Stent Graft Blush

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Statement of Confidentiality

The complete senior project report was submitted to the project advisor and sponsor. The results of this project are of a confidential nature and will not be published at this time.

Statement of Disclaimer

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Abstract

In order to better understand Type IV endoleaks ("blush"), the Cal Poly Senior Project team GraftTest has developed a blush evaluation system able to mimic several of the aorta's environmental parameters. Capable of both pressure and flow rate control, this bench top system accommodates Medtronic's wide range of abdominal and thoracic aortic stent grafts. Having researched endoleaks, stent grafts, and numerous other factors affecting stent graft blush, a system was developed with the aim of assessing and comparing the performance of Medtronic's stent grafts with regard to blush. Furthermore, this system has been designed to provide reliable and repeatable results in accordance with the formal engineering design process. Our mark I design proposal utilizes a combination of measurements, including: water weight, flow rate, and pressure in order to qualitatively measure stent blush resistance values. In addition our design allows for realistic visualization of blush by submerging the stent graft in water and allowing for dye injection into the stent graft.

Chapter 1: Introduction

Sponsor Background and Needs

This 2012-2013 Cal Poly Senior Project is sponsored by Medtronic, the largest medical technology company in the world with 45,000 employees and annual revenues of $15.9 billion. It is headquartered in Minnesota but has locations throughout the world serving 120 countries. We are working with the Keystone/Applied Research group based in the Endovascular headquarters in Santa Rosa, CA. This group looks at technology five to ten years out and does initial research and modeling. Our project contact is Jeff Wootton, PhD, Senior R&D Engineer. The stakeholders for our project are Medtronic's Keystone/Applied Research Group and Cal Poly San Luis Obispo's Mechanical Engineering department, represented by our faculty advisor Dr. Tom Mase.

Formal Problem Definition

Our goal is to create a bench top system to evaluate and compare stent graft blush, or leakage through stent graft material, in aortic aneurysms. We will focus specifically on how much fluid leaks through the stent graft and the effect of fabric porosity on blush. This testing system will be used within Medtronic only.

Medical Background

Stent grafts are small tubes made of a metal frame (the stent graft) surrounded by fabric,

as shown in Figure 1. They are inserted into aortic aneurysms, which are balloon-like bulges in the aorta caused by weakened aortic walls. Aortic aneurysms are classified as either thoracic (occurring in the chest cavity near the heart) or abdominal (occurring in the stomach cavity). The job of stent grafts is to reduce pressure inside aneurysms to keep them from rupturing. Ruptures cause massive bleeding in the chest or abdomen, leading to a life threatening emergency. Stent grafts protect the aneurysm sac from rupture by diverting blood flow through the stent graft itself, reducing pressure on the walls of the aneurysm (see Figure 2).

Figure 1: Medtronic's Talent model abdominal stent graft (for source see Appendix H)

Stent grafts can experience different types of blood leaks, or endoleaks, into the aneurysm sac which may nullify their pressure reducing abilities. If fluid leaks into the sac, the pressure remains high and there is still the risk of rupture. Endoleaks are classified into four or five types depending on their cause. Types I, II, and III are due to leaks from a specific joint or location (e.g. through the connection between stent graft and aorta, through junctions between different stent graft limbs, or through stent graft defects such as tears). Type IV endoleaks are leaks through the pores of the stent graft fabric. They are the least serious type of leak and not a clinical risk, but they are a nuisance because they can hinder detection of more serious endoleaks or be mistaken for other types of endoleaks. According to Medtronic, they are the top customer complaint for abdominal aortic aneurysm (AAA) stent grafts.

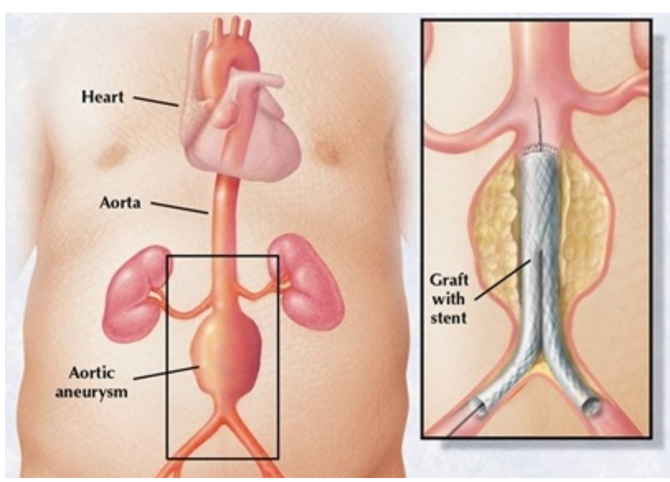


Figure 2: Abdominal aortic aneurysm with stent graft (for source see Appendix H)

Endoleaks are visualized by injecting radiopaque contrast dye into the bloodstream and then using imaging techniques such as angiography (either CT—computed tomographic, or MR—magnetic resonance imaging) to look for any contrast dye migrating out of the stent graft. The contrast dye presents dark on the image outside of the stent graft channel, enabling doctors to see leakage from the stent graft. Ideally the stent graft wall should be clearly defined if there is no endoleak present. Some leaks look like obvious "jets" coming through the stent graft wall; others look like a darkish haze blurring the stent graft wall. This haze is known as blush and typifies type IV endoleaks. Since these leaks clot within 30 days of stent graft insertion, blush is a concern primarily because it can obscure more serious leaks during imaging, as well as create uncertainty and a lack of confidence in the stent graft product.

Objective/Specification Development

The objective of this project is to develop a test system for assessing the effect of stent graft fabric porosity effects on blush. We will achieve this objective by creating a system that accurately measures or compares the movement of materials representing contrast agents and blood components across the stent graft fabric over time. Because we want to assess the blush performance of the stent graft in a human patient, we must control engineering specifications to be similar to in vivo values, where possible, while producing reliable and repeatable results. This will create an environment which will more accurately predict performance of the stent graft fabrics in the human body.

Engineering specifications were determined with a primary focus on test reliability and repeatability, and with a secondary focus of closely mimicking physiological parameters. We began by determining the objective and requirements given by the customer, Medtronic, and then set out to obtain a fundamental understanding of the task at hand. We conducted extensive background research on the physiology of the aorta (both healthy and aneurysmic), the endovascular stent graft procedure, and blush and the method by which it occurs. We derived most of our engineering specifications from this research by setting values for pressure, flow rate, temperature, and pulsatile rate based on the physiological values we expect an implanted stent graft to experience. Next we looked into the endovascular aortic repair procedure to develop other specifications such as the concentration and the injection method of the contrast dye. Then we held several brainstorming sessions to enumerate all the possible clinical, environmental, procedural, and material factors in blush performance, and we narrowed down this list to the most important factors that we would focus on. These factors drove our engineering specifications. Finally, we created a Quality Function Deployment table where we related the customer requirements to our own specifications.

We worked with Medtronic to develop a comprehensive list of variables which affect stent graft blush (Appendix G: Factors Affecting Stent graft Graft Blush—Comprehensive List). These include environmental factors, stent graft device factors, procedural factors, and non-technical factors. With Medtronic's input and guidance, we divided this list into factors that we will control in our test, factors that we will vary, and factors that we will not consider as they cannot be

reliably measured. In this way, the customer requirements line up closely with the engineering requirements. See Appendix A: Decision Matrix for Design Selection.

Project Management

The purpose of the management plan was to assign responsibility within the team, thereby assuring that all tasks are accounted for. Thus, it is important to note that while a specific title may be assigned to a certain person, this title implies more of an organizational and accounting role. The purpose is to designate a specific person to keep track of specific project roles (e.g. communication or research material), therefore making them a delegator and not necessarily the sole task performer. This is done to both allow greater work load flexibility and to encourage full participation by all team members. Table 1 lists all team members and their responsibilities.

Table 1: Team Member Responsibilities

Team Member	Responsibilities	Title Description
Mike Morelli	CFO	Manage budget. Keep an expenditure spreadsheet and allocate monetary resources.
	Information Organization	Manage Skydrive.com account and all associated documents, specifically aggregation and organization of all research materials and project generated reports.
	Medical Relevance	Communicate with medical industry representative: cardiologist and Medtronic customer/product user.
Vanessa Barrett	Communications	Manage sponsor communication. Organize communication in a timel and efficient way. Keep everyone involved up-to-date.
	Documentation of Project	Project note keeper. Record and organize specific project details and specifications.
	Project Progress	Schedule and progress management.
Thomas Matzinger	Manufacturing Considerations	Provide insight into the manufacturability of the test setup.
	Prototype Fabrications	Oversee final manufacturing process.
	Testing Plans/Validation	Organize and schedule testing/validation of the final test system.

Chapter 2: Background

Existing Products

There are no existing products on the market which evaluate stent graft blush.

Current State of the Art

Currently, there are no reliable ways to evaluate blush in the industry. Medtronic uses a water permeability test for coupons (1 cm square pieces) of stent graft material, but this is a very simplified model which doesn't take into account many important variables such as stent graft shape, fluid properties and flow properties. Our goal was to create a system to evaluate blush between Medtronic's different stent graft models, specifically how much fluid leaks from the stent graft and the effect of fabric porosity on blush.

Specific Technical Data

Our project needed to be a bench top system which accommodates all sizes and shapes of Medtronic stent grafts, including straight and bifurcated shapes, different diameters, and different limb lengths. We only needed to consider woven polyester weave stent graft fabric, not ePTFE (another type of stent graft fabric commonly used in the industry). We needed to be able to model contrast dye injection methods to control the flow rate of fluid during the tests, as this varies from patient to patient depending on health and genetic factors. Modeling pulsatile blood flow was an option, but was not required for our test. In addition, we set out to allow for use of both automatic and manual contrast agent injections.

Medtronic wanted to be able to compare performance between their different stent graft models, so they were most interested in comparative data. Since blush is so understudied, there are no established baselines or typical performance numbers, so our data did not necessarily have to be quantitative. As long as it provided a clear comparison between different stent graft models, any comparison metric was fine (e.g. color differences, light and dark contrast, amount of fluid leaked, flow rate).

As determined from clinical data, we set out to run the system at flow rate of 6.4 L/min and a static pressure of 40mm Hg, which corresponds to 0.77 psi. In Table 2 we list the specifications we followed for our first iteration of the system design. After testing and optimizing the first iteration, we planned to expand our design parameters for the second iteration to include those in Appendix H: Future Design Parameters. In the second iteration, we planned to control fluid temperature to 37 °C, the average core body temperature, by using a heater. In the first iteration we did not control for temperature because water's fluid properties do not vary a significant amount from room temperature to core body temperature.

Table 2: Stent Graft Blush Formal Engineering Requirements

Spec #	Parameter Description	Target Value	Tolerance	Risk	Compliance
1	System Size	4 x 3 x 3 ft.	max	Low	Inspection
2	Pressure Differential	40 ± 20 mmHg	±5%	Med.	Measure
		0.77 ± 0.36 psi	±5%	Med.	Measure
3	Flow rate	6.4 L/min	±5%	Low	Measure
4	Project Cost	$1,000	max	Low	Inspection
5	Stent Diameter	10 mm	min	Med.	Inspection
6	Stent Diameter	60 mm	max	Med.	Inspection
7	Stent Length	50 mm	min	Med.	Inspection
8	Stent Length	250 mm	max	Med.	Inspection

List of Applicable Standards

Because this test system will be used solely internally at Medtronic, there are no externally enforced testing or safety standards to accommodate. Even though Medtronic's stent grafts are medical devices that must comply with all the accompanying FDA regulations, our test method does not need to meet the same regulations because it will only be used inside Medtronic. Still, the more clinically relevant we make our test method, the more useful it will be to our sponsor.

