Final Detailed Design

Team 314: Abbott Reusable RF Probes

Introduction

Radiofrequency spinal ablation is a common medical procedure used in the treatment of chronic pain. To conduct this treatment, a stainless steel electrode is inserted into the spinal column where the aggravated nerve is located and uses an RF generator to heat the tip of the electrode to burn the nerve tissue. This process stops the nerve tissue from sending pain signals to the brain for six to twelve months. Our project mainly focuses on improving the reusability of an RF electrode that Abbott is currently producing. Their current reusable electrode has a lifespan of roughly 50 uses before it begins to physically degrade to the point of unusability. Abbott has challenged our team with redesigning the probe so that it can achieve a lifespan greater than 100 uses. To do this, we have broken down the current electrode into its various parts to investigate and determine exactly which components are limiting the lifespan so that we may improve upon the original design and achieve our goal.

After generating the customer needs, we determined the specific requirements for our design concept, which are: Signals from 2 Hz to 460 kHz can be transmitted, voltages ranging between 1.845 V and 7.2 V can be transmitted, Rf signal can be converted into thermal energy ranging from 50º C to 110º C, temperatures at the ablation site ranging from 50º C to 110º C can be read, reusability is at 100 uses or more, cost per unit is near $200, and the device can undergo repeated medical sterilizations after each use. After determining the requirements our project needed to meet, we were able to proceed forward with generating 108 possible viable concepts for our project before narrowing down our list to a select few concepts and choosing the best one to base our design on.

Design Concepts

We considered three different material choices for our design to replace the polymer used in the hub. The first material we researched was polyethersulfone, also known as PESU. This material offered good chemical resistance, a high heat deflection temperature of 204º C, and dimensional stability. This material is commonly used in electronics, health care, and the automotive industry. However, this material has a very high cost.

The second material choice we considered was Polycyclohexylenedimethylene Terephthalate, also known as PCT. This polymer had similar mechanical properties to PET (the material currently used to manufacture the hub). However, this material's resistance to hydrolysis and heat is superior to that of PET. This material is most commonly utilized in the electronic and automotive industries.

The third material choice considered was Polysulfone, also referred to as PSU. This material has outstanding mechanical, electrical, and thermophysical properties that allow it to tolerate high temperatures for extended periods of time while retaining a very high tensile strength. However, this material has poor resistance to a select few moderate polar solvents. It is most commonly used for components that are subjugated to steam and hot water, such as faucet components, hot water fittings, and medical devices.

Ultimately, our final concept was neither of the three above. We choose Polyphenylsulfone (PPSU) for our hub material and 304 stainless steel for our shaft material. PPSU was favored over the three materials previously mentioned because of its capabilities to withstand virtually unlimited steam sterilizations, according to the manufacturer. PPSU is a super-tough, high-heat polymer that has been used in the healthcare industry for over 30 years. This polymer passes ISO 10993 Biocompatibility testing, which is indicative of patient safety when the material comes in contact with the human body. Also, it has excellent resistance to commonly used hospital disinfectants. Medical grade 304 Stainless Steel was chosen for its excellent corrosion resistance, high strength, and oxidation resistance. It is also widely used in existing medical devices, such as orthopedic implants and surgical tools, approved by the FDA (proving its biocompatibility).

Detailed Designs

Upon further research, we found out that the hubs in the current Abbott prototype are filled with epoxy resin. Thus, we selected an epoxy resin to add to our final detailed concept. The epoxy we choose is Loctite EA ML-31.

Final Detailed Design

For our final detailed design, medical-grade 304 stainless steel material will be used for the shaft, polyphenylsulfone (PPSU) polymer will be used for the hub of the electrode, and Loctite EA ML-31 two-part epoxy will be used to fill the hubs.