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Article

Efficacy of a Novel Treatment Approach for Obstructive Sleep Apnea

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Abstract

Objective: This study characterizes the efficacy of a novel approach to oral appliance therapy for the treatment of obstructive sleep apnea. This approach utilizes a systemized, repeatable, treatment protocol and a precision-custom oral appliance. **Methods**: Sixty patients diagnosed with OSA were treated at Sleep Better Austin using a structured, multi-step protocol and a precision-custom oral appliance (ProSomnus EVO). Baseline and post-treatment Apnea-Hypopnea Index (AHI) values were compared using a matched-pair design. The primary outcome was the percentage of patients achieving a residual AHI < 10 events/hour. Secondary outcomes included severity classification improvement. **Results**: Ninety percent of patients achieved the primary endpoint, and 87% improved by at least one severity classification. The mean AHI improved by 63% from baseline with the precision-custom OAT *in situ* (p < 0.001). In the moderate-to-severe subgroup, AHI improved by 70%, with 100% of severe patients achieving a residual AHI < 20 and ≥50% improvement without preselection such as drug induced sleep endoscopy. No serious adverse events were reported, and all patients continued therapy at follow-up. **Conclusions**: Precision-custom OAT, when delivered through a standardized clinical protocol, can be a highly effective and well-tolerated treatment for OSA. These findings support its broader adoption as a non-invasive alternative to CPAP and surgical interventions, particularly for patients seeking personalized, high-compliance solutions.

Keywords: obstructive sleep apnea; sleep apnea; precision medicine; dental sleep medicine; oral appliance therapy; respiratory medicine; sleep medicine; snoring; biomedicines; medical devices; personalized medicine

Introduction

Obstructive Sleep Apnea ("OSA") is a highly prevalent disease across diverse populations including an estimated 176 million in China, 54 million people in the USA, 52 million in India, 49 million in Brazil, 26 million in Germany, and 24 million people in France with an apnea-hypopnea index ("AHI") greater than 5 events per hour [1]. If left untreated, OSA is linked with elevated risks of comorbidities [1], reductions in quality of life and increased economic expense [2].

The pathophysiology of OSA involves the narrowing of airway anatomy, making the velopharyngeal and oropharyngeal airway segments susceptible to recurrent collapses during sleep breathing that deprive vital organs of oxygen [3][v]. Prior research identifies that 97% of airway collapse events involve the velopharynx while 56% of events involve the oropharynx [4]. The AHI, which is the average count of collapse events per hour, is used to quantify the severity of the disease. An AHI between five to fifteen events per hour is considered mild sleep apnea; fifteen to thirty events per hour is considered moderate; and more than 30 events per hour is considered severe [5].

Treatment success is often determined based on how well the therapy improves AHI relative to the baseline.

Due to limitations of existing treatment options, sleep medicine professionals are evaluating new approaches for treating patients with OSA. For example, continuous positive airway pressure ("CPAP") has demonstrated success reducing AHI, but emerging research also associates CPAP with counterproductive side effects [6] and low levels of compliance [7]. Surgical options have demonstrated modest reductions in AHI, but often involve non-reversible, invasive procedures, require preselection procedures such as drug induced sleep endoscopy, and are linked with adverse events [8] and significant expenses [9]. Traditional oral appliance therapy ("OAT") is associated with relatively higher adherence, but utilization is suppressed by inconsistent efficacy[vi]. It is also thought that OAT utilization is further limited by a paucity of published clinical data.

Materials and Methods

This study was a retrospective chart review of patients from a single dental sleep medicine practice with multiple locations. The design is organized and described according to the Population, Intervention, Comparison, Outcomes ("PICO") format [10]. For clarity, the Intervention component is divided into two sections. The first describes the treatment protocol. The second describes the medical device used in this study.

Population

Sixty patients diagnosed with OSA were referred to the Sleep Better Austin ("SBA") organization for OAT. All sixty patients completed the treatment protocol. This study population was segmented by OSA severity classification to facilitate post-hoc analyses. Forty-four of the sixty patients, 73.3% of the study population, presented with mild OSA. Sixteen patients, 27% of the study population, presented with moderate or severe OSA, with 18.3% and 8.3% being moderate and severe, respectively.

