

clinical investigations

Evaluation of Variable Mandibular Advancement Appliance for Treatment of Snoring and Sleep Apnea*

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Objective: To evaluate an adjustable mandibular positioning appliance for treatment of snoring and sleep apnea.

Methods: One hundred thirty-four patients with baseline apnea/hypopnea index (AHI) of 37 ± 28 events/h (mean \pm SD) received the appliance. The efficacy of the appliance was assessed by the following investigations, performed at baseline and with the appliance: polysomnography, Epworth sleepiness scale, bedpartners' assessment of snoring severity, patients' assessment of side effects, and overall satisfaction.

Results: Thirteen patients were lost to follow-up. An additional 46 patients had no follow-up polysomnography, but answered the questionnaires. A total of 75 patients had polysomnography at baseline and with the appliance. We found a significant reduction in AHI from 44 ± 28 events/h to 12 ± 15 events/h ($p < 0.0005$) and a reduction in the arousal index from 37 ± 27 events/h to 16 ± 13 events/h ($p < 0.05$). Epworth scores fell from 11 ± 5 to 7 ± 3 ($p < 0.0005$). Bedpartners' assessment revealed marked improvement in snoring. For example, at baseline 96% of patients were judged to snore loudly "often" or "always" by their bedpartners, whereas only 2% were judged so while using dental appliance. The most frequent side effect was teeth discomfort, present "sometimes" or "often" in up to 32% of patients. Follow-up clinical assessment in 121 patients conducted on the average 350 days after the insertion of the appliance revealed that 86% of patients continued to use the appliance nightly; 60% were very satisfied with the appliance, 27% were moderately satisfied, 11% were moderately dissatisfied, and 2% were very dissatisfied.

Conclusion: We conclude that the adjustable mandibular positioning appliance is an effective treatment alternative for some patients with snoring and sleep apnea.

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Key words: oral appliance; sleep apnea; snoring

Abbreviations: AHI = apnea/hypopnea index; BMI = body mass index; CPAP = continuous positive airway pressure; ESS = Epworth sleepiness score; MAA = mandibular advancement appliance; TAP = Thornton anterior positioner

The role of oral appliances for treatment of non-apneic snoring and sleep apnea is currently being assessed. Most patients with sleep apnea are being offered nasal continuous positive airway pressure (CPAP) as the treatment of choice. However, compliance with nasal CPAP varies, and is particularly

poor in nonapneic snorers and those with mild sleep apnea; this group of patients is notorious for poor acceptance of CPAP. That is why oral appliances constitute an attractive noninvasive alternative for

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patients with sleep apnea, provided the efficacy, compliance, long-term tolerance, and satisfaction with these appliances are established.

A very important aspect of a successful appliance is the patient's comfort. To achieve this goal the

appliance must be custom fit for the patient to minimize the discomfort. This is best accomplished with mandibular advancement appliances (MAAs). There are several such appliances in use today. Most of them are relatively bulky and cannot be adjusted *in situ*, and many have not been tested objectively by comparing respiration and sleep architecture in a large group of patients. In this study, we present the results of nocturnal polysomnography and subjective assessment in patients fitted with a new adjustable mandibular positioning appliance, described by Thornton and Roberts¹—the Thornton anterior positioner (TAP) appliance (Oral Appliance Technologies; Dallas, TX).

MATERIALS AND METHODS

Patients

All patients were referred because of suspicion of sleep apnea. We followed our customary clinical practice approach. All patients had diagnostic polysomnography. Once the results were available, they were seen for a follow-up visit, during which various treatment alternatives, including oral appliances, were discussed. Patients who expressed an interest in oral appliance were seen by the dentist trained in oral appliance therapy (J.P.), who performed a complete dental examination. It consisted of assessing condition of the teeth, periodontal health, function and tenderness of muscles of mastication, overbite, overjet, limits of lateral excursive and protrusive movements of the mandible, and tenderness, noise, or limitation of movement of the temporomandibular joint. An oral appliance was deemed to be suitable for those who had ≥ 8 to 10 teeth per arch that were structurally sound and in good periodontal health.

