EML 4905 Senior Design Project

A B.S. THESIS
PREPARED IN PARTIAL FULFILLMENT OF THE
REQUIREMENT FOR THE DEGREE OF
BACHELOR OF SCIENCE
IN
MECHANICAL ENGINEERING

IMPLANTABLE MEDICAL MICROCONNECTOR
25% Final Report

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November 25, 2013

This B.S. thesis is written in partial fulfillment of the requirements in EML 4905. The contents represent the opinion of the authors and not the Department of Mechanical and Materials Engineering.

Ethics Statement and Signatures

The work submitted in this B.S. thesis is solely prepared by a team consisting of Eric Doan, James Ciurdar, Samuel Grada, and MariaMartha Lopez and it is original. Excerpts from others' work have been clearly identified, their work acknowledged within the text and listed in the list of references. All of the engineering drawings, computer programs, formulations, design work, prototype development and testing reported in this document are also original and prepared by the same team of students.

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Abstract

Implantable neurostimulation devices generate electrical stimulation to treat various disorders involving neurological problems. A neurostimulator is composed of a connector assembly which connects to the leads, thin wires that deliver electrical pulses from the neurostimulator. There currently are a number of neurostimulators treating a wide range of disorders including migraines, back pain, hearing loss, epilepsy, and Parkinson's disease. These devices are hard-wired to the leads and have a limited number of electrodes. The permanent attachment of the leads to the neurostimulator means that failure from either component will result in removal of the entire device as opposed to a simple disconnection and replacement of one component with the use of a connector. The leads must be hard-wired because there is no connector commercially available.

Neurostimulators currently have up to 16 electrodes. While they may be effective in treating certain disorders, neurostimulators are inadequate to work with neural prostheses being developed as well as the treatment of more advanced neurological disorders such as Alzheimer's. The objective of this project is to develop a hermetic, 32 channel, implantable microconnector that is compatible for neurostimulator devices in the market. The connector is made with High Temperature Co-fired Ceramic (HTCC), a common material used in microelectronics along with titanium and platinum. The dimensions of the initial prototype are 5mm by 4mm by 3mm. Overall, this electronic packaging will provide an easier way to assemble the neurostimulator in addition to improving neural feedback.

INTRODUCTION

Problem Statement

Implanted neurostimulation devices employ a hardwired design, which means that the stimulating pads and leads are hardwired directly to the generator device. While this design is functional, it leaves little room for improvement and for the exchange of devices. In the case where the generator device must be changed, which may be due to various reasons such as generator failure, the entire assembly must be detached and taken out of the body. The main problem with this approach is the human body's tendency to adapt to foreign material. When the pads and leads are initially implanted, they are attached to the nerves or tissue, and the nerves begin to grow around the pads themselves. Therefore, tearing the tissue or nerve in order to detach the pads is very damaging and may harm the nerves or tissue.

Current device connections do not accommodate devices which require more stimulation leads than others. The treatment of neurological diseases such as Parkinson's disease, Lou Gehrig's disease, or Alzheimer's disease require more stimulation leads simply because current research cannot pinpoint the exact locations of the affected areas in the brain. Because of this, more leads are used to solve the problem with minimal trial and error in the placement of the leads.

Motivation

The motivation for this project is based on providing a more feasible way to interchange neurostimulation devices. Creating an advanced connector improves the task for the surgeon in the operating room when connecting every lead to the correct nerve. Research done at St. Jude's Children's Hospital has led to new devices being implanted which help children with various physical and neurological problems. Because technology in the medical field advances so quickly, a need for a quick, easy, reliable connection is necessary to help push research to its fullest potential. The replacement of failed devices that were implanted into hundreds of children could have devastating effects on the recovery of children that never had the ability to see or hear.

Another application outside of research would be to use the connector to help rehabilitate retired veterans who were injured while on active duty. Many veterans come back home with no hope of ever walking again or having full use of one or more of their limbs. This connector has the potential to aid in Veterans Affairs' research of new devices. Devices built for the stimulation of a prosthetic limb or treatment of non-ordinary neurological diseases may be more involved than traditional implants, thus an increased amount of leads connected to the nerves and tissues are necessary.

