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The SomnuSeal oral mask is reasonably tolerated by otherwise CPAP non compliant patients with OSA.

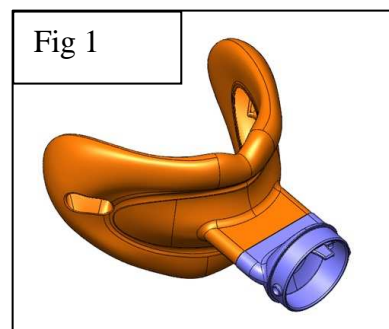
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Background: Compliance with CPAP is the major limiting factor in treating patients with OSA. Nasal masks may cause skin abrasions or eruptions, mask pressure on the ridge of nose, air leaks (eye discomfort), claustrophobia and nasal stuffiness. The novel SomnuSeal mask (Fig 1) is an oral self-adaptable mask located between the teeth and the lips, ensuring no air leaks or skin abrasions. It is more comfortable, adjusts better to the patient's specific anatomical structure, and potentially reduces rejection by claustrophobic patients. In a previous study, a mixed sample of 20 patients with OSA had slept with the SomnuSeal oral mask for an average of 1 week. Compliant patients slept for an average of 4.5 hours per night.

Aim: To evaluate the efficacy and compliance/tolerability of the SomnuSeal oral mask for a one month treatment period in otherwise non-compliant (untreated) patients with moderate-severe OSA.

Methods: So far, 29 patients with RDI>20 had tried the mask for one month. In all patients the mask was connected to an AutoPAP machine with a heated humidifier. Efficacy (respiratory indices), convenience (questionnaire) and compliance (usage meter) were monitored in all patients.



Results: Twenty nine patients (24 males and 5 females, mean age 56 ± 11 years, BMI 33.3 ± 4.7 Kg/m², RDI 48 ± 20 /h) have tried the treatment so far. Of them, 7 were satisfied and complied well with it (for an average of 27 nights, 4.8 hours per night), 4 struggled with it (used it for an average of 15 nights, 3 hours per night), and 18 could not comply with it. In all patients who slept with it, the efficacy (assessed by residual RDI derived from the CPAP device) was good, with an RDI of less than 5/hour. Interestingly, the required optimal pressure decreased from an average of 9.2cmH₂O to 4.9cmH₂O.

Conclusions: The SomnuSeal oral interface is effective, and may result in converting non-compliant untreated patients with OSA into well treated ones. In the current study so far, 7 of 29 patients (24%) who were CPAP non-compliant and remained otherwise untreated, were satisfied and well tolerated the SomnuSeal mask, while additional 4 patients (14%) struggled with it and may have ended up being treated. These results are encouraging to offer this mask and reduce the currently high prevalence of CPAP non-compliant untreated patients with OSA.