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VALIDATION OF THE MEDIBYTE PORTABLE MONITOR FOR THE DIAGNOSIS OF SLEEP APNEA IN PEDIATRIC PATIENTS

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Introduction: The prevalence of sleep apnea in children ranges from 1.2% to 5.7% and is increasing with the increase in childhood obesity. Overnight, attended, in-laboratory polysomnography (PSG) is considered the gold standard in the diagnosis of sleep apnea. However, PSG is expensive, time consuming, technically complex, and requires the patient to be at the laboratory. Sleeping in an unfamiliar environment can materially affect sleep behaviors, and this concern increases when patients are children. Moreover, there can be significant delays in diagnosis and treatment of sleep apnea in pediatric patients due to limited availability and access to PSG. Timely diagnosis and management of pediatric sleep apnea is critical to prevent progressive associated comorbidities. These factors highlight the urgent need for portable sleep monitors (PM) validated for use in pediatric patients.

Methods: A consecutive series of pediatric patients referred to the University of Illinois Sleep Science Center wore the MediByte PM while simultaneously undergoing a PSG. Data acquired from the PM and the PSG were blinded and scored separately. The apnea-hypopnea index (AHI) was calculated using sleep time for the PSG, and recording time for the PM. The PM AHI was calculated using both manual and autoscoring functions of the PM.

Results: Out of 95 PM studies, 10 studies had to be excluded mainly because the subjects could not tolerate having both studies done simultaneously. Additionally, 15 studies failed because there was less than 4 hours of interpretable PM data. The remaining 70 subjects had a median age of 10.8 years and a median body mass index z-score of 1.9. The AHI obtained by manually scored PM studies strongly correlated with the AHI obtained using the PSG (r=0.939, p< 0.001). Using a cut-off of AHI \geq 10 events/h, the manually scored PM had a sensitivity of 100% and a specificity of 98.4% to detect sleep apnea diagnosed by the PSG. The oxygen saturation obtained by manually scored PM studies showed significant correlation with that obtained using the PSG in the older age group (12 to 17 years) (r=0.699, p<0.001), but not in the younger age group (7 to 11 years) (r=0.183, p=0.240).

Conclusions: Although PSG is still recommended for the diagnosis of sleep apnea, PMs can play a great role in diagnosing moderate and severe sleep apnea especially in older pediatric patients.

Support: We would like to thank the staff at the University of Illinois Sleep Science Center for their patience and support of this project.

VALIDATION OF THREE-DIMENSIONAL AIRWAY IMAGING FOR THE SCREENING FOR SLEEP APNEA IN PEDIATRIC PATIENTS

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Introduction: The prevalence of sleep apnea in children ranges from 1.2% to 5.7% and is increasing with the increase in childhood obesity. Overnight, attended, in-laboratory polysomnography (PSG) is considered the gold standard in the diagnosis of sleep apnea. On the other hand, screening for sleep apnea is usually done using sleep questionnaires and by performing thorough clinical examinations. Timely diagnosis and management of pediatric sleep apnea is critical to prevent progressive associated comorbidities and radiographic airway analysis is an additional screening tool that can assist in this diagnosis.

Methods: A consecutive series of 103 pediatric patients referred to the University of Illinois Sleep Science Center for a PSG had cone beam computed tomography (CBCT) scans taken at the department of orthodontics. The sample was divided into two age groups: age group 1 (7 to 11 years) and age groups (12 to 17 years). Three-dimensional linear, areal, and volumetric measurements were correlated with the apnea-hypopnea index (AHI) from the PSG separately for each age group. Additionally, the receiver operating characteristic (ROC) curve was used and the area under the curve (AUC) was calculated for all three-dimensional measurements using sleep apnea definitions of AHI ≥ 5 and AHI ≥ 10. Based on the results of the correlations and the AUC, sensitivity and specificity were calculated for measurements that were deemed promising in order to propose cut-off values for these measurements to predict AHI ≥ 5 and AHI ≥ 10.

Results: Out of 103 CBCT scans taken, 4 scans were excluded because of improper patient positioning. The remaining sample of 99 had a median age of 11 years, a median body mass index z-score of 1.8, and a median AHI of 2.7. In age group 1 (N=59) the only measurement that showed significant correlation with AHI was the nasopharyngeal volume (NPV) (rho= -0.363, p=0.005). Measurements with the largest AUCs were NPV and oropharyngeal cross sectional area (OCSA). Proposed cut-off values for NPV are 2400mm³ and 1600mm³ for AHI \geq 5 and AHI \geq 10 respectively. The proposed cut-off value for OCSA is 70mm² for both AHI \geq 5 and AHI \geq 10. In age group 2 (N=40), similarly NPV showed significant correlation with AHI (rho= -0.367, p=0.020). The measurement with the largest AUC was OCSA. Proposed cut-off values for NPV are 3500mm³ and 2700mm³ for AHI \geq 5 and AHI \geq 10 respectively. Proposed cut-off values for OCSA are 110mm^2 and 75mm^2 for AHI \geq 5 and AHI \geq 10 respectively.

Conclusions: Three-dimensional airway measurements can be valuable in evaluating the upper airway in pediatric patients. Contrary to findings in adults, the NPV might be of great importance when screening for sleep apnea. The OCSA might also be significant when screening for sleep apnea and this finding is similar to findings in adults.

Support: We would like to thank the sleep physicians at the University of Illinois Sleep Science Center for their support of this project.

ADHERENCE OF MANDIBULAR ADVANCEMENT DEVICE FOR OBSTRUCTIVE SLEEP APNEA IN A VETERAN POPULATION

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Introduction: Obstructive sleep apnea (OSA) is a common health problem with significant cardiovascular complications. Nonsurgical treatment options include continuous positive airway pressure (CPAP) as well as mandibular advancement devices (MAD). CPAP is highly effective; however, many patients find it to be intolerable, and long-term adherence rates in some series are less than 50%. Randomized controlled trials have shown that Oral appliances such as MAD are a good alternative for snoring and OSA because of their low cost, relative comfort, and ease of use, which may result in greater patient adherence. A recent study in 2017 by Feinstein, et al. found that adherence among all patients using MAD was 66.8% at 2 weeks, and 58.3% at 6 months. We sought to determine the adherence rate of custom-fit MADs, and the factors that may affect this adherence, within a veteran population with OSA.

Methods: This is a retrospective chart review of patients receiving a custom-fit MAD for the OSA from Nov 2016 to September 2017. Each MAD appliance had a DentiTrac® microrecorder embedded within the MAD. Adherence was defined as patients wearing the MAD for > 4hours/ night, for at least 70% of the time. This was recorded at day 14, day 30, and day 90 of wearing MAD. Patient demographic and clinical characteristics were reviewed to determine factors affecting adherence.

Results: The 57 subjects had an average age of 54.6 years (range = 29 to 82), BMI 30.7 (range = 21 to 44), and had an average AHI before treatment of 15.3 (range = 2.6 to 46). 50% of the patients had an AHI between 7.6 and 21.2. After 14-days 65% of the patients had 70% adherence (35 of 54), and at 30-days 56% had 70% adherence (27 of 48), and at 90-days 50% had 70% adherence (17 of 35). We screened each of the predictors in Table 1 and age, BMI, and pretreatment AHI to determine which may be related to the 14-day adherence percentage. None passed a screening significance level of alpha=.20 except pre-treatment AHI. A repeated-measures mixed-model indicated that pre-treatment AHI was negatively related to the 14-day, 30-day, and 90-day adherence percentages (P = 0.0226). That is, the higher the AHI the lower the adherence.

