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A M E R I C A N C O L L E G E O F



P H Y S I C I A N S[®]

Mandibular Advancement Device in Patients With Obstructive Sleep Apnea*

Long-term Effects on Apnea and Sleep

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Study objectives: To evaluate the long-term effects on apneas and sleep and the tolerability of a mandibular advancement device in patients with obstructive sleep apnea.

Design: Prospective study.

Setting: Department of Respiratory Medicine, University Hospital, Umeå, Sweden.

Patients: Thirty-three consecutively treated patients.

Interventions: Individually adjusted mandibular advancement devices.

Measurements and results: Polysomnographic sleep recordings on 1 night without the device and 1 night with the device were performed after 0.7 ± 0.5 years (mean \pm SD) and after 5.2 ± 0.4 years from the start of treatment. Nineteen of the 33 patients experienced a short-term satisfactory treatment result with an apnea-hypopnea index of < 10 events per hour and a satisfactory reduction in snoring. Fourteen patients were regarded as being insufficiently treated with the device. Seventeen of the short-term satisfactorily treated patients (90%) and 2 of the remaining patients continued treatment on a long-term basis. The apnea-hypopnea index was reduced by the device from 22 ± 17 to 4.9 ± 5.1 events per hour ($p < 0.001$) in these 19 long-term treatment patients, which did not differ from what was found at the short-term follow-up visits in these patients. Patients with their devices replaced or adjusted experienced a better long-term effect than patients still using their original devices ($p < 0.05$).

Conclusions: The long-term effect and tolerability of a mandibular advancement device are good in patients who are recommended the treatment on the basis of a short-term sleep recording, provided that the device is continuously adjusted or replaced with a new one when needed. A short-term follow-up is valuable in the selection of patients who will benefit from long-term treatment with a mandibular advancement device. (CHEST 2001; 120:162-169)

Key words: activator appliances; advancement mandibular; long-term effect; polysomnography; sleep apnea syndromes

The beneficial effects on apneas and sleep using a mandibular advancement device in patients with obstructive sleep apnea have been confirmed in a number of short-term studies.¹⁻¹⁰ So far, the reported side effects are few during longer-term treatment with mandibular advancement devices.^{11,12} The device is particularly effective in patients who suffer from supine position-dependent obstructive

sleep apneas.⁷ The method is noninvasive, inexpensive, and simple to use, and would therefore be preferred by a large percentage of patients suffering from snoring and sleep apnea. The long-term effects of a mandibular advancement device on apneas and sleep have, however, not yet been evaluated, and this is needed for the establishment of clinical follow-up routines. The aims of the present study were to evaluate the long-term effects on apneas and sleep and the tolerability of a mandibular advancement device in patients suffering from obstructive sleep apnea.

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The study was conducted at the Sleep Laboratory at the Department of Respiratory Medicine, University Hospital, Umeå, Sweden.

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MATERIALS AND METHODS

Subjects

Thirty-three consecutive patients who received treatment with mandibular advancement devices from September 1989 until March 1994 were included in the study. The patients suffered from mild sleep apnea or more severe disease and were unable to

tolerate treatment with nasal continuous positive airway pressure. There were 29 men and 4 women aged 52 ± 11 years (mean \pm SD) at the onset of treatment. Approval for the participation of the patients in the study was obtained from the Medical Ethics Committee at Umeå University.

Polysomnographic Sleep Recordings

Polysomnographic sleep recordings for 1 night without the device and 1 night with the device were performed short term after 0.7 ± 0.5 years and long term after 5.2 ± 0.4 years from the start of treatment. The patients were told to sleep without their mandibular advancement devices for 1 week prior to the polysomnographic sleep recordings without the device to avoid a possible lag in the effect of the device. Polysomnographic sleep recordings (Nightingale; Judex; Aalborg, Denmark) included EEGs, electro-oculograms, submental electromyograms, oronasal air flow using a three-way thermistor (Ze-732A; Nihon Kohden; Tokyo, Japan), abdominal and chest movements (RespEZ; EPM Systems; Midlothian, VA), finger oximetry (Biox 3740; Ohmeda; Louisville, CO), body position (Body position sensor; Vitalog; Redwood City, CA) and ECGs (V_5).

