4-Year Follow-up of Treatment With Dental Appliance or Uvulopalatopharyngoplasty in Patients With Obstructive Sleep Apnea*

A Randomized Study

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Study objectives: **To evaluate the effects of treatment with a dental appliance or uvulopalatopharyngoplasty (UPPP) on somnographic variables in patients with mild-to-moderate obstructive sleep apnea (OSA) followed up for 4 years, and compliance and complementary treatment.**
Design: **Randomized study.**
Setting: **Central Hospital, Västerås, Uppsala University, Sweden.**
Patients: **Ninety-five male patients with confirmed mild-to-moderate OSA (apnea index [AI] > 5 and < 25) were randomized to treatment with a dental appliance or UPPP. Sleep studies were performed before and 1 year and 4 years after intervention. Thirty-two patients in the dental-appliance group and 40 patients in the UPPP group completed the 4-year follow-up.**
Results: **The success rate (percentage of patients with at least 50% reduction in AI) in the dental-appliance group was 81%, which was significantly higher than in the UPPP group, 53% ($p < 0.05$). Normalization (AI < 5 or apnea/hypopnea index < 10) was observed in 63% of the dental-appliance group and 33% of the UPPP group after 4 years. The difference between the groups was significant ($p < 0.05$). The compliance to use of the dental appliance was 62% at the 4-year follow-up. Thirty patients (75%) in the UPPP group continued without complementary treatment. The dental appliances had few adverse effects on the stomatognathic system, and the number of adjustments and repairs of the appliances over time was moderate. Pronounced complaints of nasopharyngeal regurgitation of fluid and difficulty with swallowing after UPPP were reported by 8% and 10%, respectively.**
Conclusions: **The dental-appliance group showed significantly higher success and normalization rates regarding the somnographic variables compared to the UPPP group, but the effectiveness of the dental appliance was partly invalidated by the compliance of 62% at the 4-year follow-up. However, the appliances had few adverse effects on the stomatognathic system and required only moderate adjustments. Use of a dental appliance with regular follow-up can be recommended for long-term treatment of OSA.** ***(CHEST 2002; 121:739–746)***

Key words: dental appliance; 4-year follow-up; obstructive sleep apnea; randomized controlled trial; randomized study; somnography; uvulopalatopharyngoplasty

Abbreviations: AHI = apnea/hypopnea index; AI = apnea index; BMI = body mass index; CPAP = continuous positive airway pressure; CI = confidence interval; ODI = oxygen desaturation index; OSA = obstructive sleep apnea; SI = snoring index; TMJ = temporomandibular joint; UPPP = uvulopalatopharyngoplasty

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Obstructive sleep apnea (OSA) is a common syndrome that affects 1 to 4% of middle-aged men, and the prevalence increases with age up to 60 years.[1–3] The most frequent symptoms in patients with OSA are snoring, excessive daytime sleepiness, and affection of cognitive performance.[4,5]

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In a large epidemiologic study,[6] a significant increase in both overall and cardiovascular mortality was found among men with both snoring and excessive daytime sleepiness. Furthermore, patients with OSA and coronary artery disease have an increased risk of cardiovascular mortality compared to coronary artery disease patients without OSA.[7] A higher-mortality rate has been found in patients with severe OSA than in those with mild-to-moderate OSA.[8] OSA has been shown to be a progressive disease; therefore, mild-to-moderate OSA may become severe over time.[9] Treatment may therefore be indicated not only to alleviate the symptoms but also to decrease the risk of mortality, an effect that has been reported from a limited number of studies.[10,11]

Uvulopalatopharyngoplasty (UPPP) is the main surgical treatment in patients with mild-to-moderate OSA. However, long-term studies after UPPP have shown a decreasing success rate over time in terms of somnographic variables,[12–15] and late postoperative complications may also occur, such as nasopharyngeal regurgitation of fluid and difficulties with swallowing.[16–18] In recent years, treatment of OSA with mandibular advancement devices has gained increased attention and acceptance. There have been no follow-up studies $>$ 1 year, only a few short-term studies,[19–24] all of which have shown positive effects of treatment of OSA on somnographic variables. Nor have there been any investigations of compliance over a period $>$ 1 year or of adverse effects $>$ 2 years in patients using a dental appliance with mandibular advancement by 50% of the patient's maximum protrusive capacity.[25,26]

The primary aim of this study was to evaluate the effects of treatment with a dental appliance or UPPP on somnographic variables over a period of 4 years in patients with mild-to-moderate OSA, and compliance and complementary treatment. The secondary aims were to determine the occurrence of adverse effects of treatment with a dental appliance or UPPP, and of technical failures of the dental appliance.

