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Original article

Comparison of three oral appliances for treatment of severe obstructive sleep apnea syndrome☆

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Abstract

Objective: To compare three different oral appliances: a mandibular advancement device (Snoreguard), a tongue retaining device, and a soft palate lift, for treatment of severe obstructive sleep apnea syndrome (OSAS).

Background: Oral appliances are therapeutic options for patients with OSAS.

Methods: Eight patients with a mean apnea hypopnea index (AHI) of 72.1 (SD ± 39.9) were studied. Polysomnographic measures during each of the treatment nights were compared to baseline.

Results: Eight out of 8 patients completed the mandibular advancement device (MAD) night; 5/8 tolerated the tongue retaining device (TRD); only 2/8 could sleep with the soft palate lift (SPL) in place. Improvement using the MAD reached significance: overall AHI (mean ± SD) decreased from 72.1 ± 39.9 at baseline to 35.5 ± 39.4 with the appliance in place ($P < 0.02$). There was a non-significant increase in slow wave sleep (SWS) from 9.6% ± 8.7 to 14.4% ± 10.5 with the MAD in place. In five responders, the mean AHI decreased from 60.0 ± 36.6 to 9.0 ± 4.8; all were subjectively improved, using the MAD at 1 year follow-up. However, three non-responders had persistence of AHI > 40. With the TRD, AHI decreased from 50.3 ± 18.9 at baseline to 43.5 ± 32.5 (ns). The SPL was not effective with an AHI at baseline of 52.4 ± 8.0, and 47.3 ± 31.0 with the device in place (ns), and not well tolerated.

Conclusions: A mandibular advancement device is an effective treatment alternative in some patients with severe OSAS. In comparison, the tongue retaining device and the soft palate lift do not achieve satisfactory results.

Keywords: Sleep; Sleep apnea syndrome; Oral appliance; Mandibular advancement device; Tongue retaining device; Soft palate lift; Treatment; Polysomnography

1. Introduction

Obstructive sleep apnea syndrome (OSAS) is a disorder characterized by repetitive obstruction of the upper airway, resulting in apneic and hypopneic episodes during sleep. Therapeutic interventions include weight loss, avoidance of alcohol, nasal continuous positive airway pressure (nCPAP) [1],

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uvulopalatopharyngoplasty, maxillomandibular surgery, or tracheostomy [2]. Many of these therapeutic modalities are limited by patient compliance, lack of efficacy, or serious side effects. For instance, a study assessing compliance with nCPAP, found that only 46% of patients used the device for more than 4 h per night for more than 70% of the nights [3].

Oral appliances are alternative therapies for patients with OSAS. They mechanically increase the oropharyngeal space by advancing the mandible and/or the tongue. More than 60 different oral appliances are in use, with considerable variations in design. Schmidt-Nowara [4] summarized the results of 20 publications encompassing a total of 304 adults, mostly middle-aged, overweight men treated with various oral appliances for snoring and OSAS. Of the 271 cases with data reported in a form suitable for calculation, the mean apnea-hypopnea indexes (AHIs) showed a 56% reduction, from 42.6 to 18.8 following treatment. Fifty-one percent of treated patients achieved an AHI of less than 10. However, as many as 39% of the treated patients were left with significant respiratory disturbance (AHI $>$ 20). Side effects were generally mild and tolerable, and compliance varied between 50 and 100%. The authors concluded that oral appliances represent a useful alternative to nasal CPAP, especially for patients with snoring, mild apnea, and patients with obstructive sleep apnea syndrome who cannot tolerate CPAP therapy. An official position paper by the American Sleep Disorders Association (ASDA) supports their findings [5]. Similar improvement was noted in two recent studies which included patients with moderate obstructive sleep apnea syndrome. [6,7].

There are no studies comparing the efficacy of various types of appliances in the same patient. This may be important, as oral anatomy varies from patient to patient, and some may not be suited for any intraoral device, such as patients with a compromised intraoral space (e.g. micrognathia, or macroglossia). When comparing oral appliances in different patient groups, the results may reflect differences between the groups, and not the oral appliances.

