Development of a Gynecologic Laparoscopic Trainer

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Abstract

Laparoscopic surgery is a minimally invasive alternative to open surgery in that it only requires a few small incisions. However, the complexity of this type of surgery due to the inability to see directly into the patient's abdomen requires surgeons to master a variety of psychomotor skills. Laparoscopic trainers are devices that allow medical residents to safely practice these psychomotor skills, but the extent to which they enable proficiency of surgical skills is limited due to their lack of complexity. The team designed a cost-effective and accurate gynecologic laparoscopic trainer for OBGYN residents and surgeons at UMass Medical that mimicked the female human pelvis and allowed for the simulation of realistic gynecologic procedural steps. The resulting design incorporated silicone-molded vasculature and organs phantoms, an adjustable abdominal casing, and 3D printed structures to accurately simulate the pelvic region of a patient.

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Section 1. Introduction

Laparoscopic surgery is a minimally invasive surgical method that has become significant in the gynecological field. This type of surgery is a great alternative to open surgery as it reduces postoperative complications such as minimized pain and bleeding. Due to its reduced invasiveness, however, laparoscopic surgery requires a demanding set of psychomotor skills that are not needed for other types of surgery. Because of this, more training is desired in order to master the essential laparoscopic skillset. The position and view surgeons have of their patients during laparoscopic surgery varies with each procedure, but direct visualization of the abdomen without the use of a monitor is concealed. As a result, specialized techniques, instruments, and skills are necessary to successfully practice laparoscopic procedures. Laparoscopic box trainers are often used during laparoscopic training, and while the utilization of these trainers proves to be an effective method for training medical residents, few box trainers bridge the gap between low cost and anatomical accuracy. As a result, integrating sufficient and effective box trainers into residential programs is a challenge to many medical schools.

Residents at the University of Massachusetts Medical Center experience variability in their surgical training and are not able to accurately practice procedures using the trainers accessible to them. Virtual reality trainers are often expensive and do not offer effective haptic feedback, while reasonably priced box trainers do not accurately depict the gynecological anatomy and landmarks that appear during gynecologic procedures. More specifically, the box trainers available at UMass Medical are geared towards general surgery, especially with regards to the positioning of the anatomical features. These trainers are more focused on practicing skills rather than actual gynecological procedures. Therefore, there is a need for a cost-effective and accurate gynecologic laparoscopic trainer for OBGYN residents and surgeons that mimics the female human pelvis and allows for the simulation of realistic gynecologic procedural steps, resulting in more consistent and satisfactory training that can be incorporated into the residency curriculum.

The goal of this project was to develop a low-cost, high fidelity laparoscopic trainer for surgical residents that mimics the female pelvis, its surrounding organs, and necessary vasculature to allow for simulation of realistic gynecologic surgery case steps, primarily for hysterectomies and laparoscopic vaginal cuff closure.

A 3D pelvic model and abdominal casing that includes the bony pelvis, lumbar spine, psoas major, common iliac, external and internal iliac, ureter, ovarian artery and vein, and the uterine artery is needed in order to create an effective trainer for laparoscopic procedures. It was also important for the model to have the ability to attach a vaginal cuff, infundibulopelvic (IP) ligament, round ligament, and uterine artery easily, with a vaginal cuff model that mimics the natural properties of an in vivo vaginal cuff. The client also asked for models of the uterus, fallopian tubes, and ovaries that can be inserted into the trainer. This trainer would be an advancement to the existing trainers available at UMass Medical, where the resources are more geared towards general surgical applications and practicing skills, not procedures. The Ob-Gyn residents at UMass Medical would be better equipped to meet their necessary laparoscopic surgical practice hours and perform these procedures more successfully and confidently.

Section 2. Background

2.1 Laparoscopy

Laparoscopic surgery has become significant in the medical field, now being considered the standard care for many different types of procedures. It is a minimally invasive surgical technique that has developed over the years, beginning as an invasive diagnostic tool, and advancing to gold standard surgical treatment on several different organ systems, specifically the reproductive and digestive system [1]. During laparoscopic procedures, surgeons operate through small incisions and use specialized instruments and a monitor to navigate the tissues encountered in the operating field. This method differs from open surgery as the surgeon does not have a direct view of their actions, but the patient experiences less pain, a shorter recovery time, and less scarring as a result [2]. Laparoscopic surgery also offers other advantages such as less damage to tissues, less need for drugs after the operation, decreased incidence of wound infections, and lower perioperative morbidity [1, 2]. This technique is widely used in varying applications, including for cholecystectomies, fundoplication, gastrostomies, colon resections, appendectomies, diagnostic procedures, ovariohysterectomies, and hysterectomies [1, 2, 3]. The position and view the surgeons have of their patients vary with these types of procedures along with the number of incision sites, the specific tools used, and the landmarks encountered.

2.1.1 Gynecological Laparoscopic Surgeries

Laparoscopy plays a major role in the gynecological field, as reconstructive operations, biopsies, and diagnostics are performed on the pelvic region [4]. There are several different gynecological laparoscopic surgeries performed so that patients experience a more minimally invasive procedure that will result in fewer scars, a quicker recovery time, and less pain [5]. Some common gynecological laparoscopic procedures include laparoscopic-assisted vaginal hysterectomy (LAVH), ovariohysterectomy, tubal ligation, and diagnostic laparoscopy. Ovariohysterectomy is the removal of an ovarian cyst, oftentimes by enucleating the ovarian cyst or aspirating it. Tubal ligation is a method of contraception, usually for women over 30 years old, where the fallopian tubes are "tied off". Diagnostic laparoscopy has become very applicable, as it can be used to investigate chronic pelvic pain and infertility, discovering endometriosis, adhesions, pelvic disease, and urinary tract or bowel pathology [5].

The hysterectomy is one of the most performed surgeries in the United States, with nearly 600,000 done each year [6]. There are several different procedures used, including vaginal, abdominal, and laparoscopic hysterectomies, but it has been seen that the vaginal and laparoscopic methods have resulted in decreased blood loss, quicker recovery time, and fewer abdominal wall infections compared to abdominal hysterectomies [6, 7]. Although the vaginal technique is less expensive, there are some limitations to the approach when patients have a more complicated history with several other issues regarding their pelvis [6]. Laparoscopic hysterectomy could therefore be the best procedure to use, however, there has been evidence that shows that there has been a relatively slow adaptation to this approach due to the insufficient and limited exposure and training during residency [6].

The total laparoscopic hysterectomy begins with the patients placed in a dorsal lithotomy position at maximum Trendelenburg as seen in Figure 1. The positioning of the patient is critical as it allows for the operating area within the pelvis to become more accessible and clearer. The lithotomy position allows for lateral movement of the uterine manipulator with the buttocks slightly above the edge of the table to facilitate uterine manipulation as well [8]. Trendelenburg position is needed so that the small bowel can move out of the pelvis completely, allowing for visualization of the promontory and the right ureter crossing the external iliac artery [8]. The use of a specific foam or mat is necessary so the patient does not slide in this position. The angling of the pelvis creates a unique viewpoint and position for the surgeons as they look at the monitor and coordinate their hand movements. The operating table is often kept in a low position as well with a monitor directly in front of the surgeons, so an ergonomic environment can be kept [8]. The surgeon usually stands on the left side of the patient if they are right-handed and the first assistant is placed across from them. The second assistant stands in between the legs, and the members of the surgical team should have a clear view of the monitor, while still maintaining an ergonomic neck position [8].

Figure 1. Maximal Trendelenburg and dorsolithotomy positioning for hysterectomy [9].

The tools used during this type of surgery can include a laparoscope with the 5-mm one most often used, a scalpel, a reusable bipolar grasper, three 5-mm trocars, and a 12-mm trocar, duckbill graspers, a Uterine Manipulator, a suction irrigator, triple hook clamps, and sutures [6]. These tools may vary depending on the surgeon and hospital, but ultimately, it is important to keep a simple equipment list that the surgeon is very familiar with to prevent crowding in the operating room and allow for other staff to become familiar with the equipment being used. Knowing the instruments well will also help improve the efficiency and outcome of the surgery. Trocars are also used as a way to gain access and insert instruments into the peritoneal cavity [5]. They vary in size, ranging from 5mm in diameter to 1.2 cm in diameter. There are several different kinds of forceps used for various tasks, such as dissecting and grasping. Scissors also come in different variations, including straight or curved blades, serrated, and hook-like. The morcellator systems remove large tissue specimens, such as the uterus [5]. The length of the instruments varies, but they are typically 36 cm in length.

Before the trocars are inserted, the anatomy and reference points should be defined. The surgeon must mark the anterior superior iliac spine, the navel, and the midline area and check the location of the epigastric vessels and umbilical artery to avoid injury [8]. Another check done before the surgical steps begin is on the uterine manipulator, ensuring that it is placed deep enough in the uterine cavity where maximum uterus mobility is available. Finally, the ureters should be checked and exposed to avoid any damage [8]. Although the surgical steps for the hysterectomy can change from surgeon to surgeon, the basic steps that are taken include first the division of the round ligaments, then the treatment of the adnexa. Next, the vesico-uterine space should be dissected, and the posterior peritoneum is opened. The uterine vessels are then divided, followed by a colotomy, where an incision is made in the back wall of the vagina. The uterus can then be retrieved vaginally if possible. Vaginal closure is then done by suturing a sufficient width of vaginal mucosa and fascia and includes both utero-sacral ligaments for pelvic support [8]. This is one of the most difficult aspects of the procedure and can be done either vaginally or laparoscopically [7]. The pelvis is then irrigated and aspirated and the surrounding anatomical landmarks should be checked to ensure no injury occurred, especially with regards to the ureters, bladder, and vaginal cuff. Finally, the trocar can be removed and the skin incisions closed [8].

2.2 Anatomical Landmarks

When performing laparoscopic procedures, it is critical to be able to identify and maneuver around anatomical landmarks, including certain bones, organs, and vasculature. For gynecological surgeries, specifically hysterectomies, surgeons primarily work in the female pelvis and encounter several reproductive organs and pelvic vessels. The bony structure of the pelvis plays a role in the positioning of the patient, while the vasculature represents landmarks that the surgeon needs to be cautious around. The pelvic organs and tissues, such as the uterus, fallopian tubes, ovaries, and vaginal cuff are the tissues the surgeons will be cutting, suturing, and manipulating to successfully complete their procedure.

2.2.1 The Bony Pelvis

The pelvis plays a crucial role in elements of the gastrointestinal, reproductive, and genitourinary systems. It is responsible for structurally supporting the weight of the upper body when sitting and transfers the weight of the lower limbs when standing, as it serves to connect the abdomen to the lower limbs [10]. There are three main parts of the pelvis, including the bony pelvis, the pelvic cavity, and the pelvic floor. The bony pelvis, or “pelvic girdle”, is connected to the spine on the posterior side and includes the right and left hip bones, the sacrum, and the coccyx. These bones are connected to one another to form a largely immobile and weight-bearing structure so that it can act as a strong foundation for the upper body [11]. The ilium, pubis, and ischium converge at the center of the lateral side of the hip bone and create a deep, cup-shaped cavity known as the acetabulum. The obturator foramen is the opening in the anteroinferior hip bone. The upper, broad space between the pelvic bones is known as the greater pelvic cavity and is laterally defined by the large, fan-like portion of the hip bone. Parts of the small and large intestines occupy this area and are often more closely associated with the abdominal cavity [4]. The lower, more narrow rounded space between the pelvic bones holds the bladder and other pelvic organs and is therefore called the lesser pelvis or true pelvis. This pelvic inlet separates the lesser and greater pelvis and is defined by lines formed by the pubic symphysis, the pectineal line of the pubis, the arcuate line of the ilium, and the sacrum [4]. The lower part of the lesser cavity is called the pelvic outlet, which is a large opening related to the pubic symphysis, the ischiopubic ramus, the ischial tuberosity, the sacrotuberous ligament, and the inferior tip of the coccyx. The lesser pelvis is oriented with the pelvic inlet anterior superior to the posteroinferior pelvic outlet. The pelvic floor is the muscular portion of the true pelvic cavity, connecting many of the bones to one another [4]. Figure 2 labels and depicts the pelvis bony structure.

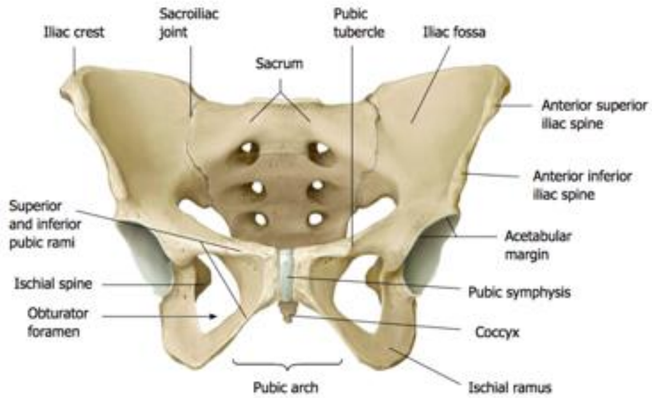


Figure 2. Superior view of the female pelvis [12].

The female pelvis differs in many aspects from that of a male, especially with regard to the weight and structure of the bones. The female pelvis often has lighter and thinner bones than that of a male and the pelvic inlet has a round or oval shape. This is because the female sacral promontory projects less into the pelvic cavity [4]. The lesser pelvic cavity is relatively short and wide, and the pelvic outlet is rounded and large in a female because the ischial tuberosities of females are farther apart than in males. The subpubic angle in females is also normally greater than 80 degrees due to the increased pelvic width. These obvious differences between male and female hip bones result in differing laparoscopic procedures, positioning, and steps during surgery [4].

2.2.2 Pelvic Organs and Tissues

The pelvic organs significant to gynecological surgery include the uterus, ovaries, fallopian tubes, cervix, vagina, rectum, bladder, and urethra. The anatomy of the female pelvis and the pelvic organs within is essential to know for all clinicians, especially in the field of obstetrics and gynecology [13]. The uterus is located in the center of the pelvic cavity and is commonly in the anteverted and anteflexed position, with "version" referring to the angle between the cervix and the vagina. Therefore, an anteverted uterus is tipped forward in the pelvic cavity, while a retroverted uterus is tipped backward and can lead to several issues. Anteflexed indicates that the uterus is bent forward, as "flexion" refers to the angle between the cervix and the uterine body [13]. Above the uterus lies the bladder and below is the rectum. The bladder stores the urine brought through the ureters from the kidneys until it is expelled through the urethra. The rectum is the storage house for feces and is at the base of the large intestine. The recto-uterine space or posterior cul-de-sac is the space between the uterus and the rectum that can be prone to fluid collection due to pelvic abscesses, drop metastasis from gastrointestinal cancer, and endometriosis [13]. The fallopian tubes stretch from the uterus to the ovaries and the cervix is the connection between the uterus and the vagina. The cervix has a thick layer of mucus that acts as a barrier for preventing bacteria from traveling to the uterus [13]. The main organs that are encountered when performing laparoscopic surgeries are the uterus, fallopian tubes, and ovaries and can be seen in Figure 3.

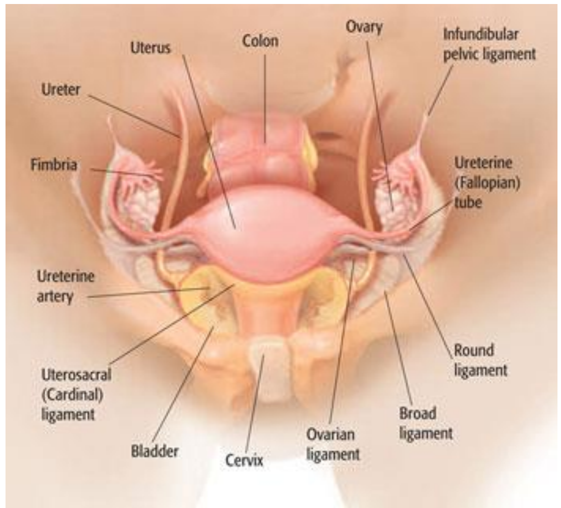


Figure 3. Illustration of several pelvic organs, ligaments, and tissues [14].

Three major ligaments support the uterus. The uterosacral, the pubocervical, and the transverse cervical ligaments anchor the uterus posteriorly, anteriorly, and laterally, respectively [13]. The transverse ligament differs from the others because it contains a vascular structure, the uterine artery [13]. The utero-ovarian, or ovarian, ligament is also an important structure of the pelvis as it supports the ovary, extending from the ovary to the uterine body. The infundibulopelvic ligament supports the ovary superiorly and is known as the suspensory ligament. It comes down from the lateral aspect of the abdominal wall and holds the ovarian neurovascular bundle [13]. Finally, the broad ligament covers the uterus, fallopian tubes, and ovaries, acting as the inferior most extension of the parietal peritoneum [13]. It is divided into three parts based on location, with the lateral most section known as the "mesovarium" and covers the ovaries. The fallopian tubes are covered by the "mesosalpinx" division and the largest part of the broad ligament, the "mesometrium", covers the uterus [13]. Each ligament plays a significant role in supporting the major organs within the pelvis.

2.2.3 Pelvic Vasculature

The vasculature present within the pelvis is a very important feature to consider when practicing laparoscopic procedures. Figure 2 highlights the common iliac, external and internal iliac, ureter, ovarian artery and vein, and uterine artery, which are some of the most important vessels within the pelvis. The external iliac arises from the femoral vein and drains deoxygenated blood from the leg. It is located anterior to the abdominal wall and pubic region. The internal iliac artery is the main source of vasculature for the pelvis, supplying blood to the pelvic walls, pelvic viscera, external genitalia, perineum, buttock, and medial part of the thigh [15]. The ureters transport urine from the kidney to the bladder and arise from the abdomen as a continuation of the renal pelvis [16]. The outer layer of the ureter contains fibrous and connective tissue while the middle layer has smooth muscle, as it is responsible for pushing urine through the duct. The inner layer of the ureters is made of mucosa, transitional epithelium tissue that secretes mucus [16]. The ovarian artery and vein supplies blood to and from the ovary and comes from the abdominal aorta, below the renal artery (artery), or to the inferior vena cava (vein). The uterine artery is a division of the internal iliac artery and supplies blood to the uterus and other reproductive organs in females [15].

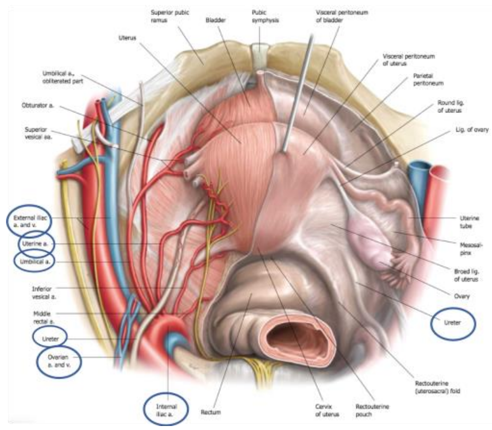


Figure 4. Vasculature in the female pelvis with important vessels circled [12].

The size and positioning of the major vessels in the pelvis are important to recognize when operating. Table 1 outlines the average diameter of the most significant vessels to consider during a gynecological laparoscopic procedure. Most of these arteries and veins are major blood suppliers and if damaged, could endanger the patient greatly.

Table 1. Vessel diameters [17].

Vessel	Iliac Artery	Iliac Vein	Uterine Artery	Umbilical Artery	Ureter	Ovarian Artery	Ovarian Vein
Diameter	9.7-12.3mm	3.6mm	2-4mm	1.43-1.66mm	3-4mm	1-3mm	7.2-8.5mm

2.3 Current Devices and Limitations

Due to its nature, a demanding set of psychomotor skills is needed to be successful at laparoscopic surgery. In order for residents to develop these psychomotor skills, medical schools incorporate a variety of laparoscopic training equipment into their programs. This training equipment allows residents to practice surgical techniques, and it also acts as a platform to evaluate residents' skills. The most commonly used laparoscopic simulation technologies are cadaver models, virtual reality trainers, and box trainers. The following sections provide an overview of each of these simulations and describe the advantages and limitations of their ability to mimic the environment of laparoscopic surgery.

2.3.1 Cadaver Simulation

Between the three simulation technologies, cadaver models are the most effective way for residents to learn laparoscopic techniques. Cadaver simulation utilizes a previously frozen cadaver which allows true anatomical features to be used in practice. The cadaver specimens can vary from human, pig, sheep, or any other readily available species. While cadaver simulation is beneficial in permitting the use of real tissue during training, it does not fully encompass every detail of laparoscopic surgery. The main drawback of this type of simulation is its inability to generate a pneumoperitoneum, or a presence of gas in the abdominal cavity, without equipment. Having CO2 gas in the abdomen during laparoscopic surgery is necessary in creating abdominal pressure in order to inflate the stomach so there is enough space for procedures to effectively take place [18]. Because this gas is introduced into the abdomen through the use of an insufflator, the cost of this device increases the total cost of cadaver simulation. In addition, depending on the method in which the cadaver is preserved, other anatomical features including vessel color and strength differ from their true forms as they are in a living body [18]. Another limitation associated with cadaver simulation lies within ethics. Using a human or animal cadaver for the purpose of training students is often deemed unethical by many, thus, other alternatives are looked for that provide similar training opportunities in a more ethical manner.

2.3.2 Virtual Reality Trainers

Virtual reality (VR) trainers are one of the most common methods for training laparoscopic surgeons as they can provide full procedural training with a realistic practice environment. Although live animal models are also full procedural trainers and offer very realistic, non-patient environments, they have cost and ethical issues and have therefore not been incorporated into the surgical resident curriculum. On the other hand, virtual reality trainers offer a digital recreation of the procedures, specific anatomy, and the environment of laparoscopic surgery [2]. However, there are no VR trainers that are currently used as a standard for laparoscopic surgical trainers due to the extremely high costs and in turn, low availability [2]. These trainers can range in price from about $80,000 to $120,000, without including additional maintenance fees, technical support, or optional modules for the system [2]. Therefore, not many hospitals would have access to multiple or even one of these systems and it was found that if they are, they are underused because they are physically locked away [2]. Another limitation of the VR trainer is their lack of effective haptic feedback, as well as their fidelity of the visual feedback. Without the proper response from the trainer, it is difficult for the surgeon to accurately practice a full surgical procedure. Figure 5 depicts several of the laparoscopic trainers that are available today.

Figure 5. Examples of commercial virtual reality laparoscopic trainers [2].

There are also VR part-task trainers that can simulate simple laparoscopic tasks like cutting, grasping, and suturing to learn basic skills necessary for performing real laparoscopic surgeries. The available VR trainers on the market include the LAP-Mentor, LapVR, LapSim, and Lap-X, several of which can be both part-task trainers, as well as full procedural trainers [2]. Table 2 outlines some important features of the systems.

Table 2. Overview of Commercial VR Trainers [2]

Company	VR Trainer	Cost	Key Features

Simbionix	LAP Mentor	~$2,000	- Custom hardware interface with haptic feedback - Library of multidisciplinary modules designed for training camera manipulation, hand-eye coordination, clipping, grasping, cutting, and electrocautery - Tasks including peg transfer, pattern cutting and ligating loop tasks
CAE Healthcare	LapVR	~ $115,000	- Contains laparoscopic instruments connected to computer - Tasks including peg transfer, cutting, and clip application - More modules like Procedural Skills Module, General Surgical Procedures Module, and OB-GYN Procedure Modules
Surgical Science	LapSim	~$55,000	- Provides modules for mimicking tasks including camera and instrument navigation, coordination, grasping, cutting, clip applying, as well as more advanced skills like suturing and “running the small bowel’ - Measures time, instrument path length and procedure specific errors
Medical-X	Lap-X	~$9,000-$20,00	- Provides peg transfer, pattern cutting and suturing - Portable - Light user interface with haptic feedback

While all of these trainers are able to simulate skills and procedures necessary for gynecological surgeries, some allow for more advanced training or more accurate environment simulations. Several of these systems are comparable to the standard box trainer. However, while both are able to efficiently train and assess basic laparoscopic skills, the physical box trainer is more widely used and known due to its lower cost, higher validity of performance measurements, and greater visual and haptic fidelity.

2.3.3 Box Trainers

Box trainers are the cheapest among the three laparoscopic training simulators, and utilization of these trainers proves to be an effective method for training medical residents [19, 20]. Box trainers consist of a casing with holes to mimic laparoscopic incisions, and they are often used in conjunction with small modules for practicing basic laparoscopic skills [21]. These modules are often small molds meant for practicing suturing, cutting, knot-tying, or any introductory level laparoscopic skill. Figure 6 below highlights some of these modules and the skills students can practice with them.

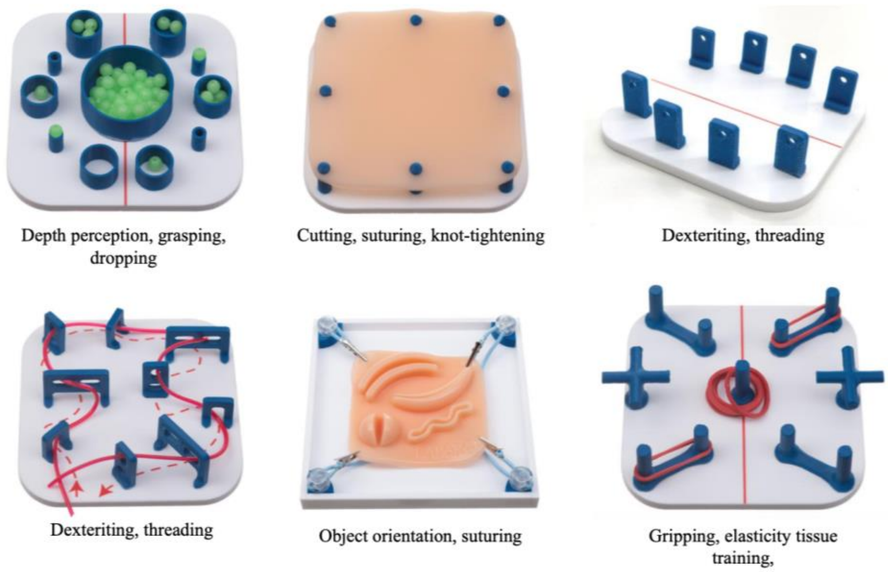


Figure 6. Training modules used in a laparoscopic box trainer [21].

The Fundamentals of Laparoscopic Surgery (FLS) box trainer is a common laparoscopic box trainer used by many medical programs. This box trainer incorporates a skin frame consisting of two attachable, black neoprene pads on its top surface with two pre-made incision holes [22]. The box is made from acrylic and uses rubber strips on opposite sides for reinforcement. The front of the trainer contains an adjustable window to control the amount of light entering the interior. The producer of the FLS trainer, Limbs & Things, offers this trainer in three different packages. The least expensive of these packages provide the customer with the trainer, a set of skills-training modules, and a tv camera for a total cost of $1,164 [22, 23]. In addition to everything that comes in the first package, the second package also comes with an adjustable cart bench and a TV screen for a price of $3,528 [22, 23]. The final package also includes an instrumentation set and costs $6,510 [22, 23]. Figure 7 below depicts the FLS trainer, its included training modules, and the mobile cart bench and tv included in the second and third packages.

Figure 7. FLS Trainer package with training modules, cart bench, and TV [22].

