Simulator Model for Training Cesarean Sections in Kampala, Uganda

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Abstract
Cesarean section (CS) is the most common obstetric surgery performed worldwide and can be a lifesaving procedure when performed properly. Many underserved areas lack access to appropriately trained physicians and other healthcare professionals resulting in increased incidence of CS complications and high maternal mortality rates. Uganda’s National Health Ministry has implemented a surgical skills training program, Essential Training in Operative Obstetrics (ETOO), in partnership with the American College of Obstetricians and Gynecologists (ACOG) and Drexel University College of Medicine (DUCOM). The program objective is to increase the availability and quality of CS training in Uganda, with the ultimate goal of increasing access to CS and decreasing national maternal mortality and morbidity rates. The ETOO program emphasizes the use of benchtop training simulators, which are considered the most effective tool for increasing physician competency. However, there are no affordable, representative CS training models on the market; there is a clear need for a mid-fidelity model that offers robust, representative training while being cost-effective and globally accessible. A training model was designed for ETOO that simulates the Joel Cohen surgical technique (JCM), allows for part-task training, and costs approximately US$3.00 per use. The model includes uterine, bladder, abdominal muscle, fat, fascial, and skin analogs cast from commercially available silicones. Uniaxial dynamic tensile testing was used to evaluate the silicone’s ability to replicate stretching behavior of native tissues. Overall, the design was deemed successful in its ability to teach CS by stakeholders, who rated the quality of the model 4.2 out of 5. Future work includes expanding the model’s capabilities to include rare CS cases and other obstetric and gynecologic procedures not simulated by the current design.

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Abbreviations and Definitions
a. CS: Cesarean section
b. SSA: Sub-Saharan Africa
c. ACOG: American College of Obstetricians and Gynecologists
d. DUCOM: Drexel University College of Medicine
e. JCM: Joel Cohen Method
f. ETOO: Expanding Training in Surgical Skills and Operative Obstetrics Program
g. OB/GYN: Obstetrics and Gynecology
h. EM: Elastic Modulus
i. Blunt dissection: Separation of tissues along natural lines of cleavage using fingers rather than cutting
J. Fistula: an abnormal connection or passageway that connects two organs or vessels
k. Postpartum hemorrhage: severe, life threatening bleeding from the uterus following birth
l. Laparotomy: a surgical incision into the abdominal cavity in preparation for surgery

Problem Description
Cesarean section (CS) has a mortality rate five times greater than that of vaginal births; however, when performed properly CS is a lifesaving operation, highlighting the importance of physicians receiving comprehensive training\textsuperscript{[1,2]}. In underserved areas such as many developing countries, this is not the case. Sub-Saharan Africa (SSA) has a population three times that of the USA\textsuperscript{[3]} and has the highest birth rate in the world. Uganda, specifically, has a birth rate of 5.59 per woman\textsuperscript{[4]}. Despite the large patient volume, SSA has less than 1% of the number of surgeons as the USA\textsuperscript{[5]}; Uganda specifically has a doctor-to-patient ratio of 1:24,725, while the World Health Organization recommends 1:1,000\textsuperscript{[5,6]}. Due to these incredibly high patient volumes and limited numbers of trained physicians, CS remains a dangerous procedure in SSA. Ugandan maternal mortality is very high at 343 per 100,000 live births compared to 21.5 per 100,000 in the USA\textsuperscript{[7,8]}. New Mulago Hospital, the primary location of the training program sees 2 maternal deaths per day. Therefore, there is a clear need for improved accessibility and quality of CS training in underserved countries such as Uganda. To address this the Ugandan National Health Ministry implemented a surgical skills training program in partnership with the American College of Obstetricians and Gynecologists (ACOG) and Drexel University College Of Medicine (DUCOM) in 2015 to increase physician competency, and decrease maternal morbidity and mortality. The simulation-based portion of the program is highlighted as its most valuable. Currently available training models can not accurately and affordably simulate CS, leaving program instructors to use low-fidelity, homemade foam-and-fabric models to teach surgical obstetric skills. Although lifelike, high-fidelity models do exist, they cost upwards of US$50,000 with operation costs of US$200 per use, rendering them inaccessible to the developing world. In settings where high-fidelity models are financially viable, the repeated expenses prevent them from being a regular, efficient training method. There is a need in both the developing and developed world to design a mid-fidelity, affordable CS simulation model that allows for robust training and multiple student uses.

