Final Project

MEEN 3130

April 29, 2013

Hayley Dawkins
Perry Pickett
Daniel Raherimanjato
Fergus Reid
Cristian Ugarte
La Gronie Wyatt
Report outline

Cover Page...........................................................................................................................................Page 1
Report Outline...............................................................................................................................................Page 2
Executive Summary.......................................................................................................................................Page 3
Background and Motivation..........................................................................................................................Page 3
Project Objective..........................................................................................................................................Page 6
Analysis.......................................................................................................................................................Page 8
Conclusion and Recommendations.............................................................................................................Page 18
Reference....................................................................................................................................................Page 19
Executive summary

According the center for disease control and prevention, about 600,000 people die annually from heart diseases in the United States (CDC Staff). This is greatly reduced with the use of stents. When blood is pumped through the heart it passes through an artery to take the blood to other parts of the body. Over time these arteries can wear thin or plaque can build up causing a potential risk of the artery bursting. To combat this, a doctor will implant a stent into the artery. “A stent is a small mesh tube that's used to treat narrow or weak arteries,” (NHLBI). They are generally made of a metal mesh or a thin fabric. For this research we will be looking at what stresses are placed on the stent due to the heart pumping and determine if those stresses are enough to break the stent.

Background and Motivation

The surgery to implant a stent is called a percutaneous coronary intervention (PCI) or angioplasty. During this procedure the stent is moved through the vein to reach the blocked artery. When the stent is the correct location, the balloon is inflated causing the stent to stretch and open the artery. Once the stent had reached its maximum size it will lock into place causing the artery to stay open. The catheter and deflated balloon are then removed. The open artery allows for better blood flow and a more stable artery. This reduces the risk of a heart attack or ruptured artery. There are multiple sizes of stents and a wide range of material that make up the stent. Therefore, no matter what size or condition the artery is in, a stent can be used to help prolong the life of the artery and the patient (American Heart Association). However, the question arises are the risks of using a stent equal to the benefits that are gained.
This surgery has numerous advantages over other procedures. One of the most beneficial features of using a stent is the low recovery time. The procedure is considered minimally invasive. A “minimally invasive medical procedure is defined as one that is carried out by entering the body through the skin or through a body cavity or anatomical opening, but with the smallest damage possible to these structures,” (Hogan). This allows the patient to only be in the hospital a day before being allowed to be sent home. Another positive is that there is no anesthesia need to perform the procedure. Therefore, with no anesthesia need it makes the process cheaper and safer. The overall effectiveness of the stent is a positive one if none of the major complications occur.

However, there are also risks to using stents, which share many similarities to other medical procedures. There is a possible risk of infection at the site of the catheter entrance. Patients' bodies can regard stents as injuries and respond accordingly by generating scar tissue (SCAI). This can lead to the patient going into shock and having a heart attack or stroke. The stent itself has the possibility of restenosis (re-narrowing) or not completely locking into place depending on the type of stent used. However, this can be combated with the use of drug-eluted stents. These specially coated stents, which were introduced after being approved by the FDA in 2003, help with restenosis that would otherwise cause the patient to have another surgery. Another danger of having a stent implanted in the artery is called stent thrombosis. “Stent thrombosis is a blood clot that occurs following stent implantation,” (Medtronic Cardiovascular). This blood clot can clog the artery and cause a heart attack or cause the patient to go into cardiovascular arrest. However, this can be deterred if the patient will take an anti-clog medication.
Though most stents perform as expected, there are instances in which stents fail. These failures can happen for a number of reasons. The main cause is improper stent deployment. In one study, “Failure to deliver the stent to the lesion site was the main cause in 139 patients (92%)” (Nikolsky). The leading cause of this comes from a lack of experience in the professional performing the procedure, but when placed properly, failures are mostly attributed to mechanical failure from pressure exerted by the arteries and blood. A stent can fail mechanically in multiple ways. For instance, in another study, “Of the 60 patients with stent graft fatigue, 43 patients had metallic stent fractures, 14 had suture disruptions, and three had graft holes,” (Jacobs). Because of the location of the stents in the body and differences in the patients’ arteries, the stents can fail for different reasons, and these failures often go unnoticed for extended periods. “The average time to the recognition of failure [is] 19 months,” (Jacobs). Because of this, being able to accurately test stents before they are inserted in patients is important in order to prevent complications that arise from mechanical failures. Otherwise, it might be too late once the failures are found.

