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Immediate Intraoral Adaptation of Mandibular Advancing Appliances of Thermoplastic Material for the Treatment of Obstructive Sleep Apnea

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Key Words

Mandibular advancing device · Sleep apnea · Snoring · Prefabricated thermoplastic material · Sleep stages · Costs

Abstract

Background: In the treatment of obstructive sleep apnea (OSA), mandibular advancing devices (MAD) are usually individually fabricated on plaster casts of both jaws from polymethyl-methacrylate. The potential disadvantages of these devices are (1) the costs and (2) the time required to construct the device. ***Objective:*** In this study, the efficacy and feasibility of a cheap MAD consisting of thermoplastic material (SnorBan®), which can be directly moulded intraorally, were evaluated. ***Methods:*** In a prospective study, the effect of an MAD consisting of thermoplastic material was investigated in 22 consecutive patients with OSA [respiratory disturbance index (RDI) 32.6 ± 18.4/h]. Polysomnographic sleep was recorded prior to treatment and after 3 months of treatment with the MAD. ***Results:*** Three of the 22 patients who did not tolerate the MAD were excluded from the analysis, whereas 11 patients were classified as responders. In the responder group, the mean RDI decreased from 27.6 ±7.3 to 7.3 ± 2.9 ($p < 0.01$), correspondingly the sleep quality and the Epworth Sleepiness Scale improved ($p < 0.05$). Eight patients proved to be non-responders without relevant changes for the measured parameters. ***Conclusions:*** In 50% (11 of 22) of the patients, the MAD improved the OSA to a clinically relevant degree. In contrast to the majority of established MAD, the MAD investigated is cheap and immediately adaptable and thus a feasible strategy to 'screen' the efficacy of this therapeutic principle. Thus the construction of unnecessary MAD is avoided.

Introduction

The management of less severe cases of obstructive sleep apnea (OSA) and snorers and the recent reports of the overall reduced compliance of patients treated with nasal continuous positive airway pressure (n-CPAP) [1] have led to an advocacy of alternative treatment approaches in patients with OSA. Oral devices to treat patients with sleep-disordered breathing have been introduced more than 10 years ago [2, 3]. Recently, there has been a dramatic increase in the number of devices and their structural variety [4]. The American Sleep Disorders Association (ASDA) has reviewed 21 publications investi-

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gating oral appliances for snoring and OSA [5]. It was concluded that oral appliances may present a useful alternative to n-CPAP, especially to treat snoring and when n-CPAP therapy is not tolerated. The structural spectrum of oral devices ranges from simple [6, 7] to complex appliances [8–10]. The main effect of most devices results from the prosthetically induced mandibular advancement. The appliances are designed to protract the mandible thereby increasing the cross-sectional dimension of the upper airway. Unfortunately, not all patients benefit from a mandibular advancing device (MAD), and presently no method exists to predict the outcome prior to fabrication of the MAD. The MAD mostly consist of an acrylic resin polymethylmethacrylate, individually fabricated on plaster casts of both jaws of the patient. The fabrication of such a MAD is relatively time consuming and expensive; in addition, whether the patient will benefit or not is not indicated before therapy. Therefore, the efficacy and feasibility of a prefabricated MAD was studied. This MAD consisted of thermoplastic material which is much cheaper and which is adapted to the patient within minutes.

Patients and Methods

Prior to study entry, every patient was examined by an oral maxillofacial surgeon. The examination consisted of: visual inspection of the naso-/oropharynx, dental status, dental occlusion, temporomandibular joint (TMJ) function, and craniofacial anatomy. Exclusion criteria included nasal polyposis, large tonsils, craniofacial changes (maxillo-mandibular deficiency), inadequate dental anchoring structures for the device (periodontitis, partially edentulous with more than 2 teeth missing per quadrant), and TMJ dysfunction.