Adherence % showed a statistically decline across the three time periods. At the 14 day recall, Adherence % was 72% and by the 90 day recall it was 65% (p = 0.001).

Conclusions: The MAD should be considered a valuable first-line treatment option for mild or moderate OSA in the Veteran population, although maintaining adherence across time seems to be a challenge. It appears that MAD adherence may be superior to CPAP adherence in this population.

THE EFFECTS OF MANDIBULAR ADVANCEMENT APPLIANCE THERAPY ON JAW CLOSING MUSCLE ACTIVITY DURING SLEEP IN OBSTRUCTIVE SLEEP APNEA PATIENTS

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Introduction: Previous studies have shown that contractions of the jaw-closing muscles (JCMs) often occur shortly after respiratory events during sleep in obstructive sleep apnea (OSA) patients. It has been hypothesized that such non-specific motor activations may contribute to the restoration of a compromised upper airway during respiratory events. However, a recent study suggested that JCM contraction after a respiratory event in OSA patients is dependent on the arousal response rather than on the respiratory events *per se*. Based on this observation, we hypothesized that an effective mandibular advancement appliance (MAA) therapy would result in a significant reduction of the JCM activity after respiratory events with arousals (viz., respiratory arousals) without having effect on the JCM activity related to non-respiratory arousals in OSA patients. Therefore, the aim of this study was to investigate the effects of MAA therapy on the JCM activity related to respiratory arousals and on the JCM activity related to non-respiratory arousals during sleep in OSA patients.

Methods: Eighteen OSA patients $(49.4 \pm 9.8 \text{ years})$ with a mean $\pm \text{SD}$ apnea-hypopnea index (AHI) of 22.0 ± 16.0 events/hour of sleep participated in a randomized controlled crossover trial, in which two ambulatory polysomnograpic recordings, one with an MAA *in situ* and another without the MAA *in situ*, were performed in a random order. The JCM activity related to respiratory arousals and JCM activity related to non-respiratory arousals were the assessed primary outcome variables.

Results: In line with our hypothesis, no significant effect was observed of the MAA on the non-respiratory arousal index (T = -0.23; P = 0.81) and on the JCM activity related to non-respiratory arousals (T = 0.40; P = 0.69), while significant reductions in the AHI (T = 3.35; P = 0.00), in the respiratory arousal index (T = 3.254; P = 0.01), and in the JCM activity related to respiratory arousals (T = 2.34; T = 0.03) were found with the MAA *in situ*.

Conclusion: The outcomes of this study support previous findings suggesting that emergence of jaw-closing muscle contractions after a respiratory event in OSA patients is associated with arousals rather than with the respiratory events *per se*.

COMPARISON BETWEEN IMAGING SOFTWARE PACKAGES FOR THREE DIMENSIONAL MEASUREMENTS OF UPPER AIRWAY VOLUME AND MAXIMUM CONSTRICTION AREA

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Introduction: Several software packages report ability to perform different procedures, but results are sometimes inconsistent among software, making it difficult for a practitioner to communicate and compare values. The aim of this study was to compare 4 imaging software packages for measuring the upper airway volumes and maximum constriction areas

Methods: Twenty eight cone-beam computed tomography scans were randomly selected, the upper airway volumes (OPV) and the maximum constriction areas (MCA) were calculated. Dolphin3D (version 11.9, Dolphin Imaging & Management Solutions, Chatsworth, Calif). InVivo- Dental (version 5.4.5, Anatomage, San Jose, Calif), OnDemand3D (version1.0.10.6388CyberMed, Seoul,Korea), and ITK-SNAP software programs were used to measure the OPV and the MCA. The measurements were repeated after 2 weeks, and the Intraclass correlation coefficient was used for the reliability tests. A repeated measurements analysis of variance (ANOVA) test and post-hoc tests were used to compare software programs

Results: The reliability was high for all programs. ANOVA test did not show any statistical significance between the software programs in measuring the OPV and the MCA. Also Post Hoc Group Comparisons did not show significant difference between the software programs

Conclusions: All 4 imaging software packages were reliable and accurate when measuring the OPV and the MCA.

POSTER #006

A NOVEL USE OF COMPLETE DENTURE PROSTHESIS AS MANDIBULAR ADVANCEMENT DEVICE IN THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA IN EDENTULOUS SUBJECTS

Tripathi A

Introduction: Mandibular advancement devices have been used to efficiently treat mild to moderate obstructive sleep apnea by effecting a forward positioning of the tongue- mandible complex and a resultant increase in oropharyngeal volume. These devices are essentially tooth anchored and hence, work well in dentate patients. However, it is difficult to anchor such devices in an edentate mouth. This clinical study presents a case series on use of complete dentures modified to function as mandibular advancement device.

Methods: Ten edentulous OSA patients (8 male and 2 female, aged 61 ± 4 years; BMI 22 ± 5 ; AHI 15-30) who volunteered and provided written informed consent were included in the study.

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All of them were provided with complete dentures, and after 1 month of comfortable wear and attaining optimum function, the prosthesis was modified to serve alternatively as a mandibular advancement device. Use of complete dentures as MAD was recorded separately. Five variables were assessed preoperatively and after 6 months of wearing the modified mandibular advancement device. The variables were: sleep efficiency, apnea-hypopnea index, oxygen desaturation events/h, mean O2 saturation, and snoring index. Overnight polysomnography was done to evaluate the sleep variables preoperatively and after 6 months of wearing the modified mandibular advancement device.

Results: A significant decrease in apnea-hypopnea index (AHI) from 22.5 preoperatively to 4.8 postoperatively (p = 0.005) and snoring index from 7.9 preoperatively to 2.1 postoperatively (p = 0.005) was observed after 6 months of use of the modified oral appliance. Sleep efficiency increased from 62.55% preoperatively to 73.20% postoperatively (p = 0.005).

Conclusions: The results indicate that within the limits of the present study, this specific MAD can be effective in reducing sleep apnea by lowering the AHI, reducing snoring and oxygen desaturation events/h and increasing sleep efficiency.

Support: Self-supported study

POSTER #007

CLINICAL BENEFIT OF BOTULINUM TOXIN THERAPY FOR ADVERSE EVENTS AFTER THE USAGE OF MANDIBULAR ADVANCING ORAL APPLIANCE AS TREATMENT FOR OBSTRUCTIVE RESPIRATORY APNEA SYNDROME

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Introduction: In individuals with obstructive sleep apnea (OSA) who use mandibular advancing oral appliance (OA), the occlusal contact area is smaller in the morning than in the evening because of a bite change associated with mandibular protrusion during night. OSA patients are encouraged to use an oral appliance daily. Recently the number of OSA patients who find it difficult to use an oral appliance regularly has been increasing due to the occurrence of adverse events such as breaking of OA, occlusal dysfunction including mandibular advancement, and temporomandibular disorder (TMD). The oral myofunctional therapy or physical therapy can be used as a measure for those problems. However, the success rate is not very high because the therapeutic efficacy depends on patients effort in many cases. In this study, we hypothesized that the adverse effect is caused by the overactivity of the masticatory muscles. Patients with OSA were injected with botulinum toxin to inhibit the overactivity of the masticatory muscles to verify the improvement of the adverse events.

Methods: Ninety-two patients were enrolled into the study. All were OSA patients who received their oral appliances after diagnosed as OSA based on polysomnography, and currently experiencing the adverse events. To verify the hypothesis, the activity of masticatory muscle was

measured using electromyograph. Also the presence of breaking of OA, occlusal dysfunction including mandibular advancement, TMD was confirmed. After that, botulinum toxin was injected and the change in muscle activity and improvement of adverse events were verified.