Sleep stages were scored manually in 30-s epochs according to Rechtschaffen and Kales.¹³ An apnea was defined as a cessation of airflow for at least 10 s. A hypopnea was defined as a decrease of $> 50\%$ in the thermistor tracing compared with baseline for > 10 s in combination with an oxygen desaturation of $\geq 3\%$. An obstructive apnea was scored if respiratory movements continued during the apnea. A concomitant fall in both thermistor tracing and respiratory movements was considered to indicate a central apnea. The apnea-hypopnea index was the average number of events per hour of sleep. It was subclassified into the supine-position, lateral-position, and prone-position apnea-hypopnea indexes. The oxygen desaturation index was defined as the average number of oxygen desaturations of $\geq 4\%$ per hour of sleep. A satisfactory treatment result by the device was defined as an apnea-hypopnea index of < 10 events per hour in combination with a satisfactory reduction in snoring.

The Mandibular Advancement Device

The mandibular advancement devices were fabricated on individual plaster casts of the dentition and according to construction bites in wax taken directly on the patients with their mandibles protruded by 4 to 6 mm and opened at least 5 mm in order to prevent airway obstruction and snoring.⁶⁻⁸ After a 2-month habituation period, the device was adjusted in patients who experienced side effects or an insufficient treatment effect. A construction bite with the mandible in a new position was taken by the dentist. The upper and lower parts of the device were then separated and repositioned by a dental technician. The effects of the device on apneas and sleep were evaluated in polysomnographic sleep recordings.

The degree of mandibular repositioning by the device at the long-term follow-up was measured on the pretreatment casts. The maxillary and mandibular casts were positioned according to the most recent construction bite and compared with the casts in centric occlusion. The mandibular protrusion by the device was measured in the premolar area along an occlusal plane, defined by the mesial cusp of the upper right first molar or a premolar and the edge of the right upper central incisor. The mandibular opening by the device was measured on the right central incisor. A possible long-term change in dental occlusion induced by the device was measured as the difference in overjet between pretreatment casts in centric occlusion and long-term casts in centric occlusion.

Subjective Effects

A bedroom partner or relative estimated the effect of the device on disturbing snoring as "satisfactory effect" or "unsatisfactory effect" at the short-term and the long-term follow-up visits. At the long-term follow-up visit, the patients were asked about excessive sleepiness during the day more than once a week during the last year of treatment.¹⁴ They were asked if this sleepiness had occurred during the study period. The patients were also asked whether they had experienced any side effects in terms of craniomandibular symptoms or changes in dental occlusion during the study period. Finally, the patients were asked whether they had been "satisfied," "partially satisfied," "slightly dissatisfied," or "dissatisfied" with the treatment. All of the questions had a "don't know" alternative.

Statistical Methods

Wilcoxon's signed rank test was used to evaluate the long-term and short-term effects on respiratory and sleep variables with and without the device.¹⁵ The Bonferroni *post hoc* correction for multiple comparisons was used when more than two groups were compared. The Mann-Whitney *U* test for independent samples was used to compare the long-term treatment patients with the remaining patients in terms of age, body mass index, and respiratory and sleep variables. The influence of sleep position, weight, snoring, daytime sleepiness, and factors related to the device on the difference in the apnea-hypopnea index between the short-term and the long-term follow-up visits was evaluated using linear regression analysis.¹⁵ A *p* value of < 0.05 was considered significant. Calculations were performed using software (9.0 version; SPSS; Chicago, IL).

RESULTS

Thirty-three patients with obstructive sleep apnea were evaluated for the short-term effects of a mandibular advancement device on apneas and sleep. Nineteen of the 33 patients were still using their mandibular advancement devices at the long-term follow-up visit after 5.2 ± 0.4 years (range, 4.5 to 6.1 years) and reported that they had used their devices for 50 to 90% of the nights since the onset of treatment. There were 17 men and 2 women among these long-term treatment patients. The age of the patients was 50 ± 12 years (range, 25 to 71 years) and their body mass index was 26 ± 3.5 kg/m² (range, 20 to 33 kg/m²) at the onset of treatment. They had increased in weight by 3.7 ± 3.8 kg (range, -3 to 11 kg) at the long-term follow-up visit.

