Two different degrees of mandibular advancement with a dental appliance in treatment of patients with mild to moderate obstructive sleep apnea

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The objective of this study was to evaluate the effect of 2 different degrees of mandibular advancement, 50% vs. 75% of maximum protrusive capacity, on somnographic variables after 1 year of dental appliance treatment in patients with mild to moderate obstructive sleep apnea (OSA). A further purpose was to compare the number of adverse events on the stomatognathic system. In a prospective study, 74 male patients were randomly allocated to receive a dental appliance with either 50% (38 patients) or 75% mandibular advancement (36 patients). After 1 year of treatment, 55 patients completed the follow-up. Somnography was performed to measure treatment effects before and 12 months post-treatment. The apnea, apnea/hypopnea, and oxygen desaturation indices decreased significantly in both groups after 1 year ($P < 0.001$); however, there were no differences between the groups. Normalization (apnea index <5 and apnea/hypopnea index <10) was observed in 79% in group 50 and in 73% in group 75. Few patients (<5%) reported symptoms from the stomatognathic system except for headache (> once a week), which was reported in one-third of the patients. Headache was significantly more infrequent after 1 year of treatment in both groups ($P < 0.001$). No serious complications were observed except for 2 patients who reported a painful condition from the temporomandibular joint in either group. In conclusion, mandibular advancement with a dental appliance effectively reduces the sleep-breathing disorder measured as frequency of apneas, and a pronounced mandibular advancement did not show a greater improvement of the medical problem compared to less advancement for patients with mild to moderate OSA. On the basis of few adverse events in the stomatognathic system or other complications we can recommend dental appliance treatment and, for patients with mild to moderate obstructive sleep apnea, not starting treatment by more than 50% mandibular advancement. ☐ *Oral appliance; randomized clinical trial; sleep apnea; somnography; treatment*

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Obstructive sleep apnea (OSA) is a syndrome characterized by repeated collapse of the upper airway during sleep, resulting in recurrent episodes of apneas. A dental appliance with a mandibular advancement is one of the current and successful treatment modalities used to improve this sleep-related breathing disorder (1–5). Different fixed degrees of mandibular advancement (50% or 75% of the patient's maximum protrusive capacity) have been used in previous studies (6, 7). Most dentists use a 1-piece appliance with a fixed degree of advancement because it is easier to use and cheaper to manufacture than adjustable appliances. In some studies, adjustable appliances have been used to ascertain patient comfort (8–10). Although some authors believe that adjustability and titration are essential for optimal patient management (11, 12), no clinical randomized, controlled study has confirmed the long-term superiority of adjustable appliances over non-adjustable appliances.

In one observational study the effect of different degrees of advancement was assessed among patients with moderate OSA (13). Advancement of the mandible produced a dose-dependent closing pressure reduction of the pharynx and concomitant reduction of nocturnal desaturations. However, no randomized study comparing 2 different degrees of mandibular advancement in the treatment of patients with mild to moderate OSA has been undertaken.

The primary aim of this study was to compare the effect of 2 different degrees of mandibular advancement (75% vs. 50% of the maximum protrusive capacity) on somnographic variables after 1 year of dental appliance treatment in patients with mild to moderate OSA. A secondary aim was to compare the number of adverse events on the stomatognathic system.

Patients and methods

Definitions

Apnea was defined as cessation of respiratory airflow for 10 s or longer, as measured by a thermistor. Hypopnea occurred when there was a 50% reduction of the airflow signal recorded by a thermistor combined with a decrease in hemoglobin oxygen saturation of at least 4%. The apnea index (AI) was defined as the average number of

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apnea episodes per hour of sleep; AHI was defined as the average number of apneas and hypopneas per hour of sleep. The oxygen desaturation index (ODI) was defined as the average number of episodes of oxygen desaturation of at least 4% per hour of sleep.

The diagnosis OSA was defined as AI $\geq$5 or AHI $\geq$10 in accordance with the guidelines established by the Swedish Medical Research Council in 1994 (14). The success rate was defined as the percentage of patients with a decrease in AI or AHI of at least 50%. Normalization was defined as AI <5 and AHI <10.