Chapter 3: Design Development

Discussion of Conceptual Designs

To develop our design, we analyzed it as two systems: the base system, which focused on the basic components involved in pumping fluid, and the blush assessment system, which focused on the method used to evaluate and compare blush between stent grafts. Our base system consisted of a holding tank containing the stent assembly and a connected reservoir (see Figure 3). We had several different ideas for piping components, such as hard PVC, flexible tubing, or accordion tubing (see Figures 3 and 4). The base system design allows for three methods of blush assessment. Assessment #1 is the water weight method, seen in Figure 5, which entails weighing water that leaks out of stents. The contrast dye and image processing method in Figure 6 entails pumping a dye mixture through the stent graft and using an image-processing program to quantify the resulting dye blush. The pH method in Figure 7 entails pumping a weak acid or other chemical mixture through the stent graft and measuring change in pH of the surrounding fluid with respect to time. The whole system is designed to be adaptable to all of our blush assessment methods. The holding tank can be filled with water and the stent assembly submerged, for example, to use pH and contrast dye assessment methods (see Figures 6 and 7). The system is capable of controlling and measuring pressure and flow rate of fluid through the stent graft.

The reservoir holds the fluid which will be pumped through the stent graft. Fluid travels through the pump, past the bypass line, and to the stent graft assembly. The fluid then flows through a control valve, flow meter, and tubing leading to the pressure transducers. A dye injection port allows the catheter to be inserted so that dye may be injected upstream of the stent graft. The dye injection port is approximately six inches from the stent, thus the catheter may be adjusted to inject dye up to six inches from the stent. Ports for pressure gauges (either the pressure transducers or needle gauges) have placed on either side of the stent, allowing for the pressure drop across the stent graft to be measured.

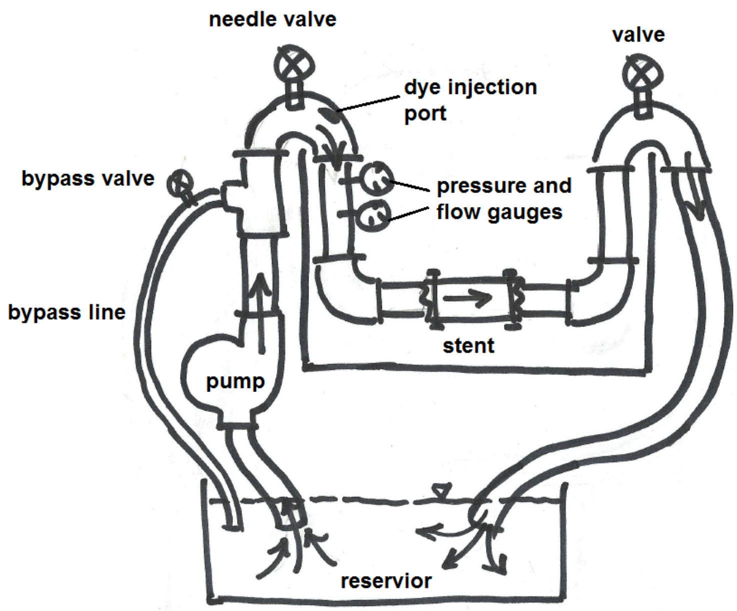


Figure 3: Build #1, PVC and Overall System

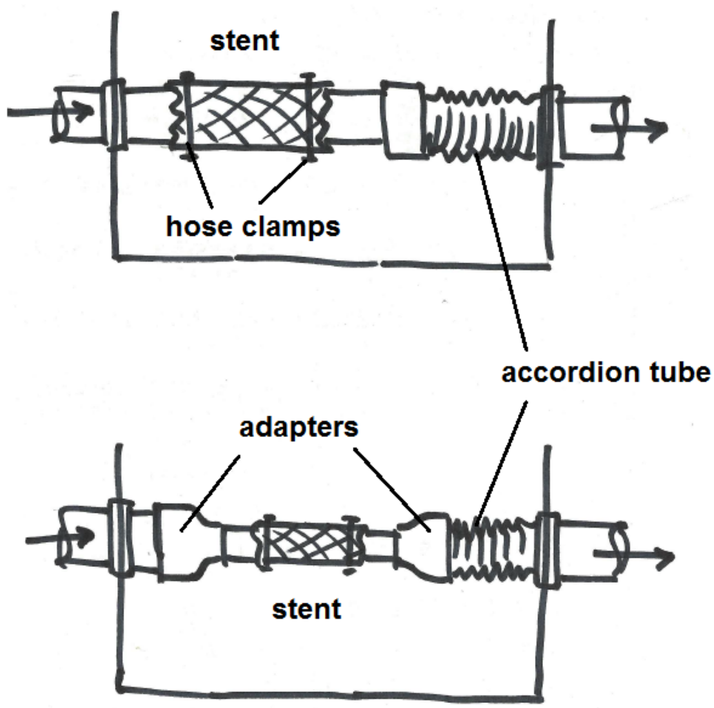


Figure 4: Build #2, Accordion Tube

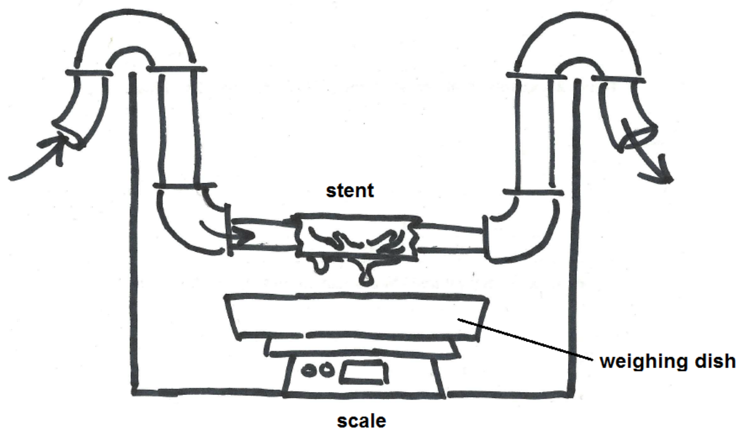


Figure 5: Assessment #1: Water Weight

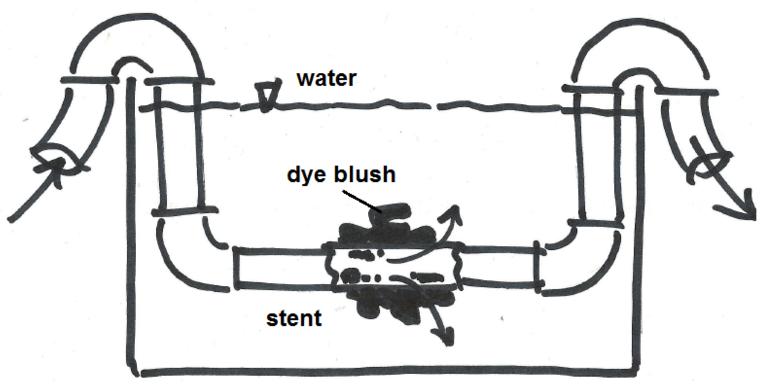


Figure 6: Assessment #2: Dye and Image Processing Method

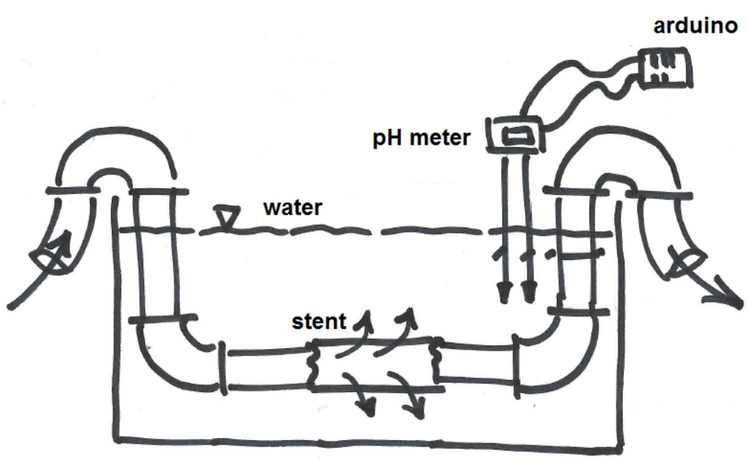


Figure 7: Assessment #3: pH Method

Concept Selection

We used a weighted pro-con list to select our top concept. Our design is relatively simple, with basic components and few moving parts. We decided that this simple idea selection tool would be best, as recommended by Dave Schoch, Senior Design Assurance Engineer at Medtronic. We created weighted pro-con lists for both design systems: how we would build the physical system, and how we would evaluate blush within that build. Again, we wanted to build a universal system which would accommodate several different methods of blush evaluation. We also wanted to pick the best method of blush evaluation to try first. Later iterations could incorporate other evaluation methods, whether implemented as part of our project or by Medtronic after the project's conclusion.

We created two weighted pro-con lists. See Appendix A: Decision Matrix for Design Selection. One list addressed the way we would build the system—either with rigid PVC throughout or with flexible accordion tubes at the exit of each stent to allow for varying stent graft diameters and lengths. The other list addressed the methods we would use to actually assess and compare blush between different stents, whether quantitative or qualitative. We listed several ideas for each design, then weighed each idea based on importance. If an idea met the consideration, it was scored as a pro and assigned a point value of +1. If it failed a consideration, it was scored as a con and assigned a point value of -1. Multiplying each pro or con by its weight and summing the weighted scores gave the total value for each design. The design with the highest total value was considered to be the best.

For the system construction, basic considerations included cost to build, durability, and potential for leakage at component joints. Another consideration was the ease of switching out different stent grafts to test. Since we would be testing several different sizes of stent grafts with different lengths and diameters, there was the issue of adapting each stent graft to fit within the main fluid line. We sized the main fluid line to accommodate the widest and longest stent we would test, about 1 inch in diameter. To fit narrower stents, we designed contracting size-adapter couplings; for larger stents we designed expanding size-adapter couplings. To fit shorter stents, we needed to add more line to fill in the gap in length. If we incorporated flexible accordion tubing into the design, we could avoid the need for precise length measurements and extra sections of PVC, as the tube would simply stretch to fit any gaps. However, accordion tubing does have some drawbacks. It is less durable than PVC, and because it is ridged, it introduces undesirable changes in fluid flow. An accordion tube bunched up into a shorter length creates one kind of ridged surface profile over which fluid flows. The same accordion tube stretched over a longer length creates a different surface profile which seems smoother. These different profiles will affect fluid flow in unpredictable ways, adding uncertainty and turbulence in a manner which is difficult to quantify. Our goal was to assess blush performance only between different stent grafts, so we wanted to control for flow behavior. Since flow behavior may affect the amount of blush a stent graft produces, we wanted to ensure that flows are as similar as possible between different stents. The other option was to find a correlation or

otherwise adjust for the effects of stretched and unstretched accordion tube on fluid flow, but this is a fairly complicated analysis. Because of these drawbacks of using accordion tube, the PVC method won for best system build design.