Results: After the injection of botulinum toxin, the median of the masseter potential decreased from 2mV to 0.5mV. The activity of masticatory muscle showed significant supression effect (p<0.05). By inhibiting the muscle activity of masseter, effect of improving the adverse events such as stability of the masseter including the posterior shift of mandibular, and remission of TMD were observed.

Conclusion: Administration of botulinum toxin not only improved the adverse events, but also contributed to the improvement of QOL for OSA patients by releaving the stiff neck, headache, hypersensitivity, and bruxism.

POSTER #008

JAPANESE MULTICENTER SURVEY OF ORAL APPLIANCE THERAPY FOR OBSTRUCTIVE SLEEP APNEA (JAMS) STUDY

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Introduction: We conducted a multicenter survey of oral appliance (OA) therapy for obstructive sleep apnea (OSA) to grasp and analyze the current situation about OA therapy in Japan.

Methods: The survey was undergone for OSA patients in 10 institutions associated oral appliance therapy during two years, from 2014 to 2015, retrospectively. Age, sex, body mass index (BMI), baseline apnea-hypopnea index (AHI), OA type, re-titration, side effect with OA, AHI with OA were elicited from the patient clinical record.

Results: Included OSA patients were 3217. The patients with OA therapy were 2947. 1600 patients were evaluated the OA treatment. Patients treated with OA were most common in 50s in both male and female. In terms of OSA severity, snorer was 2.3%, mild was 38.5%, moderate was 39.9%, and severe was 19.3%. Mono bloc appliance was 91.8%, bi bloc appliance was 7.9%, and tongue retaining device (TRD) was 0.3%. After OA treatment, AHI decreased 22.4/h to 9.3/h. AHI reduction rate with OA was 52.0%. Complete responder (residual AHI <5 with

OA) was 35.6%, partial responder (AHI reduction rate > 50% with OA) was 31.3%, and non-responder (AHI reduction rate < 50% with OA) was 33.0%.

Conclusions: This study revealed the current situation and problems about OA therapy in Japan.

Support (optional): This study was supported by the Japanese Academy of Dental Sleep Medicine.

POSTER #009

CT IMAGE EVALUATION ON THE MORPHOLOGICAL CHANGES OF PHARYNGEAL AIRWAY SPACE ACHIEVED AFTER MANDIBULAR SURGICAL SET BACK

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Introduction: In recent years, many reports have stated that relocating the mandible in a backwards position due to mandibular set-back surgery may narrow the pharyngeal airway or cause changes in the sleeping respiratory function. Therefore, in this study, we used the Multiplanar Reconstruction (MPR) image obtained by the lateral cephalography and multi-slice computed tomography (MSCT), to evaluate and confirm the changes in the morphology of the pharyngeal airway after surgical mandibular set-back.

Methods: Eight patients (3 men, 5 females, average age 30.7 ± 10.2 years old) who underwent mandibular set back movement by Sagittal Split Ramus Osteotomy surgery after being diagnosed with mandibular protrusion); five measurement points were evaluated, they were defined as palatal pharyngeal space (PPS), superior posterior pharyngeal space (SPPS), middle pharyngeal space (MPS), inferior pharyngeal space (IPS), epiglottic pharyngeal space (EPS). In the lateral cephalographs, the linear anteroposterior diameter of these five points was measured; for the MPR image, the anteroposterior diameter, width diameter, cross sectional area and airway volume of these 5 sites were measured and compared before and after surgery. Lateral cephalograms were taken twice, one week and six months post-surgery, MSCT tomography was taken twice, a week before and after surgery respectively. *T-test* was performed to evaluate statistical significance (p>0.05).

Results: After assessing the cephalometric images, the antero-posterior diameter of was significantly decreased 1 week after surgery; MPS and the anteroposterior diameter of IPS were significantly decreased about 6 months post-surgery. In comparison with the MPR images, a decreasing tendency was observed in all measurement sites and items except for the anteroposterior diameter of post-surgery. In particular, the antero-posterior diameter, width diameter, cross-sectional area, and width decreased significantly. Also, the airway volume decreased significantly.

Conclusions: In the cephalographs, the anteroposterior diameter of IPS and MPS decreased significantly after surgery, assessing with the MPR image, the posterior diameter, width and

cross-sectional area of SPPS were significantly decreased post-surgery, the width diameter of EPS was significantly decreased, it can be said that the airway volume decreased significantly. This could be explained by stating that the volume in the oral cavity decreases due to the backward movement of the mandible and the dorsum of the tongue is lifted. It could be inferred that the linear measurements of SPPS and EPS were narrowed by the soft palate positioned rearward post-surgery. In addition, the anterior-posterior diameter, the width diameter, and the cross-sectional area in other measured points, excluding the anteroposterior diameter of PPS showed a decreasing trend, although no significant difference was observed. However, it is necessary to consider the possibility that swelling of soft tissues occurs due to the invasive surgical procedure and that the narrowing of the pharyngeal airway is likely to occur, especially for the results obtained one week after surgery. Therefore, future tests need to be done.

POSTER #010

THE SIGNIFICANCE OF PROTRUSION LEVEL, STARTING POINT AND MEASURMENT TECHNIQUES IN ORAL APPLIANCE THERAPY: A SYSTEMATIC REVIEW

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Introduction: Oral appliance therapy is a non-invasive treatment option for patients diagnosed with obstructive sleep apnea (OSA). In literature, there is a consensus that the target protrusion, i.e. the most effective mandibular protrusion, needs to be determined individually for every patient. This target protrusion should be a weighted compromise between the most optimal protrusion in terms of OSA reduction and side effects like temporomandibular joint problems. The aim of this systematic review was to give an overview on the level of protrusion required for efficacious treatment with oral appliance therapy, and to evaluate whether or not there is a consistent method of measuring and reporting these values.

Methods: A literature search in the electronic Pubmed Medline and Cochrane databases was carried out to identify studies relevant to titratable oral appliance therapy. A systematic search by using the terms 'sleep apnea, obstructive' or 'sleep breathing disorders' and 'oral or dental or mandibular' and 'advancement or repositioning' and 'mandibular protrusion' or 'mandibular range' was used. The search was limited to human randomized clinical trials and English language.

Results: Initially, 112 references were retrieved from primary database search. Seventy-nine be excluded since they did not describe any information on titration. At the end, 33 studies were included in this review. Twenty-nine studies reported a sleep study before start of the oral appliance treatment (OAT), and all but one of these studies also performed a follow-up sleep study.

Only two studies reported clearly on the starting point for the protrusive position selected for the construction of the OAT. Twenty-six studies reported on the selected protrusive position for the

oral appliance: 8 studies fixed the oral appliance in 75% of maximum protrusion, 4 studies used 50% of maximum protrusion, 2 studies protruded to maximal comfortable protrusion, while in the other studies the protrusive level ranged from 25 % of maximal protrusion to maximal comfortable protrusion.

Only four studies reported on the relation between the protrusive level and side-effects. Furthermore, thirteen studies defined the vertical opening,

Conclusions: At this moment, the titration procedure itself remains trial and error. Furthermore, there is no consistency in reporting and measuring the mandibular protrusion amount: very few studies described a well-defined starting and end-point, and it was not clear whether or not the end-point was an efficacious protrusive position. These deficiencies make it difficult to compare any reported data on mandibular protrusion/advancement between different studies. Therefore, it is recommended to introduce a standard method of reporting protrusive position, both in terms of starting point and efficacious protrusion.

