The Physiologic Sleep Bite and the MicrO$_2$ Sleep Device

A Winning Combination

There is no doubt that using the best bite technique available will improve overall treatment success, but how important is selecting the appropriate sleep device for your patients and your practice? To seek an answer to this question, I gathered patient data to take a retrospective look at the performance of two sleep-breathing appliances I was using to treat patients to see if the data showed significant differences in success. My suspicion was that one sleep appliance was out performing the other in overall practice efficiency and in patient outcomes.

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Data was analyzed on patients whom I treated with two popular sleep devices over about a three year time period. The first group of patients was treated for a sleep breathing disorder with a dorsal fin appliance titrated with a jackscrew mechanism, called Population 1. The second group of patients, Population 2, was treated with a twin fin CAD/CAM sleep appliance, titrated using combinations of splints. Population 1 included 17 cases that were diagnosed between the dates of April 2013 and April 2014 and consecutively completed treatment. Population 2 consisted of 20 cases that had been diagnosed between the dates of October 2014 and November 2015 and consecutively completed treatment.

"Consecutively completed treatment" was defined as patients who had an initial Polysomnogram (PSG), followed the treatment protocol with the delivered sleep appliance, followed up with a final home sleep test (HST) and had reported significant improvement in symptoms and quality of sleep. The patients who fell within these populations but did not follow up with a final HST or have not reached a conclusion in their treatment were not included in the data for this report. Additionally, patients who started treatment with one sleep device and then chose to switch to a different sleep appliance were not part of this analysis.

The technique for capturing the bite for all of the patients in both Populations 1 and 2 was consistent over the 3 year span. The Neuromuscular or Physiologic approach utilizing TENS (Transcutaneous Electrical Neural Stimulation) to prepare the patient for the bite and determining the bite position as taught at the Las Vegas Institute (LVI, Las Vegas NV) was used for all the patients treated with sleep devices. Any variation to patient treatment was subject to patient compliance and their schedule, but the plan typically was as follows in **Table 1:**

Step	Activity
1.	Symptom Discovery and OSA Screening in office
2.	PSG consult referral and MD OAT Prescription, Insurance Coordination and Documentation
3.	Appliance Selection and Patient Records
4.	Appliance Delivery and Education
5.	2-4 week Follow Up for Symptom Review and Initial Calibration/Titration
6.	Final HST and additional Follow Up as needed

Table 1: Patient Path

For steps 1 and 2, patients presented with symptoms which ultimately lead to Obstructive Sleep Apnea (OSA) screening, diagnosis and treatment. The Epworth Sleepiness Scale, as well as, an OSA assessment worksheet was used in these populations to help understand patient symptoms in terms of pain and overall well being. I worked closely with physicians in my area to treat CPAP intolerant patients and patients whom the physicians believe were good candidates for oral appliance therapy (OAT). Specifics of Steps 1 and 2 were not included in this report as this was widely variable due to insurance plan's required documentation for acceptance and sleep physician appointment availability. Details of Step 3, capturing the patient's physical records for appliance fabrication and ordering, was also not included. For this analysis, data regarding the patients in the two populations begins with Step 4, the appliance delivery appointments and continued through Step 6, once the final HST report showed that the patients sleep breathing disorders were "treated."

Technically, a "treated" patient is described as having a 50% reduction in AHI or achieving an AHI of less than 10, with the goal of complete treatment at an AHI of less than 5. Oftentimes, patients will complete their own treatment, vis-a-vis by feeling significantly better and/or they stopped seeing the need for further appointments. Of course, our goal as doctors is to achieve the best possible outcome by encouraging patient follow through and completion.

In Population 1, there were 17 patients overall, with an average age of 57.0 +/- 10.4 years, an average BMI of 31.4 +/- 7.1, an average starting PSG AHI score of 33.5 +/- 22.7. In Population 1, there were 11 Females and 6 Males. All patients in Population 1 were treated with the **SomnoDent® Lingual-less Sleep Device (Aurum Labs, Las Vegas, NV)** shown in **Figure 1A and 1C**. Population 2 consisted of 20 patients with an average age of 54.1 +/- 12.0 years, an average BMI of 32.4 +/- 5.9, starting with an average PSG AHI score of 35.6 +/- 23.1. This group had 14 Females and 6 Males. All patients in Population 2 were treated with the **MicrO2™ Sleep Device (MicroDental Labs, Dublin, CA)** shown in **Figure 1B and 1D.**