Short-term Follow-up After 0.7 ± 0.5 Years ($n = 33$)

The short-term apnea-hypopnea index was reduced from 25 ± 16 to 8.8 ± 7.6 events per hour by the device in the 33 patients ($p < 0.001$). Nineteen of the 33 patients had a short-term satisfactory treatment result with the device. The other 14 patients had a short-term insufficient effect with the device and were recommended other treatments for sleep apnea.

Long-term Follow-up After 5.2 ± 0.4 Years
($n = 19$)

At the long-term follow-up visit, 17 of the 19 short-term satisfactorily treated patients (90%) were still receiving treatment. Two of the 14 patients with a short-term insufficient effect were still using their devices, as they were satisfied with the treatment and had experienced a reduction in the apnea-hypopnea index to < 20 events per hour by the device. Consequently, the long-term treatment group consisted of all but two patients with a short-term satisfactory treatment result, plus two patients who experienced a short-term insufficient treatment effect.

The long-term apnea-hypopnea index was reduced from 22 ± 17 events per hour without the device to 4.9 ± 5.1 events per hour ($p < 0.001$) with the device in the 19 patients who continued to use their mandibular advancement devices on a long-term basis (Table 1; Fig 1). These values did not differ from those found at the short-term follow-up visit in these patients, when the apnea-hypopnea index was reduced from 24 ± 16 events per hour without the device to 5.0 ± 4.5 events per hour with the device ($p < 0.001$; Figs 2–4). Changes in the percentage of sleep in the supine position, severity of the disease, snoring, weight, or daytime sleepiness did not influence the results. The oxygen saturation index decreased and the lowest arterial oxygen saturation increased with the device at the long-term follow-up visit (Table 1).

Sixteen of the 19 long-term treatment patients (84%) had an apnea-hypopnea index of < 10 events per hour with the device at the long-term follow-up visit (Fig 1). Fourteen of the 17 patients (82%) with a short-term satisfactory treatment result who con-

tinued long-term treatment experienced a stable long-term effect on apneas with the device (Fig 3). All three patients with severe sleep apnea and an initial apnea-hypopnea index of > 40 events per hour had an apnea-hypopnea index of < 10 events per hour at the short-term and the long-term follow-up visits with the device (Figs 1–4).

Subjective Symptoms at the Long-term Follow-up
($n = 19$)

Fourteen of the 19 long-term treatment patients reported that the device was still having a satisfactory effect on snoring. Five patients reported that the effect of the device on snoring had decreased from a satisfactory effect to an unsatisfactory effect. Thirteen of the 19 patients reported that excessive sleepiness during the daytime had occurred less than once a week during the past year. Five of the six patients who had experienced excessive sleepiness during the daytime more frequently during the past year reported that this sleepiness had occurred during the study period. One patient had experienced the same degree of daytime sleepiness with the device during the whole study period. All the patients who reported an increase in snoring and/or experienced daytime sleepiness had an apnea-hypopnea index of < 10 events per hour with the device.

No patient reported any increase in craniomandibular symptoms during the study period. Two patients reported that they had experienced a change in dental occlusion in the morning but that this feeling had disappeared during the day. Another 2 of the 19 patients reported that they did not know if their occlusion had changed during treatment. Seventeen of the 19 patients reported that they were satisfied

Table 1—Respiratory Variables at the Short-term and Long-term Follow-up Visits With and Without the Device

Variables	Short-term Follow-up						Long-term Follow-up					
	Without Device			With Device			Without the Device			With the Device		
	No.	Mean \pm SD	Range	No.	Mean \pm SD	Range	No.	Mean \pm SD	Range	No.	Mean \pm SD	Range
Apnea-hypopnea index, events/h	19	24 ± 16	6.5–60	19	$5.0 \pm 4.5^*$	0.4–18	19	22 ± 17	3.9–59	19	$4.9 \pm 5.1^{\dagger\dagger}$	0.0–20
In supine position	13	40 ± 19	12–61	12	$6.6 \pm 6.2^*$	0.7–23	19	43 ± 18	13–75	19	$11 \pm 15^{\dagger\dagger}$	0.0–52
In lateral position	11	10 ± 15	0.0–48	12	2.8 ± 5.5	0.0–19	19	13 ± 17	0.0–47	18	$2.1 \pm 3.4^{\dagger}$	0.0–14
Longest apnea, s	13	53 ± 18	30–82	13	$28 \pm 8.7^*$	16–44	19	49 ± 18	27–106	19	$33 \pm 16^{\dagger\dagger}$	15–79
Time in apnea, %	12	17 ± 12	4.3–44	12	5.6 ± 11	0.1–40	17	14 ± 9.1	1.6–28	17	$3.7 \pm 3.9^{\dagger\dagger}$	0.1–13
Central apnea-hypopnea index	19	1.8 ± 2.7	0.0–11	19	$0.4 \pm 0.8^*$	0.0–3.2	19	2.2 ± 4.5	0.0–18	19	1.3 ± 2.7	0.0–11
Lowest SaO ₂ , %	18	80 ± 3.8	73–88	19	$87 \pm 5.5^*$	72–92	19	82 ± 8.1	56–91	19	$89 \pm 5.4^{\dagger\dagger}$	76–95
Oxygen desaturation index, desaturations/h	7	12 ± 6.7	3.9–24	4	1.1 ± 0.6	0.3–1.6	19	15 ± 14	0.8–58	19	$4.4 \pm 4.3^{\dagger}$	0.8–18