Materials and Methods

Definitions

Apnea was defined as cessation of respiratory air flow for a minimum of 10 s as measured by a thermistor. Hypopnea was considered to be present when there was a 50% reduction of the air-flow 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 apneas per hour of sleep, and the apnea/hypopnea index (AHI) was defined as the average number of apneas plus 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%/h of sleep. Snoring was recorded with a sound-level meter placed on a table close to the patient's head. The snoring index (SI) was defined as the registered duration of snoring per hour of sleep.

The diagnosis of OSA was defined as an AI $\geq$ 5 or AHI $\geq$ 10 in accordance with the guidelines established by the Swedish Medical Research Council in 1994.[27] The success rate was defined as the percentage of patients with a decrease in AI or AHI of at least 50%.

Trial Design

All patients in the catchment area of 260,000 people (the county of Västmanland) with suspected OSA were referred to the sleep laboratory at the Central Hospital, Västerås. The standard of practice was to refer patients with mild-to-moderate OSA to UPPP or dental-appliance treatment and patients with severe OSA to continuous positive airway pressure (CPAP).

Ninety-five male patients fulfilling the inclusion criteria, confirmed mild-to-moderate OSA (AI $>$ 5, AI $<$ 25), and not the exclusion criteria were randomly assigned to either treatment with a dental appliance or UPPP. Exclusion criteria were individuals $<$ 20 years and $>$ 65 years old, AI $>$ 25, mental illness, drug abuse, significant nasal obstruction, insufficient number of teeth to anchor an appliance, pronounced dental malocclusion, severe cardiovascular, and neurologic and respiratory disease.

Four patients in the dental-appliance group and three patients in the UPPP group withdrew after randomization but before treatment. In the dental-appliance group, three patients reversed their decision to participate; in one patient, the dental appliance could not be anchored properly. In the UPPP group, two patients reversed their decision to participate; in one patient, gastric cancer was diagnosed. Eighty-eight patients were eligible for treatment with the dental appliance (n = 45) or UPPP (n = 43; Fig 1).

The results are presented according to the intention-to-treat principle, *ie*, all randomized and treated patients who attended the 1-year and 4-year follow-ups were included in the analysis in the group they belonged to. The study protocol and informed consent form were approved by the ethics committee of Uppsala University, Sweden.

Somnography

The sleep studies were performed before treatment and 1 year and 4 years after intervention. They were carried out in the patient's home with a portable unit. The following five variables were recorded simultaneously: arterial oxygen saturation, by pulse oximetry with a finger probe; flow through the nose and mouth, by 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 were transferred to a personal computer for subsequent data analysis. One technician, who was blinded regarding treatment group, performed all the analyses. Sleep studies lasting $<$ 4 h were not accepted; in such cases, a second recording was made.

Dental-Appliance Treatment

Before the intervention, a clinical examination of the stomatognathic system, including measurement of the mandibular mobility, palpation of the temporomandibular joints (TMJs), and masticatory muscles, and recording of pain on mobility, was performed. In the present study, the same dentist treated all