Our three ideas for blush assessment included water weight, pH or another chemical differential, and image processing with contrast dye. Basic considerations for the pro-con lists included the cost and ease to build and operate each method, and whether it gave quantitative results, making our system more clinically relevant, or just qualitative results. As explained in the requirements, qualitative results are acceptable because Medtronic is simply looking for a way to assess and compare the performances of their own stent graft models. They want to know which model experiences the most blush, the least blush, and so on. One important consideration was if the assessment method could potentially damage the stent graft. The water weight method passes water through the stent, which is not damaging (if distilled water is used, clogging is not an issue), but the other two methods have potential for damage. We do not know how stent grafts react to the slightly basic solution or other chemical we would use for the pH method, or the dye we would use in the image processing method. At worst, the stent would be damaged by these methods, but at best, the stent graft integrity would be uncertain. We could not assume the stent graft was not damaged without running additional tests.

Additionally, the contrast dye and image processing method was rated a con for both cost and ease of operation. This method would require using a camera (potentially expensive) and creating an image processing program in MATLAB (definitely time consuming).

The most important and highest weighted consideration was precedent: had this method been used to assess blush in the past, and had it been successful? The only method for which there was a precedent was the water weight method, which is adapted from Medtronic's currently used coupon permeability test. A small coupon of stent fabric is clamped into place over a pipe opening through which water flows, and the water leakage out of the coupon is collected and weighed. Since there was a successful precedent for the water weight method, it was rated a pro for precedent on our idea selection matrix. To our knowledge, the other assessment methods had not been attempted before, so they were rated cons.

The water weight method won for best blush assessment design, as shown in Table 6 of Appendix A. It was the cheapest to operate, the working fluid being water (the pH method would require a chemical additive). It was the most durable design, and the critical factor was that it had a precedent: the coupon test that was currently running successfully at Medtronic.

Using weighted pro-con lists as a selection tool, our winning design idea was determined to be an all PVC system, which would assess blush, by the water weight method.

Supporting Preliminary Analysis

We made some preliminary calculations to determine what kind of flow behavior we wanted to induce through the stent graft. The Reynolds number for water at 21°C flowing through a 1 inch diameter pipe is higher than that for blood at 37 °C (body temperature) flowing through a 1 inch diameter pipe. In this case the Reynolds number for blood, 1610, indicates that flow in the aorta is laminar. In reality, we know that blood flow is heavily pulsatile in the aorta since it is so close to the heart, and this adds turbulence. In later iterations of the design we could try to mimic this behavior by adding a laminar flow nozzle and a pulsatile flow device, but in the first iteration we emphasized simplicity and repeatability of the design over matching the in vivo conditions exactly. As many of the in vivo flow conditions could not be met with our other design criteria, similarity of testing was more important.

Detailed calculations consisted primarily of fluid flow analysis in order to size the required pump. A detailed set of these calculations can be seen in Appendix E: Detailed Supporting Analysis. From these calculations we were able to analyze head loss through the system and thus estimate the necessary pump size required.

Proof of Concept Analysis or Testing

It is important that our test system produces reliable and repeatable results. We want to ensure that our design runs at a constant flow rate, static pressure, and does not leak significantly onto the weighing scale from any point other than the stent graft itself. We plan to first ensure that our measurement devices are properly calibrated for standardized testing. After calibrating and ensuring that our measurement devices fit our specifications, the system will be run until steady state is reached and the flow and static pressure are within our specifications. After these qualifications are met, the scale will be placed under the stent graft so it can catch all the water leaking out. Once the test is finished, the scale will be removed and the water weighed.

Proof of concept testing was conducted throughout the build process, the main objective of most of the testing being to ensure that the system components fit together correctly. Additionally, flow rate through the stent was assessed on multiple occasions in order to ensure that the head loss through the pipes was not so great as to reduce flow rate below the desired rate.

Chapter 4: Final Design

Overall Description and Layout including Solid Model

The Stent Graft Blush test system is composed of five major components: the pump, the flow control system, the sensor system, the removable stent graft assembly, and the blush assessment system. Figure 8 shows the overall system layout. For the first iteration system, we will use water as our fluid. The pump draws fluid from a reservoir tank and delivers it to through the flow control system and removable stent graft assembly; from there the fluid which does not leak out of the stent graft is directed to the discharge tank. Any fluid which exits the stent graft is collected and measured in the stent graft tank. Additionally, dye can be injected into the stent graft flow branch through a Luer lock catheter port.

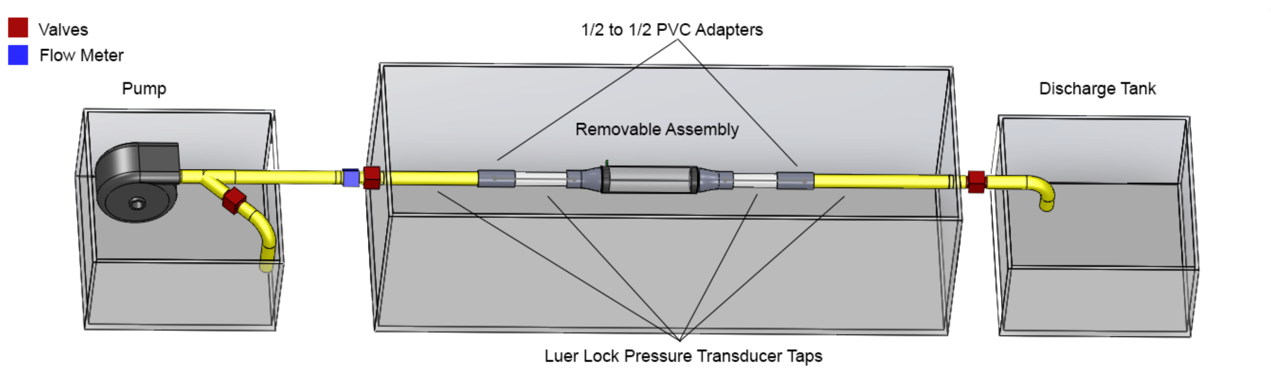


Figure 8: Full Test System

Detailed Design Description

One inch diameter PVC was initially selected for the piping immediately prior to the removable stent graft assembly because of its ability to be adapted to any of Medtronic's stent graft sizes. We lathed custom-fit adapters from solid PVC to attach the stent grafts to the PVC. To lower the number of adapters required for valves and flow meter as well as minimize the size and cost of valves, we ended up using ½ inch PVC as the standard piping diameter. The adapters fit over the outside of the stock ½ inch PVC and the stent graft will be secured on the outside of the adapters using rubber and zip ties. We believe that the use of ½ inch PVC will not significantly affect flow characteristics when compared to the 1 inch PVC.

Pump

In order to supply flow to our system, a simple utility pump was purchased from Ace Hardware. Sizing is based on a flow rate of 6.4 L/min, a standard resting flow rate through the adult aorta. Pump head was based on a 40mmHg pressure differential, the standard pressure differential between stent graft and aortic sac, as well as the dynamic head required for the desired 6.4 L/min flow rate. However, we later choose to base our initial system around a flow rate of 6.4 L/min as opposed to 40 mmHg. This is due to the fact that when using a fluid with the viscosity of water achieving a pressure differential of 40 mmHg requires a flow rate across the fabric of the stent alone of 20 L/min. This much higher flow rate requires a much larger pump, flow meter, and more importantly exaggerates blush flow rates to much above that which would be seen in the body. In future iterations the pump could be replaces with one capable of pumping fluid with higher viscosities, thus allowing the system to maintain the current flow rate and to achieve a pressure closer to 40 mmHg.

Flow Control System

The flow control system shown in Figure 9 is composed of three valves and two ports for pressure transducers and a flow meter, each providing important tuning and control capabilities. The bypass flow valve, a simple ball valve, will allow excess water flow from the pump to be routed back into the system reservoir, thus allowing further control of flow rate through the stent graft. A flow meter placed before the first valve and connected to an LCD screen will provide the user with current flow rate into the stent graft. The globe and needle valves allow tuning of flow rate and pressure in the stent graft. The pressure control valve after the stent graft will be a needle valve in order to allow precise control of the static pressure within the stent graft. In addition to flow control, a Luer lock tap will provide an access port for contrast dye injection through a variable length catheter.

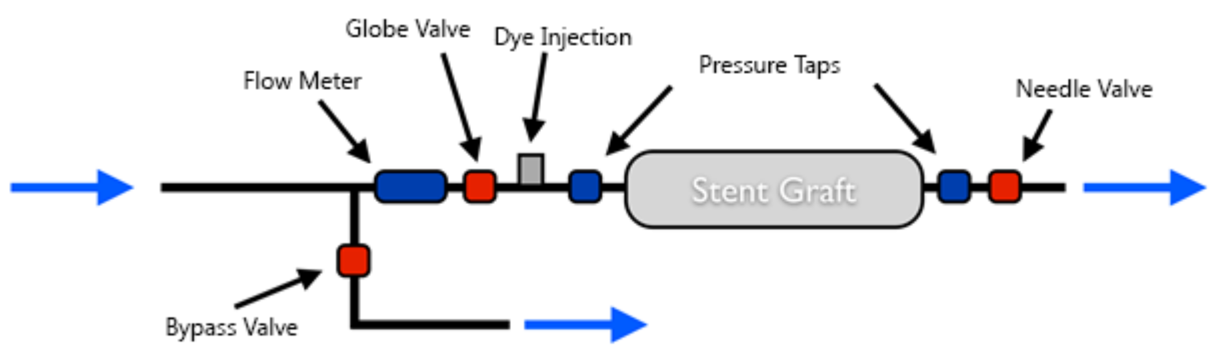


Figure 9: Flow Control System

Sensor System

Two pressure transducer Luer lock taps are located on either side of the stent graft in order to determine and tune the pressure within the stent graft. A flow meter is located before

the first valve to obtain flow rates into the stent graft. Both pressure and flow sensors will be connected to an Arduino, a microcontroller capable of measuring data from our electronic components. A 4x20 character LCD connected to the Arduino will display flow rate in LPM, total flow in L, and static pressure for both taps in mmHg. This setup will allow the greatest amount of adaptability for future design iterations while also providing a real time display of the static pressure and flow rate.

Location of the pressure transducers is the primary issue of the sensor system. We want to place the transducers as close to the stent graft as possible to ensure accurate static pressure readings inside the stent. However, this means that when creating new stent graft assemblies, new Luer locks must be inserted into the adapters. The solution we created was to place Luer lock taps before and after the stent graft on the permanent fluid line sections, while also allowing for Luer locks to be placed on the stent graft adapters themselves if desired.

Removable Stent Graft Assembly

The removable stent graft assembly is located inside the main stent graft tank, between the valves and ½ inch PVC pipe lengths. As shown in

Figure 10 and 11, it consists of the stent graft with size adapters on either end joining it to ½ inch piping, which will be cut to length and connected to the permanent ½ inch PVC. The size adaptors will be custom fabricated on the CNC lathe from solid PVC if stock PVC sizes do not fit. Custom adaptors were chosen to allow for stent grafts of all diameters to be accommodated. To minimize leakage, rubber gaskets were placed inside and outside of the stent graft where it would be secured to the pipe with zip ties. Sizing the adapters to fit the stent graft exactly eliminated folds and bunching in the fabric through which leaks could occur. SolidWorks drawings of a sample adapter appear in the Drawing Packet (Appendix B).

