

# Evaluation of Therapeutic Efficacy of Adjustable Mandibular Advancement Device in the Management of Obstructive Sleep Apnea

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## Abstract

**Background:** Medical Dental Sleep Appliance (MDSA) is an adjustable MAD recommended for treatment of snoring and OSA. There are very few studies on Indian population which evaluate the therapeutic efficacy of mandibular advancement devices in the management of OSA.

**Material and methods:** A prospective clinical study was carried out. 20 Polysomnography diagnosed Obstructive Sleep Apnea patients fulfilling the inclusion and exclusion criteria were treated with MDSA and changes in pre and post treatment sleep parameters (AHI, ESS) were recorded.

**Results:** Mean differences in Pre-treatment ( $T1 = 30.7 \pm 5.0$ ) and post-treatment ( $T2 = 17.2 \pm 3.9$ ) AHI values and ESS pre-treatment ( $T1 = 17.2 \pm 0.6$ ) and post-treatment ( $T2 = 10.9 \pm 0.9$ ) were highly statistically significant ( $p < 0.001$ ). Clinically the maximum improvement was observed in mild and moderate OSA cases. Although significant clinical improvement was also observed in severe OSA cases, the post treatment AHI and ESS were still high.

**Conclusion:** MDSA is a non invasive, low risk and cost-effective treatment option for patients suffering from mild and moderate obstructive sleep apnea and also in cases of severe OSA who are not comfortable with CPAP or not willing for surgery.

**Keywords:** MDSA, OSA, AHI, ESS

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## Introduction

Obstructive Sleep Apnea (OSA) is a condition that results due to partial or complete obstruction of airway when patient assumes a supine position and goes to sleep. In the last three decades mandibular advancement devices (MAD) have been used to treat OSA. MADs move the mandible forward to improve upper airway patency and are the most evaluated type of appliances. An influential review of Oral Appliance (OA) therapy for OSA, accompanied by practice parameters of American Sleep Disorder Association signaled the entry of dentistry into main stream sleep medicine<sup>1</sup>. Adjustable mandibular advancement appliance became predominant form of dental therapy for sleep disordered breathing since the 1990s<sup>2</sup>. Controlled studies in the last decade and a half have shown effectiveness and preference for oral appliances compared to Continuous Positive Air Pressure (CPAP) in mild and moderate cases<sup>3-5</sup>. Studies have also reported gross improvement in severe cases if patient selection is based on stringent inclusion criteria<sup>6</sup>.

MADs have shown to significantly improve objective parameters, such as AHI, arousal index, snoring and arterial oxygenation. They have shown to improve quality of life, blood pressure and improvements in cardiovascular outcomes and inflammatory markers similar to CPAP<sup>7</sup>.

There are several designs of adjustable mandibular advancement devices for OSA patients but there is no consensus on the design of adjustable MAD. Medical Dental Sleep Appliance (MDSA) is an adjustable MAD and a third generation intraoral dental device recommended for treatment of snoring and OSA. It is readily available in India and one of the most cost effective appliances, custom fabricated in the dental laboratory.

There are very few studies on Indian population which evaluate the therapeutic efficacy of mandibular advancement devices in the management of OSA<sup>6-8</sup>. In view of the above it was proposed to evaluate the therapeutic efficacy of Medical Dental Sleep Appliance, an adjustable MAD in the management of OSA objectively and subjectively.

## Aim and Objectives

### AIM

To evaluate the therapeutic efficacy of Medical Dental Sleep Appliance (MDSA), an adjustable mandibular advancement device (MAD), in the management of OSA by testing the null hypothesis that there is no difference in pre and post treatment sleep parameters in patients treated with MDSA.

### Objectives

The objectives of the study were:-

- To compare baseline and post treatment Apnea Hypopnea Index (AHI) scores.
- To compare baseline and post treatment Epworth Sleepiness Scale (ESS).

## Material & Methods

A prospective clinical study was carried out at the Department of Orthodontics and Dentofacial Orthopedics of Armed Forces Medical College, Pune. 20 Polysomnography diagnosed Obstructive Sleep Apnea patients referred from Dept of Pulmonary and Sleep Medicine, Military Hospital (CTC), Pune and Dept of Otorhinolaryngology, Armed Forces Medical College, Pune, fulfilling the inclusion and exclusion criteria were inducted for the study.

