The Choice between Mandibular Advancement Devices and Bite Openers for Treatment of Obstructive Sleep Apnea Patients

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Abstract: Purpose: The aim of this study was to evaluate and compare the effect of changing either the amount of mandibular protrusion or the vertical jaw separation on apnea/hypopnea index (AHI) and snoring index (SI) In patients suffering from obstructive sleep apnea (OSA). Material and methods: Twenty fully dentulous patients suffering from obstructive sleep apnea were randomly divided into two equal groups; group I: In which patients were treated by screw-type adjustable two-piece mandibular advancement devices (MADs) that were initially adjusted at 50% (1st stage), then readjusted at 75% (2nd stage) of the maximum protrusion, and group II: in which patients were treated by two ready-made bite openers (BOs); the first provides 7 mm (1st stage), while the second 11mm (2nd stage) vertical jaw separation. Polysomnography (PSG) was used to evaluate AHI and SI and to compare between both groups and between the stages within each group. Data were collected to calculate the mean values for all stages and the mean differences between both stages in each group. Statistical analysis was performed using two-way ANOVA test to detect significant differences between both groups. On the other hand, Pearson's correlation test was used to compare between the stages within each group. Results: Regarding the AHI mean differences the comparison among different stages of group I and II revealed a statistically significant difference among all stages except stage I of group I and stage II of group II, while regarding SI mean differences, no statistically significant difference was found among them except stage II of group I and stage I of group II. Within each group, a statistically significant difference was found between the base line and both stages regarding AHI and SI. On the other hand, the comparison between the stages revealed a statistically significant difference regarding the SI mean differences only. Conclusion: MADs are capable of achieving better results than BOs regarding AHI, while both appliances can achieve comparably equal results regarding SI. Clinical implication: For patients complaining of OSA, it is recommended to use MADs adjusted at 50% advancement rather than 75% to minimize the possible side effects and the possible extra annoyance that may happen. On the other hand, for snorers, it is advisable to use BOs rather than MADs as they are simpler, more tolerable and cheaper.

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1. Introduction

Many people experience sleeping difficulties, a thing that affects their daily life. This may be attributed to backache, neck pain, stomach problems and breathing disorders during sleep [1, 2]. Sleep disordered breathing (SDB) is a term that describes breathing disorders occurring during sleep and they include snoring, upper airway resistance syndrome (UARS) and sleep apnea. The symptoms and complications of such disorders range from just simple snoring and excessive daytime sleepiness to serious risks as ischemic heart disease and strokes [3]. The most widely studied breathing disorder is the obstructive sleep apnea syndrome (OSAS) which is characterized by repeated episodes of upper-airway obstruction during sleep (apnea is a cessation of airflow for 10 seconds or more) associated with reduced blood oxygen level causing gasping, snoring, chocking, repeated arousals through the night, fatigue and even pulmonary hypertension in severe cases [4, 5].

According to the cause of airflow cessation, sleep apnea is classified into: Central and/or obstructive sleep apnea. Obstructive sleep apnea (OSA) is the most prevalent type. When the disturbances of normal sleep are combined with excessive daytime sleepiness it is called obstructive sleep apnea syndrome (OSAS) [6].

It was found that obesity is the main predisposing factor for OSA. Over-weight results in the increase of the fat contents and consequently the size of all body parts including the structures of the upper airway [7]. Craniofacial anomalies like micrognathia and retrognathia, orofacial features such as enlarged palatine tonsils, enlarged uvula, long soft palate, nasal septum deviation, long anterior facial height, steep and short anterior cranial base, inferiorly displaced hyoid bone and

disproportionately large tongue may also predispose to OSA [8, 9]. It was found also that smoking, consumption of alcohol and sedatives may aggravate existing OSA as they relax the airway muscles making it more prone to obstruction [10, 11].

