DEVELOPMENT OF ULTRASONIC SCALPEL

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DECLARATION

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LIST OF ABBREVIATIONS

AC	Alternating Current
ACE	Harmonic Scalpel ACE
CNC	Computer Numerical Control
DC	Direct Current
DXF	Drawing Exchange Format
EDM	Electrical Discharge Machining
ESD	Electrosurgery Device
EUA	Existing Ultrasonic Actuator
FDM	Fused Deposition Modelling
FE	Finite Element
LV	LigaSure V
PT	Plasma Trisector
SLA	Stereolithography
US	Ultrasonic Scalpel

ABSTRAK

Penggunaan alat-alat elektrik tradisional dalam pelbagai bidang disiplin perubatan mempunyai banyak keburukan seperti potensi pembakaran di bahagian lain dalam badan disebabkan arus elektrik yang tinggi, kerumitan operasi, kesan selepas pembedahan yang teruk, dan kos pembedahan yang lebih tinggi. Pisau ultrasonik untuk pembedahan pelbagai tisu telah direka dan prototaip. Ciri-ciri pisau ultrasonic telah diuji. Ia digunakan untuk menggantikan peranti arus elektrik monopolar dan arus elektrik bipolar yang sering digunakan dalam pembedahan laparoskopi dan pembedahan terbuka. Dalam peranti pisau ultrasonik, ia termasuk bekalan kuasa dengan penjana isyarat voltan ultrasonik-gelombang, penggerak ultrasonik, penguat ultrasonik, sepasang pisau yang tumpul, dan penutup plastik dengan mekanisme untuk tekan. Ciri-ciri telah diujikan pada peranti pisau ultrasonik sedia ada untuk memastikan ia dapat membedah tisu-tisu dengan cekap. Reka bentuk konsep dilakukan dengan menggunakan Solidworks, dan reka bentuk diperbaiki sehingga reka bentuk yang terbaik telah diperolehi. Prototaip reka bentuk akhir dilakukan dengan menggunakan proses pemesinan untuk komponen logam dan teknologi prototaip cepat untuk bahagian plastik yang akhirnya dipasang untuk tujuan pencirian. Hasilnya menunjukkan bahawa kekerapan semulajadi pisau ultrasonik yang direka ialah 29.28kHz, dengan getaran puncak ke puncak sebanyak $40\mu m$. Peranti pisau ultrasonik yang direka boleh membedah tisu seperti otot ayam dalam masa $16.6s$ pada suhu maksimum $81.72°C$ di sepanjang tapak pembentukan.

ABSTRACT

The usage of traditional electrosurgery devices in different field of medical disciplines consists of disadvantages such as the potential of alternatives site burn due to high current density, complexity of the operation, severe postoperative effects, and higher operation cost. An US for soft tissue dissection has been designed, prototyped, and characterized. It is used for cutting and cauterizing soft tissue. In this device, it includes power supply with ultrasonic-wave-signal generator, ultrasonic transducer, ultrasonic amplifier, a pair of end effectors, and a casing with trigger mechanism. Characterization is done on the existing ultrasonic actuator to ensure it can dissect soft tissue efficiently. Conceptual design is done by using Solidworks, and the design is refined until optimum design is obtained. The prototype of the final design is done by using machining process for the metal components and rapid prototyping for the plastic parts which are finally assembled for characterization purpose. The result shows that the natural frequency of the designed US is 29.28kHz, with peak to peak vibration stroke of $40\mu m$. The designed US can dissect muscle tissue of chicken in $16.6s$ at the maximum temperature along the dissection site of $81.72°$.

CHAPTER 1

INTRODUCTION

1.1 Research Background

Surgical scalpel is a small and extremely sharp bladed surgical instrument used by a surgeon for dissection. It is commonly single-use or disposable to ensure blade's sharpness. It has wide application in minimally invasive surgery. Minimally invasive surgery is a surgery minimizing surgical incisions to reduce blood loss and postoperative pain, lessen scarring and speed recovery. It would require an energy source to dissect tissue and achieve haemostasis simultaneously [1]. Laparoscopic surgery is the first type of minimally invasive surgery where it is a surgery done through one or more small incisions, rather than a larger incision through abdominal wall. It is done by using small tubes, imaging system, and surgical instruments with extension rod [2]. The common diameter for laparoscopic instruments is 5mm, and it may go up to 12mm. The length of the instrument may range from 34 to 37cm. Laparoscopic instruments may divide into two categories, which are non-energy devices and energy devices. For non-energy devices such as graspers and scissors, they commonly have insulated sheath, a central working device, a handle, and a rotating capability at the working end which contribute to total of four degree of freedom, which are three translational and one rotation. Energy devices include monopolar, bipolar, and ultrasonic devices [3].

The energy devices such as electrosurgery devices and ultrasonic devices can be used in cauterization process to apply heat and burn the tissue in body to stop bleeding or remove tissue [4]. In any surgery which require surgeon to dissect or cut through any tissue of body such as skin and muscle which will lead to bleeding, thus it is essential to control the amount of blood loss. Since cauterization process can stop bleeding and allow minimum of blood loss, thus it plays an important role is any surgery. When heat is applied in the cauterization process, the heat will cauterize the dissection site, which is then seals off the blood vessel and stops the bleeding. During the surgery, this will reduce the difficulty of the surgery as the surgeon does not have to manage the blood flowing into the surgical site. This process also allows less blood transfusion during the surgery. Furthermore, the cauterization process can be applied for tissue removal from the body of patient such as tumours or cancer cells. Normally, the tissue removal is done by using scalpel, with its hard and sharp blade to dissect through the tissue. Hence, in cauterization process, it can dissect through the tissue without causing bleeding and seals off the blood vessels simultaneously during the process, which lead to the wide applications of cauterization process in many surgeries of different medical disciplines.

As early as 1993, ultrasonic scalpel (US) was developed by Amaral, called 'laparoscopic scalpel' for laparoscopic surgery by allowing simultaneous coaptation, coagulation and dissection of blood vessel [5]. This reduces the operating time, difficulty and blood loss as compared to the conventional electrosurgery devices. Furthermore, it is also proven that the lateral thermal spread by US for laparoscopic surgery is reduced to less than 2mm as compared to the electrosurgery devices [6], [7]. Hence, it is said to be an efficient and safe energy device to be used as compared to the electrosurgery device. Due to the numerous advantages, it is also widely applied in different medical disciplines such as orthopaedic for musculoskeletal trauma treatment [8], oral maxillofacial for the tissue dissection at the mouth, jaws, and face regions [9], urological such as nephrectomy for kidney removal [10], and peripheral vascular surgery for removal of plaque build-up inside of blocked artery [11]. Generally, US is used for tissue dissection, fragmentation, and ablation [12], thus it is flexible to be used in wide range of applications.

