



# Oral Appliances for the Treatment of Mild and Moderate Obstructive Sleep Apnea

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## Abstract

**Introduction:** Continuous Positive Airway Pressure (CPAP) is considered as a golden standard for the treatment of Obstructive sleep apnea (OSA), but the low compliance and intolerance of the patients to the machine calls for alternative treatment. Oral appliances could be a viable alternative to CPAP in patients with mild or moderate forms of OSA.

**Method:** This study consists of case series of 37 OSA patients treated with two different types of oral appliances. The diagnosis was set by using thorough examination by an otorhinolaryngologist of the upper airways by endoscopy, sleep endoscopy, polysomnography and Epworth sleepiness scale (ESS). Apnea Hypopnea Index (AHI) and ESS score were obtained before and after the treatment.

**Results:** According to our study, the success rate of the treatment of the patients, measured as AHI reduction less than 10 events/hour, is very high (95%). The mean AHI reduction is 9.5 events/h. compared to 19.45 before the treatment and corresponds with the results of other authors. The mean Epworth Sleepiness Scale result after the treatment was 8.6, compared to 12.7 before the treatment.

**Conclusion:** Oral appliances are high effective in the treatment of selected patients with OSA, mainly mild and moderate cases according to AHI and ESS. The precise pretreatment work out is of uppermost importance in assessment of the grade of OSA and the site of obstruction. The combined treatment with surgery and oral appliances could be a viable option for patients with multilevel obstruction of the upper airways.

**Keywords:** OSA, oral appliances

**Running title:** OSA treatment with oral appliances

## Introduction

Obstructive Sleep Apnea (OSA) is a condition characterized by apnoic pauses during sleep, decrease of the oxygen pressure in the blood, frequent arousals and other symptoms (1).

The prevalence of OSA is about 2 – 4% of the population (2). The symptoms are due to upper airway collapse and obstruction during sleep. The obstruction of the upper airways is stressful and can lead to heart, metabolic diseases, impotence etc. That is why, the diagnostic and treatment of OSA is multidisciplinary.

Polysomnography (PSG) is considered as a golden standard for diagnostic of OSA. The Apnea-Hypopnea-Index (AHI) is an objective, sensitive and specific measure of the severity of OSA. It allows useful disease grading, although differing hypopnea definitions introduce variability. The American Academy of Sleep Medicine defines mild OSA as an AHI of 5 – 14 events per hour; moderate OSA as 15 – 30 events per hour; and severe OSA as an AHI of greater than 30 events per hour (3).

Treatment of OSA with Continuous positive airway pressure (CPAP) is recommended as a method of choice in the standards of the American (3, 4) and

European societies of sleep medicine (5), which leads to prescription of CPAP almost to every patient with OSA. The other methods of treatment like surgery and oral appliances are considered as “alternative therapies”, although they could solve the patient’s problems better in selected cases. On the other hand, CPAP effectiveness is limited by intolerance and poor compliance, with failure rates of 46 – 83% (6), especially in young people, which indicates that different methods of treatment should be offered to the patients, when indications for them exist. The custom indications for the alternative methods are mild and moderate OSA, but in patients, who do not tolerate CPAP, they could be used as well, even in cases with severe OSA.

An oral appliance was considered as treatment for mandibular deficiency and upper airway obstruction as early as 1934 (7). In 1934 Pierre Robin described a monoblock functional appliance, that was used to pull the jaw and, therefore, the tongue forward. Robin’s appliance was utilized for cases of micrognathia in both children and adults. One limitation of the intraoral appliance approach, that Robin noted, was that it was not usable in the newborn without any teeth (7).

Since then, due to the advances of dentistry and the improvement of the materials, many types of oral appliances were created. They are called with different names like oral (dental) appliances (OA), mandibular advancement device (MAD), mandibular advancement splints (MAS), mandibular repositioning appliances (MRA), etc. The main principle of their action is to protrude the mandible in a forward position and therefore enlarge the upper airway (8, 9, 10). When such an appliance is inserted into the mouth, it works directly by enlarging the pharyngeal airway primarily in the velopharyngeal and oropharyngeal areas due to stretching of the pharyngeal soft tissues attached to the mandible (10).

