DESIGN AND ENHANCEMENT OF RADIOFREQUENCY CANNULA FOR CHRONIC PAIN MANAGEMENT

BY

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ABSTRACT

Radiofrequency (RF) cannula is one of important component in the treatment of chronic pain known as Radiofrequency (RF) procedure. This procedure has become a common and alternative procedure for chronic pain management since it gives pain relief without causing damage to the nerve tissue. The main issue or problem in existing design related to placement of cannula to target nerves which are ability to firmly hold the cannula and adjustment of the cannula to the target nerve. Thus, through conceptual design development, new design of cannula hub may improve placement of cannula to target nerve and gripping ability. In conceptual design and development, product design specification is established from user's requirements and existing cannula. Six design concept sketching is generated according to product design specifications which were evaluated by user of RF cannula. In evaluating these design concepts, several criteria are defined to satisfied user most through details questionnaire. Final concept design is selected through concept screening and concept scoring phase. A design of prototype cannula hub is created using Catia V5 software with improvised features. This study proposes the fabrication prototype cannula hub using Fused Deposition Modeling (FDM) machine. The prototype cannula hub attached with insulated needle was tested on chicken tissue to compare the performance of new prototype cannula hub with existing cannula during radiofrequency procedure. It is found that, the new prototype cannula hub more effective in term of gripping ability and placement to target tissue. Essentially, this study may benefit a lot in providing alternative design of cannula hub while promising a better performance of RF cannula.

ملخص البحث

الترددات الراديوية (RF) قنية هي واحدة من المكونات الهامة في علاج الألم المزمن الترددات الراديوية (RF) قنية هي واحدة من المكونات الهامة في علاج الألم المزمن والمعروفة باسم الداخلي (RF) للترددات الراديوية. لقد أصبح هذا الإجراء إجراء شائع وبديلة لإدارة الألم المزمن لأنه يعطي لتخفيف الآلام دون التسبب في الأضرار التي لحقت الأنسجة العصبية. القضية الرئيسية أو مشكلة في تصميم القائمة المتصلة وضع قنية لاستهداف الأعصاب التي هي القدرة على الاحتفاظ بقوة قنية وتعديل قنية في العصب المستهدف. وهكذا، من خلال تطوير التصميم النظري، قد التصميم الجديد للمركز قنية تحسين وضع قنية لاستهداف الأعصاب والقدرة التي تحتاج. في التصميم النظري والتنمية والتي أنشئت المنتج مواصفات التصميم من متطلبات المستخدم وقنية القائمة. يتم إنشاء ستة عظيمين مفهوم التصميم وفقا لمواصفات تصميم المنتجات التي تم تقييمها من قبل المستخدم من قنية RF. في تقييم هذه المفاهيم التصميم، وتعرف عدة معايير للمستخدم من خلال استبيان رضى معظم التفاصيل. يتم تحديد مفهوم التصميم النهائي من خلال فحص المفهوم ومفهوم المرحلة التهديف. يتم إنشاء مركز تصميم النموذج الأولي باستخدام قنية كاتيا V5 البرنامج مع ميزات مرتجلة. هذه الدراسة تقترح قنية النموذج تصنيع باستخدام النمذجة تنصهر ترسب (FDM) الجهاز. يتم اختبار النموذج الأولي قنية على الأنسجة الدجاج لمقارنة أداء النموذج الجديد قنية قنية مع محور القائمة أثناء إجراء موجات اللاسلكية. تبين أن والجديدة مركزا قنية النموذج أكثر فعالية في المدى من القدرة التي تحتاج والتنسيب لاستهداف الأنسجة. أساسا، هذه الدراسة قد تفيد كثيرا في توفير بديل تصميم المحور قنية في حين واعدة أفضل أداء قنية RF.

APPROVAL PAGE

I certify that I have supervised and read this study and in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for degree of Master of Science (Manufacturing Engineering).

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DECLARATION

I hereby declare that this dissertation is the result of my own investigation, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or any other institutions.

Shafie Kamaruddin

Signature..... Date…….....

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LIST OF ABBREVIATIONS

ABS	Acrylonitrile butadiene styrene
ASIPP	American Society of Interventional Pain Physician
CO2	Carbon dioxide
CT	Computed tomography
DRG	Dorsal root ganglion
et al.	*(et alia)*: and others
etc	Et cetera
UV	Ultraviolet

LIST OF SYMBOLS

°C	Degree celcius
in	Inch
min	Minute
mm	Millimeter
s	Second
V	Voltage
μm	Micrometer

CHAPTER ONE

INTRODUCTION

1.1 GENERAL BACKGROUND

Chronic pain is a public health concern which could affect the quality of life of an individual and also a great loss to a nation in term of workforce utilization. ASIPP (2007) defined chronic pain as pain which is not within the usual course of an acute disease or a normal recovery period, causes by chronic pathologic processes for long period of time, persistent pain that is not amenable to routine pain treatment procedure and healing of pain may unlikely to occur.

Previously, when a patient has a chronic pain problem, pharmacology treatment or conventional surgery is used as one of the methods to control the pain. As the conventional method of procedure is not effective to control the pain, an alternative to that procedure is introduced which one of its methods is used as pulsed radiofrequency to provide pain relief without causing damage to the nervous tissue (Mohamed, 2012). The procedure for radiofrequency treatment consists of equipments which are radiofrequency (RF) electrode, radiofrequency (RF) cannula and radiofrequency (RF) generator.

As the application of pulsed RF in treatment of chronic pain management is widely accepted by most of patient as an alternative for pain management, demand for single use RF cannula contributes to the need on enhancement of existing cannula design. Therefore, by redesigning this cannula hub provides alternative design concepts and able to perform the procedure more effectively.

1.2 PROBLEM STATEMENT AND ITS SIGNIFICANCES

Chronic pain is often associated with health and economic impact. In United States, chronic pain problems cause workers functional impairment, activity restriction, reduced quality of life, disability, unemployment, reduces work productivity and direct medical cost (ASIPP, 2007). Therefore, research into treatment of chronic pain is an interest of many researchers and practitioners alike.

Among common procedure in chronic pain management is using pulsed radiofrequency (RF) procedure. The fundamental issue of designing and fabricating cannula hub prototype is to provide alternative design concepts and improve its current design. Although several designs of cannula are available in the market, the main issue or problem in the existing design is related to placement of cannula to target nerve which are the ability to firmly hold the cannula and adjustment of the cannula to the target nerve.

In earlier studies, few research and development are being carried out in developing cannula hub for chronic pain management. Table 1.1 highlights several researches that have been carried out on improving RF cannula. Most of this previous research concentrated on improving performance of other components of RF cannula. In the current study, investigation emphasizes on improvement of cannula placement to the target nerve by redesigning cannula hub through product development process providing an alternative design concept. Thus, improved design of cannula hub according to user specification is expected to provide more users of pulsed radiofrequency for chronic pain management more effectively. Therefore, this study may benefit a lot in terms of the effectiveness of the procedure while promising a better quality of product.

Table 1.1
Previous research on development of RF cannula

Author/ Researcher	Title	Figure/ Description	Advantages	Remark
Arramon et al. (2011)	Cannula having asymmetrically shaped threads	Asymmetrically thread profile on cannula tip which is able to penetrate bone structure.	Ability to penetrate bone structure not being pulled out of bone body during procedure.	Increased cost as additional features added to this cannula design.
Cosman and Cosman (2011)	Integral High Frequency Electrode	Has a flexible injection tube and port to allow injection of anesthetics or saline solution fluid to target tissue.	Better accuracy placement on human tissue due to less movement.	Increased geometry complexity and increased cost because of additional features
Darmos et al. (2008)	Hybrid Cannula/ Electrode Medical Device and Method	Single device serves both cannula and electrode.	Eliminate the need to purchase, sterilize and use two separate devices.	Simplifying the surgical procedure.
Jasper (2008)	Radiofrequency Cannula with Active Tip Radio opaque Marker: Image Analysis for Facet, Gray Ramus and Dorsal Root Ganglion Techniques		The marker is visible under fluoroscopy to distinguish active tip and insulated needle.	Optimized visualization of cannula for better placement to target nerve.
Shah et al. (2005)	Electrosurgical Cannula	Has lateral aperture feature to allow treatment composition flows along cannula surface.	Better flow of treatment composition through lateral aperture.	May not be necessary to have this feature for some applications.

1.3 RESEARCH OBJECTIVES

The research would be focused on the design and development of prototype cannula hub for chronic pain management. The main objectives of the research are:

1. To improve the effectiveness of the existing design of the cannula hub using advanced quality control tools.
2. To generate alternative design concepts of cannula hub with improvised features.
3. To validate the proposed design by building a prototype.

1.4 RESEARCH SCOPES

This study presents a development of a current commercial RF cannula design by considering design from other brands and researchers, providing a better grip of cannula hub. Product design specification for RF cannula is translated from user's requirements. Several design concepts are generated using Catia V5 software. Then, these concept designs are evaluated by RF cannula's users for concept selection. Selection of the design concept was done in two phases which are concept screening and concept scoring. In the selection of the design concept for further development, a prototype of cannula hub was fabricated using Fused Deposition Modelling (FDM). The performance of this prototype was tested with chicken tissue to verify its effectiveness.

1.5 RESEARCH METHODOLOGY

This research has been conducted within a period of six months through steps as follows:

The conceptual design and development for this research starts with gathering of information about user's requirements through interviews with cannula's users and considering the design of existing available cannula. Target specification is established from the user's requirements and relationships between these two elements are identified using need-metric matrix. Each metric is benchmarked over existing competitive product which then ideal and marginally acceptable target value for each metric is set.

Concept model is generated using an established product design specification. Each model is evaluated based on a define selection criteria from the users. Six concepts are generated and evaluated through concept screening and concept scoring phase in selecting final design concept.

The prototype for this cannula is fabricated using rapid prototyping method which is Fused Deposition Modelling (FDM). Then, it is tested by performing radiofrequency procedure to a chicken tissue. The result using existing cannula and improved cannula is compared in performance by users.

1.6 EXPECTED OUTCOMES

Expected outcomes of this research are:

1. Enhancement of existing design cannula hubs by redesigning considered designs from other brands and researchers.
2. Generation of alternative design concepts cannula hub with improvised features.
3. Selection of a design concept through concept screening and concept scoring.

4. Design and prototype fabrication of newly improved cannula hub

1.7 THESIS OUTLINE

This thesis is organized into six chapters; Chapter One discusses briefly the idea of philosophy and the objectives of the study. Following this chapter, Chapter Two, focuses on the review of recent related literature which covers on sub chapters including chronic pain management, overview on radiofrequency procedure, product design and development and rapid prototyping. Chapter Three presents the methodology on design and enhancement of RF cannula. In this chapter, it presents the translation of user's requirements to product design specifications. Furthermore, this chapter discusses several concepts of cannula design generations according to product design specifications. Then, selection criteria of this design concept will be discussed before final concept selection. Chapter Four presents prototype cannula hub fabrication and testing procedures details. Chapter Five discusses result of testing on chicken tissue in details. The design concept analysis will also be discussed in this chapter. General conclusions and recommendations of further work are summarized in Chapter Six.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

Pulsed radiofrequency is an alternative for chronic pain treatment which offers an advantage over conventional continuous radiofrequency in term of tissue damage. According to Byrd and Mackey (2008), continuous radiofrequency was first used for pain treatment in 1974, varies from lumbar radicular pain to intercostal neuralgia and cervicogenic headaches. Then, an alternative for continuous radiofrequency was introduced, known as pulsed radiofrequency mode with the ability to provide ample radiofrequency energy to modulate the electrical field without causing tissue thermo coagulation. Even though both mode lesionings are proven acceptable for pain treatment but conventional radiofrequency treatment has high potential of nerve damage since thermal destruction of nervous tissue takes place at 45°C.

Sluijter and Racz (2002) explained that the RF treatment is done with fluoroscopy to position the tip of the RF cannula near the neural target structure. Then, the needle electrode tip which is connected to a RF lesion generator is introduced through the cannula to deliver the radiofrequency current. The mechanism of action behind pulsed RF is by delivering short (20msec) bursts twice per second followed by a quiet phase (lasting 480msec) in which no current is applied. This mechanism of action allows heat to dissipate, thus allowing the tissue temperature within the neuro destructive threshold of 45°C.

Previously study done by Erdine et al. (2005) and Zundert et. al (2005) discovered that pulsed radiofrequency on rat dorsal root ganglia (DRG) and rabbit

dorsal root ganglia (DRG) using pulsed radiofrequency electrodes at 42°C shown minimal thermal damage. Both studies showed the potential of pulsed radiofrequency in treating pain especially patients with axial low back pain problem. Recently, Rosenthal (2009) mentioned that the use of pulsed radiofrequency has also widened its application which includes facial pain, inguinal pain and miscellaneous pain syndrome. This finding on application of pulsed radiofrequency is further to be explored in other different applications of chronic pain management.

As pulsed radiofrequency becomes acceptable for chronic pain management, the treatment procedure requires a non-reusable radiofrequency cannula for different patients for safety reasons. Currently, the radiofrequency cannula is available in the market but requires improvement on the cannula hub design to provide better placement to target nerve. Therefore, this study represents an enhancement of the existing design with improvised features.

2.2 CHRONIC PAIN MANAGEMENT

Nowadays, chronic pain is considered as the critical issue in our modern time in spite of modern development in medicine. It is a complex phenomenon that could affect life quality of a person by disturbing sleep, appetite, creating fatigue and impairing recovery from illness or injury (Manchikanti et al., 2007). According to ASIPP (2007), chronic pain is defined as pain which is not within the usual course of an acute disease or a normal recovery period, is caused by chronic pathologic processes for a long period of time, persistent pain that is not amenable to routine pain treatment procedure and healing of pain may unlikely to occur.

Manchikanti et al., (2000) differentiate pain into two major categories which are pain of spinal origin and pain of non spinal origin. Pain of spinal origin is pain due

to various structures of spine whereas non spinal pain includes other painful conditions ranging from peripheral neuralgias to reflex sympathetic dystrophy and arthritis. Among the structures responsible for the pain in the spine are vertebrae, intervertebral discs, spinal cord, nerve roots, facet joints, ligament muscles, atlanto-occipitul joints, atlanto-axial joints and sacroiliac joints.

In contrast, muscle, ligaments, joints, sensory nerves, the sympathetic nervous system and visceral organ are associated with pain of non spinal origin. Most pain from non spinal origin include pain in the neck, upper back, mid back, low back, upper and lower extremities. It is postulated that, for any pain mentioned above to be considered as cause of back pain, its structures should have a nerve supply, have the ability to cause pain, susceptible to diseases and been identified to be sources of pain using reliable and recognized diagnostic technique by pain physician. However, few chronic pain problems may also be associated with psychological problems such as depression, generalized anxiety disorder and some behavioral problems.

2.2.1 Interventional Techniques

The application of interventional techniques in pain management started in the early of 19th as epidural injections for lumbar nerve root were reported. Since that time, pain physician continue to develop other multitude nerve blocks and procedures for management of chronic painful conditions (Manchikanti et al., 2000). Currently, many guidelines systematic reviews and articles published on interventional pain management either on spinal pain, non spinal pain or cancer pain intended for interventional pain physician. According to Medicare Payment Advisory Commission (MedPAC, 2001), spinal interventional techniques can be defined as minimally invasive procedures such as needle placement of drugs in targeted areas, lesioning of

targeted nerves and other surgical techniques, such as discectomy and the implantation of intrathecal infusion pumps and spinal cord stimulators.

One of the methods used in interventional techniques is known as pharmacological intervention. Most common drug used for interventional procedures include corticosteroids, local anaesthetics (lignocaine and bupivacaine), alcohol or phenol. A non-pharmacological intervention is known as radiofrequency (RF) lesioning of nerves or ganglion. Radiofrequency (RF) lesioning is a non destructive procedure that utilizes continuous heat to generate controlled tissue ablation (thermocoagulation), thus modulating pain transmission with minimum nerve damage (Nocom et al., 2009).

2.3 OVERVIEW ON RADIOFREQUENCY PROCEDURE

Radiofrequency procedure is proven as one of the alternative methods to provide long term pain relief. In general, there are two categories of radiofrequency procedures which are known as continuous radiofrequency (CRF) and pulsed radiofrequency (PRF) procedure (Rosenthal, 2009). The difference between these two types of radiofrequency procedures is continuous radiofrequency (CRF) procedure which uses high frequency alternating current to induce coagulation at the target tissue, while pulsed radiofrequency (PRF) uses short pulses of RF signal at the target tissue (Bryd & Mackey, 2008).

Zundert et al. (2002) explain the principle of radiofrequency (RF) during CRF lesioning, the ground plate and electrode is connected to the generator as in Figure 2.1. RF current flow through the tissue as the body tissue acts as conductive electrolytic media to complete the circuit, result in an electric field. Then, an electric force on the ion in the tissue electrolytes is formed by the electric field. As the

generator continuously producing alternative current in, it will cause the ionic current to oscillate at a high rate. The oscillations of the ionic current generate heat in the tissue and subsequently, the electrode is heated by the tissue (Bogduk, 2006). The resultant lesion shape generated surrounding electrode is spheroid as shown in Figure 2.2.

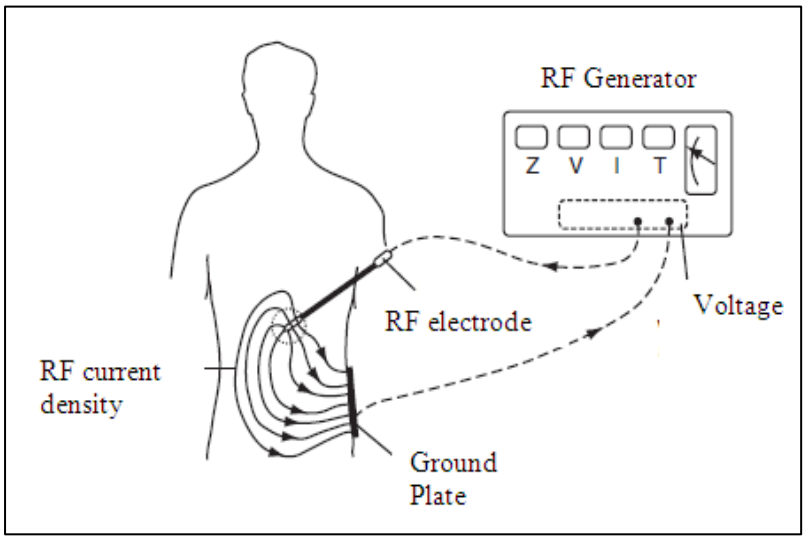


Figure 2.1: Sketch of the circuit during RF procedure (Zundert et. al, 2002)

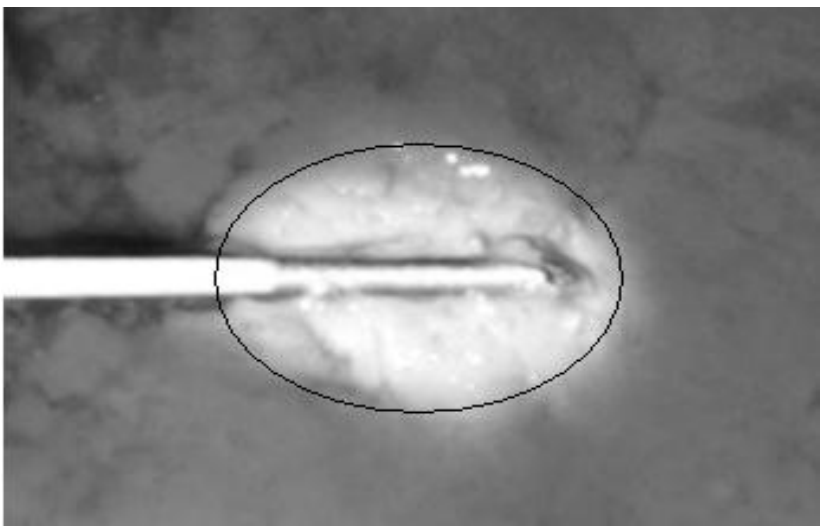


Figure 2.2: Spheroid shape of lesion generated on electrode tip in liver (Cosman & Cosman, 2005)

There are several factors contributing to lesion size in RF procedure. Among the factors is tip temperature as shown in Figure 2.3. The tip temperature during RF procedure depends on power deposition. Chua et al., 2011 mentioned that for RF of 420 kHz, the power deposition:

$$\text{Power deposition} = \frac{\text{Voltage applied}^2 \times \text{Exposure time}}{\text{Tissue resistivity}}$$

The relation of tip temperature with lesion size is shown in Figure 2.3 except for non spherical electrode. Temperature measurement asymptotically decreases to body temperature for larger distance from electrode tip. An increase in voltage will increase the tip temperature from T2 to T1. This increase in tip temperature contributes to larger lesion size. Therefore, lesion size is dependent on tip temperature except for non spherical electrode tip.

