W. L. Gore Stent Crimper

Preliminary Proposal

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Mechanical Engineering

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DISCLAIMER

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1 BACKGROUND

1.1 Introduction

The project goal is to develop, produce, and evaluate a low-force stent crimping device that utilizes a crush iris and a radial force readout. The project would be multidisciplinary, with the electrical engineering team and our mechanical engineering capstone team working together under the direction of the Gore Medical product division. The mechanical engineering team will primarily focus on machine design and material component selection, as specified by the client. Our client and sponsor for the project is Tanner Moll from W.L GORE, team advisor Dr. Pete, and the medical authorities, as well as the people who will benefit from the device, are the most important stakeholders in the project.

The importance of this device comes along with a serious medical procedure in manufacturing endovascular stent grafts. Endovascular stent graphing is the treatment use to help patients with aneurism. A balloon-like bulge in the aorta, the main artery that delivers blood from the heart through the chest and body, is known as an aortic aneurysm. The strain of blood pumping can separate the layers of the artery wall, enabling blood to flow in between them, causing aortic aneurysms to dissect or rupture [1]. The best method to repair an aneurysm depends upon several factors, including the location and shape of the aneurysm as well as the physical condition of the patient [1]. Surgeons perform surgery inside your aorta using thin, long tubes called catheters. It involves placing a stent surrounded with a fabric liner to reinforce the weak spots. Endovascular grafting is a minimally invasive method to treat an aortic aneurysm instead of an open aneurysm repair [1].

The market value of the endovascular crimping devices is in exceedingly high. Also, there are no stent crimpers that can crimp under radial forces and diameters simultaneously. If the machine regulates the force, the diameter is dependent on the stent. If the machine sets the force is a dependent variable, however, both mechanisms have their own advantages and disadvantages, which the team can fix if the mechanism can set both settings simultaneously. Therefore, this is one of the major challenges our project is facing, whereas finding the radial forces and diameters that would work according to this interchangeability.

1.2 Project Description

The following project description, submitted by the client, focuses mostly on the requirements that the team must meet to finish the overall design output focusing on the mechanical components of the device. “The scope of this project is to design, build, and evaluate a low force stent crimping machine utilizing a crush iris with a radial force readout.”

Apart from the main scope given in the general context, the client gave the overall compatibilities, the design should contain. The device should correlate under the safety standards given by the ANSI (American National Standards Institute), OSHA, and or other available safety standards. The team needs to generated iris designs for the device per requirements. As mentioned previously under the introduction range of diameters, radial forces and the team need to establish stent lengths and the team needs to justify the selections. Moreover, the team must ensure the designs meet the stepwise design process. Additionally, Graphic User Interface (GUI) shows the crimping forces and diameter data for the crimped stent.

Apart from the focus on the project requirement the client also believes the project will be iteratively attribute understand customer requirements into design specifications in the real world. Whereas students will learn how to develop and utilize the design process to prototype & build a machine and iteratively improve it. Also, since this project have demands on both electrical and mechanical components client the project introduces the team into the field of mechatronics (how mechanical and electrical components interface). Students will learn about Gore's culture and what it is like to work as an engineer daily, while improving the essential skills as a leader, team player and how to understand business aspects of a real-world project.

2 REQUIREMENTS

When designing, teams must certain criteria for the client, as well as details that specify what details the engineer must meet to properly complete the project. This section outlines the requirement given by the customer as well as the engineering requirements that the team determined.

2.1 Customer Requirements

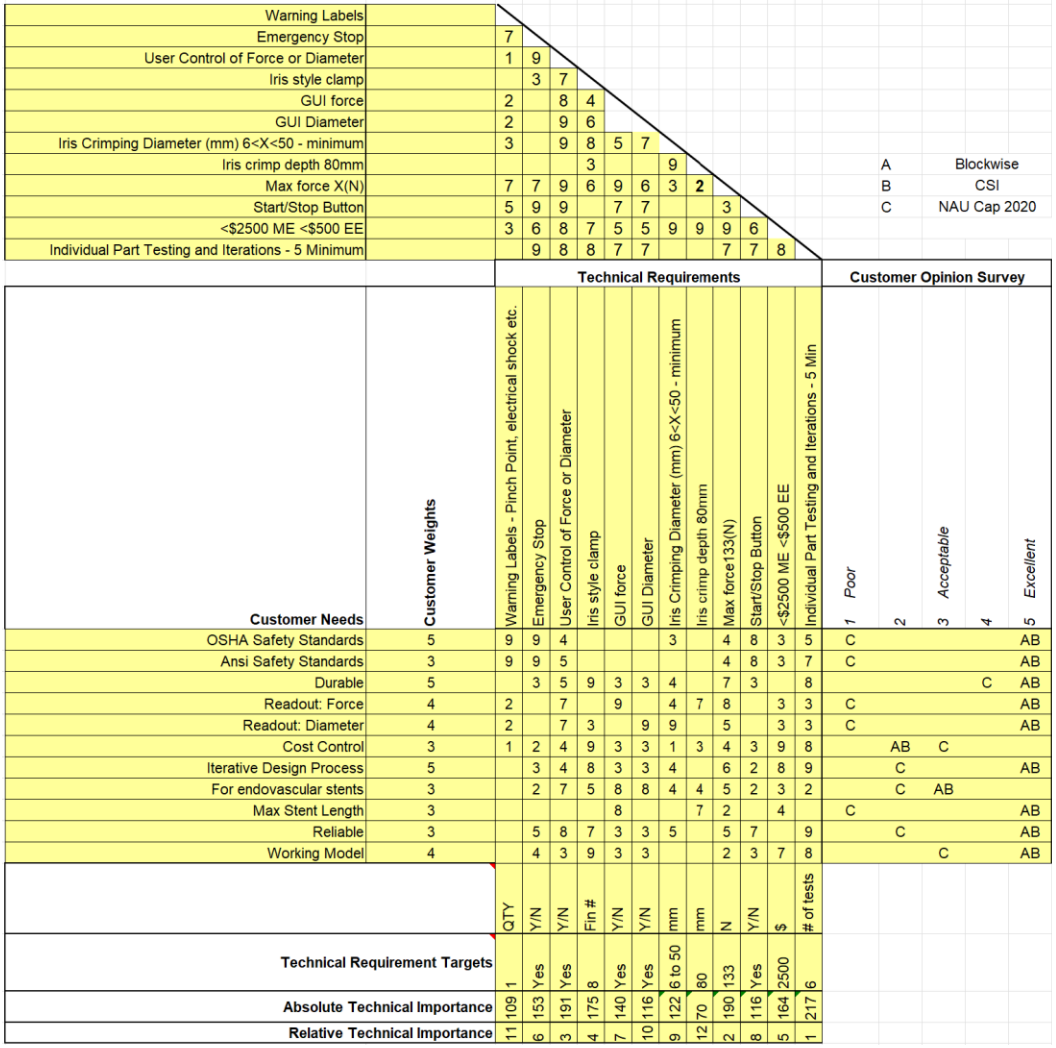
The requirements are given weights out of 5 points with 5 being the most important. The client wanted the stent crimper to follow all relevant safety guidelines to protect the user from hazards what has a weight of 5. They also wanted the device to readout the current force and diameter of the iris which each has a weight of 4. The team must present the client with a working model that follows multiple tests and iterative designs with a weight of 4. The model must be durable and reliable which will be a part of the testing process with a weight of 3. For this project, the entire team has $3000. This requirement is given the weight of 3 since the parts shouldn't come near the allotted budget. Further into the project, the team may share funds as necessary. The client wanted the stent crimper to be for endovascular stents. This requirement has a weight of 3 since, the dimensions for an endovascular stent are included, but others can be crimped as they also fall into the same range of criteria as endovascular stents.

