Article published online: 2023-11-22

Condylar Position in the Treatment of Obstructive Sleep Apnea with a Mandibular Advancement Device: A Pilot Study

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Sleep Sci 2023;16(4):e381–e388.

Abstract

Objective To evaluate, through a tomographic analysis, the positional changes of the condyle when using a mandibular advancement device (MAD) for the treatment of obstructive sleep apnea (OSA), and to assess if the condylar positions influence OSA polysomnographic patterns.

Materials and Methods Ten OSA patients underwent treatment with an MAD, and polysomnographic and tomographic examinations were performed before therapy (T0) and after MAD placement (T1).

Results By comparing the T0 and T1 measurements, we observed advancement and extrusion of the condyles in all patients ($p < 0.001$), as well as a decrease in the apnea-hypopnea index (AHI) ($p < 0.001$), increases in the mean ($p = 0.001$) and minimum ($p < 0.001$) oxyhemoglobin saturation, and a significant correlation between the anterior displacement of the right ($p = 0.003$) and left ($p = 0.015$) condyles.

Discussion Condylar advancement was directly correlated with OSA improvement: the greater the advancement, the better the AHI.

Keywords
- obstructive sleep apnea
- mandibular advancement
- mandibular condyle
- cone-beam computed tomography

Introduction

Obstructive sleep apnea (OSA) is characterized by recurrent upper airway obstruction events during sleep, and it is associated with clinical signs and symptoms. Obstruction can manifest as a respiratory effort-related or arousal-related awakening and as a limitation or reduction in airflow (hypopnea), or complete cessation of airflow (apnea), upon persistent breathing movements.[1,2] The etiology of OSA is multifactorial, with the possible involvement of anatomical, functional, and neuromuscular characteristics, and its diagnosis is based on polysomnography (PSG).[3]

The apnea-hypopnea index (AHI) is a PSG parameter that classifies OSA as mild (AHI = 5 to 15 events/hour), moderate (AHI = 15 to 30 events/hour), or severe (AHI $\geq$ 30 events/hour).[4,5] Moderate OSA may be associated with cardiac arrhythmias, while severe OSA may be associated with heart or coronary insufficiency. To prevent cardiovascular risks and

received
June 9, 2022
accepted
January 23, 2023

DOI https://doi.org/10.1055/s-0043-1776870.
ISSN 1984-0659.

Thieme Revinter Publicações Ltda., Rua do Matoso 170, Rio de Janeiro, RJ, CEP 20270-135, Brazil

other OSA symptoms, such as snoring, nonrestorative sleep, excessive daytime sleepiness, neurocognitive alterations, depression, and anxiety, the treatment of this disorder is essential.[3,6–8]

Continuous positive airway pressure (CPAP) is the gold-standard treatment for OSA; however, orthognathic surgery for mandibular advancement[9] and the use of a mandibular advancement device (MAD) are efficient therapies for patients who are not eligible for the CPAP treatment.[3,6–8] The mechanism of action of an MAD is based on the extension and distension of the upper airway; this distension prevents the collapse of the oropharynx and the base of the tongue, which, in turn, prevents the closure of the upper airway.[3,10] Although the mechanism of action of MADs is well understood, their effects on the condylar position during OSA treatment remain unclear.[1,11,12]

Cone-beam computed tomography (CBCT) enables a reliable evaluation of the morphological and positional changes of the mandibular condyles. The three-dimensional (3D) evaluation of images from CBCT scans may significantly help in the identification and quantification of mandibular condyle changes during MAD use for OSA treatment.[13] Accordingly, the present study aimed to evaluate and quantify the positional changes of the mandibular condyle using CBCT images during treatment with MADs, and assess whether these changes in condylar influence OSA PSG parameters.

Materials and Methods

Study Design

In the present before-and-after pilot study, 10 volunteers with mild to moderate OSA were referred for MAD treatment. Initially, 83 patients were selected from the Sleep and Breathing Disorders Center of the Universidade Federal do Ceará, state of Ceará, Brazil. Following the inclusion criteria, 33 patients diagnosed with mild or moderate OSA were referred for treatment with an MAD; of these 18 were excluded; subsequently, based on the exclusion criteria, another 5 subjects were excluded, resulting in a final sample of 10 patients (►**Fig. 1**), who underwent a sequence of evaluations: initial, sequential, and final. Cone-beam computed tomography and PSG assessments were performed

