Design and Fabrication of a Trocar Attachment for Laparoscopic Bariatric Surgery

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ABSTRACT

Bariatric laparoscopic surgery is a minimally invasive solution for weight loss that involves the use of surgical trocars for maintaining insufflation of the abdominal cavity. However, these trocars have been known to release carbon dioxide throughout the procedure. For this reason, the team's goal was to create a design for a trocar seal that was able to maintain insufflation throughout the passage of tools, while not inhibiting the functions of a standard trocar. To accomplish this, the team constructed an attachment for the commonly used Medtronic VersaOne trocar. This design consisted of an outer plastic casing attached to the cannula, that houses an inflatable seal that compresses around the surgical tool in use. The tests conducted on the finished prototype indicated that the seal attachment can successfully maintain insufflation, was resistant to rupture, and is not known to inhibit functions of a standard trocar. The team concluded that their device met the objectives, and speculated that it would enhance the performance of the traditional trocar during surgery.

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CHAPTER 1 - INTRODUCTION

The number of laparoscopic surgeries performed is on the rise from year to year and is becoming a standard option for most traditional forms of open surgery. In 2014, more than 17.2 million surgeries were performed [1]. Of these, laparoscopic surgery was a large percentage of procedures completed. Laparoscopic surgery refers to an operation performed through the use of small incisions rather than large openings, thus is a less invasive alternative over other procedures. While there are a multitude of applications for such surgeries, laparoscopy is predominantly used in urology, gynecology and gastroenterology [2]. Another use of laparoscopic surgery is during bariatric, or weight loss, operations.

Following the trend of laparoscopic surgery, the number of bariatric surgeries in 2014 were estimated at 193,000 and is increasing rapidly [3]. This is thought to be tied to the rise in the population who are classified as obese or morbidly obese and have the desire to live a healthier life. Specifically in the United States, about 35% of individuals fit the criteria for obesity with an additional 3% to 7% in the morbidly obese category [4]. While weight reduction is the primary goal of each type of bariatric surgery, there are a wide variety of techniques available. The four primary bariatric surgeries performed are Sleeve Gastrectomy, Roux-en-Y Gastric Bypass, Gastric Bypass Revision and Lap Band Removal. In each of these surgeries, a different part of the stomach or digestive tract is removed or rerouted with the aid of trocars.

Surgical trocars are utilized during laparoscopic bariatric surgeries due to their ability to pass surgical tools while also maintaining insufflation in the abdominal cavity. To ensure a safe environment for the surgeon to successfully operate, the trocars must guarantee carbon dioxide

cannot escape from the abdominal cavity once insufflated. While this is often successful, a problem has arisen where carbon dioxide leaks from the abdominal cavity out of the trocar, thus disrupting the operation and creating increased patient risk.

Initial meetings with the bariatric surgeon who supervised this project, Dr. Laura Doyon of Emerson Hospital, revealed carbon dioxide leakage as a major issue encountered during surgery. It became the team's overall goal to design a new component of a trocar for laparoscopic bariatric surgery that eliminates this leakage throughout the entirety of the procedure. Through completion of background research and continuous conversations with Dr. Laura Doyon and the project's advisor, Professor Tiffiny Butler, the team identified four main objectives: (1) Safe Insertion and Placement, (2) Aid in Creation of Carbon Dioxide Insufflation, (3) Allow for Passage of Tools and (4) Maintain Insufflation During Tool Insertion and Removal.

Based on the design objectives created for this project, the team established smaller goals throughout the year to ensure a successful final product. The team first created four conceptual designs that aimed to address the problem presented to them. Upon further development, the final design was selected after analyzing the design objectives, design constraints, and feasibility. In order to conduct this analysis, a Pairwise Comparison was created to identify the design objectives of most importance. From these results, a Pugh Analysis was used to compare the potential designs and choose a final design for further development. The team then created extensive models of the design through SolidWorks, and moved into printing and ordering parts to construct their final prototype. From there, the team conducted multiple rounds of testing on their final design versus the Medtronic VersaOne trocar used by Dr. Laura

Doyon. The data collected was analyzed with the goal of identifying which trocar design is quantitatively more effective at accomplishing the design objectives. Finally, the last few chapters of this paper highlight the results of the tests completed by the team. They were able to validate the success of their design while also identifying potential areas for improvement in the future.

CHAPTER 2 - LITERATURE REVIEW

2.1 Laparoscopic Surgery

Laparoscopic surgery is an operation that is performed using only small incisions, typically of about an inch in length [5]. For this reason, laparoscopic surgeries are often referred to as minimally invasive surgeries (MIS). During laparoscopic surgery, the abdomen is inflated with carbon dioxide to provide room for surgical instruments and allow for visualization. Trocars, which are tubular hollow instruments, are inserted through the incision and have seals that prevent the carbon dioxide from escaping. The laparoscope, a fiber optic telescope, is inserted inside a trocar. The laparoscope is connected to a camera which allows the surgeon to visualize the abdominal cavity while performing surgery [6].

Laparoscopic surgeries are predominantly used in urology, gynaecology, and gastroenterology. Through these procedures, surgeons can obtain a sample of tissue for further testing as well as repair or remove damaged organs and tissue [2]. An example of a laparoscopic surgery can be seen in Figure 1, which illustrates a laparoscopic hysterectomy, the surgical removal of the uterus.

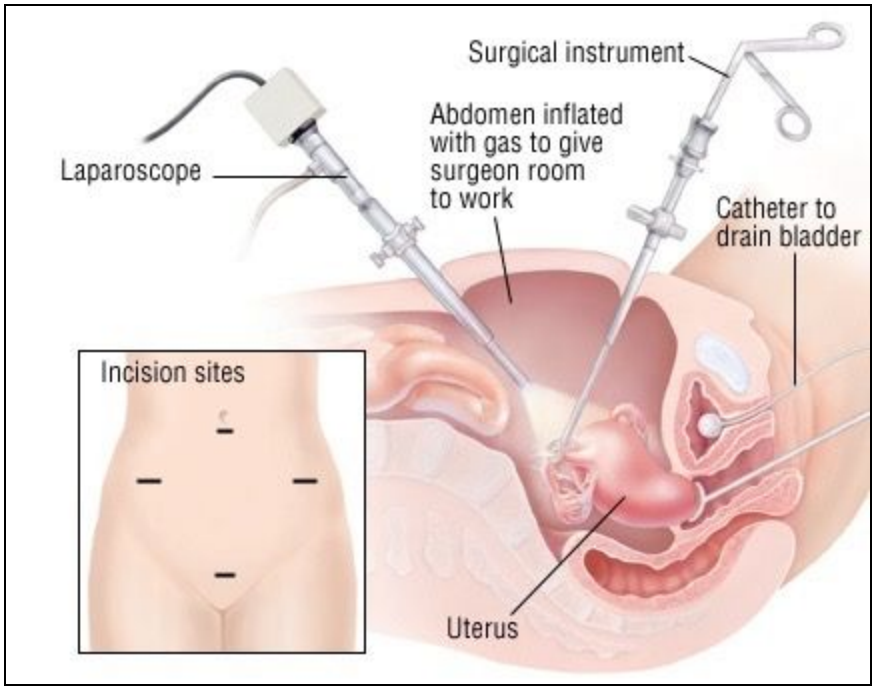


Fig.1. Laparoscopic Hysterectomy [7]

2.1.1 History

The first occurrence of minimally invasive surgery was in Scotland in 1847, where Sir James Simpson introduced chloroform narcosis, a state of unconsciousness as a result of chloroform exposure. [8] This discovery led to the first endoscopic evaluation of the abdominal cavity in 1901 on a canine subject. However, it was not until 1963 that this procedure was performed on a human subject, which paved the way for the use of endoscopic surgery on more complicated procedures such as appendectomies in 1980 and the first cholecystectomy in 1985 [6]. The success of the cholecystectomy ignited the rapid acceptance and evolution of laparoscopic surgeries. [9]. The acceptance of laparoscopic surgery in the 1980s is greatly credited to the development of the computer chip television camera and video laparoscopy. Laparoscopic surgery was quickly adopted across many fields and used to substitute open

surgical procedures. According to the American Hospital Association, by the year 2000 approximately 80% of abdominal operations can be converted to MIS procedures [10].

2.1.2 Equipment

Laparoscopic surgeries require a well-equipped operating room which consists of imaging devices, carbon dioxide gas insufflator, ports of entrance in the abdominal cavity and surgical instruments. In order to obtain images during surgery a laparoscope is utilized. This instrument contains a digital imaging chip within the camera which transmits the images to the video monitors. Laparoscopes can have a diameter from three to twelve milimeters depending on the size of the port of entry.

Fig. 2. Laparoscopic Operating Room [11]

Carbon dioxide insufflators are used to administer carbon dioxide in the peritoneal cavity in order to provide access and visualization of the surgical field. During surgery loss of gas

volume in the abdominal cavity can occur due to frequent suction of irrigation solution, therefore electrical pressure control insufflators are preferred for laparoscopic surgery.

The ports of entry are created through the use of a veress needle and trocars. The veress needle is used to access the peritoneal cavity and filter carbon dioxide into the cavity, while trocars are the port through which the surgeon accesses the abdominal cavity. Trocars are utilized as shafts for different instruments. The standard diameters for trocars are 3.5mm, 5.5mm, 11mm, 12mm, 15mm and 22mm, thus the instrument used during surgery must successfully traverse the trocar .

There are multiple sets of instruments used during laparoscopic surgeries that can be categorized by their functions. Dissecting and grasping instruments are used to cut up the body and manipulate the tissue within it. These instruments include forceps of varying sizes and tip styles as seen in Figure 3, as well as scissors.

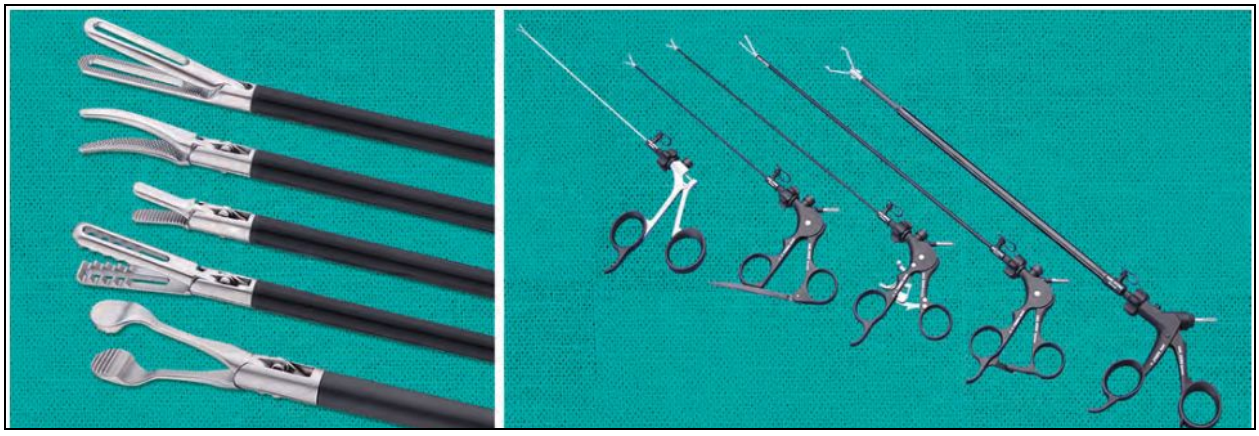


Fig. 3. Grasping Forceps (atraumatic, fenestrated, dissectors and traumatic) [12]

Operating instruments used for closing and connecting tissue and organs include staplers and needle holders. There are different staplers, staples and cartridges available for different surgical procedures. Each stapler has different features that make them suitable for a particular

procedure. During the selection of a stapler surgeons must consider the ability to access the target site through the trocar, ability to complete the stable line and cut, and the ability to maneuver the stapler to position the tissue correctly [13]. Needle holders are used to perform suture and knots and can vary from straight to curved handle and tip.

Other instruments can include probes which are used to move organs and tissue exposing certain areas to allow a better view. Morcellators are commonly used to remove large volumes of tissue by cutting the tissue into small pieces and storing them in the hollow section of the instrument. Irrigation and suction are used to clear the surgical area from debris or blood and drain the fluid, respectively. Suction is performed by a vacuum supply system or suction pump. Large suction-irrigation instruments (10mm) are often used in removing blood clots.

There are many instruments available for laparoscopic surgery and each of them has slight variations intended to facilitate the operation and ensure a better result. It is vital that this equipment works accordingly and surgeons are well versed with the equipment in order to avoid complications and achieve a successful surgery [13].

2.1.3 Limitations

Laparoscopic surgeries require a highly trained team and advanced technological equipment. In the majority of cases, laparoscopies have a longer operation time than open surgeries, and often these laparoscopies are converted into open surgeries due to complications during the laparoscopy, technical difficulty and change in planned treatment [14]. Not only is the surgery duration longer, but the rate of complications is also higher. Some of the complications that can arise during laparoscopic surgery include: hollow viscus perforation, solid viscus injury, hemorrhage, biliary leakage pneumothorax, gas embolism, carbon dioxide absorption with rise in

the arterial carbon dioxide, cardiac arrhythmias and cardiac arrest [10]. More information on complications of laparoscopic surgeries can be found in the following section.

2.1.4 Adverse Events

Despite being a minimally invasive surgery, laparoscopy still presents complications. As seen in [4] group laparoscopic complications can be grouped in three categories: (1) complications of access, (2) physiologic complications of the pneumoperitoneum and (3) complications of the operative procedure.

2.1.4.1 Access Complications

Access complications refer to injuries that occur during the process of establishing a primary port used to access the peritoneal cavity. According to a study conducted by the Physician Insurers Association of America (PIAA), it was determined that access injuries occur in between 5 per 10,000 and 3 per 1,000 patients undergoing laparoscopic surgery [6]. Out of all the complications suffered when establishing the primary port, 76% were bowel, rectal or retroperitoneal vascular injuries.

2.1.4.2 Physiologic Complications of the Pneumoperitoneum

Pneumoperitoneum is the abnormal presence of air or gas in the peritoneal cavity. During laparoscopic surgery, the abdomen is insufflated with carbon dioxide. A study aimed to determine the incidence of deep venous thrombosis (DVT), blood clot formation, after laparoscopic cholecystectomy showed that patients undergoing laparoscopic cholecystectomy were at high risk for developing DVT. This condition can lead to a heart attack or stroke. After three months, 40% of the patients that underwent laparoscopic cholecystectomy had DVT and

15% had axial vein DVT. In addition, pneumoperitoneum leads to other hemodynamic alterations. During surgery, cardiac output decreases by 30% and systemic vascular resistance is also increased [6].

2.1.5 Benefits

During laparoscopic surgery, patients are less likely to undergo tissue trauma and blood loss due to the fine instruments and small incisions. Less anesthesia is required and therefore patients exhibit fewer side effects. Since the abdomen does not have to be open, organs are not exposed which results in the prevention of cooling, drying, excessive handling and retraction of organs. The presence of carbon dioxide has beneficial effects for patient recovery, including decrease in postoperative pain and metabolic stress response and hepatic catabolic response [9]. Overall, laparoscopic surgery reduces the recovery period, which decreases the risk of postoperative complications such as bone loss, muscle atrophy, and urinary retention. Along with a shorter recovery period, laparoscopic surgery provides minimal patient discomfort and great cosmetic results [15]. There are many different types of laparoscopic surgeries, however, for this project the team will be taking a closer look at laparoscopic bariatric surgeries.

2.2 Bariatric Surgery

Bariatric surgery is the medical name for weight loss surgery. It typically is an option for individuals who find themselves classified in the obese or morbidly obese categories and have had no previous success in other weight loss regiments. As a surgical intervention, bariatric surgery has been noted with a history of aiding patients in effectively transforming their health. Bariatric surgery was first performed in the 1950s. Specifically, the first operation was a

Jejunoileal Bypass, but various types and techniques began to arise in the later years of the 1960s to the 1980s. These included Gastric Bypass, the Biliopancreatic Diversion and Duodenal Switch, Gastroplasty, Gastric Banding and Laparoscopic Adjustable Gastric Banding and many more.

From the initial operations, the risks of bariatric surgery are not only becoming lessened, but also the operation is becoming more popular. More specifically, the newly proven surgical approach in combination with the failure of normal dieting has marked improvement in quality of life. Additionally, quicker recovery for minimally invasive surgeries has led to a large increase in the number of bariatric procedures performed annually over the last ten years [16]. According to one study, there was a rise from 196,000 to 216,000 metabolic and bariatric procedures performed in 2015 and 2016, respectively, with sleeve gastrectomy also following an increasing trend [3]. These numerics correspond to the data as seen in the table from the American Society for Metabolic and Bariatric Surgery (ASMBS), Figure 4 below.

	2011	2012	2013	2014	2015	2016	2017
Total	**158,000**	**173,000**	**179,000**	**193,000**	**196,000**	**216,000**	**228,000**
Sleeve	17.80%	33.00%	42.10%	51.70%	53.61%	58.11%	**59.39%**
RYGB	36.70%	37.50%	34.20%	26.80%	23.02%	18.69%	**17.80%**
Band	35.40%	20.20%	14.00%	9.50%	5.68%	3.39%	**2.77%**
BPD-DS	0.90%	1.00%	1.00%	0.40%	0.60%	0.57%	**0.70%**
Revision	6.00%	6.00%	6.00%	11.50%	13.55%	13.95%	**14.14%**
Other	3.20%	2.30%	2.70%	0.10%	3.19%	2.63%	**2.46%**
Balloons	–	–	–	–	0.36%	2.66%	**2.75%**

Fig. 4. Estimate of Bariatric Surgery Numbers, 2011-2017 [16]

Along with these trends, there has been an increased emphasis on the safety of the procedures. The Agency for Healthcare Research and Quality (AHRQ) and recent clinical

studies have reported that the overall mortality rate for bariatric surgery is about 0.1 %, which is less than both gallbladder and hip replacement surgery. Additionally, studies have shown that life expectancy can be improved by up to 89% and the risk of premature death is reduced by 30% to 40% [17]. Thus, in typical cases, it appears as though the risks of morbid obesity outweighs the risks of weight-loss surgery.

2.2.1 Conditions for Surgery

While there are many individuals who may find themselves looking for weight loss solutions, there are many criteria which must be met in order to be eligible for surgery. To be a potential candidate, an individual must be considered either obese or morbidly obese. Thus, according to the National Institute of Health, these candidates must have a Body Mass Index (BMI) of greater than 40 kg/m^2 or must have a BMI of greater than 35 kg/m^2 with one or more related health problems caused by obesity, including hypertension, diabetes, sleep apnea, severe joint pain, hyperlipidemia, non-alcoholic fatty liver disease or heart disease and many more. Additionally, they must have the inability to achieve weight loss by other means, and their efforts must have been sustained for a notable period of time [17]. In the United States, up to 35% of adults are classified as obese and 3% to 7% currently suffer from morbid obesity [4]. These figures give evidence to the large number of candidates for bariatric surgery.

2.2.2 Types of Bariatric Surgery

While the primary goal of weight loss is the same for all types and techniques of bariatric surgery, the varied options work in two general ways: restriction and malabsorption. Restriction refers to the action of limiting the amount of food that can be eaten, ensuring that patients feel

satisfied or “full” with less food. On the other hand, malabsorption poses a limit on the actual number of calories and nutrients that the individual’s body can absorb [4]. While there are many types of bariatric surgery, the four primary options, in order of most to least prevalent, are: Sleeve Gastrectomy, Roux-en-Y Gastric Bypass, Gastric Bypass Revision and Lab Band Removal. Each of these surgeries are performed using various techniques and have their own benefits and complications [17]. Although there are a wide variety of options, it is important to note that without striving to live a healthy life of exercise and less caloric intake after surgery, positive results are not promised.

2.2.2.1 Sleeve Gastrectomy

Sleeve Gastrectomy was first performed in 2000 and involves changing the stomach from the size of a football to the shape of a banana. This correlates to a size of about 60 to 150 mL. Generally done laparoscopically, the operation involves removing the fundus, the upper right rounded portion of the stomach, which accounts for 75 to 80% of the organ. This area produces a hormone that controls appetite, known as ghrelin. Thus, the removal of the fundus is likely the reason why a sleeve gastrectomy is not just a restrictive process. During this operation, small abdominal incisions of a few millimeters to a centimeter are made, trocars are placed in these incisions, there is insufflation of carbon dioxide and the internal organs are examined with a laparoscope. The liver is lifted from the stomach and from the tissues attaching to the omentum, which is removed before the cutting and sealing of small blood vessels on the greater curvature. Next, the stomach is separated from the spleen and bowels before being divided at the gastroesophageal junction, where stapling along the length formed by bougie, a flexible surgical instrument for dilating a body passage, creates a narrow tube. Once complete, the resected

stomach is placed in a specimen bag and extracted through the surgical trocar [18]. An example of possible trocar placement can be seen in Figure 5 below and a diagram presenting sleeve gastrectomy is found in Figure 6.

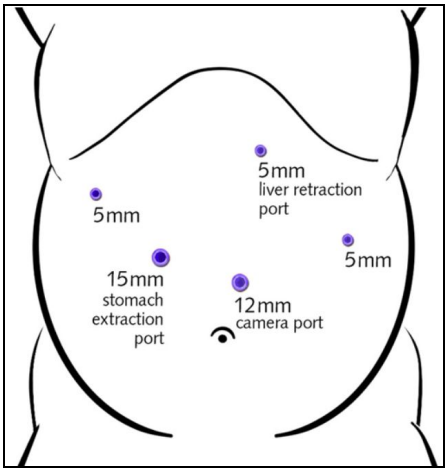


Fig. 5. Trocar Placement - Sleeve Gastrectomy [19]

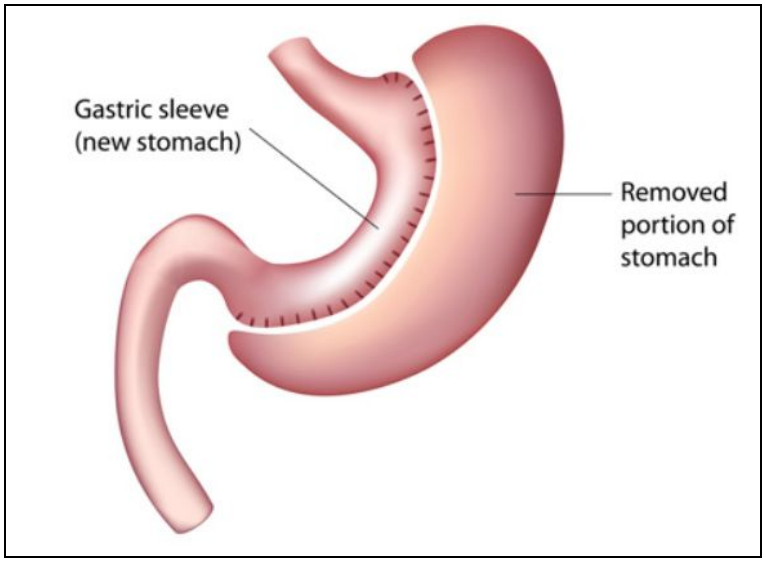


Fig. 6. Diagram of Sleeve Gastrectomy [19]

There are many benefits of sleeve gastrectomies. In general, gastric sleeve is a relatively simple bariatric surgery that has a low operating time of about 40 to 70 minutes. There is a low probability of adverse reactions, as risks only affect about 1% to 2% of patients, yet has a potential for 50% to 70% excess weight loss. Additionally, there is a low chance for nutrient and vitamin deficiency with very rare chances of bowel obstruction, marginal ulcers or internal hernias. Along with these benefits, sleeve gastrectomy also does not induce any foreign objects and does not bypass or re-route the food stream [19] [20].

While the risks are low, there are many complications that could arise during and after surgery. Reported in about 0.7% to 3% of surgeries, leakage can occur at the staple line as well as the presence of stricture/stenosis. Other complications include staple lines becoming infected, the formation of scar tissue, bleeding, blood clots, heart-burn, excess skin and potential for weight regain. Weight regain is possible as the portion of the stomach that is kept intact throughout the surgery can begin to stretch with increased food intake, and thus the patient may require more interventions [19]. Overall, these problems are rare and major complications typically occur in less than 1% of all cases [21].

2.2.2.2 Roux-en-Y Gastric Bypass

Roux-en-Y Gastric Bypass is considered the “gold standard” of weight loss surgery worldwide. It involves making a small stomach pouch by dividing the top from the rest of the stomach and then dividing the small intestine such that the bottom end is connected to the newly created small stomach pouch. Additionally, to ensure that the stomach acids and digestive enzymes mix with the food, the top end of the small intestine is connected to itself further down. Through gastric bypass, caloric restriction as well as nutrient malabsorption occurs. This

procedure has the advantage of good short term weight loss of approximately 60% to 80% of excess weight, as well as being the most durable for long term results. While the benefits are prevalent, there are still a number of potential disadvantages. For example, the rate of long term complications are slightly higher than those for sleeve gastrectomy. Along with this, patients are not allowed to take any form of NSAIDS(non-steroidal anti-inflammatory drugs) after surgery and must be on vitamins for the rest of their lives as there is a particular deficit in vitamin B12, iron, calcium and folate caused by the surgery [22]. A diagram presenting the Roux-en-Y Gastric Bypass can be seen in Figure 7.

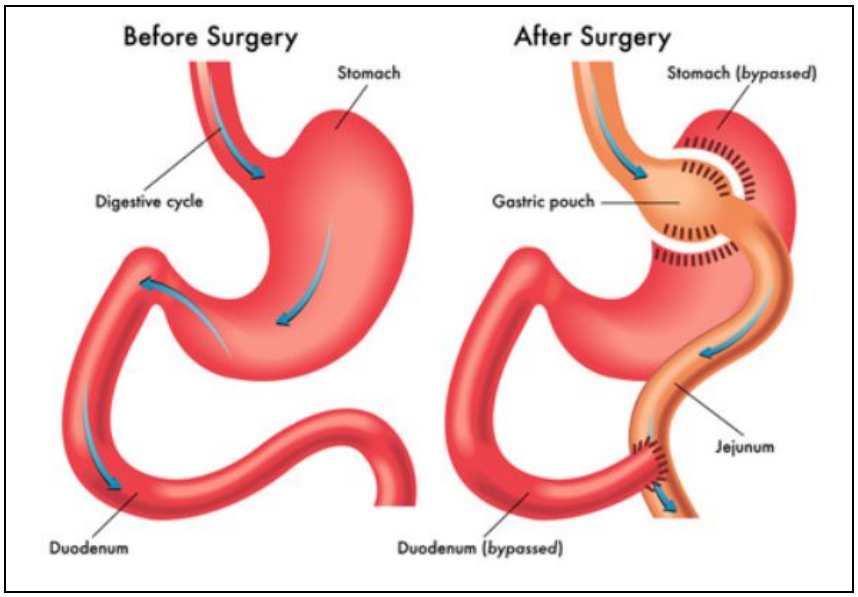


Fig. 7. Roux-en-Y Gastric Bypass Diagram [22]

2.2.2.3 Gastric Bypass Revision

This procedure, also known as Laparoscopic Distal Roux-en-Y Gastric Bypass, is a minimally invasive treatment for individuals who had weight regain after Gastric Bypass. The procedure works by minimizing the ability of the patient to absorb food and calories. While the

Roux-en-Y Gastric Bypass displaces the first 200cm of the small intestine, the revision surgery bypasses about another 300cm of the small intestine. This only allows the food to be mixed with digestive juices for about 150cm to 200cm of the small intestine, therefore minimizing intake.

There are many possible complications with this procedure. Similarly to the Roux-en-Y Gastric Bypass, there are risks of excessive weight loss due to malnutrition, so patients must take high vitamin doses for the rest of their lives. Additionally, many will have increased bowel movements post surgery. Positively though, compared to other weight loss surgeries, the distal gastric bypass offers more significant weight loss. Due to its laparoscopic nature, it also has much lower risks [23]. Figure 8 shows the set-up of the bypass revision.

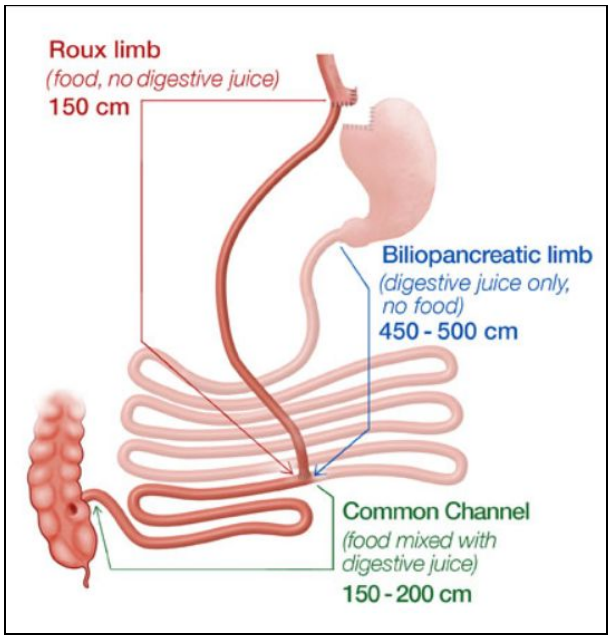


Fig. 8. Gastric Bypass Revision Diagram [23]

2.2.2.4 Lap-Band Surgery

Lap Band Surgery, also known as gastric band surgery, involves a surgeon placing a thin, adjustable ring around the upper portion of the stomach, creating a smaller pouch. This is done laparoscopically and helps to reduce weight by lessening the flow of food between the superior and inferior parts of the stomach. By providing pressure to the stomach, the individual shall feel more full with less intake of food. The most important advantage is that this is the least invasive surgery for weight loss as there is no cutting, stapling or rerouting of the intestines or stomach. Additionally, there is a low risk for nutritional deficiencies that are typically associated with other forms of bariatric surgery and the adjustable band allows the surgeon to customize the ability of flow through the stomach with future adjustments. Finally, it is not a permanent process as the band can be removed. But, due to the nature of the procedure, there tends to be less weight loss compared to other procedures with the risk of postsurgical weight gain [24]. There is also risk of ulceration at the band site as well as dehydration and indigestion. Figure 9 below presents a depiction of the surgery.

