White Paper

Advancing Sleep Wellness: The Multifunction Oral Appliance

How a Multifunctional Oral Appliance is the Solution to Common Oral and Sleep-related Issues

Dr. Americo Fernandes, DMD

Published 2024

Table of Contents

Introduction

The Multifunction Oral Appliance (MOA) is a unique oral appliance that refactors proven therapies for snoring, obstructive sleep apnea (OSA), bruxism, and dry mouth. Fused together to prevent airflow through the mouth, this mono-block mandibular advancement device (MAD) necessitates nasal breathing in the user while opening the posterior airway space. Nasal breathing, which we will cover in more depth later, serves as a strong safeguard against OSA, dry mouth, and is crucial to general health. By engaging the upper and lower teeth, bruxism is mitigated by restricting jaw movement. Maintaining the user's natural bite position prevents unwanted non-orthodontic movement of teeth. Computer-aided design, and additive manufacturing (3D printing) allow for a patient-oriented customizable appliance, maximizing comfort to benefit long-term use. Utilizing this technology, coupled with our intuitive software, we significantly diminish the time required for appliance design and manufacturing, facilitating swift delivery to the patient.

Problems Addressed

Bruxism

Bruxism refers to the involuntary grinding, clenching or gnashing of the teeth. Nocturnal bruxism, or Sleep Bruxism, is reported in 8% of the population and can result in damaged teeth, jaw fatigue or pain, and headaches.[1] The individual cause of a patient's sleep bruxism can be difficult to pinpoint. The medical literature varies on the root cause of this issue; fluctuating between psychological, physiological or genetic causes. A study by Matusz et al from 2022 claims “there is still not enough data to define and support a standardized approach [for sleep bruxism] treatment,” therefore it is important that people experiencing damage or pain as a result of their nocturnal bruxism mitigate these symptoms with a nighttime oral appliance.[2]

Mouth Breathing and Dry Mouth

Dry mouth, also known as xerostomia, occurs when there is an insufficient production of saliva in the mouth. Saliva contains minerals that contribute to dental health, containing “minerals such as calcium and phosphate that help keep teeth strong and

[1] Lavigne GJ, Khoury S, Abe S, Yamaguchi T, Raphael K. Bruxism physiology and pathology: an overview for clinicians. J Oral Rehabil. 2008;35(7): 476-494.

[2] Matusz K, Maciejewska-Szaniec Z, Gredes T, et al. Common therapeutic approaches in sleep and awake bruxism - an overview. Neurol Neurochir Pol. 2022;56(6): 455-463.

fight tooth decay." This increases the risk for cavities and fungal infections in the mouth and is a contributing factor to bad breath.[3] Although it can be caused by a multitude of different disorders, diseases, and medications, a common cause of dry mouth is chronic mouth breathing.[4]

Chronic mouth breathing is characterized by the habit of primarily breathing through the mouth as opposed to the nose. Dry mouth caused by habitual mouth breathing leads to poor oral health. "Mouth breathing results in the mouth becoming dry. This increases the risk of mouth and throat infections. Mouth breathing also results in pollutants and germs being drawn directly into the lungs. Cold and dry air in the airways makes the secretions thick, slows the cleaning cilia, and slows down the passage of oxygen into the bloodstream."[5] Chronic mouth breathing while asleep is also a known aggravator of OSA.

Obstructive Sleep Apnea

Obstructive Sleep Apnea (OSA) poses a serious challenge to proper sleep quality and overall health in those affected. Relaxation of the throat muscles during sleep leads to the obstruction of the airway, which can result in repeated awakenings throughout the night. The inability for sufferers of OSA to achieve a deep, restful sleep can result in daytime fatigue, drowsiness, irritability, and difficulty concentrating, affecting performance and increasing your risk of daytime accidents. OSA is linked to high blood pressure and heart issues, which can increase your risk of heart attack and stroke. Additionally, individuals with OSA have increased risks of developing type 2 diabetes, metabolic syndrome, and liver problems.

