ABSTRACTS

http://dx.doi.org/10.15331/jdsm.7298

2023 AADSM Annual Meeting Abstracts and Case Reports

Disclaimer: The following are the abstracts and case reports accepted for the 2023 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.

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

ABSTRACT #001

ROOT LENGTH CHANGES ASSOCIATED WITH THE USE OF MANDIBULAR ADVANCEMENT DEVICE IN CONJUNCTION WITH MORNING REPOSITIONERS

Aram S. Alnoury, BDS, MsC,[1] Ahmed I Masoud BDS, MS, PhD,[1] Doaa H Alsaggaf, BDS, DScD,[1]
[1] Department of Orthodontics, Faculty of Dentistry, King Abdulaziz University, Jeddah, Saudi Arabia

Introduction: Obstructive sleep apnea (OSA) is a common disorder featured by upper airway obstruction completely or partially during sleep. Mandibular Advancement Device (MAD) is one of the treatment modalities for mild to moderate OSA patients. Morning repositioner was used to counteract the dental side effects of MAD such as labial tipping of the lower incisors and lingual tipping of the upper incisors. This back and forth phenomena called jiggling and it might cause root resorption. The aim of this study is to evaluate root lengths changes associated with the use of oral appliances to treat obstructive sleep apnea (OSA) in conjunction with morning occlusal guides.

Methods: The sample included panoramic radiographs of 68 patients (age 40-70 years) who have been wearing oral appliances to treat obstructive sleep apnea, followed by morning occlusal guides, for up to 5 years. Adobe photoshop was used to measure root and crown lengths to assess root to crown (R/C) ratios before the start of oral appliance use (T1) and after 3 to 5 years of appliance wear (T2).

Results: Paired sample t-test showed statistically significant differences between the R/C ratios at T1 compared to T2 for multiple teeth ($p < 0.05$). The greatest changes were found in lower central incisors, ($p \leq 0.001$) with a mean difference in R/C ratio of 0.1 and in lower left first molars, ($p \leq 0.004$) with a mean difference in R/C of 0.1.

Conclusion: Root length changes were found in patients using oral appliances to treat obstructive sleep apnea (OSA), in conjunction with morning occlusal guides. Although root length changes may not be clinically significant, new consent forms should be developed to make patients aware that root resorption may occur during treatment.

Support: None

ABSTRACT #002

PREDICTORS OF FIRST-ONSET TEMPOROMANDIBULAR DISORDERS DURING MANDIBULAR ADVANCEMENT DEVICE THERAPY FOR OBSTRUCTIVE SLEEP APNEA

Anna Alessandri Bonetti[1,2], Linda Sangalli[1,3], Isabel Moreno Hay[1]
[1] Orofacial Pain Clinic, University of Kentucky, Lexington, Kentucky, USA.; [2] Institute of Dental Clinic, A. Gemelli University Policlinic IRCCS, Catholic University of Sacred Heart, Rome - Italy.; [3] College of Dental Medicine – Illinois, Midwestern University, Downers Grove, Illinois, USA.

Introduction: First-onset temporomandibular disorders (TMDs) have been shown to develop in some patients

during mandibular advancement device (MAD) therapy for obstructive sleep apnea (OSA). Although TMDs are often self-limiting, they can lead to therapy discontinuation in some patients.

The aim of this study was to investigate possible predictors of first-onset TMDs from the clinical examination findings. The hypothesis was that patients reporting pain upon palpation of the masticatory muscles and/or TMJ at baseline would present greater risk of developing TMD during MAD therapy.

Methods: Retrospective data were collected from 219 TMD-free adult patients (119 males, 99 females; mean age: 56.1±14.3, mean apnea-hypopnea index: 19.0±14.9) referred to the Orofacial Pain Clinic at University of Kentucky for the management of OSA with MAD. All patients underwent a complete TMD examination according to the DC/TMD protocol at baseline and at each follow-up. Variables recorded were: pain evoked by mouth opening and/or palpation of temporalis, temporal tendon, masseter, SCM, anterior digastric, and TMJ; range of mandibular excursion; and TMJ sounds. At the follow-ups, two groups were created and assigned a value of 1 = first-onset TMDs, and 0 = TMD-free. For this analysis, the patients that developed first-onset TMD at any of the follow-up were classified as first-onset TMD. Chi-square and Fisher's Exact tests were used as appropriate to compare the two groups in the variables analyzed at baseline (α=0.05).

Results: Out of 219 TMD-free adults at baseline, 129 patients (58.9%) never presented TMDs at any of the follow-up, while 90 patients (41.1%) developed fist-onset TMDs. Participants were followed on average for 1.5 years after delivery of the MAD. Those who developed first-onset TMDs presented at baseline with significantly higher presence of TMJ sounds (20.7% vs 9.7%, $X^2(1)=4.99$, p=.026, OR=2.44 (95% CI 1.10, 5.43)), pain upon palpation of temporalis muscles (7.1% vs 0.8%, p=.018, OR 9.49 (95% CI 1.12, 80.3)), temporal tendon (15.3% vs 4.8%, $X^2(1)=6.87$, p=.009, OR=3.61 (95% CI 1.32, 9.92)) or masseter muscle (8.2% vs 1.6%, p=.032, OR=5.61 (95% CI 1.14, 27.7)). Also patients developing first-onset TMD presented at baseline with statistically less mouth opening (47.9±4.5 vs 49.7±5.2 mm, $t(200)=2.39$, p=.018) compared to patients not developing TMDs.

Conclusions: Presence of TMJ sounds, pain upon palpation of temporalis muscle, and less mouth opening at baseline were significantly more common in those patients that later developed first-onset TMDs during MAD therapy, and more likely predicted first-onset TMDs. Patients with such clinical findings at baseline should be carefully monitored during MAD therapy to manage any potential TMDs.

Support: None

ABSTRACT #003

THE IMPACT OF INCREMENTAL INCREASES IN VERTICAL DIMENSION OF OCCLUSION ON THE RELATIONSHIPS BETWEEN PRE- AND POST-TREATMENT AHI VALUES AND ACOUSTIC PHARYNGOMETER MEASURES

Daniel J. Levendowski MBA[1], Jonathan Lown MD[2], Todd Morgan DMD[3], Gandis Mazeika MD[1]
[1]Advanced Brain Monitoring, Inc., [2]Delta Sleep Center, [3]Todd Morgan Dental Corp.

