Brachytherapy Teaching Tools: Building a Multi-material Three-Dimensional (3D) Modular Gynecological Phantom

by

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Thesis submitted in partial fulfillment of
the requirements for the degree of
Master of Science in the Department of
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2021

ABSTRACT

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Abstract

In recent years, there has been a decline in the use of brachytherapy for the treatment of cancers. One of the reasons attributed to this is the unease in implementing these procedures at the initial stage of the practice due to limited hands-on practice for Radiation Oncology MD residents during their training. Although the period of residency exposes them to the various steps of the procedure by observing treatments of patients with different pathologies, it is evident that being able to simulate these skills on a phantom will be an added advantage. Specifically, due to the complex nature of the High Dose Rate (HDR) procedure for cervical brachytherapy, it requires to a great extent, exposure to hands-on training. This requirement led to the need to develop a modular phantom for training in various intracavitary and/or interstitial HDR GYN brachytherapy procedures.

A first such brachytherapy prototype kit was previously designed by our group to focus on High-Dose Rate (HDR) cervical cancer therapy.[1] The focus of this project was to address several limitations in the original design, like the inability to fit all sizes of the ovoid caps in the vaginal canal, lack of real-life feel of the containment box and overall ease of use. The goal was to construct a modular gynecologic brachytherapy phantom by integrating an improved version of the prototype kit with an existing gynecologic phantom Gaumard (S504.100). The feasibility of integrating the existing phantom with

our in-house kit was investigated first, followed by designing new parts of the modular training kit and integrating it with the existing gyn Gaumard phantom. The main designed component was the pelvic insert which comprised of a combination of the vaginal canal and the pelvic floor. This newly designed anatomical part was printed in multi-material Agilus with shore value of 30A. In addition, a frame was built to secure the training kit in the phantom.

The modular connectivity of the uterus to the cervix of the vaginal canal had to be re-designed because the peg locking mechanism used in the prototype had a limitation. The method of having the uterus Boolean subtracted from the vaginal canal in the initial peg design could not accommodate the large uterus. This new design involves a locking mechanism using flanges.

The modular phantom was evaluated by a radiation oncology resident to assess usability and ease of use. The feedback is a resource in improving the phantom to fit their training needs.

In conclusion, a new improved HDR brachytherapy modular gynecologic phantom was designed to improve MD resident training.

Dedication

This page is dedicated to Jesus Christ. He is the center of my world.

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Acknowledgements

I would like to thank my family (Mr. and Mrs. S.D. Babawale, Mr. Bolaji Babawale, Mrs. Folake Oladapo nee Babawale, and Mrs. Fehintola Adesoyin nee Babawale) for their financial, emotional, and spiritual support throughout the time of undergoing this degree.

I would also like to thank my advisor Dr. Craciunescu for all her hard work and support in making this project a success.

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1. Introduction

1.1 Brachytherapy

Brachytherapy is a form of radiation therapy that uses sealed radiation sources positioned on, inside or next to a cancerous tissue for treatment[2]. A major advantage of brachytherapy is the ability to place the radioactive source close to the tumor which reduces radiation exposure to other healthy tissues around. It is used in the treatment of various kinds of cancers such as oral (mouth), breast[3], lungs, prostate[4,5] , skin[6], and gynecologic cancers[7]. The accurate implantation of these sources is pertinent to achieving the desired treatment outcome. Depending on the method of delivering the treatment in terms of applicator placement, the procedure could be intracavitary, interstitial, intraluminal, or surface application.

The dose rate of the radioactive source can be used to categorize the procedures for which they are used. The first category is the Low-Dose Rate (LDR) procedure. The seeds deliver dose at the rate of 0.1 – 2 Gy/hr. They can be implanted permanently as in the case of LDR prostate cancer or temporarily as in HDR brachytherapy for cervical cancer. One major disadvantage of LDR treatment procedure for gynecologic cancers is the long duration of treatment. Patients may need to stay immobile with the radioactive sources inserted for as long as 50 hours. This could potentially lead to serious complications.

The High-Dose Rate (HDR) has a dose rate of about 12 Gy/hr which significantly shortens the treatment duration and enables delivery of treatment in fractions. Another benefit of the HDR is the use of an afterloader in delivering the dose. Unlike the LDR treatment procedure that requires hot loading the applicator, the HDR process uses an afterloader that is automated to insert the radioactive seeds into applicators. Another major improvement is the large specific activity of Ir-192 – a common radioactive source used in HDR brachytherapy- which corresponds to a high source strength resulting in smaller source and applicators compared to the LDR procedure. This eliminates the need for dilating the cervix.

The scope of this project encompasses the use of HDR brachytherapy in the management of cervical cancer. Cervical cancer occurs in the cells of the cervix (see figure 1). Most cases develop due to exposure to Human Papillomavirus (HPV). There are two major types of cervical cancer: the squamous cell carcinoma which forms in the lining of the cervix and the adenocarcinoma which forms in the mucus producing cells. Generally, the treatment plan entails the use of HDR brachytherapy exclusively or External Beam Radiation Therapy (EBRT) and an additional boost of brachytherapy.

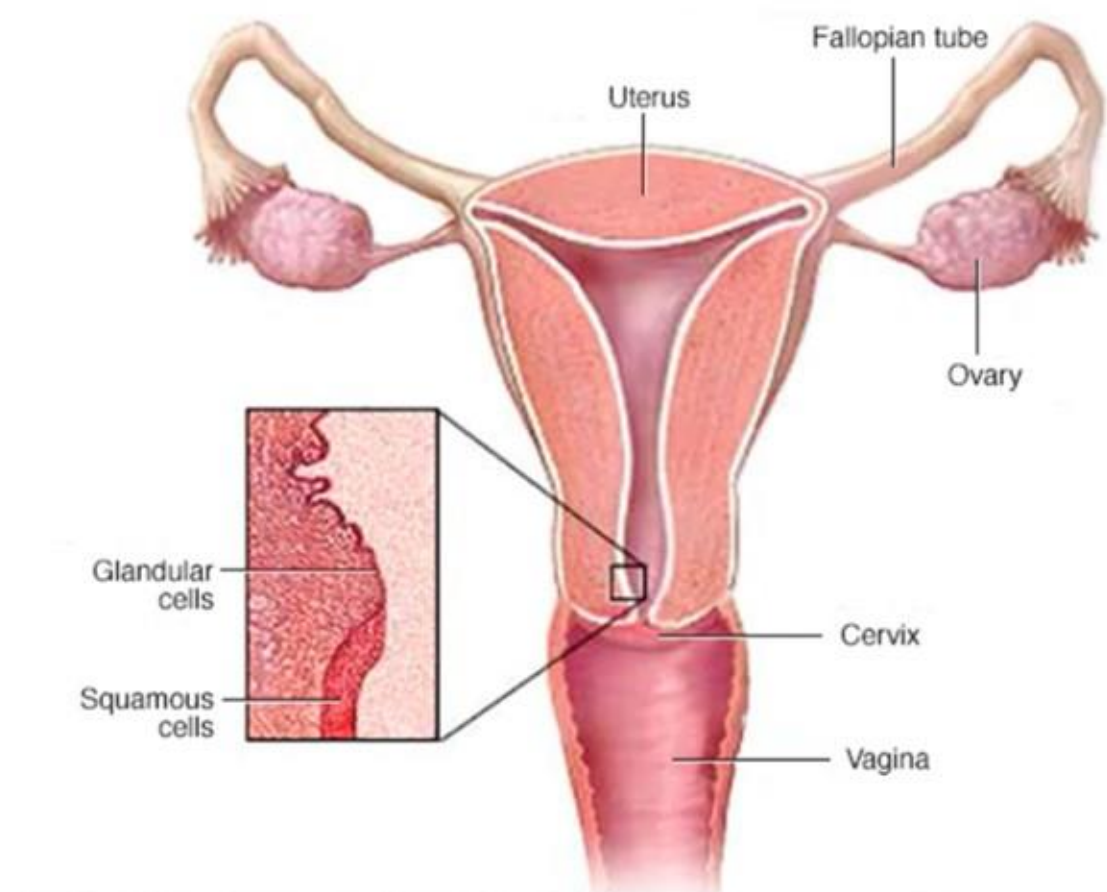

Figure 1: Cross-section of the Female anatomy[8]

The HDR gynecological procedure at Duke involves the use of CT and Magnetic Resonance (MR) images for treatment planning. CT images are used for applicator delineation dose calculation and some limited contouring. The high quality of the soft tissue contrast in MR images makes it valuable for contouring target volumes such as High-Risk Clinical Target Volume (HRCTV), Intermediate Risk Clinical Target Volume (IRCTV), and other critical structures. HRCTV is the Gross Tumor Volume (GTV) at the time of the brachytherapy treatment. In cervical cancer treatment, this volume includes the GTV, the whole cervix and presumed clinical extension of the tumor. IRCTV is the GTV during diagnosis which includes the HRCTV with some safety margins.[9]

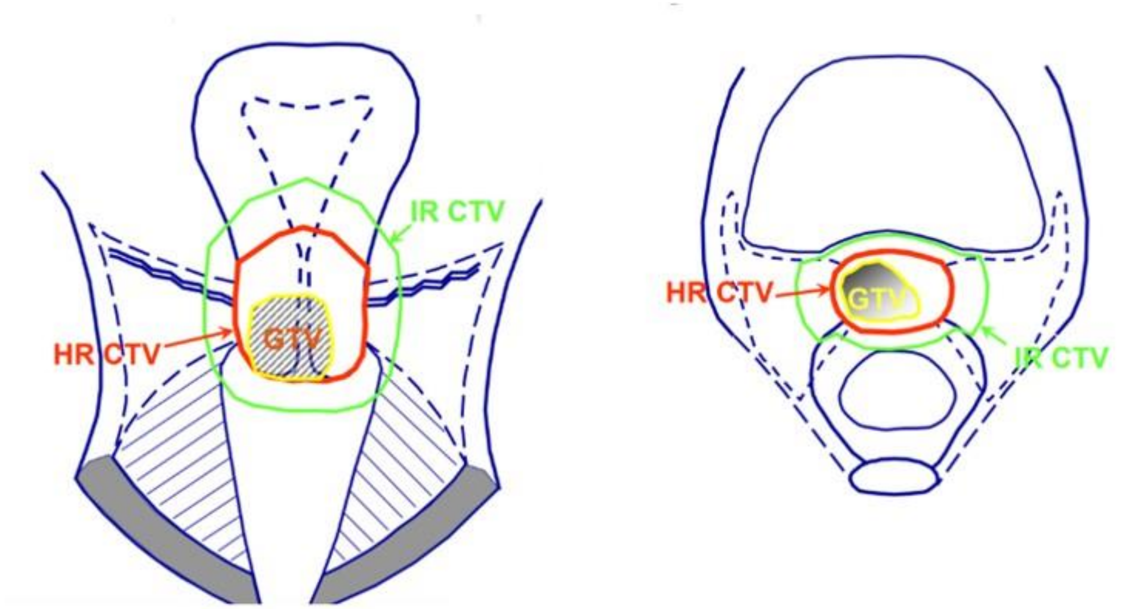

Figure 2: HRCTV and IRCTV Contours[8]

One drawback in brachytherapy is the difficulty in achieving good coverage for different HRCTV shapes. In previous years, the HDR procedure was predominantly intercavitary. However, more recently there has been the advent of the addition of interstitial needles for better dose distribution to the target, while minimizing dose to normal tissues[10].

