Paracervical Block Training Model

October 8th, 2025

Biomedical Engineering 300/200

PCBTM

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ABSTRACT

The team's client, Dr. Jessica Dalby, requested a paracervical block training model for training students on gynecological procedures, specifically the paracervical block. A paracervical block is performed to provide local anesthetic for procedures such as IUD insertion. Currently, there are no accessible models that have the correct landmarks, specifically the cervicovaginal junction, to teach the paracervical block. These lack of models results in less clinicians feeling confident in the procedure and less women having access to pain relief during a painful procedure. The team's solution is to modify a current task trainer to incorporate the cervicovaginal junction as well as more accurately shaped uterus to assist in training future clinicians on the paracervical block to ensure they feel more confident on the procedure. There will be comprehensive mechanical and physical testing for the compressive strength of the materials used for the cervix and uterus along with physical testing with our client to determine accuracy. Through this analysis, the team will be able to conclude if the design meets the client and design specifications. In the future, the team hopes to conduct testing in clinician training sessions in order to decide if the model is ready for mass production and sales.

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I. INTRODUCTION

1.1 Motivation/Impact

The impact of this project spans beyond the scope of our clients classes at UW-Health. It is becoming ever more common for young women to pursue an IUD as a form of birth control. In a planned parenthood study they found 42% of younger women have intrauterine devices whereas in the general population they make up for only 12% [1]. Because of this increased interest it is consequently becoming more important for providers to know the proper pain management techniques. However, with that being said, 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. With our model kit in the hands of aspiring medical students and physicians, the future for IUD insertion and the simplicity of the process is greatly impacted, and with it access to this incredible birth control method for the youth.

1.2 Existing Devices & Current Methods

There are four main existing models that have attempted to create an accurate model to perform gynecological procedures such as the paracervical block. The Miya Model 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.

Figure 1: Image of the Miya Model used for gynecological procedures [2]

While this model includes all important aspects required for training, it is not feasible due to its cost of about 6000 dollars.

Another model, the Task Trainer for Gynecological Procedures created by the University of Nebraska Medical Center is a model that is made of basic hardware supplies, a 2-part silicone mixture, and multiple 3D printed components which require access to a 3D printer.

Figure 2: The Task Trainer for Gynecological Procedures [3]

This model is incredibly effective however, lacks certain aspects such as the cervicovaginal junction as well as an accurate vaginal opening.

The next design is the Venus Model which consists of a realistic vulva exterior, vaginal canal with a visible cervix, and life-like silicone texture.

Figure 3: The Venus Pelvic Health Educational Model [4]

This design is fantastic for use in device demonstrations like insertions of speculums (small), menstrual cups (small), tampons, dilators, pelvic wands, contraceptives, and vaginal weights. However, it is severely limited in its ability to perform procedures such as IUD insertion, paracervical blocks, and cervical aspiration.

Our client's current model, The Roma Tomato Model, consists of a dixie cup with the bottom cut out, a roma tomato, and a condom. The tomato emulates the uterus and the region where the dixie cup and the tomato intersects acts as the cervix. The condom which comes out through the center of the dixie cup is meant to mimic the vaginal canal. 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.

1.3 Problem Statement

The goal of our team is to create a realistic, reproducible, and low cost model that includes a realistic cervicovaginal junction to simulate PCB injections to train healthcare professionals to make this procedure more accessible. Creating an anatomically accurate model with materials that better simulate the mechanical properties of the female reproductive tissues by having a needle insertion resistance of 1.09N, and elasticity of 1.94 kPa/mm [5]. This will allow providers to practice needle placement, injection, and IUD insertion in a supervised safe learning environment. Ultimately, our goal is to improve provider access to learning the PCB procedure and expand patient access to pain management in women's healthcare.

II. BACKGROUND

2.1 Anatomy and Physiology

The female anatomy is equipped to handle many gynecological procedures, extreme deformation, and dilation during labor. However, some of the most frequent gynecological procedures prove to be extremely painful, such as IUD insertion, despite the adaptable nature. 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 opening and increase visibility. Through that opening is the vagina, which leads to the cervix and uterus, where paracervical blocks take place. At the cervicovaginal junction, which is where the cervix and uterus meet the vaginal canal, 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 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. This process is used to most effectively numb the patient for the rest of their procedure.

