ABSTRACT

Title: PROTOTYPING A PIEZOELECTRIC ENERGY-HARVESTING SYSTEM FROM THE SIMULATED MECHANICAL PULSATION OF A 3D-PRINTED HEART MODEL

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Abstract: Individuals have to frequently undergo pacemaker replacement surgeries

increasing the chance of surgical complications. A system was developed for an alternative energy source for pacemaker technology. We aimed to capture energy from the mechanical pulsation of a 3D-printed synthetic heart - as a viable simulation of a functional adult heart - using different types of piezoelectric materials. Our study evaluated maximum voltage captured by piezoelectric materials from pulsatile stimulation of the heart model. Initial tests generated 9V, suggesting that piezoelectric material is an adequate alternative energy source for pacemakers. Future investigation will aim to optimize the electrical and mechanical parameters of our system, laying the foundation for the development of a “heart-powered pacemaker.” Our research investigates the feasibility and mechanisms associated with harvesting mechanical motion from the heart itself, converting it into usable electrical energy, and evaluating whether this captured

and converted energy is sufficient to power a commercially used cardiac pacemaker.

PROTOTYPING A PIEZOELECTRIC ENERGY-HARVESTING SYSTEM FROM THE SIMULATED MECHANICAL PULSATION OF A 3D-PRINTED HEART MODEL

By

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1. INTRODUCTION:

Roughly six million people live with life-sustaining cardiac pacemakers worldwide. Currently, pacemakers are powered by lithium ion batteries, which have a lifespan of 6-7 years on average (Nery, et. al, 2010). This suggests that about one million people in the US undergo invasive pacemaker battery-replacement surgeries every year. Over the course of their life, most people who require a pacemaker to regulate their heart will require battery-replacement surgery up to 3 times. Avoiding the need to replace pacemaker batteries would reduce the frequency of invasive surgical intervention, as well as the risk of infection associated with such an invasive procedure. Studies show that up to 2.2% percent of pacemaker-related surgeries result in infections, often leading to subsequent surgeries or even death in extreme cases (Shulz, 2009). In a study done in Germany that looked at the 27,000 deaths, 15 were pacemaker-surgery related (Schulz, 2009). Although, seemingly a small percentage of complications, it is crucial to evaluate the cause and nature of these deaths. From a public health standpoint, 1% of pacemaker replacement related casualties is a sufficiently low number, taking into account the size of the overall population. However, optimizing the system to potentially reduce this rate further is our perspective. It is also reported that pacemaker batteries fail more often than manufacturers are willing to acknowledge (Kesich, 2011).

This study will focus on 3D-printing an anatomically correct heart model that will be programmed to pulsate at the same rate. Volume displacement will also be measured to replicate the stroke volume. It will also be revolved around measuring and collecting energy from piezoelectric materials, connected to the 3D printed prototype.

1.1. Pacemakers: Benefits and Limitations

This project strives to eliminate the associated risk of cardiac implantable electrophysiological devices (CIED). A paper published in the Journal of the American College for Cardiology analyzes probability of acquiring an infection with a CIED, specifically for pulse generator replacement with either dual-chamber or cardiac resynchronization devices (Greenspon, 2011). Analysis of 15 years of data collection from this longitudinal model suggests that the current infection rate of infection for CIED implantation is 1.1%. In Figure 1, the graph from “16-Year Trends in the Infection Burden for Pacemakers and Implantable Cardioverter-Defibrillators in the United States” shows an upward trend in the demand for pacemakers as well as the increasing incidence of CIED.

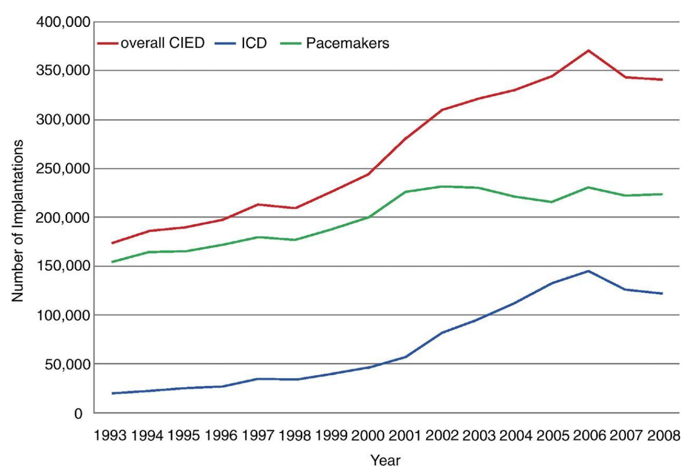


Figure 1.1. Graph showing the positive trend of pacemakers and CIEDs after a 16 year long study.

This graph ultimately supports that many patients are impacted by post infection consequences from pacemakers and that the invention of a rechargeable pacemaker would decrease this trend. This paper is relevant to team CARDIO because an alternative pacemaker sustainably powered by the beating of the heart would decrease the amount of surgeries and thus decrease the probability of complications during minor, frequent surgeries.

The detrimental effect of pacemaker replacement surgeries on post surgical recovery is further elucidated in a growing body of literature. One study conducted by researchers at the School of Medicine in Shanghai looked at complication and mortality rate for patients receiving a second pacemaker-related surgery. The study considered a sample of patients who underwent invasive surgery to replace bioprosthetic-related devices, most of which were required due to pre-existent infections. Of 26 patients monitored, 11.5% died shortly after the surgery and another 7.7% required subsequent surgery due to recurrent infections. There were no deaths related to thrombosis, embolism, or bleeding, indicating that operative-induced infections are a leading cause of concern in patients with bioprosthetic implanted devices. The researchers concluded that the increasing number of patients with bioprosthetics, including pacemakers and tricuspid valves, will lead to higher numbers of post operative deaths and other complications if infection rates cannot be reduced (Zhiwei 2017).

Surgeons at the Department of Cardiovascular Surgery in Osaka, Japan, investigated the standard procedures for defining the optimal treatment for pacemaker related infections (Satsu, 2010). They found that although these infections are serious and often fatal, there is no standard of care method to treat them. Often, if inflammation goes unnoticed for prolonged periods of time, the patient would require an invasive surgery to directly target the infection with antibiotics, putting them at additional risk for excessive bleeding and additional infections. If, however, the pacemaker-induced infection was identified early on, a technique known as vacuum assisted wound close could be used as a less-invasive option. The wounds would still require sutures and the procedure takes an average of 19 days, however the risk for subsequent infections is greatly reduced. Optimally, a non-invasive alternative would eliminate infections and not require any form of surgery (Satsu, 2010).