With respect to applicators, there are two major types used for HDR GYN procedures. The first group is the intercavitary applicators include tandem and ovoids, and tandem and rings. They are called intercavitary because the applicator is implanted through the vaginal cavity up to the cervix. It can be used to treat the upper vagina, cervix, and the uterus.

Figure 3: Titanium Fletcher-Suit-Delclos Tandem and Ovoid Applicator Set[11]

Figure 4: Ring and Tandem Applicator[12]

The second group is the interstitial applicators which comprises of needles. They are named interstitial because of their mode of implanting sources in tissues.

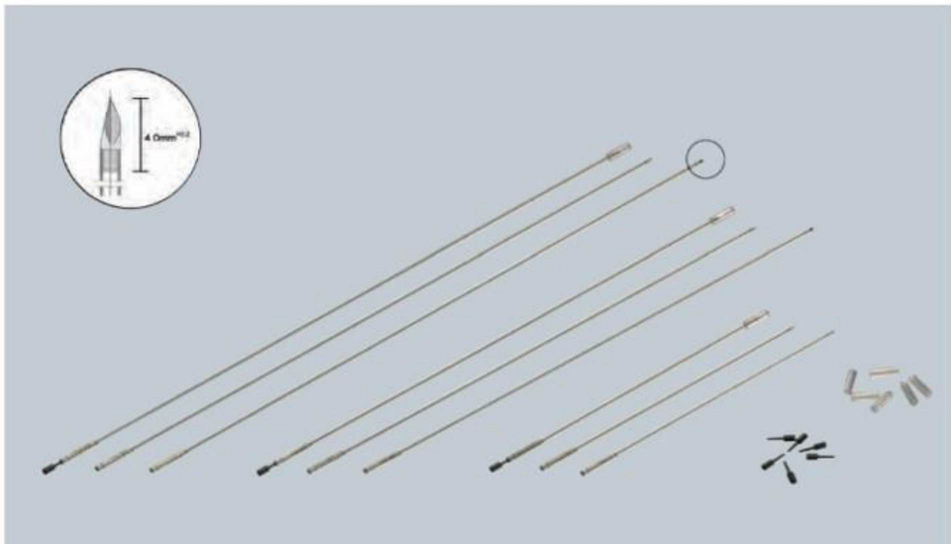

Figure 5: HDR Interstitial Titanium Needles (1.47 mm)[10]

1.2 Three-Dimensional Printing

Three-Dimensional (3D) printing is an additive manufacturing method that prints solid objects from digital files. Contrary to subtractive manufacturing method which creates 3D objects by sculpting or molding materials to form a solid, this process is done by layering up thin slices of the digital model to produce a solid, 3D object. These digital models are commonly Computer-aided design (CAD) drawings, making them versatile and easy to manipulate to fit the user's desired results[1]. This ability to progress from product idea to modeling and then having the printed part is a major advantage in 3D printing ad makes it suited to rapid prototyping of products.

Furthermore, 3D printing is an inexpensive manufacturing option as molds and other subtractive manufacturing steps are not needed. With access to a modeling software such as Autodesk Fusion 360, and a 3D printer, an idea of a 3D object can be materialized.

There are various methods of 3D printing depending on how the layers are deposited and the materials used in producing the object[13]. For plastic 3D printing, there is the polymer 3D printing that uses Stereolithography (STL) - also called Standard Tessellation Language - files as input to produce finished 3D objects.[14] It works by extruding liquid plastic layer by layer to form the 3D object. It is principally used in the medical field for producing anatomical models and microfluids[15]. The Polyjet method of printing is similar to the polymer method except that it gives the flexibility of creating parts multiple materials and/or colors. Multiple polymer materials can be combined to form a single material providing the option of products with varying texture and elasticity.

The parts were printed with the Stratasys J750 multi-material 3D printer. It can capture model details with resolution of about 200 microns based on the geometry of the model and material used[16].

The printing process commences with the 3D printer extruding a polymer in liquid form onto a plate for cooling and hardening. The polymer of this thinly sliced, extruded layer is cured using ultraviolet lamps. After this, another layer of polymer is deposited onto the previous layer and so the process continues until the 3D object is fully printed[1].

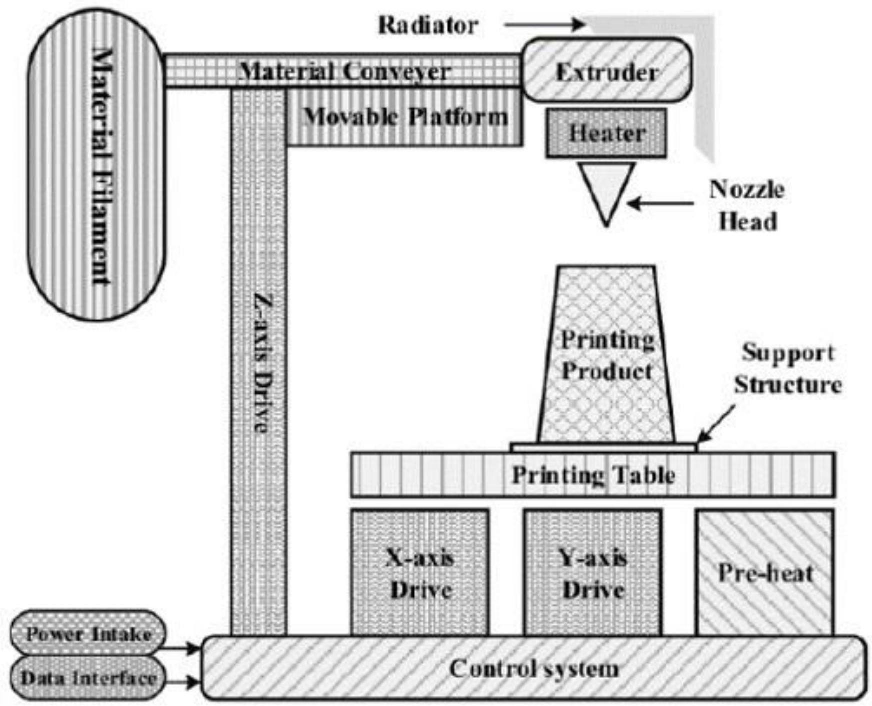

Figure 6: Schematic diagram of a 3D printer[17]

The Stratasys J750 multi-material 3D printer can input and fuse multiple polymers to produce a desired shore value. It uses different materials such as the Acrylonitrile Butadiene Styrene – Biocompatible (ABSi) used in printing translucent parts for automobiles and medical devices. The Agilus30 is another material used by the J750 printer. The Agilus30 is a flexible polymer used in producing rubber-like, bendable parts. This is the material used to produce the parts for this phantom[18].

Figure 7: Stratasys J750 Multi-Material Printer[1,19]

As stated above, STL files are digital files of CAD models that are input to 3D printers to produce parts. These files can be created as outputs from different software packages such as 3D Slicer, Meshmixer and *Autodesk* Fusion 360. Majority of the modeling for this project was done with *Autodesk* Fusion 360. It is a clod-based CAD modeling software. It is versatile with design options to create solids, 2-Dimension drawings (.DXF files), and mesh models. It is vastly used in engineering and medical designs. The advantage of it being cloud-based is that teams can collaborate on projects. Also, it keeps track of the history and changes made to a model. Finally, the process of slicing this STL file is the final stage before the 3D printer commences printing. [20]

Due to the advantage of rapidly prototyping parts, 3D printing has found numerous applications in medicine. The flexibility of iteratively modifying models and building patient-specific customized parts based on patient's anatomy has made it valuable for use in medicine. For example, it is used to print anatomical parts like joint, dental, and cranial implants[21]. Furthermore, it is being used in radiation oncology to construct quality assurance (QA) phantoms, complex radiotherapy bolus[22], and in brachytherapy to produce applicators.[23]

1.3 The Need for a Modular Phantom

Brachytherapy is effective in the treatment of gynecological cancers such as cervical cancer. HDR treatment procedures involves the insertion of radioactive sources into the uterine canal using applicators such as tandem and ovoids as well as needles.

However, there has been a decline in its use which has been linked to several reasons including the limited training of radiation oncologists in the field. The major limitation observed was the inability to practice HDR applicator insertion procedures (on a phantom) before treating a patient in the clinic. This is largely due to the unavailability of appropriate phantoms to practice these procedures on. Available gynecologic phantoms such as Gaumard's ZOE S504.100 phantom used for integration in this project, are used primarily to train clinicians for clinical examination. The lack of training phantoms for HDR GYN brachytherapy led to the designing and production of a first prototype of a 3D printed modular brachytherapy training kit that can be used by radiation oncology residents (Campelo S. et al, *Brachytherapy* 2020). Dimensional and pathological variability were investigated by performing a 50-patient study after which a kit was designed that comprised of a vaginal canal, uteri (small, average, and large), High Risk Clinical Target Volumes (HRCTV) and organs of interest (rectum and bladder)[1]. Furthermore, the quality of multi-material utilized in producing the prototyped 3D printed kit corresponds with the texture of those parts of the female anatomy. This was done by calculating the shore values of individual critical anatomical structures using young's modulus and then 3D printing using the corresponding material. Another consideration incorporated in the prototype design is the potential variation in pathology from one patient to the other.

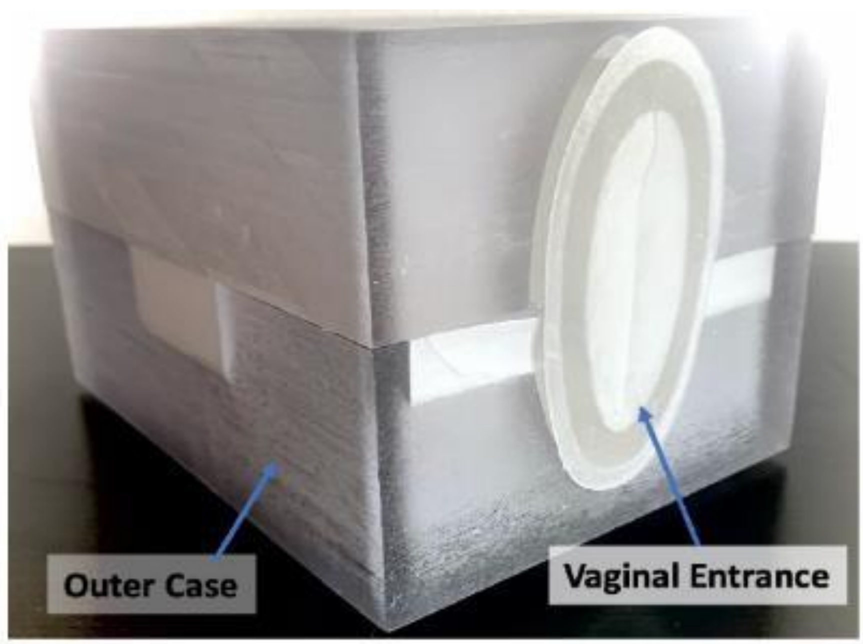

Figure 8: Closed phantom set up for use[1].