Diagnosis of OSAS is achieved by polysomnography (PSG), which is the gold standard diagnostic modality [2, 12]. The Apnea\Hypopnea Index (AHI) and Snoring Index (SI) are commonly used for diagnosis of the degree and severity of OSA and snoring. [5]AHI is computed by counting the number of apneas and hypopneas that occur while the patient is sleeping and dividing this number by the number of sleeping hours, while SI is determined by the total number of minutes snored in each hour [13].

Several treatment options have been attempted for treatment of OSAS, The primary and simplest treatment option will be behavior modification, followed by insertion of oral appliances (OAs) in those patients with mild to moderate OSAS. On the other hand, continuous positive airway pressure (CPAP) and surgical intervention with or without OAs are the treatment of choice in severe cases [4, 14].

Several oral appliances can be used for treating patients suffering from OSA, such as mandibular advancement devices (MADs), tongue retaining devices (TRDs), soft palate lifters (SPLs) and bite openers (BOs). MADs and BOs are the most commonly used oral appliances for the treatment of such cases. MADs act by altering the airway shape and/or increasing its size, improving the upper airway muscle tone and thus decreasing its collapsibility. All types of MADs perform the same actions, but they differ in their fabrication techniques, connection to the jaws, materials, and adjustability of the degree of mandibular protrusion [2, 4, 15]. On the other hand, bite openers (BOs) are found to be more effective in patients with mild obstructive sleep apnea rather than with moderate or severe degrees. Snoring is also dramatically improved by the use of these appliances [13].

Reviewing the literature, revealed that reliable guide lines for the selection between these two, most commonly used oral appliances with their variable degrees of mandibular protrusion and/or vertical jaw separation to treat patients suffering from OSA are still lacking.

This study was conducted to evaluate and compare the effect of different MADs and BOs on the apnea/hypopnea index and the snoring index of mild to moderate OSA patients

2. Material and Methods

Twenty fully dentulous patients were selected from the ENT Department, Faculty of Medicine, Cairo University. Their ages ranged between 25-45 years old (average 37.6). All of them showed proper neuromuscular coordination, were able to protrude the mandible not less than 6mm, had good oral hygiene and periodontally sound maxillary and mandibular natural teeth. Patients with T.M.J disorders, abnormal masses, long soft palate, long uvula, large tonsils and Angle class II jaw relation were excluded.

Degree of OSA of all patients was assessed by polysomnographic (PSG) reports including the AHI and SI. Only snoring patients having an AHI from 10-20 events /hour (mild to moderate OSA patients) were included in the study. Patients were randomly divided into two equal groups:

For Group I:

Patients of this group were treated by MADs. The George gauge bite registration kit[1] and the screw-type adjustable MAD kit[2] were used.

1) Bite registration was carried out using the George gauge bite registration kit ***(Fig.1)*** according to the following steps:

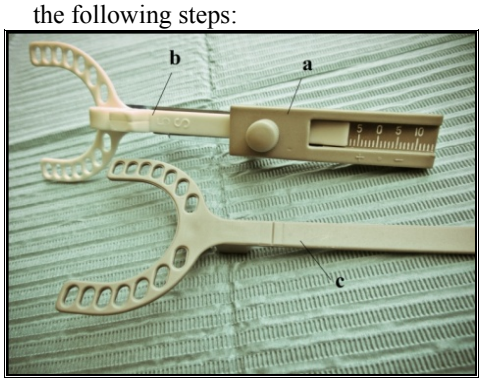

Fig (1): a) George gauge body. b) White bite fork. c) Gray bite fork.

- The lower turn screw was loosened and the incisor clamp was moved forward. The midline indicator was then, centered over the lower central incisors and the turn screw was then, tightened.
- George gauge was then removed from patient's mouth and the bite fork was placed into the body of George gauge. The patient was instructed to close into the upper incisor notch of the bite fork, with upper midline indicator placed between the upper central incisors.
- The patient was then instructed to slide his mandible first into the most retruded (centric) relation and then into the maximum protrusive position. These positions were observed and

[1] Dr. Peter T. George, Honolulu, Hawaii, USA
[2] Intra oral snoring therapy (IST) appliance kit, Scheu dental technology, Germany

recorded on the millimeter scale of the George gauge body.