Adapter tolerances are a consideration, but since we are making single, custom pieces, they are not as critical as if we were mass producing them. The Cal Poly CNC lathe is capable of a ±0.0005 inch tolerance. PVC pipe has a tolerance of ±0.01 inch. We are creating couplings which will permanently join to the ½ inch PVC and the stent, so they won't need to accommodate different PVC pipes. For this reason, tolerancing isn't as important; we will simply measure the exact PVC section we are looking to fit.

We will connect the ends of the removable assembly (1/2 inch PVC) to the rest of the 1/2 inch PVC line using stock ½ inch to ½ inch couplings.

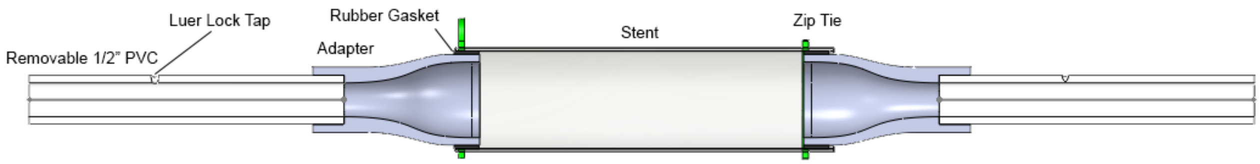


Figure 10: Cross Section of Removable Stent Graft Assembly

Figure 11: Removable Stent Graft Assembly with custom adapters

Blush Assessment System

Finally, our test system utilizes the highest-weighted blush evaluation method from the decision matrix. Once the system's pump starts and water passes through the stent graft at the desired rate and pressure, the water which leaks out of the stent graft fabric will be captured and measured. Having measured flow rate, we will then be able to accurately determine the quantity of fluid that has leaked, or blushed, from the main branch of flow through the stent graft.

In addition to the water weight method, we have provided a way to visualize blush by submerging the stent graft in water and allowing dye injection through the use of Luer locks. We did not complete the plans of adapting the system for the pH assessment method. This can be done in future iterations of the design, if necessary.

Cost Breakdown

The total cost of our prototype comes in at roughly $970 with the majority of the cost absorbed by the flow meter system, Arduino, pump, pressure transducers, pressure gauge, valves, acrylic for the box, and the technician cost for the custom adapter samples. The generalized cost breakdown can be seen in Table 3 below. For a fully itemized cost breakdown, see Appendix J.

Table 3: Cost Breakdown

Category	Cost
Sensors and Gauges	$ 298.79
Flow System	$ 330.75
Boxes	$ 72.12
Manufacturing Supplies and Labor	$ 253.26
Presentation Supplies	$ 14.00
Shipping and Tax	$ 139.31
	$ 968.92

Wiring Diagram

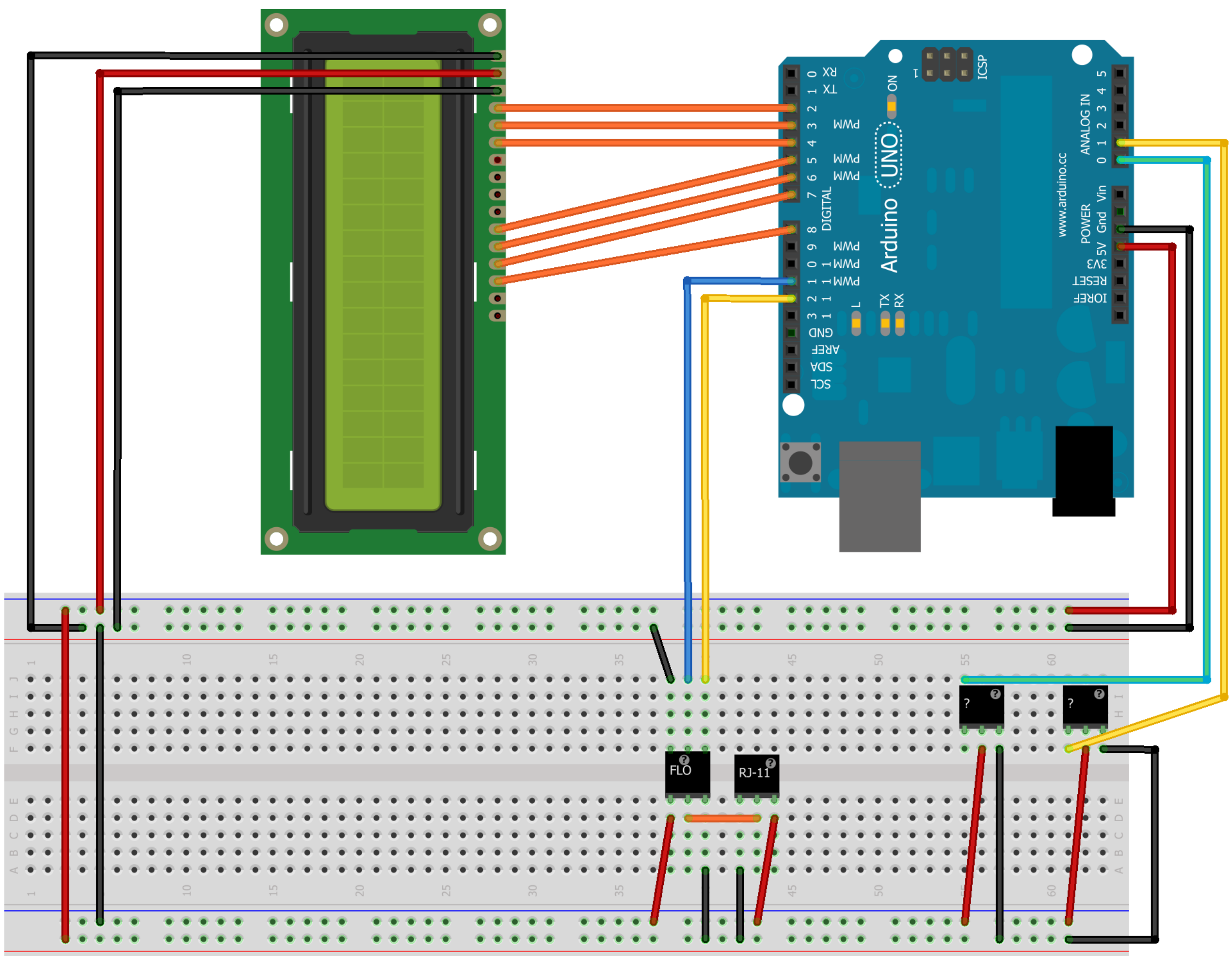


Figure 12: Wiring Diagram for Arduino, 2 Pressure Transducer (right), and Flow Meter chips (left)

Safety Considerations

Proper care should be taken to ensure all wires are connected and not near water or other liquid. When disconnecting the pressure transducer tubes, water may still be in the tube. Care should be taken to ensure that water does not get onto the Arduino. Before operating the system, all connections and seals should be checked for leaks.

Maintenance and Repair Considerations

The flow meter may lose accuracy over time if particulates are allowed to collect inside of it. To flush the flow meter, run distilled water in the reverse direction until the flow meter is clear.

Chapter 5: Product Realization

Manufacturing Process

The first stage of the manufacturing process consisted of assembly, reconfiguration, and optimization of the test system. The vast majority of our components are purchased off the shelf, and thus the greatest difficulty came from interfacing these components. The acrylic box was custom made using acrylic panels bonded with acrylic glue and sealed with silicone caulk. After the initial assembly process, the manufacturing process focused mainly on system streamlining, usability and reliability. This consisted of arranging the system as a convenient, easily adjustable bench top assembly.

Prototype Differences from Planned Design

Our test plan specified pumping water at 40 mmHg (0.77 psi) through a stent graft that is mounted above a water catchment and then measuring the rate of leakage. The main problem we faced was trying to keep the pressure through the stent graft at a high enough value while the water leaks out. After running the system at steady state with settings for highest possible pressure (bypass valve completely closed), we found that it was impossible to achieve the desired 40 mm Hg of pressure with the current pump and fluid viscosity. This was because blood is much thicker than water and therefore has much lower leakage rates. To deal with this issue, we decided that we would plug the trailing end of the stent graft and measure the leakage with no flow leaving the stent graft. This allowed us to keep the pressure constant through the stent graft, albeit at a lower value, and collect more relevant data. Additionally this allowed us to measure fluid leakage through the stent graft using only the flow meter.

The bypass valve turned out to be unnecessary as it was difficult to get up to the desired 40 mm Hg of pressure using brand new stent grafts; however, it remains in the system to accommodate possible future upgrades involving a more powerful pump and/or a more viscous fluid. For our initial testing the outlet of the stent graft was blocked so that all the water entering leaked out of the stent graft, thus pressure was increased. Because all water flowing through the system was leaking out of the stent graft, we could now simply label the system flowrate as leakage. We measured leakage in this way, by reading the flowrate given on the LCD, instead of using the original method of collecting and weighing the leaked water. This change gave us the advantage of avoiding having to use an expensive, delicate scale in our project, as wellas making it much easier to measure leakage (by simply reading a flowrate off the LCD screen instead of dealing with a heavy bucket of water which could spill).

Figure 9 shows the senior project's flow control system, which is used to set nominal pressure and, to a lesser extent, flow rate. The bypass flow valve, a simple ball valve, allows excess water flow from the pump to be routed back into the system reservoir, thus enabling user control of flow rate through the stent graft. A flow gauge placed directly before the stent graft

and connected to the Arduino displays current flow rate on the LCD. The pressure control valve is a needle valve which allows precise control of flow and pressure entering the stent graft. A backpressure needle valve ensures that the fluid exiting the stent graft is not simply exposed to atmospheric pressure as it returns to the system reservoir. For our testing purposes, the backpressure valve remained closed.

Originally we had planned to use dial gauges to measure pressure and a simple scale to weigh the leaked water and calculate the leakage rate through various stent grafts. However, because we ended up needing to run the system at lower pressures than the desired 40 mm Hg, our dial gauges were now not sensitive enough to our new operating pressures. They measured (0 to 5 psi)?, with a resolution of 0.25 psi (or 12.9 mm Hg). We needed a different pressure measure with a higher sensitivtiy, since we were now running in the 0-15 mm Hg range. To solve these problems, we added a flow meter, pressure transducers, and an Arduino microcontroller to allow for faster and more accurate data acquisition and analysis.

Chapter 6: Design Verification Plan (Testing)

Test Description

Component Calibration

Before testing, we ensured that our measurement devices were properly calibrated. Since the flow meter was precalibrated by the manufacturer, we just needed to verify that it read properly. We did this by running a known quantity of fluid through the flow meter and ensuring that it read the proper quantity (within the accuracy specified by the manufacturer).

The pressure transducers were not precalibrated by the manufacturer. They measure pressure in the range of -1 to 1 psi and output a voltage from 0.5 to 4.5 volts. (So zero psi gauge corresponds to roughly 2.5 volts). We wanted them to output stent graft fluid pressure in mm Hg to the LCD. To do this, we needed to program the proper voltage/pressure correlation into the Arduino code. To calibrate the transducers and find this correlation, we held the tubing attached to each pressure transducer port vertically, creating a column. After securing the empty tube, we recorded the pressure transducer's voltage output. This was the voltage associated with atmospheric pressure (0 mm Hg gauge). Water was then added to the column in approximately one inch increments. Each time, the water height was measured and its corresponding pressure transducer output (in voltage) to the LCD was recorded. Water was added up to about 30 inches high, creating a pressure or 30 inches of water, or about 57 mm Hg. This was sufficient to cover the 0-40 mm Hg pressure range we were interested in. We converted the pressure in inches of water to mm Hg and plotted the results. The data was highly linear, and a best fit line provided us with the proper correlation to include in the Arduino code. The two pressure transducer calibration curves can be seen in Figures 13 and 14.