The above process, performed during a period of 18 months, resulted in selection of 134 consecutive patients. They were generally healthy outpatients without any significant chronic disease.

Oral Appliance

The TAP appliance is a mandibular advancement device (Fig 1) composed of two separate arches—upper (maxillary) and lower mandibular) containing the advancing mechanism, which permits a maximum of 16 mm advancement of the lower jaw.

These arches are made of shells containing thermoplastic material that becomes soft when placed in boiling water. The dentist inserts the warm arches into the patient's mouth to obtain an impression. The arches are then removed and allowed to cool, thereby maintaining the shape of the teeth indefinitely. After this, they are reinserted and the advancing mechanism is engaged. The screw mechanism in the upper jaw is then turned to advance the mandible until the patient begins to feel any discomfort in the temporomandibular joint or in the facial muscles. The advancing screw was then turned back two turns to ascertain patient comfort. This became the initial position for home use.

Patients were instructed in the proper use and care of the appliance, told about possible side effects, and given a return appointment 1 to 2 weeks later. If snoring was still present, the appliance was advanced forward. This procedure was performed until snoring improved, no further advancement was possible, or the patient developed discomfort. It took two to four visits for a period of 1 to 3 weeks to make certain that the appliance was properly fitted and the patient was comfortable. The patient was advised to keep the appliance away from heat sources.

The final protrusion of the jaw was not recorded because the patients were instructed how to change the amount of protrusion depending on symptoms and did so regularly at home.

Investigations

Objective investigations included in-hospital nocturnal polysomnography with measurements of respiration (inductance plethysmography using RespiTrace (Ambulatory Monitoring, Inc.; Ardsley, NY), temperature of exhaled air using thermistors), oxygen saturation (using a pulse oximeter), sleep architecture (EEG, chin electromyogram, and electrooculogram), ECG, and leg electromyogram. Apneas were defined as complete episodes of cessation of breathing lasting ≥ 10 s. Hypopneas were defined as episodes with $> 50\%$ reduction in respiratory flow accompanied by oxygen desaturation of $> 4\%$. Arousals were defined as 3 to 15 s of alpha and fast theta EEG frequency.

Subjective assessments included Epworth sleepiness scale (ESS) and a questionnaire dealing with snoring answered by the bedpartner (Table 1).

After the appliance was manufactured and final adjustments completed, all of the above investigations were repeated. Polysomnography was performed with the appliance. An additional questionnaire (Table 2) dealing with side effects was answered by the patients.

At least 4 weeks after wearing the appliance, the patients were assessed clinically or contacted by telephone and asked about their current use of the appliance and their overall level of

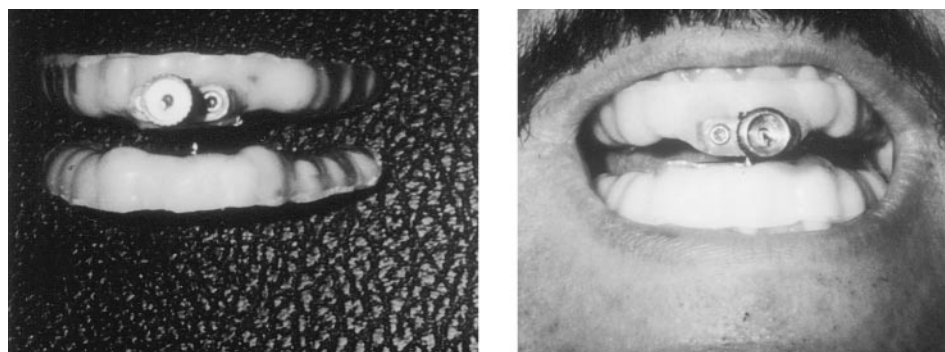


FIGURE 1. TAP appliance (*Left*) inserted into the mouth (*Right*).

