Spring Final Design Report

Endovascular Tissue Removal Device for Calcified Valve Leaflets

Christopher Guay, Josh O’Brien, Cathy Yee

Team 6

Client: Dr. Wei Sun, Ph.D.
University of Connecticut
BRONWELL 207
860-486-4939
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1. Introduction

The purpose of the project is to create a minimally invasive endovascular tissue removal device for the removal of calcified aortic valve leaflets. The device will be inserted into the femoral artery, and threaded endovascularly to the aortic valve. Due to the tight path through the arteries that the tool must travel before reaching the aorta, it must be collapsed inside the catheter, with the ability to expand when at the destination. The optimal design is a modified version of the three alternative designs.

When in the proper location, the two expandable portions- termed the cutter and the holder- will open up with two different types of linear actuators that are connected. The serrated cutting blade, on the proximal end, will be powered by an external motor. The cutting of the calcified tissue will produce calcified debris, which will in practice be vacuumed out of the body, so as to not clog up the blood system. The vacuum removal of calcified debris, however, will not be in the scope of the project. After cutting, the device will be collapsed back into the catheter and threaded back out of the body. The three preliminary designs all culminated in the final prototype, with aspects of all three included. The use of a serrated blade with leverage provided by a backplate and positioned by linear actuators was a design that developed as a hybrid of the initial designs.

Figure 1: The series of events to deploy the endovascular removal tool (EVRT)
Figure 2: Basic Component Flow Chart
All the calculations of the forces and moments, measurements and constructions must be very precise because heart surgery is a very delicate procedure. Although this poses less risk than traditional open heart surgery, this percutaneous removal of calcified valve leaflets still entails many risks to the patient if not done correctly. The device will be modeled via software programs Autocad Inventor simulation, Multisim, Microsoft C++ coding, and MPLab before being physically tested on a pig aorta. Retesting and redesign will be an inevitable process of such a delicate procedure. The project has some realistic constraints pertain to mechanics, economics, environmental, and manufacturability. Sustainability, health, and safety are also key topics that will be investigated in the paper.

The finished aortic valve leaflet removal device will have a significant impact on healthcare. The device can be used in surgical rooms of hospital for minimally invasive, and therefore safer heart surgery. The risk of morbidity and mortality will reduced significantly, having a positive impact on health globally.

1.1 Background:

The device is designed to perform an endovascular procedure which will cut out or macerate calcified or diseased tissue in order to prepare the site for valve replacement prosthesis. This surgery is intended to be much less evasive and more effective than current techniques to treat these issues. By entering via an artery, the device would be threaded all the way to the aorta inside of a catheter. Using a technique like this would improve the recovery times of patients, especially those who are elderly or have weakened immune systems. However, working in such small space constraints will force the tool to be as small and simplistic as possible while still generating enough force to cut through hardened leaflets.

Many previous devices and procedures such as stents and angioplasty simply leave the valve leaflets intact and pressed against the aortic wall, causing distortion of the prosthesis, paravalvular leakage, or regurgitation.

Endovascular procedures reduce the risk of severe complications of the surgeries that they would be replacing, especially in patients with advanced age or co-morbidities. This product
would be greatly useful due to the fact that aortic stenosis is the most common valvular heart disease in the western world.

1.2 **Purpose of the Project:**

The purpose of this project is to create an endovascular tissue removal device that operates with the most minimal invasive procedure possible in the aortic root to remove valve leaflet tissue, both healthy and severely calcified, to prepare for the introduction of prosthesis.

Due to the tight path that the tool must travel before reaching the aorta, the device must be collapsed inside the catheter, with the ability to expand when at the destination. Because of the large lack of ability to do much manipulation of the tool once inside the aorta, the blades must be constructed out of a material that has high enough strength to still cut the leaflets, while having the ability to expand and re-collapse before and after the procedure. This cutting blade would be attached to a thin wire that would be driven by a motor external to the body. While not the direct focus of our portion of the project, the floating debris would then be required to be suctioned into an attached catheter via a funneling filter which would still allow blood to flow past. This filter would need to be attached to the cutting blade in a manner that doesn’t impede the ability of the driveshaft to rotate.

The device will be run using a computer program specifically designed to work with the device. The program will allow the user to control the blade rpm, as well as control the electrical impulse needed to expand the device once it reaches the aorta.

1.3 **Previous Work Done by Others:**

Over the last three to four years, a few groups have looked at ways to improve the efficiency of the surgical techniques to remove damaged valve leaflets. While looking at previous works, there are a few designs that attempt to accomplish the same desired result as this project. Most of the research that was found was very recent, ranging from the earliest of 2005 until present. A few teams had some success using various mediums for clearing the calcified leaflets; however, none quite could combine speed and accuracy of cutting in the in vitro environment with the necessary task of debris removal.
1.3.1 Products

A team from Germany’s University of Kiel had experimented with using high pressured water streams to resect the valves. While this technique was successful in cutting the leaflets, the procedure damaged the aortic wall in multiple cases, as well as superficial lesions that were revealed with microscopic analysis.

This same team came back with another design in early 2007. Instead of using high pressured water, this time lasers were used. Using an Er:YAG laser with a purpose specific fiber coupling device and fiber tip was used to cut the leaflets. It was seen that while this technique was quicker than the previous design (~15 mm/min) it was still very slow in their minds, as well as creating pieces of debris up to 1 mm in size.

More recently, (March 2009 - Florian Hauke et al.) a collapsable cutting blade using Nitinol metal was created. This “memory” metal allows the device to go into the artery collapsed, and then expands once situated. Meanwhile, the blade itself was machined from a nickel-titanium alloy. The blade was used in tandem with a slightly larger diameter holder which was placed on the other side of the leaflet. This provides the blade with some leverage to cut the tissue. With the blade having a saw-tooth like design, the method for cutting that was chosen that of a “rotating punching” technique. This saw the leaflet being sandwiched between the holder and the blade, with the blade approaching the holding ring with a combination of translation and rotation, until the leaflet is chipped away. The team determined that valve resection could be performed in less than 30 seconds with this technique. However, this experiment lacked actual in vitro testing, or any sort of suction filter for debris removal.

1.3.2 Patent Search Results:

Searching on the U.S. Trademark and Patent Office’s website yielded no results for searches including “calcified valve leaflet removal” and over 1,600 results for the less specific “valve leaflet.” After sifting through most of them, however, it was found that nothing was in any way related to our project, most of them being primarily related to the ballooning technique that pushes the calcified tissue further toward the aortic walls. All of the research that was discovered on the topic seemed to stem from Europe, and specifically Germany. Most of the
research was done mainly by groups that were working in research at universities. Dr. Sun has expressed interest in eventually acquiring a patent for a similar system upon completion of the project next year.

2. Project Design

Before a finalized design was agreed upon, several other designs were presented and adapted in order to find the best possible design to accomplish the goal. The first of which was a basic design broken up into two portions; the cutting blade assembly, and the controller unit. In this design, the cutting blade is positioned on the distal end of the assembly at the end of the catheter. This blade will be directly attached to the catheter cap and flexible rotary shaft of approximately 4mm in diameter which will run the length of the catheter from the motor into the body to the tip where the blade will be affixed. In this model, the blade is circular with sharpened blade in the fashion of a scalpel blade with no serrated edges or saw teeth. The blade will be mounted to the shaft by a tripod shaped set of supports which would be affixed to the blade by very small rivets with a diameter of .6 mm. This blade would be directly attached to the shaft and end cap which would allow for the whole distal end of the assembly to rotate in the cutting motion. Opposite of the cutting blade would be a parallel back plate. The back plate would also be mounted in a similar four piece support system. The back plate would consist of a slightly thicker piece of material in order to allow for an adequate cutting surface for the blade as well as acting as a gripper to control the location and movement of the leaflet that is being resected. This linear motion will be obtained by installing a ring on a bushing which would be attached to the shaft where the back plate will be affixed. This plate would be actuated using two proximal linear mechanical actuator cables which would be located within the catheter alongside the shaft.