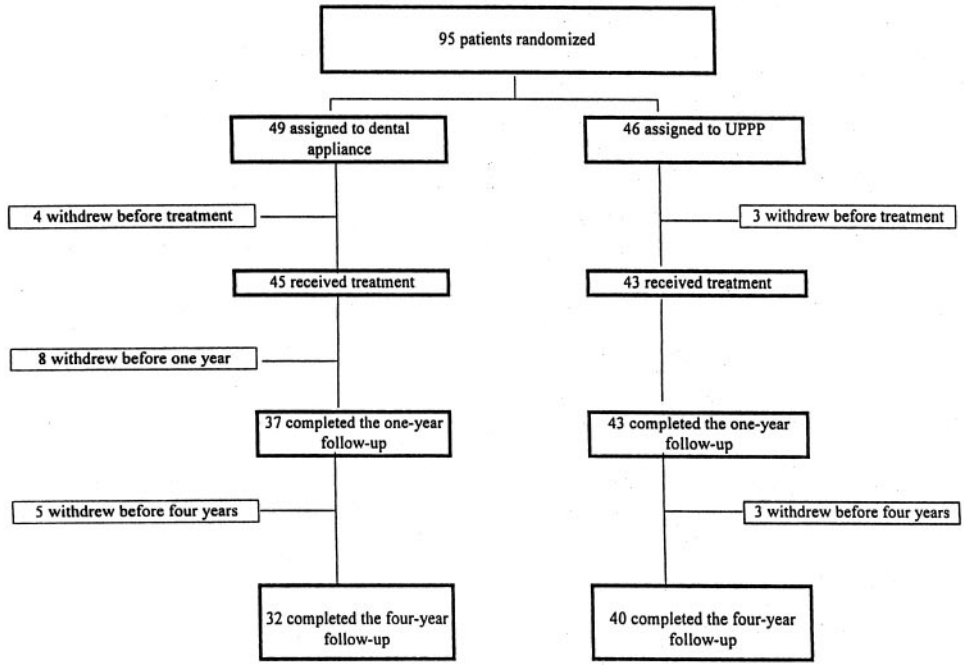

FIGURE 1. Trial profile.

patients and one dental technician was responsible for the manufacturing of all the appliances. The one-piece, individually designed dental appliance was made of acrylic polymer, and advanced the mandible by 50% of the patient's maximum protrusive capacity as measured from a position of intercuspidation, *ie*, 4 to 6 mm (Fig 2). The construction of the appliance meant that the vertical distance between the upper and lower teeth increased by a mean of 5 mm. The Eichner index was used as an indicator of occlusal stability between the maxilla and the mandible.[28] Follow-up visits, with a clinical examination of the stomatognathic system and a questionnaire about compliance to use of the dental appliance, were made at 2 weeks, and 3, 6, 12, and 48 months following intervention. At these visits, adjustment of the acrylic part or the clasps could be done. No change of the mandibular advancement degree of the dental appliance was done during the treatment period. More detailed information on the results of the clinical examination after 1 year of follow-up has been given previously.[25]

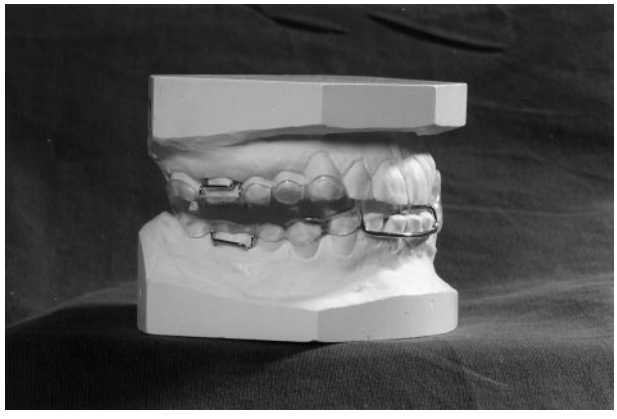

FIGURE 2. The dental appliance used in this study.

Surgical Treatment

All UPPP procedures were performed under general anesthesia by the same ear, nose, and throat surgeon, using a standardized procedure described by Fujita et al.[29] The procedure involved tonsillectomy and resection of excess fat and mucosa in the soft palate, including the uvula. The palpable musculature was saved, and several sutures approximated the anterior and posterior tonsillar pillars.

The patients were followed up for 1 year and 4 years after the operation, with a clinical examination of the palatopharyngeal system. At the 4-year follow-up, each patient was questioned about any nasopharyngeal regurgitation of fluid and difficulties in swallowing.

Statistical Analysis

All numerical results are expressed as means and 95% confidence intervals (CIs). Differences in somnographic variables, age, and body mass index (BMI) between the groups and over time were tested by Student's t test. A nonparametric test (χ^2) was used to calculate differences in smoking, success, and normalization rates between the two groups.

RESULTS

The mean length of follow-up time measured from the time of randomization was 4.1 years (range, 3.8 to 5.4 years). The baseline values, previously pub-

lished,[23] did not differ significantly between the groups in any of the recorded somnographic variables or in age or BMI.

