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A Compact Trocar System for Laparoscopic Tissue Extraction

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Authorship:

All members of the project team completed equal portions of work both in prototyping and in the creation of this report. Alexandra was mostly involved in the creation of testing devices and editing written work, Casey was responsible for the majority of the completed background research and coordinated the filing of a provisional patent, Leslie was invaluable with her ability to create CAD models and manage prototype printing with the Rapid Prototyping Office of WPI. The team collaborated throughout the year and met weekly to remain on schedule.

Casey Arpin	Background research Filed provisional patent Co-writer
Leslie Tepanecatl	SolidWorks design models Managed prototyping Analyzed test data Co-writer
Alexandra Wolfe	Created test protocols and devices Co-writer Editor

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Abstract:

Laparoscopic surgery is an increasingly popular form of abdominal surgical intervention. Typically, these procedures are performed using multiple trocars placed in various locations on the abdomen. Current laparoscopic practice and trocar placement creates scarring over the abdomen and improper trocar use can lead to postoperative complications such as hernia formation and bleeding. This project aimed to develop a trocar system that enables the use of multiple trocars in the umbilicus to maximize postoperative cosmetic results and ensure the most minimally invasive procedure. A final stage prototype was designed in SolidWorks and manufactured by stereolithography. Through mechanical testing and data analyzation the design prototypes were validated to have achieved the original project goals.

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Chapter 1: Introduction

Within recent years, minimally invasive surgery known as laparoscopy has become one of the most popular surgical techniques performed in the United States, with approximately 15 million surgeries performed annually, and has come into favor with several specialties including gynecology [1]. The market for laparoscopic instrumentation has grown exponentially and is predicted to continue growing. According to Markets to Markets, a market research firm, in 2016, the market value for gynecologic surgical instruments was 1.73 billion United States dollars and is expected to reach 2.44 billion United States dollars by 2021 [3]. Since the market is expected to grow and the field is moving toward single site laparoscopies, there is a need for new improvements in the industry. Therefore, the development of a new trocar system, benefits both healthcare and the surgical instrument industry.

Laparoscopy utilizes small incisions to introduce a camera and instrumentation into the body to perform procedures as opposed to a laparotomy, or open surgery, in which a large incision is created and manual manipulation is used. Laparoscopic surgery has many benefits over laparotomies; laparoscopy eliminates large abdominal incisions that leave noticeable scars on the abdomen, is considered a minimally invasive procedure, has a faster recovery time, and has less postoperative pain [6]. When a complication arises in laparoscopy, improper entry into the abdominal cavity is the common culprit [5]. The entry process, if not completed correctly can lead to puncture of the bowel, an internal organ, or of a major blood vessel; all of which can be life threatening. The abdominal cavity is typically entered using a series of trocars, or ports, and if the cavity is not sufficiently insufflated or the trocar is inserted in an improper location, serious damage could occur leading to complications. Trocars are most commonly placed around the abdomen resulting in several small (1-2 cm) postoperative scars which, although improved from

laparotomy scars, are cosmetically displeasing to many patients.

Single site laparoscopies are a form of laparoscopy where trocars are placed in a single location on the abdomen, usually the umbilicus, in order to reduce unnecessary scarring. However, there are few options for single site trocars that enable the surgeon to maximize efficiency. Typical trocars are not designed for close interaction and cannot achieve the proper angles for gynecologic procedures such as tubal ligation. With an increase in laparoscopic gynecologic surgery and the desire of surgeons to perform the most minimally invasive surgery, there is a deficit in the available port instrumentation.

The scope of this project targeted surgeons performing laparoscopic surgeries specifically, gynecologic procedures such as tubal ligation. Tubal ligation is a common form of female sterilization where the fallopian tubes are removed, clipped, or blocked to prevent pregnancy. Since tubal ligation and other gynecologic procedures are common, there is a current need to develop a trocar system that minimizes the risks of laparoscopic surgery from improper entry into the body while keeping the procedure minimally invasive and maximizing cosmetic results.

There is currently a variety of trocars available on the market today, many of which are chosen based on surgeon preference and cost rather than function. Applied Medical has various types of trocars that are intended for laparoscopic surgery including the Kii Access Systems. The Kii includes a series of trocars that minimize forward migration into the abdominal cavity when instruments are inserted and slippage when instruments are removed [7]. The Kii Fios first entry is a very useful trocar with insufflation capabilities that separates fibers of the abdominal wall during insertion rather than cutting the tissue. The Kii is not an ideal system for single site surgery however, because the detachable head is too large to interact with another trocar in the

umbilical space. Medtronic, another leader in medical instrumentation and technology, has a single site compatible, multiport trocar called the SILS Port [4]. This access system allows several trocars to be inserted at one time through the same incision. While this is a unique approach to single site surgery, the SILS Port requires a single incision that spans the diameter of the umbilicus rather than two significantly smaller incisions in the same space. There is a significant number of trocars on the market each boasting their own strength, yet there is currently no product that allows a system of multiple trocars to coexist in the umbilical space with minimal incision lengths during a gynecologic procedure.

The overarching goal of this project was to design, test, and evaluate a trocar system for use in single site gynecologic procedures. The team aimed to develop a trocar system that minimizes and localizes scarring to the umbilicus while facilitating single site surgeries as an alternative to traditional laparoscopic female sterilization procedures.

The needs of patients and surgeons are constantly evolving and it is necessary for surgical tools and technology to evolve as well. A newly designed trocar system would be able to fit two trocars into the umbilicus, effectively eliminating abdominal scarring during female sterilization procedures and possibly other laparoscopic gynecologic surgeries. This is beneficial and preferable for many women undergoing these procedures because the cosmetic impact of surgery can be detrimental to a patient. By localizing the trocar insertion to the umbilicus there will no longer be obvious scarring on the abdomen postoperatively. The creation of a trocar system that is located only in the umbilical space also prevents organ damage from improper insertion by providing a consistent puncture site that is a safe distance from major organs. Overall, this new system should provide surgeons and patients with improved intraoperative and postoperative results as well as providing a step towards micro-laparoscopy.

In order to develop an improved single site trocar system, the team had to prioritize design objectives and clarify necessary functions through research and client statements. The most important objectives of this project were determined to be the devices ability to minimize trocar interaction, the elimination of abdominal scarring outside of the umbilicus, and allowing for manual insertion. Design specifications were narrowed down to requiring 71.4N [36] or less of force for insertion into the abdominal cavity, maintaining abdominal insufflation between 10-20 mmHg [37], fitting in the 20mm umbilical space, and accommodating specimens up to 5mm. Once objectives and specifications were established the design aspect of the project can begin taking shape.

To ensure the success of the project the team worked together to organize and plan the intended path of the project over the entire academic year. This was done by creating weekly agendas that consisted of short-term goals and accomplishments as well as utilizing a system of Gantt charts to organize deadlines. Completion of this project required the team to stay on task and progress through the engineering process.

Chapter 2: Literature Review

Laparoscopic surgery is a form of minimally invasive surgery that is completed with a laparoscope and a camera as well as other grasping, cutting, and tissue manipulating tools [10]. Both major and minor surgeries can be performed laparoscopically through small incisions that measure an average of one inch. Access to the abdominal cavity is gained by placing trocars through these incisions and the abdominal wall so surgical instruments can easily access the desired tissue.

2.1 Evolution of Laparotomy to Laparoscopy

Laparotomy is a procedure that requires a large incision, rather than trocar introduction, to be made for access to the abdominal cavity [11]. The same operations can be performed during laparoscopy as would be done during laparotomy yet, there is a 40% lower risk of minor complications to occur after laparoscopic surgery as opposed to its open counterpart [12]. Laparotomy was a general practice for many years before the technology of laparoscopy was available, however, open surgery is more likely to cause postoperative pain, wound infection, abdominal hernia, and multi day hospitalization. In the United States, between 2-25% of patients develop a wound infection after laparotomy and 4-18% of patients experience an abdominal hernia. Surgeons believe that the prevalence of hernias and wound infection is caused by the large incision needed to perform the surgery. Laparoscopy became favored because the small incisions that are protected by a trocar proved to reduce complications. As surgery continues to evolve, laparoscopic procedures continues to be modified to reduce the amount or size of incisions.

2.2 History of Laparoscopic Surgery

Dimitri Ott, Georg Kelling, and Hans Christian Jacobeus introduced the beginning stages

of laparoscopic surgery in the early 1900s [13]. In 1901, Ott inspected the abdomen of a pregnant women using a mirror head and Georg Kelling performed a procedure known as the koelioscopie, where he was able to visualize the peritoneal cavity of a dog with a cystoscope and insufflation. Following 1901, several European and American authors performed laparoscopic procedures for diagnostic purposes. Laparoscopic procedures did not become popular in gynecology until the rod-lens optical system and the cold light fiber-glass illumination was developed. A major breakthrough in laparoscopic surgery was the development of the computer chip television camera [14]. Viewing an image of the abdominal organs became possible while completing the surgery allowing the surgeon's hands more free movement for more complicated procedures. Laparoscopy was originally used in general surgery for diagnosis specifically for liver disorders and abdominal trauma. In 1987, a French gynecologist, Mouret, performed the first acknowledged laparoscopic cholecystectomy with the use of trocars [15]. Mouret's approach helped advance operative laparoscopy tremendously. The procedure was introduced to the United States in 1988. Within two years, between 1990 and 1992 approximately fifteen-thousand surgeons were trained to perform laparoscopic surgery. Laparoscopy continued to gained popularity and skilled surgeons expanded the use of this procedure to many aspects of medicine.

2.3 How is a Laparoscopy Performed?

Laparoscopy allows surgeons access to the abdomen to complete surgical procedures with small incisions using trocars, abdominal insufflation, surgical instruments, and external video projection [16]. Laparoscopic surgery is performed under general anesthesia. Small incisions are made in the abdomen and trocars are inserted. A trocar is a port that pierces through the abdominal wall and allows the laparoscope and other tools to enter into the abdomen. The

laparoscope is a surgical instrument that contains a light and a camera, the camera allows the surgeon to view inside the abdomen without making an incision larger and creates a video feed that is projected on a monitor that is visible to the surgeon. Many trocars also contain a port for tubing that introduces CO2 gas into the abdomen. Having a direct port for constant CO2 gas flow is important for keeping the abdomen insufflated which gives the surgeon better vision and access to the organs to perform the surgery. These surgeries are often day procedures; the patients are usually not required to stay overnight in the hospital making the procedures extremely convenient. Minor complications typically occur one out of every one hundred surgeries. These include minor bleeding, bruising, nausea, or infection of the incision site. Major complications occur one in approximately every one thousand surgeries and can include damage to an organ or artery during the entry process, blood clotting, or CO2 entering into the bloodstream. Laparoscopy has diagnostic and surgical applications and is commonly used in gynecology, urology, and gastroenterology.

2.4 Gynecologic Uses for Laparoscopic Surgery

While laparoscopy has a variety of uses in many different medical disciplines, it is very prevalent in gynecologic surgery. The delicate procedures performed require precision, a quality that laparoscopy offers. The following sections detail the most common uses of laparoscopy in gynecology.

2.4.1 Removal of Endometriosis, Ovaries, Fibroids, and Cysts

This type of surgery can be used for endometriosis, ovarian cysts, adhesions, ectopic pregnancies, and removal of the ovaries and uterus [17]. Hysterectomy and myomectomy are two common procedures performed as laparoscopic gynecologic surgery [18]. Myomectomy is the removal of the uterine fibroids without the removal of the uterus allowing the woman to

maintain fertility. A hysterectomy is the removal of the uterus and can have varying levels of severity. Endometriosis occurs when the lining of the uterine wall grows outside of the uterus and is removed to alleviate intense pain and bleeding [19]. This most commonly occurs on the ovaries and the fallopian tubes and affects 11% of American women. Ovarian cysts are fluid filled sacs in the ovaries that can be up to 10 mm in diameter and occur in 8% percent of women [20]. Ovarian cysts can occur during pregnancy, develop due to endometriosis, or be the result of hormonal issues. The majority of these procedures can be completed through laparoscopic same day surgeries but have slower recovery times than other gynecologic procedures.

2.4.2 Female Sterilization

Female sterilization is a procedure that permanently prevents women from becoming pregnant [21]. This procedure can be completed through tubal ligation or tubal implants. Tubal ligation can include the banding, sealing, or cutting of the fallopian tubes. If the fallopian tubes are cut, they are often removed from the body. Tubal implants are placed in the fallopian tubes to encourage scar tissue to form in the fallopian tubes blocking the sperm from reach the egg. Tubal ligation is one of the most popular methods of permanent contraception and is mostly commonly performed surgically through simple laparoscopy [22].

