



Oral appliance for Obstructive Sleep Apnea: Prototyping and Optimization of the Mandibular Protrusion Device

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Abstract

Obstructive Sleep apnea is a public health problem. This disease is associated with daytime sleepiness, increased motor vehicle accidents, heart failure and stroke. Treatment options include weight loss, positive airway pressure, pharyngeal and orthognatic surgery. However, selected patients have good response to oral appliances devices that intended to protrude and stabilize the mandible mechanically during the night in order to reduce the collapsibility of the upper airway. Selection of patients includes primary snoring, mild, moderate and positional apnea. The perfect mandibular advance device has not yet been designed. For these reasons, the objective of this paper is to present a new thermoadjustable chair-side oral appliance. Device integrates the best characteristics of custom made and boils and bite previous designs and minimizes inconveniences and possible side effects. The device is a titratable mandibular advancement appliance. It consists of two independent prefabricated trays adaptable to the shape of adult dental arch and linked to each other by a protrusion mechanism. Each tray contains a hard outer shell and a soft thermoplastic resin inner body. The position of the jaw can be adjusted by moving an aluminum rack into, or out from, the guide so the ratchet may get locked into a certain position ensuring the length of the mechanism. The protrusion mechanism is fixed to the splint using small rings that are articulated over a “t” button. Our prototype satisfies the requirements of an effective oral appliance, in terms of retention, comfort, safety and efficacy. It is easy to fit, durable, low cost, quickly titratable, not bulky and easy cleaning. Thermoplastic appliances are specially used like a predictor of treatment response in apnea patients. The device described is a cost-effective introduction to mandibular advancement technology. A qualified dentist or trained sleep doctor could mitigate dental side effects and reduce their incidence.

Keywords Thermoplastic oral appliances · Obstructive sleep apnea · Prototype · Medical product design · Mandibular protrusion mechanism

Introduction

Obstructive Sleep Apnea (OSA) is characterized by repetitive episodes of partial or total upper airway obstruction during sleep, resulting in a decrease of oronasal airflow. OSA leads

to sleep fragmentation and hypoxia. Apnea is defined as cessation of airflow lasting ≥ 10 s and hypopnea is defined as a $\geq 30\%$ reduction of airflow associated with $\geq 4\%$ oxygen desaturation. The Apnea-Hypopnea Index (AHI), representing the average number of apneas and hypopneas

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per hour of sleep, is determined by Performing a Polysomnography (PSG) or polygraphy using a portable sleep monitor. The AHI is used to classify the severity of OSA: mild OSA ($5 < \text{AHI} \leq 15$ events/h), moderate OSA ($15 < \text{AHI} \leq 30$ events/h) and severe OSA ($\text{AHI} > 30$ events/h) [1].

The prevalence of OSA increases with age. The current prevalence estimates moderate to severe OSA ($\text{AHI} > 15$) is 3% of women among 30–49 years old and 9% among 50 to 70 years old, and 10% men among 30 to 49 years old and 17% among 50 to 70 years old [2].

OSA has been associated with a wide range of consequences including excessive daytime sleepiness, learning and memory failure, motor vehicle and industrial accidents, cardiovascular conditions metabolic syndrome, cancer and increased mortality [3].

The pathogenesis of OSA is complex, involving a combination of neurological, genetic (family history of OSA), anatomic (dentofacial deformities), and demographic factors that may influence the onset of upper airways obstruction, such as, a high body mass index, age over 40 years old and male sex—the three main demographic risk factors for sleep disordered breathing. Large neck, upper airway abnormalities, menopause, smoking and alcohol use before bed time and night time nasal congestion are other risk factors for OSA [4].

Continuous Positive Airway Pressure (CPAP) is currently the gold standard treatment for moderate to severe OSA and high risk patients: obese, congestive heart failure, atrial fibrillation, hypertension, type 2 diabetes, stroke, nocturnal dysrhythmias, pulmonary hypertension and high-risk driving population [1]. CPAP can be highly efficacious in reducing related morbidity and mortality [5]. However, its clinical effectiveness is often limited by unsatisfactory adherence with around 50% of patients using CPAP at long-term follow-up [6].

The primary action of an oral appliance (OA) is to increase and stabilize the oropharyngeal and hypopharyngeal airway space by repositioning and maintaining the lower jaw in forward status during sleep. Widening of the upper airway occurs in both the lateral and the anteroposterior dimension due to the anterior displacement of the base of the tongue, epiglottis, and soft palate with OAs [7]. Various OAs are available whose differences on design, material of fabrication, size and thickness [8].

