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Treatment of Sleep Apnoea Using a Mandibular Advancement Splint – An Open Prospective Study

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Abstract. *Obstructive sleep apnoea (OSA) may cause considerable disturbances, including the development of health problems. This study was performed in order to evaluate the results of treating OAS with a mandibular advancement splint (MAS), and to evaluate the effects of this treatment. This was a prospective open longitudinal study. Ninety patients were randomly selected and included in the study. All 90 patients received an MAS. Forty-eight patients concluded the study, whereas 27 dropped-out and 15 were excluded. The sleep pattern was monitored at home with portable equipment. There was a clear tendency towards a reduction in the apnoea/hypopnea index (AHI) and the oxygen desaturation index (ODI) between the two investigations. Furthermore, there was a tendency towards reduced sleep apnoea; ratings on the Epworth sleepiness scale were lower, indicating a reduction in daytime sleepiness. Treatment with MAS in our study reduced sleep apnoea and snoring, and lowered the values of the Epworth sleepiness scale, indicating a reduction in daytime sleepiness in the majority of the patients. Lifestyle factors are not believed to have affected the results.*

Snoring and collapse of the airways lead to a condition called obstructive sleep apnoea (OSA), which causes considerable disturbances, including the development of health problems (1, 2). Repeated periods of OSA cause a reduction in the oxygenation of the blood (3), usually resulting in sudden awakening, upon which the airways open up. This can be repeated many times during the night, seriously disturbing a person's sleep, thus reducing the quality of life (4). It may also have life-threatening consequences, as OSA is associated with cardiovascular diseases, such as heart attack or stroke (5-7). In addition to these night-time symptoms associated with OSA, snoring, suspension of breathing, irregular sleep patterns and sudden awakening, a lack of rapid eye movement (REM) sleep, is also observed (8). Normally, a large proportion of sleep towards morning is REM sleep. Patients can also experience panting (9) and a feeling of suffocation, as well as violent physical movements. This causes daytime symptoms that may include abnormal sleepiness, difficulties in concentration, and personality changes such as increased irritability, depression and morning headaches (4, 10). Those suffering from daytime sleepiness may be a danger to themselves and to others through accidents in traffic and at work, or through a general lack of concentration (11, 12). Various forms of treatment of OSA are available (13): surgical reduction of the tissue in the oropharynx and oral cavity (14); continuous positive airway pressure (CPAP), *i.e.* providing compressed air through a mask during sleeping (15); non-invasive treatment using a mandibular advancement splint (14, 16, 17). A mandibular advancement splint (MAS) is a flexible device inserted into the mouth to bring forward the lower jaw in order to prevent collapse of the airway during sleep. There are various kinds of MAS (18-20). The increase in the area of the upper airway in response to mandibular advancement is variable (21). A therapeutic target and prediction of success would eliminate a sometimes long adjustment period that has the best effect on OSA. A non-adjustable design set at the target could reduce the time needed for positioner test, the treatment time and thereby reduce costs (22).

This study was performed in order to evaluate the quality of treating OAS with an MAS, as well as to evaluate the effect of this treatment. In addition, we elucidated the possible effects of changed lifestyle, such as weight reduction and change of tobacco and alcohol habits, on the result. We also analysed what characterized the patients who discontinued the treatment and the possible effect on the outcome in relation to age, sex, and general health. Finally, we explored if treatment with an MAS causes any negative effects on the temporo-mandibular joint, the occlusion, the function of the jaw muscles, or any other oral problems.

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Patients and Methods

This study followed the guidelines of the Helsinki Declaration. It was designed as a prospective open longitudinal study. Furthermore, the treatment using the splint was carried out as part of standard care in our clinic. The treatment of OSA with MAS was initiated upon referral after an examination by either a (ENT) specialist or a specialist in pulmonary medicine, which included the recording of sleep patterns. This procedure was followed to exclude other diseases that may have the same or similar symptoms. Exclusion criteria for treatment with MAS were: not approved by the county council purchasing organization; poor dental status, including untreated parodontitis, too few teeth, infection, *etc*.; problems with the mandibular joint or muscles.

