Project Number: P13021

IMPLANTED TRANSCUTANEOUS ENERGY TRANSFER SYSTEM FOR LEFT VENTRICULAR ASSIST DEVICE

Alexander Turner	**Ariel Christopher**	**Charles Borton**
Industrial Engineer	Industrial Design	Mechanical Engineer
Ian Dominick	**Andrew Hladky**	**Mike Brown**
Mechanical Engineer	Mechanical Engineer	Mechanical Engineer
Kyle Pickard	**Paul Blaszczynski**	**Abdoulaye Diaw**
Electrical Engineer	Electrical Engineer	Electrical Engineer

Abstract

Left Ventricular Assist Device (LVAD) heart implants have helped hundreds of patients live longer, healthier lives, with many of them outliving their failing hearts and depending entirely on the LVAD pump. Currently, the LVAD is a bridge to a full heart transplant; a temporary life support measure. However, the possibility of using it as a destination therapy instead of a bridge is becoming increasingly realistic. As this change occurs, the support systems which control and power the LVAD are being examined more closely. The support systems have now become the weak link in heart pumps. One of the leading causes of death for patients is sepsis, which often starts at the drive line [1]. If the drive line could be eliminated and the system powered, controlled, and monitored wirelessly, then this treatment could further extend and improve the quality of life for those with failing hearts. Eventually this treatment may match or exceed the performance of a heart transplant.

One of the primary challenges is transferring the necessary power wirelessly. This project advances the usability and practicality of a system developed by a previous team, who explored the possibility of using magnetic couplings to transfer power across a gap. The goal of this project was to expand the scope of that system from a proof- of- concept prototype developed previously to a more comprehensive, potentially marketable, prototype. This was accomplished by developing an intuitive user interface and power conditioning system. The prototype can now be activated at the push of a button and it transfers enough power across a gap to run an LVAD pump and store the excess in a battery.

While a number of setbacks caused the team to miss opportunities for improving the transcutaneous transfer itself, the result of this project is a much more comprehensive prototype. The particular shortfalls are that the size constraints were not met, the implant generates too much heat, and the amount of power transferred was about half of the ideal value of 30 Watts. Improvements include the addition of a user interface, an implanted battery pack, and an integrated motor controller. It expands the boundaries of the system to include nearly all of the elements of a commercially viable device.

Nomenclature

AC: Alternating Current
DC: Direct Current
ESC: Electronic Speed Controller
LVAD: Left Ventricular Assist Device
FMEA: Failure Mode and Effect Analysis
PWM: Pulse width Modulation (Used in Arduino)
RPM: Rotations per Minute
Stator: A Coiled conductor that generates a potential when exposed to magnetic flux.
TET: Transcutaneous Energy Transfer
UI: User Interface
UX: User Experience
VCO: Voltage Controlled Oscillator (used in the Rectifier)
Xbee: Wireless Communication Chip
Arduino: Microcontroller Enclosed in the UI
Volumetric Energy Density: The amount of energy stored in a battery per unit volume.
Specific Energy Density: The amount of energy stored in a battery per unit mass.
Driveline: The cord/cable system through which power is transferred throughout the system.
Decubutis: The creation of a sore on the skin from excessive and prolonged pressure.
Therma Runaway: A phenomena which occurs in Lithium Ion batteries in which the internal temperature reaches a critical point and an internal reaction continues to fuel the heat increase until the cell explodes.

Introduction

The LVAD heart pump is used to assist or sometimes replace the function of a failing heart. For patients that have been dealing with a weak heart, the LVAD can increase the quality and longevity of their life. One patient, interviewed by the project team, who has had an LVAD for nearly 6 years now, remembers being short of breath simply while eating. A few short months later with the help of an LVAD, he was golfing. The device, however, is not without its shortfalls. Of patients with a heart pump who have died, the vast majority did not die because of pump related issues, but rather because of complications and infections associated with the driveline. The driveline, which must always be connected to a power source and a controller, can become infected as a result of trauma to the ingrown tissue around the cable or simply from bacteria that can be in the water used to clean it.

