The Monosense:

Minimally Invasive Monocusp Aortic Valve Replacement with Integrated Magnetic Sensor

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Introduction

The aortic valve operates between the aorta and the left ventricle. It utilizes a tricuspid design that constitutes three leaflets as opposed to other valves which may use two. Functioning off the basic principle of pressure-differentials, the aortic valve opens during ventricular contraction, allowing the flow of blood into the aorta. When the pressure within the aorta equals and overcomes that in the left ventricle, it closes once more.

A human heart will beat thousands of times a day, every day, for years. As such, the aortic valve will open and close millions of times throughout its lifetime. When the valve begins to fail, the patient may experience several symptoms: chest pain, dizziness, and fainting, to name a few [1]. The physiological effects are extreme and difficult to ignore. Heart valve failure could be a result of a plethora of issues. In aortic valve stenosis, for example, the leaflets of the valve begin to become thick and stiff. When this occurs, the leaflets become less mobile and restrict blood flow to the aorta. Over time, this opening of the valve becomes smaller, and the conditions with which the patient must cope become more dire.

The "triggers" for aortic valve failure are often out of the hands of the patients. Many are simply genetically inclined to valve failure, while others may simply have been born with heart disease. However, nearly everyone is able to help mitigate heart issues and bolster cardiovascular health through appropriate diet and exercise, the lack of which can exacerbate existing conditions.

Mechanical heart valves are built to replace those natural valves that have fallen too far from operational standards. Be it the natural passage of time, disease, or bad luck, the heart valve has become too irreparable for the patient, and it must be replaced. Biological heart valves exist that come from pigs and other animals. They come with the advantages of not requiring an excessive amount of blood thinners or anticoagulants, but they are temporary. They, too, will eventually need replacement [2]. Mechanical valves are designed to fully replace dysfunctional valves and are intended to last indefinitely. However, mechanical valves require a lifetime of either blood thinners or anticoagulants while also creating an audible "clicking" noise that could affect the quality of life of the patient [3]. However, this psychological detriment has been shown to reduce with time.

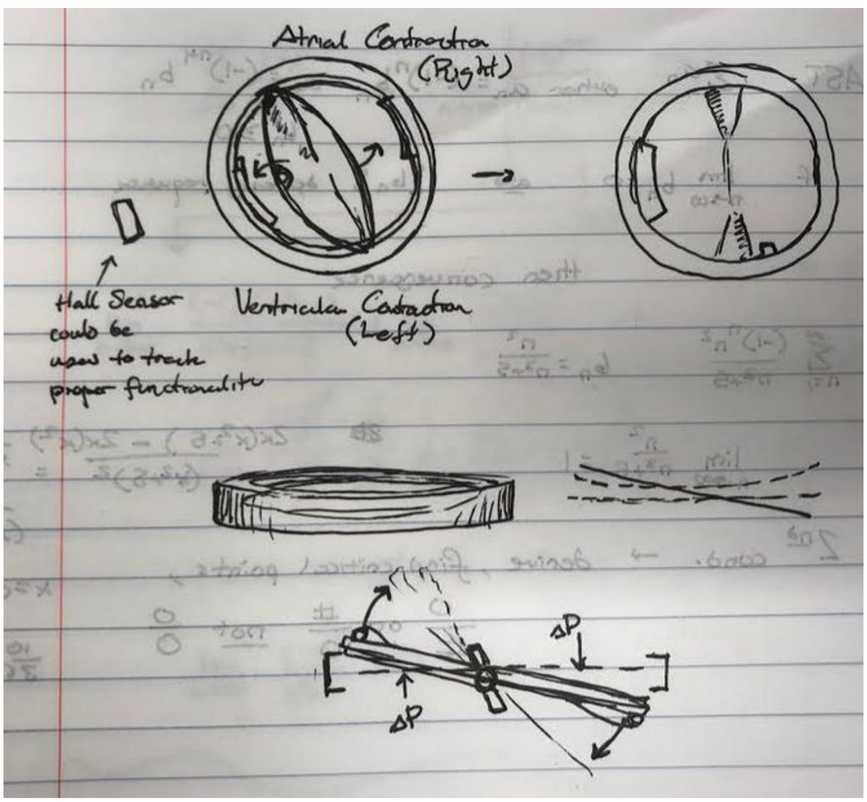
The first design we looked at was the "ball-and-cage" style valve. The mechanical valve operated on the same principles of pressure differentials as the original valve while also possessing zero actual moving parts. With so few parts, the design seemed efficient and simplistic enough to ensure consistent operation [4]. However, we felt that, if this valve were to fail, it could fail catastrophically. The patient would suddenly find themselves with a free-floating silicon sphere in either their heart or aorta as well as a wire cage. They would suddenly be missing their aortic valve altogether. Similarly, we feared that the ball and cage would disrupt the laminar flow of the blood itself.

Other popular mechanical valve designs based themselves around the natural structure of the valve itself. These artificial valves replicated the mult-leaflet design and operated on the same physical principles as before. The valve we focused on was the On- X heart valve by CryoLife, Inc. It advertised a structure with which a patient could survive with significantly less blood thinners while also allowing the same laminar flow as was present in the natural valve [5]. It possessed several attractive qualities we wanted to emulate and expand on.

