

Journal of Pharmaceutical Research International

33(60B): 3500-3507, 2021; Article no.JPRI.79699

ISSN: 2456-9119

(Past name: British Journal of Pharmaceutical Research, Past ISSN: 2231-2919,

NLM ID: 101631759)

Critical Overview on Oral Appliances for the Management of OSA

Bhawna Shyamsukha ^{a*≡}, Sharayu Nimonkar ^{b∞}, Vikram Belkhode ^{b∞}, Sweta kale Pisulkar ^{c#} and Surekha Godbole ^{c#}

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2021/v33i60B35039

Open Peer Review History:

This journal follows the Advanced Open Peer Review policy. Identity of the Reviewers, Editor(s) and additional Reviewers, peer review comments, different versions of the manuscript, comments of the editors, etc are available here:

https://www.sdiarticle5.com/review-history/79699

Review Article

Received 20 October 2021 Accepted 26 December 2021 Published 28 December 2021

ABSTRACT

Obstructive sleep apnea is caused by obstruction of the upper airway during the sleep This illness is characterised by a wide range of symptoms and associated comorbidities. OSA is a complex illness that necessitates a comprehensive approach to diagnosis and treatment. The craniofacial structure, as well as the soft tissues and muscles that surround it, all contribute to OSA. Obstructive sleep apnea affects 936 million individuals around the world. After China, India comes second with 81 million OSA patients. Continuous positive airflow (CPAP) as an interventional option and Oral Appliances as a non-interventional alternative have both been mentioned in the literature as therapy options for OSA. The clinical findings associated with OSA should be noted by the dentist during the initial session so that an early diagnosis, proper treatment planning, and the avoidance of long-term consequences can be accomplished. Dentists are crucial in diagnosis, treatment, and screening of OSA patients.

^a Sharad Pawar Dental College And Hospital, Datta Meghe Institute of Medical Sciences (Deemed to be University), Sawangi (Meghe), Wardha, Maharashtra, India.

b Department of Prosthodontics, Shard Pawar Dental College And Hospital, Datta Meghe Institute of Medical Sciences (Deemed to be University), Sawangi (Meghe), Wardha, Maharashtra, India.
c Department of Prosthodontics, Sharad Pawar Dental College and Hospital, Wardha, Maharashtra,

Department of Frouthous missos, Sharad Fawar Demar Sonege and Frospital, Warana, Manare

[■] BDS (Intern);

MDS Prosthodontics, Assistant Professor;

[&]quot; Professor;

^{*}Corresponding author: E-mail: Bhawna.26jain@gmail.com;

Oral appliances for mandibular advancement and tongue stabilisation have been shown to be successful in treating OSA. The clinical studies, and current clinical practice suggest utilising oral appliances to treat OSA when patients cannot tolerate CPAP. Dental appliance therapy is a non-invasive treatment for obstructive sleep apnea syndrome that involves the use of a variety of dental appliances. This review provides an update on the most recent trends in Oral Appliances as a therapeutic option for managing OSA.

Keywords: Mandibular advancement device; obstructive sleep apnea; oral appliance; continuous positive airway pressure.

1. INTRODUCTION

Obstructive sleep apnea (OSA) is a disorder of sleep in which upper airway becomes partially or fully closed. Constriction or collapsing of the pharyngeal walls is the reason for the upper airway to collapse. OSA can result cardiovascular and mental problems. [1]. They have also been observed to have daytime tiredness and a low quality of life. A skilled sleep professional medicine uses nocturnal diagnose OSA. polysomnography to OSA patients have a soft palate that is posteriorly positioned and near to the pharyngeal wall during phonation. Uvula is bulky and prominent in OSA [2].

To classify the severity of OSA, the apneahypopnea index (AHI), or the number of apneas and hypopneas episodes recorded in an hour of sleep, is utilised. OAS is characterised as mild (AHI5–15), moderate (AHI15–30), or severe (AHI>30) based on the AHI. [3].

Some of the therapeutic options for OSA include positional therapy, surgical therapies (pharyngeal and maxillomandibular operations), continuous positive airway pressure (CPAP), and oral appliances (OA) such as the mandibular advancement device (MAD). [4,5,6].