Literature Survey

Current Products

The survey began by investigating what is currently available in the marketplace. There currently is a patent issued to Neurostream Technologies for a high density implantable connector for neurostimulators. This device has 9-channel connectors. The designs were sold to a German company called Ottobock. Ottobock is using this device exclusively for their stimulator to treat stroke victims suffering from foot drop. Currently, this connector is not available as a standalone product. The second problem with this product is that it only has nine channels. Many neurostimulators in the market have 16 channels. Moreover, the size of this product poses a problem. While the patent application did not provide the dimensions, their scale appears much larger than our proposed design of 2mm by 7mm by 3 mm. This gives the physician more flexibility in the placement of the connector.

Biocompatible Materials

This device is implanted into the human body; consequently, the materials used for this device case must be biocompatible. There are a number of materials that are compatible with the human body ranging from certain metals, some plastics, and some ceramics.

HTCC is High Temperature Co-fired Ceramic which is biocompatible while LTCC is Low Temperature Co-fired Ceramic which is not biocompatible. These materials are widely used in microelectronics. Preliminary research indicates that LTCC

and silver are used for the internal microelectronics. These materials play a vital role in building a device so small with many connectors.

Some metals that are biocompatible include stainless steels, cobalt alloys, and titanium alloys. The focus was on titanium as this metal has a high tensile strength, low density and is highly resistant to bodily fluids. Titanium is currently the primary material used for neurostimulator and pacemaker cases.

Lead Attachment

Conventional neurostimulator systems consist of leads connected directly from the nerves through an extension (if necessary) and subsequently into the neurostimulator. There are a few methods of attaching leads depending on what type of leads will be used. Proximal leads, which are the lead ends connected directly to the neurostimulator, are often set into the connection junction using setscrews once the leads are set into position. As described in the proposed design of the connector, the connection points lead to corresponding pads to which the incoming lead ends will be connected. The employment of this connection system requires each half of the connector to link to the corresponding leads ends (one half to the stimulator, the other to the extension leading to the stimulating pads). In order to show the feasibility of the system, one scope of the project is to investigate how the connector is fused to the leads.

The most simple and reliable method of attaching the leads to the connector pads is micro-welding. One mil platinum wires, configured in line with the length axis of the connector, will be grouped together. They are all insulated from one another. This configuration is more favorable in this design application as it results in a streamlined design, which is desirable in implanted devices. The device used to fuse the wires to the pads is a Hughes Micro-Welder. This machine has the capability to perform micro-scale resistance spot welding, which is necessary to fuse the one mil wire to the connection pads and is accessible for use in the Advanced Materials Engineering Research Institute (AMERI). The benefits of welding the wires into place include the assurance of good electrical contact as well as the added pull strength of the connection. If the wires are configured in line with the length axis of the device, it is desirable for the connection of the wires to the pads to have good resistance from being torn off when pulled should the leads move around while implanted. Loss of connection between the wires and the pads

would result in stimulation loss of the corresponding leads. The method of micro-spot welding, using equipment similar to the Hughes Micro-Welder, is widely seen in medical implanted devices.

O-Rings

An O-ring is a toric joint used for sealing. It closes off a pathway in order to prevent unwanted air or fluid from escaping as well as unwanted fluid from entering the device. O-rings are placed in flanges or grooves so they can block the passage. This is accomplished through material memory. When an O-ring is compressed in a space, it wants to return to its original shape. Because of this, it pushes against the walls of the groove in which it was placed, creating a seal through force. However, it is important to keep in mind what causes an effective seal. This is determined through the inner diameter of the O-ring. The stretch of the gland diameter should not be greater than 5%, rather it should remain between 1% and 5%. If the O-ring has a higher stretch percentage, the pressure will cause wear in addition to cross section reduction. For this device, the use of a micro O-ring is necessary due to the small scale of the connector.

Furthermore, the O-ring must be composed of medical-grade material in order to be biocompatible with the human body and to withstand the corrosive environment. The O-ring can be inserted during lamination. If the material of the O-ring is not compatible with its surroundings, the O-ring may fail, which will in turn cause the entire device to fail. In order to determine the success of the O-ring, the device was subject to various tests.

