Efficacy of an Oral Appliance for the Treatment of Obstructive Sleep Apnea

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Purpose: The aim of this study was to validate the use of a mandibular repositioner appliance (MRA) to treat obstructive sleep apnea (OSA) and primary snoring, comparing polysomnographic and Epworth Sleepiness Scale (ESS) data obtained prior to and during MRA treatment. ***Materials and Methods:*** Sixty-three patients who presented with different degrees of OSA severity or primary snoring were fitted to a PM positioner between 2009 and 2011. The diagnosis was established by a polysomnogram (PSG) prior to treatment and after 6 months to verify the efficacy of MRA therapy. Subjective daytime sleepiness was evaluated by ESS questionnaire prior to treatment and at the follow-up. ***Results:*** Patients were divided into primary snoring and OSA groups. For the primary snoring group, PSG variables did not show significant results, except for a decrease in snoring. For the OSA group, the mean apnea-hypopnea index (AHI) was reduced from 23.0 ± 11 to 5.3 ± 4.0 and median ESS reduced significantly from 13.0 to 8.5. Complete response (AHI < 5) was found in 25 (40%) patients and partial response (AHI ≤ 10) in 27 (43%) patients. ***Conclusion:*** The findings validate the efficacy of the adjustable PM positioner for the safe treatment of OSA. *Int J Prosthodont 2013;26:334–339. doi: 10.11607/ijp.3284*

Oral appliance (OA) therapy is one of the most routine treatments for obstructive sleep apnea (OSA), although continuous positive airway pressure (CPAP) is the gold standard for OSA.[1] In the last decade, studies addressing OA efficacy have proven that it is a safe therapeutic approach for patients with OSA.[2] A growing body of research on sleep disorders and the physiopathology of OSA has demonstrated the important role dentistry plays in increasing the lifespan of individuals with OSA. The etiology of this condition appears to be a combination of craniofacial abnormalities and neuromuscular factors that lead to the collapsibility of the upper airways.[3]

There are more than a hundred types of OAs on the market, but fewer than 15 have been rigorously tested scientifically as an effective treatment for OSA. A mandibular repositioning appliance (MRA) differs in the material from which it is made and the possibility of mandibular advancement, also known as titration. A recent randomized crossover trial has demonstrated that custom-made devices are more effective than prefabricated ones, which are also known as boil-and-bite devices.[4] Likewise, an adjustable MRA appears to be more effective than a monoblock or single-arch positioning device, which does not allow titration.[5] It is therefore very important for clinicians to have enhanced knowledge in the field of sleep medicine to be able to indicate what kind of device offers the best efficacy and fewest side effects. These differences are decisive to the efficacy of an OA in treating OSA.

A number of studies have proven the efficacy of MRA use in decreasing the apnea-hypopnea index (AHI), increasing oxyhemoglobin saturation (SaO_2) during sleep, reducing blood pressure, and improving heart rate variability.[6–10] According to the American Academy of Sleep Medicine, MRA use is the first treatment option for snoring, upper airway resistance syndrome, and mild to moderate OSA, as well as the second option when patients with severe OSA refuse CPAP therapy.[1] In clinical practice, it is common for patients with severe OSA to prefer an MRA over CPAP despite the greater efficacy of the latter in such cases. Randomized studies comparing CPAP and MRA use have shown that, despite being less effective in reducing the AHI, an MRA improves attention and cognitive function and reduces sleepiness to similar levels to those achieved with CPAP therapy.[11–14]

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In Brazil, as in other countries, there are a variety of MRA designs available on the conventional and internet markets and it is common to see patients using devices without proven efficacy and not supported by scientific studies. The lack of knowledge on the part of clinicians regarding sleep medicine and the design of such appliances can be considered dangerous, as OSA is a complex disease that can lead to cardiovascular, endocrine, and cognitive problems as well as other comorbidities.

The aim of this study was to validate the use of an MRA denominated the adjustable PM positioner in Brazil for the treatment of OSA and primary snoring, comparing data from polysomnography and the Epworth Sleepiness Scale (ESS)[15] prior to and after 6 months of MRA usage.

Materials and Methods

Subjects

A prospective study was carried out involving patients with different degrees of OSA severity who were fitted with a PM positioner between 2009 and 2011. It is a consecutive large sample study, with no control subjects or control condition. This work is an arm of a trial study registered with the Brazilian Registry of Clinical Trials (ReBEC: trial RBR-93GGRM). According to the international committee of medical journal editors, any clinical trial with humans must be registered on a national registry test clinic. The ReBEC is a joint project of the Ministry of Health, the Pan American Health Organization, and the Oswaldo Cruz Foundation.