### Inclusion Criteria

- PSG diagnosed adult OSA cases (mild, moderate OSA cases and severe OSA cases not amenable to CPAP therapy or surgery).
- BMI  $\leq$  30 kg/m<sup>2</sup>
- Any of the following two findings on the lateral cephalogram
  - SNB  $\leq$  78°
  - MPH (Hyoid distance) > 15 mm
  - Angle ANB > 4°
- Posterior airway space (linear distance from posterior border of tongue to pharyngeal wall measured along the B-Go line) < 10 mm
- Minimum mandibular protrusion of 5 mm
- Minimum interincisal opening of 35 mm

### Exclusion Criteria

- Central sleep apnea
- Mixed sleep Apnea
- Severe accompanying respiratory disorders
- Advanced periodontal disease
- Partial edentulous cases (< 14 healthy permanent teeth)
- Adenotonsillar hypertrophy, septal deviation, turbinate hypertrophy or nasal polyp

### Sample Size Calculation

The sample size was calculated for one tailed hypothesis testing for the hypothesis  $H_0: \mu_1 - \mu_2 = 0$  against  $H_1: \mu_1 - \mu_2 < 0$  with  $\alpha = 0.05$  (5%) and  $\beta = 0.80$  (80%). Pre and Post AHI and ESS scores (based on data from reference no. 6) were as follows:

S.No	Parameter	Pre		Post	
		Mean	SD	Mean	SD
1.	AHI	47.63	7.93	20.61	5.78
2	ESS	12.70	1.82	8.50	1.26

Thus, minimum sample size required works out to be 4 for data for AHI and 7 for data for ESS. In this study 20 subjects were included.

### Procedure Methodology

- All the study subjects were subjected to lateral cephalometric micro-entography as per standard protocol. Lateral cephalograms were recorded at end expiration and the patients were asked not to deglut / swallow during the process of radiography. All the radiographs were traced by a single operator and five lateral cephalograms were retraced after one week by the same operator to rule out any discrepancies.
- Data collection was divided into two sections as follows:
  - Sleep disordered breathing form was used to record the medical and sleep history including an ESS. Using this scale, the subjects were asked to rate, on a scale of 0-3, how likely they were to doze off or fall asleep in each of the eight different situations. In the ESS, a 4-point scoring scale was used as under:

- 0 = would never doze
- 1 = slight chance of dozing
- 2 = moderate chance of dozing
- 3 = high chance of dozing

The ESS was recorded pretreatment and again post treatment after assessment of subjective improvement.

- Baseline and post treatment Polysomnography (PSG) was utilized for Apnea Hypopnea Index (AHI).

Patients meeting the selection criteria were taken up for treatment with the Medical Dental Sleep Appliance (MDSA Pty Ltd, Australia)[Fig 1,2], an adjustable mandibular advancement device. Titration was done with a key provided in the kit depending on subjective improvement. Titration did not exceed 70% of maximum protrusion. The patients were recalled weekly to ascertain subjective improvement in sleep parameters. After ascertaining subjective response from the patient or bed partner in terms of reduction / cessation of snoring, excessive day time sleepiness and regularity in use of the prescribed appliance, the patient was subjected to recording of ESS and PSG with MDSA in situ. The patient was observed for discomfort in the TMJ area or teeth, excessive salivation or any other appliance related problems.

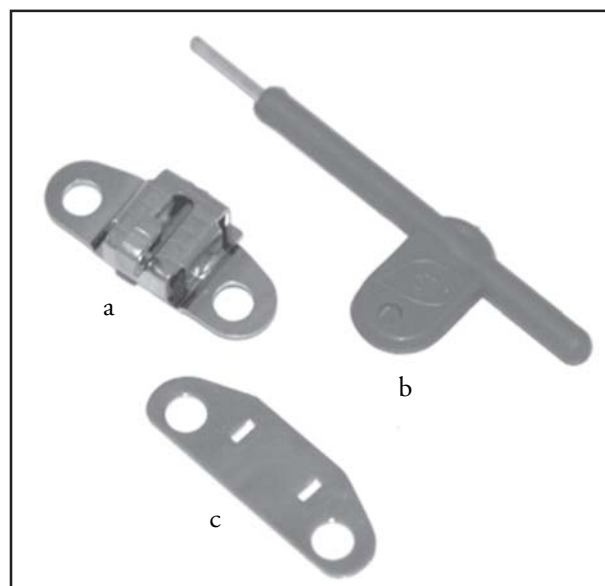


Figure 1: Components of Medical Dental Sleep Appliance (MDSA)

