Objective measurement of compliance during oral appliance therapy for sleep-disordered breathing.

Olivier M. Vanderveken, Marijke Dieltjens, Kristien Wouters, Wilfried A. De Backer, Paul H. Van de Heyning, Marc J. Braem

ONLINE DATA REPOSITORY

Methods - online extended version

Patients and Ethics

A total of 54 consecutive patients with a recent polysomnographic diagnosis of sleep disordered breathing, being a suitable candidate for oral appliance therapy with a custom-made titratable mandibular advancement device (Figure E1) based on dental examination, were invited to participate in this study. After receiving a full explanation on the nature and aspects of the study, three patients out of 54 refused to take part in this study stating that participating to the study protocol might be too time-consuming for them. As a result, participation rate for this study was 94 % (n=51).

Ethical approval for this study was obtained from Institutional Review Boards of the Antwerp University Hospital and the study was officially registered at Clinical Trials.gov (NCT01284881).

Oral Appliance (OA) therapy

Subjects all used the same custom-made titratable mandibular advancement device type of OA (Respident Butterfly MRA®, Respident, Schoten, Belgium; see Figure E1). Following the OA fitting by the dental sleep professional, subjects were instructed regarding the titration procedure based on the evolution of snoring and/or daytime sleepiness[E1].

OA compliance monitor

OA compliance was measured objectively using an embedded microsensor thermometer with on-chip integrated read-out electronics (TheraMon®, IFT Handels- und Entwicklungsgesellschaft GmbH, Handelsagentur Gschladt, Hargelsberg, Austria). The TheraMon® microsensor has received CE Mark in Europe (2010) and has been studied for

objective measurement of wearing times for removable orthodontic devices[E2]. The microsensor has a weight of 0.40 ± 0.01 g, a length of 13.0 ± 0.1 mm, a width of 9.0 ± 0.1 mm and a height of 4.3 ± 0.1 mm (see Figure 1 main manuscript). Temperature was recorded by the microsensor at a sampling rate of 1 measurement per 15 minutes (every 900 seconds). The memory capacity of the microsensor thermometer was within the range of having data storage from 100 consecutive days.

The microsensor was embedded in the OA by a dental technician at the right side of the upper part of the two-piece mandibular advancement device (see Figure 2 main manuscript). Thereafter, it was electronically coupled with the patient's ID within the electronical medical record so that it will be recognized during future read-outs. A confirmation message of successful coupling was provided with each embedded chip. Objective compliance measurement was based on the assumption that the OA therapy was followed when the temperature measured, exceeds 35 °C.

Subjects enrolled in the study were not aware that their OA use was being measured objectively and were not paid for their participation. Subjects were informed that a microsensor was embedded in their OA to serve fundamental research of intraoral mucosal temperature shifts during the night and as such were blinded to the aim of the study.

All participating patients were instructed to return for follow-up consultation 1 month and 3 months after the start of the study, for readout of the OA compliance data using the readout station (Figure E2). During each visit, OA compliance was registered objectively using the readout characteristics of the OA compliance monitor data, that was performed using the dedicated reading station (Figure E2) connected to a PC via USB cable. During the readout procedure, the microsensor embedded in the OA was placed parallel to the antenna of the reading station (Figure E2). During this readout procedure the strength of the magnetic field,

required for the readout, is presented using a color code: green giving sufficient strength, orange as a warning of decreasing strength, with finally red representing insufficient strength. Exposure of the microsensor to the magnetic field of the reading station leads to recognition by the TheraMon® software. Transmission via radio-frequency identification (RFID) technology allows wireless readout of the microsensor data. Subsequently, the software provides the actual OA wearing times in hours per day and generates graphic output of the length of OA use on each day and a summary of OA use across days.

Statistics

Possible correlations between objective OA compliance data and other anthropometrical and polysomnographical data were assessed using Spearman nonparametric correlation tests.

Results

Seventeen out of 51 patients (28%) had a history of intolerance for CPAP.

A custom-made titratable mandibular advancement device (Figure E1) [29] was fitted to all participating patients (n=51). The titration protocol was based on the improvement of symptoms and/or until maximal comfortable protrusion was reached [30], resulting in a mean (± SD) titrated mandibular protrusion of 10.4 (± 2.9) mm.

Objective OA compliance data and their association with other parameters

Spearman nonparametric correlation tests were used to check associations between the data on objective OA compliance and the data given in Table 5. Objective mean rate of OA use consistent over 3 months was correlated with the overall decrease in arousal index. Apart from this positive association, no other significant association was observed between objective mean rate of OA use and any other described anthropometrical and polysomnographical parameter.

Figure E1.

The custom-made titratable mandibular advancement device used in this study.

Figure E2. The dedicated readout station.

During the readout procedure, the microsensor that is embedded in the OA is placed parallel to the antenna of the reading station.

References (online data repository)

E1.   Dieltjens M, Vanderveken OM, Van de Heyning PH, Braem MJ. Current opinions and clinical practices in the titration of oral appliances in the treatment of sleep-disordered breathing. Sleep Med Rev 2012;16:177-185.

E2.   Schott, T. C., B. Ludwig, B. A. Glasl, J. A. Lisson. A microsensor for monitoring removable-appliance wear. J Clin Orthod. 2011;45:518-520.