During the years 2005 and 2006, 284 patients in total were referred to the Department of Oral and Maxillofacial Surgery at the Uppsala University Hospital, from the Departments of Pulmonary Medicine and Otorhinolaryngology, for examination and possible treatment of OSA. Out of 284 patients referred during the period from December 2005 to February 2006, 90 were randomly selected, 30 from each of three responsible hospital dentists were included in the study. The patients were divided into four groups: 1. All patients – Patients attending first visit (n=90); 2. Participants – Patients attending visits 1 and 2 and where the majority of the patients records were available (n=48); 3. Drop-outs – Patients that discontinued treatment (n=27); 4. Excluded – 15 patients were excluded for not attending the follow-up visit or their sleep pattern was not recorded before and after treatment (n=15).

All 90 patients received an MAS (Figure 1). The MAS used in this study was manufactured on working dental models mounted in an articulator. Based on the clinically registered protrusion the lower jaw model was advanced equivalent to a mandible advancement of approximately 50% of the protrusion (Figure 2). Then two independent soft splints, covering the teeth plus the alveolar ridges and the palatal mucosa of the maxilla, were fabricated and then fused together. The responsibility for collecting and entering data into the case report form (CRF) lay with the hospital dentist who was responsible. Information regarding the patient's medical history and the clinical findings obtained at the first visit and at the follow-up visit, following the recording of sleep patterns with and without the MAS, were entered into the CRF. Investigations were performed at home by the patients using portable equipment (BREAS, SC20, Mölnlycke, Sweden) (3). The sleeping pattern recordings were evaluated automatically by the equipment, and manually by the doctor. The results were used to identify trends. Out of the patients entered into the study, a group of 22 patients were selected, with an apnoea hypopnoea index (AHI) >20, and were analysed manually by a specialist in otorhinolaryngology, and were used as a control group.

General health. The patients' general health was classified according to the scale of the American Society of Anesthesiologists (ASA), modified for dental care, to assess their general physical status (23).

Epworth sleepiness scale. The patients completed an Epworth sleepiness scale (ESS) questionnaire (24) to obtain a subjective measure of their daytime sleepiness before and after treatment with the MAS. The questionnaire consists of eight questions and the answers are graded from 0 to 3, having a maximum score of 24. The questions were of the type: How probable is it that you would doze off or fall asleep in the following situations, rather than only feeling tired?

Table I. *Values of the Epworth sleepiness scale (ESS). The ESS questionnaire consists of 8 questions with scores 0-3, the maximum value is thus 24.*

All patients (Visit 1) n=87*		Participants (Visit 2) n=48	
Mean (range)	Median	Mean (range)	Median
10 (0-20)	10	7 (0-19)	6.5

*Not all data were available for all patients.

Table II. *Values of the apopnea/hypopnea index and the oxygen saturation index on the two occasions sleep patterns. were recorded.*

	All patients (Visit 1) (Baseline values)			Participants (Visit 2) (With the MAS)		
	n*	Mean (range)	Median	n*	Mean (range)	Median
AHI	82	29 (10-77)	26	47	19 (0-53)	14
ODI	78	22 (0-70)	20	48	10 (0-44)	7.5

*All data were not available for all patients and participants.

Evaluation of the treatment. The sleep pattern was monitored at home with portable equipment. The outcome of the treatment was evaluated by comparing the sleep pattern recording before treatment, and after using the MAS. The AHI and the oxygen desaturation index (ODI) were determined. The definition of apnoea is total cessation of airflow through the nose or mouth for a period of at least 10 seconds. Hypopnoea is defined as a reduction in air flow of at least 50% for 10 seconds or more, which causes desaturation of ≥3%. The severity of OSA is assessed by the degree of daytime sleepiness and the number of breathing disturbances per hour of sleep and is expressed using the AHI. We applied the following definition of the AHI (25, 26): slight: 5-15 times per hour of sleep; moderate: 15-30 times per hour of sleep; severe: >30 times per hour of sleep. The data were entered into a database especially constructed for this study, allowing for statistical analysis (Uppsala Clinical Research Centre, Faculty of Medicine, Uppsala University). The anonymity of the patients was guaranteed by blinding the identity of the patients and assigning each patient a code number, stored separately and securely at the Department.