a. Titratable screw b. Lower platform c. Allen key

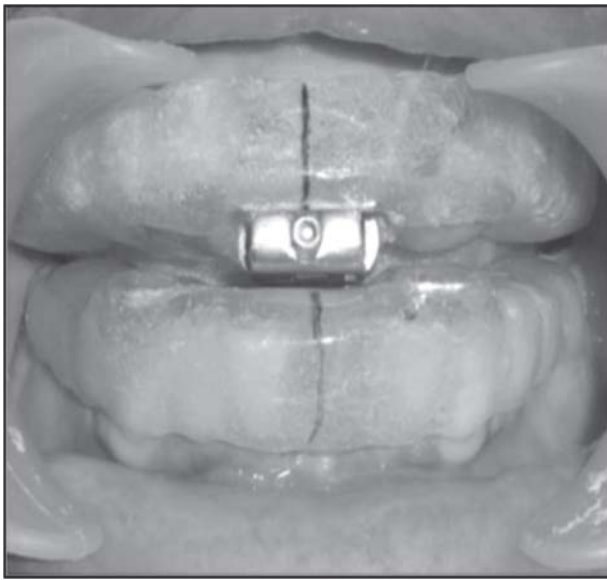


Figure 2: MDSA Delivered to Patient

### Data Compilation and Statistical Analysis

The entire data was statistically analyzed using Statistical Package for Social Sciences (SPSS ver 11.5, Inc. Chicago, USA) for MS Windows.

The data on pre and post treatment AHI and ESS is presented as Mean ( $\pm$  Standard Deviation). The statistical significance of difference of pre and post treatment parameters was tested using paired 't' test, after confirming the underlying normality assumption using Shapiro – Wilk's test. The statistics on the difference is presented as mean value along with the 95% confidence interval.

The p-values less than 0.05 were considered to be statistically significant. All the hypotheses were formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference).

### Results

#### Descriptive Statistics for Patient Variables

Data compiled from the study is consolidated as Table 1.

Table 1: Consolidated Data

S.No	Age	Gender	BMI	SNB	ANB	MPH	PAS	Pre AHI	Post AHI	Pre ESS	Post ESS
1	42	M	25.2	77	5	20	9	17.3	7.4	16	10
2	60	M	26.6	80	2	18	7	20.9	10.9	19	12
3	63	M	29.3	81	4	21	6	56.7	40.0	21	17
4	44	M	24.4	76	7	15	9	40.6	37.4	18	16
5	50	F	25.4	77	6	14	10	8.8	2.5	13	8
6	40	M	22.7	78	6	17	8	35.4	2.9	16	7
7	68	M	24.7	77	4	19	7	63.4	28.8	22	14
8	40	M	27.8	77	7	13	11	27.8	10.2	16	11
9	49	M	29.0	80	9	19	12	60.7	50.4	18	15
10	57	M	29.5	76	8	16	10	12.3	1.2	13	6
11	43	M	29.4	79	6	15	9	8.3	2.1	14	5
12	55	M	27.8	78	4	30	7	87.5	61.5	23	17
13	65	M	28.6	76	6	21	8	39.9	23.3	15	10
14	52	F	24.2	78	4	12	12	24.0	13.2	17	12
15	35	M	22.5	79	2	17	8	7.8	3.2	15	9
16	50	M	28.0	74	8	17	10	12.9	2.8	17	6
17	59	M	27.3	76	5	15	9	14.8	12.4	19	16
18	49	M	25.4	77	6	14	11	19.3	10.0	17	9
19	51	M	27.2	79	4	16	9	11.1	7.2	14	10
20	63	M	24.3	74	10	12	6	44.1	16.3	20	8

The mean  $\pm$  SD for pretreatment AHI for the group was calculated to be  $30.7 \pm 5.0$  as shown in Table 2. Seven cases (35.0%) had mild OSA (AHI = 5-15 events/hr), five cases (25.0%) had moderate OSA (AHI = 15-30 events/hr) and eight cases (40%) had severe OSA (AHI > 30 events/hr).