2.4.3 Diagnostic Exploratory surgery

Diagnostic exploratory laparoscopic surgery is a procedure that allows surgeons to look around the abdomen [23]. This surgery is completed under general anesthesia and the abdomen is insufflated with CO2 similar to other laparoscopic surgeries. The surgeon checks the abdominal cavity for abnormalities that did not appear during imaging or ultrasound. Diagnostic exploratory surgery can also be used to check the abdominal cavity for internal bleeding after an accident or in cancer patients to see if the cancer has spread. If any abnormalities are found, the

surgeon can remove them during this procedure or gain a better idea of what type of procedure needs to be completed to get the best results.

2.5 Benefits of Laparoscopy

The benefits of laparoscopy include less postoperative pain, smaller incisions, shorter hospital stays, and shorter recovery times as compared to laparotomy and other forms of surgery [24]. Cosmetically, laparoscopic surgery leaves small scars that are often hidden within the umbilicus leading to more favorable results for patients. The surgeon also has a better view of the abdominal cavity since images of the abdomen are viewed on a monitor with minimal blood loss.

2.6 Single Site Laparoscopy

Single access site surgery (SAS) involves the performance of laparoscopic procedures through a single site on the abdomen, typically in the umbilicus [25]. The laparoscopic instruments are introduced into the abdominal cavity through only incisions made in the umbilicus. A retrospective chart review from procedures performed at the Stanford University Medical Center compared the need for conversion from laparoscopy to laparotomy, operative time, length of hospitalization, cosmetic outcome, and complications for twenty SAS surgeries. All of the surgeries were conducted through laparoscopy and the need for conversion to laparotomy was unnecessary in all twenty procedures. Depending on the type of procedure, the average time of operation did not exceed 165 minutes and the hospital stay ranged from 1 day to 2.5 days. All twenty SAS patients were satisfied with the outcome of the surgery cosmetically as these procedures allow for scar less entry into the abdominal cavity. According to this study, the outcome was similar to normal laparoscopic surgeries, however SAS procedures are more beneficial cosmetically.

Single access site surgery provides less scarring compared to normal laparoscopic surgeries. Laparoscopic surgeries require four to five incisions while SAS surgeries require one or two contained in the umbilicus, an existing scar [26]. Benefits of these procedures also include less postoperative pain and a shorter recovery time. Although it takes approximately the same time for SAS procedure and a normal laparoscopic procedure, the SAS procedure can be considered more complicated. In the instance of single port SAS surgery, the surgeon must manipulate several laparoscopic surgical instruments in one port rather than separate ports, increasing the difficulty of the procedure. There are several factors that would eliminate a patient from being considered for a SAS procedure including obesity, adhesions, or scarring from previous surgeries. The SAS procedure is mainly used for cosmetic purposes and leaves little to no scarring other than the naturally occurring scar in the umbilicus.

2.7 The Importance of Trocars

Trocars are an integral aspect of laparoscopic surgery, they create a pathway for abdominal access, facilitate insufflation, and protect tissue. Trocars have developed over the years but continue to have similar structures and functions in laparoscopic uses.

2.7.1 Trocar Structure

The typical structure of an abdominal trocar can be seen in the majority of the laparoscopic trocars used today. The common trocar consists of a cannula or shaft, a head, and a valve [27]. The cannula enters into the body with the help of a guide element, an additional piece that inserts into the cannula and acts to part the tissue fibers as the trocar is advanced through the abdominal wall. The guide element is removed once the trocar is in place to allow surgical tools access through the cannula. The head of the trocar is the visible portion outside of the body at the top of the shaft. Traditionally, the head of the trocar contains a gas port to maintain carbon

dioxide levels in the cavity and a valve that prevents gas from escaping. Certain trocars include a balloon around the outside of the shaft that is inflated inside the body and prevents the trocar from being displaced. In multi-site laparoscopic surgery, traditional trocars are sufficient for completing most procedures.

2.7.2 Potential Complications

Many complications can result from the abdominal entry process for laparoscopic surgery. There are several types of abdominal entry processes including the open (Hassan) technique, the closed (Veress Needle) technique, direct trocar entry techniques, and optical (direct vision) technique [28]. The open technique is a small incision that is made directly into the abdominal wall with direct vision. The closed technique is insertion of the Veress needle directly into the abdominal wall and has a higher risk of failed entry over the open entry technique. There are three entry sites that a laparoscopic procedure can be completed from. These sites include the umbilicus, Lee-Huang Point (middle of the abdomen), or the Palmer's point (middle upper abdomen). In a majority of cases, the primary trocar is the result of a procedure's complications and the likelihood that a major injury will occur in the entry process is 1.1/1000, 0.7/1000 for bowel injuries, and 0.4/1000 for vascular injuries.

Other complications that can arise from the use of trocars are hernia and site bleeding. Incisional hernias occur when the abdominal wall is weakened enough that organs begin protruding through pockets in the tissue. In laparoscopic surgery, this complication typically occurs where a trocar was placed [29]. Reviews of laparoscopic tip designs have revealed that there is a greater risk of hernia when a sharp tip trocar is used as opposed to a conical tip design. Often, this complication requires a second surgery to repair the abdominal wall and remove the hernia. Trocar site bleeding is a relatively overlooked complication of laparoscopy that occurs

when the trocar is removed [30]. Although not routinely alarming, site bleeding can occasionally require more surgery to control the bleeding which increases operating room time and procedure difficulty. An ideal trocar design would minimize the risk of these and any other potential complications during laparoscopic procedures.

2.8 Current State of the Art

The laparoscopic surgical market has a plethora of trocars on the market for several different applications. The current state of the art trocars for SAS procedures include the Applied Medical Kii Trocar and the Medtronic SILS Port. Applied Medical is a medical device company that produces a variety of trocar systems that aid minimally invasive surgery [7]. Applied Medical Kii trocar products can have different tips and sleeves. The Applied Medical Kii Advanced Fixation Sleeve trocar ensures minimum penetration and superior abdominal wall retention. This trocar allows for rapid disinflation and specimen removal, maximum visibility, and minimal cannula depth [31]. The 5 mm trocar system the market value for this product is approximately $30 USD [32]. However, drawbacks of this device include the lack of ability to act as multiport and the large removable heads do not function well when multiple devices are inserted into the umbilicus.

A gold standard multiport trocar available in today's market is Medtronic's multiport trocar system, SILS™ Port [4]. Single site incisions made with a multiport trocar system are more favorable compared to the multiple site incisions made by using a traditional trocar system. The SILS™ Port has the advantage of being able to accommodate a maximum of three laparoscopic instruments by acting as a multiport and being inserted through a 2 cm incision [33]. Advantages also include maximum maneuverability, adjustable cannulas, easy set-up, and a hidden scar. The market value of this product is approximately $510.10 [34]. The cons of this

device include the need for a slightly larger fascial incision to accommodate the port, and the market cost. The need for more cost-effective and multiport devices is required to aid in single-site laparoscopic surgery.

2.9 The Big Picture

Laparoscopic surgery is an effective, popular form of surgery that can be found in many medical specialties, including gynecology. These procedures can help female patients in a variety of aspects from cancer treatment to contraception and many things in between. Many aspects of laparoscopy are important to different involved parties; hospitals focus on the efficiency and cost of procedures and materials, doctors pay attention to ease of use and risk of complications, and patients are primarily focused on recovery and cosmetic outcomes.

As medicine continues to advance and demands of institutions, providers, and patients become more specific minimally invasive surgery is becoming even more minimally invasive. The adoption of single access site surgery is an example of this evolution but is not a perfect solution. The current methods of female sterilization and other procedures through SAS procedures come with a variety of complications. These complications center around the problem that there is not currently an existing system of trocars designed for SAS procedures through the umbilicus for gynecologic procedures.

Chapter 3: Project Strategy

3.1 Initial Client Statement

The initial client statement given to the team by Dr. Ryan Callery of the University of Massachusetts Medical School (UMMS) was very broadly based around improving surgical equipment for laparoscopic gynecologic surgery. The original client statement received by the team was, "Develop a trocar specifically designed for dual trocar, umbilical access during female sterilization gynecologic procedures. The trocar should maintain insufflation, reduce the risk of hernia, and be no greater than 5mm in diameter, preferably 3mm." As expected with initial client statements, the aim of the project was further specified as the project progressed.

3.2 Design Requirements: Technical

3.2.1 Objectives

Building off of the client statement and research of trocars currently on the market, several design objectives were created that gave the project tangible goals. These objectives, as displayed in Table 3.1, included primary objectives that were necessary in order to deem the project successful, and secondary objectives that consisted of additional goals the team had for the design.

Table 3.1. Project objectives

Objective	Justification
Eliminate Abdominal Scarring	a. Must produce improved aesthetic results
	b. Increased patient satisfaction
Manual Insertion	a. The device must pierce through the abdominal wall without the use of another device
Minimal Trocar Interaction	a. Must enable single site procedures
	b. Must allow surgeon manipulation
Proper Abdominal Insufflation	a. Must maintain visibility
	b. Insufflation protects organs

These objectives were based around the need for an improved system of abdominal access during laparoscopic tubal ligation as expressed to the team by Dr. Callery.

Eliminate Abdominal Scarring

The device must eliminate unnecessary scarring on the abdomen to increase aesthetic results and minimize complications. This is a primary objective because many patients refuse proper treatment due to the scarring that laparotomy and traditional laparoscopies cause therefore, it is necessary to minimize this negative result to improve patient satisfaction.

Manual Insertion

Creating a device that is capable of manual insertion was deemed a primary objective as well because even the most helpful device would be considered useless if the surgeon cannot insert it properly into the abdominal cavity. The device should not be any more difficult to insert than a typical trocar while maintaining the ability to pierce through the abdominal wall without the assistance of another device.

Minimal Trocar Interaction

The device must enable single site surgeries by allowing dual trocar use in a single location. To do this the trocars must be able to compliment one another's movement and not restrict the surgeon's motion or ability to operate.

Proper Abdominal Insufflation

It would also be beneficial to create a system that maintains insufflation of the abdomen directly. This maintains visibility and protects organs during procedures by managing insufflation from the trocar itself rather than another device.

3.2.2 Constraints

There are several constraints throughout this project that are placed on the team and the device. The constraints as shown in Table 3.2 are stemmed from the client's requirements as well as the limitations set by WPI.

Table 3.2. Project Constraints

Constraint	Justification
Must accommodate 5 mm instrumentation	a. Surgeon preference
	b. Standard instrumentation
Must Fit Within Umbilicus	a. No abdominal scarring
Time	a. One academic year beginning 09/2017 and ending 05/2018
Budget	a. $750.00 for the entire project
	b. Must remain under $750 for materials, manufacturing, publishing, and all other possible costs

1. Accommodate Instrumentation

A constraint placed on the device by Dr. Callery was the need for a trocar diameter to accommodate a 5mm laparoscopic scope. The smaller instruments are not suitable for tubal ligations so the minimal diameter of each trocar must be able to fit the instrumentation.

2. Must Fit Within Umbilicus

Another constraint imposed on the device by Dr. Callery was that the whole device must fit within the umbilicus. This would reduce abdominal scarring by operating in an already existent scar, providing patients with the best possible cosmetic outcome.

3. Time

This project was deemed to be completed in an academic year, approximately nine months, which limited the amount of time that could be spent on each aspect of the design and on the testing process. To increase efficiency, the team placed schedule constraints on themselves to ensure the project would be completed by May 2018.

4. Budget

Financially, the team was only allotted $750.00 for the entirety of the project, meaning that materials and the creation of multiple generations of prototypes had to be carefully budgeted. Additionally, the team did not conduct testing in vivo so an alternative method had to

be constructed which increased the time and financial restraints required.

3.2.3 Functions

A list of functions was developed from the primary and secondary objectives. The functions shown in Table 3.3 create a trocar system that is single site compatible. The function-means table creates a visual representation of potential avenues to incorporate into the design. In order for the device to be successful and attractive to surgeons who are currently using different products, the device should include all of these functions in one design.

Table 3.3. Function-Means Table

Function	Means of Accomplishing		
Maintain Visibility	Continuous gas exchange through a port on cannula	Manual gas exchange via stopcock	Leak proof valves on trocar heads
Promote Single Site Procedures	Scarring only in umbilicus	Compatible trocar heads	
Accommodate Specimen	Consistent cannula diameter	Removable trocar head	Specimen shield
Simultaneous Use of Multiple Instruments	Multiple independent trocars	Connected interdependent trocars	Single trocars with several cannulas

Maintain Visibility

Maintaining visibility is a crucial aspect of laparoscopic surgery, if carbon dioxide escapes from the abdominal cavity the laparoscopic visual is lost and the procedure cannot be completed. In order to maintain visibility, insufflation must be maintained so the team aimed to create a leak proof valve that will prevent gas from escaping when tools are inserted, removed, or manipulated. Additionally, a gas port was included on the cannula that can connect to insufflation tubing to add or remove carbon dioxide from the abdominal cavity either manually or continually.