Other producers of commonly used laparoscopic box trainers are Ethicon, 3B Scientific, Inovus Medical, and Simulab. Among these producers of box trainers lies a variety of unique components that distinguish each trainer from the next. Table 3 below outlines box trainers produced by these companies, their key features, and average costs of the technology.

Table 3. Overview of laparoscopic box trainers [21, 24, 25].

Company	Box Trainer	Cost	Distinguishing Features
3B Scientific	T9 Laparoscopic Trainer 120v	$3,405	- Slide out drawer for adding/removing simulated organs
3B Scientific	Laparo Advance	$1,827	- 5mm and 10mm instrumentation inserts (i.e holes in abdominal casing) -Portable training box -includes basic models to practice basic skills (suturing, needle threading)
3B Scientific	T5-RM Large RM 240V	$3,300	-14 laparoscopic ports in pelvic box -dimensions: 21" x 13.5" x 12" ; 18lbs -includes different tissue models (vaginal cuff, soft tissue suture pad)
Inovus	Pyxus HD Move	$700	- Portable, easily assembled, and includes 4 skills tasks - 180p scope for illuminating operation field
Inovus	Bozzini	n/a	- 2, 5mm ports for instruments + 10mm port for scope -magnetized side walls → removable for insertion of training tasks
Inovus	Pyxus Pro Move	n/a	- port entry pad, screen mount, 8 bolts to construct box - 2, 5mm laparoscopic ports, zero lag scope, camera port
Simulab	LapTrainer	$1,250	- adjustable camera offering different scope angles - portable; 22"x18"x8" ; 22lbs
Simulab	Pop-Up Trainer	$195	- lightweight, collapsible, 6 lbs, 16"x16"x18.5"

While the majority of the current laparoscopic box trainers have features that are consistent with one another, some features stand out more than others. One key component that every box trainer has is a top casing that acts as the abdominal platform for incision ports. While some trainers use a type of plastic for this portion of the box, others utilize a skin sheet to better mimic the elasticity and resistance of skin. The Bozzini box trainer does well to preserve the haptic feedback and peritoneal popping effects experienced when cutting into the skin through the use of a tissue-based platform [24]. In a similar manner, the 3B Scientific trainers utilize grommets of different diameters to simulate the ports, but these structures lack any material representation toward skin [21]. Another important specification that is a commonality between the trainers is their dimensions. Apart from the Pop-Up trainer, these box trainers weigh between 18 and 22 pounds and have similar lengths, widths, and heights [21, 24, 25]. In Figure 8 below, the laparoscopic box trainers described in the table are shown.

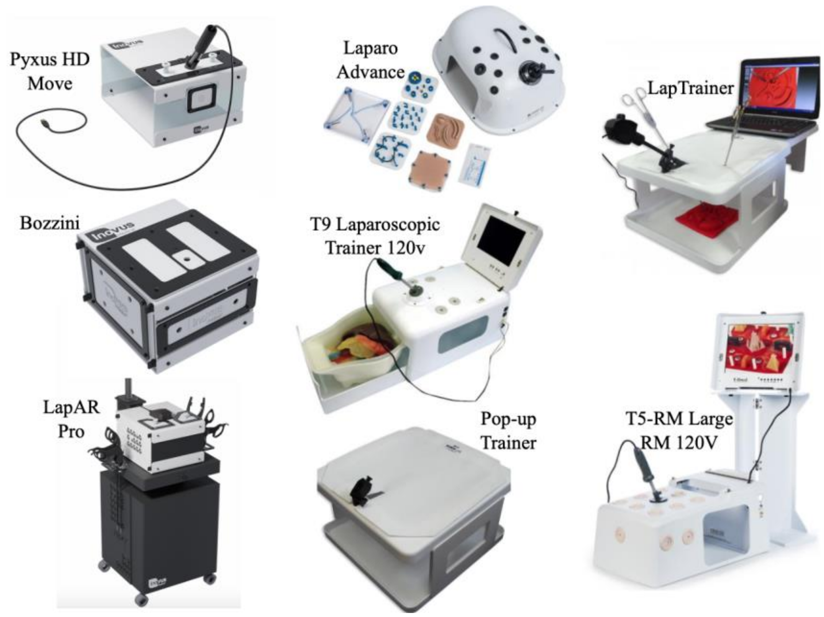


Figure 8. Common laparoscopic box trainers used for training.

While these trainers do well to teach residents the psychomotor skills needed for laparoscopic surgery, a universal downfall of many trainers exists within their task platforms or training modules. Most box trainers have an operating space that is meant for small training tasks that allow one or two skills to be practiced at a time. Although the T9 Laparoscopic Trainer 120V incorporates a pullout drawer with a variety of organ models, the drawer size limits the capacity of organs that can be trained on at once which decreases the anatomical accuracy available during use [21]. From these trainers, those offered by 3B scientific offer the widest assortment of practice modules that use materials and molds to mimic the effects of real tissue, such as the vaginal cuff model that allows users to practice cuff closing procedures [21].

2.3.4 Pelvic Models

The downfall to many gynecologic laparoscopic trainers is their inability to accurately model the true anatomy of the area of focus. While the training task modules that are commonly used with these trainers do well to teach users basic surgical skills, an entire pelvis model would expand the skills training opportunities for users. The bony pelvis skeleton is readily available for purchase, but few models exist that include the vasculature and organs of the pelvis. Models that do exist are primarily created for visual purposes rather than for surgical use in that they are designed to simply show the layout of the pelvis. On top of that, there are few laparoscopic trainers that directly target the pelvis and are used in conjunction with a pelvis model. Creating a pelvis model to go hand in hand with a laparoscopic box trainer would improve training programs for residents.

The Miya Model is a patented model (patent number 9830834) of the pelvis that is used in training for different pelvic surgeries [26]. This model includes detachable organs and vessels, and it is suspended by metal rods which allow it to rotate to generate trendelen and reverse trendelen views [26]. Although this model does not include every anatomical landmark in the pelvis, it consists of those necessary for practicing specified gynecologic procedures including pap smears, vaginal hysterectomies, insertion of IUDs, and more. One standout feature of this model is its preservation of mechanical functions of the organs. Made from Polyurethane, the hollow bladder model includes an opening and a plug which enables it to be filled to simulate the flow of urine. In addition, the bladder model also has a hole to mimic the urethra valve to allow catheters to be inserted into it [26]. The uterus model incorporates simulated vasculature with the ability to be pressurized through the attachment of IV tubes. The simulated organs are easily attached to the entire model through grooves on the bony pelvis, small fasteners, and elastic stretching of the models. The materials used to simulate each portion of the pelvic model simulate the textures and elasticity of the true structures. Silicone rubber is used for the obturator and perineum, casted rubber with tyvek reinforcement for the sacrospinous ligaments, and polyurethane elastomer for the uterus tubes and ovaries [26]. The entire Miya Model is seen below in Figure 9.

Figure 9. Front and back views of the Miya Model.

In addition to producing laparoscopic box trainers, 3B Scientific also designed and sells a female pelvis model. This model incorporates removable models of the uterus, ovaries, vagina, and fallopian tubes, in addition to permanently attached pelvic floor muscles. The drawback of this model is that it is intended for studying the layout of the pelvis and therefore, the anatomical landmarks are made from rigid materials and cannot be used for practicing surgeries [21]. In a similar manner, a manufacturing company called Educational & Scientific Products (ESP) sells a six-part pelvis model solely intended to visually represent the locations of key anatomical features of the pelvis [27].

2.4 Biomaterials Analysis

An integral aspect of the model is finding and utilizing biomaterials that accurately and properly exemplify the nature of its respective anatomical feature. The purpose of incorporating simulative materials is to provide greater aid for students and residents alike to perform gynecologic surgical techniques for practice and education. Many laparoscopic box trainers used by OB/GYN students today do not employ biomaterials that mimic certain anatomical features. For instance, the FLS Trainer depicted in Section 2.3.3 consists of training modules and tools that are helpful for learning certain fundamental surgical skills in laparoscopy. The modeled “organs”, however, are made out of foam, and therefore do not properly reflect the nature of the actual organs [22]. Additionally, the FLS trainer does not include modeled parts for blood vessels that would be found within the abdominal casing. Thus, the utilization of materials that closely match the behavior of the vasculature allows trainer users to obtain a realistic sense of the surgeries while building up their skills, and consequently bringing their experiences more confidently to the operating room. For laparoscopic gynecologic trainers, materials must be analyzed for the blood vessels, vaginal cuff, and the bony pelvis.

2.4.1 Biomaterials for Vasculature

Important properties to consider when selecting materials for vessels include durability, blood vessel viscoelasticity, and tensile strength. Some mechanical considerations include burst pressure, suture retention, fatigue resistance, and compliance [28]. For convenience purposes, the gynecologic trainer will not consider blood or fluid-related properties in vessels, as the trainers for surgical education does not prioritize this. Biomaterials commonly or recently used for vasculature can be sectioned into two categories: synthetic polymers and Biopolymers, as depicted in Figure 10 below.

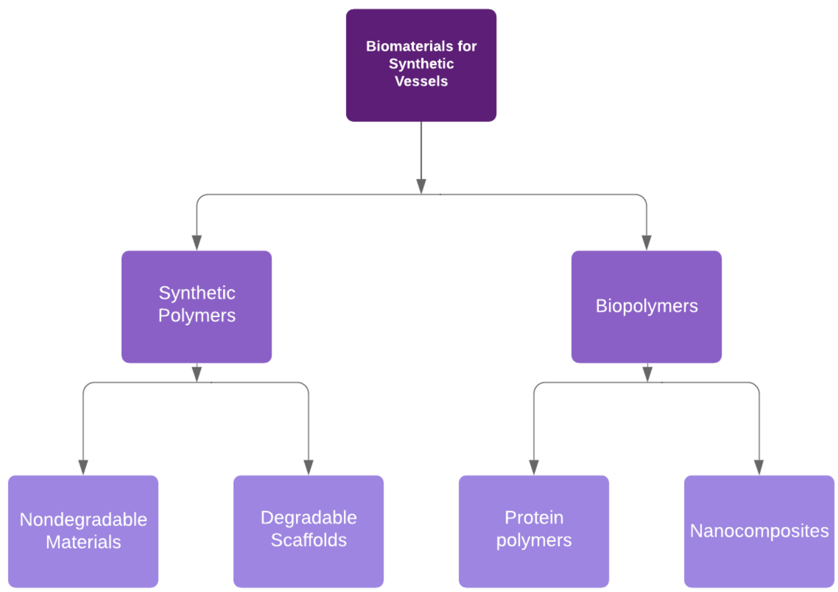


Figure 10. Organizational chart of types of biomaterials used for blood vessel mimicry.

Synthetic polymers are commonly used for artificial grafts and have been studied extensively in vascular engineering. Their popularity in cardiovascular applications is primarily due to ease of use and flexibility in modifying their mechanical properties [29]. Synthetic polymers can be further delineated as non-degradable polymers and degradable scaffolds, of which the latter is more applicable for in vivo scaffolding applications rather than modeling. Non-degradable polymers are commonly and currently used as vascular grafts. The most common non-degradable polymers are expanded polytetrafluoroethylene (ePTFE), polyethylene terephthalate (known industrially as Dacron), and polyurethane [29]. Dacron is typically used for cardiovascular applications like aortic replacement. It is typically a prosthesis that is able to mimic the dynamic behavior of the human aorta and other large vessels [30]. They are often crimped in order to increase its flexibility, elasticity, and kink resistance. Meanwhile, ePTFE is another commonly used non-degradable polymer that is porous with an electronegative surface. The synthetic polymer polyurethane consists of three types of monomers: a diisocyanate hard domain, a chain extender, and a diol soft domain [29]. The different monomers provide modifiable properties to reflect vessel behavior at physiological temperatures - the diol domain gives the copolymer flexibility, and the hard domains provide strength. Its compliance is closely similar to that of human arteries. When reinforced with knitted polyester fibers, polyurethane was found to have higher durability than ePTFE [29]. The use of polyurethane as a vascular graft for a vessel is demonstrated below in Figure 11.

Figure 11. Photographed polyurethane vascular graft in situ in carotid artery [31].

Biopolymers are alternatives to synthetic and degradable polymers. For biopolymers, proteins (type I collagen, fibrin) are manipulated to emulate the architecture of native extracellular matrix (ECM). They can embody the same characteristics as arterial walls to attain ample mechanical integrity. Such examples include decellularized allogeneic or xenogenic tubular tissues that have structurally organized ECM. These biopolymers, however, pose drawbacks such as viral transmission from animal tissue and progressive biodegradation [29].

2.4.2 Materials for Vaginal Cuff Mimicry

To simulate laparoscopic hysterectomy cuff closure, a model of the vaginal cuff for surgical training is imperative. Vaginal cuff closure is an operation that is a critical component of minimally invasive hysterectomies and can encompass variations in suturing techniques and skills [32]. Training models are necessary to assess and validate the surgical skills required for laparoscopy pertaining to gynecologic surgery. An overview of vaginal cuff models has been developed and its features are outlined in Table 4.

Table 4. Laparoscopic training models for vaginal cuff closure skill development [32].

Description of Model	Materials Used	Assessed Tasks
Repurposed uterine manipulator with sacrocolpopexy tip/vaginal stent, and a vaginal cuff placed in FLS trainer box	Neoprene lined with swimsuit material (nylon and spandex)	Vaginal cuff closure
Pelv-Sim box model trainer, simulated open vaginal cuff including ovary, 2 infundibulopelvic ligaments, and fascia with optional laparoscope attachments	Burlap	Vaginal cuff closure, ovary transposition to pelvic wall, ligation of IP ligament, closure of port-site fascial incision
Vaginal cuff model placed in FLS box trainer	Liquid latex	Vaginal cuff closure
Vaginal cuff model in box trainer with ipsilateral and	Corduroy fabric (vagina), internal neoprene layer (vaginal	Vaginal cuff closure

suprapubic ports	mucosa)	

At a combined meeting for the International Urogynecologic Association and American Urogynecologic Society, participants that were gynecologic staff and students tested out a hysterectomy cuff closure model. The model system consisted of a sacrocolpopexy tip/vaginal stent and a Cooper Surgical vaginal cuff sleeve made out of neoprene with nylon and spandex (swimsuit) material [33]. Neoprene best simulated the thickness of the vaginal cuff, and swimsuit material best mimicked vaginal epithelium as seen in Figure 12.

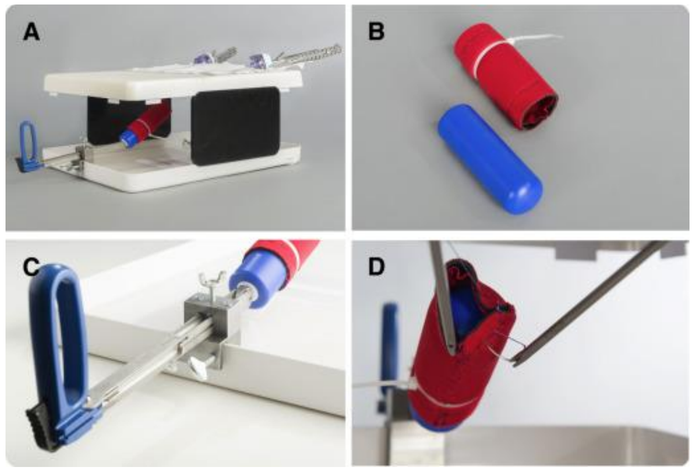


Figure 12. FLS Simulator Box Trainer with Neoprene/Swimsuit Material Vaginal Cuff [33].

2.4.3 Materials for Bony Pelvis Construction

The Axis Scientific life-size model is an example of a typical 3D model of the female pelvis. It costs $40 and can be used for gynecological study. The replica is made from dense Polyvinyl chloride (PVC) plastic and lasts long-term as seen in Figure 13.

Figure 13. Axis Scientific female skeletal pelvis model [34].

Silicone models have been recently studied by OB/GYN residents for laparoscopic technical training. To collect postgraduate residents' opinions about the box simulator training at the OB/GYN department of University Medical Center, Utretch, residents practiced several technical laparoscopic skills and procedures with a silicone pelvis in a gynecologic simulation box. As a result, residents found that the design of the silicone model was anatomically accurate and realistic but was limited in tissue feeling. Despite the drawback, the consensus among residents was that the silicone would be useful for residency training [35].

Polylactic acid (PLA) is a material commonly used in 3D printing and has been used in modeling the female pelvis. PLA is beneficial such that its plastic consumable price for 3Dprinting is low-cost at €6 (approximately $7.02) [36]. Another material used for modeling the pelvis is 3D printed ultraviolet-cured resin (Figure 14). The novel model was used as a guide for laparoscopic surgery for surgeons specializing in rectal cancer and can be beneficial for residents to learn about intricate pelvic anatomy [37]. Despite its usefulness in understanding complicated anatomy, the 3D printed resin pelvic model had limitations such as high cost (approximately $2250), no elasticity, and anatomical structures within the model were not movable, and would not prove suitable for surgical simulations [37].

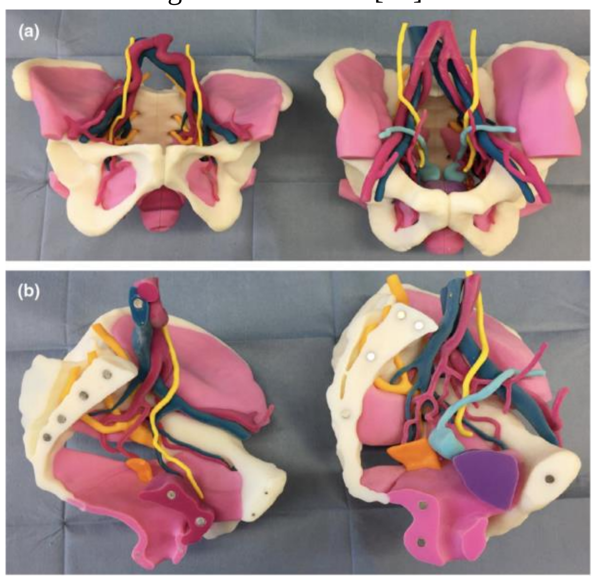


Figure 14. a) Frontal view of male and female 3D printed ultraviolet-cured pelvic models. b) Medial view of male and female 3D printed pelvic models [37].

2.5 Processing Techniques

Laparoscopic surgery has evolved, and this requires the residents to acquire more skills. Incorporating a laparoscopic training curriculum is vital for surgical training. Laparoscopic trainers can often be developed through 3D printing or injection molding. Both of these options are viable when producing plastic parts and components [38]. They both are helpful processing techniques when it comes to production efficiency of creating parts that accurately replicate the human anatomy. These processes can be used to model the abdominal cavity in the designed laparoscopic trainer.

2.5.1 3D Printing

3D printing is best suited for a low volume production, designs with frequent changes, and relatively small parts or components [38]. When designing parts for 3D printing, they must first be developed using computer-aided designs (CAD) [39]. A CAD design is needed for each individual part before printing. Each CAD file can then be sent to be 3D printed and assembled. When products are 3D printed, they can be produced quickly and won’t deteriorate. Monash University created major parts of the body by scanning real anatomical specimens with a CT or a surface laser scanner. They were then 3D printed in a plastic-like powder or plastic, which resulted in high resolution and accurate color reproduction [40]. They used radiographic imaging to capture the information within each layer. This data allows for the printed result to be a recreated body part that has each layer necessary and is made to scale. Through 3D printing, Professor McMenamin and his team were able to produce realistic 3D replicas of the forearm with the small nerves and vessels clearly shown and highlighted by colors [41]. The result had a high degree of accuracy and was relatively inexpensive.

University of Pavia also aimed to 3D print patient-specific models for laparoscopic abdominal surgeries. They formed Multi Detector Computed Tomography (MDCT) image elaboration to reconstruct patient-specific anatomy [42]. MDCT images are made through using contrast dye with a slice-thickness resolution of at least 2mm. The image elaboration can take from 1 to 3 hours. They were able to use ITK-Snap software to apply an algorithm to identify and mark the arteries, veins, and other necessary structures in each MDCT slice. The model was exported using the Standard Tessellation Language (STL) format that can be processed for 3D printing. They used an Objet Pro 3D printer to print their models. High-resolution is essential so that all of the details in the anatomical structures can be reproduced correctly. The models were printed using a white rigid photo-polymeric material. This material was displayed in liquid form and was cured with UV light throughout the printing process. The printing process of each model can take up to 23 hours.

By using 3D printing, manufacturers are able to use natural materials instead of plastic or metal. 3D printing can provide great aid in surgical planning and resident education. This process is beneficial because it allows for modifications of designs, it is relatively cheap, and the process does not take very long.

2.5.2 Injection Molding

Injection molding is best suited for high volume production, final designs, and parts of any size or complexity [41]. Because it is used for high volume productions, this process would be better suited for future uses, where the design model is finalized. At Kobe University, they developed a 3D laparoscopic surgical simulation system with anatomically accurate bio elastic organ replicas with MDCT data of abdominal organs and skin. The replicas were made from simultaneous jetting of different types of materials and injection molding and polyvinyl alcohol (PVA) and water. Each replica organ mold was injected with a synthetic resin to make it feel more life-like to a surgeon. Plastic injection molding for medical devices has been found to be very effective in terms of attaining the quality and specifications needed from medical suppliers [43]. The plastics in injection molding have superior strength and durability. They tend to be designed to be resistant to contaminants and can be easily sterilized [44].

Plastic molding is known to have a fast production rate with high efficiency. There is a large selection of polymer resins to choose from to use as the materials. It also has the ability to include any metal or plastic inserts. However, upfront costs can be high. This is due to the design, testing, and tools required. Small runs of parts can also be costly. Before making each product, it is necessary to remove all of the previous material because of the complexity of tooling. This results in the setup time to become lengthy [45]. There is limited flexibility in making design changes with this process. It is important to use uniform thickness because any inconsistencies can cause defects in the model. It is easier to modify a design using 3D printing.

Section 3. Project Strategy

3.1 Initial Client statement

The goal of this project is to develop a laparoscopic trainer for surgical residents that mimics the female pelvis, its surrounding organs, and necessary vasculature using material processing techniques to allow for simulation of realistic gynecologic surgery case steps.

3.2 Design Requirements

Based on the initial client statement, several design requirements were developed to ensure that all aspects of the project were addressed. Several main objectives of the device were brainstormed and compared with one another using a Pairwise comparison chart to find the most important objectives to consider when designing the device. The constraints that could have been faced were also considered, as well as the functional and performance specifications necessary to create a working and effective trainer.

3.2.1 Objectives

From the initial and revised client statements and requirements, several objectives were developed to outline the needs of the project. The top objectives for the device were evaluated using a pairwise comparison chart to help determine the aspects of the device that are necessary for the success of the project. Table 5 depicts the ranking and scores of each objective. Each objective was compared with another and given a score based on which was more significant to the outcome of the project. The "0" score represents less importance, while the "1" score shows that the objective was more important than the other. The highest number scores were the most needed functions of the project.

Table 5. Pairwise comparison chart for top six technical objectives.

	Cost-effective	Anatomical accuracy	Pelvis mobility	Portable	Easily replaceable parts	Adaptable to different procedures	**TOTAL**
Cost-effective		0	0	1	0	0	**1**
Anatomical accuracy	1		1	1	1	1	**5**
Pelvis mobility	1	0		1	1	1	**4**
Portable	0	0	0		0	0	**0**
Easily replaceable parts	1	0	0	1		1	**3**
Adaptable to different procedures	1	0	0	1	0		**2**

The results of the pairwise comparison showed that the most important objectives to consider were the anatomical accuracy of the trainer, followed by the pelvic and abdominal casing mobility. This indicates that these two features were needed in order to create a device that will satisfy the client and be an advancement to the current devices available to the client.

While these objectives seen in Table 5 summarize the most important requests for the entirety of the laparoscopic trainer, objectives for each specific component of the device exist in order to meet every request. The bony pelvis must be light enough as to not weigh down the abdominal casing, but it must be durable enough to withstand the weight of its component parts including the vessels and organ phantoms. The bony pelvis must also be accurate in shape in size and closely resemble a female pelvis. The abdominal casing must be adjustable to offer different planes of view, and it must resemble an inflated female's abdomen as seen during laparoscopic surgery. In addition, the abdominal casing must have a way to insert a camera through the side of it to be used for training and visualization of the practice surgeries. The top of the abdominal casing should also contain incision ports with accurate dimensions and locations as seen during typical laparoscopic surgeries for the insertion of tools. The simulated vessels should have appropriate diameters and lengths, and the vessel branches should be accurately placed in respect to one another. The vessels should also be permanently adhered to the bony pelvis, unlike the organ phantoms which should be able to detach from the pelvis. The vaginal cuff and uterus should be flexible and made from a material that simulates the true tissue. The pelvic floor should be permanently attached to the pelvis to engulf the vessels to prevent them from free flowing. The pelvis as a whole should be permanently attached to the abdominal casing. The laparoscopic trainer in its entirety should allow

3.2.2 Constraints

While many design features must be met to meet the clients' requests, a few constraints exist that must be taken into account. The main constraint is the $1000 budget that must not be exceeded. This spending limit will help in preserving materials, making necessary and effective purchase choices, and producing a cost-effective laparoscopic trainer which is one of the most important design requests. Another constraint is the dimensions of the 3D printers accessible through WPI. As the team will only be utilizing WPI 3D printers as they are the most readily available option, and with the 3D printing demand of this project, large components of the device will need to be sectioned into multiple pieces in order to be compatible with the 3D printer sizes. There is also a time constraint placed on this project. Although given four school terms to complete this project, the client requested the final product by the beginning of winter or the new year to be tested as much as possible. It is also important to note the resource and time constraints placed on the project due to the current pandemic. Due to the necessary restrictions placed on the WPI campus to limit the spread of COVID, in-person group meetings are not allowed which hinders the ability to create design components as a team. This has also restricted the in-person meetings with the advisor and clients. Additionally, there are tighter restrictions on accessing WPI equipment needed for the project (3D printers, laser cutter) which causes a delay in weekly productivity of the device.

3.2.3 Functional Specifications

The utilization of laparoscopic box trainers proves to be an effective method for training medical residents [38, 39], but few box trainers bridge the gap between low cost and anatomical accuracy. As a result, integrating sufficient and effective box trainers into residential programs is a challenge to many medical schools. Commonly used box trainers average about $1500 to $3000 and are used in conjunction with small modules for practicing basic laparoscopic skills [40]. While practicing introductory skills is a great way to introduce new residents to the demanding skill set needed for laparoscopy, a gynecologic box trainer with a full-size, anatomically simulated pelvic model would expand the competency developed during training. To build such a trainer that offers residents a chance to practice skills beyond the realm of introductory techniques, accuracy must exist within every piece of the box trainer. The trainer should include a 3D pelvic model and abdominal casing that includes the bony pelvis, lumbar spine, psoas major, common iliac, external and internal iliac, ureter, ovarian artery and vein, and the uterine artery to allow for the effective practice of laparoscopic procedures. The model should also have the ability to attach a vaginal cuff, infundibulopelvic (IP) ligament, round ligament, and uterine artery easily, with a vaginal cuff model that mimics the natural properties of an in vivo vaginal cuff. If time and resources allow, the client also asks for models of the uterus, fallopian tubes, and ovaries that can be inserted into the trainer. Table 6 lists the functional specifications that are significant to the success of the developed trainer.

