Pilot Study of a Novel Mandibular Advancement Device for the Control of Snoring

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Objective—Mandibular advancement devices (MADs) have been introduced as a conservative, non-invasive treatment for socially disturbing snoring and mild obstructive sleep apnea (OSA). A prospective, non-randomized pilot study was conducted to investigate the efficacy, feasibility, side-effects and compliance of Somnoguard†, an immediately intraorally adaptable MAD made from thermoplastic material.

Material and Methods—Twenty consecutive heavy snorers with a respiratory disturbance index of <20 events/h were prospectively selected. Prior to the adaptation of the appliance, ambulatory polygraphy was carried out without a MAD. After a 1-month habituation period, a polygraphic evaluation was carried out with the device. Treatment success was defined as a reduction in the apnea–hypopnea index (AHI) of at least 50%.

Results—The results indicated a success rate of 65%. The AHI decreased from 8.4±2.9 events/h at baseline to 3.9±1.8 events/h with the device (p=0.001). At 1-month follow-up, significant reductions in the snoring index (p<0.001) and the Epworth Sleepiness Scale (ESS) score (p=0.036) were noted. At 6-month follow-up, similar results were achieved, with significant drops in the snoring index (p=0.025) and ESS score (p=0.033).

Conclusion—We conclude that immediate intraoral adaptation of a low-cost fabricated “one-size-only” MAD is a feasible and well-tolerated treatment for snoring and mild OSA. Further research is needed to evaluate this thermoplastic appliance as a strategy to “screen” the efficacy of MAD treatment in the individual patient with a less expensive appliance before constructing a more expensive custom-made MAD. Key words: cost, oral appliances, patient satisfaction, polysomnography, prefabricated thermoplastic material, sleep, sleep apnea, treatment.

INTRODUCTION

Habitual snoring is a common affliction, with prevalences of up to 32% in men and 14% in women (1–3). Snoring is a cardinal symptom of obstructive sleep apnea (OSA) syndrome (4). There is increasing evidence that snoring, even without OSA, is not only bothersome to the bed partner but may also be harmful to the patient. Snoring contributes to excessive daytime sleepiness (EDS), cardiovascular disease and arterial hypertension (4, 5).

First-line treatment of snoring starts with the avoidance of aggravating factors such as alcohol consumption, smoking and the use of sedatives or muscle relaxants, and the treatment of obesity. In addition, both surgical and non-surgical treatment options are available (5, 6).

Snoring has been primarily treated with uvulopalatopharyngoplasty (UPPP) (4, 5, 7–9). The results of this surgical intervention are variable and equivocal (6–8). In addition, only short-term results have been reported in most studies. A tendency for snoring to relapse over time has been reported in long-term studies of UPPP (10). Therefore, enthusiasm for UPPP has declined in recent years (4, 8). Consequently, there has been growing interest in non-surgical or minimally invasive procedures for the efficient treatment of snoring (8).

Oral appliances have gained increased attention and acceptance as a non-invasive alternative treatment for the management of sleep-related breathing disorders (SRBD) (8, 9). Oral devices may be indicated in habitual snorers with or without associated EDS. Therapy with an oral appliance may be useful in subjects with severe OSA who do not tolerate or comply with nasal continuous positive airway pressure (n-CPAP) or as a temporary alternative (5, 11, 12). Oral appliances should also be considered as a rescue treatment in patients with persistent snoring or OSA after UPPP (5, 6, 11, 13, 14).

Dentition-anchored appliances of various designs have been proposed and studied for the treatment of snoring and OSA (5, 6, 15). Intraoral devices used in the treatment of SRBD fall into three main categories, based on their intended mode of action. Soft palate lifters aim to reduce vibrations from the soft palate by elevating both the soft palate and uvula; however, there is little evidence regarding their effectiveness. Tongue retaining devices prevent the tongue from falling back into the pharyngeal airway. They have been found to reduce sleep apnea only moderately and, in addition, are poorly tolerated. The last category comprises the so-called mandibular advancement devices (MADs). These appliances, which are worn intra-orally at night to advance the lower jaw,
have emerged as an increasingly popular alternative for controlling snoring and OSA (6). The mechanism of action of MAD, is usually assumed to involve enlargement of the retroglossal space by anterior displacement of the tongue, the major muscle of which, the genioglossus muscle, is inserting at the lingual surface of the anterior mandibular arch. By means of these anatomical changes MAD, can diminish collapsibility and thus reduce the severity of snoring and OSA by widening the cross-sectional dimension of the upper airway (5, 13, 15–17).

