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Mandibular advancement devices, irrespective of amount of movement, are effective in treating young patients with obstructive sleep apnea

Wei Min Natalie Tan^{1*}, Kok Weng Lye^{2,3}, Seyed Ehsan Saffari⁴ and Choy Yoke Poon¹

Abstract

Introduction Mandibular advancement devices (MADs) increase the airway by providing a stable anterior position of the mandible, advancing the tongue and soft palate and potentially changing the genioglossus muscle activity. As such they are an accepted non-surgical treatment option for obstructive sleep apnea (OSA). The study aimed to investigate whether the amount of mandibular advancement impacts treatment outcomes of OSA. Secondary aims included identifying variables correlated with treatment response and assessing changes in polysomnography (PSG) parameters based on advancement.

Methods This retrospective study included patients aged ≥ 18 years diagnosed with OSA and treated with MADs. Data were collected from clinical notes, pre- and post-treatment PSG sleep studies. Amount of advancement was determined by the final titrated advancement achieved. Patients were grouped according to whether the final amount of advancement was ≤ 8 mm or > 8 mm. Treatment responses were classified as complete (symptom resolution and $RDI < 5/h$), partial (symptom improvement and $\geq 50\%$ reduction of RDI but $RDI \geq 5/h$) and no response ($< 50\%$ reduction in RDI and RDI remaining $\geq 5/h$). Treatment responses and changes in PSG parameters ($T90$, $LSAT$ and RDI) were then compared between the two groups of patients.

Results The study included 49 patients (42 males, 7 females) with mild ($n = 9$), moderate ($n = 28$), and severe ($n = 12$) OSA. No statistically significant difference was found for OSA severity between male and females. Complete response rate was 11.1% for ≤ 8 mm advancement and 19.4% for > 8 mm advancement, but this difference was not statistically significant. Similarly, changes in RDI , $LSAT$ and $T90$ were not statistically significant between the two groups. There was statistically significant difference in treatment response between age groups, with younger patients (≤ 50 years) showing better response.

Conclusion Effectiveness of MADs in the treatment of OSA does not depend on the final titrated advancement achieved. However, younger patients benefit more from MADs, highlighting age as a critical parameter in treatment responses.

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Clinical implications There is strong evidence to support the use of MADs as a functional second line treatment option to CPAP, and thus understanding the factors that contribute to positive treatment of OSA is important.

Keywords Mandibular repositioning appliances, Obstructive sleep apnea-hypopnea syndrome (OSAHS), Magnitude of advancement, Treatment outcome

Background

Obstructive Sleep Apnea (OSA) is defined by the American Association of Sleep Medicine (AASM) as a condition with “repetitive obstructions of the upper airway often resulting in oxygen desaturation and arousals from sleep” (Sleep-Related Breathing Disorders in Adults 1999). The treatment and management of OSA aims to reduce the critical closing pressure of the upper airway and maintain airway patency, in order to improve sleep quality, eliminate daytime sleepiness and prevent long-term medical complications and consequences (Foldvary-Schaefer and Waters 2017).

Continuous Positive Airway Pressure (CPAP) therapy is currently the gold standard in the non-surgical treatment of OSA. However, oral appliances, such as Mandibular Advancement Devices (MADs), is recognised as an alternative treatment option for patients who are unable to tolerate nasal continuous positive airway pressure or who present with high surgical risks. A recent clinical consensus statement group has recommended that MADs can be an effective treatment in single-level pharyngoplasty surgery failure with identified postoperative base of tongue collapse (Iannella et al. 2024). The appliances work by increasing the airway, providing a stable anterior position of the mandible, therefore stabilising the upper airways in retro-palatal and retro-lingual areas (Iannella et al. 2024; Almeida and Lowe 2009). MADs also advance the tongue and soft palate, potentially changing the genioglossus muscle activity (Almeida and Lowe 2009). Treatment of OSA with MADs has been found to be effective regardless of OSA severity. Studies have found that reductions in Apnea-Hypopnea Index (AHI) and improvements in lowest oxygen saturation were significant with MAD therapy (Park et al. 2016a, b; Haesendonck et al. 2016; Sharples et al. 2016).