1.2. Surgical Complications of Pacemaker Insertion

Initial pacemaker insertion is considered a minimally invasive procedure, negligible post surgery restrictions. The procedure itself is also relatively painless and most patients only need minimal pain medication afterwards (Yarlagadda 2014). The most widely employed technique by physicians is a transvenous incision to expose the heart chambers with a local anesthetic. Once the local anesthetic, dosage dependent on body weight, is administered intravenously an hour before the actual procedure, the physician can then access the pectoral site (the chest) for insertion of the pacemaker. In addition, prior to the procedure, an antibiotic is also administered to the patient in order to protect against potential bacterial infections.

After administration of preoperative antibiotic and anesthetic a needle is used to access a central vein of the body, such as the subclavian or the jugular, to maneuver a guide wire to the right atrium or the vena cava area, the area that deoxygenated blood back to the heart. A guide wire is inserted through the needle, and the guide wire itself is utilized later in the procedure to insert a dilator, sheath, and the leads. After the guide wire is in place, the needle is removed, and if necessary for the patient, another guide wire will be inserted. Once the guide wires are in place, a pocket is created in the infraclavicular area, or right below the shoulder, for the implantation of the pacemaker. The guide wires are utilized at this point to place a sheath and dilator in the right atrium. Once the sheath is in place, the guide wire and dilator are retracted. A thin wire, known as a stylet, is then inserted and adhered to an integral channel of one of the pacemaker leads to confer more rigidity (Yarlagadda 2014). The stylet is maneuvered to lie across the tricuspid valve, which then enables it to subsequently move the ventricular lead to the tricuspid valve. Once the leads are placed in the correct position, then the leads are adhered to the endocardium, either with a screw or miniature hooks called tines (Yarlagadda 2014).

At this point, the sheath that was placed prior is removed from the heart, while the lead remains attached to the endocardium. 10 Volts are then delivered through the leads to ensure that the leads do not inadvertently stimulate the diaphragm in addition to the heart (Yarlagadda 2014). Inadvertent stimulation of the diaphragm would lead to uncontrollable expansions of the lung. After the injected voltage, the proximal end of the lead is then affixed to part of the cardiac tissue with nonabsorbable sutures. These sutures firmly attaches the proximal end of the lead to the tissue underneath and make sure that the lead does not slip or become displaced over time. Once the proximal lead is maneuvered into place and attached to the underlying tissue, the entire pocket in the infraclavicular area is washed with antimicrobial solution, and the primary pulse generator of the pacemaker is attached to the leads secured prior (Yarlagadda 2014). The pulse generator can also be affixed to underlying tissue with non-absorbable sutures, similar to the proximal leads were attached to the tissue in a prior portion of the procedure.

After the leads and the pulse generator have been implanted in the patient, the pocket is closed with absorbable sutures, as well as strips of adhesive. The arm on the same side as the sealed pocket is also immobilized for a period of around 24 hours to inhibit any movement and possibility that sutures may rupture after the operation. A short while after the completion of the procedure, a chest radiograph is conducted to ensure that the leads and the pulse generator are properly in place and have not moved since the operation. These radiographs also serve to rule out potential pneumothorax due to the implantation of the pacemaker (Yarlagadda 2014).

1.3. Normal Blood Perfusion

It is well known that the normal heart rate for adult humans ranges from 60-100 beats per minute. Additionally, the heart is able to pump around 70 mL of blood per beat, as also commonly known in documents by Swedish researchers in article published in Acta Physiologica (Holmgren, 1960). This translates roughly into a volume of around 5.6 liters of blood passing through the heart every minute. This indicates a change of volume of this same amount in the heart, which would likely be significant if its mechanical motion was harvested and converted into electric potential.

Blood is also both more viscous and more dense than water (and air), so for experimental purposes, if one wanted to achieve the same displacement of volume of water or air to match that of blood being displaced by the heart per beat, less mass of fluid would be required (Kenner, 1989). For purposes related to collecting mechanical energy to be converted into electrical energy, it is volume that dictates how much energy will be harvested. It is important to note that the viscosity difference between the model and actual conditions may have small effects on the harvesting abilities of the piezoelectric material, although if small enough they can be considered negligible.

1.4. Energy Storage for Charging Pacemaker

Energy conversion and storage are essential components for a successful piezoelectric based energy-harvesting system that ultimately will power a pacemaker. Energy must be converted to a useable form that would be adequate to sustainably power a low voltage device. There are many forms of energy from somatic cells that can be directly harvested for use or converted to another form. Energy output of select somatic cells include mechanical, vibrational and electrical energy.

One research group focused on converting biomechanical energy created by muscle movements into electricity using a piezoelectric nanowire-based Nanogenerator. Our group used a similar principle by harnessing the mechanical pulsation of the heart by converting it to electrical energy. Piezoelectric wires are very reliable material that are able to create electricity upon direct contact including mechanical interaction. Yang describes his single wire generator (SWG) that consists of a substrate and an attached wire that helps facilitate the flow of electrons when paired with SWGs, can conduct electricity up to 0.1-0.15 volts. Up to four SWG's can be integrated to increase the voltage output. This study shows that piezoelectric beams and/or cantilevers have proven to effectively harvest mechanical and vibration energy. The research focuses on a variety of muscle movements ranging from tapping of a finger to running. The SWG is attached to a finger and the movement of the finger causes ZnO NW to deform which then produces a piezoelectric potential within the wire that pushes the flow of external electrons to produce electric power output (Yang 2009). The SWG's results have supported that piezoelectric wires are successful in harvesting biomechanical energy from muscle stretching, such as a human finger tapping or even the body movement of a live hamster.

Another team additionally explored the idea of eliminating batteries from biomedical devices like pacemakers, heart rate monitors, cardioverter defibrillators, etc. because cardiac movements are an inexhaustible form of energy that can conduct mechanical to electrical transduction mechanisms with piezoelectric materials (Dagheviren Canan, 2014). This group developed flexible devices using piezoelectric

ZnO nanowires. The article harvested energy from the heart, lungs and diaphragm proving that piezoelectric nanowires can harvest a significant amount of energy.

Use of piezoelectric energy harvesters can pick up energy from cardiac motion, muscle movements, and blood circulation to convert that energy to electrical energy. Many teams have looked at piezoelectric materials such as: ZnO nanowires, BaTiO3 thin film, and lead zirconate titanate thin films (Yang et., al 2013). They have been able to provide energy for devices; however, they do not provide enough energy to power a cardiac pacemaker efficiently. There are other materials that have piezoelectric charge coefficients, which allows a higher conversion rate of mechanical to electrical energy (Yang et., al 2013).

1.5. Piezoelectricity

The piezoelectric strips used in this research are thin pieces of metal surrounded by positive charges on one side, and negative charges on the other. Piezoelectric materials can also be in crystal forms, such as quartz, topaz, and cane sugar. The root of piezoelectricity, piezo, is Greek for pressure to clarify that when pressure is applied, an electricity will initiate. A piezoelectric material is neutrally charged at rest in an undeformed position. However, when stress is applied to this structure, the previously charge canceling microscopic dipoles spread charge across the material. This alternating current voltage is created and then can be stored to sustain electricity to devices (Anton, 2007). Similarly, if a current is applied to the material, there will be a deformation (Anton, 2007). Piezoelectric materials have huge potential in creating a more sustainable future. These materials tend to discharge the electricity as soon as it is connected to a load, so to be successful, this device will require sustained pulsation or vibrations as opposed to a constant pressure (Anton, 2007). Team CARDIO has used various forms of piezoelectric materials (strips, ropes, films) that all ultimately produce electricity when deformed.

