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Research paper

Cam synthesis applied to the design of a customized mandibular advancement device for the treatment of obstructive sleep apnea

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ABSTRACT

Mandibular Advancement Devices (MAD) have proved to be effective in the treatment of slight to moderate Obstructive Sleep Apnea (OSA). These devices open the upper airways by keeping the jaw forward with respect to its resting position. To date, none of the available devices have taken into account the kinematic behavior of each patient's mandible. This work presents a customized MAD for the treatment of OSA. A study of the mandible kinematics is carried out to determine the relationship between mouth opening and mandible advancement. The device includes two cams, one on each side, to make the mandible move forward. The cam profile is designed using a Bezier cubic curve that is optimized by means of an evolutionary algorithm. The kinematics of each patient's mandible is taken into account to ensure that the jaw does not move backwards at any time while opening the mouth. A real case study is presented to validate the proposed methodology.

1. Introduction

Sleep apnea is a common disorder in which a person stops breathing while sleeping [1,2]. It is a leading cause of excessive daytime sleepiness. The most common type of sleep apnea is Obstructive Sleep Apnea (OSA). Untreated sleep apnea increases the risk of developing cardiovascular diseases such as arrhythmias, heart failure and stroke [3–5].

OSA is a chronic disorder that requires long-term treatment [6]. Apart from lifestyle changes, the main treatment options are Continuous Positive Air Pressure (CPAP), Oral Appliances (OA) and surgery. A CPAP machine is a pump connected to a face or nose mask that forces air into the nasal passages at mild pressure to keep the upper airways continuously open. Oral appliances open the upper airway, either by mandibular repositioning or by keeping the tongue forward with respect to its resting position. The most used OA are Mandibular Advancement Devices (MAD). Their main advantages compared to CPAP are that they are soundless, economic, manageable and do not require power supply.

Sutherland et al. [7,8] compiled the results of different works that confirmed that most patients preferred using OA to CPAP treatment. Moreover, the effectiveness of OA has been validated in numerous studies [9–14].

There is a great variety of MAD models [7]. There are one-piece and two-piece devices. The first ones are manufactured for a predefined protrusion value while most two-piece devices can achieve different protrusion levels [15]. Both of them

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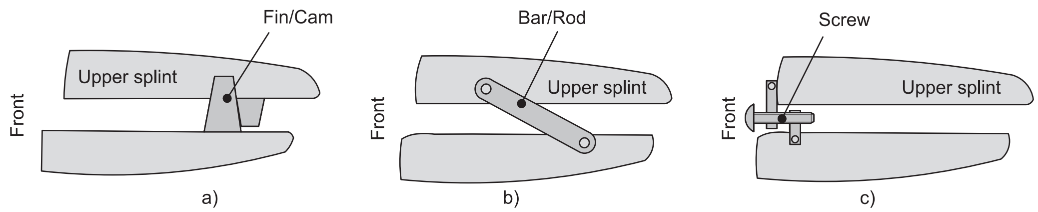

Fig. 1. Different systems used to couple the two plates of two-piece devices: (a) Fin or Cam (b) Bar or rod (c) Screw.

can be either prefabricated or custom-made. The splint of the latter is adapted to the patient's dentition in coordination with the dentist. It shows better results, mainly because of its improved overnight retention and protrusion control in contrast with the prefabricated devices [16].

There are different systems used to couple the two plates of two-piece devices, such as bars, elastic straps, springs, telescopic rods, tube connectors and lateral fins among others [17] (see Fig. 1). More than 70 oral appliances exist that have been approved by the FDA (U.S. Food & Drug Administration), each with their own advantages and disadvantages. The differences between the designs affect comfort and effectiveness. Customers prefer models with high freedom of mandibular movement (vertical and lateral) and maximum tongue space. Most patients do not feel comfortable with pieces occupying space in their mouth or metallic parts being in contact with their tongue. Devices with lateral fins (or cams) offer more comfort than other systems because they maximize tongue space, allow opening the mouth (to breathe, drink or talk) and permit mandibular lateral movement.

Comparative effectiveness studies for different MAD models have been accomplished by numerous researches [7,8,13,15,18–20]. These works have demonstrated that the effectiveness mainly depends on mandibular protrusion. Although the initial protrusion can be adjusted in all the studied models, protrusion varies in each model in a different way when patients open their mouth. Lawton et al. [18] affirmed that one of the patients′ main complaints was that they woke up during the night and that their mandible had "slipped back". Although this problem was associated to a specific MAD model, it remarked the importance of the device design. The devices should not allow the jaw to move backwards at any time while opening the mouth. Other technical disadvantages of most two-piece adjustable devices are breakages and frequent adjustments [14,18]. These last problems are quite common in devices with bars, rods and connectors and less frequent in those designed with fins. This is mainly due to the fact that they do not have moving metallic parts.

To date, none of the existing devices have been manufactured considering each patient's mandibular kinematics, hence operating differently in each individual. Bloch et al. [15] stated in their work that the effect of a device might vary among different patients. Yow [21] assured that some factors needed to be studied to reach optimal long-term effectiveness. The device design and patients′ characteristics stood out among these factors. According to Yow, it is essential to consider each patient's individual requirements. Texeira et al. also pointed out differences in individual responses to OA therapy [22].

Focusing on devices with lateral fins or cams being used nowadays, none of them can guarantee that the mandible does not move backward when opening the mouth. This is due to the fact that they use straight lines for the profiles of the fin (in the mandible) and the follower (in the maxilla). Some of these MADs try to mitigate this limitation by adding lateral elastic hoods to close the mouth during the night.

MAD design can be improved by using cams with an optimized profile to assure that the jaw does not move backwards while opening the mouth. Numerous studies have presented different approaches for either kinematic or dynamic cam optimization [23–35]. Some of them have proposed the use of genetic algorithms [25,28,32] or evolutionary techniques [31]. Other methods are based on a unified optimization strategy, including a single objective optimization procedure for kinematics and a dynamic model for the cam-follower mechanism [34,35]. The cam design for a MAD does not need to take into account dynamic behavior. The cam profile can be optimized to guarantee that a point of the jaw follows a predefined path. Sahu et al. [36] reviewed the basic curves and splines used to design cam profiles by different researchers in the last twenty years. Bezier curves have frequently been used when dealing with non-complex curves that can be represented with a low number of precision points [24,30].

In this research the design of a customized two-piece MAD that contemplates patients′ mandible kinematic behavior is presented. The protrusion control is assured by means of two cams, one at each side of the device. A deep study of mandible kinematics is carried out to establish the relationship between mouth opening and protrusion. In order to achieve the desired movement, the cam profile is optimized by means of an evolutionary algorithm developed by the authors of this work [37]. The final design guarantees that the mandible does not move backwards at any time while opening the mouth. The design also considers those factors that help to improve the comfort level such as high lateral movement, free tongue space, non-metallic pieces and a non-intrusive cam design.

This paper is structured as follows. In Section 2, a kinematic study of mandible movement is presented. Once the desired path for a point on the mandible has been specified, the optimal design of the cam is carried out in Section 3. Then, in Section 4, the developed method is applied to a real case. Section 5 analyses the results, which are used to create a virtual model in a 3D CAD-CAE parametric software application. This model is used to manufacture the device with a 3D printer. Finally, Section 6 draws the conclusions of this work.