



RESEARCH ARTICLE

Creation of a Novel 3D-Printed Amniocentesis Simulation Model and Impact on Resident Confidence

Kelsey J. Pape, MD¹, Ms. Ashtin Wilson, MSBME², Ms. Nichole Cronin, BSBME², Mr. Jacob Parmenter, BSBME², Mr. Nick Ellis, BSBME², Caroline E. Rouse, MD¹, Anthony L. Shanks, MD, MEd¹,

¹ Indiana University School of Medicine, Department of Maternal-Fetal Medicine

² Indiana University Purdue University, Department of Biomedical Engineering



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ABSTRACT

Background: Non-invasive prenatal screening has decreased opportunities for diagnostic antenatal procedures during residency training. Commercially available models are often cost prohibitive while homemade models can be low fidelity and non-reusable.

Objective: To create a training tool with realistic anatomy, tissue-specific tactile sensation, and cost-effective assembly for amniocentesis procedural technique practice and evaluate its impact on trainee confidence with performance.

Study Design: Collaborating with biomedical engineering students, our team defined several characteristics to achieve a high-fidelity model: compatible with ultrasound, anatomically accurate, demonstrate tactile realism, endure repeat use, and be cost-effective. A 3-D printed model was created that satisfied fidelity guidelines after rigorous materials and imaging testing.

Results: We implemented the model in the observed structured clinical exam for Obstetrics and Gynecology residents in which trainees (PGY2-4) performed an amniocentesis after guided practice with Maternal-Fetal Medicine faculty. Residents were given pre and post-simulation Likert scale surveys regarding confidence and satisfaction with the model. Descriptive analyses and paired t-test were used for analysis. 19 residents completed both pre and post surveys. Mean resident confidence in performing an amniocentesis increased from 1.6 to 3.2 ($p < 0.001$, scale 1-5) after the practice session. Most residents (89.5%) strongly agreed that the model was easy to use and would use it to practice independently.

Conclusion: This novel 3-D printed, ultrasound compatible, anatomically accurate, and cost-effective amniocentesis model provides high-fidelity procedural practice and improved trainee confidence. Models such as these have the potential to greatly impact skill development for rare procedures. Future directions include modifying this model for additional fetal procedures, such as cordocentesis.

Keywords: procedure simulation, interdisciplinary collaboration, amniocentesis, prenatal testing, graduate medical education

Introduction

Prenatal diagnostic and therapeutic procedures, such as amniocentesis, chorionic villus sampling, and percutaneous umbilical artery sampling, are critical to offering comprehensive obstetric care.¹ Access to safe and appropriately timed procedures provides patients with important information regarding pregnancy continuation and prognoses. Non-invasive prenatal screening allows patients excellent access to risk stratification of aneuploidies and select genetic disorders, however, has decreased opportunities for diagnostic procedures which are still considered the “gold standard” for prenatal diagnosis.^{2,3} Pertinent risks of prenatal diagnostic procedures include miscarriage and fetal loss, which are approximately 0.5% for amniocentesis, 1% for chorionic villus sampling, when including the transcervical approach, and 1.4-1.9% for cordocentesis.⁴⁻⁷

It is challenging to quantify the proportion of fetal loss due to user operator experience alone. Retrospective cohort studies demonstrate significant differences in centers with higher volume compared to those with lower volume. Further, a small but significant difference has been noted with more than three needle insertions, which could be used as a proxy for user experience.⁸ Khurshid et al described a formal amniocentesis curriculum integrated into a maternal-fetal medicine fellowship that included an eco-flex silicone simulator. First and second year fellows who completed the curriculum decreased needle insertions compared to those who did not in over 250 reviewed amniocenteses.⁹ Given its continued clinical relevance, it is imperative to create training opportunities for invasive diagnostic procedures.

Amniocentesis performance remains an educational objective prescribed by the Council on Resident Education in Obstetrics and Gynecology; therefore, amniocentesis simulation was selected for evaluation in this project.¹⁰ To encourage departments to invest in procedure simulation, it is critical that training tools are low-cost, compatible with existing ultrasound curricula, realistic, and durable enough to withstand repeated use. Lack of experience or

low confidence may amplify the inherent risk of invasive prenatal procedures and increase complications for both the maternal and fetal patient, highlighting the importance of high fidelity practice.⁷⁻⁸ The objective of this project was to create a training tool that mimics realistic anatomy, provides tissue-specific tactile sensation, and is cost-effective, and to increase trainee confidence after attending a hands-on practice session. The secondary objective was to evaluate trainee satisfaction with model practice.

Materials and Methods

This project was in collaboration with the Departments of Biomedical Engineering and Maternal Fetal Medicine. The team included two maternal-fetal medicine faculty, two biomedical engineering faculty, and five undergraduate biomedical engineering students who selected this as a senior capstone project. Amniocentesis was determined to be the procedure of highest importance for this project; therefore, 20 weeks of gestation was selected to be the anatomical proportion for the model. Relevant anatomy included the uterus and its surrounding tissues at 20 weeks of gestation. Operative requirements were defined at project outset: ultrasound compatibility, realistic biomechanics, anatomically accurate, ability to endure repeat use, and cost-effective. A budget of \$500 was set.

