Oral Appliance Effectiveness and Patient Satisfaction with Obstructive Sleep Apnea Treatment in Adults

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Source of support: Departmental sources

Background: Indication of oral appliances for the treatment of an obstructive sleep apnea (OSA) includes both patients with primary snoring and mild OSA, as well as patients with moderate to severe OSA who refuse other treatment or in whom such treatment failed. The aim of this study was to verify the effectiveness of current OSA treatment by objective measurements, and to assess by means of a questionnaire patients' satisfaction with oral appliances manufactured in our laboratory.

Material/Methods: The study enrolled 58 adult patients (40 men, 18 women) with mean age of 50.5 years; most were overweight or had class I obesity; mean baseline apnea-hypopnea index (AHI) value prior to the beginning of treatment was 31.3, range 0.6–71.

Results: Average AHI reduction in the entire group was 10.4; 31% of patients experienced AHI reduction by at least 50%. Significant AHI reduction was proven when using the appliance. Appliances affect the reduction of AHI and patients tolerate the appliances well.

Conclusions: Oral appliances complement positive-pressure treatment and do not interfere with it in any way. Craniometric parameters seem to be applicable as predictors of success or failure of appliance treatment.

MeSH Keywords: **Administration, Oral • Adult • Sleep Apnea, Obstructive**

Full-text PDF: https://www.medscimonit.com/abstract/index/idArt/911242

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Background

Treatment of rhonchopathy and obstructive sleep apnea by means of oral appliances (OA) is wide-spread around the world [1]. Typically, it is a plastic aid inserted into the mouth to dilate the upper respiratory tract and prevent its further constriction, collapse, or vibrations during sleep. Different mechanisms are employed to affect the airway, depending on the type of appliance. Upon insertion into the mouth, the appliance may affect mandibular advancement (mandibular advancing device, MAD), fix the tongue and prevent it from falling back, or advance the hyoid bone by means of advancing the mandible or support the soft palate (directly or indirectly by acting on other structures) [1,2].

OA indication for treatment of OSA was established by the American Academy of Sleep Medicine (AASM) and includes patients with primary snoring or mild OSA who do not respond to sleep regimen change, patients with moderate or severe OSA who do not tolerate or who refuse continuous positive airway pressure (CPAP) treatment, and patients who refuse surgical treatment or in whom such treatment is not indicated or already failed [3].

There are many OA types around the world; sleep centers usually use their own appliances. Ready-made appliances are formed by heating in hot water, which softens the appliance's material, and the patients fit the appliance to their dental arch by biting down on it. These "boil and bite" appliances are non-prescription products and are available at sleep centers and pharmacies, or over the Internet. A second type is individually created in a dental laboratory from dental arch imprints.

According to the available literature, the mandible-advancing OAs are considered the most efficient. They may be manufactured with a fixed measure of advancement, or they can contain a mechanism (usually a screw) by means of which advancement can be continuously adjusted according to an individual patient's tolerance. Other aids fix tongue position or advance the tongue; their mechanism of action is based on sucking the tongue into a cavity created by the appliance, which fixes the tongue in place or moves it slightly out of the mouth. These OAs are among the less efficient and probably are also less well tolerated. The third type are soft palate supports that rest against the base of the soft palate, lifting it slightly, which reduces the possibility of palate vibration. The last type comprises various oral screens and tapes. These are OAs that prevent breathing through the mouth by keeping the mouth shut or inhibiting air flow through the mouth [1].

In general, efficacy of treatment with OAs ranges between 19% and 80%, depending on selected parameters. Many studies of OA efficacy [4–6] indicated that their effect depends on many factors, including: type and design of the OA; the patient's age, sex, state of health, and BMI; cephalometric parameters; and OSA severity.

Unfortunately, treatment with OAs may be also associated with adverse effects such as excessive salivation, pressure on the teeth and jaws, contusions of the tongue or gums, possible development of pain or stiffness of the temporomandibular joint or muscles of mastication, and bite change or even bite impairment after prolonged use of an inappropriate OA.

We are interested in pointing out other non-surgical ways to treat snoring and OSA by means of oral appliances. We are steadily improving the methodology of this treatment and striving to optimize our approach to patient selection and laboratory manufacture of the appliance as well as ways of evaluating treatment efficacy. Available sources [4–6] indicate that this may be an efficient method that can be very beneficial to the particular patient. The aim of this study was to verify the effectiveness of current OSA treatment with OAs by objective measurements, and, using a questionnaire, to assess patient satisfaction with the use of OAs manufactured in our laboratory.