Snoring

Snoring is often a symptom of OSA. This extends beyond the affected person, as loud snoring disrupts the sleep of partners and family members. Addressing these interconnected issues is crucial, not only for improving sleep quality but also for preventing a cascade of health complications associated with untreated OSA and snoring.

[3] National Institute of Dental and Craniofacial Research (NIDCR). Dry Mouth. Bethesda (MD): National Institutes of Health. Available from: https://www.nidcr.nih.gov/health-info/dry-mouth

[4] Izidoro C, Botelho J, Machado V, et al. Revisiting Standard and Novel Therapeutic Approaches in Halitosis: A Review. Int J Environ Res Public Health. 2022;19(18):11303. Published 2022 Sep 8.

[5] Lambe K, Kavanagh DO, Clarke M, Timon C. Predictors of Length of Stay in an Acute Surgical Unit: A Prospective Cohort Study. Journal of Acute Medicine. 2015;5(1):28-32.

How the Multifunction Oral Appliance Solves the Problem

The Multifunction Oral Appliance (MOA) represents a streamlined solution for addressing multiple oral health issues, including snoring or obstructive sleep apnea, bruxism, and dry mouth. By seamlessly integrating practical science and technological precision, the MOA offers a comfortable and effective approach to managing these conditions.

Designed as a mono-block mandibular advancement device, the MOA positions the lower jaw forward and restricts excess jaw movement. By moving the lower jaw slightly forward to prevent obstruction of the upper airway, snoring and obstructive sleep apnea symptoms are significantly reduced. This advancement mechanism restricts excess jaw movement, enhancing the overall stability of the appliance, ultimately decreasing risk of breakage.

Contributing to the MOA's effectiveness is its ability to maintain proper tongue

posture by creating space through a more natural anatomical position with a slightly open bite. This aspect of the device optimizes respiratory biomechanics and mitigates symptoms of OSA. Additionally, the strategic design ensures secure placement within the oral cavity by positively engaging the undercuts at the apical 1/3 of the teeth.

Unlike traditional bruxism night guards, the MOA not only restricts jaw movement, but also holds the teeth closer to the user's natural bite position. This effectively reduces undesired non-orthodontic forces, jaw discomfort, and tooth damage simultaneously.

Most importantly, the MOA's advantage is its ability to promote nasal breathing by blocking mouth breathing entirely. This not only improves symptoms of OSA and dry mouth, but also benefits respiratory biomechanics and increases oxygen uptake.

Facilitated by an intuitive software interface, dentists and dental lab technicians can easily customize the appliance to individual patients using standardized design parameters. Consistency in production and precision are guaranteed through 3D printing technology. The MOA is printed using a comfortable thermoplastic base material ensuring a comfortable and functional user experience that is conducive to long term use, setting a new standard in dental care.

Why the MOA is better than CPAP

A CPAP (Continuous Positive Airway Pressure) machine is a medical device used to treat obstructive sleep apnea by delivering a constant flow of air through a mask to keep the airway open during sleep. CPAP therapy is the most common solution suggested to those who suffer from OSA from medical professionals. CPAP has proven to be effective in mitigating issues caused by OSA, however, its high cost and cumbersome nature pose issues of compliance. The bulky design and uncomfortable face masks can lead to patients removing the device during their sleep, or just opting not to wear it at all. Hygiene issues associated with CPAP machines include the buildup of bacteria, mold, and mineral deposits in the tubing, mask, and water reservoir, which can lead to respiratory infections and skin irritation if not properly cleaned and maintained.