*Significant short-term with the device compared to without it.

†Significant long-term with the device compared to without it.

‡Significant short-term without the device compared to long-term with it.

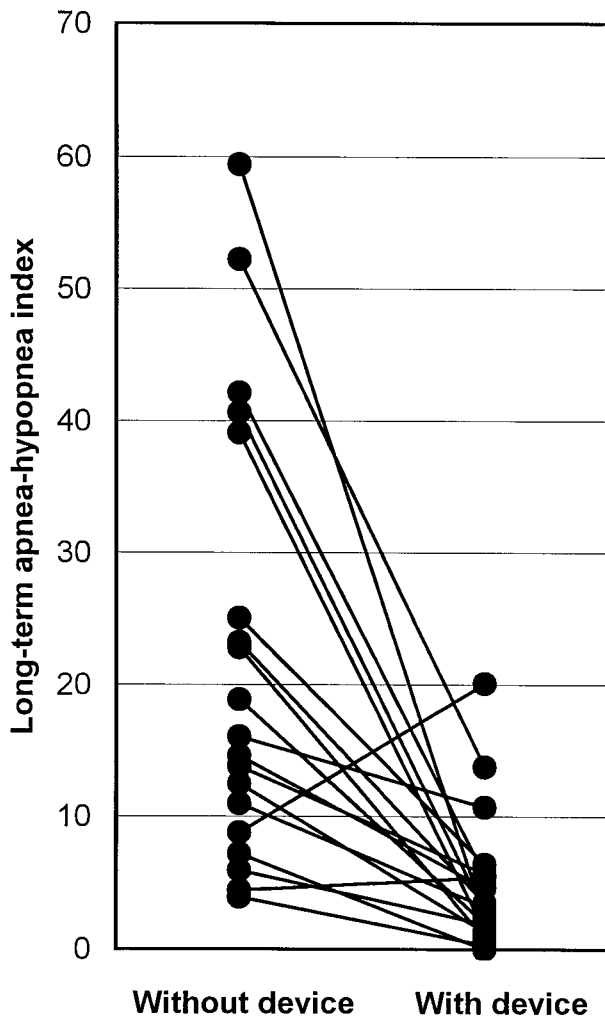


FIGURE 1. The apnea-hypopnea indexes (number of events per hour) with and without the mandibular advancement device at the long-term follow-up visit ($n = 19$).

with the treatment. The remaining two patients reported that they were partially satisfied with the treatment.

The Mandibular Advancement Device at the Long-term Follow-up Visit ($n = 19$)

Six of the 19 long-term treatment patients had had their devices replaced with new ones with a design similar to that of the original ones because of a poor fit or the loss of the device. Two of the 19 patients had their original devices adjusted between the short-term and the long-term follow-up visits. One patient received a decreased mandibular protrusion by the device, since he had experienced pain from the craniomandibular system. The other patient requested an increased mandibular protrusion by the device. The remaining 11 patients were still using their original devices.

At the long-term follow-up visit, the mandibular

protrusion produced by the devices was 5.3 ± 1.4 mm (range, 2 to 8.5 mm) and the mandibular opening produced by the devices was 10 ± 1.4 mm (range, 6 to 12 mm). The mean mandibular protrusion and opening did not differ between the short-term and long-term follow-up visits. The device induced a change in overjet of -0.9 ± 1.2 mm (range, -3.3 to 1.0 mm; $p < 0.05$) during the study period.