OAs are intended to decrease the frequency and/or duration of: apneas, hypopneas, Respiratory Effort Related Arousals (RERAS) and primary snoring. The update practice parameters from American Academy of Sleep Medicine recommend the use of OAs for patients with mild to moderate OSA and those with severe OSA who cannot tolerate continuous positive airway pressure therapy (CPAP). OAs has been demonstrated to improve nocturnal oxygenation as well as the adverse health and social consequences of OSA and snoring [9].

An OA is custom fabricated using digital or physical impressions and models of an individual patient's oral structure.

It is made of biocompatible materials and engages both the maxillary and mandibular arches. The OA has a mechanism that allows the mandible to be advanced in increments of 1 mm or less with a protrusive adjustment range of at least 5 mm. In addition, reversal of the advancement must be possible. The protrusive setting must be verifiable. The appliance is suitable for placement and removal by the patient or caregiver. It maintains a stable retentive relationship to the teeth (at least 6 teeth on each arch) or dental implants and retains the prescribed setting during use. An OA maintains its structural integrity over a minimum of three years [10].

Non-custom OA, commonly known as boil and bite device, are primarily prefabricated and usually partially modified to an individual patient's teeth. Non-titratable OA holds the mandible in a single protrusive position, and no changes are possible over the course of treatment [9].

Many mandibular advancement mechanism has been designed to connect maxillary and mandibular dental splints: elastic straps, telescopic connector, dorsal screw, anterior connector, connecting rods, palatal connector, mated buccal posts or titanium buccal chamber [11]. The degree of mandibular advancement has a positive correlation with the efficacy of the OA. Recommendations for initial jaw protrusion vary from 50% to 75% of maximum jaw protrusion, depending on clinician's expertise, Temporomandibular Joint (TMJ) symptoms and apnea severity [12].

OA therapy is not completely effective in all patients. Several studies have shown that OAs are more effective in patients with the following characteristics: younger age, lower body mass index, small neck size, positional OSA, female gender and retrognathic mandible. Low mandibular angle and reduced hyoid bone to mandible distance were positively correlated with treatment outcome [13].

Common side effects of OA therapy reported are excessive salivation, bite discomfort, occlusal change, pain in teeth and symptoms of temporomandibular disorder (TMD). Discomfort from the appliance is the major cause for discontinuation of treatment or poor compliance [14].

American Academy of Dental Sleep Medicine (AADSM) recommend that a qualified dentist use a custom, titratable appliance over non-custom oral devices and survey for dental-related side effects or occlusal changes and reduce their incidence. Sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy for patients treated with oral appliances [9].

Experimental details and clinical protocol

The perfect OA has not yet been designed. The objective of this paper is to present a new customizable and adjustable chair side OA. In recent years, in fact, several authors have managed to improve the performance of medical and

biomedical devices thanks to the application of engineering to medical problems. For example, Blaya et al. presented in their study a new arm splint printed in 3D [15, 16]. Ruggiero et al. presented the results obtained with the tribological characterization of materials for hip and knee joint prostheses in order to optimize them [17, 18].

The device integrates the best characteristics of the previous designs and minimizes inconveniences and possible side effects. The design prerequisites were: effectiveness treatment of OSA and snoring, easy assembly and titration, safety, comfortable and not bulky, good retention, low cost, durable, easy cleaning and adaptable to the shape of adult dental arch.

Pubmed search was performed with a combination of terms: “mandibular advancement device”, “oral appliance”, “intraoral device”, “thermoplastic”, “sleep apnea” and “snoring”. We selected only OA studies with statistical clinical data. Also we searched Federal Drug Administration (FDA) 510 K premarket notification for intraoral devices for snoring and/or obstructive sleep apnea. 51 different designs were identified. Pro and cons characteristics were analyzed by the authors (sleep doctor and oral and maxillofacial surgeons and mechanical, materials and design engineers) proposing the present design.

Device description

The device is a titratable mandibular advancement appliance. It consists of two independent prefabricated trays linked to each other by a protrusion mechanism.

Each tray contains a hard outer shell and a soft thermoplastic resin inner body. The inner body is comprised of medical grade, FDA approved ethylene vinyl acetate. The outer hard tray consists of a solid clear medical grade, FDA approved polyamide that adds strength and structural support. Appliance is made of a hypoallergenic component with no latex or bisphenol.

OA is available in one arch size only based on the most commonly used impression trays, although it allows slight adjustment to different arches width (Figs. 1 and 2).