Figure 1-1 shows the schematic diagram of generic US for soft tissue dissection, illustrating ultrasonic transducer, waveguide, jaw and its blade, and control mechanism.

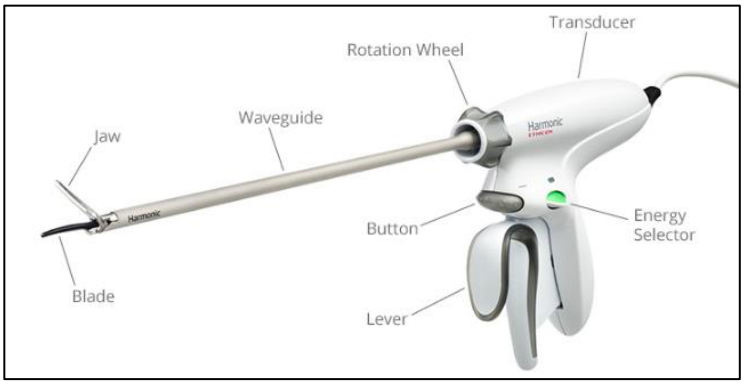

Figure 1-1 HARMONIC HD1000i Shears by Ethicon [13].

Within the US, alternating current (AC) is applied to electric generator which convert to direct current and into oscillated current at desired frequency. Piezo crystal acts as transducer to converts electrical energy into mechanical vibration energy at frequencies ranges from 20kHz to 60kHz. The vibration energy produced oscillate the active blade of the US linearly and the active blades movement ranges from 50 to 100μm [14]. Tissue is held between the active and counter blade and heat is generated from the friction between active blade and the counter blade to denature the protein in the tissue resulting in coagulation. Main advantages of US include less instrument traffic as it can perform vessel sealing and tissue cutting simultaneously, and less smoke generation [15]. The temperature generated ranges from 50°C to 300°C, which reduces the lateral thermal spread and less charring[16]. In the case of lower density tissue with high water content, the intracellular water is vaporized by the heat generated causing 'cavitation effect' further assisting in the dissection by separating tissue layers [3]. The efficiency of dissection by US is dependent on the nature of the tissue such as its water content, and the tissue strength which is directly related to the type of tissue, amount of collagen and its organization.

When applying US to a tissue, there are three main effects of cavitation, coagulation, and cutting. Firstly, in the cavitation effect, oscillating pressure field is produced due to the linear stroke from the active blade and causing the expansion and contraction of intracellular fluid and the tissue around the dissected site at ultrasonic frequency. When it is in the expansion stage, the pressure of the intracellular fluid dropped below its vapor pressure, causing vapor bubbles to be generated within the tissue. In contraction stage, the pressure is then raised rapidly causing the vapor bubbles to collapse. Since it is at ultrasonic frequency, shock wave is produced, and jet-like ejections is generated into the intracellular fluid. These phenomena happened in micro-second scale and over a period, the tissue will be dissected [17]. Cavitation is essential because it causes the separation of tissue planes facilitating the dissection process later. Next, for the coagulation, it occurs when the frictional heat generated between tissue and active blade is transmitted into tissue, which might heat up to 60°C to 100°C. Denaturation of protein or collagen starts and result in occlusion of blood vessel. Denaturation of protein happened because the tertiary hydrogen bonds between collagen and protein is broken. The proteins denature and convert from colloidal proteins into an insoluble gel that helps on occlusion. Lastly, the cutting effect is achieved by the high frequency oscillation of the active blade applied to the tissue [18].

Monopolar and bipolar devices are categorized as electrosurgery devices where they generate high frequency current (above 100kHz) to coagulate and dissect tissue by generating heat due to the resistance of tissue at the cutting site. In monopolar device, the current passes from the active electrode to the tissue, and through patient back to return electrode to complete circuit. Heat is produced by the flow of radio frequency electric current at the high current density site due to the narrow active electrode to vaporize and transect the tissue. The heat generated is ranging from 150°C to 400°C [19]. Potential hazard is the pad site (return electrode) burns caused by adverse conditions at the pad-patient interface which result in increased current density. Current density increases when contact area at the pad-patient interface is too small, heat is applied for long time, and the power setting is too high. In bipolar device, the current only pass through the tissue between the two forceps shaped electrodes, thus lower power setting required, and it greatly reduce the potential risks as compare to monopolar device. Furthermore, different type of tissue will have different electrical resistance and, the power setting must be adjusted from time to time depending on the type of tissue dissected in the surgery. For example, fat or adipose tissue, and bone tissue are relatively weak conductors of electricity as compared to muscle and skin tissue. Thus, with the same power setting for both surgeries, dissection of fat and bone tissue is relatively more time consuming. The main disadvantages of the electrosurgery device are the potential of alternative site burns, surgical fires, and carbonization [20]. These safety issues are eliminated by replacing the electrosurgery devices with the US's.

1.2 Problem Statement

Nowadays, US's are widely available on the market. Different brands of US's share the common function to cauterize and dissect tissue but different in designs, characteristics of the US, and the selling price. Different designs and characteristics of US will affect the performance of it during the surgery. Next, the selling price of an US's far outweighs the selling price of traditional electrosurgery device. To promote the usage of US's in surgery, the price can be a stumbling block for hospitals and clinics to consider it.

1.3 Objectives

The aims of this project are:

i. To develop an US as it can be used for cutting and cauterizing tissue. The design of US includes its ultrasonic transducer, ultrasonic horn, trigger mechanism, active and counter blades, and the casing of the US.

ii. To characterize the designed US in terms of frequency, stroke, elevated temperature, and the ability to cut tissues.

1.4 Scope of Research

In this project, the CAD model of US will be designed in Solidworks, and the design will be fabricated through machining process and rapid prototyping technology. However, the design of electrical circuit for the power supply or the ultrasonic signal generator will not be covered in this project as it is out of scope of study. Simulation will be done to measure the resonant frequency of the system and the result will be compared to the experimental result. Impedance analysis will not be conducted as it is not the focus of the project. Next, the vibration stroke of US is only measured experimentally, as simulation in vibration stroke cannot be done by using Solidworks software. It requires more time to study finite element (FE) analysis and using other simulation software such as Ansys or Abaqus to perform the simulation. In the experiment to measure its efficiency of dissection, chicken breast is selected as the sample to represent soft tissue due to its wide availability. Thus, characterization is done on the dissection of chicken tissue to measure the time taken of dissection, and the maximum temperature elevated at dissection site by using the prototype fabricated.

CHAPTER 2

LITERATURE REVIEW

2.1 Overview

In this section, the applications of the US will be reviewed, and compared with the conventional electrosurgery devices in terms of its advantages and disadvantages. In the past, researchers have focused on the design and characterization of the ultrasonic surgical instruments for different medical disciplines. Most of the designs share the same generic working principle but different in other subsystems such as its trigger mechanism, design of active blade and counter blade, and the electric circuit of the power supply. Due to the design approach applied by each research is different, these will be reviewed in following paragraphs.