Patients who had their devices replaced with new ones or had them adjusted during the study period experienced a better long-term effect with the device than patients who were still using their original devices ($p < 0.05$). This finding was independent of changes in mandibular repositioning by the device or dental overjet during the study period.

Sleep-Stage Patterns at the Long-term Follow-up Visit ($n = 19$)

Stage 1 sleep decreased while slow-wave sleep and rapid eye movement sleep increased with the device

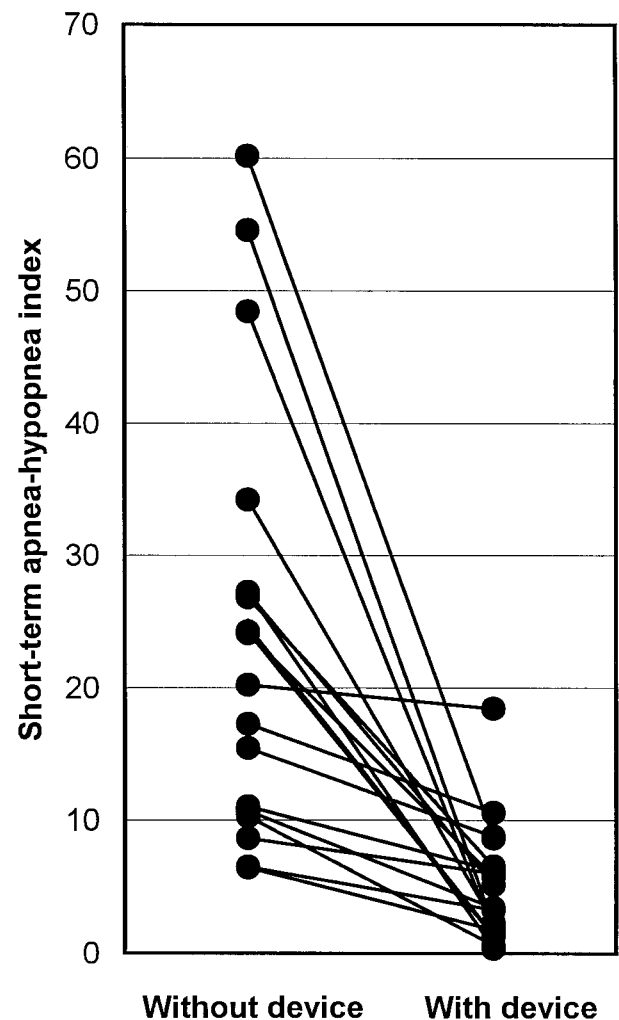


FIGURE 2. The apnea-hypopnea indexes (number of events per hour) with and without the mandibular advancement device at the short-term follow-up visit ($n = 19$).