2.2 Engineering Requirements

Based on the customer needs, the team developed engineering requirements and specified values as necessary. To meet compliance, the team needs to include warning labels such as pinch point, electrical shock and for the user to wear safety glasses [2,3]. The team will contain the components in a box so there are no loose wires exposed. The device will also include an emergency stop to meet the safety standards [2,3]. The client was not to be able to tell the device what force to crimp to, and what diameter the stent should be at, while the GUI reads the live values out to the user. The team decided to include a graphic user interface that will contain these specifications. The iris must be able to crimp a variety of endovascular stents. After researching endovascular stents, the team determined the iris must have an eye of 6 mm and open to 50mm to account for stents ranging from 16 mm to 45 mm diameters [4]. The leaflets must be 80mm deep to account for the largest stent of 46 mm resting and approximately 70 mm crimped [5] with a 5 mm tolerance on either side in case the surgeon does not center the stent. The iris eye must be able to output 132.94 N of force to account for the strongest material used in endovascular stents at 28.9 N/cm with the longest stent of 46 mm [6]. The device will have a start and stop button in addition to the emergency stop so the user can have complete control over the device. The team broke up the funds with starting values of $2500 for the mechanical engineering team and $500 for the electrical engineering team. The mechanical engineering team is responsible for designing the iris crimp and base, while the electrical engineering team is responsible for the user interface, code and wiring of the systems. The team will meet work together when determining the sensors to use. The team will also include a minimum of 5 iterations of the iris and sufficient testing to ensure the device is reliable and durable.

2.3 *House of Quality*

Based on the correlation between the technical requirements to the customer needs, the team found the individual part testing and iterations to be the most important requirement to focus on. The team needs to have at least 5 iterations of the design that can be evaluated. The next relative technical importance is the max force. The team needs to determine how the machine will apply the force and accurately read from the device as it crimps. The third important concept is the user control of force or diameter. The team must determine for the sensor will read to allow the device to accurately apply the force or crimp to the diameter the user has preset into the graphic user interface. While each concept in figure 1 is important to the design of the project, there are some requirements the team does not need to focus on as much as others, such as warning labels. They are essential to the safety of the user as well as the iris depth, however they are easy to apply. This value is important for the team to utilize when designing the leaflets, however, since the team has the value, they do not have to focus on how to make that value incorporated or calculate the value itself. Figure 1 show the weights the team gave to each of the correlations from the customer needs to the technical requirements, as well as the technical requirements to each other. The bottom row shows the overall technical importance of the engineering requirements.



Warning Labels											
Emergency Stop	7										
User Control of Force or Diameter	1	9									
Iris style clamp		3	7								
GUI force	2		8	4							
GUI Diameter	2		9	6							
Iris Crimping Diameter (mm) 6<X<50 - minimum	3		9	8	5	7					
Iris crimp depth 80mm				3			9				
Max force X(N)	7	7	9	6	9	6	3	**2**			
Start/Stop Button	5	9	9		7	7			3		
<$2500 ME <$500 EE	3	6	8	7	5	5	9	9	9	6	
Individual Part Testing and Iterations - 5 Minimum		9	8	8	7	7			7	7	8

A	Blockwise
B	CSI
C	NAU Cap 2020

		Technical Requirements												Customer Opinion Survey				
Customer Needs	**Customer Weights**	Warning Labels - Pinch Point, electrical shock etc.	Emergency Stop	User Control of Force or Diameter	Iris style clamp	GUI force	GUI Diameter	Iris Crimping Diameter (mm) 6<X<50 - minimum	Iris crimp depth 80mm	Max force133(N)	Start/Stop Button	<$2500 ME <$500 EE	Individual Part Testing and Iterations - 5 Min	1 *Poor*	2	3 *Acceptable*	4	5 *Excellent*
OSHA Safety Standards	5	9	9	4				3		4	8	3	5	C				AB
Ansi Safety Standards	3	9	9	5						4	8	3	7	C				AB
Durable	5		3	5	9	3	3	4		7	3		8				C	AB
Readout: Force	4	2		7		9		4	7	8		3	3	C				AB
Readout: Diameter	4	2		7	3		9	9		5		3	3	C				AB
Cost Control	3	1	2	4	9	3	3	1	3	4	3	9	8		AB	C		
Iterative Design Process	5		3	4	8	3	3	4		6	2	8	9		C			AB
For endovascular stents	3		2	7	5	8	8	4	4	5	2	3	2		C	AB		
Max Stent Length	3					8			7	2		4		C				AB
Reliable	3		5	8	7	3	3	5		5	7		9		C			AB
Working Model	4		4	3	9	3	3			2	3	7	8			C		AB
		QTY	Y/N	Y/N	Fin #	Y/N	Y/N	mm	mm	N	Y/N	$	# of tests					
Technical Requirement Targets		1	Yes	Yes	8	Yes	Yes	6 to 50	80	133	Yes	2500	6					
Absolute Technical Importance		109	153	191	175	140	116	122	70	190	116	164	217					
Relative Technical Importance		11	6	3	4	7	10	9	12	2	8	5	1					

Figure 1: Stent Crimper House of Quality

3 DESIGN SPACE RESEARCH

3.1 Literature Review

Base on the main needs of our project and to specifically receive information on how each subcomponent will align together our team has done the literature review. Before moving towards the next steps in the team members has initially referenced these journal reviews as it is mandatory to have the developing system.

3.1.1 Student 1 (Alex Nagle)

The first literature review covers the topic of Endovascular Stent grafts, what they are, and how surgeons use them. This is essential information as our design heavily revolves around understand the specifics of the stent grafts and how surgeons will use them. There were five diverse sources used, including 2 textbook chapters and 3 journal articles. The first source is a Medical Device textbook, primarily chapter 2.2.2, "Endovascular Stents". The textbook states that surgeons use an endovascular stent graft in a clinical procedure to treat abdominal aortic aneurysms, also known as AAAs [7]. The source a very elementary however crucial information about the Endovascular stent grafting procedure.