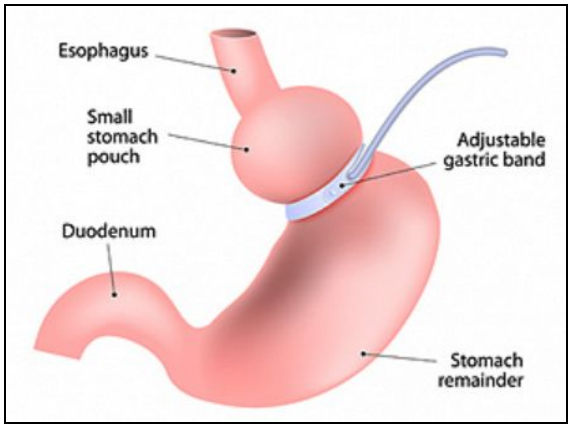


Fig. 9. Lap Band Surgery [24]

2.3 Surgical Trocars

Trocars have revolutionized the safety of surgeries by making laparoscopic and minimal access surgery an option for a variety of applications. Specifically, trocars are useful in bariatric surgery, as their ability to create space in the abdomen leads to successful surgeries without any dangerous and large incisions. Through providing an entryway into the abdomen, maintaining insufflation, and allowing for the passage of surgical tools, trocars foster a safe and effective environment for surgeons.

2.3.1 History

Trocar-like devices are recorded to have been used for thousands of years, with medical encyclopedias around the world detailing them from all the way back to the 900s. The term "trocar" was officially used in the 1700s, originating from the French language as a combination of the words "three" and "edge." Trocars were originally used to drain fluid and gas from the body, but this purpose would change over time as the use and design were developed by modern surgeons. The first documented trocar used in laparoscopic surgery occurred in the early 1900s by Georg Kelling, and it was at this point where surgeons began to advocate for minimal access surgeries to decrease patient risk. Later, in the 1950s, German gastroenterologist Heinz Kalk was one of the first surgeons to introduce the dual trocar method. He refined the techniques and established it as a safe and effective method of surgery. This led to the practice of modern laparoscopy, where surgeons typically use one trocar for the laparoscope, and between one to three other trocars for the passage of surgical tools [25].

2.3.2 Structure

Trocars typically consist of an obturator, or stylus-like part, with a tip at one end. The obturator fits through a cannula or sleeve that is attached to the head of the instrument. This tip can break through the abdominal wall to secure the trocar into the body at the required location. The obturator can then be pulled out through the cannula, which is typically 1mm in diameter larger than the obturator, leaving an open pathway through the cannula into the abdomen. The head of the instrument, which sticks out of the body, has a seal that creates the door to this cannula, where tools such as a laparoscope can be inserted into the abdomen. Also at the head of the instrument is a gas intake port, which attaches to a machine that supplies carbon dioxide to the body. This is used to maintain a certain inflow pressure of gas that inflates the abdomen and provides adequate space for surgeons to complete their work [26]. See Figure 10, for a diagram that the team created, which outlines these various components.

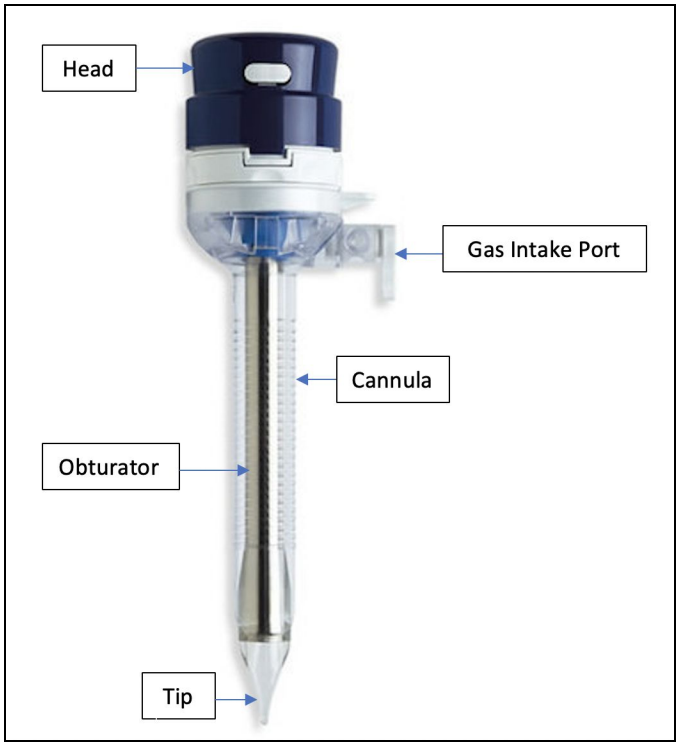


Fig. 10. Diagram of a Trocar [27]

2.3.3 Important Features

Each component of the trocar mentioned above plays an important role during laparoscopic surgery. There are specific features within each component that make the design unique. An example of the functions of each component are as follows: the obturator is responsible for piercing through the abdomen wall; the cannula remains in place during surgery and acts as the port that surgical instruments can be passed through; and the seal is responsible for making sure that carbon dioxide does not leak from the abdomen during the passing of instruments. When analyzing what features should be included within the trocar components, the functions above need to be considered.

The obturator's main feature that can be designed in many different ways is the tip. Typically, the obturator has been designed with either a conical or pyramidal tip, also referred to as a blunt or bladed tip, respectively. Figure 11 shows an example of a conical versus pyramid tip obturator.

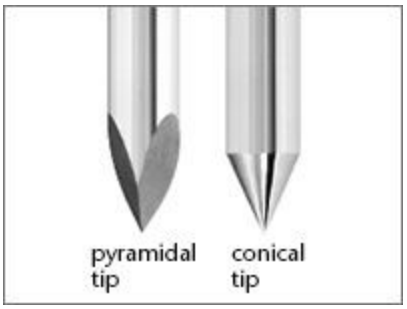


Fig. 11. Representative example of pyramidal vs. conical obturator [28]

The importance of the tip design is that it determines the force required to pierce through the abdominal wall, the force required to remove the trocar, and the size of the incision made in the abdominal wall [29]. Meta-analyses have been completed to analyze the difference of the obturator tip design. Randomized studies were identified that resulted in trocar insertion related complications, such as abdominal wall trocar site bleeding and visceral injuries. Based on the meta-analysis, the researchers concluded that there is a lower risk of abdominal bleeding or visceral injury when using a blunt tipped obturator [30].

The cannula is a hollow piece of the trocar that remains in the abdomen throughout the surgery for the passage of instruments. Variations that were identified in the design of the cannula were the smoothness of the outer surface and whether or not there was an inflatable balloon. During surgery, it is important that the cannula does not move out of place when

instruments are being passed through it. Often, cannulas have a ribbed surface, as seen in Figure 12, so that there is secure abdominal wall retention.

Fig. 12. Ultimate Universal Cannula that has a ribbed outer surface [31]

A more advanced design for the cannula includes an inflatable balloon at the distal end of the cannula. After insertion of the trocar into the abdomen, this balloon can be inflated in order to secure the cannula against the inner abdomen [32]. The purpose is to ensure a secure fit in the desired location throughout the laparoscopic procedure. An example of the inflatable balloon trocar can be seen in Figure 13.

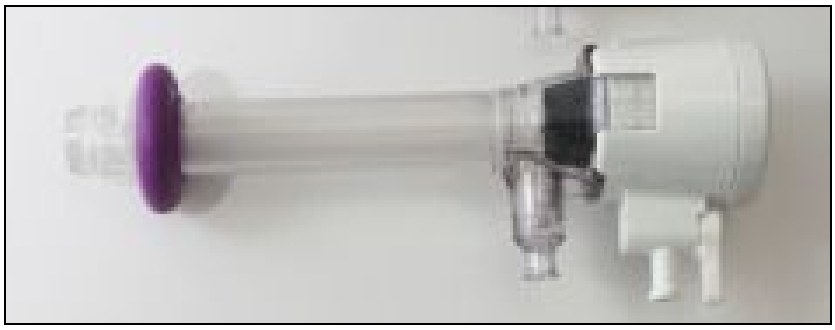
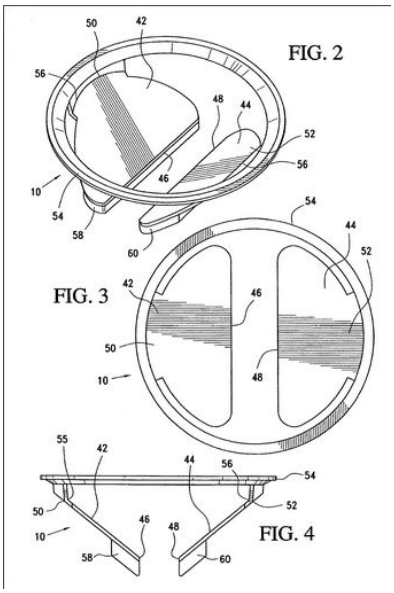
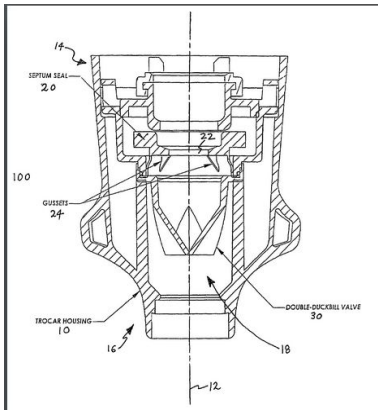
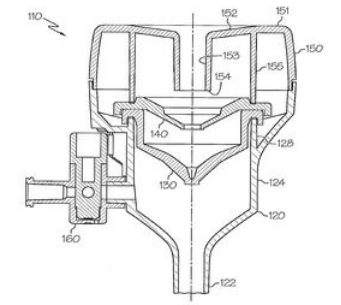
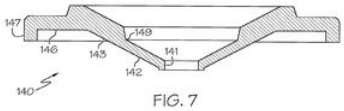
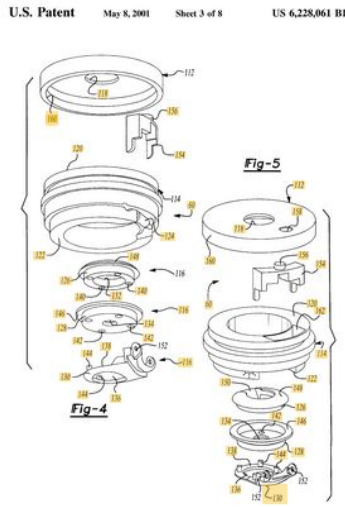


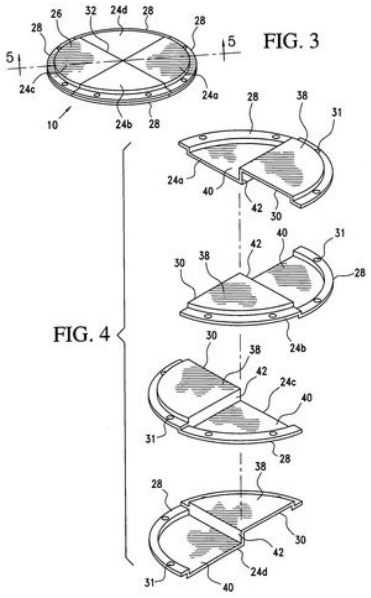
Fig. 13. Trocar with an inflatable balloon on the distal end [33]

The seal is one of the most important components of the trocar. This piece allows for instruments of different sizes to be inserted and removed through the abdomen without disrupting carbon dioxide insufflation [34]. This seal can vary depending on the manufacturing company or on the purpose of the trocar, however ultimately, the seal in a trocar needs to be designed specifically for the type of surgery being done. The functions of trocars can fall into three different categories: static applications, linear motion applications, and rotary applications [35]. For laparoscopic bariatric surgery, the seal design is focused with a linear motion application. Currently, there are many patents for different trocar seal designs. A breakdown of these designs can be seen in Table 1.

Table 1. Examples of Seal Assembly Designs

Seal Design Type	Figure	Description
Duckbill seal [36]		A seal that is adapted to allow for selective open and closing and the passing of instruments.
Anti-inversion seal [37]		A seal that has a diameter less than the surgical instrument being passed, in order to create a tight suction.

Retraction seal [38]	 FIG. 6  FIG. 7	A seal that is composed of a bending and base portion that creates an opening alignment channel.
Dual seal [39]		A seal that is composed of an upper and lower seal. The upper seal has a larger diameter and the lower seal is attached to a hinge plate and can be removed when larger instruments have to be passed.

Ethicon seal [40]		A seal that is composed of primary and secondary segments that have a peripheral and seam edge that overlap.

2.3.4 Products on the market

Trocars are a commonly used tool during laparoscopic surgery, so there are a plethora of different types. Trocars come in a variety of sizes and designs that allow for the surgeon to choose the best one to be used for their application. For example, with bariatric surgery, a 15mm trocar is typically used so that the large stapler can be inserted into the abdomen. In Table 2 below, a compilation of the major companies that design trocars for bariatric surgery are listed.

Table 2. Market Analysis for Trocars Used in Bariatric Surgery

Company	Type	Highlighted Feature	Function of Highlighted Feature	Figure
Medtronic [41]	VersaOne	• Dolphin nose tip • Ribbed Cannula	• Smooth Insertion • Port Fixation	
Ethicon [42]	B15LT Endopath Xcel	• Controlled entry • Integrated thread on cannula • Housing and seal	• Low insertion force • Abdominal wall retention • Low drag force	
Applied [43]	Kii optical access system	• Inflatable Balloon on cannula • Blunt tip • Seal detachment	• Abdominal wall retention • Minimal facial defect • Rapid desufflation and specimen removal	

Each medical device company targets a different component of the trocar to focus on. This allows the company to have a competitive advantage. A current gap in the trocar market is seal technology. The seals need to be improved because the modern designs are decreasing productivity of surgeons and causing complications. Designing a new seal component will allow for an increase in efficiency and safety during laparoscopic surgery.

2.3.5 Complications

Experts are certain that minimal access surgery is superior to open surgery, however no laparoscopic method has been able to eliminate all complications associated with surgeries. There are specific complications that arise due to the improper use or design of trocars that can cause dangerous risk to patients undergoing laparoscopic surgery.

One common complication associated with trocar use is entry injuries. According to a study conducted in the Netherlands, the overall rate of intestinal injuries and major complications in laparoscopic surgery was 5.7 per 1,000 procedures, with 70% of these being related to the primary port entry [44]. Major entry complications are especially likely to occur in the abdomen, as there is easy access to major blood vessels and the gastrointestinal tract. If these areas of the body are damaged, the patient can be in extreme danger. Vascular injuries are one of the most deadly complications in laparoscopic surgery, but unfortunately they are very likely due to the close proximity of the abdominal wall to the retroperitoneal vascular structures. This separating distance can be as little as two centimeters [44]. If a trocar is placed in the body and happens to accidentally contact any arteries or other vascular structures, issues such as hematoma may occur and the patient's life may be at risk [9]. Other common injuries include bowel injuries. Unlike vascular injuries where the effects can usually be seen immediately, bowel injuries are likely to go unrecognized and get worse with lack of treatment. One example is trocar site incisional hernias, which can cause extreme pain and risk to patients. According to one study conducted in 2017 in Sweden, hernias can occur as often as three out of every 26 surgeries for gastric bypass [45]. These entry complications can occur very easily and quickly in the abdomen, so it is

important that all safety procedures, in trocar design and placement, are taken to mitigate these risks.

Complications can also arise through the creation and maintenance of a pneumoperitoneum, or the insufflation of the abdomen. Though this is a small aspect of the entire surgery, more than 50% of all complications occur during this period [46]. Amongst the most dangerous are embolism and deep venous thrombosis, which can occur from the presence of carbon dioxide. Though this is extremely uncommon, it can lead to damaged organs and difficulty breathing [44], [9]. Creation of a pneumoperitoneum can also lead to complications with blood flow. There is an increase in systemic vascular resistance and a decrease in stroke volume, which can decrease cardiac output by up to 30%. This can cause the body's arterial pressure to increase by up to 16%. It is important that patients with cardiac issues are closely monitored during surgery to ensure that they can tolerate pneumoperitoneum. Issues relating to pneumoperitoneum are more likely to occur in obese patients that are receiving bariatric surgery, as the fat surrounding the abdominal wall makes it complicated to find the perfect location to begin insufflation. This can lead to the potential of incorrect preperitoneal insufflation, which can be dangerous to endure during surgery [44].

CHAPTER 3 - PROJECT STRATEGY

3.1 Initial Client Statement

The initial client statement was created by the team's advisor, Professor Tiffiny Butler, in collaboration with the team's mentor, Dr. Laura Doyon, who is a bariatric surgeon from Emerson Hospital. The initial client statement provided to the team reads:

"Design and fabricate a new trocar that eliminates the valve leak problem to maintain carbon dioxide insufflation when passing instruments through the device."

The ambiguous wording of the initial client statement left the team with plenty of freedom to redesign any aspect of a trocar that they felt would solve the "leak problem." In order to achieve the goal set by this client statement, the team needed to research and analyze modern trocars, create conceptual designs, and evaluate their best design through various rounds of testing.

3.2 Design Requirements

After completing comprehensive background research and identifying the initial client statement, a set of design objectives, constraints, functions, and specifications were developed by the team to assist them in creating their conceptual designs.

3.2.1 Design Objectives

The team created four design objectives that summarize the most important aspects of the

new trocar design, based on feedback from the project's advisor and the overseeing bariatric surgeon. These objectives are displayed in Table 3.

Table 3. Project Design Objectives

Primary Objective	Explanation
Safe Insertion and Placement	To ensure safety throughout the entire surgical procedure. To minimize patient risk and scarring after the procedure.
Aid in Creation of CO_2 Insufflation	To create enough space and visibility for adequate access and sight to reduce patient risk.
Allow for Passage of Tools	To allow surgeons to utilize all the tools required to conduct a successful surgery.
Maintain Insufflation During Tool Insertion and Removal	To maintain visibility and space for surgeons while they are using various tools.

To begin, the team wanted to create a trocar that promotes safe insertion and placement into the abdominal cavity. It is important that the trocar tip can pierce through the abdominal wall, smoothly move into the abdomen, and avoid causing injury to underlying intra-abdominal structures. It is common after trocar entrance to encounter vascular and bowel injuries caused by insertion, so the tip and obturator shall have features that prevent major slip and unwanted displacement during surgery. The patient's safety is of the highest priority during this process.

Next, it is crucial that the trocar can create insufflation of carbon dioxide into the abdomen through the use of a valve or gas intake port. The design must include an opening that can accommodate a pump or machine that supplies carbon dioxide as well as a valve that allows the surgeon to start and stop the flow into the abdomen. This step is critical, as the surgeons need sufficient space and visibility to ensure that they carry out a successful surgery.

In addition, the new design must allow for the passage of different surgical tools commonly used during bariatric surgery. Surgeons need a trocar that can support tools of various shapes and sizes, thus the seal must be able to accommodate the housing of all potential instruments without breaking or compromising its strength. The seal must also minimize friction during the insertion and removal of tools to ensure that the surgeons can move as quickly as possible during surgery.

Finally, the team wanted to construct a prototype that will maintain proper carbon dioxide insufflation while tools are being inserted and removed. During surgery, the seal of the trocar can be compromised; it may lose strength as instruments are being pulled and pushed through the trocar. When this occurs, carbon dioxide is likely to spill out of the seal and the necessary insufflation is lost. It is crucial that the components of the trocar are unsusceptible to damage caused by tool insertion and removal.

3.2.2 Design Constraints

There are certain Major Qualifying Project criteria set by Worcester Polytechnic Institute's Biomedical Engineering Department that the team had to abide by in order to complete their project. There are also additional criteria set by the bariatric surgeon, Dr. Laura Doyon, that the team had to prioritize. Some of these guidelines were seen as constraints, as they had the potential to limit the team in creating their final design. These constraints are presented in Table 4.

Table 4. Project Design Constraints

Constraint	Definition
Time	The project must be completed by April 24th, 2020.
Financials	The team is given a budget of $1,000.
Resources	The materials to complete the design must be available or attainable for the team.
Size	The trocar must be able to hold the 15mm stapler that is commonly used by bariatric surgeons.

3.2.3 Design Functions

After establishing the overarching design objectives and the design constraints, the team created a list of design functions. These primarily consist of behavioral and operational statements of what the instrument must do to perform its basic purpose. The listed design functions are:

- The device shall maintain constant distention in the abdominal cavity.
- The device shall not cause an adverse reaction to the patient.
- The device shall have a valve for the attachment of a carbon dioxide input.
- The device shall be able to house laparoscopic surgical tools.
- The device shall have the ability to pierce through the abdominal wall.

3.2.4 Design Specifications

There were several design specifications that the team identified in order to develop their prototype. These specifications provided quantitative and qualitative methods that the team could

use to evaluate the effectiveness of their final design. These specifications are outlined in the list below and further explained with a descriptive paragraph.

The device:

1. Shall pierce through the abdominal wall after a small incision is made.
2. Shall not slip during surgery by more than the length of the device at the original insertion.
3. Shall connect to a pump to supply 15mmHg of carbon dioxide to the abdomen.
4. Shall have an opening and sleeve with a diameter size of 15mm.
5. Shall aid in maintaining visibility through the use of a cannula material of at least 80% of total transmittance.
6. Shall have a seal made out of a biocompatible, elastomeric material capable of adjusting to various sizes and shapes of surgical tools.
7. Shall allow smooth removal and insertion of various tools with a maximum frictional force of 8N.
8. Shall be capable of limiting carbon dioxide from escaping through the trocar.
9. Shall meet biocompatible standards.

Shall pierce through the abdominal wall after a small incision is made.

There are a significant amount of complications during a laparoscopic procedure due to the blind entry of the initial insertion of the trocar. With a blind entry, the surgeon runs the risk of potential organ or vascular damage caused by the tip of the trocar [47]. In order to mitigate the probability of internal injury upon entry, the final design of the trocar obturator should have a tip

that allows for radial dilation. Radial dilation is possible using a conical tipped obturator that allows for a smaller incision to be made and as force is applied to the trocar, the tip evenly separates the abdominal wall layers [48]. Using radial dilation to gain entry decreases the likelihood of vascular damage and hernia formation because the cone-shaped obturator requires less penetration force and the tip facilitates the separation of the abdominal wall allowing for an easier closure of the fascia after the surgery is complete [49]. This technique allows for minimal incision and dissection and creates a gas tight fascial seal [50].

Shall not slip during surgery by more than the length of the device at the original insertion.

After insertion of the obturator through the abdominal wall, the cannula is left in place for the duration of the laparoscopic procedure. Throughout the procedure surgical tools will be inserted and removed through the cannula, which applies forces to the device that can cause the cannula to move inwards or outwards of the abdomen [51]. During this movement, the cannula is expected to stay in place, so as to not disturb the flow of the procedure. If the trocar does not stay in the proper location, it requires the surgeon to readjust or reinsert the device, which causes the loss of the pneumoperitoneum and is very inconvenient during surgery [52]. To measure the dislodging of the cannula after the initial insertion, the distance from the skin to the head of the trocar should be measured. Throughout the procedure, measurements should be taken to ensure that this distance has not changed. If the distance increases then the cannula is moving extra-abdominally, and if the distance decreases then the cannula is moving intra-abdominally. The final design of the trocar shall have a threaded outerwall to prevent the cannula from slipping during surgery.

Shall connect to a pump to supply 15mmHg of carbon dioxide to the abdomen.

It is crucial that the team's final trocar supports the insufflation of the abdominal cavity to 15mmHg of carbon dioxide, as this is the pressure commonly set by bariatric surgeons in order for them to have optimal operating conditions [53]. The final design must include a valve or gas intake port, which can be attached to carbon dioxide insufflators used in operating rooms. Upon attachment, the final trocar must consistently provide 15mmHg of carbon dioxide to the valve, through the cannula, and then into its surroundings in the abdomen. This insufflation must be sustained for the entire length of surgery, which is typically around one to two hours. The trocar must also maintain insufflation through typical surgical conditions, such as the entrance and removal of surgical tools through the trocar's cannula and seal.

Shall have an opening and sleeve with a diameter size of 15mm, large enough to fit the stapler used during bariatric surgery.

Two main components of the trocar are the seal and cannula. The seal is responsible for allowing surgical tools into the cannula while preventing the outward flow of carbon dioxide, and the cannula is responsible for providing a straightforward pathway into the body. Though these components can be redesigned in many ways by the team, there is a strict requirement set by the client stating that they both must have 15mm diameters. Bariatric surgeons use large staplers to section off certain parts in the abdominal cavity, so the trocar that they are using must be able to accommodate this tool. However, it should not be built larger than this 15mm diameter. A larger trocar would require a larger incision into the abdomen, which creates more scarring and extended recovery that the patient must go through.

Shall aid in maintaining visibility through the use of a cannula material of at least 80% total transmittance.

The cannula of a trocar plays an important role in helping to maintain visibility during surgery. It can be made out of transparent plastic, which gives surgeons the opportunity to see the area surrounding the cannula [25]. For this reason, the team prioritized making their final cannula out of similar transparent material. Polycarbonate has proven itself to be a useful plastic in the medical field, as it is biocompatible, very strong, and has a high heat distortion temperature [54]. Importantly for this application, it also has exceptional optical clarity. It is known to have a total transmittance of around 88%, meaning that 88% of incident light is transmitted by the material [55]. For this reason, the team decided to choose a polycarbonate that has a total transmittance of at least 80%, as the ribbed design and cylindrical shape may interfere with the purity of the material.

Shall have a seal made out of a biocompatible, elastomeric material capable of adjusting to various sizes and shapes of surgical tools.

The internal seal of the surgical trocar must be made of a material capable of adjusting to and withstanding the repetitive insertion and removal of various sized surgical tools. The seal must have the ability to rebound to the original shape when tools are removed to ensure proper carbon dioxide insufflation is not lost. It is important to choose an elastomeric material, which is a natural or synthetic polymer that has elastic properties, as the seal must have a high tensile strength, ability for elongation and abrasion resistance yield strength for this application. One example of a good material choice such a dynamic application is polyisoprene, due to its excellent elastomeric properties. This material has a Young's modulus of 1.7×10^6 to 2.6×10^6

Pascals, thus it can withstand a large amount of elastic deformation before experiencing plastic deformation [56].

Shall allow smooth removal and insertion of various tools with a maximum frictional force of 8N.

The smooth removal and insertion of tools through the sleeve and seal of a surgical trocar is of utmost importance in regards to ease of use and safety. The tools must be able to slide in and out with a maximum frictional force of 8N. One way to reduce this frictional force is through the addition of lubrication to the seal, which must be compatible with the material makeup of the trocar and required tools. When the obturator is lubricated with silicone oil, the peak resistance force is reduced by 75%, which eliminates the risk of the stick-slip phenomenon seen in non-lubricated obturators. Studies have shown that by providing a low friction port, there is improved haptic feedback to the surgeon, thus increasing proprioception and the ease of the procedure [57].

Shall be capable of limiting carbon dioxide from escaping through the trocar.

Insufflation of carbon dioxide during laparoscopic surgery is vital for the visualization of the surgical field and manipulation of the internal organs [58]. The optimal pressure for the peritoneal cavity during laparoscopic surgery is 15mmHg, however if there is a loss of carbon dioxide that occurs during surgery, the pressure will drop under the optimal level [58]. The loss of carbon dioxide can limit the visualization of the surgical field and can result in extended surgeries. For this reason, the designed trocar shall meet or exceed the percentage of carbon dioxide retained by trocars that are currently on the market for the duration of the surgery.

The device shall meet the biocompatible standards.

Biocompatibility as described by Barrère et al. is "the ability of a material to perform with an appropriate host response in a specific application" [59]. Thus the device design must be able to fulfill its purpose during the surgery without eliciting any negative responses from the host [60]. The International Organization for Standardization (ISO) classifies medical devices based on the nature of the devices's contact with the body in order to select the criteria for the appropriate biocompatibility testing. In line with the classifications found in ISO 10933-1:2009, trocars are external communicating devices which are in contact with tissue, bone and dentin [61]. Thus, as an external device with a limited contact duration of less than 24 hours, trocars must undergo cytotoxicity, sensitization, and irritation or intracutaneous reactivity testing. In addition to the test recommended by ISO 10993 1:2009, the U.S Food and Drug Administration (FDA) recommends acute systemic toxicity and material-mediated pyrogenicity testing [61]. The device must undergo and satisfy the tests recommended by the ISO and FDA to ensure biocompatibility of the materials and prevent the presence of any adverse events.

3.3 Design Standards

The International Organization for Standardization (ISO) and the U.S Food and Drug Administration (FDA) provide specifications and guidelines for products to ensure quality, safety and efficiency for the global consumer [62] [63]. In order to ensure safety and success, multiple design standards set forth by the ISO and FDA were taken into consideration during the fabrication of this device.

