國立交通大學

機械工程學系

碩士論文

下顎前置型口內止鼾裝置之機構設計

A Study on the Mechanism Design of the Mandibular Advancement Device

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中華民國九十六年六月

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摘要

本論文主要是針對下顎前置型之口內止鼾裝置做機構設計。透過市場調查、品質機能展開(QFD)、概念設計、有限元素分析法、決策矩陣法，提供一完整之工程設計流程。

在著手進行工程設計流程之前，首先要對打鼾機制進行了解。打鼾是一種普遍存在的現象，也是睡眠呼吸障礙症最顯著的表徵，忽略睡眠呼吸障礙症的治療將導致嚴重的健康問題。透過瞭解打鼾的機制以及診斷和治療方式之發展，確定了口內止鼾裝置之高療效以及病患高接受度，其中又以下顎前置型口內止鼾裝置為最。

市場調查包含市售產品調查及專利分析。根據市售產品調查，由於睡眠醫療逐漸受到重視，以及美國睡眠醫療學會(AASM)發表了口內止鼾裝置為打鼾之標準治療方式，自 1995 年起逐年皆有新的可調整式下顎前置型口內止鼾裝置問世。透過專利分析發現，目前的設計仍存在許多缺點有待改進，例如：佩帶舒適度、高價位、體積過大及不容易調整等，而在實際使用經驗上，更有裝置損壞之問題。

依據品質機能展開法之步驟，定義出顧客需求並將其轉換為可量化之工程規格，並評估市場現有產品規格，與其比較之後定義出最終的工程目標。接下來進行概念設計階段，使用子系統分解法將口內止鼾裝置分解成數個次系統，搭配使用腦力激盪法來結合出一系統化之程序，並產出四個最終概念。利用有限元素分析法對所有最終概念及一現有產品進行整體強度分析，來比較彼此間之效能優劣。最後，使用決策矩陣法，根據顧

客需求的重要程度，從所有最終概念中挑選出最符合客戶需求之設計，再與品質機能展開法中所定義出之工程目標進行比較，其中有所差異之部分將可做為未來改善之參考依據。

A Study on the Mechanism Design of the Mandibular Advancement Device

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ABSTRACT

This study focuses on the mechanism design of mandibular advancement devices (MAD). A complete engineering design process including market survey, quality function deployment (QFD), conceptual design and embodiment design is used.

Before the design process proceeded, the realization of snoring is necessary. Snoring is prevalent and is the most significant feature of sleep-disordered breathing (SDB). Ignore the therapies of SDB will lead to serious problems in health. Based on the research of mechanisms, diagnosis, and treatments of snoring, oral appliances are ensured in therapeutic effect and compliance, especially the MAD.

Market survey includes commercial product reviews and patent analyses. Due to pay more attention to the sleep medicine, the oral appliances are considered as a standard treatment of snoring that promoted by American Academy of Sleep Medicine (AASM). There are more and more adjustable MADs developed since 1995. According to the patent analyses, there are many drawbacks existing in the present design, such as uncomfortable, high cost, bulky volume, and complex to adjust, etc. According to the experiences of usage, this device

is suffered from the failure problem which requires to be improved in the future.

In accordance with the procedure of QFD, the customers' requirements are obtained and translated to the measurable engineering specifications. Evaluate the commercial product to ensure the competition specifications, and set the engineering target at the end of the QFD process. In the conceptual design phase, a systematic procedure for generating concepts combines the functional decomposition which is used to divide the MAD into several sub-functions and the brainstorming method which is used to generate concepts for sub-functions. After that, four concepts are generated by the conceptual design process. The finite element analysis (FEA) is introduced to proceed the strength simulation for all of the concepts and one commercial product to evaluate the performance between each other. Finally, the decision-matrix method is used to evaluate all of the concepts based on the customers' requirements and their own importance to select the best one. The comparison between engineering targets and specifications of the final design is carried out to estimate the performance of the final design, and to be considered as a criterion for further design works.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

NOTATIONS

σ_1	Maximum Principal Stress
σ_3	Minimum Principal Stress
S_t	Tensile Strength
S_c	Compressive Strength
n_d	Design Factor

ABBREVIATIONS

AASM	American Academy of Sleep Medicine
ADSA	American Sleep Disorders Association
AHI	Apnea-hypopnea Index
ANP	Atrial Natriuretic Peptide
APAP	Automatic Self-adjusting Positive Airway Pressure
BPAP	Bilevel Positive Airway Pressure
CDRH	Center for Devices and Radiological Health
CPAP	Continuous Positive Airway Pressure
CSA	Central Sleep Apnea
ECG	Electrocardiography
EDS	Excessive Daytime Sleepiness
EEG	Electroencephalography
EMG	Electromyography
ENDS	External Nasal Dilator Strips
EOG	Electrooculography
ESS	Epworth Sleepiness Scale
FDA	Food and Drug Administration
FEA	Finite Element Analysis
GAHM	Inferior sagittal mandibular osteotomy and genioglossal advancement with hyoid myotomy and suspension.
HR	Heart Rate
IND	Internal Nasal Dilators
LMG	Laser Midline Glossectomy
LSAT	Lowest Oxygen Saturation

MAD	Mandibular Advancement Device
MMO	Maxillomandibular Osteotomy and Advancement
MRD	Mandibular Reposition Device
MSAS	Mixed Sleep Apnea Syndrome
OA	Oral Appliance
OSAHS	Obstructive Sleep Apnea-hypopnea Syndrome
OSA	Obstructive Sleep Apnea
OSAS	Obstructive Sleep Apnea Syndrome
OSDB	Obstructive Sleep-disordered Breathing
OSHS	Obstructive Sleep Hypopnea Syndrome
PAP	Positive Airway Pressure
PMMA	Polymethylmethacrylate
PSD	Primary Snoring Disorder
PSG	Polysomnography
QFD	Quality Function Deployment
REM	Rapid Eye Movement
SDB	Sleep-disordered Breathing
SPL	Soft Palate Lift
TMJ	Temporomandibular Joint
TRD	Tongue-retaining Device
UARS	Upper Airway Resistance Syndrome
UPPGP	Uvulopalatopharyngoglossoplasty
UPPP	Uvulopalatopharyngoplasty
USPTO	United States Patent and Trademark Office

CHAPTER 1

INTRODUCTION

1.1 Sleep-disordered Breathing

Respiration plays the key role of human life which moves air in and out from the lungs. Oxygen and carbon dioxide can be exchanged between air and blood to supply the needs of all activities in human body. The passageways between the ambient environment and the gas-exchange unit, the alveoli, in the lungs are called the conducting airways. The conducting airways are divided into the upper airways and the lower airways, as shown in Fig. 1.1-1 [1] [2]. If there is some resistance occurred in these airways to reduce the quantity of inspiration into the lungs when the time of sleeping, it might be the symptom of sleep-disordered breathing.

1.1.1 Anatomy of Upper Airways

The upper airways are composed of the nose, oral cavity, pharynx, and larynx, as shown in Fig. 1.1-2. The larynx represents the transition between upper and lower airways. The primary functions of the upper airways are to humidify and warm the inspired air, and to filter out and prevent foreign materials from entering the tracheobronchial tree.

According to Fig. 1.1-2, the maxilla forms the anterior portion of the nasal cavity floor, called the hard palate. The posterior portion of nasal cavity floor is the muscular soft palate [3]. After the inspired gas passes through the nasal cavity, it enters the pharynx. The pharynx is divided into three parts which are the nasopharynx, oropharynx, and laryngopharynx. The nasopharynx is located on the posterior portion of the nasal cavity and superior to the level of soft palate. Next to the nasopharynx, the oropharynx lies between the soft palate superiorly and the base of the tongue inferiorly. The laryngopharyx, also called the hypopharynx, is the space below the oropharynx and above the entrance of the esophagus.

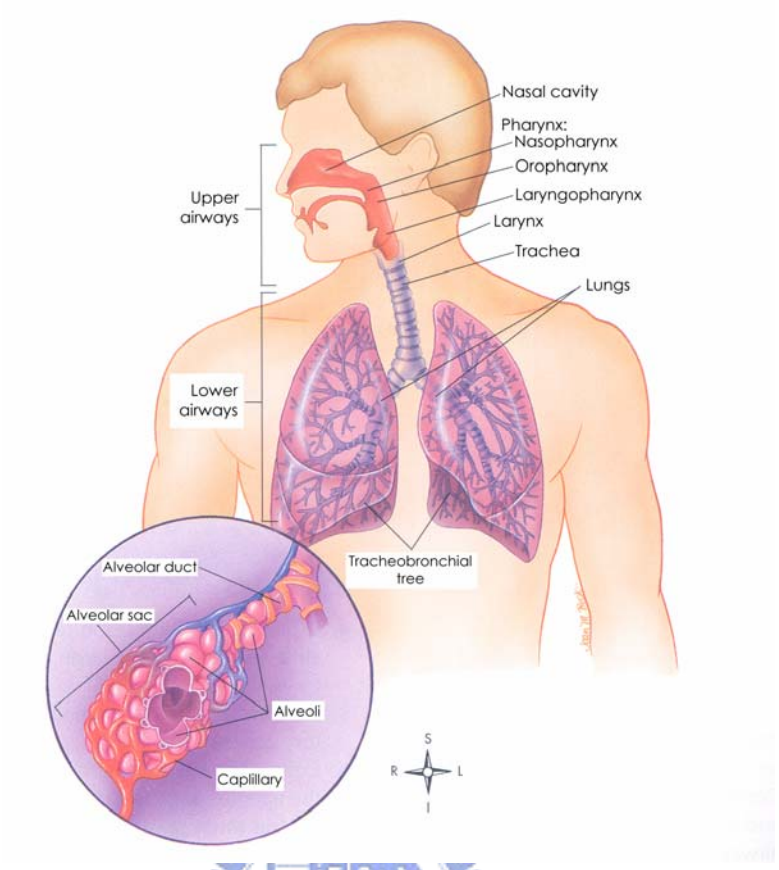


Fig. 1.1-1 Structure of the respiratory system [1]

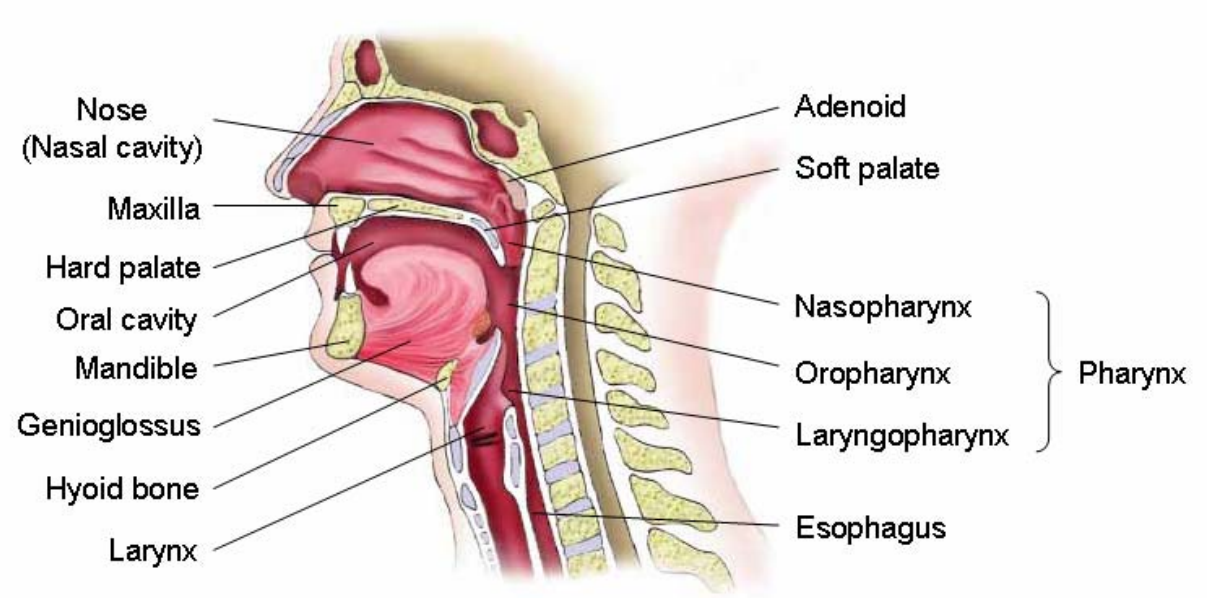


Fig. 1.1-2 The sagittal section of the upper airway [2]

The resistance of the airflow through the nose is greater than that through the mouth. The reason is that the structures in the nose are designed to accomplish the filtering, warming, and humidifying functions. The raising resistance sometimes causes people to switch to mouth breathing. Therefore, the oral cavity is considered as an accessory respiratory passageway to ensure the quantity of sufficient inspiration for needs.

1.1.2 Levels of Sleep-disordered Breathing

As the sleep-disordered breathing (SDB) occurred, it may possibly affect the patient's sleep quality possibly. The patient's sleep fragment will cause awakening or partial awakening, or disrupt the patient's sleep. It makes the patient feel restless and sleepiness in the daytime. SDB is a term including several different states of breathing disorder. In accordance with the degrees of the severity, from mild to severe, it can be classified progressively as follows [4]:

- Primary snoring disorder (PSD): snoring without sleep disruption and without excessive daytime sleepiness (EDS).
- Upper airway resistance syndrome (UARS): usually accompanied by snoring. Besides, increasing respiratory effort against airway resistance may lead to sleep fragmentation and cause excessive daytime sleepiness.
- Obstructive sleep hypopnea syndrome (OSHS): snoring with partial airway obstruction, but not complete apneas, associated with excessive daytime sleepiness and other symptoms of OSAHS.
- Obstructive sleep apnea-hypopnea syndrome (OSAHS): snoring with documented hypopneas and apneas, associated with excessive daytime sleepiness and other symptoms of OSAHS.
- Obstructive sleep apnea syndrome (OSAS): snoring with documented apneas,

associated with excessive daytime sleepiness and other symptoms of OSAHS, practically synonymous with OSAHS.

- Mixed sleep apnea syndrome (MSAS): combination of central sleep apnea (CSA) and obstructive sleep apnea (OSA), associated with symptoms of OSAHS.

Therefore, snoring can be seen as an obvious representation of the sleep-disordered breathing during human sleep.

1.2 Motivation

Snoring, the lay term for obstructive breathing during sleep, is one of the most prevalent of obnoxious human habits. In the adult population in the United States, 59% of them have had the experience of snoring. Furthermore, 32% of them snore at least three nights a week. The person who snores more than three nights a week is called as a habitual snorer; and further, 24% of these adults snore every night or almost every night [5]. Therefore, snoring is really a serious problem that could not be disregarded and ignored.

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 [6]. According to an investigation in the United States [5], 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 [7]. 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 resect 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. 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.

1.3 Thesis Outline

In this study, a complete engineering design process is performed to bring out a new design of mechanism in the mandibular advancement device. According to the market survey, QFD process is used to generate the engineering specifications and to ensure that all engineering specifications are conformed with the customer requirements. Based on the results of QFD, a conceptual design process will be proceeding to generate new concepts. The final target of this study is to generate a new, feasible, and durable mandibular advancement device after completed whole design process.

Chapter 2 introduces the pathophysiology of snoring by which the mechanisms of snoring will be realized. Furthermore, the diagnosis and treatments are presented to assist the overall understanding in the medical field. Finally, to make sure of the mandibular advancement device is one of effective therapies and treatment with high efficacy.

Chapter 3 focuses on the present developments on the mandibular advancement devices. According to the survey of patents and products on market, the patent analysis, the functions of components in mandibular advancement devices, and the comparisons of products will be proposed in this chapter.

Chapter 4 introduces the QFD method to proceed a procedure from collecting customers' requirements, evaluating the relative importance, evaluating the competitive products, generating the engineering specifications, and defining the target specifications at the end.

Chapter 5 applies the functional decomposition and the brainstorming method to provide a systematic procedure to generate complete concepts of the MAD. Brainstorming method is used to generate concepts for every sub-function initially, and then the complete conceptual design is generated by combining those concepts of sub-functions.

Chapter 6 introduces the Finite Element Analysis method to simulate the stresses under a force, and evaluate the strength of four concepts generated from chapter5 and one commercial product. The decision-matrix method is also introduced in this chapter in order to evaluate all the concepts for selecting the best one.

Finally, chapter 7 makes some conclusions for this study and promotes some recommendations for further researches in the future.

CHAPTER 2

SNORING AND OBSTRUCTIVE SLEEP APNEA

2.1 Pathophysiology of Snoring

Snoring and obstructive sleep apnea may be considered under the scope of obstructive sleep-disordered breathing (OSDB), which is a type of sleep-disordered breathing. It means that snoring occurs because of the obstructions formed in the airways. Snoring can be defined as an inspiratory noise produced by vibration of the soft parts of the oropharyngeal wall [8]. When portions of the soft parts collapse, that will form the obstructions in the airways and lead to snoring.

2.1.1 Stages of Sleep

The stages of sleep were discovered in the 1950s [7] in the experiment of brain wave using the electroencephalogram (EEG) during sleep. Neurophysiologists recognize two phases of sleep, slow-wave sleep and paradoxical sleep. The initial phase, called slow-wave sleep, can be divided into four stages, each successive stage having a particular EEG pattern. As the proceeding of slow-wave sleep from light sleep (stage 1) to deep sleep (stage 3 and 4), the EEG patterns have slower frequency and higher amplitude progressively, and the patterns are the alpha rhythm, theta rhythm, and delta rhythm in sequence [9], as shown in Fig. 2.1-1. Besides, the tension in the skeletal-muscles become progressively more relaxed as slow-wave sleep progresses until the stage 4 is achieved.

Sleep always begins with the slow-wave sleep progression from stage 1 to stage 4 which normally takes 30 to 45 minutes and then reverses itself. After the slow-wave sleep, the second phase of sleep, paradoxical sleep, also called rapid eye movement (REM) sleep, comes up. During the REM sleep, the EEG pattern characterizes as resemblance to the alert and awake state, the beta rhythm, however, the behavioral characteristic of sleep continues at this

time, and the sleeper is difficult to be aroused by others. The REM sleep period usually lasts 10 to 15 minutes. At this time, the lower muscle tone leads to paralysis of skeletal-muscle except the eye muscles and the muscles of respiration. If sleep uninterrupted, it continues slow-wave sleep and REM sleep by turns, called the sleep cycle, until awakening, as shown in Fig. 2.1-2.

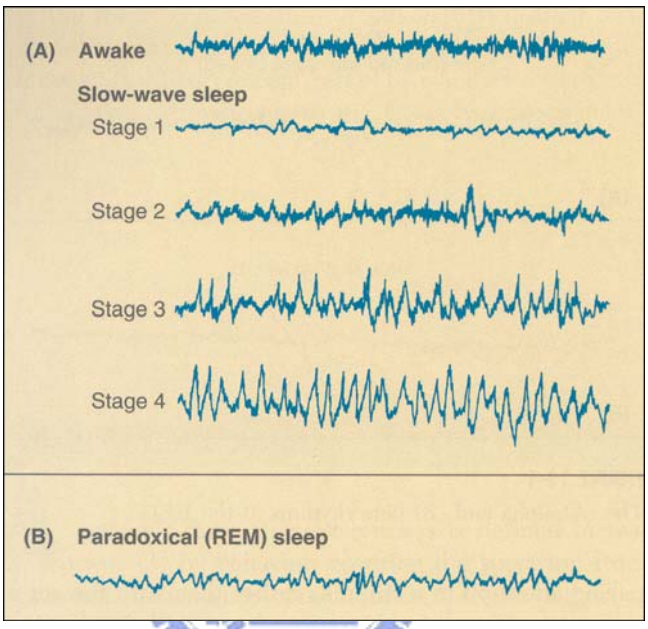


Fig. 2.1-1 EEG patterns in awake, slow-wave sleep, and REM sleep states [9]

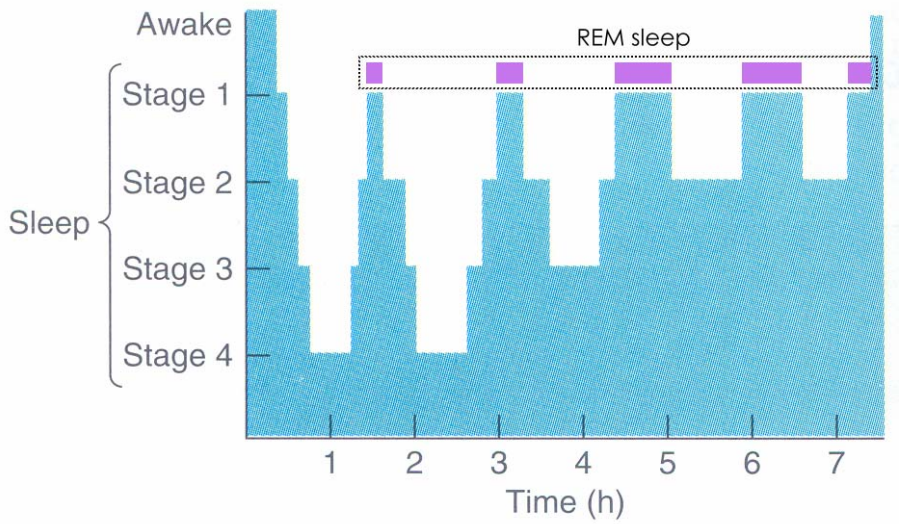


Fig. 2.1-2 A typical night's sleep record of an average young adult [9]

2.1.2 Mechanisms of Snoring

The origin sounds of snoring generation is from the collapsible part of the airway without rigid support. Snoring generation involves the soft palate, uvula, tonsils, base of tongue, pharyngeal muscles, and pharyngeal membranes, as shown in Fig. 2.1-3. Five causes below, acting either alone or combination, contribute to snoring:

- Poor muscle tone in the palate, tongue, and pharynx:

  This is the cause of most adult snoring. In deep sleep stages, such musculature fails to participate in the respiratory cycle to open the airway during inspiration. The dilator effect of the pharyngeal muscles and the protrusive effect of the genioglossus muscle are inadequate. Thus, the tongue falls backward into the airway and vibrates against the floppy pharynx during inspiration. Snoring may appear as soon as the snorer falls asleep in stage 1, increasing progressively with deepening of slow-wave sleep and reaching a peak in stage 4.

- Space-occupying masses or tissues in the pharynx:

  Children who snoring almost have enlarged tonsils and adenoids. Many adults also have large tonsils which form the obstruction in the airway and are notable in obese persons. Those excessive bulky pharyngeal tissues cause narrowing of the air passageways and lead to snoring.

- The receding mandible:

  It may not be effective in keeping the tongue sufficiently forward when the muscles relaxed in sleeping time.

- Excessive length of the soft palate and uvula:

  The long soft palate narrows the nasopharyngeal aperture. As it dangles in the relaxed situation, its lower edge often lies below the horizontal plane of the tongue

and it acts as a noisy flutter valve during inspiration. If the patient lies in the supine position, that will lead to a more apparent snoring. Besides, a long uvula makes matters even worse.

- Obstructed nasal airways:

  The rising resistance of airflow in the nose requires extra effort to inspire the air. This increases the vacuum in the airway and produces a negative pressure to draw together the floppy tissues in the collapsible parts where they vibrate and cause snoring. Therefore, many persons who ordinarily do not snore may snore when they catch a cold or get an allergy attack.

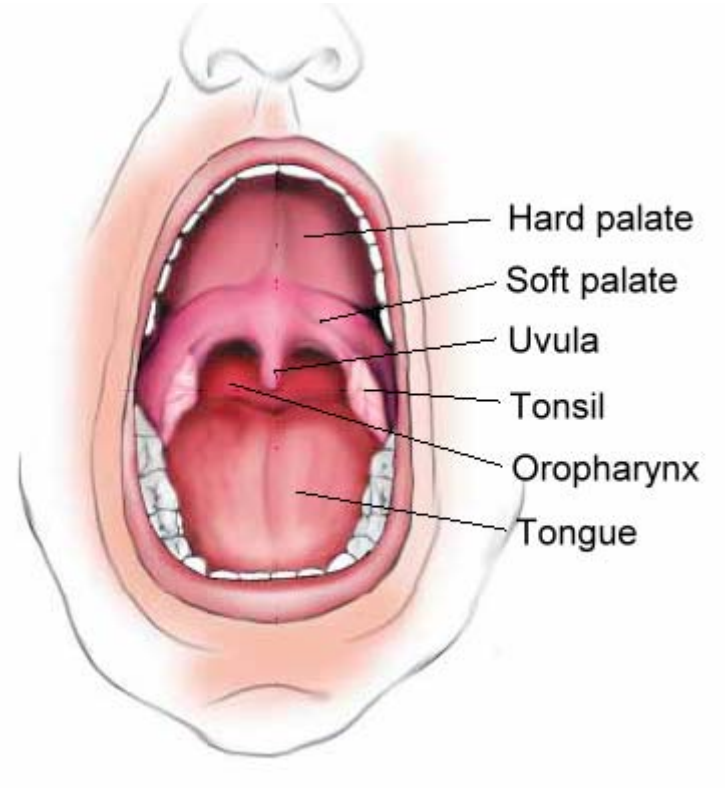


Fig. 2.1-3 Oral cavity [2]

As described above, those are the causes of snoring and they may be influenced by several factors, such as anatomy [10], age, sex, hormones, Genetic factors, and etc. These factors may affect the thickness of soft tissue in the upper airway, the muscle tone during rest,

the pharyngeal cross sectional area, the upper airway dilator activity, and etc [11]. Without doubt, anatomy is the most important factor when dealing with the patient with snoring and it can be divided into the factors which related to the soft tissue or the skeleton; and further, it is more obvious than other factors that leading to snoring.

2.2 Evaluation of Obstructive Sleep Apnea

Apnea is a Latin medical term meaning “without breathing.” When the interruption to breathing occurs during sleeping time and is caused by an obstruction in the airway, it is “obstructive sleep apnea.” Obstructive sleep apnea is the most severe state of obstructive sleep-disordered breathing and usually accompanies severe snoring and other symptoms either in sleeping time or in daytime. Sleep apnea was first discovered in the search for the pathophysiological process behind the pickwickian syndrome with nocturnal polygraphic monitoring of abnormal breathing patterns during sleep in 1960s. At present, several methods have been developed to diagnose the probability of suffering from OSA.

2.2.1 Symptoms

Typical symptoms of obstructive sleep apnea include snoring, observed apnea, excessive daytime sleepiness, or a combination of them. When any signs are expressed that relate to sleep apnea, the patient and observer should be questioned about other known symptoms, as shown in Table 2.2-1.

Since the patient is asleep, he or she is often not aware of many nocturnal signs. The bed partner of patient or other observer is needed to determine the severity of snoring, snorting, struggling to breathe, irregular breathing, and observed apnea. Abnormal movements during sleep, such as thrashing in bed and arm or leg jerks, would be known only by an observer. Patients just feel restlessness after they wake.

Frequent urination during the night is a common occurrence in patient with moderate to

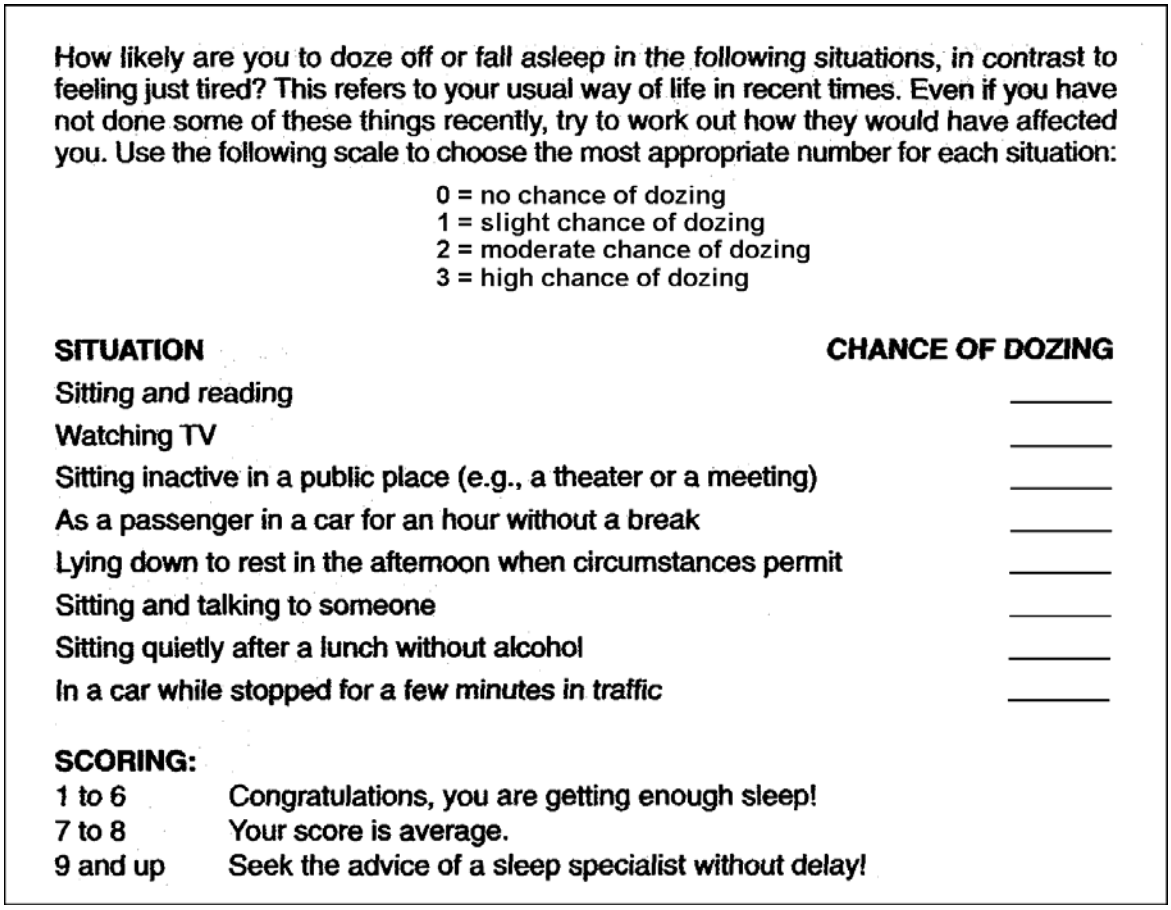
severe sleep apnea. Associate with arousals, decreased esophageal pressure, and hypoxemia, the increased atrial natriuretic peptide (ANP) stimulates urinary excretion. This symptom is more common in children than in adults that causes enuresis.