Introduction: Acoustic pharyngometry uses sound waves to reliably measure the airway length and volume. It was previously demonstrated that the minimal cross-sectional area (MCA) at functional residual capacity (FRC) could differentiate mild from moderate-severe obstructive sleep apnea. This study was designed repeat the procedure in order to replicate the finding, and to assess the relationships between treatment outcomes achieved while sleeping with oral appliances (OA) at incrementally increased vertical dimension of occlusion (VDO) and acoustic pharyngometer values obtained at baseline and while wearing the OAs.

Methods: Seven females and 14 males (age=54±8.7) completed the entire protocol. Subjects wore the ARES Unicorder to derive AHI measures: a) at pre-treatment baseline, b) with an OA at 5mm VDO (OA-5mm) across multiple nights to determine the optimal protrusion, and c) with an OA at 10mm VDO (OA-10mm) at the OA-5mm protrusion.

Acoustic pharyngometer measures were acquired at baseline while seated: a) during tidal breathing and b) at functional residual capacity (FRC). These procedures were repeated while wearing the: a) OA-5mm and b) OA-10mm. Eccovision software providing Mean-Area, Minimum Cross-sectional Area (MCA), and Distance-to-MCA values, for all measures and conditions, resulting in a total of 18 values per subject.

Statistical analyses included Fisher-Exact probability and Mann-Whitney U-Tests. Pearson correlations were used to measure the association between the AHI and acoustic pharyngometer values. Multiple logistic regressions utilized an AHI reduction ≥50% as the endpoint.

Results: OA outcomes The mean AHI decreased from a baseline of 22±15.1 events/hour to: a) 8.7±4.4 with an OA-5mm, and b) 8.6±4.9 with an OA-10mm (P<0.001). The association between the with OA-5mm and OA-10mm AHI values were strong (r=0.70, P<0.0001). Of

the 21 cases, 57% exhibited a successful outcome with an OA-5mm and 67% with an OA-10mm. No significant sex-related differences were observed in the baseline, OA-5mm and OA-10mm AHI values or the in proportion of males and females who responded with OA-5mm and OA-10mm.

Associations between AHI and Acoustic Pharyngometer values The MCA values during tidal breathing at baseline were significantly associated with the OA-5mm AHI values (r=0.46,P<0.05). The Distance-to-MCA values obtained while wearing the OA-5mm and tidal breathing were associated with the OA-10mm AHI values (r=0.55, P=0.01).

Predicting OA Outcomes Based on logistic regression, Distance-to-MCA at FRC while wearing the OA-10mm was independently associated with ≥50% AHI reduction while sleeping with the OA-10mm (P=0.03, odds=0.51, 95%CI: 0.28-0.94).

Conclusions: We were unable to replicate the association between MCI at FRC and pre-treatment AHI value, however the Distance-to-MCA at FRC with an OA-10mm inserted was strongly associated with outcome while wearing the OA-10mm. We also identified acoustic pharyngometer measures acquired during tidal breathing that were associated with post-treatment AHI values impacted by different VDO settings.

While this pilot study takes a step toward establishment of acoustic pharyngometer parameters that could assist with VDO selection, these findings should be interpretated with caution given the small sample contributed to relatively low statistical power.

Support: This study was funded by the National Institute of Dental and Craniofacial Research grant R44DE016772.

ABSTRACT #004

A PILOT INVESTIGATION TO DETERMINE IF ORAL APPLIANCES AT INCREMENTALLY INCREASED VERTICAL DIMENSIONS OF OCCLUSION PROMOTES PROPORTIONATE CHANGES IN OSA SEVERITY AND ACOUSTIC PHARYNGOMETER MEASURES

Daniel J. Levendowski MBA[1], Jonathan Lown MD[2], Todd Morgan DMD[3], Gandis Mazeika MD[1]
[1]Advanced Brain Monitoring, Inc., [2]Delta Sleep Center, [3]Todd Morgan Dental Corp.

Introduction: Acoustic pharyngometry previously differentiated mild from moderate-severe OSA using the minimal-cross-sectional area (MCA) at functional residual capacity (FRC). When used to guide oral appliance (OA) therapy, ideally, pharyngometer measures would change after insertion of an OA at different vertical dimensions of occlusion (VDO) proportionate to the corresponding changes in OSA severity.

Methods: Seven females and 14 males (age=54±8.7/years) wore the ARES Unicorder to derive apnea-hypopnea index (AHI) measures: a) at pre-treatment baseline, b) with an OA at 5mm VDO across multiple nights to select the optimal protrusion (OA-5mm), and c) with an OA at 10mm VDO and at the same protrusion as optimal for the OA-5mm (OA-10mm). Hypopneas were based on the 4% SpO_2 criteria.

Pharyngometer measures were acquired while seated: a) during tidal breathing and b) at FRC at baseline. These conditions were repeated after insertion of the: a) OA-5mm and b) OA-10mm. Eccovision® software was used to calculate the MCA, Mean-Area, and Distance to MCA (Distance) values during tidal breathing and at FRC for all three conditions.

Pharyngometer change-scores were calculated using differences between the baseline values and those obtained with the inserted a) OA-5mm or b) OA-10mm, for a total of 18 change-scores per subject. Analyses included Mann-Whitney U-tests, Pearson correlations, linear regressions, and receiver operating characteristic (ROC) curves.

Results: The mean AHI decreased from a baseline of 22±15.1 events/hour to: a) 8.7±4.4 with an OA-5mm, and b) 8.6±4.9 with an OA-10mm (both P<0.001). The association between pre-treatment AHI values and OA-10mm AHI values (r=0.40, P<0.07) strengthened with only males compared ((r=0.63, P<0.02).
An increase in VDO from OA-5mm to OA-10mm resulted in an AHI improvement ≥4 event/hour in three males and worsening using the same threshold in two females.

In males, the percent changes in OA-10mm AHI values were significantly associated with Mean-Area change-scores during tidal breathing while wearing the OA-10mm (r=-0.69, P=0.007), but not with the OA-5mm (r=-0.49, P=0.078).

The Mean-Area change-scores while wearing the OA-5mm and OA-10mm were linearly regressed to the corresponding percent AHI decreases across all patients, and only with males. ROC curves then compared the regression-derived predicted percent AHI changes (based

on Mean-Area change-scores) to actual AHI changes ≥50%. With OA-10mm, ROC curves increased from 0.56 when fitted across all subjects to 0.91 when fitted exclusively to males, while the corresponding OA-5mm ROC curves increased from 0.47 to 0.62.