Promote Single Site Procedures

To create a device that encourages surgeons to use a single site method of laparoscopy the device must be improved from standard trocars. This was achieved by ensuring that the device was fully contained within the umbilicus and does not cause any abdominal scarring. The heads of the trocar were also designed to be compatible in such a small space.

Accommodate Specimen

An important function of the device is that it accommodates the specimen without causing herniation or requiring additional incisions. Possible means to enabling this function were to create a cannula with a uniform diameter and a removable trocar head so the specimen can be removed while the device is still in place. Alternatively, a specimen shield could be created to smoothly guide the specimen out of the body once the device is removed.

Simultaneous Use of Multiple Instruments

During laparoscopic procedures it is essential to have multiple tools in the abdominal cavity at one time. To accomplish this the trocar system consists of two independent trocars that are both inserted into the umbilicus. However, it may be more efficient to create a system of connected, interdependent trocars that move together while allowing tools to be independently manipulated. A third option to allow for the use of multiple tools is a single trocar that has many ports or cannulas, this would require a larger incision but would reduce unwanted trocar interaction.

3.2.4 Specifications

There are several design specifications that need to be met with the design of this device. The cannula diameter for any part that is inserted through the abdominal wall must be 5mm. The abdomen must be insufflated with carbon dioxide at a consistent pressure between 10-20mmHg

[37]. Additionally, the force required to insert the trocar through the abdominal wall must be no greater than 71.4N [36]. These specifications serve as measurable aspects of the design that are confirmed through testing.

3.3 Design Requirements: Standards

When building a medical device, it is extremely important to adhere to the standards and regulations put forth by the International Organization for Standardization (ISO) and the Food and Drug Administration (FDA). The outcome of this project resulted in development of a class II medical device that will be used in laparoscopic gynecologic single site incision surgeries as well as other laparoscopic gynecologic surgeries. In order to prove that this device works, the device must be tested under the ISO 10993-1:2009 standards for biological evaluation for medical devices. The biological safety of the medical device will be assessed and it will be determined if the medical device meets the ISO standard. Since the device will be used inside the human body, it is important that the device is sterile. The medical device must meet ISO standard 11737-1:2006 for sterilization for medical devices. ISO 16142-1:2016 Medical Devices and ISO 13485 Quality Management Systems can be used to determine if the medical device meets all the standards and has been evaluated with all of the proper standards. The medical device must also comply with the FDA's Center for Device and Radiological Health Standards. The device is classified as a class I, II, or III device and must meet the standards and regulations of that category. It is important that our device falls within the standards and regulations because failure to do so would result in a medical device that is unusable for our client and others performing laparoscopic surgeries.

3.4 Revised Client Statement

After deliberating with Dr. Callery as well as Professor Butler and analyzing where the

need lies in the laparoscopic gynecologic field, the scope of the project was further defined. The revised client statement created by the team stands as follows, "Develop a trocar system that provides a scar-less alternative to traditional female sterilization procedures. The design of the system should allow dual trocar access into the 20mm umbilical space, which will eliminate abdominal scarring during gynecologic and other laparoscopic surgeries. The trocar system must accommodate the simultaneous use of multiple laparoscopic tools and insufflation of the abdomen should be maintained at a pressure of 10-20 mmHg [37]. Also, each trocar should be 5 mm in diameter, should have direct insufflation capabilities, and should minimize the interaction of trocar heads during procedures." Although this client statement is longer than what was originally given to the team, it clarified the focus of the project and allowed the team to create a more useful device.

3.5 Management Approach

In order to complete the project in the required academic year the team created a timeline for milestones and goal completion throughout the four term academic year. The overarching timeline consists of four sections; research and design, prototyping, testing, and documenting. Each section was completed in an academic term in the order listed. This system allowed the team to stay on track and ensure that the project reached completion. Each milestone was necessary in the engineering design process to be able to fully solve the problem at hand. Without accurate research and the creation of multiple designs the team would not have been equipped to create a successful prototype that could then be tested to prove its value.

A tool used to ensure that the team stayed on track is a Gantt chart. The Gantt chart allows all tasks both completed and upcoming to be shown in a timeline system where the team could always know whether or not the project is moving at the correct speed. The Gantt charts

used for each term of this project can be seen below in Fig. 3.1-3.3.4.

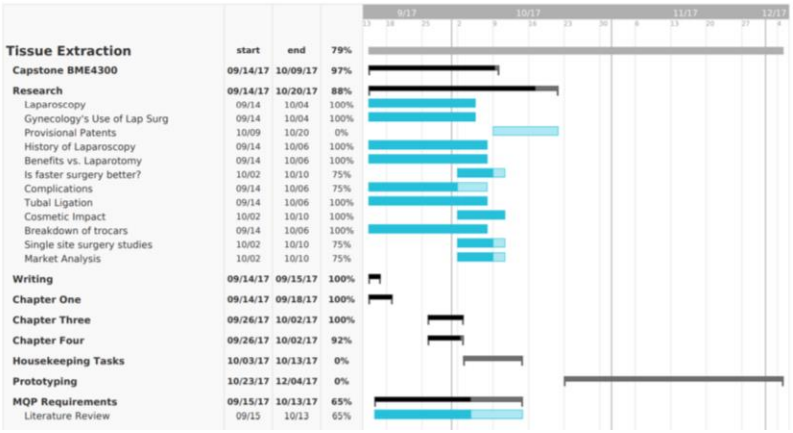

Figure 3.1. A Term Gantt Chart

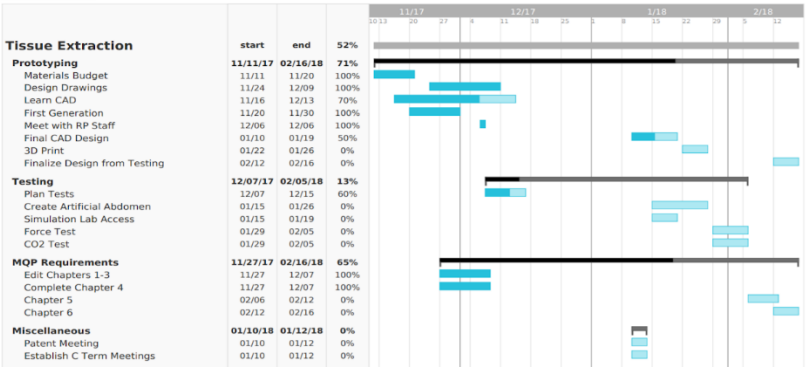

Figure 3.2. B Term Gantt Chart

Figure 3.3. C Term Gantt Chart

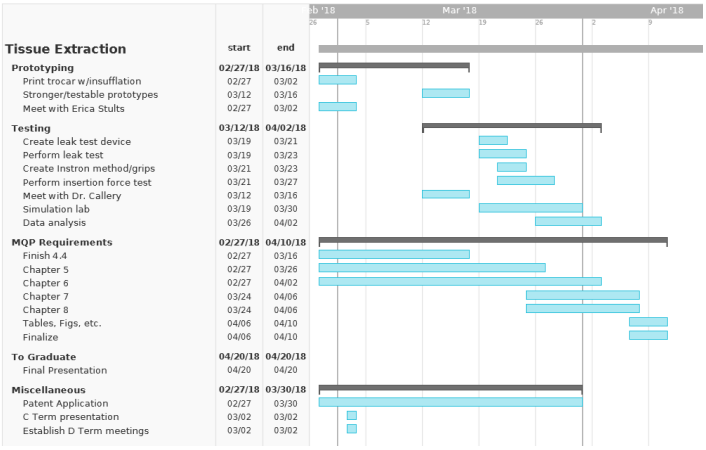

Figure 3.4. D Term Gantt Chart

The Gantt chart used by the team included both written and physical tasks as well as miscellaneous requirements.

3.5.1 Financial Statement

The financial aspect of the project had to be carefully considered. The team had a relatively small budget of $750.00 meaning that it was crucial that finances were handled well. The majority of the costs predicted for this project were the prototyping and testing costs. The prototyping stage required many materials and all machining costs. The team predicted that 60% of the team's budget or $450.00 will be allotted for the prototyping stage. The testing costs were predicted to include the materials needed to construct a simulation abdomen and any fees associated with using the UMMC laparoscopic simulation laboratory. The team predicted that 15% of the budget would be put towards gathering materials such as artificial skin for the testing stage, totaling approximately $113.00. The remainder of the budget, 25% or $180.00 will be reserved for backup funds and miscellaneous expenses. In order to manage these finances, the team created a detailed budget and adhere to it. However, the budget predictions were significantly higher than the actual cost of project completion. The team spent no more than $200.00 on materials, prototyping, and testing for this project allowing them to come in significantly under budget.

Chapter 4: Design Process

4.1 Needs Analysis

Since laparoscopic surgery is the most common type of surgery performed within the United States, there is a need for an improved trocar system that enables single site incision surgery while also eliminating unnecessary scarring. Approximately 15 million laparoscopic surgeries are performed annually worldwide [8]. Therefore, there is a demand for performing single site incision surgeries which have diminished intraoperative and postoperative risks [9]. In order to have the most effective device for surgeons performing laparoscopic gynecologic surgeries, it is essential that their specific needs were incorporated into the design of the device. The design must eliminate the bulky head of typical trocars and reduce unnecessary abdominal scarring while allowing for two trocars to fit into the umbilicus. The device must remain cost efficient and be within the same price range as current trocars on the market today.

The primary function of the design is the creation of a trocar system that makes placing two trocars in the umbilicus more feasible. In order for the trocar to be successful, it needed to meet the objectives requested and fit within the set constraints. The device needs to be usable for single site incision surgeries; having this capability will help reduce unnecessary abdominal scarring. By allowing two trocars to fit into the umbilicus at one time, there is no more need for the second trocar to be inserted into the abdomen. This means that the design needs to be contained within approximately 20mm, the diameter of the average umbilicus. This would eliminate any scars that would have occurred through abdominal entry outside of the umbilicus. To ensure the trocars will fit and diminish the risk of umbilical hernia, the diameter of each cannula must be within 3-5 mm.

The secondary functions the sponsor would like to have incorporated into the design of

the device are less important to functionality but would increase versatility. If possible, the trocar should have a port for direct insufflation that has the ability to release 4-6 L/min of CO2 into the abdomen at a pressure of 10-20 mmHg [37]. By reducing the size of the trocar head, the insertion process becomes more difficult. The insertion of the trocar into the abdomen should be as easy as when the trocar head stabilizes the hand during the entry process of the current design. The entry force should remain at approximately 71.4 N which will reduce the likelihood of damage to internal organs during the entry process [36]. The team used a pairwise comparison chart, as seen in Table 4.1, to prioritize the objectives for the design of a new trocar. If the objective in the column outweighs the objective in the row, the objective gets a value score of 1, if the objective in the column was not deemed as pressing as the objective in the row the function got a value score of 0, and if both objectives were even they receive a score of 0.5.

Table 4.1. Pairwise Comparison Chart of Design Objectives

Objectives	Eliminate Abdominal Scaring	Manual Insertion	Proper Insufflation	Minimal Trocar Interaction	Score
Eliminate Abdominal Scaring	X	1	1	0.5	2.5
Manual Insertion	0	X	1	0	1
Proper Insufflation	0	0	X	0.5	0.5
Minimal Trocar Interaction	0.5	1	0.5	X	2

Based on the results of Table 4.1, the most important objective of the project is to create a device that eliminates abdominal scarring followed by minimizing trocar interaction. The team used a second pairwise comparison chart to determine the most important functions of the device. This chart can be seen in Table 4.2 below and determined that the ability to maintain visibility was the most important function followed by the simultaneous use of multiple tools.

Table 4.2. Pairwise Comparison Chart of Design Functions

Function	Maintain Visibility	Promote Single Site Surgery	Accommodate Specimen	Simultaneous Use of Multiple Instruments	Score
Maintain Visibility	X	1	1	1	3
Promote Single Site Surgery	0	X	0	0	0
Accommodate Specimen	0	1	X	0	1
Simultaneous Use of Multiple Instruments	0	1	1	X	2

The technical constraints of the project determined the number of design objectives that could be incorporated into the design. The technical constraints include time, cost, and device requirements. The time frame of one academic year 2017-2018 was allotted to design and develop a working prototype of a trocar and develop an extensive MQP report. Within the time allotted, research about existing devices and procedures was conducted to help aid our design process and testing of the prototype was completed. The cost of the development of the design must remain within the budget provided by the BME department. Each team member received $250 giving the team a total of $750 to complete all research and development and create a working prototype. The limited budget could have impacted the prototyping process and cost of manufacturing of the final device. In order to determine if the device meets the requirements set by Dr. Callery, a simulation of the abdomen must be created to perform testing of trocar insertion as well as compatibility of the trocars with each other and the laparoscopic surgical instruments. To stay within the allotted budget, use of the simulation lab at the University of Massachusetts Medical School with supervision from Dr. Callery eliminated some costs of creating a simulation model. The device must meet industry standards set by International Organization for

Standardization and the Food and Drug Administration, it must be biocompatible and allow for safe and efficient surgical dissection.

