Commentary

Oral appliances for obstructive sleep apnea: Emerging issues, upcoming challenges, and possible solutions

Vikram Belkhode¹, Surekha Godbole¹, Sharayu Nimonkar¹, Sameer Parhad², Pranali Nimonkar³

¹Department of Prosthodontics, Sharad Pawar Dental College and Hospital, Datta Meghe Institute of Medical Sciences (Deemed to be University), Sawangi (Meghe), Wardha, Maharashtra, ²Department of Orthodontics, Dr. Rajesh Ramdasji Kambe Dental College and Hospital, Akola, Maharashtra, ³Trauma Care Centre, Government Medical College and Hospital, Nagpur, Maharashtra, India

Abstract

Background: As per the current epidemiological studies, the prevalence of obstructive sleep apnea (OSA) among the adult population is very high. Oral appliances (OAs) have emerged as the most recommended alternative treatment option for mild to moderate OSA. **Objective:** The objective of this article is to propose or develop a new design of OA named "customized maxillary oral appliance (CMOA)," for managing moderate OSA syndrome. **Methods:** The design proposed in this article is first of its kind that is fabricated on the maxillary arch. CMOA is developed by combining the principles of the three most popular OAs used in OSA, namely, soft palate lifters, tongue retaining devices, and mandibular advancement devices. **Conclusions:** Given the potential impact of OSA on general and mental health and the side effects of existing appliances, there is a need for a new remedy to be introduced in the field of sleep medicine. This novel design can provide a new therapeutic option for patients with moderate OSA.

Keywords: Apnea/hypopnea index, customized maxillary oral appliance, mandibular advancement device, obstructive sleep apnea, polysomnography

Abbreviations: OSA, Obstructive sleep apnea; OA, Oral appliances; MAD, Mandibular advancement device; CMOA, **Customized maxillary oral appliance**; AHI, Apnea-hypopnea index; CPAP, Continuous positive airway pressure; 3D, 3 Dimension; BMI, Body mass index; TMDs, Temporomandibular disorders; CAD-CAM, Computer-aided design- Computer-aided manufacturing; SPL, Soft palate lifters; MAS, Mandibular advancement splint; TRD, Tongueretaining devices

Address for correspondence: Dr. Sharayu Nimonkar, New SBI Colony, Nisargnagri Nagpur Road, Wardha - 442 001, Maharashtra, India. E-mail: snimonkar@gmail.com

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Introduction

Obstructive sleep apnea (OSA) is a term used for the repetitive obstruction of the upper airway partially or completely during sleep. It is due to the narrowing or collapse of the pharyngeal walls. It results in microarousals and oxyhemoglobin desaturation, which leads to sleep fragmentation and loud snoring.[1,2] OSA has the potential to adversely affect the cardiovascular system and can also cause neurocognitive impairment.[3] Daytime sleepiness and poor quality of life have also been reported among them.[4-7] Early diagnosis and primary care in the form of intervention can reduce the risk for developing the cardiovascular diseases. Evidence that sleep apnea is a risk factor for stroke is strong and its prevalence among stroke survivors is high. After the stroke,

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OSA may be an underappreciated risk factor for both poor functional outcomes and stroke recurrence.

Diagnosis of OSA is made with nocturnal polysomnography by a trained specialist in sleep medicine.[8] Clinically, OSA shows a posteriorly positioned soft palate that is adjacent to the pharyngeal wall and nonprominent uvula even while phonation.[9] These clinical findings should be identified by the dentist during the first visit for early diagnosis, appropriate treatment planning, and to avoid developing severe complications in the long term. A dentist plays a key role in screening, diagnosing, and treating patients with OSA.

The severity of OSA is classified based on the apnea-hypopnea index (AHI), i.e., the number of apneas and hypopneas events within an hour of sleep is recorded. Depending on AHI, OSA is classified as mild (AHI 5–15), moderate (AHI15–30), or severe (AHI >30).[10]

Various treatment options for OSA are behavioral and surgical weight loss therapies, positional therapy, pharmacological therapy, surgical therapies (pharyngeal and maxillomandibular surgeries), continuous positive airway pressure (CPAP), and oral appliances (OA) such as mandibular advancement device (MAD).[11,12]

OA is considered to be the most viable and accessible treatment option for patients with OSA. OA mechanically enlarges the pharyngeal space by moving the mandible and/or the tongue in a forward position.[13] Currently, there are more than 60 different OAs in use, with considerable variations in design.[14] However, none has achieved the position of "Gold standard." The present clinical technique focuses on a novel OA named "customized maxillary oral appliance (CMOA)," to provide a new therapeutic option for managing moderate OSA.

