The use of an oral mandibular advancement device out of thermoflexible vinyl in connection with sleep related breathing disturbances.

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Summary

1. Trial objectives
In an open study design the following objectives in patients suffering from snoring with and without sleep-related respiration disturbances were to be investigated under application of the oral mandibular device SnorBan®:

- the influence on the duration and intensity of snoring,
- the frequency of apnea and hypopnea during sleep,
- the oxygen content in the blood to examine the sleep structure and finally the
- daytime sleepiness/fatigue.

The oral mandibular advancement device consists of a thermoflexible material that is fitted to the patient after heating up in hot water and used during the night.

2. Inclusion criteria
- nocturnal snoring
- proper nose respiration
- complete tooth status

3. Exclusion criteria
- gulping (würgen) when pressing with the spatula on the rear two thirds of the tongue
- gulping when brushing teeth
- progenia
- extreme dysgnathia that makes fitting impossible

4. Methods
After complete polysomnography medical personnel performed the fitting of the mouthpiece in those patients, who met the inclusion criteria and had given informed consent to participate in the clinical study. After fitting the correct tightness and the form of the prosthesis were controlled. After a period of 4 to 8 weeks patients got accustomed to the mouthpiece and subsequently underwent follow-up polysomnography, clinical examination and were interviewed about symptoms, treatment effectiveness, side effects and satisfaction with their mouthpiece.

5. Study population
Out of 53 patients who were consecutively selected 5 rejected study enrollment, and 7 patients were excluded for dental reasons. Altogether 41 patients were supplied with SnorBan, whereby 39 appeared for re-examination and thus made up the evaluable group that consisted of 33 men and 6 women with an average age of 51.1 + / - 9.2 years.

6. Results
All patients confirmed to get well along with the oral mandibular advancement device. A total of 79.5% confirmed that they were very satisfied (23.1%) or satisfied regarding comfort of everyday usage and effectiveness, only 20.5% were dissatisfied. Under SnorBan 45.9% of all patients reported an improved general health condition, only 7.7% reported a general impairment.
Increased salivation was indicated by 22 patients. Transient toothache in the morning was indicated by 17 patients, jaw joint pain by 7 patients, and nausea by 3. Deformations by using the mandibular advancement device had not been indicated. The average period of time of getting accustomed to the mouthpiece was in between a time frame of 0 to 21 days (average value: 4 days).

Furthermore, 43.6% of patients indicated a significant and still 33.3% a moderate reduction of the intensity of snoring and its duration under SnorBan. Regarding sleep apnea patients it was indicated that the nocturnal respiratory arrests had decreased considerably in all cases (average AHI reduction of around 51%).

Polysomnography revealed an average reduction of the total snoring period by 59.5% on average. Regarding patients with an initial AHI exceeding 10/h this value decreased under SnorBan by 50 to 80% on average. Even a reduction of initially high AHI values to those being below 10/h had been demonstrated, e.g. from initially 56.5 to 3.8. In one case there was an increase of the AHI value from initially 6.5/h to 25.6/h. Overall compliance was 75%.

7. Judgement
Neither severe side effects nor health endangering complications had been reported under SnorBan.

Currently available subjective and objective outcome parameters are interpreted as promising hints for the application of SnorBan not only in habitual snoring, but in obstructive sleep apnea too.

The use of SnorBan is medically recommended in appropriate indications. In- and exclusion criteria must be considered.