Design

Our mechanical aortic valve utilizes a ribbed monocusp design housed in a flared, segmented pyrolytic carbon housing which is then wrapped in a teflon fabric sewing ring containing a self-expanding nitinol stent. The valve also contains a sufficiently powerful magnet in order to detect the functionality of the valve with an external hall sensor.

We went with a monocusp design in order to cut down on points of contact within the mechanical valve itself. There is only one axis on which any part rotates thus restricting the sources of potential mechanical failure. When the pressure within the left ventricle is greater than that in the aorta, the disc will rotate, allowing blood to flow through. Since the axis is offset, the larger section of the “circle” will move in the direction of the pressure differential. There exists two outcrops that stop the disc from rotating too far. If the disc were to do so, the mechanical valve would be unable to close itself, and the mechanical valve would become more of a threat to the patient than a life-saving measure.

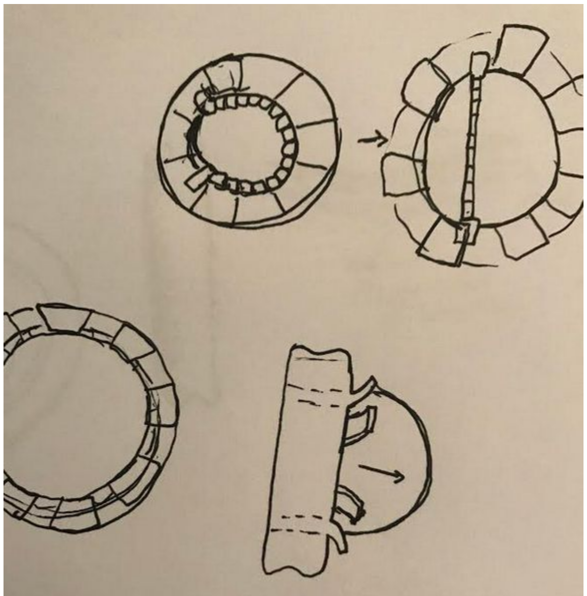


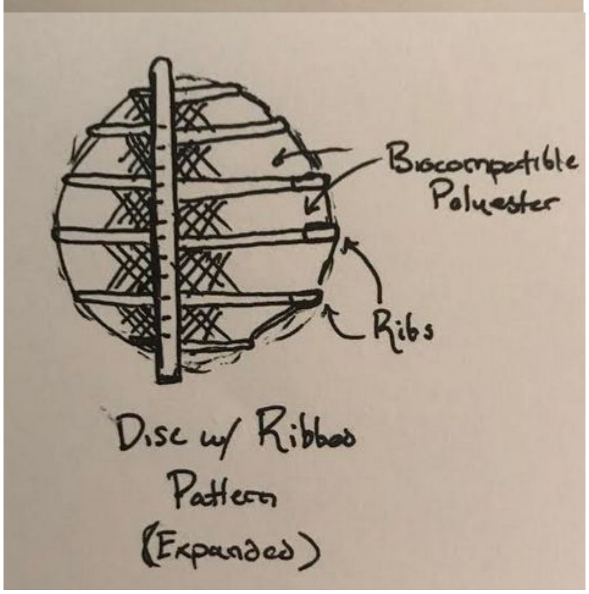
Many aspects of the valve are segmented to allow for compression when inside a catheter. In this way, the valve may expand to full size when placed within the aortic valve after a minimally invasive transcathater aortic valve replacement. The axis of rotation for the disc is modeled after a wired-spine, for instance, to allow the axis to bend as it is contained within the catheter. The endpoints of the axis are anchored inside the outer ring's stent which itself rests in the fabric outer ring of the valve. The outer ring expands outwards when placed within the valve, securing the new addition inside the heart. With only two points of contact, the axis should undergo minimal stress from normal operation.

The segmented portions of the "inner ring" flare outwards to encourage laminar flow through the valve. Though avoiding the disruption of laminar flow is a high priority, we acknowledge that our monocusp design will unfortunately permit some level of baseline turbulence.

The disc itself consists of the "spinal" axis, a series of pure pyrolytic carbon ribs, and teflon fabric membranes connecting each rib to each-other and to the spine. This design allows the disc to collapse while in the stent and unfold as the stent expands within the failing vale. The fabric will also allow some level of flexing for the disc, potentially increasing the disc's responsiveness to pressure changes. In future versions of this implant, transitioning to a "stem-cell-capturing collagen scaffold" [6] may allow the heart to connect the ribs using its own cardiac tissue.

As mentioned previously, the disc will house a sufficiently powerful magnet that, when coupled with an external hall sensor, will allow professionals to monitor the effectiveness and responsiveness of the mechanical valve. As the valve opens and closes, the magnet will be picked up by the sensor.

