# The impact of the Adjustable PM Positioner appliance in the treatment of obstructive sleep apnoea

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# Abstract

**Introduction:** Obstructive sleep apnoea (OSA) is regarded as a potentially lifethreatening condition characterized by repeated narrowing/collapse of the pharyngeal walls during sleep. The efficacy of oral appliances (OA) in the treatment of sleepdisordered breathing has been rigorously investigated and proven in the last decades. Due to patients preferring OA therapy, many designs have been developed, including the Adjustable PM Positioner. The aim of this study was to evaluate the efficacy of the Adjustable PM Positioner in the treatment of obstructive sleep apnoea, comparing polysomnograms (PSG) pre-treatment and with the OA in situ.

**Material and methods:** Twenty-nine patients were enrolled in this study. The sample was divided into two groups: the non-obstructive sleep apnoea (NOSA) group, with 5 snoring patients, and the OSA group, with 24 patients. They used the appliance for 6 months and then underwent another PSG with the appliance in situ.

**Results:** The results showed no statistically significant differences in all variables of the NOSA group, except for the presence of snoring, which was reduced, according to PSG findings. For the OSA group the results for apnoea/hypopnoea index (AHI), rapid eye movement (REM) sleep, nadir, mean and basal oxyhaemoglobin saturation (SaO2), showed statistically significant differences. The presence of snoring also decreased according to PSG findings.

**Conclusions:** We conclude that the adjustable PM Positioner is effective in the treatment of OSA comparing baseline and post-treatment respiratory variables.

Key words: sleep apnoea, oral appliance, treatment.

# Introduction

Obstructive sleep apnoea (OSA) is regarded as a potentially lifethreatening condition characterized by repeated narrowing/collapse of the pharyngeal walls during sleep [1]. Interest in the use of oral appliances as a treatment for snoring and OSA has existed since its inception in the early days of dentofacial orthopaedics [2]. Since then, the mandibular repositioning appliance (MRA) has been increasingly recognized in the management of OSA [3, 4] and its efficacy in the treatment of mild to moderate sleep-disordered breathing has been rigorously investigated during the last 25 years [5-8]. However, there are a reduced number of papers supporting MRA efficacy in the treatment of severe OSA [9].

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Considering the anatomic site where OSA occurs, odontology may play an important role in the treatment of this syndrome and in the improvement of life span, since mandible repositioning allows changes in the upper airways and in adjacent structures. A number of factors contribute to upper airway obstruction in patients with OSA [10-12]. Body position plays an important role, since the number of breathing events during sleep is greater in the supine than in other positions [13, 14]. Clinically, OSA patients show both daily and nocturnal symptoms which affect quality of life [15-17].

Clinicians soon identified a need for an oral appliance (OA) that could be adjusted and did not require a series of remakes if the initial jaw position was not adequately positioned forward. Currently, the kind of appliance widely used in the treatment of OSA is the MRA, and among these, widely used designs are the Klearway [18], the Karwetzky [19], the Herbst [20] and the adjustable PM Positioner [21]. The aim of this study was to evaluate the impact of the Adjustable PM Positioner on sleep respiratory variables and subjective symptoms in Brazilian patients with OSA, comparing polysomnograms (PSG) prior to treatment and with the OA "in situ", based on three criteria, AHI <5, AHI <10 and AHI <15.

# Material and methods

# Population

Twenty-nine healthy consecutives patients, 11 women and 18 men, who reported OSA symptoms such as snoring and daytime symptoms, were referred by a single clinical physician to the Sleep Disorder Laboratory at the University of Vale do Paraíba (UNIVAP), Brazil. The demographic data are shown in Table I. All patients underwent the initial PSG recordings. Patients with body mass index (BMI) over 33 kg/m<sup>2</sup>, severe bruxism, measured clinically [22], pain in the temporomandibular joint (TMJ), active periodontal disease, obstructed upper airway and predominant central sleep apnoea were excluded from the treatment. To be treated with an adjustable mandibular repositioning appliance, they had to present healthy periodontium, at least a 7 mm maximum mandibular protrusion and 40 mm mandibular opening. Only a clicking at the beginning of jaw opening was tolerated. In the current literature, another inclusion criteria is to present 8-10 teeth on

**Table I.** Demographic data of all 29 subjects enrolled in this study

Demographic data	Mean/SD
Age [years]	47.9±12.5
BMI [kg/m²]	26.2±3.6
Neck circunference [cm]	40.2±3.0

BMI – body mass index

each arch [18]; consequently, edentulous patients and those with an inadequate number of teeth were excluded, although, at this time, it is already possible to fit the OA on a total maxillary prosthesis and on partially edentulous individuals (less than 8-10 teeth on each arch). The method was described elsewhere [23, 24]. All patients gave informed consent, and approval for the study was obtained from the Ethics Committee at Univap University.