4.2 Conceptual Designs

Conceptual designs were created based on research of current products on the market and improvements to current designs requested by the sponsor. The initial designs aimed to create a trocar feasible for single site incision laparoscopic gynecologic surgery. The designs of the trocars aimed to meet all the functions specified in the previous section and remain within design constraints.

4.2.1 Initial Designs for Single Site Incisions

Single site incision surgery is important to help reduce the amount of incisions needed to perform the procedure and to reduce postoperative complications. Single site incisions are more cosmetically pleasing because the total amount of scarring is reduced by confining the scarring to one area such as the umbilicus.

Trocar Pair with Complementary Heads

A conceptual design was to create a trocar pair with complementary heads that would reduce the size of the trocar head overall but not eliminate bulkiness. This design would create a trocar with a circle shaped head and a trocar with a crescent shaped head that would fit together. This design would allow the trocars to move independently from each other while also remaining at a 90-degree angle to the abdomen. These trocars could have insufflation ports on one or both trocars and the cannula of the trocars would be within the 3-5 mm range. This design has two cannulas which allows for multiple laparoscopic tools to be used at once but eliminates unwanted interaction between tools. Each tool has a separate cannula and entry point into the abdomen, this design can be seen in Fig. 4.1 below.

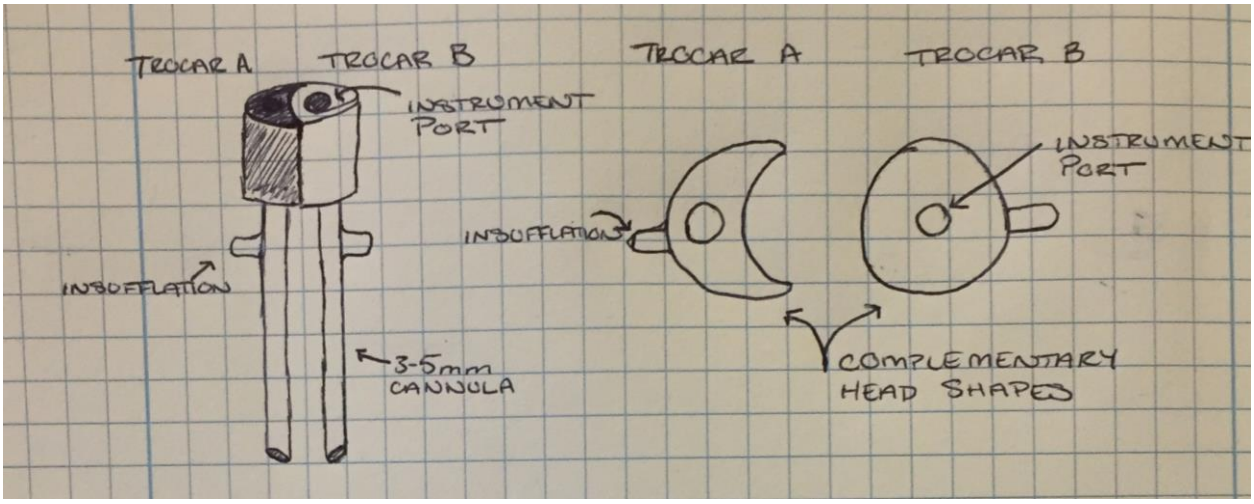

Figure 4.1. Design for a Trocar Pair with Complementary Heads

Clipped Cannulas

This conceptual design would reduce the size of a standard trocar head. A clip would be created to hold the two trocars together. An approximately 20 mm incision would be made in the umbilicus for the trocars to be inserted into. The trocars will not be able to move freely when clipped but could be unclipped to be moved freely. This would keep the devices at a 90-degree angle to the abdomen. Insufflation ports could be present on one or both trocars. This design has two cannulas which allows for multiple laparoscopic tools to be used at once and can be seen in Fig. 4.2.

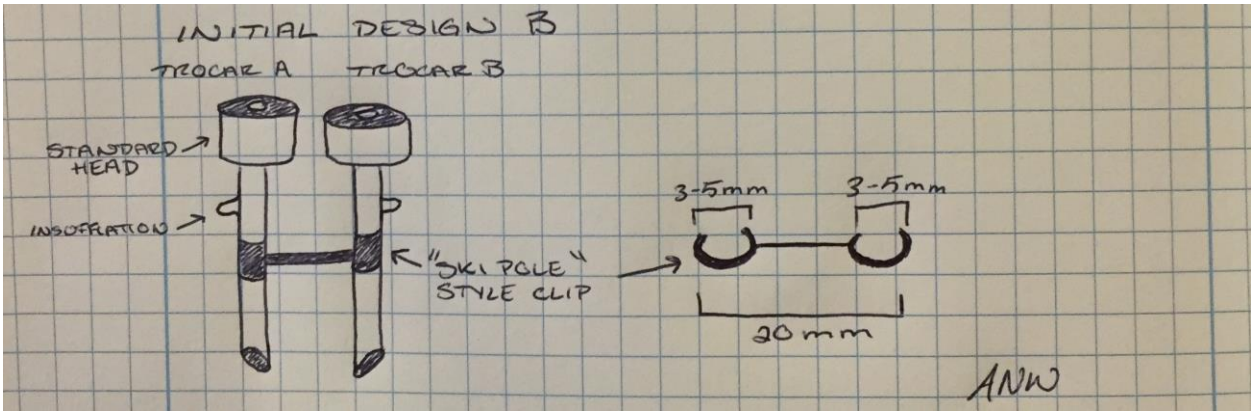

Figure 4.2. Trocar Design with Clipped Cannulas

These designs would be more efficient for single site incision surgeries and would reduce abdominal scarring by eliminating the second trocar from being inserted directly into the abdomen. Both trocars would be able to be inserted into the umbilicus. The cannulas would be within the specified 3-5 mm keeping the incision within the 20 mm area of the umbilicus. The system would also allow for direct insufflation. The head size would continue to keep insertion into the abdomen at 15 N. To test the feasibility of these designs, the devices were evaluated based on the design constraints. The designs were also reviewed by Dr. Ryan Callery, a gynecological surgeon at UMMS. Based on his review of the designs, changes were made to further develop and improve these designs leading to a final design.

4.2.2 Design Concept Prototyping

To begin the prototyping process and evaluate original design ideas, baseline prototypes were created out of everyday materials. Models were made from the design drawings outlined in Fig. 4.1 and Fig. 4.2, this included the complementary head trocar system as well as the clipped cannula trocar system. These models provided visualization of the design in 3D and made it easier to determine the changes that needed to be made before reaching a final design. The 3D models were made with basic crafting materials given to us by the Biomedical Engineering Department at WPI. The baseline prototypes were made with a hollow pen to represent a cannula and with Model Magic from Crayola, a hardening modeling dough, to represent both the complimentary heads and the clip that holds together the cannulas. The finished models can be seen in the figures below with Fig. 4.3 representing the original complimentary head design and Fig. 4.4 representing the clipped cannula design. From these models the team was able to realize that neither design satisfied each design objective and constraint and presented several issues such as limiting the surgeons range of motion. Therefore, from these feasibility studies it was

determined that more design ideas needed to be created and modeled before a final design was reached.

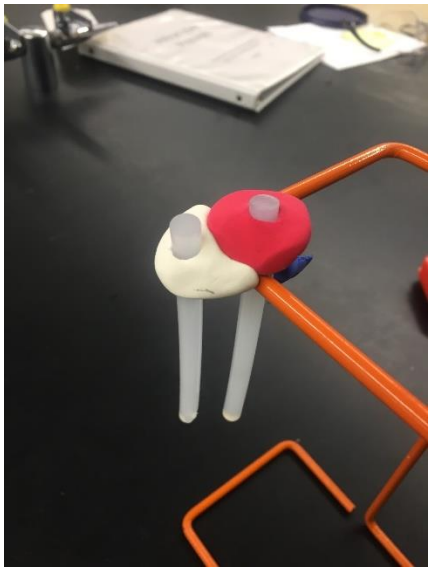

Figure 4.3. Baseline Prototype Complimentary Heads

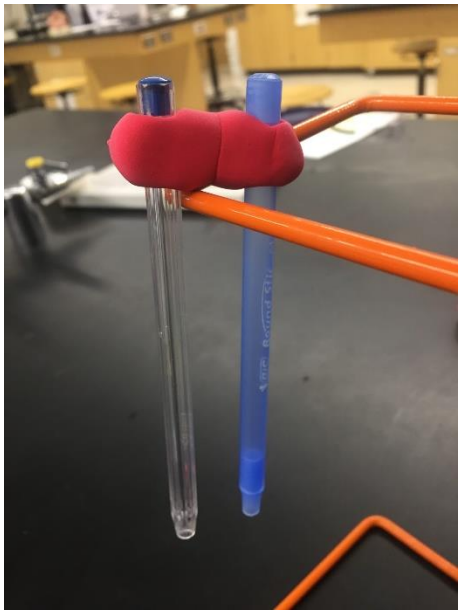

Figure 4.4. Baseline Prototype Clipped Cannulas

4.3 Alternative Designs

Multiport Trocar

The design of a multiport trocar was created as an alternative to the project's initial designs. The multiport trocar would have a single head enlarged to fit multiple ports for

instrument insertion. This design has only one cannula. The size of the cannula must be enlarged to fit multiple instruments at one time which would also increase the size of the incision. The cannula would have a direct insufflation port. This design could also have a multiport trocar with separate cannulas to help eliminate instrument interaction inside the body.

This design would be the last resort if the other designs are not feasible. This design does not meet many of the required design functions. It would be outside of the 3-5 mm cannula range which would increase the risk of umbilical hernia. The incision may be larger than 20 mm range leading to increased scarring. It may also require another insufflation technique if direct insufflation is not possible. If this design is required, it will be developed with CAD software and test in the simulation lab at UMMS.

4.4 Final Design Selection

After analyzing the design concept prototypes and having a comprehensive discussion with our sponsor Dr. Callery, the team determined that there were several flaws in the original two designs and they did not meet the specific design requirements that were necessary for the project to be successful. The complementary head trocar system (Fig. 4.1) was well liked because it was compatible for a small diameter such as the umbilicus and had a unique design. However, it had a limited range of motion due to the fact that the heads were always in contact, this is a detrimental feature that would impact surgical efficiency. Similarly, the clipped cannula design (Fig. 4.2) promoted individual incisions, yet it had many limitations that did not meet the set design specifications. The placement of the clip in this design limits insertion, would not reduce the size of the trocar head significantly, and prevents the cannulas from moving individually which limits the surgeons range of motion. The multiport trocar that was proposed as an alternate design also did not meet the design specifications because it would not allow for

two separate incisions and the use of two individual trocars.

Once the feedback from the original designs was collected it was applied to a modified design that encompassed more specifications and constraints. SolidWorks (Dassault Systemes, 2016, Version 24.4.0,0086) was the software chosen to complete the computer aided design for this idea and all subsequent modifications. The trocar pieces were designed and then assembled into one file to be rapid prototyped using the Dimension SST 1200es 3D printer which prints in polylactic acid (PLA) filament. The components of this trocar system design were two identical trocars, two caps for the cannulas, and two introducers for insertion into the abdomen. The cannula was designed to be 120-122 mm in length, have an inner diameter of 3mm, and an outer diameter of 5mm. The cap for the cannula was 15mm in diameter and with a 3mm hole cut in the center. The introducer was a length of 175mm, have a diameter of 3mm, and a pointed tip to make insertion easier. At Dr. Callery's request two versions of this design were created, one without any insufflation ports (Fig. 4.5) and one with insufflation capabilities (Fig. 4.6). The first round of printing the non-insufflation prototype did not go as smoothly as planned and the dimensions were significantly off from what was expected.