This project explores the possibility of eliminating the driveline all together by implanting a device that can accept wireless power and charge an implanted battery. This allows the patient to be completely independent of cables or additional equipment while the batteries are not charging. A previous team pioneered the wireless transfer prototype. The current project is focused on building a system which includes a user interface and power conditioning circuits that will allow the received power to charge a battery as well as directly power the LVAD.

Methodology

A previously constructed, working TET prototype was the basis of this project. Therefore, this team focused on expanding the scope of the system. This includes making the internal components implantable, developing a user interface (UI), and creating power conditioning circuits which allow the power to be used to charge a battery and power an LVAD pump. A basic flow of the power transfer and communication between devices can be seen in Figure 1. This report will examine each step in the process from strapping on the device to charging the battery and powering the heart pump.

Figure 1: Flow Path of Power and Communication Signals

User Interface and Experience

Externally, the entire process begins with putting on an elastic belt. Elastic material and Velcro is used to ensure a snug and comfortable fit around the patient's waste while ensuring that the belt would not move. It is important to keep the belt from moving because it keeps the external motor and magnetic array aligned with the implanted generator. Slight misalignment can be tolerated, but it increases the risk of decoupling the magnets or engaging them off center. This would prevent the system from running and may cause damage to the device. The belt is a tri-panel design, with the center panel resting on the patient's back. Velcro and contrasting white piping are used to ensure it is easy to take on and off, even for elderly patients with impaired vision.
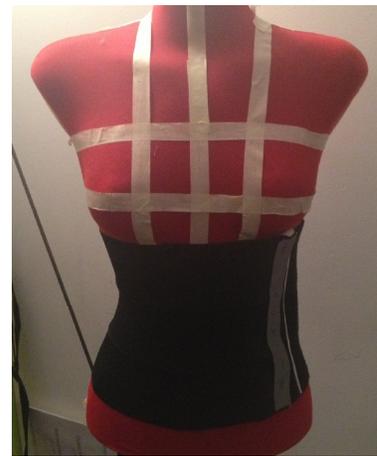
Figure 2: Final Belt Construction

Once the belt is secured, the patient begins the process of starting the device using the user interface (UI), a small handheld device which communicates the system's status to the patient. It utilizes an LCD screen to display the charge status of the implanted battery pack. The entire unit will vibrate when the implanted batteries are depleted and need to be recharged. There are three indicator lights which communicate the status of the power transfer process; whether or not it is initializing (red), ramping up (yellow), or at full speed and transferring power (green). The UI is designed to be small and light enough to be attached to the mounting belt or the waist of a garment. It continuously monitors the status of the system, and alerts the user of any action they need to take. To start the operation of the system, a single, large button needs to be pushed. The system requires 14 seconds from the initial push of the button to ramp up to full speed and power output.

Inside the UI is an Arduino, a small customizable micro-controller. As the patient starts the device, the Arduino reads the input from a push button on the UI and sends a signal along a three pin connector leading out of the UI module to the electronic speed controller (ESC) in the power supply. The ESC ultimately controls the motor. This signal is pulse width modulated (PWM) to allow the Arduino to control the revolutions per minute (RPM) of the motor during the ramping cycle, discussed later.

The Arduino also communicates with the Xbee, a small wireless communication device that reads a wireless serial line sent from the internal battery monitor. It also reads the voltage from the rectifier to determine whether or not the system is coupled and charging the battery. The battery monitor value is transmitted as a series of hexadecimal bits, which are reconstructed in the Xbee and sent to the Arduino to display. The LCD then displays the implanted battery charge status. The PWM signal being sent by the Arduino is compared to the measured increase in battery monitor levels. As a result, three indicator LEDs light as the power transfer increases.