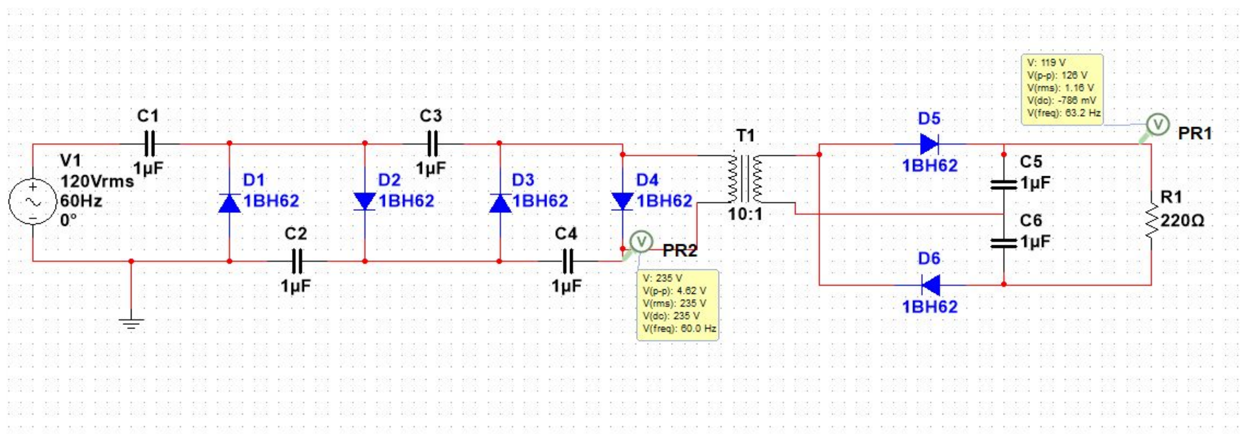




Sensor Design and Functionality

The initial design for added feedback to our artificial heart valve is to attach a remote disk to rotate a DC motor to act as both the 'the sensor' and as the power source. When one spins a DC motor, it becomes a DC generator. The sensor operates on the idea that, while the disc is rotating in place, a DC voltage source is generated that powers an RF emitter. These RF pulses allow third parties to judge valve/sensor functionality. These pulses can then be read by an RF receiver. However, there are multiple problems with the idea. For example, no over-voltage or current protection circuits are present. There's a small likelihood that the DC motor could short with the electrical nerves of the heart killing the patient. Plus, even the smaller DC motors would simply take up too much space inside the patient, and the doctor would have to remove heart tissue to make room for the circuit's components.

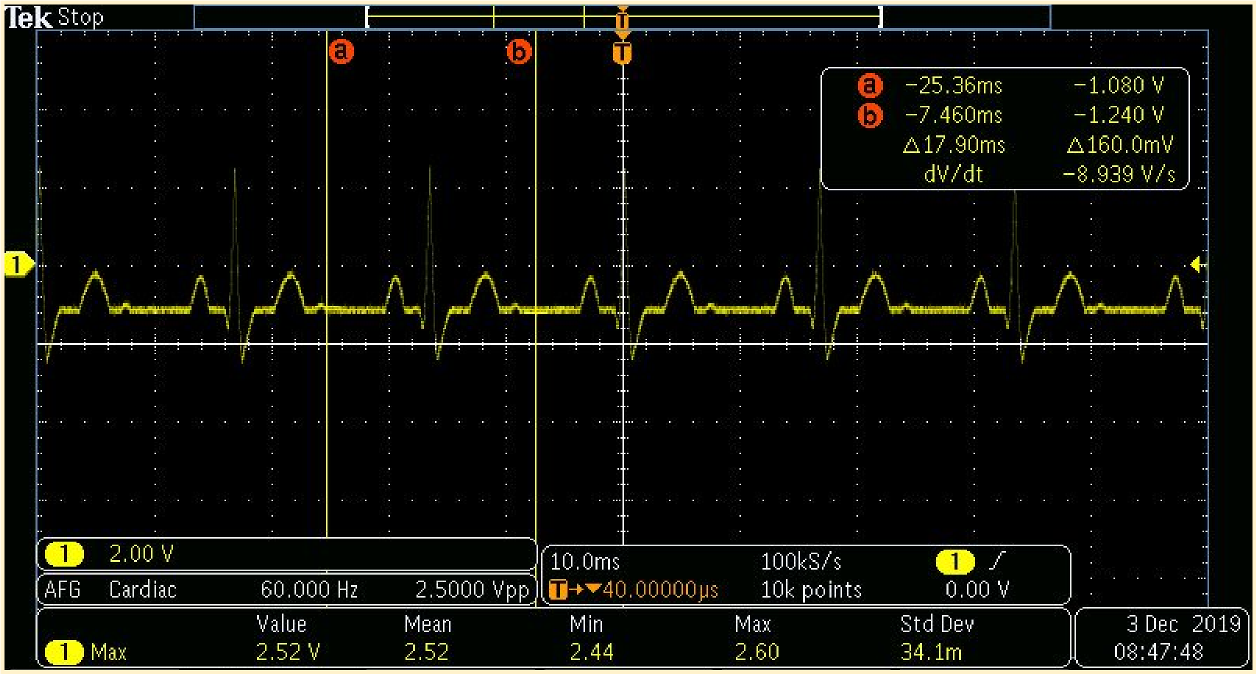
The second design for the sensor was a theoretical set-up, and was added mostly to prove that there is more than one way to measure data from the same mechanical auction. The theoretical design includes a power source in the form of a piezo-crystal that, when struck, becomes an AC voltage source. The Voltage is doubled using two voltage doublers in series, transformed with a transformer, then finally doubled by a full Wave doubler circuit on the end of DC signal side of the transformer as is demonstrated by the schematic below.

