Ultrasound-Compatible Gynecologic Training Phantom for Hydrogel Injection

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Technical Summary

ABSTRACT —

PURPOSE: During brachytherapy planning for cervical cancer treatment, needle insertion for hydrogel spacing is a highly skill-dependent task. To address the difficulty of training for residents, we propose a fast and low cost method for building an ultrasound-compatible female pelvic training phantom that can be used to train physicians on hydrogel injection and other gynecologic procedures.
METHODS: Phantoms are made from plastisol mixed in ratio with plastic softener and hardener to produce realistic texture. Ultrasound compatibility is possible through variation of glass microbead density mixed into the plastic prior to cooling. This mimics the acoustic properties of actual tissue. Manual volume segmentation of patient MRI is used to 3D print molds for the manufacturing of the phantom to allow for anatomical accuracy in shape.
RESULTS: Phantom prototypes with realistic texture, variation in echogenicity, and anatomical accuracy were constructed. Needles are inserted into phantoms to test for reliability and reusability. The phantoms are imaged under abdominal and transrectal ultrasound, and anatomical structures were successfully identified.
CONCLUSION: An improved method for constructing gynecologic phantoms using plastisol was developed. It is characterized by realistic texture, ultrasound compatibility, and anatomical correctness. It can be used to help training in hydrogel injection during brachytherapy planning and other related procedures.

Keywords—brachytherapy, phantom, ultrasound, hydrogel spacing, etc.

I. INTRODUCTION

Locally advanced cervical cancer is a common presentation among unscreened women. Cervical cancer is the third most common cancer among women worldwide. It is estimated that in 2018 alone there will be 13,240 new cases of cervical cancer, accounting for 0.8% of all new cancer cases. Unlike early-stage disease, locally advanced cervical cancer has finite survival times and cannot be cured by surgery alone (with a high relapse rate at 30%). The current standard of care includes brachytherapy, the insertion of a radiation source directly into the cancerous tissue. Recent data have repeatedly and consistently shown the benefit of administering brachytherapy following external beam radiotherapy (EBRT) to prolong survival and to improve patient outcomes (when coupled with chemotherapy). While other

imaging technologies have been investigated (e.g. intraoperative MRI and preoperative MRI/CT), they are limited in terms of practicality and cost. This is especially a challenge in resource-limited countries which often harbor the highest rates of locally advanced disease, in part due to limited screening and unavailability of vaccines.

Despite these relative strengths, brachytherapy is a complex, challenging procedure which requires accurate, real-time tracking and contouring of the cervical tumor mass to achieve maximal tumor control while maintaining minimal radiation toxicity to surrounding nearby structures e.g. the bladder and rectum. There is a clear need to differentiate the cervical tumor mass from surrounding normal tissues e.g. the rectovaginal septum or bladder sparing, in order to minimize complications as a result of brachytherapy. During brachytherapy planning, one solution is to inject a hydrogel spacer to minimize radiation dose to normal anatomical structures. However, this is a challenging procedure, and inaccurate needle placement can lead to complications such as accidental perforation of the bowel and rectum.

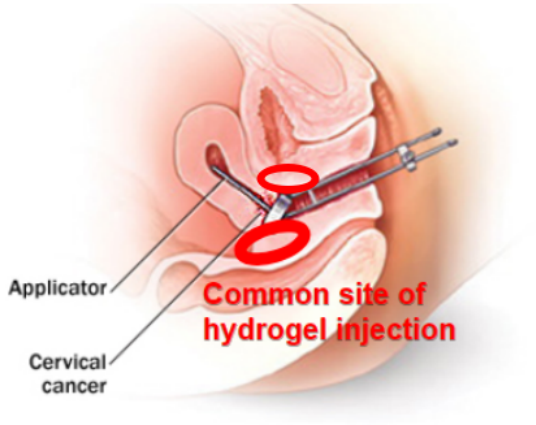

Fig. 1. *Common sites of hydrogel injection are in the tissue between the bladder and the vaginal cavity, as well as in the rectovaginal septum between the rectum and the vagina. As these tissues can be as thin as 0.5 cm, injecting hydrogel compound into these layers without perforating the tissue is a challenging task.*

For this project, we propose the use of advanced ultrasound imaging systems in addressing this important clinical problem. We hypothesize that advanced ultrasound imaging techniques can be applied to needle design for reliable and accurate guidance of needle placement into the recto-vaginal septum for hydrogel injections during brachytherapy.

There are two goals for the overarching project:

1. Adapt needle for ultrasound-compatibility in guidance for hydrogel spacer injection in the recto-vaginal septum.

2. Develop an ultrasound-compatible phantom to assist training on localizing and visualizing a needle for hydrogel space injection during the preparation of a patient for brachytherapy.

My scope, in terms of this course, is primarily focused on item 2, the construction of the phantom.

II. PROBLEM

Phantoms are artificial models representing actual anatomical structures, used for training or demonstrative purposes in medicine, education, and quality assurance. To optimize for a specialized purposes, phantoms are often manufactured to reflect specific geometric and material properties that are valuable to the user. Some examples include a MRI-compatible head phantom made from material with metabolites, a phantom with realistic elasticity by controlling the ratio of gelatin to safflower oil, a head and neck phantom made of polyurethane for deformable image registration, and a polyvinyl chloride rectum and prostate phantom made for transperineal needle insertion.

Phantoms are particularly useful in the training of difficult procedures used in brachytherapy. When residents learn new procedures, the traditional learning model involves mere observation within a limited field of view with limited cases for actual hands-on learning of procedures. In the case of hydrogel spacing injection, the hurdle is high due to the deep location and delicacy of the structures involved. Besides the difficulty of accurate placement, the insertion of the hydrogel needle must not perforate tissue layers that are sometimes as thin as 0.5 cm. With repeated practice on a phantom, this learning process can be significantly more efficient.