Follow-up of patients treated with a MAD is recommended due to the presence of marked orthodontic side-effects in individual patients (16). Poor compliance and bad tolerance are the commonest limiting factors for the use of a MAD, although early side-effects often resolve after a few weeks (5, 6, 15, 17).

MADs are usually individually fabricated from plaster casts of both jaws and are made from polymethyl-methacrylate. The potential disadvantages of these custom-made devices are the cost and time required to construct them (13).

The main objective of this study was to evaluate the efficacy, feasibility, acceptance and patient compliance of a low-cost fabricated MAD made from a thermoplastic material, which can be directly adapted intraorally. The MAD used in this study (Somnoguard®; Tomed Dr. Toussaint GmbH, Germany) is shown in Fig. 1.

A second aim was to investigate whether this MAD can be used as a screening tool prior to fabrication of a more expensive custom-made device.

MATERIAL AND METHODS

Only adults seeking treatment for heavy, anti-social snoring with a respiratory disturbance index (RDI) of <20 events/h were included in the study. The RDI was determined by means of standard polysomnography.

Dental requirements for inclusion in the study were the absence of any pre-existing dysfunction of the temporo-mandibular joints (TMJ) and the presence of enough natural teeth to anchor an appliance. Before every adaptation, a single trained dentist performed a clinical examination of the stomatognathic system, including measurement of mandibular mobility, palpation of the TMJ and masticator muscles and recording of pain and mobility. The same procedure was repeated at both the 1- and 6-month follow-up visits.

The adaptation of the MAD was performed according to the manufacturer’s recommendations. During the fitting procedure the MAD is positioned by means of a wooden spatula that holds the device through the front opening (Fig. 1). The prefabricated MAD is then immersed in water that has just stopped boiling for \( \approx 10–15 \) s. Afterwards the patient is asked to bite into the soft resin in a protrusion halfway between maximal protrusion and the habitual position, and is guided by the dentist to do so. Finally, the mouthpiece is rinsed with cold water. This fitting procedure is quite straightforward and can take only 10 min with experience. At each visit, there is the possibility for refitting if necessary. The costs of the MAD amount to \( \approx \text{US$60} \).

A standard 10-cm visual analogue scale (VAS) ranging from zero (no snoring noise) to 10 (extreme noise: bed partner has to leave the room or sleep in a separate room) was used to evaluate the status of snoring during sleep as assessed by the sleeping partner. Heavy snoring was defined as a score of at least seven on this VAS. The VAS was completed before adaptation and at each follow-up visit. A difference of at least three points on this snoring index is considered to be significant. To be considered a satisfactory result, snoring must be reduced to a level that is no longer considered bothersome, i.e. to a snoring index of \( \leq 3 \).

To assess daytime sleepiness the subjects completed an Epworth Sleepiness Scale (ESS) at each evaluation (18). EDS was defined as an ESS score of \( > 10 \).

Polysomnography included the recording of a four-channel electroencephalogram (C3, C4, references A1 and A2), a two-channel electrooculogram and a chin electromyogram, determination of oronasal airflow using an external thermistor, oxygen saturation using pulse oximetry with a finger probe and thoracic and abdominal movements using strain gauges and detection of snoring sounds by means of a microphone. The RDI was calculated as the total number of respiratory events/h of sleep (total sleep time). Primary snoring was defined as an RDI of \( < 10 \) events/h without EDS,
RESULTS
Of the 20 study patients, 9 had a polysomnographic diagnosis of primary snoring, 9 of non-apneic snoring and 2 of mild OSA. The overall mean age at the time of fitting was 46 years (range 27–72 years). Baseline characteristics of the study population are presented in Table II.

Snoring
A statistically significant reduction in subjective snoring scores was observed at both follow-up visits compared to baseline. The pre-treatment snoring score was $9.0 \pm 0.3$ and snoring scores with the device were $5.0 \pm 0.7$ at the 1- ($p < 0.001$) and $6.8 \pm 0.7$ at the 6-month follow-ups ($p = 0.025$). VAS values before adaptation and at the 1- and 6-month follow-ups are shown in Fig. 2.