The shaft itself would be a 3.8mm shaft comprised of an hollowed Nitinol tube. This shaft would travel the length of the catheter from the motor all the way to the end cap of the cutting assembly. The shaft would have no linear motion, only rotational. All linear displacement of the proximal back plate would be accomplished by the parallel linear mechanical actuator cables that will be controlled by the Controller Unit.
The Controller Unit would be the user interface for the device. It would include a brushless DC motor and speed controller unit, as well as an AC/DC power supply, LCD screen, as well as a linear actuator in order to control the mechanical cables within the cutting assembly unit. The brushless motor would be mounted horizontally within the controller box, with connection to the flexible shaft coming from a custom made bracket to connect the two shafts. The motor would be controlled by a potentiometer-style knob which would be regulated by the speed controller. The LCD screen would read out to the user the current RPM of the cutting blade at the motor. This would be accomplished by using the voltage output of the speed controller and running it through the analog input of a microcontroller. After a simple A/D routine, and linearization of the maximum and minimum voltage, the voltage signal would be transformed into a digital numerical readout of the cutting blade RPM. The controller unit would also contain a linear servo motor and slider control for the linear motion of the back plate with respect to the cutting blade. The controller unit would also contain two switches; one for the overall power of the system, and one for the motors so that they can function separately and independently. Also, for the sake of safety, there will be an emergency shutoff punch button mounted to the top of the box in case there is any failure during the resection process in order to protect the client. This would exist as a simple power cutoff and/or emergency breaking system for the rotational motion of the shaft.

Fig. 3: Design option one of cutting blade/ back plate assembly
This second design differs from the first design because the rotating cutting blade is on the proximal end of the resection tool. While no longer on the distal end, the cutting blade is once again a smooth sharp edge that will cut through the calcified leaflets. The distal portion of the resection tool will act as a holder onto the functional part of the tricuspid aortic valve, holding it in place so that healthy tissues will not be cut off by the cutting blade. It will not act as a cutting surface; the cutter will just cut freely at the calcified tissue. The distal portion of the resection tool will also act as an actuator, sliding up and down the soft shaft by an amount that varies on a case-by-case basis to be determined and controlled by the surgeon. Both the cutter and the holder will be able to be collapsible inside the catheter so that it can be snaked through the arteries and into the aorta. Once inside the aorta, they can expand to full width. As in the other designs, the shaft will be hollow so that wires can be snaked through the resection device to power the three types of motion: the sliding of the actuators, the expanding of the cutter, and the
cutting of the calcified tissue. The end cap at the distal end will be rounded so as to lead the catheter smoothly through the arteries without tearing anything.

Like in the other designs, the parameters of the resection device such as the speed in rpm, and the option of either expanding or collapsing, will be controlled in the controller box. An LCD display will show the parameter settings. The difference is that in this case, the actuator control would be separate from the controller motor box. It would look like a syringe with measurements in mm, indicating how far the actuator would move in relation to the holder and valve leaflets. This external and separate actuator controller would be more portable and easy to handle for doctors and surgeons, which is essential for precision. Another handle on precision is that the mechanical actuator would be more like a pipette syringe with set measurement stops for each half mm or so, leading to minimum room for human error.

![Figure 5: Autodesk drawing of alternative design 2.](image)

The third proposed design takes some elements of both designs 1 and 2, as well as adding in a new feature of a saw-toothed blade. As opposed to our other designs that utilize a razor edged blade, this design uses a something that takes cues from a hole saw. Additionally, this design uses a user input hand controller for maneuvering, instead of the computer based graphical user interface. Again, based on budget and feasibility, the blade is connected to the
distal end of the shaft, with the back plate being linearly adjustable with a pair of actuators, like the first design.

Figure 6: Saw-toothed blade

The blade is the most distinguishing feature of this design. As opposed to a smooth, scalpel-like blade of the first two designs, this toothed design should require less force to cut through the leaflet tissues. Additionally, the use of teeth would also result in less blade maintenance versus the smooth blade which would need to be sharpened much more often. However, this design could also prove to be too destructive and cause damage to unwanted areas. The blade would be connected to the shaft by using two supports. As with all the designs, the blade needs to be collapsible in order to fit inside the 7.6mm catheter. It would then expand to a diameter of 15mm when at the operating position. This will be possible by using Nitinol metal as the choice of the blade, supports, and back plate, thanks to its hyper-elastic properties. The back plate will have a diameter slightly larger than the cutting blade at 17mm. This piece will act as the leverage for the blade by holding the leaflets in place.

The back plate will be adjustable by 2 linear mechanical actuator cables that would be located on opposite sides of the shaft. The adjustability will be aided by using two actuators as opposed to just one, as well as utilizing a grooved “track” that will help guide the movement,
ensuring that the back plate remains parallel to the blade. This should prevent any contact between the blade and back plate from occurring. This design also uses a 3.8mm shaft comprised of an inner core of wire mesh. This solid wire is more practical and less expensive than a hollow shaft from design 2. The flexible shaft should guide the tool through the artery, and also be strong enough to provide the rotating force needed for cutting hardened leaflets. The tool will be operated by a simple hand control which will allow the user to linearly adjust the position of the tool by pulling forward or backward on a handheld slide. This will be less expensive than having the control box with the led screen, however is slightly cruder. The device will be powered the same as the other designs, using a brushless DC motor, with user controlled speed through use of a potentiometer. Additionally there will be an emergency power cutoff which will be used in case of any patient related emergency that will stop the cutting process immediately.

There are some serious constraints that need to be considered while considering this project. Size of this device is a huge issue. Since the Aorta and arterial tissues range in size in millimeters to centimeters in diameter, and designed to be in a standard 24F catheter, the size of the device is limited. The drive shaft must be incredibly flexible and mobile as it needs to be snaked through the patient’s circulatory system in order to reach the procedure site in the aorta. In addition to being flexible, it needs to at the same time be strong and deliver enough force to cut through calcified tissue. Since the area that needs attention in the aorta is larger than the rest of arteries it will pass through upon entering and exiting the body, the cutting portion of the device needs to be entirely collapsible. Another issue that arises with the procedure is the cutting blades cannot come into harmful contact with aortic walls, which could potentially cause damage or possibly rupture. Also, the materials must be completely biocompatible and bioinert as they must be within the body’s environment throughout the entire time of their operation. That is the reason that Nitinol and stainless steel have been chosen as materials for this project as they have been proven previously to be bioinert and compatible with the human body’s fluid environments.

The design has gone through many iterations throughout the brainstorming process. The optimal design, takes all of the strong points shown above, and adapts them into a unit that will utilize the many ideas presented and with some changes accomplish the goals that were set out to complete. Some examples of how these adaptations include taking the idea of the hollow shaft, with a serrated blade at the proximal end, able to actuate and perform as intended. Several
portions were modified due to certain restrictions. The sheer size of the device dictated that the wire coil be eliminated to make way for specially designed Nitinol tubing instead and the two-section blade design, a more complex and flexible 4-part design as adopted. More adaptations will be clearer later on, however it remains clear the basic design remains as it was in the first design, consisting of a main flexible shaft, controller box, and blade assembly with a supporting back plate against which the blade will perform its resection.

2.1.1 Objective

The objective of this design is to create a working proof of concept for the endovascular removal of valve leaflet tissue using a motorized rotational cutting blade made out of Nitinol Materials. This device is set to cut valve leaflet tissues from the aortic arch and prepare the site for the insertion of an artificial heart valve that would be presented to the body after the valve was resected and the tool being designed removed from the circulatory system, job being completed in as short a period as possible.

2.1.2 Subunits

The following sections describe the most current design in its entirety broken down into different minute portions in order to illustrate the full scope of the project as it stands in this revision.

2.1.2.1 Cutting Blade Assembly:

There are a few processes by which this resection tool will work. The first process involves the threading the catheter surrounded cutting unit into the femoral artery through the body until it reaches the aorta. The second step entails the expansion of the cutter and holder. They must expand from the size of the catheter (approx. 7.6mm) to a dimension of about 16mm in order to hold the leaflets in place and perform their cutting operation. The third process involves the rotation of the cutting blade to eliminate the calcified aortic valve leaflets. (The next step would in practice involve the removal of debris by vacuum suction for the health and safety of the patient. However, that is not within the scope of this project.) The fourth step would be to
collapse the cutter and the holder so that they fold back within the catheter. The fifth and final step would be to thread the catheter back out of the patient’s body back through the arteries.

a. Catheter:
A standard 24F catheter, which is approximately 7.6 mm in diameter, will be inserted into the femoral artery and wound through the arteries until it reaches the aorta. The catheter will comprise the outer sheath of the whole device for safety, so that none of the parts can catch and tear at the arteries or heart.

b. Cutting Blade
The actual resection blade is comprised of several different parts. First of all, the blade itself is comprised of four pieces of Nitinol metal, a hyper elastic material with strong shape-memory characteristics. This blade, based on the drawing below, is comprised of four blade sections each containing a support to make an “L” shape. These four blade sections are held together via tiny rivets (outer diameter of ~.6mm) similar to [1] and attached to the support in a similar manner. This whole assembly, when open should be approximately 16mm in diameter. This will allow for the cutting of the individual leaflets with accuracy and allow to leave as much of the neo-annulus as necessary in order to insert the replacement valve.

