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Comparison of Two Mandibular Advancement Devices in the Treatment of Obstructive Sleep Apnea: The Effect of the Vertical Mouth Opening

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ABSTRACT

Objective: The design of mandibular advancement devices (MADs) could be a factor that may influence the degree of mouth opening and their efficacy. This study aimed at comparing the therapeutic position for obstructive sleep apnea (OSA) of two MADs that differently increase the mouth opening.

Methods: This is a single-center retrospective study. The OSA Patients were selected if they had been treated with MAD (Orthoapnea or BTI DIA). The design of both devices provoked differences in the vertical mouth opening during fabrication. The following variables were collected and analyzed: Demographic data, sleep-related subjective and objective variables, mandibular movements and position and frequency of symptoms.

Results: Sixty-one patients received the Orthoapnea device and 56 the BTI DIA device. The increase in the vertical dimension was significantly higher in the Orthoapnea device (median: 9 mm) compared with the BTI DIA (median: 4 mm). The median of the total mandibular advancement was 8 mm for the Orthoapnea device and 3 mm for the BTI DIA device. The frequency of patients achieved a reduction of the AHI by more than 50% was 94.5% for BTI DIA and 88.5% for the Orthoapnea device. The BTI DIA showed statistically significant changes in the severity of the OSA before and after treatment but not the Orthoapnea device.

Conclusions: Both devices have been effective and safe in the treatment of obstructive sleep apnea. The differences in the vertical mouth opening have significantly affected the degree of mandibular advancements required to treat obstructive sleep apnea.

Keywords: Mouth Opening; Mandibular Advancement; Mandibular Advancement Device; Obstructive Sleep Apnea; Comparative Study

Abbreviations: MADs: Mandibular Advancement Devices; OSA: Obstructive Sleep Apnea; CPAP: Continuous Positive Airway Pressure; AHI: Apnea-Hypopnea Index

Introduction

Obstructive sleep apnea is a sleep respiratory disorder that is characterized by total (apnea) or partial (hypopnea) obstruction of the upper airway during sleep, causing snoring, sleep fragmentation and intermittent hypoxia [1]. Clinically, it is characterized by daytime hypersomnia, snoring and pauses in breathing during sleep. This disease, with time, may produce important health problems like arterial hypertension, cerebrovascular accidents, infarctions, immune alterations, cognitive and sexual disturbances, and higher mortality [2,3]. OSA is a prevalent disease that could be present in more than 50% of the population, as estimated by Heinzer, et al. [4]. The main symptom of OSA, daytime hypersomnia, has serious consequences on the familiar, social, and professional life of the patients [5]. For that, obstructive sleep apnea is an important public health problem. Mandibular advancement devices (MADs) have been considered a simple, silent, minimally invasive, tolerable, and effective treatment for snoring and

mild to moderate sleep apneas [6,7]. They are also an alternative treatment for those patients who cannot tolerate or do not want to use continuous positive airway pressure (CPAP) machines [8]. MADs support the mandible in a forward position and prevent it from falling backwards, bringing forward the base of the tongue, causing pharyngeal stretching and reducing the collapse of the upper airways [9].

In addition, recent studies confirm their efficacy in improving daytime sleepiness, AHI, cardiovascular health, improved arterial oxygen saturation levels and arousal frequency [6]. In adult patients, MADs can achieve an estimated mean reduction in AHI of 13.60 events/h (95% confidence interval (95%CI): 15.57-12.20) [6]. They have a modest improvement in minimum oxygen saturation (a mean of 3.09% (95% CI: 2.43-3.76)) and reduction in oxygen desaturation index. They also reduce the rate of micro-arousals but do not appear to have a significant effect on sleep architecture or efficacy [6]. MADs also improve quality of life and reduce blood pressure (between 2- and 3-mm Hg), which is like the blood pressure reduction obtained by CPAP [6]. The design of the MADs could be a factor that may influence their efficacy, safety, or the adherence to therapy. The range of mandibular advancement, the degree of mouth opening, the type of material and the process of fabrication of the MADs are factors that may affect their efficacy, safety, and patient's adherence to therapy [10,11]. For example, the degree of mouth opening should be optimized not to increase the risk of mandible falling backwards and thus altering the device efficacy [10]. The risk of having side effects is increased by the increase in the magnitude of mandibular advancement [12,13]. For that, there is a need to personalize the optimal mandibular protrusion that results in the highest reduction in the Apnea-hypopnea index (AHI) and in producing the least side effects.