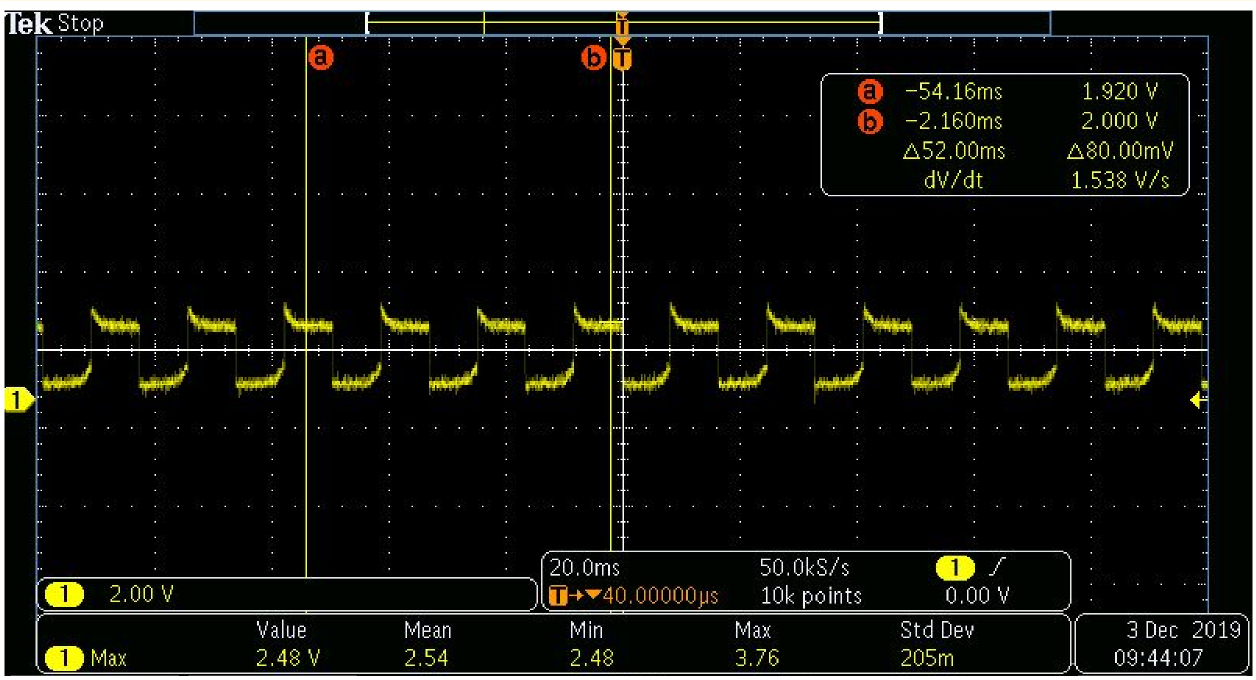


In the schematic above, the SineWave AC Voltage source is meant to represent the AC signal that is given off from striking the piezo-crystal. The resistor at the end of the circuit represents an RF emitter that sends the signal 'HIGH' when activated. The RF signal is captured by an RF receiver; the signals are then interpreted by a computer for further analysis.

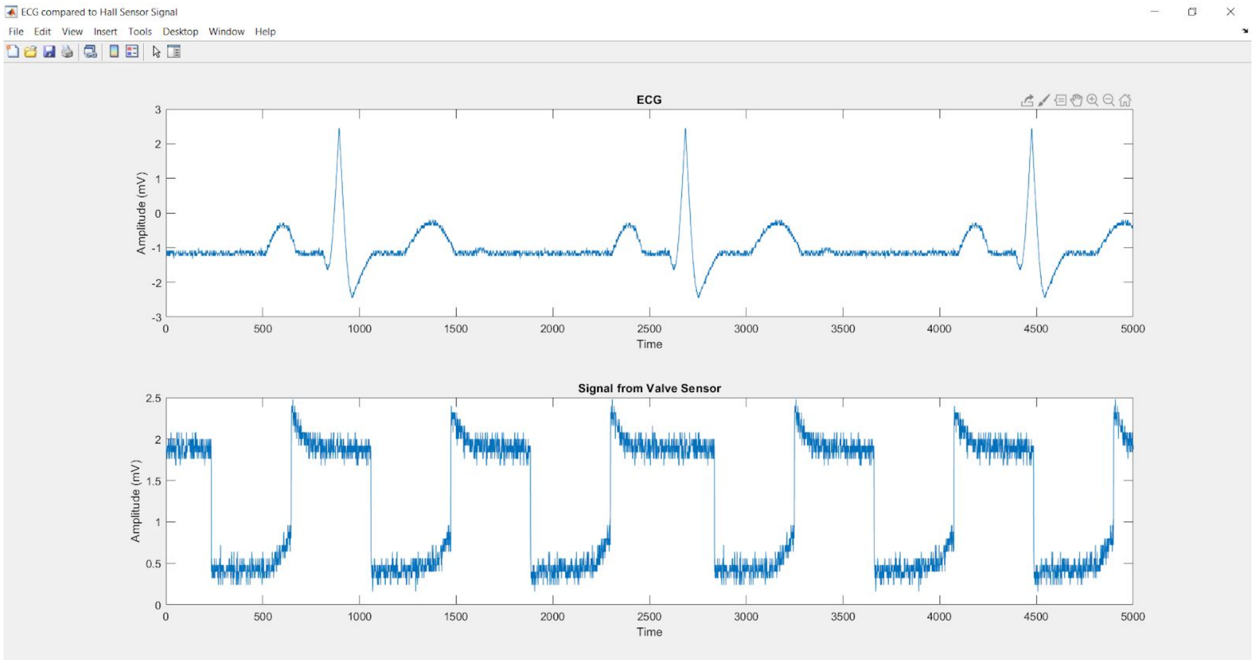
Nevertheless, the design we settled upon is a hall sensor. Hall sensors measure the change in magnetic fields. A magnet is placed on one side of the valve, and, when the disc swings back and forth, the magnet moves with it. When a magnet moves, so, too, does the magnetic field around it. The hall sensor measures that change.