Figure 7: Diagram of Cutting Blade Assembly
This blade will be serrated on one face as is depicted in the diagram in order to ensure the resection of tissue. It was determined that a simple smooth blade had a higher chance of simply getting caught up within the tissue attempting to be resected and would therefore simply bind the blade. This blade assembly will be collapsible which is why the joints are simply riveted together to allow for movement in that one plane and allow for ease of folding while not jeopardizing the structural integrity or strength of the assembly. This folding mechanism will be discussed below.

Manufacture

The manufacturing of this part will be rather difficult. Nitinol is a very expensive material and needs to be treated as such with care and precision. The flat blade portions will need to be laser cut on a CNC machine to ensure that all these components are of the appropriate dimension considering the thickness of the material we are using lies in the order of approximately .35mm. This thickness was determined by [1] to have the appropriate strength vs. elasticity that is necessary for this sort of application.

Once all of the parts are laser cut out, the blade itself will need to be sharpened and pieced together. The ends will need to be drilled and tabbed so that they fit together precisely. This will be accomplished with grinders or a Dremel in order to achieve the appropriate shape and size. Once this is accomplished the blade will have to be sharpened in the serrated pattern shown above. This will be achieved either by systematically grinding the blade, or very precisely created by the Dremel. Delicate care in the layout of the blade’s sharpening is required because any deviation could cause a snag in the cutting process. All surfaces must be smooth and polished to ensure this will not occur.

Attachment

The blade will attach directly to the outer Nitinol which will be directly connected to the motor, as will be discussed later. This blade must rotate in order to perform the cutting motion as well as move distally and proximally in order to position itself against the stationary holder plate opposite it. The shaft will connect directly to the motor which will be actuated distal and
proximal to the aorta in order to position the blade. In this case, the motor must be actuated along a linear actuated track. The Nitinol blade supports will be attached to the outer shaft by AgSn solder which has been found to be of appropriate properties to make these attachments.

c. Tissue Holder and Cutting Surface

Much like the cutter, the holder will be expandable from the inner diameter of the catheter to a diameter of approximately 17mm. The reason for the extended outside diameter is due to the fact that this mechanism needs to have enough surface area so that the cutting blade will be able to cut against it and come in contact with it once the tissue removal has been accomplished. The holder serves to grip the leaflet tissue for stability of the device so that it can control the leaflet during resection and it also serves as a cutting service for the blades of the cutting assembly. The holder is comprised of a thicker circular ring and four supports. These supports will attach to the non-rotating inner shaft. This cutting surface will not rotate as it will be responsible for holding the leaflet tissue steady during the resection process.

Manufacture

The manufacture of this part will be significantly less involved than that of the cutter since we do not need to worry about the sharpening process. However, the other aspects apply, such as the laser cutting and the drilling of holes for the attachment by way of rivets since this portion of the device also needs to collapse into the capsule in a similar way as the cutting assembly. This portion, too, will consist of four parts each in an “L” shape that will be riveted together in a similar fashion as that of the cutting blade. The supports of this assembly will be attached directly to the inner hollow shaft of the device. All attachments to the Nitinol shafts will be done using AgSn solder which by research has been found to hold quite well.

d. Proximal Capsule Portion
This portion of the capsule remains rigid and is attached directly to the catheter. This cylindrical portion, made out of thin stainless steel tubing, will act as an actuation point and will enclose the cutting blade assembly within its diameter. This tubing will act to force the blade to fold, while the linear actuators pull the outer shaft and motor back and forcing the blade into the tube.

![Figure 8: EVRT cutting blade assembly.](image)

e. Distal End Cap

The distal end cap functions as its own linear actuator. When the device is opened or deployed, this cap is moved distally. This will expose and release the folded cutting surface to its appropriate dimension. The closing of this cap will force the cutting blade assembly down into the tube in a similar fashion as the case of the proximal capsule.
Figure 9: EVRT Capsule

Attachment

A linear actuator cable will need to be attached to the inside tip of the end cap. This cable will subsequently run the entire length of the inner shaft to a linear actuator in the controller unit (covered more in the Motor Gearing section). The capsule will be supported by a ring, which will allow for linear movement of the cap proximal and distal to the cutting blade. The ring’s outer diameter will fill up and attach to capsule’s inner diameter. The ring will be soldered to the inner shaft at its distal end and will act as a support so that the end cap moves in a planar fashion. This end cap will actuate linearly along this shaft by means of the linear actuator. As this actuator moves proximally to the cutting blade, the capsule will enclose the cutting surface ring, folding it down similarly to the cutting blade assembly. When at its most proximal position, the distal portion of the capsule will meet up with the proximal capsule portion, sealing the device inside and readying it for delivery or removal from the system. The very tip of this device must be very smooth and made of some other material than the steel capsule as it needs to protect the vessel walls during navigation throughout the circulatory system.

f. Testing the Subunits and Whole Device

Each portion of the device will need to be tested individually, from the physical movements of the blades to the appropriate folding of the blades against the shaft. Additionally,
the effectiveness of the linear actuators pulling on the actuator rings as described will need to be tested. Each piece created will be checked for tolerances before assembling, such as each ring will be tested on the shaft. Diameters will be double checked and connections insured before any mechanical testing is performed. Each component will be mechanically tested separately before combining with the end product to ensure that one portion will not foul up the entire process. As much preparation will be done as possible including finite analysis and other tests to ensure that the forces dealt with will be consistent and feasible both within the body and based on constraints laid out within the device itself.

2.1.2.2 Shaft Assembly:

This design entails the use of a hollow, flexible shaft that runs the length of the catheter in order to actuate the spinning blade at the distal portion of the device. This shaft needs to be hollow to accommodate the linear actuator that will translate motion to the end cap of the assembly, opening and closing the device while it is one to two meters deep in vivo. This shaft needs to rotate to transmit the necessary force to the cutting blade as well as be flexible enough to contour to the human circulatory system, which is far from linear.

A double shaft made from Nitinol Tubing will accomplish these goals. An inner shaft which would fit very snugly within the outer shaft would attach to the distal cutting surface as well as house the linear actuator wire that would actuate the distal endcap. The outer shaft would be the one which rotates and would have the cutting blade attached directly to it. This outer shaft is the one that would be actuated distally and proximally in order to move the cutting blade into position as well as to retract the blade back into the capsule at the end of its deployment. From Johnson Matthey Medical, Nitinol tubing comes in a variety of diameters and thicknesses. Their part (82724) that would be of most use to us would be a 1 meter tube with outer diameter of 3.37 mm and a thickness of .20 mm.[3] The next size down would also be used as it has an outer diameter of 3.05 mm which is very close to the ID of the first shaft as they need to fit closely
within one another. Since this is merely a prototype and not a design that will be immediately tested in vivo, nothing longer than the 1 meter would really be necessary, and would minimize the cost impact of upgrading to Nitinol. The issue with Nitinol tubing--which was specially designed for medical catheter applications--is its cost.

Assembly

The two shafts will be threaded through the catheter and within one another. The proximal end of the inner shaft will be attached and mounted within the controller unit so that it does not move, either linearly or rotationally. The external shaft will be mounted to the motor assembly and will move both linearly and rotationally. A single linear push-pull wire will be inserted down the center of the inner shaft and will actuate the distal end cap of the device. This wire will be attached to a separate linear actuator which will be mounted behind the motor in the controller box. Both linear actuators will move a total of 20mm each as the device itself will only require this much movement.