Twelve patients (60%) had an important reduction in snoring after 1 month and the VAS value was reduced to $\leq 3$ in 6 patients (30%). Six months after the initial fitting of the device, 9 patients (45%) reported an important reduction in snoring and snoring was still satisfactorily reduced in 5 (25%).

Experience of daytime sleepiness
The ESS scores, adjusted for multiple comparisons, were significantly lower at the 1- and 6-month follow-ups as compared with the values before adaptation (Fig. 3). The ESS score decreased from $8.8 \pm 1.1$ at baseline to $6.6 \pm 1.2$ at the 1-month follow-up ($p = 0.036$), and to $5.4 \pm 1.0$ at the 6-month follow-up ($p = 0.033$).

Eight patients had complaints of EDS before starting therapy. Of these, 5 patients (62.5%) scored $\leq 10$ on the ESS at both evaluations, suggesting elimination of EDS with the MAD.

Sommography
Respiratory polygraphy both with and without Somnoguard inserted ($n = 17$) showed significant differences in AHI. AHI values decreased from $8.4 \pm 2.9$ events/h at baseline to $3.9 \pm 1.8$ events/h with the device ($p = 0.001$) (Fig. 4). In terms of reduction in AHI, the success rate was 65% ($11/17$).

Table II. Baseline characteristics of the study population ($n = 20$)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>46.8 ± 12.1</td>
</tr>
<tr>
<td>Gender</td>
<td>75% male</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>26.7 ± 3.5</td>
</tr>
<tr>
<td>Snoring index (VAS 0–10)</td>
<td>9 ± 1.3</td>
</tr>
<tr>
<td>ESS (0–24)</td>
<td>8.8 ± 4.7</td>
</tr>
<tr>
<td>RDI (events/h)</td>
<td>5.5 ± 4.6</td>
</tr>
</tbody>
</table>

Table I. The number of patients ($n = 20$) who complained of the commonest side-effects of MAD treatment according to the literature at the 1- and 6-month follow-up visits

<table>
<thead>
<tr>
<th>Side-effect</th>
<th>1 month</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypersalivation or dribbling</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Morning discomfort</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Loss of device</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Pain from TMJ or teeth</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Breathing problems</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Device too big</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Nausea</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Suffocation</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Altered bite</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Compliance
After 1 month, 12 subjects (60%) claimed to use their device every night. Patients were using Somnoguard on average for 5.6 nights per week and for 6.5 h per night. A decline in compliance was seen after 6 months, with only 35% of subjects still using the device every night. Compliance had dropped to 3.3 nights per week and 4.6 h per night.

Side-effects
The thermoplastic MAD, Somnoguard, used in this study was well tolerated during the entire study period. None of the patients complained of adverse effects severe enough to cause them to stop using the device. The reported side-effects are shown in Table I. Side-effects were usually minor and most of the initial side-effects were only temporary and resolved within 3–4 weeks. Hypersalivation was the adverse effect most often mentioned. After 4 weeks, 11 (55%) subjects had experienced excessive salivation. Five months later only two persons were still complaining of hypersalivation. With regard to morning discomfort and lack of retention of the device, a similar habituation over time occurred as with the effect of hypersalivation. A sensation of altered occlusion was not reported by any of the patients.

Satisfaction
After 4 weeks, 5 patients (25%) were “very satisfied” with the treatment while another 8 (40%) reported “satisfaction”. Seven patients (35%) reported “no satisfaction”. After 6 months, 40% of patients were still “satisfied”, while the number of “very satisfied” subjects had dropped towards 15%. Follow-up at 6 months revealed nine patients who were not satisfied with Somnoguard.

Dental and TMJ aspects
Two patients were asked to stop treatment with the dental appliance after 1 month. Both patients had signs of temporo-mandibular dysfunction on clinical examination during the evaluation session.

DISCUSSION
The presented data demonstrate that use of Somnoguard results in statistically significant reductions in subjective snoring and daytime sleepiness in heavy snorers and those with mild OSA. The success rate based on the change in AHI was 65%, which is
consistent with other studies (8, 9, 21). The overall reported use of the MAD in the test population was rather high, with 12/20 subjects claiming use of the device each night at the 1-month follow-up. Side-effects were minor and not frequent. Most of the adverse effects seemed to be confined to a habituation period of 2–3 weeks. No severe side-effects on dentition were found, although two patients were asked to stop the treatment after 1 month because of signs of temporo-mandibular dysfunction on clinical examination.

