# Effectiveness of a mandibular advancement device alone versus add-on positional therapy for mild to moderate sleep apnea

## Preliminary data from a prospective cross-over trial

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## Introduction

Although continuous positive airway pressure treatment (CPAP) remains the primary intervention for moderate to severe obstructive sleep apnea (OSA), a wide array of therapeutic interventions exist for treating the milder sleep-related breathing disorders (SRBD) (1). Oral appliances (in particular mandibular advancement devices – MAD) and positional therapy (PT) are the most frequently used in day-to-day practice as a result of their affordable pricing as well as their relative ease of use (2, 3). To this day, only one prospective study design investigated the combined effects of MAD and PT in this specific patient population (4).

## Methods

10 patients free from any sleep interfering drug treatment, without any major physical or mental co-morbid condition, presenting with mild to moderate OSA (5 ≤ AHI < 20) and co-morbid snoring, were enrolled in a prospective cohort study (table 1). The protocol consisted of a total of four nights of polysomnography (PSG) in an academic sleep lab. Inclusion was based on the first two consecutive PSG, the second night being a baseline night without treatment intervention. Afterwards, in a randomized cross-over design, patients spend two consecutive months using alternately one of both treatment configurations at home for one month, being either MAD alone (Somnofit-S®) or combined with a sleep positioning pillow (Posiform®) (picture A). At the end of each month, they underwent respectively a third and fourth PSG under active treatment. Sleepiness, fatigue and sleep quality were assessed with the Epworth Sleepiness Scale (ESS), the fatigue severity scale (FSS), the Pittsburgh Sleep Quality Index (PSQI) and the Function Outcomes of Sleep Questionnaire (FOSQ) at baseline and after each month of treatment, alongside reported satisfaction and compliance ratings after each month of treatment.