Table 6. Functional Specifications.

Specifications	**Value/Attribute**
Cost-effective	• More accessible to purchase • Buy in bulk
Anatomically accurate bony pelvis, pelvic vessels, abdominal casing, and pelvic organs	• Mimic the reality of the gynecological procedures, not just the skills • Location and size
Portable	• Allow for more accessible practice
Easily Replaceable Parts	• Allow for different procedures to be practiced multiple times • Certain organs may be inapplicable for certain procedures
Adaptable	• Modifiable to the different procedures
Aesthetics	• Casing/landmarks appealing to the eye while resembling a human abdomen
Longevity	• Can be used to practice operations/techniques multiple times
Pelvis Mobility	• Certain angle is necessary for these procedures

Monitor attachability	• Connection between the camera and a monitor for visualization of the pelvic model

3.2.4 Performance Specifications

While the objectives and functional specifications do well to summarize the necessary functions needed to meet the clients' requests, performance specifications are necessary in targeting each component of the laparoscopic trainer to ensure their production is met with precision. The main performance specifications are the required dimensions for the abdominal casing, pelvis, vessel models, and organ phantoms. In addition, the rotational or adjustable aspect of the abdominal casing is another specification that will be kept in mind. The incision ports should also be dimensioned and positioned based on surgical norms. Mechanical properties of the vessel and organ models should also be taken into account in order to preserve the anatomical accuracy of these features. Table 7 below summarizes the performance specifications needed to meet the clients' requests and to create an efficient laparoscopic trainer.

Table 7. Performance Specifications.

Specification	Measured Value	Significance
Bony pelvis dimensions	Pelvic arch: 90-100°	Model the structure of the female bony pelvis for anatomical accuracy
	Distances from different parts of the pelvis: See Figure Y	
Vessels diameters	Iliac vein: 9.7-12.3mm Iliac artery: 3.6mm	Model the vessel placement and relative size to one another for anatomical accuracy
	Uterine artery: 2-4mm	
	Umbilical artery: 1.43-1.66mm	
	Ovarian artery: 1-3mm Ovarian vein: 7.2-8.5mm	
	Ureter: 3-4mm	
Abdominal casing angles	~ 25-40° from horizontal	Mimic the Trendelenburg positioning of the patient for procedural accuracy
Incision port diameters	5, 3 cm ports	Allow for instruments of various sizes to be inserted (largest diameter of trocar is 1.2 cm) for procedural

		accuracy
Vessels elastic modulus	6 MPa	Allow for repeated use without damage while maintaining similar behavioral properties of the vessels for anatomical accuracy and longevity
Port degrees of freedom	2 degrees of freedom	Model the degrees of freedom the instruments used in laparoscopic surgery offer to surgeons for procedural accuracy

3.3 Engineering Standards and Medical Regulations

The standard that can be primarily applied to the trainer device is ISO 13485:2016. This international standard delineates the requirements for a quality management system of an organization to completely provide the device with consistent customer and regulatory needs. Organizations would be involved in design and development, production, distribution, and other associated cycles of provision for the device. ISO 13485:2016 can also be utilized for justification of exclusion from the quality management system if there are applicable regulatory requirements that allow for exclusion of design and development facilitation. Therefore, this standard enforces and ensures that the organization is responsible for the monitoring, maintaining, and facilitation of quality control standard processes [46].

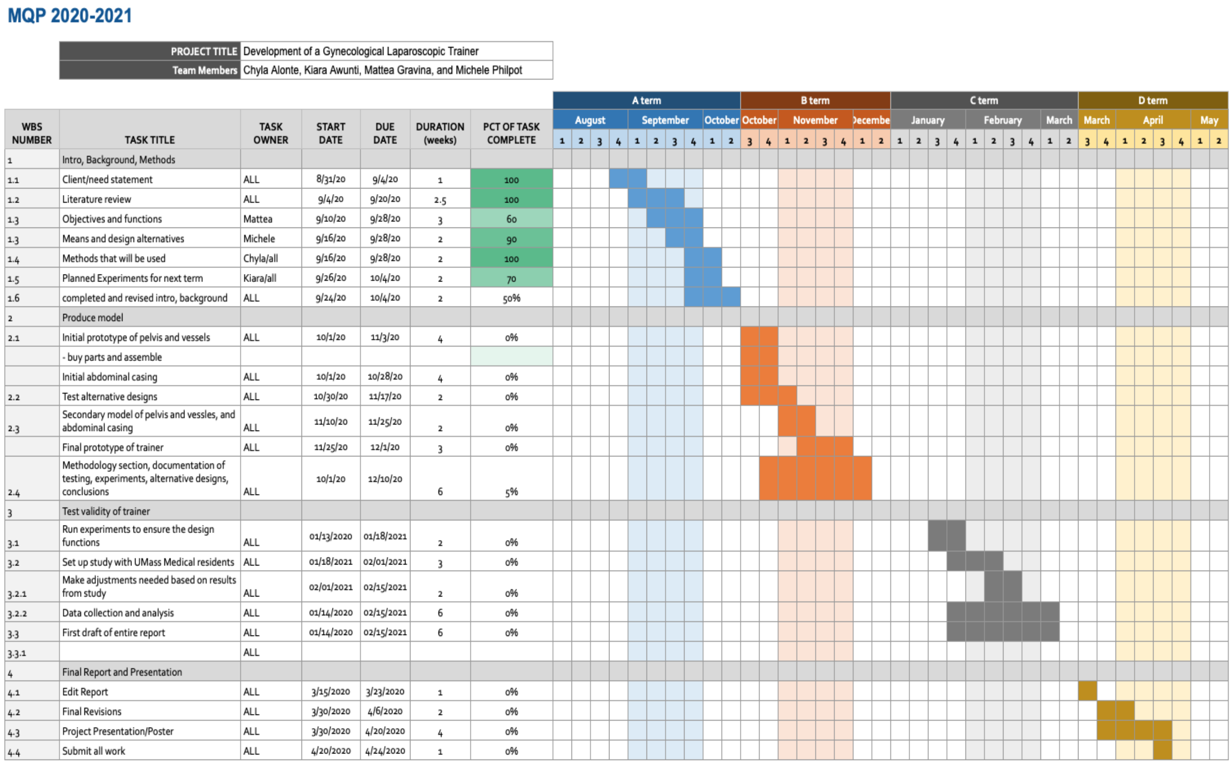
To follow medical school standards, the device must comply with standards enacted by the Liaison Committee for Medical Education (LCME), which grants accreditation to UMass Medical. As demonstrated in *Functions and Structure of a Medical School (2020)*, there are 12 standards that must be upheld. In relation to the trainer, Standard 7 outlines that the institution's medical curriculum sufficiently provides enough resources and information for medical students entering residency and subsequent programs or practices. The trainer would be integrated into the Ob/Gyn program for residents to use to meet necessary laparoscopic training for gynecologic practice, and furthermore serve as a fundamental part of the content and clinical experiences of the curriculum for long-term problem-solving skills. The device is also compliant with Standard 9.4 which details the assessment system of the medical student's achievements and acquisition of knowledge in the program. The laparoscopic trainer would employ the Global Operative Assessment of Laparoscopic Skills (GOALS) to measure competency in gynecologic laparoscopic proficiency. Standard 9.4 of LCME involves both technical and direct observation for medical student assessment [47].

3.4 Revised Client Statement

There is a need for a cost-effective, anatomically accurate gynecologic laparoscopic trainer for Ob/Gyn residents and surgeons at UMass Medical that mimics the female human pelvis and its significant landmarks which will allow for simulation of realistic gynecologic procedural steps that can result in a more consistent and satisfactory training to be incorporated in the Ob/Gyn residency curriculum. The goal of this project is to develop a low cost, high fidelity laparoscopic trainer for surgical residents that mimics the female pelvis, its surrounding organs, and necessary vasculature to allow for simulation of realistic gynecologic surgery case steps, primarily for hysterectomies and laparoscopic vaginal cuff closure.

3.5 Project Management Approach

In order for the team to stay on track and manage their time wisely, a year-long Gantt chart was created that summarizes the necessary weekly and monthly accomplishments for the project, as seen below in Figure 15.



WBS NUMBER	TASK TITLE	TASK OWNER	START DATE	DUE DATE	DURATION (weeks)	PCT OF TASK COMPLETE
1	Intro, Background, Methods					
1.1	Client/need statement	ALL	8/31/20	9/4/20	1	100
1.2	Literature review	ALL	9/4/20	9/20/20	2.5	100
1.3	Objectives and functions	Mattea	9/10/20	9/28/20	3	60
1.3	Means and design alternatives	Michele	9/16/20	9/28/20	2	90
1.4	Methods that will be used	Chyla/all	9/16/20	9/28/20	2	100
1.5	Planned Experiments for next term	Kiara/all	9/26/20	10/4/20	2	70
1.6	completed and revised intro, background	ALL	9/24/20	10/4/20	2	50%
2	Produce model					
2.1	Initial prototype of pelvis and vessels	ALL	10/1/20	11/3/20	4	0%
	- buy parts and assemble					
	Initial abdominal casing	ALL	10/1/20	10/28/20	4	0%
2.2	Test alternative designs	ALL	10/30/20	11/17/20	2	0%
2.3	Secondary model of pelvis and vessles, and abdominal casing	ALL	11/10/20	11/25/20	2	0%
	Final prototype of trainer	ALL	11/25/20	12/1/20	3	0%
2.4	Methodology section, documentation of testing, experiments, alternative designs, conclusions	ALL	10/1/20	12/10/20	6	5%
3	Test validity of trainer					
3.1	Run experiments to ensure the design functions	ALL	01/13/2020	01/18/2021	2	0%
3.2	Set up study with UMass Medical residents	ALL	01/18/2021	02/01/2021	3	0%
3.2.1	Make adjustments needed based on results from study	ALL	02/01/2021	02/15/2021	2	0%
3.2.2	Data collection and analysis	ALL	01/14/2020	02/15/2021	6	0%
3.3	First draft of entire report	ALL	01/14/2020	02/15/2021	6	0%
3.3.1		ALL				
4	Final Report and Presentation					
4.1	Edit Report	ALL	3/15/2020	3/23/2020	1	0%
4.2	Final Revisions	ALL	3/30/2020	4/6/2020	2	0%
4.3	Project Presentation/Poster	ALL	3/30/2020	4/20/2020	4	0%
4.4	Submit all work	ALL	4/20/2020	4/24/2020	1	0%

Figure 15. Gantt chart laying out project deadlines for the year.

The team was also provided $1000 to complete the design, prototype and final product of the project. A budget was created to monitor how much is being spent and what is being purchased. The budget lists items that were purchased, as well as items that still need to be purchased and outlines the cost and quantity of each. Based on research, the team gave an estimated amount that would be spent on each section of the budget. Once an item is purchased, the sheet calculates how much over or under the item is from the budgeted amount. A total amount spent is also provided, along with the amount remaining. The information for the team's current budget is found in Figure 16.

Category and Item	Quantity	Price	Budget	Actual	Purhcased	Difference	Description
ABDOMINAL CASING							
PLA (top curve)	1	$36.24	$10.00	$36.24		-$26.24	
acrylic board	1	$24.40	$50.00	$24.40			
L-Brackets	1			$0.00			
Plywood	1			$0.00			
screws	2	$6.50	$20.00	$0.00		$20.00	
magnets	3	$10.00	$10.00	$31.99	yes	-$21.99	
aluminum rod	1		$20.00	$0.00		$20.00	
Total			**$110.00**	**$92.63**		**-$8.23**	
BONY PELVIS							
PLA (pelvis parts)	1	$36.65	$50.00	$36.65	yes	$13.35	
screws	1	$6.50	$10.00	$6.50		$3.50	
epoxy glue	1		$10.00	$0.00		$10.00	
3D CAD model	1		$40.00	$0.00		$40.00	
initial prototype model	1	$40.00	$60.00	$40.00	yes	$20.00	
Total			**$170.00**	**$83.15**		**$86.85**	
VESSELS/ORGANS							
tubing connectors	1	$6.00	$10.00	$6.00	yes	$4.00	3/16" , Amazon Prime
3D printed mold (uterus)	1	$1.66	$10.00	$1.66			
3D printed mold (vessels)	1	$0.44	$100.00	$0.44		$99.56	
Sil-Poxy adhesive	1	$17.51	$20.00	$17.51		$2.49	0.5 oz, Amazon Prime
Silicone mold release agent (spray)	1	$16.50	$18.00	$16.50	yes	$1.50	
silicone mold making kit	2	$27.90	$30.00	$55.80		-$25.80	21.16 oz, Amazon Prime
silicone rubber pigment (dye)	1	$10.99	$15.00	$10.99	yes	$4.01	10 ml; add to part B of mold
silicone tubing	1	$5.60	$15.00	$5.60	yes	$9.40	1/8" diameter
PDMS							
Total			**$218.00**	**$114.50**		**$95.16**	
TOTAL PROJECT PURCHASES			**$498.00**	**$290.28**			
Remaining Budget			**$502.00**	**$709.72**			

Figure 16. Project budget.

Section 4. Design Process

Evaluation and comparison matrices were used to compare the features of proposed designs to one another. These evaluations analyzed the key components of the laparoscopic trainer individually, including the design of the abdominal casing, bony pelvis, vessels, organ phantoms, and pelvic floor muscles. Similarly, the best method for assembling the components of the device was identified through decision matrices that focused on assembling between two components at a time. In addition to the decision matrices, the final design was selected by also taking into account the user requirements, technical specifications, time constraints, and budget. Preliminary tests were done to gain an initial evaluation of each aspect of the trainer and the assembly process. Alternative methods for each part were also discussed as proactive responses to failures or issues that could have occurred. Prior to creating each component with the selected design choices, an initial prototype was created from makeshift materials to layout the entirety of the device before producing the final prototype with the true materials. This initial prototype focused on the design of the pelvic model to visualize how the layout of the vessels and organs. In a second prototype, a purchased pelvic model was used alongside purchased silicone tubing, plastic tubing connectors, and plywood to model the abdominal casing, the pelvis, and its component structures. Several different materials, such as PLA, silicone, magnets, and adhesives, and methods, including CAD modeling, laser cutting, silicone molding, and purchasing, were used to create each part of the trainer.

4.1 Needs Analysis

After consideration of the design requirements, client statement, engineering standards, and possible limitations, the need for the project and possible outcomes were developed. The current devices and situation were also considered when discussing the need of a new OBGYN laparoscopic trainer for residents. The problem and project scope were analyzed and a solution was created that addressed the needs of the client.

4.1.1 Need statement

With the understanding of the significance of training to successful gynecologic laparoscopic surgery, the residents at the University of Massachusetts Medical Center have realized that they experience variability in their surgical training and are not able to accurately practice procedures using the trainers accessible to them. Residency programs are struggling to integrate simulation of gynecologic laparoscopic surgeries into the curriculum due to the high cost of effective trainers, and low applicability of low-cost trainers. Virtual reality trainers are often expensive and do not offer effective haptic feedback, while reasonably priced box trainers do not accurately depict the gynecological anatomy and landmarks that appear during gynecologic procedures. More specifically, the boxes available at UMass Medical are geared towards general surgery, especially with regards to the positioning of the anatomical features. These trainers are also more focused on practicing skills rather than actual gynecological procedures. Therefore, there is a need for a cost-effective and accurate gynecologic laparoscopic trainer for OBGYN residents and surgeons that mimics the female human pelvis and allows for the simulation of realistic gynecologic procedural steps, resulting in more consistent and satisfactory training that can be incorporated into the residency curriculum.

4.2 Conceptual Designs

The necessary concepts to meet the needs of the project and design requirements were developed using a concept map, initial prototyping, and feasibility studies. Each aspect of the trainer was considered when creating the concept map and several methods to achieve the conceptual ideas were also developed. A couple of initial prototypes were fabricated in order to gain a better understanding and visual of the conceptual designs and to determine whether some of the ideas were feasible or not.

4.2.1 Concept Map

To understand the demands for each element of the laparoscopic box trainer, it can be thought of as three separate pieces:

1. Abdominal casing
2. Bony pelvis
3. Anatomical landmarks

Dividing the trainer into three subsections allows the design of each piece to be focused on in its own manner, and this also allows work to be divided beyond the team.

In order to strategize and pinpoint relevant aspects of the laparoscopic trainer, a concept map was created to aid in visualization of necessary design components. As demonstrated in Figure 17, eight primary concepts were brainstormed. These concepts addressed the need for biomaterials for mimicry of anatomical components, adjustability of the trainer for orientation, accuracy of anatomical representation, and incision holes for laparoscopic surgery simulation.

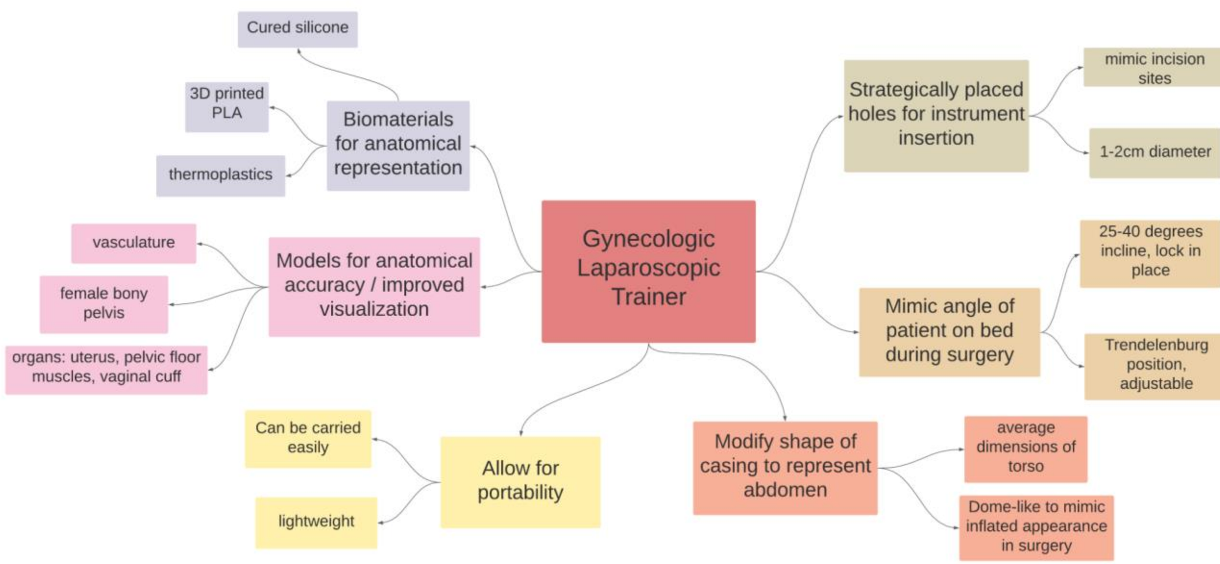


Figure 17. Concept map.

Each primary concept was considered and studied, allowing for possible solutions, methods, designs, and ideas to be developed in response to creating a functional and efficient gynecological laparoscopic trainer. Several different methods were discussed as solutions to concepts needed for each aspect of the trainer, aiding in the overall design of the laparoscopic trainer. The concept map in Figure 17 depicts the thought process and web of ideas for creating the ultimate product of gynecological residents.

4.2.2 Initial Prototypes and Feasibility Studies

To understand the mechanisms and criteria needed for the final design, two initial prototypes were created. These prototypes were used in assessing the feasibility of certain components such as the rotational casing mechanism, and for visualizing the layout and attachment mechanisms of the vessels and organ phantoms. The first prototype was made using scrap materials. The bony pelvis was made from paper plates, and the vessels were made from straws. The uterus and vaginal cuff were modeled using cardboard and construction paper, respectively. Hot glue was used to assemble all of the pieces together. Cardboard and cups were used to create the abdominal casing and the rotational mechanism to create different view planes. The turnout of this mock-up prototype is seen below in Figure 18 with the mock-up of the pelvis model shown on the left and the mock-up of the abdominal casing and rotational mechanism shown on the right.

Figure 18. Pelvis mock-up in abdominal casein (left) and rotational mechanism of mock-up (right).

Although not dimensionally or anatomically accurate, this initial mock-up prototype provided insight into future challenges that the team could have faced when proceeding with the final design. Although the straws provided little elasticity, the placement of them provided a general layout of where the vessels would need to be placed in the final design. The creation of the uterus and vaginal cuff were useful in understanding their sizes in relation to the bony pelvis, which were to be much smaller than anticipated. The rotational aspect on the abdominal casing mock-up allowed visualization of how the mechanism worked and what would be needed to make this an efficient feature in the final design. While this prototype served to bring written ideas to fruition, a second prototype was created with more dimensional and anatomical accuracy to assess the feasibility of our initial design ideas.

The second prototype consisted of plywood, screws, and L-brackets purchased from Home depot, and silicone tubing, connectors, and a pelvis model purchased on Amazon. Plywood was used to create the abdominal casing consisting of a bottom piece and two side pieces. Dimensions of these pieces were based on a prior meeting with the clients and measurements taken of their current assortment of laparoscopic trainers. The bottom piece was cut to 16 inches in length and 12 inches wide. Each of the side pieces was cut to 16 inches in length and 8 inches in height. The side pieces were assembled to the bottom piece using L-brackets and screws. The red, silicone tubing was cut into pieces and connected in different ways with the tubing connectors to represent arterial branches to create a vessel network. Hot glue was initially used to adhere the vessels to the pelvis, but inefficiencies in the adherence method led to the use of string to hold the vessels down onto the bony pelvis. The result of the second prototype of the pelvis is seen on the left in Figure 19, and the orientation and projected placement of the pelvis in the abdominal casing is seen on the right in Figure 19.

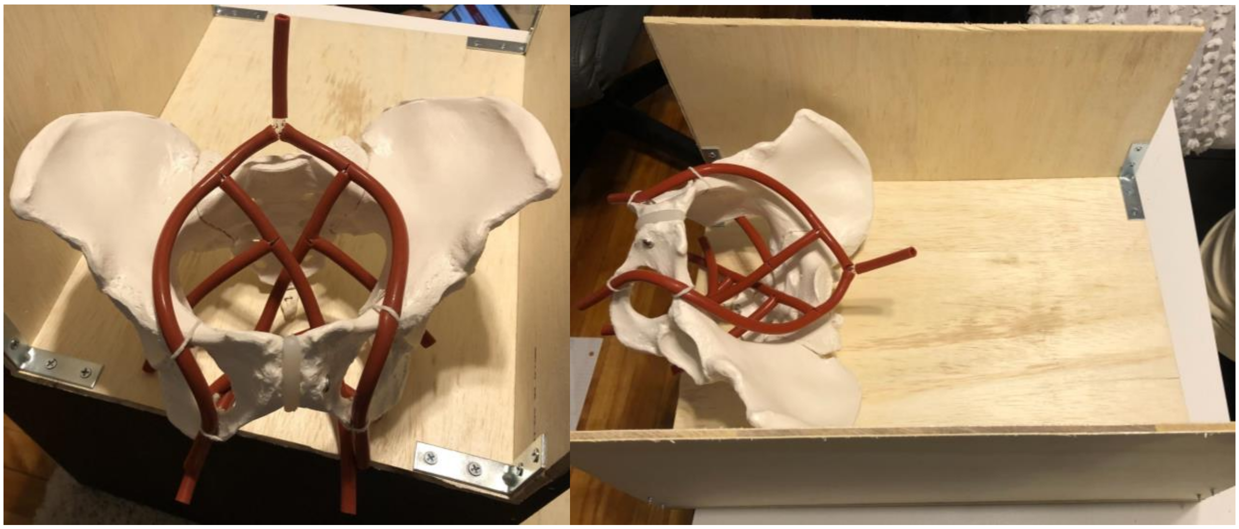


Figure 19. Second prototype used in feasibility analysis for analyzing vessel layout (left) and pelvis placement in the abdominal casing (right).

Compared to the initial prototype, the second prototype provided a better understanding of the dimensions and how big or small pieces needed to be in relation to one another. The purchased pelvis model was smaller than the requested pelvis size, and the silicone tubing was thicker than anticipated. However, using the tubing connectors to create a vessel network was very useful in visualizing the branching of different arteries and how the design should be modeled in SolidWorks. The main takeaway from the vessel network designed in this prototype was that the diameters for the different arteries needed to be adjusted in SolidWorks to not create a vessel network with one, constant diameter as this would eliminate the minimum accuracy of the design. From this prototype, the team solidified the attachment mechanism of the abdominal casing sides as the L-brackets proved to be stable and reliable. A meeting with the clients and this prototype also allowed the team to make final dimensional choices on the casing sides. Overall, although not complete with the organ phantoms, rotational mechanism, or curved top, this prototype was beneficial in moving forward with the proposal of alternative designs and the creation of the final design.

4.3 Alternative Designs and Evaluations

Creating the initial mock-up assemblies of the laparoscopic trainer allowed the team to solidify design choices before proposing alternative ideas. The creation of the first mock-up led the team to consider different materials for the top of the abdominal casing that best-resembled skin texture or that best-resembled the shape of the abdomen during laparoscopy. More ideas for the rotational mechanism of the casing were proposed to meet the client's request for removable sides as the original rotational stand and metal bar mechanism prohibited this feature as shown in the conceptual design feasibility study. The initial mock-up designs also confirmed the vessel network design approach, so the alternative ideas for this design aspect focused on the method for creating the vessels. Similarly, the proposed alternative designs for the organ phantoms and pelvic floor model focused on the best method for creating these design features.

With the vast amount of alternative design ideas, the team created design matrices for each specific part of the laparoscopic trainer to ensure that each component reached the clients' requests. In evaluating the bony pelvis, the two main manufacturing choices to decide between were 3D printing the pelvis or purchasing it. The abdominal casing alternative designs were compared to one another based on rotational mechanism, ability to accurately simulate a female abdomen, and ability to preserve anatomical accuracy with the incision ports. The vessel network simulation methods were compared based on ease of manufacturing, cost efficiency, and ability to provide dimensional control over the vessel creation. Similarly, the organ phantom manufacturing approaches were compared based on the ability to preserve anatomical accuracy while being easily reproducible. Finally, the assembly techniques used to compile the device as a whole were evaluated against one another. The final design choices were chosen based on the outcomes of the evaluation techniques for each device component.

4.3.1 Abdominal Casing Mobility

One of the most significant aspects of creating an improved gynecological laparoscopic trainer was designing for abdominal casing mobility, as this would allow for the resident users to control the angle to better mimic the positioning of the patient and anatomy during surgical procedures. The patients are normally placed in the Trendelenburg position, with their heads down and legs bent and up in the air. According to the residents, during a gynecological laparoscopic surgery, the patient can be at angles ranging from 20 to 40 degrees. Therefore, when developing the abdominal casing, several different concepts were thought of to follow these criteria. After researching and studying the current laparoscopic trainers available to the residents, an initial, simple wedge design was developed to address the challenge of the mobility of the casing. Some of the current trainers have a plastic wedge that can be placed under one end of the trainer. Although this provides one position to work in, the angle cannot be easily adjusted with just the wedge. Therefore, the concept for the "wedge" for the new trainer was to have adjustable stilts that would allow for changes in angles of the orientation of the box by manual manipulation of the legs. Figure 20 shows the initial design of the wedge mobility created on SolidWorks. The pelvis is also shown attached to the casing, as the casing and the pelvic model move as one unit.