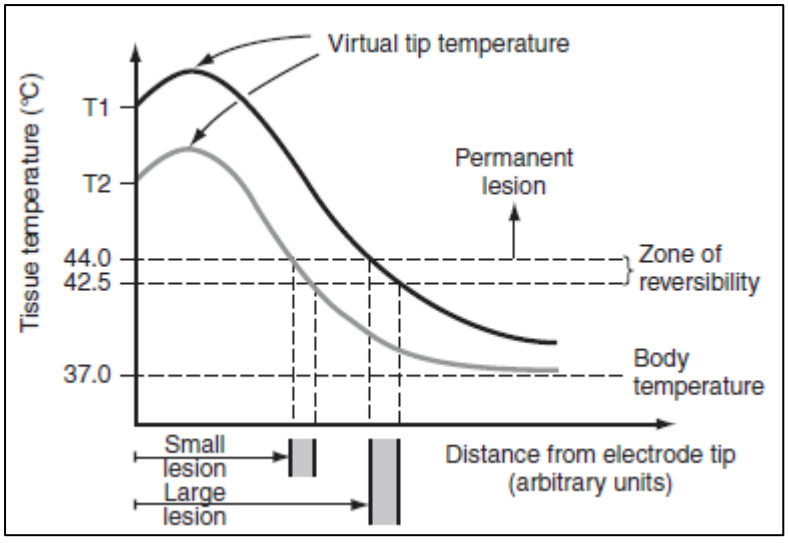


Figure 2.3: Tissue temperature as a function of distance from the electrode tip (Zundert et al., 2002)

Other factors contributing to lesion size are electrode tip dimension, electrical resistivity, thermal conductivity and convection of surrounding tissue (Zundert et al.,

2002). These factors also contribute to lesion size in RF procedure but it is assumed fix in this model. In RF procedure also it is desirable to have a consistent lesion throughout the procedure. The first study on relationship between lesion size, temperature and lesioning duration was done on dorsal root entry of a cat. It was found that at a tip temperature of 75°C the lesion size would only increase by about 20% beyond a lesion time of 30 seconds and lesion size remains constant after a period of 60 seconds (Zundert et al., 2002). Thus, this finding shows that to achieve a consistent lesion size, proper tip temperature is hold for 30-60 seconds for electrode tip sizes that are typically used in neurosurgery and pain treatment and for relatively uniformed soft tissue environments.

The second type of RF procedure is known as pulsed radiofrequency lesioning (PRF) which used pulsed RF signal (Figure 2.4). In pulsed radiofrequency (PRF) lesioning mode, there are two active cycles per seconds followed by a quiet phase (lasting 480msec) which no current is applied to allow heat dissipation so that the target tissue is kept below 42 °C (Sluitjer & Racz, 2002). During this active phase, RF is delivered at normal frequency of 500 kHz. The output voltage in CRF mode is between 15-20 volts while for PRF mode the most common voltage used is 45 volts.

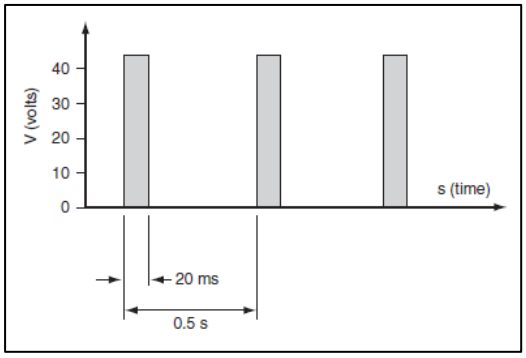


Figure 2.4: Schematic drawing of the duty cycle during pulsed radiofrequency (Zundert et al., 2002)

Early findings on pulsed RF procedure found that it is a non destructive procedure but later through experimental work this theory has been argued by Cosman & Cosman(2005), as it is found that there is a destruction in a very thin layer of electrode tip. This finding shows that pulsed RF should not be considered as a non destructive RF procedure because this thin layer shows that there is lesioning. Even though it is still not fully understood the mechanism of action for pulsed RF, it has been successfully used as an alternative treatment for pain relief.

According to Todorov (2011), pulsed RF produces a weak magnetic field but due to active non-insulated tip of radiofrequency cannula, an electric field with high current density generated stronger than the continuous RF procedure. This electric field can induce charges on tissue and dislocate charged molecular structures, thus disrupting cell function without any increase in temperature. This theory is proven by neurophysiology studies that demonstrate PRF changes synaptic signaling and cause electroporation (Cosman & Cosman, 2005).

In addition, Rosenthal (2009) explains that from an animal study which applies pulsed RF current to rat dorsal root ganglion (DRG) causes both early and late induction of the protein C-Fos in layers 1 and 2 of the dorsal horn bilaterally. As pulsed RF energy applies to DRG, a gene expression changes within the dorsal horn of the spinal cord. The rapidly alternating current produces an effect to alter pain transmission via activation of a protein called C-Fos. These effects do not occurred as a result of tissue heating but due to current fluctuations.

2.3.1 General Facilities for RF Procedure

General facilities for RF procedure in general consist of a procedure table (with radiolucent), a RF generator, needles or cannulas and electrodes (Zundert et al., 2002).

The needles or cannulas have different range of sizes and lengths depending on the application. Fluoroscope is one of the important tools in RF procedure because most of the procedures is performed under visualization by fluoroscopy and other techniques such as computed tomography (CT) and ultrasound. Though still the most commonly used tools for visualization is fluoroscope where it facilitates the targeted nerve.

2.3.1.1 Radiofrequency Generator

Basically, there are various RF generators (Figure 2.5) available for RF procedures but the most common used RF generator should have features such as nerve stimulation, impedance monitoring and temperature monitoring.

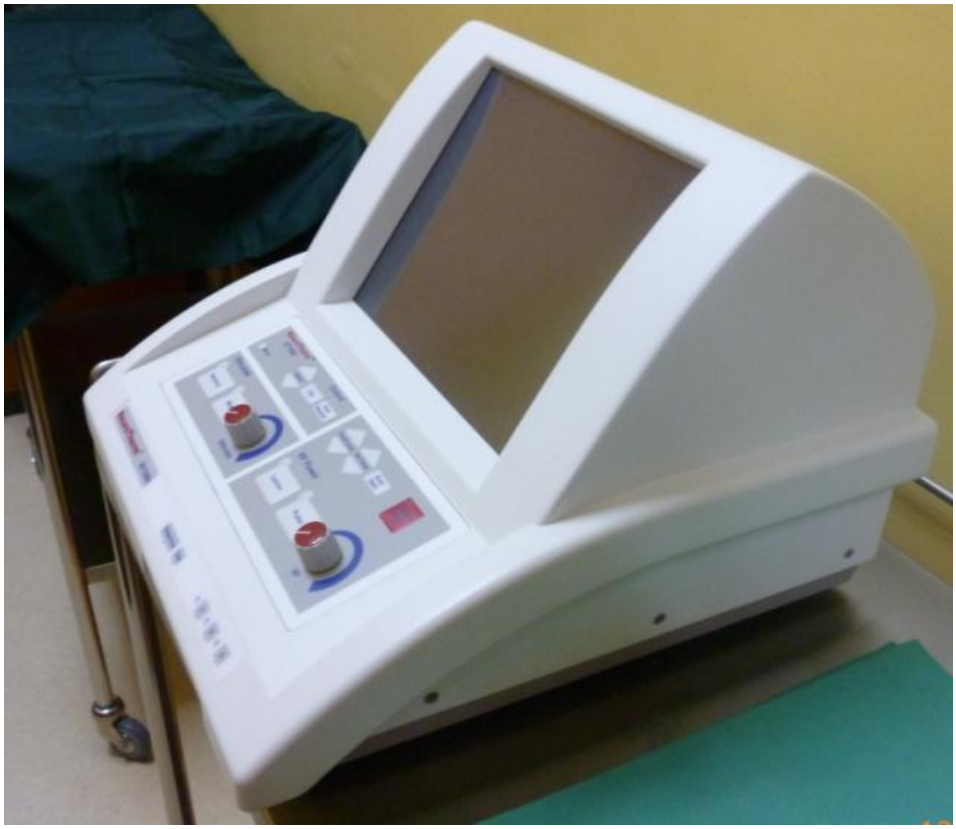


Figure 2.5: RF generator (‘NeuroTherm’ brand)

Impedance monitoring is one of the important features in RF generator as to confirm the continuity of electrical circuit and to detect any short circuit. Then, another important feature is nerve stimulation which is done after placement of cannula at the target nerve. It is done under fluoroscopic control to ensure the right position of the electrode and allow minor adjustment. Third feature for RF generator is temperature monitoring which is performed by thermocouple. The thermocouple consists of a junction of two dissimilar metal elements, producing a thermodionic voltage which is proportional to temperature. The thermocouple is placed at the tip of the electrode which is the hottest part of the lesion.

2.3.2.2 Electrode and Cannula

Needle or cannula (Figure 2.6) is another important component in interventional procedure especially for RF procedure. There are several types of needles currently available such as epidural needles which are used for peripheral nerve blocks. The main features in which differentiate RF cannula with other needles are that they are insulated except for the active tip. This insulator function is to prevent leakage of current during the procedure except at the active tip.

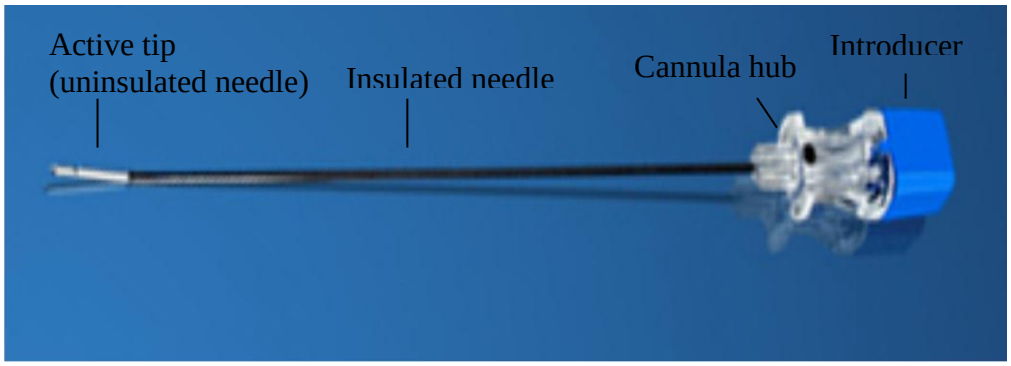


Figure 2.6: ‘Cosman’ brand radiofrequency cannula

Another important component in RF procedure is RF electrode (Figure 2.7) which during the RF procedure it is connected to the RF generator. RF electrode is designed with a thermocouple sensor located at ist tip to measure temperature at the hottest lesion area. Basically, its main function is to deliver thermal and pulsed RF output to the target nerve through RF cannula.

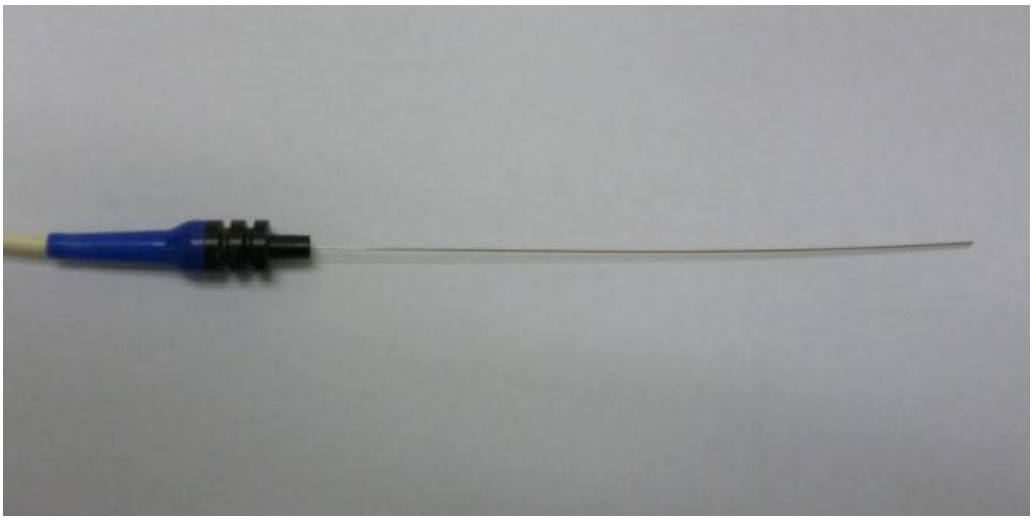


Figure 2.7: RF electrode

2.3.2 RF Procedures

Over the years the number of reports on clinical use of RF procedure in various applications is being published. The application of RF procedure on different area of painful condition also continues to be explored by pain physicians. Though that different application of RF procedure may follow different guidelines, generally the procedure is as the following (Racz & Ruiz-Lopez, 2006):

i. Placement of insulated cannula (needle) to the target nerve guided by fluoroscopic.

ii. Confirmation of active tip within the target nerve is done by nerve stimulation. If necessary, minor adjustment of active tip position may be done. It is done at 50 Hz to confirm the proximity of the electrode to the sensory fibers. Two hertz stimulations are done to detect muscle contractions, indicates that cannula placement is near to motor fibers.

iii. An electrode is passed through the insulated cannula to the tip after the right position is established.

iv. Lesion around the tip will be formed due to heat around the tip tissues caused by current passing through the electrode.

v. Remove the cannula and electrode after finish lesion.

The most commonly used RF for making lesion is continuous and pulsed RF. Zundert et al. (2002) explain that, continuous RF (CRF) uses a constant high frequency electric current to generate temperatures of 45°C or more (the temperature at which permanent nerve damage occurs). As for pulsed RF, radiofrequency current is applied in pulses instead of continuously. Two bursts of 20 milliseconds each are delivered in 1 second. Following the active phase of 20 milliseconds the silent period of 480 milliseconds allows for washout of the generated heat. The output is usually set at 45 V, which is much higher than the output used in continuous RF, which is 15–20 V.

2.4 PRODUCT DEVELOPMENT PROCESS

Product development process is the arrangement of activities which is done to conceive, design and commercialize a product. Most of these steps and processes involved intellectual and organizational activities. A design process is the set of

technical activities within a product development process that work to meet the marketing and business vision. Concept development process is activities of identifying and analyzing new market opportunity, produce alternative design and selecting concept through details evaluation. These concepts basically focus on its detail design specification such as a description of its form, function and features of the product. Figure 2.8 shows the activities comprising development process phase. In this study, development process phase in Figure 2.8 provides guidelines to the development of cannula. Currently, this study only followed the development phase until selection of the product concept.

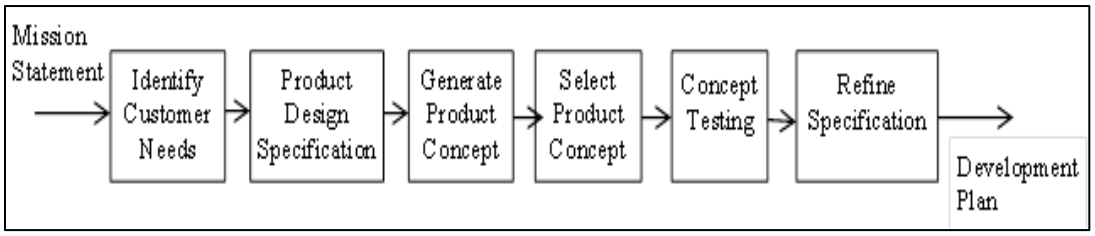


Figure 2.8: Concept development phase (Ulrich & Eppinger, 1995)

Concept development could be divided into several phases. Each phase is explained as the following (Ulrich & Eppinger, 1995):

a) Identifying customer needs:

In this phase, customer's needs are identified through communication between user and development team. The activity in this step results in customer's statements lists with importance weightings.

b) Product Design Specifications:

Product design specification is a translation of customer's needs into technical terms. It is the specification that represents which satisfies

customers the most. Each specification consists of metric, marginal and ideal values for that metric.

c) Concept generation:

The main objective of concept generation is to generate as much as possible design concept of a product. These concepts are generated according to product design specification established in the previous phase. Most commonly, a set of design concept is represented by a sketch with descriptive explanation.

d) Concept selection:

Concept selection is the activity of analyzing and evaluating of various product concepts. The output of this activity is a selection of the most suitable design concept for further development.

e) Concept testing:

In this phase, selected product concept is tested to verify its functioning ability. Most commonly, if the result of this testing satisfies users, further development may be done, whereas if the result is poor, necessary earlier activities may be repeated.

f) Final specifications:

The target specification may be refined after concept selection and concept testing. At this stage, limitations for selected potential concepts are already identified.

2.4.1 Identifying Customer Needs

The main aspects of the product development process are identifying customer needs, competitive benchmarking, establishment of product specification, concept generation

and concept selection. It is very important to identify customer needs because it will ensure the product being developed is according to customer needs. This process of identifying customer needs forms in five step method (Ulrich & Eppinger, 1995):

i. Collection of raw data from users.

ii. Translation of raw data to customer's needs.

iii. List all the needs into a hierarchy if necessary.

iv. Establish the relative importance for each need.

v. Reflect on the results and the process.