The tongue is affected by all the appliances, either directly by forward movement of the muscle, or indirectly by advancing the mandible. The airway space is mostly enlarged laterally, thought to be due to traction on soft tissue connection between the pharynx and mandibular ramus (11).

This reduces the upper airway collapsibility by altering the upper airway morphology, structure, and function. In addition, oral appliances treatment may influence the neuromuscular function in the upper airway (10).

The aim of this study is to share our experience, based on case series of 37 patients mainly with mild and moderate OSA, in setting the correct diagnosis, indications for treatment and treatment results of the patients with 2 types of oral appliances.

## Material and Methods

37 patients with OSA were treated with one of two different types of oral appliances in the period of 2014 – 2017.

The results of the treatment were analyzed in 2018. The patients were between 22 and 51 years of age. Thirty of the patients were men (81%) and 7 women (19%), which means a ratio of male to female of 4,3:1.

Our diagnostic plan included the interdisciplinary consultation and examination by an otorhinolaryngologist, dentist and specialist of sleep medicine. It consisted of anamnesis, body mass index (BMI), Epworth sleepiness scale, otorhinolaryngological status assessed by endoscopy, Müller’s maneuver, rhinomanometry, sleep endoscopy, done by ENT specialist; dental status, done by a qualified dentist with experience in oral appliances for OSA; polysomnography or polygraphy done by specialists of sleep medicine. If comorbidities were found, a consultation with other specialists like cardiologists, neurologists, endocrinologists, pulmonologist, etc. were performed.

A detailed anamnesis referring to sleep disturbances, comorbidities, upper airways and dental problems was obtained in all of the cases.

Epworth sleepiness scale (ESS) was filled by all patients before and six month after the treatment. The ESS is a self-administered questionnaire with 8 questions. Respondents are asked to rate, on a 4-point scale (0 – 3), their usual chances of dozing off or falling asleep while engaged in eight different activities. The ESS score (the sum of 8 item scores, 0 – 3) can range from 0 to 24. The higher the ESS score, the higher that person’s average sleep propensity in daily life (ASP), or their ‘daytime sleepiness’. The questionnaire takes no more than 2 or 3 minutes to answer.

In general ESS scores can be interpreted as follows:

0 – 5 Lower Normal Daytime Sleepiness

6 – 10 Higher Normal Daytime Sleepiness

11 – 12 Mild Excessive Daytime Sleepiness

13 – 15 Moderate Excessive Daytime Sleepiness

16 – 24 Severe Excessive Daytime Sleepiness

The otorhinolaryngological examination was performed by fiberoptic nasopharyngoscopy or nasal endoscopy or laryngeal endoscopy in cases with specific pathology. Special attention was drawn to the nasal patency and pathological conditions like deviation of the nasal septum, hypertrophy of the inferior turbinates, nasal polyps etc.; the volume of the tonsils and the tongue were measured according to Friedman's scale (from 0 to 4); the position of the hard and the soft palate, the length of the uvula and lateral pharyngeal narrowing were assessed (Fig. 1, 2, 3).