The team's trocar abides by the standards specified in ISO 13485, which regulates medical devices to ensure their quality and safety [64]. The potential risks were also evaluated according to ISO 14971 standards, which focus on the application of risk management for medical devices. This standard assesses the risk associated with a certain device and monitors the effectiveness of the device during its entire life cycle [65]. In addition, the biocompatibility of the device is crucial to prevent any harm to the patient and ensure the success of the surgery, thus the team has considered the ISO 10993 standards [66]. Along with biocompatibility, the sterility of surgical devices are fundamental to minimize patient risk. With this in mind, the standards included in ISO 11737, which regulate the enumeration and characterization of viable microbial populations in healthcare products, were followed [67].

Since safety is a priority for both patients and manufacturers, the standards included in FDA 21 CFR 820 were applied to warrant the safety of the device and the fulfillment of the quality system requirements for manufacturing processes. As stated in Section 820.1, "The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use" [68]. Finally, ISO 16142 was used as a guide to assess and determine standards that when met will indicate that the device follows essential principles of safety and fulfills its purpose [69].

3.4 Revised Client Statement

Upon further evaluation of background information and continuous conversations with Dr. Laura Doyon and Professor Tiffiny Butler, the team recognized that their original client

statement lacked quantitative benchmarks that the new design had to accomplish. The team revised the statement to include more specific information, such as the diameter of the trocar cannula and the pressure of carbon dioxide that must be maintained during bariatric surgery. Additionally, with the added quantitative data, the team was able to test the final product to determine if it in fact satisfied the needs of the client.

After reviewing the criteria, it was determined that the issue was only due to the seal and not related to the other components of the trocar. For this reason, the team decided to create a seal attachment for a trocar rather than redesign a new trocar in its entirety. Additionally, due to time and material constraints, this was a more feasible direction to move forward with. The revised client statement reads:

*"Develop a trocar attachment that eliminates the valve leak problem in surgical **15mm** trocars to maintain carbon dioxide insufflation **(pressurized to 15mmHg)** when passing instruments through the device."*

3.5 Project Approach

In order to successfully complete the Major Qualifying Project (MQP) in one academic year, from August 2019 to May 2020, the team outlined a project approach. The team decided to split the project approach into three categories: Technical Approach, Management Approach and Financial Approach. These categories are further defined in the following subsections.

3.5.1 Technical Approach

To approach the project in a technical aspect, the team planned out various goals to

accomplish each term. The goals are noted in Table 5 below.

Table 5. Term Goals

Term	Goal
A Term	● Gain Background Information / Need ● Initial Meetings with Advisor & Surgeon ● Weekly Meetings with Advisor ● Meetings with Surgeon as Needed ● Compile Background Research ● Create Initial Design Objectives ● Create Initial Client Statement ● Complete Literature Review ● Defile Design Requirements ● Define Design Specifications ● Develop Conceptual Designs ● Choose Final Design ● Meeting to Discuss Patents ● First Drafts of Chapters 1 to 4 ● Term Report ● Term Presentation
B Term	● Weekly Meetings with Advisor ● Further Develop Conceptual Design ● Create CAD Models of the Conceptual Design ● Gain Qualitative Data from Surgeon Survey ● Material Research ● Continue Communication with Surgeon ● Explore Prototyping Options - Meet with WPI Facilities: ○ Makerspace ○ Washburn Shops ○ Higgins Lab Prototyping ● Print / Machine Prototype ● Reiteration of Chapters 1 to 4 ● First Draft of Chapter 5 & 6 ● Term Report ● Term Presentation

C Term	• Weekly Meetings with Advisor • Continue Communication with Surgeon • Reiteration of Conceptual Design • Manufacture Prototype of Final Design • Complete Testing on Final Design • Final Design Verification • Final Design Validation • Completion of Chapter 5
D Term	• Edit & Complete Final Paper • Manufacture of Final Device • Final Project Presentation & Submission

A Term

During the months prior to A Term, the team had their initial meeting with Dr. Laura Doyon, where she informed them of the insufflation problems. With this information, the team wanted to complete as much background research as possible to gain a wide understanding of the problem at hand. The goal was to get a grasp on surgical procedures, specifically laparoscopic and bariatric, as well as the trocars used for these applications. Once the background information was gathered, the team moved towards working on the design requirements, specifications, functions and constraints, followed by researching relevant design standards. After this, the team focused on creating conceptual designs as well as compiling deliverables for the end of the term. These included the first draft of Chapters One to Four of this report as well as the term presentation and report. Throughout the term, the team had weekly meetings with the project advisor, as well as meetings with the involved surgeon as necessary.

B Term

During B Term, the team continued to have meetings with the project advisor while they

worked towards developing a conceptual design and printing initial prototypes. In order to have a physical model of the new component to be used with current surgical trocars, the team first began by utilizing SolidWorks to prepare a CAD model of the design. Once an initial CAD model was created, the team met with various resources on the WPI campus in order to seek guidance on tools and materials that could be utilized as well as sought help in terms of printing physical parts. These resources included members from the Foisie Innovation Studio Makerspace, Washburn Shops and Higgins Lab Prototyping. These meetings combined with information found online allowed the team to determine possible materials to use for an initial prototype as well as ideate those for a final model in the future. Along with working towards finalizing a conceptual design, the team also focused on the reiteration of Chapters One through Four of this report along with drafting Chapters Five and Six. Finally, the team compiled all of these deliverables along with a final report and presentation.

C Term

The main objectives that were completed in C Term focused on the verification and validation of the final design. The team continued to print prototypes and edit their CAD model until the desired design was obtained. The team utilized the 3D printers in Foisie and Higgins to explore their printing options, until settling on the Form 2 printer in Higgins to print their final prototype. Once the team had a prototype, they determined the best assembly protocol to efficiently and successfully build the seal. To complete the verification and validation, the team tested their design choice in a multitude of different ways. This was followed by documentation in Chapter Five of this report. Furthermore, the team reflected upon the work done so far as well as the goals for the coming term. Along with these deliverables, the team also continued to have

weekly meetings with the project advisor and sought guidance from the involved bariatric surgeon as necessary.

D Term

In order to conclude this MQP, the team utilized D Term to pull together the deliverables of each term and finalize all work. The team completed this final report, manufactured a final device and performed a final presentation. With advisor approval and the help of Dr. Laura Doyon, the MQP was completed and successfully submitted.

3.5.2 Management Approach

Along with the technical goals, the team created a timeline of deliverables in order to complete the Major Qualifying Project in the appropriate time period. Specifically, the team produced four detailed Gantt Charts, one per academic term, that lists the start and end dates for each task. By utilizing this system, the team was able to track their progress in the long-term as well as on a daily basis. The four Gantt Charts can be found in Appendix A.

3.5.3 Financial Approach

For the completion of the Major Qualifying Project, a budget of $250 was provided per student by the Department of Biomedical Engineering of Worcester Polytechnic Institute. As the team consists of four members, this accumulates to a total budget of $1,000. The expenditure of this budget was split between the various requirements of each step of the engineering design process. These costs may include, but are not limited to, those related to material acquisition, obtaining current products on the market, manufacturing and testing of prototypes and

manufacture of a final-stage surgical trocar. The team allotted the following cost breakdown: (1) 10% ($100) for gathering market products, (2) 40% ($400) for prototyping, (3) 10% ($100) for testing materials, (4) 20% ($200) for manufacturing of the final device and (5) 20% ($200) reserved for other miscellaneous expenses. To ensure the designed surgical trocar is competitive in the market, the team strives to keep the cost of manufacturing the final device to be below $50.

The material for device fabrication was purchased both internal and external to Worcester Polytechnic Institute. Prototype testing and manufacturing was completed on equipment in WPI's biomedical engineering labs and in the Foisie MakerSpace. The estimated cost of the final device is listed in Chapter 7.

CHAPTER 4 - DESIGN PROCESS

The design process began once the team completed the literature review and collected information from meetings with their mentoring bariatric surgeon. After completing a need and gap analysis, the team was able to identify the important components that must be included in their final design. Following need identification, the team created conceptual designs based on the requirements of the device. Through iterations, prototyping, and testing of these designs, the team was able to come up with the final project design.

4.1 Needs Analysis

Currently the market for laparoscopic tools offers a variety of options for 15mm trocars that can be used during bariatric surgery. These products can be seen in Section 2.3.4, Table 2. However, despite there being so many companies producing trocars for this use, surgeons are finding issues relating to current designs. Among these issues is the creation and maintenance of the pneumoperitoneum. Through conversations with the project's overseeing bariatric surgeon and advisor, the team identified problems with current devices and created specific need criteria. This criteria is based on the design objectives seen in Section 3.2.1. The Pairwise comparison for the device needs are in Table 6.

Table 6. Pairwise Comparison Based on Device Design Needs

	Safe Insertion and Placement	**Create CO_2 Insufflation**	**Allow for Passage of Tools**	**Maintain Insufflation During Tool Insertion and Removal**	**Total**
Safe Insertion and Placement	-----	0	0.5	0.5	**1.5**
Create CO_2 Insufflation	1	-----	0.5	0.5	**2.5**
Allow for Passage of Tools	1	0.5	-----	0	**2**
Maintain Insufflation During Tool Insertion and Removal	1	0.5	1	-----	**3**

After completing the Pairwise comparison chart, it was clear that the most important criteria to focus on was maintaining insufflation during the insertion and removal of surgical tools. The aspect of maintaining insufflation is lacking in current trocar designs. In order to maintain insufflation throughout the procedure, the inner seal of the trocar needs to be able to withstand the stresses of the surgery. Despite identifying insufflation as the main priority, the other criteria still need to be met when designing the attachment for the trocar. It is important that the trocar attachment is biocompatible, does not cause complications during surgery, and allows for the passing of tools. Using the need criteria, the team was able to create conceptual designs that attempt to solve the most important problems of the current market designs.

During the evaluation of the needs for the user and the industry, the team also identified some non-essential needs for the device. For example, the new device should be cost efficient and user friendly. Making the device cost efficient allows for it to be marketable; users are more likely to try a new device if it is priced similarly or for a lesser value than the ones already on the market. Next, if the device is user friendly, people will be more receptive to trying it. The device should be made as simple and straightforward to use as possible without losing the functionality. These non-essential needs are not mandatory to the success of the device, but would increase the desire for use by surgeons.

4.2 Primary Conceptual Design

After the needs analysis, design criteria and literature review were complete, the team brainstormed four initial conceptual designs. These designs sought to be potential solutions to the need presented by the client. The team evaluated these designs by comparing them to one another and to the trocar used by Dr. Laura Doyon in her practice. The design idea that was evaluated as having the most potential for success was selected for continued development. The conceptual design below displays this favored idea and provides information on its development.

Inflatable Seal

This conceptual design works as an attachment to the Medtronic VersaOne Optical Trocar and resembles the inflation of a circular/donut-shaped pool float or inner bike tire tube. It is designed so that the seal would be enclosed in a plastic casing, which would attach to the head of the cannula. It would contain both original Medtronic seals in addition to the new inflatable

seal. Thus, the new attachment will resemble the original Medtronic piece, yet have the team's new seal design.

For the new seal, the team had to select a material that can inflate to provide compression around the tools inserted through the trocar. Since tools are being inserted and expansion must occur, the seal must be composed of a material resistant to piercing by the tool in use, but also flexible enough to allow for inflation and therefore compression. Additionally, since the design is desired to be reusable, the seal and attachment must be made out of a material that is not only biocompatible, but also able to be autoclaved without the loss of functional ability and strength.

Functionally, the seal is designed such that with enough inflation, the seal provides an airtight system that does not allow carbon dioxide to escape through crevices that are often created between the trocar seal and the inserted tool during surgery. In order to inflate the seal, the trocar is equipped with a second port that attaches to a syringe filled with air. When opened, the port allows the air from the syringe to be inserted into the inflatable seal, thus expanding the seal to fit around the tool being used. The sketch of this conceptual design can be seen in Figure 14 below.

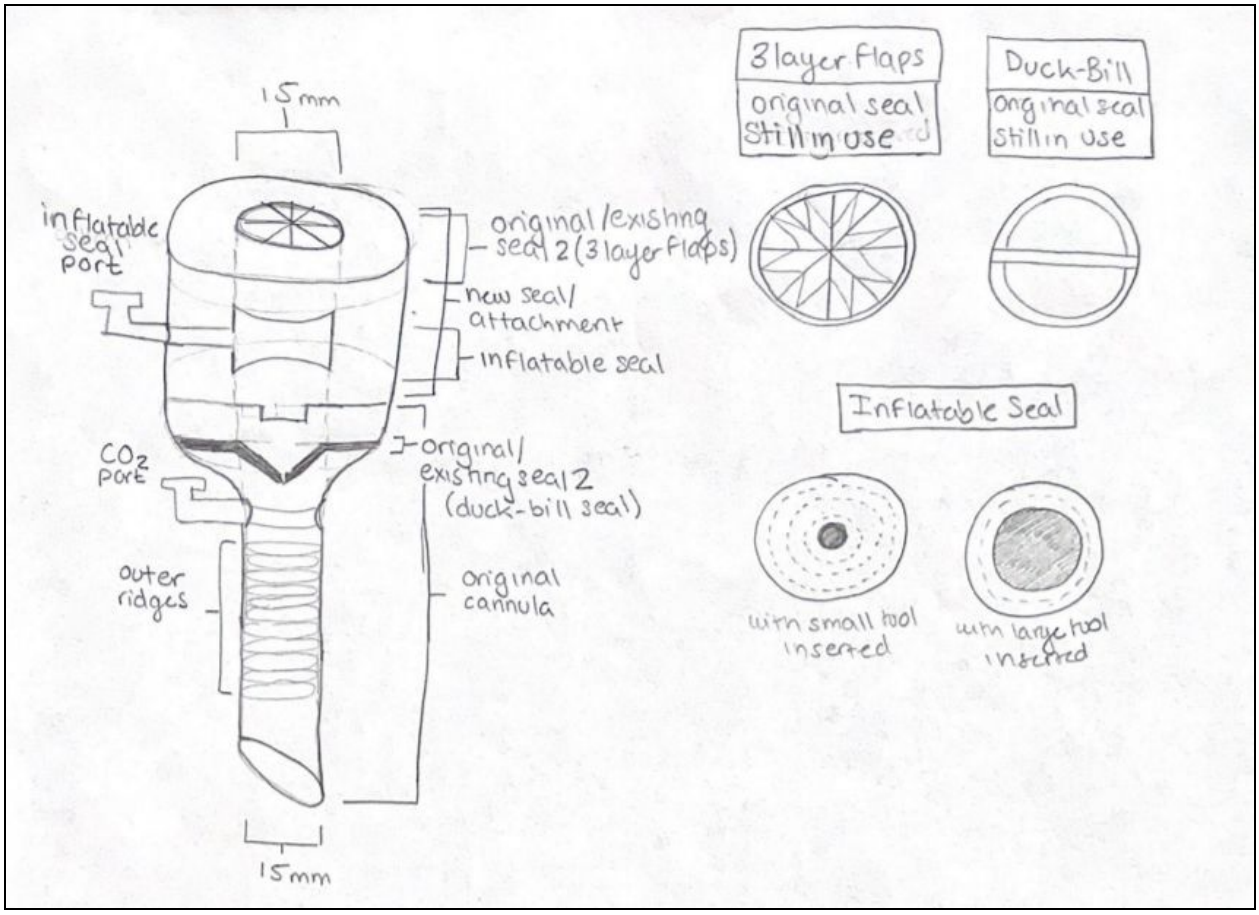


Fig. 14. Sketch of Inflatable Seal Conceptual Design

As with any design, this concept has a few advantages and disadvantages to be considered. One positive feature is that the seal can be inflated or deflated in order to fit variously sized tools, allowing it to be used universally. This ensures tight compression around the tool and does not allow carbon dioxide to escape during use. Another positive feature is that the seal is likely to be resistant to fatigue, since the surgical tools are not pushing through the seal, causing it to open and close like most others; it is instead providing compression against the sides of the tool. Along with this, the design is ideally made to be reusable, thus it creates less waste than similar single-use products and is more cost friendly in the long term. On the other hand, one disadvantage of this design is that the new seal would not aid in stopping the loss of

carbon dioxide when no tools are present in the trocar, as there is a small circular center that cannot be plugged. However, the team found this not to be too important of an issue, as both of the original seals are still implemented in this design. This original seal design has not been noted to have an issue with the loss of carbon dioxide when no tools are present. The team looked to feasibility and functional testing to determine the prominence of the advantages and disadvantages of this conceptual design.

4.3 Alternative Conceptual Designs

The team created three other conceptual designs that they ultimately chose not to pursue past the brainstorming phase. These designs also aimed to solve the client statement, however there was not enough proof that any of these designs would outperform the Inflatable Seal design presented above.

Camera Shutter Seal

The Camera Shutter Seal design adds a mechanical component that allows surgeons to twist the trocar head to adjust the seal to the size of the tool they are using. When the component is rotated, the seal responds by either expanding or retracting to fit the tool's outer diameter, similar to how a camera shutter works when taking a photograph. This allows the surgeon to create a tighter seal, despite any drastic size differences in their tools. The Camera Shutter Seal would have been made of a biocompatible metal on the outer diameter while the inside tips will be made of an elastomeric material. This seal would have been placed between the two other Medtronic VersaOne seals. The purpose of this third seal is to be the main source of sealing

protection from carbon dioxide leakage. A diagram of the Camera Shutter Seal can be seen in Figure 15.

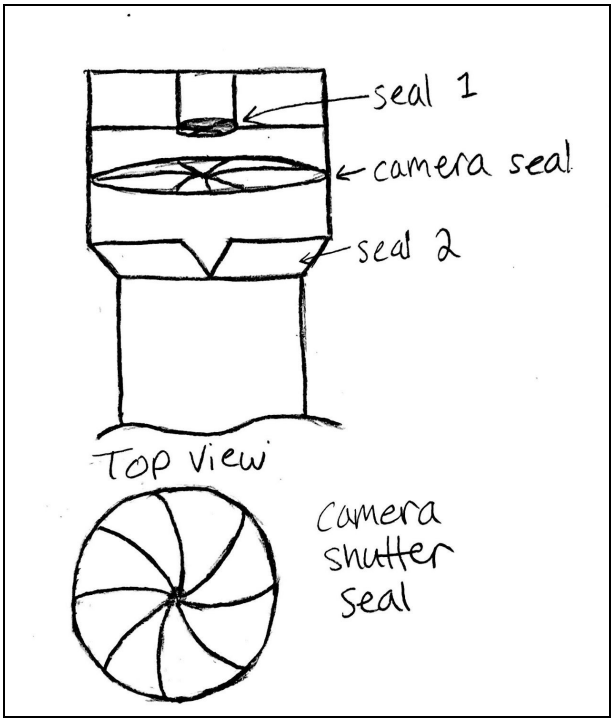


Fig. 15. Camera Shutter Seal Conceptual Design

The benefits of using the Camera Shutter Seal design are for increased sealing around the surgical tool. Primarily the issue with commonly used trocars is that their inner seal stretches and deforms when instruments are inserted and removed. With this shutter seal, the instruments will not have to be forced through the seal; they will simply enter the cannula and then the seal will be adjusted to fit the size of the instrument. This will prevent the seal from deforming throughout the surgery and minimize the amount of carbon dioxide leakage. Another benefit with this design is that since it is adjustable, it has the ability to be implemented into trocars of different sizes, making it more useful in the market. A downfall of this design, however, is that it might limit the mobility of the surgical tool. Depending on the material chosen, it could decrease the flexibility

of the seal leading to a decrease in range of motion that surgeons normally experience. Additionally, this design may not perform as well with tools that do not have a cylindrical outer diameter.

Overlapping Seals

The Overlapping Seals conceptual design enhances the simpler seals that are currently present in the market for trocars. This design involves placing two seals at the bottom of the head of the trocar, with one seal only a few millimeters above the other. It first aims to prevent the leakage of carbon dioxide by having overlapping flaps; each seal has a right and a left flap, with one flap resting slightly over the other. It also aims to prevent leakage by having the slits of these two seals be set in a perpendicular configuration compared to one another. The slit of one seal would run horizontally from one end of the instrument to the other, and the slit of the second seal would run vertically. This can be seen in Figure 16. Carbon dioxide deflation in the abdomen is minimized through this design as it decreases the amount of small crevices that gas can leak out of. This design also includes the original top seal of the Medtronic VersaOne trocar. These seals would all be made out of a flexible, biocompatible material that could adapt to tools of various sizes and allow for small movement of the tools in the trocar. They would work together to allow for the smooth passage of tools into the abdomen while preventing the outward flow of gas.

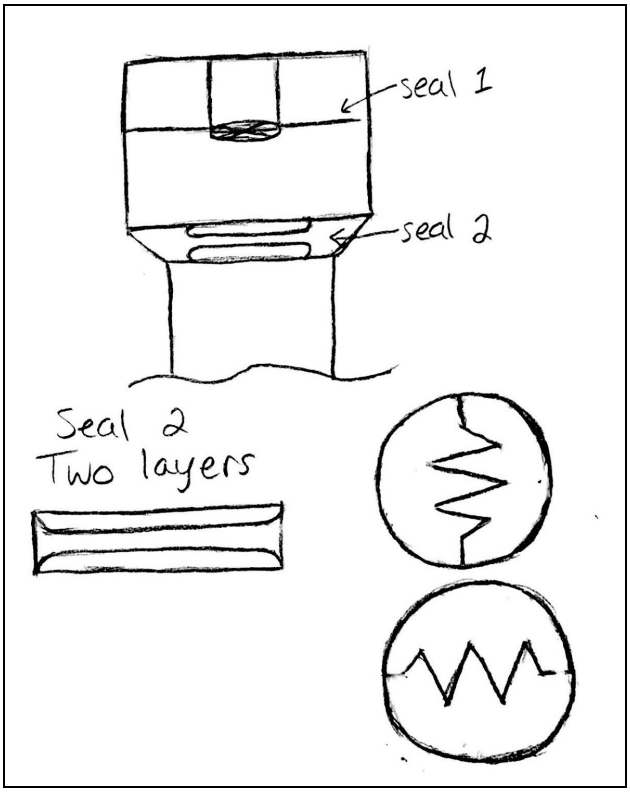


Fig. 16. Sketch of Overlapping Seals Conceptual Design

The team identified a few positive and negative aspects of this design when analyzing the concept. To begin, a strong element of this design is that the overlapping flaps would be likely to prevent the leakage of carbon dioxide through the employment of a very simple design. If the flaps were made out of a rubber-like material, they will easily lay on top of one another, creating an airtight seal. The other seal designs on the market are known to stretch and wear out throughout the surgery, creating small, detrimental holes with nothing to block them. The overlapping flaps will minimize crevices from being created, and the two seals placed on top of one another establishes a large barrier that can help to prevent carbon dioxide from moving into the head of the trocar and therefore out of the body. This design is also simple, as the placement of circular seals in the head of the instrument and the use of flexible seal material is already

present in modern trocars. There are a couple of negative aspects that helped lead this design to becoming an alternative concept. One of the biggest disadvantages is that the surgeon would have to use a lot more force to get the tools through all three seals compared to the two that are commonly used now. Another aspect that worried the team is the fact that the seals would be made out of the same or very similar material to the seals that currently make up the Medtronic VersaOne Optical Trocar, and these seals are known to wear out during surgery. The team was not confident that this new seal design would prevent the overall seal from weakening.

Rubber Stopper

This conceptual design was derived from the rubber stoppers commonly used for flasks in a laboratory. This design consists of disposable, hollow cylinders that when attached to the tool forms an airtight ring around it, blocking the space between the trocar and the tool to prevent the leakage of carbon dioxide. The outside diameter of the cylinder is approximately equal to the diameter of the trocar opening, while the inside diameter is slightly larger than the tool's diameter allowing enough room to fit in between both of these components. The stoppers are utilized by sliding the tool through the opening in the stopper and then inserting the tool into the trocar, with the stopper in the head of the instrument. A drawing of this conceptual design can be seen in Figure 17.

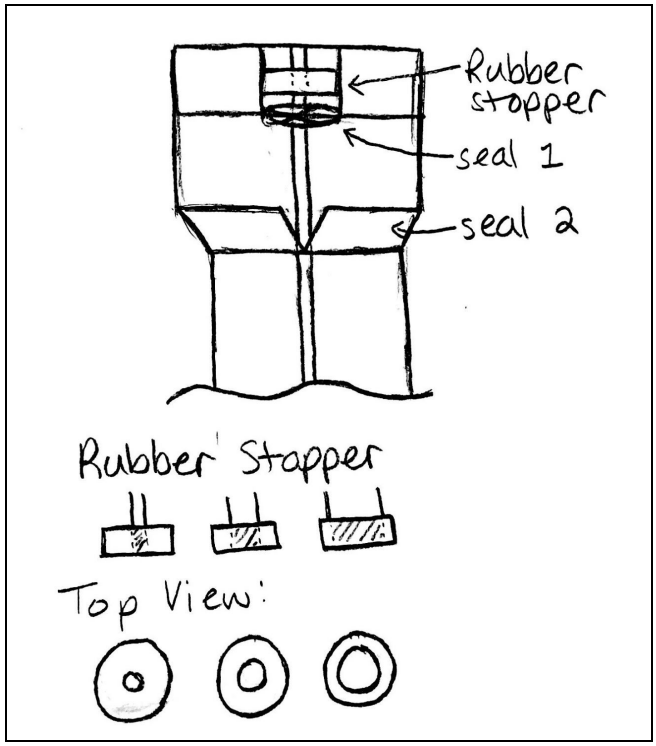


Fig. 17. Sketch of Rubber Stopper Conceptual Design

With the use of this design, none of the existing tools and instruments must be replaced. The stoppers would be purchased as an additional component and added onto the tools required for the surgery. Since trocars are available in different sizes, different sets of the stoppers would have to be developed, as seen in Figure 17. In addition, the stoppers must account for the different size tools, some of which do not have a uniform cross section. Another challenge presented by this design is the potential loss of mobility. The stopper will obstruct the area around the tool thus limiting the lateral and vertical range of mobility. Also, the increase of friction between the trocar and the stopper requires an increase in the force used to insert and remove the tool, which increases the potential risks both the patients and surgeons.

4.4 Final Design Selection

To determine which conceptual design to move forward with, the team performed a Pugh Analysis. As a decision matrix, this analysis allowed the team to evaluate all designs based on the objective criteria and in comparison to the gold standard. For this project, the team measured their four possible design solutions in comparison to Medtonic's VersaOne Optical Trocar as this is the device used by Dr. Laura Doyon. The completed Pugh Matrix can be seen in Table 7 below.

Table 7. Pugh Matrix - Final Design Selection

Requirement	**Weight**	VersaOne Optical Trocar	Inflatable Seal	Camera Shutter Seal	Overlapping Flaps	Rubber Stopper
Maintain Insufflation During Tool Insertion and Removal	4	0	+2	+1	0	0
Create CO_2 Insufflation	3	0	0	0	0	0
Allow for Passage of Tools	2	0	-2	-1	0	-1
Safe Insertion and Placement	1	0	0	0	0	0
RANK SCORE	--	**0**	**4**	**2**	**0**	**-2**

As seen in the decision matrix above, each of the design objectives were ranked

according to their significance. With a numeric ranking of four being the most important and a ranking of one being the least important objective, the different design ideas were compared to the gold standard. This comparison was done using a numeric ranking system but using values spanning from negative two to positive two. A negative ranking indicates the solution is less successful than the gold standard, while a positive scoring represents a more successful solution, and zero is equivalent. According to these rankings, the Inflatable Seal design has the largest positive score, therefore this design concept was chosen for continued development.

CHAPTER 5 - DESIGN VERIFICATION

In the medical device industry, design verification and validation is of utmost importance. Not only do these processes ensure safety of medical devices, they also work to ensure that the device is feasible and will perform as intended. Thus, for design verification, testing was performed to ensure that the final design met the necessary specifications and could successfully perform required functions. The procedures for these tests as well as results can be found in the subsequent sections within this chapter.

5.1 Testing Procedures

In order to complete design verification, individuals must perform procedures that prove that the system meets all of its specified requirements at a particular stage of its development. Therefore, the team decided upon four investigations for verification of the design of the trocar seal: Inflatable Seal Failure, Insufflation Proof of Concept, Quantitative Leak Test, and Range of Motion. The testing protocols can be found in Appendix C.

5.1.1 Inflatable Seal Failure

To begin the testing process, the team sought to analyze various failure properties of the new inflatable seal. Specifically, they wanted to observe how the seal breaks or pops due to overinflation as well as how resilient it is to puncture to ensure patient safety. This was important in determining the overall durability and safety of the design as well as if it meets applicable specification listed earlier in this report:

- *The device shall meet biocompatible standards.*

The team first gathered appropriate materials such as the attachment that incorporated the new seal design, as well as a 60 cubic centimeters air syringe and objects (as listed in Table 8) that represent tools commonly used during laparoscopic surgery. To begin the test, the team placed the bottom piece of the inflatable seal attachment face up on the table without the trocar attached to clearly observe the rupture. They attached the 60 cubic centimeters syringe and inserted air into the seal in intervals of 20 cubic centimeters, with two seconds in between injections, making sure to note observations during the entire process. The team first attempted to observe how much air was utilized to fully inflate the seal and furthermore how much air was needed to cause rupture, if applicable. If the seal had popped, the team would have examined how the material failed, noting if any part became completely detached. This allowed the team to begin to understand what to expect during further testing when the view of the seal is obstructed. The team then moved to completing the same procedure to rupture, utilizing various inflation speeds and attachment configurations.