#### Mandibular repositioning appliance

A single dental technician made the mandibular repositioning appliance from stone casts of the teeth and constructive wax bite, approximately 65% of maximum protrusion, obtained by the dentist. Only one design for the device was used in all patients, the adjustable PM Positioner (aPMP) [21]. This appliance is fabricated in two parts, one for the upper arch and one for the lower arch, with complete coverage of the occlusal sides of the teeth, joined together by one expander on each side, which allows for titration according to each individual need. The MRA was intended to be 65.0-75.0% of maximum protrusion, and the mandibular opening 2.0-6.0 mm between the edges of the incisors. The placement of the mandibular repositioning appliance (MRA) proceeded with advice given about the care and hygiene of the device. After 2 weeks of device placement, titrations (0.25 mm) were done weekly to prevent TMJ and muscular pain. The forward amount was based on reports by the patient and his wife about the reduction in snoring and apnoea. The total advancement reached a mean of 9.4±0.5 mm (in a range of 8.0-10.0). Patients underwent a second PSG, with the appliance "in situ", after 6 months.

# Polysomnographic recording

The patients underwent the PSG recording at the Sleep Disorder Laboratory of UNIVAP, and it was adopted as level 1, gold standard, according to Rechtschaffen and Kales [25]. The records were scored and interpreted by physicians especially trained in sleep medicine. The channels were 2 electroencephalographic leads, 2 electro-oculographic leads, submental surface electromyography, nasal-oral air flow, snore sensor, abdominal and thoracic respiratory effort, oximetry, body position, anterior tibialis surface electromyography, and an electrocardiography rhythm strip.

#### Statistical methods

The t-test for paired observation was used to analyze the effects of the device on respiratory variables. The software MINITAB Release 14.2 Upgrade (USA) was used in all calculations and P<0.05 was considered significant. Lílian C. Giannasi, Luiz C. de Mattos, Márcio Magini, Maricília S. Costa, Cláudia S. de Oliveira, Luis V.F. de Oliveira

**Table II.** Polysomnographic findings pre-treatmentand with OA "in situ". NOSA group

Polysomnogram	n	Without OA	With OA	Р
АНІ	5	3.1±1.0	1.1±0.9	NS
AI	5	4.4±6.4	0.3±0.3	NS
HI	5	3.0±3.2	0.7±0.8	NS
S <sub>1</sub>	5	6.3±5.7	6.2±2.5	NS
S <sub>2</sub>	5	56.8±4.1	58.4±9.9	NS
S <sub>3,4</sub>	5	16.0±6.0	16.0±10.5	NS
REM	5	20.8±1.2	19.0±3.8	NS
SaO <sub>2</sub>	5	98.7±0.5	99.0±0.0	NS

OA – oral appliance, AHI – apnea/hypopnea index, PSG – polysomnogram, AI – apnea index, HI – hipopnea index, S<sub>1</sub> – sleep stage 1, S<sub>2</sub> – sleep stage 2, S<sub>3,4</sub> – sleep stage 3,4, REM – non-rapid eyes movement sleep, SaO<sub>2</sub> – oxyhemoglobin saturation, NS – no significant

# Results

The sample was divided into two groups: the NOSA (non obstructive sleep apnoea) group, consisting of 5 patients, and the OSA (obstructive sleep apnoea) group, consisting of 24 patients. The latter was subdivided into mild OSA (27%), moderate OSA (53.8%) and severe OSA (4.0%). In 27 patients (94%) the temporary side effects, such as dry mouth, teeth discomfort, and muscular discomfort, disappeared within 1-2 months, and in 2 patients (6%) they lasted 5-6 months. The findings were analyzed according to the criterion of the AASM, AHI < 5.0; the criterion called liberal, AHI <10/h; and the criterion AHI <15/h. The results were not significant for the NOSA group (Table II) except the presence of snoring, which decreased, according to bed partner recount. There was one patient whose AHI increased from 2.0 to 2.2 (Figure 1). For the OSA group (Table III) the results were as follows.