The UI was designed using solid works and printed on a 3D printer. The printer uses acrylonitrile butadiene styrene, also known as ABS plastic to construct its models. The UI was printed with two halves, allowing it to be assembled easily by making it simple to create all the necessary internal electronic connections before sealing the two halves together. A battery door was also incorporated into the back half to allow the user to remove the 9V battery from the user interface when it is depleted. The UI was able to be prototyped with the necessary holes for the LCD battery status screen, LED ramping lights, and battery door. Much like a remote control, the battery located inside the UI will serve only to power the internal components of the device; none of this power will be used to power the external motor unit.

Figure 3: Final Rendering of UI Housing

While 3D printing is a great technique for bringing initial ideas and prototypes to life, it is a slow and inefficient process that is not well suited to high volume production. While the goal of this project was to yield a commercially viable prototype, the processes used to manufacture this prototype are far from commercial viability. The user interface design is best suited to an

injection molding process where costs per unit drastically decrease with high production numbers. The injection molding process can be accomplished in a much quicker time frame as opposed to the eight or more hours required for 3D printing.

External Unit (Motor)

Figure 4: External Unit Exploded Assembly

The PWM signal sent from the Arduino in the UI is received by the ESC and sent to each phase of the 3 Phase Maxon EC45 50Watt flat motor. This motor was selected for its ability to reach high speeds, approximately 10,000RPM, and it's stout shape. It is short enough to approach the stringent thickness specification (2") for the external unit. The motor then spins a magnetic array, which has been pressed and adhered to the motor shaft. The Arduino in the UI directs the ESC to slowly ramp the RPM to maintain the magnetic coupling between the motor and internal generator. The motor spins the magnetic hub array which then transfers power across the gap to the generator.

The previous team, P12026, manufactured their own magnetic couplings out of plastic and neodymium magnets. This magnetic coupling worked well, but it did have some shortfalls. As the distance between the couplings increased, the coupling would slip and begin to reduce power output. Additionally, due to some misalignment in the coupling, the system was difficult to start up. With these issues in mind, it was decided to use a purchased part as our magnetic couplings. A precision manufactured part would be better balanced and create a stronger, more consistent connection than a coupling manufactured in-house. In order to meet size and weight considerations, the MTD-0.6-0000 magnetic hubs from Magnetic Technologies, LTD is used in the system. A significant effort was made to model the pull force of the magnetic coupling and determine if the torque available would be enough to generate the optimal power. Additionally, the breakaway torque was tested to ensure that it would not exceed what the specified motor-generator pair could handle. At the desired separation distance between the implanted and external device, a pull force between 3-5N between the magnetic coupling was expected. This was well within an acceptable range where decubitus would not be a factor. The theoretical model and testing also showed that enough torque would be available with the chosen magnetic arrays to achieve the desired power range of 30-50W and that breakaway torque would not be exceeded with the specified motor generator pair.

The purchased magnetic hubs did require some modifications. There was a step on each hub of a smaller diameter that was faced down so that each magnetic hub would be shorter. Additionally, each hub required a hole for the motor shaft that had to be drilled. The smallest pre-drilled shaft size from the manufacturer was 6 mm, which is too large for the 4mm shafts on the Maxon motors.

The purchased magnetic arrays performed well. The magnets are strong enough that they do not slip with the selected motor-generator pair. There is either a one-to-one rotational connection between the magnetic arrays or little to no connection at all. Because there are so many magnets in each hub, if they begin to slip, then the individual magnets begin to rotate over an opposite magnetic field which then repels the magnets away from each other. This causes them to either slip or stop rotating at large separation distances. The internal unit will never be implanted deep enough for this phenomenon to occur. The maximum case to case separation distance at which the system will function under load is 13mm. Also, as the separation distance increases, the magnetic hubs tend to disconnect if the ramp rate of the motor is too high. However, with a slower ramp up algorithm they work well together.