2.1.2.3 Controller Unit Assembly:

Motor Assembly and Control:

a. DC Brushless Motor

The motor chosen for this system is a DC brushless motor (P/N 3441S001-R3) which is a 12V DC motor in the Pittman Elcom SL Series. [4] The reason for a brushless motor versus a less expensive traditional brushed one is the cleanliness of operation. Since this device is planned to be utilized within the sterile environment of the operating room, it needs to maintain a cleanliness of its own. Brushless motors remain much cleaner than brushed motors, as they do not collect nearly as much dust within their windings. Also, since the motor will be housed within an enclosed aluminum box, the need for the cooler operation that the brushless motor will
provide is a welcome property. This should allow for passive heat dissipation rather than needing to include fans to remove heat from the system.

![Image](image.png)

**Figure 10: Pittman SL #3441S001-R3**

DC Motor Control and Pulse Width Modulation (PWM) will present the motor with an average of a number of pulses of a full 12V source voltage. This is opposed to presenting the motor with a variable DC voltage in order to control the motor’s speed. This can be accomplished by either the use of a speed controller such as the MX033 from qkits.com, or the digital output of the microcontroller. The former is a potentiometer-based PWM controller that would directly adjust the speed of the motor from the potentiometer. The second and more precise way to accomplish this is to utilize the digital output of a microcontroller. In this case a PIC16F877 is used to output a pulse width modulation signal to the speed controller which will convert the signal to one that will drive the motor. This is accomplished by comparing the internal clock of the PIC microcontroller with the output signal of the PWM from the PIC microcontroller. The speed controller then takes this decoded signal and converts it to an analog DC signal which drives the motor precisely. [5]

**Testing and Implementation**

The microcontroller and PWM controller will be programmed and tested via protoboard before implementing or installing in the system. There will be considerable adjustments that need to be made in order to synchronize the pulse clock of the microcontroller with that of the PWM speed controller. The motor itself will be tested and measured for various speeds and analyzed. This will ensure that the speed presented to the motor is the rate at which the shaft and the blade will be turning.
b. Motor Feedback

The motor chosen contains a built-in optical feedback sensor which will calculate the revolutions per minute for the device as it is in motion. This feedback will be inputted back into the microcontroller where it will be analyzed and compared to the output signal. This is to ensure that the motor is moving the way that the microcontroller intends it to. This is also a way of calibrating the PWM circuit and code to ensure that the motor is doing precisely what it is intended to do at the appropriate speed for any given setting on the controller. This system will also allow for the display of the actual speed of the blade to the LCD screen which will be mounted on the front of the controller box. This system will help in the testing of the motor to feedback the speed to make sure that it works as expected and that the input is equivalent to the output.

c. Motor Gearing

Since it is necessary in this design to insert a linear actuator wire down the center of the device, the motor needs to be geared. This will allow for the insertion of a hollow drive shaft that enables for the inner shaft and linear actuator wire to travel down and be sustained within the spinning external shaft. To do this, two unitary spur gears were chosen. Unitary means a 1:1 ratio is used, so as not to change the output speed of the motor. The gears will be mounted on top of each other, and the first being directly connected to the shaft of the motor. The other gear will be mounted on the drive shaft of the blade which will be hollow. This will be supported by bearings at the insertion point of the controller box and a support which will hold up the motor. The linear actuator will thread an actuator cable directly through this second shaft and down the flexible shaft of the cutting blade assembly to the end cap. At this point, it will apply its force and motion. Since the shaft is stationary and does not need to flex, and ideally should not, simple inexpensive steel tubing can be used for this application. The entire motor assembly must be on a
linear actuating track which will move the motor and the outer shaft along a set distance and path which will move the cutting blade distally and proximally as was designed.

Linear Actuators

a. Use of PQ-12f

The linear actuator that needs to be used for the distal endcap will be of the type described here. For these applications the PQ-12f “high force” linear actuators from Firgelli Technologies fit the bill. [6] This actuator is easy to program and very easy to control.

![Figure 11: Firgelli Technologies PQ-12f Linear Actuator](image)

These self-contained units with a 15N force should accomplish all they are intended to. These actuators have built-in feedback devices in the form of a linear resistor which acts internally to determine whether or not the device is in the appropriate position. These systems also utilize PWM in their control. Though this is only a 5V source instead of a 12V one, it is controlled in a very similar way. These actuators have their own interface boards which allow for linear slider-controls for the position of the actuator. The position of the cutting blade will have to be monitored and controlled remotely via the user interface. These actuators have a stroke of 20mm, which should be more than enough for the applications needed as the estimated total length of the capsule itself is about 20mm.

Testing

These actuators will be bench tested and measured to ensure the slider controllers accurately depict the linear displacement of the actuator’s arm. This is important because of the small tolerances within the device itself. If the actuator does not open enough or opens too much, the EVRT could be severely damaged.
b. Linear Actuator Cables

The linear actuators will be connected to long thin cables which will translate the motion down the shaft of the device to the insertion point. The cable will act as the translation of motion to the end cap and will act to apply the force needed to enclose the support blade within that capsule, collapsing it to the appropriate size to slide within the capsule.

User Interface:

a. Display

The controller assembly will contain an LCD screen on the front face which will relay the speed at which the motor is currently running. This will be attained by the microcontroller’s output to the LCD screen which will display two lines. The first is the title “Current RPM” and the second being the numerical rotations per minute value as computed by the microcontroller from the feedback optical sensor of the motor. All of these circuits and coding will be tested in pspice, as well as bench tested on a protoboard. This is to ensure they will work before they are implemented into the system to avoid unnecessary errors or failures.

Sample Code for displaying on LCD:

```c
void LCD() //This function uses the DisplayC function
{
    //to write text to the LCD screen
    if(resetLCD)
    {
        resetLCD = 0;
        clear_display(); //This function clears the LCD display
        //so it can accommodate new characters
        
        DisplayC(0x80, "Current RPM"); //This function writes "Current
```
// RPM" starting at
//the top left of the screen (0x80)
DisplayC(0xC0, speed); //This writes the speed in rpm
    //starting at
    //the bottom left of the screen
}
return;

Figure 8: Internal View of Drive train in Controller Unit

b. User Controls
This whole system will be controlled with three user inputs, the first being the control of the speed of the motor. This will be controlled digitally by using two buttons on the surface of the front face of the controller box which will increment and decrement the speed of the blade by a set value. This will allow for testing of the unit to determine the appropriate and optimal speeds for the cutting blade. Since research that has been done in this regard is sparse, and as each system is different, this would have to be tested extensively. A digital control of this parameter would allow for precise data collection and study at precise speeds. This is done in hopes that a later model would be able to have set speeds that were already optimized for the user, allowing for a less technical operation and greater ease of use. The two linear actuators will be controlled by linear sliders on the front panel of the controller box. These sliders would directly indicate the position along the throw of the linear system that the actuation is currently located. In both cases, actuator rings are used and this can be translated to the distance from the closed origin the ring has traveled.
c. Power Controls

Power will be handled by two switches. One switch will be for the overall power of the system, and the second switch will control the 12V source to the motor so that the motor can be shut down separately. This is done in case there is some sort of malfunction or failure with the blade assembly at the distal end of the shaft, the user can simply kill the power to the motor and control the situation.

d. Testing

Each electrical component will be tested separately and without load before assembling or placement within the controller box. The motor’s control will be bench tested for accuracy and all calibrations will be made before the final controller is assembled.

2.1.2.4 Mechanisms:
Firstly, the device is delivered via catheter to the aorta. The device is positioned so that the seam between the end cap and the proximal capsule is just above or proximal to the aortic valve, with the distal portion of the capsule within the left ventricle. At this point, the linear actuator that controls the cable running through the center of the shaft is activated and moved to its most extended point, moving the end cap distally into the left ventricle. This expands the cutting surface which is positioned beneath the valve to support the leaflets. Once this is in position, the second linear actuator is activated, moving the external shaft and the cutting blade down and out of the proximal capsule to come in contact with the valve leaflet. Once exact position is ensured with the appropriate amount of neo-annulus remaining, the cutting blade is activated. The speed of the blade can be pre-adjusted by the user interface and when the blade is turned on it proceeds to cut through the calcified leaflet tissue.