The adherence of the patients to the treatment with MAD would be the net outcome of patient's subjective enhancement, comfort, and side effects. Currently more than 100 different oral appliance designs exist on the market that differ in the type of material used, the position of the junction between the upper and lower part of the appliance, the possibility of titration, the degree of customization, the magnitude of the vertical opening and the lateral movements of the jaw [14]. Therefore, there is a need for comparative studies that assess the efficacy, side effects and adherence to therapy of different MAD. Two of these devices are BTI DIA and Orthoapnea device. Both devices share several characteristics including the control of mouth opening, pull mechanism, occlusal stability, and freedom of lateral movement. However, they differ in the degree of vertical mouth opening required to fabricate the device, the initial advancement, the anteroposterior freedom of movement and the position of the coupling mechanism. For that the purpose of this study has been the comparison of these two types of MADs in the treatment of OSA.

Materials and Methods

This observational and retrospective study has been performed following the STROBE guidelines for observational studies. The study was performed in a single private center (Clinica Bisheimer, Madrid, Spain) between January 2018 and December 2021. It was performed according to the 1964 Helsinki declaration and its later amendments. All patients signed informed consent. Patients were selected according to the following criteria: diagnosis of obstructive sleep apnea, treatment with BTI DIA (BTI Biotechnology Institute, Vitoria, Spain) or Orthoapnea device (Orthoapnea, Malaga, Spain), had finalized the titration of the mandibular advancement device and had at least two sleep studies (one before treatment and one after titration). Patients who did not fulfill these criteria were excluded from the study. Patients starting treatment between January 2018 and December 2019 were treated with Orthoapnea device and patients starting treatment between January 2020 and December 2021 were treated with BTI DIA.

Type of devices

BTI DIA (BTI Biotechnology Institute, Vitoria, Spain): the device was prepared using thermoforming plastic sheets and vacuum pressure (1.5 mm in thickness for the mandible and 1 mm for the maxilla). For each splint, two metallic buttons (one on each side) were fixed on the lateral surface of the splint. During titration, 2 plastic retainers (of different lengths) were connected to the ipsilateral buttons of the upper and lower splints. The starting position was set at maximum retrusion + 3 mm (in anterior direction). This corresponded to 25% of maximum mandibular protrusion. During titration, 2 plastic retainers (of different lengths) were connected to the ipsilateral buttons of the upper and lower splints. Orthoapnea (Orthoapnea, Málaga, Spain): the device was prepared using thermoforming 3 mm thick hard/soft sheets and vacuum pressure. The two splints were connected by inverted rod screw as described previously [15]. The starting position was set at maximum retrusion + 8 mm (in anterior direction). This corresponded to 60% of maximum mandibular protrusion. Both devices were fabricated to allow balanced occlusal forces. They controlled and limited the vertical mouth opening to avoid mandibular retrusion during sleep. They also allowed for lateral mandibular movements but only the DIA device allowed for protrusion (Figure 1).

Figure 1: The effect of the overbite on the vertical mouth opening to accommodate the mandibular advancement devices (Orthoapnea blue device, BTI DIA transparent device).

