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**Review Article**

# Effectiveness of Mandibular Advancement Splint in Treating Obstructive Sleep Apnea: A Systematic Review

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## ABSTRACT

Mandibular advancement devices (MADs) are considered a primary treatment option for people with mild-to-moderate obstructive sleep apnea (OSA) and for those with severe OSA who are unable or unwilling to use continuous positive airway pressure (CPAP). Compared to CPAP, mandibular advancement devices offer advantages such as ease of use, portability, and higher patient compliance. The present study aimed to review the effectiveness of mandibular advancement splint in the treatment of obstructive sleep apnea. A comprehensive literature review covering the years 2001 to 2023 was conducted using the Medline, PubMed, and ScienceDirect databases. The search used the keywords "mandibular advancement splint, obstructive sleep apnea, and randomized control studies." After applying the inclusion criteria, 11 studies were selected, the majority of which supported the use of a mandibular advancement splint as an effective treatment for OSA. The research analyzed provides valuable information regarding the safety and effectiveness of various oral appliances in the management of obstructive sleep apnea and related sleep disorders. While some studies show that MADs improve subjective outcomes, such as perceived sleep quality and snoring reduction, others indicate that CPAP remains superior in significantly reducing the apnea-hypopnea index (AHI).

**Keywords:** Orthodontics, Obstructive sleep apnea, Mandibular advancement splint, Randomized control trials

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## Introduction

Obstructive sleep apnea (OSA) affects nearly one billion people aged 30 to 69 years, creating a substantial global health burden. The primary treatment for severe obstructive sleep apnea is nasal continuous positive airway pressure (CPAP); however, long-term adherence is often inadequate. Mandibular advancement devices (MADs) are the most commonly used oral appliances for managing OSA and serve as an alternative treatment option [1]. These devices function by repositioning the lower jaw forward, advancing the tongue, and widening the lateral dimension of the retropalatal airway, which helps increase upper airway capacity, lower upper airway closure pressure, and reduce the likelihood of airway collapse. Patients with favorable upper airway anatomy improved passive collapsibility, and more stable respiratory control (low loop gain) tend to show better responses to MAD therapy [2].

MADs are considered the first-line treatment for mild-to-moderate OSA and for severe cases in individuals who are unable or unwilling to use CPAP. Compared to CPAP, MADs offer advantages such as greater

portability, ease of use, and better patient compliance. Although CPAP is more effective in reducing the frequency of obstructive episodes, the overall therapeutic success of MADs is comparable due to higher adherence rates. After one year of treatment, both approaches demonstrate similar effects on symptom improvement and quality of life [3].

The present study aimed to review the effectiveness of mandibular advancement splint in the treatment of obstructive sleep apnea.

## Materials and Methods

A thorough review of the literature published between 2001 and 2023 was carried out using the Medline, PubMed, and ScienceDirect databases. The search was conducted with the keywords "randomized control trials, obstructive sleep apnea, and mandibular advancement splint." The process for selecting relevant studies was illustrated using a PRISMA flowchart **(Figure 1)**.

Studies had to fulfill specific criteria to be included in the review:

- Case-control or randomized control trials.
- Published in English between 2001 and 2023.
- Conducted on human subjects (in vivo).

The exclusion criteria were as follows:

- Studies published outside the specified timeframe.
- Articles are written in languages other than English.
- Research conducted in vitro.
- Systematic reviews, meta-analyses, expert opinions, or narrative reviews.

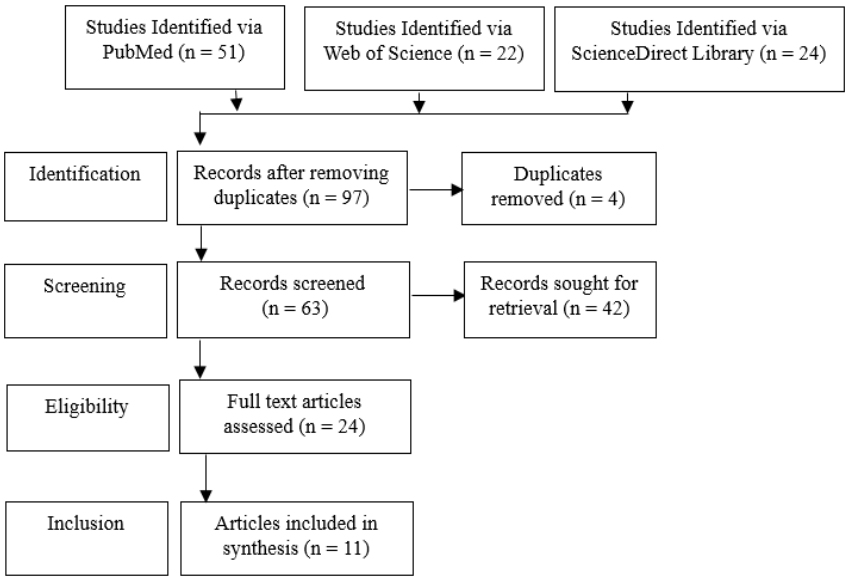


**Figure 1.** PRISMA flow diagram

*Risk of bias assessment*

The quality of the included studies was evaluated using the Cochrane risk of bias assessment method **(Table 1)**.