Patients

The study population comprised 74 patients referred for treatment by the ENT Department to the Department of Stomatognathic Physiology, Central Hospital, Västerås, Sweden. The inclusion criteria were: individuals with confirmed mild to moderate sleep apnoea (OSA), AI $\geq$5 but $\leq$25, sufficient dental support to anchor the dental appliance, i.e. at least 1 premolar or molar tooth in both the upper and lower jaws and on both right and left sides, and no severe cariogenic and/or a periodontally compromised dentition. The exclusion criteria were: individuals aged <20 and >65 years, severe cardiovascular, neurological or respiratory disease, significant nasal obstruction, overbite of anterior teeth >6 mm, formerly not treated for OSA by continuous positive airway pressure (CPAP) or by the surgical intervention uvulopalatopharyngoplasty (UPPP), and active temporomandibular joint (TMJ) pain or obvious myalgia in jaw muscles. The patients who fullfilled the inclusion criteria were randomized to treatment with a dental appliance with either a mandibular advancement of 50% (group 50) or 75% (group 75) of the patients' maximum mandibular protrusive capacity. Randomization in blocks of 4 patients was performed using a closed-envelope system where the envelopes were drawn in sequential order.

Trial design

Of the 74 patients, 38 were randomly assigned to group 50 and 36 to group 75 (Fig. 1). Nine patients in group 50 withdrew before the 1-year follow-up for the following reasons: 1 died, 3 cooperated badly, 3 could not tolerate the dental appliance, and 2 had other dental treatments over long periods and did not use the appliance. Ten patients in group 75 withdrew before the 1-year follow-up for the following reasons: 1 died, 3 cooperated badly, 1 for other medical reasons, 1 could not tolerate the dental appliance, 2 had other dental treatment over long periods and could not use their appliance, and 2 had TMJ pain on movements of the mandible.

The ethics committee of Uppsala University approved the study design and the participants gave their informed consent. The results are presented in accordance with the intention-to-treat (ITT) principle, i.e. the patients were included in the analysis to the group they were randomized into.

Methods

Treatment extended over a 1-year period. The sleep studies were performed in the home of the patients using a portable unit (15). The following 5 variables were recorded simultaneously: hemoglobin oxygen saturation using pulse oximetry with a finger probe, flow through the nose and mouth using a thermistor, respiratory movements by impedance measurements between one electrode placed on each side of the chest, body position with a sensor on the chest, and snoring sounds using a sound level meter. These data were stored in a digital recording unit (SAMBA, Electronico AB, Västerås, Sweden) and transferred to a personal computer for subsequent data analysis. The technicians who performed all the analyses were blinded regarding treatment group. Sleep studies lasting less than 4 h were not accepted: in such cases, a second recording was made.

Each patient was assessed on 3 occasions with somnographic registrations, the first one at baseline, the second at the 6 months follow-up, and the third after 1 year of treatment.

Dental appliance treatment

Clinical examination of the stomatognathic system was performed at baseline and at the 1-year follow-up. This examination included measurements of mandibular range of motion, overbite, overjet, palpation of the TMJ and masticatory muscles, registration of pain on mobility and TMJ sounds. The mandibular range of motion was measured with a steel ruler to the nearest millimeter. Intermaxillar tooth contacts were registered in intercuspidation with the aid of occlusal foil (GHM, occlusal foil). The contacts were quantified in the Eichner index of occlusal support zones measured as the number of zones (0–4), i.e. occlusal contacts in the premolar and molar zones on right and left side (16). All except 4 patients had dental support in all 4 possible support zones. Three patients had support in 3 zones and 1 patient had support in 2 zones. Technical failures in the dental appliances were registered at follow-up.

