DESIGN AND ENHANCEMENT OF RADIOFREQUENCY CANNULA FOR CHRONIC PAIN MANAGEMENT

BY

SHAFIE KAMARUDDIN

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Kulliyyah of Engineering
International Islamic University
Malaysia

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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).

….....…….....
Wan Ahmad Yusmawiza Wan Yusoff
Supervisor

…….....
Abdul Hadi Mohamed
Co Supervisor

…….....
Mohamed Saufi Awang
Co Supervisor

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).

……...
Internal Examiner
Mohd Hanafi Ani

.....
External Examiner
Riza Sulaiman

This dissertation was submitted to the Department of Manufacturing and Materials and is accepted as a fulfilment of the requirement for the degree of Master of Science (Manufacturing Engineering).

...…….....
Mohammad Yeakub Ali
Head, Department of Manufacturing
& Materials

This dissertation was submitted to the Department of Manufacturing and Materials and is accepted as a fulfilment of the requirement for the degree of Master of Science (Manufacturing Engineering).

……..**.....**
Md Noor Hj Salleh
Dean, Kulliyyah of Engineering

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