POSTER #011

EVALUATION OF THE OVERALL CLINICAL EFFECTIVENESS AND CARDIOVASCULAR EFFECTS OF A MANDIBULAR ADVANCEMENT DEVICE IN THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA: PRELIMINARY RESULTS

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Introduction: The aim of this prospective clinical trial is to evaluate the cardiovascular effects of oral appliance therapy using a custom-made, titratable mandibular advancement device (MAD) in patients with obstructive sleep apnea (OSA).

Methods: Fifty patients with moderate to severe OSA were treated MAD therapy (SomnoDent® FlexTM, SomnoMed Ltd, Australia). After habituation, MAD titration was guided by subjective relief of cardinal symptoms like snoring and daytime sleepiness. At baseline and 6-month follow-up, participants underwent a type 3 home sleep test (HST; MediByte, Braebon Medical Corporation, Kanata, Ontario, Canada), 24-hour blood pressure (BP) monitoring, a comprehensive 2D Doppler and tissue Doppler echocardiography combined with speckle tracking, and objective compliance measurement.

Responders are defined as patients with a reduction in AHI that was equal to or more than 50% compared to baseline.

Results: Up to this date, 31 out of 50 patients completed the 6-month follow-up (age: 46±12 years; 77% male; baseline AHI-HST: 13.1±10.2 events/hour; body mass index (BMI): 27±4 kg/m²; 24-hour systolic blood pressure (SBP): 128±12 mmHg, 24-hour diastolic blood pressure

(DBP): 77±8 mmHg). Fourteen patients were lost to follow-up, mainly due to the time-consuming protocol, and in 5 patients the 6-month follow-up is being planned as a function of the individual timing when the MAD was fitted.

After 6-month follow-up, a statistically significant decrease in AHI (p=0.001) to 6.9 ± 6.9 events/hour of time in bed was observed on HST as compared to baseline. Eighteen patients (58%) were defined as responders.

Overall, systolic and diastolic blood pressure values, left ventricular ejection fraction (LVEF, Simpson method) and pulmonary arterial pressure (PAP) were within normal ranges and stayed normal under MAD therapy. However, in the responder group, a statistic significant improvement in LVEF could be observed, from 57 ± 7 to $61\pm7\%$ (p = 0.02) and a trend towards an improvement in PAP, from 27 ± 10 to 25 ± 11 mmHg (p = 0.09).

Conclusions: The preliminary results of this ongoing clinical trial showed that MAD is efficacious in reducing OSA severity. Overall, the cardiac parameters were within normal ranges and stayed normal under MAD therapy, However, in the responder group, echocardiography showed a statistic significant improvement in LVEF and a trend towards improvement in PAP.

POSTER #012

SCORING OF FATIGUE AND SLEEPINESS IN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA TREATED WITH A TITRATABLE CUSTOM-MADE MANDIBULAR ADVANCEMENT DEVICE

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Introduction: Fatigue is an important health outcome parameter in public and occupational health care. Most patients with obstructive sleep apnea (OSA) report excessive daytime sleepiness and/or fatigue besides snoring. Mandibular advancement (MAD) treatment is associated with reduction of sleepiness using the Epworth Sleepiness Scale (ESS) questionnaire. However, somnolence and fatigue are often mixed-up. A clear distinction could be imperative in therapy decision-making. In this study we compared the discriminant ability of the Checklist Individual Strength (CIS) with ESS outcome in patients with OSA treated with MAD, related to reduction of apnea-hypopnea index (AHI).

Methods: The CIS (CIS_tot) measures 20 items (max score 140) in four dimensions of fatigue organized in subscales each to be scored from 1 to 7: fatigue severity (CIS_sc1 8 items max score

56), concentration problems (CIS $_{sc2}$ 5 items max score 35), reduced motivation (CIS $_{sc3}$ 4 items max score 28) and activity (CIS $_{sc4}$ 3 items max score 21). On CIS $_{sc1}$, a score of \geq 35/56 defines severe fatigue whereas an ESS score \geq 11/24 indicates excessive sleepiness. All patients starting MAD-treatment filled out both the ESS and CIS questionnaires at baseline and at each recall. The scores for both questionnaires comparing 3-month versus baseline in a consecutive study population are reported (n=58).

Results: Complete datasets after 3 months of 41 patients were available.

Baseline results were (mean±SD):

AHI=28.6±17.2/hr; ESS=9±5; CIS_tot=82±34; CIS_sc1=37±15; CIS_sc2=21±11; CIS_sc3=13±7; CIS_sc4=11±5.

Results (mean±SD) after 3 months were:

AHI=9.9±11.5/hr; ESS=6±4; CIS_tot=63±31; CIS_sc1=27±14; CIS_sc2=15±9; CIS_sc3=12±6; CIS_sc4=9±5. Data were not normally distributed. Analysis was then performed in R using the Wilcoxon rank sum test for pairwise comparison and Spearman correlation for correlation analysis.

Significances were:

AHI p<0.000001; ESS p=0.000001; CIS $_{tot}$ p=0.000015; CIS $_{sc1}$ p=0.000005; CIS $_{sc2}$ p=0.000040; CIS $_{sc3}$ p=0.074940; CIS $_{sc4}$ p=0.011960.

Conclusions: MAD treatment resulted in a significant decrease from baseline to 3-months in all parameters investigated, including the combined CIS_{tot} scale, except for CIS_{sc3}.

A CIS_tot≥76/140 increases the risk for prolonged absence at work, putting the average OSA patient at risk with baseline CIS_tot=82/140, but not any more after MAD treatment with CIS_tot=63/140.

At baseline the average CIS_{_sc1}=37/56 revealed severe fatigue in the study population whereas the average ESS=9/24 failed to express this feature.

The correlation analysis demonstrated a significant correlation between the changes in ESS en CIS_sc1 describing fatigue, while the ESS and CIS were not correlated on the three remaining subscales indicating concentration, motivation, and activity after three months of MAD treatment. The CIS questionnaire itself did however reveal statistically significant changes in the CIS subscales concentration, motivation and activity following MAD-treatment for 3 months. No correlation of a change in questionnaire outcome either ESS or CIS could be demonstrated regarding delta AHI.

In the present study the CIS questionnaire was a discriminant measure for the changes in fatigue during OSA treatment with MAD and offered additional information compared to ESS.

POSTER #013

PROSPECTIVE EVALUATION OF THE EFFECT OF MAXILLOMANDIBULAR ADVANCEMENT SURGERY ON UPPER AIRWAY COLLAPSE PATTERNS DURING DRUG-INDUCED SLEEP ENDOSCOPY

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Introduction: Complete concentric collapse at the level of the palate (CCCp) in obstructive sleep apnea (OSA) patients, as observed during drug-induced sleep endoscopy (DISE) is associated with decreased surgical success rate. CCCp predicts failure in reduction of apnea/hypopnea index (AHI) with upper airway stimulation (UAS) therapy (Vanderveken OM et al. J Clin Sleep Med. 2013). Consequently, according to the Food and Drug Administration approval statement, CCCp is an exclusion criterion for UAS therapy. This study evaluates the change in CCCp patterns using DISE and the effect on AHI in patients that received maxillomandibular advancement (MMA) surgery after mandibular advancement device (MAD) treatment.

Methods: Nineteen patients diagnosed with OSA underwent MAD treatment for OSA, followed by MMA surgery. In 14 patients (57% male, age 51 ± 7 y; BMI 25.6 ± 3.7 kg/m2; AHI baseline 40.2 ± 25.6 / h of sleep) baseline DISE CCCp as well as after MMA surgery were obtained. During DISE upper airway collapse patterns were scored in a standardized way by one ENT surgeon with broad experience in DISE. Normality was checked using Shapiro-Wilk tests. Baseline AHI was compared with AHI under MAD treatment and after MMA surgery using paired t-tests. The proportion of CCCp in the study group prior to the interventions (MAD treatment and MMA surgery) was assessed using unpaired t-tests. To compare AHI differences between the patients with and without CCCp, both at baseline and after interventions, paired t-tests were performed.