2.2 Comparison between Ultrasonic Scalpel (US) and Electrosurgery Devices (ESD's)

The comparison for dissection between US's and electrosurgery devices in laparoscopic cholecystectomy has been studied. The result shows that in overall, there is a significance improvement by US in term of shorter operating time, hospital stay, sick leave, lower gallbladder perforation risk and lower pain or nausea for postoperative time [18]. However, there are some drawbacks for the US, which are difficulty in handling, and the cost of US. The cost of US is found to be significantly more expensive than electrosurgery device, 59,000 and 26,000 US Dollar respectively [10]. The cost is the main issue for all US, which outweighs the potential clinical benefits, and thus require further cost-benefit analysis [18]. Thus, to promote the usage of US in laparoscopic surgery, it is important to develop an US at lower cost or the cost-benefit analysis should be carried out to ensure that most of the clinics or hospitals afford to have the US. The active blade of US reaches the temperature of 80°C and even on prolonged use stays below 250°C which is far less than any electrosurgery devices such as monopolar device and bipolar device [21], [22]. Furthermore, the vibration of active blade in US prevents the sticking of coagulated tissues over it.

In electrosurgery devices, the smoke produced and the adhesion of tissue to electrodes is a major concern as it brings trouble to surgeon. The sticking of tissue to the electrodes increases the electrical resistance and thus the efficiency of energy delivered to the tissue is reduced. It also reduces the accuracy of operation and increase the operation time which in overall, increase the difficulty of the operation. Additional method required to solve the issue of tissue adhesion while using electrosurgery devices such as cold saline irrigation, anti-stick coatings, and thermal management system which in return increase the complexity of the operation [23]. Thus, US brings less side-effects to the operation and greatly reduce the complexity of the operation as compared to electrosurgery devices.

2.3 Comparison between Ultrasonic Scalpels (US's) that Available on Market

The performance in minimally invasive surgery between branded US which are Thunderbeat, LigaSure, and Harmonic Scalpel has been studied [21]. It is concluded that the performance of Thunderbeat has superseded the LigaSure and Harmonic Scalpel in term of its versatility. It is appealing, safe for coagulation and dissection during surgery, decreases time for surgical procedures, and increases versatility in surgical procedures. The performance of these US is compared in different categories, which are visibility, operation time, burst pressure and lateral thermal spread. In the visibility, Thunderbeat has clear visibility, but for LigaSure and Harmonic Scalpel, there are smoke production and mist production respectively which affect the visibility during operation. For the operation time, Thunderbeat, LigaSure, and Harmonic Scalpel are arranged in ascending order. The burst pressure test is to verify the durability of blood vessel after sealed by US by how much burst pressure the wound site will be able to withstand. In this experiment, only Thunderbeat and LigaSure can seal the 7mm blood vessel and the wound site is able to withstand almost 1800mmHg and 1000mmHg respectively. In term of operation time, Thunderbeat, Harmonic Scalpel, and LigaSure are arranged in ascending order, which are 10.7s, 18.8s, and 26.9s respectively. Lastly, in term of lateral thermal spread, Thunderbeat shows the least lateral thermal spread, where Harmonic Scalpel shows less than 1mm of lateral thermal spread and LigaSure shows 2mm of lateral thermal spread.

Next, the temperature profile of Harmonic Scalpel ACE (ACE), LigaSure V (LV) and Plasma Trisector (PT) were compared. From the result obtained, ACE device produced the highest temperature of (195.9 ± 14.5°C) when applied to the peritoneum (anterior abdominal wall), and it is higher than LV = 96.4 ± 4.1°C, and PT = 87 ± 2.2°C [16]. Lastly, in the laparoscopic nephrectomy, a study has been done to prove that the estimated blood loss for US is less than that of electrosurgery devices, 140.8ml and 182.6ml respectively [10].

2.4 Applications of Ultrasonic Scalpel (US)

The study of US in both open and laparoscopic surgery has been done. US is a part and parcel of open, laparoscopic, and minimally invasive surgery. For the laparoscopic group, cholecystectomy, appendectomy, hysterectomy, ovarian cystectomy, ectopic pregnancy, ureteric calculi, kidney stone, and herniorrhaphy are the cases employing US. For open group, Lumpectomy and simple mastectomy of breast, tonsil, perianal, thyroidectomy, glossectomy, and parotidectomy operations are the cases been operated by US. Meta-analysis has been carried out to perform thyroidectomy and the performance of US is compared with the traditional techniques [24]. The traditional techniques applied the monopolar electrosurgery device with the aid of clamp, cut, and tie. Based on the result of analysis, application of US in thyroidectomy has reduced the operative time by 31%, which is equivalent to 29 minutes. It also reduced the blood loss by 45ml as compared to the conventional instrument and the length of hospital stay is reduced by 0.70 day [25]. From the cases studied, the advantages and disadvantages of US can be concluded. The advantages of using US are its capability of coagulation of arteries of medium size, coagulation, dissection of soft tissue with bleeding control simultaneously, less operation time, used in both laparoscopic and open surgery, minimum blood loss thus blood is rarely required during operation, operative field remains clean, fast recovery, less heat production, bowel can be cut without damage and surgeon friendly. For its disadvantages, the main issue is the instrument cost as some patient could not afford to pay for the instrument, followed by high maintenance cost, long term practice is needed for expertise, delicate soft handling is required, incision on bone is impossible, and it is not intended for contraceptive tubal occlusion. In short, US is a very suitable instrument for both open and laparoscopic surgery but costly for the device itself and operation [26].

2.5 Selection of Ultrasonic Transducer / Actuator

The selection of ultrasonic transducer is crucial part as it is the source of vibration. There are two types of active material which are magneto strictive transducer and piezoelectric transducer that are widely used in the market, depends on the range of the working ultrasonic frequency [27]. Magneto strictive works when ferromagnetic material such as nickel and iron are arranged parallel to magnetic field. The oscillated current supplied induced oscillated magnetic field around the ferromagnetic material. Hence, the ferromagnetic material suffers changes in its length, and the vibration stroke is produced. However, magneto strictive is only for low frequency applications. Energy is also loss due to the hysteresis and eddy current, thus the efficiency of energy conversion is relatively low. For the piezoelectric application in ultrasonic transducer, it is widely used as compared to magneto strictive because of the high efficiency in energy conversion from electrical energy to mechanical energy. Furthermore, the performance of piezoelectric is independent of the ambient temperature and humidity, unlike magneto strictive. The efficiency of energy conversion as a ultrasonic transducer is at 7% and 0.5% for piezoelectric and magneto strictive respectively [28].

