

The Efficacy of Various Orthodontic Appliances in the Treatment of Obstructive Sleep Apnea

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Abstract

Objective. The goal of this review was to determine the effectiveness of different types of monobloc and bibloc mandibular advancement device (MAD) devices in the treatment of all forms of obstructive sleep apnea (OSA), by reviewing the available literature. **Methods.** A systematic literature search was performed in PubMed, ResearchGate, NCBI and Google Scholar databases. The search included articles in English, published in the inclusive time period from 2000 to 2024. **Results.** A total of 13 studies were analyzed that directly compared the effectiveness of monobloc and bibloc devices. The studies were published in the period from 2000 to 2024, and included crossover and parallel randomized controlled trials, as well as cross and parallel cohort studies. Out of the 13 studies, four were classified as RCT parallel studies, six were RCT crossover studies, two cohort parallel studies, and one cohort crossover study. The duration of the studies was variable, ranging from four weeks to one year, with six studies having a so-called “washout period” between the use of monobloc and bibloc MAD devices. **Conclusion.** Both monobloc and bibloc devices show significant success rates in the treatment of mild to moderate OSA.

Key Words: Obstructive Sleep Apnea ■ Mandibular Advancement Device ■ Monobloc Oral Appliance ■ Bibloc Oral Appliance.

Introduction

Obstructive sleep apnea (OSA) is a common, chronic disorder characterized by successive episodes of upper airway collapse with an increase in the airflow resistance, which leads to a decrease (hypopnea) or complete cessation of airflow (apnea) during sleep. The prevalence of the disorder in the general population varies from 3 to 7% in adult males, and 2% to 5% in adult females (1). Breathing cessation causes acute adverse effects, such as desaturation of oxyhemoglobin, vomiting, high blood pressure and heart rate, increased sympathetic activity, sleep fragmentation, etc. (2).

Risk factors for the development of obstructive sleep apnea primarily include: older age, male gender, obesity, and craniofacial anomalies, as well as anomalies of the upper respiratory pathways. The prevalence of sleep related problems,

including obstructive sleep apnea, increases with age. The prevalence increases steadily until the age of 60, after which it reaches a plateau. Possible reasons for the increase in the prevalence of OSA during aging are structural changes in the parapharyngeal area, such as increased deposition of fatty tissue and lengthening of the soft palate (1). Treatment of patients with obstructive sleep apnea requires a multidisciplinary approach. Therapeutic options include continuous positive pressure therapy (CPAP), followed by weight loss, surgical interventions to the upper respiratory pathways, and intraoral orthodontic devices (3).

Intraoral devices, as a therapeutic option for OSA, are recommended for the treatment of mild and moderate OSA, as well as severe OSA in patients who do not tolerate CPAP therapy, or when CPAP therapy has proven to be unsuccessful (4). Intraoral devices can be divided into three groups:

tongue retainers (TRD); soft palate lifters (SPL) and devices for mandibular protrusion – a mandibular advancement device (MAD). SPL devices have been completely abandoned for use today, while the remaining two groups of devices are still in use. TRD device design constitutes an extraoral flexible protruding part that leads to gentle suction of the tongue under pressure, pulling the tongue forward and subsequently opening the airway during sleep (5).

The most commonly used intraoral devices are mandibular advancement devices (MAD). MADs consist of splints which are placed on the upper and lower teeth, with the aim of protruding the mandible and keeping it in a protruded position (3). This leads to the expansion of the upper airways, by lateral movement of parapharyngeal fatty deposits, as well as the forward positioning of the base of the tongue. Additionally, there are also changes in muscle activity, with the focus on relaxation of the genioglossus muscle, and activation of the masseter and submental muscles. By their action, MAD devices reduce the collapsibility of the upper respiratory pathways, resulting in a reduction in apnea episodes during sleep (4). Current research on the effectiveness of different oral devices for the treatment of OSA has conflicting opinions (6).

The goal of this review was to determine the effectiveness of different types of monobloc and bibloc MAD devices in the treatment of all forms of OSA, by reviewing the available literature.