1.5.1. Poling. The properties of piezoelectric materials vary depending on the different poling processes with which they were made. Dr. Shifeng supported in his paper that amplified piezoelectric properties are developed by increasing the poling field, poling time, and poling temperature (Shifeng, 2004). Poling is implemented to make piezoelectric materials much more sensitive to changes in pressure or electricity. In Dr. Shifeng's development of lead zirconate titanate (PZT), researchers apply an electric field to align the dipoles to face the same direction, this way one side will have negative charge and the other positive upon deformation (Shifeng, 2004). Team CARDIO does not need to design the poling properties of the piezoelectric materials used, however, this process is taken into account in understanding the different properties of various piezoelectric materials.

1.5.2. Polyvinylidene difluoride (PVDF). Team CARDIO primarily conducted experiments with this material due to its properties that encourage its incorporation into smaller, wearable devices. PVDF is a piezoelectric polymer made up of repeating CH2-CF2 monomers, as shown in Figure 2.2 (Ueberschlag, 2001).

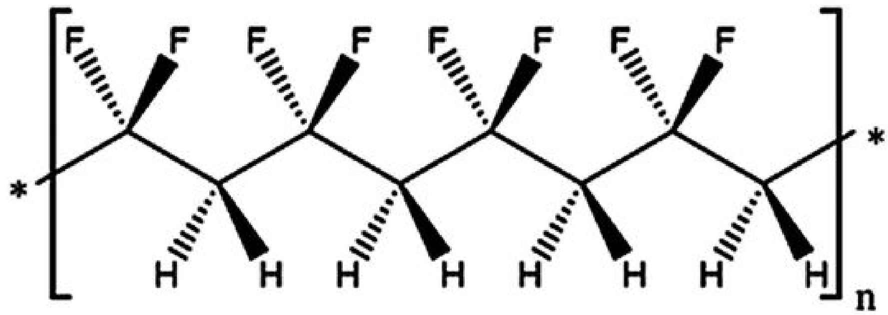


Figure 1.2. The atomic structure of PVDF as a piezoelectric material (Li, 2014).

The asterisks on either end of the figure represent the atomic structure of PVDF stretching indefinitely in either direction.

According to "Energy harvesting from low frequency applications using piezoelectric materials," PVDF is the most common piezoelectric material used (Li, 2014). The piezoelectric polymer is beneficially more flexible compared to other categories of piezoelectric materials such as ceramics and crystals. This flexibility allows the material to withstand more mechanical resistance because it can create electricity by stretching and bending as opposed to receiving a direct pressure force (Ueberschlag, 2001). Additionally, a flexible material can be applicable to more designs with inorganic or curved surfaces since the material can be more easily molded. PVDF additionally has a more lightweight nature than alternatives like PZT because it is semi-crystalline film. In fact, piezoelectric polymers have densities less than 1/4 of PZT ceramics (Li, 2014). This is significant to take into consideration when striving to create a wearable, lightweight device. For example, PVDF has been used to power wearable items like shoes and backpacks (Li, 2014).

1.5.3. Lead Zirconate Titanate (PZT). PZT is a ceramic with it's most common forms being PZT-5H and PZT-5A (Li, 2014). Figure X shows that this structure is made of repeating monomers of Pb $[Zr_xTi_{1-x}]O_3$ (Piezo Technics).

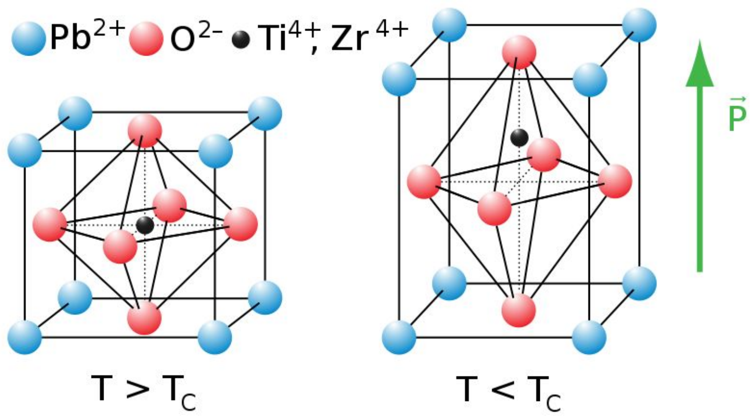


Figure 1.3. The structure on the left shows PZT stable above the Curie temperature (T_C). *The structure on the right shows a pressure applied to the PZT crystal, and is labeled that the temperature is less than the Curie temperature, indicating the structure is not stable, and electricity will be created.*

Most piezoelectric materials used in contemporary times are composed of some form of PZT. This is due to its low cost, strong piezoelectric properties and its high Curie temperature (Li, 2014). Above the Curie temperature, the ability of the piezoelectric material to depolarize is lost (Ueberschlag, 2001). PZT is often integrated into cantilever designs stacked in sheets and plates because ceramic piezoelectric materials can withstand stronger mechanical forces. This material was not used in team CARDIO's experiments because its properties were not as suitable for lightweight, wearable devices, and it additionally was more challenging to find and order in various shapes and sizes.

1.5.4. Micro-electro-mechanical System (MEMs). Due to the challenge in charging a piezoelectric material, MEMS was explored as a solution. Dr. Yu and Dr. Zhou combine a vibration-based MEMS device with a piezoelectric energy harvester to amplify the piezoelectric material's voltage output (Yu, 20014). In this study, the MEMS was wireless and able to be implanted. These researchers glued strips of PZT to a cantilever that had a frequency of its own to maintain a constant vibration (Yu, 2014). Although, this device can amplify output signal, it requires battery replacement so the piezoelectricity would be used to recharge the MEMs as well. A MEMs device could be used in team CARDIO's ideal prototype to amplify the signal from the piezoelectric material.

2. MATERIALS AND METHODS

2.1. Materials

The three types of piezoelectric materials used in our study are ultrasonic transducer Dual Layer 110m, piezo-polymer coaxial cable, and silver ink polymer, all manufactured by TE connectivity. For the construction and printing of the 3D heart models, a Connex 300 3D printer from the University of Maryland was used. During experimental testing of the maximum voltage acquired from material deformation, an oscilloscope was used for data collection. The oscilloscope utilized for our study was the DSO-X-2014A InfiniiVision 100Hz from Agilent Technologists.

