



THE CHALLENGES OF MANDIBULAR ADVANCEMENT DEVICES - A NEW DESIGN ADJUSTABLE DENTAL APPLIANCE FOR THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA

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ABSTRACT

Introduction: Obstructive Sleep Apnea is one of the prevalent breathing sleep disorders, especially among the elderly population of the modern world. Obstructive sleep apnea is defined as the occurrence of five or more episodes of complete or partial upper airway obstructions per hour during sleep. Over the years, we have seen many different appliances that target treating patients with apnea syndrome. The result is that they all seem to deal with the problem at hand on a scale from mild to moderate OSA.

Aim: The goal we set was to create a new design of an adjustable dental appliance which will help patients with obstructive sleep apnea.

Materials and Methods: Impressions of the mandible and maxilla were obtained to create the specific dental appliance. The special design of the appliance includes an adjustable metal bar that is placed frontally to the anterior upper teeth and can be adjusted to the different levels of mandibular advancement. Adam's clasps have been affixed to the first lower molars, and two occlusal splints to the occlusal surfaces of all lower teeth in order to secure the device in place. To prevent mouth opening during sleep, two barriers have been built into the vestibular surfaces of the upper premolars and molars.

Conclusion: With the help of this innovative appliance design, dental professionals may now properly position and make necessary corrections in patients who suffer from obstructive sleep apnea and snoring.

Keywords: Obstructive sleep apnea, Mandibular Advancement Devices, Treatment of Sleep Apnea,

INTRODUCTION

Obstructive Sleep Apnea is one of the prevalent breathing sleep disorders, especially among the elderly population of the modern world. Obstructive sleep apnea is a common chronic sleep disorder.

These occurrences are attributed to the hypertrophy of the tonsils, immense adipose formations around the tonsil area and posterior pharyngeal wall, plus hypertrophy of the tongue, narrow and short lower jaw, and retrognathia, contingent upon the patient's morphology in the pharyngeal area.

In 2014, the American Academy of Sleep Medicine (AASM) created the International Classification of Sleep Disorders (ICSD-3), which defines primary snoring (PS) as a sleep-related breathing disorder. PS is classified under the subcategory of isolated symptoms and normal variants.

In his 2009 study, Church S proved that primary snoring affected about 40% of the population. It has also been found to affect middle-aged men more often [1].

Obstructive sleep apnea (OSA) is a common chronic sleep disorder. According to Lv R et al., this problem affects between 9% and 49% of the entire population [2].

More specifically, OSA is defined as the occurrence of five or more episodes of complete (apnea) or partial (hypopnea) upper airway obstruction per hour during sleep. The severity of the condition can be assessed by the Apnea-Hypopnea Index (AHI) and the Respiratory Disturbance Index (RDI), especially when it comes to symptoms associated with sleeping disorder [3].

A number of epidemiologic studies in both OSA patients and the general population demonstrate that Obstructive Sleep Apnea (OSA) leads to systemic hypertension [4].

Some studies have suggested that this relationship may be mediated by concomitant risk factors such as obesity. However, according to others, OSA has been shown to be a major factor in the pathogenesis of hypertension [5].

Sleep Apnea can lead to accidental phenomena such as long Apnea – Hypopnea with prolonged gaps, at times lasting longer than 2 minutes. The desaturation of the blood and impossibility of breathing in these accidental phenomena could lead to serious changes in the quality the patient’s sleep as well as serious interactions with daytime consequences [6].

The multidisciplinary approach to treating patients with apnea syndrome has led to the development and introduction of numerous types of oral appliances for the treatment of OSA. Undoubtedly, these devices are all suitable for use in mild to moderate cases of OSA.

Mandibular advancement devices (MAD) are regarded as the main treatment tool for patients with mild to severe OSA. For the treatment of severe OSA patients who are unable to tolerate continuous positive airway pressure (CPAP), MAD can be a practical option. With the help of the primary purpose of MAD – advancement of the lower jaw and the tongue towards an anterior position, these appliances support the upper airway (UA) to enlarge and decrease the collapsibility of UA during sleep [7].