At baseline and at the 1-year follow-up each patient was given a questionnaire with questions about: headache frequency (once a month, 1–2 times monthly, once a week, several times/week or daily), presence of tiredness/stiffness in the masticatory muscles, TMJ sounds, TMJ pain, TMJ locking and pain on mandibular movements. At the follow-up, questions were asked about the compliance of using the dental appliance, effects on daytime sleepiness, snoring, and experience of apnoeas.

All patients in the present study were treated by 2 dentists with long experience in dental appliance treatment, and 1 dental technician was responsible for manufacturing all the appliances used. The appliances were

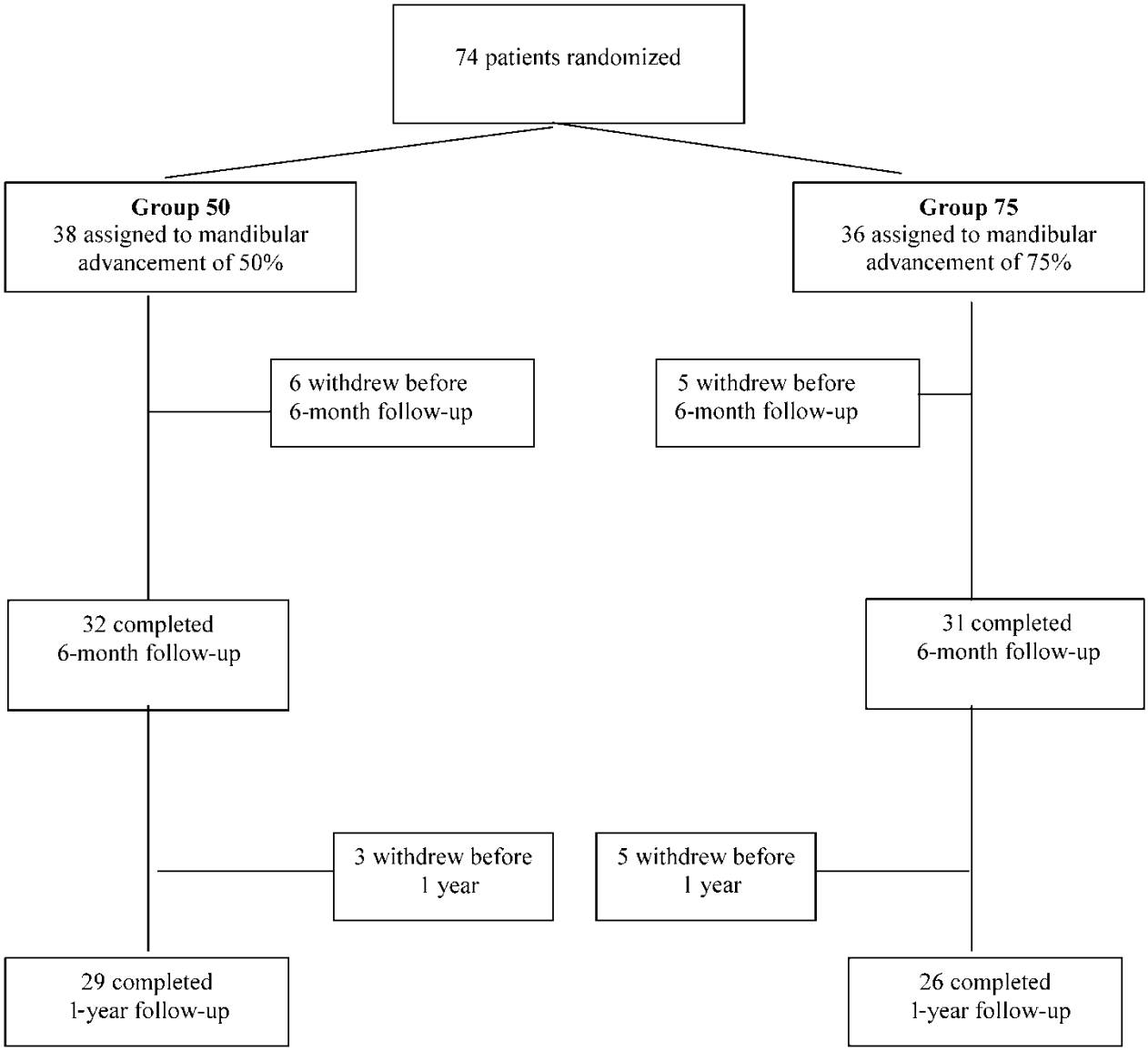

Fig. 1. Trial profile.