Table 2.2-1 Nocturnal and daytime symptoms of OSA [4]

Nocturnal Symptoms	Snoring, snorting, struggling to breathe, irregular breathing, and observed apnea Trashing in bed, disrupted sleep Nocturnal gasping or choking Frequent awakenings Nocturnal palpitations Insomnia
Daytime Symptoms	Nonrestorative sleep, morning fatigue Excessive daytime sleepiness Memory deficits, forgetfulness Troubled concentration Morning headaches Morning dry mouth or sore throat Depression, irritability Impotence, sexual dysfunction

Daytime tiredness or fatigue is a common complaint of OSA patients. The cause of excessive daytime sleepiness is due to a combination of arousals, sleep fragmentation, and reductions in delta and REM sleep. Patients may also complain of inability to concentrate and of deterioration of memory and judgment. The EDS also leads to psychiatric disorder, such as depression and irritability, and the suddenly fall asleep which will cause car accidents during

driving time. A widely used short questionnaire, the Epworth Sleepiness Scale (ESS), has been developed to measure the severity of daytime sleepiness, as shown in Fig. 2.2-1. The lowest score is zero and the highest twenty-four, and above ten is considered abnormal.



How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you. Use the following scale to choose the most appropriate number for each situation:

0 = no chance of dozing
1 = slight chance of dozing
2 = moderate chance of dozing
3 = high chance of dozing

SITUATION	CHANCE OF DOZING
Sitting and reading	_____
Watching TV	_____
Sitting inactive in a public place (e.g., a theater or a meeting)	_____
As a passenger in a car for an hour without a break	_____
Lying down to rest in the afternoon when circumstances permit	_____
Sitting and talking to someone	_____
Sitting quietly after a lunch without alcohol	_____
In a car while stopped for a few minutes in traffic	_____

SCORING:

1 to 6	Congratulations, you are getting enough sleep!
7 to 8	Your score is average.
9 and up	Seek the advice of a sleep specialist without delay!

Fig. 2.2-1 Epworth Sleepiness Scale [12]

Morning headaches are attributable to the presence of sleep apnea. The nocturnal oxygen desaturation is the cause of morning headaches. There are still other morning symptoms such as the morning dry mouth or sore throat that is due to mouth breathing and snoring.

Impotence, sexual dysfunction, and loss of sex drive are also linked to the presence of sleep apnea with a severe state. It is not known if the cause of impotence is similar to other symptoms. Sexual dysfunction is usually reversible with treatment of the sleep-disordered breathing.

Many symptoms are known to discriminate patients with or without OSA probability. If someone snoring with those symptoms, he or she should seek the further examination from a sleep specialist as soon as possible.

2.2.2 Diagnosis

A sleep study should be applied to the patient with sleep-disorder breathing. The aims of testing are to establish the diagnosis, to determine the frequency and severity of abnormal respiratory events, and to evaluate the physiologic consequences during sleep. The American Academy of Sleep Medicine (AASM, formerly the American Sleep Disorders Association [ADSA]) has defined four types of sleep testing: standard polysomnography (PSG), which requires the presence of a trained technician, and three variations of unattended studies [4], see Table 2.2-2.

Table 2.2-2 Types of sleep studied for evaluation of sleep breathing disorders [4]

	Type 1	Type 2	Type 3	Type 4
Monitors	7 or more	7 or more	4 or more	1-2
EEG	Required	Required	Optional	Not measured
EOG	Required	Required	Optional	Not measured
Chin EMG	Required	Required	Optional	Not measured
ECG/HR	ECG	ECG or HR	ECG or HR	Optional
Airflow	Required	Required	2 of effort or 1 airflow	Optional
Respiratory effort	2 channels	2 channels	1 of effort	Optional
Oximetry	Required	Required	Required	Usual/optional
Leg movement	Usual/optional	Optional	Optional	Not measured
Personnel	Present	Absent	Absent	Absent
Intervention	Possible	Not possible	Not possible	Not possible

EEG: electroencephalography, EOG: electrooculography, EMG: electromyography, ECG: electrocardiography, HR: heart rate

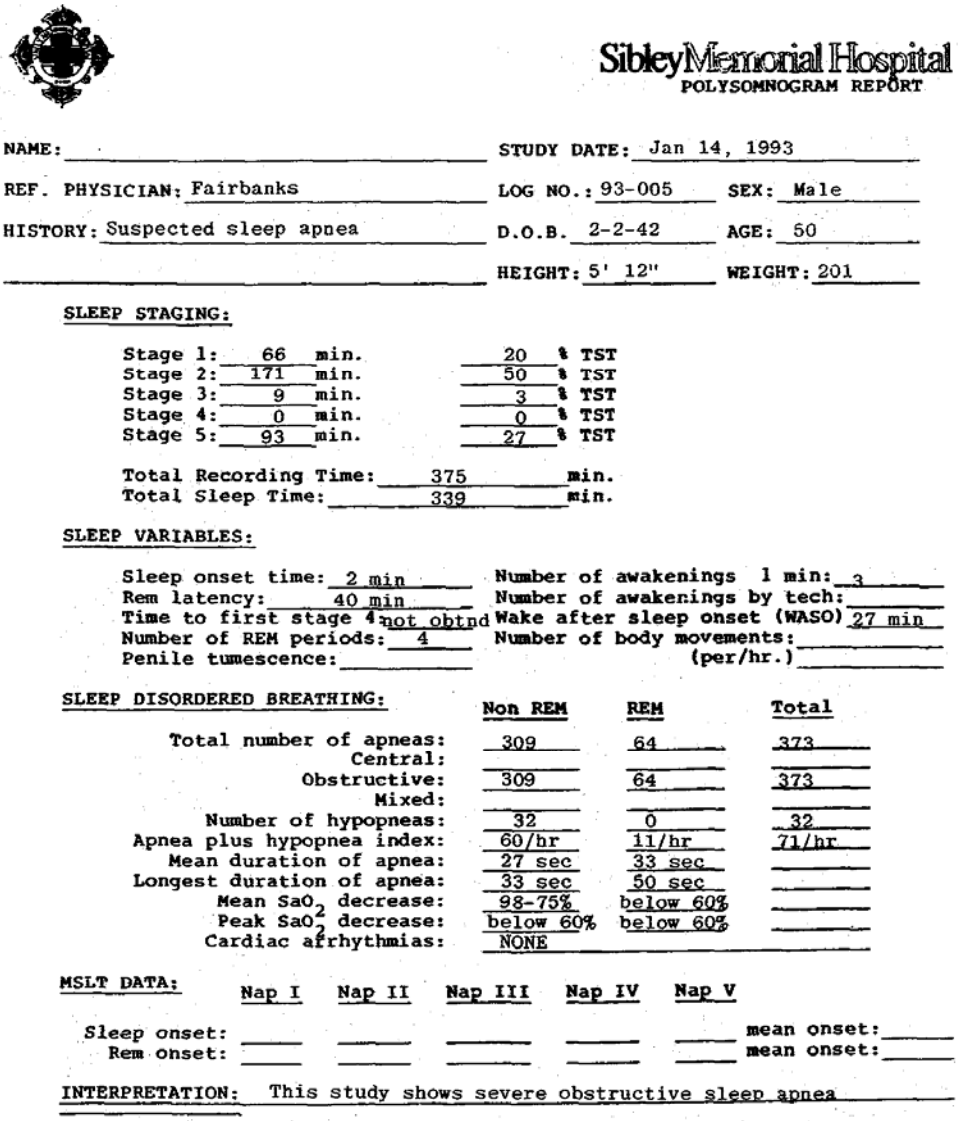
Among all the types of studies, the type-1 sleep study is the overnight polysomnography which is routinely indicated for the diagnosis of sleep-disordered breathing [13]. Polysomnography, which is performed in a sleep laboratory with a technician present, is a continuous recording of sleep for at least six hours during a patient's normal sleeping time. As the study proceeding, the following parameters listed in Table 2.2-3 are routinely measured [13].

Table 2.2-3 Parameters measured in the Polysomnography [13]

No.	Items	No.	Items
1	Electroencephalogram (EEG)	**7**	Thoracic movement
2	Electrooculogram (EOG)	**8**	Abdominal movement
3	Chin electromyogram (EMG)	**9**	Leg electromyogram
4	Electrocardiogram (ECG)	**10**	Snoring sound
5	Nasal/oral airflow	**11**	Body position
6	Blood oxygen saturation (SaO_2)		

EEG, EOG, and chin EMG are used together to determine sleep stage, wakefulness, and arousals from sleep. The ECG is used to detect arrhythmias during sleep. Nasal and oral airflow can detect not only apnea and hypopnea but also flow limitation associated with upper airway resistance. Blood oxygen saturation is measured with finger sensor and oximeter to determine the degree of desaturation. Other parameters are also measured by specific devices to detect and record data for later analysis. Then, all detected parameters will be used to construct a polysomnographic report, as shown in Fig. 2.2-2.

In clinical definitions, apnea is defined as a cessation in breathing for at least ten seconds without airflow measured on the airflow sensor. If the event is obstructive during apnea, there is effort to breathe. Several clinical definitions of hypopnea are in clinical use and there is no clear consensus. An AASM position paper defines hypopnea as an abnormal respiratory event with at least a 30% reduction in thoracoabdominal movement or airflow lasting at least ten seconds, and with 4% oxygen desaturation or greater [14]. The number of apneic plus hypopneic episodes per hours is defined as the apnea-hypopnea index (AHI). Based on the AHI and lowest oxygen saturation (LSAT) can determine the severity of OSA, as shown in Table 2.2-3.



Sibley Memorial Hospital
POLYSOMNOGRAM REPORT

NAME: _____ STUDY DATE: Jan 14, 1993

REF. PHYSICIAN: Fairbanks LOG NO.: 93-005 SEX: Male

HISTORY: Suspected sleep apnea D.O.B. 2-2-42 AGE: 50

HEIGHT: 5' 12" WEIGHT: 201

SLEEP STAGING:

Stage 1:	66 min.	20 % TST
Stage 2:	171 min.	50 % TST
Stage 3:	9 min.	3 % TST
Stage 4:	0 min.	0 % TST
Stage 5:	93 min.	27 % TST

Total Recording Time: 375 min.
Total Sleep Time: 339 min.

SLEEP VARIABLES:

Sleep onset time: 2 min	Number of awakenings 1 min: 3
Rem latency: 40 min	Number of awakenings by tech:
Time to first stage 4: not obtnd	Wake after sleep onset (WASO) 27 min
Number of REM periods: 4	Number of body movements:
Penile tumescence:	(per/hr.)

SLEEP DISORDERED BREATHING:

	Non REM	REM	Total
Total number of apneas:	309	64	373
Central:			
Obstructive:	309	64	373
Mixed:			
Number of hypopneas:	32	0	32
Apnea plus hypopnea index:	60/hr	11/hr	71/hr
Mean duration of apnea:	27 sec	33 sec	
Longest duration of apnea:	33 sec	50 sec	
Mean SaO_2 decrease:	98-75%	below 60%	
Peak SaO_2 decrease:	below 60%	below 60%	
Cardiac arrhythmias:	NONE		

MSLT DATA:

	Nap I	Nap II	Nap III	Nap IV	Nap V	
Sleep onset:						mean onset:
Rem onset:						mean onset:

INTERPRETATION: This study shows severe obstructive sleep apnea

Fig. 2.2-2 Polysomnographic report [4]

Table 2.2-4 Severity of obstructive sleep apnea [4]

	AHI	LSAT
Mild	5 – 14	86% – 90%
Moderate	15 – 29	70% – 85%
Severe	≥ 30	< 70%

AHI: apnea-hypopnea index, LSAT: lowest oxygen saturation

Besides the sleep study, the clinician makes judgments also by the clinical history of patient and the physical examination. According to the results of diagnose in many directions, clinicians will make the more helpful suggestion to patients with sleep-disordered breathing based on their own experiences. Therefore, the right remedies will more suitable for each case.

2.3 Treatments

Various treatments of snoring and OSA have been proposed. All the treatments can be generally classified into surgical treatments and non-surgical treatments. Operations to treat snoring and OSA are the treatments which belong to surgical, others are non-surgical. Those non-surgical treatments include behavior modification, pharmacologic treatment and various mechanical devices to reduce or eliminate snoring and OSA. Standard treatments for OSA proven by AASM include upper airway surgery and the use of positive airway pressure appliance and oral appliance [15].

2.3.1 Surgical Treatments

The surgical modifications of the upper airway for the treatment of OSA can be divided into three categories: classic procedures, specialized procedures, and tracheotomy [19]. Before the surgery, the anatomic regions of obstruction should be identified first. The pharynx can be functionally divided into two portions: the retropalatal pharynx, the region of the pharynx posterior to the soft palate, and the retrolingual pharynx, the region of the pharynx posterior to the vertical portion of the tongue. Based on the above basis, patterns of pharyngeal obstruction, narrowing, or collapse can be classified into the following way [20]:

- Type I: narrowing or collapse in restropalatal region only.
- Type II: narrowing or collapse in both restropalatal and restrolingual regions.

- Type III: narrowing or collapse in retrolingual region only.

Classic surgical techniques have been developed to alter the soft tissue and skeleton of nose, such as nasal-septal reconstruction, cauterization, and outfracture of turbinates. Classic pharyngeal procedures such as tonsillectomy have been used to enlarge the pharyngeal space. However, these procedures were frequent failure so that new surgical approaches were developed.

Fujita [21] introduced the Uvulopalatopharyngoplasty (UPPP) as the first specialized surgical procedure to treat OSA in 1981. UPPP is a procedure that operates on the tonsil to enlarge the retropalatal airway. The procedure trims the posterior and anterior tonsillar pillars, and resects the uvula and posterior portion of the palate. Then, another operation, the Uvulopalatopharyngoglossoplasty (UPPGP), combines a modified UPPP with limited resection of the tongue base. Laser midline glossectomy (LMG) and lingualplasty are two procedures that create an enlarged retrolingual airway by laser extirpation of a midline. The difference between LMG and linguaplasty is that additional tongue tissue is extirpated in LMG. GAHM is an abbreviation used to represent the whole procedure of inferior sagittal mandibular osteotomy and genioglossal advancement with hyoid myotomy and suspension. The two components of the procedure create an enlarged retrolingual airway. In GAHM, the hyoid bone is advanced and suspended from the mandible by a fascial trip that will not change the dental occlusion. The last one in specialized surgical procedure, the maxillomandibular osteotomy and advancement (MMO), provides maximal enlargement of the retrolingual airway and some enlargement of the retropalatal airway. Moving the maxilla forward simultaneously with mandible permits greater forward motion of the mandible because of the maintenance of dental occlusion.

Tracheostomy is a surgical procedure that creates a percutaneous opening into the trachea. Use rigid or semirigid hollow tube inserting into the opening of trachea to breathe

and maintain the stoma. The tracheostomy tube is with sufficiently small diameter that, when plugged, it permits air inspiration through upper airway from nose and mouth to the lungs pass around the tube.

2.3.2 Non-surgical Treatments

Non-surgical treatments include behavior modification, pharmacologic treatment and the use of mechanical devices. Behavior modification is the self-help remedy which contains alteration of sleep position, avoidance of alcohol and sedative medication, and weight-reduction programs. Pharmacologic treatments are not recommended to treat OSA because of the lack of clinical trials and the conclusions on efficacy, but some of them may effective to reduce the side effect of OSA [22]. At present, drugs should be considered as either second line therapies or as adjuvant therapies [23]. Further, several mechanical devices are used to remedy the snoring and OSA, and will be introduced below.

2.3.2.1 Non-prescription Treatments

Non-prescription treatments mean that the therapies performed without a prescription or even a medical evaluation. Those treatments include some pharmacologic products, several mechanical products, and others. There are so many commercial products become popular to many snorers. As described above, the efficacy of pharmacologic products are not obvious. Mechanical products, such as external nasal dilator strips (ENDS) and internal nasal dilators (IND), are also with limited evidence to suggest the use of them [24]. Most of these products are without obvious efficacy and the use of them may also delay proper evaluation and treatment of the snoring and OSA. Therefore, go to see a doctor and evaluate the condition of snoring and OSA maybe better than use the product without prescription.

2.3.2.2 Positive Airway Pressure

Positive airway pressure applied by nasal mask remains the most effective and least

invasive treatment for OSA [4]. Types of PAP treatment include continuous PAP (CPAP), bilevel PAP (BPAP), and automatic self-adjusting PAP (APAP). The most widespread application of PAP is the treatment of OSA with CPAP. The application of CPAP prevents collapse of the upper airway by promoting the balance of the forces that keep the airway open versus that innately collapse it. The basic CPAP appliance is composed of an electronically controlled compressor and a pressure gauge, which can be adjusted to personal settings. The pressure setting is established by a titration study with attended PSG to adjust to the optimal pressure for maintaining airway patency. The sufficient pressure for preventing apnea is variational in all sleep stages and all sleep postures. Use the titration to find a fixed single pressure for subsequent nightly usage. The CPAP treatment is high efficacy but without enough acceptance and tolerance. The reasons for the CPAP noncompliance are listed in Table 2.3-1.

Table 2.3-1 Typical reasons for CPAP noncompliance [4]

No.	Reasons	
1	Nasal stuffiness and discharge	Rhinitis, irritative, from cold/dry air Rhinosinusitis, bacterial/viral/fungal, from poor hygiene or contagion Uncorrected nasal, septal, turbinate deformities Untreated allergies, sinusitis, polyps, masses
2	Mask problems	Poor fit, discomfort, claustrophobia Air leakage, dry eyes, conjunctivitis Skin rashes/abrasions
3	Equipment problems	Noisy or cumbersome devices High air-pressure-level discomfort Travel problems Social/spousal aversion
4	Failure to gain sufficient recognizable benefit	
5	Failure to understand medical necessity	
6	Failure to receive educational, instructional, and motivational counseling at onset	
7	Cost, insurance noncoverage	

2.3.2.3 Oral Appliance

The application of the oral appliance for the treatment of obstructive sleep apnea was first introduced in 1984 [25]. Various oral appliances have been developed for the treatment of snoring or OSA. With different designs, they can be classified into three basic categories as follows:

- Mandibular advancement devices (MADs): it also termed as the Mandibular reposition devices (MRDs). These 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.

- Tongue-retaining device (TRD): it is designed to keep the tongue in an anterior position during sleep. The tongue is held in place by a negative pressure in a soft plastic bulb, which protrudes out of the mouth. The lips are closed over a flange which fits between the lips and teeth to hold the device.

- Soft palate lift (SPL): these removable devices are also for nighttime use during sleep. A posterior extension is fitted up upper teeth to lift the soft palate and uvula out of the pharyngeal airway. These devices have not demonstrated efficacy in reducing either snoring or OSA.

All oral appliances produce downward rotation of the mandible, many of them also move forward the mandible by design. In a comparative study, a strong patient preferences appeared for the MAD. The MAD was an effective treatment and the TRD and SPL were less tolerable and significant improvements [26].

Oral appliances may improve upper airway patency during sleep by enlarging the upper airway or by decreasing upper airway collapsibility. The mechanism action of oral appliances is at least three ways. First, they bring the mandible and base of tongue forward. Second, they stabilize the mandible to prevent it from falling open during sleep. And third, they alter the mandibular position through downward rotation, thereby causing an increase in cross

sectional airway size and muscle tone. After the oral appliance therapy, snoring is improved in 73% to 100% of patients [27]. Those patients with mild to severe OSA have a 52% chance of being able to control their sleep apnea to reach a level of AHI less than 10 by using oral appliances [28]. Whole OAs are less effective than CPAP but may be better accepted by patients than CPAP in whom used both treatments. The common side effects of oral appliance, such as excessive salivation, dryness of the mouth, or transient discomfort, may prevent early acceptance. The major long-term problems are temporomandibular joint (TMJ), or jaw discomfort and limited movement of the teeth. Those effects can be minimized if the appliance is adjusted to so as to avoid excessive advancement of the mandible.

The standard treatments of snoring and OSA promoted by AASM include surgery, CPAP, and oral appliance. Among all of three, CPAP and oral appliance are noninvasive treatments. The CPAP is more effective than oral appliance, but the compliance of oral appliance is better than CPAP. Further, some drawbacks of CPAP in the equipment, interface, or appearance will lead to intolerable to use or inconvenience of usage in some occasions. Therefore, this study will focus on the oral appliance, even the mandibular advancement device, to innovate.

CHAPTER 3

MANDIBULAR ADVANCEMENT DEVICE

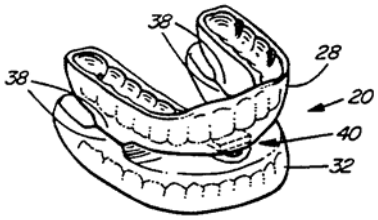
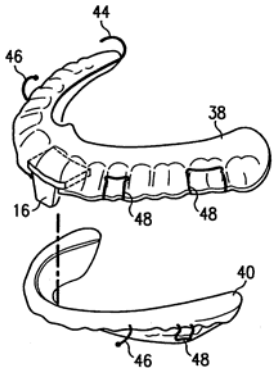
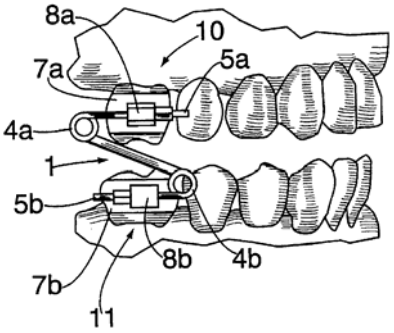
3.1 Patents

The patent review of this study is based on the patents published in the United States since 1976. They can be searched from the patent full-text and full-page image databases in the United States Patent and Trademark Office (USPTO) [29]. 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 review, the analysis results can be classified into several categories by functions which will be discussed in following subsections. In general, patents are invented to improve the disadvantages existed in prior arts. The disadvantages refer to the analysis including uncomfortable to use, low compliance, high cost, can not or complex to adjust, bulky volume, lack of customizability, and etc.

3.1.1 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 parts of MADs are directly fixed on the teeth by mounting. Those devices are usually used to treat the malocclusion, but the advancement of the mandible also can eliminate snoring (Table 3.1-1).

Table 3.1-1 The fixers of mandibular advancement device

Thermoplastic material	Thermoplastic material and Clasp	Mount directly
		
U.S. Patent No. 5365945 [30]	U.S. Patent No. 5427117 [31]	U.S. Patent No. 5645423 [32]

3.1.2 Connector

In the two-pieces MAD, the 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 3.1-2).

- Button

  An elastic button-like connector couples with a aperture to interconnect upper and lower mouthpiece. This kind of connector connects two mouthpieces in a fix degree of advancement without the function of adjustment during using. The decision of degree of advancement is applied during the impression process by the therapist.

- Screw

  The screw connector means either the traditional screw or the dual-thread screw. Using screws as the connector to connect the upper and lower mouthpiece can be very tight and high strength. However, it is usually not convenient to use because it

needs be wrenched by a screw driver.

- Wire

  Wire connector can be shaped to the oral cavity to prevent the movement space of tongue from being occupied by connected and adjusted mechanism. The strength of the wire may be concerned according to its failure.

- Surface contact

  An object is fixed to one mouthpiece and contacts with another one. This condition can be considered as that upper and lower mouthpieces are connected by contacting. Therefore, contacting is the connector in this kind of appliance.

- Post

  The post is coupled with the aperture restrainedly or freely depended on the shape of the post. It may be single or numerous locating in the anterior or posterior portion or both on the mouthpiece.

- Interlocking member

  Interlocking member, for example the Velcro, is a connector with two phases that are engaged by contacting and are disengaged by tearing. It can be connected in any position that is convenient to use and adjust. But it is also easy to be separated which leads to the poor strength.

- Elastic band

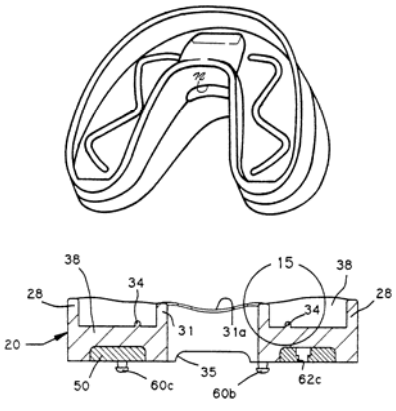
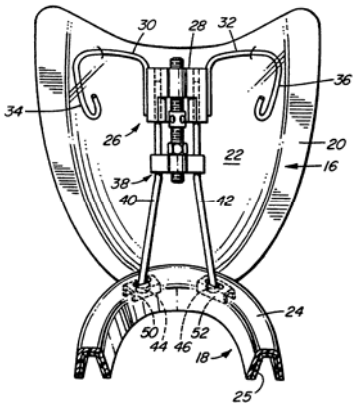
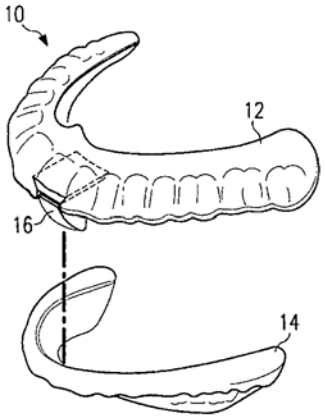
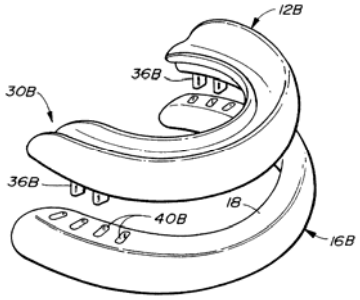
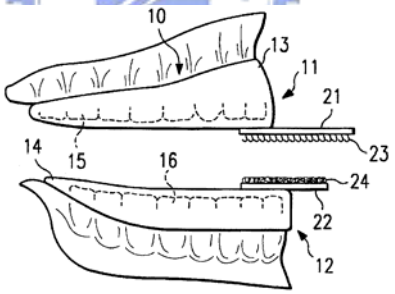
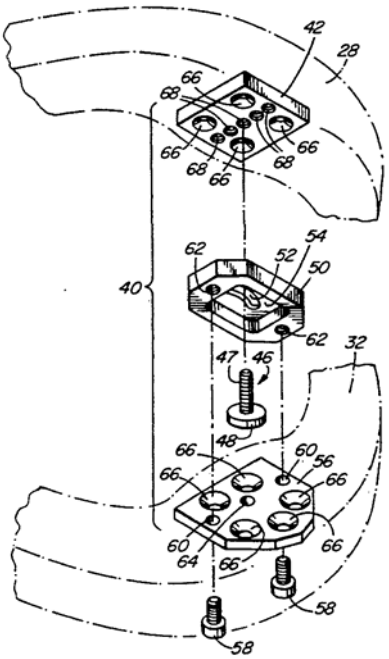
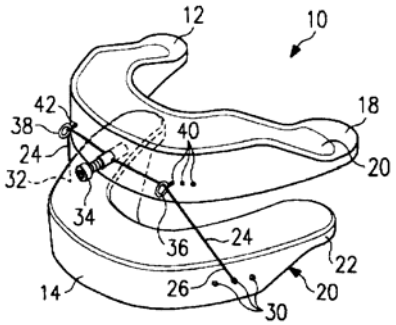
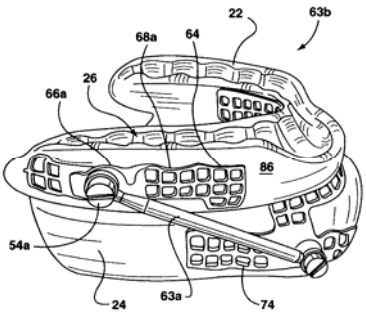
  Elastic band is a flexible material used to pull the mandible advancement. Because of the flexibility, the movement of the mandible still keeps large degrees of freedom after advanced. It means it is unstable.

- Linkage

  The linkage connector includes links and pivots which are installed on or between

upper and lower mouthpieces to drive the mandible advancement. The link may be a scope-like structure that is variational in length.

Table 3.1-2 The connectors of MAD

Button	**Wire**	**Surface contact**
		
U.S. Patent No. 5313960 [33]	U.S. Patent No. 5409017 [34]	U.S. Patent No. 5566683 [35]
Post	**Interlocking member**	**Screw**
		
U.S. Patent No. 5499633 [36]	U.S. Patent No. 5642737 [37]	
Elastic band	**Linkage**	
		
U.S. Patent No. 5755219 [38]	U.S. Patent No. 6418933 [39]	U.S. Patent No. 5365945 [30]

3.1.3 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 (Table 3.1-3).

3.1.3.1 Protraction and Retraction

- Series of aperture

  This is one of position-fixed adjustments. The series of apertures are usually coupled with the screw or the post, and they are equal in interval. Choose one of those apertures as the preferred position to connect.

- Screw

  The screw works as a continuous adjustor with high precision. It can satisfy the requirement of adjustment in a small amount. The screw usually works as a component of the connector to adjust its position.

- Dual-thread screw

  The dual-thread screw is a combination of two screws in the opposite threaded direction. The performance of the dual-thread screw is double to the traditional screw.

- Conjugate shape

  Identical shape arranges in series to connect with its conjugate shape face-to-face worked as a position-fixed adjustor. The commonly used shape is the saw-shaped interface. This kind of adjustor may need an additional component to fix the two

surfaces together.

- Interlocking member

  This kind of adjustor may be considered as a continuous adjustor or a position-fixed adjustor with tiny interval between one and one interlocking members. It is easy to operate by touching the interlocking member together anywhere you preferred.

- Elastic band

  The degree of advancement depends on the length of the elastic band. Some additional components are used to adjust the length. The force applied on the mandible may be changed by replacing the elastic band in different stiffness.