**Table 1.** Summary of Cochrane risk of bias assessment

| Study | Selection Bias/Appropriate control selection/baseline | 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 *et al*. [4] | + | - | + | + | + | + | + |
| Belkhode *et al*. [5] | + | + | + | + | + | + | + |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Tan *et al*. [6] | + | + | + | + | + | + | + |
| De Vries *et al*. [7] | + | + | - | + | + | - | + |
| Vecchierini *et al.* [8] | + | + | + | + | + | + | + |
| Mehta *et al*. [9] | + | + | + | + | + | + | - |
| Shete *et al*. [10] | + | + | - | + | + | + | - |
| Marty *et al*. [11] | + | + | + | + | + | - | + |
| Deane *et al.* [12] | + | - | + | + | + | + | + |
| Almeida *et al*. [13] | + | + | - | + | + | + | + |
| Lima *et al.* [14] | + | - | + | + | + | + | + |

**Results and Discussion**

Durán-Cantolla *et al.* [4] evaluated the effectiveness and safety of MAD in managing mild-to-moderate OSA and chronic roncopathy. The study included 38 participants who completed the trial, with an average age of 46 ± 9 years, of whom 79% were male. The use of MAD resulted in a reduction of the AHI by 3.4 ± 15.9, whereas the PD led to an increase of 10.6 ± 26.1. Subjective assessments indicated that MAD improved sleep quality perception, but objective evaluations of roncopathy did not show significant improvements **(Table 2)**.

Belkhode *et al.* [5] examined the assessment of treatment efficacy between customized maxillary oral appliances and MAD in individuals with moderate OSA. This prospective interventional study, structured as a randomized controlled trial, is planned to include 40 participants with a polysomnography (PSG) report showing an AHI of 15–30. Findings suggest that a customized maxillary oral appliance is more effective than MAD for managing moderate OSA. If the study's hypothesis is confirmed, this custom device could be established as the "gold standard" for treating moderate OSA.

In a randomized, prospective, cross-over study, Tan *et al.* [6] evaluated the effectiveness of nCPAP and MAS in treating patients with OSA. The study included 20 male and four female participants with mild to moderate OSA (AHI between ten and 49 events per hour). Questionnaire responses indicated that both treatments led to significant improvements in the participants' overall health ($P<0.001$). However, nCPAP was the only treatment that significantly reduced daytime fatigue ($P < 0.001$).

De Vries *et al.* [7] conducted a study comparing the clinical outcomes and cost-effectiveness of MADs and CPAP therapy for individuals with mild OSA. After one year, the researchers calculated cost-effectiveness and cost-utility ratios (ICER/ICUR), incorporating quality-adjusted life years and reductions in AHI using data from the EuroQol Five-Dimension Quality of Life questionnaire. Among 85 randomized patients, CPAP therapy produced a more significant reduction in AHI compared to MAD treatment over the 12 months.

Vecchierini *et al.* [8] investigated the long-term effectiveness of MAD therapy in patients with OSA who either accepted or rejected continuous positive airway pressure (CPAP). The study followed 172 out of 331 participants who received a custom-made computer-aided design/computer-aided manufacturing bi-block MAD over five years. The results revealed that a slight decline in respiratory parameters over time did not correspond with significant changes in symptoms or fatigue. The multivariate analysis identified that successful treatment within 3-6 months, baseline moderate to severe OSA, and no previous CPAP usage were significant predictors of sustained success after five years. Over the long-term follow-up, no new safety concerns were identified. At the five-year mark, 91.3% of patients reported using their MAD for fewer than 6 hours each night, compared to 93.3% who wore it for less than 4 hours per night, 4 days a week. Additionally, 96.5% expressed a continued preference for MAD therapy after five years.

