

ORIGINAL RESEARCH

A mandibular advancement device for the ENT office to treat obstructive sleep apnea

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OBJECTIVE: To prospectively evaluate the efficacy of the mandibular advancement device (MAD) Somnoguard in the treatment of OSA patients.

STUDY DESIGN AND SETTING: Forty-four patients with OSA and noncompliant to continuous positive airway pressure were enrolled in this case series. Somnoguard is made of thermoplastic material. Direct intraoral fitting was done by an otorhinolaryngologist. Polysomnographic data concerning sleep and respiration were assessed at baseline and after familiarization with the MAD.

RESULTS: Sleep efficiency and sleep stages distribution did not change significantly. The RDI could be reduced from 31.5 ± 17.6 to 18.2 ± 17.0 ($P < 0.05$), the minimal oxygen saturation increased from 78 ± 12.9 to $82 \pm 12.5\%$ ($P < 0.05$). According to standard criteria, 18 patients were cured, 12 were improved, 8 remained unchanged, and 6 worsened. Snoring time decreased from 223 ± 132 to 183 ± 134 minutes ($P < 0.05$).

CONCLUSION AND SIGNIFICANCE: With Somnoguard 68% of the enrolled OSA patients could be cured or substantially improved. It is a simple MAD for the otolaryngologist.

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Obstructive sleep apnea (OSA) is a dyssomnia that affects about 2% to 4% of the adult population.¹ It is characterized by a recurrent partial or complete collapse of the pharyngeal airway that causes hypopneas and apneas with consecutive oxygen desaturations. These breathing impairments are terminated by arousals associated by a sympathetic activation that reopen the airway thus normalizing

breathing and blood gases. However, each arousal also leads to a disruption of the sleep continuity and an increase of the heart rate and the arterial blood pressure. Nonrestorative sleep with excessive daytime sleepiness, irregular snoring, hyperhidrosis, and hypertension are some of the symptoms of OSA² and an increased morbidity and mortality due to accidents³ and cardiovascular diseases⁴ have been proven during the last decades.

Nasal ventilation therapy with continuous positive airway pressure (CPAP) has become the gold standard in the treatment of OSA because it is able to reverse sleep-disordered breathing and reduce or even eliminate symptoms as well as its increased morbidity and mortality.⁵ However, compliance remains an unsolved problem. Therefore, 20% to 40% of the patients do not use their CPAP-device sufficiently over time.^{6,7}

In this context, alternative techniques have gained increasing interest among the public. Since the first publication about the tongue-retaining device in 1982 by Cartwright and Samelson,⁸ various types of oral devices have been invented whereby mandibular advancement devices (MAD) are proven to be most efficacious with the highest degree of evidence.⁹ They intend to actively open the airway and increase the tension of the pharyngeal and tongue muscles. This mechanism is considered to prevent the upper airway from collapsing. Success rates have been reported to be in the range of 70% for OSA. However, success cannot be predicted in the individual patient. In addition, custom fit oral appliances are expensive. Thus, a trial with a cheap

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MAD would be of great interest for patients and insurance companies. For this purpose, we evaluated the MAD “Somnoguard” made of thermoplastic material. The aim of this study was to determine its efficacy in the treatment of OSA patients.

METHODS

This study was a prospective, nonrandomized clinical trial in a group of OSA patients primarily rejecting or secondarily noncompliant to nasal CPAP ventilation. Patients with primary snoring were not included. A sufficient dental and gingival status as well as a protrusion of the mandible of at least 0.5 cm was necessary to be offered participation in this study. Patients with teeth grinding, a strong gagging reflex, or temporomandibular joint disorders of any kind were excluded.

Polysomnography (PSG) was scheduled at baseline and after familiarization with the MAD to assess snoring, sleep, and respiration. One night of fully attended PSG was performed and evaluated in our sleep disorders center according to standard criteria¹⁰ in every patient at each time point. Patients returned for PSG with the MAD 122 ± 131 days (range, 19 to 543) after fitting. For this study, the apnea index (AI), hypopnea index (HI), respiratory disturbance index (RDI), mean oxygen saturation (O₂mean), lowest oxygen saturation (O₂min), respiratory arousal index (RAI), snoring time (snore), the time in bed (TIB), total sleep time (TST), sleep efficiency (SE), and the sleep stage distribution (W, S1-S4, REM) according to Rechtschaffen and Kales¹¹ were recorded. Six months after the fitting procedure all patients were phoned and asked whether the device was still intact. Those who did not attend for the control-PSG until that date were asked to do so.

Daytime sleepiness was assessed by the patient using the Epworth Sleepiness Scale (ESS).¹² A treatment success was defined as at least a 50% reduction of the RDI and below 10. Patients were considered improved if their RDI was reduced by more than 20% and worse if the RDI increased by more than 20%. Quan et al¹³ found that the RDI differs about 20% from one night to another. Therefore, an increase and decrease of the RDI of less than 20% were defined as unchanged.

