http://dx.doi.org/10.15331/jdsm.7338

2024 AADSM Annual Meeting Abstracts and Case Reports

Disclaimer: The following are the abstracts and case reports accepted for the 2024 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, uniqueness, clarity, 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.

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ABSTRACT #001

SLEEP MEDICINE EDUCATION AMONG US POSTGRADUATE DENTAL SPECIALTY PROGRAMS. A CROSS-SECTIONAL STUDY.

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Background: Dental sleep medicine is an emerging field within dentistry. While evidence has shown limited education in sleep medicine among US predoctoral dental schools, no study has been conducted among postgraduate dental programs. This study investigated extent and exposure to sleep medicine education among US postgraduate dental programs.

Methods: A REDCap survey was distributed among US CODA-accredited postgraduate programs of orthodontics (N=61), pediatric dentistry (N=81), orofacial pain (OFP, N=12), general practice residency (GPR, N=158), and advanced education in general dentistry (AEGD, N=117), comparing sleep medicine education with chi-square and ANOVA (Bonferroni as post-test).

Results: Out of N=459 programs contacted, N=68 emails did not reach the recipients. Among 391 invitations sent, 68 programs completed the survey (17.4% response rate): 45.2% GPR (16.1% of all GPR programs), 19.4% AEGD (8% of all AEGD programs), 16.1% orthodontics (18.0% of orthodontic programs), 11.3% pediatric dentistry (8.3% of pediatric dentistry programs), 8.1% OFP (50% of OFP-programs). Among N=819 faculty, 7.7% had received sleep medicine training, while 2.7% were board-certified. 31.3% of these programs were affiliated with sleep laboratories (60.0% of OFP, 42.9% of GPR, 40.0% of orthodontic programs), and 17.5% offered sleep rotations. Sleep medicine course was taught in 42.2% of the programs and consisted of 8.0h/year (from 0h in 22.6% to 80h in 1.6%).

OFP programs had a significantly higher number of faculty with sleep training (3.0±1.2) compared to orthodontic programs (0.5±0.9, p=.001), pediatric dentistry (0.1±0.4, p<.001), AEGD (0.5±0.9, p<.001), and GPR (1.2±1.3, p=.019). OFP programs offered greater hours of didactic teaching/year (44.0±27.7) compared to orthodontic programs (9.4±12.2), pediatric dentistry (2.2±1.9), AEGD (2.9±5.4), and GPR (5.0±8.0, all p's<.001). There were statistically significant differences in treatment of sleep disorders among specialties (p=.005), with 100% of OFP programs, 42.9% of GPR, and 33.3% of orthodontic programs providing treatment, in contrast with 14.3% of pediatric programs and 8.3% of AEGD. Common treatments included mandibular advancement devices (90.0%), maxillofacial surgery (25.0%), rapid-palatal expanders (25.0%), behavioral interventions (25.0%). Use of screening questionnaires varied significantly across specialties (p=.005), with 100% in OFP, 35.7% in GPR, 37.5% in orthodontic, 14.3% in pediatric dentistry, and 8.3% in AEGD programs. Screening questionnaires included Epworth Sleepiness Scale (70.0%), STOP-Bang (55.0%), Pittsburg Sleep Quality Index (20.0%). Only orthodontic and OFP programs had residents involved in sleep research (p=.003). The content of sleep medicine education was similar across programs in obstructive sleep

apnea (70.3%), sleep-related bruxism (62.5%), central sleep apnea (52.6%), insomnia (42.2%), but differed in sleep physiology (p=.020), hypersomnia (p=.028), narcolepsy (p=.025), parasomnia (p=.025), RLS (p=.026), circadian rhythm (p=.015), and pain/sleep relation (p=.045). Most of this content was delivered through didactic teaching.

Conclusion: Within our sample size, our findings highlight the limited sleep medicine teaching of 8.0h/year on average. High variability observed in extent and exposure to sleep medicine across postgraduate dental specialties emphasizes the need of implementing sleep medicine education into these programs to better address the growing prevalence of sleep disorders in the population.

Support: none

ABSTRACT #002

NON-SLEEP RELATED OUTCOMES OF MAXILLOMANDIBULAR ADVANCEMENT, A SYSTEMATIC REVIEW

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Introduction: Maxillomandibular advancement has been shown to be an effective treatment for obstructive sleep apnea; however, the literature focuses mainly on sleep-related parameters such as apnea-hypopnea index, respiratory disturbance index and Epworth sleepiness scale. Other factors that may be important to patients, such as esthetics, patient satisfaction, nasality, swallowing problems and so forth have been reported in the literature but have not been systematically studied.

Methods: Together with an information specialist, an extensive search in Medline, Embase and Scopus yielded 1592 unique articles. Titles and abstracts were screened by two blinded reviewers. In total, 75 articles were deemed eligible for full-text screening and 38 articles were included for qualitative synthesis.

Results: The most common categories of non-sleep related outcomes found were surgical accuracy, facial esthetics, functional outcomes, quality of life, patient satisfaction, and emotional health. All categories were reported using heterogenous methods, such that meta-analysis could not be performed. There was lack of consistent methods to assess these outcomes.

Conclusion: This work is the first to systematically review non-sleep related outcomes of maxillomandibular advancement. Despite growing interest in evaluating surgical outcomes through patient subjective experiences, this review points to the need of standardized, validated methods to report these outcomes.

Support: This work was carried out without any funding.

ABSTRACT #003

SMART MANDIBULAR ADVANCEMENT DEVICES FOR OBSTRUCTIVE SLEEP APNEA: A SYSTEMATIC LITERATURE REVIEW

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Introduction: The purpose of this review is to provide sleep physicians, dentists, and researchers with an evidence-based overview of the literature on technological innovations in mandibular advancement devices for the treatment of obstructive sleep apnea.

Methods: A systematic literature search was conducted by two blinded reviewers and an information specialist. The bibliographic databases Medline, Embase, and Scopus were used to identify relevant publications. Studies were included if they described any stage of development of smart mandibular advancement devices.

Results: A total of 3162 titles and abstracts were screened for their relevance. In total, 58 articles were selected for full-text screening, 26 of which were included in this review. The overall quality of the available literature was low. Most of the studies were applied-research articles or observational clinical research articles. An overview is supplied of all the medical and technical aspects of these innovations, including their purpose and their technological readiness level.

Conclusions: This review provides an evidence-based overview of current innovations in mandibular advancement devices, updates professionals on the latest developments, and discusses various possible research opportunities. In the near future, smart mandibular advancement devices could improve the efficiency of obstructive sleep apnea treatment and possibly provide new treatment options.

Support: This work was carried out without any funding.

ABSTRACT #004

SELF-REPORTED MOUTH BREATHING HABITS DURING SLEEP AND ITS EFFECTS ON SLEEP-DISORDERED BREATHING: A CASE-CONTROL STUDY

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Background: Mouth breathing has been associated with increased pharyngeal collapse, which may contribute to an obstructive form of Sleep-Disordered Breathing. However, little is known about the relationship between mouth breathing and key variables in home-sleep studies (HST) among patients seen in a Cardiology practice.

Objective: To assess the key indices of home-sleep studies (Apnea Hypopnea/AHI, Respiratory Disturbance/RDI and Oxygen Desaturation/ODI) in patients who self-report mouth breathing during sleep (MB) versus those who are non-mouth breathers(NMB) in a Cardiology office setting.

Methods: Retrospective case-control study using electronic medical records of adult patients managed in a Cardiology office who underwent a Type 3 HST between January 2019 to June 2023. Inclusion criteria consisted of patients screened for mouth breathing tendencies who underwent an HST and excluded those actively treated for OSA. Primary endpoints focused on differences in average AHI, RDI and ODI between MB and NMB patients across different severity levels (Set 1: AHI, RDI and ODI >= 30 vs. < 5; Set 2: AHI, RDI, and ODI >= 30 vs. < 30). Odds Ratios were calculated with "mouth breathing" as the exposure.

Results: Baseline characteristics for MB and NMB populations noted separately. 377 patients met inclusion criteria; 62 were excluded due to inadequate responses to the mouth breathing question, leaving 213 MB and 102 NMB patients. In Set 1, mouth breathing was associated with a higher AHI, RDI and ODI (OR: 5.5, 5.0 and 12.0, respectively; $p < 0.001$). In Set 2, similar trends were observed (OR: 3.5, 2.9 and 8.9 respectively; $p < 0.005$). Of note, there was a greater incidence of hypertension, snoring and daytime fatigue in MB versus NMB that was statistically significant (62% vs 50%, 79% vs 44% and 69% vs 52%, respectively; $p < 0.05$).

Conclusion: Self-reported mouth breathing during sleep is associated with increased odds of higher sleep apnea severity in patients in an outpatient cardiovascular medicine practice.

ABSTRACT #005

CORRELATION BETWEEN INTRAORAL MARKERS AND THE RISK OF OBSTRUCTIVE SLEEP APNEA IN CHILDREN

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Introduction: Background: Pediatric Obstructive Sleep Apnea (OSA) is a condition in which there is total or partial closure of the airway while a child is sleeping, which can have profound detrimental impacts on the child's development yet go largely undiagnosed. Previous research on pediatric OSA focuses primarily on its effects and association with extraoral markers. There is conflicting literature to date on the association of intraoral measurements to OSA. There is a need to investigate if specific clinical characteristics could predict sleep apnea risk in children. Specific aims: The aim of this study was to explore the association between various intraoral markers and the risk of OSA in children.

Methods: Orthodontic patients aged 8-17 were recruited at the VCU Graduate Orthodontic Clinic. At the initial appointment, intraoral measurements were collected from patients (n=100) by treating doctors. At this time, the Pediatric Sleep Questionnaire (PSQ) and the Pediatric Symptoms Checklist (PSC) screening surveys were also completed by the parents/legal guardians of the subjects. Analyses were performed to determine the association between the intraoral markers and the risk of pediatric OSA. Specifically, nine intraoral clinical characteristics were analyzed: presence and level of dental wear, ankyloglossia, tonsillar grade, Friedman's classification, skeletal and dental classification, palatal vault height, and posterior crossbite. The correlation between these features and the PSQ and PSC scores were assessed.

