

EFFICACY OF MANDIBULAR ADVANCEMENT SPLINT TO MANAGE OBSTRUCTIVE SLEEP APNEA PATIENTS: A SYSTEMATIC REVIEW

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ABSTRACT

As first-line therapy, MADs are recommended for mild-to-moderate OSA and severe OSA in those who cannot tolerate or refuse to use CPAP. Compared to CPAP, MADs provide several advantages, including simplicity, portability, and patient acceptance. PubMed, Medline, and ScienceDirect databases were used to conduct a comprehensive evaluation of the literature from 2001 to 2023. The search terms were "Mandibular advancement splint, obstructive sleep apnea, and randomized control studies." After screening, 11 studies were included, most of which indicated that a mandibular advancement splint is a good alternative for treating individuals with OSA. The reviewed studies provide significant insights into the safety and efficacy of several oral appliances and devices for the treatment of obstructive sleep apnea (OSA) and associated sleep disorders. While some studies show that mandibular advancement devices (MADs) may be beneficial in enhancing subjective measures like the perception of sleep quality and the reduction of snoring, other studies emphasize that continuous positive airway pressure (CPAP) is more effective in lowering the apnea-hypopnea index (AHI).

Key words: Mandibular advancement splint, Obstructive sleep apnea, Randomized control trials, Orthodontics.

Introduction

Nearly 1 billion people aged 30-69 suffer from obstructive sleep apnea (OSA), substantially impacting global health. The first-choice therapy for severe OSA is nasal continuous positive airway pressure (CPAP), although long-term compliance is often insufficient. Mandibular advancement devices (MADs), the most popular oral appliance controlling OSA, are another option [1]. To enhance upper airway capacity, lower upper airway closure pressure, and lessen the likelihood of the upper airway collapsing, MADs move the jaw forward, advance the tongue, and raise the retropalatal airway's lateral diameter. Patients with OSA with better passive upper airway collapsibility and architecture and more stable respiratory control (low loop gain) may respond more favorably to MAD treatment [2].

For mild-to-moderate OSA and severe OSA in individuals who cannot tolerate or won't utilize CPAP, MADs are advised as first-line treatment. MADs have many benefits over CPAP, including mobility, patient acceptability, and simplicity. Although MADs are less efficient than CPAP in reducing the number of obstructive episodes, overall effectiveness is comparable because of higher treatment

adherence. The effects of MADs and CPAP on symptoms and quality of life after a year of therapy are comparable [3].

Materials and Methods

Using PubMed, Medline, and ScienceDirect databases, a comprehensive evaluation of the literature from 2001 to 2023 was conducted. "Obstructive sleep apnea, randomized control trials, and mandibular advancement splint" were the keywords that were used. The method of selecting the articles that were searched for was shown in a PRISMA flowchart (**Figure 1**).

The following requirements must be met for inclusion:

- Case-control and randomized control studies.
- Published in English between 2001 and 2023.
- In vivo (humans).

Exclusion criteria:

- Outside of the designated period.
- Language other than English.
- In vitro.
- systematic research, meta-analyses, opinions of specialists, or narrative reviews.