In the application of piezoelectric as an ultrasonic transducer, there are two different modes applied in different applications. Commonly, D33 mode of sandwich ultrasonic transducer is used. In this mode, the stack of piezo ceramic is poled in the thickness direction and vibrates in the same direction. It produces relatively large amplitude of vibration stroke as compared to D31 mode. But due to its limitations such as high voltage requirement and the relatively large size of tool, it limits the scope of applications. In D31 mode, the vibration stroke produced is perpendicular to the poling direction. The design of the ultrasonic surgical tool is as shown in the Figure 2-1. In this figure, it shows the stainless-steel blade is sandwiched by two D31 plates, and the D31 plates are clamped on the stainless-steel blade through the bridge.

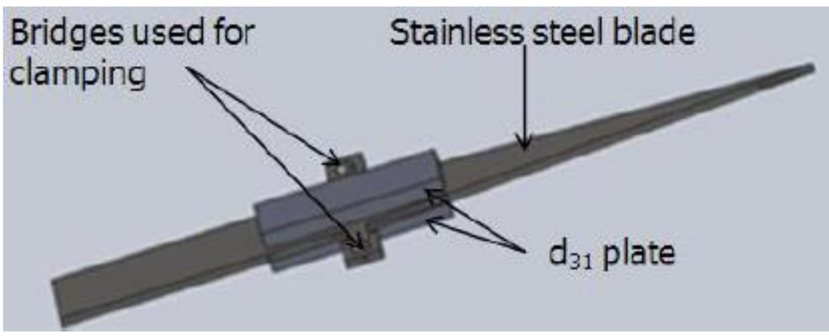

Figure 2-1 Design of Ultrasonic Surgical Tool in d31 Mode [29].

The D31 plates are bonded onto the stainless-steel blade firmly by applying epoxy adhesive AD066 to ensure that there is no relative motion between D31 plates and stainless-steel blade. Since piezoelectric coefficient in D31 mode is higher than that in D33 mode, thus lower driving voltage is required to generate the vibration stroke. When driving voltage is lower, less heat is generated within the ultrasonic transducer, and the thermal effect can be reduced. However, the difference in heat generated due to D31 mode and D33 mode is insignificant, which is very low compared to the D33 mode driven at typically 500V direct current (DC). The amplitude of the vibration stroke produced is within 10 μm at the driving voltage of 25V. The amplitude is relatively low unless ultrasonic horn is integrated into design to boost the amplitude of vibration stroke [29].

2.6 Material Selection for Ultrasonic Wave Transmitting Element

Micromachined silicon has also been used in the development of US [17]. In the design, instead of using titanium-based alloy or other metal for ultrasonic transmitting medium, which connect the piezo ceramic to the end of active blade, silicon is selected as the material for the waveguide and the ultrasonic horn. This is because sound travel at a higher speed in silicon as compared to the other metal alloys due to its particle arrangement in the elements. Furthermore, silicon element has lower thermal conductivity and density as compared to the metal alloy and due to its material property. These two factors are crucial because in the operation, the heat generated at the dissection site should not be conducted to the equipment, thus poor thermal conductivity material will be considered. Low density of the silicon element will contribute to less load and weight to the ultrasonic transducer and US respectively, thus the efficiency of energy transmitting will be higher and more user friendly to the surgeon due to the lightweight design. Another factor contributing to the idea of silicon is selected as transmitting material is that the production cost is greatly reduced by microfabrication technologies such as anisotropic etching. However, one drawback is that silicon is very brittle and not suitable to function as a transmitting element as the high stress occur during vibration will cause cracking on the silicon element and requires frequent change of silicon element on the US.

Next, there are other materials are used such as aluminium alloy EN-AW-7075, titanium alloy TI-6AI-4V-STA, and carbon steel for the wave transmitting element [30], [31]. Titanium alloy is said to perform well in sound transmission. It has the highest strength-to-weight ratio among other metallic elements. It also shows the excellent corrosion resistance and good high temperature mechanical properties. These criteria have met the requirement as an ultrasonic wave transmitting element. However, due to the high cost of titanium, aluminium alloy and high strength steels are always used in making the waveguide and ultrasonic horn.

2.7 Modelling and Measurement of Natural Frequency

In modelling of the natural frequency of the system, finite element (FE) analysis is carried out to predict the natural frequency of the system. FE model was generated and the simulation performed using Ansys software for different geometries of ultrasonic transducer [30]. Fine meshing size is required to obtain more accurate result by generating a greater number of nodes in the model. The result obtained from the simulation shows the graph of vibration amplitude against the frequency supplied to the system. From the simulation result obtained, the natural frequency of the system can be predicted by observe the frequency supplied where maximum vibration amplitude can be obtained. The graph obtained was cross checked with the graph of impedance against frequency as shown in Figure 2-2. In this figure, the x-axis represents the frequency, and the y-axes represent amplitude of vibration and impedance of the system. The solid line shows the amplitude of vibration within the range of frequency where the dashed line shows the impedance of the system at different frequencies.

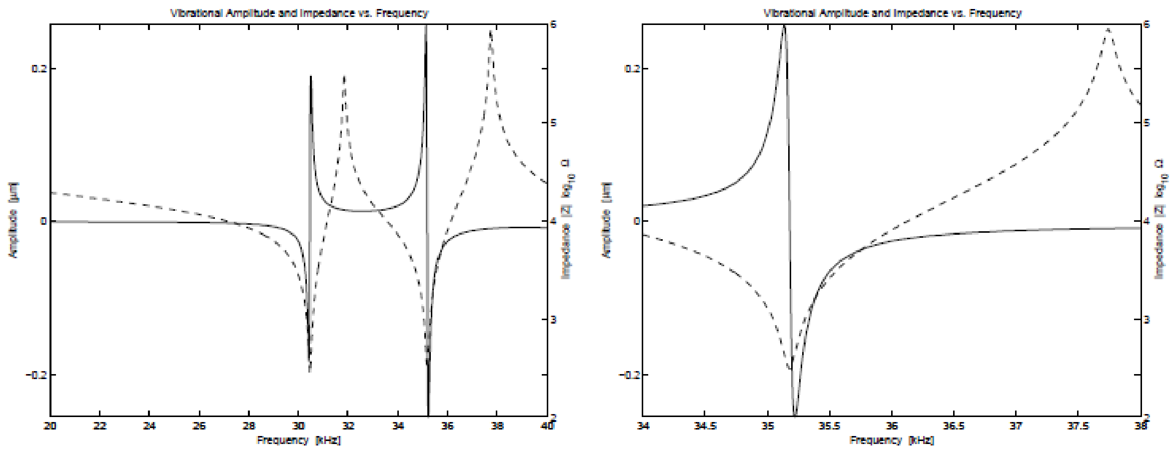

Figure 2-2 Graph of Impedance Against Frequency [30].