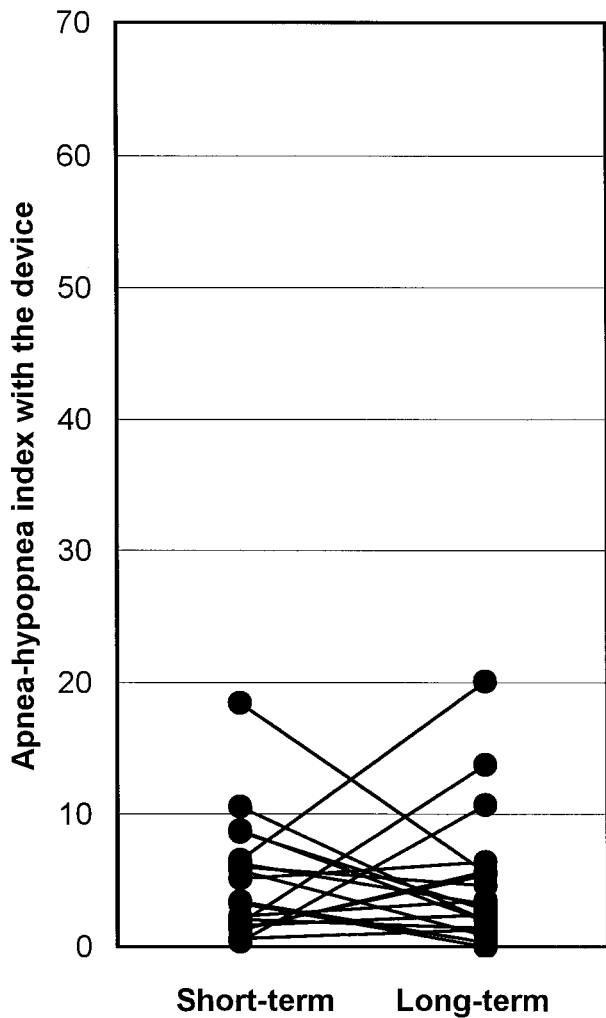


FIGURE 3. The apnea-hypopnea indexes (number of events per hour) with the device at the short-term and long-term follow-up visits (n = 19).

at the long-term follow-up visit (Table 2). Total sleeping time, the percentage of sleep spent in the supine position, and the percentage of sleep spent in different sleep stages were unchanged between the short-term and the long-term follow-up visits with the device (Table 2).

Patients Who Discontinued Treatment or Received Complementary Treatment (n = 14)

Ten of the 33 patients discontinued treatment. Eight of these 10 patients experienced an insufficient effect with the mandibular advancement device at the short-term follow-up visit. Two patients experienced side effects with the device during the study period. One of these two patients developed a marked forward migration of the lower dentition in relation to the upper dentition, and the other patient

argued that she could no longer tolerate the device after 3 years of treatment.

Four of the 33 patients used their devices as a complement to other treatment for snoring and sleep apnea at the long-term follow-up visit. Two of these four patients alternated between the use of their mandibular advancement devices and treatment with continuous positive airway pressure. The other two patients continued to use their mandibular advancement devices for at least 70% of the nights, but they had also undergone uvulopalatoplasty during the study period. These two patients had short-term apnea-hypopnea indexes of 31 events per hour and 64 events per hour, respectively, without the device and 7.2 events per hour and 14 events per hour, respectively, with the device. Their long-term apnea-hypopnea indexes were 17 events per hour and 7.8 events per hour, respectively, without the

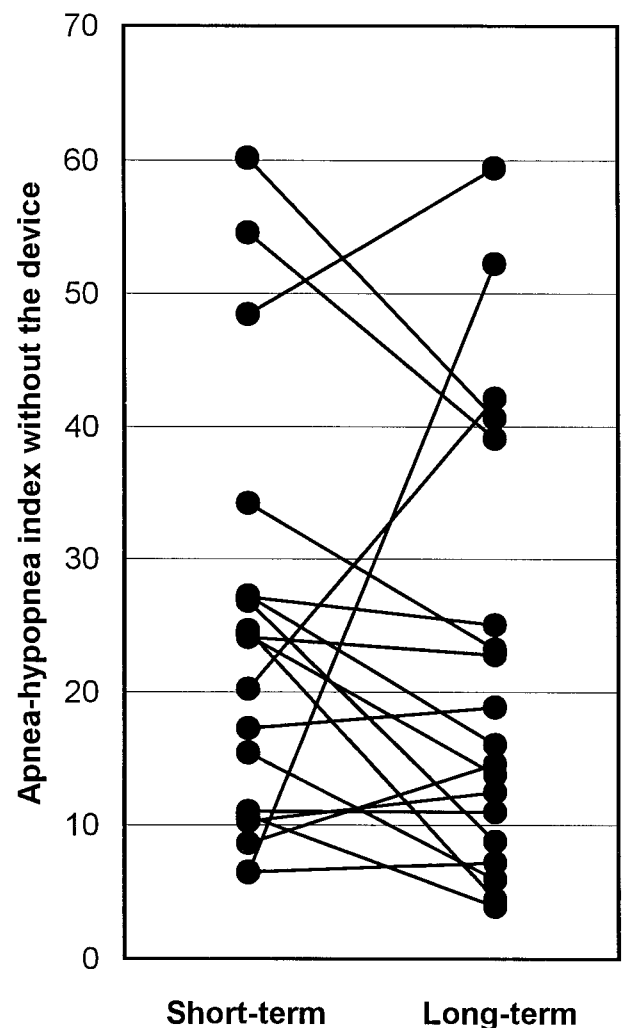


FIGURE 4. The apnea-hypopnea indexes (number of events per hour) without the device at the short-term and long-term follow-up visits (n = 19).

