

# The Effect of a Mandibular Advancement Device on Apneas and Sleep in Patients With Obstructive Sleep Apnea\*

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**Objective:** To evaluate the effects of a mandibular advancement device on apneas and sleep in mild, moderate, and severe obstructive sleep apnea.

**Design:** Prospective study.

**Subjects:** Forty-four of 47 patients included.

**Intervention:** Individually adjusted mandibular advancement devices.

**Measurements:** Polysomnographic sleep recordings for 1 night without the device and 1 night with it, with a median of 1 day and no changes in weight, medication, or sleep position between the recordings.

**Results:** The device reduced the median obstructive apnea-hypopnea index from 11 (range, 7 to 19) to 5 (range, 0 to 17) ( $p < 0.001$ ) in 21 patients with mild sleep apnea, from 27 (range, 20 to 38) to 7 (range, 1 to 19) ( $p < 0.001$ ) in 15 patients with moderate sleep apnea, and from 53 (range, 44 to 66) to 14 (range, 2 to 32) ( $p < 0.05$ ) in 8 patients with severe sleep apnea. The arousal index decreased and the sleep stage patterns improved in all severity groups. Twenty-eight of 44 patients were successfully treated with an obstructive apnea-hypopnea index of below 10 and a subjective reduction in snoring. Nine of 16 patients with treatment failure still reported a reduction in snoring. The success rate correlated inversely to the disease severity ( $r = -0.41$ ;  $p < 0.01$ ).

**Conclusions:** A mandibular advancement device reduces apneas and improves sleep quality in patients with obstructive sleep apnea, especially in those with mild and moderate disease. A follow-up sleep recording during treatment is necessary because of the risk of silent obstructive apneas without subjective snoring with the device. (CHEST 1998; 113:707-13)

**Key words:** dental appliances; polysomnography; sleep apnea syndromes; sleep stages; snoring

A mandibular advancement device is a promising new approach in the treatment of snoring and obstructive sleep apnea.<sup>1-11</sup> The device is noninvasive and costs about \$400 US in northern Sweden. The effect of the device on sleep-disordered breathing has been reported to vary.<sup>1-10</sup> Previous studies have indicated that the success rate with a mandibular advancement device is higher in those with moderate sleep apnea than in those with severe sleep apnea.<sup>5,10</sup> However, to our knowledge, the effects of

the mandibular advancement device on subjects with milder forms of the disease have not been studied. Obstructive sleep apnea is associated with an increased prevalence of cardiovascular complications, such as arterial hypertension, coronary artery disease, and nocturnal angina.<sup>12-14</sup> The indications for the mandibular advancement device and the routines for following up sleep recordings have not been established. The aim of the present study was to evaluate the effects of a mandibular advancement device on apneas and sleep in patients with mild, moderate, and severe obstructive sleep apnea.

## MATERIALS AND METHODS

### Subjects

Forty-three men and four women who did not accept treatment with nasal continuous positive airway pressure or were not

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offered that treatment because of mild obstructive sleep apnea were invited to participate in the present study. Twenty-six patients were consecutive and thereafter only patients with an obstructive apnea-hypopnea index of  $>20$  according to preceding sleep apnea recordings were included. Three men of the invited 47 patients refused to take part in the study and were thus excluded from further evaluations. Treatment with mandibular advancement devices was not initiated in patients with Cheyne-Stokes respiration, a body mass index  $>40$  kg/m<sup>2</sup>, arthralgia or myofascial pain from the craniomandibular system, edentulous jaws, or mesial occlusion. The median age of the 44 patients included in the study was 58 years (range, 37 to 72 years) and the median body mass index was 28 kg/m<sup>2</sup> (range, 22 to 37 kg/m<sup>2</sup>).

Approval for the study was obtained from the Medical Ethics Committee at Umeå University.

#### *The Mandibular Advancement Device*

The mandibular advancement device was intended to move the mandible forward by 4 to 6 mm in order to prevent upper airway obstruction and snoring (Fig 1). An initial advancement of  $<4$  mm was used in patients with limited protrusion of the mandible and in patients with a tendency toward mesial occlusion. Holes in the acrylic between the incisors and molars provided space for the tongue and permitted mouth-breathing and speech with the appliance in position (Fig 1). The degree of mandibular advancement was measured on plaster casts in the premolar area and perpendicular to the occlusal plane. The mandibular opening was measured at the central incisors. The mandibular positioning was measured on two separate occasions and the mean value of these measurements was used in the evaluations.