The natural frequency of system happens at the lowest impedance point with maximum admittance. From the graph, the results are consistent and shows the natural frequency of 35.25kHz.

In order to measure the natural frequency of ultrasonic devices, impedance analyser (HP4294A, HP4395A) were used to do impedance analysis [17], [29]. The result obtained from the impedance analysis shows the graph of impedance magnitude against frequency of the system. The result obtained from measurement can be used to verify the result from simulation.

2.8 Vibration Stroke Measurement

In the vibration amplitude measurement, many have use laser vibrometer as an approach to measure the amplitude of the stroke [29], [30]. A single-point laser vibrometer (Polytech OFV- 534 & OFV-2570) is used by applying Doppler Effect of the laser to measure the velocity and displacement of the vibration. The vibrometer focus a laser beam on the piezoelectric actuator. When the piezoelectric actuator is actuated, it will scatter the and reflect light pointed from the laser source, then the phase shift of the scattered light is measured, and signal is sent to the receiver. Signal detected is then converted into voltage signals. Through some signal processing and amplifying algorithm, the displacement of the vibration can be measured. From the measurement, it shows that vibration amplitude is decreased with the increase of operating frequency. The schematic diagram for the amplitude measurement is as shown below in Figure 2-3. It shows that the laser beam strikes on the surface of piezoelectric actuator on the anti-vibration table, then the vibrometer meter is used to measure the vibration amplitude and frequency extracted from the Doppler shift of the reflected laser beam when the piezoelectric actuator is vibrating. Function generator is used to supply desired voltage signal to actuate the piezoelectric actuator and oscilloscope is used to visualize the voltage signal from function generator and vibrometer.

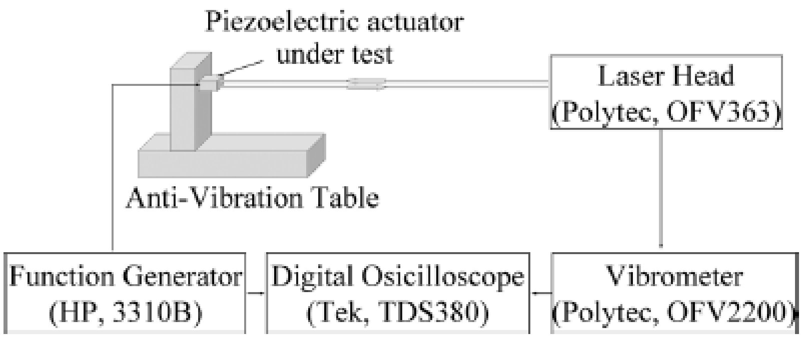

Figure 2-3 Schematic Diagram of Vibration Stroke Measurement [32].

The experimental setup as shown in Figure 2-3 required many precise equipment, and careful setup is required due to the high sensitivity of the vibrometer.

Next, scanning laser vibrometer system (PSV 300-F/S, Polytech GmbH, Waldbronn, Germany) was used to measure the vibration amplitude of a piezo-powered ultrasonic dental scaler [33]. Laser beam of He-Ne laser from the scanning laser vibrometer is focused onto the end of scaler tip. Virtual measurement grid is used to guide the laser beam and scanning is done on the surface of scaler tip when it is oscillating. Fast Fourier Transformation is done to determine the longitudinal and lateral vibration amplitude of the scaler tip. Hence, it depends on up to which extent the accuracy of the measurement required as the cost of experiment is also increased with the accuracy.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Overview

In this chapter, the methodology to carry out the project will be discussed. The overall flow of project is as shown in the Figure 3-1. There are 5 main stages in developing an US.

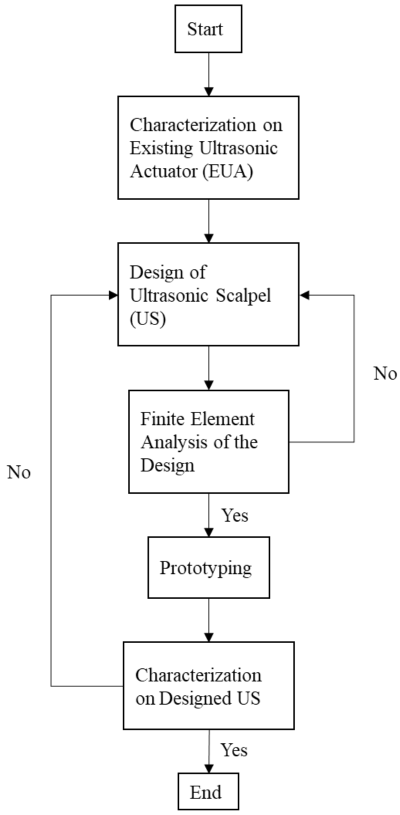

Figure 3-1 Overall Flow of Project

It starts from the characterization on existing ultrasonic actuator (EUA) to the design of CAD model of US in Solidworks, then to the finite element (FE) analysis on the CAD model. If the result obtained from the FE analysis does not show the desire result, the CAD model of US is redesigned again until optimum result is obtained. Next, prototyping is carried out to fabricate and assembly the designed US. Lastly, characterization of the fabricated US is done. When characterization on the fabricated US does not show satisfying result, the process will start again from the design of US in CAD model.

3.2 Characterization on Existing Ultrasonic Actuator (EUA)

In the characterization on EUA, several parameters will be measured which are frequency of the driving voltage signal from power supply, natural frequency of the system, vibration stroke produced by the tip of ultrasonic actuator, and the capability on soft tissue dissection. These will be used to determine the if the EUA has the capability to perform as an US before proceeding to the design of US.

3.2.1 Measurement of Voltage Signal from Power Supply

A generic US is normally operated at a frequency of 20kHz to 60kHz. Thus, the frequency of voltage signal from the power supply for the EUA is required to be measured to ensure that it is operating within the desired frequency range. The measurement can be done by using oscilloscope, and connected to the power supply through electrical circuit, and the details of voltage supply can be measured from the oscilloscope. Figure 3-2 shows the schematic diagram of the circuit connection to measure the power supply of EUA.