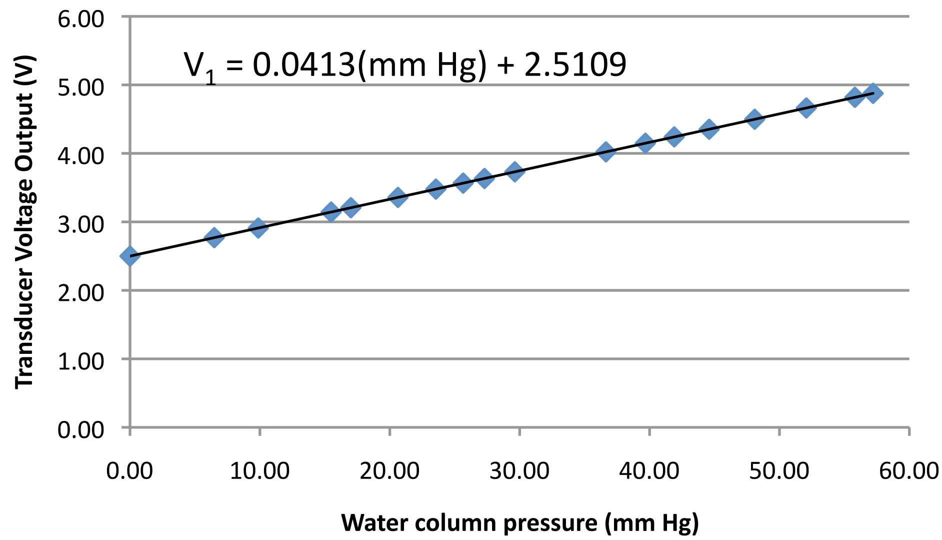


Figure 13: Pressure Transducer #1, Calibration Curve

This plot shows water column pressure and the pressure transducer's corresponding voltage output.

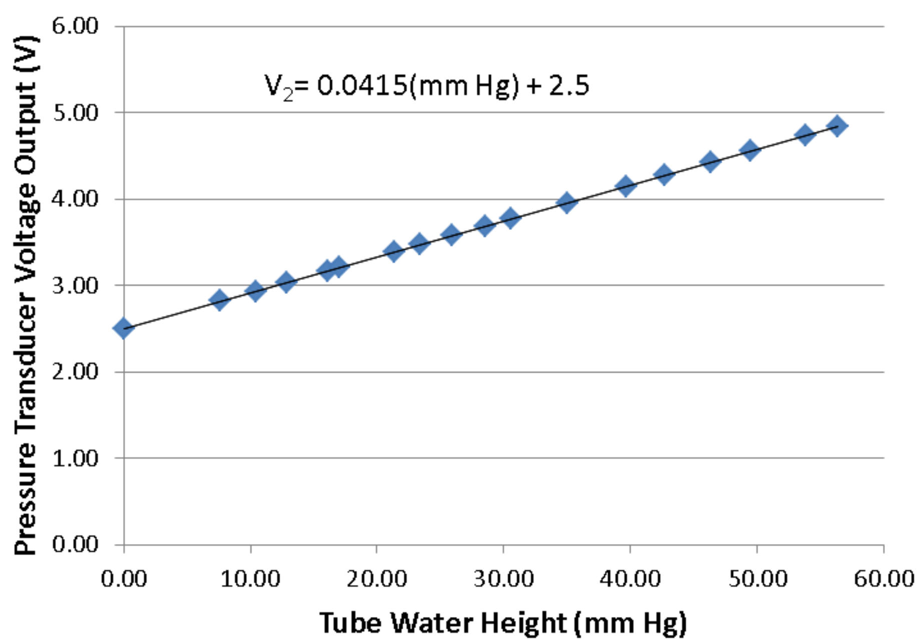


Figure 14: Pressure Transducer #2, Calibration Curve

This plot shows water column pressure and the pressure transducer's corresponding voltage output.

Test Procedure

We split the data acquisition into two steps. The first step was equilibrium pressure testing. We fully opened the needle valve and let the system run until it reached steady state (steady pressure and flowrate), which took approximately 30 seconds to 1 minute. We then let the system run for another minute or so to collect data on stent graft leakage. Since the end valve was completely closed, all water flowing through the system exited out of the stent graft. So the flowmeter's flow rate value simply reflected leakage. We recorded this flow rate and run time to find the amount of leakage out of the stent graft in liters. We measured all three stent grafts this way and found that the stent graft with the lowest steady state pressure was the Endurant bifurcated, with a nominal pressure of 12 mmHg. For the second step of data acquisition, we ran each stent graft at the same pressure, the lowest pressure of 12 mm Hg from the first test. We closed the needle valve slightly to lower the pressure for each stent graft. After some tuning, each stent graft ran at a 12 mm Hg steady state pressure. The leakage flowrate was then recorded as in step 1. Finally, we normalized these results by dividing the leakage rate by the surface area of the stent graft so that an accurate comparison between stent graft designs can be reached.

Detailed Results

Our final results were normalized to give resistance values as:

$$R_{RESISTANCE} = \frac{P_{PRESSURE}}{\left(\frac{F_{FLOW}}{surface\_area}\right)}$$

This equation was derived from the general system model where Pressure was considered as a general across variable and Flow/surface area was considered as a normalized through variable. This allows us to compare different stent graft designs, sizes and materials while still getting meaningful data. The data we get with this test device will be used to qualitatively compare different stent graft designs and materials so the actual numbers are less important than the ability to compare similar systems. The normalized results for our three different stent grafts can be seen in Figure 15. As can be seen, the cuff and the bifurcated stent graft have similar resistance values while the thoracic stent graft has a much higher resistance. We have come up with two possible explanations for this; first, the thoracic stent graft has a much simpler geometry that may lead to better seals on the seams and at the ends. Second, and much more likely, the thoracic stent graft has become clogged. It was used for three quarters as a test piece, and without distilled water, the small pores in the fabric have become clogged, leading to high leak resistance. Getting a new thoracic stent graft and re-testing it.

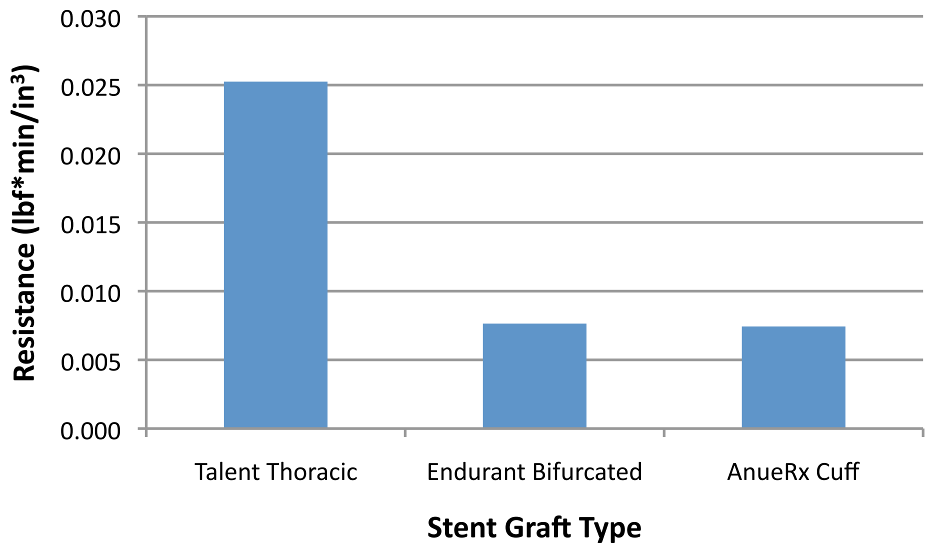


Figure 15: Results of stent graft assessment. Resistance normalized over area.

Chapter 7: Conclusions and Recommendations

We designed, built, and tested a bench top test system capable of measuring stent graft blush. It can measure resistance values for both bifurcated and straight stent grafts. The best stent graft has a high resistance (low leakage). Additionally, our test system offers a way to visualize blush and qualitatively compare stent graft performance by imitating the injection of radiopaque dye into the blood stream. This is an important application for doctors who need to perform medical imaging on new stent graft patients. They are the people truly affected by stent graft blush, as well as the customers for Medtronic's stent graft products.

Future iterations of this project should build upon our current test system. While we have a qualitative, visual method of evaluating blush using dye, a method to quantify that dye leakage is also desirable. One way to achieve this would be to use a high-speed camera and digital imaging software. The advantage of this method is that it would be a highly effective and appropriate visual aid for doctors who struggle with stent graft blush in their medical imaging. Another option would be to hang a basin with force transducers to catch the leakage, making the system capable of measuring blush rate and amount in real time. Additional recommendations to make the system more closely mimic in-vivo conditions involve using a more viscous, non-Newtonian fluid as well using a pulsatile pump to mimic the body's pulse. Brand new stent grafts and distilled water should be used to reduce pore clogging effects in stent grafts which was seen in our testing.

Chapter 8: Prototype Delivery to Sponsor

We plan to deliver the completed test system assembly to Jefferey Wootton at Medtronic's Santa Rosa office by August 1, 2013. This will include the bench top components (pump, housing and reservoirs, and piping) and the electronic components (Arduino microcontroller and breadboard, LCD, and Arduino power supply).

pendix A: Decision Matrix for Design Selection

Table 4: Build Idea Selection

Build Idea	Issue	Pro	Con	Weight	Total	
1: PVC	Cost to build	1	0	0.4	0.4	
	Adaptable to bifurcated stents	0	0			
	Adaptable to diff erent size stents	0	0			
	Ease of building-length tolerances	0	1	0.2	-0.2	
	Ease of replacing stent sample	0	0		0	
	Size of overall assembly	0	0		0	
	Durability	1	0	0.2	0.2	
	Leakage potenti al	0	0			
	Sytem modeling:					
	Does not induce turbulent fl ow aft er stent (modeling issues)	1	0	0.2	0.2	
					0.6	**WINS**
2: Accordion Tube	Cost to build	1	0	0.4	0.4	
	Adaptable to bifurcated stents	0	0		0	
	Adaptable to diff erent size stents	0	0		0	
	Ease of building-length tolerances	1	0	0.2	0.2	
	Ease of replacing stent sample	0	0			
	Size of overall assembly	0	0			
	Durability	0	1	0.2	-0.2	
	Leakage potenti al	0	0			
	Sytem modeling:					
	Does not induce turbulent fl ow aft er stent (modeling issues)	0	1	0.2	-0.2	
					0.2	**LOSES**

