Paracervical Block Training Model

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ABSTRACT

The paracervical block (PCB) is a widely used gynecological procedure that provides local anesthesia for interventions such as intrauterine device (IUD) insertion. However, many clinicians receive limited training on this technique due to the lack of accessible models that accurately represent key anatomical structures. In particular, existing devices do not include the cervicovaginal junction, a critical landmark required for proper PCB needle placement. This gap reduces clinician confidence and restricts patient access to effective pain-management options.

To address this need, the team partnered with Dr. Jessica Dalby to develop an improved PCB training model. Current models, including the Miya Model, the University of Nebraska Task Trainer, and the Venus Model, are proven to be useful tools but lack anatomical accuracy, durability, or affordability. Our solution modifies an existing task trainer by integrating an anatomically accurate cervicovaginal junction to better simulate the PCB administration.

Mechanical testing was conducted to evaluate compressive behavior and elasticity of selected materials, and physician testing with the client and her coworkers assessed the model as a whole. Results indicate that the modified model more closely resembles human cervical tissue behavior and improves the spatial realism required for training needle placement. Feedback from client testing confirmed enhanced anatomical fidelity relative to the original design.

These findings suggest that the redesigned trainer has strong potential for preparing future clinicians to perform the PCB procedure more safely and effectively. Further clinician-based evaluation will determine readiness for broader implementation and future production.

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I. INTRODUCTION

1.1 Motivation / Global Impact

The impact of this project spans beyond the scope of our client's classes at UW-Health. It has become increasingly more common for young women to pursue an IUD as a form of birth control. In a Planned Parenthood study, they found 42% of women 25 or under have an IUD as their form of birth control, whereas in the general female population, IUDs make up only 12% of contraception[1]. Because of this increased interest it is consequently becoming more important for providers to know the proper pain management techniques. Currently, pain management is quite scarce, an example of this is, "for IUDs only 30% of physicians offer anesthesia during IUD insertion, even though 70% of women report moderate to severe pain during the procedure" [2]. Clearly, there is a lack of training in this field of practice for many reasons, one of the most prevalent being the lack of accessible trainers for physicians. By providing medical students and physicians with this training model, providers' familiarity with pain management during IUD insertion will be greatly improved, therefore increasing accessibility to this exceptional birth control method.

1.2 Existing Devices & Current Methods

Several existing gynecological training models attempt to teach procedures such as the paracervical block (PCB), speculum insertion, and IUD insertions. However, these models vary significantly in anatomical accuracy, material properties, durability, and cost. Although each provides some value, none incorporate an anatomically accurate cervicovaginal junction, which is essential for realistically training the PCB procedure.

The Miya Model (Figure 1) consists of a pelvic frame and multiple replaceable anatomical structures. It includes lifelike skin and life-size organs, realistic cutting and puncturing tensions, palpable surgical landmarks, a pressurized vascular system that can simulate bleeding due to inadequate technique, and an inflatable bladder that leaks water if damaged. While this model provides extensive anatomical detail and can be used for all major vaginal surgical procedures, its cost of ~$6000 makes it inaccessible for many smaller clinics and training programs which require multiple models per training session [3].

Figure 1: Image of the Miya Model used for gynecological procedures.

The University of Nebraska Medical Center Task Trainer (Figure 2) is a low-cost alternative constructed from basic hardware, a silicone mixture, and 3D-printed components [4]. Although this model provides a good representation of pelvic anatomy, it lacks several key features, specifically a cervicovaginal junction, a realistic vaginal canal opening, and the correct length for the materials used by our client during PCB training procedures. Due to these limitations, the model is useful primarily for simple IUD insertion procedures rather than for training clinicians in a PCB procedure that requires the cervicovaginal junction.

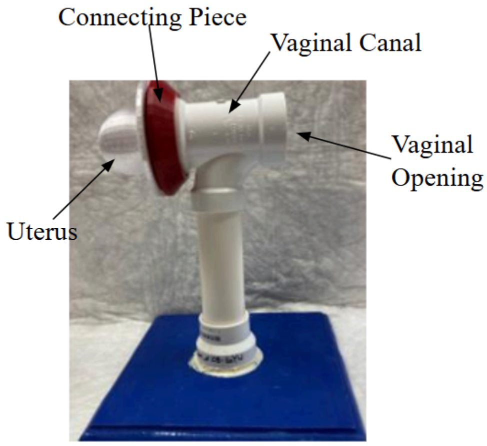


Figure 2: The Task Trainer for Gynecological Procedures

The Venus Model (Figure 3) includes a vulva exterior, a vaginal canal, and a visible cervix molded from silicone material [5]. In educational settings, instructors often label anatomical features such as the vaginal opening, cervix, and surrounding exterior structures to facilitate orientation. The model supports demonstrations of speculum insertion, tampon or menstrual cup placement, pelvic wand use, contraceptive positioning, and vaginal weight training. However, because its internal geometry is simplified and its materials are not designed to withstand repeated instrumentation, the model cannot be used for procedures requiring deeper access or force-dependent interactions, such as paracervical block injections, cervical grasping with a tenaculum, or IUD insertion.

Figure 3: The Venus Pelvic Health Educational Model.

Our client's current training tool, the Roma Tomato Model (Figure 4), provides a minimal and inexpensive representation of the pelvic structures involved in PCB. It consists of a Dixie cup with the bottom removed, a Roma tomato serving as the cervix and uterus, and a condom positioned through the cup to represent the vaginal canal. While this model is extremely easy to assemble and offers a simple way to visualize basic relationships between structures, it does not provide anatomically accurate mechanical properties and must be rebuilt for every demonstration. The softness of the tomato does not resemble the firmness of cervical tissue, the junction between the cup and tomato does not replicate the cervicovaginal junction, and the geometry varies considerably each time the model is constructed. These factors make it insufficient for training clinicians.

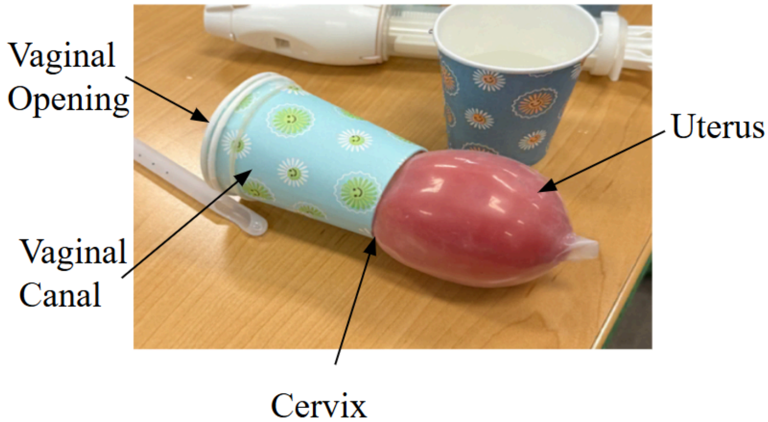


Figure 4: The Roma Tomato Model.

Collectively, these existing designs lack an anatomically accurate cervicovaginal junction, do not replicate appropriate mechanical properties, are either excessively expensive or overly simplistic, and fail to provide the depth, durability, and structural realism needed for effective PCB training. These limitations highlight the need to develop a more accurate, low-cost, and durable model capable of simulating the critical anatomical features and tactile feedback required for mastering the paracervical block procedure.

1.3 Problem Statement

The goal of our team is to create a realistic, reproducible, and low-cost model that includes an anatomically accurate cervicovaginal junction. Our model should allow for the simulation of a paracervical block injection to train healthcare professionals and make this procedure more accessible. We aim to achieve this by selecting materials that match the mechanical properties of the female reproductive tissues, including a needle insertion force of 1.09 N and an elasticity of 19.4 kPa [6]. Developing a model with these characteristics will allow providers to practice needle placement, injection, and IUD insertion in a supervised learning environment. Ultimately, our goal is to improve access to PCB training and expand patient access to pain-management options in women's healthcare.

II. BACKGROUND

2.1 Anatomy and Physiology

Although the female reproductive system is adapted to accommodate major physiological changes, including menopause and labor, several common gynecological procedures can still cause significant discomfort, such as IUD insertion. For this discomfort one of the most common methods of pain management is a paracervical block. This procedure begins at the vaginal opening where the doctor will insert a speculum to dilate this canal and increase visibility. Through the vagina is the junction between the cervix and uterus, where paracervical blocks take place (Figure 5). At this cervicovaginal junction, the doctor will administer lidocaine injections above and below the nerve bundles in the area. Thinking about the cervix like the face of a clock, the physician can elect to do a preliminary injection at the 12 o'clock position to aid with pain from tenaculum placement. From there they will take a metal tool, similar to forceps, called the tenaculum, and get a firm grip on the cervix to stabilize. With that grasp the doctor will administer 4 more injections, these are injected approximately at the 2, 4, 8, and 10 positions (Figure 6) [7]. This process is used to most effectively numb the patient for the rest of their procedure.

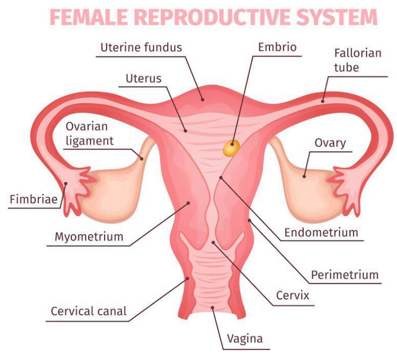


Figure 5: Female Reproductive System [8]

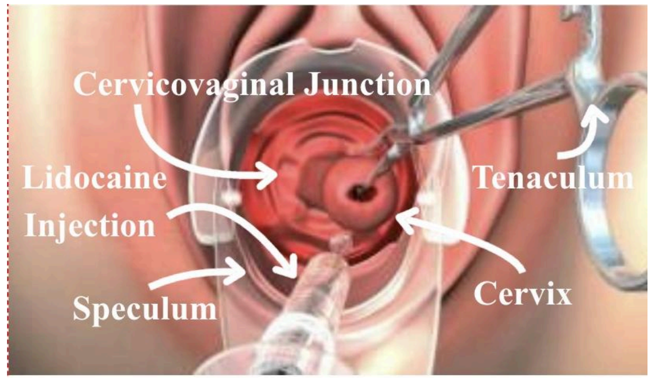


Figure 6: Parcervical Block [7]

2.2 Client Information

The client, Dr. Jessica Dalby, is a family medicine physician at UW Health and an associate professor at University of Wisconsin School of Medicine and Public Health. She frequently trains physicians and medical students on the process of paracervical block administration. She is seeking a more realistic and practical task trainer to aid in her clinics and training.

2.3 Design Specifications

The Paracervical Block Training Model must provide a realistic and reproducible simulation of the cervicovaginal junction. The model will use biocompatible materials that mimic tissue elasticity and needle insertion resistance (approximately 6.2 ± 3.1 kPa for vaginal tissue and 1.09 N for insertion resistance) while withstanding repeated use and injections [9]. The model will allow for fluid injection without leakage or hazard, and the cervicovaginal junction component must be replaceable after wear. The model will simulate adult female anatomy with a vaginal canal length between 6.4–9.5 cm and cervix dimensions of 2.5–4.1 cm long and 2.0–3.0 cm wide [10]. The uterine cavity depth will be 6–9 cm [11]. The structure will include a stable stand to maintain the canal at mid-torso height for ergonomic training and allow angulation adjustment to accommodate user preference. All materials must be non-toxic, non-corrosive, and safe for repeated handling without gloves. The model will be constructed from medical-grade silicone or comparable polymers with a Shore A hardness of 10–30 to simulate soft tissue compliance [12]. The model must weigh between 0.23–0.68 kg for stability and portability and withstand typical classroom use for up to ten practice sessions [13]. It should operate and be stored at room temperature (20–24°C) and humidity of 30–50% [14]. The design must be low cost, targeting $50 per unit and $500 total for ten models. Additional design specifications can be found in Appendix 1.