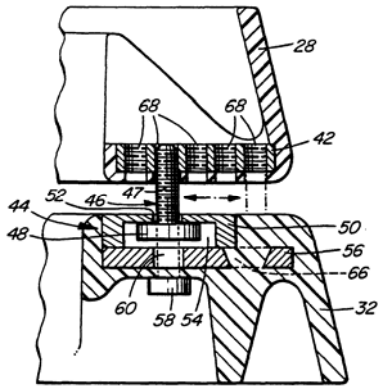
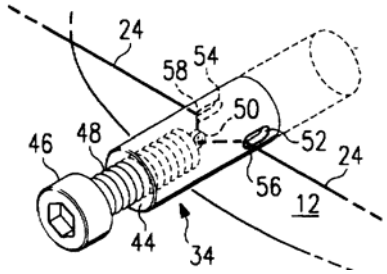
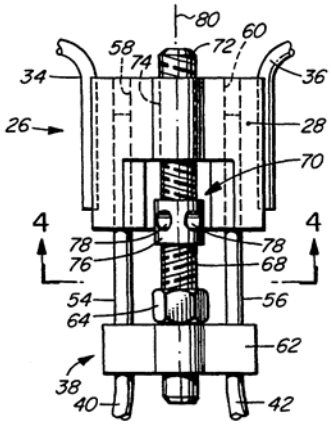
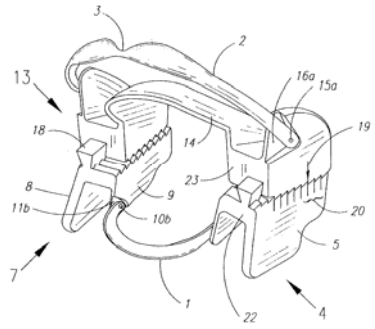
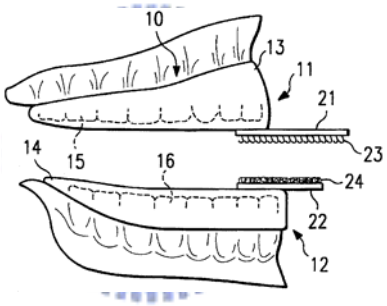
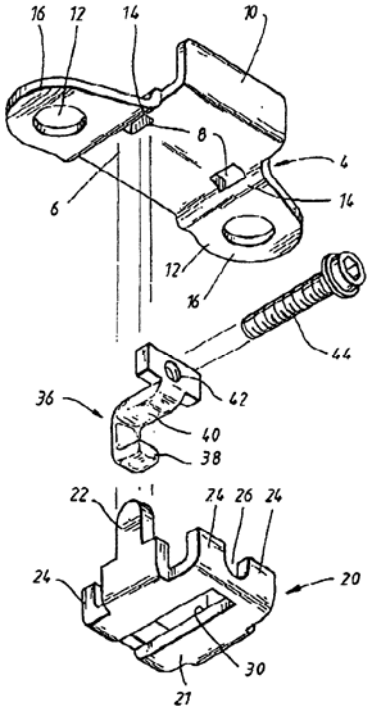
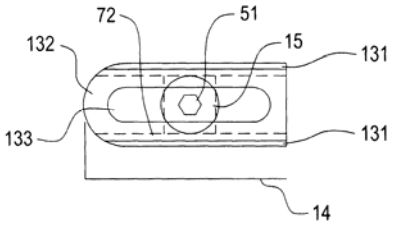
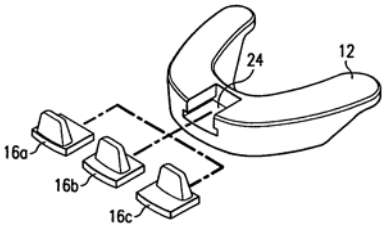
- Slot

  The connector slides in the slot to adjust the position of the mandible continuously. A fastener is usually used to fasten the connector on the slot in a preferred position.

- Replace component

  Various components are applied for replacing to change the position of the mandible. This kind of adjustment is position-fixed and may be inconvenient to use because of lots substitute components should be prepared.

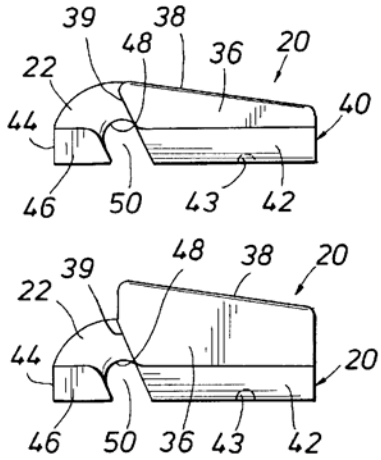
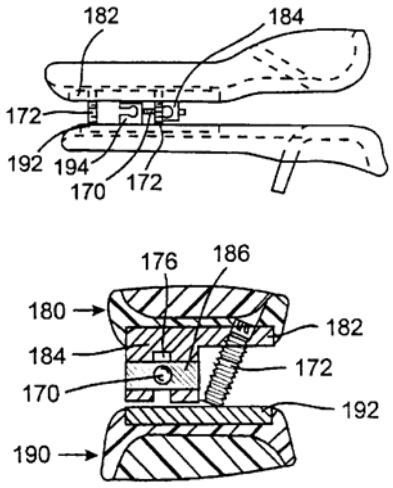
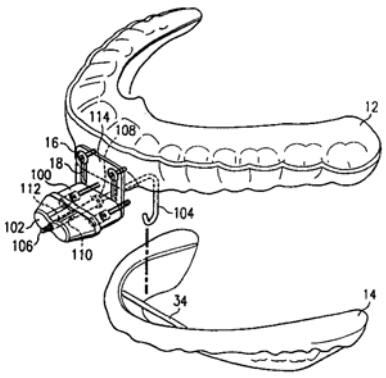
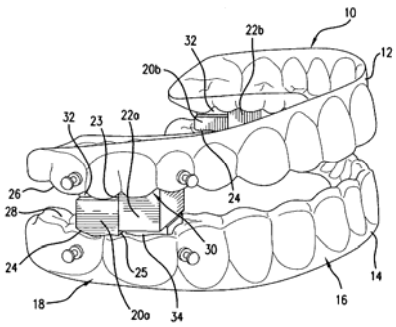
Table 3.1-3 The adjustors of MAD (Protraction and retraction)

Series of aperture	Elastic band	Dual-thread screw
		
U.S. Patent No. 5365945 [30]	U.S. Patent No. 5755219 [38]	U.S. Patent No. 5409017 [34]
Conjugate shape	**Interlocking member**	**Screw**
		
U.S. Patent No. 5570704 [41]	U.S. Patent No. 5642737 [32]	
Slot	**Replace component**	
		
U.S. Patent No. 6769910 [42]	U.S. Patent No. 5427117 [31]	

3.1.3.2 Elevation and Depression

The adjustment of elevation and depression of the mandible is not usually designed as a function of the MAD. The purpose of this function is to make the product suitable for most people. The methods which used to adjust the elevation and depression of mandible include replacing component, screw, slot, and surface contact (Table 3.1-4).

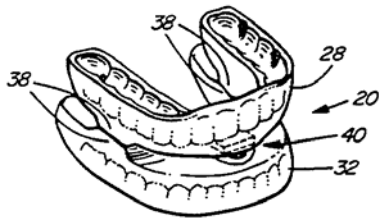
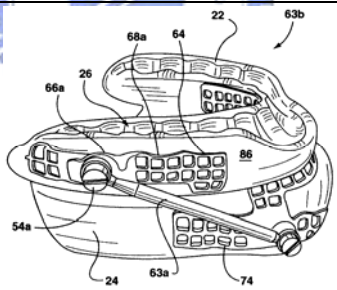
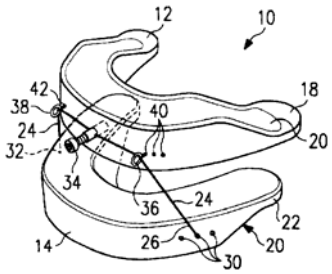
Table 3.1-4 The adjustors of MAD (Elevation and depression)

Replace component	**Screw**
 U.S. Patent No. 5947724 [43]	 U.S. Patent No. 6055986 [44]
Slot	**Surface contact**
 U.S. Patent No. 6305376 [45]	 U.S. Patent No. 6983752 [46]

3.1.4 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 the 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 3.1-5).

Table 3.1-5 Types of acting force of MAD

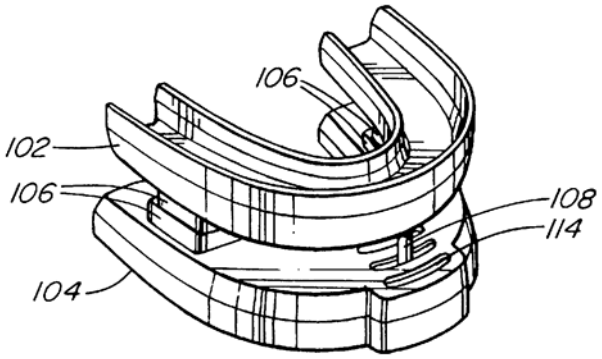
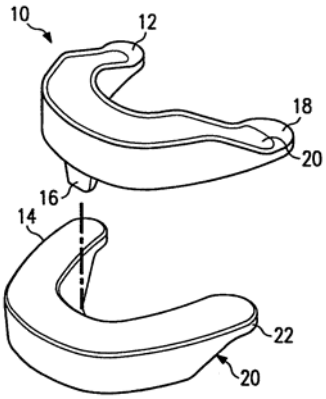
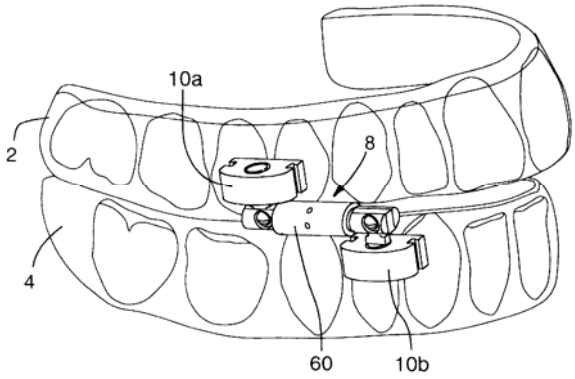
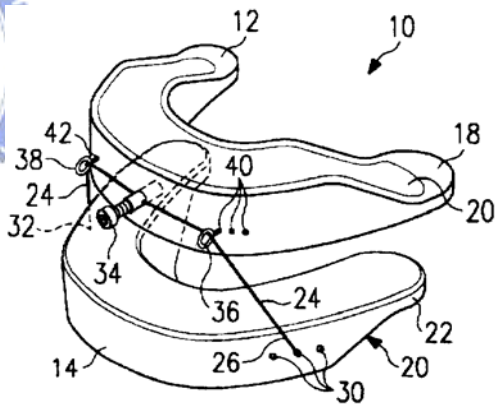
Perpendicular force	Pushing force	Pulling force
		
U.S. Patent No. 5365945 [30]	U.S. Patent No. 6418933 [39]	U.S. Patent No. 5755219 [38]

3.1.5 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 3.1-6).

Table 3.1-6 Types of lateral movement of MAD

Slot	Surface contact
 U.S. Patent No. 5868138 [47]	 U.S. Patent No. 5427117 [31]
Linkage	**Elastic band**
 U.S. Patent No. 6012920 [48]	 U.S. Patent No. 5755219 [38]

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.

3.2 Products

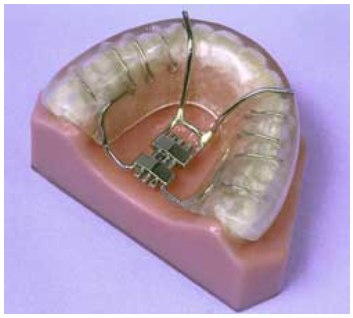
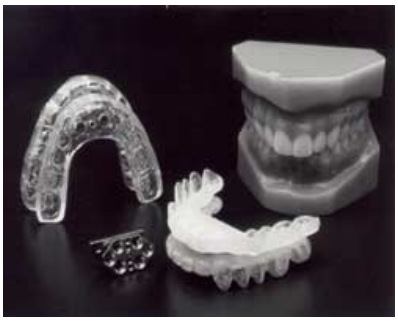
The U.S. Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation in the United States [49]. The mission of Center for Devices and Radiological Health (CDRH), one department of FDA, is to assure that new medical devices are safe and effective before they are on market. The FDA has classified all the medical devices into three classes. Each of those devices is assigned to one of three classes based on the level of control necessary to assure safety and effectiveness of the device. Everyone who wants to market Class I, II, and some III devices intended for human use in the U.S. must submit a premarket notification, 510(k), to FDA at least 90 days before marketing unless the device is exempt from 510(k) requirements. The oral appliances are assigned to the Class II devices [50] that must receive a 510(k) from FDA for the treatment of snoring or OSA. Therefore, all the OAs for snoring and/or OSA can be searched within which devices have received the 510(k) clearance and are available in the CDRH 510(k) database.

For the purpose of searching for all related products of the snoring or OSA treatment, the more effective method is to search by category rather than by other terms. Each category is referring to an individual product code. The intraoral devices for snoring and/or OSA are referring to the following product codes: “LRK”, Anti-Snoring Device; “LQZ”, Jaw Repositioning Device. There are totally 72 products in these two categories including all kinds of oral appliances. Depending on sifting all the products carefully, there are at least 16 products which are the adjustable two-pieces mandibular advancement devices. These devices with their specification are collected and listed in Table 3.2-1 and Table 3.2-2.

Table 3.2-1 List of adjustable MAD products

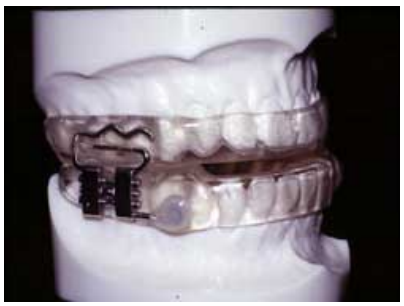
Model	Applicant	Approval Date
Klearway®	Dr. Alan A. Lowe, Inc.	05/25/1995
Silencer®	Silent Knights Ventures, Inc.	10/30/1995
Adjustable PM Positioner®	Jonathan A. Parker, D.D.S.	02/08/1996
Herbst Appliance®	Univ. Dental Assoc. Dept. of Orthodontics	03/20/1996
TAP®	Airway Management Inc.	01/24/1997
Silent Nite®	Glidewell Laboratories	09/18/1997
EMA®	Frantz Design, Inc.	09/29/1997
Adjustable TheraSnore®	DISTAR, Inc.	11/12/1997
Snoring Control Device®	Kenneth Hilsen	01/09/1998
Snore-Aid plus®	Dental Imagineers, LLC	07/22/1999
NORAD®	Dennis R. Bailey, DDS	05/28/2002
SUAD®	Strong Dental Inc.	07/08/2003
OASYS Oral/Nasal Airway System®	Mark Abramson, D.D.S., Inc.	08/26/2003
MDSA ™	RJ & VK Bird Pty Ltd.	10/27/2004
SomnoMed MAS ®	Somnomed Ltd	07/12/2005
TAP-T®	Airway Management Inc.	07/12/2006
SomnoGuard AP/AP Pro®	Tomed Dr. Toussaint GmbH	09/08/2006

Table 3.2-2 Comparison of adjustable MAD products

		Model	
		Klearway®	Silencer®
Photo			
Company		Dr. Alan A. Lowe, Inc.	Silent Knights Ventures, Inc.
Inventor		Alan A. Lowe (Canada)	Leonard W. Halstrom (Canada)
FDA	**Approval Date**	05/25/1995	10/30/1995
510(k)	**Reg. No.**	K950763	K954530
Treat Snoring		Yes	Yes
Treat OSA		Yes	Yes
Connector		Wire	Screw/Post
Adjustor (P-R)		Dual-thread screw	Series of aperture
Adjustor (E-D)		N/A	N/A
Lateral movement		Slot	Slot
Patents		US 5409017	US 5365945, US 5868138

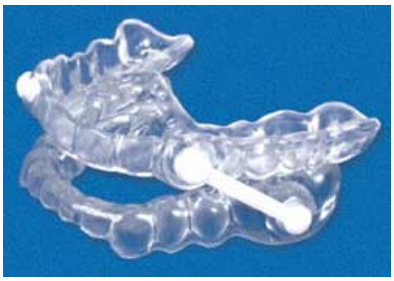
(All rights of the pictures belong to individual incorporation respectively)

Table 3.2-2 Comparison of adjustable MAD products (cond.)

		Model	
		Adjustable PM Positioner®	Herbst Appliance®
Photo			
Company		Jonathan A. Parker, D.D.S.	Univ. Dental Assoc. Dept. of Orthodontics
Inventor		Jonathan A. Parker (U.S.)	(No data)
FDA 510(k)	**Approval Date**	02/08/1996	03/20/1996
	Reg. No.	K955503	K955822
Treat Snoring		Yes	Yes
Treat OSA		Yes	Yes
Connector		Wire	Linkage
Adjustor (P-R)		Dual-thread screw	Screw
Adjustor (E-D)		N/A	Elastic band
Lateral movement		Linkage	Linkage
Patents		US 5816799	(No data)

(All rights of the pictures belong to individual incorporation respectively)

Table 3.2-2 Comparison of adjustable MAD products (cond.)

		Model	
		TAP®	Silent Nite®
Photo			
Company		SCHEU-DENTAL GmbH	Glidewell Laboratories
Inventor		W. Keith Thornton (U.S.)	(No data)
FDA 510(k)	**Approval Date**	01/24/1997	09/18/1997
	Reg. No.	K964516	K972424
Treat Snoring		Yes	Post (Hook)
Treat OSA		Yes	Screw
Connector		Post (Hook)	Slot
Adjustor (P-R)		Screw	N/A
Adjustor (E-D)		Slot	US 6305376
Lateral movement		Surface contact	Elastic band
Patents		US 6305376	(No data)

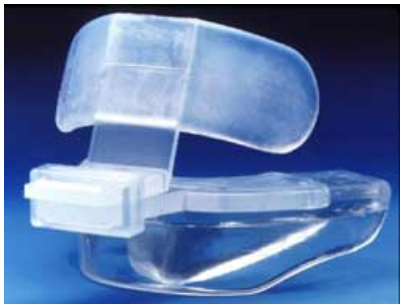
(All rights of the pictures belong to individual incorporation respectively)

Table 3.2-2 Comparison of adjustable MAD products (cond.)

		Model	
		EMA®	Adjustable TheraSnore®
Photo			
Company		Frantz Design, Inc.	DISTAR, Inc.
Inventor		Don E. Frantz (U.S.)	Thomas E. Meade (U.S.)
FDA	**Approval Date**	09/29/1997	11/12/1997
510(k)	**Reg. No.**	K971794	K973038
Treat Snoring		Yes	Yes
Treat OSA		Yes	Yes
Connector		Elastic band	Elastic band
Adjustor (P-R)		Replace component	Replace component
Adjustor (E-D)		Replace component	Replace component
Lateral movement		Elastic band	Elastic band
Patents		US 5947724, US 6109265	US 5947724, US 6109265

(All rights of the pictures belong to individual incorporation respectively)

Table 3.2-2 Comparison of adjustable MAD products (cond.)

		Model	
		Snoring Control Device®	Snore-Aid plus®
Photo			
Company		Ridgewood Dental Associates	Dental Imagineers, LLC
Inventor		Kenneth L. Hilsen (U.S.)	William A. Belfer (U.S.)
FDA	**Approval Date**	01/09/1998	07/22/1999
510(k)	**Reg. No.**	K963591	K991449
Treat Snoring		Yes	Yes
Treat OSA		No	Yes
Connector		Interlocking member	Post +Surface contact
Adjustor (P-R)		Interlocking member	Elastic band (Bind posts)
Adjustor (E-D)		N/A	Surface contact
Lateral movement		Surface contact	Surface contact
Patents		US 5611355	US 20030234022

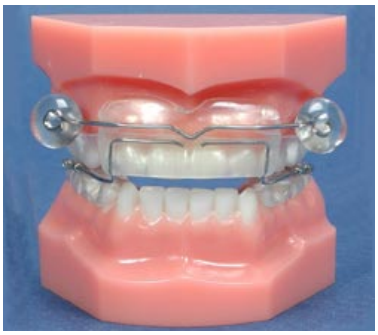
(All rights of the pictures belong to individual incorporation respectively)

Table 3.2-2 Comparison of adjustable MAD products (cond.)

		Model	
		NORAD®	SUAD®
Photo			
Company		Dental Appliance Innovators, Inc.	Strong Dental Inc.
Inventor		Charles D. Kownacki (U.S.)	Patrick J. Strong (Canada)
FDA 510(k)	**Approval Date**	05/28/2002	07/08/2003
	Reg. No.	K020893	K023836
Treat Snoring		Yes	Yes
Treat OSA		Yes	Yes
Connector		Elastic band	Linkage
Adjustor (P-R)		Series of aperture	Elastic band
Adjustor (E-D)		N/A	Elastic band
Lateral movement		Surface contact	Elastic band/Linkage
Patents		US 20040177853	US 6418933, US 6526982

(All rights of the pictures belong to individual incorporation respectively)

Table 3.2-2 Comparison of adjustable MAD products (cond.)

		Model	
		OASYS®	MDSA®
Photo			
Company		Mark Abramson, D.D.S., Inc.	RJ & VK Bird Pty Ltd.
Inventor		(No data)	John Gaskell (Australia)
FDA 510(k)	**Approval Date**	08/26/2003	10/27/2004
	Reg. No.	K030440	K042161
Treat Snoring		Yes	Yes
Treat OSA		Yes	Yes
Connector		Wire	Post (Hook)
Adjustor (P-R)		Screw/Slot (Telescope)	Screw
Adjustor (E-D)		Surface contact	N/A
Lateral movement		Surface contact	Surface contact
Patents		(No data)	US 6845774

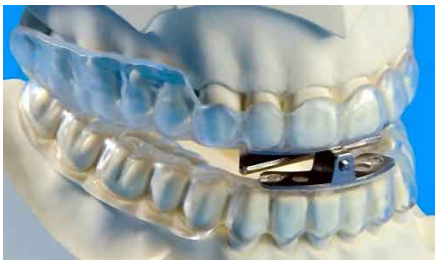
(All rights of the pictures belong to individual incorporation respectively)

Table 3.2-2 Comparison of adjustable MAD products (cond.)

		Model	
		SomnoMed MAS®	TAP-T®
Photo			
Company		Somnomed Ltd	SCHEU-DENTAL GmbH
Inventor		Richard George Palmisano (Australia)	W. Keith Thornton (U.S.)
FDA 510(k)	**Approval Date**	07/12/2005	07/12/2006
	Reg. No.	K050592	K061732
Treat Snoring		Yes	Yes
Treat OSA		Yes	Yes
Connector		Surface contact	Post (Hook)
Adjustor (P-R)		Dual-thread screw	Screw
Adjustor (E-D)		Replace component	N/A
Lateral movement		N/A	Slot
Patents		US 6604527	US 7174895

(All rights of the pictures belong to individual incorporation respectively)

Table 3.2-2 Comparison of adjustable MAD products (cond.)

		Model	
		SomnoGuard AP/AP Pro®	
Photo			
Company		Tomed Dr. Toussaint GmbH	
Inventor		Toussaint Winfried Dr (Germany)	
FDA 510(k)	**Approval Date**	09/08/2006	
	Reg. No.	K061688	
Treat Snoring		Yes	
Treat OSA		Yes	
Connector		Screw	
Adjustor (P-R)		Screw	
Adjustor (E-D)		N/A	
Lateral movement		Surface contact	
Patents		DE 20018772, EP 1203570	

(All rights of the pictures belong to individual incorporation respectively)

CHAPTER 4

QFD AND REQUIREMENTS

4.1 Introduction

The quality function deployment (QFD) method was developed in Japan in the 1970s and introduced to the United States in the 1980s. It is one of the best and currently the most popular technique used to generate engineering specifications from customers' requirements [51]. The advantage of the QFD method is that it develops the required information systematically for understanding the problem during product development. Some objectives which can be achieved by using the QFD method are showing as follows:

- To understand specifications or goals for the product.
- To understand how the competition meets the goal.
- To understand what is important from the customers' viewpoints.
- To set the numerical targets to work toward.

Furthermore, QFD is a quality control method. It supplies a process for product design to ensure the result will meet the customers' requirements. The process can be divided into four stages [52] as follows:

- Product Planning Stage (Customers' Requirements → Engineering Specifications)
- Product Deployment Stage (Engineering Specifications → Product Specifications)
- Process Planning Stage (Product Specifications → Manufacturing Requirements)
- Production Planning Stage (Manufacturing Requirements → Operating Instructions)

Among the four stages, the first stage is the most important one because its outcome will be

the input information of next stage. Besides, the engineering specifications are generated to be the criteria during product design process in this stage.

Apply the QFD steps to build the house of quality shown in Fig. 4.1-1. Each room of the house contains valuable information which needs to be filled by designers. The numbers in the diagram refer to the steps that are detailed in next section.

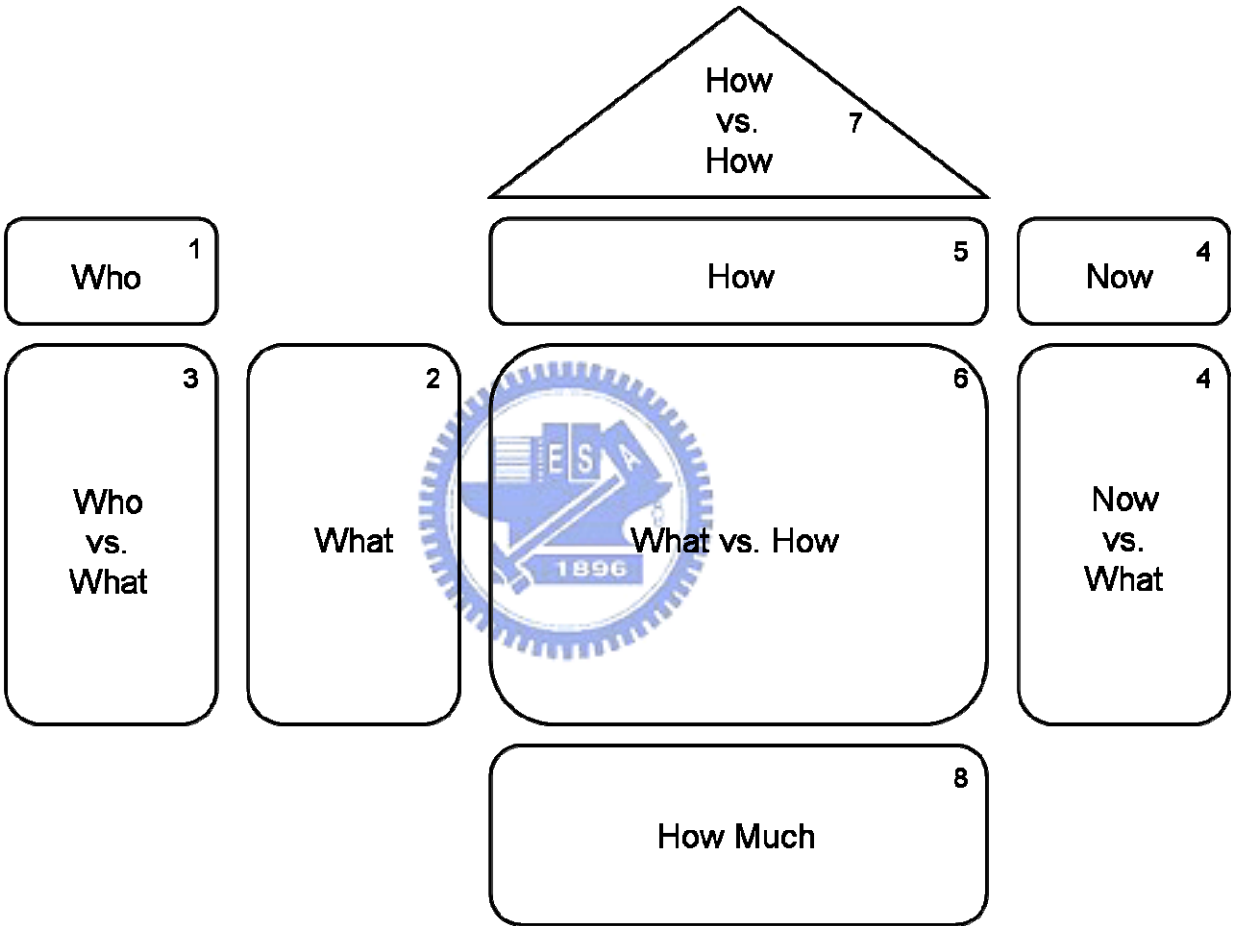


Fig. 4.1-1 The house of quality, also known as the QFD diagram

4.2 QFD for MAD

In this section, the QFD for MAD will be established step-by-step and the engineering targets for the design of MAD will be generated in the end, as shown in Fig. 4.2-1.

- *Step 1: Identify the customers (Who)*

The customers are widely defined as all personnel relating to this product, including consumers, manufacturing personnel, sales staff, service personnel, and so forth. In this case, doctors, patients, and sales staff are considered as the customers of MAD.

- *Step 2: Determine the customers' requirements (What)*

After the customers have been identified, the next step is to determine what is to be designed and what the customers want. Many requirements can be observed from customers who are using the existing products. Furthermore, surveys are usually used to gather information. For example, the literatures, the questionnaires, the face-to-face interviews, or any other ways can gather the opinions from people. All of the requirements can be classified into several types, such as functional performances, human factors, manufacturing, life-cycle concerns, and etc. In the design of MAD, the requirements are developed by the above mentioned ways and the results are shown in Table 4.2-1.

- *Step 3: Determine relative importance of the requirements (Who vs. What)*

The third step of the QFD method is to evaluate the relative importance of each customers' requirement. The elimination of the least important requirements is proceeded by customers before ranking all items. Referring to the results listed in Fig. 4.2-1, the smaller number represents the more important requirement. The results can be used to generate a weighting factor for each requirement.

Table 4.2-1 List of customers' requirements for MAD

Function	**Human Factor**
High precision of adjustment Adjustable in front-rear direction Adjustable in up-down direction Mandible advance correctly Lateral movement Wear by oneself Customization Distribute force caused by bruxism	Easy to adjust Easy to wear into mouth Easy to remove from mouth Avoid exaggeration of opening of jaw Use for a long time Comfortable to use
Period of Using	**Manufacturing**
Close mouth completely Simple operational steps to wear Opening mouth is allowed Breathing through mouth No Impingement of tongue space Not irritate oral tissues Easy to clean Difficult to disengage from dentition Without side effects	Low cost Structure of parts are simple Parts are easy to be manufactured Product is easy to be manufactured
	Others
	Long life Tiny size Difficult to break Good-looking appearance

- *Step 4: Identify and evaluate the competition (Now)*

The goal in this step is to determine the competition's ability of existing products for each of the requirements. The results can bring out what already exists and that is something can be improved on what already exists. For each customer's requirement, the existing design can be rate on a scale of 1 to 5 as follows:

1 = The product does not meet the requirement at all.

2 = The product meets the requirement slightly.

3 = The product meets the requirement somewhat.

4 = The product meets the requirement mostly.

5 ＝ The product satisfies the requirement completely.