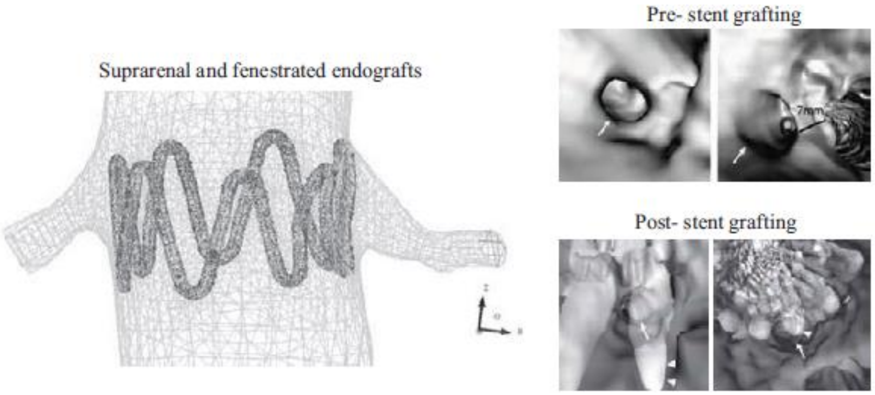


Figure 2: Virtual Endoscopy Views Stent Graft [7]

The second source is a textbook focusing on Endovascular technology, Chapter 5 "Pathology of Stents and Stent Endografts", provided information. In the source it states how stents we created through several years of texting and trials. Once it was safe, engineers created a polymer drug eluting stent. The most useful part of the source was the section on the "Pathology of Balloon Expandable…" [8]. This section detailed the process of an expandable balloon stent. This is the type of stent the team will be working with for the crimping device. The chapter then comments on the importance of the balloon stent grafting procedure as it is effective and non-invasive [8].

The journal articles covered a similar topic, how efficient endovascular stents are for which procedures. The first article is the oldest article in this literature review. It states the effectiveness of a standard endovascular stent graft procedure and if it is durable. This article is important, and it shows the change from the conventional repair of aneurysms using thoracotomy and graft interposition. It concludes with data stating the endovascular stents are not only efficient at the repair of aneurysms, but it is also durable and non-invasive enough for the elderly patients [9]. The Second article covered the use of endovascular stents for infected thoracic aortic pseudoaneurysms [10]. For patients with an infected thoracic aortic pump, endovascular stent grafting is the preferred solution as it is not as invasive and it is effect in helping the patients recover. Researchers studied this topic between 2000 to 2005 looking at 7 different patients. The article concludes that the endovascular stents are a viable and durable long-lasting solution for thoracic aortic pseudoaneurysms [10]. The third article covers endovascular stents for repairing ascending aorta/aneurysms [11]. Researchers performed this in 2016 and comments on the use of endovascular stents, as well as the future of endovascular stents. The concludes its effective but continues to look to the future of endovascular stents. This includes stent grafts made of biomaterial to prevent infection, an example for the biomaterial being Xenopericardium [11].

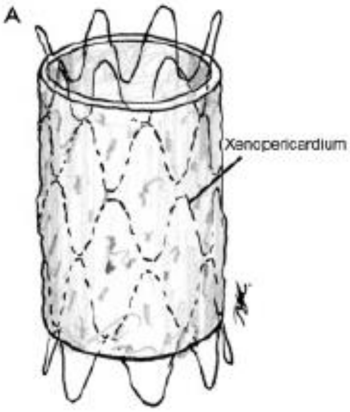


Figure 3: Xenopericardium Endovascular Stent Design [11]

3.1.2 Student 2 (Skylar Gilmore)

This literature review focuses on the iris part of the crimping device and what kind of stents the iris should be able to accommodate as well as strengths of the iris leaflets. The first source reviewed the general uses of endovascular stents and most common sizes that surgeons use in these vessels. The most common sizes are 23-25mm devices and most common larger sizes are 36mm [5]. For these stents, the crimped shape must be as circular as possible which is why surgeons use an iris to crimp the stent, otherwise the stent is no good and surgeons cannot use the graft in surgery [5].

Another source reviewed all current sizes of endovascular stents currently on the market and approved for used. The article contains a compiled graph that lays out the company, range of sizes and corresponding lengths and thickness of the stents. The lengths available for the use are 21mm to 46mm with diameters of 16mm to 42mm which is accounting for 15% to 25% larger sizes than the largest thoracic neck diameter [4]. The team cross referenced this information by the article on science direct that reviews specific stents and their working range. The longest stent which matches the 46mm resting stent size, is 69mm after teams crimp the stent [7]. This information is useful to the length of the leaflets to accommodate the longest stent with some room for error on placement of the stent inside the iris.

The last set of sources review forces need to crimp endovascular stents. The article from "Journal of Vascular and Interventional Radiology" explains that the highest force seen is on the AVE Bridge X stent at 28.9N/cm, which with the longest stent available comes to 132.94N needed to crimp this stent [12]. The team correlated this information with the Blockwise Knowledge Base which reviews diameter and force control when crimping. This source indicated that engineers could calibrate a sensor to account for a linear force from the system and display the radial force since their forces have a linear relationship [13].

This information is useful for the design of the leaflets in terms of dimensions of the leaflet and what sizes they must account for when the leaflets are working together. It also provides information on the forces that the leaflets must endure and how the system can read the force when using a calibrated sensor. This information leads the team the meet the customer requirements of an iris design and being able to crimp all kinds of endovascular stents within the stent crimper design.

3.1.3 Student 3 (Lumini Mudiyanselage)

Literature review has been focusing on the Polymeric stent crimping forces and how that would affect the selection of our lengths and the range of diameters for the machine. In conclusion received from the sources examined is to provide a direct comparison of their mechanical properties, the crimping and deployment of polymeric and metallic stents modeled using the finite element method. The results showed that polymer stents expand at a slower rate than iron stents. Due to poorer material qualities, the overall expansion of polymer stents was lower at peak inflating pressure and following balloon deflation. Stating that polymer stents have a larger recoiling impact. [14]

According to the second source about A computational study of ‘crimping and expansion of bioresorbable polymeric stents’ from T. Y. Qiu, M. Song & L. G. Zhao, it concludes there are four commercial bioresorbable polymeric stents for Stent crimping and expansion, i.e., Absorb, Elixir, Igaki–Tamai and Reva Medical stents. Individual designs of stent experienced different mechanical performances during crimped and expansion processes [14][15] Moreover, the radial stiffness and radial strength of stent are functions of the structural designs (e.g., radius and amplitude of U-bend, axial strut spacing and strut thickness) and material properties [16]

A study has shown that stent implantation leads to increased loading rate and less recoiling effect with less stress, suggesting that loading rate is a factor in the implantation of new stent devices for heart patients [17].

Engineers can crimp polymeric structures to a smaller profile and stretch them to deploy them without putting excessive loads and strains on the material, while reducing acute bends or stress concentration zones, according to another study. Manufacturing developments should increase the tube's hoop strength to improve the stent's mechanical performance. Although many innovative stent designs have been investigated in the literature, most of them have yet to enter clinical use. A computation model will be a great way to cut down on the number of tests and trials needed [17].

3.2 Benchmarking

The benchmarking process included looking at what the market currently has to offer. The team researched the internet to see what different company are doing with endovascular stent crimpers. The team decided to also evaluate the MSI’s stent crimper, MSI SC775S. This is a fellow Flagstaff company that produces Biomedical technology and produces a top-of-the-line stent crimper. The third company is Blockwise a Phoenix based biomedical technology company that produces a stent crimper. The team looked closely at Blockwise’s Model CX with Alpha-Crimp. The also decided to reference the 202 NAU Capstone “Stent Crimper”. This gives the team a better understanding of a student led stent crimper design. The team also looked at the different subsystems we can use to make our design more efficient and unique.

3.2.1 System Level Benchmarking

The team analyzed three complete systems for the benchmarking process. The MSI SC775S, the

Blockwise Model CX with Alpha-Crimp, and the NAU Capstone 2019-2020, “Stent Crimper”. Each design has its advantages and disadvantages, along with how effectively they do accomplish their goal. The team compared each Benchmark system to each other and see which was the best in induvial categories.

