Mandibular Advancement Device (MAD®) to Treat Sleet Apnoea-Hypopnoea Syndrome and Chronic Snoring

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Abstract— **This paper presents a structural and clinical validation of Mandibular Advancement Device (MAD), whose design was inspired by a need detected in patients suffering from Sleep Apnoea-Hypopnoea Syndrome and/or chronic snoring. The main objective of MAD is to advance or move the jaw with respect to the maxilla, in order to keep the airway open or released to a sufficient degree, in such a manner that its fortuitous or unconscious closure is prevented. It is, therefore, an effective device to treat Sleep Apnoea-Hypopnoea Syndrome and chronic snoring. The validation of MAD was conducted in two different ways: (1) Structurally, by applying the finite element model, which evidenced aptness from a structural point of view, in terms of resistance, as required by the MAD load. This study had not been developed to date in any MAD. (2) Clinically, by carrying out polisomnographic tests (40 patients); and statistically by analyses, which registered significant results (p<0,05) in patients using MADs. The use of MAD resulted in an average increase in the volume of the upper airway of 34% in the patients studied.**

Keywords—- **Chronic snoring, Sleep Apnoea-Hypopnoea Syndrome (SAHS), Upper airway, Mandibular Advancement Device (MAD).**

I. Introduction

Sleep Apnoea-Hypopnoea syndrome (SAHS) [1] is characterised by the presence of repeated episodes of complete (Apnoea), or partial (Hypopnoea) obstruction of the upper airway owing to the collapse and closure of the soft parts of the pharynx during sleep.

It has been proved that SAHS reduces quality of life, can cause artery hypertension, cardiovascular and cerebrovascular diseases, can increase the risk of death, and is a factor of traffic, occupational and domestic accidents [2]. In the infant population, it has been related to learning difficulties, behavioural disorder and even domestic accidents [3].

Therefore, SAHS is considered a highly important health problem, which forces doctors to identify subsidiary treatments for patients. However, in spite of the existence of effective treatments, only 5-9% of the patients have been diagnosed and treated. 1,200,000 of the 2,150,000 individuals, that it has been reckoned, are affected by SAHS in Spain.

The guideline symptoms to suspect a SAHS are:

- Jerky or abrupt snoring.
- Choking episodes and respiratory pauses during sleep, observed by the persons who live with the patient.
- Excessive daytime sleepiness.

The typical patient is a male aged between 45 and 55, obese, who has been told that he "snores and stops breathing while sleeping" and who experiences sleepiness in the daytime. The patient tends to speak about his sleep as unrestful "I usually wake up more tired than I was at bedtime"; "I fall asleep as soon as I am sitting down". Since sleepiness is a common symptom, which can be due to other conditions apart from SAHS, it is important to dismiss other causes, amongst which the most frequent is not getting enough hours of sleep.

II. The current situation of the sleep apnoea-hypopnoea syndrome

In recent years, sleep breathing disorders and specially the Apnoea-Hypopnoea Syndrome have generated increased interest for the medical community. Thus, all the internal medicine manuals and specialised periodicals have dedicated wide attention to SAHS. In fact, a search with the term "sleep apnoea" into Medline (PubMed) provided 18,832 results, out of which 2,453 were dated in 2008.

All this information has facilitated greater awareness of physicians and society as a whole, which has resulted in the patients' claim of their right to prompt assistance and precise diagnosis as well as to adequate treatment. Different epidemiologic studies carried out in the United States and in Europe have evidenced that SAHS is a prevalent medical condition which affects 4-6% of males and 2-4% of females within the general middle-aged adult population [4].

Less than 10% of the population in Spain has been diagnosed for SAHS. In addition, it has been recognised that diagnostic availability is key to the solution of the problem.

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Therefore, on a global basis, different diagnosis methods have been sought as an alternative to conventional nocturnal polisomnography (PSG), which, in spite of being considered a reference and first-choice test is not without problems, in addition to being costly and not being available in many health centres because of the high consumption of resources it requires.

The main alternatives to complete PSG have been polisomnographic studies during broken nights, naps and even polisomnographies implemented at the patient's own home. Similarly, the introduction of simplified systems, such as Breathing Polisomnography (PR), carried out both at hospital and at the patient's home, has achieved a reduction of test costs; and above all, it has allowed the decentralization of reference diagnosis units, which are often crowded, facilitating smaller health centres to access diagnosis through this method.