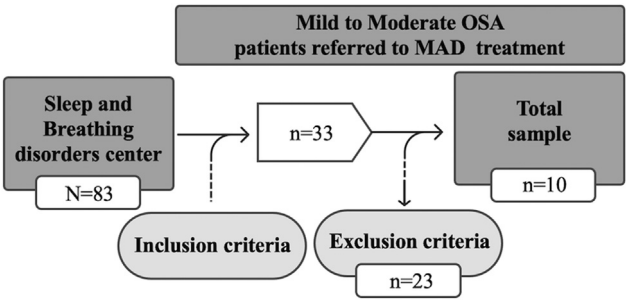

Fig. 1 Study sample.

before the MAD treatment (T0) and after 8 months (T1) of MAD placement (►**Fig. 2**).

Eligibility Criteria

The present study included individuals of both genders aged between 18 and 65 years, with a body mass index (BMI) $\leq$ 35 kg/m^2, an AHI $>$ 5 and $<$ 30 (mild to moderate OSA), with a varied spectrum of severity levels according to the criteria of the American Academy of Sleep Medicine (AASM),[4] and negative diagnosis of temporomandibular disorders (TMD) according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD).

The exclusion criteria were as follows: loss of posterior dental support that compromised the retention of an MAD; active periodontal disease; dental crown/dental root ratio $\leq$ 1; need for primary dental treatment (for caries, endodontic treatments, or retreatments and dental prostheses, for example); anterior open-bite; mandibular protrusion movement $<$ 5 mm; limited mouth opening; history of alcoholism; use of sleep inducers; patients with habits or professions that led to the deprivation of sleep or alterations in the sleep-wake cycle; sleep disorders other than OSA; history of OSA treatment (for example, MAD, surgeries or CPAP, or diagnosis of TMD according to the RDC/TMD); and patients with tomographic images that did not enable adequate evaluations due to movements during acquisition. Of the 33 patients initially selected, 23 were excluded; therefore, the total sample comprised 10 OSA patients.

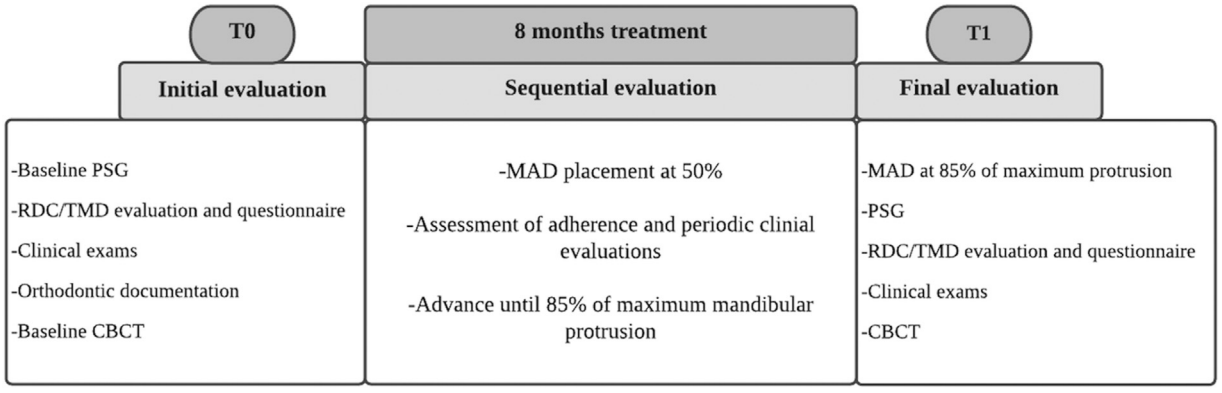

Fig. 2 Study design.