Other studies have found that young female patients with a low Body Mass Index (BMI) and small neck circumference may be the best candidates for MAD therapy (Chen et al. 2020). Patients who have less severe OSA, narrower airway, shorter soft palate, increased mandibular plane to cranial base angle, and supine-dependent OSA may also have a better response with MAD therapy (Ng et al. 2012; Mehta et al. 2001; Liu et al. 2001; Marklund et al. 2004). Patients who suffer from nasal congestion, increased BMI, for those who have high therapeutic CPAP pressures with previous CPAP therapy are unlikely to benefit from MAD therapy (Marklund et al. 2004).

A greater amount of mandibular advancement has been suggested to produce improved effects of a MAD, but no precise linear relationship between mandibular advancement and treatment success has been described in literature (Marklund et al. 2019). A previous study on the effectiveness of MADs has indicated that there is a higher rate of treatment success when mandibular advancement was >5 mm. However, the study did not quantify the difference in success rates between patients who achieved <5 mm of mandibular advancement to those who achieved >5 mm of advancement. It was also not known if the difference was statistically significant (Marklund et al. 1998). It has also been reported that a large mandibular advancement of >10 mm is required in the surgical management of OSA via Maxillo-Mandibular Advancement surgery (Nimkarn et al. 1995), but this degree of advancement may not be feasible with a MAD due to the physiologic limitations in amount of mandibular protrusion. Woelfel et al. (2014) found that the mean physiologic maximum protrusion of the mandible was 8 mm, and this formed the basis for groupings in this present study. It has also been observed in another study that a significant increase in cross-sectional shape of the upper airway was found when the mandible was advanced to 8 mm as compared to smaller advancements, and since an association between increased airway volumes and improvements in AHI/RDI has been established, we expect larger advancements to produce increased upper airway volumes that will ultimately increase the rate of treatment success with MADs (Zhao et al. 2008).

Based on the above, it was postulated that a patient who is able to achieve and tolerate a greater amount of mandibular advancement will potentially be able to achieve significant benefits with the MAD. As such, it can be inferred that patients who present with a retrusive mandible (i.e. Class II skeletal relationship) will be better able to achieve a >8 mm advancement.

Objectives

The primary aim of this study was to determine the proportions of patients who achieved positive response with MAD therapy between the two groups. Secondary aims were to investigate the correlation of various variables with treatment responses, and changes of PSG variables with the amount of advancement.

Materials and methods

Study design

This is a retrospective cohort study, looking at patients who first consulted/attended OSA clinics, and were subsequently treated with MADs in National Dental Centre Singapore (NDCS) and NDCS Department of Oral and Maxillofacial Surgery at Changi General Hospital (CGH) from 1st January 2011 to 31st October 2017.

Patient selection

All patients identified within the stipulated time frame from NDCS and CGH were recruited and subjected to the following inclusion and exclusion criteria.

Inclusion criteria:

- Patients ≥ 18 years of age.
- Patients diagnosed with OSA and treated with MAD.
- Patients with baseline and treatment (with MADs at final titrated advancement achieved) Full-night Polysomnography (PSG) Sleep Studies.
- Patients with baseline lateral cephalograms.

Exclusion criteria:

- Concurrent usage of other treatment interventions (e.g. CPAP, nasal drops).
- Surgical interventions or medical events, that occurred during the course of MAD therapy before baseline PSG was done.
- Inability to standardise comparisons of Respiratory Disturbance Index (RDI)/AHI between baseline and treatment PSG.