A total of 44 patients (35 men and 9 women) with OSA (RDI, $32 \pm 17.6/h$; range, 15 to 89) proven by polysomnography were enrolled from October 2001 to December 2002. They had a mean BMI of $28.6 \pm 4.2 \text{ kg/m}^2$ (range, 21.9 to 41.9) and were 48.9 ± 8.1 years old (range, 25 to 76).

Somnoguard (Fig 1) is a MAD made of the thermoplastic material ethylvinylacetatocopolymer, which softens when heated above 45°C. Fitting was done as proposed by the manufacturer (Tomed Dr Toussaint GmbH, Bensheim, Germany) by an otorhinolaryngologist in the outpatient department. After practicing the fitting procedure with the cold device, patients had to actively advance their mandibles as much as possible. Then the aspired protrusion (50% to 75% of maximal advancement) was determined, and the patients had to demonstrate that they were able to achieve that protrusion by themselves. One wooden tongue depressor was inserted into the frontal breathing opening to be used as a handle while fitting. Warming Somnoguard in simmering water for 35 seconds softens the material to become moldable, without burning the oral mucosa. At this point, the lower groove was put on the teeth of the lower jaw and the teeth of the upper jaw were inserted into the upper groove. After having gained sufficient contact between teeth and grooves, the patient advanced his or her mandible to the previously defined protrusion and bit firmly into both grooves while molding the device with the tongue toward

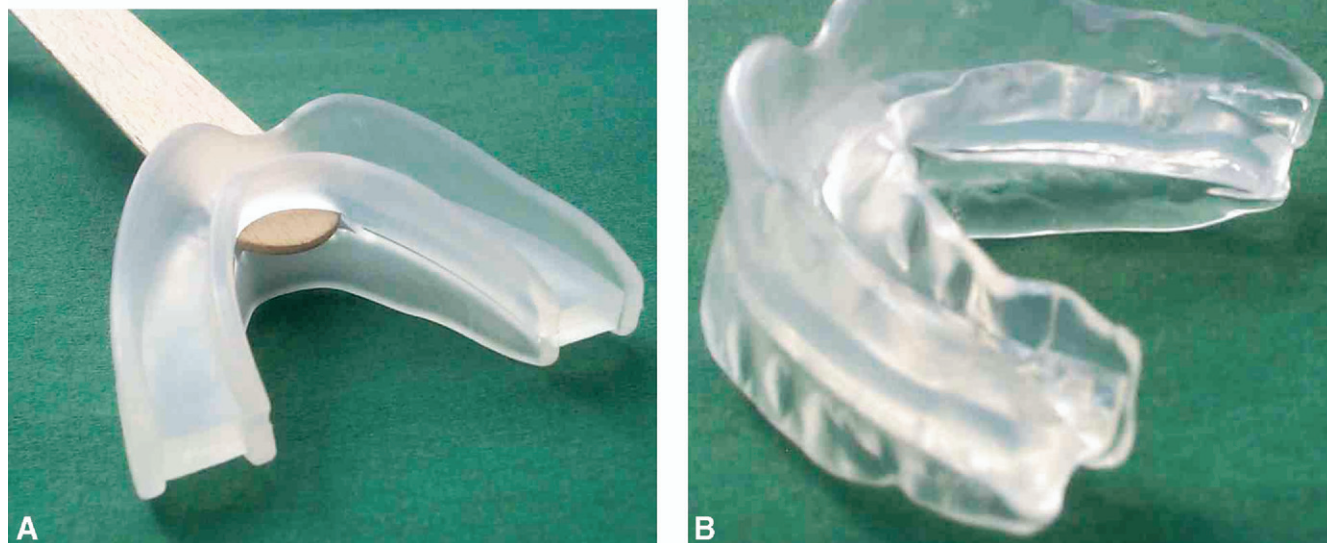


Figure 1 Somnoguard before (A) and after (B) the fitting procedure.

Table 1
Respiratory parameters with and without Somnoguard

	Without Somnoguard	With Somnoguard
AI (n/h)	15.2 ± 15.9	7.3 ± 11.3
HI (n/h)	16.4 ± 11.7	10.8 ± 9.6*
RDI (n/h)	31.5 ± 17.6	18.2 ± 17.0*
RAI (n/h)	20.6 ± 19.4	17.4 ± 24.8*
O ₂ mean (%)	92.8 ± 2.3	93.5 ± 2.0
O ₂ min (%)	78.0 ± 12.9	82.3 ± 12.5*
Snore (min)	223 ± 132	183 ± 134*
Snore/TIB (%)	42.0 ± 29.7	33.8 ± 27.7*

AI, apnea index; HI, hypopnea index; RDI, respiratory disturbance index; RAI, respiratory arousal index; O₂mean, mean oxygen saturation during the recording; O₂min, minimal oxygen saturation during the recording; Snore, snoring time; Snore/TIB, snoring time per time in bed.

