DESIGN AND FABRICATION OF SLEEP APNEA DEVICE

TAN ANN NIE

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(Mechanical and Manufacturing Engineering)

2018

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DESIGN AND FABRICATION OF SLEEP APNEA DEVICE

TAN ANN NIE

A dissertation submitted in partial fulfilment

of the requirement for the degree of

Bachelor of Engineering with Honours

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To my beloved family and friends.

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ABSTRACT

Obstructive sleep apnea (OSA) is a sleeping disorder that occurs when the upper respiratory airway is blocked by collapsed soft tissues in the back of throat or tongue as the muscles relax during sleeping. The common symptoms of OSA include repetitive breathing pauses, excessive daytime sleepiness and loud snoring which indicates partial airway obstruction. Existing sleep apnea devices include continuous positive airway pressure (CPAP), mandibular advancement device (MAD), tongue retaining device (TRD) and contour pillow. One common disadvantage of these devices is that they are associated with discomfort and side effects such as mouth dryness and blocked up nose, resulting in low compliance of OSA patients with the treatments. The purpose of this research is to create alternative sleep apnea device that can effectively reduce snoring without compromising the comfort of patients. The concept adapted in this research is the head-tilt chin-lift maneuver, which is a clinical technique used to open an obstructed airway of unconscious person during emergency situations. The anti-snoring system is designed based on Arduino UNO, whereby the device lifts the patient's neck to open an obstructed airway after snoring (decibel > 50) is detected by a sound sensor.

ABSTRAK

Obstructive Sleep Apnea (OSA) adalah gangguan tidur yang berlaku apabila saluran pernafasan bahagian atas disekat oleh tisu lembut yang terjatuh di belakang tekak atau lidah apabila otot berehat semasa tidur. Gejala-gejala umum OSA termasuk episod pernafasan terhenti berulang-ulang, rasa mengantuk di siang hari yang berlebihan, dan berdengkur kuat yang menunjukkan halangan pernafasan separa. Alat-alat *sleep apnea* yang sedia ada termasuk *continuous positive airway pressure* (CPAP), *mandibular advancement device* (MAD), *tongue retaining device* (TRD) dan bantal kontur. Satu kelemahan yang sama bagi alat-alat ini adalah bahawa mereka membawa ketidakselesaan dan kesan-kesan sampingan seperti kekeringan mulut dan hidung tersekat, mengakibatkan pematuhan rendah pesakit OSA kepada rawatan. Tujuan penyelidikan ini adalah untuk mencipta alat *sleep apnea* alternatif yang dapat mengurangkan berdengkur dengan berkesan tanpa menjejaskan keselesaan pesakit. Konsep yang diadaptasi dalam penyelidikan ini adalah manuver *head tilt-chin lift*, ia merupakan teknik klinikal yang digunakan untuk membuka saluran udara orang yang tidak sedar dalam keadaan kecemasan. Sistem anti-berdengkur ini adalah direka berdasarkan Arduino UNO, di mana alat tersebut mengangkat leher pesakit untuk membuka saluran udara yang tersekat selepas berdengkur (decibel> 50) dikesan oleh sensor bunyi.

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AHI	-	Apnea-Hypopnea Index
CPAP	-	Continuous Positive Airway Pressure
CSA	-	Central Sleep Apnea
MAD	-	Mandibular Advancement Device
MSA	-	Mixed Sleep Apnea
OSA	-	Obstructive Sleep Apnea
TRD	-	Tongue-Retaining Device

CHAPTER 1

INTRODUCTION

1.1 General Background

First discovered in the year 1960, sleep apnea is a sleeping disorder that is characterized by breathing pauses during sleeping and excessive daytime sleepiness. The breathing pauses might last for 10 seconds or up to minutes and could occur hundreds of times during sleep in severe cases. People who suffer from sleep apnea often have very poor sleep quality which consequently leads to several health issues such as obesity, diabetes and hypertension (Karandikar, Le, Sa-ngasoongsong, Wongdhamma, & Bukkapatnam, 2013). Sleep apnea can be subdivided into three forms: Central sleep apnea (CSA), Obstructive sleep apnea (OSA) and Mixed sleep apnea (MSA).