MODEL CREATION

An iterative design process was undertaken consisting of interdisciplinary meetings and materials literature review by the engineering team. At its completion, an initial prototype was designed that met aforementioned criteria, which took approximately one year. The model was designed as a cavity with a fetal simulant overlying muscle, subcutaneous fat, and skin layers. A hole-in-peg lid was placed atop to keep layers in place. The lid exhibited an open window to accommodate an ultrasound probe (Figure 1). Imperatively, the model was designed as free standing and able to be placed on a tabletop, modular to allow for individual part replacement, adjustable to account for different types of maternal habitus, able to secure a liquid medium to simulate amniotic fluid, and easily cleanable (Figure 1).

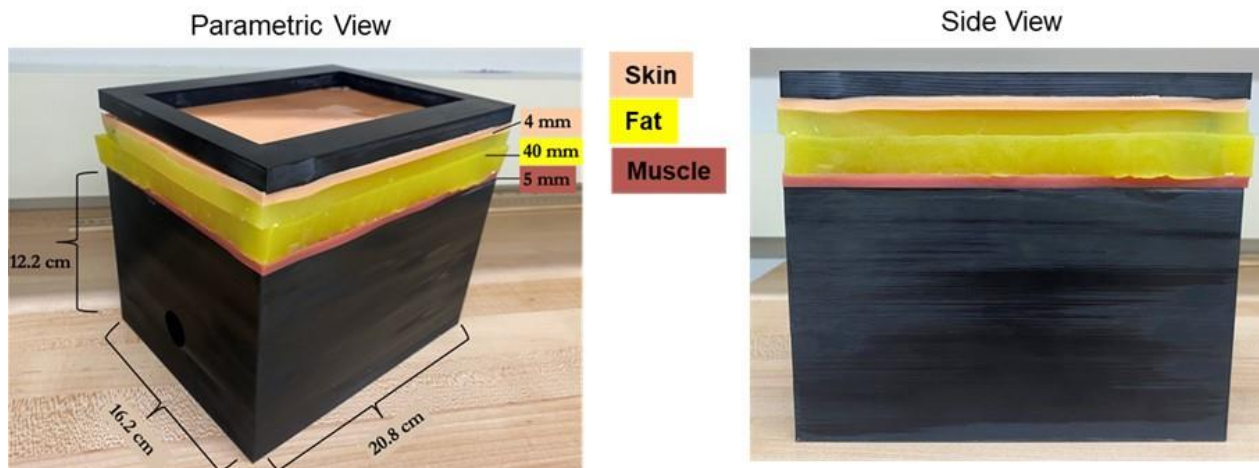


Figure 1. Assembled model with labeled tissue layers and associated depth measurements.

The housing aspect of the model was 3D printed with ABS filament and coated with Gorilla Waterproof Patch™ and Seal Spray™. A fetus simulant was 3D printed with

silicone from a freely available model and filled with cellulose to appear hyperechoic on ultrasound. The size was adjusted to fit appropriately within the housing

model. The housing base was placed in a polycarbonate moat sealed with silicone caulking to minimize bubble formation once filled with water, the amniotic fluid simulant. 3D printing allows for precise dimensions, but commercially purchased materials can be substituted.

For the tissue layers (skin, subcutaneous fat, and uterine muscle), material mixing with silicone (EcoFlex™ 00-30 Part A and B) and sequentially increasing densities of cellulose was performed. Ultrasound imaging testing was performed on each mold recipe using standardized preset imaging settings and coupling gel. This was further controlled by using the same machine and settings on the same day on a CIRS Multi-Purpose Multi-Tissue Ultrasound Phantom for quality assurance testing. Intensity of images obtained using molds were recorded and compared to established averages of human tissue.¹¹⁻¹² Once achieved, a tactile mutator (Slacker™) was added to each recipe to alter rebound properties and meet the goal of tactile realism. This product is added to silicone products to transform a rubber feel to a flesh-type feel. Intensities of each mold were

recalculated after the addition of Slacker™ and demonstrated no change to sonographic characteristics. Compression testing of each layer was used to compare to established values for human tissue. The depth of each tissue layer followed reported averages at 20 weeks gestation: 2mm for skin, 15-45mm for subcutaneous fat depending on body mass index, and 10mm for myometrium. To allow for modifying the subcutaneous fat layer to mimic different body habitus, this layer was made 10mm deep and with the ability to stack multiple layers.

Ultrasound testing was repeated to confirm brightness were maintained once all components were placed in tandem (Figure 2). Three sites were measured for each layer and averaged. Comparison to known tissue average ranges demonstrated the model fell within these measures.¹² Puncture testing of each tissue layer was performed by inserting testing needles with random patterns and angles and completing compression testing after increments of 10 needle insertions.