Material and Methods

Patients referred to University Hospital Ostrava (teaching hospital) with complaints indicating obstructive sleep apnea (OSA) participated in the study. Severe OSA with CPAP intolerance was the most frequent indication for treatment, followed by moderate or mild OSA or simple snoring in patients who did not want to undergo a surgical procedure of the soft palate and tongue at the Department of Otorhinolaryngology (ENT) or maxillomandibular advancement at the Department of Maxillofacial Surgery. The appliance was further indicated in patients with relapse after ENT surgery or after unsuccessful ENT treatment.

Snoring with the mouth either open or closed (breathing through the nose only) and with or without mandibular advancement was simulated in each patient. A probable good effect of the appliance was assumed in cases where mandibular advancement improved air flow (snoring simulation was not possible).

Contraindications for the appliance were refusal of the patient, absence of teeth, bite disorder, prominent gagging reflex, or the presence of extensive fixed dental bridges anchored to limited abutment teeth (posing a risk that the appliance may dislodge the bridge). Corrective dental work (treatment of caries, extraction of loose teeth) was mandatory before treatment. Additionally, the appliance was not indicated in patients who had problems with nasal patency.

All involved patients gave written informed consent to participate in the study. The study enrolled 58 adult patients who underwent all necessary examinations, including follow-ups, and who could be included in the assessment. These comprised 40 men and 18 women with a mean age of 50.5 years; the age range in women was 44–65 years (mean 54.6±2.8 years) and 24–68 years (mean 48.7±2.7 years) in men. Most were overweight or had class I obesity (BMI range in men was 22.6–47.8 with mean 29.5±1.1, in women 25.2–36.6 with mean 31.3±1.2). The mean baseline apnea-hypopnea index (AHI) value prior to the beginning of treatment was 31.3 (+–4.4), range 0.6–71.

Cranial radiography and limited sleep polygraphy were conducted in all enrolled patients. Patients were then referred to the Department of Maxillofacial Surgery, where a solution to the problems was proposed and possibilities of conservative treatment with the appliance were presented to the patient. Then, control polygraphy and cranial radiography were performed 3 months later.

Limited polygraphy

Recording of respiratory effort (movement of the abdomen and chest), air flow through the nose and mouth, and pulse oximetry were carried out simultaneously during the polygraphy, which is a simplified screening examination focused predominantly on OSA. Polygraphy also records snoring, movement of the lower extremities, and body position.

Apnea-hypopnea index (AHI) is defined as the average number of respiratory events (apnea or hypopnea) per hour of sleep. AHI values up to 5 are considered normal in adults, values 5–15 indicate mild OSA, values 15–30 indicate moderate OSA, and values over 30 severe OSA [7].

Radiography

Radiographic imaging (cephalogram) was used mainly for measuring the PAS, PASsp, and H dimensions. The posterior airway space (PAS) value defines the space behind the root of the tongue, the PASsp (Posterior airway space – soft palate) dimension defines the narrowest place behind the soft palate, and the length between hyoid and mandible (H) value represents the distance of the hyoid bone from a line intersecting the inferior edge of the mandible. The assessment focused on the change of dimensions after introduction of the appliance (baseline values marked No. 1, follow-up values marked No. 2), i.e., the degree of airway dilatation, where a positive difference between the baseline and follow-up examinations was considered an improvement in PAS and PASsp, whereas the opposite was true for the H value (decrease of the dimension is considered an improvement).

Mandibular advancement and the difference in occlusion of the upper and lower canines was also measured on a lateral X-ray image of the skull. Images from before the appliance manufacture were compared with images with the appliance inserted in order to assess whether the magnitude of advancement was directly proportional to the appliance efficacy.

Appliance manufacture

To manufacture the appliance, impressions of the maxilla and the mandible using imprinting material (Ypeen Premium, Jicin, Czech Republic) were made, and a wax (Ceradent, Jicin, Czech Republic) bite model was constructed to capture the magnitude of mandibular advancement and occlusive relation to the maxilla. To prevent excessive advancement, attention was paid to the position of the joint condyles during construction of the bite model. The extent of advancement was based on joint morphology and subjective feeling of the patient.

