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A Method for Evaluating the Mechanical Stress on Mandibular Advancement Devices

Tsung-yin Lin, Yi-yu Lee, Ching-hua Hung

***Abstract*—**This study focuses on the stress analysis of Mandibular Advancement Devices (MADs), which are considered as a standard treatment of snoring that promoted by American Academy of Sleep Medicine (AASM). Snoring is the most significant feature of sleep-disordered breathing (SDB). SDB will lead to serious problems in human health. Oral appliances are ensured in therapeutic effect and compliance, especially the MADs. This paper proposes a new MAD design, and the finite element analysis (FEA) is introduced to precede the stress simulation for this MAD.

***Keywords*—**Finite element analysis, mandibular advancement devices, mechanical stress, snoring.

I. Introduction

SNORING, the lay term for obstructive breathing during sleep, is one of the most prevalent of obnoxious human habits [1]. Loud snoring usually makes others feel noisy and uncomfortable. Snoring also influences the sleep quality of snorers' bed partners, because of the noise they do not get to sleep easily. The loudest snorer in the Guinness World Record is a Swedish, Kare Walkert, whose snoring sound reached the peak level of 93 decibels recorded in 1993 [2]. According to an investigation in the United States [1], 17% of snorers say that their snoring is very loud and can be heard in adjacent rooms. More than one-half of those who snore (57%) report that their snoring has bothered others. In addition, snoring not only disturbs others beside snorers in surrounding environment but also affects snorers themselves in physical conditions. Snoring causes the reduce of sleep quality leading to several medical problems, such as excessive daytime sleepiness, high blood pressure, increased risk for cardiovascular disease and cerebral vascular accident, and etc. These problems and related influences cost about 100 billion annually in lost productivity, medical bills, and industrial accidents [3]. It requires some improvements urgently. As described above, snoring is an extremely prevalent disorder that can lead to medical and social problems, and that forms impediments to good interpersonal relationships. In order to prevent these problems from becoming more and more serious, there are more and more researches making efforts on it. At first, there are some self-help remedies which are worth trying, such as weight deduction, avoiding getting overtired, avoiding alcoholic drinks and sleeping pills before bedtime, stopping any tobacco use, and sleeping sideways rather than on your back. Common therapies for snoring can be generally divided into surgical treatments and non-surgical treatments.

Surgical treatments mean that doing an operation on the upper airway to reduce obstructions in the passageway of the air. For example, to restrict as much excessive soft tissues as possible, to implant pillars on the soft palate, to advance the maxilla and mandible, etc. For non-surgical treatments, drugs and several types of devices have been proposed. But the curative effects on pharmacologic agents have not been proven as effective [4].

There are many non-prescription devices offered for sale on the market, but very limited data are available to support a beneficial effect of these devices on snoring and use in treating obstructive sleep apnea (OSA). Mandibular advancement devices (MADs), also termed as the Mandibular reposition devices (MRDs) are removable devices which are worn at night during sleep. Most devices require dental impression, bite registration, and fabrication by a dental laboratory. Those devices are fixed to upper and lower teeth and are adjusted to advance the mandible. The amount of protrusion is adjusted to meet the therapeutic requirements, comfort, and tolerance. Many devices have a fixed degree of advancement. Some are adjustable in a limited degree. Besides, two other therapies are considered as standard treatments for snoring and OSA which are supported by extensive scientific evidence for safety and efficacy. One is the positive airway pressure (PAP) appliance, and another is the oral appliance (OA). Those devices of PAP and OA are prescription devices that should be fitted and adjusted by doctors. Although, lots of therapies in treating snoring and OSA have been proposed already, they still have some problems, such as the efficacy and safety of therapies, the compliance and complications after treated, the failure of the device, the breakdown of the mechanism. Those shortages mentioned above are required to be solved.

II. Patent Analysis

The patent research is based on the patents published in the United States since 1976. According to the patents, the development and trend in specific techniques can be realized. In this study, the aim of patent search focuses on the mechanisms of anti-snoring devices especially the mandibular advancement devices. Referring to the patent research, the analysis results can be classified into several categories by functions which will be discussed in following subsections.

