ORIGINAL ARTICLE

Sleep Science

Efficiency of the Ocluch©MAD in the treatment of patients with OSAS and its association with craniofacial morphology

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ABSTRACT

Objective: This study uses polysomnography and the Epworth sleepiness scale to assess the efficiency of the Ocluch©MAD in patients with Obstructive sleep apnea-hypopnea syndrome (OSAS), on overall respiratory disturbance indices (RDI), supine respiratory disturbance index (SRDI), minimum oxygen saturation, microarousals, CT90 (or ID90), sleep efficacy and snoring. These data are associated with skeletal class and facial biotype in order to establish predictive parameters for its effectiveness according to craniofacial morphology. **Methods:** 22 adult patients (between 38 and 60 years of age) of both sexes (7 women, 15 men) diagnosed with OSAS in the Hospital de Carabineros de Chile (HOSCAR) Neurology Unit were recruited and given the Ocluch© MAD in the hospital's dental clinic, for its use during a three-month period. Patients were assess at the beginning and in the end of this period. **Results:** 87.5% of patients with mild OSAS achieved the success criterion and normalization; 71.5% of patients with moderate OSAS achieved the success criterion and 33.3% achieved normalization; 85.7% of patients with severe OSAS achieved the success criterion and 57.1% achieved normalization. All class I and mesofacial patients achieved normalization, but class II patients had the greatest proportional improvement. **Conclusions:** The Ocluch MAD is an efficient low-cost alternative that should be considered among the therapeutic arsenal for a multidisciplinary approach to treating this disease.

Keywords: Sleep Apnea Syndromes; Mandibular Advancement; Dental Devices, Home Care, Craniofacial Morphology.

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INTRODUCTION

Sleep medicine recognizes obstructive sleep apnea-hypopnea syndrome (OSAS) as the primary diagnosis in at least two-thirds of patients who seek treatment in sleep clinics. This syndrome is defined as a complex chronic respiratory disorder that occurs during sleep, usually with a reduction in blood oxygen saturation[1]. Affected individuals experience repetitive episodes of upper airway collapse with obstruction, resulting in reduced airflow (hypopnea) or complete cessation of airflow (apnea) followed by rhythmic respiratory efforts during sleep for at least 10 seconds[1-2].

These episodes lead to microarousals, oxygen desaturation, increases in circulating catecholamines, changes in intrathoracic pressure, sleep fragmentation and excessive daytime sleepiness. Among the diseases associated with OSAS are hypertension, type-2 diabetes, metabolic syndrome and cardiovascular diseases that have been shown in cohort studies to be associated with increased cardiovascular morbidity and mortality in patients with OSAS, especially those with an apnea-hypopnea index (AHI) = 30[3].

Blood oxygen saturation reduction is accompanied by respiratory efforts, microarousals that fragment sleep, noisy snoring and high levels of daytime sleepiness that may provoke workplace accidents and social problems. Consequently, it is considered a medical public health problem[4]. This disorder is relatively common among the general population, but it is especially common in middle-aged and elderly adults. In the United States, it is estimated that these groups have a prevalence of between 10% and 20%, a figure that is increasing due to the growing obesity rate[2].

It is more common in men by 2:1 versus women, among whom the most affected are those of menopausal age[1]. Other studies carried out in the United States, Europe and Australia estimate a prevalence of between 3% and 7% for men and 2% to 5% for middle-aged women; however, it is believed that between 70% and 80% of individuals with OSAS remain undiagnosed and untreated[5].

A study was undertaken in Brazil where OSAS was observed in 32,8% of people between 20-80 years old. Men had greater association than woman (OR=4.1) and obese individuals (OR=10.5) than individuals of normal weight. The adjusted association factor increased with age, reaching OR=34.5 for 60-80 year-olds when compared to the 20-29 years old group. Weighted prevalence estimates of OSAS symptoms show that 55% of the population experiences sleepiness, 38.9% fatigue, 20.5% report snoring, and 29.2% breathing interruptions. AHI lower than 5 was present in 61.8% of the subjects; 21.3% presented with an AHI between 5 and 14.9, and 16.9% had an AHI that was higher than or equal to 15.[6]

Conventional polysomnography (PSG) is the gold standard for making a definitive diagnosis in patients with suspected OSAS. The PSG indices mostly used to determine respiratory sleep disorders are the apnea-hypopnea index (AHI) and the respiratory disturbance index (RDI)[7].