By way of summary, it can be said that:

1. SAHS is a public health problem which provokes a deterioration of quality of life and is related to cardiovascular disease and cerebrovascular accidents.
2. SAHS can be efficiently treated in most patients.
3. The current situation for SAHS is not adequate because:
    - Most patients have not yet been diagnosed.
    - There are not enough sleep units and many of them are not sufficiently equipped.
    - There are excessive waiting lists.
4. All the healthcare professionals, and specially those in primary healthcare, labour healthcare, drivers' medical examination centres, etc, have a key role in identifying patients on clinical alert for SAHS (snoring, respiratory pauses and sleepiness).
5. It is essential to foster deeper awareness and knowledge of this issue amongst healthcare staff and population in general.
6. Sleep units and/or specialists ought to be provided with adequate resources to diagnose and treat SAHS.

The American Sleep Disorders Association (ASDA) defines MAD [5] as a device which is introduced into the mouth and modifies the position of the jaw, the tongue and other supporting structures of the UA for the treatment of chronic snoring [6] and/or SAHS. They are considered a valid alternative, which can be the first choice in simple snorers, mild SAHS patients, mild-moderate SAHS with low body mass index, and patients suffering the syndrome of increased resistance of the upper airway (IRUAS); and a second choice in patients who do not improve or cannot tolerate positive pressure devices, patients at high surgical risk and who react badly to surgical treatment. In Spain, it is considered a tailor-made health product (RD 414/1996).

III. Improved Mandibular Advancement Device (MAD)

The aim of the MAD is to improve the patient's sleep quality as well as that of the relatives or roommates, by reducing or eliminating snoring and respiratory pauses during sleep.

The use of intraoral devices in the treatment of upper airway obstructive disorders is not a new concept. Already in 1902 Pierre Robin [7] proposed the use of a device of similar features (Monobloc) with the purpose of procuring a functional advancement of the jaw, dragging it forward to a more advanced position. There are more than 50 different types of mandibular avancement intraoral devices currently in the market.

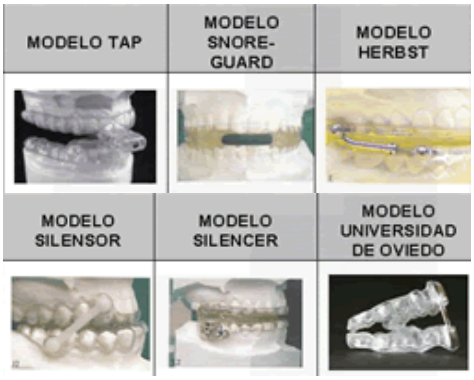


Fig. 1 Samples of Mandibular Advancement Devices

These mandibular advancement devices are introduced in the mouth and modify the position of the jaw, tongue and other Upper Airway (UA) supporting structures for the treatment of snoring and Sleep Apnoea-Hypopnoea Syndrome (SAHS); they are devices used in the medical fields of dentistry, stomatology and orthodontics and their main aim is that of protruding or advancing the jaw with respect to the upper maxillary so as to keep the airway sufficiently permeable or free from obstruction so that its fortuitous or unconscious closure can be avoided.

The Mandibular Advancement Device we propose (Fig 1) is adjusted and adapted to the upper and lower teeth so as to keep them linked with enough space to allow fluent and comfortable breathing while forcing the advancement of the jaw with respect to the upper maxillary, and allowing almost natural, though limited, mobility in all directions.

Fig. 2 Front and lateral view of the Improved Mandibular Advancement Device (DAM ®)

Figure 3 shows a front schematic view with an indication of the vertical (B-B) movement in the maximum opening position. As can be observed, the screw (8) situated in the box (3) limits the opening movement.

The second image shows the horizontal movement (C-C) in its lateral movement position. The screw (8), located in the box (3) facilitates the movement.

The third image shows how the device allows laterally-unbalanced rocking movements (D-D), thanks to the relative position of the boxes (3) and piece (1), controlled by the screws (8).

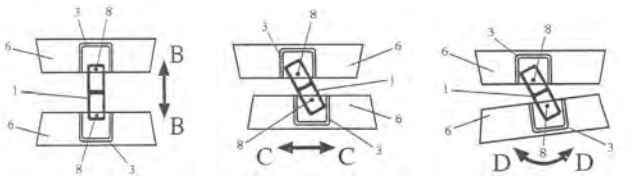


Fig. 3 Front schematic view with indication of the three types of movements: vertical (B/B), horizontal (C/C) and rocking (D/D)

This device incorporates an exchangeable piece (Figure 4) which will be regularly replaced by a similar piece of the same measures (Figure 5), in agreement with the relevant prescription, thus achieving the necessary advancement and eventually reaching the final aim of the treatment.