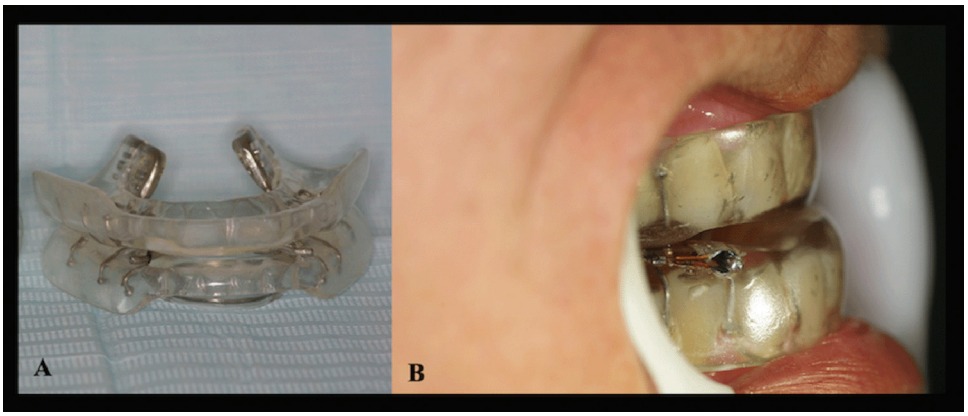

Fig. 3 (A) Frontal view of the Brazilian Dental Appliance (BRD). (B) Lateral view with the appliance placed in an OSA patient.

Mandibular Advancement Device

The MAD used in the present study was an individualized acrylic appliance with a vertical dimension of 5 mm called Brazilian Dental Appliance (BRD; NeoSleep, Curitiba, PR, Brazil). The BRD has two independent (right and left) expanding mechanisms (screws positioned with their long axes in the anteroposterior direction) positioned in the posterior palatine region of the upper acrylic base. From these expander mechanisms, two independent palatine stems (one right and one left) are inserted into two small tubes located in the anterior portion (distal to the lower canines) of the lower support acrylic base[15] (►**Fig. 3**). To make this individualized appliance, dental impressions were obtained, and the mandibular positions of centric relation and maximum protrusion were registered with the George Gauge device (Great Lakes Dental Tech, Tonawanda, NY, United States) and condensation silicone (dense). The MAD was initially placed at 50% of the maximum advancement, and all patients were instructed to advance the device by 0.5 mm each week until 85% of therapeutic protrusion was achieved, considering the improvement in signs/symptoms in the medical record.[16,17] To assess adherence to the treatment Weekly follow-up was performed until the therapeutic protrusion position was achieved to.

Tomographic Assessment

The tomographic images were obtained using the iCAT (Imaging Sciences International, Hatfield, PA, United States) set at 120 Kvp, 30 mA, and 0.4 mm voxels. To perform the CBCT examination, all patients were positioned with the Frankfurt plane parallel to the floor and were instructed not to swallow and to keep the maximum intercuspation position (T0). At T1, CBCT was performed with placement of the MAD. Reconstruction and interpretation of the 3D images and tomographic measurements of the structures were performed with the Dental Slice software (BioParts, Brasília, DF, Brazil). The images had the 3D reconstructions oriented with the axial plane passing through the orbitale (Or) and porion (Po) points (parallel to the Frankfurt plane), with the sagittal plane through the nasion (N) point, and with the coronal plane perpendicular to the axial plane, through the left and right Po points.

To determine the measurements related to the position of the right and left mandibular condyles, reference lines and measurements were performed on the CBCT images obtained at T0 and T1 (►**Fig. 4**).

Polysomnography

The 10 patients underwent PSG for the diagnosis of OSA (T0) and again with the MAD in a mandibular position at 85% of maximum protrusion (T1). The PSGs were performed at night by an experienced technician in a specialized center. The mean time between the first and second PSG assessments was of eight months, and the basal movements were calibrated before performing the examination. A computerized PSG apparatus (Embla N7000, Embla Systems, Inc., Broomfield, CO, United States) was used to record the following sleep parameters: electroencephalography (EEG: C3-A2, C4-A1, O2-A1, and O1-A2), submentonian and tibial electromyography, and bilateral electrooculography, and chest and abdominal movements were recorded using non-calibrated breathing electrocardiography (ECG; modified V1 derivation). Breathing was monitored using a nasal cannula that gauged the airflow by pressure transduction. A thermal sensor was used to measure oral flow plethysmography. For oxyhemoglobin saturation, an infrared pulse oximetry reader was placed on the fingertip of the patient. A sensor placed over the region of the sternum recorded the body position, and a tracheal microphone measured snoring. The following parameters were evaluated according to the previous criteria: sleep staging, respiratory events, arousals, and leg movements. The OSA diagnosis was established by a physician specialized in sleep medicine and the severity classification of each patient was based on the AASM criteria: mil OSA – AHI = 5 to 15 events/hour; moderate OSA – AHI = 15 to 30 events/hour; and severe OSA – AHI $\geq$ 30 events/hour.[4,5]