The tray covers incisive labial surface and minimize the force on the teeth. This prevents dental movement that may occur in the long term. Low profile of the appliance allows minimum opening of the bite. Plastic trays utilize the undercut areas of the teeth for retention. This appliance is constructed from special thermoplastic resins and vinyl polymers, which make it comfortable and very retentive.

OA possesses sufficient retention forces to resist initial jaw opening forces and full mouth opening forces. The components are very durable, more or less indestructible, inexpensive and easy to keep clean. The estimated average life of OA is two years.

Intraoral fitting

OA can be fitted without the need of taking a patient’s dental impressions. It is simple to fit chair side from a boil and bite by dentists and other medical specialists, taking about 10 min and not requiring any special tools.

To prepare fitting is necessary to heat the appliance in boiling water for around 30 s. Thereafter, when the device was removed from the hot water and has cooled down for about 10 s, a physician or his or her trained staff inserts the tray into the mouth of the patient, with the plastic still warm and moldable, and then firmly bites the plastic. When doing this, patient sucks in while closing the mouth and pressing the tongue against the inner surface of the front teeth. In parallel, doctor presses his or her fingers on the outer walls of the mouthpiece (Figs. 3 and 4). Excessive part could be eliminated with a scalpel.

Protrusion mechanism

This feature provides incremental and adjustable levels of lower jaw advancement. The jaw is moved only as far as is required to alleviate snoring and reduce OSAS. The system consists of a rigid aluminum rack that slides on a polyamide ratchet located into the guiding system (Fig. 5).

The position of the jaw can be adjusted by moving the rack into, or out from, the guide. In this way, the ratchet may get locked into a certain position ensuring the length of the mechanism. Once the ratchet locks the rack, it is prevented from moving the mandible back. The guide includes an aluminum tab that can be depressed to release the ratchet so that the rack can be loosened or removed.

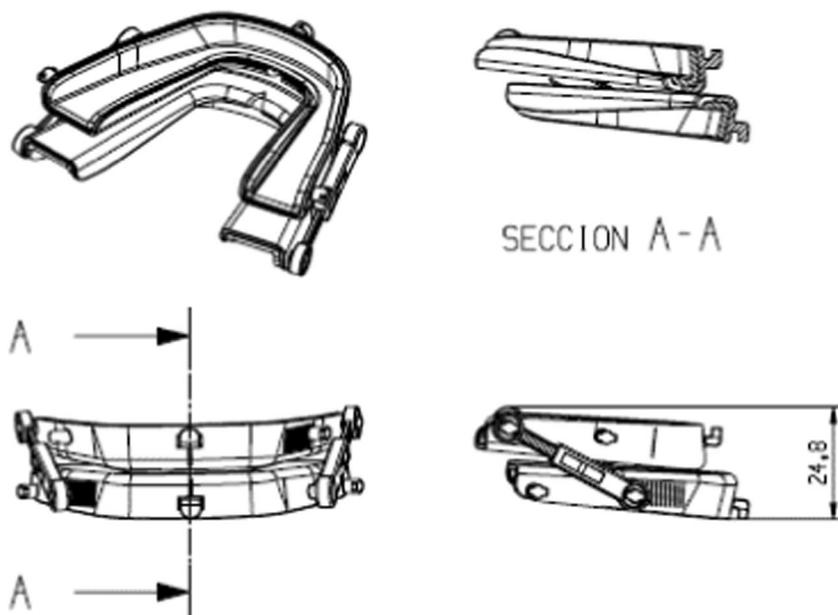
The protrusive element will extend downward 14 mm; this is equivalent to advancement on the lower jaw till 10 mm. By using an engraved millimeter triation scale on both sides of the tray we can exactly control the advancement with an accuracy of 1 mm. The adjustment is only possible extra-orally.

The adjustment mechanism is positioned on the sides of the device allows more room for tongue and full lip-seal. The protrusion mechanism is fixed to the splint using small rings that are articulated over a “t” button.

This fixation allows patients to move laterally and complete vertically without disengaging the appliance. The limited lateral movement of the lower jaw during appliance use is beneficial for TMJ comfort. OA permits normal mouth opening allows speech and drinking. Yawning and swallowing are not impaired by OA. Disassembling both trays is also necessary for cleaning.

If you put trays together, there is an open space for the tip of the tongue to go between the incisor teeth and it is large enough for emergency breathing. Vertical opening could be limited to 5–7 mm by interarch elastics on a hook in the front of the tray during sleep.