Internal Unit (Generator)

Figure 5: Internal Unit Exploded View

`   The internal, or implanted, unit contains the receiving magnetic coupling which is pressed and adhered to the shaft of the generator. The generator is a three phase Maxon EC45 30watt flat motor. This AC power on each of the three phases of the motor must be rectified to DC power which can then be used to charge the implanted battery.
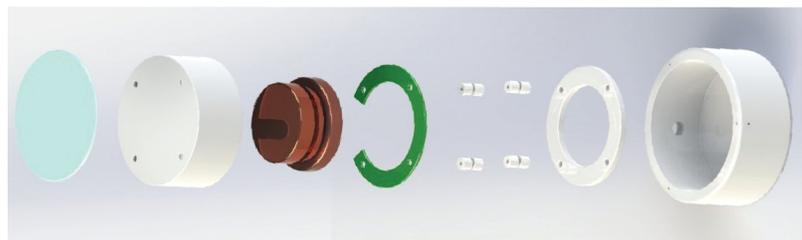
The rectifier enclosed in the generator housing is designed to tightly fit in the empty space around the generator. The rectifier is built on a breadboard which is partial ring of roughly ¼ inch width at an inner radius of

about an inch. This breadboard ring has bolt holes through it to mount the generator to the assembly casing. With the bolt holes and the small width that was available, the decision was made to use a soldering breadboard cut out to these dimensions. A PCB would not have enough room for the traces to be run with the bolt holes going through. The diodes are chosen to have a low forward voltage drop, fast switching, a high blocking voltage, and a high current capability. The chosen capacitors are as big as possible to reduce voltage ripple while still fitting in the available space.
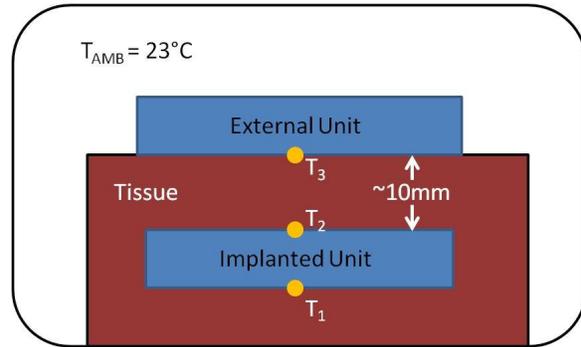
Figure 6: Thermal Testing Setup

One of the primary concerns associated with the implant is heat generation. Based on basic finite element analysis, it was determined that a heat sink would be required for proper heat distribution. The possibility of using a potting compound was considered, but later rejected. Minimal heat distribution gains would be obtained by using a potting compound. The absolute best thermally conductive potting compounds will not exceed a thermal conductivity of 3W/m·K, whereas an aluminum heat sink is rated at about 255W/m·K.. The original analysis was done assuming 50W of power generation and 90% efficiency in the generator as well as the rectifier, which was the original output power goal. Even if the 9.9W of heat were perfectly evenly distributed across the current housing (surface area of 184.8cm^2), then the heat flux would be 53.6mW/cm^2. This is already higher than the original specification of 40mW/cm^2 [2]. In the actual device, the heat cannot be evenly distributed so there will be concentrations of heat flux higher than 53.6W/cm2 to begin with. The only way to lower the heat flux through the internal device is to either use more efficient components or reduce power output. The former is possible only through advances in technology or a larger budget and the latter would result in falling short of the power generation specification. A new theoretical thermal model based on the actual power consumption was not created because it is difficult to ascertain the actual efficiencies of each component in each individual component of the system. Without these values, an accurate model cannot be made. A simple test was performed to determine the actual temperature of the units and the resulting heat flux from continuous operation.

The thermal testing performed was to determine whether or not the system would function within the maximum 40mW/cm^2 specification. The implanted unit was surrounded by raw ground beef with a thermal conductivity of about 0.4W/m·K, similar to human tissue. Three thermocouples were utilized, one located directly underneath the implanted unit, another directly on top, and another directly underneath the external unit. A basic diagram of the setup can be seen to the right in Figure 6. The system was run for 2 continuous hours like this which would be the typical charge time for the selected implanted battery. The maximum temperature recorded is 51°C at the point labeled T_3 in Figure 4. The device fails the thermal testing even when the power output is severely diminished. This is caused mostly by efficiencies much worse than 90% in the generator and rectifier because they are operating well outside of their nominal range at the lower power output. With respect to body temperature, 37°C, the maximum heat flux through the tissue is 53mW/cm^2. This is a rough one-dimensional estimate based on the maximum 51°C temperature and the thickness of the ground beef between the two units. The heat flux will most likely vary in a living organism.