Figure 1 A **Figure 1 B**

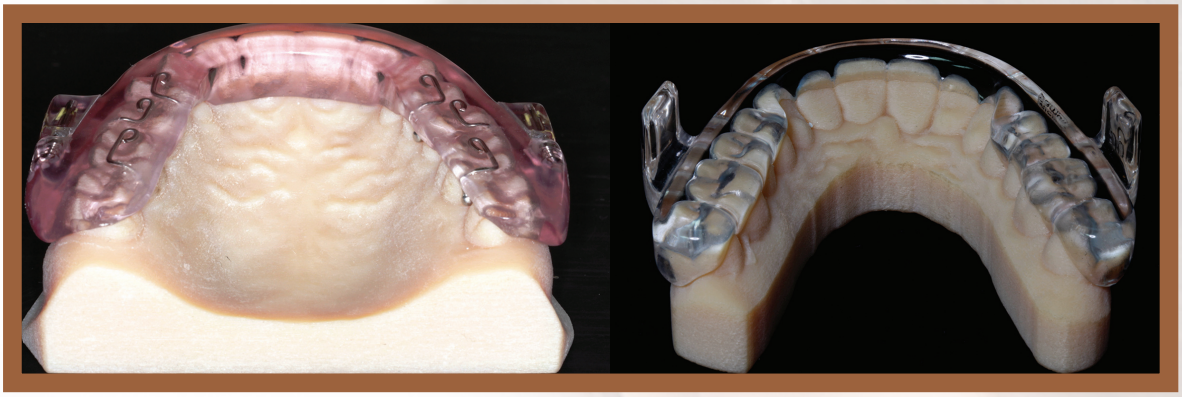

Figure 1 C **Figure 1 D**

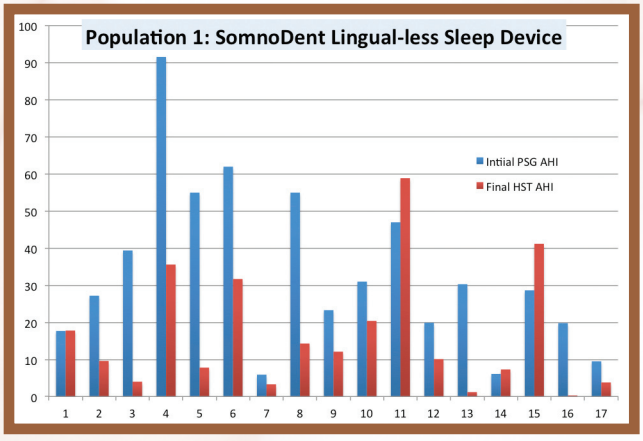

Figure 2: Pop. 1 PSG-HST data

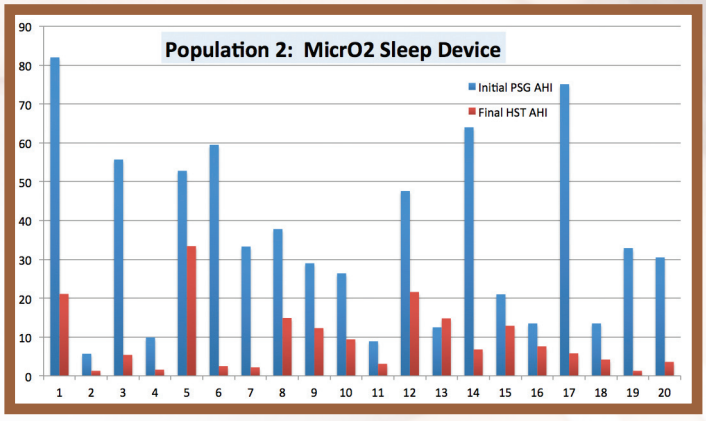

Figure 3: Pop. 2 PSG-HST data

Figures 2 and 3 show the initial diagnostic PSG AHI data in blue for each patient and the final HST AHI data for each patient in red. **Table 2** shows a summary of the difference between the average outcomes based on AHI results between the two populations, with Population 2 having a greater than 27% improved AHI average of 9.0 compared to that of 11.9 for Population 1. The table also shows that the change (delta) from initial AHI to final AHI for Population 2 compared to Population 1 is about 11% greater for all patients with a reduction in AHI, except for 4 patients in Population 1 who had an increase in AHI vs. 1 patient in Population 2. **Table 3** further compares the success in treating each population. Using the standard guidelines previously discussed, 85.0% of Population 2 were successfully "Treated" compared to 58.8% of Population 1. Those who did not meet the guidelines, but still had a significant change in AHI outcome were classified as "Patient Responded." Those patients who revealed no change or a negative change (AHI actually increased with OAT) were classified as "Not Treated."