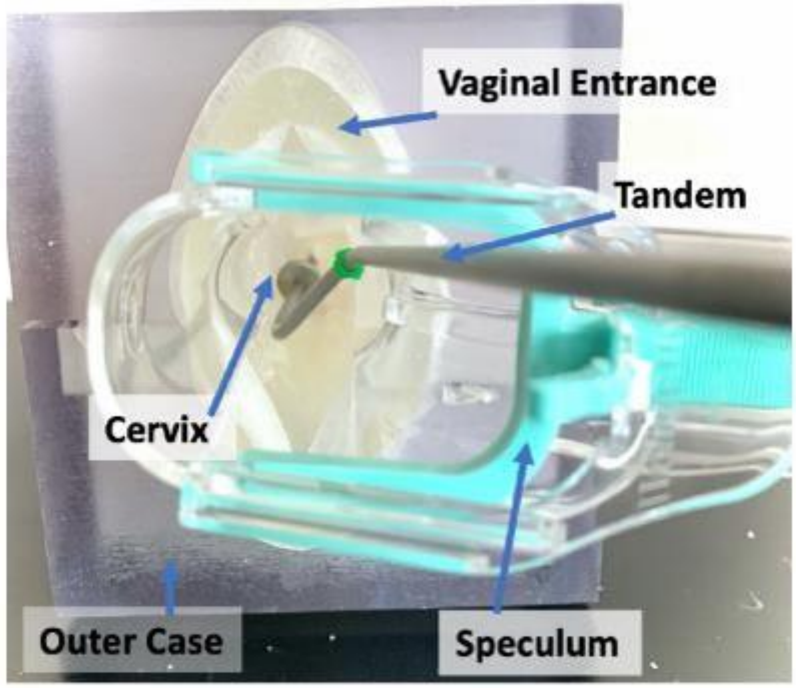

Figure 9: Speculum opening vaginal canal[1].

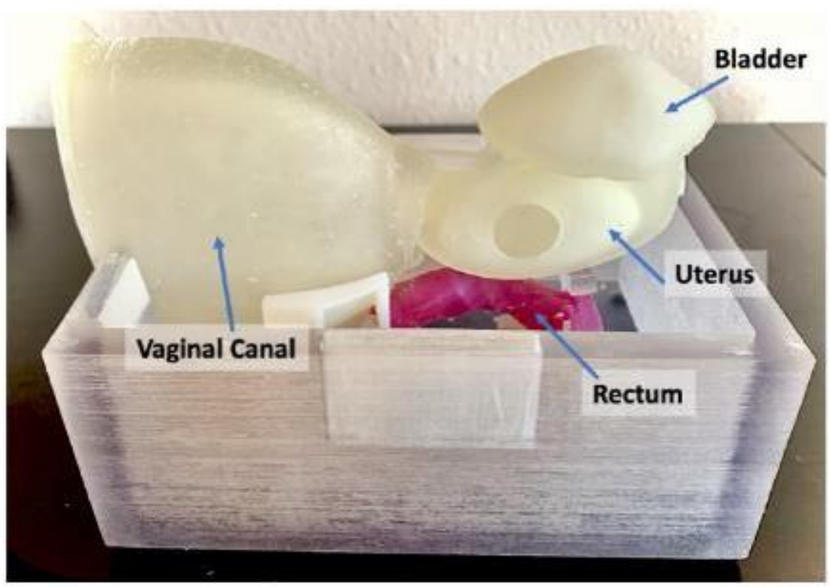

Figure 10: 3D printed bottom outer case holding modular organs of interest[1].

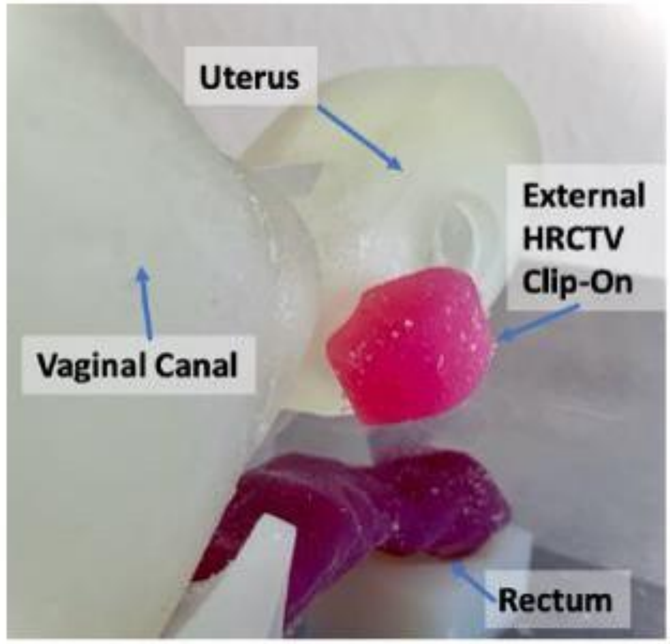

Figure 11: Attachment of external HRCTV clipped onto side of uterine body[1].

Figure 8-11 show the 3D printed prototype kit. The kit is a constructive assembly of organs of interest in a box. Figure 10 shows the speculum being used to open the vaginal canal for the insertion of the tandem applicator. Figure 11 is an up-close of the anatomical parts in the kit such as the vaginal canal, uterus, rectum, and bladder. Figure 12 shows an external HRCTV being clipped to the uterus to simulate the presence of diseased tissue.

Although the kit has been designed and printed, some limitations such as the narrow width of the vaginal canal were observed. The width of the vaginal canal was not wide enough to accommodate the various sizes of the ovoid caps. In addition, the original design incorporated the training kit in a small box hence making its use slightly challenging[1]. To make the kit more versatile and efficient for the purpose of training, it needs to be integrated with a pelvic phantom to make it a complete GYN brachytherapy phantom.

1.4 Thesis Overview

The purpose of this project is to build a modular gynecologic brachytherapy phantom by integrating our in-house prototype kit with an existing GYN phantom. This will involve designing new parts to create a unified realistic HDR GYN brachytherapy training phantom. In addition to integrating the kit with the GYN phantom, some design upgrades were necessary for the vaginal canal. The initial 3D printed prototype kit[1] revealed some limitations in inserting colpostats with the larger ovoid caps due to the width of the vaginal canal. This challenge required redesigning the vaginal canal.

Majority of the design work was done in *3D Slicer 4.10.2* and *Autodesk* Fusion 360 applications. The 3D printing was done using the Stratasys printer with Agilus material. The shore values chosen to print parts with were obtained by calculating elasticity of the human anatomy using Young's modulus.[1]

2. Materials and Methods

The major stages in the process of building the phantom were: 1) redesign the vaginal canal; 2) secure larger size uterus to the new vaginal canal; 3) integrating the training brachytherapy kit with the existing GYN training phantom.

2.1 Designing a New Vaginal Canal

In intracavitary HDR brachytherapy treatment for cervical cancer, the vaginal canal is the existing cavity through which the treatment applicator (such as a tandem and ovoid) will be inserted for implantation. Therefore, the design of the vaginal canal is critical for this phantom . The prototype design of the vaginal canal was an iterative process that required the use of the speculum dimensions.

During the design of the vaginal canal prototype, the 3D model of the structure was extracted from the acquired patient CT scans by contouring. However, because the contours only covered the thin lining of the vaginal canal, the resultant 3D printed object was weak and susceptible to tear. This led to the new approach of designing the canal utilizing the dimensions of a speculum.

A speculum is a device used in the opening of the canal prior to the insertion of applicators during treatment. Consequently, its function makes its dimensions suitable for designing the vaginal canal. The principal objective was to produce an anatomically applicable vaginal canal, stable enough to support the operation of a speculum.

Furthermore, the part needs to be flexible enough to adapt to tension when being expanded.

The dimensions of the *kleenSpec* 590 series vaginal speculum[24]. Vaginal Speculum were used to design the prototype canal. To account for insertion of ovoid caps, the final design dimensions were obtained by averaging dimensions of the large and medium sized speculums.

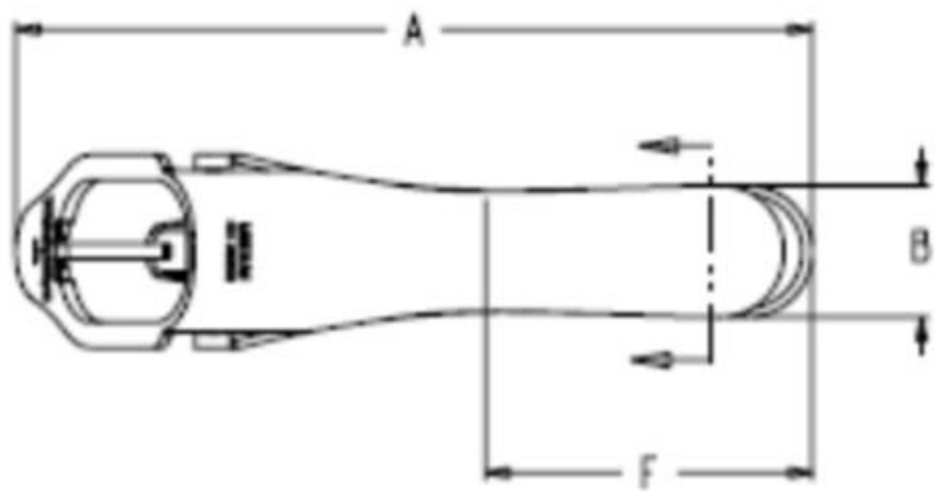

Figure 12: Schematic for KleenSpec 590 Series Vaginal Speculum Showing Dimensions for Canal Length and Width[24]

Figure 12 shows a closed speculum with labeled dimensions. F represents the length of the vaginal canal because it corresponds to the part of the speculum fully inserted in the vaginal canal while B was used as the width.

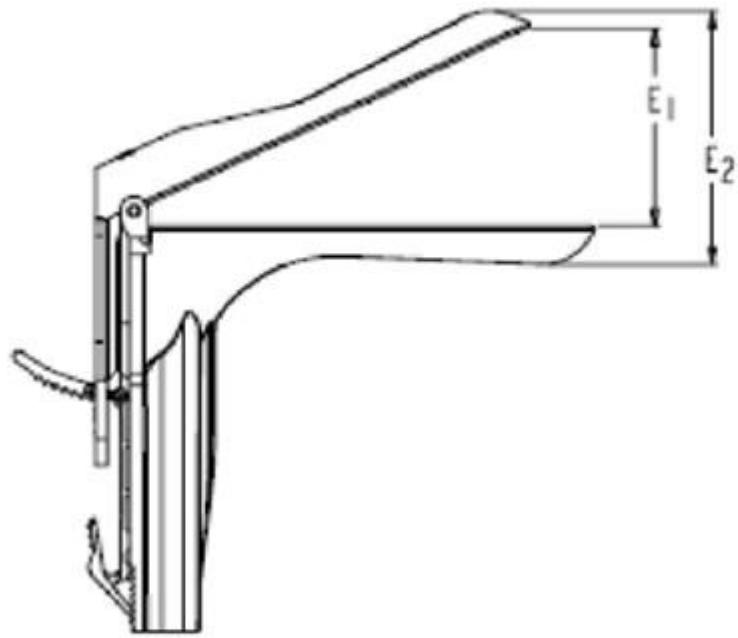

Figure 13: Schematic for KleenSpec 590 Series Vaginal Speculum Showing Dimensions for Canal Height[24]

Figure 13 is a schematic of an open speculum showing the dimensions used for determining the height of the vaginal canal. As can be seen, the speculum has a wider opening as it approaches the cervix. However, the canal was designed to ensure it tapers to a narrow end that eventually collapses around the uterus. Therefore, E1 was the vaginal height prior to narrow end before the entrance to the cervix and E2 was the height of the entrance to main vaginal cavity.