**P* < 0.05.

teeth and jaws from intraorally. Meanwhile, the examiner firmly molded the vestibular part of the MAD with his or her fingers. The patient had to keep on biting without moving his or her jaws for 30 seconds in order to reharden the material. Finally, the tongue depressor was taken out leaving a small frontal hole in the MAD for some oral breathing. If a breathing hole was not desired by the patient, the tongue depressor was taken out after the intraoral placement of the device but before molding it. If needed, the fitting procedure can be repeated but then the heating period in simmering water has to be reduced to 20 seconds.

As treatment with the MAD was not different from clinical routine and as Somnoguard is approved for the treatment of OSA by the German health authorities, a formal approval of the Institutional Review Board was not considered necessary. Nevertheless, the study was conducted according to the Declaration of Helsinki, and each patient gave informed consent before participating in the study.

A paired 2-tailed Student's *t* test was used to determine whether differences between baseline and final scores were significant. If there was a nonscalar evaluation, a Wilcoxon signed-rank test was performed. For all statistical analysis the SAS-program was used.

RESULTS

Fitting of the device was possible in all patients and always done by trained staff members. Six patients needed a second fitting as a result of insufficient protrusion, and in five cases the molar rims of the device had to be thickened with an additional plastic stripe made of the same material as the device that had been included especially for that purpose. There were no complications during the fitting procedure.

The adaptation period was 1 to 26 days. The average time to follow-up was 122 days (range, 19 to 543). Four (9%) patients used the device during the study period but felt that it was uncomfortable so they decided to stop using it after the follow-up examination. All used appliances were still intact at the follow-up visit and at the phone interview 6 months after the fitting procedure. While wearing the device all patients complained about an increased saliva production during the first week that resolved acceptably in all but six patients. Tooth pain that lasted longer than 1 hour after removing the device in the morning was mentioned in one case, 10 patients complained about weary teeth in the morning, and 5 patients about an aching masseter during the first week of the trial. Eight patients reported losing the device during sleep at least once a week.

At the time of the follow-up, PSG patients reported using the appliance 6.7 hours per night and 6.5 nights per week on average. In total, 37 patients stated using the device at least 6 hours every night and to be willing to continue to use a similar device in the future, which equals a subjective compliance of 84%.

Respiratory (Table 1) and sleep parameters (Table 2) with and without Somnoguard demonstrate a significant reduction of the severity of sleep-disordered breathing and an increase of slow wave sleep and movement time but a decrease of REM sleep while wearing the appliance. Sleep efficiency as well as RAI did not change significantly. The RDI could be reduced by 37% in average. According to the defined success criteria, 18 (41%) patients were a success, another 12 (27%) were improved, 8 (18%) remained unchanged, and 6 (14%) became worse. Two patients of the success group were severely affected OSA-patients (RDI >40/h). The Epworth Sleepiness Score decreased from 10.1 ± 5.1 to 7.6 ± 4.2 (*P* < 0.05).

Table 2
Sleep parameters with and without Somnoguard

	Without Somnoguard	With Somnoguard
TIB (min)	493 ± 61	485 ± 60
TST (min)	419 ± 76	416 ± 67
SE (%)	85.0 ± 11.2	85.8 ± 9.5
Wake (%)	11.4 ± 9.4	11.4 ± 7.4
S1 (%)	6.8 ± 7.6	8.2 ± 8.3*
S2 (%)	46.3 ± 16.4	40.5 ± 17.6*
S3 (%)	8.5 ± 6.2	11.0 ± 8.7
S4 (%)	4.3 ± 7.0	7.0 ± 11.4
SWS (%)	12.5 ± 11.1	18.1 ± 16.3*
REM (%)	18.5 ± 14.3	15.1 ± 12.2*
MT (%)	0.9 ± 1.2	1.8 ± 2.3*

TIB, Time in bed; TST, total sleep time; SE, sleep efficiency; Wake, stage wake; S1, stage non-REM 1; S2, stage non-REM 2; S3, stage non-REM 3; S4, stage non-REM 4; SWS, slow wave sleep (S3 + S4); REM, stage REM; MT, movement time.

**P* < 0.05.

DISCUSSION

In this study, we report on 44 patients with mild to severe sleep apnea who are treated with the mandibular advancement device Somnoguard, which is made of thermoplastic material and can be fitted by an ENT-specialist in his or her own office.