The key benefits of applying the five steps of identifying a customer need are ensuring that the product focuses on customer needs and that no critical customer need is forgotten, developing a clear understanding the needs of the customers, developing a fact base to be used in generating concepts, selecting a product concept and establishing product specifications. The output of identifying customer needs is a list of customer requirements with their relevance importance as the example in Table 2.1.

Table 2.1
Example of customer needs for suspension fork with their relative importance
(Ulrich & Eppinger, 1995)

No.		**Need**	**Imp.**
1	Suspension fork	Minimum vibration	3
2	Suspension fork	Allow easy traversal of slow, difficult terrain	2
3	Suspension fork	Improve capability on bumpy trails	5
4	Suspension fork	Enable sensitivity adjustment	3
5	Suspension fork	Maintain steering feature of the bike	4
6	Suspension fork	Able to install without difficulty	1

2.4.2 Product Design Specification

The Product Design Specification (PDS) is a very important aspect in the design process as it contains all the information necessary for the designer to successfully produce a solution to the design problem. It is necessary to establish target specification before proceeding to generate product concept but usually target specification will be refined after the product concept has been selected. There are four steps in establishing the target specification (Ulrich & Eppinger, 1995):

i. Prepare the list of metrics, using the need-metric matrix, if necessary.
ii. Collect the competitive benchmarking information.
iii. Set ideal and marginal acceptable target value for each metric.
iv. Reflect on the result and the process.

Step 1: Prepare the list of metrics

The first step is by preparing a list of metrics as in Table 2.2 that reflect product which satisfies the customer needs. Basically, the list metric is an interpretation of customer needs into a set of precise, measureable specification possible. This interpretation of customer needs is a specification of the product which is precise and measurable characteristic. In an ideal situation, one metric may have one need but in reality it is not possible. For example, assume that the need for suspension fork is “easy to install”. This need may be translated as average time for assemble as the metric. However, the fast installation may contribute or lead to painful condition. So, it is important to have same communications between users in establishing specifications due to inaccurate translation process.

Table 2.2
Example of list of metrics for suspension fork with relative importance and units (Ulrich & Eppinger, 1995)

Metric No.	Need Nos.	Metric	Imp.	Units
1	1,3	Attenuation from dropout to handlebar at 10Hz	3	dB
2	2	Spring preload	3	N
3	1,3	Maximun value from the Monster	5	g
4	1,3	Minimun descent time on test track	5	s
5	4	Damping coefficient adjustment range	3	N-s/m
6	5	Maximum travel (26 in. wheel)	3	mm
7	5	Rake offset	3	mm
8	6	Time to assemble to frame	1	s

Then, a simple need-metric matrix (Table 2.3) is established to represent the relationship between needs and specification. In this matrix, the row of the matrix represents the customer need while the column represents the translated specification. The relationship between customer needs and translated specification is represented by some marks in the cell. This matrix is almost similar with the graphical technique used in Quality Function Deployment (QFD) to establish a house of quality.

Table 2.3
Example of need-metric matrix for suspension fork (Ulrich & Eppinger, 1995)

	Need	1	2	3	4	5	6	7	8
	Metric	Attenuation from dropout to handlebar at 10Hz	Spring preload	Maximum value from the Monster	Minimum descent time on test track	Damping coefficient adjustment range	Maximum travel (26 in. wheel)	Rake offset	Time to assemble to frame
1	Minimum vibration	•		•	•				
2	Allow easy traversal of slow, difficult terrain		•						
3	Improve capability on bumpy trails	•		•	•				
4	Enable sensitivity adjustment					•			
5	Maintain steering feature of the bike						•	•	
6	Able to install without difficulty								•

Step 2: Collect the competitive benchmarking information

The next step in establishing product design specifications is by benchmarking it with existing competitive products. In establishing this process, information on competing products must be obtained with detail specifications. However, some of the information contained in competitor catalog may not be reliable. Thus, values for competitor specification should base on independent testing or observation if possible. This competitive chart (Table 2.4) is constructed with column of the chart as the competitive products and the rows are the metric as in step 1.

Table 2.4
Example of competitive benchmarking chart based on metrics
(Ulrich & Eppinger, 1995)

Metric No.	Need Nos.	Metric	Imp.	Units	Maniray 2	Tonka Pro	ST Tritrack
1	1,3	Attenuation from dropout	3	dB	15	9	8
2	2	Spring preload	3	N	760	480	550
3	1,3	Maximum value from the Monster	5	G	3.2	3.7	3.6
4	1,3	Minimun descent time on test track	5	S	11.3	13.2	13
5	4	Damping coefficient adjustment range	3	N-s/m	0	0	0
6	5	Maximum travel (26 in. wheel)	3	Mm	48	33	28
7	5	Rake offset	3	Mm	39	43.2	41.5
8	6	Assemble time	1	S	35	35	45

Step 3: Set ideal and marginally acceptable target value for each metric

The main objective in this step is to set ideal value and marginal target value specification from information available in step 2. Ideal target can be considered as the best target specification desired while marginally target value is the value within specification is acceptable. This ideal target and marginally target value will be used in generating concept, selecting concept and refining the specification after selecting the product concept. The list of metrics with ideal target and marginal value (Table 2.5) are based on a competitive bench chart in step 2.

Table 2.5
Example of target specification of suspension fork (Ulrich & Eppinger, 1995)

Metric No.	Need Nos.	Metric	Imp.	Units	Marginal Value	Ideal Value
1	1,3	Attenuation from dropout	3	dB	>15	>15
2	2	Spring preload	3	N	480-800	650-700
3	1,3	Maximum value from the Monster	5	G	<3.5	<3.2
4	1,3	Minimun descent time on test track	5	S	<13.0	<11.0
5	4	Damping coefficient adjustment range	3	N-s/m	0	>200
6	5	Maximum travel (26 in. wheel)	3	mm	33-50	45
7	5	Rake offset	3	mm	337-45	38
8	6	Assemble time	1	S	<60	<35

Step 4: Reflect on the results and process

The final step in this process is refining the specification as the example in Table 2.6, before proceeding to generate concepts and selecting a concept. One of the challenges in refining the specification is to decide trade-offs between the two specifications. This decision is very critical because the relation between these two specifications is inversely related. For example, one of trade-off is between mass and cost. The material for suspension fork can be replaced by using magnesium instead of aluminium. However, this way of reducing mass will further increase the manufacturing cost of the products. Other factors to consider in refining specification is assessing actual and technological limitation and expected production cost using analytical and physical model.

Table 2.6
Example of refine specification for suspension fork (Ulrich & Eppinger, 1995)

Metric No.	Need Nos.	Metric	Imp.	Units	Value
1	1,3	Attenuation from dropout	3	dB	>12
2	2	Spring preload	3	N	600-650
3	1,3	Maximum value from the Monster	5	g	<3.4
4	1,3	Minimun descent time on test track	5	s	<11.5
5	4	Damping coefficient adjustment range	3	N-s/m	>100
6	5	Maximum travel (26 in. wheel)	3	mm	43
7	5	Rake offset	3	mm	38
8	6	Assemble time	1	s	<45

2.4.3 Concept Generation

Concept generations are activities to produce product concepts which are approximately described the technology, working principles and form of the product. In this activity, a description of how the product will satisfy the customer needs is done. A design concept is usually illustrated as a sketch or as a rough three or two dimensional models. Concept generation process usually is established after identifying customer's needs and product design specifications. In concept generation, several design concepts are generated for a designer or development team to make a final concept selection. Ulrich and Eppinger (1995) mentioned the five steps of concept generation which are:

i. Clarify the problem

   Understand the problem to be solved.

ii. Search externally

Collect and gather information from users, patent, publish literature and existing products.

iii. Search internally.

Utilize knowledge of individuals in the development team before creating a solution concept.

iv. Explore systematically

Organize thinking of the team using classification trees and combination tables if necessary.

v. Reflect on the solutions and the process.

Identify potential opportunity to be improved and create a solution concept.

2.4.4 Concept Selection

In concept selection process, involve process of evaluating concepts corresponding to customer's needs and other criteria through analyzing possible advantages and limitation of each concept. Concept selection process is done in two phases which are concept screening and concept scoring. These two phases are supported by a decision matrix which is used by the designer to rate, rank and select the best concept for further development.

2.4.4.1 Concept Screening

In concept screening phases, rough initial concept is being evaluated relative to common reference concept using the screening matrix. This process of concept screening is based on decision-making tools as developed by Pugh which is also

known as Pugh charts (Otto & Wood, 2001). The aim of concept screening is to narrow down the number of concept quickly and improve the concept. These methods of selecting concept consist of the following procedure (Roozenburg & Eekels, 1995):

i. The alternative concept and concept is arranged in a matrix as in Table 2.7. If necessary, the concept can be illustrated by written description and graphical representation.

ii. Reference concept is selected to become a reference against others. Generally, this reference is either an industry standard or obvious solution to the problem. If this reference concept is chosen by a company management team, a competitive product that teams aim to surpass may also be considered as reference concept.

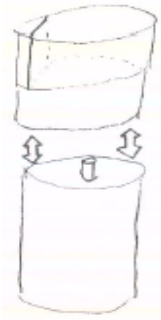
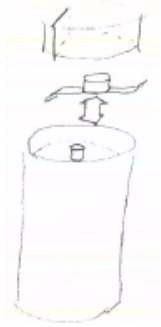
iii. Then, each of the criteria is rated relative to the reference concept. If the criteria for each concept is better than reference concept a (+) score is assigned, if worse than reference concept a (-) score is assigned and if it is same with reference concept a (0) score is assigned.

iv. The score for each concept is sum to identify ranking order.

v. Consider a high ranking concept for further consideration to be developed. If necessary these high ranking concepts can be combined which can preserve the good features and remove bad features.

vi. This process of evaluation, refinement continues until one or more concepts are selected for further refinement and analysis.

Table 2.7
Example of concept screening matrix for coffee chopper redesign concepts for cleanability (Otto & Wood, 1995)

Criteria	Concept				
	Removable chamber (reference)	Removable blade	Washable	Scraper	Removable unit
					
Cost	0	+	-	+	0
Store in grinder	0	+	+	+	-
Take out coffee	0	0	-	-	0
Power setup	0	0	0	0	-
Cleanable	0	-	0	-	0
∑ +	0	2	1	2	0
∑ 0	0	2	2	1	4
∑ -	0	0	2	1	2
Net score	0	0	-1	1	-2
Rank	0	2	3	1	4

2.4.4.2 Concept Scoring

In concept scoring phases, a number of concepts are being selected for further refinement after concept screening. Table 2.8 shows the example of remaining concept to be evaluated which is listed in matrix corresponds to measurable scales for a subset of the customer needs. In each criterion, importance weight is assigned referring to the importance level of customer requirement as in Table 2.1. Furthermore, a scale 1-5 is chosen for the ratings, where if consider the criteria “take out coffee”, an ideal time is at 10 seconds, corresponding to the score of 5. For

example, if “take out coffee” time for concept “scraper” is 6 seconds, the rating assigned for this criteria is 6. This rating scale is similar for other criterion. Then, the score for each criteria is calculated by multiplying the importance weight with rating. Total score for each concept is the summation of weighted score (Ulrich & Epinger, 1995):

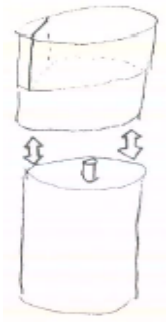
$$s_j = \sum_{i=1}^{n} r_{ij} w_i$$

where r_{ij} = rating of concept j for the ith criterion

w_i = important weight for ith criterion, n = number of criteria, s_j =total score for j

Finally, the concepts are ranked according to the total score of each concept as in Table 2.8. The final selection of concept is not directly selected from the highest ranking but it should be used for further evaluation by conducting a sensitivity analysis. Weight rating can be varied to determine the effect on the ranking. By investigating how sensitive the ranking is to variations in particular rating, it can determine whether uncertainty about a particular rating has a large impact on chosen concept.

Table 2.8
Example of concept scoring matrix for coffee chopper redesign concepts for cleanability (Otto & Wood, 1995)

Criteria	Weight (%)	Concept					
		Removable chamber (reference)		Removable blade		Scraper	
							
		Rating	Score	Rating	Score	Rating	Score
Cost	20	3	0.6	3	0.6	4	0.8
Store in grinder	20	3	0.6	4	0.8	3	0.6
Take out coffee	10	3	0.3	5	0.5	4	0.4
Power setup	15	3	0.45	3	0.45	5	0.75
Cleanable	35	3	1.05	4	1.4	4	1.4
Total score (s_j)		2.7		3.75		3.95	
Rank		**3**		**2**		**1**	
Develop?		no		no		yes	

2.5 RAPID PROTOTYPING

Rapid prototyping also known as solid free form fabrication or layer manufacturing which utilized material addition process to generate a three dimensional physical model layer by layer from a computer-aided design (CAD). This rapid prototyping technique provides an alternative for producing prototype and functional models which is opposite with material removing machining technique. It can build complex shapes part in layers with low cost and less time (Noorani, 2006). The fundamental of the rapid prototyping process is almost similar, where an object is constructed by

producing very thin cross section of the part, one on top of the other, until the physical part is completed. Although there is a different process of rapid prototyping with a variety of material, the basic processes in almost all process consist of the following steps:

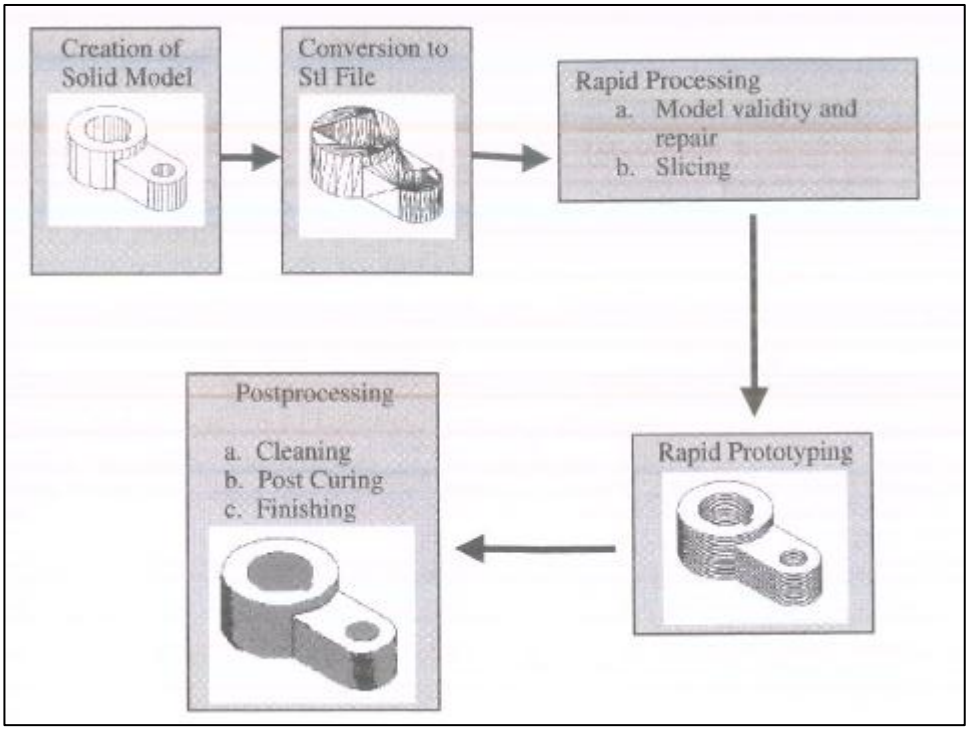


Figure 2.9: Basic rapid prototyping process (Noorani, 2006)

The first step in a rapid prototyping process is creation solid model using standard drafting software packages available such as AutoCAD, Pro/Engineer or Solid Works. Then, the CAD model is converted to stereolitography (STL) format because currently it is the standard format in most of the rapid prototyping system. Initially, this file format is originated from 3D system which a pioneer in stereolitography process. Then, Albert Consulting Group under contract to 3D System further developed the format until it is widely accepted as a standard format (Kai &

Fai, 1997). Then, the STL file format approximates the surfaces of the model using triangle as shown in Figure 2.10. In an STL file, triangular facets are represented by a set of x, y, and z coordinates for each of the three vertices and also includes the direction of the normal vector for each triangle, which points to the outer surface of the model (Kai & Fai, 1997).

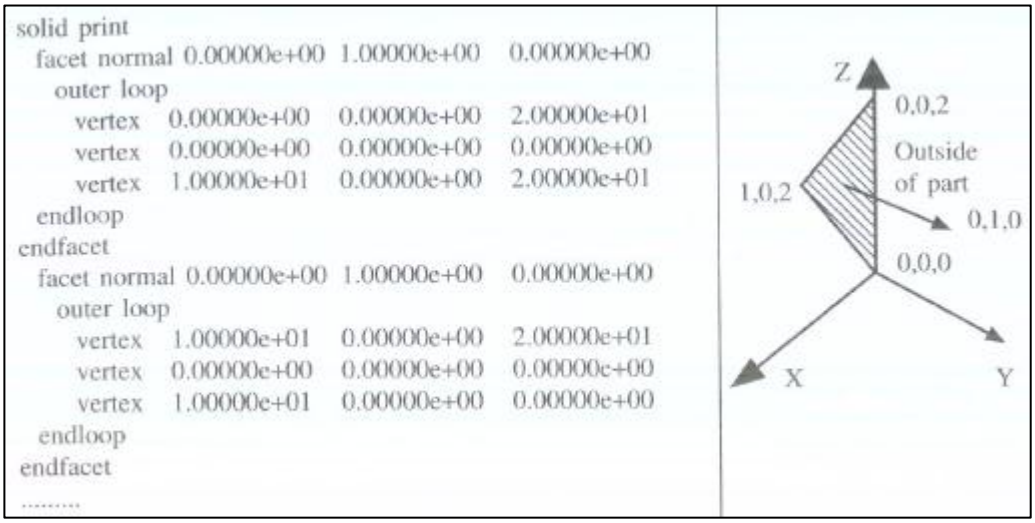


Figure 2.10: A sample of STL file (Kai & Fai, 1997)

Then, the file is sliced into a cross section which this cross section will be systematically built through solidification of liquid, powders or fusing of solids to form a 3D model. Generally, the model is sliced into thinnest layer as possible to achieve high accuracy prototype model. The next step is building process where usually it is fully automated. This building process takes up to several hours depending on quantity and dimension of the part required. Final step for rapid prototyping process is post processing, at this stage manual operation usually is necessary to remove the support material. Each of different types of rapid prototyping process will require different post processing procedures.

2.5.1 Classification of Rapid Prototyping

Rapid prototyping (RP) technologies can be divided into a variety of categories based on the physic of the process, sources of energy, the type of material and size of material. Noorani (2006) divided RP system into three categories which are liquid based, solid based and powder based system as shown in Table 2.9. These categories of RP system are divided based on the state of prototype material before prototype formation. Most of liquid based technologies build part by cures or solidifies photo curable liquid resin under exposure to laser radiation. Then, a solid based RP system involved solid state raw material included in the form of a wire, a roll, laminates and pellets. Powder based RP system builds part by selective joining powder by laser or a binding material.