Subjects with complaints of snoring, choking during sleep, and daily sleepiness were referred to the sleep laboratory of the Master's Program in Rehabilitation Sciences of Nove de Julho University, São Paulo, Brazil, and to the private clinic of one of the authors for treatment for sleep respiratory disturbance. Subjects with basal polysomnography (PSG) and a 6-month follow-up titration with PSG were enrolled. The inclusion criteria were complaints of snoring, sleepiness, choking during sleep, OSA demonstrated by PSG, presence of eight to 10 teeth per arch, and good compliance (at least 4 nights per week) with MRA usage. The exclusion criteria were mandibular protrusion less than 7 mm, mandibular opening less than 35 mm, severe cariogenic or periodontally compromised dentition, predominant central sleep apnea, or the presence of muscle/joint pain. All subjects agreed to participate and signed a statement of informed consent. The study received approval from the Ethics Committee of Nove de Julho University.

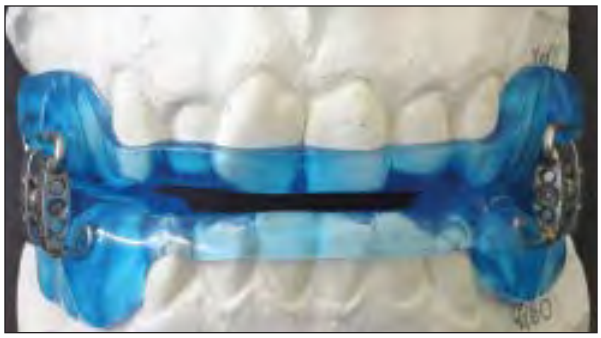

Fig 1 Example of the mandibular advancement splint used in this study (PM Positioner).

Polysomnography

PSG was performed using the Somnologica Studio (Embla A10, version 3.1.2., Flaga hf Medical Devices) recording device. A standard level 1 16-channel sleep study was performed. The readouts were scored and interpreted by physicians specially trained in sleep medicine based on the method proposed by Rechtschaffen and Kales.[16] The channels consisted of two electroencephalographic leads, two electrooculographic leads, submental surface electromyography, nasal-oral airflow, snore sensor, abdominal and thoracic respiratory effort sensor, oximetry, body position sensor, tibialis anterior surface electromyography, and an electrocardiographic rhythm strip. The AHI was defined as the number of episodes of apnea plus episodes of hypopnea per hour of sleep. OSA was defined as AHI > 5.[17]

Study Protocol

The diagnosis and severity of OSA were established by PSG prior to the study. On the first appointment, a dental history was taken, a clinical evaluation was performed, and patients filled out the ESS. Casts were made, and mandibular advancement was determined using a George Gauge.

All patients were treated and followed up by a single sleep clinician throughout the study period. A single dental technician constructed the custom-made MRA for each patient with 65% to 75% maximal protrusion[2,17] and vertical opening of 3 to 4 mm between incisor edges based on bite wax impressions.[18] The MRA used by all patients was the adjustable PM positioner (Fig 1). It offers good retention and adaptation, and the screws do not interfere with tongue space. In addition, it is approved by the US Food and Drug Administration and has been used in previous studies assessing the efficacy of OA usage for the treatment of OSA.[6,7,19–21]

Table 1 Demographic Patient (n = 63) Data

Demographic data	Mean ± SD
Age (y)	48.0 ± 11.0
BMI (kg/m^2)	26.7 ± 3.6
Neck circumference (cm)	40.6 ± 3.0
Sex (M/F)	49/14

SD = standard deviation; BMI = body mass index.

Table 3 Side Effects Presenting with OA Use

Side effects	n (%) in 7 snoring patients	n (%) in 56 OSA patients
Dry mouth	–	9 (16.0)
Excessive salivation	1 (14.0)	27 (50.0)
Occlusal changes	–	4 (7.0)
Teeth discomfort	1 (14.0)	17 (30.4)
TMJ discomfort	–	2 (3.6)

TMJ = temporomandibular joint.