Standard polysomnographic recordings were done with an Edit-sleep (MAP, Martinsried, Germany), and polygraphic recording with Poly-MESAM (MAP). Standard polysomnographic recordings consisted of two EEG derivations (C4-A1 and C3-A2), electro-oculogram, electromyogram of submental and tibialis anterior muscles and electrocardiogram (modified V_2 lead). Respiration was monitored using oronasal thermistors, and thoracic and abdominal movements with inductive plethysmography. Body position and oxygen saturation (SaO_2) using finger pulsoximetry were also recorded. Breathing sounds were monitored using a microphone which was placed just below the larynx using a MESAM 4 device (MAP). Sleep was hand scored in 30-second epochs according to the criteria of Rechtschaffen and Kales [11]. We determined sleep efficiency as the total sleep time divided by the total time in bed. Sleep latency was defined as the time from the start of the study (lights off) to sleep onset [11]. The arousal index was defined as the number of arousals per hour of sleep; arousals were scored according to the ASDA criteria [12]. Apnea was defined as a complete cessation of oronasal air flow for at least 10 s. Apneas were classified as obstructive in the presence of thoracic or abdominal movements. A central apnea was scored if a complete cessation of oronasal air flow for at least 10 s occurred in the absence of thoracoabdominal movements. A hypopnea was defined as a 50% or greater reduction in the amplitude of the airflow waveform from a preceding stable baseline associated with a decrease in SaO_2 of 4% or more. Several indices of sleep-related respiratory abnormality were calculated. These included the apnea index (AI, the number of apneas divided by hours of sleep), the sum of the apneas and hypopneas (respiratory disturbance index, RDI, number of apneic and hypopneic episodes divided by hours of sleep). The mean SaO_2 and the lowest SaO_2 (nadir SaO_2) associated with an abnormal respiratory event during the total sleep time were determined. The snoring index (SI) was calculated from the number of intervals between two snores longer than 11 and shorter than 60 s. Furthermore, the snoring intensity at baseline and with use of the appliance was quantified by the bed partner using a 5-point visual analogue score. The presence of clinical symptoms associated with sleep-disordered breathing was determined by the patient using the Epworth Sleepiness Scale [13].

The costs of the MAD (SnorBan®, Snoring Relief Labs, Sacramento, Calif., USA) amount to approximately $27. The adaptation procedure of the MAD was performed according to the recommendations of the manufacturer. The prefabricated MAD (fig. 1) is put into hot water (90–95 °C, not boiling) for exactly 10 s except for the holding tab to soften the resin. The oral placement of the MAD is performed as follows. After adaptation of the mouthpiece to the upper dental arch, the patient has to protrude the mandible to its maximum frontal position and to bite together with slight retrusion (fig. 2). The permanent maximum protrusion of the mandible is often not acceptable for long-term use due to TMJ discomfort. The amount of protrusion was measured as change in overjet of the first incisors as previously described [14]. A protrusion of the mandible of at least 75% of the maximum protrusion could be achieved in all cases. Finally, the mouthpiece is dipped into a glass of cold water and the holding tap is removed by cutting it off. This adaptation procedure lasts approximately 5 min. Positioning and removal of the device can easily be performed by the user. If the patient feels uncomfortable or the position is incorrect, refitting is possible at least 3 times.

Study Design

The protocol was approved by the ethical committee of the hospital, and all subjects signed informed consent to participate in the study. In a prospective study design, 22 consecutive patients were selected based on clinical features of sleep-disordered breathing. After polygraphic recordings only subjects with OSA with an RDI >10/h were included in the study. There was no upper limit for RDI. During the study, n-CPAP was not offered to the patients. However, patients who reported a reduced alertness while car driving or an automobile accident in the past due to daytime sleepiness were excluded from the study and treated with n-CPAP.

In the laboratory, baseline polysomnographic recordings were obtained from all subjects prior to the adaptation to the MAD in the sleep laboratory. After an adaptation period of 14 days at home wearing the MAD every night, the MAD was rechecked and, if necessary, refitted. The patients completed diary cards recording the total time using the device (h/night). If subjects exhibited tolerance problems they were instructed to use the MAD at least twice at daytime for at least 2 h and to contact us if technical problems persisted. After the 2-week adaptation period, a 3-month period of nightly oral device use followed. At the end of this period the patients were invited to the sleep laboratory for a follow-up recording with the oral device in place. During the week prior to baseline polysomnographic recordings and the follow-up study, patients were instructed to keep regular sleep-wake schedules and to exert alcohol abstinence. To avoid con-