AIM

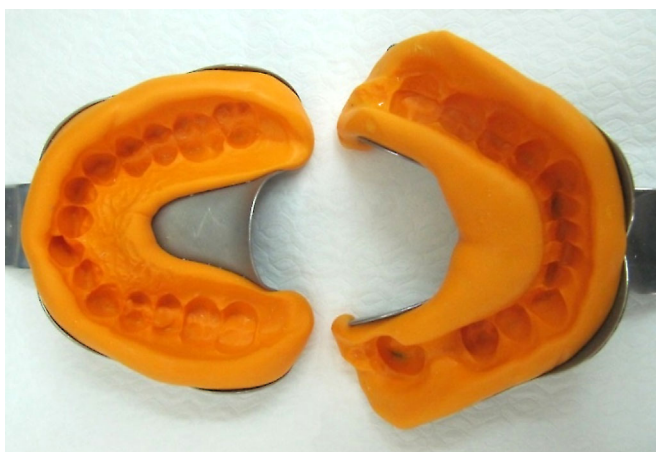
The goal we set was to create a new design of an adjustable dental appliance which will help the treatment of patients with obstructive sleep apnea. This new item will be positioned in a group of the Mandibular Advancement Devices.

MATERIALS AND METHODS

Methodology of manufacturing a functional-reflex mandible - positioning applicator

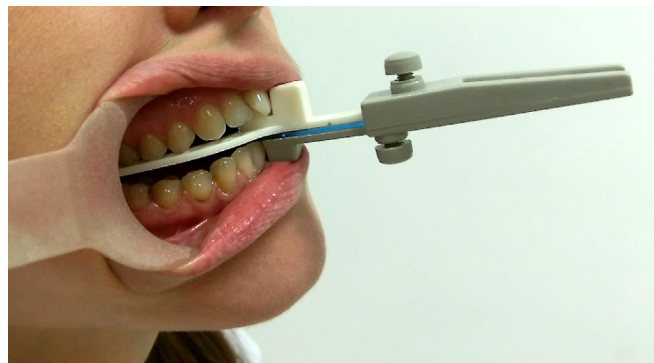
For the creation of the particular dental appliance, silicone impressions of the maxilla and mandible were taken (figure 1). After casting the impressions, the stone models were prepared to analyse the patient’s tooth rows. The analysis of the teeth rows in the upper and lower jaws we made adhering to clinical and laboratory findings in particular patient – the position of the teeth, the correspondence between both of the jaws in a correct relationship, the position of the lower jaw after protrusion.

Fig. 1. Impressions of the maxilla and mandible



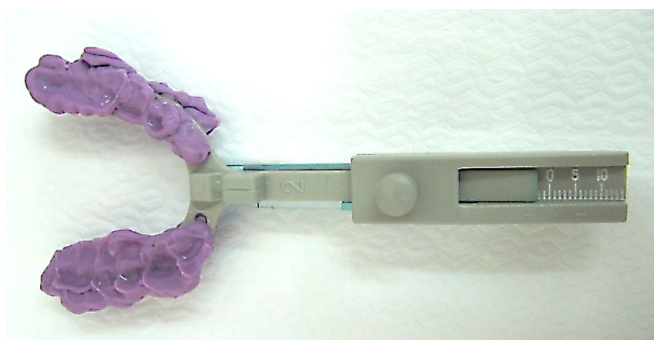
The position of the mandible has been determined to be at 50% of the maximum protrusion. We used the George Gauge tool to determine the ideal mandibular placement ¹⁰(figure 2). This instrument shows with absolute accuracy the level of protrusion using the ruler in a sliding box.

Fig. 2. George Gauge instrument fixation of protrusion



A special bite fork for the determination of the mandibular protrusion has been used (figure 3).

Fig. 3. Bite fork



After the bite fork is positioned between the patient’s teeth rows, the patient cautiously closes their mouth and begins to push their lower jaw forward as hard as they can until the bite fork starts to hurt the Temporomandibular joint (TMJ). After that, the patient begins to shift their lower jaw backward until the mandibular teeth are in their most retrusive position. The specialist can ascertain the correct position in the sliding box of the instrument based on the George Gauge scale thanks to these forward and backward movements of the mandible. In order to reach the maximum protrusive and retrusive position of the mandible, the patient begins to repeatedly slide the jaw forward and backward.