The core criteria for a diagnosis of OSAS are largely unchanged from ICSD-2. The diagnosis requires either signs/symptoms (eg, associated sleepiness, fatigue, insomnia, snoring, subjective nocturnal respiratory disturbance, or observed apnea) or associated medical or psychiatric disorder (ie, hypertension, coronary artery disease, arterial fibrillation, congestive heart failure, stroke, diabetes, cognitive dysfunction, or mood disorder) coupled with five or more predominantly obstructive respiratory events (obstructive and mixed apneas, hypopneas, or respiratory effort-related arousals, as defined by the AASM scoring manual) per hour of sleep during PSG. Alternatively, a frequency of obstructive respiratory events 15/h satisfies the criteria, even in the absence of associated symptoms or disorders.[8]

OSAS severity is defined as mild when AHI is = 5 and = 15 per hour, with an oxygen saturation level of at least 85% (with saturation greater than 90% considered normal), and minimal disability during the day. It is considered moderate when AHI is > 15 and = 30 per hour, oxygen saturation is between 75% and 85% and when there is clinically significant decrease in work performance and social isolation due to daytime sleepiness and loss of concentration. Finally, it is considered severe when AHI > 30 per hour, oxygen saturation < 75% with difficulty in work and/or social activities caused by the sleep disorder and is not attributable to another disorder[9-10]. However, there is no single clinical criterion to determine the severity of the disorder in all patients, given that symptoms do not always correlate with the syndrome's severity. Studies have shown that if you only include AHI in the diagnosis, 30% of patients would remain without treatment[11]. For this reason, use of RDI is preferred over AHI because the former includes events related to reductions in airflow that result in microarousals, in addition to apnea and hypopnea events.[7]

Therapeutic options range from biobehavioral and postural modifications, to surgical procedures aimed at increasing airway space, as well as pharmacological treatments, intraoral mandibular advancement devices and administration of continuous positive airway pressure (CPAP), which has been the treatment of choice for stabilizing the upper airway and avoiding its collapse in most patients. However, efficacy depends on adherence and tolerance to the device and the perceived feeling of improvement.[3] Mandibular advancement devices (MAD) offer a noninvasive option with less discomfort for patients than CPAP[3]. Studies have revealed an effectiveness of 63% with MADs in patients with mild to severe OSAS[12]. There is no single universal MAD and its contribution to improvement of polysomnography indices in patients, according to their level of OSAS severity, depends on the manufacturing technique, its material and the design based on individual sagittal and vertical propulsion parameters[13].

The treatment of choice for OSAS continues to be CPAP, which consists of a compressor that introduces titrated positive pressure atmospheric air into the individual's airway, thereby avoiding airway collapse. Among the effects CPAP are

normalization of respiratory episodes, elimination of snoring, prevention of oxygen desaturation and electroencephalographic microarousals, normalization of sleep patterns and prevention of daytime hypersomnia. Despite all these advantages, CPAP is not free of adverse reactions including aerophagia, epistaxis and skin allergies to the mask, all of which significantly affect treatment adherence[7].

The American Academy of Dental Sleep Medicine (AADSM) defines intraoral devices as those that are placed in the mouth to modify the position of the mandible, tongue and other support structures in the upper airway for the treatment of snoring and/or OSAS. They are generally used in patients who do not tolerate or who reject CPAP and the best results with MADs are obtained in mild to moderate OSAS. These devices must be installed by qualified dentists who are trained and experienced in the treatment of the temporomandibular joint and dental occlusion[13]. Three studies that included mild to severe OSAS reveal an effectiveness of 63% with the use of MADs. In subjects with mild to moderate OSAS, efficiency increases to 79%[14]. Another study demonstrated that patient compliance with the use of these devices was 82% and therapeutic efficacy was 53%[15]. Patients show a good understanding of how to use the devices, which results in a high level of treatment adherence[16].