2.2. 3D Printing

An STL file was created for 3D heart model which was scaled down 1.5X. Semiflex PLA proved to be the best material to use for printing. PVDF material was then attached to the 3D printed heart model using a variety of strategies including silicon based adhesive, hot glue or rubber bands in order to optimize the power generated by the model. Oscilloscope was then connected to the model to record the voltage. Pulsatile pressure was applied simultaneously to mimic normal cardiac pulsation. Initially a rudimentary model was used, simply to mimic the overall shape and volume displacement of a human heart during a cardiac cycle. Once this model was verified as suitable for experimental purposes, a more anatomically correct model, with specific wall thickness and contours, was used as the standard for the rest of the project (Figure 3.1).

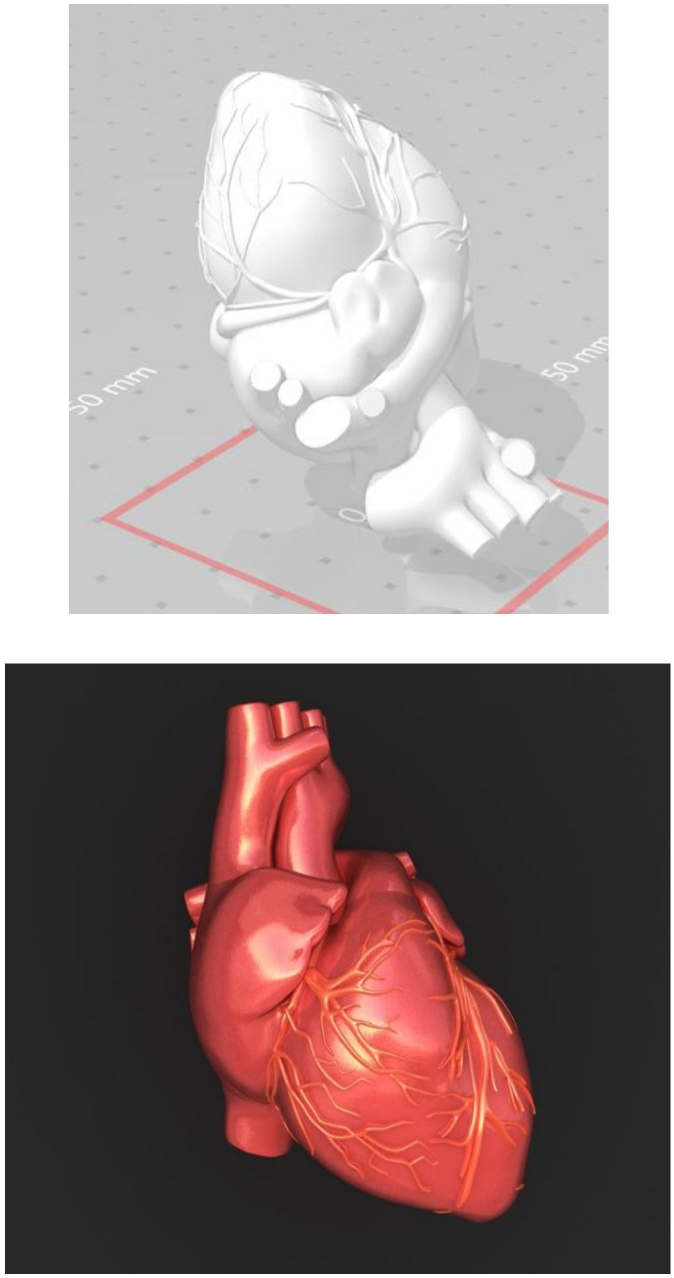


Figure 2.1: STL file of complex 3D heart model. Right image is colorized version of left.

2.3. Testing

Data was gathered for three different types of piezoelectric materials attached to the 3D printed model using elastic. A set of control measurements was done for each type of material by simply bending/tapping without involving any sort of attachment. Various 3D printed hearts were utilized for the voltage tests related to attachment, and in all cases a rubber band was used to hold the PVDF in place while heart pulsations were manually simulated. Both maximum voltage as well as voltage peak to peak were recorded for each test, using an oscilloscope with probes attached to the piezoelectric material. 25 trials were conducted per material/test condition, and results were graphed to compare statistical significance.

3. RESULTS

Initial tests were conducted using the Dual Layer Transducer PVDF with simple heart model to test two parameters; (a) whether the piezoelectric material can generate minimum voltage and (b) whether the material used for printing 3D heart is sufficient. Results indicated that the piezoelectric material is adequate as it alone generated around 40V while the piezoelectric material attached to the heart generated around 4V when pulsated (figure 3.1). 4V were enough to power a rechargeable battery for the pacemaker as only 2-3V are necessary. Additionally, the material used for simple heart needed to be less flexible and thus for the complex heart model, semiflex was used. Furthermore, our initial testing with the piezoelectric material attached to the simple model suggested the use of another method to attach the piezoelectric material with the heart as the glue interfere with the ability of the piezoelectric material and damaged the material.

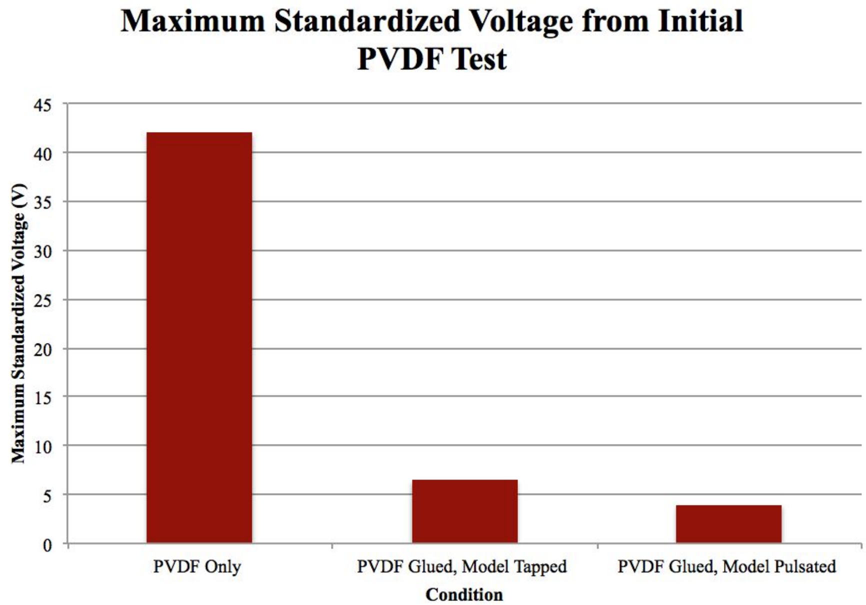


Figure 3.1: Maximum Standardized Voltage from preliminary PVDF tests. *Initial Test for generating voltage using PVDF dual transducer layer piezoelectric material in three conditions (a) alone, (b) when glued to model (c) when glued to model with model is pulsated. Values indicated by bars are average measurements.*

After the initial testing, our group printed a final model heart out of semi-flex which represented an actual human heart in appearance and dimensions which was made from our STL file(figure 3.1). We then measured mean internal volume (mL) for both of the models. Our data indicates that the new model, the complex heart model better represents human heart. As seen in figure 3.2, mean internal volume for complex heart was around 70-80 mL compared to about 260-270 mL for simple heart model. On average, human heart pumps 70 mL of blood.

