Optimal Design Report

Endovascular Tissue Removal Device for
Calcified Valve Leaflets

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1.1 Introduction

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 optimal design is a modified version of the three alternative designs. The device will be inserted into the femoral artery, and threaded endovascularly to the aorta valve. Due to the tight path of 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. 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, and all 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.

1.2 Subunits

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.

The processes themselves require different parts and mechanisms of action that work together to accomplish the delicate task of valve leaflet resection in a person’s heart. The
resection device excluding the external motor and LED is composed of 8 main parts. The 24F catheter, a hollow shaft with a coil within its center and a linear groove on its outer surface, a metal washer, an expandable cutting blade, an expandable holder, two different hollow casing with ridges that surrounds the hollow tube (one for the cutter, and one for the holder), and an end cap.

I. 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.

II. Cutting Blade

The actual resection blade is comprised of several different parts. First of all, the blade itself is comprised of two pieces of Nitinol metal, a hyper elastic material with strong shape-memory characteristics. This blade, based on the drawing below, is comprised of two blade sections and four supports. These two blade sections are held together via tiny rivets 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 3: Diagram of Cutting Blade Assembly
This blade will be serrated in a wave pattern 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 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 shaped. This will have to be done by heating of the blade and bending and shaping it on a die of the appropriate diameter. Once this is done, 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 wave pattern as is depicted. 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 to an actuator ring which will be directly connected to the linear actuators, as will be discussed later. This ring is comprised of an outer plate on either side with a keyed inner ring that will be connected to the blade. This inner ring will rotate as the shaft of the system rotates, while the outer ring shell will remain independently still. This outer ring will act as the actuation arm for the system, allowing for the blade to move proximally and distally
toward and away from the leaflets and the cutting surface. This motion is also what allows the blade to be collapsed back into the capsule, and will be discussed in detail below. By retracting the ring all the way, the blade will be forced into the tube, folding the hyper elastic Nitinol.

III. 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 extension to the shaft via a cover plate which will be channeled and surround the shaft on the distal tip of the device. 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.

IV. 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 blade into the tube.
V. 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.

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 flexible shaft to a linear actuator in the controller unit (covered more in the Motor Gearing section). The capsule will be supported by a slotted 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. This slotted ring will sit upon a similarly slotted shaft at the distal portion of the device, also serving as the attachment piece for the holder supports. 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.

VI. 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.

1.2.2 Shaft Assembly:

Nitinol vs. Wound Spring

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.

The current design calls for the manufacture of a counter-clockwise-wound helical spring shaft, tentatively made out of high-carbon steel which would have to be heated and wound around a rod of desired internal diameter to create a shaft. The shaft would both contour to the
changes in direction of the blood vessels as well as be strong enough to translate the rotational motion from the motor to the spinning cutting blades. The diameter of this wound spring-like shaft was to be made at approximately 4mm outside diameter with at least 1mm inside diameter so that a linear actuator cable would be able to fit within the system.

Very recently, it was found that there is small Nitinol tubing which would contain the same flexible properties that the wound spring approach would, while at the same time it would be stronger and easier to handle. 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] 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. This material is ideal for this situation but it will have to be reviewed more thoroughly as to whether our budget will allow for such an application.
Assembly

The shaft itself, whether it be made of Nitinol or a wound spring-like wire, will be fitted within a 24F catheter. Alongside this shaft will be two linear actuator cables which will be connected to the actuators mounted in the controller unit assembly. These wires, parallel to the shaft, will actuate the cutting blade as it spins within the cutting blade assembly. A third actuator wire will be threaded through the hollow shaft which will attached to the distal cap of the cutting blade assembly and enact the closing of the capsule for removal from the body. All components of this shaft assembly will connect both at the cutting blade assembly with the controller unit. It will act as motion translators only, no other mechanisms are at play in this assembly. In vivo the shaft would need to be up to two meters in length to reach the aortic arch, however, our proof of concept will only contain approximately one meter of shaft. This will make the design easier to work with, demonstrates the idea of the flexible design, as well as decreases the cost of making or purchasing such a long shaft.

1.2.3 Controller Unit Assembly:

Motor Assembly and Control:

I. 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.
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.

**II. 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.

III. Motor Gearing

Since 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 linear actuator to traverse the spinning 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. One of the two linear actuators 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.

Linear Actuators

I. Use of PQ-12f

Two linear actuators will be used in this design. One will be used to actuate the end cap of the device, while the second will actuate the linear motion of the cutting blade proximal and distal to the cutting surface. For these applications the PQ-12f “high force” linear actuators from Firgelli Technologies fit the bill. [6]
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.

**II. 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 first will be through the center of the shaft, and the second will entail two cables which will run parallel to the flexible shaft. They will run through two small holes on either side of the shaft output from the controller box and be actuated together by the second PQ-12f. The reason for two actuator cables is the device will be acting upon a ring running along a track. This cannot be attached by the center, instead at a point along the radius of the ring. To avoid any sort of racking or torsion stress on the ring, which could cause it to bind and fail, two actuators will act on opposite sides of the proximal face of the ring. To combine these two wires back to the single actuator arm, a similar actuator ring will be used attached to the linear actuator’s arm where both the cables will originate.
User Interface:

I. 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
    if(resetLCD) {     //to write text to the LCD screen
        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;
    }
}
```
II. 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.

Figure 9: User Control Box Front Panel

III. 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.

IV. 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.

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 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. REALISTIC CONSTRAINTS

2.1 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.

2.2 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.

2.3 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.

2.4 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.

2.5 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.

2.6 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.

3. 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 in case 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.

4. IMPACT OF ENGINEERING SOLUTIONS

4.1 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.

4.2 SOCIOETAL 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.

5. 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.
6. 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