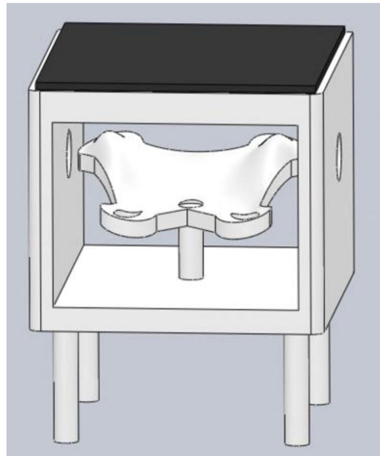


Figure 20. Wedge CAD design for the mobility of abdominal casing.

In addition to the simple wedge idea, there were several other concepts to explore for obtaining optimal abdominal casing mobility. These concepts included a rod system that would call for a stand for the trainer with two metal rods inserted in each side of the box to allow for it to easily rotate around one axis. However, with this concept, the mechanism for tightening the box in place once the desired position was found needed to be further discussed. Another concept considered was a "lawn chair" mechanism where there were two legs to the box that had notches which would allow for the trainer to be manually moved to different angles. This design, shown in Figure 21 implements a movable bar in contact with grooved legs. The bar could be rotated to fit any of the grooves, allowing the angle to range from 20 to 40 degrees. Vertical adjustability of the movable bars on one side of the box lifts the edge, increasing the angle between the box edge and the surface it rests on. As the opposite side of the box stays grounded to the surface, this creates an increasing angle at which the box is positioned, allowing for different planes of view. Figure 21 depicts preliminary drawings of the concept.

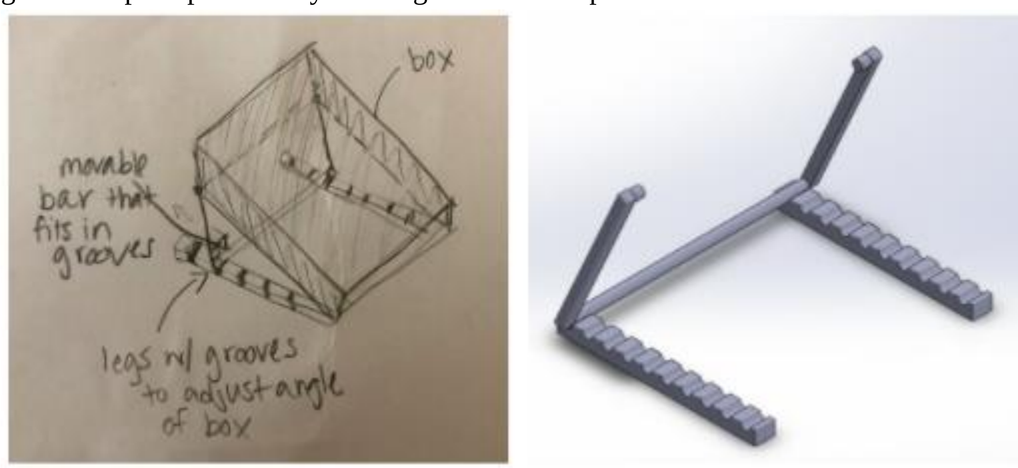


Figure 21. Sketch and CAD model of potential "lounge chair" abdominal casing set up.

The lawn chair design is a viable option for the mobility mechanism; however, the angles and positions of the box are limited to the grooves made on the legs of the stand. Moreover, the grooved legs would have to be attached to the box to ensure that the one end of the box remains immobile, perhaps making the trainer as a whole more difficult to assemble and replicate. Therefore, another design was developed to address some of these issues.

The CAD model shown in Figure 22 was designed to mimic the effects of a Gimbal mount often seen in camera equipment. This design has a holder that can be attached to the bottom of the abdominal casing box to hold it in place on the stand. There are also two bolts surrounded by a plastic piece that has grooves for easy grip. The bolts turn screws on each side, tightening the sides of the holder around the abdominal casing box, while also tightening the sides of the stand around the holder. This mechanism will allow for many degrees of mobility while the bolts are loose, and easy immobilization once the desired position is reached. Figure 22 portrays the stand, holder, bolts, and grips, but does not include the screws needed for tightening and attachment.

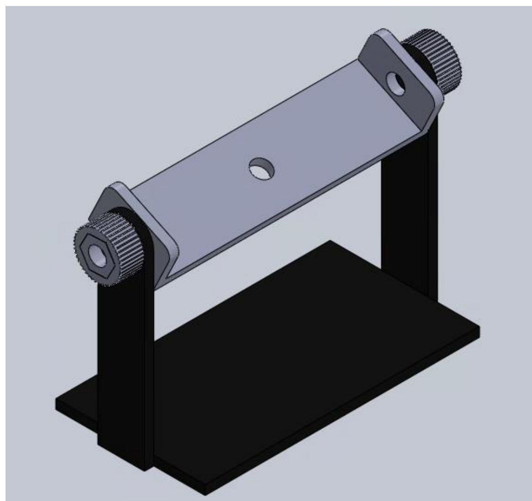


Figure 22. CAD model of the gimbal mount design.

Although this design is favorable in ease and mobility, there are still several design limitations to consider. The dimensional accuracy of the box holder must be very high, which may prove to be difficult to achieve through the methods available with the budget and equipment provided. In addition, slipping with regards to the box in the holder, as well as the holder out of the desired position may occur as a result of the weight of the box trainer and pelvic model. However, small plastic pieces could be inserted between the holder and the stand sides to aid with both the fit and the slipping, if necessary.

4.3.2 Abdominal Casing Box

In designing the abdominal casing, three features imperative to the clients' requests were considered. The casing needed to be adjustable to produce different view planes, mimic the shape of the abdomen, and provide resistance at the sites of incisions/trocars. Many box trainers are made from wood, metals, or plastics that don't mimic the effects of skin. Using a skin-like material for the abdominal casing would serve to simulate the true effects of cutting into the skin during laparoscopic procedures. Silicone, agar gel, polyurethanes, and epoxy are some of the most common materials used to make artificial skin [14]. To lower the cost of this casing, the use of one of these skin-like materials could be limited to the top of the casing, which can act as a removable lid. In this way, the bottom and sides of the box can be 3D printed from PVC, and the removable lid can be molded. A removable top would also make it easier to customize the box for different procedures with different locations of incisions without having to reprint the entire box. A basic model of one way the abdominal casing could appear is seen in Figure 23. The box is made from PVC and has 1-inch grooves for the silicone lid to fit into. Holes on opposite sides of the box are to allow metal rods to attach to the bony pelvis to allow for mobile orientation. Gaps in the front and back end of the box are included to reduce the amount of material used to lower the cost.

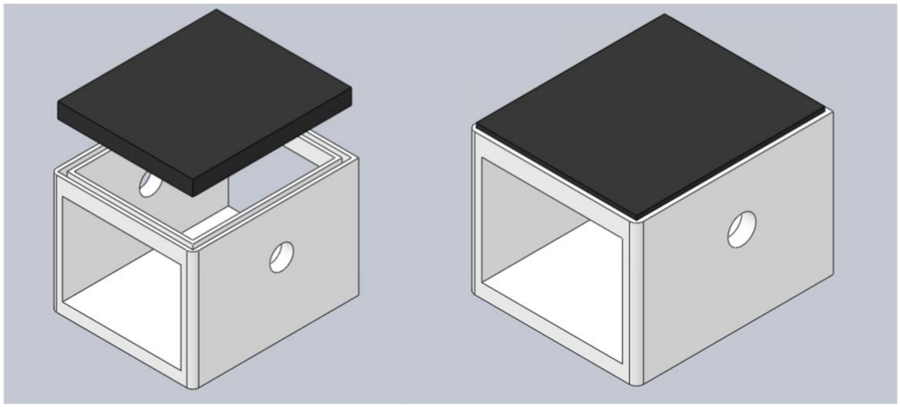


Figure 23. Example of a basic abdominal case setup with removable top.

The second proposed box trainer would be shaped similar to a realistic abdomen, as pictured in Figure 24. The abdominal cavity should be made of a material that can protect the organs and be supportive. The material could be PLA or another rigid, lightweight plastic. This casing would be attached to a stand to allow for the trainer to be rotated when needed. Part of the trainer would be open to place artificial organs inside and could be covered with a dome-shaped lid to mimic the skin over the stomach, such as PEG. The trainer would also be at an angle to mimic what the residents would see in surgery. The lining of the abdominal wall should be made of a material that resembles the real-life lining. There would be around 3-5 incision sites cut in the lid of the trainer. These would be fairly small compared to a normal 3-6-inch-wide incision. The sites would be lined with some sort of rubbery material and allow the resident to maneuver the scopes efficiently and effectively. There would also be a spot to attach a vaginal cuff. The vaginal cuff could be made out of neoprene and lined with swimsuit material. Any ligaments could be made of rubber tubing and any synthetic organs can be made of plastics, silicone, or latex. The veins and arteries are lined on the pelvic bone and can also be made of replaceable tubing. There would also be a monitor attached to the trainer and an inserted camera.

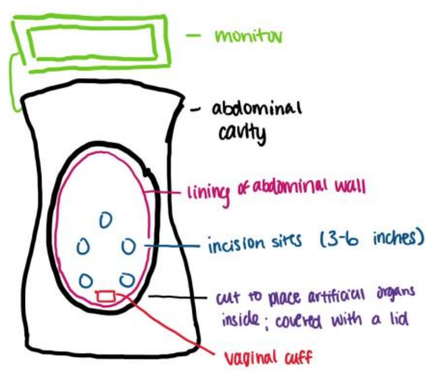


Figure 24. Abdominal casing design idea with curved surface to mimic the shape of an abdomen.

Another design idea incorporates mobility of the abdominal casing with a fixed pelvis inside, as well as the ability to have a monitor directly in front of the surgeon. As shown in Figure 25A, the box portion is attached to an outer stand via a metal rod, allowing for the casing to be rotated to the desired angle. The screw mechanism would also allow for the casing to be locked into place by inhibiting the rod's ability to spin through threaded parts that could be tightened and secured. The stand would also have an extension that could hold the monitor that would attach to the camera on the instruments being used. This part of the design would also be adjustable through a pin mechanism so it could be moved to best fit the height of the user. These extendable arms could be made out of metal rather than plastic to better support the monitor and move more easily. The abdominal casing would be in the shape that mimics the abdomen and have different materials where the incision sites for a laparoscopic hysterectomy would be as shown in Figure 25B. These areas would have holes about 1.2 cm in diameter to allow for a wide range of laparoscopic instruments to be inserted. The areas would have multiple layers of varying materials, such as neoprene, silicone rubber, foam, and other plastics that would simulate the layers of the abdominal wall. The thickness of the top portion of the casing would also be similar to that of the actual abdominal wall. Finally, the 3D printed pelvis would be attached to the casing through several screws to secure it in place, making the abdominal casing and pelvis one unit, as seen in Figure 25C. This would allow for the pelvis to be immobile in the box as the bony pelvis alone does not change angles within the body.

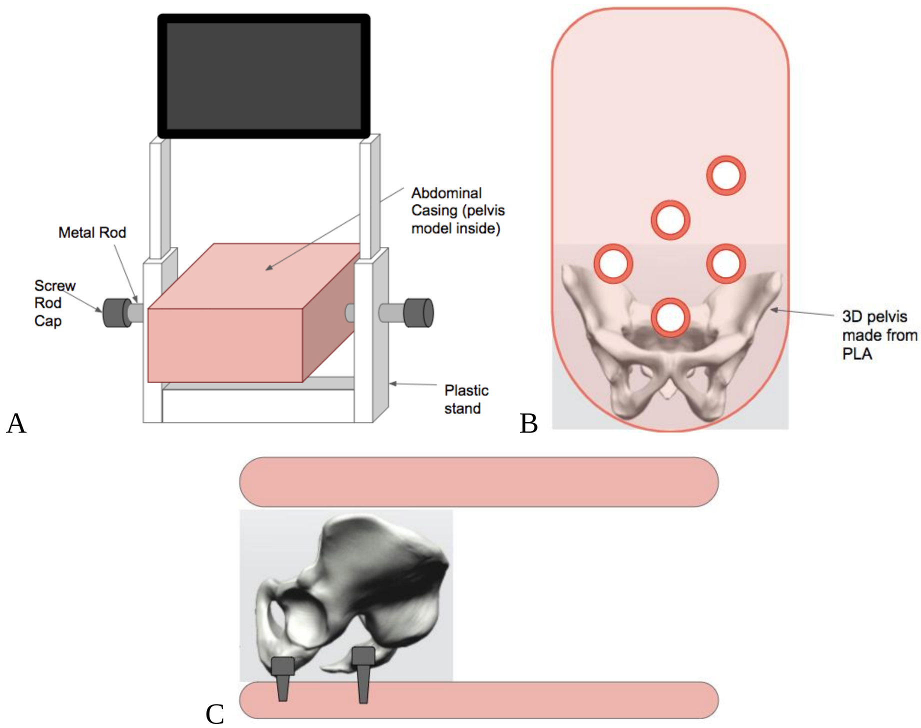


Figure 25. Abdominal casing design idea. (A) Overview of the entire design idea with adjustable casing and stand for monitor. (B) Abdominal casing and hole placement in top view. (C) Side view of the casing with bony pelvis attached with screws.

Another preliminary design idea for the abdominal casing involved a secured pelvis to the abdominal casing, with a protruding modeled vaginal cuff as seen in Figure 26. The design idea depicts a close-up version of the casing in a transverse view. The pelvis would be 3D printed and made out of PLA to provide rigidity. The top of the model would have holes of various diameters to account for the trocars implemented in the real surgeries. They would be strategically placed on the top of the casing in areas that are ideal for minimally invasive surgeries. These holes would also be lined with rubber or other synthetic polymers that would simulate the viscoelasticity of the surrounding skin. Metal screws would be used to secure the modeled pelvis in place such that it maintains one unit with the abdominal casing. Vessels would be molded and cured using PDMS or Silicone to their standard diameter measurements. To secure vasculature to the casing and other parts, they could be clipped or adhered using Sil-Poxy or other bonding adhesives for synthetic plastics and rubbers.

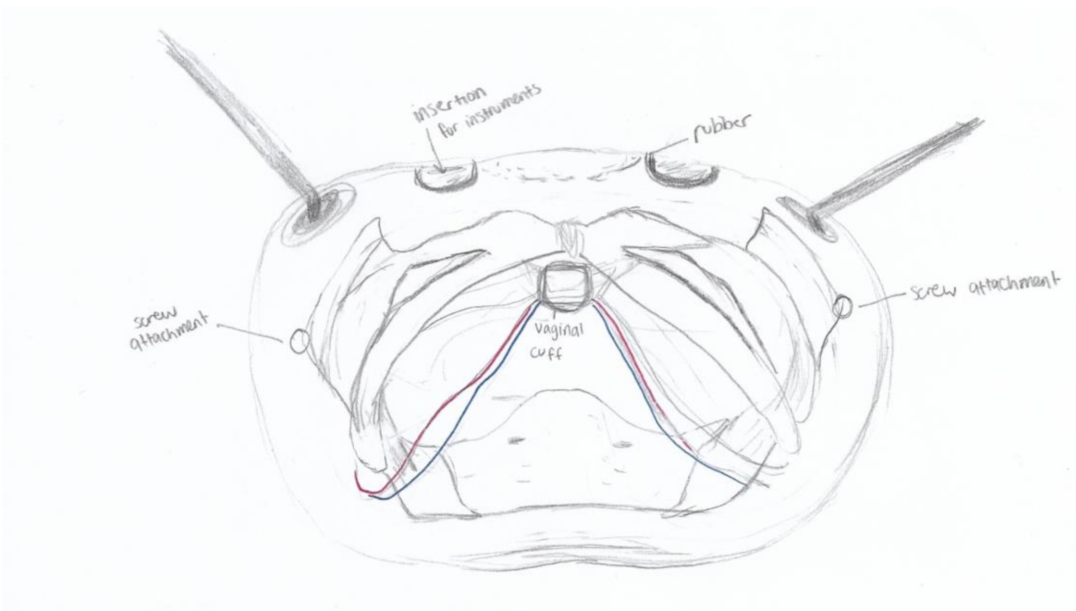


Figure 26. Design idea of the abdominal casing with attached pelvis model; transverse plane view.

The critical design choices that needed to be solidified existed for the design of the abdominal casing, vessels, and organs. To evaluate each component, the proposed designs were compared to the five most critical requirements for that specific part of the device. For the abdominal casing, this comparison between the proposed ideas is seen below in Table 8. While multiple designs were proposed, the three designs with the most standout features were chosen for comparison. Design 1 represents the casing with the lounge chair mechanism as seen in Figure 21, design 2 represents the casing with the curved surface to mimic the abdomen shape as seen in Figure 24, and design 3 represents the casing with the rotational rod as seen in Figure 25.

Table 8. Rank score comparison for three top abdominal casing designs.

ABDOMINAL CASING DESIGN					
Requirement	**Weight**	**Baseline**	**Design 1**	**Design 2**	**Design 3**

Casing must be cost-effective (<$1000)	3	0	1	1	1
Casing should mimic the shape of the abdomen	4	0	-1	1	-1
Casing must be adjustable to produce different view planes	5	0	1	-1	1
Casing should be portable/light	2	0	1	0	0
Casing should include incision/trocar sites that mimic the resistance of skin	4	0	-1	0	-1
RANK SCORE			**2**	**2**	**0**

From their rank scores, designs 1 and 2 had comparable features and offered similar benefits to the effectiveness of the device. As requested by the clients, the ability of the abdominal casing to be adjustable was of main priority. While design 2 lacked this feature, it made up for it through its ability to mimic the shape of the abdomen which design 1 did not. Considering both designs included important features that the other does not, the combination of features from both designs to create a final abdominal casing design allowed for the creation of a casing that best met the clients' requests.

4.3.3 Bony Pelvis Production

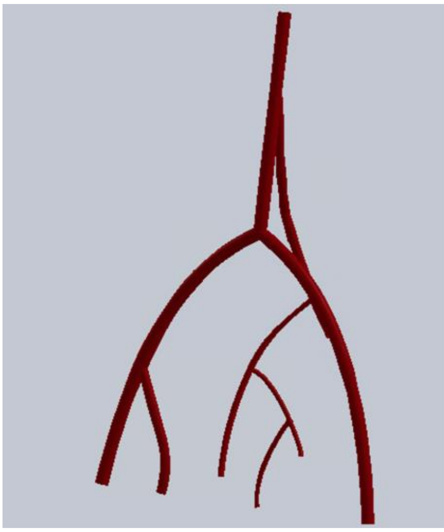
The bony pelvis could be created in two ways: 3D modeled in SolidWorks or commercially purchased. The drawback of purchasing the bony pelvis model was that it would not include the dimensions that were asked for in this model, which consequently would not represent the female pelvis accurately. Designing the pelvis in SolidWorks grants more dimensional adaptability, but the model would need to be printed in multiple parts as it is too large to print as one entity. A relative sagittal plane symmetry to the pelvis can be assumed for designing the model. From the Iliac to the Ischium, the pelvic bone is similar on both the left and right sides. Thus, the bony pelvis can be designed in a few different ways. One way is to design the structure in three sections, as shown below in Figure 27, with each of the three sections highlighted in a different color. First, the left or right side of the pelvis would be designed, and a mirror feature could be used to create the other half. The third part of the structure would be the sacrum, which would fit into grooves on the left and right ilium and be secured with screws. The left and right ischium could be secured with screws across the pubic symphysis. Each piece would be printed from ABS or PLA as accessible by WPI's 3D printing stations, which would reduce the cost significantly.

Figure 27. The pelvic model divided into three parts to allow it to be 3D printed.

In evaluating the proposed ideas of each part of the laparoscopic trainer, some parts required more consideration than others. The choice to either purchase a bony pelvis model or 3D print the model was simply decided by considering the option that provided the most control over the design. Purchasing a bony pelvis model provided an initial prototype that was used to layout the vasculature to see where adjustments needed to be made. For the final design, however, making minor adjustments to a pre-made 3D pelvis model in SolidWorks provided more control over the design of the pelvis which allowed it to be printed in a material of choice and modified to include the requested dimensions.

4.3.4 Vessel Network Simulation

To simulate the vessels with accurate diameters, one solution was to 3D design and print molds for different vessels. The molds could be made from a basic plastic or rubber material, and appropriate biomaterials could be injected inside them to create a tissue-like texture. Figures 28 and 29 below are potential CAD designs of how two mold networks could be used to simulate the structure and layout of the vessels. The image on the left is a molded network of attached vessels. This network could be cross sectioned to act as a casting die which could be filled with a viscoelastic biomaterial. Casting the vessels would allow them to be assembled as one unit. The image on the right involves a mold with two different materials: one to fill the vessel structures, and one to fill the surrounding space to act as a film to connect the vessels. This design idea would create a vessel matrix in which the vessels are connected through a thin filament material to simulate tissue.



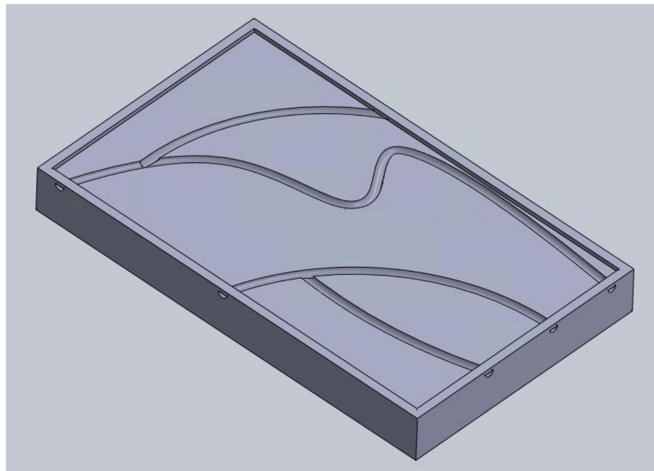


Figure 28. Vessel network. *Figure 29. Vessel matrix.*

Unlike the simulated organs, the vessels needed to be a permanent part of the pelvic model which reduced the need for them to be completely anatomically accurate. While materials such as ePTFE and Dacron are commonly used in the simulation of blood vessels for *in-vivo* use [51], the elasticity of Silicone resembles the elasticity of blood vessels enough to model these vessels. To create the vessels from Silicone, an extrusion die can be 3D printed from PLA or metal, and Silicone can be extruded through it to produce hollow tubes to simulate the arteries. This gives control over the diameters of each artery. The use of either a platinum or peroxide curing bath will solidify and increase the mechanical strengths of the vessels [51]. Dying either the silicone or the curing bath would also allow the color of the silicone vessels to visually match the colors of true vessels. A schematic of this extrusion process is seen below in Figure 30.

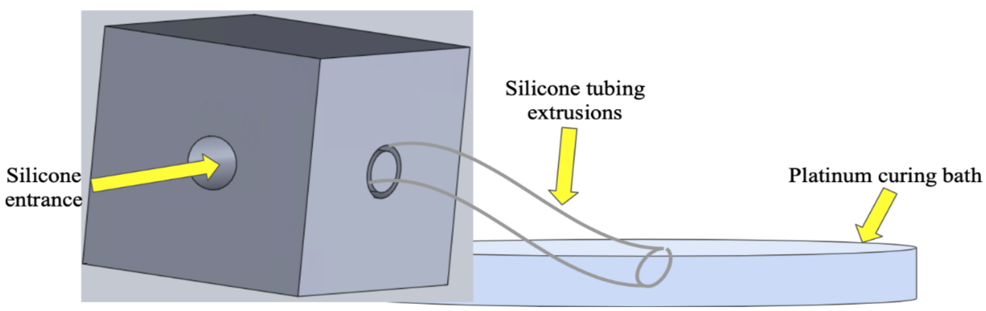


Figure 30. Silicone tubing extrusion process.

Similar to the idea shown in Figure 30, the use of flexible plastic tubing of varying diameters could be used to model the pelvic vessels. Tubing made out of materials such as PTFE, FEP, PVC, and silicone rubber is available in different sizes and lengths for reasonable prices. The tubing is elastic, compatible with different tube fittings, and can be adhered to other plastics. The cost of these materials ranges from $0.20 to $3.20 per foot of tubing and each type is available in red [52, 53, 54, 55]. This would allow for the client requirements to be met at a low cost and with little production. Purchased bonding clips would also allow individual tubes to be connected to create one big vessel network. However, exact diameters of the vessels may not be found and the ability to manipulate the tubing to match the vessel placement may be difficult.

To account for tubing manipulation and accurate dimensioning of vessel size, another alternative was to 3D model and print a casting die in the shape of a vessel network. Filling this casting die with silicone, PVC, or another elastic material would allow the tubing to retain the shape of the casting network which would produce an interconnected vessel network without the use of bonding clips. In this way, the vessels could be dimensioned to any size, and there would be more control over the vessel's proximities to one another. The drawback of this method was the impurities that would be produced in the material due to inaccuracies of the casting process which could reduce the mechanical strengths of the vessels. A potential design of the casting die is seen below in Figure 31. Although this design shows a straight tubular shape, it could be modified to include branches of different diameters.

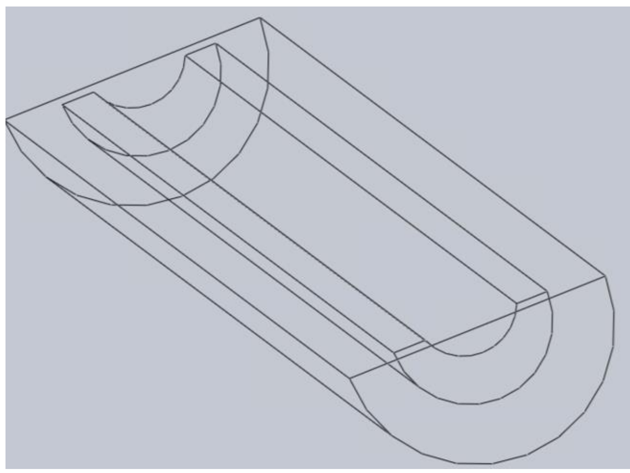


Figure 31. 3D modeled casting mold for creating vessels.

Per request by the clients, it was most important that these vessels be interconnected to form a network. This interconnected network could be accomplished by combining ideas suggested through all of the proposed ideas. This could be done by creating a 3D modeled casting die network that would naturally allow the material to branch off, or by use of bonding clips to attach individual vessels to one another. The latter method would be used in the case of extruding the vessels or purchasing the vessels. Additional requirements for the vessels are that they should be cost-effective, accurately simulate true vessels, be resistant to tear, and be easily attachable. Table 9 below compares the three proposed methods of vessel formation (extrusion, casting, purchased) to the requested requirements.

Table 9. Rank score comparison chart for the formation of the vessels.