#### *Satisfactory Treatment Result*

A satisfactory result was defined as a subjectively evaluated satisfactory reduction in snoring in combination with a decrease

in the obstructive apnea-hypopnea index to  $<10$  during treatment, or as a reduction in the obstructive apnea-hypopnea index of at least 50%.<sup>2</sup>

#### *Study Design*

The effect of the device on disturbing snoring was estimated by a bedroom partner or a relative during a 2-month habituation period according to a four-grade questionnaire: "satisfactory effect," "slight effect," "no effect," or "worsened effect." Further mandibular advancement was made, if possible, in patients who did not report a "satisfactory effect." The upper and lower parts of the device were separated and fixed in a new position.

The effects on apneas and sleep were evaluated after the habituation period on 2 separate nights: 1 night without the mandibular advancement device and 1 night with it. The patients were told to sleep without the mandibular advancement device for 1 week prior to the polysomnographic sleep study. The median time between the two polysomnographic recordings was one day (range, 1 to 168 days).

In all patients with an obstructive apnea-hypopnea index of above 10 during treatment, an attempt to further increase the mandibular advancement was initiated. The effects of the adjusted devices on apneas and sleep were evaluated in a second polysomnographic sleep recording in five patients. The present results were obtained from the final polysomnographic sleep recording.

Daytime sleepiness was reported as "reduced," "unaffected," or "never existed."

#### *Polysomnographic Sleep Recordings*

Polysomnographic recordings (Nightingale; Judex; Aalborg, Denmark) included EEGs, electro-oculograms, submental electromyograms, nasal and oronasal airflow using a three-way thermistor (Nihon Kohden Ze-732A; Tokyo, Japan), abdominal and chest movements (Resp-EZ; EPM Systems; Midlothian, Va),



FIGURE 1. The mandibular advancement device.

finger oximetry (Ohmeda Biox 3740; Louisville, Colo), body position (Vitalog Monitoring Inc; Redwood City, Calif); and ECGs (V<sub>5</sub>).

Sleep stages were scored manually on 30-s epochs according to Rechtschaffen and Kales.<sup>15</sup> An apnea was defined as a cessation of airflow for at least 10 s and a hypopnea as a decrease of >50% in the thermistor tracing compared with baseline in combination with an oxygen desaturation of ≥3%. An obstructive event was scored if respiratory movements continued during apnea. A concomitant fall in both thermistor tracing and respiratory movements was considered to indicate a central apnea. An arousal was recorded if sleep was interrupted by continuous alpha activity and increased electromyogram activity over 3 s.<sup>16</sup> The apnea-hypopnea index was the average number of events per hour of sleep. The oxygen desaturation index was defined as the average number of oxygen desaturations of ≥4% per hour of sleep. The arousal index was the average number of arousals per hour of sleep. Sleep efficiency was defined as the total sleep time divided by the time from sleep onset to final awakening in the morning.

Mild sleep apnea was defined as an obstructive apnea-hypopnea index of <20, severe sleep apnea as an obstructive apnea-hypopnea index of ≥40, and moderate sleep apnea was defined as the values inbetween.

#### Statistical Methods

Wilcoxon's signed rank test for paired observations, Fisher's Exact Test, Spearman correlation, and one-way analysis of variance were calculated (SPSS 6.1 Statistical Package; SPSS, Inc; Chicago). The null hypothesis was rejected at the 5% level (p<0.05).

## RESULTS

### General Findings

Mild sleep apnea (obstructive apnea-hypopnea index <20) was defined in 21 of the 44 patients,

moderate sleep apnea (obstructive apnea-hypopnea index 20-40) was found in 15 patients, and severe sleep apnea (obstructive apnea-hypopnea index ≥40) was found in 8 patients. The three severity groups did not differ in terms of age, body mass index, total sleep time, and the percentage of sleep spent in the supine position. Medication, body mass index, and total sleep time did not differ between the two study occasions (Tables 1-3). The sleep spent in the supine position increased in patients with mild sleep apnea (p<0.05), but was unchanged in patients with moderate and severe sleep apnea.

### Effect on Apnea and Hypopnea

The apnea-hypopnea index and the oxygen desaturation index were reduced in all three severity groups (Tables 1-3 and Fig 2). The median obstructive apnea-hypopnea index decreased during treatment from 11 (range, 7 to 19) to 5 (range, 0 to 17) (p<0.001) in patients with mild sleep apnea, from 27 (range, 20 to 38) to 7 (range, 1 to 19) (p<0.001) in patients with moderate sleep apnea, and from 53 (range, 44 to 66) to 14 (range, 2 to 32) (p<0.05) in patients with severe sleep apnea (Tables 1-3). The central and mixed apnea-hypopnea index decreased in patients with mild and moderate sleep apnea (p<0.05).