Table 5: Blush Assessment Idea Selection

Blush Assesment Idea	Issue	Pro	Con	Weight	Total	
1: Water Weight	Quanti tati ve?	1	0	0.25	0.25	
	Cost to build	1	0	0.067	0.067	
	Cost to operate	1	0	0.067	0.067	
	Ease of building	1	0	0.067	0.067	
	Ease of operati on	1	0	0.067	0.067	
	Precedent (has it worked before?)	1	0	0.3	0.3	
	Durability	1	0	0.05	0.05	
	Parts availability	1	0	0.067	0.067	
	Potenti al damage to stent	1	0	0.067	0.067	
					1.002	WINS
2: pH	Quanti tati ve?	1	0	0.25	0.25	
	Cost to build	1	0	0.067	0.067	
	Cost to operate	0	0	0.067	0	
	Ease of building	0	0	0.067	0	
	Ease of operati on	1	0	0.067	0.067	
	Precedent (has it worked before?)	0	1	0.3	-0.3	
	Durability	0	0	0.05	0	
	Parts availability	0	0	0.067	0	
	Potenti al damage to stent	0	1	0.067	-0.067	
					0.017	LOSES
3: Dye/Image Processing	Quanti tati ve?	1	0	0.25	0.25	
	Cost to build	0	1	0.067	-0.067	
	Cost to operate	0	0	0.067	0	
	Ease of building	0	1	0.067	-0.067	
	Ease of operati on	0	1	0.067	-0.067	
	Precedent (has it worked before?)	0	1	0.3	-0.3	
	Durability	0	1	0.05	-0.05	
	Parts availability	0	0	0.067	0	
	Potenti al damage to stent	0	0	0.067	0	
					-0.301	LOSES

Table 6: QFD Table (House of Quality)

Stent Graft Blush -- House of Quality				Engineering Requirements (HOWS)													
	Medtronic R&D (Keystone/Applied Research Group)	Dr. Mase	Pressure (bar)	Viscosity (Mu)	Heparin (#)	Flow Rates (Liters/Min)	Flow Type (Turbulent/Laminar)	Flow Type, Pulsatile (bpm)	Temperature (C)	Dye Levels (#)	Dye Injection (cm)	Blush Number (#)	Fabric Type (#)	Fabric Shape (#)	Fabric Size (#)	Randomization of Variables (#)
Customer Requirements (Step #2)																	
Blush Comparison	*		9	9	9	9	9	9	9	9	9	9	9	9	9	9
Mimics Pressure	*		9			3	3	3	1			9				9
Mimics Viscosity	*		3	9		3	9	3	9			9				9
Variable Heparin	4		3	3	9	3						9				9
Mimics Flow Rates	*		3	3		9	3	3				9				9
Mimics Flow Type (Turbulent/Laminar)	3		3	3		3	9	9				9				9
Mimics Flow Type (Pulsitile)	1		3	3		3	3	9				9				9
Mimics Temperature	*	N/A				1	1	3	9			9				9
Variable Dye Levels	*						1	1		9	3	9				9
Variable Dye Injection	*						1	1		9	9	9				9
Blush Number	2		9	9	9	9	9	9	9	9	9	9	9	9	9	9
Variable Fabric Types	*											9	9	3	3	9
Variable Fabric Shapes	*											9	3	9	3	9
Variable Fabric Size	*											9	3	3	9	9
Randomization of Variables	*		9	9	9	9	9	9	9	9	9	9	9	9	9	9

*Boxes marked N/A: There is currently no method used to evaluate blush in the Stent Graft Industry.

Appendix B: Final Drawings

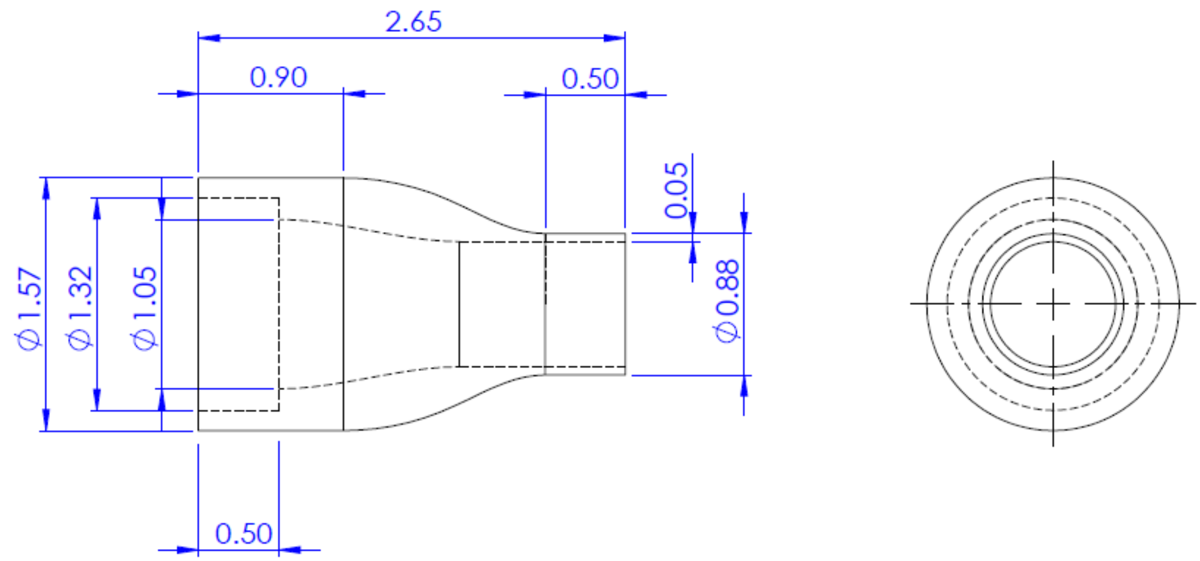


Figure 16: Custom Coupling for 28 mm diameter Valiant stent graft, 10% undersized

Appendix C: Vendor and Pricing Information

Digikey Corporation

www.digikey.com
701 Brooks Avenue South • Thief River Falls, MN 56701
(800) 344-4539

McMaster-Carr

www.mcmaster.com
9630 Norwalk Blvd.
Santa Fe Springs, CA 90670-2932
(562) 692-5911

Miner's Ace Hardware

http://www.minershardware.com/
2034 Santa Barbara Ave,
San Luis Obispo, Ca, 93401
(805) 543-2191

SparkFun Electronics

www.sparkfun.com
6175 Longbow Drive • Boulder, CO 80301
(303) 284-0979

Appendix D: Vendor Supplied Component Specifications and Data Sheets

Integrated Silicon Pressure Sensor On-Chip Signal Conditioned, Temperature Compensated and Calibrated

MPXV7007 Series

-7 to 7 kPa (-1 to 1 psi)
0.5 to 4.5 V Output

The MPXV7007 series piezoresistive transducers are state-of-the-art monolithic silicon pressure sensors designed for a wide range of applications, but particularly those employing a microcontroller or microprocessor with A/D inputs. This transducer combines advanced micromachining techniques, thin-film metallization, and bipolar processing to provide an accurate, high level analog output signal that is proportional to the applied pressure.

Features

- 5.0% Maximum Error Over 0° to 85°C
- Ideally Suited for Microprocessor or Microcontroller-Based Systems
- Temperature Compensated Over –40° to +125°C
- Thermoplastic (PPS) Surface Mount Package
- Patented Silicon Shear Stress Strain Gauge
- Available in Differential and Gauge Configurations

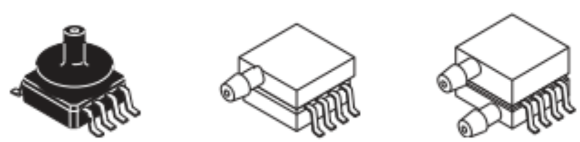
Application Examples

- Hospital Beds
- HVAC
- Respiratory Systems
- Process Control

ORDERING INFORMATION

Device Name	Package Options	Case No.	# of Ports			Pressure Type			Device Marking
			None	Single	Dual	Gauge	Differential	Absolute	
Small Outline Package									
MPXV7007DP	Trays	1351			•		•		MPXV7007DP
MPXV7007DPT1	Tape & Reel	1351			•		•		MPXV7007DP
MPXV7007GC6U	Rails	482A		•		•			MPXV7007G
MPXV7007GC6T1	Tape & Reel	482A		•		•			MPXV7007G
MPXV7007GP	Trays	1369		•		•			MPXV7007GP

SMALL OUTLINE PACKAGE



MPXV7007GC6U/C6T1 CASE 482A-01 | **MPXV7007GP CASE 1369-01** | **MPXV7007DP/DPT1 CASE 1351-01**

Table 1. Pin Numbers(1)

1	2	3	4	5	6	7	8
N/C	V_s	Gnd	V_{out}	N/C	N/C	N/C	N/C

1.Pins 1, 5, 6, 7 and 8 are internal device connections. Do not connect to external circuitry or ground. Pin 1 is noted by the notch in the lead.

Appendix E: Detailed Supporting Analysis

Reynolds Number calculation for water flow through a 1 inch tube

$$Re = \frac{\rho V D}{\mu}$$

$$V = \frac{Q}{A}$$

$$A = \frac{\pi D^2}{4} = \frac{\pi (0.0254m)^2}{4} = .000507\ m^2$$

$$Volumetric\ Flow\ Rate = 6.4\frac{L}{min} = 1.067E - 4\ \frac{m^3}{s}$$

$$V = \frac{Q}{A} = \frac{1.067E - 4\frac{m^3}{s}}{.000507\ m^2} = .2104\frac{m}{s}$$

$$Re = \frac{\left(\frac{1000kg}{m^3}\right)\left(.2104\frac{m}{s}\right)(.0254\ m)}{1.002 * 10^{-3}\left(\frac{Ns}{m^2}\right)} = 5333$$

→ Transitional/Turbulent behavior

Pressure Sensor Sizing Calculations:

Target pressure = 40mmHg (0.76 psi)

$$0.76 \frac{lb_f}{in^2} \left(\frac{0.375\,in}{2}\right)^2 \pi = 0.083\, lb_f$$

Force felt by sensor = 0.083 lbf

Pump Work:

$$\frac{P_1}{\rho} + \frac{1}{2}\alpha_1 \bar{V}_1^2 + g z_1 + \frac{\dot{W}_s}{\dot{m}} = \frac{P_2}{\rho} + \frac{1}{2}\alpha_2 \bar{V}_2^2 + g z_2 + h_{\ell_T}$$

$$\frac{\dot{W}_s}{\dot{m}} = \frac{\Delta P}{\rho} + g(z_2 - z_1) + h_{\ell_T}$$

Height change

$$g(z_2 - z_1) = g(2Ft)$$

Pressure change

P1= 1 atm

P2= 1 atm + 0.76 psi

$$\frac{1}{\rho}(P_2 - P_1) = \frac{1}{\rho}(0.773\,psi)$$

Head loss

$$h_{L_T} = h_{L_{Major}} + h_{L_{minor}}$$

Parameters	Values
Hydraulic diameter (minimum)	D = 0.375 in
Reynolds number	Re = 18.5 k
Friction factor	f = 0.05
Pressure change	ΔP = 40mmHg
Average flow rate	Q = 6.5 LPM
Estimated total pipe length	l = 6 ft
Estimated height change	ΔZ = 2 ft