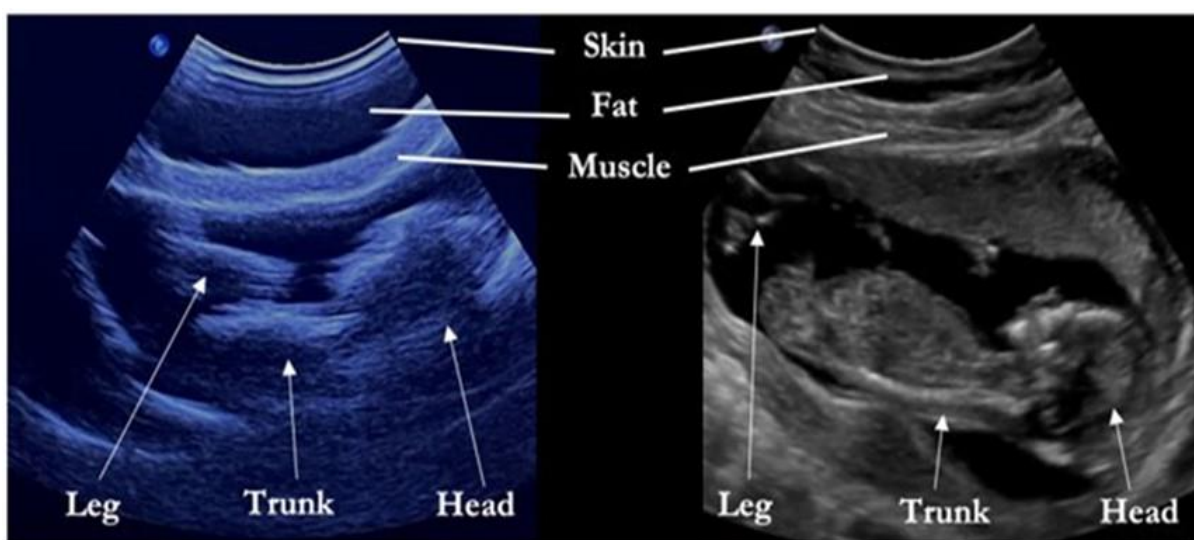


Figure 2. Sonographic of model (left) to live patient (right).

IMPLEMENTATION

Narrative feedback was obtained by faculty experts to confirm procedural integrity and evaluation of meeting preset standards (Figure 3). To evaluate resident confidence and experience with the model, an amniocentesis station was integrated into the annual objective structured clinical exam for second, third, and fourth year obstetrics and gynecology residents at our institution. This study was approved by the Institutional Review Board (IRB Protocol #16101). A Maternal-Fetal Medicine faculty proctored the station, starting with background questions, followed by a one-on-one training session utilizing the model. After a guided round, the residents independently attempted to complete an amniocentesis. Pre- and post-simulation surveys were administered to compare self-graded confidence and

satisfaction with the model using 5-point Likert scales (1-5, strongly disagree to strongly agree). These surveys were modeled after those employed in prior studies evaluating trainee confidence.¹³ Additional objective information such as number of needle insertions and duration to complete an amniocentesis were collected for potential future studies. Surveys were anonymous and collected without identifying information. Residents were asked about experience performing amniocenteses and prior use of amniocentesis models (Appendix 1). All analyses were performed in SPSS. The primary outcome of trainee confidence was evaluated by comparing the mean confidence scores between pre- and post-simulation groups using a dependent sample t-test. A p-value <0.05 was considered significant.

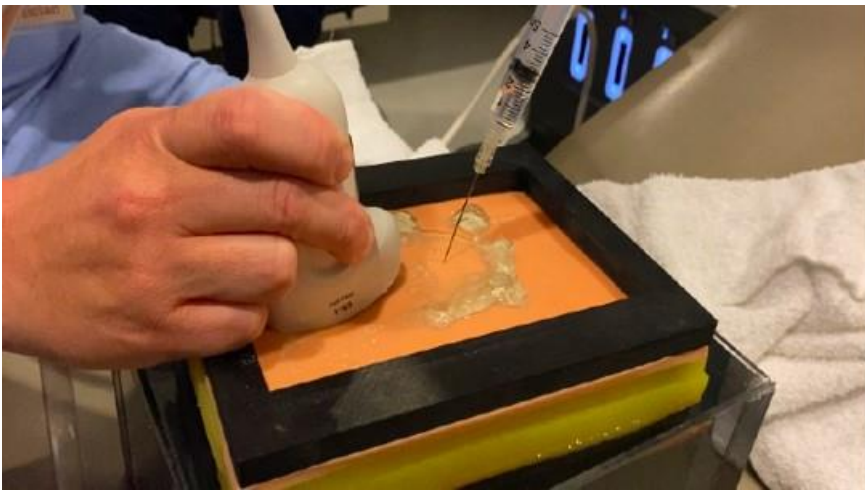


Figure 3. Maternal-fetal medicine faculty performing amniocentesis with prototype.

Results

Narrative responses were elicited from the clinical faculty leader, which included praising the ease of assembly and realistic feel. Time testing demonstrated approximately 225 seconds to assemble the model with two layers of fat. Minimal change in compression was noted at 60

pokes for each layer and repeat use testing was discontinued at 60 pokes for futility. Further, the tissue layers demonstrated self-healing properties with no visible ‘ghost tracks’ from prior needle insertions. Lastly, total model cost was \$240 with replacement costs for tissue layers being approximately \$30 (Table 1).