If this was an actual medical device and not simply an experimental proof of concept, this device would also include a grinder and suction in order to collect any and all debris created in this process and remove it through the hollow portion of the shaft. That is not in the scope of this project since this is merely a study of the effectiveness of the valve resection blade design.

After the diseased leaflet tissue has been removed, the device’s purpose has been accomplished and is ready to be closed and removed from the body. This process is almost exactly the inverse of the process described above. First, the resection blade is retracted back into the proximal capsule where it will be folded up by the contact between the supports and the capsule casing. The linear actuator that accomplishes this should be in the fully closed position as it will be indicated on the controller box. After this has been accomplished, the linear actuator for the distal cap will be innervated to close the distal portion of the device so that the distal edge and the proximal edge meet, effectively closing off the device and fully enclosing it within itself. The device is now ready for transport out of the body. The device will then exit the body through the femoral artery as it entered, readying the patient for the subsequent endovascular valve replacement that will next be implemented. Hopefully this process of valve leaflet removal will be similar in timeframe to that of [1] and allow for quick and easy resection while ensuring precision.
2.2 Prototype

In building the prototype during the spring semester, the design underwent significant modifications. In essence, we were unable to make the ideal prototype due to material costs constraints and size constraints. The Nitinol material that was necessary due to its memory shape elastic properties was too expensive, and did not fall within the client’s budget. The Nitinol sheet metal for the blades and the Nitinol tubing for the design were necessary for the ideal prototype in order for the device’s cutter and holder to expand out of and collapse into its surrounding catheter. The Nitinol tubing was needed to transmit the torque necessary to rotate the blade and the force necessary to actuate the circular cutter and holder. Because the ideal prototype was not able to be constructed, three different prototypes were built in order to exemplify the physical mechanisms and principles of the device.

The first prototype was constructed out of Al foil (with a thickness of .002 in.), and portrayed the folding property of the device. The holder was constructed out of 4 T-sections, and the blade was constructed out of 4 T-sections that were scalloped on top. The T-sections for each part were joined using a spot-weld. They were then attached to the inner aluminum tubing of the device using a ring clamp. After testing and modification of the design dimensions, the flexible prototype was able to collapse into the outer aluminum shaft. When the inner shaft was pulled further back down into the outer shaft, the circular blade was able to fold in on itself in a clover-leaf configuration and fit within the outer tubing. This is due to the mechanical force exerted by the outer shaft pressing in on the thin and flexible foil.
As for the expansion motion of the prototype, the blade was able to expand up and out of the outer catheter when the inner shaft was pushed up. However, the configuration still maintained the clover leaf configuration due to the properties of the stainless steel foil. It must be noted that with a memory shape alloy such as Nitinol, the blade would “snap” back into its circular form when pushed up and beyond the constraints of the outer catheter.
A second prototype was constructed to demonstrate the cutting ability of the blade as well as to serve as a preliminary example of the final prototype, which will be discussed subsequently. The material used for the T-sections of the blade and the holder was Al-3003-h14 that had a thickness of 0.062 inches. The blade and holder of the EVRT aluminum prototype were constructed in the UConn machine shop. Four pieces of the Aluminum metal were cut using the shear, and the band saw was used to make rough cuts of the T-shaped figures. To get all four pieces to be precisely the same dimensions, the miller was used. Computed numerically controls were used to get the precise shape that was desired for the pieces. The T-shaped sheet metal had to be aligned within the machine using scraps of metal to hold it in place. The method wasn’t ideal and required a lot of adjusting to make the pieces sturdy. However, it was necessary in order to get very exact dimensions for all four pieces simultaneously. All four pieces of the blade were cut at the same time using techniques of end-milling and side-milling. After getting all four pieces of equal size, holes were drilled into the siles of the sections for riveting later on.
When putting these pieces together, there exists some overlap due to the nature of the design. It was reasoned that tapering each edge down to a point on the end would allow for easy fitting of the pieces together. However, our technology was limited, and it seemed that this idea may have been beyond our capabilities. Instead, the first method fitting the four T-sections together involved end-milling the tips to half their thickness. This created a large point of stress, however, and also limited the range of motion for its ability to fold. This method of adjoining section is not ideal, and was modified in the final prototype. When connected, the blade formed a 10 inch diameter. In order to cut the serrations on the top of the blade, the CNC miller was used. The next steps in the construction of the blade was making the ridges sharp, and bending the T-sections so that they fit together in a circle, and riveting them together. Holes were drilled into the edges of the T-sections and the pieces were riveted together. The bending for this prototype was done by hammering the pieces into a circular configuration. This is not a very effective method, and the final prototype was constructed using a different technique.
The holder portion of the aluminum prototype was constructed in a similar manner, minus the scallops for the blade. The top of the holder was flat instead. The cutter and holder were then attached to the inner rod of the device using two clamps. The inner rod was then placed within the outer rod, however the cutter and holder were not able to fit within the outer rod as was to be expected of this second prototype. The aluminum prototype broke apart at the sections adjoining the different T-sections, and the prototype was not sharp enough to cut. Therefore, the device underwent design modification in the final model.
Errors in the aluminum prototype design were identified and analyzed, so that modifications could be made for the final model. Modifications included the adjoining sections of the T-sections, the connection of the T-sections, the bending of the blade and holder, the sharpening of the blades, as well as the overall dimensions of the blade and holder. Modification of the adjoining portions of the T-section involved end-milling the sides at an angle to minimize stress. The aluminum prototype had a sharp cut off at the end where the thickness dropped from .60 inches to half. In the final prototype, the side of the T-section was end-milled at a slant so that there would be no sharp transitions that would allow for high stress concentration factors. Therefore when bending the pieces into a circular shape, part of the material won’t snap off like it did before. The junctions of the T-sections in the final prototype involved split spring pins rather than rivets, which allowed for axial rotation between pieces. This allowed for greater mobility. The expansion and collapsing of the blade and holder could then rotate between the T-sections in order to make the design more stable.
The bending of the blade and holder in the new design involved rolling the material over tubular rollers instead of hammering. This was much more effective in making the pieces form into a uniform circular shape. The sharpening of the final prototype was done using the belt sander instead of using a file. This required careful touch while producing each piece, but the results were much better.

After being bent, the tips of the blades were held at an angle to the belt sander, and creating sufficient sharpness. As a result of the height of the blade being reduced so drastically, the overall design had to be changed so the integrity of the piece around the attachment points was not compromised. The peaks of the serrations were placed over the ends of the T-sections instead of in the center of them. This gave the design more structural rigidity at the junctions.
The corner cut was used instead of the miller for cutting out the T-section pieces for the final model. Spring steel proved to be much more difficult to work with than aluminum. When placed in the miller, the pieces bent to the side rather than being cut. Accuracy was obtained through the careful alignment of the pieces within the machine.

The type of material used in the final model differed from that of the aluminum prototype as well. 1095 spring steel was used instead of the aluminum, with the thickness cut down from .64 inches to .32 inches. The spring steel allowed for more flexibility than the aluminum in terms of folding, and it was also a harder material which allowed for better cutting properties. The gauge of steel chosen is commonly used for various knives, as well as Japanese katana swords. The spring steel holder and cutter were constructed in a similar fashion to that of the aluminum prototype.

![Figure 20: Inventor images of completed blade and back plate T-sections](image)

After the T-sections were cut and bent, the eight total pieces were put into a oven at 1400° Fahrenheit for annealing. After one hour in the oven, the pieces were quenched in oil before being put back into the oven to complete the hardening process at 700°F for another hour’s time. The heat treatment gave the pieces increased hardness; however, it was not elastic enough to be able to collapse within the catheter as the Nitinol material would be expected to behave. Hardening at a higher temperature (~1000°F) possibly could have helped gain some additional flexibility, but likely the lack of flexibility was just a product of the much cheaper material that the budget forced us to use.
Annealing works with the diffusion of atoms in a solid material so that it approaches its equilibrium state. The atoms and redistributed and dislocated in the metal so that it deforms more easily. This translates to increased ductility. Internal stress is relieved in a spontaneous process that speeds up with heat. The dislocations and alteration of the metal’s crystal lattice cause the changes in hardness and ductility that are observed.

Figure 21: Inventor image of a quarter blade and back plate section in their final conformation.