In this study, the most popular products in the market, TAP-T, is selected as the competition benchmark, as shown in Fig. 4.2-1.

- *Step 5: Generate engineering specifications (How)*

In this step, the customers' requirements will be translated into a set of measurable engineering specifications which are the parameters for design, as shown in Fig. 4.2-1. A set of units is associated with each of the measures. Furthermore, the direction of improvement, more is better (↑) or less is better (↓), is also developed here.

- *Step 6: Relate customers' requirements to engineering specifications (What vs. How)*

The center portion of the house of quality represents the relationships between engineering specifications and customers' requirements. Each cell of the portion will be mentioned according to the strength of relationship. Different numbers are filled in cells to refer to different strength as follows:

9 ＝ strong relationship

3 ＝ medium relationship

1 ＝ weak relationship

Blank ＝ no relationship at all

The results in this step are presented in Fig. 4.2-1.

- *Step 7: Identify relationships between engineering requirements (How vs. How)*

Engineering specifications may be dependent on each other. Realize the dependency during design process can help us to know the work for meet one specification may cause positive or negative effects on others. The results are presented in Fig. 4.2-1 by referring to several typically used symbols as follows:

= Negative

× = Strong Negative

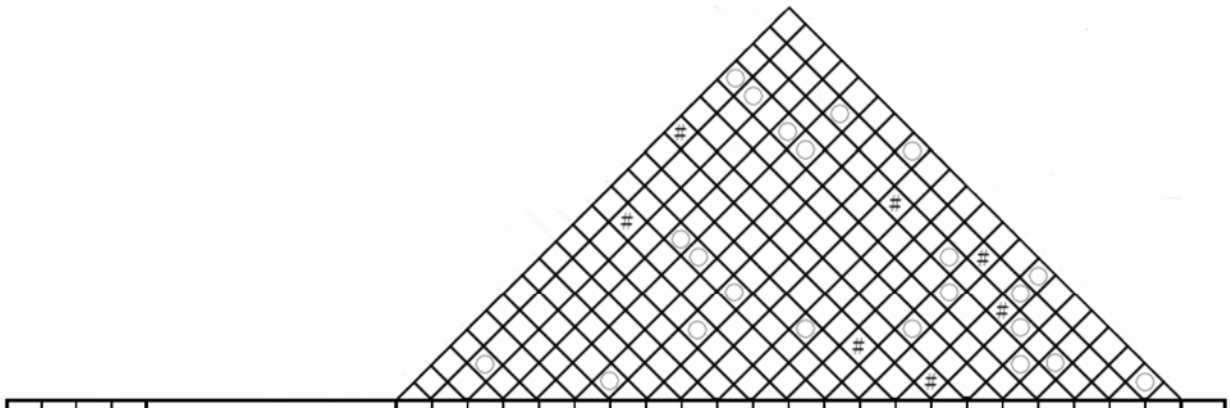
◉ = Strong Positive

○ = Positive

- *Step 8: Set engineering target (How much)*

The final step in the QFD is to determine a target value for each engineering specification. Comparing to the specifications of competition products can establish the target for the new product. All the target values for the design of MAD are given in Fig. 4.2-1.

After the QFD house has been established, the design problem is fully understanding, and the product specifications are also determined. In the following of the product design process, conceptual designs can be obtained.



Sales	Doctors	Patients	SUM	QFD for MAD	Adjustable range (Front-rear)	Adjustable range (Up-down)	Pitch of adjustment	Jaw rotate downwardly	Lateral movability	Tray	Dentition-fitted tray	Contact area	Even contact	Steps to adjust	Height of the inner wall of tray	Separate height of mechanism	Time of using MAD	Steps to wear	Disengage mechanism	Depth of mechanism	Biocompatible material	Steps to clean	Time for adaptation	# of componenets	Durable time	Maximum load	TAP-T
				Direction of Improvement	–	–	↓	–	–	–	–	↑	–	↓	↓	↓	↑	↓	–	↓	–	↓	↓	↓	↑	↑	
				Units	mm	mm	mm	y/n	mm	y/n	y/n	mm^2	y/n	#	mm	mm	hr	#	y/n	mm	y/n	#	week	#	yr	N	
				Function																							
20	16	18	54	Adjustable in front-rear direction	9		3							1				1		1				3			5
21	17	19	57	Adjustable in up-down direction		9	3							1				1						3			1
19	18	17	54	Mandible advance correctly	3	3		9								3	1						1				4
18	15	20	53	Lateral movement					9								3						3	3			3
7	14	2	23	Wear by oneself						9	9																5
1	1	1	3	Custom made							9				3												5
6	3	21	30	Distribute force caused by bruxism								9	9						3					1	3	3	2
				Human factor																							
12	5	9	26	Easy to adjust			3	1						9		1				1							4
16	6	6	28	Easy to wear into mouth						3	3				9	9		9									4
17	7	5	29	Easy to remove from mouth						3	3				9	9	1										4
11	22	7	40	Avoid exaggeration of opening of jaw											9	9											4
2	23	8	33	Use for a long time				1	3		3						9										5
3	2	4	9	Comfortable to use				1	3		9				1	1	3				1		3				5
				Period of using																							
13	20	14	47	Simple operational steps to wear	1	1				3	3			1				9									4
22	19	13	54	Opening mouth is allowed		1													9								1
14	13	21	48	No Impingement of tongue space	1										1				1	9							3
4	12	10	26	Not irritate oral tissues																1	9						5
23	11	12	46	Easy to clean						1	1				1	1				1		9		3			3
15	21	3	39	Difficult to disengage from dentition						3	9				3												4
5	23	11	39	Without side effects				1	3							1	1						9				4
				Manufacturing & Others																							
24	4	21	49	Structure of mechanism is simple			1		1							1			3	1				9			5
9	10	16	35	Long life								1					1		1					1	9	9	3
8	8	21	37	Tiny size	3	3			1						3	9			1	9				3			4
10	9	15	34	Difficult to break								3							9					1	3	9	3
				Target	3-8	0	0	y	8	y	y	50	y	1	9	8	>8	3	y	14	y	3	1	10	3	100	
				TAP-T	7	0	0	y	7.5	y	y	55	y	1	9	7	>8	3	n	12	y	3	1	6	3	–	

Fig. 4.2-1 QFD diagram for MAD

CHAPTER 5

CONCEPTUAL DESIGN

5.1 Design Method

Based on the results generated from QFD, the conceptual design phase is proceeding to innovate and create concepts for new designs. A general conceptual design process can be described as follows:

- Problem formulation: make sure the problem required to be solved.
- Overall function: generate the main function of the product.
- Functional decomposition: divide the overall function into several sub-functions.
- Concept generation: generate concepts to achieve each sub-function respectively.
- Concept combination: combine the concepts from sub-functions to form various complete conceptual designs for the new product.

There are still some problems existing in the commercial products. The most significant one is the failure of the MAD during using. The failure of the MAD will lead to the ineffective treatment and the extraneous expenses for repairing the device. Therefore, the problem here is to design a new MAD which will not break easily during the using time. The main function of the MAD is to make the jaw move forward to achieve the purpose of treating snoring and OSA. Thus the overall function in designing the MAD can be defined as: maintain the jaw position advancement. In according to the overall function, the functional decomposition proceeded to identify all the sub-functions, and the result is shown in Fig. 5.1-1.

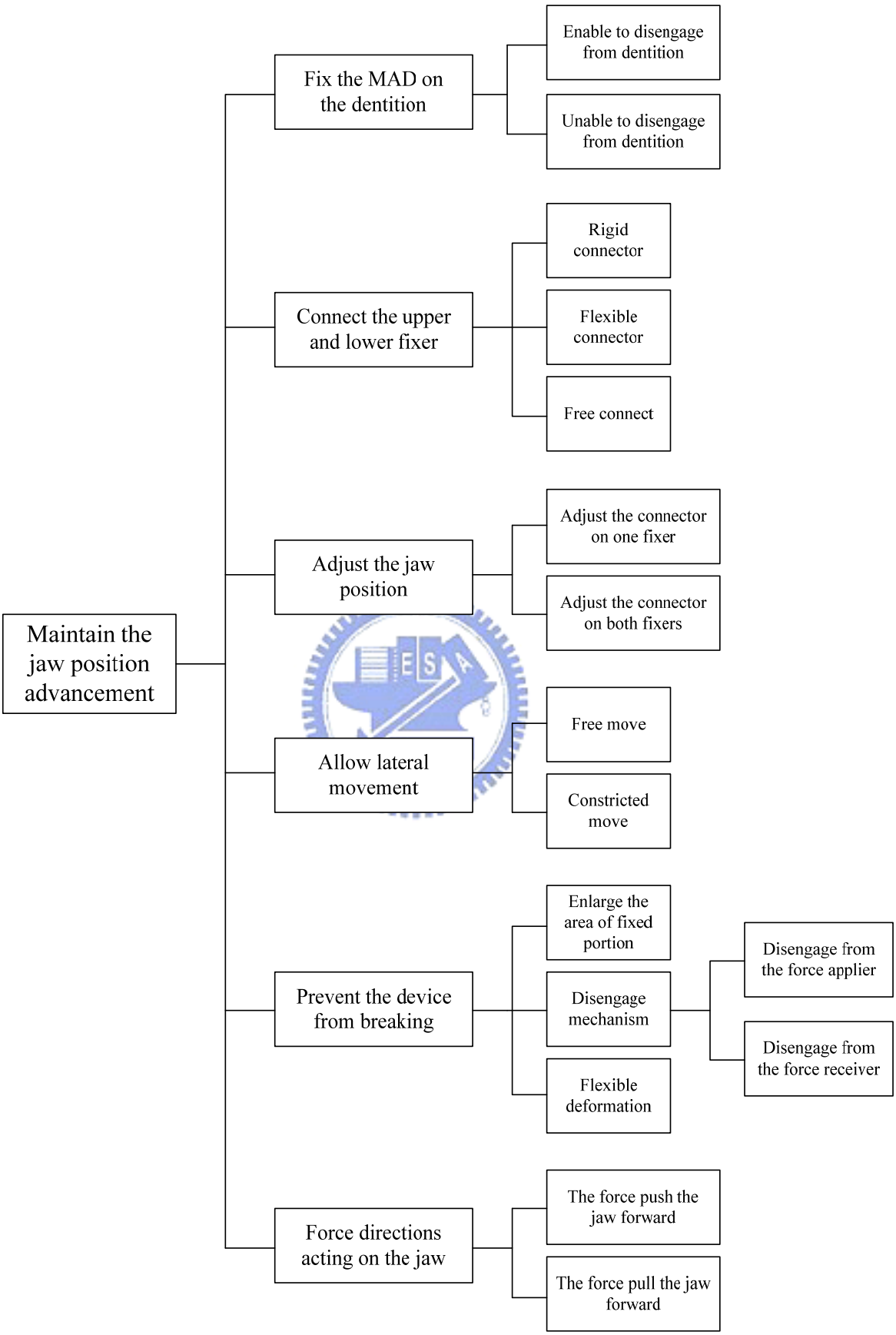


Fig. 5.1-1 Functional decomposition of MAD

The overall function is divided into several sub-functions by the consideration of the functions which should be included. The functional decomposition leads to a better understanding of the design problem. In the MAD, six primary sub-functions promote the effective work on treating snoring and OSA, which are the fixation of the MAD, the connection between both fixers, the adjustability of jaw advancement, the lateral movement of the jaw, the prevention of the device from breaking, and the force directions acting on the jaw.

After all sub-functions have been developed, the next goal is to generate as many concepts as possible for each sub-function. A popular method, brainstorming, is selected to generate concepts because of its advantage of gathering ideas from each group member in their own viewpoint. The group of idea sources is formed by the members in my laboratory. As the brainstorming method proceeding, all of the members should follow the four rules below [51]:

- Record all the ideas generated.
- Generate as many ideas as possible, and then verbalize these ideas.
- Think wild. Silly or impossible ideas sometimes lead to useful ideas.
- Do not allow evaluation of these ideas, just the generation of them.

The result of concept generation is a list of concepts generated for each function. The next step is to combine the individual concepts into complete conceptual designs by using the method that is to select one concept for each function and combine those selected into single design. Finally, various conceptual designs will be generated by accomplishing the conceptual design process.

5.2 Concepts

There are many combinations can be generated by combining individual concepts of each sub-function which described in the above section. However, some of them are impossible to be assembled together. Among the useful combinations, the relation between each individual concept should be good for arranging in pairs and without incompatible. In addition, some combinations are similar or almost the same with existent design or commercial products. At last, four complete concepts are selected and going to be described individually bellow.

5.2.1 Concept 1

Fig. 5.2-1 shows the conventional assembly of the 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 the 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 concept 1 is composed of an upper plate, a bottom plate, a sliding plate, and two screws, as shown in Fig. 5.2-2.

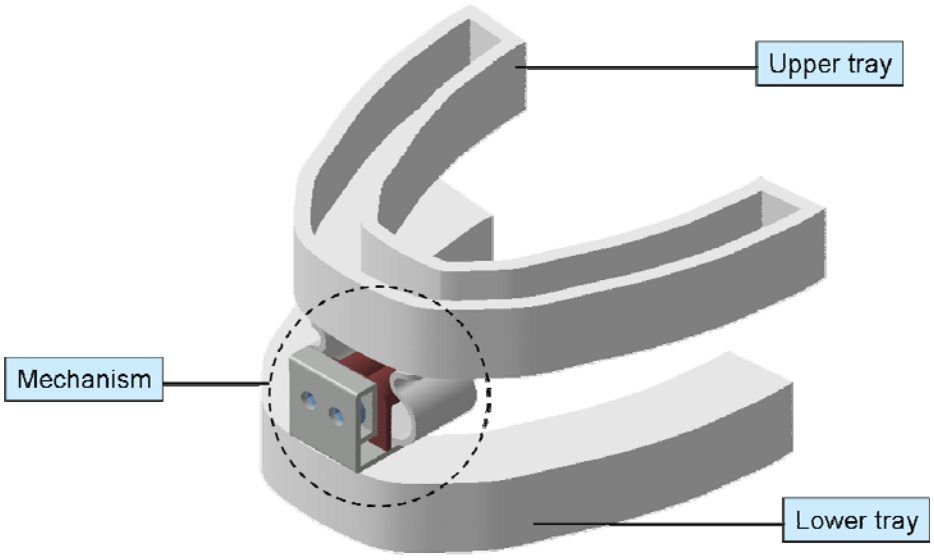


Fig. 5.2-1 Conventional assembly of MAD

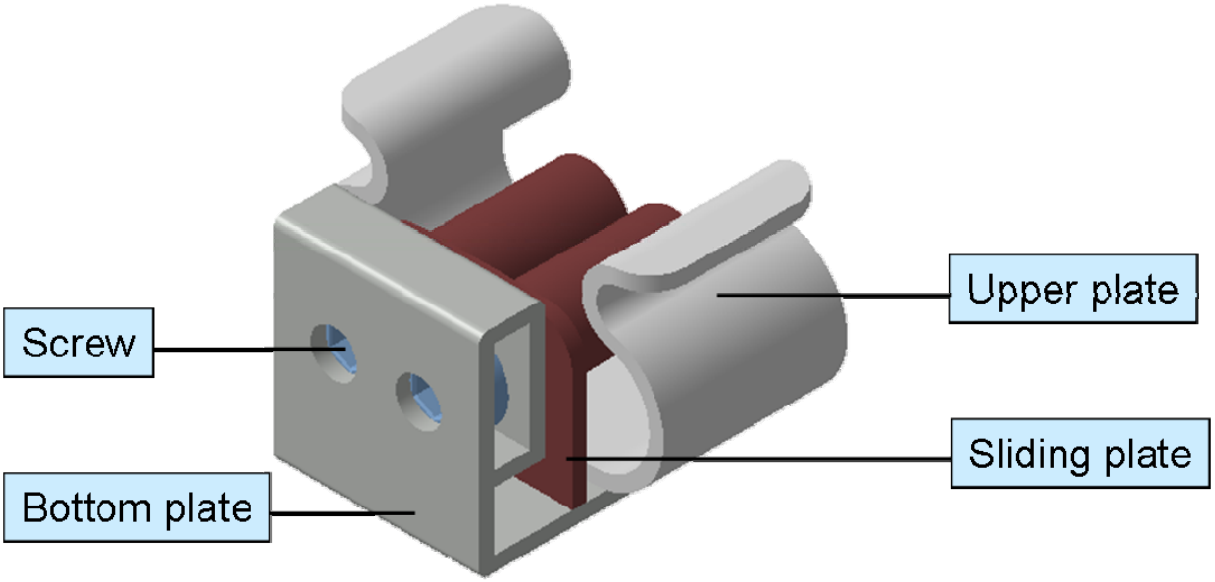


Fig. 5.2-2 Structure of mechanism in concept 1

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.

This concept is workable for moving the lower jaw forward with an adjustable amount. Furthermore, the proper height of the mechanism makes the lower jaw opening and downward slightly that causes the advancement more smooth to prevent TMJ from soreness. However, adjustor is composed of two screws. It means that each adjustment process has to make twice efforts.

5.2.2 Concept 2

This concept includes the disengagement function to prevent the device from failure. Fig. 5.2-3 shows the whole assembly of concept 2. In this concept, the mechanism is composed of an upper plate, a bottom plate, and a screw, as shown in Fig. 5.2-4. The grooves on the upper and bottom plates are used to fix them more secure to the tray respectively. The upper plate provides a nut to connect with one end of the screw. On the other end, the root of the notch head tracks within a slot which is provided by the bottom plate.

The screw between the upper and bottom plate can adjust the amount of the jaw advancement and limit the moveable region of the lower jaw in the lateral direction. As the lower jaw move more widely to keep in touch with the side wall of the slot, the notch head receives the force applied from the border of the slot and starts to deform and shrink until the notch head disengages from the slot. The amount of the force for disengagement should less than the force which can make the device failure. However, the only method about how to adjust the disengagement force is the replacement of different materials. Maybe this is difficult to achieve and become a disadvantage of this concept.

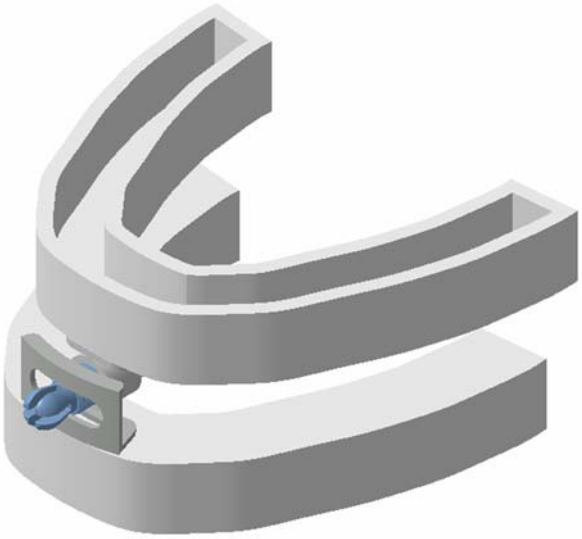


Fig. 5.2-3 Assembly view of concept 2

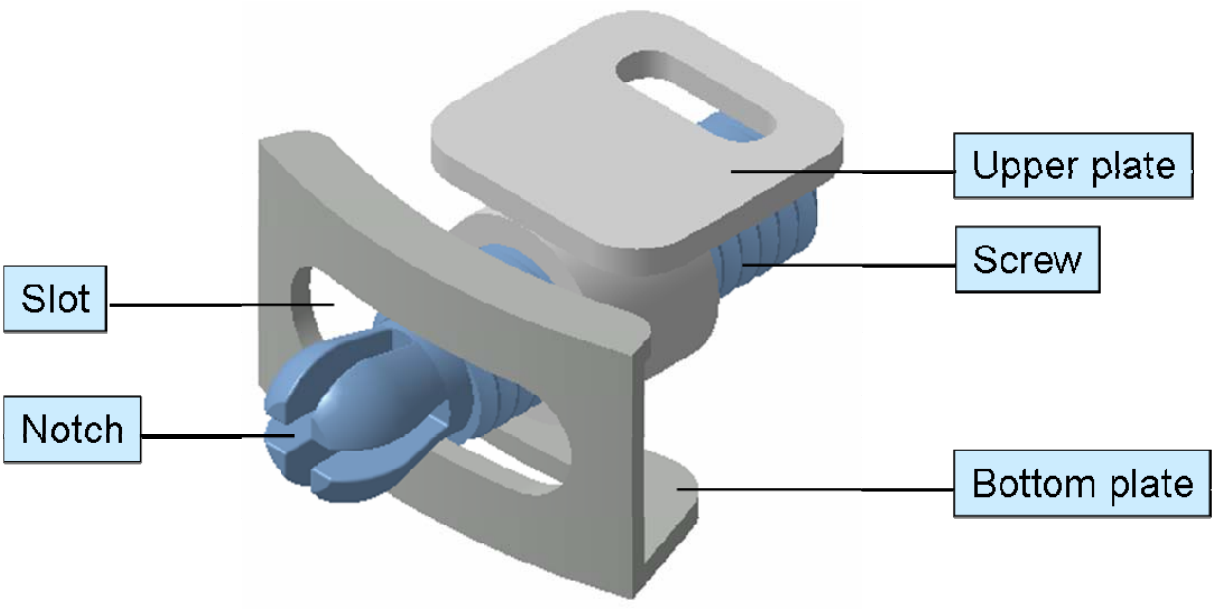


Fig. 5.2-4 Structure of mechanism in concept 2

5.2.3 Concept 3

This concept includes the disengagement function to prevent the device from failure. A concept of the adj-slider integrated the adjustment function. Therefore, lateral movement is provided and combined in this concept. The adj-slider is installed in the upper tray opposite to the disengagement mechanism which is installed in the lower tray, as shown in Fig. 5.2-5. The adj-slider is composed of a sliding base, a sliding post, a screw set, a telescopic tube, and an upper plate, as shown in Fig. 5.2-6. The upper plate and the two ends of the sliding base are fixed to the upper tray to form a triangle. The sliding post slides along the slot of the sliding base at one end, and connects with the telescopic tube at another end. Then, the telescopic tube pivot to the upper plate to form a telescopic sliding mechanism in the triangle. The screw set is installed coaxial to the sliding post to receive the retractive force from the lower jaw and transfer to the sliding base during using time. As the screw set elongates, not only pushes the lower jaw forward but also limits it to a narrower range for lateral movement. The result of moveable region conforms to the border movement of the mandible recorded in the horizontal plane [53].

The disengagement mechanism is composed of a bottom plate, a fixed plate, a rotational plate, a pin, a spring, and a connector. It is fixed to the lower tray at the bottom plate. The bottom plate fixes the fixed plate together to hold a pin to be the rotational axis of the rotational plate. In Fig. 5.2-7, a spring installed between the bottom plate and the rotational plate provides a restoring force which is used to hold the connector to connect with the adjustor. As the device works to reach the limitation of the sliding base, the continuous applying forces lead to the deformation of the spring and the disengagement of connector. The magnitude of the force for disengagement can be adjusted by designing different spring constant to meet the requirement.

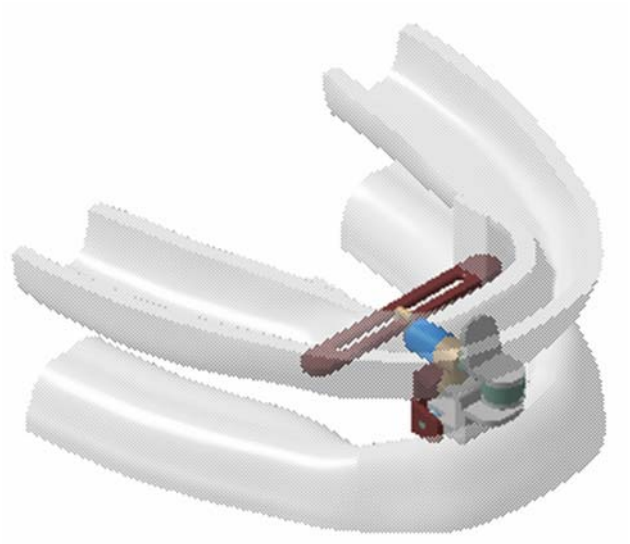


Fig. 5.2-5 Assembly view of concept 3

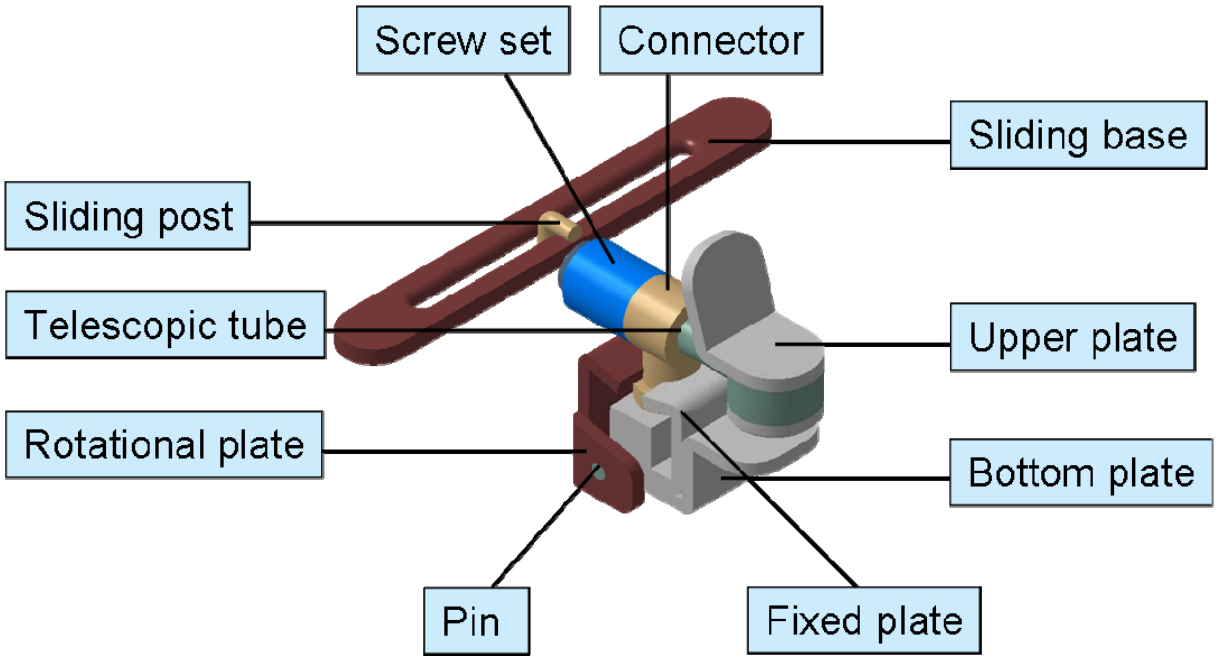


Fig. 5.2-6 Structure of mechanism in concept 3

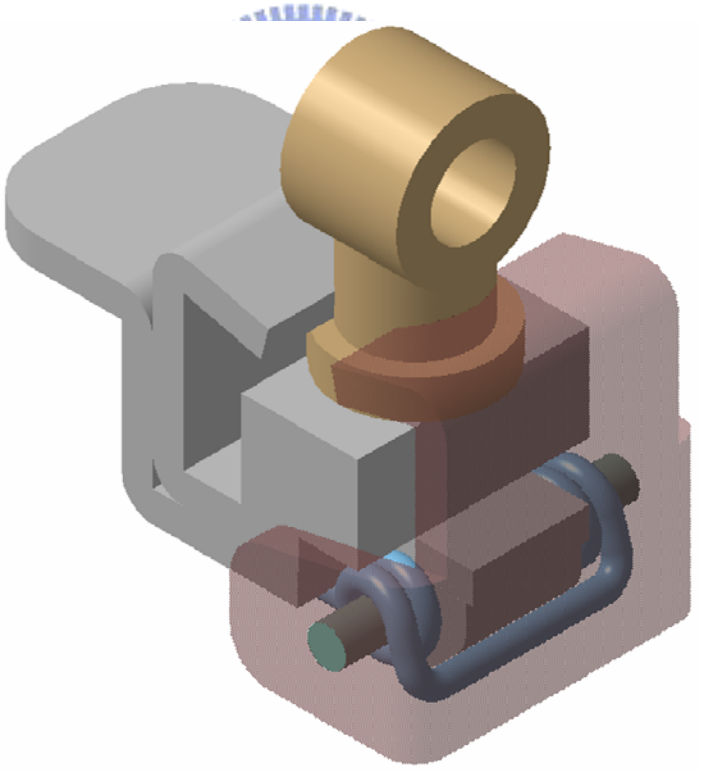


Fig. 5.2-7 The spring installed in concept 3

5.2.4 Concept 4

This concept is similar to concept 3 except the disengagement mechanism, as shown in Fig. 5.2-8. The disengagement mechanism is composed of a bottom plate, a connector, two rotational cylinders, and two springs, as shown in Fig. 5.2-9. It is installed on the lower tray by fixing the bottom plate and connected to adjustor by the connector. The rotational cylinder is assembled with a spring to install to the bottom plate, and there are two cylinder sets in this concept. The stop pad lies on the bottom plate between the two rotational cylinders, it is used to stop the rotation of the rotational cylinder and the spring in a specific direction. The two rotational cylinders are designed to rotate in the same direction that allows the installation of the spring with a preload. When the disengagement occurs, the connector disengages from one rotational cylinder. It means that if the connector disengages from the anterior rotational cylinder at one side, then it must disengage from the posterior rotational cylinder at another side. In this concept, the magnitude of the force for disengagement also can be adjusted by changing different spring and setting different preload to meet the requirement. However, the manufacture of disengagement mechanism seems to be difficult on this concept.