Patients who met the inclusion criteria were found to have been prescribed one of two devices – either the Thornton Adjustable Positioner (TAP) (Airway Management Inc., Dallas, Texas, United States) or the SomnoDent appliance (SomnoDent, SomnoMed AG, Australia). The type of device prescribed was changed from the TAP appliance for earlier patients, to the SomnoDent appliance in later patients as the laboratory had discontinued the TAP appliance.

The initial amount of mandibular advancement was determined using a George Gauge, and the amount of advancement was titrated accordingly, over a varying number of review visits, until the patient was comfortable with the amount of mandibular advancement and was no longer experiencing any side effects during application of the device. A repeat PSG with application of the MAD was then arranged for patients.

Treatment responses were categorised following previously published criteria (Mehta et al. 2001; Kim et al. 2014; Campbell et al. 2009):

- **Complete Response:** Resolution of symptoms and reduction in RDI to $< 5/h$.
- **Partial Response:** Improvement of symptoms and $\geq 50\%$ reduction in RDI, but RDI still remaining $\geq 5/h$.
- **No Response:** Ongoing symptoms, with $< 50\%$ reduction in RDI, and RDI remaining $\geq 5/h$.

Variables

Relevant data for the study was obtained through a detailed review of patient case notes and PSG reports. Patient characteristics included gender, age at presentation, race, baseline height and weight, and BMI, as well as dental parameters such as the amount of overjet (OJ) and overbite (OB). Study parameters encompassed the final titrated amount of mandibular advancement achieved and PSG variables, which were assessed both at baseline and during treatment. These variables included the overall respiratory disturbance index (RDI), total time spent in desaturation ($SpO_2 < 90\%$) as a percentage of the sleep study duration (T90), and the lowest oxygen saturation reached during the study (LSAT). Additionally, patient-reported side effects associated with MAD therapy were documented.

Statistical methods

Based on the final amount of advancement, patients were grouped accordingly if the amount of advancement was ≤ 8 mm or > 8 mm. Treatment responses and changes in PSG parameters (T90, LSAT and RDI) were then compared between the two groups of patients.

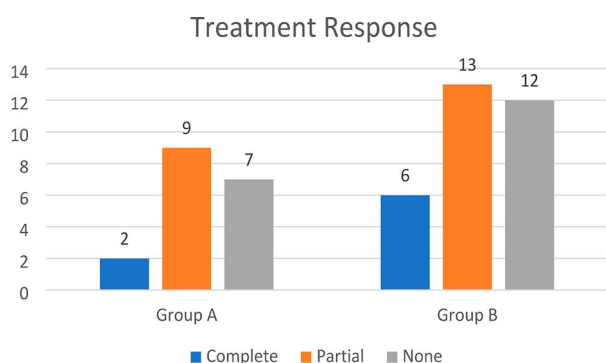
Bland-Altman plots and Intraclass Correlation Coefficient (ICC) were performed to determine test-retest reliability for lateral cephalogram measurements in 25% of measurements. Categorical parameters were reported as frequency and percent, and the distribution of continuous parameters were described by mean, standard deviation, median, minimum and maximum. Groups of interest were compared for continuous and categorical difference using two independent sample t-test (or Mann-Whitney U test, if normality assumption was not tenable) and chi-squared (or Fisher exact test, where appropriate), respectively. When more than two groups were analysed, ANOVA (or Kruskal Wallis test, if normality assumption was not tenable) were applied. Univariate linear regression analysis was conducted to investigate the association between different variables and outcomes. Normality assumption of the residuals in the linear regression analysis was assessed via quantile-quantile plots and no major deviation from normality assumption was observed. All statistical significance was set at $p < 0.05$.