Devices Used to Manufacture

The use of AMERI labs makes manufacturing devices on such a small scale possible by providing the necessary equipment and machinery. In order to use the green ceramic tape, a precision CNC punch is needed to punch the vias. The KEKO PAM Precision punch machines are able to punch very precise holes on a very small scale, between 100, 150, and 250 μm in diameter. The design is exported in a CAD file, which is uploaded into the punch machine. The machine then takes the LTCC or HTCC tape and punches out the design, which consists of the vias and the alignment holes that are

used to align the layers of tape. About 25 layers of the design can be made out of one sheet of LTCC or HTCC.

Once the designs are punched out, the sheet is placed on the PTC-1000 vacuum assisted bladder filler, which filled the holes with the high-viscosity silver or platinum ink by applying downward pressure evenly across the entire sheet. After the bladder filler operation is completed, the sheets undergo a process similar to screen printing, where the ink is sheared over the vias. These two processes done in conjunction allow for a high chance of every via being filled. During the filling process, a mask is placed over the tape that allows only the vias to be exposed to the ink. The mask is made at the same time the tape is punched in the machine. This ensures that the same mechanical pins that align the tape on the machine can be used to align the mask as well.

After the vias are filled, the sheet of tape is placed in a small oven set to about 85 degrees Celsius for 10-15 minutes, solidifying the ink enough so it can stay in the vias while the tape is cut on the laser cutter. After the layers are cut out on the laser cutter, they are stacked using a simple jig consisting of four alignment posts and two metal plates. The stack is the placed in the PTC lamination press, which uses heat and about 1,500 psi of pressure to laminate the individual layers into one, which can then be fired in Lindberg 1700 oven. The box-style oven is favorable in this application as it gives greater control over the desired temperature and uniformity of heat distribution.

DESIGN ALTERNATIVES

Overview of Conceptual Design

Before conceiving any other designs, it is important to test the manufacturability of certain components. The simplest design has been chosen due to the size of the connector and the constraints of manufacturing it. Once the preliminary testing of what can be manufactured is complete, then alternative designs can be considered. When designing alternatives, components such as size, shape, amount of pins, and additional aspects can be changed and improved; however, it is all reliant upon manufacturability of the device.

This particular connector is the testing grounds for what is possible to manufacture on such a small scale. There have not been any similar devices developed that can be used as reference to what can be accomplished. It is still uncertain whether this particular design concept of pins and holes can be manufactured, which is why preliminary testing must be conducted. The first component of the microconnector that was tested for manufacturability is the pins. If the pins can be manufactured, then this design can be further developed. In addition to making the pins, the routing of the wires that connect the pins to the pads also has to be tested. This is done by screen printing but because of the small size, it becomes a tough process in manufacturing. Once these two factors were tested for manufacturability, the final design was developed.

When designing the microconnecter, several factors have to be taken into account. The major constricting factor in designing the microconnector is the manufacturing process. In addition, the ability to make the microconnecter hermetic also plays a major role in the design of the microconnecter. Because of these two factors, there were many limiting constraints on the design. To keep manufacturability as simple as possible, the connector consists of 32 posts and 32 holes. One half of the connector will have posts while the other half will have holes. The device connects through the posts going inside the holes. This method seems to be the simplest to manufacture. Because of manufacturing at such a small size, the major change in design occurs with the orientation of the pins and the shape of the connector.

Design Alternate 1

The first design considered was a connector with a 4 by 8 array of pins and holes, and pads on the other side for micro welding the wires of the leads. The size of the connector is 3mm wide and 14mm long. This proved to be an effective size and a good pin and hole configuration. In addition, the manufacturability of this specific design was simple as well, but there were some minor problems with this arrangement. One of the concerns with this design is that it is too wide. When dealing with implantable medical devices, the microconnector should be streamlined and as thin as possible. This is because it is easier to implant, and it takes up less of a footprint inside the human body. Shown in Figure 1 is the first design consideration. Notice the width compared to the length.