Table 8. Objects Used During the Inflatable Seal Failure Testing

Object
Phillips Head 1 (3mm tip width)
Phillips Head 000 (1.5 mm tip width)
Flat Head (1.5 mm tip width)
Knife of Cuticle Pusher
Pointed Wooden Pretzel Stick
Pointed Metal 3D Printing Tool

After completing the tests for rupturing, the team moved towards testing the seal for its ability to withstand puncture. Employing the seal in an inflated state, the team used a representative tool to stab the seal multiple times. They recorded how many times the seal could be pricked before it began to deflate and was no longer considered functional. Similar to the previous test, this was performed multiple times, using various tools to obtain more reliable results.

5.1.2 Range of Motion

During the verification process it was important for the team to ensure the new attachment met or exceeded the functionality of the original Medtronic VersaOne trocar. Range of motion testing with the device was completed to quantitatively analyze the circumferential distance that the tools can move when the seal is inflated to compression in comparison to the original trocar. This allowed the team to verify that their attachment was meeting the following specifications as detailed in section 3.2.4 of this report:

- *The device shall have a seal made out of a biocompatible, elastomeric material capable of adjusting to various sizes and shapes of surgical tools.*
- *The device shall have an opening and sleeve with a diameter size of 15mm.*

The purpose of this test is to verify that the range of motion of the tool by the surgeon is not affected with the new attachment. In order for the team to have conclusive results from this test, both the Medtronic VersaOne trocar and trocar with the team's attachment needed to be tested so the values could be compared. To perform this test, the team used two bench vices to stabilize the trocar and video recording technology. The set up for the test can be seen in Figure

18 below. Next, the team needed to gather various objects that differ in diameter size, ranging from 1mm to 15mm, to represent laparoscopic tools that might be used. The objects used and their sizes can be seen in Table 9 below.

Fig. 18. Setup for the Range of Motion Testing

Table 9. Objects Used During the Range of Motion Testing

Object	Diameter	Image
Large Compact Dowel	14.8 mm	
Medium Wooden Dowel	12.3 mm	
Small Wooden Dowel	7.5 mm	

For the test, the object was placed through the trocar, which had the team's attachment in place, and then the seal was inflated to the point of compression around the object. Once completely compressed, the user angled the tool towards the top of the attachment and then moved it in a clockwise direction until the tool was back to the starting position (this pattern can

be seen in Figure 19). During this rotation, the user was pushing the tool towards the outer edge of the attachment to demonstrate full range of motion. This sequence was completed five times with each object so that there would be an average range of motion. To standardize the test and the results, the same team member completed each trial to ensure that the forces and movements applied to the object were comparable. Finally, during each trial of the test, a camera was positioned horizontally to the fixture at a distance of three feet so that the circumferential distances of each object could be recorded and later analyzed using ImageJ software.

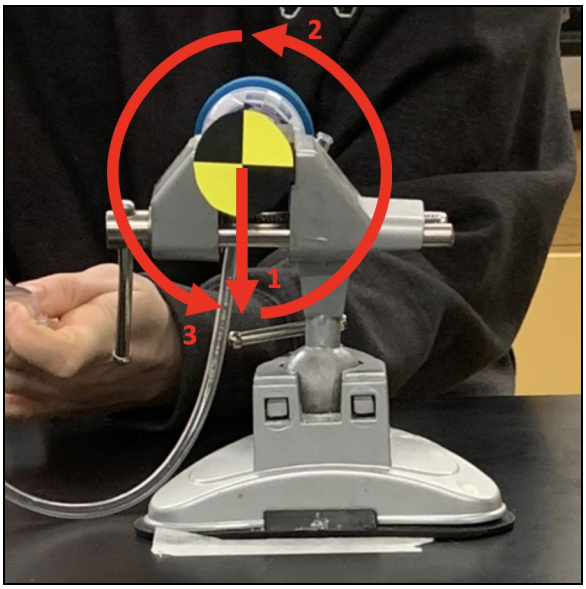


Fig. 19. Pattern of Rotation During Range of Motion Test

5.1.3 Insufflation Proof of Concept

To begin to understand how the seal performed in terms of maintaining insufflation, the team moved on from testing how the inflatable seal breaks to a proof of concept examination. This proof of concept insufflation tests the following specifications:

- *The device shall be capable of limiting carbon dioxide from escaping through the trocar.*

To complete this test, the team utilized a trocar with the new seal attachment, inflatable balloons, and variously sized objects that resemble different laparoscopic tools used in surgery. The team first assembled a fully-equipped trocar with their attachment by removing the previous seal attachment from the Medtronic VersaOne and connecting their prototype in its place. Then, as seen in Figure 20, a latex balloon of 12 inch measurement was manually inflated and placed on the bottom of the cannula of the trocar, covering the entire opening. The team visually observed if there was any leakage from the balloon during the following stages: without tool insertion and with tool insertion of various shapes and sizes. While no quantitative data was collected during this testing, it allowed the team to see that their design has the ability to succeed in maintaining insufflation during various conditions, thus allowing them to proceed to more specific and detailed procedures.

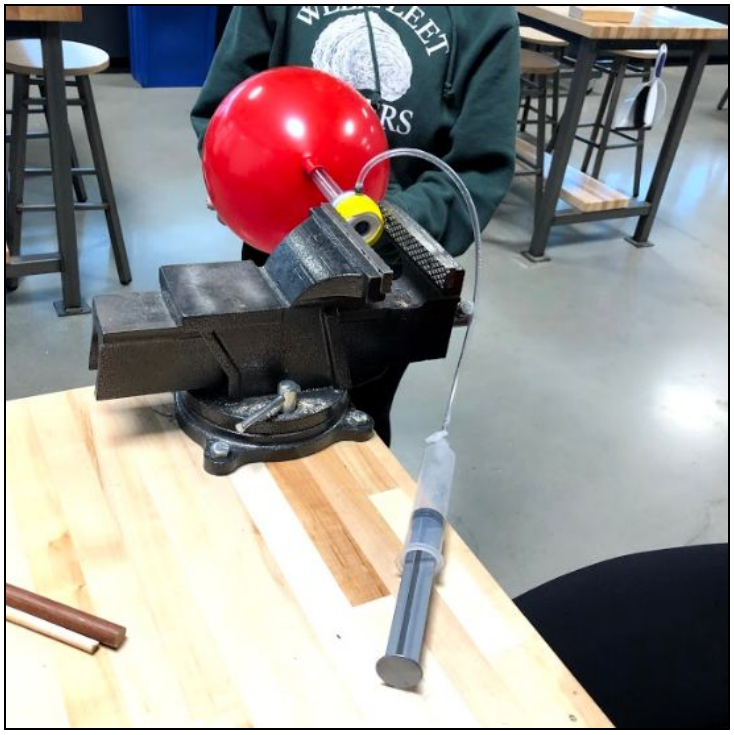


Fig. 20. Proof of Concept Setup

5.1.4 Quantitative Leak Test

Following the proof of concept tests, the team wanted to quantitatively analyze the trocar's ability to assist in maintaining insufflation with their attachment on the instrument in comparison to the original Medtronic VersaOne trocar. This was important for determining if the final design successfully incorporated the following specification as detailed in section 3.2.4 of this report:

- *The device shall be capable of limiting carbon dioxide from escaping through the trocar.*

To perform this test, the team set up an environment simulating a human abdomen, which consisted of a sphygmomanometer, surgical tubing, T barbed connections, small o-rings and the

trocar. The sphygmomanometer was used to create and read pressure throughout the test. It was attached to the T barbed connection, which created a closed loop between the trocar and sphygmomanometer. The trocar did not contain the obturator, as this test was meant to simulate what it is like once the trocar has already passed through the abdominal wall. See Figure 21 for a picture of the setup of this test.

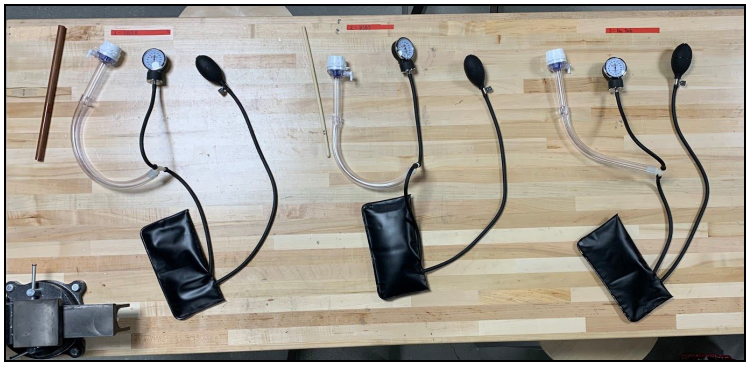


Fig. 21. Setup of the Quantitative Leak Test

This test was completed with three different conditions utilizing three abdomen setups. The first condition consisted of the following process: one hour with the small tool (7.5 millimeters) and one hour with the large tool (14.8 millimeters), repeated twice for a total of four hours. The second condition was the same as the first, yet the test began with the large tool for an hour, followed by the small small tool. Finally, the third condition was a control in which no tools were used throughout the test. The test was performed with the following steps:

1. Inflate all three abdomens to 15mmHg.
2. Insert small tool (7.5mm) into abdomen one and large tool (14.8mm) into abdomen two.
3. Record new pressure for both abdomens.
4. Reinflate both abdomens to 15mmHg.

5. At ten minute intervals until the one hour is reached, record the pressure in all three abdomens.
6. After one hour, reinflate all three abdomens to 15 mmHg.
7. Take the old tool out, note any changes in pressure.
8. Reinflate all three abdomens, if applicable, to 15mmHg.
9. Insert the large tool into abdomen one and small tool into abdomen two.
10. Record any changes in pressure in the abdomens.
11. Reinflate to 15mmHg and record the pressure in ten minute intervals until one hour is reached.
12. Repeat steps 6-11 two more times such that each tool is inserted again into both of the abdomens.

This test was completed with both the original Medtronic VersaOne trocar as well as the Medtronic trocar with the team's new seal attachment.

5.2 Testing Results

After completion of the testing protocols, the team analyzed all of the results. They utilized a number of applications in order to accurately relay the information such as Microsoft Excel, ImageJ and Matlab. The findings are presented in the following sections.

5.2.1 Inflatable Seal Failure

The first test that was completed intended to show the team how the seal would fail if punctured or overinflated in a condition similar to laparoscopic surgery. Overall, they found the test to be successful as the seal outperformed the team's expectations. Specifically, during the

rupture test in which the seal was inflated past its ideal volume, the increase in air had no effect on the seal's performance and never ruptured the material throughout all five trials. Additionally, during the puncture test, the seal was stabbed eighteen times before failing, which greatly surpassed the team's expectations for the material. When the seal did finally rupture, the material remained entirely inside the plastic casing. The observations for both tests can be seen in Tables 10 and 11 below.

Table 10. Results from Inflatable Seal Failure - Rupture Test

Rupture Test		
Trial Number	Attachment Setup	Observation
1	Bottom attachment with seal face up	Inflated slowly as air went in, paused for 2 seconds at 20CC
		Slight deflate during 2 second pause likely due to backflow of air in the tube
		Seal never popped with 60CC of air inflation
2	Bottom attachment with seal face up	Inflated slowly as air went in, paused for 2 seconds at 20CC
		Slight deflate during 2 second pause likely due to backflow of air in the tube
		Seal never popped with 60CC of air inflation
3	Bottom attachment with seal face up	Inflated slowly as air went in, paused for 2 seconds at 20CC
		Slight deflate during 2 second pause likely due to backflow of air in the tube
		Seal never popped with 60CC of air inflation
		Seal inflates over the edges of the attachment rims
4	Complete attachment with bottom face up	Inflated slowly as air went in, paused for 2 seconds at 20CC
		Quicker deflate than trials 1-3 during 2 second pause likely due to backflow of air in the tube as well as extra pressure from the top attachment
		Seal never popped with 60CC of air inflation
		Seal inflates through bottom hole of attachment
5	Complete attachment with bottom face up	Inflated extremely quickly, without stopping at 20CC intervals
		Seal never popped with 60CC of air inflation
		Seal created massive bubble but held constant pressure for about a second
		Seal returned to normal inflation size after inflation was ceased

Table 11: Results from Inflatable Seal Failure - Puncture Test

Puncture Test				
Trial Number	Tool	Contact Angle	Inflation Speed	Observations
1	Phillips Head 1 (3mm tip width)	~45°	slow inflation to 60CC	Seal did not pop with full inflation Seal inflated around the tool without puncture
2	Phillips Head 1 (3mm tip width)	~45°	slow inflation to 60CC	Seal did not pop with full inflation Seal inflated around the tool without puncture
3	Phillips Head 1 (3mm tip width)	~45°	slow inflation to 60CC	Seal did not pop with full inflation Seal inflated around the tool without puncture
4	Phillips Head 1 (3mm tip width)	~45°	fast inflation to 60CC	Seal did not pop with full inflation, but formed bubble Seal inflated around the tool without puncture
5	Phillips Head 1 (3mm tip width)	~45°	fast inflation to 60CC	Seal did not pop with full inflation, but formed bubble Seal inflated around the tool without puncture
6	Phillips Head 000 (1.5mm tip width)	~45°	slow inflation to 60CC	Seal did not pop with full inflation Seal inflated around the tool without puncture
7	Phillips Head 000 (1.5mm tip width)	~45°	slow inflation to 60CC	Seal did not pop with full inflation Seal inflated around the tool without puncture
8	Phillips Head 000 (1.5mm tip width)	~45°	slow inflation to 60CC	Seal did not pop with full inflation Seal inflated around the tool without puncture
9	Phillips Head 000 (1.5mm tip width)	~45°	fast inflation to 60CC	Seal did not pop with full inflation, but formed bubble Seal inflated around the tool without puncture
10	Phillips Head 000 (1.5mm tip width)	~45°	fast inflation to 60CC	Seal did not pop with full inflation, but formed bubble Seal inflated around the tool without puncture
11	1.5 Flat Head	~45°	slow inflation to 60CC	Seal did not pop with full inflation Seal inflated around the tool without puncture
12	Knife of Cuticle Pusher	~45°	slow inflation to 60CC	Knife edge held with pointy edge around tool Seal did not pop with full inflation Seal inflated around tool without puncture

13	Knife of Cuticle Pusher	~45°	fast inflation to 60CC	Knife edge held with pointy edge around tool
				Seal did not pop with full inflation
				Seal inflated around the tool without puncture
14	Pointed Wooden Pretzel Stick	~45°	slow inflation to 60CC	Seal did not pop with full inflation
				Seal inflated around the tool without puncture
15	Pointed Wooden Pretzel Stick	~45°	fast inflation to 60CC	Seal did not pop with full inflation, but formed bubble
				Seal inflated around the tool without puncture
16	Pointed Metal 3D Printing Tool	~45°	slow inflation to 60CC	Seal did not pop with full inflation
				Seal inflated around the tool without puncture
17	Pointed Metal 3D Printing Tool	~45°	fast inflation to 60CC	Seal did not pop with full inflation, but formed bubble
				Seal inflated around the tool without puncture
18	Pointed Metal 3D Printing Tool	~0°	inflated seal to 60CC before stabbing	Seal did not puncture
				Seal wrapped around tool without puncture
19	Pointed Metal 3D Printing Tool	~90°	inflated seal to 60CC before stabbing	Seal punctured after stabbing
				When tool was removed, the seal completely deflated

5.2.2 Range of Motion

The Range of Motion test allowed the team to determine if their attachment on the trocar limited the mobility of surgeons during surgery, as this could potentially be disadvantageous for their design. After completing multiple trials with various tools for the trocar with and without their attachment, the team utilized ImageJ to track their circular motion. The software allowed them to find eight positions of interest for each trial, as seen in Figure 22. They identified the pixels related to these positions, and found the radii for each circle. After identifying the pixel values, the team used the known diameter of the fiducial marker to translate their pixel values into centimeters, as seen in Table 12. From there, the team utilized Matlab to create graphs

representing the motion of each trial. These graphs, along with each trial's average, can be seen in Figures 23 and 24. The team also used Matlab to perform statistical analyses, such as finding any potential outliers for the trials (highlighted in blue in Table 12) and to determine the statistical significance of the results. The code used for this test can be seen in Appendix E.

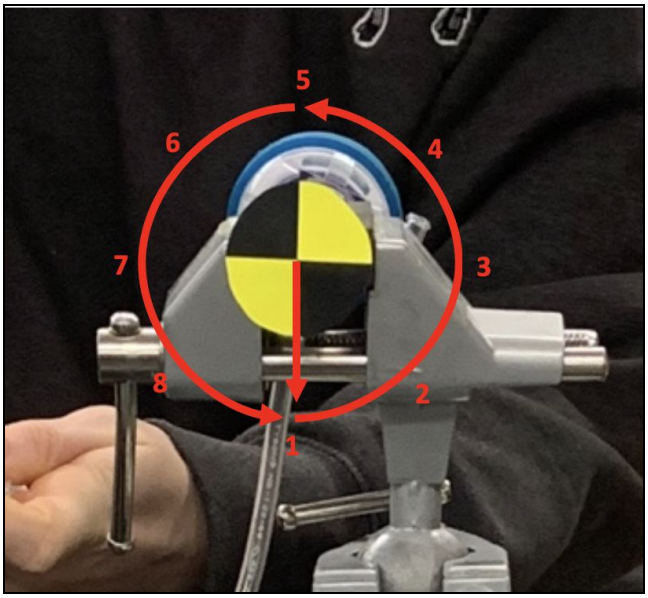


Fig. 22. The Eight Positions Identified in ImageJ for Range of Motion Test

For this test, the team determined the null hypothesis to be: the difference between the mean radius without the attachment and the mean radius with the attachment is zero (H_0: $\mu_{original} - \mu_{new} = 0$). Through visual observation, the Matlab graphs for the small and medium tool appear to show that the team's attachment does limit motion of the tools in the trocar (as seen in Figure 26). On the other hand, the Matlab graph for the large tool appears to have the opposite result, where the attachment provides more mobility for the tool than the original trocar (as seen in Figure 25). However, upon performing an unpaired, two tailed t-test in Matlab with all of the data, the team cannot conclude that the two datasets are significantly different. The resulting p-values from the t-test were all higher than 0.05 (as seen in Table 13) and therefore the team

failed to reject the null hypothesis (see Appendix E for Matlab outcomes). This means that the difference between the two datasets are not significant and the team cannot be sure that their attachment alters motion. Based on these results, the team cannot conclude that their attachment hinders motion, supporting the success of their design.

Table 12: Results from Range of Motion Test

Trocar	Tool Size	Trial Number	Radius (pixels)	Radius (cm)
Medtronic VersaOne Trocar	Big (14.8mm)	1	3.522	0.285
		2	2.140	0.173
		3	3.280	0.266
		4	3.216	0.261
		5	2.945	0.239
	Medium (12.3mm)	1	5.748	0.466
		2	6.455	0.523
		3	4.455	0.361
		4	4.106	0.333
		5	4.039	0.327
	Small (7.5mm)	1	9.723	0.788
		2	10.045	0.814
		3	9.902	0.802
		4	9.960	0.807
		5	10.375	0.840
New Attachment	Big (14.8mm)	1	1.995	0.162
		2	7.898	0.640
		3	2.177	0.176
		4	27.665	2.241
		5	4.298	0.348
	Medium (12.3mm)	1	3.738	0.303
		2	3.987	0.323
		3	4.553	0.369
		4	3.415	0.277
		5	3.173	0.257
	Small (7.5mm)	1	8.454	0.685
		2	8.497	0.688
		3	10.235	0.829
		4	10.452	0.847
		5	9.802	0.794

Table 13: Statistical Analysis Results from Range of Motion Test

	Mean w/ Attachment	Mean w/o Attachment	Standard Deviation w/ Attachment	Standard Deviation w/o Attachment	p-Value
Small Tool	0.769 cm	0.803 cm	$\pm$ 0.077	$\pm$ 0.022	0.298
Medium Tool	0.306 cm	0.372 cm	$\pm$ 0.043	$\pm$ 0.064	0.139
Large Tool	0.331 cm	0.245 cm	$\pm$ 0.222	$\pm$ 0.043	0.495

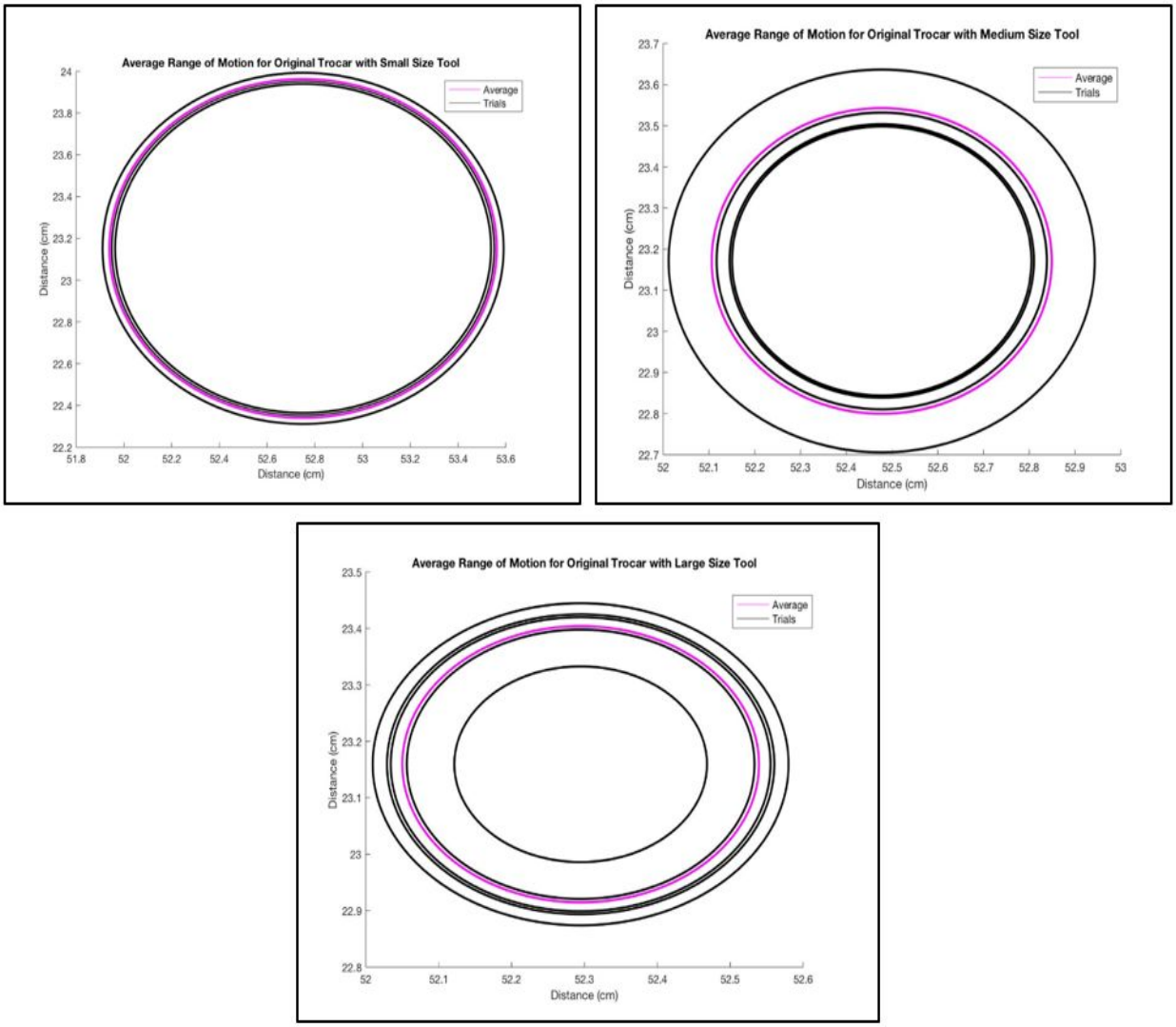


Fig. 23. Range of Motion Mapping - Medtronic VersaOne Trocar

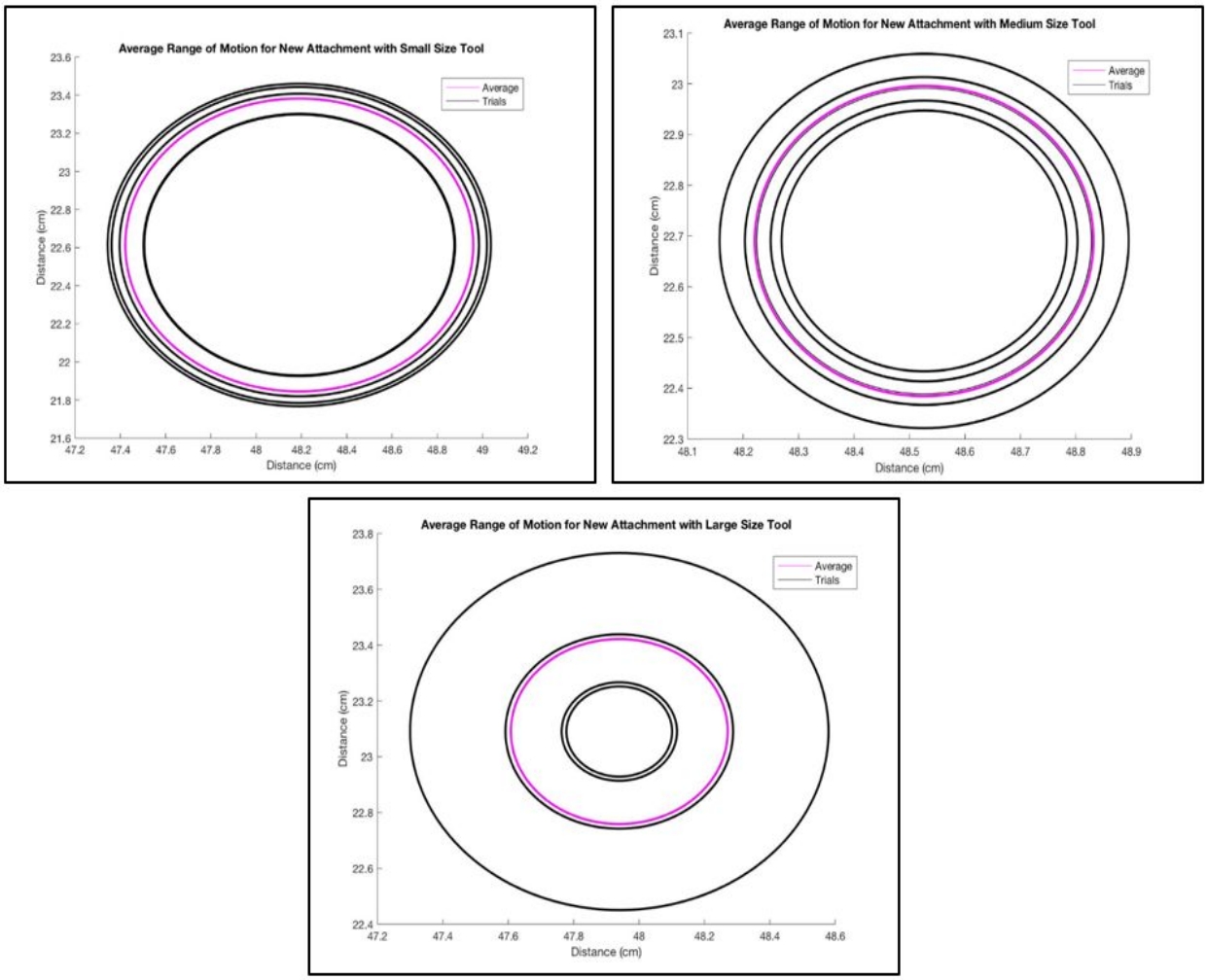


Fig. 24. Range of Motion Mapping - New Attachment

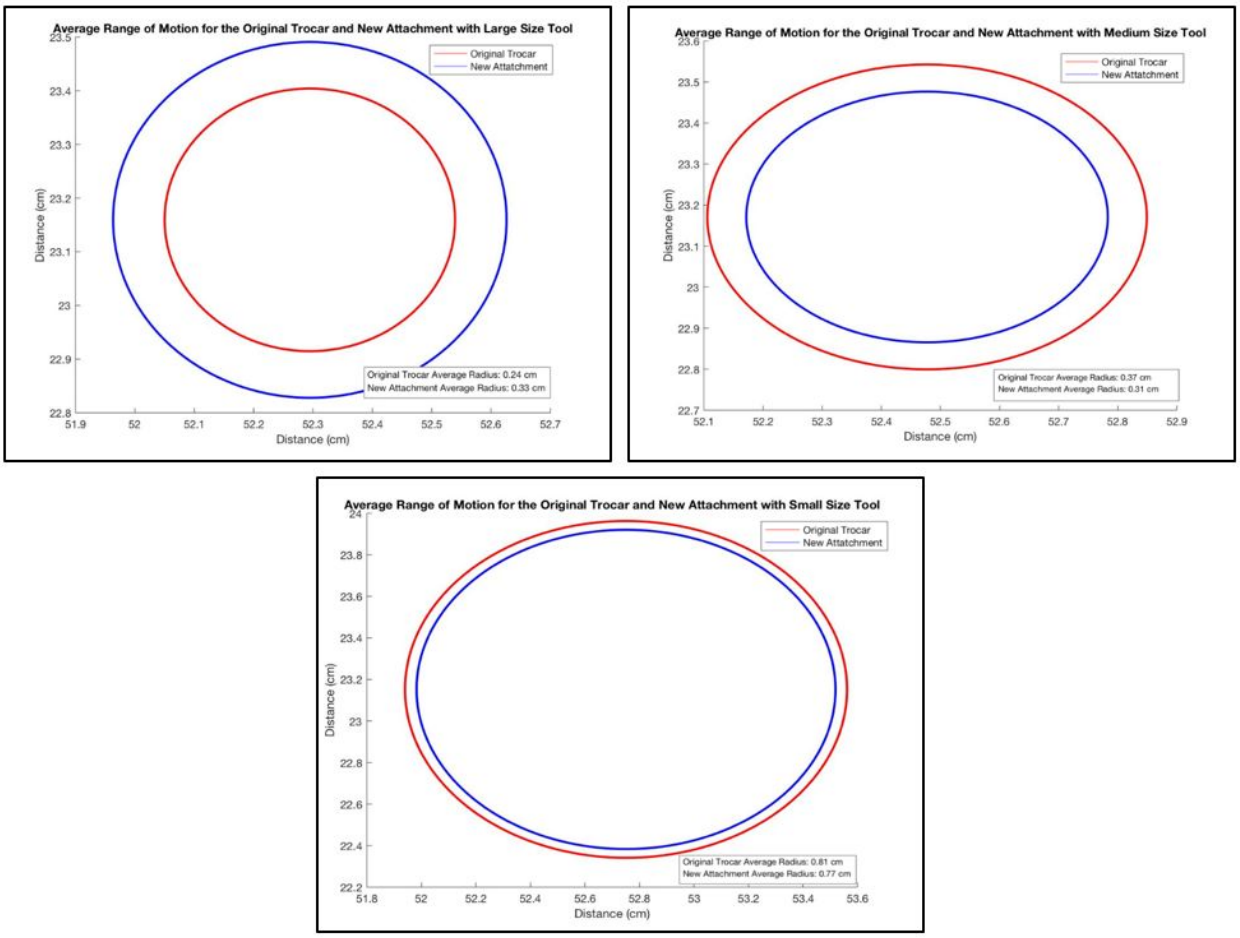


Fig. 25. Range of Motion Mapping - Average Comparisons

5.2.3 Insufflation Proof of Concept

When conducting the proof of concept test for the new seal attachment, the team saw positive and negative results. The team was surprised to see that the balloon did slowly leak air when tools were placed in the trocar. Over each two minute trial, the balloon appeared to lose about one-third of its initial volume. However, after a few trials, this leakage was determined to be due to the attachment's connection to the cannula rather than the functionality of the team's seal. When the team went on to repeat the test without inflating their seal, it was found that the

balloon deflated more rapidly and to completion over the two minute period. This occurred consistently for every trial. Ideally, the balloon should not have deflated at all during the test, but the fact that the balloon deflated at a quicker rate without the team's seal inflated provided positive results.

