Self-Reported vs Objective Measured Compliance with Oral Appliance Therapy for Obstructive Sleep Apnea Hypopnea Syndrome

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Background
Oral appliances, such as Mandibular Repositioning Appliances (MRA), have emerged as a conservative treatment option for sleep-disordered breathing (SDB). Up to this date, no objective method is available to measure compliance during oral appliance treatment for SDB. As with CPAP in the early years, the sleep apnea community nowadays has a strong interest in the objective measurement of oral appliance use and adherence. Subjective measures and self-report commonly result in overestimation of compliance.

Methods
We will perform a 12-week clinical trial comparing active/objective measurement of compliance with subjective self-reported usage.

We will enroll 50 patients with an established diagnosis of SDB that received treatment with a titratable, duobloc MRA (RespiDent Butterfly® MRA, RespiDent, Nijlen, Belgium). Active microsensors (TheraMon®, Handelsagentur Gschladt, Hargelsberg, Oostenrijk) are provided by the Handelsagentur Gschladt (Hargelsberg, Oostenrijk) without any costs. The sampling interval of the recording will be done at a rate of 1 measurement per 15 minutes (every 900 seconds). Using this sample interval, the capacity of the active microsensor allows for data acquisition during a 100 day period.

The microsensors are intercalated into the MRA devices by the dental technician.

Participants receive explanation to the purpose of the study, in the fact that the investigators want to study temperature fluctuations during the night in the oral cavity. As a result, the subjects are unaware that their MRA use and compliance is being measured.

A first follow-up appointment is scheduled after the first 4 weeks. A second and final follow-up visit is scheduled again 12 weeks after the start of the study.

During each follow-up visit patients are asked to fill out a questionnaire containing questions about MRA wear during the last 4 or 8 weeks (mean hours/night, mean nights/week), respectively. The objective measurement of MRA wear time (total hours of wear time and the mean hours of wear per night over the respective period) will be based on the assumption that the MRA has been worn when the chip records a temperature intraorally.

This study design will provide a 12-week evaluation of all patients (n=50).

Perspective and Hypothesis
The removable nature of an oral appliance warrants an objective assessment of the effective use and compliance with overnight MRA treatment for SDB.
We hypothesize that objective compliance might turn out to be significantly lower compared to the subjectively reported compliance.