Since stents can fail in multiple ways, there are several tests used to evaluate stents before they are used. These assessments include tensile, flexural, radial force, stent securement, and fatigue tests, which determine the mechanical properties of the stent and its materials. Tensile tests use a clamp-like device to measure the tensile strength and elongation of the stent. Flexural tests determine the stent’s ability to bend by applying loads from different angles. Radial force tests measure the radial force the stent exerts on an artery wall. Stent securement tests focus on the insertion of the stent from the balloon catheter. Finally, fatigue tests are used to determine how the stent will react to wear from being in the human body over extended periods.
This project focuses on the fatigue tests and how to improve their reliability. One way to test fatigue uses hydrodynamic pulsation to simulate blood pumping through an artery. “The method involves placing complete devices into mock arteries and subjecting them to 400 million cycles of internal pressure pulsation (10 years of human heartbeats),” (Kemp). This method makes it possible to simulate 10 years of a stent being in a human artery in a matter of months. The criterion for passing or failing the test is simple: If any fractures appear on the stent, it is considered a failure. Another method involves continuously subjugating the stent to forces until a fracture appears and using the number of cycles required for failure to evaluate the stent’s durability.

**Project Objective**

All of the benefits that a stent that can provide vastly outweigh the risks. However, when researching the risks it is seen that some of these cannot be controlled and others can. It is up to a company to determine how long the stent will last and be useful. To ensure the quality of the stent there must be as many precautions taken as possible. One of the major issues that can be addressed is the multiple types of mechanical failures. There are a number of ways that a stent’s mechanical stability can be tested.
We followed Table 1-1 and Table 1-2 when working through the project.

<table>
<thead>
<tr>
<th>Table 1-1</th>
<th>A Design Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Identification of need</td>
</tr>
<tr>
<td>2</td>
<td>Background research</td>
</tr>
<tr>
<td>3</td>
<td>Goal statement</td>
</tr>
<tr>
<td>4</td>
<td>Task specifications</td>
</tr>
<tr>
<td>5</td>
<td>Synthesis</td>
</tr>
<tr>
<td>6</td>
<td>Analysis</td>
</tr>
<tr>
<td>7</td>
<td>Selection</td>
</tr>
<tr>
<td>8</td>
<td>Detailed design</td>
</tr>
<tr>
<td>9</td>
<td>Prototyping and testing</td>
</tr>
<tr>
<td>10</td>
<td>Production</td>
</tr>
</tbody>
</table>

For this research we looked at the stents and the stresses that occur over time. We looked at designing a system that can simulate a heart in order to help determine and prove our results. Then, determine when the stent will fail given specific dimension for the stent. Given the previous knowledge mentioned in the section above we made the necessary assumptions to analyze the heart.
Analysis

A pump is a device used to move liquids or gasses through a tube or pipe. This is done by using pressure differential; the gasses and liquids are moved from lower pressure to higher pressure. Pumps are needed when it is necessary to move a liquid or gas against the grain. There are many different pumps for moving liquids or gasses against the pressure gradient, all of which possess different methods for moving the material. The two main types of pumps are centrifugal and positive displacement pumps.

A reciprocating pump uses the back and forward or reciprocating movement of components, such as pistons, plunger or diaphragms to move fluids. One common type of reciprocating pump is the piston pump. A piston pump is being used to model a heart’s pump. This type of pump has a positive displacement pump where high pressure seal is stationary and smooth cylindrical plunger slides through the seal. AutoCAD was used to simulate the pump that would work similar to one of the pumps in the heart. Since the stent is on the coronary artery, only one of the pumps is needed for the simulation.