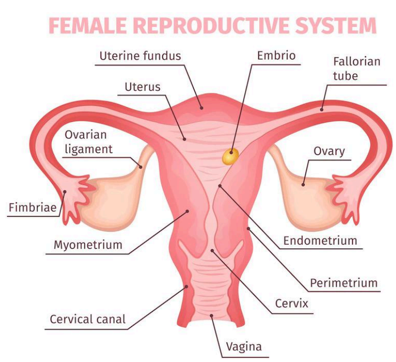


Figure 4: Female Reproductive System [6]

Figure 5: 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 instructs 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 [8]. 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 [9]. The uterine cavity depth will be 6–9 cm [10]. 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 [11]. 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 [12]. It should operate and be stored at room temperature (20–24°C) and humidity of 30–50% [13]. The design must be low cost, targeting $50 per unit and $500 total for ten models. Additional design specifications can be found in Appendix 10.1.

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. This device has several limitations however as it lacks a vaginal canal, cervicovaginal junction, and an anatomically accurate uterus. As seen in Figure 5, 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 clinician with a more realistic procedure. The benefits of this design is that all of the parts are detachable, allowing for the model to be cleaned, customized for different training procedures, and enabling 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 also both affordable materials that can be found at most hardware stores. This design also positions the cervix around eye level with the clinician, which provides for a more realistic procedure. Despite these improvements, there are some downsides to this device. Its larger size and weight makes the model less portable and limits the ease of transport for training sessions in different locations. This model is also much taller giving it a higher center of gravity, making it more prone to tipping during speculum insertion or other procedures.

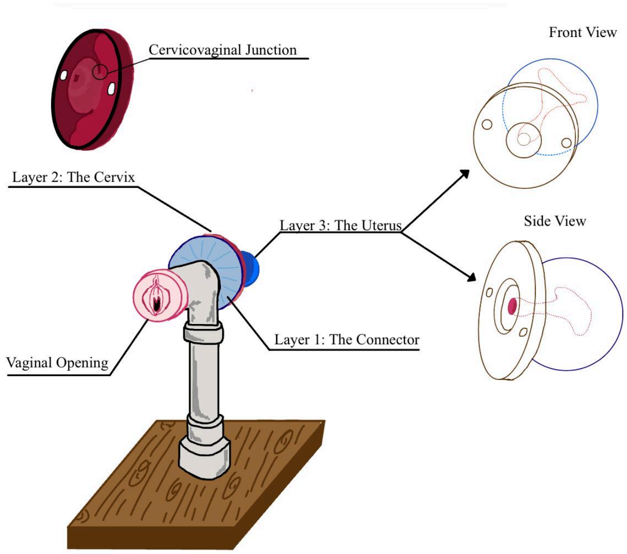


Figure 6: Modified Task Trainer Design

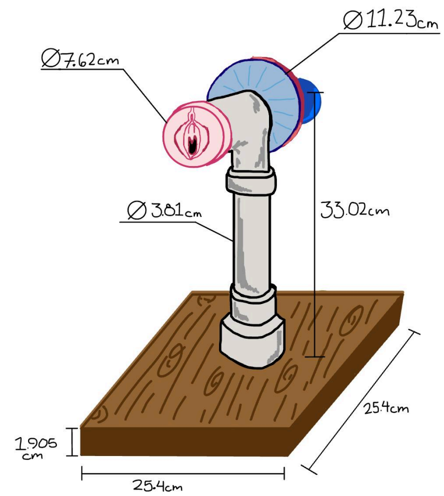


Figure 7: Modified Task Trainer Dimensions

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. 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. This anatomy 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 1. 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.

This design has some major anatomical upsides. 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.

One of the Shoebox Design's greatest negatives is its fabrication process. Our 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 far more difficult and time-consuming than we would prefer it to be. 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 highly 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 hugely inaccurate when compared to realistic vaginal canals, which are fully complete cylinders.

