUCTIVE SLEEP APNEA: A RETROSPECTIVE STUDY

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**Introduction:** According to the literature, the use of mandibular advancement devices (MAD) is a feasible and accepted option for management of mild-moderate obstructive sleep apnea (OSA), and in severe cases when indicated. However, management of OSA with MAD requires dynamic and regular monitoring during the titration period and over time, to detect changes in compliance and reappearance of OSA-related symptoms. Aim of the study was to investigate the difference in compliance and change of self-reported OSA symptoms over time in *responders* and *non-responders* to MAD therapy.

Methods: Retrospective chart review of patients referred to Orofacial Pain Clinic (University of Kentucky) between 2016-2021 for management of OSA with MAD was performed. Inclusion criteria were participants with a post-treatment sleep study with MAD in situ, and follow-ups for at least 3 months investigating compliance and OSA-related symptoms. Participants were divided into responders (50% reduction of baseline AHI) and non-responders. Compliance was evaluated in terms of days/week and hours/night of MAD use. Subjective symptoms were recorded using a 100-mm Numerical Rating Scale (NRS), and included bedpartner report of loudness of snoring (0-100 NRS, 0=not snoring at all) and apneic episodes (0-100 NSR, 0=never), tiredness upon awakening (0-100 NRS, 0=completely rested), daytime fatigue (0-100 NRS, 0=not at all tired), subjective sleep quality (0-100 NRS, 0=very sound restful), daytime sleepiness (0-24 Epworth Sleepiness Scale, 0=not sleepy at all), subjective percentage of improvement with MAD therapy (0-100 NRS, 0=no improvement).

*T*-test was used to compare *responders* and *nonresponders* at baseline and post-treatment parameters. Repeated-measures ANOVA was performed to evaluate change in compliance and OSA symptoms over time ( $t_0$ , before post-treatment sleep study;  $t_1$ , at 3 months from post-treatment sleep study;  $t_2$ , at 6 months;  $t_3$ , at 12 months;  $t_4$ , at 18 months;  $t_5$ , at 24 months;  $t_6$ , at 30 months:  $t_7$ , at 36 months).

Results: From 79 patients, a total of 54 participants (46.3% female, mean  $_{age}$  64.4±10.71 y/o) were included; of those, 30(55.6%) were classified as responders, 24(44.4%) as non-responders. Responders and nonresponders differed at baseline for AHI (28.29±19.89 vs 16.75±8.94, p=.007), loudness of snoring (54.66±28.41 vs 71.74±24.06, *p*=.026), sleep quality (49.83±26.942 vs 64.79 $\pm$ 24.65, p=.042), and at post-treatment for AHI  $(7.43\pm6.49 \text{ vs } 15.47\pm8.29, p=.000)$ . Compliance in MAD use and subjective OSA symptoms did not differ between groups at  $t_0$  (all *p*'s>0.05). Although fluctuating in both groups, no difference was found over time in compliance in MAD use (7 nights/week for 7 h/night), loudness of snoring, witnessed apneas, tiredness upon awakening, sleep quality and subjective improvement between the two groups (all p's>0.05). Responders and nonresponders significantly differed at t<sub>4</sub> in daytime fatigue  $(45.08\pm29.53 \text{ vs } 20.22\pm15.67, F(1,20)=5.284, p=.032)$ and in daytime sleepiness (higher normal daytime sleepiness: 6.38±4.29 vs lower normal daytime sleepiness: 2.78±2.91, F(1,20)=4.794, p=.041).

**Conclusions:** Based on the results of this study, compliance in MAD use was maintained over an observation period of 36 months. Although self-reported OSA symptoms were fluctuating over time, only daytime fatigue and sleepiness significantly worsened at 18 months in *responders* compared to *non-responders*, although daytime sleepiness was still within a normal range.

### Support: None

### ABSTRACT #023

### TEMPORAL RELATION BETWEEN SLEEP BRUXISM AND OBSTRUCTIVE SLEEP APNEA IN CHILDREN AND ADOLESCENTS

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**Introduction:** Obstructive Sleep Apnea (OSA) and Sleep Bruxism (SB) are two enigmatic entities that have puzzled many academicians and clinicians alike. The one common consensus agreed upon is that both these conditions are prevalent and can present deleterious consequences to the overall well-being of an individual. Moreover, if the individual is a child or adolescent. Only a small number of studies have attempted to explore the associations between SB and OSA. This study aims to evaluate the temporal relation between apnea-hypopnea (AH) events, a marker of OSA, and rhythmic masticatory muscle activity (RMMA) events, entity related to bruxism, in children and adolescents, and thereby assess the association between the two phenomena.

Methods: 72 Individuals between the ages of 6 and 17 and diagnosed with OSA by the means of 1-night PSG were included in the study. Mild OSA was diagnosed if the participant had an AHI of more than 1 and no more than 5 events per hour, moderate OSA if AHI was more than 5 and no more than 10 events per hours, and severe OSA if AHI was of more than 10 events per hour. RMMA was recorded by specific EMG pattern recorded from lead placed on the submental muscle, along with increase in heart rate preceding the event. The participants were diagnosed with SB in the presence of >2 episodes of RMMA per hour of sleep (RMMA index). The two temporal patterns were considered in the study are as follow: T<sup>1</sup>: when the sleep AH event preceded the SB event (AH to SB), T<sup>2</sup>: when the SB event preceded the sleep AH events (SB to AH). SB events were scored within a window of 2-minutes before or after the sleep AH event.

**Results:** Amongst the 72 participants (mean age 10.7, SD 3.28) included in the study, 41 (56.9%) were males, and 31 (43.1%) were females. 50% of the participants were diagnosed with mild OSA, while 27.8% were with moderate OSA, and 22.2% with severe OSA. 43% of the participants met criteria for SB and they presented with an average of 25.1 RMMA episodes per night. A temporal association between SB and AH was found in 61% (T<sup>1</sup>= 33%, T<sup>2</sup>= 28%) of the events (*p* =0.001). Pearson's correlation coefficient analysis showed that RMMA Index was highly correlated with T<sup>1+2</sup> episodes (*p*=0.001).

**Conclusions:** The present study determined that SB is common in children and adolescents diagnosed with OSA, and both entities are likely related to a common mechanism. Although a temporal relation was found between SB and apnea-hypopnea events, more studies are needed to understand the causality between these two entities in hopes to provide an early diagnosis that can decrease future morbidity and mortality in these patients.

Support: N/A.