Battery

Currently, most LVAD patients wear a vest outfitted with about nine pounds of batteries which run the LVAD. This allows the patient some basic freedom of movement throughout the day, but they must always wear the vest which is heavy and cumbersome. This significantly diminishes the quality of life of these patients. Ideally, these batteries would weigh less than one pound and would be implanted as well, allowing complete freedom for the patient while they are not connected to a power source.

The selected battery is not sufficient for a destination therapy device. However, it works well in this prototype as a placeholder for future battery technology that will have a greater volumetric energy density. For now, the battery was selected to best meet customer needs. Many battery chemistries and sizes were reviewed and ultimately the Tenergy Li-Ion 18650 2600mAh 18.5V rechargeable battery was selected. Within the $1000 overall budget, this is the highest performing battery available which would suit the needs of the LVAD system. Since it is lithium based, it is lightweight and has the best volumetric and specific energy density available while still being stable. Higher performing options exist, such as lithium polymer batteries, but they are not yet consistent and safe. This battery pack also has a built in power management circuit which balances each individual cell and prevents overcharging, which is the most frequent cause of thermal runaway in lithium ion batteries. This included circuit

helped reduce manufacturing and development time as one less custom board needed to be designed and manufactured.

Once rectified, the generated power from the internal unit is sent from the implant to the battery box. The battery is charged by any excess power not being delivered to the LVAD heart pump. Also located in the battery box is a monitoring system which continuously checks the battery's voltage level and sends the data wirelessly via an Xbee to the Arduino in the UI. Once the battery reaches its charged voltage of 21V, a signal should be sent to stop the charging process the stop the external motor. Unfortunately, the code for this process wasn't completed. Once the external unit is disconnected from the system then the LVAD runs solely on the power stored in the battery. The LVAD will run for about 5 hours solely on battery power. A signal is also sent wirelessly to the UI once the battery is near depletion, at about 15V, indicating that it must be recharged. In the battery box, the rectified power, which is at about 14V, passes through a boost converter to output 21V to the battery in order to charge it. From the battery, there are two separate outputs. One is to a buck converter which lowers the voltage to 3.3V to power the Xbee. The second is a 21V to 14.6V buck converter which outputs to the device made by P13022. Their system runs the LVAD.

Results and Discussion

The original goal of this project was to design a commercially viable and implantable device, one that could perhaps be tested inside a pig. The successes of this project do not extend so far, but they significantly expand on the successes of the previous team, P12026. In the end, the system created was merely a prototype and a proof of concept design. The greatest restrictions which kept the device from being implantable were the material used, the heat generation, and the power output. A final overview of each individual metric, it's specification, as well as the result of the project can be seen in Figure 7.

Engineering Metric	Importance	Location (Inside/ Outside)	Function	Specification (Metric)	Measured in: (Units)	Actual Value	Acceptable Value	Ideal Value
EM1	9	Inside	Output Power	Power	Watts	16	**10**	50
EM2	9	Inside	Voltage Output	Voltage	Volts	21v		21v
EM3	9	Inside	Product Life	Time	Years	~4 years	**7**	> 10
EM4	9	Inside	Waterproof	IEC60529	Ingress	Untested	**IP67**	IP68
EM5	3	Inside	Thin	Thickness	Meters	0.0354 (1.397 in)	**0.0254 (1 in)**	< 0.0254 (1 in)
EM6	3	Outside	Product Life	Time	Years	~10 years	**1**	5
EM7	3	Outside	Thin	Thickness	Meters	0.0421 (1.66 in)	**0.0508**	< 0.0508
EM8	3	Outside	Water-tight	IEC60529	Ingress	Untested	**IP43**	IP43
EM9	3	Outside	Time to Start	Time	Seconds	Estimated 30	**60**	5
EM10	9	Both	Reliable	% reliability	%	<95%		0.99
EM11	9	Both	Minimal Heat	Heat	Heat Flux	53mW/cm^2	**40**	< 40
EM12	9	Both	Electrical Insulation	Leakage	Amps	Leakage = 0 Amps		0
EM13	3	Both	Lightweight	Mass	Kilograms	I= 0.39	E = 0.44	**0.45**	< 0.45
EM14	3	Both	Small	Diameter	Meters	I =0.0823 (3.240 in)	**0.0762 (3 in)**	< 0.0762
EM15	3	Both	Contact Pressure	Axial Pressure	Pascals	689 pascals		<3500 pascals
9 = must have, 3 = nice to have, 1 = preference only								

