Increasing Accessible Gynecological Care for Women with Cerebral Palsy: A Redesigned Speculum

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A Major Qualifying Project submitted to the Faculty of Worcester Polytechnic Institute in partial fulfillment of requirements of the Degree of Bachelor Science

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Authorship

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Abstract

Women with mobility limitations, such as Cerebral Palsy (CP), are 35% less likely than able-bodied women to have ever received a Pap smear. Women with CP experience poor muscle tone, tight muscles, and involuntary movements making it hard for them to maintain the positioning necessary to place a speculum. This project aimed to design a device to allow for proper and comfortable examinations for women with CP who may have challenges getting into the proper exam position. To accomplish this, we constructed a camera-guided speculum consisting of a flexible hollow tubing, rather than rigid metal and plastic, allowing the device to bend to 49.7 ± 4.2°. The device also has an inflatable balloon at the cervix-facing end of the device with inner and outer diameters of 1.6 cm and 3.0 cm. The device yielded clear images of the model cervix, and a brush mimicked the collection of cervical cells, suggesting the device could facilitate successful Pap smears for this underserved population.

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Chapter 1: Introduction

The importance of women's healthcare procedures cannot be overstated since a gynecologist performs many important tests and exams to detect cancer and other abnormalities. The outcome of these diseases, such as cervical cancer, depends heavily on early diagnosis. For this reason, women over the age of 21 are encouraged to receive a pelvic exam and Pap smear yearly ("Well-woman visit," 2018). Alarmingly, disabled women are less likely than able-bodied women to receive yearly care, such as Pap smears or pelvic exams (Armour et al., 2013). One study found that women with mobility limitations are 35% less likely than able-bodied women to have ever received a Pap smear (Drew & Short, 2010).

These disparities can extend to women with Cerebral Palsy (CP), a group of neurological disorders, which affect motor coordination and body movement (Schwartz et al., 2020). One factor impacting these disparities for women with CP is inaccessible equipment such as the speculum. The speculum is the instrument used in most vaginal examinations and tests that allows a physician visual access to the patient's cervix through the opening of two rigid bills after insertion in the vagina. The most common materials for this instrument are plastic and metal. Many women with CP have trouble maintaining the proper positioning for insertion of the speculum. If insertion of the speculum is possible, involuntary muscle movements may make the procedure painful or hinder the doctor's ability to collect a sample (Schwartz et al., 2020).

Disabled women deserve access to medical devices that work for them. This project aimed to design an instrument that will work for women with CP in order to increase access to lifesaving procedures and examinations.

Chapter 2: Literature Review

2.1 Women's Healthcare

Women's health care is the branch of medicine that focuses on the prevention, diagnosis, and treatment of various disorders and diseases that can affect a woman's physiology (Drew & Short, 2000).

2.1.1 Common Procedures and Instruments

A woman's health care provider performs many crucial examinations in a woman's life. A yearly well-woman visit to a gynecologist includes screening for cervical and breast cancer, reproductive counseling, and immunizations. A gynecologist performs a breast exam, a pelvic exam, and a Pap smear to assess a woman's risk of cancer or structural abnormalities. Early detection of these diseases is crucial, and a gynecologist is often the first point of contact for women in detecting these diseases before they progress; thus, the importance of yearly exams and screening cannot be overstated ("Well-woman visit," 2018).

2.1.2 Pelvic Exams and Pap Smears

Pelvic exams are performed by a physician to check for structural abnormalities in a woman's reproductive organs including the vulva, vagina, cervix, ovaries, uterus, and pelvis ("Pelvic exams," 2020). A Pap smear is usually performed in conjunction with a pelvic exam. The American College of Obstetricians and Gynecologists currently recommends that cervical cancer screening should begin at age 21. Then screening should occur every three years unless there is another risk factor such as a history of cervical cancer or abnormal smears.

The standard exam positioning for a Pap smear is called the lithotomy position (Figure 1). A woman will be asked by her physician to sit at the end of the exam table with her legs apart and her feet or legs in stirrups.

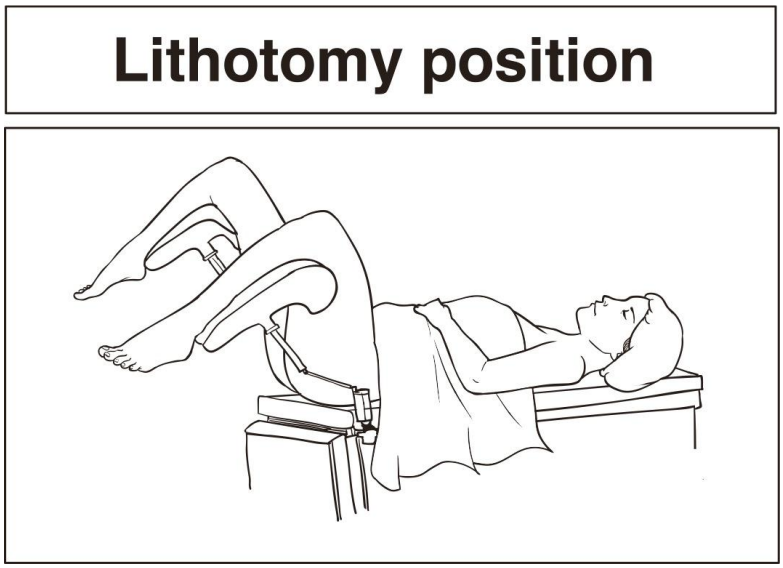


Figure 1: The typical exam positioning for a Pap smear called the lithotomy position.

During a Pap smear, a physician typically uses either a metal or plastic speculum to separate the vaginal walls and provide access to the cervix. The physician will then use a wooden or plastic spatula or a soft brush to collect cells from the cervix ("Updated cervical cancer screening guidelines", 2021) as seen in Figure 2.

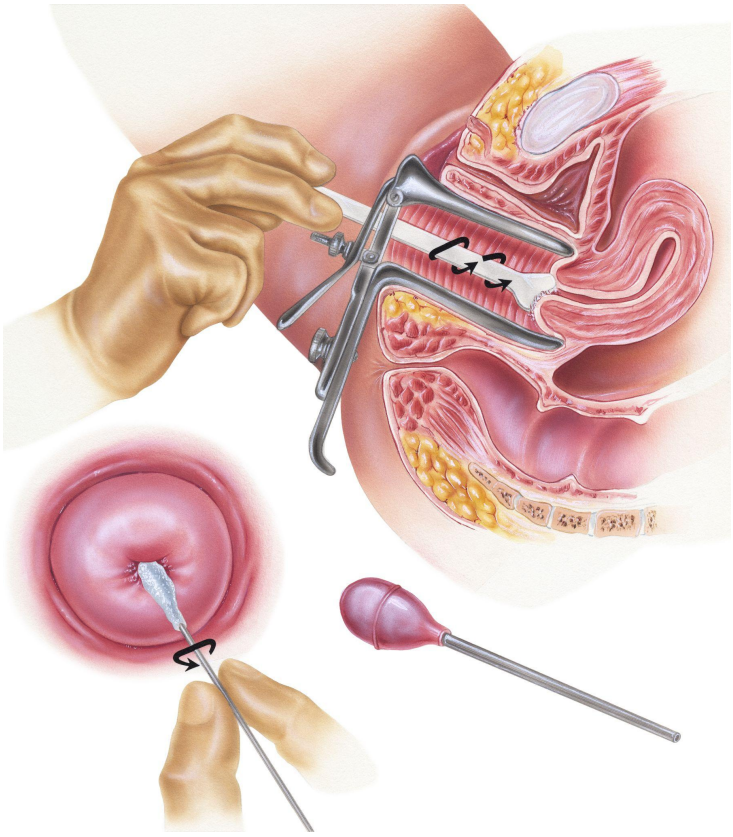


Figure 2: Collection of cervical cells during a Pap smear using a spatula and endocervical brush.

The cells collected are analyzed during microscopy for any cancerous or precancerous indicators.

2.1.3 Women's Healthcare for Disabled Women

Given the importance of yearly exams and screening, it is troubling that disabled women report receiving them less frequently than abled-bodied women. Disabled women are less likely than able-bodied women to report receiving a mammogram during the past 2 years. Disabled women are also less likely to report receiving a Pap smear in the past 3 years with 78.9% self-reporting compared to 83.4% of able-bodied women (Armour et al., 2013). One study found that women with mobility limitations are 35% less likely than able-bodied women

to have ever received a Pap smear (Drew & Short, 2010). Various factors influence these disparities including negative assumptions or attitudes about disabled women, poverty or lack of health insurance, lack of transportation to healthcare facilities, and inaccessible medical equipment (Matin, 2021).

During the background research stage of this project, we interviewed a healthcare provider, Virginia Reed PhD, MPH, and a woman with Cerebral Palsy, Brittany DiMatteo, to obtain information on their experiences (Appendix A, Appendix B).

Dr. Reed explained to us various aspects of the OB/GYN field and the challenges women with disabilities may face when receiving reproductive health care examinations. Specifically, we discussed difficulties physically disabled women or women with mobility limitations might face when obtaining a Pap smear or pelvic exam. Dr. Reed posed to us numerous questions one might have to consider:

> "Can [the patient] get to an exam table? Can they sit? Can they lie down? Can they be in position for a PE, or a variation of those positions, as well as the mechanics of getting in those positions. One group of things you might think about is what are the mechanics of just simply the physical exam, and that's not thinking about tools, or procedures, that's the positioning piece. And then you look at what instruments are typically used: a stethoscope - not a big deal. Probably, nothing that requires any kind of positioning until you get to the pelvic exam and then there are standard types of things."

This conversation illustrated to us how the inaccessibility of women's health procedures and instruments can result in 'diminished' care for disabled women. In our discussion with Ms. Dimatteo, she described similar challenges in her experience going to the gynecologist:

> "The hardest part about it, about the whole process of going to an OB/GYN is due to my CP, my muscles are extremely tight, so it makes it difficult to maintain the positions they need to do the exams, so what often ends up happening is that they're only able to get a partial test result. They're not able to do a full exam, most of the time, just because my body can't handle it."

After the conversation Ms. Dimatteo, we narrowed down the target population to focus on women with CP. During both conversations the speculum was brought up multiple times as being one of the more inaccessible yet widely used instruments in OB/GYN; therefore, we decided to concentrate on designing a more accessible and accommodatable speculum to better suit women with CP for our narrowed scope.

2.2 Cerebral Palsy

2.2.1 What is Cerebral Palsy?

Cerebral Palsy is the most common motor disability in childhood. According to the CDC'S Autism and Developmental Disability Monitoring Network, in 2010, about 3 per 1,000 (1 in 345) 8-year old children were identified with cerebral palsy in the United States ("Data and statistics for cerebral palsy," 2020). *Cerebral* refers to the brain and *palsy* refers to the impairment or loss of motor function. Together, Cerebral Palsy, or CP for short, is a group of neurological disorders that affects motor coordination and body movement permanently. CP does not have a cure but treatments can improve the child's capabilities ("Cerebral palsy: Hope through research," 2021). CP varies from person to person but does not worsen over time. Someone with mild CP might walk a little awkwardly but may not need specialized help. Someone with severe CP, however, might need lifelong care, equipment to help them walk, or may not be able to walk at all ("What is cerebral palsy?," 2021).

2.2.2 Causes

Cerebral Palsy affects the cerebral cortex, which directs muscle movement. In some cases, the damage is a result of a brain injury that happens before, during, or after birth. In

other cases, CP is a result of abnormal development of the cerebral cortex during fetal growth ("Cerebral palsy: Hope through research," 2021). Congenital CP is when the child is born with the condition and constitutes the majority of cases. The causes of congenital CP include maternal fevers/infections, congenital brain malformations, genetic abnormalities, or fatal injury. Acquired CP is when the disorder begins shortly after birth, which is the minority of cases. The causes of acquired CP includes problems with blood flow to the brain, brain infections, brain damage, or head injuries. There are four main types of brain damage that can cause its characteristic symptoms including damage to the white matter of the brain, abnormal development of the brain, bleeding in the brain, or severe lack of oxygen to the brain. Damage to the white matter of the brain, periventricular leukomalacia (PVL), is when the white matter has tiny holes that cause interference in normal transmission signals. Abnormal development of the brain, cerebral dysgenesis, is when during fetal growth, there are interruptions in normal brain development, such as mutations, that cause interference in brain transmission signals. Bleeding in the brain, intracranial hemorrhage, is when a fetal stroke causes blocked, weakened, broken, or malformed blood vessels leading to bleeding. Severe lack of oxygen in the brain, asphyxia, is caused by an interruption in breathing or poor oxygen supply commonly due to labor and delivery ("Cause and timing," n.d.). In many cases, however, the cause of CP is unknown. ("Cerebral palsy: Hope through research," 2021).

2.2.3 Diagnosis

Most children will be diagnosed in their first two years of life. A child will be diagnosed with CP through evaluations and brain imaging techniques. During doctor visits, they will order a series of tests for evaluating the motor skills of the child. These tests may include the child's growth, development, vision, hearing, age-appropriate motor control,

muscle tone, posture, and coordination. The tests will help rule out other disorders with similar symptoms to CP ("Diagnosis," n.d.). Brain imaging (neuroimaging) techniques allow doctors to detect brain abnormalities that indicate movement disorders. There are four main types of neuroimaging techniques, which include cranial ultrasound, computed tomography, magnetic resonance imaging, and an electroencephalogram. Cranial ultrasound is one of the least invasive techniques as it uses high-frequency sound waves that will produce pictures of infants' brains. Computed tomography (CT) uses x-ray to show images of the brain structure and damaged areas. Magnetic resonance imaging (MRI) can create an anatomical picture of the brain's structure and tissues using a magnetic field, a computer, and radio waves. An electroencephalogram detects electrical activity in the brain using electrodes on the scalp. A change in the electrical pattern can help identify epilepsy ("Cerebral palsy: Hope through research," 2021).

2.2.4 Types of Cerebral Palsy

There are four types of CP. They are determined by the type, extent, and location of the abnormality. CP is classified by the type of movement disorder involved -- stiff muscles (spastic), writhing movements (athetoid), or poor balance and coordination (ataxic) -- and any additional symptoms such as paralysis (plegia) or weakness (paresis). The four main types include spastic CP, dyskinetic CP, ataxic CP, or mixed CP ("Cerebral palsy: Hope through research," 2021).

Spastic CP is the most common type of CP where the person has stiff muscles and awkward movements. There are three types of spastic CP including spastic hemiplegia/hemiparesis, spastic diplegia/diparesis, and spastic quadriplegia/quadriparesis. Spastic hemiplegia/hemiparesis typically affects the arm and hand on one side of the body (left

or right) and it can also include the leg. Spastic diplegia/diparesis includes muscle stiffness most severe in the legs and less severe in the arms and face. Spastic quadriplegia/quadriparesis is the most severe type of CP that affects the whole body and is often associated with a moderate-to-severe intellectual disability. Dyskinetic CP involves slow and uncontrollable writhing or jerky movements of the limbs. Dyskinetic CP also includes dystonic, athetoid, and choreoalthetoid CP. Ataxic CP affects depth perception and balance where they have poor coordination and walk unsteadily. Mixed CP is usually some combination of symptoms that do not refer to any one type of CP. For example, someone might have both too tight and too loose muscles for mixed CP ("Cerebral palsy: Hope through research," 2021).

2.2.5 Symptoms

CP symptoms can vary from person to person and may even change over time. Everyone with CP has posture and movement problems and some may exhibit an intellectual disability. People with CP may also have other medical disorders such as abnormal physical sensations or perceptions, impaired vision or hearing, communication issues, and seizures. There are general symptoms associated with CP and then, there are symptoms associated with a certain type of CP (summarized in Table 1) ("Signs and Symptoms," n.d.).

Table 1: CP Symptoms ("Signs and Symptoms," n.d.)

Type	Symptoms
General CP	● Weakness in one or more arms or legs ● Shaking (tremor) ● Random involuntary movements ● Variations in muscle tone (too stiff or too floppy) ● Excessive drooling ● Difficulties swallowing or speaking ● Delays in reaching motor skill milestones ● Difficulty with precise movements (writing or buttoning a shirt) ● Walking (on the toes, a "scissored" gait, or a crouched gait)
Ataxia CP	● Lack of muscle coordination when performing voluntary movements
Spasticity CP	● Exaggerated reflexes ● Stiff or tight muscles

2.2.6 CP Lifestyle

Many adults with CP will live full and independent lives. The level of independence will vary with each case. Adults with less severe types of CP may live on their own and work full-time jobs. Others with more severe types of CP may require full-time assistance to complete daily activities and tasks. Assistance can come in many forms including a personal care attendant and/or a service dog. As CP is a non-progressive disorder, the symptoms of CP will not decline. CP can be managed through various forms of alternative treatment methods, surgery, medications, or therapy (Cerebral Palsy Guide, 2021). As mobility limitations are a life-long concern, physical therapies can evaluate mobility, help improve joint movement, and improve overall strength. Wheelchairs or other assistive equipment (walkers, canes, and/or support devices) may be needed to help minimize limitations from decreased mobility. Some people with CP also have communication problems. Speech therapy can help provide individuals with resources for their communication needs (Warmbrodt, 2020). In addition to

CP, some people with CP may also experience other conditions such as intellectual disabilities and learning difficulties. About 30-50% or 1 in 2 people living with CP will have an intellectual disability. For those with spastic quadriplegia, intellectual disabilities are more common than those with other CP types. The brain damage can cause language development and intellectual functioning that may make it difficult to process specific auditory and spatial information ("Cerebral palsy: Hope through research," 2021). Many people with CP live full lives but will face challenges. One of those challenges should not be finding adequate basic healthcare ("Women's health initiative," n.d.).

2.3 Intersection of Women's Healthcare and Cerebral Palsy

Disabled women face challenges around women's healthcare and receive significantly less care than abled-bodied women. There are numerous reasons for this. In the U.S., 80% of doctors graduate from medical school without ever treating a disabled woman. In the doctor's offices, there is a lack of knowledge on how to provide adequate care or there is a physical access barrier. Also, real medical issues are far too often dismissed as a byproduct of CP. Consequently, women with CP may suffer from depression and isolation to having greater incidences of cancer. For example, the breast cancer mortality rate is three times higher than for able-bodied women ("Women's health initiative," n.d.).

In 2016, Byrne et al. interviewed 30 women with CP to define their experiences in the women's health care setting. They found five major and recurring themes from the interviews and focus groups that identified the absence of continuity of care. The five themes were (1) 85% discussed limited knowledge of providers and patients; (2) 61% discussed attitudinal barriers; (3) 58% discussed lack of accommodations; (4) 45% discussed the transition to adult care; and (5) 25% discussed exiting the healthcare system due to negative experiences. This

study was essential to developing a research agenda for addressing the deficiencies and barriers to care (Byrne et al., 2016).

The Cerebral Palsy Foundation (CPF) created the women's health initiative to identify the barriers to better healthcare, develop, and implement new approaches. The CPF is working with four partnering institutions each of whom is addressing a different aspect of women's healthcare. Gynecological needs and services are being investigated by the Weinberg Family Cerebral Palsy Center at Columbia University Medical Center. Sexual and reproductive health among adolescents is the focus of the work done at the Complex Care Service at Harvard's Boston Children's Hospital. Mammography patient-centered care is being promoted by the Rehabilitation Institute of Chicago and Northwestern University. Reproductive life planning and obstetrical care improvements are being looked at the Center for Cerebral Palsy at the UCLA Medical Center ("Women's health initiative," n.d.). There is also a need to address the medical equipment that remains inaccessible to women with CP.

2.4 Speculums

One of the most ubiquitous instruments in the field of gynecology is the speculum, a device used to hold open the walls of the vagina. It allows physicians to visualize the cervix and the interior of the vagina, perform examinations, and collect specimens such as cervical cells in a Pap smear ("Pelvic exams," 2020).

2.4.1 State of the Art

The current state of the art for speculum involves manual opening of the vaginal canal using two bills, sometimes referred to as blades. These bills are together as the physician inserts the speculum. Once the speculum is inserted into the vaginal canal, an adjustment lever

is engaged to separate the speculum's two bills, opening the vaginal walls and providing access to the cervix (Schwartz et al., 2020). Speculums are made from plastic and metal and come in a variety of sizes (see Figure 3 and 4).