In Mehta *et al.*'s [9] study, the effectiveness of a novel mandibular advancement splint (MAS) for treating OSA was explored. The sample consisted of 28 patients diagnosed with OSA. After a one-week washout period, participants underwent three separate one-week nocturnal polysomnography sessions, each following treatment with either MAS (B) or a control (A) based on random assignment. The results indicated that MAS significantly improved AHI ($P<0.0001$), MinSaO2 ($P<0.0001$), and the arousal index ($P< 0.0001$) compared to the control. The control device had minimal impact on AHI and MinSaO2. Among the participants, 62.5% showed a complete (n= 9) or partial (n=6) response to treatment. This study concluded that MAS is an effective treatment option for OSA, particularly for those with moderate to severe cases.

In their 2017 study, Shete *et al.* [10] investigated whether mandibular advancement devices (MADs) could effectively enlarge the upper airway in patients with obstructive sleep apnea (OSA). Thirty-seven individuals diagnosed with OSA through polysomnography were assessed using the Epworth Sleepiness Scale, oxygen saturation levels, and cone-beam computed tomography. The results showed statistically significant improvements (P<0.001), with the average oxygen saturation increasing from 87.97% ± 4.43% to 94.89% ± 1.54%. Additionally, airway capacity was significantly enhanced, rising from 2050 $mm^3$ to 2360 $mm^3$ (P< 0.001).

Marty *et al.* [11] conducted a pilot study to assess the efficacy and adherence of a custom-fitted thermoplastic MAD in managing moderate to severe OSA. The study involved 33 men and 8 women, with 35 patients completing the trial. The effectiveness of the device was evaluated using the Epworth Sleepiness Scale, polysomnography, and snoring measurements, both at baseline and 45 days post-treatment. Results indicated significant improvements (P<0.0001) in snoring, sleep quality, and Epworth Sleepiness Scale scores. Patients reported using the device 6.5 nights per week, demonstrating high compliance. Side effects were minor and temporary, and patient feedback was generally positive.

Deane *et al.* [12] evaluated the effectiveness of mandibular advancement splints (MAS) and tongue stabilizing devices (TSD) in treating obstructive sleep apnea (OSA). A total of 27 participants (7 women and 20 men) were selected from a tertiary hospital sleep clinic. The devices were randomly assigned to the patients, who then used each for four weeks, completing questionnaires throughout the 8-week acclimatization period. Both MAS and TSD led to a significant reduction in Epworth Sleepiness Scale (ESS) scores (P = 0.001 for MAS and P = 0.002 for TSD). Improvements in sleep quality and snoring were reported, with MAS yielding better results than TSD. The 2 devices differed in terms of adverse effects, with TSD showing lower compliance. 91% of participants preferred MAS over TSD.

Almeida *et al.* [13] explored whether MAS could serve as a temporary alternative to CPAP for OSA patients. The study included 22 patients who were regular CPAP users, each using MAS for an average of four months. No significant differences were found in the SAQLI between MAS and CPAP treatments, although the ESS score was lower with MAS. A positive correlation was observed between MAS usage and treatment effectiveness (r=0.52; P<0.05). 75% of patients reported being sufficiently satisfied with MAS, opting to continue using it as a short-term therapy instead of CPAP.

Lima *et al.* [14] aimed to evaluate the effectiveness of mandibular advancement splint (MAS) therapy as a short-term solution for obstructive sleep apnea-hypopnea syndrome (OSAHS) and snoring. The study involved 20 patients (mean age 48 years, mean BMI 27.07; 13 men and 7 women) diagnosed with OSAHS. Polysomnographic assessments were conducted before and 60 days after the application of MAS therapy. Results indicated a significant decrease in the apnea-hypopnea index (AHI) following the treatment (P < 0.05). Additionally, improvements in sleep quality and a reduction in snoring were observed in the polysomnography results (P < 0.05).



**Table 2.** Summary of the findings from included studies

| Author's name | Objective | Patients | Follow-up period Period | Results |
|---|---|---|---|---|
| Durán-Cantolla *et al.* [4] | The study evaluated the effectiveness and safety of mandibular advancement devices (MAD) in treating individuals with mild-to-moderate obstructive sleep apnea (OSA) and persistent snoring (chronic roncopathy). The research aimed to determine how well MADs perform in managing these conditions. | 38 | 46 | The MAD led to improvements, enhancing the perception of sleep quality. |
| Belkhode *et al.* [5] | This study will evaluate the effectiveness of mandibular advancement devices (MAD) and personalized maxillary oral appliances in individuals with mild obstructive sleep apnea (OSA). | 40 | | A custom-fitted maxillary oral appliance outperforms MAD in the treatment of moderate OSA. |
| Tan *et al.* [6] | This study aims to compare the effectiveness of nasal continuous positive airway pressure (nCPAP) and mandibular advancement splints | 20 men and 4 women | 1 year | Both therapies significantly enhanced the overall health scores (P < 0.001). |

