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EFFICACY OF MANDIBULAR ADVANCEMENT APPLIANCE IN EDENTULOUS PATIENTS WITH OBSTRUCTIVE SLEEP APNEA

Dental Science

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ABSTRACT

Purpose: To assess the efficacy and compliance of mandibular advancement appliance (MAA) for the treatment of mild to moderate obstructive sleep apnea, under patient-care driven protocol on completely edentulous patients.

Methods: Thirty non denture wearer patients aged between 45-60 years with BMI (Body Mass Index) more than 25 were enrolled for the sleep study based on the sleep questionnaire and pre-operative Epworth sleepiness score (ESS). Out of thirty, twenty three patients who had mild to moderate apnea hypopnea index (AHI) score were chosen to receive a MAA which was fabricated at physiologic rest position. Five patients having severe obstructive sleep apnea (OSA) were referred for continuous positive airway pressure (CPAP). Subjective and objective evaluations of the patient were done using a 4 channel sleep study for continuous six nights and the quality of life questionnaire was assessed before and after the treatment.

Results: Frequency of respiratory events, AHI score, daytime sleepiness, patient's sleep quality and ESS improved significantly with the MAA. The mean values of pre-operative ESS and AHI were found to be 14.0000 and 17.5728, respectively. However, after insertion of the device for 30 days, the mean values of post-operative ESS and AHI were noted to be 7.2800 and 12.1080, respectively. Side effects and patient complains were minor and transitory. No serious side effects or pathological aggravation were observed.

Conclusion: This study confirms that 4 weeks of MAA therapy along with behaviour modification improved the quality of life (ESS scores) and sleep value parameters (AHI) in completely edentulous patients with mild to moderate OSA. Hence, the MAA treatment under a simple patient driven protocol of care with control of efficacy by the nocturnal 4 channel study is appropriate in dental practice for mild to moderate obstructive sleep apnea patients.

KEYWORDS

Mandibular device; Epworth sleepiness score; apnea hypopnea index; Obstructive sleep apnea

1. INTRODUCTION

Obstructive sleep apnea (OSA) is a common sleep-related breathing disorder and is characterized by the repetitive upper airway obstruction and disruptive sleep patterns [1]. This obstruction can be either partial (hypopnea) or complete (apnea). When a complete or partial airway obstruction is manifested by (i.e., >50%) in oronasal airflow of at least ten seconds, the respiratory event is defined as apnea or hypopnea, respectively [2]. A moderate reduction in airflow (i.e., <50%) of ten seconds or longer is also defined as hypopnea when associated with an oxygen desaturation (>3%) or brief awakening from sleep. Normal upper airway patency is usually re-established after an increased respiratory effort in response to hypoxia and hypercapnia (i.e., abnormal increase in $PaCO_2$ [3]. These increased efforts result in brief awakening from the sleep that usually goes unnoticed by the patients [4]. Recurrent arousals are associated with sleep fragmentation and depletion of rapid eye movement (REM), ultimately resulting in excessive day time sleepiness[5, 6].

Other consequences of recurrent arousals include neurocognitive functioning, an impaired quality of life and increased risk of motor vehicle accidents [5, 6]. Hemodynamic consequences include sustained periods of hypertension [7] and increased risk for cardiovascular diseases such as myocardial infarction, congestive heart failure including Cerebrovascular accidents [8, 9, 10, and 11] and even increased mortality rate has been documented in severe cases of OSA [12]. The basic cause for the OSA is reduced pharyngeal diameter. The etiology behind the narrowing of the pharyngeal airway is thought to arise from a combination of anatomical and patho-physiological factors. Anatomical factors include retro positioned facial skeleton, reduced oro-pharyngeal dimension and large tongue as implicated on the posterior pharyngeal wall. The patho-physiological factors include functional impairment of upper airway muscles due to decreased tone of the pharyngeal muscles [13]. Diagnosis of OSA is based on the following parameters such as **(i)** a comprehensive history from the patient and his/her sleeping partner, **(ii)** examination of ear, nose and throat, **(iii)** body mass index, and **(iv)** four channel sleep study/overnight polysomnography [14].