III. PRELIMINARY DESIGNS

3.1 Design 1: Modified Task Trainer

The modified task trainer is adapted from the current task trainer model shown in Figure 2. This existing device consists of a slip-joint tee connected to a PVC pipe mounted on a wooden base. One end of the tee remains open, and the other end holds the connector plate, a silicone cervix, and a 3D printed uterus. However, the current task trainer model has several limitations, as it lacks a vaginal canal, cervicovaginal junction, and an anatomically accurate uterus. As seen in Figure 7, our modified design addresses these shortcomings by including a removable silicone vaginal opening to the front of the PVC piping and integrating a cervicovaginal junction onto the cervical plate. The uterus was also modified with a T-shape cavity into the spherical portion of the model. The addition of the cervicovaginal junction, T-shaped uterus and removable silicone vaginal opening make this device much more anatomically accurate and will provide the user with a more realistic procedure.

In this design, all of the parts are detachable, allowing for the model to be efficiently cleaned, customized for different training procedures, and for individual components to be replaced when needed. This feature also makes the design more affordable because individual components can be remade from the original molds instead of replacing the entire device after multiple uses. The PVC piping and wooden base are both affordable materials that can be found at most hardware stores. This design positions the cervix around eye level with the clinician, which provides for a more realistic procedural experience.

Due to the large size and weight of this model, the ease of transportation is greatly limited. This model is also taller than our other designs, giving it a higher center of gravity and making it more prone to tipping during speculum insertion or other procedures.

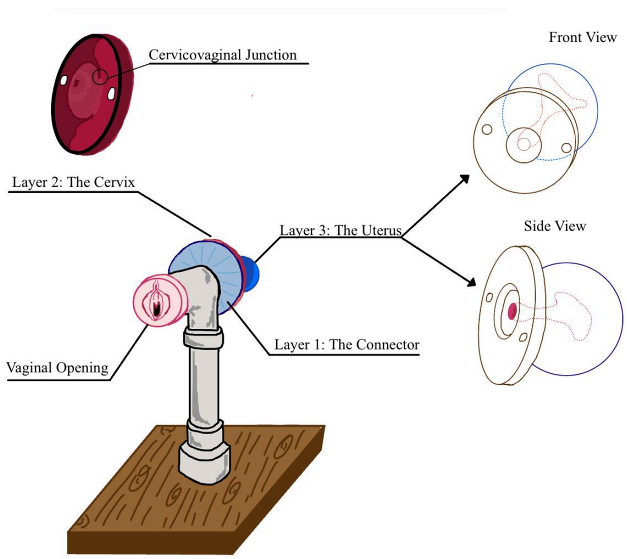


Figure 7: Modified Task Trainer Design

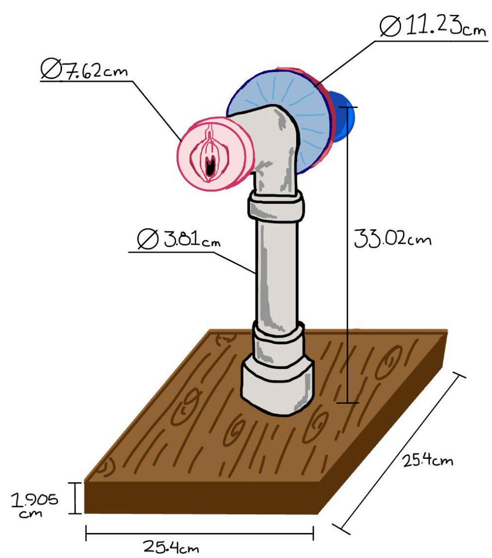


Figure 8: Modified Task Trainer Dimensions

3.2 Design 2: Shoebox Design

The Shoebox Design would be built inside of a rectangular box with a removable lid, similarly to a real shoebox (Figures 9 and 10). The vaginal opening would be against one side of the rectangular box, while the rest of the reproductive anatomy would be contained within the box. The model would include a semicircular vaginal canal, uterus, and replaceable cervix. The cervix design would be based off of the current cervix within the Task Trainer pictured in Figure 2. However, some notable changes would be made in order to improve the cervix design. A cervicovaginal junction would be added, and the shape would be altered to be rectangular. The vaginal canal would be cast with a PVC tube, and the cervix would be cast with a small rectangular box. These would both be first cast with spray foam insulation, then the materials would be removed, and finally the areas would be coated in silicon. The uterus would be fabricated by 3D printing a mold and casting it in ecoflex.

The addition of a cervicovaginal junction greatly improves the anatomical accuracy of the cervix. Additionally, the T-shaped uterine cavity will give users the ability to practice inserting an IUD after administering a paracervical block. Furthermore, the materials used, such as silicon and ecoflex, would give users a very realistic portrayal of working with anatomically correct tissue properties. There are also several benefits to the design outside of anatomical accuracy.

Namely, the replaceable cervix makes the design very durable. After receiving injections during training sessions, each cervix could be easily replaced from the top of the box, allowing the model to last through many training sessions. The removable lid also allows users to get a visual into the anatomy as they practice the procedure, making this a great learning opportunity for our client's students. The lid could be left on or off, depending on what skills are being honed during each unique training session.

The complicated nature of the design leads to a difficult fabrication process. The client has requested ten models, however each model of the Shoebox Design would have to be made one by one. This process would end up being undesirably difficult and time-consuming. Additionally, due to some of the materials required for the design, such as the sprayfoam and custom boxes, would also make this design expensive. Another drawback is that the Shoebox Design requires users to bend down to the height of the table in order to work. In a real paracervical blocking procedure, practitioners are working at eye level. Thus, to best attain procedural accuracy, the final design should allow for its users to work at eye level as well. Finally, the semicircle shape of the vaginal canal is anatomically inaccurate. In order to give users a view into the anatomy from the top of the box, the entire upper half of the vaginal canal had to be taken out. As a result, the model's portrayal of the vaginal canal is inaccurate when compared to realistic vaginal canals, which are fully cylinders.

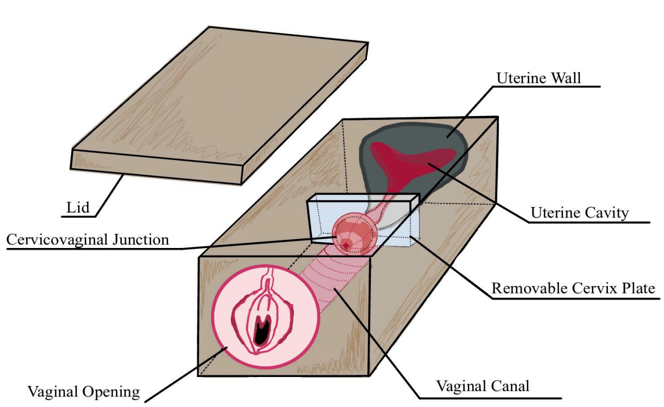


Figure 9: Shoebox Design

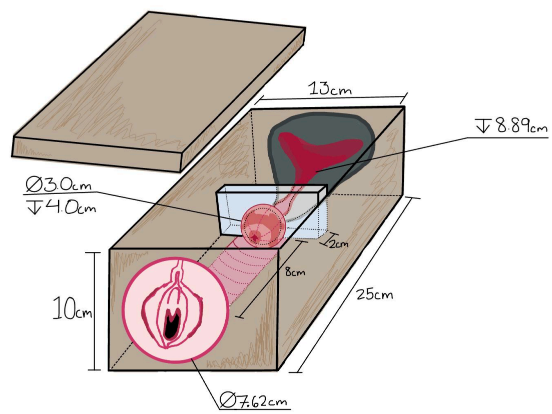


Figure 10: Shoebox Dimensions

3.3 Design 3: Modified Venus Design

The Modified Venus Design consists of a tabletop stand featuring a silicon vagina, which encloses a vaginal cavity with a cervix at the base (Figures 11 and 12). Off the back of the stand is the uterus, which is covered by a uterine wall and not visible from outside. The entire model is made up of silicon. The design would be created with the use of a singular mold, making the entirety of the design one piece, as opposed to multiple pieces that can be disassembled as needed. The vaginal opening will emulate the same resistance as a real vagina, meaning the speculum can be used to open the vagina using the same force as it would in a true paracervical block procedure.

Benefits of this design include the visual accuracy of the vagina and cervix components, as these are realistic and provide a user a good sense of what to look for when performing the paracervical block procedure in a clinical setting. Another accurate feature of this design is the ability of the vagina to be opened by the speculum. This will allow users to get a feel of both the force required during the procedure and the limited cervical working space while the speculum is being used. The model's small size makes it easy to transport and store while not in use, which is convenient for the client. Additionally, the model's low center of mass means it would remain stable and have a low risk of tipping over during training sessions. Ensuring this stability is important for maintaining an accurate portrayal of the procedure for students. The model should remain steady for needle injection and placement of the tenaculum in order to be true to the procedure.

One of the drawbacks of this design is that the small size of the device means it sits low to the table and requires a user to bend down to use it. This is not accurate when compared to what would be expected in a real procedure, where the cervix of the patient would be at the practitioner's eye level. Furthermore, the junctional angles between the cervix and uterus are inaccurate. The anatomy should be at an anteverted angle, or a forward bend of about 170 degrees [15] . Incorrect angles during training may lead to confusion during a real procedure regarding needle placement, as well as IUD insertion, which our client also anticipates using the model to train students in. The inseparable nature of the design's parts also poses an issue. Once the cervicovaginal junction sustains too much repeated needle use, the entire model will be rendered unusable and a replacement of the entire silicon design will be required. This is neither cost effective nor time effective for the client.

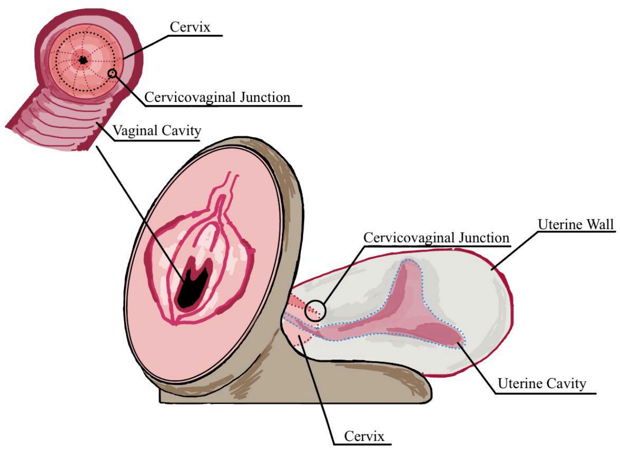


Figure 11: *Modified Venus Design*

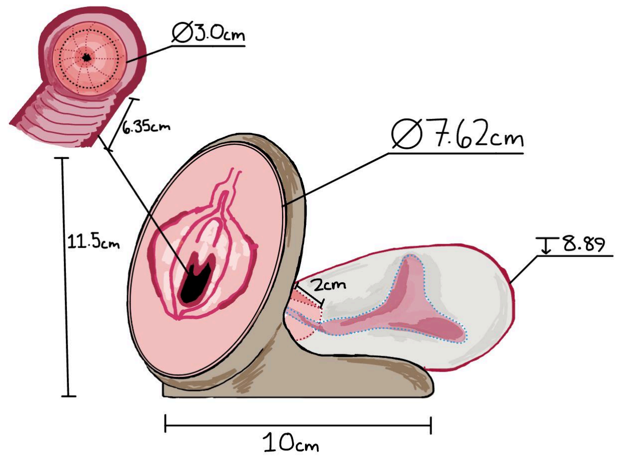


Figure 12: *Modified Venus Design Dimensions*

IV. PRELIMINARY DESIGN EVALUATION

4.1 Design Matrix

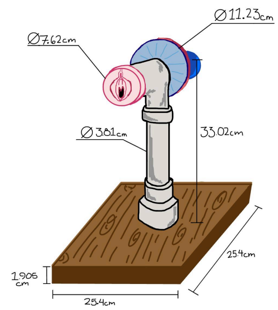
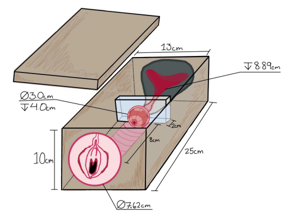
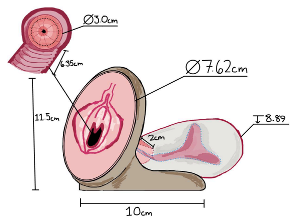
Criteria (Weight)	Modified Task Trainer 		Shoebox Design 		Modified Venus Design 	
Realistic (25)	5/5	25	4/5	20	2/5	10
Ease of Fabrication (25)	5/5	25	1/5	5	1/5	5
Anatomical Accuracy (20)	4/5	16	2/5	8	3/5	12
Cost (15)	5/5	15	3/5	9	4/5	12
Portability (10)	3/5	9	3/5	9	4/5	12
Safety (5)	4/5	1	5/5	5	5/5	5
Total (100)		91		56		56