The appliance was made from plastic vacuum-pressed templates. The plastic plate was heated evenly and vacuum-pressed onto a plaster-of-Paris model of the jaw, creating an exact impression of the dental arch. The plastic imprints of both jaws, positioned with help of an articulator (a simulator of occlusion), were joined in the desired position with polymethylmethacrylate (dental resin).

Follow-up and questionnaire survey

Following manufacture, the appliance was fitted in the patient's mouth and adjusted as needed. During a follow-up examination 1 month after insertion of the appliance, its functionality and possible complications (e.g., pressure on the teeth and pain in the temporomandibular joint) were assessed by a questionnaire and an interview, and a follow-up radiography and limited polygraphy (on the same instrument as at baseline) were carried out with the appliance in place (Table 1). The patients reported frequency of use (daily or several times a week) by a questionnaire and evaluated how effective the appliance was in resolving issues associated with OSA, as well as their subjective feeling of satisfaction with the appliance (whether it fits them and whether they have complications). If the patient was satisfied and the follow-up limited polygraphy did not show deterioration, periodic annual follow-ups ensued; if the patient was dissatisfied or ventilation parameters deteriorated, a different kind of treatment was recommended. Patients used the appliance until the AHI index fell below 5, which might have been due to weight loss in some cases.

Statistical analysis of data

Statistical analysis of data was performed with IBM SPSS software, version 23. Data normality was tested with the chi-squared test. Given the small size of the set and absence of

Table 1. Detailed distribution of patients within the set (Ø=mean).

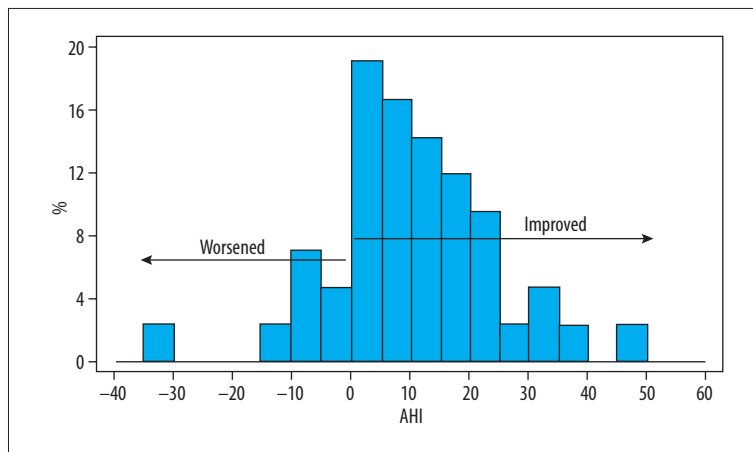| Groups	Total	Men	Women	Ø age	Range	Ø BMI	Range
Polygraphy	41	29	12	51.8	33–68	29.8	22.6–47.8
Radiography	48	35	13	50.0	24–68	30.4	24.5–47.8
Questionnaire	51	34	17	50.2	24–68	29.9	22.6–47.8
Questionnaire + polygraphy	40	26	14	51.3	33–68	30.0	22.6–47.8
Completely assessed	30	21	9	50.7	33–68	30.2	24.5–47.8

Figure 1. Histogram of AHI change after appliance introduction (columns in 5-unit increments, number of patients given as percentage).

normal data distribution, we used non-parametric methods (Wilcoxon paired U test), and also the paired t test (5% level of significance). Interdependence of values was ascertained by means of correlation coefficient. Statistical significance of correlations was analyzed by means of the test statistic $\chi=\frac{r\sqrt{n-2}}{r\sqrt{1-r^2}}$, which was inputted into the distribution with $n-2$ degrees of freedom. Since the study describes 41 patients, the significant correlation cut-off is 0.44 (i.e., greater than 0.44 or less than −0.44).

Results

The aim of this study was to assess effectiveness of oral appliances in the treatment of OSA and rhonchopathy. Effectiveness of the appliance was monitored by means of objective measurements (limited polygraphy, change of upper respiratory tract space according to radiographic dimensions) and patient's subjective evaluation by means of questionnaire survey. The 41 patients who underwent both baseline and follow-up polygraphy were assessed (Table 1).