Fig. 1 Plan of the device design. General dimensions of the trays are in mm



Prototyping

Several concept tests were carried out to check the feasibility of the prototype and introduce improvements. The polyamide parts were high-resolution manufactured on 3d printer Formlabs® Form 1 by laser sintering of photopolymerizable resin. Sculpteo® sintered aluminum parts, the rack and the tab (Figs. 5, 6, 7 and 8).

Triation

Initially, the mandibular position of the device was preset at approximately midway between maximal protrusion and the normal bite position of the respective patients. Afterward, its position was advanced by 1 mm every 1 week by adjusting the rack, until patients were either most satisfied with symptom relief or they could not tolerate the increasing discomfort.

Patients were scheduled for a PSG with the OA in place at 3 months after final position of the device was achieved.

The patient should be evaluated every 6 months for the first year and at least annually and verify OA efficacy and occlusal stability, to check the structural integrity and ensure that there is maintenance of previously resolved symptoms.

Results and discussion

OAs is a safe and effective treatment for snoring and mild to moderate sleep apnea [19]. OA are smaller and more portable. OA offer advantages over CPAP in that they do not require a source of electricity and are less cumbersome, especially with travel.

Custom-made OA fabricated from a dental laboratory have been recommended for OSA treatment. However, most of

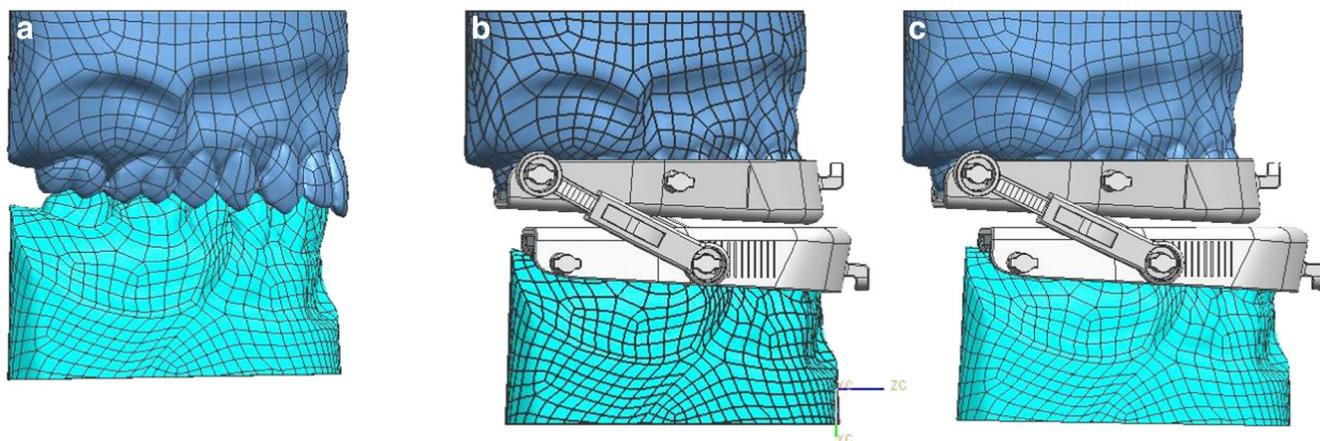
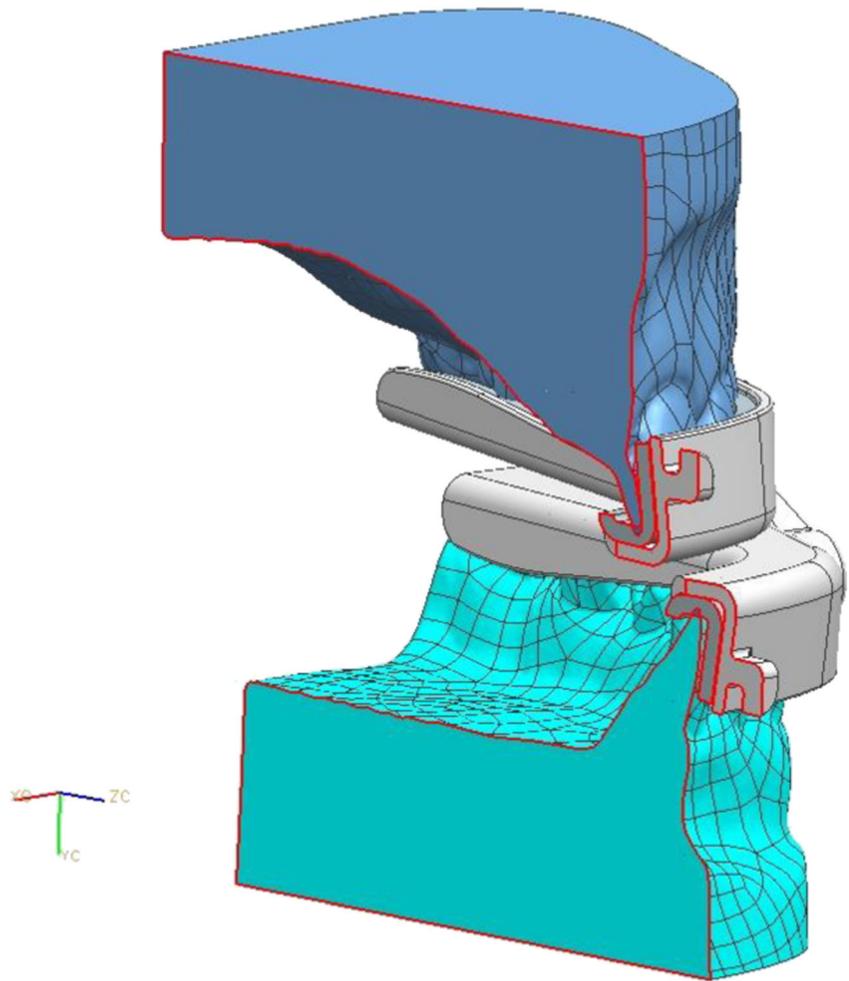