In some studies comparing CPAP with MADs, quality of life results were similar for daytime sleepiness and social interaction. However, CPAP continues to be more effective with regards to nighttime apnea-hypopnea index as measured by PSG[17]. Therefore, dentists not only play a role in recognizing and referring patients who show or who are at risk for OSAS, but should also inform and educate patients on the health risks of OSAS, in addition to participating in interdisciplinary teams and getting actively involved in treatment.

All of these intraoral devices have a registered trademark and are manufactured abroad, which increases treatment cost. This study proposes evaluating the efficiency of a customized MAD - manufactured in a local dental laboratory without the need for prefabricated accessories - on the overall respiratory disturbance index, the supine respiratory disturbance index, minimum oxygen saturation, microarousals, saturation time below 90 (T90), sleep efficacy and snoring as measured by polysomnography at initial diagnosis (timepoint 0) compared to a final polysomnography after 3 months of MAD use. The Epworth sleepiness scale was also used to evaluate improvements brought by the use of the device in daytime sleepiness. These data are associated with the patient's skeletal class, biotype and craniofacial morphology in order to establish predictive parameters for effectiveness.

METHODS

Out of a total of 101 examined patients, twenty-two adult patients (between 38 and 60 years old) of both sexes (7 women, 15 men), diagnosed with OSAS according to the second edition of the International Classification of Sleep Disorders (ICSD - 2), supported by PSG, were recruited in the Hospital de Carabineros de Chile (HOSCAR) Neurophysiology Unit.

Inclusion criteria were adult patients = 18 years of age of both sexes, with complete dentition or Kennedy class III edentulism (McCracken, 11th Edition). The sample excluded patients who had degenerative pathologies of the temporomandibular joint, complete or partial Kennedy class I and II edentulism, and/or those who used a removable or implant-supported prosthesis, or those who had moderate to advanced periodontal disease. Patients were also excluded if they were taking muscle relaxants, hypnotics and/or sedatives, as well as pregnant women or those who were at risk for pregnancy. All subjects were informed about the study and asked to sign an informed consent approved by the hospital's ethics committee in accordance with the principles of the Declaration of Helsinki (Appendix 1).

Body mass index (BMI) was measured; neck circumference was also measured for all subjects. Patients were asked to complete the Epworth sleepiness survey. Values between 0 and 6 were considered normal, while values between 7 and 13 were considered mild, values between 14 and 19 were considered moderate and values between 20 and 24 were considered severe for sleepiness.

Lateral teleradiographies were then taken on all subjects in the hospital's radiology department. Patients were maintained in a standardized head position on the sagittal plane, parallel to the plane of the film and perpendicular to the central ray. The head was stabilized using a cephalostat, orienting the Frankfort plane parallel to the floor in maximum dental intercuspation. The SIRONA XG D5/CEPH (2008 model) was used to obtain the radiographs and the images were processed using SIDEXIS software. A profile teleradiography was requested in order to determine skeletal class, defined as the anteroposterior relationship of the maxilla and the mandible calculated using the Steiner ANB angle which classifies skeletal class into class I, II and III[18], and the facial biotype proposed by Rickets which is calculated according to VERT, separating biotypes into mesofacial, dolichofacial and brachyfacial[19].

Intervention

All subjects were given an intraoral acrylic bimaxillary Ocluch©MADs (registered in the Dibam Department of Intellectual Property under code nº 247.768 and date of issue Nov 14th 2014), manufactured by the Temporomandibular Disorders and Orofacial Pain Department at the hospital's dental clinic. This device is made of two heat-curing acrylic parts with flat surfaces that allow for freedom of lateral movement, adjusted for each dental arch.

Both are hooked up in the front section by means of a double wire of acrylized stainless steel (diameter 1mm, length 7cm), attached to the upper device that stands out and forward from the palatine section, to hook up in the front lingual section of the lower device -in a rectangular cavity of approximately 5mm. Both devices installed in the mouth do not increase front facial height over 10mm.