Titration

After 4 weeks of the delivery of the device at the starting position, subjective (patients reported symptoms and comfort) and objective (Apnea-hypopnea index) titration was performed. Additional mandibular advancement was made at a rate of 1 mm every 2-3 weeks. The final therapeutic position was defined by the mandibular position that resulted in the maximum improvement in subjective symptoms and maximum reduction of the AHI. Thence after, the patients were recalled after 3 months to review the side effects (muscles, TMJ, device, the occlusion). A validated respiratory polygraphy (BTI APNiA, BTI Biotechnology Institute, Vitoria, Spain) was employed to perform the sleep study at the patient's own home according to the criteria of the American Academy of Sleep Medicine. [16] The following data were extracted from the patients' records: Type of MAD, demographic data (age and sex), body mass index (BMI; Kg/m^2), neck perimeter (mm), smoking (yes/No), snoring (yes/No), excessive daytime somnolence (EDS; yes/No), observed apnea (yes/No), over jet (mm), over bite (mm), percentage of mandibular protrusion, mandibular advancement (mm), maximum mouth opening (mm), lateral mandibular ranges of movement (mm), maxilla-mandibular protrusion (mm), apnea-hypopnea index (AHI; events/h) and frequency of symptoms (muscles, TMJ) and type of symptoms management.

Statistical Analysis

The Shapiro-Wilk test was applied to verify the normal distribution of the variables. Descriptive statistics were performed. Quantitative variables following the normal distribution were described by mean and standard deviation otherwise, the median and range were used. Frequency was calculated for qualitative variables. The comparison between qualitative variables was performed by the Chi square test. Student tests and repeated measures ANOVA were used to compare quantitative data following the normal distribution. Mann-Whitney, Wilcoxon and Friedman tests were selected to compare the quantitative data not following the normal distribution.

Results

Table 1 shows the demographic data of the study groups. Sixty-one patients received the Orthoapnea device, and 56 patients received the BTI DIA device. The results show similarity between the two groups in age, BMI, smoking, ESD and observed apnea. However, the patients in the Orthoapnea group had lower neck perimeter.

The use of both intraoral devices had induced changes due to mandibular positioning in more forward position. Indeed, patients treated with the Orthoapnea device had 66% of mandibular protrusion and those treated with BTI DIA had 25% (Table 2). The median

of the total mandibular advancement was 8 mm for the Orthoapnea device and 3 mm for the BTI DIA device. Moreover, the increase in the vertical dimension was higher in the Orthoapnea device (median: 9 mm) compared with the BTI DIA (median: 4 mm). Both devices showed no significant differences in relation to jaw movements although individually they increased the MMO and the left mandibular excursion (Table 2). The use of both devices had a significant effect in reducing the AHI with no significant differences between them (Table 3). The reduction in the AHI for both devices were higher than 75%. BTI DIA reduced the AHI by more than 50% in 94.5% of the patients. This value was 88.5% for the Orthoapnea device. Furthermore, 41% and 86% of patients treated with BTI DIA had an AHI < 5 and AHI < 10 events/h, respectively. Orthoapnea device had achieved these threshold values in 38% and 75% of the patients, respectively.

Table 1: Demographic data.

	BTI DIA	Orthoapnea	p-value
Age (mean (SD))	54 (10)	58 (9)	0.033[a]
Sex (amount of Females/number of males)	14/42	16/45	0.879[b]
Body mass index (Kg/m^2) (median (range)	26.9 (21.3 - 46.0)	26.3 (19.6 - 45.3)	0.129[c]
Neck perimeter (cm)	41 (38 - 44)	39 (31 - 44)	0.000[c]
Smoking (yes)	10	9	0.649[b]
Snoring (yes)	56	61	NA
ESD (yes)	40	50	0.177[b]
Observed apnea (yes)	48	54	0.650[b]

Note:
SD: Standard deviation
a: Student test
b: Chi square test

c: Mann-Whitney test

Table 2: Occlusion-related variables.