BMI did not differ between the dental-appliance and UPPP groups at the 1-year and 4-year follow-ups (1-year follow-up, $p = 0.223$; 4-year follow-up, $p = 0.278$). There was a significant change in BMI during the course of the study in both groups, although the absolute increases were small (dental appliance, $p < 0.01$; UPPP, $p < 0.05$). The 32 dental-appliance patients who completed the 4-year follow-up had a mean BMI at baseline of 25.9 (95% CI, 24.9 to 27.0), after 1 year of 26.2 (95% CI, 25.0 to 27.4), and after 4 years of 26.7 (95% CI, 25.4 to 27.9). The corresponding BMI values for the 40 UPPP patients who completed the 4-year follow-up were 27.0 at baseline (95% CI, 26.1 to 27.9), 27.1 at 1 year (95% CI, 26.2 to 27.9) and 27.5 at 4 years (95% CI, 26.5 to 28.5). There was no significant correlation between changes in BMI and AHI from baseline to the 4-year follow-up within the dental-appliance and the UPPP groups.

The smoking habits did not differ between the two groups at the 4-year follow-up; the proportion of smokers was 25% both in the dental-appliance group (8 of 32 patients) and in the UPPP group (10 of 40 patients). Fifty percent of the smokers in each group smoked > 10 cigarettes a day.

Compliance in the Dental Appliance Group

Compliance at the 1-Year Follow-up: Thirty-seven of the treated patients completed and were still using the dental appliance at the 1-year follow-up, *ie*, the compliance after 1 year was 82% (Fig 1). Eight patients withdrew for the following reasons: epilepsy (one patient), maxillofacial cancer (one patient), and recurrent aphthous ulcer due to an allergic reaction to acrylic polymer (one patient); two patients were not comfortable with the dental appliance, and three patients did not improve.

Compliance at the 4-Year Follow-up: Of the 37 patients who completed the 1-year follow-up, 5 patients withdrew between the 1-year and 4-year follow-up studies. The reasons for withdrawal were as follows: two patients were not comfortable with the dental appliance, two patients moved from the catchment area (of whom one was still using the appliance), and one patient did not improve. Altogether, there were 13 patients who dropped out, 9 of whom had treatment failures over the 4-year follow-up.

Thirty-two patients completed the 4-year follow-up. Of these 32 patients, 4 patients chose the UPPP treatment instead and 1 patient had chose no therapy. One of the five patients who dropped out had treatment failure. Twenty-seven patients were followed up with somnography after 4 years.

Twenty-eight patients (including 1 patient unavailable for somnographic follow-up) continued to use the dental appliance without any complementary treatment, *ie*, the compliance after 4 years was 62%. Twenty-one patients (78%) used the appliance regularly without any long breaks. Six patients stopped using the appliance for a period of at least 2 months during the 4-year period, for the following reasons: no improvement with the treatment; a long, severe cold; the appliance was broken; or the appliance did not fit after dental treatment. The patients used their appliance on average 6.1 nights per week (median, 7.0 nights). Two patients reported low regular use (≤ 3 nights per week). One of them had nasal surgery and was not convinced about the benefit of using the dental appliance after this operation; in the other patient, the dental appliance did not fit after other dental treatment. When the 27 patients (who were followed up with somnography) were asked how they experienced using the appliance during the night, 23 patients (85%) answered that they were very satisfied and 4 patients stated that the experience was neither good nor bad.

Complementary Treatment in the UPPP Group

Forty-three patients (94%) completed the 1-year follow-up without any complementary treatment (Fig 1). Of the 43 patients who completed the 1-year follow-up, 3 patients did not attend the 4-year follow-up. One of these patients died of a non-apnea-related cause, and two patients withdrew for medical reasons other than OSA.

Of the 40 patients who completed the 4-year follow-up, 10 patients received a dental appliance between the 1-year and 4-year follow-ups because of failure of UPPP treatment (*ie*, somnographic variables not normalized). These patients underwent sleep studies with and without the dental appliance. At the 4-year follow-up with the dental appliance, 6 of these 10 patients showed positive treatment results. Thirty patients (75%) were satisfied with the UPPP and continued without any complementary treatment.