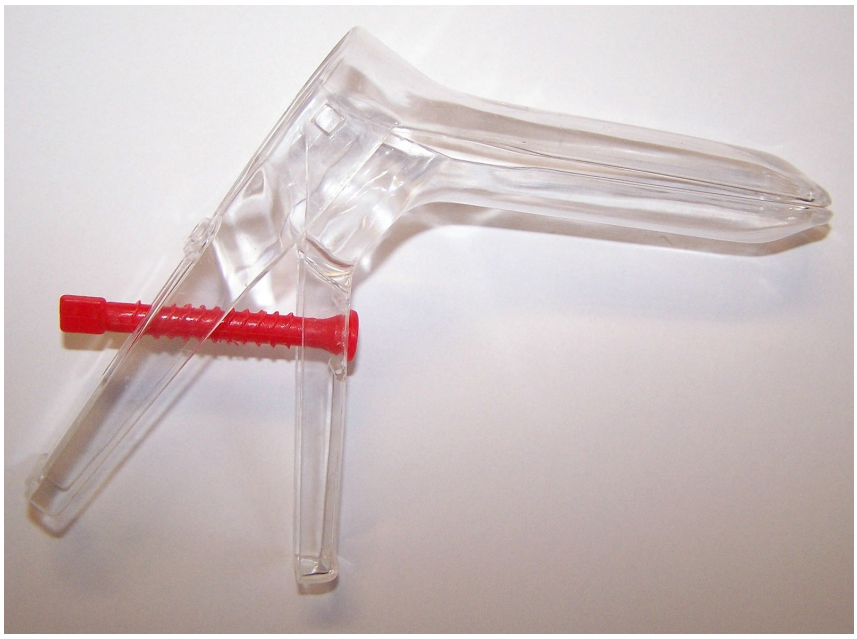


Figure 3: A clear, plastic speculum before deployment.

Figure 4: Stainless steel speculum.

This device is a crucial aspect of obstetrics and gynecology and allows a physician to perform many ‘crucial’ procedures. These procedures include pelvic exams, Pap smears, intrauterine insemination, obstetric examinations, and more; however, the device can be inaccessible, painful, or impossible to use for some disabled women.

2.4.2 Patents

The ‘duck-billed’ speculum is the most common and well-known device used to perform these crucial procedures in obstetrics and gynecology; however, there are other patented speculum designs aimed at improving the current ‘duck-billed’ design. The team researched existing patents and found two common designs including an inflatable speculum and camera-guided speculum.

2.4.2.1 Inflation Speculum

One common theme found when doing a patent search was inflatable speculums. Two patented devices were found that use an inflation mechanism (Figure 5). The first patent used an “un-rolling” mechanism (i.e., when inflated, it would be unrolled/unraveled to expand into a hollow cylindrical shape) and is a mandrel. The device was made of an elastic, inflexible, biomaterial material (i.e., polypropylene, polyethylene, rubber, or plastic) with an antimicrobial compound coating that does not collapse. However, the device did contain an emergency release mechanism that was within the physicians and patients control (Deslauriers et al., 2003). The second patent that was looked at had the inflatable material folded up in a trapezoidal cross-sectional shape that when inflated using a pump, would become a hollow cylinder. The device had two flexible layers and a light source (DesLauriers et al., 2006).

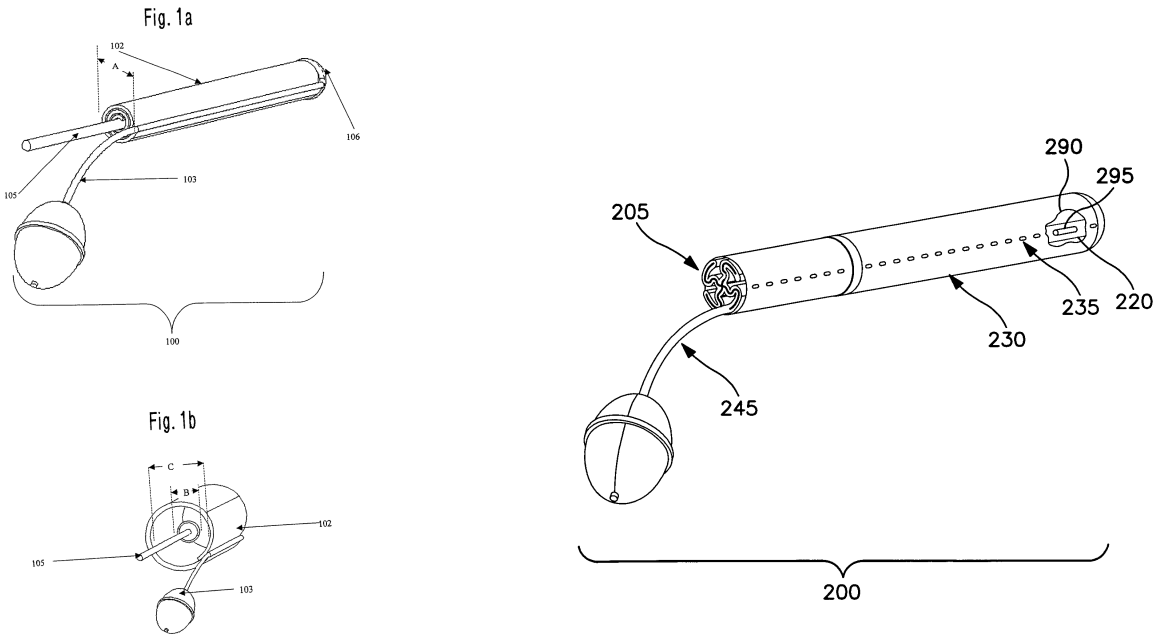


Figure 5: Left: Unrolling Inflatable Mechanism Speculum Patent (Deslauriers et al., 2003). Right: Inflatable Trapezoidal Cross-Sectional Shaped Speculum Patent (DesLauriers et al., 2006).

2.4.2.2 Camera-Guided Speculum

We also found two patents for a camera-guided device (see Figure 6). The first patent was for a device that had a camera and a light source that was used to guide the swab to the cervix; however, the whole device was needed to move in order to move the swab. The device also had pH and temperature probes for measurements inside the cervix (Millard et al., 2017). The second patent was an inserter with an image capturing device that had an LED, a control panel, and an anti-reflection coated, hydrophobic window for viewing. The device could fit different cervix sizes meaning it could transition from an ellipsoid cross-sectional to a circular cross-sectional profile. The device could also allow a swab to pass through its internal space to collect a sample (Ramanujam et al., 2019).

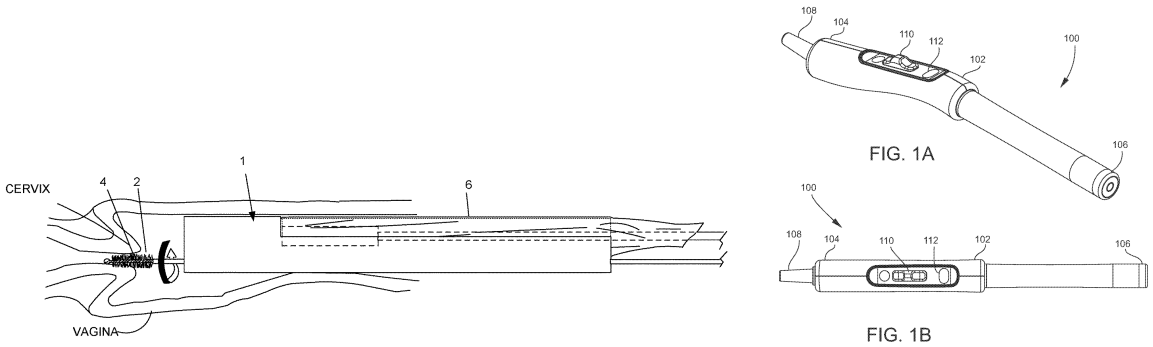


Figure 6: Left: Camera Speculum Patent (Millard et al., 2017). Right: Inserter with Image Capturing Speculum Patent (Ramanujam et al., 2019).

2.4.3 Inaccessibility and Inadequacies

During most procedures that require a speculum (such as pelvic exams, Pap smears, or vaginal exams during pregnancy), the patient will be asked to lay on her back and put her legs in an open position, oftentimes with the use of stirrups ("Well-woman visit," 2018). This positioning can be problematic for women with CP. Schwartz et al. conclude that "positioning should be varied according to their physical limitations and contractures and may require extra staff or special equipment for assistance." This extra equipment may include adjustable exam tables or accessible stirrups; however, some women may still not be able to get into the ideal positioning for these exams due to shaking, involuntary muscle movements, tight muscles, or poor muscle tone. Thus, the physician may have trouble inserting the speculum or using the device to perform examinations and tests. The exaggerated reflexes and stiff and tight muscles that women with CP experience may result in discomfort or injury while the doctor is performing the examination. These factors may lead to incomplete test results or a doctor discontinuing the use of the speculum for a disabled patient. For this reason, the most commonly used speculums remain inaccessible to many women with CP.

2.4.4 Importance

The importance of a woman receiving proper reproductive healthcare is crucial to her overall health. Pap smears specifically, which can detect cancer and other abnormalities are of vital importance since the prognosis of these diseases, such as cervical cancer, depend heavily on early screening. Hence why women over the age of 21 are encouraged to receive a pelvic exam and Pap smear yearly ("Well-woman visit," 2018). However, disabled women are less likely than able-bodied women to receive yearly care, such as Pap smears or pelvic exams (Armour et al., 2013). The rigid body of the speculum used to perform a Pap smear can cause problems for women with CP and result in painful or incomplete tests and examinations. Disabled women deserve access to medical devices that work for them. This project aims to design a speculum that will work for women with CP in order to increase access to life-saving procedures and examinations.

Chapter 3: Project Strategy

This chapter reviews our project strategy, specifically the client statement, functions, objectives, and constraints that we outlined in order to reach our project goals

3.1 Initial Client Statement

Women's healthcare is vital, yet disabled women still have worse health outcomes than abled-bodied women. Medical devices and procedures used in obstetrics and gynecology (OB/GYN) can be very unaccommodating to disabled women. Our MQP aims to evaluate the ways a specific sect of OB/GYN (ex: a medical device or a specific practice) is inaccessible to disabled women. Then redesign or propose a new, more accommodating and comfortable method.

3.2 Design Requirements

The functions, objectives, and constraints were determined after narrowing down the project population to women with CP and scope to the speculum used in OB/GYN exams. These will be used in the design process.

3.2.1 Functions

Five key functions were identified for the device's optimal performance.

3.2.1.1 Provide Access to the Cervix

The instrument will need to provide the doctor access to the cervix even if the patient cannot assume typical exam positioning (lithotomy position). The instrument will also need to allow the doctor the ability to see the interior structures of the cervix.

3.2.1.2 Maintain Access

The instrument will need to maintain the ability to access the cervix for long enough to visually assess the area and capture specimens for testing (ex: capturing cervical cells).

3.2.1.3 Minimally Invasive

The instrument will need to be minimally invasive. It will also need to allow for quick and relatively painless insertion.

3.2.1.4 Adjustable

The instrument needs to have adjustable functions which include the size starting as minimal as possible, giving the doctor the ability to expand as needed, and performing the above functions while also maintaining comfort.

3.2.1.5 Accommodate Movement (i.e., withstand bending)

The instrument needs to be able to withstand bending for any involuntarily or voluntarily shifts in movement during the exam. It also cannot be painful or pinch the tissue if it moves once the exam starts. This can be done through using a flexible material that can accommodate the patient's muscle tone and their ability to get into position.

3.2.2 Objectives

Two main objectives were identified to make the device not only functional, but amenable to our target population of women with cerebral palsy.

3.2.2.1 Accommodatable

The instrument will need to accommodate women with physical disabilities, such as CP. It will also need to perform the above functions for a doctor examining a woman with CP, who may have challenges assuming or maintaining the “proper” exam position due to muscle tone.

3.2.2.2 Completion of Exam

The instrument will need to allow for proper examinations. It will also need to allow for a complete collection of any samples while also not causing the patient any pain or discomfort.

3.2.3 Constraints

There are four constraints that will need to be considered when designing the final product/instrument.

3.2.3.1 Size

A 1996 study measured the shape and dimensions of the vagina by making 3D vinyl polysiloxane casts. The vaginal lengths were found to be between 6.86cm to 14.81cm. Our device should be long enough to reach this maximum length of 14.81 cm. The internal widths were found to be between 4.8cm to 6.3cm and the introital diameters (i.e., the opening of the vagina) were found to be between 2.39cm to 6.45cm. The device, therefore, should never

expand more than this to ensure comfort and safety. It is necessary for the device to be as small as possible upon insertion. (Pendergrass et al., 1996).

3.2.3.2 Time

A typical pelvic exam usually takes 3-5 minutes from start to finish, with the insertion of the speculum taking an average 1-2 minutes (Ben-Joseph, 2017). Therefore, our instrument should be able to be inserted within 1-2 minutes. It should also be able to remain in place for the entirety of the procedure, a maximum of 5 minutes.

3.2.3.3 Usability

The instrument should be easy to use and intuitive for the doctor to become knowledgeable on its use relatively quickly.

3.2.3.4 Patient-Friendly

The instrument should be patient-friendly. This means the aesthetics of the device should not be intimidating or overwhelming when presented to the patient.

3.3 Revised Client Statement

Women's healthcare is vital to preventing, diagnosing, and treating many diseases, yet disabled women, such as those with Cerebral Palsy (CP), have worse health outcomes than abled-bodied women. This may be in part due to medical devices and procedures used in obstetrics and gynecology (OB/GYN) being unaccommodating to disabled women. Our MQP aims to evaluate the ways a standard speculum is inaccessible to women with CP. We aim to design a device that will allow for proper and comfortable examination of a woman who may have challenges getting into the proper exam position due to her disability. To accomplish this,

this device should provide access to the cervix, without creating an expansion force of over 13 Newtons or expanding to a width greater than 3 centimeters to allow for swab collection of cells as well as patient comfort; furthermore, the device should be at least 15 centimeters long to provide access to the cervix of patients with various vaginal lengths.

3.4 Project Approach

At the beginning of each term, we made a proposed plan for what we wanted to accomplish by the end of the term.

3.4.1 A Term

During A Term, we conducted research to narrow down the scope of the project and become knowledgeable on the narrowed scope. At the beginning of A Term, we began with the initial client statement. Next, we conducted background research, literature review, stakeholder interviews, and patent searches to define the project scope. Finally, A Term ended with a revised client statement that included functions, objectives, and constraints. See Table 2 for the week-by-week timeline of A Term.

Table 2: A Term Plan

WEEKS:	1	2	3	4	5	6	7
DATES:	8/30-9/3	9/6-9/10	9/13-9/17	9/20-9/24	9/27-10/1	10/4-10/8	10/11-10/13
GOALS							
Final decision on topic							
Literature Review							
Draft Introduction							
Conduct Interviews							
Design Section							
- Objectives							
- Functions							
- Means							
- Design Alternatives							
- Revised Client Statement							
Planned Methods							
Gantt Chart for B term							

3.4.2 B Term

During B Term, we focused on brainstorming ideas for our preliminary and final designs. B Term also focused on designing the methods and experiments for testing the preliminary and final design by researching dimensions, forces, and standards. Continuously throughout B Term, we updated the report with the new information from the preliminary designs to the final design selection. We also updated the report with any recommended revisions from the A Term report. See Table 3 for a week-by-week timeline for B Term.

Table 3: B Term Plan

WEEKS:	1	2	3	4	5	6	7	8
DATES:	10/25-10/29	11/1-11/5	11/8-11/12	11/15-11/19	11/22-11/26	11/29-12/3	12/6-12/10	12/13-12/16
GOALS								
Incorporate revision on A-term Report								
Update report with new information								
Description of experimental methods used to test alternate designs								
Description and documentation of all experiments and tests								
Conclusions from tests								
Choice of preliminary design or final design								

3.4.3 C Term

The focus of C Term was to finalize the design and build a prototype of the device. Also, during C Term, we created methods and began testing those methods for validation and verification. This helped with redesigning and completing the final design. We also

incorporated any feedback from B Term into the report and had a completed outline of the first draft of the final report. See Table 4 for a week-by-week timeline for C Term.

Table 4: C Term Plan

WEEKS:	1	2	3	4	5	6	7	8
DATES:	1/12-1/14	1/18-1/21	1/24-1/28	1/31-2/4	2/7-2/11	2/14-2/18	2/21-2/23	2/28-3/4
GOALS								
Engineering Design								
Finalize Mechanism Specifications								
Calculate Device Dimensions								
Order Materials								
Construct Prototype								
Testing								
Create Validation and Verification Methods								
Test Validation and Verification								
Final Design (Redesign)								
Report								
Incorporate Feedback into Report								
Finish Chapter 4								
Write Chapter 5								
Write Chapter 6								
Write Chapter 7								
Write Chapter 8								
Finish First Draft of Report								

3.4.4 D Term

In D Term, we obtained materials to build the final prototype and the cervical model we used for validation testing. We also finished verification and validation testing and analyzed the

data. Two abstracts were written; one was submitted to the Northeastern Bioengineering Conference and one was submitted to the WPI BME department in preparation for Project Presentation Day. We also created and practiced our final presentation for Project Presentation Day. Lastly, we incorporated feedback, finalized, and submitted the final report for the eCDR. See Table 5 for a week-by-week timeline for D Term.

Table 5: D Term Plan

WEEKS:	1	2	3	4	5	6	7
DATES:	3/14-3/18	3/21-3/25	3/28-4/1	4/4-4/8	4/11-4/15	4/19-4/21	4/25-4/29
GOALS							
Engineering Design							
Obtain materials for updated prototype and model	■						
Finalize Version 3.0	■	■	■				
Construct model for validation testing	■	■	■				
Create multiple balloons for testing	■	■	■				
Testing							
Finish V&V testing	■	■	■	■			
Finish Analyzing Data	■	■	■	■	■		
Important Due Dates							
Final Title of Project (March 25)		■					
One Page Abstract (Mar 21)	■	■					
Two-Page Abstract (April 4)		■	■				
Create and practice presentation					■	■	
Final Presentation (April 22)						■	
Incorporate Feedback into Report			■	■	■	■	
Finish writing final report	■	■	■	■	■	■	
Final report edits					■	■	
Submit eCDR (April 28th)							■

Chapter 4: Design Process

This chapter reviews the design process on how the final design was selected. First, the needs analysis and design requirements are discussed to describe the functional needs and design specifications for the device to meet. Next, the preliminary designs are discussed and then narrowed down to the two alternative designs. The alternative designs were described a step further in the design process before the final design was selected.

4.1 Needs Analysis

The criteria the device needed to meet and those that it would be advantageous but not critically necessary for it to meet are described in the Needs and Wants Analysis, and the functional needs are ranked by order of importance.

4.1.1 Needs and Wants Analysis

The goal of this device is to allow disabled women, specifically those with CP, to receive comprehensive and comfortable Pap smears. Consequently, this device must provide a physician with access to the patient's cervix for visual assessment along with the ability to capture of cervical cells. Ideally, the device would accomplish this with a design that is not only functional, but aesthetically pleasing and unintimidating to the patient. It would also be beneficial for the cost of the final product to be comparable to or less than that of current speculum models. The cost of the product will be dependent upon whether it is reusable or single use.

4.1.2 Functional Needs

The functions discussed in section 3.2.1 were ranked in order to assess their overall importance to the design in relation to each other (Table 6). Each function was ranked against the others. If the team judged one function to be more important than the other, it received a 0.5. If it was less important, it received a 0, and if more important, a 1. These scores were totalled.

Table 6: Weighted Functions and Objectives

	Access to the Cervix	Maintain Access	Minimally Invasive	Adjustable	Accommodate Movement (i.e., able to bend)	TOTAL
Access to the Cervix	X	0.5	1	1	1	**3.5**
Maintain Access	0.5	X	1	1	0.5	**3**
Minimally Invasive	0	0	X	0.5	0.5	**1**
Adjustable	0	0	0.5	X	0.5	**1**
Accommodate Movement (i.e., able to bend)	0	0.5	0.5	0.5	X	**1.5**

Based on the weighted functions chart, the highest ranked, and therefore most important, function was access to the cervix with a score of 3.5. The next most important function was maintaining access followed by accommodating movement. The two least important functions were being adjustable and minimally invasive. Ranking the functions will allow the team to see what is the most important function that the device will need to have, which influenced the design.

4.2 Design Requirements

Before building a prototype, we considered the standards and specifications the device will need to follow.

4.2.1 Engineering Standards

For any medical device, the FDA will classify them into one of three classes (class I, II, III) ranging from low to high risk medical devices. The FDA classifies vaginal speculums under vaginal pessary devices, which is also what this device will be classified as. The vaginal pessary devices are class II devices (i.e., moderate risk) and are exempt from a 510(k) submission. The vaginal pessary device does not contain specific standards associated with it besides the international standards (Product classification, 2021). The international recognized standards are used to ensure good manufacturing practices are in place to protect the patients.

- ISO 13485:2016: Quality Management For Medical Devices
- ISO 10993: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 14971: Medical devices - Application of risk management to medical devices

Our device, should it ever be brought to market, would need to meet the requirements outlined in these international standards.

4.2.2 Specifications

4.2.2.1 Expansion Force

A 2007 study at the University of Michigan evaluated intravaginal closure pressure through studying the force of maximal voluntary contractions. The women in the study all

exhibited a range of forces at various examinations, with the highest value being 13 newtons (N) (Miller et al., 2007). Therefore, the device should be able to withstand and exert 13 N of force in order to hold the vaginal walls open.