Materials and Methods

Information Sources

For the purpose of this review, a systematic literature search was performed in PubMed, ResearchGate, NCBI and Google Scholar databases. The search was conducted using MeSH search strategies and using combined texts: obstructive sleep apnea and oral appliance, monobloc oral appliance, bibloc oral appliance, mandibular advancement device, fixed mandibular advancement device, custom-made mandibular advancement device, monobloc mandibular advancement

device, and bibloc mandibular advancement devices. The search included articles in English, published in the inclusive time period from 2000 to 2024.

Selection Process

The literature review included two steps. In the first step, a literature search was performed with an overview of the available abstracts. The second step included collection of the full text of all studies that fully met the inclusion criteria. Ultimately, this review paper included a total of 13 studies directly comparing the impact of both monobloc and bibloc types of devices.

Eligibility Criteria

The studies include randomized controlled studies, nonrandomized prospective studies, clinical studies with organized data collection, and cohort studies. The inclusion criteria were: studies that evaluated the performance of two or more types of devices that had to be classified as monobloc or bibloc type; a definitive diagnosis of OSA established on the basis of polysomnography studies with an apnea-hypopnea index (AHI) value greater than five; the outcome of therapy with a MAD device assessed on the basis of a controlled polysomnographic study, and the ESS score (Epworth scale drowsiness) or SAQL score (Sleep Apnea Quality of Life). Exclusion criteria were non-English articles, case reports and review articles, different diagnostic criteria for OSA, and articles with insufficient data for analysis.

Presentation of Data

The recorded data include: the name of the authors and date of the publication of the research; study design, device design, demographic data; BMI values; the number of patients in the study; mandibular protrusion value and vertical dimensions; the degree of OSA; success of the therapy; unwanted effects of the device; acceptance of therapy; and the economic profitability of the type of

device. The success criterion is defined by AASDM (American Academy of Dental Sleep Medicine) as a reduction in the AHI value by 50% from the basal level, or a reduction in the degree of OSA.

Results

A total of 13 studies were analyzed that directly compared the effectiveness of monobloc and bibloc devices. The studies were published in the period from 2000 to 2022, and included crossover and parallel randomized controlled trials, as well as cross and parallel cohort studies. Out of the 13 studies, four were classified as RCT parallel studies, six were RCT crossover studies, two cohort

parallel studies, and one was a cohort crossover study. The duration of the studies was variable, ranging from four weeks to one year, with six studies having a so-called “washout period” between the use of monobloc and bibloc MAD devices. That period implies a time period during which the subject does not use any type of MAD device, and it was used in the studies where one group of subjects used both types of devices (Table 1).

Four studies showed the equal effectiveness of both types of MAD devices by measuring the basal and control values of the AHI index (Table 2). Six studies reported the greater efficacy of monobloc MAD devices (Table 3). Three studies showed the better efficacy of the bibloc MAD device (Table 4).

Table 1. Comparison of the Studies Analyzed by Type and Duration, and the Degree of OSA*

| Researchers | Year of publication | Type of study | Duration of study | Degree of OSA* |
|-----------------------|---------------------|------------------------------------|--|--------------------------|
| Isacsson et al. (7) | 2017 | Cohort parallel study | 1 year | N/A [†] |
| Isacsson et al. (8) | 2019 | RCT [‡] parallel study | 6 weeks | Low to moderate |
| Yanamoto et al. (9) | 2021 | RCT [‡] crossover study | 4 weeks + 2 week “washout period” | Low to moderate |
| Al-Dharrab (10) | 2017 | RCT [‡] , crossover study | 4 months + 2 week “washout period” | Low to moderate |
| Bloch et al. (11) | 2000 | RCT [‡] , crossover study | 156 days of adaptation, 1 week of use per device | N/A [†] |
| Mantia et al. (12) | 2018 | RCT [‡] , crossover study | 10 weeks + 2 week “washout period” | N/A [†] |
| Umemoto et al. (13) | 2019 | RCT [‡] parallel study | 3 months | N/A [†] |
| Lee WH et al. (14) | 2013 | Cohort parallel study | 3 months | Low, moderate and severe |
| Geoghegan et al. (15) | 2015 | RCT [‡] crossover study | 12 weeks (10 weeks wear + 2 weeks acclimatization) + 2 week “washout period” | N/A [†] |
| Zhou et al. (16) | 2012 | RCT [‡] crossover study | 3 months + 2 week “washout period” | Low to moderate |
| Sari et al. (17) | 2011 | RCT [‡] parallel study | 1 month | N/A [†] |
| Tegelberg et al. (18) | 2020 | RCT [‡] parallel study | 1 year | N/A [†] |
| Lettieri et al. (19) | 2011 | Cohort crossover study | N/A | Low, moderate and severe |