Project Objective
This project objective was to create a bench-top CS training model to meet the needs of Uganda’s training program, Essential Training in Operative Obstetrics (ETOO). DUCOM physicians are ETOO program collaborators and instructors. Under their recommendation, the scope of the training model was confined to the instruction of three critical surgical skills required to perform successful CS: utilizing blunt dissection, avoiding incision of the bladder, and properly suturing tissue layers. The Joel Cohen cesarean surgical technique (JCM) is taught by DUCOM physicians due to its improvements in maternal healing. JCM is characterized by blunt finger dissection and stretching tissues along their natural lines of cleavage to reduce bleeding and nerve damage. Identification and manipulation of the bladder prevents its accidental incision which can cause fistulas and infection. Finally, proper stitching techniques prevent hemorrhage and improve maternal recovery rates. To simulate CS in accordance with these three critical skills, the training model must contain anatomically- and mechanically-representative components resembling the uterus, bladder, abdominal muscle, fat and skin in relation to native tissue. The final design is innovative in its ability to merge affordability with accuracy. It is the only model whose dissected components (typically skin, fat, fascia, and uterus) are affordably replaceable by the customer; as well as allowing for multiple
uses before requiring replacement. An innovation of this design is the abdominal wall component, which can be used individually to train multiple laparotomies. This component is also unique in that it can be removed from the container, rotated 180°, and put back into place for a fresh incision surface. No other model on the market is designed in such a way. The uterine component was made symmetrical, forgoing exact anatomical geometry, to maximize the number of incisions capable before replacement, further reducing the model’s overall cost. The rounded, hollow shape of the component is innovative as most models only provide a flat uterine layer, not congruent with uterine natural geometry. The rounded, protruding abdomen provides realistic feedback to trainees.

**Constraints**

**Design Constraints:** Overall, the model was limited in design by its use in developing countries. To remain accessible, all materials and components used in the model must be cost effective, commercially available, and nontoxic. Additionally, as physician instructors travel to training programs in underserved countries, the model must be globally transportable; therefore, it must comply with commercial airline size and weight restrictions. The model was also constrained by the training methods that it must support. The DUCOM/ACOG physicians teach JCM, therefore the final model must accommodate the standard incisions and tissue stretching that is characteristic of this technique. Additionally, instructors requested that the model be adaptable for part-task training, meaning it can be easily and quickly disassembled. The individual components can then be used separately to train specific portions of the procedure. An additional request was the inclusion of an open cervix for manual manipulation of the fetus and additional capabilities.

**Project Constraints:** A project duration of 9 months limited project scope; additional obstetric procedures originally discussed with physicians were delegated to future work. Funding was limited to $1,000 and provided by the School of Biomedical Engineering, Science, and Health Systems and an ASTM International grant.

**Design Requirements**

**Joel Cohen Method (JCM):** The model’s size must fit the standard 10-15 cm transverse incision and 7-12 cm longitudinal stretching of the abdominal wall. JCM additionally entails stretching of the skin, fat, abdominal muscle, and uterus; the materials selected for these tissue analogs should replicate native tensile elastic moduli (skin: 4.0 ± 3.81 MPa, fat: 11.7 ± 6.4 kPa, abdominal muscle: 42.5 ± 9.0 kPa, myometrium at full term: 0.51-2.33 MPa). As properly stitching tissues is crucial to maternal recovery, the materials used must also be able to hold sutures without tearing.

**Anatomical Geometry:** The model should also replicate anatomical geometry to ensure the skills mastered on the model are easily translated to clinical practice. A uterus at full term has dimensions of 35x25x20 mm and a myometrial thickness of 4.68 ± 0.48 mm. The thicknesses of native skin, fat, and abdominal muscle tissues are 1.2 ± 0.3 mm, 13 ± 2.7 mm, and 9.8 ± 1.7 mm respectively.