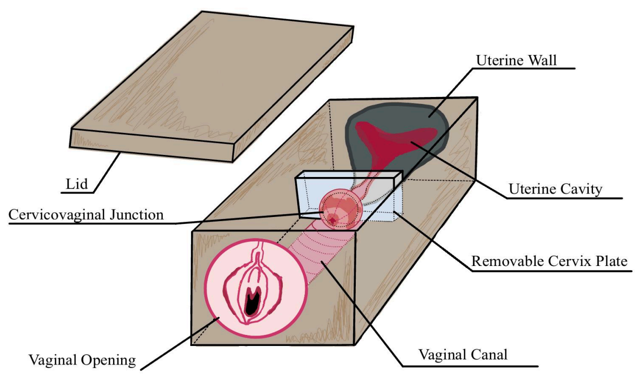


Figure 8: Shoebox Design

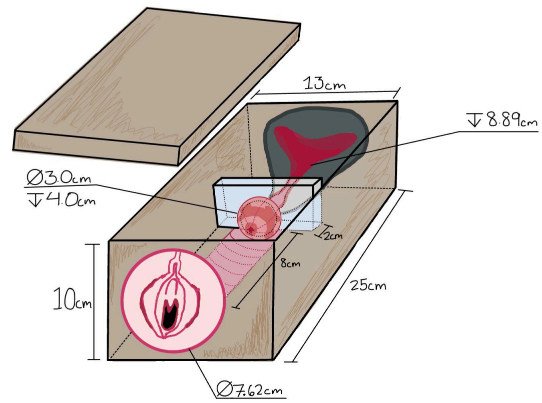


Figure 9: Shoebox Dimensions

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. Beyond the cervix is the uterus off the back of the stand, 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, with the entirety of the design being 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 the true paracervical block procedure.

Benefits of this design include the visual accuracy of the vagina and cervix components, as these are realistic to a real human body and provide a user a good sense of what to look for when performing the paracervical block procedure in a clinical setting. Also contributing to the accurate features of this design is the ability of the vagina to be opened by the speculum, which is useful for getting a feel for the force required and limited working space a user will have on the cervix while the speculum encloses the area. Its small size makes it easy to transport and store while not in use, which is convenient for the client, allowing her to move the model as needed between training sessions. Additionally, Venus' low center of mass means it would remain stable and have a lesser 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.

As far as the drawbacks of this design, the small size of the device means it sits low to the table and requires a user to bend down to use it, which is not what would be expected in a real procedure, where the cervix of the patient would typically be at the practitioner's eye level. Furthermore, the junctional angles between the cervix and uterus are inaccurate. On a real human body, an anteverted angle (a forward bend of about 170 degrees) is most common. 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 irreplaceable nature of the design's parts also pose an issue, as once the cervicovaginal junction sustains too much repeated needle use, the entire model will be rendered unusable and requires a replacement of the entire silicon design. The entire silicon mold would need to be remade. This is neither cost effective nor time effective for the client.

