

counter-intuitive, ODI from a one-night study is not a good estimate of the outcome ODI.

Support (If Any): Zephyr Sleep Technologies, Prosomnus Sleep Technologies.

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A MULTI-CENTRE EVALUATION OF A MOUTHPIECE DEVICE FOR THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA SYNDROME

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Introduction: Continuous positive airway pressure (CPAP) devices are considered as the first line therapy for obstructive sleep apnea syndrome (OSAS). However, there is an increasing tendency to use oral appliance as an alternative treatment due to poor patient compliance of CPAP devices. The evaluation of the oral appliances in the treatment of OSAS are conducted via magnetic resonance image (MRI) segmentation of upper airway structures and polysomnographic variables. This study aims to evaluate the efficacy of a mouthpiece device (Dormio™, Respo Gadgets) on patients with OSAS by the comparison of oropharyngeal volume and polysomnographic variables with and without the device. The study is reorganized as multi-center and blinded clinical trial. The mouthpiece device increases intraluminal pressure by using patients' own breath while reshaping the lower jaw and tongue position.

Methods: Each patient (targeted n=24) underwent MRI of the upper airway during wakefulness at baseline and with the novel mouthpiece device. Since the proposed novel mouthpiece device design allows patient to breathe orally, the oropharyngeal volume change has been evaluated instead of the velopharyngeal volume. The oropharyngeal volumes of the participants have been reconstructed as 3D models from the acquired MRI images. Afterwards, The patients attended the sleep laboratory in 5 centers on two nights with and without the mouthpiece device for full diagnostic polysomnography. After the diagnose night, the patients had a 7-days acclimatization period with the mouthpiece and their 8th night was recorded in the sleep laboratory. Total apnoea-hypopnea index (AHI) and oxygen-desaturation index were scored blindly using AASM criteria.

Results: The results (current n=12) show that the use of proposed device enlarged the oropharynx volume 71% on average while reducing the apnea hypopnea index by 53% on average. On the other hand, the polysomnographic variables have been significantly improved by the use of novel mouthpiece device. The oxygen desaturation index reduced 94% on average. Lowest oxygen saturation values improved 3.6% on average.

Conclusion: The clinical results show that the proposed mouthpiece design offers a promising alternative oral appliance for OSAS patients.

Support (If Any): Respo Gadgets.

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TREATING OSA WITH ORAL APPLIANCES: A FEEDBACK CONTROLLED MANDIBULAR POSITIONER PROSPECTIVELY IDENTIFIES RESPONDERS

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Introduction: We have developed a feedback controlled mandibular positioner (FCMP) incorporated into a home sleep test (HST) to predict outcome with oral appliance therapy (OAT). A previous clinical

trial with prototype FCMP device demonstrated significant prospective predictive accuracy. The purpose of the present study was to assess prospective predictive accuracy of a final device (MATRx plus).

Methods: Patients with OSA (n=53; mean AHI: 29.5 hr⁻¹; mean BMI: 30.9 kg/m²) received a 2- to 3-night FCMP test in the home, and all patients received custom OA by a blinded dentist. AHI and ODI values were measured at baseline and outcome (custom OA in place) in the home using the HST component of the device.

Results: Using a success criterion of ODI < 10 hr⁻¹, agreement analysis between the FCMP prediction and OAT outcome yielded sensitivity, specificity, positive and negative predictive values (%) for the present study of 90.5%, 90.9%, 97.4%, and 71.4%, for the previous study of 85.3%, 92.9%, 96.7%, and 72.2%, and for both studies combined of 88.2%, 90.0%, 97.3% and 71.9%, respectively. The overall accuracy of the two studies was comparable (present: 90.5%; previous: 87.5%). Use of AHI < 10 hr⁻¹ as a success criterion was available only in the present study, and the values for the above agreement parameters were 88.1%, 90.0%, 97.3%, and 64.3%, respectively.

Conclusion: The equivalence of the agreement parameters derived from these two independent studies suggests that the results of the FCMP test are generalizable to other OSA populations. We conclude that the final product embodying our FCMP technology provides a feasible home test that accurately predicts OAT outcome. These results also indicate that the FCMP test accurately predicts OAT outcome in an AHI framework.

Support (If Any): Zephyr Sleep Technologies, Prosomnus Sleep Technologies.

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IN-SLEEP MANDIBULAR BEHAVIOUR CHANGES IN PATIENTS UNDERGOING ORAL APPLIANCE THERAPY TITRATION

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Introduction: The mandibular movements (MM) derived indices are reliable markers of respiratory effort (RE) during sleep disordered breathing. We aim at measuring the effectiveness of mandibular advancement device (MAD) therapy by examining MM hourly indices (MM-RDI), in comparison to the apnea-hypopnea (AHI), the oxygen desaturating hypopnea (HDI) and the oxygen desaturation (ODI) hourly indices.

Methods: OSA patients were initially diagnosed by conventional PSG, then treated with a custom MAD (Herbst appliance) for averagely 58 weeks before assessed again by Type-3 PSG during titration when snoring was reported disappearing. Both polygraphs were equipped with a magnetometer to capture vertical MM (Brizzy®, Nomics-BE). The scoring was manually performed following AASM 2012 rules. MM-based events were scored blindly with the others indices. Total sleep time (TST) was provided by MM analysis. MAD effect on the outcomes was evaluated using Bayesian multilevel models.

Results: a group of 43 OSA consecutive patients (median age =48.2 yrs) showed at baseline, HDI, AHI, ODI and MMRDI median values of 5.3, 9.5, 7.6 and 6.7 respectively. Median MM-RDI duration was 38% of TST. After being adjusted for TST and random individual variances, the models indicated significant improvements in all outcomes: The median reduction rates were -54%, -53%, -68.4% and -82% for HDI, AHI, ODI and MM-RDI, respectively. MM-RD duration was also reduced by 34% compared to baseline. Bayesian inference showed that the plausibility of MAD effects was largest for MM-RDI (Bayes-factor