A reciprocating pump has the following components: a cylinder which is located inside casing, a piston, a connecting rod and two valves (a discharge valve and a suction valve). The connecting rod connects the piston to a device that moves the piston back and forward. When the piston moves back on the suction stroke, it reduces the pressure inside the cylinder. The reduced pressure closes the discharge valve, opens the suction valve and draws fluid into the cylinder.
When the piston moves forward, on the discharge stroke, it exerts the force on the fluid that increases its pressure. The increased pressure closes the suction valve, opens the discharge valve and pushes the fluid out of the pump. At the end of the second stroke, the piston is in its initial position and the cycle begins again. The piston draws fluid into the cylinder and then positively displaces it. In other words, the piston takes the place of the fluid, the pressure of the piston pressing against the fluid gives the fluid the pressure it need to move through the discharge piping.

![Diagram](image)

Figure 1

In figure 1 (above) it shows the first process described above with liquid being pumped into cell 2 from the piston cell. Once the piston has fully extended pushing liquid into cell 2 it retracts pulling in new fluid from cell 1. This pressure makes the top valve open and the bottom valve close. This most resembles a heart because of the way it moves fluids through the cells. The
human heart has four chambers, two superior atria and two inferior ventricles. Even though our pump only shows two chamber, cell 1 and cell 2 it is still practical and similar to the process of a heart. The atria are the receiving chambers, which is the same as our cell 1 in the pumping system. The ventricles are the discharging chambers, and are similar to our piston that pumps the fluid in and back out of to the cells. The pathway of blood through the human heart consists of a pulmonary circuit and a systemic circuit. Deoxygenated blood flows through the heart in one direction, entering through the superior vena cava into the right atrium and is pumped through the tricuspid valve into the right ventricle before being pumped out through the pulmonary valve to the pulmonary arteries into the lungs. It returns from the lungs through the pulmonary veins to the left atrium where it is pumped through the mitral valve into the left ventricle before leaving through the aortic valve to the aorta. The pulmonary vein is the example of cell 2 which pumps the liquid back into the body. This is where the stent will be placed, as seen in figure 3.

Figure 2
In figure 2 it shows an example of a heart, and in comparison to our pump you can see the similarity of the two. The heart is much more complex than our pump but they both have the same concept. The heart beat is a pulse that most the fluid through the atrioventricular which is the same process as our piston moves back and forth to create a similar pulse. The atrioventricular resembles the valves that we have placed to regulate the amount of fluid that flows in and out of the ventricle which are the cells in the pump. This pump is also known as a piston pump.

Figure 3

The stent is a very small mesh tube for narrow or weak arteries to help the treatment of coronary heart disease and angioplasty. Our stent is placed in cell 2 to show where the stent would be placed if there was a need for one. The stent would keep this particular length open and clear of any possible clogs.
When we analyzed the stent while it is in use we used the Soderberg equation. After analyzing the stent under cyclic loading we found that the stent will never fail. It reaches an endurance stress and becomes steady on the S-N curve. Below in Chart [1] is a description of this curve.
The chart above shows that after a high number of cycles the stress reaches its endurance limit in the situation of our stent, it will never pass this limit.

The Soderberg equation sues the average stress, range stress, stress concentration factor of the material, yield point stress, and factor of safety. This equation compares the actual stresses to a ratio of yield point stress over the factor of safety. Ultimately the results are used to find whether the machine or part under speculation will fail.

Before analysis we pulled some material properties for 316L steel. The values are shown in Table [2] below.
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yield Strength</td>
<td>43,500 Psi</td>
</tr>
<tr>
<td>Endurance Strength</td>
<td>37,700 Psi</td>
</tr>
<tr>
<td>Elongation</td>
<td>40%</td>
</tr>
<tr>
<td>$K_f$</td>
<td>1</td>
</tr>
<tr>
<td>$q$</td>
<td>1</td>
</tr>
</tbody>
</table>

We assumed the stress concentration factor to be one because there are no features on the stent such as holes, fillets, or size deviations. We also assumed that the material sensitivity is 1 because the stent is a ductile material that is under normal operating conditions i.e. not extreme.

The user of the stent will typically be someone over the age of 55 years old, usually with bad health conditions and high blood pressure. The systolic pressure was found to be 160 mmHg and the diastolic pressure was found to be 100 mmHg. This gives a pressure range of 1.93 psi to 3.09 psi with a heartbeat of 85 beats per min.