Conclusions: Novel transformations of pharyngometer values demonstrated that, in optimally protruded male patients, negative Mean-Area change-scores could predict AHI changes with OA-10mm, but not with OA-5mm or in females. These findings suggest OA outcomes may be enhanced with increased VDO in males and confounded in females. Given the central airways of females are 20-35% smaller than males, these findings further suggest that differences in airway anatomy may need to be considered when interpreting pharyngometer values. Pilot study limitations included a small sample size acquired under controlled OA-VDO and -protrusive conditions, and inclusion of pharyngometer measures during tidal breathing, which may have different degrees of repeatability compared to FRC.

Support: NIDCR-R44DE016772.

ABSTRACT #005

MOUTHGUARD MECHANICAL PROPERTIES RELATED TO CRANIOFACIAL INJURIES AND OSA WEAR

Cole Duncan[1] , Logan Buerk[2]
[1,2] Southern Illinois University-School of Dental Medicine (Alton, IL)

Introduction: Previous studies have supported the use of mouthguards across multiple sports in preventing craniofacial injuries including orofacial lacerations, mandibular dislocations, temporomandibular joint (TMJ) trauma, and tooth fractures. While it is clear that, in general, use of mouthguards for sports is well supported, it is less clear what specific parameters of a particular mouthguard are needed to prevent severe craniofacial injuries. The same can be said for oral sleep appliances (OSA) in terms that their usage is well supported, but it is less clear what material is needed to best prevent bruxing wear. To measure retentive features of mouthguards, lateral and anterior /posterior (AP) displacement are most used, although it's a subpar method of measuring retention at best. There is no universal measurement for impact resistance in terms of mouthguards although it is most commonly tested through pendulum hits measured by triangulation laser sensors. Our method of applying increasing compressive strength closely approximates those experienced during sport and bruxing activities.

Methods: Compressive forces will be applied to each of three mouthguards until the point of permanent deformation. The tested mouthguards will include the (1) Game-On mouthguard composed of a propylene-based elastomer, (2) SISU Aero Guard composed of a patented thermoplastic elastomer based material (T.P.E.), and (3) a conventional ethylene vinyl acetate (E.V.A.) material. The goal of this study is to compare the physical capabilities of three different mouthguard materials (more specifically the compressive strength) in order to investigate which material resists permanent deformation under greater compressive strengths such as those exerted during sport activities or bruxing. The acquired data will be related to desirable properties of mouthguards to better prevent orofacial injuries and wear of OSA appliances. The compressive strength of each mouthguard will be measured using an Electro-Mechanical Load Frame (60,000lb load capacity) equipment housed in the engineering department at Southern Illinois University at Edwardsville (SIUE). Increasing levels of tensile force will be applied to each of the three mouthguards with the Instron until permanent deformation is observed. These tensile strengths are directly correlated to deformative properties of these materials, which have a significant effect in the amount of biomechanical force they can handle in relation to protective properties.

Results: Resulting data suggests E.V.A. based mouthguards (218,389 kPa) display resistance to deformation at higher compressive strengths when compared to the propylene-based elastomer (128,780 kPa) or T.P.E. based materials (138,841 kPa). At a significant p- value ($a<.05$) there is a clinically significant difference between the compressive strain of EVA as compared to the other materials ($p=0.00683861$). Approximately 0.6% of distribution may be attributed to random chance.

Conclusions: These findings suggest E.V.A. material has the potential to significantly outperform the involved related materials in terms of absorptive qualities upon compressive load during sport activities and bruxing.

Support: Dr. Cinnamon Van Putte, Dr. Jagath Gunasekera, and Dr. Paul Nativi (DMD)

ABSTRACT #006

PRECISION VS. TRADITIONAL ORAL APPLIANCE THERAPY: A COMPARISON OF THERAPEUTIC EFFICACY

Erin Mosca, PhD[1], John Remmers, MD[1]
[1] ProSomnus Sleep Technologies

Introduction: Oral appliances (OAs) for the treatment of

obstructive sleep apnea (OSA) are often considered equivalent to one another; the mechanisms of action, i.e., protrusion of the mandible and attachment to the teeth, are generally similar amongst most OAs. However, differences in appliance design, material, titration mechanism, and manufacturing techniques do exist, and they could impact treatment efficacy. The objective of this study was to determine if precision OAs, defined as those that use digital manufacturing processes that replicate the bite position (bite transfer) with a high level of accuracy, differ in efficacy from traditional OAs, defined as those that use fully or partially non-digital manufacturing processes and bite transfer.

Methods: Published literature and abstracts presented at scientific meetings were systematically reviewed. Sources were included if they used a commercial OA, stratified data by OSA severity, and specified the criterion used to define therapeutic success (e.g., apnea-hypopnea index [AHI] < 10 h^{-1}).

Results: Fifteen sources were identified for mild/moderate OSA and 12 sources were identified for severe OSA. In mild/moderate OSA, the median efficacy was 92% (range: 85-98%) for precision and 75% (range: 30-85%) for traditional OAs. In severe OSA, the median efficacy was 59% (range: 52-76%) for precision and 50% (range: 38-61%) for traditional OAs. Of note, in studies that separately presented data for mild OSA, precision OAs were efficacious in 100% of individuals (five sources; pooled n = 109) while traditional OAs were only efficacious in 85% of individuals (seven sources; pooled n = 355).

Conclusions Precision OAs appear to be more efficacious than traditional OAs. Further studies are required to directly compare efficacy between the two types of OAs and to elucidate possible causes of this apparent difference.

Support: The authors are employees of ProSomnus Sleep Technologies.

ABSTRACT #007

ORAL APPLIANCE NETWORK ON GLOBAL EFFECTIVENESS (ORANGE) FOR OBSTRUCTIVE SLEEP APNEA SYNDROME: AN UPDATE OF A MULTICENTER COHORT STUDY

Yanlong Chen[1], Fernanda R. Almeida[1], Nelly T. Huynh[2], Marijke Dieltjens[3], Olivier M. Vanderveken[3], Kate Sutherland[4], Peter Cistulli[4], Ghizlane Aarab[5], Frank Lobbezoo[5], Zhengfei Huang[5]

[1]University of British Columbia, Vancouver, BC, Canada; [2]Université de Montréal, Montreal, QC, Canada; [3]University of Antwerp, Antwerp, Belgium; [4]University of Sydney, Sydney, NSW, Australia; [5]Academic Centre for Dentistry Amsterdam (ACTA), The Netherlands

Introduction: Oral Appliance Network on Global Effectiveness (ORANGE) is a multinational, multicenter observational cohort study developed to evaluate the long-term effectiveness of oral appliance (OA) therapy in patients with obstructive sleep apnea (OSA), and to assess long-term health outcomes of OA therapy related to cardiovascular disease. This study started with support of the American Academy of Dental Sleep Medicine (AADSM) and included 5 centers from 4 countries in the development phase.