Table 2 Polysomnographic Variables for 56 Patients with OSA

	N = 56	
Variables	Without MRA	With MRA
AHI	23.0 ± 11.0	5.8 ± 4.0**
REM (% of TST)	18.2 ± 5.2	22.0 ± 4.3*
SaO_2 basal (%)	97.5 ± 1.8	97.7 ± 2.2
SaO_2 mean (%)	93.0 ± 2.0	94.0 ± 2.7*
SaO_2 nadir (%)	81.5 ± 8.2	87.0 ± 7.5**
TST (min)	412 ± 53.0	400.5 ± 32.0
Sleep latency (min)	18.2 ± 3.0	15.4 ± 2.3
PLM index	8.1 ± 1.3	4.3 ± 1.7
Arousal index	31.0 ± 13.0	11.4 ± 2.4*
SE (%)	85.5 ± 8.0	87.0 ± 6.5
Median ESS (range)	13 (3–24)	8.5 (2–13)

AHI = apnea-hypopnea index; REM = rapid eye movement; SaO2 = oxyhemoglobin saturation; TST = total sleep time; PLM = periodic limb movement; SE = sleep efficiency (total sleep time/total bed time: the ratio of time spent asleep to the amount of time spent in bed); ESS = Epworth Sleepiness Scale. *P < .01; **P < .0001.

This appliance was fabricated with thermosensitive acrylic resin in two parts (one for the maxilla and one for the mandible), with complete coverage of the occlusal sides of the teeth, joined together by a hyrax 11-mm expansion screw on each side allowing titration based on the needs of each individual with mandibular advancement of 0.25-mm increments per turn. The MRA was fitted on the second appointment.

Titrations were performed at the dental office on a weekly basis, with advancements of 0.5 to 1.5 mm. The amount of advancement was based on reports by the patient and their partners regarding reductions in snoring and apnea events and/or based on physiologic limitations. Subjective daytime sleepiness was evaluated using the ESS both prior to treatment and at the 6-month follow-up. The efficacy of MRA therapy was determined using additional PSG with the oral appliance in situ after a minimum of 6 months of MRA use (range, 6 to 9 months). Patients with severe OSA and who refused CPAP therapy were also included in this protocol.

Success Criteria and Statistical Methods

There is a lack of consensus regarding the definition of a successful treatment outcome.[20] Thus, three different cutoff points were defined in the present study. *(1)* Complete response: AHI < 5.0; *(2)* partial response: AHI ≤ 10.0 or 10.0 > AHI ≤ 15.0 or at least a 50% reduction in basal index; and *(3)* nonresponse: less than a 50% reduction in basal AHI.

The two-tailed *t* test for paired observations was used to analyze the effects of MRA use on polysomnographic variables. The MINITAB Release 14.2 Upgrade program was used for all calculations. Data are presented as median for ESS and mean ± standard error, with *P* values < .05 considered significant. The sample size was estimated at 34 subjects, considering α = .05 and power = 80% based on values reported in the literature.

Results

Seventy-one patients met the inclusion criteria and 63 finished the protocol. Eight patients withdrew (1 had a gag reflex, 2 moved to another city, 1 was in a depressed state, and 3 did not want to use the OA). Thus, the study population comprised 63 patients (49 men and 14 women); mean age: 48.0 ± 11.0 years (range, 32 to 74 years); neck circumference: 40.6 ± 3.0 cm; and mean body mass index (BMI) 26.7 ± 3.6 (Table 1). The mean period of OA use before performing a second PSG was 7.2 months (range, 6 to 9). Twenty-six patients used an OA for 6 months, 12 for 7 months, 10 for 8 months, and 15 for 9 months. Comorbidity was present in 45.5% (5) of patients with mild OSA (3 with hypertension and 2 insulin resistance), in 22.0% (7) of patients with moderate OSA (4 with hypertension and 3 with diabetes and hypertension), and in 70% (9) of patients with severe OSA (9 with hypertension and 3 with hypertension and diabetes). To achieve a more detailed evaluation,