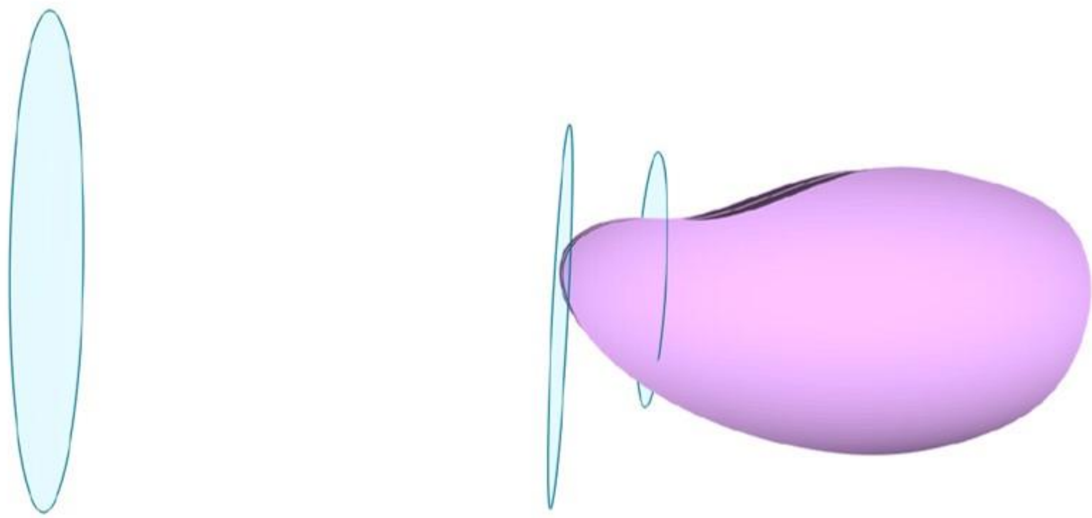

Figure 14: Sketches of ellipses used to design vaginal canal[1]

The ellipses in figure 14 were combined using the loft feature in *Autodesk* Fusion 360.

The new vaginal canal was designed in *Autodesk* Fusion 360 starting from the dimensions of the first prototype which were obtained from the *kleenSpec* 590 series vaginal speculum. Although most of the previous dimensions were retained, the width of the canal was increased from 32.5 mm to 35 mm to allow access to larger ovoid caps. This was done by creating three ellipses, separated by the length of the prototype canal, and then merging all three components using the loft feature in *Autodesk* Fusion 360.

Additionally, a circular knob was added to the end of the canal. This serves as the connection point to the uterus. The locking mechanism used to attach the uterus to the canal will be discussed in more detail below.

Table 1: Updated Dimensions of Vaginal Canal[1]

Anatomical Component	Dimensions (in cm)
Vaginal Canal Length	7.85
Vaginal Entrance Height	7.67
Vaginal Canal End Height	6.07
Vaginal Canal Width	3.5
Vaginal Canal Wall Thickness	0.6

2.2 Integrating Prototype Kit with GYN Phantom

Integrating the kit with the existing phantom involved several steps and the use of multiple model-designing platforms like *3D Slicer 4.10.2*, *Autodesk Meshmixer version 3.5.474*, *Autodesk* Fusion 360, and *OnShape*. Each step will be discussed in the subsections below.

2.2.1 The GYN Phantom

To evaluate how the prototype kit would fit inside the existing GYN phantom, a model of it was created. The GYN phantom is the ZOE S504.100 product of Gaumard. It is a gynecologic training phantom with inserts for a regular uterus as well as a pregnant uterus. It was designed by doctors for use in practicing laparoscopic examination.

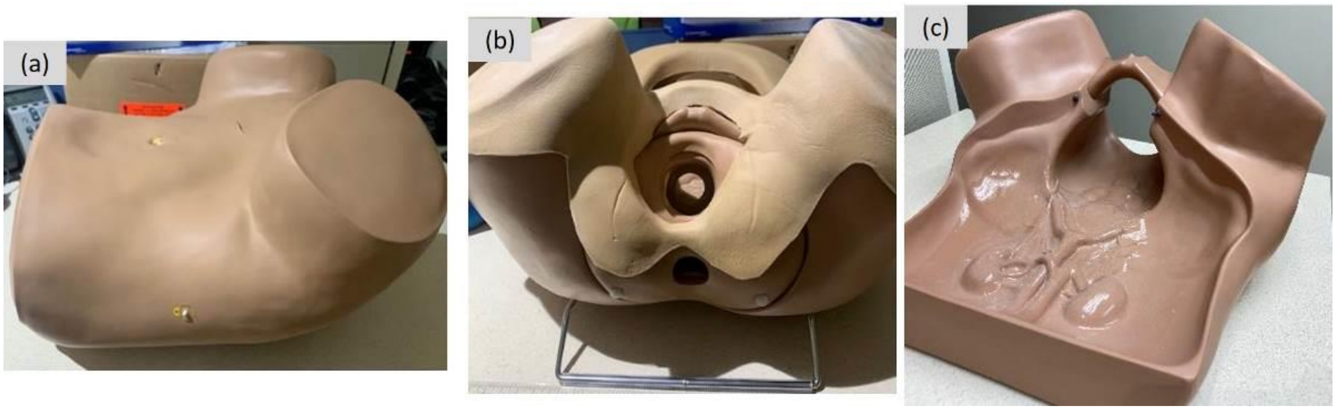

Figure 15: Pictures of the GYN Phantom (a) the phantom with skin on and all its components together (b) skin removed showing the pelvis area (c) the main structure of the phantom scanned for overall dimensions

The GYN phantom was CT scanned on a Siemens Biograph mCT, with 1 mm slice thickness and the acquired images were loaded into 3D Slicer version 4.10.2. The 3D Slicer application is an open-source software that can be used for contouring Stereolithography (STL) files from CT images[25]. The difference in amplitude from different structures in an image is utilized in contouring out 3D models of each structure. Depending on the slice thickness of the CT images, contouring each structure of interest on multiple 2D slices of CT images will produce a 3D model of the structure. The application is robust and can be potentially used in contouring different anatomical structures by using the variation in amplitude. However, the software struggles in areas of low amplitude which can result in gaps in models. The model is usually saved as an STL file that can be read into *Autodesk* Fusion 360.

After the contouring, the STL file of the GYN phantom was exported from Slicer 4.10.2 and loaded into *Autodesk* Fusion 360 as a model. Having the model in *Autodesk* Fusion 360 was advantageous because the model of the prototype kit can be inserted into the GYN model and evaluated for dimensional discrepancies as well as design challenges.

After evaluating the possible options of achieving the goal of integrating both kit and phantom, it became apparent that a new pelvic area had to be designed to accommodate the kit's canal.

2.2.2 Designing the Pelvic Area

Designing the new pelvic area required understanding the dimensions of the current part by creating an STL model of it. Therefore, CT images of that part of the GYN phantom was obtained and loaded into the slicer application for contouring.

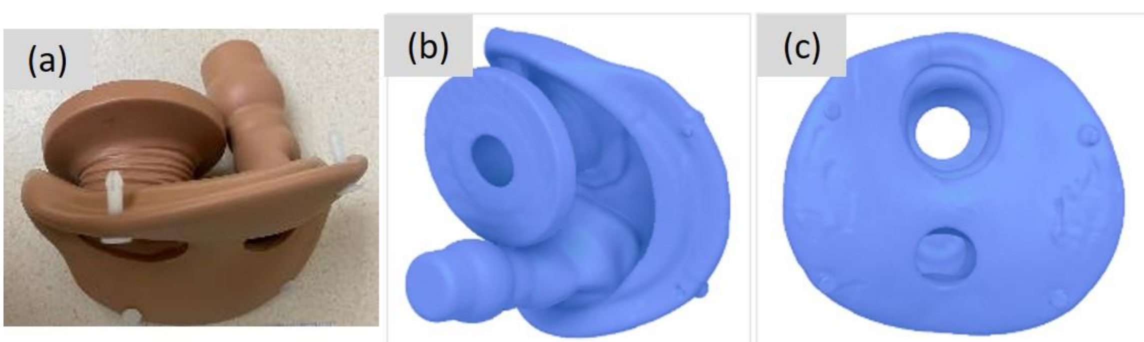

Figure 16: Pelvic part of the existing GYN Phantom(a) Picture of part (b) Angled side view of model (c) Back view of the model

Figure 16 shows a picture and the model of the pelvic area from the GYN phantom. The idea was to create a cover for the pelvic area. This was done by removing the vaginal canal and rectum from model shown above to make room for our group's vaginal canal. In addition, a slit was created to represent the canal lip that needs to be opened to access the vaginal canal and cervix. The length of the slit was about 9 cm with a thickness of 3 mm. The shore material used for this part was the Agilus 30A.

2.2.3 Merging of Canal with Pelvic Part

The vaginal canal and the newly designed pelvic part were combined to better simulate the pelvic area of the female anatomy. Additionally, the slit in the pelvic part showed a tendency to rip when in use and so this new update will mitigate that risk.

The combination of these two parts was performed using *Autodesk* Fusion 360. By reason of this the curved surface of the pelvic cover, and the flat surface of the vaginal canal, the merging could not be performed directly using the join operation in the combine feature for models. Moreover, the canal length and other dimensions had to be retained as they were based on actual patient dimensional study.

The first step in combination process was to extend the length of the vaginal canal. Next, the curved face of the pelvic cover was used as a separation plane to cut through vaginal canal at the desired length the canal. The goal is to re-design the vaginal canal to have a curved surface identical to the pelvic cover. Finally, with the two parts having identical curved surface, they are merged using the join operation of the combine feature.

2.3 Modular Components: Lock Mechanisms

In the initial prototype kit, the uterus was attached to the vaginal canal using the pegs as a modular component. Using Boolean subtraction in *Autodesk* Fusion 360, the average uterus was cut out of the vaginal canal at the cervix and stability was maintained using pegs as shown in Figure 17.