4.2.2.2 Dimensions

As stated in Chapter 3, a 1996 study measuring the internal dimensions of the vagina found vaginal lengths (6.86cm to 14.81cm), internal widths (4.8cm to 6.3cm), and the introital diameters (2.39cm to 6.45cm) (Pendergrass et al., 1996). Also, the diameter of the cervix is about 2.5 cm in diameter (Nott et al., 2016). The device should be at least 15 cm long to accommodate women of all anatomy, though the device does not need to be fully inserted for every patient. The width when the device is closed should be within 1-2cm in diameter to be as small as possible and still be under the minimum introital diameter. When the device is open, it should be 3cm in diameter as this will provide enough visualization to the cervix, while being smaller than the minimum internal width.

4.2.2.3 Reusability and Disposability

Materials comprising the tubing portion of the device should be disposable for ease of production as well as increased sterility. For cost effectiveness, any medical imaging components, such as cameras, can be reusable, but must be able to be disinfected to prevent microbial growth, which could cause infections.

4.2.2.4 Safety

At all times, the device cannot pose a threat of injury to the patient. The insertion of the device should be relatively painless, regardless of the exam position the patient assumes. After

insertion, any opening mechanisms should cause no pain, pinching, tearing, or have sharp edges.

4.3 Conceptual Designs

We created several preliminary designs to meet the requirements outlined in section 4.2. We then evaluated these concepts and selected three to move forward in our design process.

4.3.1 Preliminary Designs

During the early stages of brainstorming, five original preliminary designs were considered.

4.3.1.1 Inflatable or Expandable Speculum

One of the first ideas discussed was from the concept of stents used to hold open narrowed or blocked arteries. The idea for this would be to have a catheter-sized tube that would be inserted. Then, either have a mesh-like structure that would expand or a hollowed balloon that would be inflated to provide visual access to the cervix. The inflation/expansion mechanism would be different from the current mechanism of opening two bills because it would stay as one piece while the diameter of the cylinder would expand. However, the mesh structure of a stent is made of a rigid metal material with angles that could pinch surrounding tissue upon opening/closing of the device.

4.3.1.2 Camera-Guided Device

The idea for a camera-guided device came from camera-guided surgeries such as an endoscopy. As cameras are used for visualization during common medical procedures without

needing much space, it was thought that they could be used for visual access of the cervix. The whole device can be as small as a urinary catheter and would not necessarily need to open once inserted. Catheters are very flexible materials so this device could potentially move with any involuntary movements that women with CP may experience during the exam; however, some challenges with this device would be how to collect a specimen sample with a swab.

4.3.1.3 Backwards Speculum

While researching the current speculum designs, it was noticed that one end of the speculum stayed fixed while one end opened. For instance, the diameter of the speculum was held fixed at the opening of the vagina whereas the diameter of the speculum at the cervix was expanding when the bills were opening. The idea for this design would be to hold the diameter of the speculum at the cervix fixed and make bills open (i.e., expand the diameter) at the opening of the vagina. The mechanism would not change from the current speculum. The device would just open in the opposite direction, which was thought to maybe be more comfortable for the patient. However, it was found early on that the problem with pelvic exams is with the speculums so this design may not help fix the problem using the same mechanism.

4.3.1.4 Collapsible Speculum

Another design concept initially explored was the idea of a speculum with a less permanent opening than the deployment of the traditional speculum. Though most speculums can be deployed at various sizes, once the size is selected by the doctor - in plastic speculums, this occurs as the device makes a clicking sound - it can only be undone by the doctor. The force of the patient's body or any movements they make would not likely be enough to undo this mechanism or shift or close the device. For disabled women, specifically those with CP,

poor muscle tone, or involuntary movement, this may be a source of the inaccessiblity of the speculum; therefore, we entertained the idea of a device that uses less force to open and could close according to the patient's movement.

4.3.1.5 Opening at Cervix

The final concept proposed during the initial stage of the design process was a tool that opens only at the cervical-facing end, rather than along the entire instrument. The vaginal walls would experience less displacement, potentially increasing the comfort for women with CP during a cervical exam. However, a major challenge with a design that opens at the cervix, but stays narrow throughout the vagina, would be visualization of the cervix and extending a swab through the device to collect cervical cells.

4.3.2 Narrowed Designs

The five preliminary designs were then narrowed down to three potential designs. The designs were either combined or crossed out altogether. The three designs were an inflatable speculum, expandable and collapsible speculum, and camera-guided catheter. These were chosen because of the potential room to improve them without redesigning current devices. The inflatable and expandable/collapsible speculum would also incorporate the idea of a less permanent opening. The camera-guided design will incorporate an opening that is at the end instead of the whole device. However, the backwards speculum was crossed out altogether because it was very similar to the existing speculum. For the narrowed three designs, a more in-depth patent search was done and the ideas were then expanded.

4.3.2.1 Inflatable Speculum

Two patents were found in section 2.4.2.1 for inflation speculums. There was room for improvements to create our design to make them more patient-friendly and aesthetically appealing. Our design would use the balloon-stent mechanism that was the preliminary idea but will end up being a hollow cylindrical device when inflated. It will be hollow to allow visual access to the cervix and allow for a swab to pass through the middle of it to collect a sample of cells. The material will be flexible. The device will have an automatic emergency release mechanism to allow the device to deflate if something happens and the physician could not release it quick enough. The device will be able to hold in place under a certain amount of force. However, if the force is exceeded and/or the patient moves, the automatic emergency release will be triggered and the device will collapse. See Figure 7 for a preliminary drawing of this idea.

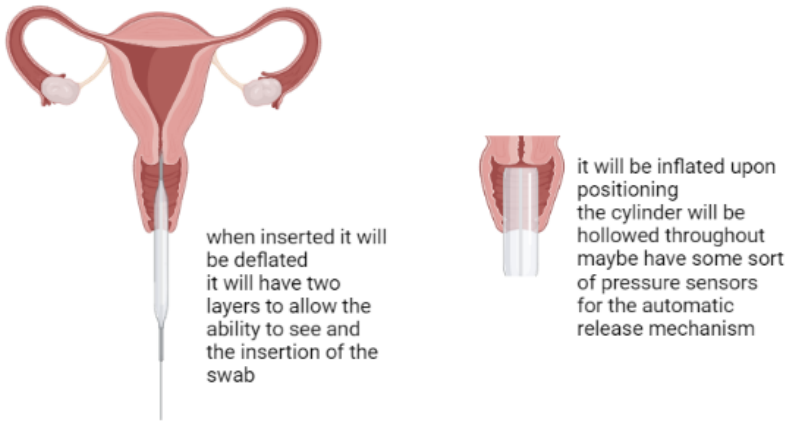


Figure 7: Preliminary Drawing of the Inflatable Speculum

4.3.2.2 Expandable and Collapsible Speculum

A flexible speculum that could expand and contract with patient movement remained an attractive idea as designs were narrowed down. At the preliminary design stage, the

mechanism of this concept was modeled after a stent: an expandable lattice network that remains closed until deployment. If, like a stent, the expandable lattice work was made of metal, this network would have to be encapsulated in an expandable, comfortable material to ensure the device would not cause pinching or discomfort. A physician could initiate expansion of the device after insertion into the vagina using a lever at the handle; however, unlike traditional speculums, the lever would not lock into place; consequently, if the patient were to shift voluntarily, contract vaginal muscles, or have an involuntary muscle movements, the device would respond to the force exerted on it by collapsing to the smaller diameter. At the handle there would be a viewfinder, for the physician to visualize and access the cervix, and cells could be collected for a Pap smear. Unlike the traditional rigid speculum, the lattice expansion could offer a degree of flexibility. This could benefit women with CP, who might not be able to get in the lithotomy exam position. Figure 8 shows a preliminary drawing of this idea.

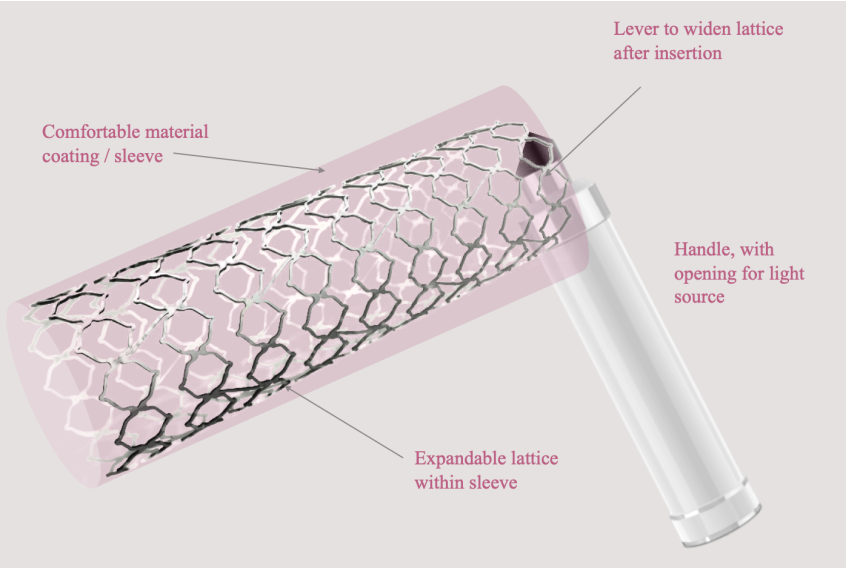


Figure 8: Preliminary schematic for the Expandable and Collapsible Speculum

4.3.2.3 Camera-Guided Catheter

In section 2.4.2.2, another patent search was done and two patents were found for a camera-guided device. There was room for improvements to create our design to be more accommodable and patient-friendly. Our design would use a thin tube (catheter-like size) with a camera at the end. The camera could potentially be the size of a grain of salt with a light source. The camera will provide visual access during the exam and will help guide the swab to collect the specimen sample. There could potentially be an opening aspect at the end of the device to allow the physician to collect the sample. Also, the swab could be made of a small flexible material that could be inserted through the catheter. For instance, during some robotic surgeries using a camera, samples are taken and this technology could potentially be used to take samples from the cervix. See Figure 9 for a preliminary drawing of this idea.

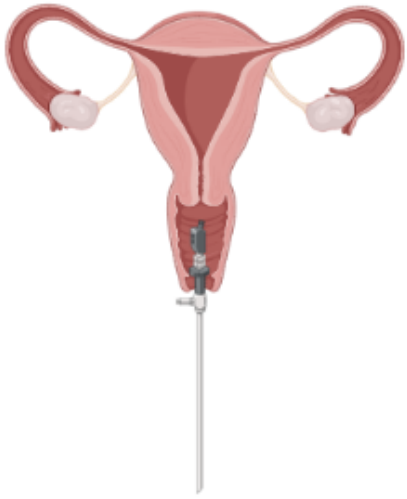


Figure 9: Preliminary Drawing of the Camera-Guided Catheter

4.4 Alternative Designs

The three designs were narrowed down to two: the flexible and collapsible speculum and the camera-guided catheter. The two designs were chosen using a pairwise comparison

chart (see Table 7). We compared the three designs from above to the current duck-bill speculum as the baseline for each function identified in Section 3.2.1. The ranking were -1 if the concept lags behind baseline, 0 if concept was comparable to baseline, and 1 if concept outperforms baseline.

Table 7: Pairwise Comparison Chart of Preliminary Designs

	Baseline: Duck-bill speculum	**Inflatable Material**	**Expandable & Collapsible Speculum**	**Camera-guided Instrument**
Access to the Cervix	0	0	0	0
Maintain Access	0	-1	-1	0
Minimally Invasive	0	0	1	1
Adjustable	0	1	1	0
Accommodate Movement (i.e., able to bend)	0	1	1	1
Total	**0**	**1**	**2**	**2**

Based on the pairwise comparison chart, the expandable and collapsible speculum and camera-guided instrument was tied for the highest score. The inflatable material speculum had the lowest score. Also, the inflatable speculum did have similar patents already. There was room for improvements with the inflatable speculum, however, based on the score and patents, it was taken out of the running for the potential final design. Therefore, our two alternative designs were the expandable and collapsible speculum and camera-guided catheter. We took each of these ideas a step further before determining the final design.

4.4.1 Flexible and Collapsible Speculum

Due to its ability to meet the core functions of our device, the idea of a flexible and collapsible speculum was explored further. Many features were conserved, such as the metal lattice contained within a comfortable material and device opening to allow for visualization and exam specimen collection.

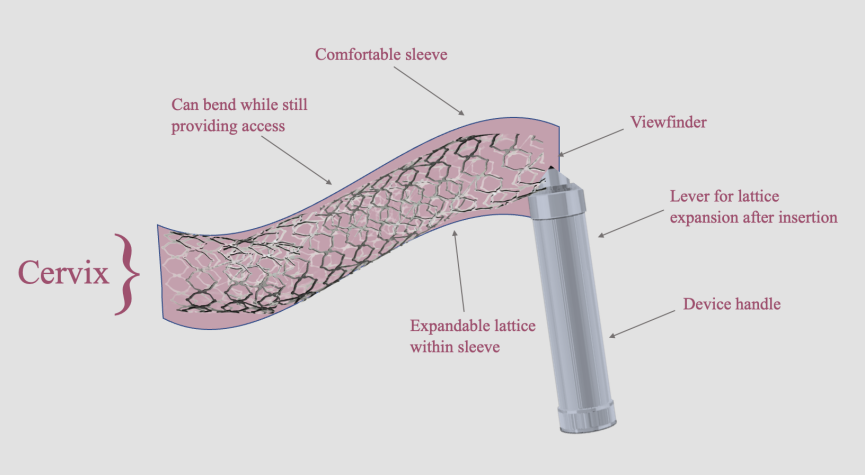


Figure 10: Updated Drawing of Flexible Speculum

If the patient was unable to get in an exam position (lithotomy position), the device could bend slightly, as seen in the updated Figure 10. The flexible speculum could also expand and contract with patient movement. The expandable lattice network would remain closed during insertion until deployment. Upon deployment, this device would expand, exerting enough force on the vaginal walls to separate them to a maximum of 3 cm at the cervix-end. Unlike a traditional speculum, the goal of this device would not be to lock into place. If the patient was to shift during examination, the device should flex with their body movements, not remain in a fixed conformation, which could pose a risk of injury or discomfort. The figure also details a lever that the physician could deploy. To ensure accommodation, the lever could trigger opening at various degrees.

4.4.2 Camera-guided Catheter

The updated design for the camera-guided catheter included the combination of two of the preliminary ideas. The combined idea was a camera-guided catheter with a flexible cone-shaped opening at the end of the catheter. The catheter will be made of a flexible material to move around a 'bend' if the patient is not in the ideal position, which will be important for the target population. The device will be made of three components: the camera, the catheter, and the swab. The camera component will include a monitor to display images and it will be reusable, which also means it will be disinfectable. The catheter will be used to guide the camera and swab to the cervix and will be disposable after a single-use. The swab will be used to collect a specimen sample of the cervix. A more updated drawing was made (see Figure 11).

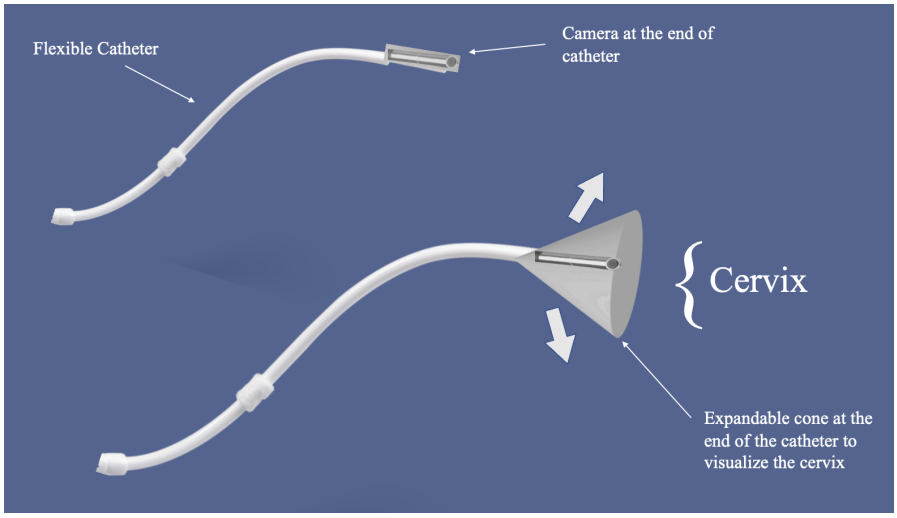


Figure 11: Updated Drawing of Camera-Guided Catheter

4.5 Final Design Selection

The two updated alternative designs were compared using another pairwise comparison chart (see Table 8) to select the final design. The same rankings were used as before.

Table 8: Pairwise Comparison Chart of Alternative Designs

	Baseline: Duck-bill speculum	**Expandable & Collapsible Speculum**	**Camera-guided Catheter**
Access to the Cervix	0	0	0
Maintain Access	0	-1	0
Minimally Invasive	0	1	1
Adjustable	0	1	1
Accommodate Movement (i.e., able to bend)	0	1	1
Total	**0**	**2**	**3**

Based on the pairwise comparison chart, the design with the highest score was the camera-guided catheter. The team also thought the camera-guided catheter had the most potential for innovation and suiting the target population. Therefore, the camera-guided catheter was chosen as the final design.

4.5.1 Preliminary Mechanisms

Once the camera-guided design was selected, the first design challenge was to create a mechanism of separating the vaginal walls at the cervix, so the camera could visualize this structure. Four preliminary design ideas were created to propose a mechanism of opening for this part of the device.

4.5.1.1 Petals-Opening

One concept the team explored was a four blade mechanism, as opposed to the two blades of the traditional speculum. In this concept, the blades would open up in four directions; therefore, a possible advantage of this choice would be retraction of the vaginal walls in

multiple directions, as opposed to up and down. This mechanism could be powered by a pin and slot joint and would possible be loaded by a spring as seen in Figure 12.

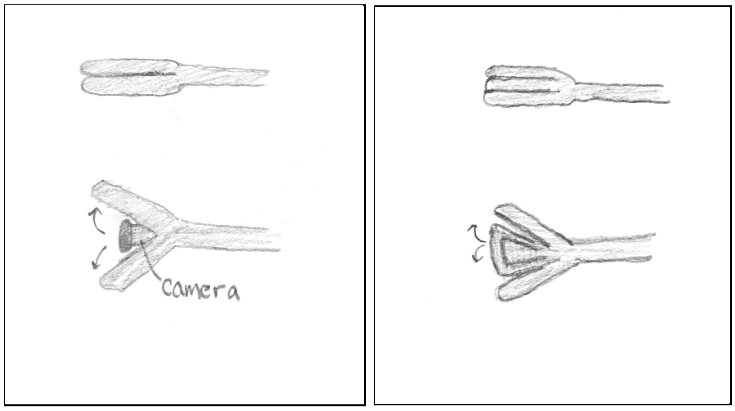


Figure 12: Preliminary sketch for a two-billed (left) or four-billed (right) opening of the device around the camera at the cervix.

4.5.1.2 Pull or Push-Triggered Expansion

A second concept was a lever-triggered expansion of a network of spokes. Similar to an umbrella, this concept would involve metal wires encircled in a comfortable material beginning in a closed configuration. Then, the physician would trigger the expansion of the wires through deployment of a lever. This concept would require the translation of horizontal force and displacement at the instrument handle to expand the four spokes as seen in Figure 13.

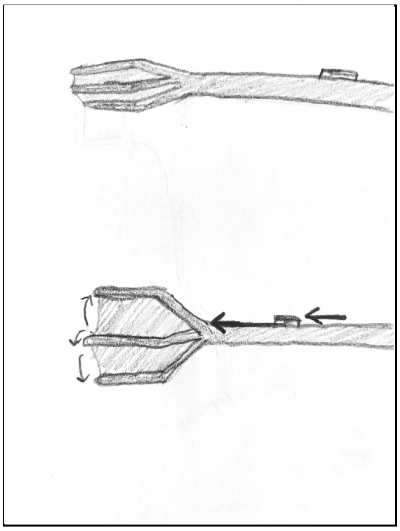


Figure 13: Preliminary sketch for a pull or push-triggered expansion mechanism.

We proposed that the opening of these spokes would expand upon the anterior and posterior walls of the vagina at the cervix-end and allow the camera access.

4.5.1.3 Inflation-Powered Opening

Another potential idea for an opening mechanism was an inflation-powered opening. This inflation-powered opening would use the same concept as a blood pressure cuff where the device would have an air pump to inflate the balloon-like material that is at the end of the catheter. The mechanism device would be deflated upon insertion. Then the physician would inflate the device with air and it expands like a balloon, as seen in Figure 14. The inflated device would provide the camera visualization of the cervix.