3.2.1.1 Existing Design #1: MSI SC775S

The MSI SC775S is a compact stent crimper that uses radial eye design, produced since 2010. This Machine solution, MSI stent crimper features a crimp to force and crimp to diameter operation. This machine can crimp stent made with blades made of stainless steel, thermoplastic, and a film crimp head. It has a max crimp force of 300lb for the stainless-steel blades, and a crimp diameter range from 0mm to 10mm [18].

Figure *4*: MSI SC775S [18]

3.2.1.2 Existing Design #2: Blockwise Model CX with Alpha-Crimp

The Blockwise Model CX with Alpha-Crimp, is a stent crimper with a sleek design with the most recent technology making a competitive design in the market. With a max radial force of 600lbf, and a 0mm to 8mm crimping diameter, it is highly effective. The die made of hardened stainless steel is the overall most versatile model Blockwise offers [19].

Figure *5*: Blockwise Model CX with Alpha-Crimp [19]

3.2.1.3 Existing Design #3: NAU 2021 Capstone 2019-2020

The NAU 2021 Capstone 2019-2020, is a unique and creative design created by fellow undergraduate students. Due to limited funding and resources this stent crimper is not to the same quality as the two on the market. Using a straight edge stent crimper die and a gear driven crimping system it produces enough force to crimp an endovascular stent graft 20.

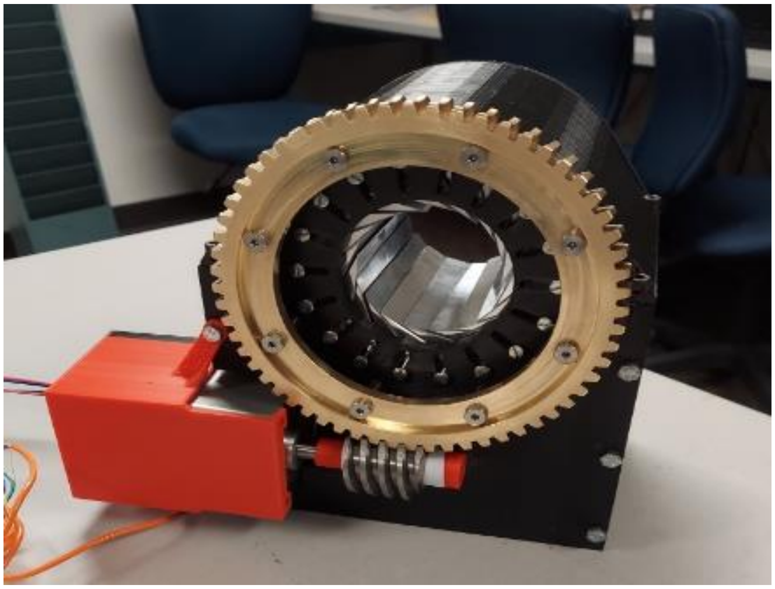


Figure *6*: NAU 2021 Capstone 2019-2020 [20]

3.2.2 Subsystem Level Benchmarking

3.2.2.1 Subsystem #1: Radial Eye

The Radial Eye is the actual die that crimps the stent to the desired diameter. There are currently three different Radial eyes work in the market. The Curved Leaflet, The Straight Edge Leaflet, and a Revolving Plate design.

3.2.2.1.1 Existing Design #1: Curved Leaflet

A Curved Leaflet deigns is an intuitive design as it gives the device a larger range of diameters to crimp. This is also in addition to its ability to have a larger radial force with less leaflets. However, it is major downfall is its difficulty to maneuver and manufacture. The Curved blades will be harder to adjust and put into the device, because of its shape.

3.2.2.1.2 Existing Design #2: Straight Edge

The Straight Edge design is the most universal design for the stent crimpers. Each of the Benchmarked devices used this subsystem. It features an easy to manufacture straight edge and uses a radial pin system to move them inward to crimp the stent. It is a cost-effective method but lacks in its range and max radial output.

3.2.2.1.3 Existing Design #3: Revolving Plate

Only a few stent crimpers utilized this design. It has different plates that revolve around the iris face to crimp the stent to its desired diameter. Unlike the other iris systems consisting multiple blades there are no moving parts and unique pieces to manufacture separately before putting together.

3.2.2.2 Subsystem #2: Device Input Method

There have been diverse ways to input information into the stent crimper to get your desired radial force or the desired diameter. The team chose to focus on three ways to control our device.

3.2.2.2.1 Existing Design #1: Screen Input

Like the Blockwise product, there are ways to have preprogrammed inputs for the stent crimper. Buttons on the device select the desired program to run.

3.2.2.2.2 Existing Design #2: Analog Knob control

This input uses knobs to carefully input what desired diameter or force to crimp the stent. Giving the user more control over how to change the desired input instead of buttons.

3.2.2.2.3 Existing Design #3: Analog Button

The simplest way to input information into the device, a button system that increases and decreases the desired output. This is the most cost-effective design allowing funds to be allocated into the blades or the gears.

3.2.2.3 Subsystem #3: Power System

The final subsystem the team looked at was the power system. The team researched different power sources for stent crimpers. This was by looking at what is on the market as well as looking at different medical instruments.

3.2.2.3.1 Existing Design #1: AC Plug

Most designs for the stent crimper used a wall plug to power the device. A steady flow of power often used for large devices. This is also true for medical instruments as they require a constant high power.

3.2.2.3.2 Existing Design #2: Internal Source

By having an internal Source of energy, the system will not need to have a constant power to plug into. This makes the design more portable and easier to move around. It is also easy to implement this power source within the system.

3.2.2.3.3 Existing Design #3: Computer Input

The final power system found to power a stent crimper is to directly plug the system through a computer port. This will allow only a limit amount of power to go into the device however, it allows for better data collection and control of the device through a computer program.

3.3 Functional Decomposition

The team discusses the main subsystems of the stent crimper above: the iris crimping unit, power source and the output screening system. The functional modelling process includes a full diagram of the operations of the device given in the figure 8. that details the inputs and the outputs of device based on the black box indicated below. The purpose of the black box model is to identify the major flows of operation and their inputs and outputs. For this project black box is specifies how the operation of an endovascular stent crimper under the given diameter or the radial force. Since the team must design the machine to operate simultaneously for the radial force and the diameter it identifies this component separately at the given state. It also identifies the endovascular stent, the accompanied length of the stent, energy and the signals required in the opening and closing states.

Using the Black box model, we related the highly ranked customer requirements to the functional model. For instance, the requirement of safety, having the ability to crimp the stent on force or the given diameter which scored 5 are reflected in the functional model. We have also indicated the importance of a function read out system to process the generated results. The team followed the general method of functional modeling to create our hypothetical functional model.

3.3.1 Black Box Model

The Black box model included in the figure 7 identifies the major flows and output for crimping a stent under the iris operation and consolidate the operation of overall device. The purpose of the black box model is key when identifying primary features, the overall stent crimping machines inputs and outputs. Under the given structure presented in figure 7 the main inputs to the device would energy using a power source; most definitely electric power using a motor as the user can control easier compared to a complete mechanical system; with the guidance human conduct. The material flows were the Endovascular stents under the a given length. For the signal flow it was the start/ pause button, emergency stop, and selected force or diameter read per requirement. The outputs of the system would be a crimped stent with minimal or error, power cut off if given to emergency, an indicator to stop the process and force and diameter readouts.