Study Error

To avoid study bias, the measurements were performed by an experienced examiner and an assessment of intraexaminer reliability was performed by repeating the 3D measurements 3 times with an interval of 7 days, without statistical differences among the measurements in the 3 time points. The reliability data were subjected to the Kolmogorov-Smirnov

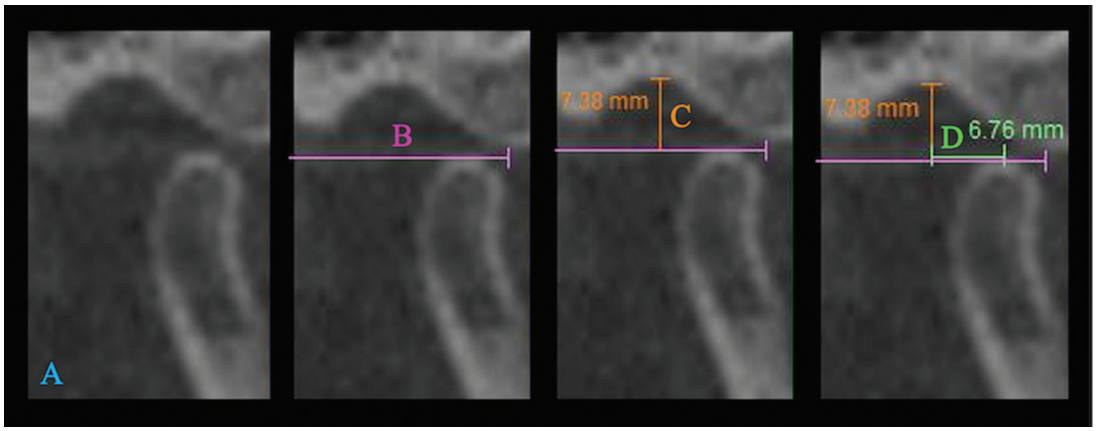

Fig. 4 (A) Sagittal view perpendicular to the long axis of the condyle to determine all lines and measurements. (**B**) Line B, reference line tangent to the uppermost portion of the mandibular condyle, used to determine its highest point. (**C**) Line C, vertical measurement from the deepest point of the joint fossa up to line B, used to determine the extrusion of the mandibular condyle in relation to the joint fossa. (**D**) Line D, horizontal measurement from the highest point of the mandibular condyle up to line C, used to determine the advancement of the mandibular condyle.

normality test, as well as to the Friedman test and Spearman correlation analysis (nonparametric data), to evaluate the calibration of the operator in three moments (the data were expressed as mean ± standard deviation [SD] and median [minimum–maximum] values).

Statistical Analysis

After tabulation and analysis of the sample distribution pattern through the Shapiro-Wilk normality test, all variables were analyzed through the paired *t*-test (parametric data) and subjected to Pearson correlation analysis. The analyses were performed using the SPSS Statistics for Windows software,version 17.0 (SPSS Inc., Chicago, IL, United States), with confidence set at 95%.

Results

Study Error

There were no statistically significant differences regarding the first (4.0 ± 3.2; 3.9 [-2.3–10.3]), second (4.3 ± 3.7; 4.8 [-2.1–12.1]), and third (4.4 ± 3.6; 4.9 [-2.7–11.8]) condylar measurements ($p = 0.880$; Friedman test). There was a statistically significant correlation between the first and the second ($p < 0.001$; r = 0.791), the first and the third ($p < 0.001$; r = 0.817), and the second and the third ($p < 0.001$; r = 0.973) measurements (Spearman correlation).

Tomographic Assessment

We observed an increase in the advancement and extrusion values of the right and left mandibular condyles in all patients with the use of the MAD (►**Table 1** and ►**Fig. 5**); the extents of the advancement and extrusion were statistically significant ($p < 0.001$) (►**Table 2**).

Polysomnography

Comparing the T0 and T1 PSG results, with the use of the MAD, all patients presented a decrease in AHI during sleep and an increase in the values of minimum oxyhemoglobin saturation. Seven patients presented an increase in the mean percentage of oxyhemoglobin saturation, while three maintained their initial values (►**Table 3**). The changes in AHI ($p < 0.001$) and in mean ($p = 0.001$) and minimum ($p < 0.001$) oxyhemoglobin saturation were statistically significant (►**Table 2**).