There are few female pelvic phantoms specifically made for the purpose of brachytherapy training that can be conveniently made in the research setting. Most commercial phantoms available on the market are costly and degrade significantly over time, which is non-ideal for training purposes. One notable attempt to develop a low cost phantom was done by Nattagh et al. at University of California, San Francisco. Their phantom was made of gelatin and rubber and included the uterus, vaginal cavity, and rectum. In their paper, Nattagh et al. demonstrated that their phantom was visible under computer tomography and ultrasound, and when experienced by an attending physician, felt similar actual tissue. However, there were also a number of weaknesses. Firstly, the longevity of their product was a mere two weeks before the gelatin liquefied. The phantom geometry was simple and did not reflect anatomical complexity. Under the imaging modalities, the contrast was binary and did not allow for gradation as would be seen in actual tissue. The physician also commented on the material weakness to tear as well as the phantom's resistance to motion during cervical examination that did not resemble the elasticity of actual tissue.

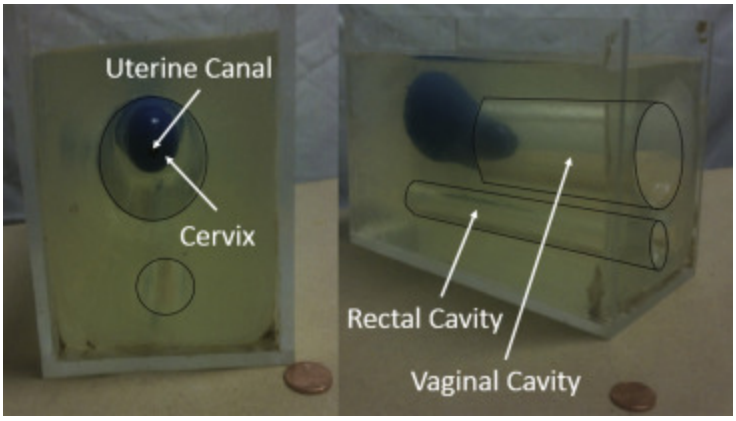

Fig. 2. *Nattagh et al. developed a gynecologic gelatin phantom for brachytherapy procedures with simple geometry.*

This project aims to improve on Nattagh's model by incorporating more anatomical accuracy and realistic texture and imaging properties to the phantom. In addition, this phantom aims to promote reusability and a longer lifetime. This phantom will be specialized for the insertion of the hydrogel needle and injection of the spacer.

III. MATERIALS & METHODS

The project consisted of three prototypes. The first prototype determined realistic texture differences between structures. The second prototype explored gradation in echogenicity between structures. Finally, the third prototype improved on the second by including anatomical accuracy. The prototypes were then tested by a physician and viewed under ultrasound.

A. Phantom Manufacturing

My minimum deliverable was to produce a design and manufacture plan for the phantom. Compared to gelatin, which can liquefy in a matter of weeks, plastisol seemed like a reasonable alternative as it has a much longer shelf life. M-F Manufacturing Super Soft Plastic was used as the base for the material used in the phantom. It is available for purchase from their website. The plastisol was cooked in a standard metal pot over a hot plate. It is important to ensure that the plastic was well mixed prior to heating (by shaking the container). The hot plate needs to be able to reach temperatures above 180 °C. To speed up the heating, you could heat with as high as 500 °C if cooking with a pot. The plastisol was cooked until it turned transparent, was less viscous, and started fuming. This is best done in a hood, because the fumes from the plastisol cooking can smell quite bad. A picture of the manufacturing environment is shown below. The plastic should be stirred slowly as it cooks in order to minimize the formation of air bubbles. If the plastic re-cooks or over-cooks, the color of the mixture will turn yellow. The cooling happens at room temperature, but can be expedited by placing the mold in cold water or by refrigeration after some cooling at room temperature. It is hypothesized that excessive length in cooling and motion during cooling may contribute to the formation of increased air bubble formation towards the end of the cooling process. The control of air bubbles as contributed by heating, cooling, and stirring is a fairly difficult task and will require multiple iterations to become familiar with. Once the plastisol has cooled, its surface was extremely adhesive, and it was important to wearing gloves when handling the plastisol to ensure long-term clearness of the plastisol. Tape could be used to remove dust and other particles covering the surface.

***Fig. 3**. Image of sample plastisol heating and curing environment showing hood, plastisol, dyes, glass molds and a heat plate.*

The plastic was compatible with glass molds, but not as reliable with wood or metal. It merges well with smooth surfaces, while bubbles tend to be trapped around rough surfaces, such as with the surface of low-density 3D prints. We found that ABS and PLA printed plastic experience slight deformations when experiencing plastisol that is fully heated, but it is not enough to cause significant changes, especially if cooled quickly. Due to its heat tolerance up to 232°C, platinum silicone from Moldstar could be used to make a negative mold from other materials that are less compatible with plastisol. Once mixed, Moldstar silicone can dry within an hour, so it is not an extremely time consuming process. When we experimented with this process, where we made silicone molds from 3D printed parts, and then used the negative molds to form plastisol positives, we found that we had trouble creating structurally strong components and air often got trapped within the mold. This might be an issue that can be resolved with repeated practice and further investigation.

B. The First Prototype: Realistic Texture

The expected deliverable was to construct a phantom that demonstrated realistic texture. In order to create gradation in texture, we mixed M-F Manufacturing Super Soft Plastic in various ratios with M-F Manufacturing Plastic Softener and M-F Manufacturing Plastic Hardener, such as 4:1, 3:1, 2:1 plastisol: softener, or 0% softener. We found that the subjective softness to touch of the resulting plastisol depends somewhat on the shape, size, and thickness of the plastic, as these structural factors contribute to the cohesive property of the plastisol. Through experimentation, we found representative softness and thickness ratios for the various anatomical structures we included in our phantom. **Table 1** below shows the detailed specifications for each of the compartments included in the 1st prototype phantom.