Table 1 Age and BMI of sample population

Variable	Male (n = 42)				Female (n = 7)				P-value*
	Mean (SD)	Median	Min	Max	Mean (SD)	Median	Min	Max	
Age (yrs)	46.2 (11.9)	47.5	18.0	68.0	54.4 (7.9)	51.0	44.0	66.0	0.116
BMI (kg/m ²)	26.2 (3.4)	25.6	19.2	33.1	27.9 (4.2)	28.3	23.6	34.1	0.310
RDI (events/hr)	27.8 (13.4)	25.4	9.3	66.0	21.8 (10.6)	26.7	8.3	33.6	0.530

SD = Standard Deviation, Min = Minimum, Max = Maximum

*Mann-Whitney U test

**Fig. 1** Treatment response and final titrated amount achieved

Results

Participants

A total of 138 patients diagnosed with OSA and treated with MADs were identified between 1st January 2011 to 31st October 2017. Only 49 individuals met the inclusion criteria, consisting of 42 males and 7 females. All patients were treated by a single clinician for MAD therapy.

Descriptive data

The mean age of the population was 47.4 years. The age range of male patients in this sample was wider than that of female patient, but this was not statistically significant ($p=0.116$). The median BMI of the total sample was 25.8 kg/m². BMI distribution was not significantly different between male and female populations ($p=0.310$). The mean baseline RDI was 26.91 events/hr. No statistically significant difference was detected in baseline RDI between males and females ($p=0.530$). Age, BMI and baseline RDI of the sample population are demonstrated in Table 1.

Among the subjects, 9 individuals were diagnosed with mild OSA, 28 with moderate OSA, and 12 with severe OSA. No statistically significant difference was found for OSA severity between male and females ($p=0.632$).

Majority of patients had Class I skeletal relationship ($n=32$). 12 patients had Class II skeletal relationship, and 5 patients had Class III skeletal relationship. The mean overjet and overbite in the population was 3.9 mm \pm 1.9 and 3.1 mm \pm 1.4 respectively.

Table 2 Treatment response and age at presentation

Age	Treatment Response			P-value*
	Complete	Partial	None	
< 50 (yrs)	7 (28.0)	13 (52.0)	5 (20.0)	0.010
\geq 50 (yrs)	1 (4.2)	9 (37.5)	14 (58.3)	

Parentheses indicate proportions represented as %

*Fisher exact test

Table 3 Treatment response for ≤ 8 mm and > 8 mm of final titrated advancement achieved

Amount of advancement	Treatment Response			P-value*
	Complete	Partial	None	
≤ 8 mm	2 (11.1)	9 (50.0)	7 (38.9)	0.794
> 8 mm	6 (19.4)	13 (41.9)	12 (38.7)	

Parentheses indicate proportions represented as %

*Fisher exact test

Main results

Eight patients achieved complete response, 22 partial response, and 19 had no response with MAD therapy. This translated into a 16.3% and 44.9% complete response rate and partial response rate, respectively. No response rate was 38.8%.

Treatment responses between the two groups of advancement were not statistically different ($p=0.794$). There was a response rate of 11.1% for those with ≤ 8 mm of advancement and 19.4% for those with > 8 mm of advancement when considering only complete responses ($RDI < 5$) (Fig. 1). When both partial and complete responses were considered, there was a drastic increase in response rates seen, with both groups seeing similar response rates. Treatment response is illustrated in Table 2.

Other analyses

There was a statistically significant difference when the population was analysed according to age for treatment response ($p=0.01$). This is illustrated in Table 3. 80.0% of patients in the younger age group were able to achieve a treatment response (complete or partial), in comparison to 41.7% of older patients. There was a higher rate for complete response in younger patients (28.0%) than older patients (4.2%). There was no statistically significant difference noted between males and females for treatment response.

Table 4 Changes in PSG parameters

	≤ 8 mm (n = 18)				> 8 mm (n = 31)				P-value*
	Mean (SD)	Median	Min	Max	Mean (SD)	Median	Min	Max	
RDI (events/hr)	-11.6 (11.1)	-12.2	-40.3	3.6	-15.8 (11.4)	-13.8	-53.9	0.9	0.223
LSAT (%)	4.3 (7.6)	5.5	-11.0	14.0	4.3 (7.2)	4.0	-15.0	20.0	0.972
T90 (%)	-1.3 (1.7)	-0.8	-4.1	2.5	-0.5 (4.0)	-0.4	-11.2	16.7	0.453

SD = Standard Deviation, Min = Minimum, Max = Maximum

*Mann-Whitney U test

Absolute changes in RDI, LSAT and T90 are demonstrated in Table 4. No statistically significant differences were observed between ≤8 mm and >8 mm of final titrated advancement achieved.