Based on these findings, the team focused on improving the connection between the new seal attachment and the original cannula of the trocar. Due to the material and printing constraints, the team could not modify the CAD model to fix this issue. Therefore, to stop air leakage from the attachment site and accurately analyze the team's seal during the quantitative leak test, they decided to caulk around the connection.

5.2.4 Quantitative Leak Test

The purpose of the quantitative leak test was to compare the pressure changes that occur in an artificial abdomen using the original Medtronic VersaOne Trocar versus one that included the team's attachment. Unfortunately, the team was unable to complete the testing with their attachment due to unforeseen circumstances. Prior to the start of the team's final term, there was a global pandemic, which caused WPI to move classes completely online and close the campus for the entirety of D term. This prevented the team from having access to their prototypes and testing supplies. Because of this, the team analyzed only the Medtronic VersaOne Trocar data and used these results to make assumptions on how their attachment would perform.

The results for the first test, with the Medtronic VersaOne Trocar, were gained by tracking changes in pressure of the three abdomens in 10 minute increments for one hour, with a total of 4 trials each. The testing setup was as follows: (1) Abdomen 1 - small tool, big tool,

small tool, big tool, (2) Abdomen 2 - big tool, small tool, big tool, small tool, (3) Abdomen 3 - no tools. The team chose to have a different testing order of tool sizes for Abdomen 1 and 2 to see if the size of the tool had an effect on the Medtronic seals during the first trial when they were brand new, as well as in the following trials after the seal may have been damaged. The team formatted the results they found in Table 13, which displays that for all trials and abdomens with tools, the pressure consistently dropped over time. Due to the drop in pressure, the abdomens required the team's manual inflation in between each trial in order to remain at the necessary level for surgery. However, the abdomen with no tools barely experienced pressure drops, displaying that the Medtronic VersaOne Trocar performs best when there are no tools inside of it. Following the collection of this data, the team used Microsoft Excel to create graphs of each abdomen over time(seen in Figure 26). This allowed the team to visualize pressure drops and the beginning of new trials over the four hour period. Again it can be seen here that Abdomen 3 with no tools had the smallest pressure drops over the four hour period. Additionally, in both Abdomen 1 and Abdomen 2 when the small tool was inserted, there was an instant drop in pressure during each trial. As the small tool sat in the abdomen over time, it consistently faced large pressure drops. This can be seen in the dips in the graphs for Abdomen 1 and Abdomen 2. After only 10 minutes, the value often dropped as low as 1mmHg, which would be unacceptable during surgery. The pressure drops were less significant for the big tool trials, but were still notable. When the big tool was inserted into the abdomen, the pressure typically increased from where it previously left off. However, over the one hour period, the pressure often dropped between 1-2mmHg below the required level of 15mmHg.

Table 14: Results from Quantitative Leak Test - Medtronic VersaOne Trocar

Trial 1					
Abdomen 1- Trial 1 (Small tool)		**Abdomen 2 -Trial 1 (Big tool)**		**Abdomen 3 -Trial 1 (No tool)**	
Time (min)	Pressure (mmHg)	Time (min)	Pressure (mmHg)	Time (min)	Pressure (mmHg)
Insufflation set to 15mmHg		Insufflation set to 15mmHg		Insufflation set to 15mmHg	
0 (tool insertion)	5	0 (tool insertion)	19	0	15
Insufflation was immediately returned to 15mmHg		Insufflation was immediately returned to 15mmHg			
10	2	10	15	10	14
20	0.5	20	15	20	13
30	0.5	30	15	30	13
40	0.5	40	15	40	13
50	0.5	50	15	50	13
60	0.5	60	14.5	60	12
Insufflation was immediately returned to 15mmHg		Insufflation was immediately returned to 15mmHg			
Remove Tool	7	Remove Tool	5		

Trial 2					
Abdomen 1- Trial 2 (Big tool)		**Abdomen 2 -Trial 2 (Small tool)**		**Abdomen 3 -Trial 2 (No tool)**	
Time (min)	Pressure (mmHg)	Time (min)	Pressure (mmHg)	Time (min)	Pressure (mmHg)
Insufflation set to 15mmHg		Insufflation set to 15mmHg		Insufflation set to 15mmHg	
0 (tool insertion)	21	0 (tool insertion)	4	0	15
Insufflation was immediately returned to 15mmHg		Insufflation was immediately returned to 15mmHg			
10	14	10	0.5	10	14
20	14	20	0	20	14
30	13	30	0	30	14
40	13	40	0	40	13.5
50	12	50	0	50	13
60	12	60	0	60	13.5
Insufflation was immediately returned to 15mmHg		Insufflation was immediately returned to 15mmHg			
Remove Tool	8	Remove Tool	10		

Trial 3					
Abdomen 1- Trial 3 (Small tool)		**Abdomen 2 -Trial 3 (Big tool)**		**Abdomen 3 -Trial 3 (No tool)**	
Time (min)	Pressure (mmHg)	Time (min)	Pressure (mmHg)	Time (min)	Pressure (mmHg)
Insufflation set to 15mmHg		Insufflation set to 15mmHg		Insufflation set to 15mmHg	
0 (tool insertion)	6	0 (tool insertion)	19	0	15
Insufflation was immediately returned to 15mmHg		Insufflation was immediately returned to 15mmHg			
10	1	10	14.5	10	15
20	1	20	15	20	14
30	1	30	14	30	14
40	1	40	14	40	14
50	1	50	13.5	50	14
60	1	60	13	60	13
Insufflation was immediately returned to 15mmHg		Insufflation was immediately returned to 15mmHg			
Remove Tool	10	Remove Tool	5		

Trial 4					
Abdomen 1- Trial 4 (Big tool)		**Abdomen 2 -Trial 4 (Small tool)**		**Abdomen 3 -Trial 4 (No tool)**	
Time (min)	Pressure (mmHg)	Time (min)	Pressure (mmHg)	Time (min)	Pressure (mmHg)
Insufflation set to 15mmHg		Insufflation set to 15mmHg		Insufflation set to 15mmHg	
0 (tool insertion)	21	0 (tool insertion)	6	0	15
Insufflation was immediately returned to 15mmHg		Insufflation was immediately returned to 15mmHg			
10	15	10	1	10	15
20	14.5	20	1	20	15
30	14	30	1	30	15
40	14	40	1	40	15
50	14	50	1	50	15
60	13.5	60	1	60	15
Insufflation was immediately returned to 15mmHg		Insufflation was immediately returned to 15mmHg			
Remove Tool	7.5	Remove Tool	10		

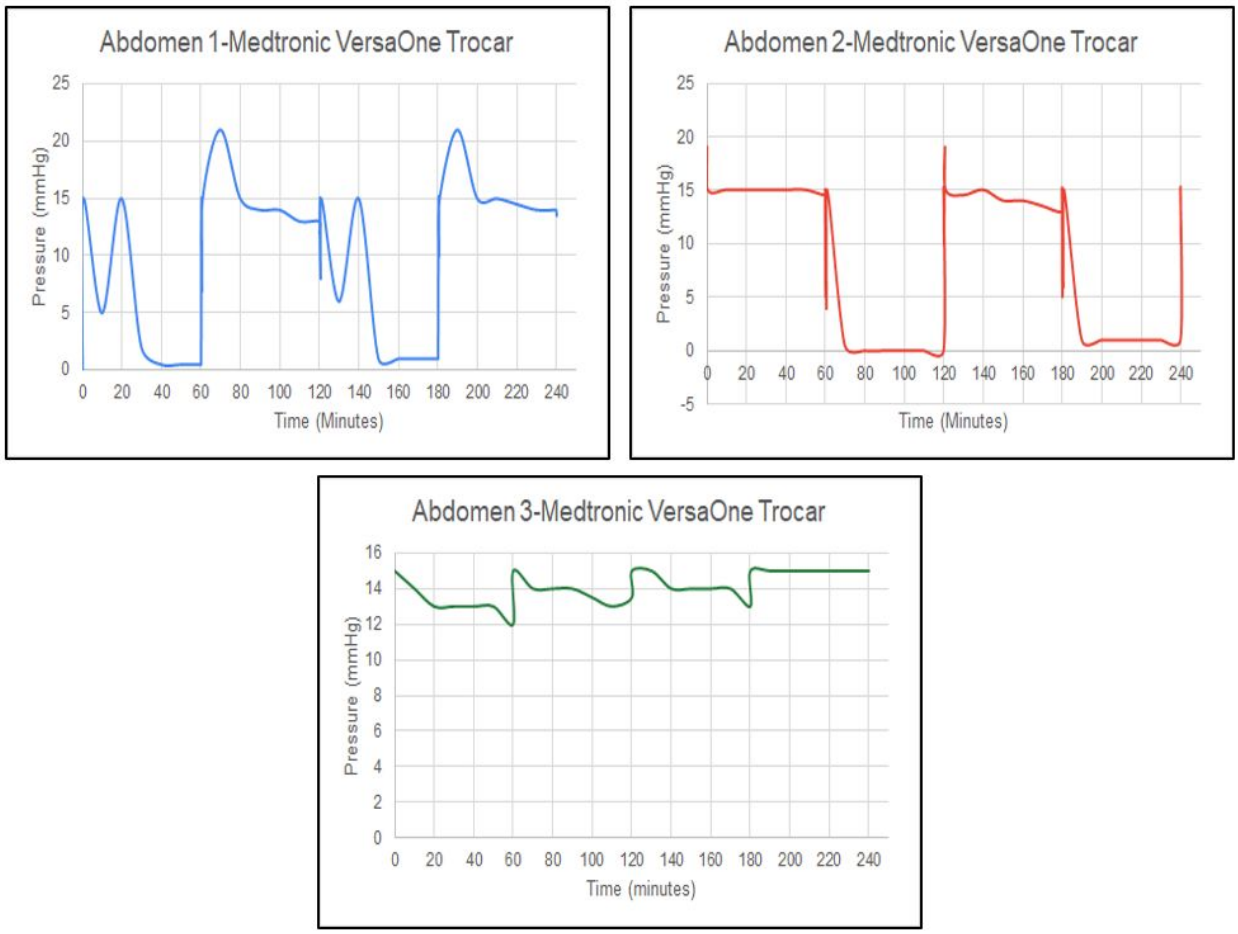


Fig. 26. Graphs from Quantitative Leak Test - Medtronic VersaOne Trocar

Due to the closure of the WPI campus in D term, the team was unable to access their materials, inhibiting the completion of the Quantitative Leak Test with their prototype. Based on this situation, the team made predictions and assumptions of what may have occurred during the test. These assumptions were decided from observations made during other tests and the differences in designs between the team's attachment and the original Medtronic VersaOne trocar seals. The team made the following predictions about the Quantitative Leak Test with their attachment: (1) the abdomen would experience less of a decrease in pressure, or the same decrease in pressure as the Medtronic VersaOne trocar during testing, (2) the abdomen without a

tool inserted would perform the best and have the smallest decrease in air pressure and (3) there would have been a potential for leakage through the trocar connections between the cannula and attachment.

The team assumed that since they did not remove any of the Medtronic seals, the team's attachment will not perform worse, in terms of total pressure drop, in comparison to the original trocar, meaning that the housing of tools during the hour long trial will not cause the abdomen's pressure to drop a significant amount. The team would expect to see an initial pressure drop during the insertion of the tool, due to the fact that it would take time to inflate the team's seal after insertion. After this pressure drop, the team's seal would be compressed around the tool with intention to stop any additional leakage, therefore reducing the total pressure drops that would occur over the hour. The concept of the team adding an extra seal that inflated to the size of the tool led them to believe that the attachment would provide an extra layer of protection to escaping air, and perhaps produce better results than the Medtronic VersaOne test alone. On the other hand, a factor the team identified that may be an issue during the testing of their prototype is the connection between the attachment and the cannula. Since the team's attachment does not perfectly connect to the trocar's cannula, air can escape. This can be attributed to the manufacturing abilities of the team. Due to tolerances on the 3D printer, the team could not verify a tight connection which could allow some leakage from the abdomen. Originally, the team intended to mitigate this issue by adding a layer of caulk around the connection between the cannula and the attachment. The addition of this would ideally create an airtight seal at the connection reducing leakage and would give the team more accurate results of the seal's performance. From these results, the final design section can be found in the following chapter.

CHAPTER 6 - FINAL DESIGN AND VALIDATION

6.1 Final Design Selection

After selecting the final conceptual design the team was able to successfully fabricate a final prototype by separating the attachment into two parts; the skeleton or frame of the attachment and the inner seal. For each of these components, multiple iterations were developed and several materials were tested in order to arrive at the final design.

The skeleton of the attachment was built using SolidWorks to develop a computer aided design which was rapidly prototyped using the Ultimaker 3 printer with polylactic acid (PLA) All subsequent iterations were developed using PLA as the material and the printing parameters found in Table 13 until the team was completely satisfied with the designed prototype. PLA was chosen for the initial iterations because it is inexpensive and easily accessible. This material paired with the specified printing setting resulted in a piece that met the desired dimensions and could withstand the strains of assembly and preliminary testing. Once the team was comfortable with their design, the final prototypes were developed using the Formlabs Form 2 printer with tough resin as the material. Since the design contained extremely small and thin details that were crucial for attachment to the cannula, the part required high deflection and resistance to forces. Thus, tough resin was selected as the final prototype material due to its low flexural modulus (1.6 GPa) and high ultimate tensile strength (55.7 MPa) when compared to PLA which has a flexural modulus of 3.2 GPa and an ultimate tensile strength of 49.5 MPa [70], [71] .

Table 15: Ultimaker 3 Print Settings

Nozzle	0.4 mm
Layer Height	0.05mm
Wall Thickness	0.8mm
Infill	100%

In order to develop the frame, the team first printed an exact replica of the Medtronic VersaOne cannula head in order to test the printer tolerances. Based on this model, multiple iterations were developed with alterations in order to improve the prototype and facilitate its assembly. Table 14 provides a detailed explanation of the alterations implemented for each iteration that allowed the team to arrive at the final design (iteration 3) illustrated in Figure 27. The final design consists of 35.18 mm tall and 55.36 mm wide cannula head, with an external 17.65 mm opening and a 11.00 mm long port protruding from the side. The internal structure of the lower segment of the cannula head was modified to incorporate two concentric cylindrical walls with an upper rim . A hollow cylinder was extruded parallel to the top external opening in the top segment in order to incorporate the original duckbill seal and the height and width of both segments were increased to facilitate the seal assembly.

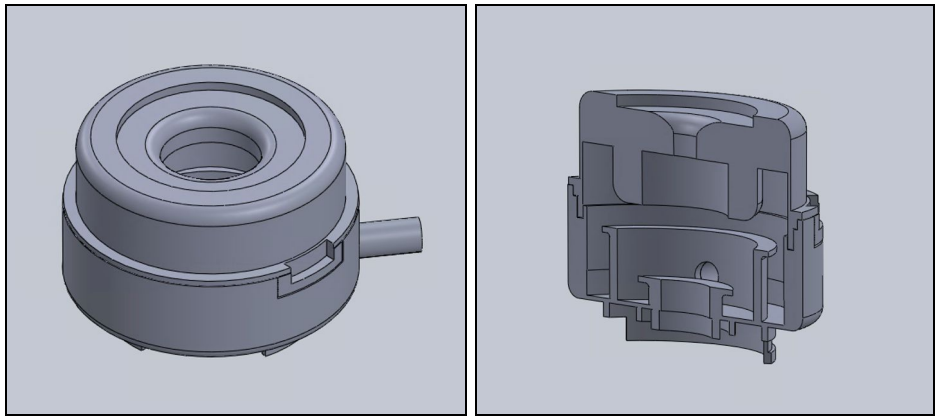
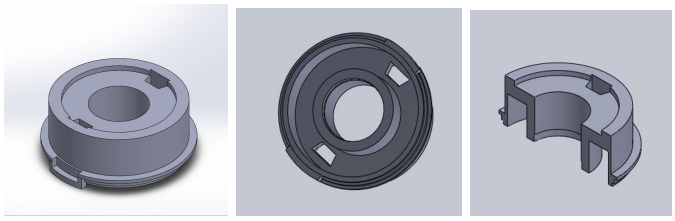
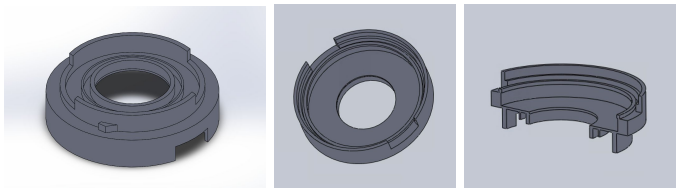
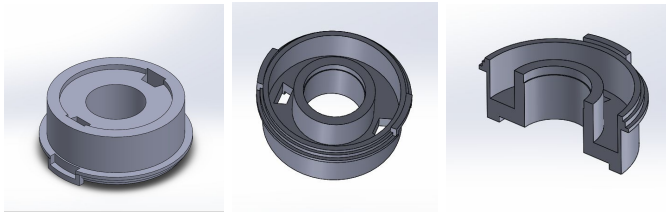
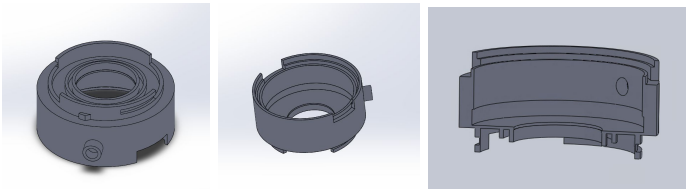
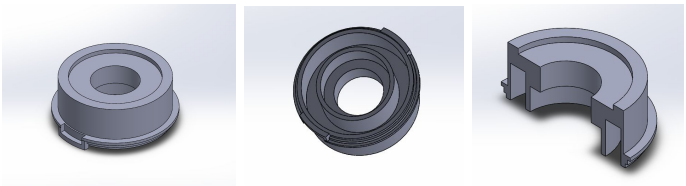
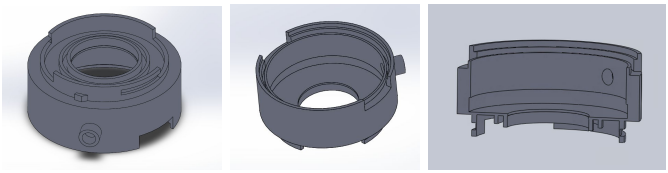
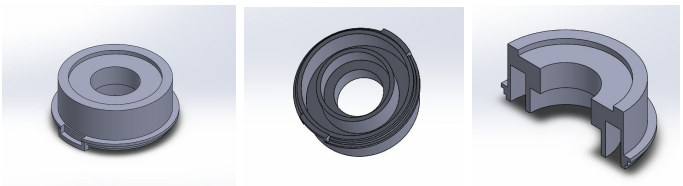
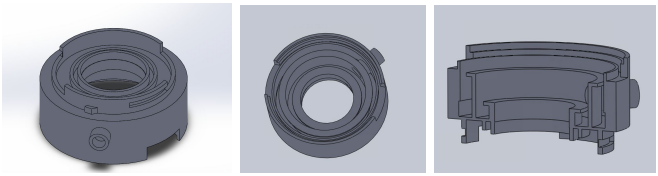
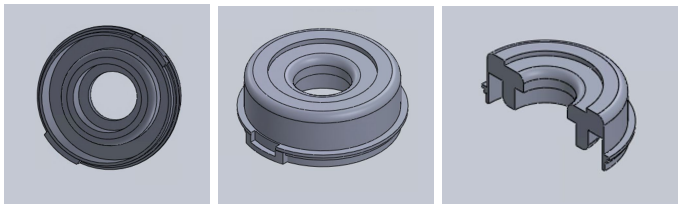
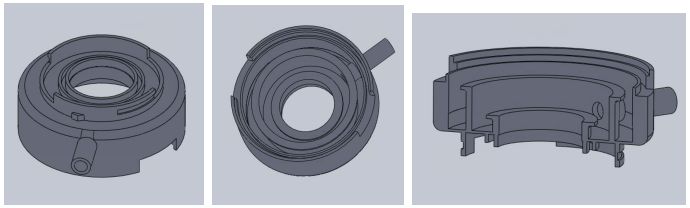
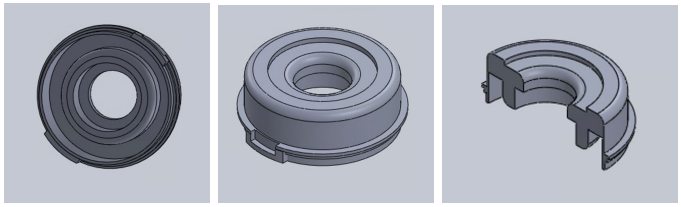
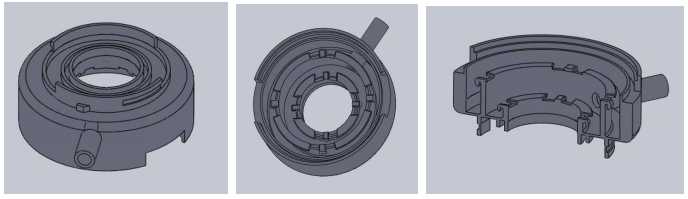


Fig. 27. Final Design (Front View and Cross Sectional View)

Table 16: Design Iterations

Piece	Top View, Inside View and Cross Sectional View	Modifications
Original Trocar Head		
Top		The original trocar head top was replicated on SolidWorks
Bottom		The original trocar head top was replicated on SolidWorks
Iteration #1		
Top		All dimensions were restricted to a minimum of 1mm for test printing and the insertion hole was increased to 17mm

Bottom		All dimensions were restricted to a minimum of 1mm for test printing. Height was doubled to a total of 16mm and the syringe port was inserted.
Iteration #2		
Top		All dimensions under 1mm were restored to the original dimensions. Obturator insertion holes were removed and the diameter of the bottom half of the piece was increased to 24mm
Bottom		All dimensions under 1mm were restored to the original trocar measurements. The top ridges were adjusted to fit the top piece of the cannula head.
Iteration #2.1		
Top		No modifications were made to this iteration
Bottom		A wall with a diameter of 19 mm was extruded from the tool's exit port. A concentric wall with a diameter of 30mm was extruded around the smaller wall. In addition an overhang was included at the top of each wall.

Iteration #3		
Top		The diameter was increased by 6.35 mm and the rough edges were filleted.
Bottom		The diameter was increased by 6.35mm and the rough edges were filleted. The syringe port was resized to fit the surgical tubing and extended.
Iteration #3.1		
Top		No modifications were made to this piece.
Bottom		Four equally spaced overhanging hooks were added to the two inner walls.

The seal was fabricated using a 6cm segment of a latex condom and different sized (14mm and 20 mm diameter) o-rings. Other materials such as balloons and latex gloves were tested for the seal material, however the pre-existing cylindrical shape and dimensions of the condom proved to be a better fit for the team's model and more easily inflated than the alternatives. Furthermore, the o-rings were superior to different types of rubber bands and elastics due to the increased surface contact area and durability. To build the seal one end of the

latex condom was fixed to the inner cylindrical wall of the bottom segment of the cannula head with a compressing o-ring while the other end of the latex cylinder was placed along the outer cylindrical wall and fixed with an o-ring as well. The rim at the top of the cylindrical walls inhibited the o-ring from sliding upwards or dislodging from the wall. A thin dull instrument was required in order to place the o-ring around the wall without tearing the latex; the team utilized cuticle pusher for this purpose. See Appendix B for full assembly protocol. Overall the latex condom was effective in the seal fabrication. Per the medical device standards described in chapter three, more specifically the ISO 10993 standards which evaluates the biocompatibility of medical devices, the final product for this project should be biocompatible. Due to the limited budget and resources, the prototype is not biocompatible, however the team recommends that future designs be built with a biocompatible material such as polycarbonate (PC) for the frame of the attachment and polyisoprene for the balloon seal.

Fig. 28. Inflatable Seal Pre and Post Inflation

The final design consists of a cannula attachment with an overlapping flaps seal and a balloon seal that compresses the laparoscopic tool without restricting the surgeon's range of motion. The compression seal can be easily inflated with a 60 cc syringe connected through surgical tubing to the cannula head’s outside port. This attachment has the ability to restrict the

flow of air even after extended use and deformation of secondary seals. The overall success of the prototype is further discussed in the following section.

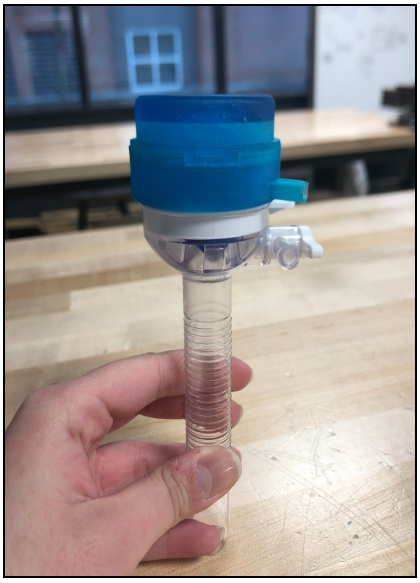


Fig. 29. Medtronic Trocar with New Attachment

6.2 Experimental Methods

Upon completion of the final design selection, the team created the testing protocols detailed in Chapter 5 to ensure that their prototype met all of their original design requirements. At the point when these requirements, such as the design objectives and specifications, were created, the team had been planning on making an entirely new trocar. This entailed creating new designs for the cannula, obturator, tip, etc. However, once the team began the prototyping process and took a more hands-on look at the problem they were attempting to solve, they realized that it was unnecessary to redesign all parts of the trocar. They could improve the leak problem simply by creating a seal attachment for the cannula while also saving time, materials

and money. For this reason, the extensive design requirements originally determined were not all applicable to the team's final prototype.

The four design objectives (listed in section 3.2.1) for the trocar were: Safe Insertion and Placement, Aid in Creation of CO_2 Insufflation, Allow for Passage of Tools, and Maintain Insufflation During Tool Insertion and Removal. Because the team was no longer creating a new obturator or cannula, the Safe Insertion and Placement objective is automatically met by the original Medtronic trocar that houses the team's attachment. In addition, the team's attachment did not in any way affect the trocar's gas intake port, so their device does not play a role in the trocar's ability to "create" CO_2 insufflation. However, the final two objectives remained crucial to the team's prototype and were tested through the team's experimental methods.

The team further broke these objectives down into design specifications, as detailed in section 3.2.4. These specifications were meant to create benchmarks for the team to evaluate if their prototype was meeting its basic needs. The specifications are displayed in the following list. The bolded specifications are the ones that ended up being impacted by the team's attachment and therefore tested through the team's experimental methods.