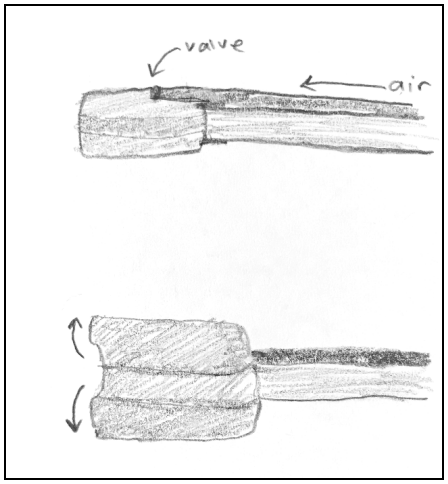


Figure 14: Preliminary drawing of an inflation-powered opening of the device.

4.5.1.4 Spring-Loaded Slider

The last potential idea for an opening mechanism was a spring-loaded slider. The idea behind this mechanism would be to have a cover that can slide off to allow the device to spring open, as seen in Figure 15. The device would have spokes encased in a comfortable material that was spring-loaded, which would allow the natural position of the spokes to be in the expanded form. The cover can slide back on over the spokes allowing the device to close and become narrow for insertion and removal of the device. There would be a button or lever that can help control sliding the cover on/off. However, one safety concern with this mechanism is with the spokes and springs potentially pinching or tearing the tissue upon opening/closing the device.

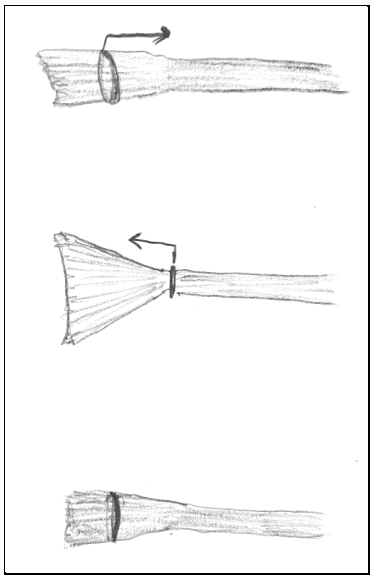


Figure 15: Preliminary drawing of a spring-loaded slider

4.5.2 Alternative Mechanism

The four preliminary mechanisms were narrowed down to two: petals-opening and inflation-powered opening. The two mechanisms were chosen using a pairwise comparison chart (see Table 9). We compared the four mechanisms from above to the current duck-bill speculum as the baseline for each function identified in Section 3.2.1 along with the design specifications identified in 4.2.2. The same rankings were used as above.

Table 9: Pairwise Comparison Chart of Preliminary Mechanisms

	Standard: Duck Bill	Petals	Umbrella	Inflation	Spring-Loaded
Access to the Cervix	0	0	0	0	0
Maintain Access	0	0	0	0	0
Minimally Invasive	0	1	1	1	1
Adjustable	0	-1	-1	1	-1
Accommodate Movement (i.e., able to bend)	0	1	1	1	1
Expansion force of 13 N	0	0	0	0	0
Starts at 1-2 cm, opens to maximum of 3 cm (in diameter)	0	1	1	1	1
Safe to use	0	1	-1	0	-1
Fast deployment of mechanism	0	0	0	0	1
Patient-friendly aesthetics	0	1	1	0.5	0
Total	0	4	2	4.5	2

Based on the above pairwise comparison chart, the petals-opening and inflation-powered opening had the two highest scores. The pull or push-triggered expansion (umbrella) and spring-loaded slider were tied for the lowest score and had some safety concerns associated with the spokes. Therefore, the pull or push-triggered expansion and spring-loaded slider were taken out of the running for the potential final mechanism. Our two alternative mechanisms were the petals-opening and inflation-powered opening, which we took a step further before determining the final mechanism.

4.5.2.1 Petals-Opening

Before taking this mechanism a step further, similar existing mechanisms were explored. Currently, three devices had similar mechanisms for opening a multi-bladed speculum. One device was specifically made for obese patients and used a rotating collar mechanism. Upon rotation of the collar, the four blades would spring open to allow an unobstructed view of the cervix or close for the insertion/removal of the speculum (Barra et al., 2002). Another device was the Patton speculum that had a squeezing mechanism with a ratchet lock. For this mechanism, the physician would squeeze the handle to expand the four blades and then lock in place allowing a visual of the cervix ("510(k) Summary: Patton Speculum," 1999). The last device explored was a four bladed speculum that utilized a screw mechanism. The screws were rotated to expand and hold the blades in place for visualizing the cervix (Advanced Medical Innovation, n.d.). Although these device mechanisms were similar, the blades were along the entire length of the device that was inserted. Our mechanism would only need the petals directly at the end of the device. Therefore, these mechanisms would not work for our device, but we would use multiple blades/petals to allow better visualization like in these three devices.

As the speculum mechanism was not an option for our device, we had to take inspiration from the surgical endoscopic grabber. The surgical endoscopic grabber used a pin and slot joint with lever mechanism. This mechanism allowed the physician to squeeze the handle at one end of the lever that would cause the springs/cables at the other end to move in the slot joint at the other end, opening/closing the grabber (Frecker et al., 2005). An advantage of this mechanism would be to have multiple blades, as opposed to the conventional two-bladed speculum. The multiple blades could exert more force on the vaginal walls and provide a more complete view of the cervix. However, the location of the pin and slot joint do

not leave much room for other components such as a camera and swab. One way around this is to move the pin and slot joint to the outside of the catheter. Although this would allow the camera and swab more room and visualization, it would make the device more bulky, which may cause it to be more invasive than warranted. Another concern is the use of springs and cables because of the potentially sharp edges, they may cause pinching or damage to the tissue.

4.5.2.2 Inflation-Powered Opening

For this mechanism, the patent search which was done in 2.4.2.1 discussed two patents that had similar inflation mechanisms. The first patent used an "un-rolling" technique (Deslauriers et al., 2003) and the other patent was folded up in a trapezoidal cross-sectional shape that when inflated would become a hollow cylinder (DesLauriers et al., 2006). These two patents still allowed room for improvements that could include being more aesthetically appealing, accommodating, and patient-friendly.

The revised mechanism idea for the inflation-powered opening was to make the opening either a cone- or donut-shaped balloon. The material would be like a blood pressure cuff in that it would hold the shape flattened and have the ability to expand and open up the vaginal walls. The inflated balloon would open to a maximum diameter of 3 cm for the camera to have an unobstructed view of the cervix. Another similar feature as the blood pressure cuff is to have an air pump and release valve to allow the physician to inflate the device. Although, one question with this inflation-powered opening is will this small balloon be able to exert 13N of force.

4.5.3 Final Mechanism

For the mechanism of opening the instrument at the cervix-end of the device, we selected inflation. Theoretically, the inflation of a ‘donut’ shaped balloon at the end of the device could displace the vaginal walls allowing the camera-portion of the device to see the cervix, and the swab to reach the cervix and collect cells. We believe inflation could produce enough force to provide this displacement without posing a significant risk of injury to the patient. Additionally, a thin device that opens at the end via inflation could be more amenable to disabled women because it would be less invasive and more flexible, allowing the device to move with any movements caused during the exam.

Furthermore, inflation is not a conventional choice for gynecological equipment, and therefore, provides more room for innovation. Lastly, a method involving pin and slot joints or springs would have some unfavorable design components for our device’s intended use as they could pose a serious hazard of injury to patients if they were to malfunction during insertion. We perceived inflation to be an equally promising, but safer, option to instigate the opening at the end of our device.

4.5.4 Initial Prototype

4.5.4.1 Materials

When purchasing materials to construct our initial prototype, price, material properties, ability to be disinfectable, and favorable interaction with the body were considered. Tubing made of polyvinyl chloride in diameters of 0.5 and 1/8 inches was purchased. An industrial endoscope camera 5.5 mm in diameter with a built-in monitor was used for the purposes of the prototype to simulate a medical grade camera. The medical grade camera will be

approximately the same size and provide the same or better image quality as the industrial endoscope camera that was purchased. Finally, polyvinyl chloride sheeting and sealant was purchased to construct the inflatable balloon. Some materials and components would not be candidates for the final design, but were deemed suitable for the proof of concept prototype.

4.5.4.2 Mechanism Calculations

After choosing the final mechanism, we wanted to check the feasibility of the mechanism before moving further. We first defined some parameters. These parameters included exerting 13 N of force and opening to be a maximum diameter of 3 cm. Based on the tubing chosen for the main body, the inner diameter of the balloon would be ⅝ inches (1.5875cm). We also made the assumption that the balloon would be in a torus shape, which would be closest to the balloon's actual shape. Once we decided to use the torus shape it was easy to find the surface area:

$$A = \pi^2 * (r_{outer} - r_{inner}) * (r_{outer} + r_{inner})$$

$$A = \pi^2 * (\frac{3}{2}cm - \frac{1.58}{2}cm) * (\frac{3}{2}cm + \frac{1.58}{2}cm)$$

$$A = 16.047\ cm^2$$

The first approach we took was to try to solve for force using the radii. We did this by the ideal gas law (PV=nRT) to solve for the pressure and then solve for force. However, we could not accurately assume the number of moles that would be needed to solve for pressure. Therefore, we moved on to a different approach. We knew the radii and the amount of force the balloon would need to exert; therefore, we used P=F/A to find the pressure:

$$P = \frac{F}{A} = \frac{13N}{16.047\ cm^2}$$

$$\text{P} = 0.8101\frac{N}{cm^2} = 8.101kPa$$

$$P = 60.767 mmHg$$

The inflation mechanism was based on a blood pressure cuff that is usually inflated to a maximum of 210 mmHg (Healthwise Staff, 2020). The pressure found for the balloon-inflation mechanism, 60.767mmHg, was much lower than the 210mmHg for the blood pressure cuff. Therefore, this mechanism was deemed feasible to move forward.

4.5.4.3 Engineering Drawing

Once the final inflation mechanism was selected, the specifications outlined in section 3.2 were used to create a scaled drawing of the planned device as seen in Figure 16.

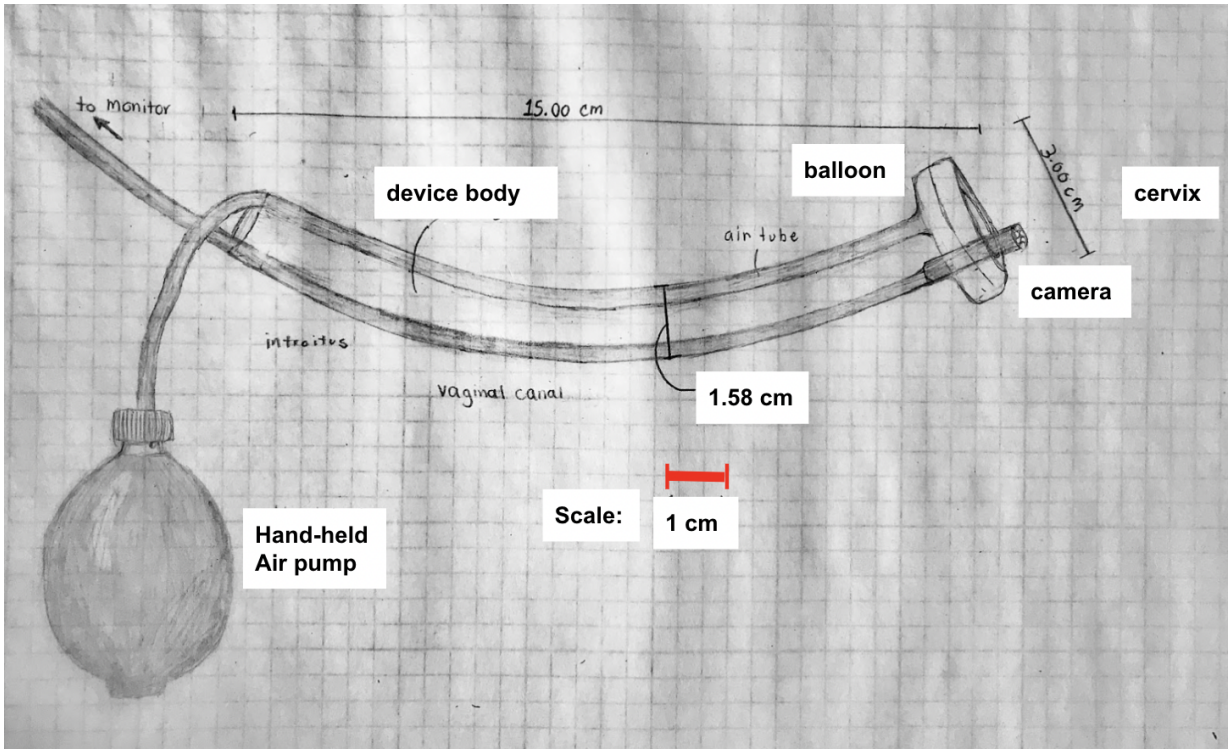


Figure 16: Schematic of the device, including the 15 cm long tube, hand-held air pump for inflation, balloon, and camera components.

4.5.4.4 Construction of Initial Prototype

The initial version of the prototype consisted of a polyvinyl chloride (or vinyl) balloon connected to a vinyl tube body (Figure 17). The 4.0 mm thick vinyl sheets were measured to a circle of approximately 3.0 cm (outer) and 1.6 cm (inner) in diameter. The device is designed to have a final, outer diameter of 3.0 cm in order to expand to the diameter established above. The extra half centimeter in diameter was added to give a margin for gluing and expansion. An inner circle with a diameter of 1.6 cm, which is the outer diameter of the tubing, was measured and cut. Locktight vinyl sealant was used to glue along the 0.5 cm margins of the outer circle.

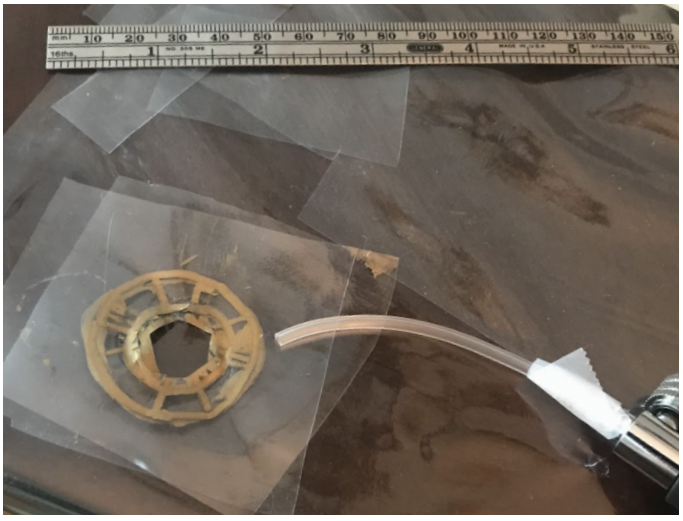


Figure 17: The first prototype of the balloon was constructed by measuring and cutting vinyl sheets.

Once the glue was dry, the air tube was fed into the 15 cm long tube and the edge of the balloon was glued to the end of the tube. At the other end of the air tube, the hand-held air pump (obtained from a blood pressure cuff) was attached. The camera, attached at one end to the monitor, was then fed through the tube as seen in Figure 18.

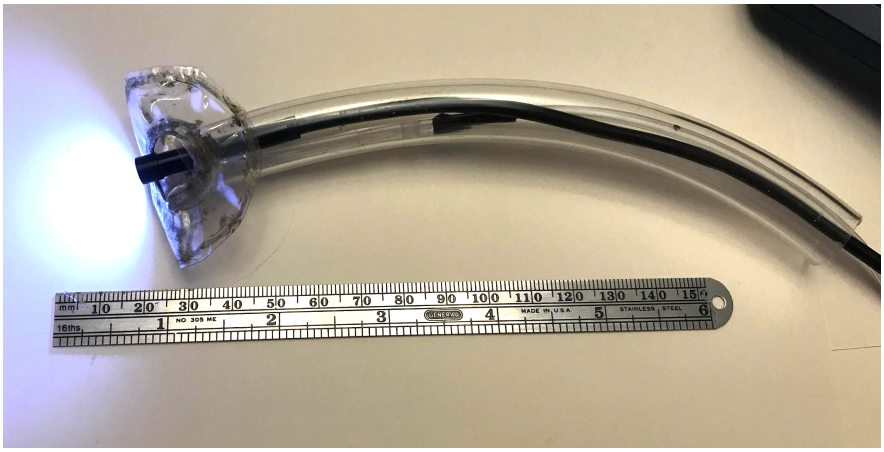


Figure 18: The first version of the prototype, with the camera and light at the cervix-end of the device connected to the monitor. The balloon is also at the cervix end and is fed through an air tube.

Chapter 5: Design Verification

This chapter begins with redesigning the initial prototype to create version 2.0. Next, we discuss verification testing that was done with version 2.0 to ensure the device met the functions including some of the successful and failed testing.

5.1 Version 2.0

Once the initial prototype, discussed in section 4.5.4.4, was created the vinyl's seal was assessed by submerging the balloon in a small bath of water and inflated. A leak was found through the air bubbles rising from a point near the air tube. To obtain a better seal, the design was tweaked. Four concentric circles with radii of 0.5 cm were marked on vinyl sheeting to create a diameter of 3 cm with a margin of 0.5 cm for sealing. This was done twice to yield both sides of the balloon that would be sealed together (Figure 19).

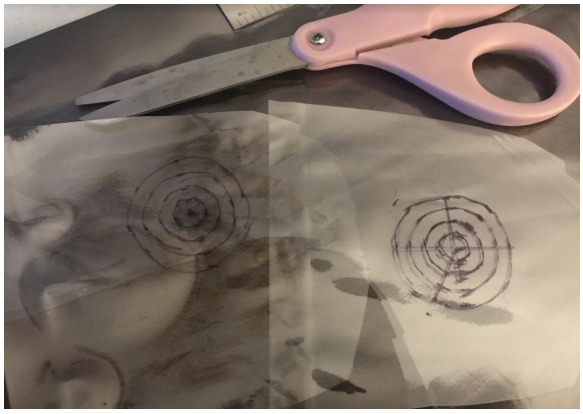


Figure 19: Concentric circles of +0.5 cm

In this iteration, however, the innermost circle was cut in a way that allowed the air tubing to be wrapped on both sides with the vinyl (Figure 20) in an attempt to obtain a complete seal.

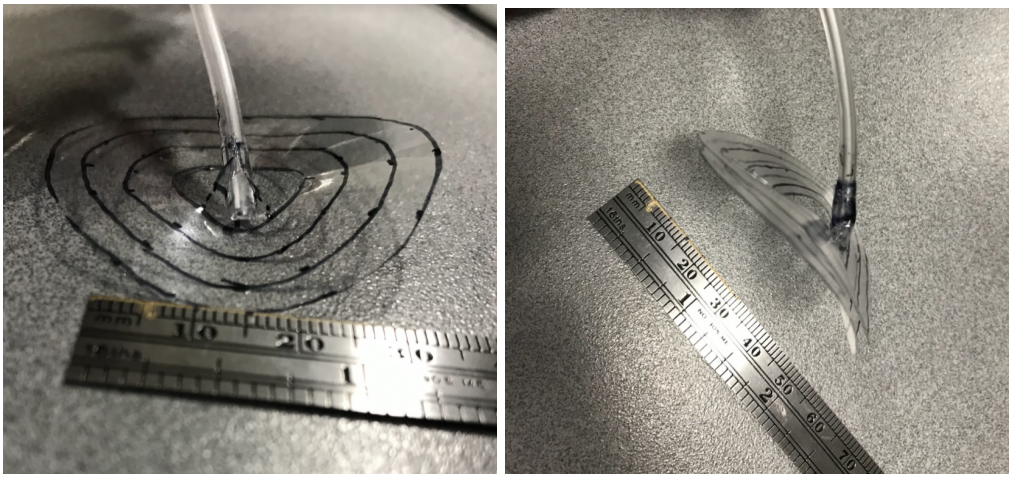


Figure 20: Left: The air tubing sealed to one half of the balloon during assembly. Right: The air tubing attached to both circles with flaps of vinyl wrapped around it.

While this change to our design provided a more straightforward and effective way of attaching the balloon to the device body, it still did not provide an airtight seal. A water bath test once again showed air bubbles emanating from the site of the air tube insertion, and the balloon did not remain pressurized after inflation using the air pump. The verification tests discussed subsequently in 5.2 were performed on Version 2.0 of the device since they were not dependent on the balloon component.

5.2 Device Verification

This section evaluates two successful verification tests performed on version 2.0.

5.2.1 Accommodate Movement (i.e., withstand bending)

One of the functions, laid out in Chapter 3, was for the device to withstand bending caused by any involuntary or voluntary movement during the exam. From the literature, the vagina lies 45.0° to the perineum (Łaniewski & Herbst-Kralovetz, 2018). The minimum baseline angle the device should be able to bend, therefore, is 45.0°. This should be the

minimum because if the patient cannot get in the ideal position and needs to be in a different position (i.e., lying flat on her back or even lying on her side), the device would need to bend at least 45.0° in order to enter the vaginal canal.

For the verification of this test, we measured the angle two different ways: (1) with the camera and air tube inside the catheter, and (2) with the camera, air tube, and swab inside the catheter. Once the components were inside the catheter, we began to bend the catheter until it could not bend further, or it began to fold unto itself potentially causing pinching of tissue or compromised access. We then measured the angle the catheter bent with a compass (see Figure 21). The angle was recorded into Table 10 and the procedure was repeated for three trials without and with the swab (see Appendix C for the step-by-step procedure).