VESSEL DESIGN					
Requirement	**Weight**	**Baseline**	**Extrusion**	**Casting**	**Purchase**
Device must be cost-effective (<$1000)	3	0	1	1	1

Vessels must be anatomically accurate (appropriate materials + dimensions + colors)	3	0	0	0	0
Formation of smooth network between multiple vessels	5	0	0	1	0
Durable + tear resistant	3	0	0	0	1
Easily attachable/replaceable	2	0	1	1	1
RANK SCORE			**5**	**10**	**8**

The casting method for the production of the major vessels ranked the highest out of the designs. Although it may not be the most durable or tear-resistant, it was the only idea that allowed for a network of vessels to be created. On the other hand, the second-highest ranked method, purchasing flexible tubing, would provide a more durable and long-lasting material but would be more difficult to make into the smooth network of vasculature that is seen in the pelvis. The extruded vessels do not allow for the formation of an interconnected network nor would they be able to be used repeatedly. Therefore, based on the specifications that need to be met to create an effective trainer, the vessels were formed through the casting process, with a 3D printed mold and silicone filling to create an interconnected vasculature.

4.3.5 Organ Simulation

In addition to the vessels, a similar casting method could be used to create the organs. Molds could be created in SolidWorks that resemble the basic shape of the requested organs (vaginal cuff, uterus, ovaries, etc.). One study [56] created a 3D model of the bladder through the use of 3D printed molds that they sandwiched together. One mold was filled with PDMS, and a mold of the same shape but a smaller diameter was placed into the PDMS-filled mold to produce half of the bladder [56]. This method was created a second time, and the two halves of the bladders were seamed together. Similarly, using PDMS or silicone in conjunction with 3D printed molds of the organs that are to be simulated would allow tissue-like material to be used in the simulation of these organs.

Some of the main requirements for the pelvic organs were the behavioral and mechanical properties that mimic the actual tissue of the organ. It was also imperative that the organs be easily detachable and cost-effective so they can be replaced after use. The client also required that the fabricated organs model the *in-vivo* organs in shape, size, and location. With these specific factors in mind, one idea for the fabrication of the organs was to create a 3D printed mold in the shape of the organ. Phantom organs have been previously created via this method and have used materials such as poly(dimethylsiloxane) (PDMS), agar, cellulose, and gelatin [56, 57]. Similar to the bladder phantom [56], the same mold of the organ but with different dimensions could be printed to allow for layers to be made to replicate the layers of the organ. This would also allow for the control of the thickness of the layers. The materials used to make the mold could be ABS or PLA, both of which are often used and readily available. The material for the actual organ could be PDMS as it is easy to form into complex shapes, has tunable and elastic properties, has a low enough viscosity to enable thin layers, and is thermally curable [56]. Another material option for the organ tissue is a combination of different concentrations of agar and cellulose, as this will allow for simulation of real tissue [57]. It was also found that PDMS was difficult to cure on the PLA without an acetone adhesive spray [56]. Therefore, the mold could be fabricated from either silicone or ABS, and the filling could be several different materials to best simulate the tissue layers present in each organ.

Per request by the clients, it was most important that these vessels be interconnected to form a network. This interconnected network could be accomplished by combining ideas suggested through all of the proposed ideas. This could be done by creating a 3D modeled casting die network that would naturally allow the material to branch off, or by use of bonding clips to attach individual vessels to one another. The latter method would be used in the case of extruding the vessels or purchasing the vessels. Additional requirements for the vessels were that they should be cost-effective, accurately simulate true vessels, be resistant to tear, and be easily attachable. Table 9 below compares the three proposed methods of vessel formation (extrusion, casting, purchased) to the requested requirements.

In comparing the two proposed methods for creating the organs (3D printing vs mold casting), a simple comparison of the advantages and limitations of each was used to decide the best method. Table 10 below compares these two methods.

Table 10. Rank score comparison chart for the formation of the organs.

ORGAN DESIGN				
Requirement	**Weight**	**Baseline**	**3D Printing**	**Mold-Casting**
Inexpensive	4	0	-1	1
Produces few impurities	3	0	1	0
Dimensional accuracy	4	0	1	1
Anatomical accuracy	5	0	1	1
Easily reproducible	5	0	-1	1
RANK SCORE			**3**	**18**

Based on the comparison chart of the organ designs, mold-casting the organs proved to be the most beneficial and cost-effective method for creating the organs. Although 3D printing would produce accurate organ phantoms with few impurities, mold-casting the organs would allow easier re-production of the individual organs. One of the most critical requests was to create organ phantoms that are easily replaceable since constant use of them will lead to deformation, in which case they will need to be replaced with new organ phantoms frequently. Having readily available molds of the phantoms and the appropriate biomaterial (silicone, PVC, gelatin) would allow multiple organ phantoms to be replicated in a short period of time. Although this method is often susceptible to the formation of impurities, such as gas bubbles or pores, this was not a factor that was critical in avoiding, so the advantages of this method outweighed the limitations.

4.3.6 Assembling Techniques

After acquiring all the aforementioned products from constructing the abdominal casing, female pelvis, vasculature, and vital organs, the trainer needed to be compiled to test its functionality as a whole unit. Allowing some landmarks to be replaceable, however, was also considered to account for other surgical procedures that do not require the presence of these parts in the trainer. Therefore, some parts should not be permanently adhered to each other, or be easily removable and attachable for multiple uses. Furthermore, forms of attachment would vary for the different prototypes. For example, the initial, mockup prototype had a lower demand for permanent attachments due to its model purpose of figuring out orientations and positioning of parts. For the purposes of this trainer, the points of attachment that were considered were:

1. Vessels-to-Pelvis
2. Vessels-to-Vessels (interconnected structure)
3. Pelvis-to-Casing
4. Floor-to-Pelvis

The blood vessels of interest could be attached in different ways to the modeled bony pelvis. Vessels may be close enough to make contact with the sides of the pelvis or may need to attach to the pelvis as a modified endpoint.

There are two ways that the silicone vessels can be attached to the female bony pelvis model: permanently through a silicone-bonding adhesive, and detachable with multiple alligator clips. Permanent adhesion would be implemented for areas where vessels of interest would need to remain attached to the pelvis in the model, if necessary. For this, Smooth-On Sil-Poxy, a rubber and silicone adhesive, would be needed due to its ability to fixate silicone materials to plastics, plasters, and fabrics. For instance, some branches of the left and right internal iliac arteries and veins make contact with the internal side of the ilium. Using Sil-Poxy as an adhesive would permit for greater accuracy of the vessels' positioning on the pelvis. Thus, intricate positioning of vessel branches like the left and right Iliolumbar (posterior branch of the internal iliac arteries) could be carefully placed on the two Ilium parts. Meanwhile, for any vessels that may be removable depending on gynecological training or simple prototyping, alligator clips could be situated along the sides of pelvic walls. The mouth of alligator clips would be large enough to fit the diameter of the silicone tubes so that they stay in place conveniently. Furthermore, while one of the critical necessities of the model is to retain anatomical accuracy, endpoints may need to be created for vessels to end for the sake of delineation in an enclosed pelvic unit. Sil-Poxy can also be used to attach the simulated blood vessels to the modified endpoints. Manual pressure would be applied to the surface of the pelvic model while holding the silicone tubes in place to aid the curing and adhesion process of the Sil-Poxy. Proper safety precautions such as wearing gloves and safety glasses are imperative to minimize risks of contamination.

To recreate a realistic structure of blood vessels, the parts needed to be able to be interconnected to match a network that a gynecologic resident would expect to encounter in surgeries. The prototype of the model would incorporate molded silicone tubes as mentioned in the above section and would already have its branches incorporated so that they could solely require attachment onto the pelvis model's surface. For initial prototyping, however, different vessels could also be interconnected in a detachable manner by implementing plastic tubing connectors. These connectors would match the sizing of the tubes to establish sufficient security. The connectors are capable of establishing connectivity in either Y or T forms for three-way connections, and L and horizontal forms for two-way connections. The various forms in connecting allow for various branching and bifurcating structures that can be used to simulate different branches of each major artery and vein while having the ability to be detachable.

The molded pelvic floor muscles would be positioned deep of the pelvic brim and stretch at the bottom from the coccyx to pubic symphysis and would be permanently attached to the pelvis. As mentioned above, the floor muscles would be constructed from PDMS (silicone-based) or silicone, thus, the adhesive Sil-Poxy is a possible option for permanent adhesion.

The orientation of the pelvis inside the casing, as well as the casing's angled incline in Trendelenburg position, must be considered so that the unit stays steadily in place. While elevated, the lower part of the coccyx would be situated towards the elevated side of the casing. For the side of the casing that is elevated and provides a transverse view of the pelvis and its surroundings, a screw can be attached where the coccyx of the pelvic model makes contact with the abdominal casing wall. Additional screws could be added along the abdominal casing walls that represent the sides of the torso to attach the left and right iliac crests to the casing. The holes on the acrylic boards would be accurate to the size of the screws. A summary of the possible attachment mechanisms is seen below in Table 11.

Table 11. Summary of attachments to be implemented for each structure.

Structures involved	**Form of attachment**	**Permanent / Removable**
Vessels to Pelvis	Alligator clips	removable
	Sil-Poxy	permanent
Vessels to Vessels	Tube connectors	removable
Vessels to endpoints	Sil-Poxy	permanent
Pelvis to abdominal casing	washer/screws	removable
Pelvic Floor to Pelvis	Sil-Poxy	permanent

4.4 Final Design Selection

Evaluation of each design component of the laparoscopic trainer led to the decision of the final design choices. Acrylic board casing pieces, a rotating rod mechanism, a female pelvis CAD model found online, silicone mold-casted vessels and pelvic floor muscles, and PDMS-molded organ phantoms were all chosen and used in the final design of the laparoscopic trainer. Each of these features best met the objectives of the final design and the requests made by the clients.

4.4.1 Rotational Abdominal Casing

The abdominal casing for the gynecological laparoscopic trainer was a significant aspect in creating an effective product. There were several factors considered when making the abdominal casing, with the main objectives of this component being as follows:

1. Allow for rotation to mimic patient positioning
2. Replicate the shape and dimensions of the average female abdomen
3. Incorporate accurate sites for instrument insertion

With the consideration of these objectives, the abdominal casing aspect of the trainer allowed for a more accurate representation of the patient and the procedural steps of laparoscopic surgery. The design of the abdominal casing contained several different materials and parts to fulfill the above objectives, including a plastic base and top, plastic sides, and metal rods. Table 1 lists the specific materials used for each part of the casing. The dimensions of the pieces are also listed in Table 12.

Table 12. Materials list for Abdominal Casing.

Part	Quantity	Material	Dimension
Base	1	Acrylic board	Length: 14 in [1, 2] Width: 10 in Thickness: ⅛ in
Side Frame	2	Acrylic board	Length: 14 in Height: 6 in Frame thickness: 1 in Thickness: ⅛ in
Side Wall	2	Acrylic board	Length: 14 in Height: 6 in Thickness: ⅛ in
Top curve	1	PLA	Distance from iliac crest to highest point in the curve: 20 cm
Angle Brackets	4	Steel	Side lengths: 2 cm height : 1.5 cm
Magnets	8	N/A	Diameter:
Curve covering	N/A	Duct tape	N/A
Trocar Inserts	4	PLA and silicone mat	Inner diameter: 2.9 cm Outer diameter: 5 cm Extruded bottom: 0.5 cm
Rotational mechanism	1	Adjustable light	N/A

The abdominal casing was created by laser cutting acrylic boards into the several different pieces listed in Table 12. Laser cutting was used because it is readily available, inexpensive, and each piece is flat, making it relatively simple to cut. Similarly, acrylic boards were chosen as the material for the model casing because it is lightweight, strong, inexpensive, readily available, and compatible with laser cutting. Due to the size of the abdominal casing, it was cut into several parts (base, sides, top). A CAD model of each of the parts of the abdominal casing was created using SolidWorks with the dimensions shown in Table 12. The base of the casing is rectangular in shape and the average distance from the pubic symphysis to the xiphoid process in a female [1, 2]. The width and height of the casing were based on the size of the female pelvis. The sides of the casing are open but framed with another plastic piece that has magnets adhered. There is an additional flat side piece that contains magnets as well so that it can be added or removed when desired. Both the Extrude Boss and Extrude Cut features in SolidWorks were used to create these models. After the creation of the CAD models, each part was converted to the laser cutting software and the acrylic was cut using the laser cutter available in Foisie Innovation Studio at WPI. The pieces were assembled using angle brackets and screws specific for plastic. Figure 32 shows the current abdominal casing box frame with the bony pelvis placed inside.

Figure 32. Abdominal casing box with pelvic model placed inside. Removable walls with magnets shown (left). Sidewalls removed (right).

The curvature of the abdominal casing was an important concept that the team needed to consider when designing the gynecological laparoscopic trainer. Several different concepts were considered when designing the abdominal casing, both with regards to the shape of the top casing as well as the fabrication of the casing. Based on the current trainers available, the initial concept for the top of the trainer was to only provide holes on a flat surface to allow for the laparoscopic instruments to be inserted and used to practice on the model. However, after discussing the limitations of the current trainers with the clients, it became clear that the anatomical accuracy of the abdomen was an important aspect of creating a trainer that was more geared towards gynecology, allowing for better training for residents. Therefore, the focus became fabricating the casing to accurately depict the curvature of the abdomen during gynecologic laparoscopic procedures. Initially, a CAD model was created using the Dome Feature to illustrate the abdomen, however, no dimensions for the curve were used. After further discussion with the client, it was found that there were specific relationships between the top of the abdominal casing and the pelvis that would lead to a more accurate model for training. After several drawings were made to conceptualize the curvature, several ideas on how to obtain the shape were brainstormed. These included 3D printing, thermoforming heat-sensitive plastic around a mesh structure, clay molding over a mesh structure, as well as utilizing casting material. However, with cost, accuracy, and feasibility considered, 3D printing appeared to be the best choice for an initial prototype of the design. Reference planes and the Loft feature were used in SolidWorks to create a model of the curved top abdominal casing, with cut extruded holes where the most common incision sites for GYN laparoscopic surgeries were located. The dimensions of the top piece of the abdominal casing are referenced from the pelvis, with the highest point of the curve being about 20 cm from the iliac crest of the pelvis. Figure 33 displays the 3D printed abdominal curved top piece.

Figure 33. 3D printed model of the top abdominal curve.

After printing the scaled-down version of the abdominal casing curved top, the normal-sized top was printed in PLA. Due to the dimensions of the available 3D printers, the piece was printed in three parts. The middle portion of the abdominal casing top is seen below in Figure 34. While the curvature and dimensions of this print turned out well, the finish on the surface was not as smooth as intended. From the initial small-scale print, two methods of printing the piece were compared to see which provided the smoothest finish. The initial print was printed with the curved part at the top, and the second print was printed with the curved part on the bottom. Since the smoothest finish of the piece came from printing the piece inverted, the large-scale model was printed in this way.

Figure 34. Final abdominal casing top PLA print.

The curved portion of the large-scale piece was the sturdiest part of the entire casing top, but the finish in the center was rough due to the curvature of its shape. The other pieces of the casing top were printed successfully, with some roughness along the curve and Super Glue was used to attach the three pieces together. However, there was some weakness along the points of attachment, so Duct tape was used to reinforce the part as a whole. This also allowed for a smoother finish for the top curve. An image of the final top curve as one piece is shown in Figure 35, and the dimensional drawing is seen in Appendix A.

Figure 35. Abdominal casing top as one piece with Duct tape covering.

The final design of the top casing of the trainer also included parts that could be inserted in the holes that represent the incision sites during procedures. Initial designs of the part were found to be too large in diameter to fit into the holes of the top casing and too thin to be able to be easily moved from site to site. Therefore, several modifications were made to the CAD model, and the insert parts were created so that the instruments used in training could be easily switched when necessary. The parts can be removed with little resistance and contain a silicone mat, which allows for a rubber-like material that will better simulate the resistance that might be felt during a real procedure. Each of the four insert pieces contains a trocar of specific diameter and can be moved from site to site. An image of the insert part in and out of the abdominal casing top can be seen in Figure 36. The pieces were designed in SolidWorks and 3D printed in PLA, based on the dimensions of the holes in the abdominal casing top. The dimensions of the part can be found in Table 12, and the dimensional drawing is seen in Appendix B.

Figure 36. Abdominal casing inserts for instruments. CAD model of insert part (top left), 3D printed model with silicone top (bottom left), and parts inserted into top curve (right).

The instruments will be supplied by the hospital and inserted by the residents based on their process during laparoscopic surgery. After the top curve of the abdominal casing box was completed, the rotational mechanism for the box was considered and created.

Although there were several ideas for a rotational mechanism that would allow for the abdominal casing to move into the positions necessary for the resident to train in, the final prototype of the design included a pre-existing mechanism to rotate the box. After several attempts of designing and creating a new rotational piece, due to time constraints, 3D printer dimensional limitations, and lack of appropriate materials, a device was purchased to account for the mobility necessary for the trainer. Based on the mechanisms designed in the brainstorming step of the design process, several different items were considered for the mobility part. These included camera tripods, swivel mounts, rotational mirrors, and adjustable lights. The product that is used in the final design is an adjustable light that has been altered to best fit the trainer. This product was chosen because of its cost, applicability, and availability. The light was removed from the fixture and the adjustable stand was attached to the bottom of the abdominal casing box. An image of the modified light fixture stand is shown in Figure 37.

Figure 37. Modified adjustable light fixture for the rotational mechanism of abdominal casing box.

The box can sit on the rectangular light piece of the product and the handle can be loosened to move the piece up and down and tightened to lock the position in place. The rectangular open box piece also contains a thin border of foam, which is beneficial in attaching the box to the mechanism, so the risk of the abdominal casing box sliding is reduced. Moreover, the adjustable mechanism is on a stable stand that is still light and portable. The box can be moved into the necessary positions for accurate training, as shown in Figure 38.

Figure 38. Abdominal casing box placed on the purchased rotational mechanism.

The box was placed on the adjustable light and was able to be moved back and forth without slipping. Once each piece of the box was completed, including the pelvis, and all parts inside the pelvis, the box was permanently attached to the adjustable part.

4.4.2 3D Printed Bony Pelvis

In making the bony pelvis, multiple CAD file designs of a female pelvis found online were compared to one another. Due to the size of the available 3D printers, the chosen pelvis design was based on printing capability, dimensions, and the number of parts. Entire, one-piece pelvis CAD models were found, but the size of the files restricted editing abilities and was too large to print as one piece. The final pelvis model file was chosen due to its dimensional accuracy and ability to be printed in six parts. The bony pelvis was 3D printed from black PLA. The first print was oversized by four inches in width, from one iliac crest to the other. A second print, each part scaled down**,** more accurately achieved the proper dimensions as requested by the clients. The six printed pieces were attached with superglue to create the pelvis assembly. The final bony pelvis design used in the final laparoscopic trainer design is seen below in Figure 39.

Figure 39. Final design of bony pelvis.

The pelvic floor is made up of layers of muscle and tissue. Initially, the muscles were drawn onto pieces of felt. They were cut out and taped down to the bony pelvis to depict proper placement. Once the placement was confirmed to be correct, each muscle was removed and subsequently traced onto a silicone mat. A pink silicone mat was used to mimic the color and texture. They were then cut out and placed into position on the pelvis. Once each muscle was placed correctly, they were glued down with Sil-Poxy glue to stick them to the pelvis. This method proved to not be as strong enough to hold the organ phantoms and vasculature network. Instead, a mesh material was placed in hot water to make it flexible. Once flexible, it was manipulated to form the shape of the pelvic floor and left to harden. This final design is seen in Figure 40.

Figure 40. Pelvic floor on the pelvis.

4.4.3 Silicone-Molded Interconnected Vessel Network

Silicone molding was used to design the interconnected vessel network. The final model included the branched silicone tubing, mimicking the interconnected networks. SolidWorks was used to create a 3D model of the vessel network. The initial CAD model was used to test the silicone molding process, and limited dimensional accuracy was used in this design. This SolidWorks design is seen in Figure 35. The vessel network was generated as a solid body to create the mold. The vessel design was 3D printed in PLA plastic. This 3D printed vessel network is seen below in Figure 41. Due to the small dimensions of this design, the 3D print did not print as intended. The branches with the largest diameters maintained relatively accurate diameters and circular cross-sectional shapes, but the smaller branches printed with rectangular cross-sections. To create the molded vessels, an initial silicone-molding trial was carried out with the first vessel network prototype to assess the validity of this molding process. The Limino Silicone Mold Making Kit was used to create this first mold. The silicone was poured into a Tupperware container, and the vessel network was placed on top, with the bottom half of the model submerged in the silicone and the top half uncovered, exposed to the air. After about 12 hours of sitting, the silicone cured effectively. An image of the first vessel SolidWorks design is seen below in Figure 41.

Figure 41. Vessel network CAD model (left), 3D printed PLA vessel network (middle), and vessel network in silicone molding process (right).

To generate the second half of the mold, a release agent was sprayed onto the surface of the exposed vessel network and the hardened silicone before pouring the new silicone onto the mold. The top of the mold with the exposed vessel network piece was then coated with silicone and left alone to harden. Upon solidification of the second half of the silicone mold, the release agent did not work as intended and the two halves were unable to be easily separated from one another to create the two halves. As a result, the mold had to be cut in half so two halves could be created. An image of this silicone molding process is seen below in Figure 42.

Figure 42. Silicone molding process for creating a vessel network mold.

Upon separating the two halves of the vessel mold, the 3D-printed part was removed from the mold. To create the silicone vessels, saran wrap was inserted into the mold to act as a makeshift release mechanism to prevent the silicone from sticking to the mold and becoming one piece. Silicone was then poured into the mold with the vessel indents. The second half of the mold was placed on top, and more silicone was poured into the mold to ensure it was completely filled. The silicone was left to harden, and the two halves were carefully removed once it was solidified. The resulting silicone molded vessels are seen below in Figure 43. Although not a clean finish, the molded vessels showed promising capabilities for the final design.

Figure 43. Initial trial of silicone molded vessels.

Following the initial trial with silicone molding, a final SolidWorks model of the vessels with accurate dimensions was created. The final vessel model designed in SolidWorks was based on a felt mockup of the vessels created by the clients. This model provided visualization of the vessels on the final bony pelvis model, which allowed accurate locations of arterial branches to be simulated in SolidWorks. In translating this felt vessel network mockup to SolidWorks, a few main features were utilized. The abdominal artery and the external iliac arteries were created as one unit. Reference planes were created at angles from the external iliac arteries to create the branching of the internal iliac arteries. The same concept of reference planes was used to create branched arteries from the internal iliac arteries to represent the ovarian, uterine, and umbilical arteries. Circles of similar diameters were created on all reference planes, and they were extruded using the swept boss feature. The final SolidWorks model of the vessels and the subsequent 3D print are seen below in Figure 44, and the dimensional drawing of the model is seen in Appendix C. Due to the large size of the vessel network, the model was split along a mid-plane to create three separate bodies that fit in the printer. The three separated 3D printed pieces are indicated by different colored pieces of the entire model which were glued together.

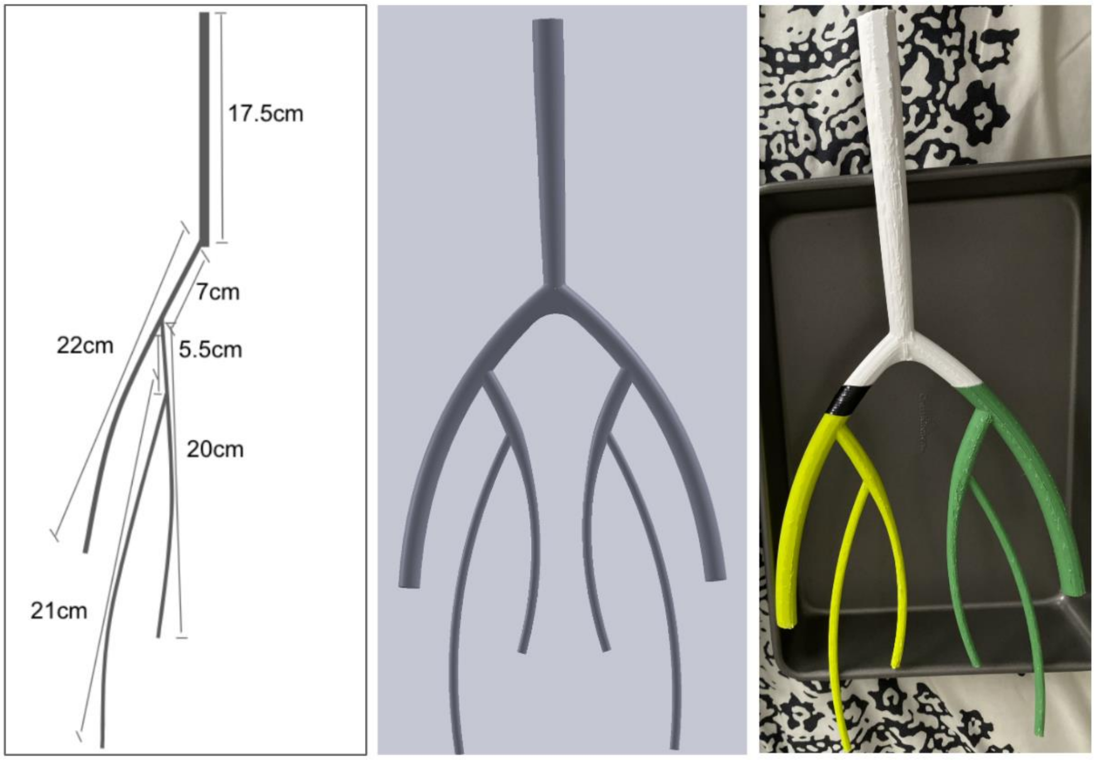


Figure 44. Artery lengths (left), final SolidWorks vessel model (middle), and 3D printed PLA print.

This final model of the vessels includes the abdominal artery, left and right common iliac arteries, left and right external and iliac arteries, uterine arteries, and umbilical arteries. The abdominal artery of 17.5cm in addition to the external iliac arteries of length 22 cm were all created with a diameter of 17 cm. The internal iliac arteries were created with a diameter of 10cm, and both the uterine and umbilical arteries were created with a diameter of 4 cm. From the 3D printed vessel network piece, three different attempts at generating the silicone molded network were done. The first trial involved creating a silicone mold from the 3D-printed part. Due to a combination of lack of silicone and the large dimensions of the mold, the resulting silicone network was not successful. The second mold was created by using moldable clay. The 3D printed vessel model was pushed into the clay, and the clay hardened with the vessel network indent. This mold was overlaid with saran wrap to minimize the sticking of the silicone to the clay. The silicone mixture was poured into this model, but the resulting silicone vessel network did not solidify completely. This was most likely due to the fact that the moisture from the clay seeped into the silicone which prevented it from completely solidifying.

Figure 45. Finalized 3D printed molding part for silicone vessel network.

The final and most successful method of creating the silicone vessel network was completed by using the 3D printed PLA vessel network as the mold. The solid SolidWorks model was hollowed out, and it was split down the middle to create half a mold. Caps were added onto the ends to prevent the silicone from escaping at the ends during the filling process. This piece was then used to create the silicone vessels by filling them with the silicone mixture and letting it solidify. The resulting vessel network was flat on one side and round on the other as a result of half of the entire piece being used (Figure 45). The flat side of the vessel network phantom also allowed for easier attachment of the vessels to the pelvis. The three molds used for the silicone molding process and the final creation of the silicone vessel network phantom and the 3D printed part are seen in Figure 46. The phantom creation was repeated using a different dye color for visible differentiation between arteries and vessels.