Given this model the team now has a clear idea in concept generation and how to make the correlation between each subcomponent. Moreover, the team will analyze this model again when initializing the main forces and the diameters the device should be working under. After creating the black box model, the team used the flow inputs and outputs to create hypothesized functional model and the functional basis table.

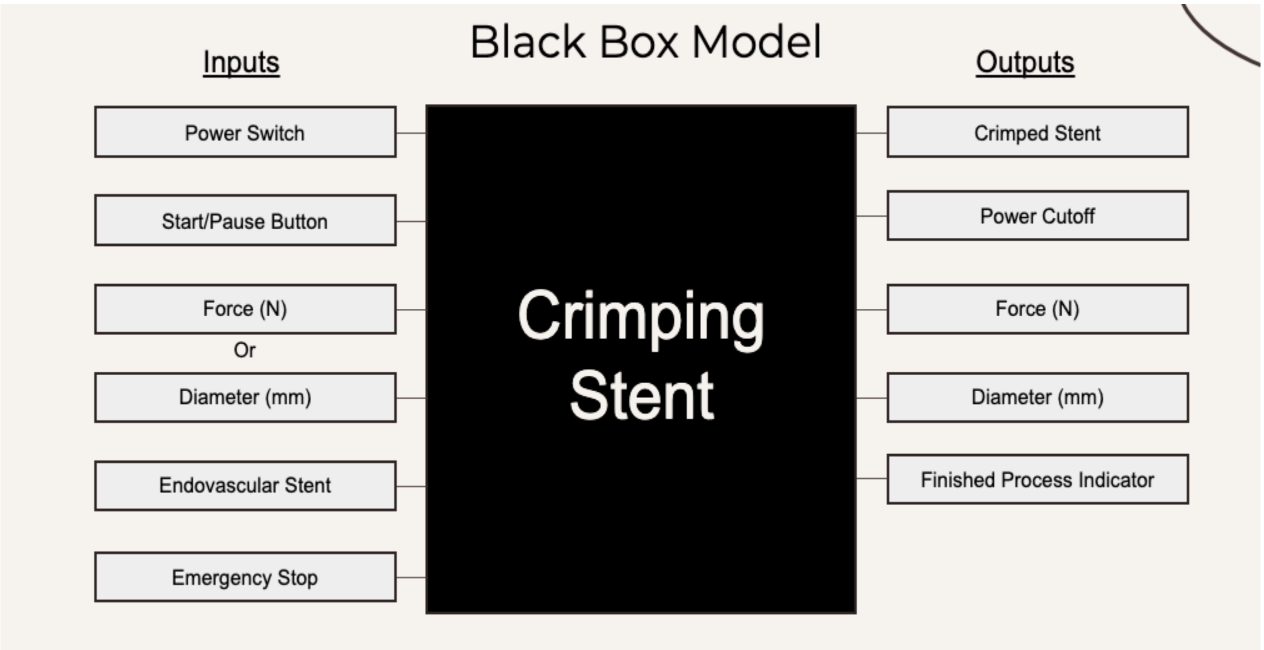


Figure 7: Black box Model

3.3.2 Functional Model and Functional Basis table

Table 1: Functional Model

Class	Primary Function	Secondary Function
Material	Human conduct, Determine force or diameter selection	Endovascular stent
Energy	Electric energy stored in a Battery, Releases energy, Releases heat, Releases vibrations	Rotation, Crimping, Display
Signals	Power switch, Emergency Stop, Force or Diameter selection,	Finished process indicator, Power cutoff, Force and diameter readouts

Using the black box model and the highly ranked customer needs the team developed the hypothesized functional model, for example the device having the ability to crimp the stent for a given diameter or a radial force and the client wanted the stent crimper to follow all relevant safety guidelines to protect the user from hazards what has a weight of 5.,also wanted the device to readout the current force and diameter of the iris which each has a weight of 4 reflected in the functional model. In the table 1 shows functional basis table which relates the customer needs the black box model input and output flows. The functional bias table separates primary and secondary models. The team indicated each function separated by a comma in these categories. The secondary functions are all related to the primary function.

This will be later used in creating the actual functional model for the finalized design at the prototyping stage. In this stage the team will be marginalizing the effectiveness of the finalized iris model to cope us the input variables, To further modernizations within the design.

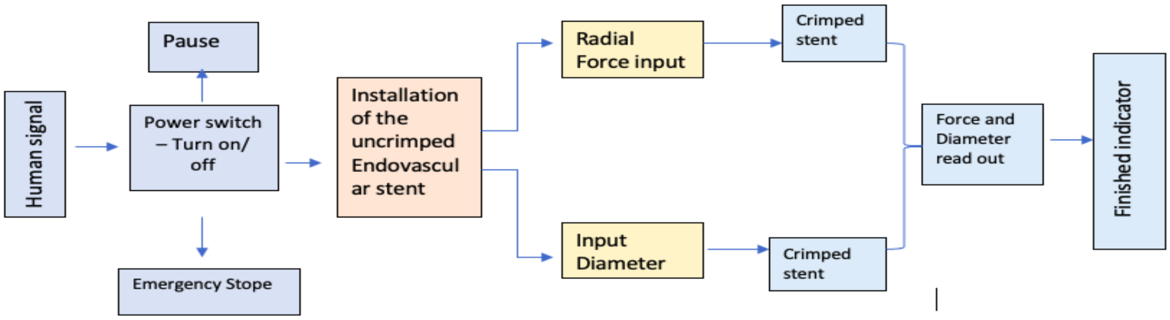


Figure 8: Hypothesized Functional model

4 CONCEPT GENERATION

4.1 Full System Concepts

4.1.1 Full System Design #1: Curved Leaflet with an AC Plug System and Touchscreen input

The first full system design is the Curved Leaflet with an AC Plug System and Touchscreen input. The team created this design because it has the increased range for the diameters with the curved blades as well as the most steady and reliable battery/power source. The touchscreen input would make the design efficient and unique, separating it from what is on the current market.