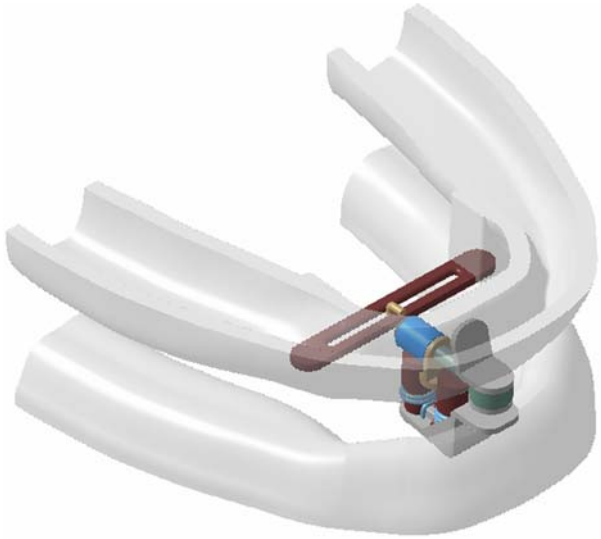


Fig. 5.2-8 Assembly view of concept 4

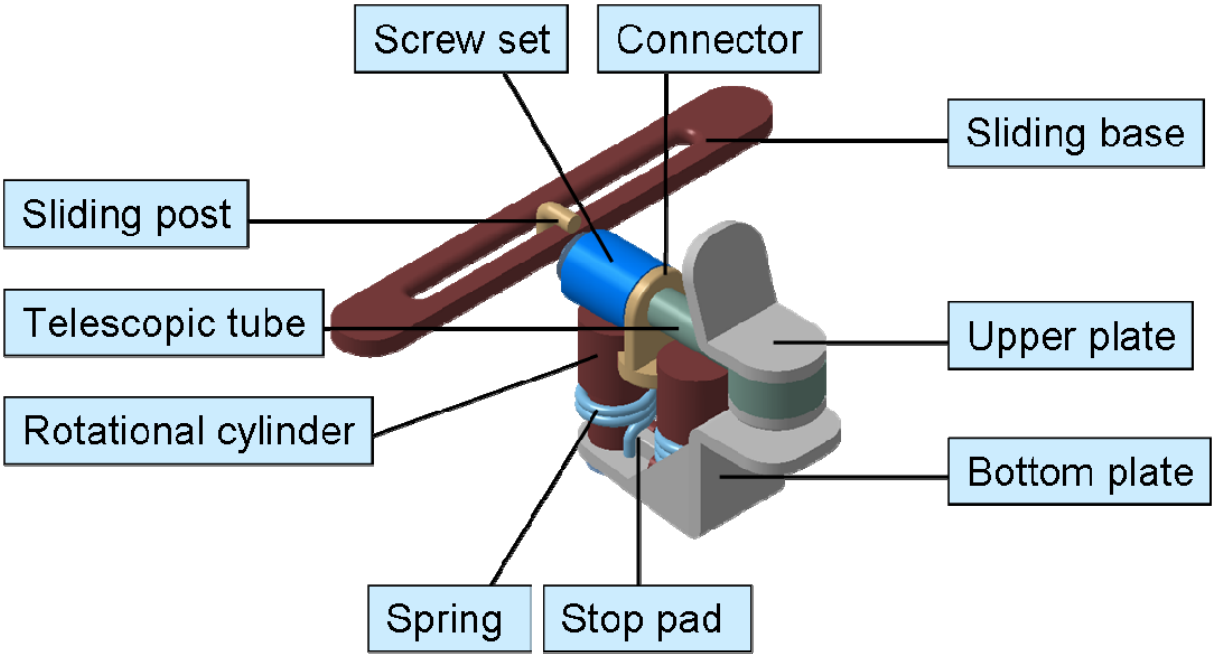


Fig. 5.2-9 Structure of mechanism in concept 4

In this section, four concepts are developed and described according to their construction, motion, and characteristic respectively. In next chapter, Finite Element Analysis (FEA) is introduced to estimate the conditions under force applied and the decision matrix will be used for concept evaluation. Finally, a concept will be selected for further design works.

CHAPTER 6

SIMULATION AND ANALYSIS

After four concepts are 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 properties 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. The analysis of four aforementioned conceptual designs and one commercial product are going to be discussed below.

6.1 Analysis Conditions

6.1.1 Load and Boundary Condition

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 [54]. 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. A study mentioned that an axial load of 100N is simulated to indicate as bruxism in their finite element analysis [55]. 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.

6.1.2 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 [56]. 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 Table 6.1-1 for using in FEA process.

Table 6.1-1 Material properties for FEA

	PMMA	**Stainless Steel (SUS 316L)**	**Titanium Alloy (Ti-6Al-4V)**
Young's Modulus (GPa)	3.8 [57]	193 [59]	116 [61]
Poisson Ratio	0.388 [58]	0.263 [59]	0.34 [61]
Density (kg/m^3)	1180 [57]	7950 [60]	4420 [62]
Tensile Strength (MPa)	55.2 [57]	586 [60]	1016 [62]
Compressive Strength (MPa)	75.9 [57]	—	—

6.1.3 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 have 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 25.24 MPa [63] and 34.7 MPa [64] 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 [65]. The Coulomb-Mohr criterion judges failure by maximum principal stress σ_1 and minimum principal stress σ_3, as shown in Fig. 6.1-1 [66]. The failure strengths relate to the equation 6-1.1 to equation 6-1.3, where S_t and S_c mean the tensile strength and compressive strength.

$$\frac{\sigma_1}{S_t} - \frac{\sigma_3}{S_c} = 1 \qquad \sigma_1 \geq 0, \sigma_3 \leq 0 \tag{6.1-1}$$

$$\sigma_1 = S_t \qquad \sigma_1 > 0 \tag{6.1-2}$$

$$\sigma_3 = -S_c \qquad \sigma_3 < 0 \tag{6.1-3}$$

$$n_d = \frac{Failure\ Strength}{Stress} \tag{6.1-4}$$

The design factor n_d is introduced as an index to compare the strength between all finite element models. Design factor is a factor of safety that is calculated by the stress and the failure strength, as shown in equation 6.1-4. The larger value of design factor represents the more safety design. All of the stress values in the results of FEA are going to be translated into design factors that the smallest one is considered as the design factor of whole finite element model. Finally, the relative strength between each model is obvious by comparing the smallest design factor value in each model.

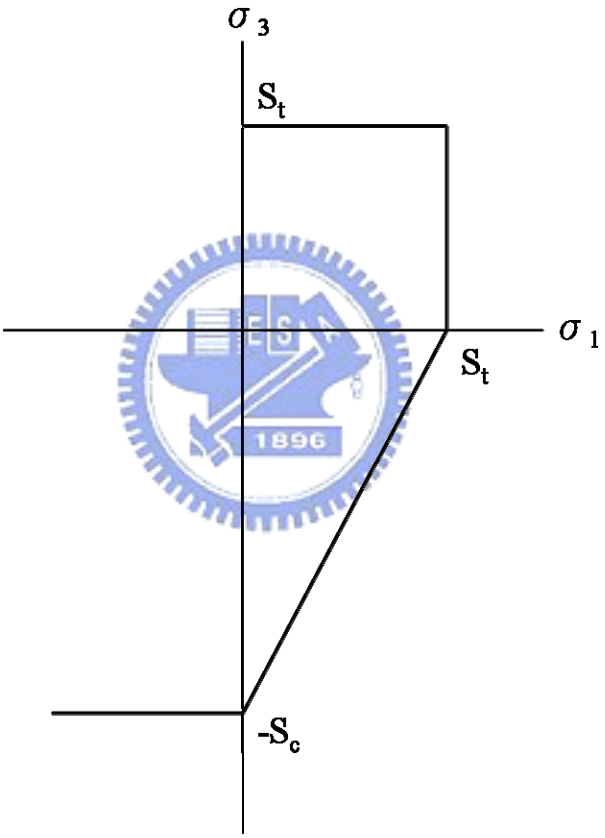


Fig. 6.1-1 Coulomb-Mohr criterion

6.2 Analysis Results

6.2.1 Case I – The Results of Concept 1

Fig. 6.2-1 to Fig. 6.2-4 show the simulation results of bonding interface and resin in the upper portion of concept 1. The maximum principal shear stress on bonding interface is 3.04 MPa. 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. 6.2-5 to Fig. 6.2-8 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 0.76 MPa. 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 concept.

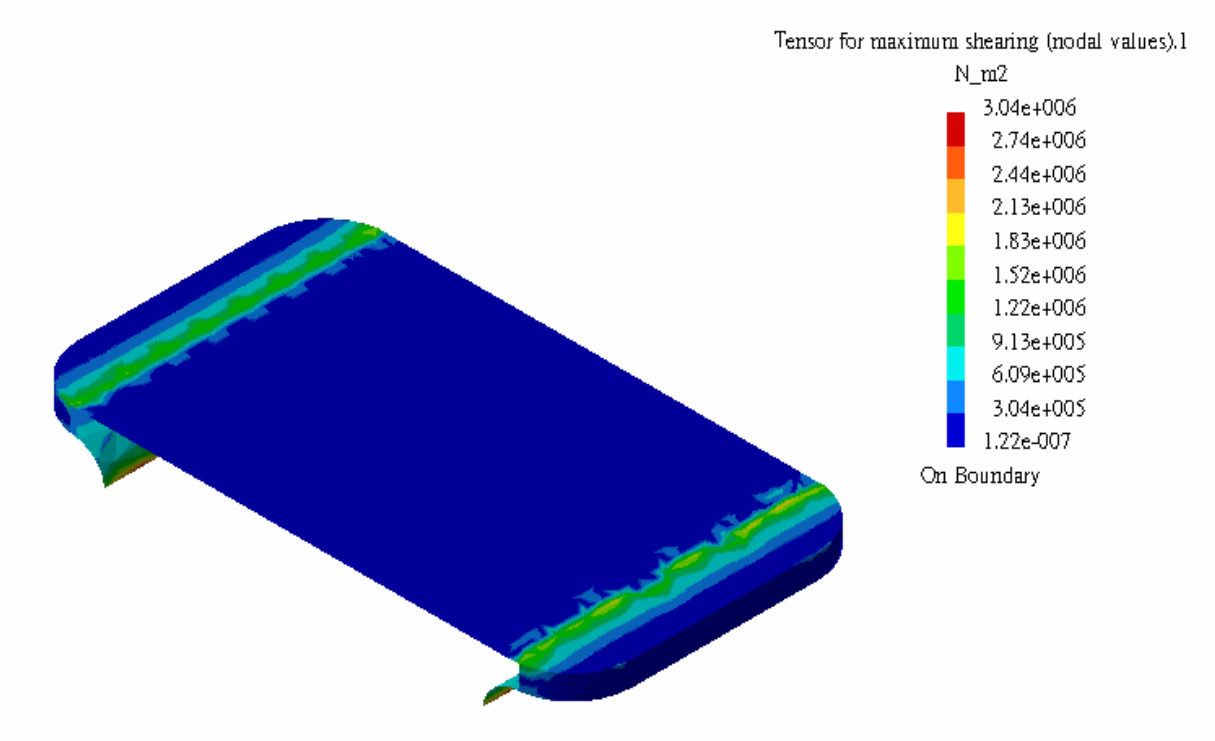


Fig. 6.2-1 The principal shear stress distribution on bonding interface of concept 1

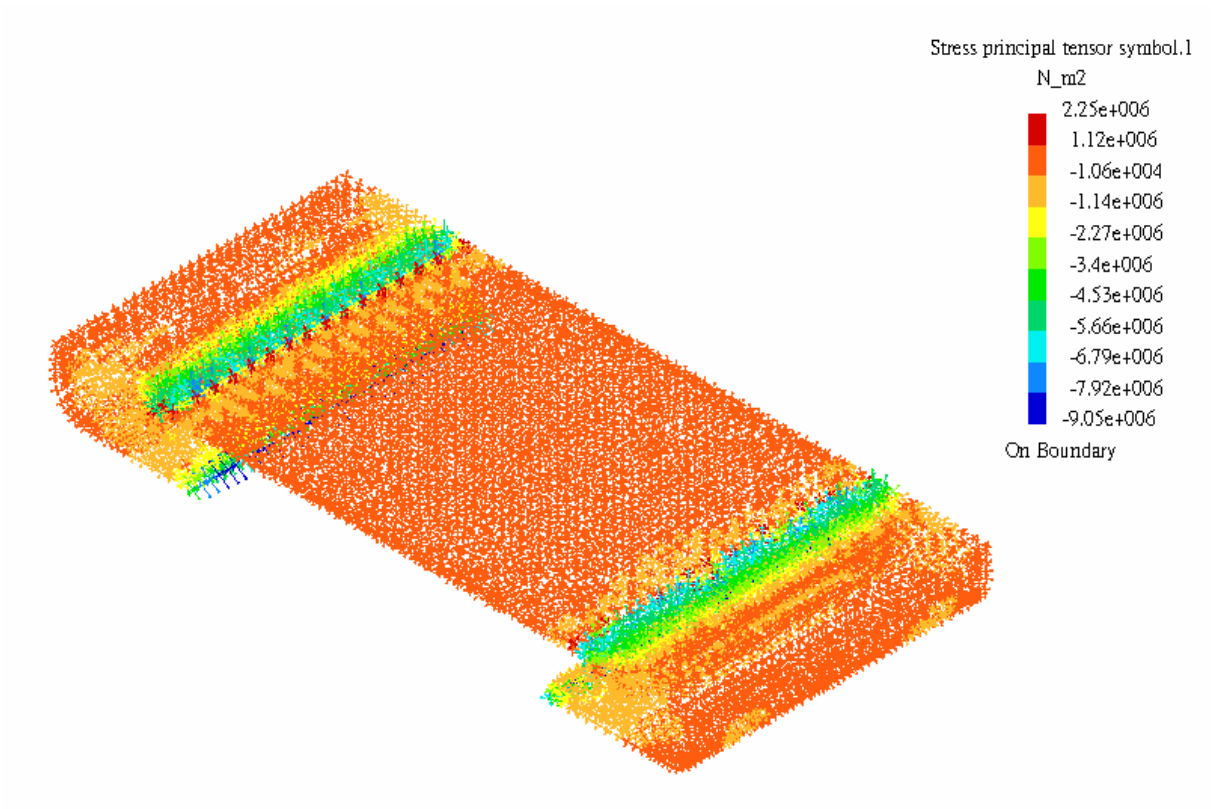


Fig. 6.2-2 The principal stresses distribution in resin of concept 1

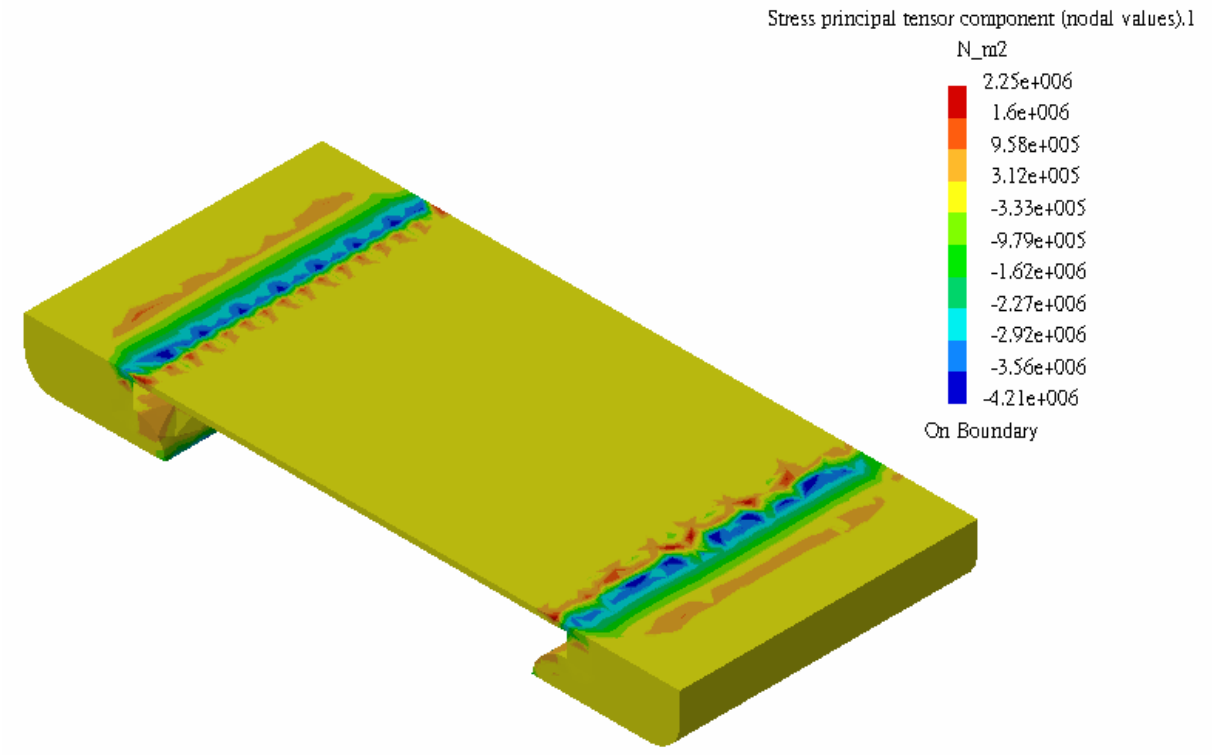


Fig. 6.2-3 The maximum principal stress distribution in resin of concept 1

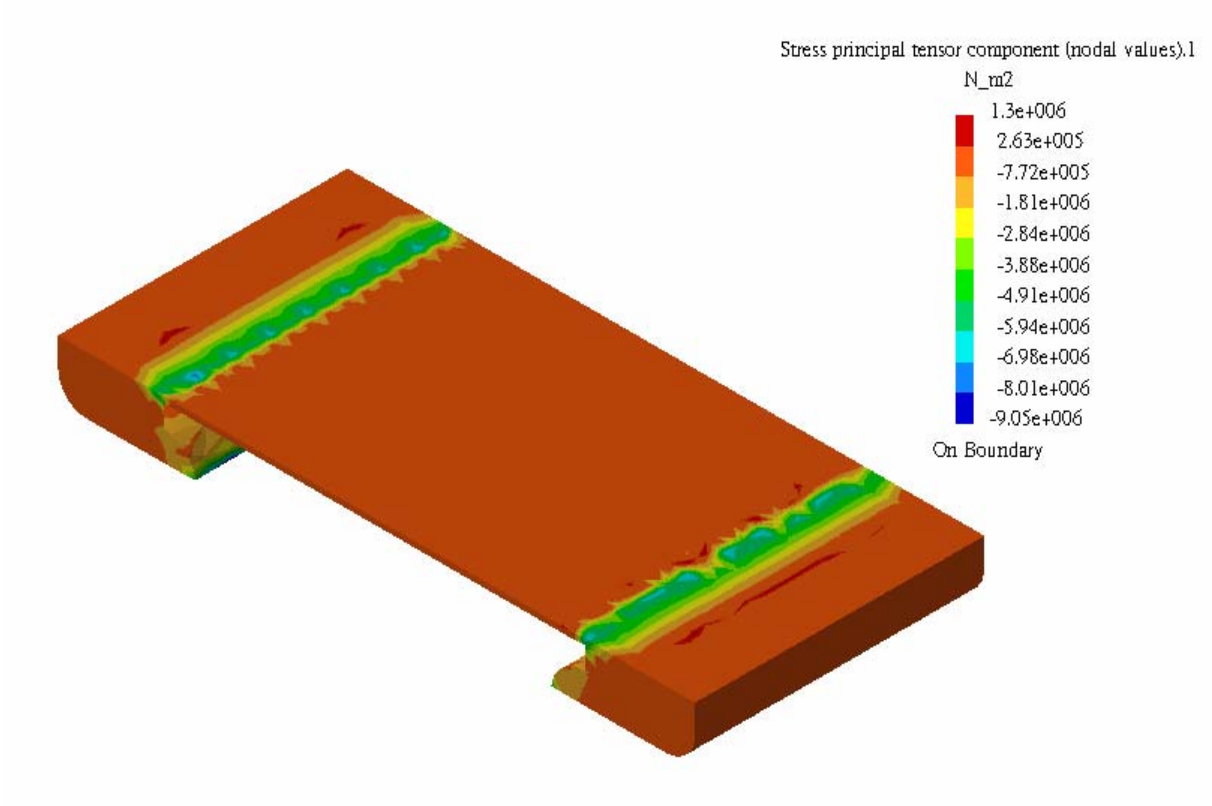


Fig. 6.2-4 The minimum principal stress distribution in resin of concept 1

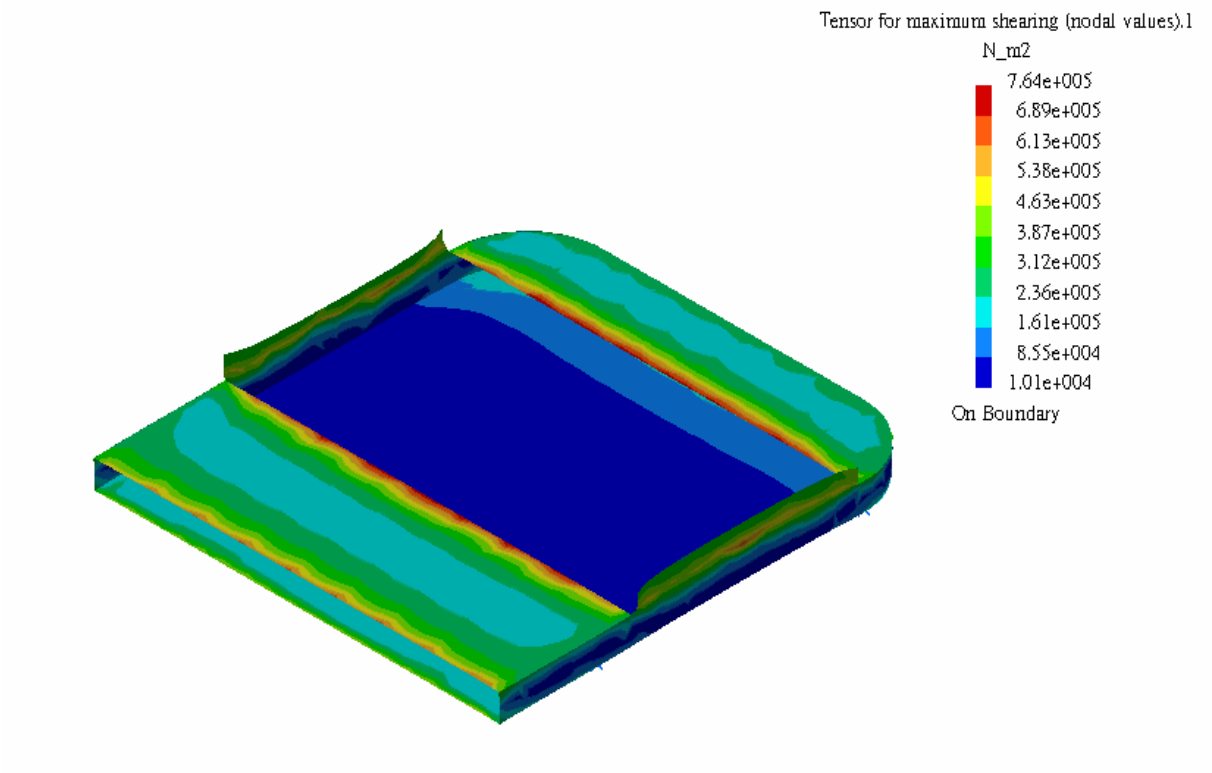


Fig. 6.2-5 The principal shear stress distribution on bonding interface of concept 1

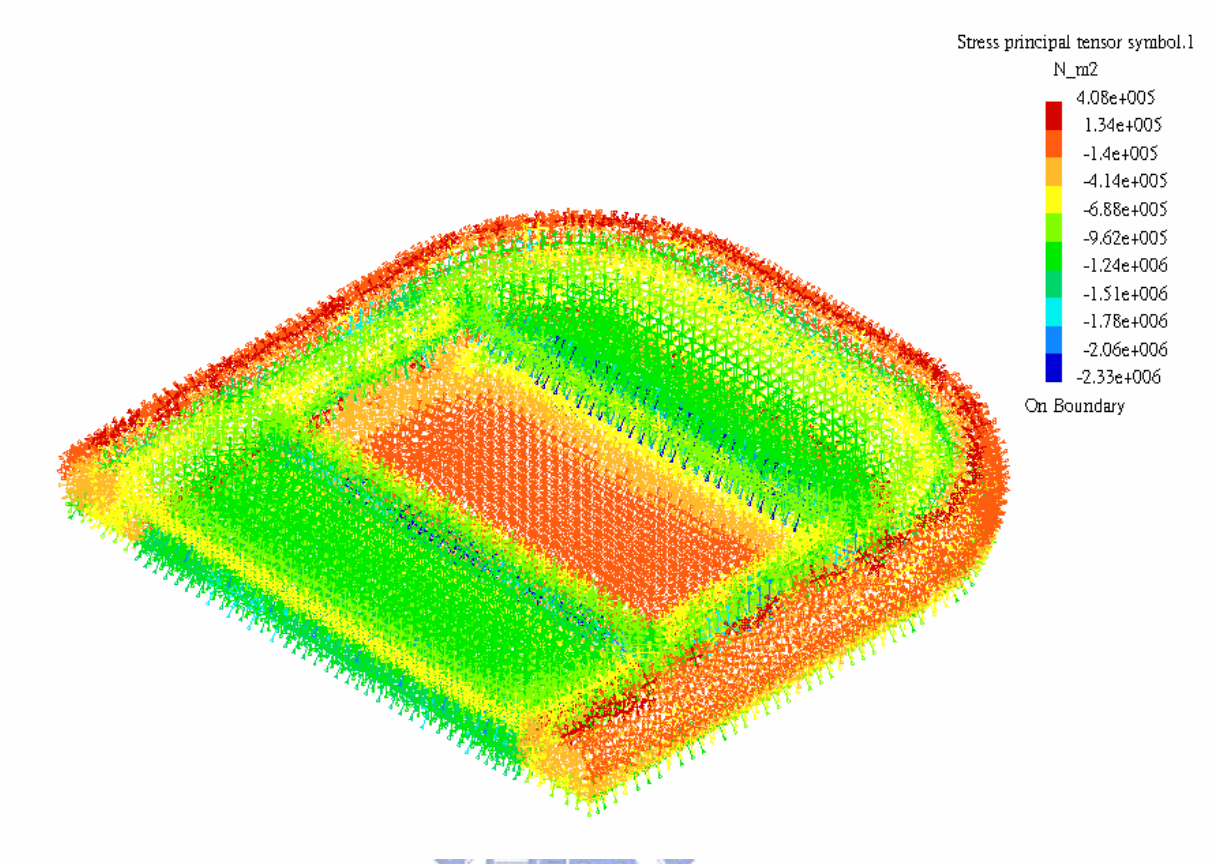


Fig. 6.2-6 The principal stresses distribution in resin of concept 1

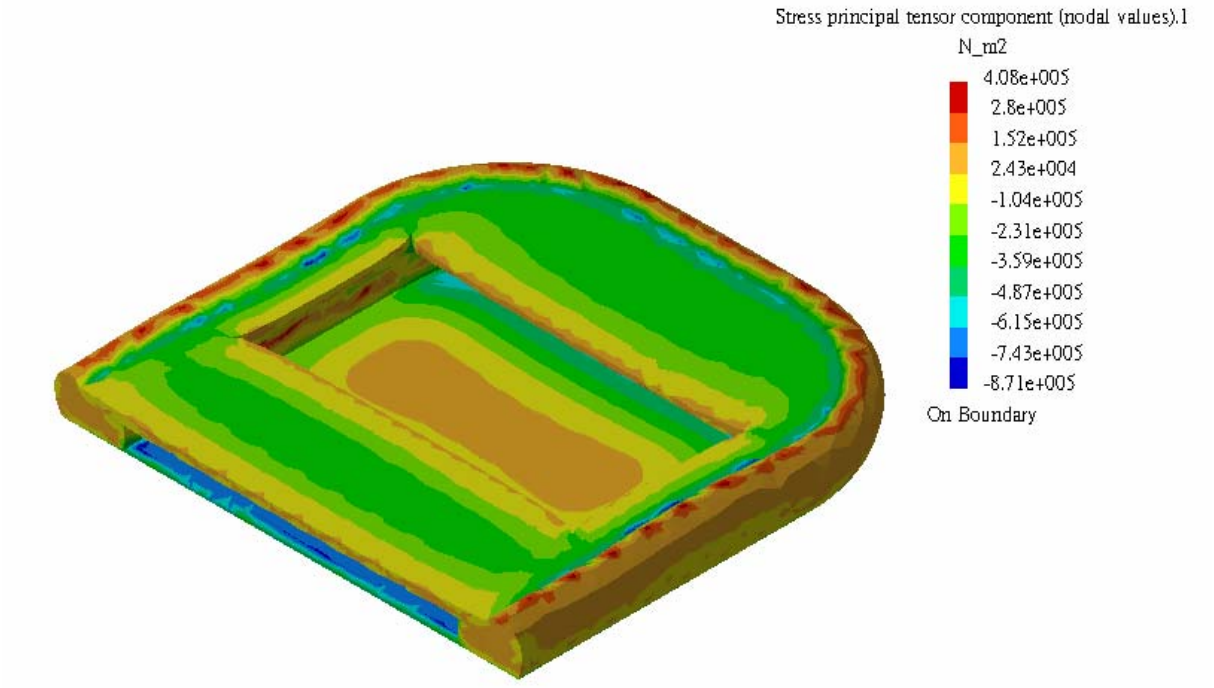


Fig. 6.2-7 The maximum principal stress distribution in resin of concept 1

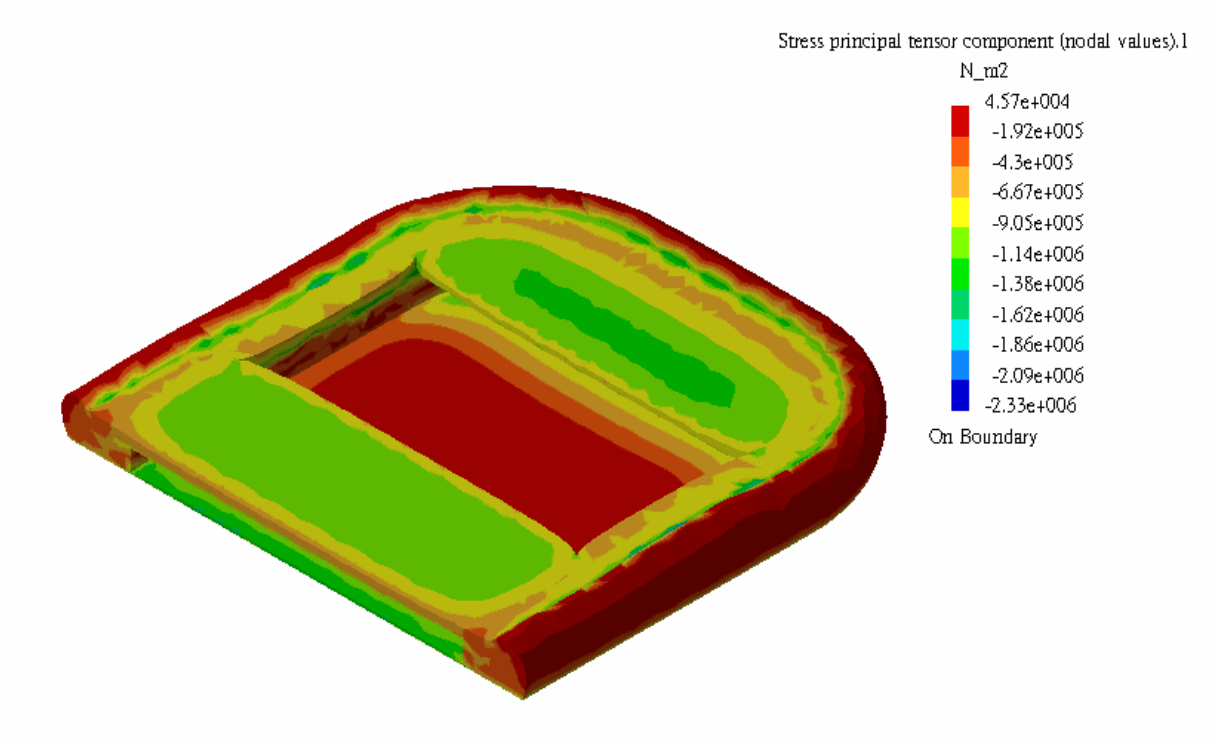


Fig. 6.2-8 The minimum principal stress distribution in resin of concept 1

6.2.2 Case II – The Results of Concept 2

Fig. 6.2-9 to Fig. 6.2-12 show the simulation results of bonding interface and resin in the upper portion of concept 2. The maximum principal shear stress on bonding interface is 24.3 MPa. The design factor is 1.04 for the bonding interface and 1.18 for the resin. The bonding strength is on the edge of failure.