1. Shall pierce through the abdominal wall after a small incision is made.
2. Shall not slip during surgery by more than the length of the device at the original insertion.
3. Shall connect to a pump to supply 15mmHg of carbon dioxide to the abdomen.
4. **Shall have an opening and sleeve with a diameter size of 15mm.**
5. Shall aid in maintaining visibility through the use of a cannula material of at least 80% of total transmittance.

6. **Shall have a seal made out of a biocompatible, elastomeric material capable of adjusting to various sizes and shapes of surgical tools.**
7. **Shall allow smooth removal and insertion of various tools with a maximum frictional force of 8N.**
8. **Shall be capable of limiting carbon dioxide from escaping through the trocar.**
9. **Shall meet biocompatible standards.**

To begin, specifications 1 and 2 relate to the "Safe Insertion and Placement" objective. The team's device does not alter the original trocar's obturator and cannula, so these specifications were met by the original trocar and did not need to be tested.

Specification 3 was created to address the "Aid in Creation of CO_2 Insufflation" objective. However, similarly to specifications 1 and 2, the team's design does not alter the original trocar's gas intake port. Again, this specification was met automatically by the original trocar and did not need to be tested.

Specifications 4 through 7 fall under the "Allow for Passage of Tools" objective. Specification 5 was the only specification no longer applicable after the team decided to create an attachment, since the team was not adjusting the original trocar's cannula. Specification 4 was met through the team's CAD model. By creating the model with an opening diameter of 17mm and closely analyzing their resulting print, the team ensured that their device was the appropriate size to fit the necessary laparoscopic tools. Additionally, through the success of the Range of Motion test that used a tool with a diameter of 14.8mm, the team was sure that their device met this specification. Specifications 6 and 7 were also very important in making sure that any tools used by the surgeon can be supported by the team's attachment. Specification 6 was tested partly

through the team's material selection process, where they eventually settled on the material that they found to be the strongest and most flexible. It was also tested through the Range of Motion test, where the team found that their prototype does support variously sized tools. Specification 7 was also partially tested through the Range of Motion test. The test proved that tools can be easily inserted and removed through the team's attachment, and that their attachment did not have a negative impact on the ability of the trocar to house different instruments. However, the team was unable to make conclusions about the quantitative aspect of this specification. Yet due to the nature of the team's attachment, their seal is not inflated until after the tool is placed completely into the trocar. For this reason, the team did not believe it was necessary to test the force required to insert the tool, since their prototype had no impact on the force needed to insert a tool through the trocar's original seals.

Specification 8 was created to address the final objective, "Maintain Insufflation During Tool Insertion and Removal." This specification was extremely important since the motivation behind this project was to stop carbon dioxide leakage from the trocar. This specification was tested through the team's Insufflation Proof of Concept test and the Quantitative Leak Test. The Proof of Concept displayed that inflating the team's seal around the chosen tool did help to mitigate leakage from the top of the trocar. Though the team identified a new problem, being the poor connection between their attachment and the trocar's cannula, they were able to overall conclude that their extra layer of protection does aid in preventing leakage if this connection could be fixed. Unfortunately, due to time constraints and the change in WPI's schedule, the team was not able to perform the Quantitative Leak Test for their attachment. Because of this, they cannot make any official conclusions on how well, quantitatively, their device achieves the

given objective. However, based on qualitative conclusions, the team felt strongly that the addition of their device would outperform the original trocar in regards to this specification.

Finally, Specification 9 was written to ensure that the team's device was safe overall and would not provide any harm to the patient. This is necessary for the product to be successfully used during surgery and be one day brought to market. This specification was achieved firstly through the team's design itself. By creating only an attachment, the design is not harming the already-present safety of the original trocar. Due to time and budget constraints, the team could not make their prototype out of biocompatible materials. However, the team has identified ways that their product could be manufactured from biocompatible materials in the future. Additionally, the Inflatable Seal Failure procedure sought to identify the point of failure of the team's seal. This test allowed the team to make conclusions about how their seal could harm the patient if it were to burst during surgery. The team saw that it was extremely difficult to break the seal. It had to be stabbed multiple times with the sharpest tool possible in order to pop, and when it did pop, all of the material remained inside the plastic casing. Given all of these observations, the team felt that their device would be safe for use in patients.

For all of the above reasons, the team concluded that their attachment successfully met the objectives and specifications determined for this project.

6.3 Data Analysis

In order to properly assess the success of the experiments and therefore the team's device, a multitude of techniques were utilized. The first test, Inflatable Seal Failure, looked to determine the conditions in which the team's new seal would fail. Since the test involved mostly qualitative observations, Microsoft Excel was used to present all information in a logical and

easy-to-read format. Overall, the team was excited to determine the test a success as their seal design was both resistant to puncture and rupture. While the Insufflation Proof of Concept test also focused on qualitative results, the team believed the best way to convey information was to describe the results and therefore did not utilize any programs for analysis. During this test they did note some slight deflation of the balloon, but also found positive results that ultimately enabled their design to perform better after a few alterations. While these tests focused on qualitative information, the other two looked to also explore the success of the team's design in a quantitative manner.

The Quantitative Leak Test aimed to determine how well the team's trocar attachment could aid in maintaining the ideal pressure inside an individual's abdomen during surgery. Since the results, mainly pressure, were known to vary over time, the team recorded the results using Microsoft Excel to create tables and scatterplots to visually display the trends. While this test was only able to be completed for the original Medtronic VersaOne trocar, no conclusions could be made regarding how the new attachment performed in relation.Yet this test did serve another important function: the test enabled the team to see the leakage problem first-hand. The artificial abdomen containing the trocar without any tools inserted only saw a few drops in pressure over each hour long trial, yet when the small tool was inserted, the pressure often fell close to zero, which would be an extreme issue in the surgical room. Finally, the Range of Motion study looked to analyze results a step further and test statistical significance. To display the information, Microsoft Excel and ImageJ were used, but the results were evaluated utilizing Matlab. While the results did appear to differ between the team's attachment and the original surgical trocar, the statistical analysis revealed that the datasets were not significantly different,

and therefore no conclusion could be made. Overall, the team utilized many formats to analyze and display the results gathered, allowing them to deem their prototype successful.

6.4 Product Impacts

With any new products, the potential impacts must be considered throughout the design process. The team considered the following topics when weighing the possibilities of the design.

6.4.1 Economics

When determining the economic impact of the team's device, various topics such as reusability, sterilization, manufacturability, and many more have to be considered. While broad in scope, it was important to review these topics in terms of the costs associated with them and therefore how it would affect the market. In terms of reusable versus single-use surgical trocars, the economic costs can be viewed in both the short-term and long-term. In the short term, reusable surgical devices are more expensive, but they can be used for multiple procedures and do not require disposal after each operation. However, reusable surgical devices require sterilization between each procedure which adds to their cost. Over time, the cost of reusable and single-use devices seem to become more balanced as the low-cost of single-use devices adds up as hospitals have to buy brand new parts for every operation performed. Therefore, the benefit of reusable trocars could outweigh the potential excess monetary cost. Additionally, manufacturing costs of both types of devices is important to the overall price of the device and therefore the economic impact.

While these considerations are prevalent, the everyday living costs to individuals who undergo the procedure is likely not to change drastically. This is due to the fact that the team's

trocar attachment would likely only be used for one of the many trocars in laparoscopic bariatric surgery, thus the slight excess cost of the procedure would not have a large impact and may be covered by insurance. Additionally, patients typically receive only one procedure that involves such surgical trocars, making the slight increase in cost not too steep. Along with this, in order to succeed in industry, the total cost of the trocar with the additional attachment should fall in the same range as those currently on the market.

6.4.2 Environmental Impact

One area relating to the environmental impact surrounds the idea of single-use versus reusable devices. Similarly to the economic considerations, a single use device is thought to cause more physical waste as these surgical trocars must be disposed of after each procedure. Not only does this include the trocar itself, but also the waste from packaging, transportation and manufacturing. On the other hand, while reusable devices may have less physical waste, they tend to have more chemical impacts on the environment due to the need for sterilization. The market has now also looked at reprocessing single-use devices, with one example being laparoscopic surgical trocars, such that they undergo extra processing to be used again in the future. To confirm the positive impact, the FDA noted that "a key section reported the reprocessed SUDs do not present an increased health risk to patients when compared to new, unused devices." Therefore, not only does this process save hospitals and patients money as new devices are not always required to be purchased, the amount of physical waste is drastically reduced [72].

More specifically, the team's design may utilize more material compared to some trocars currently on the market since it can be used as an attachment, but it was tested to perform at a

higher level. Due to the advanced performance of stopping carbon dioxide leakage from the abdominal cavity during laparoscopic bariatric surgery, there are two major factors affecting the environmental impact. The first benefit is the decrease in the potential need for inserting a new trocar during surgery. Not only does this lessen the amount of physical waste per surgery, it also reduces patient risk. The second benefit is the decrease in the amount of carbon dioxide emissions for each surgery. According to a study conducted in 2009, out of 2,520,223 MIS procedures, the total direct and indirect carbon dioxide emissions came to 303 tonnes and 355,621 tonnes, respectively [73]. While these numbers may seem insignificant in the contribution to global warming, any step towards reducing leakage and therefore increasing patient safety is beneficial. Thus, by decreasing the amount of carbon dioxide leakage from the patient's abdominal cavity, there would be a decrease in carbon dioxide emissions which would have a positive environmental impact.

6.4.3 Social Influence

Overall, the team's new design for laparoscopic surgical trocars would have a positive influence on society. For example, with the addition of a new seal to existing trocars in the market along with its positive results, patients would experience less risk and complications as well as decreased incidence of injury and death. In other words, this design creates a safer surgical environment and procedure for the patients, which would ultimately decrease the number of individuals who avoid medical care due to fear. Additionally, through its use as an attachment to existing trocars on the market, surgeons are much more likely to utilize the product as they do not need to learn how to operate using an entirely new device. Thus, there is an improvement in efficiency, which promotes positive social influences relating to the surgeon, the

patient and all other involved members. Outside of these influences, the new device will likely not have an effect on the general public, especially those outside of the medical and healthcare industry.

6.4.4 Political Ramifications

The team does not foresee any serious political challenges or ramifications to arise from their project. However, the team may face political or government interference if they decide to manufacture and sell their product in and out of the United States. The FDA would need to be involved in order to address compliance with all medical device regulations, particularly when it comes to testing the device and ensuring its safety and efficacy in surgery [74]. In addition, because this device can have a large impact on the success of the operation, there would need to be product liability procedures in place if anything went wrong. Complications would have to be handled in a thorough, fair way to avoid any additional law or government interference [75]. The team would also look into manufacturing and selling their products globally. Typically, manufacturing products in other countries is cheaper than manufacturing in the United States, which is an incentive for the team to look elsewhere when creating their device. However, doing this could create some political concern. Interacting with other countries could cause some pushback, as each country has their own set of guidelines when it comes to medical device regulations, importation, and relationships with international companies.

The device was created to improve the health of citizens, therefore it could have a positive political effect. The additional trocar piece will make surgeries safer and more successful, so citizens are likely to be of healthier weights post surgery. Also, creating a new, effective device can bring publicity and political awareness to a problem that perhaps not enough

people know about. This can convince government sectors into funding more research on the causes and complications of obesity, to hopefully one day enforce more prevention methods.

6.4.5 Ethical Concerns

There are no serious ethical considerations in regard to the new trocar attachment. The most significant concerns relate to issues with the environmental impact, as described in other sections of this chapter. Overall, the device created by the team is meant to improve the lives of those that require bariatric surgery. Implementing trocars to perform laparoscopic surgery instead of open surgery is more beneficial for patients, as it involves less risk and easier recovery. By improving the trocar, the team is helping to progress the medical field in a positive direction for the future; one that involves less major, overly invasive surgery. In addition, through the creation of an improved trocar system for the specific purpose of weight loss surgery, the team can aid in improving the safety of many people affected by obesity. These individuals will be able to lead healthier lives, with more positive outlooks for their futures and on their image in society.

Other ethical concerns would emerge should there be further testing on the product. Human or animal testing is often necessary to send a new medical device to market, however this can be very risky, as many unforeseen complications can arise that could potentailly harm the human or animal. The ethics of tests such as these are often debated in modern society, and invoke a variety of responses. In some instances people believe it is necessary to put some humans or animals at risk for the potential to benefit many others, however in other cases people say it is not right to harm a living thing under any circumstances. The team would have to deeply consider the ethics of any future tests that they would plan to perform on a human or animal.

6.4.6 Health and Safety Issues

During the design process it was important for the team to consider the impacts on health and safety, based on the changes being made. Since the final product is a medical device it has to meet current standards that the industry sets for this class of device. The team had to consider: patient and user safety, biocompatibility and procedure standards.

With the decision to make an additional piece that will attach to current trocars on the market, the majority of safety concerns of this device were mitigated. The team chose not to change the traditional design of the trocar, so this reduces the chance of an increase in hernias or infections during or after the procedure. Next, the addition of the team's attachment reduces the leakage of carbon dioxide which will improve safety for the patient during the procedure.

Finally, for patient safety it was important to ensure that the final product material was biocompatible. Even though this attachment will not be inside the body it is important to ensure that it does not cause any adverse reactions to the patient. To verify this, the attachment would be reviewed with biocompatibility standards for medical devices. During this process the attachment was tested to confirm that adding an additional seal does not have any major effects on how the device is used. In order for this attachment to be beneficial, it had to meet or exceed current standards set for health and safety.

6.4.7 Manufacturability

The team's attachment piece has the ability to be manufactured in multiple ways, these include: Additive Manufacturing, Subtractive Manufacturing and Injection Molding. The team's

final prototype was manufactured by 3D printing using a Form 2 printer, but ideally, a final product would be done using injection molding.

Additive manufacturing or 3D printing is one of the most beneficial manufacturing tools to the team. Additive manufacturing is the process of using a computer automated design (CAD) and a printer to add layers upon layers until a model is created [76]. The benefits of using 3D printing are that there is a lot of flexibility with the design process. Since it is done as an additive process, the CAD drawing can be modified and highly customized. The process of 3D printing is also low cost in comparison to others because it does not require molds to be made prior to manufacturing.

Other manufacturing tools include subtractive manufacturing and injection molding. Subtractive manufacturing is the process of starting with a large sample of material and removing aspects of it until the desired model is created [77]. This is often done by computer numerical control (CNC) machining. Additionally, it is more expensive and creates more waste than 3D printing a prototype. Another method is injection molding, which requires a mold to be created and then material filled into it. This type of manufacturing is cost effective once the design is finalized because the mold can be used repeatedly and with multiple different materials. Otherwise, this is not the most beneficial method because it is expensive and time consuming to create a new mold for each design iteration [78].

6.4.8 Sustainability

In order to make a sustainable medical device, a few considerations need to occur during development. These include the following: manufacturing style, material and reusability [79]. The team focused on making an attachment for trocars that are currently on the market. Since the

team did not have to completely design a new device, it would allow surgeons to continue using the trocars that are already in stock and just purchase the additional piece. This additional attachment reduces the chance of trocars already manufactured having to be disposed of without use, creating a more sustainable system.

During the design process and prototyping, the team mainly used 3D printing. This allowed the team to make multiple iterations of their design while being cost efficient and environmentally conscious. Using 3D printing during manufacturing has been a way that was demonstrated to reduce the carbon footprint of a product. This method of prototyping is considered additive manufacturing, so the design can be continually added to during the process. This is compared to typical subtractive manufacturing procedures, which typically require molds and an excess of material [80]. This allows for less material to be wasted during the design process and potentially manufacturing making the team's product more sustainable.

The team ultimately decided to make a reusable attachment that can be used with the Medtronic VersaOne trocar. Traditionally, trocars used in bariatric surgery are single use devices, which creates a large amount of medical waste. If the team's device was reusable this would eliminate an increase in the waste that is already created. Besides the packaging of the device, the attachment would be able to be sterilized, reducing the waste and costs of having to buy a new attachment for each procedure. This would ideally keep the sustainability of the device at the same level.

CHAPTER 7 - DISCUSSION

The overall goal of this MQP was to prevent trocars from leaking carbon dioxide during bariatric surgery. Surgeons rely on the insufflation from these trocars to provide them with ample space to perform necessary tasks, so a trocar that leaks is extremely dangerous in this environment. Upon initial interactions with the surgeon that oversaw this project, Dr. Doyon, the team knew that they had to come up with a unique design to solve this problem that she constantly encountered. They needed to create a device that would help to maintain insufflation of carbon dioxide in the abdomen while allowing for the passage of tools into and out of the trocar, and at the same time not harm the trocar's ability to remain safely in place. With this in mind, the team successfully created an attachment that housed inflatable seals that surgeons could clip into the top of their trocars after removing the defective seals. Their design allows for a seal that can be inflated around the tool inside the trocar, rather than having the tool push through the seal, which likely causes immediate damage and stretching. The addition of their attachment creates an extra layer of protection that provides surgeons with a safer environment to perform successful operations. In order to ensure the success of the attachment and compare its performance to the original trocar, a series of tests were conducted. These protocols involved an analysis of the device's behavior at failure, the device's maximum allowable range of tool motion and the device's ability to maintain insufflation.

The behavior of the trocar at failure revealed that the seal will withstand significant amounts of stress and strain. The seal failed once out of the 19 trials which indicated that the seal's rupture depends on the contact angle and contact area. An angle of 90° and a small contact

area will increase the probability of the seal rupturing. Therefore, it is recommended that the seal is inflated after the tool has been inserted, and that the tool is inserted parallel to the cannula. Although the test was not conducted with laparoscopic tools, a multitude of instruments with sharp edges were utilized to attempt to rupture the seal. Additionally, when the seal did rupture, all of the seal material remained completely inside the outer casing, therefore presenting no harm to the patient. If this were to occur, the surgeon should replace the attachment with a new one, which can be achieved in a matter of seconds.

The new attachment allowed for a very similar range of motion as the original trocar. A slightly more limited motion was displayed with the small and medium sized tools tested in the new attachment, however, the statistical analysis indicated no significant differences between the average ranges of both attachments. Therefore, the surgeon's ability to maneuver the tools inside the abdomen will not be hindered by the new attachment. Because the seal compresses around the tool, it is reasonable that the mobility of the tools could require gentle force to maneuver the tool around the abdomen without resulting in significant impairment of mobility. Unlike the small and medium sized tools, the large sized tool exhibited an increased range of motion which could have resulted from shifting of the trocar within the vise or the vise itself while the tool was being rotated. An increased number of trials and a variety of tool geometries should be able to provide a more accurate and precise representation of the attachments allowable range of motion.

In addition, the Quantitative Leak Test for the Medtronic trocar proved that there is indeed air leaking through the trocar while the tools are inside of it. If we assume that the Medtronic seals did not endure any deformation during the four hour period and only take into account the loss of air while the tools were inserted, the average percentage of air lost in 60

minutes for abdomens with the small sized tools, large sized and no tools were 95.83%, 11.67 %, and 10.83%, respectively. This indicates that the Medtronic trocar would not be able to maintain insufflation at 15mmHg without constant reinflation of the abdomen while the tools are inserted in the trocar as well as after tool insertion and removal. Moreover, for both the abdomens tested after the trial with the big tool, the pressure during the small tool test decreased dramatically within the first ten minutes and then plateaued. This could be evidence of the seals' deformation or stretching due to the large diameter of the big tool. We cannot confirm that the seals did indeed stretch, however, if more trials were to be run for longer periods of time and with different shaped tools, the team speculates that the deformation of the seals would be significant and increase the percentage of air lost.The deformation could potentially render the trocar unable to maintain insufflation after an extended period of time.

Because of the closure of the WPI campus, the team was unable to conduct the Quantitative Leak Test on their prototype. Although the team cannot confirm whether the prototype outperformed Medtronic's original seals, the team speculates that the percentage of air lost would have decreased due to the incorporation of their compressive seal. Reinflation of the abdomen after tool insertion and removal would still have to occur, however, it is likely that no reinflation would be needed while the tool is inside of the trocar. In addition, even if the duckbill and overlapping flaps seals were to experience deformation, the compressing seal would ensure that the trocar was still viable for the remainder of the surgery. It is important to note that the team would still expect a small percentage of air loss, especially when inserting or using small size tools. In these cases, the team suggests utilizing smaller diameter trocars if possible.

The team was unable to find significant evidence of the problem in clinical literature, therefore, the team had to rely solely on the experiences of the client, Dr. Doyon, when creating their prototype. Through extensive conversations and interviews between the surgeon and the team, the team was able to grasp the issue at hand and create a design that would be successful in solving the problem she faces. Even though this problem was not prevalent in any scientific or medical literature, the team replicated the problem that Dr. Doyon is facing when completing their Quantitative Leak Test. When placing the Medtronic VersaOne trocar in the artificial abdomen without the team's prototype, it was clear that there was a substantial leakage problem. However, it is important to note that the team was only able to notice this problem with the 15mm Medtronic VersaOne trocars that they had access to, since they were not able to obtain any other trocars on the market. Despite the lack of evidence supporting the inability of the trocar to maintain insufflation at 15mmHg, the team has experimentally proved that the original trocar does not meet this standard. Thus, a surgeon performing a laparoscopic surgery at an insufflation of 15mmHg would encounter this problem. With this said, the team speculates that their developed attachment would not decrease the performance of the trocar, and, on the contrary, would only enhance its functionality. The team's attachment would be a great addition to any surgeon's laparoscopic procedure.

As previously mentioned, before beginning the design process, the team researched surgical trocars currently on the market. Specifically, the team was hoping to find information around highlighted features and potential problems associated with the current designs. While they were able to discover key information about various products, the team was unable to find any literature supporting the carbon dioxide leakage problem at an insufflation pressure of

15mmHg. The team focused on three of the main medical device companies that contribute to the trocars market to compare their design to: Medtronic, Ethicon and Applied Medical. These companies produce an array of products, but the team decided to direct their research to 15mm trocars as this was the request from the overseeing surgeon. For each trocar, a few features were highlighted. The Medtronic VersaOne trocar utilized a dolphin nose tip for smooth insertion into the abdominal cavity along with a ribbed cannula for stability throughout the surgery. The Ethicon B15LT Endopath Xcel featured a custom seal design that enabled a low drag force as well as a cannula with an integrated thread to enable abdominal wall retention. Lastly, Applied Medical's Kii Optical Access System incorporated an inflatable balloon on the cannula to aid in fixation and a blunt tip for minimal fascial defects post surgery. After comparing the key features and discussing with the involved bariatric surgeon, the team decided to focus on the Medtronic trocar due to its availability and use in the client's practice.

When beginning the design process, the team determined it was more feasible to design an attachment for the trocar rather than redesign an entirely new device as the focus was on seal integrity. Through their research, the team found the most common seal types to be those listed in Table 1: duckbill, anti-inversion, retraction, dual and overlapping flaps. The two seals found in the Medtronic VersaOne trocar are the duckbill seal and the overlapping flaps. The duckbill seal allows for selective opening and closing for the passage of instruments, while the overlapping flaps are composed of primary, secondary and tertiary segments with slits in the center. The team believed the best solution to the issue would be to design a unique seal to be used in conjunction with those currently housed in the Medtronic trocar. The team's seal is unique in that the material compresses around the tool after insertion to prevent damage to the seal. This differs

from the current Medtronic seals that require the tool to push through the seals upon insertion and removal. Furthermore, the inflation of the seal allows for adaptation to the size and shape of the laparoscopic tool in use. Additionally, since the team decided to produce an attachment for trocars currently on the market, ideally the cost would be significantly less than that of a full trocar. While the team did find positive results throughout the testing of their prototype, they did note limitations in their design process which hindered the data.

The main obstacle the team found throughout the testing of their prototype was slight air loss with the inability to determine the source. They believed this could have been due to limitations in two main areas: manufacturing of the materials and experimental procedures. The team had to utilize materials that were quickly accessible and affordable in order to produce multiple prototypes for testing. With this, the materials themselves had their own limitations. Specifically, the outer casing of the attachment was prototyped using tough resin from a Form 2 3D printer. Since the prototype was 3D printed, internal supports were required, which sometimes resulted in small perforations in the casing when the supports were removed. For the seal, the team was highly limited in material selection due to the shape and elasticity required for the design. For this reason, latex and polyisoprene condoms were selected for the seal design. One possible cause for air leakage could have been the fact that such material may not be completely air-tight. Secondly, to attach to the outer casing, the team had to manipulate the material which involved cutting, stretching and compressing the thin condom. The manipulation of the material altered the condom's susceptibility to tears, thus increasing the potential causes for the slight air leakage. The manufacturing process, while consistent, did not confirm that the

prototype was completely airtight. Before testing, the team inspected their prototype to ensure that there were not any obvious flaws that would cause air leakage.

Aside from the material selection, the experimental procedures could have affected the outcomes. Specifically for the Quantitative Leak Test, the team was not able to use a real abdomen, therefore they had to replicate the surgical environment with limited resources. Not only was the material makeup significantly different from that of human muscle and skin, the size also varied. However, because the purpose of this test was to identify whether the prototype allowed for air leakage and not to analyze how the trocar acts in a human body, the team found this setup to be acceptable. Additionally, throughout all of the tests that were run, the team did not have access to real surgical tools, so they had to utilize representative tools from WPI's lab. With this, the team mainly focused on mimicking the size of the tool rather than its functionality. These tools could have skewed testing, such as the data obtained from the Range of Motion test. However, since the same tools were utilized for the team's attachment as well as the original Medtronic trocar, the results are valid in the comparison. Furthermore, during the Quantitative Leak Test, the tools were left untouched throughout each one hour trial, which differs from the normal function the tools perform during surgery. Based on the limitations and results discovered, the team was able to obtain conclusions and develop future recommendations for their design.

CHAPTER 8 - CONCLUSIONS AND RECOMMENDATIONS

Throughout the entirety of the academic year, the team worked hard to create their design, construct their prototype, test their device, and analyze its success. Even though there were some challenges in the way, including budget, time constraints, and their inability to access campus in D Term, the team believes that they were able to achieve the goal of creating a trocar attachment to limit leakage of carbon dioxide. Through the Proof of Concept test, the team witnessed their device reducing the normal air leakage out of the top of the trocar. The team was not able to complete the test where they would quantify this reduction, however, based on the success of their Proof of Concept experiment and the innovation of their design, they speculate that their device would assist in preventing carbon dioxide leakage during surgery. Their device works by creating a new, extra layer of protection without inhibiting the function of the seals that are already in place. Their inflatable design brings a new concept to the seals in the trocar market, since it is able to be compressed around the tool once the tool is already in place. With this idea, their seal is extremely resistant to stress and strain, and therefore less likely to wear out during the length of surgery. Also, since the seal material is so flexible, it can adapt to different sized and shaped tools used by surgeons. The team is confident that because they created an additional, successful seal in the trocar, this attachment would advance the trocar's ability to maintain insufflation throughout the passage of tools.

In addition to the success of their device in regard to this objective, the team was also able to prove that their seal is safe to use and does not inhibit the surgeon's range of motion in the trocar. Because their seal was so resistant to rupture, surgeons can be confident that they most likely will not accidentally break the seal during surgery. And, if this were to happen, the patient would remain safe because the seal material would stay completely inside the outer casing. Through the Range of Motion test, the team concluded that their attachment does not change the typical mobility provided by the original trocar. This device will assist surgeons in completing successful procedures, where they can perform all of the tasks required and worry less about the danger of loss of insufflation in the patient's abdomen.

Although the team was able to draw a few strong conclusions throughout this design process, there are many ways in which the study could be improved upon or furthered in the future. Thus, the team established future recommendations that fall into the categories of material selection and design, the manufacturing process, experimental procedures, and universal usage. In terms of material selection, the team focused on using materials that were functionally correct, but also readily available during the design and prototyping phase. When it comes to the final product, the team believes that it would be beneficial to manufacture the outer casing of the trocar attachment using a transparent material to allow surgeons to view the performance of the seals that are placed within. This would provide the users the ability to view how well the inflatable seal is compressing around the surgical tool, as well as be able to inspect if any issues arise. Additionally, they believe it would be best to construct the inflatable seal out of a thicker material than the latex condoms used in the prototype to enhance durability. Furthermore, the team speculates that using a gel-type liquid to inflate the seal, rather than air, would have the

potential of producing better results in regard to maintaining abdominal insufflation. This thicker substance would be unable to leak out of microscopic holes within the product that carbon dioxide can easily leak out of. When altering these materials and ideating possible solutions, the team also proposed the benefit of the attachment being reusable. If the design were to be autoclavable, the device would be able to become a multi-use product which would have a variety of benefits that include, but are not limited to, the areas of economic impact, environmental impact and sustainability.

To further these recommendations, the team ideated ways in which the inflatable seal could be better designed. If they had more time, the team would have liked to determine the feasibility of making a seal that is comparable in design and function to an inner bike tire or inflatable pool inner tube. The design would have a ring of material that only has one port to allow for inflation. Through utilizing such a design, there would be less concern about potential air leakage where the team's current seal attaches to the outer casing as it is a closed chamber, other than the singular port. Thus, the underlying concept of using air or a gel-like liquid to inflate such a seal would be the same, but ideally this design would combat many of the problems and limitations the team experienced.