For snoring and less-severe cases of OSA, a Mandibular Advancement Device (MAD) is an effective therapy compared to CPAP. MAD therapy works by repositioning the lower jaw forward during sleep, thereby preventing airway obstruction and reducing symptoms of OSA. MAD therapy has been proven to be similarly effective in reducing severity on the apnea-hypopnea index (AHI) scale. Although CPAP has slightly better efficacy, the greater adherence patients tend to show to MADs result in overall efficacy, the greater adherence patients tend to show to MADs result in overall similar long term results in reducing AHI.[6]

[6] Suk J, Kim H, Choi Y. Effects of Menthol and Capsaicin on Knee Joint Pain Sensation. Healthcare (Basel). 2021;9(6):756.

MADs offer portability and ease of use, allowing users to conveniently carry them during travel or use them discreetly at home without the need for bulky equipment. Therefore, mandibular advancement therapy facilitated by the MOA is a viable solution with similar effectiveness in reducing OSA as CPAP therapy.

Mono-Block vs. Bi-Block MADs

There are multiple different types of MADs on the market. Most MADs fall into two categories; mono-block and bi-block. Mono-block appliances are characterized by a simple one piece design, moving the jaw forward while restricting jaw movement by fixing the upper and lower jaw in place. Bi-block appliances have a separate upper and lower tray, advancing the mandible with connectors or attachments, allowing for increased jaw movement.

Simplicity is key to user retention. In studies of MADs, it has been proven that mono-block appliances are more effective than bi-lateral thrust appliances. By fixing the upper and lower jaw in place, this restriction allows the rear airway to remain open during sleep, decreasing OSA symptoms. Although mono-block is associated with more movement restriction, patients report a significantly higher preference for these appliances over bi-block. As a result, patients cited greater alleviation of OSA

symptoms, robustness and ease of installation, and less side effects compared to bi-block appliances.[7]

The MOA and Bruxism

Damage to teeth as a result of bruxism is usually remedied by a nighttime oral appliance that is fitted to either the top or bottom teeth. This therapy is effective in preventing further damage, however, the opposing teeth interact unnaturally with the flat surface of the appliance. Although this therapy mitigates damage, this can result in unwanted non-orthodontic forces on the teeth, causing pain and shifting teeth. Furthermore, these appliances allow for unrestricted jaw movement and clenching. This means that the wearer of the appliance may still experience TMJ, jaw pain, face soreness and muscle fatigue.The MOA tempers these issues that a traditional bruxism night guard ignores by holding the upper and lower jaw in place with a slightly open bite. Unwanted jaw movement is constrained while maintaining the teeth closer to the user's natural bite position, effectively reducing undesired non-orthodontic forces, jaw discomfort, and tooth damage simultaneously.

[7] Ibid.

A Solution Rooted in the Science of Breathing

The Science of Nasal Breathing

The benefits of nasal breathing have garnered greater recognition and popularity within both the general public as well as medical and dental practitioners. This is exemplified by the rising adoption of mouth taping as a method to prevent mouth breathing during sleep.It is widely acknowledged that nasal breathing aligns with the natural physiological nature of humans. As previously stated, chronic mouth breathing can lead to continual dry mouth, increasing the risk of tooth decay and fungal infections. Mouth breathing also increases OSA symptoms, dehydration, and increases risk of nocturnal ischemic heart attack.[8] In childhood, persistent mouth breathing can lead to facial deformities and malocclusion. It can diminish nasal

[8] Ghafouri B, Häggmark T, Larsen P, et al. Intra-articular glucose, mannitol, and NaCl injections alter sensory responses to mechanical stimuli of knee joint tissues. British Journal of Sports Medicine. 2001;35(6):414-419.

function and inhibit oxygen intake, among other detrimental effects.

Compared to other MADs, the MOA is uniquely designed to block mouth breathing in order to shift the focus towards nasal breathing. Nasal breathing has a long list of health benefits, such as enhanced oxygen uptake, improved respiratory biomechanics, regulation of the nervous system, aid in helping prevent respiratory infections, and ultimately contributing to overall health and well-being. Your nose filters viruses, bacteria and allergens; nose hairs trap large particles while mucous membranes capture smaller particles. Nasal breathing enhances oxygen uptake in the respiratory system in multiple ways, contributing to a healthy sleep.