Table 2—Sleep Variables at the Short-term and Long-term Follow-up Visits With and Without the Device

Variables	Short-term Follow-up					Long-term Follow-up				
	Without Device			With Device		Without Device			With Device	
	No.	Mean ± SD	Range	Mean ± SD	Range	No.	Mean ± SD	Range	Mean ± SD	Range
Sleep time, min	19	422 ± 39	309–466	408 ± 70	217–535	19	384 ± 67	275–506	378 ± 51†	255–469
Supine sleep, %	13	47 ± 31	11–100	45 ± 30	0.0–100	19	29 ± 20	6.2–79	34 ± 25†	3.2–100
Stage 1 sleep, %	19	26 ± 12	5.6–57	21 ± 7.2	5.0–32	19	32 ± 15	7.6–66	24 ± 9.9*	6.6–42
Stage 2 sleep, %	19	53 ± 11	25–67	53 ± 6.4	42–65	19	50 ± 14	22–80	47 ± 7.9	32–63
Slow-wave sleep, %	19	6.5 ± 5.2	0.0–19	8.7 ± 5.1	0.2–19	19	4.3 ± 3.8	0.0–12	11 ± 6.3*	0.0–21
Rapid eye movement sleep, %	19	15 ± 4.8	2.1–26	18 ± 6.6	0.0–25	19	14 ± 6.2	0.0–24	18 ± 6.5*†	1.4–30

*Significant long-term with the device compared to without it.

†Significant short-term without the device compared to long-term with it.

device and 3.0 events per hour and 1.4 events per hour, respectively, with the device.

The 14 patients who discontinued treatment or received complementary treatment did not differ from the 19 long-term treatment patients in terms of age, weight, respiratory, and sleep variables at the short-term follow-up visit without the device. The short-term apnea-hypopnea index with the device was higher in the 14 patients who discontinued treatment or received complementary treatment than in the 19 long-term treatment patients (Fig 2, 5).

Disease Severity in the Long-term Treatment Patients (n = 19)

The short-term apnea-hypopnea index without treatment was 24 ± 16 events per hour in the 19 long-term treatment patients and did not differ from the long-term apnea-hypopnea index without the device (22 ± 17 events per hour; Fig 4). The apnea-hypopnea index without the device at the short-term and long-term follow-up visits was also similar when the percentage of sleep in the supine position and changes in body weight were taken into consideration.

DISCUSSION

At the long-term follow-up visit, the apnea-hypopnea index was reduced from 22 ± 17 events per hour without the device to 4.9 ± 5.1 events per hour with the device in 19 patients with sleep apnea who received treatment with mandibular advancement devices for 5.2 ± 0.4 years. This result was similar to the findings at the short-term follow-up visit after 0.7 ± 0.5 years. Patients who had replaced or adjusted their devices during the study period experienced a better apnea reduction at the long-term follow-up visit than patients still using their original devices. Sleep-stage patterns were also similar at the

short-term follow-up visit and the long-term follow-up visit with the device.

Fourteen of the 17 patients (82%) with an apnea-hypopnea index of < 10 events per hour with the device who continued long-term treatment still had this result at the long-term follow-up visit (Fig 3). No patient had an apnea-hypopnea index of > 20 events per hour with the device at the long-term follow-up visit. Increased weight, snoring, or daytime sleepiness during the study period was unrelated to the long-term effects of the device among the present patients. Consequently, subjective reports of increased snoring and/or sleepiness are unreliable for the detection of increased apneas during long-term treatment.

All three patients with an apnea-hypopnea index of > 40 events per hour and a short-term satisfactory treatment result had a long-term apnea-hypopnea index of < 10 events per hour with the device in the present study. This finding is in contrast to reported results after uvulopalatopharyngoplasty, where none of seven patients with a pretreatment apnea-hypopnea index of > 40 events per hour experienced treatment success after 4 to 8 years.¹⁶ These results on the effect of uvulopalatopharyngoplasty are in agreement with the findings by Wilhelmsson et al,¹⁷ who found a higher success rate among patients treated with mandibular advancement devices than in patients treated with uvulopalatopharyngoplasty.