Table 1: *The preliminary design matrix was created to judge the three preliminary designs (Modified Task Trainer, Shoebox Design, and Modified Venus Design) on the chosen criteria. The criteria weighted in importance are as follows: Realistic, Ease of Fabrication, Anatomical Accuracy, Cost, Portability, and Safety, with a final section of the total scores for each design which shows that the Modified Task Trainer design scored the highest overall.*

4.2 Design Matrix Criteria Analysis

Realness

Overall weight: Simulating a realistic paracervical block procedure is weighted at 25/100, since it's one of the top priorities for the paracervical block model. This category's importance is because it is a top priority of the client, and it is also because the entire purpose of the device is tied to the extent of its realism. Ensuring a user has a realistic experience of the procedure is critical for increasing a user's readiness for the real procedure and reducing future, potentially harmful, errors. This includes ensuring the model stands at a typical height for the procedure and portrays the proper resistance of female cervical and vaginal tissue.

Score justifications: This category assesses the models ability to simulate the paracervical block procedure. The Modified Task Trainer received a 5/5, since this design is the only one with a stand to simulate the height of a clinician's eye level while performing the paracervical block procedure. The Shoebox design received a 4/5. Similarly to the Modified Task Trainer, the ecoflex used reflects the resistance and physical feel of the vaginal tissue. It received a lower score because the height at which the procedure is performed is much lower than the clinician would actually expect. The Modified Venus Design received a 2/5, as it is also performed at a lower angle than one would actually perform a paracervical block. The Venus model has an inaccurate uterine angle, as the uterus simply lies off the back of the model. In 80% of women, the uterus is in an anteverted position, meaning it lies at a right angle to the vagina with a forward tilt [16]. This inaccuracy would lead to confusion in students and incorrect ideas of placement of the needle during the procedure, as it is vital to avoid injection into the uterus while performing injections.

Ease of Fabrication

Overall weight: Ease of fabrication is weighted equally with realism, at 25/100. Over time, repeated needle injections into the ecoflex cervicovaginal junction at the points of injection, at 2, 4, 8, and 10 o'clock, will eventually cause the silicon to wear out and tear [7]. The client needs to be able to replicate the model when pieces wear out as easily as possible. Due to the client's busy schedule, the replaceable parts of the product need to be easy and fast to recreate in between training sessions once worn out, and should not require research or learning of new skills to reproduce. In order for the model to serve its intended purpose as a convenient method to teach paracervical blocking for classes, the simple restoration of the silicon parts is essential.

Score justifications: The Modified Task Trainer received a score of 5/5, because the client is already familiar with and has used former versions of the Task Trainer. The PVC tubing and stand can be easily assembled, and the presence of the threads makes the device quick to disassemble as necessary when replacing pieces. The Shoebox Design scored a 1/5, because the building process requires multiple steps, including casting and 3D printing for the uterus, and would require substantial effort on the client's part to recreate. Similarly, the Modified Venus Design also scored a 1/5, as replicating its assembly would not be intuitive and low-effort when compared to the Modified Task Trainer. It would require learning and understanding how the uterus attaches to the cervix in the particular model, as our client would not be familiar with the new layout and materials.

Anatomical Accuracy

Overall weight: Anatomical accuracy was weighted at 20/100, as it is critical for a task trainer to visually replicate the anatomy of its models in order to fulfill its purpose of training users in performing the paracervical block. The model's ability to differentiate the vaginal canal, cervix, and uterus is essential to provide medical students with the most realistic training experience possible. The essential parts involved in the procedure, particularly the cervicovaginal junction and cervix itself, must be visually accurate for insertion of the needle at the correct 2, 4, 8, and 10 o'clock positions [7].

Score justifications: The Modified Task Trainer received a score of 4/5 because its attachments can be adjusted to meet various anatomical training needs, while its base structure remains unchanged. This model also incorporates the design of cervical folds, which are distinctive anatomical features that help differentiate the uterus from the cervix.The Shoebox Design scored 2/5 due to its poor visual representation of the uterus, cervix, and vaginal canal, despite maintaining basic biomechanical function. The Modified Venus Design received a score of 3/5. While this model is also interchangeable and reflects the general appearance of uterine, cervical, and vaginal structures, it does not accurately represent the junctional angles between the cervix and uterus.

Cost

Overall weight: The cost effectiveness of our design was weighted to be 15/100, since multiple models will be produced for the client. There should be ten finished functional models fabricated, because the client intends to use this product for classes and presentations. During these presentations, medical students will perform the procedure on their model using one task trainer each. This allows for maximum practice time for each individual. Given the project's $500 budget, each model will need to be produced at a cost effective rate of $50 each.

Score justifications: The Modified Task Trainer receives a 5/5 on cost effectiveness because its pieces are easily accessible and purchased at a low cost. Additionally, this model requires a relatively lower number of components, ultimately greatly reducing the cost to construct it. The Shoebox Design receives a 3/5. This score arises because the design is the most complicated from a manufacturing standpoint, containing more molded components which are made of more expensive materials like silicone. Lastly, the modified venus design received a 4/5. As previously stated, the Venus design is relatively simple to construct and purchase components for but possesses more complexity than the simple Modified Task Trainer.

Portability

Overall weight: Ten models will be used at a time in a classroom setting, and will require storage and transport in between classes. The client needs to move trainers to and from storage and training areas, and possibly between buildings in order to train providers in many locations. It should be relatively easy to lift, possibly disassemble, and transport as needed. A reasonably portable design is convenient for the client, though not a larger priority than some of the more critical design aspects, such as the realisticness. For all three designs, none of their sizes are prohibitively large, meaning that they are all adequate and relatively mobile. For these reasons, portability received a weight of 10/100.

Score justifications: The Modified Task Trainer was rated a 3/5 as it has a flat base, making it easy to set, store, and transport. However, the unusual shape prohibits it from being packed efficiently together. On the other hand, the Shoebox Design's small, rectangular box shape makes it ideal for packing together and being easily transported in a box, car, or more. However, the replaceable cervix component is hard to transport comfortably. For these reasons, the Shoebox Design received a 3/5. The Modified Venus Design can be easily transported due to its flat base and simple, table-top design which allows it to safely stand up during transportation. The relatively simple and durable components also make it easily portable, thus giving the Modified Venus Design a score of 4/5.

Safety

Overall weight: The model should not pose a risk to the user, even in the event of improper use, as it is intended to be a learning device with room for errors. It must be made of safe, non-toxic material, which can be safely touched without gloves or precautions, as it will be used in a classroom setting, and will be handled by many individuals over time. The model should not tip over or present a risk of hitting the user while they attempt to perform a block, including during the process of inserting the speculum into the vaginal opening and opening the device, and grasping the cervix and pulling with the tenaculum. While safety is important, it is not a very critical aspect of our design, as none of the models propose a great hazard to the user, and will likely never be in a situation to cause harm in general. Therefore, it is rated lowest in terms of importance, at a weight of 5/100.

Score justifications: This category ranks the relative safety of each design. All designs essentially have the same level of safety which is why all designs received high scores. The Modified Task Trainer received a 4/5 because it is the only design that is elevated and puts it at a slightly higher risk of tipping. Both the Shoebox Design and the Modified Venus Design received a 5/5 because they have a lower center of mass on the table and have a very small risk of falling.

4.3 Proposed Final Design

The chosen final design is the Modified Task Trainer, as it performed best in the design evaluation and meets the key criteria of ease of fabrication, realism, anatomical accuracy, and cost effectiveness, as shown in Table 1. This design provides clinicians with the most realistic preparation for performing procedures on real patients.

It would be fabricated using the same structure of the existing Task Trainer, shown in Figure 2, but will include improvements such as a vaginal opening, cervicovaginal junction, and T-shaped uterus. These features will be designed in Solidworks, 3D printed, and cast in silicone to replicate the mechanical properties of the vagina, cervix and uterus. The base structure of the model will be easily constructed with a tee-slip and a PVC pipe that will be mounted to a wooden base.

Each component on this device is fully removable, allowing for the design to be easily disassembled for cleaning, replacement, or modification for different training procedures. This modularity makes the entire device cost effective, as individual parts can be remade from the original molds instead of having to replace the entire model after repeated use. This feature differs from other designs that have a fixed structure. With the molds being available to the client, the additional materials will be accessible and inexpensive so the design can be easily reproduced.

The Modified Task Trainer also achieves a realistic and anatomically accurate structure in several areas, hitting two of the more important criteria. Specifically, the shape, appearance, and size of the silicone cervix that will be cast in the cervical mold (Figure 13) are anatomically correct. The depth of the vaginal canal and size of the vaginal opening will also be anatomically accurate, and the feel of the ecoflex cervicovaginal junction will closely resemble vaginal tissue. The addition of the cervicovaginal junction allows clinicians to perform paracervical blocks in the correct anatomical location, while the vaginal opening will support the speculum so clinicians can practice realistic insertion and procedural training. The T-shaped uterus will further enhance anatomical accuracy and allow for procedures such as IUD insertion to be performed more effectively. The model's height positions the cervix at around eye level with the clinician, providing the best simulation for gynecological procedures compared to the other tabletop designs.

While the Modified Task Trainer has significant advantages, it also has a few limitations. This model would be less portable than the other two designs due to its weight and larger size, making it more difficult to transport models between training sessions. However, by adding threads to the PVC tee-slip joint, the top could be disassembled for easier transportation. This model also has a higher center of gravity, putting it at risk of tipping during the procedure. This could be fixed by adding a heavier base for improved stability. Despite these downsides, the benefits of the Modified Task Trainer outweigh the limitations, making it the optimal choice for the paracervical block training model.

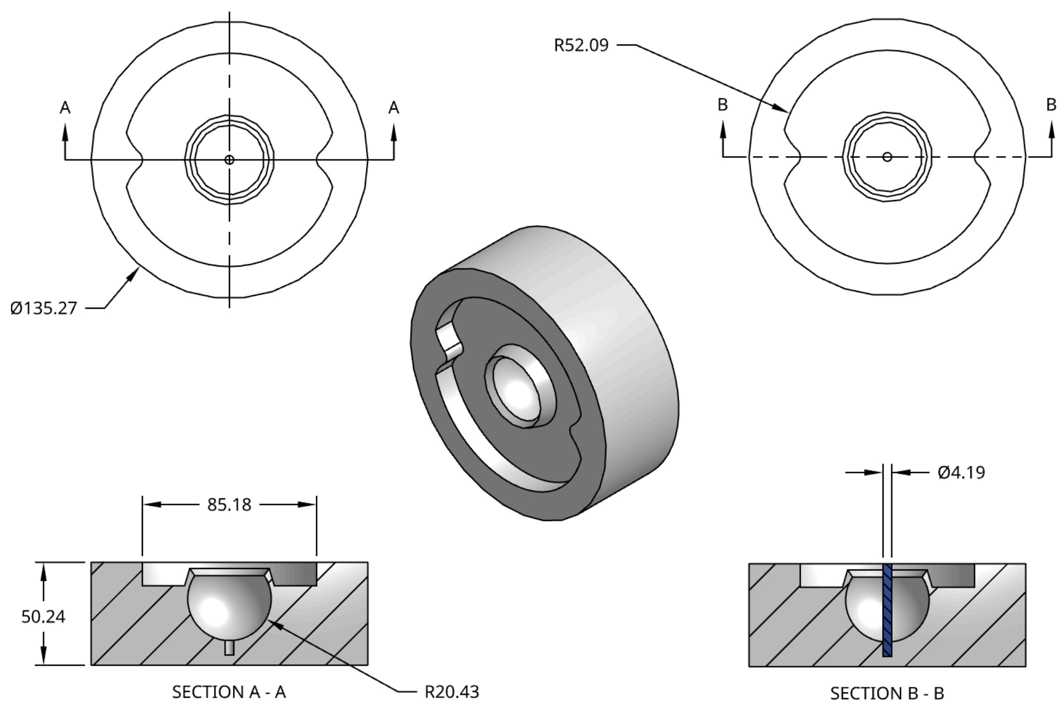


Figure 13: Drawing of the cervix mold to enable silicone casting.