Methods

Proposed design of oral appliances for OSA – Customized maxillary oral appliance (CMOA)

The CMOA comprises of two plates, namely, a base plate and a counter plate. The base plate lies on maxillary hard and soft tissues. This plate gains its retention from the maxillary teeth and the slopes of the hard palate. This plate is overextended posteriorly in the soft palate by approximately 1 mm beyond the posterior palatal seal area. This feature of the plate provides support to the soft palate and lifts it. The base plate has an opening in the anterior region of the plate (central incisor region) for the continuous inflow of fresh air. The other plate that lies over the base plate is named counter plate. This plate is designed by keeping a 2 mm gap between it and the base plate. This increases the vertical dimension by 2 mm. This gap of 2 mm is made hollow. The counter plate has the occlusal anatomy of the maxillary teeth so that it occludes in present occlusal relation with mandibular teeth in an increased vertical dimension. This increase in vertical dimension moves the mandible in a downward and forward position and thus helps in enlarges the pharyngeal

space. The hollowness aids in further directing the air from the anterior region of the mouth to the posterior region (pharynx). A bulge is provided on the palatal surface of the counter plate that comes in contact with the tongue that helps to keep the tongue in a forward position and also prevents its backfall during sleep. [Figure 1]

Fabrication

Impressions of the upper and lower arch are recorded. The cast obtained from the impression is scanned for computer-aided design (CAD) designing with the help of CAD software. This design is 3D printed in polymethylmethacrylate material. The patients should wear the appliance daily while sleeping at least for 6 h.

Discussion

OAs have achieved the popularity of being the most recommended and opted treatment modality over CPAP for mild to moderate OSA. Zhang M, *et al.*[15] and Schwartz M, *et al.*[16] performed a meta-analysis to evaluate the effectiveness of OA versus CPAP in treating OSA. They found CPAP to be more efficient in reducing AHI when compared to OA, at the same time, they also reported significantly lower compliance for CPAP making no differences in quality of life, cognitive, or functional outcomes compared to OAs. Patient intolerance has been reported to CPAP due to nasal dryness, facial ulcerations at the mask interface, and claustrophobia caused by its use.[17] Phillips CL, *et al.*[18] and Young T, *et al.*[19] in a crossover trial found a high adherence rate to OA over CPAP by approximately 1.5 h/night.

OA used in the treatment of OSA is generally classified into three categories: Soft palate lifters (SPL), mandibular advancement splint (MAS), and tongueretaining devices (TRD).[20] Various types of commercial design of OAs (Boil and Bite) are also available in the market. However, customized OAs have shown the best results.[14] Among these, MAD has come up as the most promising treatment option. MAD works on the principle of moving mandible downward and forward that reduce upper airway collapse.[13] This opening of the bite has reported many dental problems such as abnormal occlusion, muscle tenderness,
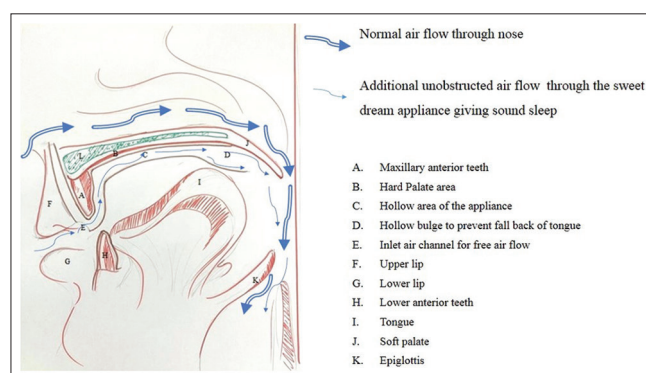

A.	Maxillary anterior teeth
B.	Hard Palate area
C.	Hollow area of the appliance
D.	Hollow bulge to prevent fall back of tongue
E.	Inlet air channel for free air flow
F.	Upper lip
G.	Lower lip
H.	Lower anterior teeth
I.	Tongue
J.	Soft palate
K.	Epiglottis

Normal air flow through nose

Additional unobstructed air flow through the sweet dream appliance giving sound sleep

Figure 1: Proposed design of oral appliance for OSA-CMOA

jaw stiffness, tempromandibular dysfunctions, retroclined upper incisors, proclination of the lower incisors, decrease in overjet and overbite, tipping of teeth, loss of esthetics, and many other.[21,22] To overcome these lacunae, an attempt is made to introduce a new design of OA named "Customized maxillary Oral Appliance." This is the first OA for OSA that is designed for the maxillary arch. It fulfills all three general principals of OAs (SPL, MAS, and TRD) in treating OSA.

Inclusion criteria for use of CMOA are:
1. The patients diagnosed with apnea/hypopnea [AHI] >5–15.
2. Patients noncompliant to CPAP and refused surgical intervention.
3. BMI (range 17–39 kg/m^2).