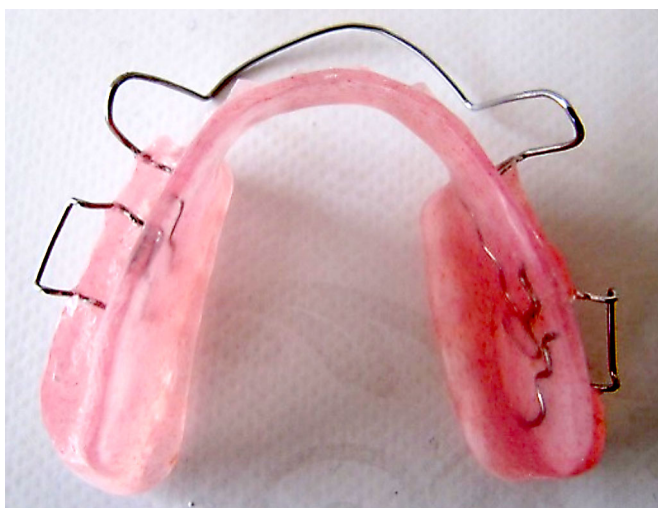
The chosen position must fix the lower jaw in a way that opens the retropharyngeal space while allowing the mandible to be seated to the maxilla without causing pain in the TMJ. The patient can obtain the maximum mandibular protrusion with the use of this tool and expert guidance. Generally speaking, a lot of publications and authors advise keeping the lower jaw positioned at 75%

of its maximum potential protrusion. According to well-known protocols of the desirable mandibular position in the treatment with MAD, we achieved 50% of the maximal protrusion of the patient with the help of George Gauge [8].

The special design of the appliance includes an adjustable metal bar, which has been placed frontally to the anterior upper teeth (11, 12, 13, 21, 22, 23) and can be adjusted to the different levels of the mandibular advancement. A 0,9 mm orthodontic wire was used in the manufacturing of the metal bar.

Two Adam's clasps have been affixed to the first lower molars, and two occlusal splints to the occlusal surfaces of all lower teeth in order to secure the device in place (figure 4). The Adam's clasps are made with orthodontic wire that has a diameter of 0.8 mm.

Fig. 4. Elaborated dental appliance



During the wearing of the appliance through the sleep period, the splints covering the masticatory surfaces of the lower teeth maintain a consistent spacing between the rows of maxillary and mandibular teeth, increasing the area available for continuous airflow. However, the increased interdental space between the upper and the lower teeth rows must be very precise because any inaccuracy

can lead to stress in Temporomandibular joints and masticatory muscles in the patients. At the same time, when the achievement of the proper mesial position of the mandible is not well determined, the increased space can become an obstacle to the successful treatment with the newly designed intraoral appliance.

The lingual portion of the lower teeth has been covered in resin to stabilise the appliance in a fixed position during sleep and allow for free airflow. Additionally, while the appliance is being worn, this lingual portion allows the tongue to be positioned in a more optimally frontally oriented position. The metal bar made from orthodontic wire can be adjusted to the acceptable inclination to the frontal upper teeth with the instrumentation of bending the wire in lingual or vestibular direction and using this, the lower jaw can be seated at the different protrusive positions from the maximal protrusion.

Two barriers of the vestibular surfaces of the upper premolars and molars have been constructed to avoid free opening of the mouth during the sleep period. These barriers cover the vestibular (facial) surfaces of the premolar and molar teeth over the equators of the facial surfaces. Thus, during the time of use, the patient can be comfortable wearing the appliance without the risk of freely opening the mouth due to the relaxed facial muscles.

Dental specialists can elaborate on the appliance using acrylic resin and/or soft (elastic) resin-based materials. We specifically used both acrylic and soft (elastic) resin materials in the development of the new appliance to cure OSA and snoring.

Thus, the appliance must be delivered to the patient after careful adjustment, which includes adjustment of the occlusal splint and vestibular barriers giving careful attention to the retentive elements – Adam's clasps.

RESULT

Measurements of basic anthropometric markers were made early in the study in patients with OSA receiving oral applicator treatment (table 1).