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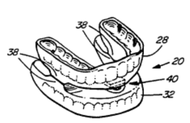
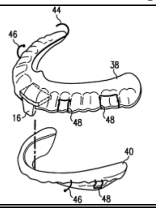
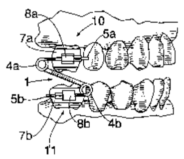
A. Fixer

The function of the fixer is used to install the mandibular advancement device in the oral cavity by fixing on the teeth. The usage of most MADs is inserting into the mouth during sleep and removing after getting up. Because of the requirement of removability, the fixer is usually designed just to fit but not mount on the teeth. Thermoplastic materials are usually used to form the fixer like a mouthpiece. Some appliances add clasps on to make MAD more stable during wearing time. Finally, a little part of MADs is fixed on the teeth by mounting directly. Those devices are usually used to treat the malocclusion, but the advancement also can eliminate snoring.

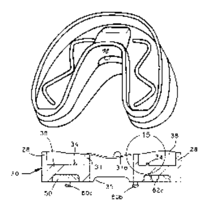
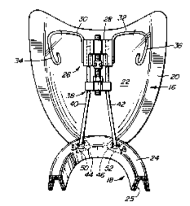
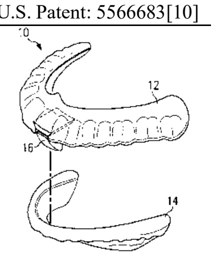
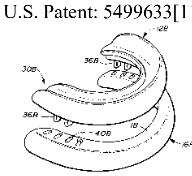
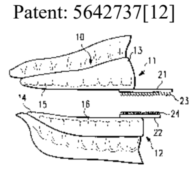
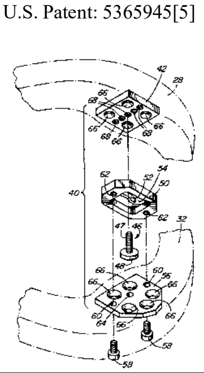
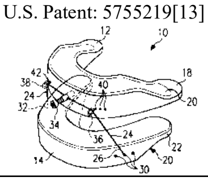
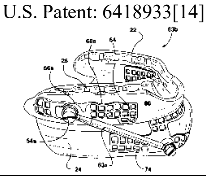
TABLE I
FIXERS OF THE MAD

Thermoplastic material	Clasp	Mount directly
U.S. Patent: 5365945[5]	U.S. Patent: 5427117[6]	U.S. Patent: 5645423[7]
		

B. Connector

In two-pieces MAD, connector connects the upper and lower mouthpiece adjustably. Different from the two-pieces MAD, the one-piece MAD which is entirety made by one material does not need the connector and cannot be adjusted. Therefore, all the MADs discussed here are the two-piece MAD which various connectors are used.

TABLE II
CONNECTIONS OF THE MAD

Button	Wire	Surface Contact
U.S. Patent: 5313960[8]	U.S. Patent: 5409017[9]	U.S. Patent: 5566683[10]
		
Post	Interlocking member U.S. Patent: 5642737[12]	Mount directly
U.S. Patent: 5499633[11]		U.S. Patent: 5365945[5]
		
Elastic Band	Linkage	
U.S. Patent: 5755219[13]	U.S. Patent: 6418933[14]	
		

C. Adjustor

In aforementioned descriptions, connectors are used to connect the upper mouth piece and lower mouthpiece to form the MAD. The adjustor is either as a part of the connector or as an individual component to perform the function of adjustment. The way of adjustment can be divided into two types: continuous adjustment and position-fixed adjustment. The direction of adjustment makes the mandible not only protraction and retraction but also elevation and depression.