IV. DEVELOPMENT PROCESS

5.1 Materials

The materials selected for this design must exhibit realistic mechanical, visual and tactile properties that closely replicate the vagina, cervix and uterus. The materials used should also be able to withstand repeated instrument use. The cervix in particular should remain functional for around 20-30 practice procedures before it must be replaced. The materials must be affordable, durable, easy to clean and have similar properties to the target tissues.

The vaginal tissue is made of a soft, flexible connective tissue with an elastic modulus of around 7-13 kPa [17]. The uterus is moderately stiff and is a highly muscular tissue that has an elastic modulus of around 20-100 kPa [18]. The cervix is made out of a very stiff tissue to act as a barrier between the uterus and vagina. It has an elastic modulus of around 2.17-243 kPa and has a Shore hardness of 10-30 [18], [19]. Note that these values vary widely due to biological variability and the lack of research and funding in women's health. However, this project will be using these averages as well as the experience and opinion of our client to verify if the materials mimic the feel of an actual uterus, vagina or cervix.

Based on these ranges we will be using Ecoflex 00-20 to cast the cervix, vagina and uterus. Eco-flex 00-20 is a soft, stretchy platinum-cure silicone rubber that is very accessible and easy to work with. This Ecoflex has a Shore hardness of 00-20 and an elastic modulus of around 55kPa which falls within the physiological stiffness ranges of these different tissues [20]. A Smooth-On Silicone thinner can be added with the Ecoflex 00-20 to fine-tune the softness and feel of the tissue [21]. Ecoflex 00-20 also has a tensile strength of 1.1 MPa and a 845% elongation at break, which should provide excellent durability for multiple sessions while replicating the realistic feel of the reproductive tissue

Figure 14: Eco-Flex 00-20

5.2 Methods

The team began development by importing the STL files provided by our client in the project description during project selection. These files were provided from the University of Nebraska Task Trainer Model (Figure 2). Initial modifications were made to ensure anatomical accuracy, specifically by adding a cervicovaginal junction to the cervix model. The connecting piece and uterus were printed directly from the client-provided STL files without further alteration for the first prototype as seen in Figure 15.

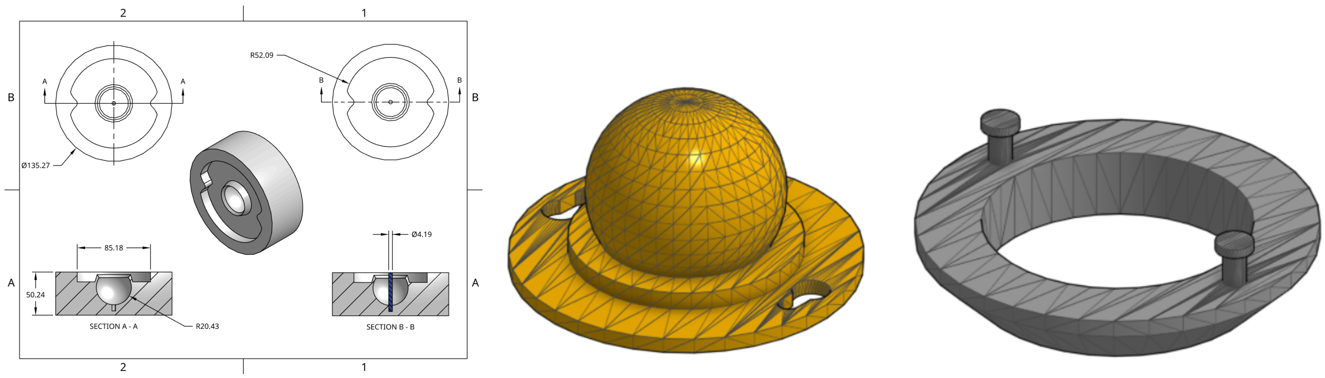


Figure 15: *(a)* The team's initial OnShape drawing of the cervix mold, which incorporated a cervicovaginal junction. *(b)* Client-provided STL file of the uterus model. *(c)* Client-provided STL file of the connecting piece.

Following the initial round of fabrication, the team met with the client to evaluate the accuracy of the cervix based on the changes the team had made. She noted that the vaginal walls provided by the PVC pipe were not sufficient as the cervix sits more snug within them. After receiving this feedback, the team created a revised mold that extended vaginal walls from the cervix to improve upon the anatomical accuracy of our model as seen in Figure 16. While doing this, the team also redimensioned the connecting piece so that it better fit the PVC tubing ordered by the team. A mold was created for the vaginal opening which would be placed opposite the cervix on the Charlotte pipe serving as the vaginal canal (Figure 17). However, the initial mold dimensions were inaccurate, causing the vaginal opening to stretch excessively over the pipe. In addition, the final opening had to be cut manually, resulting in an uneven and inconsistent edge.

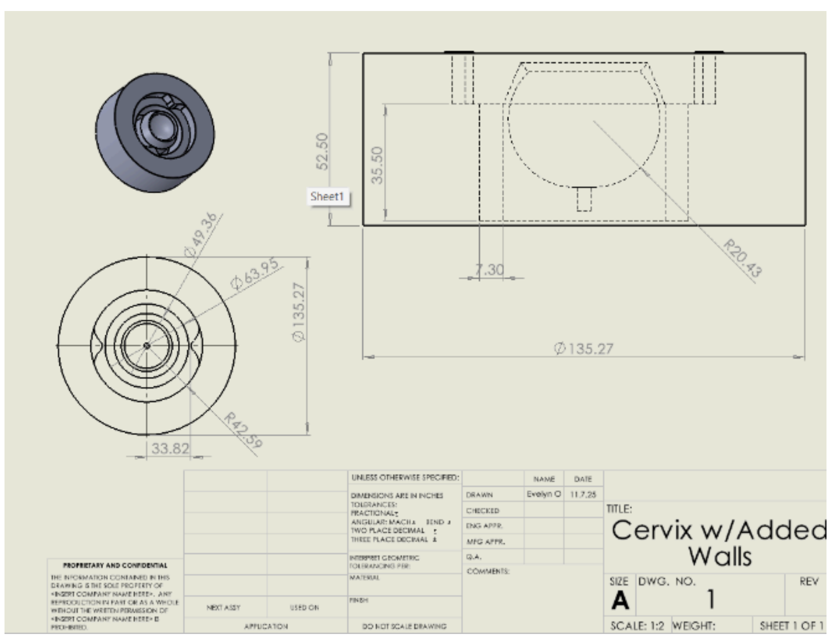


Figure 16: Solidworks model of the cervical model with added wall.

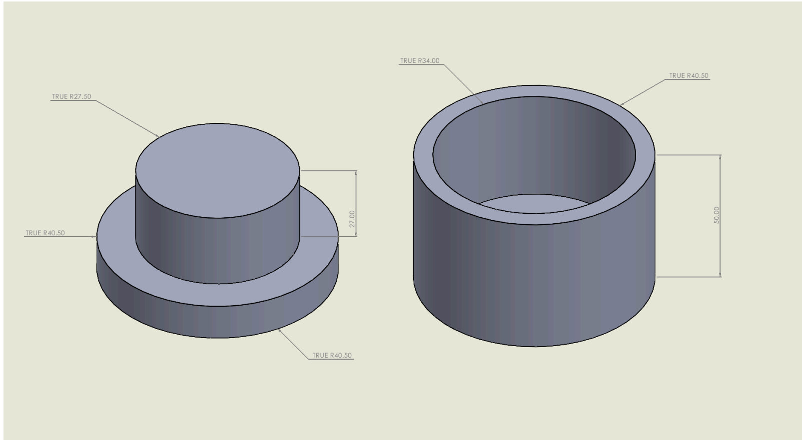


Figure 17: Solidworks model of the initial vaginal opening mold.

A second meeting with our client was held to review the first complete prototype. She highlighted some key areas of improvement, specifically that the Charlotte pipe that served as our vaginal canal was too long for the materials used during training and that the cervical mold required modifications, including adjusting the cervical geometry and widening the cervicovaginal junction to improve visualization. To address the issue with the Charlotte pipe, the team created a revised model that shortened the top section and reduced the neck diameter while maintaining the original base diameter so it would still fit the existing tubing, which can be seen in Figure 18(a). The cervical mold was modified by changing the geometry of the cervix to have a more elliptical shape rather than a sphere shape, as well as increasing the width of the cervicovaginal junction, seen in Figure 18(b). Along with the two main modifications requested by our client, we also adjusted the vaginal opening mold to improve its geometry and increase its length so that it was more stable on the pipe and would not risk being pulled off during speculum removal. In this revision, we also incorporated the vaginal opening directly into the mold to improve consistency in the size of the opening, as seen in Figure 19.

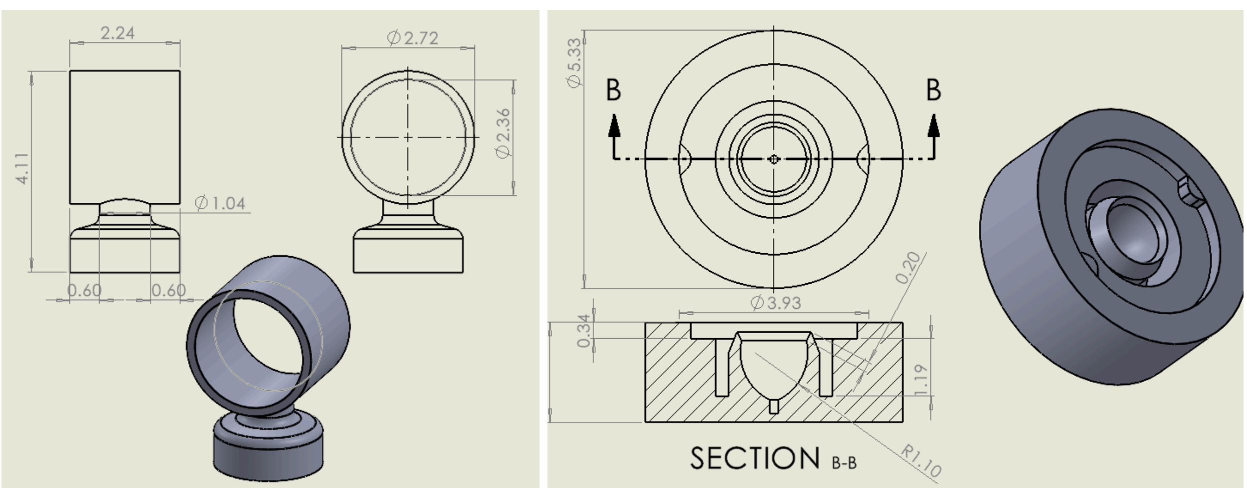


Figure 18: *(a)* SolidWorks drawing the modified Charlotte pipe that decreased the length while still allowing for placement of the connecting piece and vaginal opening. *(b)* SolidWorks drawing of the modified cervical mold that has a more elliptical shaped cervix and an increased cervicovaginal junction.