Results: MMA surgery reduced the AHI to 9.9 ± 7.2 /h of sleep (p=0.0001). Overall MMA surgery did not significantly differ from MAD treatment regarding AHI reduction (p=0.1614). Six patients out of 14 (43%) showed baseline CCCp; 8 patients did not. Baseline patient characteristics in terms of age, BMI and AHI did not significantly differ between patients with and without CCCp. AHI is equally reduced afer MMA, whether (p=0.0145) or not (p=0.0075) CCCp was present at baseline. All patients had partial or complete resolution of CCCp (p=0.0159) after MMA surgery, that resulted in a normalized sleep-related breathing pattern or alleviated the severity of OSA to mild to moderate.

Conclusions: As opposed to UAS, CCCp appears not to be an exclusion criterion for MMA surgery outcome in terms of AHI reduction and could therefore be an alternative for patients with CCCp, currently excluded from UAS. As such, MMA broadens the perspective for personalized medicine based on DISE diagnosis. The results of this prospective study indicate the potential of complete elimination of CCCp after MMA surgery.

REMOTELY CONTROLLED MANDIBULAR POSITIONING DURING DRUG-INDUCED SLEEP ENDOSCOPY PRECEDING MANDIBULAR ADVANCEMENT DEVICE THERAPY: PROTOCOL AND FEASIBILITY

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Introduction: Stepwise protrusion of the mandible, referred to as titration, may yield to resolution of upper airway collapsibility in patients with obstructive sleep apnea (OSA). This can be done remotely under poly(somno)graphy using a remotely controlled mandibular positioner (RCMP; Kastoer C et al. J Clin Sleep Med. 2016). The optimal mandibular position is referred to as effective target protrusive position (ETPP). The aim of this study is to repeat these findings under drug-induced sleep endoscopy (DISE).

Methods: Ten patients diagnosed with OSA (50% male; age 54 ± 9.5 y; BMI 26.9 ± 2.1 kg/m²; Apnea-Hypopnea Index 28.4 ± 13.2 events/hour of sleep) were enrolled prospectively. Dental RCMP trays were fitted during wakefulness. Maximal protrusion and edge-to-edge positions were measured. Upper airway collapsibility was scored during DISE with RCMP within 45 minutes. ETPP was defined as the mandibular threshold protrusion yielding a stable upper airway in the absence of snoring, oxygen desaturation and apneas.

Results: RCMP trays were retentive and no adverse reactions occurred. RCMP was fitted intraorally prior to sedation with maxillary and mandibular trays in edge-to-edge position. Upon sedation, reversed titration was performed followed by progressive protrusion until ETPP was noted. In 8 out of 10 patients ETPP could be determined successfully while in one patient snoring, apneas and oxygen desaturations did not resolve within the patients' range of motion (ROM) from maximal retrusive position to maximal protrusive position of the mandible. In another patient RCMP needed to be removed due to adverse clenching.

Maximal retrusion, maximal protrusion, ETPP and ROM varied largely between patients. Mean ETPP was 67% of total ROM. For individual patients an ETPP range from 37% to 88% of ROM was noted.

Conclusions: The results of this study illustrate that it is feasible to use RCMP during DISE and to determine ETPP within 45 minutes. Comparative research with poly(somno)graphy would be useful to further validate the therapy outcome upon use of RCMP during DISE.

Support (optional): Zephyr Sleep Technologies Inc. Kindly provided the remotely controlled mandibular positioner (MATRxTM) and trays.

OPTIMIZING PRACTICE AND TREATMENT EFFICIENCY BY UTILIZING A FULLY DIGITAL CLINICAL WORKFLOW FOR ORAL APPLIANCE THERAPY: PATIENT ASSESSMENT TO SEATING THE APPLIANCE TO SUCCESSFUL OUTCOMES IN 30 DAYS

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Introduction: Every step counts when it comes to treating the symptoms of OSA. Ineffective titration protocols leave patients discouraged and untreated, with lingering discomfort that can lead to poor compliance. The precision of a digital workflow has been shown to be the preferred path by patients. Fueled by advancements in digital dental technology, more dentists are implementing fully digital workflows (FDW). The efficiency of an FDW relies on easy, accurate, and predictable tools and techniques. The purpose of this study is to demonstrate the efficiency of a complete FDW that starts with systematically preselecting those likely to respond to OAT, accurately capturing their bite at a position that is known to provide effective treatment and translating the digital impression into a CAD/CAM appliance. The goal is to establish treatment quickly, with minimal titration. Improvements to the challenging step of digitizing an open sleep bite using a novel "Digital Bite Fork" (DBF) is demonstrated, as well as speed to care.

Methods: Prior to OAT, all subjects (n=60) were tested with a feedback controlled mandibular positioner (MATRx plusTM) in the home to predict response to OAT and to provide a predicted effective protrusion (PEP). An Intraoral Scanner (iTero) was used to capture the digital records using the DBF by a novice user and a CAD/CAM OA (ProSomnus[®]) was manufactured only utilizing the digital data. The DBF was designed to facilitate digital open-bite registration by supporting the posterior teeth support, while not requiring registration material in the scanning segment. The OA was either inserted at the PEP, or adjusted forward to the PEP at the pace recommended by the dentist. The OA fit was evaluated intra-orally. All adjustments, including dental and occlusal, were recorded. Time to treatment was tracked.

Results: Digital impressions using the DBF were used in all except 1 subject, due to partial edentulism. At the time of fitting, subjects benefitted from the following adjustments: 1 to the OA occlusal surfaces; 13 to the dental surfaces; and 6 that were not related to occlusal or dental fit. All subjects (100%) identified as responders by could be inserted immediately at their PEP. The OA was confirmed by follow up HST to be immediately effective in 87% of subjects at the PEP provided by the MATRx plus, and only 13% required a titration process to establish effective therapy. The OA effectiveness in a population that ranged evenly from mild to severe OSA was found to be 97.4%. The mean time to treatment was less than 3 weeks from insertion (mean: 20.4; min: 4.0; max: 54.0 days).

Conclusion: Using the MATRx plus in conjunction with digitized patient data, the Digital Bite Fork and a CAD/CAM device produced fast and effective treatment for patients. The scanning process with the DBF was easy, with the OA requiring minimal adjustments and accurately

replicating the intended bite. By utilizing these new tools and technologies, it may be possible to create easy, accurate, and predictable fully digital workflow models for OAT.

POSTER #016

EFFECTIVENESS AND EFFICIENCY OF THE PROSOMNUS® [IA] SLEEP DEVICE FOR THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA - THE EFFECTS STUDY

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Introduction: This study evaluates the effectiveness of a new MAD (Prosomnus® [IA]) fitted with a compliance tracker in a population of patients with mild to severe obstructive sleep apnea (OSA). Long term effectiveness was measured using home sleep testing (HST), validated sleep and quality of life questionnaires, and consumer sleep trackers.

Estimating the mean disease alleviation (MDA) of a treatment is critical for evaluating outcomes when comparing known treatment modalities. Confirming compliance is also important to institutions that regulate and license commercial drivers. As MADs become mainstream treatment for sleep apnea it is important to demonstrate effectiveness, the combination of efficacy and compliance. Treating the patient with a CAD/CAM custom appliance, the ProSomnus® [IA] sleep device, can optimize comfort and efficacy to ensure excellent compliance.