### Apnoea/hypopnoea index (AHI)

The mean AHI of the entire OSA group was reduced from 19.1±7.5 to 5.6±4.0 (P≤0.05) and AHI  $\leq$ 5.0 was found in 50%, AHI  $\leq$ 10.0 was found in 83.3% and AHI  $\leq$ 15.0 was found in 100.0% of this group. According to disease severity, a decrease to AHI  $\leq$ 5.0 was found in 50.0% and a decrease to AHI ≤10.0 was found in 100.0% in mild OSA patients; a decrease to AHI  $\leq$ 5.0 was found in 50.0% and a decrease to AHI ≤15.0 was found in 100.0% in moderate OSA patients; and a decrease to AHI  ${\leq}10.0$  was found in 50.0% and AHI  ${\leq}15.0$  was found in 100% in severe patients, an over 50% reduction from before oral appliance treatment. As we can notice, almost half of the OSA group (45.8%) have returned to a normal condition and all 24 patients have achieved treatment success, independently of the treatment success rate considered.

Table III.	Polysomnographic	findings	pre-treatment
and with	OA. OSA group		

PSG	n	Without OA	With OA	Р
AHI	24	19.1±7.5	5.6±4.0	*
AI	24	9.7±7.3	1.9±2.0	*
Н	24	9.9±5.4	3.6±2.5	*
S <sub>1</sub>	24	8.9±10.5	6.6±5.2	NS
S <sub>2</sub>	24	52.1±10.2	53.9±8.3	NS
S <sub>3,4</sub>	24	18.8±9.4	17.4±8.6	NS
REM	24	18.6±4.2	21.4±4.3	*
SaO <sub>2</sub>	24	98.1±1.3	98.8±0.5	*
mean SaO <sub>2</sub>	24	93.2±2.1	94.2±1.6	*
SaO <sub>2</sub> nadir	24	81.1 ±7.8	87.5±5.5	*
SE	24	85.0±9.5	89.1±6.6	NS

OA – oral appliance, AHI – apnea/hypopnea index, PSG – polysomnogram, AI – apnea index, HI – hipopnea index, S<sub>1</sub> – sleep stage 1, S<sub>2</sub> – sleep stage 2, S<sub>3,4</sub> – sleep stage 3,4, REM – non-rapid eyes movement sleep, SaO<sub>2</sub> – oxyhemoglobin saturation, SE – sleep efficiency, NS – no significant, \*P<0.05



Figure 1. Results from entire population. PSG pre and post OA treatment

# Oxyhaemoglobin saturation (SaO<sub>2</sub>)

The mean minimum oxyhaemoglobin saturation (SaO<sub>2</sub> nadir) increased from 81.1 $\pm$ 7.8 to 87.5 $\pm$ 5.6 (P<0.001); the mean change of mean oxyhaemoglobin saturation (mean SaO<sub>2</sub>) increased from 93.3 $\pm$ 2.1 to 94.5 $\pm$ 1.8 (P<0.05); and the mean basal oxyhaemoglobin saturation (SaO<sub>2</sub>) increased from 98.1 $\pm$ 1.4 to 98.7 $\pm$ 0.6 (P<0.05).

# Sleep architecture – non-rapid eye movement sleep (NREM)/REM sleep and sleep efficiency (SE)

The mean of stages S<sub>1</sub>, S<sub>2</sub>, S<sub>3,4</sub> and SE showed no statistical significance, but REM sleep increased from 17.9 $\pm$ 5.6 to 20.9 $\pm$ 5 (P<0.05) in all 24 patients.

Concerning the side effects, there were temporary complaints of dry mouth and excessive salivation in

the first month of device usage. None has complained of pain in the TMJ region.