manufactured in one-piece heat-cured acrylic polymer (Fig. 4a, b). The appliances advanced the mandible from a position of intercuspidation. The construction of the appliances meant that the vertical distance between the upper and lower teeth was 2 mm. Labial and lingual to the mandibular front teeth, bars linked the acrylic parts of the construction on each side in the premolar-molar areas. Adam's clasps mostly retained on the first molars in each jaw were used as an extra attachment and to make individual adjustment possible.

Subjective evaluation of the treatment effect

The patients answered 2 questions about changes in experience of daytime sleepiness and inconvenience associated with apnoea and snoring after treatment. Each question was rated on a 7-point scale with the anchor definitions 1 = a large decrease in the degree of symptom severity and 7 = a large increase in the degree of symptom severity.

Statistics

Numerical results are expressed as means and 95% confidence intervals (CI). Differences in somnographic variables, BMI, mandibular mobility, and age between the 2 groups at baseline and over time were tested using Student's *t* test. The chi-square test was used to compare

Table 1. Comparison of values at baseline and after 1 year for somnographic variables and mouth opening, protrusion capacity, and overbite between individuals in the 2 treatment groups who completed the follow-up

	Group 50 ($n = 29$)		Baseline—1 year *P*-value	Group 75 ($n = 26$)		Baseline—1 year *P*-value	Difference between the 2 groups at 1 year *P*-value
	Baseline	After 1 year		Baseline	After 1 year		
AI	8.9 (±1.8)	2.0 (±1.4)	<0.001	10.5 (±1.8)	2.7 (±1.2)	<0.001	ns
AHI	16.2 (±2.9)	6.0 (±3.7)	<0.001	18.9 (±4.7)	6.3 (±2.0)	<0.001	ns
ODI	17.0 (±4.2)	7.3 (±4.0)	<0.001	20.5 (±6.2)	8.0 (±2.9)	<0.001	ns
Mouth opening capacity (mm)	48.1 (±2.7)	49.4 (±2.8)	<0.05	46.6 (±2.5)	48.4 (±2.4)	<0.05	ns
Protrusion capacity (mm)	9.2 (±0.6)	9.6 (±0.6)	ns	8.3 (±0.5)	8.8 (±0.6)	<0.01	<0.05
Overbite (mm)	2.5 (±0.5)	2.4 (±0.6)	ns	2.9 (±0.7)	3.0 (±0.8)	ns	ns

Data are presented as mean value and confidence interval (±95%).
AI = apnea index; AHI = apnea/hypopnea index; ODI = oxygen saturation index.

differences in success and normalization rates between the 2 groups. Statistical significance was accepted at $P < 0.05$.

Results

Mean age (95% CI) for group 50 was 51.8 years (49.0–54.6), and for group 75 mean age was 54.4 years (52.4–56.4). The mean value (95% CI) for BMI was 27.4 (26.4–28.4) in group 50 and 27.9 (26.6–29.3) in group 75 before intervention. Obesity, i.e. a BMI ≥30, was observed in 30% of the patients. Mandibular advancement in group 50 was mean 4.5 mm (s (standard deviation) ±0.93), while in group 75 mean was 6.4 mm ($s \pm 1.16$). The patients in both groups have used their dental appliance on average 6.7 nights/week (median 7.0; range 5–7). All except 1 patient used their dental appliance regularly, i.e. ≥5 nights/week. The patients evaluated use of their appliance as very good in 66% in group 50 and in 75% in group 75. Compliance at the 1-year follow-up was 76% in group 50 and 72% in group 75.