The percentage of sleep spent in apnea or hypopnea decreased during treatment in all three severity groups (p<0.05) (Tables 1-3). The obstructive apnea-hypopnea index consisted of fewer apneas than hypopneas during treatment than without the device in all three severity groups (p<0.05).

**Table 1—Mild Sleep Apnea (n=21)**

	Without the Device		With the Device		p Value
	Median	Range	Median	Range	
<b>Respiratory variables</b>					
Obstructive apnea-hypopnea index	11	6.5-19	5.3	0.0-17	<0.001
Obstructive apnea index	5.5	1.6-18	1.4	0.0-13	<0.001
Obstructive apnea—longest, s*	37	16-78	22	0.0-61	0.002
Obstructive hypopnea index	4.2	1.5-10	2.9	0.0-7.3	0.005
Central and mixed index	1.2	0.0-11	0.3	0.0-24	0.03
Time spent in apnea or hypopnea, %*	6.1	3.0-20	3.1	0.0-14	0.002
Oxygen desaturation index†	6.5	2.7-14	3.9	0.6-12	0.008
<b>Sleep variables</b>					
Total sleep time, min	426	309-500	410	272-499	0.79
Sleep efficiency, %†	87	64-95	88	72-95	0.57
Supine sleep, %*	25	3.0-77	41	7.9-70	0.04
Stage 1 sleep, %	22	13-41	19	7.1-32	0.002
Stage 2 sleep, %	51	40-63	50	38-63	0.99
Slow-wave sleep, %	7.3	0.0-22	8.6	0.0-18	0.37
Rapid eye movement sleep, %	15	10-22	21	7.3-34	0.005
Arousal index*	13	5.1-26	8.5	2.5-16	<0.001

\*n=20.

†n=12.

‡n=19.

**Table 2—Moderate Sleep Apnea (n=15)**

	Without the Device		With the Device		p Value
	Median	Range	Median	Range	
Respiratory variables					
Obstructive apnea-hypopnea index	27	20-38	7.2	1.3-19	<0.001
Obstructive apnea index	13	1.1-30	1.1	0.0-12	0.003
Obstructive apnea—longest, s*	47	13-111	25	0.0-91	0.03
Obstructive hypopnea index	10	5.1-26	6.0	1.0-13	0.002
Central and mixed index	0.5	0.0-6.1	0.3	0.0-4.5	0.048
Time spent in apnea or hypopnea, %*	19	8.6-30	4.4	0.7-21	0.001
Oxygen desaturation index <sup>†</sup>	24	9.9-31	6.9	0.7-15	0.008
Sleep variables					
Total sleep time, min	410	266-466	414	294-493	0.55
Sleep efficiency, %*	85	59-93	88	60-97	0.07
Supine sleep, % <sup>‡</sup>	28	1.4-100	34	8.3-66	0.12
Stage 1 sleep, %	29	12-57	18	8.9-27	0.001
Stage 2 sleep, %	46	25-61	52	40-63	0.14
Slow-wave sleep, %	5.8	0.0-17	7.2	0.2-23	0.004
Rapid eye movement sleep, %	16	8.1-26	21	10-27	0.02
Arousal index*	23	10-37	10	5.3-28	0.002

\*n=14.

<sup>†</sup>n=9.<sup>‡</sup>n=13.

### Effect on Snoring

Snoring was satisfactorily reduced in 20 of 21 patients with mild sleep apnea, in 12 of 15 patients with moderate sleep apnea, and in 5 of 8 patients with severe sleep apnea (Fig 2).

### Satisfactory Treatment Result

An obstructive apnea-hypopnea index of less than 10 and a satisfactory reduction in snoring was found

in 17 of 21 patients with mild sleep apnea (81%) during treatment, 9 of 15 patients with moderate sleep apnea (60%), and 2 of 8 patients with severe sleep apnea (25%) (Fig 3). Thus, 28 of the total of 44 patients had a satisfactory treatment result (64%). The frequency of patients with a satisfactory result correlated inversely with disease severity ( $r = -0.41$ ;  $p < 0.01$ ).