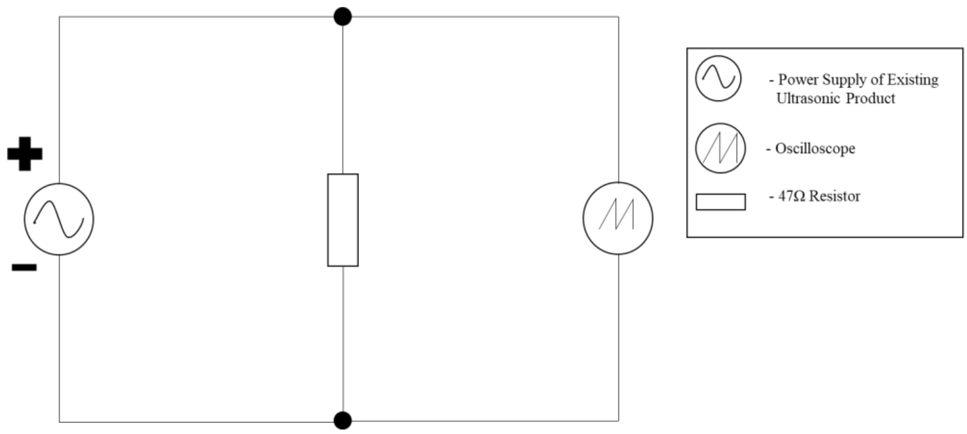

Figure 3-2 Circuit Design for Measurement on Voltage Signal from Power Supply.

The concept is to measure the potential difference across the resistor. The oscilloscope is functioned as a voltmeter where the connection is parallel to the resistor. The schematic diagram of the setup is as shown in Figure 3-3.

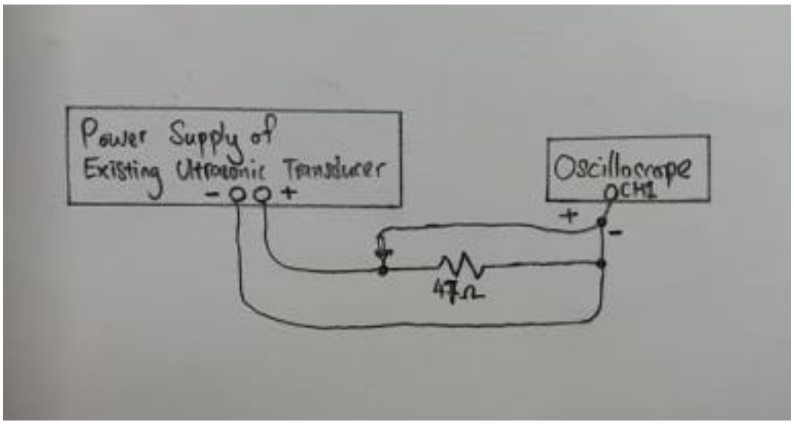

Figure 3-3 Schematic Diagram for Measurement of Voltage Signal from Power Supply.

The procedure of experiment is as follow:

1. The setup of measurement is as shown in the Figure 3-3.
2. The connection of circuit is as shown in the schematic diagram in Figure 3-2.
3. Power supply of the EUA was turned on and the power level is set to maximum level.
4. The setting on oscilloscope (Agilent Technologies, DSO3062A) was adjusted to ensure that the voltage signal is shown with proper scale on screen and data can be obtained.

3.2.2 Measurement of Natural Frequency of the Existing Ultrasonic Actuator (EUA)

It is essential to know the natural frequency of the system because when the EUA is excited at its natural frequency or resonant frequency, it will generate the maximum amplitude of stroke. Thus, the efficiency of the system is at its optimum level.

To measure the natural frequency of the system, function generator, oscilloscope, and the EUA can be connected through electrical circuit, as shown in the Figure 3-4.

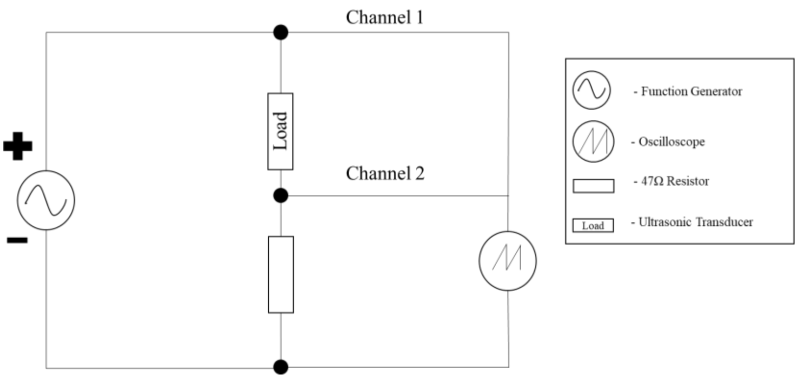

Figure 3-4 Circuit Design for Measurement on Natural Frequency of the EUA.

When the EUA is excited at its natural frequency, the impedance of the EUA, Z_{load} is at its lowest point as the EUA vibrates at its maximum amplitude. The 47Ω resistor is connected in series to the EUA, both loads share the same amount of current within the circuit. According to Ohm's Law,

$$Z = \frac{V}{I}$$

$$I = constant$$

Since $Z_{load} \ll 47\Omega$, the voltage drops across the EUA is at the least amount. Most of the voltage drops across the 47Ω resistor and it shows the maximum potential difference across the circuit. If EUA vibrates at its natural frequency, the difference between the root mean square voltage, V_{rms} should be at its minimum, and the two voltage signals across EUA and resistor should be ideally in phase.

The procedure of experiment is as follow:

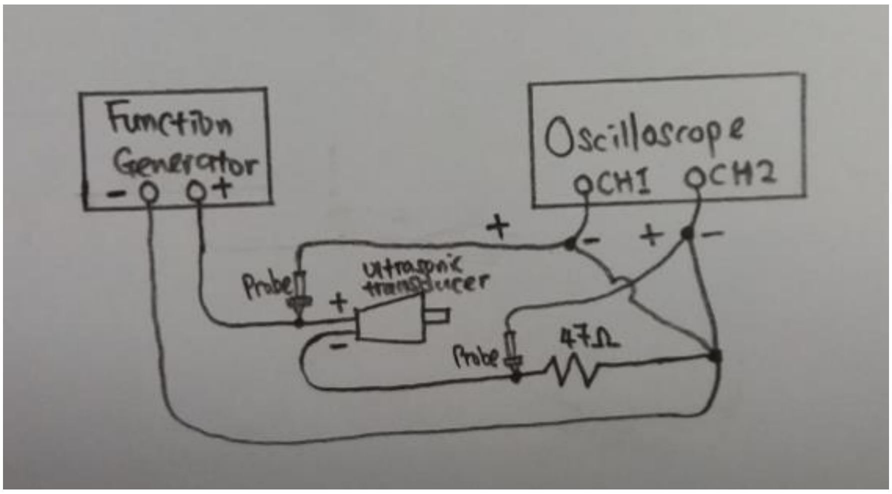

Figure 3-5 Schematic Diagram for Measurement of Natural Frequency of the EUA.

1. The setup of measurement is as shown in the Figure 3-5.
2. The connection of circuit is as shown in the schematic diagram in Figure 3-4.
3. Function generator (Stanford Research Systems, DS335) was turned on and switched to sine wave mode.
4. The voltage signal sent to the circuit was started from 1kHz.
5. The setting on oscilloscope (Agilent Technologies, DSO3062A) was adjusted to ensure that the voltage signals for both EUA and resistor detected from the Probe 1 and Probe 2 are displayed on the screen.
6. From the function available on the oscilloscope, root mean square voltages of the

EUA and resistor were displayed and difference between the root mean square voltage were shown.

