

Individual Analytical Analysis

Capstone Team 5

Gore Stent Crimper



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Introduction

This report analyzes the leaflet's design for functionality and proof of concept. The project requires team 5 to create an iris stent crimper. In the current design the leaflets are symmetrically moved altogether and as the stent is crimped, the goal is to keep a radial shape. The leaflet is one of the most essential components when creating an iris as they are what make the design an iris. The analysis reviews the curvature of the leaflet to maximize the area and radial shape of the crimped stent. The location of the slot for the motion pin and the hold for the stationary pin is dependent on the shape of the leaflet. The forces on this slot are analyzed to ensure a working design with the required forces based on the given endovascular stent type by the client.

Leaflet Curve

One of the customer requirements is to utilize an iris design to provide a radial shape when the stent is crimped. While the team is utilizing this design, the output shape is more of a dodecagon at larger diameters. Due to this, the team has utilized curved leaflets in the design. The first prototype used a small curve however this needs to be refined to maximize the internal space and provide the most radial design. Based on Estrada's design, the best way to design the curvature of the leaflet is to use the shape of the resting position desired [1]. For the current design, figure 1 shows the desired resting position with enough space to accommodate the largest stent of 45mm with a minimum of 2.5mm of extra space for ease of access on either side of the leaflet.

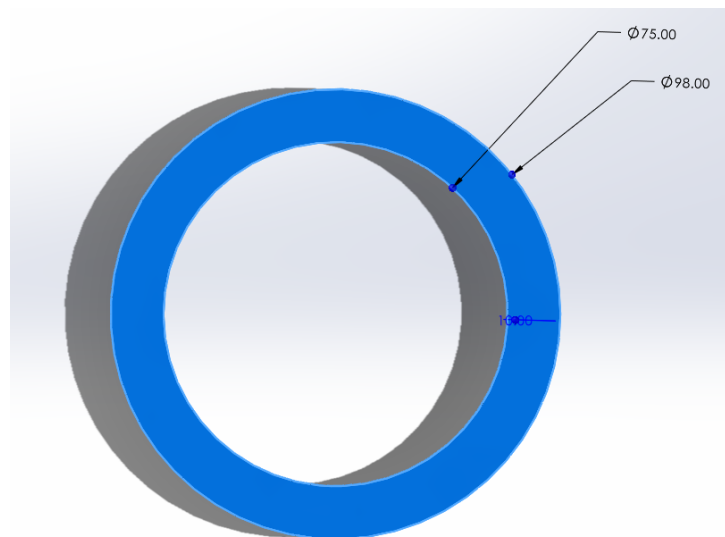


Figure 1: Reference Geometry

Utilizing figure 1, the leaflet curve must stay within the reference geometry and maintain a symmetrical shape. To achieve this the design will be divided in 12 sections with half of each leaflet overlapping the next for a total of 45 degrees of the geometry. The outcome of these stipulations is seen in figure 2.

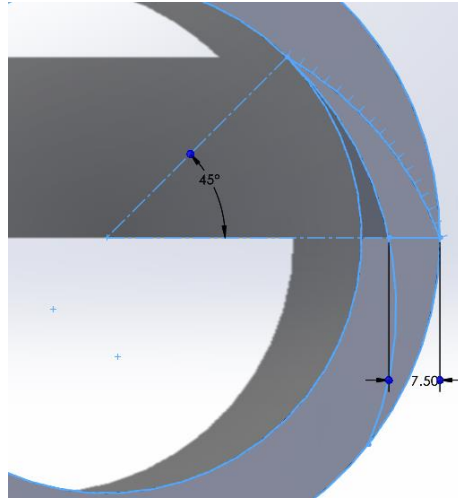


Figure 2: Leaflet Stipulation Implementation

This design must accommodate for a 3.175mm pin which is used to control the movement of the design. Since this slot undergoes 12N of force, there must be as much space between either side of the slot as possible which comes out to 0.14mm seen in figure 3.