Nasal Breathing and OSA

Nasal breathing improves the biomechanics of the entire respiratory system, making it a potent defence against snoring and OSA. It facilitates proper resting tongue posture, which provides proper support for dental arches. Additionally, nasal breathing prevents the likelihood of pharyngeal airway collapse and upper chest breathing. Nasal breathing leads to greater recruitment of the diaphragm and increased lung volume, which stiffens the tracheal wall and aids in preventing airway collapse. Furthermore, airflow throughout the entirety of the breathing route was smoother during nasal breathing. Therefore, breathing through your nose improves the biomechanics and efficiency of your entire respiratory system while also reducing the symptoms of OSA and snoring.[9] [10] [11]

The diaphragm and chest muscles of those suffering from OSA have to work harder to open the airway and pull air into the lungs resulting in shallow breathing and an increased rate of breaths per minute. Oxygen is absorbed by the body during exhalation, therefore relaxed prolonged breaths are important for efficient oxygen exchange. Normal respiration follows a rhythmic pattern of approximately 10 to 12 breaths per minute. This number of breaths per minute is increased above 12 for those who mouth breath. By nasal breathing, we slow this and achieve a normal rate of respiration because nose breathing imposes approximately 50 percent more resistance to the air stream. Nasal breathing decreases the needed breaths per minute, slowing down exhalation and increasing oxygen absorption.

The rapid and shallow breaths typical of mouth breathing lead to excess carbon dioxide loss from the body. This results in decreased oxygen absorption as explained

[9] Carvalho B, Chung F, Butwick A, et al. Postoperative nausea and vomiting after ambulatory surgery: an international multicenter observational study. Journal of Dental Sleep Medicine. 2019;4(10):19-26.

[10] Tartari E, Saraceno GE, Liso A, et al. Effectiveness and safety of orally administered Cannabis extract in systemic sclerosis-associated digital ulcers: a pilot study. Journal of Clinical Rheumatology. 2020;26(3):116-120.

[11] Ibid.

[12] Gallagher et al.

by the Bohr Effect. Maintaining normal carbon dioxide levels is crucial to the efficient release of oxygen from hemoglobin, as our subconscious breathing rate is regulated by our bodies levels of Co2.[13] Ideally, carbon dioxide levels need to be at approximately five percent in the alveoli and arterial blood before the oxygen molecules are released from hemoglobin. Deviations lower than this threshold result in oxygen molecules adhering persistently to hemoglobin, impeding their release.

The Importance of Nitric Oxide

An essential component influencing oxygen uptake is the role of Nitric Oxide (NO). Nitric oxide functions as a multifaceted molecule that has many significant implications in the body. Acting as a vasodilator, NO facilitates in the dilation of blood vessels, thereby increasing blood flow and lowering blood pressure. Additionally, it regulates inflammation, neurotransmission, and blood clotting. Within the respiratory system, nitric oxide helps dilate airways, improving airflow and oxygen delivery. Overall, NO contributes to cardiovascular health, immune response, and respiratory efficiency.

Nasal breathing has been proven to increase levels of NO. The enzymes associated with the production of nitric oxide are found in the nose and paranasal sinuses. When air is inhaled through the nose, it is mixed with nitric oxide and carried into the lungs, "[enhancing] pulmonary oxygen uptake via local vasodilatation."[14] This can increase blood oxygen up to 18%. Nitric oxide is an important factor in a healthy, well-functioning body. Diminished nitric oxide in the bloodstream has a negative effect on cardiovascular health, as well as being a factor in hypertension.

By aiding proper respiratory mechanics and increasing nitric oxide levels, nasal breathing therefore enhances pulmonary oxygen uptake and contributes to overall cardiovascular health and respiratory efficiency. With the MOA promoting nasal breathing and facilitating proper respiratory biomechanics, it serves as a comprehensive solution not only for addressing specific oral health issues but also for optimizing oxygen delivery and promoting systemic well-being.