Results: Eighteen percent of the subjects demonstrated a high risk for sleep-disordered breathing based on the PSQ survey and 10% for emotional or behavioral problems based on the PSC survey. There was a strong association between PSQ and PSC for high risk for OSA (p-value<0.0001). Subjects deemed high risk of OSA based

on the PSQ survey were more likely to have a higher tonsillar grade, a higher Friedman Classification, and a more shallow palatal vault, although none of these associations reached statistical significance.

Conclusions: In this study, 18% of subjects were concluded to be at high risk for OSA, as determined by the validated PSQ. While none of the intraoral markers reached statistically significant associations with sleep-disordered breathing as measured by the PSQ, some variables showed trends. Future studies with a larger sample size and increased statistical power are needed to investigate further a possible association between the clinical features and OSA.

Support: The project was supported by the Alexander Fellowship Grant.

CASE REPORT #006

MAD THERAPY FOR OSA PATIENT WITH COMORBID TMD SYMPTOMS: A CASE REPORT

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Introduction: Mandibular Advancement Device (MAD) is being used widely nowadays for Obstructive Sleep Apnea (OSA) patient as a treatment option for those who are intolerable to Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BiPAP). Many OSA patients also have Temporomandibular Disorders (TMD) in conjunction with. This report is to present a case study of a patient who has both TMD and OSA and presents how we have treated this patient.

Report of Case: A 44-year-old Caucasian female was referred by her sleep physician for MAD due to intolerance of CPAP/BiPAP and headache symptom. After the review of previous records and detailed in-person comprehensive examination following Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) protocol, it was identified as a tension type headache and myofascial pain of masticatory and cervical muscles induced by sleep bruxism. Fabrication of a maxillary orthotic repositioning appliance (MORA) to resolve TMD symptoms was implemented as first step. After 6 months of appliance therapy jointly with physical therapy, symptoms were considerably resolved, and we proceeded with MAD therapy for OSA. Bilateral interlocking MAD was fabricated, fitted, and adjusted during follow-up appointments. A follow-up Polysomnography (PSG) sleep study to verify efficacy, and showed improvement of AHI from 17/hr to 4.5/hr (normal <5). Patient reported improvement of her TMD symptoms and sleep quality.

Discussion: TMD coexist in many OSA patients. It is critical to evaluate and examine them in detail to diagnose and help patients' symptoms. Also, possible increase in TMD symptoms could be reported after using MAD, so long-term and frequent follow-ups are needed. Further clinical research is critically needed for the assessment and management of coexist TMD in OSA patients.

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

CASE REPORT #007

EFFICACY OF ORAL APPLIANCE THERAPY ON POSITIONAL OSA: A CASE REPORT

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Introduction: Obstructive sleep apnea (OSA) is a widespread condition that affects 1 in 7 individuals worldwide. Positional OSA occurs when the majority of episodes are linked to the sleeping position. Effectively addressing OSA requires a collaborative approach, taking into account various treatment options. Positive air pressure (PAP) has been a primary treatment since the early 1980s, particularly for severe cases. However, patient adherence to PAP therapy can decline over time, posing challenges. Current guidelines advocate for mandibular advancement devices (MADs) in cases of mild to moderate OSA. This case report demonstrates the successful management of severe OSA through MAD therapy, considering the significance of anthropometric factors, sleep study data, and the clinical expertise of healthcare providers before initiating treatment.

Report of Case: A 33-year-old male diagnosed with moderate to severe obstructive OSA by a sleep physician (Total AHI = 26.5/hr, Supine AHI = 44.2/hr, Non-supine = 15.57/hr, and 84% O2) and subjectively reporting a score of 4/24 on the Epworth Sleepiness Scale (ESS). He initially attempted positive air pressure (PAP) therapy as the primary treatment for this severity level. Due to intolerance to the PAP machine, he was referred to the Tufts Dental Sleep Clinic for assessment and mandibular advancement device (MAD) therapy.

Upon clinical examination, the patient had a BMI of 32.5, a neck circumference of 17 inches, and cephalometric analysis indicated a low mandibular angle and reduced hyoid bone-to-mandible distance. Impressions and bite registration were taken, and a MAD with a bilateral traction design, providing 80% mandibular advancement initially,

was fabricated. The patient received a morning repositioning aligner as well. Follow-up appointments were scheduled to evaluate symptom changes, with one additional titration of the oral device required, and the patient reported no side effects.

After completing the MAD clinical protocol, the patient was referred back to the sleep physician for a follow-up sleep study, which objectively showed a reduction to normal values of respiratory events (Total AHI <5, Supine AHI = 9.8/hr, Non-Supine = 2.08/hr, and 95% O2). The patient also reported improved daytime sleepiness with a score of 0-3/24 on the ESS. Long-term follow-up was integrated as part of standard dental sleep medicine clinical care.

Discussion: Clinical practice guidelines advise sleep physicians to prescribe mandibular advancement devices (MADs) for adult patients who cannot tolerate positive air pressure (PAP) therapy. The effectiveness of MADs in severe OSA cases is selective and demands an appreciation of patient characteristics and factors predicting success. This case report illustrates the successful treatment of moderate to severe OSA using MAD therapy, emphasizing the importance of thoroughly considering anthropomorphic factors, sleep study data, and the clinical expertise of the healthcare provider before initiating treatment.

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

ABSTRACT #008

PHYSICAL PROPERTY TESTING TO SUPPORT 3D PRINTED MANDIBULAR ADVANCEMENT DEVICES

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Introduction: Multiple options exist to anteriorly position the mandible to treat sleep apnea, yet limited options exist that are inexpensive and allow for at the point-of-care delivery. Technologies that already exist in the dental office have the potential to facilitate the in-office manufacturing of mandibular advancement devices. 3D printing is an additive manufacturing technique that is already used for dental indications such as surgical stents, dentures, and occlusal guards among others. While 3D printing technology is currently being used for other indications, limited independent testing has been conducted using current 3D printed resins for the purpose of mandibular advancement devices. Mandibular advancement devices would have forces to move the mandible anteriorly and would require material properties sufficient to prevent breakage.

Methods: Three 3D printed resins, resin A (RA), resin B (RB), and resin C (RC) were investigated for physical properties at maximum load in newtons (N), flexural modulus (MPa) and sorption/solubility (µg/mm^3). All 3D materials printed using Asiga UV Max with recommended manufacturer's instructions for post-processing.

Six samples in a geometry of a dorsal wing were 3D printed to test the active element of a mandibular advancement device for peak load and modulus using a universal testing machine at crosshead speed of 1.0 mm/mm. Circular blocks, 50 mm x 5 mm, were used to test sorption/solubility, n=6. Specimen were desiccated in oven at 37°C for 23h, further desiccated at 23°C for 1h and weighed for and repeated until a constant mass (w_1) was achieved. Samples were wet in water at 37°C for 7d and recorded the mass (w_2). Finally, samples were desiccated using the same conditions initially and weighted to record the mass (w_3). Water sorption calculated as (w_2-w_3) / V and water solubility calculated as (w_1-w_3)/ V, where V represents the volume of the sample.

Results: The physical properties of maximum load and FM of the geometric dorsal wing samples for RA was 159N and 118 MPa, RB was 565N and 351 MPa, and RC was 401N and 340 MPa respectively.

The water sorption and solubility of RA was 14.5µg/mm^3 and 2.4µg/mm^3, RB was 15.3µg/mm^3 and 1.5µg/mm^3, and RC was 21.5µg/mm^3 and 1.6µg/mm^3. While statistically significant differences existed between resins all met acceptable standards to prevent degradation and ensure prolonged fit of material to teeth (sorption <32µg/mm^3 and solubility <5µg/mm^3).

Conclusions: In the geometry tested, both RB and RC resistant of force pressures of 400N and all tested resin showed to be stable. The long-term fit of 3D printed mandibular advancement devices based on these data would be successful with all materials tested.

Support: Keystone Industries supplied RA and RB and Whip Mix supplied RC resins at no cost.

ABSTRACT #009

A SURVEY OF THAI PHYSICIANS' KNOWLEDGE, PRACTICE, AND ATTITUDE TOWARD ORAL APPLIANCE THERAPY ON THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA

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Introduction: Continuous positive airway pressure

(CPAP) is currently regarded as the gold standard treatment for obstructive sleep apnea (OSA). Nevertheless, past studies demonstrated that patient acceptance, tolerance, and adherence to CPAP were suboptimal, and hence diminished its efficacy. Oral appliance therapy (OAT), an alternative treatment to CPAP, has gained popularity over the past 2 decades. There is a considerable amount of literature demonstrating the efficacy of OAT in terms of alleviating OSA and improving associated health outcomes. OAT is recommended as the primary treatment for patients with primary snoring, mild to moderate OSA and those with severe OSA or for patients who failed CPAP. Physicians play a vital role not only in the diagnosis of OSA but also treatment prescribed. They should be knowledgeable of all types of treatment options including OAT. Therefore, it is essential to investigate their knowledge, clinical practice, and attitude towards the use of OAT for the treatment of OSA. The objective of this study was to study experience and perceptions in prescribing oral appliances and/or orthodontic therapy as a treatment option for management of OSA among physicians in Thailand.

Methods: A self-administered questionnaire was developed, consisting of 6 sections (38 items). The questionnaire was distributed via Google Forms to physicians who attended the annual meeting of the Sleep Society of Thailand in 2022. Descriptive statistics and multiple linear regressions were performed to analyze the data.

Results: There were 30 participants who completed and returned the questionnaire (a response rate of 51.72%). Oral appliance therapy (OAT) was perceived as an effective treatment by the participants with a score of 5.97±1.24 (out of 7). Physicians who were trained in sleep medicine were likely to achieve higher knowledge scores in the part of OAs for adult (P=0.007). A period of practice appeared to have impact on knowledge score regarding OAT for children (P=0.049). However, training experience during undergraduate programs was found to have no significant impact on their current practice. Most of respondents were likely to agree that OSA management should be performed by dental sleep medicine specialists (86.7%) or orthodontists (76.7%).