With the help of an oscilloscope, we measured the waveform and simulated an ECG signal with the aid of the oscilloscope's AFG Cardiac Function for comparison to the hall sensor signal later on. We took a screenshot of each signal and also captured the data in a .csv file for further analysis in MATLab and in Python.

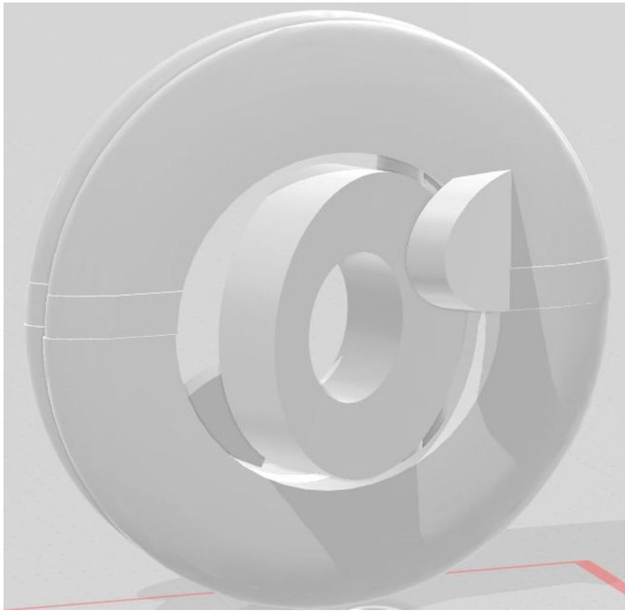
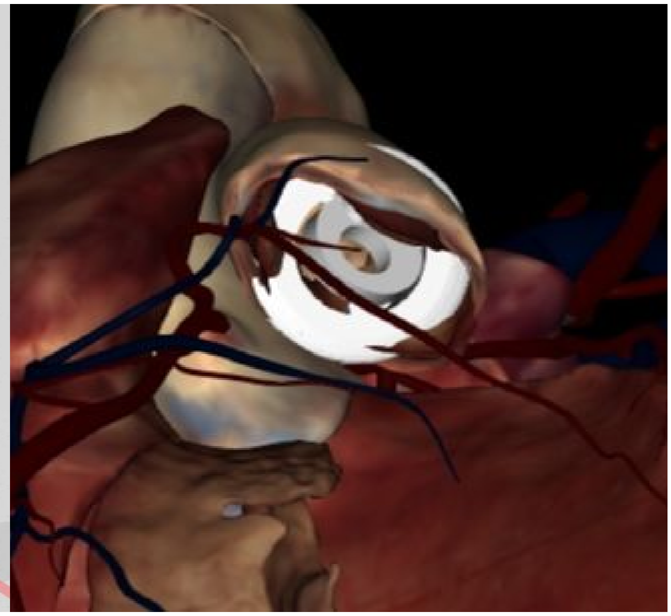




Since we didn't have access to an actual heart for us to capture the actuation of the valve, we placed a magnet and moved it with a servo motor in a rhythm/motion that approximates the heart actuating the valve. This way, we could match the waveform from the sensor to the actual waveform we would detect within a functional heart; however, the timing is not exact. The side-by-side comparison for the ECG to Sensor Signal is more of an approximation of what one should see when comparing those two signals rather than a direct comparison between the two. Below is a MATLAB figure of the ECG and sensor waveform signals for easier comparison.



How could our sensor design be improved upon? The first improvement that came to our minds is to connect two hall sensors to the V+ and the V- leads of an instrumentation amplifier in order to filter out noise. Instrumentation amplifiers have an extremely high CMRR compared to most differential operational amplifiers. In addition, we would take the discrete fourier transform of the signal to see its frequency spectrum and which frequencies are in the signal to determine where noise can be filtered out. For example, if there's a spike of 60Hz in the signal, then you can suspect that the noise is coming from the main's voltage and can be easily filtered out using a notch filter.