Figure 7: Engineering Metrics and Associated Values

First, the material used for construction of the implanted pieces, the battery box and generator housings, was simple high density polyethylene plastic donated by Curbell. Any FDA approved plastic material for implantation would have cost about three times the original budget alone. With this knowledge, the team didn't pursue the original housing design to completion. In the CAD package, the housings should have rounded edges for comfort in implantation and the internal unit would be sealed via o-ring. However, these features were omitted to save time and for ease of constant assembly and disassembly. A commercially viable product would have to include these features. The battery box was also not designed to be sealed and implanted, which would have to change for production.

The heat generation of the combined internal and external device is also too great for implantation. Even though the heat is distributed more evenly throughout the internal unit than the previous team's attempt due to an aluminum heat sink, the heat flux is simply too large. The issue with heat generation is that there is simply a limit to how much heat can be produced in the small implant size. Either a much more efficient motor and generator pair needs to be used or the pair needs to operate closer to nominal efficiency. Until the efficiency of the selected motor and generator is much greater, the heat flux will always be above the threshold. Unfortunately, such a selection would have been well outside of the budget for this project. Currently, the generator is creating very little power and

generating a lot of heat, indicating that it is operating at a very low efficiency. If the current generator were to operate at peak efficiency and power output, then the heat flux would likely decrease.

Lastly, the power output of this device was insufficient to both quickly charge a battery and power an LVAD system simultaneously. While an LVAD requires at most 10W of power, an extra 40W of power would be required to charge an appropriate battery in about 1.5 hours. A 30W motor was selected to act as a generator over the previous team's 50W motor to help reduce the package size. The generator was also purchased at lower, 12V operating voltage instead of the previous team's 36V operating voltage. This resulted in different speed constants which meant that when used as a generator, it will greatly decrease the output voltage for the same RPM. With the higher voltage difference for the same load, a higher current would flow which would mean there would be more torque on the magnetic coupling; but there would also be a greater power transferred. Initially, when choosing the generator, it was assumed that a 30W motor would act as a 30W generator because the current would increase for a lower voltage motor with the same power rating. This assumption was incorrect because the output voltage is actually a function of the RPM and the current is based on the load.

 Current battery technology is sufficient to power this device for 8 or more hours without connecting to a power source. Future iterations of this project may consider using lithium ion pouch cells instead of the commercialized 18650 form factor for weight and size considerations. However, pouch cells are much less safe and do not have the protection of an aluminum casing in the case of a thermal runaway. In order for the LVAD system to run for 8 hours without a recharge, a battery pack with a capacity of approximately 56Wh, or 3000mAh at an average voltage of 18.5V must be used. Currently, the battery pack will last up at 5 hours when connected to a 6.4W system. According to data collected by team P13022, an LVAD runs at approximately 5.5W. When strained, the system power consumption will increase. In order to mimic a worst case scenario, the battery was tested on a 6.4W system.

In order to quantify the contact pressure of the device, the magnetic force between the couplings was measured using a test rig built for that purpose by a previous senior design team, P12022. At the minimum depth of 10mm below the skin at which the internal unit is expected to be implanted, the pressure was at 689Pa. This result is a fraction of the acceptable 3500Pa value [3]. The contact pressure is not a concern during the charging cycle.