Conclusion: Most of the respondents had demonstrated proficient knowledge and positive perceptions toward the effectiveness of OAT in OSA management. However, it had not been yet frequently prescribed, due to few qualified dentists, treatment cost and reimbursement issue.

Support: None

ABSTRACT #010

COMPARISON OF PREFERENCE FOR TWO MANDIBULAR ADVANCEMENT DEVICES IN OBSTRUCTIVE SLEEP APNEA PATIENTS: A PILOT RANDOMIZED CROSSOVER TRIAL

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Introduction: There is a large variety of commercially available mandibular advancement devices (MADs) available for patients with obstructive sleep apnea (OSA). However, there is limited evidence on the influence of MAD design on preference in OSA patients. Patient preference is an integral part of patient-centered care, because it plays an important role in adherence to, and acceptance of treatment. Both MAD-S (SomnoDent® Flex, SomnoMed Ltd, Sydney, Australia) and MAD-N (Narval CC®, ResMed, Lyon, France) are widely used two-piece custom-made titratable MADs. Their designs differ in color, size, weight, material, and couple-mechanism between the two splints. It was hypothesized that patients prefer a small-sized MAD of a lightweight material (viz., MAD-N). The primary aim of this study was to compare both MADs on preference in patients with OSA. The secondary aims were to compare both MADs on adherence, efficacy, and quality of life.

Methods: Twenty patients with OSA (mean ± SD age = 45.7 ± 11.4 years; mean ± SD apnea-hypopnea index (AHI) of 24.7 ± 13.0 events/h) participated in a randomized controlled crossover trial. Both MADs were applied for 9 weeks, in random order, and evaluated with a polysomnographic (PSG) recording with the MAD *in situ* at the end of the titration period. After the first 9 weeks, a wash-out period of one week was applied. The patients handed in the first MAD prior to the wash-out period. Preference, adherence, and quality of life data were collected by using online surveys (viz., custom-made questionnaires for preference and adherence, and the SF-36 for the quality of life). Efficacy was based on the change in AHI between baseline and therapy evaluation (viz., ΔAHI).

Results: Nineteen patients (mean ± SD age = 45.0 ± 11.4 years) completed the study protocol. One patient dropped out because of temporomandibular problems. At baseline, 9 patients preferred MAD-N, 7 patients preferred MAD-S, and 3 patients had no preference. After completing the

study protocol, 7 patients preferred MAD-N, and 12 patients preferred MAD-S. There was no significant patients' preference for one of the two MADs at baseline and at the end of the study (P= 0.804, and P= 0.359, respectively). There was no significant difference in adherence between both MADs either (P=0.97). The median (interquartile range) adherence in hours/night was, respectively, 7.0 (5.0 – 8.0) in the MAD-N group, and 7.0 (5.1 – 8.0) in the MAD-S group. The MAD-N showed a significant improvement in the apnea-hypopnea index ($P_{MAD\text{-}N}$= 0.048) in comparison with the MAD-S ($P_{MAD\text{-}S}$= 0.151). However, there was no significant difference in ΔAHI between both groups (P= 0.546). Similar results were found for the quality of life: both groups showed improvement in different domains (range $P_{MAD\text{-}N}$= 0.001 – 0.04 and $P_{MAD\text{-}S}$= 0.004 – 0.018). However, there was no difference between both groups (range P=0.14 – 0.92).

Conclusions: This pilot study suggests that there is no significant difference in patients' preference between two commonly prescribed MADs in patients with OSA. No significant differences in efficacy, adherence, and quality of life are present either.

Support: The study was funded by research grants of Vivisol BV (Industry) and TKI Health Holland (Government).

ABSTRACT #011

GENDER DIFFERENCES IN MANDIBULAR ADVANCEMENT DEVICE TREATMENT IN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA: A ONE-YEAR FOLLOW-UP

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Introduction: Obstructive sleep apnea (OSA) has long been considered as a condition predominantly affecting men, but women with OSA are receiving increasing attention. Gender differences have been found in various aspects of OSA, such as in prevalence and pathophysiological phenotype. However, due to limited available data, it remains unclear whether there are gender differences in mandibular advancement device (MAD) treatment outcomes. Therefore, this study aimed to determine the long-term differences in MAD treatment outcomes between men and women with OSA. Given that women have a less collapsible upper airway and, in general, less severe OSA than men, we hypothesized that women have better treatment response and, as a result, better adherence to MAD treatment than men. In addition, because women are more vulnerable to temporomandibular disorders (TMD) than men, it is hypothesized that TMD-related side effects are more prevalent in women than in men.

Methods: OSA patients who received MAD treatment between May 2017 and February 2020, and had complete treatment records after one year, were included in this cohort study. At baseline, patient characteristics (viz., age, gender, and body mass index [BMI]) and OSA-related data (viz., apnea-hypopnea index [AHI] and OSA-related symptom[s]) were extracted. At one-year follow-up, data on adherence (i.e., frequency of MAD usage; night/week; in percentage), remaining OSA-related symptoms, and side effect(s) were extracted. Data were presented as median (interquartile range). Chi-square and Mann-Whitney U tests were used to investigate differences between the two groups.

Results: Ninety-two OSA patients were included. Of the 92 participants, 21 dropped out (22.8%; 15 men and 6 women; P=0.93), mainly due to compromised treatment efficacy (n=7), opted for other treatment (n=5), and discomfort (n=5). The remaining 71 participants (50 men and 21 women), with a mean follow-up period of 14.6 months, were included in analyses. At baseline, women were found to have higher BMI (men: 25.8 [24.6-28.0], women: 28.2 [26.1-30.8]; P=0.02) and AHI (men: 13.2 [7.0-19.3], women: 19.3 [9.4-23.5]; P=0.02) than men, while there was no significant difference in age (men: 52.0 [41.0-62.0], women: 53.0 [45.5-63.0]; P=0.59). Both groups reported snoring, daytime fatigue, and non-restorative sleep as the most common symptoms, with no significant difference in the incidence (P≥0.05). At the one-year follow-up, both groups showed similarly excellent adherence to MAD treatment (men: 100% [90-100], women: 100% [100-100]; P=0.47). In addition, reports of daytime fatigue and frequent awakenings during sleep as remaining OSA-related symptoms were more prevalent in women than in men (P=0.05 and P<0.01, respectively). TMD-related side effects (notably stiffness of the musculus masseter) were more prevalent in women than in men at the one-year follow-up (P=0.01).

Conclusions: This study indicates that women who receive MAD treatment are more obese and have more severe OSA than men. Men and women have similar OSA-related symptoms at baseline and comparable adherence to MAD treatment, however, reports of daytime fatigue and frequent awakenings during sleep are more prevalent in women than in men at one-year evaluation. In addition, TMD-related side effects are more prevalent in women than in men.

Support: Not applicable.

CASE REPORT #012

ORAL APPLIANCE THERAPY COMBINED WITH HYPOGLOSSAL-NERVE STIMULATION: CASE REPORT

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Introduction: Obstructive sleep apnea (OSA) is a prevalent condition affecting approximately three to seven percent of males and two to five percent of females in the adult population and it's characterized by repetitive upper airway collapse during sleep. Multiple treatment modalities are proposed to be used to manage OSA, including weight loss, positional therapy, mandibular advancement devices (MAD), positive airway pressure therapy (PAP), and surgery. PAP is considered first line therapy for severe OSA. Upper Airway Stimulation (UAS) is indicated for moderate and severe OSA who cannot tolerate or fail PAP. According to current guidelines, MAD is indicated for patients with mild to moderate OSA and for patients to fail the use of PAP. This case report demonstrates the management of severe OSA combining MAD and UAS.

Case report: A 62-year-old female with history of severe OSA with an AHI of 49 events/hour (normal <5). Symptoms included snoring, witnessed apnea, and waking up unrefreshed. Her BMI 25 and neck circumference 14". She attempted PAP therapy but was intolerant to it. Multiple surgeries were done, including septoplasty, functional endoscopic sinus surgery, tonsillectomy, and UPPP. However, the outcome was not satisfied AHI 37 event/hour and 75% minimum O_2. The decision was made to enroll her in hypoglossal nerve stimulation (HNS). She underwent implantation after fitting the inclusion criteria. Despite all these attempts, the AHI still at 10 events/hour and 86% minimum O_2. Sleep study with HNS titration to adjust electrical stimulation and setting revealed 1.3–2.3 v. After different treatment options, the patient reported mild improvement in her sleep quality; however, mild OSA and residual snoring persist. The patient presented to Tufts Dental Sleep Clinic for assessment and therapy of MAD in addition to HNS. Bilateral interlocking MAD device with 70% protrusion was fabricated and fitted. Bilateral acrylic resin was added in the posterior area to add space in the anterior area to accommodate the tongue protrusion during activation. After completion of MAD clinical protocol, a follow-up sleep study objectively revealed a reduction to normal values of respiratory events AHI 1.4 event/hour and 89% minimum O_2 and the final voltage was 1.6. Long-term follow-up was implemented as a standard of dental sleep medicine clinical care.

Discussion: Multidisciplinary collaboration with different specialties is a common approach, particularly for severe OSA. One key point in this case is that the MAD was customized to accommodate the tongue protrusion during activation, emphasizing the synergy between two therapeutic modalities. Both the HNS amplitude and MAD degree of advancement could be reduced compared to when each was used as monotherapy.

Support: The authors declared no conflict of interest, and no financial support was provided for this case report.

CASE REPORT #013

PERSISTENT EXCESSIVE DAYTIME SLEEPINESS AFTER RESOLUTION OF OBSTRUCTIVE SLEEP APNEA

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Introduction: Obstructive sleep apnea is a globally prevalent sleep disorder with excessive daytime sleepiness (EDS) being an important subjective symptom. Various indications of EDS are falling asleep while driving or watching TV, daytime fatigue, irritability, impaired alertness and overall poor quality of life. Studies have shown that severity of EDS does not correlate with that of OSA. Despite normalization of apnea events, residual EDS often persists in some patients thereby necessitating the use of wake-promoting pharmacotherapy. An important cause for persistent EDS is psychosocial comorbidity such as depression and anxiety.