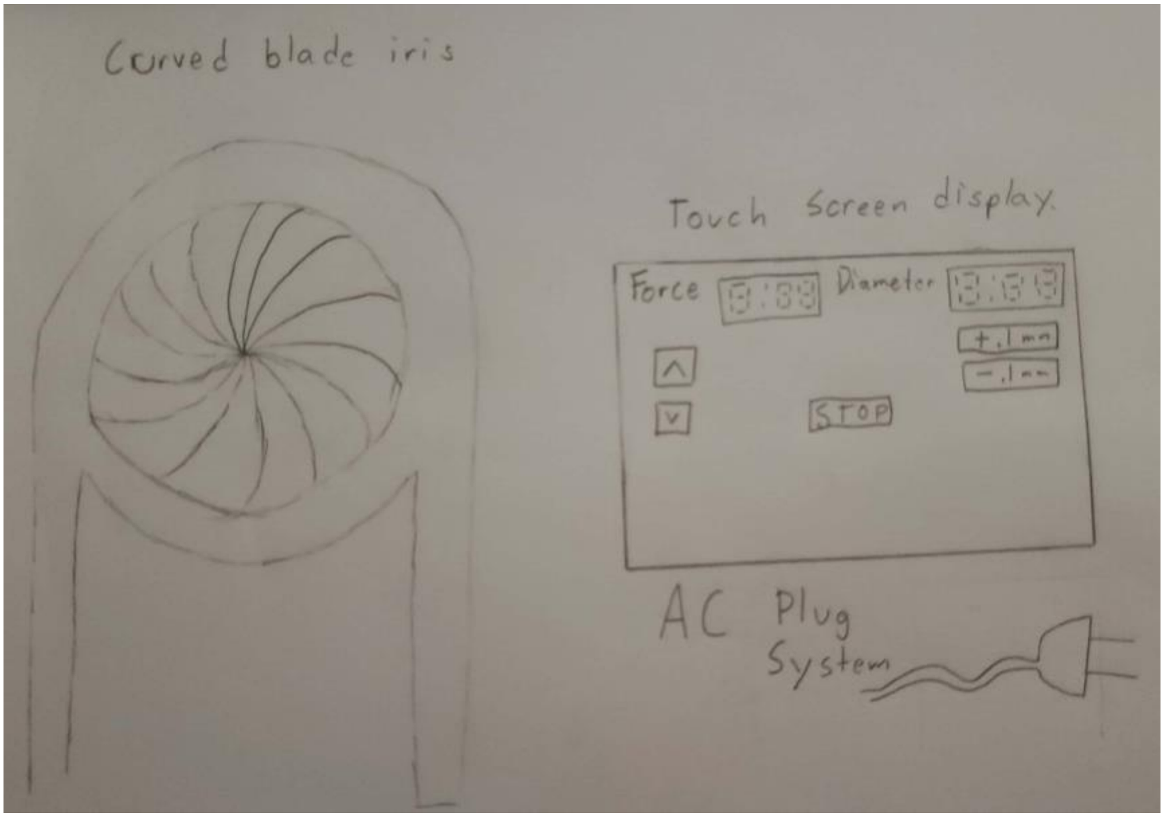


Figure 9: Curved Leaflet with an AC Plug System and Touchscreen input

4.1.2 Full System Design #2: Curved Leaflet with AC Plug System and Analog Knob

The second full system takes advantage of the curved leaf blades that give more radial force and diameter range, however with an Analog knob the team will be able to cut down on costs to make the product more affordable. This design also uses an AC Plug System as the team saw it as the most efficient choice.

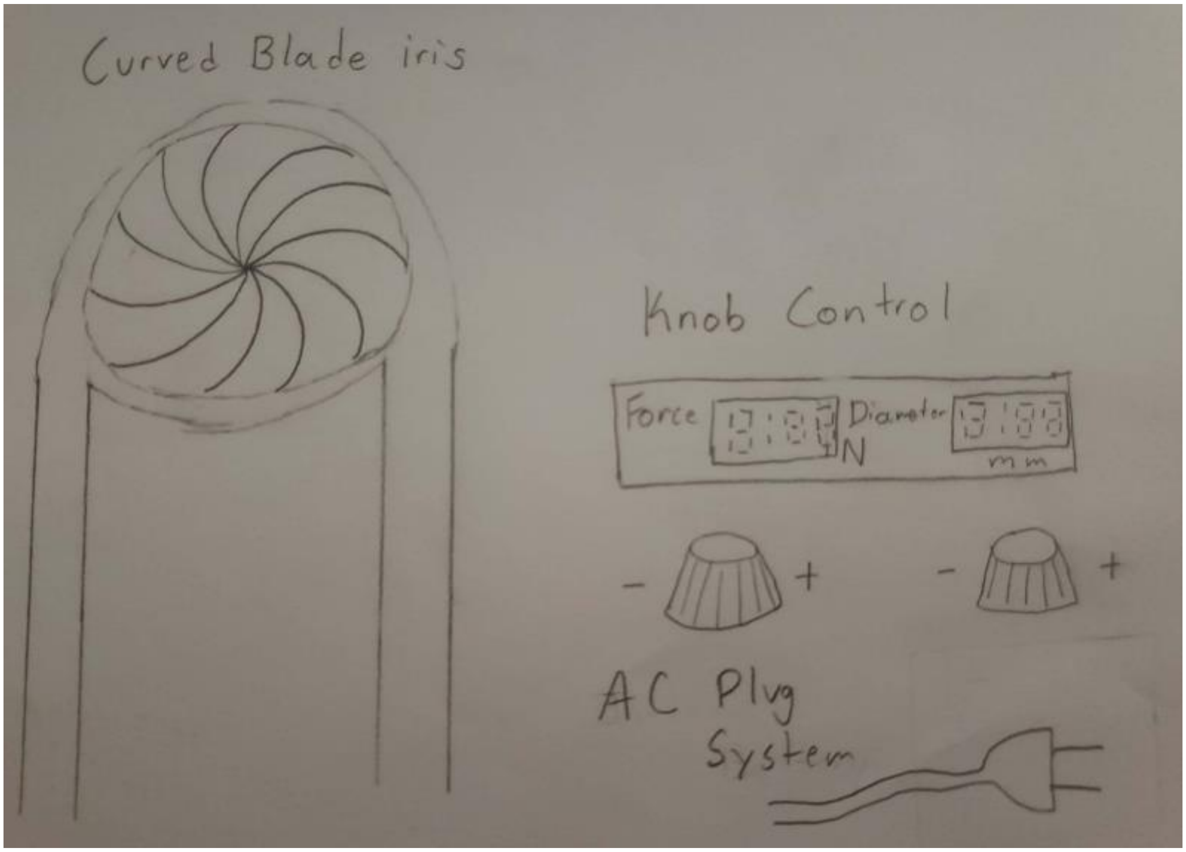


Figure 10: Curved Leaflet with an AC Plug System and Analog Knob

4.1.3 Full System Design #3: Straight Leaflet with an AC Plug System and Touchscreen input

The final system uses the straight leaflet that most products on the market use. This allows for an easier manufacturing and cost. The straight leaflet however lacks the same power and diameter range that the curved leaflets offer. The team decided The AC plug system would be best because the design will need the constant power source.