Due to the multifactorial nature of OSA, management includes a multidisciplinary approach. In this study, we identified the completely edentulous non denture wearer patients with snoring and symptoms of OSA and referred them to the sleep specialist, who in turn evaluated the sleep patterns of the patients by doing a sleep study and decided on the type of OSA [14]. Patients with mild to moderate OSA are advised to wear an oral appliance however severe cases are considered for continuous positive airway pressure (CPAP) therapy [15]. Most of the recent studies involving the dentate patients have proved that wearing an oral appliance reduces the apnea/hypopnea index by 50% or to <10 events/h [14, 17]. However, very few studies have been done to evaluate the design and efficacy of oral appliances in edentulous patients [14]. Hence, it was hypothesized in this study that wearing of oral appliances by completely edentulous patients at night will reduce the AHI and improve the quality of life of these patients.

2. MATERIALS AND METHODS

2.1. Selection of the patients

Hundred male completely edentulous patients of the age group 45-60 years, reported to the Department of Prosthodontics for the fabrication of complete dentures, were given a questionnaire and assessed to see if the patients had pre-disposing factors of obstructive sleep apnea (age, sex, snoring, excessive day time sleepiness and fatigue). Epworth sleepiness scale (ESS): daytime sleepiness was assessed using the parameters of ESS ranging from 0 to 24, as described previously [18]. Based on the ESS (value more than 10) and willingness to participate in the study, out of hundred, thirty patients were selected and were referred to the sleep study centre for an overnight four channel sleep study for six nights for definitive diagnosis and to obtain the AHI index which could be: mild (5-15 events/h), moderate (15-25 events/h) and/or severe (>25 events/h).

Further, twenty five male patients with mild to moderate sleep apnea were chosen to receive the mandibular advancement appliance, which was custom made with heat polymerized clear acrylic resin. The exclusion criteria for the study participants were **(i)** pr-existing temporomandibular joint disorders, **(ii)** maximum mandibular

advancement lesser than 5mm, **(iii)** patients with related caAHIo vascular risks, **(iv)** severe nasal passage obstruction, and **(v)** patients with severe OSA. **(vi)** Body mass index (BMI) less than 25.

2.2. Sleep study design

Treatment options suggested for the patients with mild to moderate OSA included least invasive options such as behaviour modification and oral appliances. Behaviour modification measures which included changing the sleep position from the supine position to the side position and positioning of the pillow that they cannot roll on their back (positional training) were suggested. Patients were also advised to abstain from alcohol and sedatives as they can act as muscle relaxants and could aggravate the obstruction. In obese patients, weight reduction was suggested [15]. The protocol used in this study was approved by the Institutional Ethical Committee of Saveetha University, Chennai, Tamilnadu, India and was in accordance with international standard on the care and use [16]. Besides, an appropriate informed consent was received from all the participants. The patients were undergone home nocturnal four channel sleep study for six nights with nasal flow, thoracic and abdominal efforts, oxygen saturation and heart rate channels. The equipment used for recording AHI values was the sleep recorder (Respironics, USA), which is a respiratory monitoring device (Fig. 1). Sleep recorder is a small device which is suitable for the patients to use in the comfort of their homes. The ultra-portable unit is worn on the chest and the three sensor plugs are directly connected into the recorder. The readings were monitored by the same staff for all the patients.

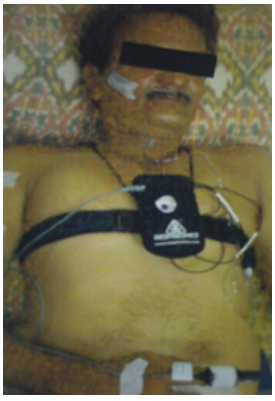

Fig. 1. Stardust Sleep Recorder - A portable sleep recorder powerful enough to generate comprehensive four-channel reports

Airflow Sensor:	measures breath rate
Oximeter:	measures pulse rate and oxygen saturation
Effort Sensor:	measures chest or abdominal effort
Body Position Monitor:	measures supine or non-supine sleep positioning

2.3. Device fabrication

The experimental devices were fabricated following the protocols such as preparation of maxillary and mandibular preliminary impressions using modelling plastic impression compound (Pinnacle, Kerr) and diagnostic casts obtained from the preliminary impression. Definitive impressions were made using medium body silicone impression material in border molded custom trays. Particular attention was made to attain the maximum functional extension of the lingual borders in order to aid in retention and stability.

Wax occlusal rims were then constructed over the heat polymerized clear acrylic resin record bases. Maxillo-mandibular relations were recorded in order to maintain the patient's vertical dimension at rest. Vertical marks were made bilaterally on both of the wax occlusion rims at the centric relation position. The patient was then asked to protrude maximally, and another line was marked on the maxillary rim corresponding to the centric relation line in the mandibular rim.