Dental appliance therapy is a non-invasive treatment for obstructive sleep apnea that employs a range of dental appliances (OSA). OA causes jaw and/or tongue to shift forward in the mouth, thus expanding pharyngeal space. There are around 60 different types of OA in use today, each with substantial architectural changes. None, on other hand, has been designated as a "gold standard." [7,8].

For patients with mild to severe OAS, MAD has been shown to be a feasible alternative. Some studies have revealed that MAD has a good contribution in lowering AHI and enhancing quality of life in these patients when compared to

CPAP [9,10]. MAD is based on the idea of clasping the jaw forward and downward to broaden the upper airway and lower AHI [11].

Long-term model analysis studies have described tooth pain, temporomandibular joint difficulties, xerostomia (excessive salivation), and gum irritation [12,13,14]. TMD symptoms in patients wearing an occlusal splint have been observed to last up to 3-4 months in other investigations. The majority of patients' symptoms had disappeared after 5 years [15].

Oral appliances come in a variety of shapes and sizes, and the number continues to expand. They are divided into three categories: soft palate lifters, tongue holding devices, and mandibular advancement devices. [16,17,18].

The aim of this review article is to provides an critical overview on oral appliances present in the market for the management of OSA.

2. MATERIALS AND METHODS

A review was conducted as per the most opted reporting protocol (PRISMA) for a systematic review. Two electronic databases (PubMed and Cochrane Library) were explored for manuscripts published from 1991 till September 30, 2020. Two reviewers were appointed to screen the titles and abstract independently. Full texts of articles that fulfilled the inclusion criteria were obtained. The final search was done manually the selected articles for the cross-references and citations, to include all relevant articles and to improve the electronic search.

2.1 Inclusion Criteria

- 1. Language of publication English
- 2. All article types (case reports, techniques, RCTs)
- Articles related only to Oral appliances in OSA

3. RESULTS

After the electronic and manual search the total number of articles that were displayed for the search were analysed and tabulated in

Table-1. The Full text of the articles were obtained and after a thorough assessment by both the reviewers for these articles independently checked for duplications.

Table 1. Literatures were analysed

Authors (Year)	Aim	Findings
Fernando R Carvalho et al.	Effect of oral and functional	Found that it is considered in
in 2016	orthopedics appliances	specific cases who have
		craniofacial anomalies.
Jing Hao Ng, Mimi Yow in	Effectiveness of oral appliances	Oral appliances are less
2018		predictable in managing OSA
		compared with CPAP therapy.
Bartolucci ML et al in 2019	Effectiveness of different MAD	Result found that AHI improvement
	design in AHI reduction and	to be not proportional to mandibular
	oxygen desaturation.	advancement.
Vikram Belkhode et al. in	To develop new design of OA	Proved potential impact of OSA on
2021		general and mental health.

4. DISCUSSION

4.1 OA in OSA

4.1.1 Mandibular advancement device

It is a custom-made device that moves mandible forward to expand the airway. Tongue is linked to lower jaw behind chin, and forward movement of the tongue and other airway muscles keeps collapsible part of airway open while jaw moves forward.

Indication

- 1. 1)Mild to moderate sleep apnea
- 2. 2)Patient who do not tolerate CPAP.
- 3. 3)Young people with retrognathic mandible

Contraindication

- 1. There are no enough teeth to sustain device.
- 2. Tooth mobility is caused by periodontal problems.
- 3. TMJ disorder that is active

Advantages

- 1. Can help with OSA symptoms such as daytime tiredness, mood swings, and concentration issues, as well as lessen or eliminate snoring.
- 2. Is more convenient to travel with.
- 3. Works without electricity

Disadvantages

- 1. Discomfort around the jaw and mouth area
- 2. Toothache and Gum irritation
- 3. Temporomandibular disorders
- 4. Supraeruption
- 5. A need for dental work replacement