Fig. 2 Assembly of the device: **a** Result of the used mouth prototype; **b** Assembly of the device; **c** Protrusion of the lower jaw

Fig. 3 Cross-section of the mandibular advancement device



these have a relatively high cost and delay in treatment while the device is manufactured; this is not suitable for some

patients. Recently, prefabricated thermoplastic OA, also known as boil and bite OA, have been reported. These devices

Fig. 4 The Assembly of the Intraoral fitting in the device

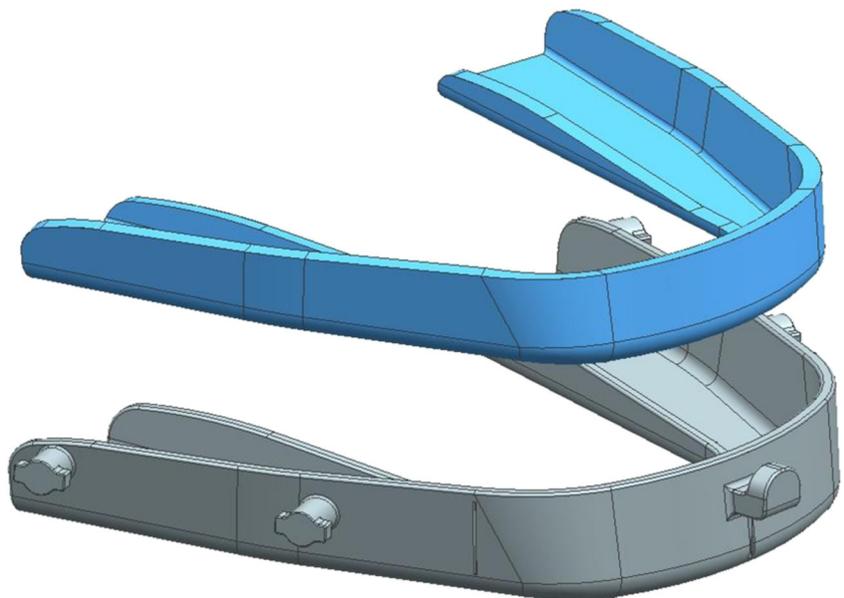
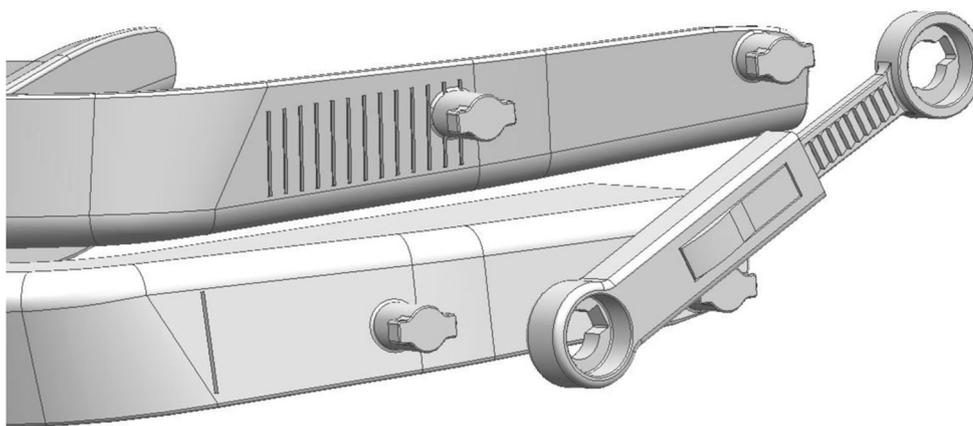