Treatment effect on somnographic variables

After 1 year of treatment, the mean AI, AHI, and ODI values had decreased significantly compared to the pretreatment values in both groups ($P < 0.001$) (Table 1). No significant difference was observed between either group for any of the somnographic variables. The individual values of AI before intervention, at the 6-month follow-up, and at the 1-year follow-up are shown in Figs 2 and 3. Efficacy in terms of success rate (50% reduction of the initial AHI) and normalization rate (i.e. AI <5 and AHI <10) after 1 year of treatment did not differ between either group (Table 2).

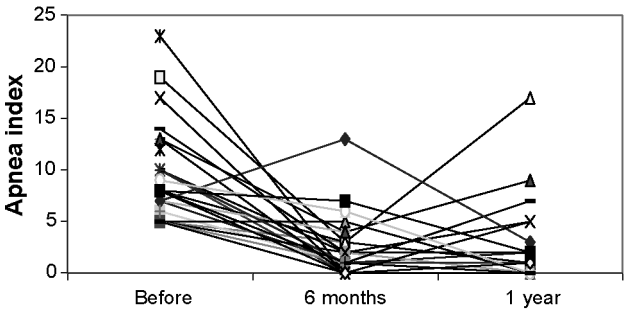

Fig. 2. Individual AI values ($n = 38$) in group 50 before intervention (median 8.0), at the 6-month follow-up (median 1.0), and at the 1-year follow-up (median 1.0).

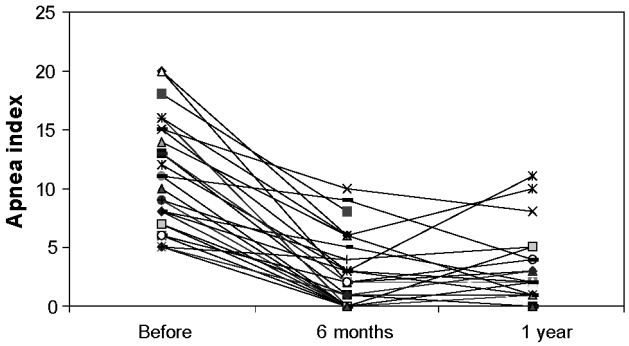

Fig. 3. Individual AI values ($n = 36$) in group 75 before intervention (median 9.5), at the 6-month follow-up (median 2.0) and 1-year follow-up (median 2.0).

Subjective evaluation of the treatment effect

Eighty-two percent of patients in group 50 and 84% in group 75 reported a decrease in daytime sleepiness. No

Table 2. Success and normalization rates at the 1-year follow-up in the 2 treatment groups

	Group 50 $n = 29$	Group 75 $n = 26$	Difference between groups, *P*-value
Success rate (≥50% reduction)			
AI	86%	77%	ns
AHI	79%	62%	ns
Normalization (AI <5 and AHI <10)	79%	73%	ns

AI = apnea index; AHI = apnea/hypopnea index.

Table 3. Number of patients with reported symptoms from the stomatognathic system at baseline and 1-year follow-up in the 2 treatment groups

	Group 50		Group 75	
	Baseline $n = 29$	After 1 year $n = 29$	Baseline $n = 24$	After 1 year $n = 24$
Tiredness/stiffness on jaw function	3	4	3	1
TMJ pain	2	2	0	1
TMJ sound	2	2	4	2
TMJ locking	1	1	0	1
Headache, Once a week or more often	6	1	12	3

difference in daytime sleepiness was reported by 11% in group 50 and by 17% in group 75. Problems with apnoeas and snoring in groups 50 and 75 decreased by 87% and 79%, respectively. None of the patients reported increased problems with daytime sleepiness, apnoeas, or snoring at follow-up.

Adverse events on the stomatognathic system

Mandibular movements such as mouth opening capacity changed significantly for both groups and the protrusion capacity changed significantly for group 75 (Table 1). None of the patients in either group observed any changes in tooth contacts at intercuspidation after treatment. There were few patients who reported symptoms from the stomatognathic system (Table 3).