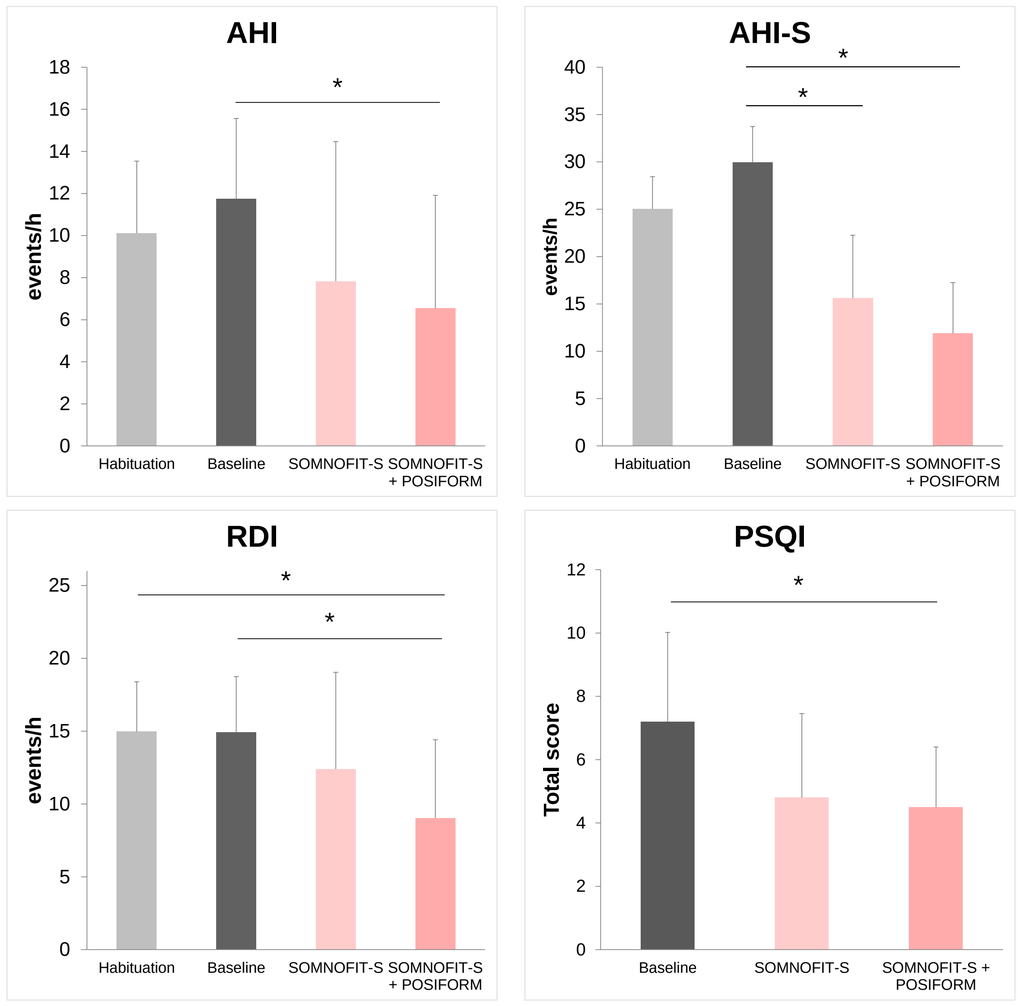
## Results

Significant reductions of apnea/ hypopnea index (AHI), apnea/ hypopnea index in supine position (AHI-S), respiratory distress index (RDI), obstructive apnea index (OAI) and hypopnea index (HI) were observed between baseline and the combined treatment of both MAD and PT. Furthermore, a significant reduction of AHI-S was also observed between baseline and MAD alone. In addition, we obtained a significant improvement in sleep quality impairment (Pittsburgh Sleep Quality Index - PSQI) between baseline and the combined treatment (figure 1). No particular treatment effects were observed on sleep architecture.

## Conclusions

**Significant improvement on both sleep-related respiratory variables and perceived sleep quality were observed after one month of the combined treatment of a mandibular advancement device and a sleep positioning pillow compared to the baseline night. Furthermore, reported compliance and overall satisfaction of patients as well as bedpartners appeared to be high and comparable after both months of treatment.**

**Figure 1: Evolution of sleep-related respiratory variables and symptom scales**




**Legend:** apnea/hypopnea index (AHI), apnea/hypopnea index in supine position (AHI-S), respiratory distress index (RDI) and Pittsburgh Sleep Quality Index (PSQI). * *p*< .05

**Picture A: Sleep positioning pillow (Posiform®) and mandibular advancement device (Somnofit-S®)**


**Table 1 : Overview of patient characteristics, reported compliance and overall satisfaction**

| | |
|---|---|
| **Characteristics** | **Age (years)** 47,6 ± 7,7 |
| | **Gender** 82 % male |
| | **BMI (kg/m²)** 28,7 ± 3,8 |
| | **Neck circumference (cm)** 40 ± 3,2 |
| | **APOC I** 8 patients ; **APOC II** 2 patients |
| **Compliance** 1 month; 2 months | **Days / week** 6,4 ± 0,9; 6,8 ± 0,3 |
| | **Hours / night** 6,6 ± 1,3; 6,9 ± 0,9 |
| **Satisfaction** 1 month; 2 months | **Auto-evaluation** 7,1/10 ± 1,8; 7,3/10 ± 2,5 |
| | **Hetero-evaluation** 8,3/10 ± 0,6; 7,5/10 ± 1,2 |

**Legend:** Body mass index (BMI), Amsterdam Positional Obstructive Sleep Apnea Classification (APOC), > 10% of total sleep time in both best and worst sleep position as well as apnea/hypopnea index < 5 in best sleep position (APOC I), > 10% of total sleep time in both best and worst sleep position as well as apnea/hypopnea index of best sleep position in a lower obstructive sleep apnea category than overal apnea/hypopnea index (APOC II)

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