Table 1—Bedpartners Questionnaire

Please answer the following questions as follows:
1—never, 2—rarely, 3—sometimes, 4—often, 5—always

1. Does your husband/wife snore loudly?
2. Does your husband/wife snore in all positions?
3. How often were you kept awake by snoring?
4. How often were you forced to sleep in another room?

satisfaction with it (very satisfied, moderately satisfied, moderately dissatisfied, or very dissatisfied).

Data Analysis

The results were analyzed using *t* tests and χ^2 tests to compare the differences in sleep variables before and with oral appliance and changes in snoring. In an attempt to determine whether response to oral appliance can be predicted from the initial patient data, we used linear regression analysis to determine the relationship between percent improvement in apnea/hypopnea index (AHI) and age, initial body mass index (BMI), and initial AHI. Statistical significance was defined as $p < 0.05$. All data analysis was performed using SAS software, version 6.12 (SAS Institute; Cary, NC).

RESULTS

Of the 134 patients fitted with dental appliance, we were able to contact 121. However, only 75 agreed to undergo repeat nocturnal polysomnography with the appliance. The reason for refusal was either lack of time, dissatisfaction with appliance, or just the opposite—perception that the appliance works well and no further investigations are necessary. Consequently, baseline and appliance polysomnography data is available for 75 patients, but the subjective assessment of current use and level of satisfaction is available for 121 patients (65 of whom had worn the appliance for > 1 year).

Table 3 shows age, sex, initial BMI, initial AHI, and initial ESS in four groups of patients: the initial set, those who were contacted in follow-up, those lost to follow-up, and those who had sleep studies with the TAP appliance.

There was little difference between the entire initial set of patients and the subgroups. Those lost to

follow-up had higher (but not significantly) mean ESS; they were all men; only 1 of 13 patients (8%) was a habitual snorer, vs 49 of 121 patients (41%) for the rest of the group.

Effect of Dental Appliance on Polysomnographic Variables

Sleep studies with the appliance were conducted in 75 patients—68 males and 7 females. The average age was 50 years, ranging from 28 to 74 years. Patients wore the appliance for an average of 85 days before polysomnography. There was no significant difference in BMI between the diagnostic and follow-up studies (29.3 ± 5.3 kg/m² vs 28.9 ± 5.8 kg/m², respectively).

The individual AHIs for all patients are shown in Table 4. The patients are grouped into responders ($AHI_{\text{appliance}} < 10$ events/h), nonresponders ($AHI_{\text{appliance}} > 10$ events/h), nonapneic snorers, and those who got worse ($AHI_{\text{appliance}} > AHI_{\text{baseline}}$).

In 38 of 75 patients, sleep apnea was abolished (baseline AHI, 39 ± 21 events/h; appliance AHI, 5 ± 3 events/h). In an additional 31 of 75 patients with sleep apnea, there was a significant reduction in AHI (baseline AHI, 54 ± 31 events/h; appliance AHI, 20 ± 12 events/h). There were three nonapneic snorers whose AHI remained unchanged (baseline AHI, 5 ± 1 events/h; appliance AHI, 4 ± 1 events/h), and three additional patients (two nonapneic snorers and one with severe sleep apnea) whose AHI was higher on the night with the appliance than at baseline.

If we define the response to the appliance as a reduction in AHI to < 10 events/h, we find that 51% were responders. Alternatively, if we define the response as reduction in AHI by $\geq 50\%$, we find that 61 of 75 patients (81%) were responders (baseline AHI, 47 ± 27 events/h; appliance AHI, 10 ± 9 events/h). Even these 61 patients responded on the average with a $> 50\%$ reduction in AHI. In all subsequent descriptions we shall use the term responders in its most strict sense—appliance AHI < 10 events/h.

The mean results for the entire group, as well as for responders (defined as appliance AHI > 10 events/h) and nonresponders, are summarized in Table 5.

Only AHI and arousal index, but not other variables, were significantly ($p < 0.0005$) reduced with the appliance, even in the nonresponders.