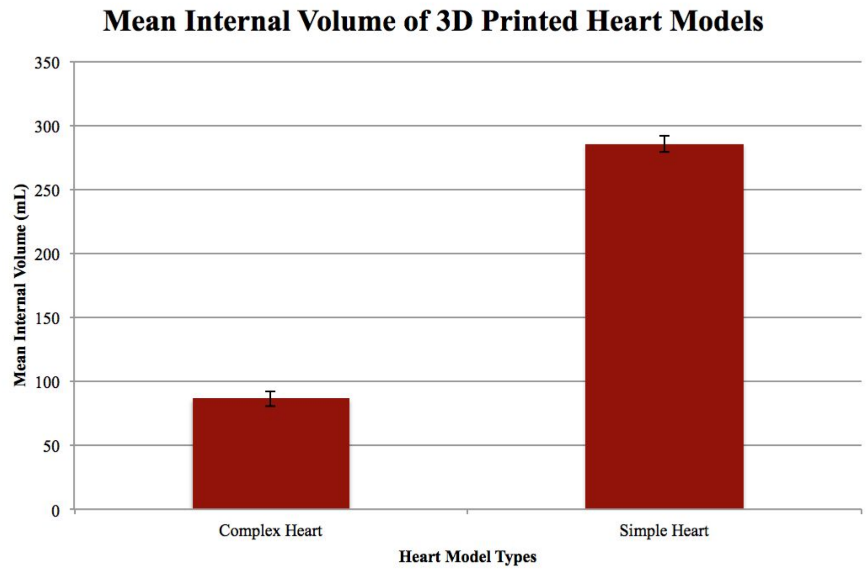


Figure 3.2: Mean Internal Volume Measurements acquired from Heart Models. *The data represents the internal volume measured in mL of the 3D-printed heart models, both simple and complex. Both are statistically different. Data are average ± standard deviation (n =10).*

Next, our group ordered different types of piezoelectric material to assess the effectiveness of different piezoelectric material. The types of piezoelectric material used were PVDF in three different forms: (a) dual layer transducer, (b) silverink polymer and (c) silver piezo film. From our initial testing, we concluded that an alternative method of attachment is needed and thus elastic was used to connect the piezoelectric material with the heart model. Simple heart model was used for preliminary testing of all three piezoelectric material. As seen in figure 3.4, piezoelectric material alone generates more energy than when attached with a model that is pulsated. Additionally, dual layer transducer outshines the other piezoelectric material with 35V compared to about 26V for silverink polymer and about 2V for silver piezo film. Furthermore, dual layer transducer again generates higher voltage than other materials when attached to the heart model (~ 6V) (Figure 3.3).

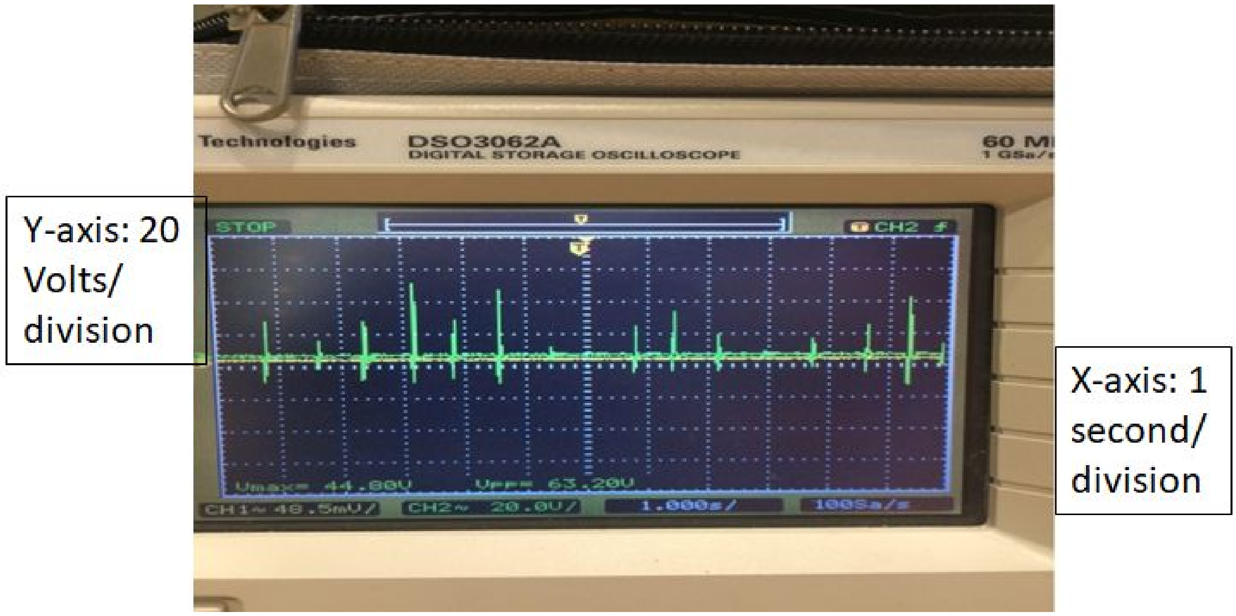


Figure 3.3: Oscilloscope reading output measured. *The voltage was obtained when the Complex Heart Model was mechanically pulsated with the dual layer transducer piezoelectric material attached to it. As shown at the bottom of the image, the x-axis is 1 second per division while the y-axis for channel 2 (the green line) is 20 Volts per division.*

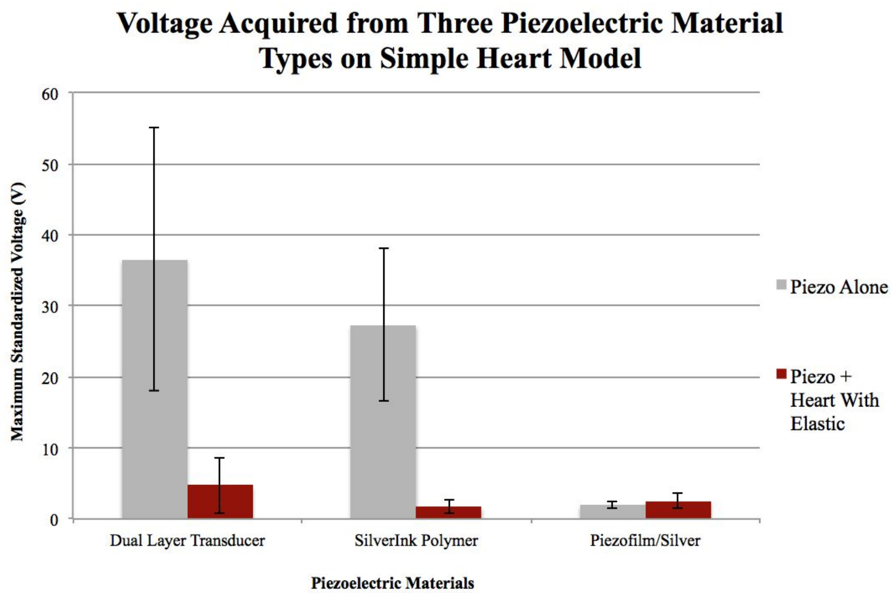


Figure 3.4: Maximum Standard Voltage Testing using Simple Heart Model. *Voltage readings from the pulsatile motion of simple heart model when attached to three different piezoelectric materials compared to using piezoelectric material alone. Data are mean ± standard deviation (n= 25).*