Fig. 4. *Molds used in the manufacturing of the phantom were fastened in order to maintain the shape of the cavities in a glass container.*

In addition to texture, we also included color in our model in order to differentiate with compartments from each other. The dye came with M-F Manufacturing and was mixed into the plastisol prior to heating. Fuming was used to determine whether the colored plastisol had been cooked sufficiently. **Table 1** below shows the distribution of color between the compartments for the 1st prototype phantom.

Compartment	Color	Ratio by Volume (Plastisol : Softener)
Vaginal Cavity	Pink	4:1
Rectum	Pink	4:1
Cervix	Transparent	3:1
Surrounding Fat/Tissue	Transparent	2:1

Table 1*: Manufacturing specifications (color and texture) for anatomical structures in the 1st prototype.*

In order to make the phantom layer by layer and compartment by compartment, first we secured two metal pipes perpendicularly placed in a glass bottle. We made the surrounding fat/tissue first by pouring around the metal pipes. Then, we removed the pipes and instead placed metal rods in the

cavity formed from the removal of the pipes. In the space between the rods and the surrounding fat/tissue, we poured in the plastisol used to form the vaginal cavity and rectum. When the plastic cooled, we removed the rod molds, and the resulting cavities had dimensions of 16.6 mm OD, 5 mm thickness, and 65 mm length.

We then used the characteristic bottom of a wine glass to form the shape of the cervix in a separate container. After making the cervix, we then placed it over one of the cavities, then surrounded the cervix with more of the plastic of the surrounding fat/tissue category until the cervix has been immersed. Then, the structure was left to dry. Once it was done, a needle was passed through the cavities and manual maneuvers were done to the phantom to test its qualities.

C. The Second Prototype: Echogenicity

My maximum deliverable was to make the phantom ultrasound-compatible. In order to produce acoustic qualities similar to tissue under ultrasound imaging, we experimented with several densities of Sigma Aldrich 75 micron acid-washed glass microbeads and took ultrasound images of plastic with that density of microbeads, then compared the densities to actual ultrasound images. This was based on the properties of the glass scattering the acoustic signal, producing the speckle seen on an ultrasound image. Below, you can see the difference in contrast between plastisol with different micro bead concentrations.

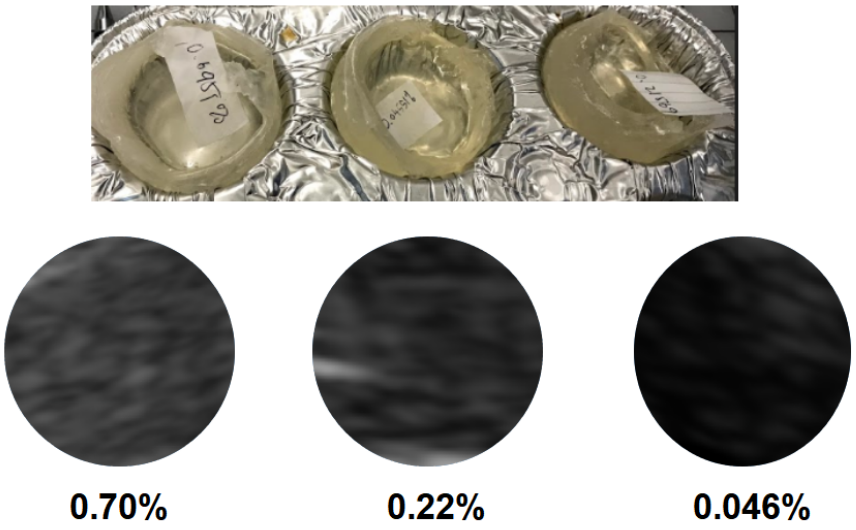

Fig. 5. *Example of three different micro bead densities and corresponding ultrasound contrast.*

Based on these observations, we decided on differences in micro bead density between the wall of organ structures and the surrounding tissue. In our literature search, we found that the majority of cervical cancers appear either isoechoic or hypoechoic under ultrasound, so we decided to have tumor mass be less contrasted than the organ structures. **Table 2** below shows the detailed specifications for each of the compartments included in the 2nd prototype phantom, which accounts for the ultrasound compatibility of the phantom.

Compartment	Color	Ratio by Volume (Plastisol : Softener : Hardener)	Microbead Density (% weight)
Vaginal Cavity	Pink	4:1:0	0.695%
Rectum	Blue	4:1:0	0.695%
Cervix	Green	4:1:0	0.695%
Tumor Mass	Black	2:0:1	0.216%
Surrounding Fat/Tissue	Transparent	2:1:0	0.0455%

Table 2 *Manufacturing specifications (color, texture, and microbead density) for anatomical structures in the 2nd prototype.*

A number of experiments revealed that the best time to add the glass microbeads was after the plastic had cooked and was ready for cooling. We added this procedural step as well as slight variations to color scheme of the components. We also introduced a tumor mass that was made with plastic hardener made prior to the rest of the phantom. It was made from a semicircular plastic mold, then trimmed with scissors to produce the irregular shape of real tumors. This was then embedded in the cervix as the cervix was made. The other compartments were manufactured in a process similar to as described in the production of the 1st phantom.