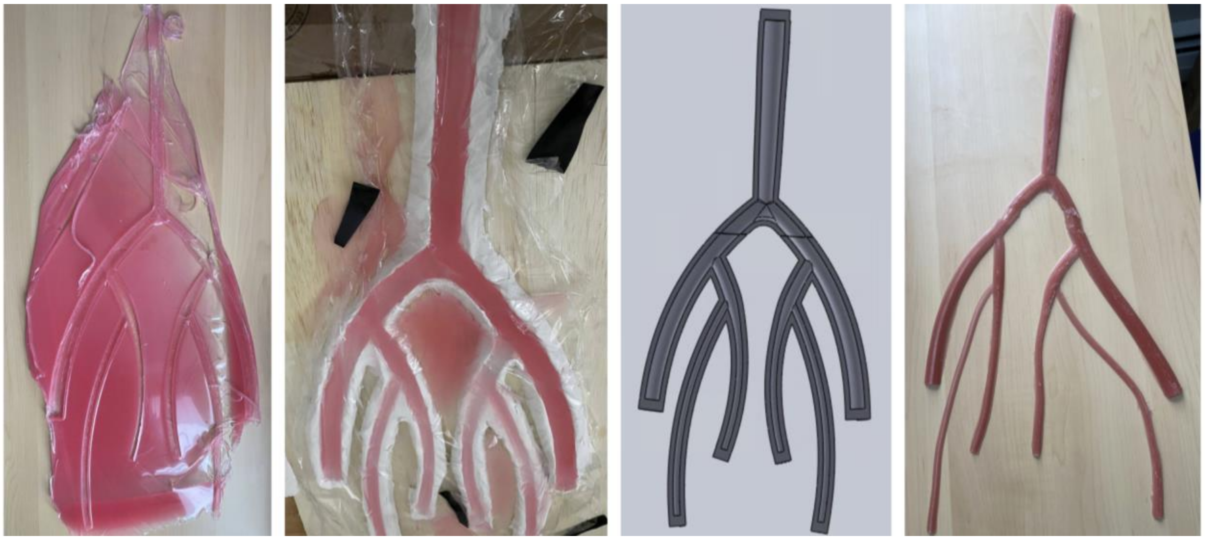


Figure 46. Three molds used in the vessel network silicone molding process of creating the vessel network; silicone mold (left), clay mold (middle left), 3D print PLA mold (middle right), and final vessel network phantom (right).

For the finalized vessel network phantom, the Limino kit's silicone preparation instructions were followed. Using a measuring cup provided in the kit, about 45 ml of the Part B mixture was poured into a plastic container. Then, brown and red liquid silicone coloring dye was added to the same container. The two colors were of best interest due to past silicone curing experiments that showed more visually realistic appearances. After mixing with a wooden flat stick for approximately 3 minutes, 45 ml of the Part A mixture was poured into the container using a different measuring cup. After mixing thoroughly for about 5 minutes, the mixture was poured into a plastic squeeze bottle to allow for easier pouring into the 3D printed molding part (Figure 41). With the squeeze bottle, all the liquid was poured into the mold and stored at room temperature for adequate curing for 12 hours.

With the same 3D printed molding part (Figure 45), two silicone-based ureter models were created as seen in Figure 47. This process required only about 10 ml of Part A and Part B mixtures each, and the same colorant dyes were added before curing. Instead of requiring the entire part, however, the narrower, inner branches were used for molding. This is due to the similar diameters of the ureters to those respective branches.

Figure 47. Silicone-molded ureter models.

4.4.4 Silicone-Molded Uterus Phantom

The requested organs to be included in the final design of the laparoscopic trainer were the uterus and vaginal cuff. The uterus was created using 3D printed models to be used for creating the phantoms from silicone using a molding process. An initial uterus model was designed in SolidWorks for testing, so no dimensional accuracy existed within this first model. An image of this model is seen below on the left in Figure 48, and the corresponding 3D print is seen on the right. This initial print in PLA plastic did not print as expected, with the curved bowl shape of the uterus not printing any material. This printing malfunction was most likely contributed to the thin wall thickness used to create this design in SolidWorks. Based on this initial print, the wall thickness of the second uterus model was increased to avoid this printing malfunction for future prints.

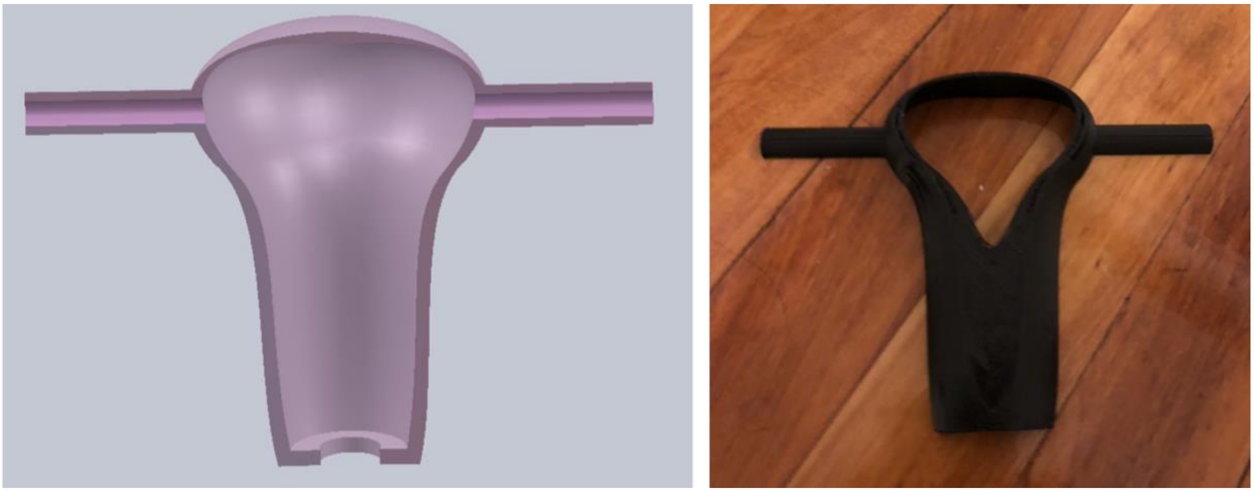


Figure 48. First SolidWorks design of uterus (left) and first 3D print of uterus (right).

Following the initial print of the uterus model, a new SolidWorks model was generated to include more accurate dimensions based on literature as well as an increased thickness to prevent future 3D printing malfunctions. To create 3D printed molds compatible with the silicone molding process in which the uterus would be hollow, an outer hollow piece and inner solid piece were created. Figure 49 below provides a SolidWorks image of these two pieces with the inner mold placed inside the outer mold. The addition of this inner mold allowed the outer hollow piece to be filled with silicone and hollowed out by placing and pressing down the inner mold on top of the silicone. The length, width, and depth of the outer uterus model and thus the silicone mold were 9.7 cm, 7.6 cm, and 2.4 cm, respectively. The inner model had a length, width, and depth of 8.94 cm, 6.68 cm, and 2.4 cm. In this model, the fallopian tubes branch off with a length of 0.434 cm and a diameter of 0.30 cm. The dimensions of the fallopian tubes in addition to the uterus were overestimated to take into account the shrinkage that occurs during the silicone molding process. An image of the inner and outer uterus models created in SolidWorks is seen below in Figure 49 along with the resulting PLA 3D prints. The dimensional drawings of the models are seen in Appendix D.

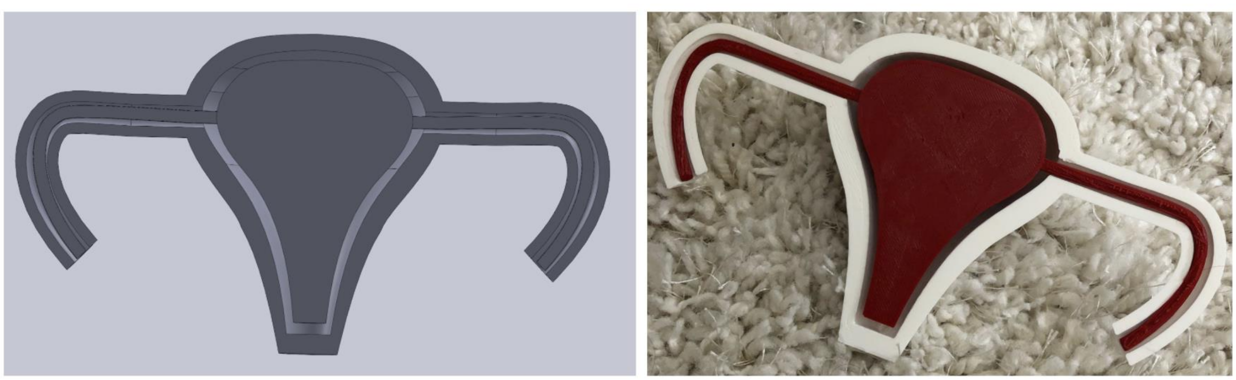


Figure 49. Second uterus SolidWorks model.

Following the 3D printing success of the inner and outer final uterus models, the silicone molding process was completed. The preparation and curing process followed for the uterus model was similar to that of the vessel network, except only about 20 ml each of Part A and Part B mixtures were utilized and mixed. Solely brown dye was also added to allow for slight color variation between the uterus and vessel models.

After pouring in the mixture to the hollow uterus mold (white), the smaller, scaled-down part (red) was pressed into the bigger part. A small box was placed directly on top of the smaller part to add stability and prevent excessive floating as seen in Figure 50. This was to create a hollowed-out mold for one-half of the uterus. After allowing the silicone mixture to cure for approximately 12 hours, a small knife was used to carefully remove excess silicone, and peel off the cured silicone from the sides of the mold. The process was repeated to create the second half of the uterus model. Once cured, the two halves were adhered together using Sil-Poxy.

Figure 50. Silicone molding process for creating half of the uterus phantom.

The result of the silicone molding process to create the initial and final silicone molded uterus phantom is seen below in Figure 51. This final model was hollow and included the fallopian tubes. In its entirety, the flexibility of the fallopian tubes and the uterus did well to mimic the texture and feel of tissue.

Figure 51. Initial silicone molded uterus phantom.

Although the length and width of the uterus model were accurate according to literature and fit well with the 3D printed pelvis, the depth of the uterus was too large. Thus, the depth of the SolidWorks uterus model in the z-direction was scaled down to a depth 0.9 times the original depth. The length and width of the uterus model, however, maintained the same dimensions as the original model. The resulting 3D PLA print was used to create a new, final silicone uterus phantom. The resulting inner and outer PLA molds and the silicone uterus phantom are seen below in Figure 52.

Figure 52. Final uterus 3D printed PLA parts (left) and final silicone uterus phantom (right).

4.4.5 Vaginal Cuff Model

The creation of the vaginal cuff required more detail to anatomical accuracy as this organ phantom was intended to experience repetitive contact from residents using the laparoscopic trainer. An initial SolidWorks model was created using dimensions found through literature. As seen below in Figure 53, the vaginal cuff was created with a height of 4 cm, an outer long diameter of 3.5 cm, and an outer wide diameter of 2 cm. The inner lengthwise diameter was 3.2 cm, and the width-wise inner diameter was 1.8 cm. Through research, it was found that the cylindrical shape of the vaginal cuff tends to taper outwards with the increasing height, so the SolidWorks model was designed as such to mimic this effect. As a result, the diameters of the top end of the piece were 0.2 cm longer in all directions in relation to the previously mentioned dimensions for the bottom end. The wall thickness of the vaginal cuff was created to be roughly 0.3 cm as an average value found through literature.

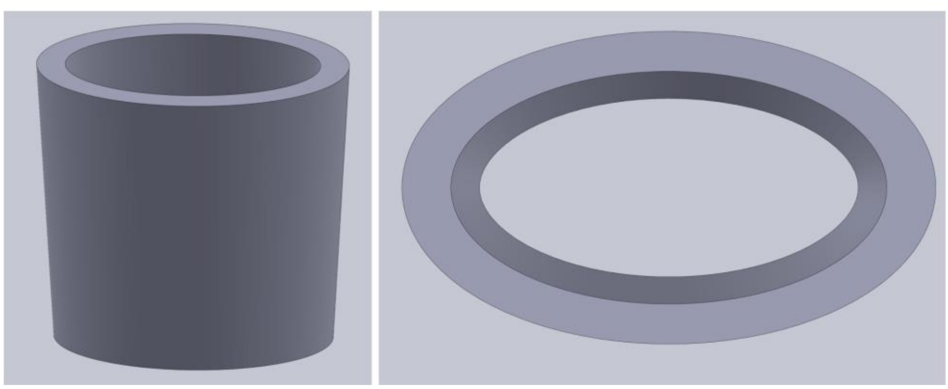


Figure 53. SolidWorks CAD model of vaginal cuff.

As the vaginal cuff is very flexible and the accuracy of the vaginal cuff phantom was of higher importance compared to the accuracy of the other organ and vessel phantoms, Thermoplastic Polyurethane (TPU) was used to 3D print the SolidWorks model. The initial print of the vaginal cuff in TPU is seen below in Figure 54. While this model turned out to be compressible, the part itself was not flexible in terms of being easily bendable.

Figure 54. Vaginal cuff model 3D printed in TPU.

After consulting with an expert on 3D printing and the printing materials, TPU remained the material of choice, however, modifications were made to the printing process to obtain a more bendable piece. The infill density of the sliced model was lowered, and the orientation of the piece was changed to get a part that is more flexible in the desired direction. The new 3D-printed vaginal cuff was more bendable than the initial model and more compressible.

The model printed in TPU did not meet the requirements for the residents, as it could not be sutured shut. Therefore, the same silicone molding process used for the vessels and uterus was done for the vaginal cuff. A mold for the cuff, based on the dimensions of the vaginal cuff provided, was created with CAD on SolidWorks, and was 3D printed in PLA. The outer part of the mold was rectangular with the outer dimensions of the cuff used to create a cutout of the part. The inner dimensions were then used to create a removable inner piece that would allow for the vaginal cuff to be hollow with thin walls. The drawings of the inner and outer mold designs can be found in Appendices E and F. There were some challenges with removing the silicone model from the mold due to the small dimensions of the part, however with some adjustments to the mold, the silicone vaginal cuff was able to be produced. The final silicone cuff fabricated using the 3D printed mold and silicone mixture is shown in Figure 55.

Figure 55. Silicone molded vaginal cuff model.

4.4.6 Assembly of the Entire Device

Various techniques were explored for the different prototypes, but the final design was narrowed down to mostly permanent forms of attachment. Some parts of the model are removable, however, but stay securely in place unless carefully taken out (i.e., fastened by screws). One attachment consideration that was taken into account for the entire design was connecting the vessel network to the pelvis. The team decided that attachments of the silicone blood vessel models to the 3D printed pelvis needed to be securely affixed to retain the final prototype's salient concept of improved visualization and anatomical accuracy. The silicone blood vessels were attached to the bony pelvic model using alligator clips, as manipulation and adjustments to the model placement could be made if necessary. The positioning of the vessels was obtained using the prototype altered by a surgical resident as a reference. The pathway for the placement of the vessels was initially drawn on to ensure that anatomical accuracy was achieved. Although it was difficult to place them exactly where they lie in the body, due to the fact that they can differ in placement from person to person and can move slightly based on the positioning of the patient, the alligator clips used accounted for adjustments being necessary. The general placement of the vessels was achieved so that residents can get a better understanding of where they are when practicing laparoscopic procedures. The pelvis with the produced vasculature and organs can be seen in Figure 56.

Figure 56. Bony pelvis with vasculature and organs.

After the vessels were secured to the pelvic model, the model was attached to the casing box. Several options were considered for attachment, including screws and superglue. However, it was found through initial prototyping that superglue was not a sufficient adherent for the pelvis to the box. The pelvic model must be secure as the box will be moving positions frequently and the two must move as one unit. Therefore, the pelvic model was screwed onto the box. Holes will be drilled into both the pelvis, as well as the box to allow the screw to be inserted into both pieces. To obtain the correct positioning of the pelvis in the box, screws were placed in the iliac crests to the sides of the casing. This also allowed for maximum security of the pelvis to the box. The abdominal top curve was then attached to the box using Velcro strips so that it could also be removed if desired. The trocar inserts were placed into the incision and the box was attached to the mobility mechanism. The final prototype of the laparoscopic trainer can be seen in Figure 57.

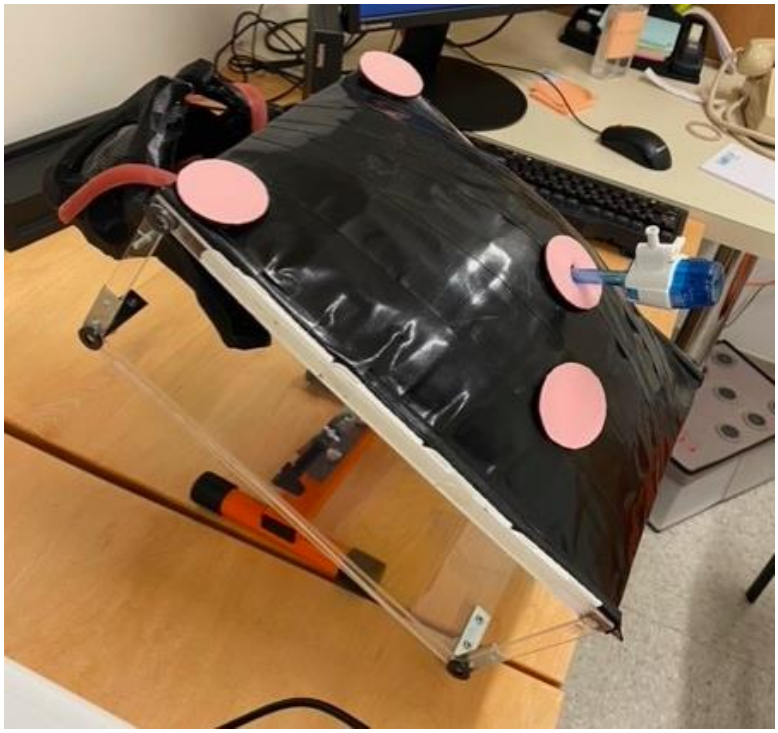


Figure 57. Final prototype of gynecological laparoscopic trainer.

Section 5. Design Verification and Validation

To ensure the team's device met the client's requests and main design objectives, verification methods and subsequent data analysis to validate these features were administered. While many design objectives were specified for each component of the device (pelvis, casing, and organs/vessels), the overall design objectives included anatomical accuracy, cost-effectiveness, and trainer adjustability. By looking at the device in its entirety, it is seen that the device meets these requirements. However, it was of interest to determine to what extent the final design met these objectives. To determine this extent, quantitative and qualitative tests were carried out. The first set of tests consisted of qualitative, mechanical testing in which the anatomical accuracy of the silicone was evaluated through Instron testing. The second group of tests consisted of resident testing. Utilizing initial surveying and post-surveying, this testing provided qualitative validation of the final design from residents who would be most likely to use the device. Overall, both types of testing allowed the team to verify specific design choices used in the process of creating the device in addition to validating the device as a whole in regard to the specified design objectives and client requests.

5.1 Mechanical Testing

A mechanical test was performed to verify and validate one of the components of the design, anatomical accuracy of the vaginal cuff to ensure that closure of it could be practiced, as well as the accuracy of the vessels/and organs. Mechanical testing for the vaginal cuff model was carried out through compression testing to analyze the durability of the silicone at various ratios of mixing agent to silicone mix. Evaluating the flexibility and compression strengths of the silicone allowed the team to validate the choice of using silicone and specifically, the choice to use a specific ratio. Various ratios of the silicone mixtures created three different material compositions that could be compared to real vaginal tissue to find which most accurately resembles the true anatomy. The corresponding ratio and mechanical properties of the models confirmed the choice of silicone flexibility. Mechanical properties and behavior such as modulus of elasticity and flexibility are most relevant to the vaginal cuff as this is the structure that will be operated on most by the residents. Cross-referencing the results with values found through literature searches provided a means of validation of the material chosen for the aspect of the trainer.

5.1.1 Compression testing of silicone

To verify the decision to use silicone in producing anatomically accurate vessels and organs in terms of haptic feedback, a compression test was done. Various mixtures of silicone to curing agents were used to create three vaginal cuffs of varying flexibility. The ratio of Part A, the curing catalyst to Part B, the polymer bases of silicone mix for each of the vaginal cuff models is shown in Table 13.

Table 13. Outline for Silicone Compression Testing.

Silicone Compression Testing		
Trial #	**Part A (mL)**	**Part B (mL)**
1	**20**	**20**
2	**20**	**15**
3	**15**	**20**

Following the fabrication of the three silicone vaginal cuff models, the protocol outlined in Appendix G was followed to obtain the modulus of elasticity of each of the models. Each specimen was placed under compressive loads and the displacement of the part was measured. The experimental setup is shown in Figure 58, with F being the load applied to the model, $L_{1,initial}$ the initial height of the cuff opening when laying on its side, $L_{2,initial}$ the initial width of the cuff opening, and $L_{1,final}$ and $L_{2,final}$ the final dimensions of the cuff opening after the load was applied.

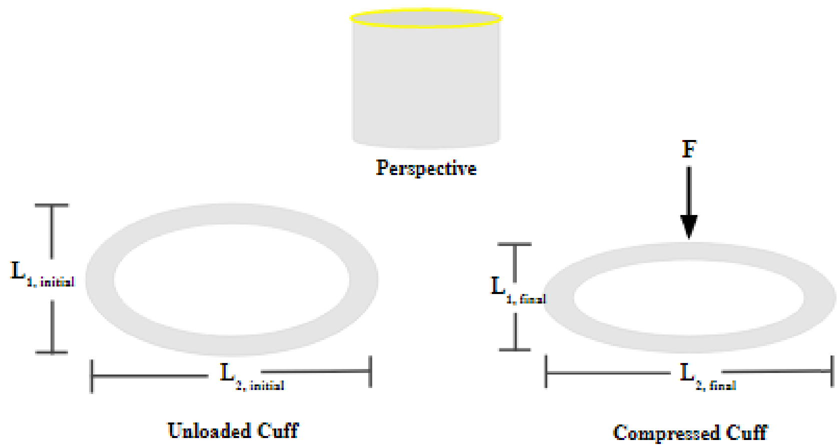


Figure 58. Compression test for vaginal cuff model set up.

The compression testing showed that the three different vaginal cuff models had varying mechanical behavior. Each test was done three times to ensure that enough data was collected to perform statistical analysis. Using the calculated stress and measured strain from the experiment, the equations given in the protocol seen in Appendix G were used to find the elastic modulus of each of the models. Three different load sizes were used to increase the data collection sample size. The average data values from the three trials for stress, σ, lateral strain, ε_{lat}, longitudinal strain, ε_{long}, and elastic modulus, E for the three loads are shown in Table 14, Table 15, and Table 16.

Table 14. Average compression test data for 0.111N load

Force 1: 0.111 Newtons				
Cuff	**σ [Pa]**	ε_{lat}	ε_{long}	**E [Pa]**
1	93.96	0.031	0.128	897.81
2	82.77	0.066	0.106	984.07
3	82.77	0.026	0.119	717.36

Table 15. Average compression test data for 0.222N load

Force 2: 0.222 Newtons				
Cuff	**σ [Pa]**	ε_{lat}	ε_{long}	**E [Pa]**
1	187.91	0.044	0.134	1516.74
2	165.54	0.092	0.209	831.40
3	165.54	0.037	0.215	772.53

Table 16. Average compression test data for 0.333N load

Force 3: 0.333 Newtons				
Cuff	**σ [Pa]**	ε_{lat}	ε_{long}	**E [Pa]**
1	281.87	0.079	0.178	1602.31
2	248.32	0.113	0.279	896.70
3	248.32	0.016	0.029	793.72

The vaginal cuff model 1 was found to have the highest elastic modulus for each of the applied loads, with an average value of 1339 +/- 511.2 Pa. The high elastic modulus of Cuff 1 demonstrates the higher strength of the silicone material when equal parts of the silicone mix is used. It shows that there was less deformation seen when a load was applied, as the longitudinal and lateral strain values are smaller for Cuff 1. The third model showed the lowest elastic modulus values, averaging to be 761.2 +/- 100.6 Pa, indicating that there was more deformation seen when a load was applied and therefore demonstrated a lower strength material. The 1:1 ratio of the silicone mixtures therefore produced the highest strength vaginal cuff model while the 3:4 ratio mixture produced the lowest. The average elastic modulus values for each of the cuff models can be seen in Figure 59, with the error bars showing standard deviation.

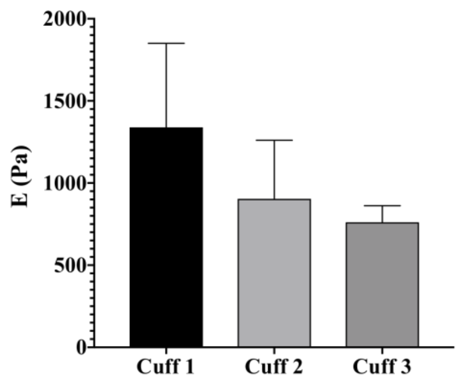


Figure 59. Elastic modulus of the three vaginal cuff models of different composition.

The mechanical testing of the silicone vaginal cuff models showed that a mixture of equal parts of curing catalyst and polymer base produced the model with the highest elastic modulus. In order to analyze this data and the significance to the trainer, comparisons between the three different vaginal cuff models, as well as real vaginal tissue were made. This allowed for analysis of whether the vaginal cuff model would be a good representation of the mechanical behavior seen in actual vaginal tissue.

5.2 Trainer Validation by OB/GYN Residents

The team's trainer underwent validation testing by gynecologic residents of UMass Memorial to garner client perspective on its features and capabilities. This ensured that the trainer met the client's needs for gynecologic laparoscopic training, and it measured the extent of improvement from their curriculum's current trainers. The questions targeted the Ethicon and FLS trainers at UMass in addition to the team's design of a trainer. These questions involved abilities to perform surgical tasks that are relevant to current laparoscopy for gynecologic practice. Validation measurements using these questions were divided into two surveys: a pre-questionnaire that focused on the capabilities of the trainers at UMass and a follow-up survey that focused on the team's design. Both surveys required rating respective trainers and room for the testing residents to list improvements or describe further recommendations to gain more input and perspective that was otherwise not gathered from the other questions.

5.2.1 Pre-Questionnaire

The pre-questionnaire contained questions for residents to answer regarding their currently used trainers at UMass. This survey was provided to three residents of different levels of training prior to testing the team's trainer to collect their perspectives on the current trainers used at UMass and the extent to which those trainers allow for surgical laparoscopic practice. The questions in this survey are seen in Appendix H. These questions were formed to get resident feedback on the ability of the trainers at UMass to improve basic surgical skills such as depth perception, bimanual coordination, camera manipulation, intraoperative communication with peers, and skills directly related to gynecological procedures. The other questions in this survey were related to resident training levels, the trainers residents had experience in using, resident perspective on the ability of the trainers to improve their skills, suggested improvements of the current trainers, and limitations of the current trainers. The results of the pre-survey are summarized below in Table 17. All question topics are specific to the current trainers at UMass including the Ethicon trainer, the FLS trainer, and a third plastic trainer. All questions that involve a rating were rated on a scale of 1 to 5.