Report of Case: 53-year-old male diagnosed with mild obstructive sleep apnea (OSA) with an AHI of 10.9 events/hour and baseline Epworth Sleepiness Scale (ESS) score of 14/24. He tried using CPAP therapy but was intolerant to it. He was referred to our center for oral appliance therapy. He was fitted with a bilateral interlocking oral device and his follow up sleep study showed resolution of OSA with an AHI of 3.7 events/hour, however he reported persistent excessive daytime sleepiness and fatigue with the latest ESS score being 11/24. Additional test such as Multiple Sleep Latency Test was done to rule out narcolepsy. He also reported psychological comorbidity in terms of depression. A psychosocial assessment was done with the PHQ-9 score of 11 (moderate depression). He was prescribed antidepressive medication by his mental health provider. In order to address his persistent EDS, he was prescribed a wake promoting medication by his sleep physician. He continues to be monitored at our center on routine long term follow-up visits to assess oral appliance therapy for OSA and update on his EDS.

Discussion: The mechanisms underlying EDS in OSA are

quite complex and multifactorial. Depression is one of the most common psychiatric illnesses that could contribute to the varying causes of EDS. The relationship between depression and EDS is bidirectional and highlights the need to assess the psychosocial health of OSA patients presenting with EDS. Also, comprehensive screening and testing for EDS should be considered in depression.

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

ABSTRACT #014

FIVE-YEAR, PROSPECTIVE, MULTICENTER, REAL-WORLD STUDY TO ASSESS THE LONG-TERM SAFETY, INITIAL MANAGEMENT, AND EFFECTIVENESS OF A CAD/CAM, 3-D PRINTED ORAL APPLIANCE IN THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA: UPDATED INTERIM ANALYSIS

Professor Frédéric Gagnadoux, Pulmonologist, Angers University Hospital Center, France for the Study Team; Robyn Woidtke MSN, RN, CCSH, RPSGT, RVW Clinical Consulting, United States; Martine Fortin, Panthera Dental, Quebec Canada; Mohammed Sedki, Paris-Saclay University & Inserm U1018

Introduction: Obstructive sleep apnea (OSA) is a significant, chronic medical condition. Patients with OSA are often prescribed an oral appliance (OA). The Panthera D-SAD is a CAD/CAM, 3D-nylon printed OA allowing a patient-matched design. Changeable rods provide the mechanism for protrusion. A collaborative approach (sleep physician/sleep dentist) is required to manage the patient's care. This study presents a real-world view of the patient's journey, from first-time fit through final OA titration and three-month follow-up sleep testing. The study will assess the primary endpoint of at least a 50% reduction from baseline apnea-hypopnea index (AHI) at five years. However, interim analysis allows the study team to track study progress at the first-time fit visit and follow-up sleep study. This study will fulfill French reimbursement requirements. Ethics committee approval was obtained from South-Mediterranean Persons Protection Committee II, Sainte Marguerite Hospital.

Methods: OA naïve individuals with moderate OSA (AHI 15-30) or those with severe OSA (AHI 30 or greater) who decline CPAP and who meet all other criteria will be included. Standard of care in France for the study duration will be followed. 217 participants will be enrolled at 15 centers in France. Consecutive sampling is used. A Somnologist will assess participants for entry criteria, and a prescription for OAT obtained. A dental evaluation for suitability is conducted (V0) . Initial OAT fitting occurs at Visit 1 (V1). Evaluation time points are (V2) three to six months (medical), six months (dental), and five years (both). Secondary endpoints include OAT side effects, oxygenation metrics, quality of life, self-reported adherence, and subjective symptoms at the aforementioned time points.

Results: Enrollment began April 13, 2022. One hundred seventy-one participants have had their sleep and orthosis evaluation for entry into the study. Baseline demographics for those who have completed V0 (n=171): averages (SD) age 49.7 (13.0); AHI of 22.2 (8.7), ODI 17.16 (11.92), SpO2 91.7 (2.18), BMI 26.75 (4.81). Initial rod length of 27 mm (1.62). This abstract summarizes initial titration and a subset (n=50) with sleep testing (V2). At V1, rod changes (protrusive) were required in 14 % of patients. Compared to baseline, 64% of patients tested had at least a 50% reduction in AHI at V2. At baseline, 90% of participants had moderate OSA and 10% had severe. At three months (V2), for those with severe OSA, 60% transitioned to moderate and 20% to mild. Participants with moderate OSA, 84% transitioned to a lower severity category and 16% remained moderate. The average weekly reported use of the device was 6.8 days and 84% indicated they used the device for ≥ 4 hours a night. None of the devices were returned for defects.

Conclusion: This interim data demonstrates positive trending of initial adherence and reduction in AHI. No devices required a remake or return thus enhancing throughput and reducing the patient's therapeutic burden. Due to these factors, improved chair time also benefits the clinician.

Support: The study is supported by Panthera Dental, Quebec, Canada

CASE REPORT #015

CASE REPORT OF SIX CONSECTIVE PATIENTS TREATED WITH A NOVEL ORAL APPLIANCE

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Introduction: There are many factors that make an oral appliance an effective treatment for obstructive sleep apnea (OSA). Compliance is one such factor which comfort, and ease of use is a part of. The apnea hypopnea index (AHI) through a home sleep apnea test (HSAT) is one objective measure of the effectiveness of oral appliance treatment.

Report of Case: In this report six consecutive before and after AHIs were recorded with the Nightowl (Ectosense,Parkland, Florida, USA) HSAT from the author's private practice using a novel oral appliance, the Elevate (Serena Sleep Solutions, Lakeland, MN). The before AHIs ranged from mild to severe (10,13,23,26,39 and 49). Once the appliance was clinically titrated for each

patient, an after AHI were recorded again with the HSAT. The corresponding results were (3, 0, 5, 6, 15 and 16). All patients AHI were reduced by at least 50%.

Discussion: This report shows, with objective results, that this appliance is an effective new oral appliance to reduce AHI. None of the six patients reported "jumping the bite" or having the upper and lower appliances become disengaged. If this was the case, it would have been seen in the results. The unique design of the oral appliance allows the maxillary and mandibular parts to stay engaged both in the protrusive and lateral positions. The appliance is digitally designed to each patient which is then 3d printed with Nylon PA 2200. Once printed, it goes through a finishing process that seals the nylon which makes it smoother and easier to clean than other nylon appliances. Being it is made from nylon and the design itself; it has one of the lowest profiles and volume for an oral appliance which makes it easy to wear. The adjustment mechanism does not interfere with the vestibule area, and it is directly over the dental alveolus allowing the forces of advancement to be more natural, reducing temporal mandibular joint stress. There is no anterior constriction which allows the tongue to naturally posture forward. The mechanism of adjustment makes it simple to use in that there are no screws or nuts to turn or straps or links to change out. The patient just interchanges upper and lower appliances for the advancement per the dentist's instructions. Once this appliance is discovered it will be no longer be novel.

Support: None

ABSTRACT #016

COMPARISON OF THE CLINICAL EFFICACY OF TWO CUSTOM-MADE TITRATABLE MANDIBULAR ADVANCEMENT DEVICES IN OSA

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Introduction: Mandibular advancement is an upcoming method in the first-line treatment of mild to moderate obstructive sleep apnea (OSA). Specific manufacturing designs and titration mechanisms of mandibular advancement devices (MAD) have been developed throughout the years, differing in titration mechanism, vertical opening, and fabric. Choice of MAD is often arbitrary and non-patient specific. In the present study, we investigated the impact of design and titration mechanism on the clinical efficacy of two custom-made titratable MADs and their effects on OSA.

Somnomed Flex (MAD A) has a lateral screw mechanism to advance the lower jaw up to 6mm. The newer Somnomed Avant (MAD B) has a frontal exchangeable advancement strap with fixed lengths as titration mechanism. This mechanism claims to result in less vertical opening provoked with MAD A causing a counter-clock rotation, with a maximal advancement up to 9mm in 1mm steps. We aimed to assess the associations between the type of MAD prescribed and determining factors of treatment outcome.

Methods: Data from 209 patients were analyzed (165 male, age: 53.9 years (+/-10.9), body mass index (BMI): 27.4 kg/m^2 (+/-4.1) and apnea/hypopnea-index (AHI): 26.9 events/ hour sleep (+/-12.7), 118 treated with MAD A and 91 with MAD B. All patients were diagnosed with a type 1 polysomnography with moderate to severe OSA ($15 \leq$ AHI ≤ 65 per hour sleep) and BMI <35 kg/m^2. The MAD was fitted starting in the maximal comfortable protrusion regardless of the type of MAD selected. After 3 months of subjective titration until resolution of subjective symptoms or achieving physical limits, checkup with home-polygraphy followed. Treatment success was defined as "AHI reduction $\geq$50% of baseline AHI and AHI with MAD <10 events per hour".
A significant decrease in ESS and VAS was defined as ESS<11 whereas before ≥ 11 and VAS decrease of ≥ 3 points. Treatment success and AHI reduction was analyzed using unpaired t-tests. Logistic regression was used to assess independent associations between responder and non-responder status.

Results: On MAD pooled data, 58% of all patients achieved treatment success with AHI reduction from 26.7 (SD 12.6) to 10.6 (SD 9.6) events per hour of sleep. MAD A achieved 65% treatment success versus 48% for MAD B ($P<0.05$), which is a significant difference between the two MADs. Overall, AHI reduction was 66% for MAD A ($P<0.05$) vs. 49% for MAD B ($P<0.05$).

There was a significant decrease in ESS and VAS after treatment, however between the two devices there was no significant difference using these criteria for snoring and daytime sleepiness, respectively.

Conclusions: This study shows that choice of an MAD will impact the treatment outcome and could become an important consideration in selecting the type of MAD for precision treatment of OSA patients. The Somnomed Avant device showed a significantly greater reduction in total AHI.