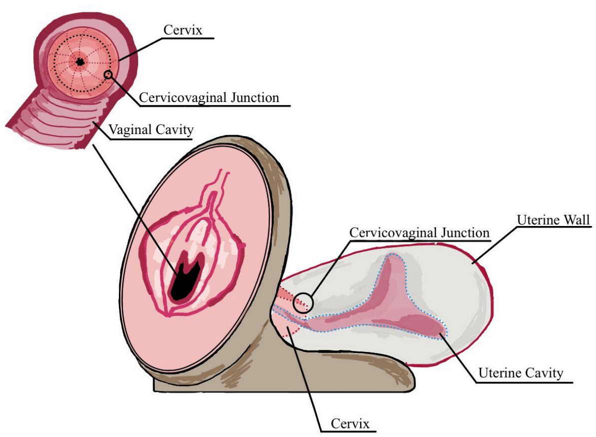


Figure 10: *Modified Venus Design*

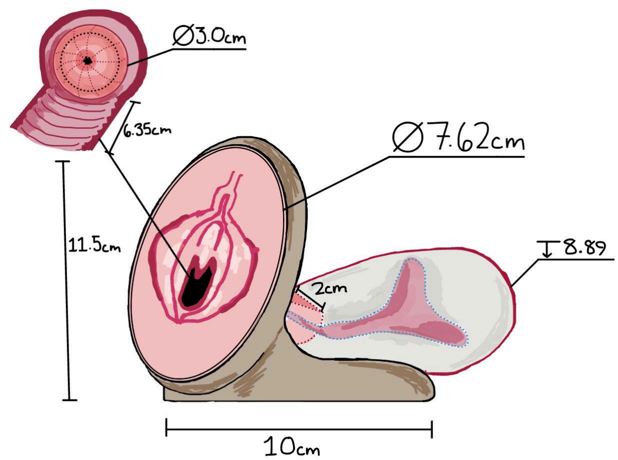


Figure 11: *Modified Venus Design Dimensions*

IV. PRELIMINARY DESIGN EVALUATION

4.1 Design Matrix

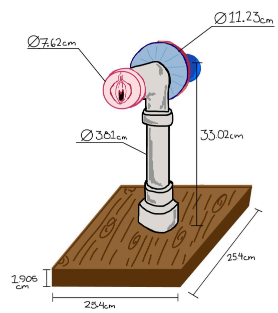
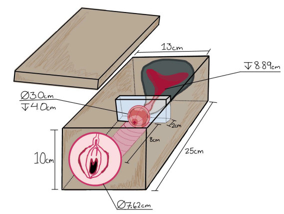
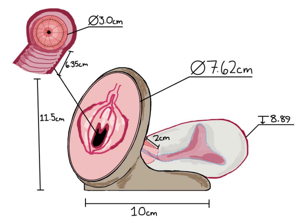
Criteria (Weight)	Modified Task Trainer 		Shoebox Design 		Modified Venus Design 	
Realistic (25)	5/5	25	4/5	20	2/5	10
Ease of Fabrication (25)	5/5	25	1/5	5	1/5	5
Anatomical Accuracy (20)	4/5	16	2/5	8	3/5	12
Cost (15)	5/5	15	3/5	9	4/5	12
Portability (10)	3/5	9	3/5	9	4/5	12
Safety (5)	4/5	1	5/5	5	5/5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

Realistic (25): This category assesses the models ability to simulate the paracervical block procedure. The Modified Task Trainer received a 5/5 because this design is the only one with a stand to better simulate the height clinicians would be at when performing the paracervical block procedure. The Shoebox design received a 4/5. Similar to the Modified Task Trainer, the materials used, ecoflex, are similar to that of the gynecological properties. However, the reason it received a lower score is 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 because it is again performed at a lower angle than one would actually perform a paracervical block as well as having the uterus at an angle that is not accurate causing students when learning the procedure to have an unreliable estimate on where to place the needle.

Ease of Fabrication (25): Ease of fabrication was weighted at 25/100, as it was one of the client's priorities to have something simple to replicate as needed. 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 extra time and research to reproduce. 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 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 (20): Anatomical accuracy was weighted at 20/100, as it is critical for a task trainer to visually replicate the anatomy of its models. 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 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 it 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 (15): The cost effectiveness of our design was weighted to be 15/100, this is due to the fact that this model will need to be made in larger quantities. This is an important factor for our client and our designing process because the client aims to use this product for classes/presentations. During these presentations she hopes to be able to hand out multiple of our trainers to the students so they can practice independently. Given that we have a $500 budget, each model will need to be produced at a cost effective rate, nearly $50 each. The modified task trainer receives a 5/5 on cost effectiveness because its pieces are easily accessible and purchased at a low cost, additionally it only requires a couple components, ultimately greatly reducing the cost to construct. 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, this middle ground score makes sense because 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 (15): The portability of each design is weighted to be 15/100, since the final training model should be easily transported. This is an important aspect to consider when designing as the client needs to be able to transport ten task trainers to and from storage and training areas, and even hopefully between buildings in order to train providers in many locations. For all three designs, none of their sizes are prohibitively large, meaning that they are all adequate and relatively mobile. The Modified Task Trainer was rated a 3/5 as it does have 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 (5): 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 Figure 5. 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 more of 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, hitting two of the more important criteria. 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 that 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, but 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.