CSA occurs when one's brain temporarily fails to send breathing signals to the respiratory muscles. Breathing is then ceased until the altered blood oxygen and carbon dioxide level trigger the breathing mechanism. Ottaviani (2014) stated that this form of sleep apnea mostly occurs in premature infants where their breathing can be interrupted for seconds and this condition is known to be one of the causes of sudden infant death syndrome.

OSA occurs when the upper respiratory airway is blocked by collapsed soft tissues in the back of throat and tongue as the muscles relax during sleeping. In this condition, the respiratory muscles remain their efforts to carry out breathing actions despite the airway being obstructed. Among the three forms, obstructive sleep apnea is the most common condition and it affects more than 100 million people globally (Kryger, Roth, & Dement, 2015).

MSA is a combination of central and obstructive sleep apnea. MSA can be identified upon the application of continuous positive airway pressure (CPAP) treatment (Neu, Balkissou, Mairesse, Pefura-Yone, & Noseda, 2017). The patients typically suffer from OSA, but when CPAP is applied and obstructive element has been eliminated, CSA persisted.

Sleep apnea affects all ages and gender where most of them are undiagnosed and untreated due to the vague symptoms that are usually neglected by people. The common risk factors and symptoms of sleep apnea are shown in Figure 1.1 and 1.2 below.

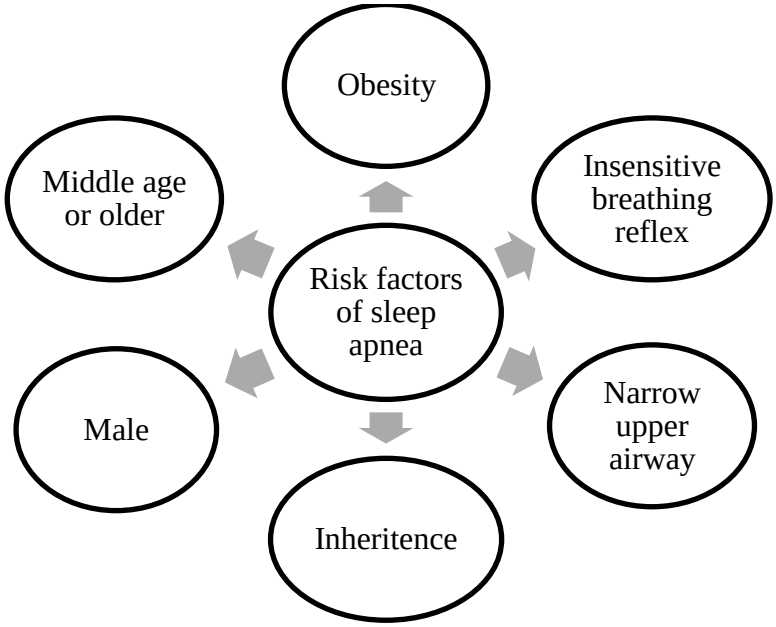

Figure 1.1: Risk Factors of Sleep Apnea (Pascualy, 2008)