Influence of Condylar Position in Polysomnography

A correlation between condylar advancement and AHI values was observed: the greater the anterior displacement of the right ($p = 0.003$; r = -0.792) and left ($p = 0.015$; r = -0.685) condyles, the better the AHI and the lower the number of respiratory pauses per hour of sleep. The mean percentage of oxyhemoglobin saturation decreased with the anterior position of the condyles. There was no correlation between condylar advancement and the increase in minimum oxyhemoglobin saturation (►**Table 4**).

Discussion

The present study assessed the effects of an MAD in the condylar position, as well as the influence of condylar displacement on PSG parameters in OSA patients. Several studies[18–21] have evaluated the effectiveness of MADs, which have been reported to ensure an increase in airflow in the upper airway, reduce the AHI, and minimize the clinical signs and symptoms of OSA. However, the literature still fails to explain condylar positioning after OSA treatment with an MAD.

The present study showed that the use of an oral appliance resulted in extrusion and advancement of the right and left mandibular condyles in all cases. In addition, we observed that, when 85% of maximum mandibular protrusion was achieved, there was a greater anterior displacement of the mandibular condyles and a significant reduction in the AHI of the patients, as well as an increase in the mean and minimum oxyhemoglobin saturation. There was a significant association between condylar anteriorization and improvements in the AHI. In agreement with the present study, de Almeida et al.[12] after analyzing six OSA patients treated with an MAD,

Table 1 Tomographic measurements of the position of the right and left mandibular condyles before (T0) and after (T1) the placement of a mandibular advancement device.

Patient	Temporomandibular joint	T0	T1
1	Right extrusion	+1.12	+2.65
	Right advancement	0	+7.87
	Left extrusion	+0.89	+3.71
	Left advancement	0	+7.03
2	Right extrusion	+2.64	+6.09
	Right advancement	-2.13	+2.4
	Left extrusion	+3.26	+6.33
	Left advancement	-1.91	+2.16
3	Right extrusion	+4.42	+9.02
	Right advancement	-1.57	+6.60
	Left extrusion	+4.04	+5.51
	Left advancement	0	+6.43
4	Right extrusion	+3.76	+5.28
	Right advancement	0	+5.01
	Left extrusion	+3.66	+6.2
	Left advancement	0	+5.67
5	Right extrusion	+4.8	+9.63
	Right advancement	0	+7.64
	Left extrusion	+5.76	+8.53
	Left advancement	0	+4.65
6	Right extrusion	+2.55	+8.01
	Right advancement	-2.2	+4.95
	Left extrusion	+3.01	+8.81
	Left advancement	-1.51	4.85
7	Right extrusion	+3.75	+7.62
	Right advancement	0	+7.49
	Left extrusion	+4.59	+7.38
	Left advancement	0	+6.76
8	Right extrusion	+4.54	+7.85
	Right advancement	-1.7	+7.49
	Left extrusion	+4.12	+7.85
	Left advancement	0	+10.41
9	Right extrusion	+1.52	+6.82
	Right advancement	0	+6.02
	Left extrusion	+2.02	+6.82
	Left advancement	-2.13	+5.41
10	Right extrusion	+3.43	+8.41
	Right advancement	0	+8.76
	Left extrusion	+2.4	+7.53
	Left advancement	-1.03	+5.95