Table 1. Basic anthropometric markers in the patients under study

	Mean±SD
Age	46.3±8.1
Height	1.8±0.01
Weight	88.8±13.8
BMI	29.0±4.8

A polysomnographic test was used to assess the therapy's efficacy both with and without an applicator (table 2).

Table 2. A polysomnographic test was used to assess the therapy's efficacy both with and without an appliance

n=20	Baseline	OralAppliance	p
	Mean±SD	Mean±SD	
TRT(min)	386.0±122.5	467.9±73.9	0.002
TST(min)	307.3±126.2	372.8±70.5	0.004
Latency	26.8±18.1	24.7±14.6	0.409
N1pro	5.5±2.3	4.9±4.3	0.534
N2pro	65.7±13.3	62.7±11.9	0.088
N3pro	16.5±13.0	16.2±11.1	0.786
REMpro	12.3±8.2	16.1±6.2	0.016
Awakenings	22.0±10.2	31.8±23.2	0.05
WASO	51.9±22.7	70.5±32.8	0.028
	83.9±10.1	84.1±6.7	0.905
AHI	45.5±30.8	33.4±31.1	0.001
AHINREM	44.0±30.9	30.8±32.8	0.001
AHIREM	52.7±32.4	39.6±24.4	0.036
AI	27.3±28.3	23.1±29.1	0.159
HI	18.2±11.0	10.3±9.1	0.023
ApMeanDur	24.1±6.4	20.9±6.9	0.005
HypoMeanDur	32.1±5.8	27.9±7.4	0.042
ArIndex	46.4±12.0	31.0±14.2	0
SpO₂mean	92.9±1.8	93.5±1.9	0.011
SpO ₂ nadir	77.9±7.3	79.9±7.0	0.126
SpO₂desatav	8.5±3.0	5.6±2.4	0
HRmin	51.4±6.2	52.5±7.2	0.437
HRmax	92.0±13.4	96.7±9.7	0.054
HRaverage	67.0±8.5	65.8±9.3	0.253

The Increase in REM sleep and the reduction of the arousal index indicate improvement in both micro- and macro architecture of sleep and correspond to patients reporting better sleep quality and an amelioration in daytime sleepiness.

Walker Engström et al. I also report a significant decrease in daytime sleepiness in the sixth month since the initiation of the therapy, which mildly correlates with AHI. On the other hand, Arab et al. report no significant effect on REM sleep and daytime sleepiness; however, a reduction in respiratory microarousals was present in their patients. No significant improvement in daytime sleepiness was reported in other studies as well. These discrepancies may originate in the complex nature of sleepiness and its problematic assessment by questionnaires only.

The placebo effect cannot be excluded in non-randomized studies as ours. The increase in the number of

awakenings and the increased duration of time after sleep onset may be a possible side effect of the oral appliance application, which patients do not report subjectively. Though not infrequent, the side effects of OA appear to be mild and transient, usually disappearing with consistent use of the device, and commonly include pain and Temporomandibular joint locking, headache, hypersalivation and xerostomy.

We found a remarkable reduction in AHI, both in REM and in NREM sleep, with changes being more distinguished during NREM sleep. The duration of apneas and the associated desaturations were also improved. Several non-randomized uncontrolled studies report either normalization or a significant decrease of AHI when applying treatment with OA.

In a randomized study, including 77 patients with an OSA, 45% of the cases presented with normal AHI, exhibiting a 92% treatment compliance. Our results are in agreement with previous reports, demonstrating a significant reduction in respiratory events, measured by AHI (33.4±31.1 vs 45.5±30.8, p<0.001). Moreover, these data suggest the possibility of even further improvement in regards to long-term use of the appliance.

Having in mind that OSA requires a tenacious treatment approach, additional studies are needed to assess the full therapeutic potential of OA.