Intervention, Protocol

Patients were referred to SBA for OAT after being screened, tested and diagnosed with OSA by a managing physician. The protocol described in Chart 1 and below was implemented consistently for each patient enrolled in this study, across seven SBA clinic locations in the Austin, Texas metropolitan area (Southwest, Central, Cedar Park, Georgetown, Kyle, Killeen, and Waco), involving multiple SBA team members.

Chart 1. The Sleep Better Austin Treatment Protocol Map.
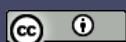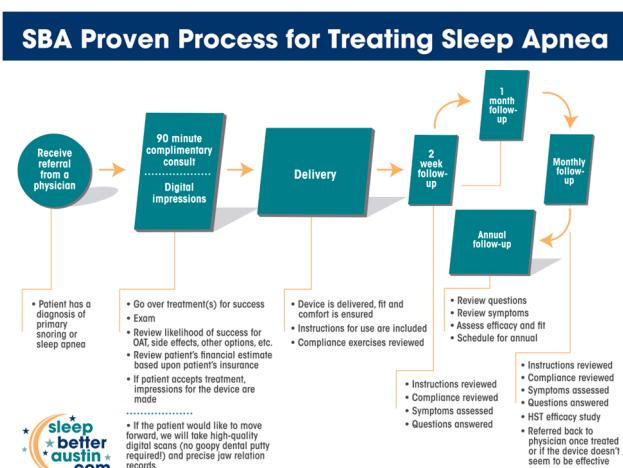
The first step of the SBA OAT treatment process was the consultation. SBA invested approximately 90 minutes in each consultation. The consultation included an oral/dental examination to ascertain suitability for OAT, and an evaluation for contraindications and risks of side effects. The consultation also included a review of medical insurance coverage.

SBA captured digital records of the patient's oral structures immediately following the consultation if the patient agreed to treatment. Digital records included 1. a digital scan of the patient's upper teeth; 2. a digital scan of the patient's lower teeth; and 3. a digital scan of the therapeutic mandibular position. The therapeutic mandibular position was achieved using a George Gauge tool. The therapeutic mandibular position was established at 50%-60% of each patient's maximum protrusive range of motion. This package of digital records, along with a digital prescription, was electronically transmitted to the manufacturer (ProSomnus Sleep Technologies, Pleasanton, CA) to fabricate the precision-custom OAT device.

The second step of the SBA process was delivery of the precision-custom OAT device. During the delivery appointment, SBA's team ensured the fit and comfort of the device. Instructions were provided on how to insert, remove and care for the OAT device. Compliance exercises were reviewed.

The third step of the SBA process was the initial follow up appointment. The follow up appointment was conducted approximately 2-weeks after delivery of the OAT device. During this follow up appointment the SBA team reviewed instructions, compliance, symptoms and answered any questions that each patient might have.

The fourth step of the SBA process was the monthly follow up sequence. Patients were scheduled for monthly follow up visits to review instructions, compliance, and symptoms. A type-3 home sleep test (NightOwl, Resmed, San Diego, CA) was utilized to assess response to treatment and optimize titration. Patients were referred to their managing physician for confirmation testing and placed on an annual recall schedule if they successfully responded to therapy.

Intervention, Oral Appliance

An FDA cleared, precision-custom OA (ProSomnus EVO, Pleasanton, CA) was used to treat patients enrolled in this study. Precision-custom means that each device is 100% custom made from the oral records for each individual patient [11]. Unlike traditional oral appliances that rely on prefabricated, non-custom components, such as screws, mechanical hinges, nylon rods or elastomeric straps, to reposition, stabilize and titrate the mandible, precision-custom devices do not have prefabricated items [12]. Avoiding prefabricated items, and the modification steps required to embed them into devices, eliminates tolerance stacks, optimizing personalization, and reducing variability in performance [13].

Figure 1. ProSomnus EVO Precision-custom Oral Appliance.

This OA is also entirely made from a material that satisfies the US Pharmacopeia's requirements for the Medical Grade Class VI designation [14]. Class VI represents US Pharmacopeia's highest standard for medical device material biocompatibility.

This precision-custom OA also uses a familiar and clinically proven dual post design for repositioning, stabilizing and titrating the mandible into the prescribed therapeutic location. Titration

is accomplished with a stepwise sequence of trays, each with a different, prescribed, protrusive setting. This stepwise titration approach offers many benefits to both the provider and the patient including: definitive titration, easier communication, enhanced durability, smaller volume in the mouth, and the elimination of metal components.