Method of Deployment

Previous artificial heart valves require invasive, open heart surgery. Our valve utilizes Transcatehter Aortic Valve Replacement (TAVR). This process is minimally invasive and only requires a catheter going through a patient's femoral artery. Similarly, a guiding tool will be deployed through a small incision in the apex of the heart. When the artificial valve is transported through the femoral artery and into the aortic valve, the surgeon will perform a balloon angioplasty to widen the natural valve in preparation for the artificial.

Once the balloon is removed, the valve will be moved into the gap, and the self-expanding nitinol stent will anchor the valve within. This expansion will allow the disc to flatten into its functional shape, and the walls of the inner ring will allow blood to flow through the valve unhindered. With the fabric sewing ring placed firmly against the walls of the former valve, the surgeon can then sew the artificial valve in place.

This deployment process may be seen as preferable for patients who are not physically capable of handling open-heart surgery as well as those who simply don't want to risk the procedure. We feel that patients will experience better quality-of-life with less scarring and physical trauma than would be experienced with open-heart surgery. Plus, with the FDA having just recently approved TAVR's use in "low risk patients", this method is now a viable option for anyone in need of a mechanical heart valve. [7]

Materials

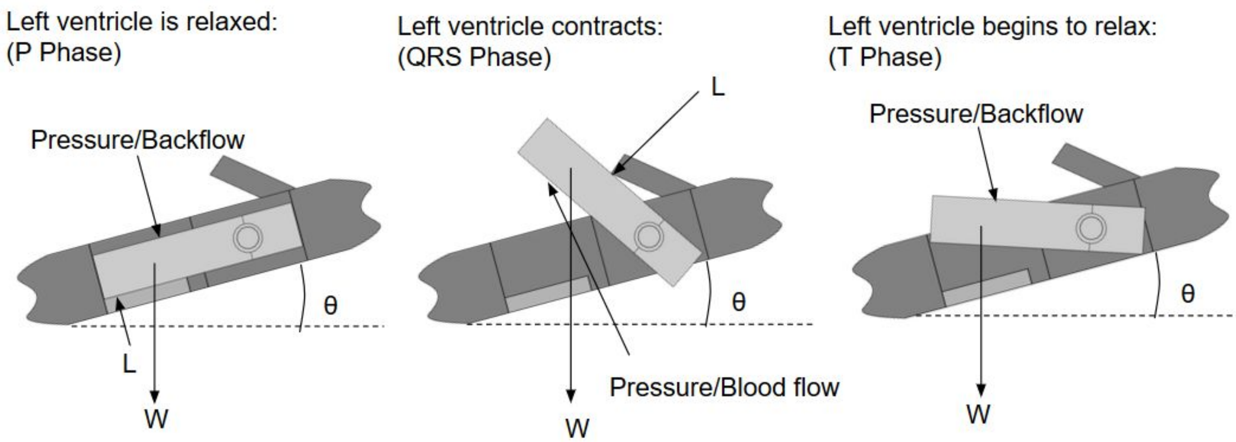
Our mechanical heart valve, the “Monosense”, consists of five general components: the outer ring, the inner ring, the disc, the spine, and the membrane. Each is uniquely designed with materials that best suit the component’s purpose.

The Outer Ring is designed to hold the valve in place indefinitely while also maintaining the shape of the valve itself. As such, it consists of a self-expanding nitinol stent coated in a teflon fabric outer sewing ring. Teflon has been shown as an effective material for sewing rings in nearly every other prevalent valve on the market. The self-expanding stent will allow the mechanical valve to remain firmly in place due to the combined efforts of constant internal pressure and having been sewn into surrounding tissue [8].

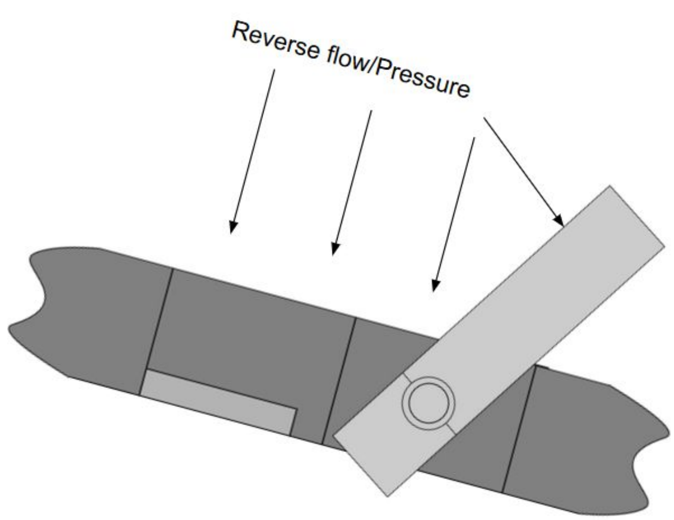
The Inner Ring is segmented to allow for contraction and expansion of the artificial valve during the implantation process. Consisting of a series of flared plates, the Inner Ring is constructed from pure pyrolytic carbon which is a widely used biomaterial for cardiac applications. Similarly, it experienced “no failures… when batches of 29 specimens were tested above the service stress of 6 x 10^8 cycles.” [9] This ring will be embedded in the Outer Ring’s nitinol mesh to expand when it, too, expands.