Both the internal and external units were weighed on a balance after they were assembled. The internal unit weighs only 0.39kg and the external unit weighs 0.44kg. Both of these values are just under the acceptable maximum value of 0.45kg.

The team was tasked with creating an implant which would be "about the size of a hockey puck". Based on this rough estimate, the team set forth a maximum diameter of 3 inches and a maximum thickness of 1 inch. The current prototype measures 0.240 inches over on the diameter and 0.397" over on the thickness for a few reasons. Any spinning components need clearance room; the current setup allocates 0.050" of radial and axial clearance between stationary and moving parts. The electronic components cannot be placed next to or in front of the magnetic array or there would be interference with the rectifier. The extra radial space in the implanted unit is being occupied by internal components for the rectifier. This package is quite dense when taking into consideration that the implanted unit contains the rectifier in addition to the generator and magnetic array. The previous team did not include a rectifier in the implanted unit.

The magnetic array which was chosen for increased torque transfer and power generation caused the thickness to go over 1 inch. The chosen generator and hub measured 1.03 inches when assembled, already over specification. The savings of using a smaller generator were offset by utilizing a purchased magnetic array. Despite lower power output, the use of a purchased magnetic array is still be justified by the consistency and strength of the magnetic coupling at large separation distances.

After performing a fairly basic FMEA on the device, based on the 7 year life specification, the largest risk to the patient is the degradation of the battery. It is not an immediate risk, but it will force the patient back into surgery early and often to have the battery replaced. This greatly limits the system's ability to meet the product life specification
.

The reliability of the system isn't quantifiable, but it is questionable. Each component is reliable on its own, but there are chains of single point failures within the device. Particularly the flow of information from the battery to the patient via the user interface and wireless communication is susceptible. A failure anywhere along that chain could cause a sudden, undetected failure of the LVAD and also pose a great risk to the patient. Without more data about each component, it is impossible to calculate the reliability. That being said, without parts that are more rigorously tested, the system cannot confidently be said to have met the reliability specification of 99%.

An actual implanted device would have to be completely watertight. However, the current prototype would mostly likely not be watertight. The original design incorporated an o-ring groove at the top in order to completely seal the device. The actual product should be manufactured from PEEK or UHMWPE in order to achieve a truly medical grade device and include the o-ring seal found in the original CAD files. Such materials unfortunately are not within the budget.

The team was able to successfully connect to the system developed by P13022 and transfer power. When the P13022 system was connected to an LVAD and had a fully discharged battery, the TETS device was connected. It was able to power both P13022's control systems as well as the LVAD.

Conclusions

Looking back on the process of designing and building this prototype, there are clearly opportunities to improve. Setbacks, some preventable, some not, left a number of our specs unachieved, with opportunities for improvement on the table. This team's work in creating a system around the transcutaneous transfer has definitely moved what was a proof of concept towards a commercially and medically viable implant system.

Future teams would do well to move forward with this team's work alongside the successes of team 12026. Combining their thorough technical analysis with this team's comprehensive approach to the system should yield a system which is ready for implementation in the near future. It would also be beneficial consider different form factors for the battery, a generator with a higher operating voltage, and using medical grade materials for the housings. Creating a smaller package may be possible by creating a custom magnetic array which is precision machined and balanced instead of purchasing a commercially available product. The battery box, which was not designed to be implanted, should also be modified to properly house the printed circuit boards and battery pack in a smaller, sealed unit.

References

[1] Lietz, Katherine, et al., 2007, "Outcomes of Left Ventricular Assist Device Implantation as Destination Therapy in the Post-REMATCH Era," Center for Advanced Cardiac Care, Division of Cardiology, Columbia-Presbyterian Medical Center, New York, NY.

[2] Griffith, Jim M., et al., 1997, "Human Skin Temperature Response to Absorbed Thermal Power," W. L. Gore & Associates, Inc., Phoenix, AZ.

[3] Chesterton, Linda S., et al., 2002 "Gender Difference in Pressure Pain Threshold in Healthy Humans," Keele University, Staffordshire, UK.

Acknowledgements