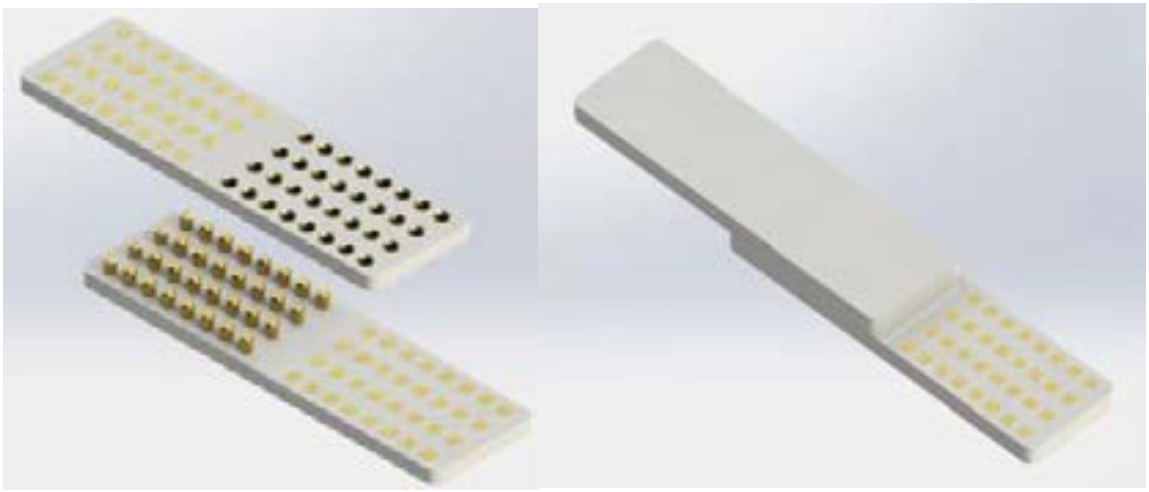


Figure 1: Preliminary Design of Microconnector

Design Alternate 2

A secondary design alternative is a circular connector. This type of geometry allows for more pins to be placed, which in turn provides a good version of it but has some design constraints. Furthermore, this design incorporates an O-ring, which allows for the device to be hermetic. Similar to the first proposed design, the circular geometry is not streamlined, and it is 7mm in diameter. This occupies a lot of space in terms of an implantable connector device. In addition, the pads that connect the wires from the neurostimulator to the leads will have to be placed on top of the connector which makes

the connector sit in a vertical position rather than a horizontal position. Shown in Figure 2 is the circular design alternative.

Figure 2: Circular Microconnector Design Alternative

Proposed Design

With considerations from the design alternatives, a final proposed design was produced. Using the same considerations for manufacturability and streamlining the design, a new arrangement of the pins and holes were set up. The new arrangement features 3 rows of ten pins with two additional pins on each end in the middle. The proposed design also incorporates an O-ring for having a hermetic boundary set up. Similar to the first design alternative, pads were set up on each end of connector for micro welding the lead wires. The final width of the design is 2mm and a length of 12mm. Although this may not seem like a major improvement from the first design alternative, the small decrease in size has a major effect in the human body.