Comparison

This investigation was a matched pair study design. It compared baseline OSA values for each patient against residual OSA values with the therapeutic oral device *in situ*.

Baseline OSA, assessed using AHI (events per hour), was the primary basis for comparison.

Outcomes

Providers critically evaluated success by comparing the actual treatment outcomes relative to pre-determined performance goals. Performance goals were established by referring physicians, and according to normal and customary criteria, specifically:

- Primary Performance Goal:

    o 65% of patients with a residual AHI of < 10 events per hour

- Secondary Performance Goals:

    o % of patients that improved by at least one OSA severity classification

    o % of patients with a residual AHI of < 10 and a > 50% reduction from baseline

    o % of severe patients with a residual AHI < 20 and a > 50% reduction from baseline

The primary performance goal of 65% of patients achieving the primary endpoint of AHI < 10 events per hour with the OA in situ was based on the literature[xii].

Compliance and safety were evaluated during follow-up visits, based upon oral examinations and subjective patient feedback.

Statistical Methods

Data were analyzed using GraphPad Prism v10.0 (GraphPad Software, LLC, Boston, MA). Significance level was set at α = 0.05 using two-sided statistical testing. Non-parametric statistical methods were used due to the non-normal distribution of the AHI metric. Descriptive statistics include the mean, standard deviation, median, and interquartile range.

Results, All OSA Severities

The mean baseline AHI for our study population of sixty patients was 14.0 ±11.3 (range: 5.0-69.8) events per hour and a median of 10.3 (IQR 9.7) events per hour. The mean baseline AHI for the mild cohort was 8.8 ± 2.7 (range: 5.0-14.9) events per hour. The mean baseline AHI for the moderate to severe cohort was 28.2 ± 13.6 (range: 15.1-69.8) events per hour.

Treatment with OAT reduced the mean AHI by 9.8 events per hour, representing a 63% improvement relative to baseline. The mean AHI with OAT was reduced to 4.2 ±3.8 (range: 0.0-18.9) events per hour and a median of 3.0 (IQR 3.9) events per hour. The Wilcoxon signed-rank test indicated a significant reduction in AHI from baseline to outcome (p < 0.001). Figure 1 shows a box-and-whisker plot of baseline and residual AHI.

Figure 1
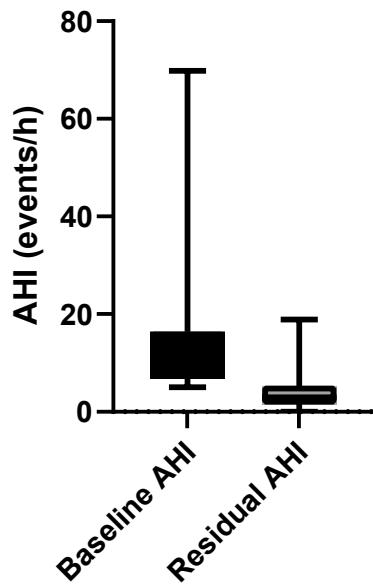
**Figure 1.** Box-and-whisker plot showing baseline and residual AHI.

Fifty-four of 60 (90%) patients achieved the primary threshold for therapeutic success, defined as AHI < 10. This result of 0.9 [95% CI 0.79-0.96] met the performance target of 0.65 (65%) of patients achieving a residual AHI < 10. Figure 2 displays the matched pair change in AHI.

Figure 2
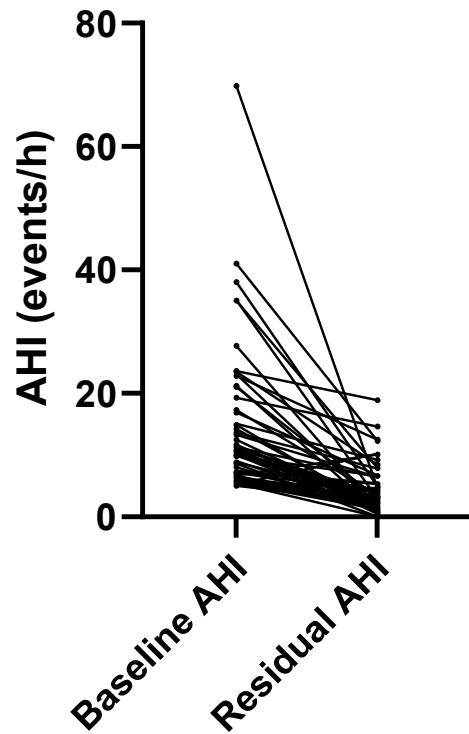
Figure 2. Individual patient responses to OAT.