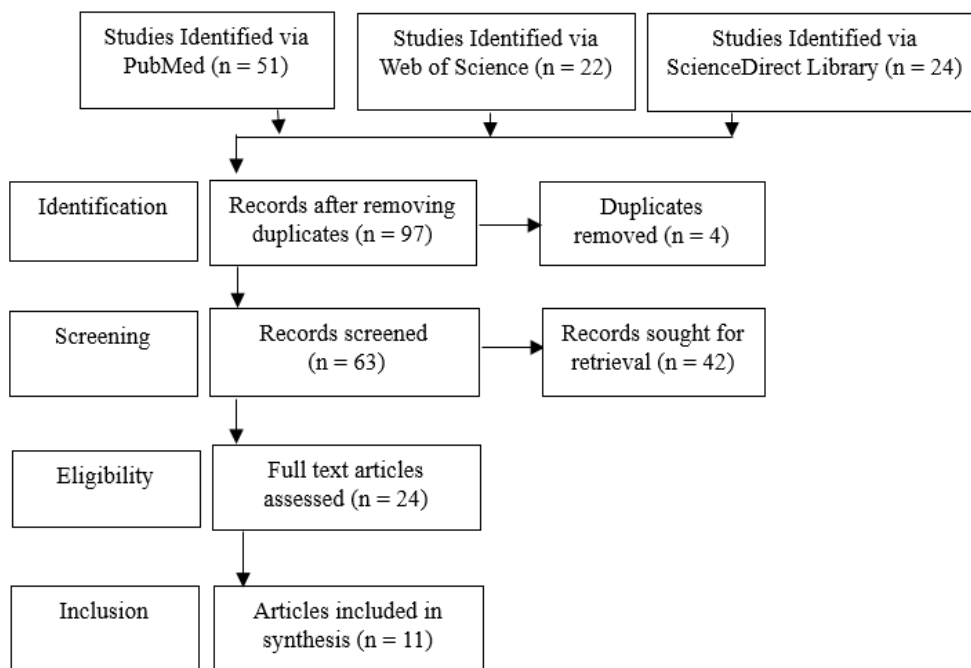


Figure 1. PRISMA Flow Diagram

Risk of bias assessment

Cochrane risk of bias assessment method was used to assess the quality of the studies included (Table 1).

Table 1. Summary of Cochrane Risk of Bias Assessment

Study	Selection Bias/Appropriate control selection/baseline characteristics similarity	Selection bias in randomization	Selection bias in allocation concealment	Performance-related bias in blinding	Reporting bias/Selective reporting of outcomes	Detection bias Blinding outcome assessors	Accounting for confounding bias
Durán-Cantolla <i>et al.</i> (2015) [4]	+	-	+	+	+	+	+
Belkhode <i>et al.</i> (2022) [5]	+	+	+	+	+	+	+
Tan <i>et al.</i> (2002) [6]	+	+	+	+	+	+	+
De Vries <i>et al.</i> (2019) [7]	+	+	-	+	+	-	+
Vecchierini <i>et al.</i> (2021) [8]	+	+	+	+	+	+	+
Mehta <i>et al.</i> (2001) [9]	+	+	+	+	+	+	-
Shete <i>et al.</i> (2017) [10]	+	+	-	+	+	+	-
Marty <i>et al.</i> (2017) [11]	+	+	+	+	+	-	+
Deane <i>et al.</i> (2009) [12]	+	-	+	+	+	+	+
Almeida <i>et al.</i> (2013) [13]	+	+	-	+	+	+	+
Lima <i>et al.</i> (2013) [14]	+	-	+	+	+	+	+

Results and Discussion

Durán-Cantolla *et al.* (2015) [4] investigated the MAD effectiveness and safety in treating mild-to-moderate OSA

and chronic roncopathy. Thirty-eight patients participated in the trial and finished it. The average patient age was 46+/- 9 years, and 79% of patients were men. The AHI was decreased by 3.4 +15.9 when the MAD was used. However,

it increased by 10.6 +26.1 when the PD was used. According to the subjective assessment of roncopathy, the MAD had improved the quality of sleep perception. However, the objective assessment of the roncopathy did not reveal any appreciable improvements (**Table 2**).

Belkhole *et al.* (2022) [5] investigated how the efficacy of customized maxillary oral appliances and MDA is assessed in patients with moderate OSA. A prospective interventional study using a randomized controlled trial will include 40 participants (sample size) having a polysomnography (PSG) report of AHI>15-30. When treating moderate OSA, a customized maxillary oral appliance works better than MAD. This custom maxillary device will be known as the "gold standard" for treating moderate OSA if the present study's hypothesis is true.

In a prospective, randomized, cross-over investigation, Tan *et al.* (2002) [6] compared the efficacy of nCPAP and MAS in treating patients with OSA. Twenty men and four women with mild to moderate OSA (AHI between 10 and 49 occurrences per hour) were enlisted in the study. The answers from the questionnaire indicated that both treatments significantly raised the respondents' overall health scores ($P<0.001$). Only nCPAP considerably decreased daytime tiredness ($P<0.001$).

The clinical and cost-effectiveness of MAD treatment and CPAP therapy for individuals with mild OSA are compared in a study by De Vries *et al.* (2019) [7]. Subsequent cost-effectiveness and cost-utility ratios (ICER/ICUR) were calculated after a year, taking into account quality-adjusted life years and the decrease of annual health incidence (AHI), using data from the EuroQol Five-Dimension Quality of Life questionnaire. In the 85 randomized patients, the AHI reduction was significantly greater with CPAP therapy than with MAD treatment after 12 months.