	BTI DIA	Orthoapnea	p-value (between groups)	p-value (BTI DIA)	p-value (Orthoapnea)
Overjet baseline (mm)	3.2 (0 - 7.0)	4.0 (0 - 9.0)	0.014[a]	0.009[c]	0.000[c]
Over jet - start treatment (mm)) (median (range)	3.0 (3.0 - 3.0)	8.0 (7.0 - 11.0)	0.000[a]		
Overjet at the last visit (mm)) (median (range)	3.0 (3.0 - 6.0)	8.0 (7.0 - 11.0)	0.000[a]		
Overbite baseline (mm)) (mean (SD)	2.5 (1.7)	3.2 (1.8)	0.030[b]	0.020[d]	0.000[d]
Overbite - start treatment (mm) (median (range)	2.0 (2.0 - 2.0)	5.0 (5.0 - 5.0)	0.000[a]		
Overbite at the last visit (mm)) (median (range)	2.0 (2.0 - 2.0)	5.0 (5.0 - 5.0)	0.000[a]		
Protrusion - start treatment (%)) (median (range)	25.0 (20.0 - 30.0)	66.0 (54.0 - 73.0)	0.000[a]	0.000[e]	0.000[e]
Protrusion at the last visit (%)) (median (range)	25.0 (20.0 - 60.0)	66.0 (54.0 - 88.0)	0.000[a]		
Mandibular advancement (mm) (median (range)	3.0 (3.0 - 6.0)	8.0 (7.0 – 11.0)	0.000[a]		
Total increase in the vertical dimension (mm) (median (range)	4.0 (2.0 – 7.0)	9.0 (5.0 – 12.0)	0.000[a]		
MMO baseline (mm)	44.8 (3.2)	45.0 (4.0)	0.792[b]	0.000[f]	0.000[f]
MMO at the last visit (mm)	46.4 (2.9)	45.8 (3.3)	0.277[b]		
Right excursion baseline (mm) (median (range)	8.0 (6.0 - 12.0)	8.0 (6.0 - 12.0)	0.758[a]	0.089[e]	0.094[e]
Right excursion at the last visit (mm) (median (range)	8.5 (6.0 - 11.0)	9.0 (6.0 - 11.0)	0.800[a]		

Left excursion baseline (mm) (median (range)	8.0 (6.0 - 11.0)	8.0 (6.0 - 12.0)	0.849[a]	0.000[e]	0.000[e]
Left excursion at the last visit (mm) (median (range)	8.5 (7.0 - 12.0)	9.0 (7.0 - 12.0)	0.788[a]		
Maxilla-Mandible protrusion baseline (mm) (median (range)	12.0 (10.0 - 15.0)	12.0 (10.0 - 18.0)	0.734[a]	0.000[e]	0.000[e]
Maxilla-Mandible protrusion-last visit (mm) (median (range)	13.0 (11.0 - 15.0)	13.0 (8.0 - 18.0)	0.669[a]		

Note:
SD: standard deviation
a: Mann-Whitney test
b: Student test
c: Friedman test
d: Repeated measures ANOVA
e: Wilcoxon test

f: Paired Student test

Table 3: Obstructive sleep apnea data

		BTI DIA	Orthoapnea	p-value	p-value (BTI DIA)	p-value (Orthoapnea)
AHI baseline (events/h) (median (range)		24.4 (10.0 - 76.0)	25.1 (12.0 - 92.0)	0.380[a]	0.000[c]	0.000[c]
AHI at the last visit (events/h)) (median (range)		5.7 (1.0 - 32.0)	7.9 (1.8 - 38.5)	0.112[a]		
Reduction in the AHI (%) (median (range))		79.2 (from -92.9 to 93.8)	75.3 (from -153.8 to 94.42)	0.374[a]		
Success (number of patients (%))	Worsening in the AHI	2 (3.6%)	2 (3.3%)	0.291[b]		
	Reduction < 50%	1 (1.9%)	5 (8.2%)			
	Reduction ≥ 50%	53 (94.5%)	54 (88.5%)			

Note: AHI: Apnea-hypopnea index
a: Mann-Whitney test
b: Chi square test

c: Wilcoxon test

Table 4 shows the changes in the severity of the OSA before and after treatment. The BTI DIA showed a statistically significant effect but not the Orthoapnea device. Interestingly both devices had a positive effect in patients reporting muscles and TMJ symptoms (Table 5). On one hand,10 patients in each group had symptoms related to temporalis and masseter muscles at baseline. Absence of these symptoms was reported by 9 patients in the BTI DIA group and 5 in the Orthoapnea NOA group. On the other hand, 13 and 12 patients reported symptomatic TMJ in the BTI DIA and Orthoapnea NOA groups, respectively. At the end of the follow-up, all the patients in the BTI DIA were asymptomatic while 4 patients in the Orthoapnea were still symptomatic (Table 6). Jaw relaxation exercises were needed in 4 and 11 patients in the BTI DIA and Orthoapnea groups, respectively. None of the patients in both groups required any occlusal adjustments, morning positioner or medications.