This study compares three different types of oral appliances in patients with severe obstructive sleep apnea syndrome: a mandibular advancement device (MAD) [8], a tongue retaining device (TRD) [9], and a soft palate lift (SPL) [10]. All three devices have been reported to improve snoring and/or obstructive sleep apnea.

2. Materials and methods

2.1. Subjects

Eight patients with known severe OSAS (AHI of 72.1 $\pm$ 39.9, mean $\pm$ SD) were studied. There were seven men and one woman; ages ranged from 31 to 80 years (57.6 $\pm$ 21.5). All patients had been offered nasal CPAP, but were unable to tolerate the device. The study protocol was approved by our institutional committee on human research, and written informed consent was obtained from all subjects before enrollment. Subjects were not paid for their participation, but had the appliances supplied without cost.

2.2. Experimental design

We used three types of appliances: a mandibular advancement device (Snoreguard, Distar, Albuquerque, NM) to protrude the mandible; a tongue retaining device (ProPositioners, Racine, WI) to maintain the tongue in an extended position to preclude posterior displacement into the airway, and a soft palate lift (Dentalogic, Yonkers, NY) elevating the soft palate. The degree of protrusion of the mandibular advancement device was adjusted based on individual patient anatomy and tolerance. The goal was to minimize nocturnal apneas and snoring, while maintaining a comfortable fit. Average mandibular protrusion was three to five millimeters. After the last fitting, patients were asked to sleep every night while wearing that device until polysomnography was performed. Time elapsed between the final technical adjustment of each device and the post-treatment sleep study was at least 4 weeks; time elapsed between the baseline night and completion of the protocol was eight months on average, and under one year in all cases. This timespan was dictated by the capacity of our sleep laboratory. All patients underwent baseline polysomnography, followed by polysomnography with the MAD, then the TRD, then the SPL in place. The patients were asked to wear each device whenever asleep until the follow-up study with that device was performed. The patients were encouraged by telephone as well as during their visits at our orthodontist's office to regu-

larly wear the devices. However, we had no objective means to control if the patients were compliant with the study protocol. None of the patients had a substantial change in weight or underwent upper airway surgery during the study. In addition to collecting objective polysomnographic data, efficacy of each device and side effects were judged subjectively by administering a questionnaire on the morning after the sleep study asking for quality of the previous night's sleep, patient satisfaction with the device, and side effects.

2.3. Polysomnography

Standard attended polysomnography was performed using the following channels: two EEG leads (C4, O1), two EOG leads, one submental EMG, one nasal-oral airflow (thermistor), one abdominal and one chest respiratory effort band, one EKG rhythm strip, and one ear oximetry channel. The records were manually scored by a polysomnographer certified by the American Board of Sleep Medicine using the criteria of Rechtschaffen and Kales [11]. The scorer was not informed of appliance use while analyzing the records.

2.4. Statistical analysis

Polysomnographic data were analyzed using a paired Student *t*-test, with values of $P < 0.05$ required for significance. Data are expressed as mean ± SD. The following polysomnographic measures were compared: apnea index, apnea-hypopnea index, mean nadir of oxygen saturation with respiratory events, maximal apnea duration, and stages of sleep.

3. Results

3.1. Mandibular advancement device

Eight patients (100%) completed treatment with the mandibular advancement device (Table 1). This was associated with statistically significant improvement in both the apnea index (AI) (63.1 ± 42.3 (mean ± SD) pretreatment, 24.1 ± 24.7 post-treatment ($P < 0.02$)), and the AHI (72.1 ± 39.9 pretreatment, 35.5 ± 39.4 post-treatment ($P < 0.02$)). The MAD reduced AHI in all patients. A clinically significant decrease defined as a reduction of AHI to below 15 was achieved in five patients (patients # 1–5). In these patients, the AHI declined by a factor of 3 or greater, from 60.0 ± 36.6 at baseline to 9.0 ± 4.8 with the MAD in place (Fig. 1). Similarly, the AI in these patients fell from 51.3 ± 39.6 to 7.1 ± 4.1 with the device. The three patients who did not respond continued to have AHIs greater than 40.