**Model Implementation:** Per program instructors’ request, the model would allow for 5-10 uses before any components require replacement and cost US$1 per use. Due to high large class sizes, time is limited during trainings, so an assembly time of <5 mins was requested by program instructors. The model will be taken to Uganda and must meet airline luggage restrictions: a perimeter of <158 cm and weight of <32 kg.
Design Documentation

Design Concept 1: Roll Model for Abdominal Wall
The first design approach involved using a box as the model's container, with a roll of the abdominal wall analog made from commercially available silicones attached to the side, as seen in Figure 1. This roll would be stretched across the opening of the container; the material would be unrolled slightly after each laparotomy to create a fresh incision surface, optimizing material usage. A feasibility experiment revealed this design to be bulky, cumbersome, and therefore impractical. Stakeholder feedback highlighted that fascial and subcuticular layers were missing from the abdominal wall, and that hard stops needed to be incorporated in the layers to avoid overstretching, tearing, and wasting of material.

Design Concept 2: Frame Model for Abdominal Wall
The second design approach involved using a generic plastic box as the model's container, with the abdominal wall layers attached to the underside of the box's lid. This minimized material used, reduced overall costs and provided a hard stop as requested by physician stakeholders. A mathematical model and proof of concept of this design revealed the approach was feasible for its ability to remain taut and form a dome from the intra-abdominal pressure. After multiple meetings with physician stakeholders, this design was refined and selected for the final model. The decision was made to glue the layers of the abdominal wall together to prevent them from separating when incised, improving representation of native tissue. Adjustments were made to the layers of the abdominal wall including addition of a subcuticular layer in between the skin and fat analogs to aid in holding sutures, and a double-layered fascia, simulated by thin cotton fabric.

Feasibility of Frame Design: Mathematical Model. Before moving to prototyping the design, a mathematical model was developed to establish feasibility. The resulting force at each attachment point of the abdominal wall was determined from an incision force of 2N at an angle of 60°, the typical incision used to penetrate skin\textsuperscript{[23,24]}. This was done to verify that the material used for the skin analogue, the thinnest layer, would not tear at the attachment points when under tension from the incision force. The maximum force was 0.75N, which translated to a pressure of 3.8 kPa on the surrounding material. This pressure is lower than the ultimate tensile strength of the skin analogue (1.39 MPa\textsuperscript{[25]}), indicating that this was a feasible design to move forward with.

Final Prototype
The final solution, schematic shown in Figure 2, contains artificial organ and tissue analogs, cast with commercially available silicones in 3D printed molds or simulated with fabric. Each component is removable allowing for part-task training as well as for easy replacement once the maximum amount of incisions has been made.
Specifications for each of the model components are listed in Table 1. An expanded model is shown in Figure 3, each component is described in more detail below, and the final model is shown in Figure 4. An assembly video can be found at the following link: https://drive.google.com/file/d/1wiqu0aNr0F9Ec-AkhhrVpAUrJ90OqBsS/view?usp=sharing.

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
<th>Recorded Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Box Opening</td>
<td>Length x width</td>
<td>36.8 x 28.9 cm</td>
</tr>
<tr>
<td>Attachment Piece</td>
<td></td>
<td>29.5 x 24 cm</td>
</tr>
<tr>
<td>Skin</td>
<td>Thickness</td>
<td>&lt;1.5 cm</td>
</tr>
<tr>
<td></td>
<td>Material</td>
<td>Platinum Cured Silicone Rubber</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Ecoflex 00-30)</td>
</tr>
<tr>
<td>Fat</td>
<td>Thickness</td>
<td>11 mm</td>
</tr>
<tr>
<td></td>
<td>Material</td>
<td>Soma Foama 15</td>
</tr>
<tr>
<td>Abdominal Muscle</td>
<td>Thickness</td>
<td>10 mm</td>
</tr>
<tr>
<td></td>
<td>Material</td>
<td>Platinum Cured Silicone Rubber</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Ecoflex 00-50)</td>
</tr>
<tr>
<td>Uterus</td>
<td>Thickness</td>
<td>5 mm</td>
</tr>
<tr>
<td></td>
<td>Dimensions (LxWxD)</td>
<td>32.5 x 20 x 20 cm</td>
</tr>
<tr>
<td></td>
<td>Material</td>
<td>2:1 ratio of Platinum Cured</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Silicone Rubber Dragon Skin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30A: Soma Foama 15</td>
</tr>
<tr>
<td>Bladder</td>
<td>Material</td>
<td>4:1 ratio of Platinum Cured</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Silicone Rubber Ecoflex 00-10:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Soma Foama 15</td>
</tr>
<tr>
<td>Locking Mechanism</td>
<td>Diameter</td>
<td>106 mm</td>
</tr>
</tbody>
</table>