Table 1. Cost of prototype development materials.

Materials	Units/Item	Item Price Contribution
EcoFlex Trial*	2	\$20.06
SlackerTM*	4	\$5.20
Thinner*	6	\$2.44
Release Spray	100	\$0.21
Cellulose*	50	\$1.21
Sealant Spray	10	\$1.29
Waterproof Tape	10	\$1.14
Acrylonitrile Butadiene Styrene (ABS)	70 in ³	\$124.60
Power-mesh	1 ft ²	\$0.66
Silicone Pigment*	10	\$1.08
Polycarbonate	5 ft ²	\$26.90
Adhesive Caulk	10	\$1.28
Polyactic Acid (PLA)	10 in ³	\$5.10
Total	1 prototype	\$191

*Material required for replacement of tissue layers.

Twenty-three residents participated in the annual exam and nineteen provided complete pre and post-surveys for review (five PGY-2, six PGY-3, and eight PGY-4). Only three (15.8%) residents reported having performed at least one amniocentesis previously. One (5.26%) resident reported having practiced with an amniocentesis model before.

The mean self-graded confidence scores improved from 1.6 to 3.2 (scale 1-5), which was significant ($p < 0.001$). Confidence score ranges improved from 1-2 to 2-5. Additional descriptive confidence related questions included:

- “I feel more prepared to perform a live amniocentesis,” with 12 (63.2%) residents strongly agreeing and seven (36.8%) somewhat agreeing.
- “The model improved my ability to perform an ultrasound-guided needle procedure,” with 12 (63.2%) residents strongly agreeing and seven (36.8%) somewhat agreeing.

Regarding the satisfaction questions, all participants strongly agreed that the model was easy to use. All

residents agreed that they would use the model to practice, with 17 (89.5%) residents strongly agreeing.

Discussion

We present here an affordable, realistic training model and associated recipes for replication resulting from a successful interdisciplinary collaborative effort. Simulation is a critical learning method for trainees in procedural specialties. With advancements in 3D printing, affordable and high-fidelity models are achievable as demonstrated here.

Several meta-analyses demonstrate that repetitive simulation improves knowledge and skill compared to traditional teaching techniques regardless of learner level or specialty.¹⁴ Data on whether simulation subsequently improve patient outcomes are limited; however, increasing operator experience has been repeatedly associated with procedure success, particularly in the field of obstetrics.¹⁵⁻¹⁷ Simulators allow participants to train through a learning curve in a low stakes environment, but incur significant cost depending on the degree of tactile fidelity and durability.

Commercially available high-fidelity ultrasound compatible models exist, but are often prohibitively expensive (BluePhantom™, AMNIO ABBY™).¹⁸⁻¹⁹ The Blue Phantom cordocentesis model, priced at \$7,450.00, consists of a hard plastic abdomen covered with proprietary soft rubber material. The models are made from durable materials, which can withstand more than 1,000 needle punctures and include refilling ports for synthetic amniotic fluid and blood.¹⁹ The materials are advertised to mimic the appearance of human tissue under ultrasound. These models are expensive and function for only one procedure, leaving the market open for an affordable, multi-procedure tool. Many academic departments use homemade models that are low fidelity, often made of food products, requiring materials purchase for each use. Making a gelatin mold and suspending an object to represent a fetus is a popular modeling tool as it is affordable and compatible with ultrasound. While low fidelity models are inexpensive, they often do not have properties similar to real human tissue, can be messy and often are one time use.²⁰⁻²³ On the contrary, Zubair et al created a model with formalin preserved pig uterus in a Ziploc bag filled with ultrasound gel to mimic distinct tissue layers that allowed for several repeat insertions. Dalton et al published a reusable silicone and rubber second trimester simulation model that exhibits skin, adipose, and myometrial layers and is modifiable for percutaneous umbilical blood sampling. However, unlike the present study, these prior models do not provide the same degree of tissue testing to assure anatomic accuracy or reusability.²⁴

This is an especially promising area in the field of obstetrics, which is affected by increasingly effective non-invasive genetic screening and decreasing opportunities for invasive prenatal procedures.¹⁻³ This was highlighted in our study where only three residents out of nineteen had previously performed an amniocentesis. Ultrasound-guided procedures in obstetrics are unique, involving two patients and often performed on awake patients, which can make immediate feedback delivery difficult. Moreover, complications from diagnostic prenatal procedures are rare, but significant.³⁻⁷ Stereotactic ultrasound skills and needle-following technique are required but was a gap identified among 152 general obstetrics and gynecology residency graduates who participated in an annual ultrasound-guided simulation workshop.²⁵ Accessibility to simulation promotes practice before trialing newly developed skills on patients as demonstrated by Khurshid.⁹ In addition, our data demonstrate that residents would eagerly use this model for repetitive practice and its endurance, as well as ease of assembly and mobility facilitate this. Not only can effective simulators allow skill development for learners, but also can promote skill maintenance for experienced providers.