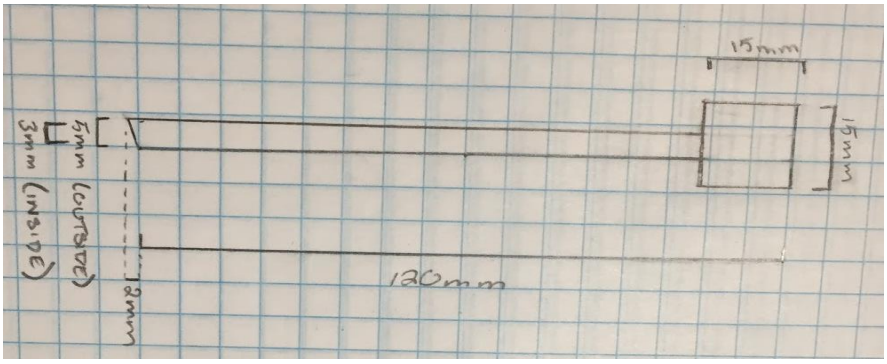

Figure 4.5. Cannula without Insufflation

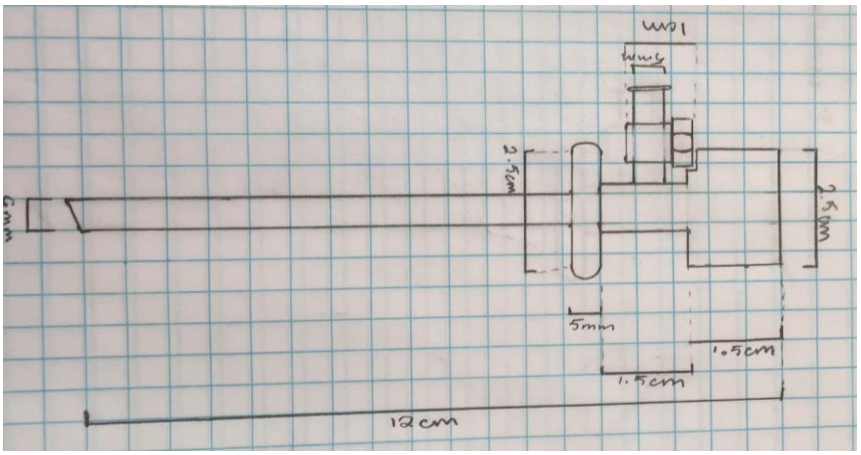

Figure 4.6. Cannula with Insufflation

As a result of failed, printing the team once again went back and discussed what went wrong and where improvements could be made. In order to print a prototype with the proper dimensions it was necessary to recreate more accurate SolidWorks files that can be seen in Fig. 4.7-4.13 below. These files then were printed in PLA resulting in a prototype that was much more accurate.

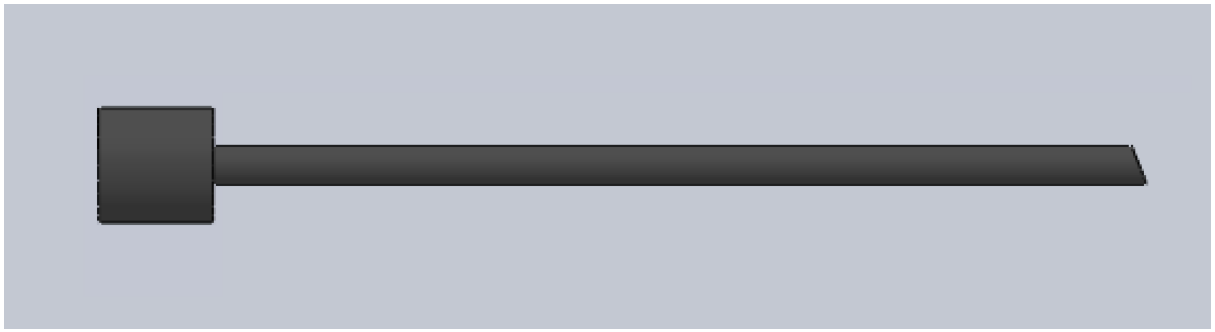
Figure 4.7. Trocar Side View.

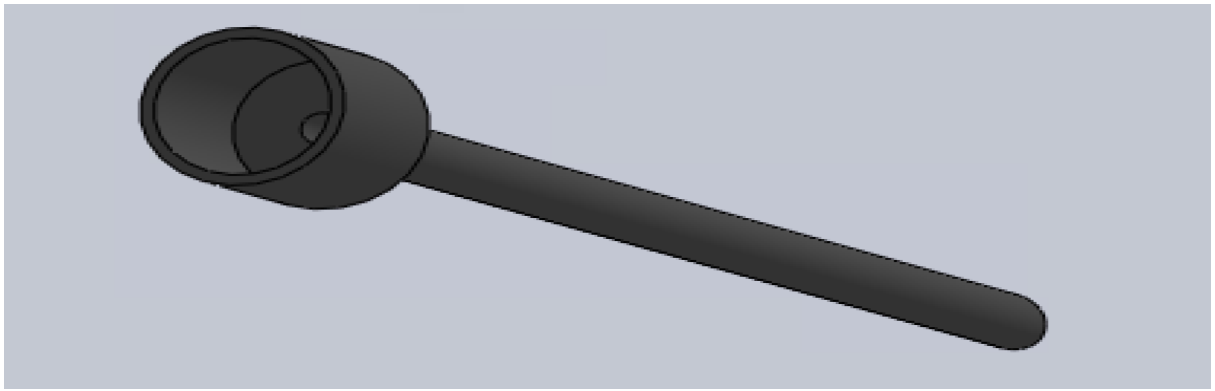
Figure 4.8. Trocar Angled View.

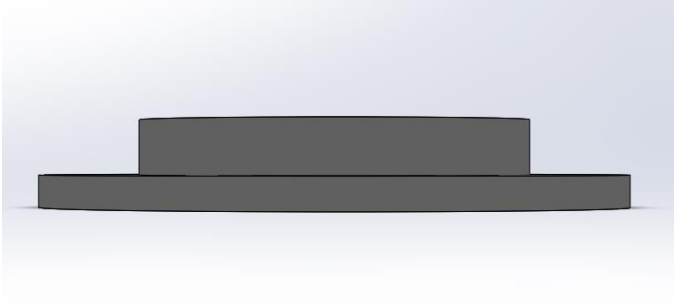

Figure 4.9. Cap Side View.

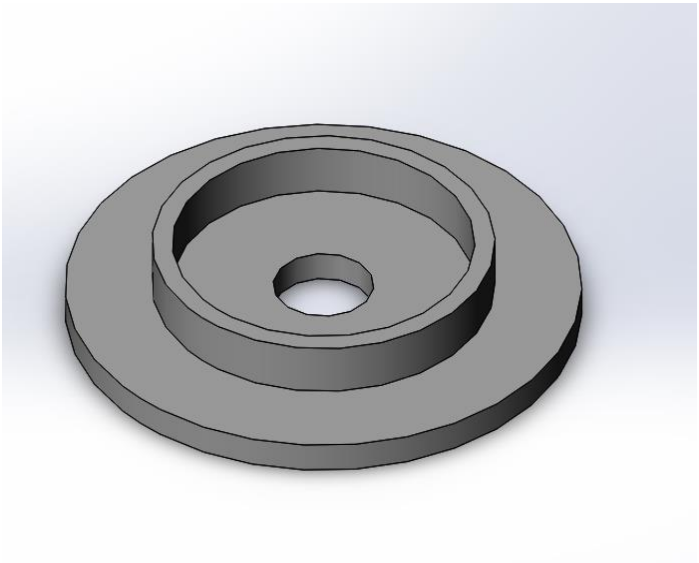

Figure 4.10. Cap Angled View.

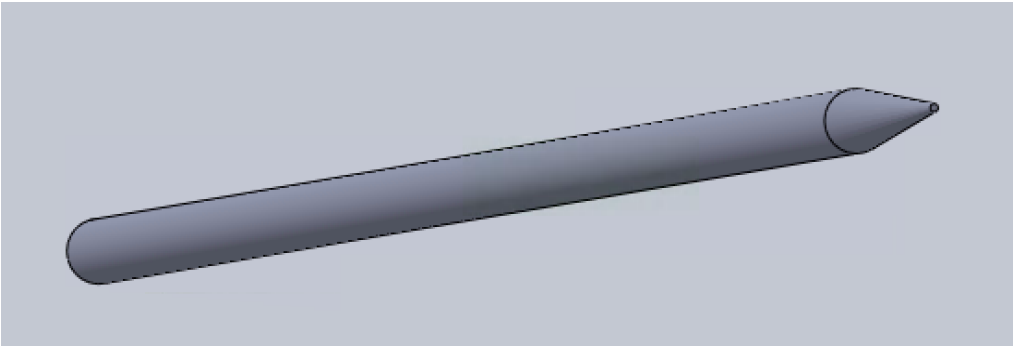

Figure 4.11. Introducer Angled View.

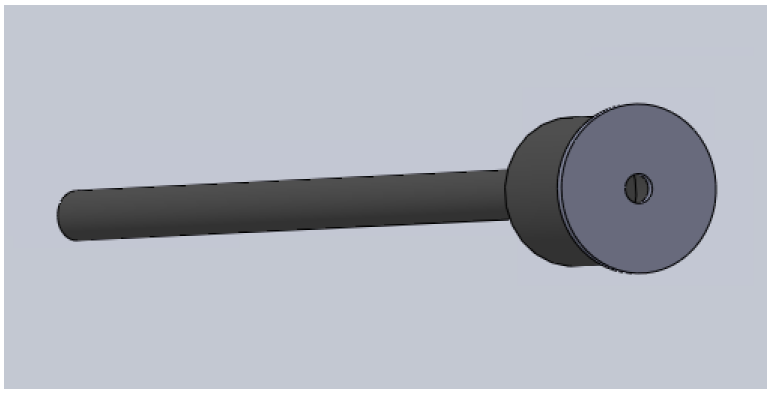

Figure 4.12. Trocar with Cap.

Figure 4.13. Trocar with Insufflation Port.

It was determined that the PLA filament was not a suitable material for prototyping and testing because the filament resulted in very weak trocars. Therefore, the team went through a material selection process as shown in Table 4.3 and ultimately selected the Tough resin from Formlabs for the final prototype due to its high MPa and ability to withstand the most force. However, this material was backordered for a period of time so the team chose to use the Rigid White resin as a backup.

Table 4.3. Material Selection

	Tough	Durable	Rigid White	Polylactic Acid
Flexural Modulus	1.6 GPa	0.82 GPa	3.7 GPa	4.0 GPa
Tensile Modulus	2.7 GPa	1.26 GPa	4.1 GPa	3.5 GPa
Elongation	24 %	49 %	5.6 %	6.0 %
Ultimate Tensile Strength	55.7 MPa	31.8 MPa	-	50 MPa
Force (7 mm)	2143.6 N	1223.8 N	-	1924.2 N
Force (5.5 mm)	1323.3 N	755.5 N	-	1187 N

The final prototypes were printed using the Formlabs Form2 printer and Tough resin as shown in Fig. 4.14. The final system consists of one 7 mm trocar with an insufflation port and one 5.5 mm trocar without a port, both trocars are 136 mm in length and have 15 mm diameter heads. Surgical tools will enter into the cannula through the hole in the cap of each trocar. Underneath the cap is a rubber seal with a small hole which allows the tools to enter while also keeping CO_2 from leaking outside of the abdomen during surgery. The caps are detachable to accommodate the removal of specimen. This final design does not completely eliminate the head portion of the trocar but it significantly reduces the size which allows the trocars to work in close proximity with a better range of motion. The head portion allows the surgeon to insert the trocar into the abdomen easily and completely eliminating it would not allow a place for the surgeon's hands to firmly grip the trocar for insertion. The final design of the system allows for the trocars to be inserted separately giving the surgeon freedom of where the devices need to be placed for each individual.

Figure 4.14. Final Tough Trocars.

Chapter 5: Design Verification

In order to ensure that the final design has met the necessary specifications and can perform required functions, testing was performed. One such test that was conducted was a leak test to assess the ability of the trocars to maintain insufflation, a crucial function. The force of insertion required to pierce the abdominal wall was also measured through testing to verify that the design would not be significantly more difficult to insert than existing trocars. The final test performed was a range of motion and general function test that was performed by Dr. Callery to confirm that the prototypes were beneficial towards the efficient completion of tubal ligations and other laparoscopic procedures. The results of these tests, as reported below will be further analyzed and compared to the results of existing trocars which underwent the same testing.

The leak test was conducted with both the Rigid White prototypes and the Tough prototypes along with two Stryker trocars that are currently on the market (referred to as Green Stryker and Purple Stryker). The trocars were tested for leakage, ability to maintain insufflation, and approximate sustained pressure. The data for this test can be seen in Table 5.1, with successful results from the Stryker and Tough trocars.

Table 5.1. Leak Test Results

	Green Stryker	Purple Stryker	Rigid White w/Port	Rigid White w/o Port	Tough w/Port	Tough w/o Port
Leakage (Y/N)	N	N	Y	Y	N	N
Maintained Insufflation (Y/N)	Y	Y	N	N	Y	Y
Approximate Pressure (mmHg)	17	17	5	5	16	18

The insertion force test was conducted with the Tough prototypes as well as the Stryker trocars. Two trials were run for each trocar and the data shown in Table 5.2 reflects the average of those trials. The data in the table can also be seen in Fig. 5.1, as a graph of force-displacement curves for each trial.