Methods: Patients older than 19 years old and eligible for OA therapy will be recruited from all centers and followed for 5 years. During the 5 years study there will be a minimum of 6 follow-up clinic visits (baseline, 3-month, 6-month, 1-year, 3-year, and 5-year) and 2 phone follow-ups (2-year and 4-years).

During each visit, data of anthropometrics, medical history, sleep tests, questionnaires, dental exam variables, objective and subjective side effects, adherence, and titration factors will be collected. Anonymous and standardized data will be entered and stored in a secure server at the University of British Columbia. Additionally, the long-term cardiovascular incidents will be monitored by linking the patient information to country databases when possible.

OA treatment efficacy will be quantified by comparing predictors of treatment outcome to baseline, including the severity of sleep disordered breathing, improvement of symptoms, improved health outcomes and adherence. All predictors will be analyzed in relation to background data and living habits. In a parallel assessment, the cost effectiveness of treatment will also be analyzed.

Results: By November 2022, a total of 163 patients from 4 research centers have been entered into the database. Through initial analysis of baseline data, there are 128 male and 35 female, with a mean ± SD age of 48.9 ± 11.4 years and mean BMI ± SD of 27.7 ± 4.1 kg/m^2. 84.5% of the patients had snoring as their main complaint; 7.8%, daytime sleepiness. The mean ESS ± SD score was 8.9 ± 5.4.

Among the patients (N = 134) with a baseline sleep study, the mean ± SD AHI was 18.12 ± 13.22; the mean ± SD ODI (3%), 10.31 ± 11.43. There were 25, 53, and 63 patients diagnosed with mild, moderate, and severe OSA, respectively. Most patients (87.3%) were prescribed with a custom-made, titratable oral appliance, and would perform titration in the follow-up visits.

Conclusion: ORANGE has started its data collection from centers spread across the globe. This will provide a unique opportunity for healthcare researchers to explore the effectiveness and cardiovascular outcomes of OA therapy in OSA patients. Current efforts are expected to facilitate funding opportunities and enlarge the number of centers and patients in the cohort.

Support: Protocol development supported by AADSM.

ABSTRACT #008

COMPARISON OF CLINICAL EFFECTIVENESS AND PATIENTS' PREFERENCE FOR TWO NON-INVASIVE TREATMENT OPTIONS FOR PATIENTS DIAGNOSED WITH MODERATE TO SEVERE OBSTRUCTIVE SLEEP APNEA: THE FLOSAT STUDY

Marijke Dieltjens[1,2], Shouresh Charkhandeh[1], Karlien Van den Bossche[2], Sanne Engelen[2], Dorine Van Loo[2], Johan Verbraecken[3], Marc J. Braem[2], Olivier M. Vanderveken[1,2]

[1]Translational Neurosciences, Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium; [2]Department of ENT, Head and Neck Surgery, Antwerp University Hospital, Edegem, Belgium; [3]Multidisciplinary Sleep Disorders Centre, Antwerp University Hospital, Edegem, Belgium.

Introduction: Continuous positive airway pressure (CPAP) is generally recommended as a first-line treatment option for patients with moderate to severe obstructive sleep apnea (OSA), while mandibular advancement device (MAD) therapy is frequently seen as second-line when CPAP is discontinued. A more personalized approach could be selecting the therapy best matched to the individual patient's medical profile and preference. The aim of this clinical trial is to compare the clinical effectiveness of both MAD and CPAP therapy in a cross-over setting, while asking for the patients' preference at the end of the study.

Methods: Patients diagnosed with moderate to severe OSA fulfilling the inclusion criteria (body mass index (BMI)<35 kg/m², 15 events/hour≤obstructive apnea/hypopnea index (oAHI)<65 events/hour of sleep, central AHI<30% of total AHI, no history of CPAP or MAD) were contacted to start MAD therapy for three months (ProSomnus EVO Sleep and Snore Device, ProSomnus Sleep Technologies) as a first-line treatment option with measurement of objective adherence using an embedded active thermomicrosensor (Theramon, MC Technology GmbH), followed by polysomnographic evaluation. Subsequently, after a two-week wash-out period, all participants underwent CPAP treatment for three months, followed by a polysomnography and read-out of the objective adherence. At the end of the study, patients' preferences (MAD, CPAP or no preference) was recorded. Data are presented as median (quartile 1, quartile 3) if not normally distributed and as mean±standard deviation if normally distributed. Thereafter, mean disease alleviation (MDA) was calculated as the product of efficacy and compliance in an intention-to-treat analysis.

Results: To date, 130 patients have been included in this ongoing clinical trial. Twenty-three of these patients (78% male, age: 49±11 years, BMI: 27.8±3.5 kg/m², AHI: 22.9 (16.9; 31.9) events/hour) completed all study visits up till now, including the questioning on patient's preference. Overall, AHI decreased significantly from 22.9 (16.9; 31.9) events/hour to 8.0 (4.8; 11.7) events/hour with MAD (p<0.001) and to 1.4 (0.3; 3.9) events/hour with CPAP (p<0.001). Four patients (17%) failed to comply with CPAP therapy where all patients complied with MAD therapy. In an intention-to-treat analysis, the average use was 6.6±1.6 hours/night for MAD therapy which was significantly higher than the 4.5±2.7 hours/night for CPAP therapy (p=0.018). The resulting MDA was 64.5±26.7% for MAD and 57.8±35.7% for CPAP (p=0.524). Regarding patients' preference: 13 patients (56.5%) had a preference for MAD, where 8 patients (34.7 %) preferred CPAP and 2 patients (8.8 %) expressed no preference.