A reduction in the obstructive apnea-hypopnea index of at least 50% together with a satisfactory

**Table 3—Severe Sleep Apnea (n=8)**

	Without the Device		With the Device		p Value
	Median	Range	Median	Range	
Respiratory variables					
Obstructive apnea-hypopnea index	53	44-66	14	1.6-32	0.01
Obstructive apnea index	40	17-55	4.9	0.0-28	0.01
Obstructive apnea—longest, s	60	31-84	48	0.0-64	0.02
Obstructive hypopnea index	11	1.8-32	4.0	1.6-16	0.07
Central and mixed index	2.5	0.1-11	2.0	0.0-12	0.58
Time spent in apnea or hypopnea, %	36	24-50	8.9	0.7-28	0.01
Oxygen desaturation index*	53	19-72	14	2.6-35	0.04
Sleep variables					
Total sleep time, min	418	348-483	429	339-480	0.89
Sleep efficiency, %	88	67-98	92	77-97	0.26
Supine sleep, %	36	1.7-100	39	0.0-100	0.61
Stage 1 sleep, %	29	15-58	24	16-40	0.07
Stage 2 sleep, %	56	41-69	47	32-53	0.05
Slow-wave sleep, %	0.2	0.0-3.3	8.8	0.8-17	0.01
Rapid eye movement sleep, %	14	0.0-18	20	6.9-28	0.01
Arousal index	34	30-67	16	3.0-28	0.01

\*n=5.

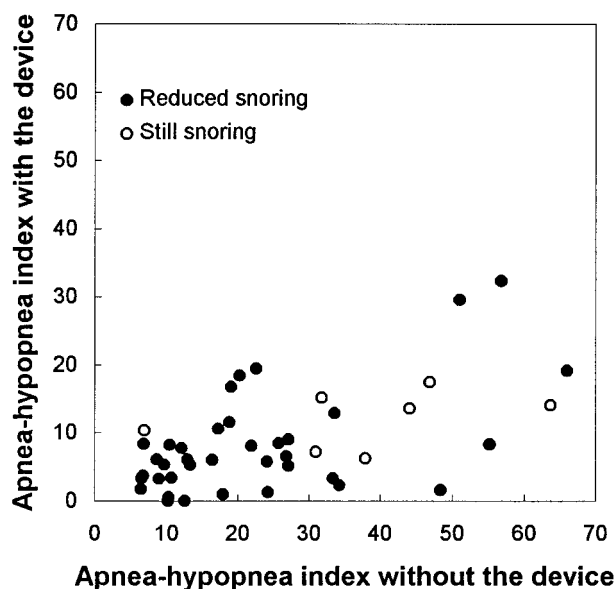


FIGURE 2. Obstructive apnea-hypopnea index and snoring in all single patients with and without the device.

reduction in snoring was found in 10 of the 21 patients with mild sleep apnea (48%), 10 of 15 patients with moderate sleep apnea (67%), and 3 of 8 patients with severe sleep apnea (38%). A satisfactory result was found in 23 patients in the total sample (52%), using this definition.

#### Unsatisfactory Treatment Result

Snoring was satisfactorily reduced but the obstructive apnea-hypopnea index was not in 9 of 16 patients with an overall unsatisfactory result (Fig 4). These

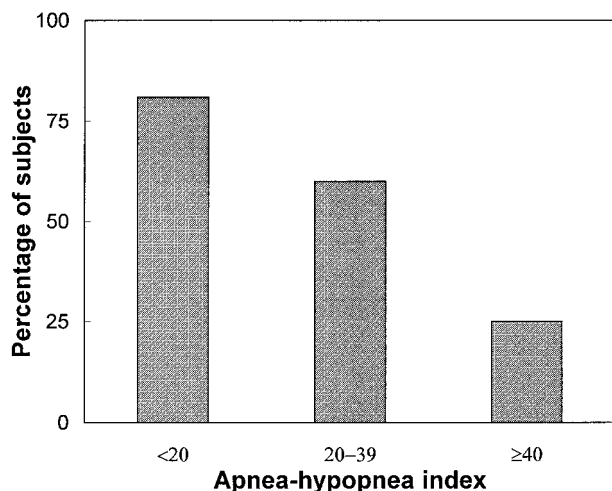


FIGURE 3. Satisfactory treatment result with the mandibular advancement device in patients with mild sleep apnea (n=21), moderate sleep apnea (n=15), and severe sleep apnea (n=8).