The device is manufactured by a dental technician out of individual models of each patient, which are related by an interoclusal register in a vis-à-vis position. Afterwards, the device is adapted in the clinic with self curing acrylic in the lower device in order to reach up to 70% of maximum protrusion for each patient, which has been described as the most effective advancement percentage[20]. Patients received written instructions on usage and hygiene of the device. They were subsequently monitored periodically for a period of three months (Figure 1).

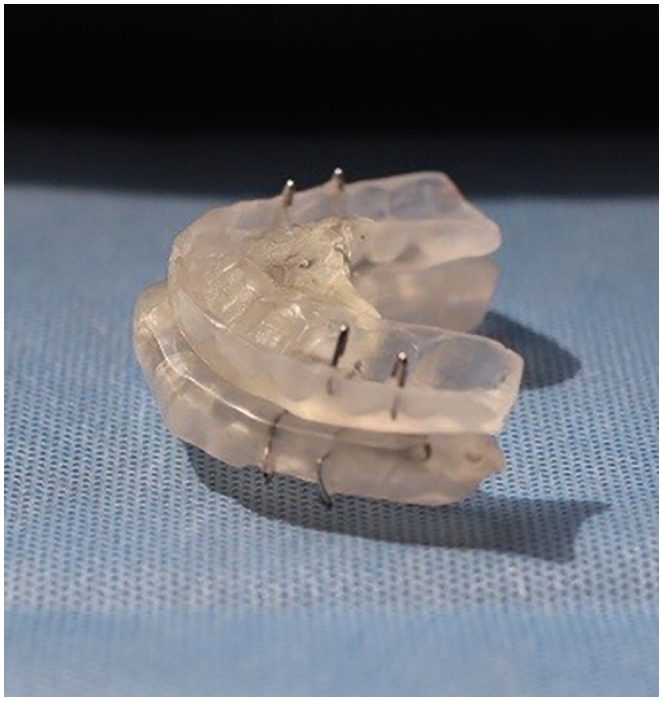

Figure 1. Ocluch©MAD portrayed as it would be articulated in the mouth.

After three months of nocturnal use of the device, a final polysomnography of the patient using the device was ordered for post-treatment follow-up under the same initial parameters, at the same HOSCAR neurophysiology unit.

The primary success criterion for treatment with the Ocluch©MAD was the proportion of patients with a decrease in RDI of at least 50% from the initial diagnosis as defined by Martínez-Font[21].

The following initial PSG parameters (without MAD) were also compared with the final PSG parameters (with MAD) at three months of use during sleep: respiratory disturbance index (RDI), supine respiratory disturbance index (SRDI), microarousals index (MAI), minimum oxygen saturation (O_2Sat), saturation time below 90 (T90) and percentage of snoring time (%Sn). In addition, patients were asked to once again complete the Epworth sleepiness survey.

Statistical analysis

This is a prospective study based on pre- and post-treatment evaluation of the same subjects. The results are shown as comparative mean and percentage values using the Shapiro-Wilk normality test for paired samples. The findings were then statistically analyzed using the Mann-Whitney nonparametric test with a *p*-value of = 0.05 considered significant. Statistical analysis was carried out using Past 3.11. (Hammer, O., Harper, D.A.T., Ryan, P.D., 2001).

RESULTS

Out of a total of 101 patients examined, 22 adult subjects (between 38 and 60 years of age) of both sexes (7 women, 15 men) diagnosed with OSAS according to the second edition of the International Classification of Sleep Disorders (ICSD-2), supported by PSG were recruited in the Hospital de Carabineros de Chile (HOSCAR) Neurophysiology Unit between November 2013 and November 2014. Body mass index (BMI) was measured, the lowest value being 23.8 and the greatest value being 34.93 (mean 27.4). Neck circumference was also measured for all subjects: the lowest value for women was 35.5 cm and the greatest value was 39 (mean 37.2 cm). The lowest neck circumference value for men was 38 cm and the greatest value was 45 cm (mean 41.1 cm). Lateral teleradiographs were then taken on all subjects in the hospital's radiology department.

Prior to starting therapy with the Ocluch©MAD, patients were asked to complete the Epworth daytime sleepiness scale (Table 1).