Univariate linear regression analysis between percent improvement in AHI, defined as $100 \times (AHI_{\text{baseline}} - AHI_{\text{appliance}}) / AHI_{\text{baseline}}$, and age, initial BMI, and baseline AHI revealed no correlation with age, but there was a significant

Table 2—Side Effects Questionnaire

Please answer the following questions as follows:
1—never, 2—rarely, 3—sometimes, 4—often

1. How often do you have teeth discomfort?
2. How often do you feel that your teeth are apart in the morning?
3. How often do you have tongue discomfort?
4. How often do you have jaw discomfort?
5. How often do you have gum discomfort?
6. How often do you have excessive salivation?

Table 3—Initial Data in Patients According to Follow-up Status*

Variable	Initial Set	Contacted for F/U	Lost to F/U	Before and With TAP Sleep Studies
N	134	121	13	75
M/F	117/17	104/17	13/0	68/7
Age, yr	50 ± 10	50 ± 10	47 ± 10	50 ± 11
BMI, kg/m ²	30 ± 6	30 ± 6	28 ± 5	29 ± 5
AHI, events/h	37 ± 28	38 ± 29	30 ± 23	44 ± 28
ESS	11 ± 5	11 ± 5	14 ± 3	11 ± 5

*F/U = follow-up.

inverse correlation with BMI ($r = -0.33$, $p = 0.008$) and AHI ($r = 0.27$, $p = 0.18$).

Questionnaire Results

Side Effects of Oral Appliance: These are summarized in Table 6. The entries in this table represent

the percentage of patients with a particular side effect. Teeth discomfort, excessive salivation, and jaw discomfort were the most common side effects.

Benefits of Oral Appliance: The ESS was reduced significantly ($p < 0.0005$) from 11 ± 5 to 7 ± 3 . The

Table 4—Individual AHIs at Baseline and With Dental Appliance

Responders			Nonresponders			Nonapneic Snorers			Worsening AHI		
Patient No.	Baseline	Appliance	Patient No.	Baseline	Appliance	Patient No.	Baseline	Appliance	Patient No.	Baseline	Appliance
1	17	0.6	39	52	23	70	5.6	2.8	73	3.4	16
2	46	3.6	40	92	25	71	6.0	5.0	74	9.0	21
3	89	4.6	41	52	23	72	3.6	3.1	75	9.3	95
4	38	3.1	42	35	12						
5	27	0.8	43	34	11						
6	49	7.8	44	50	18						
7	13	0.9	45	98	29						
8	75	6.2	46	39	14						
9	69	8.8	47	76	10						
10	47	1.0	48	15	12						
11	49	1.8	49	49	13						
12	27	3.3	50	17	14						
13	21	7.3	51	15	11						
14	28	1.6	52	29	20						
15	12	5.7	53	20	13						
16	48	5.3	54	30	13						
17	22	6.2	55	112	26						
18	19	1.7	56	49	13						
19	29	7.1	57	27	11						
20	65	1.3	58	27	17						
21	31	6.4	59	70	27						
22	40	0.6	60	87	41						
23	46	9.4	61	93	73						
24	19	0.6	62	27	11						
25	36	0.6	63	54	22						
26	45	4.3	64	115	30						
27	27	8.2	65	25	14						
28	17	5.4	66	86	16						
29	25	5.4	67	93	11						
30	47	9.0	68	23	16						
31	43	3.0	69	82	23						
32	20	8.3									
33	110	8.7									
34	35	7.0									
35	17	7.9									
36	37	0.2									
37	45	7.6									
38	42	0.6									
Mean	39	5		54	20		5	4		35	50
SD	21	3		31	12		1	1		44	44