*Obstructive sleep apnea; [†]Randomized control trial; [‡]Not applicable (not stated in the study).

Table 2. Basal and Control Values of AHI[†], with the Same Efficacy of Both Types of MAD[‡]

| Study | Monobloc | Monobloc | Bibloc | Bibloc |
|---------------------------------------|------------------------|--------------------------|------------------------|--------------------------|
| | Basal AHI [†] | Control AHI [†] | Basal AHI [†] | Control AHI [†] |
| Isacsson et al. (7). (\bar{x}) | 23 | 12.7 | 22 | 13.8 |
| Isacsson et al. (8). (\bar{x}) | 25.2 | 12.5 | 26.8 | 12.3 |
| Yanamoto et al. (9). (\bar{x}) | 12.5 | 5.0 | 12.5 | 5.8 |
| Al-Dharrab (10). ($\bar{x} \pm SD$) | 25.8 \pm 4.87 | 5.95 \pm 2.54 | 25.8 \pm 4.87 | 6.02 \pm 2.59 |

[†]Apnea-hypopnea index; [‡]Mandibular advancement device.

Table 3. Basal and Control Values of AHI* with Higher Efficacy of Monobloc MAD†

| Study | Monobloc | Monobloc | Bibloc | Bibloc |
|--|------------|--------------|------------|--------------|
| | Basal AHI* | Control AHI* | Basal AHI* | Control AHI* |
| Bloch et al. (11). ($\bar{x}\pm SD$) | 22.6±3.1 | 7.9±1.6 | 22.6±3.1 | 8.7±1.5 |
| Mantia IL et al. (12). ($\bar{x}\pm SD$) | 28.5±5.7 | 8.5±3.2 | 28.5±5.7 | 14.2±4.5 |
| Umemoto et al. (13). ($\bar{x}\pm SD$) | 21.4±5.7 | 14.7±9.4 | 20.6±11.5 | 11.2±9.7 |
| Lee WH et al. (14). ($\bar{x}\pm SD$) | 34.7±14.7 | 12.5±11.1 | 30.9±15.3 | 15.3±12.6 |
| Geoghegan et al. (15). (\bar{x}) | 21.1 | 5.9 | 21.1 | 15.2 |
| Zhou et al. (16). ($\bar{x}\pm SD$) | 26.38±4.13 | 6.58±2.28 | 26.38±4.13 | 9.87±2.88 |

*Apnea-hypopnea index; †Mandibular advancement device.

Table 4. Basal and Control Values of AHI* with Higher Efficacy of Bibloc MAD†

| Study | Monobloc | | Bibloc | |
|---|------------|--------------|------------|--------------|
| | Basal AHI* | Control AHI* | Basal AHI* | Control AHI* |
| Sari et al. (17). ($\bar{x}\pm SD$) | 17.9±6.8 | 9.1±4.9 | 18.8±7.3 | 7.3±3.3 |
| Tegelberg et al. (18). (\bar{x}) | 23.1 | 11.3 | 25.4 | 8.6 |
| Lettieri et al. (19). ($\bar{x}\pm SD$) | 30.1±24.4 | 10.0±12.4 | 29.7±24.1 | 7.6±9.7 |

*Apnea-hypopnea index; †Mandibular advancement device.