Table 17. Summary of pre-survey results from residents.

Question Topic	**Resident 1**	**Resident 2**	**Resident 3**
Level of training	PGY1	PGY2	PGY3
Trainers used	FLS, Ethicon	FLS, Ethicon, plastic trainer	FLS, Ethicon, plastic trainer
Current trainers' usefulness	3, somewhat useful	4, very useful	2, minimally useful
Ability to practice depth perception	3, somewhat similar to *in vivo* laparoscopy	3, somewhat similar to *in vivo* laparoscopy	2, minimally similar to *in vivo* laparoscopy
Ability to practice bimanual coordination	4, fairly	3, somewhat	1, not at all
Ability to practice camera manipulation	1, not at all	1, not at all	1, not at all
Ability to practice angles or space of procedures	N/A	1, not at all	1, not at all
Ability to practice gynecological procedural skills	N/A	3, some skills/steps	2, few skills/steps
Ability to practice intraoperative skills with peers	N/A	1, not at all	2, minimally
Improvements	N/A	N/A	pelvic anatomy, vaginal cuff closure
Limitations	N/A	tool availability; trainers cater to general surgeons only	Time

The three pre-surveys were filled out by residents at three different stages in their residency, and all residents had experience in using the Ethicon and FLS trainers at UMass. The general results of the survey validated the fact that UMass residents feel the current laparoscopic trainers offered to them could do better to provide more learning opportunities to advance their learning. Feedback showed that the main limitations of the current trainers are their assortment of tools, time spent using the trainers, and the fact that the trainers are geared towards general surgeon procedures versus gynecological procedures. In terms of the overall usefulness of the trainers as viewed by the residents, the average score was a 3.3 in which residents feel the trainer is somewhat useful in advancing their skills. An average score of 2.6 was given to the trainers' abilities to allow residents to practice depth perception, and an average score of 2.7 was given to their ability to allow residents to practice bimanual coordination. The only category in which all residents provided the same rating was for the ability to practice camera manipulation using the trainers, which was rated a score of 1, meaning the trainers do not allow for camera manipulation. Scores of 1 were also provided by two of the three residents relating to the ability of the trainer to allow for the practice of laparoscopic surgery in a female pelvis with regard to the angles and space of procedural skills. The pre-survey results also showed that residents feel that while the current trainers allow them to practice some skills, improvements could be made such as the incorporation of pelvic anatomy and the ability to practice vaginal cuff closures. The results of these pre-surveys were later compared to that of the follow-up survey following testing of the team's laparoscopic trainer.

5.2.2 Follow-Up Survey

Following the collection of data from the pre-questionnaire, participating residents had the opportunity to perform surgical simulations on the team's trainer and validate its effectiveness in achieving these tasks. Their input and observations were subsequently noted through the follow-up survey, which encompasses similar questions to the pre-questionnaire that was given to them before testing. The follow-up survey questions for the team's simulator are as seen in Appendix I. As aforementioned, the questions and tasks required for participating residents were closely related to the methods of assessment of the GOALS validation for laparoscopic surgery. The questions involved gathering residents' perspectives on the new trainer's ability to simulate depth perception, dexterity skills, anatomical handling, and certain gynecologic steps in surgery.

The results of the follow-up survey were compared to that of the pre-questionnaire and further analyzed to determine if there were any forms of improvement or efficiency gained from the new trainer in juxtaposition to current trainers. The residents' feedback on further forms of improvement for the new trainer were taken into consideration for future prospective. This data and provided feedback are demonstrated below in Table 18.

Table 18. Summary of post-survey results and feedback.

Question topic	Resident
Level of training	PGY3
Overall rating of team's trainer	3, Somewhat useful
Ability to practice depth perception/spatial awareness	4, very similar to *in vivo* laparoscopy

Ability to practice bimanual coordination	4, fairly
Allow for practice of camera manipulation	4, fairly
Allow for practice of laparoscopic surgery in pelvis (regarding angles and space of common procedures)	3, somewhat similar to *in vivo* laparoscopy
Ability to practice specific steps or skills required for common laparoscopic gynecologic procedures	3, some skills/steps
Ability to practice teamwork and intraoperative communication	4, fairly
Improvements	Improve angle of pelvis; Improve pelvic floor; Improve trocar sites (lessen the thickness of bottom lip); Improve ability to adhere vessels/organs

Due to time limitations, only one gynecologic resident was able to fill out and complete the new simulator survey and provide ample feedback for improvements. Overall, the team's trainer was evaluated to be somewhat useful for gynecological laparoscopic settings, and in terms of spatial awareness and depth perception, its simulation is similar to *in vivo* laparoscopy. For bimanual coordination and camera manipulation, the resident provided a score of 4 on the survey to indicate that practicing for these skills are fairly capable. The ability for teamwork practice and communication was also given a score of 4. In terms of specific skills that are commonly found in laparoscopic gynecologic operations, a score of 3 was provided, indicating that only some skill and steps could be simulated on the trainer. The resident also provided a list of improvements for the team's trainer, which included improving pelvis angle, pelvic floor design, trocar site thickness, and anatomical model adhesion.

Section 6. Discussion

The data collected through the validation and verification tests were analyzed using simple statistical tests in order to gain a more quantitative understanding of the success of the developed laparoscopic trainer. The discussion of the comparative tests done using ANOVA and t-tests provides the necessary evaluation of the functionality of the device. The mechanical testing analysis determined the material needed for the vaginal cuff model to be able to be practiced on, as well as how the model should be fabricated. The resident testing analysis provided both qualitative and quantitative information on the overall success of the developed trainer. The feedback and scores given through the pre- and post-surveys allowed for comparison between the current laparoscopic trainers used by UMass residents and the developed gynecological laparoscopic trainer to identify if the new trainer was able to provide a better training for residents.

6.1 Mechanical Testing Analysis

Following the mechanical testing of the silicone vaginal cuff models, the results were analyzed to quantitatively determine which silicone composition would produce the best vaginal cuff model for the practice of suturing a real vaginal cuff closed. Comparisons between the mechanical properties of the three different composition models were also made to find if there is a significant effect of mixing ratios on the mechanical behavior of the material. The analysis of the data collected through the compressive mechanical test provided a more quantitative understanding of silicone material for simulation of anatomically accurate models and was able to validate the use of the material for the final device. Statistical testing was done using a simple ANOVA test as multiple comparisons were made. The resulting p-values from the test indicated whether there was a significant difference between the values, with a p-value less than 0.05 meaning there is significance between values. Smaller p-values show a greater significant difference. It was found that the values for each of the cuff models for the lowest applied load were not significantly different from one another, while for the higher load applied, the values were more varied. Additionally, there was not a significant difference between the elastic modulus found for Cuff models 2 and 3 as the p-value was 0.8389, as well as for Cuff models 1 and 2 which had a p-value of 0.0801. However, there was some significance found between Cuff 1 and 3 as the p-value was 0.0128. Figure 60 displays the results of the average elastic modulus, E, of each cuff and the elastic modulus found for vaginal tissue, with the asterisks indicating the level of significance found from the ANOVA statistical testing. When comparisons were made between the vaginal tissue value, which was found in the literature to be 3.0 KPa [48], a significant difference was seen between each cuff and the known value. However, the p-value found for Cuff 1 and the vaginal tissue was larger than for Cuff 2 or 3 and vaginal tissue, equaling 0.0012, showing that Cuff 1 is most similar to the vaginal tissue with regards to elastic moduli.

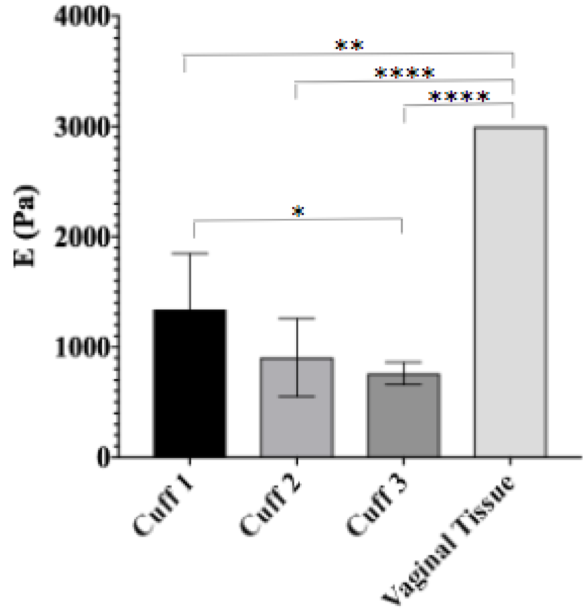


Figure 60. Elastic moduli of Cuff 1, 2, 3 and vaginal tissue with asterisk indicating significant differences based on p-values found through ANOVA test.

The statistical testing used to compare the elastic moduli of the vaginal cuff models and vaginal tissue allowed for the best composition of silicone mixture to be determined. Since there was less difference seen between Cuff 1 and the vaginal tissue than the other cuff models, Cuff 1 showed the most accurate mechanical behavior for the trainer. Therefore, the final device used a silicone vaginal cuff model fabricated from equal parts of the silicone mixture. The two parts of a complete silicone mixture are 1) a curing catalyst and 2) a polymer base with a crosslinker and cure inhibitor, so altering these ratios from the standard, recommended 1:1 resulted in different mechanical properties. By adding more of the Part A compound, it was expected that the silicone cuff would be denser and less flexible, while adding more of the Part B polymer base compound was expected to result in a cuff model with more flexibility and would be softer to the touch. Furthermore, a silicone model with a traditional 1:1 composition of Part A to Part B was expected to have property values and behavior that lie between those of the other two silicone compositions. However, the results did not show this as there was no significant difference observed between Cuff 2 and 3 or Cuff 1 and 2, and Cuff 1 resulted in the highest modulus. This could be due to the relatively slight changes in mixture composition. Additionally, using equal parts of the two components may have resulted in the strongest material as the silicone kit was designed for using this ratio between parts.

6.2 Resident Testing Analysis

Following the testing and surveying done by the residents to validate the device, the data collected was studied and analyzed to determine the success of the device. Both questionnaires given allowed for the residents to provide scores of one through five, with a higher score indicating more positive results. Through studying the results of the questions individually, the team developed a better understanding of which aspects of the current and new trainer are satisfactory and which may need improvement. Scores from the questions from the pre-survey were also compared to the scores from the same question found on the post-survey to find if one trainer excels in a specific task or characteristic. Since the same questions are asked in both the pre- and post-questionnaires, the scores were compared to analyze the difference in residents' opinions on the two trainers with regards to individual aspects and abilities for training. Table 19 below compares the average scores per question from the pre-survey to the scores from the post-survey for the same questions.

Table 19. Average ratings for pre-survey and post-survey questions.

Question Topic	Pre-Survey Ratings	Post-Survey Ratings
Current trainers' usefulness	3.3	3
Ability to practice depth perception	2.6	4
Ability to practice bimanual coordination	2.7	4
Ability to practice camera manipulation	1	4
Ability to practice angles or space of procedures	1	3
Ability to practice gynecological procedural skills	2.5	3
Ability to practice intraoperative skills with peers	1.5	4

Although the pre-survey consisted of a sample size of 3 residents and the post-survey data was collected by only one resident, scores from the surveys were used to gage a general idea of how the team's trainer compared to the trainers used at UMass. Scoring higher in every category except for the overall usefulness of the trainer, it is seen that the team's trainer accounts for some of the limitations provided by those at UMass. The most drastic difference in ratings between the team's trainer and those at UMass was related to the ability of the trainer to allow residents to practice bimanual coordination and to simultaneously practice intraoperative skills with peers. Additionally, the team's trainer improved upon the ability for residents to improve their depth perception skills, camera manipulation skills, and angling of tools. The team's trainer also better allows residents to practice skills pertaining to gynecological skills which was a limitation mentioned by residents in the pre-survey feedback.

Comparing the features of the trainers currently used at UMass and the features of the team's design provides insight into some of the reasons as to why the ratings for the two sets of trainers vary. In terms of depth perception, the FLS and Ethicon trainers have flat tops and do not provide an adjustability component to angle the trainer at similar angles of those used in surgical procedures. The team's implementation of a curved top to mimic a gas-filled abdomen and an adjustability component to angle the trainer provide a more realistic operating environment which improves the ability of residents to practice depth perception with surgical tools. The improved score from the pre-survey to post-survey in regard to bimanual coordination could be due to the fact that the team's trainer incorporates incision ports on the abdominal casing as they would be located during actual gynecological procedures. The FLS trainer involves only two large regions of rectangular size in which the tools can be placed, and the Ethicon trainer incorporates size holes lined up in pairs. The strategic placement of the port incisions on the team's device with respect to the pelvis simulates the space in true procedures which allows residents to more accurately practice bimanual coordination specific to gynecological procedures. The curved top also provides a more realistic way for residents to get comfortable with using tools in both hands at the same time.

In terms of camera manipulation, per request by the clients, the team’s design incorporates removable sides which allow for cameras to be more easily placed in the trainer in the desired location compared to the other trainers. Additionally, the accurate placement of the incision ports allows camera manipulation to be practiced more closely to how it would be used in procedures. For the purpose of training using laparoscopic trainers, having removable sides allows the operating space to be analyzed more closely by outside viewers. In a similar manner, the curved top of the team’s design allows the angling of surgical tools to better mimic those used during real procedures as they provide sufficient degrees of freedom. While the trainers used at UMass also allow the same degrees of freedom, their lack of curved tops limit their ability to mimic the angles at which surgical tools would be inserted into a patient. Furthermore, the team’s trainer scored higher than the trainers at UMass in regard to its ability to allow residents to practice full laparoscopic procedures due to its incorporation of pelvic models with simulated organs and vessels. Lastly, the team’s design scored higher in terms of allowing residents to practice skills simultaneously with other residents. This could be due to the fact that the improved anatomical accuracy provides a more realistic setting for practicing procedures, so residents may have found it to be a better way to practice team skills compared to the other trainers.

Based on the pre-survey and post-survey feedback for limitations and possible improvements for the trainers at UMass, the benefits and downfalls of the trainer were analyzed. Pre-survey results suggested that the UMass trainers could be more useful in the advancement of resident training if they incorporated pelvic anatomy, the ability to practice vaginal cuff closures, and provided the opportunity to practice gynecological procedures rather than only general surgical practices. The team’s design meets these objectives by incorporating a full pelvic model which allows gynecological skills to be practiced. Additionally, its incorporation of a vaginal cuff specifically allows vaginal cuff closures to be practiced. While the post-survey results agree with the fact that the team’s design does better to focus on gynecological procedures, the extent to how well these suggestions are met by the team’s designs cannot be concluded as the post-survey questions were not targeted towards their suggestions.

Although the team’s design scored better on the majority of the survey questions, many improvements were suggested in the post-survey as well including improved angling of the pelvis, improved pelvic floor, improved trocar design, and improved vessel and organ adherence to the pelvis. Although the design is adjustable to allow the pelvis model to rotate to different angles, improving the angle at which the pelvis is screwed to the abdominal casing would improve the overall accuracy of the design. Similarly, the pelvic floor does not do well to distinguish between individual muscles, so designing a way to create the pelvic floor with distinguishable muscles would increase the anatomical accuracy of the design to better meet the clients’ requests. Improvement of the trocar sites would involve decreasing the lip on the bottom of their designs to prevent them from inhibiting surgical tool motion and their degrees of freedom. Additionally, although per request by the clients to have detachable organ phantoms, adhering them to the bony pelvis would provide a more realistic layout of the pelvis. Table 20 below summarizes the main objectives of the team’s trainer and in what way the trainers from UMass and the team’s design meet these objectives.

Table 20. UMass trainers and team's trainer compared to the design objectives.

Objectives	Trainers at UMass	Our Design
Anatomical accuracy	vaginal cuff model made from elastic material	pelvic model that simulates anatomical feature placement and feel; curved abdominal top to simulate gas-filled abdomen
Adjustable	wedge mechanism that allows an angle to be created	adjustable platform that provides 45-degree rotation in two directions
Cost-effective	>$6,510	$210
Adaptable to different procedures	use of training modules that enable training of cutting, suturing, dexterity, etc.	implementation of anatomical phantoms; use of alligator clips to attach and detach organ phantoms

To statistically analyze how well the team's laparoscopic trainer compares to the current trainers used at UMass, the scores of all the questions were summed for each survey so an overall score could be given to each of the trainers. The sum for the pre-survey was 14.6 and the sum for the team's design was 25. By comparing these two values, it is seen that the team's design scored better overall, representing more appeal to and preference by residents compared to trainers used at UMass. These total scores for each trainer underwent t-testing to analyze whether a significant difference existed between the abilities of them.

Although a significant difference existed between the two trainers per the t-test, the number of residents used in pre- and post-surveying was limited, limiting the overall accuracy of the statistical testing. Overall, however, the results of the pre- and post-surveys were useful in analyzing the difference between the two. The main takeaway from the results is that while the current trainers at UMass do well to enable basic skills training through the use of its training platforms, the team's device allows specific procedural skills to be practiced through the use of its anatomical structures and detachable components, which residents feel could be an integral improvement to their learning.

6.3 Impact of Device

Following the development of a gynecological laparoscopic trainer, the impact of the device was explored. Economical, environmental, societal, political, and ethical impacts were considered with regards to the developed trainer. Although the device may not have significant influence on several of these factors, they were necessary to consider when designing and developing the device, as well as for future work. The manufacturability and sustainability of the laparoscopic trainer was also discussed to gain a better understanding of the influence it may have at UMass Memorial and the overall impact the device may have.

6.3.1 Economical Impact

This project would not have an impact on the economy of everyday living. If the device were to be patented and sold on the market, the impact would increase. This development would create jobs, which would positively impact the economic status of individuals.

6.3.2 Environmental Impact

The majority of the development of this device consisted of PLA and silicone. PLA comes from renewable, carbon-absorbing plants, meaning it will not emit toxic fumes when incinerated. PLA is biodegradable, though it breaks down slowly. Silicone is made from silica found in sand. Silicone products can be recycled and are more durable than plastic.

6.3.3 Societal Influence

If this device becomes patented and sold on the market, it will create more jobs. The design of this device could also be further enhanced and improved by others. The development process would require individuals to be hired to assemble the trainer together. If the manufacturing process were to become automated, individuals would still be needed to ensure that any machines were running smoothly.

6.3.4 Political Ramifications

This product would likely not affect the cultures of other countries.

6.3.5 Ethical Concerns

This project does not have any negative ethical concerns. The device would allow surgical residents to improve upon their skills and perform better in actual procedures. This trainer is relatively low-cost and accessible while still providing the opportunity to acquire laparoscopic skills. The product itself does not raise ethical concerns or burdens.

6.3.6 Health and Safety Issues

This project should not result in any health or safety issues. The trainer is a very low-risk device and will not cause harm to those using it.

6.3.7 Manufacturability

This device could very easily be reproduced. The CAD designs and drawings can be made available and the assembly of the device is straightforward. The pelvic model is split into parts and printed in PLA. The mold for the arteries and veins was designed on SolidWorks and hollowed out with capped ends so that the silicone mix could be easily poured into it without spilling. This was 3D printed with PLA and filled with red-dyed silicone to produce the vessel network and left to cure. A cross-sectional outer, hollow model and a cross-sectional inner solid model were 3D printed from PLA, and silicone was sandwiched between the two to create a hollow half of the silicone uterus phantom. The process was repeated, and the two halves were seamed together. A 3D-printed mold of the vaginal cuff was printed in PLA and filled with silicone. The box was created from an acrylic board that was laser-cut and included removable sidewalls. The abdominal top was created in SolidWorks and printed in three different parts in PLA with holes where incisions are normally made during the procedures and trocars can be inserted. To obtain the correct positioning of the pelvis in the box, screws were placed in the iliac crests to the sides of the casing. The abdominal top curve was then attached to the box using Velcro strips so that it could also be removed if desired. The trocar inserts were placed into the incision and the box was attached to the mobility mechanism.

6.3.8 Sustainability

This product would not have an influence on the environment in regard to renewable energy.

Section 7. Conclusions and Recommendations

The development of a gynecological laparoscopic trainer had several successful aspects that addressed the client's requirements and needs and that were evaluated through mechanical testing and resident survey feedback. The overall device developed was cost-effective, adjustable, and included the pelvic anatomy desired by residents. Although the final prototype was fabricated and tested, there were several limitations to the device and design process. These limitations led to several recommendations that could be made to improve the functionality and effectiveness of the laparoscopic trainer. Future work that had not been completed due to time and resource limitations, for further iterations of the device was also considered and discussed.

7.1 Final Device

The final device was able to meet many of the original specifications. The abdominal casing included the actual box, the top abdominal curve, and trocar inserts. The acrylic box had removable side walls to allow the residents to view the pelvic model if needed. The top abdominal curve accurately mimicked the inflated abdomen seen in laparoscopic surgeries and it included holes to replicate the incision sites for procedures. The trocar inserts can be placed in these incision sites, where different sized instruments can be interchanged to match what is needed for the procedure practiced at that time. The casing was also made adjustable by attaching the box to a moveable light fixture. The handle can be loosened to move the box up and down and tightened to lock the position into place to allow for accurate positionings seen in surgery. The bony pelvis represents an accurate female pelvic model and was securely attached to the box. The pelvis also included the organ phantoms, including the uterus and fallopian tubes, along with a saturable vaginal cuff and the pelvic vasculature, including the ovarian, uterine, umbilical, external iliac, internal iliac, and abdominal arteries and veins. These components were included to ensure anatomical accuracy. The trainer was also inexpensive, costing only $210 to create and develop.

7.2 Limitations

The project was successful in creating an initial prototype for a gynecological laparoscopic trainer for surgical residents to practice on. The main focus was to create an anatomically accurate trainer that residents could practice full procedures on and was cost-effective. This device developed is much less expensive than those currently used at UMass Memorial and it allows for specific procedural skills to be practiced through the use of its anatomical structures and detachable components. There were, however, some limitations the team faced during its development.

A limitation faced was a component of the original methodology. The pelvic floor was originally made using a pink silicone mat to represent each muscle and they were glued into the pelvic model. However, this method proved to be uncooperative as it was not sufficient enough to hold all of the necessary vasculature and organ phantoms. An alternate strategy was needed, thus taking the additional time that was not originally accounted for.

Another limitation faced was gathering a sufficient amount of data. Through pre- and post-surveys, the team was able to obtain feedback on the developed trainer. It would have been favorable to gather more data to have more responses. By having more responses, the team would have been able to effectively determine any precision between them. Additionally, the team planned on gathering observations of the trainer prior to when they did to attempt to make any simple adjustments the residents saw fit.

The process of verifying the modulus of elasticity of the material of the vaginal cuff model also entailed a limitation in testing. As aforementioned, the three compositions were 1:1, 4:3, and 3:4 of Part A to Part B, so differences were not drastic. The limited differences are imperative to note due to the caution of silicone mixtures not curing well, or remaining in a liquid state, therefore mechanical testing would not be possible to carry out. Nonetheless, further improvements such as fabricating more models with different ratios of Part A to Part B could provide more conclusions to verify the utilization of the standard 1:1 composition and affirm its ability to best simulate the realistic anatomy.

Due to time constraints, the team was unable to better enhance certain aspects of the trainer. The design fell short in regard to vasculature adherence and the trocar sites. With more time and resources, these obstacles could have been improved. Though there are some limitations to the device created, the device was able to meet the project objectives. These limitations can be addressed as part of future work.

7.3 Recommendations and Future Work

Although the final device was able to meet many of the initial design requirements and the client's requests, there is room for improvement and advancement of the laparoscopic trainer developed. Based on the resident feedback provided in the post survey and the limitations of the device, it is recommended that the angle of the pelvis, the pelvic floor, the attachability of the vessels and organs, and the trocar inserts be improved to allow for the trainer to be more functional for practice by residents. Therefore, several recommendations for each part of the trainer, including the bony pelvis, the abdominal casing, and the organs and vessels are provided.

7.3.1 Bony Pelvis Recommendations

Although the 3D printed female bony pelvis was successful in providing a dimensionally accurate, hard, lightweight, and strong model, there were several other aspects of the part that could be improved. The current material used for the pelvic floor was adequate for providing a hard material to lay the vasculature, however, it did not allow for accurate depiction of the real pelvic floor muscles. Therefore, a new material or a mold could be used to allow for the production of a more anatomically accurate pelvic floor that allows for the pelvic vasculature to be better positioned in the pelvic model as well. One material that could be used for this could be PLA, as the floor could be modeled using CAD and 3D printed with the bony pelvis. This would require adjustments to the current bony pelvis CAD model and therefore, an advanced skill set in SolidWorks or another CAD program. The angle of the bony pelvis could also be manipulated to better represent the angle seen during laparoscopic procedures. This could be done through moving the site of attachment of the bony pelvis on the box. Finding a more adjustable way to attach the pelvis could allow for easier manipulation of the angle so the desired orientation and positioning of the pelvis could be obtained.

7.3.2 Abdominal Casing Recommendations

There were several design flaws in the dimensions of the trocar inserts as the current design does not allow for the necessary degrees of freedom needed for the movement of instruments. Therefore, it is recommended that the dimensions of the insert be slightly altered to account for this issue. Additionally, the removable wall design could be improved through adding more magnets to ensure that the walls remain in place when desired. A new mechanism could also be designed and used, including a hinge mechanism where the walls could open and close more like a door. It is also suggested that the acrylic board used for the side walls not be transparent, as the residents should not be able to see the pelvic model through the sides when practicing procedures. It is also recommended that the top curve of the casing be 3D printed in one piece if possible. However, if not possible due to 3D printer constraints, the curve adhesion should be reinforced. The adjustable mechanism of the box could also be improved in later iterations of the project. Currently an adjustable light fixture is used as a stand, however, a new mechanism more specific to the project needs could be designed on CAD and 3D printed.

7.3.3 Vessel and Organ Recommendations

The vessels and organ attachment mechanism could be further studied as the alligator clips used inhibit the anatomical accuracy of the placement of the models and impede the movement of the instruments. Therefore, alternative attachment methods, such as permanent attachment through adhesive glue or use of Velcro to allow for easier removal may be used in future iterations of the device. The material used for the vaginal cuff and vessels could also be modified to obtain a material that better mimics the behavior of the actual tissue. Additionally, several other significant organs typically seen in gynecological laparoscopic surgery were not created. However, similar processes that were used for the fabrication of the uterus could be done for new organs and tissue such as the bladder, ovaries, and significant ligaments.

7.3.4 Future Work

Due to time and resources, there were also several other parts of the gynecological laparoscopic trainer that were not able to be designed and produced, including an instrument to hold a camera for practice of camera manipulation needed during real procedures. Future work could include design of this instrument as well. Moreover, as a result of time limitations, adequate testing of the device was not able to be done on the initial prototype developed. Consequently, further feedback and results could be obtained in the future to gain a better understanding of specific improvements that could be made to increase the functionality of the trainer. More long-term testing on future iterations of the device could be done to find the effects of a more high-fidelity trainer on the outcome of gynecological surgical procedures and the residency curriculum at UMass Memorial.