The dimensions of the stent are important to know when analyzing the forces on the stent. The outer diameter is between 0.01 - 0.16 inches and the thickness is between 0.0036 - 0.0049 inches. The length of the stent is between 0.3 – 1.5 inches.

Using the Soderberg equation below, we can determine whether the part will fail.

$$S_{avg} + S_r K_f \left( \frac{S_{yp}}{S_e} \right) \leq \frac{S_{yp}}{F_s}$$

This is where $S_{avg}$ is the average stress, $S_r$ is the range stress, $K_f$ is the stress concentration factor, $S_{yp}$ is the yield point stress, $S_e$ is the endurance stress and $F_s$ is the factor of safety.
We will need to find the axial loads for the stent. To find the axial loads we will need to calculate the pressure, cross sectional area, minimum stress and maximum stress.

First we calculated the force over the entire cross sectional area of the stent with the force of the pump pushing blood. An image of the cross sectional area is shown below in Image [3].

![Image [3]](image)

Using the blood pressure figures, and the cross sectional area of the artery, the force exerted by the fluid onto the face of the stint can be calculated. The cross sectional area of the artery can be assumed as circular, with a radius equal to the maximum radius of the stint. In this case we took this as 0.045 inches and so the cross sectional area of the artery is \(6.36 \times 10^{-3} \text{ inch}^2\). This gives a maximum force of \(6.36 \times 10^{-3} \times 3.09 \text{psi} = 0.01966 \text{lb.f}\). The minimum force of \(6.36 \times 10^{-3} \times 1.93 \text{psi} = 0.01228 \text{lb.f}\).
Using these forces, which will be applied to the very small end wall of the stint, we can calculate the stresses exerted on the stint, which can then be used in the Soderberg equation. The surface area that the force is exerted on is calculated using:

\[ A = \frac{\pi(D_o^2 - D_i^2)}{4} = 5.934 \times 10^{-4} \text{ inch}^2 \]

This gives a maximum stress of 33.13 psi, and a minimum stress of 20.69 psi. A range stress of 6.22 psi thus can be calculated, with a 26.91 psi average stress.

A factor of safety is assumed as 2. With a K of 1 and a q of 1, the K_f=1. Therefore, inputting all of this into Soderberg equation we get:

\[
26.91 \text{ psi} + 6.22 \text{ psi} \times 1 \times \frac{43,500 \text{ psi}}{37,700 \text{ psi}} \leq \frac{43,500 \text{ psi}}{2}
\]

\[
34.09 \text{ psi} \leq 21,750 \text{ psi}
\]

Therefore, from the Soderberg equation, the stresses exerted on the stint are far lower than the tolerable amount for 316L stainless steel, and so following the Soderberg failure criteria; the stint will not fail under fatigue. Furthering this, the endurance limit of 316L stainless is 37,700 psi, which is greater than the calculated 34.09 psi and so the part should never fail under cyclic loading.

Below in images [3] and [4] are simulations ran on Solid Works to find the points on the stent that endure the most stress.
This image shows the Von Mises stress throughout the stent. The stress seems to be consistent throughout the simplified model. In the real model the joints of the mesh structure will be areas of high stress concentration.
This image shows the stress on the stent caused by deflection. The farthest end of the stent in this simulation was fixed therefore it undergoes the most stress. The total elongation was found to be $2.2 \times 10^{-5}\%$, which is extremely negligible.

Conclusions and Recommendations

Designing the pump allowed us to see how the heart works and is equal to a pump. This lead to a better understating of what stresses would be placed on the stent when it was in the artery. The majority of the stress is applied at one end of the stent and therefore is not enough to break it or cause and fracturing to happen. Stents are more likely to fail due to an incorrect procedure than they are from too much stress. Overall, the stresses applied to the stent from the valve pressure and blood flow are not enough to cause the stent to fail. It is our recommendation that more precaution needs to be taken when it comes to the implantation process. If this is done then most of the issues that arise from stents will be avoided according.
References