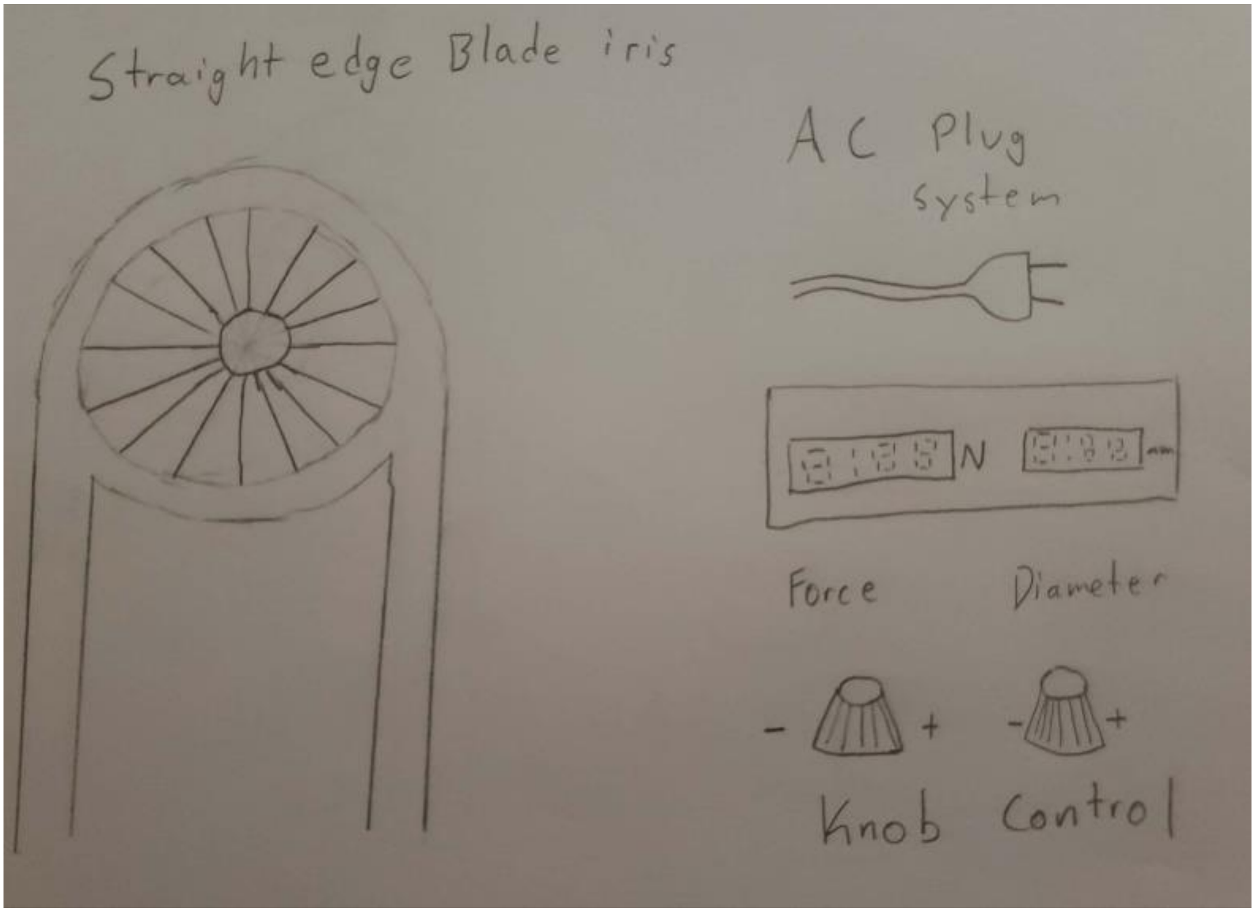


Figure 11: Straight Leaflet with an AC Plug System and Touchscreen input

4.2 Subsystem Concepts

4.2.1 Subsystem #1: Radial Eye

4.2.1.1 Design #1: Curved Leaflet

The team modeled the curved leaflet iris to include multiples blades varying from 8-20 according to the force and the range of diameter for crimping. This iris model has good proportion of the stent crimping than other crimping techniques due its wide area in each leaflet for crimping and the crimper requiring having a less power requirement.

4.2.1.2 Design #2: Straight Leaflet

Straight leaflet iris crimpers are usually employed in surgical procedures and teams do not implement the designs into crimping mechanisms very often. This is because the blades must be highly exact in their application of force while shaping stents because the edges produce an octagonal shape rather than curved resolutions. Furthermore, because the area of the blade's point is small, the range of forces available to the user to crimp the stent are limited, as there is a higher risk of damaging the stent.

4.2.1.3 Design #3: Revolving Plate

All the above-mentioned types of irises can be notably distinct from revolving plate iris. This blade is a single blade that spirals around its axis. However, because it revolves around covering layers, this type of iris plate has higher energy requirements, and the distance between the plates must have a significant gap. The design could be suitable for a crimping system for a wide range of diameters due to the blades' movability. However, it would not be especially useful in a wide variety of radial forces.

4.2.1.4 Design #4: String/wire Crimp

The string/wire design is an innovative design the team produced. Instead of having blades crimp the stent the team thought of a design where a wire or string would tighten around the stent to crimp it to the desired size. This would have cost for manufacturing several plates and would ensure a round, smooth crimp along the stent. However due to coordination about the exact way the design will work, how to retract and feed the string/wire, the team decided to forgo any design with this system.

4.2.2 Subsystem #2: Device Input Method

4.2.2.1 Design #1: Touchscreen Input

A unique design the team created for the device. Instead of just having a screen with preprogrammed diameter and forces, the team will seek to create a touch screen monitor that controls the entire device. Allowing the user to have more control in smaller workspace. This will save costs by not needing additional parts to control the device, however there will be a need for a programable touch screen interface.

4.2.2.2 Design #2: Analog Knob

The analog Knob would control the device by inputting a desired radial force or diameter. There will have to be 2 knobs, one for force and diameter. The knobs will also need to have an additional switch to choose which knob will be the dominating input. This would cost the team additional resources to add and integrate knobs to the device output.

4.2.2.3 Design #3: Analog Button

Analog buttons would be the most cost-effective method and the easiest to integrate into the design. There will be around 2 sets of 2 buttons that increase/decrease the radial force output or the desired diameter. The disadvantages to the button system are that it lacks control over the device and restricts the features of the stent crimper.

4.2.3 Subsystem #3: Power Source

4.2.3.1 Design #1: AC plug

An AC plug would give the device the highest voltage input to run and will always have a steady source of power. However, this would make the device hard to move and transfer as it will always need to be near an electrical output. This would also cause a need to integrate an AC power into the device.

4.2.3.2 Design #2: Computer Powered

Computer powered, would mean that user plugs the device into a computer port and use the power from the computer. This would be the lowest voltage input into the device however it will allow for better data collection for the device. By connecting the device to the computer, the team could also set up a program making the device controlled by the computer itself with no need of an input control. The biggest concern would be if a computer could output enough electricity to power the device through a USP port.

4.2.3.3 Design #3: Internal Battery

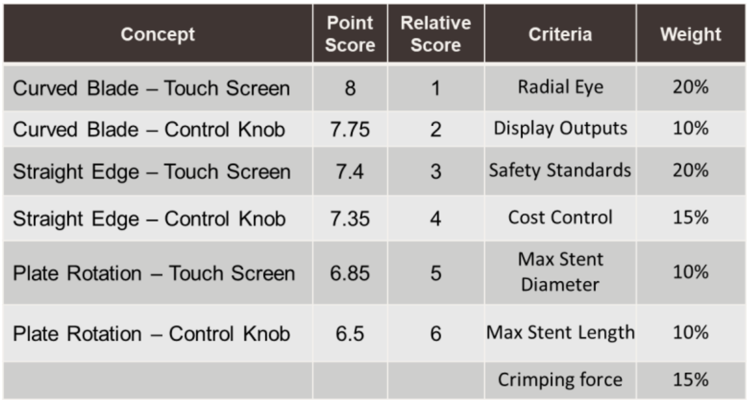
An internal battery would be the most portable form of power source for the device. If the battery is in good condition the device will have a steady source of power and would not have any location or movement restrictions. The major disadvantage of the internal battery would be the cost of buying a batter each time one would run out or getting a rechargeable battery. By adding an internal battery that would also make the device much heavier as it will be within the device.