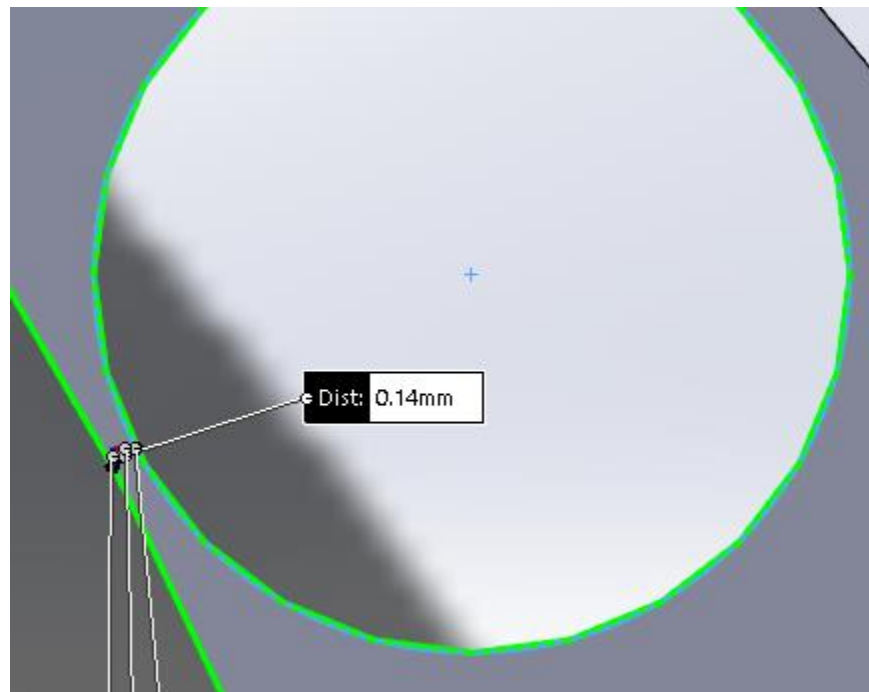


Figure 3: Weakest Point with Max Spacing

Notch Forces

Based on the client's choice of endovascular stents, the max force required is 132.94N total and 11.08N per leaflet. This analysis uses 12N per leaflet for a safety factor of 8.3 using equation 1 [2].

$$FOS = 1 - \frac{\theta_{th}}{\theta_{actual}} \quad (1)$$

FOS = Factor of Safety

θ_{th} = Theoretical Yielding Point for given forces

θ_{actual} = Actual Yielding Point for given material

This design needs to be consistently accurate, therefore, neither fracture nor yielding can occur. Based on this, the mild steel or low carbon steel yielding tensile strength of 350MPa is used. Using equation 2, the stress of the internal pin on the weakest point of the material, which is where it is the thinnest. Equation 2 shows the strength of the material after the number of cycles performed on it, for this analysis 1000 cycles is used [2].

$$S_{fn} = \sigma' (2N)^b \quad (2)$$

S_{fn} = Fatigue Strength after n cycles

σ' = True Stress = 350+345 MPa = 695 MPa

N = Number of cycles = 1000

$$b = -\frac{\log\left(\frac{\sigma}{S_e}\right)}{\log(2*N)}$$

S_e = Endurance Limit = 0.5*350Mpa = 175MPa

Using this equation $b = -0.1996$ and the total fatigue strength is 175 MPa. This is the most amount of force the material can withstand. Using equation 3 the relative applied stress is calculated using the moment and inertia of the model [2].

$$\theta = \frac{M}{I} \quad (3)$$

M = Moment = F*D = 12*0.001 = 0.012Nm

F = Force

D = Distance to force contact point

I = Inertia = $W*H^3/12 = 2.28E-14 \text{ m}^4$

W = Width = 0.1 m

H = Height = 0.00014 m

θ = Force = 524781.34 MPa

As the force is much larger than the endurance limit, this design is going to fail and needs to be reevaluated. The other possible failure point is the rod being used within the slot at 3.175mm

diameter. This pin is under a shear stress which is calculated with equation 4 for shear strength [2].

$$\sigma = \frac{4\theta}{\pi D^2} \quad (4)$$

D = Diameter = 0.003175m

θ = Applied Force = 12N

σ = shear strength = 1.516 MPa

Based on this calculation, the applied for on the rod is small enough that the rod can support the load and meet the yield requirements from equation 2 for mild steel.