The purpose of this study was focused on model creation and subjective initial implementation testing. There remain opportunities to comprehensively validate ultrasound-guided diagnostic simulators for obstetric training and correlate with clinical outcomes. As mentioned previously, Khurshid et al formally integrated an amniocentesis simulator into Maternal-Fetal Medicine fellowship curriculum with improvements in objective

procedure measures (needle insertions).⁹ Given the modifiability of our model for additional procedures, such as cordocentesis and intracardiac injection, next steps include comparing objective procedure data between novices (trainees) and experts (faculty), as well as designing a specific curriculum for trainees for these procedures and comparing procedure outcomes to before and after simulation curricula implementation.

Strengths of this project include our collection of qualitative feedback from learners who would most benefit from the device. Further, this model can be replicated by institutions with access to engineering laboratories and 3D printers. Model recipes can be found online (Appendix 2). Additionally, this model is cost-effective compared to commercially available models. It is versatile and has the potential to be customized for cordocentesis and chorionic villus sampling. It can be reused multiple times making it a worthwhile investment for educational departments.

Limitations of this project include its small sample size and single institution implementation. Use of the model by outside institutions would increase its validity and confirm its ability for replication. In addition, this study was largely limited to trainee feedback and collecting expert feedback would assure its clinical validity. There are no validated surveys to evaluate trainee procedural confidence and those used here were written by the study authors, which could contribute to bias. Importantly, although we found a significant increase in qualitative procedural confidence, this does not signify an improvement in provider skill.

Conclusions

We plan to continue utilizing this model as part of our program's annual observed structured clinical exam, which will provide long term satisfaction feedback and repeat use testing. We are integrating the model as part of our Maternal-Fetal Medicine fellowship education and develop cordocentesis and chorionic villous sampling targets.

This ultrasound compatible, anatomically accurate, and cost-effective model provides realistic practice and improves perceived trainee confidence in a world of limited on the job experience with diagnostic procedures. As advancements in surgical education continue, this promotes simulation training in our procedural field to work towards minimizing procedural complications, while being able to offer patients important information.

Disclosures: No relevant financial disclosures.

Conflicts of interests: No relevant conflicts of interests.

Presentation: This project has been previously presented as a poster presentation at the CREOG & APGO Annual Meeting in National Harbor, Maryland on February 28, 2023, as well as an oral presentation at the Indiana University School of Medicine Education Day in Indianapolis, Indiana on April 28, 2023.