The Disc consists of several pure pyrolytic carbon ribs expanding out from a flexible spine of the same material. Pure pyrolytic carbon was chosen for these components for the same reasons listed above: consistent biocompatibility coupled with a high resistance to fatigue. Between each rib there exists a thin membrane of teflon fabric that allows the disc to bend in accordance with pressure differentials and implantation. As mentioned previously, an ideal configuration would have the membranes constructed from a “stem-cell capturing collagen scaffold” so that the artificial heart valve can use the body’s natural cardiac tissue in its own implementation, thus hindering potential thrombosis or other methods with which the body may reject the implant. Another membrane option would consist of a biocompatible mesh as detailed by US Patent 9,603,698 B2. [10].

Heart Valve Mechanics

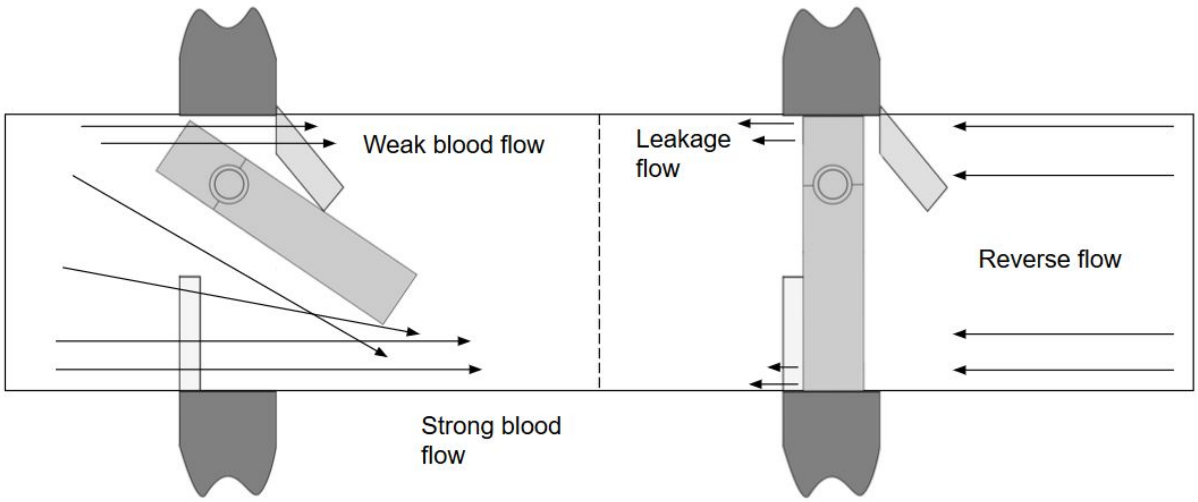


The forces that will be affecting the valve must be taken into consideration and understood in order to make sure the valve will work properly. There are three main forces that will influence the valve: gravity, blood pressure, and the force due to the lips. Because the axis and embedded magnet are off center, the center of gravity will not be on the center of the disc on the axis like most rotating disc designs, but will instead be off center, closer to the opposite end of the axis. This allows gravity to have a greater part in closing the valve while not hindering its ability to open.