Headache with a frequency at least once a week was the most commonly reported symptom before intervention. This symptom was significantly reduced after 1 year of treatment in both groups.

Technical failures of the dental appliance

No damage was found in the acrylic parts of the construction or of the linking metal bars at the 1-year follow-up. Only Adam's clasps, the weakest part of the construction, were broken in 6 dental appliances (4 dental appliances in group 50 and 2 in group 75) during the treatment period.

Discussion

The results of this study show that mandibular advancement with a dental appliance reduces the sleep-breathing disorder measured as frequency of apneas. The treatment effect with less mandibular advancement was similar to a more pronounced degree of advancement in terms of normalization rate for patients with mild and moderate OSA. The degree of mandibular advancement in the proportion of an individual's capacity is not always expressed when evaluating treatment effect with a dental appliance, which may be of importance in the treatment outcome. Kato et al. (13) have shown that different degrees of mandibular advancement in the same patient gave an improvement of 20% in reduced number of nocturnal desaturations for each 2 mm advancement and the therapeutic effect appears to be >4 mm advancement. Corresponding results were found by Marklund et al., who reported a higher success rate in patients with a more pronounced mandibular advancement, i.e. >5 mm (1). However, the question remains at what level most of the patients will respond and have treatment effects on their sleep-breathing disorder. One aim of the present study was therefore to evaluate whether there are differences in treatment effects with 2 different standardized degrees of mandibular advancement in the dental appliances.

The fact that our study included 26% dropouts strongly suggests that not everyone is comfortable with an intraoral appliance, and so this kind of treatment is not a panacea for all patients with OSA. In this study there were no differences in numbers of dropouts between the groups,

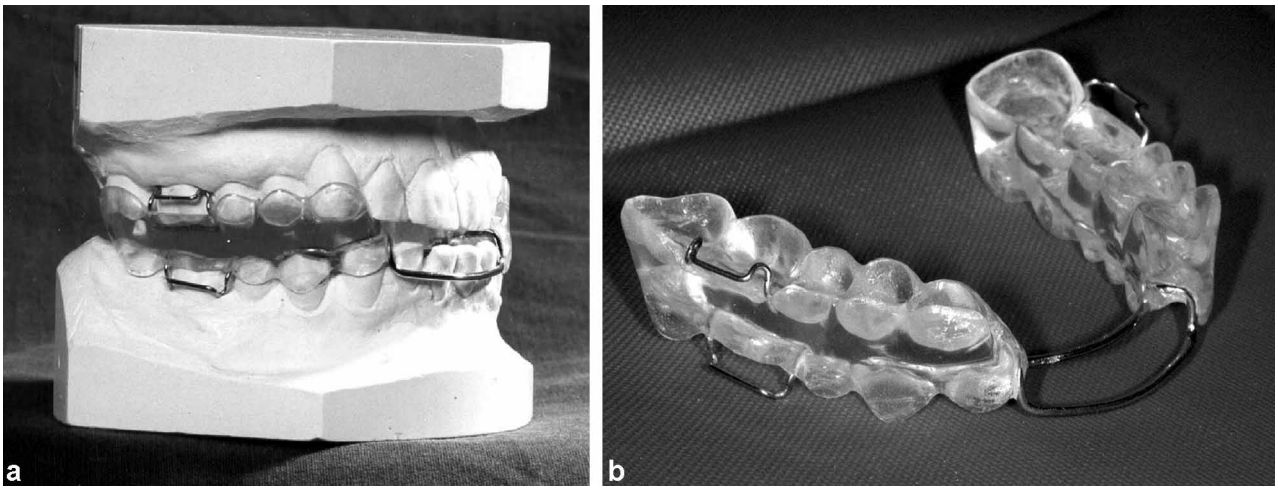

Fig. 4. a, b The dental appliances used in this study were manufactured in one-piece heat-cured acrylic polymer

which indicates that difference in advancement degree was not a main reason for the dropout. Compliance in using the dental appliances in this study was 74%, which is comparable with other studies with similar follow-up time. However, there is a wide variation in results, which could be because of differences in study design, study population, evaluation form, and observation time (4, 17). The majority of the patients used the dental appliance regularly, which demonstrates that acceptance of the appliance was good. However, one critical point of successful treatment is compliance with the treatment, as the appliance needs to be used regularly. This was obvious in a study by Tegelberg et al. (7), where pathological somnographic values recurred in 74% of patients between one night registered with an appliance inserted and the next night without. No washout period was used between the 2 registrations.