References

1. American College of O, Gynecologists' Committee on Practice B-O, Committee on G, Society for Maternal-Fetal M. Screening for Fetal Chromosomal Abnormalities: ACOG Practice Bulletin, Number 226. *Obstet Gynecol.* Oct 2020;136(4):e48-e69. doi:10.1097/AOG.0000000000004084
2. Midtrimester amniocentesis for prenatal diagnosis. Safety and accuracy. *JAMA.* Sep 27 1976;236(13):1471-6. doi:10.1001/jama.1976.03270140023016
3. Tabor A, Vestergaard CH, Lidegaard O. Fetal loss rate after chorionic villus sampling and amniocentesis: an 11-year national registry study. *Ultrasound Obstet Gynecol.* Jul 2009;34(1):19-24. doi:10.1002/uog.6377
4. Alfirevic Z, Navaratnam K, Mujezinovic F. Amniocentesis and chorionic villus sampling for prenatal diagnosis. *Cochrane Database Syst Rev.* Sep 4 2017;9(9):CD003252. doi:10.1002/14651858.CD003252.pub2
5. Akolekar R, Bower S, Flack N, Bilardo CM, Nicolaides KH. Prediction of miscarriage and stillbirth at 11-13 weeks and the contribution of chorionic villus sampling. *Prenat Diagn.* Jan 2011;31(1):38-45. doi:10.1002/pd.2644
6. Tabor A, Alfirevic Z. Update on procedure-related risks for prenatal diagnosis techniques. *Fetal Diagn Ther.* 2010;27(1):1-7. doi:10.1159/000271995
7. Ghidini A, Sepulveda W, Lockwood CJ, Romero R. Complications of fetal blood sampling. *Am J Obstet Gynecol.* May 1993;168(5):1339-44. doi:10.1016/s0002-9378(11)90761-3
8. Silver RK, Russell TL, Kambich MP, Leeth EA, MacGregor SN, Sholl JS. Midtrimester amniocentesis. Influence of operator caseload on sampling efficiency. *J Reprod Med.* Mar 1998;43(3):191-5.
9. Khurshid N, Trampe B, Heiser T, et al. 420: Impact of an amniocentesis simulation curriculum for training in MFM fellowship program. *American Journal of Obstetrics and Gynecology.* 2014;210(1):S212-S213. doi:10.1016/j.ajog.2013.10.453
10. Council on Resident Education in Obstetrics and Gynecology EDUCATIONAL OBJECTIVES Core Curriculum in Obstetrics and Gynecology 13th Edition. <https://www.acog.org/-/media/project/acog/acogorg/files/creog/creog-educational-objectives-13th-edition.pdf>
11. Chiavacci I, O'Gorman P. Propagation speed. *Radiopaedia.org.* Published online July 23, 2016. doi:https://doi.org/10.53347/rid-46915
12. Database Summary» IT'IS Foundation. <https://itis.swiss/virtual-population/tissue-properties/database/database-summary/>
13. Johnson BA, Timberlake M, Steinberg RL, Kosemund M, Mueller B, Gahan JC. Design and Validation of a Low-Cost, High-Fidelity Model for Urethrovesical Anastomosis in Radical Prostatectomy. *J Endourol.* Apr 2019;33(4):331-336. doi:10.1089/end.2018.0871
14. Cook DA, Hatala R, Brydges R, et al. Technology-enhanced simulation for health professions education: a systematic review and meta-analysis. *JAMA.* Sep 7 2011;306(9):978-88. doi:10.1001/jama.2011.1234
15. Nitsche JF, Brost BC. The use of simulation in maternal-fetal medicine procedure training. *Semin Perinatol.* Jun 2013;37(3):189-98. doi:10.1053/j.semperi.2013.02.011
16. Tongprasert F, Srisupundit K, Luewan S, Phadungkiatwattana P, Pranpanus S, Tongsong T. Midpregnancy cordocentesis training of maternal-fetal medicine fellows. *Ultrasound Obstet Gynecol.* Jul 2010;36(1):65-8. doi:10.1002/uog.7626
17. Wijnberger LD, van der Schouw YT, Christiaens GC. Learning in medicine: chorionic villus sampling. *Prenat Diagn.* Mar 2000;20(3):241-6.
18. AMNIO ABBY® - Ultrasound Guided Invasive Procedures Simulator. *GTSimulators.com.* Published 2021. Accessed December 11, 2023. <https://www.gtsimulators.com/products/amnio-abby%C2%AE-ultrasound-guided-invasive-procedures-simulator-ar60>
19. CAE Blue Phantom™ Percutaneous Umbilical Cord Blood Sampling Ultrasound Training Model. *www.worldpoint.com.* Accessed December 11, 2023. <https://www.worldpoint.com/percu-umbcord-blood-samp-ustm>
20. Zubair I, Marcotte MP, Weinstein L, Brost BC. A novel amniocentesis model for learning stereotactic skills. *Am J Obstet Gynecol.* Mar 2006;194(3):846-8. doi:10.1016/j.ajog.2005.08.068
21. McWeeney DT, Schwendemann WD, Nitsche JF, et al. Transabdominal and transcervical chorionic villus sampling models to teach maternal-fetal medicine fellows. *Am J Perinatol.* Aug 2012;29(7):497-502. doi:10.1055/s-0032-1310518
22. Tassin M, Cordier AG, Laher G, Benachi A, Mandelbrot L. [Amniocentesis trainer: development of a cheap and reproducible new training model]. *J Gynecol Obstet Biol Reprod (Paris).* Nov 2012;41(7):679-83. Simulateur d'amniocentese : interets et developpement d'un nouveau modele reproductible et economique. doi:10.1016/j.jgyn.2012.05.002
23. Nourallah G, Ryan G, Abbasi N, et al. Development of a Training Model for Teaching Intrauterine Fetal Blood Transfusion. *J Obstet Gynaecol Can.* Aug 2022;44(8):931-933. doi:10.1016/j.jogc.2022.03.019
24. Dalton SE, Gregg AR, Ho M. Second-Trimester Uterine Model for Teaching Ultrasound-Guided Obstetric Procedures. *J Ultrasound Med.* Aug 2017;36(8):1723-1731. doi:10.7863/ultra.16.08040
25. Codsí E, Brost BC, Nitsche JF. Hands-on Simulation Workshop for Obstetric Ultrasound-Guided Invasive Procedures. *MedEdPORTAL.* 2022;18:11250. doi:10.15766/mep_2374-8265.11250

Appendix

Appendix 1: Pre and Post-Simulation Trainee Surveys

We are conducting research on trainee confidence after amniocentesis simulation. This will help provide useful information on procedural education for residents and fellows. The survey should take less than five minutes to complete. Your completion of this survey implies your consent to participate in this study. Participation is completely voluntary and you may withdraw from the study at any time. No further identifying information will be collected about you outside of what is provided in this survey. This information will not be used for performance evaluations. The survey results are de-identified with an anonymous study identification number known only to you. The information released and used for this research will include information about your performance using the simulation device. The following individuals and organizations may receive or use your identifiable information: The researchers and research staff conducting the study, the Institutional Review Boards (IRB) or its designees that review this study, or the university. Thank you for your time.

Please enter your unique study ID using the following instructions. This will be used to link your pre and post-surveys: 1. First letter of your first name 2. Day of birth (DD) 3. Month of birth (MM) 4. First letter of your middle name (if none, use X) 5. First letter of city/town you were born.

Select your level of training.

- PGY1
- PGY2
- PGY3
- PGY4
- PGY5
- PGY6
- PGY7

Number of live amniocenteses you have performed before today.