Fig. 6.2-13 to Fig. 6.2-16 show the simulation results of bonding interface and resin in the lower portion of concept 2. The maximum principal shear stress on bonding interface is 1.7 MPa. The design factor is 14.88 for the bonding interface and 13.41 for the resin. This means that resin is weaker than the bonding interface. Furthermore, the upper portion is weaker than the lower portion in this concept.

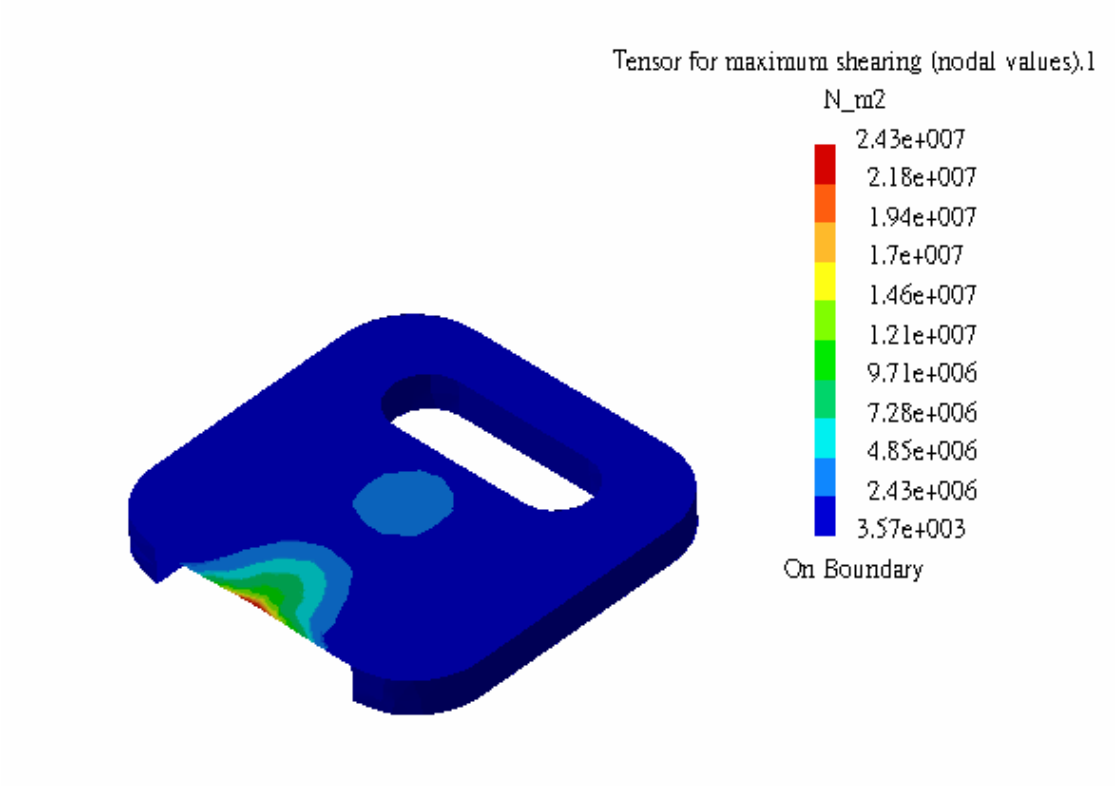


Fig. 6.2-9 The principal shear stress distribution on bonding interface of concept 2

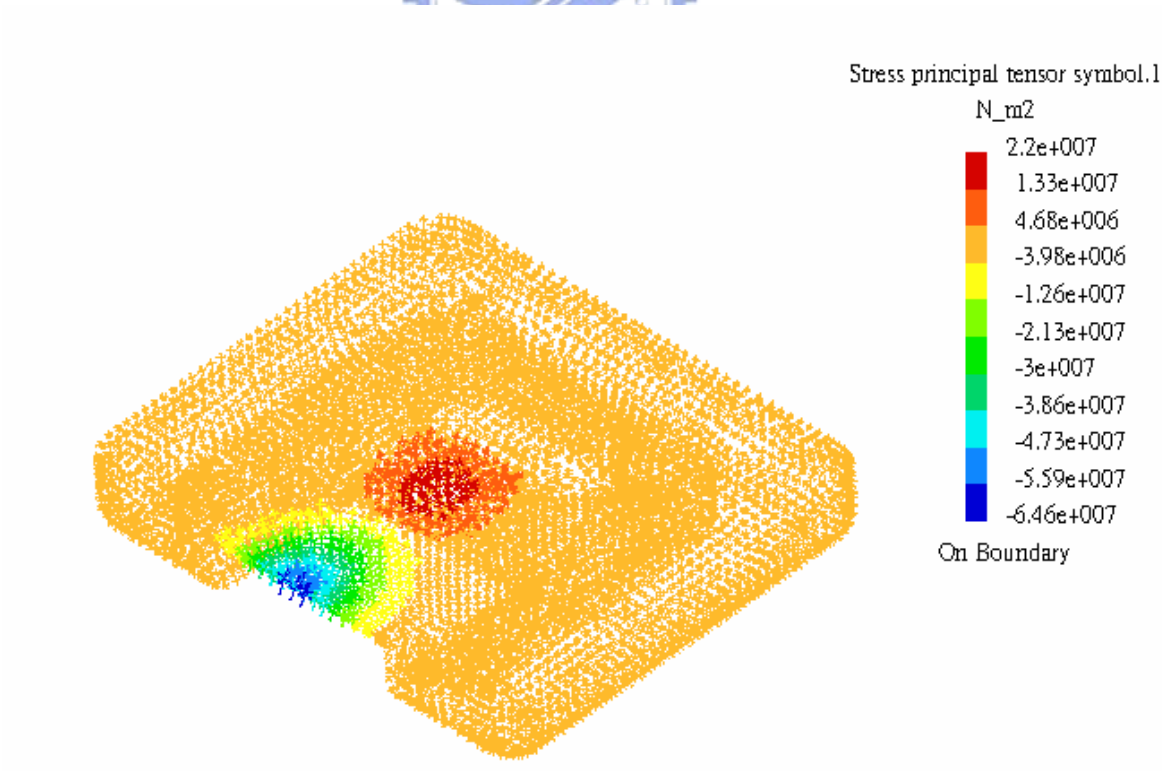


Fig. 6.2-10 The principal stresses distribution in resin of concept 2

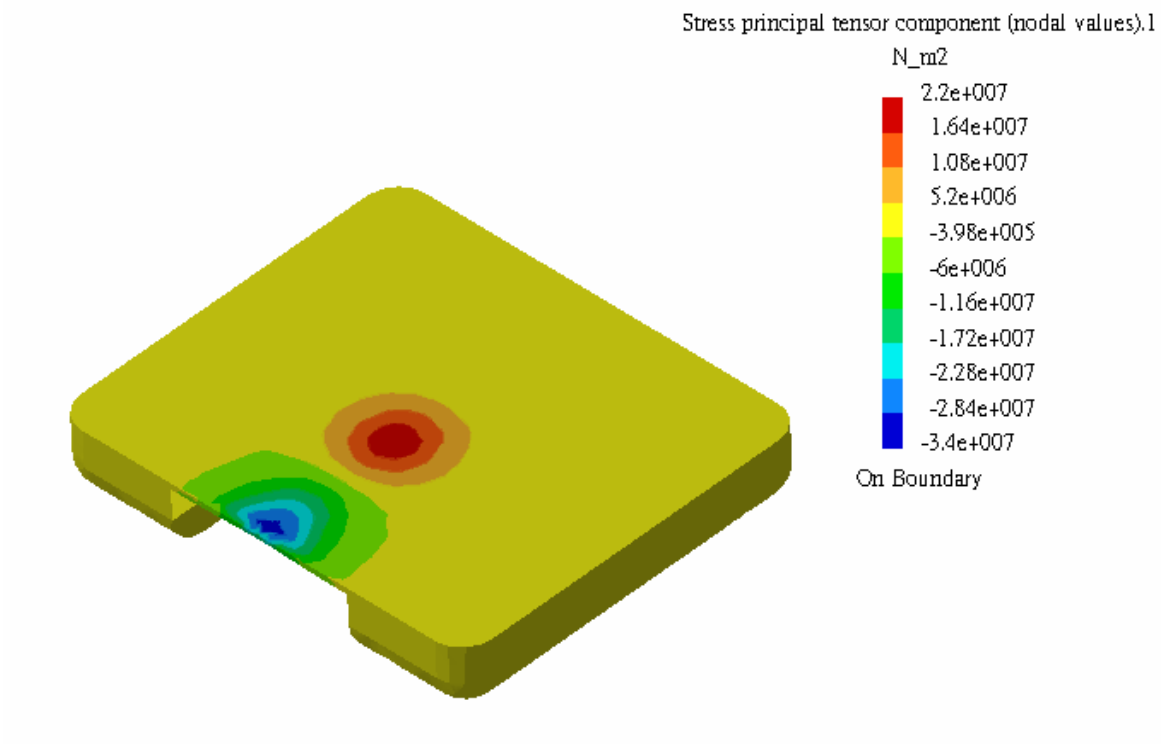


Fig. 6.2-11 The maximum principal stress distribution in resin of concept 2

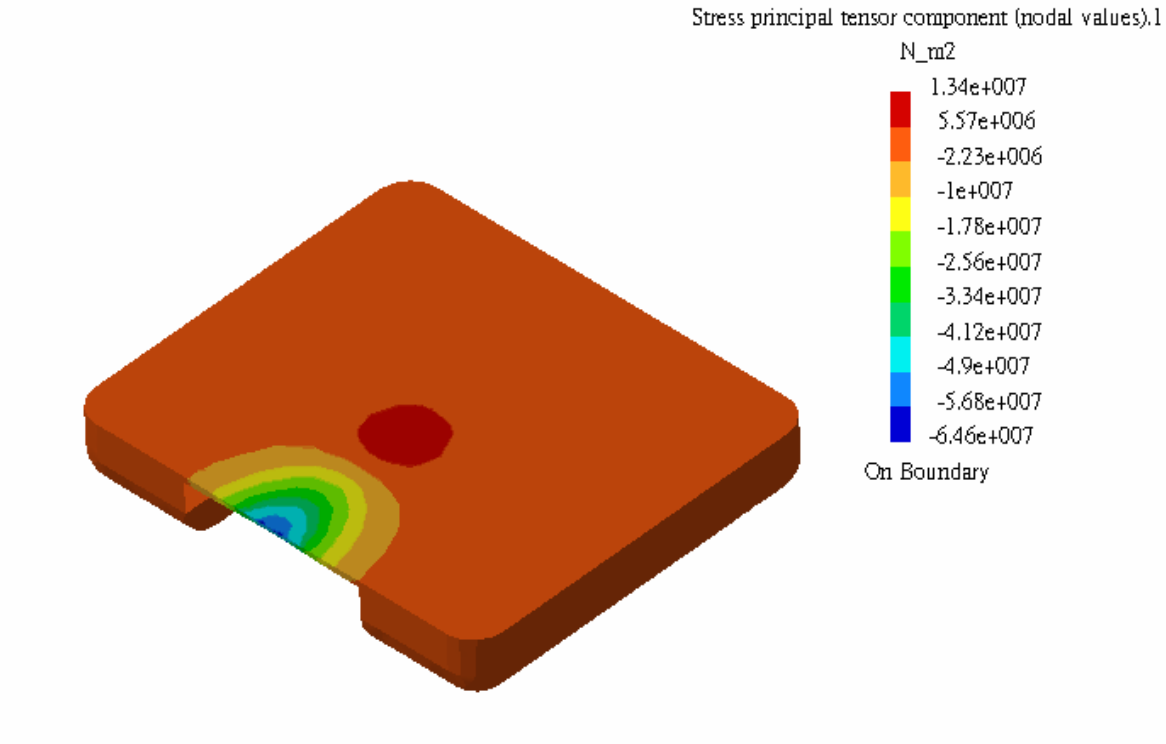


Fig. 6.2-12 The minimum principal stress distribution in resin of concept 2

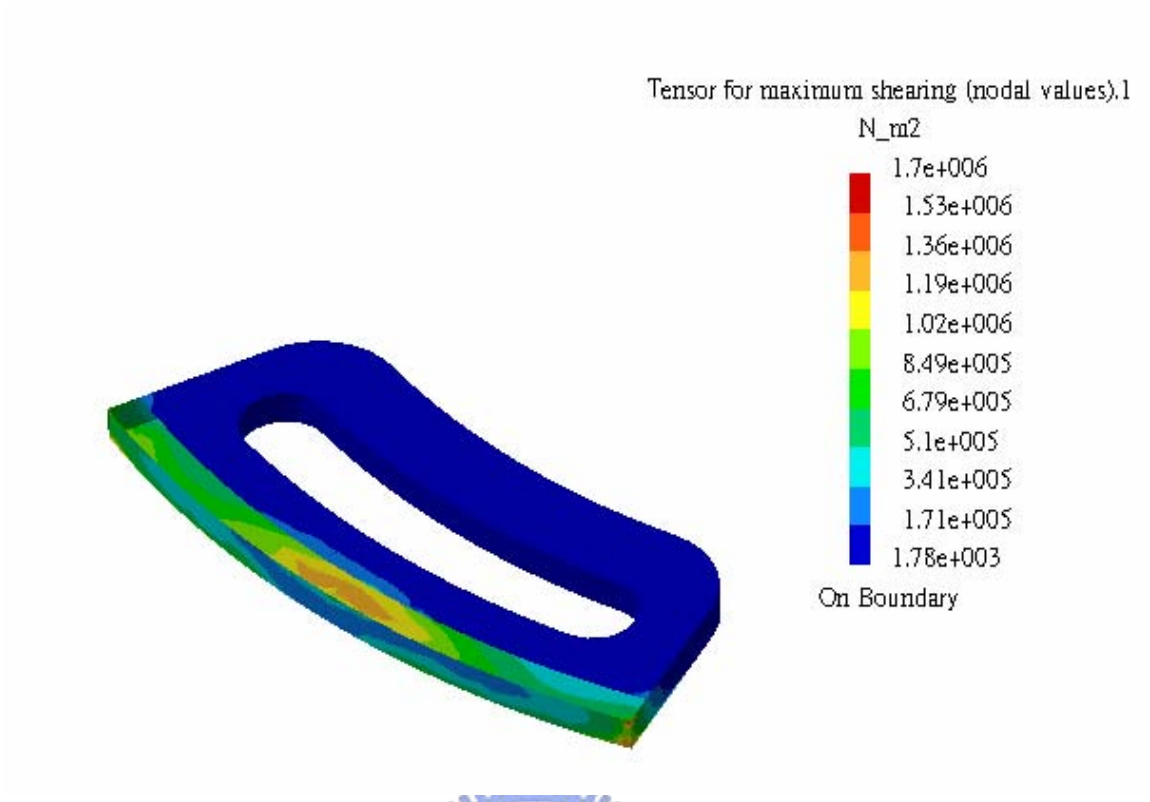


Fig. 6.2-13 The principal shear stress distribution on bonding interface of concept 2

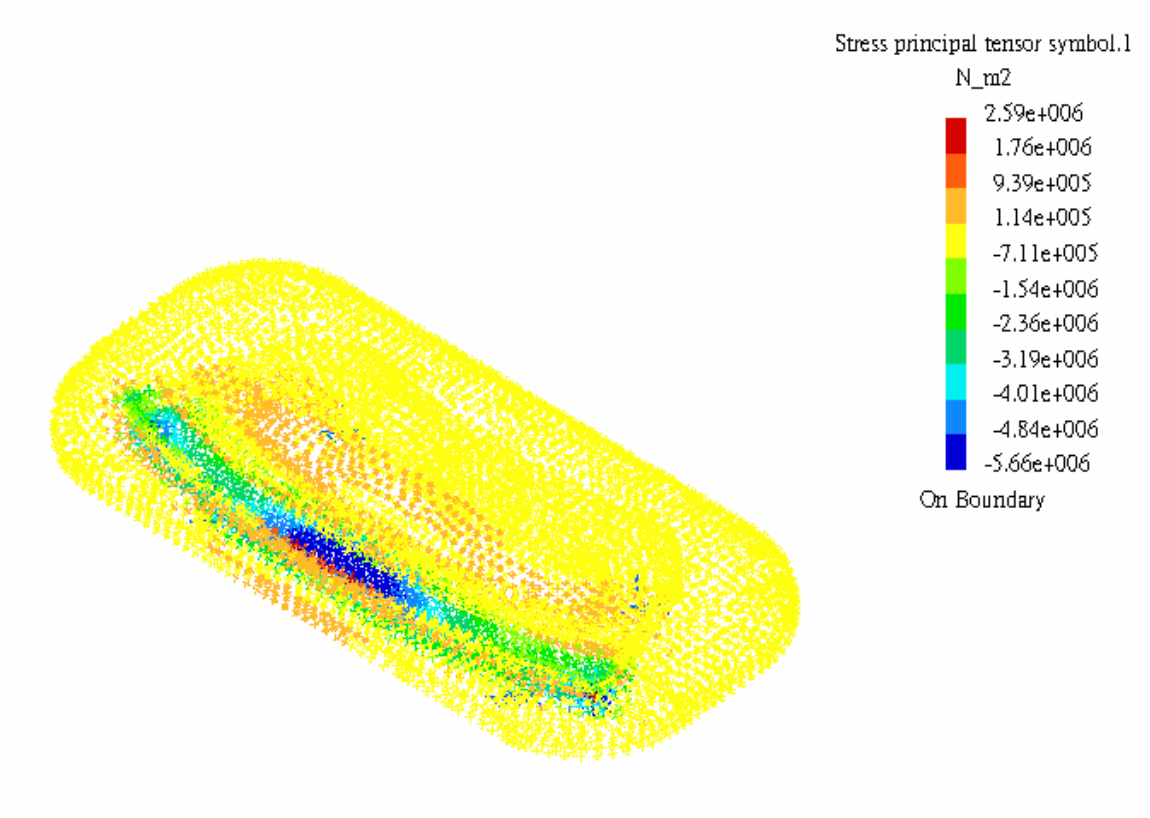


Fig. 6.2-14 The principal stresses distribution in resin of concept 2

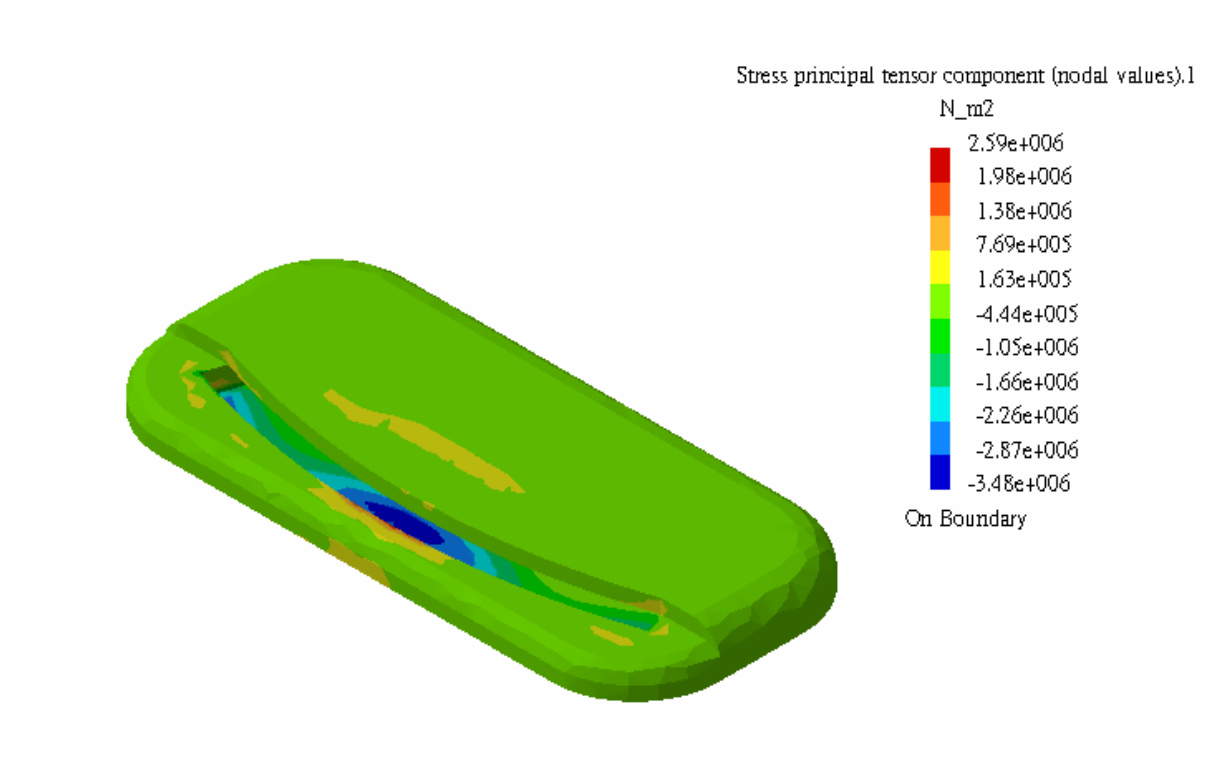


Fig. 6.2-15 The maximum principal stress distribution in resin of concept 2

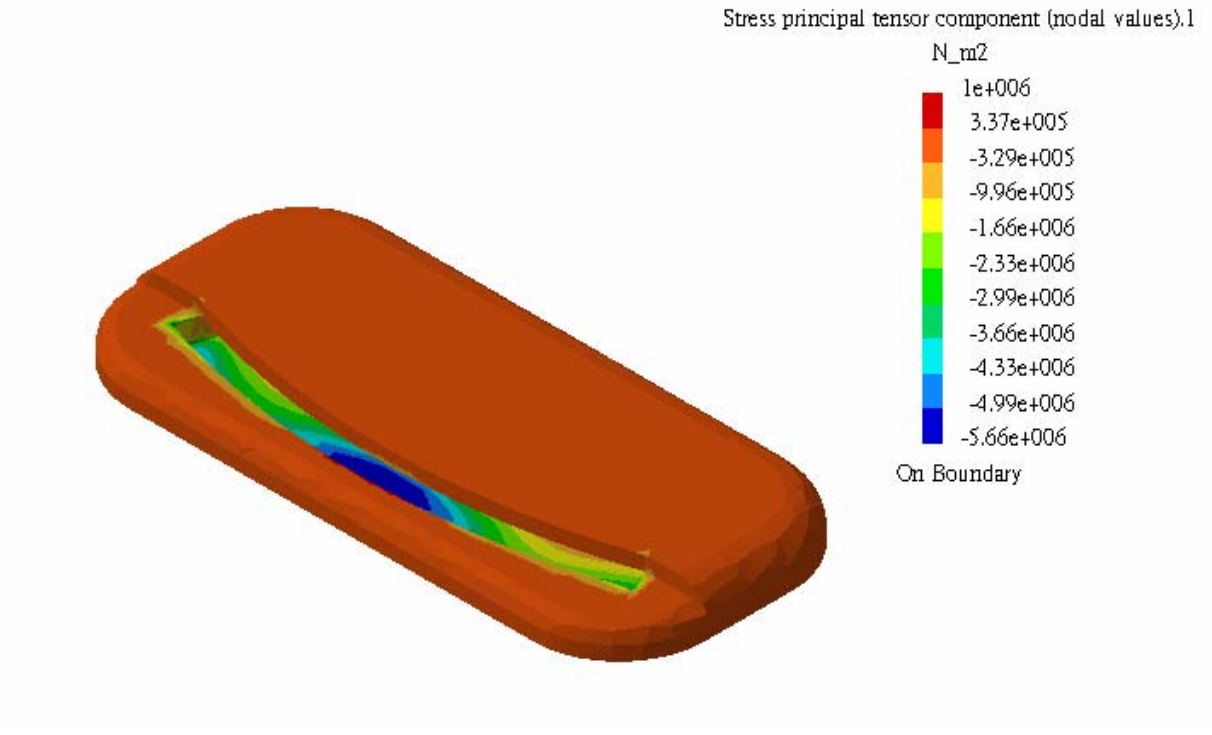


Fig. 6.2-16 The minimum principal stress distribution in resin of concept 2

6.2.3 Case III – The Results of Concept 3

Fig. 6.2-17 to Fig. 6.2-20 show the simulation results of bonding interface and resin in the upper portion of concept 3. The maximum principal shear stress on bonding interface is 9.91 MPa. The design factor is 2.55 for the bonding interface and 1.95 for the resin. This means that resin is weaker than the bonding interface.

Fig. 6.2-21 to Fig. 6.2-24 show the simulation results of bonding interface and resin in the lower portion of concept 3. The maximum principal shear stress on bonding interface is 15.3 MPa. The design factor is 1.66 for the bonding interface and 1.46 for the resin. This means that resin is weaker than the bonding interface. Furthermore, the lower portion is weaker than the upper portion in this concept.