Out of the 20 cases studied, 6 cases (30.0%) had a BMI between 18.5 to 24.9 (Healthy category) and 14 cases (70.0%) had a BMI between 25.0 to 29.9 (Overweight category). The mean  $\pm$  SD of BMI of the entire group of cases was  $26.5 \pm 2.2$  kg/m<sup>2</sup>.

### Descriptive Statistics for Pre and Post Treatment Variables

To identify the significance of post-operative changes with respect to pre-operative values, a Student's paired t-test was used for all pre and post AHI and pre and post ESS after confirming the underlying normality assumption using the Shapiro - Wilk's test.

Results of comparison for AHI pre-treatment ( $T_1 = 30.7 \pm 5.0$ ) and post-treatment ( $T_2 = 17.2 \pm 3.9$ ) values shows an average change in  $T_2$  values of 13.5 which is highly statistically significant ( $p < 0.001$ ).

Comparison for ESS pre-treatment ( $T_1 = 17.2 \pm 0.6$ ) and post-treatment ( $T_2 = 10.9 \pm 0.9$ ) values shows there is average decrease of 6.3. This mean difference is highly statistically significant ( $p < 0.001$ ) and shows the improvement in night time sleep quality and reduction in day time sleepiness with MDSA.

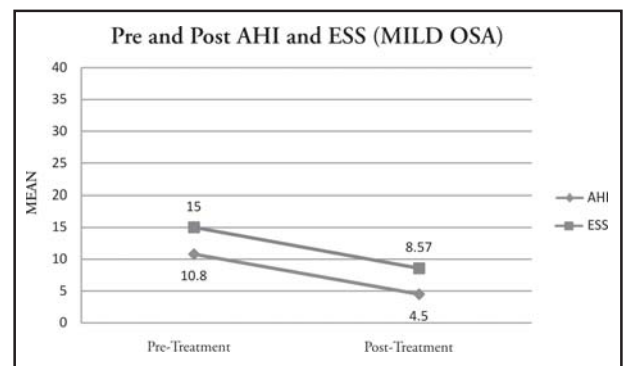
For Mild OSA cases, comparison for AHI pre-treatment ( $T_1 = 10.8 \pm 2.6$ ) and post-treatment ( $T_2 = 4.5 \pm 3.9$ ) values show an average change in  $T_2$  values of 6.4 which is statistically significant ( $p < 0.005$ ) and ESS pre-treatment ( $T_1 = 15.0 \pm 2.24$ ) and post-treatment ( $T_2 = 8.57 \pm 3.6$ ) values shows there is average decrease of 6.43. This mean difference is extremely statistically significant ( $p < 0.001$ ).

For Moderate OSA cases, AHI pre-treatment ( $T_1 = 21.8 \pm 4.1$ ) and post-treatment ( $T_2 = 10.3 \pm 2.1$ ) values show an average change in  $T_2$  values of 11.5 which is extremely statistically significant ( $p < 0.001$ ) and ESS pre-treatment ( $T_1 = 17.0 \pm 1.2$ ) and post-treatment ( $T_2 = 10.8 \pm 1.3$ ) values shows there is average decrease of 6.2 which was again extremely statistically significant ( $p < 0.001$ ).

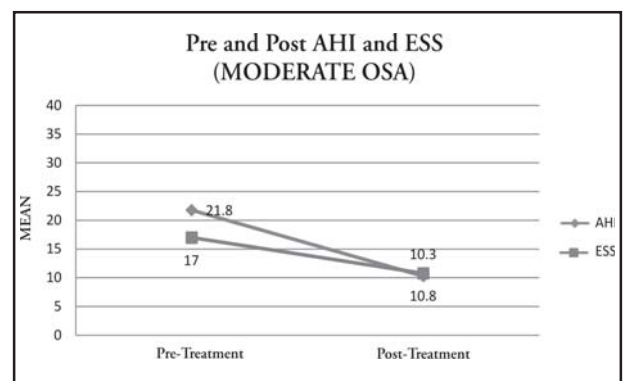
AHI pre-treatment ( $T_1 = 53.5 \pm 17.2$ ) and post-treatment ( $T_2 = 32.6 \pm 18.8$ ) values for severe OSA cases show an average change at  $T_2$  of 20.9 which is statistically significant ( $p < 0.005$ ) and ESS pre-treatment ( $T_1 = 19.1 \pm 2.8$ ) and post-treatment ( $T_2 = 13.0 \pm 4.1$ ) values shows there is average decrease of 6.1 which was again statistically highly significant ( $p = 0.001$ ).