Table 4: Changes in the severity of the OSA.

MAD	Severity of OSA	OSA Severity After Treatment				Total	p-value
		No OSA	Mild	Moderate	Severe		
BTI-DIA	Mild	5	0	1	0	6	0.031[a]
	Moderate	15	16	1	0	32	
	Severe	3	13	1	1	18	
	Total	23	29	3	1	56	
Orthoapnea	Mild	2	1	0	1	4	0.202[a]
	Moderate	12	18	1	0	31	
	Severe	9	14	2	1	26	
	Total		33	3	2	61	

Note:
MAD: Mandibular advancement device
OSA: Obstructive sleep apnea

a: Chi square test

Table 5: Number of patients with symptomatic muscles.

		Left		p-value[a]	Right		p-value[a]
		BTI DIA	Orthoapnea		BTI DIA	Orthoapnea	
baseline	Temporalis	6	6	0.876	6	6	0.876
	Masseter	4	4	0.900	4	4	0.900
< 3 month	Temporalis	0	4	0.051	0	4	0.051
	Masseter	0	2	0.172	0	2	0.172
> 3 months	Temporalis	0	2	0.172	0	2	0.172
	Masseter	1	3	0.352	1	3	0.352

Note: a: Chi square test

Table 6: Patients with TMJ symptoms.

		Left		p-value[a]	Right		p-value[a]
		BTI DIA	Orthoapnea		BTI DIA	Orthoapnea	
baseline	Pain	4	3	0.612	4	3	0.612
	Noise	9	9	0.844	9	9	0.844
< 3 month	Pain	1	2	0.610	1	2	0.610
	Noise	0	4	0.051	0	4	0.051
> 3 months	Pain	0	1	0.336	0	1	0.336
	Noise	0	3	0.093	0	3	0.093

Note: a: Chi square test

Discussion

This study has shown the clinical efficacy and safety of the two mandibular advancement devices (BTI DIA and Orthoapnea device) for the treatment of OSA. The BTI DIA has a mean reduction of the baseline AHI of 23.1 events/h (95% confidence interval: 18.6 - 27.7 events/h). Similarly, the Orthoapnea device has achieved a mean reduction of 24.1 events/h (95% confidence interval: 19.7 - 29.1 events/h). Data from meta-analysis in adult patients has shown that the MADs can achieve an estimated mean reduction in AHI of 13.60 events/h (95% confidence interval (95%CI): 15.57-12.20) [6]. The mean difference of AHI reduction of both devices in this study has been -1.3 events/h (95% confidence interval: -7.8 - 5.2 events/h). This mean difference has a range of -5.0 to 1.9 events/h in studies that compared different MADs [17-22]. Furthermore, 41% and 86% of patients treated with BTI DIA had an AHI < 5 and AHI < 10 events/h, respectively. Orthoapnea device had achieved these threshold values in 38% and 75% of the patients, respectively. The good function of both devices could be related to the efficacy of both devices in avoiding mandible falling backwards by limiting the vertical mouth opening

and retaining the mandible in the therapeutic position during sleep. Attali et al. have reported an AHI < 5 events/h in 56% and AHI < 10 events/h in 67% of treated patients [23]. Haesendonck, et al. have reported the achievement of these thresholds in 31% and 57% of the patients, respectively [24]. Furthermore, similar results have been obtained by Byun et al (31% and 64.4%, respectively) [25].