**Container:** A plastic drop-front shoebox was selected because the drop-front opening allows for insertion of a doll and easy replacement between each JCM simulation. This container also allows for the desired 180° rotation of the lid which can be attached to the container in either direction.

**Abdominal wall:** Composed of skin (brown), subcuticular layer (green), fat (yellow), and fascia (purple) analogs held together by silicone adhesives and secured to the lid of the model with ten nylon M6x25mm screws. To better distribute forces upon layer stretching, an attachment piece (teal) was designed to provide further stability to the abdominal wall.

**Muscle:** Designed as separate from the abdominal wall because the rectus abdominis muscle is not incised during CS, as the muscle experiences diastasis recti and naturally separates due to the intra-abdominal pressure. The component is pre-cut, and is able to be stretched as required in JCM. It does not need to be replaced, further supporting the project objective of maximizing amount of uses per training model. During assembly, the muscle layer is placed over the uterine component and stretched by the pressure exerted from below.

**Uterus:** Cast from an experimentally determined ratio of silicones based on physician suggestion. The determined ratio improved tactile similarity and provided the ability to hold suture. A hollow, plastic sphere was placed inside the component to hold a baby doll, maintain
shape and provide intra-abdominal pressure to create the characteristic rounded shape of a pregnant abdomen.

**Bladder:** Designed as an individual component, attached to the lower uterine segment via Velcro. This component serves as a static marker (visual) and dynamic marker (moving out of the way) to remind students to avoid the bladder during the procedure. Students will not be making incisions in the bladder; thus, a specific elastic modulus or tactility was not detailed nor requested by physicians. Future work could include designing peritoneum so that bladder flap techniques may also be taught and trained on the model.

**Locking mechanism:** Connects the uterine-cervical analog securely to the container, allows for easy rotation, and visual quantification of the number of rotations performed. The locking mechanism consists of two 3D-printed components that fit together seamlessly. The outer and inner components attach through a hole cut into one face of the container and the uterine-cervical analog can be set in place and attached. Specifically, there are four locations (small holes) on the inner component where the uterine-cervical analog can be fastened with brad pins. The outer component features numbers which indicate each 90° turn so that it is easy for the user to track.

![Figure 4. Final prototype (left) and cross section of layers (right): (a) skin and subcuticular layers, (b) fat, (c) fascia, (d) abdominal muscle, and (e) uterine analog components](image_url)

**Proof of Functionality**

Design requirements were confirmed via verification testing per ASTM Standards where applicable. The elastic moduli and physical geometries of simulated tissues were measured, as well as assembly time, overall dimensions, and cost per use. Statistics were performed using a two-sample t-test, \( \alpha = 0.05 \).