From a dental point of view, a few considerations are worth mentioning concerning the device evaluated in this study. First, visual control over the wanted protrusion is rather hard to obtain during the adaptation procedure, so that one cannot be very sure about the reproducibility of the achieved position. Moreover, Somnoguard tends to deflect when the patient bites into the wooden spatula, thereby deviating from the mediosagittal plane. Ultimately, therefore, the reproducibility of the mandibular position is questionable. Second, retention of the MAD has proven to be insufficient in the case of adverse dental situations, such as prognathic or very protruding upper incisors, even if enough teeth are present to anchor the device. Such poor retention leads to loss of the device at night. Sometimes, patients bite through the device with their incisors during the fitting. This can make a bad impression on the patient, but turned out not to be an adverse factor in terms of the performance of the device. Finally, it is not always possible to avoid the patient biting into the margins of the MAD during adaptation. In such case, the MAD is most often lost and one has to start the adaptation procedure again using a new device.

The present study is the first to have extensively evaluated the novel thermoplastic MAD Somnoguard. There have been several reports on the effects of MADs in snoring and OSA (5, 6, 8, 9, 11, 13, 15–17, 20, 21). Overall, reported success rates with MADs in the treatment of SRBD vary from 14% to 95% (5, 8, 15). In a recently published, randomized, 4-year follow-up study, higher success rates were reported with MADs than with UPPP in the treatment of mild-to-moderate OSA (8). As a result, MAD therapy has become a valid alternative in the treatment of snoring and mild-to-moderate OSA, although there is a tendency for effectiveness to decline with time (13). The majority of established MADs are expensive because they are individually fabricated (5, 13). The average costs for a custom-made MAD range from US$400 to > US$1000. In the present pilot study, we evaluated a less expensive (~ US$60) prefabricated MAD. To our knowledge this paper is only the fourth report in the literature concerning an immediately intraorally adaptable MAD made from thermoplastic material. The dental orthosis “SnoreGuard” was evaluated by Schmidt-Nowara et al. (21): their results were very similar to ours, with a significant drop in objective as well as subjective parameters. The oral device “Noiselez” was studied by Borgersen et al. (15). As their results suggested little or no effect on snoring and sleep apnea, and as 86% of their patients found the “Noiselez” inconvenient to use, the authors could not recommend this appliance, which was made from semisolid material, for clinical use (15). Schönhofer et al. (13) evaluated Snorban”, which improved OSA to a clinically relevant degree in 50% of their population. Those authors were the first to propose thermoplastic devices as a strategy for testing the efficacy of the therapeutic principle of mandibular advancement in the individual patient. The present data, like the results of Schönhofer et al. (13), confirm that about half the patients treated with a MAD may not respond to or comply with therapy (5, 13). The best strategy in order to counter this problem seems to be to screen treatment efficacy using a splint, which is simple, quickly adapted and inexpensive. Somnoguard seems to fulfill these conditions. In this way, fabrication of an expensive device can be avoided in the non-responders.

CONCLUSIONS

Traditionally, construction of a MAD requires dental impressions, bite registration and fabrication of the device by a dental technician. In contrast to these classical, custom-made devices, the appliance evaluated in this pilot study can be individually adapted to the patient’s teeth in the outpatient clinic.

Although side-effects and adverse events in the stomatognathic system with this novel dental appliance are few and predictable, treatment should be performed using a multi-disciplinary approach with close collaboration between ENT specialists and dentists and long-term follow-up of symptoms and polygraphic values to evaluate its effectiveness.

We conclude that the commercially available MAD Somnoguard has been shown to be a valuable, cost-effective treatment method and deserves to be added to the first-line arsenal for the control of snoring and mild OSA. In addition, further evaluation of this immediately adaptable technique is necessary to assess the screening of candidates for a custom-made MAD. Studies that compare the effect of both custom-made and thermoplastic devices, preferably in a cross-over design, are required to determine whether a less expensive, thermoplastic MAD can be used as a screening tool before the adaptation of a more expensive, custom-made device.
REFERENCES


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