Success criteria are shown based on the subjects' risk factors: by sex (male/female); by BMI (=25 considered overweight); by increased neck circumference (=37 in women and =43 in men); by initial severity at OSAS diagnosis; by skeletal class and by facial biotype. Finally, the supine positional component was evaluated (Table 1).

An RDI decrease of = 50% from the initial diagnosis was achieved in 86.7% of the sample: this percentage reached 73.4% in men and 100% in women (Table 1), of whom 13 subjects between men (46.6%) and women (85,7%) had an RDI reduction of = 5, which is considered within normal limits. Moreover, 71.4% of subjects with a BMI < 25 achieved the success criterion and 57.1% achieved normal parameters; 86.7% of overweight subjects achieved the success criterion and 60% achieved normalization; 83.3% of subjects with a normal neck circumference achieved the success criterion, of whom 55,6% achieved normalization. Among subjects with an increased neck circumference, 75% achieved the success criterion and 75% achieved normalization.

Based on the OSAS diagnosis, 100% of patients with mild OSAS achieved the success criterion and 83.3% achieved normalization; 75% of patients with moderate OSAS achieved the success criterion and 50% achieved normalization; and 66.7% of patients with severe OSAS achieved the success criterion and 33.3% achieved normalization.

Based on skeletal class, 60% of class I patients achieved the success criterion and 80% achieved normalization; 87.5% of class II subjects achieved the success criterion and 50% achieved normality. The single class III subject achieved both criteria.

Based on biotype, 77% of dolichofacial subjects achieved success and 38.5% achieved normalization; 80% of

Table 1. The Table 1 shows results -percentage and numerical- for primary success criterion (improvement over 50%) and normality criterion (RDI<5), before and after using Ocluch©MAD.

Primary success criterion (RDI)	Greater than 50%		RDI <5	
	YES	NO	YES	NO
Male	73.4%	26.6%	46.6%	53.4%
Female	100%	0%	86%	14%
BMI				
<25	71.5%	28.5%	57.1%	42.9%
>25	86.7%	13.3%	60%	40%
Neck circumference				
Normal	92.8%	7.2%	50%	50%
Increased	87.5%	12.5%	75%	25%
OSAS Severity				
Mild	87.5%	12.5%	87.5%	12.5%
Moderate	71.5%	28.5%	33.3%	66.7%
Severe	85.7%	14.3%	57.1%	42.9%
Skeletal Class				
Class I	60%	40%	80%	20%
Class II	87.5%	12.5%	50%	50%
Class III	100%	0%	100%	0%
Facial Biotype				
Dolichofacial	77%	23%	38.5%	61.5%
Mesofacial	80%	20%	100%	0%
Brachyfacial	100%	0%	75%	25%

mesofacial subjects achieved success and all subjects achieved normalization; and 100% of brachyfacial subjects achieved both criteria (Table 1).

Regarding RDI measured by PSG, 18 of the 22 subjects analyzed achieved success, of whom 13 subjects reduced RDI to < 5 with the MAD. Out of the 4 remaining subjects, 3 improved by at least 40% and a single subject had an improvement of 14.5% (Figure 2).

The primary SRDI success criterion was achieved by 19 of the 22 patients analyzed, two of whom improved by at least 40% and only one subject had an improvement of 14,5%. The SRDI index with MAD was reduced to < 5 in 8 subjects, which is considered within normal respiratory parameters (Figure 3).

Out of all the subjects studied, minimum oxygen saturation increased in 15 subjects. The value remained unchanged in 2 subjects and decreased slightly in 5 subjects. However, the index was = 90 in 10 patients that used the MAD. Oxygen saturation for the entire sample increased by 3.7% (p=0.005). The percentage of total sleep time with saturation below 90 (T90) decreased for the whole of the sample and 17 subjects achieved normal levels of < 1%. The mean decrease was 2.29% (p=0.00016) (Figure 4).