Vecchierini *et al.*'s research (2021) [8] examined the long-term effectiveness of MAD therapy in OSA patients who either tolerated or refused continuous positive airway pressure. A five-year follow-up's data are shown. Data was available for 172 of the 331 patients who got a tailored computer-aided design/computer-aided manufacturing bi-block MAD. There was no correlation seen between the little decline in respiratory characteristics over time and any notable changes in symptoms or fatigue. The results of multivariate analysis showed that treatment success at 3-6 months, moderate or severe OSA at baseline, and no previous use of continuous positive airway pressure were significant independent predictors of 5-year treatment success. In the course of the long-term follow-up, no new safety signals emerged. After five years, 91.3% of patients said they had used their MAD for less than six hours each night, compared to 93.3% who used it for fewer than four hours per night, four days a week. At a 5-year follow-up, 96.5% of patients expressed a desire to keep receiving MAD therapy.

Mehta *et al.*'s study (2001) [9] aimed to investigate in-depth if a novel mandibular advancement splint MAS is beneficial for patients with OSA. There were twenty-eight people in the sample who had established OSA. Following a one-week washout period, patients experienced three 1-weekly nocturnal polysomnograms. Each polysomnogram was conducted following a week of treatment with either MAS (B) or control (A) based on the sequence that was assigned at random. Comparing the AHI ($p<0.0001$), MinSaO₂ ($p<0.0001$), and arousal index ($p<0.0001$) to the control, MAS significantly improved all three metrics. AHI and MinSaO₂ were not much affected by the control plate. A CR ($n = 9$) or PR ($n = 6$) was obtained in 62.5% of patients. MAS treatment is effective for some OSA patients, especially those with moderate to severe OSA.

Shete *et al.*'s study from 2017 [10] examined whether obstructive sleep apnea patients might effectively increase upper airway size with a mandibular advancement device. Thirty-seven people with polysomnography-diagnosed obstructive sleep apnea were evaluated using the subjective Epworth sleepiness scale, oxygen saturation percentage, and cone-beam computed tomography. Based on statistical significance ($P<0.001$), the mean oxygen saturation level improved from 87.97% 4.43% to 94.89% 1.54%. There was a significant mean increase in airway capacity, measured at 2360 from 2050 mm³ ($P<0.001$).

Marty *et al.* (2017) [11] evaluated the effectiveness and compliance of a specially fitted thermoplastic MAD to treat moderate to severe OSA symptoms in this pilot trial. Epworth, polysomnography, and snoring measures were used between and 45 days after inclusion. There were 33 males and 8 women in the study group, and 35 patients finished it. Snoring, sleep quality, and the Epworth Sleepiness Scale score all fell with using the device ($p < 0.0001$). Patients used the device 6.5 nights a week, with great compliance rates. Patient complaints and side effects were modest and temporary.

The efficacy of MAS and TSD in treating OSA was assessed by Deane *et al.* (2009) [12]. Twenty-seven people—seven women and twenty men—were chosen from a sleep clinic at a tertiary hospital. The patients were given the devices in a random sequence and asked to fill out questionnaires throughout an 8-week acclimatization period (four weeks for each device). The ESS scores decreased with the mandibular advancement splint and TSD ($P = 0.001$) and ($P = 0.002$). Subjective improvements in sleep quality and snoring have been reported, with MAS responding better than TSD. The two modalities' adverse impact profiles differed, and TSD exhibited lower compliance. Ninety-one percent of the patients judged MAS to be adequate in comparison to TSD.

To determine if MAS may be a temporary treatment option for CPAP in people with OSA, Almeida *et al.* (2013) [13] carried out a clinical investigation. The study comprised 22 patients who received CPAP therapy regularly. Every patient

used the MAS for an average of four months. There were no discernible differences in SAQLI between MAS and CPAP treatment, even though ESS was decreased on MAS. There was a correlation between MAS self-reported intake and treatment efficiency ($r = 0.52$; $p < 0.05$). Seventy-five percent of the patients said that they were satisfied enough with MAS to continue using it rather than another short-term therapy.

The purpose of the study conducted by Lima *et al.* (2013) [14] was to assess the efficacy of MAS as a short-term treatment for OSAHS and snoring. Twenty OSAHS patients (mean age, 48; mean BMI, 27.07; 13 men and 7 women) were included in the sample. Before and sixty days after the mandibular advancement splint therapy, polysomnograms were obtained. Following therapy, there was a substantial reduction in the apnea-hypopnea index (AHI) ($p < 0.05$). Polysomnograms showed that sleep quality improved and snoring reduced ($p < 0.05$).