| | | | | |
|---|---|---|---|---|
| | (MAS) in the treatment of individuals with obstructive sleep apnea (OSA). | | | |
| De Vries *et al*. [7] | This research compares the clinical outcomes and cost-effectiveness of CPAP therapy and MAD treatment for patients with moderate obstructive sleep apnea (OSA). | 85 | 5-year follow-up | The reduction in AHI was notably more significant with CPAP compared to MAD treatment. |
| Vecchierini *et al*. [8] | Research examining the long-term effectiveness of MAD therapy in patients with OSA who either accepted or declined continuous positive airway pressure (CPAP) treatment. | 172 | 5 years | Multivariate analysis indicated that the absence of prior continuous positive airway pressure use, along with moderate or severe OSA at baseline, were key factors. |
| Mehta *et al*. [9] | To thoroughly evaluate the effectiveness of a new mandibular advancement splint (MAS) in treating patients with OSA. | 28 | 4 weeks | Significant improvements were observed in AHI, MinSaO2, and the arousal index with MAS when compared to the control group. |
| Shete *et al*. [10] | To determine if the mandibular advancement device can successfully enhance the size of the upper airway in individuals with obstructive sleep apnea. | 37 | 8 weeks | The average oxygen saturation level rose from 87.97% ± 4.43% to 94.89% ± 1.54%, a statistically significant change ($P < 0.001$). |
| Marty *et al*. [11] | The effectiveness and adherence to a specially designed thermoplastic MAD in managing moderate to severe OSA symptoms were evaluated. | 35 | 45 days | The use of the device led to reductions in snoring, improved sleep quality, and a lower score on the Epworth Sleepiness Scale. |
| Deane *et al*. [12] | The effectiveness of a mandibular advancement splint (MAS) and a new TSD in treating OSA was evaluated. | 27 | 6 days | All participants rated MAS as satisfactory, with 91% expressing a preference for it over TSD. |
| Almeida *et al*. [13] | A clinical trial was conducted to determine if MAS could serve as a temporary alternative to CPAP for individuals with OSA. | 22 | 4 months | No notable differences in SAQLI were observed between MAS and CPAP therapy. |
| Lima *et al*. [14] | The study aimed to evaluate the effectiveness of a mandibular advancement splint as a temporary solution for obstructive sleep apnea-hypopnea syndrome and snoring. | 20 | | Polysomnography results showed a reduction in snoring and an improvement in sleep quality. |



MAS could serve as an alternative treatment for individuals with OSA who are effectively managed with CPAP. In most cases, MAS was successful in reducing sleep-disordered breathing. All participants, except one, found MAS beneficial and either replaced CPAP with MAS for home use or opted for it during travel. Although some patients would not consider using it while traveling, the technique is well-received and minimally disruptive for those who regularly use CPAP. MAS provides an effective alternative, and patients are more inclined to use it during travel rather than skip treatment. This study is the first to explore the potential of using titratable MAS as an alternative therapy for CPAP users during travel [15].

The primary finding of the study is that all measures used to assess respiratory events showed significant improvement with the use of a mandibular advancement device compared to PD. When evaluated

by a bed partner or roommate, MAD notably reduced chronic roncopathy as a secondary benefit. However, when snoring was measured objectively, the reduction was not significant.

Recent review studies have investigated the role of mandibular advancement devices (MAD) in treating obstructive sleep apnea (OSA), with findings indicating that while the device helps reduce the AHI, it is not as effective as CPAP therapy [16]. Research comparing the effects of monobloc and bibloc appliances on AHI showed reductions of 12.7 and 13.8, respectively [17].

In general, patients accepted the use of the mandibular advancement splint (MAS). Most required a second visit to achieve a good fit and a minor adjustment in mandibular protrusion to push the lower jaw forward. Out of 24 initial patients, 12 experienced some jaw discomfort in the morning, though only one patient was unable to adapt to the device. There were no significant oral health concerns. While some patients reported mild TMJ discomfort, muscle soreness, or tooth pain upon waking in previous studies, these symptoms usually improved over time [18]. Interestingly, the MAD treatment showed a better cost-effectiveness ratio compared to CPAP when considering the cost per QALY gained, suggesting that patients using MAD experienced better health outcomes, which could have long-term benefits for healthcare. CPAP is recommended for individuals with mild OSA, but MAD presents itself as the next viable option if CPAP is ineffective. It also serves as a suitable alternative for patients who refuse CPAP, as it reduces AHI, alleviates daytime sleepiness, and improves overall quality of life. In this trial, the dropout rate exceeded expectations, with 18 patients (21%) transitioning between therapies—ten from MAD to CPAP and eight from CPAP to MAD. Two patients from the CPAP group and five from the MAD group needed follow-up polysomnography assessments [19].