Support: None

ABSTRACT #017

ANALYZING FORCE DISTRIBUTION AND ADVERSE EFFECTS IN A NOVEL MANDIBULAR ADVANCEMENT DEVICE FOR OBSTRUCTIVE SLEEP APNEA THROUGH FINITE ELEMENT STUDY

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Introduction: Obstructive sleep apnea (OSA) is a sleep-related breathing disorder characterized by repeated episodic collapses of the upper airway during sleep. Mandibular advancement device (MAD) serves as an alternative treatment modality, particularly for primary snoring and mild-to-moderate OSA. MADs, often recommended for patients, face barriers to widespread use, including high costs that make them unaffordable for many and limited accessibility, demanding customization by qualified dentists. This study aimed to 1) develop a novel MAD based on preferences of dental sleep clinicians and patients, and 2) test its stress distribution and adverse effects on teeth, alveolar bone, and temporomandibular joint in simulated situations.

Methods: A survey was conducted to determine preferences of dental sleep clinicians and patients regarding the characteristics of MADs. A three-dimensional skull model was constructed from dental CBCT of a human subject. The relationship between maxillary and mandibular teeth was registered at 50% mandibular protrusion and captured by TRIOS4 intraoral scanner. The newly designed MAD was constructed by SolidWorks and Dental LT Clear resin was a material of choice. Stress distribution of newly designed MAD was analyzed by finite element analyses (FEA) under three simulated situations, including mandibular protrusion, mandibular protrusion with clenching, and mandibular protrusion with lateral teeth grinding at 50% and 75% mandibular protrusion under determined boundary conditions, using ANSYS V20R2 software.

Results: The novel MAD was designed according to the survey findings, indicating that dentists favored MADs that were custom-made, duobloc, and titratable, whereas patients sought MADs that were comfortable and reasonably priced. FEA demonstrated that both compressive and shear stress affected the newly designed MAD. However, primary stress was concentrated on the device due to compressive forces. The maximum von Mises equivalent stress was found at lateral fins of mandibular splint and the lower anterior corner of protrusive buttons during all simulated situations. Nevertheless, the maximum compressive stress did not exceed the compressive strength of the material of choice in any of the situations. Moreover, chromatic distribution showed that the highest equivalent stress on teeth was observed at distal aspects of upper and lower molars during clenching at 50% protrusion. For the alveolar bone, it was demonstrated that lateral portion of the palate and alveolar socket of lower molars had the highest stress during grinding at 50% protrusion. Additionally, for the temporomandibular joint, we observed that medial portion of the middle of the articular disc had the highest stress during clenching at 75% protrusion. Safety factors of Dental LT Clear Resin at 50% protrusion during clenching, lateral teeth grinding, and protrusion were 1.08, 1.89, and 3.90, respectively. At 75% protrusion, safety factors were 1.11, 1.35, and 2.13 for the same scenarios.

Conclusions: The recently developed In-house MAD demonstrates suitable biomechanical characteristics and the capacity to withstand clenching and grinding forces at certain limit. Based on FEA, this In-house MAD, fabricated with Dental LT Clear Resin, is deemed secure, presenting minimal risk of harm to teeth, alveolar bone, or articular disc. Phase I clinical trial is recommended to assess safety and effectiveness in clinical settings.

Keywords: Mandibular advancement device, Obstructive sleep apnea, Finite element analyses

Support: This study was supported by 1) Tawanchai Foundation for Cleft Lip-Palate and Craniofacial Deformities 2) The Fundamental Fund of Khon Kaen University, which has received funding support from the National Science, Research, and Innovation Fund (NSRF).

ABSTRACT #018

OVERALL CLINICAL EFFECTIVENESS OF ORAL APPLIANCE THERAPY AS A FIRST-LINE TREATMENT OPTION COMPARED WITH CONTINUOUS POSITIVE AIRWAY PRESSURE IN PATIENTS WITH MODERATE TO SEVERE OBSTRUCTIVE SLEEP APNEA: THE FLOSAT STUDY

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Introduction: Continuous positive airway pressure (CPAP) and mandibular advancement device (MAD) therapy are non-invasive treatment options for patients with moderate to severe obstructive sleep apnea (OSA). Differences in efficacy and adherence of these treatment modalities are likely to influence the clinical effectiveness.

The aim of this clinical trial is to evaluate the overall effectiveness of custom-made, titratable MAD therapy as first-line treatment option in patients with moderate to severe OSA and to compare it with CPAP therapy in the same patient cohort.

Methods: Patients diagnosed with moderate to severe OSA with no history of CPAP or MAD were contacted to start MAD therapy for three months (EVO, ProSomnus). After a wash-out, all participants underwent CPAP treatment for three months. Objective adherence measurements as well as polysomnography was performed of each treatment arm. The intention-to-treat (ITT) mean disease alleviation (MDA) was calculated as the product of efficacy and adherence on an individual basis as well as on group level.

Results: In this study, 136 patients were included with 94 patients (86% male, age:51±12 years, BMI:28.1±3.4kg/m², AHI:24.1(17.8; 32.3)/hour) completing all study visits. Overall, AHI decreased significantly to 8.4(5.3; 12.8)/hour with MAD ($p<0.001$) and to 4.0(2.2; 12.6)/hour with CPAP ($p<0.001$). Twenty-one patients (22%) discontinued CPAP where only three patients (3%) discontinued MAD. Regarding patients' preference: 52% of patients had a preference for MAD, where 40% of participants preferred CPAP and 8% expressed no preference.

In an ITT analysis taken into account the adherence failures, the average use was 6.1±2.0 hours/night for MAD therapy which was significantly higher than the 4.3±2.7 hours/night for CPAP ($p<0.05$). The averaged individual ITT-MDA was 51% for MAD and 46% for CPAP, whereas on a group level, the ITT-MDA was 51% for MAD and 37% for CPAP, respectively.

A multivariate logistic regression model for MAD success (AHI<10/h) including gender, baseline BMI, age and CPAP pressure levels showed that women had a 13-fold higher chance on success compared to male patients. Furthermore, younger age and lower CPAP pressure levels were associated with treatment success.

Conclusions: In this FLOSAT trial, MAD therapy as a first-line treatment option showed a good efficacy combined with high patient adherence which was two hours higher as compared to the average CPAP use in an ITT analysis. Female gender, younger age and lower CPAP pressure levels were correlated with MAD treatment outcome.

Support: The MAD devices (ProSomnus EVO) used in this study were provided free of charge by ProSomnus Sleep Technologies, Pleasanton, CA, USA.

ABSTRACT #019

ASSESSING HEALTH OUTCOMES WHEN TREATING OBSTRUCTIVE SLEEP APNEA WITH MANDIBULAR PROTRUDING APPLIANCES

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Introduction: Apnea-hypopnea index (AHI) is a frequency-based index used to define the severity of obstructive sleep apnea (OSA). However, the existing evidence does not support the hypothesis that AHI is a valid surrogate for long-term health outcomes as it is not predictive of OSA-related risk. Conversely, sleep apnea-specific hypoxic burden (SASHB) appears to be predictive of OSA-associated risk. While SASHB has been studied in cohorts of untreated individuals, it has not been examined in relation to health outcomes of OSA therapy. We present here the first assessment of precision oral appliance therapy (OAT) action in reducing SASHB and the first use of SASHB in defining therapeutic efficacy.

Methods: Data from three prospective clinical studies that investigated the prediction of response to precision OAT in OSA were analyzed. Data from 152 participants with all severities of OSA completed two-night type 3 home sleep tests before and after receiving an oral appliance (ProSomnus Sleep Technologies, Pleasanton, CA). Apnea-hypopnea index and SASHB were calculated. For SASHB, a cut-off of 60 %min/h was used based on data indicating that values above this limit are associated with OSA-related risk; for AHI, cut-offs of $< 10\ h^{-1}$ and $< 15\ h^{-1}$ were used because of their prevalence in clinical practice. In the current analysis, only those with a baseline AHI $> 10\ h^{-1}$ were included.

Results: Oral appliance therapy decreased the median AHI and SASHB in all severity strata. Using AHI $< 10\ h^{-1}$ as the criterion for therapeutic efficacy, 82% of moderate and 52% of severe participants were efficaciously treated. However, when SASHB < 60 %min/h was used as the criterion of therapeutic efficacy, 98% of moderate and 84% of severe participants were treated by the oral appliance. An agreement analysis between AHI and SASHB showed that 15% of moderate and 32% of severe participants were misclassified as therapeutic non-responders (based on

AHI) when their SASHB was below the threshold of increased risk.

Conclusions: In the studied population, precision OAT significantly improved SASHB. The use of AHI, a frequency-based index of OSA, appears to misclassify some individuals as therapeutic non-responders to precision OAT despite their having an SASHB in the low-risk range. Sleep apnea-specific hypoxic burden likely provides a more meaningful assessment of OSA treatment efficacy than AHI as it accounts for the risk associated with the disease.

Support: ProSomnus Sleep Technologies

ABSTRACT #020

THE EFFECT OF INCREASED WEIGHT AND OBESITY ON AHI REDUCTION AND MANDIBULAR ADVANCEMENT DEVICE EFFECTIVENESS IN THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA

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Introduction: Excess body weight and obesity are common findings in patients suffering from Obstructive Sleep Apnea (OSA).

The accumulation of fat in the tissues surrounding the collapsible upper airway predisposes to narrowing. Many other elements amongst which decreased muscle tone, anatomical factors, enlarged soft tissue, respiratory reflexes, etc., lead to episodes of partial and/or total occlusion of the upper airway during sleep. Some of these factors cannot be altered.
According to the World Health Organization, that it is estimated in North and South America 62.5% of adults are overweight and in Europe, this figure is approximately 60%. Of these overweight adult patients, it is estimated that 28% are clinically obese. The forecast for the next 5-10 years is that these values will increase and therefore have a major impact on OSA frequency and severity.

For this reason, the prime and most important therapeutic recommendation for the treatment of OSA is weight loss but in reality, few patients are aware of this and very few achieve effective weight reduction.

In this abstract, we will focus on the relationship of excess body weight and obesity on OSA levels and the effectiveness of Mandibular Advancement Device (MAD) treatments.

