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By

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Abstract

Innovative means for achieving hemostasis in the gastrointestinal tract centers on delivering a powder, hemostatic agent, to the wound site by means of a mechanical device and an endoscope. The catheter, connected to the mechanical device, which will be passed down the endoscope, which the powder will travel through, kinks and clogs. Three design components, the Luer Lock connection, the catheter, and the tip modification, were optimized to minimize kinking and clogging. Computational Flow Analysis was performed on the Luer Lock connection, mechanical testing was performed on the catheter material, and theoretical calculations and functionality testing were completed to determine the optimal fitting, catheter material, and tip modification. The results show that the custom Luer Lock connection performs better than off the shelf components and that Material Y is the optimal choice for the final catheter, and the tip modification prevents clogging when passing the catheter through a wet endoscope.

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Chapter 1 Introduction

This MQP will focus on creating a catheter to increase product efficiency while helping save patient lives by stopping life threatening gastrointestinal bleeding. Gastrointestinal (GI) bleeding patients will be treated using clinical endoscopy, a minimally invasive procedure using small tools requiring a catheter to deliver them to the final location. Surgery is often a last resort and physicians commonly practice endoscopy even in difficult cases (Minami et al., 2006). In 2009 there were roughly 18.6 million endoscopies performed in the United States (Peery et al., 2012). Most of these 18.6 million cases encounter some form of bleeding. Current treatment can achieve hemostasis, or bleeding cessation, without additional difficulty. Endoscopic cases of acute bleeding account for 300,000 hospitalizations per year in the United States (El-Tawil 2012). These cases are always treated with devices that are passed down the channel of an endoscope by means of a catheter. As an integral but often overlooked medical device, the catheter has widespread use in many medial disciplines. Modern catheters can be shaped, extruded, or molded to fit the changing procedures and are often used as a means to accomplish a difficult surgical task. With tunable properties catheters offer a platform for surgeons and researchers to innovate and further develop new techniques for surgery which often improves patient care, quality of surgeries, as well as decreased recovery time from formerly complex and invasive procedures (Kim et al., 2014).

Current treatment for gastrointestinal bleeding includes hemostatic clips, band ligation, cyanoacrylate glue, epinephrine injection, or balloon tapenade (Liu and Saltzman 2009). Ideally, these methods would achieve hemostasis in every case and situation where extensive bleeding occurs. According to internal Boston Scientific Voice of Customer (VoC) data, these methods are known to fail when used in tortuous anatomy, diffuse bleeding, diseased tissue, hard ulcer

beds, friable tissue, or cancerous lesions to name several. In order to achieve successful hemostasis in these scenarios, especially in emergent cases, a hemostatic powder has been developed. This powder can spray over a large area, absorb water from the blood, turn to a gel, aggregate red blood cells and platelets, and stop the bleed through mechanical pressure. The natural clotting cascade is allowed to occur in the presence of the mechanical barrier created by the gelled powder.

A significant use for the blanket powder application to achieve hemostasis is in emergency care. Endoscopy is a highly skilled form of surgery that requires many years of practice and training; however, in situations where a trained endoscopist is not on call or is unavailable – achieving hemostatic control with a pull of a trigger would be extraordinarily useful. A nurse or technician could administer the hemostatic agent which may save lives whether it is late at night, a high-pressure situation, or no trained physician is available.

Several difficulties and gaps in current treatment for heavy GI bleeding have been noted by physicians and medical device manufacturers. Commonly, the catheter in this procedure comes in contact with fluids such as blood or the mucosa, any moist mucous membrane, in the GI tract. Contact with the wet environment causes the powder to swell occluding the powder delivery channel of the catheter leading to surgical failures resulting in failed bleeding control, loss of time and money, and dissatisfaction of surgeons and patients. When the powder delivery channel clogs, the immediate fix requires removal of the catheter from the endoscope and subsequent disposal. An alternative, less sanitary approach, requires that the technician or nurse assisting the surgeon cut off the clogged end of the catheter and re-administer the catheter through the endoscope to resume the procedure. An additional difficulty in administering powder via catheter is clogging, powder contacts flat surfaces or moisture causing the particles to compact or stick to

each other and aggregate into a clog further occluding the powder delivery channel. Both challenges threaten the efficacy of the procedure costing both patient and hospital time and money.

A competitive device, powder, and catheter currently exists, but experiences many cases of clogging – so much so they include two catheters in the package of their device and instruct doctors to cut the end of the catheter when it clogs according to several sources including (Huang et al., 2014; Ibrahim et al., 2013; Sulz et al., 2014). This current solution uses extremely high pressure air in the delivery system, attempting to eliminate any moisture or compaction caused clogging. The 30psi of the competitive device causes some concern – it may be possible to overcome arterial bleeding pressure shooting particles into the blood stream which, in a worst-case scenario, may cause embolism and lead to stroke, death, or other complications. The high pressure also causes concern in patients who are not properly ventilated – as seen in preclinical trial observations high pressures have a tendency to expand the gastrointestinal tract raising worries of perforating the stomach or intestines. The competitive device reduces visualization through the endoscope to a minimum. The catheter design, powder particle size, and delivery device, work in tandem to release a cloud of powder, coating the surrounding tissue and the endoscope alike. This dangerous side effect causes doctors to remove the endoscope from the bleeding or injured site, clean off the camera, and reinsert. These additional steps frustrate doctors and increase procedure time.

The focus of this project will be designing a catheter for use through an endoscope inside of the gastrointestinal tract, used specifically in a procedure to apply the hemostatic agent while minimizing major failure modalities like kinking or clogging. This will be accomplished through the design process. A breadth of research lays the foundation for the background and customer

requirements which will be compiled into a list of functional needs. Several designs will be created using the functional needs to drive the creation. CAD models of the alternative design sketches were created and models will be selected for prototyping. After prototyping, testing will be a cornerstone of this project. Effective and reliable evaluation of the device will be needed to prove its usefulness in the ultimate endoscopic application. Lastly, the design, development, and verification process will be documented in this report for future reference and use by the client.

Chapter 2 Literature Review and Background

Section 2.1 Clinical Statistics and Needs Analysis

Gastrointestinal bleeding is a severe medical complication that often requires intensive emergency care and monitoring from doctors and nurses as well as extended stays in the hospital and complex surgical techniques. Gastrointestinal bleeding can be caused by many different diseases ranging in severity and mortality. GI bleeds may affect over 300,000 people in the United States per year. Many GI bleeds can be controlled and will achieve hemostasis with a clip or tapenade pressure, for this needs analysis the focus will be bleeds that cannot be controlled by clip or tapenade (Westhoff et al., 2004).

GI bleeding is among the most fatal GI complications. GI bleeding is separated into upper and lower GI bleeding. Upper GI bleeding specifically accounts for 20,000 deaths per year (El-Tawil, 2012). Causes of upper GI bleeding include hemorrhage, esophageal varices, and gastric varices to name a few. Hemorrhage occurs in 1:1000 people and 10% of those are included in esophageal varices. Esophageal varices have a 30% mortality rate and 70% chance of rebleeding – bleeding that occurs after initial hemostasis is achieved. Of the patients who experience rebleeding 1/3 of them will succumb to the upper GI bleed.

Lower GI bleeding accounts for only 20-33% of gastrointestinal bleeding and nearly half of these patients have some related or compounding condition that contributes to the bleeding rate. Lower GI bleeds accounted for 8,737 patient deaths (Strate et al., 2008). Lower gastrointestinal bleeding is more often fatal than upper gastrointestinal bleeding. This is largely due to the fact that the anatomy of the small bowel is difficult to image and control with current

endoscopic tools and may require extensive invasive surgical procedures beyond the realm of surgical endoscopy.

Reduced or eliminated clogging, no kinking, and good visualization during powder spray will save time and frustration leading to cost savings over time. Average patient stay in the operating room costs 62 dollars a minute (Macario, 2010). Decreasing time spent switching, cutting, replacing, or unclogging catheters, even by 1 minute, is a cost-effective way to save significant money for the hospitals as well as patients. Saving 30 seconds over the course of 20,000 treatments saves $62,000.

Through reading Boston Scientific collected VoC, or voice of customer questions, it was determined that some of the most common indications for a hemostatic powder include hard ulcer beds, diseased tissue, arterial bleeding, and heavy diffuse bleeding. These results were compiled from a total of 27 physicians contacted between 2015 and 2016. In the case of an uncontrollable bleed, a non-clogging catheter will provide physicians another tool in their arsenal to combat heavy bleeding.

Section 2.2 State of the Art

The current state of the art device for powder delivery utilizes an 8 French catheter made from polyethylene. This catheter has a slight taper at the distal end. There is a logo printed on the distal end to provide physicians with a landmark of how far the physician should remain away from the mucosa when applying the powder. This catheter has a wall thickness of 0.028 inches (outer diameter equals 0.10 inches; inner diameter equals 0.072 inches)

The catheter designs explored in this project will improve the qualities of kinking, clogging, and amount of powder delivery through the introduction of surface changes, catheter

tipping, material selection, and features which may include cutaways, flaps, caps, and plugs to produce an optimized design. The catheter design of this project will retain the single use capability and will attempt to be competitive in price.

Section 2.3 Current Procedure and Powder Delivery Device

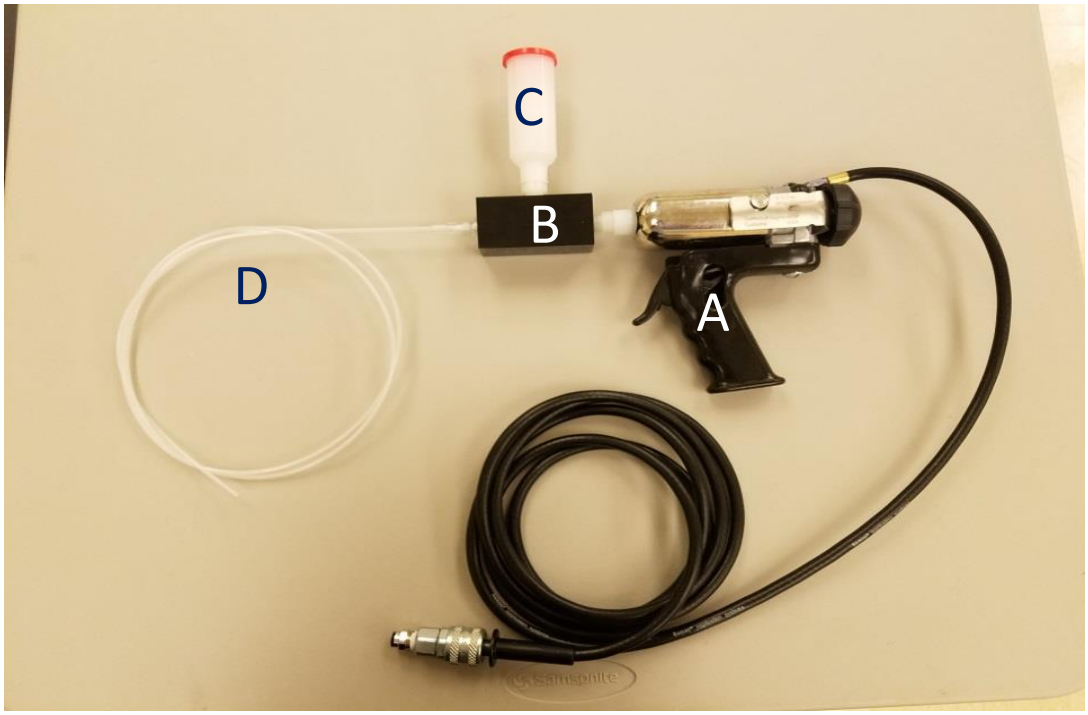


Figure 1. BSC works like prototype of the powder delivery device. The black hose connects to CO2 which connects to a Semco device (A). The Semco device attaches to the main component the mixing chamber (B) which connects the powder canister (C) to the catheter (D).

At this time, the powder delivery is accomplished, as seen in Figure 1 by means of a gravity fed device that pulls powder, from a reservoir, into an expulsion chamber and is pushed through the catheter using compressed gas. The device has the flexibility to work with both low and high pressures in its prototype state. It connects to an air source – hospital gas line, pressurized nitrogen, or compressed CO2.

Since the Boston Scientific internal device is not yet on the market, there is no defined procedure. However, the proposed use model is for application in the GI tract for the treatment of

uncontrollable or un-clippable bleeds. The doctor will place an endoscope into the patient to locate the source of the bleed using direct visualization available on the scope. The nurse or technician will give the catheter of the powder delivery device to the doctor who will feed it through the working channel of the endoscope. Then the nurse or technician will deliver powder through the device and out the catheter by activating the mechanical device.

Section 2.4 Obstacles to Current Use

Obstacles to current use include difficulties delivering powder through a narrow tube largely due to the nature of the powder. Currently the properties of the powder cause clogging. Powder, when contacting flat surfaces or moisture, compacts causing blockage which is caused by friction when particles come in contact with the catheter. Clogging occurs in the connection from the device to the catheter itself. The catheter also kinks when the physician attempts to push the catheter through the biopsy cap on the endoscope.

The final obstacle to current use is the clogging of the catheter due to a moist environment. This occurs during several time points during the procedure. Initially when the catheter is passed through an endoscope it must pass through water (especially if the physician has used water or suction previously in the procedure). The second-time water or liquid may be introduced to the catheter tip is upon powder delivery. When the physician delivers the powder, he may accidentally touch the mucosa or the blood from the wound site. This causes the powder to swell and clog the working channel of the catheter.

Additionally, the volume of air needed to deliver the correct volume of powder to the wound site is too large. This difference insufflates the stomach and bowels of the patient too much potentially causing perforation and complications.

Section 2.5 Preclinical Trial Observations

September 19th and 20th

On September 19th and 20th of 2016 the team visited CBSET, Concord Biomedical Sciences and Emerging Technologies, located at 500 Shire Way, Lexington MA. At CBSET the team performed a clinical trial at which the novel hemostatic powder and delivery device were tested in a porcine model. There were four physicians participating in the animal study, two pigs were used each day – one per doctor.

In order to successfully evaluate the hemostatic device, the doctors each created defects using snares, needle knives, and endomucosal resection (EMR). Difficulties in creating defects arose because the porcine stomach is resilient and the mucosa is extraordinarily thick compared to a human. However, doctors were able to create oozing bleeds to evaluate the device. The catheter used in the procedure was a Nylon 12 catheter with a 0.01 mm wall thickness. The doctors provided valuable feedback on the catheter design in the form of direct comments and observations that will be examined in the following paragraphs.

A spraying technique was devised to avoid filling the catheter with water as it passed through the endoscope and to avoid powder clogging in the body of the mechanism or the catheter body junction. Prior to the doctor passing the catheter down the endoscope the device is held upside down to prevent powder, from the gravity fed canister, entering the body of the device. As the doctor pushes the catheter through the endoscope, the device operator pumps air through the catheter to prevent moisture from entering. Once the doctor is in position the device operator flips the device right side up and pumps the trigger while shaking and tapping the body. This prevents powder from clogging at any junctions.

Doctor 1 noticed significant catheter kinking when the catheter was passed through the endoscope. From observing Doctor 1's actions, it was noted that he was throwing the catheter down the endoscope forcefully. In addition to passing the catheter forcefully down the endoscope, the endoscope was positioned such that the catheter had to pass through a tortuous path to reach the end of the scope. It was observed that the kinking and bending of the scope filled certain portions of the scope working channel with water thus wetting the catheter on the inside and outside as it passed through the scope. It was noted that passing air through the catheter as it passed through the endoscope helped alleviate clogging difficulties but raises concerns of too much insufflation and potential bowel perforation.

Doctor 2 noticed that, if powder is applied then the catheter is pulled back inside of the endoscope, and then applied again a second time, the catheter clogs. With Doctor 2, the catheter kinked and clogged. Powder also built up and packed together at the connection between the device mixing chamber and the catheter causing significant clogging. When the powder is allowed to stop flowing in the catheter, the clogs occur more frequently. There was significant back spray when the catheter tip was close (within 2cm of the mucosal wall). The back spray made visualization difficult, caused buildup of powder on the outside catheter walls, and eventually clogged the catheter. Potential solutions include reducing particle size and pressure needed to deliver powder.

Doctor 3 noted that he would like to be able to spray powder, pull the catheter back to visualize, and then apply powder again. Additionally, Doctor 3 would like to eliminate the extra air flow through the catheter prior to powder spray due to concerns of perforation. The additional air in the pig stomach caused too much inflation and Doctor 3 fears perforation. It was observed that Doctor 3 bends the scope for leverage and proper placement, creating a 180-degree path for

the catheter to follow after entering the endoscope which may cause kinking and passability issues.

Doctor 4 commented negatively on the amount of clogging which occurred often at the tip of the catheter due to contact with the mucosal wall. He also expressed interest in providing more powder per spray. The powder per spray may not be a function of the catheter but more a function of the gravity fed powder canister or particle size.

Overall the doctors commented most on catheter clogging. It was observed that most of the clogs occur because of moisture powder interaction or kinking. Spraying 1 to 2 cm away from the mucosa was observed to be ideal. Clogs frequently occur at the site of catheter connection to mixing chamber.

December 5th and 6th

On December 5th and 6th 2016 the team visited CBSET, Concord Biomedical Sciences and Emerging Technologies, located at 500 Shire Way, Lexington MA. At CBSET the team participated in a preclinical trial at which the novel hemostatic powder and delivery device were tested in the porcine model. There were three physicians participating in the animal study one pig was used per doctor.

To successfully evaluate the hemostatic device, the doctors each created defects using snares, needle knives, and EMR. Difficulties in creating defects arose because the porcine stomach is resilient and the mucosa is extraordinarily thick compared to a human. However, doctors were able to create oozing bleeds to evaluate the device. The catheter used in the procedure was a Nylon 12 catheter with a 0.01 mm wall thickness. The doctors provided valuable feedback on the catheter design in the form of direct comments and observations.