Table 2. Summary of the findings from included studies

Author's name	Objective	Patients	Follow-up period	Results
Durán-Cantolla <i>et al.</i> (2015) [4]	Effectiveness and safety of the MAD in the treatment of mild-to-moderate obstructive sleep apnea and chronic roncopathy.	38	46	the MAD had improved, and the quality of sleep perception had increased
Belkhode <i>et al.</i> (2022) [5]	The efficacy of MAD and customized maxillary oral appliances for those with mild OSA will be assessed in this study.	40		A tailored maxillary oral appliance is more effective in treating moderate OSA than MAD
Tan <i>et al.</i> (2002) [6]	To compare the efficacy of (nCPAP) and MAS in treating individuals with OSA.	20 men and four women	One year	Both treatments considerably improved overall health ratings ($P < 0.001$).
De Vries <i>et al.</i> (2019) [7]	In this study, the clinical and cost-effectiveness of CPAP therapy and MAD treatment for individuals with moderate OSA are compared.	85	five-year follow-up	AHI reduction was substantially better with CPAP than with MAD treatment.
Vecchierini <i>et al.</i> (2021) [8]	Studies investigating the long-term effectiveness of MAD therapy in individuals with OSA who either tolerated or refused continuous positive airway pressure.	172	5 years	Multivariate analysis revealed no prior use of continuous positive airway pressure, moderate or severe OSA at baseline
Mehta <i>et al.</i> (2001) [9]	To fully assess the efficacy of a novel mandibular advancement splint MAS in patients with OSA.	28	4 weeks	AHI, MinSaO ₂ , and arousal index all showed substantial improvements with MAS in comparison to the control.
Shete <i>et al.</i> (2017) [10]	To find out whether the mandibular advancement device can effectively increase upper airway size in individuals with obstructive sleep apnea.	37	8 weeks	The mean oxygen saturation level increased from 87.97% 4.43% to 94.89% 1.54%, which is statistically significant ($P = 0.001$).
Marty <i>et al.</i> (2017) [11]	For the treatment of moderate to severe OSA symptoms, the efficacy and compliance of a specifically fitted thermoplastic MAD were assessed.	35	45 days	Snoring, sleep quality, and the Epworth Sleepiness Scale score all fell with using the device.
Deane <i>et al.</i> (2009) [12]	To assess the efficacy of a mandibular advancement splint MAS and a novel TSD in the management of OSA.	27	60 days	Compared to TSD, all patients found MAS satisfactory, and 91% preferred MAS.
Almeida <i>et al.</i> (2013) [13]	To find out whether MAS may be a short-term treatment option for CPAP in people with OSA, the researchers ran a clinical trial.	22	4 months	there were no significant changes in SAQLI between MAS and CPAP therapy

Lima <i>et al.</i> (2013) [14]	The purpose of the study was to assess the efficacy of a mandibular advancement splint as a short-term treatment for obstructive sleep apnea-hypopnea syndrome and snoring.	20	According to polysomnograms, snoring decreased, and sleep quality increased.
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MAS may be an alternate therapy for individuals with OSA successfully treated with CPAP. In most patients, MAS was successful in decreasing sleep-disordered breathing. Except for one patient, all participants thought MAS was helpful and either switched from CPAP to MAS at home or only used it while traveling. Although many patients would not utilize it when traveling, this technique is highly accepted and not bothersome for patients who consistently use CPAP therapy. MAS is an effective alternative therapy and patients are more likely to utilize it while traveling than to forgo care. This is the first research that looks at the viability of using an alternative therapy while traveling, using titratable MAS on patients who comply with CPAP [15].

The main conclusion of this research is that all the parameters used to quantify respiratory events have significantly improved when compared to PD while using a mandibular advancement device. When assessed by the roommate or bed partner, the MAD has dramatically decreased the chronic roncopathy as a secondary result. When the snoring was objectively assessed, this decrease was insignificant.

Several review studies evaluating the use of the MAD in managing OSA have been published recently. These trials concluded that although this device reduces the AHI, it is less effective than CPAP therapy [16]. Researchers compared how monobloc and bibloc appliances affected AHI. For monobloc and bibloc, the mean decreasing values of AHI were 12.7 and 13.8, respectively [17].

In general, the MAS was generally accepted. For most patients, it took a second visit to get a snug fit and one modification to the mandibular protrusion to move the lower jaw forward. Twelve of the original 24 patients initially had minor jaw pain in the morning, but just one patient could not get used to the device. There were no oral health issues. Previous reports of some degree of TMJ, facial musculature, or tooth pain upon awakening have been made; these are typically minor and improve with time [18]. However, the fact that MAD treatment performed better than CPAP therapy when expenses per QALY gained were considered suggests that patients getting MAD therapy had improved health status, which may have significant long-term health (care) implications. Individuals with mild OSA should be counseled to begin using CPAP. MAD treatment is presently the next-best choice once CPAP fails. A MAD may also be a good alternative for patients who reject CPAP treatment since it lowers AHI, eliminates excessive daytime drowsiness, and enhances health-related quality of life. In our trial, the dropout and discontinuation rates were more significant than anticipated. Eighteen patients (21%), 10 from MAD to CPAP and 8 from CPAP to MAD, converted

to the alternative treatment. In contrast to the two patients randomly assigned to CPAP, five patients randomly assigned to MAD required further PSG assessments [19].