In order to improve the reliability of the attachment, the team recommends adjusting the manufacturing process. For their prototype, the team used 3D printing and a handmade seal. The first modification the team would suggest is to use injection molding for the outer casing of the attachment rather than 3D printing. Choosing to use injection molding makes the production process more time and cost effective, while also allowing for a variety materials to be used. Doing this would also support the suggestion of utilizing a material that makes the attachment

autoclavable and biocompatible. In addition this process is much more consistent, which mitigates the concerns that the team's prototype may have had holes in it. Another area in the manufacturing process that the team thought could be improved upon is how the seal is placed in the outer casing. In the current process, the team used o-rings to hold the seal in place. If the seal design was not to be altered, it is recommended to find a better method for anchoring the seal to ensure there are no gaps where carbon dioxide could escape. This could be done by using an adhesive to keep the material in place.

Before the prototype could be produced and distributed, the team recommends the following testing be expanded upon: Quantitative Leak Test, Tool Insertion and Removal test and cadaveric stimulation testing. The Quantitative Leak Test should be run for a longer duration than one hour to observe what may happen if the surgery is prolonged. This test should also be run with more tools over the duration of the test, allowing the user to see how quickly it takes the pressure to recover when tools are being changed out more frequently. Additionally, once the test was completed with the team's attachment, statistical analysis should be run to determine if the results are significant in order to make conclusions. Specifically, the team would suggest running a t-test to determine the validity of the potential quantitative differences in air leakage of the original Medtronic VersaOne trocar to that with their attachment. Another test that the team deemed not necessary to complete for their objectives was the Tool Insertion and Removal test (seen in Appendix D). This test would have been completed in order to determine the force required to insert and remove a tool through the trocar. Since the team's seal is not inflated until after tool insertion and therefore would not alter such force, this was not tested. However, this information is still beneficial to know if the attachment was to go to market. Additionally, the

team recommends using real laparoscopic surgical tools, rather than the representative items available to them during their testing. To further aid in providing data displaying the efficacy of the team's device, the team suggests performing cadaveric studies. A similar procedure to the Quantitative Leak Test would be performed on a human cadaveric abdomen in which the changes in pressure would be recorded over multiple one-hour trials. This would allow the team to understand how the device performs in a realistic setting without any human risk. If successful, the team would next move into clinical trials before marketing their device to the public.

The final recommendation about the team's design and prototype is to develop a way to make the attachment universal, meaning that it could be used on multiple brands and different sized trocars. This will make it a significantly more marketable product. Finally, with the implementation of these final recommendations, the team hopes that this device will have a positive impact in bariatric laparoscopic surgery.

APPENDICES

Appendix A: Term Gantt Charts

A Term Gantt Chart

TASK ID	TASK TITLE	START DATE	DUE DATE	PHASE ONE										PHASE TWO										PHASE THREE										PHASE FOUR					
				WEEK 1 - 8/26					WEEK 2- 9/2					WEEK 3 - 9/9					WEEK 4 - 9/16					WEEK 5 - 9/23					WEEK 6 - 9/30					WEEK 7 - 10/7					
				M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F		
1	**Project Planning**																																						
1.1	Gaining Background Information	8/23/2019	10/4/2019																																				
1.2	Design Objectives	8/23/2019	9/6/2019																																				
1.3	Client Statement	8/23/2019	9/6/2019																																				
1.4	Literature Review	8/30/2019	9/23/2019																																				
2.0	**Initial Ideation**																																						
2.1	Design Requirements	9/9/2019	10/4/2019																																				
2.2	Design Specificaitons	9/9/2019	10/4/2019																																				
2.3	Conceptual Design	9/9/2019	10/10/2019																																				
2.4	Meeting to Go Over Patents	8/28/2019	9/4/2019																																				
2.5	Plan Experiments/Testing	9/30/2019	10/4/2019																																				
3.0	**Writing**																																						
3.1	Chapter 1-Introduction	9/23/19	10/4/2019																																				
3.2	Chapter 2-Literature Review	8/30/2019	9/23/2019																																				
3.3	Chapter 3-Project Strategy	9/9/2019	10/4/2019																																				
3.4	Chapter 4-Design Process	9/9/2019	10/4/2019																																				
3.5	End of term paper	9/23/2019	10/4/2019																																				
4.0	**Project Presentation**																																						
4.1	Create Presentation	9/23/2019	9/30/2019																																				
4.2	Practice Presentation	9/30/2019	10/3/2019																																				
4.3	Present	10/4/2019	10/4/2019																																				

B Term Gantt Chart

TASK ID	TASK TITLE	START DATE	DUE DATE	PHASE ONE										PHASE TWO										PHASE THREE										PHASE FOUR					
				WEEK 1 - 10/21					WEEK 2 - 10/28					WEEK 3 - 11/4					WEEK 4 - 11/11					WEEK 5 - 11/18					WEEK 6 - 11/25					WEEK 7 - 12/2					WEEK 8 - 12/9				
				M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F
1.0	**Prototyping**																																						
1.1	Identify Resources on Campus																																						
1.2	CAD Design Drawing																																						
1.3	Identify First Iteration Materials & Budget																																						
1.4	Reach out to Sales Rep																																						
1.5	Meet with Resources																																						
1.6	Print / Machine First Iteration Prototype																																						
1.7	Final CAD Design																																						
1.8	Print / Machine Final Iteration Prototype																																						
2.0	**Testing**																																						
2.1	Plan Tests																																						
2.2	Create Artificial Abdomen																																						
2.3	-- Add other testing material here --																																						
3.0	**Writing**																																						
3.1	Edit Chapters 1-4																																						
3.2	Write Chapter 5																																						
3.3	Write Chapter 6																																						
3.4	Revise Paper																																						
3.5	Write B Term Paper																																						
4.0	**Project Presentation**																																						
4.1	Make Presentation																																						
4.2	Practice Presentation																																						
4.3	Present Term Presentation																																						

C Term Gantt Chart

TASK ID	TASK TITLE	START DATE	DUE DATE	PHASE ONE										PHASE TWO										PHASE THREE										PHASE FOUR									
				WEEK 1 - 1/13					WEEK 2 - 1/20					WEEK 3 - 1/27					WEEK 4 - 2/3					WEEK 5 - 2/10					WEEK 6 - 2/17					WEEK 7 - 2/24					WEEK 8 - 3/2				
				M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F
1	**Prototyping**																																										
1.1	Fix CAD Model and Send to Higgins	1/17/2020	2/21/2020																																								
1.2	Acquire Prototype from Higgins	2/3/2020	2/28/2020																																								
1.3	Build Seal	2/3/2020	2/28/2020																																								
2.0	**Testing**																																									
2.1	Acquire Materials	1/17/2020	2/7/2020																																								
2.2	Set up all Tests	1/27/2020	2/14/2020																																								
2.3	Run Tests	2/2/2020	2/28/2020																																								
2.4	Analyze Test Results	2/17/2020	3/3/2020																																								
3.0	**Writing**																																									
3.1	Outline Final Paper Sections & Testing	2/17/20	2/28/2020																																								
3.2	Edit Previous Paper Sections	2/24/2020	3/6/2020																																								

D Term Gantt Chart

TASK ID	TASK TITLE	START DATE	DUE DATE	PHASE ONE										PHASE TWO										PHASE THREE										PHASE FOUR									
				WEEK 1 - 3/23					WEEK 2 - 3/30					WEEK 3 - 4/6					WEEK 4 - 4/13					WEEK 5 - 4/20					WEEK 6 - 4/27					WEEK 7 - 5/4					WEEK 8 - 5/11				
				M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F
1	**Testing**																																										
1.1	Perform Quantitative Leak Test	3/25/2020	3/25/2020																																								
1.2	Analyze Quantitative Leak Results	3/25/2020	3/27/2020																																								
2.0	**Writing**																																									
2.1	Finish Chapter 5	3/23/2020	3/31/2020																																								
2.2	Finish Chapter 6	3/23/2020	3/31/2020																																								
2.3	Write Chapter 7	3/30/2020	4/3/2020																																								
2.4	Write Chapter 8	4/6/2020	4/10/2020																																								
2.5	Abstract	4/13/2020	4/17/2020																																								
2.6	Introduction	4/13/2020	4/17/2020																																								
2.8	Edit Paper	4/20/2020	4/24/2020																																								
3.0	**Project Presentation**																																									
3.1	Create Final Presentation	4/13/2020	4/24/2020																																								
3.2	Practice Presentation	4/27/2020	5/1/2020																																								
3.3	Present	5/4/2020	5/4/2020																																								
3.4	Submit eCDR	5/11/2020	5/11/2020																																								

Appendix B: Inflatable Seal Assembly Protocol

Materials:

- Trocar bottom (no hooks)
- 2 small, thin o-rings (14mm diameter)
- 1 big, thin o-ring (20mm diameter)
- Condom
- Scissors
- Ruler

Procedure:

1. Using a ruler, measuring from the rolled end of the condom cut at 6 centimeters.
2. Put the condom through the center hole, rolled part down
3. With the unrolled end, fold some material over the bottom rim, evenly all the way around
4. Stretch one small o-ring to hold the condom in place around the rim
5. Stretch the other small o-ring on top of the first
6. Pull the rest of the condom through the center hole (rolled part)
7. Insert rolled part over the top rim, using the cuticle cutter to push it to the bottom of the wall
8. Check to see that the bottom and the top of the condom are aligned
9. Stretch larger o-ring to hold the condom in place around the rim
10. Attach bottom and top piece of the trocars

Appendix C: Verification Testing Protocols

Test 1 - Inflatable Seal Failure

Materials:

- Medtronic VersaOne trocar and new attachment
- 60 CC air syringe
- Fix It Kit Tools
- Inflatable seals

Protocol:

Rupture Test

1. Gather all necessary materials listed above.
2. Build the inflatable seal according to Assembly protocol seen in Appendix B.
3. Place the bottom piece of the attachment with the inflatable seal face up on the table.
4. Connect the syringe to the attachment's port and insert air in the seal in intervals of 20CC with 2 seconds between injections.
    a. Note how much air until full inflation.
    b. Note how much air at rupture and characteristics of how the seal fails, if applicable.
5. Repeat steps 2-4 multiple times with various inflation speeds.

Puncture Test

1. Gather all necessary materials listed above.
2. Build the inflatable seal according to the Assembly protocol in Appendix B.
3. Place the bottom piece of the attachment with the inflatable seal face up on the table.
4. Hold the tip of one of the tools against the wall of the seal at a forty five degree angle from the horizontal.
5. Connect the syringe to the attachment's port and insert air in the seal until 60CC is reached.
6. Repeat steps 2-5 for all of the various tools.

Test 2 - Insufflation Proof of Concept

Materials:

- Medtronic VersaOne Trocar and new attachment
- Inflatable balloons
- Variously sized objects (similar to common surgical tools)
    - 7.5mm dowel
    - 12.3mm dowel
    - 14.8mm dowel
- Clamp on bench vise

Protocol:

1. Gather all required materials listed above.
2. Assemble a trocar with the new inflatable seal attachment.
3. Manually inflate a 12 inch latex balloon and place on the bottom of the cannula of the trocar such that it covers the entire opening.
4. Place the trocar with the attached balloon in the clamp on bench vise, with the balloon facing horizontally.
5. Examine for two minutes if the balloon appears to have any leakage while no tools are inserted.
6. Repeat steps 3-5 two more times such that there are three trials.
7. Repeat steps 3-6 three times for each of your objects. Ensure that the tool is completely compressed by the inflatable seal.
8. Note any observations during the experiment.

Test 3 - Quantitative Leak Test

Materials:

- Medtronic VersaOne trocar and new attachment
- 60 CC air syringe
- Materials for artificial abdomen
- Variously sized objects (similar to common surgical tools)
    - 7.5mm dowel
    - 14.8mm dowel

Protocol:

1. Gather all required materials listed above.
2. Set up the artificial abdomen, which consisted of a sphygmomanometer, surgical tubing, T barbed connections, small o-rings and the trocar.
3. Inflate all three abdomens to 15mmHg.
4. Insert small tool (7.5mm) into abdomen one, large tool (14.8mm) into abdomen two and no tool in abdomen three.
    a. Abdomen three will be left as a control (no tool inserted) throughout the test.
5. Record new pressure for both abdomens.
6. Reinflate both abdomens to 15mmHg.
7. At ten minute intervals until the one hour is reached, record the pressure in all three abdomens.
8. After one hour, reinflate all three abdomens to 15 mmHg.
9. Take the old tool out, note any changes in pressure.
10. Reinflate all three abdomens, if applicable, to 15mmHg.
11. Insert the large tool into abdomen one and large tool into abdomen two.
12. Record any changes in pressure in the abdomens.

13. Reinflate to 15mmHg and record the pressure in ten minute intervals until one hour is reached.
14. Repeat steps 6-11 two more times such that each tool is inserted again into both of the abdomens.
15. Repeat all steps listed above for the team's seal attachment.

Test 4 - Range of Motion

Materials:

- Medtronic VersaOne Trocar and new attachment
- 60 CCAir syringe
- Clamp on bench vise (x2)
- Variously sized objects (similar to common surgical tools)
    - 7.5mm dowel
    - 12.3mm dowel
    - 14.8mm dowel
- Video Recording Technology
- Marker
- Fiducial markers

Protocol:

1. Gather all required materials listed above.
2. Place the original Medtronic VersaOne trocar horizontal into a bench vise and tighten the grips to prevent movement.
3. Position a camera in front of the setup using a bench vise so that the end of the cannula can be seen.
4. Measure 4.4in on the first object and draw a line.
5. Insert the first object into the Medtronic Trocar. Stop at the 4.4in line.
6. Place the fiducial marker on the end of the dowel. Ensure that the marker is 3 feet away from the camera.
7. With the camera recording, the user will angle the object to the top of the trocar head and move in a clockwise direction until returning to the starting position.
8. Repeat step 6 a total of five times with the same object.
9. After the fifth trial, remove the tool from the trocar.
10. Repeat steps 5-9 with the objects listed above.
11. Loosen the vise and remove the original Medtronic VersaOne trocar from the grips.
12. Place the original trocar that includes the team's attachment into the vise and tighten the grips to prevent movement.
13. Insert the first tool into the trocar and inflate the seal around it.
14. Place the fiducial marker on the end of the dowel. Ensure that the marker is 3 feet away from the camera.

15. With the camera recording, the user will angle the tool to the top of the trocar head and move in a clockwise direction until returning to the starting position.
16. Repeat step 12 a total of five times with the same tool.
17. After the fifth trial remove the tool from the trocar.
18. Repeat steps 12-17 with the tools listed above.
19. Loosen the vise to remove the team's trocar from the grips.

Appendix D: Future Testing Protocols

Tool Insertion and Removal

In order to complete the verification process, the team would assess whether the developed trocar would fulfill its purpose of allowing the passage of tools without presenting a risk for the patient or physician. This test was performed to assess the following specification listed in chapter three:

- *Shall allow smooth removal and insertion of various tools with a maximum frictional force of 8N.*

Materials:

- Trocar and new attachment
- Stabilizing fixture
- Variously sized objects (similar to common surgical tools)
    - 7.5mm dowel
    - 12.3mm dowel
    - 14.8mm dowel
- Instron 5544
- Instron tensile grips
- Blue Hill test methods
    - Tension test
    - Three-point flexure test

Protocol:

1. Gather all required materials listed above.
2. Create a tension test method with the following parameters:
3. Create a three-point bend test method with the following parameters:
4. Place the trocar with the attachment in the stabilizing fixture.
5. Set up the upper and lower tensile grips.
6. Mount the stabilizing fixture with the trocar in the lower grip and the object in the upper grip.
7. Verify that the tool is vertically aligned with the trocar's opening and that both objects are firmly gripped.
8. Complete the three-point flexure test. Save the recorded data.
9. While the tool is still inside the trocar, attach the syringe to the attachment's port and inflate the seal to compress around the object.
10. Complete the tension test. Save the recorded data.
11. Repeat steps 7-10 a total of three times with the same object.
12. Remove the object from the upper grip.

13. Repeat steps 6-12 with the objects listed above.
14. Remove the trocar with the team's attachment and place the original Medtronic VersaOne trocar in the lower grip.
15. Repeat steps 6-13 with the original Medtronic VersaOne.
16. Record any observations during the experiment.

Appendix E: Matlab Script for Range of Motion Test

```
%% RANGE OF MOTION
%% Trocar MQP
%% Select Desired Test
prompt = 'Enter "1" for ROM Test, "2" for ROM Overlay, and "3" for Statistical Test: ';
test_input = input(prompt);

%% Run ROM Test
 if test_input == 1
   %% Select Desired File
   prompt2 = 'Select the number of the file you would like to analyze: \n1: OGB_Range_of_Motion\n2: OGM_Range_of_Motion\n3:
OGS_Range_of_Motion\n4: NB_Range_of_Motion\n5: NM_Range_of_Motion\n6: NS_Range_of_Motion\n';
   file_input = input(prompt2);

   %% Assign input to File Name
   if file_input == 1
      fileName = 'OGB_Range_of_Motion';
   elseif file_input == 2
      fileName = 'OGM_Range_of_Motion';
   elseif file_input == 3
      fileName = 'OGS_Range_of_Motion';
   elseif file_input == 4
      fileName = 'NB_Range_of_Motion';
   elseif file_input == 5
      fileName = 'NM_Range_of_Motion';
   elseif file_input == 6
      fileName = 'NS_Range_of_Motion';
   else disp('Please select a number from 1-6 from the list above');
   end

   %% Read File
   [num, text, raw] = xlsread(fileName);
   %% Define Variables
   %Size of data
   n = size(num);

   %Extract X & Y Points
   xCoord = [num(1:n, 3)];
   yCoord = [num(1:n, 4)];
   nCoordRows = length(xCoord);

   %% Create Points Matrix && Convert Results to cm
   %Create 40x2 matrix with zeros as place holders
   P = zeros(nCoordRows, 2);

   %Diameter of fiducial marker
   pix = 44.44325;
   cm = 3.6;
   in = 1.45;

   cm_pix = cm/pix

   in_pix = in/pix;

   %Populate the points matrix with coordinates
   for i = 1:nCoordRows;
      P(i,1) = (xCoord(i,1)* cm_pix);
      P(i,2) = (yCoord(i,1)* cm_pix);
```

```
end

%% Separate Points Matrix By Trial
 Trial1 = P(1:8,:);
 Trial2 = P(9:16,:);
 Trial3 = P(17:24,:);
 Trial4 = P(25:32,:);
 Trial5 = P(33:40,:);

%% Circle Fit
%Output of the cirle fit is: [a,b,c]; center = (a,c); radius = c
 Parameters1 = CircleFitByPratt(Trial1);
 Parameters2 = CircleFitByPratt(Trial2);
 Parameters3 = CircleFitByPratt(Trial3);
 Parameters4 = CircleFitByPratt(Trial4);
 Parameters5 = CircleFitByPratt(Trial5);

 %% Create centers and radii matrices
 %Create a matrix with all the centers and radii

 centers = [Parameters1(1,1), Parameters1(1,2); Parameters2(1,1), Parameters2(1,2);Parameters3(1,1), Parameters3(1,2); Parameters4(1,1),
Parameters4(1,2); Parameters5(1,1), Parameters5(1,2)];

 if strcmp(fileName,'OGM_Range_of_Motion') == 1
    radii = [Parameters1(1,3);Parameters3(1,3);Parameters4(1,3);Parameters5(1,3)];
 elseif strcmp(fileName,'OGS_Range_of_Motion') == 1
    radii = [Parameters1(1,3);Parameters2(1,3);Parameters3(1,3);Parameters5(1,3)];
 elseif strcmp(fileName,'NB_Range_of_Motion') == 1
    radii = [Parameters1(1,3);Parameters2(1,3);Parameters3(1,3);Parameters5(1,3)];
 else
    radii = [Parameters1(1,3);Parameters2(1,3);Parameters3(1,3);Parameters4(1,3);Parameters5(1,3)];
 end

%% Average Center & Radius

center_Mean = mean(centers);
radius_Mean = mean(radii);

%% Create a matrix with the mean center to correlate with the radii of each circle

if length(radii) == 4
    centers_all = zeros(4,2);
    for k = 1:4
    centers_all(k,1) = (center_Mean(1,1));
    centers_all(k,2) = (center_Mean(1,2));
    end
else
    centers_all = zeros(5,2);
    for k = 1:5
    centers_all(k,1) = (center_Mean(1,1));
    centers_all(k,2) = (center_Mean(1,2));
    end
end

%% Average with Trials Plot
 figure
 hold on
 %Add title to the graph
 if strcmp(fileName,'OGS_Range_of_Motion') == 1
    title('Average Range of Motion for Original Trocar with Small Size Tool');
 elseif strcmp(fileName,'OGB_Range_of_Motion') == 1
```

```
    title('Average Range of Motion for Original Trocar with Large Size Tool');
 elseif strcmp(fileName,'OGM_Range_of_Motion') == 1
    title('Average Range of Motion for Original Trocar with Medium Size Tool');
 elseif strcmp(fileName,'NS_Range_of_Motion') == 1
    title('Average Range of Motion for New Attachment with Small Size Tool');
 elseif strcmp(fileName,'NB_Range_of_Motion') == 1
    title('Average Range of Motion for New Attachment with Large Size Tool');
 else
    strcmp(fileName,'NM_Range_of_Motion') == 1
    title('Average Range of Motion for New Attachment with Medium Size Tool');
 end

% Use average center for all circles
% Plot all the trial
viscircles(centers_all,radii,'Color', 'k');
hold on;
% Plot the average
viscircles(center_Mean, radius_Mean, 'Color', 'm');
xlabel('Distance (cm)');
ylabel('Distance (cm)');

%% Individual Circle Plots
figure
hold on;
%Add title to the graph
 if strcmp(fileName,'OGS_Range_of_Motion') == 1
    title('Range of Motion for Original Trocar with Small Size Tool');
 elseif strcmp(fileName,'OGB_Range_of_Motion') == 1
    title('Range of Motion for Original Trocar with Large Size Tool');
 elseif strcmp(fileName,'OGM_Range_of_Motion') == 1
    title('Range of Motion for Original Trocar with Medium Size Tool');
 elseif strcmp(fileName,'NS_Range_of_Motion') == 1
    title('Range of Motion for New Attachment with Small Size Tool');
 elseif strcmp(fileName,'NB_Range_of_Motion') == 1
    title('Range of Motion for New Attachment with Large Size Tool');
 else
    strcmp(fileName,'NM_Range_of_Motion') == 1
    title('Range of Motion for New Attachment with Medium Size Tool');
 end

 %% Plot all circle using the same center and their individual radii

 if strcmp(fileName,'OGM_Range_of_Motion') == 1
     viscircles(center_Mean,Parameters1(1,3), 'Color','r');
     hold on;
     viscircles(center_Mean,Parameters3(1,3),'Color','b');
     hold on;
     viscircles(center_Mean,Parameters4(1,3),'Color','c');
     hold on;
     viscircles(center_Mean,Parameters5(1,3),'Color','m');
     xlabel('Distance (cm)');
     ylabel('Distance (cm)');
     hold off;
 elseif strcmp(fileName,'OGS_Range_of_Motion') == 1
     viscircles(center_Mean,Parameters1(1,3), 'Color','r');
     hold on;
     viscircles(center_Mean,Parameters2(1,3), 'Color','g');
     hold on;
     viscircles(center_Mean,Parameters3(1,3),'Color','b');
     hold on;
     viscircles(center_Mean,Parameters4(1,3),'Color','c');
```

```
        xlabel('Distance (cm)');
        ylabel('Distance (cm)');
        hold off;
    elseif strcmp(fileName,'NB_Range_of_Motion') == 1
        viscircles(center_Mean,Parameters1(1,3), 'Color','r');
        hold on;
        viscircles(center_Mean,Parameters2(1,3), 'Color','g');
        hold on;
        viscircles(center_Mean,Parameters3(1,3),'Color','b');
        hold on;
        viscircles(center_Mean,Parameters5(1,3),'Color','m');
        xlabel('Distance (cm)');
        ylabel('Distance (cm)');
        hold off;
    else
        viscircles(center_Mean,Parameters1(1,3), 'Color','r');
        hold on;
        viscircles(center_Mean,Parameters2(1,3), 'Color','g');
        hold on;
        viscircles(center_Mean,Parameters3(1,3),'Color','b');
        hold on;
        viscircles(center_Mean,Parameters4(1,3),'Color','c');
        hold on;
        viscircles(center_Mean,Parameters5(1,3),'Color','m');
        xlabel('Distance (cm)');
        ylabel('Distance (cm)');
        hold off;
    end
end

%% Run ROM Overlay

if test_input == 2
    %% Select Desired File
    prompt3 = 'Select the first file you would like to overlay: \n1: OGB_Range_of_Motion\n2: OGM_Range_of_Motion\n3: OGS_Range_of_Motion\n4:
NB_Range_of_Motion\n5: NM_Range_of_Motion\n6: NS_Range_of_Motion\n';
    file_input1 = input(prompt3);

    prompt4 = 'Select the second file you would like to overlay: \n1: OGB_Range_of_Motion\n2: OGM_Range_of_Motion\n3: OGS_Range_of_Motion\n4:
NB_Range_of_Motion\n5: NM_Range_of_Motion\n6: NS_Range_of_Motion\n';
    file_input2 = input(prompt4);

    %% Assign input to File Name
    if file_input1 == 1
        fileName1 = 'OGB_Range_of_Motion';
    elseif file_input1 == 2
        fileName1 = 'OGM_Range_of_Motion';
    elseif file_input1 == 3
        fileName1 = 'OGS_Range_of_Motion';
    elseif file_input1 == 4
        fileName1 = 'NB_Range_of_Motion';
    elseif file_input1 == 5
        fileName1 = 'NM_Range_of_Motion';
    elseif file_input1 == 6
        fileName1 = 'NS_Range_of_Motion';
    else disp('Please select a number from 1-6 from the list above');
    end

    if file_input2 == 1
        fileName2 = 'OGB_Range_of_Motion';
    elseif file_input2 == 2
```

```
    fileName2 = 'OGM_Range_of_Motion';
elseif file_input2 == 3
    fileName2 = 'OGS_Range_of_Motion';
elseif file_input2 == 4
    fileName2 = 'NB_Range_of_Motion';
elseif file_input2 == 5
    fileName2 = 'NM_Range_of_Motion';
elseif file_input2 == 6
    fileName2 = 'NS_Range_of_Motion';
else disp('Please select a number from 1-6 from the list above');
end

%% Read File
[num1, text1, raw1] = xlsread(fileName1);
[num2, text2, raw2] = xlsread(fileName2);

%% Define Variables
%Size of data
n = size(num1);

%Extract X & Y Points
xCoord1 = [num1(1:n, 3)];
yCoord1 = [num1(1:n, 4)];
nCoordRows1 = length(xCoord1);

  %Extract X & Y Points
xCoord2 = [num2(1:n, 3)];
yCoord2 = [num2(1:n, 4)];
nCoordRows2 = length(xCoord2);

%% Create Points Matrix && Convert Results to cm
%Create 40x2 matrix with zeros as place holders
P1 = zeros(nCoordRows1, 2);
P2 = zeros(nCoordRows2, 2);

%Diameter of fiducial marker
pix = 44.44325;
cm = 3.6;
in = 1.45;

cm_pix = cm/pix;

in_pix = in/pix;

%Populate the points matrix with coordinates
for i = 1:nCoordRows1;
    P1(i,1) = (xCoord1(i,1)* cm_pix);
    P1(i,2) = (yCoord1(i,1)* cm_pix);
    P2(i,1) = (xCoord2(i,1)* cm_pix);
    P2(i,2) = (yCoord2(i,1)* cm_pix);
end

 %% Separate Points Matrix By Trial

 Trial1A = P1(1:8,:);
 Trial2A = P1(9:16,:);
 Trial3A = P1(17:24,:);
 Trial4A = P1(25:32,:);
 Trial5A = P1(33:40,:);

 Trial1B = P2(1:8,:);
```

```
Trial2B = P2(9:16,:);
Trial3B = P2(17:24,:);
Trial4B = P2(25:32,:);
Trial5B = P2(33:40,:);

%% Circle Fit
%Output of the cirle fit is: [a,b,c]; center = (a,c); radius = c
Parameters1A = CircleFitByPratt(Trial1A);
Parameters2A = CircleFitByPratt(Trial2A);
Parameters3A = CircleFitByPratt(Trial3A);
Parameters4A = CircleFitByPratt(Trial4A);
Parameters5A = CircleFitByPratt(Trial5A);

Parameters1B = CircleFitByPratt(Trial1B);
Parameters2B = CircleFitByPratt(Trial2B);
Parameters3B = CircleFitByPratt(Trial3B);
Parameters4B = CircleFitByPratt(Trial4B);
Parameters5B = CircleFitByPratt(Trial5B);

%% Create centers and radii matrices
%Create a matrix with all the centers and radii
centersA = [Parameters1A(1,1), Parameters1A(1,2); Parameters2A(1,1), Parameters2A(1,2);Parameters3A(1,1), Parameters3A(1,2); Parameters4A(1,1),
Parameters4A(1,2); Parameters5A(1,1), Parameters5A(1,2)];

if strcmp(fileName1,'OGM_Range_of_Motion') == 1
   radiiA = [Parameters1A(1,3);Parameters3A(1,3);Parameters4A(1,3);Parameters5A(1,3)];
elseif strcmp(fileName1,'OGS_Range_of_Motion') == 1
   radiiA = [Parameters1A(1,3);Parameters2A(1,3);Parameters3A(1,3);Parameters5A(1,3)];
elseif strcmp(fileName1,'NB_Range_of_Motion') == 1
   radiiA = [Parameters1A(1,3);Parameters2A(1,3);Parameters3A(1,3);Parameters5A(1,3)];
else
   radiiA = [Parameters1A(1,3);Parameters2A(1,3);Parameters3A(1,3);Parameters4A(1,3);Parameters5A(1,3)];

end

centersB = [Parameters1B(1,1), Parameters1B(1,2); Parameters2B(1,1), Parameters2B(1,2);Parameters3B(1,1), Parameters3B(1,2); Parameters4B(1,1),
Parameters4B(1,2); Parameters5B(1,1), Parameters5B(1,2)];

if strcmp(fileName2,'OGM_Range_of_Motion') == 1
   radiiB = [Parameters1B(1,3);Parameters3B(1,3);Parameters4B(1,3);Parameters5B(1,3)];
elseif strcmp(fileName2,'OGS_Range_of_Motion') == 1
   radiiB = [Parameters1B(1,3);Parameters2B(1,3);Parameters3B(1,3);Parameters5B(1,3)];
elseif strcmp(fileName2,'NB_Range_of_Motion') == 1
   radiiB = [Parameters1B(1,3);Parameters2B(1,3);Parameters3B(1,3);Parameters5B(1,3)];
else
   radiiB = [Parameters1B(1,3);Parameters2B(1,3);Parameters3B(1,3);Parameters4B(1,3);Parameters5B(1,3)];
end


%% Average Center & Radius

center_MeanA = mean(centersA);
radius_MeanA = mean(radiiA);

center_MeanB = mean(centersB);
radius_MeanB = mean(radiiB);


%% Plot average center and radius

  %Add title to the graph
```

```
        figure
        hold on
        if strcmp(fileName1,'OGS_Range_of_Motion') == 1
          title('Average Range of Motion for the Original Trocar and New Attachment with Small Size Tool');
        elseif strcmp(fileName1,'OGB_Range_of_Motion') == 1
          title('Average Range of Motion for the Original Trocar and New Attachment with Large Size Tool');
        else
          strcmp(fileName1,'OGM_Range_of_Motion') == 1
          title('Average Range of Motion for the Original Trocar and New Attachment with Medium Size Tool');
        end
       % Plot both circle using the center for circle A
       viscircles(center_MeanA, radius_MeanA, 'Color', 'r');
       viscircles(center_MeanA, radius_MeanB, 'Color', 'B');
       text_radA = round(radius_MeanA,2);
       text_radB = round(radius_MeanB,2);
       text = ['Original Trocar Average Radius: ',num2str(text_radA),' cm' '\newlineNew Attachment Average Radius: ',num2str(text_radB), ' cm'];
       %annotation('textbox', [0.4, 0.3, 0.39, 0.09], 'String', text);
%       annotation('textbox',dim,'String',text,'FitBoxToText','on');
       xlabel('Distance (cm)');
       ylabel('Distance (cm)');

end

%% ROM Statistical Analysis
   if test_input == 3
   %% Outlier Test
   fprintf('\nOutlier Test:\n');
   for file_input = 1:6
      %% Assign input to File Name
      if file_input == 1
         fileName = 'OGB_Range_of_Motion';
      elseif file_input == 2
         fileName = 'OGM_Range_of_Motion';
      elseif file_input == 3
         fileName = 'OGS_Range_of_Motion';
      elseif file_input == 4
         fileName = 'NB_Range_of_Motion';
      elseif file_input == 5
         fileName = 'NM_Range_of_Motion';
      elseif file_input == 6
         fileName = 'NS_Range_of_Motion';
      else disp('Please select a number from 1-6 from the list above');
      end

      %% Read File
      [num, text, raw] = xlsread(fileName);
      %% Define Variables
      %Size of data
      n = size(num);

      %Extract X & Y Points
      xCoord = [num(1:n, 3)];
      yCoord = [num(1:n, 4)];
      nCoordRows = length(xCoord);

      %% Create Points Matrix && Convert Results to cm
      %Create 40x2 matrix with zeros as place holders
      P = zeros(nCoordRows, 2);

      %Diameter of fiducial marker
```

```
    pix = 44.44325;
    cm = 3.6;
    in = 1.45;

    cm_pix = cm/pix;

    in_pix = in/pix;

    %Populate the points matrix with coordinates
    for i = 1:nCoordRows;
        P(i,1) = (xCoord(i,1)* cm_pix);
        P(i,2) = (yCoord(i,1)* cm_pix);
    end

    %% Separate Points Matrix By Trial
     Trial1 = P(1:8,:);
     Trial2 = P(9:16,:);
     Trial3 = P(17:24,:);
     Trial4 = P(25:32,:);
     Trial5 = P(33:40,:);

    %% Circle Fit
    %Output of the cirle fit is: [a,b,c]; center = (a,c); radius = c
     Parameters1 = CircleFitByPratt(Trial1);
     Parameters2 = CircleFitByPratt(Trial2);
     Parameters3 = CircleFitByPratt(Trial3);
     Parameters4 = CircleFitByPratt(Trial4);
     Parameters5 = CircleFitByPratt(Trial5);

     %% Create centers and radii matrices
     %Create a matrix with all the centers and radii
     centers = [Parameters1(1,1), Parameters1(1,2); Parameters2(1,1), Parameters2(1,2);Parameters3(1,1), Parameters3(1,2); Parameters4(1,1),
Parameters4(1,2); Parameters5(1,1), Parameters5(1,2)];
     radii = [Parameters1(1,3);Parameters2(1,3);Parameters3(1,3);Parameters4(1,3);Parameters5(1,3)];

      TF = isoutlier(radii);

      ind = find(TF);

      if size(ind) == 1
        fprintf('%s: Trial %d is an outlier\n', fileName, ind(1,1));
      elseif size(ind) > 1
        fprintf('%s: Trials %d are outliers\n', fileName, ind(:,1));
      else
        fprintf('%s: no outliers\n', fileName);
      end
  end

    %% Normal Distribution
     fprintf('\nNormal Distribution Test:\n');

    for file_input = 1:6
    %% Assign input to File Name
    if file_input == 1
       fileName = 'OGB_Range_of_Motion';
    elseif file_input == 2
       fileName = 'OGM_Range_of_Motion';
    elseif file_input == 3
       fileName = 'OGS_Range_of_Motion';
    elseif file_input == 4
       fileName = 'NB_Range_of_Motion';
```

```
elseif file_input == 5
   fileName = 'NM_Range_of_Motion';
elseif file_input == 6
   fileName = 'NS_Range_of_Motion';
else disp('Please select a number from 1-6 from the list above');
end

%% Read File
[num, text, raw] = xlsread(fileName);
%% Define Variables
%Size of data
n = size(num);

%Extract X & Y Points
xCoord = [num(1:n, 3)];
yCoord = [num(1:n, 4)];
nCoordRows = length(xCoord);

%% Create Points Matrix && Convert Results to cm
%Create 40x2 matrix with zeros as place holders
P = zeros(nCoordRows, 2);

%Diameter of fiducial marker
pix = 44.44325;
cm = 3.6;
in = 1.45;

cm_pix = cm/pix;

%Populate the points matrix with coordinates
for i = 1:nCoordRows;
    P(i,1) = (xCoord(i,1)* cm_pix);
    P(i,2) = (yCoord(i,1)* cm_pix);
end

%% Separate Points Matrix By Trial
 Trial1 = P(1:8,:);
 Trial2 = P(9:16,:);
 Trial3 = P(17:24,:);
 Trial4 = P(25:32,:);
 Trial5 = P(33:40,:);

%% Circle Fit
%Output of the cirle fit is: [a,b,c]; center = (a,c); radius = c
 Parameters1 = CircleFitByPratt(Trial1);
 Parameters2 = CircleFitByPratt(Trial2);
 Parameters3 = CircleFitByPratt(Trial3);
 Parameters4 = CircleFitByPratt(Trial4);
 Parameters5 = CircleFitByPratt(Trial5);

 %% Create centers and radii matrices
 %Create a matrix with all the centers and radii

 centers = [Parameters1(1,1), Parameters1(1,2); Parameters2(1,1), Parameters2(1,2);Parameters3(1,1), Parameters3(1,2); Parameters4(1,1),
Parameters4(1,2); Parameters5(1,1), Parameters5(1,2)];

 if strcmp(fileName,'OGM_Range_of_Motion') == 1
    radii = [Parameters1(1,3);Parameters3(1,3);Parameters4(1,3);Parameters5(1,3)];
 elseif strcmp(fileName,'OGS_Range_of_Motion') == 1
    radii = [Parameters1(1,3);Parameters2(1,3);Parameters3(1,3);Parameters5(1,3)];
 elseif strcmp(fileName,'NB_Range_of_Motion') == 1
```

```
        radii = [Parameters1(1,3);Parameters2(1,3);Parameters3(1,3);Parameters5(1,3)];
    else
        radii = [Parameters1(1,3);Parameters2(1,3);Parameters3(1,3);Parameters4(1,3);Parameters5(1,3)];
    end

    %% Average Center & Radius

    center_Mean = mean(centers);
    radius_Mean = mean(radii);

    %% Normal Distribution Test

    h = lillietest(radii);

    if h == 0
        fprintf('%s: has a normal distribution\n', fileName);
    else
        fprintf('%s: does not have a normal distribution\n', fileName);
    end

    %% Unpaired two tailed t test
    if strcmp(fileName,'OGS_Range_of_Motion') == 1
        ogs = radii;
    elseif strcmp(fileName,'OGM_Range_of_Motion') == 1
        ogm = radii;
    elseif strcmp(fileName,'OGB_Range_of_Motion') == 1
        ogb = radii;
    elseif strcmp(fileName,'NS_Range_of_Motion') == 1
        ns = radii;
    elseif strcmp(fileName,'NM_Range_of_Motion') == 1
        nm = radii;
    else
        nb = radii;
    end

end

%% Unpaired two tailed t test

[hs,ps] = ttest2(ogs, ns,'Vartype', 'unequal');
[hm,pm] = ttest2(ogm,nm,'Vartype', 'unequal');
[hb,pb] = ttest2(ogb,nb,'Vartype', 'unequal');

fprintf('\nT-Test:\n');

if hs == 0
    fprintf('Trocars with small tool have equal means with a p-value of %.3f\n', ps);
end

if hm == 0
    fprintf('Trocars with medium tool have equal means with a p-value of %.3f\n', pm);
end

if hb == 0
    fprintf('Trocars with large tool have equal means with a p-value of %.3f\n', pb);
end

%% Standard Deviation

ogs_bar = std(ogs);
ogm_bar = std(ogm);
```

```
    ogb_bar = std(ogb);

    ns_bar = std(ns);
    nm_bar = std(nm);
    nb_bar = std(nb);

    fprintf('\nStandard Deviation:\n');
    fprintf('OGS STD: %f\n', ogs_bar);
    fprintf('OGM STD: %f\n', ogm_bar);
    fprintf('OGB STD: %f\n', ogb_bar);
    fprintf('NS STD: %f\n', ns_bar);
    fprintf('NM STD: %f\n', nm_bar);
    fprintf('NB STD: %f\n', nb_bar);


end

%% STATISTICAL ANALYSIS OUTPUT
%%  Outlier Test:
% OGB_Range_of_Motion: no outliers
% OGM_Range_of_Motion: Trial 2 is an outlier
% OGS_Range_of_Motion: Trial 5 is an outlier
% NB_Range_of_Motion: Trial 4 is an outlier
% NM_Range_of_Motion: no outliers
% NS_Range_of_Motion: no outliers
%
%% Normal Distribution Test:
% OGB_Range_of_Motion: has a normal distribution
% OGM_Range_of_Motion: has a normal distribution
% OGS_Range_of_Motion: has a normal distribution
% NB_Range_of_Motion: has a normal distribution
% NM_Range_of_Motion: has a normal distribution
% NS_Range_of_Motion: has a normal distribution
%
%% T-Test:
% Trocars with small tool have equal means with a p-value of 0.298
% Trocars with medium tool have equal means with a p-value of 0.139
% Trocars with large tool have equal means with a p-value of 0.495
%
%% Standard Deviation:
% OGS STD: 0.022348
% OGM STD: 0.064418
% OGB STD: 0.043191
% NS STD: 0.077238
% NM STD: 0.043321
% NB STD: 0.222293
```