Fig. 5 Lateral view of the device with protrusion mechanism



offer several advantages over custom-made OA including lower cost, simplicity, and ready to use nature.

Thermoplastic adjustable OA, which costs approximately 100–150 €, is cheaper than custom-made OA, which cost 900 to 1.500 €. However, thermoplastic OA required to be replaced in 1–2 years while custom-made devices in 3–5 years.

AADSM suggests that a qualified dentist use a custom made, two-piece, minimal vertical opening and adjustable appliances over non-custom oral devices [10].

However, prefabricated thermoplastic OA could be fitted and adjusted by a basic trained otolaryngologist, pulmonologist, neurologist or sleep physician too. With learning curve, the time for fitting procedures could be reduced to only 10 min. The time per visit of the device adjustment could also be reduced to 5 min, and the final position of the device could be achieved within only 3 to 4 visits after an initial fitting in a majority of patients. Physicians and dentists must instruct adult patients to return for periodic office visits.

OA reduces the frequency and intensity of snoring, improve sleep quality for both patients who snore and their bed partners, and improve quality of life. Custom, titratable OA modestly reduces blood pressure in adult patients with OSA. There was no significant difference between OA and CPAP in the percentage of mild OSA patients achieving their target (AHI < 5) after treatment. For patients with moderate to severe OSA, however, the target AHI were significantly greater with CPAP than with OAs. CPAP is superior to OAs in reducing arousal index, and oxygen desaturation too. OA therapy should be reserved for use in severe OSA patients who did not benefit from CPAP therapy or were intolerant to CPAP [9].

A systematic review of the evidence has shown that custom, titratable OA reduce the AHI, arousal index, and oxygen desaturation index and increase oxygen saturation to a greater extent than do non-custom OA. However recent studies conclude that thermoplastic OA improved respiratory and somnolence parameters, with response rates similar to those published in the literature with other devices. Marty et al. reported

Fig. 6 Oral Appliances for Obstructive Sleep Apnea

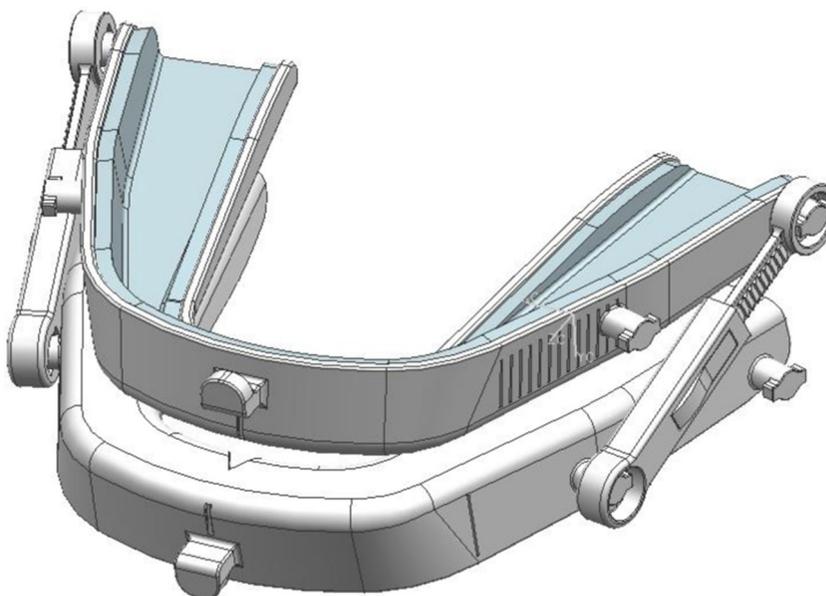
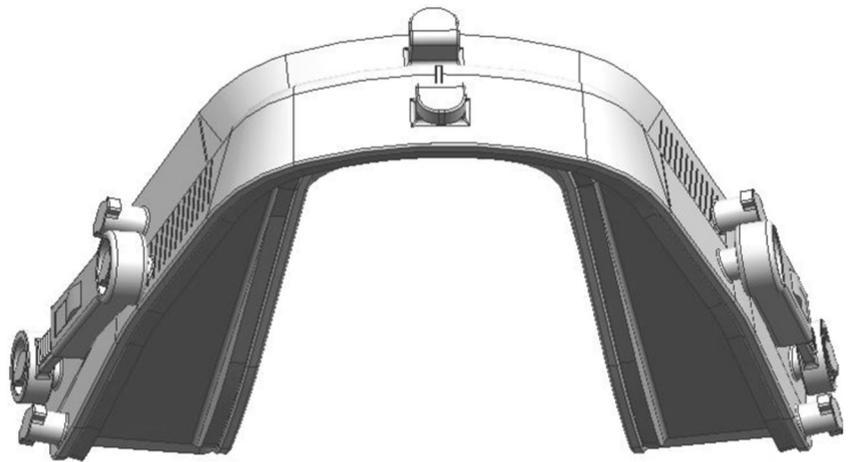