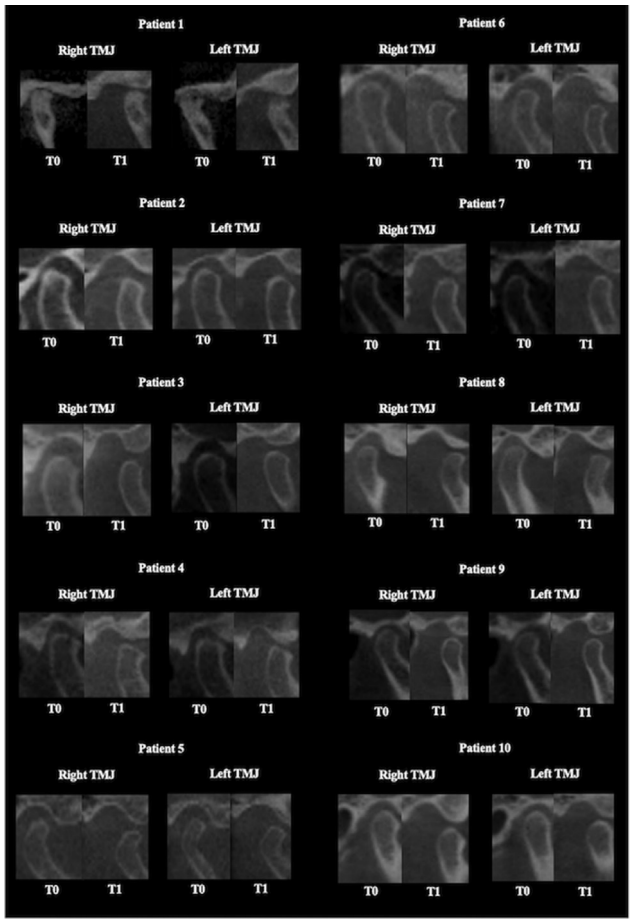

Fig. 5 Tomographic images of the temporomandibular joint (TMJ) of the 10 patients before the treatment with a mandibular advancement device (MAD; T0) and 8 months after (T1) MAD placement.

reported that this device may decrease the AHI. In contrast to the present findings, the authors[12] reported no important condyle anterior displacement with MAD therapy, the minimum oxyhemoglobin saturation significantly only increased in one patient, and no correlation was observed regarding the condylar positions and the PSG findings.[12] Chen et al.[22] evaluated changes in the temporomandibular joint (TMJ) after bilateral sagittal split ramus osteotomy for mandibular advancement and noted different outcomes: three months after the mandibular advancement surgery, the condyles were placed in a concentric position in relation to the glenoid fossa, not showing an anterior alignment after the procedure.

There are several types of oral appliances for OSA therapy, of different shapes and materials, which fit into two main categories: tongue retention devices and MADs, or mandibular advancement devices; the latter are the ones most commonly used in the treatment of sleep disorders. These devices may vary according to the manufacturer (noncustomized or personalized devices), and in terms of retention, titration of the mandibular position, anterior vertical opening, freedom of mandibular movement, and clothing material, among other factors.[7] It should be emphasized that nonadjustable repositioning devices present difficulties regarding patient adaptation and efficiency. The MAD used in the present study was the BRD, which is an appliance made in a specialized laboratory and individualized for the shape of the dental arch of each patient. Use of the BRD may result in stable vertical (opening) and anteroposterior (mandibular protrusion) mandibular positions, and the device is extremely versatile due to its ability to yield progressive and measurable mandibular advancements.[7] To reduce obstructive events during sleep, the maximum mandibular protrusion should preferably be higher than 70%. In the present study, the percentage of mandibular advancement was initially of 50%, which was increased considering the OSA improvement. Patients with 70% of advancement who did not respond had their percentages increased as tolerated.[16,17] The patients in the present study showed improvement in the signs/symptoms of OSA with mandibular advancement of 85%, which is an extensive protrusive position that should be carefully determined, taking into account the results observed in each patient. The treatments should aim for lower levels of advancement with better results.

Based on the responses obtained with the RDC/TMD questionnaire and with the examination of the muscular and articular structures according to the RDC/TMD criteria, none of the patients presented with adverse effects with MAD use, leading to a high adherence to the treatment and, consequently, to the study. In the present study, the second evaluation was performed at 8 months, when the duration of

Table 2 Advancement and extrusion values of the right and left mandibular condyles and polysomnographic parameters.

	T0: mean ± SD	T1: mean ± SD	*p*-value
Right TMJ extrusion	3.25 ± 1.26	7.14 ± 2.05	< 0.001
Right TMJ advancement	-0.76 ± 1.00	6.42 ± 1.88	< 0.001
Left TMJ extrusion	3.38 ± 1.39	6.87 ± 1.52	< 0.001
Left TMJ advancement	-0.66 ± 0.89	5.93 ± 2.10	< 0.001
AHI	17.71 ± 5.63	4.50 ± 3.44	< 0.001
Mean SpO_2	80.40 ± 9.80	94.90 ± 1.91	0.001
Minimum SpO_2	90.20 ± 2.90	96.50 ± 0.97	< 0.001

Abbreviations: AHI, apnea-hypopnea Index; SpO_2, oxyhemoglobin saturation; SD, standard deviation; T0, before the treatment with a mandibular advancement device (MAD); T1, eight months after MAD placement; TMJ, temporomandibular joint.
Note: $^{*}p < 0.05$; paired *t*-test (mean ± SD).

Table 3 Polysomnographic values in T0 and T1.

