The efficiency of **mandibular advancement devices** for the treatment of **snoring** and mild and moderate sleep **apnoea-hypopnoea**.

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**Abstract:**

In the treatment of snoring and sleep-disordered breathing the mandibular repositioning devices are an increasingly important instrument. Its mechanism is based on the advancement of the mandible, which increases the dimensions of the upper airways and the air flow during sleep. Aim of this study was the investigation of the efficiency and tolerability of two types of adjustable devices: OrthoApnea and TAP, custom made appliances placed in 30 patients (22 men and 8 women), mean age 48.6 years old, undergoing an ambulatory, uncontrolled sleep screening before and after using the appliance during one month (placed onto the teeth during sleep).

Key Words: OSAS, MAD, sleep apnoea, snoring.

**Introduction:**

In nowadays the OSA Syndrome (obstructive sleep apnea syndrome) is one of the clinical pictures that play an important role in the chronic diseases (1). It has been demonstrated that a timely diagnosis and an adequate treatment can decrease neurological consequences and have a favorable effect on the cardiovascular health status of affected patients (Punjabi, 2008) (2). Clinically it consists in the obstruction of the air flow during sleep that is caused by a partial or total collapse of the upper airway structures. These respiratory obstructions are accompanied by “snoring” and frequent arousals.

As a result affected people show a number of symptoms: daytime sleepiness and fatigue, due to a restless sleep; morning headache, loss of intellectual capacities and nighttime micturition (McNicholas, 2008). Sleep apnea affects approximately 5% of the adult population, but the problem may be underestimated, due to the growing global prevalence of obesity (Bannon et al., 2006). For decades the continuous positive airway pressure (CPAP) mask has been the treatment option of choice, but its' disadvantages, rejection and intolerance on part of the patients complicate the optimum compliance of the therapy and it has lost its therapeutic hegemony compared to other available alternatives. This resulted in the necessity of working on other solutions that are equally effective but more tolerable.

One of the leading options of this new therapeutic line is based on the increasing interest in the application of oral appliances, especially of mandibular advancement devices as OrthoApnea. The use of these devices is a simple, non-invasive and completely reversible treatment option that achieves many advantages in comparison to other treatment solutions by an easy and immediate therapeutic way. Besides, these systems underwent tremendous technological developments in the last years and they are currently one of the treatments of choice for patients who suffer from with snoring and mild or moderate sleep apnea.
Significance of the treatment of snoring and sleep apnea

Snoring and sleep apnea represent an enormous health importance based on the following reasons:

1. Its prevalence is very high in today’s society, as various studies have demonstrated in the last years. There exists an incidence of 25.4% for snoring, approximately 45% of adults snore frequently and 25% habitually. The prevalence of OSA ranges from 4-6% in males and 2-4% in women among the general adult, middle aged population and this numbers increase markedly with age (3).

2. As a pathology it represents a problem in two aspects, the social that converts these patients in intolerable bed partners and the more serious clinical impact of significant morbidity (4). These impacts can reach a noise level of about 80-90dB (equal to the noise of a truck at high speed on a highway). The limit for hearing damages is estimated at an intensity of 65 dB. Snoring disturbs social and family relationships of patients. Its psychological pressure influences both lives, the daily routine of people who snore, as well as the every day life of people, who suffer from the noisy consequences causing problems in the partnerships.

3. Sleep disordered breathing is very habitual and, therefore, a constant source of problems regarding health and economic impacts. Poor sleep habits aggravate the impairments of health and quality of life causing countless traffic accidents, labor accidents and accidental home injuries. The majority of these disorders lead to drowsiness in its clinical description, disabling affected patients to drive. In all countries the number of fatal accidents increases constantly. According to the WHO, traffic accidents are the fourth leading cause of mortality in the world, and it represents the first cause in men aged between 15 and 24. For every fatality occur 7 serious and 15 minor injuries.

4. The access to diagnosis possibilities is the major problem facing the specialists, as only about 5 to 9% of the population with relevant OSA is diagnosed (5). Clinical researchers seek for diagnostic alternatives to the costly polysonography that is currently the first diagnosis commendation (6). The OSAS is rarely known to the public. The lack of diagnosis is the main medical problem to solve. Recent studies show that in only 6% of medical examinations of primary care, explicit references regarding possible sleep disorders are included. This incorrect diagnosis involves fatal consequences because the pathology is ignored by patients that, without being diagnosed, do not know how to justify and cope with the symptoms that they face day by day. Finally, school and work absence and the reduced capacity at work also cause economic damages.

Study objectives and hypotheses

Study Hypothesis

Mandibular advancement devices (MAD) are efficient for the treatment of snoring and mild to moderate sleep apnea.

Objectives

1. Applying a nocturnal cardio-respiratory and pulse oximetry monitoring ("ApneaLink") in a qualified "snorer" population evaluating the OSA grade (mild/moderate) and if the patient is a candidate for MAD treatment.

2. Describe the clinical findings of the situation before and after treatment with two types of mandibular advancement devices in a series of adult patients.

3. Comparative analysis of the effectiveness of mandibular advancement devices by means of objective and subjective criteria.

4. Evaluating the possibility of implementing this system as an efficient method for the treatment of mild or moderate OSA and cases that do not tolerate CPAP.

Methodology

Description and subject group selection

The study group consists of 30 snoring adults, with mild/moderate sleep apnea, aged between 36 and 68 years, 8 women and 22 men, who were treated with a mandibular advancement device (MAD).