Proposed Solutions

Using the data from above two solutions were developed. The first solution is to use 50 14-gauge plates with a hole centered for the pin which changes equation 3 to output 27.78MPa, using the values listed below, which meeting the stress requirement. This design is seen in figure 4 with 12 plates shown.

F = 12N

D = 0.001m

W = 0.002m

H = 0.006m

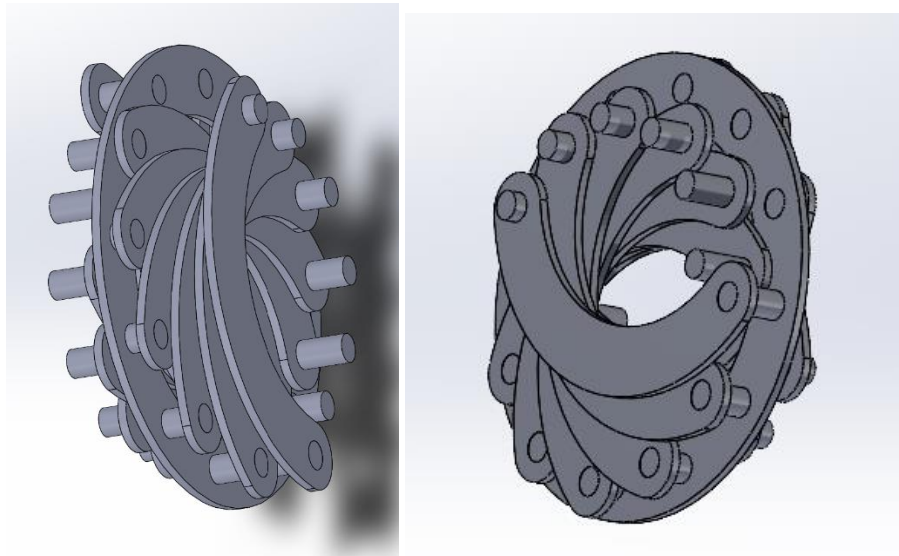


Figure 4: Plate Design

The second solution modifies the original design and has the pin welded to each side of the leaflet. This design is seen in figure 5. The force of this design follows equation 4 with the same strength of 1.516 MPa which is under the max strength before yielding.

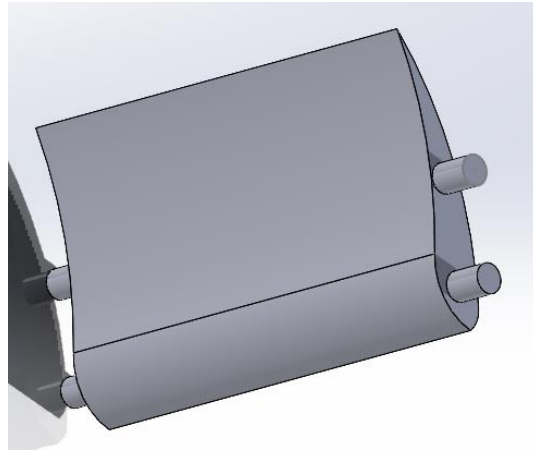


Figure 5: Welded Pin Design

Conclusion

Overall, the leaflet is at its ideal curve and opens to the max size that the largest endovascular stent requires. The forces on the original design would have a catastrophic failure at the max required load, but utilizing one of the solutions, this can be changed to a strong enough design to account for the max strength before the material yields. Design solution 1 is the stronger of the two design solutions, however, this design leaves too much space between the contact points of the plates and the stent causing an oblong shape instead of a radial design even though the center is radial when looking from the front face. The second design meets the force requirements and meets the ideal shape for the radial crimp on the stent. From these conclusions, the welded pin design will be implemented into the upcoming prototype and the final design for the first semester of the project.

References

- [1] Y. Lei, K. Zhang, C. Chen, H. Song, T. Li, D. Lin, and Z. Liu, "Experimental research on the mechanical properties of porcine Iris," *Clinical Biomechanics*, vol. 23, 2008.
- [2] R. G. Budynas, J. K. Nisbett, and J. E. Shigley, *Shigley's Mechanical Engineering Design*. New York: McGraw-Hill, 2016.