Doctor 1 commented on the powder saying it had superior performance and would use after every procedure. In this scenario, the catheter did not clog before or during spray but did clog after spray stopped. The doctor was able to apply enough powder to the affected area without the catheter clogging. This doctor did not flush water through the scope channel and did not use suction on any wet portions of the GI tract. Powder and catheter with no modifications were easily delivered to the stomach; however, the catheter did clog when the CO2 stopped flowing. CO2 was being pumped through the catheter during insertion through the scope to avoid moisture penetrating the catheter orifice.

Doctor 2 had severe clogging. The catheter and scope clogged. The physician applied powder to the affected site and during spray pulled the catheter back into the scope. He was then unable to pass the catheter through the scope again. This may be due to the nature of that specific powder formulation. It forms a thick sticky gel upon contact with water. During another trial the catheter was extremely wet and was pushed into mucosa when it passed through the scope – it clogged this second time as well.

Doctor 3 did not clog the catheter did not clog during first spray but did clog after the spray stopped. This doctor was able to spray enough powder to the affected area. However the catheter clogged when it was pushed into mucosa during the second attempted spraying.

Several attempts at spraying failed due to kinking at the proximal end during spraying – at the connection between catheter and mixing chamber. It was noted that during two procedures the catheter clogged due to being passed through an extremely wet scope channel. In order to fix this problem, the team removed and replaced the catheter.

Section 2.6 Background Summary

Through an understanding of endoscopic procedures used to stop bleeding, several gaps are visible and can be corrected. The use of a powder to achieve hemostasis has many advantages, but has inherent delivery challenges as seen in the current device on the market. Clinical observations were able to confirm the need for a catheter that will be robust to both clogging and kinking. To achieve this goal a project strategy has been developed and a design testing plan was implemented.

Chapter 3 Project Strategy

Section 3.1 Introduction

A project strategy was developed to coordinate the design and development of a novel catheter for endoscopic powder delivery. The project strategy begins with the initial client statement reviewed below and contains objectives and constraints, clinical trial observations, and concludes with a revised client statement.

Section 3.2 Initial Client Statement

In order to achieve hemostasis in gastrointestinal bleeds, a powder has been developed which requires delivery through an endoscope. Delivering powder through an endoscope requires a catheter; however, they are often prone to clogging. Clogging can occur by several different means including static and obstruction by the swelling hemostatic agent. The objective of this project is to design and optimize a catheter for endoscopic powder delivery. More specifically, design catheter iterations, create prototypes, and develop a test method to determine the optimal catheter for powder delivery.

Section 3.3 Requirements, Objectives, and Constraints

Constraint 1 – The catheter must fit down a 3.7 mm working channel of an endoscope. The catheter must fit down the 3.7 mm working channel of the endoscope which is a common endoscope size for many practices to have. This scope is routinely used in emergency cases.

Constraint 2 – There must be no change in delivery of this catheter outside of the technique commonly used by surgeons. The surgeons and technicians are comfortable with the clipping platform and this device should be similar in use to a clip. It should not require extraneous techniques or a high learning curve.

Constraint 3 – The device must be safe for the doctor and patient. The device should not pose any harm to the doctor, technician, or patient.

Constraint 4 – The device must be inexpensive. The entire device must cost less than two hemostatic clips or roughly $500. The catheter is only a small portion and should be no more than $5.

Constraint 5 – The Device must be disposable after use. The device must be disposable since it will be a biohazard after contacting bodily fluids. It will cost the hospital money to clean the product if it were reusable. The goal of the company's project is to develop a single use device.

Constraint 6 – The catheter must connect by Luer Lock to the delivery device. For packaging purposes the catheter will come detached from the mechanical device. It must connect quickly and efficiently, therefore a Luer system was chosen.

Constraint 7 – The device must accommodate particle size of 425 µm and less. For visibility and efficiency purposes when spraying powder, a particle size of 435 µm was determined to be optimal.

Objective 1 – Device incorporates an anti-static component. Incorporating an anti-static component to the device would be an added benefit because it would result in less static cling. The powders cling statically to the inside of the catheter walls and moisture contacts them easier. This would further limit the creation of a clogging environment.

Objective 2 – Device can be sprayed through more than once during the procedure. The device would be most effective if the doctor could apply powder then stop spraying to watch

the effect then continue to spray if needed. The goal is to be more than a one shot device. This would allow the doctors to control how much powder they spray per bleed and cover multiple wound sites in a single pass.

Objective 3 – The device should be easy to manufacture. The catheter should be easily machinable such that the product can be produced easily and consistently within specifications. The machinability largely determines the cost of the product. For a disposable catheter the cheaper the product the more cost effective it will be. The goal is to make a cost effective machinable product. A simple design is preferred over a complex expensive design.

Objective 4 – The device should be simple and require minimal operational steps. A goal of this project is to make a simple and effective product than can be used to deliver powder in emergency situations. Creating additional steps could reduce time to treatment and cost additional money. The goal is to streamline the design into a user-friendly device.

Objective 5 – The device may have an option to allow localized powder dispersion. A goal of the device is to spray the powder specifically to the bleed site if the doctor knows where the bleed is originating from. If the physician does not know where the bleed origin is, then wide angle dispersion is sufficient.

Objective 6 – Device should minimize kinking when being passed through the scope by physicians. During procedure, the physician will pass the catheter through a biopsy cap on the endoscope. The biopsy cap resists the push of the catheter often causing kinking. Kinking should be reduced to a minimum when passing through tortuous anatomy as defined by BSC tortuous anatomy paths.

Objective 7 – Device should minimize clogging when passed through the endoscope.

The endoscope is often full of fluid, water, blood, and gastric secretions, these liquids work their way up through the catheter causing the powder to swell and clog at the distal end. The device must incorporate a design to overcome this issue.

Section 3.4 Revised Client Statement

The objective of this project is to design and optimize an inexpensive powder delivery system that is compatible with an existing endoscope and air driven powder dispensing device that does not clog or kink when passed through the endoscope. More specifically, provide a working catheter with design justification.

Section 3.5 Client Meeting - January 18, 2017

On January 18, 2017, the team spoke about the design process, specifically initial designs. Designs were brought forth and pared down based on features and requirements met. Another factor was the score of the design selection matrix. The client expressed that they would like the simplest and cheapest version of the catheter overall. The major objective of the project is that the catheter design should reduce clogging to a minimum if it is passed down an endoscope that is filled with water. While a nice to have is that the catheter can spray multiple times during the procedure after contact with water, mucosa, or blood.

Section 3.6 Standards

The American society for gastrointestinal endoscopy offers guidelines for safety in the gastrointestinal endoscopy unit. The device must comply with ISO 13485 standards for quality management for medical devices. ISO 209695 gives compliance guidelines for feeding catheters which are of a similar function to the medical device being created. Standards for sterilization

will be referenced from ISO 11737-2:2009 which covers sterilization of medical devices. These standards will be kept in mind during the process of designing the medical catheter for powder delivery (Wong et al., 2012).

Section 3.7 Project Breakdown

Further subdividing the project yields three main components: the quick connect from catheter to delivery device, the catheter itself, and any modification of the tip that will prevent clogging. The three subcomponents of the project will be approached systematically through iterative tests culminating in a final design.

Chapter 4 Design Process

Section 4.1 Design of Quick Connect

The process of designing the quick connect was constrained by size and connection type. The Luer Lock fitting was a requirement since the technician or nurse will assemble the device in the operating room looking for speed and efficiency. The Luer Lock allows for quick assembly time which is necessary for ease of use. The Luer platform is largely familiar in all hospitals since it is the common connection for syringes, needles, and other devices. The area requiring innovation is the central taper. The inner diameter fits a Luer Lock male connector; this diameter must reduce to fit the inner diameter of the catheter. Initial testing was conducted using off the shelf Luer Lock tapers UV glued to catheters.

Table 1. Quick connect fittings functionality testing.

Part Number	Catheter Size (French)	Taper	Hole diameter (in.)	Success or fail
Drilled out taper	9	none	>0.09	Success
65257	9	yes	<0.088	Success
65259	7	yes	<0.072	untested
11103	8	yes	>0.072	untested
41524	7	yes	<0.072	untested
65120	8	yes	<0.088	untested
65258	9	yes	>0.088	Success
65290	9	yes	>0.088	Success
65226	10	yes	>0.088	Success

Functionality testing several off the shelf products allowed this design seen in Figure 2 to be modeled. During functionality testing it was found that if the powder contacted a flat surface, the powder would clog in the connection as seen in Figure 3. Several different styles of Luer Lock catheters were designed and many were successful as seen in Table 1.

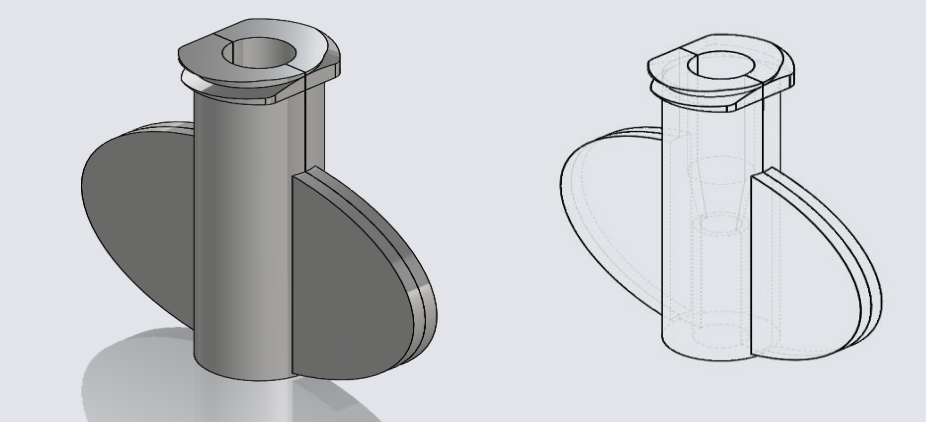


Figure 2. CAD modeled Luer Lock fitting in a solid body and wire frame view.

Figure 3. Powder clogged this off the shelf fitting at the stepped surface of the steep taper.

After modeling was completed Solidworks Flow simulation was used to study differences among Qosina Fittings and the custom designed fitting. The flow simulation also aided in dimensioning the fitting. The first design modeled was the same height as the Qosina fittings. Two other designs were created with 1.5x original taper length and 0.5x original taper length.

These showed no difference when compared to the original size custom fitting. Flow simulation data can be seen in Figure 4. The Qosina fitting has high pressure flow with mixing after the step from taper to catheter where the custom fitting has no mixing and gently decreases in pressure across the length of the fitting.

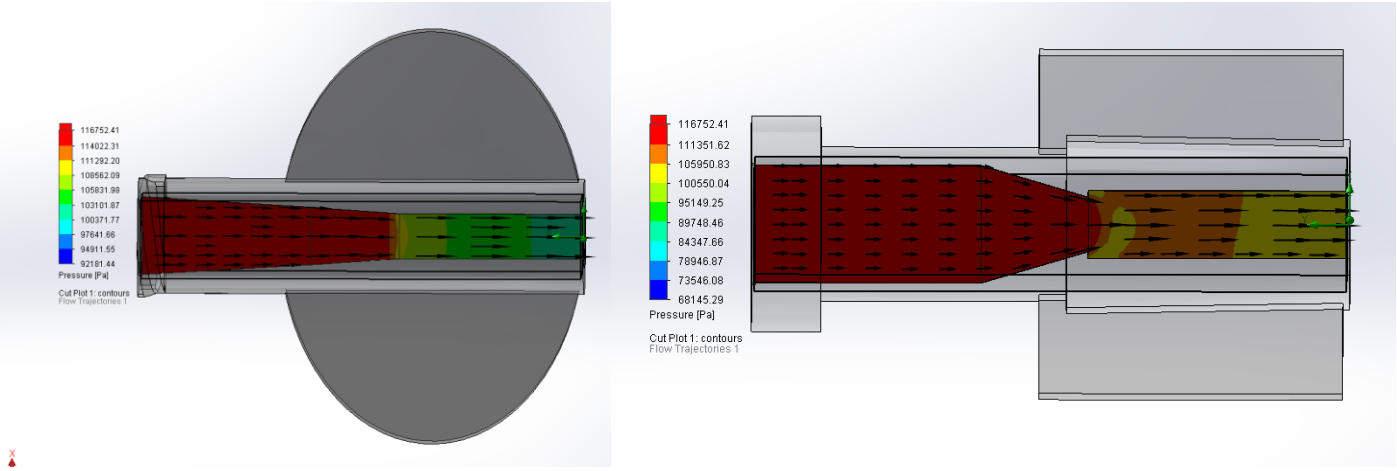


Figure 4. Solidworks Flow Simulation showing gentle pressure drop for the custom fitting on the left and mixing high pressure flow for the Qosina fitting on the right.

Alternative designs were explored for the length of the Luer Lock taper. A fitting 1.5 times the size of the custom fitting and a fitting 0.5 times the size of the custom fitting were tested. These fittings showed similar results to the original fitting created and can be seen in Figure 4. Since the results showed the same steady decrease in pressure from high to low evenly through the channel, the original design was chosen. The custom fitting was printed using a Stereolithography (SLA) machine and the resultant product can be seen in Figure 5.

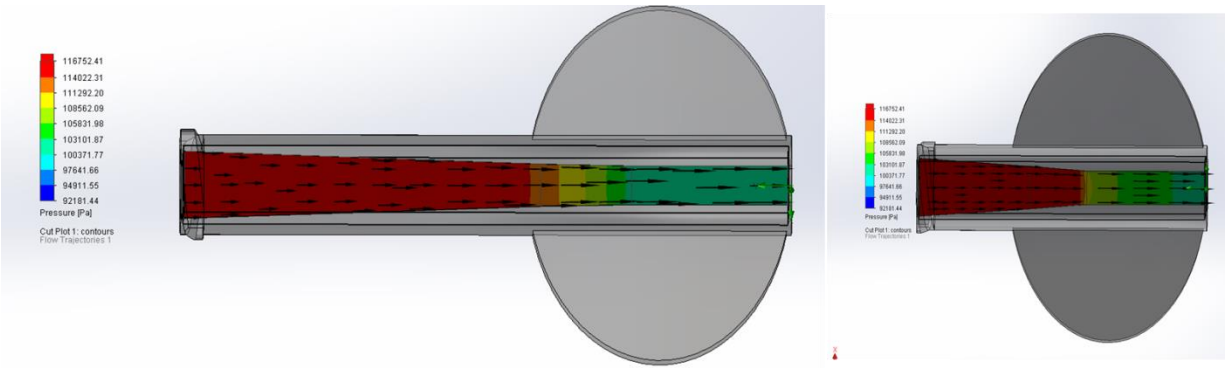


Figure 5. Alternative designs tested in the flow simulation. The fitting on the left shows the 1.5x longer taper while the fitting on the right shows the 0.5x shorter fitting. These fittings act similarly to the original custom fitting.

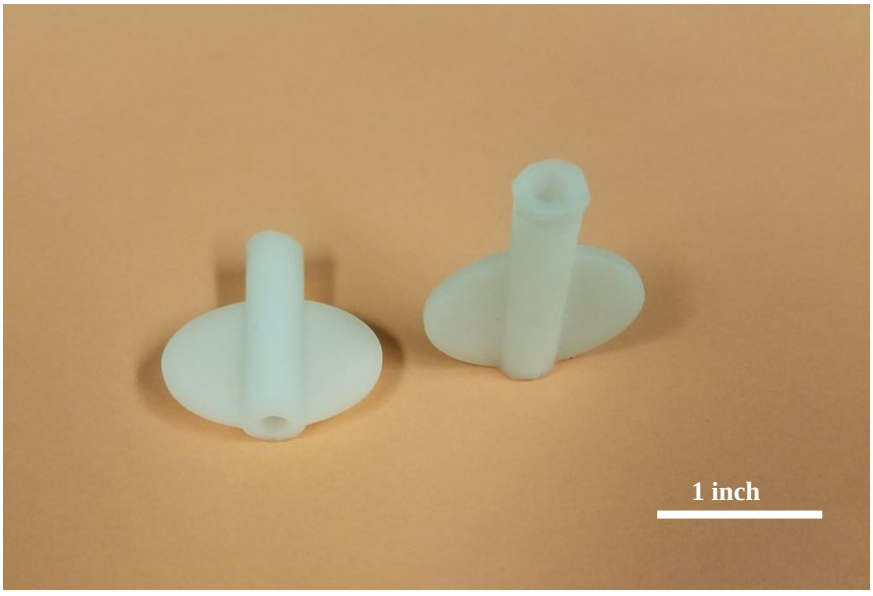


Figure 6. SLA printed quick connect.

Section 4.2 Design of Catheter Material, Outer Diameter, and Wall Thickness

Catheter design began initially as functionality testing. The initial need was to get a catheter that worked for feasibility testing of the powder. This process was initiated by testing catheters that were currently available in stock in the BSC facility. The length of the catheter is constrained by the length of the endoscope and the outer diameter of the catheter is constrained by the endoscope working channel size. The length of the catheter must also take into consideration the distance away from the doctor that the technician would prefer to stand. In order to effectively characterize this, the team spoke with a former endoscopy technician. The endoscopy technician recommended a catheter length of 100 inches. The first catheter material tested was Nylon 12, also known as Vestamid.