The distance between the two marks on the maxillary rim was ascertained, and then 75% of the distance from the central region (CR) line was marked on the maxillary rim. The mandibular rim was then made to occlude so that the CR line of the mandibular rim coincided with the 75% line in the maxillary occlusal rim. Maxillo-mandibular relations were recorded at that position and the casts were articulated (Fig. 2).

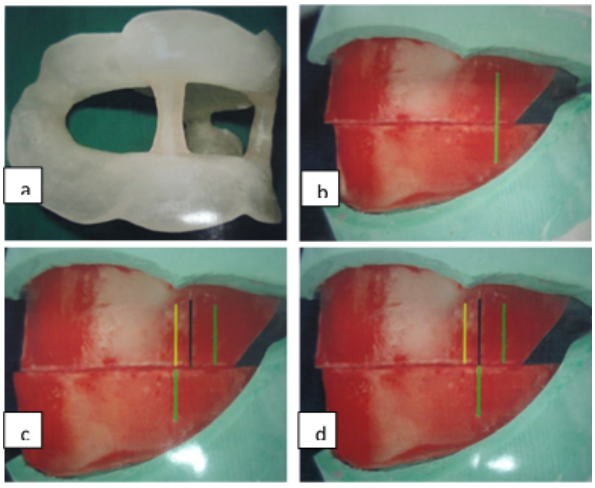

Fig. 2. (a). **Mandibular Advancement Appliance**-heat polymerized clear acrylic resin is used to fabricate the appliance. MAA holds the lower jaw and tongue forward making more space to breathe and prevent pharyngeal obstruction (b). **Centric Jaw Relation**, (c). and **Jaw relation at maximum protrusion** – the mandible is in most protruded position (d). **Jaw relation at 75% protrusion**- 75% of distance between centric relation line (green) and maximum protrusion line (black on maxillary occlusal rim)

After the articulation, wax rims were removed carefully from the denture base. Upper and lower denture bases were now fused using clear auto polymerizing acrylic resin in the retro molar pad and maxillary tuberosity area posteriorly as well as in the canine region anteriorly. The patient's recorded vertical dimension and protrusion were maintained. After finishing and polishing, the appliance was inserted and checked for adequate border extensions, retention and patient's comfort.

The advantage of this technique is its simplicity, as the clinical procedures are similar to those for fabricating a conventional complete denture. However, this appliance is not titrable, adjustments to increase protrusion cannot be made easily. The fabricated MAA was inserted and the patients were recalled on the next day, one week and two weeks later in order to check and verify the compliance of the appliance. Methods to assess the subjective and objective efficacy of the mandibular advancement appliances have been documented previously [17, 19].

In this study the ESS values and AHI were the parameters to assess the efficacy of the developed MAA. Various oral appliances have been suggested for dentulous patients [14]. These could be custom made or titrable/adjustable appliances, which include MAA or MAD, tongue retaining devices, tongue trainers and soft palate lifters [20]. Commonly recommended appliances for the treatment of mild to moderate OSA are the MAA and tongue retaining devices (TRDs). Considering all the aspects of treatment options available, a MAA was chosen to be delivered to the edentulous patients in this study (Fig. 3).

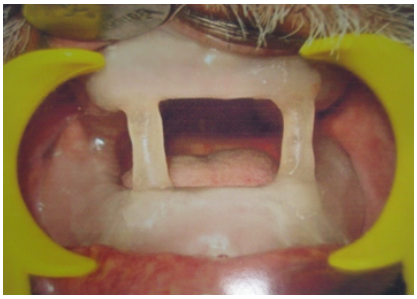

Fig. 3. Mandibular Advancement Appliance In-Situ: MAA holding the patient's mandible in forward position which prevents the base of the tongue to fall back on the posterior pharyngeal wall.

3. RESULTS

3.1. Pre- and post-operative assessment of ESS

In this study, the pre-operative ESS values of twenty five patients with mild to moderate OSA were ranged from 12 to 16, and are given in

Table 1. The mean of pre-operative and post-operative Epworth sleepiness scale was noted to be 14.0000 and 7.2800 respectively and the standard deviation value was obtained as 1.21421 and 0.90453 respectively (Table 3). Further, the custom made MAA fabricated for each patient was inserted, and the patients were recalled on the next day and every week in order to verify the compliance and facilitate minor adjustments of the appliance if required. In addition, the post-operative ESS values after a treatment period of one month were ranged from 6 to 9 (Table 1), and the patient acceptance was satisfactory (95.66%).