The microarousals index decreased in all subjects studied, except one. In 16 subjects, microarousals decreased to = 10 episodes/hour. The mean decrease in episodes per hour was 11.72% (p=0.000046). Snoring percentage decreased by a mean of 15.81% for 20 subjects (p=0.00019). The value was < 5% in 15 subjects and 0% in 7 subjects (Figure 5).

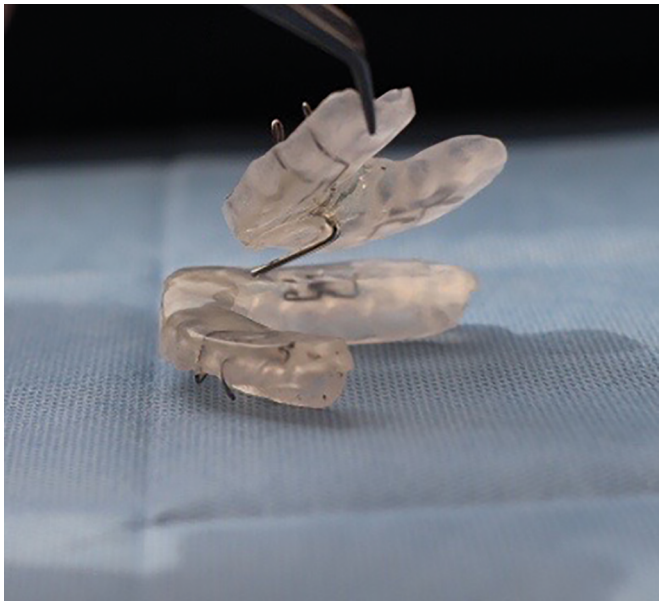

Figure 2. Ocluch©MAD portrayed as separate devices and showing the attachment system.

Regarding the results from the initial Epworth sleepiness survey, 2 subjects had values of less than 6, classified as no daytime sleepiness; 8 subjects had mild sleepiness; 10 had

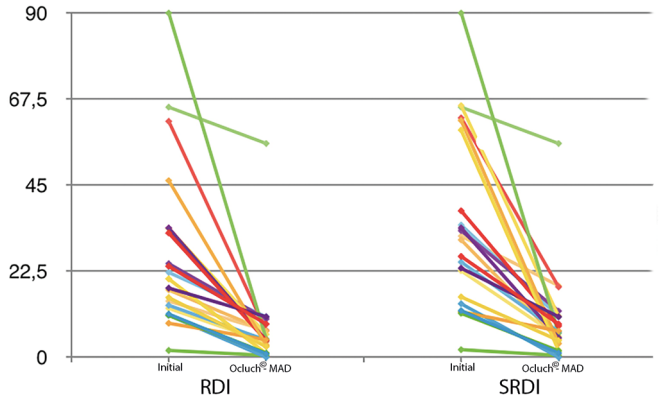

Figure 3. Respiratory disturbance index (RDI) and supine respiratory disturbance index (SRDI) variation for each subject, measured in events per hour. The variation of RDI and SRDI from initial PSG and final PSG using the Ocluch©MAD, shows an improvement in all subjects. The significant difference was $p<0,05$ in both cases.

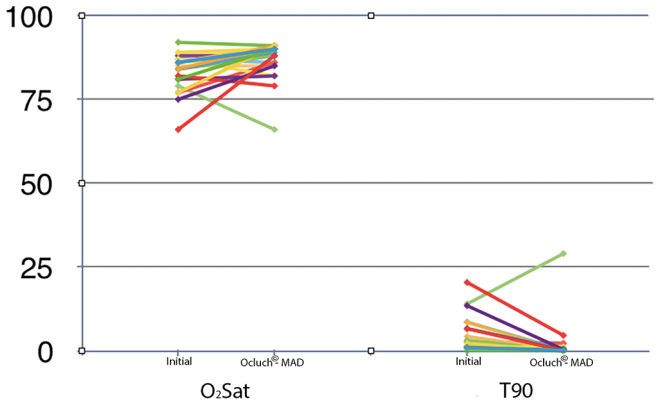

Figure 4. The minimum oxygen saturation (O2Sat) per night and the percentage of total sleep time with saturation below 90 (T90) variation for each subject. The variation of O2Sat and T90 from initial PSG and final PSG using the Ocluch©MAD, shows an improvement in all subjects with significant differences $p<0,05$ in both cases.