The Nylon catheter worked well but had several flaws. The Nylon catheter was designed for a large endoscope and it has a 0.131 inch outside diameter and 0.121 inch inner diameter. This catheter worked well initially and carried the device and powder through initial testing stages, but the catheter did have visible problems that were characterized through the beginning functionality testing. The problems included static build up, kinking at the connection between mixing chamber and Luer Lock, and difficulty in scope passability due to its large diameter and very small wall thickness which led to kinking. The outer diameter was determined to be too large for scope passability and will be reduced in the next iteration. This design, despite its flaws will be considered in final design decisions due to its positive performance overall.

The next catheter material chosen for prototyping was High Density Polyethylene (HDPE) because it is lubricious and the competitive device uses a polyethylene catheter to deliver powder. Polyethylene has inherent anti-static properties - RCP Imagineering Plastics uses this to create permanently anti-static plastic components. Unfortunately, due to limitations of the

extruding process, mainly holding a cylindrical shape, this material could not be extruded at the Marlborough site. When extruding HDPE as the material enters the cooling vat of water the polymers align and form an oval extrusion instead of a circular cross section. While this material cannot be formed within the Marlborough site, the Maple Grove Boston Scientific site has the equipment – a vacuum chamber to hold diameter – and expertise to correctly shape the HDPE catheters. This will be kept as an option should no alternative material be found.

The next material chosen for extrusion was a HDPE and Tapas blend. 20% HDPE and 80% Tapas were extruded together with an outside diameter of 0.118 inches and inner diameter of 0.088 inches. Tapas is a high performance material which is similar to HDPE and is commonly used as an additive in HDPE extrusion. This blend was easy to extrude but was incredibly stiff. The material kinked and shattered irreparably when put under shear stress. The outer and inner diameter of the catheter works well, offering scope possibility and improved powder spray. This size is also standard for an extrusion die. This size will be chosen for all following iterations. The HDPE Tapas blend was excluded from final consideration due to the reduced flexibility and propensity to shatter when put under shear stress.

As an alternative to HDPE, polypropylene was extruded next because it has similar properties of lubricity as HDPE. This material was extruded with an outer diameter of .121 inches and inner diameter of 0.096 inches. This catheter could not pass functionality testing without kinking. The outer diameter was determined to be slightly too large for scope passability and inner diameter being so large led to increased kinking. The outer diameter and inner diameter will be reduced in the next iteration. The catheter failed and kinked when it looped on itself 180 degrees. The polypropylene material was excluded from final consideration due to the increased propensity to kink over the previously tested Vestamid.

Next, a Low-Density Polyethylene (LDPE) was extruded with hopes that the inherent flexibility will reduce or eliminate any kinking issues. The LDPE was extruded with an outer diameter of 0.118 and inner diameter of 0.088. Kinking properties were improved drastically however the inherent “tacky-ness” and flimsiness of the LDPE led to scope passability difficulties. The catheter when pushed into a scope working channel resists movement and bends instead of being pushed through the scope. This material will be excluded from final consideration due to lack of passability through the scope.

After speaking with two Boston Scientific extrusion experts, next steps were identified to extrude catheter materials. Linear Low Density Polyethylene will be extruded with the hope that the aligned polymer chains will help increase stiffness and passability without sacrificing the kink resistance. Neither LLDPE nor HDPE/LDPE Blends are extrudable with the equipment at the Marlborough site. Future developments will require these extrusions to be made in Maple Grove, Minnesota.

The next iteration of catheter development will include Materials X and Y. These materials are polymers with an elastic modulus that falls within the range of 0.3 and 1 GPa. Their names will be withheld due to the proprietary nature of medical device development. Materials X and Y function very well in the tests for flexural modulus or kink resistance, compressive stress, and tensile properties compared to the competitor.

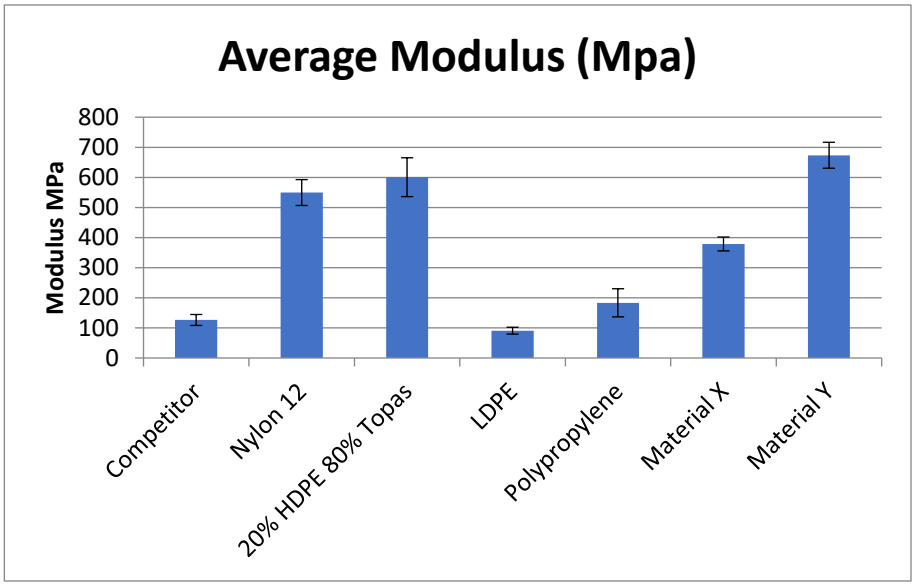


Figure 7. Average modulus of the ten tests for each material. The error bars represent plus or minus one standard deviation. For this test, a higher modulus is desired.

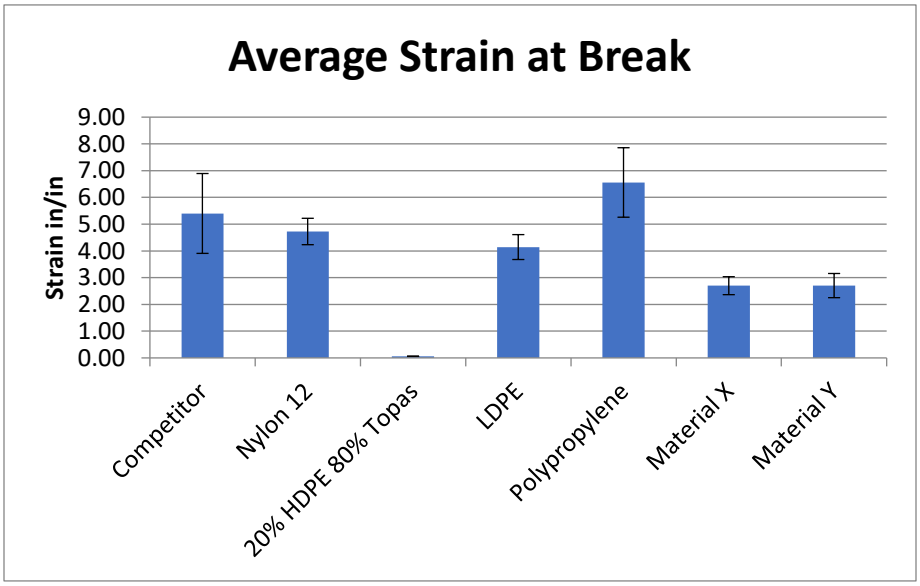


Figure 8. Average strain at break of the ten tests for each material. The error bars represent plus or minus one standard deviation. For this test, a higher strain at break is desired.

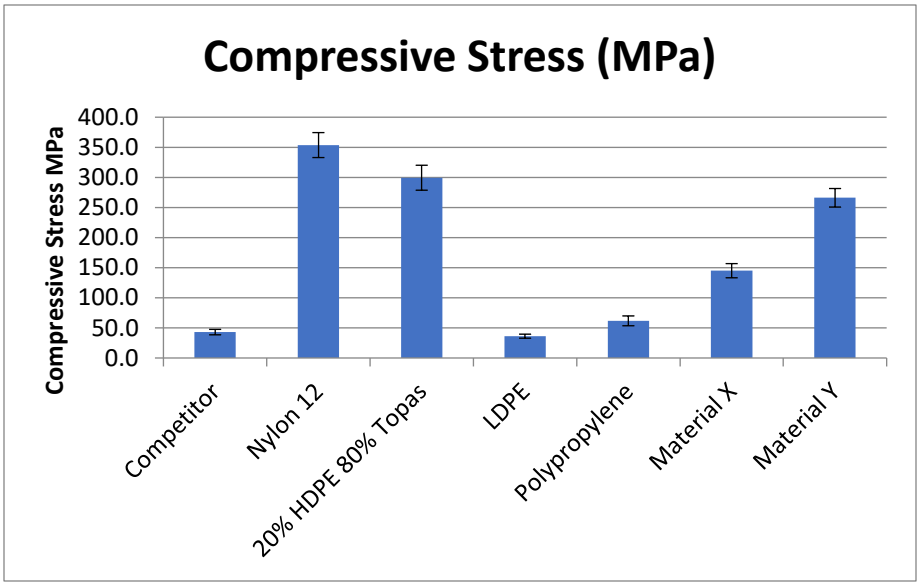


Figure 9. Average compressive stress of the ten tests for each material. The error bars represent plus or minus one standard deviation. For this test, a higher compressive stress is desired.

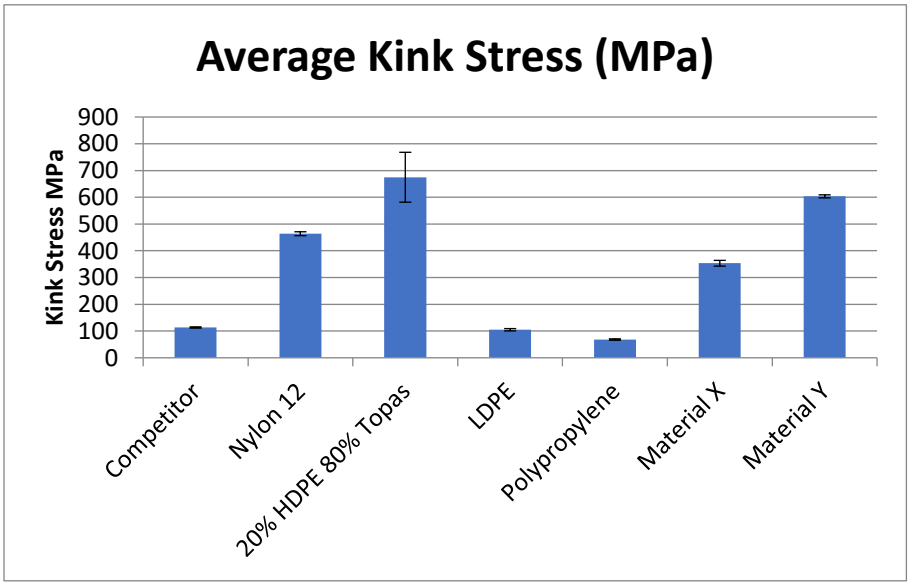


Figure 10. Average kink stress of the ten tests for each material. The error bars represent plus or minus one standard deviation. For this test, a higher average kink stress is desired.

Three mechanical tests were employed using an Instron – 3-point bending, compression, and tensile tests. The three-point bending characterized the catheter's response to shear stress,

the compression test characterized the response to columnar buckling forces, and the tensile test characterized the intrinsic mechanical properties of the material as seen in Figure 7 and Figure 8.

For the tensile test the Instron program asks for inputs inner and outer diameter. From this input the program calculates peak load, peak stress, strain at break, and modulus. Peak load, is found by the program searching for a maximum value. Force is converted to stress by dividing by area and extension is converted to strain by dividing the original length plus the extension divided by the original length. The modulus is calculated as the slope of the stress strain curve in the linear region. Peak stress is found by the program by searching the data set for the largest value of stress and strain at break is found by searching the data set for the largest value of strain. The tensile test follows ASTM Method D638-14. Equations for the tensile test are as follows:

Stress – Where F is force and A is cross sectional area.

$$\sigma = \frac{F}{A}$$

Cross Sectional Area – where r_o is outer radius and r_i is inner radius:

$$A = \pi * (r_o - r_i)^2$$

Strain – Where L_o is original length and ΔL is extension.

$$\varepsilon = \frac{L_o + \Delta L}{L_o}$$

Modulus

$$M = \frac{\sigma}{\varepsilon}$$

For the kink test, or 3-point bending test, the Instron only outputs force. The peak force is interpreted as the largest force the catheter can withstand before kinking. ASTM method E290-14 for kink force was followed. This force was translated after the test into kink stress. This was done to normalize the values of force for different catheter cross sectional areas. The kink stress was needed to compare the materials side by side. Raw force values can be found in the appendix. The equations used in determining kink stress are included below:

Kink Stress – Where F is peak force, L is anvil to anvil span length, and I is moment of inertia.

$$\sigma_k = \frac{F_{max} * L}{I}$$

Moment of Inertia – Where r_o is outer radius and r_i is inner radius.

$$I = \frac{\pi * ({r_0}^4 - {r_i}^4)}{4 * r_i}$$

For the column buckling test the Instron only outputs force. The peak force is interpreted as the largest force that the catheter can withstand before buckling. ASTM method D695-15 for column force was followed. The force was translated, like above, into column buckling stress for purposes of comparing catheters of different cross sectional areas. The raw force values can be found in the appendix. The equations used for determining column stress are included below:

Column Buckling Stress – Where F is peak force and A is cross sectional area.

$$\sigma_c = \frac{F_{max}}{A}$$

Cross Sectional Area – Where r_o is outer radius and r_i is inner radius.

$$A = \pi * (r_o - r_i)^2$$

Each material was tested 10 times in each of the three tests for a total of 30 tests per material. Data for modulus and strain at break characterize the raw material. Compression stress and kink stress were chosen as the value to report for column buckling and 3-pont bending which can be seen in Figure 9 and Figure 10. These were chosen because stress is a normalized representation of the force. Since the wall thicknesses vary from sample to sample, stress was chosen to normalize the data. Table 2 presents the average data and standard deviations for each of the four graphed categories. Raw data for all tests can be found in the appendix. This table also denotes the preferable material (Material Y) in green and presents why the other materials were not considered for the final design. These disqualifying properties are highlighted in red and yellow.

Table 2. Average Data from Instron Testing.

Material	Modulus (Mpa)	±StDev	Kink Stress (MPa)	±StDev	Compressive Stress (MPa)	±StDev	Strain at Break	±StDev
Competitor	126	18.2	113	2.12	43.0	4.52	5.40	1.49
Nylon 12	550	42.9	464	7.26	354	20.7	4.73	0.493
20% HDPE 80% Topas	601	64.5	675	93.2	299	20.7	0.059	0.007
LDPE	90.8	11.3	105	4.36	36.3	3.34	4.14	0.465
Polypropylene	183	46.7	68.1	2.62	61.7	8.15	6.56	1.30
Material X	379	23.1	353	10.7	145	11.8	2.70	0.335
Material Y	674	43.1	603	5.62	266	15.4	2.70	0.452

Section 4.2.1 Plastic Extrusion

Extrusion is a method of forming filaments, sheets, tubing, and other geometries using a multi-step process that allows the operator freedom in material selection. Plastic extrusion uses plastic in bulk pellet form to create the final product. The process begins with the plastic pellets loaded into a hopper or vibrating reservoir which keeps pellets from clogging together obstructing the machine's feed. The pellets are deposited from the hopper into a series of heating zones. The heating zones are controlled by a user interface and temperatures can be adjusted. Typically, extruders contain three heating zones in order to ease the plastic into a malleable form. The plastic mass is moved from one heating zone to another using an agar, a large screw that moves its threads in a forward direction. The agar's speed is controlled by the operator as well; this allows the user to control the volume of plastic reaching the die at one time. The plastic is then fed into the die which forms the final geometry.

The process for plastic tube forming requires more sophistication and complexity. The die contains an adjustment to vary outside diameter while the inside diameter is maintained or adjusted through air flow through a small metal tube. Plastic passes over a small hollow metal tube which has a specified air pressure passing through it. This process allows the plastic to form a cylindrical shape with an orifice in the center. The same process is duplicated for multi lumen catheters, or catheters with many orifices, with the addition of other metal tubes with their own air pressure hook up.

Figure 11. Commercial extruder with the hopper (A), the melting chamber (B), the location of the die (C), and the water bath (D).