D. The Third Prototype: Anatomical Accuracy

To improve on my maximum deliverable and exceed my original production plans, I experimented with the concept of using 3D printed molds to introduce greater anatomical accuracy to the model. Patient MRI was imported into the software 3D Slicer, which is freely available for download from its website. Using its volume segmentation functions, the appropriate structures were labeled by hand then smoothened for form 3D representations of the patient's pelvic organs. These were then exported as .STL files that were sent to a 3D printer for printing. Images of the process can be shown in **Fig. 6** below. Based on considerations of tool size and plastisol availability, size of all the organs were scaled as appropriate. Then, the 3D printed parts were used as molds to follow the same manufacturing plan as demonstrated in the 2nd phantom. **Table 3** below shows the detailed specifications for each of the compartments included in the 3rd prototype phantom, which improves on the 2nd through addition of a bladder and anatomical accuracy in the shape of structures.

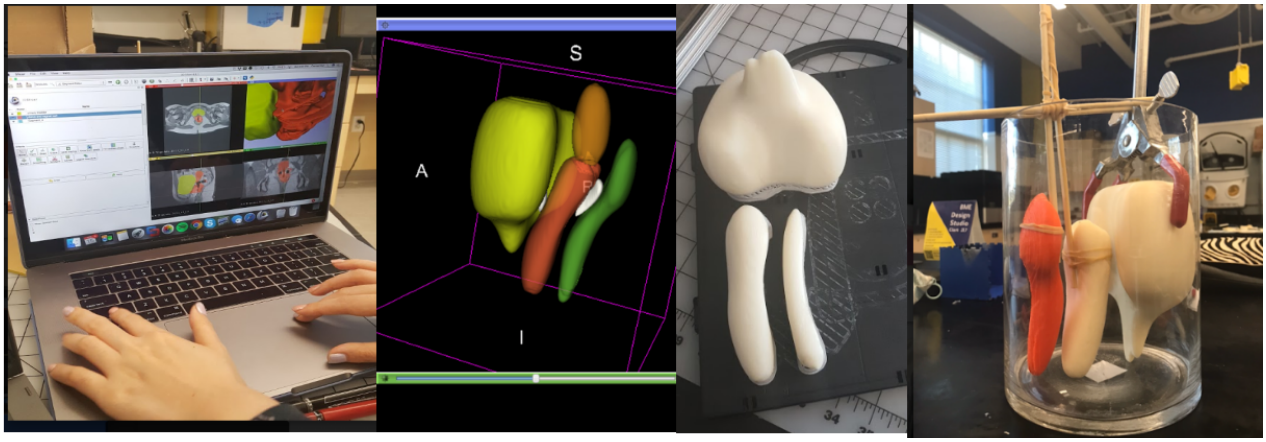

Fig. 6*. Patient MRI scans were used for manual volume segmentation in 3D Slicer software to generate .STL files. These files were then exported and 3D printed to form molds.*

Compartment	**Color**	**Ratio by Volume (Plastisol : Softener : Hardener)**	**Microbead Density (% weight)**
Bladder	Green	1:1:0	0.05%
Vaginal Cavity	Pink	4:1:0	0.7%
Rectum	Blue	4:1:0	0.7%
Cervix	Pink	4:1:0	0.7%
Tumor	Black	2:0:1	0.2%
Surrounding Fat/Tissue	Transparent	2:1:0	0.35%

Table 3 *Manufacturing specifications (color, texture, and microbead density) for anatomical structures in the 3rd prototype.*

The plastisol was made in layer by layer in a 6” diameter 8” tall glass vase, so the molds could be removed and the plastisol filled in place. For walled organs such as the vaginal cavity and the rectum, we printed separate internal and outer molds in order to preserve the hollow nature of the organ when we poured in the plastisol to make the wall structure. Funnels were used to ensure that the colored plastisol did not escape the intended location. Slight adjustments to the color and micro bead densities were made. In addition, the bladder was also included to better reflect the anatomy of the area, as well as the fact that hydrogel is often injected both between the bladder and the vaginal cavity, as well as in the rectovaginal septum between the vaginal cavity and the rectum.

E. Testing and Evaluation

To determine the usability of these phantoms, we subjected the phantoms to repeated needle injections and observed for signs of damage. In addition, we imaged the phantoms under ultrasound and

performed cervical exam maneuvers on the phantom. Finally, we had an attending physician practice ultrasound imaging and maneuvers on the phantom then comment on the extent to which it resembled real human tissue.

IV. RESULTS

We were able to successfully manufacture all three phantoms. Below, we discuss some of the qualitative observations we had regarding the performance and functionality of these phantoms.

A. The First Prototype: Realistic Texture

In our first prototype, we aimed to replicate the differences in tissue texture between the various structural anatomy of the female pelvis. We were able to observe this, as the walled structures were tougher than the surrounding fat in the phantom to the touch. When we passed a needle through the phantom, we found that the plastic refused over the needle track fairly well. The needle track was also not blatantly visible, although still observable if examined closely. Due to properties of the plastisol, when we removed the needle, we saw that the plastic refused over the area where the needle was pretty well, a property that is not necessarily present in some commercial phantoms. We did observe however that the cavity spaces in the phantom were not big enough to accomodate two fingers as would be used in a cervical exam performed on an actual person. An image of the resulting phantom can be shown below.