With and Without MRA Use Divided by Baseline Disease Severity

Mild OSA (n = 11)		Moderate OSA (n = 32)		Severe OSA (n = 13)	
Without MRA	With MRA	Without MRA	With MRA	Without MRA	With MRA
12.5 ± 2.0	3.0 ± 2.6**	21.6 ± 3.0	5.0 ± 3.4**	44.5 ± 13.5	9.0 ± 4.3**
17.2 ± 6.9	25.6 ± 25.5	18.5 ± 5.0	20.7 ± 5.0	18.4 ± 4.8	21.5 ± 2.9*
98.5 ± 0.4	95.5 ± 6.0*	97.5 ± 1.7	98.0 ± 1.2*	95.8 ± 1.5	96.9 ± 3.6
92.0 ± 1.3	95.5 ± 1.6	92.9 ± 1.9	94.2 ± 1.6*	92.1 ± 1.9	93.9 ± 4.7
86.5 ± 6.3	89.6 ± 2.7**	81.9 ± 5.0	86.5 ± 4.8**	75.7 ± 9.4	87.0 ± 3.6**
409 ± 41.0	392.3 ± 39.0	413 ± 51.0	398 ± 52.0	390 ± 41.0	407 ± 52.0
16.4 ± 4.1	14.2 ± 3.2	17.2 ± 3.6	16.0 ± 2.1	17.8 ± 2.4	16.7 ± 2.7
0.00	0.00	5.3 ± 1.9	2.1 ± 1.0	9.7 ± 2.3	5.2 ± 1.9
5.7 ± 1.4	4.9 ± 1.1	13.3 ± 5.0	9.0 ± 2.0*	38.5 ± 10.2	10.7 ± 2.5*
84.5 ± 11.4	87.1 ± 7.1	85.6 ± 7.7	87.9 ± 7.6	86.6 ± 7.2	87.9 ± 5.6
9.5 (4–14)	5.8 (1–9)	13.7 (9–20)	9 (2–12)	16.6 (8–24)	9.6 (5–13)

the sample was further divided into two groups after basal PSG according to the examination results: a primary snoring group without sleep apnea and an OSA group. In the primary snoring group (2 women and 5 men), no significant differences in PSG variables were found prior to and following MRA use. Snoring was not objectively measured in the PSG beyond recording its presence or absence. Moreover, this study relied on reports from partners to determine if snoring had diminished or was eliminated. For the 56 patients in the OSA group (12 women and 44 men), the results will now be described.

Polysomnographic Results

The AHI of the entire OSA group was reduced from 23.0 ± 11.0 to 5.3 ± 4.0 ($P \leq .001$). Within the success treatment criteria cutoff points used, complete response (AHI < 5.0) was found in 35 (55.5%) patients, partial response (AHI ≤ 10.0 or 10.0 > AHI ≥ 15.0 or at last 50% basal index reduction) in 56 (100%) patients, and nonresponse in zero patients. According to disease severity, among patients with mild OSA (11), the mean AHI reduced from 12.5 ± 2.0 to 3.0 ± 2.6 ($P < .0001$); 63.6% were complete responders and 36.4% partial responders. For the moderate group (32), the mean AHI reduced from 21.6 ± 3.0 to 5.0 ± 3.4, with 62.0% complete responders and 38.0% partial responders. In the severe group (13), the mean AHI was reduced from 44.5 ± 13.5 to 9.0 ± 4.3, with 31.0% presenting complete response, 92.0% partial response, and 0% no response. In the analysis of 56 patients, rapid eye movement (REM) sleep significantly increased from 18.2% ± 5.2% to 22.0% ± 4.3% of total sleep time ($P < .001$) and the severe group showed an improvement. There were no significant changes in other sleep architecture parameters. For the entire OSA group, MRA therapy significantly increased the SaO_2 nadir from 81.5 ± 8.2 to 87.0 ± 7.5 ($P < .001$) and the mean SaO_2 increased from 93.7 ± 1.9 to 94.5 ± 2.7 ($P < .001$). According to disease severity, patients with moderate OSA had a statistically significant improvement in mean, basal, and minimum SaO_2 ($P < .001$). The severe OSA group showed a significant improvement in the SaO_2 nadir and in REM, and the mild OSA group presented significant improvement in basal and SaO_2 nadir. Apnea related to sleep position was predominant in the mild OSA group. Periodic leg movement index, total sleep time, and sleep latency presented no significant results. Arousal index showed statistical significance for the moderate and severe OSA groups. All values are presented in Table 2.

Subjective Evaluation

The median ESS score for the entire OSA group was significantly reduced from 13.0 (range, 3 to 24) to 8.5 (range, 2 to 13). Thirteen patients had severe daytime sleepiness prior to the study, five of whom had moderate daytime sleepiness following MRA usage. Twenty-four patients experienced short-term side effects, such as excessive salivation, dry mouth,

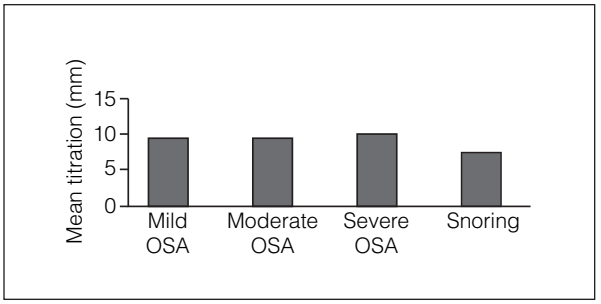

Fig 2 Mean mandibular advancement (mm) achieved divided by baseline disease severity.