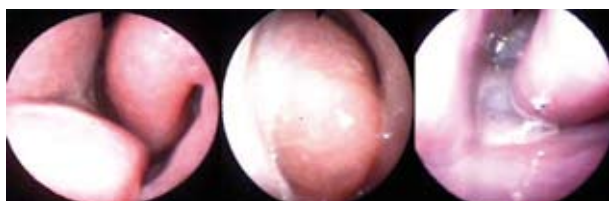


Fig. 1 a, b, c: Nasal obstruction indicated for surgery

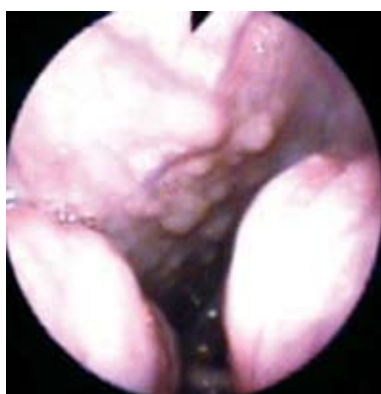


Fig 2: Multilevel obstruction

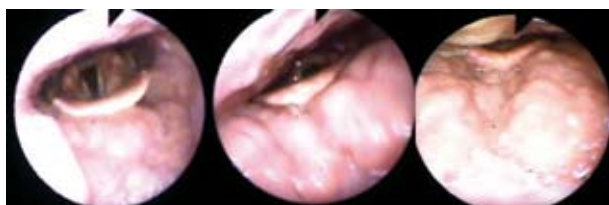


Fig. 3 a, b, c: Endoscopy in patients with mild, moderate and severe OSA

Müller's maneuver was done to all the patients (Fig. 4). The technique is designed to look for collapsed sections of the upper airways. In this maneuver, the patient attempts to inhale with his mouth closed and his nostrils plugged, which leads to a collapse of the airway. After a forced expiration, an attempt at inspiration is made with closed mouth and nose, whereby the negative pressure in the chest and lungs is made very subatmospheric; the reverse of Valsalva manoeuvre. Introducing a flexible fiberoptic scope through the nose in the pharynx to obtain a view, the examiner may notice

the collapse and identify weakened sections of the airway. Müller's maneuver is used to help determine the cause of sleep apnea. A positive test result means the site of upper airway obstruction is likely below the level of the soft palate, and the patient will probably not benefit from a uvulopalatopharyngoplasty alone.

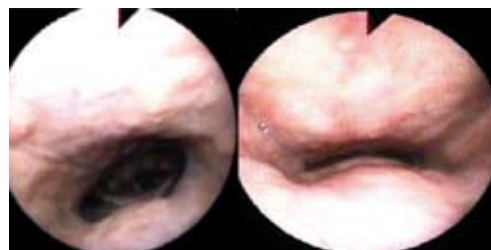


Fig. 4. a, b: Müller's maneuver

Sleep endoscopy- this diagnostic method was done in only 9 patients in which surgery for nasal obstruction was performed before the treatment with oral appliances. The endoscopy was done just before the patient was put under general anesthesia. Propofol was used for sleep induction. Fiber endoscopy was performed through the nose and the site and the volume of the collapse of the soft tissues of the palate, pharynx and the tongue were documented. This method is more precise than the Müller's maneuver, for the patient is asleep and the conditions are closer to the natural sleep.

Polysomnography and polygraphy were performed by specialists of sleep medicine in different certified laboratories or at the home of the patient. AHI, O<sub>2</sub> desaturation, snoring events were evaluated. Based on the AHI OSA was graded as mild, moderate or severe – mild OSA as an AHI of 5 – 14 events per hour; moderate OSA as 15 – 30 events per hour; and severe OSA as an AHI of greater than 30 events per hour.

The dental examination included the assessment of a full dental status, occlusion check and screening for temporomandibular joint disorders (TMD). Condition for the treatment with oral appliance was the presence of at least 20 teeth, showing no dental or periodontal pathologies, sufficient prosthodontics restorations and no TMD symptoms, such as pain by palpation of the lateral and dorsal area to the TMD, articular sounds, pathology of the masticatory muscles, deviation and limitation of the mandibula mobility.

On the first visit, for manufacturing of the oral appliances, we took impressions of the the upper and lower jaw with a vinyl polysiloxane (VPS) impression

material with a prefabricated standard impression trays and registered the position of the mandibula, using the George-Gauge™ (Fig. 5) bite registration set (Scheu Dental GmbH). For the registration we measured the distance between the centric relation and the maximal protrusion with the integrated millimeter scale. The needed protrusion for the patient was calculated as 85% of the measured distance. We used the upper screw to fix the determined position of the mandibula and after that we registered the bite with an a-silicon registration material.