Patient Population	AVG Initial PSG	AVG Final HST	AVG Delta AHI
1	33.5 +/- 22.7	11.9 +/- 8.9	24.9 +/- 16.3
2	35.6 +/- 23.1	9.0 +/- 8.6	27.8 +/- 21.1

Table 2: Comparison of average PSG outcomes for Populations 1 & 2

Patient Population	AHI < 5	AHI < 10	AHI Reduced 50%	Patient Responded	Not Treated	% Treated
1	5	3	2	3	4	58.8%
2	8	5	4	2	1	85.0%

Table 3: AHI Comparison of successfully treated patients in populations 1 & 2

Patient Population	Treatment Appointments	Treatment Duration (Months)
1	7.8 +/- 3.6	10.3 +/- 7.0
2	6.0 +/- 3.0	3.8 +/- 2.9

Table 4: Comparison of Appointment Efficiency for Populations 1 & 2

Table 4 reveals data regarding practice efficiency. The data here includes all patient appointments during treatment steps 4, 5 and 6 in which clinical notes in the patient charts described fitting/ delivering the appliance, titrating the appliance, adjusting the acrylic to the appliance, and/or responding to a patient concern about appliance comfort or pain possibly due to oral appliance therapy.

Understanding the differences in titration modalities of the two appliances is important to help analyze practice efficiency. The **SomnoDent** oral appliance utilizes a jackscrew with a 0.1mm titration per turn which is a standard adjustment type in some sleep devices. Titrations for this appliance were as few as 1 to 3 turns as commonly taught in the sleep appliance arena. The **MicrO_2** sleep device Series A used offered 1mm adjustments, therefore patients were titrated at those increments. Not only did my patients tolerate those adjustments well, they moved to a successful treatment position more quickly. This is easily seen in the number of appointments and treatment duration. Typically for either appliance I would make the initial titration and educate the patients to do their own subsequent titrations. Patients responded well and easily titrated the **MicrO_2** Sleep Devices. However, for the jackscrew adjustments, some patients could not easily manage the adjustment process due to age, dexterity or simply making adjustment mistakes. This added to the number of clinical appointments for Population 1.

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The patients in Population 2 showed 30% fewer overall patient appointments from 7.8 to 6.0 and even more significant reduction in overall treatment duration, from an average of 10.3 months for Population 1 to 3.8 months for Population 2.

The analysis of these two patient Populations revealed very acceptable outcomes with both groups having over 58% treatment success. I do believe treating patients with the Neuromuscular Physiologic approach was paramount in the overall success seen in the above data. However, it is important to understand the whole picture and discuss why there are outcome differences between two statically similar patient populations and to what the success and efficiency in treating OSA with specific Oral Devices can be attributed? Specifically, a device that is fabricated into a sleek profile, low volume design and allows as much space for the tongue as possible. Both the lingual-less **SomnoDent** and the CAD-CAM **Micro$_2$** oral appliances provide significantly more space for the tongue than most appliances on the market, with the **Micro$_2$** Sleep Device providing slightly more room. You can see in comparing **Figure 1C to 1D** that the **Micro$_2$** Sleep Device has significantly less material behind the anterior teeth and overall less bulk. In my opinion, this specific feature may be the reason for the high treatment success of 85.0% for this group. It also contributes to what may be the most important aspect of treatment success, patient comfort and compliance.

Another specific feature that differentiates these two appliances is the angle degree of the dorsal fins. The **SomnoDent** oral appliance features a 70-degree fin vs. the 90-degree fin on the **Micro$_2$** Sleep Device. It is hard to identify specific reasons for treatment success, but I believe the design of the 90-degree fin does in fact maintain better protrusion during the full range of mouth positions during sleep. In my observation, there have been no negatives to this feature and could be one more explanation to the impressive results of Population 2 when compared with Population 1.

The difference in the titration modalities definitely contributed to the "ease of use" of the appliances in Population 2. More patients struggled with the jackscrew mechanism than they did placing the **Micro$_2$** Sleep Device splints. The extra appointments needed by some patients in Population 1 prolonged treatment time contributing to delayed health outcomes and potentially to decreased patient follow through. Additionally, it would make sense that the smaller increments of titration used for the first population also contributed to prolonged treatment. Both the simplicity of the **Micro$_2$** system and the increased titration increments has lead to quicker resolutions of patient symptoms and faster patient treatment completions. I suspect that more positive patient experiences and increased patient referrals also resulted with this appliance therapy.

In summary, proper oral appliance selection delivered impressive results showing lowered AHI scores matched with patient reports of better sleep quality, increased daytime energy and an overall better sense of wellbeing. Additionally, patients required fewer appointments and less treatment duration resulting in greatly enhanced practice efficiency. These are important factors when it comes to patient satisfaction and the success of a dental sleep practice. We now know that we have the ability to achieve very high success rates in all AHI ranges by utilizing the Neuromuscular bite technique and the **Micro$_2$** Sleep Device. Together they are certainly a winning combination.

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