Conclusion: In this ongoing clinical trial, MAD therapy as a first-line treatment option showed a good efficacy in reducing AHI, combined with high patient adherence which was two hours higher as compared to the average CPAP use in an intention-to-treat analysis. This in turn resulted in a comparable overall effectiveness for MAD therapy vs CPAP. Finally, there was a higher preference rate for MAD compared to CPAP.

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

ABSTRACT #009

PULSE RATE AND OXYGEN SATURATION VARIABILITY PREDICT CHANGES IN APNEA-HYPOPNEA INDEX VARIATIONS IN THE COURSE OF ORAL APPLIANCE THERAPY FOR THE MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA: A PILOT STUDY

Diego Fernandez-Vial[1], Fernanda Yanez-Regonesi[1], Sara Pasha[2], Ian Boggero[1], Jeffrey Okeson[1], Eduardo Vazquez[3], Isabel Moreno-Hay[1]

[1]Orofacial Pain Center, University of Kentucky College of Dentistry, Lexington, USA; [2]Internal Medicine, University of Kentucky College of Medicine, Lexington, USA;

[3]Craniomandibular Institute, Barcelona, Spain.

Introduction: There is a need for simple and reliable methods to assist in the titration of mandibular advancement devices (MADs) to determine the amount of protrusion required to achieve the maximal therapeutic benefit. Several predictive factors have been studied previously with inconclusive results, thus, a sleep study with the MAD in situ remains the most reliable method to this date. Aim: To describe the reliability of pulse rate and oxygen saturation variability as biomarkers to predict changes in the apnea-hypopnea index (AHI) during the titration of MADs for the management of mild-to-moderate obstructive sleep apnea (OSA).

Methods: Preliminary data from participants diagnosed with mild-to-moderate OSA enrolled in an ongoing clinical trial between January 2022 and September 2022 were obtained. Excluded participants that presented with any other concomitant sleep disorder, use of antiarrhythmic drugs, and/or any pathologies related to pulse rate changes. Procedures: All the participants received a MAD at 50% of the mandibular protrusive range. Additional advancements were performed on a rate of 10% every 14-21 days until reaching treatment success. Successful management was considered when the following 3 criteria were met: (1) residual AHI<5 measured using a HSAT (manually scored; 3% desaturation cutoff), (2) Epworth Sleepiness Scale <10, and (3) 70% reduction of snoring, observed apneic events, and daytime fatigue as reported by the patient in a numerical rating scale. Variables considered for analysis: age, sex, BMI, AHI, AHI reduction (ΔAHI; %), level of mandibular advancement (%Adv; %), mean pulse rate (PR-m; bpm), highest pulse rate (PR-h), lowest pulse rate (PR-l), pulse rate variability (PR-v=(PR-h)–(PR-l)), mean oxygen saturation (SpO2-m; %), highest oxygen saturation (SpO2-h), lowest oxygen saturation (SpO2-l), oxygen saturation variability (SpO2-v=(SpO2-h)–(SpO2-l)), pulse rate variability variation (ΔPR-v=($_{initial}$PR-v)–($_{final}$PR-v)), and oxygen saturation variability variation (ΔSpO2-v=($_{initial}$SpO2-v)–($_{final}$SpO2-v)). Significance was set at $p<.05$.

Results: Fourteen participants met the inclusion criteria (42.9% males, Age_{mean}=55.14, BMI_{mean}=31.01, AHI_{mean}=10.98). Using paired-samples t-tests to compare values at pre- and post-evaluation, no significant changes were found for BMI, PR-m, PR-h, PR-v, SpO2-m, SpO2-h, SpO2-l, and SpO2-v. However, AHI significantly reduced ($t(13)=4.092$, $p<.001$) and the PR-l increased ($t(13)=-.227$, $p=.044$). %Adv and ΔAHI were uncorrelated but significant correlations were found between ΔAHI and both ΔHR-v ($r(12)=0.588$, $p=.027$) and ΔSpO2-v ($r(12)=.659$, $p=.01$). When entered as simultaneous predictors in a multiple linear regression, ΔHR-v and ΔSpO2-v together significantly predicted ΔAHI ($F(2,11)=5.52$, $p=.022$, $R^2=.50$), however, neither variable were independently associated with ΔAHI (β=0.32, p=.25 for ΔHR-v and β=0.48, p=.09 for ΔSpO2-v).

Conclusions: This pilot study found that pulse rate and oxygen saturation variability predict changes in AHI during the titration of MADs. Further research is needed to replicate these initial results, including a larger sample size and a control group. If these biomarkers show adequate reliability, some simple and inexpensive electronic devices already available in the market could be tested and then used to monitor these changes in clinical settings.

Support: The MADs were provided by the OrthoApnea® laboratory (Malaga, Spain).

CASE REPORT #010

USE OF A NOVEL ORAL APPLIANCE IN THE MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA: CASE REPORT

Iturbe-Zabala Carmen [1], Correa Leopoldo P.[2], Picaza-Iglesias Oiane[1].
[1] Private practice Bilbao, Spain. [2] Tufts University, Boston.

Introduction: Obstructive Sleep Apnea (OSA) is a frequently encountered form of breathing sleep disorder in our daily practices. The most common treatment options for this condition are positive air pressure (PAP) therapy and mandibular advancement devices (MAD). This case report aims to shed light on using a novel and low-cost custom-fabricated provisional MAD (DAMI®) to assess efficacy in the management of OSA before the fabrication of a final oral device.

Report of Case: 69 years old female, diagnosed with severe OSA with an apnea hypopnea index (AHI) of 30.2 (normal ≤ 5) with history of hypertension referred from hospital sleep unit to assess treatment with MAD due PAP intolerance. Patient characteristics include body mass index <30, denied smoking or drinking, Friedman classification D, patent nasal passage; Epworth Sleepiness Scale (ESS) 7/24, Stop-Bang 4/8. Negative findings of temporomandibular disorders symptoms.

The initial mandibular protrusion was taken at 70%; upper and lower dental impressions were utilized to fabricate the novel MAD as phase I. The oral appliance was fabricated with a maxillary vacuum press mouth guards adding an anterior resin ramp and bilateral posterior occlusal blocks on the upper mouth guard to prevent mandibular retrusion. A mandibular mouth guard

was also fabricated and adjusted it in the mouth with a tripod occlusal contacts design. The oral device was titrated by adding/removing resin from the anterior resin ramp, achieving a therapeutic mandibular position at 80% protrusion.