**Fig. 5:** George- Gauge™ bite registration fork

The integration of the oral appliance was conducted on the second visit in the dental office after the manufacturing by the dental technician. We controlled the sufficient fitting of the upper and lower splint, as well as the right position of the mandibula and instructed the patients how to use and take care of their oral appliance. One week after the intergration of the splints the patients were recalled for a check up.

The patients could choose between two types of oral appliances: Silenor- sl® (Erkodent Erich Kopp GmbH) (Fig. 6) and Torton-Adjustable-Repositioner – TAP® (Scheu Dental GmbH) (Fig. 7). In both cases the basic function of the oral appliance was to hold the jaw forward, so the tongue and soft tissues of the throat do not collapse, causing snoring and sleep apnea. The preference of the patients was based on the price difference of the appliances.



**Fig. 6:** Silenor-SL® oral appliance (source: Erkodent GmbH, <https://www.erkodent.com>)



**Fig. 7:** TAP® oral appliance (source: Scheu Dental GmbH, <http://produkte.scheu-dental.com>)

23 of the patients used Silenor-sl®, the rest 14 used TAP® oral appliances. The Silensor-sl® appliances were manufactured in a certified dental laboratory in Sofia, Bulgaria; the TAP® appliances – in certified dental laboratory in Bonn, Germany. Both Silenor-sl® and TAP® devices consist of one splint for the upper jaw and one for the lower jaw, that are connected by different mechanisms. In the Silensor-sl® appliance the lower jaw is held in the predetermined position by two connectors, that are fixed laterally to the splint. The jaw movements are possible, but no falling back of the lower jaw. In the TAP® device the mandibular and maxillary splits are joined with a fixed mechanical hinge and inseparable pivot point during sleep. The TAP® is titratable with a single point of central adjustment, which prevents uneven bilateral adjustment that may create an irregular bite and jaw discomfort.

The success rate of the therapy with oral appliances was measured according to the AHI before and six months after the treatment. The criteria for successful treatment was the reduction of the AHI with more than 50% from the base line or treatment outcome with AHI of less than 10 events/hour. Based on these criteria the mean AHI reduction was calculated and analyzes- before and after treatment with oral appliances. Furthermore the mean pre and post treatment results of the ESS were compared in order to assess the influence of the oral appliance on the quality of sleep.

## Results

### Pretreatment results

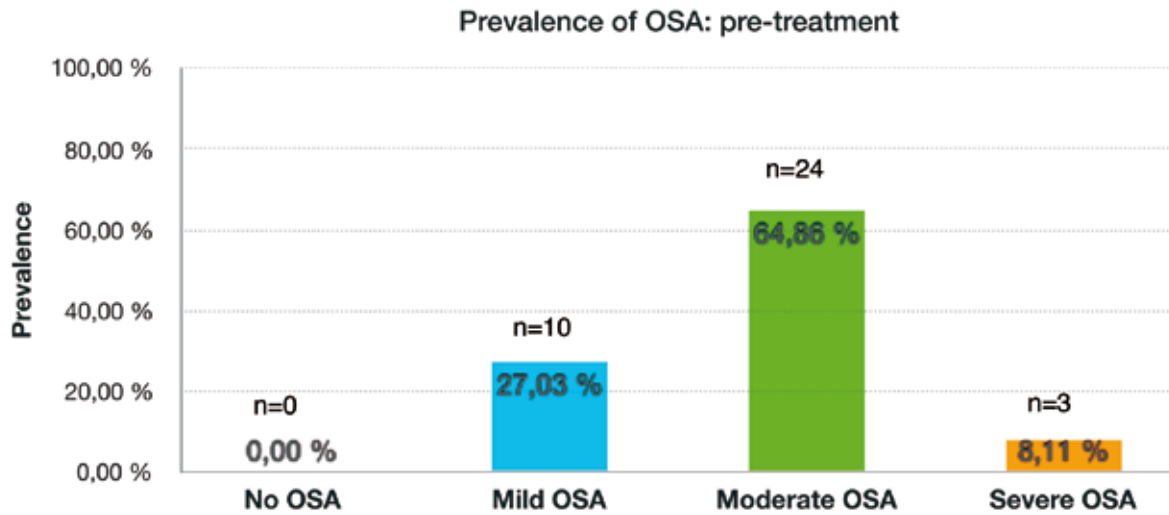
According to the grade of OSA, based on the AHI before the treatment, 10 of the patients suffered from