Clinically, it was observed that maximum improvement in snoring and day time sleepiness was observed in mild and moderate OSA cases. Although significant clinical improvement was also observed in severe OSA cases, the post treatment AHI and ESS were still high.

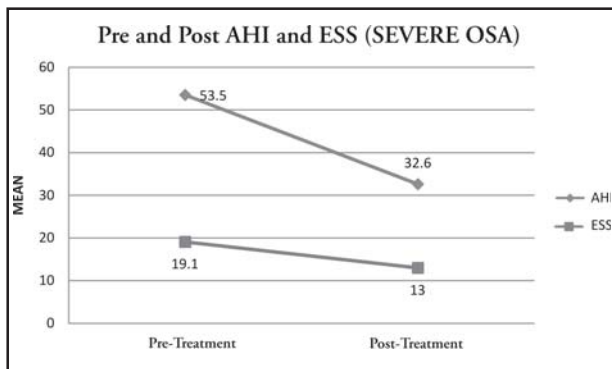
Comparison of Pre and Post treatment AHI and ESS for the mean of differences for mild, moderate and severe OSA are presented vide Graph 1a, Graph 1b and Graph 1c, respectively.



Graph 1a: Comparison of Pre And Post Treatment AHI and ESS (Mild OSA)



Graph 1b: Comparison of Pre and Post Treatment AHI and ESS (Moderate OSA)



**Graph 1c: Comparison of Pre and Post Treatment AHI and ESS (Severe OSA)**

### Adverse Effects of MDSA

Nine participants experienced increased salivation and difficulty in sleeping with the appliance in situ. However, these effects decreased gradually and most patients comfortably wore the appliance for the entire duration of sleep after 1 week of appliance delivery.

However, one participant (S.No 4) experienced continued discomfort with the appliance during sleep and also complained of appliance dislodgement during sleep. Despite best efforts to assure the participant and performing suitable remedial actions, the problems persisted and he showed minimum decrease in AHI (T1 = 40.6 and T2 = 37.4) and ESS (T1 = 18 and T2 = 16).

None of the other patients showed any adverse effects in the dentition or masticatory system due to wearing of MDSA.

### Discussion

Obstructive sleep apnea is a common sleep disorder characterized by recurring collapse of the upper airway during sleep, resulting in sleep fragmentation and oxygen desaturation. OSA is defined as the occurrence of five or more episodes of complete (apnea) or partial (hypopnea) upper airway obstruction per hour of sleep (apnea-hypopnea index)<sup>9</sup>. Daytime symptoms such as sleepiness, cognitive impairment, and effects on quality of life require appropriate treatment. Furthermore the association of OSA with increased risk of motor vehicle accidents, cardiovascular morbidity and the subsequent increased risk of mortality, emphasize the need for effective long-term treatment<sup>10</sup>.

Most common treatment options for OSA include behavioral strategies, such as weight reduction, alcohol avoidance, smoking cessation, and alteration of sleeping position, a range of surgical procedures of the upper airway, continuous positive airway pressure (CPAP) and oral appliances<sup>11</sup>. The gold standard treatment for OSA is to pneumatically splint open the upper airway during sleep using continuous positive airway pressure. CPAP is highly efficacious in preventing upper airway collapse but patient acceptance, tolerance and adherence is often low, thereby reducing effectiveness<sup>3</sup>.

Hence, there is a major need for effective alternative treatment modalities. Custom made mandibular advancement devices are an effective treatment option for snoring, upper airway resistance syndrome and obstructive sleep apnea. Evidence based data indicates their efficacy, and international sleep societies recommend oral appliance therapy for patients with sleep related breathing disorders<sup>1,10,12</sup>. The rationale behind the efficacy of MADs is that advancement of the mandible and tongue improves upper airway patency during sleep by enlarging the upper airway and by decreasing upper airway collapsibility, thereby preventing collapse during sleep<sup>4</sup>. A mandibular advancement appliance should positively place the lower jaw in a predictable and maximally therapeutic position.