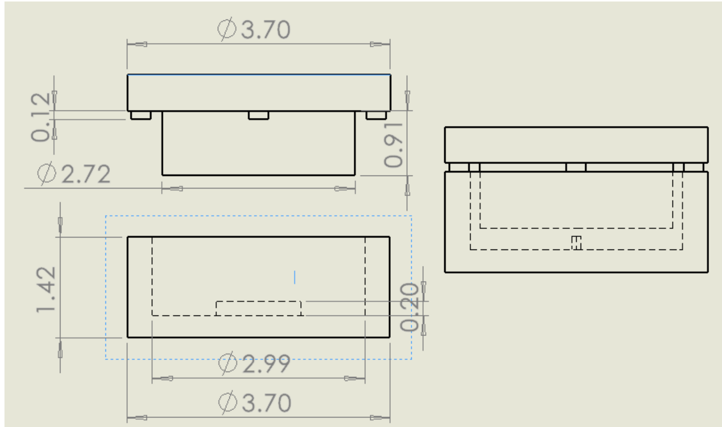


Figure 19: SolidWorks drawing of the final vaginal opening mold which increased the length of the mold and had a pre cut vaginal opening.

Along with these two changes, our client asked the team to explore ways of creating an interior component for the uterus that more accurately reflected the shape of the uterus while still preserving the existing outer structure which had been serving as our uterus. The team developed a SolidWorks model of a potential design that incorporated a more anatomically accurate internal section based on a current IUD insertion model, as seen in Figure 20. However, this model failed to 3D print using the intended material of ClearV5. Although it was able to print in PLA, the supports that required for a successful print were unable to be removed without also removing the supports that had been included in the design; the supports also filled the interior portion and rendered the interior portion unusable.

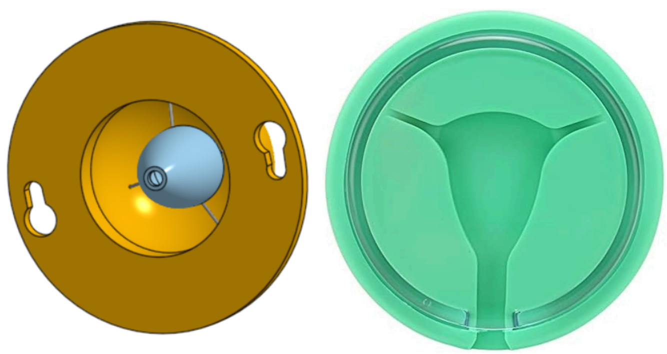


Figure 20: The team's SolidWorks model (on the left) of the potential design with an interior uterus component that was based on current IUD insertion models (on the right.)

5.3 Final Design

For the final prototype, the cervix and revised uterus and connecting piece were assembled with the modified Charlotte pipe and mounted to the base consisting of a 6-inch vertical PVC tube attached to a 12” × 12” wooden platform (Figure 21a). The assembly process began by placing the connecting piece with the alignment pins facing away from the Charlotte pipe. The cervix was then inserted into the Charlotte pipe as seen in Figure 21b, followed by the uterus, which was twisted into the connecting piece to lock it into place. Finally, the vaginal opening was positioned on the opposite end of the pipe to complete the model. The team attempted to incorporate an internal uterine structure to improve anatomical realism; however, fabrication, printing failures, and time limitations prevented its successful implementation, and the simplified uterus model was used for physician testing.

Figure 21: *(a)* Final complete paracervical block training model with all components attached to the base. *(b)* Cervix and cervicovaginal junction as seen looking down the Charlotte pipe with the vaginal opening removed.

V. TESTING AND RESULTS

Material Evaluation of Ecoflex 00-20

Tensile MTS Testing

The tensile properties of Ecoflex 00-20 were evaluated using an MTS uniaxial testing machine. Dumbbell-shaped samples were prepared according to ASTM D412 Type C standards, with a 6 mm × 3 mm cross-sectional area and 33 mm gauge length, and cured overnight. Each sample was pulled in tension at a constant strain rate until failure, generating stress–strain data (Figure 22). A 100 N load cell ensured accurate measurement across the full deformation range. A more complete testing protocol can be found in Appendix 10.2.

Young's modulus and ultimate tensile strength were calculated from the resulting stress–strain curves. Six replicate samples were tested to allow for statistical analysis and to assess how closely Ecoflex 00-20 mimics the mechanical behavior of soft cervical and cervicovaginal tissues. MATLAB was used to compute strains, stresses, and Young's modulus for each sample, and an average stress–strain curve was plotted (Appendix 10.4A).

The recorded Young's modulus in tension was 0.389 ± 0.062MPa, which falls within the reported range for cervicovaginal tissue (~0.01–1 MPa) [22], [23]. Despite some variability in the data, these results indicate that Ecoflex 00-20 exhibits mechanical stiffness comparable to cervicovaginal tissue.

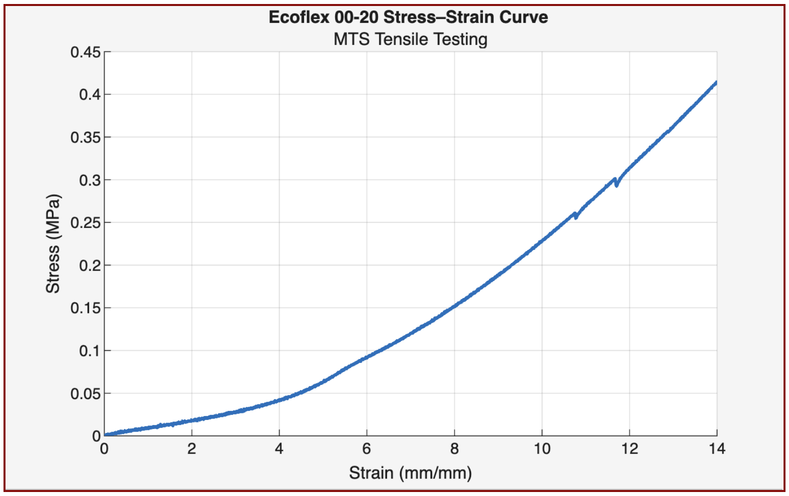


Figure 22: Average Stress-Strain Curve of EcoFlex 00-20 in Tension.

Compressive MTS Testing

The compressive behavior of Ecoflex 00-20 was characterized using the MTS machine. Cylindrical samples were prepared according to ASTM D575 Type C standards, with 12 mm height and 25 mm diameter, and cured overnight. Samples were compressed between parallel plates at a controlled displacement rate, and a 50 N load cell collected accurate force data [24]. Stress–strain curves were generated up to the onset of significant deformation, and the compressive modulus was extracted from the linear region of each curve (Figure 23).

MATLAB was used to compute strains, stresses, and Young's modulus for each sample (Appendix 10.3B). The average stress–strain curve was plotted, and Young's modulus was determined from the linear region, yielding a value of 0.071 ± 0.01065 MPa.

This modulus is lower than that measured in tension, which is expected for a soft, hyperelastic material like Ecoflex 00-20. Its stress–strain response is nonlinear and depends on the mode of loading, strain magnitude, and chain alignment, therefore the strength in tension may differ from that in compression. Regardless, the compressive modulus still falls within the physiological range for cervicovaginal tissue (~0.01–1 MPa) [22], [23], [25]. Overall, these results demonstrate that Ecoflex 00-20 is a suitable material for mimicking the mechanical behavior of cervicovaginal tissues under both tensile and compressive loading.

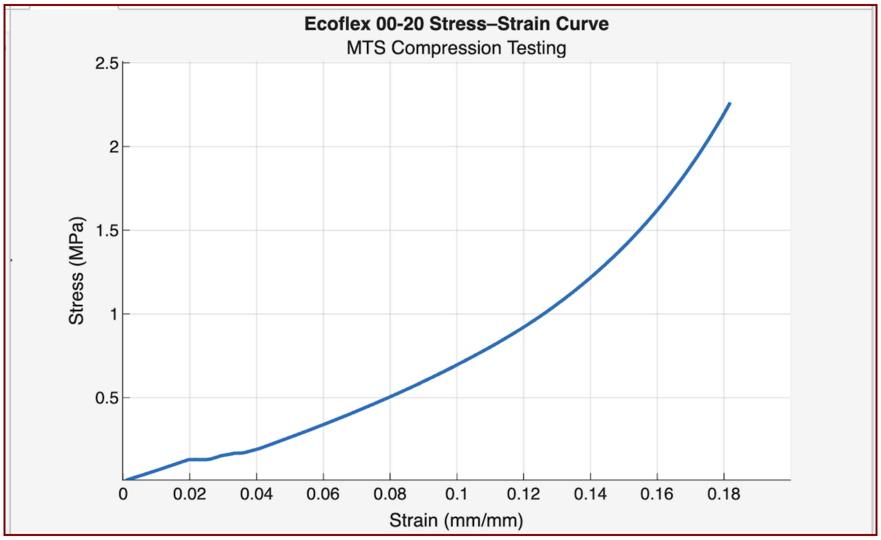


Figure 23: Average Stress-Strain Curve of EcoFlex 00-20 in Compression.

Physician Feedback

Feedback was obtained from 6 physicians and 1 resident to evaluate the realism of the Paracervical Block Training Model in simulating cervicovaginal tissue, and the models overall effectiveness. Due to limited quantitative data on the mechanical properties of these soft tissues, we relied on the opinion of medical professionals to assess the material's performance. Medical professionals were provided with structured feedback sheets that asked them to rate key aspects, including anatomical accuracy, tissue texture, ease of landmark identification, needle insertion realism, and overall fidelity compared to actual tissue *(Appendix 10.4)*. Responses were collected through a Qualtrics survey, using a combination of Likert-scale ratings and open-ended questions, allowing semi-quantitative analysis alongside qualitative insights. This approach enabled us to systematically capture expert assessments and identify areas for potential refinement of the Ecoflex 00-20 material and the training model.

Physicians evaluated the Paracervical Block Training Model across multiple success categories using a 1–10 scale on structured feedback forms, (Figure 24) with 1 being completely unsatisfactory and 10 being completely satisfactory. Mean scores and standard deviations were calculated to assess both performance and consistency. Overall, the model demonstrated strong performance across all evaluated domains. 100% of medical professionals indicated that they would recommend the model to colleagues. Performance metrics yielded an 86.67% satisfaction rate, an 88.33% effectiveness rate, and a 98.00% intuitiveness score. High scores in realism, intuitivity, and ease of use further supported the model's functional design and practical applicability in a training setting.