- The gauge was then removed from patient's mouth and marking end of the bite fork was set over the required position on millimeter scale, which was 50% of the maximum protrusion at the initial adjustment and 75% of the maximum protrusion at the second adjustment visit. When these positions were determined, the upper turn screw was tightened.
- Putty silicone[3] was placed on the bite fork after which the gauge was returned to mouth with the lower notch centered over the lower incisors. The patient was given a mirror, and instructed to close into the upper incisor notch. Finally, when registration material had sufficiently hardened, the whole assembly was removed from the patient's mouth.**(Fig.2)**
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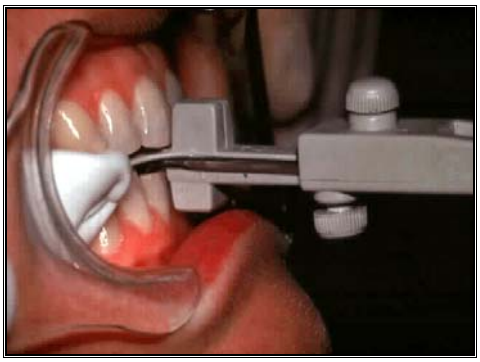

Fig (2): George gauge with putty silicone placed in patient's mouth.

2) Maxillary and mandibular master casts were duplicated using rubber base impression material and the obtained protrusive jaw relation was attached to the maxillary and mandibular master casts to be mounted on the articulator[4].
3) On the duplicate casts, poly-vinyl vacuum-formed thermoplastic maxillary and mandibular stents were constructed following the manufacturer's instructions.
4) Stents were replaced on the articulated casts and checked for proper fit after which two fixation screws, one on each side, were attached to the upper stent buccally at the first molar region, and then two other screws were attached to the lower stent buccally at the canine/first premolar region.
5) Adjustable guiding telescopes[5] were used to join the fixation screws and accordingly to connect the upper and lower stents in the predetermined position. A protrusion nut that acted as a stopper was then fixed in this position. The appliance was checked for function during opening, closing and lateral movements.**(Figs.3,4)**

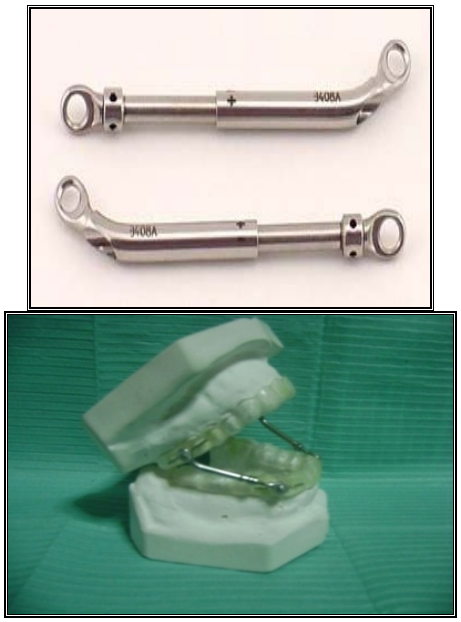

Fig (3): Adjustable guiding telescopes.
Fig (4): The MAD appliance placed on master casts.

6) Finally, the appliance was delivered to the patient after being adequately checked for fit, retention, proper closure in the predetermined position and for smooth uninterrupted gliding during different mandibular movements **(Fig.5)**.

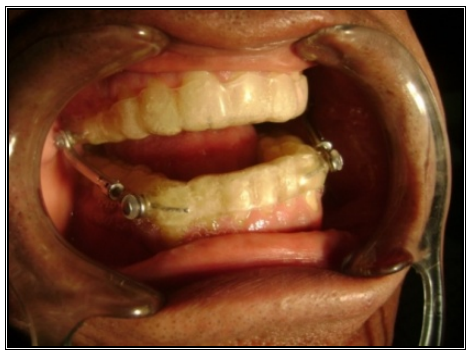

Fig (5): The MAD appliance in patient's mouth.