Methods: A sample of 133 OSA study patients [99 males (74%) and 34 females (26%)] were weighed, measured and underwent sleep polygraphy or polysomnography pre-treatment. All were successfully treated in terms of subjective symptom reduction with the OrthoApnea NOA® MAD. After 6 months, a second polygraphy was performed and the patient was re weighed. The weight and height values were used to calculate individual patient Body Mass Indices (BMI).

The sample was classified according to BMI and the Apnea-Hypopnea Index (AHI) pre and post MAD treatment were analyzed.

Results: The 133 patients were classified According to BMI: 21 as 'normal weight' (18.5<BMI<25), 73 as 'overweight' (BMI 25-29), 26 as 'obese' (BMI 30-40) and 13 as 'extremely obese' (BMI>40). After 6 months, no patients showed any change BMI.

The results of pre- and post -treatment AHI across the various weight categories were as follows:

- 'Normal weight' group: AHI pre 21.8 and AHI post 5.9 (75% reduction).
- Overweight: AHI pre 24 and post AHI 7.2 (70% reduction).
- Obesity: AHI pre 23.4 and post AHI 11.8 (50% reduction).
- Extreme obesity: AHI pre 26.5 and AHI post 14.8 (44% reduction).

Conclusions: Overweight and Obese patients have higher baseline AHI values, as expected. The study finds no statistical difference in treatment efficacy between the different groups, which means that the NOA® MAD is effective in reducing AHI regardless of the patient's BMI. However, in the individual data for each group shows smaller reduction in AHI as the BMI increases. If we compare the post-treatment AHIs of the three 'heavier' cohorts to the 'Normal weight' group: The Overweight group post-treatment AHI is 22% higher, the Obese group post-treatment AHI is 100% higher and the Extreme Obese patient group AHI is 151% higher.

Support: OrthoApnea's R&D team was only involved in the interpretation of the results.

ABSTRACT #021

INCIDENCE OF ADVERSE EFFECTS WITH MANDIBULAR ADVANCEMENT DEVICE THERAPY AND IMPACT ON TREATMENT MODALITY CHOICE IN PATIENTS DIAGNOSED WITH SEVERE OBSTRUCTIVE SLEEP APNEA

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Introduction: Treatment of obstructive sleep apnea (OSA) with custom-made, titratable mandibular advancement devices (MAD) is commonly utilized for patients with mild to moderate OSA, while continuous positive airway pressure (CPAP) is the first-line treatment for more severe cases. Despite preliminary evidence supporting MAD effectiveness in severe OSA, concerns persist regarding the potential protrusion requirements and adverse effects. This study aims to assess the incidence of adverse effects associated with MAD treatment in severe OSA patients and evaluate its impact on treatment modality preference.

Methods: This paper report on a subset analysis of the FLOSAT study, a controlled crossover trial in which eligible patients with moderate to severe OSA (BMI < 35 kg/m², 65>AHI>15 events/hour, no CPAP or MAD history) underwent MAD treatment (ProSomnus EVO) for three months, followed by CPAP for an additional three months. The protrusion level was measured in reference to the individual MCP (maximum comfortable protrusion), with starting point of MCP minus 3mm. Patients then chose their preferred treatment modality. Adverse effects, efficacy, protrusion levels, and treatment preferences were recorded.

Results: We report on 23 severe OSA patients (4 female, 19 male, average AHI: 39 events per hour +/- 8.2, average BMI: 29.3 +/- 3.6, Average age: 52.4 +/- 11.2. MAD success rate was 87% (20 out of 23) using Sher criteria, with an average AHI of 11.6 +/- 8.6 with precision MRD. On average the final position was 0.74 mm behind MCP. This was similar to the moderate group in this study where the average final position was 0.84 mm behind MCP . Adverse effects related to MAD treatment occurred in 6 patients (26%), including pressure on teeth(1), a dislodged crown(1), muscle and joint discomfort(4). All these adverse effects were temporarily and could be resolved with minor interventions. More patients with severe OSA preferred MAD (12; 52%) than CPAP (10; 44%) while one patient (1; 4%) opted for the combination of both treatment options. Adverse effects did not significantly impact treatment choice (3 out of 7 patients chose MAD, 4 chose CPAP).

Conclusions: In this study, custom-made titratable MAD demonstrated substantial efficacy in reducing AHI for severe OSA patients. Protrusion levels were comparable to the moderate OSA group and was behind the MCP. Adverse effects were easily manageable and did not influence treatment modality preference (CPAP vs MAD), suggesting MAD as a viable option for severe OSA patients.

Support: The study received support from ProSomnus Sleep Technologies, providing the precision MRD (ProSomnus EVO) free of charge.

ABSTRACT #022

EFFICACY OF ORAL APPLIANCE THERAPY FOR OBSTRUCTIVE SLEEP APNEA IN A VIRTUAL WORKFLOW. A REVIEW OF 1,242 CASES.

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Introduction: Current adoption of telemedicine consultations for diagnosis and treatment of sleep apnea and the recent advances in single patient use home sleep testing; allow for a fully virtual workflow, improving access to efficient and affordable sleep apnea care. We reviewed our experience with patients entering the sleep care system through the BlueSleep virtual portal and workflow; and examined objective improvement in pre and post AHI (Apnea Hypopnea Index) scores for patients with mild, moderate, and severe obstructive sleep apnea.

Methods: From May 2022 to November 2023, we treated 6,250 new sleep patients and identified 3,387 patients treated for sleep apnea by CPAP and/or OAT. Of a total of 1,895 patients who chose oral appliance therapy as treatment, 1,342 were prescribed a Prosomnus MAD. Dental considerations, medical insurance requirements and patient preference dictated the type of MAD device used: (EVO, EVO PH, or PH). Initial consultations, home sleep test, and follow up visits were all by telemedicine. 75% of deliveries were virtual, and 25% were in person. Pre and post HST (Home Sleep Apnea Test) were ordered in all patients and shipped to patients' homes.

Results: The average age of patients treated was 40, with 69% males and 31% female. Fifty percent of patients did not complete a post treatment HST despite having the HST device in their possession. Average post treatment AHI improved by more than 50% compared to average pre treatment AHI in all severity categories and were statistically significant. Severe: pre AHI 42 to post AHI 18, Moderate: pre AHI 22 to post AHI 10, Mild: pre AHI 9 to post AHI 4.

Conclusions: The current state of sleep apnea diagnosis and treatment requiring in person visits for consultations, sleep tests, and multiple in person visits for treatment can only serve a very small percentage of the population waiting for diagnosis and treatment. This review confirms that a virtual workflow including telemedicine consultations, home sleep tests shipped to patients' homes, and virtual delivery of MADs is a valid alternative to the

current in person model. The virtual workflow is a scalable model that is rapid, affordable, effective, and can better serve the one billion people affected by obstructive sleep apnea globally.

Support: Financial support provided by Prosomnus Sleep Technologies. Pleasanton, CA.

ABSTRACT #023

COMPARISON OF TELEMEDICINE VERSUS IN-OFFICE DELIVERY OF MANDIBULAR ADVANCEMENT DEVICES. A REVIEW OF 757 CASES.

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Introduction: Recent advancements and acceptance of telemedicine is making the treatment of sleep apnea more accessible. We reviewed our experience treating patients diagnosed with obstructive sleep apnea through a virtual workflow. This report focuses on the telemedicine deliveries of mandibular advancement devices (MADs) as an alternative to in-office appointments for the delivery of MADs. We tested the hypothesis that there is no significant difference in the number of post delivery adjustment visits required for in-office to telemedicine deliveries.

Methods: From May 2022 to November 2023, BlueSleep treated 1,895 patients with MAD. A chart review was conducted and 757 patients were chosen for the study. These patients had follow-up with the diagnosing medical provider and were provided the same bilateral unattached dorsal fin style device. This was to reduce the variable of differing device styles and to remove those patients lost to follow up.

Delivery type was decided by dentist recommendation and patient preference. Virtual telemedicine inserts were conducted through a HIPAA compliant telemedicine system and in-office inserts were conducted at the clinical center in New York, NY. Adjustment appointments were appointments necessary after delivery to alter the fit of the device.

Results*:* From the total 757 patients, 193 received in-office delivery and 564 received telemedicine delivery. Of the 193 in-office deliveries, 45 required an adjustment. In comparison, of the 564 telemedicine deliveries 96 required an adjustment appointment.

Conclusions: There was no significant difference in post delivery adjustment visits based on the initial delivery type. Telemedicine delivery of MADs can be used to increase access to MAD treatment and did not increase the need for post delivery adjustment appointments.

Support: None to disclose.

ABSTRACT #024

RECENTLY DIAGNOSED OBSTRUCTIVE SLEEP APNEA PATIENTS: KNOWLEDGE AND MINDSET

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Introduction: Obstructive sleep apnea (OSA) is a progressively prevalent condition with serious effects on cardio- and cerebrovascular systems caused by recurrent collapse of the upper airway during sleep, resulting in oxygen desaturation and interrupted sleep patterns. Currently, 98% of the OSA patient population in Belgium is treated with continuous airway pressure (CPAP), while mandibular advancement devices (MADs), another first-line treatment, is chosen by 2%. However, CPAP compliance among patients is known to be relatively low, leading to suboptimal treatment. The mindset of the patients is an important factor influencing compliance. Besides these first-line treatments, there are other possible treatment options, including maxillomandibular advancement (MMA) surgery, with the potential to lead to a permanent solution.

The aim of this study was to assess the patients' knowledge regarding their medical condition and their mindset concerning two first-line treatment options including CPAP and MAD, and a second-line, permanent treatment option, the MMA surgery. A second objective was to investigate whether their treatment mindset changed after receiving information about the treatments.

Methods: After obtaining ethical approval from the Antwerp University Hospital, patients were enrolled during their visit at the sleep center. A questionnaire was used comprising demographics, medical condition, treatment knowledge, personal treatment choices and factors influencing the treatment choice. Data from this questionnaire was combined with results from their overnight polysomnography (PSG). Nominal logistic regressions and chi square analyses were used to provide insights into any potential associations or influences.