7. The frequency of the voltage signal from the function generator was increased slowly until the minimum difference between root mean square voltages is obtained.
8. The frequency shown on the function generator will be the natural frequency of the EUA and was recorded.

3.2.3 Measurement of Vibration Stroke of the Existing Ultrasonic Actuator (EUA)

From the EUA, it is crucial to measure the vibration stroke produced as the stroke will facilitate the cutting process. The vibration stroke to be achieved by an US range from 50µm to 100µm [34]. Thus, an experiment was carried out to measure the vibration stroke produced by EUA.

The EUA was fixed on 80/20 T-slotted aluminium extrusion by locking a thin aluminium plate with screws. Next, small rectangle pieces of aluminium plate was used as specimen and it was locked in front of the ultrasonic handpiece to ensure the tip is in contact with the specimen. Aluminium is selected as the specimen due to its mechanical property. It is soft to ensure that the vibration of the tip can make a scratch mark on it. Since the scratches made on the specimen is in microscale, a high-resolution optical measurement instrument will be used to measure the dimension of scratches and the geometry of the scratches were observed. Alicona Infinity Focus will be used as the measurement instrument as shown in Figure 3-6.

Figure 3-6 Alicona Infinity Focus

From scratches made on the specimens, the vibration stroke can be calculated with the following formula:

$$Vibration\ Stroke = Length\ of\ Scratch - Width\ of\ Tip\ Head \quad (1)$$

The schematic diagram is as shown in Figure 3-7. When the active tip is in contact with the aluminium specimen and oscillating back and forth. A dent will be created with the length equals to the length of scratch provided there is no relatively motion between the EUA and the specimen. The vibration stroke is then calculated by applying Equation (1).

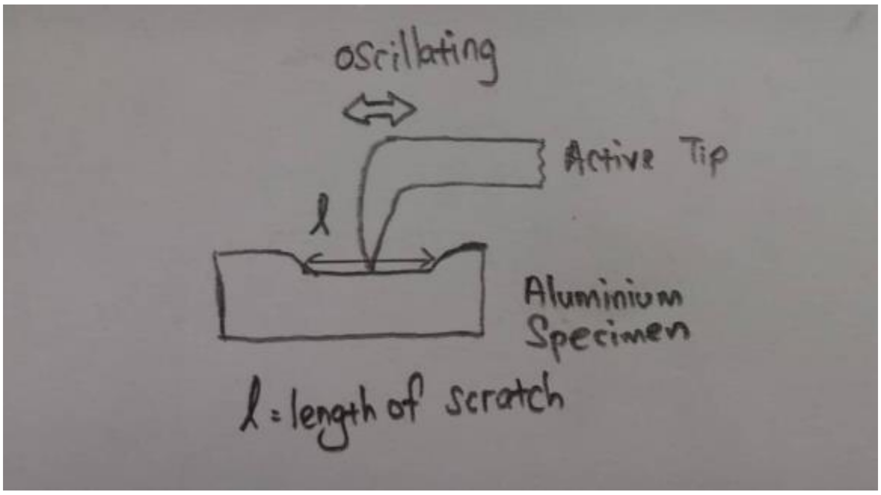

Figure 3-7 Schematic Diagram for Measurement of Vibration Stroke of the EUA.

The procedure of experiment is as follow:

1. The setup of measurement is as shown in Figure 3-8.
2. The washer is added accordingly between the specimen and T-slotted aluminium extrusion to adjust the height and ensure that the specimen is in contact with different type of tips.
3. The power generator is switched on and the power level is set to maximum level.
4. The foot pedal switch is pressed, and the operation is started.
5. For each of the specimens, 5 scratches must be made on it on different location.
6. Steps 2 to 5 are repeated by applying different type of tips.
7. The geometry of scratches and tips used will be observed under Alicona Infinity Focus.
8. The data obtained are recorded and tabulated.

Figure 3-8 Setup of Measurement of Vibration Stroke of the EUA.

3.2.4 Soft Tissue Dissection by Existing Ultrasonic Actuator (EUA)

The cutting of soft tissue is carried out to measure the time taken for dissection and maximum temperature variation during dissection. Hence, the active blade and counter blade were designed and fabricated for soft tissue dissection purpose.

The design of tip will be done by modifying the curved tip of EUA to an active tip as shown in the Figure 3-9.

Figure 3-9 The Modified Tip of the EUA.

For the design of counter blade, it was designed based on the geometry of active tip to ensure that it can match with the active tip. The CAD model of counter surface is drawn in Solidworks as shown in Figure 3-10, it was then converted into IGES format for Computer Numerical Control (CNC) machine to fabricate it. The material used is stainless steel as it is hard, ductile, and good resistant to rust. Thus, the geometry of the counter blade is not easily altered. The fabricated counter blade is as shown in Figure 3-11. The rough surface or the profile on the surface of blades is used to provide friction to the tissue and facilitate the dissection process. The four through-holes around the counter blade are used for the screw to lock it on the setup of experiment.

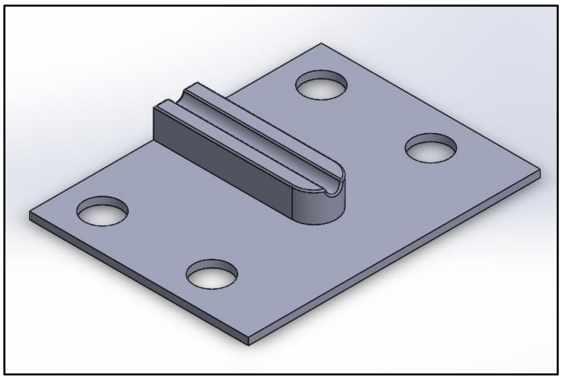

Figure 3-10 The CAD Model of Designed Counter Blade.

Figure 3-11 The Fabricated Counter Blade.

The setup of experiment was designed by using Solidworks to ensure that the geometry and dimension will be suitable when setting up the experiment. Once the design of setup of experiment was done, it was then fabricated and assembled as shown in Figure 3-12. The four threaded rods at each of the corners was used for the nuts on it to rotate and thus adjust the height of handpiece locked on the aluminium plate. The counter blade was locked on the load cell to ensure that when the experiment is carried out, the load applied on the sample can be obtained and monitored. The size of sample tissue will be made as uniform as possible to ensure consistency.