Discussion

The success of the treatment on the basis of the AHI index, differs between these studies. In 10 studies, the complete success of the treatment is defined as a value of AHI <5 after MAD. Therapy, or a reduction in the AHI value by 50% after MAD therapy. The results of therapy success in relation to the AHI index also differ. In 2017 and 2019, Isacson et al. achieved equal success in both groups.

A positive response to therapy, defined as a reduction in the AHI value to less than 10 events per hour, was achieved in 61% of subjects in the monobloc group, and 56% of subjects in the bibloc group (7).

In the 2019 study, it is said that both monobloc and bibloc MAD devices led to a decrease in AHI values by 12 to 14 apneic events per hour (8). A significant improvement was recorded in the AHI index in both groups of devices by Yamamoto et al., with complete success of the therapy in almost half of the subjects in both groups (9). The Al-Dharrab study showed the same result, where both types of devices showed a reduction greater than

50% in mean AHI, which coincides with the definition of treatment success (10) (Table 2).

This study has a limitation because the sample size was relatively too small to highlight any difference between the two appliances. Five studies included in this review demonstrated the superiority of monobloc devices in lowering the AHI value (Table 3). The greater success of the monobloc devices compared to the bibloc devices was noted by Bloch et al. The definition of successful treatment in this study was a reduction in AHI values below 10 events per hour, which was achieved in 18 subjects with a monobloc device (75%), and 16 subjects with a bibloc device (67%) out of the total number of 24 subjects. Although both types of device led to a decrease in the value of the AHI index, the monobloc device resulted in statistically more significant reduction values (11). Clinical application of the results revealed reduced snoring and certain aspects of impairment in daily activities were more pronounced with the monobloc than with the bibloc device. In addition, there was a trend toward greater improvement in several objective variables of breathing and sleep disturbance with the monobloc device.

La Mantia I, Umemoto et al. and Hyun Lee et al. also demonstrated the greater success of monobloc devices in reducing the value of the AHI (12-14). In the La Mantia study, both MADs showed efficacy in improving objective parameters compared to the baseline, with a significant difference in favor of the monobloc in terms of improving AHI (12). The monobloc group had 14 subjects with a complete response to therapy, i.e. the complete success of therapy, while complete success of therapy was noted in only five subjects in the bibloc group (13). In the study by Lee WH et al. therapy success, defined as a reduction in AHI values by 50%, was noted in 77.4% of subjects in the monobloc group and 58.3% in the bibloc group (14). Greater success in reducing AHI values in the monobloc group was noted by Geoghegan et al. (15), while Zhou et al. reported an absolute decrease in AHI to less than 10 events per hour, in 68.0% of subjects in the monobloc group, compared to 56.3% in the bibloc group (16).

The greater success of the bibloc type of device was demonstrated in three studies included in this review paper (Table 4). Sari et al. demonstrated the better success of the Clearway bibloc device in lowering AHI index values on follow-up PGS analyses. The follow-up was carried out after 7 days and after one month from the start of using the device, where the second follow-up analysis showed a more significant decrease in the value of the AHI index (17). All patients subjectively reported more restful sleep with a reduction in snoring. In addition, minimum oxygen saturation increased at the end of the first week, and also increased above 90% oxygen saturation at the end of the first month in both groups.

At follow-up examinations after one year of using the MAD device, Tegelberg et al. reported the greater success of the Narval bibloc device compared to the monobloc device. Although a significant decrease in the value of the AHI index was recorded in the bibloc group, successful therapy (AHI<10) was recorded in 68% of subjects in the bibloc group and 65% of respondents in the monobloc group (18). Lettieri et al. reported a greater reduction in obstructive events in the bibloc group.

In the bibloc group, the AHI value decreased by 74.4%, and in the monobloc group that value was 64.9%. Complete success of therapy, defined as AHI value reduction to less than 5 events per hour, was achieved in 57.2% of subjects in the bibloc group, or 46.9% in the monobloc group (19).