Effects on Somnographic Variables

Follow-up After 4 Years: In both groups AI, AHI, ODI, and SI were significantly lower at the 4-year follow-up than at baseline (Table 1). AI, AHI, and ODI, but not SI, increased significantly between 1 year and 4 years in both groups (Table 2).

After 4 years, there were significant differences in

Table 1—*Comparison Between the Baseline Values for the Somnographic Variables and the Values After 4 Years of Follow-up in the Dental-Appliance and UPPP Groups

Variables	Dental Appliance (n = 32)		Difference Baseline to 4 yr p Value	UPPP (n = 40)		Difference Baseline to 4 yr p Value	Difference Between the Two Groups at 4 yr p Value
	Before	4 yr		Before	4 yr		
AI	10.5 (1.7)	3.2 (1.6)	< 0.001	12.1 (1.6)	6.8 (2.2)	< 0.001	< 0.01
AHI	17.9 (2.9)	7.2 (2.6)	< 0.001	19.9 (3.0)	14.2 (3.4)	< 0.01	< 0.001
ODI	16.5 (3.3)	6.7 (2.5)	< 0.001	17.9 (3.5)	13.1 (3.5)	< 0.01	< 0.01
SI	0.7 (0.1)	0.5 (0.1)	< 0.01	0.7 (0.1)	0.5 (0.1)	< 0.001	NS

*Data are presented as mean value (± 95% CI). NS = not significant.

AI, AHI, and ODI between the two groups, to the advantage of the dental-appliance group. The individual AI values in the dental-appliance and UPPP groups before intervention and at the 1-year and 4-year follow-ups are shown in Figures 3, 4.

Success Rate: Between 1 year and 4 years of follow-up, the only significant decrease was the success rate for AHI in the UPPP group ($p < 0.05$). The success rate regarding AI in the dental-appliance group at the 4-year follow-up was 81%, which was significantly higher than that in the UPPP group, 53%. The corresponding data for AHI were 72% and 35%, respectively, a difference that was also significant (Table 3).

Normalization: According to the criteria for OSA (AI ≥ 5 or AHI ≥ 10), 63% of the patients in the dental-appliance group attained normalization after 4 years, a proportion that was significantly higher than that among the patients in the UPPP group, 33%. The number of patients showing normalization did not differ significantly between the 1-year and 4-year follow-ups in either group (Table 3).

Twenty-eight of the patients in the dental-appliance group and 30 patients in the UPPP group continued with the original treatment. Analysis according to the per-protocol principle yielded the same results as the analysis according to the intention-to-treat principle, except that there was no significant difference in success rate in AHI between the 1-year and 4-year follow-ups in the UPPP group, and no significant difference in AI between the dental-appliance and UPPP groups at the 4-year follow-up.

Effects and Adverse Events of the Dental Appliance on the Stomatognathic System

The maximum mouth-opening capacity did not change significantly over the 4-year period. The mean value before treatment was 51.2 mm and after 4 years was 52.6 mm.

The mean maximum protrusive capacity was the same, 9.7 mm, at the 4-year follow-up as before treatment. No patient changed their protrusive capacity > 2 mm.

Before treatment, all patients had sufficient dental support in the four possible support zones. During treatment, three patients lost two to three teeth in the support zones but had dental support in three zones. These patients used their appliance regularly, *ie*, > 5 nights per week; in all of them, the somnographic values became normalized.

Twenty-two patients did not notice any changes in tooth contacts at intercuspidation, and four patients

Table 2—*Comparison Between the Values for the Somnographic Variables After 1 Year of Follow-up and Those After 4 Years in the Dental-Appliance and UPPP Groups*

Variables	Dental Appliance (n = 32)		Difference 1 to 4 yr p Value	UPPP (n = 40)		Difference 1 to 4 yr p Value
	1 yr	4 yr		1 yr	4 yr	
AI	1.5 (0.8)	3.2 (1.6)	< 0.05	5.1 (1.8)	6.8 (2.2)	< 0.05
AHI	4.5 (2.6)	7.2 (2.6)	< 0.01	9.8 (2.5)	14.2 (3.4)	< 0.01
ODI	4.3 (2.7)	6.7 (2.5)	< 0.01	8.4 (2.3)	13.1 (3.5)	< 0.01
SI	0.5 (0.1)	0.5 (0.1)	NS	0.5 (0.1)	0.5 (0.1)	NS

*Data are presented as mean value (± 95% CI). See Table 1 for expansion of abbreviation.