The testing will involve cutting a material that’s similar to, but less hard, than the calcified aortic valve leaflet. This cutting principle can then be applied to the ideal device constructed out of Nitinol. The ideal Nitinol would be able to cut the calcified aortic valve leaflets because it is made of a harder material.
Figure 22: Full version of the EVRT in Autodesk Inventor

The testing of our model involves two separate experiments. First, it needs to be seen that our product can deliver the force and torque necessary to cut through a tissue analog by itself. This was done using thick pieces of meat, along with pericardium tissue. Additionally, it would need to be seen that the blades would be able to fold up into the scaled size of the catheter. It is important that the assemblies can be proved to fold up and spring back to their original form.

Figure 23: Completed EVRT

In creating the test set-up for the aluminum prototype, it was determined that three key constraints must be evaluated. The first is the torque and rotational power. This is determined by
the power in the motor and the dimensions of the design. Using equations for the stress due to torsion (shear stress) and the torsional deformation, the number of rotations per unit time were calculated. The motor’s speed is adjustable, so the blade speed can be set by the user. The shear stress in the calcified tissue (or testing tissue to be used) is equal to the shear stress in the device. The stresses caused in the tissue and device are equal because stress=force/area. The forces are equal and opposite according to Newton’s law, and the surface areas in contact with each other are also equal. Therefore, in order to ensure deformation only in the tissue and not in the device, the device must be made of a harder material than the tissue.

Hardness is the second constraint. Therefore the determination of the most suitable material must be evaluated. Different types of spring steels such as ASTM-A228 music wire and ASTM-A232 alloy steel were evaluated, because steels tend to have a higher Young’s modulus than most aluminum alloys. The type of spring steel that was decided upon was 1095 spring steel. The different properties and hardness values of the materials were taken under consideration. The specific hardness of calcified aortic valve leaflets was found to be 225HB. In the final prototype design, the testing will be done on various soft tissues instead of the calcified aortic valve leaflets. This is due to the economic constraints that called for the product’s design to be less hard than ideal. The hardness of spring steel in comparison to that of the tissue is 210HB, whereas the hardness of Nitinol compared to that of the calcified aortic valve leaflets is 265.

Figure 24: Completed and mounted EVRT blade and back plate
The third constraint is sharpness. The blades were made to be serrated so that they were very sharp, and so that the shear stress would play a large factor. It was preferable to have the sharpness play a larger factor than the compressive stress on the tissue. It was desirable that the device cut more than it punched or pushed the tissue. The sharpness also ties back into the hardness of the blade material in order to prevent the blades from breaking. The prototypes are more proof-of-concept to show that the device actually cuts, collapses and expands.

Figure 25: Complete EVRT assembly bench test setup

The final set-up involved clamping the blade portion onto the outer tubing and placing the outer tubing within the gears of the motor device and actuator. The holder portion was clamped onto the inner tubing. This fit within the outer tubing so that the cutter and the holder were facing each other, allowing for the tissue sample to be placed in between.
The testing apparatus was set up so that two ring stands were attached to two ring clamps, which then clamped onto the tissue preparation. The tissue preparation was constructed out of two circular rings that were 4.5 inches in diameter and .7 inches thick by using the lathe to carve out the middle of a steel tube. The dimensions were set so that the cutting blade would be able to fit within the rings, allowing for tissue resection with ample space around the sutured portions. The holder was also able to grip onto the back of the sample for structural support. The tissue sample that was used was three pieces of ham that were arranged in between the two metal rings so that they resembled a tricuspid aortic valve. The rings and the tissue were held in place with suture as can be seen from the figure.

Figure 26: Mock Tissue Sample Tricuspid Aortic Valve
Figure 27: Test Tissue mounted to the test rings via suturing

The tissue sample was then placed in between the holder and cutter of the EVRT using the two ring clamps.

Linear Stage for Linear Actuation of Blade

The linear stage is an assembly which is purchased from Parker Motion. This stage is simply a plate of metal which is free to move due to its embedding in the lower portion of the stage and supported by two sets of slide bearings. The upper portion of the device is driven forward and back along the slide bearings by a worm gear screw. This worm gear is controlled by a NEMA 17 Stepper motor which drives the worm gear.

The linear stage does not have any form of limit switches or otherwise and care must be taken while using it as the program which controls the motors is the only thing which can set the limits.

The linear stage comes set with several ¼-20 bolt holes which can be directly used for mounting of equipment. This feature is used by this device to mount the upper motor support.
Upper Motor Support

The upper motor support is made of precision-machined aluminum. The 6-inch square aluminum plate which is designed to interface with the surface of the linear stage contains six ¼ inch holes for ¼-20 bolts to bolt to the tapped holes in the surface of the linear stage. An additional four bolt holes are in the center which are counter sunk for use of four cap nuts in order to mount the rest of the upper motor mount to the linear stage.

These cap screws mount to the two uprights of the assembly. The front one has four holes and a square frame with beveled corners. The four holes serve as bold holes for four through bolts which mount the NEMA 23 Chassis motor to the motor assembly. Below this position (exactly 2 inches center to center) resides a precision milled hole with a pressed ball bearing.

Opposite this upright support is a second, shorter support which the larger motor rests on. It also contains a precision hole with a ball bearing pressed in it which lines up precisely with the first bearing hole. Through these bearings, the outer 5/8” shaft is fitted and lubricated.

Affixed to the shaft of the motor is a 2” spur gear and aluminum bushing. These are secured to the shaft by a #10-28 set screw through both the gear and the bushing which fits in the slotted portion of the motor shaft. A second gear is positioned directly below this one, affixed to the 5/8th outer shaft which is supported by the two bearings. This gear is affixed to the shaft by a #4-40 set screw directly in contact with the outer shaft.

Through the outer shaft (which is hollow) is inserted the inner .5” shaft (which is also hollow). Both of these shafts have been polished on the lathe and are greased to eliminate as much of the friction between the metal as possible.

NEMA 17 Stepper Motor (Linear Motion)

The NEMA 17 Stepper Motor (National Instruments, P/N CTO12ELF10MMAA0) provides the motorized linear motion of the EVRT blade. Dimensionalized in fig. 13, the stepper has a peak holding torque of 80 oz-in (.56 N-m) and a maximum speed of 3000 RPM with 200 steps per revolution standard. For this application, the NEMA 17 Stepper motor moves at a
A modest twelve (12) rotations per minute in order to utilize its full torque potential in the movement of the system’s linear stage. Acceleration rates on this device are in the range of 10 revolutions per second, so it takes roughly one second to reach this maximum speed.

![Torque versus Speed](image)

**Figure 28: Torque Curves, Dimensions, and wiring diagrams for the NEMA 17 Stepper Motor**

This motor is a “four-lead” motor type with two phases and runs off of a nominal 24Vdc power source delivered by the motor controller. This motor is mounted to the linear stage by four cap screws in the rear of the stage which align with the four holes on the adapter plate on the NEMA 17 stepper motor. The shaft connects to the worm gear of the linear stage by a spring shaft coupler which is accessible by turning the linear stage over and inspecting the small gap near the motor housing. To connect the shaft simply insert the shaft of the motor into the coupler and tighten the hex bolt on the coupler. This secures the shaft of the motor to the worm gear of the linear stage. The wires of this motor are configured in the following way (Table 1) where the numbers indicate the port number of the green connector of the NI motor driver.
### Table 1: Wiring Diagram for NEMA17

<table>
<thead>
<tr>
<th>Port # on Connector</th>
<th>Wire color</th>
<th>Connected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Orange</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Blue</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>EMPTY</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Red</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Yellow</td>
<td></td>
</tr>
</tbody>
</table>

3.6 NEMA 23 Stepper Motor (Rotational Motion)

The NEMA 23 stepper motor (Parker Automation, P/N LV232-02-10) provides the motorized rotational motion of the EVRT blade through the unitary gears which will translate the rotation from the NEMA 23 chassis motor to the 5/8\(\text{th}\) inch shaft which supports the EVRT blade. This motor, though it can command up to 70Vdc, this device runs it at a modest 24Vdc. The motor, wired in the series mode for an eight wire motor to the green connector for the NI motor driver (Table 2) provides a higher torque curve at lower speeds and therefore is favorable for this device (fig 27).
Table 2: Wiring Diagram for NEMA 23

<table>
<thead>
<tr>
<th>NEMA 23</th>
<th>8-wire Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Red</td>
</tr>
<tr>
<td>2</td>
<td>Black</td>
</tr>
<tr>
<td>3</td>
<td>Case Ground (Purple)</td>
</tr>
<tr>
<td>4</td>
<td>White</td>
</tr>
<tr>
<td>5</td>
<td>Green</td>
</tr>
<tr>
<td>Combine</td>
<td>Orange &amp; Brown</td>
</tr>
<tr>
<td>Combine</td>
<td>Blue &amp; Yellow</td>
</tr>
</tbody>
</table>

The LV232 is a two-phase stepper motor with maximum speeds of 3000 RPM and maximum holding torques of 120 oz-in (.84 N-m) (fig 28). This motor is run at a modest 15 RPM when cutting to ensure that the motor is capable of the torque necessary to cut through tissue during testing. This value can be adjusted approximately 25% up or down but it is not recommended to go outside of these limits at risk of damaging the motor as it is still a relatively small motor for the application.
The motor is mounted into the front upright portion of the motor assembly by four through bolts and nuts which align with the four mounting holes in the motor case of this device. When installing the motor must be pulled to the top of the limits of which it may be located as this will allow for proper placement and meshing of the two gears.