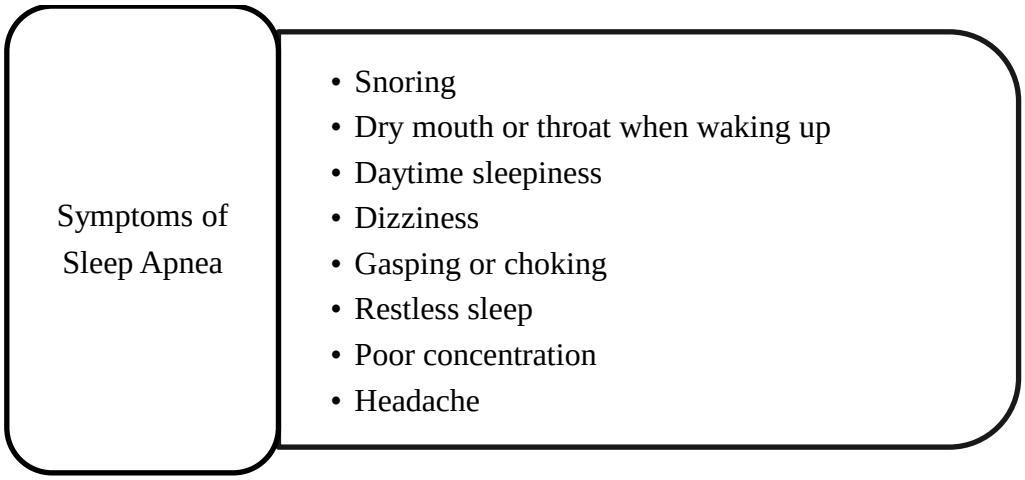

Figure 1.2: Common Symptoms of Sleep Apnea (Sleep Education, 2016)

1.2 Problem Statement

OSA is the most common disorder among the three forms of sleep apnea. According to Philips Respironics (2015), a global sleep survey conducted in 10 different countries reported that 6% of 8,000 respondents suffer from OSA. This result indicates that there are more than 100 million people suffer from OSA globally. It is also estimated that 80% of OSA patients remain undiagnosed.

There are several medical device treatment options for OSA such as continuous positive airway pressure (CPAP), mandibular advancement device (MAD), tongue retaining device (TRD) and anti-snoring pillow. CPAP prevents the collapsing of airway by delivering constant air flow into the nasal passages through the nose. Up to this time, CPAP has been widely recognized as the most effective treatment for severe OSA patients despite the huge discomfort associated with the mask that covers nose (Scanlan, Heuer, & Rodriguez, 2017). MAD and TRD are oral appliances that hold lower jaw and tongue forward to allow bigger airway passage. These oral appliances also bring mild discomfort to users as they have to be inserted into patient's mouth throughout sleeping. Anti-snoring pillow is specially designed pillow that provides proper head and neck support to prevent snoring. For those patients who cannot tolerate the discomfort associated with CPAP and MAD, contour pillow is their preferred choice. However, treatment using anti-snoring pillow is only valid for mild to moderate OSA (Albares et al., 2013).

Side effects of existing devices also became barriers that refrain OSA patients from fully utilizing the devices. CPAP therapy which is known for its effectiveness has its downside as well. According to Ulander, Johansson, Ewaldh, Svanborg, and Broström (2014), dry mouth, blocked up nose and increased number of awakenings are some common side effects of CPAP therapy. Studies also reported that MAD therapy has side effects such as mouth dryness, excessive salivation and temporomandibular disorders (Makihara et al., 2016), which are the similar side effects reported by TRD users. Therefore, it remains a need to create alternative sleep apnea device that is effective without compromising the comfort of patients.

In a nutshell, the major problem with existing sleep apnea device is non-compliance of patients due to the discomfort and side effects associated. In terms of user's comfort, contour pillow is the better preferred solution as patients can go to sleep like normal without wearing any mask or oral appliance. Since snoring is a very common symptom of OSA, this study will focus on the solution of reducing snoring without compromising patients' comfort. The design of smart anti-snoring pillow needs to be effective yet user-friendly and brings no side effects.

1.3 Objectives and Limitations of Research

The objectives of this research are:

1. To study and investigate on obstructive sleep apnea.

2. To design a user-friendly, anti-snoring mechanism for obstructive sleep apnea patients.

3. To produce a model of the sleep apnea device.

Limitations of this research include:

1. Choices of components are limited by the compatibility with Arduino UNO.

2. The design solution is only valid for mild to moderate OSA patients as severe OSA patients need advanced treatment such as CPAP.