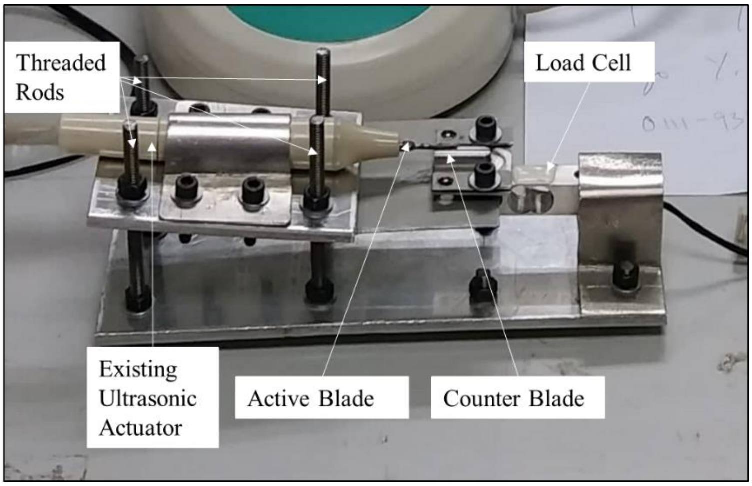

Figure 3-12 The Setup of Experiment for Soft Tissue Dissection by the EUA.

For the preparation of samples, there are 2 types of samples that were used in the experiment, which are muscle tissue and skin tissue of chicken. The chicken breast is sliced into smaller pieces as shown in Figure 3-13. The wide of each sample is about 6mm.

Figure 3-13 Soft Tissue Samples for Dissection.

The procedure of experiment is as follow:

1. The setup of experiment is as shown in Figure 3-12.
2. The samples are prepared from muscle tissue and skin tissue of chicken with the wide of each sample is to be kept within 6mm.
3. The load cell indicator is turned on and calibrated to neglect the weight of the counter surface locked on it to ensure that the value displayed is the load applied on the sample.
4. The muscle tissue of chicken as sample is placed across the counter surface.

5. The alignment of the active tip and its counter surface must be parallel to each other to ensure all the area are in contact.
6. The nuts on the four threaded rods are adjusted so that the load applied is about 5N.
7. The power is turned on and set to the maximum power.
8. The phone camera is clamped at a fix position to record the experiment for reference purpose.
9. The foot pedal is pressed, the stopwatch is pressed to measure the time taken, and the dissection is started.
10. At the time interval of 30 seconds, the infrared camera (Fluke, Ti27) is used to capture the thermography of the contact side.
11. When the high amplitude of sound is heard, which means the active tip and its counter surface are in contact, then the foot pedal is released.
12. The time taken to dissect through the sample is recorded.
13. Step 4 to Step 11 are repeated for different load applied, 6N, 7N, 8N, and 9N.
14. Step 12 is repeated by using skin tissue as sample.

All the data are recorded and tabulated.

3.3 Conceptual Design of Ultrasonic Scalpel (US)

After the characterization of the EUA is done, and satisfying result is obtained from the characterization, a conceptual design of US will be proposed in CAD model.

The design of US includes two independent working systems, which as shown in Figure 3-14.

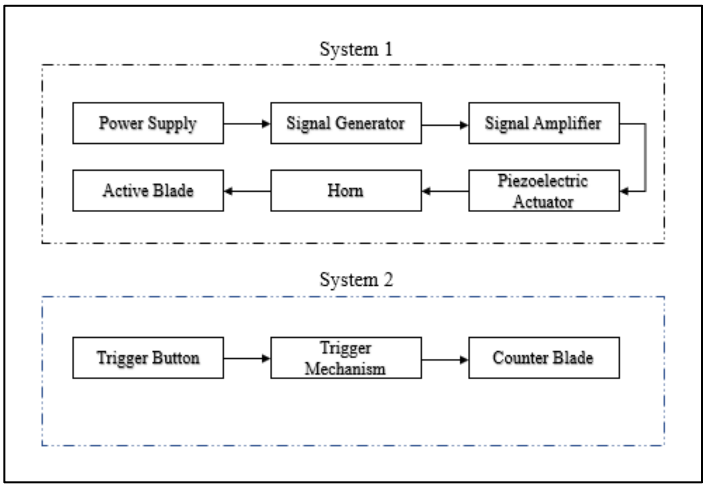

Figure 3-14 Two Working Systems in US.

In System 1, the AC power supply is first been converted into direct current oscillated sine wave electrical signal at ultrasonic frequency. The ultrasonic sine wave is then amplified to a value to actuate the stacked piezo ceramic within the ultrasonic handpiece. The piezo ceramic stack will eventually produce linear stroke in the direction of applied electric field. This is called d33 effect. Ultrasonic horn is required to amplify the strain rate produced by the stacked piezo ceramic to ensure that the linear stroke produced can achieve in the range of 50µm to 100µm. The design of the ultrasonic horn is varied among the three designs with its aim to produce the maximum amplitude of vibration at the end of the ultrasonic horn. This will ensure that the active blade will vibrate at its maximum. Metal housing is required to support the stacked piezo ceramic to ensure all the linear stroke produced goes to the front of stacked piezo ceramic. The design of ultrasonic transducer is shown in Figure 3-15.

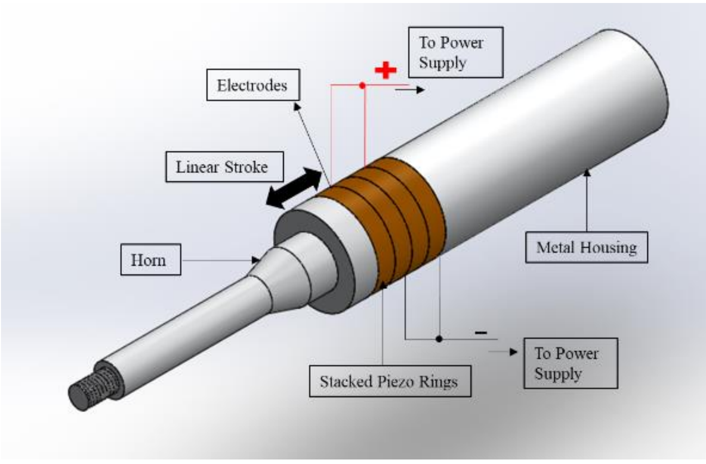

Figure 3-15 The Ultrasonic Transducer in Ultrasonic Handpiece.

In the System 2, the trigger mechanism will be proposed. The trigger mechanism is functioned to convert or translate the force or load applied by the surgeon, to the movement of counter blade. In ideal condition, there is no energy loss due to damping of the system within the mechanism, the amount of energy of surgeon applied should be all goes to the counter blade to hold the soft tissue firmly.

After the two systems are designed, both systems will be integrated as the US by design an appropriate casing to enclose the systems.

3.4 Finite Element (FE) Analysis

After the CAD model of the proposed US is generated in Solidworks, then CAD model can be used for FE analysis. FE method is used to simulate the behaviour of the designed