Product Design Specifications:

Paracervical Block Training Model

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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) [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 realistic, reproducible and low cost so it can be widely used in skills labs and teaching centers.

Client Requirements

The client, Dr. Jessica Alby, 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, in order to properly instruct physicians on the procedure.

- 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 [2]. 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 [3]. 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 [4].

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 use a sound to measure the depth of the uterine cavity, as is consistent with regular placement of an IUD. The uterine cavity should be 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, 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 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 [5]. 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 [6]. 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 [7]. Approximately, the cervix is 4 cm in length and 3 cm in diameter [8]. 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 [9].

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.

d. **Life in Service**

i. The models should last for several years and many 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 between 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. Prior to storing, there should be minimal required disassembly of the components.

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 [10]. 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 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]

ii. 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. [12]

iii. 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.

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

v. The model should be adjustable and have the ability to be tilted to different angles and moved vertically to accommodate the clinician's preferences.

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

vii. 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 [13].

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 [14].

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. [15]

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 [16] [17]. 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 [18]. 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 [19].

iii. The training model does not need to be biocompatible by Use of International Standard ISO 10993-1 [20].

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 [21]

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 [22]

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 [23]

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.

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