Maxillary and mandibular arches alginate impressions (DPI Algitex) were produced and Poured At 50 percent maximum mandibular protrusion and 20 percent maximum interincisal openness, an interocclusal recording was made. Only 20% of the maximum in between incisors aperture is used to accommodate the expansion screw assembly. The casts were mounted on a free-plane articulator using the interocclusal record. For retention, Adam's and pinhead clasps were placed on both sides of posterior teeth in both arches. Individually waxed maxillary and mandibular foundation plates were treated, completed, and polished in transparent heat polymerized acrylic resin (Trevalon, Dentsply). Acrylic blocks were made to adhere to the maxillary and mandibular plates. The waxup was taken in polyvinyl siloxane impression material with blocks waxed on either side of key slot end of an expansion screw. As a result, a mould for manufacturing acrylic blocks was developed. The expansion screw's breadth, length, and thickness in this device are 7.3 mm, 11 mm, and 3.1 mm, respectively Acrylic blocks surround extension screw (medium-dentaurum ref no.600-301-10). Two moulds of same design were made The screw was put into mould, and then autopolymerizing resin (Trevalon, Dentsply) was poured into it. The acrylic blocks with the screw were taken out of mould after polymerization and finished. At premolar region, autopolymerizing resin (Trevalon, Dentsply) was applied to both sides of screw block assembly on the articulator at observed mandibular protrusion and opening The acrylic expansion screw was carefully attached such that arrow pointed outward It had been polished and was now ready to use. When key provided screw is adjusted in direction indicated by arrow, mandibular component will travel forward. As a result, appliance's titration is straightforward.

Fig.1. Procedures For Fabrication: The following are steps in making appliance

4.1.2 Tongue stabilizing device

It's a small piece of plastic that sits on the lips and looks like a larger pacifier with a hole for your tongue to go through. When utilised, it can help to keep the tongue forward, which can help with sleep apnea.

Indication

- Mild snoring in non-apneic snorers due to a lack of tooth support or edentulous snorers.
- 2. Down syndrome.
- 3. In case of macroglossia.

Contraindication

- Patient with excessive salivary flow
- 2. Patient who has difficulty in swallowing.

Advantages

- 1. Simpler
- 2. More economical than other therapies.

Disadvantages

- 1. Causes tonsil enlargement
- Allergies
- 3. Might cause abnormal facial anatomy.

For mild to moderate OSA, oral appliances have gained popularity as the most recommended and preferred treatment option over CPAP. A metaanalysis was conducted by Zhang M et al [19] and Schwartz M et al [20] to compare the effectiveness of OA versus CPAP in treating OSA. They discovered that CPAP was more effective than OA at reducing AHI, but that CPAP had significantly lower compliance, with no differences in quality of life, cognitive, or functional outcomes when compared to OAs. Nasal dryness, facial ulcerations at the mask interface, and claustrophobia has all been reported as side effects of CPAP use. In a crossover trial, Phillips CL et al [21] and Young T et al [22] discovered that OA had a higher adherence rate than CPAP by about 1.5 hours per night.

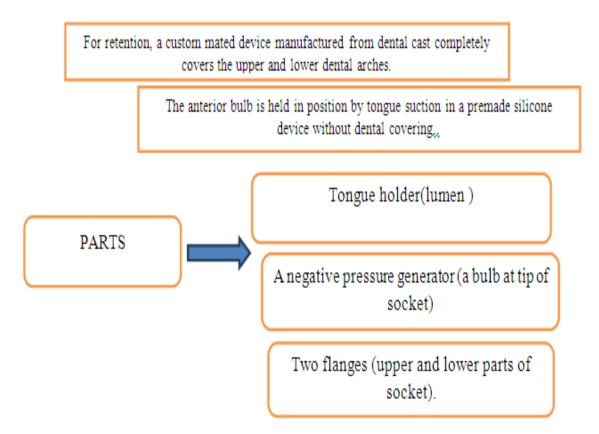


Fig. 2. Procedures for Fabrication

Chart 1. Treatment for OSA in oral appliances

	Mandibular advancement device	Tongue stabilizing device
Patient compliance	Non complacent	Not complacent, poor aesthetics
Fabrication	Difficult	Difficult
Developing time	5 to 10 days	10 to 15 days
Speciality inputs	Always required	Always required
Functional issues	Creates occlusal derangement	Strains tongue musculature