Table 2.9
Categories of RP system (Noorani, 2006)

Categories of RP system	**Brand/Manufacturer**
Liquid-based system	3D System stereolitography apparatus (SLA)
	D-MEC's solid creation system (SCS)
	CMET solid object UV laser plotter
	EOS's stereos system
	Meiko's rapid prototyping system
Solid-based system	Stratasys' fused deposition modelling (FDM)
	Helisys' laminated object modelling (LOM)
	Solidscape, Inc.'s ModelMaker-6B
	3D System's multijet modeling (MJM) systems
	Kira's selective adhesive and hot pass (SAHP) system
	IBM's rapid prototype system (RPS)
	Laser-engineered net shaping (LENS)
	Solidica
Powder-based system	3D System's selective laser sintering (SLS)
	Soligen's direct shell production casting (DSPC)
	Fraunhofer's multiphase jet solidification (MJS)
	MIT 3D printing
	EOS's laser sintering

2.5.1.1 Liquid Based Rapid Prototyping System

Among the popular currently available RP system is stereolitography apparatus (SLA). The SL system is a process of that fabricate prototype from a monomer resin which forms a polymer and solidifies when exposed to UV light. Kai & Fai (1997) describe the SL process is basically build part from a photo curable liquid resin that solidifies when sufficiently exposed to laser beam as the laser scan across the surface of the resin. Then, the building process is done layer by layer as each layer being scanned, the elevation mechanism system lower the moveable substrate for next layer to be scan on top of previous layer until part is completed. This mechanism is shown in Figure 2.11.

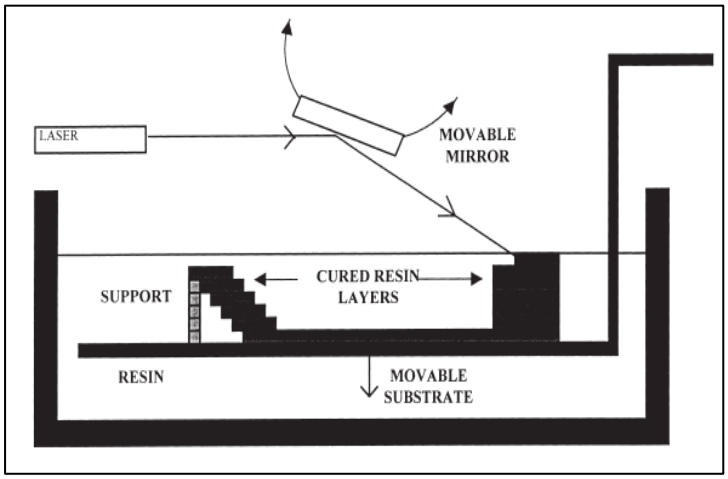


Figure 2.11: Schematic view of stereolitography process (Pham & Gault, 1998)

Once the part is completed, excess resin is drained and part is removed from moveable substrate. Then, support material is removed from completed part and then is postcured in a UV oven to ensure no excess or partially cured resin remains.

2.5.1.2 Solid Based System

Another Rapid Prototyping (RP) system available in the market is Fused Deposition Modeling (FDM) which is very familiar among rapid prototyping system users. Initially, this fused deposition was developed by Stratasys Inc to produce accurate and functional prototypes for testing and final design verification (Noorani, 2006). Over the years, fused deposition modelling process become one of the most desirable processes in rapid prototyping because it is the least expensive to buy and operate.

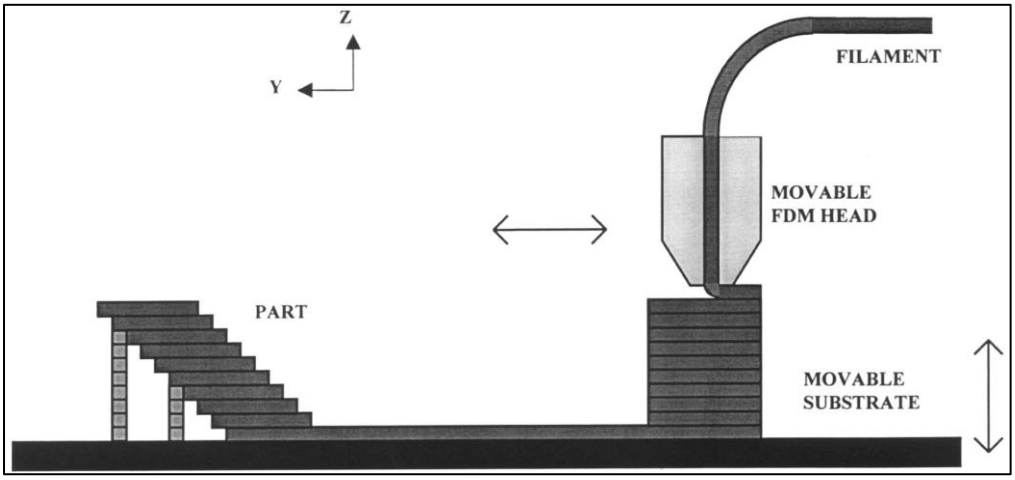


Figure 2.12: Schematic view of fused deposition modelling (FDM) process (Pham & Gault, 1998)

Fused Deposition Modelling (FDM) is based on extrusion of thermoplastic material (Figure 2.12) which feeds by a moveable extrusion head to form a thin cross-sectional slice of the part. The moveable substrate is then lowered relative to the nozzle and the next slice of the part is deposited on top of the previous slice. The built material is cold weld to the previous layers by heating it to 0.5 °C above melting temperature to ensure it solidifies 0.1s after extrusion (Pham & Gault, 1998). A second nozzle is used to extrude a different material in order to build-up support

structures for the part where needed. Once the part is completed the support structures must be broken away from the part (Upcraft & Fletcher, 2003).

2.5.1.3 Powder based rapid prototyping

Another category of rapid prototyping is classified as powder based rapid prototyping which uses powder form material as a basic medium for prototyping. The most common process for powder based rapid prototyping is selective laser sintering and 3D printing. Other available techniques based on powder based material are Direct Shell Production Casting (DSPC), Multiphase Jet Solidification (MJS) and Ballistic Particle Manufacturing (BPM) (Kai & Fai, 1997).

Selective Laser Sintering (SLS) is rated as among one of the effective and accurate Rapid Prototyping (RP) systems available, which uses powder form based material. The principle of Selective Laser Sintering (SLS) is illustrated in Figure 2.13. Prototype model is produced similar with other Rapid Prototyping (RP) system which is layer by layer. For each layer, the fusible solid powder is heated by a CO2 laser selectively according to cross section of the part. Then, for the next layer, a thin layer of new material from the feed cartridge approximately between 100 μm to 125μm spreads across the part build cylinder which will be lowered down in readiness for the next laser scanning process (Yusoff & Thomas, 2008). This process will continue until part is completed.

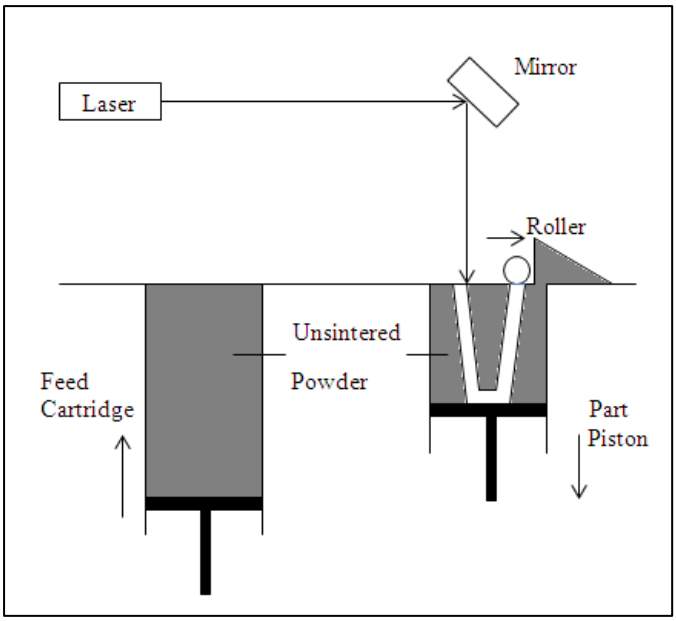


Figure 2.13: Schematic view of selective laser sintering process

Even though selective laser sintering is known to have the capability to achieve high quality products in term of accuracy, this process is among the most expensive to buy and operate (Waterman & Dickens, 1994). An alternative to this process is another powder based rapid prototyping process which is known as Three Dimensional Printing (3DP) developed by Massachusetts of Technology (MIT). 3D printing is a RP technology whereby the sliced two-dimensional (2D) profile of a computer model is printed selectively by suitable binder on a fresh layer of powder (Castilho et al., 2011). Successive 2D profiles are then printed, each time on a freshly laid layer of powder until the whole model is finished. Selectively binder is deposited via an inkjet head, would join the respective profiles of each layer together. Unbound powder is removed from the part upon completion of the fabricated part and suitable post processing is carried out to increase durability and strength the part by infiltrated with resin and other materiasl.

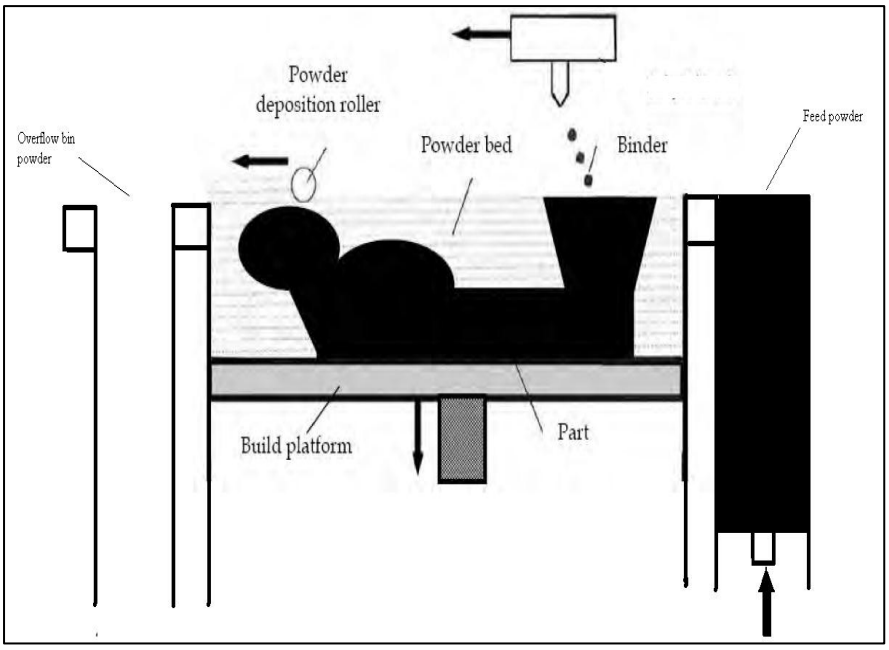


Figure 2.14: Schematic view of 3D printing process.

The 3DP printing process, begins with the printer first spread a layer of powder in the same thickness as the cross section to be printed. Then, a binder solution from the print head is deposited selectively to bind the powder particle to one another. This process is repeated with the feed piston comes up and build platform lowered down enable next layer until the entire part is completed and post processing is done on completed part if necessary (Leukers et al., 2005).

Fused Deposition Modelling (FDM) is chosen among rapid prototyping technology to fabricate prototype cannula hub. The selection of Fused Deposition Modelling (FDM) for current study is because of its availabilities and least expensive than other rapid prototyping techniques available in the market.

CHAPTER THREE

CONCEPTUAL DESIGN DEVELOPMENT

3.1 INTRODUCTION

RF cannula is one of the component commonly used by pain specialists for RF procedure in chronic pain management. In this conceptual design development phase, product design specification is established by translation of user's requirements through interviews with cannula's users and considering existing cannula available in the market. Product design specification is established from translation of user's requirements to design specifications. Then, six concepts of cannula hub are generated and evaluated in this development phase before being selected for the final design. Method of selection is done in two phases which are concept screening and concept scoring which aim to list out the best possible concept and choose the best concept design. In this phase, advantages and disadvantages for each concept are evaluated based on user's criteria through details questionnaires. The final concept design selected in this development phase is further developed by fabricating a prototype and tested to verify its effectiveness.

3.2 USER REQUIREMENT

The process of identifying user's requirements is a critical part of the product development process because establishment of product specification, concept generation and concept screening dependent on user's requirements. The process of identifying user's requirements consists of five steps as mentioned by Ulrich & Eppinger (1995). The first step is defining the scopes of the effort which the team

involved in this cannula development process specifies a particular market activity, lays out broad constraints and objectives of this research. In this research, the scope efforts focus on development of cannula with insulated needles which are used in RF procedures for chronic pain management. The development of this cannula more emphasize on improving its handling and effectiveness.

The second step of identifying customer's requirements is by gathering data from users which involves with this device. Two methods were used in this research for gathering data. One of the methods is by considering current existing cannula designs available in the market. Most of the cannula have similar features and size but have different holders or also known as cannula hubs. Another method used is by conducting an interview with users of RF cannula. In this research, the interviews on user needs for this device were done with Dr. Abdul Hadi Mohamed, a pain specialist at Kulliyyah of Medicine, International Islamic University Malaysia and Dr Mohamed Saufi Awang, Neurosurgery Department, Kulliyyah of Medicine, International Islamic University Malaysia.

The next step in identifying customer's requirements is by interpreting the raw data in term of customer needs. Each of the raw data gathered is translated into user needs for this device as illustrated in Table 3.1.

Table 3.1
Customer raw data translation to interpreted need

No	Customer Statement	Interpreted Need
1	I need needle that can penetrate skin	Needle can penetrate skin, tissue or muscle
2	The needle should not cause allergic to patient	Biocompatible material
3	The needle should not break	Moveable or flexible and not easily broken
4	I need cannula that can be used several times	Reusable if possible (sterilization)
5	Different patient need different length of needle	Variety of needle length
6	The thermocouple probe should be able to be inserted through the needle	Needle diameter size compatible with thermocouple probe
7	The uninsulated at the tip of needle should have several lengths	Variety of active tip length
8	Sometimes, need to use tip with different shape	Variety of active tip geometry
9	It should be lightweight	Lightweight
10	I want it less than RM100	Affordable (cost)
11	Easy to identify needle length	Can easily identify needle length
12	Easy to identify needle diameter	Can easily identify needle diameter
13	The holder or cannula hub is comfortable to hold	Comfortable or easily to hold the cannula (hub)
14	Can remove tissue during needle insertion	An introducer to remove tissue during needle insertion
15	Can guide to the target nerve more accurate	Accurate positioning of the target nerve
16	I need curve tip for several patients	Can identify orientation of curve tip
17	More effective than current cannula	Active tip able to emit heat
18	Safe to be used by patients	Non-active tip does not emit heat (insulator)

Then, the fourth step in identifying customer needs is by establishing the relative importance of each need (Table 3.2). Even though the fourth step is supposed to be organized into a hierarchy, this step only applies if a customer statement is gathered from a large number of users. In this research, there are only two people directly involved with this device for chronic pain management. So, it is not needed to organize it into a hierarchy because redundant or similar statement can easily be eliminated. In establishing relative importance of the needs, a survey was used to evaluate the needs.

Table 3.2
RF Cannula survey

No	User's needs	Imp.
1	Needle can penetrate skin, tissue or muscle	5
2	Needle non interact with tissue to cause allergy reaction	5
3	Moveable or flexible and not easily broken	5
4	Reusable if possible (sterilization)	4
5	Variety of needle length	4
6	Need diameter size compatible with thermocouple probe	5
7	Variety of active tip length	4
8	Variety of active tip geometry	4
9	Lightweight	3
10	Affordable (cost)	3
11	Can easily identify needle length	2
12	Can easily identify needle diameter	2
13	Comfortable or easily to hold the cannula (hub)	4
14	An introducer to remove tissue during needle insertion	5
15	Accurate positioning of the target nerve	3
16	Can identify orientation of curve tip	4
17	Active tip able to emit heat	5
18	Non active tip does not emit heat (insulator)	5

For each of the following RF Cannula's features, using scale of 1 to 5, weighting is assigned for each need by users:

1 Feature is undesirable. Product without this feature is not acceptable.

2 Feature is not essential but not necessary to be added.

3 Feature would be nice to have but is not necessary.

4 Feature is highly desirable but user may consider product without it.

5 Feature is critical, user would not consider without this feature.

3.3 PRODUCT DESIGN SPECIFICATIONS

The target specifications are established after identifying user needs but before concept generation and concept selection. This target specification which is also known as a preliminary specification will be refined after a final concept is selected. This step of establishing target specification consists of four steps. The first step is by preparing a list of metric as in Table 3.3 with possible measurable units for each specification.

Table 3.3
List of Metric for RF Cannula

Metric No.	Need Nos.	Metric	Imp.	Units
1	1,3	Needle material hardness	5	HB
2	1	Needle tip sharpness	5	–
3	2	Biocompatible material for needle	5	list
4	3	Needle and hub are fixed together firmly	5	subj
5	4	Melting temperature of cannula hub	4	°C
6	4	Sterilize able by stream autoclave	4	°C
7	5	Needle length	4	mm
8	6	Needle diameter (ID & OD)	5	Gauge (G)
9	7	Active tip length	4	mm
10	8	Curve needle	4	Degree (°)
11	8	Straight needle	4	list
12	9	Total mass	3	kg
13	10	Price	3	$
14	11	Colour coded length cannula	2	list
15	11	Length label printed on hub	2	subj
16	12	Colour coded diameter	2	list
17	12	Needle diameter printed on hub	2	subj
18	13	Round shape hub	4	subj
19	13	Square shape hub	4	subj
20	13	Hexagonal shape hub	4	subj
21	13	Hub with wing	4	subj
22	13	Hub with grip profile	4	subj
23	14	Introducer compatible with cannula	5	mm

Table 3.3 - Continued

Metric No.	Need Nos.	Metric	Imp.	Units
24	14	Introducer fix on cannula	5	subj
25	15	Needle with radiopaque marker	3	subj
26	16	Curved tip orientation marked on the hub	4	subj
27	17	Needle material thermal conductivity	4	W/m °C
28	17	Needle material heat capacity	5	J/kg°C
29	18	Insulator thermal conductivity	5	W/m °C
30	18	Insulator heat capacity	4	J/kg°C
31	18	Insulator melting temperature	5	°C
32	18	Insulator electrical conductivity	5	S/m

In addition to the list of metric for RF Cannula, a need-metrics matrix (Appendix I) is established to represent the relationship between needs and metrics. In this matrix, the rows are corresponding to user needs while the columns correspond to list of metric. The mark “dot” in the cell represents that, there is a relationship between associated need and metrics. Thus, this matrix ensures performance relative to the metric will influence the degree to which the device satisfies user the most.

The second step in establishing target specification is by collecting the competitive benchmarking information in a form of benchmarking chart (Appendix II). This step is accomplished by entering down list of metric in a column. Then, the value of the metrics for each competitive product was entered if available because there are also needs that are subjective or immeasurable.

The third step of establishing target specification (Appendix III) is by setting the ideal and marginally acceptable target value for each metric. This step was established by listing the metric, ideal target and marginal value in a table form in which the value of marginal value and ideal value are based on the competitive information values.