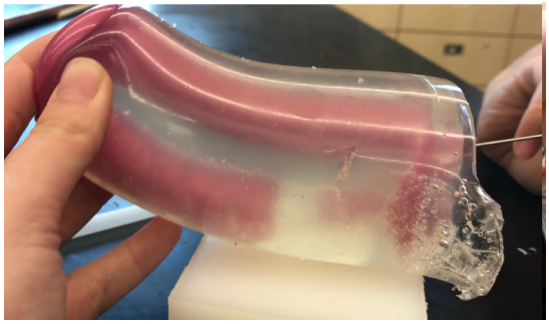

Fig. 7*. The resulting first prototype with a vaginal cavity, a rectum (both in pink), and a less visible cervix (transparent) under needle insertion.*

B. The Second Prototype: Ultrasound Compatibility

In our second prototype, we wanted to introduce ultrasound compatibility to the tissue. The resulting phantom is shown below:

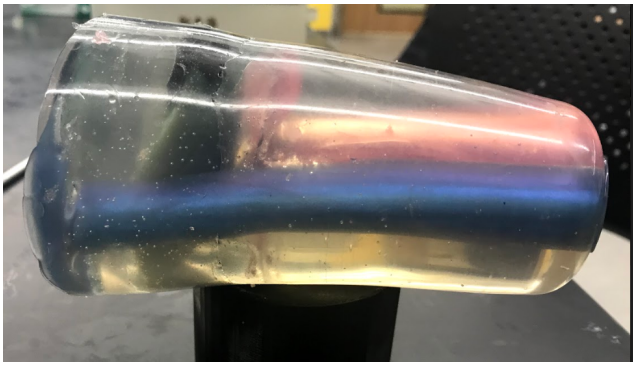

Fig. 8. *The resulting second prototype with a vaginal cavity (pink), rectum (blue), cervix (green), and tumor (black) in surrounding tissue (transparent).*

We thus imaged the phantom using an abdominal ultrasound (Ultrasonix). We were able to visualize the different cavities in various views, along with the tumor. We were also able to image the needle as it passed through structures. Some of the ultrasound images we found are shown below:

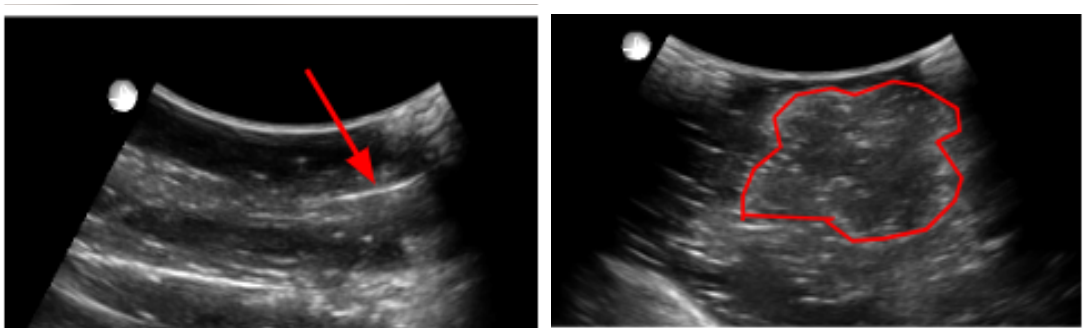

Fig. 9. *Ultrasound images of the second prototype. (left) ultrasound image showing needle on upper right corner bright line. (right) ultrasound image showing tumor embedded in the cervix.*

Thus, our second prototype successfully demonstrated ultrasound compatibility through sufficient contrast between structures.

C. The Third Prototype: Anatomical Accuracy

In our third prototype, we introduced anatomical accuracy to our phantom by incorporating molds 3D printed from actual patient scans. Under ultrasound imaging, we found that our phantom was very similar to actual ultrasound images of patients. For instance, the image below compares an ultrasound image taken from the third prototype with an ultrasound image of an actual patient. Notice the structural similarities.

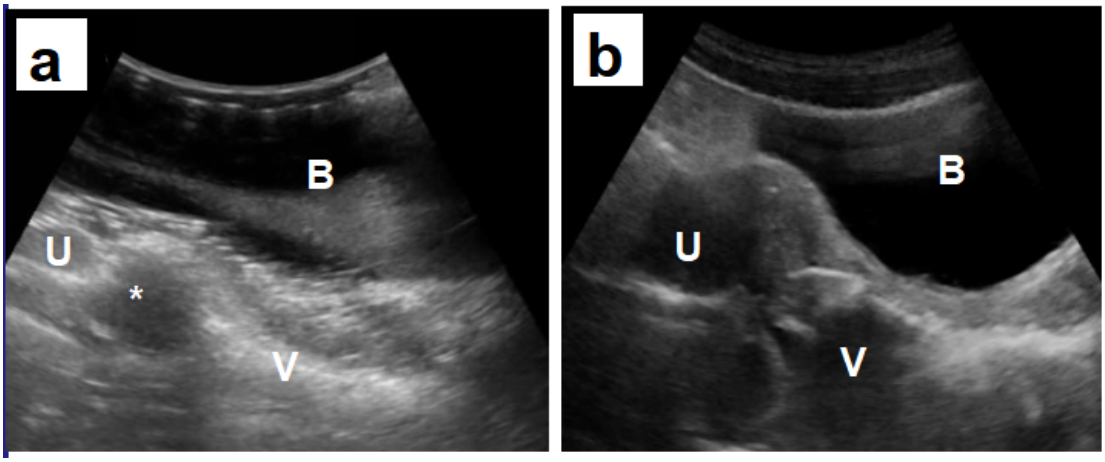

***Fig. 10**. Ultrasound images of the pelvic anatomy. (left) 3rd prototype under ultrasound. (right) actual patient ultrasound. Note the similarities in structure between the two. Structures included in both are bladder (B), uterus (U), vagina (V). Tumor indicated by asterisk (*).*

The anatomical structures were visible from various views under both abdominal and transrectal ultrasound. These are shown in the figures below.