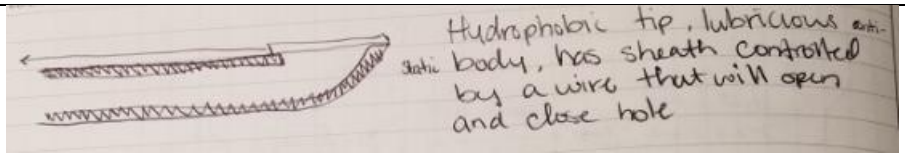
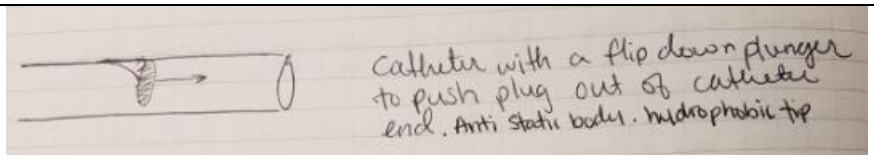
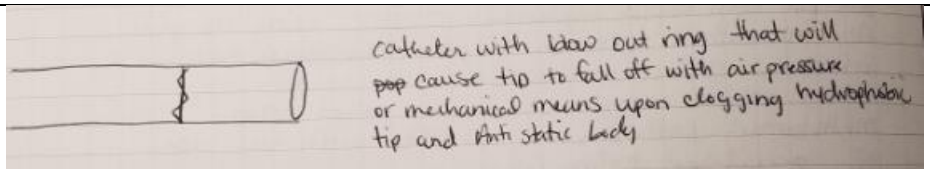
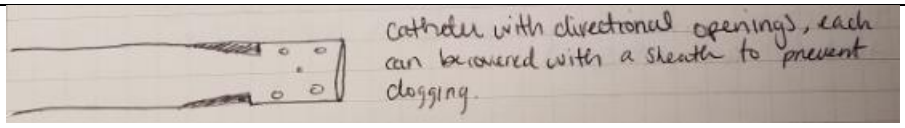
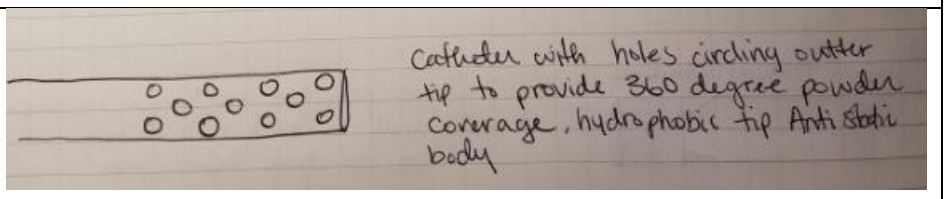
As the catheters exit the die they are immediately fed into a temperature controlled water bath as seen in Figure 11. The temperature of the water bath is adjusted by the operator and dependent on the materials crystallization properties. The tube, upon exiting the water bath will be at its final geometry. It then passes through a laser measuring system, which measures outside diameter, for quality control. This process is automated by a puller, which, as its name implies, pulls and guides the tube through the process of exiting the die, entering and exiting the water bath, through the measurement device, and ultimately into the slicer which cuts and standard set lengths. The puller does have an effect on the outside diameter of the tube decreasing it slightly

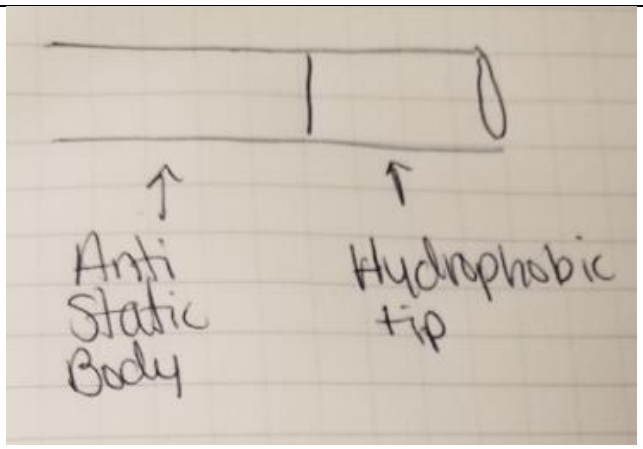
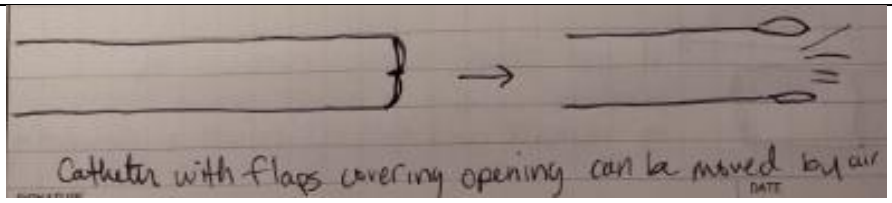
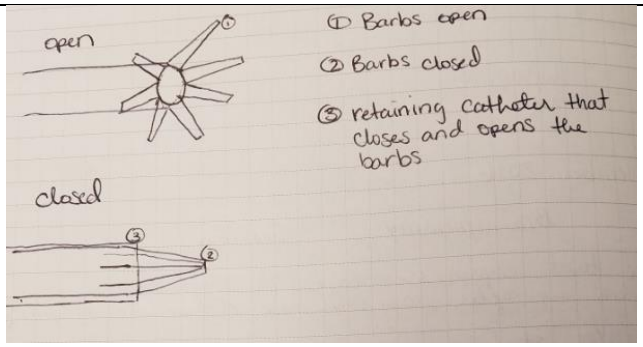
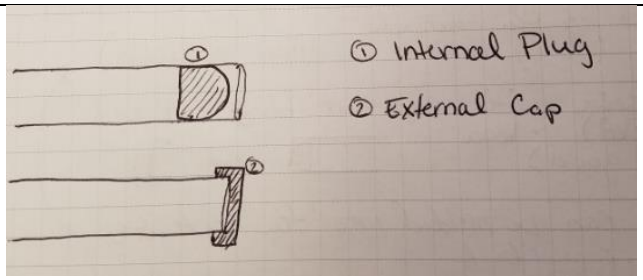
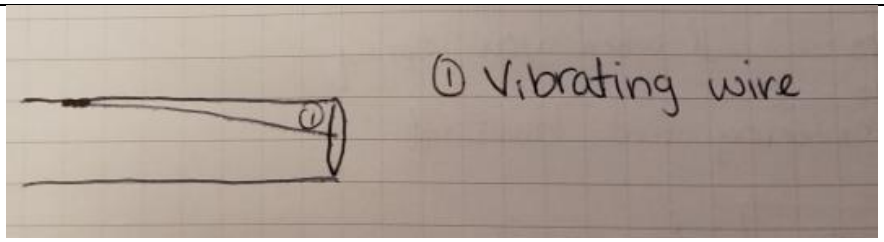
with the higher pulling speed. This minor difference is adjusted for in the agar feed (Pat Phongsavanh, personal communication, January 12, 2017)

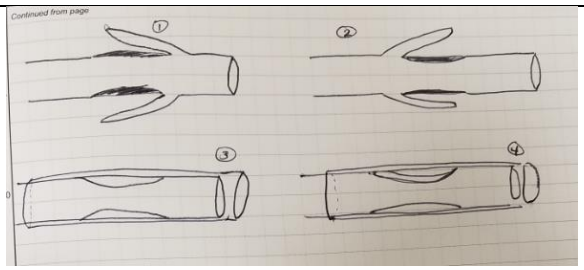
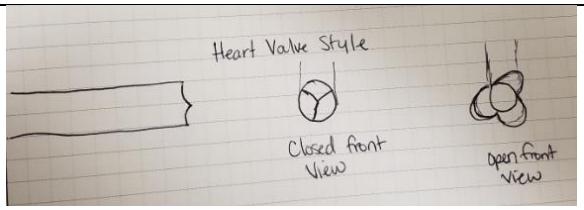
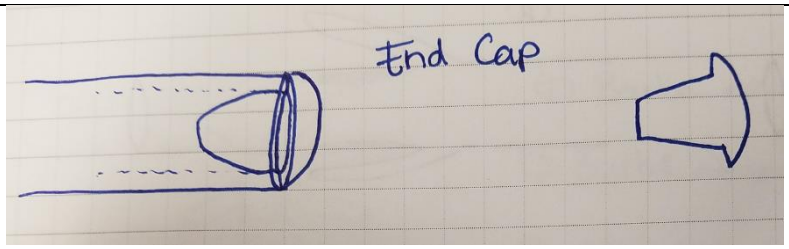
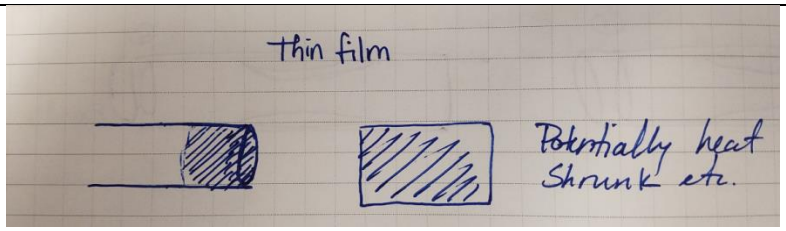
Section 4.3 Tip Modification

Conceptual designs were developed, as seen in Table 3, keeping in mind the need to accomplish each of the constraints and ranking them against each other to determine those that best meet the objectives. Tip objectives include: incorporating an antistatic component, ability to spray through device more than once during the procedure, easy manufacturing, inexpensive to produce, simple and requires minimal operational steps, and the device allows localized powder dispersion.

Table 3. Catheter tip modification designs.

Design 1	
Design 2	
Design 3	
Design 4	
Design 5	

Design 6	
Design 7	
Design 8	
Design 9	
Design 10	

Design 11	
Design 12	
Design 13	
Design 14	

The next step in the design process was to determine the most applicable design for prototyping. This was accomplished using a design matrix.

Table 4. Objective Weights.

Objectives	Weight
Device incorporates an Anti Static Component	1
Device can be sprayed through more than once during procedure	5
Device is easily manufacturable	3
Device is inexpensive to produce	5
Device is simple and requires minimal operational steps	3
Device allows localized powder dispersion	3

Objectives	Weight	Design 1	Design 2	Design 3	Design 4	Design 5	Design 6	Design 7
Device incorporates an Anti Static Component	1	1	-1	1	1	1	1	1
Device can be sprayed through more than once during procedure	5	1	1	0	-1	-1	-1	1
Device is easily manufacturable	3	-1	-1	0	-1	-1	0	0
Device is inexpensive to produce	5	0	-1	1	0	0	1	0
Device is simple and requires minimal operational steps	3	0	-1	0	1	1	1	1
Device allows localized powder dispersion	3	1	0	0	-1	-1	0	0
Rank Score		**6**	**-7**	**6**	**-7**	**-7**	**4**	**9**
Meets Requirements		Yes	Yes - low scoring	Yes	Yes - low scoring	Yes - Low Scoring	Yes - low scoring	Yes

Objectives	Weight	Design 8	Design 9	Design 10	Design 11	Design 12	Design 13	Design 14
Device incorporates an Anti Static Component	1	1	1	1	1	1	1	1
Device can be sprayed through more than once during procedure	3	1	-1	1	0	1	-1	-1
Device is easily manufacturable	5	0	1	-1	-1	-1	1	1
Device is inexpensive to produce	5	0	1	-1	0	0	1	1
Device is simple and requires minimal operational steps	3	0	1	1	-1	1	1	1
Device allows localized powder dispersion	3	0	0	0	-1	0	0	0
Rank Score		**6**	**7**	**1**	**-8**	**6**	**7**	**7**
Meets Requirements		No - external catheter	Yes	Yes - low scoring	No - external catheter	Yes	Yes	Yes

Figure 12. Design matrix weighing the objectives and ranking the design alternatives. Green designs were high scoring and met most objectives. Yellow designs were in the middle of scoring and met some objectives. Red designs were low scoring and did not meet majority of objectives.

A weighted score was given to each of the designs as seen in Table 4. As seen in the design matrix in Figure 12, designs were ranked based on their weighted objective scores. Designs with an external catheter, designs 8 and 11, were excluded since they will require a great reduction in the catheter inner diameter thus limiting the amount of powder deployed during use and potentially causing clogs with a larger particle size powder. Other low scoring designs 2, 4, 5, 6, and 10 were excluded from the final design choice because the manufacturability is very difficult or, in the case of design 6, the change does not solve the clogging issue. The first design chosen to prototype is design 13. This design was chosen because it can be easily manufactured

with tools available, Stereolithography or printing using a resin bath and light to cure the resin, and has the theoretical ability to solve the major challenges while meeting all requirements.

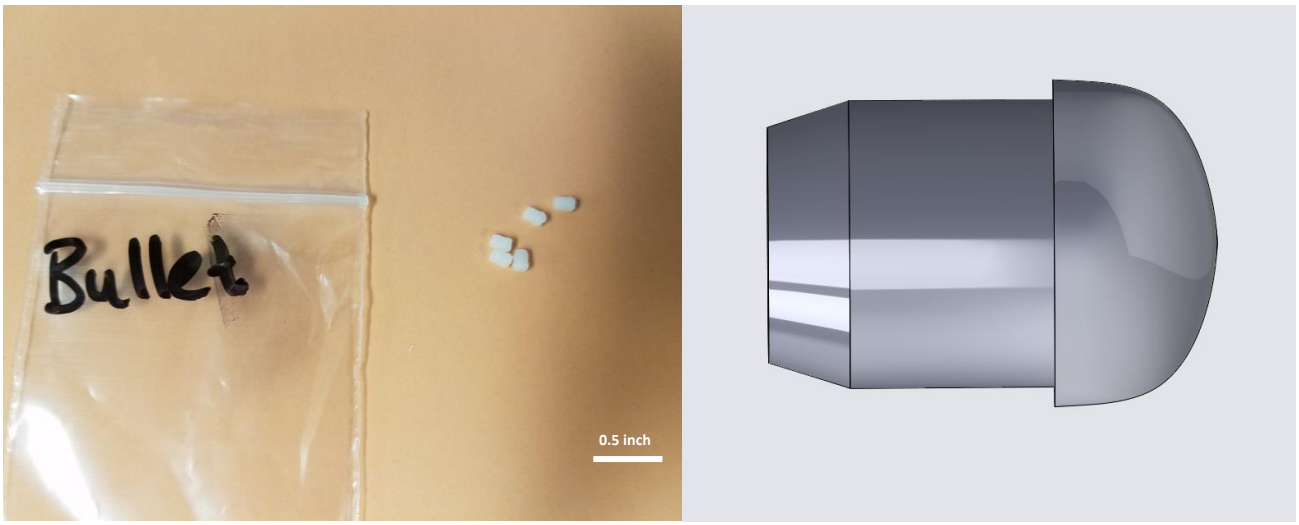


Figure 13. This design is the first of three different variations of the catheter plug design. The image on the left shows the SLA printed caps and the image on the right shows its corresponding CAD design.

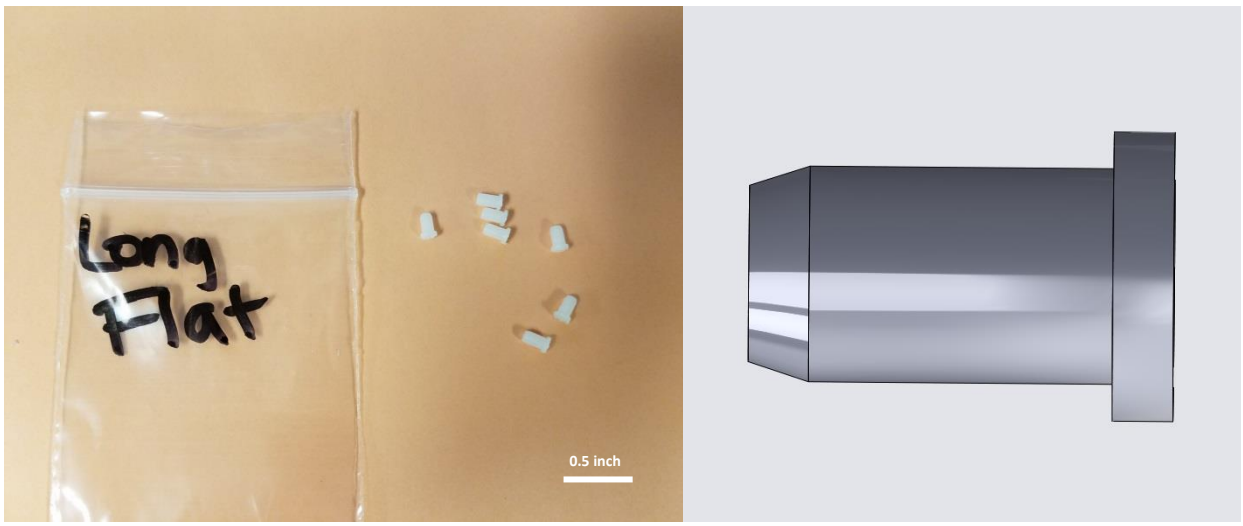


Figure 14. This design is the second of three different variations of the catheter plug design. The image on the left shows the SLA printed caps and the image on the right shows its corresponding CAD design.

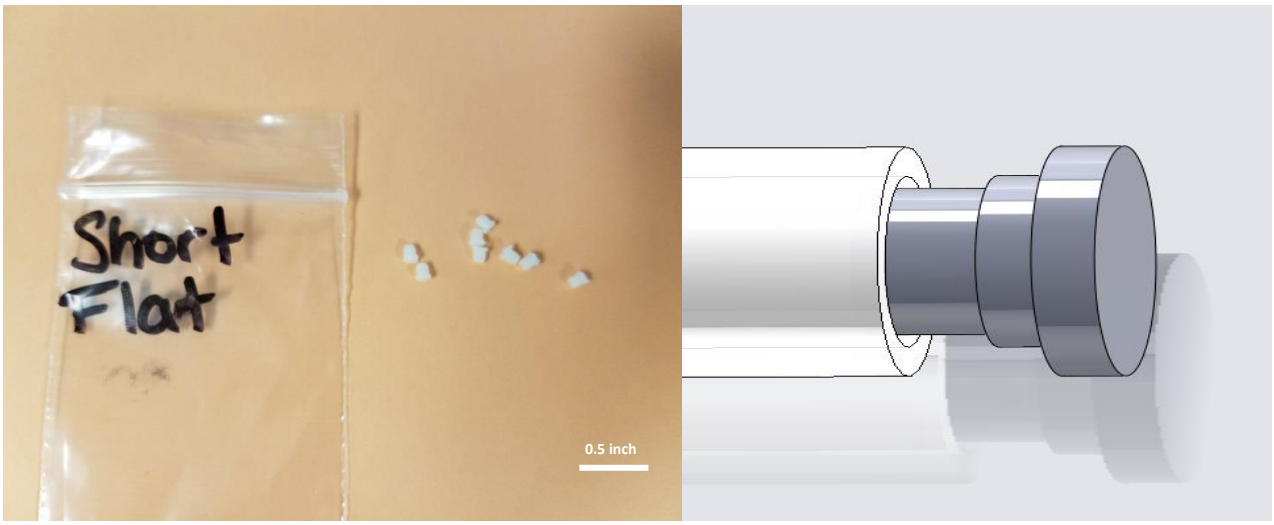


Figure 15. This design is the third of three different variations of the catheter plug design. The image on the left shows the SLA printed caps and the image on the right shows its corresponding CAD design. The third iteration was created to reduce surface area contacting the inner diameter of the catheter.