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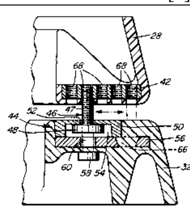
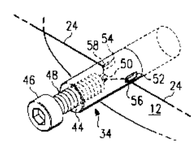
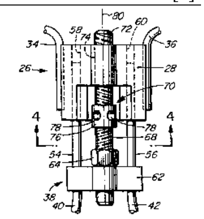
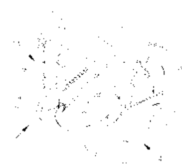
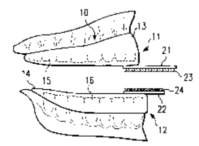
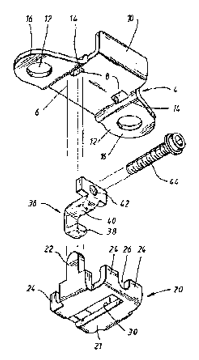
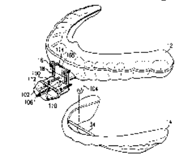
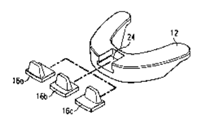
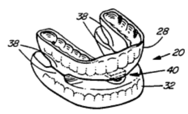
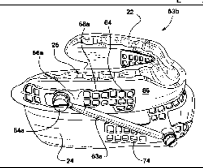
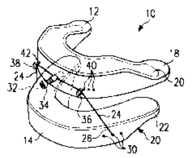
TABLE III
ADJUSTORS OF THE MAD

Series of aperture	Elastic band	Dual-thread screw
U.S. Patent: 5365945[5]	U.S. Patent: 5755219[13]	U.S. Patent: 5409017[9]
		
Conjugate shape	Interlocking member	Screw
U.S. Patent: 5570704[15]	U.S. Patent: 5642737[12]	U.S. Patent: 6845774[17]
		
Slot	Replace component	
U.S. Patent: 6305376[16]	U.S. Patent: 5427117[6]	
		

E. Acting Force

The force acting on mandible to advance it can be divided into the pulling force and the pushing force. The pulling force usually acts from the anterior portion of upper mouthpiece to the posterior portion of the lower mouth piece, the pushing force acts oppositely. However, most connectors are connected between the same portion of upper and lower mouthpiece. The force acts as a perpendicular force on the connector, and it is used to prevent the mandible backward which is similar to the pushing force. Therefore, the acting force includes perpendicular force, pushing force, and pulling force. In the mechanical terminology, they are shear force, compression force, and tensile force acting on the connector respectively.

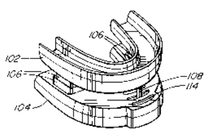
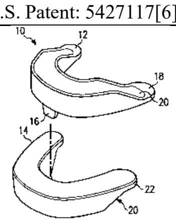
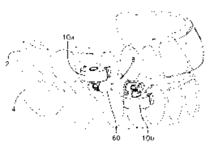
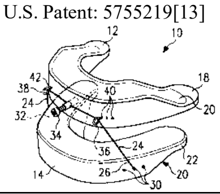
TABLE IV
ACTING FORCE OF THE MAD

Perpendicular force U.S. Patent: 5365945[5]	Pushing force U.S. Patent: 6418933[14]	Pulling force U.S. Patent: 5755219[13]
		

F. Lateral movement

A function of allowing limited lateral movement during using the MAD is required. The lateral movement can prevent facial muscles from stiff and avoid the TMJ dysfunction. That will make the patients feel more comfortable and tolerated in using the MAD. The methods which have promoted to patents include using slots, linkages, surface contact, and elastic bands. Using the slot and the linkage to perform this function are better than the surface contact and the elastic band. Because the slot and the linkage can limit the range of motion to ensure the therapeutic effect will not be affected by non-limited motion.

TABLE V
LATERAL MOVEMENT OF MAD

Slot U.S. Patent: 5868138[17]	Surface Contact U.S. Patent: 5427117[6]
	
Linkage U.S. Patent: 6012920[18]	Elastic band U.S. Patent: 5755219[13]
	

According to the patent reviews, more systematic results of analysis are presented. Those results can help to realize the disadvantages in prior products and find out the requirements. Further, those will be very useful for patent around that will prevent the new design from infringing other intelligence properties.

III. A NEW MAD DESIGN

Fig. 1 shows the new MAD which includes an upper tray, a lower tray, and a mechanism to maintain the jaw advancement. The upper and lower tray are made by acrylic resin, one kind of thermoplastic material, which can provide a good fit with dentition to make the well-fixed MAD. All of the concepts are going to use this method to perform the function of fixation. The mechanism of this MAD is composed of an upper plate, a bottom plate, a sliding plate, and two screws, as shown in Fig. 2. The upper plate is fixed on the upper tray. Within the upper plate, the space provides a moveable region for sliding plate to allow the lateral movement of the lower jaw. The “S” shape is designed to form the side wall of the upper plate. When the biting force applies on the bottom surface of the upper plate, the “S” shape makes less torque and tensile force applying to the fixed portion to avoid the failure of the MAD. The bottom plate fixes on the lower tray and assembles two screws together. These screws connect to the sliding plate with nuts to adjust its position and against the bottom plate moving backward.