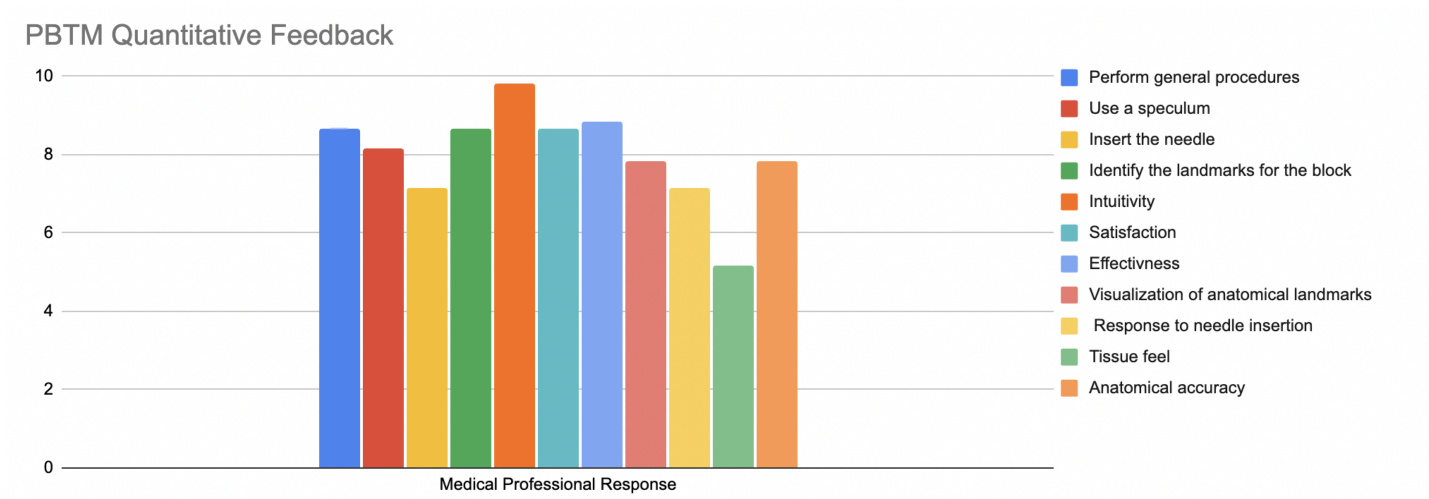


Figure 24: Quantitative Feedback Form Results

Qualitative feedback highlighted the model's effectiveness as a procedural training tool, with physicians noting the clarity of instructional guidance, the realistic tactile feel, and the intuitive structure. Suggestions for improvement included introducing greater variability in tissue material to better simulate patient diversity and refining the cervical tilt angle to more accurately reflect anatomical conditions. Overall, physician feedback indicates that the PBTM is a well-designed and effective training tool, while also identifying opportunities to enhance realism and educational value in future works.

VI. DISCUSSION

Mechanical testing through compressive and tensile loading on Ecoflex 00-20 produced a Young's modulus for the material. This represents the ratio of applied stress to the resulting strain, and is calculated using the slope from the linear region of the stress-strain curves (Figure 22 and 23). The results revealed that the compressive and tensile moduli fell within the ranges for the cervicovaginal tissue (~0.01-1MPa) [22], [23]. Therefore, our materials were reasonably within the range of true cervical tissue. Although Young's modulus differed in tension and compression, showing that the material's stiffness is not uniform under different types of loading, this is expected behavior for an nonlinear, viscoelastic silicon material [26]. Since both values remained within the normal range for cervical tissue, this variation in data is not a concern. This gave us confidence that our material's adherence to realism was satisfactory.

Our material testing showed that the Ecoflex 00-20 material had properties that fell within the ranges of reported literature values of reproductive tissue. This indicates that the Ecoflex was an appropriate material to use in our model to mimic the cervical tissue. However, the reported literature values contain a great amount of variability. This is likely due to the long-standing lack of research and funding in women's healthcare. Deeply rooted gender biases in medicine have further limited studies for women's pain and physiology [27], [28]. This results in limited, inconsistent, and often low quality mechanical data on reproductive tissues, particularly the cervix. In addition, the wide range of reported tissue stiffness and dimensions reflects the variability from one patient to another, further contributing to the large range for stiffness and Young's Modulus values [29], [30]. Due to these reasons, the literature values we used are the best available estimates but are not entirely reliable to base our model off of. Therefore, input from physicians who are experienced in performing paracervical blocks was essential for assessing the realism of the materials and the authenticity of the procedure.

Our team worked closely with Dr. Dalby throughout prototyping, making changes based on her feedback, and 6 physicians also tested the model and answered a survey to reveal their assessment with the model. The survey results revealed a few technical issues with the model. The speculum was not as supported by the vaginal opening as expected and they felt that the stiffness of the cervix was too low when securing the tenaculum. However, they were very satisfied with the feel of the needle insertion in the cervix and cervicovaginal junction, which they felt was more important for training purposes. They felt there was limited visibility through the uterus when trying to visualize the needle, and the uterine angle needed improvement. In the current model this angle is not realistic to the true anteverted angle of the cervix. Ideally, our model would be modified to this anatomically accurate angle to provide a more realistic procedural experience.

Therefore, there are many improvements that can still be made in order to make the model more realistic. Due to the modularity of the model, improvements can easily be integrated to individual components without having to change the entire model. However, despite their critiques, 100% of physicians who practiced on and reviewed the model recommended it for training use. One physician commented that it was "more realistic than any other model I've ever worked with," and many others were especially pleased with the accuracy of cervical procedures. This gives us confidence that the existing model accomplishes its purpose of helping clinicians gain knowledge and familiarity with the paracervical block procedure, despite a few shortcomings.

Toward the end of the project, the team also made efforts to create a more anatomically accurate uterus. The design was constructed in OnShape so the original spherical component would contain a smaller, 3D printed uterus within. This inner component would be the anatomically correct shape and size, and would mimic the feeling of incorrect needle placement if the needle came into contact with the uterus. However, this iteration could not be successfully printed due to limitations with the 3D printer and time constraints. The geometry required supports for printing that would compromise the interior of the uterus, and there was insufficient time to redesign the model to avoid these issues. Nonetheless, due to the modularity of the design, future improvements could easily be made in order to improve the anatomical accuracy of the uterus.

VII. CONCLUSION AND FUTURE WORK

A paracervical blocking procedure is a local anesthetic injection at specific sites in the cervicovaginal junction [7]. There are a few models currently available for providers to practice the procedure on, such as the Venus Model (Figure 3), the current Task Trainer Model (Figure 2), or the Miya Model (Figure 1). None of these models fulfill the client's need for an accurate, affordable model that can be used for various procedures and training activities. The Venus model is too limited in its procedural scope, and the Task Trainer model lacks anatomical accuracy. Additionally, the Miya model is too expensive for the client's budget. Currently, the client uses the Roma Tomato Model, which is created through a dixie cup, roma tomato, and condom. The bottom of the dixie cup is removed, and the tomato placed on the other side of this opening. The condom is placed around the tomato and stretched though the dixie cup to act as the vaginal walls. With the tomato acting as the uterus, users practice injecting into the intersection between the cup and tomato. While the mechanical properties of the tomato are not entirely inaccurate, it is missing the landmarks such as the cervicovaginal junction, vaginal entrance, and has a completely inaccurate vaginal canal.

The goal of this project was to design and fabricate ten gynecological training models for use in paracervical block administration training sessions. These task trainers should be anatomically accurate in both their dimensions and the properties of the materials used. Additionally, the final design must remain under a budget of $500. In the final design chosen, the model is mounted on top of a PVC tube attached to a wooden base. The design includes a silicon cervix, 3D printed uterus, cervicovaginal junction, vaginal canal, and vaginal opening. This design combines several aspects that the team greatly desired, such as the ability for users to work at eye level height and a cervicovaginal junction. Furthermore, the individual components within this model are detachable and can be easily replaced via their original molds.

The team performed MTS testing on the silicone material, Ecoflex 00-20, which was used in the model to emulate reproductive tissue. For the tensile testing, dumbbell-shaped models were tested on an MTS uniaxial machine in tension according to ASTM D412 Type C standards. Young's modulus for this material was 0.389 MPa +/- 0.062MPa, while the physiological range for cervicovaginal tissue is ~0.01-1.0 MPa. Since the resulting value fell within this range, the silicon material succeeded in mimicking human cervicovaginal tissue's stiffness. The compressive testing was performed according to ASTM D575 Type C, and the team used flat, cylindrical samples of the silicon material. The compressive modulus was 0.071 +/- 0.01065 MPa, which also satisfied the physiological range for cervicovaginal tissue. Thus, the MTS testing shows that the Ecoflex 00-20 successfully simulates the mechanical properties of human cervicovaginal tissue. Additionally, physician feedback was used to evaluate the model's anatomical and procedural accuracy, using both open-ended questions and Likert-scale ratings. The model scored highly in realism, intuitivity, and ease of use. Additionally, all of the physicians surveyed reported that they would recommend the model to colleagues. From this physician feedback, the model was also found to be proficient in acting as a sufficient model for both anatomy and procedural training.

During the prototyping process, several components were altered from their original design. The majority of these modifications, such as alterations to the vaginal canal and cervix, were executed successfully. The cervix was changed to be more elliptical, with a wider cervicovaginal junction. The vaginal canal was shortened. One of the only unsuccessfully attempted changes was with the uterus component. This alteration would create a T-shaped pocket within the uterus, mimicking a uterus' internal characteristics. Despite a promising potential design, improvements to the interior section of the uterus were unable to be successfully printed due to issues with the supports. This remains an aspect of the design that can be refined in the future. Overall, the final design's fabrication was highly successful, and resulted in a working model that accurately mimicked anatomy and procedural processes.

In the future, there are several aspects of the model that can still be improved upon. It would be useful to create a more streamlined process for the removal of the cervix from its mold. Different molding techniques should be tested to find the most efficient strategy for fast, successful mold removal. Additionally, printing difficulties were encountered when attempting to print the uterus from the material Clear v5. If found, a more optimal clear material would be more successfully printed while still maintaining the ability to look inside of the uterus. In order to help practicing users maximally benefit from their time working with the model, a feature should be added that notifies users of an incorrect paracervical block administration. When users inject too far or at an incorrect location, this electronic component would detect the error and send off an alert, such as a buzz. Physician feedback also relayed several ideas for future changes, such as a range of shades of the tissue material, which could be achieved through different colors of silicon that more accurately reflect the diversity of patient anatomy. Additionally, physicians noted that the cervical tilt angle could be more accurate. The model should be adjusted to show an anteverted angle between the vagina and uterus. Once executed, these modifications will ensure that the model is fully anatomically accurate and optimized for the client's needs.

VIII. ACKNOWLEDGEMENTS

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X. APPENDIX

10.1 Product Design Specifications

Function

A paracervical block (PCB) is a medical procedure in which a local anesthetic, such as lidocaine, is injected into the tissue at the cervicovaginal junction, where the vaginal wall meets the cervix, at four locations (2,4,8,and 10 o'clock) [1]. This procedure is performed to reduce pain during intrauterine device (IUD) insertion and other gynecological procedures. However, many women undergo these procedures without the benefits of a PCB due to limited provider training. This lack of training is often related to the lack of realistic, affordable models for practice. Current task trainers used to teach IUD insertion typically do not have a cervicovaginal junction, preventing students from practicing proper PCB technique. The lack of opportunities results in fewer providers who feel confident in performing the procedure, and thus more patients without access to this form of pain management. The development of a Paracervical Block Training Model (PCBTM) solves this problem. The PCBTM uses tissue-mimicking materials to replicate the cervicovaginal junction, allowing learners to practice in a safe, repeatable environment. This model must be designed to be both anatomically and mechanically realistic, reproducible so that our client can continue to cast new pieces after wear and tear, and low cost, around 500 dollars, so it can be widely used in skills labs and teaching centers.

Client Requirements

The client, Dr. Jessica Dalby, has requested the following specifications to be made to the design:

- The design should be a realistic, reproducible, and low cost task trainer for practicing paracervical block administering.
- We should create this training model to be anatomically accurate with materials that emulate both the properties and visual landmarks of the cervicovaginal junction, such as the squamocolumnar junction, the transformation zone, and the external os, in order to properly instruct physicians on the procedure [2].

- This model can be either easily reproducible, or able to be disassembled for easy transportation and use in larger lecture-like environments.
- The model training kit should possess a mechanism for viewing success/failure throughout the instruction process, so that students can verify effectiveness in terms of parameters like depth and pressure of the needle.
- Additionally the model should have the capacity to be used for IUD insertion after paracervical block instruction.
- The team is being provided with information regarding the old design for educating the new residents, and the process of instruction as well.