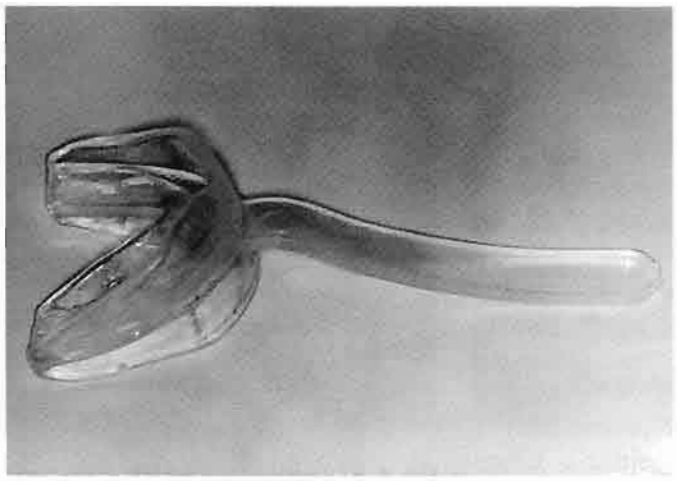

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Fig. 1. The prefabricated thermolabile MAD used in this study.
Fig. 2. The orally inserted thermolabile device with the holding tab with the mandible in the protruded position.

founding effects due to adaptation to patient monitoring was preceded by 1 adaptation night with full recording equipment.

Local side effects of the MAD, subtyped as acceptable and unacceptable, were documented by the subjects using a questionnaire. These included tension of the masticatory muscles, pressure marks on the teeth and gingiva, excessive salivation and narrowness of the oral space. In the following prospective study period, patients were divided into compliant and non-compliant according to their ability to accept treatment with the oral device. In non-compliant patients who were unable to wear the device longer than 2.5 h, a follow-up polysomnography was not performed. Responders were defined according to the efficacy of the device (reduction in RDI >50% in comparison to the baseline value and post-treatment RDI ≤ 10/h, no relevant side effects). In all responders an adjustable MAD, which we have investigated elsewhere [15], was constructed individually after the study. Non-compliant and non-responding patients were subsequently referred for titration with n-CPAP. Neither of these post-interventional trials were part of this study.

Statistical Analysis

Results were expressed as means ± SE. The Wilcoxon signed-rank matched-pair test for non-parametric data was used for statistic comparison. The two-sided Mann-Whitney test was used to evaluate the presence of statistically significant differences between groups for variables with non-gaussian distribution. A p value <0.05 was considered to be significant.

Results

In total, 22 patients (age: 48.6 ± 8.9 years, RDI: 32.6 ± 18.4/h, body mass index: 31.4 ± 5.0 kg/m^2) were studied. Six patients were excluded according to the above-mentioned criteria. After 3 months, 19/22 patients (86.4%) were compliant. Due to unacceptable side effects (pain in the TMJ, hypersalivation, or gingival pressure marks) in the adaptation phase, 3 patients refused to continue the MAD therapy. According to the definition, the responder rate was 11/22 patients (50.0%). Eight patients were non-responders (36.4%). According to the patients' documentation, the MAP was used 5.9 ± 0.9 h/day. In total, the MAD was 1.5 ± 0.4 times refitted.

Table 1 shows an overview of the parameters for the responder and non-responder groups, respectively. In the responder group compared to the baseline, AI, RDI, SI, desaturation and arousal indices, and non-REM-1,2 decreased significantly due to the MAD (table 1). Correspondingly, non-REM-3,4 and REM sleep, mean SaO_2 and SaO_2 nadir increased (table 1). Figures 3 and 4 show the RDI of responders and non-responders. According to the ESS and the visual analogue scores, both daytime sleepiness and snoring decreased in the responder group (table 1). In the non-responder group, compared to baseline, there was no effect of the MAD shown with regard to AI, RDI, SI, desaturation and arousal indices, mean SaO_2 and SaO_2 nadir, the sleep stages, the Epworth Sleepiness Scale and the snoring score (table 1).

There was no parameter to predict success and compliance with respect to the baseline data obtained so far. Furthermore, both groups did not differ with respect to the amount of protrusion.

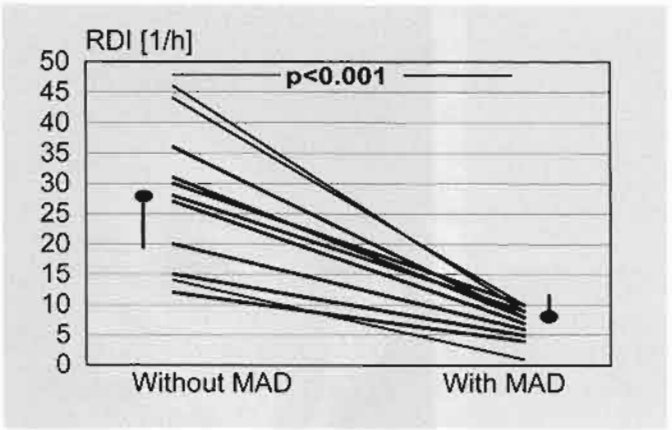

Fig. 3. RDI without and with MAD in responders.