Variations of design 13, the external cap and plug, were prototyped and printed using SLA as seen in Figure 13, Figure 14, and Figure 15. These plugs will be assembled into the final device prototype and tested for blow out ability and they will be tested for water permeability when passed through a wet endoscope.

Section 4.4 Prototype Design

The final device prototype was modeled in Solidworks then assembled using SLA parts for the Luer Lock fitting and the catheter plug. The catheter itself is extruded plastic. A shortened catheter is used to show the entire prototype on an easily discernable scale. The taper of the Luer-Lock leading directly into the inner diameter of the catheter is shown in Figure 16. The butterfly wings of the Luer Lock fitting allow for easy turning of the catheter fitting. The plug is detailed at the far right of Figure 16. The final prototype, seen in Figure 17, shows the external features of the modeled assembly. The final prototype is shown in Figure 18. This prototype was

created to show the concept of the design. A full-length catheter will replace the current catheter in the final model.

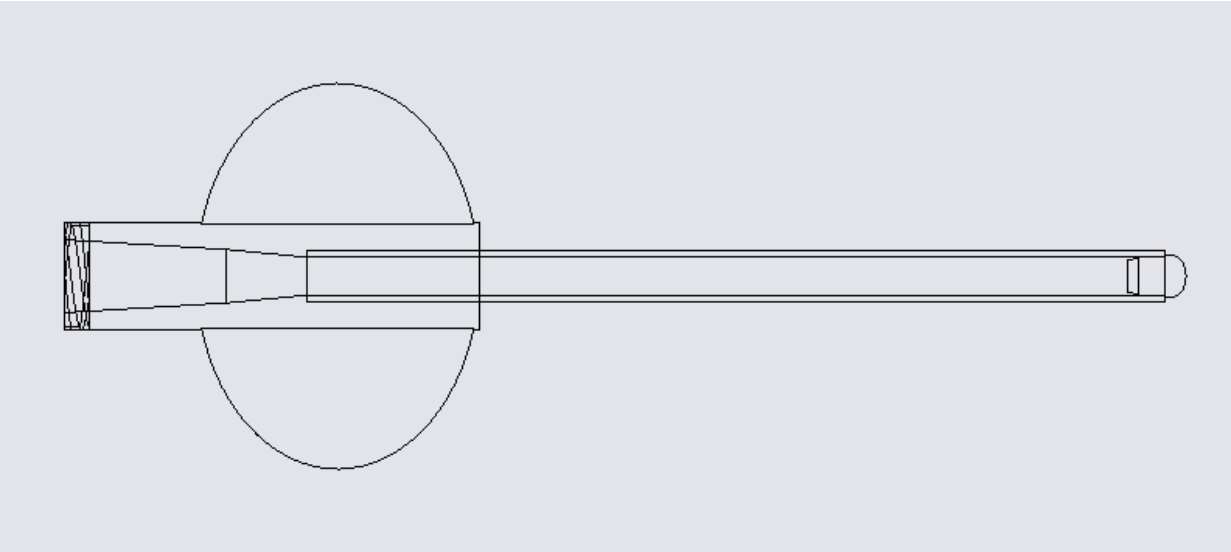


Figure 16. The wireframe view of the CAD model of the final prototype. Here you can plainly see how the taper enters the inner diameter of the catheter. Additionally, the tip modification is detailed at the distal end.

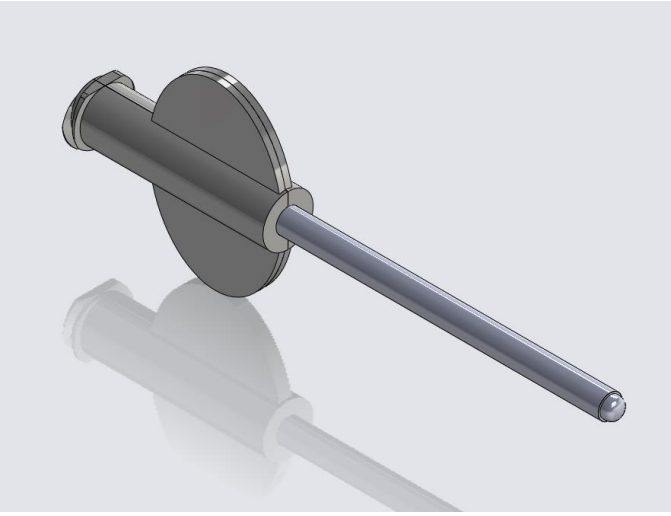


Figure 17 CAD Designed model showing external features of the final prototype.

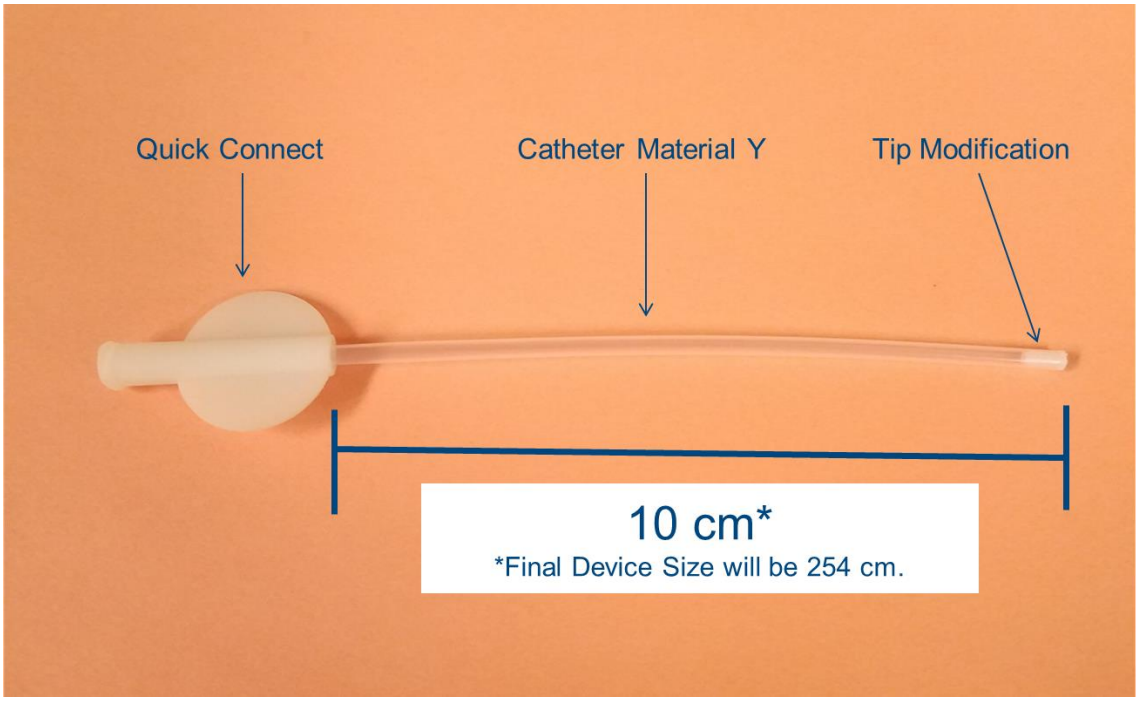


Figure 18. Final prototype design which includes the SLA Luer Lock quick connect fitting with a shortened Material Y catheter and a catheter plug.

Chapter 5 Design Verification

Section 5.1 Testing Introduction

To effectively complete this device design, a design process was followed as put forth in the text *Biodesign the Process of Innovating Medical Technologies* by Yock et al. This process heavily relies on three cornerstones of device design which includes Identify – covered by needs finding and needs screening, Invent – which include concept generation and concept screening, and finally Implementation – strategy development and business planning. Within the scope of this project Identify and Invent will be the focus. However, it is in the forefront of the team's mind that the end goal is to launch the product through strategy development and business planning. The steps taken to progress this project through the Identify and Invent stages are included in the Gantt chart and Work Breakdown Structure in the appendix. User requirements were determined through carefully watching the current device in use as well as gathering feedback from a focus group of physicians. This data was accumulated and formulated into an objectives tree, design matrix, and a list of constraints. The objectives tree can be found in the appendix. Design alternatives were brainstormed and whittled down to a final concept which was tested and reported on in this chapter.

Section 5.2 Testing Methods

Initial failure modes were determined by functionality testing in the ex-vivo lab at Boston Scientific. These tests were completed using a bleed model and porcine stomach to replicate human anatomy. There will be several testing protocols that determine the efficacy of the prototype design from the quick connect through the tip modification

Quick Connect. The quick connect will be put through functionality testing where the powder spray will be applied through the device to the quick connect and through a full-length

catheter. Any clogging in the quick connect will be determined as failure. This will prompt redesign of the quick connect piece. One trial will be done with an off the shelf fitting as a control and one trial will be completed with the quick connect fitting. A procedure and proper delivery device fittings list can be found in the appendix.

Catheter. The catheter will be put through testing by ASTM standards for tensile properties, kinking, and column strength, Boston Scientific internal procedures will be followed in conjunction with these standards. ASTM Method E290-14, method for a guided 3 point bend test will be used to quantify force required to kink a catheter. The internal BSC test procedure followed can be found in the appendix, PDM (product data management) number 90786849. ASTM Method D638-14 for tensile tests will be followed with modification while using an internal BSC procedure for modulus and yield strength, PDM number 90041471. The deviation from the ASTM method comes when asked to narrow the tubing to make the cross section dog bone shaped. Due to processing and time restrictions this step was omitted. The procedure can be found in the appendix. ASTM Method D695-15 will be used to characterize column strength. The internal BSC procedure, PDM number 90487533, followed can be found in the appendix. Additional calculations of pressure loss will accompany these testing results.

Tip Modification. The tip modification will be tested by functionality testing by passing the device through a submerged endoscope then spraying shortly after. Clogging before initial spraying will constitute failure. Spraying a second time will be attempted; clogging in this scenario will be noted. Failure will be determined by the client during second spray. Calculations for pressure needed to remove catheter plug will accompany these testing results.

Section 5.3 Initial Ex-Vivo Testing

Figure 19. The external bleed models. On the right is the bleed model used with simulated blood where the left is the bleed model with porcine blood.

Initial proof of concept testing was performed in the Ex-Vivo lab at Boston Scientific. A porcine stomach acquired from Endosim was attached into an endoscopy practice box as seen in Figure 19. Two variations of this model were tested. The first variation used a glycerol and water mix to simulate blood and a syringe to simulate arterial pressure. This setup ultimately failed since the pressure from the syringe continued much higher than normal arterial pressure with different flow characteristics. The second test was more applicable to human anatomy and the disease state. This method required a pump to continuously flow porcine blood, acquired from Endosim, into a cup which was fixed such that the open portion was covered by the stomach. A small defect was made in the stomach so arterial bleeds could be characterized. A pressure sensor was connected to the model to readout the current pressure provided by the pump and defect. The catheter was then tested through an endoscope. Initially a thin film of polycaprolactone (PCL) was rolled up and placed inside of the catheter acting as a mechanical

plug as seen in Figure 20. This film was blown out of the end of the catheter successfully. After catheter contact with blood, it filled quickly with powder and was removed from the endoscope. The resultant catheter can be seen in Figure 20.

Figure 20. Catheter and PCL plug on the left and the right image shows the clogged catheter post removal.

Section 5.4 Quick Connect Testing Results

Spray tests were performed such that the modeled quick connect could have a point of comparison to the off the shelf fitting. In this testing the setup requires the spray gun, compressed air, powder canister, and catheter. The quick connect provides connection between the catheter and the spray gun "black block." The setup for this experiment can be seen in Figure 21. Results from the off the shelf Qosina Fitting can be found in Table 5. The results from the spray testing with the SLA part can be found in Table 6.

Figure 21. In this image, the common setup for spray tests is shown. Not shown is the source of compressed air. The quick connect provides connection from the catheter to the "Black Block."

Table 5. Spray Testing With Qosina Fitting and Old Short Catheter.

Spray Test				
Qosina Fitting	Particle Size	Initial Weight (grams)	Final Weight (grams)	Amount Sprayed (grams)
Test 1	<425	21.72	18.83	2.895
Test 2	<425	21.77	19.03	2.740
Test 3	<425	21.78	19.06	2.726
Test 4	<425	21.76	19.08	2.683
Test 5	<425	21.81	19.36	2.448
Test 6	<425	21.80	19.28	2.519
Test 7	<425	21.75	18.99	2.760
Test 8	<425	21.80	19.07	2.725
Test 9	<425	21.76	18.96	2.797
Test 10	<425	21.78	19.20	2.589
Test 11	<425	21.70	19.09	2.610
Test 12	<425	21.75	19.18	2.565
Test 13	<425	21.70	18.97	2.724
Test 14	<425	21.81	19.18	2.628
Test 15	<425	21.76	19.06	2.706
AVG		**21.76**	**19.09**	**2.674**
STDEV				**0.1150**

Note: Clogging occurred before tests 4, 7, 11, and 12. These results were not recorded in the powder totals but are noted for design purposes.

Table 6. Spray Testing with SLA Fitting and New Catheter – No clogging Occurred.

Spray Test				
SLA Fitting	Particle Size	Initial Weight (grams)	Final Weight (grams)	Amount Sprayed (grams)
Test 1	<425	26.79	24.35	2.441
Test 2	<425	27.54	24.71	2.830
Test 3	<425	27.17	25.11	2.056
Test 4	<425	27.51	25.42	2.090
Test 5	<425	28.25	26.00	2.253
Test 6	<425	27.50	25.13	2.370
Test 7	<425	27.48	25.08	2.395
Test 8	<425	27.99	25.78	2.203
Test 9	<425	27.97	25.57	2.406
Test 10	<425	28.24	25.98	2.260
Test 11	<425	28.18	26.27	1.910
Test 12	<425	28.00	25.67	2.329
Test 13	<425	27.95	25.72	2.235
Test 14	<425	28.13	25.83	2.298
Test 15	<425	28.29	26.42	1.869
AVG		**27.80**	**25.54**	**2.263**
STDEV				**0.2338**

Section 5.5 Design Analysis and Results

Section 5.5.1 Pressure Loss Calculations

In order to complete pressure calculations, initial assumptions must be realized. The air flowing through the catheter will experience loss dependent on type of flow such that turbulent flow will experience greater loss. It will be assumed that the flow is turbulent as in the worst case scenario. The next assumption will be that the pipe is smooth, since surface roughness affects loss. According to *Pipe Flow fluid thinking software solutions,* drawn plastics have extremely low roughness values (0.00006 inches) such that they will be considered negligible for these calculations. The next assumption is volumetric flow rate. The value for volumetric flow rate will be set at 10 liters per minute as found in the product specification for a common endoscopy insufflator. Characteristically sticking with worst case scenario, it will be assumed that the catheter is coiled with a 9-inch diameter. The Darcy-Weisbach equation will be used to determine pressure loss. The Darcy friction factor will be estimated using the Blasius Correlation. Results can be seen in Table 7.

Table 7.

Assumptions: Turbulent Flow, Smooth Tube, Volumetric Flow Rate equals Insufflation Rate, Coiled Tube.

Velocity of Air

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

Variables

Q = 10 $\frac{L}{min}$ = 0.000167 $\frac{m^3}{s}$ (Karl Storz Endoflator 50)

r = radius = 0.044 inches or 0.0011 meters

A = Cross sectional area = $\pi * r^2$ = 3.80 x 10^{-6} m^2

Reynolds Number

$$R_e = \frac{\rho V L}{\mu}$$

Variables

V = 43.94 $\frac{m}{s}$

ρ = density of air = 1.2754 $\frac{kg}{m^3}$ (Dry Air Properties - Engineering Toolbox)

L = Catheter length = 2.54 meters

μ = Dynamic Viscosity of Air = 1.846 x 10^{-5} $\frac{kg}{m*s}$ (Dry Air Properties - Engineering Toolbox)

Darcy Friction Factor using the Blasius Correlation Accounting for Coiled Tube

$$f_D = 0.316\, R_e^{\frac{-1}{4}} + 0.0075\sqrt{\frac{D}{2R_c}}$$

Variables

R_e = Reynolds Number = 7,745,000

R_c = Radius of Curvature (estimated for worst case) = 4.5 inches or 0.1143 m

D = 0.088 inches or 0.0022 meters

Darcy-Weisbach Pressure Loss Equation for Turbulent Flow

$$\frac{\Delta p}{L} = f_D * \frac{\rho}{2} * \frac{V^2}{D}$$

Variables:

$f_D = 0.006$

Δp = pressure loss = 9524 Pascal's or 1.38 psi

Table 7. Pressure Loss Calculation Data.

Calculated Variables				
Unit System	English	metric	English	metric
Velocity	n/a	m/s	n/a	42.5
Reynolds Number	unitless	unitless	unitless	7450000
Fd Friction Factor	unitless	unitless	unitless	0.006
Pressure Loss	psi	Pascal's	1.18	8140

Section 5.5.2 Instron Data

Instron testing, using an Instron 5544 machine and TestWorks 4 Software, was conducted using methods described by ASTM standards called out in methods and Boston Scientific protocol. Three mechanical tests were employed – 3 point bending, compression, and tensile tests. The three point bending characterized the catheter's response to shear stress, the compression test characterized the response to columnar buckling forces, and the tensile test characterized the intrinsic mechanical properties of the material. The average values recorded for Peak Load, Peak Stress, Strain at Break, Modulus, Yield Stress, Kink Force and Column Buckling Force are reported in Table 8. These tests were performed as simple tensile tests as seen in Figure 22, guided three point bend tests as seen in Figure 23, or columnar compression buckling tests, as seen in Figure 24. The raw data can be found in the appendix.