Before proceeding to concept generation and concept selection, the fourth step is refining the specification (Appendix IV). This step is the most difficult process as trade off occurs between two specifications that are inherent in selected product concept. In establishing this step, it is accomplished in a form of table with list of metrics precise measurement value for each need.

3.4 CONCEPT GENERATION

Initially, twenty design concepts were generated but after discussions with users, only six design concepts are selected for further evaluation. Six design concepts of cannula hub sketching had been developed. The concept sketches are based on user's requirements as established in refining specification table. The sketch and description of each concept are shown as following. In addition, to visualize this concept design, a prototype for each concept design was fabricated using Fused Deposition Modelling (FDM).

3.4.1 Concept A

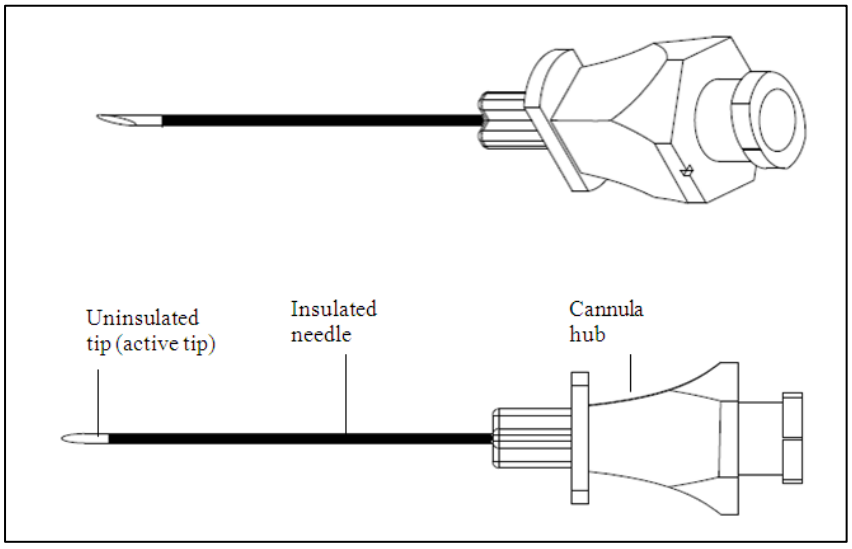


Figure 3.1: Design concept A (isometric view and schematic view)

3.4.1.1 Concept Description

The design concept of RF cannula consists of all features possessed by the existing cannula with different cannula hubs. In this design concept, the cannula hub is design to have hexagon shape. Similarly, this cannula hub design concept has hexagon shape to improve its handling position which will improve positioning to target nerve.

3.4.2 Concept B

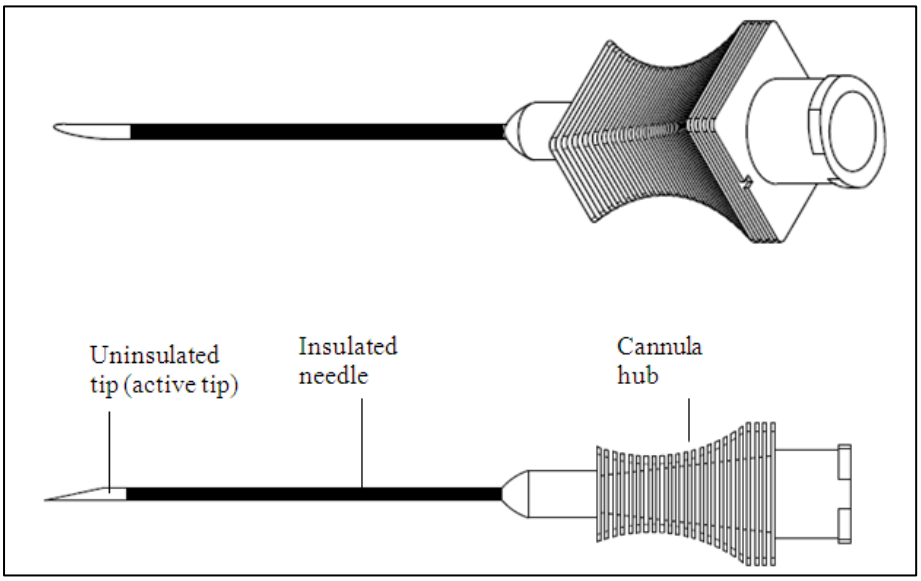


Figure 3.2: Design concept B (isometric view and schematic view)

3.4.2.1 Concept Description

This design concept of RF cannula consists of all features of the existing cannula with different cannula hubs. In this design concept, the cannula hub is designed to have a square shape with curve profile to hold it. Similarly, this cannula hub design concept has a square shape to improve its handling position which will improve positioning to target nerve.

3.4.3 Concept C

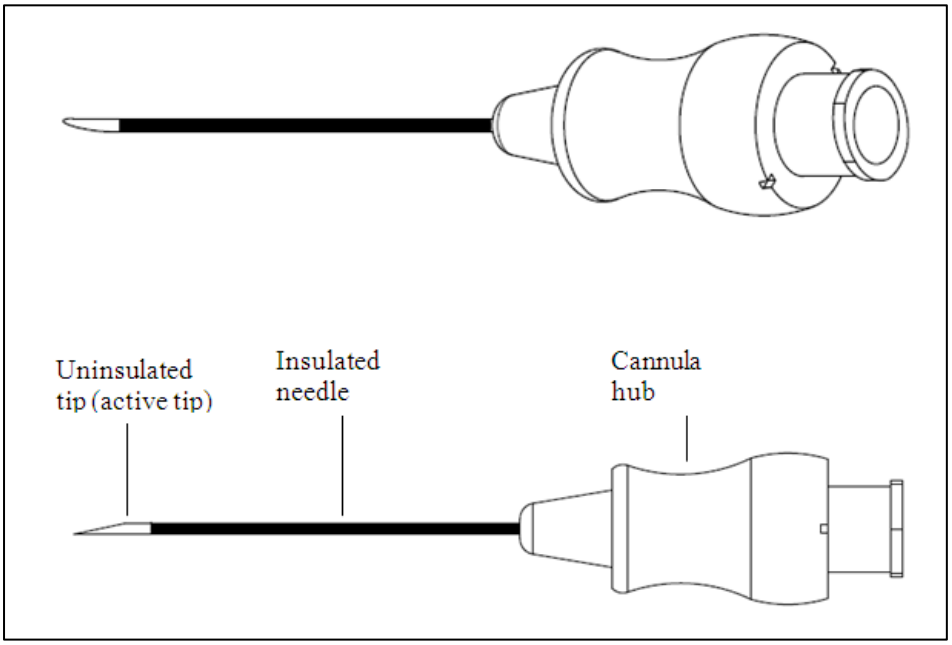


Figure 3.3: Design concept C (isometric view and schematic view)

3.4.3.1 Concept Description

This concept design of RF cannula consists of all features of the existing cannula with different cannula hubs. In this design concept, the cannula hub is designed to have a similar shape design with a pen. Basically, the function of cannula hub during RF procedure is as a holder for cannula. The objective in pen shape like cannula hub is to allow similar condition of holding a pen in writing.

3.4.4 Concept D

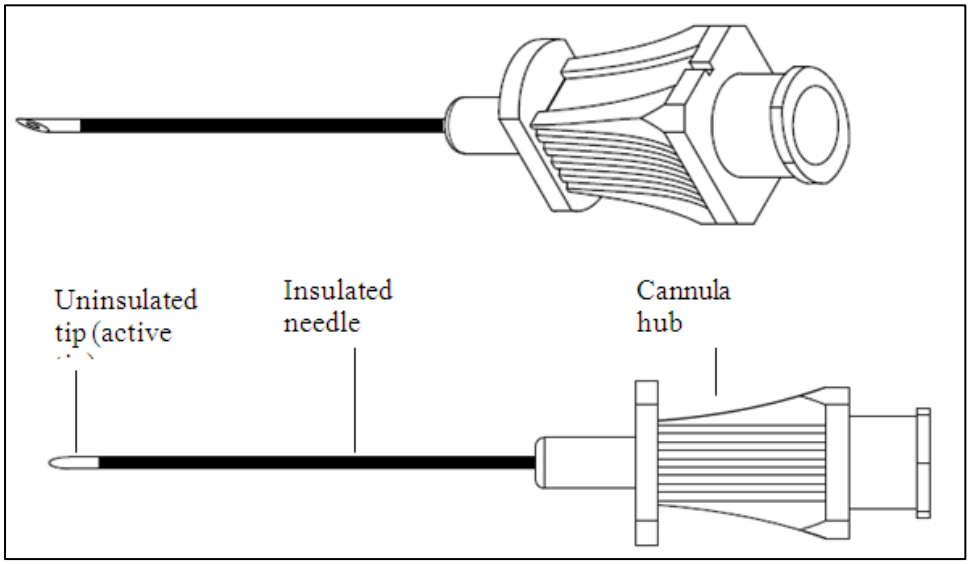


Figure 3.4: Design concept D (isometric view and schematic view)

3.4.4.1 Concept Description

This design concept of RF cannula consists of all features of the existing cannula with different cannula hubs. In this design concept, the cannula hub is designed to have a square shape with curve profile to hold it and a grip profile to firmly hold the cannula. Similarly, this cannula hub design concept has a square shape to improve its handling position which will improve positioning to target nerve.

3.4.5 Concept E

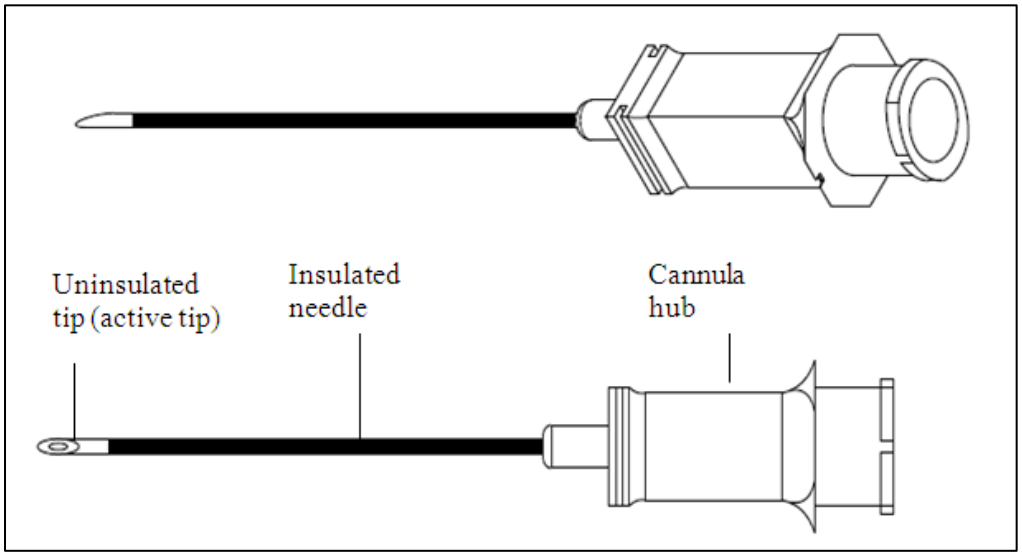


Figure 3.5: Design concept E (isometric view and schematic view)

3.4.5.1 Concept Description

This design concept of RF cannula consists of all features of the existing cannula with different cannula hubs. In this design concept, the cannula hub is designed to have a square shape to reduce and simplify the design. Similarly, this cannula hub design concept has a square shape to improve its handling position which will improve positioning to target nerve.

3.4.6 Concept F

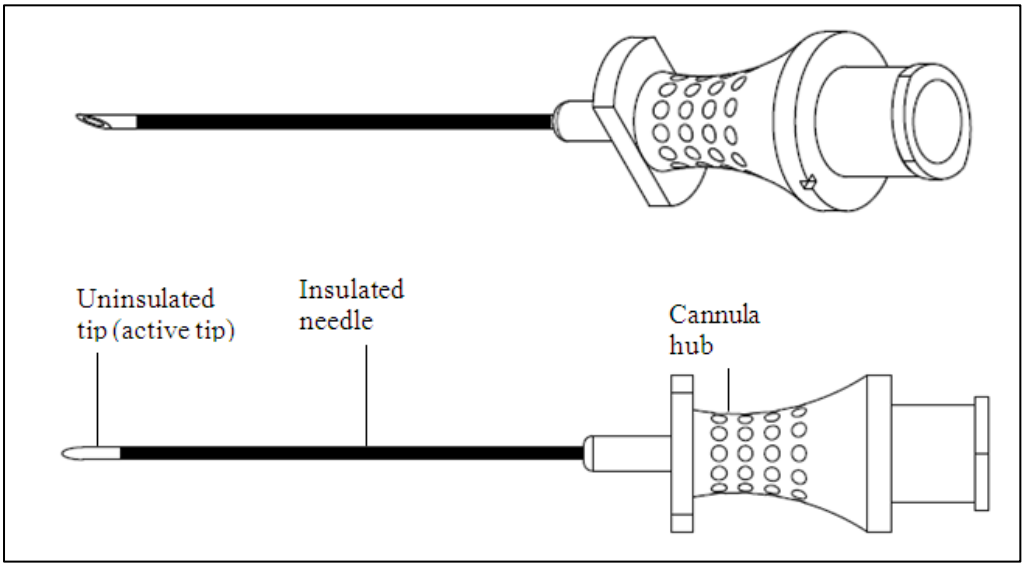


Figure 3.6: Design concept F (isometric view and schematic view)

3.4.6.1 Concept Description

This design concept of RF cannula consists of all features of the existing cannula with different cannula hubs. In this design concept, the cannula hub is designed to have a round shape with a rough surface to firmly hold the cannula. Similarly, this cannula hub design concept has a round shape to improve its handling position which will improve positioning to target nerve.

3.5 SELECTION CRITERIA

In evaluating these design concepts, several criterion are defined by the users for selecting which design concept satisfied users the most. Therefore, several selection criterion are identified and these selection criterion then are to be arranged starting with the most important requirement and then followed by others. Selection criterion under consideration are summarized as the followings:

i. Functionability

It is considered one of the most important criterion for a cannula to be as lightweight as possible because by having lightweight apparatus, handling and operation will become easier. Another criteria is having a cannula compatible with existing thermocouple probe.

ii. Convenience

Other criteria to be considered in the selection of this cannula is convenience towards the user. This design concept selected should be easy and comfortable to grip by its user. Then, the shape of this cannula also should be convenient for new users to hold it. It is commonly occurred that, new users of RF cannula to have difficulty in holding it and put into placement to the target nerve.

iii. Ergonomic

Criteria to be considered in this cannula is an ergonomic design which consists of fix-release function of the introducer with the cannula and ability to hold the cannula with one hand. This cannula should have an introducer to remove tissue inside the needle before thermocouple probe is inserted.

iv. Appearance

An attractive and non-complicated appearance is also a criteria needed to be considered for the selection of a design concept. To compete with existing cannula hubs available in the market, this cannula hub should have commercial values in term of appearance.

v. Manufacturing ease

High complexity or product normally needs to undergo various steps in designing and manufacturing process. The cost will increase if it requires special manufacturing process to fabricate the apparatus. Therefore ,development of this RF cannula will consider all the manufacturing aspects for ease of manufacturing including low complexity part, low cost material and lower number of assembly steps.

vi. Easy to identify needle size

In RF procedure, different application may require different size of needle. Then, it is necessary for this cannula to have color coded hub to identify thesize of the needle. Most commonly, this color is marked on the cannula hub with several different colors according to needle size.

vii. Surface texture

Smooth surface, rough surface and gripping surface area are among the features of surface texture to be considered in selecting design concept. This feature is important as during the RF procedure, surface texture contributes to the ability to firmly hold the cannula.

viii. Size or dimension

Another criteria to be considered in selecting design concept is size or dimension of the cannula hub. This criteria is important because different users may not be very comfortable using the same size of cannula hub. Therefore, during this development phase different size of cannula hub was designed such as small, medium and large cannula.

ix. Geometric shape

In the selection of the design concept, another aspect to be considered is the geometric shape of the cannula hub. In this research, different shape of

design concept was generated to satisfy user needs. Among geometric shapes used for this research are symmetry, cylindrical, square and hexagon shape cannula.

3.6 CONCEPT SCREENING

Based on the selection criteria provided by the users, the concept screening matrix had been developed to narrow the number of designs quickly. Concept screening stage evaluates variants against selection criteria defined by the users and narrows the range of concepts under consideration. In this research, a single concept of reference concept was decided not to be defined for all of the decision criteria. During screening process, design concept is being rated 1 for poor, 2 for fair, 3 for good, 4 for very good and 5 for excellent. The selection criterion are listed along the left hand side of the screening matrix. Table 3.4 shows screening matrix used during this stage.

In this screening stage, concept B, D and E were selected for further refinement and analysis due to its high ranking and satisfy most criteria defined by users. Concept A was not selected for further development because its holder or cannula hub is not comfortable to hold and complex design. Concept C and F are not considered for further development due to its low ranking in the screening matrix. In the next stage of selection, a concept scoring method was used to finalize the concept design. The final design selected in this stage was evaluated, improved and redesigned for final design concept.

Table 3.4
Screening matrix (Appendix 5)

Selection criteria	A	B	C	D	E	F
1. Functionability						
Lightweight	4	4	4	4	4	4
Compatible with thermocouple probe	4	4	1	4	4	4
2. Convenience						
Easy/comfortable to grip	2	5	3	4	4	3
Easy placement to target nerve for new user	2	5	3	4	4	3
3. Ergonomic						
Introducer fix/release with hub	4	4	4	4	4	4
Hold with one hand	2	5	3	4	4	3
4. Appearance						
Attractive	2	4	3	4	4	4
Non complicated	2	4	3	4	4	4
5. Manufacturing ease						
Low cost materials	2	3	4	3	4	2
Low complexity of parts	2	4	3	4	4	3
Low number of assembly step	4	4	4	4	4	4
6. Easy to identify needle size						
Colour coded hub	4	4	4	4	4	4
7. Surface texture						
Smooth surface	3	2	4	3	4	3
Rough surface	3	5	2	4	3	5
Gripping surface area	3	5	3	4	3	4
8. Size/Dimension						
Small	3	3	4	3	5	2
Medium	4	4	4	4	5	4
Large	5	5	5	5	5	5
9. Geometric shapes						
Symmetry	1	5	5	2	5	5
Cylindrical	1	1	5	1	1	5
Square	2	2	1	3	5	1
Hexagon	5	3	1	5	3	1
Sum	64	85	73	81	87	77
Rank	**6**	**2**	**5**	**3**	**1**	**4**

3.7 CONCEPT SCORING

In scoring stage, a matrix was established as shown in Table 3.5 for all criterion as in screening matrix table. The main purpose in this stage is to evaluate and identify concept which most satisfy user needs. The total score for each selection criteria is calculated as follows (Ulrich & Eppinger, 1995):

$$s_j = \sum_{i=1}^{n} r_{ij} w_i$$

where r_{ij} = rating of concept j for the ith criterion, n = number of criteria,

s_j =total score for j, w_i = important weight for ith criterion

In this scoring stage, the concept that achieves the highest ranking is concept B, but the final selection of the design concept does not directly select the concept which achieved the highest ranking. Therefore, it is agreed that concept D was the promising design rather than concept B. In discussion with the users of this device, concept B was not considered for this research because of limitation in fabricating the prototype. So, instead of concept B, concept D is selected for final design and development with several improvements.