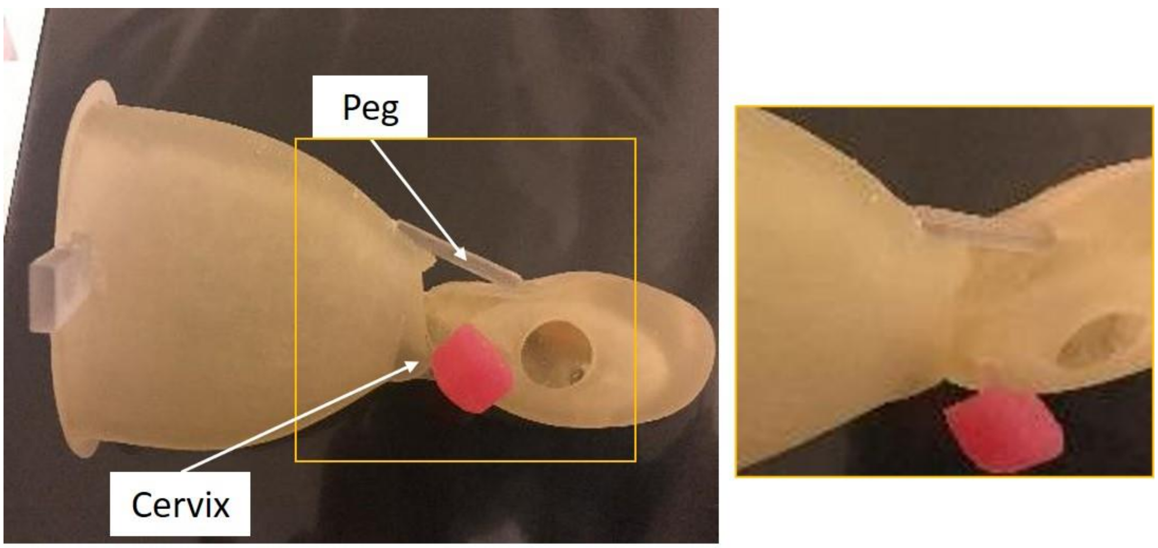

Figure 17: Peg Design of the First prototype – Pegs attaching Uterus to Vaginal Canal[1]

However, using this method for the large uterus was challenging. A design issue encountered was because although the size of the canal remained unchanged, the enlarged dimensions of the large uterus made it unsuitable for the design. The cervix area which was the connection point of the uterus to the canal became limited in capacity to house the large uterus. Due to this challenge, it was decided to design an updated locking mechanism that would work efficiently with varying-sized uteri.

During the design phase, multiple options were considered for the modular component. Two of these will be discussed:

2.3.1 Twist-Fit Mechanism

The twist-fit mechanism involved creating a cylindrical case and cover that can lock when twisted in the clockwise direction. It was designed by creating a male and an adjacent female component that fit into each other and lock in place when twisted.

This locking mechanism did not yield favorable result due to tolerance of size associated with 3D printing. Although the model worked well, the printed version revealed the need for the male and corresponding female components to be larger than can be accommodated for this phantom. In addition, the successful implementation of this method required that the non-anatomical part be printed in single polymer hard plastic while the anatomical feature will be printed using the soft, pliable Agilus30 material that would simulate the texture of skin. Merging these two parts together could easily become non-trivial and so this method was not pursued further.

2.3.2 Flanges

Following the structural challenges of the twist-fit method, we investigated a flange design for connecting the vaginal canal with the uterus. This solution is not complex and locks the uterus with the canal without significant change to the anatomy.

There was no need to consider joined two different pieces of plastic and the flanges are held together by nylon bolts and nuts. The connection point of the canal to the uterus was adjusted to accommodate the design of the flanges.

These flanges were designed using the half-moon concept to facilitate fastening it. Also, having eight 5 mm holes to keep the parts together reduces the tension on the multi-material which mitigates tearing of the pelvic cover.

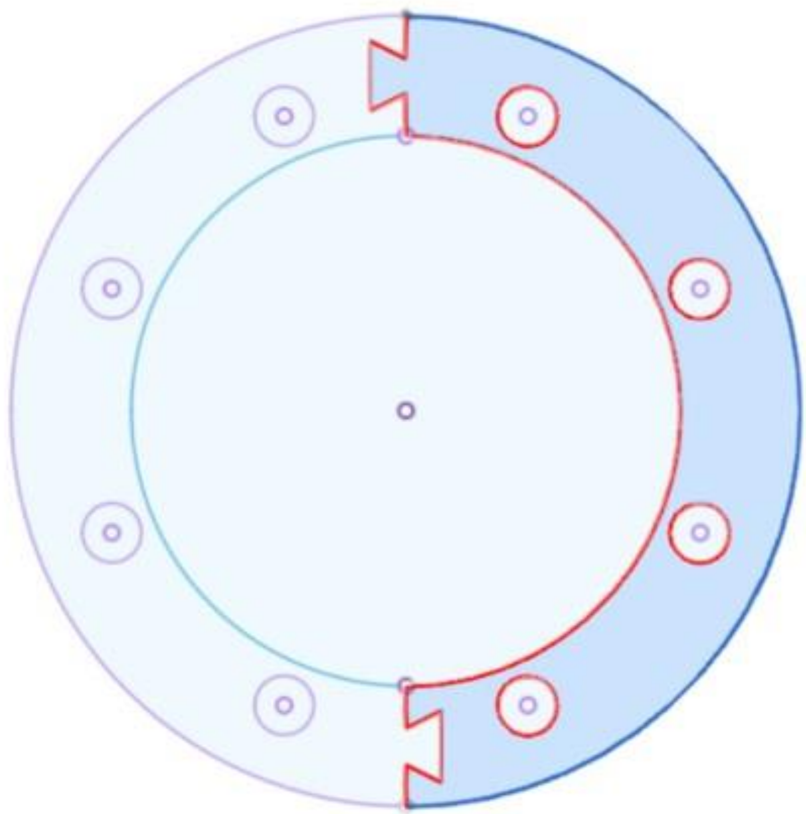

Figure 18: 2D Sketch of flanges showing half-moon concept.

2.4 A Support Frame

During the insertion of applicators (tandem, ovoids and needles) into the phantom, it is imperative to ensure the canal - with the uterus attached - is well supported in the existing GYN pelvic phantom to withstand the different levels of pressure from the insertion procedure itself. To ensure this stability, a support frame was designed.

The frame was created to fit inside the phantom, close to the entrance of the vaginal canal. Although it was initially designed to be printed in hard PLA material, it was revised to have a silicone portion at the center for flexibility when expanding the vaginal canal with the speculum. The outer part of the frame is used as a mold to cast the silicone inner part.

For this project, the Polyjet 3D printing method was utilized with the Agilus30 multi-material.[1] The anatomical parts were printed using the Stratasys J750 multi-material 3D printer. Three sets of the prototype which include pelvic and uteri of three different sizes (small, medium, and large) will be printed for use by radiation oncology residents.

3. Results

The goal of this project was to build a functional, gynecologic brachytherapy modular phantom that allows for the simulation of HDR procedures by residents prior to performing such procedures on patients. This was achieved by integrating our group's brachytherapy prototype kit with an existing *Gaumard* ZOE S504.100 GYN phantom. As explained in the methods section, the result was a combination of multiple processes with a few iterative designs, the first of which was obtaining an STL file that is a model of the GYN phantom.

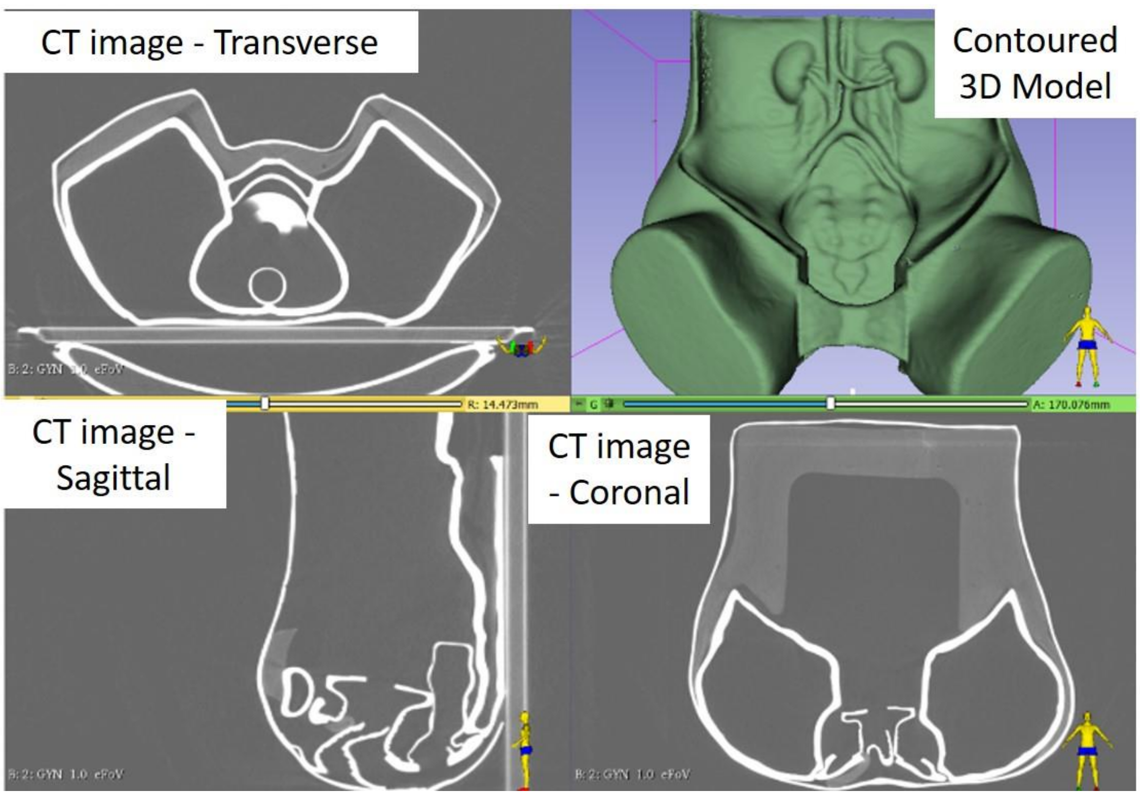

Figure 19: Contouring pelvic phantom in 3D Slicer 4.10.2

Figure 19 shows the result of the contouring in 3D Slicer 4.10.2 The top right hand of the window shows the model after contouring was complete before exporting as an STL. The model was contoured in all three views – Sagittal, coronal, and axial - to produce a true representation of the phantom.

While rendering a model of the GYN phantom from the CT images, the redesign of the vaginal canal was also ongoing.

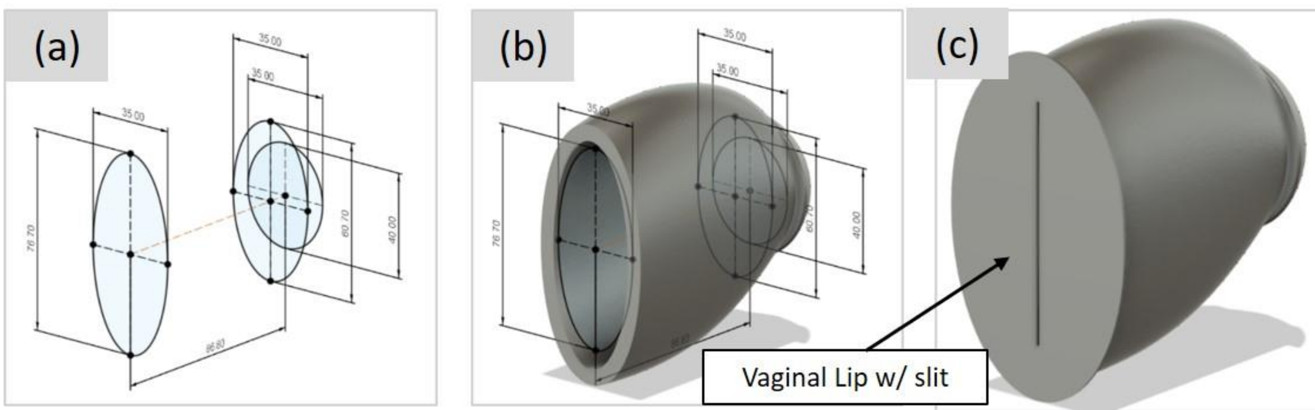

Figure 20: Vaginal Canal (a) Sketch of ellipses (b) full design (c) with lip and slit.