DISCUSSION

CPAP (continuous positive airway pressure) therapy is still the most prescribed treatment option for reducing apnea symptoms and the golden standard in the interdisciplinary protocol in the treatment of OSA, but there are many different sleep apnea treatment options readily available to patients. However, even with all the options and advances in CPAP therapy, some people are still unable to tolerate any type of CPAP due to discomfort. Oral appliances applied by dental professionals are an alternative treatment for many patients who cannot or do not want to use CPAP therapy. They come in many different designs, but in their biggest part are usually custom made. The main purpose of the dental appliance is to keep the airway open during sleep, thereby preventing the blockage of normal airflow during breathing. As a preferred treatment for CPAP therapy, OA is a rational alternative if patients cannot tolerate CPAP. Mandibular advancement devices are the logical prescription in patients with snoring and OSA because of the insufficient evidence of tongue-retaining devices [9]. The newest appliances, such as oral pressure therapy, which uses a mouthpiece and a vacuum pump to stabilize upper airway tissue, are being studied [10].

Dental devices are not intended to replace CPAP therapy for most patients and should be treated as a backup plan. According to the classification of the Mandibular Advancement Devices, they can be divided into two main

groups – monoblock and biblock intraoral appliances. Adhering to the new design of dental appliance for the treatment of snoring and OSA we can summarize that this device belongs to the group of monoblock intraoral advancement devices.

Suitable candidates for OA therapy in general are patients with sufficient healthy teeth, alveolar ridges without retentions and undercuts, absence of temporomandibular joint disorders and adequate possibility for protrusion of the mandible. Nevertheless, missing teeth or insufficient teeth in a particular jaw—the maxilla or mandible—can not be an obstacle to treatment with MAD. In these clinical cases, the implants are a corrective way of achieving good retention for the mandibular advancement appliances, as reported in many articles [11].

Following the laboratory protocol for the elaboration of the new design device with acrylic resin, we must mention that the adjustment into the mouth of the patient has been accompanied by more problems, such as difficult insertion onto the lower jaw, especially in cases with a retentional alveolar bone in lingual part, many dislocated teeth in the maxilla and mandible. When the new design device was elaborated from elastic (soft) resins, the adjustment of the appliance had no difficulties to be delivered to the patient.

Reporting the efficacy of MAD, Zhou and Li noticed better results with the monoblock appliance than with the block appliances. The design of the block appliance is used to maintain an admissible range of movements in the mandible. Because the missing interlocking acrylic resin step (occlusal pads) can prevent the decrease in the existing airway space, the enlargement of the UA spaces became unsteady in the protrusive position of the lower jaw [12]. Both monoblock and biblock advancement appliances are equivalent in periods of their use as the method of OSA treatment in a positive way and are associated with similar adverse and side effects, according to Isacsson et al. [13].

The medical community recognizes OA as a useful method of treating obstructive sleep apnea in adults, especially in mild and moderate forms of OSA. The new Mandibular Advancement Device (MAD) design allows practitioners to find the most beneficial device position throughout a patient's therapy with the device. Being able to position the mandible to the desired convexity provides a variety of attempts to find excellent convexity and excellent polysomnography results.

Decreasing the apnea/hypopnea index (AHI) with the help of MAD is one of the major benefits in the treatment of patients with OSA. Reducing the symptoms like snoring and arousals in the time of wearing MAD improves the polysomnographic parameters like the AHI compared to placebo appliances [14]. The efficacy of the application of mandibular advancement devices shows a complete reduc-

tion of the OSA symptoms obtaining an AHI $\leq 5/h$ for approximately one third of patients. The next third of patients demonstrates a decrease in AHI by 50% or more, and the last one third of patients only manifests a negligible improvement in OSA severity [28].

In many articles, it has been reported that CPAP and MAD treatment of snoring and OSA reduce in the severity of the disease; however, CPAP reduces the symptoms to a greater degree than MAD therapy according to all studies regarding patients with mild to severe OSA [15].

The main benefit of wearing MAD in the treatment of OSA has been shown to be an increase in upper airway measurements. Airflow is supposed to increase, improving the symptoms of Obstructive Sleep Apnea. Treatment success has usually been declared as a reduction in the AHI and RDI to either less than 5 times per hour or more than 50% reduction from baseline. Mandibular advancement theoretically stretches the soft palate with concomitant stiffening of the oropharyngeal wall, achieved through the strengthening effect of the lateral wall of the soft palate relative to the base of the tongue via the palatoglossal arch [16].

With increased mandibular advancement, the UA becomes wider, which explains the better results of both designs at 75% than at 50%, consistent with the results [17].