Table 3.5
Scoring matrix

Selection criteria	Weight (%)	Concept B		Concept D		Concept E	
		Rating	Score	Rating	Score	Rating	Score
1. Functionability	20						
Lightweight	5	4	20	4	20	4	20
Compatible with thermocouple probe	15	4	60	4	60	4	60
2. Convenience	15						
Easy/comfortable to grip	10	5	50	4	40	3	30
Easy placement to target nerve for new user	5	5	25	4	20	3	15
3. Ergonomic	10						
Introducer fix/release with hub	5	4	20	4	20	4	20
Hold with one hand	5	5	25	4	20	3	15
4. Appearance	5						
Attractive	3	4	12	4	12	4	12
Non complicated	2	4	8	4	8	4	8
5. Manufacturing ease	10						
Low cost materials	6	3	18	3	18	2	12
Low complexity of parts	2	4	8	4	8	3	6
Low number of assembly step	2	4	8	4	8	4	8
6. Easy to identify needle size	15						
Colour coded hub	15	4	60	4	60	4	60
7. Surface texture	10						
Smooth surface	1	3	3	3	3	3	3
Rough surface	2	3	6	4	8	5	10
Gripping surface area	7	3	21	4	28	4	28
8. Size/Dimension	5						
Small	1	3	3	3	3	2	2
Medium	3	4	12	4	12	4	12
Large	1	5	5	5	5	5	5
9. Geometric shapes	10						
Symmetry	1	5	5	2	2	5	5
Cylindrical	1	1	1	1	1	5	5
Square	7	2	14	3	21	1	7
Hexagon	1	3	3	5	5	1	1
Total score (s_i)			387		382		344
Rank		**1**		**2**		**3**	

3.8 FINAL CONCEPT SELECTION

The selection of final design concept is as discussed in Section 3.7. In concept screening and concept scoring phase, concept B achieved the highest ranking than other design concept. However, because of fabrication limitation, concept D was selected rather than concept B. The selection of concept D for further development is based on its second highest ranking and user's evaluation. It is suggested by users that concept D has the potential with improvement on its features. The features suggested to be improved are increasing the length of the wing on both sides and removing the curve profiles. Furthermore, unnecessary profiles are also being removed in this design to simplify the design. The final design concept is as below:

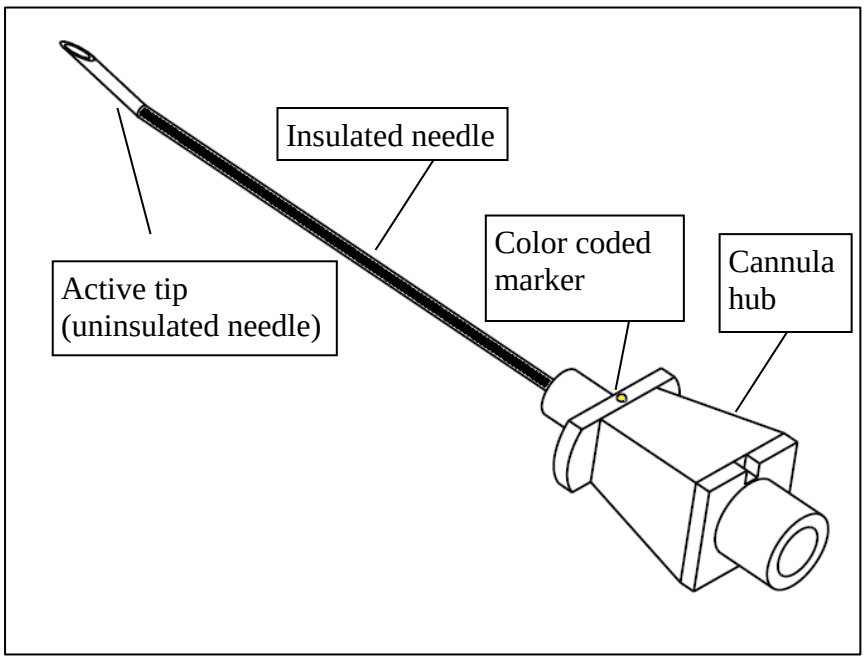


Figure 3.7: Final Design Concept (Appendix VI)

3.9 SUMMARY

Selection of the suitable design concept is one of the challenging tasks during design and development activities. The generation of several design concepts is needed to be carried out before choosing one of the concepts for further development. Generation of the design concepts is based on the Product Design Specification which is being prepared based on customers or user's requirements. Generating several design concepts is expected to give different performance and result. In order to select the suitable design concept that fulfils user requirements, concept screening and concept scoring is applied to select the most suitable design concept. In screening stage, the design concept is done by concept screening, while for finer selection the concept scoring method was used. Six design concepts are generated and undergone an evaluation process.

During concept screening, evaluation and comparison between the design concept is done through a detail questionnaire. Through concept screening evaluation and assessment, the highest score is obtained from design concept B and concept D and design concept E. Concept scoring method evaluation is done by preparing concept scoring matrix. At this stage, design concept B, design concept D and design concept E are evaluated again by giving weighted to selection criteria using relative performance rating. The result of concept scoring shows that concept B achieved the highest score followed by concept D and concept E. However, as discussed in Section 3.8, concept D was selected for further development based on its second highest ranking and user's evaluations.

CHAPTER FOUR

PROTOTYPE FABRICATION

4.1 INTRODUCTION

This chapter presents the fabrication of prototype cannula for selected concept design and verification on the effectiveness of this prototype by testing it on chicken tissue. It consists of two main sections. Section 4.2 displayed the fabrication of prototype cannula using Fused Deposition Modelling (FDM) machine. In this section, the design of prototype cannula with improvised features is displayed and fabrication details are presented. The verification on the effectiveness of this cannula is presented in section 4.3 of this chapter. Testing procedure details to ensure functionality and effectiveness of this prototype cannula is presented through this section.

4.2 PROTOTYPE FABRICATION

Fused Deposition Modelling **(**FDM**)** is chosen among rapid prototyping (RP) technology available as discussed in Chapter 2 to fabricate the prototype of this cannula. The prototype fabrication flow chart is as the following:

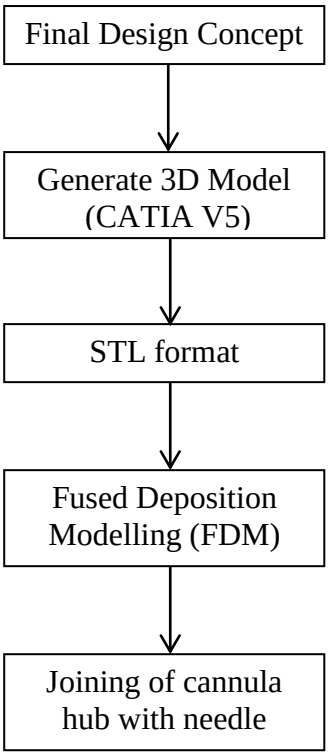


Figure 4.1: Prototype fabrication flow

4.2.1 Design of Cannula Prototype

The design and enhancement of cannula prototype are categorized into several stages. RF cannula design taken from different manufacturers, which has been discussed in Chapter three, is analyzed. Throughout the investigations, some improvements are done on the cannula design. In this study, the cannula is designed without curve surface and unnecessary profile is removed. Finally, after final concept selection a model of the cannula is constructed using Catia V5. In this process, by using Catia software, the cannula hub and introducer design are placed on the 2D form (Figure 4.2) before it was converted into 3D form (Figure 4.4).

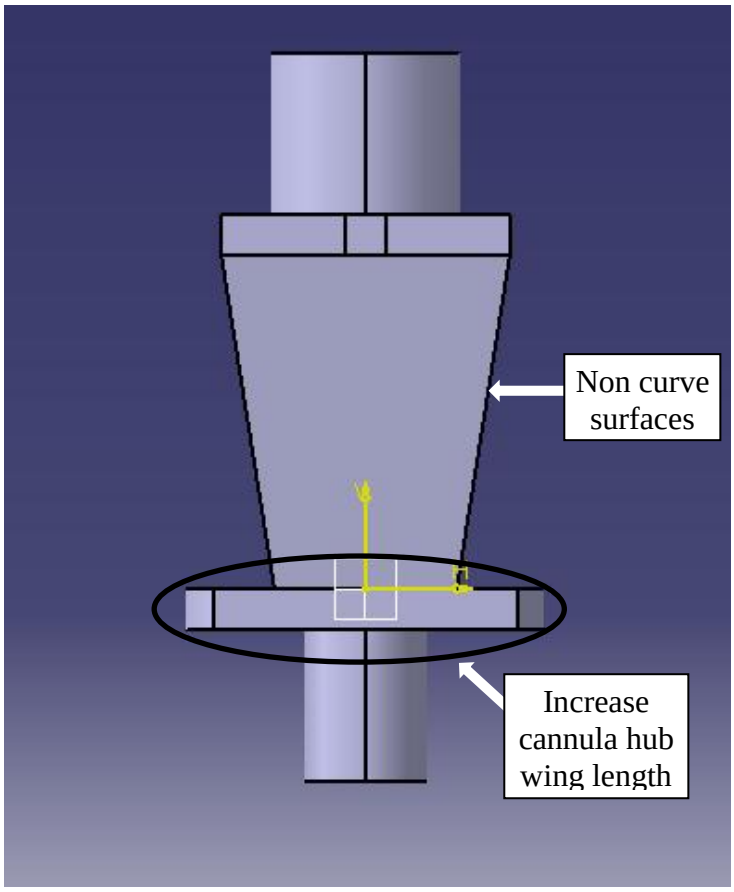


Figure 4.2: Drawing of the cannula hub prototype in 2D

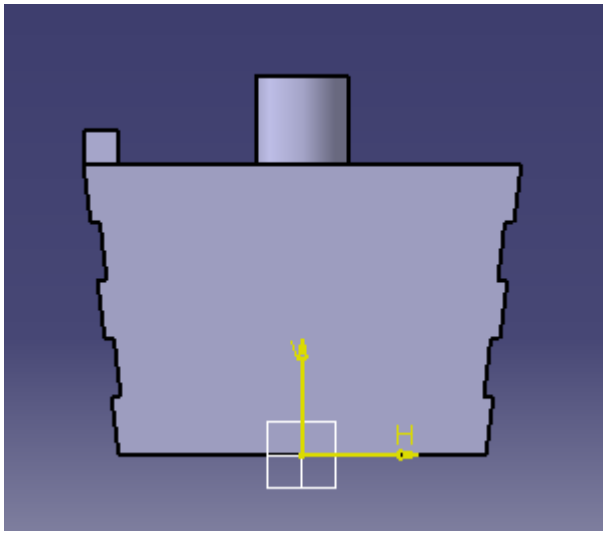


Figure 4.3: Drawing of the introducer in 2D

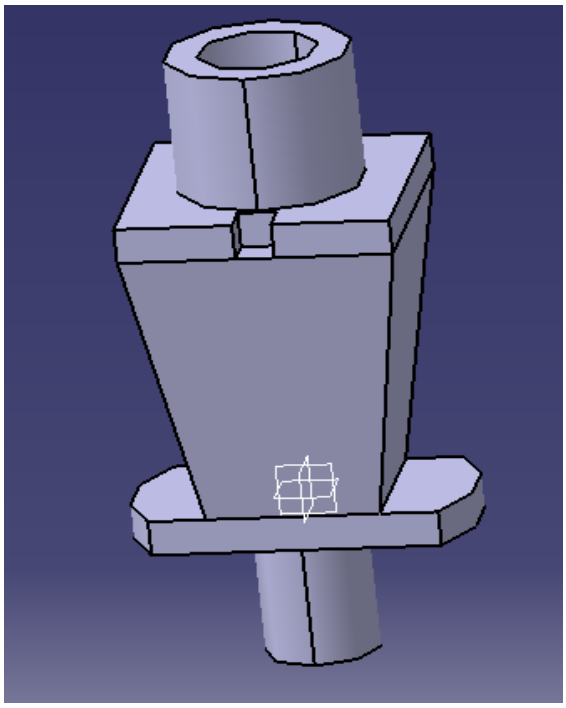


Figure 4.4: 3D Design of cannula hub

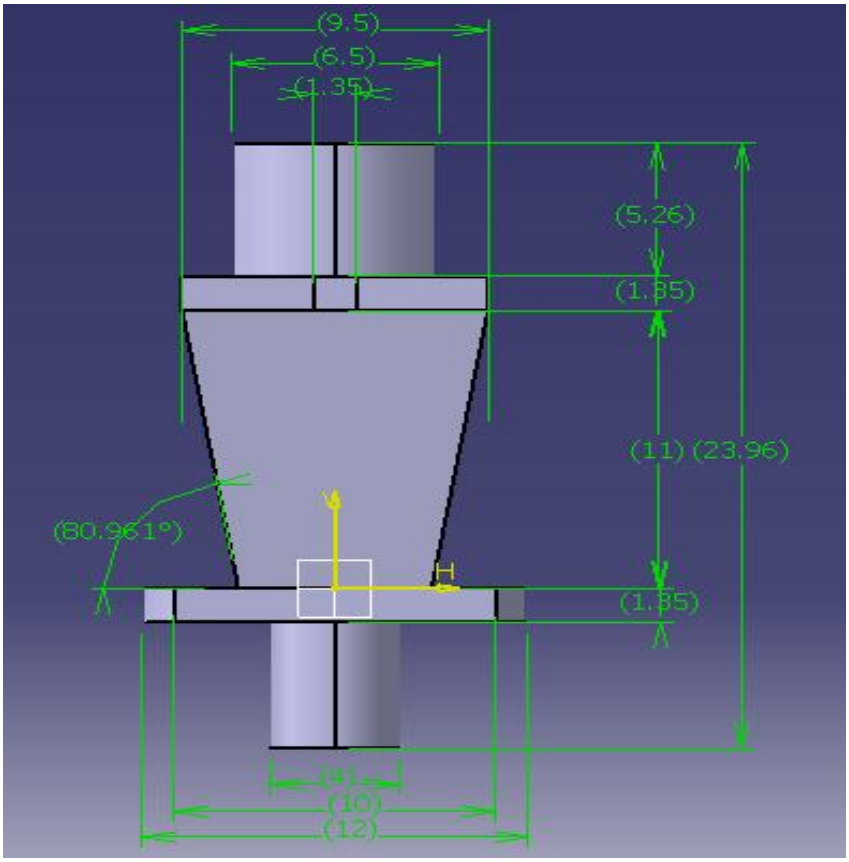


Figure 4.5: Cannula hub with full dimension (unit in mm)

4.2.2 Fabrication of Prototype Cannula

In this study, Fused Deposition Modelling (FDM) machine which use ABS thermoplastic as a material is used to produce the prototype cannula hub. Firstly, the 3D model of cannula hub was converted into a mesh-based surface representation known as standard triangulation language (STL) format. STL format is an accepted format which is readable by the fused deposition modelling (FDM) machine. FDM machine type Dimension SST768 as in Figure 4.6 was used to build the prototype cannula hub.

Figure 4.6: Fused Deposition Modelling (FDM) machine

The Fused Deposition Machine (FDM) model used Catalyst® EX software which has the ability to import STL files, orients the part accordingly, slices the file into cross sections and generates support structures. Catalyst® EX also provides file management abilities, builds time estimation, material consumption and system status information. For developing support structures, Catalyst® EX software automatically creates any needed support structures to complete the part.

In this research, the volume of material used to fabricate the cannula hub is 0.67 in^3 for model material and 0.46 in^3 for support material respectively. Therefore, the cost of material to fabricate the cannula hub is as below:

$$\text{Material cost} = \text{volume} \times \frac{\text{Price per cartridge}}{\text{Volume per cartridge}}$$

Price per cartridge = RM 1650, Volume per cartridge = 50 in^3

$$\text{Model material cost} = 0.67\ in^3 \times \frac{\text{RM 1650}}{50\ in^3} = \text{RM } 22.11$$

$$\text{Support material cost} = 0.46\ in^3 \times \frac{\text{RM 1650}}{50\ in^3} = \text{RM } 15.18$$

Total material cost = RM 22.11 + RM 15.18 = RM **37.29**

The complete prototype requires being dip into soluble liquid concentration at certain temperature to remove the support material builds during the prototype fabrication. Then, completed cannula hub prototype is attached to the insulated needle with curve tip (Figure 4.7).

Figure 4.7: Prototype RF cannula

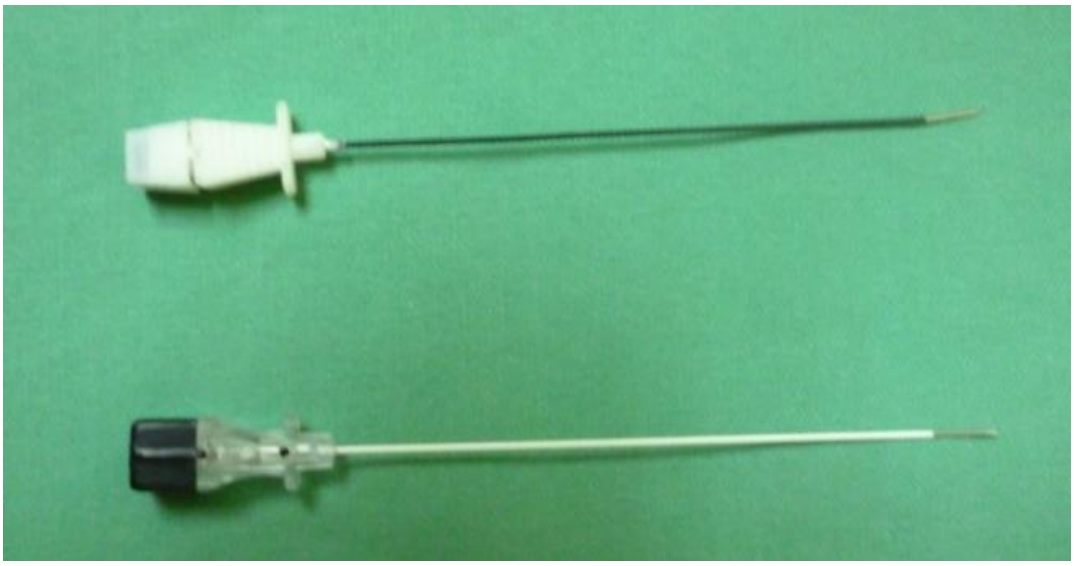


Figure 4.8: Prototype RF cannula (above) and current RF cannula (below) respectively

4.3 TESTING PROCEDURE DETAILS

In this study, the prototype RF cannula is tested to verify the effectiveness of new cannula hub over the existing cannula hub. The main objective of this testing is to verify that the prototype cannula hub is able to function more effectily than thevexisting cannula. This testing is done on chicken tissue to verify the effectiveness

of prototype cannula hub ability to provide better gripping and accurate placement to target tissue area. Even though it is discussed in Chapter Two that liver was used in a study of lesion shape, the most easily tissue available is chicken tissue. This testing was performed on the 29th of September 2012 at Kulliyyah of Medicine, International Islamic University Malaysia, Kuantan Campus by Pain Specialist, Dr. Abdul Hadi Mohamed.