For Group II:

[a] Swiss plus, Coltene Whaledent, France
[4] MagicArt™-2, Alphadent Co., LTD, Korea
[5] IST Guiding telescopes, Scheu dental technology, Germany.

Patients of this group were treated by ready-made bite openers (BOs)[6], which were made of a soft flexible silicone material and were available in two degrees of vertical jaw separation. The first provides 7mm, while the second 11mm vertical jaw separation. These separations represent the stages of the BO **(Fig.6)**.

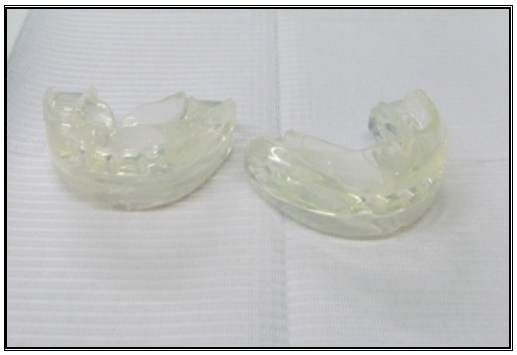

Fig (6): 7mm and 11mm ready-made BOs.

Each patient was trained how to insert the appliance and was also asked to return for help if any discomfort persisted for more than two days. Patients were asked to wear the appliances at least 4 hours daily for the first two days, to get adapted to it, then, to wear it when they were ready to fall asleep comfortably with it. Finally, strict oral hygiene instructions were given to all patients.

Subjective evaluation of the appliance behavior was assessed depending on patients ' reports. All patients were subjected to an objective full-night polysomnographic examination [7] in a sleep laboratory, in which a skilled staff member observed the patients throughout the whole night. Data were recorded and analyzed on a computerized system.

The apnea/hypopnea index (AHI) and the snoring index (SI) were evaluated by the PSG examination prior to treatment, then two weeks after the delivery of the appliances set at their 1st stage and finally two weeks after the placement of the appliances set at their 2nd stage.

Data obtained from polysomnographic reports were collected, tabulated and statistically analyzed using **two-way ANOVA test** that was followed the least significant difference (LSD) for paired comparisons. Correlation between AHI and SI in both MADs and BOs groups was done using **Pearson's Correlation test.**

3. Results

Subjective evaluation revealed that patients of both groups, weather treated by mandibular advancement devices (MADs) or bite openers (BOs), reported that there were overall marked improvements in their snoring and apnea. Moreover, these improvements were evident in stage two rather than stage one of each group.

Polysomnographic findings

For apnea/hypopnea index:

- By comparing the AHI mean values of both groups, a statistically significant difference was found between the baseline on one side and stage I or II on the other side **(Table. 1)**.

- On the other hand, the comparison between the AHI mean differences of both groups revealed no statistically significant difference among the two stages in each group and a statistically significant difference among all stages of both groups except 50% advancement of MAD group and 11 mm BO ***(Table.2)***.

Regarding snoring index:

- By comparing the SI mean values of both groups, a statistically significant difference was found between the baseline on one side and stage I or II on the other side.**(Table. 3)**

- On the other hand, the comparison between the SI mean differences of both groups revealed a statistically significant difference among the two stages in each group and no statistically significant difference among all stages of both groups except 75% advancement of MAD group and 7mm BO **(Table. 4)** .

Correlation between AHI and SI

No statistically significant correlation was found between AHI and SI in different stages of MAD group ($r=0.5177$) or in different stages of BO group ($r=0.2152$).Correlation was considered significant at ($p \leq 0.05$).