Design Requirements

1. **Physical and Operational Characteristics**
    a. **Performance Requirements**
        i. The model must allow the user to practice a paracervical block by injecting the appropriate areas. It must simulate a cervix and the adjacent vaginal wall, and the cervix will need to be secured by a tenaculum. The tissue around the cervix near the uterosacral and cardinal ligaments must be injected into. The simulated anterior lip of the cervix will be injected into first at 12 o’ clock. The cervix must then be grasped by the tenaculum, followed by injections of the cervicovaginal junction at 2, 4, 8, and 10 o’ clock, as is consistent with a four-site paracervical block procedure [3]. The cervix, upper vagina, and lower uterine segment have parasympathetic fibers which enter the cervix with uterine blood vessels at 3 and 9 o'clock, and the model will enable the user to practice anesthetizing these nerve bundles through the block [4]. It should be able to both withstand and realistically simulate different varying injections, as some practitioners prefer to use a two-site block, which includes two injections at 4 and 8 o’ clock instead of the four at 2, 4, 8, and 10 [5].
        ii. The model must be usable for practicing all parts of the process of IUD insertion, including hiding the strings. It should allow the user to sound to measure the depth of the uterine

cavity, as is consistent with regular placement of an IUD. The uterine cavity should have a depth between 6 and 9 cm for most IUDs. The model must also permit for the rest of the insertion process to be performed. After aligning the flange with the IUD arms and setting it to the distance the uterus was sounded to, an inserter rod will be placed into the insertion tube at the end opposite the arms of the IUD. The IUD will then be inserted until the flange is against the cervical os, the opening of the cervix where the lower part of the uterus connects to the vagina [6]. The tube will be pulled back by 2 cm so the IUD arms can expand, and then slowly moved forward for positioning purposes. The insertion rod is then removed by holding the insertion tube still and removing the tube and tenaculum. Lastly, the threads will be cut to a length of 3 cm [7]. The uterine cavity will need to be correctly shaped in order to hold the IUD and allow a user to confirm it is properly positioned. The model should also allow for troubleshooting to be practiced, including scenarios such as hiding the strings.

b. **Safety**

i. The model must be made from non-toxic and non-corrosive materials. It should be safe to be touched and handled without gloves, and easily moved. It must not present a hazard to the user, before, after, or during use in a training setting.

ii. There should be a safe and efficient way to replace any parts of the model as needed. Possible fluid buildup from injections should not present a hazard to the user.

c. **Accuracy and Reliability**

i. The model must somewhat accurately depict the size of the vagina and cervix, and should include distinguishable physical features, including the anterior lip of the cervix, which will need to be secured by the tenaculum, and the vaginal fornices, which are the protrusions of the cervix into the vagina. There are two lateral fornices; anterior fornix and posterior fornix [8]. The average vaginal length is roughly 62.7 mm from cervix to opening, while the width varies from the opening to the cervix. On average, at the opening of the vagina, the width is 26.2 mm, and increases through the pelvic diaphragm as it approaches the proximal vagina, where it is widest at a width of 32.5 mm [9]. Approximately, the cervix is 4 cm in length and 3 cm in diameter [2]. However, a realistic feel in order for trainees to assess the previously mentioned appropriate minimum depth (6 cm) and positioning is a priority over a hyper-realistic visual model of a vagina and cervix.

ii. The model should accurately portray the resistance of vagina wall tissue adjacent to the cervix for injection, although it does not need to depict varying levels of vaginal stiffness at a certain time of the month or any other small fluctuations that may occur within the body. Under normal conditions, the average values for tissue elasticity for the posterior compartment of the vagina, where a paracervical block is performed, are 6.2 ± 3.1 kPa [10].

iii. The model should reliably hold up over time, and is expected to last in a classroom setting for many uses. The simulated cervicovaginal junction must be capable of sustaining wear from multiple repeated injections. All parts of the model must be fully functional, or at least can be easily exchanged and replaced to remain fully functional, over time.

iv. The model should simulate the mechanical properties of cervical and vaginal tissue by having accurate texture, needle insertion resistance of 1.09N, and elasticity of 1.94 kPa/mm [11] .

d. **Life in Service**

i. The models should last for several years and ~10 uses.

ii. The models should be reusable and withstand being practiced upon by many different residents over a period of different learning sessions. If needed, certain components, like the cervicovaginal junction area being injected into, should be easily replaceable after ~10 learning sessions.

iii. The models should be strong enough to withstand classroom, conference, and other learning environments.

e. **Shelf Life**

i. The model should be able to be easily stored in between the client's training sessions.

ii. Storage conditions should be at room temperature, ~70°F, and standard humidity, 30% to 50%.

f. **Operating Environment**

i. The models will be used in classrooms and other similar learning environments. It will remain in a typical room temperature range, 20-24 degrees celsius, both while in use and in storage [12]. The models are expected to be handled calmly and carefully by different users who are learning about paracervical block administration.

ii. Longevity-wise, the training model's greatest area of concern will be the cervicovaginal junction component that is receiving injections. This component should withstand a 3 cm injection depth from a total of four injections [1]. The other components, like the one representing vaginal wall tissue, will be far less impacted during the models' usage.

g. **Ergonomics**

i. The product must include a stand to position the vaginal canal at a realistic height of the patient, approximating mid-torso level for a clinician seated at an examination table. [13]

ii. The vaginal canal opening should incorporate materials that provide frictional and structural support to the speculum, so it can remain securely in the model without falling out. The materials must be able to withstand the force of the speculum against the vaginal walls, around 3.1 N [14].

iii. The base of the model should provide sufficient stability to prevent tipping while a paracervical block or IUD insertion is being performed.

iv. The model should accommodate many different sizes of gynecological instruments such as forceps, IUD inserters, syringes.

v. The cervicovaginal junction component of the model should be easily replaceable to withstand normal wear from repeated practice sessions.

h. **Size**

i. To ensure anatomical accuracy, each component of the model must reflect the size of an adult female.

ii. The uterus should measure 6.4–8.9 cm long, 3.2–5.7 cm wide, and 2.0–5.1cm thick. The cervix should be 2.5–4.1cm long, with an external diameter of 2.0–3.0 cm and a cervical canal lumen of 0.8–1.0 cm. The vaginal canal should be 6.4–9.5 cm long, with widths ranging from 2.0–3.6 cm and wall thicknesses of 0.3–0.8 cm. The canal must also accommodate speculum blades up to 3–10 cm wide [15].

   iii. The tabletop model should sit 10.2–15 cm above the surface of the table to replicate the anatomical distance from the posterior to the vaginal opening.

i. **Weight**

   i. The vaginal canal section of the model must be light enough to handle and reposition easily, while still providing stability during use.

   ii. The component should weigh between 0.23–0.68 kg to replicate realistic tissue mass without creating excess strain on the tabletop mount [16].

j. **Materials**

   i. The model must be made of durable, safe, and tactilely realistic materials that can withstand repeated instrument use while accurately replicating soft tissue feel.

   ii. Materials of the uterus, cervix, and vaginal canal components shall be fabricated from medical-grade silicone, thermoplastic elastomer (TPE), or comparable biocompatible polymers. These materials must provide a Shore A hardness of 10–30 A to replicate soft tissue compliance while maintaining tear resistance. [17]

k. **Aesthetics, Appearance, and Finish**

   i. The paracervical block model should clearly represent the vaginal canal with clear, anatomically accurate locations of the cervix and uterus.

   ii. The external surfaces of the model including the stand and outer portions of the model should be smooth and have a uniform finish that ensures safe and easy handling, and prevents interfering with the procedure.

   iii. The materials that replicate the “skin” of the model should be smooth and mimic the feel of vaginal tissue.

   iv. The vaginal canal, uterus and cervix should be visually realistic and be easily distinguished by being anatomically correct in color, size and spatial orientation.

2. **Production Characteristics**

   a. **Quantity**

i. The purpose of this design is to be used in teaching settings where there are multiple students using the trainer(s), because of this we aim to make 10 of this working prototype; however, we only need one working prototype or product style.

b. **Target Product Cost:**

i. The current working models for paracervical block insertion training have a price ranging from $5-$5,000 depending on the detail of the model [18] [19]. Our product aims to be $50 per unit, meaning $500 total for all ten of them. Maintaining this lower end of the price spectrum will allow for more education to be done on the process of paracervical blocks, and consequently better pain management during OBGYN procedures.

ii. The cost of the product will be greatly dependent on the material we chose to use for the internal features of the design. More realistic materials in terms of density, feel, porousness, and other factors will drive the price of the whole product up.

3. **Miscellaneous**

a. **Standards and Specifications:**

i. This model is expected to be categorized as Class I for general controls and Class II for specific controls based upon subpart F of 870 of Title 21 of the Code of Federal Regulations by the FDA [20]. These are the guidelines that apply to CPR mannequins used in a teaching environment which is similar to that of the PCBTM.

ii. This model is exempt from the premarket notification procedures due subpart E of 807 of Title 21 of the Code of Federal Regulation by the FDA [21].

iii. The training model does not need to be biocompatible by Use of International Standard ISO 10993-1 [22].

b. **Customer:**

i. The customer, Dr. Jessica Dalby, is a family medicine doctor at UW health. She is also an associate professor in the department of family medicine and community health.

c. **Patient-related Concerns:**

i. The model should be affordable, reproducible, and accessible so that the model can be brought to a wide range of clinicians in different regions.

ii. The model should be simple to assemble and designed with parts that can be easily produced without specialized equipment.

iii. The material of the cervix and cervicovaginal junction should have realistic mechanical elasticity of 1.94 kPa/mm and needle insertion resistance of 1.09N to provide the clinician with accurate training that reinforces proper technique. [11]

iv. The model should incorporate a safety measure, or aspiration test, to inform the clinician if the needle has gone too deep.

v. The model should be able to be easily cleaned between uses and the artificial cervix should be replaceable when it is worn down by the needle.

vi. The model should be stable so it does not tip or fall over during practice procedures.

d. **Competition:**

i. Patent: Uterus Simulation Model [23]

1. This model contains artificial organs such as a uterus, cervix, abdominal walls and muscles that are housed inside of a container with a lid and an opening for access. This model is mainly used as a training simulation model for Cesarean sections, particularly made for underserved regions. This model takes around 50 seconds to assemble and costs around $3.03 per complete JCM C-section practice session.

ii. The Miya Model [24]

1. The Miya Model is used to simulate the pelvic frame for practice of a variety of different medical procedures. This model features many different realistic organs such as a vagina, uterus, bladder, obturator complex, and perineum. This model also includes lifelike skin, realistic cutting and puncturing tension, palpable surgical landmarks, and a pressurized vascular system that is able to simulate bleeding, and an inflatable bladder that leaks water if a procedure is performed incorrectly. This model is designed so it can provide the trainee with accessibility and visibility to provide a realistic model. The full pelvic model with all the replaceable parts costs around $6,700.

iii. Venus Diversity Trio [25]

1. The Venus diversity Trio is an education model used to provide hands-on learning opportunities by replicating realistic anatomy of a cervix and vaginal canal using life-like silicone. It provides practice of perineal massage techniques, pelvic exams, dry needling, and demonstration of cervical cell collection medical devices. This model comes in a pack of three and costs $398.00.

10.2 MTS Protocol

MTS Tensile Testing Protocol – ASTM D412 Type C

Objective:
To evaluate the tensile properties (stress–strain behavior, Young's modulus, ultimate tensile strength) of Ecoflex 00-20 using standardized dumbbell-shaped specimens.

Materials and Equipment:

- Ecoflex 00-20 silicone elastomer
- ASTM D412 Type C dumbbell molds (6 mm × 3 mm cross-sectional area, 33 mm gauge length)
- MTS uniaxial testing machine with 100 N load cell
- Digital caliper or micrometer
- Data acquisition software (MATLAB or MTS proprietary software)
- Timer/stopwatch

Procedure:

1. **Sample Preparation:**
   a. Mix Ecoflex 00-20 according to manufacturer instructions.
   b. Pour into Type C dumbbell molds and cure at room temperature overnight.
   c. Remove samples from molds.
   d. Measure gauge length, width, and thickness with a caliper to calculate cross-sectional area.
2. **MTS Setup:**
   a. Install a 100 N load cell on the MTS machine.
   b. Set crosshead speed according to ASTM D412 recommendations.
3. **Testing:**
   a. Secure the specimen in the grips, aligning it so the gauge section is centered and straight.

b. Begin the tensile test, recording force and extension continuously.
c. Continue the test until specimen failure.