Fifty-eight of sixty (97%) patients demonstrated an improvement in AHI with OAT. The two patients who did not experience a decrease in their AHI with OAT had mild OSA at baseline and a negligibly higher AHI (still in the mild range) with OAT.

Fifty two of sixty (87%) patients improved by at least one severity classification with OAT. Chart 3 details the changes in OSA severity classification on a patient-by-patient basis. With OAT, zero patients were identified as having a Severe OSA classification and one patient was identified as having Moderate OSA.

Chart 3. Change in OSA Severity Classification, by Patient.

Patient #	Baseline Severity	Residual Severity
1	Severe	No OSA
2	Severe	Mild
3	Severe	No OSA
4	Severe	No OSA
5	Severe	Mild
6	Moderate	No OSA
7	Moderate	Moderate
8	Moderate	Mild
9	Moderate	No OSA
10	Moderate	Mild
11	Moderate	No OSA
12	Moderate	No OSA
13	Moderate	Mild
14	Moderate	No OSA
15	Moderate	Mild
16	Moderate	Mild
17	Mild	No OSA
18	Mild	No OSA
19	Mild	Mild
20	Mild	Mild
21	Mild	No OSA
22	Mild	No OSA
23	Mild	No OSA
24	Mild	Mild
25	Mild	No OSA
26	Mild	No OSA
27	Mild	No OSA
28	Mild	No OSA
29	Mild	No OSA
30	Mild	No OSA
31	Mild	No OSA
32	Mild	No OSA
33	Mild	No OSA
34	Mild	No OSA
35	Mild	No OSA

36	Mild	No OSA
37	Mild	Mild
38	Mild	No OSA
39	Mild	No OSA
40	Mild	No OSA
41	Mild	No OSA
42	Mild	No OSA
43	Mild	Mild
44	Mild	Mild
45	Mild	No OSA
46	Mild	No OSA
47	Mild	Mild
48	Mild	No OSA
49	Mild	No OSA
50	Mild	No OSA
51	Mild	No OSA
52	Mild	No OSA
53	Mild	No OSA
54	Mild	No OSA
55	Mild	No OSA
56	Mild	No OSA
57	Mild	No OSA
58	Mild	No OSA
59	Mild	Mild
60	Mild	No OSA

Seventy three percent of the total study population, 44 of 60 patients, achieved the secondary performance goal of a residual AHI < 10 and ≥ 50% improvement over baseline.

Results, Moderate to Severe OSA Subgroup

For the sixteen of sixty (27%) of patients diagnosed with moderate or severe OSA, the mean AHI improved by 70%, 21.1 events per hour, from a baseline of 28.2 ± 13.6 (median 23.3 [IQR 15.4]) to 7.1 ± 5.3 (median 7.1 [IQR 8.6]) with OAT. A Wilcoxon signed-rank test indicated a significant reduction in AHI from baseline to residual (p < 0.0001). Additionally, all matched pair differences were positive, indicating that the residual values were consistently lower than the baseline values. The maximum residual AHI for the moderate to severe subgroup was 18.9 events per hour. The minimum residual AHI was 1.6 events per hour.

Twelve of 16 (75%) patients with baseline moderate to severe OSA achieved a residual AHI < 10 with OAT. Twelve of 16 (75%) patients with baseline moderate to severe OSA achieved a residual AHI < 20 with ≥ 50% reduction from baseline, and all 5 (100%) patients classified with baseline severe OSA achieved a residual AHI < 20 with ≥ 50% reduction from baseline. Fifteen of 16 (94%) patients classified with moderate or severe OSA demonstrated improvement by at least one OSA classification strata, with a mean improvement of 1.7 classification strata.

After follow-up appointments, 60 of 60 patient were continuing therapy. No patients required unscheduled interventions for adverse side effects. Any side effects reported, including dry mouth, tooth soreness, jaw soreness or general discomfort were non-serious, transient, and did not compromise the continuation of treatment.

Discussion

The results of this investigation demonstrate that OAT for the treatment of OSA, when delivered by experienced providers using a comprehensive treatment protocol and a precision-custom OA, significantly reduce AHI across all severities of OSA. With a mean AHI reduction of 63%   and 90% of patients achieving a residual AHI < 10, the primary performance goal was met, exceeding the expected 65% threshold with a lower 95% CI of 79%. Of the six patients who did not meet the primary performance goal, three demonstrated an improvement in OSA severity classification.