[6] TMJ.MBV appliance, Myofunctional Research Company, Australia

[7] Alice Diagnostic Sleep System, Philips Respironics, Netherlands

Table (1): Statistical analysis of AHI mean values for MAD and BO groups using two way ANOVA test

APNEA/HYPOPNEA INDEX						
MAD	***Base line***	***50%***	***75%***	Total		
Count	10	10	10	30		
Sum	190	52.3	18.6	260.9		
Average	**19**	**5.23**	**1.86**	8.696667		
Variance	54.66667	7.295667	3.329333	77.13068		
BO	***Base line***	***7mm***	***11mm***			
Count	10	10	10	30		
Sum	174	83	52.9	309.9		
Average	**17.4**	**8.3**	**5.29**	10.33		
Variance	56.48889	24.12667	11.06989	55.87045		
ANOVA						
Source of Variation	*SS*	*D f*	*MS*	*F*	*P-value*	*F crit*
Sample	40.01667	1	40.01667	1.529522	0.221536	4.01954
Columns	2365.506	2	1182.753	45.20735	2.92E-12	3.168246
Interaction	78.73233	2	39.36617	1.504659	0.231256	3.168246
Within	1412.794	54	26.16285			
Total	3897.049	59				
LSD	**4.623**					

Table (2): Statistical analysis of AHI mean differences for MAD and BO groups using two-way ANOVA test
APNEA/HYPOPNEA INDEX

MAD	***Pre-50%***	***Pre-75%***	***Total***			
Count	10	10	20			
Sum	137.7	171.4	309.1			
Average	**13.77**	**17.14**	15.455			
Variance	26.78456	34.75156	32.13734			
BO	***Pre-7mm***	***Pre-11mm***				
Count	10	10	20			
Sum	91	121.1	212.1			
Average	**9.1**	**12.11**	10.605			
Variance	12.14889	21.061	18.11524			
ANOVA						
Source of Variation	*SS*	*D f*	*MS*	*F*	*P-value*	*F crit*
Raw	235.225	1	235.225	9.930762	0.003268	4.113165
Columns	101.761	1	101.761	4.29616	0.045417	4.113165
Interaction	0.324	1	0.324	0.013679	0.907545	4.113165
Within	852.714	36	23.6865			
Total	1190.024	39				
LSD	**4.418**					

Table (3): Statistical analysis of SI mean values for MAD and BO groups using two-way ANOVA test.

SNORING INDEX						
MAD	***Base line***	***50%***	***75%***	***Total***		
Count	10	10	10	30		
Sum	1140	681	456	2277		
Average	**114**	**68.1**	**45.6**	75.9		
Variance	900	567.8778	394.2667	1416.024		
BO	***Base line***	***7 mm***	***11 mm***	***Total***		
Count	10	10	10	30		
Sum	1173	795	596	2564		
Average	**117.3**	**79.5**	**59.6**	85.46667		
Variance	1237.122	548.5	272.4889	1231.154		
ANOVA						
Source of Variation	*SS*	*D f*	*MS*	*F*	*P-value*	*F crit*
Sample	1372.817	1	1372.817	2.101113	0.152975	4.01954
Columns	41174.43	2	20587.22	31.50899	8.55E-10	3.168246
Interaction	311.4333	2	155.7167	0.238326	0.78877	3.168246
Within	35282.3	54	653.3759			
Total	78140.98	59				
LSD	**23.103**					

Table (4): Statistical analysis of SI mean differences for MAD and BO groups using two-way ANOVA test SNORING INDEX

MAD	***Pre-50%***	***Pre-75%***	***Total***		
Count	10	10	20		
Sum	459	684	1143		
Average	**45.9**	**68.4**	57.15		
Variance	110.7667	259.6	308.6605		
BO	***Pre-7mm***	***Pre-11mm***			
Count	10	10	20		
Sum	378	577	955		
Average	**37.8**	**57.7**	47.75		
Variance	233.5111	402.4556	405.4605		
ANOVA					
Source of Variation	*SS*	*D f*	*MS*	*F*	*P-value*
Raw	883.6	1	883.6	3.512156	0.069054
Columns	4494.4	1	4494.4	17.86446	0.000155
Interaction	16.9	1	16.9	0.067175	0.796972
Within	9057	36	251.5833		
Total	14451.9	39			
LSD	**14.400**				

3. Results and Discussion

The results of this study showed that using either the MADs or the BO scan achieve a remarkable improvement in snoring and sleep apnea which was evident in the subjective clinical and/or the polysomnograghic findings.