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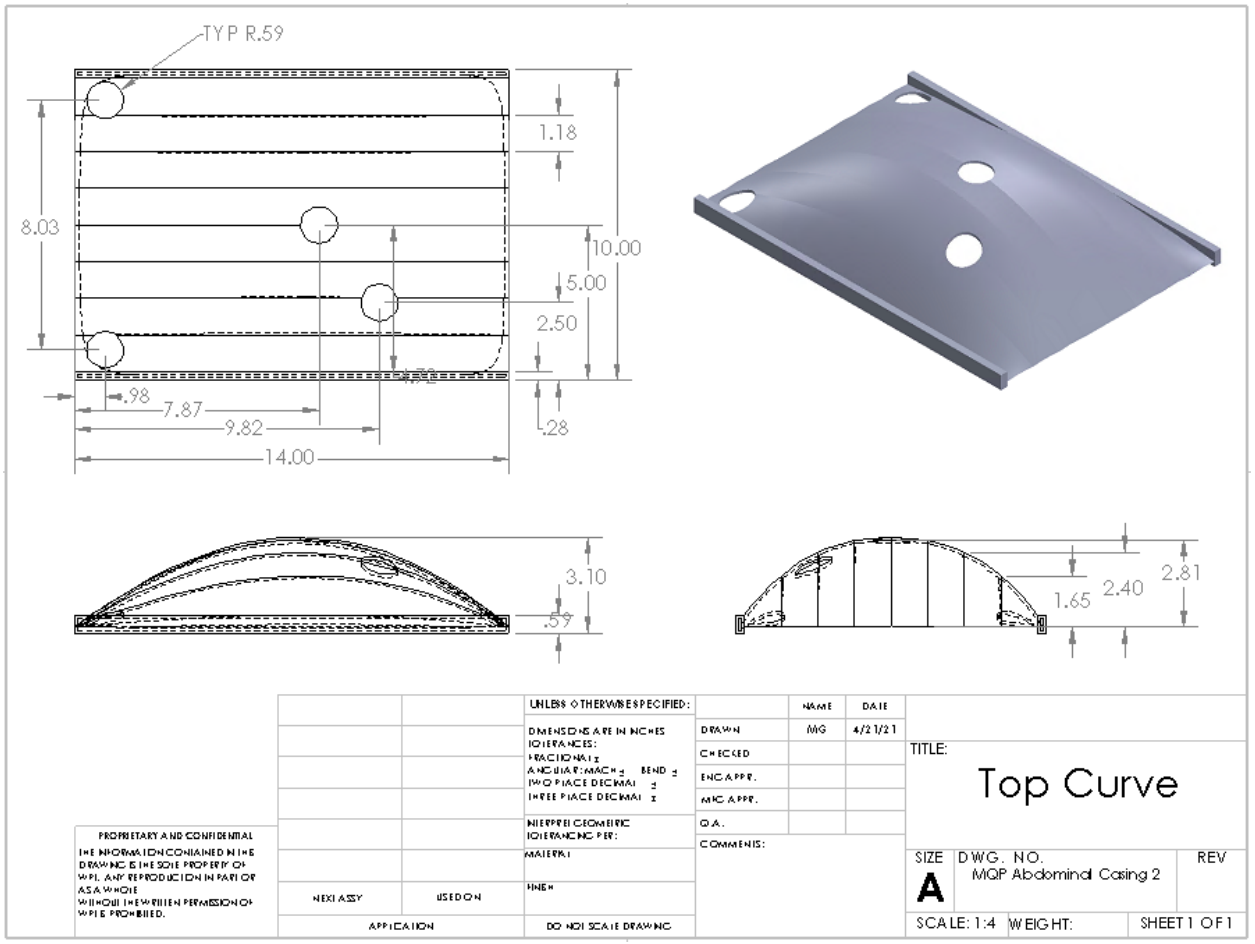
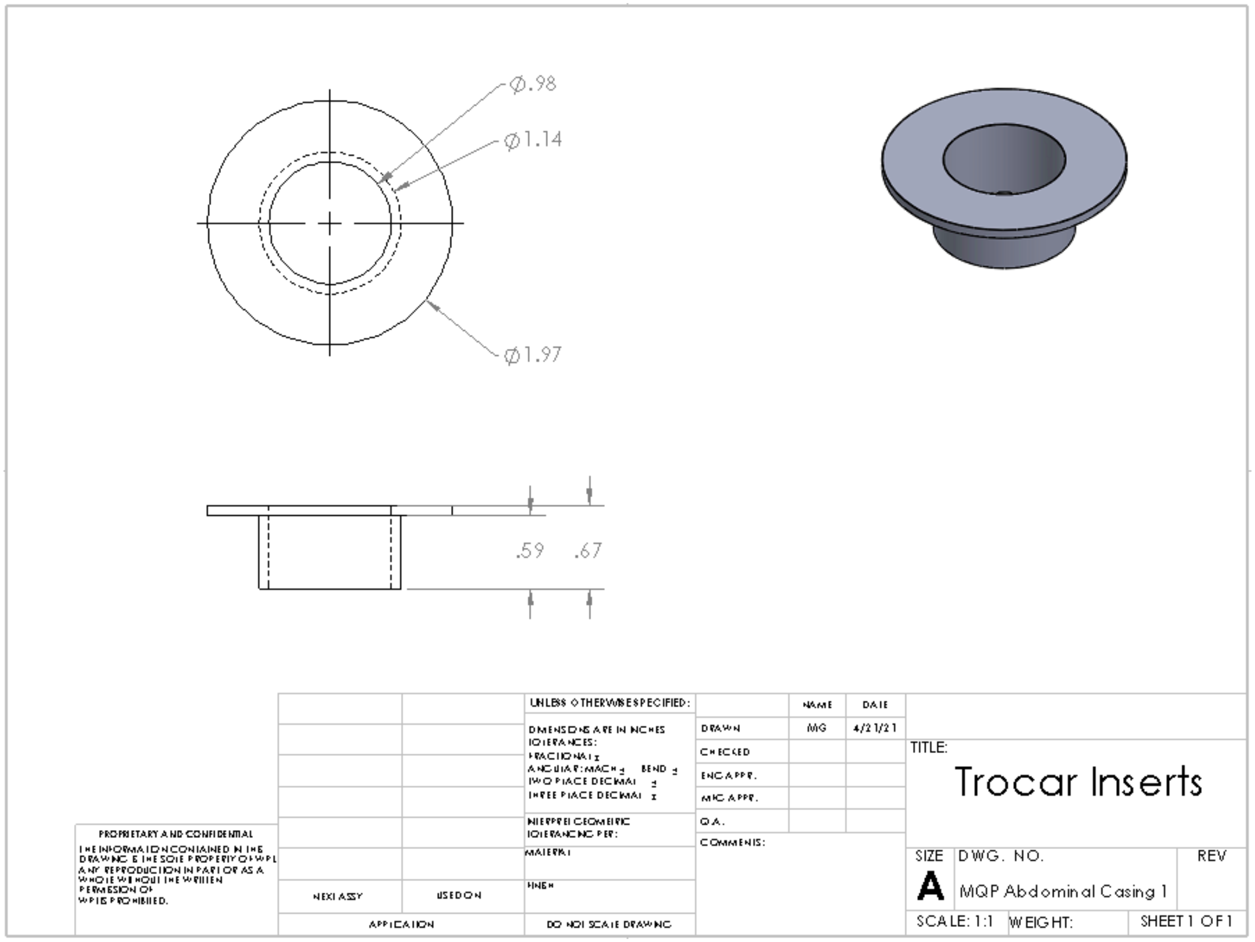
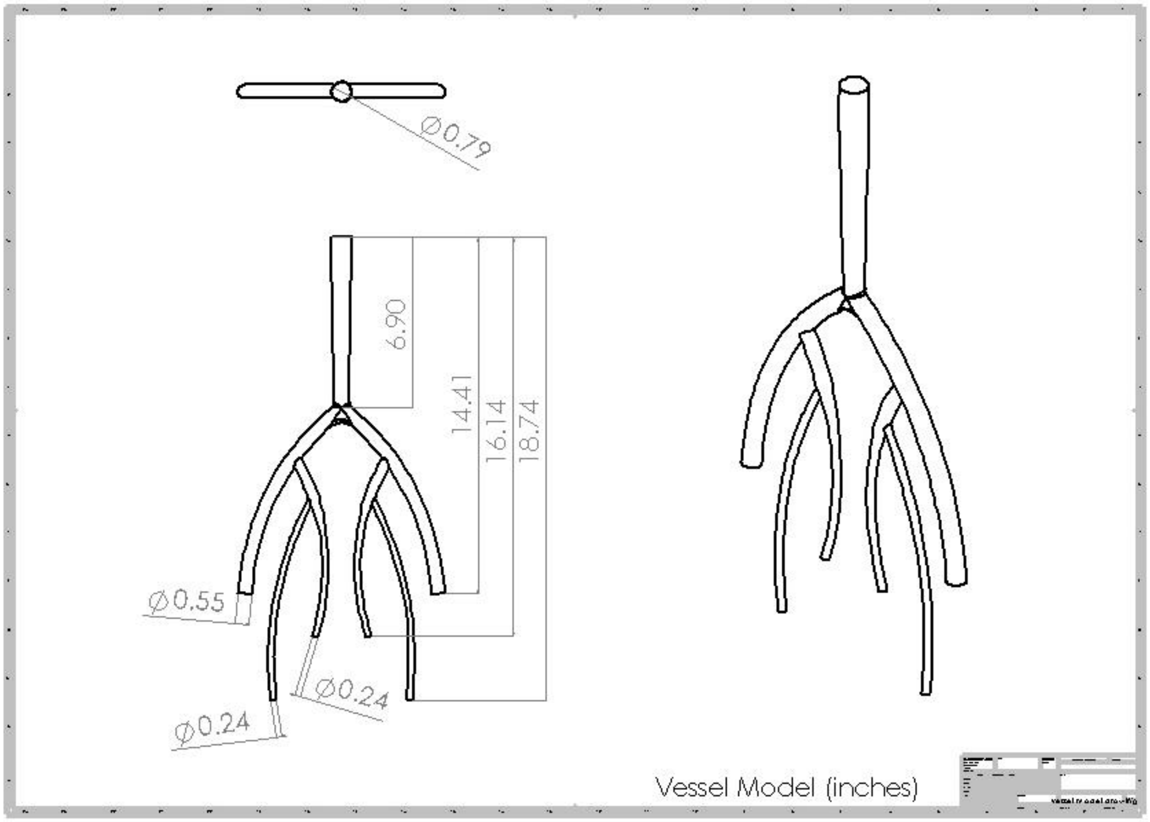
Appendix A: SolidWorks drawing of abdominal curve



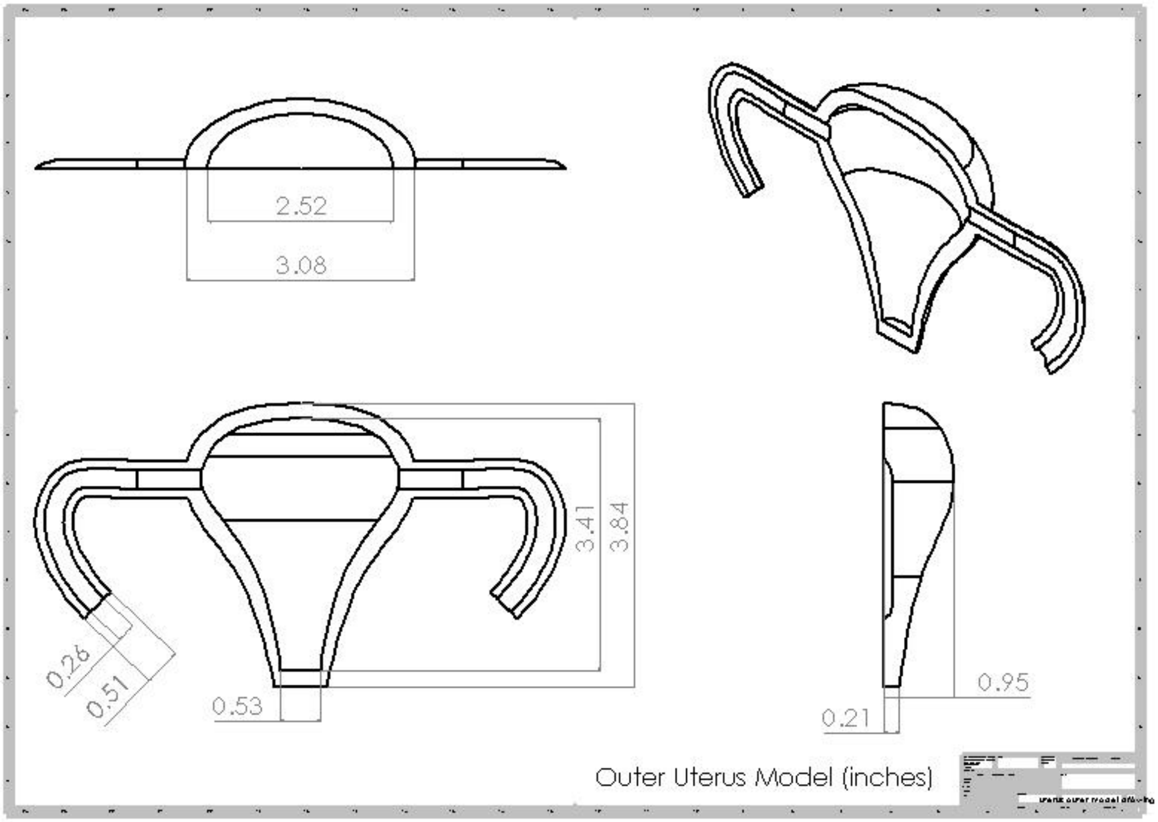
Appendix B: SolidWorks drawing of trocar inserts



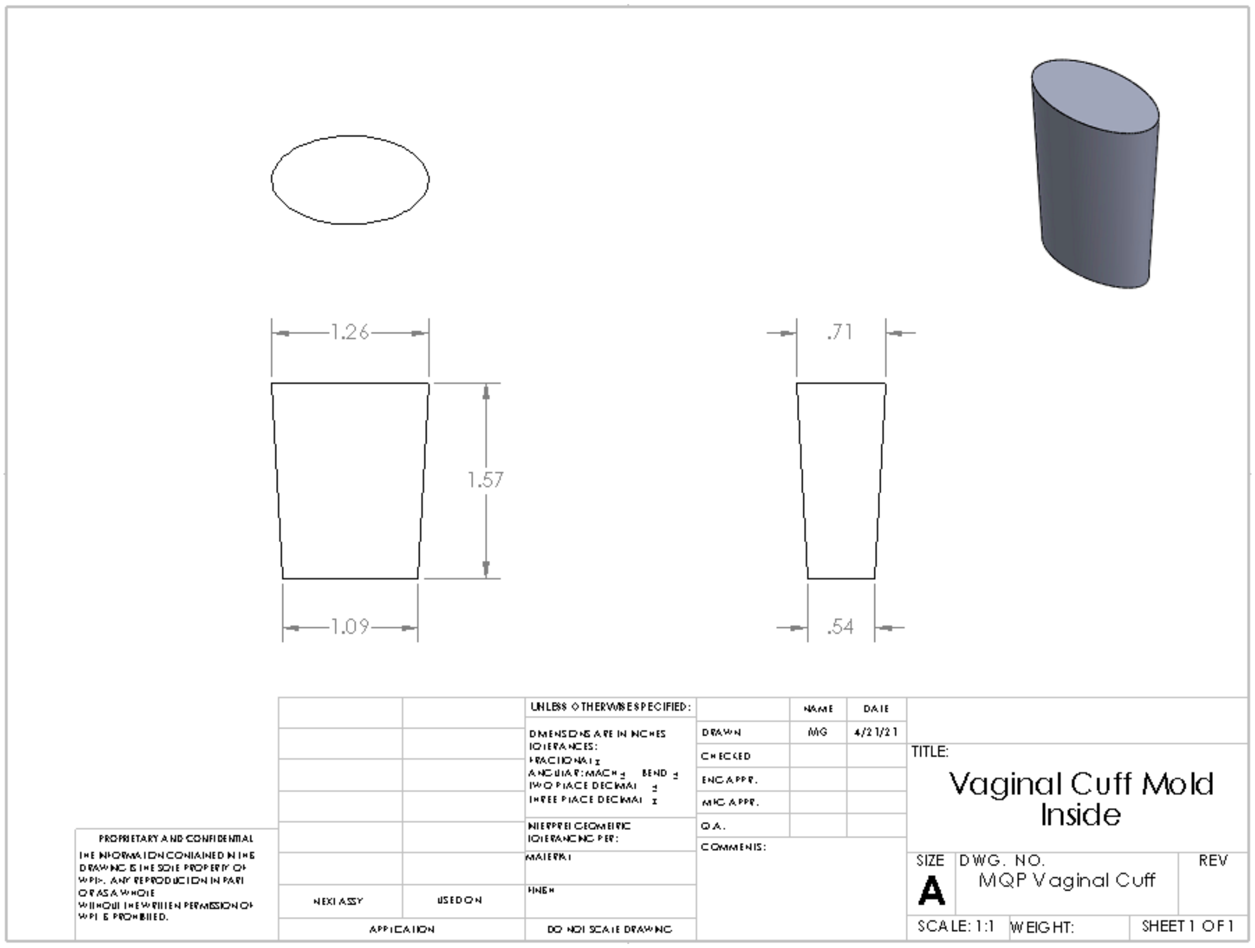
Appendix C: SolidWorks drawing of vessel network model



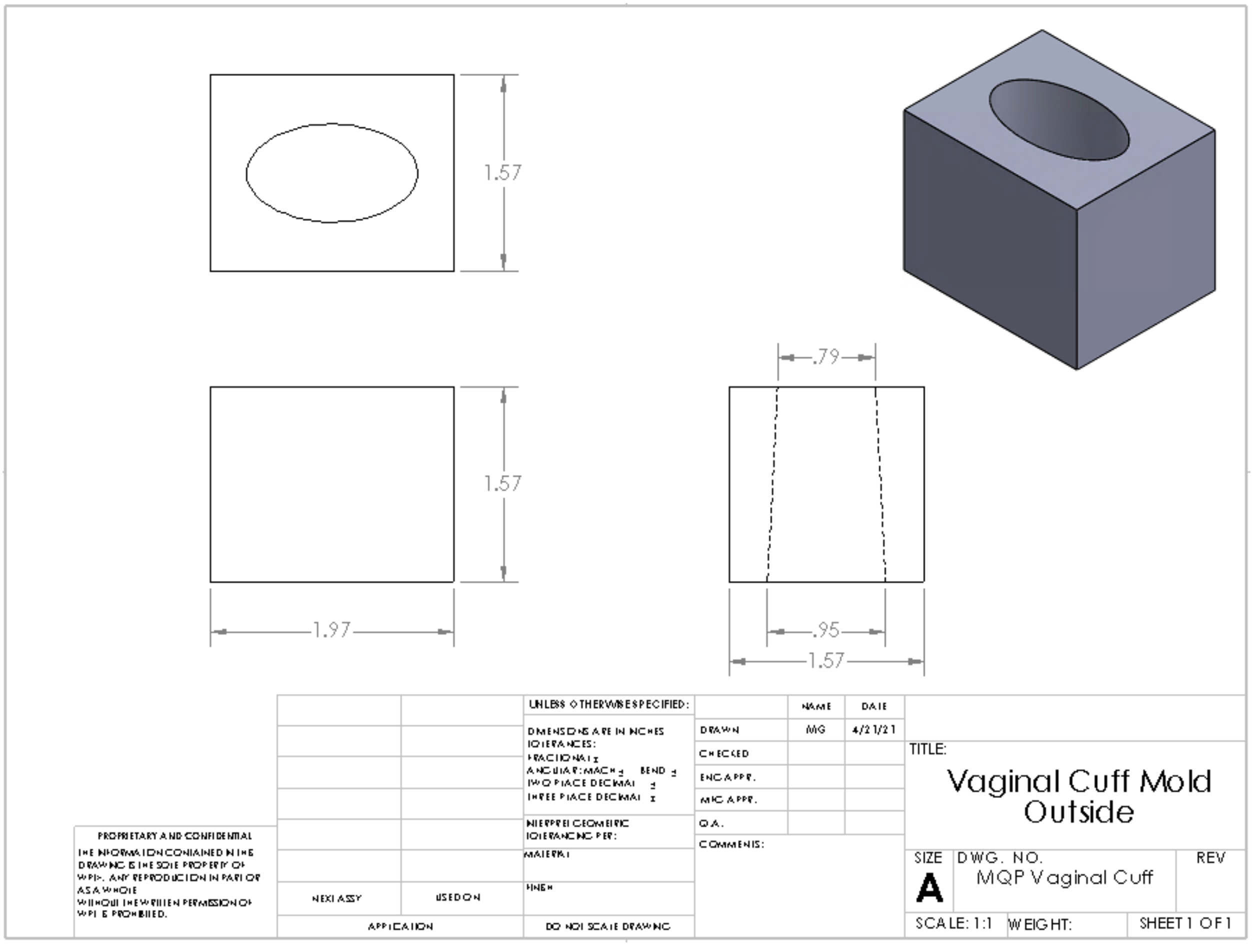
Appendix D: SolidWorks drawing of Outer Uterus Models



Appendix E: SolidWorks drawing of inside of vaginal cuff mold



Appendix F: SolidWorks drawing of outside of vaginal cuff mold



Appendix G: Protocol for testing strength of silicone vaginal cuff model

Materials

- 3 Silicone Vaginal Cuff models of different composition (Part A: Part B)
  - Cuff 1 → 1:1 ratio (20 ml: 20 ml)
  - Cuff 2 → 4:3 ratio (20 ml: 15 ml)
  - Cuff 3 → 3:4 ratio (15 ml: 20 ml)
- Quarters
- Ruler

Procedure

1. Gather three already made silicone vaginal cuffs, each with a different composition.
2. Measure the initial long and short diameter of the larger opening of the cuff using a ruler (in cm) and record values.
3. Measure the length and width of the rectangular cross section of the cuff and record values
4. Calculate the area of the cross section and record.
5. Carefully place x quarters on the edge of the vaginal cuff model (near the larger opening) when it is lying flat.
6. Measure the final long and short diameter of the larger opening while the quarters are still on the part and record values.
7. Remove the quarters and repeat steps 2-6 two more times (total of three trials).
8. Calculate the force of the load placed on the cuff from the quarters using the equation.
$$F = x * weight\ of\ quarter * g$$
$$F = force\ applied$$
$$x = number\ of\ quarters\ used$$
$$weight\ of\ quarter = 5.67\ grams$$
$$g = 9.81\ m^2/s$$
9. Calculate the stress applied to the cuff using the equation.
$$\sigma = \frac{F}{A}$$
$$\sigma = stress\ applied$$
$$A = cross\ sectional\ area = l * w$$
10. For each trial completed, calculate the lateral and longitudinal strain that resulted from the stress applied.
$$L = \frac{d_{short,f} - d_{short,i}}{d_{short,i}}$$
$$\varepsilon_{lat} = \frac{d_{long,f} - d_{long,i}}{d_{long,i}}$$
11. Calculate the corresponding elastic modulus for each trial using.
$$E = \frac{\sigma}{\varepsilon_{long}}$$

Appendix H: Pre-Survey Questions

1. What is your current level of training/practice?
   A. PGY1
   b. PGY2
   c. PGY3
   d. PGY4
   e. Fellow
   f. Attending physician
2. Which laparoscopic simulators available at your institution have you used? Check all that apply.
   a. FLS trainer box (white box trainer used during FLS exam)
   b. Ethicon laparoscopic trainer (gray, fabric box)
   c. Black laparoscopic trainer (black, plastic trainer located at University simulation lab)
3. Overall, how would you rate the current laparoscopic simulators available at your institution?
   1. Not at all useful in learning laparoscopy.
   2. Minimally useful in learning laparoscopy.
   3. Somewhat useful in learning laparoscopy.
   4. Very useful in learning laparoscopy.
   5. Essential in learning laparoscopy.
4. How well do the current laparoscopic simulators allow for practice of basic depth perception/spatial awareness?
   1. Not at all similar to *in vivo* laparoscopy.
   2.
   3. Somewhat similar to *in vivo* laparoscopy.
   4.
   5. Identical to *in vivo* laparoscopy.
5. How well do the current laparoscopic simulators allow for practice of bimanual coordination?
   1. Not at all.
   2.
   3. Somewhat.
   4.
   5. Ideal simulation.
6. How well do the current laparoscopic simulators allow for the practice of camera manipulation?
   1. Not at all.
   2.
   3. Somewhat.
   4.
   5. Ideal simulation.
7. How well do the current laparoscopic simulators allow for the practice of laparoscopic surgery in the female pelvis, specifically regarding angles and space of common procedures?

1. Not at all similar to *in vivo* laparoscopy in the female pelvis.
2.
3. Somewhat similar to *in vivo* laparoscopy in the female pelvis.
4.
5. Identical to *in vivo* laparoscopy in the female pelvis.

8. How well do the current laparoscopic simulators allow for the practice of specific skills/steps required of common laparoscopic gynecologic procedures?
   1. Not at all
   2.
   3. Some skills/steps
   4.
   5. All skills/steps
9. How well do the current laparoscopic simulators allow for the practice of teamwork and intraoperative communication?
   1. Not at all
   2.
   3. Somewhat
   4.
   5. Ideal simulation
10. List up to three improvements you would recommend for laparoscopic simulation at
11. your institution.
12. Describe any current limitations to simulation training in your current training or practice.

Appendix I: Post-Survey Questions

1. What is your current level of training/practice?
   a. PGY1
   b. PGY2
   c. PGY3
   d. PGY4
   e. Fellow
   f. Attending physician
2. Overall, how would you rate this laparoscopic trainer?
   1. Not at all useful in learning laparoscopy.
   2. Minimally useful in learning laparoscopy.
   3. Somewhat useful in learning laparoscopy.
   4. Very useful in learning laparoscopy.
   5. Essential in learning laparoscopy.
3. How well does the new laparoscopic simulator allow for practice of basic depth perception/spatial awareness?
   1. Not at all similar to *in vivo* laparoscopy.
   2.
   3. Somewhat similar to *in vivo* laparoscopy.
   4.
   5. Identical to *in vivo* laparoscopy.
4. How well does the new laparoscopic simulator allow for practice of bimanual coordination?
   1. Not at all.
   2.
   3. Somewhat.
   4.
   5. Ideal simulation.
5. How well do the new laparoscopic simulators allow for the practice of camera manipulation?
   1. Not at all.
   2.
   3. Somewhat.
   4.
   5. Ideal simulation.
6. How well does the new laparoscopic simulator allow for the practice of laparoscopic surgery in the female pelvis, specifically regarding angles and space of common procedures?
   1. Not at all similar to *in vivo* laparoscopy in the female pelvis.
   2.
   3. Somewhat similar to *in vivo* laparoscopy in the female pelvis.
   4.
   5. Identical to *in vivo* laparoscopy in the female pelvis.
7. How well does the new laparoscopic simulator allow for the practice of specific skills/steps required of common laparoscopic gynecologic procedures?
   1. Not at all

2.
3. Some skills/steps
4.
5. All skills/steps

8. How well does the new laparoscopic simulator allow for the practice of teamwork and intraoperative communication?
   1. Not at all
   2.
   3. Somewhat
   4.
   5. Ideal simulation
9. Describe any improvements you would recommend to the new laparoscopic simulator.