These findings align with prior studies[xii,xv,] [15], which reported high efficacy of precision-custom OAT devices due to their personalized design, absence of prefabricated components, and biocompatible materials. Although not a comparative study design, these results are also different from the findings of investigations involving other oral devices for the treatment of OSA that reported lower levels of efficacy [16–18]. The significant reduction in AHI demonstrated in this study underscores the potential of this therapy to address airway collapse effectively.

Notably, the moderate to severe OSA subgroup experienced a substantial reduction in AHI of 75% from baseline, with 100% of severe patients achieving a residual AHI < 20 and ≥50% reduction from baseline. This is particularly encouraging, as moderate to severe OSA is often more challenging to treat non-invasively or without continuous positive airway pressure ("CPAP").

The success in the moderate to severe OSA subgroup may be attributed to the precision-custom design, which eliminates variability from prefabricated components[xiv]. The systemized clinical follow up process, in conjunction with the stepwise titration approach of the precision-custom OA, likely further enhanced efficacy by allowing precise mandibular positioning tailored to each patient's therapeutic response and needs.

Compared to existing treatments, precision-custom OAT may offer advantages over CPAP, traditional, semi-custom oral appliances, and surgical options. While CPAP is effective in reducing AHI, its association with side effects and low compliance limits its long-term utility. Traditional, semi-custom oral appliances exhibit relatively better adherence rates, but utilization is constrained by inconsistent efficacy and durability. Surgical interventions, though effective in some cases, carry risks of adverse effects and high costs. In contrast, the high compliance rate and absence of serious adverse events demonstrated in this study suggest that precision-custom OAT may address these limitations, offering a balance of efficacy, safety, and patient adherence. These findings are consistent with a previously reported, head to head cross over study comparing the mean disease and mean risk alleviation of precision-custom oral devices and CPAP [19]. The use of medical-grade Class VI materials and the elimination of prefabricated components likely contributed to the reported continuing usage and minimal transient side effects, such as dry mouth or jaw soreness.

This study's findings also highlight the importance of a structured treatment protocol. SBA's process, including detailed consultations, digital records of each patient's oral structures, and regular follow-ups with home sleep testing, likely optimized patient outcomes by ensuring proper device fit, proper and stable mandibular repositioning, patient education, and outcome-oriented titration adjustments. This contrasts with traditional OAT, where inconsistent efficacy and limited clinical data have hindered performance and adoption.

Despite these strengths, this study has limitations. The sample size of sixty patients, while sufficient for demonstrating statistical significance, may not fully represent the broader OSA population, particularly given the predominance of mild OSA cases (73.3%). Additionally, the study was conducted at a single organization (SBA), which may introduce site-specific biases related to provider expertise or patient demographics. The reliance on home sleep testing for assessing treatment response, while practical, may not be as precise as polysomnography, the gold standard for AHI measurement. This study utilized single-night testing, which has been associated with frequent misclassification of OSA severity relative to multi-night testing [20,21]. The study did not assess long-term outcomes beyond the initial follow-up period, limiting insights into sustained efficacy or compliance. And finally, research reports that the AHI, in general and as utilized in this study, is not a good predictor of health outcomes for patients with OSA [22]. Further, these results

might not be generalizable to traditional oral appliances, or centers that do not follow a similar, comprehensive treatment protocol.

Future research should address these limitations by including larger, more representative populations and incorporating polysomnography, multi-night testing, and/or more predictive biomarkers such as hypoxic burden, for more robust outcome validation. Longitudinal studies are needed to evaluate the durability of AHI reductions and compliance over time. Additionally, comparative studies pitting precision-custom OAT against CPAP or surgical options in randomized controlled trials could further clarify the relative efficacy and cost-effectiveness of these therapies. Exploring the impact of precision-custom OAT on quality of life, comorbidities, and economic outcomes, would also strengthen the case for broader adoption of OAT with precision-custom OA's.

Conclusions

This study provides evidence that precision-custom OAT, combined with a structured treatment protocol, is a highly effective and well-tolerated therapy for OSA. The significant AHI reductions, high compliance, and minimal side effects position this approach as a promising alternative to existing treatments. Addressing the identified limitations through further research will be critical to optimizing its role in sleep medicine.

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