Major head loss

$$h_{L_{major}} = f \frac{l}{D} \frac{V^2}{2g}$$

$$V = \frac{Q}{A} \quad \frac{(\text{FLOW RATE})}{(\text{PIPE AREA})}$$

$$V = \frac{4Q}{\pi D^2}$$

$$h_{L_{major}} = f \frac{l}{D^5} \frac{8Q^2}{\pi^2 g}$$

$$\frac{\dot{W}_s}{\dot{m}} = 575 \frac{ft^2}{s^2}$$

$$\dot{W}_s = 575 \frac{ft^2}{s^2} \left(3.732e{-3} \frac{ft^3}{s} \cdot 1.931 \frac{slugs}{ft^3}\right)$$

$$= 4.144 \frac{slugs\ ft^2}{s^3}$$

$$\dot{W}_s = 0.00753\ hp$$

Minor head loss

$$h_{L_{minor}} = K_L \frac{V^2}{2g}$$

$$= \frac{\left(\frac{4Q}{\pi D^2}\right)^2}{2g} \left(K_{L_{\text{NEEDLE VALVE}}} + K_{L_{\text{CUSTOM ADAPTER}}} + K_{L_{\text{3/8" TO 1" ADAPTER}}} + K_{L_{\text{BALL VALVE}}} + K_{L_{\text{STENT GRAFT}}}\right)$$

Total pump work:

$$\frac{\dot{W}_s}{\dot{m}} = 575 \frac{ft^2}{s^2} \qquad \dot{W}_s = 0.00753\ hp$$

Calculated Results (ft^2/s^2)		Percent effect
Pump work	$W_s/m = 575$	
Height change	$\Delta Z = 64.4$	10%
Pressure change	$\Delta P = 57.64$	9%
Major head loss	$h_{major} = 3.514$	5%
Minor head loss	$h_{minor} = 450$	76%

Component	Loss Coefficient (K_L)
Needle Valve (2/3 Closed)	$K_L = 210$
Custom Adapter (see graph)	$K_L = 0.375$
3/8" to 1" Adapter (see graph)	$K_L = 0.4$
Stent Graft (Based on threaded in line flow connector)	$K_L = 1.5$
Ball Valve (1/3 Closed)	$K_L = 5.5$

Head loss across single custom adapter:

$$h_L = h_{L_{major}} + h_{L_{minor}}$$

$$= \frac{8}{g\pi^2} f \frac{l}{D^5} Q^2 + \frac{(8Q^2)}{g\pi^2 D^4} (\Sigma K_L)$$

$$= \frac{8Q^2}{g\pi^2} \left(f \frac{l}{D^5} + \frac{\Sigma K_L}{D^4} \right)$$

$f \approx 0.05$

$Q = 0.028$ gallons/s

$l = 3in$

$D = 1in$

$K_L = 0.375$

$h_L = 0.0038 \frac{ft^2}{s^2}$ (Head loss across adapter)

$\Delta p = 50.96 \times 10^{-6}$ psi (Pressure discontinuity across adapter)

Appendix F: Gantt Chart

A complete timetable of milestones follows. It includes milestones requiring Medtronic's participation (for example, the Conceptual Design Review and the Critical Design Review), as well as goals for our team (for example, building and testing deadlines).

Task Name	Duration	Start	Finish
1st Quarter	**52 days**	**Fri 9/21/12**	**Mon 12/3/12**
Team Introduction Email to Sponsor, Copy to Lab Advisor	5 days	Fri 9/21/12	Thu 9/27/12
"Visit" Sponsor This Week	5 days	Fri 9/28/12	Thu 10/4/12
Team Contract Due in Lab	5 days	Fri 10/12/12	Thu 10/18/12
Project Proposal (Requirements) Document Due PDF to Sponsor	5 days	Fri 10/12/12	Thu 10/18/12
Conceptual Model Due (Consult Lab Advisor)	5 days	Tue 10/30/12	Mon 11/5/12
Report and Presentations	5 days	Tue 10/30/12	Mon 11/5/12
Concept - Project Safety Plan	5 days	Tue 11/13/12	Mon 11/19/12
Yellow Tags	42 days	Fri 9/21/12	Mon 11/19/12
Conceptual Design Report Due, PDF to Sponsor	42 days	Wed 10/3/12	Thu 11/29/12
Conceptual Design Review "with Sponsor"	5 days	Tue 11/27/12	Mon 12/3/12
2nd Quarter	**90 days**	**Thu 12/20/12**	**Wed 4/24/13**
1st Iteration System Built	**31 days**	**Thu 12/20/12**	**Thu 1/31/13**
Steady State Flow	31 days	Thu 12/20/12	Thu 1/31/13
Fluid=Water	31 days	Thu 12/20/12	Thu 1/31/13
Manual Injection	31 days	Thu 12/20/12	Thu 1/31/13
Pressure Differential Only	31 days	Thu 12/20/12	Thu 1/31/13
No Contrast Dye	31 days	Thu 12/20/12	Thu 1/31/13
Power Injection Port	31 days	Thu 12/20/12	Thu 1/31/13
Single Size, Largest Stent graft	31 days	Thu	Thu 1/31/13

		12/20/12	
Quantitative method=Weigh Water	31 days	Thu 12/20/12	Thu 1/31/13
Test and Evaluate 1st Iteration System	21 days	Thu 1/31/13	Thu 2/28/13
2nd Iteration System Design and Build	**60 days**	**Thu 1/31/13**	**Wed 4/24/13**
Testing Methods	**60 days**	**Thu 1/31/13**	**Wed 4/24/13**
Size Accommodation	60 days	Thu 1/31/13	Wed 4/24/13
Power Injection Simulation	60 days	Thu 1/31/13	Wed 4/24/13
Simulate Blood Viscosity			
Analysis, Drawing, BOM Review	5 days	Wed 1/2/13	Tue 1/8/13
Test Plan Development	5 days	Wed 1/9/13	Tue 1/15/13
Long Lead Items on Order	21 days	Tue 12/25/12	Tue 1/22/13
Student Presentations (Practice CDR)	5 days	Wed 1/23/13	Tue 1/29/13
Individual Ethics Memo Topic Due Design Report Due, PDF to sponsor	5 days	Wed 1/30/13	Tue 2/5/13
Critical Design Review with Sponsor	5 days	Wed 1/30/13	Tue 2/5/13
Individual Ethics Memo Due	5 days	Wed 2/6/13	Tue 2/12/13
Team Ethics Presentations	5 days	Wed 2/13/13	Tue 2/19/13
Manufacturing and Test Review	5 days	Wed 2/27/13	Tue 3/5/13
End of Quarter Report	21 days	Wed 3/6/13	Wed 4/3/13
3rd Quarter	**264 days**	**Tue 6/5/12**	**Fri 6/7/13**
Test and Evaluate 2nd Iteration System	21 days	Wed 4/24/13	Wed 5/22/13
Refine Overall System	28 days	Wed 4/24/13	Fri 5/31/13
Project Update Memo to Sponsor	5 days	Mon 4/8/13	Fri 4/12/13
Project Hardware/Assembly Demo	21 days	Mon 4/1/13	Mon 4/29/13
Senior Project Design Expo XII: 4:00-7:00 PM, Thursday May 30 Location: Bonderson Bldg.	5 days	Tue 5/21/13	Mon 5/27/13
Friday June 7th: Final Reports Due (Hardcopy and PDF for Review to Sponsor/Advisor) + Library Form to Advisor	5 days	Mon 6/3/13	Fri 6/7/13
Upload to Report to Library after Instructor/Sponsor Approval	1 day	Tue 6/5/12	Tue 6/5/12

Appendix G: Factors Affecting Stent graft Graft Blush—Comprehensive List

Environmental

Blood

- Viscosity
- Heparin level/ACT (activated clotting time)
- Temperature
- Flow rate
- Flow type (laminar/turbulent)
- Pulsatile/steady flow
- Non-Newtonian behavior (shear thinning)

Contrast Dye Characteristics

- Viscosity
- Amount
- Concentration in blood
- Diffusion in blood
- Particle size

Aneurysm Sac

- Absolute pressure
- Differential pressure (compared with stent graft lumen)
- Endotension
- Size
- Temperature
- Pulsatile pressure waves
- Viscosity (liquid blood)
- % thrombosed
- Thrombus coverage on stent graft fabric (Incomplete coverage? Erosion? Too dispersed?)
- Tortuosity of aorta (and effect on stent graft shape)
- Wall characteristics (e.g. hardening, calcification, plaque)

Stent Graft

Shape

- Overall (single tube thoracic/bifurcated abdominal)
- Limb length
- Stretch areas (e.g. hips, crotch)

Fabric

- Material (polyester/ePTFE)
- Material thickness
- Thread type (mono/multifilament)
- Weave pattern
- Thread density
- Seams/seamless
- Weave orientation (warp—90° vs. 45°)
- Porosity

Procedural

Imaging Techniques

- Image resolution due to dye concentration

Contrast Dye Injection Method

- Angiogram ["blood pool" method] vs. aortogram
- Manual vs. power injector
- Injection rate
- Injection location (distance from stent graft entry)
  Injection pressure

Doctors

- Experience

Non-Technical

Complaints

- Absolute number
- Relative numbers
    - Per country
    - Per stent graft model
    - Per stent graft shape/size

Patient Characteristics

- Age
- Health
- Smoking
- Gender
- Atherosclerotic risk factors
- Platelet aggregation
- ACT (activated clotting time)

Cultural

- Attitude towards surgery in old age—quality of life vs. quantity (affects patient demographic)
- Perceived severity of blush
- Newness of stent graft procedure (when was it adopted?)
- Perception of stent graft procedure (vs. open surgery)
- Number of stent graft procedures vs. open surgeries

Appendix H: Future Design Parameters

These are possible parameters we will focus on in our second iteration.

- Control fluid temperature to 37 °C ±5%
- Measures or compares blush performance of tubular and bifurcated stent graft samples
- Viscosity of contrast and blood simulants similar to real contrast and blood values of a heparinized patient
- Flow rates of simulants from 0 up to 2L/min
- Injection flow rates of contrast dye from 0 to 2mL/sec
- Contrast dye concentration similar to values used by medical professionals
- Continuously run for 30 days of equivalent testing (2.6 million cycles)
- Pulsatile rate of 60 Hz