Exclusion criteria for CMOA:
1. The patient diagnosed with severe OSA.
2. Patients with severe periodontal diseases.
3. An edentulous arch or without a sufficient number of teeth for the adequate retention of the appliance.
4. Patients with temporomandibular joint disorders.
5. Patients with pathologic evidence of airway obstruction.

Chief features of the CMOA are-

- Increase in vertical by 2 mm that moves the mandible in a forward and downward direction that prevents the upper airway collapse by and enlarges the oropharynx and velopharynx.

- The overextension in the soft palate prevents airway collapse by stiffening the pharyngeal soft tissues.

- A bulge on its palatal surface to prevent the backfall of the tongue during sleep.

- A hole in the anterior region to promote continuous inflow of air.

- The hollowness of the plate to direct airflow towards the pharynx.

- Use of CAD-CAM for precision.

Adult patients of the age group 40–50 years often show the loss of vertical dimension of occlusion; due to occlusal wear, this appliance will also help to regain the lost vertical dimension and reestablish the original centric relation in such patients.[23] Thus, it will also help to treat the symptoms of Temporomandibular disorders. The chances of changes in the dentition are also eliminated as seen among patients treated with MAD.

Randomized control trials are recommended to authenticate the efficacy of CMOA for introducing it as a new therapeutic option for patients with moderate OSA. Diagnosing and providing primary care for patients suffering from OSA in early stage would help to regain sleep, restorative function, improvement in daytime performance, decreased risk of accidents, and may help in reducing the risk of cardiovascular diseases (stoke).

Summary

OSA has a notable life-threatening effect. This condition needs an early multispeciality treatment approach. There is a need of identifying new therapeutics and development of simplified phenotyping tools to be used in the clinic to inform targeted therapies for OSA. The research of CMOA will provide the potential to realign treatment and management approaches for this common, chronic health condition. Given the potential short- and long-term benefits and the low risk of the intervention, early evaluation and primary care in the form of OAs in managing OSA in the population seems easily justified.

Conflicts of interest

There are no conflicts of interest.

References

1. Gottlieb DJ, Punjabi NM. Diagnosis and management of obstructive sleep apnea: A review. JAMA 2020;323:1389-400.
2. Chang HP, Chen YF, Du JK. Obstructive sleep apnea treatment in adults. Kaohsiung J Med Sci 2020;36:7-12.
3. Haarmann H, Koch J, Bonsch N, Mende M, Werhahn SM, Lüers C, *et al*. Morbidity and mortality in patients with cardiovascular risk factors and obstructive sleep apnoea: Results from the DIAST-CHF cohort. Respir Med 2019;154:127-32.
4. 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.
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.
7. 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. J Contemp Dent Pract 2020;21:458-62.

8. 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.

9. Mickelson SA. Oral appliances for snoring and obstructive sleep apnea. Otolaryngol Clin North Am 2020;53:397-407.

10. American Academy of Sleep Medicine. International Classification of Sleep Disorders. 2nd ed.: Diagnostic and coding manual. Westchester, IL: American Academy of Sleep Medicine; 2005.

11. Ng JH, Yow M. Oral appliances in the management of obstructive sleep apnea. Sleep Med Clin 2020;15:241-50.

12. Kirsch DB. Obstructive sleep apnea. Continuum (Minneap Minn) 2020;26:908-28.

13. Evans EC, Sulyman O, Froymovich O. The goals of treating obstructive sleep apnea. Otolaryngol Clin North Am 2020;53:319-28.

14. 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.

15. Zhang M, Liu Y, Liu Y, Yu F, Yan S, Chen L, *et al.* Effectiveness of oral appliances versus continuous positive airway pressure in treatment of OSA patients: An updated meta-analysis. Cranio 2019;37:347-64.

16. Schwartz M, Acosta L, Hung YL, Padilla M, Enciso R. Effects of CPAP and mandibular advancement device treatment in obstructive sleep apnea patients: A systematic review and meta-analysis. Sleep Breath 2018;22:555-68.

17. Budhiraja R, Bakker JP. CPAP use: Unmasking the truth about interface. J Clin Sleep Med 2016;12:1209-10.

18. Phillips CL, Grunstein RR, Darendeliler MA, Mihailidou AS, Srinivasan VK, Yee BJ, *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;187:879-87.

19. 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;20:705-6.

20. Naik V, Khandekar N, Deogaonkar M. Neuromodulation in obstructive sleep apnea. Neurol India 2020;68(Supplement):S302-6.

21. 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 meta-regression analysis. Eur J Orthod 2019;41:89-100.

22. 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.

23. Bucca C, Cicolin A, Brussino L, Arienti A, Graziano A, Erovigni F, *et al.* Tooth loss and obstructive sleep apnoea. Respir Res 2006;7:8.