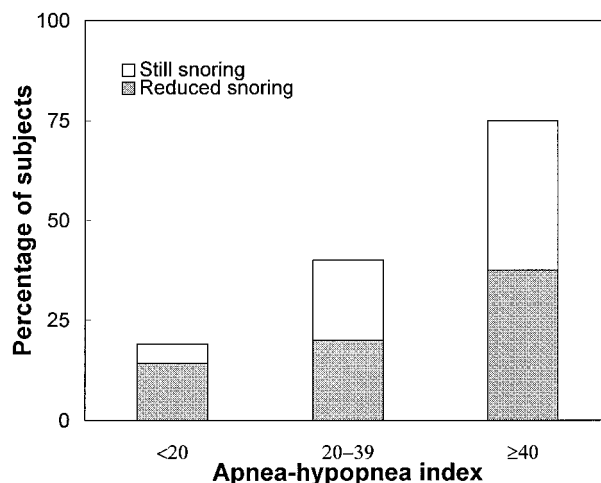


FIGURE 4. Unsatisfactory treatment result with the mandibular advancement device. "Silent apneas" with reduced snoring despite an insufficient apnea-hypopnea reduction occurred in three patients with mild sleep apnea, three patients with moderate sleep apnea, and three patients with severe sleep apnea.

patients were regarded as suffering from "silent obstructive apneas." In 2 of the 16 patients with an unsatisfactory result, the obstructive apnea and hypopnea reduction was sufficient, although snoring persisted. In the remaining five patients, snoring as well as obstructive apneas and hypopneas were insufficiently reduced.

#### Sleep Stage Patterns

The arousal index decreased during treatment with the device in all three severity groups ( $p < 0.05$ ) (Tables 1-3). Stage 1 sleep was reduced in patients with mild and moderate sleep apnea ( $p < 0.01$ ) (Tables 1 and 2). Slow-wave sleep increased during treatment in patients with moderate and severe sleep apnea ( $p < 0.05$ ) (Tables 2 and 3). Rapid eye movement sleep increased in all three severity groups ( $p < 0.05$ ) (Tables 1-3).

#### Daytime Sleepiness

Forty-two of 44 patients reported daytime sleepiness before treatment. Thirty-four of these patients reported a reduction in daytime sleepiness with the device. Seven of eight patients with persistent daytime sleepiness were regarded as treatment failures with an obstructive apnea-hypopnea index of  $>10$  during treatment.

#### Positioning of the Mandible

The median mandibular advancement in all 44 patients was 6.0 mm (range, 2.3 to 8.5 mm), which corresponded to 58% of maximum protrusion

(range, 33 to 89%). The median mandibular opening was 10.0 mm (range, 7.0 to 14 mm). The positioning of the mandible was similar in all three severity groups and did not differ between patients with a satisfactory treatment result and patients with an unsatisfactory treatment result using the device. Satisfactory results with the device were found at mandibular advancements at between 3.5 to 8.5 mm, which corresponded to 41 to 88% of maximum protrusion.

The success rate was higher in the patients who were able to advance the mandible at least 5 mm than in those who were not ( $p < 0.01$ ). Among the moderate and severe cases, a satisfactory treatment effect with the device was found only in patients who were able to advance the mandible at least 5 mm during treatment.

## DISCUSSION

In the present study, the mandibular advancement device reduced the obstructive apnea-hypopnea index and the arousal index and improved the sleep stage patterns in patients with mild, moderate, and severe sleep apnea. Satisfactory results were found more frequently in those with mild apnea than in subjects with severe apnea. More than 50% of patients who had unsatisfactory results with the device still reported a satisfactory effect on snoring. These patients were regarded as suffering from "silent obstructive apneas."

Different indexes and cutoff points have been used to define treatment success with a mandibular advancement device in the treatment of obstructive sleep apnea. Criteria, such as a decrease in the obstructive apnea-hypopnea index to  $< 10$  or  $20$ <sup>2,5,10</sup> or a reduction in the obstructive apnea-hypopnea index by  $> 50\%$ ,<sup>2,5,6</sup> have been used. Bonham et al<sup>4</sup> used both an obstructive apnea index of  $< 10$  and a 50% reduction in the obstructive apnea index to define treatment success. However, a cutoff point for treatment success based on the apnea and hypopnea reduction in percent may underestimate the treatment effect in patients with mild sleep apnea and overestimate the effect of the device in patients with a more severe disease. This is illustrated in the present study where 10 of 21 patients with mild sleep apnea experienced a 50% reduction in the obstructive apnea-hypopnea index with the device. Even so, 17 of the 21 patients were satisfied with the treatment in terms of reduced snoring together with an obstructive apnea-hypopnea index of  $< 10$  during treatment. Among the moderate and severe cases, 13 patients experienced a 50% reduction in the apnea frequency, while 11 patients had an obstructive

apnea-hypopnea index of  $< 10$  during treatment. We suggest that a satisfactory treatment result should be defined as a satisfactory reduction in snoring together with an obstructive apnea-hypopnea index of  $< 10$ , irrespective of the initial apnea-hypopnea index.