Table 5.2. Insertion Force Data

	Green Stryker	Purple Stryker	Tough w/Port	Tough w/o Port
Maximum Force (N)	52.6	67.4	30.9	54.7
Mean Force (N)	42.8	55.2	25.1	49.8
Standard Deviation (N)	14.0	17.2	8.2	6.9

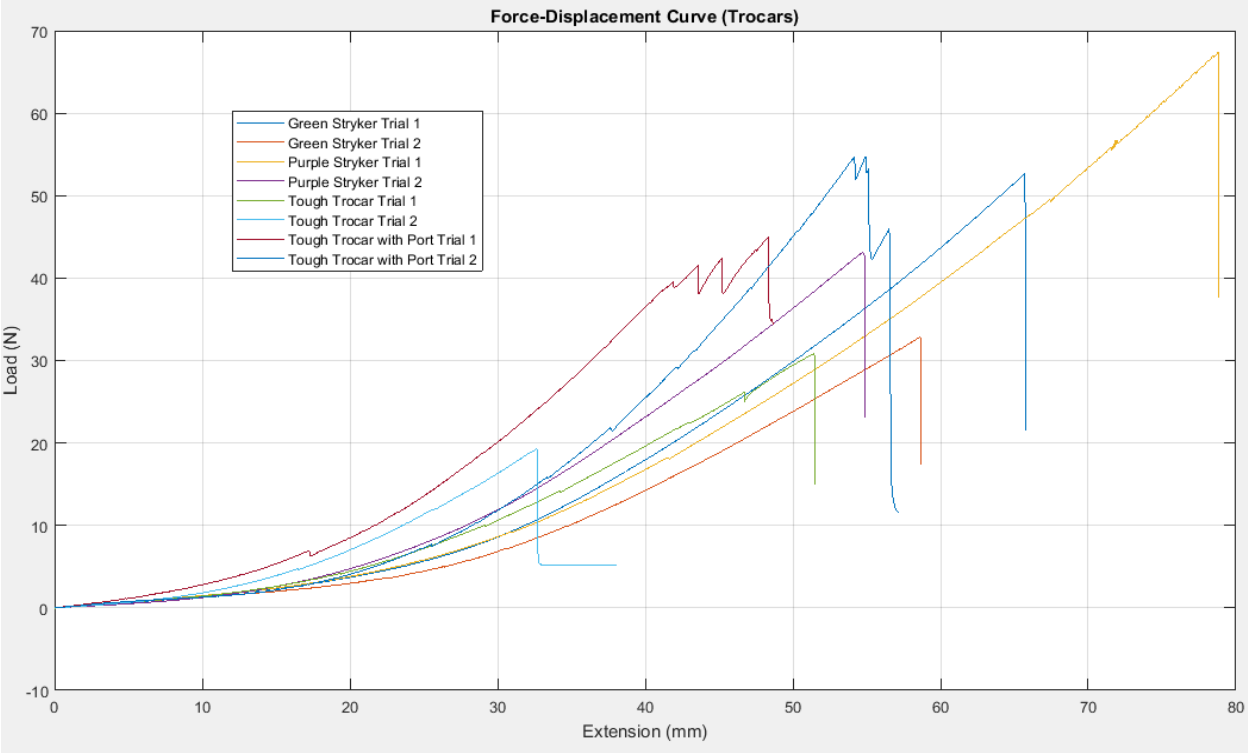

Figure 5.1. Force-Displacement Curves.

The final test conducted cannot be reported quantitatively because there were no numerical values involved. However, Dr. Callery was able to complete a laparoscopic training exercise, block moving, using the Tough prototypes in one site on the simulator. A photo of this process can be seen in Fig. 5.2 taken at the University of Massachusetts Medical School. Dr. Callery's feedback from this test revealed that the prototypes were more convenient to use in a

single site than the trocars he was previously using and that there was much less negative interaction between the heads of the prototypes.

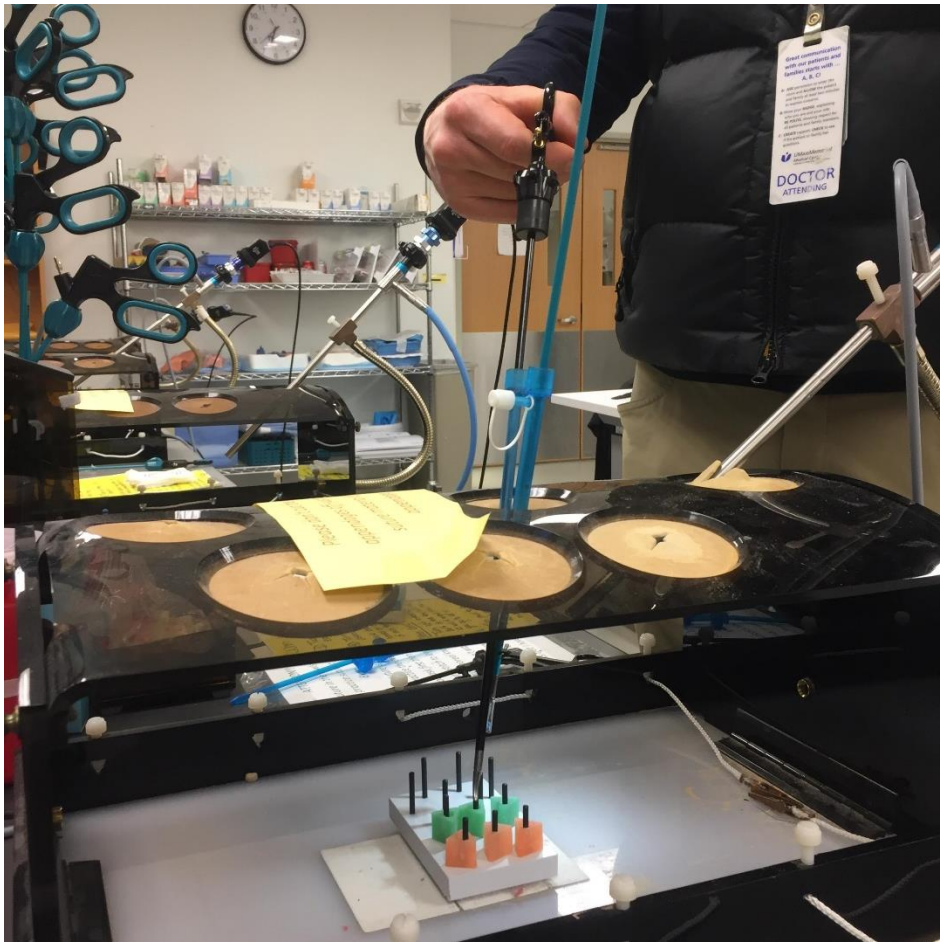

Figure 5.2. Simulation Testing.

Chapter 6: Final Design and Validation

Through testing the ability of the design to meet essential design objectives, functions, and specifications was evaluated. The leak test, insertion force test, and range of motion simulation test were all able to address different aspects of the design in relation to the goals of the trocar system (see Appendix B). The ability to maintain insufflation of 10-20mmHg [37]of CO_2 was judged by the leak test while the objective that the new trocars would be able to be manually inserted and required no more than 71.4N [36] of force was gauged by the insertion force test. The range of motion testing performed by Dr. Callery was able to evaluate several objectives and functions such as ensuring the device minimized trocar interaction, promoted single site surgery, and allowed for the simultaneous use of multiple instruments. The results for each test and the applicable specifications and design objectives that each result validates is summarized in Table 6.1 below.

Table 6.1. Results Summary

Objectives	Specification	Test Results (w/Port)	Test Results (w/o Port)	Objective Achieved (Y/N)
Proper Insufflation (mmHg)	10-20	Pressure: 16 No leakage Insufflation Maintained	Pressure: 18 No leakage Insufflation Maintained	Y
Manual Insertion (N)	<71.4	Max Force: 30.9 Mean: 25.1 StDev: 8.2	Max Force: 54.7 Mean: 49.8 StDev: 6.9	Y
Minimal Trocar Interaction	-	Confirmed with at UMMS with single site laparoscopic simulation		Y
Eliminate Abdominal Scarring	Contained in umbilicus	Reduced trocar head size (15 mm) One insufflation port per system		Y

The goal of the leak test, as previously stated, was to assess the ability of the trocars to maintain insufflation of the abdominal cavity. In order to make sure of this, a rather basic test was conducted. The Rigid White and Tough prototypes were tested separately against the standard Stryker trocars and each set of trocars was tested under the same conditions while their

ability to maintain insufflation and resist leakage was recorded.

The first test was conducted by creating a testing device as shown in Fig. 6.1 consisting of a plastic storage container which simulated the abdomen with a suture pad simulating the abdominal wall fixed to the top with epoxy. The storage container was fitted with two nozzles; one that was connected to tubing and a sphygmomanometer bulb and the other that was connected to the sphygmomanometer pressure gauge. The bulb was used to fill the artificial abdominal cavity with air while the pressure was read on the gauge. Using a scalpel, a small incision was made and the trocars were inserted.

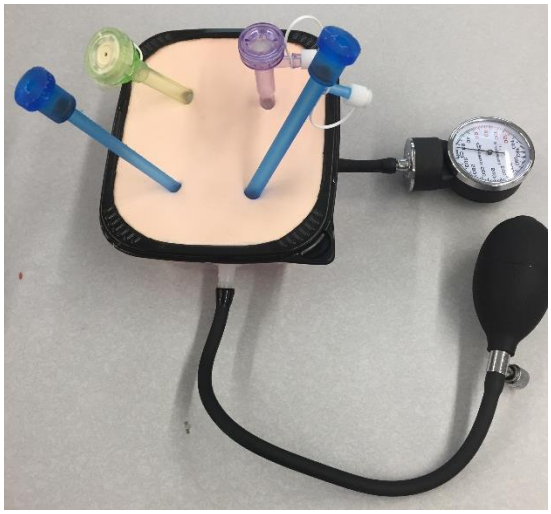

Figure 6.1. Leak Test Setup.

The results, as reported in Table 5.1, revealed that the Stryker trocars and Tough prototypes were successful in maintaining insufflation at the proper pressure while the Rigid White prototypes were not. This result is promising because the Tough prototypes were the latest iteration of the final design and the test proved that they are capable of maintaining insufflation between 10-20 mmHg and can be evenly compared with trocars that are currently on the market [37].

The insertion force test was conducted to measure the force required to insert a trocar into the abdominal cavity by puncturing the abdominal wall. The Tough prototypes and Stryker trocars were all tested on an Instron 5544 to record the force required for insertion and make accurate comparisons. To perform this test, a 3-point flexure test was setup using Bluehill 3 software (Illinois Tool Works Inc., Cat. 2450-100) to advance the trocar held by the top Instron grips towards a testing device at a rate of 4 mm/s [39]. The testing device was held by the bottom grips and consisted of a glass mason jar with 10 mm thick artificial skin sutured onto the metal collar of the jar. After each trial the pierced skin was discarded and a new piece was sutured onto the device. This test setup is shown in Fig. 6.2 and was repeated for two trials per trocar, a total of eight trials.

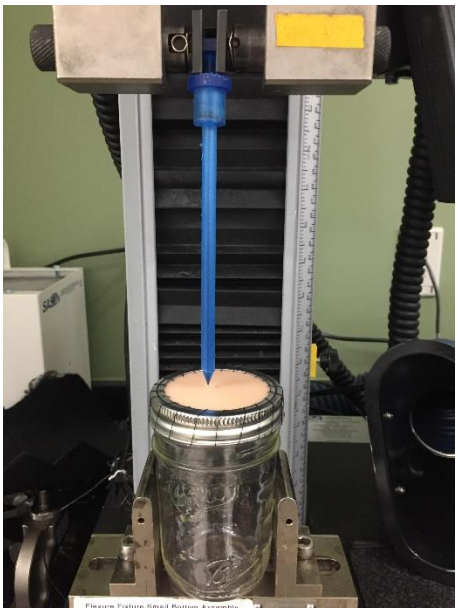

Figure 6.2. Insertion Force Test Setup.

The results for this test were also promising towards the success of the final prototypes. Using the Bluehills software that is associated with the Instron we were able to gather data on the maximum and mean force for the trials as well as the standard deviation. As seen in Table 5.2, each trocar tested within the acceptable range (under 71.4 N) with the prototypes having a lower

collective insertion force than the Stryker trocars [36]. The data was also analyzed using Matlab in order to generate the graph in Fig. 5.1 (see Appendix A). This graph displays the force-displacement curve for each trocar during both trials, providing a visual representation of the ability of our prototypes to be manually inserted with less force than standard industry trocars.