4. **Data Acquisition:**
   a. Record force (N) and displacement (mm) throughout the test.
   b. Calculate engineering stress.
   c. Calculate engineering strain.
5. **Data Analysis:**
   a. Plot stress–strain curves for each sample and average.
   b. Determine Young's modulus from the slope of the linear elastic region.
   c. Determine ultimate tensile strength and elongation at break.
   d. Analyze at least six replicate samples to assess reproducibility.
6. **Reporting:**
   a. Report average Young's modulus, ultimate tensile strength, and standard deviations.

10.3 MATLAB Code

10.3 A MATLAB Code Tensile Testing

```
%% Load data
filename = 'BME300MTStension.txt';
data = readmatrix(filename); % use readtable if header exists
% Assume columns: 1 = time (s), 2 = displacement (mm), 3 = force (N)
time = data(:,1);
displacement = data(:,2); % mm
force = data(:,3);        % N
%% Sample geometry
L0 = 33;  % mm, gauge length
A = 18;   % mm^2, cross-sectional area
%% Calculate stress and strain
strain = displacement / L0;        % strain
stress = force / A;                % stress in N/mm^2 (MPa)
%% Plot stress-strain curve
figure;
plot(strain, stress, 'LineWidth', 2);
xlabel('Strain (mm/mm)');
ylabel('Stress (MPa)');
title('Stress-Strain Curve');
grid on;
%% Calculate Young's modulus (linear region)
linear_region = strain < 0.1; % adjust range as needed
p = polyfit(strain(linear_region), stress(linear_region), 1);
E = p(1); % Young's modulus
disp(['Young''s modulus = ', num2str(E), ' MPa']);
```

10.3 B MATLAB Code Compressive Testing

```
%% MATLAB Script for Compression Testing
% Title: Average Compression Test Analysis
% Date: 12/30/25
% Author: Ellinore Letts
% Purpose: Analyze MTS compression data and plot stress-strain curve
%% Load data
filename = 'PBTM MTS comp.txt'; % change filename for compression data
data = readmatrix(filename); % use readtable if header exists
% Assume columns: 1 = time (s), 2 = displacement (mm), 3 = force (N)
time = data(:,1);
displacement = data(:,2); % mm
force = data(:,3); % N
% Ensure compression is positive
L0 = 12; % mm, initial height for ASTM D575 cylinder
d = 25; % mm, diameter
A = pi*(d/2)^2; % cross-sectional area in mm^2
%% Calculate stress and strain
strain = displacement / L0; % engineering strain (mm/mm)
stress = force / A; % stress in N/mm^2 = MPa
%% Plot stress-strain curve
figure;
plot(strain, stress, 'LineWidth', 2);
xlabel('Strain (mm/mm)');
ylabel('Stress (MPa)');
title('Compression Stress-Strain Curve');
grid on;
%% Young's modulus (linear region)
linear_region = strain < 0.1; % adjust as needed (e.g., 0-10% strain)
p = polyfit(strain(linear_region), stress(linear_region), 1);
E = p(1); % Young's modulus
disp(['Young''s modulus (linear region) = ', num2str(E), ' MPa']);
%% Save stress-strain data
csvwrite('compression_stress_strain.csv',[strain, stress]);
```

10.4 Physician Feedback Form

Participant Background

1. What is your role?
2. How much experience do you have performing paracervical blocks?
3. Have you used any paracervical block training models before?

Model Realism

4. How realistic was the anatomical structure of the model?
5. How realistic was the tissue feel during needle insertion?
6. How realistic was the response of the model to needle placement?
7. How realistic was the visualization of anatomical landmarks?
8. Were there any anatomical features that felt inaccurate or missing?

Usability

9. How easy was it to identify the anatomical landmarks for the block?
10. How easy was it to insert the needle?
11. How intuitive was the model to use overall?
12. Did you encounter any technical issues with the model?

Educational Value

14. How helpful was the model in improving your technique?
15. Would you recommend this model for training others?

Overall Assessment

18. Overall, how satisfied are you with this training model?
19. Compared to other training methods, how effective is this model for learning a paracervical block?
20. Additional comments or suggestions?

10.5 Feedback Form Results

What is your role?	Have you used any paracervical block training models before?	On a scale of 1-10, how much experience do you have using training models? 0 being none, 10 being extensive	How realistic was the anatomy of the model in terms of... - Anatomical accuracy	How realistic was the anatomy of the model in terms of... - Tissue feel	How realistic was the anatomy of the model in terms of... - Response to needle inse	How realistic was the anatomy of the model in terms of... - Visualization of anatomical landmarks	Were there any anatomical features that felt inaccurate or missing?	How easy was it to... - Identify the landmarks for the block	How easy was it to... - Insert the needle	How easy was it to... - Use a speculum	How easy was it to... - Perform general procedures	How intuitive was the model? - Intuitivity	Did you encounter any technical issues with the model?	If you did run into technical issues, please elaborate.	Would you reccomend this model to others?	What aspects of the model were most beneficial?	What improvements would make this model better?	Overall, how satisfied are you with this training model? - Satisfaction	Compared to other training methods, how effective is this model? - Effectivness	Additional comments or suggestions:	block2 progress	random

		experience. - Experience			rtion																	
Physician	Yes	10	7	6	8	5	Hard to replicate vagina	4	6	6	4	10	Yes	Using the small plastic speculum, I didn't have enough room to expose the cervical vaginal angle. When I switched to a metal speculum with a wider aperture, I could visualize the model better.	Yes	Being able to grasp the cervix with a tenaculum and expose the cervical vaginal angle for injection	Vaginal opening was difficult to get to stay in place, and when I placed the specula the uterus locking mechanism disengaged	7	8	Might need to use a light source with the speculum for better visualization of the cervix		1

Physician	No	7	9	1	9	8	A real cervix slightly tougher tissue. But this is more realistic than any other model I've ever worked with.	10	10	9	9		Yes	Would be helpful if it were angled slightly forward instead of parallel to the ground	Yes	Length and landmarks were appropriate. Excellent model for using a needle or other cervical procedures.	As above	9	9			1
Physician	No	7	7	5	4	9	Vaginal length is a little short	9	9	7	10	10	Yes	Speculum hangs down and somewhat requires holding it, which takes away a free hand. I worry that repeated use of tenaculum placement	Yes	The movement of the cervix is great	Perhaps a little bit of different colors of vaginal wall vs cervix. Longer vaginal canal to allow the speculum to stay in place.	7	7	Almost seems like it would be reasonable to add a uterus and use this model for IUD placement		1

														and injection will destroy the cervix tissue								
Physician	No	2	8	9	8	8	No	10	0	10	10	10	No		Yes	-very realistic	If the silicone portions could be a lighter pink to emulate real tissue, that would be a bonus	10	10			2
Physician	Yes	7	7	5	8	8	The consistency of the cervix was very soft with tenaculum placement, otherwise felt realistic	9	8	7	9	9	No		Yes	Seeing the land marks and being able to see how deep the needle goes through	Making the tissue pink/more realistic in color	9	9			2

Resident	No		9	5	6	9	No, color could be more realistic which would help with identification of landmarks.	10	10	10	10	10	No		Yes	Pretty realistic	Potentially having more give on the cervix would provide better simulation. The cervix often pushes away when trying to insert the needle in real life. Overall very satisfied with the model.	10	10			2

10. 6 Expenses

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Category 1										
3D Printed Prototype	Preliminary prototype of mold for cervix	Makerspace	PLA basic	N/A	N/A	10/16/2025	1	$8.39	$8.39	
3D Printed Prototype	Preliminary prototype of mold for the uterus and connecting ring	Makerspace	PLA basic	N/A	N/A	10/16/2025	1	$5.10	$5.10	
3D Printed	MTS testing dog bone	Makerspace	PLA	N/A	N/A	10/30/2	1	$3.21	$3.21	

Dog Bone	mold		basic			025				
3D printed Prototype	Prototype of Uterus (clear)	Makerspace	PLA basic	N/A	N/A	11/05/2025	1	$20.27	$20.27	
Wood Sheet	Plywood sheet 1/4 in 28x36	Makerspace	N/A	N/A	N/A	11/04/2025	1	$7.50	$7.50	
3D printed prototype	Preliminary prototype	Makerspace	PLA basic	N/A	N/A	11/04/2025	1	$1.59	$1.59	
3D printed prototype	Vaginal openeing prototype mold	Makerspace	PLA basic	N/A	N/A	11/05/2025	1	$1.92	$1.92	
3D Printed Prototype	2nd cervix mold prototype	Makerspace	PLA Basic	N/A	N/A	11/07/2025	1	$3.81	$3.81	
3D Printed prototype	new connecting piece	Makerspace	PLA basic	N/A	N/A	11/12/2025	1	$0.94	$0.94	
3D printed prototype	New cervix mold	Makerspace	PLA basic	N/A	N/A	11/12/2025	1	$3.71	$3.71	
3D printed prototype	New vagina opening mold	Makerspace	PLA basic	N/A	N/A	11/17/2025	1	$1.89	$1.89	
3D printed prototype	New Uterus mold	Makerspace	clear v5	N/A	N/A	11/22/2025	1	$22.31	$22.31	
3D printed prototype	New cervix mold	Makerspace	PLA Basic	N/A	N/A	11/20/2025	1	$6.44	$6.44	
3D Printed prototype	New cervix mold	Makerspace	PLA basic	N/A	N/A	12/01/2025	1	$1.59	$1.59	
3D printed prototype	New uterus mold	Makerspace	PLA basic	N/A	N/A	12/01/2025	1	$1.39	$1.39	
3D printed prototype	New connecting piece	Makerspace	PLA Basic	N/A	N/A	12/02/2025	1	$3.80	$3.80	
3D printed prototype	New run of the new uterus	Makerspace	PLA basic	N/A	N/A	12/02/2025	1	$3.20	$3.20	
3D printed prototype	New vaginal opening mold	Makerspace	PLA basic	N/A	N/A	12/02/2025	1	$1.13	$1.13	
3D printed prototype	New connecting piece	Makerspace	PLA basic	N/A	N/A	12/04/2025	1	$0.76	$0.76	
								Category 1 Total:	**$80.64**	
Category 2										
Tubing	Charlotte pipe coupling 1.5” x 2” PVC DWV Hub x	N/a	PVC001020600HD	Homedepot	472476	10/23/2025	10	$1.59	$15.90	link
Tubing	Hub increaser/reducer PVC pipe 1.5-inch diameter x 6-inch	N/a	PVC071120600	Homedepot	193844	10/23/2025	1	$7.32	$7.32	link

	length									
Ecoflex	Ecoflex 00-20	N/a	N/a	Smooth-On	N/a	10/23/2025	3	$32.43	$64.86	link
Tubing	PVC DWV All Hub Sanitary Reducing Tee 2 x 2 x 1.5 inches	N/a	PVC024006450HD	Homedepot	74323400	10/23/2025	10	$6.28	$62.80	link
Adhesive	Gorilla construction adhesive – 1 tube	N/a	801000300	Homedepot	100137815000	10/23/2025	1	$9.98	$9.98	link
Adhesive	Hook and loop tape with adhesive - white, ¾ inch, approximately 5” per task trainer	N/a	90277B	Homedepot	23953600	10/23/2025	1	$20.93	$20.93	link
Ecoflex Coloring	Ecoflex Silc Pig Red	N/a	N/A	Smooth-On	N/A	11/03/2025	1	$24.39	$24.39	link
Ecoflex 00-20	Ecoflex 00-20	N/A	N/A	Smooth-On	N/A	11/03/2025	3	$33.44	$100.36	link
								Category 2 Total:	**$181.79**	
								OVERALL TOTAL:	**$361.38**	

Table 2. *Total expenses incurred throughout the duration of the project.*