Table 8. Average Values from Instron Testing.

	OD (in)	ID (in)	Peak Load (N)	Peak Stress (MPa)	Strain at Break	Modulus (MPa)	Yield Stress (MPa)	Kink Force (N)	Column Buckling Force (N)
Competitor	0.100	0.072	36.4 ± 3.34	14.9 ± 1.36	5.40 ± 1.49	126 ± 18.2	27.5 ± 8.07	1.04 ± 0.020	10.5 ± 1.10
Nylon 12	0.131	0.111	111 ± 1.40	45.2 ± 1.26	4.73 ± 0.493	550. ± 42.9	26.3 ± 2.46	6.35 ± 0.100	86.7 ± 5.08
Polypropylene	0.121	0.096	31.3 ± 0.970	11.4 ± 0.354	6.56 ± 1.30	183 ± 46.7	30.7 ± 1.69	0.916 ± 0.035	17.0 ± 2.24
20% HDPE 80% Topas	0.118	0.088	90.2 ± 5.32	28.8 ± 1.71	0.06 ± 0.007	600. ± 64.5	21.7 ± 21.4	9.63 ± 1.33	93.8 ± 6.49
LDPE	0.118	0.088	34.3 ± 2.23	11.0 ± 0.728	4.14 ± 0.465	90.8 ± 11.3	29.8 ± 0.398	1.50 ± 0.062	11.4 ± 1.05
Material X	0.130	0.100	97.6 ± 2.14	27.9 ± 4.59	3.01 ± 0.335	379 ± 23.1	11.3 ± 1.35	6.35 ± 0.193	50.7 ± 4.12
Material Y	0.130	0.100	100. ± 22.19	28.613 ± 6.27	2.70 ± 0.452	674 ± 43.1	15.9 ± 2.21	10.8 ± 0.101	93.1 ± 5.38

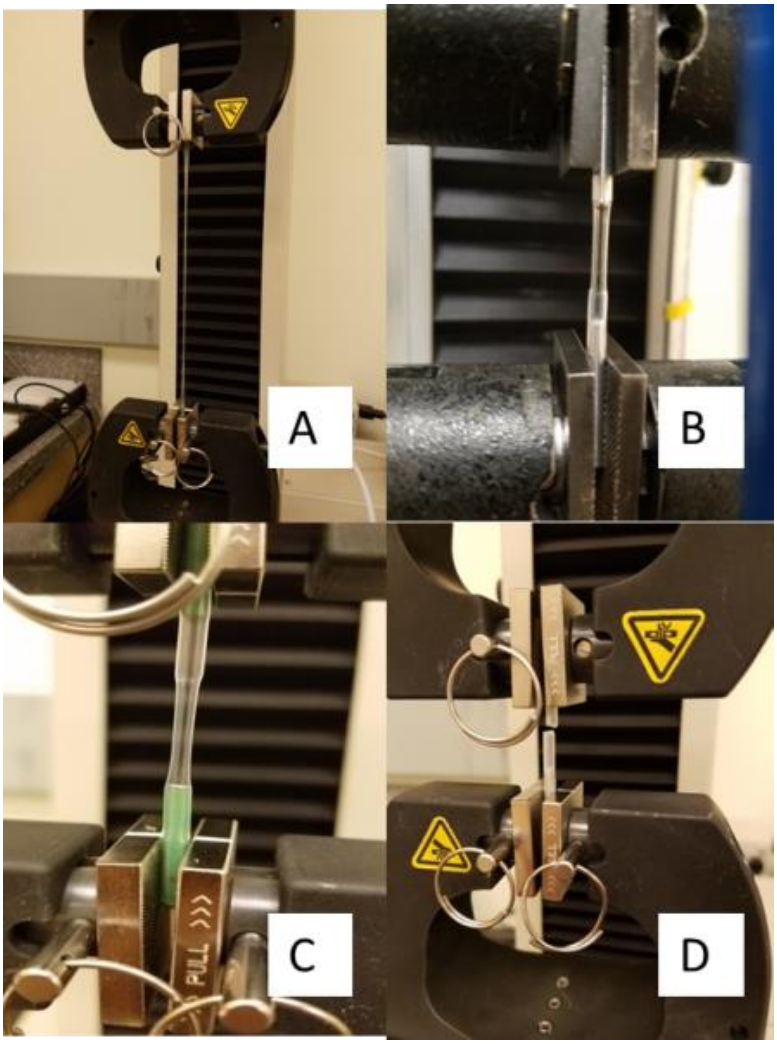


Figure 22. In this image four materials are being tested in the Instron for tensile properties. Material A is polypropylene which had a low modulus but high strain at break, Material B (LDPE) and C (Nylon) show the polymers aligning and stretching very far but Nylon had a higher modulus than A or B. Material D is HDPE/Topas Blend which had the highest modulus but cracked with almost 0% strain at break which is not ideal.

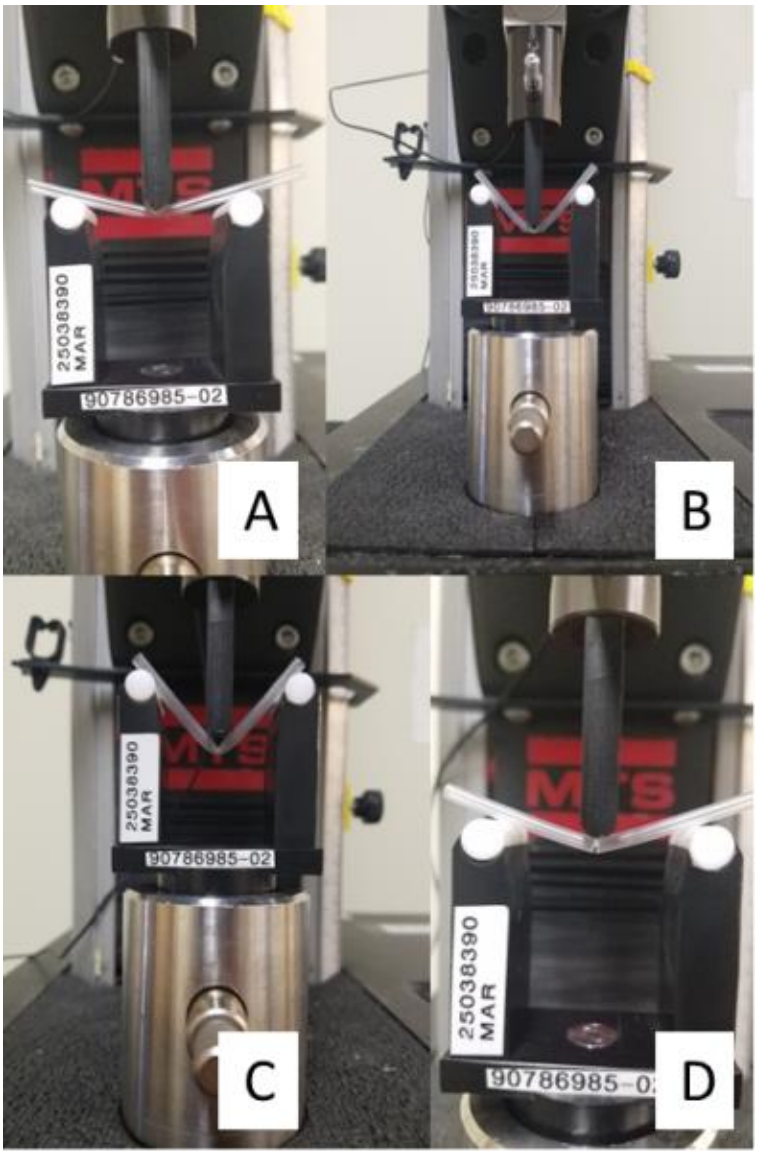


Figure 23. In this image four materials are being tested in an Instron for kink resistance by Three Point Bend testing. These pictures were taken at the point of first kink. Material A is Polypropylene which kinked under very little stress and low deformation, Materials B (LDPE) and C (Nylon) kinked with a larger deformation but Material C had a higher kink stress than A or B. Material D is HDPE/Topas Blend which kinked under a large force and also cracked which is not ideal.

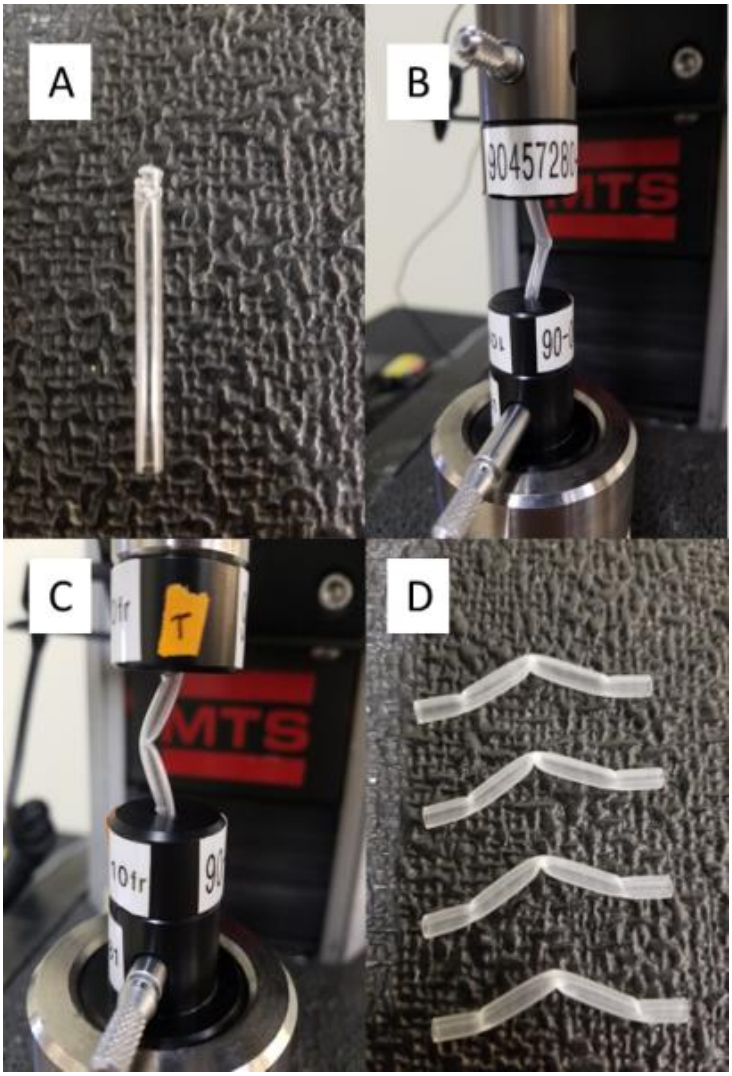


Figure 24. In this image four materials are tested in the Instron for column strength properties. Material A is polypropylene which "accordioned" when compressed, Material B is LDPE which had the lowest column buckling strength, Material C is Nylon which had a high column buckling strength, and Material D is HDPE/Topas Blend, this material was the only material that did not partially recover from kinking.

Section 5.6 Tip Modification Testing Results

The design for the catheter plugs were tested by placing them into the end of the catheter. The pressure of the system was controlled by the compressed air wall unit. The compressed air was fed through the hoses and a gauge measured the pressure just before the catheter. The setup for this test can be found in Figure 25. The end of the catheter containing the cap was placed inside a plastic bag to prevent the loss of the cap. The pressure gauge was placed near the end of the catheter so the instantaneous pressure can be recorded when the catheter cap blows off the end. The results of testing six different designs are recorded in Table 9. The end cap will also be passed through a scope to determine compatibility. These results will be mentioned in the following discussion section.

Table 9. Pressure Data: The Pressure at Which the Cap Blew out of the Catheter.

	Test 1 – psi	Test 2 – psi	Test 3 – psi	Test 4 – psi	Test 5 – psi	Test 6 – psi	Test 7 – psi	Test 8 – psi	Test 9 – psi	Test 10 - psi
Long Flat Cap	Did not work									
Short Flat Cap	Did not work									
Bullet Shape Cap	Did not work									
Cup with step	11	9.5	10	10	12	9	10	9	9	9
Cone with step	11.5	10.5	10.5	10.5	11	11.5	11	11	11	10
Bullet With Step	15	14.5	15	14.5	15	14	14.5	14	14	14

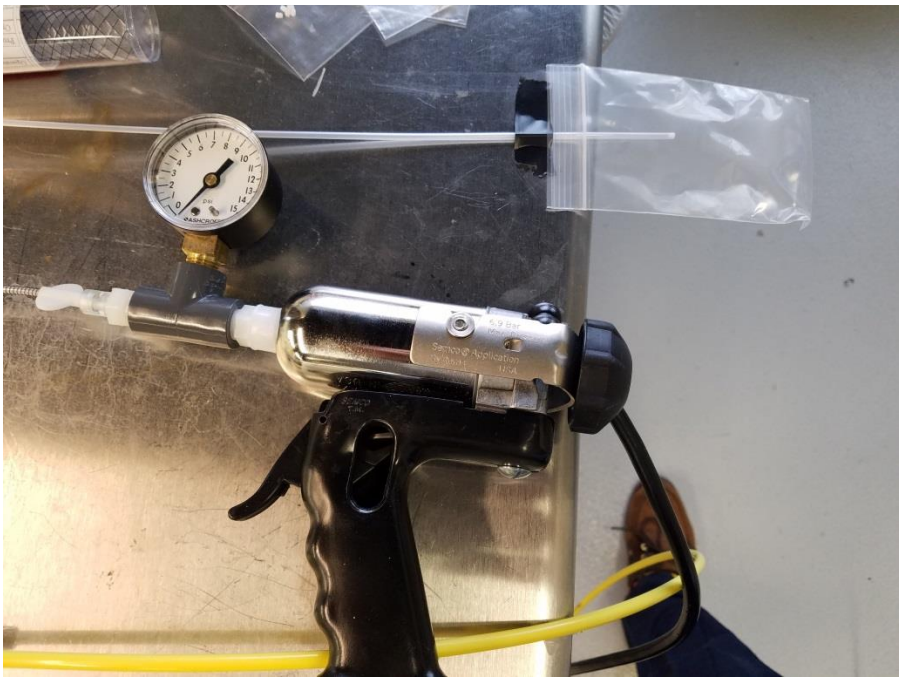


Figure 25. Setup for the end cap test with the pressure gauge and end cap close to each other to improve accuracy of results.

After the first few designs did not blow out of the catheter, the force required to remove the plug from the spray gun using the pressurized CO2 was back calculated. The force required to blow out the plug must overcome the frictional force of the plug on the catheter. The first three designs of catheter plugs required 35 psi to blow out. Using the equation, $P = \frac{F}{A}$ pressure equals force divided by area, and solving for force; the plugs required 0.93 N to blow out of the pump. The equation was solved using the cross-sectional area of the catheter as the area and blow out pressure as the pressure variable.

To reduce the force the surface area of the plugs in contact with the catheter were reduced, thus reducing the frictional force. These plugs successfully blew out of the catheter. These new plugs only require 12 psi to blow out of the catheter. Using the same equation and solving for force; these plugs only require 0.31 N of force to remove them from the catheter.

Chapter 6 Final Design and Validation

Section 6.1 Ex-vivo Analysis

During Ex-vivo testing anecdotal clogging information was obtained. For this experiment a catheter was passed down an endoscope in challenge conditions including arterial bleeding, wet scope channel, and frequent contact with the mucosal wall. From these observations it was determined that passing the catheter through a wet environment causes clogging and immediate failure of the device. This is detrimental since no treatment can be applied. The model also showed that bumping the catheter into the mucosal wall or into a pool of blood will clog the catheter. From these observations, it was determined that the catheter must be protected while traveling down the scope through a wet environment.

Section 6.2 Quick Connect Analysis

The Quick Connect piece was tested in a head to head spray test with a Qosina off the shelf fitting. Each fitting was tested by spraying powder from the powder canister for 5 seconds while recording the initial and final weight to deduce amount of powder sprayed. While the SLA designed fitting had less powder pass through it, 2.2 grams, than the Qosina fitting, 2.6 grams; it was determined that the SLA fitting was equivalent to the Qosina fitting. Equivalency was determined by speaking with the client and mechanical device contractor. Reasons for the discrepancy between spray amounts can be attributed to different catheter material, SLA parts being slightly rough after printing, and a shortened catheter length of the Qosina fitting test compared to the SLA fitting test. Additionally, the Qosina fitting clogged before spraying powder in four of fifteen scenarios. The SLA fitting did not clog once thus meeting the objective

for this piece. The part is designed specifically for the catheter attaching to it – the inner diameter tapers directly into the inner diameter size of the catheter.

Flow Simulations were completed in SolidWorks 2016. These simulations show the pressure gradient pattern and flow trajectories. The pressure is slowly stepped down across the length of the custom SLA fitting where there is obvious pressure mixing and nonlinear flow trajectory in the Qosina fitting. This led to choosing the SLA fitting over the Qosina fitting for the final design.

Section 6.3 Pressure Loss Calculation Analysis

Pressure loss calculations were performed on the catheter itself. The pressure loss may not have any impact on design considerations but it will be important for powder delivery to characterize the losses experienced. Several assumptions were made including turbulent flow, which was later proven with the large Reynolds number, smooth pipe, flow rate of 10 liters per minute, and a coiled tube (for worst case scenario). The losses amounted to 1.18 psi which is inconsequential in terms of powder delivery. Powder will flow through the tube if there is a pressure differential. For these calculations, the dynamic viscosity was assumed to be similar to the dynamic viscosity of air. This value was chosen because the powder is fluidized and there is a small amount of aggregate per volume of air – the smaller the volume of aggregate per volume of air – the more it will act similarly to air (Barthelmes et al., 2003). It is noted that if the dynamic viscosity increases by a factor of 10 then there will be significant losses, up to 2 psi. However, this is not the case since there is still air flowing through the distal end of the catheter during experimental tests. Since the system runs close to 2.5 psi, the powder will still flow out of

the tubing. There will be no/negligible pressure loss when the cap is on the end of the tube. The system will build pressure until the cap blows off.