Mean oxyhemoglobin saturation increased from 80.4 ± 10.0 at baseline to 85.2 ± 9.6 with the MAD, showing improvement in 7/8 patients (Table 1); however, this was not statistically significant ($P = 0.2$). Mean apnea duration remained the same, as did the amount of rapid eye movement (REM) sleep. Sleep architecture showed a tendency for increased percentage of slow wave sleep (SWS) from 9.6 ± 8.7 to 14.4 ± 10.5 when the MAD was worn (ns). Responses to the morning questionnaire indicated subjective improvement of sleep, and only minor degrees of discomfort, such as transient temporomandibular joint pain and/or excess salivation. All five patients who showed a statistically significant change in AHI were satisfied with the subjective improvement and continued to use the appliance at 1 year follow-up.

3.2. Tongue retaining device

Five patients (62.5%) completed polysomnography with the tongue retaining device in place (Table 2); three refused because of unacceptable levels of discomfort such as their tongue hurting in the protruded position. Mean AHI did not change significantly, declining from 50.3 ± 18.9 at baseline to 43.5 ± 32.5 with the device ($P = 0.64$). Two patients achieved an acceptable clinical response, defined as AHI falling below 15; both also responded to the MAD.

3.3. Soft palate lift

Only two patients (25%) completed the soft palate lift study night (Table 2). The remaining patients would not wear the device due to significant discomfort, mainly gagging. Apnea hypopnea index was 47.3 ±8.0 at baseline, and 57.4 ± 31.0 with the device in place. A third patient aborted the polysomnographic study after 3 h of wakefulness, complaining of gagging and choking.

Table 1
Respiratory and sleep variables without (baseline) and with the mandibular advancement device (MAD)

Patient no.	Apnea index		Apnea-hypopnea index		Mean nadir of oxygen saturation (%)		Max apnea duration (s)		REM sleep as % sleep period time		Stage 3 + 4 sleep as % sleep period time	
	Baseline	With MAD	Baseline	With MAD	Baseline	With MAD	Baseline	With MAD	Baseline	With MAD	Baseline	With MAD
1	115.8	11.0	119.5	12.9	66.4	94.6	49	45	14	5	3	27
2	63.3	9.0	63.3	10.8	85.8	87.9	15	30	11	14	21	31
3	25.0	6.8	55.7	10.1	87.1	88.0	18	16	6	3	22	18
4	31.2	8.6	36.1	10.8	90.0	90.6	35	31	3	5	17	15
5	21.7	0.2	25.3	0.6	87.6	90.0	54	0	3	6	2	12
6	137.0	67.6	143.0	110.4	63.7	63.6	37	29	18	11	4	4
7	52.9	43.7	69.2	65.5	79.6	80.2	59	65	2	2	3	3
8	58.0	46.2	65.0	63.2	82.8	86.3	43	85	8	4	5	5
Mean ± SD	63.1 ± 42.3	24.1 ± 24.7[a]	72.1 ± 39.9	35.5 ± 39.4[a]	80.4 ± 10.0	85.2 ± 9.6	38.8 ± 15.9	37.6 ± 27.0	8.1 ± 5.8	6.3 ± 4.1	9.6 ± 8.7	14.4 ± 10.5

[a] $P < 0.02$ by paired t-test.