### 3.7 NI Motor Driver

The driver / controller for both the NEMA 17 and the NEMA 23 stepper motors lie in the NI MID-7604/7602 motor driver. This is a 24Vdc output motor drive which runs of 120V AC wall current. It receives instructions from a host computer and software and transfers these signals into motion for the stepper motors. This is a very precise device which is capable of up to four axes of motion controlling four different motors at a time.

For the purposes of this device, only Axis 1 and Axis 2 of this device are used. The rotational motor is to be connected to Axis 1 via the green connector that was discussed earlier.
and the NEMA 17 linear motor is to be connected in a similar fashion to Axis 2. Both of these outputs have a nominal value of 24Vdc at 1.1Amps.

No other ports or controls are used on this device.

**Host Computer and LabVIEW software**

This device is ultimately controlled by a LabVIEW-based graphical user interface which is installed on the native host computer. The computer in question needs to have the following items installed prior to trying to run the software provided:

- NI 7xxx series PCI controller Card

- LabVIEW 8.5.1 or later OR the LabVIEW 8.5 Runtime Platform

- National Instruments Measurements and Automation Software

The program that runs this device is called EVRT Motion2.0.vi. This program will open to a Graphic User Interface (GUI) which supplies the user several controls and values they are able to select or modify. All values have been set to limits so that they cannot easily be overrun. The values would have to be changed within the full version of LabVIEW in order for the limits to be overridden.

The program allows for two different options, Manual mode and Automated Mode. Automated mode is set to factory default values and will need to have the full LabVIEW software in order to change these values for customized use. Otherwise the use of the Manual Mode is necessary. This allows for the adjustment of the absolute location of the EVRT blade as well as the rotational speed in RPM at which the blade is rotating.

This program uses the National Instruments Motion Assist programming in conjunction with the Measurements and Automation program also licensed through National Instruments to control both axes of motion in which the device moves. It does this by counting the number of steps each of the stepper motors moves at any given time. Knowing that each revolution is 200 steps, and wanting to know the RPM, we calculate the number of steps per second in which the device is to move by:
3. REALISTIC CONSTRAINTS

3.1 ENGINEERING STANDARDS

This device will be required to cut calcified or diseased valve leaflet tissue inside the aortic valve. As a result, the level of precision to this tool will need to be very high. Once set inside the aortic valve, it will be possible for there to be user adjustment in the linear actuators. While the total distance from the minimum position of the blade to the position where the blade is closest to the cutting surface and ready for cutting is not very far, the movements need to be very precise. Since all aortas are sized differently, the diameters will vary from anywhere from 22 mm to 27 mm. This means that in some cases, multiple attempts at the cuts will need to be made, meaning that very small adjustments will need to be done with the linear actuators.

The machining of the part must be precise as well. Since the cutting blade is so small, the holes to connect the halves of the blade to each other must be precise in their dimensions and distances from the edges. If the holes do not properly line up, then there could be a seam that is created by the blade pieces coming together inaccurately. If a bump is created by the seam, then there could be serious damage done to the leaflets. Any ridge on the blade once it begins spinning could cause a high force snag, which could result in a torn leaflet and possible damage to the aorta and aortic wall.

3.2 ECONOMIC CONSTRAINTS

Our project prototype will be using components that are made out of Nitinol metal. Due to the high cost of Nitinol metal, this may make the product less feasible for production based on its cost. The use of a Nitinol shaft is much more expensive than using possibly a steel shaft. The problem with the steel shaft is that in order to have it be hollow, it would need to be wrapped around in a helical pattern, making for what ultimately would turn out to be a very long spring. The Nitinol tubing is purpose built for using as a catheter wire, and it is available in the sizes that
are needed for the project. It is the perfect material, however, when looking towards mass production, it may not be the best choice based on its cost.

### 3.3 ENVIRONMENTAL CONSTRAINTS

Since the tool will be used in vivo, biocompatibility must be checked for all the components. It is important that there will not be any particles or pieces of debris that come off the tool and begin to float around in the patient’s blood stream. With this regard, the metal pieces must be ensured to be sturdy, and all other moving parts must also be ensured that they will not fail or become separated from the main portion of the tool at any time during the procedure.

It also is important that the tool does not generate excessive heat during the procedure. Since the amount of cutting that would actually take place, along with the environment of being surrounded by blood should keep the temperatures during cutting from rising too much due to friction, however this is something that should be monitored once the testing phase has been reached.

While not in the overall scope of our project, eventually before this device would be put into production, some sort of vacuum filter would need to be included in the design. It would not be ideal to have pieces of debris from the leaflets themselves floating around in the bloodstream, so some sort of waste removal would eventually need to be thought of.

### 3.4 MANUFACTURABILITY

Since the parts of this tool are extremely small and precisely machined, the manufacturability of this prototype is probably not that feasible. While the target marketing price of the tool should be around 30% of the cost of the prototype, it is difficult to see that being possible to be profitable unless some changes are made. Some things that may have to be sacrificed in the name of manufacturability include the Nitinol shaft in favor of a stainless steel produced shaft. Additionally, the serrated blade may need to be dropped in favor of a simpler design. The serrated edge will be both expensive to machine, and difficult to maintain sharp. Only after testing will it be known if these aspects of the project turn out to be necessary, or if they can be modified for the sake of mass production.
3.5 SUSTAINABILITY

Since the cutting force needed to be generated to cut through the leaflets needs to be strong while coming from such a small source, the blade sharpness is very important. There would be a need to keep the blades sharpened, or possibly make the blades easily interchangeable by the user. A replacement blade would be feasible; however being able to resharpen the blade would be more cost effective for the user. Additionally, the motor will eventually wear out, which makes it important that our choice in motor is a dependable, long lasting one.

3.6 HEALTH AND SAFETY

When dealing with any type of procedure inside the body, it is important to realize that there is significant safety risk. This is compounded by the use of a cutting blade inside the body. Much attention needs to be paid to ensure that nothing that is not supposed to be cut is damaged. Since the device needs to be much larger than the artery it will be traveling through, it needs to be able to properly expand prior to cutting, as well as collapse once the procedure is finished. If the product does not properly fold back up with the aid of the linear actuators, serious damage can be done to the arterial walls.

4. SAFETY ISSUES

There are many things to look at with respect to safety when designing this project. There could be possible issues with the blade itself, the cutting the blade needs to perform, debris in the bloodstream, as well as possible mechanical failure.

The blade must be precise in construction, as the cutting must be smooth and even. Since there is not much maneuverability in the environment the tool is to be used in, the device must properly cut the correct location each time. Additionally, no damage can be done to the aortic wall, which is cause for the cutting surface to be larger than the blade itself. The idea behind
having the cutting surface larger than the blade is that it should also provide a buffer against the aortic wall if the tool begins to get too close. This would prevent any cutting from occurring on anything other than the leaflets themselves.

Additionally, the closing of the capsule once the procedure is complete is another important part of the procedure that must be done with precision. If the capsule does not close properly, the blade will have not collapsed and will result in possibly serious damage to the aortic wall or the arterial walls. Since the blade will be expanding out to a diameter of 16 mm prior to the procedure, in order to remove the tool through the same path that it entered, it must be collapsed back down to fit inside the 7.6 mm catheter.