A complete dental examination was performed to get more detailed information about TMJ and dental and bone structure. It included: periodontal and dental examination, panoramic radiography and lateral cephalometry, evaluation of the tongue and soft tissues and, finally, possible occlusion defects.

Inclusion Criteria

- Snorers
- The patient should have the ability to advance the mandible forward and open it without significant limitations.

Exclusion Criteria

- Patients with severe OSAS.
- Patients with rhino-pharyngeal pathology.
- Inappropriately dentition, periodontal diseases without treatment.
- Serious problems in the temporomandibular joint (TMJ).
- Insufficient protrusion capacity.
Methods:

1. Cardio-respiratory polygraphy
2. Epworth test
3. Dental impressions
4. Appointment for adaptation and user instructions

Used devices:

Although there exist over three hundred systems of mandibular advancement devices, we have tested two devices that have, in our opinion, a greater international presence placing them randomly among our study group. The used devices were the Orthoapnea appliance and the TAP appliance (Figs. 1 and 2).

Procedures:

The study and evaluation were performed by the same professional with over 20 years of experience in the treatment of mandibular advancement devices. Objective and subjective assessments were performed prior to placement and after one month of treatment.

The study subjects had to fill in the Epworth test and undergo the ApneaLink after one month of treatment; they underwent also a questionnaire of satisfaction that the subjects answered in collaboration with their partners. This test evaluates the satisfaction of both regarding a better quality of life and noise.

The analyzed variables were: age, sex, MAD type, AHI before and after the MAD therapy, risk index before and after MAD therapy, Epworth index before and after MAD therapy and the level of satisfaction of the patient and his partner after MAD therapy.

Analytic study

In table 2 the mean values of the received indices before and after using MAD1 during one month are compared. The comparison of the parameters was taken by the Wilcoxon test, as it is about paired and small quantity data. In table 3 the same analysis for MAD 2 is repeated.

As reported in table 2, MAD1 has decreased the mean value of all indices, this diminution is statistically significant (p<0.005) in all indices.

Also in the use of MAD2 appeared a statistically significant (p<0.005) diminution of all indices. To compare both MADs we calculated the mean values of the differences between the indices before and after using each MAD. In table 4 the mean values of the differences (index after MAD – index before MAD) for each type of MAD and its comparison through the test of the U of Mann-Whitney is reported, as it is about two different sample groups and the group size is relatively small.

It can be evaluated that MAD2 achieves a greater reduction of all indices than MAD1, although the only statistically significant parameter (p<0.005) is the EPW.
Conclusions:

1) Considering the medical complications of snoring and OSA and the social restrictions and the negative effects on the quality of life the physician should identify the patients that need support. It is a public health problem that can be easily diagnosed and treated. Recent studies even demonstrated that the consumption of public resources is 2-3 times higher in patients with non-treated snoring and OSA than in the population without OSA.

2) It is necessary for all patients to obtain an objective valuation of the multidisciplinary diagnosis results. The specialist should perform a clinical diagnosis, a prior nocturnal monitoring and, after a period of adaptation, a new clinical valuation and objective and subjective examinations. The experienced specialist dentist in the treatment of sleep apnoea with MADs should select adequate cases, perform design and adaption of the devices and control possible side effects through a regular follow up.

3) In our study the efficiency of the mandibular advancement devices was proven. In both cases the mean values of all indices decreased and this diminution is statistically significant (p<0.05) in all indices.

4) The comparative analysis of the efficiency between both types of MADs shows that the Orthoapnea appliance achieves a greater reduction of all indices, although the only statistically significant index was the Epworth test result (p<0.05).

5) The evaluation of our medical trial should be performed through a cost and efficiency analysis, as the basic advantages of the treatment, like the decrease of the morbidity rate in the long and short term, are very evident.

6) Our data support the use of cardio respiratory polygraph monitoring for the evaluation of sleep apnoea detection in subjects of high probability of disease suspicion and a high prevalence or in populations of high prevalence of sleep breathing disorders. Although the controlled PSG is the standard diagnosis tool for sleep apnoea, not all patients have access to such a study in the sleep unit. The sleep unit installations could differ from the patients sleeps standards, there exist long waiting lists in the pneumology services, the sleep study is connected with high costs and the patient’s willingness to sleep one night in a sleep unit undergoing a nocturnal PSG without confirmed OSAS could be very low. This results show that the cardio respiratory polygraphy is a useful complementary technology for the diagnosis of sleep apnoea, due to the sensibility, specificity, and simple use of the device and the resulting low costs of the sleep study. The cardio respiratory polygraphy can be useful in situations where the PSG is a practical principle or in populations with high prevalence of sleep apnoea supporting the options of diagnosis and treatment. This could lead to a timely evaluation of sleep apnoea and a better attention to the patient causing a better health status and life style.

7) Finally we conclude that the adjustable mandibular repositioning device is an efficient treatment alternative for patients with snoring and sleep apnoea. The severity of the OSAS motivates the specialist to get a better knowledge about it and makes him aware of the importance of its multidisciplinary character. Including the participation of a dentist that is well experienced in the treatment of OSAS patients through the use of MAD, a treatment alternative with a high patients’ acceptance, because of its low treatment costs and high efficiency being an individualised treatment option or in combination with other treatments.

8) It is recommendable that the public health authorities formulate a valid preventive dentistry plan, as it was demonstrated that the sleep apnoea problem is a sanitary priority of high relevance.