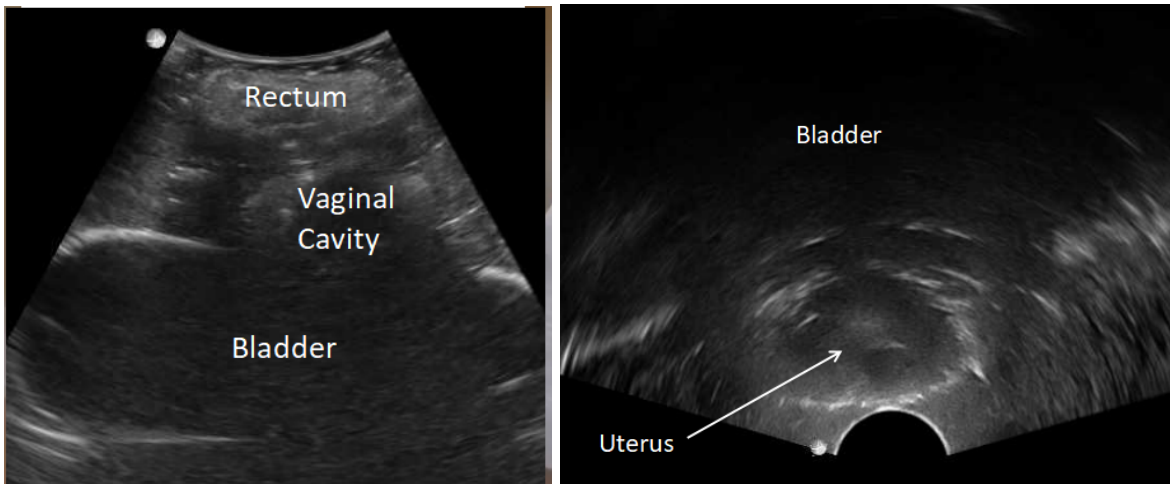

***Fig. 11.** Anatomical structures of the 3rd prototype were visible under ultrasound. (left) Phantom under abdominal ultrasound. (right) Phantom under transrectal ultrasound.*

When we passed a needle into the phantom, we saw that the insertion of the needle was also visible under both abdominal and transrectal ultrasound. However, the location of the needle was a time consuming process, and testifies to how difficult the procedure is for residents and other medical professionals in training.

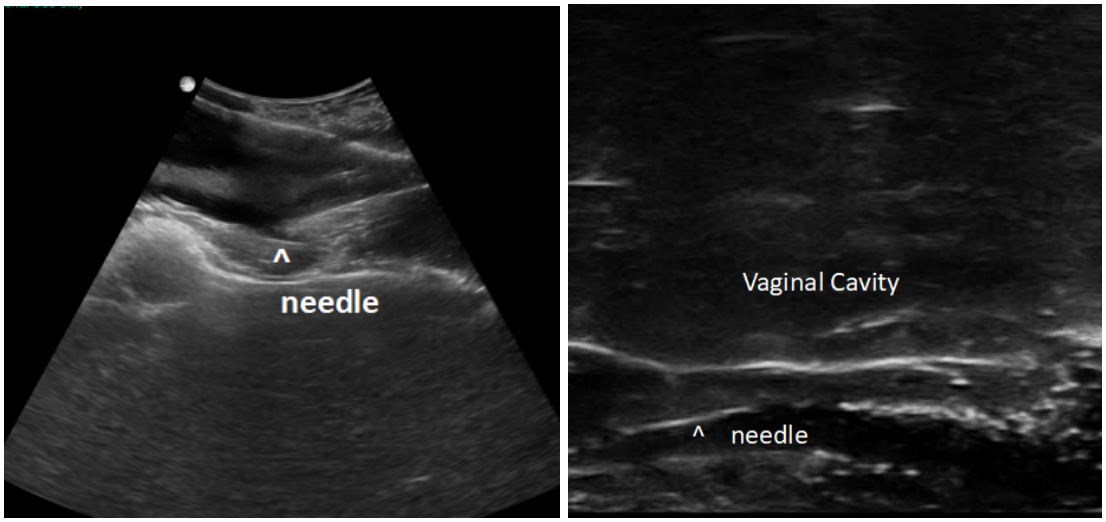

Fig. 12*. Needle was visible under ultrasound in the 3rd prototype. (left) Needle was visible under abdominal ultrasound. (right) Needle was also visible under transrectal ultrasound.*

We were also able to palpate the tumor from the vaginal cavity using the third prototype, and perform some cervical exam maneuvers using the phantom. Furthermore, we had an expert, an attending physician, try a clinically used abdominal ultrasound machine (BK Medical). She commented that the phantom felt extremely similar to actual tissue under ultrasound, as well as to the touch during manual examination. She valued the phantom's reusability and durability to repeated needle injection, in addition to its anatomical accuracy.

Fig. 13*. Various views of the third prototype phantom. (left) back view, (middle) side view, and (right) back view.*

We found that there was some weakness in the plastisol from repeated insertion and removal of the phantom from its glass container. We had to re-seal broken parts with plastisol. This seems to be a weakness due to more the tight fit of the container than from an inherent flaw in the structure of or material used in the phantom.

V. DISCUSSION

The phantom is relatively easy to manufacture. Many of the materials needed for manufacturing are readily available in the typical research lab setting. The most expensive component would be the 3D printing of the molds. However, dense 3D prints made from more heat-resistant, refined filaments will also last longer as molds, so the cost of the investment will dilute over successive phantoms manufactured, decreasing the overall cost of the phantom.

Parameters such as size, dimensions, and color can be adjusted as needed. In addition, the same manufacturing process can be applied to other anatomical structures. The ability to replicate complex anatomy, as demonstrated in the production of the third prototype, will present a particular advantage for the creation of phantoms related to complex anatomy in the body. The amount of time necessary to create the phantom is related to the complexity of the anatomy. The more walled structures there are of different lengths or dimensions, the more time it takes to complete them layer by layer. The rate limiting step in the procedure is the time it takes for the plastisol to cool. This can be expedited by using refrigeration.