Univariate linear regression analysis showed a statistically significant positive correlation between OJ and final advancement ($p=0.003$), and based on the analysis, approximately 0.4 mm increase in OJ relates to an 1 mm increase in final MAD advancement achieved. The association between OB and final advancement was found to be positive but not statistically significant by univariate linear regression analysis ($p=0.30$).

Discussion

Findings from previous studies have shown that greater advancement results in a greater decrease in AHI and hence OSA severity (Aarab et al. 2010; Walker-Engstrom et al. 2003). These studies utilised a percentage of the patient’s maximum mandibular protrusion, and observed that advancements at 50% and 75% resulted in greater reduction in AHI. The mean maximal mandibular protrusion of the patients in the study by Aarab et al. (2010), was 9.6 mm, with a range of 6–14 amongst the 17 patients. The study by Walker-Engstrom et al. (2003) reported a mean of 7.2 mm (6.7–7.6 mm) of mandibular advancement in the 75% group, and mean of 5.0 mm (4.8–5.3 mm) mandibular advancement in the 50% group. Conversely, a recent systematic review by Bartolucci et al. suggested that increases in mandibular advancement did not produce statistically significant improvements in treatment success (Bartolucci et al. 2016). This finding is consistent with the present study, which did not find any statistically significant difference in the proportion of treatment success between the two groups of advancement, and therefore the null hypothesis is rejected. This study illustrates that the amount of advancement alone is not predictive of success, which may be explained by the multifactorial pathophysiology of OSA (Eckert and Malhotra 2008).

Mandibular advancement with a MAD alone may not be sufficient for patients who may have other anatomical and physiological factors contributing to OSA. The MAD targets improvements at the lower portion of the upper airway, and will therefore not be suitable for patients with multi-level obstructions (Park et al. 2016a, b). Increasing

the amount of advancement with a MAD may not bring about better outcomes, and this has also been suggested in a previous study by Petri et al. (2008). Anatomic factors such as fat content in the pharynx and soft tissue laxity of the airway can also affect treatment outcomes with MADs (Marklund et al. 2004). Soft tissue properties such as increased soft tissue elasticity of the tongue have also been suggested as a possible limitation to mechanical transmission of the mandibular advancement force to the base of tongue, thereby affecting dose-dependent effects of mandibular advancement (Kato et al. 2000). A recent study has found that a lower compensation of the pharyngeal muscles against obstructive respiratory events is associated with a better response to treatment with MADs, which seems to indicate that the MAD can activate muscles that are initially less responsive, hence improving their action (Manetta et al. 2024a, b).

Attempts at defining the phenotypic causes of obstructive sleep apnea have been reported in various studies (Eckert et al. 2013; Manetta et al. 2024a, b). Eckert et al. (2013) presented the four pathophysiologic traits as a PALM scale – passive critical closing pressure of the upper airway (Pcrit), arousal threshold, loop gain and muscle responsiveness. This scale was developed to assist in categorising OSA patients according to anatomic and non-anatomic phenotypic traits over four categories (1, 2a, 2b, 3). Anatomic interventions, such as MADs, were found to be more effective for category 2a patients with moderately collapsible upper airway without non-anatomic traits. These interventions alone were less likely to result in improvements for patients in categories 1, 2b and 3.