Methods: Patients with AHI between 5 and 50, ages of 18-75 were selected from a population presenting to a multidisciplinary sleep center for treatment of OSA. IRB approval was obtained for the study and all patients were given informed consent. Patients were given HSTs using the Alice NightOne and the Beddit sleep tracker for monitoring total sleep time and providing a sleep quality score. Patients were treated with the ProSomnus [IA] that was fitted with the Dentitrac compliance chip. Compliance was calculated on the 4hr/night 5 day/week standard for CPAP. Patients were given two quality of life surveys the Pittsburgh Sleep Quality Index (PSQI) and the Functional Outcomes of Sleep (FOSQ).

Measurements: 2 nights of HST were averaged before OAT began (PRE) and at the point of symptom reduction (POST). PSQI and FOSQ surveys were taken at (PRE) and (POST). Beddit data was averaged for 2 weeks before patients started treatment PRE and two weeks after, POST.

Results: 27 of 40 patients have been recruited for this study. Two patients that have completed the first treatment outcome will be discussed here. Patient 1, male, 54, BMI of 26, AHI(PRE) at 23, (POST) of 6.0, and PSQI(PRE) 5, (POST) 4, FOSQ(PRE) 35, (POST)38, and Beddit(PRE)47, (POST)75 and a compliance level of 83%. Patient 2, male, 55, BMI 25, AHI(PRE) at 22, (POST) of 1.2, and PSQI(PRE) 4, (POST) 2, FOSQ(PRE) 32, (POST)37.5, and Beddit(PRE)40, (POST)92 and a compliance level of 93%.

Conclusion: Early results demonstrated the ProSomnus [IA] successfully treated patients with OSA, from an AHI of 23 to 6 (patient 1), and AHI 22 to 1.2 (patient 2). Quality survey data mirrored this improvement along with the Beddit data, showing nearly a 2x improvement in

sleep quality score. Patients that are monitored and are involved with their treatment and use a CAD/CAM custom MAD, ProSomnus [IA], were able to achieve high levels of compliance, 83% and 93% respectively, measured by the Dentitrac.

POSTER #017

ASSOCIATION BETWEEN ALTERED SLEEP, DAILY ACTIVITIES, AND OROFACIAL FUNCTION IN ACUTE DENTAL PAIN PATIENTS.

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Introduction: Acute dental pain is a common type of orofacial pain, which is often associated with severe anxiety and fear. The assessment of pain should include interference with daily activity of patients, quality of life, emotional and physical functioning and sleep-related disorders. To assess the relationship between pain related sleep interference, demographics, daily activities, orofacial function, and reported pain magnitude, we evaluated baseline data of a reliability study using the Penn Facial Pain Scale (PFPS) in subjects presenting to a dental school-based emergency service with acute dental pain.

Methods: Adult (18 or older) consecutive sample of subjects with acute dental pain who presented to CWRU SODM for an emergency visit between September 28, 2015 to October 23, 2015. Subjects were given an IRB approved PFPS to complete at baseline. De-identified data was stored in an electronic firewall protected database (REDCap®, Vanderbilt University, 2017). Descriptive analysis and non-parametric associations were explored using STATA, V.14.1, College Station, Texas.

Results: 87 subjects completed baseline data. 51.7% were female. Mean age was 39.1 years. There was no significant difference between gender groups ($\text{Chi}^2 p = 0.2$) or age (Kruskal-Wallis, p = 0.14) distribution. Mean reported interference with sleep (0-10 rating scale) was 7.4. Sleep data was categorized into three groups: 0-5 (mild) n=22, mean: 2.5, 6-8 (moderate) n=20, mean: 7.4, 9-10 (severe) n=45, mean: 9.7. Subscales from the PFPS defined daily activities, orofacial function, reported pain in the past week (worst, least, average, present). The impact of sleep interference on daily activities, orofacial function, and pain reporting was statistically significant between the mild and moderate groups (Mann-Whitney, p<0.05). There was no difference in interference with orofacial function, and average least pain when comparing moderate and severe sleep interference groups.

Conclusion: This preliminary finding supports a sleep interference value of at least 5/10 (0-10 scale) significantly impacts subject orofacial function in an acute dental pain scenario.

Support: CTSC 4UL1TR000439, Case Western Reserve University, Cleveland Clinic Foundation, Metro Health System.

MANDIBULAR ADVANCEMENT SPLINT ON OBSTRUCTIVE SLEEP APNEA DURING PREGNANCY: A FEASIBILITY STUDY

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Introduction: The prevalence and severity of obstructive sleep apnea (OSA) increases during pregnancy due to weight gain, hormonal and other physiologic changes. OSA has been linked to deleterious effects on perinatal health of the mother and child. The optimal treatment of obstructive sleep apnea in pregnant women is unknown. Although CPAP treatment is often the treatment of choice, the mandibular advancement splint would be an interesting alternative treatment. Thus, the objective of this study was to evaluate the feasibility of mandibular advancement splint to treat sleep apnea during pregnancy.

Methods: Interventional study with an uncontrolled experimental cohort of 17 pregnant women with sleep apnea. SomnoDent Flex (SomnoMed, USA) was used as mandibular advancement appliance with an objective compliance micro-recorder (Braebon Medical Corporation, Canada). Participants were included during their second trimester of pregnancy. Sleep questionnaires were filled (Epworth Sleepiness Scale, Pittsburgh sleep quality and functional (FOSQ)). Sleep recordings (PSG type II (Titanium, Natus Medical Inc., Canada), scored using standard AASM criteria) were done at home to confirm the diagnosis (2nd trimester, apnea-hypopnea index \geq 10 events/hr) and following treatment titration (3rd trimester).

Results: The mean apnea-hypopnea index (AHI) was $16.8 \pm \text{SD}$ 5.9 events/h, mean snoring time was $23.8\% \pm \text{SD}$ 23.3 and 3% oxygen desaturation index $3.1 \pm \text{SD}$ 3.7 events/h. Diagnostic AHI tended to correlate with age (Spearman r=.43, trend p=.08), but not with body mass index. Snore time was correlated with body-mass index (Spearman r=.62, p=.007). AHI and snore time were reduced with the mandibular advancement splint to 13.2 ± 7.0 events/h (Wilcoxon p=.04) and $6.6 \pm 8.5\%$ (p=.004), respectively. However, only 5 participants had an AHI ≤ 10 with the treatment. Moreover, 82% (14/17) of participants reported using the treatment, of which 71% (10/14) reported using it at least 5 nights/week. The average reported use (hours/night) was 6.7 hrs. The objective compliance data showed only 30% of participants were regular users (use ≥ 4 hours/ night use of appliance on 70% of days of therapy), while the rest were irregular users. Treatment satisfaction was high (86% of participants) and very few complications were reported (21% of participants reported complication frequency at least once a week). The few reported complications were that the mandibular advancement splint was "uncomfortable/cumbersome", "painful" or "mouth became too dry".

Conclusion: The findings of this study support the feasibility of using mandibular appliance splint to reduce sleep apnea during pregnancy. Treatment satisfaction was high, while very few complications were reported during therapy. However, different strategies should be used to improve treatment adherence during pregnancy. Postpartum results are still being collected.

Support: This study was supported by the Faculty of Dental Medicine of the Universite de Montreal, and start-up funds of both principal investigators (N.Huynh and S.Pamidi). SomnoDent and DentiTrac were in-kind support from SomnoMed (USA) and Braebon (Canada).