Table 1. Pre- and post-operative assessment of ESS.

STUDY GROUP	Pr-A-ESS[a]	Po-A-ESS[b]
Subject 1	12	6
Subject 2	14	7
Subject 3	13	9
Subject 4	15	9
Subject 5	16	9
Subject 6	16	8
Subject 7	14	7
Subject 8	15	7
Subject 9	14	6
Subject 10	12	6
Subject 11	13	6
Subject 12	16	7
Subject 13	15	9
Subject 14	12	6
Subject 15	14	8
Subject 16	15	8
Subject 17	13	6
Subject 18	14	7
Subject 19	12	6
Subject 20	14	6
Subject 21	16	8
Subject 22	15	8
Subject 23	15	9
Subject 24	12	8
Subject 25	13	6

[a]Pre- operative assessment of epworth sleepiness score.
[b]Post- operative assessment of epworth sleepiness score.

Table 3.Statistics of pre- and post-operative Epworth sleepiness score.

Paired Samples Statistics					
		Mean	**N**	**Std. Deviation**	**Std. Error Mean**
Pair 1	VAR00002	14.0000	25	1.38444	.27689
	VAR00003	7.2800	25	1.17331	.23466

3.2. Pre- and post-operative assessment of AHI

The pre-operative AHI values of the twenty five patients with mild to moderate OSA ranged from 9.39 to 24.46, and are given in Table 2. The mean of the pre-operative and post-operative AHI were found to be 17.5728 and 12.1080, whereas the standard deviation values were obtained as 4.86977 and 3.20803 (Table 4). Further, one month of the insertion of oral appliance MAA, multiple sleep studies were repeated in order to assess the symptoms. As shown in Table 2, the post-operative AHI values were ranged from 7.04 to 18.44.

Table 2. Pre- and post-operative assessment of AHI.

STUDY GROUP	Pr-A-AHI[a]	Po-A-AHI[b]
Subject 1	24.35	15.11
Subject 2	24.46	14.52
Subject 3	10.29	7.33
Subject 4	9.39	10.51
Subject 5	18.93	13.01
Subject 6	19.21	11.19
Subject 7	23.33	13.43
Subject 8	20.14	16.47
Subject 9	22.78	18.44
Subject 10	24.41	18.23
Subject 11	21.03	13.15
Subject 12	19.81	14.00
Subject 13	14.55	9.23
Subject 14	12.34	8.44
Subject 15	15.88	10.24
Subject 16	18.68	11.45
Subject 17	16.43	12.54
Subject 18	11.82	7.56
Subject 19	23.44	15.33
Subject 20	20.57	13.68
Subject 21	16.11	12.44
Subject 22	10.15	7.04
Subject 23	14.54	9.08
Subject 24	13.45	10.24
Subject 25	13.23	10.04

[a]Pre- operative assessment of apnea/hypnea index.

[b]Post- operative assessment of apnea/hypnea index

Table 4.Statistics of pre- and post-operative Epworth sleepiness score.

Paired Samples Test									
		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	VAR00002 – VAR00003	6.72000	1.17331	.23466	6.23568	7.20432	28.637	24	.000

Data interpretation for apnea/hypopnea index was performed by paired t - test and the paired samples statistics showed the mean of pre-operative and post-operative AH1 to be 5.46480, and the standard deviation was noted to be as 2.57287. The P value was found< 0.05 (P = 0.000) indicating significant statistical difference. A Wilcoxon signed rank test was also done to assess the pre-operative and post-operative AH1 values. The P-value < 0.05 (P = 0.000) showed significant statistical difference. The mean of post-operative AHI reduced to 12.1080 and the standard deviation was noted to be as 3.20803.