5 DESIGNS SELECTED – First Semester

Based on the designs seen in chapter 4, the team must narrow down the concepts and determine which would be the best to move forward with in the project. The chapter elaborates on how the team decided on their final design and why that concept is the best choice to start evaluating and prototyping.

5.1 Technical Selection Criteria

The team utilized a decision matrix to determine the top 3 designs out of the six generated in chapter 4. The team determined criteria based on the engineering requirements and added weights to each criterion based on how important they are to the design of the stent crimper. The team produced a radial eye at 20% since this is the focus of the project. The display outputs at 10% since the client wanted a user interface and readout. The safety standards at 20% since if the design is not OSHA and ANSI approved, the client cannot use it in a corporate manner. Cost control at 15% because if the design is too expensive, they team cannot fund the project properly. Max stent diameter at 10% since the diameter can vary a bit depending on the exact stent used and the criterion is set, the team must ensure the eye meets the requirement. Max stent length at 10% since the team can easily modify the design by making the leaflets deeper. Finally, crimping force at 15% since if the stent crimper cannot crimp, there is no reason to build the design. Based off this criterion the team determined the top 3 designs to be the curved blade touch screen, the curved blade knob control and the straight edge tough screen seen in figure 12. The full decision matrix is in Appendix A.



Concept	Point Score	Relative Score	Criteria	Weight
Curved Blade – Touch Screen	8	1	Radial Eye	20%
Curved Blade – Control Knob	7.75	2	Display Outputs	10%
Straight Edge – Touch Screen	7.4	3	Safety Standards	20%
Straight Edge – Control Knob	7.35	4	Cost Control	15%
Plate Rotation – Touch Screen	6.85	5	Max Stent Diameter	10%
Plate Rotation – Control Knob	6.5	6	Max Stent Length	10%
			Crimping force	15%

Figure 12: Redacted Decision Matrix

Using the finial 3 designs, the team set up a Pugh chart to see how the designs compared to each other. For this chart, the team set up their criteria as the radial eye, the force output, the practicality of the design, accuracy of the crimp, OSHA safety regulations and cost. The team chose this criterion because through the design process, the team wanted the most practical design to help stay in the budget and keep the ability to make the design with the equipment in the machine shop. The team also chose the radial eye because of the wide range of sizes and forces that the eye must accept while still being accurate in the crimp, The curved blade scored high in this area because the curved blades allow more leaflets, creating a better circular shape) than the straight edge which would form a shape closer to a decagon depending on the number of leaflets used. The design must also be safe otherwise the client will not want to use the design. Based on the design features, the team set the curved blade with knob controls as the datum. Seen in table 2. The top design is the curved blade with touch screen.

Table 2: Pugh Chart

Criteria	Curved Blade Touch Screen	Curved Blade Knob Control (Datum)	Straight Edge Touch Screen
Radial Eye	0	Datum	-
Force Output	0		-
Practicallity	+		-
Accuracy	+		-
OSHA Regualtion	0		0
Cost	-		+
Total +	2		1
Total 0	3		0
Total -	1		4
Total Score	1		-3

5.2 *Rationale for Design Selection*

The curved blade will have a higher area shown by equation 1 compared to the area of the straight edge shown in equation 2.

$$A = \pi r^2 \tag{1}$$

$$A = 10 * (r * \sin(18)) * (r * \cos(18)) \tag{2}$$

For a radius of 50 mm, the decagon would have an area of 0.00734 m^2 while the curved leaflets would have an area of 0.00785 m^2 showing there is a higher area available for the stent when using the curved leaflets. So, if the team uses the curved leaflets, they can use a smaller design, saving money while still meeting the customer's requirements.

The team would require a CNC mill to create the curved blades, making it cost more than the straight edge blades. The curved edge will also create a circular shape which is what the client wants versus the decagonal shape the straight edge leaflets would make. The accuracy of the curved leaflets is determined by the motion of the leaflet. Due to the arc of the leaflet, the team can adjust the position of the leaflet an equal amount at the straight edge, but the curved will not go as far into the stent, instead it will hug the edge and slowly compress seen in figure 13. This also shows that the straight edge leaflet will provide uneven force output to the stent while the curved edge leaflets provide a more even distribution of force on the stent.

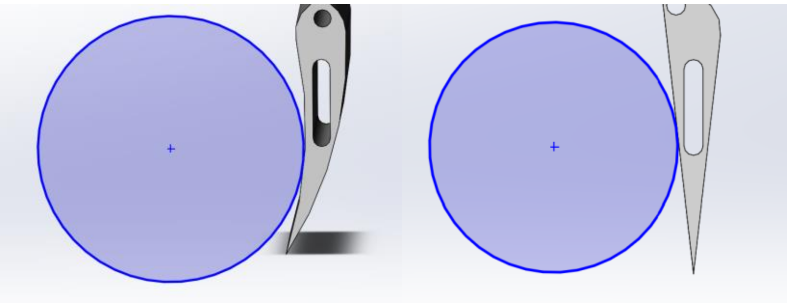


Figure 13: Crimping Reference

By using a though screen interface versus a control knob, the user can lockout the system, so the desired settings do not accidently change during the crimping process. The readout is also more user friendly to program the exact setting the user desired, versus turning a knob until the desired setting.

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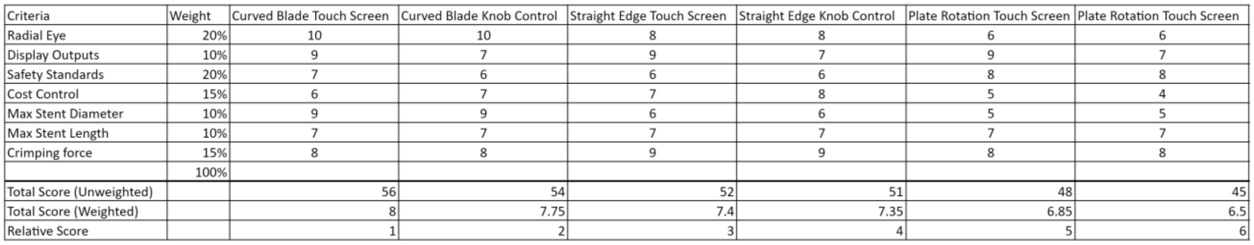
7 APPENDICES

7.1 Appendix A: Decision Matrix



Criteria	Weight	Curved Blade Touch Screen	Curved Blade Knob Control	Straight Edge Touch Screen	Straight Edge Knob Control	Plate Rotation Touch Screen	Plate Rotation Touch Screen
Radial Eye	20%	10	10	8	8	6	6
Display Outputs	10%	9	7	9	7	9	7
Safety Standards	20%	7	6	6	6	8	8
Cost Control	15%	6	7	7	8	5	4
Max Stent Diameter	10%	9	9	6	6	5	5
Max Stent Length	10%	7	7	7	7	7	7
Crimping force	15%	8	8	9	9	8	8
	100%						
Total Score (Unweighted)		56	54	52	51	48	45
Total Score (Weighted)		8	7.75	7.4	7.35	6.85	6.5
Relative Score		1	2	3	4	5	6