The testing procedure details are as followS:

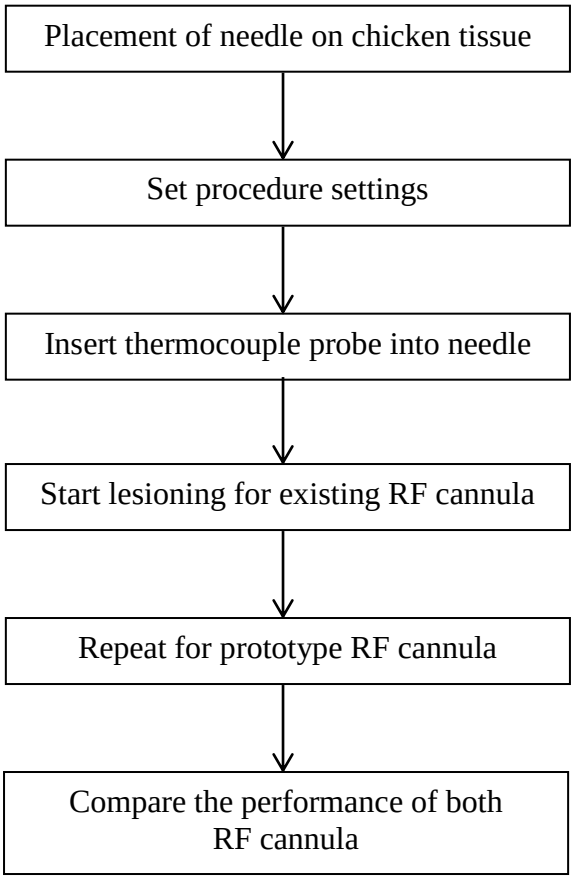


Figure 4.9: Testing procedure flow chart

Testing on chicken tissue was done to simulate and visualize lesioning in human tissue during RF procedure. In performing this testing, chicken tissue was used

as a replacement of human tissue. Firstly, both of the prototype RF cannula and existing RF cannula are placeD in the chicken tissue (Figure 4.10). Then, thermal lesion procedure settings are set for temperature 80 °C in 1 minute. Through this testing the RF generator will control voltage and current to reach 80 °C temperature in 1 minute. Before starting the thermal lesion, thermocouple probe was inserted into existing RF cannula needle which this probe is connected to the RF generator to deliver thermal lesioning. As the lesioning is starting, lesion shape or color change can be observed on the chicken tissue and the increase rate of temperature also can be visualized on the screen of RF generator. These procedures are repeated for prototype RF cannula to compare the performance of cannula hub with the existing cannula.

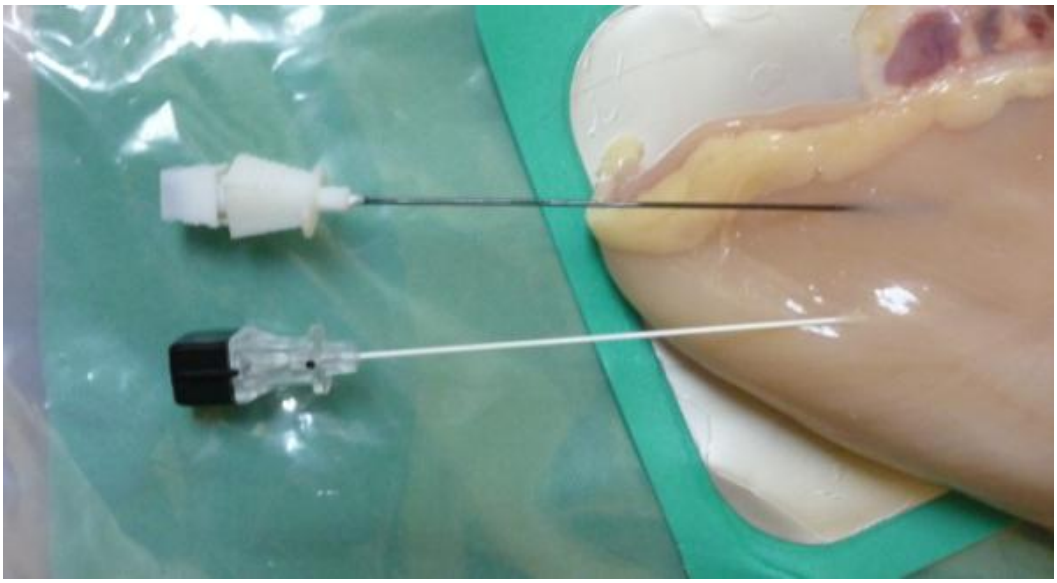


Figure 4.10: Placement of prototype RF cannula (above) and existing RF cannula (below) on chicken tissue

4.4 SUMMARY

In this chapter, fabrication of the prototype RF cannula using Fused Deposition Modelling (FDM) and testing on chicken procedures details has been described. In fabrication of the prototype RF cannula, details design using Catia software is presented in this chapter. Subsequently, the methodology fabrication of cannula hub using Fused Deposition Modelling (FDM) is also described in this chapter. Then, the testing procedure details are described which is done to verify the effectiveness of prototype RF cannula over existing RF cannula.

CHAPTER FIVE

RESULT AND DISCUSSION

5.1 INTRODUCTION

This chapter present tests with chicken tissue results as described in Chapter 4, design concepts analysis and prototype cannula analysis. It consists of three main sections. Each of the main section corresponds to the main objectives as mentioned in Chapter 1. In section 5.2, testing with the chicken tissue result is displayed and analysed. The performance of existing RF cannula and prototype RF cannula is compared based on the user's experience. Section 5.3 shows alternative design concepts analysis. Section 5.4 analyzes on the features and improvement of prototype RF cannula.

5.2 TESTING RESULT ANALYSIS

A prototype of RF cannula was tested on chicken tissue as presented in Chapter 4. In this test, thermal lesion was chosen as mode of lesioning. Procedure setting used in this procedure is set to temperature 80 °C in 1 min. The thermal lesion mode test on chicken tissue resulted in lesion shape or color change and rate of temperature increase was displayed on RF generator screen. This lesion shape is spheroidal in shape with width measurement generated by prototype cannula is 8.36 mm and 6.02 mm for existing cannula (Figure 5.1).

Figure 5.1: Width lesion shape dimension for prototype cannula and existing cannula respectively

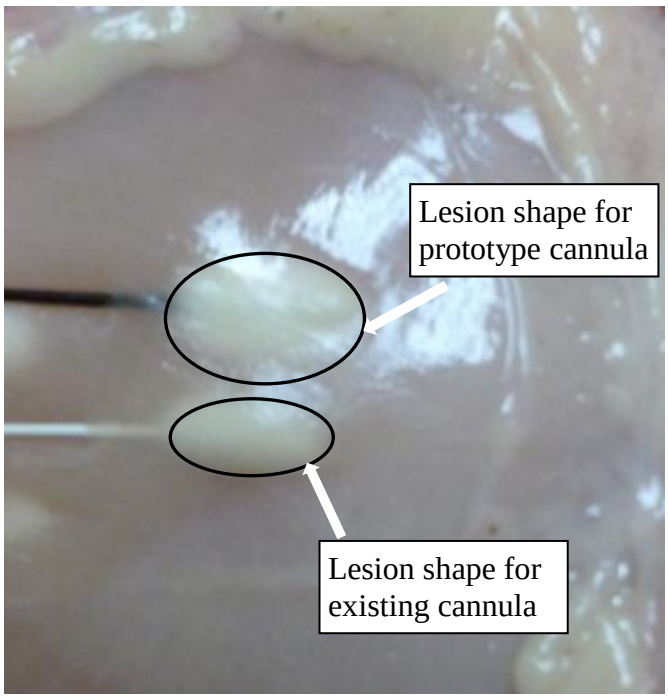


Figure 5.2: Lesion shape or color change on chicken tissue

Figure 5.2 shows the lesion shape or color change on chicken tissue after thermal lesion for both prototype cannula and existing cannula. It is observed that the lesion shape for prototype cannula is larger than lesion shape for existing cannula. There are several factors contributed to this difference on lesion size. Among its

factors are non-uniform shape of chicken tissue, tissue resistivity, needle material properties and depth of needle penetration. In this study, the factors contributed to differences in lesion size are unable to be identified because of limitation in numbers of samples. However, it is suggested that this difference could be due to the resistivity properties of needle material.

The graph in Figure 5.4 shows that the rate of temperature increase for prototype cannula is lower than existing cannula. The lesion shapes larger for prototype cannula due to the ability of active tip needle to reach 80 °C temperatures within 1 min. As in the procedure setting, it is expected that the target tissue to reach 80 °C within 1 min. However, as shown in Figure 5.4, the graph curve is not smooth and rate of temperature increase is lower than existing cannula (Figure 5.3).

Figure 5.3: Rate of temperature increase for existing cannula

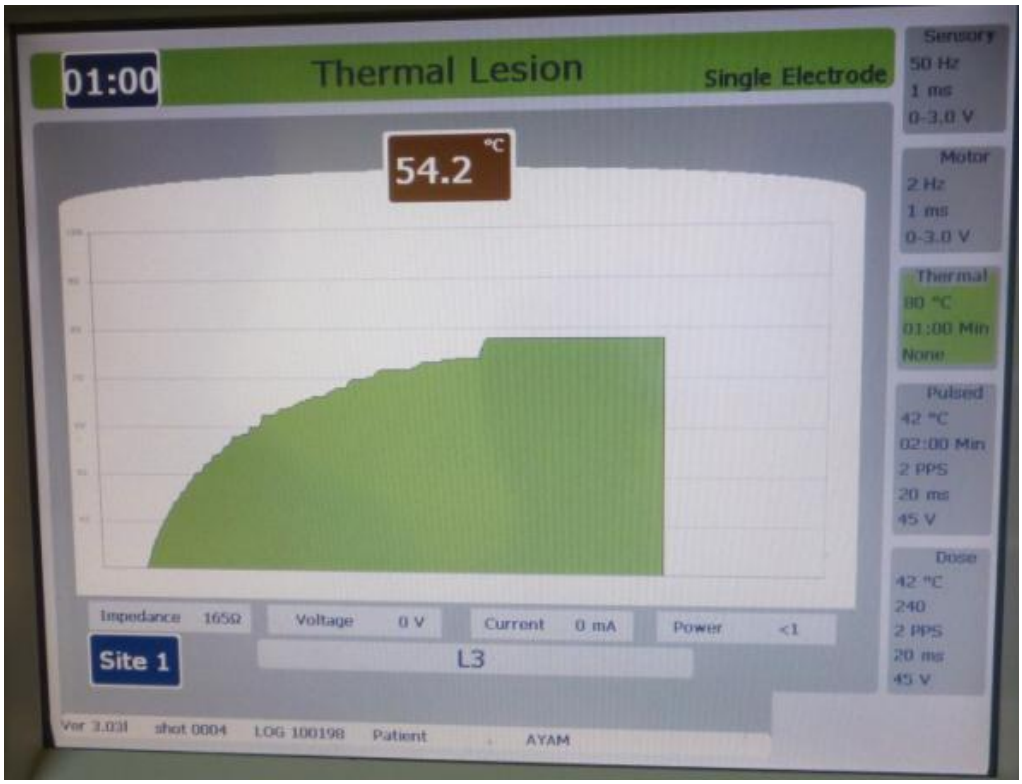


Figure 5.4: Rate of temperature increase for prototype cannula

The longer time required for the cannula to reach the target temperature, result in more tissue which is not involved in lesioning area are being ‘burn’ in thermal lesion mode. The reason of different graph curve between Figure 5.3 and Figure 5.4 is assumed due to different material properties active tip needle. Basically, material that has high electrical resistivity properties is able to emit thermal lesion more consistently at higher rates. In this study, it is suggested to select material with high electrical resistivity properties as the material for needle.

Generally, the factors contributed to the difference on lesion size could not be determined but users are able to verify that prototype cannula hub provides better gripping during needle penetration and accurate placement to target tissue than existing cannula through this test. This test was verified by Dr. Abdul Mohamed and

Dr. Mohamed Saufi Awang from Kulliyyah of Medicine, International Islamic University Malaysia.

5.3 DESIGN CONCEPT ANALSIS

In this study, redesign of cannula hub is expected to provide alternative cannula hub as it is considered as the main component of a cannula. Several design concepts are generated in this study according to user's requirements. The user's requirements related to design concepts generated in this study corresponding to customer statement no. 13 and customer statement no. 15 as shown in Table 3.1.

In addition, prototype of each of this design concept was fabricated using Fused Deposition Modeling (FDM) to give users the ability to visualize it more effectively. Six design concepts were generated with a variety of shapes and features to provide alternative designs of cannula hub. The details of six design concepts sketch and description were presented in Section 3.4. Furthermore, the prototype of these design concepts is shown in Figure 5.5. Each of these design concepts provides users better view on sketch of design concepts.

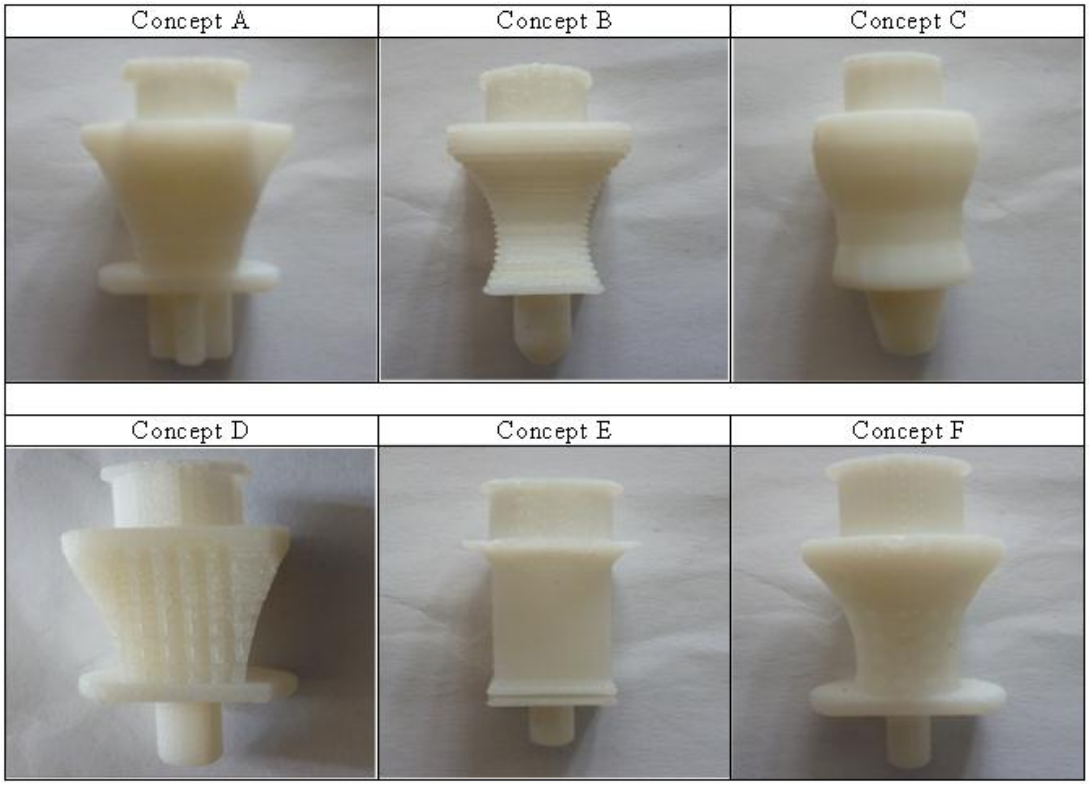


Figure 5.5: Design concepts prototype

5.4 PROTOTYPE RF CANNULA ANALYSIS

A prototype RF cannula is designed through product design and development process. From the prototype design, a prototype of RF cannula is fabricated using Rapid Prototyping (RP) technology. Acrylonitrile butadiene styrene (ABS) is used as the material for this prototype which is also the material for Fused Deposition Modelling (FDM) machine. The prototype design is created using Catia V5 software, converted to STL format as it is an acceptable format for Fused Deposition Modelling (FDM) machine. In this study, the redesigning of RF cannula focuses on improving handling of the cannula hub to provide better placement of the cannula to target nerve with lower cost.

Initially, several design concepts were generated for screening. Through screening of this design concept, concept B, D and E were selected for further

development as illustrated in Figure 5.6. This rating for each concept is presented in Table 3.4 of Chapter 3. The rating distribution of concept design shown in Figure 5.6 described that, concept design B, D, and E achieve more than 80 total rating. Thus, these three concepts were selected for further development in concept scoring phase.

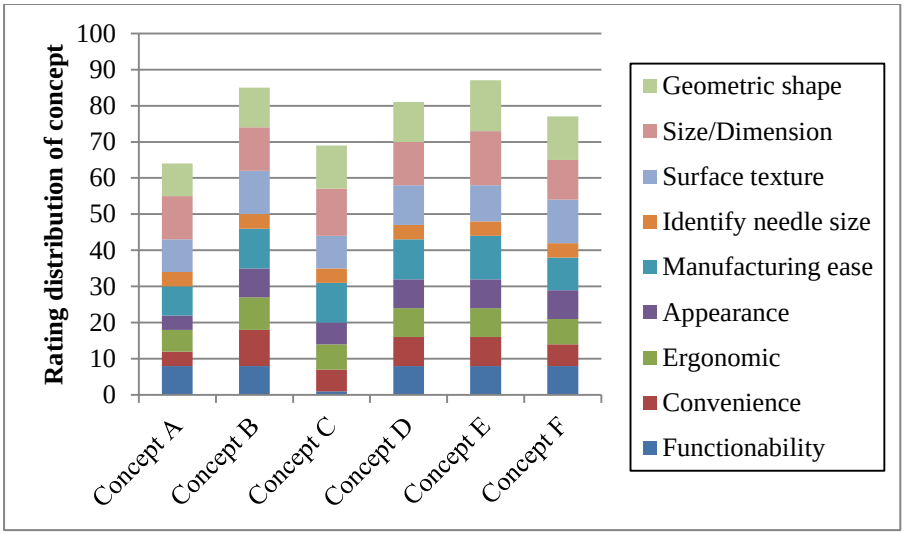


Figure 5.6: Rating distribution of design concept

Then, these concepts are further evaluated using concept scoring method as presented in Table 3.5 of Chapter 3. The distribution of scores for concept B, D and E is illustrated as Figure 5.7 below. In Figure 5.7, it is shown that concept B achieves higher score than concept D and E. However, it is decided that concept D is chosen as the final concept design with several refinements because of limitations in fabrication of prototype for concept B and potentiality of concept D to be developed.