The patient was referred back to a sleep physician as a standard clinical protocol for a follow-up sleep study with the novel provisional oral appliance. The follow-up sleep study report revealed a reduction of AHI to 7.8 (from 30.2). The patient reported improved sleep quality, decreased snoring, and daytime sleepiness. A final MAD replicating the mandibular therapeutic position from the provisional novel oral device was fabricated (phase II). Six months of follow-up assessments and an additional sleep study revealed a stable improvement with an AHI of 7.2 respiratory events per hour.

Discussion: MAD efficacy in severe OSA patients is limited and requires a thorough clinical history, examination, and assessment of clinical characteristics for successful management. This case report highlights the use of a low-cost novel **"**temporary" oral appliance (DAMI®) in a severe OSA patient to asses efficacy before the fabrication of a final MAD. The novel device can be used as temporary treatment while patients complete extensive dental work, in countries where regular MADs are unavailable, or in low-income patients. As Dental Sleep Medicine continues to evolve globally, low-cost oral appliance designs are needed to assist in the high global prevalence of OSA. Future studies are required to assess the efficacy of this novel oral sleep apnea device in a larger patient population identifying patient characteristics and stratifying OSA severity.

Support: No conflict of interest to disclose
This DAMI is in the patent process.

ABSTRACT #011

OAT DEVICE DESIGNS ARE NOT THE SAME WHEN IT COMES TO FDA ADVERSE EVENT REPORTS

Rose Rohatgi DMD D-ABDSM[1], Mark Murphy DDS D-ABDSM[2], Len Liptak MBA[3]
[1] San Diego Sleep Therapy; [2] Funktoinal Sleep; 3 ProSomnus Sleep Technologies

Introduction: This investigation analyzes whether differences in OAT device designs are associated with different frequencies of adverse event reports (AERs). The FDA defines adverse events as undesirable experiences that should be reported when the outcome is death, life threatening, hospitalization, disability, required intervention, or a serious medical event.

Methods: The FDA MAUDE database is public, accessed September 29, 2022.

Each AER identifies the OAT device used by the patient. Each OAT device was characterized using public information. Descriptive statistics were used. Investigators utilized data from public sources, such as Frost & Sullivan, to estimate prevalence.

Results: Since 2017, 352 AERs have been reported to the FDA. The most frequently reported patient events were: Reactions (allergic, swelling, rash) and Pain/Discomfort. Only 2.5% of AERs pertained to dental side effects (tooth movements, bite changes).

Materials
98.5% of AERs involved OATs made from Lab Materials (acrylics, thermoformed polymers, nylons). 1.5% of AERs involved OATs made from Engineered Materials (engineered PMMA, Medical Grade Class VI polymers).

OATs with Lab Formed materials were an estimated 22.6 times more likely to have an AER than those with Engineered Materials.

Structural Compositions
OATs with Metal Components (Herbsts, clasps, screws) comprised 55.6% of AERs. OATs with Elastomeric/Nylon Components (straps, bands, rods) comprised 42.4% of AERs. OATs with Monolithic Structures (no components) accounted for 2.0% of AERs.

Compared with monolithic OATs, OATs using Metal Components and OATs using Elastomeric/Nylon components were 18.2 and 13.9 times more likely to have an AER.

Titration Mechanisms
OATs with Anterior Clasps Mechanisms, Push Mechanisms (Herbsts), Pull Mechanisms (straps, bands, rods), 70-Degree Dorsal Posts, and OATs with 90-Degree Twin Posts accounted for 45%, 42.7%, 6.1%, 5.6% and 0.6% of AERs respectively.

Compared with 90-Degree Twin Post Mechanisms, OATs with Push mechanisms and OATs with Pull Mechanisms were 154 times and 146 times more likely to have an AER.

Liners
Lab Formed OATs with Liners, Lab Formed Linerless OATs and Precision Engineered Linerless OAT devices accounted for 77.3%, 21.2% and 1.5% of events reported, respectively.

OATs with Liners were an estimated 35.5 times more likely to have an AER than Precision Engineered Linerless OATs.

Conclusions: All OAT device designs are not the same when it comes to AERs.

More AERs are associated with reactions. Dental side effects infrequently result in AERs.

OAT devices that use Precision Engineered Materials, Monolithic Structures, 90-Degree Twin Posts and Precision Engineered Linerless designs are associated with lower frequencies of AERs.

This investigation has limitations. The FDA MAUDE database relies on reports from manufacturers, patients, and providers.

The results of this investigation suggest that medical guidelines and insurance coding should empower therapy providers with the flexibility to prescribe devices that are associated with fewer AERs.

Support: None

ABSTRACT #012

ADVERSE EVENT REPORTS FOR CONTINUOUS POSITIVE AIRWAY PRESSURE, HYPOGLOSSAL NERVE STIMULATION AND ORAL APPLIANCE THERAPY DEVICES: AN FDA MAUDE DATABASE ANALYSIS

Len Liptak MBA[1], Mark Murphy DDS, D-ABDSM[2]
[1] ProSomnus Sleep Technologies; [2] Funktional Sleep and ProSomnus Sleep Technologies

Introduction: This investigation analyzes adverse event reports (AERs) from the FDA MAUDE database for Continuous Positive Airway Pressure (CPAP), Hypoglossal Nerve Stimulation (HNS) and Oral Appliance Therapy (OAT) devices. The FDA defines adverse events as undesirable experiences associated with medical devices that should be reported when the outcome is death, life threatening, hospitalization, disability, required intervention, or serious medical events.

Methods: The FDA MAUDE database is publicly available. For this investigation, the database was accessed on September 29, 2022. Publicly available industry reports were utilized to estimate prevalence of AERs.

Results:

Overview

From January 1, 2022 to September 2022, AERs for CPAP, HNS and OAT were 72,251, 11,867 and 30, respectively. From January 2017 to September 2022, the annual count of AERs for CPAP and HNS increased 245% and 252% respectively. The annual count of AERs for OATs decreased -1.3% over the same period.

Device Problems

For CPAP, "Degradation" comprised 96.6% of the AERs. For HNS, "Event Without Problem" and "Device Sensing" comprised 78.6% and 11.0% of AERs respectively. For OAT "Event without Identification" and "Breakage" comprised 40.0% and 9.8% of AERs respectively.

Patient Problems

For CPAP, seven patient problems comprise over 80% of reports: No Clinical Signs/Conditions, 57.3%; Dyspnea, 5.4%; Headache, 5.3%; Sore Throat, 4.3%; Respiratory Tract Infection, 4.1%; Cough, 3.5%; Unspecified Respiratory, 3.0%.