The success of the treatment with intraoral Mandibular Advancement Devices can be described as a reduction in the AHI and RDI. However, the new intraoral appliance design has to be proven in dental practice after a period of application to a group of patients diagnosed with OSA and snoring, using polysomnographic results, and to be approved for use as a method of choice according to the latest guidelines of the American Academy of Dental Sleep Medicine [18].

The clinical manifestations of OSA are loud snoring and repetitive partial or complete collapse of the pharyngeal airway, resulting in oxygen desaturation, fragmentation of the sleep and increased activation of the sympathetic nerve during sleep. Daytime sleepiness, adverse cardiovascular outcome and neurocognitive impairment are the most common consequences.

The precise adjustment of the different oral appliances for the treatment of obstructive sleep apnea and snoring can be made by the patient (in a small group of titratable OA) and by the dentist in all of the custom-made appliances. This adjustment is based on symptoms like daytime sleepiness, snoring, and fatigue. In 2009 years, Almeida et al reported that 60 % advancement can be effective for 65 % of the people diagnosed with OSA, and the effectiveness of the treatment rises to 95.4 % when the mandible protrudes further [19]. In order to evaluate the therapeutic effect of this new design oral appliance with a 50 % or 75 % advancement position as the initial therapeutic mandibular position in the present pilot study, ad-

justment of mandibular advancement was not performed, and further polysomnographic test will be accomplished. Various advanced positions of the mandible could be of genuine interest in discussing and comparing the effectiveness and side effects of the particular intraoral appliance.

Many authors have reported on various side effects of Mandibular advancement devices. The literature reported evidence of occlusal disturbances, rarely toothache in clasp-supported teeth. Other studies have also related temporomandibular disorders to the side effects of MAD application and the increasing intensity of complaints with further advancement of the mandible [20]. Current evidence suggests, on the other hand, that greater mandibular advancement leads to greater improvement in OSA symptoms [21]. Mandibular advancement devices with a range of advancement between 50% or 75% significantly improved the well-known Epworth Sleepiness Scale (ESS) and sleep-related Visual Analog Scale (VAS) compared to maximum intercuspation and substantially increased the pharyngeal airway in the lateral X-ray in patients with OSA according to authors like Rashmikanthetal. in 2013. No observable difference was reported between 50% and 75% in advancement. Walker Walker Engström et al. in 2003 declared that they had not found a significant difference in the Apnea Index and Apnea-Hypopnea Index in these two positions of the mandible in patients with diagnosed severe OSA. In 2003, Tegelberg et al. reported a similar rate of treatment effectiveness in mild to moderate OSA patients [22].

This advancement is more appropriate in patients with severe OSA than in patients with moderate OSA, where 50% of advanced mandible was effective for reducing AHI and other polysomnography parameters. These clinical findings correspond to that the degree of mandibular protrusion through MAD was effective in one percent of ad-

vancement in severe OSA patients and another percentage of advancement in moderate OSA patients, respectively 75% in severe and 50% in mild to moderate OSA [23].

According to the American Academy of Dental Sleep Medicine (AADSM), "OA have to be custom made and allow the mandible to be positioned in 1 mm or less protrusive position with the help of adjustment range and to be advanced at least 5 mm". Custom-made OA decreases OSA symptoms and severity more efficiently than prefabricated thermoplastic or boil-and-bite oral appliances [24].

According to this statement of many authors, in the treatment of OSA with adjustable OA, we present a newly designed oral appliance that can be adjusted at the most appropriate position for the mandibular position during sleep.

CONCLUSION

This new dental appliance design allows dental specialists to achieve the right position of the mandible and make the correct adjustment in patients with snoring and Obstructive Sleep Apnea. Advantages of the device include custom made, effectively works for those who travel a lot or want to have a generator-free option, great to use in conjunction with CPAP therapy, more economical. At the same time, the disadvantages should be mentioned: uncomfortable to wear, less effective in treating Severe Obstructive Sleep Apnea, it can cause temporomandibular joint problems and also may cause hypersalivation.

Limitations of the study

Further studies are needed to prove the effectiveness of the proposed device by applying it to a larger group of patients.

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