Our data demonstrate that the device can be easily fitted without any complications and be used without severe side effects. Its durability is sufficient to outwear a complete testing period. We suggest that the fitting is done by trained people as we did in our study. If the patient is doing it, we expect a high rate of wrongly fitted devices without sufficient adherence to the teeth. This might result in a higher percentage of unsuccessful test periods. The short-term compliance of the device (84%) seems comparable to MADs made by a team of a specialized dentist, a dental technician, and a dental laboratory. For those devices, subjective compliance rates of 37.5% up to 100% are reported.¹⁴⁻¹⁷ However, compliance of oral appliances cannot be measured objectively and, therefore, must be considered lower in reality as is already shown for nasal CPAP-therapy.¹⁸ Up to now, there is no evidence in the literature that compliance relevantly decreases over time even though it might be expected. On the other hand, Ferguson et al¹⁹ demonstrated in a controlled randomized cross-over trial that the subjective compliance of CPAP (70%) is worse than that of oral devices (95%). Furthermore, patients preferred MAD over CPAP in that trial.

Somnoguard is able to eliminate OSA in 41% and to substantially improve OSA in another 27% of the patients. The efficacy of conventional MADs in the treatment of OSA has been demonstrated by well-controlled trials.⁹ In an evidence-based review of the literature, Ferguson et al²⁰ found a reduction of the RDI below 10 events per hour in 52% of the patients treated. This is 11% better than in our group of patients where we only achieved a success rate of 41%. This superiority might be due to the inclusion of adjustable MADs in the Ferguson et al review. They are considered to have better results than nonadjustable MADs because of the possibility of titrating the protrusion until the optimal amount is reached and efficacy is achieved.^{19,21} Our device is not adjustable and therefore the optimal protrusion may have been missed in some patients. In six patients, we realized a worsening of OSA. One patient had the highest BMI (42 kg/m²) but the remaining five deteriorations cannot be explained. The deterioration of a small subgroup of patients is well known with custom-fit MAD as well. Rose et al²² found a worsening in 19% of their patients.

In a previous investigation,²³ we have shown comparable results with a similar device in a group of less severely affected patients. Thus thermoplastic devices are offering the chance to test the feasibility of MAD treatment cost-effectively even in severely affected patients who are primarily not considered to be good candidates for oral appliances.⁹

Polysomnography showed a significant increase of slow wave sleep as a marker of better sleep quality that is reflected during the day in the ESS data. This objective self-evaluation of daytime sleepiness showed a significant improvement from mild to borderline daytime sleepiness with the use of the MAD. This parallels other studies that use custom-made devices.²⁴ On the other hand, there is no decrease of the respiratory arousal index in contrast to what one would expect. It can be hypothesized that the device causes a nuisance to the patient if it is not attached to the teeth well enough and leads to impaired breathing and finally arousals.

We did not assess any long-term data so we cannot say anything about long-term compliance, side effects, or efficacy. This was not the purpose of our study as we consider Somnoguard rather as a screening tool than a long-term treatment option. Therefore, it has to be kept in mind that a patient who was not compliant to a MAD of thermoplastic material may ultimately tolerate a custom-made MAD. As a practical approach we always recommend Somnoguard for a trial if the patient is suitable. In case of good patient compliance and proven success, the patient will be referred to a dentist for long-term treatment. If there is no patient compliance, we will also send the patient to a dentist in order to decide whether a custom fit oral device might still be worth trying. Yet, there will be no further treatment after an unsuccessful trial period despite sufficient compliance of the patient.

The primary limitation of this study is the lack of a control group. However, treatment efficacy of MADs in general has been shown by studies of high evidence levels and an evidence-based review has been published recently.⁹

A limitation of the device is the risk of losing it while asleep because the anchorage to the teeth seems weaker compared with a custom-made device. As a result, the persistence or recurrence of OSA is possible despite putting the device in place before going to bed. Second, this is not an adjustable device. Therefore the optimal protrusion of the lower jaw must be found during two fitting procedures at maximum. An adjustable positioner made of thermoplastic material could combine the advantages of a screening tool and of a boil-and-bite device for patient and physician. Another limitation is the difficulty and even impossibility of releasing certain teeth from the stress exerted on them by the device itself when forcing the lower jaw into the advanced position. These dental issues may exclude some patients from starting an individual trial period with the device.

CONCLUSION

With the MAD Somnoguard, 41% of the enrolled OSA patients could be cured and 27% substantially improved. Sleep quality could be improved as well. The appliance might be suitable as a screening tool to better predict the

efficacy of custom-made MADs in the individual patient as their results seem to be comparable with each other. The limitations of boil-and-bite devices have to be kept in mind.

Taking the results of this case series into account a randomized trial is necessary to compare Somnoguard to custom fit nonadjustable as well as adjustable oral appliances.¹⁰

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