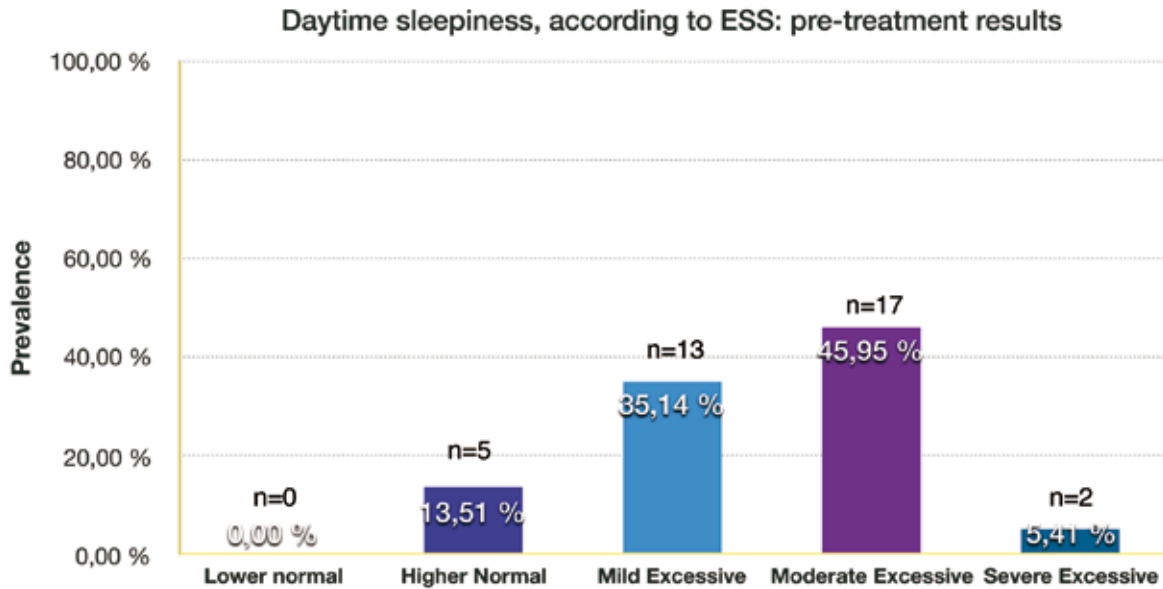
a mild form of OSA, 24 patient – from a moderate form of OSA and 3 of the cases were diagnosed with severe OSA. **Table Nr. 1** represents these results. The mean AHI was 19,45 events/hour.

**Table Nr. 2** summarizes the results of the pretreatment assessment of the ESS. The mean Epworth sleepiness scale score was 12,7.

**Table 1:** Prevalence of the different grades of OSA among the patients before the treatment (n = 37), according to AHI.