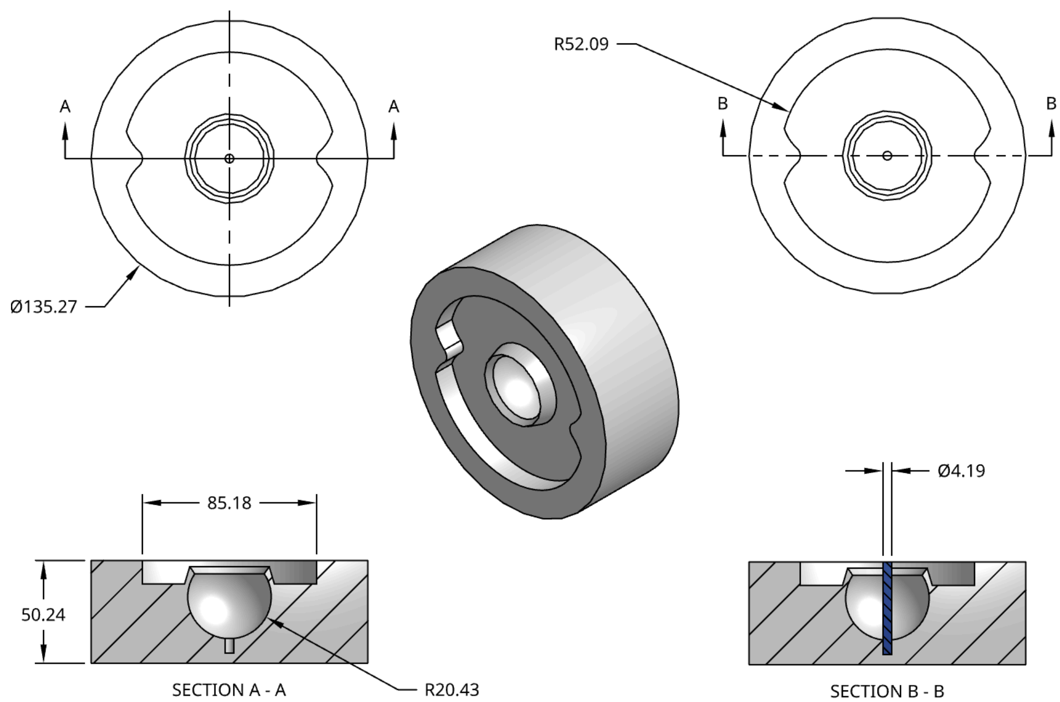


Figure 12 *Drawing of the cervix mold to enable silicone casting.*

V. DEVELOPMENT PROCESS

5.1 Materials

The materials that will be 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 [14]. The uterus is moderately stiff and is a very muscular tissue that has an elastic modulus of around 20-100 kPa[15]. 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 [15], [16]. 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[17]. A Smooth-On Silicone thinner can be added with the Ecoflex 00-20 to fine-tune the softness and feel of the tissue[18]. 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 tissues.

Figure 13: *Eco-Flex 00-20*

5.2 Methods

Until we acquire materials, we will prototype our Modified Task Trainer design. We will create a SolidWorks model of the design, and we will finalize exact dimensions and layouts of all the parts. We will also decide on varying concentrations for our silicon for the individual parts of the design. The silicon must properly mimic the differing resistances of the cervix, vaginal and uterine wall. We will analyze different resistances, utilizing the help of our client's feedback to ensure the resistance is realistic. Prototyping will continue as we modify the design over time to most accurately mimic the paracervical block procedure. If we have additional time, we may also incorporate other features, such as a way to signal errors in depth and placement of needle insertion to a user.

We will modify the existing task trainer primarily by improving its anatomical and visual accuracy. Unlike the task trainer currently in use, we plan to create our design with a visually realistic vaginal opening, capable of holding a speculum, over the vaginal cavity and cervix. The cervix itself will also have a cervicovaginal junction, which the current task trainer lacks, providing the user with a specific location to insert the needle at when practicing the procedure. As opposed to simply a ball shape for the uterus, our design will contain a uterus with a T-shape, which will be more realistic for a user attempting an IUD insertion.

We will be 3D printing a connecting ring for our parts, including molds for the cervix with a cervicovaginal junction, t-shaped uterus, and the vaginal opening. Once the molds are printed, we will pour in a silicon mixture. The mold will contain a chosen concentration of Smooth-On Silicon Thinner, Ecoflex, and red food coloring, to give it a more realistic appearance. After the mold has cured according to manufacturer instructions, we will remove the pieces from their individual molds.