3. The model produced in this research only serves the purpose of showing the overall concept of the sleep apnea device.

CHAPTER 2

LITERATURE REVIEW

2.1 Obstructive Sleep Apnea

OSA is one of the three types of sleep apnea and it is the most common form of sleep apnea, as shown in Figure 2.1. Greenstone and Hack (2014) stated that OSA is characterized by repetitive breathing pauses or air flow reduction and excessive daytime sleepiness, along with snoring being the common symptom. The condition of OSA occurs when the breathing pathway is obstructed by collapsed tongue or soft tissues as the muscles relax during sleeping, as illustrated in Figure 2.2. The collapse of upper airway results in breathing pauses that might last for 10 seconds or above, often followed by oxygen desaturation which then brain signals are sent to awaken the person to breathe again.

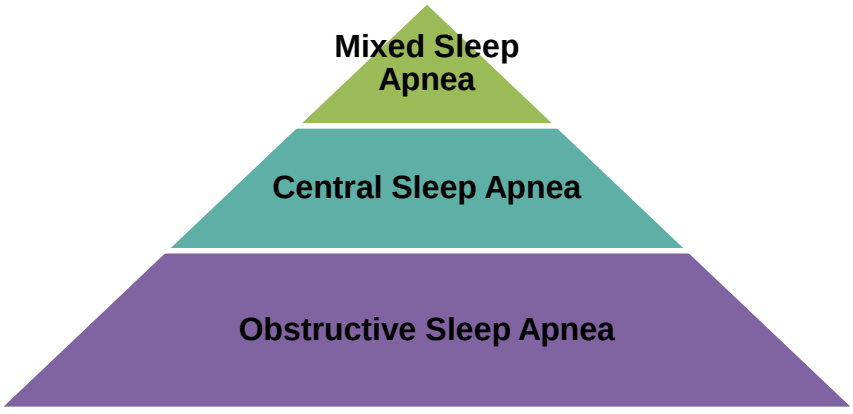

Figure 2.1: Three Forms of Sleep Apnea.

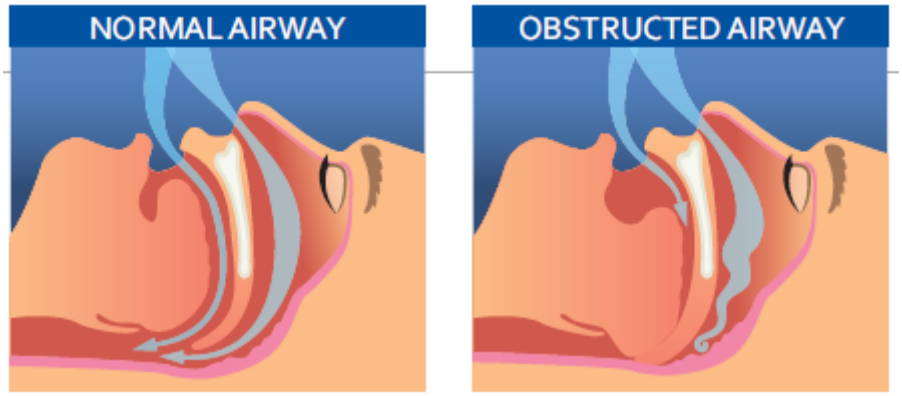

Figure 2.2: Airway Is Obstructed By Collapsed Tongue or Soft Tissues (J. A. Rowley, S. Lareau, B. F. Fahy, C. Garvey, & M. Sockrider, 2017)

According to American Thoracic Society (2017), OSA is more prevalent among men, women after menopause and elders who are above the age of 65. Other risk factors of OSA include enlarged tonsils and/or adenoids, family genetic, obesity and jaw problems such as small jaw or pulled back jaw. Symptoms of OSA can be observed both during sleep and while awake, as listed in Table 2.1 below.

Table 2.1 Symptoms of Obstructive Sleep Apnea. (Rowley et al., 2017)

Symptoms of Obstructive Sleep Apnea	
During sleep	While awake
- Loud snoring - Gasping or choking for air - Breathing pauses - Sudden or jerky body movement - Restless tossing and turning - Frequent awakenings	- Excessive daytime sleepiness - Moring headache - Dry or sore throat in the morning - Fatigue througout the day - Mood swing - Poor concentration and memory

Papandreou (2014) defined apnea as the cessation of air flow for 10 seconds or above, while hypopnea is defined as reduction in airflow with more than 4% oxygen desaturation. The severity of OSA is classified using apnea and hypopnea index (AHI), that indicates the number of apneas and hypopneas occurred per hour of sleep. Figure 2.3 shows the classification of OSA according to AHI. Periods of apnea or hypopnea can in time lead to high blood pressure, stroke, diabetes, or early death.