MDSA is a third generation two-piece appliance with separate components on maxilla and mandible. A separate component for each jaw makes fitting easier and makes it more difficult to dislodge because the removal of the appliance is in different path of opening<sup>13</sup>. Connecting the upper and lower appliance is accomplished by a single hook and latch in the anterior region. Because of the versatility and ease of adaptation the MDSA is more effective than the one piece appliance. The appliance design restricts all backward movements while still allowing the patient to move the mandible forward and side to side and open the mouth if necessary.

There are numerous studies highlighting the benefits of different mandibular advancement devices in OSA<sup>3, 5-7,14-33</sup>. However, a review on oral appliances therapy for OSA has pointed out that most studies exclude the patients with severe OSA, thus there exists a significant source of bias<sup>11</sup>. Furthermore, only a few studies have studied the third generation adjustable MADs<sup>6,7,17, 23-25,31</sup> and only one study evaluated the efficacy of the medical dental sleep appliance for the management of OSA<sup>25</sup>.

There is also a paucity of studies with regard to prescribing oral appliances with definite inclusion and exclusion criteria. Some studies have shown that if cephalometric findings like reduced posterior airway space/ retroglossal space, increased hyoid-mandibular plane distance, retrognathic mandible and BMI  $\leq$  30 Kg/m<sup>2</sup> are considered, along with established dental norms for oral appliance therapy, 70% mandibular protrusion with MDSA can bring about desired therapeutic efficacy in severe OSA cases<sup>6,7</sup>.

Keeping these criteria in mind, this prospective clinical study was performed to assess the therapeutic efficacy of MDSA in the treatment of OSA.

### Sample Characteristics

The study sample consisted of 20 subjects with 18 males (90%) and 2 females (10%). This gender bias was expected as female hormones have been shown to have a protective action against OSA in a review article by Banno and Kryger<sup>34</sup>. They reported that progesterone, a female hormone, has respiratory stimulant properties while testosterone, a male hormone, has been reported to increase upper airway collapsibility, which may increase the risk for the development of OSAS. They also stated that due to the hormonal changes, the prevalence of OSAS in postmenopausal females is higher than in premenopausal females. This correlation was reestablished in our study as both the female subjects reported to be post menopausal.

The mean BMI of the study sample was  $26.5 \pm 2.2$  kg/m<sup>2</sup>. Only patients with BMI  $< 30$  kg/m<sup>2</sup> were included in the study to rule out any confounding factor that may arise due to a positive correlation between increased BMI and severity of OSA as shown in various studies<sup>35-38</sup>. These studies suggest that the shape and dimension of the pharyngeal lumen was more dependent on BMI than on the presence of OSA and a higher BMI was related to a more severe OSA.

The mean  $\pm$  SD of baseline AHI for the group was  $30.7 \pm 5.0$ .

Seven cases (35.0%) had mild OSA, five cases (25.0%) had moderate OSA and eight cases (40%) had severe OSA who did not agree for surgery or were uncomfortable with CPAP. This was in agreement with scientific appraisals and international guidelines of different sleep societies which recommend oral appliance treatment for primary snoring, upper airway resistance syndrome, mild

to moderate OSA (AHI up to 30/h) and in severe cases, not amenable to CPAP therapy<sup>1,12</sup>.

### Therapeutic Effects Of MDSA

Due to strict adherence to the inclusion and exclusion criteria, we observed a highly significant improvement in AHI scores. The mean AHI scores decreased from  $30.7 \pm 5.0$  to  $17.2 \pm 3.9$ . As per international norms 50% reduction in AHI scores is considered successful treatment<sup>12</sup>. We could not achieve the same in ten cases. This can be attributed to the fact that 8 cases (40%) of the study population treated had severe OSA (AHI  $> 30$ ), where oral appliance therapy is not the first choice. However, the overall improvement in AHI scores in the study sample was highly statistically significant ( $p < 0.001$ ). Ten cases in the present study showed more than 50% reduction in AHI scores.

In the present study, post treatment AHI scores did not show significant difference in two cases [S.No 4 and 17]. It is not clear as to why oral appliance were effective in most except two cases. Various individual anatomic factors, the degree of vertical and saggital opening, the skeletal pattern of the skull and oro-pharyngeal tissue compliance may influence therapeutic efficacy, as reported in the literature<sup>10</sup>. Patient compliance is another factor to be taken into consideration as the initial difficulties are experienced with appliance wear and sleep parameters may take some time to improve. Although, constant motivation and counseling was carried out, some subjects tended to be impatient with the delay in response.