Table 5—Sleep Studies at Baseline and With Appliance*

Variable	All patients		Responders		Nonresponders	
	Baseline	Appliance	Baseline	Appliance	Baseline	Appliance
AHI, events/h	44 ± 28	12 ± 15*	39 ± 21	5 ± 3*	54 ± 31	20 ± 12*
LoO ₂ , %	79 ± 13	85 ± 9	78 ± 15	89 ± 5	78 ± 12	80 ± 11
MnO ₂ , %	94 ± 3	95 ± 2	94 ± 2	96 ± 2	93 ± 4	94 ± 3
TST, min	322 ± 72	304 ± 77	325 ± 67	308 ± 82	315 ± 80	299 ± 75
SWS, %	7 ± 9	9 ± 9	10 ± 9	10 ± 9	5 ± 8	8 ± 9
SL, min	21 ± 28	22 ± 35	21 ± 25	27 ± 47	22 ± 33	18 ± 13
SE, %	80 ± 14	79 ± 15	81 ± 15	79 ± 17	79 ± 15	79 ± 12
ArI, events/h	37 ± 27	16 ± 13*	30 ± 17	10 ± 8*	49 ± 31	24 ± 15*

*LoO₂ = lowest nocturnal oxygen saturation; MnO₂ = mean nocturnal oxygen saturation; TST = total sleep time; SWS = slow wave sleep; SL = sleep latency; SE = sleep efficiency; ArI = arousal index.

effect of the TAP appliance on snoring, as assessed by the bedpartner, is given in Figure 2.

We plotted the percent of patients with “often” or “always” replies to the four questions listed in Table 1; empty bars refer to replies at baseline, and solid bars refer to replies with dental appliance. The top graph depicts all patients for whom the follow-up data were available. The middle and bottom graphs depict only responders and nonresponders, as defined previously. Dramatic reduction in the attributes of snoring was achieved with the use of appliance in the entire group. For example, loud snoring occurring “often” or “always” was present in 96% of patients at baseline, and in only 2% while wearing the appliance. Moreover, 69% of the bedpartners were “often” or “always” kept awake by loud snoring at baseline, but only 2% were kept awake when the appliance was used. Of interest, even patients who did not respond objectively to the oral appliance, *ie*, appliance AHI was > 10 events/h, had a marked reduction in snoring as perceived by their bedpartners.

Final clinical follow-up was performed, on average, 350 days after insertion of the appliance. At the time of follow-up, 86% of patients continued to use the appliance nightly; 60% were very satisfied with the appliance, 27% were moderately satisfied, 11% were moderately dissatisfied, and 2% were very dissatisfied.

Table 6—Frequency of Side Effects*

Side Effect	Never	Rarely	Sometimes	Often
Teeth discomfort	17	28	32	28
Gum discomfort	66	24	8	1
Tongue discomfort	80	10	6	4
Excessive salivation	21	32	26	22
Jaw discomfort	19	41	26	14

*Data are presented as percentage of patients with side effect.

DISCUSSION

This study demonstrates that the adjustable MAA device is an effective way to treat snoring and sleep apnea.

One of the earliest mandibular positioning appliances was a nocturnal airway patency appliance described in a case report in 1985² and 2 years later in a series of five patients with sleep apnea.³ The initial success of this treatment (reduction in AHI from 48 to 9 and disappearance of snoring) contributed much to the subsequent interest in MAAs. By 1995, there was sufficient evidence for the efficacy of oral appliances, such that Schmidt-Nowarra et al,⁴ in a review written on behalf of the American Sleep Disorders Association, concluded that “. . . oral appliances present a useful alternative, especially for patients with simple snoring and others with moderate [obstructive sleep apnea] who cannot tolerate nasal CPAP”. This further increased interest in oral appliances and resulted in additional evaluation of this treatment modality.

Depending on the particular device and the particular study, > 50% reduction in the AHI, on average, was achieved using MAAs (Table 7); the mean response rate (percentage of patients whose AHI was reduced to < 10 events/h) was 53%.⁷⁻²⁶ Large variability between different studies is undoubtedly caused by differences in apnea severity, facial morphology of patients, type of appliances used and whether it was at the optimum setting at the time of sleep study, methods of end point assessment, and so forth.