Fig. 7 Frontal view of Oral Appliances for Obstructive Sleep Apnea



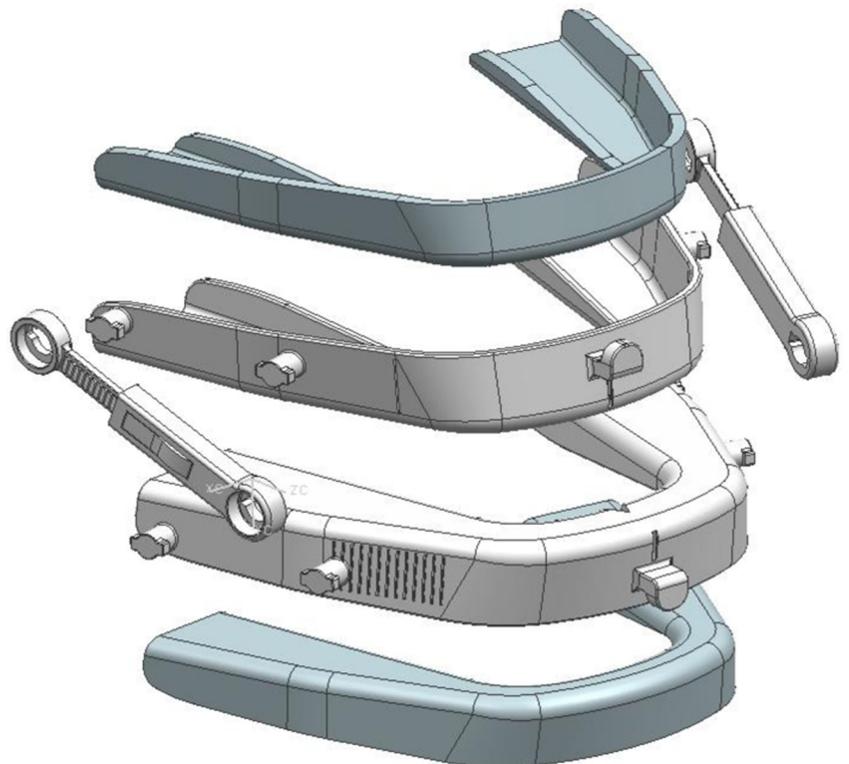
77.3% of patients with moderate OSA syndrome presented a complete response and compliance rates were high, with patients wearing the device 6.5 nights a week. Side effects and patient complaints were minor and transient [20]. Banhiran et al. publish the first study in Asians demonstrating that a thermoplastic OA, if done properly, is a practical treatment of OSA, with good outcomes [21].

Patient compliance and comfort was significantly greater with the OA than the CPAP. It considers good adherence using OA for >5 h every night on >5 nights a week. Mean reported compliance was lower in the thermoplastic OAs than in the custom-made devices [22]. Friedman compares custom-fit devices vs. thermoplastic OAs achieve higher rates of objective

improvement and cure of OSA, but significantly poorer 6-month compliance [23].