This phantom is significant because it presents a number of advantages over the state of the art gelatin gynecologic phantom presented by Nattagh et al. Due to the texture control of the plastisol softness and the use of anatomically correct molds rather than simple geometry shapes, our third phantom prototype was able to withstand cervical examination and resembled actual tissue in its tactile as well as ultrasound properties, as testified by an attending physician. Most importantly, a plastisol phantom has a shelf life of years, whereas the gelatin phantom has a shelf life of two weeks. It does not shrivel like commercial models, and if it gets dirty, that can be cleaned fairly easily. For the purpose of training, this is very important, as reuse and repeated practice is how the skills are developed.

To determine the effects of reuse, we inserted needles repeatedly into the phantom. Due to the elasticity of the material, upon removal of the needle, the plastisol around the needle track and hole of insertion refuse and the effects of the needle insertion are not extremely visible, although careful examination will reveal some remaining signs of the insertion. Under ultrasound, however, the insertion of the needle does leave a track.

When we injected water into plastisol mixed at both 4:1 and 2:1 plastisol:softener ratios, we discovered that upon release of the needle, the pressure of the material refusing pushes the water out of the compound at significant pressure. Thus, the phantom does not promote retention of the hydrogel, which is ideal for purposes of reuse. However, the phantom will not allow for hydrogel to sit in its location as it would in actual human tissue. We found that it is also possible to remove the compound fairly cleanly if the compound is extracted with the syringe still in the plastisol, i.e. without removal of the needle. After injection, however, scars in the plastisol from the enlarged cavity are visible from external examination.

There are many areas for improvement, whether it’s in the material properties or in the evaluation of the phantom. For example, further areas to explore include a consistent method to eliminate air bubbles, size adjustment to fit other tools, a reliable method for the extraction/absorption of injected compound, and finally, conducting a comparative user study with groups who have or have not used the phantom training to evaluate the effect of the phantom on clinical outcome and procedural performance.

VI. CONCLUSION

A method for manufacturing gynecologic phantoms for brachytherapy training has been developed. These phantoms feature realistic texture, ultrasound compatibility, and anatomical accuracy. The most updated plastisol prototype includes a bladder, uterus, cervical tumor mass, vagina, and rectum. The phantom is relatively low cost, reusable, and long-lasting. Abdominal and transrectal ultrasound images show realistic representation of the female pelvis and make image guided needle insertion on the

phantom possible. An attending physician confirmed the realistic qualities of the phantom under cervical exam maneuvers as well as under ultrasound imaging. This phantom can be used in training to improve resident comfort with difficult procedures, particularly with injecting hydrogel spacing into the rectovaginal septum during brachytherapy planning.

VII. Acknowledgments

This project was possible through the support of Carmen Kut, my partner & main mentor; Younsu Kim, for technical guidance & equipment; Dr. Akila Viswanathan, for clinical advice & sponsorship; Dr. Emad Boctor, for technical advice; Marc Morcos, for enthusiastic support; to Dr. Logsdon and other BME Design Studio staff for manufacturing recommendations & assistance in 3D printing.

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Management Summary

Below, I outline some of the goals and contributions related to facilitating the successful completion of this semester long project.

I. PROJECT AIMS

This project aims to create an ultrasound-compatible training phantom for medical professionals to visualize the needle and to perform accurate hydrogel spacer placement under image guidance. Deliverables include: phantom & needle design (minimum), Phantom with realistic texture (expected), and ultrasound-compatible phantom (maximum). This project expanded to include an anatomically correct phantom compatible with cervical exam maneuvers.

II. CONTRIBUTIONS

Throughout the process of this project, ideas were based on discussions between the mentors and me. On the side of the phantom, it was through conversation between Carmen Kut and Tracy Kao. On the side of the needle, the design was conceived through conversation between Dr. Emad Boctor, Younsu Kim, and Tracy Kao. The protocol for the construction of the phantom was modified from one made available from my mentor [see Ref 8]. The needle was made available from Radiation Oncology, and the piezo ceramic tube, corresponding epoxies, and ultrasound machines were made available through the Medical Imaging and Intervention Collaboration (MUSiiC Lab). Silicone Moldstar and molding material, hot plate, beakers, and a hood was available through the BME Design Studio. 3D Prints were also done by the Design Studio TAs on shift with the Makerbot and Dimension 3D Printer at the BME Design Studio. The materials used for the construction of the phantom were purchased by Carmen Kut through sponsorship by Dr. Akila Viswanathan. The construction of the phantoms, the manual segmentation of the patient MRI into .STL files, and the imaging of the phantoms under ultrasound were completed together by Carmen Kut and Tracy Kao. Dr. Akila Viswanathan also provided expert feedback on the phantom's clinical utility. Additionally, overall guidance of the project and presentation was made possible by Dr. Russell Taylor and Ehsan Azimi.

III. PLANS VS. ACCOMPLISHMENTS

The original plan for the project had a different goal and technical approach. Due to the need to develop a method for more **precise localization and/or visualization** of the needle for hydrogel injection under ultrasound image guidance during preparation of patient for brachytherapy procedure, the original objective was to develop a **needle prototype** for hydrogel injection during a brachytherapy procedure that is compatible with existing ultrasound systems. This project involved mounting a piezo ceramic tube as a point source ultrasound transducer on the tip of the hydrogel needle in order to allow for guidance between the needle and a complementary ultrasound system as an acoustic signal transceiver pair. However, logistical difficulties related to getting components in on time after an error in the fabrication process led to the improbability of finishing the project on time. Thus, the project shifted direction, and I focused instead on developing an **ultrasound-compatible phantom** to assist training on **localizing and visualizing a needle** for hydrogel space injection during the preparation of a patient for brachytherapy.