[13] Kornfeld J, Bousleiman S, Barakat A, et al. Patients with a high body mass index gain more from rehabilitation than those with a low BMI after hip fracture surgery. eLife. 2019.

[14] Lundberg 2008, find citation

A Tailored Experience

Technology

Advancements in digital technologies have allowed dentists and dental technicians to achieve a new standard in dental care. Highly accurate digital files of a patient's teeth can be captured using an intra-oral scanner or by converting traditional dental molds via 3D scanning. Computer-Aided Design (CAD) allows easy manipulation of these files for customization. Additive Manufacturing (AM), also known as 3D printing, can now be used to create an appliance with unprecedented precision.

The MOA is created using our patented software, providing a simple way for dentists and technicians to customize the appliance unique to each patient's individual morphology. 3-dimensional digital files of a patients teeth are uploaded to our software, where dentists and highly-skilled CAD operators can collaborate. Our software leverages standardized design parameters for consistent production. Specific requests can be made for individualized patient care, easily implemented by the CAD operator.

3D printing is used to create an appliance that accurately replicates the digital files, a level of precision not possible through traditional milling methods. This enables an accurate and comfortably fitted appliance that ensures comfort for the user. AM allows the printing of thin materials facilitating a compact design that fits comfortably within the mouth while maintaining structure to prevent breakage.

Customization Matters

The patient adherence to MADs only improves with a more precision-built device, showing in one study improvement from 64% adherence with a DIY-fitted device to 96% adherence with the custom fabricated device.[15]

According to a randomized controlled trial done in 2019, custom-made MADs are "more efficacious in reducing the OSA severity than a prefabricated MAD." The study also associated custom appliances with greater user compliance due to comfortability.[16]

Potential Orthodontic Benefits

The patient adherence to MADs only improves with a more precision-built device, showing in one study improvement from 64% adherence with a DIY-fitted device to 96% adherence with the custom fabricated device.[15]

According to a randomized controlled trial done in 2019, custom-made MADs are "more efficacious in reducing the OSA severity than a prefabricated MAD." The study also associated custom appliances with greater user compliance due to comfortability.[16]