The final test conducted was the range of motion simulation test which was performed by Dr. Callery at the UMMS. The goal of this test was to use laparoscopic simulation models to qualitatively assess the ability of the trocars to operate within an acceptable range of motion for gynecologic procedures and to accommodate laparoscopic instruments. In order to conduct this test, the team met Dr. Callery at the UMMS surgical simulation lab where he set up a simulation device as shown in Fig. 5.2. The team recorded Dr. Callery as he inserted the trocars into a single port on the device and proceeded to conduct a simple block rearrangement test that is standard for laparoscopic training. After the test was complete the team asked Dr. Callery to reflect on the experience and compare it to the trocars that he uses in surgical procedures.

Though there are no numerical values for this test, it was a crucial aspect of the project and solidified the prototypes' success. Dr. Callery was able to easily rearrange the blocks in the simulation device and reported that he was very pleased with the trocar design. In his expert opinion the trocars did not have as much negative interaction as the trocars he typically uses confirming the success of one objective and he was also able to manipulate multiple graspers at the same time, another objective. The overall response that Dr. Callery gave was that the trocars did indeed ease his ability to complete a single site procedure and fulfilled the need he originally sought assistance with.

In order to create a more quantitative functionality test it would be beneficial for future iterations of this project to be simulated by multiple surgeons from several different specialties.

A standardized survey could be created and given to each physician as they manipulate the trocars in their own simulation patterns. The data from these surveys could then be compiled and analyzed so the issues that are most prevalent can be addressed and the benefits of the design can be highlighted.

The results of each test provides the conclusion that the final design prototypes are successful in accomplishing each objective. However, these results reflect the beginning stages of development and the device would need to be developed much further before being introduced to market. For example, the current prototypes do not meet the current technical standards set forth by the International Organization for Standardization (ISO) in terms of biocompatibility and sterilization as previously mentioned. Also, there are many factors besides mechanical success that must be incorporated into the design process as described in sections 6.1-6.8.

6.1 Trocar Economics

Laparoscopic surgery is a big business which costs the patient as well as the hospital. The average cost for the use of disposable trocars during a laparoscopic cholecystectomy is $2000 compared to $230 for reusable trocars which includes sterilization costs [35]. The sterilization costs are included in the treatment and processing of the other instruments needed in the operative set. The average cost of a disposable 10 mm trocar is $70 and $45 for a 5 mm trocar. The average cost for a reusable 10 mm trocar is $550 and $450 for a 5 mm trocar. The ability of continuous use of the reusable trocar significantly reduces costs for surgery whereas, a set price for every disposable trocar is paid during surgery and every new trocar requires the same cost. However, the disposable trocars have an advantage of reducing the risk of exposure to bacteria and the chance for a problem with sterilization which can be worth the additional expense.

Manufacturing expenses would include the cost of the design itself, specifically the materials. Currently, the cost to produce these prototypes is $8.80 but this does not reflect a biocompatible material. Since the material chosen for this device must be biocompatible, the price of the material would increase. If the trocars were 3D printed with an Objet 260 Connex machine in MED610 biocompatible material the cost of printing would include be approximately $190.00 for a single set [38]. The initial prototype was 3D printed to scale but in order to meet the demand and amount of trocars that would need to be produced, a manufacturing process would need to be created for efficiency. The machines to complete the manufacturing as well as people to work would need to be included in the price of the trocar. Ideally, the cost of the trocar with improvements and manufacturing should be around the total cost of current trocars on the market. Otherwise, the new product would struggle to succeed in industry.

6.2 Environmental Impact

A single use design would create more waste and potentially negatively impact the environment. However, many single use surgical devices can be reclaimed and recycled into new products, reducing the amount of waste. A reusable device would reduce the amount of waste that comes out of each surgery but requires sterilization which has environmental impact such as water waste and the use of chemicals. The choice between disposable versus reusable each propose their own benefits but the reusable device would be the best for the environment. The material selected for this device must be biocompatible. This device will be used in the body during surgical procedures and biocompatibility is essential to decrease the potentially risks for complications after surgery. The material used may not necessarily be recyclable due to the necessary specifications it must meet. This would pose as a higher risk for the environment if the device was disposable because more waste would be thrown away per surgery.

6.3 Societal Influence

The introduction of a dual trocar system will have a positive societal impact. This minimally invasive system will reduce the number of potential patients who are avoiding medical care for fear of invasive procedures or complications. Surgeons will be able to explain the procedure as a simple entrance into the abdominal cavity through a single spot on the abdomen, the umbilicus, rather than multiple locations. While this product will have a positive impact on potential patients, it will most likely not have any effect on the general public outside of healthcare.

6.4 Political Ramifications

The introduction of the dual trocar system into the global market will have a major impact on international minimally invasive surgery. Public policies that can interfere with the streamline of medical devices can include federal regulation, product liability statutes, and government funding [40]. International societies that promote training of laparoscopic techniques would need to revise the standards set to incorporate the trocar system use. As well, local political and medical systems would need to be investigated to allow for the importation and implementation of the trocar system on international ground.

6.5 Ethical Concerns

There are no ethical concerns if this device were to advance to market. This product will benefit patients by facilitating life-saving procedures, easing recovery, and improving body image. Although tubal ligation is typically an elective sterilization procedure, it can also be used to remove ectopic pregnancies and other potentially life threatening medical conditions. The creation of this trocar system makes access to the abdominal space and fallopian tubes less invasive and provides a reliable medical device which reduces the risk of complications during routine and life-saving laparoscopies. In addition to facilitating procedures, the trocar system also results in a lack of scarring and easy recovery that benefits both patients and surgeons. If use

of this system is expanded past tubal ligation, both men and women will be able to benefit from single site procedures that utilize this device.

6.6 Health and Safety Issues

With medical devices it is crucial that new products ensure the health and safety of all who use them. The dual trocar system maintains these standards for both the surgeons and patients. This product facilitates safe laparoscopic technique and has been tested to verify that it meets the standards of a proper surgical device. The trocars also enable the safety of patients by reducing the risk of hernia, eliminating the need for large incisions, and minimizing the possibility of infection. The incisions required for this system are small enough that the abdominal wall is not significantly weakened which is a cause of postoperative hernias. With large incisions there is also a greater risk of infection due to the greater area of open tissue and longer healing time, the incisions required for these trocars will close quickly and easily. This dual trocar system is capable of making laparoscopic surgery as safe as possible both during the procedure itself and the healing process later.

6.7 Manufacturability

Additive manufacturing (3D printing) has become important in the manufacture of biomedical implants. One of the advantages of 3D printing is the relatively low-cost processes for producing objects. Another advantage is the flexibility provided during the manufacturing and designing process. Basically, if a 3D design needs to be fixed or modified, programming facilitates changes, prior to printing. Computer-aided-design (CAD) is used in SolidWorks, for the purpose of solid modeling. The use of CAD, facilitates the production of prototype designs.

The team's trocar can be reproduced easily with CAD files because the program allows for 3D visualization and customization of the design.

One method trocars are mass produced includes, Weldlogic Services (WSI Inc.) use of high precision laser welding and CNC grinding. Our device, would not likely be subjected to this process due to the limitations of the design material. Another method for mass production of trocars is injection modeling. It is cost-effective and efficient, and produces low scrap rates. However, 3D printing of the trocar would result in an even lower scrap rate. The disadvantages of this method include tooling costs, and time requirement. Moreover, once a tool (the finalized prototype) is created, it is very difficult to alter the design prior to mass production.

6.8 Sustainability

The production of a trocar through 3D printing would lead to an overall decrease in waste and energy use. 3D printers are eco-friendlier, because they enable the use of biodegradable or recyclable materials. Similarly, the heavy reliance on electrical power eliminates fossil fuel. Also, if 3D printers could eventually be run on solar power, there would be the advantage of using an inexhaustible source of energy.

Chapter 7: Discussion

This project set out to develop a surgical device that provided an improved approach to single site laparoscopic abdominal surgery. As discussed earlier in this report, single site surgery is beneficial to both patient and surgeon for many reasons including faster healing time, aesthetically pleasing results, reduced operating room time and cost, and minimized complication risk. However, current laparoscopic trocars are not designed specifically for this type of procedure but are used anyway, making proper procedure and instrument manipulation more difficult than necessary. The compact system of trocars developed during the course of this project was created with a focus on single site procedures and a specific list of goals and objectives.

The objectives for this project were paired with respective specifications and functions and throughout development the design was manipulated to ensure that all objectives were met at the proper specification given to the team by Dr. Callery or discovered in previous literature. These goals were ordered as follows; eliminate abdominal scarring to promote single site laparoscopy amongst patients, minimize trocar interaction to allow for simultaneous instrument use and proper surgical range of motion, allow for manual insertion, accommodate specimen, and maintain insufflation to preserve visibility. There were certain standards that several goal had to meet in order to be considered a beneficial device. These included insufflation being maintained between 10-20 mmHg [37], insertion force having an upper limit of 71.4 N [36], the entire system fitting within 20 mm, and a minimum cannula diameter of 5 mm. in order to confirm that the design was capable of meeting each goal at the proper standard a series of three tests were conducted as described in chapters 5 and 6.

The leak test was performed to ensure that the prototypes would be capable of

maintaining insufflation at the proper pressure in the abdominal cavity. From this test the prototypes were deemed to be leak proof and held pressure at 16-18 mmHg. The results of this test confirm that the new design can maintain gas in the abdominal cavity within the specified region which would allow the surgeons to maintain visibility inside the field as well as provide protection and space for the organs. It was assumed that the artificial abdomen constructed for this procedure was not perfectly leak proof and if tested again another device would have to be constructed. However, the evidence proves that the new design, with only one insufflation port per pair, is just as capable of maintaining insufflation as existing trocars used in current laparoscopy.

The insertion force test was also designed to confirm certain capabilities of the trocars, namely, if manual insertion is possible with a force under 71.4 N [36]. The testing was kept consistent with an Instron 5544 and the same coded method for each test allowing data to be accurately compared (Table 5.2). The results of the 3-point flexure test showed that each trocar was able to pierce the silicone abdominal wall with a force below the accepted standard indicating that manual insertion would be possible. However, there were several assumptions made to obtain this data with the main assumption being that the silicone suture pad used was comparable to human tissue. The suture pad was 10 mm thick and had three layers, each with different properties to mimic different layers of tissue, the pads are used for medical training and human tissue as not available so this substitute was deemed sufficient. Also, the trocars were inserted with axially downward force only, this was a limitation of the Instron which is a uniaxial machine. However, manual insertion of trocars typically involves twisting while pushing into the abdominal cavity so if the mechanical testing power was available to also include torsion it is possible that the insertion force test values would be altered.

The final test was only performed once the prototypes were proven to meet the previous mechanical testing objectives, this was a simulation test performed by Dr. Callery at UMMS. This test was crucial in identifying the strengths and weaknesses of the design and allowed the team to brainstorm future work for this project. Dr. Callery manipulated the trocars together (Fig. 5.2) while performing simulated laparoscopic tasks and then verbally evaluated the performance of the trocar system. As discussed in chapters 5 and 6 the results of this test were extremely positive and provided important validation for the trocar system design. Although the test was conducted by a practicing surgeon, there are still several aspects of the test that could be further improved upon. First, the trocars should be tested in a more accurate model, the simulation device is meant to train medical students in traditional laparoscopic technique and is not designed exclusively to test single site procedures. Also, only one test was conducted with a fairly simple laparoscopic task rather than the complex manipulation that occurs during actual surgeries. Despite these limitations, the data gathered solidified the justification for this improved trocar system specifically for single site laparoscopy.

The process and overall result of this project were very promising for the future of single site specific trocars. These first design tests validated that advancing with a tandem system of trocars is both revolutionary and impactful for both patient and surgeon. There are currently no available trocars that are designed to work in tandem in the umbilicus and the head diameter of these trocars are significantly reduced from the standard trocars that are currently used in many laparoscopic surgical fields. Although the three tests performed in this project had their limitations there were no serious limitations that were detrimental to the experimental results reported here. Each test was designed to test a specific function and if the project were to continue, further tests and modifications would need to be conducted.

Chapter 8: Conclusions

Over the span of nine months this project was able to evolve from a need brought forth by a gynecological surgeon, to a physical design that fulfilled that need. Throughout the course of this project there were several hindrances but the final product (Fig. 4.14) was able to be successfully tested and verified.

As with any project, there are always problems that can arise and throw the timeline and design off-track. During this project the main issue the team faced was the extended backorder of the Tough resin that the final prototype was to be printed in. The team was able to work around this problem by printing in the Rigid White material and working on other aspects of the project while waiting for the resin to become available. Another challenge of the project was that computer aided design programming had to be self-taught in order to create models and files for rapid prototyping. Thankfully, the use of Gantt charts and time management enabled the team to accomplish their goals and create a working trocar system.

This system of trocars can be considered successful by the results of each test that was conducted. The leak test, insertion force test, and range of motion simulation produced useful data that confirmed the design's ability to fulfill the design objectives, functions, and specifications. The trocars can also be deemed competitive because they consist of a relatively simple structure that can perform equally well, if not better, than current market trocars.