occlusal changes, and discomfort in the teeth and temporomandibular joint (TMJ) (Table 3), which were controlled within the first 2 months. Two patients reported TMJ discomfort that subsided after 4 months. Two patients reported an occlusal change in the posterior region. At the follow-up assessment, all patients reported being satisfied with the therapy. Mean mandibular advancement throughout the study period was 9.5 ± 1.0 mm in the OSA group and 7.5 ± 0.4 mm in the snoring group (Fig 2). No significant correlation was found between the amount of titration and BMI or AHI.

Discussion

The adjustable PM positioner proved to be an effective treatment for snoring and OSA and led to a reduction in daytime sleepiness. These results demonstrate that this specific MRA design is a valid therapeutic option for the treatment of OSA. Interestingly, no correlation was found between the amount of mandibular advancement and BMI or a reduction in AHI. A number of factors may contribute to the treatment success of MRA use, such as anatomical factors, tissue compliance, and neuromuscular factors. Moreover, the design of the device and the material with which it is made may influence the treatment outcome. This study is similar to previously published studies that employed the same or similar appliances for the treatment of different degrees of OSA severity.[19–28]

In a previous randomized crossover study, Gauthier and collaborators[25] compared two different titratable MRAs for the treatment of mild and moderate OSA and found that both led to a significant reduction in respiratory events, with a minimal difference between designs. In another recent randomized study also comparing two types of titratable MRAs,[26] the authors found similar effects regarding sleep outcomes with both appliances over a 2-year follow-up period. The present study evaluated a titratable appliance and demonstrated a significant reduction in respiratory events in patients with different degrees of OSA severity. It should be stressed that more than 50% of the patients achieved conditions considered normal (AHI < 5.0) using the PM positioner. These findings are similar to those achieved in the previous comparisons between appliances, and one may speculate that this MRA design has similar long-term efficacy, provided titration protocols are used with custom-made appliances.

The definition of treatment success is not homogeneous across studies evaluating MRA efficacy. Some articles describe success using an AHI ≤ 10.0, AHI ≤ 15.0 or a 50% reduction in basal AHI, or a more rigorous AHI ≤ 5.0 to define a successful outcome.[6,20,24,25] A previous study[20] evaluated the effects of a titration PSG on treatment success using the adjustable PM positioner among patients with moderate to severe OSA, analyzing the results with the same criteria employed in the present study. The authors found a significant reduction in respiratory events, with success described as 63.0% prior to PSG titration and 90.0% after PSG titration. In the present study, MRA usage successfully treated 55.5% of the patients and partially treated 44.5%. Considering those with mild to moderate OSA, 63.6% of the sample achieved AHI < 5.0. One may hypothesize that the different rate of treatment success in the present investigation compared to previous studies may be related to the characteristics of patient selection, such as a lower BMI.

Sleep variables, such as REM sleep and SaO_2 nadir, significantly improved with the use of the MRA, as reported in previous studies. With regards to side effects, there were no withdrawals in the present study due to device usage. Short-term or transitional side effects were found in the majority of the sample and these side effects did not last more than 3 months. The side effects reported were dry mouth and muscle/dental discomfort. A previous study reported similar findings in the evaluation of signs and symptoms of temporomandibular disorder (TMD) among patients using the PM positioner over a 5-year period, in which only two patients experienced TMJ pain after 6 months and treatment with an occlusal splint was implemented to manage the situation and avoid the withdrawal of the device.[27] The TMD treatment protocol used had been reported previously.[28] As reported in previous studies, an improvement in daytime sleepiness was found, as assessed using the ESS. An MRA is indicated as the first option for the treatment of snoring and mild OSA, but it can also be indicated to treat moderate to severe OSA when patients do not accept or tolerate CPAP.[1] Patients often request an oral device, and studies have shown that

such devices are also effective in treating severe conditions, offering yet another option for those affected by this disease. The results of the present study demonstrate the usefulness of an MRA as effective treatment for OSA.

Conclusion

The findings validate the efficacy of the adjustable PM positioner for the treatment of OSA in Brazilian patients. The device can also be used to treat moderate to severe OSA in patients who refuse CPAP therapy. The PM positioner provides safe treatment for those who suffer from this condition as well as confidence to dental sleep professionals when choosing an oral device for the treatment of OSA.

Acknowledgment

The authors reported no conflicts of interest related to this study.

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