(SPL), Soft palate lifters mandibular advancement splints (MAS), and tongue retaining devices (TRD) are three types of OA used in the treatment of OSA [23]. OAs (Boil and Bite) in a variety of commercial designs are also available on market. Customized OAs, on the other hand, has produced best results [24]. Among these, MAD has emerged as the most promising treatment option. MAD prevents upper airway collapse by moving the mandible downward and forward [25]. Many dental problems have been reported as a result of this opening of the bite. including abnormal occlusion, muscle tenderness, jaw stiffness, Temporomandibular dysfunctions, retroclined upper incisors, proclination of lower incisors. decreased overjet and overbite, tipping of teeth, loss of aesthetics, and others [26-27]. It is necessary to introduce a new OA design to address these flaws.

Unmet Clinical needs of present OA in managing OSA are:

- 1. Complacent and easy to use for patients.
- 2. Ease of fabrication
- 3. Digital workflow for designing and manufacturing
- 4. Less development time i.e. 1 to 2 day
- 5. Choice of material used Plastics/Silicone/ABS/PMMA etc.
- 6. Speciality inputs may or may not be required.
- 7. Functional issues should be addressed.

Future trials should include patients with more severe drowsiness symptoms to evaluate if treatment response differs between subgroups in terms of quality of life, symptoms, and usage persistence. Long-term data on cardiovascular health is required.

As a result, there is no gold standard treatment for OSA in oral appliances that meets unmet clinical needs. In addition, significant advancements in oral appliances are being made to address unmet clinical needs.

5. CONCLUSION

When compared to a control group, there is growing evidence that OA reduces subjective drowsiness and sleep disturbed breathing. CPAP appears to be more helpful than OA in treatment of sleep disordered breathing. Although there may be some prejudice in favour of one therapy over the other, there is no substantial difference in clinical response between two.Patients with minor symptoms of OSA and those who are unwilling or unable to tolerate CPAP therapy should be administered OA therapy until more solid data on the effectiveness of OA versus CPAP in terms of symptoms and long-term implications becomes documenred. OA will not correct hvpoxemia oxvhemoalobin and desaturation seen in patients with OSA.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

- Gottlieb DJ, Punjabi NM. Diagnosis and management of obstructive sleep apnea: A review. JAMA 2020;323:1389-400.
- MacKay S, Carney AS, Catcheside PG, Chai-Coetzer CL, Chia M, Cistulli PA, et al. Effect of multilevel upper airway surgery vs medical management on the Apnea-Hypopnea index and patient-reported daytime sleepiness among patients with moderate or severe obstructive sleep apnea: The SAMS randomized clinical trial. JAMA 2020;324:1168-79.
- 3. Hu J-X, Xu S-H, Mou S-X, Du C-X, Zhu M. [Three-dimensional model analysis of

- obstructive sleep apnea hyponea syndrome patients with long-term treatment of oral appliances]. Shanghai Kou Qiang Yi Xue 2020;29:202-7.
- 4. Belkhode V, Godbole S, Nimonkar S, Parhad S, Nimonkar P. Oral appliances for obstructive sleep apnea: Emerging issues, upcoming challenges, and possible solutions. J Family Med Prim Care 2021;10:3172-5.
- Belkhode VM, Nimonkar SV, Agarwal A, Godbole SR, Sathe S. Prosthodontic rehabilitation of patient with mandibular resection using overlay prosthesis: A case report. J Clin Diagn Res 2019;13:ZD10-3.
- 6. Nimonkar SV, Belkhode VM, Sathe S, Borle A. Prosthetic rehabilitation for hemimaxillectomy. J Datta Meghe Inst Med Sci Univ 2019;14:99-102.
- Nimonkar SV, Sathe S, Belkhode VM, Pisulkar S, Godbole S, Nimonkar PV. Assessment of the change in color of maxillofacial silicone after curing using a mobile phone colorimeter application. JContemp Dent Pract 2020;21:458-62.
- 8. Koutsourelakis I, Kontovazainitis G, Lamprou K, Gogou E, Samartzi E, Tzakis M. The role of sleep endoscopy in oral appliance therapy for obstructive sleep apnea. Auris Nasus Larynx. 2021;48(2):255-60.
- Haskell BS, Voor MJ, Roberts AM. A consideration of factors affecting palliative oral appliance effectiveness for obstructive sleep apnea: a scoping review. J Clin Sleep Med. 2021;17(4): 833-48.
- Heda P, Alalola B, Almeida FR, Kim H, Peres BU, Pliska BT. Long-term periodontal changes associated with oral appliance treatment of obstructive sleep apnea. J Clin Sleep Med. 2021:17(10):2067-2074.
- Sutherland K, Dalci O, Cistulli PA. What Do We Know About Adherence to Oral Appliances? Sleep Med Clin. 2021;16(1):145-154.
- Shyamsukha B, Nimonkar S, Belkhode V, Nimonkar P, Pol A. Prevalence of temporomandibular disorders among medical students of Wardha district: A cross-sectional study. J Datta Meghe Inst Med Sci Univ 2021;16:47-51
- 13. Ng JH, Yow M. Oral appliances in the management of obstructive sleep apnea. Sleep Med Clin 2020;15: 241-50.