**Table 2:** Prevalence of daytime sleepiness grade among the patients before the treatment (n = 37), according to ESS

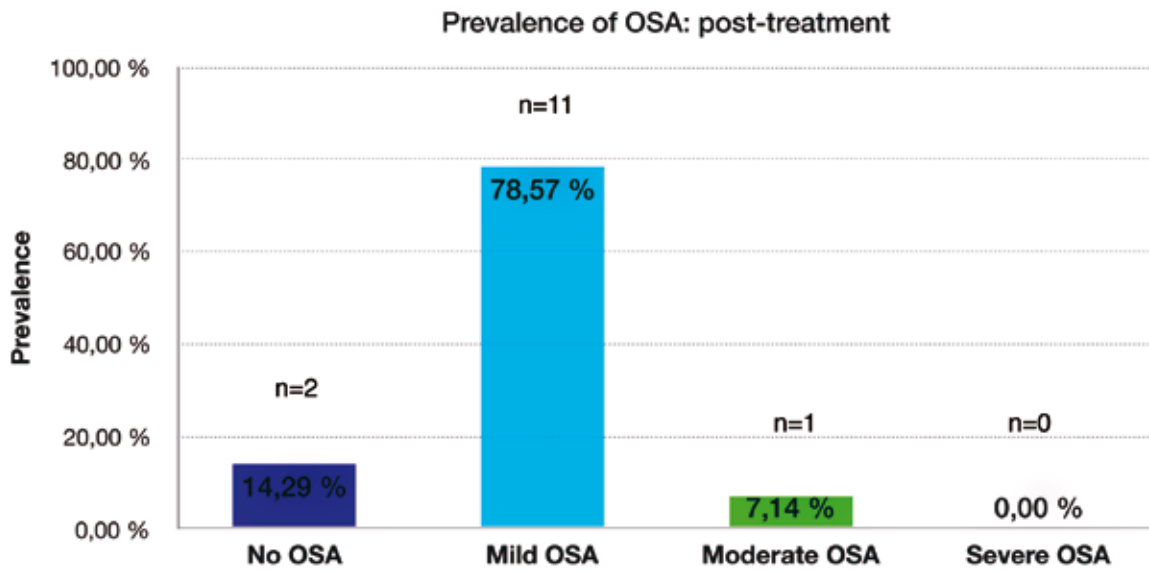


**Post treatment results**

In the post treatment period 32 patients out of 37 were followed. The other 5 answered on phone calls, but did not came for checkup and post treat-

ment assessment. In these patients the ESS was measured by phone calls. The mean post treatment ESS score was 8,6. **Table Nr. 3** represents these results.

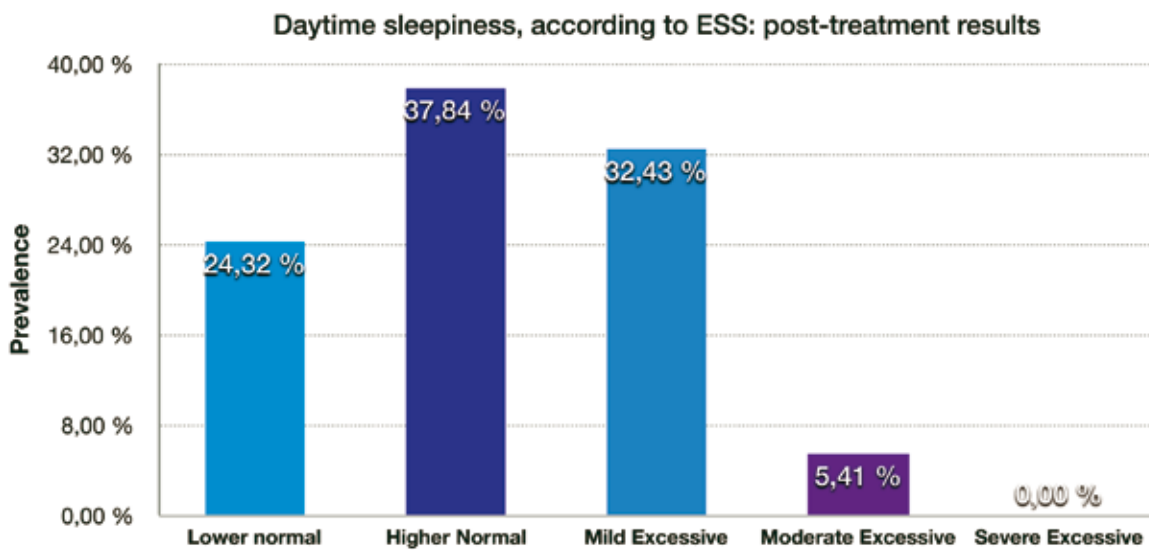
**Table 3:** Prevalence of the different grades of OSA among the patients after the treatment (n = 14), according to AHI.