Figure 3: Proposed Design - Pins and O-Ring Placement

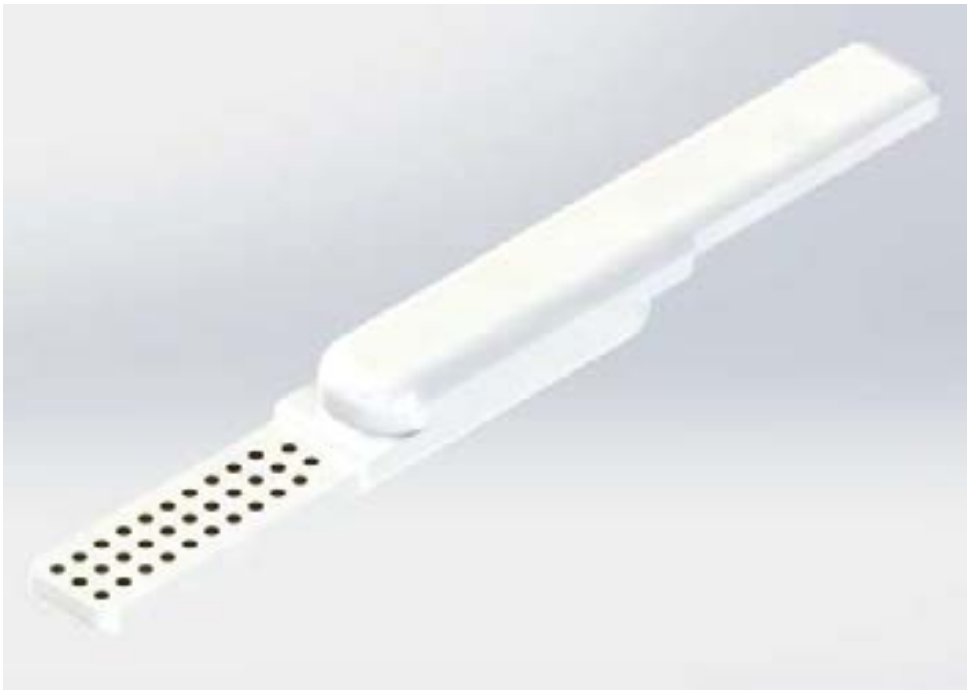


Figure 4: Proposed Design - Closed and Sealed

PROJECT MANAGEMENT

Breakdown of Work into Specific Tasks

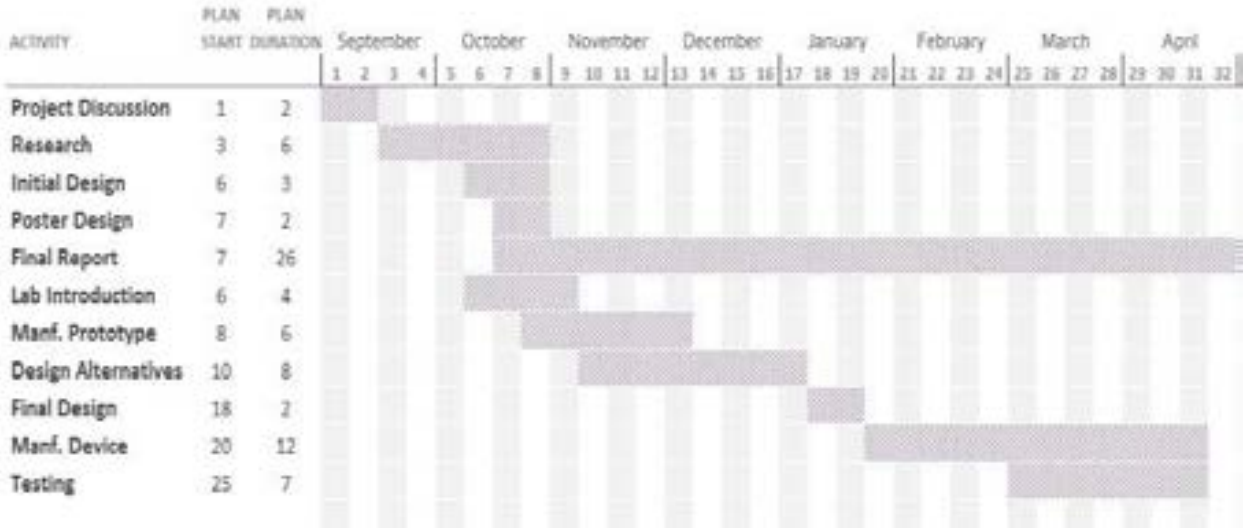
The responsibilities have been well distributed thus far. The entire team has all gone to the lab together to get a general overview of the machines in the lab and the process involved for creating our connector in the ceramics lab. While each task will have team input, certain tasks have been divided so each individual could become the expert of a given component. Each member put in approximately 40 hours for the fall semester including 8 hours in the lab.