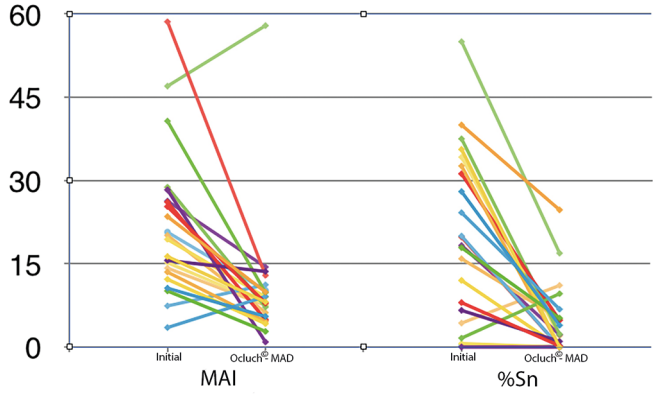

Figure 5. Microarousals index (MAI) measured in events per hour and snoring percentage of total sleep time (%S) variation for each subject. The variation of MAI and %S from initial PSG and final PSG using the Ocluch©MAD, shows an improvement in all subjects with significant differences $p<0,05$ respectively.

moderate sleepiness and 2 had results classified as severe. The mean value on the survey was 13.68. After three months using the Ocluch©MAD, survey results showed improvements in most subjects. Also, 12 subjects had values within normal limits (less than 6); 10 subjects had mild sleepiness with values of less than 14 (mean of 7) with a mean improvement of 48.8% (p=0.000039) (Figure 6).

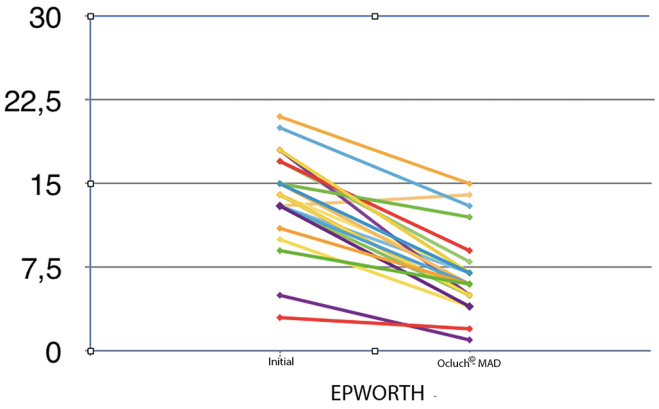

Figure 6. Results from the initial to final Epworth sleepiness survey for each subject, shows an improvement in all subjects with significant difference ($p<0,05$).

Regarding the sample's craniofacial morphology, of the 5 subjects classified as class I, 3 achieved the success criterion and 80% achieved normalization. Skeletal class II patients made up 72.7% of the sample and, of these, 87.5% achieved the success criterion and 50% achieved normalization. The only class III patient achieved both criteria. Regarding facial biotypes in the studied sample, 59% were classified as dolichofacial and, of these, 77% met the success criterion and 38.5% achieved normalization; 22.7% of the sample was mesofacial and, of these, 80% achieved the success criterion and 100% achieved normalization. In the case of brachyfacial subjects, which constituted 18.2% of the sample, 100% achieved the success criterion and 75% achieved normalization (Table 1).

DISCUSSION

MADs produce an increase in airway caliber and a widening of the oropharyngeal space as a result of mandibular protrusion. This stimulates the genioglossal muscles and generates downward movement of the tongue and forward movement of the soft palate. In addition, this effect is "dose-dependent": the greater the advancement, the greater the opening of the upper airway[22,23].

It is important to consider that, in addition to the parameters observed on polysomnography and those calculated on teleradiography, most patients were overweight based on

BMI and had an increased neck circumference. As mentioned previously, this predisposes patients to develop OSAS and is also directly associated with its severity, which is why a multidisciplinary approach to the disease is important[24].