Results: Among the total cohort of 82 patients, the level of knowledge on OSA (42.7%) and treatment options (45.1%) was moderate. OSA, CPAP and MAD knowledge tended

to be higher in younger individuals. After receiving information, patients changed their treatment choices. Participants were able to choose more than one treatment. CPAP was the preferred treatment (69.5%), followed by MAD (65.9%) and MMA (20.7%). Patients would mainly initiate treatment to be better rested (53.7%) and they find a good explanation from a doctor (82.9%) the most important factor during this process. Therapy related characteristics and side-effects showed significant association with the treatment choices.

Conclusions: Average baseline OSA and treatment knowledge of recently diagnosed OSA patients is moderate, which makes a comprehensive explanation of all treatment options after their diagnosis crucial. Additionally, involving patients in the decision-making process regarding their treatment is important. Patients have a different mindset and preference when properly informed on the possible treatment options. Thus, when proposing a treatment to a patient, it is important to not only consider the PSG results, and to automatically choose the gold-standard treatment, but also to prioritize patient's preferences. By offering a patient-centred treatment, it might be possible to initiate the appropriate therapy for the patients more rapidly, leading to enhanced satisfaction and both improved compliance and adherence.

Support: The authors declare that they have no conflict of interest. There is no financial or non-financial interests to disclose, nor affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript. The authors have no competing interests to declare that are relevant to the content of this article.

CASE REPORT #025

SLEEP APNEA AT ALTITUDE

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Introduction: Altitude has marked effects on the respiratory system during sleep. Since obstructive sleep apnea is prevalent in the general population, awareness of this is important. At high altitude, the apnea-hypopnea index is elevated in patients with Obstructive Sleep Apnea (OSA) and obstructive events can convert to central events due to respiratory alkalosis and hypoxemia.

Report of Case: A 43 year old male with a previous medical history of hypertension, presented to our practice with symptoms of snoring and waking gasping for air. He had a telemedicine consultation and a home sleep test (HST) was ordered. Baseline HST revealed mild OSA with an AHI 12 (3% desaturation levels), O2 nadir 88%. Oral appliance therapy was prescribed and the patient was fitted with a custom milled adjustable Herbst oral appliance with accufit liner. At follow-up, the patient reported a dramatic decrease in snoring, no longer gasping for air, waking feeling refreshed, and a decrease in systolic blood pressure. A post titration home sleep test was ordered and resulted in an AHI of 29 (3%), O2 nadir 85%.

The patient was advised to continue titration and two more sleep studies were ordered resulting in AHI 27 (3%), O2 nadir 79% and a few days later AHI 50 (3%), O2 nadir 77%.

The significant worsening of AHI on HST was of significant concern and did not match the patient's marked improvement in symptoms. Medical and dental teams discussed the results with the patient, reviewing any possible differences between the nights taking diagnostic HST and post titration HST with OAT. We discovered that the patient resides in multiple locations and the diagnostic sleep study was taken in New York, close to sea level while the later studies were completed in Colorado at 8,500 feet.

A new post titration sleep study was ordered and completed while the patient was not at high altitude and resulted in an AHI 2 (3%) and O2 nadir 91%.

Discussion: It is known that managing CPAP treatment at high altitude can be challenging and sometimes requires the addition of low-flow oxygen and medical treatment to reduce the rate of sleep disordered breathing. We review these strategies and how they apply to OSA patients being treated with OAT. The discussion includes if and when to repeat HSTs, the use of acetazolamide, CPAP and supplemental oxygen, and/or PAP.

Support: none

CASE REPORT #026

THERMAL LINERS IN MANDIBULAR ADVANCING DEVICES: ENHANCING ADAPTABILITY WHILE MITIGATING RISKS

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Introduction: Mandibular Advancing Devices (MADs) have emerged as a compelling alternative for managing obstructive sleep apnea in individuals looking for alternatives to continuous positive airway pressure machines. MADs continue to evolve with ongoing advancements, particularly in recent years with the

introduction of designs incorporating thermal liners. These liners revolutionize the MAD landscape by providing adaptability for individuals undergoing upcoming dental procedures. MADs can now be fabricated and tailored to their specific dental situations including future crowns, restorations, extractions, and implants.

While the thermal material enhances flexibility, it introduces a notable risk. Concerns arise regarding patients intentionally heating their MADs to achieve a "better fit." Despite the potential perceived benefits, improper remolding can lead to complications such as difficulties in removal or the appliance becoming inadvertently stuck on the patient's teeth. It is important to emphasize to patients the crucial need to refrain from intentionally heating the MAD on their own.

Report of Case: Since 2021, we have had two patients wearing a thermal-lined MAD awaken in the morning to the horror they could not remove their MAD. Not only was the MAD immovable, but their mandibles were also held in a protrusive position. The amount of anxiety, fear, and exhaustion they must have felt approaches unfathomable.

The first patient placed her appliance into a bowl of boiling water before placing her MAD into her mouth prior to falling asleep. The next morning, she visited a large group dental practice seeking emergency intervention which led to an arduous eight-hour removal process performed by two dentists. The second patient heated his MAD in a vacuum flask, leading to the same outcome. He returned to our office where we had no option but to cancel an afternoon of scheduled patients just to spend the next three hours carefully sectioning his MAD. We anesthetized each arch to prevent additional pain to the patient.

Discussion: This highlights the critical necessity for patients to strictly adhere to proper usage guidelines, avoiding attempts at self-adjustments when it comes to thermal-lined MADs. All new patients sign a disclaimer that if a thermal-lined MAD gets stuck and cannot be removed, the patient must pay a significant fee for our office to section and remove the appliance plus pay for a new MAD.

Dentists and patients should remain vigilant in ensuring the safe and effective use of thermal liners, recognizing the delicate balance between adaptability and the potential risks associated with patient-initiated modifications.

If you ever find yourself in a similar situation, follow the steps below:

- While using a carbide bur and doing your best to avoid cutting the teeth or gingiva, section off any portion that attaches the upper to lower of appliance (e.g., Herbst arms, Dorsal, etc.) to allow for retrusive and lateral movements.
- Second, section the appliance at the midlines.
- Third, if necessary, section the appliance between the canines and first premolars.
- Fourth, if necessary, section between the first and second molar.

Support: None

ABSTRACT #027

SNORING AS A PREDICTOR FOR ORAL APPLIANCE THERAPY TREATMENT OUTCOMES

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Introduction: There are no reliable predictors of treatment outcomes for oral appliance therapy (OAT) in treating obstructive sleep apnea (OSA). Snoring acoustics have shown clinical merit in providing insight on the obstruction sites in the upper airway. Integrating an acoustic-based system to predict treatment outcomes for OAT would be cost effective and clinically practical to implement. The purpose of this study is to determine if baseline snoring can be used as a reliable predictor of treatment outcomes for OAT.

Methods: This study is a retrospective analysis that extracted snoring data from two trials investigating the efficacy of the mandibular advancement device (MAD) and tongue stabilizing device (TSD) to treat OSA. Both trials collected data before and after treatment with a Level III Medibyte sleep monitor from Braebon. Only adult participants diagnosed with OSA with completed sleep studies before and after treatment with OAT were included. Snoring data was extracted from each sleep study and were sent to biomedical engineers at the University of Toronto specializing in acoustic analysis. Through this collaboration, a unique algorithm was generated using the Matlab software to extract several snoring sound features from the raw sleep study. Additionally, each sleep study generated a report summarizing the respiratory events of the night, including the Apnea Hypopnea Index (AHI). Baseline snoring features from the sleep study were compared to the treatment outcomes outlined in sleep report for both the MAD and TSD. Three success criteria were used to determine treatment outcomes: (1) AHI ≤5, (2) AHI ≤10 or (3) 50% reduction in AHI from baseline.

Results: There were 38 participants in the MAD trial and 12 in the TSD trial. In both trials, majority of the participants were male, Caucasian, and overweight (Body Mass Index > 28). There was a significant decrease in the AHI after treatment for both appliances. With respect to the

first, second and third success criteria, the MAD had 12 participants in each category whereas the TSD had 5 participants in the first two categories and 4 in the third. The MAD showed a greater decrease in the snoring index (snoring events per hour) and duration of snoring events than the TSD. However, these results were statistically insignificant. In contrast, the TSD had a statistically significant increase in the snoring index and duration after treatment. Both appliances had a slight, but statistically insignificant, reduction in snoring loudness after treatment. Multiple linear regression analysis showed that snoring sound features were a strong predictor of treatment outcomes for the TSD, but not for the MAD. However, both findings were statistically insignificant.

Conclusions: The MAD had greater improvements in snoring than the TSD with respect to the snoring index and duration. However, snoring was not a reliable predictor of treatment outcomes for either appliance. Future investigations should consider an advanced analysis using various acoustic properties of snoring to create prediction models for treatment outcomes of OAT.

Support: This project did not receive any funding.

ABSTRACT #028

SUBJECTIVE AND OBJECTIVE DENTAL SIDE EFFECTS IN ORAL APPLIANCE TREATMENT OF OSA – MULTICENTER RANDOMIZED CONTROLLED TRIAL

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Introduction: Oral appliances (OAs) are an effective and increasingly common treatment modality for the management of OSA in adults. The effectiveness of OA therapy is based on a high level of patient adherence, which may increase long-term side effects. Occlusal changes are the most common and significant clinical concerns. The study aimed to assess the efficacy of morning mandibular repositioning splint (MRS) use on minimizing the occlusal changes of OAs in the treatment of OSA adults.

Methods: This study is a single-blinded, prospective, randomized controlled trial, conducted at two clinical centers. Patients receiving the same type of OA and fully titrated were randomized into two groups: the MRS group (prescribed MRS for 1 hour every morning) and the non-MRS group. Data collection consisted of anthropometrics, medical history, home sleep studies, questionnaires, dental exam variables, objective and subjective side effects, adherence, and titration factors. The study was approved by the UBC Ethical Committee (CREB NUMBER: H17-02727).