Finally, our group decided to test all three piezoelectric material with the complex heart model. As seen in figure 3.5, piezoelectric material alone generates more energy than when attached with a model that is pulsated, which was expected based on previous testing. Furthermore, as predicted the dual layer transducer exceeds the amount of voltage generated when compared to other piezoelectric material with 35V (compared to about 25V for silverink polymer and about 1V for silver piezo film). Dual layer transducer attached to the complex heart model generated the highest amount of voltage than any condition (~ 9V). It was interesting to observe that for the silver piezo film, voltage generated was higher when attached to the heart model (~ 5V) compared to alone (~1V) but the results were statistically significant.

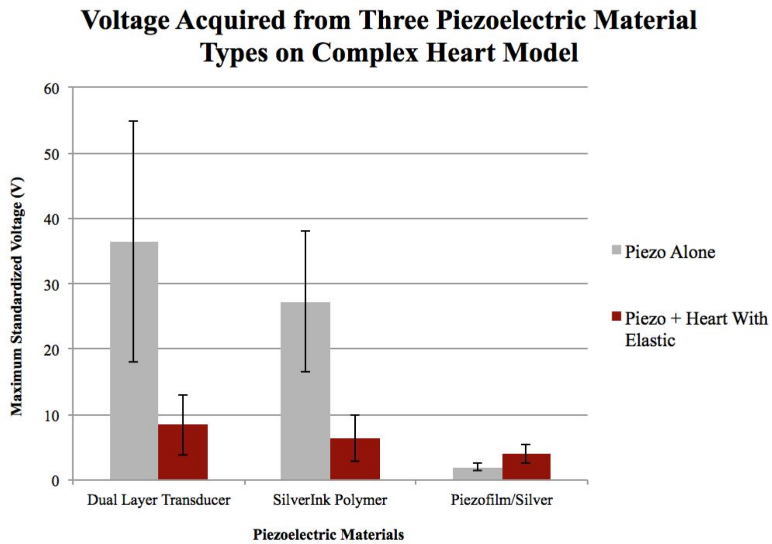


Figure 3.5: Maximum Standard Voltage Tested using Complex Heart Model. *Voltage readings from the pulsatile motion of complex heart model when attached to three different piezoelectric materials compared to using piezoelectric material alone. Data are mean ± standard deviation (n= 25).*

After collecting data for three types of piezoelectric material, each with and without being attached to a heart model, a box and whisker plot was constructed to identify any possible differences in the mean of the samples. The maximum voltage generated for each of the three materials while attached to the 3D heart are plotted in Figure 3.6. The red lines indicate the means of each sample, while the blue lines indicate the 1st and 3rd quartiles of the data.

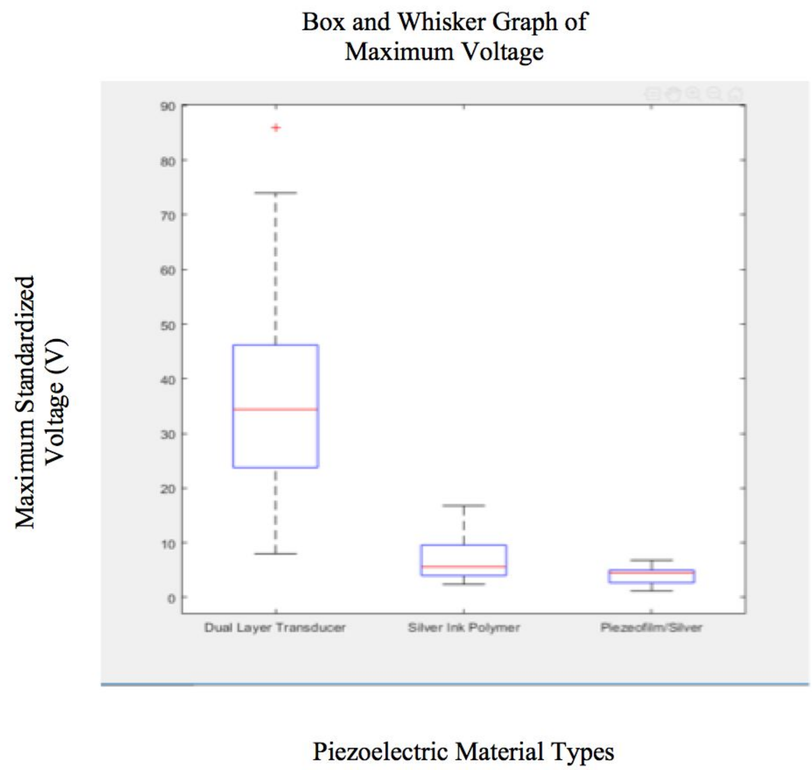


Figure 3.6: Comparison of maximum voltage obtained from piezoelectric materials.

This box and whisker plot was created to visually compare the data sets between the dual layer transducer, silverink polymer and film silver. The red lines indicate the means of the data, while the blue indicate the middle two quadrants.

4. DISCUSSION.

Results from preliminary testing show that obtaining adequate usable energy from a piezoelectric material-based alternative energy supply for cardiac pacemakers is feasible. On average, the Dual Layer Transducer generated 36.50 V +/- 8.44 V (standard deviation) when tested alone and attached to the heart, respectively. SilverInk Polymer generated 27.28 V +/- 6.45 V on average and the Piezofilm/Silver produced 2.00 V +/- 3.94 V on average. These values indicate that energy capture from testing with a heart model attached, generates a sufficient voltage from the piezoelectric materials that could potentially power a standard commercialized pacemaker, requiring approximately 2.8 V (Mallela, Ilankumaran, Rao, 2004).

Nine paired sample t-tests were performed to analyze the statistical significance between the means of the data sets collected. A paired t-test was performed between each material while attached to the heart and while detached, as well as between each of the three piezoelectric material types. All nine tests indicated that there was a statistical difference between the data sets within a 95% confidence interval. This indicates that the piezoelectric materials result in different amounts of voltage generation, and that there is a difference between simply pressing on the material strips and attaching them to a pulsating model heart.