The BTI DIA device resulted in lower mandibular advancement compared to the Orthoapnea device. BTI DIA has achieved a reduction of at least 50% of the baseline AHI in 94.5% of the patients while the Orthoapnea device has achieved it in 88.5%. Indeed, the changes (toward lower degrees) in the severity of OSA has been statistically significant only in the case of BTI DIA. One of the main differences between the two types of devices is the minimum vertical mouth opening required to fabricate the device. To manufacture the Orthoapnea device a minimum increase of vertical dimension by 5 mm is required between the edges of the upper and lower incisors. This distance is needed to accommodate the screw, and the upper and the lower splints. However, in the case of the BTI DIA device, the vertical mouth opening is only needed to accommodate the upper and lower splints (Figure 1). Such a difference may explain the differences between the two devices in the amount of mandibular advancement required to treat the OSA. Mayoral et al., who used a MAD with similar characteristics to the Orthoapnea (5 mm vertical mouth opening), have shown that an 8 mm of anterior advancement of the mandible only achieved a forward displacement of the mandible by only 1.98 mm (from maximum intercuspation position) [26]. Moreover, the morphological characteristics (overbite) of the patient may influence the amount of mandibular advancement needed to treat the OSA. This is related to the effect of the overbite on the degree of vertical mouth opening.

For that, it could be better in patients with deep vertical overbite, the use devices whose design opens less the vertical dimension. Moreover, the degree of vertical mouth opening may also affect the device efficacy [10,26,27]. Excessive increase of the vertical dimension may induce posterior rotation of the mandible compressing the upper airway and worsening the treatment outcomes. To optimize the therapeutic efficacy of MADs, several studies have indicated the interest of monitoring the mandibular movements and controlling/titrating the mouth opening [26,28,29]. Indeed, Mayoral et al. have estimated a reduction of the effective mandibular advancement by 0.3 mm for every 1 mm increase in the vertical mouth opening [26]. The higher mandibular advancement in the Orthoapnea device made more pronounced the changes in the over jet and overbite. The over jet at the last follow-up was almost twice the baseline value in Orthoapnea device. Similarly, the overbite increased 1.6-fold the baseline value. BTI DIA had provoked minimal increase in over jet and minimal decrease in the overbite. Figure 2 shows the tracing of lateral cephalometric images of one patient that used both devices but was not included in the present study, wearing no device, the Orthoapnea device and the BTI DIA device (Figure 2). The tracings corresponded to the devices at their therapeutic position (final mandibular position after titration).

Although the amount of mandibular forward displacement was different (8 mm for the Orthoapnea device Vs 3 mm for the BTI DIA), it could be observed that the area of the symphysis and the lower incisors was in the same anteroposterior position. Several factors may influence the occurrence of adverse effects such as the vertical mouth opening, the distance of mandibular advancement, and the device design [12,13]. Titration of the mandibular advancement is a key element to place the mandible in the least anterior position that is effective in the treatment of OSA. In this regard, using a device that needs lower mandibular advancement would be advantageous [12,13]. The number of patients with symptomatic TMJ and muscles have been reduced in both devices but more in the BTI DIA. The good occlusal stability and freedom of lateral movements may help explain the low rate of adverse effects at the muscular and TMJ level [30]. This study has several limitations. The retrospective design, the short follow-up time, and the absence of polysomnography study at the baseline should be considered. The study included patients with severe OSA (32% in the BTI DIA and 43% in the Orthoapnea device) that may hamper its comparison with other studies. The inclusion of severe OSA could increase the feasible margin of improvements.

Conclusion

BTI DIA and Orthoapnea devices have been effective and safe in the treatment of obstructive sleep apnea. The differences in the vertical mouth opening have significantly affected the degree of mandibular advancements to treat the obstructive sleep apnea (higher for Orthoapnea device). BTI DIA has been effective in achieving a statistically significant reduction in the severity of obstructive sleep apnea. The lower degree of advancement necessary to achieve the therapeutic position by the BTI DIA makes more comfortable the use of the appliance for the patients and reduces risk factors for muscular and TMJ adverse effects.

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