Figure 2.3: Severity of OSA Measured By AHI (Chokroverty & Ferini-Strambi, 2017)

Berlin Questionnaire and Epworth Sleepiness Scale (ESS) are two popular clinical questionnaires used to screen and detect patients who are having high risk for OSA. However for diagnosis of OSA, the ideal method is to undergo polysomnography (PSG) or home sleep test. PSG is a sleep study conducted in sleep center that requires patients to test sleep overnight, and it can diagnose various types of sleep disorders including OSA. Whereas home sleep test is carried out by patients themselves using test equipment provided by a sleep physician, and it can only test for OSA (Philips, 2014).

2.2 Impact Towards The Society

It is common that OSA is often related to patients' health issues especially cardiovascular disease such as stroke, hypertension and heart failure. However the consequences of untreated OSA affect more than just OSA patients, there are several adverse effects on the society as well. Knauert, Naik, Gillespie, and Kryger (2015) stated that the consequences of untreated OSA can be seen in medical, transportation, workplace and economy.

2.2.1 Medical

Patients suffer from OSA often experience repetitive events of apnea or hypopnea during sleep, which in turn result in episodes of hypoxia (Khayat & Pleister, 2016). Hypoxia is a condition in which body tissues receive inadequate supply of oxygen. Intermittent hypoxia resulted from OSA is recognized as a risk factor for various adverse cardiovascular diseases such as hypertension, atrial fibrillation, strokes, heart failure and metabolic complications (Ayas, Taylor, & Laher, 2016). Intermittent hypoxia along with frequent arousals also results in consequences including sympathetic activation, endothelial dysfunction, oxidation stress, activation of inflammation and insulin resistance.

As repetitive events of apnea or hypopnea often result in hypoxia, the physiological responses to OSA are triggered upon the reduction of oxygen level (Bisogni, Pengo, Maiolino, & Rossi, 2016). Khayat and Pleister (2016) explained that hypoxia activates the sympathetic nervous system that induces vasoconstriction and increases blood pressure to redistribute oxygenated blood to vital organs. As a consequence, OSA patients tend to have higher heart rates, increased arterial stiffness, and higher blood pressure than normal healthy person. Patients suffering from severe OSA (AHI $\geq$ 30) also suffer from metabolic disorder, as well as increased risk for cancer and mortality (Knauert et al., 2015). Furthermore due to poor sleep quality, it is common that OSA patients experience excessive daytime sleepiness, deteriorated cognitive function and have higher risk of developing diabetes.

2.2.2 Transportation

Besides leading to chronic health problems, OSA is also identified as one huge factor for vehicle accidents. As regular breathing is periodically interrupted during sleep and followed by sleep fragmentation, OSA patients rarely have proper sleep as well as sleep-based functional recovery. This condition leads to excessive daytime sleepiness and poor concentration which lower patients' ability to perform daily tasks for instance driving. Garbarino, Pitidis, Giustini, Taggi, and Sanna (2015) stated that people who suffer from OSA pose a two to seven fold increased risk in motor vehicle accidents (MVAs). Karimi (2014) reported that MVAs had been encountered by 5 - 10% of clinical patients and 59% of public transport operators diagnosed with OSA.

A recent investigation on commuter train crash in United States of America has further highlighted the serious consequences of undiagnosed obstructive sleep apnea. In September 2016 and January 2017, two commuter trains that were going more than double of speed limit had separately crashed into New York City-area stations, killing a woman and injuring more than 200 people. According to Sisak and Lowy (2017), U.S. National Transportation Safety Board's investigation showed that the engineers of the two commuter trains were suffering from undiagnosed sleep apnea and both have no memory of the incidents. The engineers are currently treated with pressurized breathing masks.