REFERENCES

[1] C. A. Steiner, Z. Karaca, B. J. Moore, M. C. Imshaug, and G. Pickens, "Surgeries in Hospital-Based Ambulatory Surgery and Hospital Inpatient Settings, 2014: Statistical Brief #223," in *Healthcare cost and utilization project (HCUP) statistical briefs*, Rockville (MD): Agency for Healthcare Research and Quality (US), 2006.

[2] "Laparoscopy (keyhole surgery) - NHS." [Online]. Available: https://www.nhs.uk/conditions/laparoscopy/. [Accessed: 17-Sep-2019].

[3] W. J. English, E. J. DeMaria, S. A. Brethauer, S. G. Mattar, R. J. Rosenthal, and J. M. Morton, "American Society for Metabolic and Bariatric Surgery estimation of metabolic and bariatric procedures performed in the United States in 2016.," *Surg. Obes. Relat. Dis.*, vol. 14, no. 3, pp. 259–263, 2018.

[4] "New York Bariatric Surgery | Laparoscopic.MD." [Online]. Available: https://www.laparoscopic.md/bariatric. [Accessed: 17-Sep-2019].

[5] "Minimally Invasive & Laparoscopic Surgery | Columbia University Department of Surgery." [Online]. Available: https://columbiasurgery.org/colorectal/minimally-invasive-laparoscopic-surgery. [Accessed: 17-Sep-2019].

[6] R. S. Gibbs, B. Y. Karlan, A. F. Haney, and I. E. Nygaard, "Laparoscopic Surgery," in *Danforth's Obstetrics and Gynecology*, Philadelphia, PA: Wolter Kluwer, 2008, pp. 792–807.

[7] "Laparoscopic Hysterectomy | South Shore Women's and Children's." [Online]. Available: https://southshorewch.com/gynaecology/laparoscopic-hysterectomy/. [Accessed: 17-Sep-2019].

[8] S. A. Oduntan, "Chloroform anaesthesia. A clinical comparison of chloroform and halothane administered from precision vaporisers.," *Anaesthesia*, vol. 23, no. 4, pp. 552–557, Oct. 1968.

[9] R. A. Perugini and M. P. Callery, "Complications of laparoscopic surgery - Surgical Treatment - NCBI Bookshelf," 2001.

[10] K. J. Philipose and B. Sinha, "LAPAROSCOPIC SURGERY.," *Med. J. Armed Forces India*, vol. 50, no. 2, pp. 137–143, Apr. 1994.

[11] "Laparoscopic Surgery - Liberty Animal Hospital." [Online]. Available: https://libertyanimalhospital.com/our-services/laparoscopic-surgery/. [Accessed: 04-Nov-2019].

[12] H. Ferreira, "Equipment in laparoscopic surgery," in *A manual of minimally invasive gynecological surgery*, Jaypee Brothers Medical Publishers (P) Ltd., 2015, pp. 1–1.

[13] "AIS CHANNEL - The ultimate surgical training experience!" [Online]. Available: https://aischannel.com/society/laparoscopic-surgical-staplers-theoretical-approach-uses-technical-professional-comparison/. [Accessed: 20-Sep-2019].

[14] M. Mehasseb, "Laparoscopic surgery: when to convert to laparotomy?," in *Gynecologic and obstetric surgery: challenges and management options*, A. Coomarasamy, M. I. Shafi, G. W. Davila, and K. K. Chan, Eds. Oxford, UK: John Wiley & Sons, Ltd, 2016, pp. 267–268.

[15] R. Agha and G. Muir, "Does laparoscopic surgery spell the end of the open surgeon?," *J. R. Soc. Med.*, vol. 96, no. 11, pp. 544–546, Nov. 2003.

[16] “Story Of Obesity Surgery | American Society for Metabolic and Bariatric Surgery.” [Online]. Available: https://asmbs.org/resources/story-of-obesity-surgery. [Accessed: 17-Sep-2019].
[17] “Bariatric surgery: Weight Loss Surgery, UCLA, Los Angeles, Southern CA, Central CA.” [Online]. Available: http://surgery.ucla.edu/bariatric-surgery. [Accessed: 17-Sep-2019].
[18] “Surgical Steps of Laparoscopic Sleeve Gastrectomy | Laparoscopic.MD.” [Online]. Available: https://www.laparoscopic.md/bariatric/sleeve/surgery. [Accessed: 17-Sep-2019].
[19] “Gastric Sleeve Los Angeles - What is Sleeve Gastrectomy? - UCLA Bariatric Surgery, Los Angeles, CA.” [Online]. Available: http://surgery.ucla.edu/bariatrics-gastric-sleeve. [Accessed: 17-Sep-2019].
[20] “Digestive Changes After Gastric Sleeve Surgery | Laparoscopic.MD.” [Online]. Available: https://www.laparoscopic.md/bariatric/sleeve/what-digestive-changes-occur-after-gastric-sleeve-surgery. [Accessed: 17-Sep-2019].
[21] “Gastric Sleeve Surgery: Weight Loss | Cleveland Clinic.” [Online]. Available: https://my.clevelandclinic.org/departments/bariatric/treatments/gastric-sleeve. [Accessed: 17-Sep-2019].
[22] “Gastric Bypass: What is Gastric Bypass? Gastric Bypass Surgery, UCLA, Los Angeles, Southern CA.” [Online]. Available: http://surgery.ucla.edu/bariatrics-gastric-bypass. [Accessed: 17-Sep-2019].
[23] “Gastric Bypass Revision - UCLA Bariatric Surgery, Los Angeles, CA.” [Online]. Available: http://surgery.ucla.edu/bariatrics-gastric-bypass-revision. [Accessed: 17-Sep-2019].
[24] “What is lap band surgery? Advantages and Disadvantages to Consider.” [Online]. Available: https://www.southnassau.org/sn/lapband. [Accessed: 17-Sep-2019].
[25] “Laparoscopic Trocars Provide Access Points for Surgery | Laparoscopic.MD.” [Online]. Available: https://www.laparoscopic.md/surgery/instruments/trocar. [Accessed: 17-Sep-2019].
[26] A. Schneider and H. Feussner, “Operative (Surgical) Laparoscopy,” in *Biomedical engineering in gastrointestinal surgery*, Elsevier, 2017, pp. 269–327.
[27] “Medtronic VersaOne 12 Mm Optical Trocar, Medtronic Versaone 12Mm ऑप्टिकल ट्रोकर - India Medtronic Private Limited, Mumbai | ID: 19771529112.” [Online]. Available: https://www.indiamart.com/proddetail/medtronic-versaone-12-mm-optical-trocar-19771529112.html. [Accessed: 18-Sep-2019].
[28] “trokarsysteme-trokare-und-obturatoren-trocaport-standard-trokar-en.jpg (JPEG Image, 200 × 150 pixels).” [Online]. Available: https://www.pajunk.eu/img/mic/lap/trokare/trokarsysteme-trokare-und-obturatoren-trocaport-standard-trokar-en.jpg. [Accessed: 16-Sep-2019].
[29] B. Böhm, M. Knigge, M. Kraft, K. Gründel, and U. Boenick, “Influence of different trocar tips on abdominal wall penetration during laparoscopy.,” *Surg. Endosc.*, vol. 12, no. 12, pp. 1434–1438, Dec. 1998.
[30] S. A. Antoniou, G. A. Antoniou, O. O. Koch, R. Pointner, and F. A. Granderath, “Blunt versus bladed trocars in laparoscopic surgery: a systematic review and meta-analysis of randomized trials.,” *Surg. Endosc.*, vol. 27, no. 7, pp. 2312–2320, Jul. 2013.
[31] “Ultimate-Universal-Cannula.jpg (JPEG Image, 2362 × 2362 pixels) - Scaled (25%).” [Online]. Available: https://www.purplesurgical.com/wp-content/uploads/2017/10/Ultimate-Universal-Cannula.jpg.

[Accessed: 16-Sep-2019].
[32] "US8888692B1 - Trocar cannula assembly and method of manufacture - Google Patents." [Online]. Available: https://patents.google.com/patent/US8888692. [Accessed: 16-Sep-2019].
[33] "3-s2.0-B9780128032305000075-f07-13-9780128032305.jpg (JPEG Image, 282 × 327 pixels)." [Online]. Available: https://ars.els-cdn.com/content/image/3-s2.0-B9780128032305000075-f07-13-9780128032305.jpg. [Accessed: 16-Sep-2019].
[34] J. S. Wolf, "Laparoscopic access with a visualizing trocar.," *Tech. Urol.*, vol. 3, no. 1, pp. 34–37, 1997.
[35] "Trends in Laparoscopy: Sealing Technology | MDDI Online." [Online]. Available: https://www.mddionline.com/trends-laparoscopy-sealing-technology. [Accessed: 16-Sep-2019].
[36] "EP1671596A1 - Duckbill seal protector for trocar - Google Patents." [Online]. Available: https://patents.google.com/patent/EP1671596A1. [Accessed: 16-Sep-2019].
[37] "US7112185B2 - Anti-inversion trocar seal - Google Patents." [Online]. Available: https://patents.google.com/patent/US7112185B2/en?q=trocar&oq=trocar. [Accessed: 16-Sep-2019].
[38] "US20190223907A1 - Trocar seal with retraction induced image - Google Patents." [Online]. Available: https://patents.google.com/patent/US20190223907A1/e. [Accessed: 16-Sep-2019].
[39] "US6228061B1 - Trocar seal system having dual seals - Google Patents." [Online]. Available: https://patents.google.com/patent/US6228061B1/en. [Accessed: 16-Sep-2019].
[40] "US7371227B2 - Trocar seal assembly - Google Patents." [Online]. Available: https://patents.google.com/patent/US7371227B2/en?q=trocar&oq=trocar. [Accessed: 16-Sep-2019].
[41] "VersaOne™ Access System | Medtronic." [Online]. Available: https://www.medtronic.com/covidien/en-us/products/trocars-access/versaone-access-system.html#versaone-optical-trocar. [Accessed: 16-Sep-2019].
[42] "ENDOPATH XCEL® Trocars | J&J Medical Devices." [Online]. Available: https://www.jnjmedicaldevices.com/en-US/product/endopath-xcel-trocars. [Accessed: 16-Sep-2019].
[43] "Kii Optical Access System | Applied Medical." [Online]. Available: https://www.appliedmedical.com/Products/Kii/OpticalAccess. [Accessed: 16-Sep-2019].
[44] S. Krishnakumar and P. Tambe, "Entry complications in laparoscopic surgery.," *J. Gynecol. Endosc. Surg.*, vol. 1, no. 1, pp. 4–11, Jan. 2009.
[45] S. Ahlqvist, D. Björk, L. Weisby, L. A. Israelsson, and Y. Cengiz, "Trocar site hernia after gastric bypass.," *Surg. Technol. Int.*, vol. 30, pp. 170–174, Jul. 2017.
[46] B. Cornette and F. Berrevoet, "Trocar injuries in laparoscopy: techniques, tools, and means for prevention. A systematic review of the literature.," *World J. Surg.*, vol. 40, no. 10, pp. 2331–2341, Oct. 2016.
[47] I. Alkatout, L. Mettler, N. Maass, G.-K. Noé, and M. Elessawy, "Abdominal anatomy in the context of port placement and trocars.," *J. Turk. Ger. Gynecol. Assoc.*, vol. 16, no. 4, pp. 241–251, Nov. 2015.
[48] "Radially expanding dilator improves surgical access | Design News." [Online]. Available: https://www.designnews.com/materials-assembly/radially-expanding-dilator-improves-surgical-acc

ess/148967347126072. [Accessed: 08-Oct-2019].
[49] "EP2316361A1 - Cone tip obturator - Google Patents." [Online]. Available: https://patents.google.com/patent/EP2316361A1/en. [Accessed: 25-Sep-2019].
[50] J. N. Rubenstein, L. W. Blunt, W. W. Lin, H. M. User, R. B. Nadler, and C. M. Gonzalez, "Safety and efficacy of 12-mm radial dilating ports for laparoscopic access.," *BJU Int.*, vol. 92, no. 3, pp. 327–329, Aug. 2003.
[51] "EP2586389B1 - Trocar system including cannula stabilization seal - Google Patents." [Online]. Available: https://patents.google.com/patent/EP2586389B1. [Accessed: 25-Sep-2019].
[52] V. Vrentas, A. Herrmann, C. Cezar, G. Tchartchian, P. Diesfeld, and R. L. De Wilde, "Reducing trocar movement in operative laparoscopy through use of a fixator.," *J. Minim. Invasive Gynecol.*, vol. 20, no. 6, pp. 842–847, Dec. 2013.
[53] L. Doyon, N. Toomey, A. St. Germain, and A. Mittelman, "Initial Meeting with Dr. Doyon," 18-Jul-2019.
[54] "Polycarbonate Remains Proven and Preferred for Medical Applications - Medical Design Briefs." [Online]. Available: https://www.medicaldesignbriefs.com/component/content/article/mdb/features/17693. [Accessed: 27-Sep-2019].
[55] I. CONDITIONS, "Measurement of Optical Characteristic of Plastic by UH4150 Spectrophotometer - An example of High Throughput measurements in the UV, Visible and Near-Infrared Regions -."
[56] "Polyisoprene." [Online]. Available: https://polymerdatabase.com/Elastomers/Isoprene.html. [Accessed: 25-Sep-2019].
[57] A. Alazmani, R. Roshan, D. G. Jayne, A. Neville, and P. Culmer, "Friction characteristics of trocars in laparoscopic surgery.," *Proc. Inst. Mech. Eng. H*, vol. 229, no. 4, pp. 271–279, Apr. 2015.
[58] E. Y. Park, J.-Y. Kwon, and K. J. Kim, "Carbon dioxide embolism during laparoscopic surgery.," *Yonsei Med. J.*, vol. 53, no. 3, pp. 459–466, May 2012.
[59] F. Barrère, T. A. Mahmood, K. de Groot, and C. A. van Blitterswijk, "Advanced biomaterials for skeletal tissue regeneration: Instructive and smart functions," *Materials Science and Engineering: R: Reports*, vol. 59, no. 1–6, pp. 38–71, Feb. 2008.
[60] "www.pacificbiolabs.com/downloads/Booklet Biocompatibility.pdf."
[61] "Guidance for Industry and Food and Drug Administration Staff."
[62] "ISO - Standards." [Online]. Available: https://www.iso.org/standards.html. [Accessed: 08-Oct-2019].
[63] "About FDA | FDA." [Online]. Available: https://www.fda.gov/about-fda. [Accessed: 08-Oct-2019].
[64] "ISO - ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes." [Online]. Available: https://www.iso.org/standard/59752.html. [Accessed: 08-Oct-2019].
[65] "ISO - ISO 14971:2007 - Medical devices — Application of risk management to medical devices." [Online]. Available: https://www.iso.org/standard/38193.html. [Accessed: 08-Oct-2019].
[66] "ISO - ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process." [Online]. Available:

https://www.iso.org/standard/68936.html. [Accessed: 08-Oct-2019].
[67] "ISO - ISO 11737-1:2018 - Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products." [Online]. Available: https://www.iso.org/standard/66451.html. [Accessed: 08-Oct-2019].
[68] "CFR - Code of Federal Regulations Title 21." [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.1. [Accessed: 08-Oct-2019].
[69] "ISO - ISO 16142-1:2016 - Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards." [Online]. Available: https://www.iso.org/standard/63939.html. [Accessed: 08-Oct-2019].
[70] "PLA | Professional 3D printing made accessible | Ultimaker." [Online]. Available: https://ultimaker.com/en/resources/49911-pla. [Accessed: 06-Apr-2020].
[71] "Article Detail." [Online]. Available: https://support.formlabs.com/s/article/Using-Tough-Resin?language=en_US. [Accessed: 06-Apr-2020].
[72] "AST Guideline - Environmental Practices in the Operating Room." [Online]. Available: http://www.ast.org/webdocuments/ASTGuidelineEnvironmentalPracticesinOR/index.html#10. [Accessed: 30-Oct-2019].
[73] N. E. Power, J. L. Silberstein, T. P. Ghoneim, B. Guillonneau, and K. A. Touijer, "Environmental impact of minimally invasive surgery in the United States: an estimate of the carbon dioxide footprint.," *J. Endourol.*, vol. 26, no. 12, pp. 1639–1644, Dec. 2012.
[74] "Medical Devices | FDA." [Online]. Available: https://www.fda.gov/medical-devices. [Accessed: 02-Nov-2019].
[75] "Products liability | Wex | US Law | LII / Legal Information Institute." [Online]. Available: https://www.law.cornell.edu/wex/products_liability. [Accessed: 02-Nov-2019].
[76] "AM Basics | Additive Manufacturing (AM)." [Online]. Available: https://additivemanufacturing.com/basics/. [Accessed: 03-Nov-2019].
[77] "Additive vs. Subtractive Manufacturing | Formlabs." [Online]. Available: https://formlabs.com/blog/additive-manufacturing-vs-subtractive-manufacturing/. [Accessed: 03-Nov-2019].
[78] "Plastic Injection Molding | Prototypes & Low-volume Production Parts." [Online]. Available: https://www.protolabs.com/services/injection-molding/plastic-injection-molding/. [Accessed: 03-Nov-2019].
[79] "Five top tips for making sustainable medical devices." [Online]. Available: https://www.medicaldevice-network.com/features/sustainable-medical-devices/. [Accessed: 03-Nov-2019].
[80] "3D Printing: Adding a Sustainable Dimension to Modern Life | Development | RESET.org." [Online]. Available: https://en.reset.org/knowledge/3d-printing-adding-sustainable-dimension-modern-life-02262018. [Accessed: 03-Nov-2019].