Figure 20 shows intermediate steps in the designing of the vaginal canal. 20a shows the sketches of the ellipses before being joined with the loft feature to out a solid body. Figure 20b is the model of the canal while 20c shows the vaginal lip initially designed as a cover for the canal entrance. However, the latest design with the single piece pelvic part will not require this as the skin of the *Gaumard* ZOE S504.100 phantom is functioning in that capacity.

After loading the GYN phantom into the Autodesk Fusion 360 platform, it was evaluated for fit with the prototype kit and a new pelvic flap was designed.

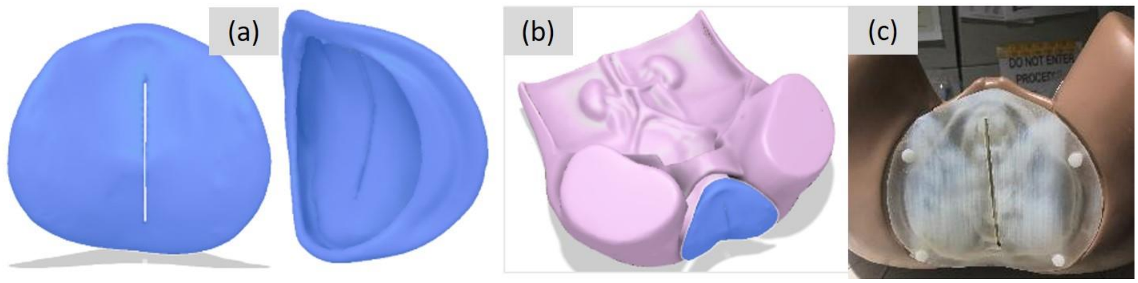

Figure 21: Designed Pelvic Part (a) Front and back views of the model (b) New pelvic area with the GYN phantom model to confirm fit (c) Printed part on GYN phantom

Figure 21 shows the designed pelvic part at various stages. The images on the left-hand side show front and back views of the model while figure 21b shows the pelvic part attached to the phantom to validate fit. The last picture shows the 3D printed pelvic cover affixed to the pelvic phantom. This pelvic cover was further merged with the vaginal canal to form single piece pelvic part.

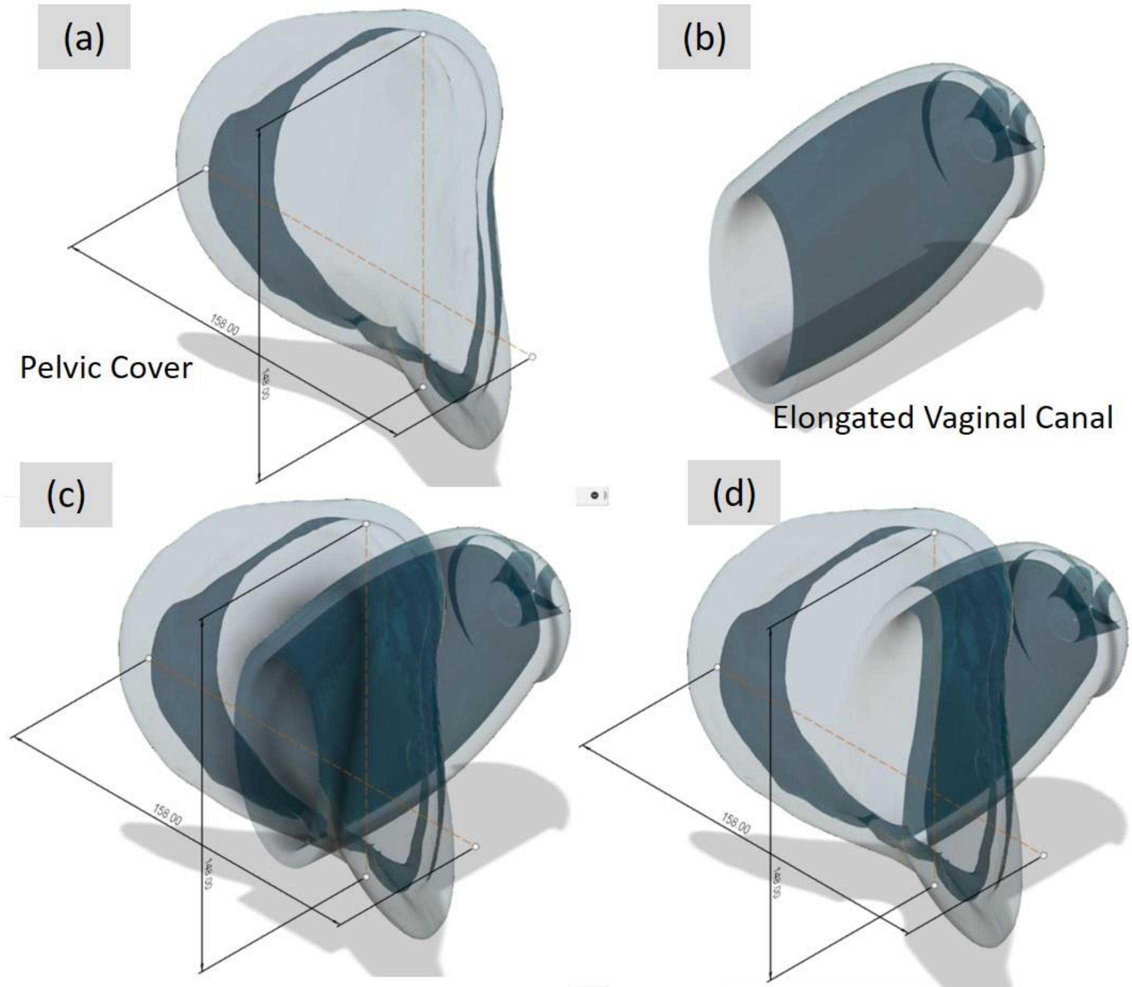

Figure 22: Merging Vaginal Canal with Pelvic Cover

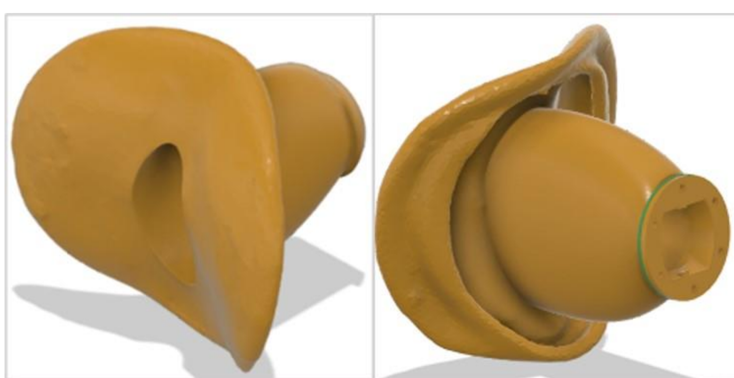

Figure 23: Single Piece Pelvic Area

Figure 23 shows the product of incorporating the vaginal canal with the pelvic cover. The entrance of the single piece pelvic design opens the canal which leads to the cervix that connect to the uterus. The skin from the *Gaumard* ZOE S504.100 phantom will cover this opening and serve as the vaginal lip that will distended with a speculum to access the canal.

Following the completion of the pelvic design, iterative designing of a system to hold the uterus and vaginal canal in place was implemented.

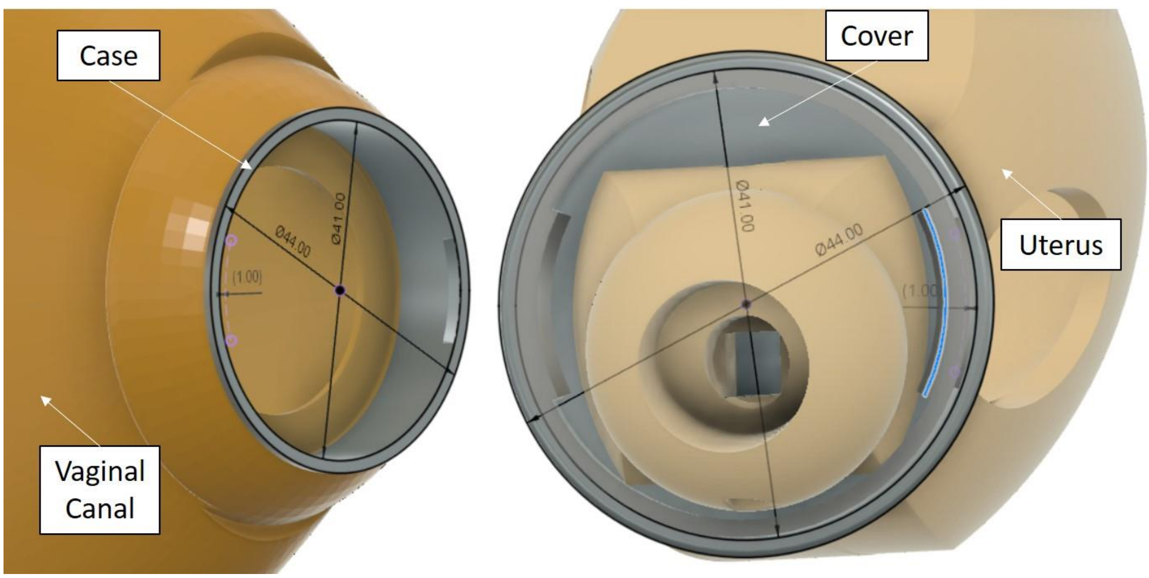

Figure 24: Twist/Fit Locking Mechanism

Figure 24 above depicts the twist/fit mechanism. On the left-hand side is an image of the vaginal canal with the case that has latch-like extensions that fit into corresponding holes in the cover (attached to the uterus).