We will secure velcro and an adhesive hook to the outer edge of the end of the PVC pipe, and the other side of the adhesive hook and velcro to the inner edge of the connective ring. The uterus, cervix, and connecting ring will be assembled, placing the knobs on the outer ring through the holes in the uterus and twisting the uterus to secure it. The connecting ring will then be placed into the end of the PVC pipe. We will attach our silicon vaginal opening over this.

5.3 Testing

A comprehensive testing protocol will be created for each testing method to ensure the model functions as intended and all specifications are met. Mechanical testing will be performed by utilizing a Universal Testing Machine (MTS). Compression testing will be completed to analyze the material properties of the separate components to ensure that they mimic that of gynecological properties. The team will collect data to generate a stress-strain curve to evaluate the modulus of elasticity, material strength, fatigue, and resistance, and plastic deformation. Theoretical analysis of all silicone components during compression will be performed in SolidWorks and compared to the experimental values gathered. These properties need to be evaluated to determine how the model can resist tensile forces during tenaculum placement without ripping and compressive forces during needle insertion.

The Shore Hardness of silicone will be evaluated according to the standards outlined in ASTM F2038-18 [19]. These standards are utilized to measure the hardness of Silicone Elastomers to ensure they meet the hardness specifications required for their intended use. The model must be strong enough to withstand the force caused by the tenaculum and injection so that the model does not deform and become ineffective. A durometer hardness test will be performed using a durometer scale to measure how resistant the material is to indentation. Additionally, theoretical values for this test will be carried out using SolidWorks Simulations.

The practical use of this device will be qualitatively analyzed through testing with our client. This involves having her practice teaching use our model to assess whether it accurately mimics the procedure. This testing will analyze the accuracy of our model to that of a real procedure.

VI. DISCUSSION

At this stage, no final prototype has been produced and no testing results are available, as the design remains in the conceptual development phase. Once constructed, the prototype will undergo evaluations of anatomical accuracy and material durability via a variety of material testing methods to validate its performance. Anticipated revisions include refining material elasticity, enhancing stability and replaceability, and addressing potential errors such as material inconsistencies, leakage, and anatomical misalignment.

VII. CONCLUSION

The goal of the project is to design and fabricate ten gynecological training models for our client to use in paracervical block administration training sessions. These task trainers should be anatomically accurate in both their dimensions and 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 box. 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, a cervicovaginal junction, and a T-shaped uterus that allows for IUD insertion practice. Furthermore, the individual components within this model are detachable and can be easily replaced via their original molds.

As the team moves forward, we will finalize which materials and supplies we decide on using. We will also create a prototype of this design and begin performing testing. Using information we learn from the tests, we can make improvements and alterations to our final design. The team will continue to research and brainstorm ideas even as we move through the prototyping and fabrication process. By the end of semester, we will have completely finished ten training models for our client.

VIII. ACKNOWLEDGMENTS

The team would like to extend their appreciation to Dr. Jessica Dalby of the University of Wisconsin-Madison School of Medicine and Public Health for her inspiration for this project and all of her support. Additional thanks to Dr. Randolph Ashton and Dr. Puccinelli for their guidance and support throughout this project.

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X. APPENDIX

10.1

Product Design Specifications

September 19, 2025

Biomedical Engineering 200/300

PCBTM

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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) [7]. 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 [20].
- 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 [21]. 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 [22]. 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 [23].

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 [24]. 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 [25]. 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 [26]. 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 [27]. Approximately, the cervix is 4 cm in length and 3 cm in diameter [20]. 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 [28].

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 [5] .

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 [13]. 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. [29]

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 [30].

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 [9].

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 [12].

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. [11]

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 [31] [32]. 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 [33]. 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 [34].

iii. The training model does not need to be biocompatible by Use of International Standard ISO 10993-1 [35].

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. [5]

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 [36]

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 [2]

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 [4]

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 Expenses

Item	Description	Manufac-turer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Category 1										
									$0.00	
									$0.00	
Category 2										
									$0.00	
									$0.00	
								TOTAL:	**$0.00**	