From the box and whisker plot, it can be concluded that the dual layer transducer piezoelectric material produced the most voltage when attached to the pulsating model heart. Since the upper three quadrants all above the mean of the other two material's voltages, it can be confidently determined that the dual layer transducer is able to generate the most voltage when the same level of force is applied.

4.1. Practical Applications.

Although these values provide evidence for successful energy capture from our model, it is crucial to address several practical considerations. Firstly, optimizing cardiac pacemakers available to surgeons, and subsequently patients, must entail an objective evaluation of the net costs and benefits of the existing technology. Currently, patients who require cardiac pacemakers, undergo a minimally invasive procedure, usually under local anesthesia. As described previously, leads are positioned and secured to the endocardium using specialized sutures. This procedure involves relatively low post-surgical pain, typically managed by intravenous pain medication. However, as mentioned in the review of previous literature, incidence of post-implant complications, including infection rates, remain high and continue to rise. The motivation for our research predominantly targets the frequency of surgeries needed over the course of a cardiac patient's life. Our perspective of intervention relies on the notion that substituting several minimally invasive pacemaker replacement surgeries with just one invasive thoracotomy during a patient's lifespan, can alleviate the compounding risk of infection and/or complication-related death from the current system. The efficacy of our proposed model, with regards to potential application in the healthcare industry, relies on the evaluation of relative risks. A large question that must be further evaluated is whether it is truly more risky for patients to undergo several minimally invasive conventional pacemaker replacement surgeries, well into old age, compared to undergoing one thoracotomy, early in a manifestation of the patient's cardiac pathology. Additionally, it is crucial to assess the longitudinal impacts of both approaches on the overall health and quality of life of a postsurgical patient. Due to the highly variable impact of surgery from patient to patient, it is likely that relative risks depend heavily on the age, sex, genetic background, medical history, and lifestyle of the patient requiring intervention.

4.2. Financial Implications.

Beyond relative risks to patients, another important consideration is the financial implications of applying our model within the current healthcare system in the United States. Firstly, the relative costs of a thoracotomy and conventional cardiac pacemaker replacement surgery must be evaluated and compared. Between 2009 and 2013, the average cost of a major surgery, such as a thoracotomy, was $23,845, with an interquartile range from $13,353 and $43,083 (Gani 2017). Specifically, for open heart surgeries, such as those that require bypass, the average cost of surgery is around $40,000. This type of procedure requires access and exposure of the chest cavity, an extremely intrusive type of surgery associated with a wide range of potential complications such as strokes, infections, or gastrointestinal bleeding (Allen 2014). In addition, many days of postoperative recovery in the Intensive Care Unit (ICU) are required after such as invasive surgery. Equipment needed for post-surgical recovery can include ventilators, and dialysis machines, which the use of each comes with its own hefty price tag. The average cost of staying in an ICU under mechanical ventilation is approximately $1,522 a day (Dasta 2005). Depending on the outcome of the surgery, the patient may have to stay in a regular hospital room or a coronary care unit (CCU) for several days or weeks, which would incur additional costs beyond the cost of surgery and the initial recovery period.

4.3. Current Protocol for Pacemaker Surgeries.

Currently, pacemaker insertion and replacement surgeries are less invasive compared to a full thoracotomy. A small incision is made in the upper chest and a wire is guided through the vein to the heart to place the pacemaker, as mentioned previously in this thesis. This procedure is less invasive since the chest cavity does not need to be opened. The average cost of surgery is around $20,000, varying from state to state. In addition, to significantly lower costs, the required stay for a pacemaker insertion is only an overnight stay if there are no surgical complications. The patient is monitored overnight, and can be discharged the next day. Generally, there are reduced costs and lowered risk factors from using minimally invasive surgery compared to a full thoracotomy. Additionally, with minimally invasive surgeries, additional costs from ICU stays and inpatient hospital stay are typically avoided and unnecessary. The drastic difference in costs and risks will make using a piezoelectric interface harder to implement in the medical field, especially given the relative costs of implementation. The current procedures are less invasive and costly compared to what would be necessary to implement this design. Changes to the design would be necessary so that open heart surgery would not be necessary to implement the interface.

However, one advantage to the piezoelectric interface would be the reduced need to replace the battery every several years, which would lower costs in the long term. In addition to complications such as infections that could occur with most types of surgeries, there were other complications such as lead damage, lead dislodgement, pacemaker infection, and malfunctions with the defibrillator generator system (Nichols 2016). The incidence of lead damage was .46% for pacemaker replacements, 1.27% for defibrillator replacements, and 1.94% for defibrillators resynchronization procedures (Nichols 2016). The respective costs for these complications were $19,959, $24,885, and $46,229 (Nichols 2016). Other complications that occur include pacemaker infections, lead revisions procedures, and generation malfunctions, which on average cost $4879, $24,459, and $13,376 respectively (Ferguson 1996).

4.4. Alternative Solutions.

Due to complications associated with utilizing heart to generate energy, an alternative solution would be to attach the piezoelectric material on other tissue types such as diaphragm and utilize that movement to generate the required voltage. The piezoelectric material will not be attached directly to the muscle but attached to the epidermal layer of the skin covering the diaphragm. A study measure muscle movements for human interfaces using thin piezoelectric material attached to the skin (Bu, 2008). The paper described that by attaching a flexible piezoelectric thin film sensor to the skin surface, energy can be captured during muscle movements by cross-sectional muscle area changes which are detected at the skin surface.(Bu, 2008). This approach can then be applied to this project. Instead of attaching piezoelectric material directly to the heart, it can be attached to the skin around the same region or around the diaphragm (whichever generates more power). This way the method would be less invasive because the piezoelectric material attached to the skin outside will be connected to the pacemaker or the leads coming from it. Attaching piezoelectric material directly onto the heart will thus not be required. Using similar techniques described above, another possible way is to attach piezoelectric material around biceps. This was done in another study where a flexible piezoelectric thin film sensor was attached around the biceps and to assess skeletal muscle performance and fatigue (Ratnovsky, 2018). Thus this is a feasible idea that can be explored and can be incorporated with this project's concept.

Once the piezoelectric strips are successfully attached to the heart or nearby muscles, energy collected in the form of electric potential must be stored until it is needed for pacemaker recharging. An analysis must be conducted on the most efficient way to recharge the pacemaker, in terms of continuity and frequency as well as amount of charge provided. If energy is not to be recirculated into the pacemaker as soon as it is collected, a compatible voltage storage must be implemented. Including a capacitor in the circuit could solve this issue. Capacitors allow for electrical potential energy to be stored by creating an electric field between two plates of opposite electrical charges. However, the downside to this approach is the added size and wiring that will accompany a capacitor's installation inside the human body.