Apnea-hypopnea index (AHI), O_2 saturation below 90% (T90%), and snoring time (SnTime) values were monitored. The assessment focused on the change of parameters after appliance introduction, i.e., on the difference between the baseline and the follow-up examinations, where a positive difference was

considered an improvement and negative a deterioration (the opposite is true for the H value, see Methods).

Limited polygraphy – objective assessment

There was not a significant age difference between the selected men and women (WMW U Test: p=0.328), nor was there a significant difference in BMI (WMW U test: p=0.294) and the baseline AHI at beginning of study. The AHI mean before treatment was 32 (SD=18.21) and with treatment 22 (SD=16.8), T90% value before treatment was 11.1% (SD=18.6) and with treatment 11% (SD=22).

AHI

The appliance caused reduction of AHI value in almost 86% of patients, as indicated by the longer, higher-placed arrow in Figure 1 (AHI improvement is plotted in 5-unit increments). The highest number of patients shows improvement by 5–25 AHI units (Figure 1). The number of patients with more pronounced improvement (AHI reduction by more than 25 units) is smaller; 2% of patients experienced maximum improvement by 48 units. Polygraphy results with the appliance were worse than without it in 6 patients (14%) (AHI value increase, the shorter, lower placed arrow in the graph), which was mostly within 5–15 units range; an outlying maximum deterioration by 34.8 AHI units was also recorded (Figure 1).
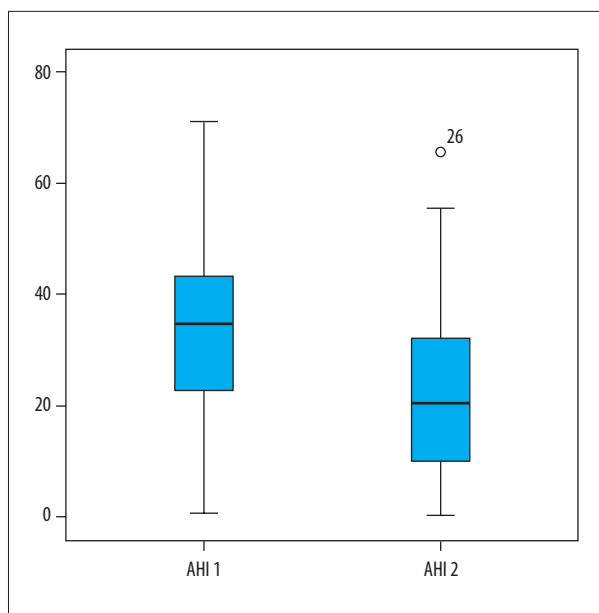
Figure 2. Comparison of global AHI change before treatment and with appliance treatment.

Figure 3. Histogram of T90% change after appliance introduction.

The average AHI reduction in the whole group was 10.4, where 13 of 41 patients (31%) experienced AHI reduction by at least 50%; AHI improved with the appliance in additional 22 patients, but the reduction was less than 50% (Figure 2). Although 14% of patients had deterioration, significant AHI reduction was proven when using the appliance (WMW U test, p=0.0).

The multiple linear regression method identified only the PASsf2 parameter as a statistically significant positive predictor of AHI reduction with the use of OA (PASsf dimension – see above, with the appliance in place, R =0.311, p=0.047).

T90% index

Statistical evaluation did not show a significant difference of T90% before treatment and with treatment (Figure 3). This may be due to the fact that our set consists of patients with relatively low baseline T90% value (WMW U test: p=0.424). Nevertheless, 6 patients had baseline T90% value higher than 20%. Even these patients did not experience a significant reduction of the T90% parameter with application of the appliance (WMW U test: p=0.463).