Results: Forty-eight OSA patients referred to OA treatment (26 males and 22 females, 57.1± 8.4 years, BMI 27.7 ± 4.1 kg/m^2, AHI 11.7/h) were randomized into the MRS group (23 patients) and control group (25 patients). The distribution age, BMI, AHI, ESS, FOSQ, OJ, OB, and Angle classification at baseline were similar in 2 groups except that more males were in the MRS group (74% vs 36). The subjective frequency and severity of the side effects were not significantly different between the two groups at 1-year follow-up. Subjective bite changes were perceived as often/always and disturbing in 13% of the MRS group and 24% in the control group. Discomfort or pain in the jaws was described as often/always disturbing in 24% of the MRS group and 8 % in the control group. The changes in intercanine, intermolar distance, overbite, and overjet were not significantly different between the two groups in 18 patients. Only 13 out of 18 patients underwent the occlusal contact analysis. In the MRS group, 6 patients showed a decrease in occlusal contact points by 23 points which went from 94 (baseline) to 71, whereas in the non-MRS group, the 5 patients showed a decrease in occlusal contact points by 50 points which went from 115 (baseline) to 65 points.

Conclusions: This is the first randomized controlled study analyzing MRS use with OA. We found no significant improvement in subjective side effects with MRS at one-year follow-up. However, the MRS group showed fewer changes in occlusal contact points than the non-MRS group after the initial 12 months of OA treatment.

Support:
AADSM funded this project.
Alpha Omega Foundation, Canada
Scholarship Department, Ministry of Higher Education, Libya

ABSTRACT #029

COMPARISON OF CONSUMER TECHNOLOGIES TO A TYPE II HOME SLEEP APNEA TEST

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Introduction: There has been an explosion in over-the-counter consumer goods targeted for use in obstructive sleep apnea and snoring. These devices are rarely tested for accuracy against gold standards and yet many are marketed as being able to detect and diagnose obstructive sleep apnea (OSA) in the absence of trained health care providers. This study initiates a research line designed to

test devices against two gold standards: (1) in-lab polysomnography (PSG) and (2) type II home sleep apnea testing (HSAT). Specifically, it examines two devices, an O2 ring and a phone app, compared to the two gold standards. The presented study will focus on comparisons involving the HSAT, where comparisons occurred over the same one-night time period.

Methods: Candidates responded to advertisements in the University of Michigan Schools of Dentistry and Medicine. Candidates participated if they met inclusion and exclusion criteria, including presence of no medical contraindications for participating in HSAT. Our goal is ultimately to achieve ~ 40 patients in each of the following four groups: no OSA (AHI 0-5), mild OSA (AHI 5.1-15), moderate OSA (AHI 15.1-30), or severe OSA (AHI $\geq$ 30) OSA. Consented subjects used five devices while sleeping at home: (1) a type II HSAT, (2) an O2 ring, (3) a phone app measuring snoring, (4) an EMG recorder that recorded activity in bilateral masseter masseters and medial cervical muscles at the level of the thyroid notch, and (5) a night-vision camera with sound. The presented study compared HSAT standard outcomes, viz., AHI, O2 time < 90%, and time snoring, to the consumer-available outcomes of the phone app and O2 ring. Z-scores were used to calculate Lin's Concordance Correlation Coefficient (ρC) and Pearson ρ (a measure of precision) using MedCalc (v.22.016) software. At present, the below results are based on 15 subjects, three with no OSA, seven with mild OSA, four with moderate OSA and one with severe OSA.

Results: Bivariate comparisons, Lin's Concordance Correlation Coefficient ρC and Pearson ρ results were as follows: HSAT-based AHI 3% O2 desat versus ring-based ODI O2 3% desat, ρC = 0.544, Pearson ρ = 0.55; O2 time < 90% for HSAT versus ring, ρC = 0.75, Pearson ρ = 0.75; total time snoring HSAT versus Snore App, ρC = 0.14, Pearson ρ = 0.14).

Conclusions: The results comparing the outputs from the ring or phone app with the HSAT data indicate very low precision. The z-score statistics were used because raw values of the ring and phone app were highly inaccurate compared with the HSAT. Future work will focus on models where consumer-available output from both the ring and phone app will be combined to improve accuracy and precision.

Support: Support was generously provided by the American Academy of Dental Sleep Medicine.

ABSTRACT #030

EFFICACY OF COMBINATION THERAPY WITH A NOVEL ACCESSORY WITH THE NOVEL ORAL APPLIANCE IN MILD AND MODERATE OBSTRUCTIVE SLEEP APNEA – A CLINICAL TRIAL

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Introduction: CPAP remains the most used option for treating moderate to severe OSA while custom fit MADs are used primarily for mild to moderate OSA. MADs work by modifying the upper airway by changing the position of the mandible and tongue. O2Vent Optima is a novel oral appliance that incorporates both mandibular advancement to reduce pharyngeal collapsibility and an air channel that allows airflow through the device to circumvent nasopharyngeal obstruction. Previous studies have established superiority of the air channel of novel appliance in the treatment of OSA. The ExVent is an optional accessory to the novel mandibular advancement device (MAD) and provides oral Expiratory Positive Airway Pressure (EPAP). Oral EPAP with the accessory is designed to provide upper airway support via similar mechanisms of action of nasal EPAP devices in commercial distribution, e.g., passive dilatation of the airway, which reduces flow limitation.

The study purpose was to assess efficacy of the combination therapy with novel mandibular advancement device and novel oral EPAP accessory as compared to the novel oral appliance in mild and moderate OSA.

Materials and Methods: A prospective, open-label study conducted at 3 sites included subjects with mild to moderate OSA (AHI $\geq$ 5 and $\leq$ 30).

Screening Phase A diagnostic in-lab PSG study was performed to confirm a diagnosis of mild to moderate OSA.

Treatment Phase I Subjects used novel oral appliance for 6 weeks and underwent an in-lab PSG sleep night while using the novel oral appliance.

Treatment Phase II Subjects used novel oral appliance and novel accessory for 6 weeks and underwent an in-lab PSG sleep night while using the combination therapy.

Primary Efficacy Measure: Change in AHI between baseline vs. novel oral appliance vs. combination of novel oral appliance and novel accessory.

Results: In 22 participants, treatment with novel oral appliance and combination therapy with novel oral EPAP appliance and novel accessory reduced AHI from 22.5±6.4/hr to 12.6±4.5/hr to 5.9±2.7/hr ($p < 0.005$ baseline

vs. novel oral appliance and novel oral appliance and novel accessory; p<0.05 novel oral appliance vs. combination therapy). Average reduction in AHI with novel oral appliance was 43% and with combination therapy was 72%. The lowest oxygen during sleep increased from 84.6±2.7% to 88.6±2.9% to 91.6±3.2% (p< 0.005 baseline vs. novel oral appliance and combination therapy p<0.05 novel appliance vs. combination therapy). Patients on treatment with novel appliance and combination therapy demonstrated no excessive adverse events or device malfunction.

Conclusions: The novel oral appliance incorporates both mandibular advancement to reduce pharyngeal collapsibility and an air channel that allows airflow through the device to circumvent nasopharyngeal obstruction. In the current study, both the novel oral appliance and combination therapy with novel appliance and novel oral EPAP accessory significantly improved OSA compared to the baseline. A greater benefit was observed with the addition of novel oral EPAP accessory to the novel oral appliance in mild to moderate OSA.

Support: Centre for Sleep and Chronobiology, Toronto, ON, Canada

ABSTRACT #031

ASSESSMENT OF SLEEP APNEA-SPECIFIC HYPOXIC BURDEN (SASHB) WITH COMBINATION THERAPY WITH NOVEL ORAL APPLIANCE AND NOVEL ORAL POSITIVE EXPIRATORY PRESSURE ACCESSORY

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Introduction: Evidence suggests that moderate to severe OSA patients have increased risk of major adverse cardiovascular events (MACE; composite of coronary heart disease, heart failure, stroke, or cardiovascular mortality) and that sleep apnea-specific hypoxic burden (SASHB) is associated with increased risk of cardiovascular disease mortality. SASHB appears to be more predictive of OSA-related risk than AHI but has not been extensively studied as a measure of therapeutic efficacy in patients treated with oral appliance therapy.

O2Vent Optima is a novel oral appliance that incorporates both mandibular advancement to reduce pharyngeal collapsibility and an air channel that allows airflow through the device to circumvent nasopharyngeal obstruction. The ExVent is an optional accessory to the novel oral appliance and provides oral Expiratory Positive Airway Pressure (EPAP) to support upper airway by passive dilatation of the airway, which reduces flow limitation.

This is the first assessment of combination therapy with novel oral appliance combined with an Oral EPAP accessory to reduce SASHB, rather than AHI, to define therapeutic efficacy.

Materials and Methods: Data obtained from a clinical study to assess efficacy of the combination therapy with novel mandibular advancement device and novel oral EPAP accessory in the treatment of OSA were analyzed. Twenty-four study participants with OSA (mild = 10, moderate = 14) completed a diagnostic PSG study to obtain the baseline AHI and confirm a diagnosis of mild to moderate OSA. Subjects used the combination tehrapy at home for >3 months and logged usage hours. Subsequent to the home Use, subjects underwent an in-lab PSG sleep night while using the combination therapy.

Results: Treatment with the combination therapy with novel mandibular advancement device and novel oral EPAP accessory reduced AHI from 22.5±6.4/hr. to 7.9±2.7/hr. (p< 0.001) and SASHB from 62.3 ± 34.1 %min/hr. to 18.7 ± 25.4 %min/hr. (p < 0.001). Average reduction in AHI with the combination therapy was 72%. Using an AHI-based definition of therapeutic efficacy (AHI < 10/hr.), 76% of participants achieved efficacy with the combination therapy. However, when the risk based SASHB definition of therapeutic efficacy (SASHB < 53 %min/h) was utilized, therapeutic efficacy with combination therapy with novel mandibular advancement device and novel oral EPAP accessory increased to 94%.

Conclusions: Therapeutic efficacy with combination therapy with novel mandibular advancement device and novel oral EPAP accessory significantly improved to 94% by SASHB criteria as compared to 72% by AHI reduction criteria. Our study demonstrated that the use of AHI measurement would have misclassified a substantial number of individuals who responded to the combination therapy with novel mandibular advancement device and novel oral EPAP accessory based on more meaningful SASHB reduction of OSA-related risk.

Support: Centre for Sleep and Chronobiology