So far, strips of piezoelectric material have been tested around a 3D printed human heart model, and up to 40 volts have been generated from the physical displacement of fluid inside the model. A human heart model was created using Solidworks CAD and 3D printed using a semi-flexible material with elastic properties that resemble human heart tissue. All but two arteries/veins were sealed off in the model to allow for controlled airflow. The piezoelectric material was installed on the heart models using both tape and rubber bands, and the models were squeezed in an attempt to create a displacement of air equal to the displacement of blood in an average adult heart per beat.

4.5. Future Directions.

Due to unforeseen complexities, the team was not able to accomplish all the goals initially proposed. In the future, team CARDIO could spend more time to improve the 3-D printed heart model, to design a more complex circuit with a pump, and to additionally transmit energy from other places in the body.

The team currently has four 3-D printed heart models. While the consecutive hearts produced were more anatomically correct, we unfortunately damaged multiple heart models between the Spring of 2018 and the Fall of 2019. Additionally, the computer with our old STL heart files was wiped. Due to this unforeseen problem the team spent more time to recreate the damaged hearts in addition to updating it to the most recent design. In the future, a heart with a pocket to slide in the piezoelectric material would ideally be developed. This method would be more consistent and realistic than a rubber band holding the piezoelectric material or glue pinning it to the heart.

Additional goals for future projects include automation of the pump and also a more accurate circuit model. A pump would ideally maintain a more consistent beating of the heart models compared to a team member squeezing the model with their hand. Also, a circuit that involves a micro-electro-mechanical device would help the overcome the challenges of piezoelectric material. Realistically, in our preliminary circuit, electrical energy converted from the heart will be lost through friction, heat, and internal resistances of components within the circuit. The development of a MEMS device coupled with a piezoelectric material would help to improve electrical output.

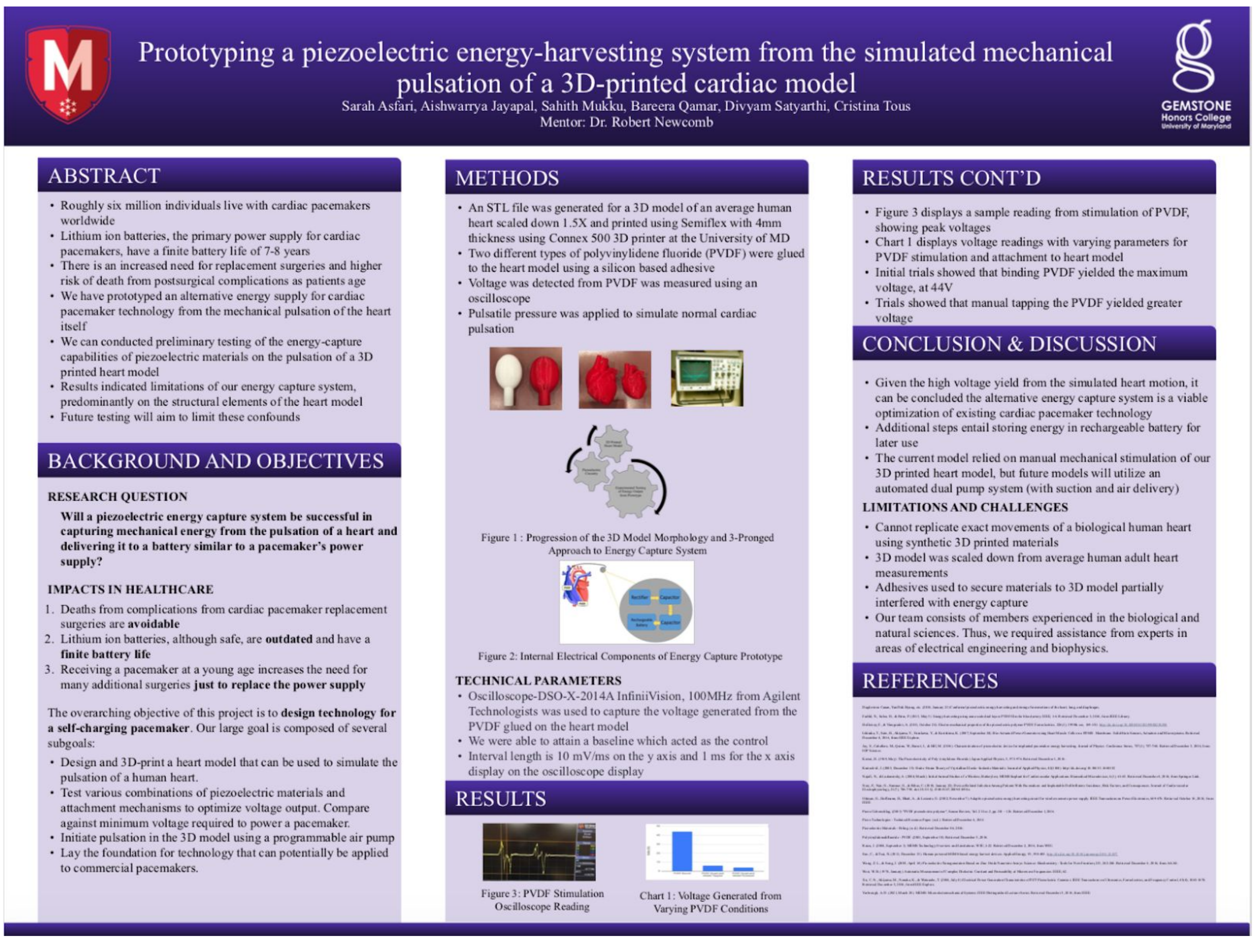
Furthermore, once sufficient voltage is captured via the piezoelectric material from the pulsating heart model, the voltage then will be converted to current using a rectifier and amplified using a capacitor. This current will then be stored in a rechargeable battery which should replace the lithium ion battery in current pacemakers.

In the future, the team could consider the possibility of using the motion from a hand or leg to power a device within the body because the power creating from these bigger movements could overcome losses in energy throughout the circuit.

After completing our research for Gemstone, we came across a research study with a similar idea to harvest the heart's energy to power a pacemaker using piezoelectric material, PVDF. Instead of focusing on the development of an accurate, plastic heart models, this research team at Dartmouth focused on harvesting as much electrical energy from a vibrating source as possible (Thayer School of Engineering, 2019). This team coupled PVDF with porous structures like "an array of small buckle beams or a flexible cantilever" that contained the piezoelectric material, which are ideas we explored in the MEMs section of this paper's background (Thayer School of Engineering, 2019). The results are similar to our project, indicating that piezoelectric material is a viable alternative energy source as it can generate enough energy to power a pacemaker. This paper exemplifies the increasing promise and excitement for the use of piezoelectric materials in the industry for biomedical devices.

5. APPENDIX

On October 27th, 2018 Team CARDIO attended the Sigma Xi Conference where team members met with other student researchers and members of Biotech startups in the Silicon Valley area. Our team learned about the challenges with implementing our project in the medical field.



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