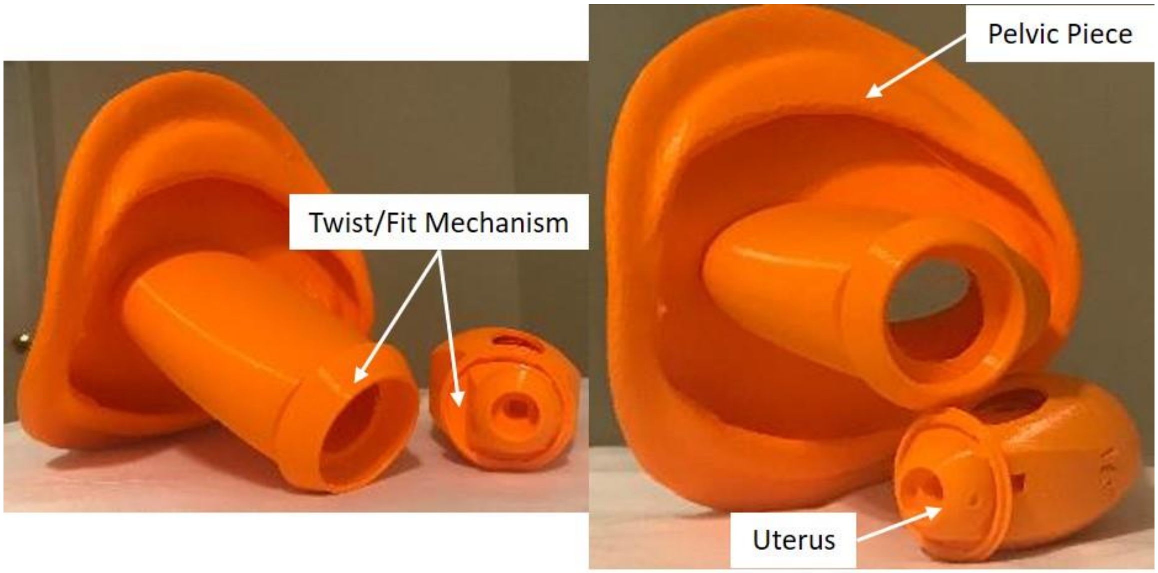

Figure 25: 3D Printed (in rigid material) Twist/fit locking mechanism.

Another locking mechanism that was developed was the use of flanges.

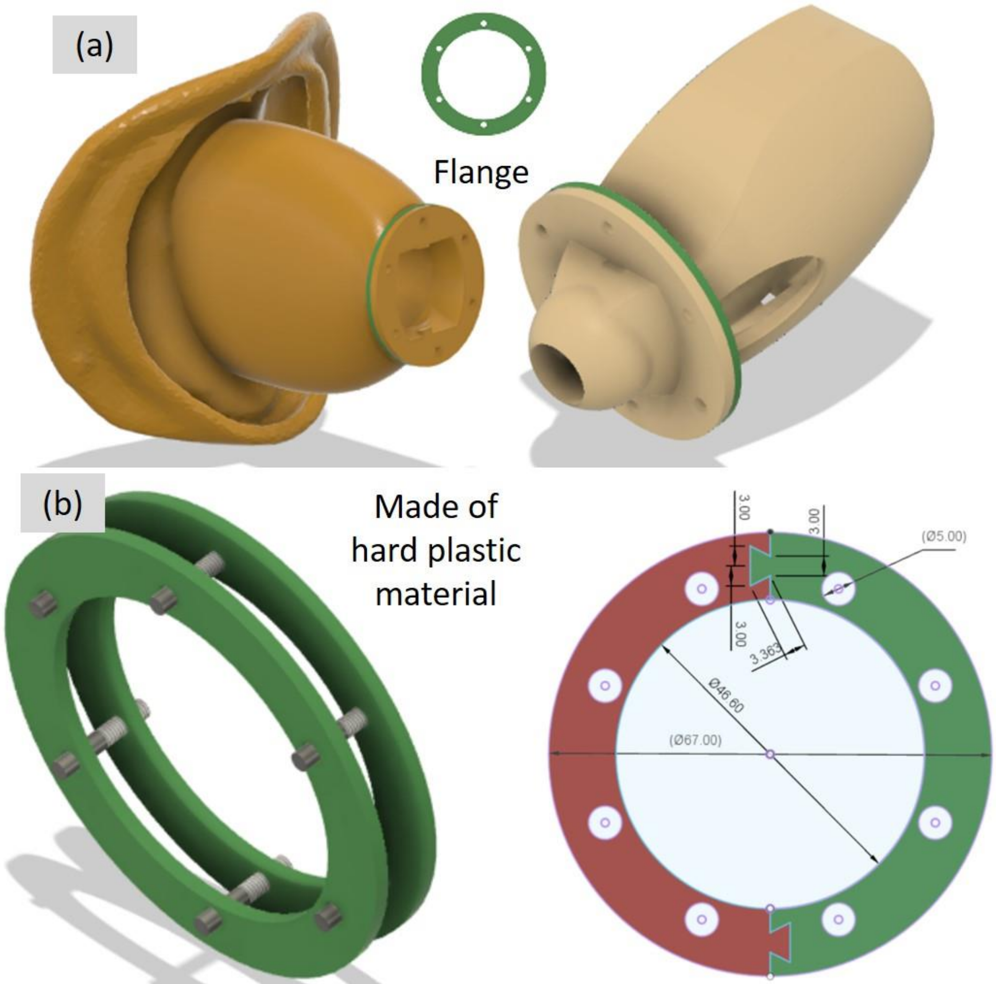

Figure 26: Flanges (a) Vaginal Canal with Plastic Flange (b) Flanges held together with bolts

Figure 26 shows the design for flanges. As seen in the figure, the combination of the flanges on both sides will keep the parts in place while the phantom is being used.

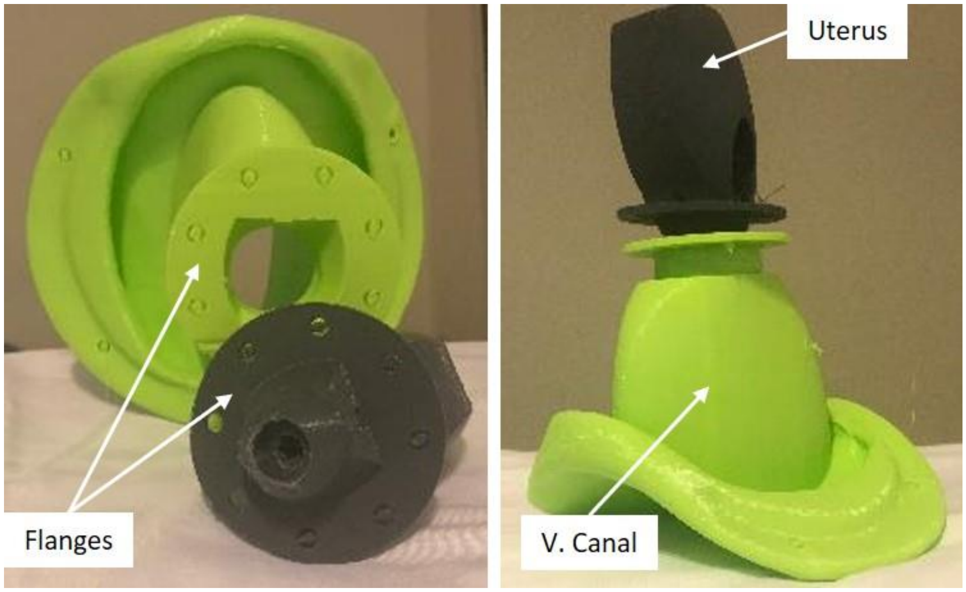

Figure 27: 3D Printed (in rigid material) Pelvic piece and Uterus showing flange lock mechanism.

Finally, a support frame was built to stabilize the anatomical parts in the phantom.

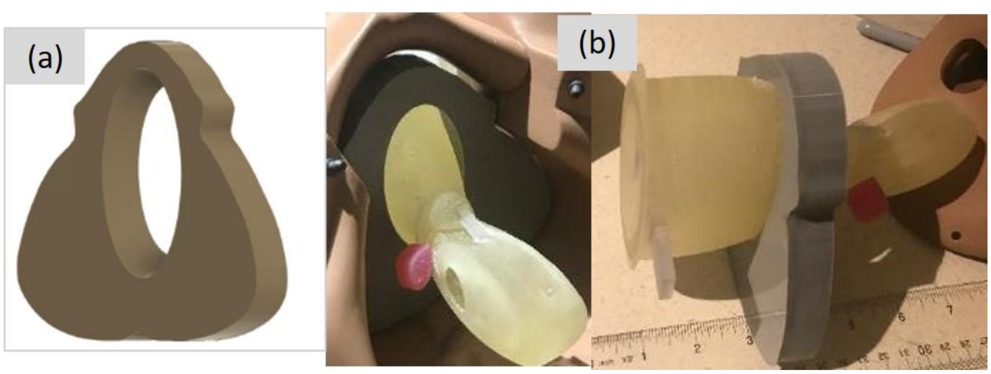

Figure 28: Support Frame (a) Model of frame (b) Frame holding canal in and outside the phantom

Figure 28 shows the frame constructed to keep the vaginal canal and uterus stable in the phantom. On the left is the model showing the outline of the area of the phantom to which it will fit as well as the opening that will seat the canal. The last two images show the 3D printed frame, in the vaginal canal to evaluate fit and ability to support the parts. This was the first iteration of the frame.

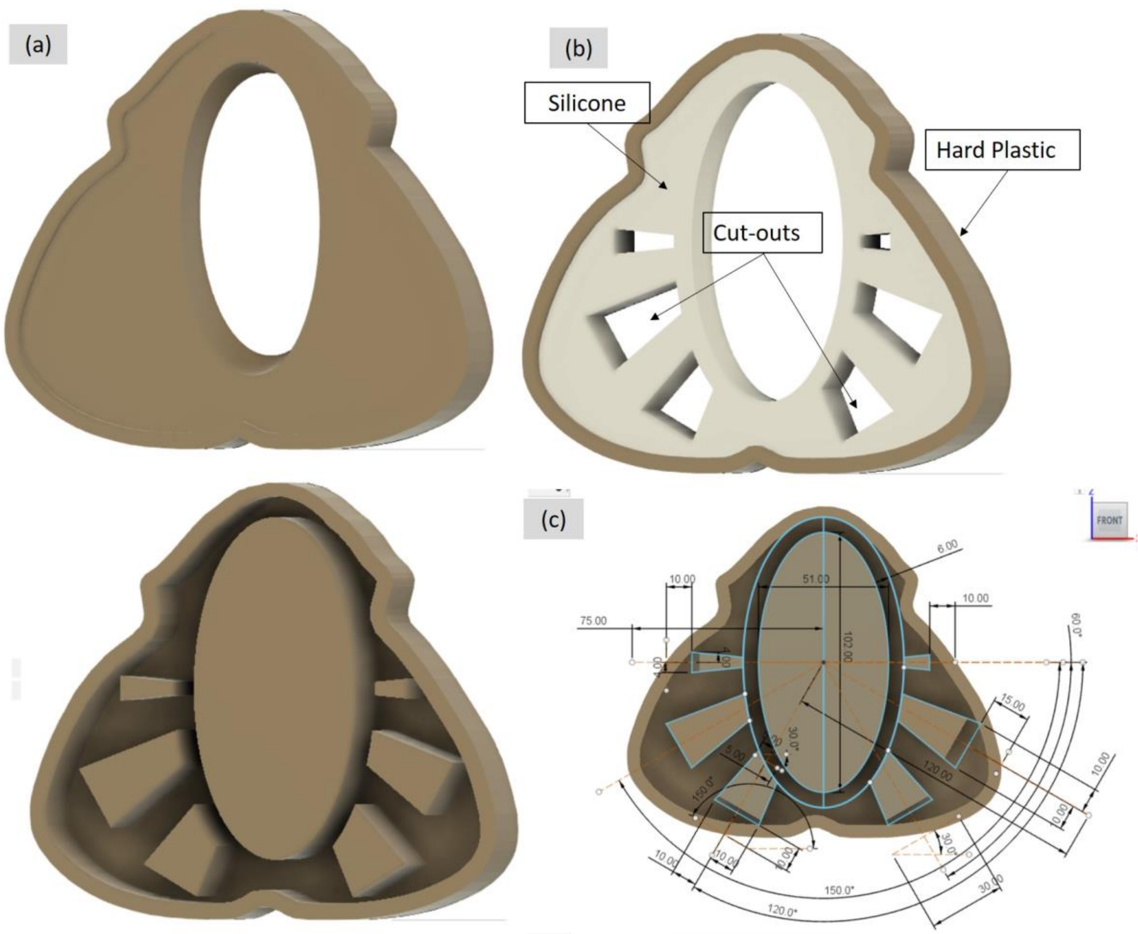

Figure 29: Final Support Frame Model (a) Initial Model (b) Second Iteration with silicone and cut-outs (c) Mold to Cast Silicone

The final iteration of this part was made with a silicone area in the center to allow flexibility of expanding the canal with a speculum during implantations.