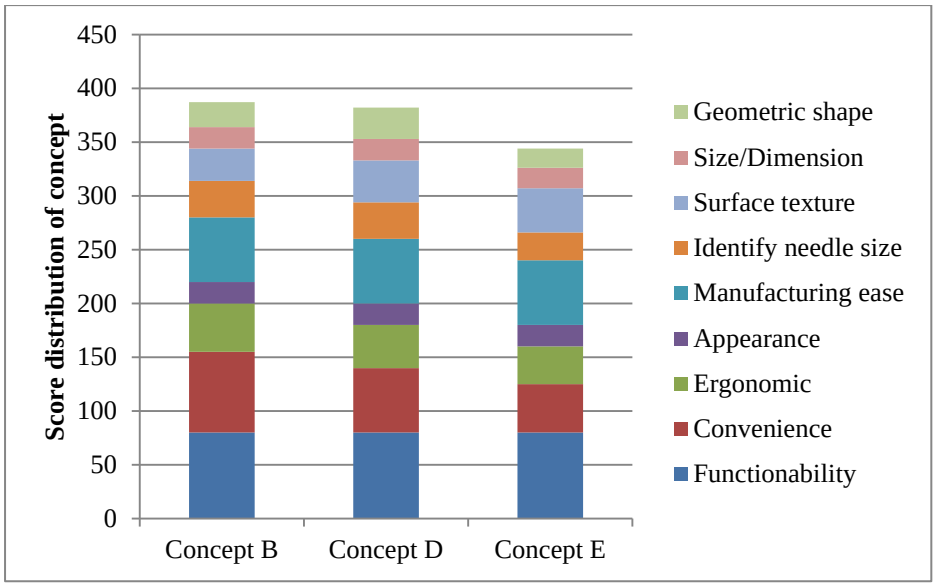


Figure 5.7: Score distribution of design concept

The final design concept of prototype cannula is established after several features refinements of concept D as discussed in Chapter 3. In the final design of prototype cannula, curve profiles are removed from this design. In addition, the length of cannula hub wings as illustrated in Figure 4.2 is increased to improve handling of cannula which contributes to accurate placement to target nerve.

Furthermore, total material fabrication cost for cannula hub including support material and model material is RM 37.29 with build time approximately 40 minutes (exclude set up time and time of removing support material). Then, the cannula hub is attached to insulated needle. This prototype cannula is found functioning as existing cannula under thermal lesion mode. The test result for this prototype cannula on chicken tissue shows its ability to emit thermal lesion. However, further improvement on needle material resistivity properties could give better lesioning performance. In order to improve the performance of this prototype cannula, different grade material is suggested to be used for the needle.

5.5 SUMMARY

In this chapter, testing of prototype RF cannula on chicken tissue to verify the effectiveness of prototype cannula is discussed. Generation of alternatives design concept analysis is done, where six design concepts are generated during these stages. Using the designed model of cannula which has been developed and displayed with added features, a prototype cannula is fabricated using Fused Deposition Modelling (FDM) machine.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

As being set in the early Chapters, the objectives of this research are to improve the effectiveness of existing design of RF cannula using advanced quality control tools and to generate alternative design concepts with improvised features. Other aims are to validate the proposed design by building a prototype. All the objectives of the research have been met and several conclusions can be made from this research:

a. For the first objective, the result obtained shows that the new improved cannula hub gives better performance than existing design in terms of gripping ability and placement to target nerve. This result was validated by performing thermal lesion mode on chicken tissue. It is verified by Pain Specialist that the new cannula hub design, more effectively than existing cannula hub design.

b. For the generation of alternatives design concepts according to user's requirement, the general conclusion that can be made from current study are six design concepts successfully generated with improvised features. These features were recommended for improving effectiveness of the cannula in terms of gripping and placement to the target nerve. The final design concept selected was improvised with three suggested features; 1) non curve surfaces of cannula hub, 2) remove unnecessary profile to reduce its complexity, 3) increase cannula hub wing length.

c. For the last objective, the prototype cannula hub is successfully fabricated using Fused Deposition Modelling Machine (FDM) which validated the proposed design. The prototype cannula hub is attached with insulated needle.

All objectives of this research have been fulfilled. However, there is a lot more improvement that can be made. Some of the improvement points have been listed in the recommendation section.

6.2 RECOMMENDATIONS

Some recommendations for future work may be made from the results obtained and observations made during the project. Based on design, development, fabrication and test conducted, the following suggestions are suggested to complement present research:

a. The present research only focused on design, enhancement and fabrication of prototype. Further research could be extended to design and fabricate mould for this cannula which will be used to manufacture RF cannula.
b. Further research to estimate the part cost details with involvement of suppliers and manufacturing expert.
c. Further research on comparison material for the needle in terms of conduction, resistance, corrosive, malleable and cost.

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APPENDIX I: NEED METRIC MATRIX

Needs		Metric	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
			Needle material hardness	Needle tip sharpness	Biocompatible material for needle	Needle and hub is fix together firmly	Melting temperature of cannula hub	Sterilize able by stream autoclave	Needle length	Needle diameter (ID & OD)	Active tip length	Curve needle	Straight needle	Total mass	Price per cannula	Color coded length cannula	Length label printed on hub	Color coded diameter	Needle diameter printed on hub	Round shape hub	Square shape hub	Hexagonal shape hub	Hub with wing	Hub with grip profile	Introducer compatible with cannula	Introducer fix on cannula	Needle with radiopaque marker	Curved tip orientation marked on the hub	Needle material thermal conductivity	Needle material heat capacity	Insulator thermal conductivity	Insulator heat capacity	Insulator melting temperature	Insulator electrical conductivity
1	Needle can penetrate skin, tissue or muscle.		•	•																														
2	Needle non interact with tissue to cause allergy reaction.				•																													
3	Moveable or flexible and not easily broken.		•			•																												
4	Reusable if possible (sterilization).						•	•																										
5	Variety of needle length.								•																									
6	Need diameter size compatible with thermocouple probe.									•																								
7	Variety of active tip length.										•																							
8	Variety of active tip geometry.											•	•																					

APPENDIX I - CONTINUED

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
9	Lightweight.												•																				
10	Affordable (cost).													•																			
11	Can easily identify needle length.								•						•	•																	
12	Can easily identify needle diameter.																•	•															
13	Comfortable or easily to hold the cannula (hub).																		•	•	•	•	•										
14	An introducer to remove tissue during needle insertion.																							•	•								
15	Accurate positioning of the target nerve.																									•							
16	Can identify orientation of curve tip.																										•						
17	Active tip able to emit heat.																											•	•				
18	Non active tip does not emit heat (insulator).																													•	•	•	

APPENDIX II: COMPETITIVE BENCHMARKING TABLE

Metric No.	Need Nos.	Metric	Imp.	Units	Neurotherm	Braun	Cosman	Pajunk
1	1,3	Needle material hardness *	5	HB				
2	1	Needle tip sharpness*	5	–				
3	2	Biocompatible material for needle**	5	list	stainless steel	stainless steel	stainless steel	stainless steel
4	3	Needle and hub is fix together firmly**	5	subj				
5	4	Melting temperature of cannula hub*	4	°C				
6	4	Sterilize able by stream autoclave*	4	°C				
7	5	Needle length	4	mm	50, 100, 150, 200	*	50, 100, 150, 200	*
8	6	Needle diameter (ID & OD)	5	Gauge (G)	18, 20, 22	*	16, 18, 20, 21, 22	*
9	7	Active tip length	4	mm	2,5,10	*	2,5,10	*
10	8	Curve needle	4	Degree (°)	15	*	15	*
11	8	Straight needle	4	list	available	*	available	*
12	9	Total mass	3	g	0.7318	1.4522	0.9155	1.1414
13	10	Price per cannula	3	RM	more than 1000	*	more than 1000	*
14	11	Color coded length cannula	2	list	No	No	No	No
15	11	Length label printed on hub	2	subj	No	*	No	*
16	12	Color coded diameter	2	list	Yes	Yes	Yes	Yes
17	12	Needle diameter printed on hub	2	subj	No	No	No	No
18	13	Round shape hub	4	subj	No	Yes	No	No
19	13	Square shape hub	4	subj	Yes	No	Yes	No
20	13	Hexagonal shape hub	4	subj	No	No	No	Yes
21	13	Hub with wing	4	subj	Yes	Yes	Yes	Yes

APPENDIX II - CONTINUED

Metric No.	Need Nos.	Metric	Imp.	Units	Neurotherm	Braun	Cosman	Pajunk
22	13	Hub with grip profile	4	subj	Yes	Yes	Yes	Yes
23	14	Introducer compatible with cannula	5	mm	Yes	Yes	Yes	Yes
24	14	Introducer fix on cannula	5	subj	Yes	Yes	Yes	Yes
25	15	Needle with radio opaque marker	3	subj	No	No	No	No
26	16	Curved tip orientation marked on the hub	4	subj	Yes	*	Yes	*
27	17	Needle material thermal conductivity	4	W/m °C	*	*	15	*
28	17	Needle material heat capacity	5	J/kg°C	*	*	500	*
29	18	Insulator thermal conductivity	5	W/m °C	*	*	0.01	*
30	18	Insulator heat capacity	4	J/kg°C	*	*	3400	*
31	18	Insulator melting temperature**	5	°C	more than 100	more than 100	more than 100	more than 100
32	18	Insulator electrical conductivity	5	S/m	*	*	0	*

* Technical specification / data not available

** Standard specification between manufacturer

APPENDIX III: TARGET SPECIFICATION

Metric No.	Need Nos.	Metric	Imp.	Units	Marginal value	Ideal value
1	2	Biocompatible material for needle	5	list	non ferrous metal	stainless steel
2	1,3	High hardness needle material	5	HB	-	-
3	1	High sharpness needle tip	5	-	-	-
4	4	Sterilize able by stream autoclave	4	°C	>100	>120
5	5	Needle length	4	mm	50, 100, 150	50, 100, 150, 200
6	6	Needle diameter (ID & OD)	3	G	20, 21, 22	22
7	7	Active tip length	4	mm	5, 10,15	5,10
8	8	Tip geometry	4	list	curve / straight	curve
9	12	Color coded length cannula	2	list	No	Yes
10	12	Length label printed on hub	2	subj	No	Yes
11	13	Color coded diameter	2	list	Yes	Yes
12	13	Needed diameter printed on hub	2	subj	No	Yes
13	14	Round shape hub	4	subj	No	Yes
14	14	Square shape hub	4	subj	No	Yes
15	14	Hexagonal shape hub	4	subj	No	Yes
16	14	Hub with wing	4	subj	No	Yes
17	14	Hub with grip profile	4	subj	No	Yes
18	15	Introducer length same as cannula	5	mm	50, 100, 150	50,100,150, 200
19	15	Fix and release mechanism of introducer	5	subj	No	Yes
20	16	Needle with radio opaque marker	5	subj	No	Yes
21	17	Curved tip orientation marked on the hub	4	subj	No	Yes
22	18	Insulated or coated shaft	5	°C	Yes	Yes

APPENDIX III - CONTINUED

Metric No.	Need Nos.	Metric	Imp.	Units	Marginal value	Ideal value
23	3	Needle and hub is fix together firmly	3	subj	No	Yes
24	11	Unit Manufacturing cost	4	RM	< 150	<100
25	9	Total mass	3	g	<1.1	<1.0

APPENDIX IV: REFINE SPECIFICATION

Metric No.	Need Nos.	Metric	Imp.	Units	Value/Attributes
1	2	Biocompatible material for needle	5	list	stainless steel
2	1,3	High hardness needle	5	HB	-
3	1	High sharpnees needle tip	5	-	-
4	4	Sterilizeable by stream autoclave	4	°C	> 100 °C
5	5	Needle length	4	mm	50, 100, 150
6	6	Needle diameter (ID & OD)	3	G	22, 23, 24
7	7	Active tip length	4	mm	5, 10, 15
8	8	Tip geometry	4	list	straight/curved
9	12	Colour coded length cannula	2	list	-
10	12	Length label printed on hub	2	subj	No
11	13	Colour coded diameter	2	list	Table 1
12	13	Needle diameter printed on hub	2	subj	No
13	14	Round shape hub	4	subj	Yes
14	14	Square shape hub	4	subj	Yes
15	14	Hexagon shape hub	4	subj	Yes
16	14	Hub with wing	4	subj	Yes
17	14	Hub with grip profile	4	subj	No
18	15	Introducer length same as cannula	5	mm	50, 100, 150
19	15	Fix and release mechanism of introducer	5	subj	Yes
20	16	Needle with radioopaque marker	5	subj	No
21	17	Curved tip orientation marked on the hub	4	subj	Yes
22	18	Insulated or coated shaft	5	°C	> 100 °C
23	3	Needle and hub is fix together firmly	3	subj	Yes
24	11	Unit Manufacturing cost	4	RM	<100
25	9	Total mass	3	g	<1.0

Table 1

22G	23G	24G

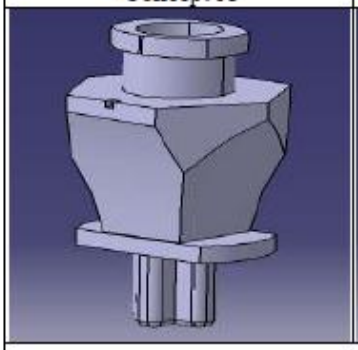
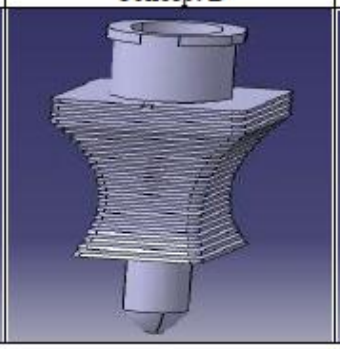
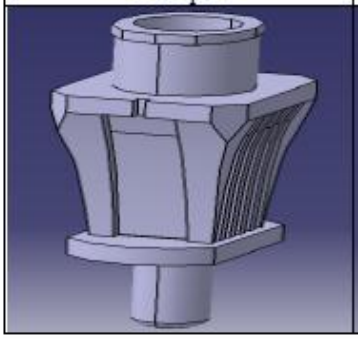
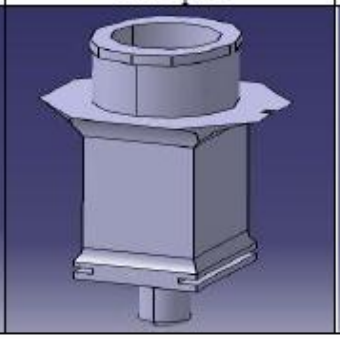
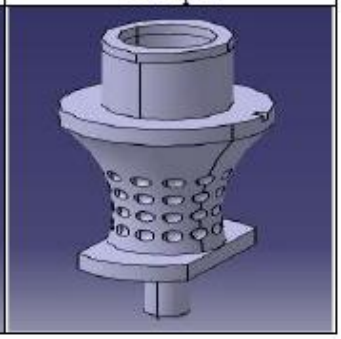
APPENDIX V: QUESTIONNAIRE

Questionnaire

Evaluation of Design Concept RF Cannula

This research seeks to design and develop radiofrequency cannula used for chronic pain management. This survey is to evaluate selection concept design of radiofrequency cannula hub. The objective of this survey is to select cannula hub base on different criteria of its users. This survey is administered part of postgraduate's thesis at the International Islamic University Malaysia (IIUM).

Please rate which concept you choose on each criteria.

Concept A	Concept B	Concept C
		
Concept D	Concept E	Concept F
		

1

APPENDIX V - CONTINUED

Selection Criterias	For the following question please indicate: 1for poor, 2 for fair, 3 for good, 4 for very good and 5 for excellent					
	A	B	C	D	E	F
1. Functionability						
Lightweight	4	4	4	4	4	4
Compatible with thermocouple probe	4	4	1	4	4	4
2. Convenience						
Easy/comfortable to grip	2	5	3	4	4	3
Convenience placement to target nerve for new user	2	5	3	4	4	3
3. Ergonomic						
Introducer fix/release with hub	4	4	4	4	4	4
Hold with one hand	2	5	3	4	4	3
4. Appearance						
Attractive	2	4	3	4	4	4
Non complicated	2	4	3	4	4	4
5. Manufacturing ease						
Low cost materials	2	3	4	3	4	2
Low complexity of parts	2	4	3	4	4	3
Low number of assembly step	4	4	4	4	4	4
6. Easy to identify needle size						
Colour coded hub	4	4	4	4	4	4
7. Surface texture						
Smooth surface	3	2	4	3	4	3
Rough surface	3	5	2	4	3	5
Gripping surface area	3	5	3	4	3	4
8. Size/Dimension						
Small	3	3	4	3	5	2
Medium	4	4	4	4	5	4
Large	5	5	5	5	5	5

2

APPENDIX V - CONTINUED

9. Geometric shapes						
Symmetry	1	5	5	5	5	5
Cylindrical	1	1	5	1	1	5
Square	2	5	1	3	5	1
Hexagon	5	5	1	5	3	1

7. Comment/Suggestion: — I would prefer concept B, D or E since easier to grip and handle.

Doctor's Particular:

DR. ABDUL RAZAK MOHAMED
PAKAR ANAESTESIOLOGI
HTAA / IUM

Thank you for your honest cooperation.

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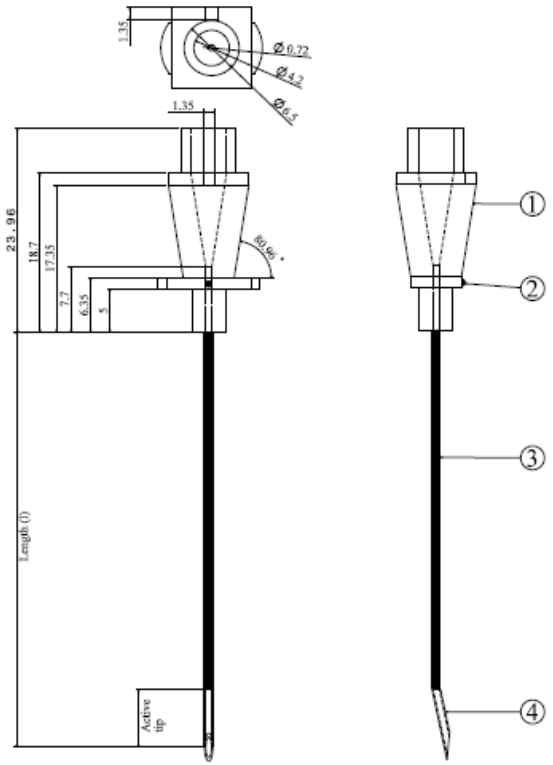
APPENDIX VI: DETAILS DRAWING



No.	Part Name	Material	Quantity
1	Cannula hub	ABS, arcylic, PC, PE, PP, PS, PU	1
2	Curve tip orientation marker	-	1
3	Insulator	polyester (PET)	1
4	Active tip (non insulated needle)	Stainless steel	1

Metric dimension in mm	Not in scale	Drawn by: Shafie Kamaruddin	Date: 15-08-2012
General tolerances		Manufacturing & Material Engineering Department Kulliyyah of Engineering International Islamic University Malaysia	
Surface texture		Name: Radiofrequency (RF) Cannula	
Material see details			