There were few central and mixed apneas among the present patients with obstructive sleep apnea. The central and mixed apnea and hypopnea index was unaffected by the device in patients with severe sleep apnea, but decreased slightly in the subjects with mild and moderate apnea.

O'Sullivan et al<sup>10</sup> report that a mandibular advancement device is more effective in patients with an obstructive apnea-hypopnea index of between 20 and 60 than in patients with an obstructive apnea-hypopnea index of  $> 60$ . This is in accordance with the results of the present study, although we also investigated milder cases. The study by O'Sullivan et al<sup>10</sup> evaluated the effect of the mandibular advancement device during 1 night: half the night with the device and half without it. We used 2 full-night polysomnographic sleep recordings to increase the validity in the small subgroups.<sup>17</sup> The patients were also told to sleep without the mandibular advancement device for 1 week prior to the polysomnographic sleep study to avoid a possible long-lasting treatment effect by the device during the study.<sup>18</sup>

In previous studies, it has been suggested that mandibular advancement devices reduce the obstructive apnea-hypopnea index to  $< 10$  in between 25% and 73% of patients with obstructive sleep apnea.<sup>2,4,5,8</sup> These disparate results could be explained by various proportions of patients with mild, moderate, and severe sleep apnea among the patients included in those studies. In a similar way, the different results in two recent studies comparing the effect of the mandibular advancement device with nasal continuous airway pressure may be explained by milder cases included in the study reporting a good effect by the mandibular advancement device<sup>19</sup> and more severe cases in the study describing an inferior effect by the mandibular advancement device.<sup>20</sup>

Clark et al<sup>8</sup> suggest that  $> 75\%$  of maximum protrusion is needed for a satisfactory effect. However, unnecessarily large mandibular advancements should be avoided, since the long-term negative side effects on occlusion and the temporomandibular joints are unknown. In the present study, a satisfactory treatment result was found at mandibular advancements ranging from 41 to 88% of maximum protrusion. The results also suggested that larger mandibular advancements are needed for treatment success in the more severe cases. It is difficult to measure the mandibular advancement as the per-

centage of maximum protrusion, since the maximum protrusion decreases as the mandibular opening increases.<sup>21</sup> We therefore suggest that the degree of mandibular advancement should be described as a distance and not a percentage of maximum protrusion.

The reason why the mandibular advancement device has less effect on severe cases than on milder ones is unknown. It is suggested that large obstructions extending from the soft palate to the base of the tongue or even to the epiglottis occur more frequently in patients with severe sleep apnea than in patients with mild sleep apnea.<sup>22</sup> It is possible that the mandibular advancement device eliminates limited obstructions more effectively, while more extended obstructions are influenced to a lesser degree by the mechanism of the device.

Normal sleep is characterized by 2 to 5% of stage 1 sleep, 45 to 55% of stage 2 sleep, 13 to 23% of slow-wave sleep, and 20 to 25% of rapid eye movement sleep in young adults.<sup>17</sup> Arousals and stage 1 sleep increase in patients with obstructive sleep apnea on account of slow-wave sleep and rapid eye movement sleep.<sup>17,23</sup> The present results indicate that sleep stages and arousal frequency change toward a more normal pattern during treatment with a mandibular advancement device.

One limitation of the present study was the lack of a snoring microphone. Even so, the present study showed that subjective reports on snoring are unreliable in the evaluation of treatment outcome regarding the effect on apneas. Objective testing of treatment effect on apneas and hypopneas is necessary.

In conclusion, treatment with a mandibular advancement device reduces apneas and improves sleep quality in patients with mild, moderate, and severe sleep apnea. A satisfactory treatment result is more likely to occur in patients with milder sleep apnea than in patients with more severe sleep apnea. A follow-up sleep study with the device is necessary in patients with moderate and severe sleep apnea, because of the risk of reduced snoring despite persistent silent obstructive apneas during treatment.

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