4. DISCUSSION

It is well known that one of the sequels of complete edentulism leads to decrease in size and tone of the pharyngeal musculature[21]. It has been observed that edentulism, by decreasing the retropharyngeal space, favors the occurrence of obstructive sleep apnea in several patients [22]. Although treatment of OSA in dentate patients with mandibular advancement splints has been well documented [23, 24, 25, 26], for edentulous patients, a search of literature revealed very few reports. However, studies have proven that in several completely edentulous patients there is improvement in the symptoms of obstructive sleep apnea due to wearing of complete dentures [22], especially at night. With this hypothesis it was decided to fabricate oral appliances for completely edentulous patients, who can wear this device during sleep in order to assess the efficacy of this mandibular advancement appliance (MAA). The advantages of fabricating MAA are to advance mandible and tongue base, increasing the space between the base of the tongue and the posterior pharyngeal wall. The tongue may also be advanced with the use of tongue retaining device. These appliances subsequently assist in reducing the obstruction. It is hypothesized that these appliances may also affect the upper airway muscle tone and decrease the collapsibility which may contribute to preservation of airway patency during sleep [27], although an increase in airway size may be the most important factor preventing airway occlusion. Increasing the vertical dimension and mandibular protrusion increase the potential airway space. The MAA fabricated for the study was done at 75% of the patient's maximum protrusion at an increased vertical dimension of 3 to 4 mm in order to facilitate an increase in the airway space. Few studies have postulated that 50% of mandibular protrusion is effective in some subjects to reduce the OSA, although in all the patients it may not be effective depending on the

severity of OSA [28]. It has been also suggested that the mandibular protrusion be kept 65% [29], 70 to 80% [30]. Patient's satisfaction with treatment at 75% mandibular protrusion is widely accepted [31]. There is also an inherent controversy whether vertical dimension established for the mandibular advancement appliance should be at physiologic rest position or at occlusion. Fabrication of MAA at physiologic rest position is advantageous as it holds the mandible in protruded position during sleep [32]. Hence, the custom made MAA was inserted to the edentulous patients after determining their pre-operative epworth sleepiness scale (ESS) and apnea/ hypopnea index (AHI) values.

The pre-treatment ESS values of the patients were ranged from 12 to 16, whereas mean was noted to be 14.0000. However, post-treatment ESS values were ranged from 6 to 9 having the mean value 7.2800. This indicated that there was a marked reduction in the subjective symptoms for all the six patients, and these results were in accordance with the previous studies done [33, 34, and 35]. On the other hand, pre-treatment AHI values which were recorded overnight by sleep studies ranged from 9.39 to 24.46 and the mean was found to be 17.5728. After one month of treatment, patients were recalled to repeat the sleep studies in order to evaluate the post-treatment AHI values which ranged from 7.04 to 18.44 having 12.1080 as the mean value. It was observed in this study that 83% of the patients showed 40 to 50% reduction in AHI values. These findings were also in confirmation with the previously reported studies [33, 36 and 37], which stated that there was 45 to 50% reduction in AHI values after insertion of MAA.

Although in this study, two patients experienced an increased salivation and partial jaw discomfort in the first week following the appliance insertion, after the insertion of the MAA for one month, patient's acceptance was found higher up to a level of 83%. However, one patient having higher AHI values indicating worsening of the OSA due to the presence of the MAA (Subject 4, Table 4), and these results were in strong agreement with a few previously reported studies [34, 38 and 39]. Hence, to analyze the basic cause of worsening of OSA, further investigation needs to be done in order to evaluate the level of obstruction. Obstruction may occur at different levels of the airway. It is designated as palatal or multilevel or tongue based [40]. If the obstruction is palatal or multilevel, mandibular advancement appliances may not decrease the symptoms or it may worsen the condition [40]. Mandibular advancement appliances are more effective in obstructive sleep apnea patients where the base of the tongue is implicated [41] as in completely edentulous patients who may have a large tongue or the tongue falling back at night as a result of removal of dentures.

Moreover, when completely edentulous patients with mild to moderate OSA were treated with mandibular advancement appliance (MMA), there was a significant improvement in the patients overall quality of life. The present finding would support the suggestions that the main mode of action of MAAs is to directly increase the dimensions of the pharyngeal airway or reducing the collapsibility [42] thereby increasing the airway patency.

5. CONCLUSION

This study has shown that four weeks of mandibular advancement appliances (MAA) therapy along with behavior modification improves day time sleepiness (ESS) and AHI in completely edentulous patients with mild to moderate OSA. Although, minor side effects such as mild discomfort and excessive salivation,were observed in the first week, the patients' level of acceptance was satisfactory. It was found in this study that there was a significant improvement in social functioning, perceived quality of sleep and overall quality of the life.This study highlighted the role of Prosthodontics in contributing the diagnosis and treatment of completely edentulous patients with mild to moderate OSA. Hence, from the results of this study, it is evident that the MMA, a non-invasive, simple, well tolerated oral appliance could be an efficient means to treat the patients with mild to moderate OSA. However, to assess the efficacy of such appliances, several factors including anatomic predisposition in patients, the level of obstruction, compliance with the tongue retaining devices and use of repositionable MMA devices need to be clarified.

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