OSA severity was found to have a statistically significant impact on treatment success. This study found that MADs worked best for moderate OSA. Patients with severe OSA did not have positive outcomes with a MAD, suggesting that these patients may have other anatomical features or sites of obstruction that are beyond the effects of an MAD and thus are not suitable for MAD therapy. Many previous studies have shown that MAD therapy is effective for mild-moderate OSA (Marklund et al. 2012; Lim et al. 2006), but this study did not observe high success rates in patients with mild OSA, which may have been limited by the small sample size.

Gender did not impact treatment outcomes, in contrast to other studies which suggested that women were more likely to achieve treatment success than men (Marklund et al. 2004; Vecchierini et al. 2019). The present study saw an equal proportion of males and females achieving success. However, this difference in findings may be due to a much smaller proportion of female patients to male patients in the study population.

A notable finding from this study was age having a statistically significant impact on treatment outcomes with MADs. This corroborates earlier findings that young age may be predictive of positive treatment outcomes with MAD therapy (Milano et al. 2013). This is possibly due to the higher prevalence of milder disease in the younger age group, as it has been suggested that increased age is associated with increased severity of OSA (Deng et al. 2014). Aging causes upper airway changes, predisposing to increased pharyngeal collapsibility and thus potentially limiting the effect of a MAD (Martin et al. 1997; Owens et al. 2008).

Limitations

The retrospective nature of the study is one of the primary limitations of this study.

Furthermore, due to the varied characteristics of the study cohort, results obtained from the various analyses may not be truly reflective of the effectiveness of MAD therapy for OSA. It is to be expected that treatment outcome can be very varied when baseline characteristics of patients are different, as this contributes to confounding factors. In order to improve on the results obtained, it may be prudent to standardise patient characteristics as much as possible by studying individual groups within the OSA population to draw better conclusions on the use of MAD therapy for OSA.

Moving forward, a prospective study design may have better utility, in terms of allowing control over the data that is collected, as well as being able to standardise characteristics between groups of patients.

There were also two different types of MADs that were prescribed to patients included in the study, and the different working mechanisms of each device may have been a confounding variable. Therefore, in future studies, there should be a standardisation of the device prescribed.

Final titrated advancement of MADs was also represented as linear measurements and comparisons made based on the linear measurements. Representing the final titrated advancement as a percentage of the patient's maximum protrusion would have made for more standardised comparisons, however the information for maximum protrusion was not readily available in patient's clinical records.

Finally, it may also be useful to collaborate with the other medical specialties that treat patients with OSA as

well. This can allow for better epidemiological analysis, as well as potentially increasing the number of patients who may be treated with MADs. Incorporating pre- and post-treatment sleep questionnaires could also be useful in future studies.

Conclusion

1. Successful treatment of OSA with MADs is not dependent on the final titrated advancement achieved.
2. Younger patients (≤ 50 years) benefit more from MADs than older patients (> 50 years).
3. Further prospective studies comparing the efficacy of MAD therapy between younger and older patients, controlled for OSA severity should be pursued.

Abbreviations

AASM	American Academy of Sleep Medicine
AHI	Apnea-Hypopnea Index
BMI	Body Mass Index
CGH	Changi General Hospital
CPAP	Continuous Positive Airway Pressure
LSAT	Lowest Oxygen Saturation
MAD	Mandibular Advancement Device
NDCS	National Dental Centre Singapore
OB	Overbite
OJ	Overjet
OSA	Obstructive Sleep Apnea
PSG	Polysomnography
RDI	Respiratory Disturbance Index
T90	Percentage of Time Spent in Desaturation ($SpO_2 < 90\%$)

Author contributions

All authors contributed to the study conception and design. Material preparation and data collection were performed by T.W.M.N. Data analysis was performed by S.E.S and T.W.M.N. The first draft of the manuscript was written by T.W.M.N and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethical approval

Approval and waiver of consent from the relevant IRB committees was sought prior to the commencement of this study. Due to the retrospective nature of the study, no further communication and participation was requested from patients included in the study. All data collected were de-identified and encrypted in accordance with Singapore's Personal Data Protection Act (PDPA) policy.

Consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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