**Elastic moduli of simulated tissues:** Tensile testing of the skin, fat, abdominal muscle, and myometrium analogs was performed in accordance with ASTM D412-16: Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension. The tensile elastic moduli (EM) of native tissues and the considered silicones are shown in Figure 5. Accurate simulation of native tactile feedback will elevate the quality of training, and facilitate the translation of surgical skills into practice. Skin has an elastic modulus of \( 4 \pm 3.8 \) MPa; however, the selected material Ecoflex 00-30’s (EF0030) EM was \( 31.1 \pm 2.9 \) kPa. Although statistically different from native tissue, EF0030 was the physicians’ preference and was therefore used in the model. Three silicones were tested to simulate the myometrium: Dragon Skin 20A (DS20), and mixtures of Dragon Skin 30A (DS30) and Soma Foama 15 (SF) at 2:1 and 3:1 wt%. Neither
of the three silicones accurately represented the EM of full-term myometrium (0.5-2MPa), with values of 0.26 ± 0.03, 0.12 ± 0.06, and 0.16 ± 0.03 MPa, respectively. However, the 2:1 ratio of DS30:SF was selected by the physicians as tactiley accurate. Two silicones were tested for abdominal muscle: EF0030 and Ecoflex 00-50 (EF0050). EF0030 (31.1 ± 2.9kPa) was not an accurate representation of abdominal muscle, and was deemed too elastic by the physician stakeholders. EF0050 replicated the EM of native abdominal muscle (42.7 ± 4.2 kPa and 42.5 ± 9.0 kPa, respectively; p=0.95), and was also approved by physicians. Two silicones were tested as fat analogs: Ecoflex 00-10 (EF0010) and SF. The EM of adipose tissue (11.7 ± 6.4 kPa) was replicated by both EF0010 (15.4 ± 2.8 kPa, p=0.34) and SF (15.6 ± 3.6, p=0.10), however SF had better tactile properties. Although only two of the four tissues met their mechanical requirements, all of the chosen silicones were approved by physician stakeholders after multiple sessions of incising, stretching, and suturing proposed materials. As the OB/GYNs have the best understanding of the tissues’ tactile behavior and are the models’ final users, the failure to meet the moduli of skin and uterine tissue does not hinder the effectiveness of the design.

**Physical geometries and thicknesses of the model components:** Measurements followed ASTM D3767-03: Standard Practice for Rubber-Measurement of Dimensions to ensure tissue analogs met their respective specifications. The procedure involved using a micrometer, caliper, or 1 mm graduated ruler to make a minimum of three measurements for lengths of <30 mm, 30-100 mm, and >100 mm, respectively. The results are shown below in Table 2.

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirement</th>
<th>Recorded Values</th>
<th>p (α=0.05)</th>
<th>Pass/Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterus</td>
<td>Geometry</td>
<td>35x25x20 cm</td>
<td>N/A</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td>Thickness</td>
<td>4.68 ± 0.48 mm</td>
<td>p=0.19</td>
<td>Pass</td>
</tr>
<tr>
<td>Skin</td>
<td>Thickness</td>
<td>1.16 ± 0.26 mm</td>
<td>p=0.02</td>
<td>Fail</td>
</tr>
<tr>
<td>Fat</td>
<td>Thickness</td>
<td>13.0 ± 2.7 mm</td>
<td>p=0.44</td>
<td>Pass</td>
</tr>
<tr>
<td>Abdominal Muscle</td>
<td>Thickness</td>
<td>9.8 ± 1.7 mm</td>
<td>p=0.21</td>
<td>Pass</td>
</tr>
</tbody>
</table>

The skin analog did not meet the requirement for native tissue. This was a design tradeoff; a thinner layer would rip when being pulled taut, and the approx. 0.5 mm difference was not tactiley discernible. Additionally, the material was approved by physicians. The uterine component is slightly smaller than the native organ which was deemed acceptable as the patient population in SSA is typically smaller than that in USA with a lower BMI. The component is also an ellipsoid rather than pear-shaped to allow for increased uses before replacement. The uterine, fat and abdominal muscle thicknesses all met the requirement for native tissue.
Assembly time: Third party users were timed to establish the average time required to completely assemble a model. The average time recorded was 47.5 ± 13.1 sec, meeting the requirement of less than 5 min.

Model size and weight: Overall dimensions of the model were determined following ASTM D3767-03 procedure. The model weight was determined by averaging the masses of three completely assembled models. The model’s overall size was 93.6 ± 0.9 cm and weighed 3.8 ± 0.3 kg, meeting the dimension requirements of commercial airline luggage restrictions.