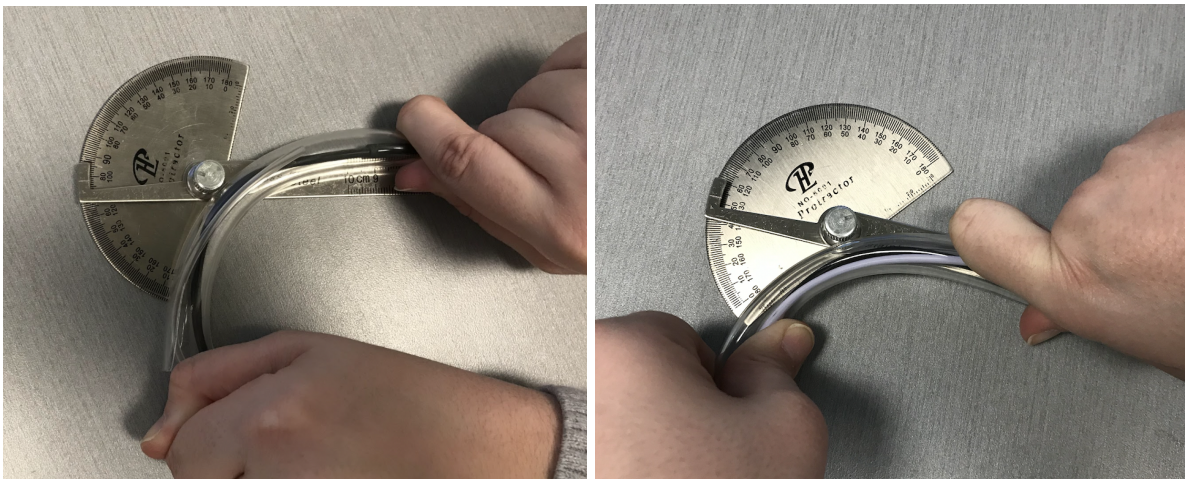


Figure 21: Picture of measuring angle of catheter without swab (left) and with swab (right)

Table 10: Angle measurements from accommodate movement verification test

Trial Number	Angle without Swab	Angle with Swab
Baseline	45.0°	45.0°
1	78.0°	53.0°
2	80.0°	45.0°
3	75.0°	51.0°
Average	77.7°	49.7°
Standard Deviation	2.5°	4.2°

The angle without the swab was found to be 77.7 ± 2.5° and the angle with the swab was found to be 49.7 ± 4.2°.

5.2.2 Disposability and Reusability

The device has multiple components that were determined to be either disposable or reusable (Table 11). The disposability and reusability for each component was determined by its price, material, ability to be disinfected, and interaction with the body.

Table 11: Disposability and reusability for each component of the device

Component	Disposable	Reusable
Main body tubing	☑	☐
Camera	☐	☑
Swab	☑	☐
Balloon	☑	☐
Air tubing	☑	☐
Air pump	☑	☐

The camera component is the only reusable component of the device. The rest of the components are disposable.

5.3 Altered Verification Testing

In this section we discuss problems we ran into while manufacturing the balloon component of our device and how this impacted subsequent verification testing.

5.3.1 Balloon Construction

As discussed previously in section 5.1, we encountered hurdles when assembling the device's balloon component. Once we determined, through our water bath testing, that the balloon had leaks, we tested various materials and sealants in an attempt to determine a better way to construct this component.

The vinyl sheeting was selected due to its stiffness. This property allowed us to set the outer diameter to be a maximum of 3 cm during expansion. This is advantageous as it allowed us to create a balloon that would not keep expanding during inflation. This is why we did not select a stretchier material; however, once we ran into challenges constructing a sealed, 3-dimensional shape out of the 2-dimensional sheeting, we explored other options. We selected nitrile which did have some stretchable properties, while not being too flimsy. We followed a similar procedure and marked concentric rings around the circle representing the 1.6 cm inner diameter out to the 3.0 centimeter diameter with a 0.5 centimeter margin (figure 22 - left).

Figure 22: Left: Concentric circles of +0.5 margins (dashed lines) on the nitrile material. Right: Inflation of balloon with nitrile material

We sealed the edges with Loctite vinyl glue and then tested the inflation (figure 22 - right). It inflated well at first, and unlike the vinyl, the extent of inflation could be easily adjusted. We still observed some deflation over time and when pressed. When we sealed the inner circle to create the torus shape, the leaks became even more pronounced.

After we still encountered sealing problems with a different material, we tested some alternative sealants summarized in Table 12. Throughout the entire prototyping process, we used Loctite vinyl glue. We then tested DAP silicone household sealant, Loctite waterproof silicone sealant, and Living Solutions Sureflex sealant on the vinyl sheeting itself and then at the gaps on a balloon.

Table 12: Sealants tested on the vinyl balloon material and results

Sealant Used	Results
Loctite vinyl glue	Sealed along the edges of balloon, but leaks persisted at balloon-air tube interface
Loctite waterproof silicone sealant	Improved seal at the air tubing, but small air bubbles still emmenated
DAP silicone household sealant	Did not improve seal
Living Solutions Sureflex sealant	Did not improve seal

None of these variations, however, resulted in an improved seal. The existing version of the device, with the vinyl balloon sealed with vinyl glue, was used in the aforementioned verification tests (section 5.2). The challenge with inflation, however, meant there were a number of verification tests we were not able to fully conduct.

5.3.2 Correct Dimensions

It was very important that our final device measured to the proper dimension outlined in our client statement and specifications (section 4.2.2.2). We estimated that the device should open to an outer diameter of 3 cm with a minimum inner diameter of approximately 1.6 cm to provide access to the cervix (whose average diameter is 2.39-6.45 cm), without causing patient discomfort by separating the vaginal walls to a painful extent (Pendergrass et al., 1996). When manufacturing the balloon, we cut the vinyl sheeting to be 3 cm in diameter with a 1.6 cm inner circle (corresponding to the outer diameter of the device body's tubing). We left a 0.5 cm margin for sealing, and trimmed this after the glue had dried. When the balloon was uninflated it was thin, but still held the 3 cm diameter. When the balloon was inflated it swelled and became marginally smaller; however, the balloon could not stay inflated long enough to measure the extent to which the diameter changed (see Figure 23).

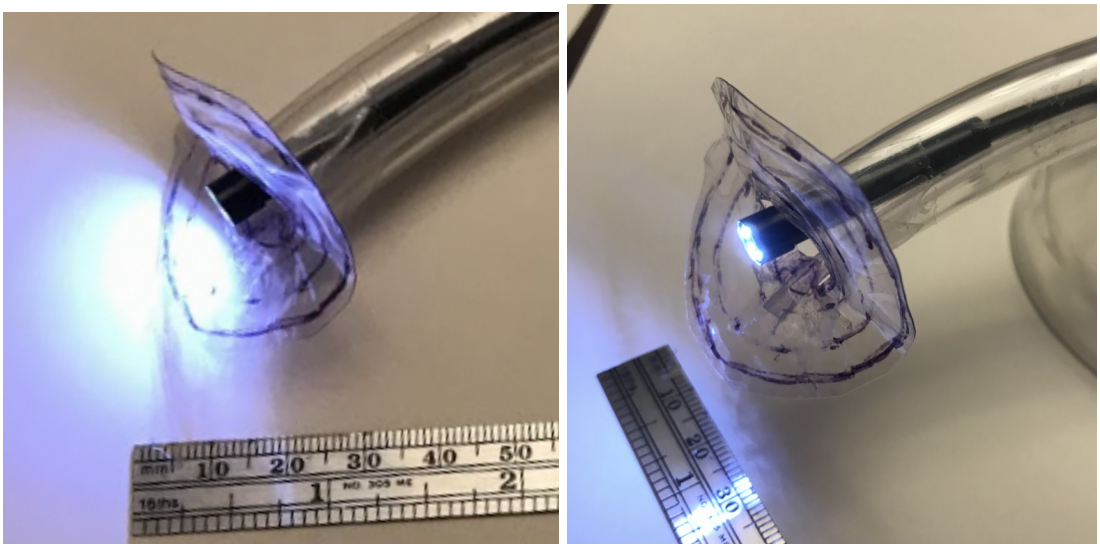


Figure 23: Left: The balloon before inflation. Right: The balloon while the air pump is being repeatedly squeezed.

Furthermore, the balloon never reached full inflation since the air was leaking out too fast. Thus, we were not able to investigate the change in dimensions to the full extent we planned. Additionally, we were not able to assess the surface area and pressure (calculated in section 4.5.4.2) at full inflation.

We were, however, able to verify the dimensions of the device body. During the materials-selection portion of our design process, we purchased vinyl tubing of 1.58 cm outer diameter and 1.27 cm inner diameter. When these materials were obtained, we verified with a capiper that the tubing did have the specified dimensions. We selected the outer diameter to be 1.58 cm to be as small as possible, while still allowing room for all the internal device components (camera, air tubing, endocervical brush). For reference, this is about the size of the smallest plastic speculum when the bills are closed before expansion, as they are during insertion of the device. We selected the inner diameter of 1.27 cm to give the device's body some rigidity (so that it would not collapse under the forces of the vaginal canal), but we did not want the walls to be so thick that it took away the device's flexibility.

5.3.3 Withstand 13 N of Force

One of the design functions outlined in section 4.2.2 was the ability for the device and balloon to exert and withstand 13N of force. This figure is based on a 2007 study that evaluated intravaginal closure pressure by measuring forces exerted by the vaginal muscles. The greatest of these forces was found to be 13N (Miller et al., 2007). We concluded that our device should be able to exert 13 N of force in order to hold the vaginal walls open.

To test the force, we planned on creating a pulley system with weights (see Figure 24). We were going to wrap a piece of velcro or string around the inflated balloon and then hang a weight off of the velcro or string. We would keep adding weights gradually until we reached1.33 kg (approximately 13N in the y direction). Then, we would measure the size of the inner diameter to find the displacement of the balloon. As the device and balloon are made of a flexible material, when force is applied, the diameter would change, which may obstruct the view and access to the cervix. Thus, the displacement of the inner diameter is measured during the force test. This would have allowed us to see if the balloon can exert 13N of force to maintain visual access to the cervix.

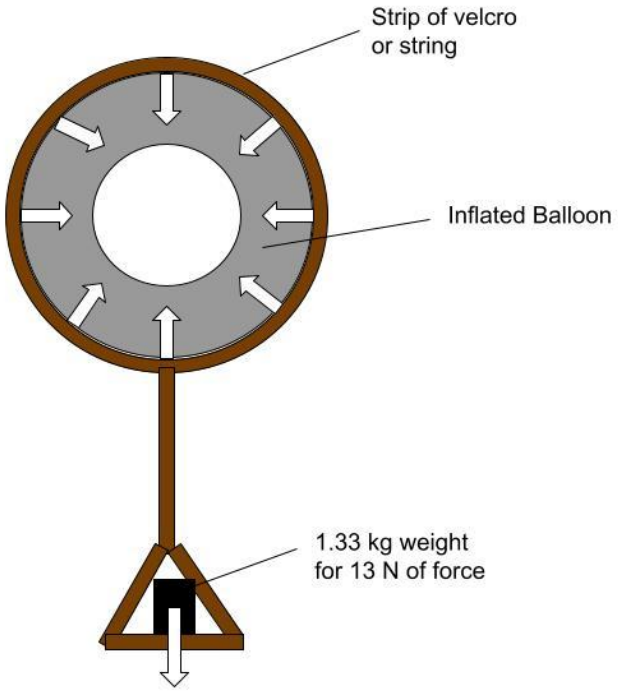


Figure 24: Pulley System for Force Testing

We were not able to test the force, however, because the balloon would not stay inflated; therefore, the balloon would have failed this verification test as it could not stay inflated. Additionally, we could not assess any changes in the device dimensions and shape as more force is loaded. This would have given us data on any diameter and shape changes the balloon and device would have experienced upon being loaded with a force.

5.3.4 Quick Insertion and Inflation

In both the functions and objectives, we discussed our device needs to provide a complete exam and be minimally invasive. The device must have the ability to be quickly inserted and inflated. Part of being minimally invasive is being as small as possible and performing the exam quickly; therefore, our device should perform the exam within a comparable time to the current speculum in order to provide the patient comfort in knowing the

exam will not take too long. The current speculum takes 1-2 minutes to insert (Ben-Joseph, 2017). Our device must be fully inserted and inflated within this range to meet the current baseline time of the traditional speculum.

The verification for the quick insertion and inflation of the device would have required two different tests: (1) the time it takes to insert and inflate the balloon and (2) the number of squeezes to the air pump needed to fully inflate the balloon. We would have used a cervical model to test the quick insertion and inflation. For the first test, we would have used a stopwatch to measure the time from when the device is about to enter the model to when the balloon was fully inflated. For the second test, we planned to count the number of times the air pump was squeezed for the balloon to be inflated and for the cervix to be in view. We were not able to perform these tests since the balloon could not stay inflated.

5.3.5 Intuitive Use and Patient-Friendly Design

A large barrier to any novel device being incorporated into standard practice is the time needed to learn the new device's operation. For this reason, we planned to bring our device to various women's healthcare providers (such as OB/GYNs, N.P.s, etc.) and assess if the device needed instruction or if it was intuitive. We would then ask them to demonstrate how they thought our device worked. If a statistically significant number of the healthcare providers, without any prior instruction, knew how to operate our device, we would deem the device's operation to be intuitive.

When we realized that we would not be able to access this within the timeframe of our project, we conducted a subjective evaluation of our device's intuitiveness. Composed of the main body, balloon and air pump, and camera, the device does not have a large number of different components which increases its intuitiveness and ease of use. There is a minimal

number of steps (turning the camera and light source on, inserting the device into the vagina, and inflating the balloon); however, it is crucial for patient comfort and device efficacy that these events be conducted in the right order. The device also does not require a great deal of precision, and the extent to which the balloon is inflated can be assessed in a similar way that a physician assesses how wide to open up the speculum's bills: stopping when a clear view of the cervix is provided. From this subjective evaluation, we concluded that our novel device is more complex than a speculum, but is still rather simple.

Patient reactions and feedback to our proposed model is also important to gauge. We planned to survey women with CP to obtain patient opinions on the device. We wanted to assess if the device could be more amenable than the traditional speculum in a number of ways. First, we planned to assess if the appearance of the device was less daunting than the duck-billed speculum which many women find nerve-wracking (Seymore, 1986). We also planned to describe the procedure for using the device and ask the women to rate their preference or lack of preference of our device's design to that of the standard speculum. Due to time constraints of the project, we were not able to conduct any psychological or social research in addition to the engineering design process; however, we conducted a qualitative analysis. The fact that our device opens only at the end whereas the bills of the speculum opens along the whole device, may make our device advantageous in terms of patient-friendliness and comfort, since this attribute marks it less invasive. In its current form, our speculum is designed to expand to 3 cm when fully inflated, comparable to the smallest speculums available and less than that of larger speculum sizes (Shoop, 2022). Additionally, the size of our device's main body is about the size of a tampon or an index finger, and this small size could add to its amenability. We do realize that the inflation mechanism may give some women

pause about using our device, but hopefully a physician's demonstration of the device's small balloon could ease any fears.

Chapter 6. Final Design and Validation

In this chapter, we discuss the redesign to the final device that will be used in validation testing. We then discuss the results of this validation testing. Finally, this chapter ends with a discussion of our device's potential societal influence, ethical concerns, health and safety issues, and manufacturability.

6.1 Redesign Device for Validation Testing

During our device verification testing, we found that the constructed balloons were unable to stay inflated. We did not overcome this manufacturing challenge during the time constraints of our project, but still wished to validate our prototype's two main functions. We needed to find a way to represent the fully inflated balloon. We decided to design a model of the fully inflated balloon in CAD software to be produced with additive manufacturing. We used PTC Creo Parametric 8.0.1.0 to create the CAD schematic. We used the same inner and outer diameters as the vinyl balloon (i.e., 1.58cm and 3cm, respectively). The CAD software used inches so we converted the diameters to the correct units (i.e., 0.63in and 1.18in, respectively). We then extruded to 0.3in because the length between each diameter is approximately 0.3in. Then we rounded each edge by 0.15in. This created smooth surfaces of the desired torus-shaped balloon. In Figure 25 and 26, screenshots of the CAD model in the software and engineering drawing with the dimensions can be seen.

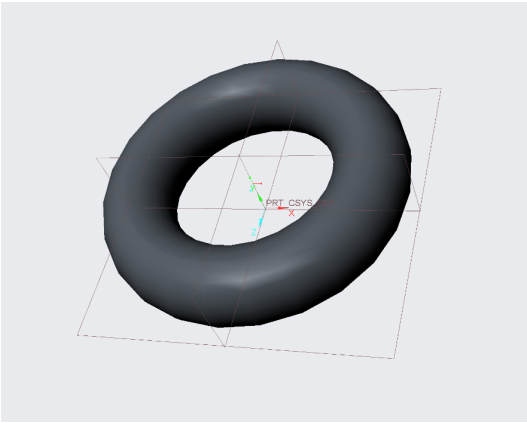


Figure 25: Rendering of the CAD model in the PTC Creo Parametric 8.0.1.0 software

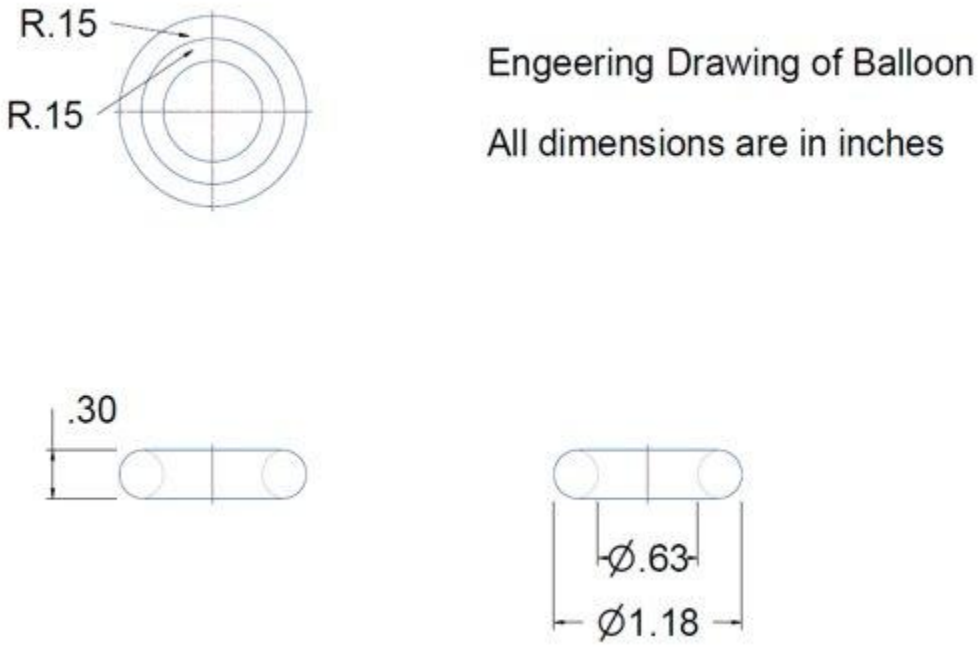


Figure 26: Screenshot of the engineering drawing with the dimensions

After the CAD model and drawing were made, the part was sent to the 3D printer. Once printed, we attached the 3D printed balloon to the main tubing of our device (see Figure 27). This created the dimensions of the "ideal" inflated balloon we predicted the vinyl balloon

would have reached if it worked perfectly. Therefore, this model was version 3.0 of our device that would be used in validation testing.

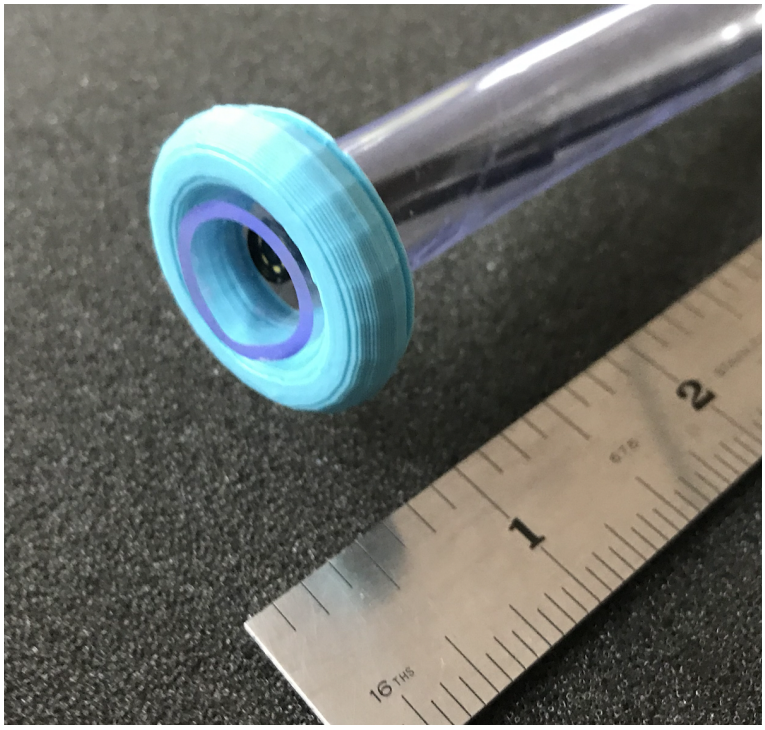


Figure 27: 3D Printed Balloon Attach to the Device's Main Body

6.2 Validation

This section evaluates two successful validation tests performed on the final device.