For HNS, nine patient problems comprise over 80% of reports: Unspecified Infection, 19%; Pain, 15.2%; No Clinical Conditions, 9.2%; Bacteria Infection, 8.7%; Perforation of Vessels, 7.1%; Erosion, 7.1%; Wound Dehiscence, 4.9%; Swelling/Edema, 4.8%; Hematoma, 4.4%.

For OAT, seven patient problems comprise over 80% of reports: Hypersensitivity/Allergic Reaction, 23.5%; Reaction, 19.0%; No Known Impact, 15.9%; Swelling, 8.7%; Pain, 6.2%; Discomfort, 4.5%; Erythema, 3.8%; Rash, 3.5%.

Conclusions: This analysis suggests that healthcare providers may wish to consider the significant differences in the frequencies and the severities of adverse events when prescribing treatment modalities for patients with OSA.

Dental side effects, a widely referenced reason for limiting the utilization of OAT devices, do not show up in the top 80% of the most frequently reported types of adverse events.

This investigation has limitations. The FDA database relies on reports from manufacturers. HNS is a Class III device whereas CPAP and OAT are Class II, which may result in different approaches to reporting.

Support: None

LATE-BREAKING ABSTRACTS

CASE REPORT #013

MANDIBULAR ADVANCEMENT DEVICE RELATED ADVERSE EFFECT MANAGEMENT CHALLENGE FOR AN OBSTRUCTIVE SLEEP APNEA PATIENT DURING COVID-19 PANDEMIC - A CASE REPORT

Chao Lu, DDS, DABOP, DABDSM; Sovna Mishra, BDS, MS; Leopoldo Correa, BDS, MS, DABDSM
Craniofacial Pain Division, Department of Diagnostic Sciences, School of Dental Medicine, Tufts University

Introduction: Mandibular Advancement Device (MAD) has been widely utilized nowadays for Obstructive Sleep Apnea (OSA) patients as an alternative treatment option due to CPAP intolerance, which requires periodic follow-up visits to monitor the effectiveness of the treatment and to control the potential adverse effects. During the COVID-19 pandemic, there have been significant challenges in accessing dental and medical services. Many medical and dental providers have shifted to provide telehealth and teledentistry services. However, there is limited evidence in the literature about the role of teledentistry to early identify and managing adverse effects related to the use of MAD. This report is to present a case study with adverse effect management challenges during the pandemic with further exploration of the role of online platform use in dental care.

Report of Case: A 43-year-old Caucasian female was referred by her dental sleep provider for management of her jaw pain, recently developed bilateral posterior open bite, and closed lock, after 6 months of using a mandibular advancement device. After the review of previous records and detailed in-person comprehensive examination following DC/TMD protocol, we revealed myofascial TMD and acute left-sided disc displacement without reduction with limited opening and secondary malocclusion due to MAD fitting concerns and lack of scheduled clinical examination to identify the early sign of mandibular positional change related bilateral posterior open bite. As the patient did not respond to her initial management plan, supervised by her dental sleep provider with only telehealth follow-ups, including self-care guidance and physical therapy referral, the consequent follow-up PSG sleep study also showed worsening of her OSA while using the MAD. The total AHI was worsened from 7.59/hr to 10.9/hr with the development of bilateral posterior open bite and jaw pain-related complaints. After cautious discussion with the patient and collaboration with the sleep physician, it was determined to immediately discontinue MAD therapy and initiate TMD stabilization appliance use at Tufts and resume CPAP reuse. At the 2-month follow-up visit, the patient reported significant improvement in jaw pain and normalized range of motion. Her bilateral posterior open bite also diminished with bilateral reproducible molar contact in the current centric occlusion.

Discussion: Secondary malocclusion and jaw pain-related adverse effects have been well documented in the OSA population with regular use of MAD. Although the utilization of virtual platforms during this pandemic may help to improve access to care and to initiate treatment, the limitations of telehealth in the orofacial pain and dental sleep medicine field, such as early identification of secondary malocclusion and pain management, remain to be cautiously evaluated and addressed. Further research is critically needed for the implementation of telehealth as an adjunct clinical option to improve the long-term outcomes of dental sleep medicine.

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

ABSTRACT #014

THE EVALUATION OF EFFECTIVENESS, EFFICACY, AND COMPLIANCE OF A CUSTOM-MADE OSA THERAPY DEVICE

Joseph Ojile, MD[1], Matthew Uhles, MS, RPSGT[1], Kevin Postol, DDS[2], James Lillenberg, DDS[3]
[1]Clayton Sleep Institute, St. Louis MO; [2]Sleep Disorder Dentistry. 3Sleep Well St. Louis

Introduction: New designs and materials of oral appliance therapy (OAT) devices have improved the treatment of obstructive sleep apnea (OSA). Custom-made OAT device's new features have improved efficacy and comfort and may have better acceptance, and adherence to therapy resulting in more effective-treatment and better quality of life for patients.

Aim: The study aimed to evaluate the clinical effectiveness of a custom-made oral appliance design (SomnoDent Avant) with a compliance tracking chip (Dentitrac, BRAEBON) in the treatment of mild and moderate OSA patients. The hypothesis for the study was that the treatment device which utilizes a strap design to retard mandibular rotation and fixes the mouth closed to encourage mouth closure and nasal breathing would have high levels of effectiveness. The evaluation of the adequate (first-time) fit of the device upon initial insertion, patients, and bed partner acceptance, was also investigated.

Methods: The study was IRB approved, 90 day prospective trial, an N=47 patients age ≥ 18 years of age diagnosed with mild (AHI >10 events/hr.) to moderate (AHI <30 events/hr) OSA confirmed on a Home Sleep Apnea Testing (HSAT) device at baseline. Initial maximal advancement of the lower jaw was done at 60%.

Treatment effectiveness is derived from two endpoints: efficacy and compliance. The efficacy of the device is defined as the change from baseline in AHI, based on one and three-month HSAT. Compliance was based on usage data obtained from the compliance chip embedded in the custom-made oral appliance therapy device's device looking at usage for at least 4 hours per night for at least five out of seven nights a week.