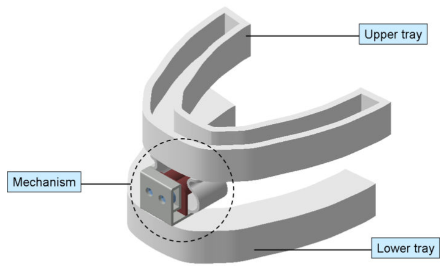


Fig. 1 Assembly view of the new MAD

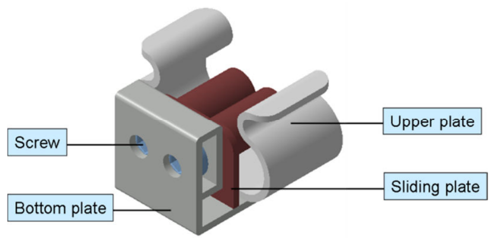


Fig. 2 Structure of the new MAD

IV. STRESS ANALYSIS (FINITE ELIMINATE METHOD)

After the new MAD is generated, the performances have to be evaluated. Preliminary studies for comparing the strength between different designs of mechanism are proposed by using the Finite Element Analysis method. The results of the finite element analysis can provide valuable information for realizing the stress distribution in material and predicting the failure will arise or not. All the conditions, such as load conditions, boundary conditions, and material property are required to be considered carefully to get more accurate results. The packaged software CATIA® is selected as the tool for establishing the finite element models and proceeding finite element analysis.

A. Load and Boundary Conditions

The load and boundary conditions should be set up according to the real situations and constraints. The MAD suffers from failure caused by sleep bruxism at present. Sleep bruxism is defined as a stereotyped movement disorder characterized by grinding or clenching of the teeth during sleep. The behavior of grinding applies force in horizontal direction and the clenching applies in vertical direction. The grinding force has not been presented in literatures until present. One study mentioned that an axial load of 100N is simulated to indicate as bruxism in their finite element analysis. Therefore, in this study, the force of 100N in vertical direction is simulated as the load condition on the MAD.

The fracture morphologies in the MAD are the detachment of the bonding interface between the resin and fixed portion of the mechanism, and the fracture of resin itself that the information is obtained from the experience of dentistry. Because the fracture usually not occurs on the tray or the interface of tray and resin, the scope of analysis in this study is only to simulate and compare the strength of resin and the bonding interface for each finite element model. The finite element model is set to fix at the interface between resin and tray. The bonding interfaces are simulated as perfect bond to calculate the stresses on those contact surfaces. The load with a value 100N is applied on the connector to meet to the real condition.

B. Material Properties

The material selection is limited to the materials for medical usage. Polymethylmethacrylate (PMMA) is a kind of self-curing resin that is used extensively for the fixation of prosthesis and orthodontic device in dentistry or other medical applications. It is a homogeneous and isotropic material which often fractures in the brittle manner. In the manufacture of the MAD, PMMA resin is used to fix the mechanism on the tray. The SUS 316L stainless steel, one kind of material for medical usage, is selected as the constructed material for the mechanism of conceptual designs. The commercial product TAP-T is made of titanium alloy (Ti-6Al-4V). All of the materials mentioned above have different properties that are listed in Table VI for using in FEA process.

TABLE VI
MATERIAL PROPERTIES [19]-[24]

	PMMA	Stainless Steel (SUS 316L)	Titanium Alloy (Ti-6Al-4V)
Young's Modulus (GPa)	3.8	193	116
Poisson Ratio	0.388	0.263	0.34
Density (kg/m3)	1180	7950	4420
Tensile Strength (MPa)	55.2	586	1016
Compressive Strength (MPa)	75.9		

C. Failure Criterion

It is necessary to introduce a suitable failure criterion for FEA results to judge whether the finite element model suffers from failure or not. In this study, two failure criteria are needed for the bonding interface and the PMMA resin respectively. The strength of bonding interface between PMMA and metal has been proposed in several studies in terms of shear bonding strength. The shear bonding strength for PMMA to bond with the stainless steel and titanium alloy are 25.24MPa [25] and 34.7MPa [26] respectively. This value is going to compare with the principal shear stress in FEA results.