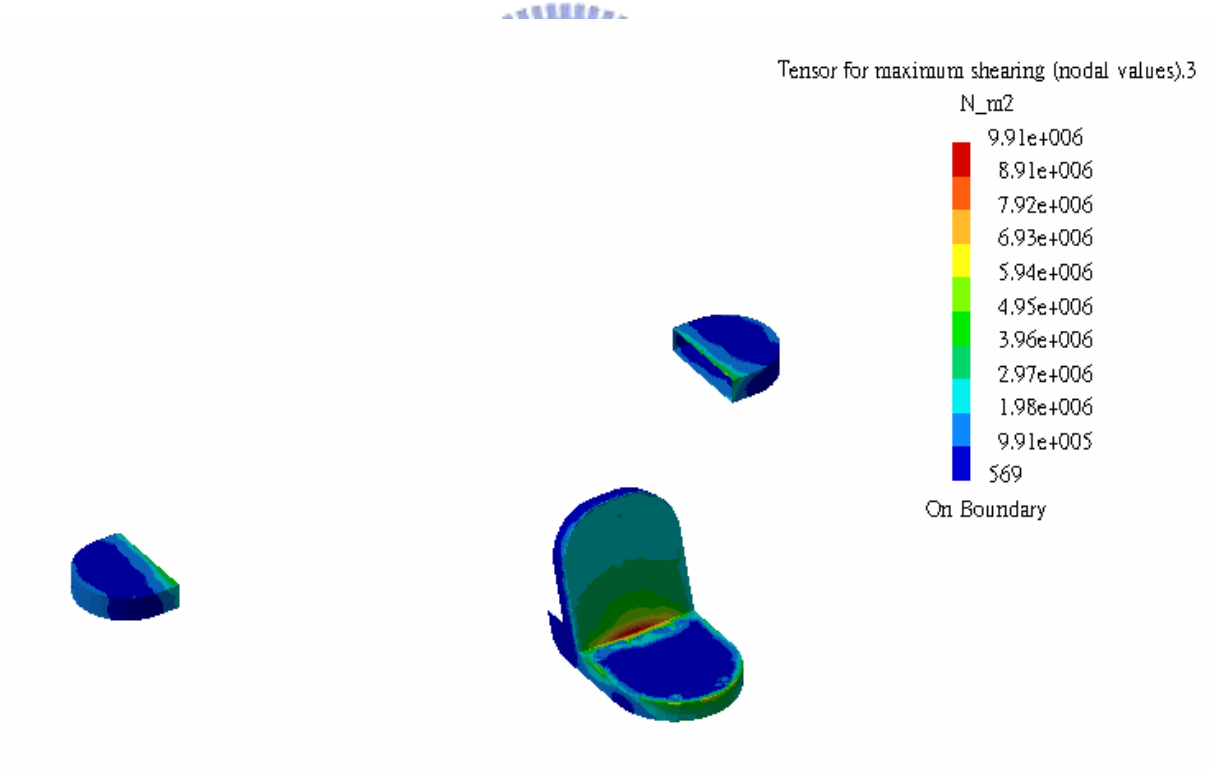


Fig. 6.2-17 The principal shear stress distribution on bonding interface of concept 3

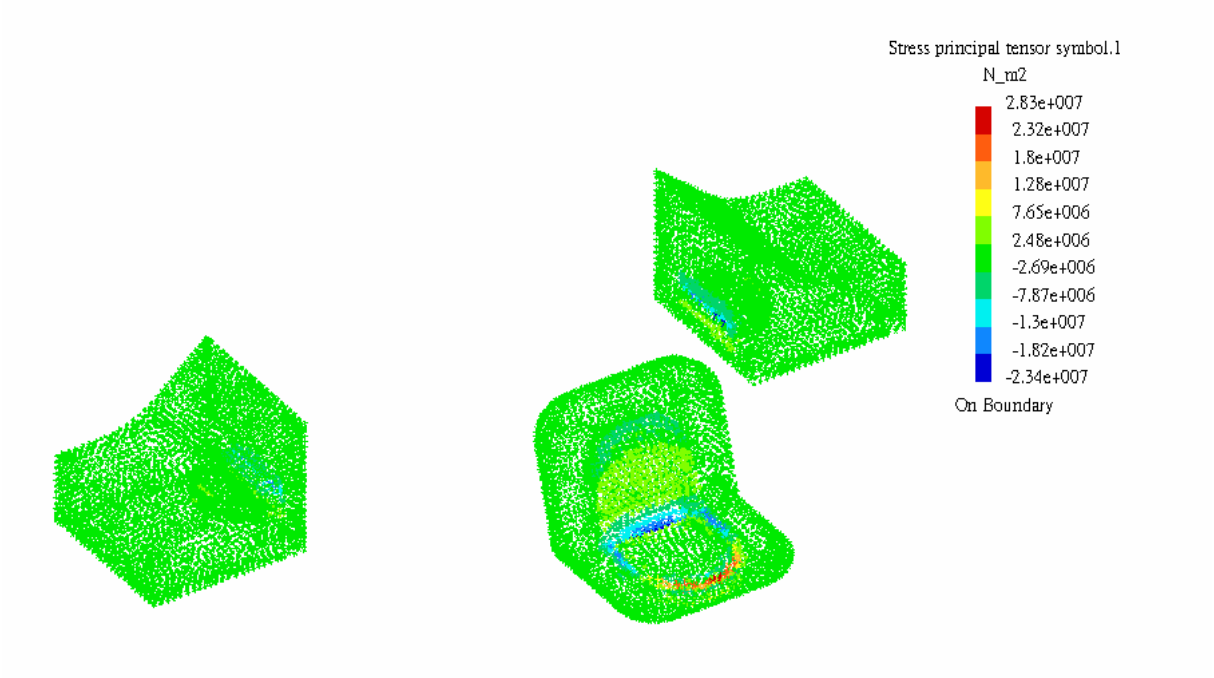


Fig. 6.2-18 The principal stresses distribution in resin of concept 3

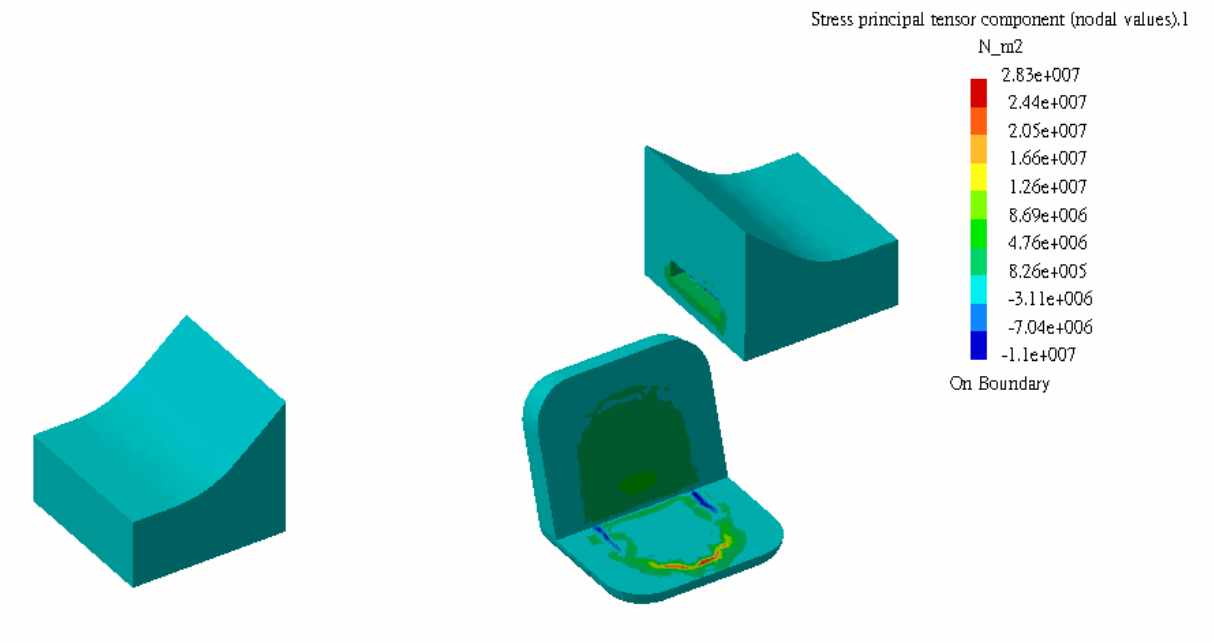


Fig. 6.2-19 The maximum principal stress distribution in resin of concept 3

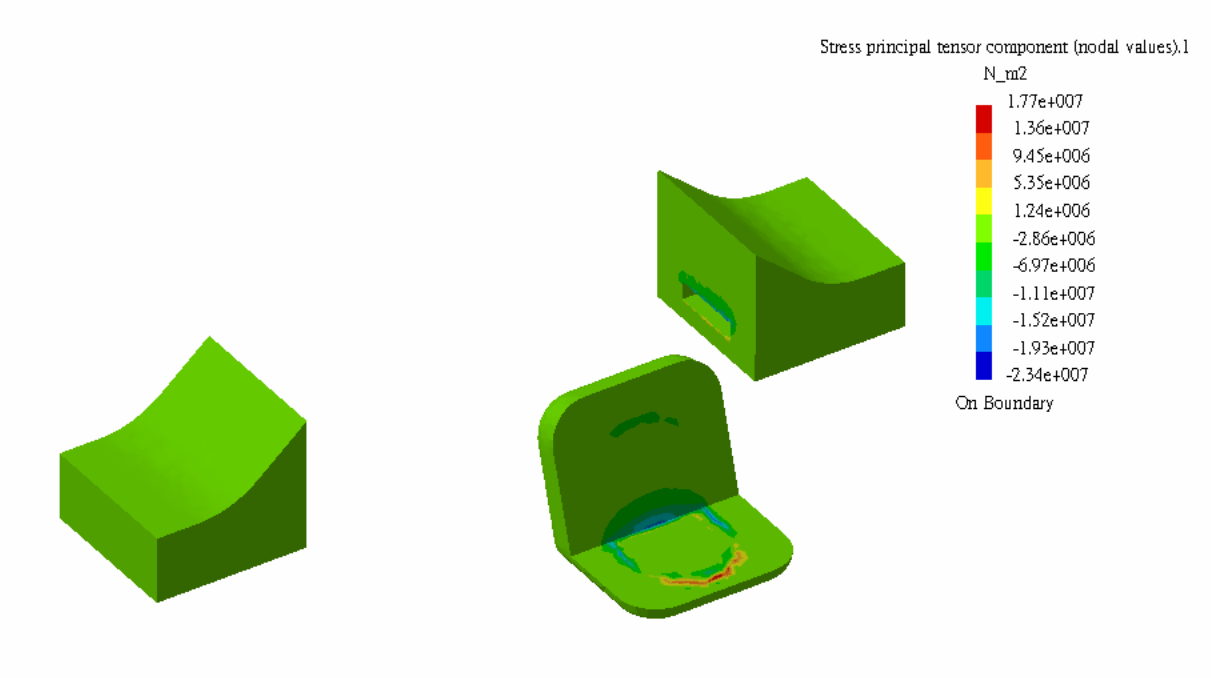


Fig. 6.2-20 The minimum principal stress distribution in resin of concept 3

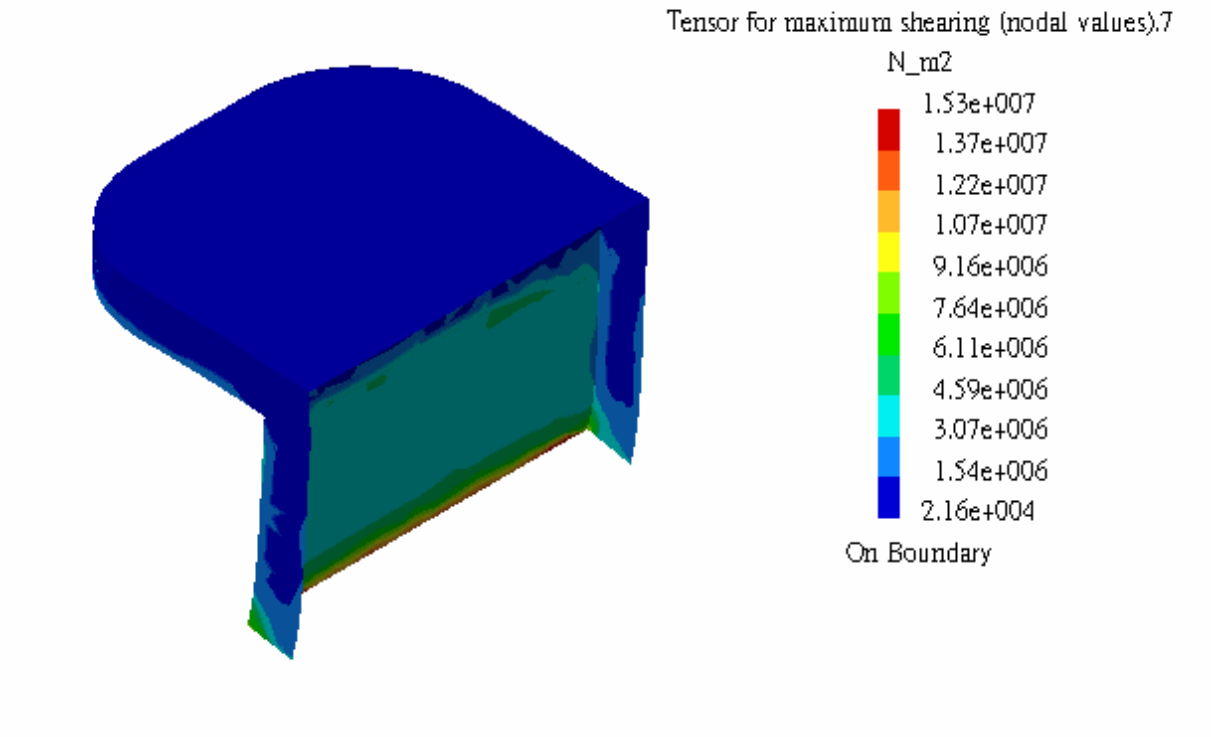


Fig. 6.2-21 The principal shear stress distribution on bonding interface of concept 3

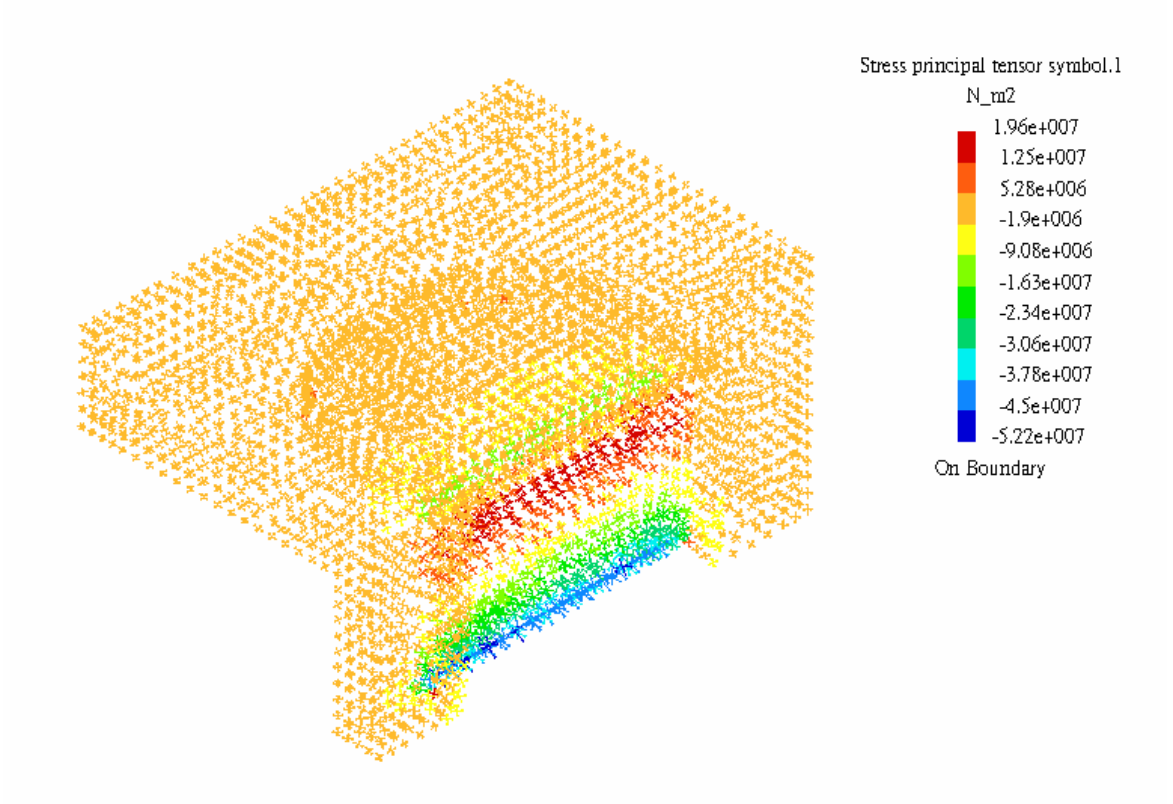


Fig. 6.2-22 The principal stresses distribution in resin of concept 3

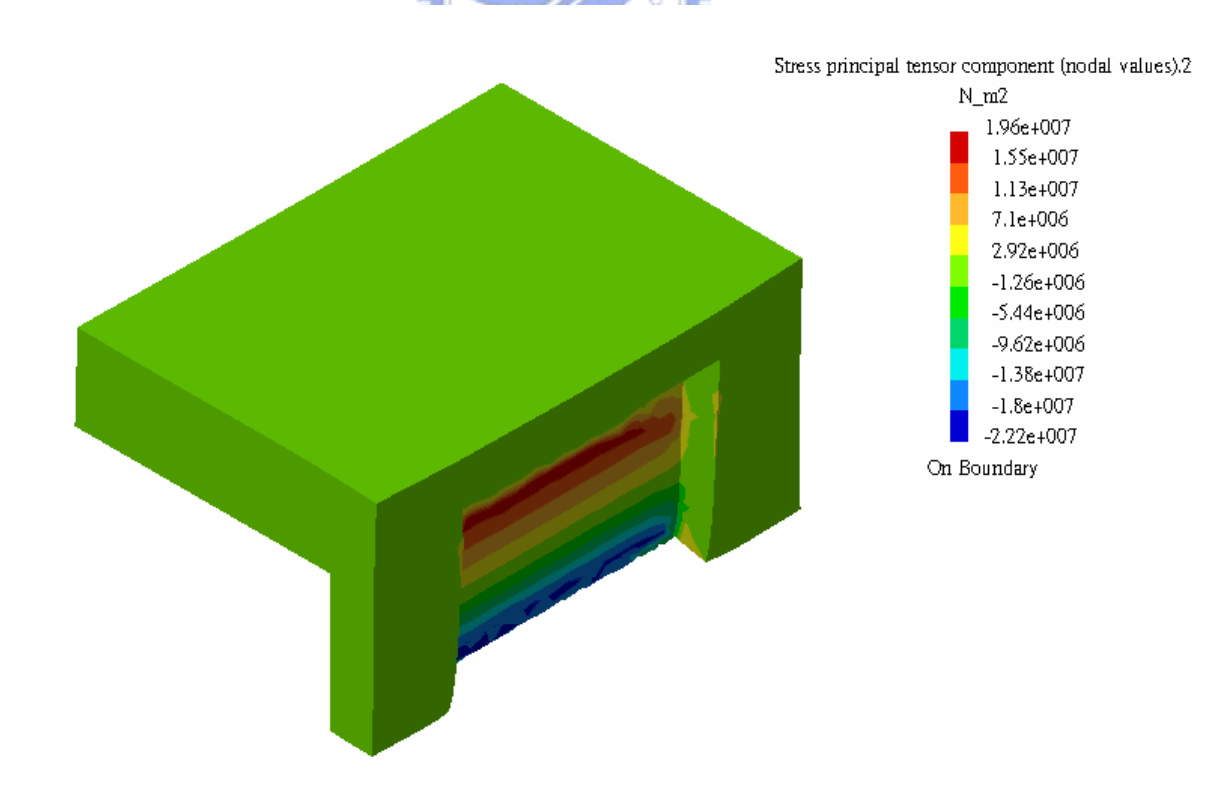


Fig. 6.2-23 The maximum principal stress distribution in resin of concept 3

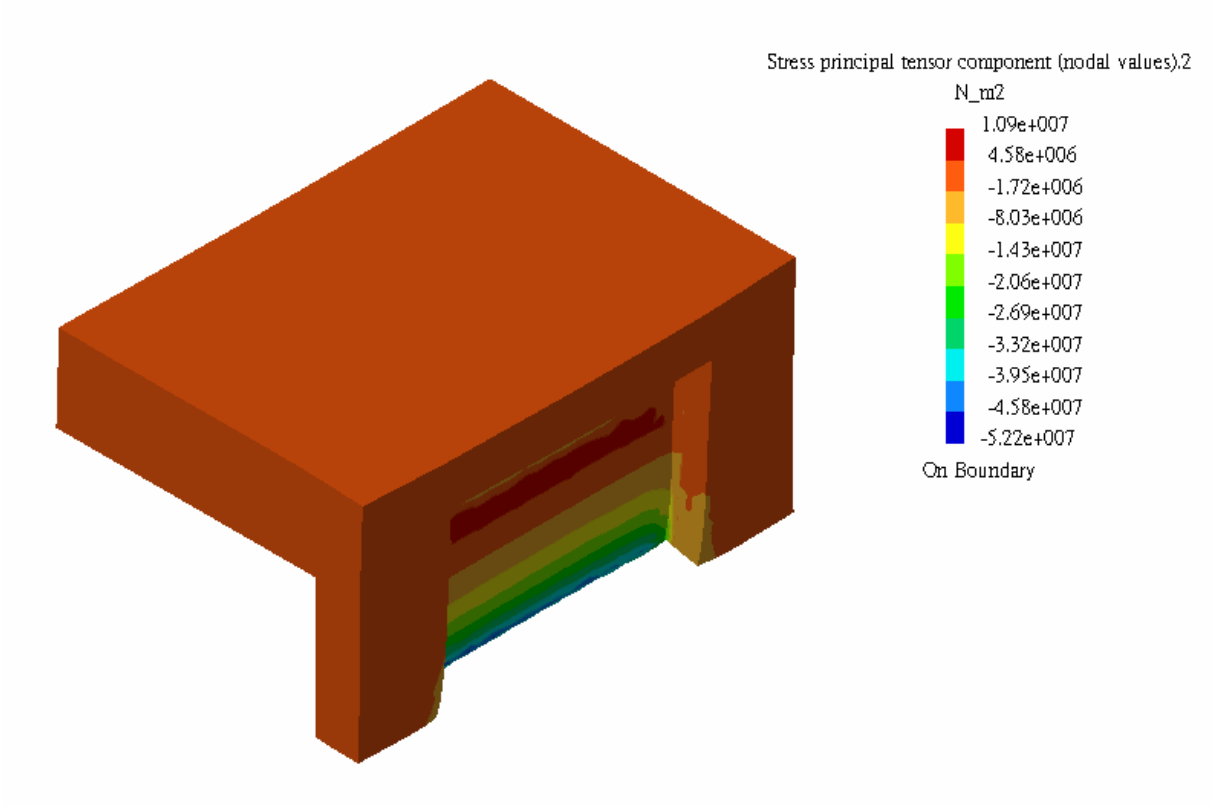


Fig. 6.2-24 The minimum principal stress distribution in resin of concept 3

6.2.4 Case IV – The Results of Concept 4

The upper portion in concept 4 is the same with the concept 3, as shown in Fig. 6.2-17 to Fig. 6.2-20.

Fig. 6.2-25 to Fig. 6.2-28 show the simulation results of bonding interface and resin in the lower portion of concept 3. The maximum principal shear stress on bonding interface is 18.9 MPa. The design factor is 1.33 for the bonding interface and 1.39 for the resin. This means that the strength of bonding interface and resin is almost the same. Furthermore, the lower portion is weaker than the upper portion in this concept.

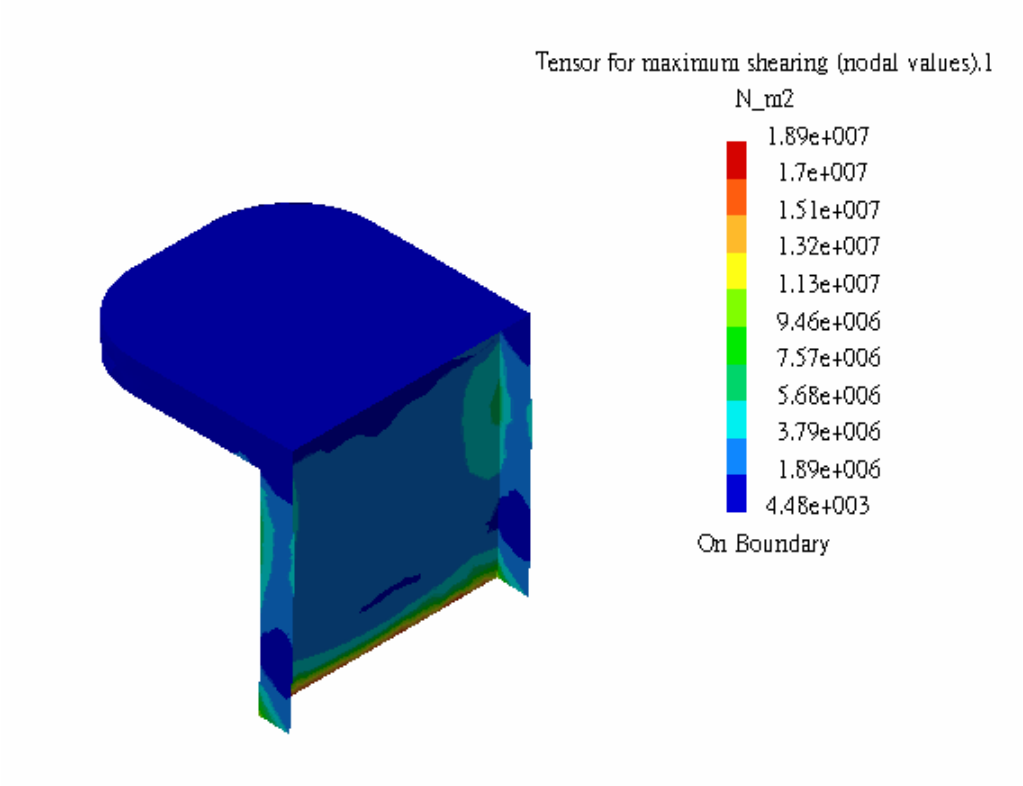


Fig. 6.2-25 The principal shear stress distribution on bonding interface of concept 4

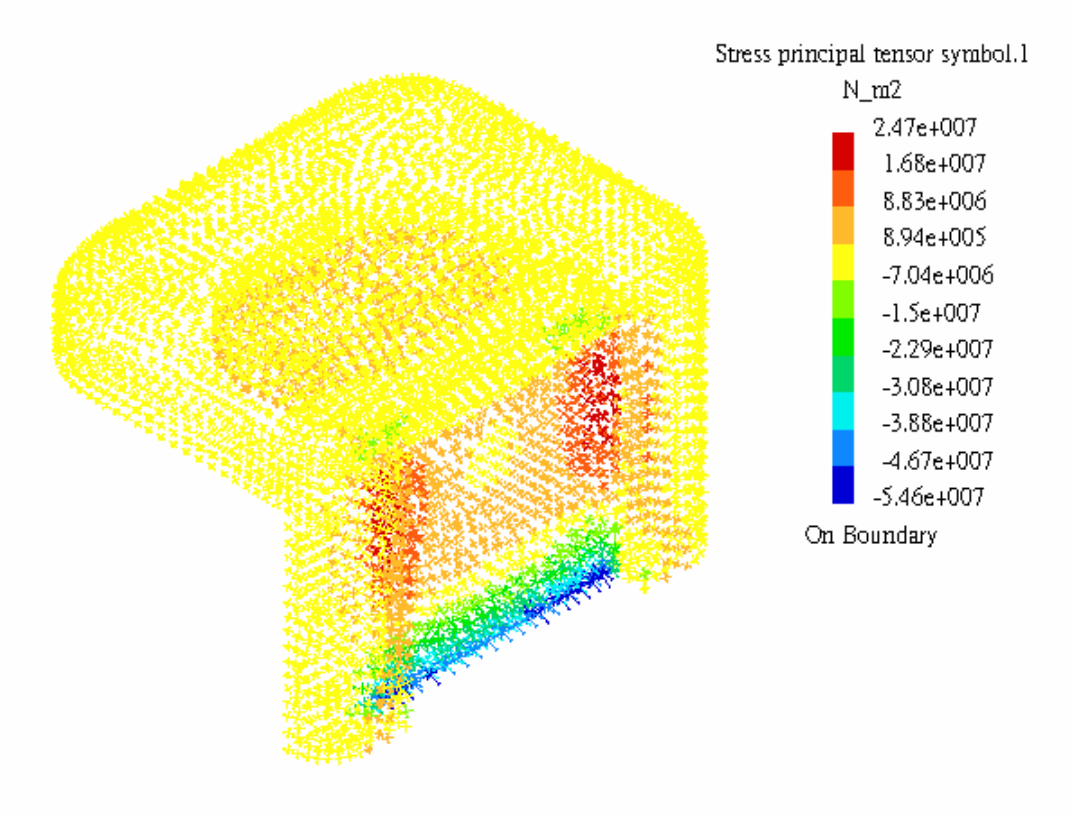


Fig. 6.2-26 The principal stresses distribution in resin of concept 4

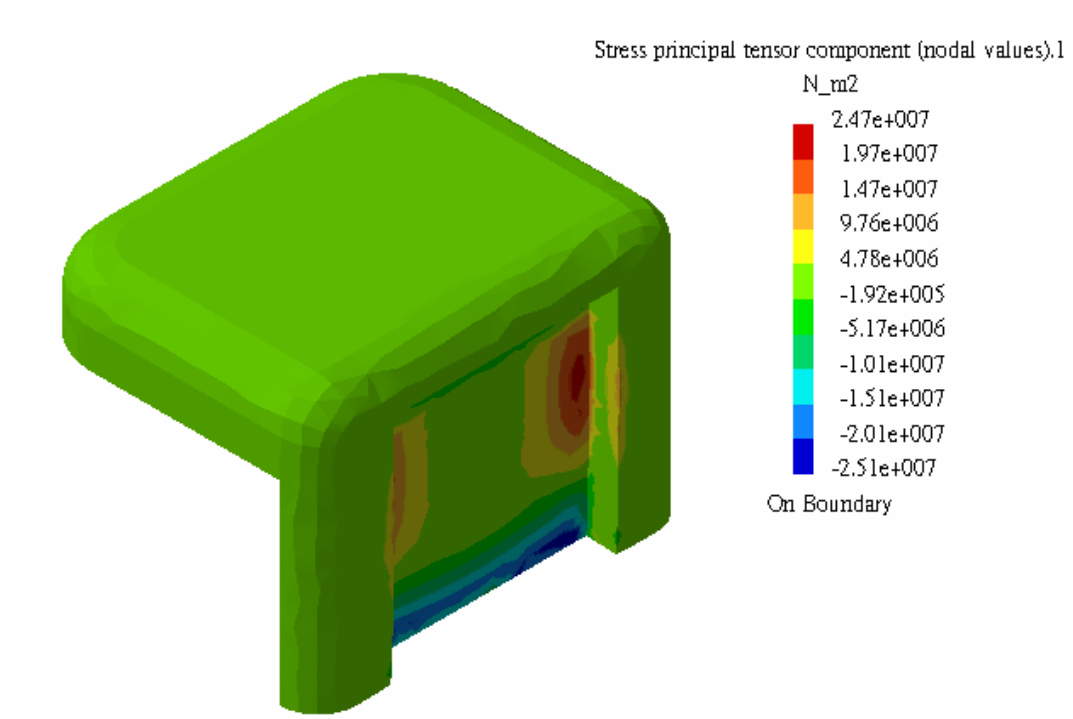


Fig. 6.2-27 The maximum principal stress distribution in resin of concept 4

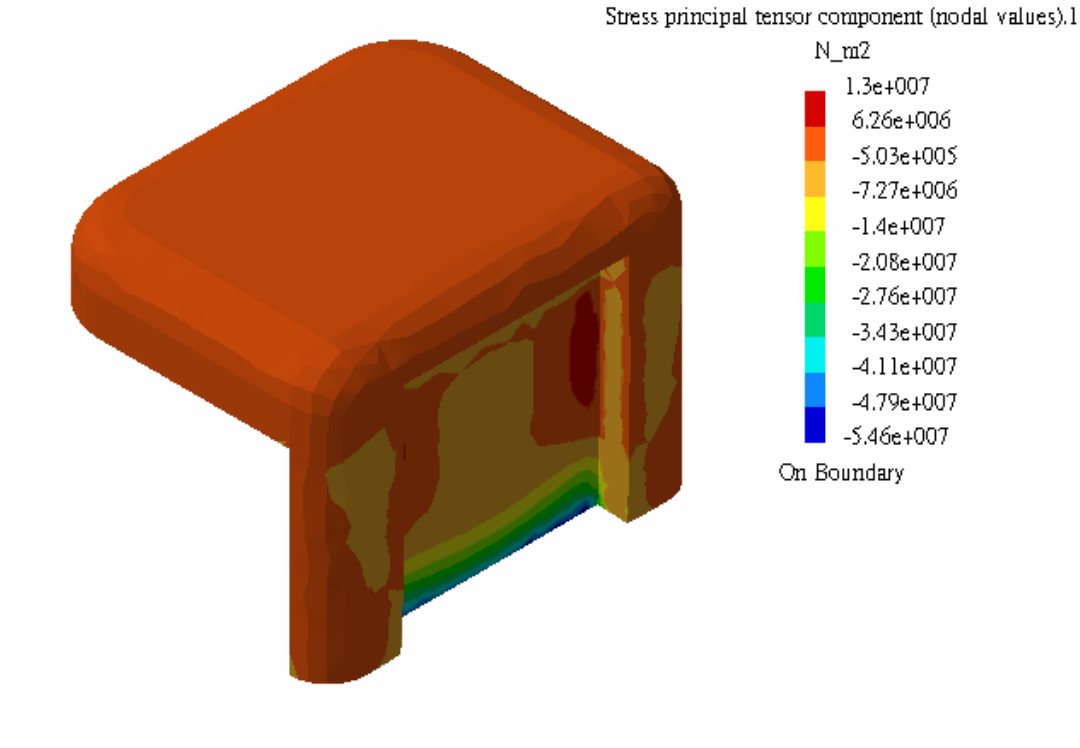


Fig. 6.2-28 The minimum principal stress distribution in resin of concept 4

6.2.5 Case V – The Results of Commercial Product TAP-T

Fig. 6.2-29 to Fig. 6.2-32 show the simulation result of bonding interface and resin in the upper portion of TAP-T. The maximum principal shear stress on bonding interface is 3.68 MPa. The design factor is 9.44 for the bonding interface and 4.61 for the resin. This means that resin is much weaker than the bonding interface.