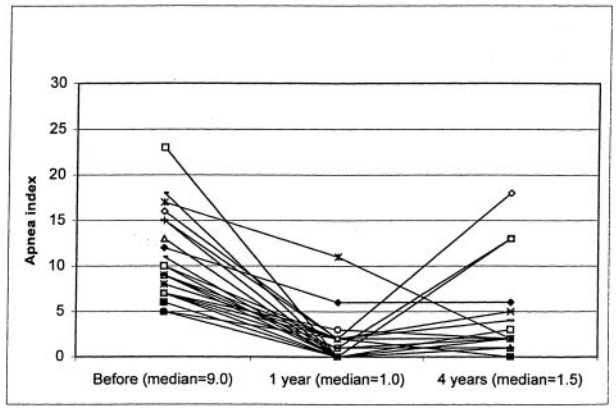

FIGURE 3. Individual AI values (n = 40) in the dental appliance group before intervention and at the 1-year and 4-year follow-ups.

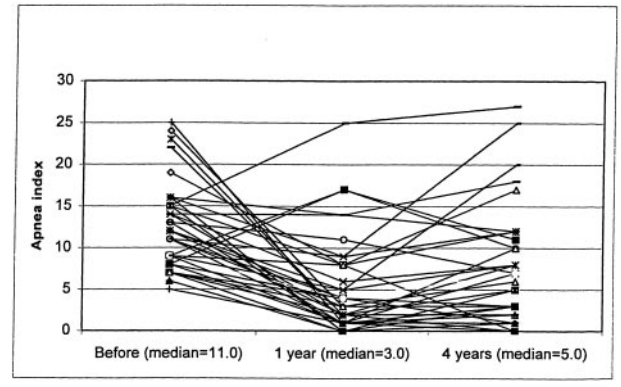

FIGURE 4. Individual AI values (n = 32) in the UPPP group before intervention and at the 1-year and 4-year follow-ups.

noted minor changes. One patient was not able to occlude his teeth in the same way as before treatment and reported TMJ pain on movement of the mandible.

Five patients reported unilateral TMJ sounds (four patients reported clicking and one patient reported crepitation). Three of these patients had reported these symptoms before treatment.

Adverse Effects of UPPP

Three patients showed a tendency to fibrotic narrowing, but without symptoms, after UPPP. Pronounced complaints of nasopharyngeal regurgitation of fluid and difficulty with swallowing after UPPP were reported by 8% and 10%, respectively.

Technical Failures of the Dental Appliance

Minor adjustments of the dental appliances were made in 14 patients (one or two adjustments per patient). Repeated adjustments were made in only one patient, to optimize the retention of the dental appliance. Twenty-one appliances were in good condition at the 4-year follow-up. Five appliances showed minor defects, and one appliance had a major defect that needed attention by a dental technician. One of the four Adams clasps, the weakest parts of the construction, was broken in seven dental appliances.

DISCUSSION

There is general agreement that patients with OSA should have treatment to reduce the frequency of apneas and hypopneas and thus alleviate the subjective disorders. There are also reasons to believe that effective treatment will have positive influence on the prognosis.[10,11]

The number of reports of long-term effects of UPPP (after > 1 year) on somnographic variables is limited.[12–14] In these studies, the effects of UPPP were found to be reduced over time. Jansson et al[14] found a decrease in the success rate regarding AHI from 64% after 6 months to 48% after 5 years. Larsson et al[12,13] reported a decrease in the success rate as measured by the ODI during the first 2 years after treatment (39%), but no further decrease from 2 to 4 years. The decreasing success rate for AHI over time was verified in our study, which showed a significant reduction from 60% after 1 year to 35% after 4 years. Thus, regular follow-up examinations are important for detection of treatment failure, which will allow any necessary treatment to be initiated. In our study, 25% (10 of 40 patients) in the UPPP group started to use the dental appliance as complementary treatment after the 1-year follow-up.