In conclusion, the combination of all the designed parts is shown in figure 30 below. The vaginal canal is connected to the uterus using flanges and assembled in the phantom. The image on the right shows an up-close look of the newly designed parts. This is the final product of the modular phantom.

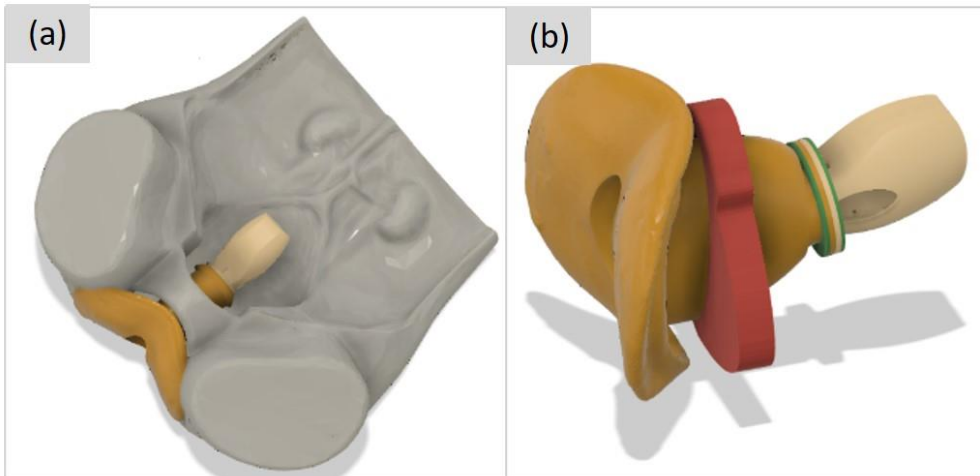

Figure 30: A modular Phantom (a) model of the GYN phantom with the inserts of designed parts held by flanges (b) Phantom inserts – Pelvic part, uterus, flanges, and support frame

4. Discussion

The process from the initial stage of physically analyzing the GYN phantom and our prototype kit, modeling the required parts in 3D Slicer 4.10.2, designing new anatomical parts and then to 3D printing has been marked with numerous learning curves and interesting discoveries. The iterative nature of designing makes it pertinent to keep printing as soon as modeling is done to validate fit. The need to adjust models that worked theoretically make this very cogent.

For example, twist-fit locking mechanism was an idea that looked viable in theory when designed. However, after 3D printing, it was discovered that the printer's tolerance was not fine enough to accommodate this design. This tolerance made the latch unsuited to fit in to its corresponding cavity leading to the failure of the product and necessitated developing another method of affixing parts. It was after all this that the flange locking mechanism was developed and it proved effective and practical when executed.

Furthermore, certain challenges became apparent after 3D printing with the Agilus multi-material and performing trials with the GYN phantom. An example of this was in the designing of the pelvic cover. Physical evaluation of the 3D printed pelvic cover revealed a likelihood of ripping through the slit. To avoid this, the pelvic cover was combined with the vaginal canal to form a single piece. Moreover, this new design better simulated the female anatomy.

Finally, the initial design of the support frame had to be adjusted to permit for flexibility when the speculum is used on it. This resulted in the utilization of silicone material as a buffer to the part of the frame adjacent to the vaginal canal.

Other challenges include the downtime experienced due to the inability to print. In 2020, at the onset of the Coronavirus-19 pandemic, Duke's printing lab (the co-lab) was closed about four months and printing could not be done. This greatly slowed down the progress of the project. To mitigate this delay, designing of some other parts were done concurrently during the lockdown. In addition, there was a month-long delay in printing due to the breakdown of the Stratasys printer. This greatly impacted the project timeline.

Finally, there has been difficulty in printing the single pelvic part. According to the co-lab technical expert, the printing commences and runs for a few hours before aborting. The job has been re-submitted about three times with the same outcome. The STL model has been reviewed and cleared of any discrepancy by technical experts and the root cause of the issue is still unknown. As at the time of submitting this report, the investigation is still ongoing, and the part has not been successfully printed. Due to the unavailability of the printed part, the MD study could not be implemented during this project.

In future, the depart should seek an alternative vendor able to provide the same services. This would mitigate the challenge of a possible project halt due to an issue with a sole service provider. Also, situations where an upgraded part is impossible to print, the previous design could be used as a substitute. However, this solution is not suitable for this project because there are other parts designed to specifically fit into this new upgrade. Situations such as this might require a workaround part should be designed.

Our group will continue to work on getting a 3D printed working prototype of the modular phantom.

5. Conclusion

The goal of this project was to build a modular phantom by integrating our in-house brachytherapy prototype kit with and existing GYN phantom. This was done by assessing the GYN phantom to identify the appropriate designs that would produce a smooth incorporation of the kit. A new design for the GYN phantom's pelvic area was necessary to accommodate the kit's vaginal canal. Furthermore, a frame was used to ensure stability of the parts (vaginal canal and uterus) while the modular phantom is being used. A locking mechanism using flanges was implemented to keep the canal and uterus attached. The constructive assembly of all this parts inside the GYN phantom yielded the modular phantom.

References

1. [1] Campelo S, Subashi E, Meltsner SG, Chang Z, Chino J, Craciunescu O. Multimaterial three-dimensional printing in brachytherapy: Prototyping teaching tools for interstitial and intracavitary procedures in cervical cancers. *Brachytherapy*. 2020. doi:10.1016/j.brachy.2020.07.013

2. [2] Suntharalingam N, Podgorsak EB, Tolli H. *Chapter 13 Brachytherapy: Physical and Clinical Aspects*.; 2005. doi:10.1016/S0167-8922(06)80061-1

3. [3] Benitez PR, Keisch ME, Vicini F, et al. Five-year results: the initial clinical trial of Mammosite balloon brachytherapy for partial breast irradiation in early-stage breast cancer. *Am J Surg*. 2007. doi:10.1016/j.amjsurg.2007.06.010

4. [4] Yamada Y, Rogers L, Demanes DJ, et al. American Brachytherapy Society consensus guidelines for high-dose-rate prostate brachytherapy. *Brachytherapy*. 2012. doi:10.1016/j.brachy.2011.09.008

5. [5] Nag S, Beyer D, Friedland J, Grimm P, Nath R. American brachytherapy society (ABS) recommendations for transperineal permanent brachytherapy of prostate cancer. *Int J Radiat Oncol Biol Phys*. 1999. doi:10.1016/S0360-3016(99)00069-3

6. [6] Alam M, Nanda S, Mittal BB, Kim NA, Yoo S. The use of brachytherapy in the treatment of nonmelanoma skin cancer: A review. *J Am Acad Dermatol*. 2011. doi:10.1016/j.jaad.2010.03.027

7. [7] Banerjee R, Kamrava M. Brachytherapy in the treatment of cervical cancer: A review. *Int J Womens Health*. 2014. doi:10.2147/IJWH.S46247

8. [8] Mayo Clinic, "Cervical Cancer" https://www.mayoclinic.org/diseases-conditions/cervical-cancer/symptoms-causes/syc-20352501#dialogId60259819

9. [9] Prescribing, Recording, and Reporting Brachytherapy for Cancer of the Cervix. *J ICRU*. 2013. doi:10.1093/jicru_ndw027

10. [10] Olson AC, Craciunescu O, Meltsner S, Cai J, Chang JZ, Chino J. Dosimetry, Feasibility, and Acute Toxicity of Combined Intracavitary Brachytherapy and Free-Hand Interstitial Needle Placement for Locally Advanced Cervix and Uterine Cancer. *Brachytherapy*. 2016. doi:10.1016/j.brachy.2016.04.140

11. [11] Varian, Brachytherapy Product Catalog https://varian.widen.net/s/wwyx9dru1f/brachy_catalog_rad10536a_september2019

12. [12] Bebig, CT/MR Ring and Tandem Applicator Sets https://www.bebig.com/fileadmin/bebig_neu/user_uploads/Products/HDR_Brachytherapy/Fact_sheet_Ring_and_Tandem_Applicator__Mick___Rev._05__English.pdf

13. [13] U.S. Food and Drug Administration, "3D Printing of Medical Devices," last modified March 26, 2020, https://www.fda.gov/medical-devices/products-and-medical-procedures/3d-printing-medical-devices.

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14. [14] Protolabs, “Types of 3D Printing Technology” accessed March 21, https://www.protolabs.com/resources/blog/types-of-3d-printing/

15. [15] SME, “Additive Manufacturing Glossary,” accessed July 17, 2020, https://www.sme.org/technologies/additive-manufacturing-glossary/

16. [16] Stratasys Ltd. J750 Digital Anatomy Printer - Datasheet. 2019:1-8.

17. [17] Peng T. Analysis of Energy Utilization in 3D Printing Processes. In: *Procedia CIRP*.; 2016. doi:10.1016/j.procir.2016.01.055

18. [18] Stratasys.com, “Our Materials”, https://www.stratasys.com/en/materials/search?technologies=731e07a1a51b42419acd1cb75142dfe6&sortIndex=0

19. [19] Stratasys Ltd. J750 Digital Anatomy Printer - Datasheet. 2019:1-8.

20. [20] 3dprinting.com, “An Overview Of The Best 3D Printing Software Tools”, https://3dprinting.com/software/#3D-MODELING-SOFTWARE

21. [21] M. Di Prima et al., “Additively Manufactured Medical Products—the FDA Perspective,” *3D Printing in Medicine* 2, no. 1 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6027614/.

22. [22] Zhao Y, Moran K, Yewondwossen M, et al. Clinical applications of 3-dimensional printing in radiation therapy. *Med Dosim*. 2017. doi:10.1016/j.meddos.2017.03.001

23. [23] Tack P, Victor J, Gemmel P, Annemans L. 3D-printing techniques in a medical setting: A systematic literature review. *Biomed Eng Online*. 2016. doi:10.1186/s12938-016-0236-4

24. [24] KleenSpec R 590 Series Vaginal Speculum Specifications. https://www.welchallyn.com/content/dam/welchallyn/documents/uploaddocs/Product-Literature/Specification-Sheet/KleenSpec-590-Vag-Spec-Specifications.pdf.

25. [25] Fedorov A, Beichel R, Kalpathy-Cramer J, et al. 3D Slicer as an image computing platform for the Quantitative Imaging Network. *Magn Reson Imaging*. 2012. doi:10.1016/j.mri.2012.05.001