Results

Twenty-seven of the patients (31%) dropped out of the study; the reasons were difficulties in learning how to use the MAS (n=10), cessation of snoring due to weight loss or corrective surgery (n=3), a negative change of the occlusion (n=1), or the MAS had no effect, or CPAP was introduced (n=13). In 8% of these patients it is not clear whether or not they

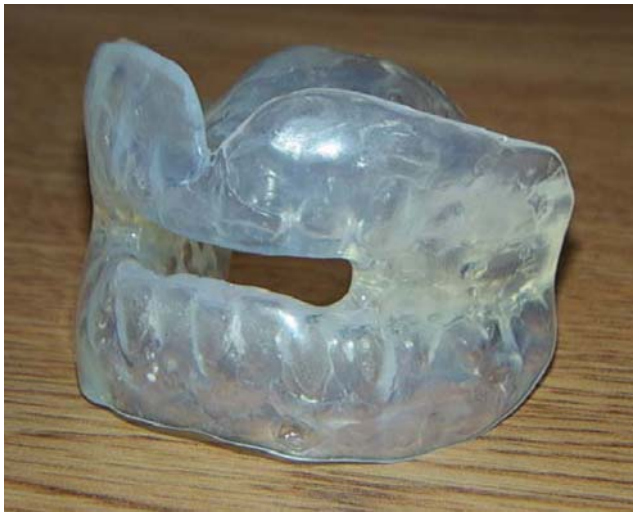

Figure 1. *The mandibular advancement splint.*

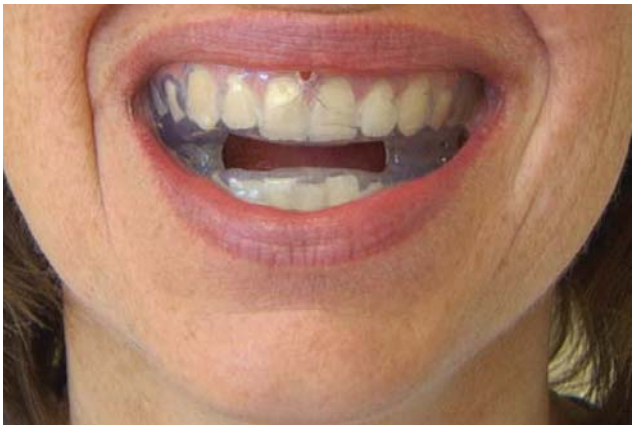

Figure 2. *The mandibular advancement splint in use.*

actually ever used the MAS, and these individuals are included in the group of patients excluded from the statistical analysis. The question regarding whether they intended to continue treatment was not answered. There was no difference in the drop-out rate between the patients being treated by any of the three dentists (n=9, 8 and 10).

Comparing all patients with the participants, it can be seen that the mean value of the ESS before treatment was lower in the participants (10 *vs*. 7) (Table I). The mandibular advancement in the drop-out group was 1 mm less than in the participants. In the subgroup of drop-outs who reported that the MAS had no effect or on whom CPAP was introduced, the mean value of mandibular advancement was even smaller (2.9 mm, *vs*. 4.5 mm in the participants). Comparison of the values obtained from the first sleep pattern recordings at baseline of all patients and participants undergoing a second sleep pattern investigation (with the MAS), showed a clear tendency towards a reduction in AHI and ODI (Table II). A group of 22 patients with AHI ≥20 who were later studied manually, also showed a decrease in the mean value of the AHI and ODI following the MAS use. The mean value in this group before treatment was 40.4 and with the MAS, it was 27.8. The mean value of the ODI also decreased in this group from 29.9 to 18.6.

Out of the patients who attended the second visit, 93.5% reported that they snored less, while 6.5% reported no difference. Eight percent (n=4) of the participants reported temporomandibular joint (TMJ) problems. None of the 27 drop-outs reported any TMJ problems. Over half of all patients (61%, n=55) stated that they intended to continue using the MAS. These fifty-five included 47 of the participants, and 8 in the group of patients excluded from the statistical analysis due to lack of data. Few changes in the patients' lifestyle were recorded (Tables III-V). Other small differences were observed between the drop-outs and the participants. The drop-outs were somewhat younger, more often men, more often used snuff, and they were generally healthier than the participants (Table VI).