Table 1: Work Distribution

Team Member	*Design*	*Lead Attachment*	*Testing*	*Manufacturing*	*Presentation*
James Ciurdar		***		***	***
Eric Doan			***	***	***
Samuel Grada	***			***	***
MariaMartha Lopez	***			***	***

Organization of Work and Timeline

Table 2: Project Timeline



ENGINEERING DESIGN AND ANALYSIS

Structural Design

The design for the microconnector does not call for a lot of structural considerations. This device will not be subjected to immense amount of forces. The one thing that needs to be considered is the microconnector becoming undone while the device is implanted. For this reason, a titanium clip is placed over the connector. This keeps the two halves of the connector from separating. In addition, there is a strain relief system in place for the wires coming out of the connector. Providing strain relief to the wires will limit the amount of force being applied to the micro welds as well as to the junction point between the wire and the connector itself.

PROTOTYPE CONSTRUCTION

Description of Prototype

One important aspect of the design is the connection pad design. In order for the 32, one mil, platinum wires to be easily welded into place while maintaining proper insulation and in-line configuration, there must be some separation of the pads. Separation in the z-direction would allow for the wires to be attached in groups (the group size being undetermined at this stage of the design). To allow for some separation of the pads, one possibility is to manufacture the pads in steps. One way to do this would be to mill the steps after the connector halves are co-fired. The design of the steps would necessitate multiple layers of platinum ink printing, which is electrically conducting ink printed on top of the LTCC material. This ink allows for the posts and holes to be connected to the corresponding pads within the connector body. Using this step design also allows the entire connector assembly to be as thin as possible while remaining resistant to outside forces.

Prototype Cost Analysis

The focus of the prototype is to determine manufacturability while trying to minimize costs. In order to minimize costs, LTCC was used instead of HTCC. LTCC costs $20 per sheet compared to $50 for HTCC. Each sheet could produce 25 layers with each device requiring five layers. The pastes used to make the posts for the prototype were silver and graphite. Silver paste costs $1.25 per gram while graphite costs $7.00 per gram. This compares very favorably to platinum paste which costs around $80 per gram. Platinum is the proposed material for the final device. There was approximately one gram of each paste for the prototype.

The second component of cost analysis for the prototype involves the human hours spent in the lab. As mentioned earlier, each member spent 8 hours in the lab in helping create the prototype. In addition to group members, Dr. Ali Karbasi assisted and instructed all group members for the 8 hours completed in the lab.

Table 3: Cost Analysis

Item	*Cost*	*Units Used*	*Hours*	*Hourly Rate*	*Cost Per Unit*
LTCC	$20.00	0.2			$4.00
Graphite Paste	$7.00	1			$7.00
Silver Paste	$1.25	1			$1.25
PlatinumPaste	$80.00	0			$0.00
Dr. Ali Karbassi			8	80	$640.00
Senior Group Lab Time			32	40	$1,280.00
				Total Cost:	$1,932.25

TESTING AND EVALUATION

Overview

Because this device will be implanted inside a body, it will be subject to various tests to determine whether or not its use is safe in the human body. While improving material selection and modifying the design due to manufacturability, the microconnector will undergo testing for hermiticity and conductivity. Hermiticity testing protocols involve leak tests such as the gross leak and fine leak test. These tests determine the effectiveness of the seal within the microelectronic. Upon successful completion of those tests, the microconnector can be tested for biocompatibility through feline studies and a simulated body fluid test. Successful results from those studies could result in application to the FDA for Investigational Device Exemption.

CONCLUSION

Conclusion and Discussion

With increasing advancement of micro technology as well as new discoveries in diseases, the demand for improved neurostimulators has increased. A microconnector that improves the interchangeability of the device is an effective measure against the problems with hardwired neurostimulators today. With double the amount of channels and reduced size, a streamlined design for the microconnector can accomplish this. The initial microconnector was built out of LTCC in order to reduce cost; however, for the final design, the microconnector will be composed of HTCC, titanium, and other biocompatible materials. Using the equipment in AMERI, the microconnector can be manufactured and tested to ensure success. Overall, improving the connector by increasing the posts and holes will make a surgeon's job easier as well as enhance comfort for the patient.

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