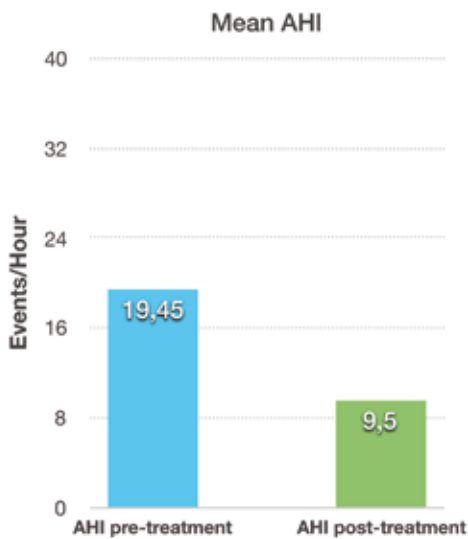
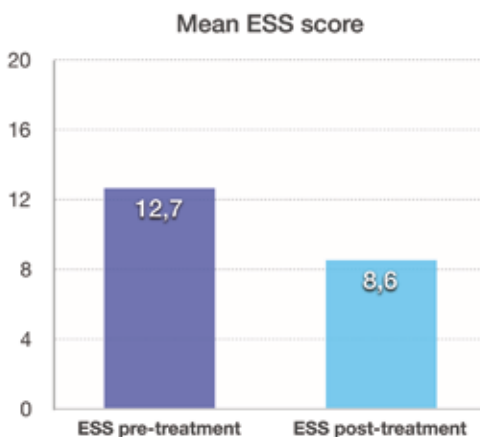
AHI after the treatment was measured in 14 patients. The others refused the PSG examination. **Table Nr. 4** summarizes the post treatment results,

according to the AHI. The mean post treatment AHI was 9,5 events/hour, which means that the success rate is 95%.

**Table 4:** Prevalence of daytime sleepiness grade among the patients after the treatment (n = 37), according to ESS



**Tables Nr. 5** and **6** compare the mean values for the AHI and ESS score before and after the treatment. None of the patients showed dental complications.

**Table 5:** Mean AHI before and after the treatment.**Table 5:** Mean AHI before and after the treatment.**Table 6:** Mean ESS score before and after the treatment.**Table 6:** Mean ESS score before and after the treatment.

## Discussion

According to most of the guidelines (3, 4, 5, 12) the oral appliances are indicated for treatment of mild to moderate OSA, or severe OSA patients unable to tolerate or adhere to CPAP. Some authors offer oral appliances as a first stage treatment in patients with the same indications (13, 14, 15). It shows that CPAP may be the golden standard for treatment of OSA, but its effectiveness is limited by intolerance and poor compliance, with failure rates of 46 – 83% (6), especially among younger patients and the so called “alternative treatment options” could be first line treatment as well in selected patients (8, 9).

OSA is a multifactorial disease with many different symptoms, so the approach towards it should be multidisciplinary. From all 37 patients our primary patients were 24. The rest 13 patients came to us looking for another option by themselves, after they have been offered CPAP treatment by sleep medicine specialists, where the initial diagnosis was set. The success rate of the treatment is typically expressed as a reduction in AHI with more than 50% from the base line, or treatment outcome with AHI of less than 10 events/hour (16, 17). According to these criteria the success rate of the oral appliances ranges from 30% to 85% and for CPAP treatment from 62% to 100% (16). These results show, that the mean AHI reduction rate is higher in the patients using CPAP (16). However, adherence to oral appliances has been reported to be 76% – 95%, which is superior compared to CPAP adherence ranging from 30% to 80% (18). Studies since 2005, that looked at therapy with MADs have reported mean AHI reductions of between 30% and 72%. Reviewing the data of these studies revealed a complete response (AHI < 5) or partial response (50% reduction in AHI from baseline, but AHI > 5) of between 45% and 100% (17, 19-24). Studies with higher response rates recruited patients with lower AHI at baseline. Blanco et al. (19) reported a 100% response rate, however the study had limitations due to small sample size and a high proportion of subjects withdrawing from the trial.