The findings from this study suggest that for patients with moderate to severe OSA who are intolerant of, noncompliant with, or refuse CPAP, MAD therapy remained effective over 5 years. While the reduction in AHI became less pronounced over time, the greatest decline in effectiveness occurred by the end of the second year, aligning with previous studies. Despite some attenuation in respiratory improvements, long-term MAD therapy helped manage daytime sleepiness and symptoms like fatigue and morning headaches, with sleep quality and morning wakefulness showing substantial and consistent improvements, as shown in earlier research [8].

However, other studies identified potential side effects such as teeth grinding, dry mouth, excessive salivation, and jaw discomfort. Due to the possibility of long-term adverse effects from the MAS, it is recommended that patients undergoing extended treatment be closely monitored. Reports indicated high short-term compliance with the MAS, which aligns with findings from previous studies on oral appliance use. While objective compliance measurements would be ideal, the necessary technology is still under development [20, 21].

The current study, being the first to directly compare TSD with MAS, demonstrates that while TSD can reduce AHI, it shows effectiveness in a smaller proportion of patients compared to MAS. A notable strength of our study is that we evaluated treatment outcomes using precise criteria, as previously outlined by our research team. Although the proportion of patients with full or partial responses was lower with TSD than with MAS, this difference was not statistically significant. Both MAS and TSD notably reduced the arousal index, consistent with prior findings in studies involving these treatments [22].

In our research, discomfort appeared around 75% of the maximum jaw advancement, which was less than the anticipated maximum protrusion. This change in the MAS design, which involved removing the titration screws for MRI procedures in a different study, could have contributed to the observed effect. A significant limitation of this study was that patients didn't continue to increase their jaw protrusion after initial adaptation to MAS, possibly hindering optimal OSA treatment. This aligns with the lower complete response rate seen in studies using this specific MAS design. Despite this constraint, the MAS still provides valuable therapeutic benefits [23].

The TSD device provided a predetermined level of tongue protrusion and suction, which patients adjusted according to their preferences. It was observed that individuals differed in how much their tongues extended within the device and how forcefully they pressed the bulb. Standardization of TSD use was not possible; instead, each user had to adjust it to their comfort level. The extent of tongue protrusion and the body’s response to the TSD might have been limited due to discomfort caused by the forward tongue positioning and the strain on the surrounding soft tissues, particularly the lingual frenum. Since the manufacturer designed the device for over-the-counter use without professional supervision, it is typically employed in this manner. However, researchers emphasize that clinical oversight is essential to ensure patient safety and achieve the best results [24].

Previous studies have demonstrated that individuals with OSA experience considerable deficits in neurocognitive function, quality of life, and daytime sleepiness. These issues can be addressed with treatments like MAS and CPAP. This information is crucial for evaluating the impact of therapy on quality of life and sleepiness. In randomized control trials comparing CPAP and MAS, subjective assessments of sleepiness and quality of life showed no significant differences. However, our study revealed an intriguing and important discovery regarding daytime sleepiness. Patients using MAS had a significantly lower ESS score compared to those on CPAP. The improvements in sleepiness were sustained over time, with patients on MAS being less likely to stop treatment periodically [25, 26].

A substantial body of research has explored the relationship between CPAP adherence and fatigue levels. High CPAP compliance is traditionally defined as four hours per night on 70% of nights. However, studies have shown a dose-response effect on subjective sleepiness, where more consistent CPAP use led to improved daily functioning. Our findings suggest that combination therapy may offer better outcomes for subjective sleepiness compared to CPAP alone, potentially achieving similar results to longer CPAP usage [24, 27, 28].

## Conclusion

In summary, the reviewed studies offer important perspectives on the effectiveness and safety of various oral devices and appliances for managing obstructive sleep apnea (OSA) and associated sleep disorders. Some studies highlight the potential benefits of mandibular advancement devices (MADs) in improving subjective outcomes, such as reducing snoring and enhancing sleep quality perception, while others emphasize the greater effectiveness of continuous positive airway pressure (CPAP) in lowering the apnea-hypopnea index (AHI). The decision between MADs and CPAP often hinges on patient preferences and the severity of OSA. Additionally, the long-term effectiveness of MAD therapy is encouraging, particularly for individuals who are intolerant to CPAP.

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**Ethics Statement:** None

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