PMMA resin often fractures in brittle manner, not in ductile. Therefore, the generally used criterion, Von Mises stress, is not appropriate for judging the fracture of PMMA. A study had presented the results of a test for the failure of PMMA under stresses, and shown the results behave following the Coulomb-Mohr criterion [27].

D. Analysis Results

Figs. 3 and 4 show the simulation results of bonding interface and resin in the upper portion of the MAD. The maximum principal shear stress on bonding interface is 3.04MPa. The design factor is 8.29 for the bonding interface and 8.39 for the resin. This means that the strength of bonding interface and resin is almost the same.

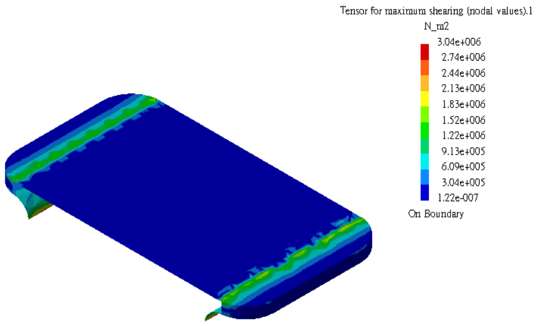


Fig. 3 Principal shear stress distribution on bonding interface (upper portion)

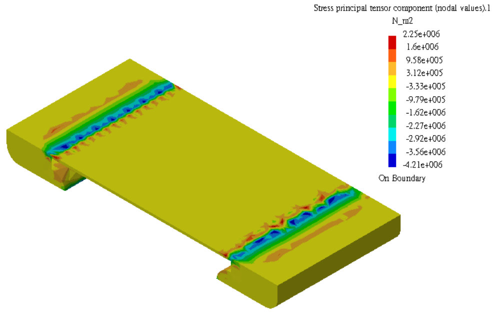


Fig. 4 Maximum principal stress distribution in the resin (upper portion)

Figs. 5 and 6 show the simulation results of bonding interface and resin in the lower portion of concept 1. The maximum principal shear stress on bonding interface is 0.76MPa. The design factor is 33.03 for the bonding interface and 32.56 for the resin. This means that the resin is weaker than bonding interface. Furthermore, the upper portion is weaker than the lower portion in this design.

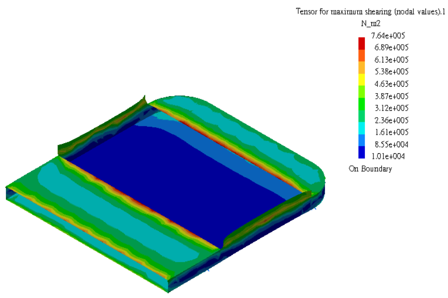


Fig. 5 Principal shear stress distribution on bonding interface (lower portion)

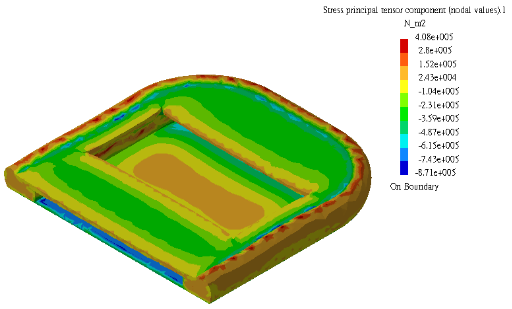


Fig. 6 Maximum principal stress distribution in the resin (lower portion)

V. Conclusion

Snoring is not only a very prevalent phenomenon during sleeping time but also an extremely prevalent disorder that influence the health of snorer. The obstruction of breathing leads to many symptoms in nocturnal and daytime that causes the variation of physical condition, the reduction of work efficiency, and even the happening of an accident. Therefore, the treatment of snoring is important. Based on the reviews of medical literatures, the MAD has been approved as an effective therapy for snoring and mild to moderate OSA. In this study, the finite element method is used to evaluate the stress conditions in MADs. An example is provided for a new MAD design. From analysis results, design factors can be obtained, and be considered as an index of strength.

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