Regular use was frequent among those who continued the treatment to the 1-year follow-up, probably due to a subjective well-being, including less daytime sleepiness. The explanations among the patients who discontinued the treatment are not fully clarified.

Most of the reported side effects were minor and did not differ between the groups and might not have a great influence on compliance. These findings are comparable to other studies (4, 7, 18, 19). A positive effect of treatment with dental appliance was the reduction of headache frequency reported in the study. Headache is one consequence of untreated sleep-disordered breathing (20), and the reduction of headache frequency was probably by improved oxygen saturation when breathing was normalized. The finding of a dramatic decrease in headache frequency at follow-up might also be an important factor for the positive outcome of the patient's experience of treatment with the dental appliance.

In the group with more marked mandibular advancement, symptoms from the stomatognathic system were not more frequent, which indicates that the masticatory muscles and TMJ function could be normalized after a night's provocation with a dental appliance. Perhaps the overall effect on better sleep quality has an overshadowing effect on the side effects.

The dental appliances were designed to position the mandible forward and thereby activate the tongue and related muscles. It has been suggested that forward displacement of the mandible moves the tongue away from the posterior wall of the pharynx and that inferior displacement of the mandible moves the tongue away from the soft palate. These displacements are assumed to enlarge the cross-sectional area of the oropharynx (21–24). However, Eveloff et al. 1994 (18) suggested that the mechanism of treatment is more complex than a simple increase in airway caliber by advancement of the mandible and tongue. Other influencing factors on treatment are the vertical opening between the front teeth in addition to the degree of protrusion. Increased vertical opening reduces the pharyngeal airway lumen (24). In this study the vertical opening between the front teeth was small when using the dental appliance in order to prevent a posterior rotation of the mandible.

Short-term efficacy with a dental appliance in this study is similar to that found in other studies (1, 2, 8, 12). Nowadays, data on long-term compliance are available showing a decrease in efficacy over time (4, 5). Without adjustments of the degree of mandibular advancement, the treatment effect may reduce over time, which indicates the need for check-ups on a regular basis, especially as the treatment is a lifelong process.

The results of this study indicate that there may be complaints regarding to the masticatory muscles and the TMJs even when the mandible is advanced moderately. However, such effects occurred more often when the mandible was advanced more than half of the individual's protrusive capacity using a Herbst appliance (25). However, the side effects are still infrequent with both the degrees of mandibular advancement in our study.

The construction of the dental appliance used in this study had few components and was anchored to the teeth. The frequency of technical failures was less than 5%, a result comparable with 2 other studies using a monobloc technique (4, 7) and those of an adjustable construction such as the Herbst mandibular advancement appliance (25).

Finally, OSA is a potentially life-threatening syndrome in the sense that its severity may increase over time to become a potentially serious medical condition (26). Treatment of OSA with a dental appliance should be performed in collaboration with a medical doctor with a special interest in sleep apnea and supplemented with both a short- and long-term follow-up using somnography to evaluate the treatment effect over time.

In conclusion, mandibular advancement with a dental appliance effectively reduces the sleep-breathing disorder measured as frequency of apneas, and a pronounced mandibular advancement did not show a greater improvement of the medical problem compared to less advancement for patients with mild to moderate OSA. Together with few adverse events in the stomatognathic system or other complications we can recommend dental appliance treatment and there is no use starting treatment by more than 50% mandibular advancement for patients with mild to moderate obstructive sleep apnea.

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