6.2.1 Provides and maintains access to the cervix

To assess the device's ability to provide a physician access to the internal structure of the cervix. A rough vaginal model was constructed using polyvinyl foam. A 15 cm long and 3 cm wide (Pendergrass et al., 1996) canal was removed from the foam at 45 degree angle (Łaniewski & Herbst-Kralovetz, 2018) from the opening to mirror the vagina's length and angle from the introitus. A model of the cervix was constructed out of plastic and paper to be

2.5 cm in diameter (Nott et al., 2016), and placed perpendicular to the canal (see Figure 28). A 500g weight (creating a unidirectional force of 4.9N) was placed on top of the model to hold the foam together and provide some of the force that vaginal muscles could exert on the device.

Figure 28: Inside the anatomical model representing the vaginal canal and healthy cervix.

The prototype's camera was powered on, illuminating the light source and a live video feed on the monitor. We inserted the device with the vinyl balloon into the introitus and fed it through the mock vaginal canal until the cervix was seen on screen (see Figure 29). We squeezed the hand-held air pump three times to inflate the balloon, but as discussed in 6.1, leaks prevented the balloon from staying pressurized.

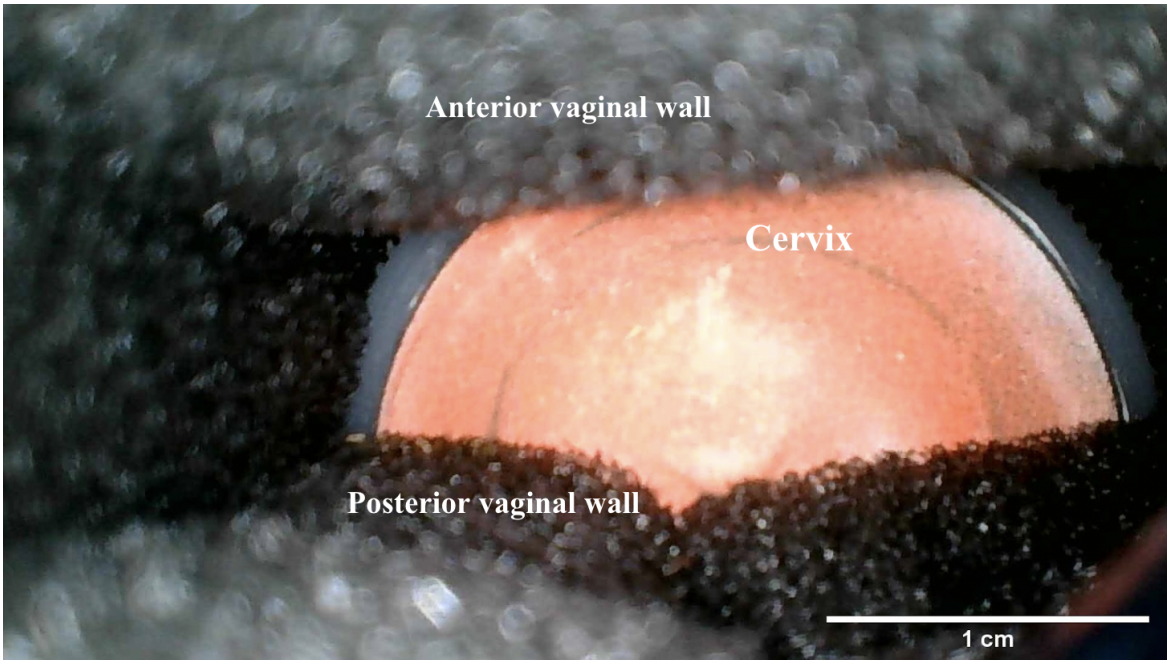
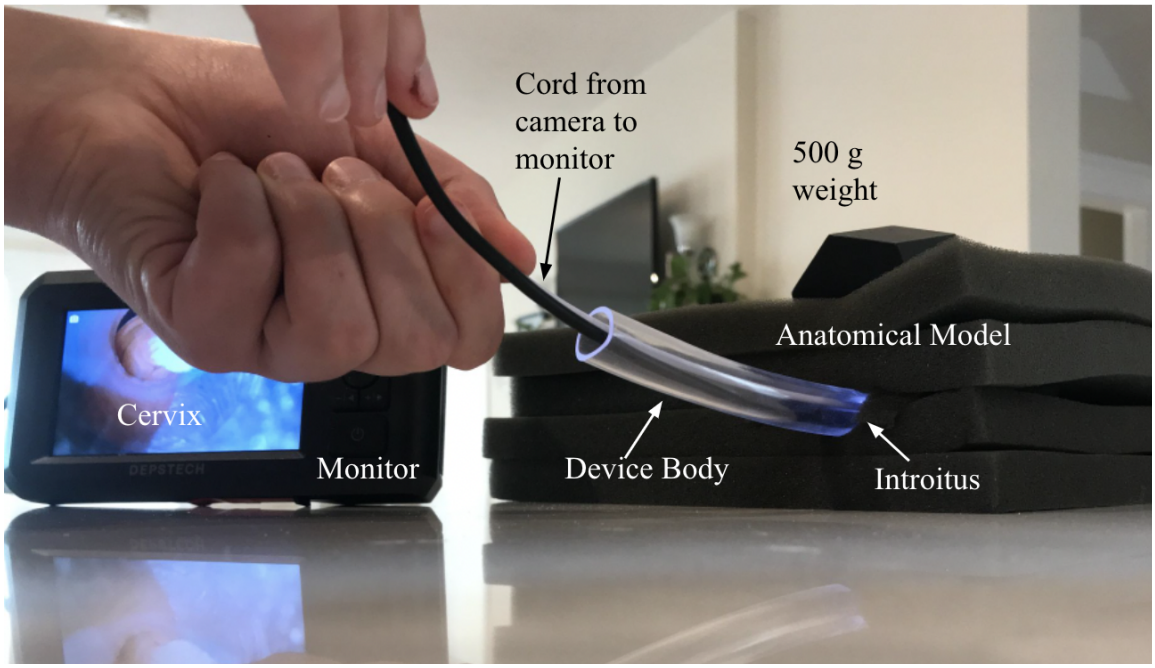


Figure 29: The interior view from the camera of the healthy cervix during the test run with the poorly-inflated vinyl balloon

Next, the device with the rigid part representing a fully inflated balloon was inserted into the model, and the monitor was used to ensure that the device could visualize the cervix (see Figure 30).



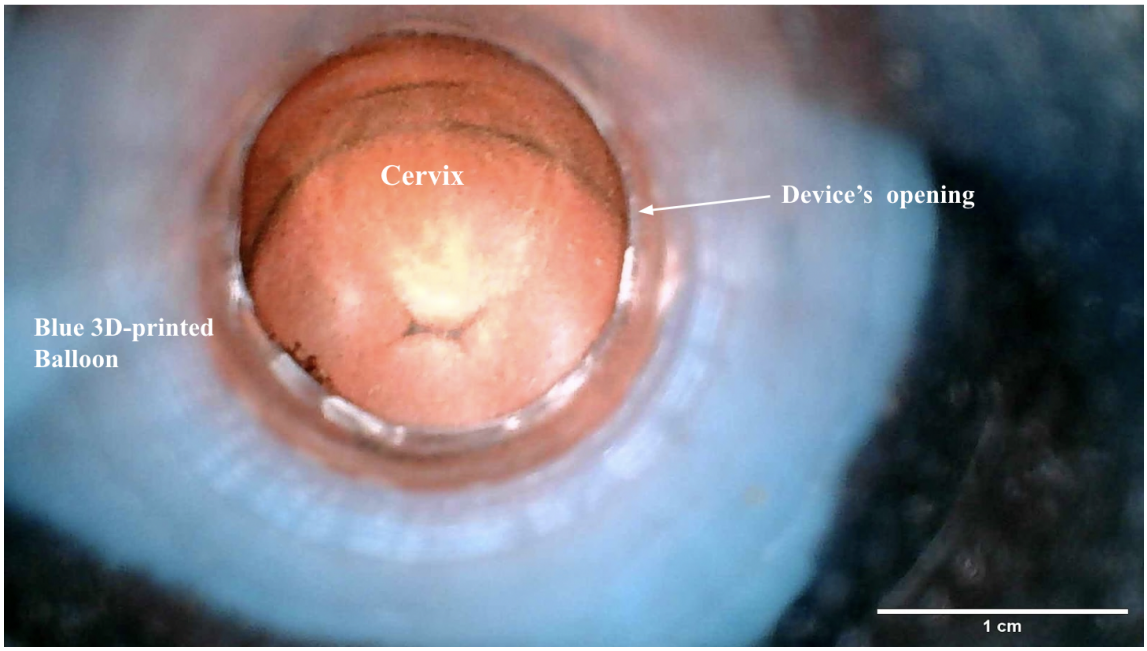


Figure 30: (Top) An exterior view of the anatomical model during testing. (Bottom) The interior view from the camera of the healthy cervix with the 3D printed balloon.

The device's positioning inside the vagina and the camera's position inside the device were adjusted as needed until view of the cervix was nearly unobscured. The device was then removed from the model.

6.2.2 Allows for the completion of a Pap smear

We used the same vaginal model described in 6.2.1 to determine if the device could facilitate a Pap smear. This testing was two-pronged: we needed to check if our device was able to maintain its inflation for a time reasonably long enough for a physician to visually assess the cervix and facilitate a Pap smear (i.e., ensure that cervical cells could be collected via a cytobrush that was fed through the device). The device with the rigid part representing the balloon at full inflation was once again inserted. We determined that the spatula, seen in the Figure 31 below, was not suitable for use with our device, as the tip was too wide to fit through the tubing. Even if the tubing had been wider, the handle was very stiff and would likely not have been able to be fed through the device. We proceeded with the endocervical or ‘cytobrush’ for testing. When a clear view of the cervix was displayed on the monitor, an endocervical brush was fed through the tube.

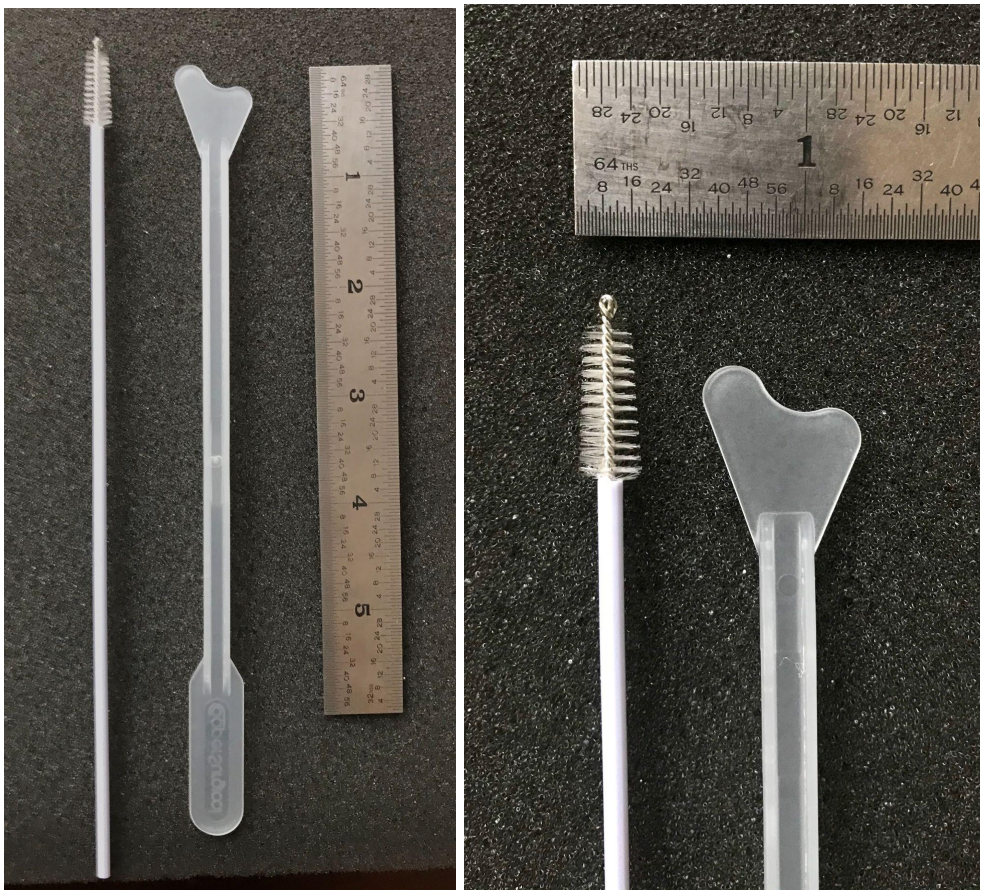


Figure 31: Cytobrush(TM) by Medscand on the left in both images, and spatula manufactured by Medscand on the right.

The live video feed on the device's monitor was used to guide the swab to the cervix. The brush reached the cervical os and squamocellular junctions, regions of the cervix from which cells are collected during a Pap smear (see Figure 32).

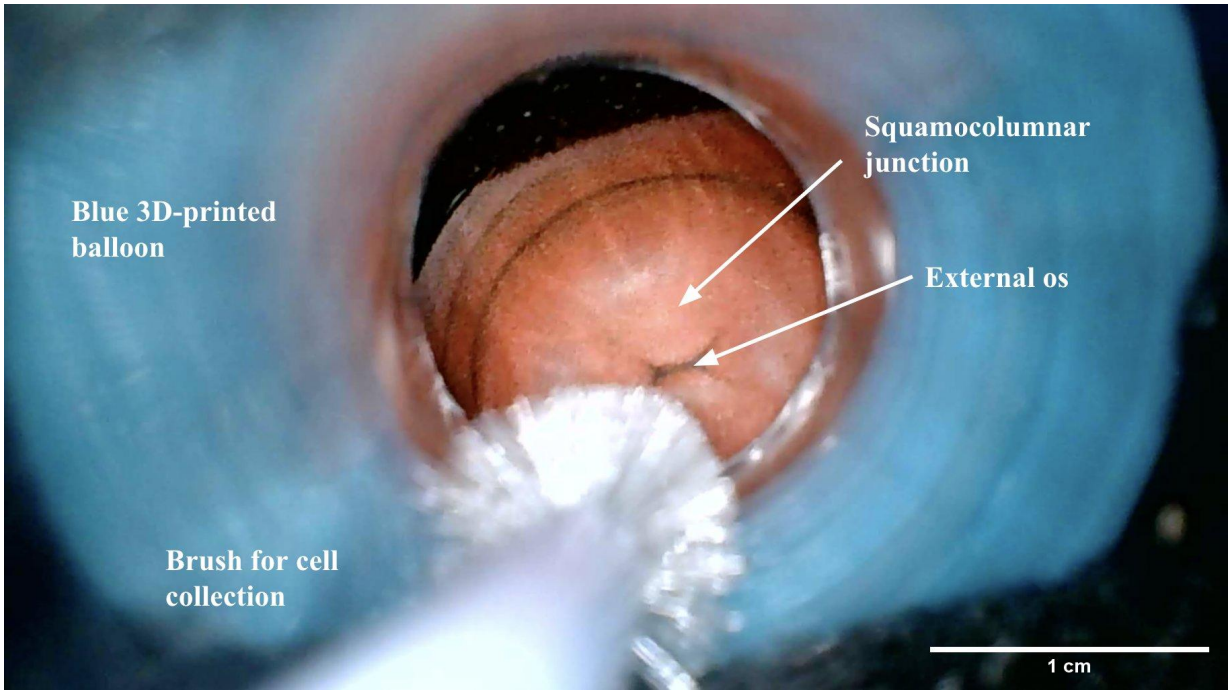


Figure 32: Image taken during simulated Pap smear showing the endocervical brush approaching the model cervix.

The brush was twirled to mimic the motion used to collect cells. Then the brush was retracted from the device. Normally an entire exam takes 5 minutes, with 1-2 minutes to insert the speculum and another 1-2 minutes to retract the speculum, leaving about a minute to perform a pelvic exam and Pap smear (Ben-Joseph, 2017). This means the baseline measurement for a Pap smear is approximately 1 minute. We then timed how long it took to simulate a Pap smear using the model cervix. The time began upon the insertion of the swab. The swab then reached the cervical os and was twirled around the cervical os a couple of times (see Figure 33). Finally, the time stops upon the retraction of the brush. The time in seconds was recorded in Table 13 below.

Table 13: Length of cell collection

Trial #	Length of Cell Collection (seconds)
1	0:37
2	0:29
3	0:30
Mean (seconds)	
0:32	
Standard Deviation (seconds)	
3.6	

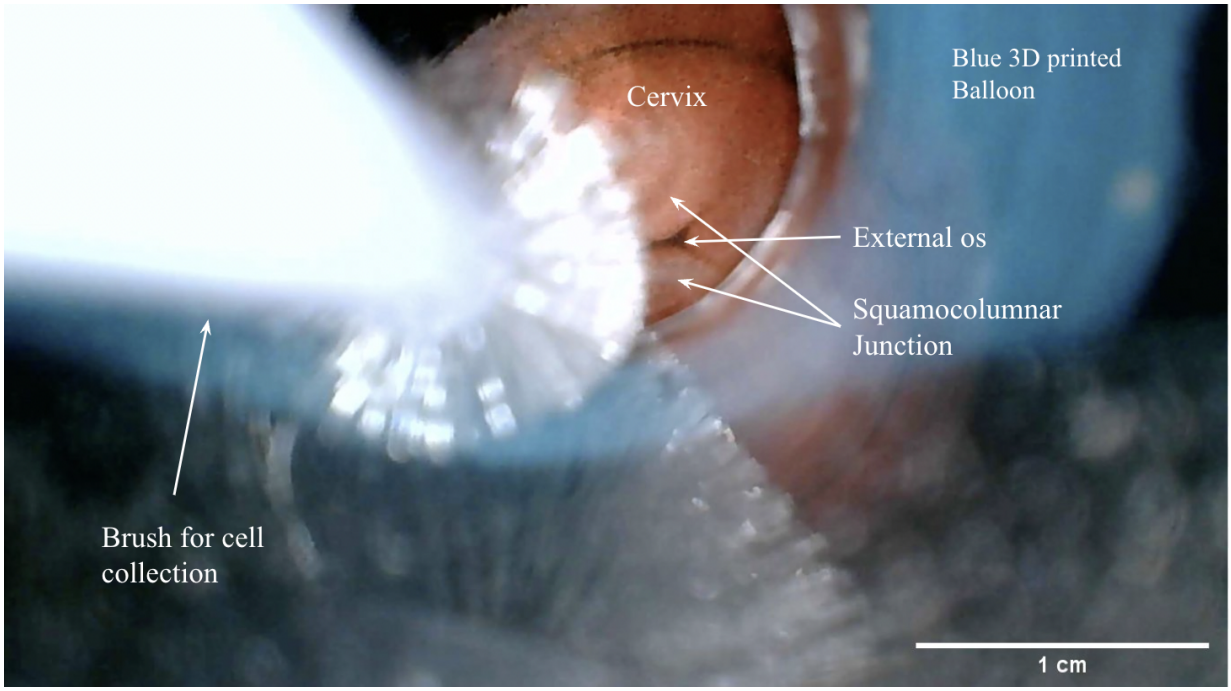


Figure 33: Image taken during simulated Pap smear showing the endocervical brush approaching the model cervix.

The average time to perform the Pap smear on the anatomical model across the three trials was 32 ± 3.6 seconds.

6.3 Special Topics

6.3.1 Societal Influence

The healthcare disparities between disabled and abled-bodied women discussed in chapter 2 were a large motivating factor during this project. Less women with disabilities, such as CP, receive Pap smears annually, as recommended, than abled-bodied women (Armour et al., 2013). In fact, women with mobility limitations are 35% less likely than able-bodied women to have ever received a Pap smear in their life (Drew & Short, 2010). This is a worrying statistic since regular Pap smear receipt is associated with a 67% reduction in the incidence of Type 1 cervical cancer, and a 95% reduction in stage 3 or greater (Landy et al., 2016).