Clinically, most patients showed subjective improvement in the form of reduction in snoring, as reported by bed partner and decreased day time sleepiness as assessed by the Epworth sleepiness scale.

ESS scores reduced from  $17.2 \pm 0.6$  to  $10.9 \pm 0.9$  which was highly statistically significant ( $p < 0.001$ ). Clinically these changes manifested as improved night time sleep quality with reduction in snoring and decreased day time sleepiness. Decrease in snoring was reported almost immediately in all cases however the day time sleepiness showed improvement over a period of 4 - 6 months. The time taken can be due to the 'sleep debt' caused due to the decreased night time sleep quality in OSA patients. However, in the two cases in which the AHI did not improve, there was no significant clinical improvement highlighting the proven correlation between AHI and ESS.

When these changes are correlated clinically it was observed that maximum improvement in snoring and day time sleepiness was observed in mild and moderate OSA cases. In severe OSA cases, although significant clinical improvement was observed, the post treatment AHI and ESS were still high in most cases. These findings are in agreement with a randomized controlled trial by Barnes et al<sup>25</sup> who reported MDSA to be effective in the management of mild and moderate OSA. A prospective study by Marklund and colleagues<sup>27</sup> also demonstrated a significant reduction in AHI in patients with MADs in a wide range of OSA severities but the greatest improvement was observed in patients with mild and moderate cases. Similarly, a randomized clinical trial by Johnston and co-workers<sup>39</sup> concluded that mandibular advancement appliance was less effective in subjects with most severe OSA (pre treatment AHI > 50). In a recent meta-analysis, Sharples and co workers<sup>40</sup> have shown that MAD results in a significant improvement in post-treatment AHI, and that the estimate of effect was similar irrespective of baseline AHI and the effect of MAD on subjective day time sleepiness measured using the ESS followed a similar pattern.

### Adverse Effects Of MDSA

All the participants were followed up for a minimum period of 6 months post appliance delivery to ascertain any short term side effects. Immediately after appliance delivery, nine participants experienced increased salivation and difficulty in sleeping with the appliance. However these effects decreased gradually in all but one patient, and they comfortably wore the appliance for the entire duration of sleep after one week of appliance delivery. Similar findings were reported by various studies in which over 80% of the patients reported some sort of adverse effect, mostly excessive salivation or dry mouth, that they attributed to the device<sup>28,41,42</sup>.

None of the patients showed any adverse effects in the dentition, in the form of changes in occlusion, or masticatory system in the form of pain and discomfort in TMJ due to wearing the MDSA over a 6 month period. Bondemark and co workers<sup>43</sup> compared masticatory system symptoms such as temporomandibular pain or clicking, headache, jaw muscle fatigue or soreness to baseline data or to a control group without mandibular repositioning appliances and reported no increase in the incidence of such symptoms. One long term study by Almeida and co workers<sup>44</sup> showed a more marked

change in overjet and overbite. However, another prospective long term study by Marklund<sup>45</sup> did not show any further changes in occlusion. Literature suggests that these changes seemed to develop during the first few years of use of the device and then stabilize. None of the studies with a follow up period of less than 6 months reported clinical signs of changes in occlusion<sup>41,42</sup>.

### Conclusion

This prospective clinical study was conducted to evaluate the therapeutic efficacy of Medical Dental Sleep Appliance (MDSA), an adjustable mandibular advancement device, in the management of OSA by testing the null hypothesis that there is no difference in pre and post treatment sleep parameters in patients treated with MDSA. The following conclusions can be drawn from the study:

1. The null hypothesis is rejected as there is a highly significant difference in pre and post treatment sleep parameters, i.e. AHI and ESS scores, in patients treated with MDSA.
2. Treatment with MDSA can benefit OSA cases with improvement in night time sleep quality and day time sleepiness, as assessed by reduction in AHI and ESS scores.
3. MDSA is a non invasive, low risk and cost-effective treatment option for patients suffering from mild and moderate obstructive sleep apnea and also in cases of severe OSA who are not comfortable with CPAP or not willing for surgery, provided that co-morbidities are carefully analyzed and patient compliance is adequate to achieve optimal results.

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