Rhonchopathy

Monitoring of rhonchopathy changes was a rather ancillary matter. There was no statistically significant difference in the SnTime parameter (WMW U test: p=0.263), but it is necessary to point out that this clinical observation was made with different instruments; moreover, the methodology for determination of snoring time is inconsistent, unlike that for AHI and
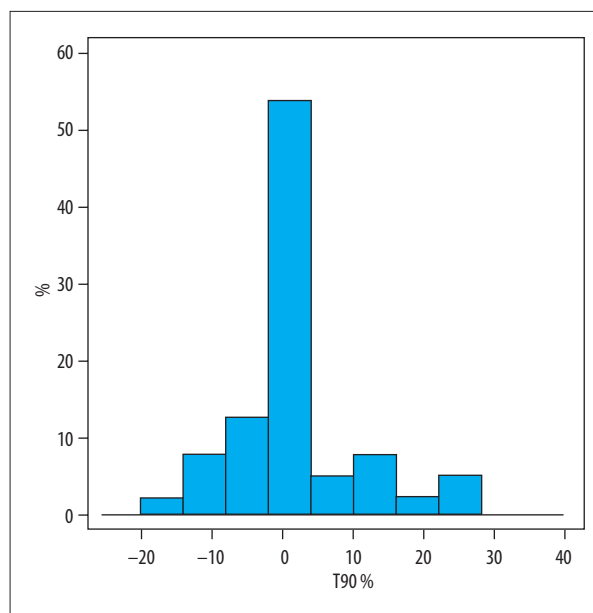
T90%. There was not a significant difference between men and women in success of treatment (Fisher's exact test: p=0.30), and the same was true for patients with deterioration (Fisher's exact test: p=0.423).

It follows from these limited polygraphy examinations that the appliance does not have much effect on either improvement of oxygen saturation (T90%) or rhonchopathy. Thus, the greatest importance of the appliance lies in AHI reduction. The average AHI reduction was 10.2, and the difference before and after treatment was statistically significant (WMW U test: p=0.0).

Comparing successful and unsuccessful cases of AHI reduction

Further analysis was therefore focused on comparing successful and unsuccessful cases of AHI reduction, where AHI reduction by 50% was considered a success. Comparison of a subset of 13 patients with AHI improvement by 50% and more with the rest of the patients did not show a significant difference in the dimensions PAS1 (WMW U test: p=0.568), H1 (WMW U test: p=0.713), PAS2 (WMW U test: p=0.125), H2 (WMW U test: p=0.687), PASsfk2 (WMW U test: p=0.158), and in H1 difference (WMW U test: p=0.989). However, successfully treated patients had significantly greater increase of the PAS dimension (PAS2 – PAS1) (WMW U test: p=0.041) (Figure 4); on the contrary, patients with deteriorated AHI finding after introduction of the appliance had significantly greater difference of the H parameter (H2 – H1) (WMW U test: p=0.013). Craniometric parameters (PAS, H1, H2) of mandibular advancement thus appear to be predictors of success or failure of treatment with the
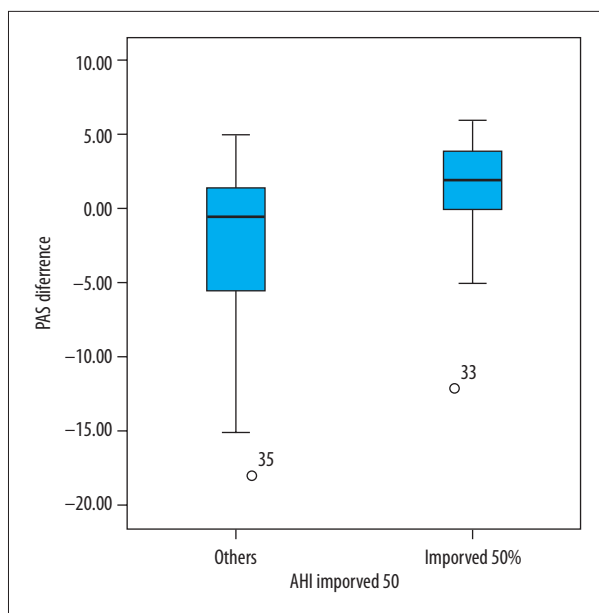
Figure 4. Comparison of PAS change in patients with AHI improvement by 50% and others (with only a mild improvement or deterioration). Patients whose AHI decreased by 50% and more with the appliance show significantly higher PAS2 difference (advancement with the appliance) compared to initial baseline PAS1.

appliance, where PAS increase predicts positive effect of appliance treatment, and by contrast, H increase predicts failure.