The reason for a better long-term apnea reduction in patients who had their devices replaced or adjusted during the study period is unknown. Changes in mandibular positioning or a change in dental occlusion during treatment did not explain this finding. It is possible that a well-fitted device is more important for an effective apnea reduction than the exact mandibular positioning in the device within a specific range. The results of the present study indicate that the life span of the mandibular ad-

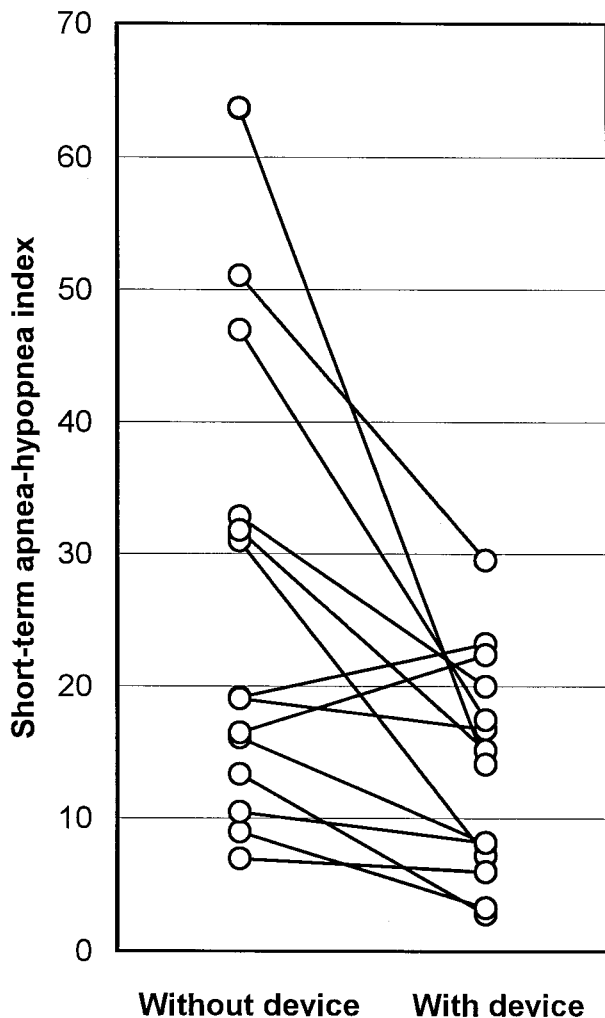


FIGURE 5. The apnea-hypopnea indexes (number of events per hour) with and without the mandibular advancement device at the short-term follow-up visit in the patients who discontinued treatment or received complementary treatment during the study period (n = 14).

vancement device is at least 4 to 5 years. It is important, however, to follow up the condition of the device.

It has been suggested that snoring and sleep apnea are progressive disorders.^{18,19} Svanborg and Larsson¹⁸ found that the mean oxygen desaturation index increased from 10 to 21 desaturations per hour of sleep during a minimum of 6 months without any treatment for snoring and sleep apnea. Pendlebury et al¹⁹ found that the mean apnea-hypopnea index increased from 22 to 33 events per hour over a mean period of 17 months. Neurogenic damage to upper-airway muscles²⁰ and to the soft palatal mucosa,²¹ and/or the formation of uvular edema,²² possibly caused by the vibration and stretching of the tissues from snoring and apneas, may explain the progressive nature of the disease. The severity of the disease

was unchanged in the present sample of patients during long-term treatment with mandibular advancement devices. It is hypothesized that treatment with a mandibular advancement device may prevent the progression of the disease by reducing snoring and sleep apnea.

Two patients in the present sample were treated with additional uvulopalatoplasty, but they continued to use their devices. Both patients had lower apnea-hypopnea indexes with their devices and without them at the long-term follow-up visit, compared with the results at the short-term follow-up visit. Millman et al²³ found that persistent sleep apnea after uvulopalatopharyngoplasty may be successfully treated with a mandibular advancement device. These findings suggest that at least some patients may benefit from a combination of a mandibular advancement device and surgery.

In conclusion, the long-term effect and the tolerability of a mandibular advancement device are good in patients who are recommended the treatment on the basis of a short-term sleep recording, provided that the device is continuously adjusted or replaced with a new one when needed. A short-term follow-up visit is valuable in the selection of patients who will benefit from long-term treatment with a mandibular advancement device.

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Marie Marklund, Carin Sahlin, Hans Stenlund, Maurits Persson and Karl A. Franklin

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