A possible reason for this disparity is the inaccessibility of the standard speculum to women with muscle disorders. The aim of our project was to take a step towards allowing women with CP to have this crucial exam with a device that poses no challenges to them due to their disability. Should this device be brought to market and into doctor's offices, we believe it could facilitate a more comfortable Pap smear to a wider range of women. Women with mobility limitations outside of Cerebral Palsy could benefit from this instrument as well. In addition to benefiting physically disabled women, this device may also be more amenable to women with intellectual disabilities, a population underserved by obstetrics and gynecology due to inaccessible medical equipment, lack of training and knowledge about treating patients with intellectual disabilities (Parish et al., 2013). Women with intellectual disabilities are 72% less likely than able-bodied women to have ever received a Pap smear (Parish et al., 2006). All women, regardless of disability status, deserve access to this crucial screening procedure. Additionally, abled-bodied women may feel more comfortable using this device as opposed to

using a speculum in the traditionally lithotomy positioning. We hope that, if this device was ever brought to market and practice, would increase access to this important, lifesaving screening.

6.3.2 Ethical Concerns

The goal of this device is to make a more accommodatable instrument for cervical exams and Pap smears using a flexible catheter and camera. However, like with all cameras, one ethical concern to consider is the patient's comfortability with medical imaging at such an intimate location. The camera will be used to provide digital medical imaging of a sensitive location that not all women may be comfortable with. Any future patients using our device would need to trust her physician to strictly maintain the doctor-patient confidentiality required by HIPAA regulations.

6.3.3 Health and Safety Issues

The current speculum has many health and safety concerns associated with it. One of the biggest risks associated with the speculum is its inability to be accommodatable and flexible. For insertion, the current speculum requires the patient to be in the lithotomy position. The rigidity of metal and plastic speculums can cause discomfort, and if the muscles are tense, which is the case with many CP patients, then it will be even more uncomfortable (Hersh, 2018). Other potential risks with the current speculums, especially the reusable metal ones, are they may experience rust, natural corrosion, and staining. The metal speculum contains bolts, crevices, and openings that biological debris can hide in, and if not sterilized properly could also cause cross-contamination (Hardcore Advertising, 2020).

Our device will address the health safety concerns associated with the current speculum. This device will be more accommodatable and flexible, which means the patient does not have to be in the ideal position and should hopefully experience less discomfort. Also, since the camera is the only reusable component and does not contain any crevices where biological debris can hide, cross-contamination should not be an issue as long as it is disinfected properly.

The camera will be of a medical-grade, like those used in endoscopy procedures. For cleaning and disinfecting an endoscope camera, a high-level disinfectant or sterilant will be selected that is compatible with the endoscope and approved by the FDA. The reusable endoscopic camera and any components will be completely immersed in the chosen high-level disinfectant or sterilant. The exposure time and temperature will vary among the high-level disinfectants and sterilants. After the high-level disinfection, the endoscope will be rinsed and flushed with water to remove the disinfectant or sterilant. Then, the endoscope will be flushed with 70-90% ethyl or isopropyl alcohol and dried using forced air. The endoscope will be stored in a manner that protects from contamination and hanging in a vertical position that facilitates drying (Nelson, 2012).

Our device addresses the health and safety concerns with the current speculum; therefore, our device has a better chance of improving the health of the target population, women with CP. It does have its own safety concerns that need to be considered. One such safety concern with our device prototype is sharp edges that may come from the balloon. For the vinyl balloon prototype, some of the edges where the vinyl was cut remained somewhat sharp. For the 3D printed balloon prototype, the material is a hard plastic that has some sharp edges. However, the 3D printed plastic will not be the material of the actual balloon as it was just used for validation testing. These sharp edges are a safety concern because sharp edges

could potentially cause pinching or tearing of the tissue. Another safety concern is the over-inflation and/or over-extension of the balloon which could cause pain, discomfort, or tearing of the surrounding tissue. It will be very important to not exceed 13N of force to prevent these complications. Another safety concern associated with our device is the camera's light source because it can become warm when left on for long periods of time. Although this is a safety concern, the camera used in the prototype was not a medical grade camera, which will be the one used when this goes to market.

6.3.4 Manufacturability

For the proof of concept prototype we created for our project, we cut and sealed vinyl sheets to create our balloon. If this were to be the final manufacturing process, a significant challenge would be to create smooth edges where the balloon is sealed so as to not injure the patient. This challenge, along with the fact that we were not able to maintain a perfect seal, may necessitate looking to other manufacturing techniques in the future. When researching other medical device balloons, we found that the practice of manufacturing angioplasty balloons may be good to reproduce for our design. These small medical balloons are formed through a process called blow molding, which involves heated jaws and compressed air that molds the balloon into the correct shape (Menary & Armstrong, 2006).

Apart from creating the device's small balloon, the device does not pose a large manufacturing challenge. Medical-grade cameras can be procured for less than $1,200 USD (Medical Expo, n.d.). We used polyvinyl chloride, or vinyl, tubing in our prototype since PVC is biocompatible and used extensively in single-use medical devices (Yianni, 1995). This material is also very inexpensive and adds to the feasibility and reproducibility of manufacturing our device.

Chapter 7. Discussion

We designed the device to provide a complete Pap smear while accommodating women with CP. The device's ability to accomplish these crucial objectives was assessed by verifying its functions, analyzing the device's design, and evaluating the results of validation testing.

7.1 Device Verification Analysis

In order to assess if the device could perform the necessary functions (outlined in section 3.2.1), we subjected it to various tests, and analyzed the results.

7.1.1 Accommodate Movement (i.e., withstand bending)

One of the device's crucial functions was the ability to accommodate movement. This function was required because our patient population may not be able to get into the lithotomy position and/or may express voluntary or involuntary movement during the exams that could cause disruptions. The current speculum is made of a rigid metal or plastic and requires the patient to be lying in the lithotomy position. Once inserted and opened, the current speculum will not budge if the patient moves. This poses a safety risk to women with CP who may express involuntary movement because if they move with the rigid speculum in place, it could potentially cause injury or tearing of the vaginal walls; therefore, it was critical for our device to be flexible.

First, we set a 45.0^{o} threshold, which was the angle between the vaginal canal and the perineum. We set this threshold because it could potentially allow the patient to be in different positions, such as lying flat on their back or on their side, or sitting on a toilet chair, while still being able to perform an exam. The device would need to bend at least 45° in order to enter the

vaginal canal, if the patient was not in the lithotomy position. Also, this threshold was set to accommodate any voluntary or involuntary movements the patient would make during the exam, which is not the case for the current rigid speculum. If the device is flexible, it may yield to any patient movements, reducing the risk of injury.

We tested the device's ability to bend by manually bending it with and without the exam brush and measuring the maximum angle it could reach without the tubing collapsing with a compass. Our device could be bent 77.7 ± 2.5° without the swab and 49.7 ± 4.2° with the swab. These two angles are above the 45.0° threshold we set. This bending test was subjective because we manually bent it with our hands without measuring the exact force or stiffness; however, we did not have to apply much force to bend our device. Although this was not a quantitative measurement, our device seems easy to bend, potentially allowing for patient movement during the exam without causing harm. Our device passed this verification test and can accommodate movement. This test showed the device has the ability to not only accommodate movement but also flexibility, which can allow the patient to not just be in the lithotomy position.

7.1.3 Disposability and Reusability

The disposability and reusability for each component was determined. Factors such as price, material, ability to be disinfected, and interaction with the body were taken into account when making these determinations. The camera component is held within the catheter and has limited direct interactions with the body and can be made of disinfectable materials; therefore, we determined the camera component is reusable. This also will also reduce manufacturing and procedural costs, with the lifetime cost of using our device declining over time after the initial cost of the camera. The endocervical brush will be disposable as it is taking cell samples

directly from the cervix. The main tubing catheter, air tubing, and balloon are directly interacting with the body and have relatively cheap material and manufacturing costs. The main tubing catheter, air tubing, and balloon are also sealed together and, therefore, are single-use as one unit. The air tubing connects to the air pump. As of today, the air pump is disposable, but could possibly be reusable in the future to reduce manufacturing cost.

7.2 Device Design Analysis

Version 2.0 of our device used a vinyl material for the balloon; however, when tested in a water bath, air bubbles were observed where there were leaks in the seal. We then tried various materials and adhesives as discussed in section 5.3.1; however, there were still leaks in the balloon seal. Achieving a perfect seal was a manufacturing issue that we could not overcome within the time and monetary constraints of the projects. In the future, the balloon could be manufactured using advanced techniques, such as mold-casting or blow-molding, to get a perfect seal and create the ideal balloon we imagined.

In the meantime, we needed to continue with our validation testing. We created a 3D printed rigid balloon as discussed in section 6.1. This rigid balloon met the originally planned dimensions and therefore, acted like the “ideal” inflated balloon in shape. However, there were some limitations to using the rigid model and it was not possible to perform all of the verification testing we initially set out to do. One such verification test was the force testing. The rigid balloon model will be unyielding when force is applied; therefore, the force nor the displacement that the force would exert on the balloon cannot be determined. This test will need to be performed once the balloon can be manufactured correctly using our proposed pulley-system setup discussed in 5.3.3. Nevertheless, based on the calculations performed in section 4.5.4.2, we believe the balloon could feasibly exert 13N of force without collapsing.

Another verification test that was not able to be performed was the quick insertion and inflation time. As the balloon was rigid, it was to the dimensions of full inflation. The insertion time nor the inflation time cannot be accurately determined because it was already fully inflated. Also, since it was fully inflated, it would be harder to insert because it was to the maximum dimensions that would only be at the cervix-facing end of the device and would only happen during the inflation period. Once the balloon is manufactured correctly, future tweaks might be needed if vinyl sheeting is used because the vinyl dimensions when uninflated was large. The vinyl might need to be rolled up or encased upon insertion to be as small as possible. A different option is to choose a different, more stretchy material that is smaller upon insertion. After the balloon material is chosen, the quick insertion and inflation verification test will need to be performed according to the test set up discussed in 5.3.4. Nonetheless, we anticipate the insertion and inflation will be relatively quick because the device and balloon are small.

Once the balloon is created through honed manufacturing techniques, its dimensions will need to be measured and tested again to verify it is within the dimensions previously set in 4.2.2.2. The honed manufacturing techniques, such as mold-casting or blow-molding which were outside the budget constraints of the current project, should not provide any problems when meeting the planned dimensions. The rigid version of the balloon allowed us to continue with validation testing. However, validation testing will need to be repeated with the manufactured balloon to ensure the device can facilitate a complete exam including a Pap smear. In the meantime, the rigid balloon provided us the ability to continue with validation testing and demonstrate that our design concept could be a feasible design and work for our target population.

7.3 Device Validation Analysis

To assess the device's ability to provide an accommodating Pap smear to disabled women, we needed to evaluate if the device was capable of facilitating this exam.

7.3.1 Provides and maintains access to the cervix

We defined providing access to the cervix as allowing the physician to visualize the organ, as well as accessing the cervical os for obtaining specimens. When the device prototype with the vinyl balloon was placed inside the anatomical model described in section 6.2.1, the camera yielded inadequate results. The device's mechanism of separating the vaginal walls was the balloon's inflation; however, the balloon could not reach full inflation due to incomplete sealing and leaks. The device was able to reach the cervix and the camera provided a partial view of the structure; however, the pieces of foam representing the anterior and posterior vaginal walls were partially obscuring the view of the cervix (figure 29). This suggests that if the model had been a human patient, the camera would not be able to fully visualize her cervix. The device maintained its visualization but human studies within our specific population would be needed to assess if the device maintained this access during patient movement.

When we moved on to performing this same test with the printed component representing the fully-inflated balloon, the camera provided a nearly unobstructed view of the cervix (figure 30). This reinforces the principle that expansion of the vaginal walls is needed to view the cervix and that a balloon is a valid and safe way to accomplish this.

The current standard instrument for Pap smears is the metal and plastic speculums discussed in Section 2.4. These instruments provide an unobstructed view of the cervix and provide direct access and visualization when paired with a light-source ("Vaginal Specula,"

2018). Our device allows the physician to see the cervix indirectly with a camera, but we concluded this is comparable. Additionally, medical-grade endoscopy cameras with light-sources provide high-quality images that would allow a physician to examine the cervix during a Pap smear and also other gynecological care such as pelvic exams. Pap smears detect malignancies and pre-cancerous indicators. Sometimes, a physician will be able to visually diagnose cancerous growths on the cervix. Other conditions, such as cervical polyps, cysts or cervical incompetence (widening of the opening of the cervix during pregnancy) can be diagnosed visually. Cervicitis (infection or inflammation of the cervix) which can be caused by sexually transmitted infections can also present visually (Farrukh et al., 2018). Our device's camera could provide a physician with images of the cervix that could facilitate diagnosis of these conditions.

This is especially important for our target population. Our device could provide an alternate way of accessing the cervix for swabbing (discussed subsequently in section 7.3.2) and inspection that could work better for women with CP. By making accessing the cervix for sampling more amenable, our device could allow more women in this underserved population to obtain exams and diagnostics or therapeutic procedures.

A limitation of these results is the fact that they were conducted using the 3D-printed piece. Once the manufacturing challenges regarding pressurization and inflation of the balloon are overcome, these tests would need to be repeated. In the future, human testing also needs to be conducted to ensure the device can visualize the cervix.

7.3.2 Allows for the completion of a Pap smear

For a Pap smear, squamous epithelial cells from the cervical os and columnar villi are analyzed for signs of malignancy (Mehta et al., 2009). It was crucial that our device allows for

the collection of these cells. In the Pap smear simulated with our device, we were able to reach the swab of both the external os and the squamocolumnar junction (Figure 32). Human testing would be needed to confirm these initial findings, but from our simulated Pap smear, we concluded that the prototype meets our most crucial device objective: allowing for a complete Pap smear.

We did encounter some limitations during this testing. The test was run successfully with an endocervical brush; however, some physicians use an extended-tip spatula in lieu of or in addition to the brush. The spatula, however, was too rigid to move through our device. We concluded that our device failed this test when the spatula was used, but passed this when the brush was used to collect cervical cells. The combination of spatula and endocervical brush is the most effective method for obtaining cervical cells; however, either by itself is sufficient for obtaining cells for laboratory analysis (Schooff & Lawlor, 2004).

The stiff handle of the cervical cell brush led to some trouble when swirling at the os and swabbing the squamocolumnar junction. A serious risk to this procedure, since the swabbing is blind, would be that the physician overestimates how much force is needed to thread the brush through the device and pushes the brush into the cervix or vaginal walls which could result in bleeding or injury. In the future, a brush with a more flexible handle could be manufactured specifically for this device, same for the spatula.

While we were not able to assess the time of insertion and inflation, as described in section 5.3.4, we timed the length of cell collection (table) and saw an average of 32 ± 3.6 seconds for cell collection. We believe the device insertion will be fast and thus, the time our device could provide a comparable experience to the 1 or 2 minutes it usually takes to perform a Pap smear with a typical speculum. A fast procedure is crucial to patient comfort. While the procedure is painless for many women, the exam positioning involving stirrups leads to an

uncomfortable experience (Boskey, 2022). This is only exacerbated for women with CP due to symptoms such as shaking, involuntary muscle weakness, poor or tight muscle tone, and/or intellectual disability ("Cerebral palsy: Hope through research," 2021). For this reason, the faster the test can be completed the better. From these results, it appears that our device could also facilitate a complete and timely exam.

Chapter 8. Conclusions and Recommendations

The aim of this project was to increase the accessibility of gynecological exams including the Pap smear, a crucial screening procedure, for women with CP by designing a more flexible vaginal speculum. We believe we have taken a step towards this goal by creating our accessible speculum prototype. The constructed prototype could provide more comfort as it is designed to only expand in front of the cervix rather than from the device handle to tip. The device is also made of a flexible material, as opposed to the rigid metal and plastic of traditional specula, which allows it to bend. It is likely the device could withstand voluntary or involuntary patient movement during an exam. The bending test showed the device has the ability to not only accommodate movement, but also has flexibility, which can provide the ability for the patient to be in a more comfortable position.

During the simulated Pap smear, the device's camera allowed for a nearly unobstructed view of the model cervix. We were also able to simulate the collection of cells with a cervical cell brush. We believe our prototype has succeeded as a proof of concept in the design of a novel speculum for accommodating women with CP.

One remaining challenge is the manufacturing of the balloon to make an airtight seal for the inflation mechanism. We feel confident future changes in manufacturing techniques could resolve this issue and in the future, fabricate different sizes and more adjustable features for the device. Once the balloon is manufactured, verification tests that were unsuccessful will need to be done for ensuring the device meets the functions including the force testing, dimensions measurements, and quick insertion/inflation tests. Validation testing will also need to be repeated with the manufactured balloon to corroborate initial findings including moving the model in different positions during the simulated exam. Human testing will be required

before the device can be marketed to ensure our device is a safer alternative for women who experience muscle tightness, involuntary muscle movements, or challenges in assuming the standard positioning.

For a future recommendation, we suggest making the device portable to carry anywhere including home clinical visits. One topic that came up in our interview with a woman with CP (Appendix B) was the challenges she faces in obtaining transportation to doctors' offices. We discussed with her the possibility of home gynecological visits for disabled if the practitioners were willing. Since transportation is a barrier women with CP and other disabilities face, the device being portable or part of a home-test kit could provide an option for these women to receive a pelvic exam and Pap smear in the comfort of their own home.

From our design process, verification, and validation testing, we believe we have succeeded in creating a proof of concept prototype of a novel speculum to accommodate women with CP. In the future, this device could not only accommodate Cerebral Palsy, but provide a more comfortable experience for all women, regardless of disabled or abled, in obtaining this crucial diagnostic experience.

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Appendices

Appendix A - Expert Interview

Interview with Dr. Virginia Reed Transcript

MV: We can tell you a bit about our project first. Julianna and I decided to propose our own project his year because we wanted to work on something we were super passionate about. We both realized we are very passionate about accessibility and wanted to take some aspect within women's healthcare and make it more accessible to women with disabilities using biomedical engineering design, which is a pretty broad topic. There's a lot within that, so we have been working this term to narrow our project down. One way we have narrowed down our scope is that we have decided to narrow our population down to women with Cerebral Palsy, and make some aspect of women's healthcare or OB/GYN more accessible for women with CP, which is still broad. The second part, the aspect of OB/GYN that we're looking to redesign , whether that be a medical device or a tool, redesigning the steps of a procedure. That's where we're still trying to hone in. Once we do that, then we will bring in engineering and design. That's where we are now.

VR: When you talk about accessibility, are you talking about physical accessibility or are you talking about other types of accessibility?

MV: I think physical accessibility, even though in Julianna's and my background research we have found things like social stigma, transportation, there's a lot of factors that could result in

the disparities research shows between women with dis. and without dis. There's a lot that could be fixed that doesn't involve engineering. So we are focusing on one aspect that could be a result of an inaccessible design.

VR: That sounds like a good first step aht you have taken. Tell me some more.

MV: That's what lies ahead of us right now: finding that problem. Julianna, can you summarize the background research and information we are using to try to make that decision?

JC: Yeah. We did a lot of research, but there's not a lot out there about the inaccessibility from an engineering problem. There's a lot out there about the social aspect, but not about the design. So we started to reach out to people and we had a discussion last week with Brittany, a woman with CP. We talked about how tables and tools can be inaccessible, and all the different aspects, but we still need to hone in on one aspect.

VR: Let me clarify: so it sounds like there's not a lot out there specific to this population?

JC: Yeah

VR: Is there other literature about other conditions that have similar physical disabilities that you could tie to?

MV: What we've found so far. There's a lot of documentation about the disparities, regarding women with disabilities, generally as the population. We found some figures like: a lower

percent of women with disabilities receive mammograms annually than their non-disabled counterparts or a fewer women with disabilities receive pap smears annually than their non-disabled counterparts or pelvic exams. So the disparities are well documented, but as we started digging into the reasons for those disparities, that's where it gets - not vague - but we were hoping to find things like "this particular instrument could cause problems" but that's not so much what we're finding. Sometimes they will point to stigma or that doctors may not have ever treated a woman with disabilities when a woman walks into their office, so that lack of education. So what we've seen so far is that there aren't a lot of sources that are pointing to medical conventions or steps in a procedure or the tools as being the source of the problem, but based on the women we've talked to and the personal accounts we've read online, we know that that is part of the problem, but it isn't document much.

VR: You'll have to tell me the scope of your project, but it sounds like at some point, you'll note all these potential sources of disparity in access, give a nod to those, and say that's not what we're talking about here. We're not talking about transportation, I assume, we're not talking about health insurance. We're talking about what happens when somebody actually gets to an appointment? Ok. And are we talking about well-woman care or prenatal care? Do you want to make that broad or narrow?

MV: I think Julianna and I are both happy to look into anything in that realm, whether it be gynecological care or involving pregnant women. We are open to anything within that, but it does have to be specific.

VR: It sounds like it needs to focus on the physical part. For example, for example, a huge part of WW and PN care is education. But it sounds like we're not talking about that

MV: Our project needs to have some component of eng. Des., but it seems like better education could really help, but our project needs to focus on the design.