Radiography – objective assessment

The 48 patients who underwent both baseline and follow-up radiography were assessed. The assessment focused on the change of dimensions PAS, PASsp, and H (defined as the distance of the hyoid bone from a line intersecting the inferior edge of the mandible), i.e., the degree of airway dilation after introduction of the appliance. The values are shown in Table 2. Differences were found between PAS1 (before) and PAS2 (after the introduction of the oral appliance). The same is true of PASsp (paired t test, p=0.01) and H (t test, p<0.001); all 3 dimensions, therefore, changed significantly after using the appliance. The seemingly small mean changes in the Table 2 for PAS and PASsp can be explained predominantly by the

relatively high number of patients in whom the parameter deteriorated, in the case of PAS with a few relatively high values of deterioration.

We further investigated correlations between AHI and BMI and between the effect of the appliance on AHI and BMI; however, no significant correlation was found. We further investigated the correlations between AHI and BMI and between the effect of the appliance on AHI and BMI; however, no significant correlation was found.

AHI values, radiographic measurements, and the degree of mandibular advancement were assessed, but no significant correlations were revealed.

Questionnaire – patients' subjective assessment

The questionnaire on satisfaction with the oral appliance and its effectiveness was completed and handed in by a total of 51 patients. Of these 51 patients, 63% used the appliance every night, almost 30% several times a week, 2% as an exception, and 6% did not wear it at all.

In terms of effectiveness, 76.5% of patients assessed the appliance positively and 23.5% of patients found its effectiveness was low. The patients giving positive assessment wore the appliance every night (59%) or several times a week (18%). Of the patients reporting low effectiveness, 4% used the appliance every night, 12% used the appliance several times a week, 2% used it as an exception, and 6% not at all.

The satisfaction assessment yielded similar results. Over 80% of patients were satisfied: those who used the appliance every night (59%) or several times a week (22%); 19.6% of patients were dissatisfied: 4% of them wore the appliance every night, the majority (8%) several times a week, 2% as an exception, and 6% not at all.

The questionnaire data (presented as "subjective" below) were subsequently compared with the polygraphy assessment results (presented as "objective" below). The assessment comprised 40 patients who underwent both baseline and follow-up polygraphy examination and completed the questionnaire

Table 2. Changes in the values of PAS, PASsp and H after treatment.

Parameter	% of patients			mm		
	Improvement	Aggravation	No change	Mean change	Max. improvement	Max. aggravation
PAS	54%	30	16	0,4	7	9
PASsp	56.5	30.5	13	0.8	7	4
H	87.5	6.3	6.3	5.9	19	5

Table 3. The results of objective functionality of the appliance and subjective patient satisfaction with the appliance.

Method – category	Number	%
Polygraphy – objective improved	32	80.0
Polygraphy – objective worsened	8	20.0
Questionnaire – subjective satisfaction	35	87.5
Questionnaire – subjective dissatisfaction	5	12.5

as well. It shows a high subjective satisfaction of the patients with the appliance (87.5% satisfied), whereas objective improvement was recorded in 80% of them (Table 3). A complete summary of objective efficacy (polygraphy) and subjective dis/satisfaction of the patients is provided in Figure 5.

Discussion

In our patient set we used a type of mandible advancing device (MAD) most frequently indicated for severe OSA with CPAP intolerance. It is an appliance individually manufactured on the basis of dental arch imprints (in our case, with fixed advancement determined during manufacture), which prevents opening of the mouth, limits breathing through the mouth, and slightly advances the jaw during sleep. Breathing with an open mouth causes the root of the tongue to drop rather significantly, which reduces the airway. Breathing through such a narrowed space is difficult; the forced air flow vibrates the surrounding tissues, generating the typical snoring sound. Breathing through the mouth also dries out the mucosa, which certainly does not enhance oral health, not to mention the associated unpleasant feeling of dry mouth and the tongue sticking to the palate. Mandibular advancement opens up the space for inspired air, reduces resistance to air flow and vibration of the surrounding tissues, and thus reduces the generation of the unpleasant snoring sound.

The literature defines success of treatment as AHI reduction with or without symptomatic improvement, which may be defined as reduction of AHI <10 or as AHI percentage reduction compared to baseline, which is considered to be of clinical importance (typically a 50% AHI reduction) [6].

In our set, the appliance led to AHI reduction in almost 86% of patients, on average by 45%, while the baseline AHI mean was 31.3, i.e., severe OSA. The highest number of patients showed improvement by 5–25 AHI units. AHI was reduced to <10 in 12% of patients. The literature presents success of treatment (reduction of AHI <10) ranging from 30% to 85% [1,8,9]. The low percentage in our set could be caused by the high baseline AHI value (severe OSA, see above). Gjerde [6] presents 75% rate of success in AHI reduction by 50%. Improvement (reduction) of AHI by 50% and higher was achieved by 33% of patients in our set. However, most of Gjerde's patients had moderate OSA.