Thermoplastic appliance as a strategy to “screen” the efficacy of OA treatment in the individual patient with a less expensive appliance before constructing a more expensive custom-made OA could be reasonable. A comparison of patient characteristics with titratable thermoplastic OA concludes that the patients in whom treatment failed had significantly higher neck circumferences (39.3 cm vs. 37.5 cm) and higher baseline AHI values (26.6 vs. 18.0) than those in the group in whom treatment succeeded [24]. We recommend not excluding patients without dental problems by polysomnographic or anthropometric criteria. Patient with severe OSA

Fig. 8 Exploded-view drawing of Oral Appliances for Obstructive Sleep Apnea



who successfully responds to OA therapy have also been reported. Predictive index test (nasopharyngeal fibroscope or remote controlled mandibular positioner) may be very useful in clinical practice for physicians and dentist concerned with whether or not OA therapy has high chances of success, especially in moderate to severe OSA patients. A temporal thermoplastic appliance would be indicated in these cases [25].

The most common adverse effects found during the initiation of treatment are Temporomandibular Joint (TMJ) discomfort, dry mouth, and excessive salivation. Other common adverse effects included, halitosis, gingival pain, toothache, intraoral soreness and problems with retaining and fitting devices. These side effects were minor and revert in a few weeks or are well tolerated by patients. Almeida et al. reported 64.1% subjects were compliant with oral appliance therapy during long periods of use (5.7 ± 3.5 years) and they had an adequate control of snoring [26].

Loosening or flaring of lower anterior teeth or general tooth movement or Temporomandibular Disorder (TMD) could be irreversible side effects. A qualified dentist should provide appropriate appliance selection and provisions to maximize comfort and minimize the development of dental changes. Additionally, the qualified dentist should take appropriate measures to attenuate the possible development of jaw discomfort and muscle fatigue. These provisions may include morning exercises, the use of a morning repositioning [27].

Dental interventions could mitigate side effects. A dentist will make necessary modifications to accommodate patients who may have allergies to metals or acrylics, are teeth grinders, or have anatomical deviations. Exclusion criteria for thermoplastic OAs are insufficient teeth for adequate retention, active intraoral disease, periodontal disease, teeth mobility and pre-existing TMJ disorders.

The main requirement for an OA to be effective is the stable retention relationship to the teeth while the patient is asleep. Moreover, the appliance is suitable for placement and removal by the patient. Larger advancement is often related to higher efficacy, and smaller vertical opening is preferred by patients and leads to a decrease in pharyngeal collapsibility in most patients. The OA proposed has a mechanism that allows the mandible to be advanced in increments of 1 mm with a protrusive adjustment range of 10 mm. In addition, reversal of the advancement must be possible.

Conclusions

The objective of this paper is to present a new customizable and adjustable chair side OA. The device is a titratable mandibular advancement appliance. It consists of two independent prefabricated trays linked to each other by a protrusion mechanism. This appliance is constructed from special thermoplastic resins and vinyl polymers, which

make it comfortable and very retentive. The device described is a quick and safety introduction to mandibular advancement technology. Thermoplastic OAs are the most cost-effective option to treat primary snoring and mild, moderate and positional apnea. The device is also an alternative for noncompliant CPAP users or those who want a more accessible treatment alternative when travelling. Boil and bite OAs would be used like a predictor of treatment response in severe OSA patients or those patients who will undergo a drug induced sleep endoscopy. Prefabricated and adjustable OAs are primarily considered by sleep specialists and dentists for short-term use in order to check patient compliance, or as a first-line screening device to find out OSA respond to oral appliance therapy. It always makes sense from an economical point of view to start treatment at first with cheaper devices before doing a larger investment for the fabrication of custom made dental appliances.

Our prototype satisfies the requirements of an effective OA, in terms of stability, comfort, degree of mandibular advancement and efficacy. It is easy to fit and quickly titratable.

A qualified dentist or trained sleep doctor could mitigate dental side effects or occlusal changes and reduce their incidence. A strict follow-up is desirable.

Thermoplastic OAs are specially indicated in patients with the following characteristics: younger age, lower AHI and BMI, small neck size, positional OSA and female gender. Boil and bite OAs are contraindicated in patients with periodontal disease, dental mobility, poor dental hygiene and TMD.

Compliance with ethical standards

Conflict of interest Néstor Montesdeoca García declares that he has no conflict of interest. Fernando Blaya declares that he has no conflict of interest. Emilio Lechosa Urquijo declares that he has no conflict of interest. Enrique Soriano Heras declares that he has no conflict of interest. Roberto D'Amato declares that he has no conflict of interest.

Human and animal rights This article does not contain any studies with human participants performed by any of the authors.

This article does not contain any studies with animals performed by any of the authors.

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