The creation of this compact system of trocars has the potential to revolutionized laparoscopy and minimally invasive surgery. This device will appeal to surgeons, patients, medical device companies, and insurance companies if it is further developed and continues to market. The ability of this device to easily pierce the abdominal wall and provide controlled, contained movement within the umbilicus without negative interaction during procedures will

appeal to surgeons in many specialties. Similarly, patients will prefer the results of single site procedures with this product because it produces minimal abdominal scarring and faster healing times. A diminished risk of complications and simple yet efficient design will appeal to medical device and insurance companies who can market and cover the trocars. However, although the prototypes have been successfully tested there are several more steps to take before the trocar system would be ready for market.

The team has several recommendations for future work in order to advance the prototypes to a marketable stage. The most important recommendation is that the design be produced and tested in a biocompatible material. In order for the device to meet the necessary ISO standards and be used in humans it must be biocompatible. Due to time and technology restraints the current prototypes are not biocompatible. A proper material would have to be biocompatible, non-degradable, cheap to manufacture, and capable of being sterilized. The second recommendation is that future researchers would need to determine whether the design is better utilized as a system of reusable instruments or as a single use device. If determined that a reusable device is more beneficial than the trocars will also need to be autoclavable. Another recommendation is that insertion force testing should also include torsion rather than uniaxial motion in order to truly mimic the surgical insertion. The final recommendation the team has is to conduct a client interview with multiple surgeons in different fields to gather interest and feedback on the current design.

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Appendix A: Matlab Code

```
%% Trocar Insertion Force Testing
clc; clear all; close all;
%% Green Stryker Trial 1
% upload the data and assign to a variable name
fileName1= 'GreenStriker1.csv';
% create a matrix of the data
data1= readMyData(fileName1);
% define all variables
t1= data1(:,1); % define variable for time
d1= data1(:,2); % define variable for extension
F1= data1(:,3); % define variable for force/load

% plot the raw data
figure
plot (d1, F1)
xlabel ('Extension (mm)')
ylabel ('Load (N)')
title ('Force-Displacement Curve (GreenStryker Trial 1)')
grid
hold on
% find the maximum force at failure
[maxForce1, posMaxForce1]= max(F1);
% mark the maximum force on the graph
plot(d1(posMaxForce1),maxForce1, 'or'); % 'or' signifies circle in red

%% Green Stryker Trial 2
% upload the data and assign to a variable name
fileName2= 'GreenStriker2.csv';
% create a matrix of the data
data2= readMyData(fileName2);
% define all variables
t2= data2(:,1); % define variable for time
d2= data2(:,2); % define variable for extension
F2= data2(:,3); % define variable for force/load

% plot the raw data
figure
plot (d2, F2)
xlabel ('Extension (mm)')
ylabel ('Load (N)')
title ('Force-Displacement Curve (GreenStryker Trial 2)')
grid
hold on
% find the maximum force at failure
[maxForce2, posMaxForce2]= max(F2);
% mark the maximum force on the graph
plot(d2(posMaxForce2),maxForce2, 'or'); % 'or' signifies circle in red
%% Purple Trocar Trial 1
% upload the data and assign to a variable name
fileName3= 'PurpleTrocar1.csv';
% create a matrix of the data
data3= readMyData(fileName3);
% define all variables
```

```
t3= data3(:,1); % define variable for time
d3= data3(:,2); % define variable for extension
F3= data3(:,3); % define variable for force/load

% plot the raw data
figure
plot (d3, F3)
xlabel ('Extension (mm)')
ylabel ('Load (N)')
title ('Force-Displacement Curve (PurpleTrocar Trial 1)')
grid
hold on
% find the maximum force at failure
[maxForce3, posMaxForce3]= max(F3);
% mark the maximum force on the graph
plot(d3(posMaxForce3),maxForce3, 'or'); % 'or' signifies circle in red
%% Purple Trocar Trial 2
% upload the data and assign to a variable name
fileName4= 'PurpleTrocar2.csv';
% create a matrix of the data
data4= readMyData(fileName4);
% define all variables
t4= data4(:,1); % define variable for time
d4= data4(:,2); % define variable for extension
F4= data4(:,3); % define variable for force/load

% plot the raw data
figure
plot (d4, F4)
xlabel ('Extension (mm)')
ylabel ('Load (N)')
title ('Force-Displacement Curve (Purple Trocar Trial 2)')
grid
hold on
% find the maximum force at failure
[maxForce4, posMaxForce4]= max(F4);
% mark the maximum force on the graph
plot(d4(posMaxForce4),maxForce4, 'or'); % 'or' signifies circle in red
%% Tough Trocar Trial 1
% upload the data and assign to a variable name
fileName5= 'ToughTrocar1.csv';
% create a matrix of the data
data5= readMyData(fileName5);
% define all variables
t5= data5(:,1); % define variable for time
d5= data5(:,2); % define variable for extension
F5= data5(:,3); % define variable for force/load

% plot the raw data
figure
plot (d5, F5)
xlabel ('Extension (mm)')
ylabel ('Load (N)')
title ('Force-Displacement Curve (Tough Trocar Trial 1)')
grid
hold on
```

```
% find the maximum force at failure
[maxForce5, posMaxForce5]= max(F5);
% mark the maximum force on the graph
plot(d5(posMaxForce5),maxForce5, 'or'); % 'or' signifies circle in red
%% Tough Trocar No Port Trial 2
% upload the data and assign to a variable name
fileName6= 'ToughTrocar2.csv';
% create a matrix of the data
data6= readMyData(fileName6);
% define all variables
t6= data6(:,1); % define variable for time
d6= data6(:,2); % define variable for extension
F6= data6(:,3); % define variable for force/load

% plot the raw data
figure
plot (d6, F6)
xlabel ('Extension (mm)')
ylabel ('Load (N)')
title ('Force-Displacement Curve (Tough Trocar Trial 2)')
grid
hold on
% find the maximum force at failure
[maxForce6, posMaxForce6]= max(F6);
% mark the maximum force on the graph
plot(d6(posMaxForce6),maxForce6, 'or'); % 'or' signifies circle in red
%% Tough Trocar Port Trial 1
% upload the data and assign to a variable name
fileName7='ToughTrocarPort1.csv';
% create a matrix of the data
data7= readMyData(fileName7);
% define all variables
t7= data7(:,1); % define variable for time
d7= data7(:,2); % define variable for extension
F7= data7(:,3); % define variable for force/load

% plot the raw data
figure
plot (d7, F7)
xlabel ('Extension (mm)')
ylabel ('Load (N)')
title ('Force-Displacement Curve (Tough Trocar with Port Trial 1)')
grid
hold on
% find the maximum force at failure
[maxForce7, posMaxForce7]= max(F7);
% mark the maximum force on the graph
plot(d7(posMaxForce7),maxForce7, 'or'); % 'or' signifies circle in red
%% Tough Trocar Port Trial 2
% upload the data and assign to a variable name
fileName8='ToughTrocarPort2.csv';
% create a matrix of the data
data8= readMyData(fileName8);
% define all variables
```

```
t8= data8(:,1); % define variable for time
d8= data8(:,2); % define variable for extension
F8= data8(:,3); % define variable for force/load

% plot the raw data
figure
plot (d8, F8)
xlabel ('Extension (mm)')
ylabel ('Load (N)')
title ('Force-Displacement Curve (Tough Trocar with Port Trial 2)')
grid
hold on
% find the maximum force at failure
[maxForce8, posMaxForce8]= max(F8);
% mark the maximum force on the graph
plot(d8(posMaxForce8),maxForce8, 'or'); % 'or' signifies circle in red


%% All Trocars
% plot the F-d Curves for all the trocar graphs
figure
plot(d1, F1)
xlabel ('Extension (mm)')
ylabel ('Load (N)')
title ('Force-Displacement Curve (Trocars)')
grid
hold on
plot(d2, F2)
hold on
plot(d3, F3)
hold on
plot(d4, F4)
hold on
plot(d5, F5)
hold on
plot(d6, F6)
hold on
plot(d7, F7)
hold on
plot(d8,F8)
legend('Green Stryker Trial 1', 'Green Stryker Trial 2', 'Purple Stryker Trial 1','Purple Stryker Trial 2', 'Tough Trocar
Trial 1', 'Tough Trocar Trial 2', 'Tough Trocar with Port Trial 1', 'Tough Trocar with Port Trial 2')

%% Data
ForceValues= [max(F1), max(F2), max(F3), max(F4), max(F5), max(F6), max(F7), max(F8)]
```

Appendix B: Validation Protocols

Range of Motion Test

Goal: To assess the ability of the trocars to operate within an acceptable range of motion for gynecologic procedures with minimal interaction.

Independent Variable: The Tough prototypes were tested.

Dependent Variable: The ability of each trocar to be used efficiently in a simulation model.

Control: The procedure and testing device was the same for each trial by a board certified surgeon.

Factors to Consider:

- Simulation models are accurate but they are not a human body which may impact results
- The experimental trocars were 3D printed which may not have the same level of integrity as mass produced trocars

Procedure:

The prototypes were tested in the University of Massachusetts Medical School by Dr. Ryan Callery. The prototypes were inserted into an artificial abdomen in a single incision to determine the interaction and range of motion of the prototypes. Surgical instruments were introduced into the artificial abdomen through the trocars. Block transfers were completed by Dr. Callery to simulate laparoscopic procedures. Both trocars were tested in the umbilical space to see if the objectives have been achieved.

Passing Test: The test was deemed successful if a block transfer could be easily completed by a board certified surgeon to imitate laparoscopy in a single site using our compact trocar system. Full range of motion manipulation and minimal trocar interaction were also required. The test was validated by the surgeon's approval and a video of the procedure was taken as proof of success.

Leak Test

Goal: To assess the ability of the trocars to maintain insufflation of the abdominal cavity.

Independent Variable: The prototypes (Rigid White and Tough) and the Stryker trocars (green and purple) were tested

Dependent Variable: The ability of each trocar to maintain insufflation and resist leakage.

Control: The procedure and testing device were the same for each trial.

Factors to Consider:

- Human abdominal wall thickness (AWT) ranges from 10mm-45mm
- The suture pad is a close comparison to human tissue but as with any artificial substance it is not 100% as accurate.
- The abdominal cavity is larger/more irregular than the storage container which could impact internal pressure

Procedure:

The testing device used for this test was a plastic storage container with a suture pad fixed to the top and sealed with epoxy. The storage container was fitted with a sphygmomanometer bulb that insufflated the storage container and a pressure gauge to determine the pressure. Four incisions were made in the top of the suture pad and the trocars were inserted. The bulb was pumped at a constant rate to mimic the flow of carbon dioxide inside the abdominal cavity. Readings from the pressure gauge were taken for each trocar to determine the ability of the trocar to maintain a pressure of 10-20 mmHg indicated in prior research as the pressure needed to maintain insufflation [37].

Passing Test:

The test was deemed successful if the pressure gauge remained between 10-20 mmHg for the duration of the test as the sphygmomanometer bulb was pumped to simulated continual flow of carbon dioxide into the abdomen.

Insertion Force

Goal: To measure the force required to insert a trocar into the abdominal cavity by puncturing the abdominal wall.

Independent Variable: The Tough prototypes, green Stryker, and purple Stryker trocar were tested.

Dependent Variable: The force required for abdominal wall puncture.

Control: The procedure and testing device were the same for each trial.

Factors to Consider:

- Human abdominal wall thickness (AWT) ranges from 10mm-45mm
- The suture pad is a close comparison to human tissue but as with any artificial substance it is not 100% as accurate.

Procedure:

To set up the test, the upper arm of the Instron will be fit with the tensile grip that can clamp the trocars in a vertical position. The lower arm will be fit with the 3-point bending grip to hold the testing device into place. The miniature testing device will be created with a mason jar and artificial skin sutured to the lid. To ensure that the trocar does not slip and the obturator remains in place, the obturator will be held in the upper grip instead of the trocar head. Once the trocar is tightened in the upper grips, it will be jogged down until the tip of the obturator was slightly above the artificial skin sutured in the testing device. The Instron Bluehill 3 software will be used to create a 3-point flexure test method. The insertion rate used in the testing method will be 4.0 mm/sec [39]. This is the rate needed for a trocar to safely puncture the abdominal wall as found in prior research. Each trocar will be tested twice for accuracy resulting in eight total trials, four for the current models and four for the prototypes of the trocar system. To perform the test, the upper arm of the Instron moved at a downward rate until the artificial skin was punctured. The test comes to a stop when the trocar fully punctured the simulated abdominal wall. The resulting forces will be analyzed and compared using Matlab.

Passing Test:

The test was deemed successful if the insertion force obtained from the flexure test fell below 71.4 N, the force necessary to puncture the abdominal wall. If the force obtained was greater than 71.4 N, the trocar would fail to safely puncture the human body [36].