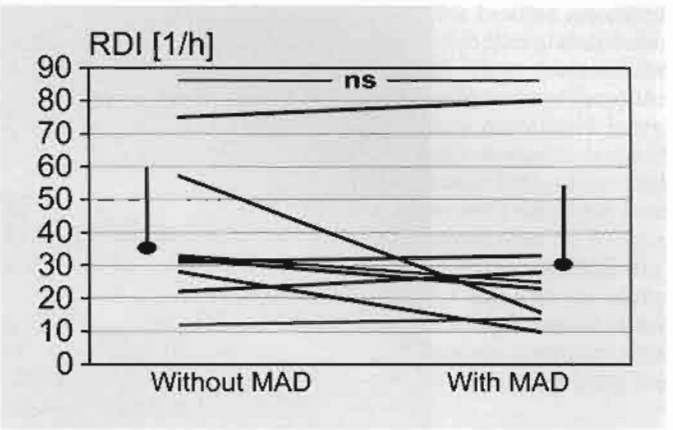

Fig. 4. RDI without and with MAD in non-responders.

Table 1. The effect of applying an MAD for 3 months on different parameters

	Responder (n = 11)			Non-responder (n = 8)		
	without MAD	p	with MAD	without MAD	p	with MAD
RDI, n/h	27.6±7.3	<0.01	7.3±2.9	36.8±22.2	NS	30.4±23.1
AI, n/h	19.1±8.7	<0.001	3.2±2.3	20.4±22.7	NS	20.6±25.2
SaO_2, %	93.4±1.9	NS	93.7±1.0	92.7±2.8	NS	92.8±8.2
SaO_2 nadir, %	79.3±11.3	<0.05	82.9±9.4	72.8±8.2	NS	75.4±8.2
Desl, n/h	27.3±20.0	<0.01	17.4±19.1	38.1±18.1	NS	33.1±19.8
SI, n/h	28.6±9.9	<0.01	15.6±8.5	43.3±19.8	NS	37.1±17.7
Snoring (VAS: 1–5)	4.5±0.7	<0.05	2.3±0.8	4.6±0.5	NS	4.0±1.1
TST, min	332.6±59.8	NS	356.7±64.2	348.6±48.0	NS	361.8±55.3
SL, min	19.1±20.8	NS	23.4±17.0	21.5±15.7	NS	16.9±19.7
SE, % TIB	84.0±11.1	NS	88.6±10.2	87.3±12.2	NS	89.5±9.8
REM, % TIB	12.5±5.3	<0.05	16.1±4.7	9.3±7.5	NS	10.8±6.2
Non-REM 1–2, % TIB	60.3±12.5	<0.05	52.7±9.3	64.2±11.8	NS	67.3±13.9
Non-REM 3–4, % TIB	14.4±6.8	<0.05	17.3±5.2	12.4±5.5	NS	13.8±6.2
Awake, % TIB	13.5±19.2	<0.05	17.2±5.2	12.9±4.8	NS	13.5±7.1
ArI, n/h	33.5±4.0	<0.01	11.8±5.9	43.1±20.3	NS	40.3±23.5
ESS	12.8±4.0	<0.05	9.3±3.6	15.5±3.7	NS	14.4±4.4

Desl = Desaturation index; TST = total sleep time; SL = sleep latency; SE = sleep efficacy; VAS = visual analogue scale; ArI = arousal index; TIB = time in bed; ESS = Epworth Sleepiness Index (0–24).

The following acceptable side effects were documented in the responder group: pain in the TMJ (1/11), tension in the masticatory muscles (1/11), hypersalivation (3/11), gingival pressure marks (5/11) and oral narrowness (2/11). The following acceptable side effects were documented in the non-responder group: pain in the TMJ (3/8), tension in the masticatory muscles (3/8), hypersalivation (6/8), gingival pressure marks (5/8) and oral narrowness (3/8).