POSTER #019

HEALTH OUTCOMES IN THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA: AN UPDATED REVIEW

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Introduction: Obstructive Sleep Apnea (OSA) is a frequently encountered form of breathing sleep disorders in our daily practices. The most common treatment options for this condition are: continuous positive air pressure therapy (CPAP) and mandibular advancement devices (MAD). The aim of this updated review is to shed light on the overall health outcomes in the treatment of OSA from a patient, provider, and an institutional health prospective.

Methods: The PICO question for this study was based on the following format: Population - studies that report on OSA; Intervention: treatment with MAD; Comparison: treatment with CPAP; Outcome: impact on overall health from various perspectives. One reviewer (MMS) with the support of an expert librarian conducted an extensive search. The PubMed was searched using MeSH terms related to the study objective. Peer reviewed articles were screened by title, abstract and full-text review. Articles pertinent to the topic were selected and analyzed for their overall health outcomes.

Results: Based on the evidence available, both CPAP and MADs can affect a patient's overall health. Specific patient's predictors and comorbidities, along with their chief complaint will guide the treatment plan options. Socio-economically, patients with medical insurance may benefit of reduced costs if they use a CPAP, while reimbursement though dental insurance for MADs is not covered to an equal percentage. Proper diagnosis and treatment of OSA can reduce health care cost with an estimate of 11 billion dollars per year. A collaborative relationship between physicians and dentists will facilitate best practices to treat patients suffering of OSA.

Conclusions: Recommendations of inter-professional collaborations between dentists and medical physicians are key for best practices. Appropriate diagnosis and treatment of OSA can have an increased impact on the overall health of our patients. Further high-level evidence studies are needed to support this topic of general interest.

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TOOTH MOVEMENT AND BITE CHANGES FOR A HARD-ACRYLIC SLEEP APPLIANCE; 2 YEAR RESULTS USING THE PROSOMNUS® MICRO₂® SLEEP APPLIANCE

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Introduction: According to the AADSM published "Dialogue" paper on Treatment Complications(1), Tooth mobility is a top ten concern during the treatment of Obstructive Sleep Apnea using an oral appliance. Recently, Norrhem(2) reported a significant difference in anterior crowding using a flexible oral appliance(OA) versus a rigid OA showing less movement with the rigid OA. This study will report on the changes in tooth movement for a hard acrylic rigid OA, the ProSomnus® MicrO₂® Sleep appliance, over a two year period. Preliminary results are reported in this abstract with the full results reported at the time of poster presentation. This work was conducted under IRB.

Methods: 20 Subjects were fitted with a ProSomnus MicrO₂ sleep appliance at the Snore Centre in Calgary. Subjects were NOT fitted with a morning aligner. Their records were stored and noted at time point zero. At the 1 and 2 year mark impressions and models were taken. Subjects were surveyed on compliance. Models were marked per the IRB to scrub the patient data. Models were scanned on a TRIOS lab scanner and scored using ORTHOCAD software. The upper and lower anterior teeth crowding was calculated using the Little's index method(2). Scanning and measurements were completed by the University of Pacific Orthodontics Department. All measurements were made in duplicate

Results: Upper and lower arches were each measured in the anterior for 5 patients at year 1. Variation from time zero to year one for individual pairs of teeth, ie between 27-26 on the lower for example and 8-9 on the upper for example had an overall average shift of 0.14mm for the upper and similarly 0.14mm for the lower. The average difference for the total Little's index for the same 5 patients at 1 year for the upper was 0.61mm total and for the lower was 0.47mm total. Within this relatively small sample these differences were not shown to be statistically significant. The average change in the patients Over Bite after one year was 0.28mm and for Over Jet 0.18mm.

Conclusions: Preliminary results show acceptable tooth movement of much less than 1-2mm as seen by Rose et.al, Chen et.al and Pliska et.al. The poster will present the final data from all the 1 and 2 year time points for all 20 patients (in-process), examine the measurement error and produce over all statistical significance of the results.

Support: Support for this study was provided by ProSomnus Sleep Technologies and approved by the Health Research Ethics Board of Alberta.

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EVALUATION OF TREATMENT OUTCOMES OF OBSTRUCTIVE SLEEP APNEA PATIENTS TREATED WITH MANDIBULAR ADVANCEMENT DEVICES AT AN ACADEMIC INSTITUTION

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Introduction: Obstructive sleep apnea (OSA) has an estimated prevalence of 17% in men and 9% in women. Studies have looked at the use of mandibular advancement devices (MADs) for the treatment of OSA and found improvements in apnea-hypopnea index (AHI), minimum SaO₂⁴ levels, and daytime sleepiness levels as defined by Epworth Sleepiness Scale (ESS). However, studies have not examined the specific benefits of MADs in the setting of a dental academic institution. The aim of this study is to evaluate the treatment outcomes of OSA patients treated with MADs in the Tufts University School of Dental Medicine (TUSDM) Sleep fellowship program.

Methods: A convenience sample of 32 OSA patients treated with MADs by one dental sleep medicine fellow at the TUSDM sleep medicine clinic, over fellowship duration (one year), were reviewed for the purpose of this study. Seven different MAD designs were used. Patient characteristics including age, Body Mass Index (BMI), and gender were collected at baseline. Additionally, AHI, ESS, and lowest O2 saturation were collected pre and post treatment. Patients were stratified into categories based on AHI: normal (<5 events/hr), mild (5-15 events/hr), moderate (15-30 events/hr), and severe (greater than 30 events/hr). Descriptive statistics were calculated, as well as comparisons of outcomes before and after use of MAD.

Results: Of the 32 patients, there were 17 females and 15 males. The mean age of the sample was 51.5 years with a mean BMI of 26.5. Of the patients with both pre and post measurements for AHI (n=26) the mean AHI, prior to treatment, was 22.47 (sd=18.14). Over the length of the fellowship, these patients showed a mean decrease in AHI of 16.12 (sd=15.82, p<0.001). Furthermore, there was a general decrease in patients' AHI severity level, with 80.77% (n=21) of patients moving to a less severe classification and 19.23% (n=5) of patients staying at the same level. Prior to treatment, the breakdown of AHI severity was: normal (3.85%, n=1) mild (50.00%, n=13), moderate (19.23%, n=5), and severe (26.92%, n=7). Post treatment, the breakdown was: normal (53.85%, n=14), mild (38.46%, n=10) and moderate (7.69%, n=2). No patients were classified as severe post treatment. Of the patients with both pre and post measurements for ESS (n=26), there was a mean decrease in ESS of 4.40 (sd=4.14, p<0.001). Of the patients with data for both pre and post 'lowest O2 saturation level' (n=10), there was a mean increase in lowest O2 saturation level of 8.10 (sd=8.28, p=0.013).

Conclusions: Patients treated with MADs, over the course of the dental sleep medicine fellowship showed improvement in their OSA control. This suggests that there is a significant utility to incorporating training about dental sleep medicine into the curriculum for students and opportunities for improved care for patients.

NONCONTACT IDENTIFICATION OF SLEEP DISTURBED BREATHING FROM SMARTPHONE-RECORDED SOUNDS VALIDATED BY POLYSOMNOGRAPHY

Niranjan, Shivdare, Freudman, Sehra, Narayan

Introduction: The U.S. Preventive Services Task Force recently concluded that screening for sleep disordered breathing (SDB) is inadequate. Dental medicine has an untapped role in screening patients, who may be unaware of SDB, then facilitating diagnosis and treatment if indicated. However, traditional SDB screening questionnaires are not personalized and have poor specificity, while polysomnography (PSG) or home sleep testing require multiple physical connections which may serve as barrier to screening. We hypothesized that a consumer smartphone could detect normal and disturbed breathing using novel algorithms to analyze ambient sound without the need for physical connections to the patient.