In our study, 14% of patients experienced deterioration (AHI increase), mostly within the interval of 5–15 units, and an outlying maximum deterioration by 34.8 AHI units was recorded in 1 patient, which may be attributable to insufficient mandibular advancement with the appliance in place, repeated dissatisfaction and adjustment of the appliance, weight gain, a course of protracted pneumonia with a finding of a benign tumor or by a history of iatrogenic pneumothorax with a finding of benign lesion in the right lung. Recently, we used drug-induced sleep endoscopy (DISE) in patients with an inserted appliance to check the efficacy of the appliance directly in the patient's mouth during artificially induced sleep. Then, the oral appliance is adjusted or a new one is manufactured.

Use of the appliance led to T90% reduction in 47.5% of patients, increase in 42.5% of patients, and 10% of patients retained the original (baseline) value during measurement with the appliance. The appliance does not improve the T90% value much, which corresponds to the literature, in which CPAP-treated patients demonstrated improvement compared to those using an appliance [9–11].
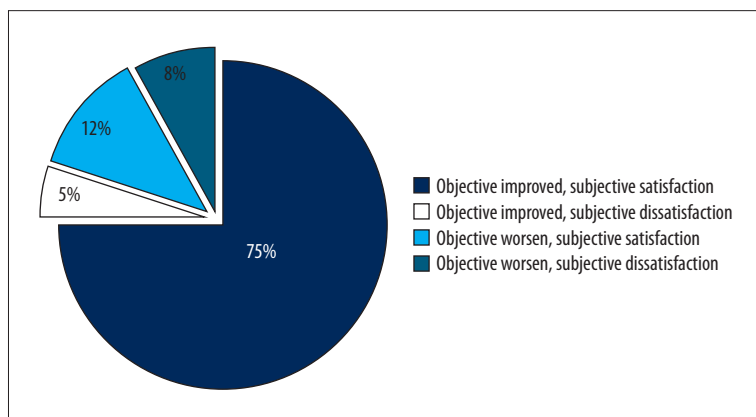
Figure 5. Representation of appliance functionality and individual patient dis/satisfaction (in%).

Legend:
- Objective improved, subjective satisfaction
- Objective improved, subjective dissatisfaction
- Objective worsen, subjective satisfaction
- Objective worsen, subjective dissatisfaction

In our study, 58% of patients experienced reduction of snoring time (SnTime), while 42% experienced a deterioration. Since rhonchopathy was measured by 2 different instruments and standardization of this parameter was not possible, our measurement of the appliance's effect on rhonchopathy is not reliable. One explanation for the resistance of rhonchopathy could be that the soft tissues of the neck were insufficiency stretched and kept vibrating during respiration.

The space behind the root of the tongue (PAS dimension) increased in more than a half of the patients (54%), and very similar values were also recorded for the PASsp dimension (56.5%). Reduction of the H value by 88% is interesting, because it indicates reduction of the airway's vertical dimension. This may manifest as improved air flow and improvement in OSA. Insufficient mandibular advancement caused by the appliance or already-exhausted muscular elasticity (impossibility to stretch them more) may have been present in the remaining patients. These parameters can be affected by the patient's age and sex, length of the soft palate, and size of the jaws [12]. Because of this, every patient with moderate and severe OSA presently undergoes DISE with a low-dose CT examination. Dissatisfied patients undergo a follow-up DISE, which will be the subject of a future study. Rose (2002) reported AHI improvement with use of an appliance, but also described a change of the anterior-posterior position of the molars, and inclination of upper and lower canines without skeletal changes as adverse effects. This is why regular and long-term patient follow-ups are recommended [13]. None of the patients in our study complained of change in teeth position, and no change was found during regular follow-ups carried out at our sites.