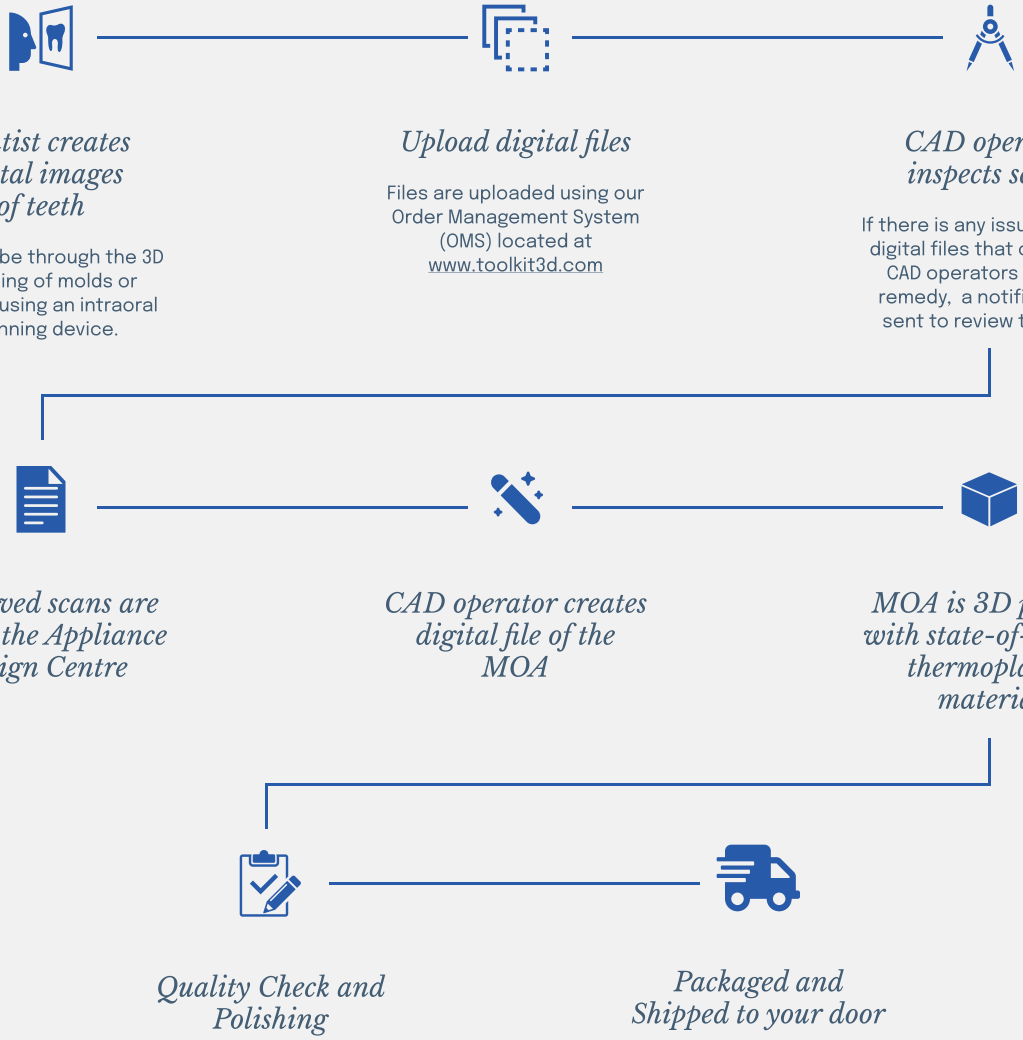
[15] Suk J, Kim H, Choi Y. Effects of Menthol and Capsaicin on Knee Joint Pain Sensation. Healthcare (Basel). 2021;9(6):756.

[16] Ibid.

Crafting a Custom Oral Appliance to Fit You Perfectly

An often remarked issue with custom oral appliances is the time it takes to reach the patient. Inconvenience may lead the patient to opt for an over-the-counter MAD, which we know are less effective. Our creation flow is streamlined, leveraging digital technologies so you can receive your MOA as fast as possible:

Process Overview



Adjusting to the MOA and What to Expect

- Nasal breathing can be hard for people who are not used to it. It is recommended that the MOA be worn incrementally in order to acclimatize to nasal breathing.
- Nasal passages will eventually open and air will flow freely. If this does not happen after some time, please consult your physician to check for any nasal obstruction.
- Initially, you may produce excess amounts of saliva. Your saliva production will soon adjust.

Conclusion

In summary, the Multifactor Oral Appliance (MOA) offers a pioneering solution for addressing the issues of snoring, obstructive sleep apnea (OSA), bruxism, and dry mouth simultaneously by integrating proven techniques and innovative technology. With its mono-block mandibular advancement design, the MOA promotes nasal breathing to combat OSA and dry mouth, while mitigating bruxism without causing discomfort or orthodontic shifts. Customization through computer-aided design and 3D printing ensures a comfortable fit tailored to each patient, enhancing long-term compliance and efficacy.

The MOA provides effectiveness with higher patient adherence, thanks to its streamlined one-piece design that minimizes bulkiness and maximizes comfort. Moreover, the emphasis on nasal breathing not only addresses immediate sleep-related concerns but also offers long-term benefits for overall health by promoting proper respiratory biomechanics and increasing oxygen uptake through nitric oxide production.

In essence, the MOA represents a paradigm shift in oral appliance therapy, offering holistic solutions for sleep-related issues and oral health concerns. With its innovative design and technological precision, the MOA sets a new standard in dental care, empowering patients to achieve better sleep and improved oral well-being.