In addition to the low response rate, some patients suffer complications after UPPP. The true incidence of complications is difficult to determine, as many of the reports concerning UPPP make no reference to complications.[17] The incidence in the reports that made such references was generally low. However, in a fairly large questionnaire study[16] of 101 OSA patients 1 year after UPPP, 24% complained of nasopharyngeal regurgitation of fluid and 10% had complaints related to swallowing. In our study, 8% of the patients reported pronounced regurgitation of fluid and 10% reported difficulties with swallowing. The incidence of late postoperative complaints is therefore not negligible.

There have been few short-term studies in which mild-to-moderate OSA has been treated with mandibular advancement by 50% of the maximum protrusive capacity and followed up with somnogra-

Table 3—*Success and Normalization Rates After 1 Year and 4 Years of Follow-up in the Two Treatment Groups

Variables	Dental Appliance			UPPP			Difference Between the Two Groups at 4 yr p Value
	1 yr (n = 37)	4 yr (n = 32)	p Value	1 yr (n = 43)	4 yr (n = 40)	p Value	
Success rate (≥ 50% reduction)							
AI	95%	81%	NS	70%	53%	NS	< 0.05
AHI	81%	72%	NS	60%	35%	< 0.05	< 0.01
Normalization (AI < 5 or AHI < 10)	78%	63%	NS	51%	33%	NS	< 0.05

*See Table 1 for expansion of abbreviation.

phy.[19–21] Only one clinical trial[23] with a follow-up time of 1 year has been undertaken to evaluate the effect of a dental appliance in comparison with UPPP.

In our extended follow-up study of patients with mild-to-moderate OSA, the success and the normalization rates of somnographic variables were still significantly higher in the dental-appliance group than in the UPPP group at the end of 4 years. This might be explained, however, by a selection bias in the dental-appliance group due to loss of follow-up. The apnea and hypopnea indexes increased significantly between the 1-year and 4-year follow-up in both groups, although the absolute increases were small.

Our portable recording device is comparable (using the same type of signals and transducers) to Edentrace 2700 (Edentec; Eden Prairie, MN), which was validated with simultaneously recorded polysomnography in 67 patients.[30] The sensitivity and specificity for OSA diagnosis were 95% and 96%, respectively, using a respiratory disturbance index of > 5, defining abnormality. In another study[31] with Edentrace 4700 (Edentec) using a respiratory disturbance index of > 10, defining abnormality, the sensitivity and specificity was 95% and 100%, respectively.

In our patients, we advanced the mandible by 50% of the patient's maximum protrusive capacity. A decreasing effect of the dental-appliance treatment over time may make it necessary to increase the advancement of the mandible to obtain a better effect. The drawback of further advancement of the mandible is a higher frequency of symptoms in the stomatognathic system.[32,33] In the present study, we found only few adverse effects on and changes in the stomatognathic system. In earlier studies,[21,22,33] there has been a wide variation in the degree of mandibular advancement. There is a need for studies to determine how different advancements affect the somnographic variables and give rise to complications on a long-term basis. A problem with dental-appliance treatment of OSA is the decreasing compliance with time. In our study, it dropped from 82% after 1 year to 62% after 4 years. Schmidt-Nowara et al[20] reported 75% compliance after 7 months of treatment with a dental appliance, with the same degree of advancement of the mandible as in our study. The compliance in patients using CPAP for treatment of OSA with a follow-up time of 2 years has been reported to be 70 to 76%.[34,35] It must be kept in mind that patients treated with CPAP have in general a more severe disorder than the dental-appliance patients in our study and might therefore be more motivated to use their device. The number of adjustments and repairs of the dental appliance that were needed over the years was moderate, and the construction would therefore seem acceptable for clinical use.

Conclusion

In this 4-year follow-up study, the somnographic variables showed a significantly higher success and normalization rate in the dental-appliance group than in the group treated with UPPP. The superior effectiveness of the dental appliance compared to UPPP is partly invalidated by the compliance of 62% in the dental-appliance group. The appliance had few adverse effects on the stomatognathic system; in view of the few adjustments and repairs that were required over time, its construction seems acceptable for clinical use. In patients with mild-to-moderate OSA, use of a dental appliance with regular follow-ups can therefore be recommended for long-term treatment.

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