The primary success criteria were met for the majority of patients studied and despite some criteria not being met in some patients, all of the indices measured did improve. A decrease was observed for RDI and SRDI variables among the study sample, in addition to a tendency towards an increase in the oxygen saturation variable with the use of the Ocluch MAD. These variations are attributable to the increase in airway caliber described above. This increase was beneficial for all subjects.

In the majority of the study sample, the SRDI value surpassed the RDI with and without the MAD, which concurs with the study by Oksenberg *et al.*[25] that indicates that the supine position favors obstructive apnea due to the posterior displacement of the tongue that occurs with muscle relaxation. Furthermore, apnea events that occur in this position are more severe than those that occur while sleeping in the lateral decubitus position. Therefore, body position during sleep exacerbates apnea events and can be minimized with the use of the MAD.

The individual's skeletal class is a factor to be considered. It has been reported that skeletal class II patients have a lower total airway volume[26]. The sample revealed predominantly diagnoses of moderate and severe among patients with class II skeletal facial morphology, which would imply an association between skeletal class II and increased OSAS severity. The MAD is indicated for mild to moderate OSAS. However, the sample contains patients diagnosed as severe who were selected because they did not tolerate or did not improve with the use of CPAP. The success criterion was met in 66.7% of these patients and 33.3% achieved normalization, which suggests that the indication for MAD should be oriented towards each patient's specific characteristics, after a diagnosis made by a specialist and not merely on the basis of PSG indices.

Regarding facial biotypes, a large portion of the sample consisted of dolichofacial individuals, whose facial pattern has been considered in a Japanese study as one of the primary risk factors for the development of OSAS[27]. These subjects showed improvements in the success criterion with the use of the MAD, but the majority did not achieve normalization, which concurs with the study published by Carlos-Villafranca *et al.*[28].

Mesofacial and brachyfacial subjects had the best response after using the MAD, in general showing a greater decrease in RDI and SRDI variables and a trend towards an increase in oxygen saturation levels.

The device presented here can be manufactured in a dental laboratory without prefabricated accessories, making it a low-cost alternative for patients. Its design allows it to be adjusted by the specialist according to the patients needs and, if the patient suffers from bruxism, it allows for lateral movements due to its flat surfaces, thereby resulting in occlusal stability. Regarding patient tolerance, the device was well accepted due to it not being a monoblock, meaning excessive opening of the mouth was not necessary.

Study limitations

Study patients were recruited in the Hospital de Carabineros de Chile (HOSCAR) Neurophysiology Unit between November 2013 and November 2014 and they were compared by diagnostic PSG parameters and with the use of Ocluch©MAD. It is necessary to undertake further studies with a control group and to establish homogeneity among skeletal classes.

CONCLUSION

The use of Ocluch©MAD leads to an increase in oropharyngeal space. Its efficacy is more apparent for patients sleeping in the supine position. Its two main advantages are that its design allows it to be adjusted by the dentist for greater comfort, which promotes treatment adherence; and that it can be manufactured in dental laboratories without the need for prefabricated patented accessories, which lowers the cost to patients.

Regarding the search for predictive parameters, our findings suggest that if the patient is skeletal class II, she/he is more likely to achieve success under multidisciplinary treatment with intraoral devices. In terms of facial biotype, mesofacial and brachyfacial patients achieved better RDI and SRDI levels with higher oxygen saturation.

We suggest that an analysis of craniofacial morphology and all exacerbating factors is necessary when a patient is diagnosed with OSAS, in order to prescribe the most appropriate treatment for such patients.

Suggestions

The results obtained in this study are preliminary. A larger patient sample is needed to establish stronger associations between the variables studied.

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Conflicts of interest

The authors declare no conflict of interest.

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APPENDIX

Appendix 1

Informed consent

I, ……, hereby agree to participate in the treatment study to improve my sleep apnea condition with the use of an oral orthopedic device that will allow for improvement of my sleep quality.

I authorize publication of the research results while protecting my identity.

This participation does not involve financial payment nor additional treatment costs, nor does it involve risks to my health. Moreover, treatment is reversible.

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Patient signature and RUT

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Specialist signature and RUT