On a scale of 1 to 5, where 1=not confident at all and 5=very confident, how confident do you feel performing a real amniocentesis?

Sliding scale from 1 to 5.

Post-simulation Trainee Survey

We are conducting research on trainee confidence after amniocentesis simulation. This will help provide useful information on procedural education for residents and fellows. The survey should take less than five minutes to complete. Your completion of this survey implies your consent to participate in this study. Participation is completely voluntary and you may withdraw from the study at any time. No further identifying information will be collected about you outside of what is provided in this survey. This information will not be used for performance evaluations. The survey results are de-identified with an anonymous study identification number known only to you. The information released and used for this research will include information about your performance using the simulation device. The following individuals and organizations may receive or use your identifiable information: The researchers and research staff conducting the study, the Institutional Review Boards (IRB) or its designees that review this study, or the university. Thank you for your time.

Please enter your unique study ID using the following instructions. This will connect your pre and post-surveys: 1. First letter of your first name 2. Day of birth (DD) 3. Month of birth (MM) 4. First letter of your middle name (if none, use X) 5. First letter of city/town you were born.

The model mimicked a real amniocentesis.

- Strongly agree
- Agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree

- Disagree
- Unsure, I haven't performed an amniocentesis.

The model improved my ability to perform an ultrasound-guided needle procedure.

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

I feel more prepared for a live amniocentesis.

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

The model is easy to use.

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

I would use this model to practice.

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

Please enter the duration of your attempt to complete the amniocentesis task in seconds.

Please enter the number of needle insertions attempted until completion of task.

How confident do you feel performing a real amniocentesis on a scale of 1-5, where 1=not confident at all and 5=very confident?

Sliding scale from 1 to 5.

I have used an amniocentesis simulation model before.

- Yes
- No

If the answer to the prior question is yes, please answer the following: This is the most useful amniocentesis model I have used.

- This is the first model I have used.

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

Appendix 2: Model ingredients and procedures

Final Product Inventory:

- 1 Base
- 1 Top
- 1 Fetal Simulant
- 3 Layer Molds
- 1 Lexan Box
- EcoFlex™ 00-30 Parts A and B: 1 gal each
- Powdered Cellulose: 500g
- Slacker™: 1 Pint
- Silicone Thinner: 1 Pint
- Smooth On Silc Pig Silicone Dye
- Powermesh Fabric: 1 Yard
- Waterproofing spray: 12oz can
- Containers for measuring and mixing
- 1 flash drive and/or SharePoint Folder containing the .3mf files of 3D-printed components

Additional necessary items:

- Water
- Ultrasound machine with transducer (specifics to follow visiting clinic)
- Ultrasound gel
- 90-150mm long 22-gauge procedure needle
- Paper towel
- Surgical gloves
- Weigh boats
- Vacuum chamber/Vacuum desiccator
- Scissors

FDM 3D Printing Specifications

- ABS or ASA Filament
- 22% Infill
- 0.12mm Layer Height

Muscle layer ingredients and recipe (5mm layer height):

75g each silicone part A & B (150g total)

7.5g cellulose powder

13.5g Silicone thinner Red silicone pigment

Procedure

1. Cover the workspace with paper towels or wax paper
2. Measure 13.5g of silicone thinner into a beaker or other smooth-walled container
3. Measure 7.5g of cellulose in a weigh boat and add to silicone thinner
4. Pour or scoop 75g of each part of silicone rubber into the mixing container using a separate scoop for each part
5. Using the stir stick, remove a small amount (~1g) of red ('blood') silicone pigment
6. Mix the silicone for a minimum of 3 minutes until fully combined and homogenous, making sure to scrape the sides and bottom of the mixing container
7. Place the mixing container on a paper towel or wax paper in the vacuum chamber and vacuum for 5 minutes, making sure the container does not overflow
8. During this time, prepare the mold labeled 'Uterine Muscle' by spraying lightly with mold release spray and place on a lined surface
9. Pour the silicone evenly around the mold and tilt slightly to fill corners
10. Scrape excess mix from the sides and bottom of the mixing container using the stir stick
11. Allow to cure for a minimum of 4 hours

Fat layer ingredients and recipe (10mm layer height):

135g each silicone part A & B (270g total)

67.5g Silicone Slacker

24.3g Silicone thinner Yellow silicone pigment

Procedure

1. Cover the workspace with paper towels or wax paper
2. Measure 24.3g of silicone thinner into a beaker or other smooth-walled container
3. Slowly add 67.5g silicone slacker
4. Pour or scoop 135g of each part of silicone rubber into the mixing container using a separate scoop for each part
5. Using the stir stick, remove a small amount (~1g) of yellow silicone pigment
6. Mix the silicone for a minimum of 3 minutes until fully combined and homogenous, making sure to scrape the sides and bottom of the mixing container
7. Place the mixing container on a paper towel or wax paper in the vacuum chamber and vacuum for 5 minutes, making sure the container does not overflow
8. During this time, prepare the mold labeled 'Subcutaneous Fat' by spraying lightly with mold release spray and place on a lined surface
9. Pour silicone evenly around the mold and tilt slightly to fill corners
10. Pour the silicone evenly around the mold and tilt slightly to fill corners
11. Scrape excess mix from the sides and bottom of the mixing container using the stir stick
12. Allow to cure for a minimum of 4 hours