Section 6.4 Mechanical Properties of the Catheter Analysis

Catheter materials were tested for mechanical properties on an Instron 5544. Three mechanical tests were completed including three point bending, column buckling, and tensile tests. Prior to the Instron testing, Modulus, Kink Stress (resistance to kinking per unit area), Compressive Stress (resistance to column buckling force per unit area), and strain at break, were identified as variables of interest. As mentioned previously, column buckling stress and kink stress were chosen to normalize the forces by dividing by area such that the samples with different wall thicknesses could be compared against one another. Modulus is a normalized measure of the materials stiffness while kink and compressive stresses show the resistance to kinking. Strain at break shows some measure of flexibility. All of the materials were compared to the competitor product. After final testing, Material Y out performs the Competitor product in Modulus, Kink Stress, and Compressive Stress. This material also passed the tortuous anatomy test. Material Y has a modulus of 674 MPa, a kink stress of 603 MPa, a compressive stress of 266 MPa, and average strain at break value of 2.70 in/in. This material has a high enough modulus to resist kinking when passing through the biopsy cap; this defining feature separates Material Y from Material X in the final design selection.

Section 6.5 Tip Modification Analysis

The tip modification which resulted in the end plug was tested by spray test and scope passability. The initial plug designs would not blow off with a pressurized system which prompted a redesign of the plug. The redesigned plugs worked effectively in the spray test.

However, these plugs upon passing them through the scope would catch on the biopsy cap (entry port for medical devices through the scope). The plugs would be pulled out of the catheter in situations where the physician would put the catheter down the scope but remove it from the scope before deploying the spray mechanism. Size limitations complicated the tip modification process, a one-way valve would have been preferred since spraying could occur multiple times in treatment, but this design met the goal of being able to pass through a wet environment and not clog. The plug that catches on the biopsy cap was redesigned to be an internal plug which will blow out like the initial designs.

Section 6.6 Device Factors

Device design must encompass many different aspects. Some that have not been covered in the material thus far will be elaborated upon in this section. These factors are impacts of the device not outside of its indicated function.

Economics

The medical device may not have an enormous impact on country specific or world economics, but may prove a useful tool in a subsection of lesser trained physicians and emergency bleeding cases. These cases are where the economics of this device will be felt. The minimalistic approach to designing this catheter will reduce the total cost of the device such that it can be more affordable for hospitals, patients, and insurance companies. The price of the device should be less than or equal to the cost of two hemostatic clips. At this price point the doctor could provide drastic hemostatic control to large areas reducing time in the operating room. This could slightly impact the hospital operating cost and the patient who will be paying for less time in the operating room.

Environmental Impact

This project may have negative environmental impacts. The device itself is disposable creating more trash in the environment. The device will be disposed of as hazardous waste and potentially burned while being sterilized in an autoclave or other process. This may release fumes from plastic into the atmosphere. However, if Material Y does survive the autoclave it is recyclable both pre and post-consumer. Scraps from production can be reused and scraps after sterilization can be sent to recycling as well. The plug however will need to be filtered out of the sewage system. The quick connect if injection molded out of polycarbonate can be recycled with high yield from recycling centers (Plastic Expert 2017).

Societal Influence

Projecting societal influence is difficult, but if used properly and approved by the FDA this project may contribute to a device that increases survival rate from drastic gastrointestinal bleeding. The delivery system should provide a more reliable device to deliver hemostatic powder potentially increasing its usage rate across Europe where a similar product currently is available. The product may also appear in other emerging markets such as the United States pending FDA approval.

Political Ramifications

There are no political ramifications due to this product. This product is an addition to a hemostatic platform. It does not push the boundaries of ethics or political lines.

Ethical Concerns

Since this device is targeted to be used as a last resort salvage therapy there are not many ethical concerns. The device's projected cost is targeted lower than other salvage therapies such as large amounts of clips or open surgery. The device if used properly may have the opportunity

to allow doctors or nurses with minimal skill in endoscopy treat drastic gastrointestinal bleeding cases.

Health and Safety Issues

This device has the potential to benefit the patient but may also pose some risk as with any medical device. This medical device may have the positive impact of providing physicians with a lifesaving tool and a platform to effectively and consistently deliver a hemostatic agent to a potentially fatal bleed. The negative impact of this device can be seen if used improperly. If the device were to fail the patient may need immediate surgery to attenuate the bleeding that the device was initially supposed to stop. Additionally, the device leaves behind a small plastic plug. This plug can be made of a bio absorbable material such that it will not affect the patient. It is also applied to the gastrointestinal tract such that the plastic may just pass through the GI tract as any hemostatic clip or band would. The device poses no health or safety concerns for the doctor or technician. This device should provide a more stable platform that is more reliable than current methods for powder delivery.

Manufacturability

In order to manufacture this product GMP (good manufacturing processes) and GDP (good documentation practices) processes must be followed and the FDA will be informed upon filing for approval. ISO standards for quality management of medical devices and catheter compliance can be found in ISO 13485 and ISO 209695 respectively. Since this product is a piece of a larger device it will require documentation of any changes during manufacturing and the subsequent reporting to the FDA. The product must adhere to the ISO standards for sterility specifically ISO 11737-2:2009. ASTM methods in conjunction with validated BSC test methods should be used to validate and verify the designs and products produced by manufacturing.

In addition to standards manufacturing of the components requires planning and execution. It is recommended that the previously SLA parts (the quick connect and the end plug) be injection molded. Injection molding allows for smooth surface finish and high volume production. This will aid in decreasing cost. The cost for the mold will be the initial investment after which the production of the parts will be quick and efficient. The catheter will be extruded which is common practice and technique across the industry. Difficulties extruding specific materials such as HDPE occur during the cooling phase. The material forms an oval shape. The problems can be avoided with vacuum controlled chambers. These chambers on the end of an extrusion machine allow for standardized wall thickness throughout the catheter. It is recommended that the extruder use a vacuum chamber regardless of material such that the tolerances on the catheter can mesh well with the tolerances of the catheter plug.

A final processing step may be required. Tipping the catheter with LDPE can add flexibility needed to be used in an endoscope with an elevator used to access the biliary ducts. The tipping process can also aid in tightening the tolerances.

Sustainability

The sustainability aspect of this product is minimal since it is made from materials found commonly throughout the medical industry. Sustainability is increased through the manufacturing process. 3D printed prototypes reduce waste while offering rapid iteration and prototyping. The quick connect and plugs are created with SLA but should later be injection molded. The material will need to be chosen by BSC to reduce cost and eliminate waste. Recommendations for this material include ABS or PEEK 9poly-ether-ether-keytone). Both of these materials are sustainable, having been used in many major industries including the medical industry. The catheter material materials tested are sustainable since they have minimal

environmental impact. This project does not relate to renewable energy since the materials will be disposed of as hazardous waste.

Chapter 7 Discussion

When considering this project in its subdivisions, the breakdown includes three main parts – the connection from catheter to delivery device, the catheter, and a tip modification. Each of these three subdivisions accomplishes a different task fulfilling the objectives of the project laid forth in the client statement. Objectives were determined by working closely with the client outlining each important aspect of the project. They were further defined by working with physicians using a works like model prototype in an animal lab at CBSET.

From observations and conversation, it was determined that the most important aspect of this project is reducing the likelihood of clogging and reducing the likelihood of kinking. Clogging was noted in two regions of the works like device – the connection between catheter and delivery device and at the end of the catheter post powder delivery. Kinking was noticed as the physician passed the catheter quickly down the working channel of the endoscope.

Problem 1 Clogging in the Connection – The cause of the clogging in the connection was determined to be a steep taper which is common to all off the shelf fittings as most are designed to accommodate liquids. Tens of fittings were ordered and tested in the works like prototype and every fitting with a stepped taper increased the likelihood of clogging. From this data, a Computer Aided Design model was created in SolidWorks which decreased the radius of the Luer Lock fitting down to the inner diameter of the catheter without any stepped transition. This design was constrained by the fact that it must connect by Luer Lock as determined in the objectives. Multiple models with different taper lengths were created in SolidWorks and tested in a flow simulation. The images containing flow contours and flow vectors were compared to the off the shelf fitting. Through comparison it was apparent that the off the shelf fitting operated at higher pressure with mixing flow at the transition between taper and catheter. The custom

designed fitting offered a slow transition from high to low pressure regions with straight flow vectors. The custom model was 3D printed using a SLA machine. The conclusions drawn from this test were confirmed through functionality testing with the works like prototype. This connection minimized the rate of clogs in the connection while accommodated the correct particle size. Future development may consider injection molding the parts in order to create a smoother surface finish and colored parts for aesthetics.

Problem 2 Kinking of the Catheter – The kinking of the catheter was commonly a result of the physician sending the catheter down the working channel of the endoscope. In order to characterize kinking properties of catheters, three mechanical tests were employed – 3 point bending, compression, and tensile tests. The three point bending characterized the catheter's response to shear stress, the compression test characterized the response to columnar buckling forces, and the tensile test characterized the intrinsic mechanical properties of the material. This design was constrained by the size of the working channel of the scope and the extrusion processes. Wall thickness for the final prototype was determined optimal at 130 thousandths of an inch outside diameter and 100 thousandths of an inch in inside diameter. This was determined by the extrusion process, trial and error, as well as benchmarking the competitor device.

All catheters were benchmarked and compared to a competitor product which was made of Polyethylene. Initially, catheters that were readily available were used in the works like model. Two materials, Nylon 12 and a 20% HDPE 80% Topas blend, were available for use in the prototype. These materials have significantly higher values for Average Modulus (549MPa Nylon12 and 600MPa HDPE/Topas) compared to the competitor (126MPa Polyethylene). The available materials also had higher values for Average Kink Stress (463MPa Nylon and 647MPa HDPE/Topas) compared to the competitor (113MPa). Both materials have higher Average

Compressive Stress than the competitor (353MPa Nylon 12, 299MPa HDPE/Topas, 43MPa Competitor). The competitor has a higher Average Strain at Break than the two available materials (5.39 Competitor, 4.71 Nylon 12, 0.06 HDPE/Topas). Nylon performed well and was kept along as the best performing material into the next iteration of material choice. HDPE/Topas blend was too brittle compared to Nylon or the competitor and was discarded as an option.

The next iteration of catheter design was directed toward mimicking the properties of the competitive product. HDPE was chosen as the material of choice to be extruded and tested, however due to extrusion limitations this material was tabled for future development since it could not be extruded in house and a request would have to be sent to Maple Grove, MN at another Boston Scientific site. Polypropylene was chosen as a substitute for HDPE and LDPE was also extruded to provide the opposite end of the spectrum compared to the HDPE/Topas blend tested earlier. LDPE (90.83MPa) had a lower modulus than the competitor (126MPa) and polypropylene had a larger modulus (183MPa). Both LDPE (104MPa) and Polypropylene (68MPa) had lower kink stresses than the competitor (113MPa). LDPE (36MPa) had a lower average compressive stress than the competitor (43MPa) and polypropylene (61MPa) had a larger compressive stress than the competitor. LDPE (4.14) had a lower strain at break compared to both the competitor (5.39) and polypropylene (6.6). Due to the substantially low kink stress of polypropylene, this material was discarded from final material selection. Polypropylene kinked under its own weight at times. While LDPE nearly matched all of the properties of the competitor device the difference in modulus was enough to discard LDPE from final material selection as well. The reduced stiffness led to issues when passing the catheter down the scope

working channel. While the LDPE material did not kink, it could not pass down the scope working channel without bending.

The final catheter iteration was completed and the goal of this step was to optimize kink resistance in both shear (3 point bending) and compression (column buckling). Materials X and Y were extruded in an attempt to optimize these properties while retaining a high modulus and some flexibility. Both Materials X (379 MPa) and Material Y (674 MPa) had higher moduli than the competitor material. They both had higher kink stress, 353MPa (X) and 603 MPa (Y), compared to 113 MPa for the competitor. They both had higher compressive stress compared to the competitor as well: 145 MPa (X), 266 MPa (Y), 43MPa Competitor. They both had lower strain at break than the competitor: 3.01 (X), 2.70 (Y), 5.50 (competitor).

Static was noted and determined to be a nonfactor in terms of clogging or kinking as static clogging was never observed in spray testing even when the catheter had a static charge that maxed out the static detector at 30 Kv. Due to the lack of static clogging it can be removed from the objectives section – it has been left in this section as a note for future reference.

Material Y was determined to be the optimal material for powder delivery as it outperformed the competitor device in several categories of mechanical testing, passed down an endoscope, and retained flexibility to work in tortuous anatomy. Material X also passed all tests but it was unable pass through the biopsy cap of the scope without kinking.

Problem 3 Clogging at the Catheter Tip – The clogging at the tip of the catheter was due to the accumulation of moisture in the catheter tip. Moisture enters the catheter tip when passing the catheter down the scope channel. The first successful modification of the works like prototype to solve this problem was to pump low pressure air down the catheter as the physician

passed the catheter down the scope channel. This worked for initial studies but was ruled out as a feature to be included in the final design due to limitations of the volume of air needed. The volume of air needed raised concerns with the physician about over filling the patient with air and it raised concerns with engineers because the air is needed to expel powder. Next during brainstorming fourteen designs were conceptualized in order to prevent clogging, allow powder to flow in the event of a clog, or eliminate clogging entirely. These designs worked on the principal of a one-way valve, thin film, directed powder flow, vibration, and caps and plugs. These designs were ranked and down selected using a design selection matrix. Most of the designs were excluded due to difficulties of manufacturing or cost. The top choice, a cap and plug design, was chosen for prototyping. Two designs for this concept were developed in SolidWorks and 3D printed using SLA. Neither design was able to be blow out of the end of the catheter at a reasonable pressure (<15psi). A modification was made to reduce the surface area of the plug that comes in contact with the catheter wall. This modification was successful and the plug blows out at 9.85psi which will not perforate skin, stomach, or intestine.

The cap and plug concept would leave a hard piece of plastic behind in the GI tract, this was determined to be a nonissue since medical devices such as metal clips are often left behind for months in the same region. Future development may consider making the plastic plugs softer.

Final Design Testing

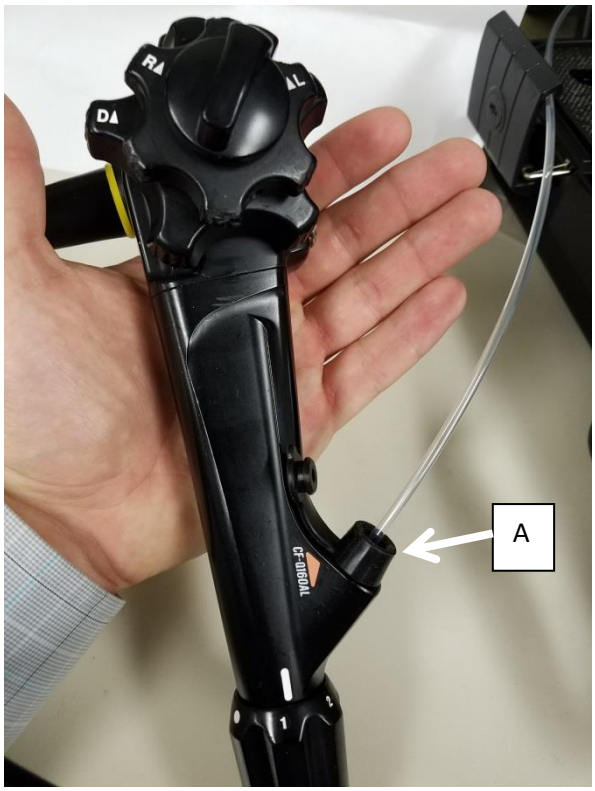


Figure 26. The final design being fed through the scope as a final functionality test. "A" calls out the biopsy cap which is a tight piece of flexible plastic through which devices are passed while maintaining insufflation pressure.

To validate the final design, the final assembly was put through three tests: scope passability, tortuous anatomy, and moist spraying conditions. These tests were all functionality based and pass fail with ten trials per test. Scope passability was successful in 10:10 cases. The catheter passed through the biopsy cap without kinking or buckling under the pressure as seen in Figure 26. Four people were chosen to push several different prototypes through a biopsy cap and through the scope. Three people chose Material Y with an outer diameter of 0.130 inches and inner diameter of 0.100 inches as their optimal choice. The fourth person chose Material Y

with an outer diameter of 0.092 inches and inner diameter of 0.072 inches. This confirms Material Y as the optimal catheter material.

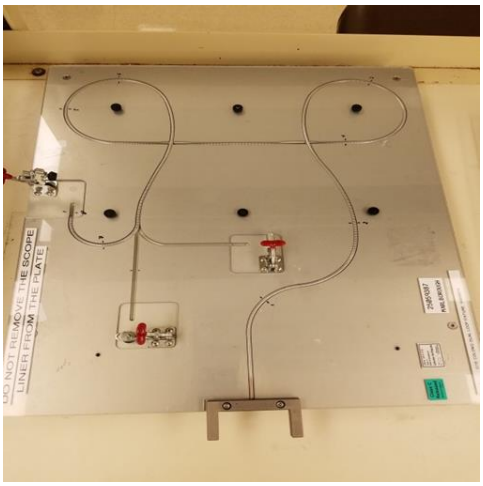


Figure 27. The tortuous anatomy track developed to mimic the most tortuous paths in the GI tract that a medical device may have to follow.