Methods: We performed combined clinical-and-computational studies to demonstrate the feasibility of analyzing sound recorded with a smartphone to detect SDB. We used data from a prospective clinical study of individuals at risk for OSA undergoing indicated PSG with sound recorded from an unmodified Samsung Galaxy S5. We identified 12352 discrete breath/non-breath sounds (386/patient), referenced to designated periods during the PSG. We developed algorithms to remove noise, then detect breaths, absences of breath and snoring associated with obstruction and arousal calibrated to the adjudicated PSG report.

Results: We recruited 32 patients (12 women, BMI 33.0±7.73 kg/m²). We found that analysis of raw Smartphone-recorded sound files ('.wav'), even when detrended to reduce noise, were difficult to interpret and discern breaths. Fourier analysis, on the other hand, displayed period events, i.e. breaths, as peaks in spectral-time series. Envelope analysis across all frequencies successfully identified the presence and absence of breaths. In receiver-operating characteristic curves, spectral analysis identified breaths and apneas (>10 seconds) with a c-statistic of 0.91, relative to PSG. We identified loud breath sounds as a large amplitude-time integral of sound, which identified possible arousals with a c-statistic of 0.95, relative to adjudicated arousal events. The approach appeared resilient to noise. The biggest limitation was separating non-obstructive (non-pathological) from obstructive snores.

Conclusions: Ambient sounds recorded from a smartphone during sleep can be analyzed to identify apnea and obstructive noises verified by polysomnography. Future studies should determine if this approach can enable early screening of sleep disordered breathing to identify atrisk patients for definitive diagnosis and therapy in the dental clinic.

PREDICTING ORAL APPLIANCE OUTCOME AND EFFICACIOUS MANDIBULAR PROTRUSIVE POSITION IN THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA

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Introduction: A recent report from our group described a feedback controlled mandibular positioner (FCMP) that predicts oral appliance therapy (OAT) outcome and an efficacious mandibular protrusive position. Shortcomings of this study included the use of a prototype FCMP and small study population; these issues are addressed in the present investigation.

Methods: Fifty-three individuals with obstructive sleep apnea (OSA) [mean BMI: 31.1 kg/m²; mean oxygen desaturation index (ODI): 30.2 hr⁻¹] underwent a 2- to 3-night in-home FCMP study using the commercial version of the device (MATRx plus, Dentsply Sirona). Outcome predictions were made by a trained artificial intelligence classifier. Baseline and outcome ODI values were measured by a full night Level III home sleep test. All participants received a custom fitted OA (ProSomnus Sleep Technologies) provided by a blinded dentist. Therapeutic success was defined as an ODI < 10 hr⁻¹ while wearing the OA, and therapeutic failure was defined as an ODI > 10 hr⁻¹ while wearing the OA. Data from our previous study (n=48) were combined with those from the present study to provide an overall assessment of the predictive accuracy.

Results: The predictive accuracy of the FCMP prediction and OAT outcome were as follows for the present study were: sensitivity, 90.5%, [CI: 0.80-1.00]; specificity, 90.9%, [CI: 0.64-1.00]; positive predictive value (PPV), 97.4%; [CI: 0.88-1.00]; negative predictive value (NPV), 71.4%, [CI: 0.46-1.00].

When the data from the present and previous studies were combined, the predictive accuracy of the FCMP prediction and OAT outcome were as follows: sensitivity, 88.2%, [CI: 0.80-1.00]; specificity, 92.0%, [CI: 0.77-1.00]; PPV, 97.1%, [CI: 0.91-1.00]; NPV, 71.4%, [CI: 0.56-1.00].

In the portion of the study that employed the commercial device, thirty-three of the 38 subjects correctly predicted to be responders experienced therapeutic success (ODI <10 hr⁻¹) at the predicted efficacious position for a target PPV of 86.8%. For the combined data for both studies, the target PPV was 86.4%. The median efficacious protrusive position for the combined study population was 69.1%. A human factors assessment was completed, and the device was found to be usable by the study population. Furthermore, 96% of participants said they found the test to be a satisfactory experience and 90% said they would recommend it to friends and family.

Conclusions: We report here a second prospective study showing that our FCMP test accurately predicts an OSA patient's response to OAT and, for responders, an efficacious mandibular

protrusive position. That the predictive performance of the test is comparable in the two studies indicates substantial generalizability of the results and supports application in diverse clinical populations.

POSTER #024

REASONS FOR THE DIFFERENT TREATMENT RESPONSE OF MANDIBULAR ADVANCEMENT DEVICES TO JAPANESE AND CAUCASIAN OBSTRUCTIVE SLEEP APNEA: A COMPARATIVE STUDY

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Introduction: Obesity is associated with decreased treatment efficacy of mandibular advancing Oral Appliances (OAm) therapy for Obstructive Sleep Apnea (OSA) (Ferguson *et al.* Sleep 2006). Generally, lower rates of obesity have been reported in Japanese populations compared to Caucasians, both with and without OSA. (WHO Expert Consultation; Lancet 2004, Genta *et al.* Braz J Med Biol Res 2008, Cho *et al.* Clin Exp Otorhinolaryngol 2016). Therefore, OAm treatment for Japanese OSA patients may result in increased treatment efficacy when compared with Caucasian patients with OSA. To test this hypothesis, we designed a comparative study for users of OAm between these two populations.

Methods: The medical records of all OSA patients treated with OAm at the Sleep Apnea Dental Clinics in the Institute of Neuropsychiatry, Tokyo, Japan and the University of British Columbia, Vancouver, Canada between 2005 to 2013 were retrospectively reviewed. The patients having both baseline and follow-up polysomnographic study data were consecutively enrolled and assumed eligible for analyses. Users of tongue retaining devices were excluded. A paired t-test was obtained to compare the difference in AHI between baseline and follow-up within each group while an unpaired t-test was used to compare the treatment change in AHI between Japanese and Caucasians. Treatment efficacy in terms of AHI was compared between the two groups by the one-way analysis of covariance after controlling for the effect of baseline AHI and BMI. A *p*-value of less than 0.05 was considered to indicate a statistically significant difference. The study protocol was approved by both ethics committees of the above two institutions.

Results: After matching the ages between the Japanese (n=176, 50.8 ± 0.7 years) and Caucasian (n=63, 50.8 ± 1.3 years) groups, there were significant differences in baseline AHI ($23.4 \pm 12.4/h$ vs $32.9 \pm 19.0/h$, p<0.05) and body-mass index (24.3 ± 3.1 vs $28.1 \pm 4.1 kg/m^2$, p<0.05). Although significant reduction in AHI was achieved in both Japanese ($23.4 \pm 12.4/h$ vs $8.6 \pm 8.6/h$, p<0.05) and Caucasian ($32.9 \pm 19.0/h$ vs $17.0 \pm 14.1/h$, p<0.05) subjects, the treatment efficacy in terms of AHI was more predominant in Japanese patient sample ($62.0 \pm 2.7\%$ vs $43.6 \pm 4.6\%$, p<0.05). However, when adjusting for variances in baseline BMI between groups, there were no differences in treatment efficacy (F=7.69, p=0.061).

Conclusions: This is the first reported study to compare OAm treatment efficacy between patient groups of Japanese and Caucasian. Overall differences in treatment efficacy are significantly related to underlying differences in BMI between the populations studies. Further large scale multicenter international studies will justify the clinical importance of these findings.

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