When I switched my project goals, my deliverables for the new project are listed below:

Level	**Item**
Minimum	Documentation: Needle Design Documentation: Phantom Design
Expected	Documentation: Needle Manufacturing and Testing Plan Documentation: Phantom Manufacturing and Testing Plan Simple Phantom (Geometric Shape and Realistic Texture)
Maximum	Simple Phantom (Geometric Shape, Ultrasound Compatibility) Molds for Manufacturing Documentation: Phantom Manufacturing and Testing Results

Table 4 *Deliverables for the Phantom Project*

I was able to achieve **all** levels of deliverables. My first prototype completed my expected deliverables and my second prototype completed my maximum deliverables. Furthermore, I was able to exceed my maximum deliverables with my third prototype, by incorporating 3D prints of patient information. I was able to meet my deadlines for my milestones as well, listed below.

- Clinical Observation & Clinical Need Evaluation (3/1/2018)
- Discussed Project Goals with All Mentors (3/6/2018)
- Documentation: Initial Design Sketch of Needle (3/8/3018)
- Documentation: Needle Specifications (3/27/2018)
- Attempt 1st Needle Prototype (4/11/2018)
- Choice of Ultrasound System (4/14/2018)
- Further Clinical Observations (4/23/2018)
- Documentation: Phantom Design and Manufacturing Plan (4/23/2018)
- 1st Geometric Phantom (4/20/2018)
- 2nd Geometric Phantom (4/27/2018)
- Documentation: Phantom Test with Needle (5/4/2018)
- Documentation: Phantom Test Data on Ultrasound System (5/7/2018)
- Finalized Wiki Page with All Documentation (5/10/2018)

By following my timeline well, I was able to expand beyond the maximum and also add an additional phantom to my deliverables and improve on the prototypes.

IV. POTENTIAL NEXT STEPS

Further improvements on the phantom can be done to improve the efficiency manufacturing process and refine the construction skills for the phantom. With more funding, it is possible to obtain 3D prints will materials that are more compatible with plastisol, and scale the phantom up to realistic sizes. In addition, after a reliable phantom has been successfully constructed, it would also be possible. Finally, the project had changed directions because of the inability to get a component here on time. With further funding, it would be possible to purchase the component and perhaps manufacture the ultrasound-compatible needle to be integrated into this system, further assisting with hydrogel injection. I do not currently have plans to follow through on these next steps, as further funding would

be necessary to expand the project. However, these are all feasible activities and the steps needed to complete these items are established.

V. LESSONS LEARNED

For a project, it is important to have sufficient resources secured from the start in order to make the timeline smooth towards completion. Although the dependencies were resolved early in this project, they were insufficient as components broke that created further dependencies or communication was not fulfilled. Similarly, budgeting for projects should include enough leeway for error and experimentation. As this project started with limited funding and time, there were limitations to what could be done in this project.

On the other hand, repeated practice and experimentation was shown to be sufficient, as even seemingly objective, streamlined tasks could improve with practice. Development requires iterative trials to explore unexpected contributing factors and to improve manufacturing skills. Many of the problems could not have been expected from the planning, and could only be discovered and resolved by repeated trials. In addition there were times when I was in danger of having my resource access removed due to timing or due to miscommunication. However, sufficient budgeting for time to resolve these problems helped.

Overall, in addition to gaining technical skills, I have also gained project management experience. I have learned the importance of documentation and how to properly present a project to supervisors.

Technical Appendices

There was no code associated with this project. The project originally included the development of a needle prototype. A figure demonstrating the construction of the needle is included below.

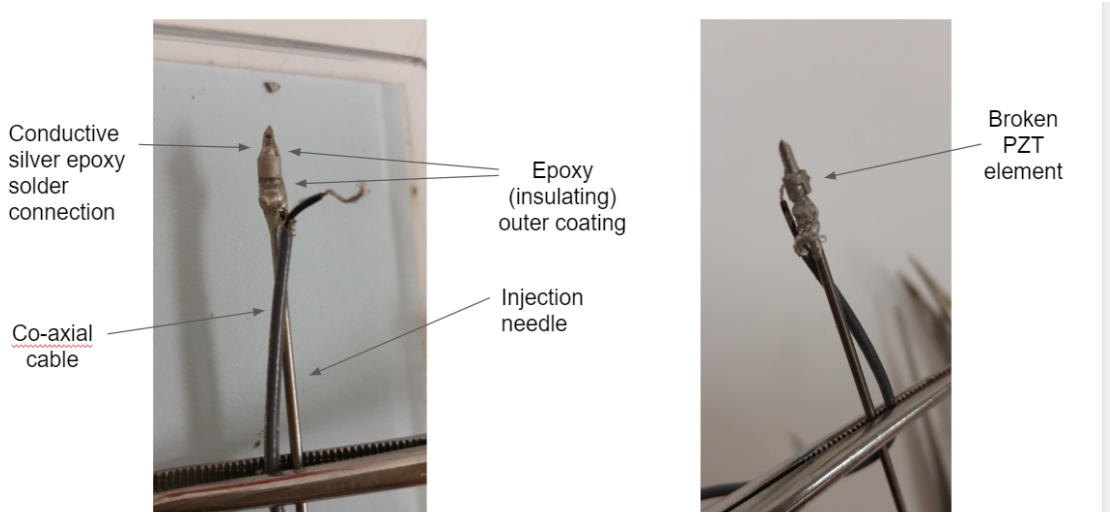

Fig. 14*. Ultrasound-compatible needle prototype construction process and display of the damaged component that led to the temporary termination of this project.*

*The .STL files for this project can be requested through tkao1@jhu.edu. Special permission from mentors might be necessary.