Discussion

The reason to choose the automatic OSA detection algorithm based on classification of nocturnal oxygen saturation (SaO_2) performed at home is that the method is not all as complex, nor as expensive and time-consuming as is polysomnography (27). The results were assessed by the doctor in charge of each patient, either manually or by using the values provided by the automatic equipment. However it should be noted that the values obtained with either of the two methods are not fully comparable. Thus, the values obtained by the automatic calculation were used to identify trends in the AHI and the ODI. In a Swedish study, Tegelberg *et al*. found that after 12 months of treatment, the apnoea, AHI, ODI, and snoring indices decreased significantly (28). This was confirmed by our study, where a clear tendency towards a reduction in AHI and ODI between baseline and the second sleep pattern recording was observed. Furthermore, 93.5% of the patients in our study reported that they snored less after MAS treatment. Since snoring can be a major social problem, this alone could be an indication for MAS treatment.

Common causes of OSA are being overweight (29), smoking and drinking (30). There was no change in BMI between the two visits in our patients, so this should not have had any affect on the results. We therefore believe that these lifestyle factors had little effect on the results in this study.

Table III. *The body mass index (BMI) of the patients on the two visits.*

	All patients (Visit 1)		Participants (Visit 2)	
	Mean	Median	Mean	Median
BMI*	27	27	27	26

*A BMI of 20-25 is considered normal.

Table IV. *Smoking habits.*

	All patients (Visit 1) n=89*		Participants (Visit 2) n=48	
	Number	%	Number	%
Non-smokers	79	89	44	92
Smokers	10	11	4	8
Cigarettes/day 1-10	8	9	3	6
11-20	2	2	1	2
≥21	0	0	0	0

*Data not available for one patient.

Table V. *Alcohol consumption.*

	All patients (Visit 1) n=81*		Participants (Visit 2) n=46*	
Risk[1]	Number	%	Number	%
Slight risk	80	99	46	100
Increased risk	1	1	0	
High risk	0		0	

*Not all data were available for all patients and participants. [1]According to the project "Drink less", at the Uppsala University Hospital. Slight risk: women ≤7 standard glasses/week, men ≤10 standard glasses/week; increased risk: women 8-13 standard glasses/week, men 11-18 standard glasses/week; high risk: women ≥14 standard glasses/week, men ≥19 standard glasses/week.

Table VI. *Drop-outs of the study according to age, gender, snuff use and ASA category.*

	Participants (Visit 1) n=48		Drop-outs (Visit 1) n=27	
	Mean (range)	Median	Mean (range)	Median
Age (years)	56 (34-77)	56	52 (26-66)	53

	Participants (Visit 1) n=48		Drop-outs (Visit 1) n=27	
	Number	%	Number	%
Women	12	25	5	18.5
Men	36	75	22	81.5

	Participants (Visit 1) n=48		Drop-outs (Visit 1) n=26*	
Snuff	Number	%	Number	%
No	43	90	19	73
Yes	5	10	7	27

*Data missing for one drop-out.

	Participants (Visit 1) n=48		Drop-outs (Visit 1) n=23*	
ASA1	Number	%	Number	%
1	30	63	16	70
2	16	33	6	26
3	2	4	1	4

*Data missing for 4 of the drop-outs. [1]See text for the definitions of the ASA categories.

In this study, TMJ problems were not the cause of drop-out in any of the 27 drop-outs. This finding has been confirmed in two earlier studies performed in Sweden (28, 31). The reasons given for not using the MAS in our study were that individuals had difficulties in learning how to use it, or they found it to have no effect. In our study, the ESS, which is a subjective measure of the degree of daytime sleepiness (32), showed a tendency towards lower values after comparing all patients with the drop-outs. This may indicate that those who had fewer problems as a result of ESS were less motivated to use the MAS. The mean value of the ESS before treatment in the relatively small subgroup who reported having difficulty getting used to the MAS was 7, which is even lower than the whole drop-out group. In this study, the mandibular advancement in the drop-out group was smaller than that in participants, and even smaller in the subgroup of drop-outs who reported that the MAS had no effect or on whom CPAP was introduced. This may partly explain why no effect was obtained with the MAS and also why they discontinued the treatment.

Conclusion

In conclusion, in our study treatment with MAS reduced sleep apnoea in the majority of the patients. The ESS values were reduced, indicating a reduction in daytime sleepiness. The patients bad no significant changes in their lifestyle with regard to weight, smoking habit or alcohol intake, thus lifestyle factors are believed not to have affected the results.

Conflicts of Interest

There were no conflicts of interest for the Authors in this study.

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