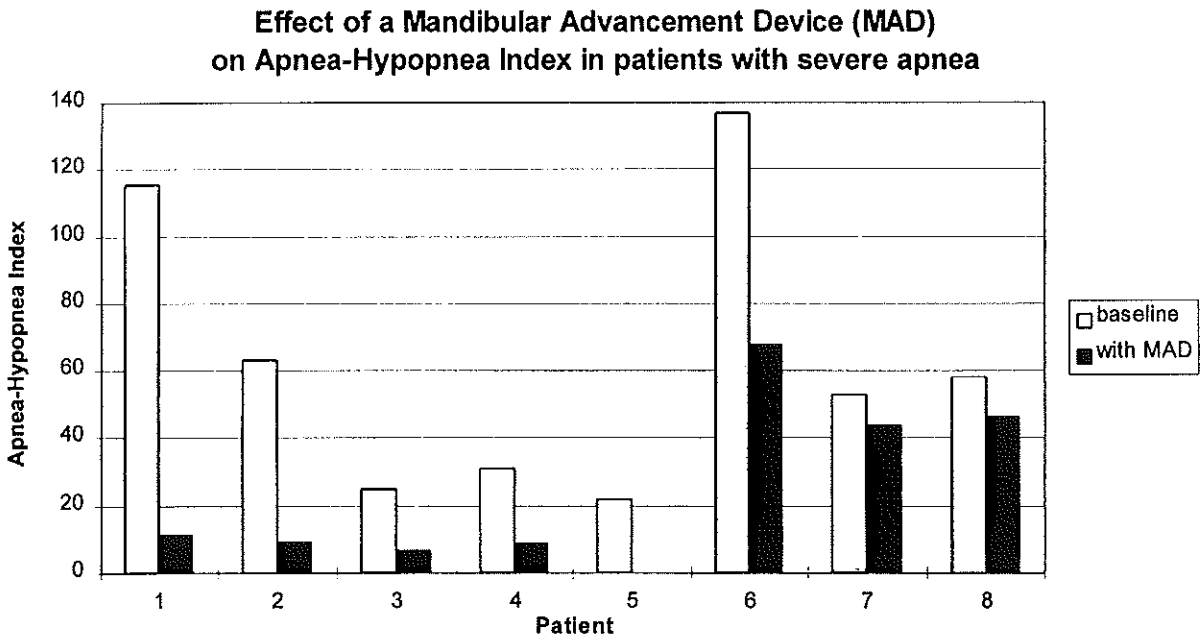

Fig. 1. Apnea-hypopnea index (AHI) for each individual patient at baseline (□) and with the mandibular advancement device (■ 'with MAD'). Patients 1 to 5 were treatment responders; mean AHI decreased from 60.0 ± 36.6 (mean ± SD) to 9.0 ± 4.8. Patients 6–8 were non-responders; AHI remained above 40.

4. Discussion

This study provides the first direct comparison of three different types of oral appliances for treating severe OSAS. We confirmed that a mandibular advancement device can produce significant reduction in obstructive apneas and hypopneas in 62.5% (5/8) of patients. We also found that this device was well accepted as long term treatment by all responders. Side effects consisted of only minor discomfort that did not seem to affect compliance. However, we were unable to verify the efficacy of either the tongue retaining device or the soft palate lift.

Combined data from peer-reviewed reports of mandibular advancement devices [8,12–20] show a decline of mean AHI from 40 to 17 in 164 patients. Fifty-three percent of the 89 patients for whom individual data were available exhibited a decrease in

Table 2
Apnea hypopnea index (AHI) without (baseline) and with the mandibular advancement device (MAD), tongue retaining device (TRD), and soft palate lift (SPL)[a]

Patient #	Baseline	MAD	Baseline	TRD	Baseline	SPL
1	119.5	12.9				
2	63.3	10.8				
3	55.7	10.1	55.7	6.0		
4	36.1	10.8	36.1	67.5		
5	25.3	0.6	25.3	11.5	25.3	56.8
6	143.0	110.4				
7	69.2	65.5	69.2	75.4	69.2	58.0
8	65.0	63.2	65.0	57.3		
Mean ± SD	72.1 ± 39.9	35.5 ± 39.4*	50.3 ± 18.9	43.5 ± 32.5	47.3 ± 8.0	57.4 ± 31.0

[a] Empty boxes indicate nights where patients were unable to tolerate the device. *$P < 0.02$ by paired t-test.

AHI to below 10. Our patients had generally more severe disease (mean baseline AHI of 72.1) and a less complete response. One investigator [20] studying the effects of a mandibular advancement device included nine patients with severe OSAS (AHI > 40). Five of the nine patients (56%) achieved a satisfactory result, defined as a decrease in AHI of greater than 50% and post-treatment AHI < 20.