The final assembly was passed through a tortuous anatomy path 10 times and this passed each time as well. This scenario was looking at kinking in sharp turns. An example of the tortuous anatomy path can be seen in Figure 27. The final test for the assembly was to submerge the endoscope in water and pass the catheter with the plug through the wet channel, blow the cap off, then spray powder. The device successfully blew off the cap and sprayed powder after passing down the moist scope channel. A final design consideration should note that the catheter plug, if passed through the biopsy cap and not blown off then removed, will catch on the biopsy cap and pull out of the catheter. This leaves behind the small plastic plug on the underside of the biopsy cap. This is not ideal but does not decrease the efficacy of the device. In order to solve this problem the physician may remove the biopsy cap and remove the plastic plug, or future developments can improve upon the design such that it does not catch in cases where the physician may pass the device into the scope but pull it back without spraying.

Chapter 8 Conclusion

Though observation, three main problems were identified in the competitive device and the current works like model for a gastrointestinal powder delivery system. Through design iteration each of these three problems, namely clogging in the catheter connection, catheter kinking, and clogging in the catheter tip, were minimized.

Through analysis of the results it can be concluded that there is substantial need to a Luer Lock fitting without any stepped surface or sharp taper. This was then confirmed through SolidWorks modeling, flow simulations, 3D printing and testing. Clogging is substantially reduced from 4 instances in 15 tests to 0 instances in 15 tests. Catheter material selection minimized the amount of kinking by choosing a material with properties such as high kink resistance and high columnar strength but also high strain at break which includes the flexibility component. Material Y was determined to be the optimal material for powder delivery as it outperformed the competitor device in several categories of mechanical testing, passed down an endoscope, and retained flexibility to work in tortuous anatomy. Material Y did not kink during final testing where Material X did. The tip modification also reduced the occurrence of clogging when passing the catheter down the working channel of the endoscope.

Higher quality extrusion equipment and vacuum extrusion chambers may have provided significantly better results in extruding materials with accurate dimensions or difficult to extrude materials like HDPE. Recommendations for future work include extruding HDPE and HDPE/LDPE blends and testing them to the same parameters set forth in this report.

An injection molded quick connect feature may have provided more accurate results during spray tests. The surface finish of the material can be controlled by polymer selection,

melting temperature, and cooling temperature. This process can create smooth surface which will allow powder to pass through the quick connect with less agitation. Recommendations include injection molding the quick connect part in the future.

The tip modification may have the most room for recommendations and future improvements. The cap and plug idea may need to be created from a softer material which will grip the hard-plastic catheter slightly better and potentially reduce irritation for patients. Future recommendations include considering a one-way valve system as well as a thin film that can blow out during powder spray.

Appendices

Quick Connect Procedure for Appendix:

1. Hold spray gun upside down and screw on the canister

2. Flip the gun right side up and hold the gun right side up for 15 seconds

3. Begin the 5 second timer and pull the trigger at full force

4. Tap the side of the gun and shake vigorously as you are spraying

5. When the timer is up stop holding the trigger and flip the gun to the upside down position

6. Remove the powder canister with the remaining powder inside of it

7. Weigh the powder canister and remaining powder, record this number

8. Record the difference between starting weight and final weight

9. Record on a 1,3,5 spectrum how the powder spray performed qualitatively with static and visibility

10. Finally add powder to the powder canister to bring it close to the initial weight. Record

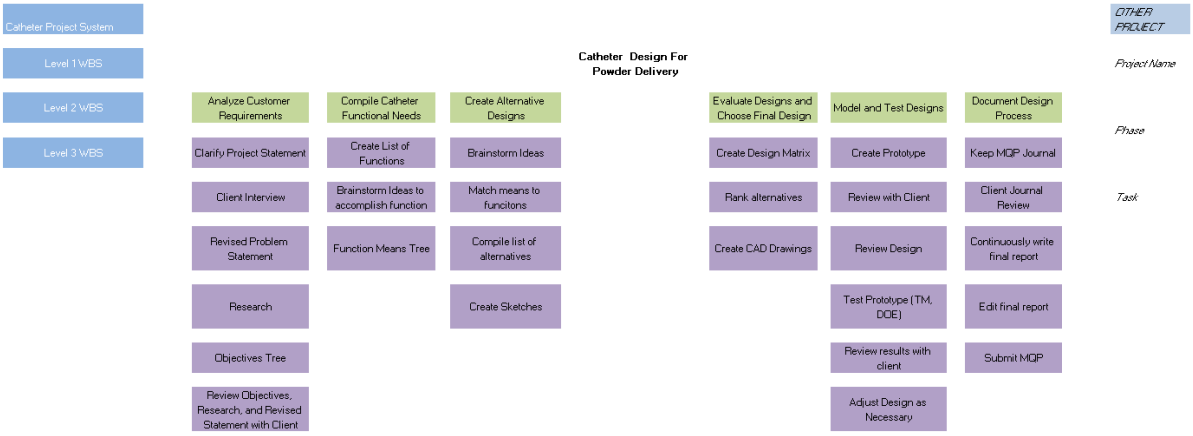
11. Clear Catheter and block by spraying air through it covering the powder insertion point then letting go 2-3 times

12. Repeat the steps.

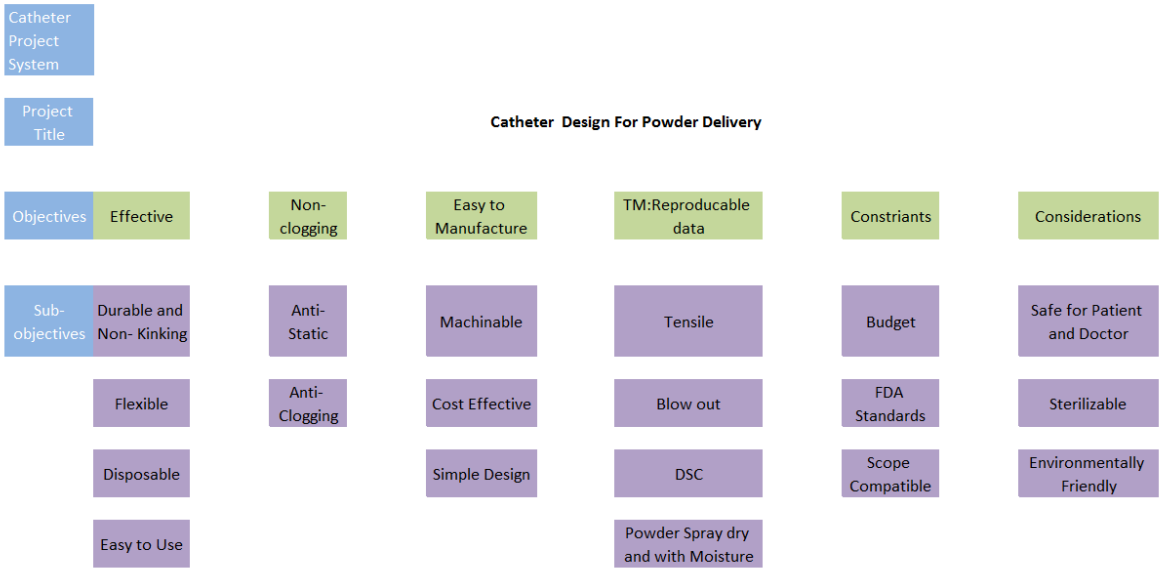
Fittings:

- Pressure Gage by dip coater set to 20psi (drops to 10 when spraying).
- Nylon tubing
- Spray gun that includes attached black tubing
- Catheter (old – Nylon) – Used with Qosina Fitting
- Catheter (new – LDPE) – Used with SLA Fitting
- One way ball valve 1/4 - 1/4 NPT
- Luer Lock Connector 1/8 NPT - Luer
- Luer To catheter connection SLA
- Spacer that creates continuous Diameter for powder spray channel from block to catheter
- 1/4 - 1/4 NPT connector from Semco Small Canister to block
- Block 1 with air hole that is the same diameter as the inner channel

Work Breakdown Structure - Andrew Pic MQP



Objectives Tree



Raw Instron Tensile Data: Values highlighted in yellow were not included in calculations due to samples slipping at the grip.

Peak Load N	Competitor	Nylon 12	Polypropylene	20% HDPE 80% ToPAS	LDPE	PEBAX	Nylon -New Dim
Test 1	39.262	115.484	32.065	94.156	33.834	105.07	121.6632652
Test 2	33.986	115.409	32.667	82.432	30.717	105.84	85.26792918
Test 3	35.354	102.665	31.537	86.371	33.911	108.68	123.4558979
Test 4	41.268	112.379	29.1	89.228	31.716	103.08	88.11034176
Test 5	30.443	114.115	31.366	93.418	35.86	105.74	97.33595004
Test 6	40.307	112.006	31.293	98.228	35.354	65.84	81.65152632
Test 7	35.253	109.58	31.195	82.081	33.351	106.79	68.09335176
Test 8	35.742	108.029	31.198	89.937	33.582	103.94	140.5415109
Test 9	38.346	112.273	30.798	94.932	35.888	69.38	103.2164969
Test 10	34.046	106.811	32.232	90.812	38.49	101.92	93.75958116
StDev	3.34393777	4.10271123	0.97046409	5.324361083	2.2339075	2.1434468	22.19012868
Average	**36.4007**	**110.8751**	**31.3451**	**90.1595**	**34.2703**	**97.628**	**100.3095851**
Peak Stress Mpa	Competitor	Nylon 12	Polypropylene	20% HDPE 80% ToPAS	LDPE	PEBAX	Nylon -New Dim
Test 1	16.1	46.884	11.7	30.1	10.8	30.34	34.47
Test 2	13.9	46.884	11.9	26.3	9.8	30.34	24.13
Test 3	14.5	43.437	11.5	27.6	10.8	31.03	35.16
Test 4	16.9	45.505	10.6	28.5	10.1	29.65	25.51
Test 5	12.5	46.194	11.4	29.8	11.5	30.34	27.58
Test 6	16.5	45.505	11.4	31.4	11.3	18.62	23.44
Test 7	14.4	44.815	11.3	26.2	10.7	30.34	19.31
Test 8	14.7	44.126	11.4	28.7	10.7	29.65	39.99
Test 9	15.7	45.505	11.2	30.3	11.5	19.99	29.65
Test 10	14	43.437	11.7	29	12.3	28.96	26.89
StDev	1.3603921	1.26703221	0.35418137	1.709093327	0.7276293	4.5891132	6.278239403
Average	**14.92**	**45.2292**	**11.41**	**28.79**	**10.95**	**27.926**	**28.613**
Strain at Break	Competitor	Nylon 12	Polypropylene	20% HDPE 80% ToPAS	LDPE	PEBAX	Nylon -New Dim
Test 1	7.015	5.513	8.974	0.06	4.144	3.14	2.51
Test 2	4.473	4.734	7.295	0.043	3.594	3.06	0.05
Test 3	3.99	4.29	7.24	0.055	4.28	2.64	2.38
Test 4	6.191	4.378	5.591	0.066	4.442	2.69	0.05
Test 5	2.894	5.045	7.389	0.059	4.825	3.23	0.07
Test 6	7.244	4.26	5.67	0.067	4.176	0.12	0.05
Test 7	4.654	3.997	4.622	0.053	3.7	3.63	0.03
Test 8	5.837	4.885	5.26	0.067	3.536	3	3.22
Test 9	7.104	5.341	6.331	0.063	3.918	0.12	0.07
Test 10	4.597	4.808	7.208	0.061	4.818	2.7	0.06
StDev	1.4928577	0.49342487	1.2981385	0.007486284	0.4650845	0.3354501	0.452143045
Average	**5.3999**	**4.7251**	**6.558**	**0.0594**	**4.1433**	**3.01125**	**2.703333333**
Modulus (Mpa)	Competitor	Nylon 12 ksi	Polypropylene	20% HDPE 80% ToPAS	LDPE	PEBAX	Nylon -New Dim
Test 1	126.371	474.407	153.138	653.271	86.311	351.86	680
Test 2	145.806	572.595	138.769	718.744	87.016	364.51	698.94
Test 3	125.68	577.512	237.624	574.411	93.341	354.94	687.07
Test 4	100.739	540.907	109.587	504.406	81.386	370.7	667.98
Test 5	140.281	472.801	172.863	600.726	82.3	385.8	656.83
Test 6	110.786	580.297	188.393	641.112	81.854	397.78	674.44
Test 7	144.482	559.951	272.614	647.646	108.199	377.47	743.85
Test 8	108.432	567.369	194.796	535.908	108.658	382.59	575.89
Test 9	109.995	597.307	174.689	555.693	100.88	431.363	698.46
Test 10	150.795	553.608	190.183	574.122	78.445	370.88	652.52
StDev	18.2150301	42.9374779	46.7178183	64.48835409	11.34167	23.132096	43.10546751
Average	**126.3367**	**549.6754**	**183.2656**	**600.6039**	**90.839**	**378.7893**	**673.598**
Yield Stress Mpa	Competitor	Nylon 12	Polypropylene	20% HDPE 80% ToPAS	LDPE	PEBAX	Nylon -New Dim
cross sectional area (me	2.28197E-06	2.45246E-06	2.74889E-06	3.13145E-06	3.1315E-06		
Test 1	23.362	26.665	31.601	14.503	30.649	12.08	19.29
Test 2	22.515	26.122	32.667	82.432	29.954	12.08	15.1
Test 3	35.354	29.85	31.328	15.137	30.231	10.07	16.7
Test 4	41.268	22.101	26.947	13.674	29.573	10.47	14.59
Test 5	23.801	29.009	28.554	16.834	29.235	12.97	15.66
Test 6	40.307	23.057	31.293	15.691	29.731	9.6	14.66
Test 7	22.545	25.954	31.195	13.984	29.63	12.64	12.98
Test 8	21.692	26.959	31.198	13.877	29.807	12.78	19.77
Test 9	21.927	24.812	30.798	15.127	30	9.5	16.66
Test 10	22.417	28.169	31.787	15.714	29.545	11.28	13.9
StDev	8.06979851	2.4609601	1.69272652	21.36253406	0.3982133	1.34585	2.214966516
Average	**27.5188**	**26.2698**	**30.7368**	**21.6973**	**29.8355**	**11.347**	**15.931**

Raw Instron Data – 3 Point Bend and Column Buckling.

Kink Force N - 3 point be	Competitor	Nylon 12	Polypropylene	20% HDPE 80% ToP	LDPE	PEBAX	Nylon -New Dim
Test 1	1.067105737	6.360687707	0.938908037	7.90888623	1.453166751	6.6	10.80403246
Test 2	1.021822857	6.319990942	0.890809434	6.877246151	1.568277788	6.48	10.81312017
Test 3	1.029242488	6.392608134	0.907943977	10.65486585	1.504107766	6.45	10.85293174
Test 4	1.050091295	6.371759326	0.980561169	10.78608389	1.524418339	6.35	11.03856041
Test 5	1.055989635	6.26569152	0.904807982	8.910011519	1.417171754	5.87	10.8206777
Test 6	1.054543964	6.163369116	0.921017296	10.18802516	1.497003959	6.43	10.63028498
Test 7	1.034108841	6.484624012	0.88037391	10.63952839	1.435187045	6.37	10.87012411
Test 8	1.034500284	6.495277499	0.886699278	9.715490749	1.474157901	6.34	10.81158998
Test 9	1.061256328	6.389845789	0.965855353	10.04837329	1.463086281	6.31	10.81257304
Test 10	1.005515683	6.293350552	0.883376458	10.6183771	1.620348651	6.27	10.90040759
StDev	0.019538385	0.09951566	0.03530881	1.330609873	0.062242583	0.192818279	0.101033807
Average	**1.041417711**	**6.35372046**	**0.916035289**	**9.634688832**	**1.495692624**	**6.347**	**10.83543022**
Compression Force(N)	Competitor	Nylon 12	Polypropylene	20% HDPE 80% ToP	LDPE	PEBAX	Nylon -New Dim
cross sectional area (me	2.4403E-06	2.45246E-06	2.74889E-06	3.13145E-06	3.13145E-06	3.49628E-06	3.49628E-06
Test 1	11.28958236	83.404125	19.34086056	91.28637084	13.59376032	57.57	89.28912006
Test 2	11.06717136	88.31495988	21.42262752	90.93051324	11.62319886	52.94	85.0277253
Test 3	10.3865937	85.45920264	14.9682603	83.39967678	11.04048204	52.6	89.37808446
Test 4	9.38129598	97.11353904	14.88819234	89.02667508	11.1427911	49.55	94.13323164
Test 5	10.90258722	85.20120588	17.96191236	103.1720147	10.12859694	45.06	95.0139792
Test 6	10.9648623	92.10484332	17.38364376	90.0986961	10.2753882	45.68	102.6070907
Test 7	10.68462444	88.83984984	14.95491564	103.3944257	11.04493026	49.11	92.3672883
Test 8	7.83776364	82.03852146	15.31077324	96.6820617	11.59206132	51.55	88.5640602
Test 9	11.565372	85.28572206	15.3908412	98.69265714	10.6312458	47.28	94.00423326
Test 10	10.8536568	79.67651664	17.90853372	91.10399382	12.49060176	55.56	100.1472251
StDev	1.10397735	5.08297364	2.23924748	6.485875621	1.046862743	4.119366186	5.377147891
Average	**10.49335098**	**86.74384858**	**16.95305606**	**93.77870851**	**11.35630566**	**50.69**	**93.05320382**

Boston Scientific PDM Numbers and corresponding ASTM standards for Instron Test Methods.

The ASTM methods and accompanying BSC document management number for testing include:

ASTM E290-14 for a guided 3 point bed; BSC PDM 90786849
ASTM D638-14 for tensile tests; BSC PDM 90041471
ASTM D695-15 for column strength ; BSC PDM 90487533

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