Debris is also a problem when performing this procedure. When the cutting will occur, the leaflet debris will begin just floating around in the bloodstream. While not in our design requirements as provided by our client, debris removal will have to be something that will be looked into and developed before this product is ready for in vivo procedures. In addition to debris from the leaflets themselves, it is important to ensure that there is no debris that is a result of the tool itself failing in any way.

As a result of the serious nature of the procedure, in case anything unplanned occurs and there is the need for stoppage, an emergency cutoff switch will be included in the control box. This will ensure that incase the procedure goes wrong at any point in time, the device will have a way of immediately stopping all cutting, and can be quickly removed from the body.

5. IMPACT OF ENGINEERING SOLUTIONS

5.1 GLOBAL IMPACT

This is a project that has not completed anywhere in the world. Inside the United States, there is no one currently working on a device of this nature. The closest anyone has come to a tool like this was the German team of Florian Hauke et al. However, their project was only produced for open heart surgeries. While they took into account a possible future endovascular procedure when developing their tool, the idea of a procedure this minimally invasive is basically still only a vague concept. They used a collapsible blade basically as a test run to
understand the mechanics for a future tool that would be used endovascularly. However, their most recent published paper only discusses this as a proof of concept, without actually building or testing anything.

5.2 SOCIETAL IMPACT

Endovascular procedures reduce the risk of severe complications of the surgeries that these procedures would be replacing, especially in patients with advanced age or co-morbidities. This product would be greatly useful due to the fact that aortic stenosis is the most common valvular heart disease in the western world. This procedure would definitely reduce the rehabilitation times for procedures that require bio prostheses for the aortic valve. Shorter recovery added to the fact that the surgery should have much less complications will result in much happier and healthier patients. Without having to go through open heart surgery, there will be much fewer complications that result from the necessary healing aspects that are required. This is especially important for those patients who are older. Elderly people’s bodies require much longer recovery times, so avoiding a procedure like open heart surgery will be very valuable to this demographic. The same goes for people with weakened immune systems or other conditions that limit their ability to properly recover from a surgery like that.

6. LIFE-LONG LEARNING

This project is the first long term biomedical engineering project that our group has worked on. It has been an important learning process from the initial brainstorming sessions, through the first sketches done of the tool, to the alternative designs and finally the optimal final prototype. This project focuses on the main purposes of biomedical engineering. The project involves the engineering aspect of the mechanical and electrical properties that go into producing any tool for any task, and combines this with our knowledge of the human body and its
properties. When developing this tool, many times ideas were generated that may have been thought of based on purely engineering logic, or purely knowledge of the body. Without combining these two, the design would never work for the task of cutting valve leaflets. What has been developed in the final prototype is a tool that considers and utilizes both proper knowledge of engineering and the body.

Over the course of the design phase, our group was forced to learn or extend our knowledge of many different things. Many programs were necessary in the design of the tool. At the onset of the project, our knowledge of Autodesk Inventor was near non-existent. As attempts at creating parts of the EVRT increased, so did our level of mastery of the program. The level of detail and precision of the parts created increased from basic shapes to something that could be sent to a CNC shop and be machined with very positive results. Additionally, our knowledge of website maintenance and Adobe Dreamweaver were both very limited. As updates to our project we needed to be posted, the intricacies of web design were learned and our comfort level with Dreamweaver rose to the point where updates to the site could be done within seconds.

Additionally, our knowledge of previously learned programs, such as MultiSim, was expanded. While having basic knowledge of MultiSim as well as the use of microcontrollers existed from prior classes, using them for our project required some additional learning. In order to control this device, knowledge in embedded C code and how to upload the program to the processor using MPLab is also something that our skills needed improvement in.

Outside the engineering portion of this project, much was also learned about the aortic valve as well as endovascular procedures. Understanding how the procedure would be done was an important step in creating the tool. Specific anatomy of the aortic valves, as well as their mechanical properties, was also important to creating our design. The shape of the aortic valve influenced our design, and also determined whether the cutting surface or the blade would be fixed to the distal end of the tool. Early in our designs, it was undecided whether the cutting would be done from the ventricular side of the heart or not, however once it was possible to get a good view of an actual valve helped make the determination.
### 7. Budget

#### 7.1 Proposed Budget

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#### 7.2 Actual Budget of Prototype

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8. Team Member Contributions

CHRIS GUAY

Chris is the lead programmer for this project. Using his expertise in coding, he is in charge of most of the embedded C code, as well as the microcontroller design. Using this ability, he will take most of the responsibility of the controller box assembly. This includes integrating the motor, along with the electronics to control the linear actuators. Additionally, Chris has assisted in producing the animation of the CAD model simulation of the procedure. Chris will also lend help in some of the assembly of the tool, specifically in connecting it to the motor and actuators. Finally, he will also assist in various portions of the test procedures.

On the final prototype, Chris was responsible for the building of the transmission and mechanical aspect of the driving of the device. He heat treated and tempered the spring steel blades and back plate to the appropriate specifications. Also, Chris wrote and programmed the LabVIEW program which controlled the whole system.

JOSH O’BRIEN

Josh is the lead mechanical designer for the project. The main assemblies of the EVRT model have been designed by Josh. He has selected most of the materials for the project as well. As a result, Josh has done most of the CAD drawings, including both the initial flattened parts to be cut, and the finalized sharpened pieces ready for assembly. Josh will be taking the lead on machining and assembly of the prototype and final model. Additionally, Josh will assist in the
assembly of the controller box, as well as some of the coding. He will also be assisting in the
execution of various test procedures.

On the final Prototype, Josh assembled the blade and back plate after heat treating and
assisted with testing of the motor assembly.

**CATHY YEE**

Cathy will be working on the assessment of the mechanical properties of the device. She will be
conducting finite analysis of the strains on the tool, as well as the forces required to resect the
valve tissue. Additionally, she will be testing the prototype and final models at various points of
their construction phase. She also designed the PCB coding. Cathy is also the group’s liaison
with the companies needed for purchasing parts and getting the final model’s pieces machined.
She will be designing all the test setups, including the final simulated surgical routine. Cathy will
also be the group’s scribe when it comes to data collection.

On the final prototype, Cathy fabricated the cutting blades and back plate.

**9. Conclusion**

The goal of this project is to create a tool that will endovascularly resect calcified or
damaged aortic valve tissue. Due to the nature of such a procedure, this device needs to be quick
and efficient in its cutting, while at the same time maintaining a high level of safety and control.
As a result of this, a control box will be used to offer speed and distance controls, as well as an
emergency cut off switch in case of any problems during the surgery. The final design consists of
a collapsible serrated style of blade that creates tension on the tissue against a back support plate.
Both of these aspects of the model are made out of nitinol metal, and are fully collapsible to fit
within a 24F catheter for transport through the femoral artery to and from the aorta. This model
will lead to much less invasive surgeries for heart valve replacement, meaning less complications
and shorter recovery times for patients.

**10. References**
[1] Florian Hauke et al., Journal of Materials Engineering and Performance, [online], vol 18, numbers 5-6, pp. 463-469, (August, 2009), Available: www.springerlink.com/content/47rp16x318018721


11. Acknowledgments

Acknowledgments must be made for Dr. Sun as our patient client in this endeavor as his input was greatly appreciated and adapted into the project’s scope. James Paolino was also a great help in understanding the circuitry needed as well as the PCB programs and answering all of our CAD and related questions.

Other acknowledgements: Pete and Serge and the rest of the UConn Machine Shop, Kewei Li, Dr. Bi Zhang, and Kelly Taylor.
12. Appendix

A. Updated Specifications

Due to the lack of funding as was discussed in the earlier sections, the project was forced to be modified to meet the budgeting issues. When attempting to use Nitinol for the device at 17mm in diameter, it was found that the project was to become a scaled up proof of concept model and the Nitinol would not be sufficient.

The device was scaled up five times (5:1) and all dimensions are scaled accordingly. Instead of flexible shafts as was stated in the original specifications, the proof of concept design called for two hollow inter-fitting shafts made of aluminum instead of the expensive Nitinol. These were rigid shafts to allow for added support for the larger model. The final dimensions of the blades and back plate can be viewed in the prototype section of this paper.