There was no correlation between mandibular advancement and AHI difference. Correlation of baseline radiographic measurements (PAS, PASsp and H) with AHI was always very small. Correlation of T90% values with radiographic measurement values was insignificant, and the only correlation of T90%1 with H1 was very week. The possible reason for this is the fact that the radiographic measurement is only 2-dimensional, whereas the third dimension (width of the airway) may be crucial for successful treatment of OSA. From this point of view, a 3D analysis by means of low-dose CT or CBCT would be desirable. According to the literature, individually manufactured appliances improve airway size [1].

In terms of effectiveness, 76.5% of patients assessed the appliance positively, which also supported the regular use of the appliance by these patients, and was confirmed by the relatively high rate of objective success according to polygraphy results. We understand the low effectiveness and thus low frequency of use in patients, to whom the appliance appeared inefficient, in terms of insufficient mandibular advancement (which could not be further increased due to the risk of hypermobility and

pain of the temporomandibular joint), but the cause may be different – factors such as tissue elasticity, BMI, anatomical and morphological relations such as jaw size, occlusion, and the position of the jaws relative to skull base can all contribute to insufficient widening of the airway in some patients; others could not tolerate the presence of any appliance in their oral cavity, the same as with CPAP. Depending on their age and general state of health, such patients may be indicated for a surgical procedure of the jaws or soft tissues of the neck following DISE [6,14]. Phillips reported satisfaction around 76% for OA and 43% for CPAP in patients who used the appliance more than 4 h/night [10].

In contrast to CPAP, patients may consider as advantages of the appliance its easy portability without the need for power supply, its low cost, and the likely favorable opinion of their partner who does not get disturbed at night. In the initial phase of treatment with OA, the patient must get used to possible adverse effects, which may include excessive salivation or, to the contrary, dry mouth, hurting teeth, or temporomandibular joint pain. Reported adverse event frequencies vary widely, which may be potentially due to differences between the appliances used. The adverse events are, however, usually temporary and typically subside during the first 2 months of use [8,15]. Patients of our set reported only minimal adverse events (several of them reported a manageable pressure on teeth), which may be attributable to the individually manufactured oral appliance and thorough patient education regarding its use.

This study is affected by several limiting factors. First, it was a retrospective study, and a blind randomized prospective study would show the resulting data more clearly. Second, the cephalometric analysis offers only a 2-dimensional analysis, which limits its applicability for determining the exact PAS dimension. All patients with moderate and severe OSA presently undergo a low-dose CT examination of the upper respiratory tract. Third, all patients' appliances were manufactured without DISE, which may account for some of the lack of success, as we were missing real-time information about the upper respiratory tract dimensions, at least in artificially induced sleep. All patients with moderate and severe OSA presently undergo a DISE.

Although our study did not establish a direct influence of patient's BMI to AHI value nor to the magnitude of AHI reduction/increase after appliance introduction, we believe that weight loss and reduction of fatty deposits in the upper respiratory tract is important for treatment of sleep apnea. This is because severity of symptoms cannot be simply derived from a single parameter. The relationships are more complex, which disallows an early estimate of the appliance's effectiveness in individual patients merely on the basis of their BMI.

The relationship of BMI and the polysomnographic examination will be the subject of our next study.

Conclusions

It follows from the presented results that obstructive sleep apnea syndrome represents a complex problem which cannot be reduced to a handful of parameters. Predisposition is primarily given by airway morphology, which is documented by the improvement associated with change of the PAS, PASsp, and H dimensions. Determination of craniometric parameters then enables prediction of success or failure of OSA therapy. Our results further clearly show that appliances have greater impact on the value of AHI than on T90%, and so should be preferentially used in cases with relatively normal T90% value (all other indication criteria being satisfied). Direct correlation with BMI was not confirmed, but it can be expected that the reduction of fatty tissue deposits will contribute to relaxation and opening of the hollow spaces within the neck, thus improving air movement. This theory will be subject to verification in our planned deeper study of OSA.

The mandibular protractor is a method of choice in patients who meet general indication criteria; it may be efficient in patients to whom continuous positive pressure therapy or surgical treatment cannot be applied. The appliance reduces complaints (particularly the quantity of apnotic pauses) due to adequate mandibular advancement, and it is well tolerated and very positively evaluated subjectively by the patients. Consequently, the appliance suitably complements positive pressure therapy and does not interfere with it in any way.

Further research is needed to improve the appliance design in order to increase its effectiveness, bearing in mind possible adverse events, and to increase accuracy of its indication, for which DISE could be useful.

Conflicts of interest

None.

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