Since our patients started with a greater degree of respiratory disturbance, it is not surprising that they exhibited a higher AHI after treatment. However, all of our responders achieved an AHI below 15. This suggests that the mandibular advancement device provides an effective therapy.

Our results support data by another group studying patients with moderate OSAS, showing little effect on oxyhemoglobin saturation [6]. The lack of normalization of percentages of REM and/or SWS might be explained by the relatively high post-treatment AHI's causing excessive arousals and awakenings.

Compilation of data from four peer-reviewed studies with 57 patients using the tongue retaining device showed a mean decrease of the AHI from 44 to 22 [9,21–23]. Less than half of these patients achieved an AHI below 10. Our results did not show significant therapeutic value for this device. Our patient population had more severe degrees of sleep apnea than those previously reported, suggesting that the tongue retaining device may not be a suitable choice when the respiratory disturbance is severe. The lack of subjective improvement is probably the basis for the refusal of many of our patients to use it. Another possible explanation for the discrepancy between our data and that of Cartwright's group could be the greater experience of their team with the tongue retaining device. We believe that the combination of the therapist's ability plus the device may influence the outcome in oral appliance treatment. A recent study, however, is in accordance with our findings, showing little therapeutic efficacy and poor compliance in patients with moderate OSAS using the tongue retaining device [24].

The palate lift was found to be effective in preventing snoring in one case report [10]. Polysomnography was not performed in that patient, and thus no data on apneas or hypopneas are available. In our study, only two out of eight patients were able to wear this appliance; neither experienced improvement in AHI.

Several investigators have addressed the question of which factors might predict the successful treatment of OSAS with oral prostheses. An increase in failure rates is seen when baseline AHI exceeds 60 events/h [7,20]. Our results support this observation. However, Schmidt-Nowara and colleagues found that low baseline AHI's did not consistently predict a significant response to use of an oral appliance [4].

Several studies have addressed predictors of success when using the tongue retaining device to treat OSAS, including nasal patency [23], body position [23–25], and body weight [22]. Unfortunately we did not monitor the effects of body position change. Body position is known to influence the severity of sleep apnea syndrome, in that the degree of respiratory disturbance usually worsens in the supine position [23]. However, if wearing an oral appliance influences sleeping posture, any resulting alteration in the respiratory disturbance could be considered part of it's treatment effect.

Our study was not randomized; each device was delivered and tested in the same order in each patient. A systematic bias could have been introduced if a given device induced an anatomical change that affected the efficacy of a subsequent device. These devices are not known to produce such effects. There was also little chance of a 'carry-over' effect from a previous device as each device was used for several weeks before individual polysomnographs (PSGs). We believe that patient bias for or against any specific device was negligible. Each device was introduced in the same sequence for the same length of time, and patients were not led to believe that any one device was more or less effective than another, only that each was developed for the treatment of sleep apnea and snoring. Patient compliance could improve with learning to tolerate different devices but that would favor the last device. However, our results showed that the first device tried (MAD) was most effective.

Recently, MADs have been developed where the degree of protrusion can be adjusted for optimal therapeutic efficacy. Fleetham and coworkers had a 61% success rate with an adjustable oral appliance, as compared to a 48% success rate with a prefabricated non-adjustable device [26]. Success was defined as reduction in AHI to <10/h and relief of symptoms. The 61% success rate approached the 66% success

rate of nCPAP used for comparison, where treatment failure was defined as non-compliance (34% of the patients). With the adjustable oral device, non-compliance was only 4%. If we had used a titratable device, our treatment results might have been more favorable.

Our study is unique in that we compared the efficacy of three different devices in the same patient. Despite the aforementioned limitations, this is, to our knowledge, the first study to address an important clinical question, which of the many oral appliance designs work best.

In conclusion, our results indicate that the mandibular advancement device can be a valuable therapeutic modality in some patients with severe OSAS. In the same group of patients, we found the tongue retaining device to be marginally effective, and the soft palate lift to be ineffective and poorly tolerated.

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