Epworth Sleepiness Scale in all recent studies of patients with oral appliances shows a significant improvement of daytime sleepiness, compared to inactive appliances (19, 20, 25, 26). Phillips CI et al. reported that oral appliances and CPAP have similar improvement in sleepiness based on Epworth Sleepiness Scale (27).

According to our study, the success rate of the treatment of our patients measured as AHI reduction less than 10 events/hour is very high (95%). The mean AHI reduction is 9.5 events/h. compared to 19.45 before the treatment, which is in accordance with the cited results.

The mean Epworth Sleepiness Scale result after the treatment was 8.6 compared to 12.7 before the treatment.

The compliance of using oral appliances was very high too. One of the patients was using his appliances only from time to time because of salivation during sleep.

The high successive rate of our patients treated with oral appliances is, in our opinion, due to the

precise pretreatment assessment of the patients. The oral appliances were used mainly in patients with mild (10 patients) or moderate (24 cases) grade of OSA, out of 37 cases. The patients with severe OSA were only 3.

However, the difference between the number of the patients, diagnosed with the three different forms of OSA, does not allow us to compare the success rate of the therapy in the different groups. Due to the study design a direct comparison between the success rate of the two types of oral appliances – TAP® and Silensor-sl®, could not be made, because every patient was treated with only one of the devices.

The extensive work out of the patients before the treatment is of uppermost importance for the prediction of the good results. The endoscopy of the upper airways, the Müller's test and the sleep endoscopy were of great value for the assessment of the site and the volume of the upper airway collapse. The exact determination of the site of obstruction is essential for the correct treatment. Most of our patients had multilevel obstruction. The nasal patency had to be surgically corrected before the treatment with oral appliances in 9 patients. The good nasal patency is of great importance of the high adherence of the patients using the TAP appliances, in which the mouth is closed and fixed by the splint.

Most of the complications of the oral appliances are mild and temporary and according to some authors their expression could be associated with the greater level of protrusion (28). Short-term side effects mostly appear in the first few weeks of the treatment and they are usually associated with oral discomfort, tenderness of the teeth, pain in the temporomandibular joint, gingival irritation, myofascial pain, hypersalivation or dryness of the mouth (10, 16, 14, 29, 30). The treatment of our patients did not show any significant side effects of the oral appliances with exception of some morning stiffness of the jaws, which was seen in 5 cases and hypersalivation during sleep in one. Possible

long term side effects of the treatment with oral appliances are noted as early as six months after beginning of the therapy and could include changes of the occlusion, decrease in overbite and overjet, involving protrusion of the lower and retrusion of the upper incisors, minor skeletal changes such as increase of face height and downward rotation and anterior movement of the mandibula (16, 29, 30, 31, 32). However, skeletal changes are not so likely to appear in adults, because of the completed skeletal growth (33, 34, 35). Despite the risk of long term dental and skeletal side effects of MAD, they are considered as a less likely reason for the termination of the treatment in comparison to the intolerance to CPAP therapy (36). With a precise dental examination and frequent recalls by an experienced dentist in the field of orthodontics and/or OSA treatment with oral appliances, as well as a proper adjustment of the MAD, the side effects appeared to be not as harmful, as previously supposed. In this connection the benefits of a successful treatment of OSA are superior than the possible dental side effects (29, 37, 38). None of our patients had such side effects. Probably the relatively short period of follow up- 2 or 3 years did not allow us to find such complications.

## Conclusions

1. Oral appliances are high effective in the treatment of selected patients with OSA, mainly mild and moderate cases according to the AHI.
2. The precise pretreatment work out is of uppermost importance in assessment of the grade of OSA and the site of obstruction.
3. If there is a multilevel obstruction, combined treatment with surgery and oral appliances could be a viable option for such patients.
4. The precise measurement of the needed protrusion and good fitting of the oral appliance probably plays a certain role in diminishing of the possible side effects.

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