Skin layer ingredients and recipe (0.3cm layer height)

45g each silicone part A & B (90g total)

4.5g cellulose powder

8.1g Silicone thinner Pink silicone pigment Powermesh fabric

Procedure

1. Cover the workspace with paper towels or wax paper
2. Cut the Powermesh fabric into a rectangle slightly larger than the interior of either mold
3. Place tape over the text in the bottom of the mold if text is not desired on the skin layer
4. Lightly spray the mold with silicone mold release
5. Cut a small hole in the corner of the fabric lining up with one peg in the mold but slightly smaller than the peg diameter
6. Stretch the fabric around the peg to secure it in place, then repeat for each of the other pegs until the mesh is formed around all 4 pegs and is flat against the bottom of the mold. Some excess fabric should ride up against all 4 walls of the mold
7. Measure 8.1g of silicone thinner into a beaker or other smooth-walled container
8. Measure 7.5g of cellulose in a weigh boat and add to silicone thinner
9. Pour or scoop 75g of each part of silicone rubber into the mixing container using a separate scoop for each part
10. Using the stir stick, remove a small amount (~1g) of pink ('Flesh') silicone pigment
11. Mix the silicone for a minimum of 3 minutes until fully combined and homogenous, making sure to scrape the sides and bottom of the mixing container
12. Place the mixing container on a paper towel or wax paper in the vacuum chamber and vacuum for 5 minutes, making sure the container does not overflow
13. Pour about half of the silicone mixture evenly over the mesh
14. Using the stir stick, flatten out any wrinkles that may have appeared in the mesh layer and form the mesh against the corners of the mold
15. Pour the silicone evenly around the mold and tilt slightly to fill corners
16. Scrape excess mix from the sides and bottom of the mixing container using the stir stick
17. Allow to cure for a minimum of 4 hours
18. Trim excess fabric from the sides of the layer to size

Tips

- Single parts (A or B only) of silicone rubber and silicone additives will not cure unless mixed and are difficult to clean with standard solvents. Use disposable measuring containers to transport raw materials.
- To clean the mixing container and stir stick, allow the silicone to fully cure and the film should easily peel off the surface
- Quantities of silicone pigment are not crucial to the recipe. However, they are quite concentrated and only a small amount is required for each recipe
- Always wear disposable gloves while working with silicone components. While they are not especially toxic, they are difficult to remove from your hands and will stain clothing
- Make sure to not reuse measuring scoops if measuring silicone rubber components from the 1 gal. buckets. Components can be poured directly from the smaller 1 pint containers.
- Mix all components thoroughly before use, as the silicone rubber will settle after long periods of time
- Recipe for fat layer is for 1 cm layer height but can be doubled or tripled for 2cm and 3cm layers. Each mold has a maximum height of 3cm.
- Working time for the silicone rubber is ~45 minutes after the two parts are mixed

Work Instructions Assembly

1. Ensure that the housing is clean
2. Remove all tissue simulant layers from their molds and set aside
3. Place the base inside the Lexan box, then on the procedure table or countertop
4. Choose how many layers of fat the model will be constructed with and adjust the pegs accordingly (if needed... TBD once housing is chosen)
5. Place the fetal simulant inside the womb
6. Fill the womb as much as possible with water, overflowing into the moat.
7. Carefully place the Muscle Layer onto the base by aligning the holes
8. Repeat Step 6 with up to 3 Fat layers
9. Repeat Step 6 with the Skin layers
10. Place the housing lid on top of the base, aligning the pegs with the holes
11. Cover the Skin layer with ultrasound gel
12. Fill the moat with water until the first layer (muscle) is fully submerged
13. Perform the procedure as directed by trainer

Disassembly, Cleaning, & Storage:

1. Use a paper towel to wipe off any excess ultrasound gel from the skin layer and housing lid
2. Carefully remove housing lid and place it aside
3. Dump out water from Lexan box
4. Remove each tissue layer, 1 at a time, and use a paper towel to wipe off excess ultrasound gel and pat dry to remove water. Set each aside on clean paper towels and allow them to air dry.
5. Carefully remove the fetal simulant from the womb and pat dry with paper towels. Set it aside on a clean paper towel and allow it to air dry.
6. Dump the water from the housing base down the drain.
7. Use paper towel to wipe as much water out of the base as possible. Take the base to a hand air-drier and securely hold the base under it to dry any trapped water.
8. If necessary, clean the housing or tissue simulants with mild soap and cool water.
9. Allow to fully dry before storing.
10. Store in a cool, dark place away from lint, dust, or cloth particles that could stick to the tissue simulants.

Replacing the Tissue Simulants:

- Replace the Skin layer after 40 punctures using the above recipe and protocol.
- Replace the Fat layers after 40 punctures using the above recipe and protocol.
- Replace the Muscle layer after 40 punctures using the above recipe and protocol.