This area of treatment is still relatively neglected, as illustrated by a recent survey conducted by Loubé et al,²⁷ indicating that dentists belonging to the Sleep Disorders Dental Society, who are presumably the biggest providers of this treatment, treated only a median of 27 patients/yr. Undoubtedly there are more patients with snoring and sleep apnea that

Effect of TAP Appliance on Snoring

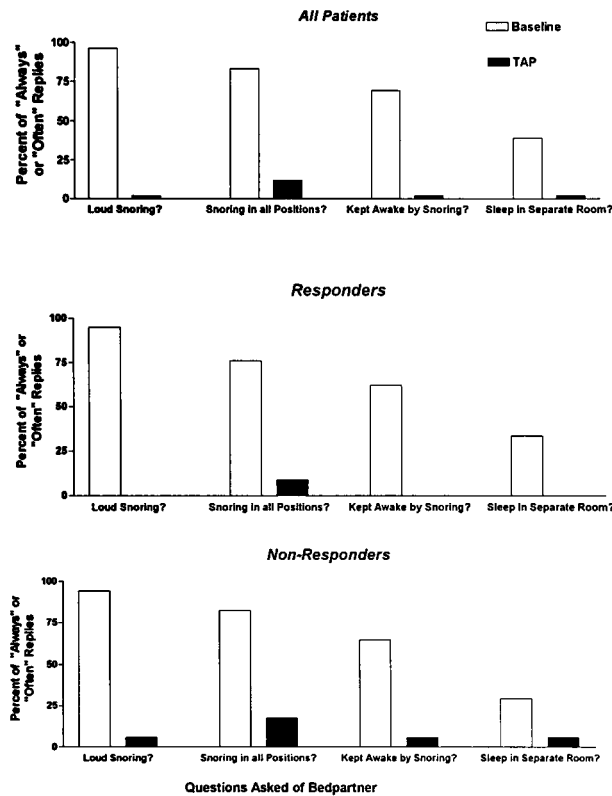


FIGURE 2. Bedpartners' assessment of the effect of TAP appliance on snoring.

could benefit from oral appliance therapy. Dentists treating snoring and sleep apnea used 25 different appliances, about a third of which were adjustable (the rest were mainly custom-fit or prefit).

The current study examined the largest group of patients to date. The results show highly significant reduction in AHI (from 44 to 12 events/h) and high response rate of 81% as defined by $\geq 50\%$ reduction in AHI. This high success rate is most likely a result of the particular type of appliance used in this study. It has several unique features not present in other adjustable mandibular appliances. The main ones are (1) a wide range (1 to 16 mm) of adjustable anterior displacements and lateral and vertical movements, and (2) the anterior location of the adjustment screw. The latter feature is important because it allows for an easy adjustment of the device. The patients themselves were able to easily adjust the appliance in response to their bedpartner's comments about snoring. Similarly, a sleep technologist may be capable of adjusting the appliance during nocturnal polysomnography, thus titrating the degree of anterior mandibular protrusion in the laboratory to eliminate snoring or apnea. The appliance is durable but can be easily repaired by the dentist in the office without

Table 7—Summary of Literature Data for MAAs*

Reference	N	AHI _{base} /AHI _{appl}	RR, %
Kloss et al, 1986 (5)	7	37/12	57
Meier-Ewart and Brosig, 1987 (6)	44	50/23	—
Bonham et al, 1988 (7)	12	54/34	—
Bernstein and Reidy, 1988 (8)	1	35/9	100
Lowe et al, 1990 (9)	1	57/2	100
Ichioka et al, 1991 (10)	14	32/9	68
Schmidt-Nowara et al, 1991 (11)	20	47/20	40
Nakazawa et al, 1992 (12)	12	50/19	—
Clark et al, 1993 (13)	24	48/12	73
Eveloff et al, 1994 (14)	19	35/13	53
Yoshida et al, 1994 (15)	20	57/26	25
Sjöholm et al, 1994 (16)	6	45/30	—
O'Sullivan et al, 1995 (17)	51	32/18	—
Clark et al, 1996 (18)	21	34/20	14
Ferguson et al, 1996 (19)	25	20/10	48
Menn et al, 1996 (20)	23	37/18	52
Miles et al, 1996 (21)	1	34/3	100
Ferguson et al, 1997 (22)	20	25/14	35
Millman et al, 1998 (23)	18	42/15	66
Stradling et al, 1998† (24)	15	193/20	100
Marklund et al, 1998‡ (25)	21	11/5	81
Marklund, 1998‡	15	27/7	60
Marklund, 1998‡	8	53/14	25
Cohen, 1998 (26)	25	33/9	72
Total	364	39/17	53%

*AHI_{base}/AHI_{appl} = mean AHI_s before and with appliance; RR = response rate defined as percent of patients with AHI_s < 10.