Cost per use: The total cost of replaceable materials required to make one complete model was divided by the number of uses per each model, as determined by physician advisors. The abdominal wall was determined by physicians to accommodate 8 laparotomies before requiring replacement, and the uterine component 20 incisions total before replacement: 12 JCM incisions and 8 vertical incisions. Vertical incisions are performed in emergent cases such as fibroid, cervical cancer, and anterior placenta accreta; this opportunity to train rare cases can further increase physician competency. Each laparotomy costs US$2.01 and each uterine incision costs US$1.02, for a total cost of US$3.03 per complete JCM CS. Although the model did not meet the requirement of US$1.00 per use as requested by stakeholders, the achieved cost is a significant improvement compared to existing models on the market, and is still accessible to the model’s intended customers of international not-for-profit organizations and universities. Increasing the scale of production will save costs on bulk material and manufacturing efficiencies.

Model accuracy and performance: Validation was conducted with DUCOM OB/GYN faculty and residents. Their feedback was collected over prototype iterations via a survey. The survey encompassed ranking overall quality, ability to teach JCM, components’ tactile and tensile accuracy, and ability to hold sutures on a scale of 1-5 (worst-best), identifying model strengths and weaknesses, and comparing the model to existing technologies. When comparing to existing models, a value of 3 indicated no difference, 1-2 a decline, and 4-5 an improvement in quality. Results are shown in Table 3. The first prototype is not included as it was a proof of concept and a starting point for physicians to give direction. Each iteration received physician feedback to improve the model, leading to the final prototype. Figure 6 shows obstetricians performing a cesarean section on the final prototype during validation testing, and the proper stretching behavior that was required by the JCM.

<table>
<thead>
<tr>
<th>Table 3. Validation Results from DUCOM Physicians and Residents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prototype 2</strong>&lt;br&gt;Mar 15, 2019</td>
</tr>
<tr>
<td>Overall quality</td>
</tr>
<tr>
<td>Teaching JCM</td>
</tr>
<tr>
<td>Compared Quality</td>
</tr>
</tbody>
</table>

Figure 6. Validation Testing  
Left: stretching of abdominal wall per JCM  
Right: Incision of the uterine component
Generally, model quality improved with each iteration. Many physicians noted that it is impossible to perfectly replicate human tissue with affordable synthetic materials, which they would deem a quality of ‘5’. Despite this, it was consistently reported that the model made significant improvements from those that are currently in use, as indicated by the average score of 4.5.

**Economic Analysis**
The current market for medical training models, specifically for CS, consists of high-fidelity models. This means they are built with highly realistic anatomy and most contain life-like tissues. These models range in cost from $500-50,000 depending on how dissectible and life-like it is. For example, the lowest cost model, CS500, is not dissectible, vascularized, or have life-like tissue density[26]. The highest cost model, Noelle S574,100, has all of these components. A computer simulated CS program, CEVL Cesarean, is able to provide audio and visual feedback but lacks the haptic feedback of physical models[26]. DUCOM physicians have designed low-fidelity models that cost <$10 per model. These lack anatomical and material accuracies and cannot be purchased. The materials need to be purchased separately and are hand-made. Currently, there is a gap in the market for mid-fidelity, moderately-priced models. Our design meets these criteria as it is able to provide anatomical accuracy through the use of cost-effective materials and has the additional features of multiple uses per model and part-task training.

**Conclusion**
We have created a prototype for an affordable, yet representative CS bench-top model that simulates the physician stakeholders’ main teaching goals. Future work can expand model capabilities to include more complicated CS cases or other gynecologic procedures. Project stakeholders have indicated that the model is ready to be implemented for teaching CS; the model will be used in June 2019 for a DUCOM residency training, and deployed in Fall 2019 for the Ugandan ETOO program. Further expansion could also bring the model to 21 other ACOG training programs in Asia, Africa, and Latin America[22]. Ultimately, the implementation of this model has the capability to increase physician competency and reduce maternal mortality around the world. The model is accessible in areas where proper training is currently lacking, and can provide increased opportunities for training in the developed world where expensive models are not practical.
References