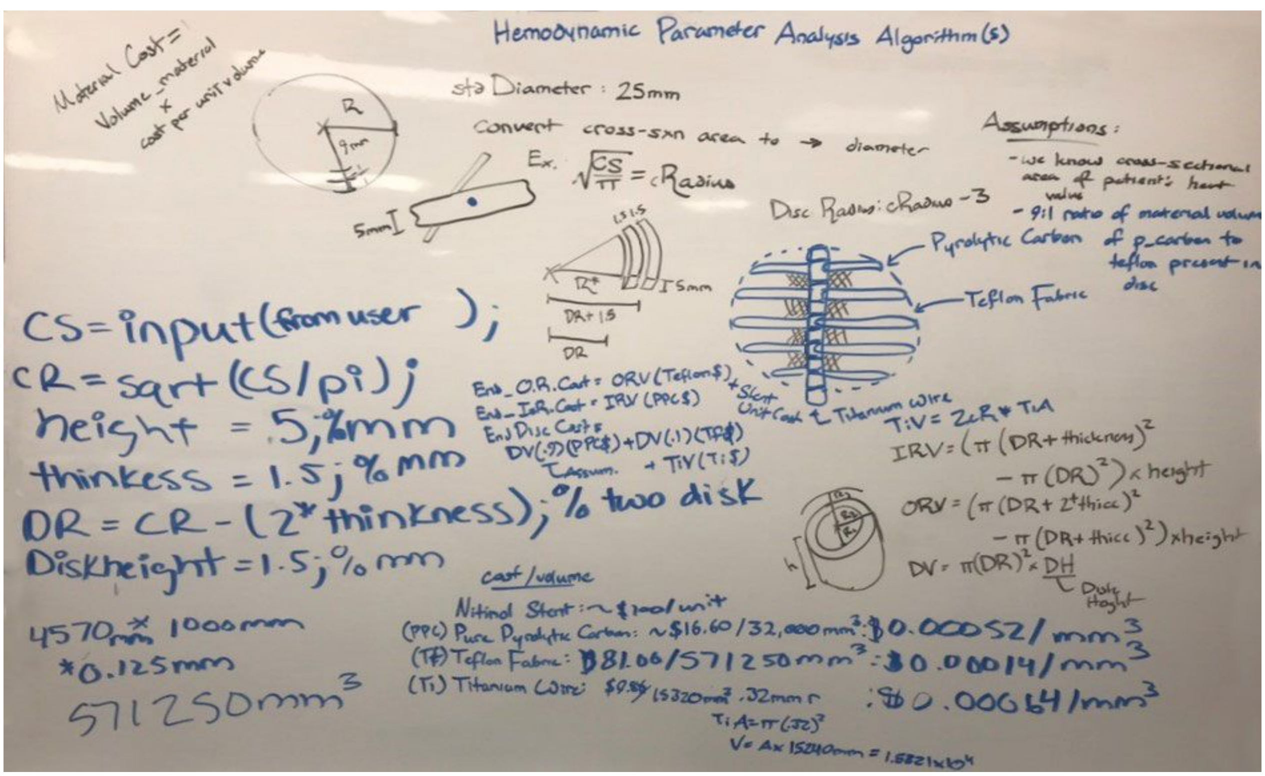


When the valve is in the closed position(P Phase), the blood pressure and gravity will keep the valve closed, while the lip(L) keeps the disc from opening on the wrong side. As the left ventricle contracts(QRS Phase), the blood pressure will rush towards the aorta, which is at a lower pressure, and open the valve. The lip will prevent the disc from opening too far. If the disc is allowed to open too far, the valve will have trouble closing as the pressure going back into the ventricle will keep the disc in place. When the heart relaxes and the left ventricle begins to re-expand, pressure will move back into the ventricle from the aorta, hitting the disc and causing it to close, and the cycle begins anew.

In regards to how the blood flow will affect the valve, it is similar to how blood pressure affects it. A strong jet of blood will rise from the ventricle as it contracts and push through the side without the axis with ease. A small gap will form on the other side of the disc with the axis, allowing a weaker blood flow through. As the blood pressure closes the valve, the blood with flow backwards into the disc. The valve may not completely close, causing some minor regurgitation as is typical with most mechanical heart valves. [11] Because of the way the valve opens, laminar flow will be disrupted as the valve cannot open all the way. However, more work can be done to determine what angle the upper lip will be at to allow the valve to open at a 90 degree angle perpendicular to the blood flow, decreasing the turbulent flow through the valve.



Hemodynamic Parameter Analysis



The Hemodynamic Parameter Analysis code calculates the cost based on one initial assumption and one input variable from the end user. The initial assumption is that there is a 9:1 ratio of pure pyrolytic carbon to teflon fabric in the inner rotating disk. In the program the user is asked for the cross sectional area of the heart valve. From this information we can calculate the volume of each component of the heart valve in order to properly fit in the specified cross sectional area. Knowing the cost of each material per unit volume and the volume of each component, we can derive the material cost of the valve based on the formula: Material Cost = Volume of Material * Cost per Unit Volume.

Design Justification

Our artificial aortic valve utilizes a monocusp design in a compressible/expandable frame that can be delivered via minimally invasive transcatehter aortic valve replacement. Previous models required open heart surgery and put significant physical strain on the patient. This naturally excludes some patients who are simply unable to undergo such an intensive surgery. Our design allows implantation via catheter. By traveling up the femoral artery, the only incision in the heart is that which must occur at the apex to ensure proper implementation. Aside from that, the patient experiences much reduced physiological strain from the procedure than they would otherwise.

The mechanical heart valve also makes use of an onboard magnet that pairs with an external hall-sensor device. When coupled with an ECG, physicians would be able to monitor the exact opening and closing of the valve and compare that to the ECG itself. That way, the functionality of the valve may be better monitored in a minimally invasive way.

With fewer moving parts, our valve poses less avenues for mechanical failure, so the lifespan of our valve would directly increase over other, more complicated designs. Similarly, the compressible nature of our valve allows for it to bend and move in accordance with surrounding tissue. This mitigates the threat of damage to surrounding cardiac muscles from the inclusion of a rigid, static device.

References/ Work Cited

[1]
https://www.mayoclinic.org/diseases-conditions/aortic-valve-disease/symptoms-causes/syc-20355117
[2]
https://www.heart-valve-surgery.com/heart-surgery-blog/2008/03/24/pig-heart-valve-how-long-do-they-last/
[3] https://cardiothoracicsurgery.biomedcentral.com/articles/10.1186/s13019-019-0956-1
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4810599/
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4881630/
[6] http://www.molbio.upol.cz/stranky/vyuka/OSE2/2011/Mixa.pdf
[7]
https://www.acc.org/latest-in-cardiology/articles/2019/08/16/13/49/fda-expands-tavr-indication-to-low-risk-patients
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1768554/
[9]
https://www.researchgate.net/profile/Robert_More/publication/292306650_Pyrolytic_Carbon/links/5ce399aa92851c4eabb174c0/Pyrolytic-Carbon.pdf
[10] https://patentimages.storage.googleapis.com/8d/c4/b7/7ac6ef0bd7ea0e/US9603698.pdf
[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2752693/