Patient	T0: AHI	T1: AHI	T0: mean SpO_2	T1: mean SpO_2	T0: minimum SpO_2	T1: minimum SpO_2
1	15.4	0.9	97	97	69	89
2	19.3	12.2	94	97	88	92
3	27.6	5.8	93	96	84	90
4	6.9	0.3	96	97	87	93
5	16.8	5.9	94	97	86	90
6	16.3	4.3	95	97	84	95
7	15.4	1.2	96	96	81	84
8	25	3.9	91	94	57	90
9	16.5	4.9	97	97	85	89
10	17.9	5.6	96	97	83	90

Abbreviations: AHI, apnea-hypopnea index; SpO_2, oxyhemoglobin saturation; T0, before the treatment with a mandibular advancement device (MAD); T1, eight months after MAD placement; TMJ, temporomandibular joint.

MAD use had not been long enough to cause adverse effects in the articular disc, occlusion, and masticatory muscle activities that are important anatomic stomatognathic structures for TMD development. These outcomes are in agreement with those of a study[6] on changes in the TMJ of OSA patients before and after the MAD treatment, which demonstrated that, in a short period, the effect of an MAD on the stomatognathic system is minimal.

A limitation of the present study is the small sample size; however, it is a pilot study, and further investigation involving a greater number of volunteers is planned in the future. The absence of a control group is also a limitation; nonetheless, this may be justified by ethical reasoning, as CBTC exposure may be unnecessary for patients without OSA diagnosis. We have found no previous studies on the correlation of mandibular condyle positional changes and the AHI or oxyhemoglobin saturation. This highlights the originality of the present paper, pointing to a lack of redundancy between the present study and other studies.

The present study provides clinicians with important knowledge on OSA treatment with an MAD. At 85% of maximum protrusion, it may be expected that patients with greater condylar advancement will present better AHI. This information is essential for adequate planning and prognosis of OSA patients to be treated with oral advancement appliances. Moreover, according to Gurgel

Table 4 Correlation between extrusion/advancement values and polysomnographic results.

		Δ right extrusion	Δ right advancement	Δ left extrusion	Δ left advanced	Δ AHI	Δ mean SpO_2	Δ mininum SpO_2
Δ right extrusion	r	–	0.234	0.515	-0.022	-0.144	0.395	-0.002
	p-value	–	0.258	0.064	0.476	0.346	0.130	0.498
Δ right advancement	r	–	–	0.088	**0.633***	**-0.792***	**-0.592***	-0.156
	p-value	–	–	0.405	**0.025**	**0.003**	**0.036**	0.334
Δ left extrusion	r	–	–	–	0.262	0.21	- 0.054	0.277
	p-value	–	–	–	0.232	0.280	0.441	0.219
Δ left advancement	r	–	–	–	–	**- 0.685***	**- 0.828***	0.003
	p-value	–	–	–	–	**0.015**	**0.002**	0.497
Δ AHI	r	–	–	–	–	–	0.569	0.082
	p-value	–	–	–	–	–	0.054	0.411
Δ mean SpO_2	r	–	–	–	–	–	–	0.050
	p-value	–	–	–	–	–	–	0.446
Δ minimum SpO_2	r	–	–	–	–	–	–	–
	p-value	–	–	–	–	–	–	–

Abbreviations: AHI, apnea-hypopnea index; SpO_2, oxyhemoglobin saturation; TMJ, temporomandibular joint.
Note: $^*p < 0.05$; Pearson correlation analysis.

et al.,[16] tomographic anatomic measurements may influence OSA severity and MAD outcomes in OSA treatment, as well as the amount of protrusion for successful therapy with intraoral advancement devices. Therefore, more studies on the anatomical positions of the condyles with an MAD and PSG parameters are still necessary.

Conclusion

- The use of an MAD for the treatment of OSA significantly changed the condylar position; the positional changes were advancement and extrusion. The amount of condylar advancement obtained with 85% of maximum protrusion showed a direct correlation with the improvement in obstructive events during sleep: the greater the advancement of the mandibular condyles, the lower the AHI.

Ethical Considerations

The present study was approved by the Human Research Ethics Committee of the Universidade Federal do Ceará, according to protocol number XX. All volunteers signed a free and informed consent form. The present study preserved patient data confidentiality and does not present any information that enables the identification of the volunteers.

Funding

The authors report that they have received no funding from agencies in the public, private, or non-profit sectors for the conduction of the present study.

Conflict of Interests

The authors have no conflict of interests to declare.

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