Results: Data from 47 participants (66.7% male, 33.3% female), age: 52.2 ± 11.7 yrs., BMI: 31.1± 7.3. A statistically significant 1-month trend change from baseline AHI -8.5 ± 7.6 and 3-month trend change from baseline AHI -11.0 ± 7. Average usage:7.0hrs/night, ESS: 3 month change from baseline (79.1% improvement), FOSQ 10: 1.7 ± 2.2 (76.7% improvement). The adequate (first-time) fit of the device upon initial insertion 90.0%, bed partner sleep improvement 81.6%, and 89.4% would recommend the use of this custom-made oral OAT device.

Conclusions:

- The a custom-made OSA oral appliance therapy device's demonstrates high effectiveness in the treatment of OSA.
- oral appliance therapy when looking at both efficacy (AHI) and compliance can be a clinically effective tool to treat OSA patients.
- statistical improvement in the quality of life
- optimum first-time fit – No major adjustments needed
- increased improvement in bed partner quality of sleep

Support: SomnoMed

ABSTRACT #015

FIVE-YEAR, PROSPECTIVE, MULTI-CENTER, OBSERVATIONAL STUDY TO ASSESS THE LONG-TERM SAFETY, EFFECTIVENESS, AND MANAGEMENT OF A CAD/CAM, 3-D PRINTED ORAL APPLIANCE IN THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA: ORAL APPLIANCE THERAPY (OAT) INITIATION

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

Introduction: Oral appliance therapy (OAT) is used to treat obstructive sleep apnea. First-time fit is important for dentists to reduce patient treatment burden and improve dental practice economics. This prospective, "real-world" collaborative (physician/dentist) study will assess the primary endpoint of at least a 50% reduction in baseline apnea-hypopnea index (AHI) at five years. Additionally, this study will assess fit and comfort during initial delivery. The Panthera D-SAD is a CAD/CAM, 3D-printed OAT. Updated design and comfort features have been integrated. Changeable rods (mechanical hinge) provide the mechanism for protrusion. This study will fulfill French reimbursement requirements. Ethics committee approval was obtained from South-Mediterranean Persons Protection Committee II, Sainte Marguerite Hospital.

Methods: OAT naïve individuals with moderate OSA (AHI 15-30) or those with severe OSA (AHI 30 or greater) who decline CPAP will be included, meeting all other criteria. An estimated 337 participants will be enrolled at 20 centers in France. Consecutive sampling will be used. Participants will be medically assessed by a Somnologist, and a prescription for OAT obtained with subsequent dental evaluation for inclusion. Initial OAT fitting occurs at Visit 1 (V1). Standard of care for the study duration will be followed. Evaluation time points are three months (medical), six months (dental), two years (both), 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: Between April 13, 2022, and February 8, 2023 a total of 73 subjects have been enrolled. This report is focused on the 52 subjects who have had OAT fit and titration visits (V1). The demographics are as follows:(F=20); Averages (and standard deviation) for the following are age 50.6 (13.4).; baseline AHI of 22.46 (10.5), ODI 18.11 (12.8), SpO2 93.3 (1.3) , BMI 27 (4.6) and rod length of 27mm (1.4), 89.1% of dentists reported at V1 that no rod (protrusive) changes were required. 88% of patients indicated the OAT was comfortable, four patients had dental or muscle pain, and one, the device was too tight.

Conclusions: V1 is a crucial step in the patient's therapeutic journey. This early data demonstrates a high OAT first-time fit acceptance rate at V1 for dentists and comfort for patients. Optimizing the initial fit through scanning techniques,3D printing and improved design reduces the need for additional fit visits, thus lowering both practitioner and patient burden and costs. Further assessment is ongoing.

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

ABSTRACT #016

PRESSURE DROP IN THE UPPER AIRWAY, A COMPARISON OF TWO METHODS: COMPUTATIONAL FLUID DYNAMICS AND *IN VITRO* PRESSURE DROP EXPERIMENTAL ANALYSIS

Silvia Gianoni-Capenakas[1], Manuel Lagravere[1]
[1] *Department of Orthodontics, School of Dentistry, Faculty of Medicine and Dentistry, University of Alberta*

Introduction: The analysis of the upper airway, especially comparing before and after orthodontic or orthognathic treatments, has been the focus of several studies lately. From the evaluation of dimensional changes to breathing effort and air resistance analysis. However, sometimes the methodologies described when Computational Fluid Dynamics (CFD) is used seem confusing leading to uncertainties regarding its results. This study focused on measuring the pressure drop and air resistance using two different methods for comparison purposes; the *in vitro* pressure drop experimental analysis and the CFD.

Methods: A single upper airway geometry, segmented using an AI model, implemented by our group, was used to establish a procedure that can be repeated using CFD and the *in vitro* pressure drop experimental analysis, to determine the pressure drop and air resistance. The geometry was segmented from a CBCT scan and was saved in STL format for printing a 3D upper airway replica to be used for the *in vitro* analysis. Also, the STL file was imported into CFX to have the CFD analysis completed. An average flow rate of 60 L/min was used in both methodologies, with the inlet being the nostrils and the outlet, the epiglottis. A study of the upper airway's internal features and flow rate allowed the estimation of the Reynolds number at various points through the airway. This determined that the flow was mostly laminar with slight turbulence at some points.

Results: The CBCT scan of one patient taken using the I-CAT new generation machine, large field of view (16x13.3cm, 0.30mm voxels, 120 kVp, 18.54mAS, 8.9 seconds) was used for this study. The scan was stored as DICOM files, and the patient code was assigned for blinding purposes. The DICOM file was transferred to the AI model to have the segmentation of the upper airway done. The segmentation was delimited anteriorly by the tip of the nose, laterally by the maxillary sinuses, superiorly by the most superior point of the nasal turbinate, posteriorly by the posterior wall of the pharynx, and inferiorly by the most anterior inferior end of the C3 vertebrae. The material used for the printed prototype is called Vero (Stratasys, USA). The *in vitro* pressure drop analysis was conducted using a vacuum pump at 60L/min airflow, the flow rate was monitored with a mass flowmeter, the pressure drop was measured using a manometer at room temperature (25-27ºC) and ambient pressure (~92kPA). The pressure drop was obtained using the implemented CFD model and a comparison was made. No statistical differences were seen between the *in vitro* and the CFD models.

Conclusions: Reliable and reproducible methodologies for air resistance and breathing effort are important to better translate the effects of therapies such as orthodontics and orthognathic surgery on the upper airway, instead of just analyzing dimensional changes.

Support: This research was supported by the AAOF – RAA award