According to these data, it has been demonstrated that both types of MAD devices lead to a reduction in the AHI index values, and thus to the success of OSA therapy (20). A large number of studies point to the greater success of monobloc devices in lowering the AHI index, however, the fact that these are short-term studies should be taken into account.

Assessment of the efficacy of monobloc and bibloc device therapies is also based on the severity of obstructive sleep apnea (OSA).

Out of the 12 studies analyzed, six studies evaluated the impact of both types of devices on the treatment of mild and moderate OSA (Table 1). All the studies resulted in the conclusion that both monobloc and bibloc devices lead to a reduction in AHI values, i.e. a reduction in AHI values by 50% in both mild and moderate OSA. Isacson et al., recorded more successful results of both types of devices in the treatment of moderate OSA (8).

The effectiveness of both monobloc and bibloc devices in the treatment of severe OSA was assessed in three of the analyzed studies. Research by Lee WH et al. showed the higher success rate of monobloc devices in the treatment of severe OSA, with a value of 86%, while the bibloc device recorded a success rate of 69.7% (14). A limitation of this study is the relatively short follow-up duration for evaluating compliance. Despite these limitations, the study may be meaningful in that it compared efficacy and compliance between mono-bloc and bi-bloc devices in the same patient population.

Lettieri et al., however, did not record the greater success of monobloc devices in the treatment of severe OSA. On the contrary, most subjects with severe OSA did not respond to monobloc device therapy, compared to a bibloc device (19). The study by Tegelberg et al., reported that both types of devices resulted in a significant reduction in values in the group of subjects with severe forms

of OSA (AHI>30), with the slightly higher efficacy of the bibloc device (18).

Preferably, the final selection of appliances should be made by dental specialists, in accordance with and adjusted to the patient, thereby introducing personalized medicine in MAD management. Cost aspects, such as appliance price and the number of return visits, are secondary factors which differ with every appliance design and per patient. Recommendations for the optimal MAD design and phenotyping of OSA patients are difficult to draw and insufficiently supported by the current literature (21, 22).

Study Limitations

It is important to acknowledge certain limitations within this review. First, the studies analyzed in this review are predominantly short-term in nature, with most having small sample sizes. Additionally, a significant portion of the studies primarily include male subjects, which may not fully represent the population affected by OSA. Given the chronic nature of OSA, necessitating lifelong therapy, there is a critical need for longer-term studies to explore the sustained effectiveness of these devices. Furthermore, due to anatomical differences in the airway between male and female populations, studies are needed that directly compare the efficacy of specific device types in both groups, as well as using larger sample sizes to enhance the robustness of the findings.

Conclusion

From the findings derived from the study's analysis regarding the efficacy of MAD devices in reducing AHI values, it can be inferred that both monobloc and bibloc devices demonstrate comparable success rates in the management of mild to moderate OSA. Nevertheless, in cases of severe OSA, the bibloc device demonstrated superior efficacy. Consequently, the initial treatment preference for mild to moderate OSA may lean towards a monobloc device, while consideration of a bibloc device may arise if the monobloc device yields

unsatisfactory outcomes, or is not well-tolerated by the patient. An alternative type of MAD device may be considered as a subsequent option in the event of an insufficient response to initial MAD therapy, before consideration of CPAP therapy referral for the patient.

What Is Already Known on This Topic:

Obstructive sleep apnea (OSA) is a common, chronic disorder characterized by successive episodes of upper airway collapse, with an increase in the airflow resistance, which leads to a decrease in (hypopnea) or the complete cessation of airflow (apnea) during sleep. Oral appliance therapy with bibloc or monobloc devices is a non-invasive treatment option that offers a wide variety of oral devices for the treatment of obstructive sleep apnea.

What This Study Adds:

This review summarizes studies published between 2000 and 2024 regarding the effectiveness of MAD devices in reducing AHI. Both monobloc and bibloc devices have been shown to be effective in cases of moderate OSA, while in cases of more severe forms of OSA, bibloc devices showed greater effectiveness.

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Conflict of Interest: The authors declare that they have no conflict of interest.

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