VR: But that's where you get to have all of your disclaimers and caveats and your roads for future research. That's all in there somewhere. So what you want to focus on is what happens from the time someone appears in the office for their appointment to the time they leave. For example, if we're talking about a WW visit, that's pretty much the same as the first obstetrics visit, those have a few more steps, but in terms of the physical parts, they're pretty much the same. Once we get to prenatal and onward, that is pretty standard and not a component of the rest of WW. For example, you don't have a full physical exam except at your first prenatal visit, but you generally have a pelvic exam at your first prenatal visit and a well woman exam, but not at other prenatal exam unless something else is going on. It's not a regular kind of thing. So, I'm guessing you are wanting to focus on the commonalities in the physical exam

MV: I think so, I think that would be good, but I think we we would be open for one of those steps that only appears in prenatal exams, if one of those steps would make a really good project, then we would be open to focusing on just that as well

VR: So, what then you want to think through are: what are the steps of a physical exam, what does it include? What does a GYN exam include? You're probably talking about trying to get from your chair or your wheelchair to an exam table if one is being used, positioning during a

variety of different parts of the exam. If somebody is going to listen to your heart and lungs, you can be sitting anywhere and somebody can do that. If you are doing a pelvic exam, you can't really do that with somebody sitting. There are standard kinds of positions, but there are adaptations you can use to. You might want to think about those. So how much ability a person has and if you want to describe a range and some examples, that's a way to do that. From virtually unlimited to very limited and somewhere in there, your description of what that might be. So then what you're thinking about is: can a person get to an exam table? Can they sit? Can they lie down? Can they be in position for a PE, or a variation of those positions, as well as the mechanics of getting in those positions. One group of things you might think about is what are the mechanics of just simply the physical exam, and that's not thinking about tools, or procedures, that's the positioning piece. And then you look at what instruments are typically used: a stethoscope - not a big deal. Probably, nothing that requires any kind of positioning until you get to the pelvic exam and then there are standard types of things.

MV: I think with personal experience and research, we are aware of the speculum, and how the cells are captured for a pap smear, things like that.

VR: That's the biggie, actually, because if somebody is going to give a pap smear or check for a yeast infection, or anything like that, it's all pretty much the same once you've used the speculum. You talked about mammograms, but those aren't going to be a problem for young women. Are you focusing on young women, or the entire age range? Where are you focusing on?

MV: We haven't narrowed that down yet. I think right now we're considering 18+ or 21+ plus for women with CP, the ages you sort of transition into adult care or see a GYN for the first time. That range up.

VR: A few other things to think about there: beyond the exam, do you want to look at the outcome of an exam? For example, many 18-45 year old women see their practitioner for contraception. Some contraception is the pill, an IUD, which is an invasive procedure, a diaphragm which is invasive regularly. If you cover the waterfront here, you may find yourself going down a lot of rabbit holes. For example, helping someone figure out how to use a diaphragm is really different than birth control, the physical piece of that. Mammograms, are you talking about teaching people self breast exams, that's not an instrumentation piece, but that's a physical ability piece. The more you can narrow your focus to a condition, or a span of time or a set of time, the easier it gets for you to focus on the tools or the procedures or the steps.

MV: We're definitely on the narrowing down part, it's the hardest step of design and that's where we are right now.

VR: It is, but you guys have already done a lot by focusing on women's health and disability, women with CP, you've done a huge piece already. So I would think the next piece would be can you narrow that some more? And then start to think about what are the common things and steps and identify along the way where there may be opportunities for you to intervene. And if you've had some conversations with folks, you're ahead of the game because done some real life interviews, and you've asked people what their experience, what worked, what didn't

work, what could work better, how could it work better, all of those kinds of things that will be really helpful in coming up with what your innovation is.

MV: We had a really great interview last week. Fortunately, she had a doctor who was really really willing to work with her and be accommodating and I think the biggest thing she had said was her physical limitation, she's almost able to position her legs so far apart. Luckily, her physician had a table that was able to get her from her wheelchair up, and that was a large part, but even there, there was only a certain way her body could be positioned, and her doctor had to work with her to perform the exam, so I know you had mentioned that earlier, characterizing the physical aspect of what we're trying to accommodate, and I think with CP - it's a range. I think our design would ideally accommodate that full spectrum. I think one commonality is muscle tone and possible limitation of movement, adn we're trying to thinka bout that, but we stil have to find the place we're going to intervene.

VR: That sounds like that was a really useful interview. That person sounds like they could describe to you, but that they got really good care that accommodates them in particular.

MV: We're trying. We've been going through Julianna's list of contacts. I don't know how many patients we have lined up, we're still reaching out to people, but that might be really helpful

VR: Even a couple more to find that things are similar or not similar . And if they're not similar, how is it: is it a totally different issue or variations on a theme or all of that. The

purpose of this isn't a rigorous, scientific description, but to take the problem you've observed and come up with a possible, biomedical engineering way to solve that problem?

MV: Exactly.

VR: Very exciting! What else can I help you with?

MV: You had mentioned that you see a lot of similarities with prenatal care and well health visit to a gynecologist, but you mentioned at a certain point with a pregnant woman, there are additional steps, with you background as a midwife, could you walk us through some of those?

VR: The first one that is markedly different is that in addition to the components of a pelvic exam that assess: take a pap smear, look at the cervix, feel the size and shape of the ovaries, feel the ovaries, feel that nothing seems out of place. Something that's done at a PN exam is something called clinical pelvimetry, which is assessing how big a pelvic exam which is important for when the baby will come on. Is this an anatomically "normal" female pelvis, which has a different shape from the male pelvis. There are certain measurements that you can assess with your hands. Does the pelvis seem "adequate" or are you concerned? That's probably the biggest difference in an initial exam. Once you get to the regular PN care, those visits are a lot of discussion, psycho-social- how are you feeling about things? What type of questions do you have? What education do we want to make sure you have? It's feeling the growth of the uterus, and that's usually done from the outside. Once the uterus has popped out of the pelvis. People don't usually get undressed for a regular prenatal exam, they usually just pull up your shirt and they palpate the belly, they listen for baby's heartbeat with a doppler or

just with a stethoscope. Once baby big-ish, 28 weeks or so, they start to think about the position: is the baby head-down. You like it when babies are head-down. They bounce around a lot during pregnancy, but usually by 30-32-34 weeks, they're usually settling down. If they're not head-down, what position are they in? Can you suggest some types of exercises that might encourage them to turn, so that kind of goes until the last month or so, and then depending on the practice or the individual way that providers do care, they may or may not check to see if the cervix has started to dilate, which it often does the last few weeks of pregnancy. So that's kind of the difference in that.

MV: Ok. We were open to the part of women's health be within the realm of obstetrics, but it sounds like there's a lot of overlap, except for those steps you just described.

VR: There is and there's nothing that's gonna change what you do, but there might be things different in positioning for labor and birth, but that sounds like a completely different subspecialization of your question.

MV: Yeah, I wonder if - we'd have to do some research. There might be some research about how doctors might be able to accommodate a woman with CP's positions

VR: Probably what you'd find... I haven't practiced midwifery in 20 years so things might have changed, but back in the day, midwives were always more open to women taking whatever position that was most comfortable for them to give birth. That could be a huge variety of things from lying down, sitting up, squatting, on their side, on their hands and knees, basically whatever was comfortable. Historically, midwives have always been accommodating.

Not based on disability, but based on whatever feels comfortable at the time. The positions, you're looking to encourage diameters of the pelvis to open up. But again, that feels like that might be a different question, one that I'm not sure if you'd find much that you could actually do.

MV: We have come upon that a couple times, like that would be very interesting or that would be a big problem, but knowing that the answer wouldn't lie within an engineering space.

VR: It's interesting to think about: what barriers are amenable to an engineering solution? And it might be... Well, I was going to say it might be the positioning piece, but then it would be coming up with position that would be... well it might be good to talk to your friend about how her friend worked with her provider to find worked for her, and was that totally manipulative or was it instrumental in some way?

MV: We can definitely follow up because we know that is a big barrier, and maybe there is a solution. I know there are more accessible tables, but I know the stirrups can not work for certain women, so perhaps designing an addition or something like that

VR: That's what I was thinking about, exactly. I mean, that could certainly be a possibility to think about.

MV: We will definitely follow up on that. That seems like a promising route. Maybe we could go to Julianna's question.

JC: Has there an instance where the steps or procedures of a visit did not work for a specific patient because of a disability? And then, was there a solution during the visit?

VR: That's a great question. Not the kind of disability you're talking about, but there are other examples. For examples, trying to do an exam on someone who is very obese is complicated sometites. Partly because the table may not be appropriate for rhythm. The stirrups may not be appropriate for them. They have folds of tissue that sometimes a speculum may doesn't work as well. That's one way you work around things. Another way you work around things is particularly if you are doing a first GYN visit on someone who is young, who is apprehensive about doing this procedure. The first thing you do is you spend a lot of time talking. You talk through every single step. You may not use stirrups. You may have the person put their feet together and open their knees, and as much as they can comfortably do. You may spend five minutes just getting them comfortable in that position before you progress. You do your exam very carefully, you start with a single finger. You're talking people through, you're looking for muscle tension, and you're waiting for them to relax at each step before you do the next step, so those kinds of things happen commonly if you will. Seeing someone who actually has a disability that makes it physically difficult for them to either get on the exam or position themselves or has restraint of motion because of muscle tightness is more uncommon.

MV: And when you had mentioned, sometimes for obese patients, the speculum doesn't work as well. In those instances, might you not use a speculum? Or would you use a different size?

VR: I would usually go to a different size, a large one. And again, those can be more uncomfortable, so it's the talking, going slowly, taking the steps one at a time and until the muscles relax.

MV: I think we heard a similar thing when we talked to the woman last week. Her doctor talked with her and found the one that worked for her. It was a lot of going slow, and taking those steps.

VR: back in the day, one of the things people figured out was that you can warm the speculum under warm water instead of straight from the draw where it's ice cold. Sometimes it's just common sense... if your goal is to relax, because the exam is a whole lot easier if people are relaxed and you can feel a lot more if their abdomen is realized, that you would do the common sense things.It's interesting to look at the changes that have happened overtime. Thinking about these things now is not a big deal, but it was years ago, because things were done they way they had "always been done."

MV: That is why we're very excited about BME, and seeing those problems that have existed for a while because it's how it's "always been done" but saying we can do better, but for us now, it's a matter finding that place where we know we can make a small tweak that will make a big change.

VR: It could also be interesting to talk to the care provider who the person you interviewed and find out from her or his perspective what she or he did different to accommodate and how

much of that was mechanical and how much of that was position, and does that person have any suggestions for a tool or a step in the procedure that might be helpful.

MV: That could be a very helpful interview. Julianna and I have started reaching out to some physicians and hoping that some will be willing to talk to us and if some are able to say "I think this is a big problem."

VR: I would talk to some nurse-midwives to see if the information you get from them is different or not.

MV: That would be really interesting since you said midwives have a history of being more accommodating.

VR: Part of it is that midwives had more time and their specialization is healthy women and healthy pregnancies and not everything that a gynecologist needs to know about. Some of it has to do with the area of expertise.

VR: I am happy to chat again if that would be helpful, or if you want to run some things by, I would be happy to take a look.

MV: That would be amazing, especially as we progress further. I know that this week the two of us were really hoping to make a list of 5 or so ideas. I know Professor Troy has been helping us. We have meetings each week, and we told her that we've been getting all this great

background research and talking to people, and she said try to make a list. But if that is something you'd be willing to get some feedback on.

VR: Absolutely! And she mentioned that she even talked with you about home visits for well woman care. I don't know anyone doing that, but that would be an interesting thing to consider too and to think about the pros and the cons of that and how much problem that would solve or not.

MV: That was one of the ideas we discussed because we know that sometimes physically getting to the office can be one of those big barriers and maybe intervening there and maybe making a kit and have that be the design aspect: designing the things in this kit that could empower physicians to treat at home possible, so that might be one of the ideas we select. We are trying to narrow it down to those ideas.

VR: But it's very exciting. Regardless, I'll be excited to hear what you come up with. Certainly best of luck to you guys and congratulations for tackling such a worthwhile project.

MV: Thank you so much. We'll be sure to let you know. And the deliverable of our project is a design, so we'll be happy to show it to you or give you our report.

VR: Absolutely!

MV: Thank you for all your help.

JC: Thank you.

VR: You're very welcome. I'm so glad to meet both of you.

MV: I'm so glad Professor Troy put us in touch.

VR: She told me she was working with you and she is very excited about it as well, so thank you for all you're doing.

Appendix B - Patient Interview

Interview with Brittany DiMatteo Transcript

JC: Studies show that disabled women receive health care less frequently and of a lower quality than non-disabled women. Why do you think this is?

BD: For me, my experience has been... Well, actually I have just started this journey with OB/GYN. This is new for me as well, and it's been an interesting one. My OB/GYN, she just left, so I'm in search of a new one, but she was really great. She didn't know much about CP, but she was willing to learn and was willing to accommodate me within reason.

So the room she would put me in had something similar to a dentist's chair, something you could push the button and would go up and down as much as you needed it to, so she would lower it so I could get onto it easier rather than a table.

The hardest part about it, about the whole process of going to an OB/GYN is due to my CP, my muscles are extremely tight, so it makes it difficult to maintain the positions they need to do the exams, so what often ends up happening is that they're only able to get a partial test result. They're not able to do a full exam, most of the time, just because my body can't handle it.

MV: Do you think that contributes to the inaccessibility of those testing procedures. Do you think that's where the problem lies of women with CP not being able to receive full test results?

BD: What they've actually had to do with me is use a separate set of instruments, of tools. Sometimes they're smaller. Sometimes they're bigger. They've had to change the size of it.

MV: That's very interesting to us because we haven't honed in yet on which process or instrument we'll be redesigning. It is an engineering project so we're looking to redesign something, so it's interesting that there are sets of instruments that can be more accommodating. Do you feel that the accommodations your doctor had made have been enough? I know you said that sometimes you receive not complete results or tests, do you think that those accommodations were enough or there's still room to be improved.

BD: I think there's still room to be improved. I think they're doing the best with what they have.

MV: That's good to hear. In our background research, it doesn't seem that every physician is as accommodating as it sounds like the OB/GYN you went to was, unfortunately, but it's great to hear that you've found resources.

BD: You have to do your looking. You have to do your research. There are some out there, but they're rare.

MV: So you mentioned that you saw this doctor, I know you're now looking for a new one, but was able to make accommodations. You mentioned the table. Could you take us through the

steps of the typical visit with this physician, and how they accommodated you with the tests they wanted to run?

BD: Of course. So, the chair they used is low enough where I could just put my walker right up to it and rotate down to it, and we're in a good position to do what we need to do. To do, for example, like a pap smear, which is routine care after a certain age for most females. Because of my CP, I can open my legs so far, so wide, so we've tried opening them or having me move them as far as I can move them and that's how far we go, and then she had the idea of "Oh, I have a smaller scope" I think it's called "to use that might be a little easier on your body to use and a little more comfortable" so we just switched those tools. In terms of - tell me if i'm getting too candid here - if it's just an examination of what my body looks like, it's just the doctor touching, which is totally fine.

MV: That's good to know that they were able to make those swaps. I know you mentioned that they had the table that was able to better accommodate you, do you think that any shift towards home visits - because that's something that Julianna and I had talked about briefly as just a first-off idea because one of the reasons some women aren't getting yearly care. I know you had mentioned pap smears and that's a yearly thing. In some background research we've found, disabled women are less likely to receive pap smears each year and we were trying to dig into why that might be. And something that came up in our conversations was perhaps it's the office itself, or getting to the offices, and then not every building has one of those tables. I know you were able to receive that care, do you think other women might benefit from shifting those visits to home if possible?

BD: Yes, if the medical community is open to it. You'd have to have a physician or a specialist that is open and willing to go because it is their own time and many people may or not like to travel, and they might argue that's a sterile enough environment, but that could be a good option because I know... there is transportation, but their hours of operations are very limited. So, for example, there's transportation where I live, but their window of operations is from like 6:30 in the morning to 8 at night during the week and 9 to 5 on Saturday and that's it, so if that schedule doesn't work for you or if you need a family member, then that's going to be an issue too.

MV: We were talking yesterday with our advisor, and she had mentioned, while we're having conversations with people, transportation will probably come up a lot in terms of barriers to access, so unfortunately, we're not surprised hearing that. And it's so unfortunate because it seems like one of the easiest things to overcome, but it's still such a barrier, so it's very disappointing to hear.

JC: You mentioned that you didn't know if physicians would be willing to come to your home. How do you feel about the practice of midwives? Because there are people who do home-births and home-visits within that?

BD: Do you mean in terms of care?

JC: Yes.

BD: I know for me, if that were an option, would I consider it? Possibly, because I, unfortunately, am not completely independent, and I need to rely on family members for various things. Even though it's the year we live in, things are not completely inaccessible. We're not at that point in society yet, so if that is an option, I would consider it. And especially because I've actually contemplated living on my own at some point, so maybe when I'm on my own, it may not be readily available for transportation or scheduling or what not, so home-visits might be a nice option if the medical community is open to it.

What I've found is that once you leave pediatric care, no one knows what Cerebral Palsy is. People kind of look at you like you're speaking a different language. And for me, I don't mind talking about it, but talking to a medical professional about it makes me a little bit uncomfortable because I feel like this is something they should already know. It's not like it's a rare disorder, it's pretty common, more than you would think. Can I use you for an example, Julianna?

JC: Yes!

BD: For Julianna and myself, we're kind of what is referred to as "higher functioning" CP. We can communicate, we can do everything everyone else can, we just have some mobility issues, and that is not always the case with cerebral palsy. It affects everyone differently, and I don't want to be the only example [the doctors] have and them say "this is what CP looks like" when it affects everyone differently.

MV: You must feel almost responsible that your doctor might think "this is my first CP patient" and extrapolate your case to everyone, but you shouldn't be responsible for that education.

They should know that this is one person and there is a range of lifestyles within this condition. You feel that you must educate their physicians once you left pediatrics? That it became a routine?

BD: Yeah.

MV: That might be why we've seen a lot in the literature that there are a lot of gaps in OB/GYN because that's pretty much, firmly, outside of pediatrics, for the most part.

BD: Right

MV: A lot of the procedures begin at 21. You probably just set off a light bulb in both of our heads. We might not have been considering that gap between pediatric care and the way a lot of people must then feel responsible for the education for their physicians that must play a role, like you just described. So thank you for sharing that. That must play a role in OB/GYN because it's so separate. We'll have to consider that. The reason we had mentioned home visits is because we're looking for a place to enter with our project. We know there are these discrepancies in health care, and looking at a point in the steps of a woman going to get healthcare, then in the exam room, and then the tools. there's many places that might be inaccessibility. We know that transportation can often be a problem, for women who are living on their own. Do you see, in your experience, going to the doctor. If you were to sort of pick a point and say this is where a lot of the problems occur, whether that be getting to the doctor, the room itself, the table, the tools, the procedure.s Is there any one area that sort of goes off at you as the point where most women might encounter problems.

BD: If I had to think about it, they need a lot of assistance. It's not a "oh I can do this myself, I can go in by myself" it's "I need help from a nurse, or from the OB/GYN or a combo of both." I know for certain for myself that, as independent as I am at this point, I am always going to need help just because, physically, how my body moves. There's always going to be a need for extra assistance, and that's where the education comes in. That's the biggest problem I think.

MV: So you think a lot of physicians aren't prepared to provide that extra assistance?

BD: In my experience, not usually. I'm in the rare case where I've had doctors who are willing to work with me. But I know, I have a lot of friends where the medical community treats them like an able-bodied adult with no issues, which is not the case. With a physical disability, there's a lot to consider, and depending on who you talk to, it's not being considered. Which is sad. As a medical professional, you should be adaptable.

MV: It is mindblowing that there are so many people that encounter this problem. Like you said it does come down to education as well

BD: It's almost as if, back to the pediatrics point, it's almost as if these children grow into adults. These children with disabilities grow into adults with disabilities and they have different... their needs may look a little different as they get over, but their needs are basically the same.

MV: It sounds like there's a lack of considering, not wondering about the health outcomes of the children that pediatrics cares for, the health outcomes of the rest of their lives. Lastly, circling back to where you mentioned your friends who were not accommodating as you were. Julianna and I were so glad to hear that you had this experience with this doctor who accommodated you so well. I'm thinking that might not be the case for other women we talk to. I know you mention the accessible chair, and that [the doctor] switched out different instruments. Do you know if any of the instruments were specially made for diabled women or if it was more your doctor using a different size or a different material?

BD: It was just her deciding based on the tools she had available what would work best. They weren't specially designed for anyone with a disability. She was using her judgment with what she had available.

MV: Thank you. And thank you so much for talking with us. We are definitely in the early stages of our project, but as biomedical engineering majors, we're definitely going to be getting hands-on and redesigning something that can hopefully improve the accessibility of OB/GYN.

JC: Thank you!

BD: Thank you so much. I look forward to hearing from you guys later on down the road.