Appendix I: Arduino Code for Flowmeter, Pressure Transducers, and LCD

```
#include <LiquidCrystal.h>
#include <SoftwareSerial.h>
#include <NewSoftSerial.h>

#define rxpin 11 //RX to Pin 11
#define txpin 12 //TX to pin 12

SoftwareSerial myserial(rxpin, txpin); //Initialize serial ports
LiquidCrystal lcd(2, 3, 4, 5, 6, 7, 8); //Initialize pins for LCD (rs,en,4,5,6,7)
String string = "o\r"; //Turn on flow meter string
String string2 = "x\r";  //Reset flow meter string
String inputstring = "";  //Holds incoming data from PC
String sensorstring = ""; //Holds data from Flow Meter
String sensorsstring2 = ""; //New string without LPH

boolean input_stringcomplete = false;  //Have we recieved data from PC
boolean sensor_stringcomplete = false; //Have we recieved data from Flow Meter
int n = 0;
int resettext = 0;
int sensorValue[5];
int sensorValue2[5];
int reading = 0;
int reset = 0;

void setup()
{
 lcd.begin(20, 4); //Set up for 20x4 LCD
 lcd.clear();
 pinMode(rxpin, INPUT);
 pinMode(txpin, OUTPUT);
 Serial.begin(38400); //Set up Flow Hardware
 myserial.begin(38400);  //Set baud rate for serial port of Flow Meter
 inputstring.reserve(5);  //Set aside bytes to revieve data from PC
 sensorstring.reserve(30);  //Set aside bytes for Flow Meter recieve


 lcd.clear();
 lcd.print("Volume (L), LPM");
 lcd.setCursor(0,1);
 lcd.print(" ");
 lcd.setCursor(0,2);
 lcd.print("Pressure (mmHg)");
 lcd.setCursor(0,3);
}

void serialEvent() {  //If hardware port receievs a char
 char inchar = (char)Serial.read();  //Get the char just recieved
 inputstring += inchar;  //Add to input string
 if(inchar == '\r') {
   input_stringcomplete = true;
 } //if incoming character is a <CR> set the flag
}
```

```
void loop()
{
  //FLOW METER
  if(reading <= 2){  //Give 3 tries to start sensor
    myserial.print(string); //Send start command "o"
    delay(100);
    myserial.print(string2); //Send reset command "x"
    reading = reading + 1; //Add to counter
  }

  //FROM PC
  if (input_stringcomplete){ //if a string from the PC has been received in its entirety

    myserial.print(inputstring); //send that string to the Flow Meter
    inputstring = ""; //clear the string
    input_stringcomplete = false; //reset the flag used to tell if we have received a completed string from the PC
  }
  while (myserial.available()) {  //while a char is holding in the serial buffer
    char inchar = (char)myserial.read();  //get the new char
    sensorstring += inchar;  //add it to the sensorString

    if (inchar == '\r') {
      sensor_stringcomplete = true;
    }  //if the incoming character is a <CR>, set the flag
  }

  //PRESSURE TRANDSDUCER AND PRINTING
  sensorValue[n] = analogRead(A0);  // Read the input on analog pin 0 into an array:
  sensorValue2[n] = analogRead(A1);   // Read the input on analog pin 1 into an array:

  // If 5 analog values have been read, then enter loop
  if(n == 4){

    //Average the 5 sensor value readings
    int averageSensorValue = (sensorValue[0] + sensorValue[1] + sensorValue[2] + sensorValue[3] + sensorValue[4])/5;
    // Convert the average analog reading (which goes from 0 - 1023) to a voltage (0 - 5V):
    float voltage = averageSensorValue * (5.0 / 1023.0);
    //  Convert voltage to pressure
    float pressure = voltage*24.213 - 60.797;  //Calibration curve equation

    //Average the 5 sensor value readings
    int averageSensorValue2 = (sensorValue2[0] + sensorValue2[1] + sensorValue2[2] + sensorValue2[3] + sensorValue2[4])/5;
    // Convert the average analog reading (which goes from 0 - 1023) to a voltage (0 - 5V):
    float voltage2 = averageSensorValue2 * (5.0 / 1023.0);
    //  Convert voltage to pressure
    float pressure2 = voltage2*24.096 - 60.241;  //Calibration curve equation


    if (sensor_stringcomplete){ //if a string from the Atlas Scientific product has been received in its entirety
      sensorstring.trim();  //Trim extra character being displayed

      if(resettext == 5){
        lcd.clear();  //Clear LCD and reset cursor to row 1
        lcd.print("Volume (L), LPM"); //Print
        lcd.setCursor(0,1); //Set cursor line 2
        int firstComma = sensorstring.indexOf(',');  //Find first comma
```

```
      int secondComma = sensorstring.indexOf(',', firstComma + 1);  //Find second comma
      lcd.print(sensorstring); //Print Flow Meter output
      lcd.setCursor(secondComma, 1);
      lcd.print("       ");
      lcd.setCursor(0,2); //Set cursor to row 3
      lcd.print("Pressure (mmHg)"); //Print
      lcd.setCursor(0,3); //Set cursor to row 4
      lcd.print(pressure); //Print pressure
      lcd.print(", ");
      lcd.print(pressure2);
      sensorstring = "";  //Clear the flow meter string
      sensor_stringcomplete = false;  //Reset the flag used to tell if we have received a completed string from Flow Meter

      resettext = 0; //reset resettext counter
     }

     else{
      lcd.setCursor(0,1);  //Set Cursor to row 2
      int firstComma = sensorstring.indexOf(',');  //Seek out first comma position
      int secondComma = sensorstring.indexOf(',', firstComma + 1);  //Seek out second comma position
      lcd.print(sensorstring); //Print Flow Meter output
      lcd.setCursor(secondComma, 1);   //Set cursor before second comma
      lcd.print("       ");  //Print blanks to remove LPH
      lcd.setCursor(0,3); //Set cursor to row 4
      lcd.print(pressure); //Print pressure
      lcd.print(", ");
      lcd.print(pressure2);  //Print pressure2
      sensorstring = "";  //Clear the flow meter string
      sensor_stringcomplete = false;  //Reset the flag used to tell if we have received a completed string from Flow Meter

      resettext = resettext + 1;  //Add to resettext counter
     }
    }
    n = -1; //reset n
   }
  n = n+1; //Add to n count

  delay(40);  //Delay 40ms
}
```

Appendix J: Fully Itemized Cost Breakdown

Manufacturer/Style	Model	Unit Cost	# Units	Total Cost
PVC Pipe	1"	$ 0.45	3	$ 1.35
PVC Pipe	.75"	$ 0.35	2	$ 0.70
PVC Clamp	1 1/16 - 2	$ 1.79	2	$ 3.58
PVC Couple	3/4"	$ 0.25	1	$ 0.25
PVC Couple	1"	$ 0.49	1	$ 0.49
Krazy Glue	Glue	$ 2.49	1	$ 2.49
PVC Couple	3/4" - .5"	$ 0.79	2	$ 1.58
Rubber Sheet	6"x6"	$ 1.59	1	$ 1.59
PVC Couple	1" - 3/4"	$ 0.99	1	$ 0.99
Tube Vinyl	5/16"	$ 0.49	0.5	$ 0.25
Tube Vinyl	.5"	$ 0.59	0.5	$ 0.30
Plastic Quick-Turn (Luer Lock) Coupling (10 Pack)	Nylon, Female X Barb, for 3/32"	$ 3.51	1	$ 3.51
Plastic Quick-Turn (Luer Lock) Coupling (10 Pack)	Nylon, Female X Barb, for 1/8"	$ 3.51	1	$ 3.51
Plastic Quick-Turn (Luer Lock) Coupling (10 Pack)	Nylon, Male X Barb, for 3/32"	$ 3.96	1	$ 3.96
Plastic Quick-Turn (Luer Lock) Coupling (10 Pack)	Nylon, Male X Barb, for 1/8"	$ 3.96	1	$ 3.96
Chemical-Resistant PVC (Type I) Rod	1-1/2" Diameter, 3' Length	$ 5.08	3	$ 15.24
Tub	16QT	$ 2.89	2	$ 5.78
Tub	41QT	$ 8.99	1	$ 8.99
Flexiforce Pressure Sensor	1 lb	$ 19.95	1	$ 19.95
Op-Amp	LM358	$ 0.95	1	$ 0.95
Resistor Kit	1/4W	$ 7.95	1	$ 7.95
Standard-Wall White PVC Pipe Fitting	1/2 Wye	$ 1.51	1	$ 1.51
Standard-Wall White PVC Pipe Fitting	1/2 Coupling	$ 0.19	2	$ 0.38
Standard-Wall White PVC Pipe Fitting	1 Coupling	$ 0.47	1	$ 0.47
Submersible Pump for Water	1/40 HP	$ 89.23	0	
Flexible Standard-Wall Clear PVC Unthreaded Pipe	1/2 x 5'	$ 11.08	1	$ 11.08
Masterkleer PVC Tubing (ft)	1/4" ID, 7/16" OD	$ 0.39	5	$ 1.95
Durable Nylon Tight-Seal Barbed Tube Fitting	1/4" Tube ID X 1/4 Male Pipe	$ 4.55	1	$ 4.55
Thick-Wall Dark Gray PVC Thread-One-End Pipe Nipple	3/8 Pipe Size X 2" L	$ 1.76	1	$ 1.76
Needle Valve, Brass	1/2" Female	$ 53.12	1	$ 53.12
Thick-Wall Dark Gray PVC Thread-One-End Pipe Nipple	1/2 Pipe x 3" L	$ 1.56	2	$ 3.12
UV-Resistant Standard-Wall PVC Pipe Fitting	1 Pipe Size, 90 Degree Elbow	$ 4.27	1	$ 4.27

Sanitary White PVDF Barbed Tube Fitting	1/4" Wye	$ 3.48	1	$ 3.48
Durable Nylon Tight-Seal Barbed Tube Fitting	3/8" Tube ID X 1/4 Male	$ 5.53	1	$ 5.53
Durable Nylon Extra-Grip Barbed Tube Fitting	3/8" Tube ID X 3/8 Female Pipe	$ 10.57	1	$ 10.57
Masterkleer PVC Tubing (ft)	3/8" ID, 9/16" OD	$ 0.54	3	$ 1.62
Durable Nylon Tight-Seal Barbed Tube Fitting	1/4" Tube ID X 3/8 Male	$ 5.53	1	$ 5.53
Durable Nylon Extra-Grip Barbed Tube Fitting	1/4" Tube ID X 1/4 Female	$ 9.25	1	$ 9.25
Thick-Wall Dark Gray PVC Threaded Pipe Nipple	3/8 Pipe Size X3" Length	$ 2.33	1	$ 2.33
Standard-Wall White PVC Pipe Fitting	1/2 NPT Male X3/8 NPT Female	$ 1.41	1	$ 1.41
ACE Pump	1/10 hp	$ 60.00	1	$ 60.00
Gauges and Adapters		$ 14.62	1	$ 14.62
Flexible PVC	1/2" x 5'	$ 11.08	1	$ 11.08
Low Pressure Gauge		$ 56.72	1	$ 56.72
Luer Lock	Male for 1/4"	$ 4.43	1	$ 4.43
Luer Lock	Female for 1/4"	$ 5.67	1	$ 5.67
Luer Lock	Nylon Cap	$ 2.41	1	$ 2.41
Acrylic	12x36"	$ 15.39	3	$ 46.17
Acrylic	12x12"	$ 5.59	2	$ 11.18
Flow Meter		$ 132.95	1	$ 132.95
Pressure Sensor		$ 13.94	3	$ 41.82
Arduino Wall Power Supply		$ 6.45	1	$ 6.45
ACE Purchase (Drill bit and other)		$ 46.15	1	$ 46.15
ACE Purchase (Caulk, Hose)		$ 16.13	1	$ 16.13
Lab Technician per Hour		$ 16.00	10	$ 160.00
ACE Purchase (Lock Nuts, Nipple)		$ 21.14	1	$ 21.14
Velcro, blue, fasteners		$ 28.49	1	$ 28.49
ACE Purchase (PVC Piping)		$ 2.07	1	$ 2.07
Aaron Brothers Purchase (Poster)		$ 14.00	1	$ 14.00
Arduino Starter Kit		$ 32.00	1	$ 32.00

Appendix K: References

Figures:

Figure 1: "Talent Abdominal Stent Graft." About the Talent Abdominal Stent Graft. N.p., n.d. Web. 23 Oct. 2012. <http://www.medtronic.com/patients/abdominal-aortic-aneurysm/device/abdominal-stents/talent/index.htm>.

Figure 2: "Mayo Clinic Health System in Eau Claire." Aneurysm Repair. N.p., n.d. Web. 23 Oct. 2012. <http://mayoclinichealthsystem.org/locations/eau-claire/medical-services/cardiac-surgery/aneurysm-repair>.

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