Fig. 4 Two front views of the piece

Fig. 5 Body on profile in different advancement positions

With the use of this Mandibular Advancement Device an adequate and comfortable advancement of the jaw is achieved. This allows good mandibular mobility in contrast to other currently known devices used with the same purpose.

Function specifications.

- The device modifies the position of the jaw, tongue and other Upper Airway (UA) structures for the treatment of snoring and/or Sleep Apnoea-Hypopnoea Syndrome (SAHS).
- Efficiency. It increases the upper airway by over 10%.
- It is comfortable and efficient in patient adaptability.
- It allows the forward movement of the tongue.

IV. Design Validation

The validation of the Mandibular Advancement Device has been carried out from the mechanic point of view and its efficiency has also been validated on patients.

Finite elements studies have been used for the analysis of device resistance, bearing in mind two issues: on the one hand, the solid parts have been simulated by means of elements SOLID92 and SOLID85. On the other hand, for the simulation of areas in contact with the polymer or with teeth contact elements of the types CONTAC52 and SPRING-DAMPER 14 have been modelled.

In order to carry out the structural analysis of the mandibular device and to check the tensions created regarding the defined specifications, it was decided to approach the problem by means of a simulation by the Finite Elements method (FEM), which would measure the device's behaviour for different calculations. The analysis application used was the general purpose FEM analysis programme ANSYS, in its 11.0 version.

Thus, with the aim of achieving precise results, a three-dimensional model of finite elements was generated, which reproduces the mandibular advancement device with great accuracy. Several different types of elements were used for the creation of each of the components of the device.

Net structures were used in the finite elements model, as much as possible, with the purpose of achieving greater accuracy in the analysis by using the available IT resources.

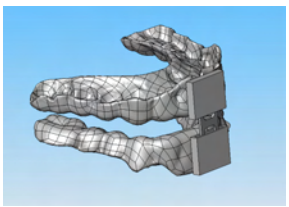
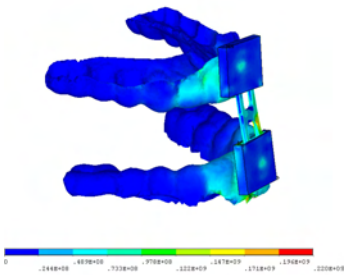


Fig. 6 View of the net structure of the Improved Mandibular Advancement Device (DAM ®)

The following figures show the Finite Elements Model generated:



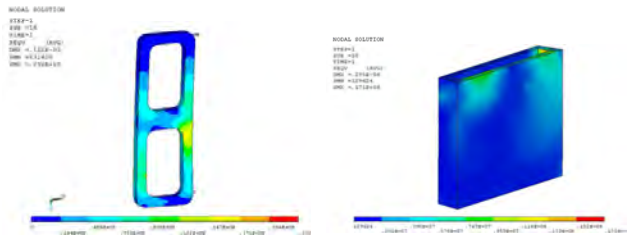


Fig. 7 Views of the tensions on the main components of the Improved Mandibular Advancement Device (DAM ®)

This structural analysis model has rendered the following results:

- The Von Mises equivalent tensions representation for each of the components of the different elements have not reached the materials' acceptable elasticity limits.
- In the load cases analysed, the tension put on most of the device as a whole is way below the required limit.

Once the resistance of the device had been guaranteed, 40 patients from the Hospital Central de la Defensa and from other public healthcare services were selected in order to analyse the efficiency of the treatment.

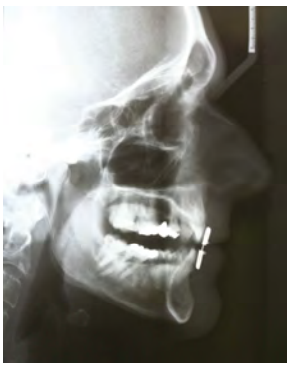


Fig. 8 Radiography of patient with fitted Improved Mandibular Advancement Device (DAM ®)

The validation methodology matches to that of an experimental design [8] applied to the polysomnographic and volumetric clinical tests carried out in patients who have used the Mandibular Advancement Device. The following figure show the sequence of analysis carried out for the statistic validation of the Mandibular Advancement Device.