†Snorers only; values in AHI_{base}/AHI_{appl} column are mean snoring indices; not used for statistics.

‡Same reference; only median values for AHI presented; not used for summary statistics.

sending it to an outside laboratory. The cost of the appliance, including manufacturing and all of the necessary follow-up visits for 1 year, is comparable to the cost of nasal CPAP equipment in Ontario.

Probably the most important drawback of the current study is the fact that 59 of 134 patients (44%) did have follow-up polysomnography with the oral appliance. Clearly, if we speculate that all of them are nonresponders, our conclusion regarding the success rate of the appliance may not be valid. However, from the initial characteristics of these 59 patients (Table 3) there is no *a priori* reason why they should all be nonresponders; the most likely scenario is that the response rate among them is similar to that seen in the 75 patients who had follow-up polysomnography. In fact, when we assumed the worst case scenario by setting AHI_{appliance} = AHI_{baseline} for all patients without a follow-up polysomnography, we still achieved a significant reduction in AHI from 38 ± 28 events/h to 20 ± 22 events/h ($p = 0.0001$). Finally, subjective information about snoring was available in 121 of 134 patients (90%), which is a very acceptable follow-up rate.

There is generally some hesitancy in recommending an oral appliance for fear that it will interfere with sleep. This fear is unfounded. Studies in which sleep architecture was monitored uniformly show either no change^{19,22,23} or improvement^{17,18,20,25} in sleep quality; our results also demonstrate a significant decrease in sleep fragmentation with the dental appliance.

Side effects occur on the average in 30% of patients as reported by various investigators^{9,12-16,18-22,24}; they range from 0 to 67% and include generally nonspecific discomfort or temporomandibular joint pain. However, many patients consider these side effects as being minor and not influencing their compliance. In the studies in which side effects were compared between wearers and nonwearers of the appliance, no significant differences in the incidence of side effects was found. We found similar results in that $\leq 45\%$ of patients complained of some side effects. The most frequent ones are excessive salivation, teeth discomfort, and jaw discomfort, occurring often in $\leq 26\%$ of patients. The frequency and the severity of side effects are undoubtedly affected by the type of appliance, wear time, degree of protrusion, and care taken by the dentist in fitting the appliance.

As with any treatment, the ability to select patients who are most likely to respond to it is important in improving compliance with therapy. Our study does not allow us to make such predictions. We did not perform any objective measurements of facial morphology, but on the basis of previous studies, such measurements are unlikely to be of clinical value over and above simple clinical examination by a qualified and experienced dentist. Although we did find inverse correlation between BMI and degree of improvement, this association does not imply cause and effect relationship and cannot be used to predict success. On the other hand, our results allow us to argue with the existing belief that oral appliances should not be used for treatment of severe sleep apnea. Of the 21 patients with severe sleep apnea (AHI ranging between 50 and 115 events/h), the use of the appliance brought AHI to ≤ 10 events/h in 6 patients, resulted in $> 50\%$ reduction in AHI in an additional 13, and had no beneficial change in AHI in only 2 patients.

Finally, we must comment on the fact that even in the nonresponders, there was a significant improvement in snoring as perceived by the bedpartner. Undoubtedly, an oral appliance modifies pharyngeal cross-sectional area and compliance of pharyngeal walls. This alters the properties of sound (frequency and amplitude) and its perception by a listener. We found the same result in our earlier investigation²⁸ of the effect of uvulopalatopharyngoplasty on snoring and apnea.

We conclude that adjustable oral appliances appear to be an effective treatment alternative for selected patients with snoring and varying degrees of sleep apnea, including those with severe obstructive sleep apnea. However, predictors for response have yet to be determined.

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