These results demonstrate that in patients with moderate to severe OSA who were CPAP intolerant, noncompliant, or rejected, MAD therapy remained beneficial throughout a 5-year follow-up. AHI reduction effectiveness did deteriorate with time. However, most of this impact attenuation was seen by the end of the second year of follow-up, in keeping with previous research. While drowsiness and symptoms (such as tiredness and morning headaches) were under reasonable control following long-term MAD treatment, sleep quality and state upon awakening showed significant and consistent improvements. This is despite a minor deterioration of respiratory metrics with time [8].

Other studies found that these included teeth grinding, salivation, dry mouth, and jaw discomfort. Because of the potential for long-term negative effects from the MAS, patients beginning long-term treatment are encouraged to have close patient monitoring. The self-report indicated that there was a high short-term compliance rate with the MAS. This compares well with rates seen in earlier studies using oral appliances. While it would be great to evaluate compliance objectively, the required technology is currently being developed [20, 21].

The current research, the first to compare TSD with MAS, shows that TSD can improve AHI in a smaller proportion of patients than MAS. One advantage of our research is that the treatment result was based on exact criteria, as our group has previously documented. Compared to MAS, TSD had a lower proportion of patients with full and partial responses, albeit this difference did not nearly approach statistical significance. Additionally, MAS and TSD substantially reduced the arousal index, consistent with other research on MAS and TSD [22].

Rather than the maximum acceptable advancement limit, Vandalism occurs at around 75% of the maximum jaw protrusion. This was due to the altered MAS design so that the titration screws were removed to conduct MRI scans for a different investigation.. This research had a significant flaw in that patients did not move their mandibles any farther when they adapted to MAS, which may have hindered some patients' recovery from OSA. The fact that studies utilizing this MAS design have revealed a lower complete response rate than before does support this theory. Despite this restriction, the MAS has substantial therapeutic value [23].

The TSD appliance delivered a fixed amount of tongue protrusion and suction, which the patient regulated. It was

noted that patients varied in how far their tongues extended inside the apparatus and how hard they squeezed the bulb. The usage of TSD could not be standardized; instead, each user had to choose their level of comfort. The amount of tongue protrusion and potential reaction to TSD may have been reduced due to the discomfort caused by the forward tongue posture and straining of the related soft tissues, especially the lingual frenum. Since the manufacturer intended for the device to be marketed over the counter for unsupervised consumption, TSD is used in this manner since that is how people use it. Researchers claim that to ensure patient safety and optimal outcomes, clinical surveillance is required [24].

Prior research has shown that individuals with OSA have significant impairments in neurocognitive function, quality of life, and daily sleepiness. These impairments may be managed with MAS and CPAP treatment. This data is critical for assessing how the therapy affects quality of life and drowsiness. Subjective drowsiness and quality of life did not significantly alter when randomized control trials compared CPAP to MAS. In terms of daytime sleepiness, we made an important and fascinating finding with our study. When compared to patients on CPAP, those using MAS had a considerably lower ESS score. The benefits of sleepiness were further cemented over time since patients were less likely to discontinue medication periodically [25, 26].

Extensive research has been done on how CPAP compliance affects fatigue. Four hours a night on seventy percent of the night is the traditional definition of high CPAP compliance. Nonetheless, researchers found a treatment dose effect for subjective sleepiness, demonstrating that a greater number of patients resumed their regular functioning with extended use of CPAP. Based on our research, combination therapy could be better than CPAP alone in terms of subjective sleepiness outcomes, and it might even be comparable to utilizing CPAP for longer amounts of time [24, 27, 28].

Conclusion

In conclusion, the studies reviewed provide valuable insights into the effectiveness and safety of various oral appliances and devices in managing obstructive sleep apnea (OSA) and related sleep disorders. While some studies demonstrate the potential benefits of mandibular advancement devices (MADs) in improving subjective measures such as snoring reduction and sleep quality perception, others highlight the superiority of continuous positive airway pressure (CPAP) in terms of reducing the apnea-hypopnea index (AHI). The choice between MADs and CPAP may depend on individual patient preferences and OSA severity. Moreover, the long-term efficacy of MAD treatment appears promising, especially for patients intolerant of CPAP.

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