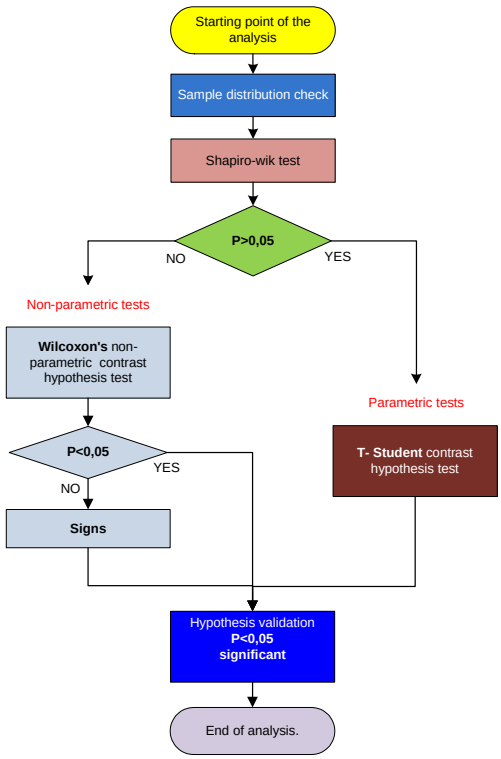


Fig. 9 Statistic validation flowchart

The results allow us to state that there are significant differences ($p<0.05$) by applying the Improved Mandibular Advancement Device.

- Polysomnography: The hypothesis is confirmed that there are significant differences in the application of MAD for the variables of the Respiratory Disturbance Index, Oxygen Desaturation, REM sleep Latency, Snoring and Sleep Efficiency.
- Volumetry: The hypothesis is confirmed that there are significant differences in the widening of the upper airway in patients fitted with the IMAD.

It has been statistically proven that the MAD used by the experimental group has had significant influence by widening the patients' upper airway as compared to the control group, without MAD.

In the images that follow, the volume increase in patients using the MAD can be appreciated.

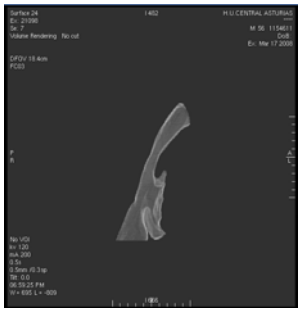


Fig. 10 Computerised tomography of patient without MAD. Lateral view

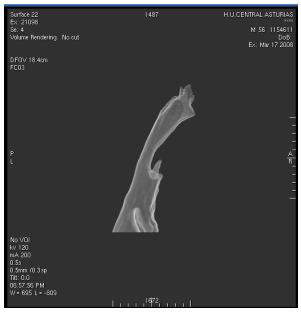


Fig. 11 Computerised tomography of patient with MAD. Lateral view

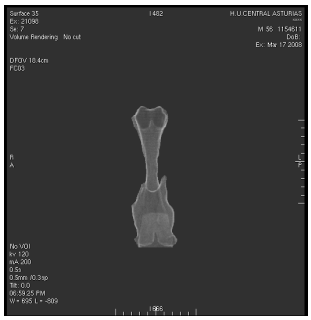


Fig. 12 Computerised tomography of patient without MAD Front view

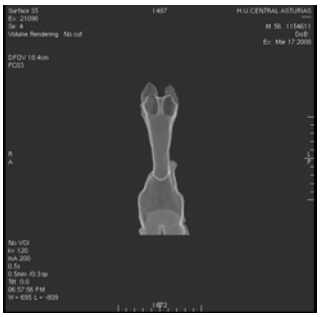


Fig. 13 Computerised tomography of patient with MAD: Front view

V. Conclusions

Summary of the Main Benefits for Patient Quality of Sleep (application of bio-engineering systems on Man's behalf OCDE, 1982).

The main advantage of the device is that it offers 100% efficiency in the treatment of snoring and Sleep Apnoea-Hypopnoea Syndrome, while its use does not involve any permanent change in the patients, and can be discarded at any moment.

With the purpose of clarifying differences, the Improved Mandibular Advancement Device presents the following main innovative features:

- It shows 100% efficient in the treatment of snoring.
- It increases the pharyngeal section with a movement that stabilizes and fixes the jaw and the hyoid bone, preventing the posterior rotation of these structures while in supine position, thus avoiding the obstruction of the airway.
- It prevents Sleep Apnoea-Hypopnoea Syndrome (SAHS) and its effects, such as minute waking periods which cause unrestful sleep, excessive diurnal sleepiness, neuropsychiatric and cardio-respiratory conditions.
- It is a reasonable alternative, since it does not imply any permanent change for the patient (as is the case with surgery) and can be discarded at any time.
- It allows easy adaptability and comfortable fitting onto teeth.
- All the necessary movements are enabled, though limited.
- Fast patient adaptation to the use of the device.
- It requires a number of simply manufacturable components

From the point of view of the study by the Finite Elements method, the Mandibular Advancement Device offers the following advantages:

- The Von Mises equivalent tensions do not reach the material's acceptable limit (elasticity limit).
- The device components are adequate from the point of view of resistance in accordance with the load requirements studied.

Acknowledgements

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