It was found that using MADs whether adjusted at 50% or 75% advancement resulted in a significant

decrease in both AHI and SI, a result that can be correlated to the expansion of the upper airway. This came in accordance with studies conducted by some authors [16, 17].However, by comparing the mean differences of 50% advancement with that of the 75%, no statistically significant difference was found between the two advancements regarding the AHI. It was stated that there is no direct correlation between the amount of mandibular advancement and the efficacy of a MAD regarding the apnea reduction, and each patient had an optimal position at which MAD can yield excellent results [18].

The results of this study also, revealed that the use of 7mm or 11mm BOs achieved a significant decrease in both AHI and SI. This can be explained through careful analysis of the mandibular movements during vertical jaw separation, in which the heads of the mandibular condyles rotate around an axis in the initial few millimeters of opening then glide against the glenoid fossa and articular eminence in a downward and forward direction during further jaw opening, thus allowing for increased retro-glossal space relieving any constriction in the airway at that level [15]. It was also concluded that the minimum amount of vertical separation required for treatment of patients suffering from OSA was 5mm more than the vertical dimension of rest, (The average free way space is about 2 mm.) forming a total of 7mm vertical jaw separation as provided within this study. Moreover, by comparing the mean differences of the 7mm BO with that of the 11mm, no statistically significant difference was found between the two BOs regarding the AHI. According to several studies [13, 19, 20],this statistically insignificant improvement of AHI between 7mm and 11mm BOs might be related to the stimulating effect of the appliance regardless of its type on the tongue and masticatory muscles during sleep. It was also stated that appliance efficacy is related to activation of the tongue muscles during passive jaw opening.

Although, no statistically significant difference was found between the two stages of both groups regarding the AHI, statistically significant difference was found regarding the SI which might be attributed to the increased airway space, with subsequent improvement in the air flow that was achieved in stage two of both groups. This controversial issue is explained by the absence of any correlation between AHI and SI that was found in the results of this study. This statistically insignificant correlation explains what had been reported in a study that snoring was the hallmark symptom of OSA patients, while snoring patients do not necessarily suffer from OSA[21].

By comparing the AHI mean differences of stages I and II of MADs group with those of BO group, a statistically significant difference was found between them except between 50% advancement and 11mm BO. This means that we have to use the 11mm BO i.e. the higher level of vertical jaw separation to achieve the same treatment effect of the 50% advancement of MAD i.e. the minimum amount of advancement employed in this study.

On the other hand, by comparing the SI mean differences of stage I and II of MADs group with those of BO group, no statistically significant difference was found between them except between 75% advancement and 7mm BO. This means that the difference in the treatment effect between the two appliances became only obvious if we compare the 75% advancement of MAD i.e. the maximum amount of advancement with the 7mm BO i.e. the lower level of vertical jaw separation.

This reflects that MADs achieve a greater improvement on AHI than BOs, while both of them achieve nearly the same degree of improvement on SI.

Conclusions:

Based on the results of this study; it can be concluded that:

- The two types of oral appliances (MADs and BOs) significantly reduce the incidence of apneas and hypopneas leading to a remarkable improvement in the sleep quality. Also the snoring has dramatically reduced after using these appliances.
- MADs are capable of achieving better results than BOs regarding AHI, while both appliances can achieve comparably equal results regarding SI.
- No correlation was found between AHI and SI in different stages of both treatment modalities.

Recommendation

For patients complaining of OSA, it is recommended to use MADs adjusted at 50% advancement rather than 75% to minimize the possible side effects and the possible extra annoyance that may happen, on the other hand, for snorers, it is advisable to use BOs rather than MADs as they are simpler, more tolerable and cheaper.

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