Cost Efficiency

In Germany, the average costs for one MAD which is conventionally constructed of acrylic resin (polymethylmethacrylate) on individual casts would have been approximately $400–$600. For 22 patients, this would amount to $8,800–13,200 in total, keeping in mind that only 50% of the population were responders. The price of the thermolabile MAD used in this study was $27.5/patient, amounting to a total of $605 for the whole group.

Additionally, the total cost for the oral surgeon was $330. The total cost of thermolabile MAD in the non-responders and patients with non-compliance was $527.5 (materials: $302.5, and dentist: $225) compared to $4,400–6,600 for individually fabricated MAD. Therefore, with our strategy we saved approximately $4,000–6,000 in the population studied, since the construction of unnecessary MAD for non-responding and non-compliant patients was avoided.

Discussion

The thermolabile MAD, which was used in this study, was well tolerated by more than 80% of the patients during the 3-month study period. However, only in 50% of these compliant patients the MAD reduced OSA to a relevant degree. This result is compatible with previously published data [16]; according to a meta-analysis of the ASDA, about 50% of the study patients were efficaciously treated with MAD, reducing the RDI < 10/h. Correspondingly, due to two recently published controlled studies on n-CPAP therapy with MAD in patients with mild to moderate OSA, compared to CPAP, MAD induced only an improvement but no normalization of breathing in sleep [17, 18]. However, in some patients the device was associated with fewer side effects and greater patient satisfaction compared to CPAP [18].

Based on our findings and previous literature, parameters to predict treatment success and compliance of the MAD are not available. Radiographic visualization or cephalometric evaluation only enabled the exclusion of craniofacial disorders [14]. As confirmed in this study, about half of the patients treated with an MAD may not respond or are not compliant to therapy. The only way to solve this problem is to test treatment efficacy with an MAD which is simple, quickly adapted and inexpensive. The thermolabile MAD used in this study fulfills these criteria. Our results demonstrate that the thermolabile MAD is comparable to other more sophisticated devices with a success rate of about 50% [16, 17]. The amount of protrusion does not explain success or failure. Maximum protrusion was tried to achieve; at least 75% of the maximum protrusion was achieved in all cases measured as the change in incisor overjet. Recently, we have found that the amount of maximum protrusion is variable and is not correlated with the efficacy of the MAD with respect to pharyngeal opening [14].

This cheap device is adapted and refitted within some minutes and worked, as we could show, at least 3 months without loosing its efficacy. According to the principle of 'trial and error', this device enables a therapeutic screening of compliant and responding patients. Having shown both compliance and response to the thermolabile MAD, the prescription of better tolerable, long-lasting, more sophisticated and more expensive individually adapted devices is justified since the durability of this thermolabile MAD might be limited by material fatigue.

Currently, the impact of MAD on OSA is not clearly defined. According to the recommendations of the ASDA paper [16], oral appliances should be considered after failure of more effectively proven treatment procedures rather than before. Therapy with an oral appliance may be useful in subjects who do not tolerate CPAP – despite multiple trials and optimal care by an experienced sleep specialist – or in those who may not be candidates for surgical therapy [19, 20]. Furthermore, an MAD may also be indicated in habitual snorers with or without associated daytime sleepiness [21] or in patients with persistent OSA after uvulopalatopharyngoplasty.

In our study, non-compliance of 3 patients was caused by unacceptable side effects of the MAD (pain in the TMJ, hypersalivation, gingival pressure marks) during the adaptation phase. We did not investigate possible reasons of the side effects (e.g. anatomical or functional disorders) or compliance to an alternative design of an MAD. Furthermore, the aim of this study was not to quantify complications of long-term use. However, MAD may have side effects as internal derangement of the TMJ and should not be advocated for long-term therapy. Certain contraindications may be observed, e.g. extensive periodontitis. Therefore, any dental appliance should only be prescribed in selected individuals controlled by an experienced sleep-disorder specialist together with a trained oral surgeon.

In about 50% of the patients, the MAD improved OSA to a relevant degree. We suggest that a thermoplastic MAD can predict treatment outcome, being a feasible strategy to screen the efficacy of an MAD with a device consisting of thermoplastic material before constructing a definitive appliance. In contrast to the majority of established MAD, the advantages of the device studied are low costs (approximately $27) and short adaptation period (some minutes).

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