- 14. Kirsch DB. Obstructive sleep apnea. Continuum (Minneap Minn) 2020;26: 908-28.
- Evans EC, Sulyman O, Froymovich O. The goals of treating obstructive sleep apnea. Otolaryngol Clin North Am 2020;53: 319-28.
- 16. Ravindar P, Balaji K, Saikiran KV, Srilekha A, Alekhya K. Oral appliances in the management of obstructive sleep apnoea syndrome. Airway 2019;2:109-19.
- Bartolucci ML, Bortolotti F, Martina S, Corazza G, Michelotti A, Alessandri-Bonetti G. Dental and skeletal long-term side effects of mandibular advancement devices in obstructive sleep apnea patients: A systematic review with metaregression analysis. Eur J Orthod 2019;41:89-100.
- Uniken Venema JA, Doff MH, Joffe-Sokolova DS, Wijkstra PJ, van der Hoeven JH, Stegenga B, et al. Dental side effects of long-term obstructive sleep apnea therapy: A 10-year follow-up study. Clin Oral Investig 2020;24:3069-76.
- Zhang M, Liu Y, Liu Y, et al. Effectiveness of oral appliances versus continuous positive airway pressure in treatment of OSA patients: An updated metaanalysis. Cranio. 2019;37(6):347-364.
- Schwartz M, Acosta L, Hung YL, Padilla M, 20. Enciso R. Effects of CPAP and mandibular advancement device treatment obstructive sleep apnea patients: a systematic review and metaanalysis. Sleep Breath. 2018;22(3): 555-568
- 21. Phillips CL, Grunstein RR, Darendeliler MA, et al. Health outcomes of continuous positive airway pressure versus oral appliance treatment for obstructive sleep apnea: a randomized controlled trial. Am J Respir Crit Care Med. 2013;187(8): 879–887.
- 22. Young T, Evans L, Finn L, Palta M. Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women. Sleep. 1997;20:705–706.
- 23. Naik V, Khandekar N, Deogaonkar M. Neuromodulation in Obstructive Sleep Apnea. Neurol India. 2020 Nov-Dec;68(Supplement):S302-S306.
- Ravindar P, Balaji K, Saikiran KV, Srilekha A, Alekhya K. Oral appliances in the management of obstructive sleep apnoea syndrome. Airway 2019;2:109-19.

- 25. Evans EC, Sulyman O, Froymovich O. The Goals of Treating Obstructive Sleep Apnea. Otolaryngol Clin North Am. 2020;53(3):319-328.
- 26. Bartolucci ML, Bortolotti F, Martina S, Corazza G, Michelotti A, Alessandri-Bonetti G. Dental and skeletal long-term side effects of mandibular advancement devices in obstructive sleep apnea
- patients: a systematic review with metaregression analysis. Eur J Orthod. 2019; 41(1):89-100.
- Uniken Venema JAM, Doff MHJ, Joffe-Sokolova DS, et al. Dental side effects of long-term obstructive sleep apnea therapy: a 10-year follow-up study. Clin Oral Investig. 2019;10.1007/s00784-019-03175-6.

© 2021 Shyamsukha et al.; This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Peer-review history:
The peer review history for this paper can be accessed here:
https://www.sdiarticle5.com/review-history/79699