Fig. 6.2-33 to Fig. 6.2-36 show the simulation result of bonding interface and resin in the lower portion of TAP-T. The maximum principal shear stress on bonding interface is 6.84 MPa. The design factor is 5.07 for the bonding interface and 1.31 for the resin. This means that resin is much weaker than the bonding interface. Furthermore, the lower portion is weaker than the upper portion in this concept. If the material of TAP-T is changed to SUS 316L stainless steel, the design factor of bonding interface will down to 6.87 for upper portion and 3.68 for lower portion.

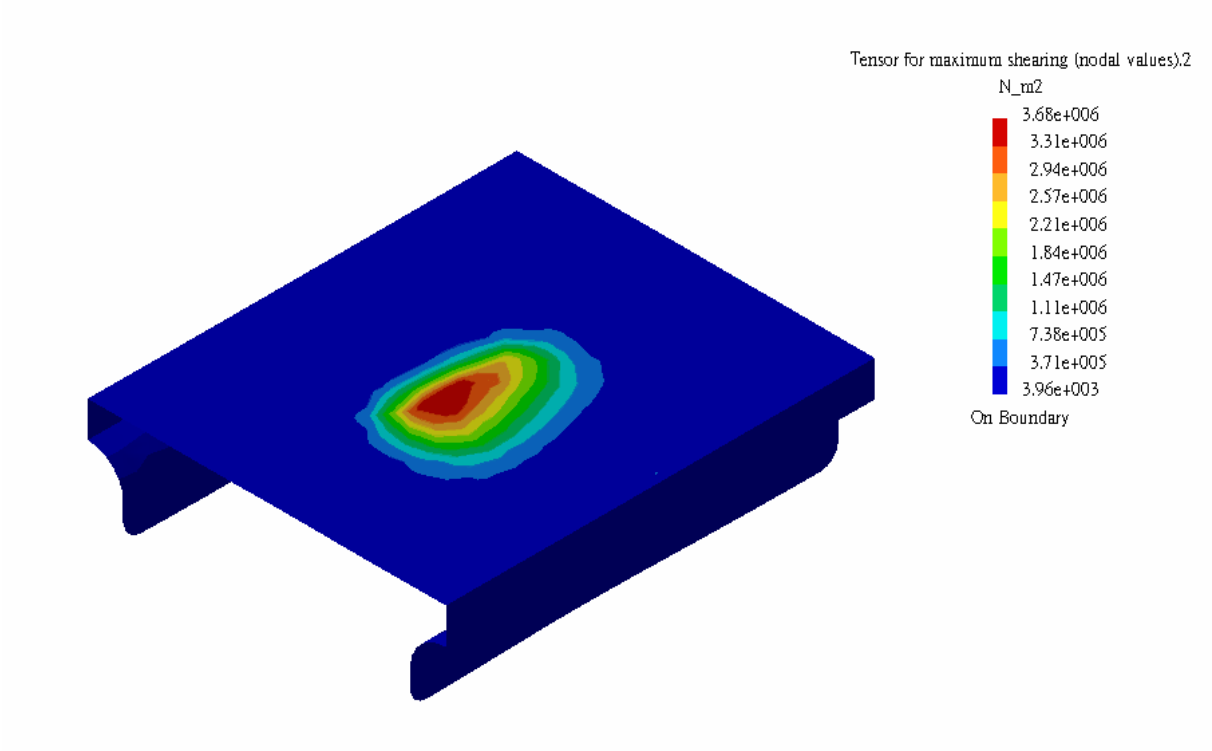


Fig. 6.2-29 The principal shear stress distribution on bonding interface of TAP-T

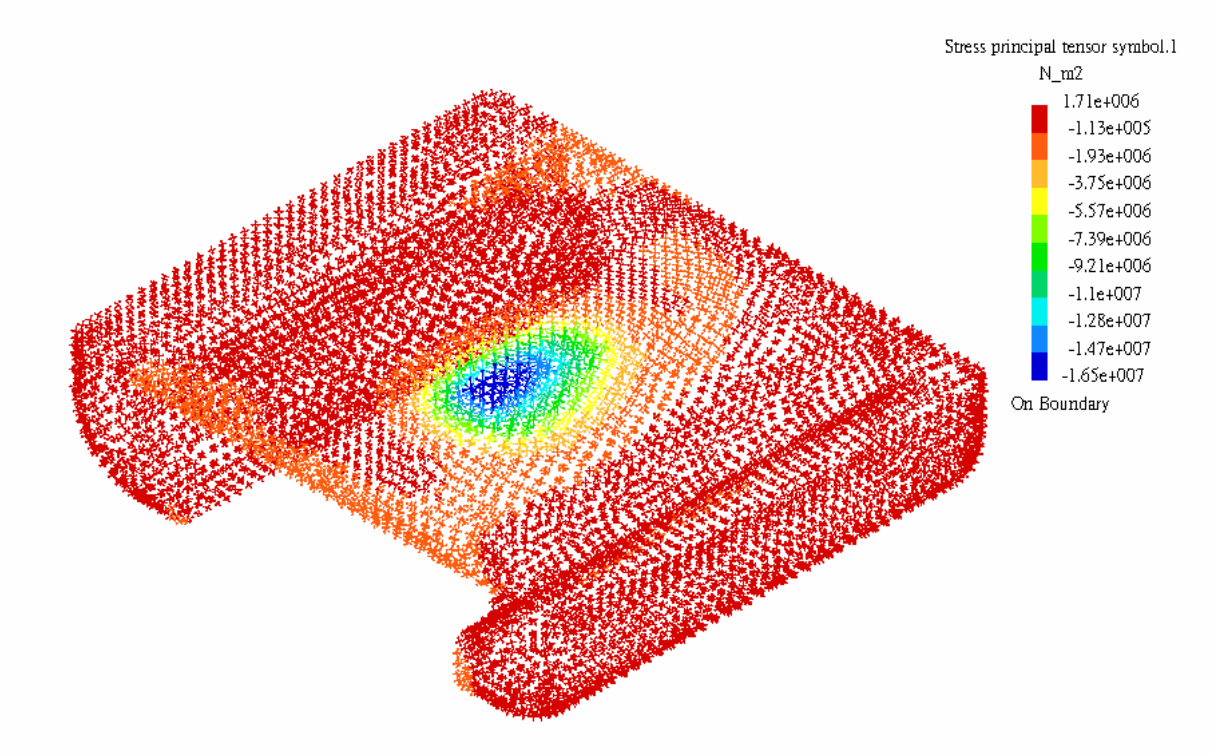


Fig. 6.2-30 The principal stresses distribution in resin of TAP-T

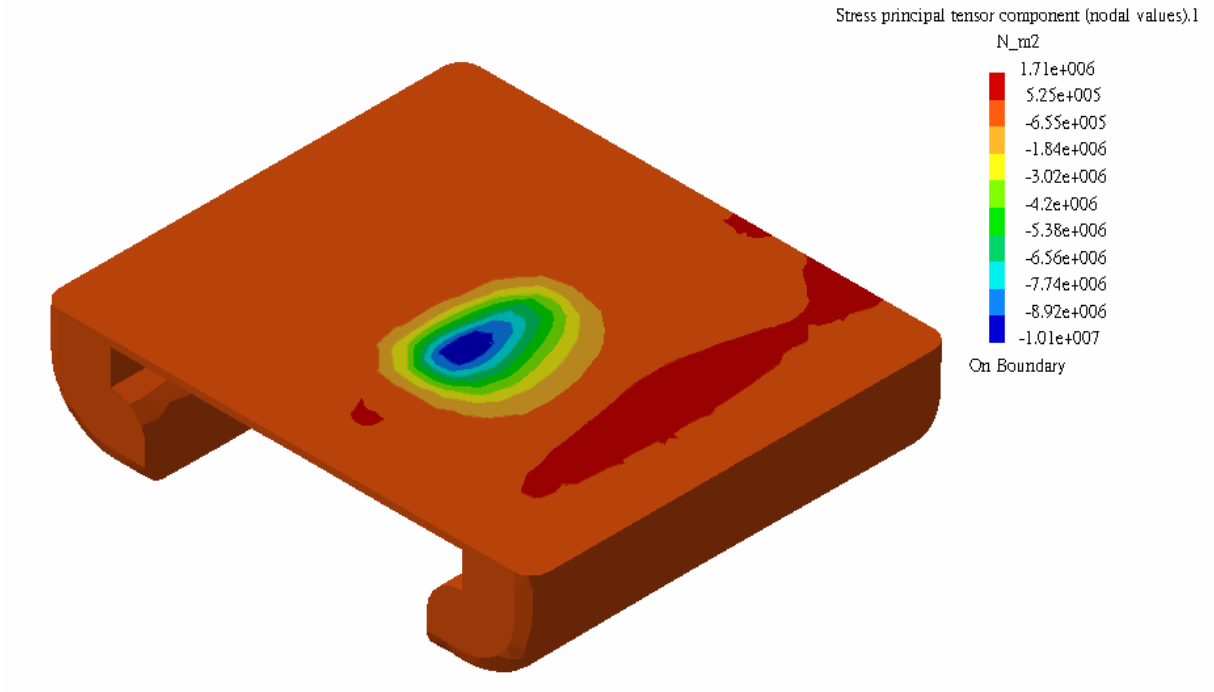


Fig. 6.2-31 The maximum principal stress distribution in resin of TAP-T

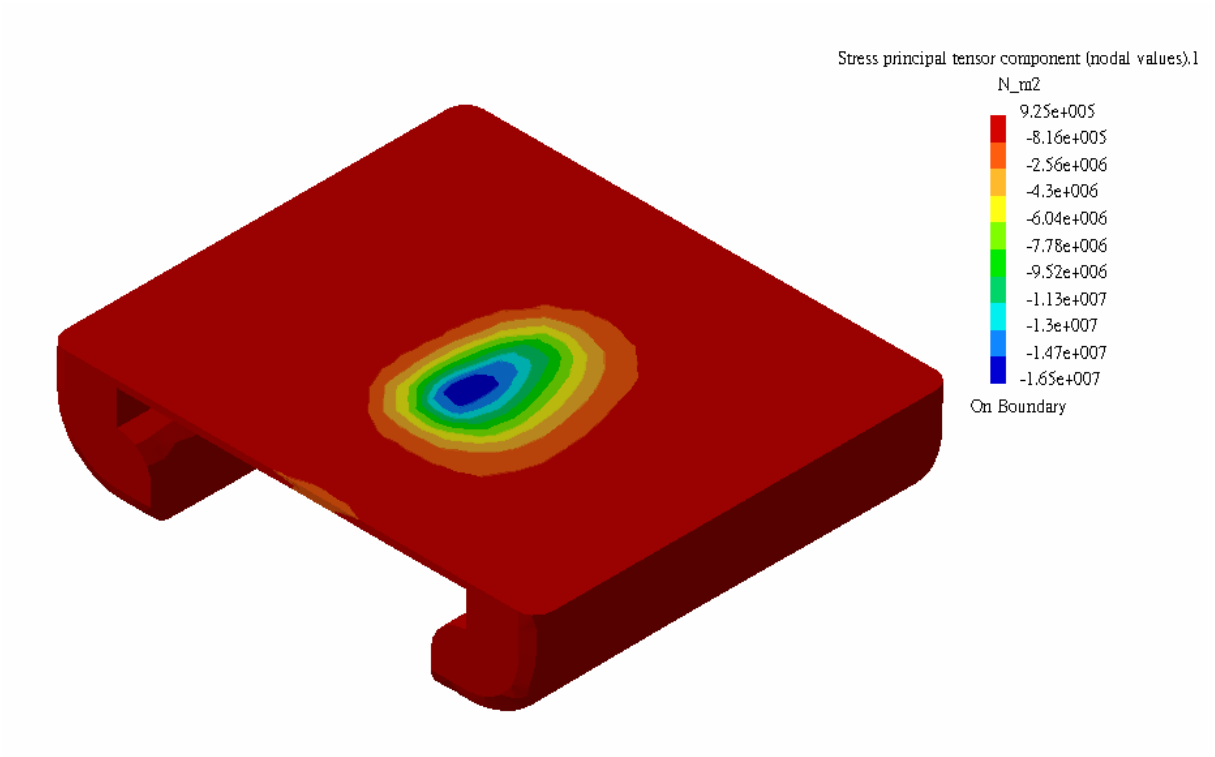


Fig. 6.2-32 The minimum principal stress distribution in resin of TAP-T

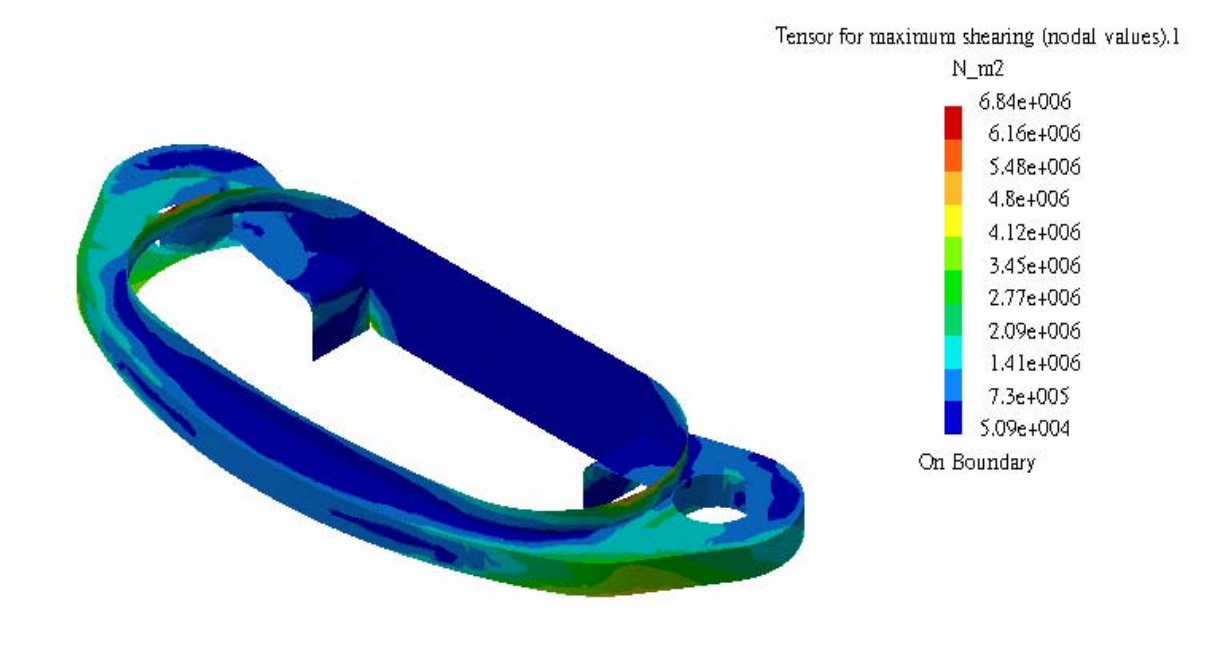


Fig. 6.2-33 The principal shear stress distribution on bonding interface of TAP-T

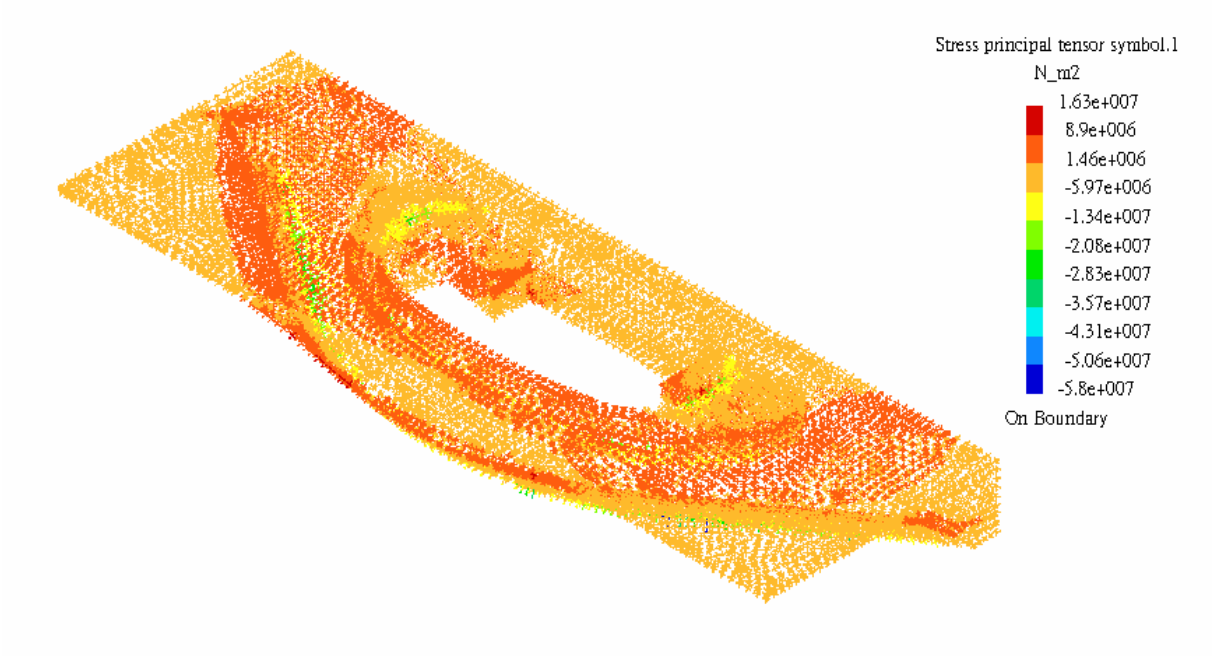


Fig. 6.2-34 The principal stresses distribution in resin of TAP-T

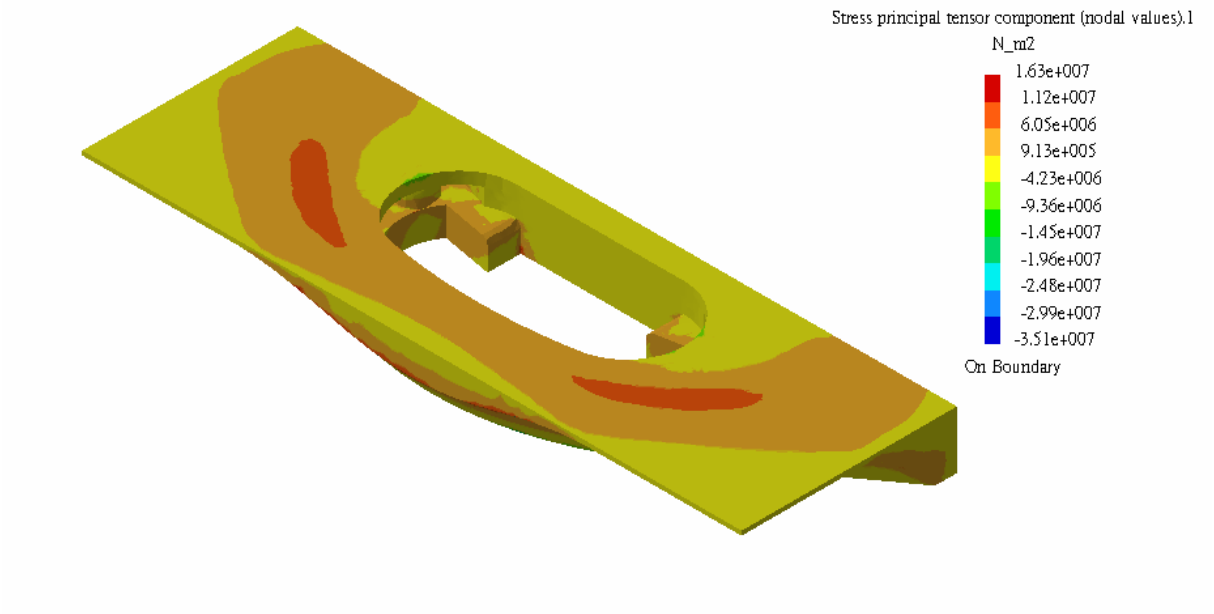


Fig. 6.2-35 The maximum principal stress distribution in resin of TAP-T

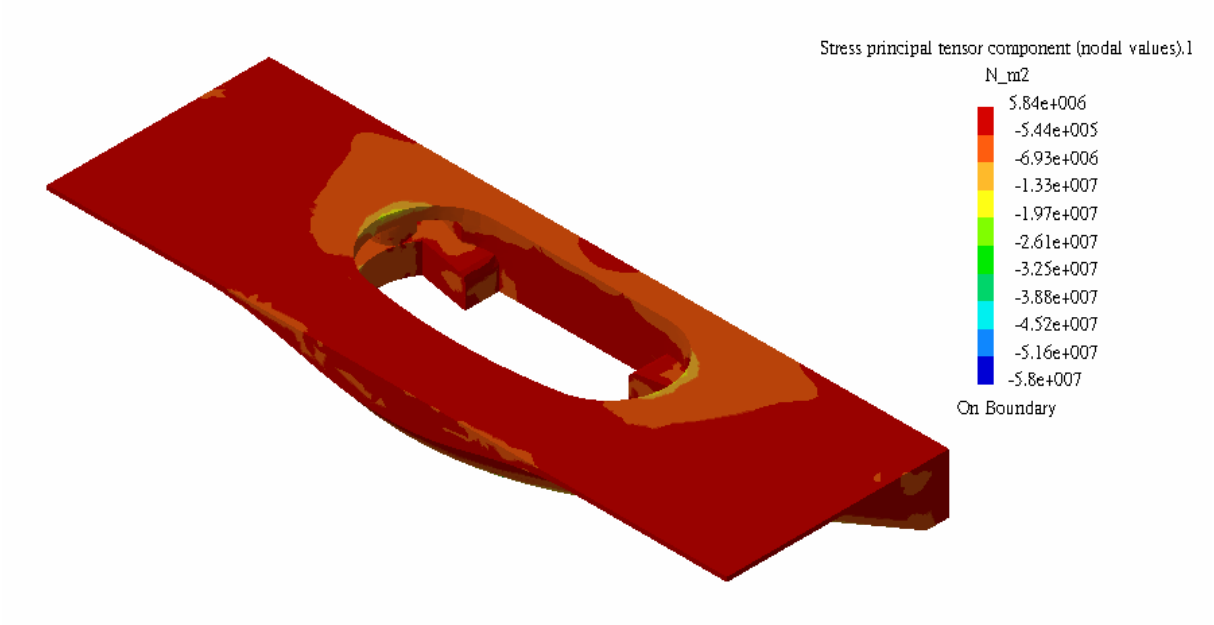


Fig. 6.2-36 The minimum principal stress distribution in resin of TAP-T

Table 6.2-1 Comparison of all finite element models

	n_d for bonding interface		n_d for resin	
	upper	**lower**	**upper**	**lower**
Concept 1	8.29	33.03	8.39	32.56
Concept 2	1.04	14.88	1.18	13.41
Concept 3	2.55	1.66	1.95	1.46
Concept 4	2.55	1.33	1.95	1.39
TAP-T	9.44	5.07	4.61	1.31
TAP-T (316L)	8.28	4.6	5.37	1.35

Table 6.2-1 shows the comparisons of all finite element models based on the index of design factor. The results may be varied by adjusting the setting of dimensions for concepts.

As the preliminary results shown, the strength of concept 1 is better than the commercial product TAP-T which made of SUS 316L stainless steel. The strength of concept 3 and concept 4 is almost the same or slightly better than TAP-T. However, a new function, the disengagement mechanism, and a mechanism which combined adjustment and lateral movement are proposed in these two concepts. All of the results from FEA are going to be considered as an important reference for concept evaluation process in the next section.

6.3 Concept Evaluation

The evaluation bases on the decision-matrix method [51]. In the decision matrix, several items should be included, such as criteria, importance, alternatives, evaluation of each alternative using criterion, and the final score for each alternative. The criteria choose from the customer requirements in QFD. The importance item in the decision matrix refers to the importance of customer requirements in QFD to calculate the weighting for each criterion by binary-matrix method [52]. The alternatives here are the four concepts described above. Before starting to evaluate, choose one concept as a datum for comparison. All other concepts are compared with the datum by judging each criterion, resulted in superior, the same, or inferior to the datum, and represented by symbol "＋", "S", and "－" respectively. Finally, compute the sum of the plus scores and minus scores which have been multiplied by the importance weighting.

After the evaluation of the decision-matrix, the concept 3 is presented as the best design which bases on the customers' requirements. The result exhibits that concept 3 is good at the lateral movement which confirms to the real condition, the small height of whole assembly, the functions to promote comfort, the easy operation process, and so on.

Table 6.3-1 Decision matrix for concept evaluation.

	Criteria (Requirements)	Importance (%)	Concept 1	Concept 2	Concept 3	Concept 4
1	Adjustable in front-rear direction	1.08	−	DATUM	−	−
2	Adjustable in up-down direction	0.00	S		S	S
3	Mandible advance correctly	1.08	S		S	S
4	Lateral movement	1.43	S		+	+
5	Wear by oneself	7.53	S		S	S
6	Custom made	8.24	S		S	S
7	Distribute force caused by bruxism	3.58	+		+	+
8	Easy to adjust	7.17	−		S	S
9	Easy to wear into mouth	6.45	−		+	+
10	Easy to remove from mouth	6.09	−		+	+
11	Avoid exaggeration of opening of jaw	3.23	−		+	+
12	Use for a long time	5.38	+		+	+
13	Comfortable to use	7.89	+		+	+
14	Simple operational steps to wear	2.51	−		+	S
15	Opening mouth is allowed	0.72	−		S	S
16	No Impingement of tongue space	2.15	+		−	−
17	Not irritate oral tissues	7.17	+		+	+
18	Easy to clean	2.87	+		S	S
19	Difficult to disengage from dentition	4.30	S		S	S
20	Without side effects	4.30	+		+	+
21	Structure of mechanism is simple	2.15	−		−	−
22	Long life	5.02	+		+	−
23	Tiny size	4.66	+		S	S
24	Difficult to break	5.02	+		+	+
	Total +		48.04	−	58.07	50.54
	Total −		29.40	−	5.38	10.4
	Summation		18.64	−	52.69	40.14

6.4 Comparisons

In last section, the final design is produced by the decision-matrix method. The QFD target which developed in section 4.2 is introduced to compare with the specifications of the final design to estimate the achievement. The QFD target is defined considerately in accordance with the patent analysis and market survey. The results of comparison are going to be an essential reference for the future works.

As the Table 6.4-1 shown, the specification of the final design is listed in the “Achieved” row. The specification achieves several QFD targets which listed in the “QFD Target” row. The adjustable range is less than the target, but larger than commercial product TAP-T. In the lateral mobility, the height of the inner wall of tray, and separate height of mechanism are better than the target. Those specifications provide the larger movable range, prevent the inappropriate touch with gums, and avoid the jaw opening exaggeratedly that all of them are referred to the comfort during using time. The contact area is referring to the area of the fixation portion on the tray. In the final design, the shape of fixation portion is just a preliminary design. It is required to be modified for obtaining the higher strength of fixation on the tray in the future. The large volume of the final design seems to be the drawbacks. Maybe the tolerable volume of mechanism for patients can be tested by clinical experiments in the future. At the same time, the durable time of the device and time for adaptation by patient are required to be tested under real using situation.

Table 6.4-1 Comparison between the QFD target and the achieved target

	Adjustable range (Front-rear)	Adjustable range (Up-down)	Pitch of adjustment	Jaw rotate downwardly	Lateral movability	Tray	Dentition-fitted tray	Contact area	Even contact	Steps to adjust	Height of the inner wall of tray
	mm	mm	mm	y/n	mm	y/n	y/n	mm2	y/n	#	mm
TAP-T	7	0	0	y	7.5	y	y	55	y	1	9
QFD Target	3-8	0	0	y	8	y	y	50	y	1	9
Achieved	3-7.5	0	0	y	9.8	y	y	23.5	y	1	8

Table 6.4-1 Comparison between the QFD target and the achieved target (cond.)

	Separate height of mechanism	Time of using MAD	Steps to wear	Disengage mechanism	Depth of mechanism	Biocompatible material	Steps to clean	Time for adaptation	# of componenets	Durable time	Maximum load
	mm	hr	#	y/n	mm	y/n	#	week	#	yr	N
TAP-T	7	> 8	3	n	12	y	3	1	6	3	—
QFD Target	8	> 8	3	y	14	y	3	1	10	3	100
Achieved	6.3	—	3	y	16	y	3	—	12	—	100

CHAPTER 7

CONCLUSIONS AND FUTURE WORKS

7.1 Conclusions

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, several new designs of the MAD are proposed and some conclusions can be made as follows:

1. The patent analyses and commercial products surveys assist the realization of the techniques and developments of the MAD which provide plenty information for consulting in the later procedures of design.

2. The QFD method is applied to clarify the customers' requirements, the engineering specifications, the evaluation and specifications of commercial products, and then defines the target specifications for designing a competitive product.

3. In the conceptual design phase, four concepts are proposed in the end of the conceptual design procedure. Moreover, the disengagement function and a combination design which integrates adjustment and lateral movement functions are proposed.

4. The results of finite element analysis are translated into the design factors to be considered as an index of strength, and compared between each concept and one commercial product.

5. The concept 3 is evaluated as the best concept between all of the concepts by proceeding the decision-matrix method.

7.2 Future Works

About the future works of this study, some points can be described as below:

1. Search for the information about the grinding force in sleep bruxism to make the strength simulations more accurate and similar to the real loading situation.

2. Dimension optimization is recommended for the final design to reduce the size and to obtain the optimum strength.

3. The prototype of the final design can be manufactured after all of the dimensions are decided.

4. The clinical experiments are required to verify the efficacy of therapy by using the MAD of the final design.

5. Apply for the 510(k) notification from FDA before the product promoting to the market.

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