#### Discussion

In our study, we have analyzed the results based on three treatment success rates: the criterion of the American Academy of Sleep Medicine (AASM), AHI  $\leq$ 5.0 (which is the desirable one) [17]; the criterion called liberal, which was an AHI <10/h, as widely used in other published studies [6, 26, 27]; and the criterion used in the previous study, which was AHI <15 [28]. Studies showing a reduction of AHI <5.0 with the use of OA for the treatment of OSA are rare [29], and this was one of the aims of our research. The findings of the present study, independently of the treatment success rate used, are in accordance with the current literature, and confirm that MRA is an efficient treatment for OSA and snoring [3, 5, 6, 26-29]. In the NOSA group, subjective symptoms and the presence of snoring were reduced, according to patients and their partner's report, but the other variables showed no significant results, maybe because the variables at baseline already presented normal values. In a study with 23 non-apnoeic snorers using an adjustable MRA, the PSG variables such as AHI, SaO<sub>2</sub> nadir and REM sleep showed no statistical results; only snoring was significantly reduced, which agrees with our findings [30]. In our study, the OSA group presented a reduction of subjective symptoms and snoring, according to patients and their bed partner reports. Analyzing their results according to three treatment success rates, we found that 45.8% of 24 patients returned to a normal condition, AHI <5; 83.3% presented a decrease to AHI <10; and 100% of patients presented a decrease to AHI <15, including the severe ones. Previous studies have reported OA success rates in reducing AHI <5 of 63.8%, in reducing AHI <10 of 33 and 48% respectively [26, 27], and in reducing AHI <15 of 71% [27]. As found in recent studies using different designs of MRA, our results showed that the highest treatment effect was obtained among moderate OSA patients [7, 28, 31-33]. In the present study, 14 moderate OSA patients returned to a normal condition, with an AHI <5. A few scientific papers report the number of patients who reached an AHI <5 after MRA usage [29]. An important point of this research was to show the number of OSA patients who returned to a normal condition with this kind of OA, which was almost 50%, in this study. The present study has opted to use the aPMP because it allows individual protrusion and there are few papers regarding this specific device [21]. We can state that the respiratory results obtained in our work are in concordance with the findings of Parker et al., (1999) [21] who found 79% of AHI <10 also using this kind of appliance. According to the study cited above, the authors also found an increase of SaO<sub>2</sub> nadir from 78.2 to 83.8% and 81.7 to 87.5% respectively, besides

an increase in REM sleep. In our study, the SaO<sub>2</sub> nadir increased from 81.0±7.8 to 87.0±5.5 (P<0.05) and REM sleep increased from 17.9±5.6 to 20.9±5.0 (P<0.05). Tsuiki et al. [32] evaluated 20 moderate and severe OSA patients using an MRA and found an increase of SaO<sub>2</sub> nadir from 77.2±11.3 to 83.6±7.2%. Our study showed no statistically significant results for NREM sleep and SE, in agreement with the published scientific papers, which also showed no significant improvement in these variables, independently of OSA severity [33, 34]. Goto et al. [9] successfully treated two severe OSA patients with a mandibular repositioning appliance as in our study. In our research, severe OSA patients, one man (aged 31) and one woman (aged 51), had AHI reduced from 38.5 to 12.3 and from 37.0 to 9.3, respectively. The aPMP, in these two cases, showed a marked efficacy to treat OSA. Many authors affirm that the improvement in respiratory variables is dependent on the amount of mandibular protrusion [12, 28, 35, 36]. Treatment success in OA therapy appears to depend not only on the anterior titration of the mandibular position, which might maximize the treatment efficacy for each patient, but also on the amount of change in the size of the UA in response to mandibular advancement [32, 36, 37]. However, the precise mechanisms controlling the function of the muscles responsible for maintaining the patency of the upper airway remain incompletely understood and more physiological research is needed to help understand the neuronal mechanisms that are activated following placement of the MRA. In a recent study, Johal et al. [38], using 50 OSA patients, evaluated genioglossus (GG), geniohyoid (GH) and masseter (M) muscle activity. Awake electromyography (EMG) activity was recorded at baseline and after 8 weeks with the MRA in situ. The authors found that a significant increases in GG, GH and M muscle activity accompanied placement of the MRA. There are several scientific papers showing that besides MRA efficacy they are more accepted among OSA patients [6, 39]. It must be noted that the OSA group presented a low BMI, which may have contributed to the significant improvement of AHI. Increase of weight is related to fat deposition in the airway region and high probability of airway collapse [10]. Due to this, obesity should be treated from childhood to avoid its increase with age leading to physiological and metabolic alterations in adulthood [40]. Considering that oral appliance treatment is the most accepted treatment among OSA patients, it is important that there is close collaboration between the dental profession and those in sleep medicine for improvement of patients' quality of life.

In conlusion, comparing baseline and post-treatment respiratory variables, the use of an adjustable PM Positioner in OSA treatment showed high efficacy in the OSA group. The oral appliance was more effective in moderate OSA patients. Snoring was markedly reduced in the NOSA and OSA groups according to the patient's partners report. The improvement of  $SaO_2$  nadir and REM in the OSA group was statistically significant. Based on the reduction of baseline AHI <5 or less, to 10 or less and to 15 or less, the OA treatment success rate is 45.8, 83.3 and 100% respectively in the OSA group. The low mean BMI of the sample could have been an important factor to achieve the significant decrease of AHI. Almost 50% of the OSA group have returned to a normal condition.

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